

Step-by-Step Guide for Percutaneous Mitral Leaflet Repair

How the quickly evolving MitraClip device can be used successfully
in concert with modern imaging technology.

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In 1991, Alfieri and his colleagues first described the surgical repair of anterior leaflet prolapse using an edge-to-edge technique by opposing the middle scallops of the anterior and posterior leaflets with a stitch, creating a so-called dual- or double-orifice mitral valve (Figure 1).¹⁻³ The clinical success and simplicity of this technique prompted interest in development of a catheter-based technology that would enable interventional cardiologists to perform percutaneous, endovascular valve repair in the cardiac catheterization laboratory. During the last decade, the MitraClip device (Abbott Vascular, Santa Clara, CA) has rapidly evolved as a percutaneous method for successful double-orifice mitral valve repair using a transseptal approach.⁴⁻⁷ MitraClip has received CE Mark approval, and its use is becoming increasingly widespread in Europe, where a high proportion of patients are at high risk for surgery. In the United States, the ultimate application of the device will depend in large part on the results of the randomized EVEREST trial.

Specific anatomical features that are favorable for this technique have been previously described.^{6,7} It is particularly important to evaluate the transthoracic, echocardiographic, parasternal short-axis images with color Doppler interrogation of the mitral regurgitation (MR) jet. This view is the single most commonly omitted part

of conventional echocardiographic examinations, which are necessary to evaluate MitraClip therapy. Adequate evaluation includes assessment of the leaflet coaptation length, the flail width, the flail gap, and the absence of leaflet calcification at the potential point of clip attachment, along with careful scanning of the mitral funnel with color Doppler interrogation in the parasternal

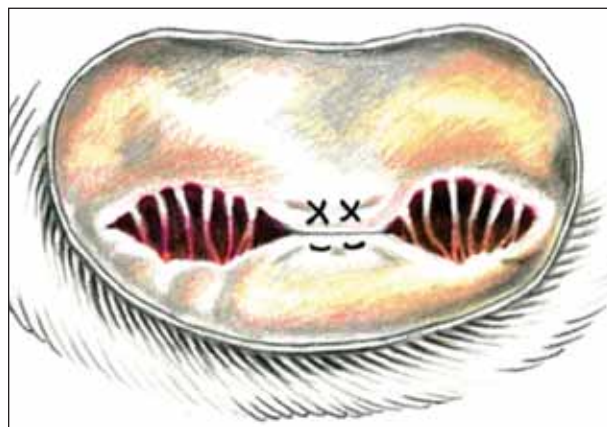


Figure 1. Double-orifice surgical mitral valve repair with suture. Surgical repair of anterior leaflet prolapse using edge-to-edge technique by opposing the middle scallops of the anterior and posterior leaflets with a stitch, creating a so-called dual- or double-orifice mitral valve.

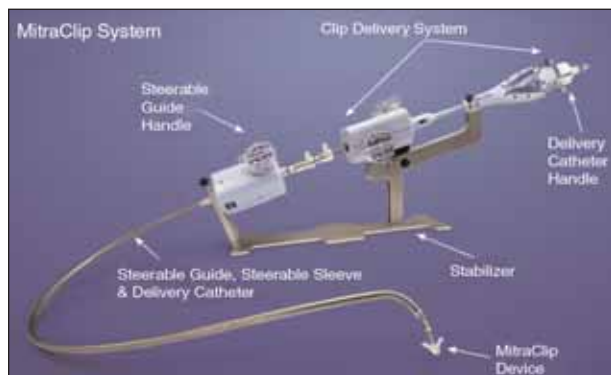


Figure 2. MitraClip system components. The valve repair system uses a detachable clip and a triaxial catheter system with a steerable guide catheter and a clip delivery system (CDS).

