

Early Hemodynamic and Clinical Outcomes of Aortic Valve Neocuspidization for Severe Aortic Stenosis: A Single-Center Experience

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Abstract

Objective: Aortic valve neocuspidization using autologous pericardium is a reconstructive option for aortic valve disease. We evaluated the early hemodynamic and clinical outcomes of the Ozaki procedure in a single-center cohort.

Methods: This retrospective study included 31 consecutive patients with severe aortic stenosis who underwent aortic valve neocuspidization between January 2023 and June 2025. Pre-operative and 6-month echocardiographic findings were compared in 30 patients with paired data. Clinical outcomes were assessed through at least 12 months of follow-up among surviving patients.

Results: Median age was 65.0 years, and seven patients (22.6%) underwent a concomitant cardiac procedure. The median mean transvalvular gradient decreased from 50.5 mmHg preoperatively to 9.0 mmHg at 6 months ($p<0.001$). The maximum gradient decreased from 83.0 to 18.0 mmHg, and peak aortic jet velocity decreased from 4.60 to 1.85 m/s (both $p<0.001$). At 6 months, aortic regurgitation was absent in 16 patients (53.3%), mild in 12 (40.0%), and moderate in two (6.7%); none had severe regurgitation. One patient (3.2%) died during the index hospitalization. Another developed infective endocarditis with acute severe aortic regurgitation at 9 months and subsequently died. Overall 1-year survival was 93.5%.

Conclusion: Aortic valve neocuspidization was associated with low transvalvular gradients and generally favorable valve competence at 6 months. The fatal endocarditis event underscores the need for continued surveillance. Larger studies with longer follow-up are needed to assess durability.

Keywords: Aortic stenosis; aortic valve neocuspidization; autologous pericardium; echocardiography; Ozaki procedure.

Ciddi Aort Darlığında Aort Kapak Neoküspidizasyonunun Erken Hemodinamik ve Klinik Sonuçları: Tek Merkez Deneyimi

Özet

Amaç: Otolog perikard kullanılarak yapılan aort kapak neoküspidizasyonunun (Ozaki prosedürü) erken dönem hemodinamik ve klinik sonuçlarını tek merkezli bir hasta grubunda değerlendirmek.

Yöntem: Bu retrospektif çalışmaya, Ocak 2023–Haziran 2025 arasında ciddi aort darlığı nedeniyle aort kapak neoküspidizasyonu uygulanan ardışık 31 hasta alındı. Ameliyat öncesi ve altıncı ay ekokardiyografik bulguları, eşleştirilmiş verileri bulunan 30 hastada karşılaştırıldı. Hayatta kalan hastaların klinik izlemi en az 12 ay sürdü.

Bulgular: Ortanca yaş 65,0 yıl idi ve yedi hastaya (%22,6) eş zamanlı kardiyak işlem uygulandı. Ortanca transvalvüler ortalama gradiyent ameliyat öncesi 50,5 mmHg'den altıncı ayda 9,0 mmHg'ye düştü ($p<0.001$). Maksimum gradiyent 83,0'dan 18,0 mmHg'ye, aortik tepe akım hızı ise 4,60'tan 1,85 m/sn'ye geriledi (her ikisi için $p<0,001$). Altıncı ayda 16 hastada (%53,3) aort yetersizliği yoktu; 12 hastada (%40,0) hafif, iki hastada (%6,7) orta dereceli aort yetersizliği vardı. Ciddi aort yetersizliği saptanmadı. Bir hasta (%3,2) ilk hastane

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yatışı sırasında kaybedildi. Bir başka hastada dokuzuncu ayda akut ciddi aort yetersizliğine yol açan enfektif endokardit gelişti ve hasta daha sonra kaybedildi. Bir yıllık genel sağkalım %93,5 idi.

Sonuç: Aort kapak neoküspidizasyonu, altıncı ayda düşük transvalvüler gradiyentler ve genel olarak iyi kapak yeterliliği ile ilişkiliydi. Ölümle sonuçlanan endokardit olgusu, düzenli klinik ve ekokardiyografik izlemin önemini göstermektedir. Kapak dayanıklılığını değerlendirmek için daha geniş ve uzun süreli çalışmalara ihtiyaç vardır.

