1-Year Outcomes With the Fully Repositionable and Retrievable Lotus Transcatheter Aortic Replacement Valve in 120 High-Risk Surgical Patients With Severe Aortic Stenosis
Results of the REPRISE II Study

Ian T. Meredith, AM, MBBS, PhD, a Darren L. Walters, MD, b Nicolas Dumonteil, MD, c Stephen G. Worthley, MD, d Didier Tchétché, MD, e Ganesh Manoharan, MD, f Daniel J. Blackman, MD, g Gilles Rioufol, MD, h David Hildick-Smith, MD, i Robert J. Whitbourn, MD, j Thierry Lefèvre, MD, k Rüdiger Lange, MD, l Ralf Müller, MD, m Simon Redwood, MD, n Ted E. Feldman, MD, o Dominic J. Allocco, MD, p Keith D. Dawkins, MD

ABSTRACT

OBJECTIVES This analysis presents the first report of 1-year outcomes of the 120 patients enrolled in the REPRISE II (Repositionable Percutaneous Placement of Stenotic Aortic Valve Through Implantation of Lotus Valve System–Evaluation of Safety and Performance) study.

BACKGROUND The fully repositionable and retrievable Lotus Valve (Boston Scientific, Marlborough, Massachusetts) was designed to facilitate accurate positioning, early valve function, and hemodynamic stability during deployment and to minimize paravalvular regurgitation in patients undergoing transcatheter aortic valve replacement.

METHODS The study enrolled 120 symptomatic patients 70 years of age or older at 14 centers in Australia and Europe. Patients had severe calcific aortic stenosis and were deemed to be at high or extreme risk of surgery based on assessment by the heart team.

RESULTS The mean age was 84.4 ± 5.3 years, 57% (68 of 120) of patients were women, and the mean Society of Thoracic Surgeons score was 7.1 ± 4.6. The mean baseline aortic valve area was 0.7 ± 0.2 cm², and the mean transvalvular pressure gradient was 46.4 ± 15.0 mm Hg. All patients were successfully implanted with a Lotus Valve, and 1-year clinical follow-up was available for 99.2% (119 of 120 of patients). The mean 1-year transvalvular aortic pressure gradient was 12.6 ± 5.7 mm Hg, and the mean valve area was 1.7 ± 0.5 cm². A total of 88.6% patients had no or trivial paravalvular aortic regurgitation at 1 year by independent core lab adjudication, and 97.1% of patients were New York Heart Association functional class I or II. At 1 year, the all-cause mortality rate was 10.9% (13 of 119 patients), disabling stroke rate was 3.4% (4 of 119 patients), disabling bleeding rate was 5.9% (7 of 119 patients), with no repeat procedures for valve-related dysfunction. A total of 31.9% (38 of 119 patients) underwent new permanent pacemaker implantation at 1 year.

CONCLUSIONS At 1 year of follow-up, the Lotus Valve demonstrated excellent valve hemodynamics, no moderate or severe paravalvular regurgitation, and significant and sustained improvement in New York Heart Association functional class status, with good clinical outcomes. (Repositionable Percutaneous Placement of Stenotic Aortic Valve Through Implantation of Lotus Valve System–Evaluation of Safety and Performance [REPRISE II; NCT01627691] (J Am Coll Cardiol Intv 2016;9:376–84) © 2016 by the American College of Cardiology Foundation. Published by Elsevier. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/)).
The repositionable and fully retrievable Lotus Valve (Boston Scientific, Marlborough, Massachusetts) was designed to facilitate accurate primary positioning, early valve function, and hemodynamic stability during deployment and to minimize paravalvular regurgitation in patients with severe aortic stenosis who are deemed at high or extreme surgical risk (1). The Lotus Valve has received CE mark in Europe based in part on the initial results of the REPRISE II (Repositionable Percutaneous Placement of Stenotic Aortic Valve Through Implantation of Lotus Valve System—Evaluation of Safety and Performance) study (2). At 30 days, the mean aortic valve pressure gradient was 11.5 ± 5.2 mm Hg, with a 1-sided 98.7% upper confidence limit of 12.6, which was significantly less than the predetermined performance goal of 18 mm Hg (1-sample t test, p < 0.0001), and, thus, the primary device performance endpoint was met. The primary safety endpoint, defined as all-cause mortality at 30 days, was 4.2% (5 of 119 patients). The observed rate of moderate or severe paravalvular regurgitation was low at 30 days, with only 1 patient (1.0%) having moderate paravalvular regurgitation and no patients having severe paravalvular regurgitation (2). This analysis of the 120-patient REPRISE II study presents the first publication of 1-year outcomes with the Lotus Valve in a substantial number of patients.

