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## Early and late results of mitral valve repair with anterior leaflet patch augmentation

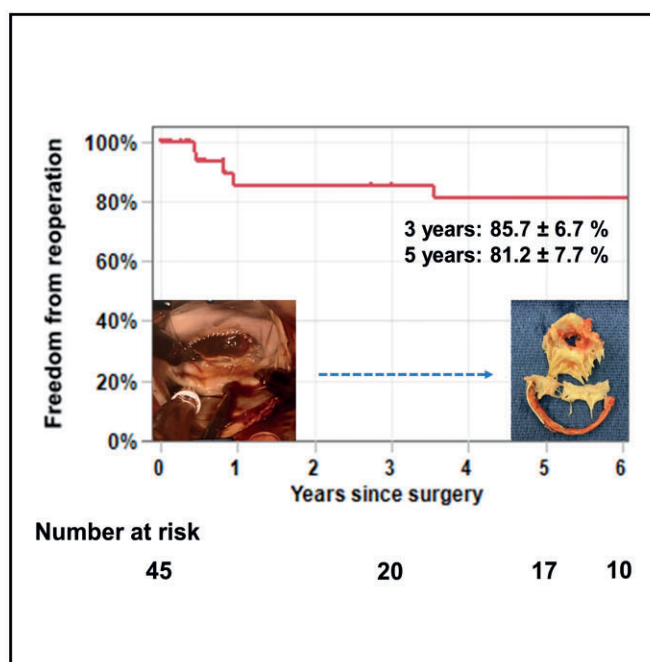
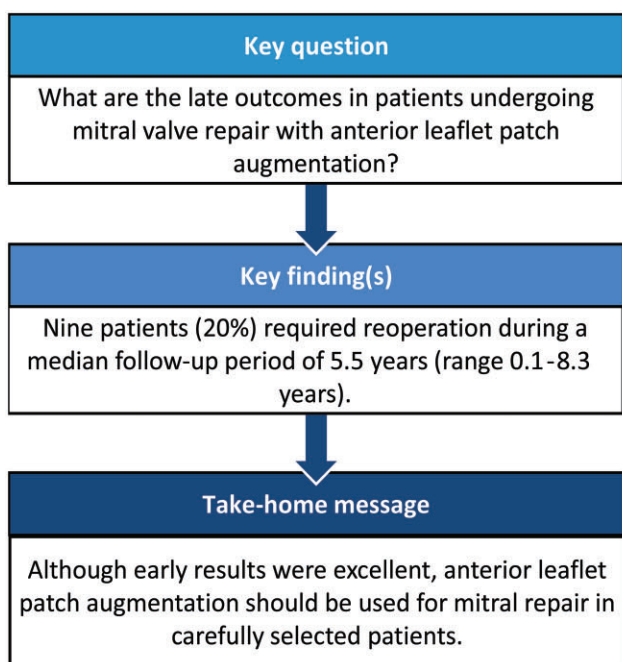
Hiromu Kehara <sup>a</sup>, Kenji Minakata <sup>a,\*</sup>, James McCarthy<sup>a</sup>, Gengo Sunagawa<sup>a</sup>, Chirantan Mangukia <sup>a</sup>,  
Stacey Brann<sup>a</sup>, Huaqing Zhao<sup>b</sup>, Robert Boova<sup>a</sup> and Yoshiya Toyoda<sup>a</sup>

<sup>a</sup> Division of Cardiovascular Surgery, Temple University and Lewis Katz School of Medicine, Philadelphia, PA, USA

<sup>b</sup> Center for Biostatistics and Epidemiology, Department of Biomedical Education and Data Science, Temple University and Lewis Katz School of Medicine, Philadelphia, PA, USA

\* Corresponding author. Present address: Division of Cardiovascular Surgery, Cooper Medical School of Rowan University, Camden, NJ, USA, Tel: +1-856-42-2141; email: minakata-kenji@cooperhealth.edu (K. Minakata)

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### Abstract

**OBJECTIVES:** The aim of this study was to determine the long-term results of mitral valve (MV) repair with anterior leaflet patch augmentation.

**METHODS:** Between 2012 and 2015, 45 patients underwent MV repair using the anterior leaflet patch augmentation technique at our institution. The mean age of the patients was 65.9 ± 13.0 years (16 males). We reviewed the MV pathology and the surgical techniques used and assessed the early and late results.

**RESULTS:** In terms of MV pathology, 43 patients (95.6%) had pure mitral regurgitation (MR) and 2 patients (4.4%) had mixed mitral stenosis and MR. Rheumatic changes were seen in 18 patients (40.0%). Postoperative echocardiography showed that 95.6% of patients had none to mild MR. During a median follow-up period of 5.5 years (range 0.1–8.3 years), there were 8 late deaths. Nine patients (20%)

required reoperation. The mean interval between the initial operation and redo operation was  $3.7 \pm 3.1$  years (range: 0.4–7.8 years). The causes of reoperation included patch dehiscence ( $n = 4$ ), progression of mitral stenosis ( $n = 2$ ), band dehiscence ( $n = 1$ ), patch enlargement ( $n = 1$ ) and unknown ( $n = 1$ ). Eight patients underwent MV replacement and 1 underwent repeat MV repair. The freedom from reoperation at 3 and 5 years was  $85.7 \pm 6.7\%$  and  $81.2 \pm 7.7\%$ , respectively.

