Long-Term Clinical and Echocardiographic Follow-Up of the Freestyle Stentless Aortic Bioprosthesis

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Background—Stentless aortic bioprostheses were designed to provide enhanced hemodynamic performance and potentially greater longevity. The present report describes the outcomes of patients with the Freestyle stentless bioprosthesis followed for ≤18 years.

Methods and Results—Between 1993 and 2011, 430 patients underwent primary aortic valve replacement with a Freestyle bioprosthesis in the subcoronary position. Mean age was 68.2±8.2 years. All of the clinical and echocardiographic data were collected prospectively. Mean overall follow-up was 9.1±4.4 years and was complete in all of the patients. In-hospital mortality was 3.5% (n=15). Overall, 10- and 15-year survival were 60.7% and 35.0%, respectively. Fifty-one patients required reoperation during follow-up, including 27 for structural valve deterioration (SVD). Overall, freedom from reoperation was 91.0% and 75.0% at 10 and 15 years, whereas freedom from reoperation for SVD was 95.9% and 82.3%, respectively. At 10 and 15 years, freedom from reoperation for SVD was 94.0% and 62.6% for patients <60 years of age and 96.3% and 88.4% for patients ≥60 years of age (P=0.002). The median time to explant for SVD was 10.7 years. SVD presented mostly as acute, severe aortic insufficiency attributed to leaflet tear (77.8%). The independent risk factors for reoperation for SVD were age <60 years (P=0.001) and dyslipidemia (P=0.02).

Conclusions—Aortic valve replacement with the Freestyle bioprosthesis in a subcoronary position provides good long-term clinical and echocardiographic outcomes for patients >60 years of age. Severe aortic insufficiency with leaflet tear is the major mode of SVD leading to reoperation in these patients. (Circulation. 2012;126[suppl 1]:S198–S204.)

Key Words: aortic valve surgery stentless bioprosthesis follow-up study

Stentless aortic bioprostheses were designed to provide enhanced hemodynamic performance and potentially greater durability because of lower mechanical stress on the leaflets, with no requirement for long-term anticoagulation.1,2 Because of their unique structural features, valve longevity, as well as mode of failure, can differ among the various available stentless bioprostheses.3 The Freestyle aortic valve bioprosthesis (FSB; Medtronic Inc, Minneapolis, MN) is a stentless porcine aortic root prepared using a proprietary low- and 0-pressure fixation process and a-amino oleic leaflet anticalcification treatment. The bioprosthesis can be implanted as a subcoronary valve replacement, as a complete aortic root replacement, or as a root inclusion.4 Previously published reports confirm excellent hemodynamic performance associated with stentless aortic valves.5–7 However, clinical outcomes, late durability, mode, and mechanism of valve failure during long-term follow-up remain to be elucidated.

The purpose of the present study was to assess the early and late clinical and echocardiographic outcomes, as well as late prosthesis durability among patients who underwent aortic valve replacement (AVR) with a Freestyle aortic bioprosthesis in a subcoronary position, prospectively followed for a maximum of 18 years.

Materials and Methods

Study Population

Patient baseline and operative information are collected prospectively for all patients and stored in our computerized cardiac surgical database. We identified 430 consecutive patients who underwent primary aortic valve replacement with an FSB in the subcoronary position between January 1993 and April 2011 at the Quebec Heart and Lung University Institute. A group of 10 surgeons was involved in these cases; the minimum number of implanted FSBs in the subcoronary position was 7, with maximum of 113 per surgeon. The operative technique has been described previously.4 The noncoronary sinus of Valsalva was preserved. Sizing is performed with the sizer provided for the FBS valve, with consideration given to the size at both the annulus and sinotubular ridge. A larger diameter measured at the latter or uncertainty based on annulus diameter would favor upsizing to the next larger valve. Concomitant coronary artery bypass graft surgery was performed in 146 patients (34.0%).

