Transcatheter Edge-to-Edge Repair

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Foreword: The MitraClip Journey

In 1991, Ottavio Alfieri, an Italian cardiothoracic surgeon, took the bold and creative initiative to perform the world's first surgical edge-to-edge repair, successfully treating a patient with symptomatic mitral regurgitation. Dr. Alfieri had previously encountered a patient with a congenital double-orifice valve that was the inspiration for this simple, elegant, and highly effective surgical technique in properly selected patients. The repair became known as the "Alfieri stitch" (Figure 1), and because of the double-orifice valve created, it is also known as the "Bow-tie" or "Figure 8" procedure.

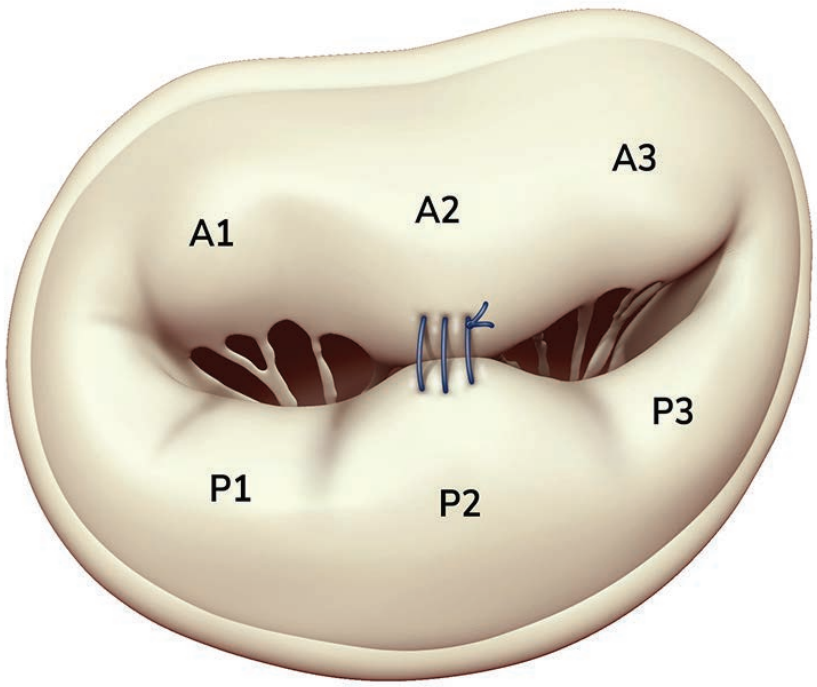

Figure 1. Alfieri Stitch

On encountering this surgical technique in 1998, it became apparent to us that there was a potential to adapt it to a transcatheter method to correct mitral regurgitation. We recruited a team of extremely talented engineers, formed a company, eValve, and embarked on efforts to develop a percutaneous therapy. Early catheter-based attempts to perform the Alfieri stitch were focused on creating two leaflet stabilizing arms that would allow percutaneous placement of a suture. After numerous iterations, it became clear that the stabilization device itself could effectively "grasp" the leaflets and bring them together, restoring coaptation. The "MitraClip" was thus born, and a novel transseptal delivery system was developed to allow steering and precise implantation of the clip, as well as repositioning if needed. The final "design freeze" occurred in 2001 and it is remarkable how similar present-day clips are to the first clinical iteration (Figure 2).

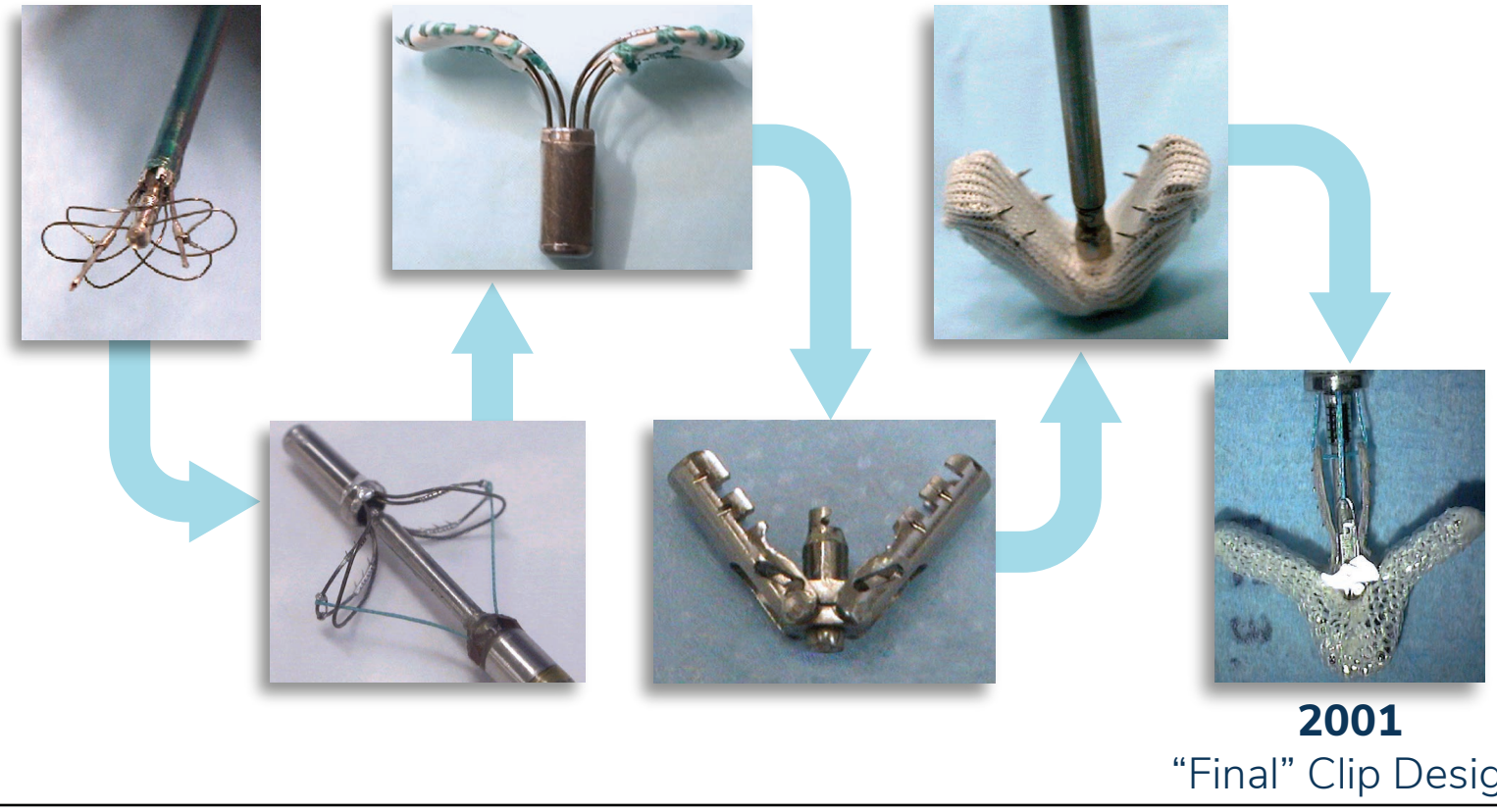

Figure 2. MitraClip Device Evolution

We performed the first human implantation of the MitraClip in 2003. The patient was a 58-year-old woman who suffered from bi-leaflet prolapse and severe, clinically debilitating mitral regurgitation. After a single clip was placed, her post-procedure mitral regurgitation was minimal and remained that way until she passed away in 2021 from a non-cardiac cause. The successful clinical use of the MitraClip today has exceeded our most optimistic hopes at inception. The procedure has been performed in more than 150,000 patients, and the device is on its 4th generation design, with a 5th generation soon to come.

Being involved with the advancement of healthcare technology is an exceptionally rewarding experience and participating in the process makes us better healthcare providers. It is a pleasure to witness the joy of patients and their families as they start life anew thanks to the hard work and passionate dedication of many clinicians, scientists, and med tech employees. Improvement in patient care is a complex, active process and does not occur without clinical leaders who are tireless advocates for bettering the care of their patients, and without whom this book would not be possible.

This MitraClip eBook is the latest expression of our current "best" understanding of the technical aspects of the MitraClip procedure, and given the online format, allows viewing of the material instantly for rapid reference. It is a remarkable accomplishment of Drs. Rogers and Asgar and all their collaborators and contributing authors. It is a privilege to be involved in this process and we reflect humbly on the number of lives that this technology has touched, and the future potential of the next wave of transcatheter valve technologies.

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Introduction from the Editors

MitraClip therapy is a unique and innovative percutaneous method of treating mitral regurgitation (MR) that has become the global “standard” for percutaneous MR treatment. One could not have imagined the exponential growth and refinement of this procedure over the last 20 years since the first human implant. And, despite the elapse of almost 2 decades, no other percutaneous treatment for MR has emerged as a significant alternative to MitraClip therapy, which has the ability to treat a vast array of different mitral pathologies.

The MitraClip procedure has special significance to us since we began our careers as this procedure was first introduced in the United States and Canada during early clinical trials, and our careers have grown alongside MitraClip with a deepening understanding of the technology and procedure. MitraClip therapy has become a large part of our interventional “DNA,” and the lessons learned have helped us to become more proficient in so many other related procedures.

We wish to acknowledge the educational grants that allowed this project to become a reality, and SCAI for providing logistic, editorial, and publishing support. The online public domain format of this book is unique and allows instant free access to anyone who wishes to consult this reference on the internet. Our vision was to make this book technologically contemporary and use the power of online content. We thank the chapter authors who are global experts in MitraClip and for sharing their expertise and “procedural pearls.” We thank our mentors, past and present, who encouraged us to continually improve and look forward.

We dedicate this book to the innovators that developed the first MitraClip system, the early adopters of the technology that paved the way, and the patients who trusted us to use this “new” percutaneous method to treat their leaking heart valves. Finally, we thank our families who are our inspiration and greatest supporters.

PART I

Pre-procedure Evaluation

CHAPTER 1
Basic Evaluation of Mitral Regurgitation

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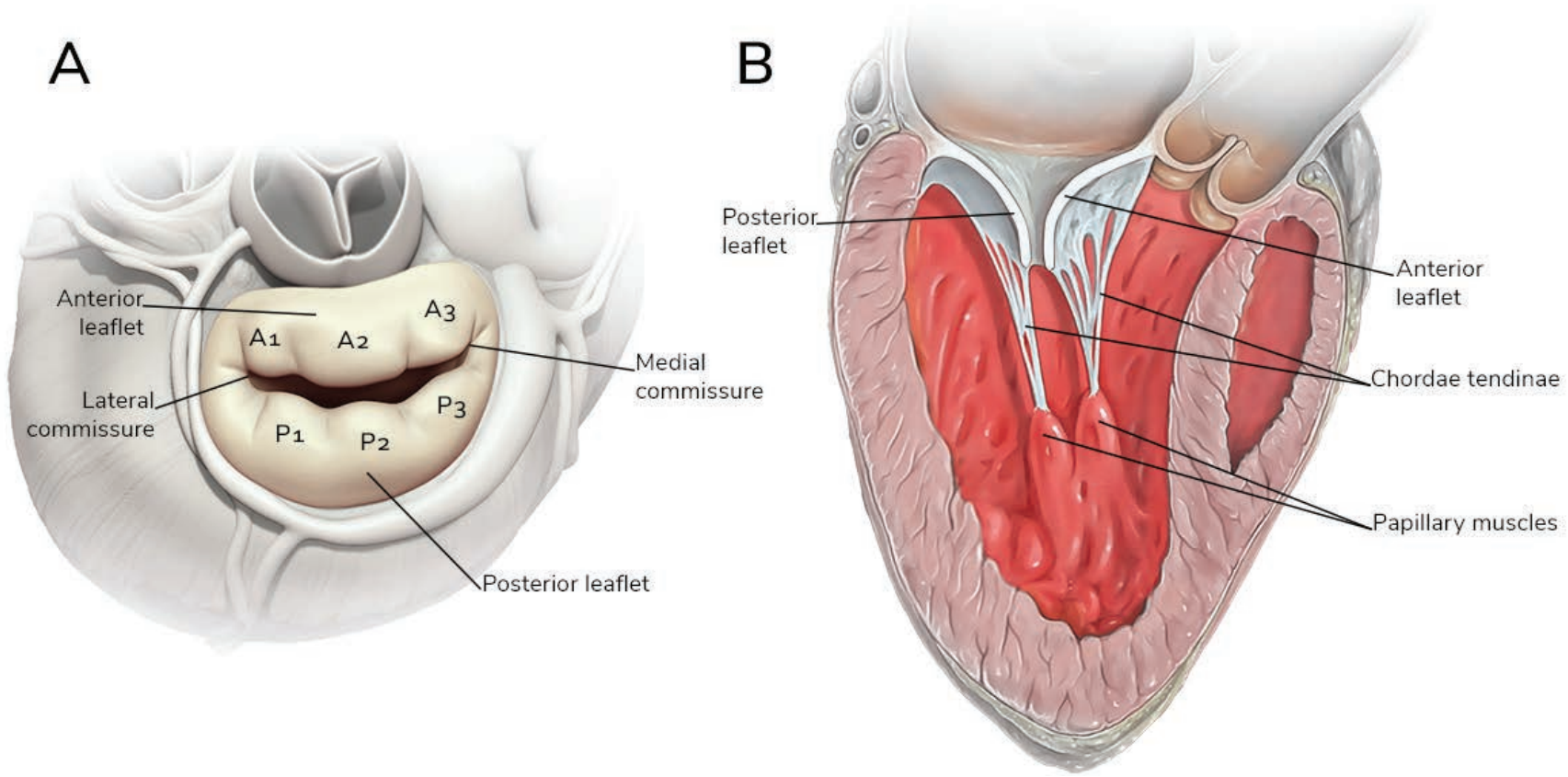
Introduction

The mitral valve (MV) is a complex and dynamic structure that is functionally dependent on the interplay of anatomic components and hemodynamic conditions. Comprehensive mitral valve imaging is necessary to understand mitral valve anatomy, the mechanism of mitral regurgitation (MR), and to plan appropriate therapies. This chapter focuses on the key anatomic features of the mitral valve, mechanisms and types of MR, and the approach to comprehensive imaging.

Basic anatomy

The mitral valve apparatus is composed of the anterior and posterior leaflets, the mitral annulus, and the subvalvular apparatus, which includes the chordae tendinae and papillary muscles (central illustration). As the left atrium (LA) and left ventricle (LV) are directly associated with the MV, these chambers also play an important role in the underlying foundation and dynamic function of the valve. Disruption to any one of these components can interfere with effective leaflet coaptation and lead to resultant mitral regurgitation. The unique interactions between these anatomic features under different volume and hemodynamic conditions can be particularly relevant in planning transcatheter mitral valve interventions.[1]



Central Illustration. Mitral Valve Anatomy

(A) Surgeon's view of mitral valve; (B) left ventricular structures

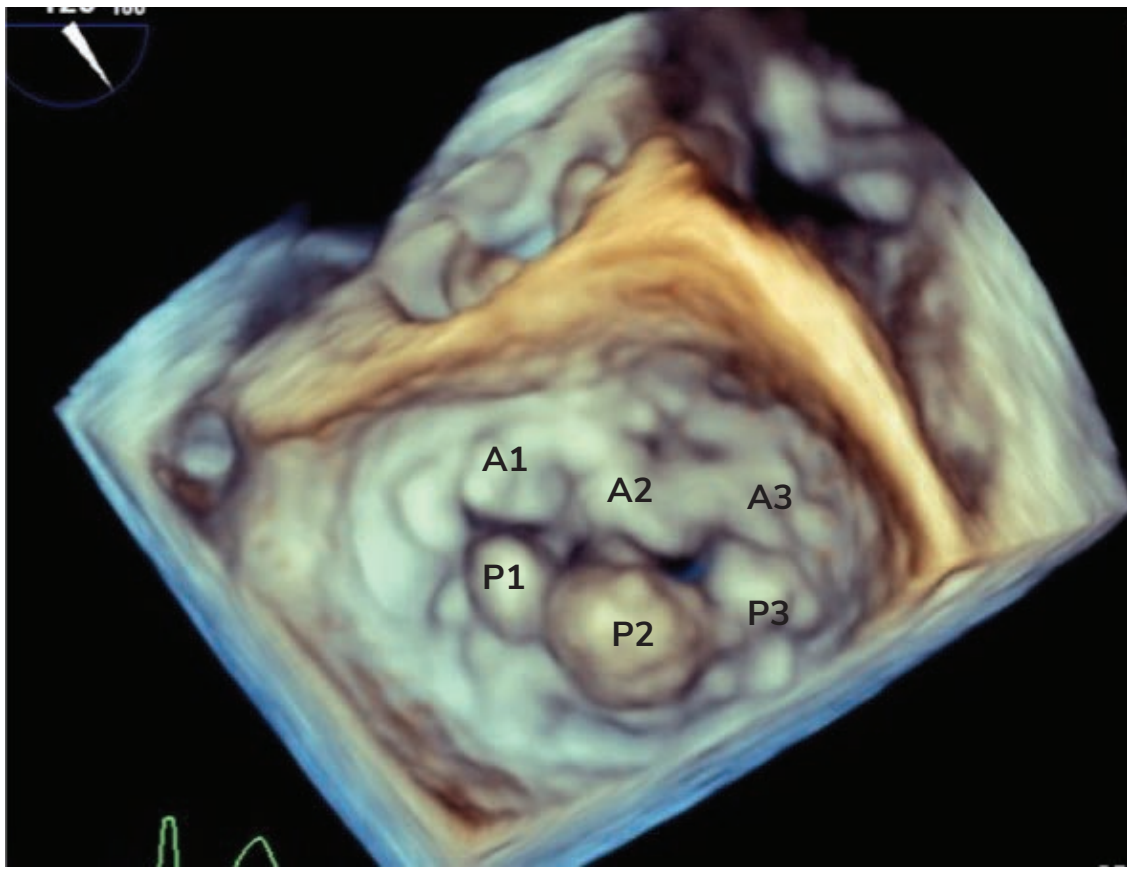


Figure 1. 3D En Face View of Mitral Valve (Surgeon's View) With Individual Leaflet Segments

Leaflets

The two leaflets of the mitral valve are structurally different with a narrow, crescentic shaped posterior leaflet that occupies approximately two-thirds of the annular circumference and a broad anterior leaflet which has fibrous continuity with the left and non-coronary aortic cusps.[2] The posterior leaflet has indentations/slits dividing the leaflet into scallops: P1 (most lateral and adjacent to the left atrial appendage), P2 (central), and P3 (most medial) (Figure 1).[3] For TEER, the graspable length of the posterior leaflet decreases medially and laterally toward the commissures. Prominent or exaggerated indentations can be seen in myxomatous mitral valve disease (cleft-like indentations which extend >50% of leaflet height). Along with true clefts (which are congenital separations most often in the anterior leaflet and associated with primum atrial septal defects), these can result in pathological regurgitation.[2] The anterior leaflet does not have such anatomical indentations, but maintains the same nomenclature with the A1 segment being the most lateral to A3 medially.

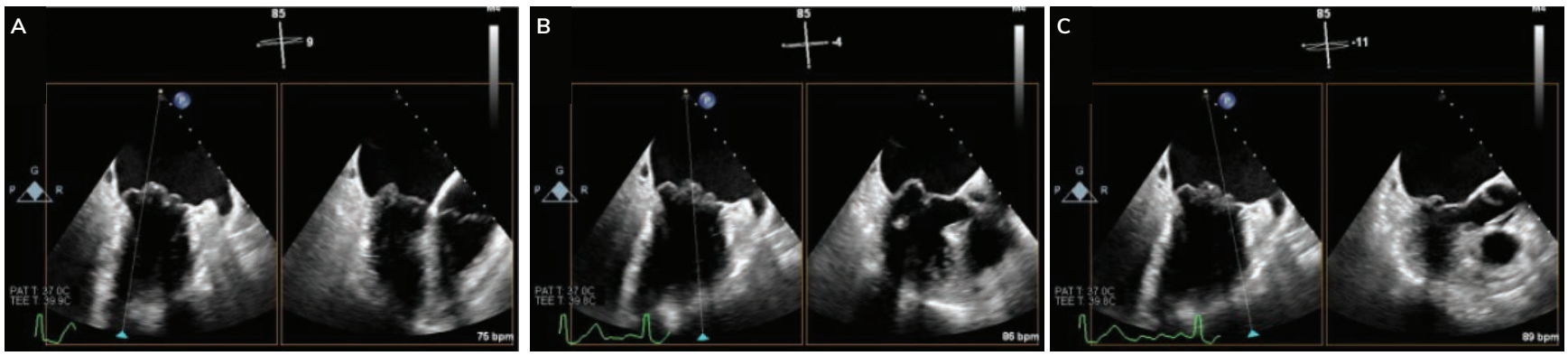


Figure 2. Biplane Images in Bicommissural View

Biplane image taken in bicommissural view help identify each segment for associated pathology as well as the relative leaflet length; (A) medial, (B) central, (C) lateral.

Annulus

The annulus is pliable, fibrous tissue that delineates the junction between the LA and LV and provides attachment for the mitral valve leaflets.[2,4] The annulus is nonplanar and saddle shaped, with anterior and posterior peaks and commissural (medial and lateral) valleys, which allow dynamic motion throughout the cardiac cycle, lessening stress on the leaflets during systole.[4] The anterior aspect is in fibrous continuity with the aortic valve, although the posterior annulus is more muscular with greater translational motion and therefore susceptible to dilation and calcification.[2]

Subvalvular apparatus

The subvalvular apparatus of the MV is composed of the chordae tendinae and papillary muscles (PM), which provide support and tethering of the mitral valve leaflets to the left ventricle. The posteromedial papillary muscle gives chords to the medial half of both leaflets and the anterolateral PM chords attach to the lateral half of both MV leaflets.[2] Primary, secondary, and tertiary chords attach to different aspects of the leaflets, providing necessary leaflet stability. Chordal density increases medially and laterally and may increase the risk of MitraClip entanglement when attempting to place a clip at these segments. The PMs play a critical and complex role in the mechanics of effective MV leaflet coaptation by maintaining optimal geometric configuration and tension on the leaflets.[3]

MR etiology

Understanding the complex anatomy and interactions of the mitral valve apparatus is imperative to identifying the mechanism of regurgitation and relevant treatment strategies. The most common method of determining MR etiology is the Carpentier classification based on leaflet motion (Table 1). Type I refers to normal leaflet motion but is related to annular dilation (secondary/functional MR) or leaflet perforation. Type II leaflet motion is excessive/redundant, most commonly due to mitral valve prolapse or flail, and Type IIIa refers to restrictive motion throughout the cardiac cycle such as in rheumatic valve disease or other post-inflammatory/valvulitic processes.[5,6] Type IIIb is restricted leaflet motion only in systole, most commonly seen in ischemic cardiomyopathy.[6] Combining this functional classification with morphological/structural assessment allows a relatively simple approach to evaluating MR mechanism.[7] Primary (degenerative or organic) and secondary (functional) MR are the main etiologies of MR with important differences that influence treatment options, although some patients can have mixed etiologies with some components of both primary and secondary MR.

