Clinical Investigation

Aortic Valve Reconstruction with Use of Pericardial Leaflets

in Adults with Bicuspid Aortic Valve Disease: Early and Midterm Outcomes

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In this study, we retrospectively analyzed the outcomes of adults with bicuspid aortic valve (BAV) disease who underwent aortic valve reconstructive surgery (AVRS), consisting of replacement of the diseased BAV with 2 or 3 pericardial leaflets plus fixation of the sinotubular junction for accurate and constant leaflet coaptation. From December 2007 through April 2013, 135 consecutive patients (mean age, 49.2 ± 13.1 yr; 73.3% men) with symptomatic BAV disease underwent AVRS. Raphe was observed in 84 patients (62.2%), and the remaining 51 patients had pure BAV without raphe. A total of 122 patients (90.4%) underwent 3-leaflet reconstruction, and 13 (9.6%) underwent 2-leaflet reconstruction. Concomitant aortic wrapping with an artificial graft was performed in 63 patients (46.7%).

There were no in-hospital deaths and 2 late deaths (1.5%); 6 patients (4.4%) needed valve-related reoperation. The 5-year cumulative survival rate was 98% ± 1.5%, and freedom from valve-related reoperation at 5 years was 92.7% ± 3.6%. In the last available echocardiograms, aortic regurgitation was absent or trivial in 116 patients (85.9%), mild in 16 (11.9%), moderate in 2 (1.5%), and severe in one (0.7%). The mean aortic valve gradient was 10.2 ± 4.5 mmHg, and the mean aortic valve orifice area index was 1.3 ± 0.3 cm^2/m^2. The 3-leaflet technique resulted in lower valve gradients and greater valve areas than did the 2-leaflet technique. Thus, in patients with BAV, AVRS yielded satisfactory early and midterm results with low mortality rates and low reoperation risk after the initial procedure.
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Key words: *Aortic valve/abnormalities/surgery; cardiac surgical procedures/methods; heart defects, congenital/surgery; heart valve prosthesis implantation; prosthesis design; reconstructive surgical procedures/methods; treatment outcome*

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Bicuspid aortic valve (BAV) is a congenital anomaly with an incidence of 1% to 2.5% and a higher prevalence in men.[1,2] In people with BAV, 85% of subsequent valvular disease consists of aortic stenosis that presents after the 5th decade of life.[3] Isolated aortic valve regurgitation is less frequent and usually manifests itself earlier in life.[4] Most patients who have BAVs associated with pure regurgitation undergo repair; however, stenotic BAVs are typically replaced with artificial valves.[5] Although regurgitant BAVs are usually repaired, repaired BAVs have significant valve gradients, and early reoperation for valve replacement is necessary.[6] In addition, because most stenotic BAVs are replaced, the patients cannot avoid the sequelae associated with mechanical valves or the problems associated with bioprosthetic valves.[7] As a result, neither valve replacement nor valve repair is a completely satisfactory therapeutic method for BAV disease.

We treated BAV disease by performing aortic valve reconstructive surgery (AVRS) that consisted of aortic valve leaflet reconstruction with the use of pericardial patches plus fixation of the sinotubular junction (STJ), and we evaluated the early and midterm outcomes.

Patients and Methods

We retrospectively analyzed the cases of 135 patients (99 men and 36 women; mean age, 49.2 ± 13.1 yr) who underwent AVRS for the treatment of BAV disease at Konkuk University Medical Center from December 2007 through April 2013 (Table I). Informed consent was obtained from all patients, and the study was approved by the Institutional Review Board at Konkuk University.

The study included BAV patients who underwent aortic leaflet reconstruction by means of AVRS. Patients who had dilation of the STJ, who were undergoing repeat