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Table 1. Baseline Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Freestyle (N=430)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female sex (%)</td>
<td>233 (54.2)</td>
</tr>
<tr>
<td>Age (mean±SD), y</td>
<td>68.2±8.5</td>
</tr>
<tr>
<td>NYHA class =3 (%)</td>
<td>312 (72.6)</td>
</tr>
<tr>
<td>Body mass index (mean±SD)</td>
<td>27.3±5.1</td>
</tr>
<tr>
<td>Previous MI (%)</td>
<td>76 (17.7)</td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>40 (9.3)</td>
</tr>
<tr>
<td>COPD (%)</td>
<td>95 (22.1)</td>
</tr>
<tr>
<td>Active smokers (%)</td>
<td>53 (12.5)</td>
</tr>
<tr>
<td>Chronic renal failure (%)</td>
<td>49 (11.4)</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>236 (54.9)</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>101 (23.5)</td>
</tr>
<tr>
<td>Dyslipidemia (%)</td>
<td>163 (37.9)</td>
</tr>
<tr>
<td>Urgent/emergent (%)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>PVD (%)</td>
<td>38 (8.8)</td>
</tr>
<tr>
<td>Atrial fibrillation (%)</td>
<td>40 (11.4)</td>
</tr>
<tr>
<td>Low EF ≤40% (%)</td>
<td>22 (6.0)</td>
</tr>
<tr>
<td>Endocarditis (%)</td>
<td>6 (1.4)</td>
</tr>
<tr>
<td>Cause of AVR</td>
<td></td>
</tr>
<tr>
<td>Aortic insufficiency (%)</td>
<td>18 (4.2)</td>
</tr>
<tr>
<td>Aortic stenosis (%)</td>
<td>370 (86.3)</td>
</tr>
<tr>
<td>Mixed (%)</td>
<td>41 (9.6)</td>
</tr>
</tbody>
</table>

Data are n (%) unless otherwise specified. NYHA indicates New York Heart Association; MI, myocardial infarction; COPD, chronic obstructive pulmonary disease; EF, ejection fraction; PVD, peripheral vascular disease; AVR, aortic valve replacement.

Patients who underwent FSB implantation as a complete aortic root replacement or inclusion cylinder “mini-root” replacement were excluded from the study. During the time period of this study, 3504 primary aortic valve replacements with or without coronary artery bypass graft were concomitantly performed, including subcoronary FSB cases. The choice of bioprosthetic aortic valve type was based on surgeon preference. The indication for aortic valve replacement with FSB in a subcoronary position and the clinical, as well as operative, characteristics of the patient population are depicted in Table 1.

All of the patients were followed annually in our dedicated valve clinic. Transthoracic echocardiograms were obtained every 2 years to measure ejection fraction, transvalvular gradients, degree of aortic insufficiency (AI), and structural valve deterioration (SVD). Transvalvular gradients and effective valve orifice areas (EOAs) were measured as described previously by our group.² The EOAs was indexed to the patient’s body surface area. Prosthesis-patient mismatch (PPM) was defined as an indexed EOA (IEOA) ≤0.75 cm²/m².

Clinical follow-up was complete in all of the patients. In accordance with the American Association for Thoracic Surgery and the Society of Thoracic Surgeons Committee for standardizing prosthetic heart valve morbidity,⁶ SVD was defined as any change in function of an FSB resulting from any valve abnormality excluding infection or thrombosis. The date of all-cause mortality was obtained from provincial vital statistics.

