Long-Term Outcomes of the Mosaic Aortic Porcine Bioprosthesis in Japan

— Results From the Japan Mosaic Valve Long-Term Multicenter Study —

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Background: This study retrospectively evaluated the long-term patient outcomes and durability of the Mosaic aortic porcine bioprosthesis in the Japan Mosaic valve long-term multicenter study.

Methods and Results: We reviewed the records of 1,202 patients who underwent aortic valve replacement with the Mosaic bioprosthesis at 10 centers in Japan (1999–2014). Patient data were collected using Research Electronic Data Capture. Patient survival was determined by Kaplan-Meier methodology. Freedom from structural valve deterioration (SVD) and valve-related reoperation and death were determined by actuarial methods. The median (interquartile range [IQR]) age of the cohort was 76 (70–80) years. The median (IQR) follow-up period was 3.52 (1.71–5.35) years. The longest follow-up was 15.8 years. The 30-day mortality rate was 2.3%. The 12-year actuarial survival rate was $59.9 \pm 7.5\%$, and the freedom from valve-related death was $81.1 \pm 7.9\%$. The freedom from reoperation was $86.4 \pm 2.6\%$ at 12 years. The freedom from SVD at 12 years was $93.5 \pm 2.9\%$ for patients aged ≥ 65 years and $98.2 \pm 1.8\%$ for those aged < 65 years. The median (IQR) systolic pressure gradient was 17 (12–23) and 19 (12–25) mmHg at 1 and 10 years, respectively. The median (IQR) effective orifice area was 1.2 (1.1–1.5) and 1.1 (1–1.5) cm^2 at 1 and 10 years, respectively.

Conclusions: The Mosaic porcine bioprosthesis showed satisfactory long-term outcomes over 12 years.

Key Words: Aortic valve replacement; Bioprosthesis; Durability; Structural valve deterioration

Porcine bioprosthetic heart valves have been used for cardiac valve replacement since the late 1960s.^{1,2} The 1st-generation bioprosthetic valves had a high rate of early failure due to valve calcification and subsequent structural deterioration.^{3,4} Continued improvements in bioprosthesis design and tissue fixation techniques in recent years, in addition to the introduction of tissue antimicrobialization technology, have improved performance and overall durability. Surgical aortic valve replacement (AVR) is a standard treatment for patients without high surgical risk,⁵ which makes the long-term durability of the bioprosthesis critical in patients undergoing standard AVR.

The Mosaic bioprosthesis (Medtronic, Inc., Minneapolis, MN, USA), a 3rd-generation stented porcine bioprosthesis,

was originally released for investigational use in the USA in 1994 and later approved for clinical use by the US Food and Drug Administration in 2000. It combines tissue fixation with 0.2% glutaraldehyde and zero pressure across leaflets and treatment with α -amino oleic acid (antimicrobialization) for improved tissue durability and hemodynamic performance. Several early and mid-term studies have established its clinical safety and efficacy, especially in terms of hemodynamic performance and thromboembolic event rates.^{6–13} A long-term, prospective, observational, non-randomized study demonstrated acceptable rates of death, reoperation, and explant due to structural valve deterioration (SVD) with the Mosaic bioprosthesis.¹⁴ In Japan, the Mosaic bioprosthesis was first introduced for clinical use in 1999.

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A recent retrospective study evaluating the mid- to long-term durability and hemodynamics of the small-size Mosaic bioprosthesis for AVR reported satisfactory hemodynamics, albeit with a few valve-related adverse events in Japanese patients.¹⁵ However, there are no reports on the long-term outcomes in a large population of Japanese patients undergoing AVR with the Mosaic bioprosthesis.

Methods

The present large, multicenter, retrospective Japan Mosaic valve (J-MOVE) study examined patient outcomes and durability associated with the Mosaic bioprosthesis device over 15 years.

Study Design

We retrospectively reviewed the records of 1,202 patients who underwent AVR with the Mosaic bioprosthesis (alone or in combination with coronary artery bypass grafting or other cardiac procedures) at 10 centers in Japan from November 1999 to December 2014. The data were collected retrospectively using Research Electronic Data Capture (REDCap).¹⁶ REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for data integration and interoperability with external sources.

