Transapical electrosurgical laceration and stabilization of mitral clips followed by transcatheter mitral valve replacement—A one-stop shop

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ABSTRACT

Objective: Electrosurgical laceration and stabilization of mitral clips (ELASTA-CLIP) is a bail-out technique to recreate a single-orifice mitral valve after transcatheter edge-to-edge repair (TEER) with subsequent transcatheter mitral valve replacement (TMVR). This technique is a novel option for patients with significant residual mitral regurgitation after TEER with high risk for conventional surgery. The original ELASTA CLIP procedure features a transseptal approach, whereas the TMVR with the Tendyne bioprosthesis has a transapical access. Hereby we tested the hypothesis that a modified transapical ELASTA CLIP technique can be safely applied transapically allowing a straightforward one-stop shop access strategy.

Methods: We developed the procedural steps in a porcine passive-beating heart model and applied the modified technique with subsequent TMVR in 2 consecutive patients with severe mitral regurgitation after previous TEER. Patients were followed up to 30 days.

Results: The modified transapical ELASTA CLIP procedure was successful in both patients. The mean total procedure time was 118 minutes, and the mean fluoroscopy duration 22 minutes. At 30 days' follow-up, both patients were alive without bleeding complications, reintervention, or prosthetic valve dysfunction.

Conclusions: The modified transapical ELASTA CLIP procedure is technically feasible and safe at 30 days. Procedure times are lower compared with previous reports of the original transseptal approach. (JTCVS Techniques 2023;22:189-96)

Modified transapical ELASTA CLIP: a novel technique to enable TMVR after failed TEER.

CENTRAL MESSAGE

Modified transapical electrosurgical laceration and stabilization of mitral clips (ELASTA CLIP) followed by TMVR to treat recurrent MR after TEER is feasible and safe at 30 days.

PERSPECTIVE

The transseptal ELASTA-CLIP procedure is a technique to recreate a single-orifice mitral valve after failed TEER. The present study shows that a transapical ELASTA-CLIP procedure is feasible and safe at 30 days. This procedure offers advantages over the transseptal approach and may therefore be the preferred option. The procedure expands the technical portfolio to treat patients after failed TEER.

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Abbreviations and Acronyms

AML	= anterior mitral leaflet
ELASTA-CLIP	= electrosurgical laceration and stabilization of mitral clips
MR	= mitral regurgitation
PML	= posterior mitral leaflet
TEER	= transcatheter edge-to-edge repair
TMVR	= transcatheter mitral valve replacement

▶ Video clip is available online.

Transcatheter edge-to-edge repair (TEER) of the mitral valve is an established minimally invasive method to treat mitral regurgitation (MR) in patients at high surgical risk. However, recurrent significant MR following TEER occurs in approximately 10% of cases within 12 months,[1] which is associated with increased heart failure hospitalizations and mortality. Traditional on-pump surgical revision of residual or recurrent MR after TEER has a high mortality between 7.1%[2] and 24%[3] at 30 days. Therefore, there is a demand for less-invasive, off-pump, transcatheter bail-out techniques.

Transcatheter mitral valve replacement (TMVR) with the Tendyne Valve (Abbott Laboratories) remains the only commercially available, Conformité Européenne–approved, off-pump mitral valve replacement. However, its implantation is not possible following TEER due to the double mitral orifice anatomy. Recently, a novel strategy of electrosurgical laceration and stabilization of mitral clips (ELASTA-CLIP) to create a single mitral orifice has been reported.[4,5] This technique includes a transseptal approach to lacerate the leaflet bridge on the site of the anterior mitral leaflet (AML) and detach the clips from the AML while the clips remain attached to the posterior mitral leaflet (PML). The resulting single mitral orifice allows the subsequent transapical implantation of the Tendyne bioprosthesis. However, this method is technically more involved and time-consuming, with a reported median procedure time of 205 minutes.[5]

We hypothesized that a modified ELASTA-CLIP using a transapical approach facilitates the procedure and allows a straightforward one-stop shop access strategy without the necessity for a transseptal puncture. The procedural steps were developed in an in vitro passive-beating porcine heart model. Hereby, we describe the first 2 patients who underwent this modified technique.