Statistical Analysis

Results are expressed as mean±SD or median (interquartile range), as appropriate, for continuous variables, and percentages for categorical variables. Patients were censored at the time of last contact. Continuous and dichotomous variables were analyzed using Student t test or χ² test, respectively. All of the parameters were initially analyzed using univariate Cox regression models to estimate the hazard ratio of each independent variable associated with long-term survival, as well as the occurrence of SVD over time. The independent variables presented to the model were as follows: (1) baseline variables, including age, sex, body mass index, hypertension, diabetes mellitus, hypercholesterolemia, New York Heart Association class, smoking history, chronic renal failure (serum creatinine ≥150 μmol/L), peripheral vascular disease, ejection fraction ≤40%, chronic obstructive pulmonary disease, previous myocardial infarction, triple vessel disease, previous cerebrovascular accident, atrial fibrillation, reason for aortic valve replacement, and bicuspid aortic valve; (2) operative variables, including FSB size, surgeon, and cardiopulmonary bypass and aortic cross clamp times; and (3) postoperative variables, including reoperation for bleeding and technical problems regarding valve implantation, prolonged (>48 hours) low cardiac output state, de novo atrial fibrillation, cerebrovascular accident, pulmonary infection, wound infection, delayed pleural and pericardial effusion, ejection fraction at discharge, presence of PPM, prolonged intubation (>48 hours), blood product transfusion, and renal and gastrointestinal complications. Variables with a P<0.20 were candidates for the multivariate Cox regression model building. Selection of variables and interaction terms was performed using a forward approach. Colinearity matrices were evaluated and, when significant, collinearity was detected between variables, and the variable that had the strongest association with the outcome on univariate analysis was chosen. Akaike information criteria and Schwarz Bayesian criteria were used to compare candidate models to choose the variable. The same approach was performed to include interaction terms in the Cox model. Martingale residuals were used to examine the functional form of the continuous variable age and to determine that no transformation was necessary. After model building, adequacy of the proportional hazards assumption was checked. To check the proportionality assumption, first the graphical representation of the logarithm of the cumulative hazard rates versus time was used to assess parallelism and constant separation among the different values of nominal variables, whereas the continuous variable age was stratified into 4 disjointed strata. Second, an artificially time-dependent covariate was added to the model to test the proportionality assumption. For all of the variables in the final model, proportional hazards assumptions were not rejected, because local tests linked to the time-dependent covariates were not significant, and scatter plots were roughly constant over time. The graphical representations of martingale and deviance residuals versus risks cores did not suggest any potential outliers. Time-related analysis was performed by the Kaplan–Meier method. A log-rank test was used to test for differences in freedom from SVD. Statistical significance was present when 2-tailed P<0.05. Analyses were performed using the statistical software version package of SAS 9.2 (SAS Institute Inc, Cary, NC).

Results

Early Clinical Outcomes

Overall in-hospital mortality was 3.5% (n=15), among whom 5 patients had concomitant CABG (P=1.0). There was no statistically significant difference between the Parsonnet score-predicted mortality compared with the observed mortality in our series (3.8% versus 3.5%; P=0.93). Causes of early death were low cardiac output state (n=1), intestinal ischemia (n=1), acute renal failure (n=1), intestinal ischemia (n=1), and multiorgan failure (n=2). There was early (during the same hospitalization) reoperation in 4 patients because of technical issues in the first year of FSB implantation at our institution. These cases were not considered SVD. Among them, 3 asymptomatic patients required reoperation for moderate-to-severe AI attributed to valve dehiscence and paravalvular leak. One symptomatic patient demonstrated a high peak transprosthetic gradient (105 mm Hg) in postoper-
ative echocardiography after implantation of a 21-mm valve probably because of inappropriate valve sizing. The latter underwent re-AVR with a mechanical valve and root enlargement procedure. Perioperative data and postoperative complications are shown in Table 2.

**Long-Term Outcomes**

**Survival**

Mean and median clinical follow-up was 9.1±4.4 (range, 0.1–18.0 years) and 9.4 years (interquartile range, 0.1–18.0 years) respectively. Unadjusted 10- and 15-year survivals were 60.7% and 35.0% in the FSB patients (Figure 1). On multivariate analysis, the independent risk factors for late mortality were: age (hazard ratio [HR], 1.1 [95% CI, 1.03 to 1.18]; \( P<0.01 \)), hypertension (HR, 2.4 [95% CI, 1.2–4.6];

![Figure 1. Kaplan–Meier freedom from all-cause mortality.](image)