Anahtar sözcükler: Aort darlığı; aort kapak neoküspidizasyonu; otolog perikard; ekokardiyografi; Ozaki prosedürü.

Introduction

Surgical aortic valve replacement remains an established treatment for patients with severe aortic valve disease. However, currently available valve substitutes have important limitations. Mechanical prostheses provide long-term durability but require lifelong anticoagulation, whereas bioprosthetic valves avoid permanent anticoagulation at the cost of structural valve deterioration and possible reintervention. Prosthetic sewing rings and stent frames may also reduce the effective orifice area and contribute to residual transvalvular gradients, particularly in patients with a small aortic annulus.^[1,2]

Aortic valve neocuspidization, commonly known as the Ozaki procedure, was developed as a reconstructive alternative to conventional valve replacement. The technique involves replacing the diseased native leaflets with individually tailored leaflets fashioned from glutaraldehyde-treated autologous pericardium. By avoiding a rigid prosthetic sewing ring and stent frame, neocuspidization aims to preserve annular dynamics, provide a larger effective orifice area, and achieve favorable transvalvular hemodynamics. Comparative observational studies have demonstrated larger effective orifice areas and low post-operative gradients following neocuspidization compared with conventional bioprosthetic valve replacement.^[3,4]

The initial large experience reported by Ozaki et al.^[5] demonstrated satisfactory midterm survival, freedom from reoperation, and sustained hemodynamic performance in 850 patients. Subsequent studies from independent centers have generally reproduced the favorable early and midterm hemodynamic findings, with low transvalvular gradients and predominantly absent or mild residual aortic regurgitation.^[4,6,7] Nevertheless, the available evidence remains largely based on observational series, and concerns persist regarding long-term durability, progressive aortic regurgitation, infective endocarditis, and the need for reoperation. Infective endocarditis has been identified as an important cause of valve-related reintervention in several reported series.^[7,8]

Additional institutional experience is therefore valuable for evaluating the reproducibility of the technique outside its originating center. This study aimed to assess the operative and clinical outcomes of aortic valve neocuspidization using glutaraldehyde-treated autologous pericardium in a consecutive single-center cohort. Particular emphasis was placed on changes in transvalvular gradients, peak aortic jet velocity, and aortic regurgitation at 6 months, together with valve-related events and survival during a minimum clinical follow-up of 1 year.

Materials and Methods

Study Design and Patient Population

This retrospective, single-center observational study included all consecutive patients who underwent aortic valve neocuspidization at our institution between January 2023 and June 2025. Patients undergoing concomitant cardiac procedures were included to reflect the institution's real-world surgical experience. The final study population comprised 31 patients, all of whom had severe aortic stenosis.

Demographic characteristics, pre-operative clinical and echocardiographic findings, operative variables, post-operative outcomes, and follow-up data were obtained from institutional medical records. All patients who remained alive were followed clinically for at least 12 months after surgery. Transthoracic echocardiography was routinely performed at 6 months.

Surgical Technique

All procedures were performed through a median sternotomy under cardiopulmonary bypass. Autologous pericardium was harvested for leaflet reconstruction. The harvested pericardium was treated according to the technique originally described by Ozaki et al.^[5] It was fixed in a 0.6% glutaraldehyde solution for 10 min and subsequently rinsed 3 times in isotonic saline solution for 6 min per rinse.

After aortic cross-clamping, cardiac arrest was achieved with antegrade Del Nido cardioplegia. The ascending aorta was then opened, and the native aortic valve leaflets were excised. Calcific deposits were carefully removed when necessary, with particular attention to preserving the integrity of the aortic annulus. The intercommissural distances were measured using dedicated Ozaki sizing devices. The treated autologous pericardium was trimmed according to the corresponding leaflet templates.

Each reconstructed leaflet was individually sutured to the aortic annulus using 4-0 polypropylene sutures with a 17-mm needle. After completion of the reconstruction, leaflet mobility and commissural coaptation were assessed, and the aortotomy was closed. Intraoperative transesophageal echocardiography was performed after separation from cardiopulmonary bypass to evaluate leaflet motion, coaptation, residual aortic regurgitation, and transvalvular gradients.