METHODS

In Vitro Heart Model

The modified transapical ELASTA-CLIP technique was designed by the authors. The procedural steps were developed and tested in a passive-beating heart model that has been described previously.[6] In brief, a MitraClip (Abbott Laboratories) was attached to the AML and PML of the mitral valve of an explanted porcine heart via a left-atrial approach to create a double-orifice-anatomy. The porcine heart was subsequently connected to a hydraulic circuit loop, simulating the pulsatile fluid dynamics of the systemic circulation. For this, the aorta of the porcine heart was connected to an external computer-controlled pumping system, which passively filled the left atrium through a preload reservoir. The modified transapical ELASTA CLIP technique as described herein was applied to free the MitraClip from the AML (Figure 1).

Study Patients

The selection criteria for this study included (1) symptomatic (New York Heart Association functional class >II) residual or recurrent severe MR after previous placement of at least 1 mitral clip; (2) ineligibility for an on-pump surgical mitral valve repair/replacement due to a prohibitive surgical risk; (3) ineligibility for an off-pump interventional placement of an additional mitral clip/vascular plug due to anatomical considerations and regurgitant jet morphology; and (4) eligibility for implantation of a Tendyne bioprosthesis as assessed by transesophageal echocardiography and contrast-enhanced cardiac computed tomography. The selection criteria were evaluated by a multidisciplinary heart team composed of interventional cardiologists, cardiac surgeons, and imaging specialists at the Kepler University Hospital Linz. The Abbott Tendyne field team assisted in the screening, procedure planning, and device preparation. The institutional review board approved the compassionate use of the device.

Modified Transapical ELASTA CLIP

All procedural steps are shown in the supplemental video file (Videos 1 and 2).

Step 1: Material and access-site preparation. Under general anesthesia, the optimal apical access site for TMVR is chosen based on the preprocedural cardiac computed tomography analysis. A left anterolateral minithoracotomy is performed, and the pericardium is opened. Before starting and during the modified transapical ELASTA CLIP procedure, all materials are flushed with 5% dextrose solution, as it is nonionic and prohibits the formation of thrombi and concentrates the charge during electrosurgery.

Step 2: Positioning of a wire loop through the double-orifice mitral valve. The apex is punctured, and over the needle an Emerald guidewire (Cordis) and an 8-Fr sheath is advanced into the left ventricle. One orifice of the double-orifice mitral valve is crossed with this guidewire. A balloon-wedge end-hole catheter is flossed along the wire from the left ventricle to the left atrium to ensure no chordal entrapment. This step is repeated using a second apical puncture and insertion of another 8-Fr sheath adjacent to the first one. Through this second sheath, a separate guidewire is crossed through the other orifice of the double orifice mitral valve into the left atrium. The balloon floss technique is again used to ensure the wire path is free. The use of 2 separate sheaths at this time point allows optimal steering and navigation of the guidewires through even small mitral valve orifices. A 4-Fr Berenstein catheter (Cordis) is inserted into one sheath, and a snare catheter into the other sheath and both catheters are advanced into the left atrium. An Astato XS 20 0.014-inch wire (Asahii-Intecc) is denuded at 150 cm over 10 to 20 mm, as well as the distal end with a scalpel. A V-shape is formed with a scalpel as a fulcrum, so the denuded part of the wire faces the inner curvature of the V. The Astato wire is inserted into the Berenstein catheter and then snared with a 27- to 45-mm EN 7F multiloop snare (Merit Medical) in the left atrium. Both 8-Fr sheaths are removed and a 22-Fr DrySeal sheath (W.L.