Table 1. Carpentier Classification

	TYPE I	TYPE II	TYPE IIIA	TYPE IIIB
Mechanism	Normal leaflet motion and position	Excessive/redundant leaflet tissue and motion	Restricted leaflet motion in both systole and diastole	Restricted leaflet motion in systole
Anatomical abnormality	Annulus dilation or disrupted leaflet integrity (tear, cleft, or perforation)	Subvalvular apparatus (chordal elongation or rupture) or excessive/ redundant leaflet tissue	Commissural fusion, leaflet rigidity with thickening/ calcification, shortened/thickened chordae	Chordal shortening, ventricular enlargement with resultant tethering
Primary MR	Leaflet perforation (ie, endocarditis) or cleft	Mitral valve prolapse or flail (ie, Barlow's disease)	Rheumatic mitral valve disease, extensive mitral annular calcification or valvulitis (SLE, radiation, drugs)	
Secondary MR	Annular dilation - left atrial enlargement (atrial functional MR) or ventricular (dilated cardiomyopathy)			Ischemic mitral regurgitation or dilated cardiomyopathy

Primary MR

Primary, or degenerative, MR refers to conditions in which the structure of the mitral valve itself is abnormal. The most common is mitral valve prolapse, which ranges from fibroelastic deficiency (FED), generally localized to 1 segment with ruptured chords, to diffuse myxomatous disease (DMD, also called Barlow's disease) with diffuse thickening/redundancy and multi-segment pathology (Figure 3).[8] Degenerative mitral valve disease may also encompass those patients with mitral annular calcification (MAC), a chronic fibro-calcific process often seen in the elderly and associated with both stenosis and regurgitation, generally limiting patient eligibility for TEER techniques.

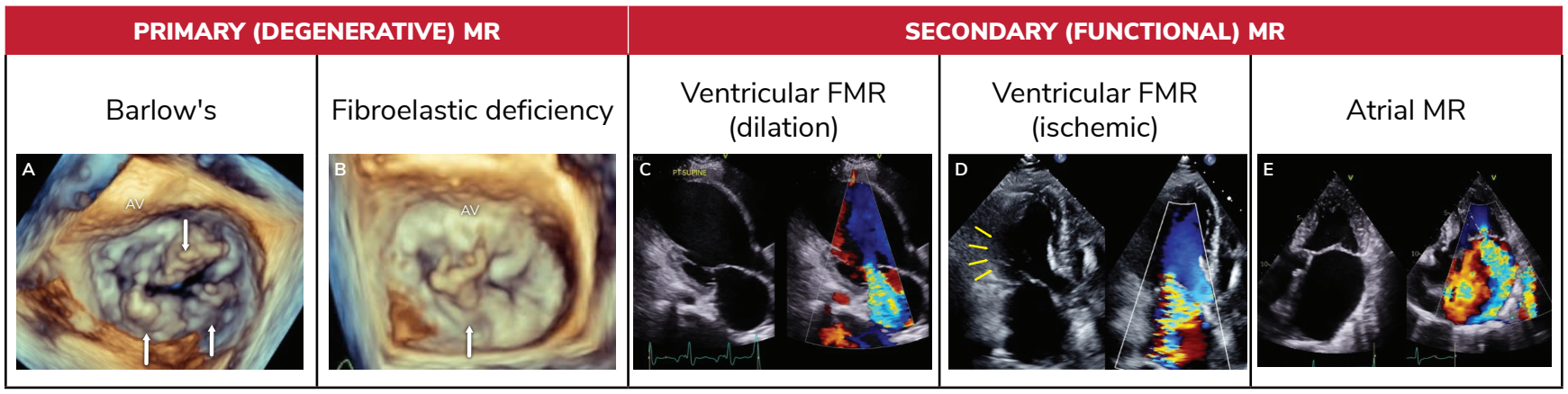


Figure 3. Mechanisms of MR

(A) Barlow's valve with multisegmented prolapse (arrows); (B) fibroelastic deficiency with an isolated segment of P2 flail (arrow); (C) ventricular FMR secondary to LV dilation and dysfunction; (D) ventricular FMR secondary to an inferolateral wall motion abnormality (arrows); (E) atrial functional MR

Secondary MR

Secondary, or functional MR refers to conditions in which the mitral leaflets themselves are normal, but regurgitation occurs secondary to forces acting on the valve related to abnormalities of the LV or LA. For example, changes in LV geometry due to LV dysfunction and dilation lead to reduced closing forces on the leaflets and systolic tethering of the leaflets into the LV.[7] This can be due to global LV enlargement and dysfunction or segmental inferoposterior wall motion abnormalities causing restriction of the posterior leaflet (ischemic).

Other causes of secondary MR include LV dyssynchrony due to left bundle branch block (LBBB) and the under-recognized group of atrial functional MR, often seen in individuals with heart failure with preserved ejection fraction (HFpEF) with significant comorbidities.[9,10] In this group of patients, isolated annular dilation may be the cumulative result of chronic atrial fibrillation (AF)-related LA enlargement with concomitant HFpEF and chronically elevated filling pressures from diastolic dysfunction.[9] While the mechanism of MR can be defined in most cases, it should be highlighted that often pathology can be multifactorial, particularly in elderly patients where a combination of intrinsic valve disease, aging-related fibrocalcific changes, and a functional component of MR can coexist.

Assessment of MR

The assessment and grading of MR is typically established first with transthoracic echocardiography (TTE). Transesophageal echocardiography (TEE) is important in inconclusive or technically difficult cases, and when surgical/transcatheter intervention is dependent on more detailed evaluation of mechanism and localization or pathology.[5] The TTE evaluation of MR uses both qualitative and quantitative criteria with 2D, 3D, and Doppler imaging. Qualitative and semiquantitative parameters are described in Table 2. Quantitative parameters (Table 3) can be derived from PISA based methods (Figure 4) or through the use of quantitative pulsed Doppler (Table 4).

Table 2. Qualitative and Semi-quantitative Assessment of MR

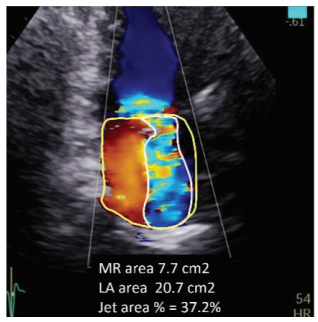
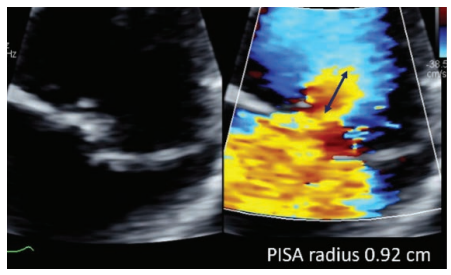
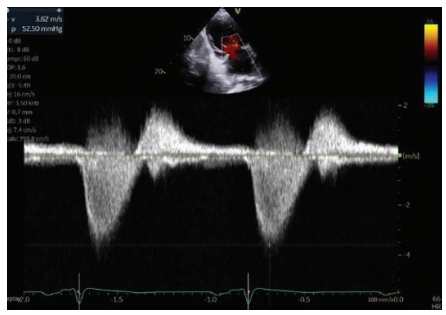
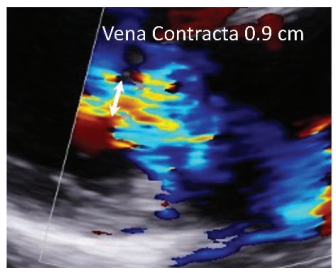
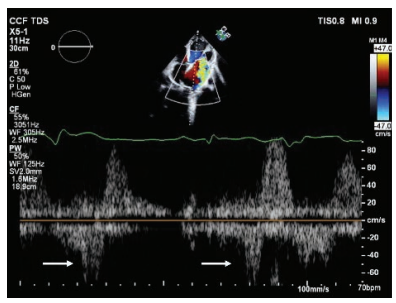
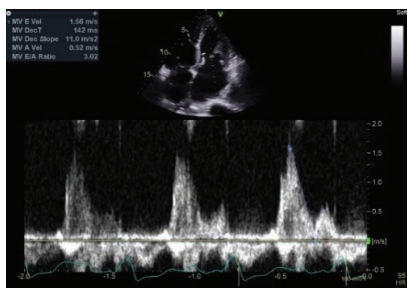
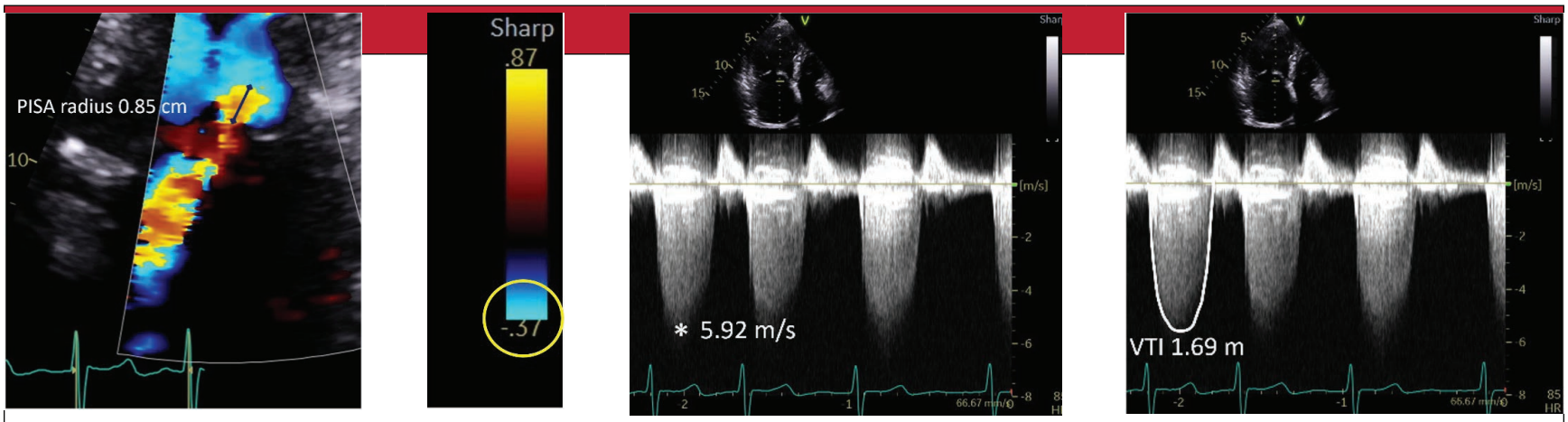
METHOD	DESCRIPTION	EXAMPLE	DEFINITION OF SEVERE
QUALITATIVE ASSESSMENT OF MR			
Jet area	• Apical view • Measure largest jet area compared to left atrial area		>50% LA
Flow convergence	• Shift the Nyquist baseline in the direction of the regurgitant jet to see hemispheric flow convergence • Measure PISA radius from vena contracta to point of color aliasing		Large, holosystolic
CW jet	• Align CW with MR jet		Dense, holosystolic, triangular
SEMI-QUANTITATIVE ASSESSMENT OF MR			
Vena contracta width	• Narrowest segment of the color jet, typically at the level of the regurgitant orifice		>0.7 cm
Pulmonary vein flow	• PW 1 cm into pulmonary vein		Systolic flow reversal
Mitral inflow	• PW at the leaflet tips in the apical four chamber view		E velocity >1.2 m/s E wave dominant

Table 3. Quantitative Assessment of MR

PARAMETER	MILD	MODERATE	SEVERE
Effective regurgitant orifice area (EROA) (cm^2)	<0.20	0.20 – 0.39	>0.40
Regurgitant volume (mL)	<30	30-59	>60
Regurgitant fraction (%)	<30	30-49	>50

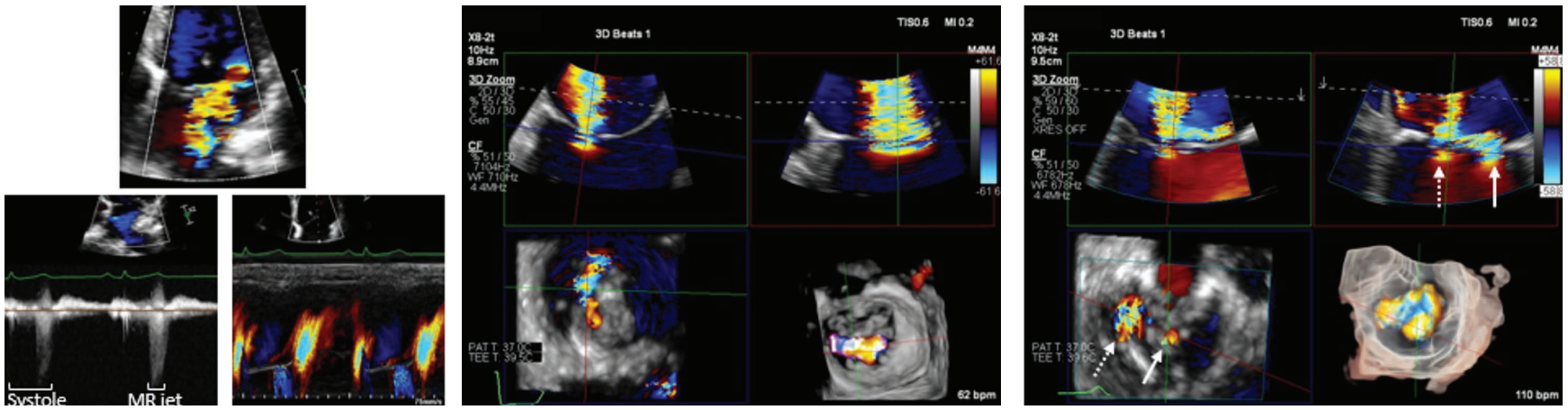
Table 4. MR Quantification Using the PISA Method



PISA radius (r) | Aliasing velocity (Va) | Peak velocity MR jet (PKVreg) | MR VTI (VTIreg)

PARAMETER	EQUATION	SAMPLE CALCULATION
Regurgitant flow (Rflow, mL/sec)	$2\pi r^2 \times Va$	$2\pi(0.85)^2 \times 0.37 = 1.67$ mL/sec
EROA (cm^2)	$Rflow/ PKV_{reg}$	$1.67/5.92 = 0.28\ cm^2$
Regurgitation volume (Reg vol, mL)	$EROA \times VTI_{reg}$	$0.28 \times 1.69 = 0.48$ mL

There are several important factors and pitfalls in the assessment of MR that require consideration. Although quantification is preferred, discrepancies can exist and are largely limited by precision and reproducibility, related to both technical and hemodynamic factors. A given value of effective regurgitant orifice area (EROA) could have a larger or smaller regurgitant volume depending on the driving velocity of flow across the valve (hemodynamic loading conditions) and the duration of MR, which is often mid to late systolic in cases of DMR/prolapse and may overestimate the severity.[7] This is particularly important in secondary MR where the complex interplay between LV end diastolic volume and LV ejection fraction can result in proportionate or disproportionate MR with resultant differences in prognostic outcomes.[11] Quantification of multiple jets of MR is challenging, and although theoretically multiple PISA-derived EROAs or VC areas could be added, validation is lacking, making accurate quantification with this method unreliable (Figure 4).[11] The PISA technique also assumes a circular origin, however particularly in secondary MR where the jet origins can be more elliptical due to the leaflet/annular distortion, this can lead to underestimation. 3D VC area is a useful method in these instances when technically feasible (Figure 5).[11] Due to these limitations, ultimately the grading of MR severity is often determined based on a combination of multiple parameters.



A. Non holosystolic MR

B. Noncircular MR orifice

C. Multiple jets

Figure 4. MR Quantification by PISA Pitfalls

(A) MR that is not holosystolic may result in overestimation of MR severity. While the PISA is measured in a single frame, this MR is only present in late systole as indicated by the CW jet and color M mode. (B) MR will be underestimated by the PISA method in the case of a noncircular orifice, in this case MR that spans the coaptation zone. (C) A case of multiple MR jets, one central (dashed arrow) and one commissural (solid arrow).

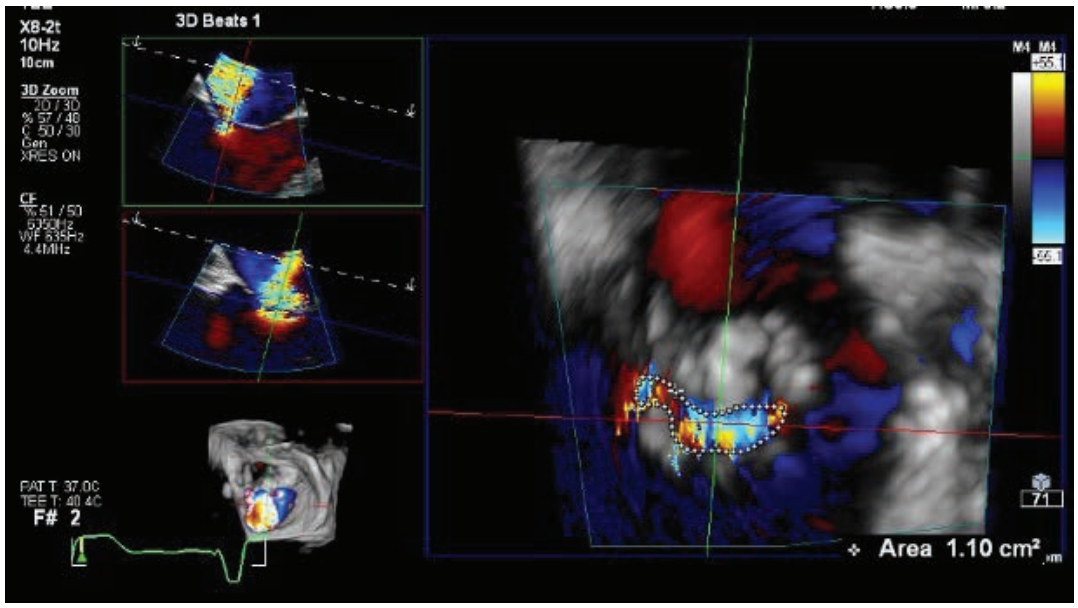


Figure 5. 3D Vena Contracta Area to Quantify MR Severity

3D data set with color and MPR planes create a short-axis view of the MR vena contracta, which is then measured.

Hemodynamic considerations

Several hemodynamic and loading conditions can impact the assessment of MR. Acute MR can be seen in critically ill patients such as in mechanical complications post myocardial infarction (MI) or endocarditis, where traditional TTE features of severe MR may be lacking. The combination of low blood pressure and high left atrial pressure reduces the driving pressure, lowering MR jet peak velocities and often creating less conspicuous color jets. Loading conditions also impact MR assessment, where lower blood pressure, such as during sedation or anesthesia, can result in underestimation of MR compared to normal physiologic conditions[5] (Figure 6). Another important etiology of MR is related to dynamic LVOT obstruction with resultant systolic anterior motion (SAM) of the mitral valve, which may be present or absent depending on the physiologic conditions, and during provocation. This dynamic cause of MR is commonly associated with hypertrophic cardiomyopathy or basal septal hypertrophy causing a classic posteriorly directed jet, which can be relevant in the operative setting (Figure 7). Finally, the assessment of MR during atrial fibrillation and ectopy can be challenging due to variable cycle lengths and rapid heart rates, and hence serial evaluation should be performed under more stable rate/rhythm conditions.

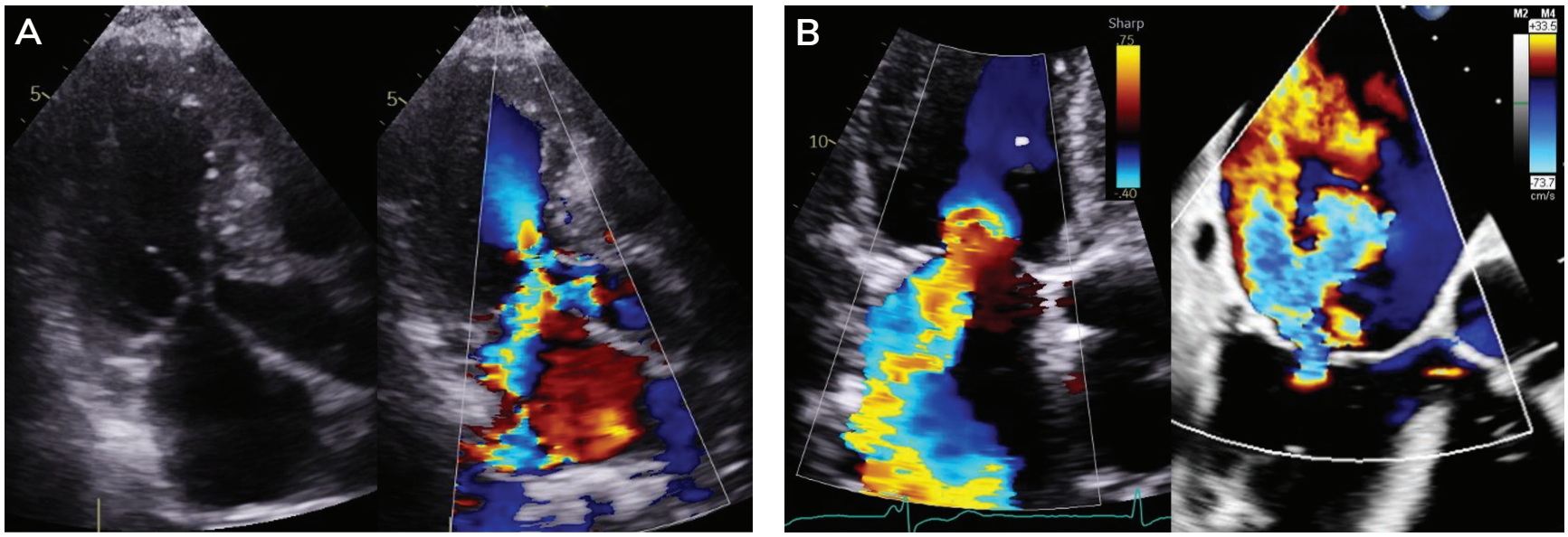


Figure 6. MR Hemodynamic Considerations

(A) Systolic anterior motion of the mitral valve with resultant MR. (B) Severe FMR on TTE (left panel) with PISA 1.3 cm at aliasing velocity 0.40 cm/s. FMR is significantly less on TEE with sedation (right panel), PISA 0.5 cm at aliasing velocity 33.5 cm/s.