Concomitant procedures were performed when clinically indicated and included coronary artery bypass grafting, ventricular septal defect closure, ascending aortic replacement, and mitral valve repair.

Data Collection and Definitions

Baseline variables included age, sex, serum creatinine level, diabetes mellitus, EuroSCORE II, left ventricular ejection fraction, aortic regurgitation grade, transvalvular gradients, peak aortic jet velocity, and the presence of pulmonary hypertension. Pulmonary hypertension was defined as an estimated pulmonary artery systolic pressure of ≥ 50 mmHg.

Operative variables included the presence and type of concomitant cardiac procedures, cardiopulmonary bypass time, and aortic cross-clamp time. Post-operative variables included prolonged mechanical ventilation, intensive care unit length of stay, permanent pacemaker implantation, cerebrovascular events, in-hospital mortality, surgical site infection, and post-operative length of hospital stay.

Prolonged mechanical ventilation was defined as mechanical ventilation lasting more than 24 h. In-hospital mortality was defined as death occurring during the index hospitalization, whereas late mortality was defined as death occurring after hospital discharge. Post-operative length of hospital stay was evaluated only among patients discharged alive.

Follow-up events included infective endocarditis, acute or progressive aortic regurgitation, the requirement for repeat aortic valve surgery, and late mortality. Infective endocarditis was identified according to the clinical, microbiological, and echocardiographic findings documented in the medical records. Aortic valve reoperation requirement was defined as the need for a subsequent surgical intervention involving the reconstructed valve, irrespective of whether the procedure could ultimately be performed. The patient who developed infective endocarditis at 9 months and subsequently presented with acute severe aortic regurgitation was categorized as having an infective endocarditis-related valve complication rather than structural valve deterioration.

Echocardiographic Assessment

Transthoracic echocardiography was performed preoperatively and at the 6-month follow-up examination. The assessed parameters included left ventricular ejection fraction, mean and maximum transvalvular gradients, peak aortic jet velocity, and aortic regurgitation severity.

Aortic regurgitation was graded as none, mild, moderate, or severe based on an integrated echocardiographic assessment. Only patients with available pre-operative and 6-month echocardiographic measurements were included in the paired analyses. The patient who died during the index hospitalization was excluded from the 6-month echocardiographic analysis.

Study Outcomes

The primary outcome was hemodynamic performance at 6 months after aortic valve neocuspidization, assessed according to the mean and maximum transvalvular gradients, peak aortic jet velocity, and aortic regurgitation grade. Secondary outcomes included in-hospital mortality, prolonged mechanical ventilation, intensive care unit length of stay, permanent

pacemaker implantation, post-operative cerebrovascular events, surgical site infection, post-operative length of hospital stay, infective endocarditis during follow-up, the requirement for repeat aortic valve surgery, late mortality, and overall 1-year survival.

Follow-Up

Follow-up information was obtained from outpatient evaluations and institutional hospital records. Transthoracic echocardiography was routinely performed 6 months after surgery. All patients who remained alive completed at least 12 months of clinical follow-up.

Clinical follow-up focused on survival, infective endocarditis, clinically relevant aortic regurgitation, and the requirement for repeat intervention involving the reconstructed aortic valve. One patient developed infective endocarditis 9 months after surgery, resulting in acute severe aortic regurgitation and the requirement for repeat surgery. The patient subsequently died.

Statistical Analysis

The distribution of continuous variables was assessed using the Shapiro–Wilk test and visual inspection of the data. Because of the small sample size and the non-normal distribution of several variables, continuous variables were summarized as medians and interquartile ranges. Categorical variables were reported as frequencies and percentages.

Pre-operative and 6-month echocardiographic measurements were compared using the Wilcoxon signed-rank test for paired observations. Analyses were based on available data, and the number of patients included in each analysis was reported when it differed from the overall cohort. The patient who died during the index hospitalization was not included in the analysis of 6-month echocardiographic findings or post-discharge outcomes.

No multivariable analysis was performed because of the limited sample size and low number of outcome events. All statistical tests were two-sided, and a $p < 0.05$ was considered statistically significant. Statistical analyses were performed using Python version 3.12 (Python Software Foundation, Beaverton, OR, USA) with the SciPy statistical package.