**CONCLUSIONS:** Anterior leaflet patch augmentation can provide excellent early results in the majority of the patients even in the presence of rheumatic pathology; however, we observed late reoperation in 20% of patients. Thus, this technique should be used with caution and careful follow-up with serial echocardiography is essential.

**Keywords:** Mitral valve repair • Anterior leaflet patch augmentation • Rheumatic heart disease • Functional mitral regurgitation

#### ABBREVIATIONS

MR	Mitral regurgitation
MS	Mitral stenosis
MV	Mitral valve
STS-PROM	Society of Thoracic Surgeons predicted risk of mortality

## INTRODUCTION

Mitral valve (MV) repair is a common procedure and the rule rather than exception in patients suffering from mitral regurgitation (MR) due to degenerative disease [1], with a repair rate of >90% by experienced centres [2, 3]. It has been demonstrated that valve repair is superior to valve replacement in terms of both early and late outcomes when performed by skilled surgeons on adequately selected patients, and it has the benefits of preserving cardiac function and no need for long-term anticoagulation therapy [4]. In fact, David *et al.* [5] reported that, at 20 years postoperatively, the freedom from severe MR was 90.7% and the probability of reoperation was only 5.9%. Because of these excellent results, the most recent guidelines recommend early surgery even in the patients with asymptomatic MR [6]. However, MV repair can be challenging in patients with other pathophysiologies, such as rheumatic morphology (Carpentier classification type IIIa) and/or restricted leaflet motion (Carpentier classification type IIIb). In these circumstances, it is well known that MV repair is associated with increased risk of surgical failure [7]. To improve the outcomes, several innovative repair techniques have been proposed, including anterior leaflet augmentation. Acceptable short- and mid-term outcomes of this technique have been reported by some authors [8–12], but there have been only a few articles reporting long-term results. The aim of this study was to assess the early and late outcomes in patients who underwent MV repair with the anterior leaflet patch augmentation technique.

## PATIENTS AND METHODS

### Ethics statement

This study was approved by the Temple University Institutional Review Board (Protocol number: 28195, approved on 10 May 2021). Patient consent requirements were waived due to minimal risk of the study.

Between January 2012 and April 2015, 45 patients underwent MV repair using the anterior leaflet patch augmentation technique at our institution. We reviewed the medical charts and the

operative records to identify the patient characteristics, aetiology of valve disease, operative techniques used and surgical results. Late outcomes were determined from clinic records when available or from written correspondence with patients' physicians.

## Indications and surgical techniques

The anterior leaflet patch augmentation technique was created to address decreased coaptation due to shortened leaflets and/or restrictive leaflet motion, particularly in patients with functional and/or restrictive aetiologies such as rheumatic changes. Our surgical technique has been described in detail elsewhere [13]. In short, patients underwent surgery via either a median sternotomy or minimally invasive right thoracotomy approach including the use of robotic technology. After the MV was inspected, the anterior leaflet was measured with an annuloplasty band or ring sizer based on the intertrigonal distance. An incision was made on the anterior leaflet at 3 mm from the annulus extending from one commissure to the other. Using the same ring sizer, the ovoid shape of the patch was created. Four types of patch materials were used: autologous pericardium, Peri-Guard (bovine pericardium, Baxter International, Deerfield, IL, USA), CorMatrix (extracellular matrix made from porcine intestinal submucosa, CorMatrix Cardiovascular, Roswell, GA, USA) and CardioCel (decellularized bovine pericardium, Admedus Regen, Malaga, WA, Australia). Autologous pericardium was fixed with 2% glutaraldehyde solution for 1–2 min. The patch was then sewn in running fashion with either 5–0 monofilament or 4–0 polytetrafluoroethylene sutures. Annuloplasty was added with a prosthetic ring or band. The size selection was based on the original sizing prior to patch augmentation.

## Follow-up

Patients were followed up for 2–6 weeks by the surgeons at an outpatient clinic, and at 3, 6, and 12 months by the referring cardiologists. In terms of oral anticoagulation, all patients were given warfarin for 3–6 months postoperatively with a target prothrombin time international normalized ratio of 2–3, following the same protocol as conventional MV repair. Transthoracic echocardiography was performed annually during follow-up. MV lesions were graded based on the guidelines defined by the American Society of Echocardiography and the European Association of Echocardiography [14, 15]. Of note, it was common to observe elevated pressure gradient across the MV after a repair using anterior leaflet patch augmentation [8]; thus, the grade of mitral stenosis (MS) was carefully evaluated based on a comprehensive assessment considering the condition of the valve and MV area by planimetry.