METHODS

The REPRISE II study design and methods were previously described in detail and are briefly summarized here (2).

DEVICE DESCRIPTION. The Boston Scientific Lotus Valve System consists of a woven nitinol-framed bioprosthesis with bovine pericardium leaflets, which is pre-mounted on a transfemoral catheter delivery system. The valve is expanded via a controlled mechanical expansion that facilitates repositioning or full retrieval even after the valve is fully expanded and locked in its final position; rapid pacing is not required during implantation, and the valve functions early in deployment, providing hemodynamic stability. The design also incorporates a polymeric outer Adaptive Seal designed to minimize paravalvular regurgitation. The Lotus Introducer Set is composed of a dilator and an introducer sheath and is used as an accessory in the procedure. Two valve sizes were available in the REPRISE II study: 23 mm (for patients with a native aortic annulus of 19 to 23 mm) and 27 mm (for patients with a native aortic annulus of 23 to 27 mm).

ABBREVIATIONS AND ACRONYMS

NYHA = New York Heart Association
SF-12 = 12-Item Short-Form Health Survey
TAVR = transcatheter aortic valve replacement
TTE = transthoracic echocardiography

See page 385
STUDY DESIGN. The REPRISE II study is a prospective, single-arm, multicenter trial evaluating the safety and effectiveness of the Lotus Valve at 14 centers in Australia, France, Germany, and the United Kingdom. The primary device performance endpoint was the mean aortic valve pressure gradient at 30 days post-procedure. The primary device performance endpoint was compared with a performance goal of 18 mm Hg. The primary safety endpoint was the rate of all-cause mortality at 30 days post-procedure. One-year clinical outcomes were pre-specified as secondary endpoints in the study protocol.

The REPRISE II study complied with the principles of the Declaration of Helsinki and all local and country-specific regulations. A locally appointed ethics committee approved the research protocol at each site, and all patients (or their guardians) provided written informed consent before enrollment. The constitution and function of the Case Review Committee has been previously described (2).

PATIENT SELECTION, PROCEDURE, AND FOLLOW-UP. Patients 70 years of age or older with symptomatic severe aortic stenosis (defined as an aortic valve area of <1.0 cm² or aortic valve area index of <0.6 cm²/m²) and a mean pressure gradient >40 mm Hg or a jet velocity >4 m/s were eligible for enrollment. Other key inclusion criteria were New York Heart Association (NYHA) functional class II or greater heart failure, native aortic annulus size between 19 and 27 mm, and a Society of Thoracic Surgeons (STS) score ≥8% or considered high risk for surgical aortic valve replacement based on assessment by the multidisciplinary Heart Team. An independent Case Review Committee also confirmed patient eligibility for the study before enrollment. The constitution and function of the Case Review Committee has been previously described (2). Key exclusion criteria included acute myocardial infarction within 30 days, stroke or transient ischemic attack within 6 months, compromised kidney function (defined as dialysis dependent or creatinine level >3.0 mg/dl), unicuspid or bicuspid aortic valve, preexisting aortic or mitral prosthetic heart valve or ring, ≥3+ mitral or ≥3+ aortic regurgitation, left ventricular ejection fraction <30%, or femoral artery anatomy unsuitable for the use of the Lotus Valve Introducer.

All investigators completed comprehensive training before performing implantations in patients and received on-site proctorship during their initial implantation procedures. Patients were assessed by transthoracic echocardiography, coronary angiography, computed tomography angiography of the aortic valve and the entire aorta, and computed tomography or invasive angiography of the iliofemoral system. The choice of valve size was determined in all cases by systematic analysis of the diameter, perimeter, and area of basal plane annulus, left ventricular outflow tract, and transsinus dimensions using the 3Mensio MDCT Aortic Valve Analysis software (3Mensio Medical Imaging BV, Bilthoven, the Netherlands). Metrics to aid the choice of either the 23-mm diameter or 27-mm diameter prosthesis were previously described (2).

