Alternative minimally-invasive surgical explantation techniques for failed transcatheter mitral valve repair devices

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Alternative surgical explantation techniques for TMVr devices

Simulation of explantation techniques
- Video documentation regarding explantation techniques

Recurrent MR after failed TMVr
- Pre-operative transesophageal echocardiography

Explantation of devices

CASE 1
CASE 2

TMVr devices may be surgically explanted without damaging the MV leaflets, so MV repair may remain an option in MV surgery

TMVR: Transcatheter mitral valve repair
MR: Mitral regurgitation; MV: Mitral valve
Alternative minimally-invasive surgical explantation techniques for failed transcatheter mitral valve repair devices

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Abbreviations

<table>
<thead>
<tr>
<th>Abbr.</th>
<th>Description</th>
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<tbody>
<tr>
<td>TMVr</td>
<td>Transcatheter mitral valve repair</td>
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<tr>
<td>MR</td>
<td>Mitral regurgitation</td>
</tr>
<tr>
<td>PASCAL</td>
<td>Precision Transcatheter Valve Repair System</td>
</tr>
<tr>
<td>TEER</td>
<td>Transcatheter edge-to-edge repair</td>
</tr>
<tr>
<td>MV</td>
<td>Mitral valve</td>
</tr>
<tr>
<td>MI-MVr</td>
<td>Minimally-invasive mitral valve repair</td>
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<tr>
<td>DMR</td>
<td>Degenerative mitral regurgitation</td>
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<tr>
<td>NYHA</td>
<td>New York Heart Association</td>
</tr>
<tr>
<td>STS-PROM</td>
<td>The Society of Thoracic Surgery predicted risk of mortality score</td>
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<tr>
<td>TEE</td>
<td>Transesophageal echocardiography</td>
</tr>
<tr>
<td>LVEF</td>
<td>Left ventricular ejection fraction</td>
</tr>
<tr>
<td>EROA</td>
<td>Effective regurgitant orifice area</td>
</tr>
<tr>
<td>LVEDD</td>
<td>Left ventricular end-diastolic diameter</td>
</tr>
<tr>
<td>AML</td>
<td>Anterior mitral leaflet</td>
</tr>
<tr>
<td>PML</td>
<td>Posterior mitral leaflet</td>
</tr>
<tr>
<td>LLI</td>
<td>Loss-of-leaflet insertion</td>
</tr>
</tbody>
</table>
Abstract

Objective: The use of transcatheter mitral valve repair (TMVr) devices is increasing in elderly and high-risk patients. However, the increasing number of patients with recurrent mitral regurgitation (MR) has confronted surgeons with the issue of how to explant the devices and whether the mitral valve should be repaired or replaced. The aim of the study is to summarize our clinical experience with the explantation of different TMVr devices and to provide alternative surgical techniques that can be performed in different clinical scenarios.

Methods: A simulator system including a dummy valve representing native valves was used to create video documentation and to develop alternative surgical methods for clip explantation. Moreover, the clip explantation techniques were shown in two patients undergoing minimally-invasive mitral valve repair after a failed TMVr.

Results: Alternative explantation techniques were described for each TMVr device; two techniques for MitraClip and three techniques for PASCAL (Precision Transcatheter Valve Repair System), which may be adjusted for each individual according to the underlying valve pathology and the degree of device encapsulation. The patients were discharged without residual MR and remained MR free at the follow-up.

Conclusion: Transcatheter edge-to-edge repair (TEER) devices can be surgically explanted without damaging the MV leaflets. Removal of each device may require a different technique.
tailored to the degree of device encapsulation and valve pathology. Increasing experience may facilitate repair in patients with recurrent MR after TMVr.

**Keywords:** Transcatheter mitral valve repair, failed TMVr, TEER, device explantation, MitraClip, PASCAL

**Central Message**

Various surgical explantation techniques can be performed without damaging the MV leaflet in a minimally-invasive setting. The removal of clip may make MV repair possible in patients with recurrent MR.

**Perspective Statement**

Various surgical explantation techniques can be performed without damaging the MV leaflet in minimally-invasive setting.