**Reoperation**

Fifty-one patients required reoperation, 27 patients for SVD, 6 for endocarditis, 4 for severe PPM, and 14 for non-SVD. Overall freedom from reoperation was 91.0% and 75.0% at 10 and 15 years, respectively (Figure 2), whereas freedom from reoperation for SVD was 95.9% and 82.3% (Figure 3) at the same time points. All of the patients with significant clinical and echocardiographic signs of SVD underwent reoperation. The mean age of patients with SVD was significantly lower than that of patients without SVD (59.1±6.7 versus 68.8±8.0 years; \( P<0.0001 \)). The median time to explant for SVD was 10.7 years (range, 3.4–15.8 years). At 10 and 15 years, freedom for SVD was 94.0% and 82.6% for patients \( <60 \) years of age and 96.3% and 88.4% for patients \( \geq60 \) years of age (\( P=0.002 \)). SVD presented mostly as severe AI because of leaflet tear (\( n=21 \) of 27; 77.8%). All of

![Figure 2. Kaplan–Meier freedom from reoperation for any cause.](image)

![Figure 3. Kaplan–Meier freedom from reoperation for structural valve deterioration (SVD).](image)
the patients with SVD presented with dyspnea either secondary to severe aortic regurgitation in 21 cases or severe aortic stenosis in 6 cases without (n=2) or with mild-to-moderate AI (n=4; including 2 leaflet tears). The interval between onset of symptoms related to SVD of FSB and reoperation was acute (<1 month) or subacute (1–3 months) in 21 patients and chronic (>3 months) in 6 patients. Twenty-three patients with aortic regurgitation attributed to SVD were found to have tears in ≥1 aortic cusp, including 8 in the left coronary leaflet, 12 in the right coronary leaflet, and 3 in both. Tears were located at the base (n=14) or in the vicinity of the commissure (n=9). Macroscopic calcification was absent in all of the patients with severe aortic regurgitation caused by leaflet tear. On histology of these explanted valves, all of the leaflets showed different degrees of degeneration of the extracellular matrix with minimal calcification and the presence of fibrotic patches. In the 6 patients with severe aortic stenosis, severe leaflet calcification was found in 4 patients, and leaflet fibrosis with mild-to-moderate calcification was found in 2 patients. The independent risk factors for reoperation for SVD were age <60 years (HR, 8.2 [95% CI, 3.6–19.0]; P = 0.001) and dyslipidemia (HR, 3.1 [95% CI, 1.1–8.2]; P = 0.02).

There were 6 reoperations for prosthetic valve endocarditis, occurring at a mean interval of 6.8±4.4 years after initial operation. There were 4 reoperations for clinical symptomatic severe PPM with very high peak transprosthetic gradient (range, 102–115 mm Hg). These occurred in 4 female patients between 1.2 and 7.1 years after implantation of two 19- and two 21-mm valves. The FSB leaflets were macroscopically normal with no evidence of calcification and pannus formation in any of the 4 cases. Severe fibrosis at the prosthetic annulus and/or suture line level was identified in 3 patients and severe root calcification in 1 patient. Among them, 3 patients underwent Bentall procedure, and 1 had AVR with root enlargement. Reoperation was required for non-SVD in 14 patients. The median time to explant for non-SVD was 6.5 years (range, 1.0–15.3 years). Among them, there were 8 reoperations because of clinically and/or echocardiographically progressive paravalvular leak, 3 reoperations because of sinotubular junction dilatation; 2 in patients with originally bicuspid valve, and 1 in patients with tricuspid valve, 2 reoperations because of pseudo-aortic stenosis with high transprosthetic gradient owing to pannus formation in subprosthetic area, and 1 reoperation for severe AI because of valve entrapment by pannus formation.

**Echocardiographic Findings**

Early and late echocardiographic parameters of ventricular function and prosthesis hemodynamic performance are shown in Table 3. Freedom from moderate or greater AI was 92.6% and 80.1% at 10 and 15 years, respectively (Figure 4).

**Prosthesis-Patient Mismatch**

A total of 101 patients (36.6%) had an IEOA =0.75 cm²/m² (mean, 0.71±0.25 cm²/m²). Perioperative characteristics of patients with or without PPM are compared in Table 4. A significantly higher proportion of 19- or 21-mm FSB valve size was implanted in the PPM group compared with the non-PPM group (44.0% versus 13.7%, respectively; P<0.0001). The proportion of female patients was higher in the PPM group compared with the non-PPM group (73.0% versus 38.3%, respectively; P<0.0001). Mean prosthetic gradient was significantly higher (4.9 mm Hg) in patients with PPM compared with patients without PPM at 5 years (11.8±4.9 mm Hg), 10 years (11.4±4.9 mm Hg), and 15 years (17.6±8.7 mm Hg).