Per protocol, all implantations were performed via the transfemoral route. Balloon valvuloplasty was required before insertion of the Lotus Valve System. Patients were considered enrolled in the study as soon as an attempt was made to insert the Lotus Valve System into the femoral artery sheath. All enrolled patients were considered for analysis in the study, and no roll-in patients were allowed. Anti-coagulant therapy (e.g., unfractionated heparin) was administered per local standard of care during the implantation procedure, with a recommended target activated clotting time of ≥250 s during the index procedure. Patients were required to be treated with aspirin and a thienopyridine before implantation of the Lotus Valve and for at least 1 month after valve implantation, and daily aspirin was recommended indefinitely thereafter per local standard of care (2,3).

Clinical follow-up occurred at discharge or 7 days (whichever came first), 30 days, 3 months, 6 months, and 1 year, and will continue annually to 5 years. Neurological status was assessed in all patients pre- and post-procedure by a qualified neurologist. Health status was evaluated using the 12-item Short-Form Health Survey (SF-12) and EQ-5D Quality of Life questionnaires administered at baseline, 1 month, 6 months, and 1 year.

DEFINITIONS. Safety and effectiveness were assessed according to Valve Academic Research Consortium 2 metrics (4). An independent clinical events committee adjudicated all VARC-related endpoints. The REPRISE II study used 4 independent core laboratories for the assessment of the following: 1) angiography and computed tomography/radiographic data (Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center, Boston, Massachusetts); 2) echocardiography (MedStar Health Research Institute, Washington, DC); 3) electrocardiography (Harvard Clinical Research Institute, Boston, Massachusetts); and 4) pathology (CV Path Institute, Inc., Gaithersburg, Maryland).

STATISTICAL METHODS. Patient demographics, risk factors, device performance, and clinical outcomes were summarized using descriptive statistics for continuous variables and frequency tables for discrete variables. All endpoints were analyzed on an intent-to-treat basis. Change from baseline to 1 year was assessed using paired Student t tests for health status data; change from baseline for hemodynamic measures was assessed using estimates of the
repeated measures and a hierarchical analysis of variance model with unstructured covariance and with random effects of country and center where center was nested within the country. Change from baseline for NYHA functional class was assessed using the paired Wilcoxon signed rank test. All calculations were performed using SAS version 9.2 or later (SAS Institute, Cary, North Carolina).

RESULTS

All 120 patients enrolled in the REPRISE II study received a Lotus Valve; of these, 61 (50.8%) received a 23-mm valve and 59 (49.2%) received a 27-mm valve. Successful vascular access, delivery, and deployment of the Lotus Valve along with successful retrieval of the delivery system occurred in all 120 patients. Repositioning or retrieval of the valve occurred in 32 patients (26.7%). One patient withdrew consent on day 13; thus, 1-year follow-up or death data were available for 99.2% (119 of 120 patients) (Figure 1). Thirteen patients died within 1 year, and trans-thoracic echocardiography assessment was completed in 99 of 106 eligible patients (92.4%). Baseline patient and echocardiographic characteristics, including frailty characteristics, are provided in Table 1. The majority of patients were female (57%), with a mean age of 84 years and an STS score (version 2.73) of 7.1 ± 4.6%.

VALVE PERFORMANCE AT 1 YEAR. At baseline, the effective aortic valve orifice area was 0.7 ± 0.2 cm², and the mean aortic transvalvular gradient was 46.4 ± 15.0 mm Hg (Figure 2). At hospital discharge, the mean effective orifice area had improved to 1.6 ± 0.4 cm² (p < 0.001 vs. baseline), and the mean aortic transvalvular gradient also improved to 12.1 ± 4.4 mm Hg (p < 0.001 vs. baseline). These results were sustained at 1 year, with an effective orifice area of 1.7 ± 0.5 cm² (p < 0.001 vs. baseline) and a mean aortic gradient of 12.6 ± 5.7 mm Hg (p < 0.001 vs. baseline). There was no or trivial paravalvular regurgitation at 1 year in 88.6% of patients, and no patient had moderate or severe paravalvular aortic regurgitation at 1-year follow-up, as assessed by the echocardiographic core laboratory (Figure 3).

