Clinical Investigation

The Mosaic Mitral Valve Bioprosthesis:

A Long-Term Clinical and Hemodynamic Follow-Up

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We reviewed the cases of 100 patients (mean age, 73 ± 10 yr; 64 men) who had mitral valve replacement with a Medtronic Mosaic porcine bioprosthesis from 1995 through 2011. The mean New York Heart Association (NYHA) class was 3 ± 0.7, and 52 patients were in atrial fibrillation. Prosthetic sizes were chiefly 27 mm (50 patients) and 29 mm (40 patients). Follow-up ended in December 2012 and is 97% complete, with a cumulative duration of 611 patient-years (mean duration, 6 ± 4.6 yr; maximum, 17.7 yr).

The early mortality rate was 10% (6% in elective patients); late deaths occurred in 31 patients (5 valve-related). Actuarial survival rates at 5, 10, and 15 years were 74% ± 5%, 50% ± 6%, and 37% ± 8%. The mean NYHA class in survivors was 1.4 ± 0.6 (P <0.0001). Thromboembolic episodes occurred in 4 patients, with an actuarial freedom at 15 years of 91% ± 5%. No cases of endocarditis were observed. Four patients needed reoperation, 2 for structural failure, and 1 each for perivalvular leakage and valve thrombosis. Actuarial freedom from structural failure and from reoperation, respectively, was 93% ± 5% and 91% ± 5% at 15 years. Echocardiographic follow-up in 24 patients with 27-mm prostheses showed a mean gradient of 5 ± 1.7 mmHg and an effective orifice area of 1.57 ± 0.3 cm^2; in 16 patients with 29-mm prostheses, the mean gradient was 4.5 ± 1.9 mmHg, and the effective orifice area, 1.63 ± 0.4 cm^2.

During nearly 17 years of follow-up, the Mosaic bioprosthesis has shown good overall clinical and hemodynamic performance after mitral valve replacement. ***(Tex Heart Inst J 2016;43(1):13-9)***

Key words: *Bioprosthesis; calcinosis/prevention & control; heart valve prosthesis; mitral valve/surgery; mitral valve replacement; oleic acids/therapeutic use; retrospective studies; thromboembolism*

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Presented at the poster session of the 7th Biennial Congress of the Society of Heart Valve Disease, Venice, Italy, 22–25 June 2013.

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Soon after their introduction into clinical practice in the late 1960s, porcine bioprostheses came to be recognized for dystrophic calcification and consequent structural valve deterioration (SVD) that adversely affected their longevity.[1,2] Since that time, the use of calcium-retarding agents to mitigate the severity of cusp mineralization has given longer durability to most commercially available tissue valves.[3-5]

The Mosaic® bioprosthesis (MB) (Medtronic, Inc.; Minneapolis, Minn) is a 3rd-generation porcine valve that became clinically available in 1994. Various reports[6-9] have shown that the MB is a safe and well-performing device in the medium and intermediate terms. More recently, data on the 13-year follow-up evaluation of the MB—when used for aortic valve replacement (AVR)—have become available.[10,11] However, little is known about the long-range performance of this device in the mitral position. We have therefore reviewed our experience with use of the MB for mitral valve replacement (MVR), and we present herein the results of our study.

Patients and Methods

This is a retrospective, long-term follow-up study of the first 100 patients who underwent isolated MVR (that is, no other valvular replacement) with the MB at the University Hospital of Pisa from March 1995 through December 2011. This study was approved by our hospital's ethical committee, and all patients gave informed consent to the use and reporting of their collected data.

Valve Design. The MB is obtained from the porcine aortic valve, then mounted on a low-profile, flexible, acetyl copolymer stent that is covered with polyester fabric. The valvular tissue is treated with α-amino oleic acid, which has been shown to mitigate cusp calcification in animal studies,[12-14] and then undergoes physiologic fixation at zero pressure, which helps to maintain the leaflet structure and root geometry of fresh aortic valves.[15-17] The MB is provided with the Cinch® II implant system (Medtronic),

which enables inward bending of the posts and thereby helps to prevent looping of the sutures around the struts during MVR; on the sewing ring, a green suture marker aids in orientation of the prosthesis when used in the mitral position.