## Statistical analysis

Categorical variables are shown as counts (percentages). Continuous variables are shown as the mean  $\pm$  standard deviation and/or median (interquartile range). The median follow-up time was calculated by the inverse Kaplan–Meier method. Overall survival, freedom from reoperation, freedom from moderate or more MR or MS, and freedom from composite end point were estimated by the Kaplan–Meier method. The composite end point was defined as death, reoperation, moderate or more MR or MS, and readmission for congestive heart failure. For the competing risk analysis, we also computed the cumulative incidence function for reoperation with death as a competing event. The associations of potential risk factors to composite end point were assessed with the Cox proportional hazards model. All statistical analyses were conducted with JMP Pro 15 software and SAS 9.4 (SAS Institute, Cary, NC, USA).

## RESULTS

### Patient characteristics

The baseline patient characteristics are shown in Table 1. Of the 45 patients studied, 29 (64.4%) were female, and the mean age was  $65.9 \pm 13.0$  years. Twenty patients (44.4%) had history of either paroxysmal or persistent atrial fibrillation. In terms of preoperative functional status, 29 patients (64.4%) were in New York Heart Association functional class III or IV. There were 7 (15.6%) redo cases. Preoperative echocardiographic data are shown in Table 2. The mean left ventricular ejection fraction was  $48 \pm 13\%$ , and there were 10 patients (22.2%) who had depressed ejection fraction of  $\leq 35\%$ . All the patients had moderate-to-severe MR, and 2 patients (4.4%) had mixed MS and MR. The mean Society of Thoracic Surgeons predicted risk of mortality (STS-PROM)

score and the European System for Cardiac Operative Risk Evaluation II score were  $3.58 \pm 3.64\%$  and  $5.37 \pm 4.45\%$ , respectively. There were 6 patients (13.3%) who had high STS-PROM scores of  $\geq 8\%$ . Of note, there were no patients who had active or healed infective endocarditis in this series.

### Intraoperative findings

Intraoperative findings are summarized in Table 3. With regard to MV pathology, 31 patients (68.9%) had organic changes, 11 patients (24.4%) had functional aetiology and 3 patients (6.7%) had mixed pathology. Of note, rheumatic changes were found in 18 patients (40.0%). These rheumatic changes included thickened or calcified leaflet/chordae/papillary muscle(s) and/or fusion of commissure(s). In terms of the patch materials utilized, CardioCel was used in 19 (42.2%) patients, CorMatrix in 17 (37.8%), autologous pericardium in 8 (17.8%) and Peri-Guard in 1 (2.2%). Concomitant annuloplasty was performed in 43 (95.6%) of the patients. Semi-rigid bands were mainly used ( $n=36$ , 80%), followed by flexible bands ( $n=6$ , 13.3%) and a semi-rigid ring ( $n=1$ , 2.3%). The mean size of the ring or band was  $28.4 \pm 2.4$  mm. Excision or division of secondary chordae was carried out in 10 (22.2%) and commissurotomy in 5 (11.1%) patients. Concomitant surgery included left atrial appendage closure ( $n=17$ , 37.8%), atrial fibrillation ablation procedure ( $n=6$ , 13.3%), atrial septal defect or patent foramen ovale closure ( $n=5$ , 11.1%), tricuspid valve repair ( $n=3$ , 6.7%) and coronary artery bypass grafting ( $n=1$ , 2.2%). The mean cardiopulmonary bypass and aortic cross-clamp times were  $130 \pm 29$  and  $88 \pm 14$  min, respectively. No patients required a second aortic cross-clamping for a revision of original repairs.

### Early outcomes

There were 4 (8.9%) 30-day mortalities. Causes of 30-day mortality included low-output syndrome ( $n=1$ ), atrioventricular dissociation ( $n=1$ ), multiple ischaemic stroke ( $n=1$ ) and possible bowel ischaemia ( $n=1$ ). Early morbidity included re-exploration ( $n=4$ ), reintubation ( $n=3$ ) and/or tracheostomy ( $n=2$ ), ischaemic stroke ( $n=2$ ), new haemodialysis ( $n=2$ ) and permanent pacemaker implantation ( $n=1$ ).

Postoperative echocardiography (Table 2) showed that 43 patients (95.6%) had none to mild MR, while 2 patients (4.4%) had residual moderate MR. None had either severe MS or more than moderate MR.

### Late outcomes

During a median follow-up of 5.5 years (0.5–7.1 years), there were 8 late deaths. The causes of death included congestive heart failure ( $n=3$ ), intracranial haemorrhage ( $n=1$ ), cancer ( $n=1$ ), sepsis ( $n=1$ ) and unknown ( $n=2$ ). Overall survival estimates at 3 and 5 years were  $78.7 \pm 6.9\%$  and  $71.4 \pm 8.0\%$ , respectively. No patient developed endocarditis during the follow-up period.

