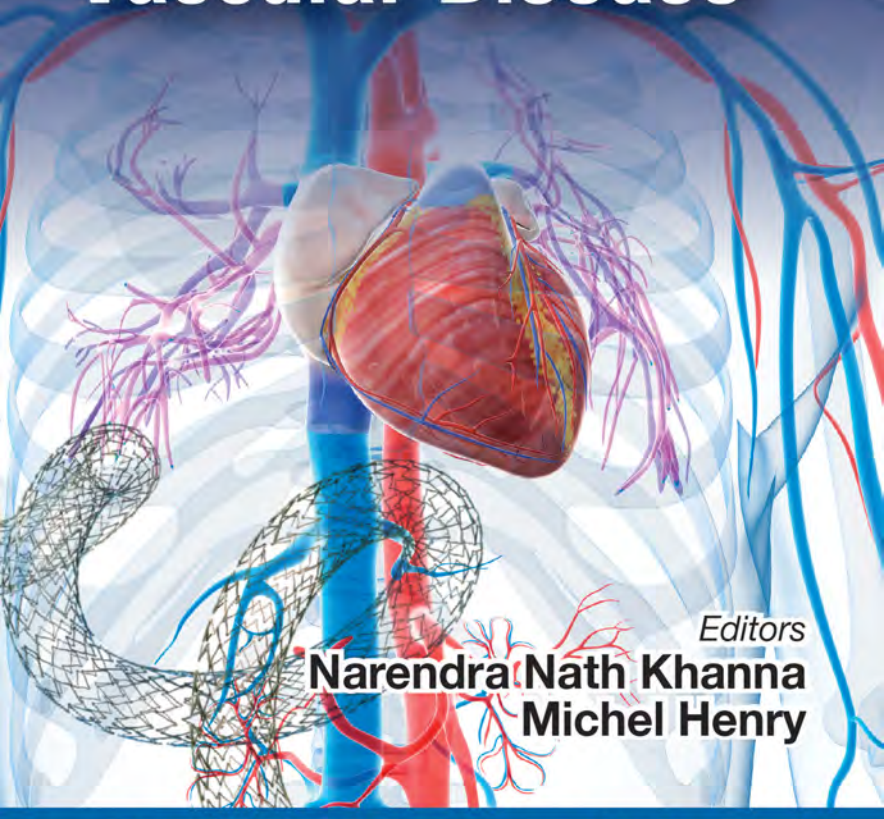
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Handbook of Interventions for Structural Heart and Peripheral Vascular Disease



Editors
Narendra Nath Khanna
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JAYPEE

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4

CHAPTER

Percutaneous Repair of Severe Mitral Regurgitation using the MitraClip System: Step-by-Step Guide

Yeo Khung Keong

JAYPEE BROTHERS

INTRODUCTION

The MitraClip is the first-in-class percutaneous therapy for severe mitral regurgitation (MR). It is a transcatheter technology emulating the double-orifice surgical techniques to MR repair pioneered by Alfieri et al.[1-3] The MitraClip device has been in US trials since 2003. The device was CE-marked in Europe in March 2008 and quickly gained early clinical acceptance as a treatment option for high-surgical risk patients with severe mitral regurgitation.[4-6] It was recently approved for use in the USA for prohibitive-risk degenerative MR in March 2014. In Singapore, the device was first approved for use in 2011, with the first case in Asia performed successfully at the National Heart Center, Singapore in April 2011.[7] This chapter reviews the basic procedural steps of the procedure.

ROOM SET-UP

The procedural room set-up is an important part of the MitraClip procedure and requires careful planning. A well-planned layout improves communication between the interventionalist, echocardiologist and anesthesiologist, reduces error and makes the entire procedure more efficient. A poorly planned room can result in excessive radiation exposure to team members or result in musculoskeletal injury.

The MitraClip procedure may be performed either in the cardiac catheterization laboratory or in a hybrid operating room. There are advantages and disadvantages to using either space but we feel this will largely be dependent on the logistics and physician preferences in each institution.