Patients' Characteristics. Table I summarizes the most pertinent clinical data. There were 64 men and 36 women, with a mean age of 73 ± 10 years (range, 28–86 yr); 78% of them were >70 years of age. The preoperative mean New York Heart Association (NYHA) functional class was 3 ± 0.7. Twenty-four patients were in class IV, 61 in class III, 9 in class II, and 6 in class I. Forty-six were in sinus rhythm and 52, in chronic atrial fibrillation (AF); 2 had a permanent pacemaker. The mean left ventricular ejection fraction (LVEF) was 0.52 ± 0.09. The predominant valvular disorder was mitral regurgitation in 64 and stenosis in 36—caused by myxomatous degeneration in 34, calcific degeneration in 30, rheumatic disease in 19, endocarditis in 7, and ischemic disease in 3. Seven patients underwent replacement of a previously implanted prosthesis. The prosthetic sizes most frequently used were 27 and 29 mm; associated procedures (predominantly coronary artery bypass grafting) were performed in 41% of the patients.

TABLE I. Characteristics of the 100 Patients Who Underwent Mitral Valve Replacement

Variable	Value
Male	36 (36)
Female	64 (64)
Age (yr)	73 ± 10
<60	6 (6)
61–70	16 (16)
71–80	57 (57)
>80	21 (21)
Rhythm	
Sinus	46 (46)
Atrial fibrillation	52 (52)
Pacemaker	2 (2)
NYHA functional class	
I	6 (6)
II	9 (9)
III	61 (61)
IV	24 (24)
Valvular lesion	
Pure or prevalent stenosis	36 (36)
Pure or prevalent incompetence	64 (64)
Cause of valvular dysfunction	
Myxomatous degeneration	34 (34)
Calcific degeneration	30 (30)
Rheumatic	19 (19)
Endocarditis	7 (7)
Prosthesis failure	7 (7)
Ischemic	3 (3)
Prosthesis size (mm)	
25	3 (3)
27	50 (50)
29	40 (40)
31	7 (7)
Associated procedures	
CABG	17 (17)
Tricuspid annuloplasty	8 (8)
Atrial fibrillation ablation	6 (6)
Other	10 (10)

CABG = coronary artery bypass grafting; NYHA = New York Heart Association

Data are presented as number and percentage or as mean ± SD.

Surgical Technique. All operations were performed through a median sternotomy; cardiopulmonary bypass was instituted by cannulating the ascending aorta and both venae cavae. Moderate systemic hypothermia was used; the heart was arrested by means of cold-blood cardioplegic solution delivered antegrade into the aortic root, supplemented by continuous external cooling of the heart with ice slush. Retrograde delivery of cardioplegic solution was never used. The mitral valve was approached through a left atrial incision parallel to the interatrial groove. The valve replacement was performed by excising the anterior mitral leaflet, leaving the posterior leaflet with its chordal attachment in place; more recently, the chordae to the anterior leaflet were also preserved and reattached to the annulus at the commissural level. The MB was implanted with interrupted sutures of 2-0 Ethibond Excel® (Ethicon, a Johnson & Johnson company; Somerville, NJ), reinforced by subannular Teflon felt pledgets. In patients with chronic AF and enlarged left atrium, the ostium of the left atrial appendage was closed in almost every instance. In patients who needed concomitant myocardial revascularization, distal anastomoses were performed before MVR; in patients who needed tricuspid annuloplasty, this procedure was performed after release of the aortic cross-clamp on a beating heart. Postoperatively, all patients received subcutaneous heparin; oral anticoagulation was started after extubation in order to reach a target international normalized ratio of 2.5 to 3.5, at which time heparin administration was suspended. Oral anticoagulants were maintained indefinitely in patients with AF or other risk factors for thromboembolic sequelae, and for approximately 3 months in patients with sinus rhythm (antiplatelet medications subsequently replaced the anticoagulants in these patients).

Patient Evaluation. After discharge from the hospital, all patients were monitored at our outpatient clinic 1, 3, and 6 months postoperatively and on a yearly basis thereafter. Direct patient interviews and visits were used to evaluate clinical status and to elicit all possible valve-related sequelae, which were classified according to established guidelines.[18] For patients unable to return to our hospital, information was obtained by telephone interviews of relatives and personal physicians. Follow-up visits with patients also included the evaluation of prosthetic function by means of 2-dimensional transthoracic echocardiographic examination, to obtain data

on left ventricular function and valve performance; in particular, LVEF, mean and peak transprosthetic gradients, and prosthetic effective orifice area (EOA) were calculated. For the current study, patient follow-up was closed in December 2012, being 97% complete. Cumulative duration of follow-up was 611 patient-years (pt-yr), ranging from 0.6 to 17.7 years (mean duration, 6 ± 4.6 yr).