NYHA FUNCTIONAL CLASS AND HEALTH STATUS AT 1 YEAR. At baseline, the majority of patients (75.8%) were NYHA functional class III or IV (Figure 4). Post-procedure, there was steady improvement in NYHA functional class overall such that 97.2% of patients were either functional class I or II at 1 year (p < 0.001 vs. baseline and p = 0.04 vs. 30 days). Health-related quality of life was significantly increased from baseline according to the SF-12 questionnaire, with the physical health summary score improving from 35.0 ± 9.2 at baseline to 38.2 ± 10.8 at 1 year (p = 0.004). The mental health summary score was unchanged at 1 year (49.7 ± 10.4 and 51.3 ± 10.6 at baseline and 1 year, respectively; p = 0.55) (Table 2). In addition, self-rated health according to the EQ-5D

![FIGURE 1 Study Flow](image)

**TABLE 1 Baseline Patient and Echocardiographic Characteristics (N – 120)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD (n/N) or % (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>84.4 ± 5.3 (120/120)</td>
</tr>
<tr>
<td>Female</td>
<td>56.7 (68/120)</td>
</tr>
<tr>
<td>Society of Thoracic Surgeons score</td>
<td>7.1 ± 4.6 (120/120)</td>
</tr>
<tr>
<td>Society of Thoracic Surgeons Plus score</td>
<td>11.8 ± 8.0 (120/120)</td>
</tr>
<tr>
<td>EuroSCORE 2011</td>
<td>6.9 ± 5.8 (120/120)</td>
</tr>
<tr>
<td>New York Heart Association functional class III or IV</td>
<td>75.8 (91/120)</td>
</tr>
<tr>
<td>Medically treated diabetes</td>
<td>22.5 (27/120)</td>
</tr>
<tr>
<td>History of atrial fibrillation</td>
<td>40.8 (49/120)</td>
</tr>
<tr>
<td>Baseline right bundle branch block</td>
<td>7.5 (9/120)</td>
</tr>
<tr>
<td>Baseline left bundle branch block</td>
<td>6.7 (8/120)</td>
</tr>
<tr>
<td>Baseline first-degree atroventricular block</td>
<td>17.5 (21/120)</td>
</tr>
<tr>
<td>Permanent pacemaker at baseline</td>
<td>6.7 (8/120)</td>
</tr>
<tr>
<td>Frailty Indices</td>
<td></td>
</tr>
<tr>
<td>5-m gait speed, s (frail if &gt;6 s)</td>
<td>9.2 ± 6.7 (119)</td>
</tr>
<tr>
<td>Mean maximum grip strength, kg (frail if ≤18 kg)</td>
<td>20.1 ± 12.8 (120)</td>
</tr>
<tr>
<td>Katz index (frail if &lt;6)</td>
<td>5.7 ± 0.9 (120)</td>
</tr>
<tr>
<td>Mini-Cognitive Assessment for Dementia (frail if &lt;4)</td>
<td>3.6 ± 1.4 (120)</td>
</tr>
<tr>
<td>Echocardiography measurements</td>
<td></td>
</tr>
<tr>
<td>Aortic valve area, cm²</td>
<td>0.7 ± 0.2 (97/120)</td>
</tr>
<tr>
<td>Mean aortic gradient, mm Hg</td>
<td>46.4 ± 15.0 (104/120)</td>
</tr>
<tr>
<td>Peak aortic gradient, mm Hg</td>
<td>76.5 ± 23.6 (104/120)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction, %</td>
<td>54.3 ± 10.7 (61/120)</td>
</tr>
<tr>
<td>Mitral regurgitation (moderate/severe), %</td>
<td>11.6 (13/112)</td>
</tr>
<tr>
<td>Aortic regurgitation (moderate/severe), %</td>
<td>15.2 (17/112)</td>
</tr>
</tbody>
</table>

Values are mean ± SD (n/N) or % (n/N). *Core laboratory assessment.
visual analog scale significantly improved from 61.6 ± 17.9 at baseline to 70.1 ± 18.0 at 1 year (p < 0.001). There was no change from baseline in health status according to the EQ-5D index values (Table 2).