![Figure 4. Kaplan–Meier freedom from aortic regurgitation (AR ≥3/4).](image-url)
aortic valve prostheses implanted in Europe in 2008.\textsuperscript{14} Being a bioprosthesis, the Freestyle aortic valve is also subject to limitations in long-term durability. The present study analyzed a variety of clinically relevant outcomes after aortic valve replacement with FSB in a large, single-center cohort prospectively followed for ≤18 years, which constitutes the longest longitudinal follow-up to our knowledge.

**Survival**

Data reflecting valve related survival are extensively studied and compared for the FSB and other available bioprostheses.\textsuperscript{15–17} Enhanced physiological behavior and earlier left ventricular mass regression of stentless valves are supposed to influence cardiac performance and survival favorably.\textsuperscript{18–20} Unadjusted 10-year survival was 60.7% in our cohort, which is comparable or slightly higher than published studies of stentless bioprostheses\textsuperscript{11,18,21} despite longer average follow-up in our study. The long-term survival reported in our study falls within the range of previously published literature of stentless prostheses (47% to 69%).\textsuperscript{22}

**Structural Valve Deterioration**

The steady increase in the use of aortic bioprostheses among younger patients emphasizes the importance of valve longevity.\textsuperscript{23} The present study confirms the excellent long-term durability of the FSB, especially in patients >60 years of age. The longitudinal echocardiographic data further support the stability of the FSB hemodynamic performance at long-term follow-up. SVD of bioprosthetic valves is a complex process that is not fully understood. The current data compare favorably with the freedom from SVD observed with currently available stented bioprostheses. However, our data suggest that the mechanisms responsible for the SVD observed with the FSB are different from those at play in the setting of other biological valves.\textsuperscript{24,25} Inflammatory and immune responses have been implicated in the calcification and degenerative process of bioprostheses as the most frequent mechanism of the contemporary glutaraldehyde pretreated porcine aortic valve degeneration.\textsuperscript{26,27} The FSB is a porcine aortic root pretreated with α-amino oleic acid, an anticalcification agent shown to abolish porcine leaflet calcification in animal models.\textsuperscript{28} The current data support the notion of a heightened anticalcification feature of the FSB valve because only 6 explanted valves showed significant macroscopic calcium deposition. Among patients with SVD, valve deterioration was related to leaflet tear in 85.2%. Such a mechanism may suggest a “wear and tear” pathophysiology in the prosthetic valves. The wear and tear phenomenon leading to valve failure has been reported with stented bioprostheses.\textsuperscript{29} A recent multicenter study also suggested leaflet tear as the mechanism of valve failure in patients with an FSB. Within the present study, the wear and tear hypothesis is substantiated by the histology of the explanted leaflets, which show variable amounts of degeneration of the extracellular matrix with minimal calcification. The leaflet tears were located on the right and left cusps, thus sparing the noncoronary cusp. Such a finding may imply an uneven stress distribution on the leaflets with premature degeneration of the overpressurized leaflets leading to leaflet tear. Because our
preferred method of implantation for the subcoronary position includes preservation of the noncoronary sinus, one may speculate that suture placement in the right and left sinuses may confer uneven stress zones on the right and left leaflets leading to leaflet tear. A higher number of tears in the right and left sinuses in the present study may confirm this hypothesis. Furthermore, our study suggests that the majority of patients who developed SVD have a rapid onset of symptoms and usually undergo reoperation within 3 months after symptom onset. Such a clinical presentation suggests a rapid transition between a normally functioning valve and severe valve regurgitation caused by leaflet tear.