Basic Room Requirements and Set-up

The basic room set-up is as shown in Figure 1. The interventionalists work on the patient's right side while the

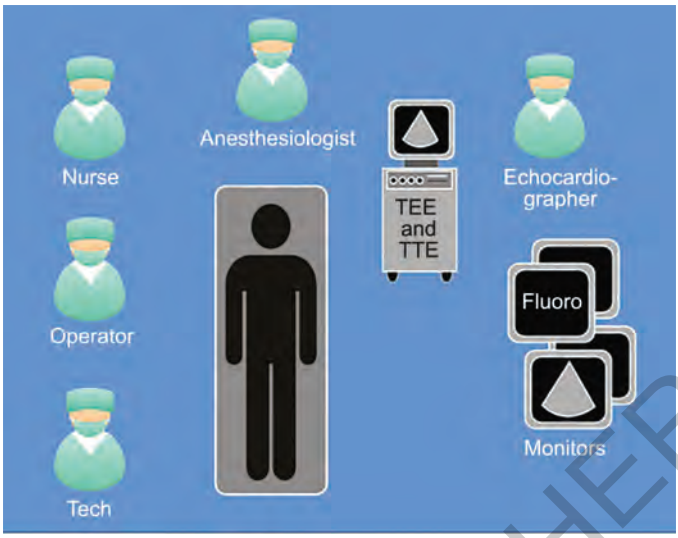


Fig. 1 Basic room set-up for the MitraClip procedure
Source: Abbott Vascular, 2012.

monitors are on the patient's left. These monitors should display real time fluoroscopic images, hemodynamics data, and echocardiographic images for the primary operator. It is not practical for the echocardiologist and the primary operator to share the same monitor. The echo machine and echocardiologist are on the left side of the patient's head. The fluoroscopy equipment is above the patient's head. The anesthesiologist and the anesthesia equipment are on right side of the patient's head. A long working table is required and located behind the operators. This allows the MitraClip guide and delivery system to be safely prepared without having any part off the sterile field. There needs to be a clear line of communication between the operator and the echocardiologist (i.e. no equipment should be in the way). Second, the echocardiologist should be in a comfortable position during the procedure. Since the echocardiologist is in close proximity to the fluoroscopy equipment, the use of lead or plexiglass shielding during the case is essential.

Device Overview

The MitraClip comprises of the clip itself, a clip delivery system (CDS), a guide, and a stabilizer (Figs 2 and 3). The clip itself is polyester-covered cobalt-chromium with two arms that are opened and closed by control knobs on the CDS. The two arms have a span of approximately 20 mm when opened in the grasping position. On the inner portion of the clip are "grippers", which appose and stabilize the leaflets from the atrial aspect as they are captured during closure of the

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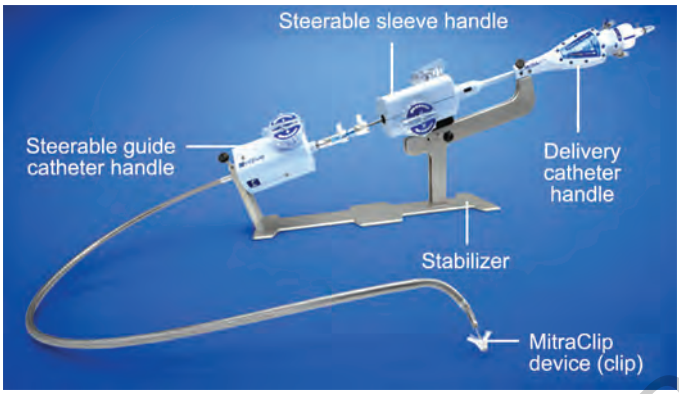
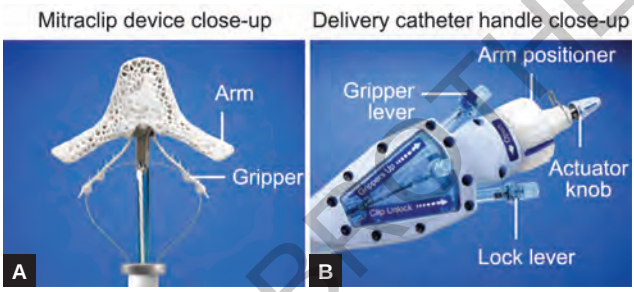
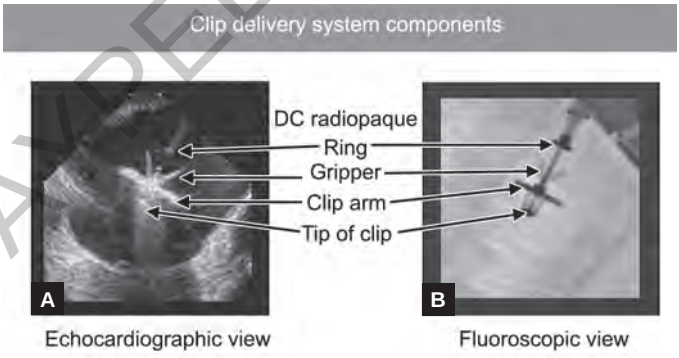