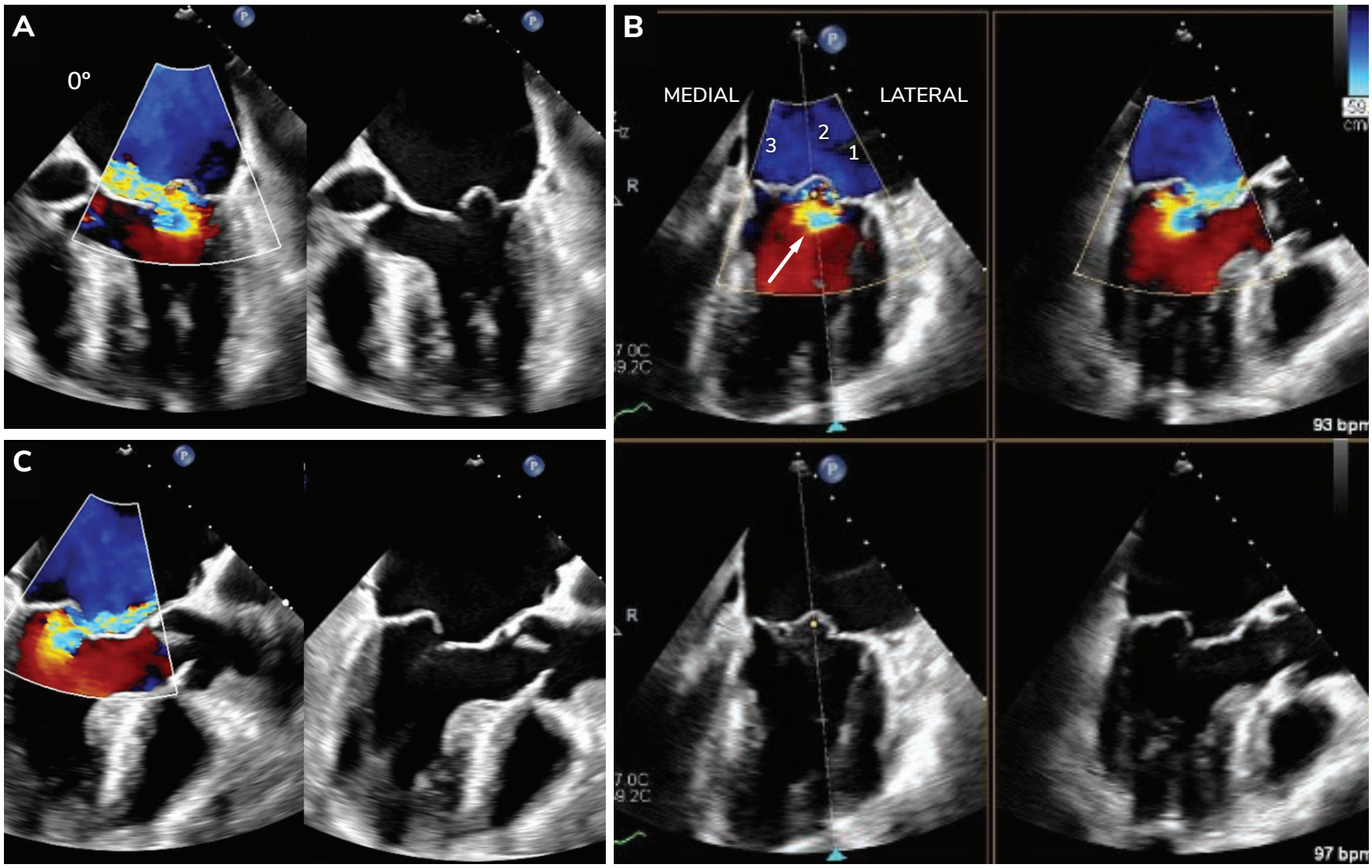


Figure 7. Key Views for 2D TEE Evaluation of MR Mechanism and Origin

(A) 0-degree view with color shows an anteriorly directed MR jet. With color turned off, the MR mechanism is shown to be posterior leaflet prolapse and flail. (B) Bicommissural view lays out the valve from medial to lateral and localizes the MR origin to the middle segment of the valve (arrow). Biplane through the MR origin shows the corresponding long-axis view of the MR jet, and with color turned off, the underlying anterior and posterior leaflet anatomy is visualized. (C) Long-axis view of the mitral valve with and without color showing posterior leaflet prolapse and flail with severe MR.

Implications for other cardiac structures

MR (regardless of etiology) ultimately results in a progressive volume overload situation on the LV with resultant elevation of LA and pulmonary venous pressures. Chronic severe MR allows some degree of compensation and left ventricular remodeling compared to acute severe MR which results in significantly elevated pressures in an unadapted LA and pulmonary circulation.[7] Secondary or functional MR has a different pathophysiology, often a consequence of other myocardial or myopathic disease processes, and is often multifactorial. For this reason, optimization of comorbid cardiac disease such as LV dysfunction, dyssynchrony, and AF, are all important prior to the accurate assessment of MR severity.

TEE evaluation

TEE is an important tool to define mitral valve anatomy, localize MR jet, and understand the mechanism of MR. Mitral regurgitation severity is defined on TEE in a similar manner to the techniques discussed previously for TTE. When evaluating the mitral valve on 2D TEE, there are two key views:

- Bicommissural view lays out the valve from medial to lateral
- Long-axis view shows anterior versus posterior leaflet anatomy and mechanism of MR

2D biplane imaging from the bicommissural view is useful by systematically assessing leaflet morphology across every segment and viewing each in long-axis orientation to understand exact pathology and location.

3D TEE of the mitral valve is instrumental for preprocedural planning and intraprocedural guidance by allowing precise definition and localization of MR origins and underlying leaflet anatomy (Figure 8). The atrial views are useful for understanding overall mitral valve anatomy, visualization of prolapse or flail segments, and general location of MR. The ventricular view is helpful to visualize the subvalvular apparatus, localize the MR origin through identification of the PISA, and confirm the presence or absence of clefts.

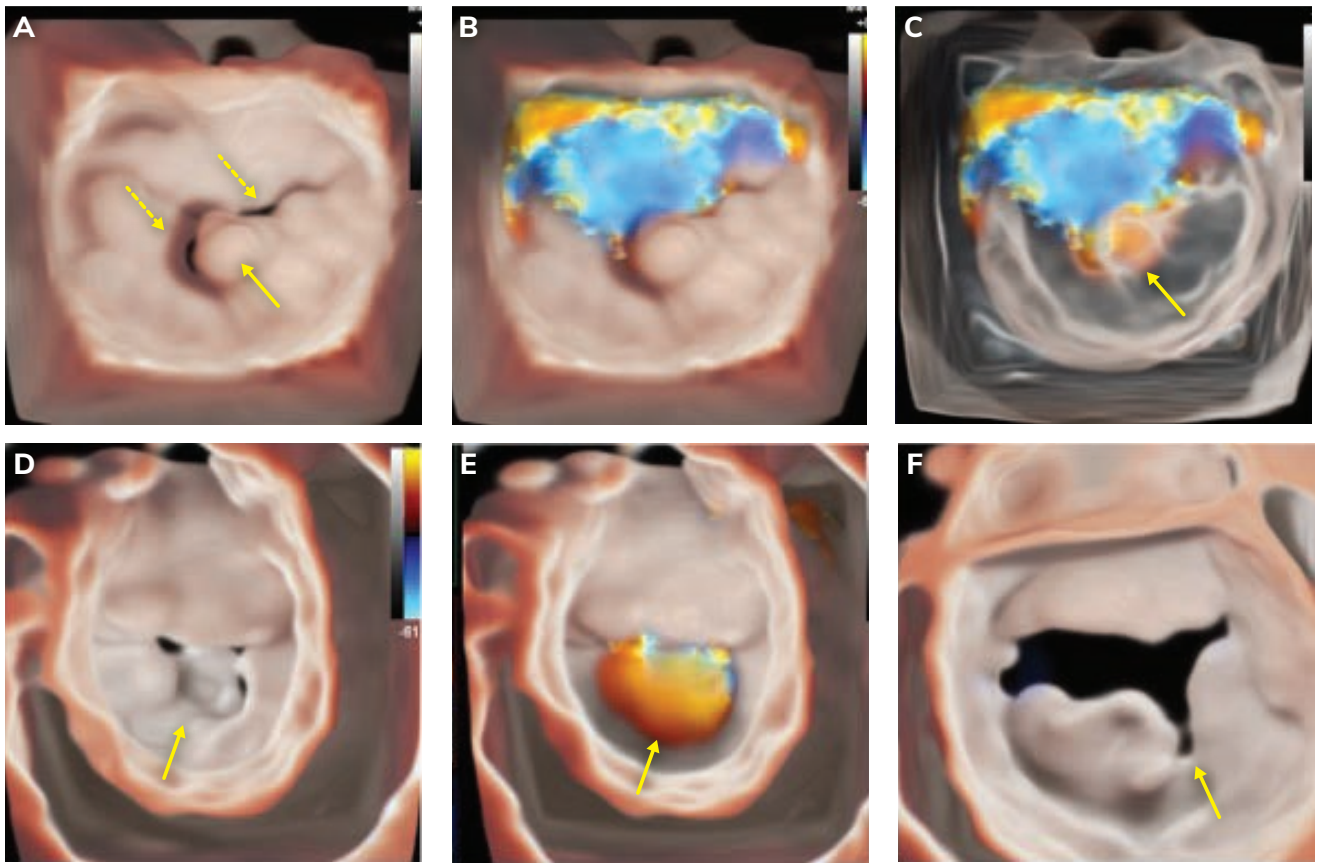


Figure 8. 3D TEE Views of Mitral Valve

(A) 3D atrial view in systole showing P2 prolapse (solid arrow) and coaptation gap (dashed arrows). (B) 3D atrial view with color showing MR jet. (C) Increased transparency to show MR origin. PISA is visualized under P2 (arrow). (D) 3D view from the ventricle showing P2 prolapse (arrow). (E) Color added to show MR origin (PISA) from the ventricle (arrow). (F) 3D view from the ventricle in diastole showing cleft-like indentation between P1 and P2 (arrow).

3D imaging is particularly useful to understand complex mitral valve anatomy that may be difficult to understand using standard 2D imaging planes. This has been demonstrated previously with greater sensitivity and specificity over 2D TEE imaging, most notably in commissural lesions, multisegment pathology, and identification of clefts.[12,13] 3D is also useful in quantification, such as through 3D VCA calculations, which doesn't involve geometrical assumptions as the PISA method which can underestimate severity particularly in cases of secondary MR.[7] Additionally, 3D mitral valve planimetry is necessary in cases of mitral stenosis or mixed valvular pathology, which can influence treatment strategies (ie, TEER). The advent of real-time 3D multiplanar reconstruction (MPR) adds further ability to view multiple planes simultaneously, which can be incremental in complex cases or when standard 2D imaging planes are challenging and non-diagnostic, and has seen increased use in intraprocedural guidance[14] (Figure 9).

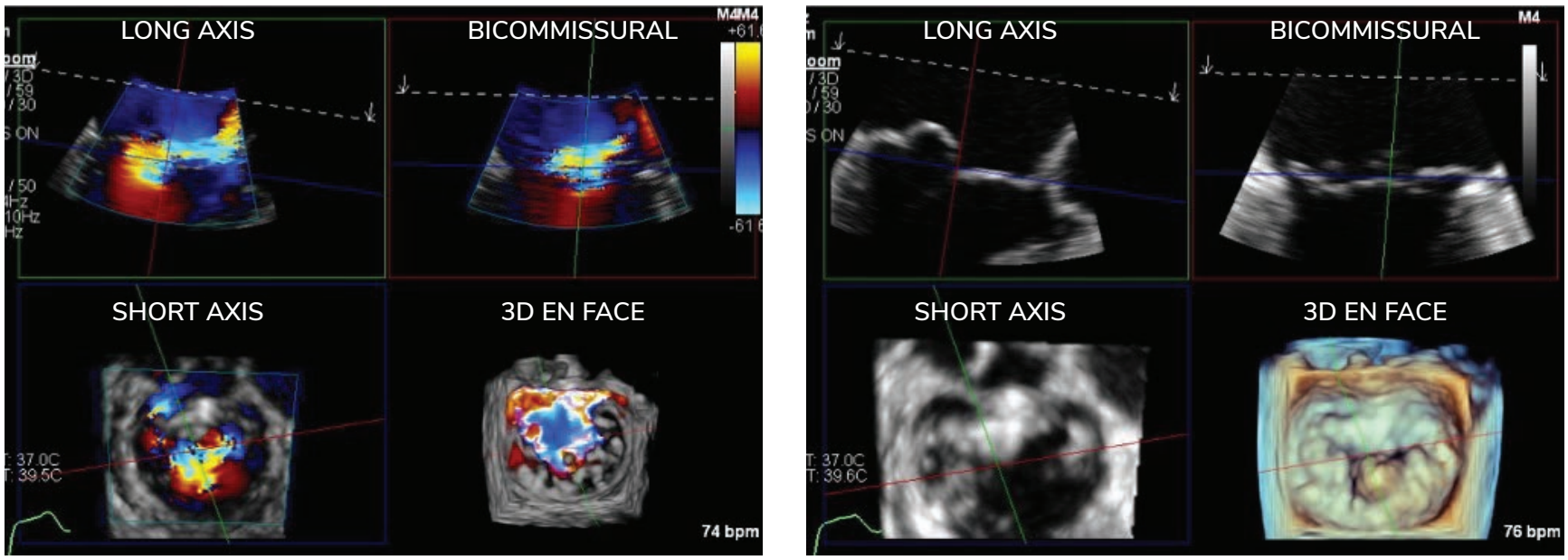


Figure 9. Standard MPR Views of Mitral Valve

3D MPR allows visualization of all key MV views simultaneously including the long-axis, bicommissural, short-axis and 3D en face views. The images with color allow localization of the MR origin, and the images without color allow understanding of underlying mechanism of MR and leaflet pathology (in this case posterior leaflet prolapse).

Multi-modality imaging

While echocardiography (TTE and TEE) forms the basis of MR evaluation, an expanding role for multi-modality cardiac imaging (CT and MRI) has emerged, particularly in discrepant cases of severity and for pre-procedural planning. Multi-phase acquisition ECG-gated cardiac CT plays an important role in planning for transcatheter intervention,[1] but in MR evaluation its role is largely limited to more advanced morphological characterization of the mitral valve apparatus, such as calcification and subvalvular relationships (Figure 10). Conversely, cardiac MRI plays an important role in discordant cases of MR severity with accurate quantification of mitral regurgitant volume/fraction, ventricular volumes and tissue characterization for fibrosis assessment if required (Figure 11).[1]

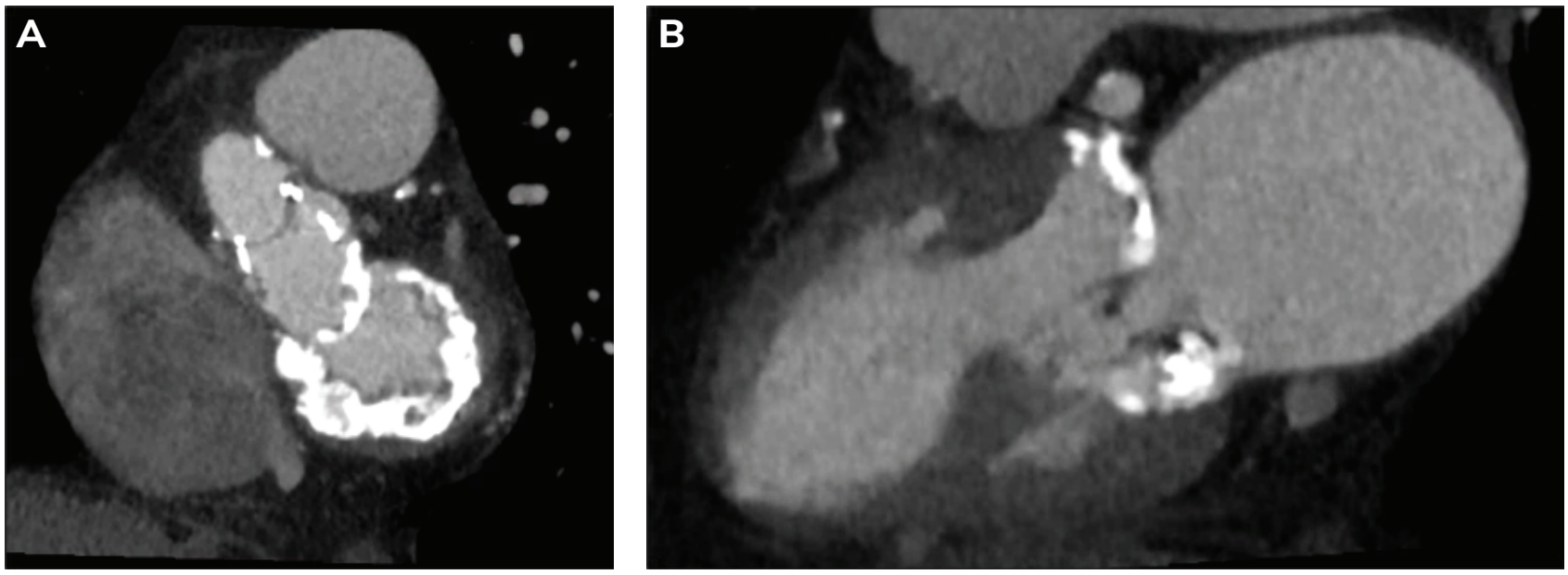
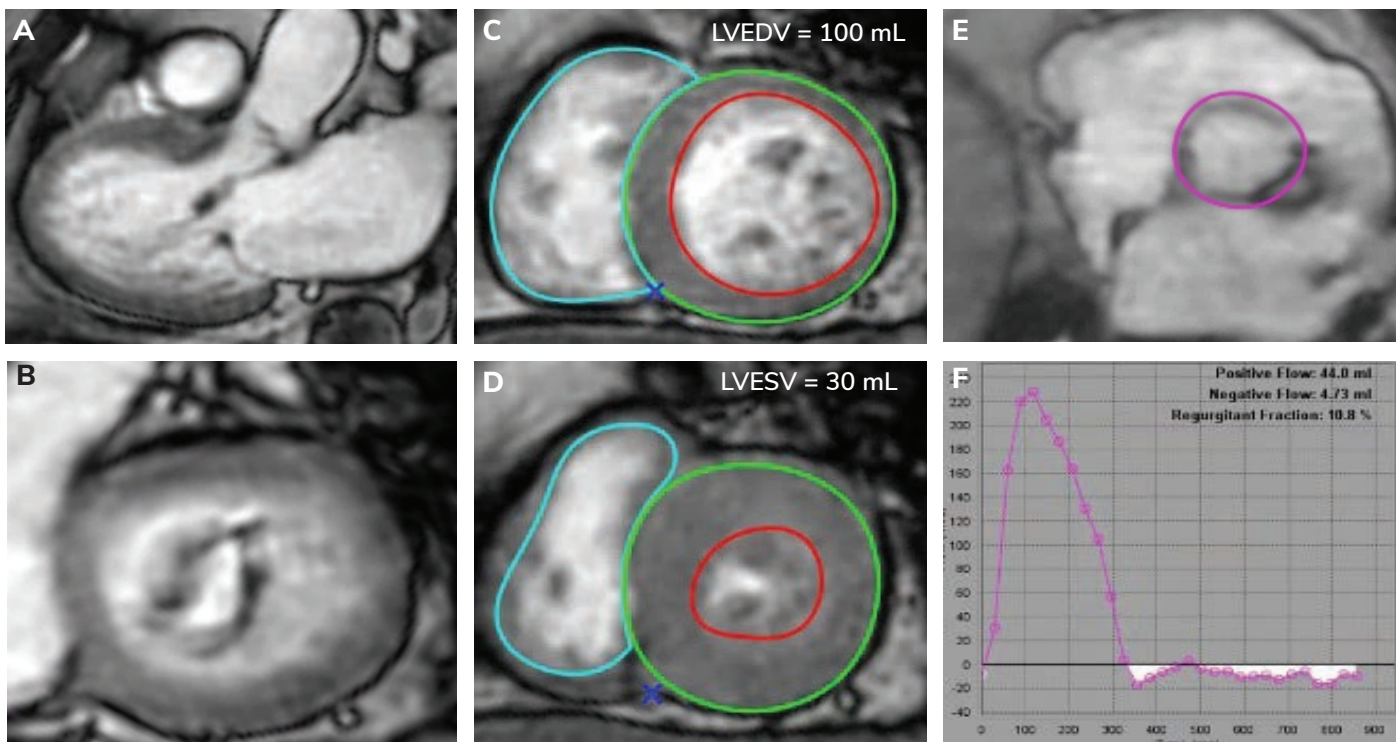


Figure 10. CT Imaging of Mitral Valve

(A) Cardiac CT demonstrates dense, circumferential mitral annular calcification on short-axis images. (B) The extent of calcification can be seen on this 2-chamber view involving the base to mid portions of the mitral valve leaflets, with relative sparing of the subvalvular apparatus.



MR Quantification:

- LVSV = LVEDV – LVESV = 70 mL
- Aortic forward flow (AoFF) = 44 mL
- MR_{vol} = LVSV – AoFF = 26 mL
- MRRF = (MR_{vol}/LVSV) x 100 = 37%

Figure 11. MRI Imaging of Mitral Valve

(A, B) Long-axis and short-axis SSFP MRI sequences respectively, with evidence of thickened mitral valve leaflet tips, posterior leaflet restriction and a degree of commissural fusion consistent with rheumatic mitral valve disease. (C, D) LV volumetric quantification at end diastole and end systole to calculate the LV stroke volume. (E, F) Phase-contrast, velocity-encoded flow imaging through the proximal ascending aorta to determine aortic forward flow. MR regurgitant volume and regurgitant fraction can then be calculated as displayed.

Conclusion

Evaluation of MR requires consideration of the mitral valve apparatus in its entirety to precisely understand mechanism and determine severity. The key questions that need to be answered, which may require a multi-modality approach, include:

- Is the MR severe, and if not, could it be underestimated?
- What is the exact mechanism of mitral regurgitation and what is the morphology of the valve?
- Are the leaflets graspable at the site of regurgitation?
- Is there hemodynamic impact on other structures/chambers (ie, pulmonary circulation and left/right heart chambers)?