TABLE I. Preoperative Characteristics of the 135 Patients

Variable	Value
Male	99 (73.3)
Age, yr	49.2 ± 13.1
Age range, yr	20–80
Age groups, yr	
≤20	1 (0.7)
21–40	36 (26.7)
41–60	70 (51.9)
61–80	28 (20.7)
Body surface area, m^2	1.75 ± 0.18
Aortic valve diseases	
Stenosis	75 (55.6)
Regurgitation	54 (40)
Stenotic insufficiency	6 (4.4)
Morphology of bicuspid valve	
With raphe	84 (62.2)
Fusion of right and left leaflets	76 (56.3)
Fusion of right and noncoronary leaflets	8 (5.9)
Without raphe (pure bicuspid)	51 (37.8)
Right–left type	41 (30.4)
Anteroposterior type	10 (7.4)
Preoperative left ventricular ejection fraction	0.65 ± 0.1
Previous cardiac surgery	3 (2.2)
Patients undergoing AVRS by year	
2007	2 (1.5)
2008	28 (20.7)
2009	24 (17.8)
2010	28 (20.7)
2011	26 (19.3)
2012	26 (19.3)
2013	1 (0.7)

AVRS = aortic valve reconstructive surgery

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

aortic valve surgery, or who had an ascending aortic dilation or aneurysm were also included in the study. However, patients who underwent combined mitral or tricuspid valve surgery or surgery for acute aortic dissection had been excluded, so that we could evaluate the outcomes of AVRS alone.

Surgical Techniques

We performed AVRS by means of techniques that have been described for the treatment of stenotic and regurgitant BAV disease.[8-10] Surgery was performed through a median sternotomy with the patients under moderately hypothermic cardiopulmonary bypass and with use of cold-blood cardioplegic solution administered antegrade and retrograde. The aortic valve was exposed and excised through a transverse aortotomy 1 to 1.5 cm above the right coronary artery ostium.

For purposes of AVRS, the diameter of the new STJ was determined first. In cases with no dilation of the aortic root, the actual STJ diameter was used; conversely, in cases of root dilation, the new STJ diameter was determined from the new annular diameter. Because the muscular part of the annulus was rarely dilated, only the dilated fibrous part of the aortic annulus was reduced, with use of inner and outer strips and 5 or 6 interrupted sutures. The new STJ diameter was the same size as that of this new annular diameter. After the STJ diameter was determined, the new commissures were made.

One of the 2 commissures in the BAV became a base for creating 3 new commissures that had the same intercommissural distances (Fig. 1A). The new 2 commissures were located at the same level and were placed at least 5 mm above the coronary artery ostia. The new commissures were marked with inverted letter Ys at a 30° to 40° angle. A new nadir was created between 2 commissures at the top angle of an inverted equilateral triangle that was drawn on the line that connected the 2 commissures, and the new nadir was marked with a medical pen (Fig. 1B). To create a new cusp attachment, the 2 commissures and the nadir were connected in a U shape (Fig. 1C). The new commissures were at least 3 mm higher than the coronary ostia. To simplify construction of the pericardial leaflets, we used 5 templates that differed in size by 2-mm increments. Three identical pericardial leaflets were sutured to the new cusp attachments with use of continuous 5-0 polypropylene sutures. The flat patch was transformed into scoop-shaped leaflets by means of pericardial plication at a 1.5:1 ratio to the cusp attachment during suturing (Fig. 1D). At each commissure, the 2 suture ends were tied inside the aorta, passed outside it, and tied again.

For 2-leaflet reconstruction (Fig. 2), another new commissure was created at the other side in the STJ, in such a manner that the 2 intercommissural distances were the same. The remaining procedures were the same as in the 3-leaflet reconstruction technique.

After the creation of the new STJ, commissures, and cusp attachments, the size of the pericardial leaflets for AVRS was determined on the basis of the STJ diameter.[11] Substantially dilated annuli were reduced by plication of the fibrous portion with use of nonexpandable inner and outer annulus strips (ScienCity Co.; Seoul, ROK) and 5 or 6 interrupted 4-0 polypropylene mattress sutures. Annular reduction was performed in only 2 patients (1.5%).

The new valve leaflets were made of Supple Peri-Guard® bovine pericardium (Synovis Life Technologies, Inc.; St. Paul, Minn). The length of the upper (coaptation) margin of the pericardial leaflet was the same as the STJ diameter, and the height of the patch was 0.7 times the length of the upper margin[12]; the 2 lower angles of the patch formed a round shape (Fig. 3A). The pericardial leaflets had an extra 2-mm-wide suture margin along their suture lines (Fig. 3B).