Statistical Analysis

Statistical analysis was performed by using commercially available SPSS software, version 17.0 (IBM Corporation; Armonk, NY). Continuous variables are shown as mean ± SD and categorical variables are presented as simple percentages. Overall survival and freedom from major prosthesis-related sequelae, including thromboembolism, anticoagulant-related hemorrhages, endocarditis, and valve dehiscence, were calculated by means of Kaplan-Meier actuarial analysis and presented as the percentage of patients who were free from that particular event ± SE. The linearized rate of postoperative sequelae was expressed as percentage per pt-yr ± SE. The Student *t* test was used for comparison of continuous data. Although the maximum follow-up period extended over 17 years, data are given at 15 years because of the small sample of patients beyond this follow-up interval. *P* values <0.05 were considered statistically significant.

Results

There were 10 hospital deaths, for an overall mortality rate of 10%. Four patients died after emergency MVR, performed because of acute ischemic mitral regurgitation in 3 and endocarditis in 1. Six patients died (4 of cardiogenic shock and 2 of sepsis) after elective MVR, for an operative mortality rate of 6% for elective cases.

There were 31 late deaths: 8 were cardiac in cause, of which 5 were considered to be valve-related (0.82% ± 0.36% per pt-yr), due to cerebral embolism in 2, reoperation in 2, and sudden unexpected death in 1. Actuarial survival rates were 74% ± 5%, 50% ± 6%, and 37% ± 8% at 5, 10, and 15 years, respectively (Fig. 1). Actuarial freedom from valve-related deaths was 97% ± 2%, 90% ± 4%, and 86% ± 5% at 5, 10, and 15 years (Fig. 2). At the last follow-up evaluation, the mean NYHA class of 56 late survivors was 1.4 ± 0.6 (*P* <0.0001); 52% of patients were in class I and 39%, in class II; 26 patients were in sinus rhythm, 26 were in chronic AF, and 4 had a permanent pacemaker.

The incidence of major postoperative sequelae is summarized in Table II. There were 3 embolic episodes at a mean time of 5.4 ± 3.5 years from MVR; all 3 patients had a cerebral embolism, which was fatal in 2 and resolved without sequelae in 1. At the time of the embolic episode, 2 patients were in AF and on chronic anticoagulation and 1 was in sinus rhythm without anticoagulants. One patient underwent reoperation 7 months after MVR because of MB thrombosis and died; she had been in sinus rhythm and not anticoagulated. Overall, 4 thromboembolic episodes were recorded, with a linearized incidence of 0.65% ± 0.33% per pt-yr. The actuarial freedom from thromboembolism at 5, 10, and 15 years was 97% ± 2%, 91% ± 5%, and 91% ± 5%, respectively (Fig. 3).

One patient, who had been taking oral anticoagulants because of chronic AF, sustained a cerebral hemorrhage, which resolved without neurologic deficits. The linearized incidence of this sequela was 0.16% ± 0.16% per pt-yr, and the actuarial freedom was 98% ± 1% at 5, 10, and 15 years. No cases of endocarditis were recorded, so the actuarial freedom from this sequela was 100%.

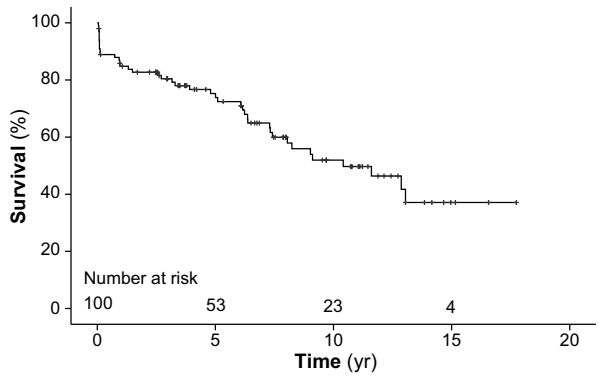

Fig. 1 *Graph shows an actuarial survival rate of 37% ± 8% after mitral valve replacement with the Mosaic bioprosthesis. The numbers on the horizontal axis indicate the numbers of patients at risk at each postoperative interval.*