These questions, particularly the last, have important implications for procedural planning necessitating comprehensive imaging. It should be noted that MR assessment is dynamic, and understanding the complex interplay of hemodynamics, loading, and the intricate mitral valve anatomy (which includes the LA and LV) is essential to any evaluation.

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CHAPTER 2
Patient Selection for Transcatheter Mitral Leaflet Repair

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Introduction

Transcatheter edge-to-edge repair (TEER) of the mitral valve (MV) has revolutionized the minimal invasive treatment of primary and secondary mitral regurgitation (MR). The procedure was first developed to mimic the surgical edge-to-edge repair during which the free edges of the anterior and posterior leaflets are approximated to create a double-orifice valve.[1] The MitraClip™ (Abbott Vascular, Santa Clara, CA) is the most widely used device for TEER. The PASCAL™ Transcatheter Valve Repair System (Edwards Life Sciences, Irvine, CA) has received CE mark in Europe and is currently under investigation in the United States.

In North America, the MitraClip was first approved for the percutaneous reduction of symptomatic, moderate-severe or severe primary MR (grade ≥3+) in patients at prohibitive risk for MV surgery. This indication was predominantly based on the results of the Endovascular Valve Edge-to-Edge Repair Study (EVEREST) II[2,3] and EVEREST II High-Risk Registry.[4] The MitraClip therapy was subsequently approved to treat symptomatic, moderate-severe to severe secondary MR (grade ≥3+) in patients with reduced LVEF (≥20% and ≤50%), NYHA class II-IVa, and an LV end-systolic dimension (LVESD) ≤70 mm despite maximally tolerated guideline-directed medical therapy (GDMT), as a consequence of the outcomes of the Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for High Surgical Risk Patients (COAPT) randomized clinical trial.[5,48] Of note, these landmark trials had rigorous anatomic inclusion and exclusion criteria. For the primary TEER studies, patients were required to have favorable anatomy for TEER involving the central MV scallops (A2-P2) without excessive degenerative changes. To be included in the COAPT trial for secondary MR, patients were required to have sufficient leaflet coaptation. As a result of these trials, these specific recommendations were included in the 2020 Focused Update of the American College of Cardiology (ACC) Consensus Decision Pathway on the Management of MR.[6]

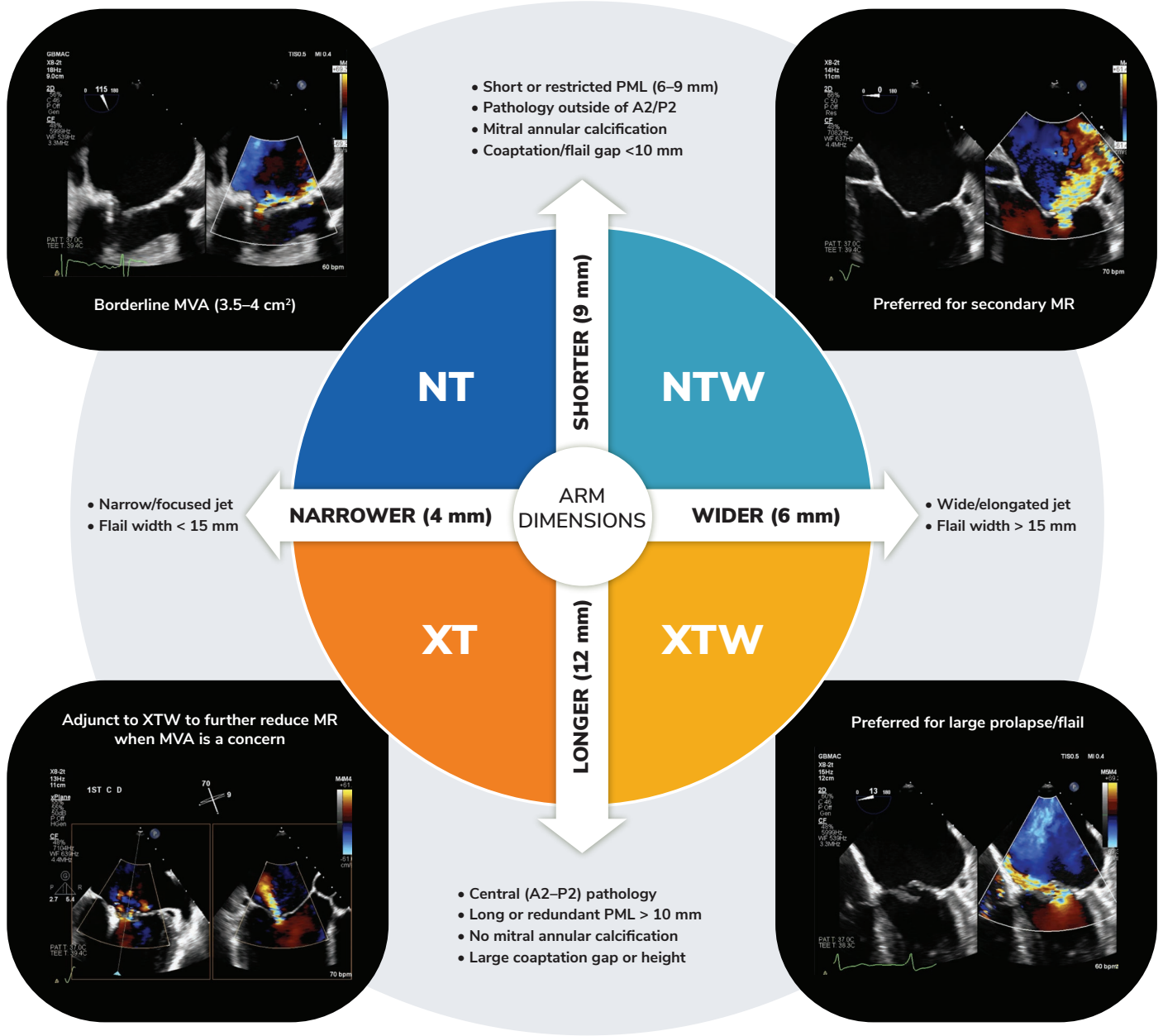
However, significant improvements in intraprocedural imaging, technical advances of the TEER technology (eg, longer and wider device arms), along with enhanced operator and imaging experience, have led to a significant expansion of the use of the TEER approach to patients that may have originally been excluded from the landmark trials (See Table 1).[7,8]

Table 1: Selection and Suitability Criteria for Transcatheter Edge-To-Edge Repair (TEER) Based on Expansion of EVEREST Criteria

OPTIMAL	SUITABLE	EXPANDED	MOST CHALLENGING/ UNSUITABLE
Central pathology in A2/P2	Commissural pathology in A1/P1 & A3/P3	Pathology involves multiple segments	Cleft or perforation
No calcification Chord-free zone present	Some calcification present but not in grasping zone	Partial calcification extending into grasping zone Annuloplasty ring s/p SLDA HCM	Extensive MAC and calcification within grasping zone
MVA >4 cm^2 (by planimetry)	MVA >3 cm^2 (by planimetry)	MVA >3 cm^2 (by planimetry)	MVA ≤3 cm^2 (by planimetry) Mean MV gradient ≥5 mmHg
Posterior leaflet length >10 mm	Posterior leaflet length 7-10 mm	Posterior leaflet length 6-10 mm	Posterior leaflet length <6 mm
Normal leaflet mobility and thickness	Excessive or normal leaflet mobility and thickness	Excessive or slightly restrictive leaflet mobility Barlow's disease Increased leaflet thickness	Rheumatic thickening and leaflet restriction (Carpentier IIIA)
Secondary MR: Tenting height <11 mm	**Secondary MR:** Tenting height ≥11 mm	**Secondary MR:** Tenting height ≥11 mm	**Secondary MR:** Tenting height ≥11 mm
Primary MR: Flail width <15 mm Flail gap <10 mm	**Primary MR:** Flail width ≥15 mm Flail gap <10 mm	**Primary MR:** Flail width ≥15 mm Flail gap ≥ 10 mm	**Primary MR:** Multiple segments with flail width ≥15 mm, flail gap ≥ 10 mm
INEXPERIENCED CENTER	**INTERMEDIATE CENTER**	**HIGH-VOLUME CENTER**	**CENTER OF EXCELLENCE**

HCM=hypertrophic cardiomyopathy; MAC=mitral annular calcification; MR=mitral regurgitation; MV=mitral valve; MVA=mitral valve area; SLDA=single leaflet device attachment

The comprehensive acquisition of a pre-interventional transesophageal echocardiography (TEE) exam is essential for patient selection and to identify the mechanism of valvular dysfunction, to quantify the severity of the MV disease, and to illustrate the specific anatomic features that permit the structural heart team appropriate procedure and device selection or exclusion.[9] In this chapter, we review the expanded selection criteria for a diverse range of mitral pathologies and case scenarios, and propose considerations for specific device selection (central illustration.)

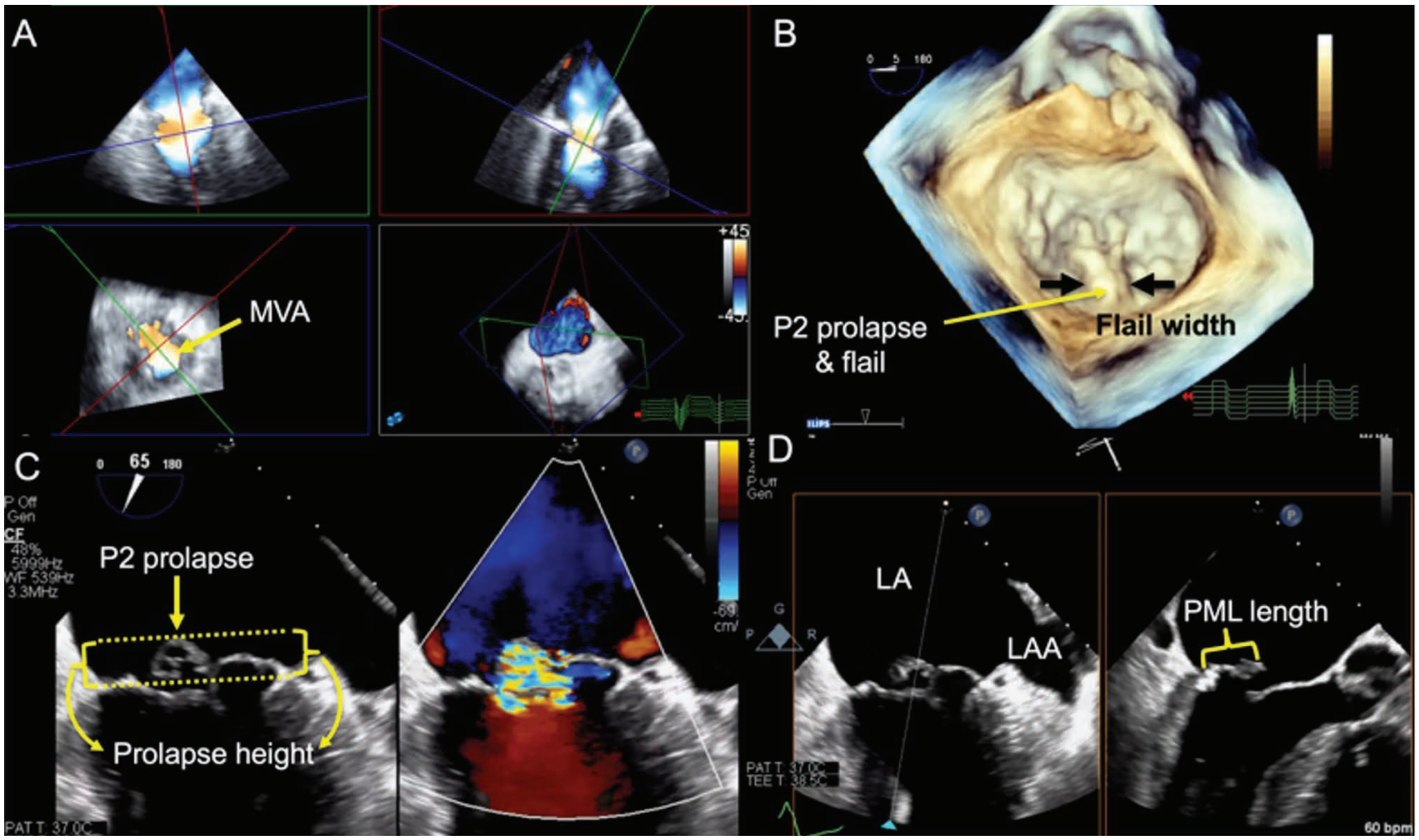


Central Illustration. (Modified from Garcia-Sayan et al.[47])

Patient-specific device selection from the MitraClip™ G4 family based on the author's personal experience, depending on the valve morphology and mechanism of mitral regurgitation.

General anatomic criteria

The successful grasp of the leaflets during the TEER procedure requires pliable, non-calcified leaflets at the grasping site, the absence of significant clefts or perforations, and a minimal posterior leaflet length of 6 mm for the shorter MitraClip NT and NTW and 9 mm for the longer MitraClip XT and XTW.[10] Additionally, a transmitral gradient (MG) of less than 5 mmHg and a mitral valve area (MVA) of at least 4 cm^2 are desirable to minimize the risk of mitral stenosis. A MVA of ≤ 3 cm^2 is considered a contraindication for TEER, and the decision to proceed in borderline cases can be individualized based on the location and severity of MR and the anticipated number of devices needed. The MVA should ideally be measured utilizing 3D multiplanar reformatting (MPR) to avoid overestimation errors that can result from 2D planimetry. Table 1 provides a summary of anatomic criteria as related to procedural complexity.



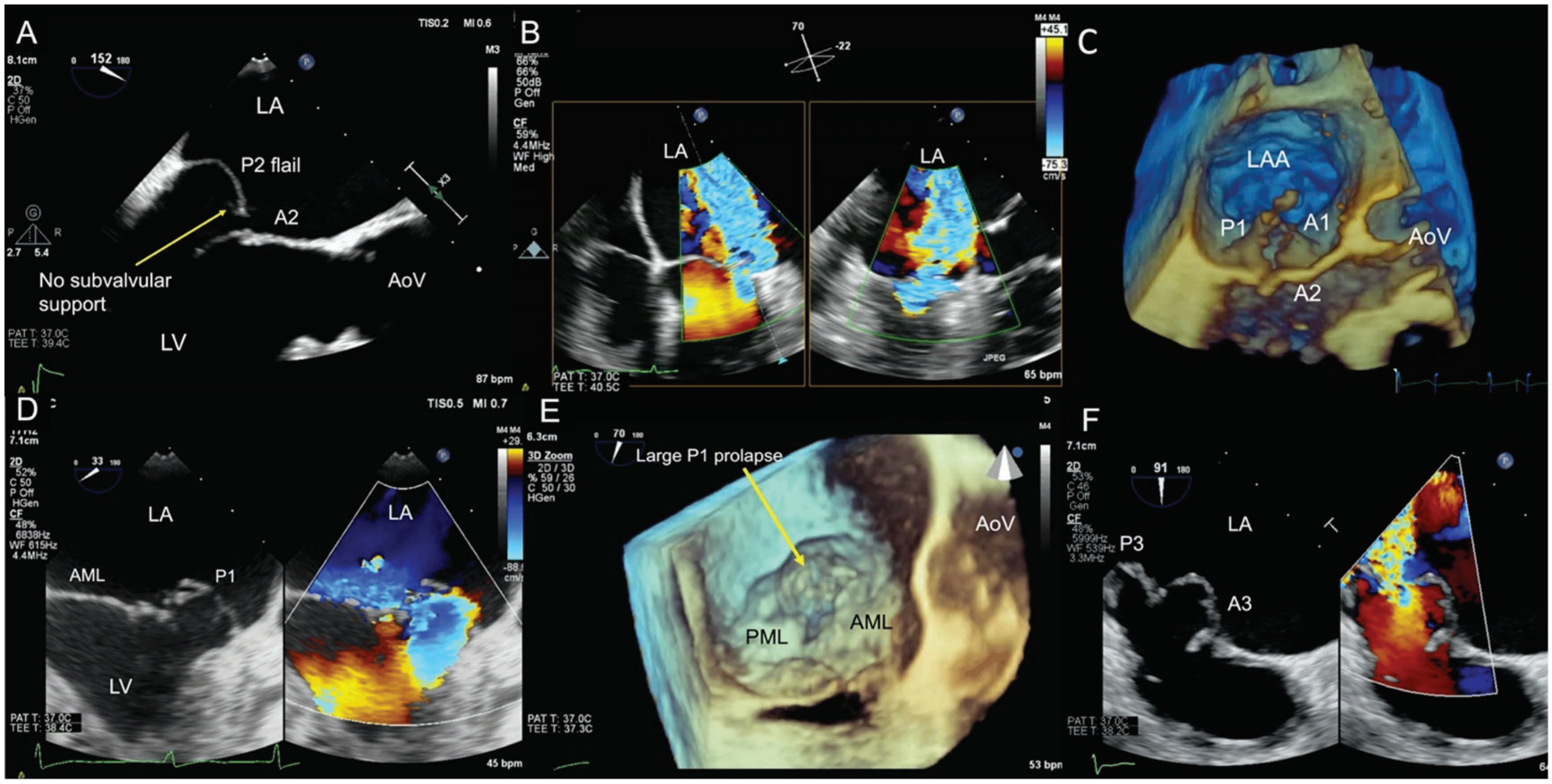
LA=left atrium; LAA=left atrial appendage; MVA=mitral valve area; P2=P2 scallop of the posterior mitral valve leaflet; PML=posterior mitral valve leaflet

Figure 1. Mitral Valve Quantification Before TEER Procedure

(A) Multiplanar reconstruction of 3D color image permits accurate planimetry of the mitral valve opening area during diastole (MVA). (B) 3D en face view demonstrates a large P2 prolapse with flail. Black arrows indicate flail width which can inform the selection of the appropriate TEER device. (C) 2D color compare of a mid-esophageal bicommissural view demonstrates a typical P2 prolapse that "overrides" the AML. The yellow dotted lines indicate the height of the prolapse above the annular plane. (D) 2D biplane view illustrates another 2D prolapse. The resulting aortic valve long axis view permits the accurate measurement of the PML length.

Primary (degenerative) MR with an excessive flail gap

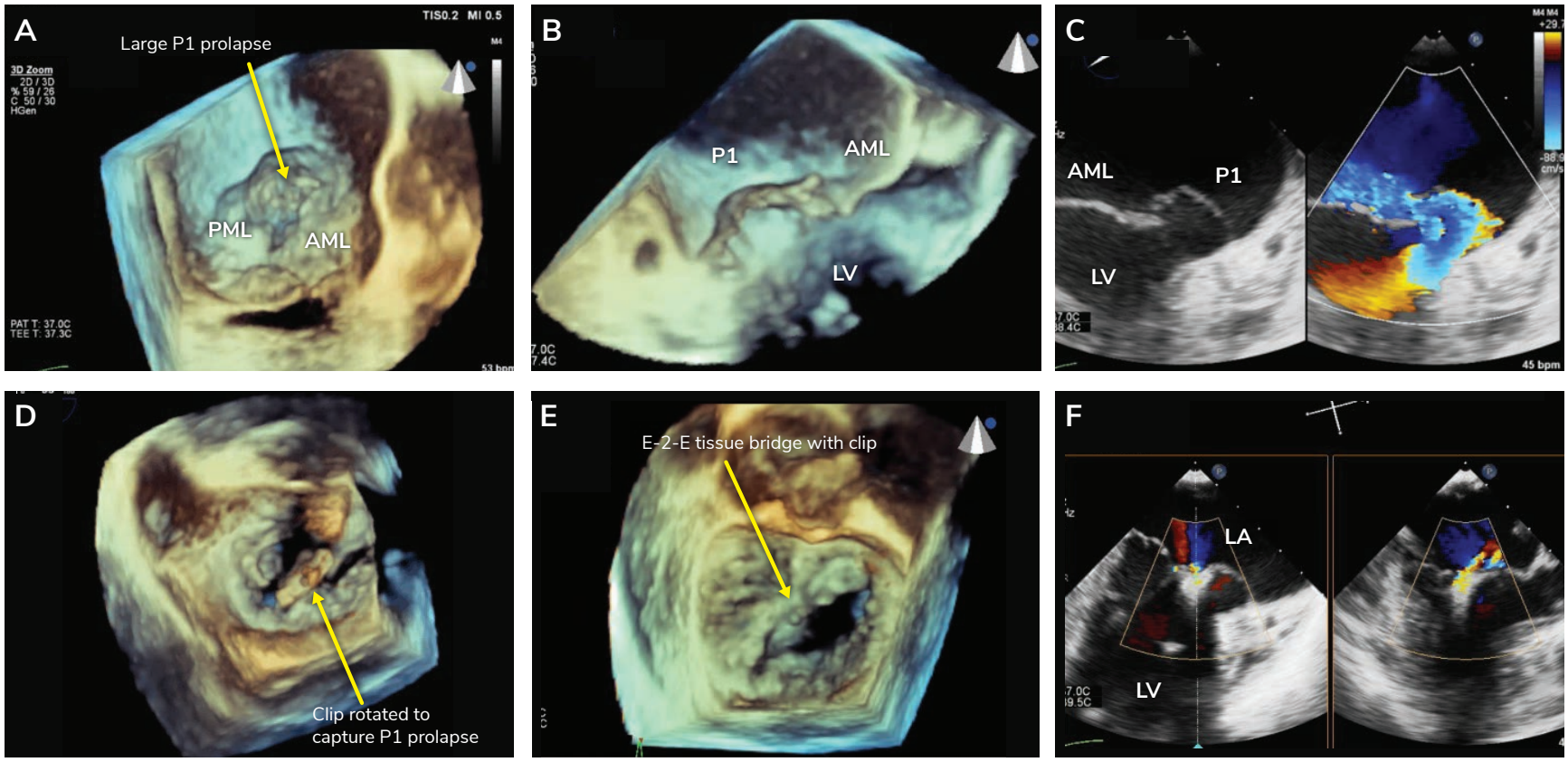
Patients with an extensive flail, defined as a flail segment width ≥15 mm or those with a flail gap ≥10 mm, were excluded from the initial clinical trials, including EVEREST II.[3] However, the treatment of degenerative MV disease with flail is one of the key applications of TEER therapy, and degenerative MV disease with flail has been linked to substantial mortality risk in the elderly.[11] Thaden et al. demonstrated that the presence of a flail leaflet segment is a predictor of a greater acute improvement in mean LA pressure after TEER[12] and reduced LA pressure after TEER has been associated with improved functional status.[13] With the introduction of longer and wider TEER devices, the treatment of wider and larger flail gaps has become a reality (Figure 2).



