Bovine pericardial versus porcine stented replacement aortic valves: Early results of a randomized comparison of the Perimount and the Mosaic valves

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Objective: A stented bovine pericardial valve might be less obstructive than a stented porcine valve. This study compared early hemodynamic function in a prospective series of 99 patients randomized to receive either a Mosaic or Perimount replacement aortic valve.

Methods: Echocardiography was performed early after surgery and at 1 year after surgery. Patients also filled in psychologic questionnaires and underwent a 6-minute walk.

Results: The groups were matched demographically. The Perimount valve was significantly less obstructive in terms of mean pressure difference (11 ± 5 vs 17 ± 7 mm Hg; $P < .0001$), with a trend in favor of a larger effective orifice area (1.47 ± 0.45 vs 1.28 ± 0.46 cm²; $P = .05$) postoperatively. There were no differences in left ventricular mass regression, aortic regurgitation, 6-minute walk, psychologic questionnaires, or mortality and clinical events.

Conclusion: The stented bovine pericardial valve was less obstructive than the stented porcine valve. Both valves were associated with similar and significant improvements in quality of life, exercise ability, and regression of left ventricular mass.

There is a perception that stented pericardial valves have better hemodynamic function than stented porcine valves.¹⁻³ However, comparing studies is difficult because of differences in echocardiographic methods and the frequent reliance on flow-dependent measures of prosthetic valve function. Sizing conventions also differ between valve types so that it may not be appropriate to compare valves of the same label size.⁴ There are few randomized comparisons, and these give contradictory results, with a pericardial design either superior⁵ or similar⁶ to a porcine valve.

We therefore designed a randomized trial to compare hemodynamic function in the Medtronic Mosaic porcine valve (Medtronic, Inc, St Paul, Minn) and the Carpentier-Edwards Perimount bovine pericardial valve (Edwards Lifesciences, Irvine, Calif). Secondary end points were clinical event rates, exercise capacity, and measures of overall health in the first year after surgery.

Methods

Patients

A total of 100 consecutive patients scheduled to have single bioprosthetic valve replacement in the aortic position were randomized. All subjects were aged 19 to 90 years and none was undergoing redo valve surgery or had a preoperative creatinine value of more than 500 μ mol/L or a coexistent illness known to have a significant mortality. After randomization, 1 patient received a mechanical valve because of an aberrant origin of both coronary arteries, which left a population of 99. Of these, because of procedural difficulties, 2 patients randomized to receive a Perimount valve received a Mosaic valve and 1 randomized to receive a Mosaic valve received

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Abbreviations and Acronyms

LV	= left ventricular
NS	= no significant difference
NYHA	= New York Heart Association
SD	= standard deviation
SF-36	= Short Form-36 health questionnaire

a Perimount instead. The study population comprised 51 with a Mosaic and 48 with a Perimount valve. The mean age was 75.5 years (range 58–89 years) and 61 (60%) were male (Table 1). The study was accepted by the local committee on ethical practice and all patients gave written informed consent.

Surgery

Both valves were implanted according to their manufacturer's recommendations, giving a supra-annular position for the Mosaic and a partially supra-annular position for the Perimount valves. The number on the sizers of the Mosaic bioprosthesis denotes the size of the valve to be used in the supra-annular position, so that the label size is expected to be larger than the annulus diameter. By contrast,

the number on the sizer of the Perimount bioprosthesis denotes the size of the valve to be used in the intra-annular position. A universal sizer (graduated in millimeters) was therefore used to determine the actual diameter of the patient tissue annulus and then both the Perimount and Mosaic sizers were used before the randomization envelope was opened. The surgeon implanted the valve by his routine technique using noneverting, vertical mattress sutures (n = 78) or continuous sutures (n = 21).

Echocardiography

The majority of studies were performed by one sonographer (H.M.R.) immediately postoperatively and at 1 year (10–14 months) using a Vivid-7 system (GE Medical, Milwaukee, Wis). All patients had a postoperative study, but 22 did not have a study at 1 year (11 dead, 3 agreed to telephone follow-up only, 1 declined all follow-up, 5 were unable to travel because of illness, and 2 were completely lost to follow-up). Measurements were made as recommended by the American Society of Echocardiography⁷ over 3 cycles in sinus rhythm or over 6 cycles in atrial fibrillation. Regurgitant jets were localized, then graded by a combination of the diameter of the base of the jet, and the density and slope of the aortic regurgitant signal recorded by continuous wave Doppler sonography. Mild regurgitation was defined by a jet height less than 25% of the outflow diameter and a complete, low-intensity continuous waveform with pressure half-time longer than 500 ms. Trivial regurgitation was defined by a thin low-momentum jet ending close to the valve with an incomplete continuous waveform. No jet in this study was found to be moderate or severe.