All patients who underwent AVR using a Mosaic valve in the aortic position during the study period were included. Patients who underwent mitral valve surgery at implantation of a Mosaic valve in the aortic position were excluded. Mortality and valve-related morbidity are reported in accordance with the guidelines of the Society of Thoracic Surgeons, the American Association for Thoracic Surgery, and the European Association for Cardio-Thoracic Surgery.¹⁷ Early death was defined as any death that occurred <30 days after surgery, regardless of the patient's location (e.g., home or in a healthcare facility). Late death was defined as any death that occurred >30 days after surgery. SVD was defined as dysfunction or deterioration of the prosthetic valve (exclusive of infection or thrombosis), such as calcification, tearing, stiffness, and cusp perforation, as determined by echocardiography (at follow-up) and/or reoperation. Nonstructural valve deterioration (NSVD) was defined as any abnormality, not intrinsic to the valve itself, resulting in stenosis or regurgitation of the prosthesis, such as pannus formation, perivalvular leakage, valve distortion, and valve dehiscence. Structural deterioration caused by endocarditis or thrombosis was not included. The bioprosthesis was considered to have deteriorated on strict echocardiographic assessment whenever severe aortic stenosis (mean transvalvular gradient >40 mmHg) or severe aortic regurgitation (effective regurgitant orifice area >0.30 cm², vena contracta >0.6 cm) was observed, even if the patient was asymptomatic. Thrombosis was defined as any thrombus not caused by infection attached to or near an operated valve that occluded part of the blood flow path, interfered with valve function, or sufficiently large to warrant treatment. Embolism was any embolic event that occurred in the absence of infection after the immediate perioperative period. Embolism may manifest as a neurological event or a noncerebral embolic event. A bleeding event was any

episode of major internal or external bleeding that caused death, hospitalization, or permanent injury or necessitated transfusion.

The ethics review board of each participating center reviewed and approved the study. Individual patient consent was waived because data were collected retrospectively and anonymized.

Statistical Analysis

Continuous variables are reported as median and interquartile range (IQR) and categorical variables as frequency and percentage. Categorical and continuous variables were analyzed using the chi-square test and the Wilcoxon's rank-sum test, respectively. Patient survival was determined by Kaplan-Meier methodology. Freedom from SVD, valve-related reoperation, thrombosis, embolism or bleeding, and valve-related death were determined by actuarial methods. The analyses of age groups (≥65 years vs. <65 years) were conducted in accordance with the recommendations for prosthesis type by the American College of Cardiology (ACC) and American Heart Association (AHA) guidelines.¹⁸ Comparisons between groups were performed using Cox regression models, including sex and dialysis as confounding factors. Hemodynamic performance was evaluated longitudinally using a random intercept model. All tests were 2-sided, and P<0.05 was considered statistically significant.

Statistical analysis was performed using statistical software R (version 3.6.1, R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient and Procedural Characteristics

The total follow-up was 4,596 patient-years, with a median (IQR) follow-up period of 3.52 (1.71–5.35) years (range: 0–15.8 years) for AVR. The 1-, 5-, and 10-year follow-up rates were 90.5%, 68.4%, and 42.2%, respectively. The median (IQR) age of the cohort was 76 (70–80) years and approximately 53% of the patients were women. A total of 635 patients (52.8%) were in New York Heart Association class II. Degenerative aortic valve disease was the most common indication (80.4%) for valve replacement surgery, with aortic stenosis being the most common diagnosis (62.0%); mixed aortic valve lesion (aortic stenosis and regurgitation) was observed in 11.7% of patients. The median (IQR) left ventricular ejection fraction was 65% (54–73%). The patients' characteristics are summarized in **Table 1A,B**.

The operative timing was elective in 92% of the patients. Redo surgery was performed in 2.7% of cases (n=33). The nominal diameter of the implanted valve was 19 mm in 24% of patients, 21 mm in 31%, 23 mm in 28%, 25 mm in 12%, and 27 mm in 5% of patients. The median (IQR) cardiopulmonary bypass time was 152 (119–196) mins and the median (IQR) aortic cross-clamp time was 103 (80–135) min (unpublished data).

Patient Survival and Valve Durability

The early mortality rate was 2.3% (n=28 in the operative period). The late mortality rate was 11.7% (n=141). Of the 169 deaths that occurred during the follow-up period, 42 (24.9%) were cardiac, 102 (60.4%) were noncardiac, 7 (4.1%) were sudden, and 18 (10.7%) were of unknown cause. Of the cardiac deaths, 7 (16.7%) were valve-related.

