Long-Term Clinical Outcomes 15 Years After Aortic Valve Replacement With the Freestyle Stentless Aortic Bioprosthesis

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Background. The Freestyle stentless aortic root bioprosthesis has excellent hemodynamics and durability through 10 years. The purpose of this report is to present clinical outcomes in a large multicenter cohort through 15 years.

Methods. The multicenter evaluation of the Freestyle valve began in 1992 at 21 centers in North America and Europe. In 1997, a long-term study continued, including 725 patients from 8 of the original centers; clinical outcomes data after 10 years have continued to be collected at 6 of 8 centers.

Results. Patient age was 71.7 ± 7.9 years. There were 402 (55.4%) men and 323 (44.6%) women. Total follow-up was 5,491.2 patient-years. There were 52 late reoperations, with explant of the bioprosthesis in 47 cases. Respective 10- and 15-year survival was 46.2% ± 2.3% and 25.9% ± 3.2%; freedom from valve-related death was 94.9% ± 1.5% and 92.7% ± 3.5%; freedom from reoperation was 92.3% ± 1.8% and 80.7% ± 5.0%; and freedom from explant owing to structural valve deterioration was 96.5% ± 1.3% and 83.3% ± 4.8%. Increased age was associated with higher risks of all-cause mortality and valve-related mortality and lower risks of reoperation and explant caused by structural valve deterioration.

Conclusions. In this long-term, multicenter, observational study, the Freestyle stentless aortic root bioprosthesis offered good clinical outcomes in terms of survival, freedom from valve-related mortality, freedom from reoperation, and freedom from structural valve deterioration. The Freestyle valve is a viable option for use in patients undergoing bioprosthetic aortic valve replacement and for anticipated desire for long-term durability.

The Freestyle aortic root bioprosthesis (Medtronic, Inc, Minneapolis, MN) is a stentless porcine aortic bioprosthesis first implanted in 1992 and approved for commercial use in the United States in late 1997. The valve previously has been shown to have excellent associated hemodynamics [1–4]. Existing data from a long-term multicenter trial suggest good prosthesis durability through 10 to 12 years [4, 5], and one recently published study reported good durability in a single-center experience through 15 years [6]. The purpose of this report is to present clinical outcomes for the Freestyle aortic root bioprosthesis in a large multicenter cohort through 15 years.

Material and Methods

Study Population
The multicenter evaluation of the Freestyle valve began in 1992 at 21 centers in North America and Europe; in 1997, at the time of approval by the US Food and Drug Administration, a long-term study of the valve continued, including 725 patients from 8 of the original centers. The safety study mandated by the US Food and Drug Administration was completed in 2004 after 100 subjects had been followed for safety through 10 years. However, because of the unique nature of the valve, a longer-term study was commenced at that time; 2 of the 8 long-term centers discontinued participation, leaving 6 centers participating in the long-term study of the valve.

Study sites and patient enrollment are shown in the Appendix. The study protocol was reviewed and approved by each participating hospital’s institutional review board or ethics committee; all subjects provided written informed consent. The long-term study group includes 725 consecutive patients having undergone implantation of the Freestyle valve; data for subjects at two sites that discontinued participation are truncated at 10 years.

Accepted for publication Aug 22, 2013.
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Drs Bach and Kon disclose financial relationships with Medtronic.

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http://dx.doi.org/10.1016/j.athoracsur.2013.08.047
0003-4975/$36.00
Table 1. Late Adverse Events Based on Implant Technique and Age at Implant