A1/A2/A3=A1/A2/A3 segments of the anterior mitral valve leaflet; AML=anterior mitral valve leaflet; AoV=aortic valve; LA=left atrium; LAA=left atrial appendage; LV=left ventricle; P1/P2/P3=P1/P2/P3 scallops of the posterior mitral valve leaflet; PML=posterior mitral valve leaflet

Figure 2. Complex Degenerative MR with Very Wide P1/P2 Flail – Expanded Indication TEER to be Treated at a High Volume Center

(A) Mid-esophageal 2D aortic valve long axis view demonstrates a significant PML prolapse involving the P2 scallop. The height of the prolapse suggests that the subvalvular apparatus below the P2 scallop is no longer intact. This is critically important to realize as the TEER procedure requires a somewhat intact subvalvular apparatus so that the leaflets can be pulled up toward the LA against some resistance during grasping. (B) 2D biplane color with baseline shift shows severe MR originating from a bileaflet prolapse and flail in the anterolateral commissure. (C) 3D image, obtained in the same patient as in B, illustrates the bileaflet prolapse of P1/A1 in relationship to the rest of the MV and the AV. Note the very large LAA which is an indirect sign of long-standing increases in left atrial pressure. (D) 2D color compare permits assessment of the extent of the PISA shell originating from a large prolapse in the anterolateral commissure (P1 scallop). (E) Rotated 3D image confirms the large P1 prolapse in the anterolateral commissure in the same patient. Note the location, extent, and height of the prolapse. (F) 2D color compare image shows another example of a significant bileaflet prolapse in the posteromedial commissure. Note the generous leaflets and leaflet length.



AML=anterior mitral valve leaflet; LA=left atrium; LV=left ventricle; MR=mitral regurgitation; MV=mitral valve; PISA=proximal isovelocity surface area; PML=posterior mitral valve leaflet

Figure 3. Complex Degenerative MR with Very Wide P1 Flail – Expanded Indication TEER to be Treated at a High-Volume Center

Illustration of a successful TEER procedure. (A) Rotated 3D image demonstrates a large P1 prolapse in the anterolateral commissure. Note the location, extent, and height of the prolapse. (B) Cropped and rotated image of the same MV as in A, with large P1 prolapse and flail seen from the side. (C) 2D color compare permits assessment of the extent of the PISA shell originating from this large prolapse in the anterolateral commissure (before TEER). (D) Large and wide TEER device (XTW MitraClip) seen above the mitral valve. Note the extensive clockwise rotation required to capture the large P1 prolapse. (E) 3D enface image shows the solid tissue bridge between the P1 scallop and the A1/A2 segments of the anterior leaflet. (F) With the correct perpendicularity and following a successful grasp, the severity of MR is reduced to trivial.

During the preprocedural assessment, the echocardiographer needs to demonstrate the availability of sufficient corresponding leaflet length to complete a grasp within the most complex pathology. To do this successfully, 3D MPR can be used to simulate the likely device orientation orthogonal to the estimated plane of leaflet coaptation rather than in relation to the angle of the flail segment, as this may be eccentric given the lack of chordal support. The treatment of larger and wider flail gaps has also been facilitated by the availability of independent leaflet grasping technology (available with both the MitraClip G4 and the PASCAL repair system). This permits the initial capture of the flail segment followed by steering of the delivery system to the non-flail leaflet to ensure a sufficient and stable grasp of both leaflets.

As an extreme example of a substantial flail gap and wide flail width, papillary muscle rupture is a rare but often fatal mechanical complication of myocardial infarction (MI). Despite minimal if any primary or secondary chordal support, even partial or complete papillary muscle tears can be successfully treated with TEER.[14-17] In the hands of highly experienced teams, and with the use of larger and wider TEER devices, even the most extreme lesions associated with a papillary muscle tear can be approached successfully.

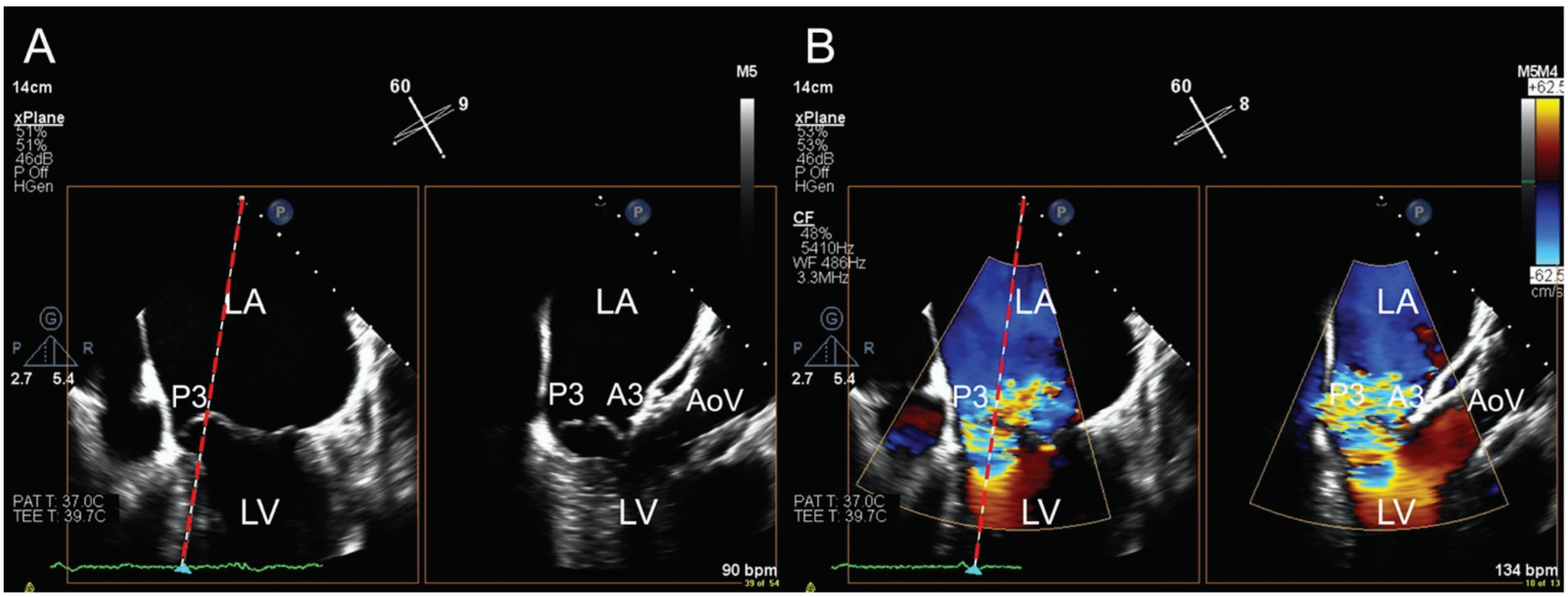
Non-central pathology (outside A2/P2)

Patients included in the EVEREST II trial had a primary regurgitant mitral jet originating from the center of the MV (A2-P2 segments). Excluding all patients with non-central MR from treatment with TEER would leave many patients untreated. It is estimated that about one-third of all patients with significant MR have non-central MR jets, often originating from the commissures and involving the very margins of the leaflets.[18,19] The deployment of a TEER device is more challenging in Carpentier's classification segments 1 and 3, especially when dealing with large prolapsing leaflets and flail segments (Figure 2). The number and complexity of the chordae tendineae within the commissures increase the risk of device entanglement and chordal disruption (Figure 4). Deviations in the orientation of the TEER device and rotational moves under the commissures can contribute to such device entanglement. Some operators avoid using the larger TEER devices, as the longer arms increase the risk of device engagement with the chordal apparatus and the LV wall; in addition, the posterior leaflet length in the commissures is shorter than the central P2 scallop, and the short device arms are often sufficient for an adequate tissue grasp (ie, <9 mm). Extensive use of 3D TEE and unconventional imaging planes are useful to visualize the full extent of the pathology and the anticipated device choice and orientation.[20]

Barlow's disease

A severe form of myxomatous MV prolapse involving multiple segments of both the anterior and posterior leaflet is referred to as Barlow's disease.[21] Although often attempted, the surgical repair of a Barlow's valve is not only challenging but may be associated with the risk of MR post-repair.[22] The last decade has seen advanced surgical repair techniques including the use of neo-chord implantation and/or sliding MV annuloplasty and overall improved outcomes but the reoccurrence rates of MR are still not insignificant.[23,24]

While the presence of severe bileaflet prolapse (Barlow's disease) prevented patients from being included in the EVEREST trials, successful TEER in this patient population is challenging: the leaflets are often hypermobile and are difficult to grasp; a significant height reduction of the redundant leaflets tissue is required to achieve a longer-lasting reduction of MR; and multiple large TEER devices may be required to achieve a meaningful reduction of the often large regurgitant orifice.[25] (See Figures 2, 3, and 4 for details.)



A3=A3 segment of the anterior mitral valve leaflet; AoV=aortic valve; LA=left atrium; LV=left ventricle; P=P3 scallop of the posterior mitral valve leaflet

Figure 4. Noncentral Bileaflet Prolapse with Severe MR – Suitable for Treatment in Intermediate-High Volume Center

(A) Mid-esophageal 2D TEE biplane view demonstrates a bileaflet prolapse in the posteromedial commissure involving the P3 scallop and corresponding A3 segment of the mitral valve. (B) The corresponding color compare image demonstrates the severity of MR originating from the bileaflet prolapse. Treating a bileaflet prolapse in the commissure can be challenging, mostly due to the dense chordal apparatus underneath the P3 and A3 segments of the MV.

Secondary (functional) MR

Patients with secondary MR of at least grade 3+, LVEF ≥20% and ≤50%, NYHA II-IVa, and an LVESD ≤70 mm who remain symptomatic despite maximally tolerated GDMT, as determined by a multidisciplinary heart team including a heart failure specialist, can be considered candidates for TEER regardless of their surgical risk.[6,26] It should be noted that the COAPT trial also excluded patients with severe pulmonary hypertension (defined as pulmonary artery systolic pressure >70 mmHg).[5] These strict eligibility criteria were recently highlighted in the Centers for Medicare & Medicaid Services Decision Memo for TEER.[46] Although a tenting height <11 mm and coaptation length >2 mm were considered favorable anatomic characteristics in secondary MR in the EVEREST II trial, the development of larger devices with independent leaflet grasping has allowed operators the ability to successfully perform TEER in patients outside of these parameters (Table 1). However, when assessing patients with significant LV dysfunction, attention should be given to ensure that secondary MR is truly hemodynamically significant, utilizing a strict echocardiographic multi-parametric approach and careful quantification.[27]

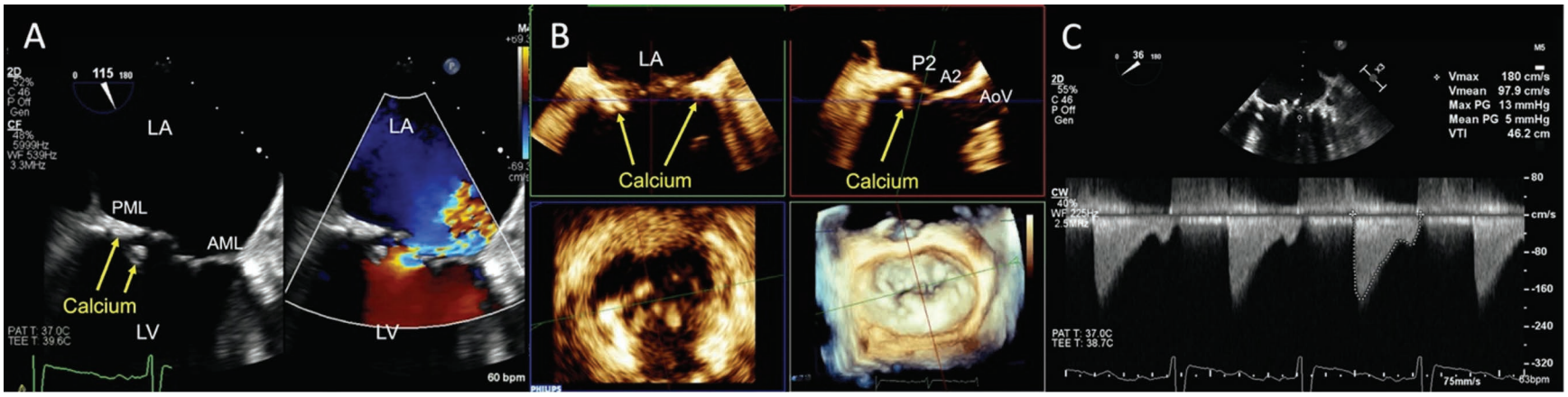
There has been much interest in reconciling the results of the COAPT and Percutaneous Repair with the MitraClip Device for Severe Functional/Secondary Mitral Regurgitation (MITRA-FR) trials, as the latter did not demonstrate improved outcomes 12 months after TEER.[28] It has been proposed that these differences may partly be explained by the criteria utilized to define severe MR: MITRA-FR utilized an effective regurgitant orifice of ≥20 mm^2 or regurgitant volume of ≥30 mL, whereas COAPT utilized a stricter effective orifice area ≥30 mm^2 and a regurgitant volume ≥45 mL, in line with the current guidelines published in the United States.[5,27,29] Furthermore, the concept that patients with MR severity that is disproportionate to the degree of LV dilatation are more likely to benefit from TEER has emerged, and something that the heart team should keep in mind for patient selection, although this hypothesis may require further validation.[30]

Finally, when considering TEER in secondary MR, one should differentiate patients with LV dysfunction and leaflet tethering (Carpentier type IIIB mechanism) from those with preserved LVEF and MR predominantly due to isolated annular dilatation (atrial functional MR, Carpentier type I mechanism). Although a subgroup analysis of patients with atrial fibrillation in the COAPT trial revealed that TEER maintained a clinical benefit, these patients had a worse prognosis than those without atrial fibrillation, and clinical data for TEER in the population with heart failure and preserved EF remains limited.[31]

Presence of MAC and mitral valve leaflet calcification

Mitral annular calcification (MAC) is a degenerative process affecting the fibrous annulus of the MV and is often associated with MR. MAC is routinely identified by echocardiography and several echocardiographic scoring systems that classify the severity of MAC have been developed.

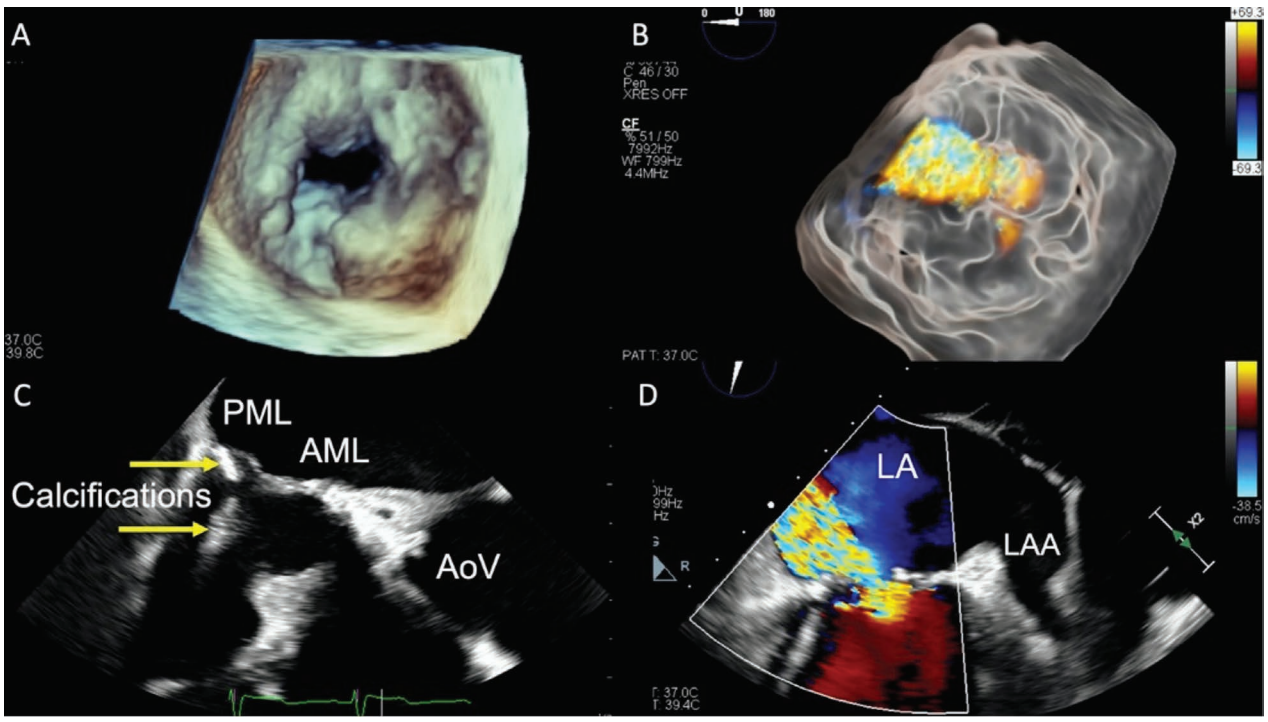
During the EVEREST trials, moderate to severe MAC and significant MV leaflet calcification within the grasping area were considered strict exclusion criteria. Grasping non-pliable, thickened leaflets is challenging, and there is an increased risk of introducing unacceptably high diastolic forward flow gradients in patients with reduced MVA (<3-4 cm^2) at baseline. However, recent studies suggest that the TEER therapy might be safe and feasible in selected patients and can result in comparable midterm durability in the treatment of MR in patients with significant MAC but without severe leaflet calcification or thickening (see Figures 5, 6, and 7 for details).



A2=A2 segment of the anterior mitral valve leaflet; AML=anterior mitral valve leaflet; AoV=aortic valve; LA=left atrium; LV=left ventricle; P2=P2 scallop of the posterior mitral valve leaflet; PML=posterior mitral valve leaflet

Figure 5. Part 1: Examples of Severe Mitral Annular and Leaflet Calcification – Unsuitable for TEER or Attempt only in Center of Excellence

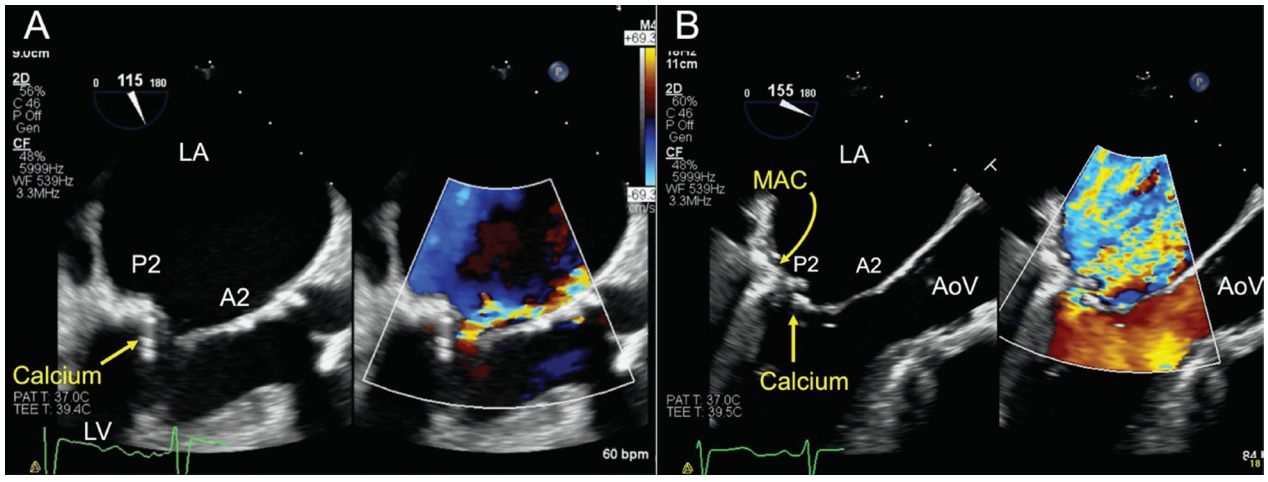
(A) 2D color compare acquisition illustrates the extent of both MAC and leaflet calcification in patient with primary degenerative MR. While the small posterior leaflet can be appreciated in the aortic valve long axis view, it appears to be small and short and will make grasping challenging. The significant subvalvular and annular calcium make this scenario even more challenging. (B) 3D multiplanar reconstruction reveals the extent of both MAC and leaflet calcification in the same patient with primary degenerative MR. The presentation of the pathology should also raise the suspicion for some degree of MV stenosis. (C) Baseline continuous wave Doppler assessment of this patient confirms an elevated mean gradient, commensurate with possibly moderate mitral valve stenosis at baseline.



AML=anterior mitral valve leaflet; AoV=aortic valve; LA=left atrium; LAA=left atrial appendage; MAC=mitral annular calcification PML=posterior mitral valve leaflet

Figure 6. Part 2: Examples of Severe Mitral Annular and Leaflet Calcification – Unsuitable for TEER or Attempt only in Center of Excellence

(A) 3D enface image shows a heavily calcified mitral valve (MV) with severe MAC and leaflet calcification in patient with primary degenerative MR. The MV shows a small opening and the MV leaflets are not well seen in this image. (B) 3D enface glass view with color illustrates the severe mitral regurgitation in this patient. (C) mid-esophageal 2D aortic valve long axis view demonstrates the thickened MV leaflets. Note the short and fragile appearing PML and the significant calcifications in the subvalvular apparatus. (D) 2D color image confirms the severity of MR in this patient.