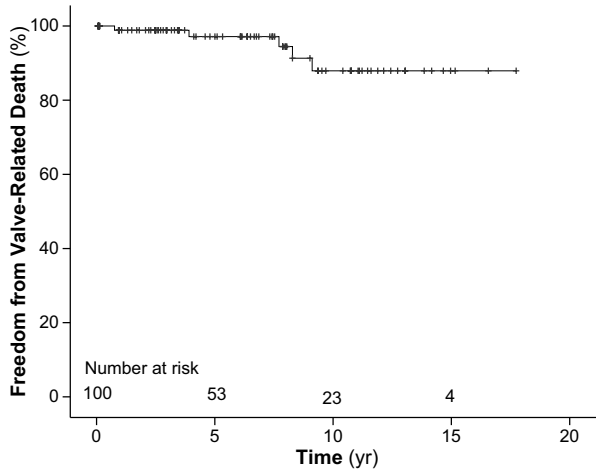

Fig. 2 *Graph shows actuarial freedom from valve-related deaths (at 15 yr, 86% ± 5%) after mitral valve replacement with the Mosaic bioprosthesis. The numbers on the horizontal axis indicate the numbers of patients at risk at each postoperative interval.*

TABLE II. Linearized Rates and Actuarial Freedom from Major Postoperative Sequelae

Sequela	No.	Linearized Incidence (% per pt-yr)	Actuarial Freedom from Sequelae (%)		
			5 yr (n=53)	**10 yr** (n=23)	**15 yr** (n=4)
Death					
Late	31	—	74 ± 5	50 ± 6	37 ± 8
Cardiac	8	—	97 ± 2	88 ± 6	88 ± 6
Valve-related	5	0.82 ± 0.37	97 ± 2	90 ± 4	86 ± 5
Thromboembolism	4	0.65 ± 0.33	97 ± 2	91 ± 5	91 ± 5
Major	1	0.16 ± 0.16	—	—	—
Fatal	3	0.49 ± 0.28	—	—	—
Hemorrhage	1	0.16 ± 0.16	98 ± 1	98 ± 1	98 ± 1
Endocarditis	0	—	100	100	100
Perivalvular leakage	1	0.16 ± 0.16	98 ± 1	98 ± 1	98 ± 1
Structural failure	2	0.33 ± 0.23	100	93 ± 5	93 ± 5
Reoperation	4	0.65 ± 0.33	97 ± 2	91 ± 5	91 ± 5
Valve-related sequelae	9	1.47 ± 0.49	95 ± 2	82 ± 7	82 ± 7

pt-yr = patient-year

Unless otherwise stated, data are presented as number or as percentage ± 95% SE.

One patient underwent reoperation because of perivalvular leak 20 months after MVR and survived, with a linearized incidence of 0.16% ± 0.16% per pt-yr and an actuarial freedom of 98% ± 1% at 5, 10, and 15 years. Two patients underwent reoperation because of SVD of their MBs, with a linearized incidence of 0.33% ± 0.23% per pt-yr. A 76-year-old woman underwent reoperation after 98 months because of regurgitation due to dehiscence of a cusp (on a 27-mm MB) without apparent calcifications; this was her 3rd mitral valve operation, and she died of cardiac failure. A 52-year-old woman had undergone MVR with a 27-mm MB, at age 41 years; 139 months later, she underwent successful reoperation because of MB incompetence. Gross inspection of the explant showed laceration of one cusp, and a radiograph revealed only focal calcification at the corresponding commissure (Fig. 4). Actuarial freedom from SVD was 100% at 5 years, and 93% at 10 and 15 years (Fig. 5). Overall, 4 patients needed reoperation, with a linearized incidence of 0.65% ± 0.33% per pt-yr. Reoperation was required for SVD in 2 patients, perivalvular leak in 1, and valve thrombosis in 1. Actuarial freedom from reoperation for all causes was 97% ± 2%, 91% ± 5%, and 91% ± 5% at 5, 10, and 15 years, respectively. A total of 9 prosthesis-related sequelae were observed: thromboembolic episodes in 4 patients, SVD in 2, anticoagulant-related hemorrhage in 1, perivalvular leak in 1, and sudden unexpected death in 1. The linearized incidence of valve-related sequelae was 0.65% ± 0.33% per pt-yr, with an actuarial freedom of 95% ± 2%, 82% ± 7%, and 82% ± 7% at 5, 10, and 15 years, respectively (Fig. 6).