Fig. 2 Components of the MitraClip device
Source: Abbott Vascular, 2012.



Figs 3A and B Close-up of components of the MitraClip device
Source: Abbott Vascular, 2012.



Figs 4A and B (A) MitraClip components on echocardiography; (B) Fluoroscopy
Source: Abbott Vascular, 2012.

clip arms. When closed, the clip has an outside diameter of 15 Fr. It can hold up to 8 mm of leaflet height (vertically) and 4 mm of width (horizontally). Figures 4A and B show the clip as seen on echocardiography and fluoroscopy. The Guide is 24 F at the point of entry into the femoral vein and 22 F when across the interatrial septum.

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Procedure

The procedure is performed under general anesthesia primarily with transesophageal echocardiography (TEE) guidance although some fluoroscopy is used as well. General anesthesia is required because of the continuous use of TEE guidance and the need for the patient to remain completely still for the procedure.[6,8] Patients should also be on dual antiplatelet therapy.

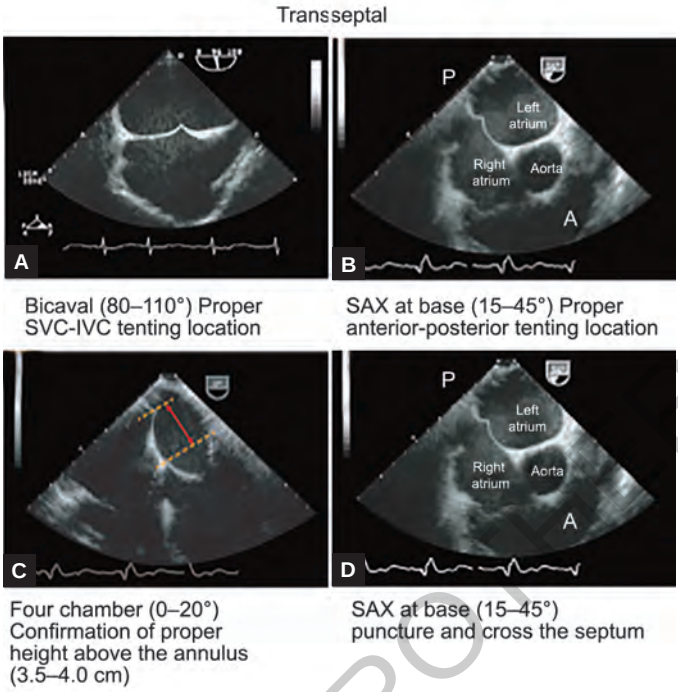
In an ideal world, the patient will have a Swan Ganz catheter and arterial line for hemodynamic monitoring. For the purpose of this chapter, we will focus only on the MitraClip procedure itself.

First, a standard 6 F or 7 F sidearm sheath may be placed in the right femoral vein. If Preclose technique for venous access hemostasis is desired, 2 Perclose Proglide devices (Abbott Vascular, Abbott Park, Illinois, USA) may be deployed at the this time.