<table>
<thead>
<tr>
<th>Variable</th>
<th>All Patients</th>
<th>Subcoronary</th>
<th>Full Root</th>
<th>Root Inclusion</th>
<th>&lt;60 Years</th>
<th>&gt;60 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths (late)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>725</td>
<td>509</td>
<td>178</td>
<td>38</td>
<td>57</td>
<td>668</td>
</tr>
<tr>
<td>Deaths/year</td>
<td>5,434.1</td>
<td>4,022.0</td>
<td>1,136.4</td>
<td>275.7</td>
<td>582.7</td>
<td>4,851.4</td>
</tr>
<tr>
<td>Cardiac deaths</td>
<td>377 (6.9 ± 0.4%/patient-year)</td>
<td>294 (7.3 ± 0.4%/patient-year)</td>
<td>63 (5.5 ± 0.7%/patient-year)</td>
<td>20 (7.3 ± 1.6%/patient-year)</td>
<td>18 (3.1 ± 0.7%/patient-year)</td>
<td>359 (7.4 ± 0.4%/patient-year)</td>
</tr>
<tr>
<td>Valve-related or unknown deaths</td>
<td>99 (1.8 ± 0.2%/patient-year)</td>
<td>82 (2.0 ± 0.2%/patient-year)</td>
<td>15 (1.3 ± 0.3%/patient-year)</td>
<td>2 (0.7 ± 0.5%/patient-year)</td>
<td>5 (0.9 ± 0.4%/patient-year)</td>
<td>94 (1.9 ± 0.2%/patient-year)</td>
</tr>
<tr>
<td>Reoperation</td>
<td>93 (1.7 ± 0.2%/patient-year)</td>
<td>73 (1.8 ± 0.2%/patient-year)</td>
<td>13 (1.1 ± 0.3%/patient-year)</td>
<td>7 (2.5 ± 1.0%/patient-year)</td>
<td>6 (1.0 ± 0.4%/patient-year)</td>
<td>87 (1.8 ± 0.2%/patient-year)</td>
</tr>
<tr>
<td>Explant owing to SVD</td>
<td>52 (1.0 ± 0.1%/patient-year)</td>
<td>38 (0.9 ± 0.2%/patient-year)</td>
<td>12 (1.1 ± 0.3%/patient-year)</td>
<td>2 (0.7 ± 0.5%/patient-year)</td>
<td>11 (1.9 ± 0.6%/patient-year)</td>
<td>39 (0.8 ± 0.1%/patient-year)</td>
</tr>
<tr>
<td></td>
<td>31 (0.6 ± 0.1%/patient-year)</td>
<td>23 (0.6 ± 0.2%/patient-year)</td>
<td>8 (0.7 ± 0.2%/patient-year)</td>
<td>0 (0.0 ± 0.0%/patient-year)</td>
<td>8 (1.4 ± 0.5%/patient-year)</td>
<td>23 (0.5 ± 0.1%/patient-year)</td>
</tr>
</tbody>
</table>

*SVD = structural valve deterioration.

Clinical Data

Surgical implantation technique and the collection of clinical data for this cohort have been previously described [4, 7]. Patients were prospectively monitored for adverse events using annual telephone contact throughout the follow-up period. Follow-up was complete in 630 (86.9%) of 725 patients. Reporting of adverse events regarding durability and mortality follows guidelines of The Society of Thoracic Surgeons and American Association of Thoracic Surgeons [8]. The present report is based on data collected through December 2011.

Statistical Methods

Continuous data are reported as mean ± 1 standard deviation when normally distributed, and as median and interquartile range (IQR) when not normally distributed. Categorical data are reported as number and percentage. Late mortality and late morbid events were defined as events that occurred at least 30 days after aortic valve replacement if the patient was discharged from the hospital. Survival analyses using the Kaplan-Meier method were used to estimate survival, freedom from reoperation, freedom from explant, and freedom from death. Peto’s formula was used to calculate the standard errors of these estimates. Cox regression models were used to evaluate the association of age as a continuous variable on outcomes, with age of 60 years and younger or older than 60 years used for illustration. Log-rank test statistics were used for comparison of outcomes among subcoronary, full root, and root inclusion implant groups. Events that occurred in the early and late postoperative periods were included in this analysis. Statistical analyses were performed using SAS (version 9.2; SAS Institute; Cary, NC).