Nine patients (20%) required reoperation (Table 4). The median interval between the initial operation and redo operation was 3.5 years (0.8 ~ 6.4 years). There were 5 patients who had had rheumatic changes. Patch materials implanted at the first operation were CorMatrix ( $n=6$ ), CardioCel ( $n=2$ ) and autologous pericardium ( $n=1$ ). The indications for reoperation were

**Table 1:** Patient characteristics

Variable	<i>n</i> = 45
Age (years), mean $\pm$ SD	65.9 $\pm$ 13.0
Female, <i>n</i> (%)	29 (64.4)
Body surface area (m <sup>2</sup> ), mean $\pm$ SD	1.9 $\pm$ 0.3
Hypertension, <i>n</i> (%)	38 (84.4)
Diabetes mellitus, <i>n</i> (%)	15 (33.3)
Hyperlipidaemia, <i>n</i> (%)	29 (64.4)
Creatinine (mg/dl), mean $\pm$ SD	1.06 $\pm$ 0.39
Haemodialysis	0
Liver cirrhosis, <i>n</i> (%)	2 (4.4)
Coronary artery disease, <i>n</i> (%)	19 (42.2)
Cerebrovascular disease, <i>n</i> (%)	9 (20.0)
Atrial fibrillation, <i>n</i> (%)	20 (44.4)
NYHA functional class, <i>n</i> (%)	
I	0
II	16 (35.5)
III	17 (37.8)
IV	12 (26.7)
Previous cardiac surgery, <i>n</i> (%)	7 (15.6)
STS-PROM score (%), mean $\pm$ SD	3.58 $\pm$ 3.64
>8%, <i>n</i> (%)	6 (13.3)
EuroSCORE II (%), mean $\pm$ SD	5.37 $\pm$ 4.45

EuroSCORE II: European System for Cardiac Operative Risk Evaluation II score; NYHA: New York Heart Association; SD: standard deviation; STS-PROM: Society of Thoracic Surgeons predicted risk of mortality.

**Table 2:** Echocardiographic data

	Preoperative (n = 45)	Early postoperative (n = 45)	Late postoperative (n = 31)
Mean interval (years), mean ± SD			3.3 ± 2.6
LVEDD (mm), mean ± SD	53 ± 15	51 ± 8	49 ± 11
LVESD (mm), mean ± SD	39 ± 14	39 ± 11	38 ± 14
EF (%), mean ± SD	48 ± 13	43 ± 19	44 ± 16
EF ≤ 35%, n (%)	10 (22.2)	12 (26.7)	6 (22.6)
MR grade, n (%)			
None or trivial	0	34 (75.6)	14 (45.2)
Mild	0	9 (20.0)	7 (22.6)
Moderate	6 (13.3)	2 (4.4)	2 (6.5)
Moderately severe	13 (28.9)	0	2 (6.5)
Severe	26 (57.8)	0	6 (19.4)
MS grade, n (%)			
Moderate	2 (4.4)	3 (6.7)	6 (19.4)
Severe	0	0	4 (12.9)

EF: ejection fraction; LVEDD: left ventricular end-diastolic diameter; LVESD: left ventricular end-systolic diameter; MR: mitral regurgitation; MS: mitral stenosis; SD: standard deviation.

**Table 3:** Intraoperative findings

Variable	n = 45
Mitral valve pathology, n (%)	
Organic	31 (68.9)
Rheumatic	18 (40.0)
Functional	11 (24.4)
Mixed	3 (6.7)
Surgical approach, n (%)	
Right thoracotomy approach	43 (95.6)
Median sternotomy	2 (4.4)
Patch material, n (%)	
CardioCel	19 (42.2)
CorMatrix	17 (37.8)
Autologous pericardium	8 (17.8)
Peri-Guard	1 (2.2)
Mitral annuloplasty, n (%)	43 (95.6)
Mean size of ring or band (mm), mean ± SD	28.4 ± 2.4
Semi-rigid band, n (%)	36 (80.0)
Flexible band, n (%)	6 (13.3)
Semi-rigid ring, n (%)	1 (2.3)
Excision or division of chordae, n (%)	10 (22.2)
Commissurotomy, n (%)	5 (11.1)
Concomitant surgery, n (%)	
LAA closure	17 (37.8)
AF ablation	6 (13.3)
ASD or PFO closure	5 (11.1)
TV repair	3 (6.7)
CABG	1 (2.2)
CPB time (min), mean ± SD	130 ± 29
Aortic cross-clamp time (min), mean ± SD	88 ± 14

AF: atrial fibrillation; ASD: atrial septal defect; CABG: coronary artery bypass grafting; CPB: cardiopulmonary bypass; LAA: left atrial appendage; PFO: patent foramen ovale; TV: tricuspid valve; SD: standard deviation.

