

Technical aspects of mitral valve repair in Barlow's valve with prolapse of both leaflets: triangular resection for excess tissue, sophisticated chordal replacement, and their combination (the restoration technique)

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Abstract

Background Histological degeneration in Barlow's valve mainly starts in the rough zone, frequently expands toward the chordae, and advances to the clear zone, resulting in a saccular aneurysm-like morphology in the prolapsed region. On this basis, we have repaired the prolapsed segment by triangular resection, chordal replacement and the combination (the restoration technique). The aim of this study was to report our initial findings and evaluate the efficacy of our technique.

Methods Twelve patients diagnosed with Barlow's valve with prolapse of both leaflets (5 women; mean age, 49 years) underwent the restoration technique between January 2008 and March 2013. We retrospectively reviewed short-term clinical outcomes. The mean duration of the clinical follow-up was 2.5 ± 1.7 years.

Results The restoration technique was successfully performed in all patients. Predominant repair techniques were isolated triangular resection (anterior 8, posterior 9), a combination of triangular resection with chordal replacement (anterior 1, posterior 1), and isolated chordal replacement (anterior 3, posterior 1). All patients

underwent complete mitral annuloplasty, and the mean ring size was 31 ± 2 mm. In-hospital mortality was not noted. Late transthoracic echocardiography showed no or trace mitral regurgitation without significant systolic anterior motion in all patients. The New York Heart Association functional class was significantly improved from 1.3 ± 0.5 before surgery to 1.0 ± 0.0 after it ($p < 0.01$). There were no late thromboembolic or bleeding events.

Conclusions Initial experience with the restoration technique has provided excellent results without significant systolic anterior motion. Our technique may contribute to improve late results in Barlow's valve.

Keywords Barlow syndrome · Billowing mitral valve · Mitral valve repair · Triangular resection · Chordal replacement

Introduction

Barlow syndrome is the common name of the systolic click(s) plus a mid-to-late systolic murmur proposed by John B. Barlow [1–4]. Dr. Barlow reported billowing (aneurysmal protrusion) of the posterior leaflet of the mitral valve as the characteristic of the systolic click(s) plus a mid-to-late systolic murmur on left ventriculography [3]. Since then, the presence of billowing has been the basic morphological characteristic of Barlow syndrome [3, 4]. Because of its anatomical characteristics, Barlow syndrome is also termed billowing mitral valve syndrome.

Mitral valve repair in patients with Barlow's valve is particularly challenging because the billowing prolapsed region accompanied by excess tissue extends over several regions [5–16]. As shown in Fig. 1, histological degeneration in Barlow's valve mainly starts in the rough zone,

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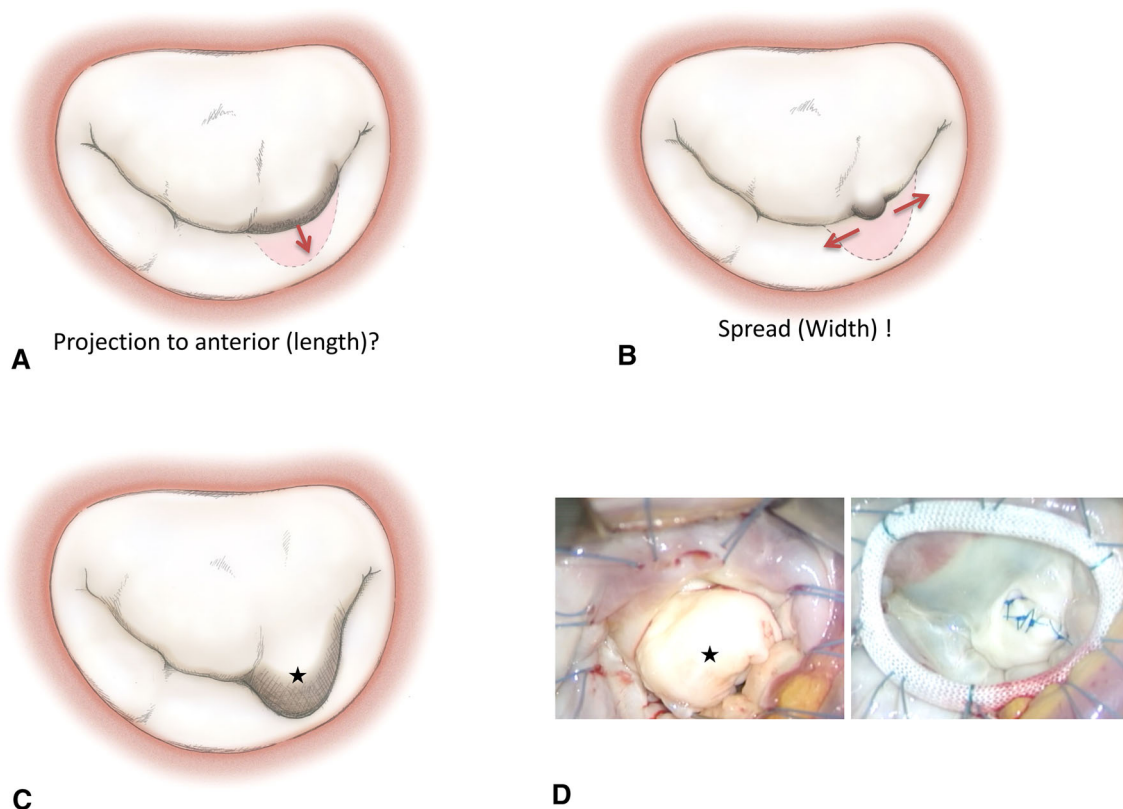