A2=A2 segment of the anterior mitral valve leaflet; AoV=aortic valve; LA=left atrium; LV=left ventricle; MAC=mitral annular calcification; P2=P2 scallop of the posterior mitral valve leaflet

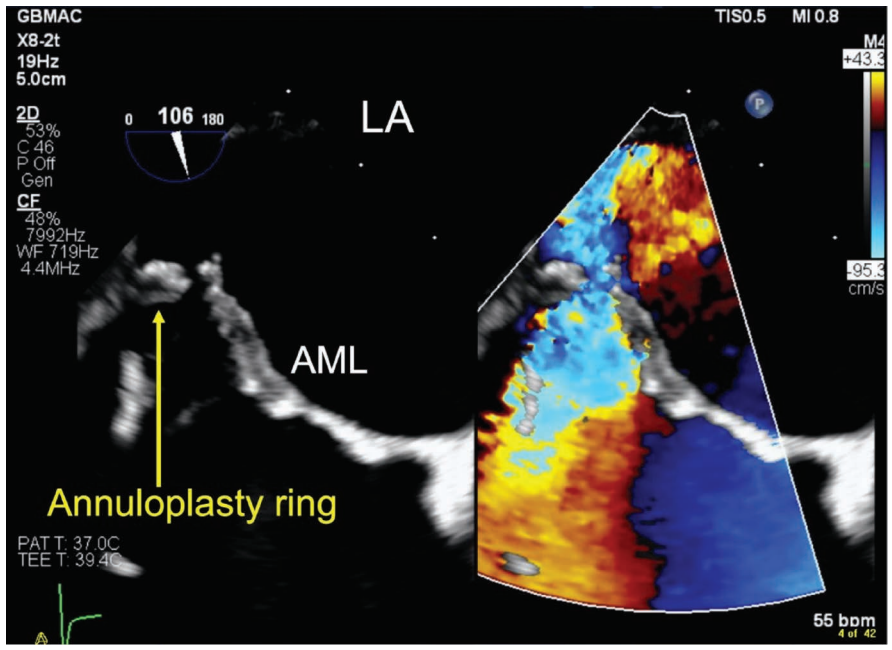
Figure 7. Part 3: Examples of Severe Mitral Annular and Leaflet Calcification – Unsuitable for TEER or Attempt only in Center of Excellence

(A) 2D color compare acquisition illustrates the extent of both MAC and leaflet calcification in a patient with primary degenerative MR. Short, calcified leaflets with insufficient leaflet length and area for grasping along with the dense and calcified subvalvular apparatus make this scenario challenging for TEER. (B) A very similar scenario as in A is seen in this 2D color compare acquisition in another patient which illustrates the extent of both MAC and leaflet calcification in the setting of severe secondary (functional) MR.

TEER in patients with failed surgical MV annuloplasty repair

Surgical MV repair does not always provide a definitive long-term solution, even when performed at centers of excellence or those with high surgical volumes.[32] As soon as 10 years after the initial surgical repair (eg, surgical repair of degenerative MR), up to 35% of patients experience moderate to severe MR.[33,34] A renewed MV repair is challenging and associated with high rates of valve replacement as well as operative complications and mortality, particularly in the high-risk patient population of elderly individuals with comorbidities.[35] Several minimally invasive options have been developed to meet this unmet clinical need. One option is a transcatheter placement of a transcatheter heart valve while using the annuloplasty ring as docking station. While feasible in select patients, however, this procedural approach is associated with significant risks of its own. These include, but are not limited to, risk of valve embolization, the occurrence of a peri-valvular leak with subsequent hemolysis, and obstruction of the left ventricular outflow tract. An alternative option is the TEER procedure. Although the safety and feasibility of TEER after failed surgical ring annuloplasty has been reported in several case series, the overall evidence for this approach is limited.[20,36-38]

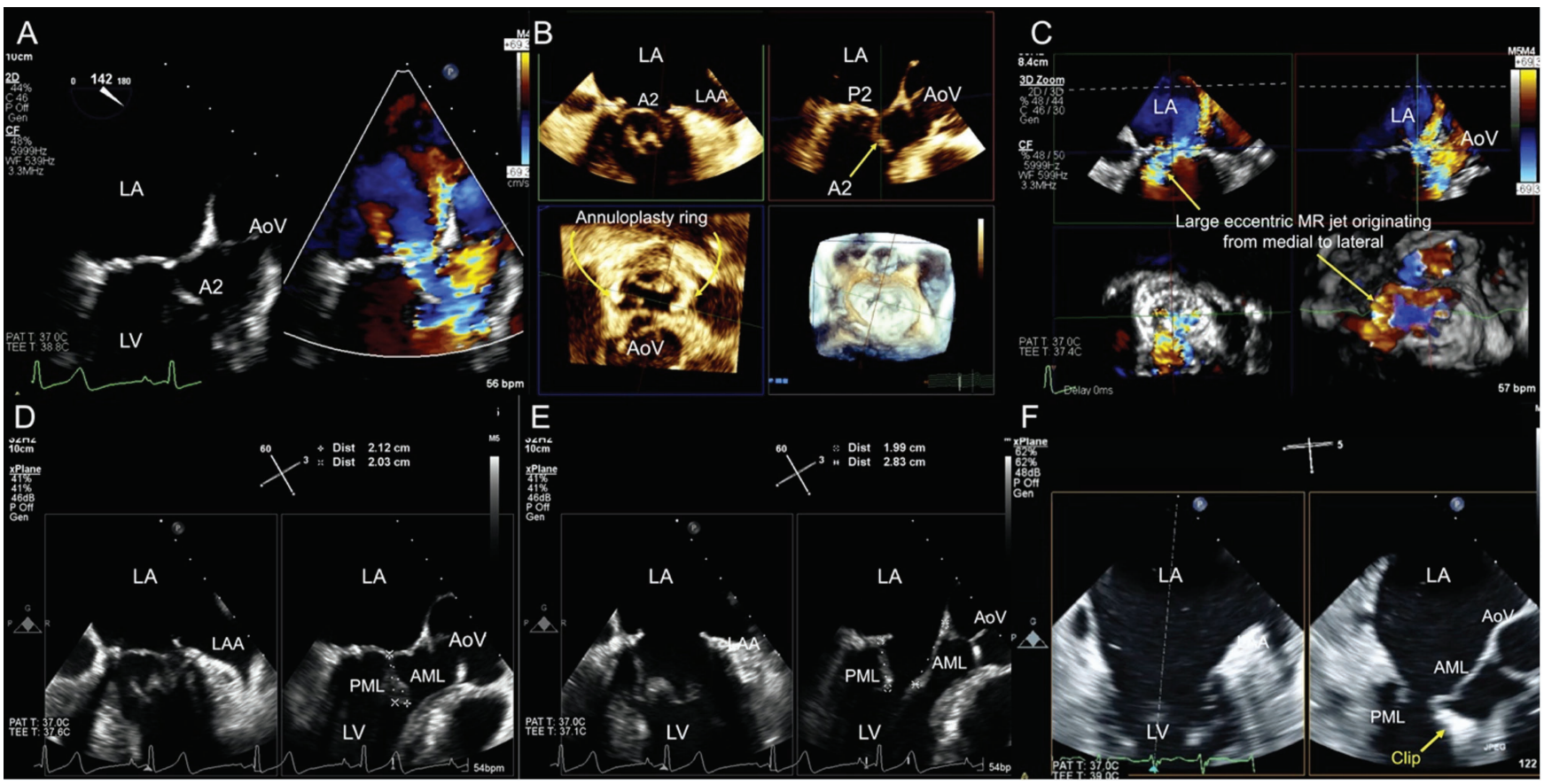
It is important to realize that patients with prior surgical annuloplasty routinely have reduced MVA introduced by the annuloplasty ring. Consequently, the structural team needs to be cautious and avoid a secondary increase in the diastolic inflow gradients, especially when more than one TEER device is required to effectively reduce MR. Another challenge is that the previous surgical MV repair may have included a reduction or resection of the posterior MV leaflet (see Figure 8). This will often result in a shortened and small and short posterior leaflet which will be more difficult to grasp during the TEER procedure. When the posterior leaflet tissue length is not sufficient, an alternative approach is to grasp the anterior leaflet and the posterior aspect of the annuloplasty ring itself, although experience with this approach is limited.[39] Other challenges include the poor visibility of the posterior leaflet underneath the annuloplasty ring (eg, drop-out), especially during grasping, and the potential entanglement of the TEER device with artificial or native chords during the procedure. In cases where the surgeon decided not to resect the posterior MV leaflet, the patient may present with redundant leaflets and a combination of MR and SAM with obstruction of the LVOT. If the patient is at prohibitive risk for redo surgery, a TEER procedure might be considered to treat both the MR and the SAM (see Figure 9).



AML=anterior mitral valve leaflet; LA=left atrium

Figure 8. Severe MR After Prior Primary MR Surgical Repair with Posterior Leaflet Resection and Annuloplasty Ring Placement – Unsuitable TEER Case or to be Attempted at Centers of Excellence Only

(A) 2D color compare AV LAX view demonstrates the absence of a meaningful posterior mitral valve leaflet. This patient is s/p failed surgical MV repair with ring annuloplasty and also had one attempt with the TEER procedure at an outside hospital which led to a single leaflet detachment from the anterior leaflet. This scenario makes a redo TEER procedure essentially impossible. While described in single case reports, attempting a MitraClip placement to the posterior ring is not well established.



A2=A2 segment of the anterior mitral valve leaflet; AoV=aortic valve; LA=left atrium; LAA=left atrial appendage; LV=left ventricle; AML=anterior mitral valve leaflet; P2=P2 scallop of the posterior mitral valve leaflet; PML=posterior mitral valve leaflet

Figure 9. Severe MR and SAM in Prior Surgical Mitral Valve Repair with Annuloplasty Ring – Failed TEER with SLDA

(A) ME 2D color compare AV LAX view demonstrates severe MR and turbulent flow in the LVOT in a patient with s/p remote MV repair with annuloplasty ring. The anterior MV leaflet is seen in the LVOT which represents systolic anterior motion (SAM) involving the A2 segment. (B) 3D multiplanar assessment illustrates the semi-closed surgical annuloplasty ring and the elongated anterior MV leaflet in the LVOT (A2) about to make septal contact during SAM. (C) 3D color illustration obtained in the same patient as in B shows severe MR along with turbulent flow in the LVOT. Note the eccentricity of the MR jet originating from medial to lateral. (D) Systolic 2D biplane image used to assess the length of the PML and AML which is essential for TEER device selection. (E) 2D biplane image acquired during diastole which allows to quantify the full extended length of the MV leaflets. (F) 2D biplane obtained in other patient who was considered for a redo TEER procedure. The patient had previously been treated with the TEER procedure at an outside hospital but suffered from a single leaflet device attachment (SLDA) from the posterior leaflet. Scenarios like these demand an experienced team and require the careful assessment of available leaflet tissue and length to attempt a new grasp.

Obstructive hypertrophic cardiomyopathy

Percutaneous treatment of the MV with the TEER approach has been pursued as an alternative treatment option for symptomatic obstructive hypertrophic cardiomyopathy (HCM).[40] With TEER, the extent of the systolic anterior motion (SAM) of the MV can be effectively reduced, thus reducing the LVOT gradient and treating the dynamic MR that is commonly observed.[41] With this approach, the motion of the anterior leaflet is restricted, thereby preventing or reducing the septal contact of the anterior leaflet with the septum and ultimately leading to a reduction of the LVOT obstruction.[42] Further studies are required to confirm the clinical efficacy and safety of the TEER procedure for the treatment of SAM and HCM. This will help to define patient selection and to identify those patients who will most benefit from TEER rather than alcohol septal ablation or surgical myectomy, or other transcatheter solutions that are under development.

Additional remarks

Other pathologies and clinical conditions that were directly excluded from EVEREST and COAPT that were shown to be feasible for percutaneous repair by MV TEER include MV leaflet perforations and cleft mitral leaflets.[43] Of note, some of these reports are limited to a single-operator experience, and the results are not to be generalized.

The importance of centers of excellence in MV surgery are now well recognized, and similar observations are being made for structural heart centers where a strong association between TEER procedural volume and outcomes exists. Data from the TVT registry demonstrate that the learning curve for TEER to obtain a large proportion (~80%) of optimal results (remaining MR 0-1+) extends out to 200 cases.[44] Therefore, operator and imager skills and experience are relevant, specifically when treating complex pathologies that go beyond A2-P2 edge-to-edge repair (see Table 1 for details).

In most patients, the TEER procedure should not be considered in patients with a small MVA (≤3 cm^2), especially when the mean transmitral forward gradient is ≥5 mmHg. Following device implantation, the mean transmitral gradient depends highly on the flow and heart rate and is poorly correlated with MVA, especially in patients with functional MR.[45] Using a multiplanar assessment of both the MVA as well as the leaflets themselves is helpful to decide if proceeding with the TEER procedure is prudent. The approach to specific device selection for the TEER procedure with the MitraClip system is summarized in this chapter's central illustration.

Conclusion

Mitral regurgitation is a heterogeneous disease with numerous etiologies and pathologic variations. Recent advances of catheter-based technologies for TEER have permitted a vast expansion of the overall selection of patients. Previously untreatable conditions are now being treated. Comprehensive echocardiography imaging during the planning and selection phase is critical to selecting the right patient for the appropriate procedure and to guarantee the success of these delicate interventions.[9] In many centers, the TEER procedure has moved far beyond the selection paradigms of the initial clinical trials, and patients with challenging valve pathology at high surgical risk are successfully treated with TEER. Importantly, this requires experienced interventional imagers and operators and thorough procedural planning.

PROCEDURAL PEARLS

- Careful preprocedural imaging using 2D, 3D, and MPR echocardiography is essential for anatomic characterization of the mitral valve anatomy.
- Pay attention to valve area, gradient, and extent of MR jet, which predict the technical complexity of the case.
- Imaging should clearly define the leaflet length and morphology at the exact site of planned grasping to ensure adequate leaflet length for grasping and to minimize the risk of SLDA.
- Although a wide variety of pathologies can be treated with TEER, we recommend that complex scenarios should be treated only at high volume centers or centers of excellence.

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PART II

Transcatheter Mitral Edge-to-Edge Leaflet Repair Device Overview

CHAPTER 3

Imaging Essentials for the Transcatheter Mitral Valve Repair Procedure

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Overview

Improvements and developments in 3-dimensional (3D) echocardiography permit better understanding of anatomic relationships and therefore enhanced communication between the interventional cardiologist and the echocardiographer for guidance of transcatheter mitral edge-to-edge repair (TEER). The posterior location and complex anatomy of the mitral valve is best imaged with transesophageal echocardiography (TEE) and the essential role of 3D TEE is now well established. In this chapter we present a comprehensive step-by-step approach for guiding TEER procedures, including useful procedural pearls on the use 3D TEE imaging.

BOX 1. MITRAL VALVE ANATOMY

A thorough understanding of the different components of the mitral valve (MV) apparatus is critical for optimal imaging guidance. The MV apparatus encompasses the mitral annulus, the two leaflets (anterior and posterior) and their commissures, the chordae tendinae, and the papillary muscles (Figure 1).[1] The annulus is D-shaped rather than circular, with the aortic valve in fibrous continuity with the anterior leaflet of the MV. The posterior annulus lacks this well-formed fibrous skeleton and tends to be weaker and more significantly affected in the setting of annular dilation.

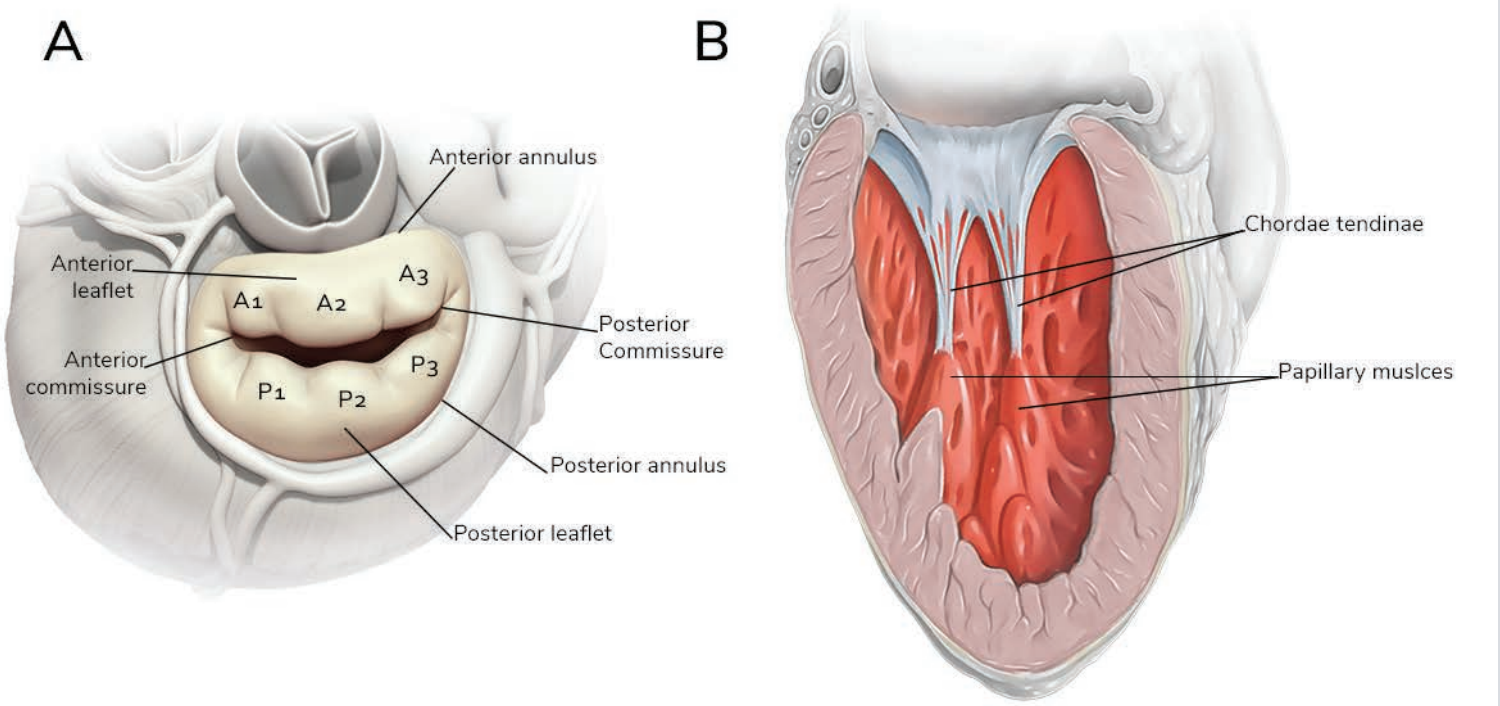


Figure 1. MV Anatomy

(A) MV from left atrial perspective, revealing anterior and posterior leaflets, each divided into 3 scallops: A1, A2, A3 and P1, P2, P3. (B) Left ventricular details.

Pre-procedure imaging evaluation

The pre-procedural transthoracic echocardiography (TTE) and TEE should be reviewed immediately prior to the procedure. After initiation of general anesthesia, perform a TEE in the procedure room to complete a quick pre-procedural checklist as shown in Box 2.[1,8]

BOX 2. PRE-PROCEDURAL IMAGING CHECKLIST

1. Confirm MR etiology, mechanism, and origin of the jet.
2. Assess MR severity under procedural conditions including assessment of pulmonary vein flow reversal, noting the BP for later reference and comparisons. Note: The origin of the MR jet must be precisely localized as it will guide the location of the transseptal puncture (higher if more medial grasp is expected, and lower for a more lateral one).
3. Measure MV gradient by continuous wave Doppler (CWD) and area using 3D planimetry, especially if not done previously, ensuring you are perpendicular to the tip of the leaflets; the use of multiplanar reconstruction (MPR) mode is very useful to make simple and adequate 3D assessment, using 3D zoom and 4 beats acquisition. An MVA ≥4 cm^2 is ideal for mTEER although ≥3.5 cm^2 may be considered in patients with small BSA. The degree of mitral annular calcification should be noted.
4. Evaluate interatrial septum for challenging anatomy and previous interventions (eg, surgical closure of atrial septal defect, lipomatous hypertrophy of the interatrial septum).
5. Briefly evaluate other cardiac features: LV and RV function, left atrial appendage thrombus, pericardial effusion, and tricuspid regurgitation (TR).
6. Measure anterior/posterior leaflet lengths at location of MR in grasping views. Note any leaflet abnormalities such as thickening, calcification, thinning/perforation, presence of cleft(s)/pseudocleft(s), prolapse/flail segment(s), and chordal calcification. Assess baseline flail gaps and leaflet coaptation lengths.
7. Evaluate optimal angles for bicommissural and long-axis views. These should be noted for quick reference in case of challenging imaging during the procedure due to shadowing related to the guide and CDS shaft.