SAFETY OUTCOMES AT 1 YEAR. All-cause mortality at 1 year was 10.9% (Table 3), representing 3 new cardiovascular and 5 new noncardiovascular deaths after the previously published primary endpoint of 30 days. Disabling stroke was 3.4%, and nondisabling stroke was 5.9%, representing 2 additional disabling and 2 nondisabling strokes that occurred between 30 days and 1 year, for a total stroke rate of 9.2% at 1 year. There was no significant difference in 1-year stroke rate between patients with and without repositioning or retrieval of the valve during implantation (9.4% [3 of 32 patients] vs 9.1% [8 of 88 patients] without repositioning/retrieval; p = 1.00). One additional case of life-threatening bleeding (the patient required transfusion following hip replacement surgery) was reported at day 301, and 1 case of prosthetic valve endocarditis (associated with urosepsis) was reported at day 165, but otherwise the Valve Academic Research Consortium 2 safety endpoints remained largely unchanged at 1 year from those observed at 30 days (Table 3).

Four additional patients required implantation of a new permanent pacemaker between 30 days and 1 year for an overall 1-year rate of 31.9%. Among patients with a new pacemaker at 1 year, 57.9% had >10% overstretch of the left ventricular outflow tract by area, and nearly 40% (39.5%) had >10% overstretch of the annulus by area (Table 3). Significantly more patients with a pacemaker at 1 year had >10% left ventricular outflow tract overstretch compared with patients without a pacemaker (57.9% vs. 33.8%, respectively; p = 0.01). There was a trend toward a greater proportion of patients with >10% annular overstretch among patients with a pacemaker at 1 year, but the difference did not reach statistical significance (39.5% vs. 24.3%; p = 0.10).

At 1 year, there were no repeat procedures for valve-related dysfunction and no valve thrombosis, migration, or embolization (Table 3).

DISCUSSION

In this 1-year follow-up of the REPRISE II study, we report that the Lotus Valve has favorable valve performance and sustained hemodynamic and clinical benefits. These observations are entirely consistent with those reported in the 30-day primary endpoint paper (1). The significant increase from baseline to 30 days in mean aortic valve gradient and effective aortic valve orifice area were sustained at 1 year and were consistent with those reported for other transcatheter valves in serial echocardiographic studies after transfemoral valve implantation (5-10). At
1 year, there were no repeat procedures for valve-related dysfunction, and no valve thrombosis, migration, or embolization. Also notable was the lack of valve-in-valve procedures or the need for late surgical conversion with the Lotus Valve.

Transcatheter aortic valve replacement (TAVR) provides a clinically viable alternative to conventional surgical aortic valve replacement for patients at high or extreme risk of perioperative mortality. Recent data from the U.S. randomized CoreValve study indicate a survival advantage for TAVR at 1 year that is preserved through 2 years and that freedom from death or stroke remains lower with TAVR than surgical aortic valve replacement (11). Although these data are excellent, several limitations remain in first-generation TAVR devices, including challenges in valve positioning and paravalvular aortic regurgitation. The Lotus Valve was designed to aid accurate primary positioning without the need for rapid pacing or hemodynamic stress, provide the opportunity to reposition or retrieve the valve if necessary, and decrease the risk of paravalvular leak, all of which are factors that may improve both short- and long-term clinical outcomes.

In this study, patients implanted with the Lotus Valve experienced a clinically and statistically significant improvement in health and quality of life status at 30 days, which was also maintained through 1 year. At 1 year, 97.2% of patients were NYHA functional class I or II, a notable and highly significant (p < 0.001) increase from baseline, where 76% of patients were functional class III or IV, and a further significant improvement from 30 days, where 91% of patients were functional class I or II (p = 0.04 for 30 days to 1 year). Similarly, the 3.2-point increase from baseline in the SF-12 physical summary score observed at 1 year, although significant (p = 0.004), also exceeded the minimally important difference of 2.5 points that is generally considered to be clinically meaningful with this instrument (12). Although the EQ-5D has been used in studies of cardiovascular disease, considerable heterogeneity between studies has limited efforts to establish minimally important differences with this metric (13,14); however, in studies of patients with cancer, minimally important differences in the EQ-5D ranged from 0.06 to 0.07 and in visual analog scale scores from 8 to 12 (15). In this regard, the significant (p < 0.001) change from baseline to 1 year of 8.5 in visual analog scale scores in the current study corroborate the changes observed in NYHA functional class assessment and the SF-12, and the EQ-5D and SF-12 results at 6 months and 1 year observed in this study are concordant with other serial studies of quality of life in patients with aortic stenosis (16-18).

