ORIGINAL RESEARCH

MitraClip After Failed Surgical Mitral Valve Repair—An International Multicenter Study

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BACKGROUND: Recurrence of mitral regurgitation (MR) after surgical mitral valve repair (SMVR) varies and may require reoperation. Redo mitral valve surgery can be technically challenging and is associated with increased risk of mortality and morbidity. We aimed to assess the feasibility and safety of MitraClip as a treatment strategy after failed SMVR and identify procedure modifications to overcome technical challenges.

METHODS AND RESULTS: This international multicenter observational retrospective study collected information for all patients from 16 high-volume hospitals who were treated with MitraClip after failed SMVR from October 29, 2009, until August 1, 2017. Data were anonymously collected. Technical and device success were recorded per modified Mitral Valve Academic Research Consortium criteria. Overall, 104 consecutive patients were included. Median Society of Thoracic Surgeons score was 4.5% and median age was 73 years. At baseline, the majority of patients (82%) were in New York Heart Association class ≥III and MR was moderate or higher in 86% of patients. The cause of MR pre-SMVR was degenerative in 50%, functional in 35%, mixed in 8%, and missing/unknown in 8% of patients. The median time between SMVR and MitraClip was 5.3 (1.9–9.7) years. Technical and device success were 90% and 89%, respectively. Additional/modified imaging was applied in 21% of cases. An MR reduction of ≥1 grade was achieved in 94% of patients and residual MR was moderate or less in 90% of patients. In-hospital all-cause mortality was 2%, and 86% of patients were in New York Heart Association class ≤II.

CONCLUSIONS: MitraClip is a safe and less invasive treatment option for patients with recurrent MR after failed SMVR. Additional/modified imaging may help overcome technical challenges during leaflet grasping.

Key Words: MitraClip ■ recurrent mitral regurgitation ■ surgical mitral valve repair

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Mitral valve surgery is the treatment of choice for symptomatic patients with severe degenerative mitral regurgitation (MR) and left ventricular (LV) ejection fraction >30%.1,2 In functional MR, surgery is indicated in patients with severe MR undergoing coronary artery bypass grafting and LV ejection fraction >30%.2 Recurrence of MR after surgical repair varies and may require reoperation.3–5 Compared with primary mitral surgery, redo mitral valve surgery can be technically challenging and is associated with a higher operative mortality, higher complication rate, and increased length of stay.6 Alternatively, transcatheter mitral valve replacement and percutaneous mitral valve edge-to-edge repair...
with MitraClip can be performed in selected patients after failed surgical mitral valve repair (SMVR). The aim of this study was to assess the feasibility and safety of MitraClip after failed SMVR and identify procedure modifications to overcome technical challenges related to the prior mitral surgery.

**METHODS**

The data that support the findings of this study are available from the corresponding author upon reasonable request.

This international multicenter observational retrospective study collected information from all consecutive patients, from 16 high-volume hospitals, who were treated with MitraClip after failed SMVR from October 29, 2009, until August 1, 2017. Selection of patients and assessment of eligibility was left at the discretion of the local multidisciplinary heart teams, which included interventional cardiologists, imaging specialists, and cardiac surgeons. Data were anonymously collected.

The medical ethics committee of the Erasmus Medical Center reviewed the study protocol and waived the need for additional informed consent because of the noninterventional design of this retrospective study (MEC-2017-1021) using anonymous data collection. The investigation conforms to the principles outlined in the Declaration of Helsinki.

**Study End Points and Definitions**

The primary end points were procedural safety expressed as “technical success” and procedural efficacy expressed as “device success,” both were modified from Mitral Valve Academic Research Consortium (MVARC) criteria.

1. Technical success is defined as successful deployment of the device with absence of procedural mortality and freedom from emergency surgery.
2. Device success is defined as proper placement of the device without procedural mortality and with reduction in postprocedural MR by ≥1 grade from baseline and to an absolute level of moderate or higher MR.
3. Significant MR reduction is defined as reduction in postprocedural MR by ≥1 grade from baseline.
4. Device time is defined as the time from guide catheter insertion to guide catheter removal.

**Statistical Analysis**

Categorical variables are presented as frequencies and percentages and compared using Pearson chi-square test or Fisher exact test, as appropriate. Continuous variables are presented as means (±SD) (in case of normal distribution) or medians (interquartile range) (in case of skewed distribution) and compared with using Student t test or Mann Whitney U test. Normality of the distributions was assessed using the Shapiro-Wilk test. A 2-sided α level of 0.05 was used to indicate significance. Statistical analyses were performed using SPSS software version 21.0 (IBM).