Ethical Considerations

This study was approved by the Koşuyolu Heart Training and Research Hospital Institutional Ethics Committee (Date: 22/09/2026, Decision no: 2026/15/1580). The study was conducted in accordance with the Declaration of Helsinki. Given its retrospective design and the use of de-identified patient data, the ethics committee waived the requirement for individual informed consent.

Results

Patient Characteristics

Thirty-one consecutive patients underwent aortic valve neocuspidization between January 2023 and June 2025. All had se-

Table 1. Baseline demographic and preoperative characteristics

Variable	Overall cohort (n=31)
Age, years	65.0 (58.5–71.0)
Female sex	21 (67.7)
Serum creatinine, mg/dL	0.82 (0.72–1.00)
Diabetes mellitus	11 (35.5)
EuroSCORE II, %	3.96 (2.87–5.63)
Left ventricular ejection fraction, %	60.0 (55.0–60.0)
Severe aortic stenosis	31 (100)
Mean transvalvular gradient, mmHg	50.0 (46.0–58.5)
Maximum transvalvular gradient, mmHg	83.0 (75.0–89.5)
Peak aortic jet velocity, m/s	4.60 (4.40–4.90)
Pulmonary artery systolic pressure $\geq$ 50 mmHg	14 (45.2)
Preoperative aortic regurgitation	
None	10 (32.3)
Mild	11 (35.5)
Moderate	8 (25.8)
Severe	2 (6.5)

Data are presented as median (interquartile range) or n (%). EuroSCORE II: European System for Cardiac Operative Risk Evaluation II.

vere aortic stenosis. Baseline demographic, clinical, and echocardiographic characteristics are presented in Table 1.

Operative Characteristics

Seven patients underwent a concomitant cardiac procedure. The types of additional procedures and operative times are summarized in Table 2.

Early Post-operative and Follow-up Outcomes

One patient died during the index hospitalization following sudden cardiac arrest during permanent pacemaker implantation. Among the 30 patients discharged alive, one developed infective endocarditis 9 months after surgery, with acute severe aortic regurgitation requiring repeat surgery. This patient subsequently died. No other patient required reoperation during follow-up. All remaining survivors completed at least 12 months of clinical follow-up. Overall 1-year survival

Table 2. Operative characteristics

Variable	Overall cohort (n=31)
Concomitant procedure	7 (22.6)
Coronary artery bypass grafting	4 (12.9)
Ventricular septal defect closure	1 (3.2)
Ascending aortic replacement	1 (3.2)
Mitral valve repair	1 (3.2)
Cardiopulmonary bypass time, min	135.0 (127.5–140.0)
Aortic cross-clamp time, min	102.0 (98.0–110.0)

Data are presented as median (interquartile range) or n (%).

Table 3. Early postoperative and follow-up outcomes

Outcome	Value
Prolonged mechanical ventilation >24 h	3 (9.7)
Intensive care unit stay, days	2.0 (2.0–2.0)
Permanent pacemaker implantation	1 (3.2)
Postoperative cerebrovascular event	1 (3.2)
In-hospital mortality	1 (3.2)
Surgical site infection	0 (0)
Postoperative day of discharge ¹	7.0 (7.0–8.0)
Infective endocarditis during follow-up ²	1 (3.3)
Reoperation requirement during follow-up ²	1 (3.3)
Late mortality ²	1 (3.3)
Overall 1-year mortality	2 (6.5)
1-year survival	29 (93.5)

Data are presented as median (interquartile range) or n (%). ¹: Calculated among patients discharged alive (n=30); ²: Calculated among hospital survivors (n=30).

was 93.5%. Other early post-operative and follow-up outcomes are presented in Table 3.

Six-Month Echocardiographic Outcomes

Paired pre-operative and 6-month echocardiographic data were available for 30 patients. The median mean transvalvular gradient decreased from 50.5 to 9.0 mmHg ($p<0.001$). Maximum gradient and peak aortic jet velocity also decreased significantly (both $p<0.001$; Table 4 and Fig. 1a-c).

The distribution of aortic regurgitation grades improved between the pre-operative and 6-month assessments ($p=0.010$).