Fig. 1 Barlow syndrome/billowing mitral leaflet. What is the process of billowing? Histological degeneration in Barlow's valve mainly starts in the rough zone, frequently expands toward the chordae, and

advances to the clear zone. The leaflet extends not only in height, but also in width, resulting in a saccular aneurysm-like morphology in the prolapsed region. *Asterisks* indicate aneurysmal protrusions

frequently expands toward the chordae, and advances to the clear zone. The leaflet extends not only in height, but also in width, resulting in a saccular aneurysm-like morphology in the prolapsed region [3, 4, 17]. Repair techniques affect the long-term outcomes of these patients, and the selection of a repair technique is the key to successful surgery [5–16]. We have focused on the finding that the main body of billowing accompanied by excess tissue is present in the rough zone in Barlow's valve, and to increase the durability of mitral valve repair, we have performed triangular resection of the excess tissue, chordal replacement, and their combination, leaving no rough zone on the left atrial side of the coaptation line at saline test following repair. We name this procedure the restoration technique. The aim of the present study was to report our initial results and evaluate the efficacy of our technique.

Patients and methods

We performed mitral valve repair on 153 patients with degenerative Carpentier's type II dysfunction between January 2008 and March 2013. We defined patients with

Table 1 Patient profiles

Number	12 pts
Age, years old	49 ± 18
Female, pts	5 pts (42 %)
BSA, m ²	1.57 ± 0.24
Sinus rhythm	12 pts (100 %)
NYHA functional class	
I	8 pts (67 %)
II	4 pts (33 %)
MR grade, severe	12 pts (100 %)

BSA body surface area, *NYHA* New York Heart Association, *MR* mitral regurgitation, *pts* patients

leaflet prolapse, an advanced myxomatous change with severe billowing with excess tissue, leaflet thickening, and a dilated annulus as having Barlow's valve. It was defined according to clinical, echocardiographic, operative, and pathophysiological findings. Of the 153 patients, thirty-three (21.6 %) were diagnosed with Barlow's valve: anterior ($n = 11$), posterior ($n = 10$), or bi-leaflet ($n = 12$). Twelve patients (7.8 %) were diagnosed with Barlow's valve with severe mitral regurgitation (MR) due to bi-

leaflet prolapse and enrolled in this study. Table 1 shows the preoperative characteristics of these patients. Carpentier's classification was used to describe the various segments of leaflet prolapse. The segmental analysis in the anterior leaflet revealed that 8 patients (66.7 %) had A2 prolapse, 3 (25.0 %) A3 prolapse, and 1 (8.3 %) A2A3 prolapse. In the posterior leaflet, five patients (41.7 %) had P2 prolapse, 4 (33.3 %) P3 prolapse, 1 (8.3 %) P1P2 prolapse, and 2 (16.7 %) P2P3 prolapse. A2 ($n = 9$, 75 %) and P2 ($n = 8$, 66.7 %) were the most commonly involved [16]. One patient had severe systolic anterior motion (SAM) of anterior mitral leaflet before surgery.

Concept of the restoration technique

We used the term restoration technique to clarify the essence required for mitral valve repair. Its main purpose is to adjust the leaflet structure, area, and coaptation morphology and line. It is comprised of triangular resection and reconstruction with artificial chordae, based on the following two concepts: the first concept is adjustment of the coaptation area by resection of the excess region of the leaflet. The second concept is adjustment of the coaptation line by resection of the excess region and/or reconstruction of artificial chordae.