Results

Patient Cohort

Demographic data for this cohort of patients have been previously published [5]. Patient age was 71.7 ± 7.9 years (range, 36 to 91 years) at the time of surgery. There were 402 (55.4%) men and 323 (44.6%) women. A total of 525 (72.4%) patients were in New York Heart Association functional class III or IV. The dominant underlying lesion was either isolated aortic stenosis (312 patients; 43.0%) or mixed aortic stenosis and regurgitation (343 patients; 47.3%). Of 725 patients, the implant technique was subcoronary in 509 (70.2%) patients, total root in 178 (24.6%), and root inclusion in 38 (5.2%). The preponderance of subcoronary implants were modified

Table 2. Clinical Outcomes for All Implant Techniques at 5, 10, and 15 Years

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>Number at Risk</th>
<th>5 Years</th>
<th>Number at Risk</th>
<th>10 Years</th>
<th>Number at Risk</th>
<th>15 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from all-cause mortality</td>
<td>511</td>
<td>75.2% ± 1.7%</td>
<td>210</td>
<td>46.2% ± 2.3%</td>
<td>50</td>
<td>25.9% ± 3.2%</td>
</tr>
<tr>
<td>Freedom from valve-related death</td>
<td>511</td>
<td>98.0% ± 0.6%</td>
<td>210</td>
<td>94.9% ± 1.5%</td>
<td>50</td>
<td>92.7% ± 3.5%</td>
</tr>
<tr>
<td>Freedom from reoperation</td>
<td>507</td>
<td>97.1% ± 0.7%</td>
<td>208</td>
<td>92.3% ± 1.8%</td>
<td>50</td>
<td>80.7% ± 5.0%</td>
</tr>
<tr>
<td>Freedom from explant owing to SVD</td>
<td>511</td>
<td>99.7% ± 0.3%</td>
<td>210</td>
<td>96.5% ± 1.3%</td>
<td>50</td>
<td>83.3% ± 4.8%</td>
</tr>
</tbody>
</table>

*Results are estimate ± standard error of the mean.

SVD = structural valve deterioration.
subcoronary, with retention of the noncoronary sinus of Valsalva. Concomitant procedures were performed in 366 (50.5%) patients; the most common were coronary artery bypass grafting in 286 (39.4%) patients, and ascending aorta repair in 57 (7.9%).

Total follow-up for the 725 patients was 5,491.2 patient-years, with an average follow-up of 7.6 years per patient (median, 7.8 years; IQR, 4.3 to 10.7 years; range, 0.0 to 18.1 years). For patients who underwent subcoronary implant, full-root implant, and root inclusion implantation, total follow-up was 4,062.4 years (median, 8.2 years; IQR, 4.7 to 11.3 years; range, 0.0 to 18.1 years), 1,150.0 years (median, 7.0 years; IQR, 3.1 to 9.0 years; range, 0.0 to 17.6 years), and 278.8 years (median, 8.2 years; IQR, 5.2 to 10.0 years; range, 0.1 to 11.8 years), respectively.

Clinical Outcomes

Operative mortality has been previously reported [8]. All late adverse events are summarized in Table 1. Of 377 late deaths, 99 were cardiac and 93 either valve-related (n = 28) or unexplained (n = 65). Valve-related deaths were attributable to thromboembolism in 8 patients, endocarditis in 6, antithromboembolic-related major hemorrhage in 3, structural valve deterioration (SVD) in 3, aortic regurgitation in 5 (central in 2, paraprosthetic in 2, and indeterminate in 1), thrombosis in 1, nonstructural dysfunction in 1, and severe aortic stenosis with mitral and tricuspid regurgitation in 1.

There were 52 late reoperations, with explant of the bioprosthesis in 47 cases. Reoperations were attributable to SVD in 31 patients, endocarditis in 10, aortic regurgitation in 9 (paraprosthetic in 7, combined central and paraprosthetic in 1, and indeterminate in 1), and nonstructural dysfunction in 2.

Data reflecting freedom from adverse events are shown in Table 2 and Figures 1 through 4. Data reflecting outcomes based on implant technique are shown in Table 3. There were no statistically significant differences based on implant technique in freedom from all-cause mortality (p = 0.81), freedom from valve-related death (p = 0.09), freedom from reoperation (p = 0.41), or freedom from explant as a result of SVD (p = 0.14). Increased age was associated with a higher risk of all-cause mortality and valve-related mortality and a
lower risk of reoperation or explant owing to SVD (Table 4). Using age as a dichotomous variable for illustrative purposes, outcomes are shown in Figures 1 through 4.