Echocardiographic Data. Out of the 56 long-term survivors, data on postoperative echocardiographic follow-up were available in 44 (78%) at a mean time of 6.9 ± 4.6 years from MVR. Data are presented only for size 27-mm and 29-mm MB, because of the small samples of other sizes implanted. In 24 patients with a 27-mm MB, the mean LVEF was 0.54 ± 0.09; the peak transprosthetic gradient, 12.6 ± 4 mmHg; the mean gradient, 5 ± 1.7 mmHg; and the EOA, 1.57 ± 0.3 cm^2. In 16 patients with a 29-mm MB, the mean LVEF was 0.50 ± 0.07; the peak gradient, 12.7 ± 4.7 mmHg; the mean gradient, 4.5 ± 1.9 mmHg; and the EOA, 1.63 ± 0.4 cm^2.

Discussion

The MB has been used clinically for almost 2 decades, and various reports have indicated that this device is associated with low incidences of valve-related sequelae, negligible incidences of SVD, and satisfactory hemodynamic results in the medium and intermediate terms.[6-9,19] Data concerning the long-term performance of the MB have been presented by Riess and colleagues[10,20] and, more recently, by Celiento and associates,[11] who reported a 10- to 13-year follow-up. Indeed, most of the data currently available concerning the MB refer to patients after AVR, whereas the performance of the MB after MVR has been evaluated mostly in multicenter studies, with short follow-up reports.[6-9,21] Recently, however, Jamieson and co-authors[22] have published a multicenter study of the MB after MVR, which is the only study to exceed ours in the number of patients reported. These

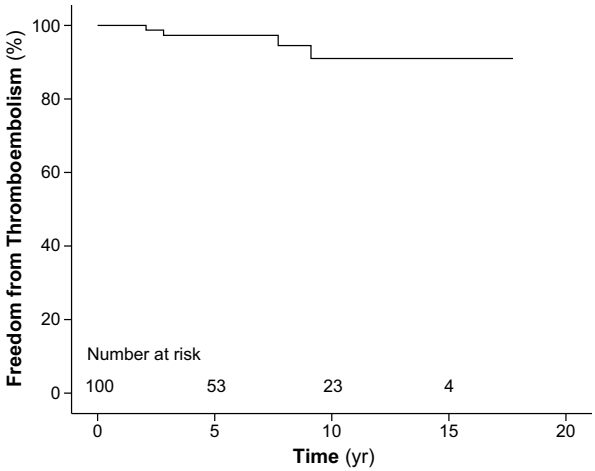

Fig. 3 *Graph shows actuarial freedom from thromboembolic sequelae (at 15 yr, 91% ± 5%) after mitral valve replacement with the Mosaic bioprosthesis. The numbers on the horizontal axis indicate the numbers of patients at risk at each postoperative interval.*

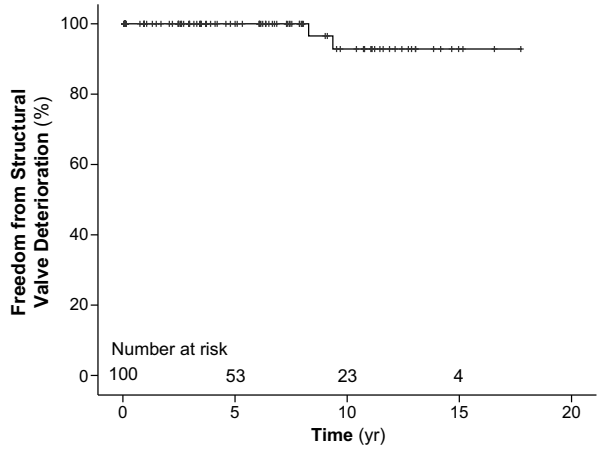

Fig. 5 *Graph shows freedom from prosthesis failure caused by structural valve deterioration (at 15 yr, 93% ± 5%) after mitral valve replacement with the Mosaic bioprosthesis. The numbers on the horizontal axis indicate the numbers of patients at risk at each postoperative interval.*