Table 1. (A) Characteristics of Patients Included in the Study (n=1,202), (B) Preoperative Echocardiographic Results	
(A)	
Patient characteristics	n (%)
Sex	
Female	643 (53.5)
Male	559 (46.5)
Age at implantation (years)	
Median (IQR)	76 (70–80)
<60	53 (4.4)
60–64	75 (6.3)
65–69	155 (12.9)
70–74	249 (20.9)
75–79	325 (27.0)
>80	345 (28.7)
Body surface area (m ²)	1.45 (1.33, 1.58)
NYHA functional class	
I	235 (19.6)
II	635 (52.8)
III	226 (18.8)
IV	60 (5.0)
Unknown	46 (3.8)
Cardiac rhythm	
Sinus	1,009 (83.9)
Atrial fibrillation	150 (12.5)
Other	43 (3.6)
Aortic valve lesion	
Stenosis	745 (62.0)
Regurgitation	292 (24.3)
Mixed	141 (11.7)
Other	23 (1.9)
Aortic pathology	
Degenerative	966 (80.4)
Infective endocarditis	39 (3.2)
Bicuspid	125 (10.4)
Aortic annular enlargement	16 (1.3)
Redo	33 (2.7)
Other	23 (1.9)
Operative timing	
Elective	1,103 (91.8)
Urgent	51 (4.2)
Emergency	42 (3.5)
Salvage	6 (0.5)
Ejection fraction (%)	65 (54–73)
Comorbidities	
Pulmonary hypertension	182 (15.3)
Diabetes mellitus	248 (20.7)
Renal dysfunction (creatinine >2.0 mg/dL)	25 (2.1)
Cerebrovascular disease	96 (8.0)
Infectious endocarditis	41 (3.4)
Chronic obstructive pulmonary disease	84 (7.1)
Cardiogenic shock	28 (2.3)
Extracardiac vascular disease	168 (14.0)
Liver dysfunction	53 (4.4)

(Table 1 continued the next page.)

(B)	AS	AS+AR	AR
LVDd (mm)	45 (41–50)	50 (45–56)	58 (52–65)
LVDs (mm)	28 (24–33)	34 (28–41)	39 (34–47)
Ejection fraction (%)	68 (59–74)	62 (50–69)	59 (48–67)
EOA/BSA (cm ² /m ²)	0.46 (0.37–0.55)	0.50 (0.38–0.59)	1.33 (1.02–1.75)
Mean PG (mmHg)	47 (36–62)	45 (29–62)	11 (7–21)
LV mass/BSA (g/m ²)	139 (112–168)	164 (127–206)	158 (128–193)
ELCo (cm ²)	0.81 (0.66–0.96)	0.92 (0.71–1.10)	2.90 (1.81–3.59)

(A) Data are presented as number (percentage) or median (IQR). NYHA, New York Heart Association. (B) BSA, body surface area; ELCo, energy loss coefficient; EOA, effective orifice area; IQR, interquartile range; LV, left ventricular; LVDd, left ventricular end-diastolic dimension; LVDs, left ventricular end-systolic dimension; PG, pressure gradient.

Figure 1. Kaplan-Meier curves for (A) overall survival and (B) overall survival by age group: ≥65 years vs. <65 years, log-rank test. AVR, aortic valve replacement.

The overall survival (OS) rate was $84.6 \pm 1.3\%$ at 5 years and $59.9 \pm 7.5\%$ at 12 years (**Figure 1A**). In patients aged ≥ 65 years and < 65 years, the 12-year OS rates were $53.8 \pm 8.9\%$ and $85.3 \pm 3.9\%$, respectively ($P=0.079$; **Figure 1B**). The freedom from valve-related death was $81.1 \pm 7.9\%$ at 12 years. The 12-year actuarial freedom from valve-related death for patients aged ≥ 65 years and < 65 years was

$76.3 \pm 9.9\%$ and $96.8 \pm 1.9\%$, respectively ($P=0.441$; **Figure 2**). Over the 15 years, 26 reoperations (patients aged ≥ 65 years, $n=19$; patients aged < 65 years, $n=7$) were performed, the etiologic reasons for which are detailed in **Table 2**. Endocarditis and SVD were the 2 major reasons for reoperations (**Table 2**). The 12-year actuarial freedom from reoperation was $86.4 \pm 2.6\%$ (patients aged ≥ 65 years,

Figure 2. Kaplan-Meier curves for freedom from valve-related death, by age group: ≥65 years vs. <65 years, log-rank test. AVR, aortic valve replacement.