Independent core laboratory adjudication of the extent of paravalvular regurgitation indicated 86.4% of patients had no paravalvular regurgitation at 1 year, and an additional 2.3% had only a trace of regurgitation. No patient was adjudicated to have moderate or severe paravalvular regurgitation at 1 year. Moderate/severe paravalvular regurgitation has been found in 9% to 25% of patients in reports using first-generation TAVR devices and is associated with increased mortality (7,19-22). Although clear causality has not been established, the mechanisms underlying the association are being elucidated and may, in part, involve a blunted remodeling response of the left ventricle after TAVR (23) or myocardial ischemia due to a higher pressure gradient associated with paravalvular regurgitation into a hypertrophied ventricle (24,25).

All-cause mortality and disabling stroke rates at 1 year were 10.9% and 3.4%, respectively. These rates are at least comparable to those reported with other contemporary transfemoral transcatheter aortic valves. Although cross-trial comparisons should be
approached with caution given a lack of randomization or propensity matching, we note that in randomized trials of other valves implanted transfemorally, 1-year mortality rates ranged from 14.2% to 24.3% for the Medtronic CoreValve (baseline STS scores: 5.3 to 10.3) (5,7,9) and from 22.5% to 30.7% for the Edwards SAPIEN/SAPIEN XT (baseline STS scores: 10.3 to 11.2) (6,8). Similarly, major/disabling stroke rates at 1 year were reported in those trials ranged from 2.2% to 5.8% for the CoreValve (5,7,9) and from 4.5% to 7.8% for SAPIEN/SAPIEN XT (6,8).

The rate of permanent pacemaker implantation at 1 year was 31.9% (38 of 119 patients) in the REPRISE II study. Reported rates for the need for pacemaker implantation at 1 year post-TAVR have ranged from 1.8% to 11.5% with SAPIEN/SAPIEN XT (6,8,21,26,27) and 19.1% to 30.3% with CoreValve (5,7,9,20–22). Pacemaker implantation has not been associated with an increased risk of mortality in the majority of published studies (28–30), although the long-term consequence of the need for pacemaker implantation should be considered for selected patient populations, such as patients with poor left ventricular function, younger patients, or those with lower surgical risk. Although 1 recent study suggested poorer outcomes when a pacemaker is implanted after deployment of the SAPIEN valve (31), another study suggested improved survival associated with pacemaker implantation (32). Greater than 10% overstretch, particularly of the left ventricular outflow tract, was associated with a significantly increased rate of permanent pacemakers in the REPRISE II study; the availability of additional valve sizes may help in this regard.

**STUDY LIMITATIONS.** First, this was not a randomized, double-blind, active-control trial. The U.S. Food and Drug Administration approval REPRISE III study that is currently enrolling patients will provide a head-to-head randomized comparison with the Core-Valve in ~1,000 patients and is expected to add considerably to the body of evidence for TAVR. Second, although pre-specified in the study protocol, our study was not statistically powered for clinical end-points at 1 year, so those results should be considered hypothesis generating only.

**CONCLUSIONS**

At 1 year in the main 120-patient cohort, the REPRISE II study demonstrated sustained and excellent value
hemodynamic results, with very low rates of paravalvular regurgitation. More than 88% of patients had no or trivial paravalvular regurgitation, and no patient had moderate or severe paravalvular regurgitation. Additionally, we observed significant and sustained improvement in NYHA functional class, significantly improved quality of life measures from baseline, and adverse event rates consistent with those reported for other transcatheter valves. The 1-year results of this study continue to suggest that the fully repositionable and retrievable Lotus Valve is a valuable new addition to the available devices for the minimally invasive treatment of aortic stenosis.

ACKNOWLEDGMENTS The authors thank Vicki M. Houle, PhD (Boston Scientific Corporation) for assistance in manuscript preparation and Edmund McMullen, MS, and Hong Wang, MS (Boston Scientific Corporation) for statistical analysis.

REPRINT REQUESTS AND CORRESPONDENCE: Dr. Ian T. Meredith, MonashHEART, Monash Health, Monash Medical Centre and Monash University, 246 Clayton Road, Melbourne, Victoria 3168, Australia. E-mail: ian.meredith@myheart.id.au.


KEY WORDS aortic stenosis, TAVR, transcatheter aortic valve implantation, transfemoral