Comment

Stentless aortic bioprostheses in general have excellent hemodynamics. The Freestyle valve has low transvalvular gradients at rest [1–4] and during exercise [2, 3], with documented postoperative left ventricular mass regression suggesting favorable long-term hemodynamics [4, 9–11]. However, the associated implant technique is more complicated than that for stented aortic bioprostheses, and questions have been raised as to whether the additional time and expertise required for stentless valve implantation are justified [12, 13].

Past Comparative Studies

There have been several comparative trials between stentless and stented aortic bioprostheses. In nonrandomized trials, aortic valve replacement with a stentless bioprosthesis has been associated with superior midterm survival [14–16]. However, findings might have been affected by selection bias favoring the use of stentless valves in younger or healthier patients. Prospectively randomized trials have included relatively few patients without truly long-term follow-up [9–11, 17, 18], and patient groups are not always evenly matched owing to limitations posed by aortic root calcification and atypical coronary artery position [9, 17]. Existing randomized trials have yielded mixed results, suggesting that the Freestyle valve compared with stented bioprostheses is associated with variably better [9, 17] or equivalent hemodynamics [11]; better [9, 10] or equivalent left ventricular mass regression [11]; better recovery of impaired left ventricular systolic function [11, 18]; superior [18] or equivalent functional status [10, 18]; and superior [17] or equivalent survival [10]. Some advantages were seen specifically among patients with impaired preoperative left ventricular function [11] or with a small aortic annulus [11, 18]. Unfortunately, practical difficulties confound the ability to study long-term outcomes using prospectively randomized multicenter trials after heart valve surgery.

Fig 3. Freedom from reoperation through 15 years. Ten-year and 15-year estimates (± standard error of the mean) for freedom from reoperation were 90.0% (±5.6%) and 68.7% (±10.3%) for patients 60 years or younger, and 92.4% (±1.9%) and 83.0% (±5.7%) for patients older than 60 years at time of implant.

Fig 4. Freedom from explant for structural valve deterioration (SVD) through 15 years. Ten-year and 15-year estimates (± standard error of the mean) for freedom from explant owing to structural valve deterioration were 97.8% (±2.8%) and 70.7% (±10.2%) for patients 60 years or younger, and 96.2% (±1.4%) and 86.5% (±5.3%) for patients older than 60 years at time of implant.
Realistically, decisions about the advantages and disadvantages of specific heart valves rest on long-term observational studies.

Prior Assessment of Freestyle Durability
Stentless valves were introduced for clinical use in the United States in the late 1990s. Existing reports on the Freestyle valve have demonstrated good durability through 9 to 12 years, with freedom from reoperation for SVD of 96% to 97% in both single-center [6, 19] and multicenter studies [4, 5]. One recently published single-center study found freedom from reoperation for SVD of 96% at 15 years [6].

Freestyle 15-Year Durability
The present report describes clinical outcomes associated with the Freestyle stentless aortic root bioprosthesis from the long-term cohort initially used for US Food and Drug Administration approval of the valve. It is the largest and longest-term multicenter study of patients implanted with this valve in North America. Ten-year and 15-year rates for freedom from reoperation were 92% and 81%, respectively, and rates for freedom from explant owing to SVD were 96% and 83%, respectively. Comparisons with other long-term studies of current-generation bioprostheses are shown in Table 5 [6, 20-30]. Although periods, patient ages, and follow-up intervals are not uniform, freedom from reoperation and freedom from SVD appear similar to most and probably inferior to none of the other bioprostheses. As is the case with other bioprostheses, younger age in the present study was associated with increased risks of reoperation and explant for SVD.

Freestyle 15-Year Survival
As with essentially all other studies of mortality among adult patients after aortic valve replacement, the present study reveals limited survival at 10 and 15 years. This likely is attributable to aortic valve replacement performed for diseases that present relatively late in life and in association with other important comorbid diseases. However, survival after aortic valve replacement with the Freestyle bioprosthesis is not qualitatively different from survival with other bioprostheses (Table 5).