Table 4. Changes in echocardiographic parameters at 6 months

Echocardiographic parameter	Preoperative (n=30)	6-month follow-up (n=30)	Median change	p
Left ventricular ejection fraction, %	60.0 (56.3–60.0)	60.0 (55.0–60.0)	0.0 (-5.0–0.0)	0.098
Mean transvalvular gradient, mmHg	50.5 (46.0–59.3)	9.0 (8.0–10.0)	-40.5 (-48.8– -36.3)	<0.001
Maximum transvalvular gradient, mmHg	83.0 (75.0–89.8)	18.0 (15.3–20.0)	-63.5 (-72.3– -58.3)	<0.001
Peak aortic jet velocity, m/s	4.60 (4.40–4.95)	1.85 (1.50–2.00)	-2.85 (-3.20– -2.40)	<0.001
Aortic regurgitation grade				0.010
None	10 (33.3)	16 (53.3)	—	—
Mild	11 (36.7)	12 (40.0)	—	—
Moderate	7 (23.3)	2 (6.7)	—	—
Severe	2 (6.7)	0 (0)	—	—

Data are presented as median (interquartile range) or n (%). Comparisons were performed using the Wilcoxon signed-rank test. The analysis included patients with paired preoperative and 6-month echocardiographic data.

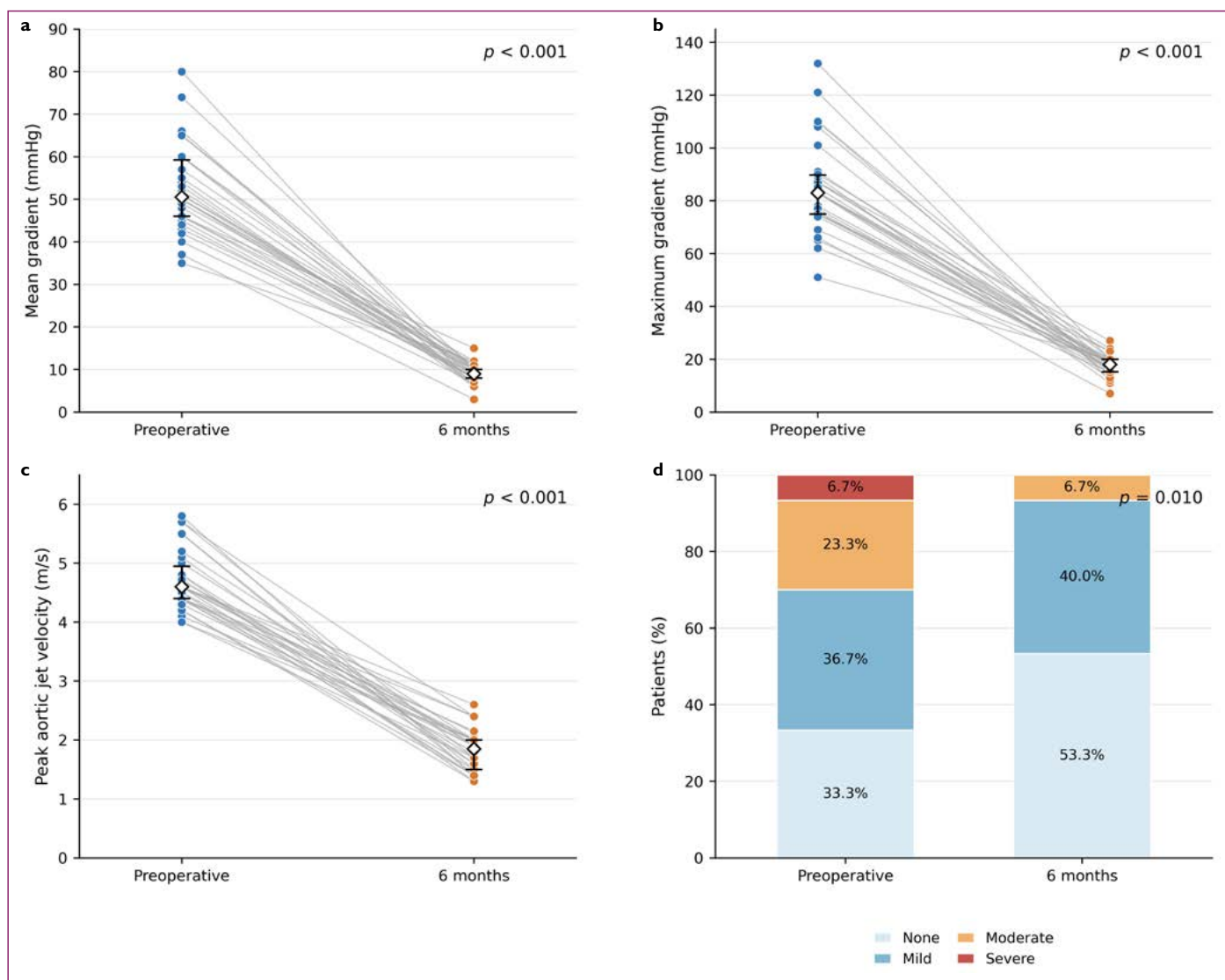


Figure 1. Changes in echocardiographic parameters following aortic valve neocuspidization. Paired comparisons of pre-operative and 6-month (a) mean transvalvular gradient, (b) maximum transvalvular gradient, and (c) peak aortic jet velocity. Connected points represent individual patients; diamonds and error bars indicate medians and interquartile ranges, respectively. Panel (d) shows the distribution of aortic regurgitation grades before surgery and at the 6-month follow-up. Comparisons were performed using the Wilcoxon signed-rank test.

At 6 months, no patient had severe aortic regurgitation (Fig. 1d). Left ventricular ejection fraction did not change significantly ($p=0.098$). Complete paired echocardiographic findings are presented in Table 4.

Discussion

The principal findings of this single-center study were that aortic valve neocuspidization using glutaraldehyde-treated autologous pericardium provided favorable early hemodynamic performance and acceptable short-term clinical outcomes in patients with severe aortic stenosis. At 6 months, substantial reductions were observed in mean and maximum transvalvular gradients and peak aortic jet velocity. Severe aortic regurgitation was not detected at the 6-month examination, and left ventricular systolic function remained preserved. Nevertheless, two deaths occurred within the 1st year, including

one in-hospital death and one valve-related late death caused by infective endocarditis.