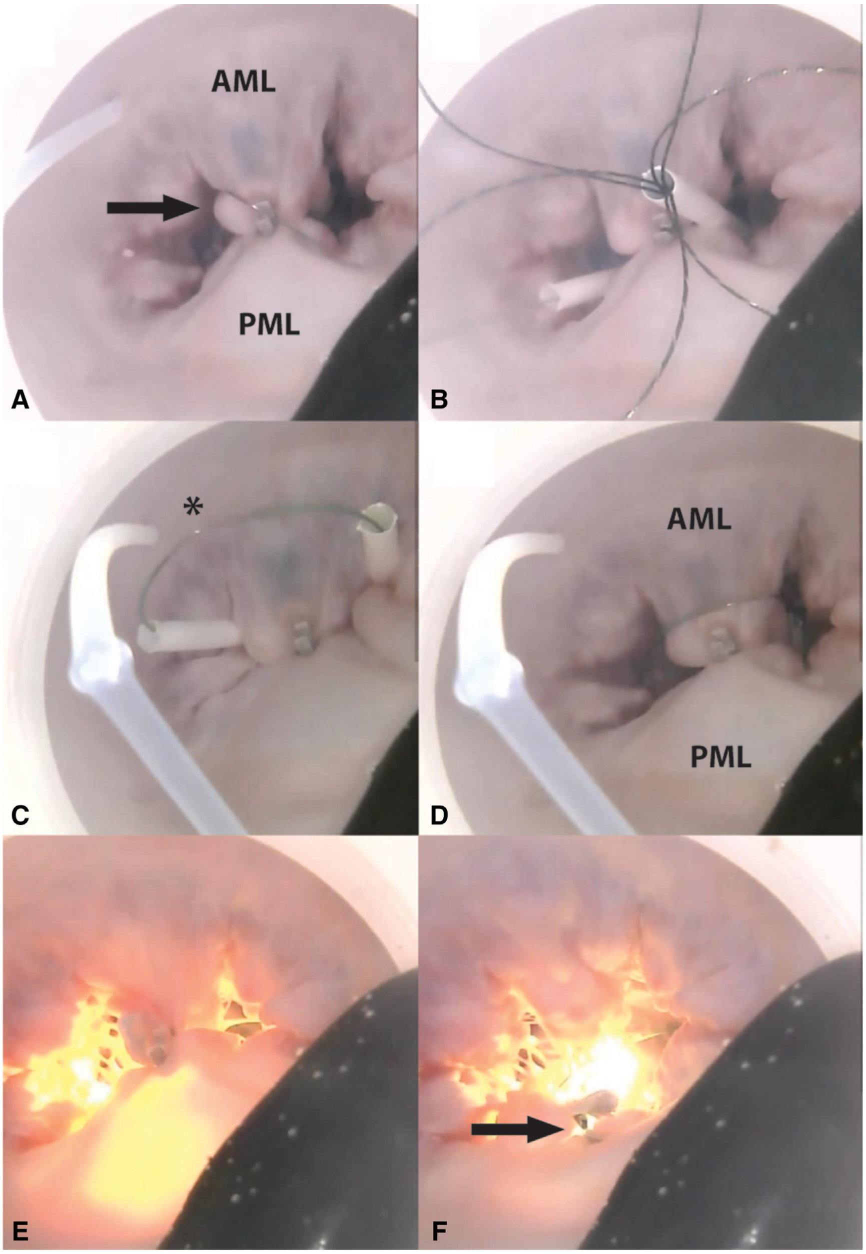
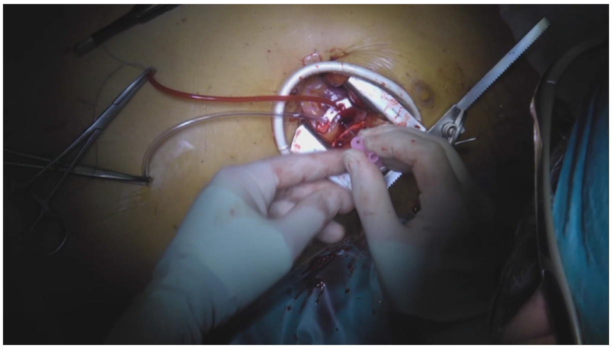