Calculations

The following calculations were performed: effective orifice area by the continuity equation ($EOA \text{ in cm}^2 = CSA \times VTI_1 / VTI_2$), where CSA is left ventricular (LV) outflow cross-sectional area (cm^2) calculated from the diameter assuming circular cross section, VTI_1 is subaortic velocity integral (cm), and VTI_2 is aortic velocity integral (cm); peak pressure difference across the aortic valve (peak ΔP in mm Hg) = $4(v_2^2 - v_1^2)$ where v_2 is transaortic peak velocity (m/s) and v_1 is subaortic peak velocity (m/s); mean pressure difference across the aortic valve (mean ΔP in mm Hg) = aortic mean ΔP - subaortic mean ΔP ; LV mass (gm) = $0.83(LVDD + IVS + PW)^3 - (LVDD)^3$, where LVDD is left ventricular diastolic diameter, IVS is interventricular septal width, and Posterior Wall width (PW) is Effective orifice area and LV mass were indexed to body surface area. Patient-prosthesis mismatch was defined by an indexed effective orifice area ($EOAi$) < $0.85 \text{ cm}^2/\text{m}^2$ and severe mismatch by $EOAi$ < $0.65 \text{ cm}^2/\text{m}^2$.

Clinical Events

Patients were interviewed at 3 to 6 months and at 1 year. The definitions used were as recommended by the guidelines of The Society of Thoracic Surgeons and the American Association for Thoracic Surgery.⁸ If the exact timing of an event was not known, it was taken as perioperative if noted at the immediate postoperative visit. It was recorded as at the midpoint between two visits if absent at the first and present at the second. Early events occurred in the first 30 days and late events between 30 days and 12 months. Dysarrhythmic deaths after recovery from the anesthetic but before discharge were included as valve-related. Dysarrhythmias after surgery were

TABLE 1. Demographic data

	Mosaic	Perimount
N	51	48
Age (y)	77 (61–89)	75 (58–88)
Male/female	30:21	31:17
Etiology		
AS	45	44
AR	3	2
Mixed AVD	3	2
Previous cardiac procedures	0	2 (1 CABG, 1 PPM)
Effective orifice area (cm^2)	0.83 ± 0.51	0.75 ± 0.41
Mean pressure drop (mm Hg)	47 ± 20	43 ± 18
Concomitant procedures	26 CABG	23 CABG, 1 aortic root replacement
Preop NYHA		
I	7	2
II	24	20
III	20	24
IV	0	2
Height (cm)	167 ± 9	166 ± 8
Weight (kg)	74 ± 13	74 ± 14
BSA (m^2)	1.82 ± 0.19	1.82 ± 0.19
BMI	26.8 ± 3.8	26.5 ± 4.5
EuroSCORE	8 ± 5	8 ± 4
Parsonnet	20 ± 8	21 ± 8

AS, Aortic stenosis; AR, aortic regurgitation; AVD, aortic valve disease; CABG, coronary artery bypass grafting; PPM, permanent pacemaker; NYHA, New York Heart Association; BSA, body surface area; BMI, body mass index.

not included as complications if already apparent before surgery. Late events were collected by telephone at 6 months and by questionnaire at the time of the 12-month echocardiogram

Functional Assessment

The Short Form-36 (SF-36) health questionnaire^{9,10} and the Hospital Anxiety and Depression scale¹¹ were given preoperatively (within 6 weeks assuming no new clinical event) and at 1 year (10 and 14 months). The mental composite score and physical composite score of the SF-36 questionnaire were calculated.⁹ New York Heart Association (NYHA) class was recorded. In addition, the 6-minute walk was recorded before surgery and at 1 year. This test has been validated for patients with heart failure and lung disease.¹² It is suitable for elderly persons who may not be able to use either a bicycle or treadmill and has physiologic validity in allowing the subject to walk at his or her own pace. The distance walked was recorded by the investigator walking with the patient and pushing a pedometer.