Surgical techniques

Surgery was performed with cardiopulmonary bypass and mild hypothermia (34 °C) after general anesthesia. Repairs were performed through full sternotomy ($n = 6$, 50 %) or a minimally invasive approach ($n = 6$, 50 %). Our minimally invasive approach was via a 6 cm right anterolateral minithoracotomy in the fourth intercostal space under the mild left lateral decubitus position. Arterial inflow was established with direct cannulation of the femoral artery, and venous drainage was obtained with percutaneous cannulation of the superior vena cava through the right internal jugular vein (EMII016AS 16F cannula; Edwards Lifesciences Research Medical Inc., Midvale, Utah) and right femoral vein (Quick Draw QD25 femoral-arteriovenous cannula; Edwards Lifesciences Research Medical Inc.). The ascending aorta was cross-clamped externally using a Chitwood clamp (Chitwood; Scanlan International, St. Paul, Minn.). Vacuum-assisted venous drainage was used in all patients undergoing a minimally invasive approach. Ascending aorta and bicaval cannulation was used in patients undergoing median sternotomy. After cardiac arrest using cold antegrade cardioplegia, the mitral valve was exposed through left atriotomy along the interatrial groove. The restoration technique was performed under a microscope.

Before performing the restoration technique, we evaluated the prolapsed segments, amount of chordal elongation, degree of redundancy, and degree of dilatation of the annulus under a microscope while referring to the findings of preoperative transthoracic and intraoperative trans-esophageal echocardiography. We confirmed the boundary between the rough zone and clear zone of the anterior and posterior mitral leaflets. Figure 2 shows the combination of triangle resection and chordal replacement as the restoration technique. Triangular resection of excess tissue is applied as the 1st step, followed by chordal replacement as the second step. We decide on application of triangular resection based on the grade of excess tissue. When excess tissue is small, chordal replacement is applied without triangular resection, that is, triangular resection is not performed when reduction of the coaptation area by triangular resection is of concern. The resected area was sewn with 5-0 non-absorbable sutures so that the resected surfaces could be anastomosed without tension. After that, cold saline was instilled into the left ventricle to examine the residual prolapse. In the case of residual leaflet prolapse, artificial chordae with 5-0 polytetrafluoroethylene (Gore-Tex; W.L. Gore & Associates, Inc., Flagstaff, Ariz.) were implanted at the resected and sutured site to fold the rough zone into the coaptation zone. Both coaptation area and line is adjusted by triangular resection alone in some cases. Figure 3 shows the presentation of a case.

The repair was completed by annuloplasty ring implantation. A complete semi-rigid artificial remodeling ring including a Carpentier-Edwards (CE) Physio Annuloplasty Ring, CE Physio II Annuloplasty Ring (Edwards Lifescience, Irvine, CA), or Sorin Memo 3D (Sorin Biomedica Cardio S.r.l., Saluggia, Italy) was employed. The ring size was selected on the basis of the intercommissural distance and the surface area of the repaired anterior leaflet. The condition for completion of the restoration technique was the absence of residual mitral regurgitation ≥ 2.0 cm [2] after weaning off cardiopulmonary bypass.

Echocardiography

Serial transthoracic echocardiography examinations were performed in all patients according to the American College of Cardiology/American Heart Association 2006 guidelines [18]. The grade of postoperative mitral regurgitation was classified as none/trace (0–2 cm²), mild (2–4 cm²), moderate (4–8 cm²), and severe (8 cm² <) according to the regurgitant Color Doppler area [19]. Recurrent mitral regurgitation was defined as greater than moderate regurgitation.