Freedom from valve-related death after Freestyle aortic valve replacement is good (approximately 93% at 15 years). As anticipated, all-cause mortality and valve-related mortality risks increased with patient age. There were no statistically significant differences in either all-cause mortality or valve-related mortality based on Freestyle implant technique.

Clinical Perspective
Questions have been raised as to whether the added time and expertise required for stentless valve replacement and potentially increased complexity at the time of reoperation warrant their use [12, 13]. Although it seems unlikely that any study will definitively demonstrate broad superiority of any stentless valve, neither does it appear that any study will demonstrate clear clinical inferiority of the Freestyle valve. Rather, it appears that the Freestyle valve is one of a number of good devices among currently available bioprostheses. Existing data suggest that it might have clinical advantages over a stented bioprosthesis in specific clinical scenarios, including patients with a small aortic root [11, 18] and patients with impaired left ventricular systolic function [11]. The clinical utility of the Freestyle valve has been demonstrated among patients with concomitant aortic root disease requiring aortic root replacement [31-34], among elderly patients with poor aortic root tissue, in the setting of aortic dissection when valve replacement is required, and in patients operated on for infective endocarditis.
Concern has been raised about whether reoperation is especially problematic after prior Freestyle aortic valve replacement. Existing literature is divided, with one report of high perioperative mortality [35] countered by another report describing good outcomes and no increase in perioperative risk [36]. It seems safe to conclude that technical expertise required for successful implantation of the valve is also necessary in the event of reoperation. How deeply the use of the Freestyle valve permeates a surgeon’s practice likely is a function of the types of patients operated on, weighing sometimes contradictory comparative data, and comfort with implant and reoperative techniques. However, based on data presented in this and other reports, the long-term durability of the valve appears excellent, making it a viable option for implantation.

Study Limitations
Follow-up through 15 years was available for a relatively small number of patients. This was an observational study, and did not directly compare the Freestyle valve with other prostheses. Acquisition of hemodynamic data was truncated by study protocol at 10 years, and data through that interval have been previously published [4]. Although this report provides longer overall follow-up duration, it is limited to clinical outcomes. Finally, the study included relatively few younger patients, and limited numbers were available at longer follow-up intervals for analysis of outcomes by implant type, with resulting limited power to distinguish differences.

Conclusions
In this long-term, multicenter, observational study, the Freestyle stentless aortic root bioprosthesis offered good clinical outcomes in terms of survival, freedom from valve-related mortality, freedom from reoperation, and freedom from SVD. The Freestyle valve is a viable option for use in patients undergoing bioprosthetic aortic valve replacement and anticipated desire for long-term durability.

Financial support for this study was supplied by Medtronic, Inc.

The authors thank the following physicians for their work with the long-term multicenter trial: John R. Doty, MD, Intermountain Medical Center, Salt Lake City, UT; John Lemmer, MD, Good Samaritan Hospital and Medical Center, Portland, OR; Jacques Metras, MD, CSPQ, Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Sainte-Foy, Quebec, Canada; Nirav C. Patel, MD, Lenox Hill Hospital, New York, NY; John Sullivan, MD, Queen Elizabeth II Health Sciences Centre, Halifax, Nova Scotia, Canada; and Kwok L. Yun, MD, Kaiser Permanente Medical Center, Los Angeles, CA.