Analysis

A sample size of 45 per group was expected to allow detection of a 5 mm Hg difference in mean gradient with 90% power. The mean and standard deviation (SD) values were calculated for variables that were normally distributed and the median and range for those that were skewed. Clinical events were expressed as a proportion of the whole population and the incidence of regurgitation was expressed as a proportion of those having echocardiograms. Comparisons were made between valve types using the unpaired *t* test or nonparametric Mann-Whitney *U* test as appropriate, with analyses both by intention to treat and actual valve implanted. There were no material differences between the two analyses, so the analysis by actual valve implanted was reported. There were no missing data points for those echocardiographic studies performed. The incidence of regurgitation was compared by the Fisher exact test. Analyses were performed by the Statistical Package for Social Sciences version 11.5.1 for Windows (SPSS, Inc, Chicago, Ill).

Results

The patients were similar in terms of preoperative characteristics (Table 1). Crossclamp time was similar, 74 (SD 25) minutes for the Mosaic and 72 (SD 17) minutes for the Perimount bioprostheses. Total bypass time was also similar, 95 (SD 31) minutes for the Mosaic and 95 (SD 30) for the Perimount valves. The label sizes for the two valve designs were similar and on average approximately 1 mm smaller than the tissue annulus diameter determined by the independent sizer (Table 2).

For peak and mean transvalve pressure difference, there were small but statistically significant differences in favor of the Perimount valve both postoperatively and at 1 year. The effective orifice area was slightly larger in the Perimount valve postoperatively, but there was no significant difference (NS) at 1 year (Table 3). These differences were also apparent in the valves when compared by label size (Table 4). Patient-prosthesis mismatch occurred in 40 (82%) Mosaic compared with 30 (64%) Perimount valves (NS). Severe mismatch

TABLE 2. Comparison between tissue annulus diameter and label size for the Mosaic and Perimount valves

Tissue annulus	Mosaic implanted		Perimount implanted	
	Mosaic size	Perimount size	Mosaic size	Perimount size
19	19.0 (0.0)	19.0 (0.0)	19.0 (0.0)	19.0 (0.0)
20	19.0 (0.0)	19.0 (0.0)	—	—
21	20.6 (0.8)	20.6 (0.8)	20.8 (0.6)	20.8 (0.6)
22	21.0 (0.0)	21.0 (0.0)	21.0 (0.0)	21.0 (0.0)
23	22.3 (1.0)	22.3 (1.0)	22.4 (1.0)	22.6 (1.2)
24	21.5 (1.0)	22.0 (1.2)	23.0 (1.6)	22.5 (1.0)
25	24.1 (1.1)	24.1 (1.1)	24.2 (1.1)	24.2 (1.1)
26	—	—	—	—
27	26.0 (1.4)	26.0 (1.4)	26.0 (1.4)	26.0 (1.4)
28	—	—	27.0 (0.0)	27 (0.0)
29	28.0 (1.4)	28.0 (1.4)	25.5 (1.0)	25.5 (1.0)

occurred in 22 (45%) Mosaic compared with 14 (30%) Perimount valves (NS).

At 1 year there was trivial or mild regurgitation through the valve in 8 Mosaic and 13 Perimount valves (NS) and trivial or mild paraprosthetic regurgitation in 4 Mosaic and 2 Perimount valves (NS). One valve in each group had regurgitant jets in both a paraprosthetic position and through the valve. Only one of the paraprosthetic jets was associated with continuous sutures.

There were no differences in preoperative or postoperative LV dimensions, LV mass index, fractional shortening, or LV outflow velocity integrals between the Mosaic and Perimount groups (Table 5). The ejection fraction was above 50% in 44 (88%) Mosaic and 38 (81%) Perimount valves and below 30% in 1 Mosaic and 2 Perimount valves.

There were no statistically significant differences in mortality and clinical events between the two valve types. There was 1 early death (within 30 days) in the Mosaic group and 1

TABLE 3. Hemodynamic function postoperatively and at 1 year

Variable	Mosaic	Perimount	P value
Postop			
N	49	47	
EOA (cm ²)	1.28 ± 0.46	1.47 ± 0.45	.05
Peak ΔP (mm Hg)	28 ± 13	19 ± 9	<.0001
Mean ΔP (mm Hg)	17 ± 7	11 ± 5	<.0001
One year			
N	40	37	
EOA (cm ²)	1.33 ± 0.31	1.42 ± 0.46	NS
Peak ΔP (mm Hg)	28 ± 11	19 ± 8	<.0001
Mean ΔP (mm Hg)	15 ± 6	11 ± 4	<.0001

EOA, Effective orifice area by the continuity equation; ΔP, pressure difference; NS, not significant.