Subsequently, the new STJ was created 2 mm above the new commissures (at least 5 mm above both coro-

nary ostia) with a nonexpandable inner ring and an outer ring or strip (ScienCity Co.) with use of 18 interrupted 4-0 polypropylene mattress sutures. Coaptation sutures were made by using a figure-eight 5-0 polypropylene suture at the upper leaflet margin, 1 to 2 mm from each commissural end of the leaflets. The aortotomy was then closed in conventional fashion.

The outer ring or strip for STJ fixation was 4 to 6 mm longer than the inner ring, depending on the thickness of the aortic wall. The 24-, 26-, and 28-mm leaflets and inner rings were used in most patients (Table II).

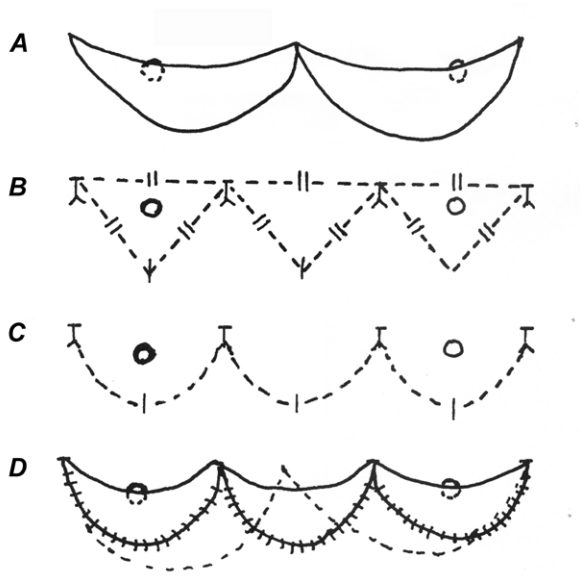

Fig. 1 *Diagram illustrates 3-leaflet reconstruction for bicuspid aortic valve diseases.* ***A****) The 3 new commissures were marked at the same height and at an equal intercommissural distance in the bicuspid aortic valve.* ***B****) The new nadirs of the cusp attachments were made at the top angles of inverted equilateral triangles that were constructed on the lines that connected 2 commissures.* ***C****) The new cusp attachments were marked by connecting the 2 new commissures and their nadirs in a U shape.* ***D****) Each pericardial patch was sutured to each cusp attachment and thus transformed into a scoop-shaped leaflet by means of pericardial plication at a 1.5:1 ratio to the cusp attachment during suturing.*

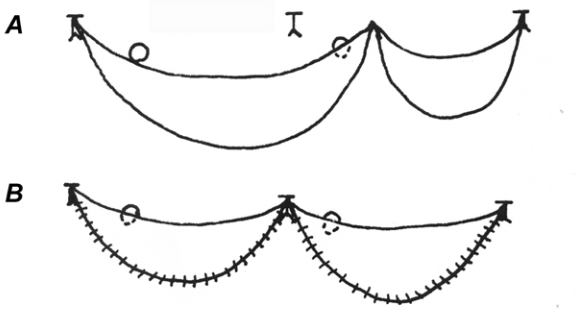

Fig. 2 *Diagram illustrates 2-leaflet reconstruction.* ***A****) One new commissure was made at the other side of one basic commissure at an equal intercommissural distance.* ***B****) Two pericardial patches were sutured to 2 new cusp attachments.*

Clinical Evaluation and Follow-Up

Transthoracic echocardiographic studies were routinely performed before surgery, upon hospital discharge, and then annually if the patients had no problems. Using the last available echocardiographic data, we analyzed the competence and hemodynamic yield of the reconstructed valves. Left ventricular mass and its indexed value (LVMI) were calculated by means of the Penn formula.[13] Follow-up after AVRS was performed in 100% of the surviving patients. An event was defined as any of the following: death from any cause, endocarditis, stroke, revascularization for new-onset angina, and repeat aortic valve surgery. In total, 385.5 patient-years were analyzed.