The most notable finding was the marked improvement in transvalvular hemodynamics at 6 months. The reductions in mean and maximum gradients and peak aortic jet velocity are consistent with previous reports of low residual gradients after aortic valve neocuspidization.^[3–8] Ozaki et al.^[5] reported sustained low gradients in their large midterm series. Subsequent reports from independent centers also described favorable transvalvular hemodynamics.^[4,6–8]

The favorable hemodynamic profile of neocuspidization may be related to the absence of a rigid prosthetic sewing ring and stent frame. Individually tailored pericardial leaflets use the native annulus as the functional orifice and may preserve annular motion throughout the cardiac cycle. Comparative observational studies have shown larger effective orifice areas following neocuspidiza-

tion than after conventional bioprosthetic valve replacement.^[3,4] However, because the present study did not include a conventional surgical valve replacement group, the observed post-operative gradients should be interpreted as descriptive outcomes rather than evidence of superiority over prosthetic valve replacement.

The distribution of aortic regurgitation also improved at 6 months. More than half of the patients had no detectable regurgitation, 40.0% had mild regurgitation, and only two patients had moderate regurgitation. No patient had severe regurgitation at this time point. Appropriate leaflet sizing, symmetric implantation, and adequate coaptation are central to achieving competent valve function after neocuspidization. The absence of severe regurgitation at 6 months supports the early technical effectiveness of the procedure in this cohort. Nonetheless, residual or progressive regurgitation remains clinically important because leaflet prolapse, commissural malcoaptation, tissue degeneration, and infective endocarditis may result in later valve failure. Longer serial echocardiographic follow-up is therefore necessary before conclusions regarding durability can be made.

Left ventricular ejection fraction remained stable at 6 months. This finding is not unexpected because most patients had preserved systolic function before surgery. The lack of a significant post-operative change should not be interpreted as an absence of ventricular benefit, as improvements in left ventricular mass, diastolic function, or myocardial deformation may occur without a measurable increase in ejection fraction. These parameters were not available in the present dataset and should be considered in future studies evaluating reverse ventricular remodeling after neocuspidization.