**Central Picture Legend**

Video documentation regarding explantation techniques using Fehling simulator
**Introduction**

The use of transcatheter mitral valve repair (TMVr) devices has become popular in elderly and high-risk patients over the last decade. However, it has been reported that 2.8-6.3% of these patients required mitral valve (MV) surgery due to recurrent mitral regurgitation (MR) at one-year follow-up [1-4]. Therefore, the increasing number of the patients with recurrent MR has confronted surgeons with the issue of how to explant failed devices and whether MV should be repaired or replaced [5-9]. Experience regarding device explantation and MV repair management is still limited. The aim of the study is to summarize our clinical experience with explantation of the different TMVr devices such as MitraClip (Abbott, Santa Clara, CA, USA)
and PASCAL (Edwards Lifesciences, Irvine, CA, USA), and to provide alternative surgical techniques for different clinical scenarios.

**Patient and methods**

The Fehling simulator system including a dummy valve representing the native valves was used to create video documentation and to develop alternative surgical methods for clip explantation (Figure 1) [10]. Moreover, the clip explantation techniques were shown in two patients undergoing minimally-invasive mitral valve repair (MI-MVr) after a failed TMVr. See Figure 5 for a graphical abstract of the study. The alternative surgical explantation techniques tailored to the degree of device encapsulation, type of device were summarized in Table 1. The presented techniques were described on the basis of our ten years experience with such operations and previously reported papers [13, 14], experience gained by practicing with the simulator system and the manufacturers recommendation.

In our center, a total of 69 patients underwent minimally invasive (n=46) or full sternotomy (n=23) MV surgery after failed TMVr. Five of patients in DMR group (n=10) underwent MV repair. The operative management of the patients undergoing MV surgery after failed TMVr is summarized in Figure 2. The patients underwent a MI-MVr through a right anterolateral thoracotomy, with three-dimensional (3D) fully endoscopic visualization as previously described in detail elsewhere [11]. Cardiopulmonary bypass was established by cannulation of the femoral artery and vein utilizing a percutaneous technique. Myocardial protection was achieved by mild systemic hypothermia and antegrade infusion of cold del Nido cardioplegia following cross-clamping.

The study was approved by the institutional ethics committee (Charité Ethics Committee, Berlin; approval number EA4/041/21, 11/21/2019). Written consent for publication of study data was obtained from all patients. Both patients were treated in
accordance with the respective European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines [12].

**Case 1: MI-MVr following failed MitraClip**

An 87-year-old female presented with recurrent severe MR four months after TMVr with 3 MitraClip implants due to degenerative mitral regurgitation (DMR). She had progressive dyspnea and New York Heart Association (NYHA) functional class III cardiac decompensation signs on readmission. Euroscore II and the Society of Thoracic Surgery predicted risk of mortality score (STS-PROM) were 9.14 and 5.03, respectively. Preoperative transesophageal echocardiography (TEE) confirmed severe MR with an eccentric jet. Left ventricular ejection fraction (LVEF) was 55%, effective regurgitant orifice area (EROA) and left ventricular end-diastolic diameter (LVEDD) were 0.49 cm² and 64 mm, respectively. The mean transmitral pressure gradient was 9.7 mmHg.

**The techniques described using the Fehling simulator**

Two techniques for Mitraclip removal were defined preoperatively using the Fehling simulator system;

As the first technique; a suture was placed through the loops of the lock harness which are located between the internal arms and act as a lock. As the suture was retracted, a forward pressure was applied by advancing a snare, a frazier suction tube or a Cor-Knot suture fastening system (LSI Solutions, Victor, New York, United States) towards the lock (**Figure 3A**). Alternatively, upward tension could be applied, by stabilizing the central part of the clip with forceps. By this maneuver, the locking mechanism was released as shown in video 1. By grasping the inner arms with a forceps, the clip was detached from the anterior mitral leaflet (AML), and posterior mitral leaflet (PML) subsequently.