recurrent severe MR ( $n=7$ ) and severe MS ( $n=2$ ). The causes of recurrent MR included patch dehiscence ( $n=4$ , Fig. 1 and Video 1), band dehiscence ( $n=1$ ), patch enlargement ( $n=1$ ) and unknown ( $n=1$ ). Of note, there was no calcification on the patch materials found in 4 reoperations done within 1 year of

the initial operation. However, patches observed >3 years after the initial operation were found to be significantly calcified. There was no specific site to develop severe calcification on the patch materials. Eight patients underwent MV replacement and 1 underwent repeat MV repair. Of note, there were no operative mortalities related to reoperations. The freedom from reoperation at 3 and 5 years was  $85.7 \pm 6.7\%$  and  $81.2 \pm 7.7\%$ , respectively (Fig. 2). The cumulative incidence function for reoperation with death as a competing event at 3 and 5 years was  $12.0 \pm 5.8\%$  and  $16.0 \pm 6.5\%$ , respectively (Supplementary Material, Fig. S1).

Follow-up echocardiographic data were also obtained in 31 patients (Table 2). The median interval between the initial operation and the most recent transthoracic echocardiography was 2.7 years (0.7–5.4 years). During follow-up, 6 patients (19.4%) developed moderate to severe MR, 6 patients (19.4%) developed moderate to severe MS, and 4 patients (12.9%) developed combined MR and MS. There were 3 patients in this series who developed severe MR and/or MS but have not undergone reoperation yet. One of these patients died of intracranial haemorrhage and the remaining 2 patients were being managed medically at the time of latest follow-up. The freedom from moderate or more MR or MS at 3 and 5 years was  $64.3 \pm 9.4\%$  and  $50.5 \pm 10.2\%$ , respectively (Fig. 3). Freedom from composite end point (death, reoperation, moderate or more MR or MS, and readmission for congestive heart failure) at 3 and 5 years was  $58.5 \pm 8.4\%$  and  $40.8 \pm 8.9\%$ , respectively (Supplementary Material, Fig. S2). On univariate analysis, preoperative and intraoperative variables associated with the composite end point included lower body mass index ( $P=0.014$ ), previous cardiac surgery ( $P=0.019$ ), higher STS-PROM score ( $P=0.001$ ) and longer CPB time ( $P=0.006$ ) (Table 5). A multivariate analysis was not performed because of the small sample size.

## DISCUSSION

The aim of anterior leaflet patch augmentation is to increase coaptation by enlarging the surface area of the leaflet in functional

**Table 4:** Summary of reoperations

	Age (years) <sup>a</sup>	Interval (years)	Aetiology	Rheumatic change	Patch material	Indication	Cause of failure	Patch calcification	Procedure	Concomitant surgery
1	34	0.9	Organic	Yes	CorMatrix	MR	Patch dehiscence	None	Replacement	
2	65	7.8	Organic	No	CorMatrix	MR	Patch dehiscence	N/A	Replacement	CABG, AF ablation LAA closure
3	56	0.5	Functional	No	CorMatrix	MR	Band dehiscence	None	Re-repair	TV repair
4	71	6.4	Organic	Yes	CorMatrix	MR	N/A	N/A	Replacement	
5	78	0.4	Mixed	No	CorMatrix	MR	Patch enlargement	None	Replacement	
6	54	3.5	Organic	Yes	CorMatrix	MS	Progressive rheumatic disease	Calcified	Replacement	TV repair
7	46	6.9	Functional	No	Autologous pericardium	MR	Patch dehiscence	Calcified	Replacement	LAA closure
8	58	6.4	Organic	Yes	CardioCel	MR	Patch dehiscence	Calcified	Replacement	TV repair
9	80	0.8	Organic	Yes	CardioCel	MS	Progressive rheumatic disease	None	Replacement	
Mean ± SD	60.2 ± 15.0	3.7 ± 3.1								

<sup>a</sup>At initial operation.

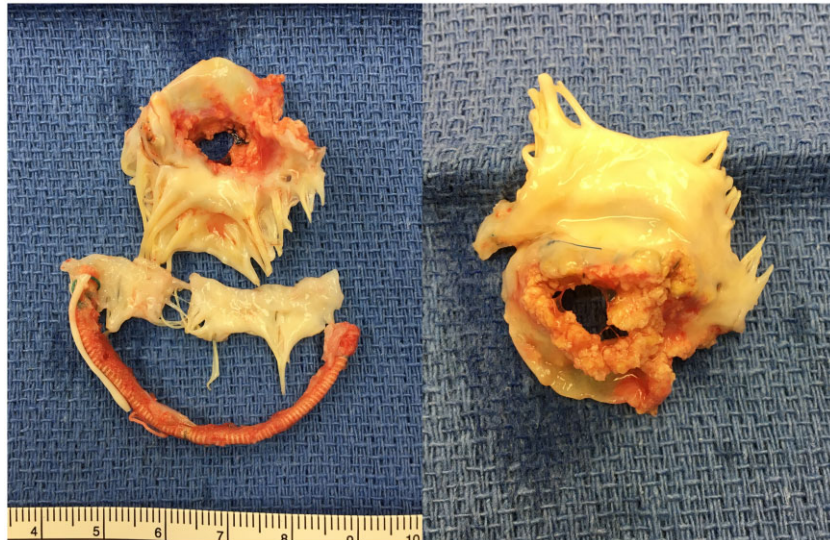
AF: atrial fibrillation; CABG: coronary artery bypass grafting; LAA: left atrium appendage; MR: mitral regurgitation; MS: mitral stenosis; N/A: not available; SD: standard deviation; TV: tricuspid valve.