References

Table 5. Long-Term Durability of Freestyle and Other Current Bioprostheses

<table>
<thead>
<tr>
<th>Variable</th>
<th>Year</th>
<th>Patients</th>
<th>Mean Age (y)</th>
<th>Follow-Up (y)</th>
<th>Survival (%)</th>
<th>Freedom From Reoperation (%)</th>
<th>Freedom From SVD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freestyle</td>
<td>Present study</td>
<td>2013</td>
<td>725</td>
<td>72 ± 8</td>
<td>15</td>
<td>26 ± 3</td>
<td>81 ± 5</td>
</tr>
<tr>
<td>Mohammadi et al [6]</td>
<td>2012</td>
<td>430</td>
<td>68 ± 8</td>
<td>15</td>
<td>35</td>
<td>75</td>
<td>82</td>
</tr>
<tr>
<td>Banbury et al [21]</td>
<td>1998</td>
<td>310</td>
<td>64 ± 11</td>
<td>12</td>
<td>34 ± 3</td>
<td>–</td>
<td>82 ± 4</td>
</tr>
<tr>
<td>Banbury et al [22]</td>
<td>2001</td>
<td>267</td>
<td>65 ± 12</td>
<td>15</td>
<td>16</td>
<td>–</td>
<td>77*</td>
</tr>
<tr>
<td>Dellgren et al [23]</td>
<td>2002</td>
<td>254</td>
<td>71 ± 9</td>
<td>12</td>
<td>36 ± 9</td>
<td>83 ± 9</td>
<td>86 ± 9</td>
</tr>
<tr>
<td>Hancock II</td>
<td>David et al [25]</td>
<td>2001</td>
<td>670</td>
<td>65 ± 12</td>
<td>15</td>
<td>47 ± 3</td>
<td>77 ± 5</td>
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<tr>
<td>Rizzoli et al [26]</td>
<td>2006</td>
<td>809</td>
<td>68 ± 8</td>
<td>15</td>
<td>40 ± 4</td>
<td>82 ± 4</td>
<td>85 ± 0.4</td>
</tr>
<tr>
<td>Vafré et al [27]</td>
<td>2010</td>
<td>302</td>
<td>66 ± 8</td>
<td>15</td>
<td>40 ± 3</td>
<td>86 ± 3</td>
<td>–</td>
</tr>
<tr>
<td>Mosaic</td>
<td>Reiss et al [28]</td>
<td>2010</td>
<td>255</td>
<td>67 ± 8</td>
<td>13</td>
<td>63 ± 4</td>
<td>73 ± 7</td>
</tr>
<tr>
<td>Jamieson et al [29]</td>
<td>2011</td>
<td>797</td>
<td>69</td>
<td>12</td>
<td>56 ± 4</td>
<td>84 ± 3</td>
<td>91 ± 3</td>
</tr>
<tr>
<td>Mitroflow</td>
<td>Minami et al [30]</td>
<td>2005</td>
<td>1516</td>
<td>&gt;70</td>
<td>15</td>
<td>6</td>
<td>63 ± 5</td>
</tr>
</tbody>
</table>

* Freedom from explant owing to structural valve deterioration.
SVD = structural valve deterioration.
Appendix

<table>
<thead>
<tr>
<th>Study Site</th>
<th>Location</th>
<th>Number of Patients</th>
<th>Total Patient-Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good Samaritan Hospital</td>
<td>Portland, OR</td>
<td>44</td>
<td>308</td>
</tr>
<tr>
<td>Hôpital Laval</td>
<td>Sainte-Foy, Quebec, Canada</td>
<td>205</td>
<td>1,942</td>
</tr>
<tr>
<td>Kaiser Permanente Los Angeles Medical Center</td>
<td>Los Angeles, CA</td>
<td>96</td>
<td>751</td>
</tr>
<tr>
<td>Lenox Hill Hospital</td>
<td>New York, NY</td>
<td>48</td>
<td>328</td>
</tr>
<tr>
<td>Intermountain Medical Center</td>
<td>Salt Lake City, UT</td>
<td>143</td>
<td>935</td>
</tr>
<tr>
<td>Queen Elizabeth II Health Sciences Centre*</td>
<td>Halifax, Nova Scotia, Canada</td>
<td>36</td>
<td>256</td>
</tr>
<tr>
<td>Southwest Washington Medical Center</td>
<td>Vancouver, WA</td>
<td>40</td>
<td>257</td>
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<tr>
<td>Wake Forest University Baptist Medical Center*</td>
<td>Winston-Salem, NC</td>
<td>113</td>
<td>713</td>
</tr>
</tbody>
</table>

* Discontinued participation after August 9, 2004.

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