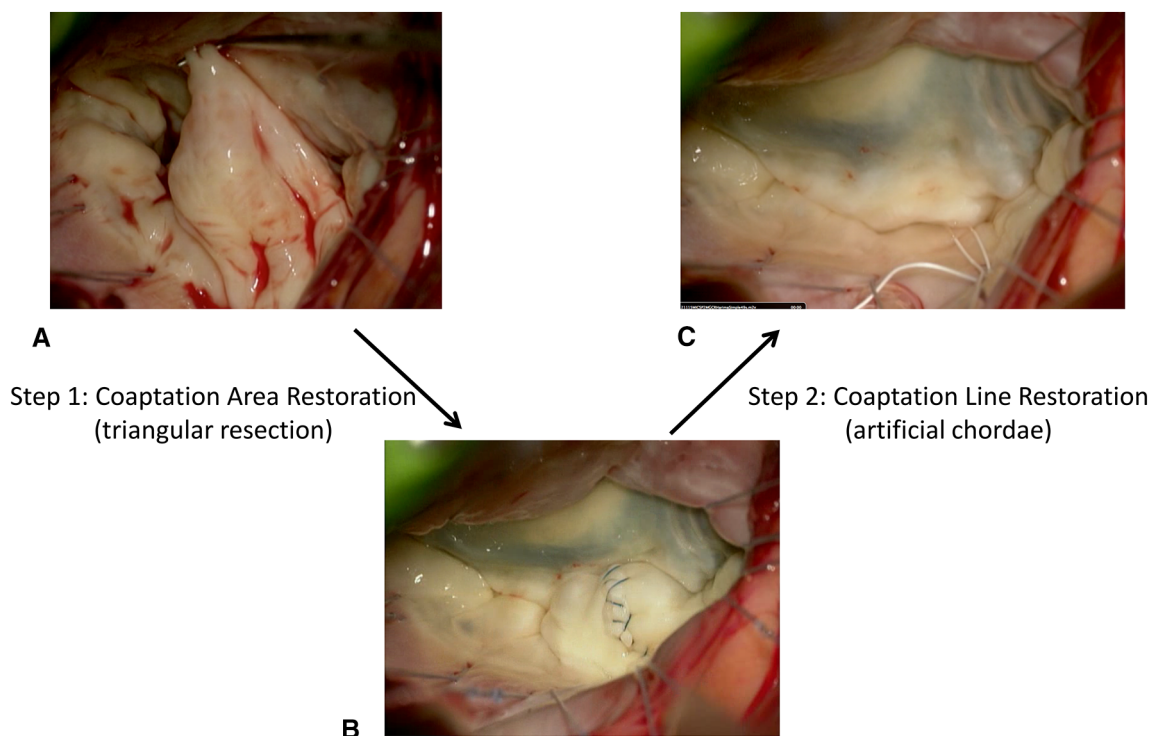


Fig. 2 Repair by combination of triangle resection and chordal replacement as the restoration technique. The concept of the restoration technique is to adjust the leaflet structure, area, and coaptation morphology and line. Its surgical procedures comprise triangular resection of the excess leaflet with prolapse, mainly the

rough zone, sophisticated chordal replacement, and their combination, leaving no rough zone on the left atrial side of the coaptation line at saline test following repair. The first step is to restore the coaptation area, and the second step is to restore the coaptation line

Follow-up

Patients were followed up by the referring cardiologists and our outpatient clinic. Medical follow-up with a physical examination, chest X-ray, electrocardiography, and transthoracic echocardiography was conducted before discharge, and at 1 month, 6 months, and every year thereafter. The final clinical follow-up of this study was on October 23, 2013. The follow-up rate was 100 %. The mean duration of the clinical follow-up was 2.5 ± 1.7 years, and the mean duration of follow-up by transthoracic echocardiography was 2.4 ± 1.6 years. Postoperative event evaluations were strictly defined according to the published guidelines of the American Association for Thoracic Surgery, European Association for Thoracic Surgery, and Society of Thoracic Surgeons [20]. Warfarin treatment was discontinued for 3 months after surgery in patients without atrial fibrillation.

Statistical analysis

Continuous data are reported as the mean \pm standard deviation and categorical variables as percentages. The paired *t* test was used to compare data before and after surgery. *P* values less than 0.05 were considered

significant. Stat-View (Version 5.0) was used for all statistical analyses (Abacus Concepts, Berkeley, CA, USA).

Results

The restoration technique was successfully completed in all patients without significant systolic anterior motion. Table 2 shows the operative procedures. The mean ring size was 31 ± 2 mm: 34 mm in one patient, 32 mm in 7, 30 mm in 3, and 26 mm in one. Concomitant procedures included cryo-pulmonary vein isolation for paroxysmal atrial fibrillation ($n = 2$) and closure of the atrial septal defect ($n = 2$). The mean cardiopulmonary bypass and mean cross-clamp times were 180 ± 66 and 105 ± 30 min, respectively. No 30-day or in-hospital mortality was noted. Postoperative complications included paroxysmal atrial fibrillation in three patients, acute pericarditis in one, and permanent pacemaker implantation for complete atrio-ventricular block in one. Pre-discharge and late transthoracic echocardiography showed no or trace mitral regurgitation in all patients. Table 3 shows follow-up echocardiography data. The left ventricular end-diastolic and left atrial diameters were significantly decreased. The New York Heart Association functional class was