**Patient-Prosthesis Mismatch**

The present study also assessed the long-term impact of moderate and/or severe PPM in FSB patients. Patients were stratified according to their IEOA at discharge echocardiogram. In the current cohort, the incidence of IEOA  0.75 cm²/m² was 36.3%. The incidence of severe mismatch (IEOA <0.65 cm²/m²) was 9.2%, rendering subanalysis of this subset of patients difficult. Within the present report, predictors of PPM were female sex and prosthesis sizes 19 or 21 mm. These findings are similar to other studies analyzing the predictors of PPM.30 The incidence of PPM at discharge varies between 20% and 70% in the literature31–33 and may be as high as 91% in patients with a small aortic annulus.34 A tendency to use this type of prosthesis in patients at risk of PPM (eg, women) may explain the relatively high incidence of PPM in our series. However, the incidence of severe mismatch was 9.2% in the present study. The minimal changes in mean gradients during follow-up were neither clinically nor statistically significant.

In the recent stented aortic valve prosthesis literature, contradictory data have been reported regarding the influence of PPM on long-term clinical outcomes after AVR. Tasca et al35 have reported that PPM (IEOA <0.80 cm²/m²) is an independent predictor of cardiac events and 5-year mortality. When evaluating patients with small size St Jude prostheses, the Mayo Clinic group found only patients with severe mismatch (IEOA <0.65 cm²/m²) to be at increased risk for long-term mortality and recurrent congestive heart failure.36 PPM did not impact all-cause mortality in their study. On the other hand, the Cleveland Clinic group showed similar functional recovery after AVR in all of the patients, even in the presence of severe PPM.37 To our knowledge, only 1 study has evaluated the impact of PPM in patients with an FSB.38 Ennker et al38 using a geometric measurement of the IEOA early postoperatively, showed a 30% incidence of PPM (IEOA <0.85 cm²/m²) in 303 patients with an FSB. The authors demonstrated an adverse impact of PPM on survival solely in patients with aortic regurgitation at an IEOA threshold <0.75 cm²/m².

Although our study establishes that PPM does not adversely impact long-term outcome in patients with Freestyle valves, certain limitations need to be addressed. The incidence of PPM was assessed only in patients with a subcoronary FSB implantation technique and may be less frequent in patients with a root replacement. Moreover, the small number of patients with severe mismatch (IEOA <0.65 cm²/m²) does not allow us to formulate specific recommendations for this subset of patients. Furthermore, PPM has been suggested to adversely impact the clinical outcome of young patients or patients with large body surface area or significant left ventricular dysfunction.31,39 Further studies addressing the impact of PPM in stentless valves in these subgroups of patients are required. Important concepts, such as the appropriate threshold value for diagnosis of PPM, end-points measured, method of calculation of the orifice area (effective versus geometric orifice area), and influence of patient-level characteristics (eg, activity level, large body surface area, and low ejection fraction), remain unresolved and further complicate the debate surrounding the clinical relevance of PPM.

**Prosthetic Aortic Valve Insufficiency**

Previously published studies showed a low prevalence of AI with FSB in the subcoronary position.9,40 The present study confirms that there is excellent freedom from moderate or severe AI throughout the whole length of follow-up. In our cohort, freedom from moderate or greater AI was 92.6% and 80.1% at 10 and 15 years, respectively. Our data demonstrated that the Freestyle aortic bioprosthesis in the subcoronary position is associated with lower rates of AI compared with the subcoronary Toronto stentless porcine valve (SPV; St. Jude Medical, St. Paul, MN). Based on published data from a multicenter study, freedom from significant AI for the Toronto stentless porcine valve decreased from 96.9% at 5 years to 82.5% at 9 years,41 probably because of progressive aortic sinotubular junction dilatation.

**Limitations**

This is a descriptive observational study without a comparator group, and lack of random treatment allocation limits the conclusions that we can draw from such data. However, the acquisition of community-wide clinical, as well as echocardiographic, data by our outpatient valve clinic out to ~20 years after surgery is a definite strength of our study.

**Conclusion**

Aortic valve replacement with the Freestyle bioprosthesis in a subcoronary position provides good long-term clinical outcomes with a low prevalence of AI, good gradients, and an acceptable rate of reoperation and SVD, especially at >60 years of age through long-term follow-up. Acute and severe AI with leaflet tear is the major mode of SVD leading to reoperation in these patients.

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**Disclosures**

None.

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