FIGURE 1. En face surgical view of the porcine mitral valve during the modified transapical ELASTA CLIP in vitro procedure. One MitraClip (*arrow*) is positioned in the middle segment A2/P2 of the porcine mitral valve to create a double-orifice valve (A). After both orifices are crossed with catheters, a multiloop snare is advanced to snare the Astato wire (B). The denuded segment (*asterisk*) of the V-tip of the Astato wire is aligned (C) and positioned adjacent to the MitraClip on the AML (D). Continuous duty bursts of electrocautery are applied (E) to restore a single-orifice mitral valve with the MitraClip (*arrow*) remaining attached to the PML (F). *AML*, Anterior mitral leaflet; *PML*, posterior mitral leaflet; *ELASTA CLIP*, electrosurgical laceration and stabilization of mitral clips.

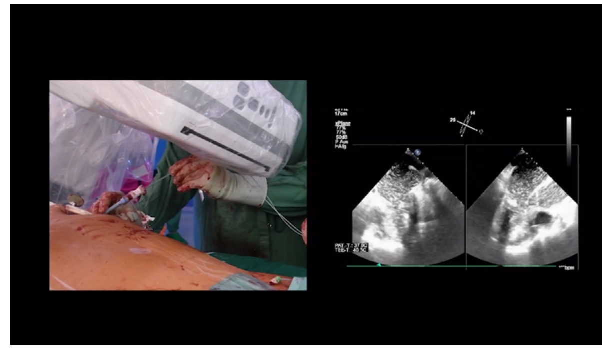
Gore & Associates) is inserted over the 2 wire ends. The use of one large-bore sheath at this time point facilitates optimal steering of the V-shaped tip toward the AML. Figure 2 shows details of procedural step 2.

Step 3: Electrosurgical laceration of the AML. Two 4-Fr Berenstein catheters are loaded over each wire end of the Astato wire and advanced close to the V to provide an additional electrical insulation. A torque device is loaded on both wire ends to secure wire control during leaflet laceration. The inverted V-shaped tip is then positioned adjacent to the previously implanted clip(s) on the AML by steering the sheath anteriorly. The DrySeal sheath is also advanced to create a higher loop, to capture the AML bridge and ensuring the V-tip does not slip down into the clip. Under fluoroscopy and transesophageal echo guidance, continuous-duty bursts of electrocautery at 100 Watts are applied under light traction for approximately 5 seconds until the AML is lacerated, creating a single-orifice mitral valve. The mitral clip(s) remain attached to the PML.

Step 4: Implantation of the Tendyne prosthesis. The Astato wire and the catheters are removed though the DrySeal sheath. A



VIDEO 1. The first in human modified transapical ELASTA CLIP procedure: Part 1. Video available at: https://www.jtcvs.org/article/S2666-2507(23)00276-6/fulltext.



VIDEO 2. The first in human modified transapical ELASTA CLIP procedure: Part 2. Video available at: https://www.jtcvs.org/article/S2666-2507(23)00276-6/fulltext.

guidewire is then advanced through the DrySeal sheath into the left atrium for the Tendyne delivery system. The Tendyne is then implanted in a standard fashion (Figure 3). To minimize the time needed for Tendyne deployment after AML laceration, the bioprosthesis was already prepared and ready-for-use before the electrosurgical laceration procedural step was executed.

TMVR With the Tendyne Prosthesis

The Tendyne system is a porcine pericardial trileaflet valve with a unique self-expanding dual-frame design.[7-9] The outer frame has a contoured design that supports a secure seal within the native anatomy. The inner frame contains the bioprosthetic valve. The device has an apical anchoring system that consists of a tether and an apical pad.[10] The Tendyne Valve is the only commercially available, CE approved, off-pump mitral valve implant.[11]

Statistics

Data are expressed as counts, percentages, and means with standard deviations.