Statistical Analysis

Categorical variables are expressed as number and percentage, and continuous variables are expressed as mean

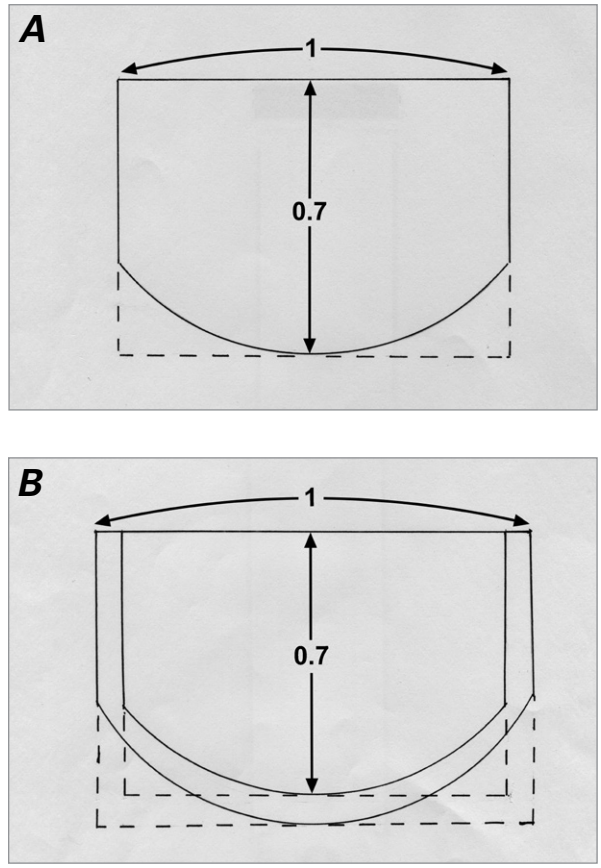

Fig. 3 ***A****) The length of the upper margin of the pericardial leaflet patch was always the same as the diameter of the sinotubular junction, and the height of the patch was 70% of the diameter of the sinotubular junction.* ***B****) The leaflet for actual use was larger than the native leaflet size because extra suture space (2 mm) was added.*

± SD. One-way analysis of variance was used to test a hypothesis if several means were equal. The Tukey multiple-comparison test was used for post hoc comparison between pairs of means. Survival and freedom-from-event probabilities were estimated by means of the nonparametric Kaplan-Meier method. A *P* value of <0.05 was used to signify statistical significance. Statistical analysis of the data was performed with use of SPSS 18.0 (IBM Corporation; Armonk, NY).

Results

Perioperative Data

A total of 122 patients (90.4%) underwent 3-leaflet reconstruction, and 13 patients (9.6%) underwent 2-leaflet reconstruction. Sixty-three patients (46.7%) underwent concomitant aortic wrapping with an artificial graft, and 13 (9.6%) underwent concomitant septal myectomy. Raphe was observed in 84 patients (62.2%), and pure BAV without raphe was present in 51 (37.8%) (Table I).

Early Morbidity and Valve Competence

No in-hospital deaths occurred. Five patients (3.7%) needed repeat exploration because of postoperative bleeding. Before discharge from the hospital, 2 patients (1.5%) had a transient cerebral ischemic attack, and another 2 patients had a cerebral infarction. Three patients (2.2%) needed catheter drainage because of pericardial tamponade caused by pericardial effusion. There were no early valve-related complications, such as valvular dysfunction or hemolysis. According to the postoperative echocardiograms upon hospital discharge, 126 patients (93.3%) had no or only trivial aortic regurgitation, and 9 patients (6.7%) had mild-to-moderate regurgitation (Table II).

TABLE II. Perioperative Data for the 135 Patients

Variable	Value
Type of AVRS	
Tricuspid	122 (90.4)
Bicuspid	13 (9.6)
Aortic cross-clamp time, min	112 ± 19.3
Cardiopulmonary bypass time, min	178.1 ± 31.2
Size of implanted leaflets, mm	
22	5 (3.7)
24	35 (25.9)
26	58 (43)
28	27 (20)
30	10 (7.4)
Intensive care unit stay, d	3.3 ± 0.8
Hospital stay, d	13.3 ± 4.9
Re-exploration for postoperative bleeding	5 (3.7)
In-hospital death	0
Aortic valve regurgitation at hospital discharge	
None	96 (71.1)
Trivial	30 (22.2)
Mild	7 (5.2)
Moderate	2 (1.5)

AVRS = aortic valve reconstructive surgery

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

Late Morbidity and Survival

The mean follow-up period was 34.3 ± 17.6 months (range, 2–66.2 mo). Three patients (2.2%) had a cerebral infarction (in postoperative months 1, 2, and 23, respectively). Repeat aortic valve surgery after AVRS was performed in 6 patients (4.3%; 5-year freedom from reoperation, 92.7% ± 3.6%). Among those 6 patients, 2 underwent repeat suturing of detached pericardial leaflets that had caused severe regurgitation. The other 4 patients had endocarditis in the reconstructed leaflets; one underwent AVRS again and 3 underwent replacement with prosthetic valves (2 with mechanical valves and one with a bioprosthetic valve).