The second technique included an approach with or without suturing through the loops; the internal arms were grasped using a forceps. The hooks of the internal arms were thus
separated from the leaflets. Then the device was pushed towards the apex and pulled back with another forceps to remove it from the leaflets.

**Surgical treatment**

The MV repair included ring annuloplasty, triangular resection of PML, neochordae implantation on AML and PML. Maze procedure using cryoablation and left atrial appendage closure were concomitantly performed.

Intraoperatively, the MV apparatus and implanted MitraClip devices were evaluated. The first clip was removed with an explantation technique including placing a suture through the loops of the lock harness. As the suture was retracted, a forward pressure was applied by advancing the snare towards the lock (Figure 3B). Upward tension could also be applied, as stabilizing the central part of the clip with forceps. By this maneuver, the locking mechanism was released as shown in video 1. By grasping the inner arms with a forceps, the clip was detached from the AML, and PML subsequently.

In some cases, the clips can become highly encapsulated by fibrin tissue over time. In this case, the second technique can be performed. The clip is dissected from the fibrin tissue to reach to loops of the lock harness as previously described [13].

As shown in the first technique, a suture was placed through the loops and then, the internal arms were grasped using a forceps. The hooks of the internal arms were thus separated from the leaflet. Then the device was pushed towards the apex and pulled back with another forceps. Subsequently, the MV was evaluated for eligibility of repair. The excess tissue on the PML was then resected by a triangular resection technique. The PML was repaired with a 6/0 Cardiomy1 suture. Thereafter, the length of the neochordae was measured. Two neochordae were implanted on the AML and PML. After the measurement for the optimal ring sizing, a 34 mm Carpentier-Edwards (CE) Physio-II Ring (Edwards Lifesciences, Irvine, California, United States) was implanted. The water test showed a good leaflet coaptation without leakage.
The post-repair TEE confirmed a good coaptation depth without residual MR. The coaptation depth was 11 mm. The mean transmitral pressure gradient decreased around 4.1 mmHg. At the one-year follow-up, the patient remained MR free.

**Case 2: MI-MVR following failed PASCAL implantation**

The second patient with recurrent severe DMR was a 70-year-old male who was referred to our clinic with NYHA class III cardiac decompensation signs one month after failed TMVR with 2 PASCAL implants. Euroscore II and STS-PROM score were 4.74% and 3.36%, respectively. Preoperative TEE confirmed severe MR and device malposition. LVEF was 60%, EROA and LVEDD were 0.55 cm² and 63 mm, respectively.

**The techniques described using Fehling simulator**

In the Fehling simulator system, different techniques regarding explantation of the PASCAL device explored by Edwards were simulated as follows;

The first technique [14] is called the “suture securing technique”; the inner arms of the device were attached to the central spacer with a Prolene suture (Figure 4A). While the central spacer was held in place by a forceps, the leaflet was gently pushed out from the central spacer. After the leaflet has been released from internal paddle, the partially opened device should be gently pushed towards the apex. The maneuver should also be repeated for the PML.

The second technique is the “walking-down method”; the internal arms were grasped using a forceps. The hooks of the internal arms were thus separated from the leaflets. The leaflet was held and gently pushed away from the central spacer. After the leaflet has been released from internal paddle, the partially opened device should be gently pushed towards the apex. The maneuver should also be repeated for the PML.

The third technique is called “Elevator method”; first, the central spacer was grasped using a forceps. The anterior clasp was then gently pushed away from the central spacer. The forceps grasping the internal arm was gently introduced deeper. The device was then pushed
towards the apex and released from the AML. The maneuver should also be repeated for the PML.

Additionally, since the PASCAL device has a nitinol-based soft-locking system, the removal techniques can be combined with the use of a cold saline solution.

**Surgical treatment**

The second patient underwent a MI-MVr including ring annuloplasty, resection of the calcified cyst at P2 and implantation of neochordae on the AML and PML, and concomitantly Maze procedure using cryoablation.