RESULTS

Patient Characteristics

Baseline patient characteristics of the 2 patients who had been selected to undergo the procedure are shown in Table 1. The mean patient age was 80 (±2) years, and both patients were male, were severely symptomatic (New York Heart Association class III), and had a preserved left ventricular ejection fraction 60 (±1) %. Concomitant comorbidities included arterial hypertension and coronary artery disease. One patient had previous aortic valve replacement and coronary artery bypass surgery, whereas the other had previous percutaneous coronary stenting. Both patients had 2 MitraClips implanted for primary MR, with a mean time from initial MitraClip implantation to the modified transapical ELASTA CLIP of 8.5 (±6) months. One patient had both MitraClips implanted in the middle region A2/P2, whereas the other patient had one clip in the middle region A2/P2 and the other clip close to the lateral commissure (A1/P1). There was no single-leaflet device attachment at baseline. The baseline mean transvalvular gradient was 4.5 (±0.7) mm Hg.

Procedural Characteristics

Procedural characteristics are shown in Table 1. The modified transapical ELASTA CLIP followed by TMVR with the Tendyne bioprosthesis was technically successful in both patients. The mean total procedure time (defined as the time span from skin incision to the completion of all procedure-related activities) was 118 (±32) minutes. The mean ELASTA-CLIP procedure time (defined by the time span from skin incision to the completion of the laceration of the AML) was 53 (±15) minutes, whereas the mean TMVR procedure time (defined by the time span from completion of the laceration of the AML to the completion of all procedure-related activities) was 65 (±17) minutes. The mean fluoroscopy duration was 22 (±6) minutes. After successful deployment of the Tendyne bioprosthesis, there was no central MR but mild paravalvular regurgitation in both patients. These paravalvular leakages were not regarded clinically significant. Three of four MitraClips were immobilized between the Tendyne frame and the posterior ventricular wall. One MitraClip (located close to the lateral commissure) was intentionally not freed from the AML and therefore was immobilized within the lateral commissure. There were no access-site bleeding complications, and there was no need to retrieve the Tendyne device. Both patients were hemodynamically stable without need of mechanical circulatory support during and after the procedure. Of note, both patients did not experience hemodynamic deterioration after laceration of the AML.

Follow-up (30-Days)

Both patients were alive at 30-day follow-up. There was no procedure-related bleeding complication, surgical reintervention, or embolization of the retained mitral clips, Tendyne dysfunction or thromboembolic events. One patient