**RESULTS**

**Baseline Characteristics**

Overall, 104 consecutive patients were included with a median age of 73 years, 70% were men, 82% were in New York Heart Association class ≥III, and the median Society of Thoracic Surgeons (STS) score was 4.5% (Table 1). The median LV ejection fraction was 50% (30%–60%), mean LV end-diastolic diameter was 60±11 mm, and transmitral gradient was 3.0 mm Hg.
MitraClip After Failed SMVR

The cause of MR pre-SMVR was degenerative in 50%, functional in 35%, mixed in 8%, and missing/unknown in 8%, and further specified in Table 2. The median time between surgery and MitraClip was 5.3 years (Table 2).

Procedural Characteristics

MitraClip implantation was feasible in 92% of patients. In the unfeasible cases (8%), reasons for not clipping were development of inacceptable mitral valve gradients in 5 cases, persistent MR in combination with inacceptable mitral valve gradient in 1 case, and inability to grasp both leaflets because of a severely tethered and short posterior leaflet in combination with poor image quality in 2 cases. Seven of

Table 1. Baseline Characteristics

| Total Population (N=104) |  |
|-------------------------|--|
| Age, median (IQR), y     | 73.0 (67.0–80.0) |
| Men, n (%)               | 73 (70) |
| Height, mean±SD, cm      | 171±10 |
| Weight, median (IQR), kg | 75.0 (65.0–85.0) |
| BMI, median (IQR), kg/m² | 24.9 (22.7–28.0) |
| NYHA class ≥III, n (%)   | 85 (82) |
| STS score, median (IQR), %| 4.5 (2.2–6.6) |

Cardiomyopathy, n (%)

| Ischemic                  | 32 (36) |
| Nonischemic              | 12 (13) |
| Hypertrophic             | 1 (1)   |

Implantable device, n (%)

| Permanent pacemaker       | 9 (9)   |
| ICD                       | 16 (15) |
| CRT                       | 11 (11) |

Atrial fibrillation, n (%)

| Paroxysmal                | 30 (29) |
| Permanent                 | 30 (29) |
| Previous myocardial infarction | 27 (27) |
| Previous coronary artery bypass graft surgery | 38 (37) |
| Previous percutaneous coronary intervention | 20 (19) |
| Previous cerebrovascular event | 7 (7)   |
| Diabetes mellitus         | 24 (23) |
| Hypertension              | 82 (79) |
| Peripheral vascular disease | 13 (13) |
| Pulmonary hypertension    | 65 (63) |
| Chronic obstructive pulmonary disease | 20 (19) |

Laboratory results

| GFR, mean±SD, mL/min      | 56±21 |
| Hemoglobin, median (IQR), mmol/L | 6.6 (7.9–8.6) |

Echocardiography

| LV ejection fraction, median (IQR), % | 50 (30–60) |
| LV end-diastolic diameter, mean±SD, mm | 60±11 |
| LV end-systolic diameter, mean±SD, mm | 45±13 |
| Mean transmural gradient, median (IQR), mm Hg | 3.0 (2.2–4.0) |

Severity mitral regurgitation

| Mild-moderate, n (%) | 3 (3) |
| Moderate, n (%)      | 12 (12) |
| Moderate-severe, n (%) | 37 (36) |
| Severe, n (%)        | 52 (50) |

BMI indicates body mass index; CRT, cardiac resynchronization therapy; GFR, glomerular filtration rate; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; LV, left ventricular; NYHA, New York Heart Association; and STS, Society of Thoracic Surgeons.

Table 2. Mitral Valve Regurgitation Cause, Treatment, and Mode of Failure

| Total Population (N=104) |  |
|-------------------------|--|
| Cause MR before surgical repair |  |
| Degenerative MR, n (%) | 52 (50) |
| Prolapse, n (%)         | 32 (32) |
| Chordal rupture, n (%)  | 7 (7)   |
| Other, n (%)            | 6 (6)   |
| Functional MR, n (%)    | 36 (35) |
| Annular dilatation, n (%) | 11 (11) |
| Leaflet tethering, n (%) | 13 (13) |
| Both, n (%)             | 9 (9)   |
| Mixed, n (%)            | 8 (8)   |
| Missing/unknown, n (%)  | 8 (8)   |
| Type of surgical mitral valve repair |  |
| Ring, n (%)             | 90 (87) |
| Chordal repair, n (%)   | 13 (13) |
| Partial leaflet resection, n (%) | 16 (16) |
| Other, n (%)            | 8 (8)   |
| Combined (ring/chordal repair/resection), n (%) | 28 (28) |
| Type of ring            |  |
| Complete ring, n (%)    | 65 (70) |
| Incomplete ring, n (%)  | 25 (25) |
| Ring size, mm           |  |
| 25–30                   | 37 (41) |
| 31–35                   | 26 (29) |
| 36–40                   | 11 (12) |
| Cause pre-MitraClip     |  |
| Degenerative, n (%)     | 46 (44) |
| Functional, n (%)       | 41 (39) |
| Mixed, n (%)            | 10 (10) |
| Ring rupture/detachment, n (%) | 7 (7)   |
| Systolic anterior motion, n (%) | 3 (3)   |
| Median time [IQR] between surgery and MitraClip, y | 5.3 (1.9–9.7) |