Table 2. Etiologies of Reoperation of the Mosaic Bioprosthesis			
Reason for reoperation	All patients (%) (n=1,202)	<65 years (%) (n=128)	≥65 years (%) (n=1,074)
Thrombosis	1 (0.08)	0 (0.00)	1 (0.09)
Endocarditis	11 (0.92)	2 (1.56)	9 (0.83)
Perivalvular leakage	1 (0.08)	0 (0.00)	1 (0.09)
Non-SVD	3 (0.25)	1 (0.78)	2 (0.19)
SVD	10 (0.83)	4 (3.13)	6 (0.56)
Total	26 (2.16)	7 (5.47)	19 (1.77)

Data are presented as number (percentage). SVD, structural valve deterioration.

Figure 3. Kaplan-Meier curves for freedom from reoperation, by age group: ≥65 years vs. <65 years, log-rank test. AVR, aortic valve replacement.

86.8±2.9%; patients aged <65 years, 85±5.8%; P=0.197; **Figure 3**). The freedom from SVD at 12 years was 93.5±2.9% for patients aged ≥65 years and 98.2±1.8% for those aged <65 years. A total of 10 explants because of SVD occurred during the follow-up period. The median (IQR) age at implantation was 69.5 (63.2–70.8) years, and the median (IQR) duration since the implant was 6.4 (3.5–

7.4) years. In 2 cases of SVD the patients were on dialysis and required early reoperations (1.4 and 4 years, respectively). The predominant lesion was leaflet tear, which occurred in 7 patients; calcification occurred in 2 patients, and limited leaflet opening occurred in 1 patient. The actuarial freedom from reoperation for SVD was 95.1±1.6% at 12 years; when stratified by age group, it was 96.3±1.6% for

Figure 4. Kaplan-Meier curves for freedom from reoperation for structural valve deterioration (SVD), by age group: ≥ 65 years vs. < 65 years, log-rank test. AVR, aortic valve replacement.

Figure 5. Kaplan-Meier curves for freedom from a composite of thrombosis, embolism, and bleeding, by age group: ≥ 65 years vs. < 65 years, log-rank test. AVR, aortic valve replacement.

patients aged ≥ 65 years and $89.4 \pm 4.8\%$ for patients aged < 65 years ($P=0.006$) (**Figure 4**).

The 12-year actuarial freedom from a composite of thrombosis, embolism, and bleeding, stratified by age group, was $95.5 \pm 0.9\%$ for patients aged ≥ 65 years and $91.8 \pm 3.3\%$ for patients aged < 65 years ($P=0.255$; **Figure 5**).

Hemodynamic performance is illustrated in **Figure 6A–D**. The echocardiographic results were 641 cases of 1-year follow-up, 325 cases of 5-year follow-up, and 42 cases of 10-year follow-up for patients aged ≥ 65 years, and 79 cases of 1-year follow-up, 51 cases of 5-year follow-up, and 15 cases of 10-year follow-up for patients aged < 65 years. The median (IQR) systolic pressure gradient was 17 (12–23) and 19 (12–25) mmHg at 1 and 10 years, respectively. The aortic mean (IQR) systolic pressure gradient for all valve sizes was 17.0 (12.0–22.7) mmHg for patients aged ≥ 65 years and 18.1 (12.0–23.0) mmHg for patients aged < 65 years, at 1 year, and 16.0 (12.0–22.0) mmHg for patients aged ≥ 65 years and 23.5 (18.3–26.9) mmHg for patients aged < 65 years, at 10 years ($P=0.876$). The median (IQR) effective orifice area (EOA) was 1.2 (1.1–1.5) and 1.1

(1–1.5) cm^2 at 1 and 10 years, respectively. The median (IQR) EOA index was 0.85 (0.73 – 1.00) cm^2/m^2 for patients aged ≥ 65 years and 0.89 (0.73 – 1.03) cm^2/m^2 for patients aged < 65 years, at 1 year, and 0.83 (0.74 – 1.00) cm^2/m^2 for patients aged ≥ 65 years and 0.67 (0.60 – 0.71) cm^2/m^2 for patients aged < 65 years, at 10 years ($P=0.271$). The median (IQR) energy loss coefficient (ELCo) was 1.51 (1.30 – 1.95) cm^2 for patients aged ≥ 65 years and 1.95 (1.57 – 2.27) cm^2 for patients aged < 65 years, at 1 year, and 2.07 (1.51 – 2.53) cm^2 for patients aged ≥ 65 years and 1.42 (1.27 – 1.57) cm^2 for patients aged < 65 years, at 10 years ($P=0.078$). The median (IQR) LV mass index was 103 (84 – 129) g/cm^2 for patients aged ≥ 65 years and 104 (82 – 118) g/cm^2 for patients aged < 65 years, at 1 year, and 101 (82 – 117) cm^2 for patients aged ≥ 65 years and 92 (83 – 113) cm^2 for patients aged < 65 years, at 10 years ($P=0.25$; **Figure 6D**).