Two late deaths (1.5%) occurred: one patient underwent repeat bioprosthetic valve replacement in postoperative month 7 and died of low cardiac output syndrome, and the other patient died of duodenal cancer in postoperative month 32. The 5-year cumulative survival rate was 98% ± 1.5%, and the 5-year event-free survival rate was 88.3% ± 3.9%.

Late Echocardiographic Follow-Up

In the last available echocardiograms after the patients' discharge from the hospital, aortic regurgitation was absent or trivial in 116 patients (85.9%), mild in 16 (11.9%), moderate in 2 (1.5%), and severe in one (0.7%). Most patients had accurate coaptation and full opening of the reconstructed leaflets during the cardiac cycle (Fig. 4).

In the echocardiograms of the 112 patients who were monitored for one year or longer, the peak and mean valve gradients were 19.1 ± 7.4 and 10.2 ± 4.5 mmHg, respectively; the mean effective aortic orifice area was 2.3 ± 0.7 cm^2; the indexed area was 1.3 ± 0.3 cm^2/m^2. Patients with 3-leaflet reconstruction had mean gradients of less than 10 mmHg (Table III). The peak and mean gradients were both significantly lower in the 26- and 28-mm leaflets than in the 24-mm leaflets. The mean valve orifice areas were significantly larger in the 28- and 30-mm leaflets than in the 24-mm leaflets (Table IV). A mean valve gradient ≥19 mmHg and an aortic valve area index ≤0.75 cm^2/m^2 were not observed in the study population.

The LVMI was reduced by 25.6% in comparison with the preoperative LVMI (*P* <0.0001) (Fig. 5).

Discussion

Aortic valve reconstructive surgery has been performed previously in patients with tricuspid aortic valve disease.[8] Diseased BAVs can easily be replaced with 2 pericardial leaflets (2-leaflet technique). By July 2009, the early period of this study, the 2-leaflet technique had been performed in only 13 patients. We observed that the reconstructed bicuspid valves had a significant valve gradient, so we exclusively used the 3-leaflet technique in subsequent AVRS. The 2-leaflet technique yielded a significant mean gradient of 14 mmHg, which was still lower than that in repaired BAVs.[6]

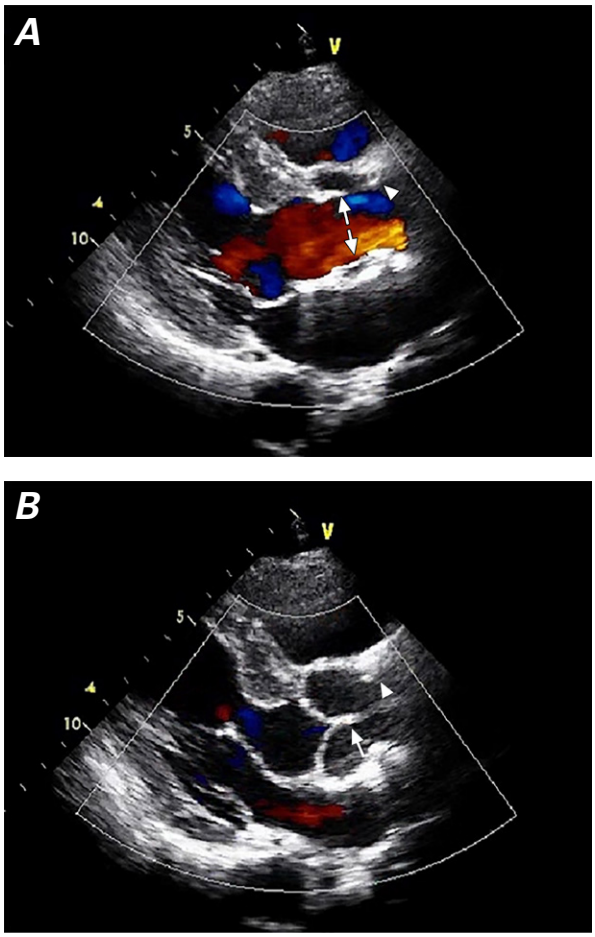

Fig. 4 *Transthoracic 2-dimensional echocardiograms (parasternal long-axis views) show* ***A****) the full opening of the aortic valve in systole and* ***B****) the competent closure of the valve in diastole, because of 3 reconstructed pericardial leaflets. Arrowheads indicate the sinotubular junction; arrows indicate the aortic valve leaflets.*

Supplemental motion images are available for Figures 4A and 4B.