MV apparatus and the implanted PASCAL devices were evaluated intraoperatively as shown in video 1. First, the PML edge grasped by the device arms was cut and released from the PML. Then, the central spacer was grasped with a forceps and retracted subsequently (Figure 4B). The device was released from the AML with this maneuver. Thereafter, the second PASCAL device was found free in the LV cavity. Subsequently, the MV was evaluated for repair eligibility. Two neochordae loops were implanted on the AML and PML. After the measurement for the optimal ring sizing, a 36 mm Physio-II ring was implanted. A calcified cyst found at P2 was removed by sharp dissection. The PML was repaired with a 6/0 Cardioynl suture. The water test showed a good coaptation of the leaflets without leakage.

The post-repair TEE confirmed a good coaptation depth without residual MR. The coaptation depth was 9.6 mm. The mean transmitral pressure gradient decreased around 1.9 mmHg. At the two-year follow-up, the patient remained MR free.

**Discussion**

This study investigated alternative surgical techniques for the explantation of failed TMVr devices to provide a removal guidance in different clinical scenarios.

The main messages and findings from the present study can be summarized as follows:

1. Transcatheter edge-to-edge repair devices can be surgically explanted without damaging
the MV leaflets. (2) Each device may require a different technique for the removal. (3) In the case of a highly encapsulated device, it may be necessary to dissect the device from the surrounding tissue and then perform an appropriate explantation technique.

As the clinical use of TMVr devices increases, the question of how to overcome recurrent MR after failed devices is being raised [6]. The surgical reoperation may be more challenging than usual in high-risk patients who were not previously deemed as appropriate candidates for open heart surgery or in patients with clip-induced complex mitral anatomy in whom valve repair could be previously considered [5, 7]. It remains unclear how the device should be explanted and whether MV should be repaired or replaced. The feasibility of surgical MV repair after TMVr has been evaluated in several studies [5-9]. In addition, several cases of device explantation after failed TMVr have been reported [13,14]. Gercek et al have reported the first case on the surgical removal of the PASCAL device and demonstrated that surgical removal of the PASCAL device without leaflet injury is possible [14]. However, the type of device and degree of device encapsulation may potentially complicate injury-free device removal. Therefore, removal of each device may require a different technique tailored to the degree of device encapsulation, type of device, and underlying valve pathology.

Although clip-induced leaflet or chordal damage may make valve repair unfeasible in some cases, the fact that the patient has previously undergone TMVr alone does not mean that the MV should be considered unrepairable [7]. Our decision-making strategy was based on underlying valve pathology, the type of device and the leaflet integrity. Due to the risk of recurrent MR following MV repair, patients with FMR should undergo MV replacement. In patients with DMR etiology, the surgical approach was based on the following criteria; (1) If there was no loss-of-leaflet insertion (LLI), the clip was kept in place and ring annuloplasty was performed to support the annulus. Additional leaflet repair techniques may be performed as needed. LLI was considered as a criterion for clip removal. The integrity of the AML and
the feasibility of PML repair were decisive for the subsequent strategy. MV replacement should be considered, if the AML is damaged and the PML is found to be unrepairable [7]. Furthermore, in patients underwent TMVr long ago, the encapsulation of the clip may limit a damage-free explantation, making a durable repair unlikely. Our treatment of choice in such patients is MV replacement. In the present paper, we demonstrated several removal methods that can be performed without leaflet damaging in different scenarios. The above-mentioned techniques were described both in-vitro on dummy valves using the Fehling simulator system and in patients with recurrent MR after failed TMVr in whom valve repair could be successfully performed. The Fehling simulator was used to establish the removal concepts presented in this study and may act as training tool prior to clinical cases. Based on the findings and the clear description of how clips can be removed, we estimate only a few training cases to complete the learning curve with the Fehling Simulator prior to be proficient enough for clinical cases. These overall concept of in vitro training and deep knowledge regarding clip removal techniques may make repair possible in patients with favourable MV anatomy and pathology.

        The presented manuscript is somehow limited by the fact that only patients referred to our hospital can be included in the study. Patients who received their clip implantation at an external hospital which were treated conservatively despite clip-failure with severe MR are not reflected in our study. This fact should be considered when interpreting the overall numbers of failed clips treated surgically. However, the primary scope of this manuscript is to describe techniques of clip removal.