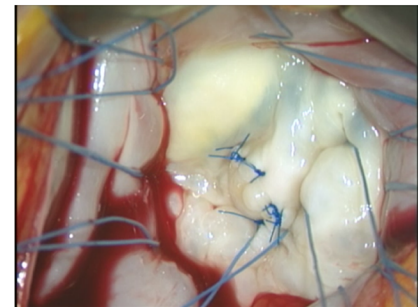
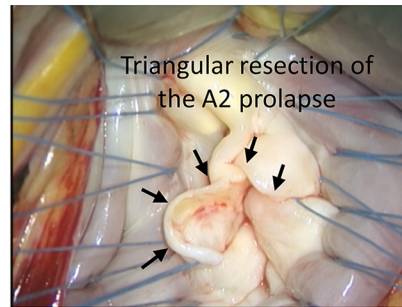
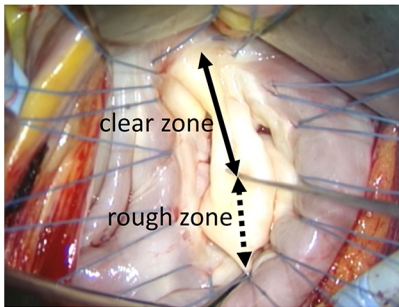
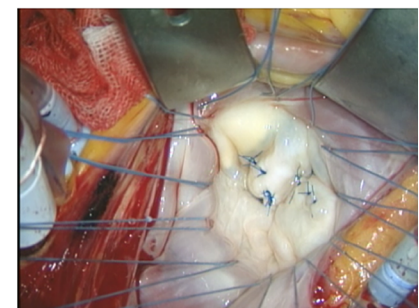
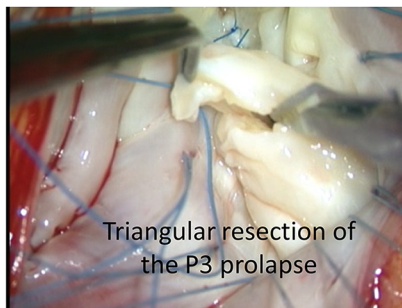
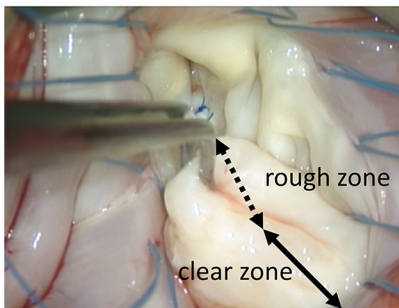
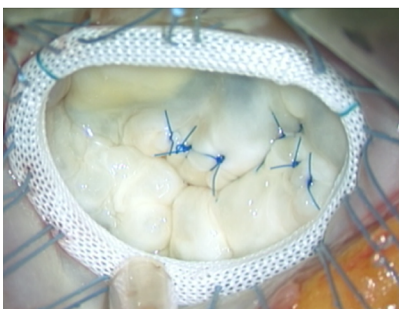
A Anterior leaflet**B Posterior leaflet****C Annuloplasty**

Fig. 3 Repair by triangle resection alone as the restoration technique (Case 1). Triangular resection adjusts not only the coaptation area but also the coaptation line in some cases. The patient was a 75-year-old female. Segmental analysis revealed A2 and P3 prolapse. After confirming the boundary between the rough zone and the clear zone in

significantly improved from 1.3 ± 0.5 before surgery to 1.0 ± 0.0 after it ($p < 0.01$). No patients had major bleeding or thromboembolic events in the follow-up period.

Discussion

Histological degeneration in Barlow's valve and significance of triangular resection and chordal replacement

Histological degeneration in Barlow's valve mainly starts in the rough zone, frequently expands toward the chordae,

the bi-leaflet prolapsed segments, triangular resection was performed for the bi-leaflet prolapse. A residual prolapse was not detected after resection and sutures. The repair was completed by implantation of a Physio II Annuloplasty Ring 30 mm in size. *Arrows* in the anterior leaflet show the triangular resected area

and advances to the clear zone. As shown in Figs. 1, 2 and 3, the leaflet extends not only in height, but also in width, resulting in a saccular aneurysm-like morphology in the prolapsed region. Resection of the excess tissue is, therefore, required to obtain a good coaptation line and prevent SAM in Barlow's valve. Carpentier et al. [21] noted in their textbook that the goal of the resection is to reduce tension on the remaining leaflet tissue and chordae, thus altering the process of further leaflet billowing and chordal elongation and, therefore, minimizing the risk of recurrent regurgitation. On the basis of the above anatomical findings, we have performed triangular resection of the excess tissue. We consider that the advantage of triangular resection may be the possibility of preventing the future