TRANSSEPTAL PUNCTURE

The next step is TEE-guided transseptal puncture (Fig. 5). This is a critical step as the position of the guide determines the ease of maneuvering the CDS to the mitral valve. The sidearm sheath is exchanged for an 8 F Mullins sheath or SL0 catheter. For the puncture, three views are required to ensure that an appropriate position is selected. Then with a standard Brockenbrough or BRK needle, the transseptal needle-sheath/catheter assembly is brought down from the superior vena cava to the interatrial septum. A TEE-guided transseptal puncture is ideally in the superior and posterior part of the interatrial septum with the aim of obtaining adequate working space and distance above the mitral annulus (the ideal height from the annulus should be 3.5–4.0 cm). First, in the bicaval view, the transseptal needle should be seen to 'tent' the interatrial septum at the junction of the muscular and membranous septum (Fig. 5A). Once this has been achieved, the echocardiologist shifts to the short-axis view of the heart at the level of the aortic valve. In this short-axis view, the anterior-posterior orientation of the transseptal needle can be appreciated (Fig. 5B). The tenting should be positioned more posteriorly, i.e. more posterior than the midline position. In most cases, this may be almost two-thirds of the distance towards the posterior edge of the septum. If the tenting is seen to be too anterior, the operator may gradually and carefully clock the transseptal assembly until it is sufficiently posterior. In some cases, it may be necessary to verify the position in the bicaval view if there is extensive manipulation of the assembly. Next, the echocardiologist transitions to the long-axis four-chamber view. In this view, the purpose is to ensure that the transseptal puncture is at a height (approximately 3.5 to 4.0 cm) that ensures sufficient

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Figs 5A to D Transseptal puncture
Source: Abbott Vascular, 2012.

working space (Fig. 5C). This translates to the ability of CDS to reach the leaflets and yet can have space to pull back and grasp the leaflets. Only when all three views are appropriately selected should the transseptal puncture be performed by pushing the needle out of the sheath/catheter. The puncture should be performed in the short axis view (Fig. 5D). Once the transseptal needle is across the septum, the sheath/catheter is advanced into the left atrium. The needle and dilator can then be withdrawn. At this time, with the sheath/catheter in the left atrium, IV heparin may be given to achieve and maintain an activated clotting time (ACT) of >250 seconds throughout the procedure, with ACT measurements taken every 30 minutes. In some cases where the transseptal puncture is expected to be difficult, some operators may choose to give a small empiric dose of heparin (e.g. 1000 to 2000 units) to reduce the risk of thrombus formation on the transseptal assembly.

GUIDE POSITIONING

After the transseptal puncture, a 260-cm (0.035-in), super-stiff J-tipped Amplatzer guidewire is placed in the left upper pulmonary vein. The transseptal sheath/catheter is then removed and exchanged for an 18 F dilator, which is then

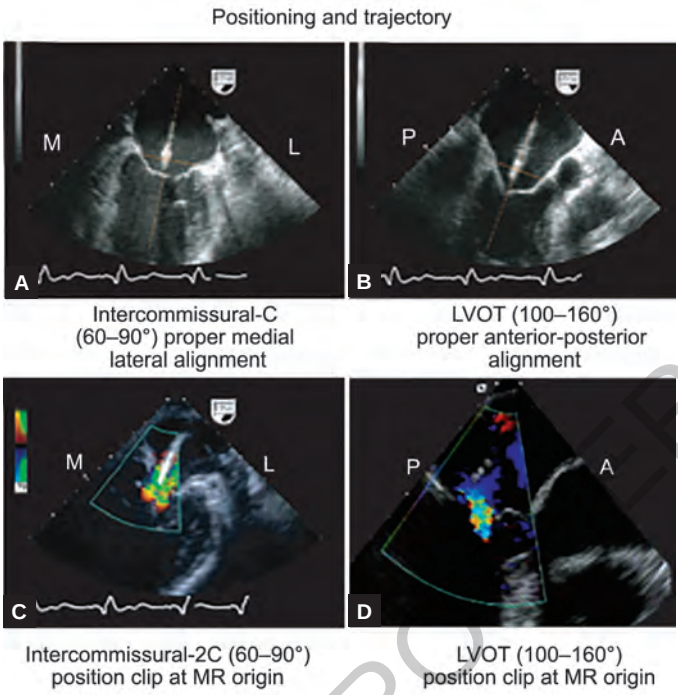
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used to dilate the femoral vein and the surrounding soft tissue. After this predilatation, the MitraClip guide is then carefully advanced into the femoral vein towards the interatrial septum. It is important to remember to turn the guide '(-)' knob so that the guide tip is as straight as possible, so as to facilitate entry into the vein and to reduce the risk of injury. All this while, fluoroscopy is used to ensure that the guidewire remains in the left upper pulmonary vein. The guide and the dilator are then visualized on TEE to cross the septum. With gentle and forward movement of the dilator tip, visible on TEE as echogenic spiral lines, the dilator tip first crosses the septum. It is important to be patient here, waiting a few seconds so as to allow the interatrial septum to stretch. This reduces the risk of tearing the septum, which may result in a large atrial septal defect. Gentle pressure will allow the dilator and then, the guide itself, to cross the septum. The tip of the guide is visible with its two ring markers. 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 its tip about 1 or 2 cm across the atrial septum in the center of the LA in the short-axis view at the base. It is critical to carefully de-air the guide catheter upon removal of the dilator and guidewire assembly once the guide catheter tip is 1 to 2 cm across the atrial septum prior to advancement of CDS.