Several materials can be used to reconstruct the aortic valve. We chose bovine pericardium because of its flexibility and easy handling. We no longer perform partial leaflet-extension procedures for aortic valve repair, because the native leaflet and the augmented pericardial patch have different flexibilities and are not well matched.

Because 3 new commissures and 3 new cusp attachments must be created to perform 3-leaflet reconstruction in BAV disease, AVRS in BAV disease might be more complex than in tricuspid aortic valve disease. However, the procedure was simplified[14] on the basis of aortic root anatomy, which was described by Dagum and colleagues.[15]

Only valve replacement has been reliable for treating BAV stenosis.[5] However, mechanical valves have sequelae related to anticoagulants, and bioprosthetic valves have unsatisfactory durability in the presence of high pressure gradients and turbulent flow.[16] Repaired BAVs have a significant mean gradient of 17 mmHg[6]; however, our patients who underwent 3-leaflet reconstruction had a mean gradient of less than 10 mmHg.

In contrast with all current commercial prosthetic valves, AVRS does not affix the annulus and thus preserves the interleaflet triangles. The size of the pericardial leaflet is determined by the patient's STJ diameter.[10,11] Because the STJ is created by fixation in the normal range of the individual,[17] significant valve gradients and turbulent flow do not develop. In this study, postoperative echocardiograms showed the same leaflet motion as in normal native aortic valves. We did not see even trivial structural deterioration except in cases of endocarditis, and the mean valve orifice area of the reconstructed valves was greater than that of previously established stentless valves (2.3 cm^2 vs 1.6–1.8 cm^2).[18,19]

TABLE III. Data for 112 Patients with Echocardiographic Follow-up of ≥1 Year after AVRS

Variable	3-Leaflet Technique (n=99)	2-Leaflet Technique (n=13)	Total (n=112)
Peak pressure gradient, mmHg	18.2 ± 7.1	25.5 ± 6.4	19.1 ± 7.4
Mean pressure gradient, mmHg	9.6 ± 4.3	14.1 ± 4.1	10.2 ± 4.5
AV orifice, cm^2	2.6 ± 0.9	2.2 ± 0.4	2.3 ± 0.7
AV orifice index, cm^2/m^2	1.3 ± 0.4	1.1 ± 0.2	1.3 ± 0.3

AV = aortic valve; AVRS = aortic valve reconstructive surgery

Values are presented as mean ± SD.

TABLE IV. Echocardiographic Findings According to Leaflet Size in 112 Patients with Follow-Up ≥1 Year after AVRS

Variable	22-mm Leaflet (n=4)	24-mm Leaflet (n=30)	*P* Value[a]	26-mm Leaflet (n=49)	*P* Value[b]	28-mm Leaflet (n=21)	*P* Value[c]	30-mm Leaflet (n=8)	*P* Value[d]
Peak gradient, mmHg	26.4 ± 1.3	22.7 ± 7.8	0.86	17.8 ± 5.2	0.02	16.8 ± 8	0.03	15.4 ± 11	0.07
Mean gradient, mmHg	14.1 ± 1.4	12.5 ± 4.5	0.96	9.4 ± 3.2	0.02	8.7 ± 5	0.02	8.1 ± 6.4	0.07
AV orifice, cm^2	1.6 ± 0.2	2 ± 0.4	0.75	2.3 ± 0.6	0.11	2.5 ± 0.6	0.03	3 ± 0.9	<0.001
AV orifice index, cm^2/m^2	0.9 ± 0.1	1.1 ± 0.2	0.81	1.3 ± 0.3	0.08	1.4 ± 0.4	0.08	1.7 ± 0.5	0.001

AV = aortic valve; AVRS = aortic valve reconstructive surgery

[a]Pooled comparison between 22-mm versus 24-mm leaflet groups
[b]Pooled comparison between 24-mm versus 26-mm leaflet groups
[c]Pooled comparison between 24-mm versus 28-mm leaflet groups
[d]Pooled comparison between 24-mm versus 30-mm leaflet groups

Values are stated as mean ± SD. *P* <0.05 was considered statistically significant.