IQR indicates interquartile range; and MR, mitral regurgitation.
the 8 patients (the unfeasible cases) had a surgical annuloplasty ring, 2 patients had a 28-mm size ring, 3 patients had a 30-mm size ring, 1 patient had a 32-mm size ring, and the ring size was missing in 1 patient. Overall, 64% of patients were treated with 1 clip, 23% with 2 clips, and 5% with 3 clips. Significant MR reduction (MR reduction ≥1 grade) and technical and device success were achieved in 94%, 90%, and 89%, respectively. There was no difference in technical and device success between patients treated with degenerative versus functional MR pre-SMVR (89% versus 97% \(P=0.23\) and 88% versus 94% \(P=0.46\), respectively) (Table 3).

In 79% of the patients, standard transesophageal echocardiography (TEE) views (ie, LV outflow tract and intercommisural view) were used during the grasping process, in 16% of the patients transesophageal echocardiography views were used with modified angles, and in 5% of the patients standard transesophageal echocardiography views were used in combination with adjunctive intracardiac echocardiography.

The median device time was 70 minutes and appeared shorter with additional/modified imaging versus standard LV outflow tract/intercommisural view (39 minutes [21–67 minutes] versus 79 minutes [56–116 minutes], \(P<0.001\)). However, there was no difference between the 2 groups (standard views versus additional/modified imaging) with regards to technical success (89% versus 95%, \(P=0.68\)) and device success (87% versus 95%, \(P=0.45\)).

**DISCUSSION**

We report the largest series of patients treated with MitraClip after failed SMVR. The findings indicate that: (1) MitraClip was feasible and safe after failed SMVR in selected patients with technical and device success rates of 90% and 89%, respectively; (2) the median time between SMVR and MitraClip was 5.3 years; and (3) additional/modified imaging techniques may facilitate leaflet grasping and shorten device time by dealing with technical challenges caused by shadowing from the annuloplasty ring (Figure 2).

Recurrence of MR after SMVR is not uncommon and is associated with an increased risk of mortality.\(^{13,14}\) Petrus et al\(^ {13}\) demonstrated that the cumulative incidence of recurrent MR (grade ≥2) after SMVR for functional ischemic MR is 27.6% (at 10 years of follow-up). One of the randomized CTSN (Cardiothoracic Surgical Trials Network) initiatives compared mitral repair with mitral valve replacement for severe functional MR and reported MR recurrence rates of 32.6% at 1 year and 58.8% at 2 years of follow-up including mortality rates of 14.3% at 1 year and 19% at 2 years of follow-up after mitral repair.\(^ {3,15}\) Another CTSN trial reported an 11.2% MR recurrence 2 years after mitral repair in patients with at least moderate ischemic MR who underwent SMVR in combination with coronary artery bypass grafting.\(^ {16}\) EVEREST II (Endovascular Valve Edge-to-Edge Repair Study II), which was predominantly composed of degenerative causes, compared MitraClip with mitral surgery (86% surgical repair), and ≈11% of the surgical arm had moderate to severe MR at 5-year follow-up.\(^ {17}\) Suri et al\(^ {18}\) showed a 15-year overall incidence rate of recurrent MR after SMVR for degenerative MR of 13.3%, while the 15-year incidence rate of mitral reoperation was 6.9%, suggesting that a substantial proportion (6.4%) of patients did not undergo redo mitral valve surgery. Compared with primary mitral surgery, redo mitral valve surgery is associated with higher operative mortality (11.1% versus 6.5%, \(P<0.0001\)), higher complication rates (such as
prolonged ventilation [28.1% versus 19.7%, P<0.0001], renal failure [9.4% versus 7.0%, P=0.004], reoperation [14.7% versus 10.3%, P<0.0001], stroke [2.8% versus 1.9%, P=0.042], cardiopulmonary bypass time [165 versus 148 minutes, P<0.0001], and intensive care unit stay [88 versus 68 hours, P<0.0001], and increased length of stay (9 versus 7 days, P<0.0001). In our study, using the MitraClip to treat failed SMVR was associated with a 2% in-hospital mortality rate and a short length of stay (3 days).