physiology. This also contributes to mobilization of the leaflet in restrictive physiology. It has been reported that anterior leaflet augmentation can provide excellent early outcomes [8–12]. In the current study, we found that the vast majority of patients (95.6%) had none or only mild residual MR early after operation even in the presence of rheumatic pathology, which is certainly comparable to MV repair in patients with degenerative aetiologies [5].

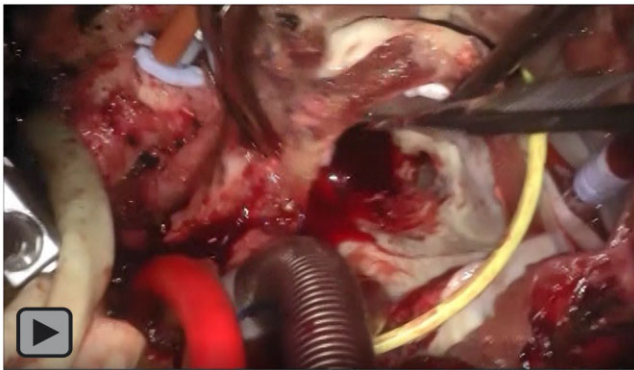
Despite the excellent early outcomes reported, little is known about the late outcomes of this technique. There have been several studies reporting mid-term outcomes. The largest study, by Malhotra *et al.*, reported that there was only a 5.4% reoperation rate among the 80 patients who underwent surgery with this technique, but the mean follow-up was limited to only 2 years [11]. Acar *et al.* reported that only 1 patient required reoperation out of 62 patients (reoperation rate: 2.5%) during 3.2 years of follow-up [8]. Romano *et al.* [9] reported the reoperation rate was 4.8% during a follow-up period of 2.2 years. Contrary to these low reoperation rates, in the current study, we observed late reoperations in 20% of patients during a median follow-up period of 5.5 years postoperatively. Fukunaga *et al.* [16] analysed 144 patients who underwent MV repair using glutaraldehyde-treated autologous pericardium. They reported that a total of 19 reoperations (reoperation rate: 13.2%) were necessary during the follow-up period (mean: 6.9; maximum: 21.1 years). Of note, calcification was recognized on the resected autologous pericardium in 5 cases at the time of reoperation. Although their study did not focus solely on anterior leaflet augmentation, the results were similar to ours in the sense that the patches were found to be calcified late after the operation. Perhaps our late results (reoperation rate of 20% at 5.5 years) may be the worst among the relevant reports. More importantly, follow-up echocardiography demonstrated even worse outcomes in terms of freedom from moderate or more MR or MS (50.5% at 5 years postoperatively). In the other words, almost 50% of the patients undergoing this technique had suffered failure of the repair at 5 years after operation.

We previously reported a high recurrence rate of severe MR for this technique when using CorMatrix (a porcine small intestinal submucosa extracellular matrix) [13]. Preclinical and early clinical studies supported the positive expectation that this extracellular matrix patch might fulfil several criteria for an ideal biological scaffold (strong, pliant and durable) [17]. We discontinued its use based on our own experiences described in our previous report [13]. Similar phenomena of early failure have also been reported by other authors [18, 19]. In the current study, patch failures were also observed in other materials. These patients were found to have progression of patch degeneration causing moderate to severe MS and eventually developed severe MR due to patch dehiscence. We then started to use the CardioCel, which is a decellularized bovine pericardium, as the next extracellular matrix patch. Although better long-term performance was expected [20], others had experienced early failures, including calcification proven by the histopathological analysis [21]. It is well known that glutaraldehyde-fixed autologous or xenograft pericardium may be associated with late calcification and stenosis [22]. No matter which patch is used, calcification and subsequent valve failure will often occur in the long term and this seems to be the critical limitation of this technique.

The optimal MV procedure in patients with rheumatic pathology remains controversial. MV replacement has been the most common surgical treatment worldwide [23]. There is a trend



**Figure 1:** Gross findings of explanted mitral valve apparatus at redo surgery. The patient had undergone anterior leaflet patch augmentation with autologous pericardium 6.9 years prior to the redo surgery. The explanted anterior leaflet was heavily calcified and there was a large perforation due to patch dehiscence. MV: mitral valve.