Discussion

J-MOVE has been the largest, retrospective, multicenter clinical study to investigate the long-term results of the

Figure 6. (A) Aortic mean systolic pressure gradient (PG), (B) effective orifice area (EOA) index, (C) energy loss coefficient (ELCc) and (D) left ventricular (LV) mass index, for all valve sizes. Age ≥65 years vs. <65 years.

Mosaic bioprosthesis device in Japan. According to the ACC and AHA recommendations, it is reasonable to select bioprosthesis in patients aged >70 years, individualize the choice (mechanical or bioprosthesis) based on patient factors and preferences in those aged 50–70 years, and select a mechanical prosthesis in those aged <50 years having no contraindication to anticoagulation.¹⁹ There has been a considerable shift towards the use of bioprosthetic aortic valves, away from mechanical valves, possibly because of the risks of anticoagulation therapy associated with the use of mechanical valves in the aging population.²⁰ In parallel, the introduction of transcatheter aortic valve implantation (TAVI), coupled with the rapid growth of valve-in-valve procedures,²¹ has further stimulated the increased use of aortic bioprostheses in younger patients. However, SVD and the need for reoperation are high in bioprostheses vs. mechanical prostheses, especially in younger patients.²² The treatment of younger patients with longer life expectancies has raised questions regarding valve durability, as the valve should ideally last longer than the patient's life expectancy. SVD leads to valve dysfunction that adversely affects durability. Valve durability has therefore emerged as a fundamental issue in the current era of AVR.

The long-term outcomes and durability of the Mosaic bioprosthesis were evaluated in the aortic position, stratified by age group. The 5-year OS was 84.6%. The long-term OS at 12 years observed in this study (59.9%) with the Mosaic bioprosthesis was similar to that observed with the Carpentier-Edwards pericardial valve 56.8% at 10 years and 36.2% at 15 years.²³ Notably, it was considerably higher than the OS at 10 and 15 years observed with the St. Jude Medical Biocor valve (43.3% and 19.2%, respectively).²⁴

No significant difference in the 12-year OS between patients aged ≥65 and <65 years was observed in this study. The 12-year OS in patients aged <65 years with the Mosaic valve (89.3%) was similar to that observed with the St. Jude Medical Biocor valve (61.2% at 10 years and 53.9% at 15 years)²⁴ and the Carpentier-Edwards pericardial valve (73% at 10 years and 59% at 15 years).²⁵

In the current study, 26 reoperations were performed during the 15-year period. A retrospective long-term study of patients aged 50–69 years reported a 15-year cumulative incidence of reoperation of 6.9% with a mechanical prosthesis compared with 12.1% with a bioprosthesis, with no significant difference in long-term survival between the valve types.²⁶ This suggests that bioprosthesis reoperation as compared with mechanical prosthesis does not have an increased risk of death in the younger population.

One of the major problems associated with bioprostheses is SVD, which reduces valve durability, necessitating reoperation. In this study, SVD was more common in patients aged <65 years than in patients aged ≥65 years, which is in line with the findings from other studies that report a younger age at implantation as a significant risk factor for SVD.^{27,28} In the current study, explantation due to SVD was required in 10 patients during the follow-up period, the predominant cause of SVD being leaflet tear in the majority of cases (70%) and calcification in 2 cases (20%). In contrast, a study of the Carpentier-Edwards pericardial valve reported calcification as the major cause of SVD (61.8%), followed by leaflet tear (28.7%).²⁹ This difference could be due to the antimineralization of the Mosaic porcine valve with α -amino oleic acid, which reduces calcification.³⁰

The freedom from SVD at 12 years for the Mosaic valve was 93.5% for patients aged ≥65 years and 98.2% for patients aged <65 years in this study, similar to that observed with the St. Jude Medical Biocor valve (66.4% for patients aged ≤65 years; 87.1% for patients aged 65–75 years; and 90.8% for patients aged >75 years).²⁴ Similarly, for the Carpentier-Edwards pericardial valve, the freedom from SVD was 77.7% and 91.6% in patients aged 60–70 years and >70 years, respectively.²⁹