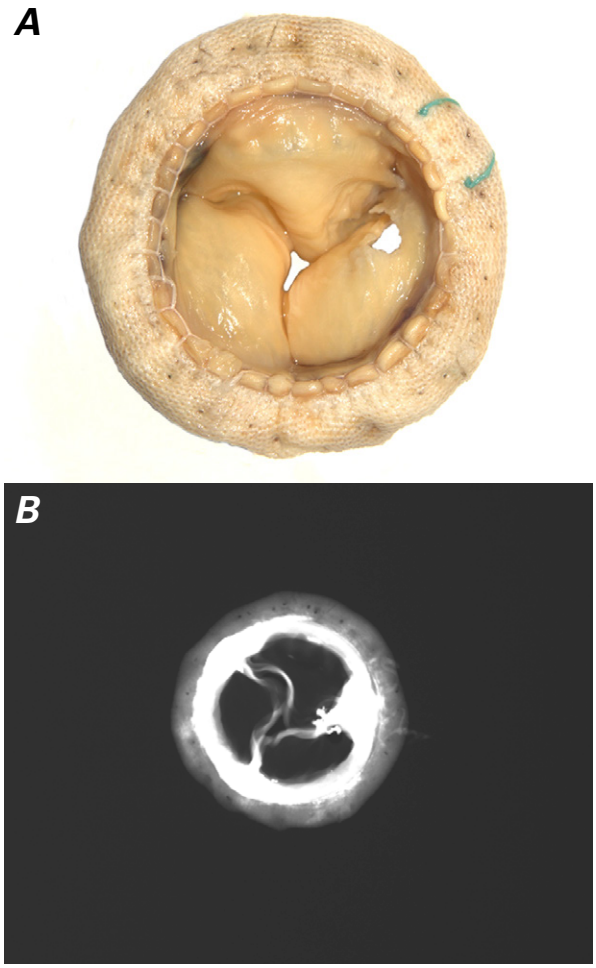

Fig. 4 ***A****) Photograph of a Mosaic bioprosthesis explanted at reoperation after 139 months shows dehiscence of one cusp.* ***B****) Radiographic image of the explanted prosthetic valve shows focal commissural calcification.*

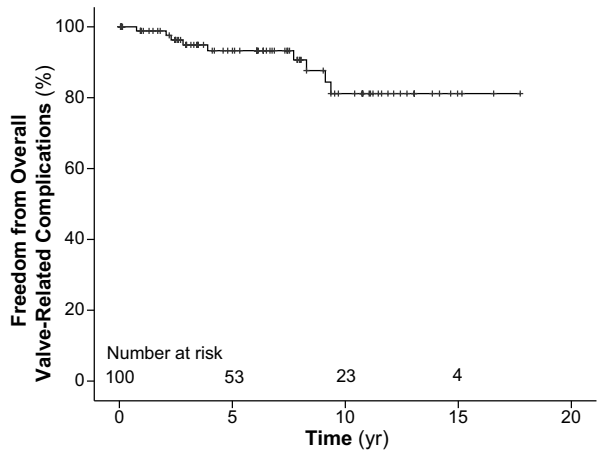

Fig. 6 *Graph shows freedom from overall valve-related sequelae (at 15 yr, 82% ± 7%) after mitral valve replacement with the Mosaic bioprosthesis. The numbers on the horizontal axis indicate the numbers of patients at risk at each postoperative interval.*

authors have found that the MB in the mitral position has shown an encouraging freedom from SVD at 12 years.

Ours is the first single-center study providing data regarding the long-term performance (up to 17 yr) of the MB in the mitral position. Late survival rates can be considered acceptable, given the old age of most patients at time of operation (>20% of them were 80 years or older); these data are similar to those reported on the Hancock II bioprosthesis in the mitral position by Valfrè and colleagues,[5] who observed a 39% survival rate at 15 years; and they are comparable with those reported by Riess and colleagues[10] at 13 years, after MVR with the MB in a smaller sample of patients. We

have observed a substantially low incidence of thromboembolic episodes (0.65% ± 0.33% per pt-yr), with an actuarial freedom from this sequela of 91% ± 5% at 15 years, and a negligible rate of anticoagulant-related hemorrhages. These results are similar to those of Riess and colleagues[10] at 13 years, but are superior to those reported by Fradet,[8,21] Jamieson,[9] and their colleagues, who observed a freedom from thromboembolism ranging from 87% to 92% (but the maximum follow-up period was 12 years).