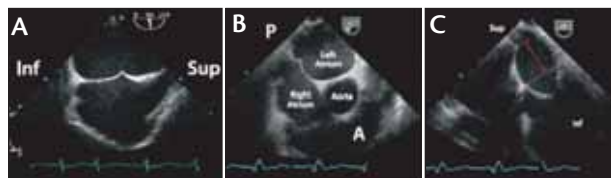


Figure 4. Transseptal puncture guided by transesophageal echocardiography (TEE). Using TEE bicaval (A) and short-axis views at the base of the heart (B), the position of the puncture site is evaluated, and tenting of the atrial septum can be seen as the transseptal needle is pushed against it. The tenting should be close to the posterior edge in the short-axis view and close to the superior edge of the fossa ovalis in the bicaval view. Afterward, using a long-axis, four-chamber view (C), the catheter tip should be moved to as high a position (at least 3 cm above the plane of the mitral valve) as possible while remaining in the fossa ovalis. Transseptal puncture should be only performed if such tenting is clearly seen in both of these views (A,B).

short-axis view to be sure that the MR jet origin is central, and ideally, relatively discrete, with the origin located within the central two-thirds of the line of leaflet coaptation.

The MitraClip system consists of a steerable guide catheter and a CDS, which includes the detachable clip itself (Figure 2). The clip is a Dacron-covered mechanical device with two arms that are opened and closed by control mechanisms on the CDS. The two arms have a span of approximately 2 cm when opened in the grasping position (Figure 3); the width of the clip is 4 mm. On the inner portion of the clip, there is a U-shaped gripper that matches up to each arm and helps stabilize the leaflets from the atrial aspect as they are captured during closure of the clip arms. Leaflet tissue is secured between the arms and each side of the gripper, and the

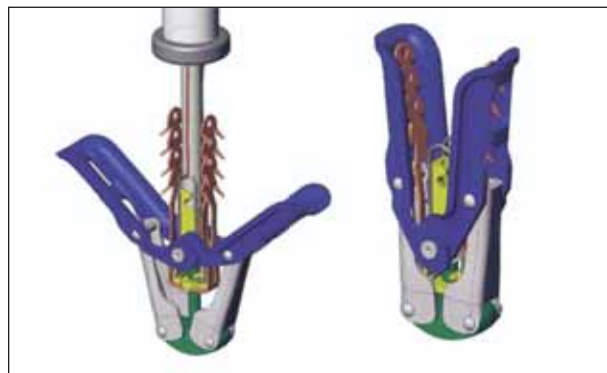


Figure 3. Schematic drawing of the components of the MitraClip device. On the inner portion of the clip, there is a U-shaped gripper that matches up to each arm and helps stabilize the leaflets from the atrial aspect as they are captured during closure of the clip arms. Leaflet tissue is secured between the arms and each side of the gripper, and the clip is then closed and locked to effect and maintain coaptation of the two leaflets.

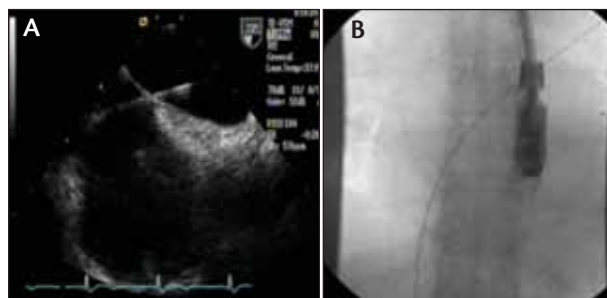


Figure 5. Advancement of a Mullins sheath and dilator over the guidewire into the left atrium (LA). After transseptal puncture, an 8-F Mullins sheath and dilator are advanced into the LA using a 260-cm, 0.035-inch, extra-stiff, J-tipped Amplatzer guidewire (AGA Medical Corporation, Plymouth, MN) (A). Ideally, the tip of the guidewire should be in left upper pulmonary vein (B).

clip is then closed and locked to effect and maintain coaptation of the two leaflets (Figure 3).

The tip of the guide catheter is delivered to the LA using a transseptal approach over a guidewire and tapered dilator. The guide catheter is 24 F proximally and tapers to 22 F at the point where it crosses the atrial septum. A steering knob on the proximal end of the guide catheter, marked as \pm , allows for flexion and movement of the distal tip.

PROCEDURAL TECHNIQUE

The MitraClip repair procedure consists of four main steps: (1) transseptal puncture and steerable guide catheter insertion; (2) steering/positioning of the guide



Figure 6. Dilation of the septum. The guide catheter and dilator tip are advanced slowly through the atrial septum by gradually advancing the dilator and steerable guide catheter assembly into the LA. The dilator is identified by its echo signature, which has a dashed or spiral appearance.