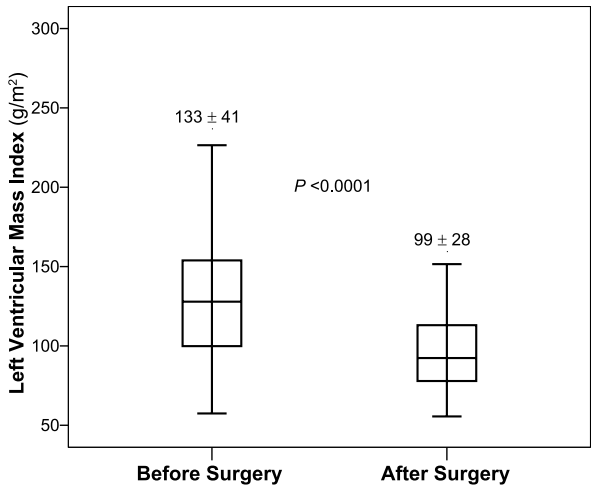

Fig. 5 *Graph shows a comparison of pre- and postoperative (final follow-up) left ventricular mass indices. In 112 patients who underwent echocardiographic follow-up ≥1 year postoperatively, left ventricular mass indices decreased by 25.6% when compared with preoperative values (*P *<0.0001).* P *<0.05 was considered statistically significant.*

The aortic valves that we reconstructed with smaller 22- and 24-mm pericardial leaflets yielded mean gradients of 10 mmHg or greater; nevertheless, this was still lower than that of currently available stentless valves or other artificial valves. In contrast, the aortic valves reconstructed with 26-mm or larger pericardial leaflets yielded lower mean gradients of 8 to 9 mmHg. No patient had a mean gradient of 19 mmHg or greater, or a valve area index of 0.75 cm^2/m^2 or below.

In a long-term follow-up study of young adult patients (mean age, 30 yr; age range, 12–68 yr) who underwent AVRS with use of bovine and autologous pericardium,[20] the 2 pericardium groups did not differ in terms of performance at 15 years or in the incidence of calcification and endocarditis. Along with recent improvements in commercial bovine pericardium, the low pressure gradients associated with reconstructed aortic valves might improve long-term durability. Five-year freedom from reoperation after AVRS is greater than or comparable to that of BAV repair or bioprosthetic-valve replacement (92% vs 89%).[6] Although the midterm results of AVRS are satisfactory, monitoring should continue, for long-term results.

Because the dimensions and geometric relationships of the human aortic valve have been well investigated,[12] we used them to design leaflets that would be sized correctly. The pericardial leaflets that are designed for AVRS are flat but are transformed into scoop-shaped leaflets by means of a simple suture technique. Attached to the cusp attachments, the pericardial leaflets create a sufficient and comfortable coaptation height under the fixed STJ. However, the cardiopulmonary bypass time was still long, because of the need to prepare the new cusp attachments and fashion the long suture lines.

In the past, similar pericardial leaflets have been designed and used to reconstruct diseased aortic valves[21]; however, STJ dilation started as soon as the aortic cross-clamp was released, because the STJ was unstable. This resulted in early failure of leaflet coaptation. In addition, because the dimension of the STJ changes during the cardiac cycle, the coaptation state of the leaflets is inconstant. On a long-term basis, the dimensions of the STJ increase with age,[22] which also causes delayed failure of the leaflet coaptation. Thus, fixation of the STJ is the most important procedure in terms of maintaining accurate leaflet coaptation during the early and late postoperative periods, and it might be related to the long-term durability of the leaflets.

In our study, the incidence of postoperative endocarditis was not low and should not be overlooked.

Because AVRS in patients with BAV disease can result in accurate coaptation and a low valve gradient without turbulent flow, we expect favorable long-term

durability of the new pericardial leaflets. The early and midterm results of our BAV patients who underwent AVRS were satisfactory; however, they should be monitored so that long-term results can be analyzed.

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