Our study confirms the feasibility and safety of MitraClip in patients with recurrent MR after SMVR. A previous report including 57 patients undergoing MitraClip after prior SMVR showed a procedural success rate of 84% (compared with 89% in our series). In that study, patients had a higher STS score of 6.0%, a 52% functional MR pre-SMVR, and 79% of patients with original repair including a ring annuloplasty (as compared with STS 4.5%, 35% functional MR, and 87% with prior annuloplasty ring in our series). However, device success in our study is still lower than what is achieved in MitraClip for native MR studies (ie, functional and/or degenerative), which varies between 91% and 96%.

### Additional/Modified Imaging and Procedure Modifications

In our study, additional/modified imaging techniques had favorable effects on device time and similar technical and device success rates. A nondehisced annuloplasty ring approximates the leaflets, minimizes the coaptation gap, and increases coaptation length, which may facilitate the grasping maneuver. Conversely, shadowing from the annuloplasty ring may obscure the echocardiographic window for posterior leaflet grasping and also limit the orifice dimensions through which the clip needs to enter the left ventricle from the left atrium. Conventional clip passing is recommended in an ≈180° open configuration to help maintain and monitor the clip orientation as the clip is positioned perpendicular to the coaptation plane before leaflet grasping. In the case of a prior surgical ring, there is a reduction in the mitral orifice such that it can sometimes be impossible to enter the left ventricle in this 180° open position, and the clip should be formally oriented in the left atrium, closed, then advanced into the left ventricle in the partially or totally closed position and reopened under the mitral plane with confirmation of the maintained correct orientation (Figure 3). The leaflets will be typically grasped well below the surgical ring and more towards the left ventricle (and more often so in secondary MR). At times, the presence of the surgical ring and the open MitraClip in the left ventricle may further impede leaflet visualization because of shadowing of the posterior leaflet by the annuloplasty ring. In cases of ring dehiscence, the ring may conflict with the delivery system, create

### Table 3. Procedural Characteristics and In-Hospital Complications

| Imaging during grasping process | Total Population (N=104) |
|-------------------------------|-------------------------|
| Standard LVOT and intercommissural view | 80 (79) |
| LVOT/intercommissural view with modified angles | 15 (15) |
| LVOT/intercommissural view with ICE | 6 (6) |
| Clips, n (%)                  |                        |
| 0                             | 8 (8)                   |
| 1                             | 67 (64)                 |
| 2                             | 24 (23)                 |
| 3                             | 5 (5)                   |
| MR reduction, n (%)           |                        |
| 0                             | 6 (6)                   |
| 1                             | 10 (10)                 |
| 2                             | 18 (18)                 |
| 3                             | 37 (38)                 |
| 4                             | 27 (28)                 |
| ≥1, n (%)§                   | 92 (94)                 |
| LV ejection fraction, median (IQR), % | 45 (28–56) |
| Mean transmural gradient postclip, median (IQR), mm Hg | 4.7 (3.0–6.0) |

ICE indicates intracardiac echocardiography; IQR, interquartile range; LV, left ventricular; and LVOT, left ventricular outflow tract.

*Device time is defined as the time from guided catheter insertion to guided catheter removal.

†Technical success is defined as successful deployment of the device with absence of procedural mortality and freedom from emergency surgery.

‡Device success is defined as proper placement of the device without procedural mortality and with reduction in postprocedural mitral regurgitation (MR) by ≥1 grade from baseline and to an absolute level of moderate or higher MR.

§ Reduction of the mitral regurgitation with 1 grade or more.
shadowing, and sometimes impede passing of the clip into the left ventricle. A transgastric short-axis view may then offer improved visualization of both leaflets to assist proper and controlled leaflet grasping (Figure 4). In some cases, the surgical ring could induce an inflow gradient, which may further increase after leaflet grasping leading

Figure 2. Overview of the main outcomes of this study.
ICE indicates intracardiac echocardiography; MR, mitral regurgitation; SMVR, surgical mitral valve repair; and TEE, transesophageal echocardiography.