It must be emphasized, however, that in our cohort almost half of the late survivors were in AF and therefore were maintained on chronic oral anticoagulants. The indication for a biological prosthesis in the mitral position in patients with AF might be questionable, but we think that the use of a tissue valve for MVR, even in the presence of AF, can be justified. Indeed, the anticoagulant treatment can more easily be managed in an elderly population, such as that of the present series and as commonly seen these days in daily practice, particularly in patients with low compliance: the benefits of a tissue valve therefore outweigh the risk of embolic or hemorrhagic sequelae, as shown in the present experience.

Durability has always been a concern with all types of biological prostheses, and progressive SVD, caused mainly by intrinsic calcification, affects the long-term performance of most tissue valves.[1,2,23] Various modifications of most models have been introduced throughout the years: particularly new valve designs and the use of calcium-retarding agents to process the tissue, preventing such sequelae. These innovations have yielded a generation of bioprostheses with substantially improved durability. This has been shown in patients over 65 years of age, who, particularly after AVR, have experienced ≥98% freedom from SVD at 20 years.[3,4] The MB incorporates some features aimed at improving durability. Chief among these is the use of α-amino oleic acid, because this anticalcification treatment has been extremely effective in mitigating cusp calcification in animal models.[13,14] Most reports so far available have indicated that the rate of SVD observed in MB recipients is extremely low. Riess and associates[24] have shown a 98% freedom from this sequela at 12 years in AVR patients over 65 years of age, and we reported[11] a 100% freedom from SVD at 10 years. Data on long-term durability of the MB in the mitral position are scarce. No cases of SVD have been reported by Thomson and colleagues[6] or Eichinger and associates[7] at 4 years, by Fradet and coworkers at 7 years,[8] or by Riess and co-authors at 10 years.[20] Jamieson and associates, 19 months after MVR, observed one case of SVR caused by cusp tears with minimal calcification.[9] Given our extended follow-up period, our results can provide some meaningful information on the late durability of the MB in the mitral position. We have observed in our series only 2 cases of SVD, with an actuarial freedom at 15 years of 93% ± 5%. In both cases, reoperation was necessary for severe mitral regurgitation caused by cusp tears (without calcification) in one and by cusp dehiscence (with only focal commissural calcification) in the other. The young age of the patient at initial MVR makes this last case particularly interesting. Although more consistent data must be acquired, this last observation—on a porcine MB explanted after more than 12 years—seems to confirm in the clinical setting the efficacy of the anticalcification treatment. Porcine bioprostheses implanted in the mitral position usually have lower durability than do their aortic counterparts, most likely because they are subjected to higher closing pressures.[3,5] We have shown that the MB has considerable resistance to SVD after MVR, which can be even superior to that of the MB in the aortic position—as observed by Riess and colleagues,[10] and more recently by our group.[11] However, the high mean age of our patients rendered us unable to explore the influence of age on MB durability, and therefore to extend the use of such a device to a younger population.

The absence of cases of endocarditis seems noteworthy, the rarity of this sequela ranging from an incidence of 0.6% to 0.8% per pt-yr 4 to 13 years after MVR, in reported series.[6-8,19,21] This lack of endocarditis invites speculation that the MB might be particularly resistant to infection. Finally, late hemodynamic evaluation by means of transthoracic echocardiography was available in 44 long-term survivors at a mean time of approximately 7 years from MVR. Our results show low transprosthetic gradients and adequate EOA, data that compare favorably with those reported previously.[6-8,10] Overall, our results indicate satisfactory performance of the MB device in the mitral position, which is indirectly confirmed by clinical improvement in functional class at follow-up.

The major limitations of this study are its retrospective nature, the relatively small number of patients included, and the small number of patients who reached the longest follow-up intervals. However, this is the first single-center study to provide a large series of patients with an MB in the mitral position, and we think that the information provided is valuable because data on the performance of the MB after MVR in the long term and in larger patient series have heretofore been reported only in a recent multicenter study.[22]

In conclusion, our results indicate that the MB provides good overall performance with a low incidence of SVD and other valve-related sequelae for up to 17 years. The MB appears to be a valid option for MVR, especially in older patients. The prospect of extended durability, paralleling that of other porcine valves,[3,4] must be evaluated for longer follow-up periods; and the prospect of offering this device to a younger patient population will first require the acquisition of more consistent data.

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