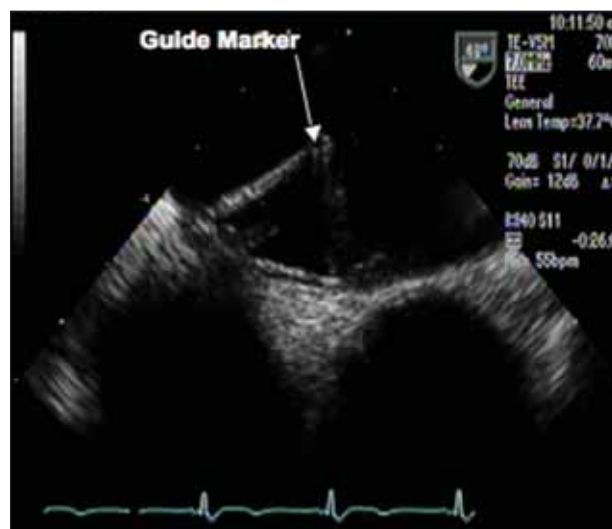


Figure 7. Advancement of the guide catheter into the LA. It is very important not to place the guide catheter tip too far into the LA to avoid contact with LA walls but rather to aim for a position of approximately 1 or 2 cm across the atrial septum in the center of the LA in the short-axis view at the base.

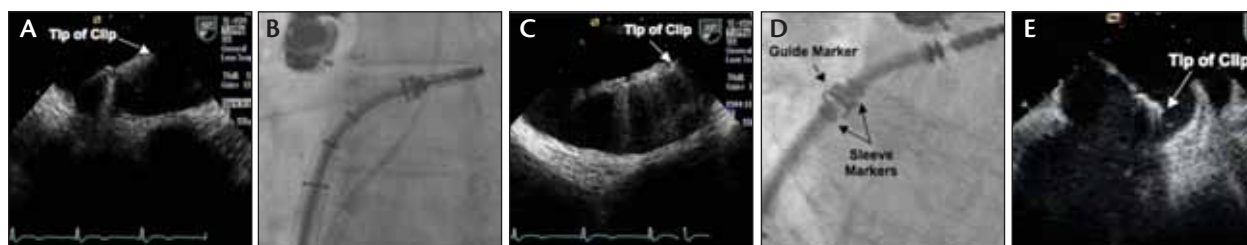


Figure 8. Steering and positioning of the MitraClip CDS in the LA. The CDS is advanced until its tip is even with the guide tip under fluoroscopic guidance. The CDS is then further advanced into the LA while observing the MitraClip device in the short-axis view at the base or two-chamber intercommissural TEE views to avoid tissue contact (A,B). The CDS is further advanced until the guide tip marker is centered between the sleeve markers, as determined by fluoroscopy. Afterward, the CDS is steered down toward the mitral valve (C-E).

catheter and CDS; (3) leaflet grasping, leaflet insertion assessment, and clip closure; and (4) MitraClip deployment and system removal.

The procedure is performed with the patient under general anesthesia using fluoroscopy, and primarily, TEE guidance. It is critical that the interventional operator and the echocardiographer have a common vocabulary for the basic procedural TEE views so that clear communication can be maintained during the procedure.

Vascular Access

A 6-F arterial and 8-F venous sheath are placed in the left femoral artery and femoral vein, respectively. A 14-F sheath is placed in the right femoral vein for transseptal access and guide catheter delivery. Using the left

femoral access, a 7-F, balloon-tipped, pulmonary artery catheter and a 6-F, pigtail, left ventricular (LV) catheter are placed. Cardiac output and baseline pulmonary capillary wedge, left ventricular, and pulmonary artery pressures are measured. An activated clotting time (ACT) of 250 to 300 seconds is maintained throughout the procedure, with ACT measurements obtained every half an hour.