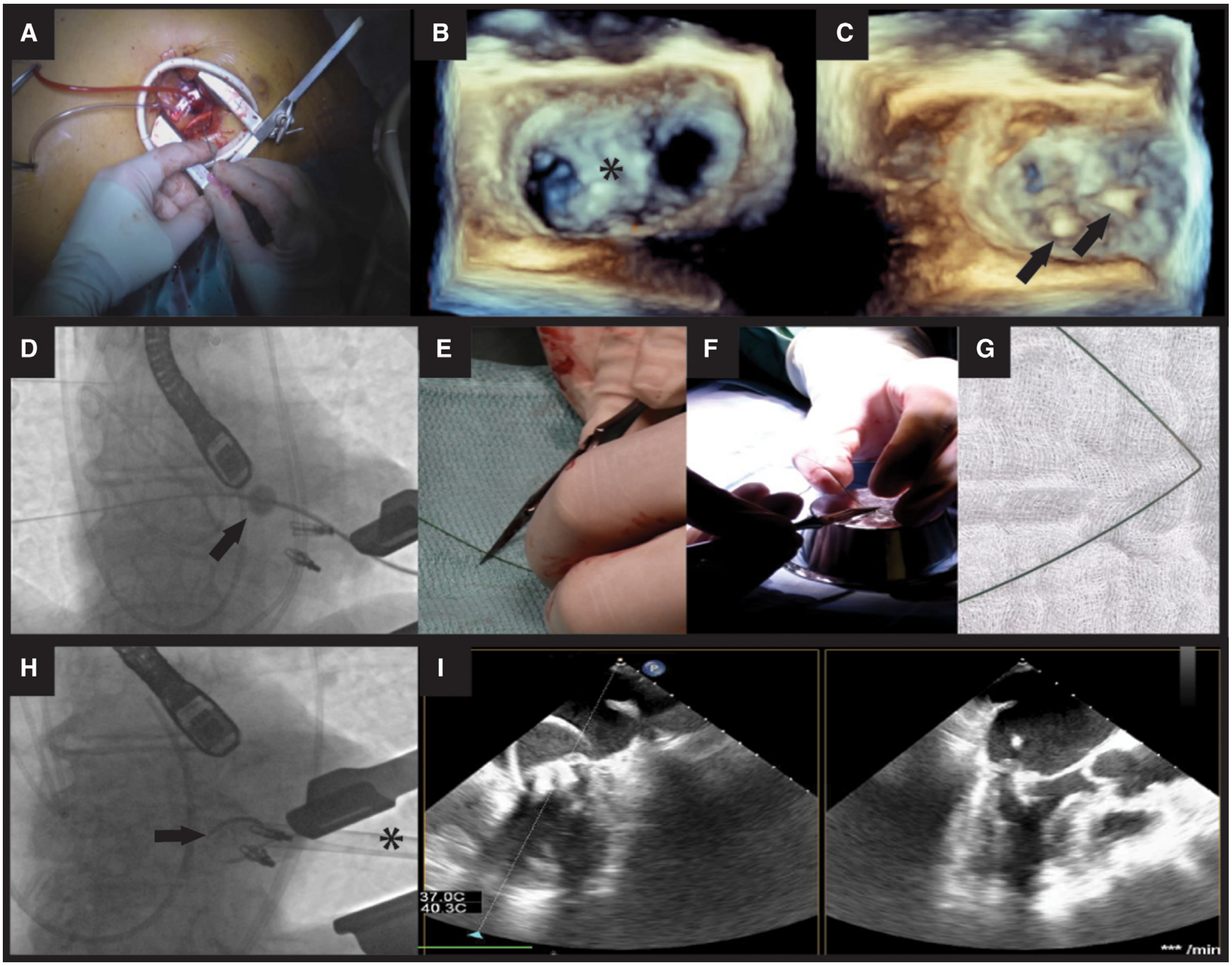


FIGURE 2. Procedural step 2 in vivo—the wire loop. The apex is punctured at the TMVR access site (A). The double-orifice mitral valve with 2 MitraClips (*asterisk*) in the middle segment (B) is crossed with 2 guidewires (*arrows*, C). A balloon wedge end-hole catheter (*arrow*) is used to confirm that there is no chordal entanglement (D). An Astato wire is denuded (E) and a V-shape is formed (F and G). The V (*arrow*) in between 2 isolating Berenstein catheters is positioned on the AML by steering the sheath (*asterisk*) anteriorly (H). The wire loop alignment can be visualized on x-plane transesophageal echo (I). *TMVR*, Transcatheter mitral valve replacement; *AML*, anterior mitral leaflet.

had postoperative acute renal failure with the need for intermittent hemodialysis. Echocardiographic follow-up showed mild paravalvular leakage without signs of hemolysis and a preserved left ventricular ejection fraction in both patients. The mean transvalvular gradient was 5.0 ($\pm$0) mm Hg. Follow-up echocardiographic characteristics are shown in Table 1 and in Figure 4.

DISCUSSION

In the present study, we investigated the feasibility of a modified transapical ELASTA CLIP procedure followed by the implantation of a Tendyne bioprosthesis. Results of our single-center study show that this procedure is feasible and can be safely applied in patients with a prohibitive risk for conventional, on-pump mitral valve surgery. The modified transapical ELASTA CLIP procedure is technically straightforward and allows a one stop-shop access site strategy. Hence, it is less time-consuming with lower radiation exposure and without additional access site complications compared with the previously reported transseptal approach.