        As a conclusion, transcatheter edge-to-edge repair devices may be surgically explanted without damaging the MV leaflets. Each device may require a different technique for removal. MV repair may remain an option in MV surgery for patients with recurrent MR after failed TMVr. Increasing experience may facilitate MV repair in patients with recurrent MR after TMVr.
References


Central Picture: Video documentation regarding explantation techniques using Fehling simulator

Figure 1: Video documentation regarding explantation techniques using Fehling simulator system including a dummy valve representing native MV.

Figure 2: Flowchart showing patient population undergoing mitral valve surgery after failed TMVr (TMVr: Transcatheter mitral valve repair; MI-MVS: Minimally-invasive mitral valve surgery).
surgery; FMR: Functional mitral regurgitation; DMR: Degenerative mitral regurgitation; TEER: Transcatheter Edge-to-Edge repair)

**Figure 3:** Illustration of the explantation technique using the simulator system; suturing through the loops of the lock harness located between the internal arms (A). Unlocking manoeuvre by applying forward pressure with advancing the snare towards the lock while retracting the suture (B).

**Figure 4:** Illustration of explantation technique using the simulator system; suturing internal paddles to central spacer (A); Release of the device from the AML and PML by grasping the central spacer and pulling it back with forceps (B).

**Figure 5:** Graphical Abstract: Alternative surgical explantation techniques for failed TMVr devices such as MitraClip and PASCAL; illustration of simulator system, pre-operative TEE images, operative illustration regarding explantation of failed devices (from left-to-right). (TMVr: Transcatheter mitral valve repair; MR: Mitral regurgitation; MV: Mitral valve)

**Video 1:** Documentation of alternative surgical techniques for failed TMVr devices using Fehling simulator system and performing these techniques in two patients undergoing MI-MVr after failed TMVr.
**Table 1:** The alternative explantation techniques tailored to the degree of device encapsulation, type of device.

<table>
<thead>
<tr>
<th>Clinical scenario</th>
<th>Techniques</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MitraClip</strong></td>
<td></td>
</tr>
<tr>
<td>Newly implanted</td>
<td>First technique; placing a suture through the loops, unlocking the mechanism</td>
</tr>
<tr>
<td>Implanted long ago</td>
<td>Second technique; dissection of fibrin tissue, grasping internal arms and separating hooks from the leaflet</td>
</tr>
<tr>
<td>Clinical scenario</td>
<td>Techniques</td>
</tr>
<tr>
<td>-------------------</td>
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</tr>
<tr>
<td><strong>PASCAL</strong></td>
<td></td>
</tr>
<tr>
<td>Newly implanted</td>
<td><strong>Suture securing technique;</strong> suturing internal paddles to central spacer, pushing external paddles away from the central spacer <strong>Elevator technique;</strong> grasping internal arm and introducing deeper to separated hooks from the leaflet</td>
</tr>
<tr>
<td>Implanted long ago</td>
<td><strong>Walking-down method;</strong> dissection of fibrin tissue between the arms, grasping central spacer, pushing internal arm away from the central spacer, detachment of internal arm from the leaflet</td>
</tr>
</tbody>
</table>
Recurrent Mitral regurgitation after TMVr
n=69

Median sternotomy group
n=23

Mi-MVS group
n=46

FMR
n=36

TEER
*MitraClip, n=35

Direct annuloplasty
*Cardioband, n=1

Device explantation and valve replacement

DMR
n=10

TEER
*MitraClip, n=8
*Pascal, n=2

Type of TMVr

Repair (n=5)

Replacement (n=5)
CASE 1
CASE 2

A

B
Alternative surgical explantation techniques for TMVr devices

Simulation of explantation techniques
Video documentation regarding explantation techniques

Recurrent MR after failed TMVr
Pre-operative transesophageal echocardiography

Explantation of devices

CASE 1

TMVr devices may be surgically explanted without damaging the MV leaflets, so MV repair may remain an option in MV surgery

TMVr: Transcatheter mitral valve repair
MR: Mitral regurgitation; MV: Mitral valve

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