TABLE 4. Hemodynamic function (mean $\pm$ standard deviation) postoperatively by label size

Label size	Mosaic	Perimount	P value
19	n = 5	n = 4	
EOA (cm ²)	0.93 $\pm$ 0.34	1.10 $\pm$ 0.29	NS
EOAi (cm ²)	0.58 $\pm$ 0.24	0.67 $\pm$ 0.17	NS
Peak Δ P (mm Hg)	42 $\pm$ 15	31 $\pm$ 8	NS
Mean Δ P (mm Hg)	23 $\pm$ 8	16 $\pm$ 4	NS
21	n = 19	n = 19	
EOA (cm ²)	1.13 $\pm$ 0.37	1.27 $\pm$ 0.25	NS
EOAi (cm ²)	0.63 $\pm$ 0.26	0.72 $\pm$ 0.16	NS
Peak Δ P (mm Hg)	34 $\pm$ 11	22 $\pm$ 7	.001
Mean Δ P (mm Hg)	19 $\pm$ 7	13 $\pm$ 5	.003
23	n = 17	n = 15	
EOA (cm ²)	1.43 $\pm$ 0.41	1.71 $\pm$ 0.42	NS
EOAi (cm ²)	0.80 $\pm$ 0.24	0.91 $\pm$ 0.23	NS
Peak Δ P (mm Hg)	24 $\pm$ 10	14 $\pm$ 6	.003
Mean Δ P (mm Hg)	13 $\pm$ 6	8 $\pm$ 4	.005
25	n = 7	n = 6	
EOA (cm ²)	1.29 $\pm$ 0.60	1.43 $\pm$ 0.55	NS
EOAi (cm ²)	0.79 $\pm$ 0.23	0.77 $\pm$ 0.28	NS
Peak Δ P (mm Hg)	19 $\pm$ 6	18 $\pm$ 10	NS
Mean Δ P (mm Hg)	13 $\pm$ 7	10 $\pm$ 6	NS
27	n = 1	n = 3	
EOA (cm ²)	1.60	2.13 $\pm$ 0.45	—
EOAi (cm ²)	0.76	1.1 $\pm$ 0.2	—
Peak Δ P (mm Hg)	15	13 $\pm$ 7	—
Mean Δ P (mm Hg)	9	7 $\pm$ 3	—
29	1		
EOA (cm ²)	2.3		—
EOAi (cm ²)	1.25		—
Peak Δ P (mm Hg)	13		—
Mean Δ P (mm Hg)	7.2		—

EOA, Effective orifice area by the continuity equation; EOAi, indexed effective orifice area; Δ P, pressure difference; NS, not significant.

in the Perimount group. There were 3 late deaths (between 30 days and 12 months) in the Mosaic group and 5 in the Perimount group. There were 3 perioperative strokes in the Mosaic group and 2 in the Perimount group. There were 2 early thromboembolic events in the Mosaic group and 1 in the Perimount group. There were 2 late thromboembolic events in the Mosaic and 1 in the Perimount group. There was no endocarditis or valve thrombosis.

Functional Measures

Six-minute walk distance for the Mosaic valve increased from 255 m (SD 119 m) preoperatively to 366 m (SD 121 m) postoperatively ($P < .0001$). For the Perimount group, the preoperative walk distance of 223 m (SD 129 m) increased to 334 m (SD 104 m) ($P = .002$). There were 51 (SD 65%) patients in NYHA class I at 1 year, 27 Mosaic and 24 Perimount. There were 25 (32%) in class II, 12 Mosaic and 13 Perimount. Only 1 Mosaic and 2 Perimount valve

recipients were in NYHA class III, and no patients were in class IV. There were no differences between the valve types either before or after surgery in terms of 6-minute walk distance or NYHA class.

There were improvements in both anxiety and depression scores after surgery for each valve design, but no difference between the valve designs (Table 6a). Similarly, both mental and physical composite scores on the SF-36 questionnaire improved after surgery but with no difference between the valve types (Table 6b). The change in physical score was greater than for mental score.