Transseptal Puncture and Steerable Guide Catheter Insertion

Initially, an 8-F Mullins sheath, and then a transseptal needle, are advanced into the right atrium (RA). Because of the need to approach the mitral valve at appropriate angles in all three planes of the valve to

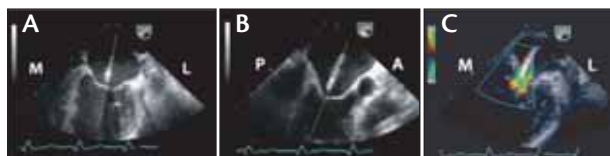


Figure 9. Steering of the clip toward the mitral valve. The MitraClip device is steered down until the trajectory is perpendicular to the line between the annular hinge points of the mitral valve in both the left ventricular outflow tract (LVOT) (A-P alignment) and two-chamber intercommissural (M-L alignment) imaging planes (A,B). The clip is positioned over the MR jet origin to split the jet (C).

ensure successful and adequate grasping of the mitral leaflets, it is critical that the transeptal puncture is placed relatively posterior and relatively high in the fossa ovalis. This high puncture allows an adequate working space and distance above the mitral leaflets (ideal height from the annulus should be 3.5–4 cm) for the delivery catheter manipulations, clip opening, and clip retraction during the grasping (Figure 4A through C). If the transeptal puncture is placed too low in the fossa, the guide catheter tip may lie just above and too close to the mitral annular plane, and subsequent orientation of the CDS to position the clip appropriately and grasp the leaflets may not be possible because of the inadequate space in the LA above the annular plane. The transeptal puncture should also be optimally positioned from the anteroposterior perspective to enable guide tip positioning near the line of leaflet coaptation (Figure 4B).

Using the TEE short-axis view at the base of the heart, positioning of the potential puncture site is evaluated prior to needle advancement. The tenting of the atrial septum can be seen as the transeptal needle is pushed against it (Figure 4B). The catheter tip should be close to the center of the fossa ovalis in this view to be able to place the guide catheter in the same plane as the line of coaptation. Additionally, using a long-axis, four-chamber view, the catheter tip should be moved to as high a position as possible while remaining in the fossa ovalis (Figure 4C). Transeptal puncture should be only performed if such tenting is clearly seen in both of these views (Figure 4B,C).

After the appropriate transeptal puncture is achieved and the LA-LV pressure is measured at baseline, a 0.035-inch, 260-cm, extra-stiff, J-tipped Amplatzer guidewire is ideally placed in the left superior pulmonary vein or is alternatively looped in the LA (Figure 5). Intravenous heparin is administered (50–70 U/kg) to achieve an ACT \geq 250 seconds.

After removal of the Mullins sheath and the dilator, the guide catheter and dilator assembly are advanced



Figure 10. Opening of the clip arms. The clip arms are opened to 180° and aligned perpendicular to the line of coaptation in the LVOT view. In the LVOT view, the open arms should be visible and symmetric (A). Arm alignments are checked again in two-chamber intercommissural and transgastric short-axis views (B,C).

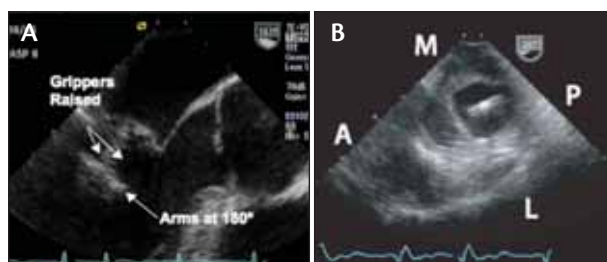


Figure 11. Crossing the mitral valve with the clip. After the proper alignment is achieved, the clip is advanced into the LV so that the clip arms are under the free edges of the mitral leaflets (A). Free motion of the leaflet edges is important to note, and restriction of the leaflets by the clip arms means it is not far enough below the free edges to achieve a successful grasp. Using LVOT and short-axis views, a final check of the perpendicular orientation is performed with the clip in the LV to be sure there is no deviation of clip orientation to the mitral leaflets (B).

into the atrial septum, and the puncture site is dilated to accommodate a 22-F guide catheter by gentle pressure and forward movement of the dilator tip, which can be visualized by echocardiography because of echogenic coils (Figure 6). Once the dilator tip is halfway to three-quarters across the septum, waiting a few seconds is often useful to allow the atrial septum to stretch. Advancement of the guide catheter tip across the septum is usually easier afterward. It is very important not to place the guide catheter tip too far into the LA but rather to aim for a position of approximately 1 or 2 cm across the atrial septum in the center of the LA in the short-axis view at the base (Figure 7).