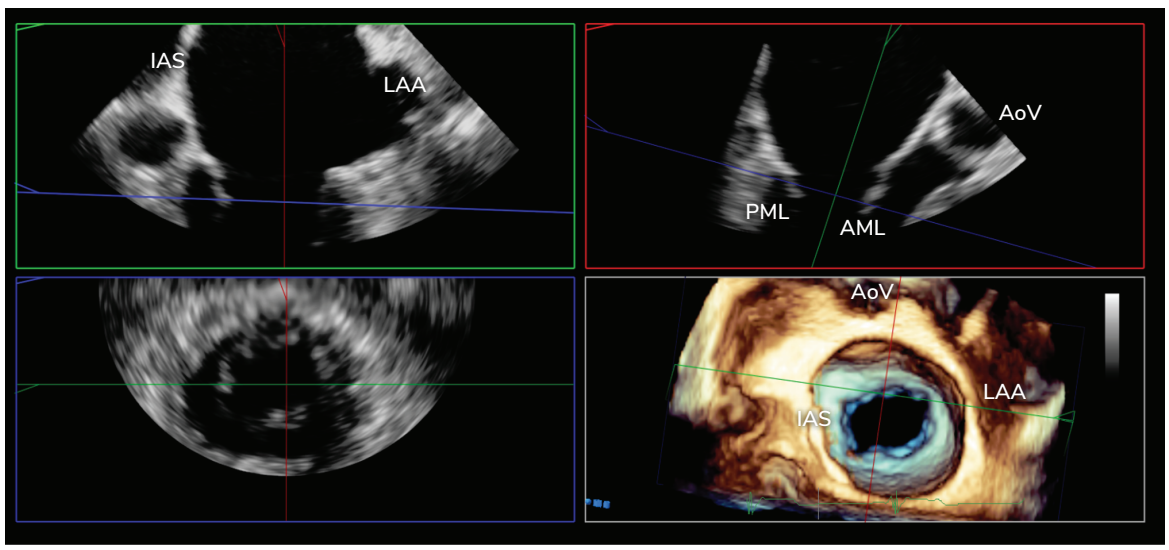
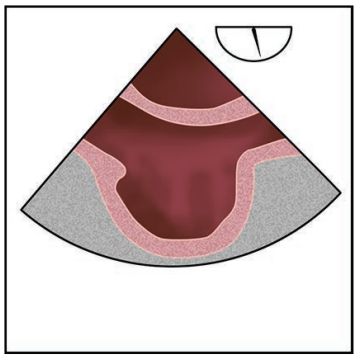
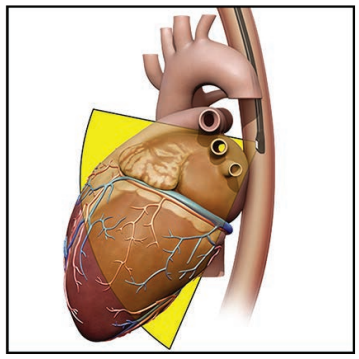
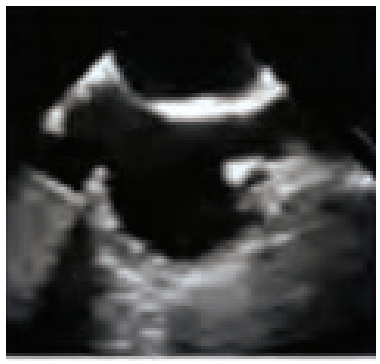


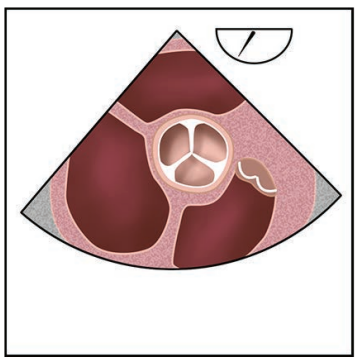
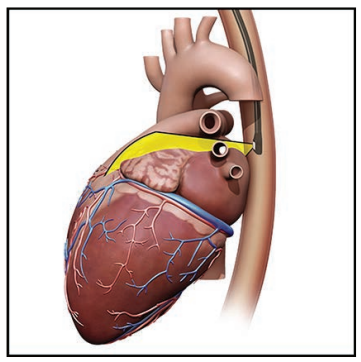
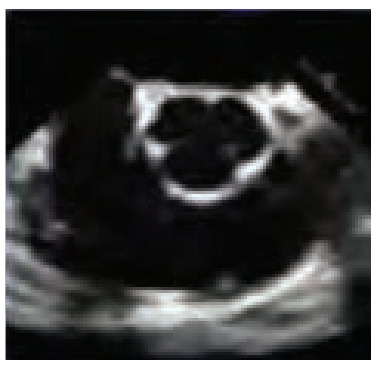
Figure 2. Mitral Valve Area Measurement

For color flow Doppler (CFD), either 3D zoom or full volume (FV) acquisition can be used; FV may be preferable with multiple beat acquisition but is not feasible in the presence of atrial fibrillation. Use standard image optimization techniques including appropriate gain, compression, and color filter settings.[9]

TRANSSEPTAL PUNCTURE

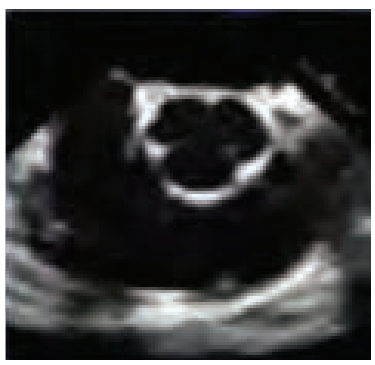
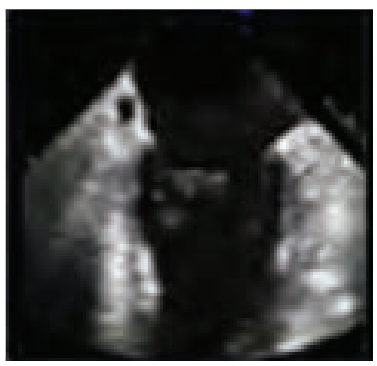
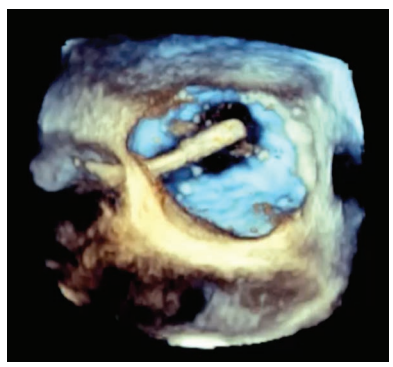




Transducer Angle: ~90 - 110°
Level: Mid-esophageal
Maneuver (from prior image): CW

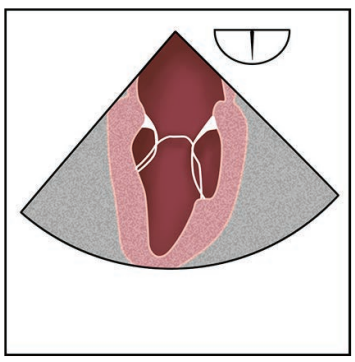
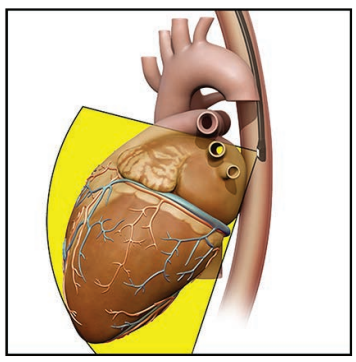
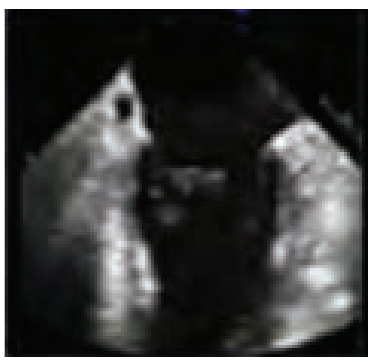
Transducer Angle: ~25 – 45°
Level: Mid-esophageal
Maneuver (from prior image): CCW, Advance, Anteflex

LEFT ATRIAL STEERING

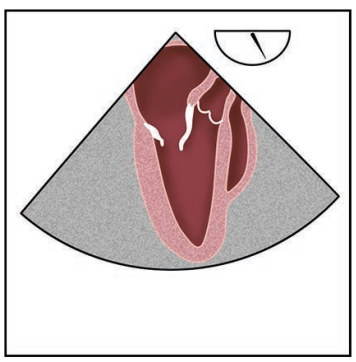
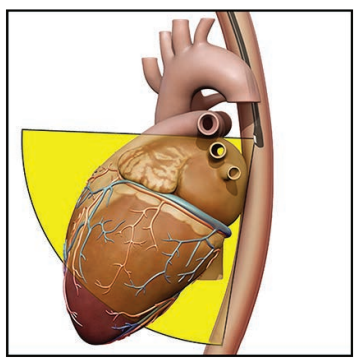
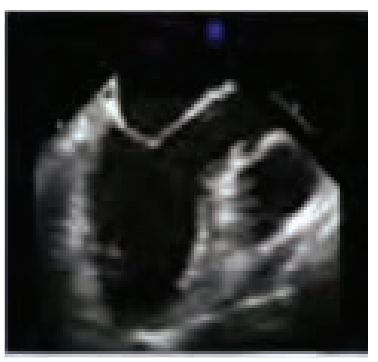




Transducer Angle: ~120 – 140°
Level: Mid-esophageal

CLIP ALIGNMENT AND LEAFLET GRASPING

Transducer Angle: ~50 – 70°
Level: Mid-esophageal

Transducer Angle: ~120 – 140°
Level: Mid-esophageal

Central Illustration

Imaging for transseptal puncture

A real-time visualization of the entire interatrial septum (IAS), including the fossa ovalis, can be obtained using a single-beat FV or 3D zoom from a 2D bicaval window. Optimize the image using the lateral width button to include most of the superior and inferior IAS rims and identify key anatomic landmarks essential for intraprocedural guidance, such as left atrial appendage (LAA), left superior pulmonary vein (LSPV), the LA dome, and its free wall (Figure 2).

Starting from the bicaval view with adequate visualization of the SVC and IVC, follow the TS catheter as it moves down from the SVC toward the IAS. This enhances visualization of IAS if transseptal needle tip and tenting on the IAS is not well seen on X-plane/biplane imaging, particularly if the planned puncture site is very posterior.

The choice of location varies according to the planned grasping area (medial, central, or lateral). Perform measurement in a mid-esophageal 4-chamber non-shortened view to the plane of the MV (Figure 3). Transseptal puncture is best visualized in the mid-esophageal short-axis view, assuring the aorta is well visualized to avoid inadvertent aortic puncture (Figure 4).

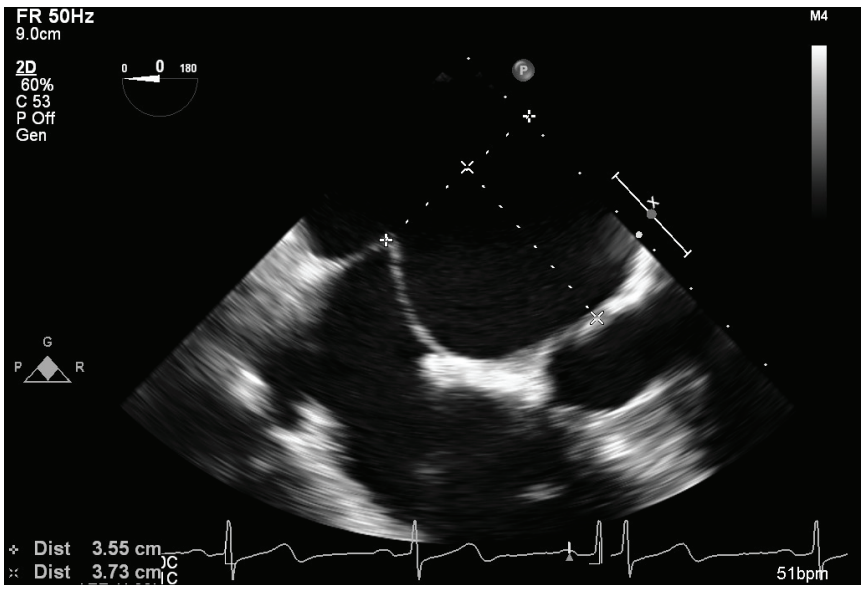


Figure 3. Positioning for Transseptal Puncture

Mid-esophageal view at 0 degree of the MV and the fossa ovalis. Note the transseptal puncture needle seen in RA posterior and superior aspect of the fossa tenting the atrial septum. The distance is measured from the transseptal site (tenting) to the level of the MV coaptation.

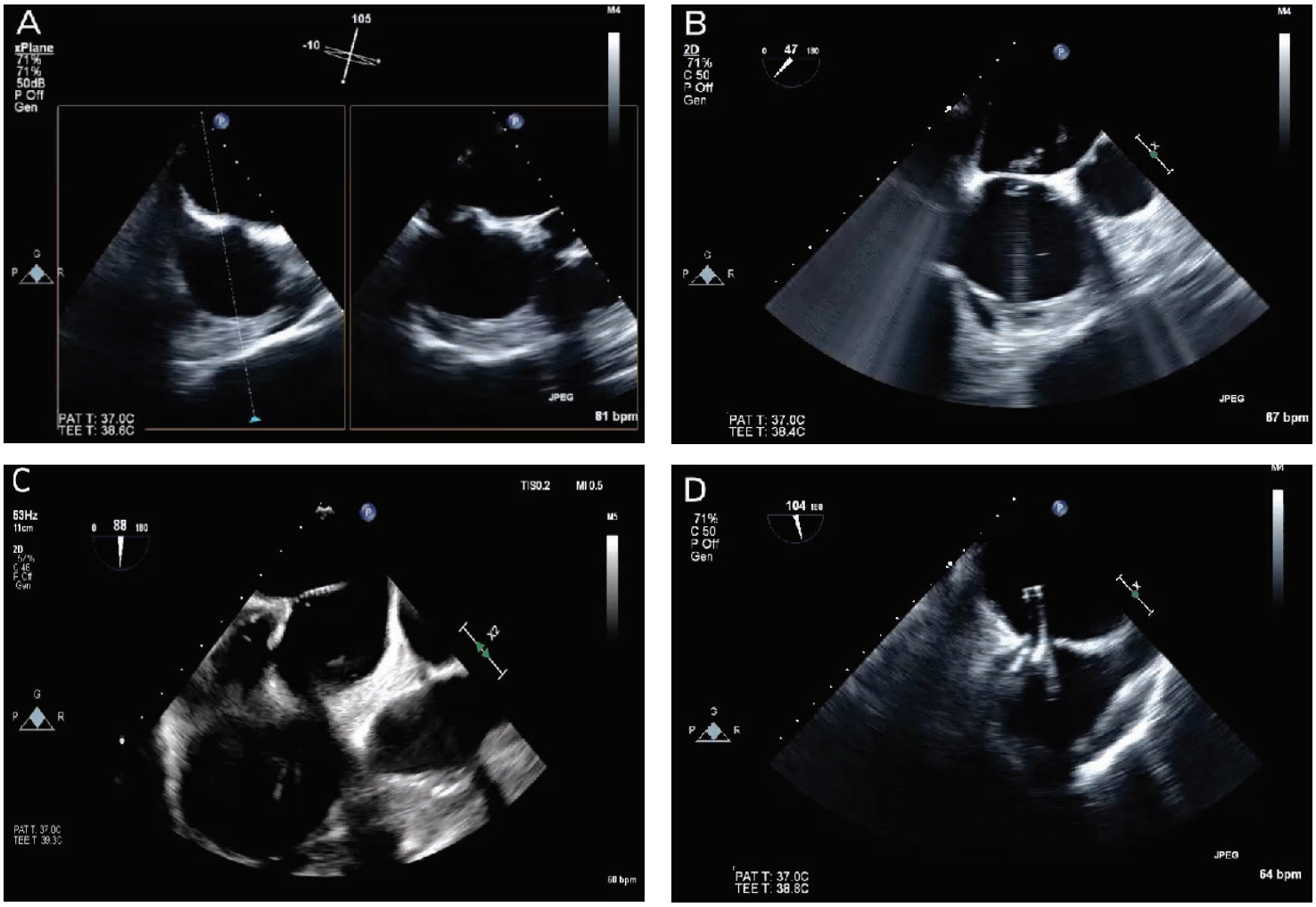


Figure 4 (videos). Transseptal Puncture (2D)

(A) With progressive counterclockwise rotation of the probe from MV view obtained from the bicaval window, the entire wall of the atrial septum is exposed; using X-plane, the short-axis view at the level of the aortic valve is obtained, with "right-invert set up" to depict the more familiar image (shown on the right side of this figure). (B) Layout of the IAS showing the puncture site with the tip of the needle and contrast appearing into the left atrium. (C) The steerable guide catheter (SGC) is seen posterior to the fossa ovalis, with the typical appearance of the dilator being advanced over the wire during septal dilatation. A typical "popping" movement can be seen as the SGC is being advanced into the LA. (D) The SGC with characteristic double-ring tip is seen once the dilator is removed.

The choice of the transseptal puncture (TSP) site is crucial. X-plane imaging allows for simultaneous visualization of the transseptal needle tip in 2 orthogonal planes, providing the necessary antero-posterior (mid-esophageal short-axis view, at the level of the aortic valve, ≅ 45°) and superior-inferior (mid-esophageal bicaval view, ≅ 105°) coordinates, a prerequisite for accurate guidance of the TSP. 3D TEE using either single-beat 3D zoom or single-beat full-volume mode provides real-time visualization of the entire atrial septum in a single-image acquisition obtained from the 2D bicaval view and may be an additional tool for transseptal puncture.[10,11] An ideal transseptal height of 4.5-5.0 cm is recommended, but certainly no less than 4.0 cm.

Imaging the steerable guide catheter

Following transseptal puncture, a wire is advanced in the LA and anchored in the LUPV or the left atrium. The outer diameter of the MitraClip steerable guide is 25 Fr at the proximal end and 23 Fr at the distal end where it crosses the interatrial septum. The 23 Fr steerable guide catheter (SGC) with its dilator is then advanced over the wire, across the septum into the LA. On TEE it appears as a tubular structure with a clear center with 2 linear rail-like dense echoes, and an echo bright radiopaque double ring at its tip, while the dilator appears as a cone with numerous crests. It is imperative to follow the tip of the guide crossing the septum. When the dilator crosses into the LA through the IAS, the operator may feel a "pop", which can be seen by TEE (see Figure 4C). The distance of the SGC tip from the septum can be measured (Figure 5). After the SGC is safely placed in the LA, the SGC is stabilized in the stabilizer, the dilator is pulled back, followed by the stiff supportive wire placed into LUPV or pre-shaped guidewire placed into LA.

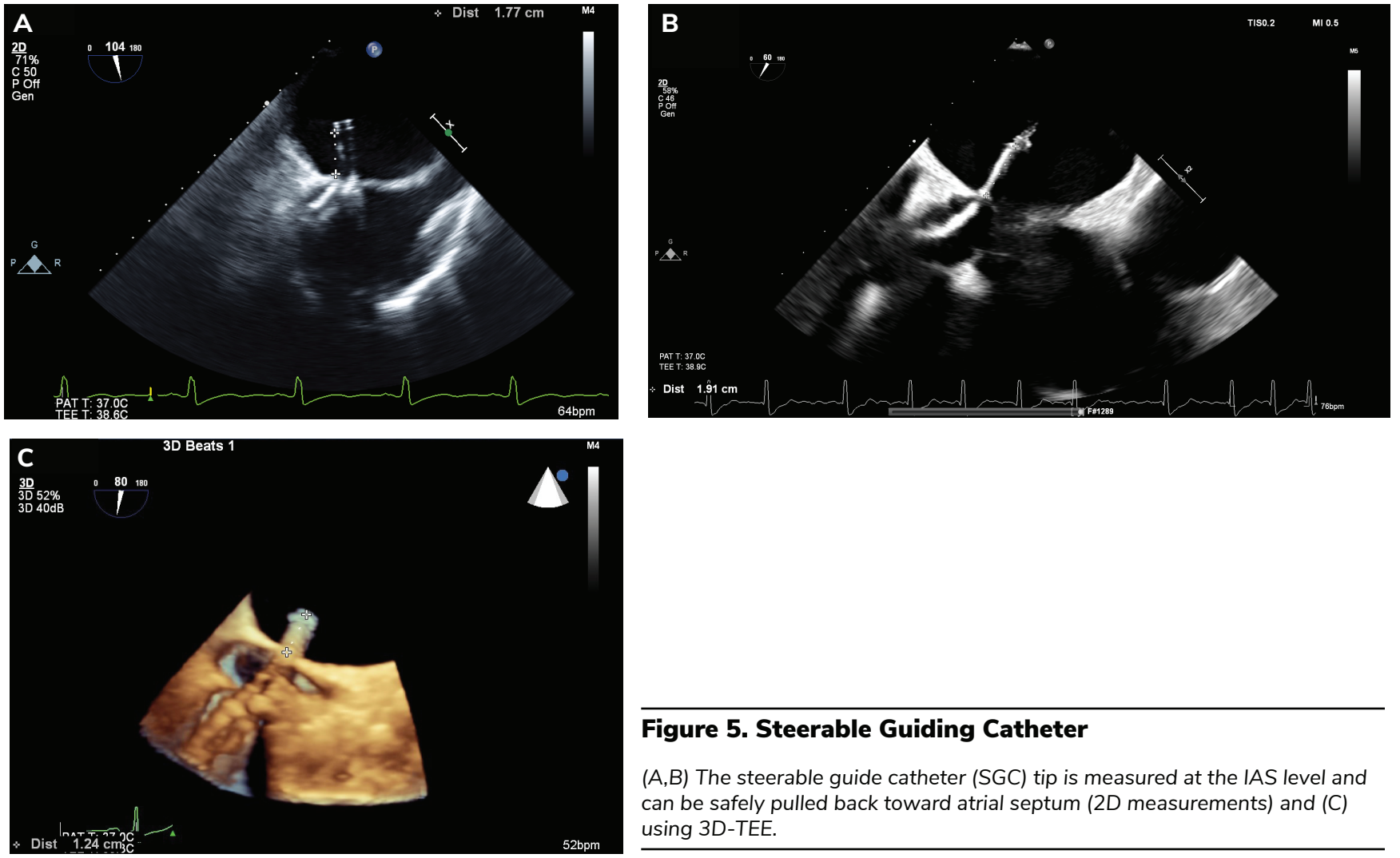


Figure 5. Steerable Guiding Catheter

(A,B) The steerable guide catheter (SGC) tip is measured at the IAS level and can be safely pulled back toward atrial septum (2D measurements) and (C) using 3D-TEE.

Imaging CDS and left atrial steering

Load the clip into the system and advance into the LA. Once the rigid system is in the LA, the imaging angle might need to be adjusted (+20-30°) as the heart becomes more vertical. Advance the clip delivery system (CDS) out of the guide until straddling (only seen by fluoroscopy), and then steer down toward the MV. It is very important to discern the distal end of the CDS as it exits the SGC in the LA to prevent contact with the roof of the LA. Once the CDS is sufficiently advanced outside of the guide, continuously observe the clip as it is steered down toward the MV. Throughout this movement, be sure to visualize the clip, the LA walls, the LAA, the LUPV, and the ligament of Marshall (often called the limbus or warfarin ridge) using a LA wide 3D-zoom (Figure 6). This view is particularly useful to help the interventionalist safely initiate the descent of the clip toward the valve leaflets without requiring much imaging adjustment or switching back and forth between 2D and 3D imaging. This maneuver may require small, gentle movements in patients with a small LA.

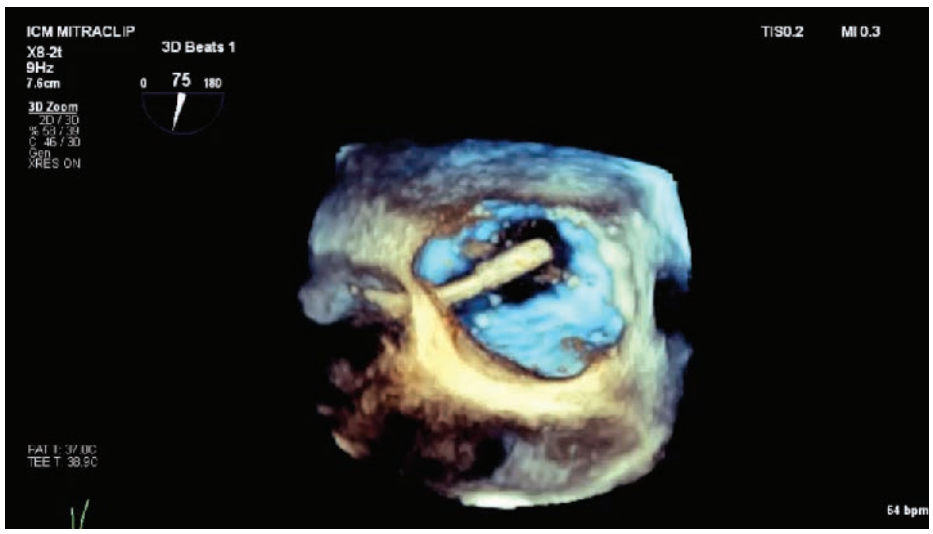


Figure 6 (video). MitraClip Steering into the LA

LA walls are seen using a wide 3D zoom, ensuring safe downward traveling of the clip. The SGC exiting from the IAS is shown on the left with the aorta at 6 o'clock and the MV at the bottom.