Table 2 Operative procedures

	Anterior	Posterior
Triangular resection, isolated	8 pts (66.7 %)	9 pts (75.0 %)
CR, isolated	3 pts (25.0 %)	1 pt (8.3 %)
Triangular resection + CR	1 pt (8.3 %) ^a	1 pt (8.3 %)

Three patients with prolapse around the postero-lateral commissure underwent edge-to-edge fixation

CR chordal replacement

^a This patient underwent chordal transfer besides triangular resection and chordal replacement

Table 3 Comparison of transthoracic echocardiography before and after surgery

	Pre-operation	Post-operation	<i>p</i> value
LVDd, mm	53 ± 8	45 ± 7	<0.01
LVDs, mm	30 ± 6	30 ± 5	NS
LVEF, %	74 ± 7	65 ± 8	<0.05
LAD, mm	40 ± 7	33 ± 6	<0.01
Trans-tricuspid peak PG, mmHg	24 ± 11	23 ± 8	NS
Trans-mitral mean PG, mmHg	NA	3.0 ± 0.8	NA

LVDd left ventricular end-diastolic diameter, LVDs left ventricular end-systolic diameter, LVEF left ventricular ejection fraction, PG pressure gradient, NS not significant, NA not available

advancement of myxomatous degeneration by removing myxomatous tissue as extensively as possible. As described above, leaflet prolapse in Barlow's valve frequently forms a saccular aneurysm-like morphology. Even though the leaflet prolapse appears to be extensive on preoperative echocardiography, the wide retention of normal leaflet tissue is unexpectedly observed during surgery; that is, coaptation tissue is not widely prolapsed, and limited coaptation tissue develops billowing and forms a saccular

aneurysm-like lesion. Accordingly, prolapse can be simply corrected by resection of this saccular aneurysm-like prolapse in some cases (Fig. 3). In our study, totals of 67 and 75 % of anterior and posterior leaflet prolapse cases, respectively, could be repaired by isolated triangular resection. When prolapse remained after triangular resection, it could be repaired by deepening the coaptation line using artificial chordae (Figs. 2c, 4c). Mitral regurgitation appears to be controlled in Barlow's valve even following chordal replacement with long artificial chordae because the rough zone is wide. Unlike a fibro-elastic deficiency, it is necessary to pull back the prolapsed leaflet to a site close to the papillary muscles in Barlow's valve, especially in patients with posterior leaflet prolapse (Fig. 4) [8]. A sufficient length of coaptation zone should be set for Barlow's valve compared with that for fibro-elastic deficiency. This is a very important point to avoid recurrent mitral regurgitation.

Ring selection and prevention of SAM

Kunzelman et al. [22] showed that a dilated mitral valve annulus increases stress on the leaflet and chordae. In addition, it may lead to tissue disruption, further dilatation, delayed coaptation, and increased regurgitation. On this basis, we considered remodeling annuloplasty with an artificial ring to be desirable for a dilated mitral valve annulus in Barlow's valve. In the present study, we used a 34 mm or smaller ring, which resulted in no SAM accompanied by mitral regurgitation. We consider that a reduction of the anterior leaflet area by triangular resection and pulling back of the posterior leaflet by artificial chordae close to the papillary muscle contributed to the prevention of SAM [8, 9, 23]. Adams et al. [16] also reported that the incidence of SAM could be suppressed to 1.5 % by the use of a 36 mm or larger ring, and the MR recurrence-free rate was 100 %. They recommended the use of a

Fig. 4 Sophisticated chordal replacement. Mitral regurgitation appears to be controlled in Barlow's valve even following chordal replacement with long chordae because the rough zone is wide (b). Artificial chordae should be pulled downward more than other normal chordae to adjust the coaptation line level (c). Unlike a fibro-elastic deficiency, it is necessary to pull back the prolapsed leaflet to a site close to the papillary muscles in Barlow's valve