Steering and Positioning of the Guide Catheter and CDS to the Mitral Line of Coaptation

Using the short- and long-axis views by TEE, the location of the distal tip of the guide catheter tip relative to the mitral valve plane must be determined (parallel vs perpendicular) (Figure 8A). Ideally, the initial transeptal

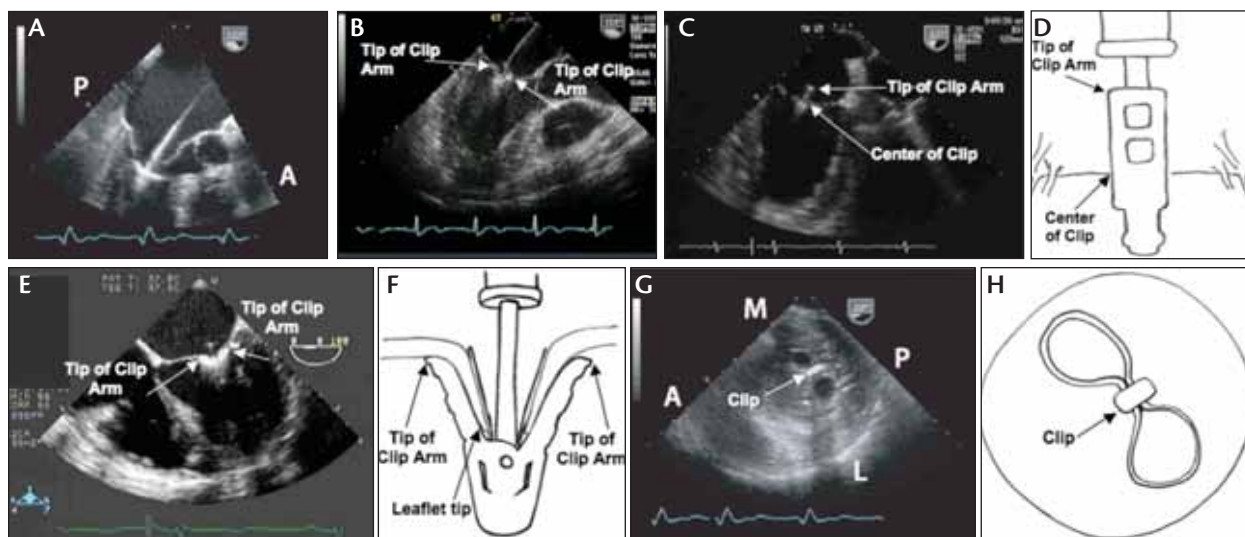


Figure 12. Grasping of leaflets. The leaflets are grasped by retracting the delivery catheter slowly as the mitral leaflets are closing in systole in the LVOT view (A,B). If the leaflets are successfully immobilized by the open clip, the grippers are then quickly lowered, and the clip is closed to approximately 60° (B-G). When fully inserted, the leaflets should appear to enter the center of the clip in the two-chamber intercommissural view, and the leaflets should be stable medial and lateral to the clip (C,D). This can also be confirmed in the four-chamber view (E,F). Finally, the MitraClip device is again assessed in the LV to confirm that the clip arms are perpendicular to the line of coaptation in transgastric short-axis view (H). There should also be medial and lateral contact between the anterior and posterior leaflet during diastole adjacent to the MitraClip device.

puncture site positions the guide catheter so that its clockwise rotation moves the tip posterior and cephalad. If the guide catheter tip is not in a favorable position, tip deflection can be added using the guide catheter steering knob.

It is critical to carefully de-air the guide catheter upon removal of the dilator and guide assembly once the guide catheter tip is 1 to 2 cm across the atrial septum prior to advancement of the CDS. TEE and fluoroscopic guidance are both necessary as the CDS exits the guide catheter tip to ensure that the tip of the clip remains away from the atrial wall (Figure 8A-D). The midesophageal, two-chamber, long-axis (intercommissural) view allows for evaluation of the clip location medially and laterally along the line of mitral coaptation (Figure 8E). The midesophageal, long-axis, LVOT view allows for assessment of clip location anteriorly or posteriorly within the mitral orifice. The transgastric short-axis view is the best view for evaluating clip arm orientation and supplants the intercommissural view for assessment of device position along the line of coaptation. Mitral leaflet grasping during pullback of the CDS is often best monitored in the LVOT view to observe the anterior and posterior leaflet capture within the open clip arms.