Despite the technical complexity of constructing three individualized pericardial leaflets, the observed operative times were acceptable for an initial single-center experience. The median cardiopulmonary bypass and aortic cross-clamp times were 135 and 102 min, respectively. Concomitant procedures were performed in approximately one-quarter of the cohort, including coronary artery bypass grafting, ventricular septal defect closure, ascending aortic replacement, and mitral valve repair. These additional procedures may have contributed to the operative durations. Because of the limited cohort size and the heterogeneity of concomitant procedures, separate comparisons between isolated and combined operations were not considered statistically reliable.

Early post-operative morbidity was relatively limited. Prolonged mechanical ventilation occurred in three patients, while permanent pacemaker implantation and cerebrovascular events each occurred in one patient. The median intensive care unit stay was 2 days, and patients discharged alive left the hospital at a median of 7 post-operative days. No surgical site infections were observed. However, one patient developed sudden cardiac arrest during permanent pacemaker implantation and died despite cardiopulmonary resuscitation, resulting in an in-hospital mortality rate of 3.2%. Given the occurrence of only one early death, its relationship with baseline or operative variables could not be evaluated.

During follow-up, one patient developed infective endocarditis at 9 months, resulting in acute severe aortic regurgitation, the requirement for repeat surgery, and death. This event is partic-

ularly relevant because infective endocarditis has been identified as an important cause of reoperation following aortic valve neocuspidization. In the 850-patient series reported by Ozaki et al.,^[5] most reoperations were related to infective endocarditis rather than structural valve deterioration. Other institutional series have likewise reported endocarditis among the principal causes of valve-related reintervention.^[7,8] The single event in our small cohort corresponds to a numerically notable proportion, but the estimate is imprecise and should not be interpreted as indicating a higher procedure-specific risk. Larger cohorts and longer observation are required to determine the incidence of endocarditis and identify potentially modifiable risk factors.

Overall 1-year survival was 93.5%. Although this finding provides an initial estimate of clinical performance, direct comparison with previously published survival rates is inappropriate because of differences in patient selection, baseline risk, operative indications, concomitant procedures, and follow-up duration. Furthermore, survival in this study was reported as a crude 1-year proportion rather than a time-to-event estimate. The results therefore primarily demonstrate the feasibility and early performance of the technique at our institution rather than comparative effectiveness against conventional surgical or transcatheter valve replacement.

Limitations

This study has several limitations. First, its retrospective, single-center design introduces the possibility of selection bias and limits the generalizability of the findings. Second, the sample size was small, and the low number of adverse events precluded multivariable analysis or meaningful evaluation of outcome predictors. Third, no control group undergoing conventional surgical or transcatheter aortic valve replacement was included; consequently, the study cannot establish comparative safety or efficacy. Fourth, echocardiographic outcomes were evaluated at 6 months, and this duration is insufficient to assess structural valve deterioration or long-term durability. Detailed parameters such as effective orifice area, indexed effective orifice area, left ventricular mass index, and global longitudinal strain were unavailable. Finally, clinical follow-up was limited to a minimum of 1 year, and exact patient-level follow-up durations were not used for time-to-event analysis. Longer prospective follow-up with serial echocardiographic assessment is required to determine the durability of reconstructed leaflets and the long-term incidence of regurgitation, infective endocarditis, and reoperation.

Conclusion

Aortic valve neocuspidization using glutaraldehyde-treated autologous pericardium provided low transvalvular gradients and generally favorable valve competence at 6 months in this single-center cohort. The early clinical results support the feasibility of the procedure, although the occurrence of fatal infective endocarditis highlights the importance of continued clinical and echocardiographic surveillance. Larger comparative studies with longer follow-up are needed to define the long-term role of neocuspidization in the treatment of severe aortic valve disease.

Disclosures

Ethics Committee Approval: The study was approved by the Koşuyolu Heart Training and Research Hospital Institutional Ethics Committee (no: 2026/15/1580, date: 22/09/2026).

Informed Consent: Given its retrospective design and the use of de-identified patient data, the ethics committee waived the requirement for individual informed consent.

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