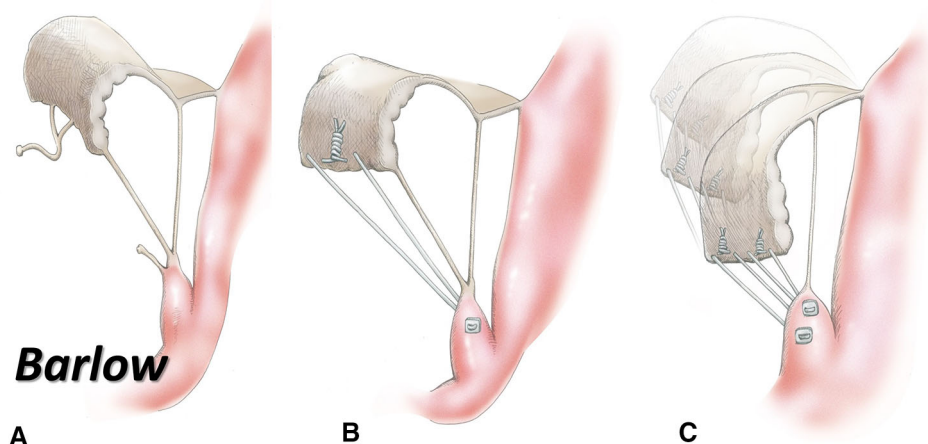


Table 4 Mitral valve repair in Barlow's valve

Authors	N	Prolapsed leaflets	FU, mean	Leaflet	Ring size	Freedom from recurrent MR
1 Jouan et al. [5] French correction	179	AL: A1 17 % A2 55.5 % A3 37.5 % PL: P1 28 % P2 88.5 % P3 40 %	77.5 months	AL: CT25.3 % CR 4.4 % resection 3.8 % PL: sliding 69.8 % resection 29.7 % CT 7.7 % PM: shortening 25.3 % sliding 10.4 %	34 mm 30 % 36 mm 46 % 38 mm 13 % 40 mm 11 %	90.2 %/8 years
2 Flameng et al. [6] Carpentier's techniques and CR	83	AL 2 % PL 17 % BL 81 %	5.9 years	AL: CT or CR without resection PL: segmental resection	<34 mm 39 % 34 mm ≤ 61 %	Overall: 6.0 %/years Without surgical risk 2.9 %/years (linearized rate)
3 Newcomb et al. [7]	183	AL 69 % PL 100 %	5.9 years	CR93 % Excess tissue in the central portion of P2 was resected as needed.	36 mm ≤ 60 %	80 %/10 years
4 Borger et al. [8, 9] Loop technique	137	BL	5.4 years	AL: loop 66 % resection 7 % PL: loop 64 % resection 28 % Edge-to-edge technique 17 % Commissural plication 9 % CT 9 %	35.7 ± 2.8 mm	90.2 %/5 years 88.4 %/10 years
5 Fucci et al. [10] Edge-to-edge	25	BL	38 months	The modified edge-to-edge technique (A triple orifice valve repair)	32 mm 9 % 34 mm 22 % 36 mm 65 % 38 mm 4 % NA	100 %
6 Mehmet et al. [11] Edge-to-edge	41	BL	35 months	A central edge-to-edge repair	NA	90.6 %/5 years
7 Fasol et al. [12]	37	BL	22.7 months	AL: a triangular resection PL: the complete resection of the middle scallop of the posterior leaflet, a sliding and folding plasty with the remaining lateral scallops Edge-to-edge	NA	100 %
8 Lapenna et al. [13] Edge-to-edge	48	BL	22.7 months	Edge-to-edge	32 mm 2 % 34 mm 20 % 36 mm 28 % 38 mm 33 % 40 mm 17 %	100 %

Table 4 continued

Authors	N	Prolapsed leaflets	FU, mean	Leaflet	Ring size	Freedom from recurrent MR (recurrence rate)
Lawrie et al. [14] American correction	61	AL 8.2 % PL 52.5 % BL 11.5 % Neither 27.9 %	1.2 years	CR 68.8 %	33.4 ± 1.9 mm	4.2 %
Speziale et al. [15]	70	BL	12.4 months	CR	NA	98 %
Adams et al. [16] Carpentier's techniques	67	AL 3 % PL 61 % BL 36 %	NA	AL: CT 37 % resection 24 % PL: resection 97 % sliding 84 %	36 mm 35 % 38 mm 33 % 40 mm 42 %	100 %

AL anterior leaflet, PL posterior leaflet, BL both leaflets, NA not available, CT chordal transposition, CR chordal replacement, PM papillary muscle, N number, FU follow-up, MR mitral regurgitation

36 mm or larger ring for Barlow's valve to prevent SAM. Since Barlow's valve is characterized by an excess leaflet, an artificial ring with a large size is necessary to avoid SAM. Their report was appropriate, but it is unclear whether a 36 mm or larger ring can be uniformly used for Japanese with a smaller physique than Westerners. We consider that the ring size should be decided in consideration of the sizes of the leaflet in which prolapse was repaired and the annulus. A ring with a size not forming an excess region of the leaflet in the placed ring should be selected.