STEERING AND POSITIONING OF THE MITRACLIP CDS

Once introduced into the guide catheter, the CDS is advanced until its tip is even with the guide tip under fluoroscopic guidance. Then, the CDS is further advanced into the left atrium while observing the MitraClip device in the short axis to avoid contact with the walls of the left atrium. The CDS is further advanced until the guide radiopaque tip ring marker is centered between the sleeve alignment markers with confirmation on fluoroscopy. Afterward, the CDS is steered down toward the mitral valve (Fig. 6A). The steering involves first turning the medial knob. As the knob is turned medially, the CDS will also turn anteriorly. Hence, the operator will need to compensate by 'clocking' the entire Guide. This turns the CDS posteriorly. These two steps are performed gradually and in tandem. The medial knob should not be clocked beyond 360 degrees. The CDS is then steered down until the trajectory is perpendicular to the line between the annular hinge points of the mitral valve in both the two-chamber intercommisural medio-lateral (M-L) (Fig. 6B) and the left ventricular outflow tract (LVOT) antero-posterior (A-P) (Fig. 6C) alignment imaging planes. The clip is positioned over the MR jet origin to split the jet (Fig. 6D).

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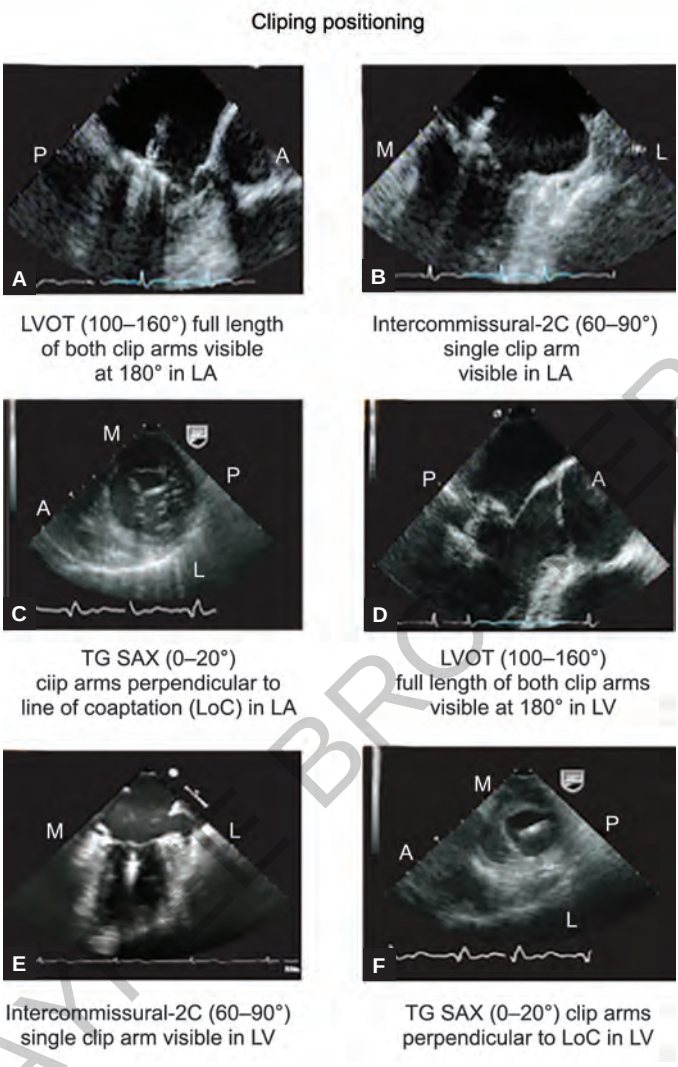


Figs 6A to D MitraClip positioning and trajectory
Source: Abbott Vascular, 2012.