Once the clip and the CDS are safely outside the guide catheter tip and the fluoroscopic CDS markers are seen to appropriately straddle the radiopaque marker

on the guide catheter tip (Figure 8D), the first adjustments in position are made to direct the clip medially toward the apex of the heart, and thereby toward the mitral orifice. Typically, this can be achieved by turning the M knob (medial flexion of CDS) to the CDS and modestly torquing the guide catheter clockwise (posterior) to avoid contacting either the posterior left atrial wall or the anteriorly located aortic root (Figure 8C). The delivery catheter of the CDS tends to advance when deflection is applied to the steerable sheath of the CDS, requiring periodic withdrawal of the delivery catheter handle.

Fine adjustments in steering can be performed incrementally to align the clip and delivery catheter parallel with the long axis of the heart and perpendicular to the mitral valve opening. Incremental medial steering changes of the CDS or modest advancement or withdrawal of the guide catheter allow movement of the clip tip to a position just over the middle scallop of the anterior (A2) and posterior (P2) leaflets of the mitral valve. Using the LVOT view, further fine steering movements in the anteroposterior direction (by modest rotation of the guide catheter [counterclockwise for anterior, clockwise for posterior] or using the A/P knob) are made to move the clip to the appropriate position (Figure 9A,B). These views must be checked several times to be certain that movement in one plane has not

changed the position of the catheter in the orthogonal plane.

The delivery catheter is then advanced 1 to 2 cm to assess the trajectory of the clip. Once in the correct position in both planes (LVOT and intercommissural views), color flow of the jet is evaluated. If the orientation of the clip is correct, the clip will split the MR jet in both views (Figure 9C). Both the guide catheter and the CDS can be advanced or pulled back slightly as one unit by pushing or pulling the stabilizing platform to help position the clip over the origin of the MR jet without significantly changing delivery catheter trajectory. While forward advancement moves the system laterally, its withdrawal moves it toward the medial commissure. Clockwise and counterclockwise guide catheter manipulation helps to adjust the device position anteriorly and posteriorly without significantly affecting delivery catheter trajectory. The clip is then opened to 180°, and the grippers are fully raised using fluoroscopy and TEE (Figure 10A,B).

Transgastric short-axis imaging is used to rotate the clip so that the orientation of the clip arms is perpendicular to the line of coaptation (Figure 10C). This step is critical because significant deviation from a perpendicular alignment may result in inadequate grasp of the mitral leaflets. Multiple, short, to-and-fro motions are made with the delivery catheter handle during rotation of the clip to orient the clip arms and relieve the torque, which tends to be stored within the CDS. After perpendicular clip arm alignment is achieved, the clip is advanced into the LV so that the clip arms are under the free edges of the mitral leaflets (Figure 11A,B). Free motion of the leaflet edges is important to note, and restriction of the leaflets by the clip arms means the clip is not far enough below the free edges to achieve a successful grasp. Generally, the most proximal portion of the gripper must be beneath the leaflets.

Using LVOT and short-axis views, a final check of the perpendicular orientation is performed with the clip in the LV to be sure that there is no deviation of clip arm orientation to the mitral leaflets (Figure 11A,B). If there is deviation, the clip arms can be everted and withdrawn into the LA, where readjustments to the position can be made. Another passage to the LV can be made because adjustment of clip position while it is in the LV is very limited and not recommended.

Leaflet Grasping, Leaflet Insertion Assessment, and Clip Closure

The leaflets are grasped by retracting the delivery catheter in the LVOT view while the clip arms are open approximately 120° (Figure 12A,B). Remarkably, the leaflets tend to fall into the clip as the clip is pulled back.