Various repair techniques for bi-leaflet prolapse, and the outcomes of mitral valve repair for Barlow's valve

Various methods to repair leaflet prolapse have been reported, such as resection and sutures [5, 21, 24], chordal shortening [24], chordal transfer [21, 24], chordal replacement [7–9, 25, 26], edge-to-edge [13], flip over [27], and so forth. Chordal shortening used in French correction is no longer employed because of a problem with durability [28]. Chordal replacement with expanded polytetrafluoroethylene reported by Vetter et al. in 1986 is capable of repairing complex lesions, such as bi-leaflet prolapse and widely extended anterior leaflet prolapse, simply and with reproducibility [7–9, 26]. There is no doubt that chordal replacement contributes to improvement of the long-term outcome of mitral valve repair, and it is an essential plastic surgical procedure together with resection and sutures [6].

Eleven reports on the outcomes of mitral valve repair applied to treat Barlow's valve are summarized in Table 4, and numbered 1–11 in the order of increasing mean duration of follow-up. The longest follow-up was 77.5 months in the study reported by Carpentier's group [5]. They investigated the long-term outcomes of French correction, and the rate of freedom from recurrence of moderate or severe MR at 8 years after surgery was 90.2 % [5]. Flameng and Adams also reported the outcomes of Carpentier's techniques [6, 16]. Flameng et al. reported that the annual rate of moderate or severe MR recurrence (linearized rate) was 6.0 %. They stated that the way to reduce the recurrence rate of MR is to use optimal surgical techniques, and the key points are no use of chordal shortening and the use of an artificial chorda and an artificial ring [6]. They reported that the annual recurrence rate of MR after mitral valve repair for Barlow's valve could be suppressed to 2.9 % by employing the ideal procedure. Although the duration of follow-up is unclear, Borger et al. reported the outcomes of mitral valve repair for Barlow's valve with prolapse of both leaflets applied through the minimally invasive approach, in which the rates of freedom from recurrent MR $\geq 2+$ at 5 and 10 years after surgery were

90.2 and 88.4 %, respectively [9]. They stated that the use of various procedures including loop technique achieved favorable durability of mitral valve repair for Barlow's valve through the minimally invasive approach. In the three reports on mitral valve repair employing the edge-to-edge technique, about 2–3 year (22.7–38 months) short-term outcomes were presented [10, 11, 13]. Lapenna et al. [13] reported that no moderate or severe MR recurred after surgery in any patient, but mild MR was observed in 31 % on echocardiography at 2 years after surgery. The edge-to-edge technique may be useful for pericommissural prolapse in Barlow's valve, but it may be necessary to wait for additional reports to be published with regard to the long-term effects on extensive anterior and posterior leaflet prolapse. Lawrie et al. [14] reported the outcomes of a non-resectional approach using an artificial chorda, namely, American correction. The mean duration of follow-up was also short, 1.2 years. The recurrence rate of MR was 4.2 % in their report, but leaflet was not repaired in 28 %, for which a report on MR control after a long interval is awaited. David's group reported the outcomes of mitral valve repair using artificial chordae [7], in which the rate of freedom from recurrence of moderate or severe MR at 10 years after surgery was 80 %. They reported that late recurrent regurgitation is common, despite correction of dilated and displaced mitral annulus and leaflet prolapse in Barlow's valve. The main cause of recurrent MR was the progression of degeneration.

Our study showed that the procedure-related recurrence of mitral regurgitation can be avoided by the restoration technique. We consider that it is reasonable to resect excess tissue to respect normal mitral valve structure. The continuation of follow-up is essential to evaluate the durability of our technique because Barlow's valve is a degenerative disease [6].

Conclusions

Initial experience with the restoration technique has provided excellent results without significant systolic anterior motion. The restoration technique may contribute to improvement of late results in Barlow's valve.

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Conflict of interest All the authors have declared no competing interest.

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