GRASPING THE LEAFLETS

Once the clip is in position, the clip arms are opened to 180° and the grippers raised completely (Fig. 7A). The clips are then aligned perpendicular to the line of coaptation in the LVOT view. In the LVOT view, the open arms should be visible and symmetric. Arm alignments are checked also in the two-chamber intercommissural and the transgastric short-axis or 3D 'en-face' views (Figs 7B and C). If the position is not ideal, the clip may be adjusted medially or laterally by withdrawing or advancing the guide (via the stabilizer) respectively. When doing so, it is important to check the position of the guide with respect to the septum so that the guide does not slip back into the right atrium. Less commonly, the clip may also be adjusted using the medial knob to turn medially or laterally. To position the clip anteriorly or posteriorly, the guide will have to be clocked or counter-clocked. The use of the Anterior/Posterior knob is reserved for advanced steering and will not be discussed here. Perpendicularity of the clip arms to the line of coaptation of the leaflet is critical. If grasped off-axis, MR can be worsened due to deformation of the valve. To check for perpendicularity, the transgastric or 3D 'en-face' view may be used and the clip may then be rotated to ensure perpendicularity.

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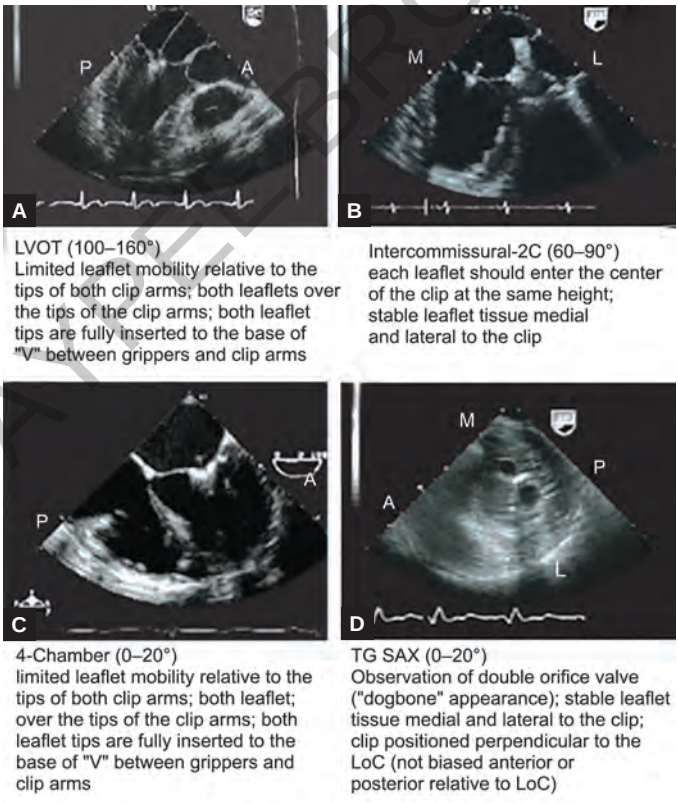


Figs 7A to F MitraClip positioning
Source: Abbott Vascular, 2012.

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. 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, intercommissural, and transgastric or 3D 'en-face' views, a final check of the perpendicular orientation is done with the clip in the LV to be sure there is no deviation of clip orientation to the mitral leaflets (Figs 7D to F). The clip arms are then closed to approximately 120° so as to allow the leaflets to 'sit' in position once they have been captured.

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The leaflets are grasped by retracting the delivery catheter slowly as the mitral leaflets are closing in systole in the LVOT view. If the leaflets are successfully stabilized by the open clip, the grippers are then lowered and the clip is closed to about 60°. When fully inserted, the leaflets should be stable and immobile at the clip entry point in the LVOT view (Fig. 8A). In the two-chamber intercommissural view, the leaflets should enter the center of the clip and be stable medial and lateral to the clip (Fig. 8B). This stability can also be confirmed in the four-chamber view (Fig. 8C). Finally, the MitraClip device is assessed once more by the transgastric view or 3D 'en-face' view to ensure that the clip arms are perpendicular to the line of coaptation (Fig. 8D). There should also be medial and lateral contact between the anterior and posterior leaflets during diastole adjacent to the MitraClip device. 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, two-chamber intercommissural, 4-chamber and transgastric short-axis or 3D 'en-face' views. On the 3D 'en-face' views,



Figs 8A to D Leaflet insertion assessment
Source: Abbott Vascular, 2012.