Treatment options for patients with significant recurrent/residual MR after TEER, who do not qualify for another clip implantation, are scarce. This, however, this is not a rare clinical scenario. Severe MR after TEER is just the tip of the iceberg, as moderate recurrent/residual MR after TEER may also impact negatively on clinical survival.[12,13] Commonly, surgical mitral valve replacement is required due to leaflet injury after clip removal. These surgical interventions are associated with high mortality rates, reflecting

TABLE 1. Patient and procedural characteristics

Characteristics	Case 1	Case 2
Baseline patient characteristics		
Age, y	82	79
Sex (male/female)	Male	Male
Weight, kg	72	64
Height, cm	168	173
NYHA class (I-IV)	III	III
STS predicted risk of mortality score	6.6%	10.0%
MR etiology (primary/secondary/mixed)	Primary	Primary
Number of mitral clips, n	2	2
Position of mitral clips (A1/P1; A2/P2; A3/P3)	A2/P2, A2/P2	A2/P2, A1/P1
Type of MitraClip	XTW, XT	XTW, XTW
Baseline echocardiographic characteristics		
Left ventricular ejection fraction (biplane Simpson method, %)	61%	59%
MR severity (0-IV)	IV	IV
Mean transvalvular gradient, mm Hg	4	5
Tricuspid regurgitation (0-V)	I	I
Tricuspid annular plane systolic excursion (TAPSE, mm)	20	18
ELASTA CLIP/TMVR procedure characteristics		
Total procedure time, min	141	96
ELASTA CLIP procedure time, min	64	43
TMVR procedure time, min	77	53
Number of clips lacerated, n	2	1
Fluoroscopy duration, min	27	18
Follow-up echocardiographic characteristics		
Left ventricular ejection fraction (biplane Simpson method, %)	56	55
Paravalvular leakage (0-III)	I	I
Central MR (0-IV)	0	0
Mean transvalvular gradient, mm Hg	5	5

NYHA, New York Heart Association; *STS*, Society of Thoracic Surgeons; *MR*, mitral regurgitation; *ELASTA CLIP*, electrosurgical laceration and stabilization of mitral clips; *TMVR*, transcatheter mitral valve replacement.

the baseline high-risk patient profile. The electrosurgical laceration of the AML via a transseptal approach followed by TMVR with the Tendyne bioprosthesis is a minimally invasive alternative without the need for intraprocedural cardiopulmonary bypass. Its feasibility has been recently demonstrated.[5] However, this intervention requires a 2-access site strategy, which prolongs the procedure time and requires high technical expertise. A median procedure time of 205 minutes and median fluoroscopy duration of 59.5 minutes has been reported.[5] In this study, we

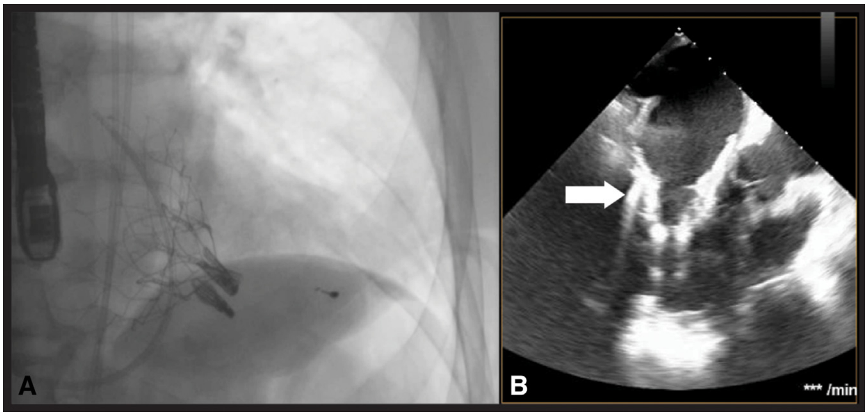


FIGURE 3. Final result of the modified transapical ELASTA CLIP procedure. Fluoroscopy (A) and transesophageal echocardiography (B) show the immobilized mitral clips (*arrow*) between the posterolateral ventricular wall and the Tendyne bioprosthesis.