**Video 1:** A 46-year-old male underwent mitral valve repair with anterior leaflet patch augmentation using an autologous pericardium. Post-repair transoesophageal echocardiography showed only trivial mitral regurgitation. At 6.9 years after the initial operation, the patient required mitral valve replacement. Intraoperative findings included a heavily calcified anterior leaflet with a large perforation due to dehiscence of the patch. MR: mitral regurgitation; MS: mitral stenosis; MV: mitral valve; TEE: transoesophageal echocardiography.

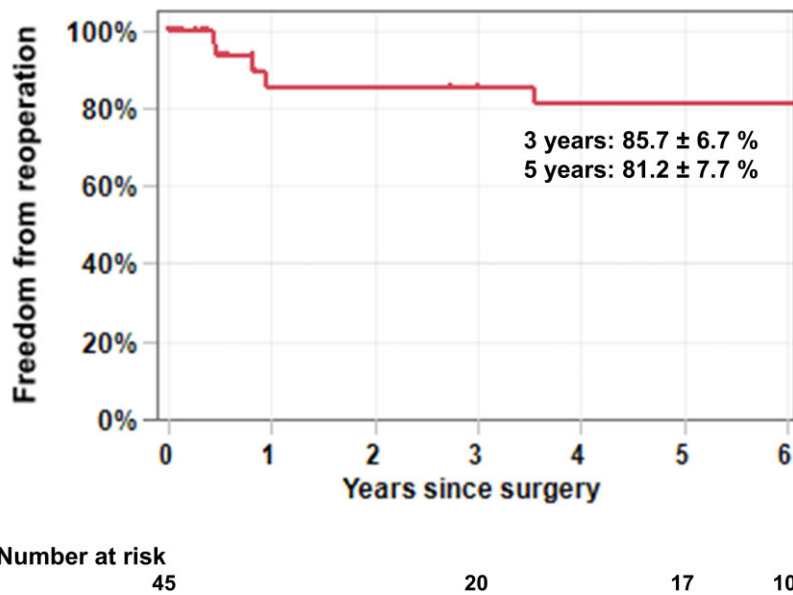
towards recognizing MV repair as a more favourable procedure in carefully selected patients [8, 9, 23, 24]. In addition to leaflet patch augmentation, surgical techniques may include a commissurotomy and various manoeuvres on the subvalvular apparatus including splitting the head of the papillary muscles and dividing fused chordal structures, with subsequent reconstruction using chordal transfer or artificial chordal implantation. Romano *et al.* [9] reported 2 reoperations for recurrent MR in patients with rheumatic pathology who had a heavily calcified subvalvular apparatus. They reported that those who have extended calcified subvalvular apparatus should have been initially considered for MV replacement. In addition to possible failure of the repair itself, we have to keep in mind that those patients with rheumatic aetiology may suffer further rheumatic degeneration of the original valve structure over time. In fact, Kuwaki *et al.* [25] reported

that progression of rheumatic disease in the repaired MV was the reason for reoperation in almost all the patients after open commissurotomy. In this study, 2 patients required reoperation due to progressive rheumatic MS without patch failure. Moreover, the patients with rheumatic pathology tend to be younger, making implanted tissue denegation and calcification even faster than older patients.

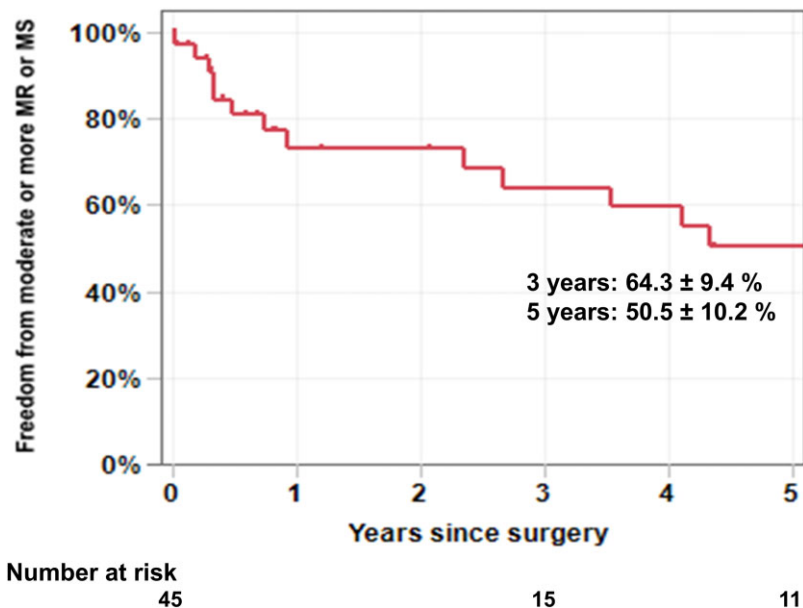
We reported herein our series of anterior leaflet augmentation, while others apply this technique to the posterior leaflet as well [11, 24, 26–28]. Chauvaud *et al.* adapted pericardial patch augmentation mainly in the posterior leaflet (75%) and reported acceptable outcomes of freedom from reoperation at 10 years of 70% [24, 26]. In contrast to the relative better outcomes for posterior leaflet augmentation, anterior leaflet augmentation tends to fail due to the following possible mechanism: the anterior leaflet with patch materials will inevitably develop calcification eventually causing significant malfunction, while posterior patch augmentation may tolerate significant calcification because the calcification can function as a baffle for coaptation with the anterior leaflet. This is similar to the fact that anterior leaflet mobility is more important to MV function than posterior leaflet mobility. Thus, this is not a matter of the type of patch or the mitral pathology, but rather a limitation of this technique itself, augmenting the anterior leaflet with large patch that may eventually fail. Our results clearly suggest that anterior leaflet patch augmentation should be used with caution, and careful follow-up with serial echocardiography is essential.