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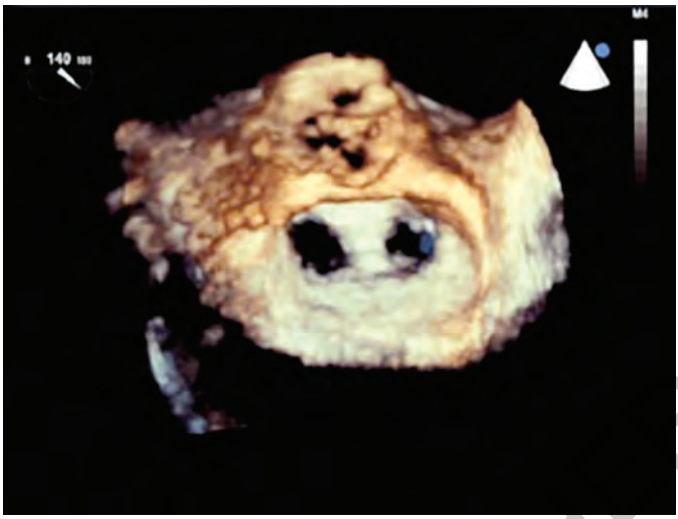


Fig. 9 3D 'en-face' view showing the dual orifice mitral valve. The aortic valve is seen superior to the mitral valve

the mitral valve will have a dual orifice appearance (Fig. 9). If there is any uncertainty about leaflet insertion or if the MR reduction is suboptimal, the clip arms may be opened and the grippers raised, so that further adjustments are made till there is a satisfactory result. Other key components of assessment include degree of MR reduction and gradient across the mitral valve. The acceptable gradient is determined on a case-by-case basis. In general, any gradient more than 5–7 mm Hg is a cause of concern. MR severity should also be assessed with the systolic blood pressure raised by vasoconstrictor drugs to simulate awake blood pressures.

MITRACLIP DEVICE DEPLOYMENT AND SYSTEM REMOVAL

Once optimal reduction in MR jet is achieved, the clip is released using fluoroscopic guidance. First, the device should undergo final arm angle check: this refers to an attempt to open the clip arms with the device in a locked state. It should not be possible to do so; this ensures that the clip cannot be opened inadvertently. Then the lock line is removed followed by another final arm angle check. The clip is then deployed by removing the safety pin and turned counter-clockwise 8 times. Once the clip is deployed, fluoroscopy is used to ensure that the clip is secure and there is no detachment of any leaflet. The gripper line is then removed. It is critical that the tip of the delivery catheter is carefully retracted back into the guide catheter to avoid damage to the left atrium. Careful and reverse steering with slow retraction of the CDS back into the guide

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catheter is performed using TEE. Once the CDS is retracted, the guide catheter is withdrawn into the right atrium (RA) and removed.

If the MR remains significant, a second clip may be placed while the guide remains in the left atrium. The steps are similar except that the clip should cross in the left ventricle with the clip arms closed so as to avoid excessive interaction with the first clip. Of course, extra caution should be instituted to avoid touching the first clip during the process of leaflet grasping.

Once the clip is deployed and the guide removed from the left atrium, the '(-)' knob is then turned to straighten the tip of the guide, and the guide removed from the femoral vein. Closure of the femoral vein access site is performed with a 'figure-of-8' suture or using the previously deployed Perclose devices. Protamine may be given to reverse anticoagulation.

CONCLUSION

This brief step-by-step description of the MitraClip procedure is only an introduction of the procedural steps. It is important to note that these basic steps apply to central MR. There are technical adjustments required for functional and degenerative MR, eccentric MR, broad jets and other scenarios. The MitraClip operator is encouraged to observe at least one procedure and undergo formal instruction by the manufacturer of the device before embarking on a case.

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