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MODIFIED TRANSAPICAL ELASTA-CLIP PROCEDURE AFTER FAILED TEER: FEASIBLE AND SAFE

PROCEDURAL STEPS
1. TRANSAPICAL ACCESS
2. CROSS ONE ORIFICE WITH A WIRE, THE OTHER ORIFICE WITH A SNARE
3. CREATE A WIRE LOOP
4. ELECTROSURGICALLY LACERATE THE AML TO DETACH MITRAL CLIPS FROM AML
5. PERFORM TMVR WITH TENDYNE BIOPROSTHESIS

PROCEDURAL CHARACTERISTICS	
Mean total procedure time	118min
Mean flouroscopy duration	22min

SAFETY AT 30 DAYS	N = 2
Prosthetic valve dysfunction (Tendyne)	0%
Bleeding complications	0%
Reintervention or death	0%

AML: anterior mitral leaflet
TEER: transcatheter edge-to-edge repair
TMVR: transcatheter mitral valve replacement

FIGURE 4. Key procedural steps, characteristics and outcomes.

demonstrated the reliable restoration of a single-orifice mitral valve via a transapical access. The procedure does not require a transseptal puncture or deflectable guiding sheaths. Wire navigation through the double-orifice mitral valve is achieved by the manual steering of 2 apically inserted 8-Fr sheaths, whereas the V-tip of the wire loop is positioned on the AML by the manual steering of one 22-Fr sheath. These maneuvers are intuitive and technically relatively easy, leading to a mean total procedure time of 118 minutes and a mean fluoroscopy duration of 22 minutes in our observational study. Entanglement of the V-tip in mitral clip elements at the atrial side did not occur in the porcine beating-heart model or in vivo.

An important finding of the present study is the hemodynamical stability after electrosurgical leaflet laceration. We did not use an elective intra-aortic balloon counterpulsation pump, and there was no need to escalate the circulatory support. Presumably, the residual leaflet tissue protects against an hemodynamical breakdown due to an intolerable MR.

The modified transapical ELASTA CLIP technique is not only applicable in patients with mitral clip(s) in the middle segment A2/P2 but also in patients with clip locations in the medial or lateral segments. The manual steering of the short sheaths allows precise wire navigation through even small orifices. In case a mitral clip has been implanted close to the commissure to maintain a single orifice valve, the ELASTA-CLIP procedure may not be needed. The clip can directly be retained within the commissure by the Tendyne bioprosthesis, as demonstrated in our second patient case.

Intra- and postprocedural echocardiography showed mild paravalvular regurgitation in both patients. In 1 patient, the leakage was attributable to the retained MitraClip in the lateral commissure at the annular level, impacting the Tendyne Valve sealing. Therefore, we recommend to immobilize the mitral clips at the ventricular level and not at the annular level whenever possible, in order to avoid paravalvular leakage. This can be achieved by pulling the partially deployed bioprosthesis down into the annulus while simultaneously pushing the mitral clips down into the ventricle. The retained mitral clips did not affect the geometry of the inner frame design of the Tendyne bioprosthesis; thus, the valve function was normal in both patients.

The ELASTA CLIP procedure followed by TMVR is a bail-out technique to treat failed TEER. As this procedure will not be applied on a routine daily basis, the technical complexity is a key criterion for its application. The ELASTA CLIP procedure is relatively easier to perform compared with other transcatheter electrosurgical techniques, such as LAMPOON (Laceration of the Anterior Mitral leaflet to Prevent Outflow ObtructioN).[14-16] The modified transapical ELASTA CLIP offers additional advantages over the transseptal approach and may therefore be the preferred technique in patients undergoing transapical TMVR. Our study results are limited by the small number of included patients.

Conflict of Interest Statement

Joerg Kellermair has received speaker's fees from Abbott. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: ELASTA-CLIP, Tendyne, TMVR, transapical, electrosurgery