Discussion

This randomized study suggests better hemodynamic function in a pericardial compared with a porcine stented valve. The peak and mean pressure differences were statistically lower with the pericardial valve ($P < .0001$) both postoperatively and at 1 year although the clinical difference was relatively small, 6 mm Hg in the mean and 9 mm Hg in the peak pressure difference. Pressure difference is dependent on flow, but there was also a non-statistically significant trend to a larger effective orifice area in the pericardial valve both postoperatively (1.47 vs 1.28 cm²; $P = .05$) and at 1 year (1.42 vs 1.33 cm²) using the relatively flow-independent continuity equation. The incidence of patient–prosthesis mismatch was lower, 30 (64%) for the pericardial Perimount compared with 40 (82%) with the porcine Mosaic valve, although the difference was not statistically significant.

There were no discrepancies in the hemodynamic results in comparison with previously published studies of the Mosaic or Perimount valves.^{13–23} In general, nonrandomized studies tend to show better hemodynamic function for pericardial compared with porcine valves. Peak pressure difference for pericardial valves of label size 23 mm is around 15 mm Hg¹ compared with a range of 18 to 32 mm Hg for porcine valves of similar label size.^{2,3} However, variations in sizing convention mean that valves of different design with the same label size may fit different patient tissue annulus diameters, which necessitates randomization of two comparator valves. A study⁵ with a design similar to ours found that the mean pressure difference at rest was higher for the Mosaic valve at 14.6 mm Hg than for the Perimount valve at 11.4 mm Hg ($P < .05$). However, the mean effective orifice area was similar, 1.49 cm² for the Mosaic and 1.56 cm² for the Perimount valve. Seitelberger and associates⁶ also found that the Perimount was hemodynamically superior to the Mosaic bioprosthesis when compared by label size. However, hemodynamic function was similar when the two valve designs were compared according to patient tissue annulus. This result is different from ours and from the previous study by Eichinger and colleagues⁵ and may be explained by differences in sizing. The Mosaic valve is a true supra-annular design, whereas the Perimount pericardial bioprosthesis has an intra-annular stent design with a supra-annular cuff. This

TABLE 5. Measure of left ventricular size and function (mean $\pm$ SD)

	Mosaic		Perimount		95% CI	P value
LVDD (cm) Pre	5.1 $\pm$ 0.86	46	4.9 $\pm$ 1.1	46	−2.7, 0.54	NS
LVDD (cm) Post	4.6 $\pm$ 0.9	49	4.7 $\pm$ 0.9	46	−0.52, 0.17	NS
LVDD (cm) 12 mo	4.5 $\pm$ 0.8	39	4.6 $\pm$ 0.9	36	−0.52, 0.36	NS
LVMI Pre	233 $\pm$ 123	41	211 $\pm$ 77	44	−23, 66	NS
LVMI g/m ² Post	176 $\pm$ 63	46	183 $\pm$ 59	42	−33, 19	NS
LVMI g/m ² 12 mo	152 $\pm$ 50	38	160 $\pm$ 62	36	−34, 18	NS
FS (%) Pre	35 $\pm$ 9	42	32 $\pm$ 11	44	−2.1, 6.7	NS
FS (%) Post	31 $\pm$ 10	44	32 $\pm$ 10	38	−5.6, 3.1	NS
FS (%) 12 mo	36 $\pm$ 8	36	34 $\pm$ 10	34	−2.2, 6.6	NS
LVOT VTI Pre	21 $\pm$ 5	51	20 $\pm$ 5	48	−1, 3	NS
LVOT VTI Post	17 $\pm$ 4	50	17 $\pm$ 4	47	−1, 2	NS
LVOT VTI 12 mo	22 $\pm$ 5	40	20 $\pm$ 5	37	−0.03, 4.3	NS

CI, Confidence interval; LVDD, left ventricular diastolic diameter; LVMI, left ventricular mass index; FS, fractional shortening; LVOT, left ventricular outflow tract; VTI, velocity time integral; NS, not significant.

would suggest that a larger Mosaic valve might be implanted. However, in our study the label sizes were similar. By contrast, in the study by Seitelberger and associates,⁶ the Perimount valves tended to be smaller inasmuch as there were 10 Perimount but no Mosaic valves at label size 19. It is possible that there was an unintentional bias in favor of the Mosaic in the study of Seitelberger and coworkers.⁶ The body surface area of the patients was not given, but there were 8 patients with a 19-mm tissue annulus diameter as measured by an independent sizer and all of these were implanted with a Perimount valve. On the other hand, our study could have been biased toward the Perimount valve if the label size of the Mosaic valve was limited not by the tissue annulus but by the size of the aortic root, as occurs with other supra-annular valves.²⁴