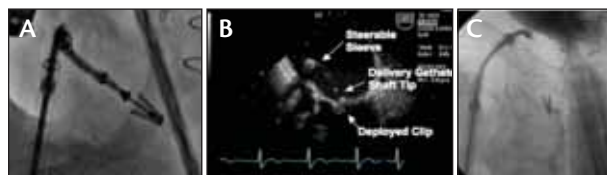


Figure 13. MitraClip device deployment and system removal. Once the optimal reduction in the MR jet is achieved, the clip is released using fluoroscopic guidance (A). Right anterior oblique caudal or left anterior oblique cranial views may be used for a side view of the clip after deployment. It is critical that the tip of the delivery catheter is carefully retracted back into the guide catheter to avoid damage to the LA. Careful and reverse steering with slow retraction of the CDS back into the guide catheter is performed using TEE (B). Once the CDS is retracted, the guide catheter is withdrawn into the RA and removed (C). Hemodynamic measurements, mainly simultaneous LV and pulmonary capillary wedge or LA pressures are repeated after clip placement.

Retraction should be done in a slow, smooth manner to capture the leaflet edges. If atrial fibrillation is present, more than one attempt may be needed to capture the leaflets.

When the leaflets are successfully immobilized by the open clip, the gripper is quickly lowered, and the clip is closed to approximately 60° (Figure 12C through G). A successful grasp captures the mitral leaflets and produces a double-orifice mitral valve with reduction in MR (Figure 12H). Careful interrogation in the LVOT view using slow-motion frame analysis is very critical to make sure that both leaflets are captured by the clip arms (Figure 12B). If there is significant motion of the mitral leaflet just as it enters the clip, the resulting grasp may not be adequate for a long-term result. Release of the clip and repeat grasping is then necessary. If the leaflets are stable and immobile at the clip entry point, an adequate grasp has been achieved. The presence of a stable double orifice should be confirmed in the short-axis view (Figure 12G,H).

Multiple TEE views with color and pulsed-wave Doppler should be used to evaluate the reduction in the MR jet. Although the clip has not been completely closed, a significant reduction in MR jet is expected. Once adequate leaflet insertion has been confirmed at 60°, continue slowly closing the clip just until the leaflets are coapted and MR is sufficiently reduced. Leaflet insertion assessment is repeated using LVOT, intercommissural, and transgastric short-axis views.

MitraClip Deployment and System Removal

Prior to clip release, the patient's systolic blood pressure is raised to the normal range using an alpha-ago-

"The MitraClip procedure is novel and has a significant learning curve."

nist, and the extent of the MR jet is re-evaluated. It is also important to remove the back tension from the delivery catheter by slightly advancing the CDS to allow proper assessment of the amount of residual MR. Once the desired endpoint is achieved, the clip is released under fluoroscopic guidance (Figure 13A).

Prior to release, the function of the locking mechanism is confirmed by rotation of the lock mechanism counterclockwise toward the open position to show that the clip remains closed and locked. The lock control line is then removed by pulling the line with a slow technique during which the operator can feel the line withdraw during each cardiac cycle. The clip is released, and the gripper line is pulled with the same slow technique as the lock line.

Right anterior oblique caudal or left anterior oblique cranial views may be used for a side view of the clip to confirm the degree of clip closure after its deployment and also to ensure that a modest space is maintained between the delivery catheter tip and the clip during lock and gripper line withdrawal. The CDS can be removed after the clip is free and the lines have been withdrawn. It is critical that the tip of the CDS is carefully retracted back into the guide catheter to avoid damage to the LA.

Careful and reverse steering with slow retraction of the CDS back into the guide catheter is performed using TEE (Figure 13B). Once the CDS is retracted, the guide catheter is withdrawn into the RA (Figure 13C) and is removed from the insertion site using figure-of-eight subcutaneous sutures, which are removed after several hours. In approximately 40% of cases, a second clip placement could be necessary for procedural success ($\leq 2+$ residual MR). If this is the case, a second CDS is advanced via the guiding catheter in a manner similar to that previously described, except during mitral valve crossing, when the clip arms are maintained in a more closed position to reduce the interaction with the first clip. The remaining steps are identical.

CONCLUSION

The MitraClip procedure is novel and has a significant learning curve. However, the main procedure elements are well developed, and this article summarizes the four

main steps: (1) transseptal puncture and steerable guide catheter insertion; (2) steering/positioning of the guide catheter and CDS; (3) grasping/leaflet insertion assessment; and (4) MitraClip deployment. Other procedural details, such as patient selection, echocardiographic considerations, and the current status of the EVEREST trial, are well described in other publications.⁸⁻¹⁴ ■

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