### Limitations

The present study has several limitations. First, this was a single-centre, retrospective observational study, which confers an inherent selection bias. The sample size was small, and some data were not available. Second, without a control group, comparison of the results was limited to historical outcomes of MV repair



**Figure 2:** Freedom from reoperation after mitral valve repair using anterior leaflet patch augmentation. A total of 9 reoperations were required during the follow-up period. The freedom from reoperation at 3 and 5 years was  $85.7 \pm 6.7\%$  and  $81.2 \pm 7.7\%$ , respectively.



**Figure 3:** Freedom from moderate or more mitral regurgitation or mitral stenosis. Six patients developed moderate to severe mitral regurgitation, 6 patients developed moderate to severe mitral stenosis, and 4 patients developed combined mitral regurgitation and mitral stenosis. The freedom from moderate or more mitral regurgitation or mitral stenosis at 3 and 5 years was  $64.3 \pm 9.4\%$  and  $50.5 \pm 10.2\%$ , respectively. MR: mitral regurgitation; MS: mitral stenosis.

with or without this technique. Thus, our results are best interpreted as support for a cautious approach in using the anterior leaflet patch augmentation technique.

## CONCLUSIONS

MV repair with anterior leaflet patch augmentation can provide excellent early results in the majority of patients even in

the presence of rheumatic pathology. However, we observed late reoperation in 20% of patients during a median follow-up period of 5.5 years postoperatively. In addition, almost half of the patients had developed moderate or more MR or MS at 5 years postoperatively. Regardless of the type of patch used and mitral pathology, patch calcification and subsequent valvular dysfunction often occur late after surgery. Therefore, this technique should be used with caution and careful follow-up with serial echocardiography is essential.

**Table 5:** Factors associated with composite end point

	HR (95% CI)	P-Value
Age (years)	1.03 (0.99–1.07)	0.191
Male	1.83 (0.81–4.12)	0.149
Body mass index (kg/m <sup>2</sup> )	0.09 (0.01–0.62)	0.014
Hypertension	1.33 (0.39–4.56)	0.636
Diabetes mellitus	1.36 (0.59–3.15)	0.479
Coronary artery disease	1.29 (0.55–3.00)	0.561
Atrial fibrillation	0.96 (0.42–2.18)	0.915
NYHA functional class	1.29 (0.78–2.16)	0.316
Previous cardiac surgery	3.55 (1.36–9.26)	0.019
STS-PROM score (%)	1.19 (1.08–1.30)	0.001
EF	0.99 (0.96–1.03)	0.716
MR grade	0.94 (0.58–1.59)	0.801
Rheumatic change	0.70 (0.30–1.62)	0.699
Right thoracotomy approach	1.34 (0.18–10.18)	0.769
Patch material		
Autologous pericardium	Reference	
CorMatrix	0.99 (0.32–2.83)	0.919
CardioCel	1.14 (0.36–3.63)	0.826
Mean size of ring or band (mm)	1.08 (0.89–1.32)	0.417
CPB time (min)	1.02 (1.01–1.04)	0.006
Aortic cross-clamp time (min)	1.01 (0.98–1.05)	0.502

CI: confidence interval; CPB: cardiopulmonary bypass; EF: ejection fraction; HR: hazard ratio; MR: mitral regurgitation; NYHA: New York Heart Association; STS-PROM: Society of Thoracic Surgeons predicted risk of mortality.

## SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

**Conflict of interest:** none declared.

## Data Availability Statement

All the co-authors have full access to the patient data. Also, the data gathered or analysed in this study are available upon reasonable request to the corresponding author.

## Author contributions

**Hiromu Kehara:** Conceptualization; Data curation; Formal analysis; Investigation; Writing—original draft. **Kenji Minakata:** Conceptualization; Methodology; Writing—review & editing. **James McCarthy:** Conceptualization; Data curation. **Gengo Sunagawa:** Methodology; Validation. **Chirantan Mangukia:** Data curation; Validation. **Stacey Brann:** Conceptualization; Data curation; Validation. **Huaqing Zhao:** Data curation; Methodology. **Robert Boova:** Supervision; Validation. **Yoshiya Toyoda:** Supervision; Validation.

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