The overriding concern in research in the past has been the objective assessment of hemodynamic function and clinical event rates including mortality. What also matters to a patient is exercise ability and quality of life. The minor hemodynamic difference did not translate to any difference in exercise ability, although after surgery both groups had large and clinically significant improvements compared with preoperative levels. The 6-minute walk is a simple physiologic

measure of exercise capacity that can be performed by most patients. It is likely to be more representative than the NYHA class. Similarly, both groups showed large improvement in anxiety and depression scores using the Hospital Anxiety and Depression scale and in mental and physical scores using the SF-36 questionnaire. The improvement was predominantly in physical score (12.8 for the Perimount valve and 10.2 for the Mosaic valve) rather than the mental composite score (4.7 for the Perimount valve and 3.5 for the Mosaic valve). Little previously published work exists, but our results are consistent with Ware and Kosinski's²⁵ estimation of mental and physical composite scores from a study of 94 patients having valve surgery.²⁶ They showed that an improvement in score at 6 months after surgery occurred mainly for the physical score (7.6 points) rather than the mental score (3.2 points). However, this may be because the mental score was less reduced before surgery than the physical score. In our study, both scores were similar after surgery to the expected normal range, which for a US population aged older than 75 years is 37.9 (SD 11.2) for physical and 50.4 (SD 11.7) for mental score.⁹ We also showed significant improvements in both the depression and anxiety scores

TABLE 6a. Hospital and anxiety questionnaire (mean $\pm$ standard deviation)

	Mosaic	N	Perimount	N	P value
Anxiety (pre)	7.2 $\pm$ 3.7	46	7.6 $\pm$ 4.4	47	NS
Anxiety (12 mo)	5.0 $\pm$ 3.0	40	4.2 $\pm$ 3.7	38	NS
P value	.001		<.0001		
Depression (pre)	5.9 $\pm$ 3.5	46	6.1 $\pm$ 4.1	47	NS
Depression (12 mo)	4.4 $\pm$ 2.8	40	4.4 $\pm$ 3.7	37	NS
P value	.003		.032		

NS, Not significant.

TABLE 6b. SF-36 questionnaire (mean $\pm$ standard deviation)

	Mosaic™	N	Perimount™	N	P value
PCS (pre)	28.1 $\pm$ 11.8	46	26.0 $\pm$ 9.9	46	NS
PCS (12 mo)	38.3 $\pm$ 11.7	38	38.8 $\pm$ 12.03	38	NS
P value	<.0001		<.0001		
MCS (pre)	47.6 $\pm$ 10.8	46	45.2 $\pm$ 11.8	47	NS
MCS (12 mo)	51.1 $\pm$ 8.6	38	49.9 $\pm$ 12.6	38	NS
P value	.005		.009		

SF-36, Short Form-36; PCS, Physical composite score; MCS, mental composite score; NS, not significant.

of the Hospital Anxiety and Depression scale. However, for none of these functional measures was there any difference between the two valve types.

Clinical Implications

There is general agreement that patient–prosthesis mismatch has adverse clinical effects, particularly in patients with impaired LV function.^{27–29} Despite this, we found no difference in exercise capacity or regression of LV hypertrophy although our patients were observed only to 1 year. It is also possible that valves with a larger effective orifice area will allow patients to avoid symptoms for longer as progressive stenosis develops as a result of primary valve failure. This could reduce the risk of cardiac events and reoperation in the long term.

Limitations

This study reports information to only 1 year, and it is possible that late event rates or durability may differ. Furthermore, the study was primarily concerned with hemodynamic function and was not powered to detect small differences in event rates. There was a trend in effective orifice area in favor of the Perimount valve, which might have been statistically significant with a larger population size. It is also possible that the hemodynamic differences might have been greater had we been able to use the Carpentier-Edwards Perimount Magna valve (Edwards Lifesciences, Irvine, Calif), which is a wholly supra-annular version of the Perimount design. However, a comparison of the Perimount Magna with the Mosaic³⁰ found a mean pressure difference of 10.2 versus 17.1 mm Hg, which is similar to our results (11 vs 17 mm Hg). Although all surviving patients were studied immediately after surgery, 22 subjects could not have echocardiography at 1 year. Despite this, the hemodynamic results were similar at both time points.

Conclusion

In this randomized comparison of the Mosaic and Perimount valves, there were minor differences in hemodynamic function in favor of the Perimount valve. Both valves were associated with similar and significant improvements in quality of life, exercise ability, and regression of LV mass.

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