In this study, the 12-year actuarial freedom from reoperation due to SVD for the Mosaic valve was 96.3% in patients aged ≥65 years, similar to or higher than that observed with the Carpentier-Edwards pericardial valve (82.7% and 98.1% in patients aged 60–70 years and >70 years, respectively).²⁹ Further, the freedom from reoperation due to SVD for the Mosaic valve was 89.4% at 12 years in patients aged <65 years in the current study compared with the Carpentier-Edwards pericardial valve, for which the freedom from reoperation due to SVD was 91% at 10 years and 76% at 15 years in patients aged 50 to 65 years.²⁵ These findings suggest that the Mosaic bioprosthesis may be superior to pericardial tissue valves in patients aged ≥65 years and comparable in patients aged <65 years with respect to long-term outcomes.

The freedom from a composite of thrombosis, embolism, and bleeding at 12 years in this study was 95.5% for patients aged ≥65 years and 91.8% for patients aged <65 years. These results were similar to the rates observed with the Carpentier-Edwards pericardial valve (freedom from thromboembolic and bleeding events at 10 years was 92.3% and 90.3%, respectively).²³

For aortic bioprostheses, the aim with regard to hemodynamic performance is to decrease the transprosthetic gradient and increase the EOA.³¹ In this study, the mean systolic pressure gradient was 17 and 19 mmHg at 1 and 10 years, respectively, which was higher than that observed with the Carpentier-Edwards pericardial valve (10.3 and 9.6 mmHg at 1 and 5 years, respectively).³¹ Further, in the current study, the mean EOA was 1.2 and 1.1 cm² at 1 and 10 years, respectively, which was lower than that observed with the Carpentier-Edwards pericardial valve (1.94 and 1.81 cm² at 1 and 5 years, respectively).³¹ Compared with Carpentier-Edwards pericardial valve, the Mosaic prosthesis is more likely to result in patient-prosthesis mismatch (PPM), especially with the 19-mm valve. In fact, the median EOA index was 0.85 cm²/m² in the elderly group and 0.89 cm²/m² in the younger group at 1 year, and 0.83 cm²/m² in the elderly group and 0.67 cm²/m² in the younger group at 10 years. Although there is a concern about progressive stenosis, LV mass index did not increase for at least 10 years in this study and the Mosaic prosthesis did not cause clinical deterioration for 12 years despite some PPM. However, further investigation is required.

In this era of increasing use of bioprostheses,²⁰ the associated low mortality risk of reoperation due to SVD with bioprostheses, compared with the increased risk of thrombosis, embolism, and bleeding secondary to anticoagulation with mechanical prostheses, potentially makes the use of the bioprosthetic valve an acceptable option in the younger population. Further, TAVI has been reported to be non-inferior to surgical AVR.³² TAVI now presents patients with a novel option for the management of SVD.^{33,34} The use of valve-in-valve TAVI after SVD could resolve the issues with reoperation, and the tendency towards the use of bioprosthetic valves in the younger generation will

potentially be increased as the long-term outcomes of TAVI become clear. However, there is a concern that a risk of PPM with valve-in-valve TAVI is more likely, compared with redo-surgical AVR.³⁵ In order to avoid the future incidence of PPM after valve-in-valve TAVI, it may be important to implant the largest bioprosthesis possible, even if aortic annular enlargement has to be performed in patients undergoing AVR, especially in young patients.

This 12-year study reported satisfactory long-term clinical outcomes with the Mosaic bioprosthesis in the aortic position even in patients aged <65 years, which is encouraging for surgeons who are challenged with making decisions on valve selection.

Study Limitations

This study was retrospective, observational, and non-randomized. The number of patients lost to follow-up was high, leading to few patients available for analysis at 15–16 years. The 10-year follow-up rate was 42.2%, which might have influenced the results significantly.

Conclusions

The Mosaic porcine bioprosthesis offered satisfactory long-term outcomes including OS and freedom from valve-related death, reoperation for SVD, and a composite of thrombosis, embolism, and bleeding through 12 years of follow-up. The actuarial freedom from SVD and reoperation for SVD was satisfactory even in patients younger than 65 years, thereby suggesting that the Mosaic bioprosthesis device is a reasonable option in this population.

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Disclosures

All authors declare no conflicts of interest.

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