Figure 3. Case example in which the mitral annuloplasty ring precluded crossing of the MitraClip in an open configuration.
A and B, The dimensions of the mitral annuloplasty ring measured with transesophageal echocardiography. (A) The anterior-posterior diameter and (B) the medial-lateral diameter. C, The length of the MitraClip with open and closed arms. D, MitraClip in open configuration was not able to cross the surgical mitral ring. Arrow indicates MitraClip; LA, left atrium; and LV, left ventricle.
to mitral stenosis. Consequently, operators may decide not to release the clip. Postprocedural mitral stenosis (ie, transvalvular mitral gradient measured invasively >5 mm Hg or echocardiographically >4.4 mm Hg) after MitraClip has been shown to have a negative impact on long-term outcome.24 Invasive transmitral pressure...

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**Figure 4.** Additional value of the transgastric view during MitraClip grasping.  
A. Poor visualization of the posterior leaflet in the long-axis view. B. Excellent visualization of both mitral valve leaflets in the transgastric view. C. The transgastric view was used during the grasping process and (D and E) resulted in significant mitral regurgitation reduction (F) after the implantation of a MitraClip. Arrow indicates MitraClip; LA, left atrium; and LV, left ventricle. *Anterior mitral valve leaflet; ∆ posterior mitral valve leaflet.

**Figure 5.** Case example in which more extreme transesophageal echocardiography angulation optimized visualization of the posterior leaflet.  
A. Poor visualization of the posterior leaflet with the standard transesophageal echocardiography view (indicated by the red circle). B. More extreme angulation offered better visualization of the posterior leaflet. LA indicates left atrium; and LV, left ventricle.
monitoring may further guide MitraClip implantation in this setting.\textsuperscript{25}

Poor visualization of the posterior leaflet caused by shadowing from the annuloplasty ring can often be addressed by manipulation of the transesophageal echocardiography probe to move the imaging element relatively more left lateral within the esophagus (Figure 5). This maneuver will often reposition the image of the posterior mitral leaflet so that it does not fall within the surgical ring shadow. In general, atypical multiplanar angles or adjustment wheel manipulation may be necessary to view the complete leaflet grasping zone. Alternatively, the MitraClip may be deployed without complete visualization of the posterior leaflet but with the knowledge that the leaflet is often vertically oriented and under chordal restriction, which limits the concern for leaflet curling within the device closure zone.

In selected cases in which confirmation of the insertion of the posterior leaflet into the MitraClip could not be achieved by standard or modified imaging planes of the transesophageal probe, some investigators have used adjunctive intracardiac echocardiography (Figure 6 and Video S1). Both venous and arterial approaches have been used to position the intracardiac echocardiography catheter in order to obtain a clear view of the anterior and posterior leaflet and visualize grasping and clipping maneuvers. Conceivably, further intracardiac echocardiography iterations (eg, 4-dimensional technology) may enhance mitral valve imaging in the near future.

In our study, patients were treated with the MitraClip NT device (Abbott Vascular). Additional device sizes

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**Figure 6.** Additional value of intracardiac echocardiography in the visualization of both mitral valve leaflets. 
A. Transesophageal echocardiographic image showing shadowing of the posterior leaflet (indicated by the arrow). B. Intracardiac echocardiographic catheter in the left ventricle (LV; indicated by the red circle). C and D. Short-axis LV visualization including both mitral valve leaflets (*anterior mitral valve leaflet; \(\Delta\) posterior mitral valve leaflet; arrow MitraClip). LA indicates left atrium.
are emerging and may generate a more individualized/patient tailored approach.

Another minimally invasive alternative for redo surgery in the setting of prior surgical mitral repair is transcatheter mitral valve replacement. Device success and 30-day all-cause mortality with transcatheter mitral valve replacement in prior surgical ring are 69.5% and 9.9%, respectively. An important and potentially fatal complication is LV obstruction. Small LV cavity, septal hypertrophy, length of the anterior mitral valve leaflet, and aortomitral angle <120° are important risk factors for LV outflow tract obstruction. Therefore, these anatomic characteristics favor MitraClip treatment.

**Limitations**
The retrospective nature of our research is susceptible to selection bias. There was no echo-core laboratory or clinical event committee for completely independent data analysis. The modest patient population, limited follow-up, and the lack of a standardized echocardiography protocol should be acknowledged. Furthermore, the overall recurrence rate of MR after failed SMVR was missing in this study. Still, this is the largest cohort to date confirming the safety and efficacy of MitraClip treatment in patients with prior SMVR. Larger trials with longer follow-up data are needed to assess long-term efficacy.

**CONCLUSIONS**
MitraClip is a safe and minimally invasive treatment option for patients with recurrent MR after failed SMVR. Additional/modified imaging may help overcome technical challenges during leaflet grasping.

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**Supplementary Material**
Video S1

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