Positioning, trajectory, gripper wave, and clip alignment

The trajectory should be established under two perpendicular views (called X-plane on the echocardiograph), with the bicommissural on the left and a long-axis view on the right, or vice versa. Using the "right invert setup button" will facilitate orientation recognition for the team (Figure 7) and allow the operator to adjust the direction of the clip (plus or minus more M torque) accordingly. Take time to find a perfect orthogonal alignment and an optimal trajectory. CFD will permit further refinement of the clip position in relation to the origin of the jet while remaining into the LA. (See also Chapter 10, Left Atrial Steering, Clip Positioning, and Trajectory)

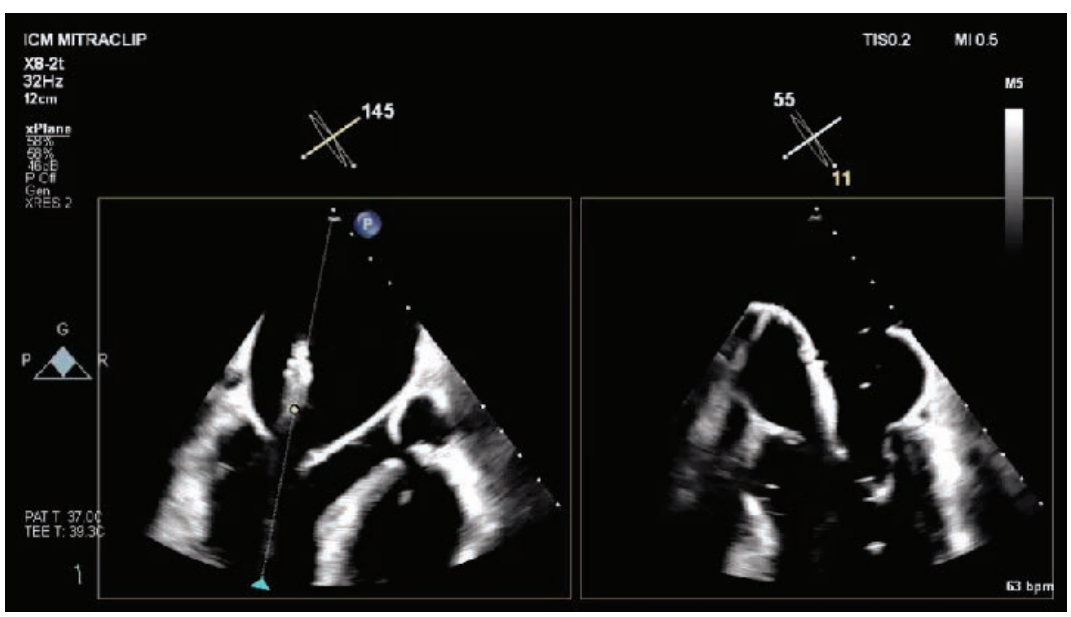


Figure 7 (video). Clip Positioning

X-plane shows a perfect orthogonal alignment and optimal trajectory as the CDS descends toward the leaflets' plane, with the long-axis view on the left and the bicommissural on the right. Use "right invert" to obtain this typical bicommissural image.

The MitraClip has 2 arms and 2 grippers used to grasp the opposing free edges of the anterior and posterior leaflet and is easily seen on TEE. The grippers can be actuated independently. With the clip open at 120-180°, a single gripper can be activated and will be identified as either anterior or posterior, a maneuver sometimes called the gripper wave or gripper identification (Figure 8).

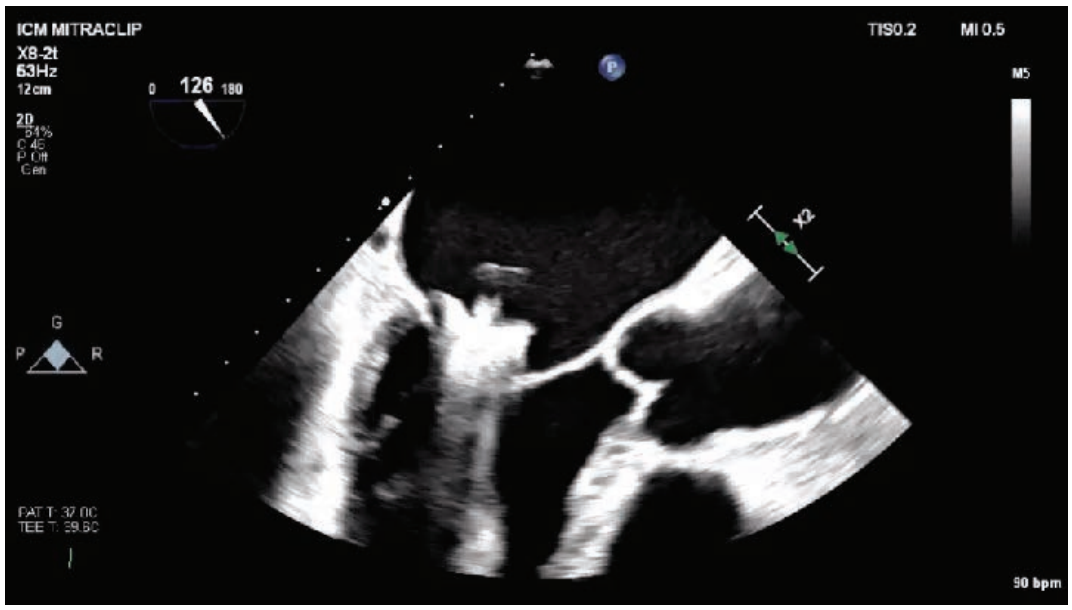


Figure 8 (video). Gripper Wave

Long-axis mid-esophageal view depicting movement of the posterior gripper on the left side of the screen.

Use 3D zoom to ensure that the open arms of the advancing MitraClip are perpendicular to the line of coaptation in the left atrium. Adjusting and repositioning the clip between lateral/medial and anterior/posterior position is done using X-plane from the long-axis view according to the jet origin. 3D en face imaging can guide clockwise or counterclockwise rotation of the MitraClip (Figure 9).

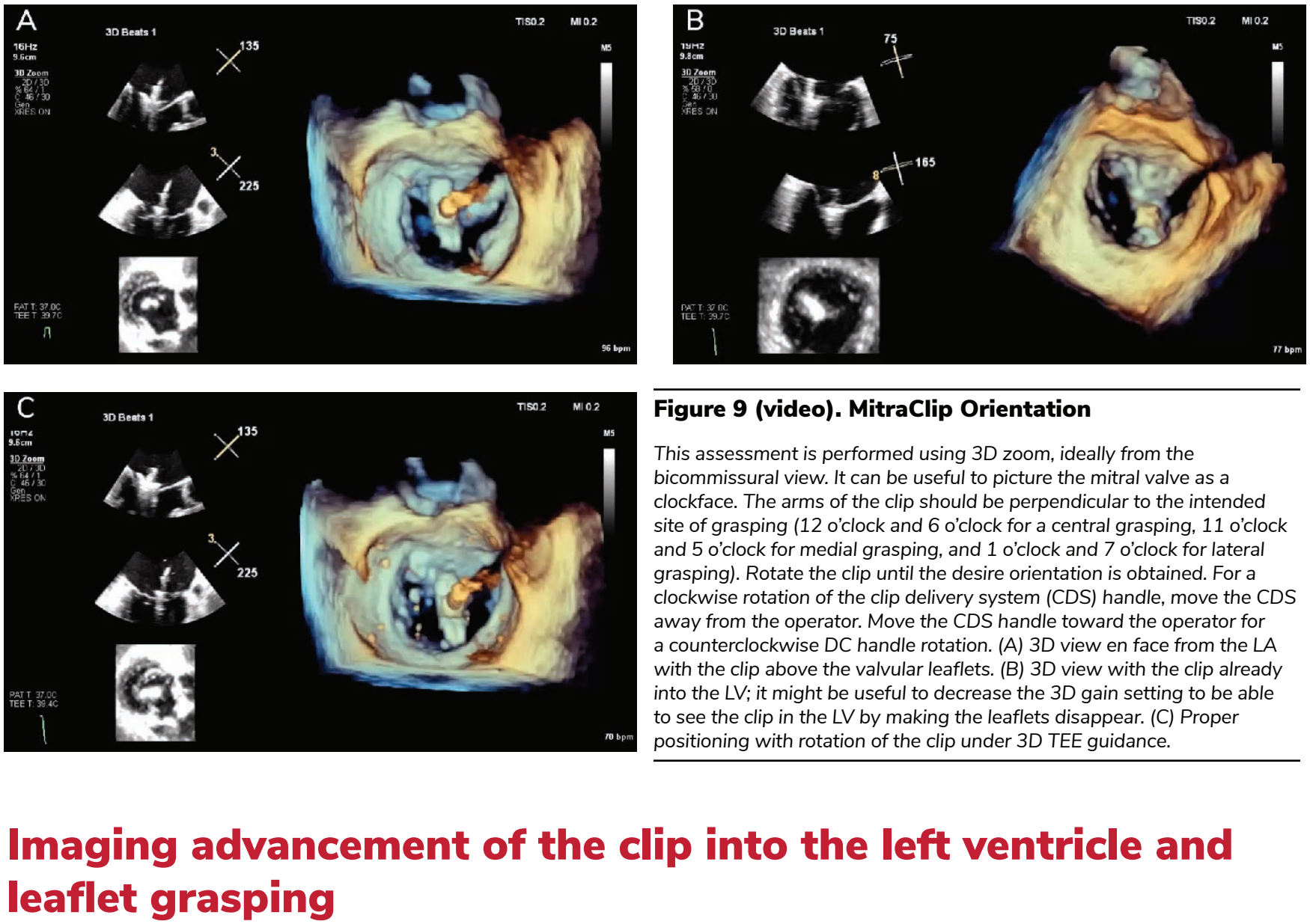


Figure 9 (video). MitraClip Orientation

This assessment is performed using 3D zoom, ideally from the bicommissural view. It can be useful to picture the mitral valve as a clockface. The arms of the clip should be perpendicular to the intended site of grasping (12 o'clock and 6 o'clock for a central grasping, 11 o'clock and 5 o'clock for medial grasping, and 1 o'clock and 7 o'clock for lateral grasping). Rotate the clip until the desire orientation is obtained. For a clockwise rotation of the clip delivery system (CDS) handle, move the CDS away from the operator. Move the CDS handle toward the operator for a counterclockwise DC handle rotation. (A) 3D view en face from the LA with the clip above the valvular leaflets. (B) 3D view with the clip already into the LV; it might be useful to decrease the 3D gain setting to be able to see the clip in the LV by making the leaflets disappear. (C) Proper positioning with rotation of the clip under 3D TEE guidance.

Imaging advancement of the clip into the left ventricle and leaflet grasping

Advancing the MitraClip into the LV is primarily guided by 2D imaging and fluoroscopy, as the device may rotate when advanced from the LA to the LV in preparation for leaflet grasping (See Chapter 11, Clip Alignment and Entering Left Ventricle). To position the CDS above the MV, angle the steerable sleeve down toward the mitral leaflets. Ideally, find an echocardiographic view that aligns the LA, LV, and the clip to avoid multiple movements while advancing the clip prior to grasping (Figure 10). If everything is aligned, rotational movements should be minimal to avoid pinwheeling as much as possible. This may require off-axis and/or a non-standard angle to eliminate the shadow from the shaft/system. Re-evaluate orientation using 3D zoom and rotate the clip according to the planned grasping area. If a clockwise rotation is needed, interventionalists should move the delivery catheter (DC) handle away from them (Figure 11).

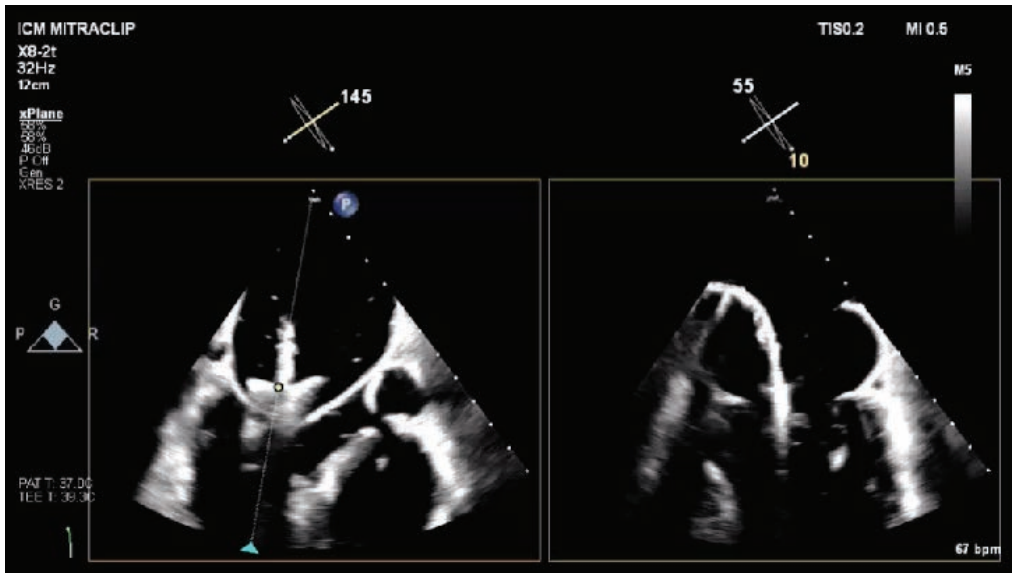


Figure 10 (video). Advancing MitraClip into LV

Long-axis mid-esophageal view with X-plane to the bicommissural view and "right invert" showing the advancement of the CDS with the open clip toward the MV leaflets.

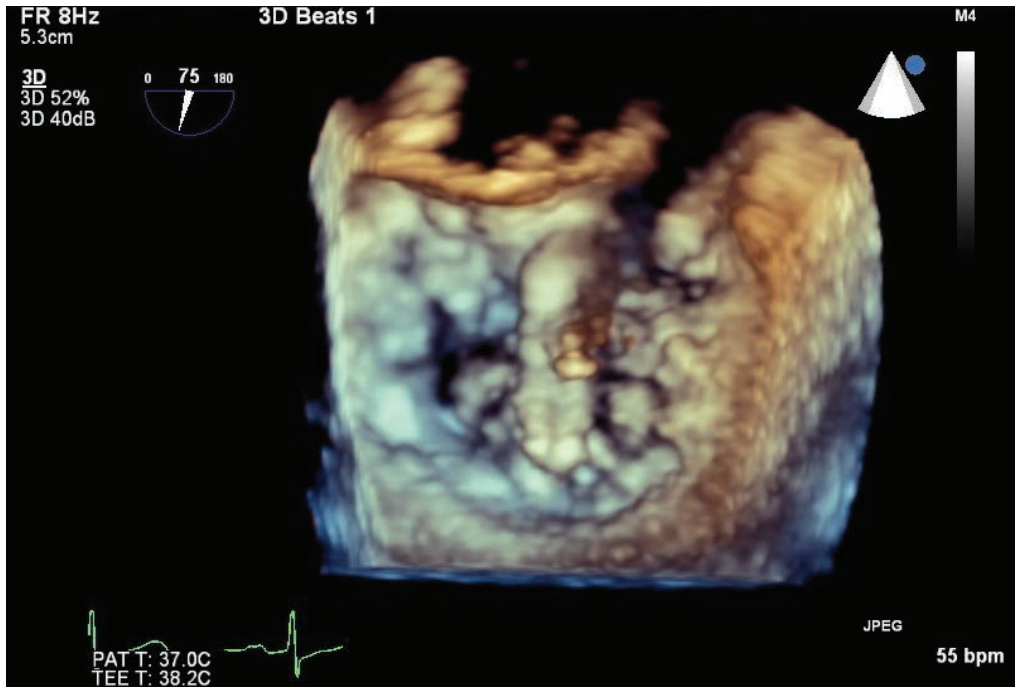


Figure 11. MitraClip Orientation

3D zoom en face view showing perpendicular alignment of MitraClip in a patient with central mitral regurgitation.

Grasping is usually performed in long-axis view. Advance the clip into the LV, just below the leaflets, avoiding the secondary chordae of the MV apparatus. Slowly retract the clip to allow the leaflets to drop on the clip arms. Once both leaflets appear to be captured, lower the grippers and close the clip to 60°. Take a long clip (8-10 beats, retrospective capture) to allow subsequent review of the grasping sequence (Figure 12).

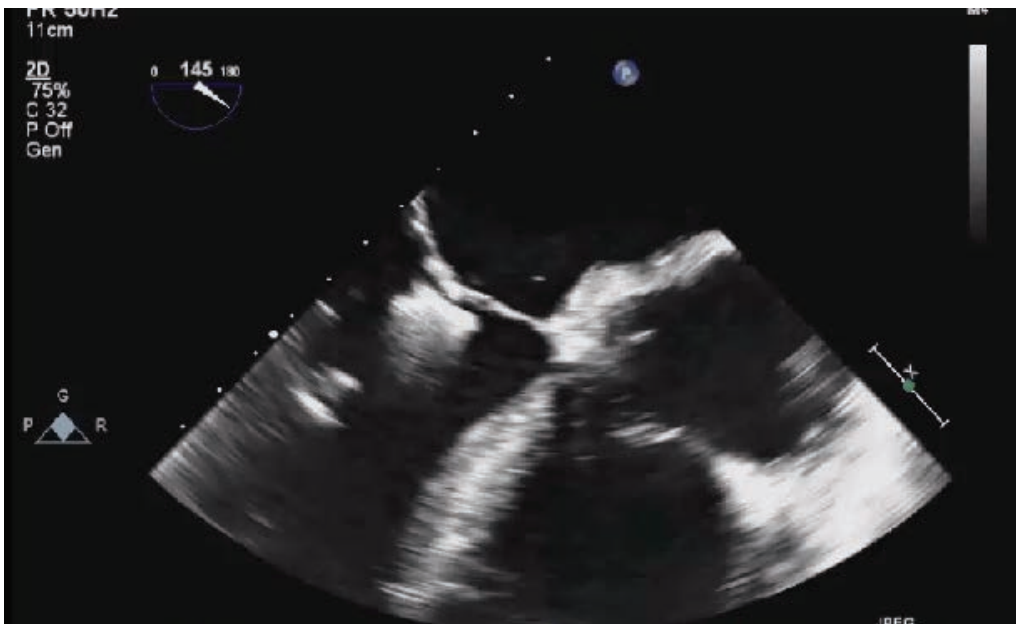


Figure 12 (video). MitraClip Leaflet Capture

Mid-esophageal long-axis 2D view of a long clip showing the 2 leaflets falling onto the clip arms and the grippers being lowered.

Imaging leaflet insertion and assessment of residual mitral regurgitation

The long-axis view usually offers the best visualization of leaflet insertion into the device. This is best accomplished live by seeing them gently fall onto the clip arms during grasping. Confirmation of leaflet insertion is performed using the bicommissural view, an LVOT/grasping view, and the 0° view especially for posterior leaflet insertion. The imager should view the leaflets on either side of the clip. In addition, motion of both leaflets should be restricted, confirming approximation of the free edges of the leaflets by the clip. Once leaflet insertion is deemed satisfactory, the clip should be locked and further closed to a distinct V shape, approximately 20°. The maximal MR severity should be viewed, and the clip is closed using that view with color. A long clip should be taken, and MR reduction re-assessed. A mean gradient is then measured (Figure 13). (See also Chapter 12. Leaflet Grasping and Additional Clips)

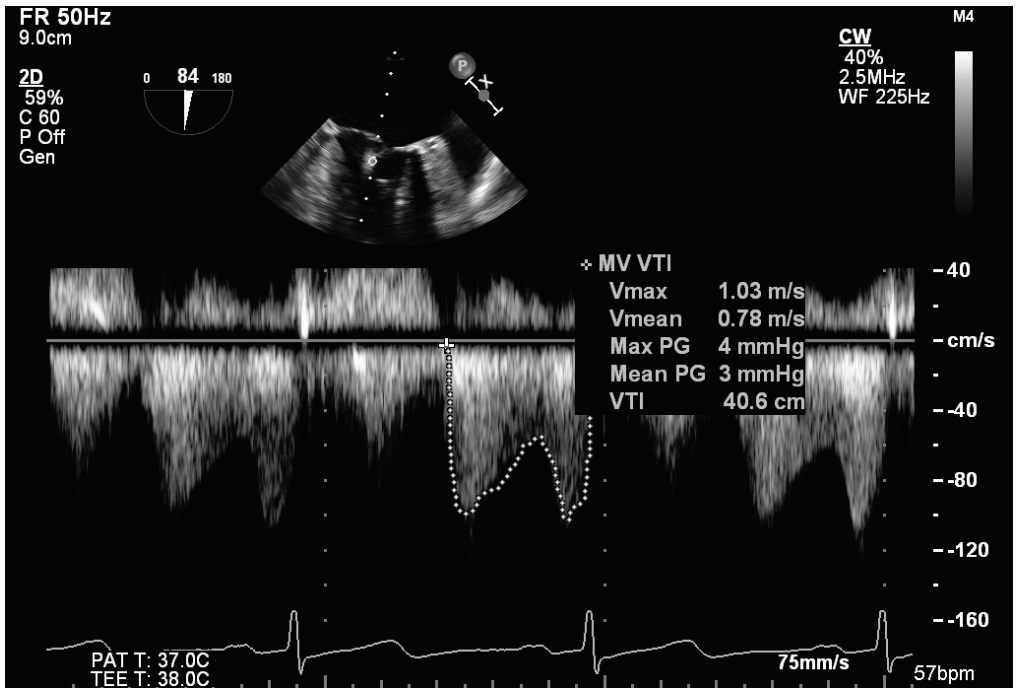


Figure 13. Transvalvular Mitral Gradient After Clip Deployment

A mean gradient of 3 mmHg is obtained in this patient in sinus rhythm with a heart rate of 57 bpm.

After the full closure of the MitraClip, the morphologic features of the valve must be assessed to determine the severity of residual regurgitation and possibility of stenosis. An eccentric residual MR jet may suggest leaflet distortion; the 3D en face view can identify leaflet distortion, confirm clip orientation, and help to confirm the origin of the residual MR jet and the need for additional clips (Figure 14).

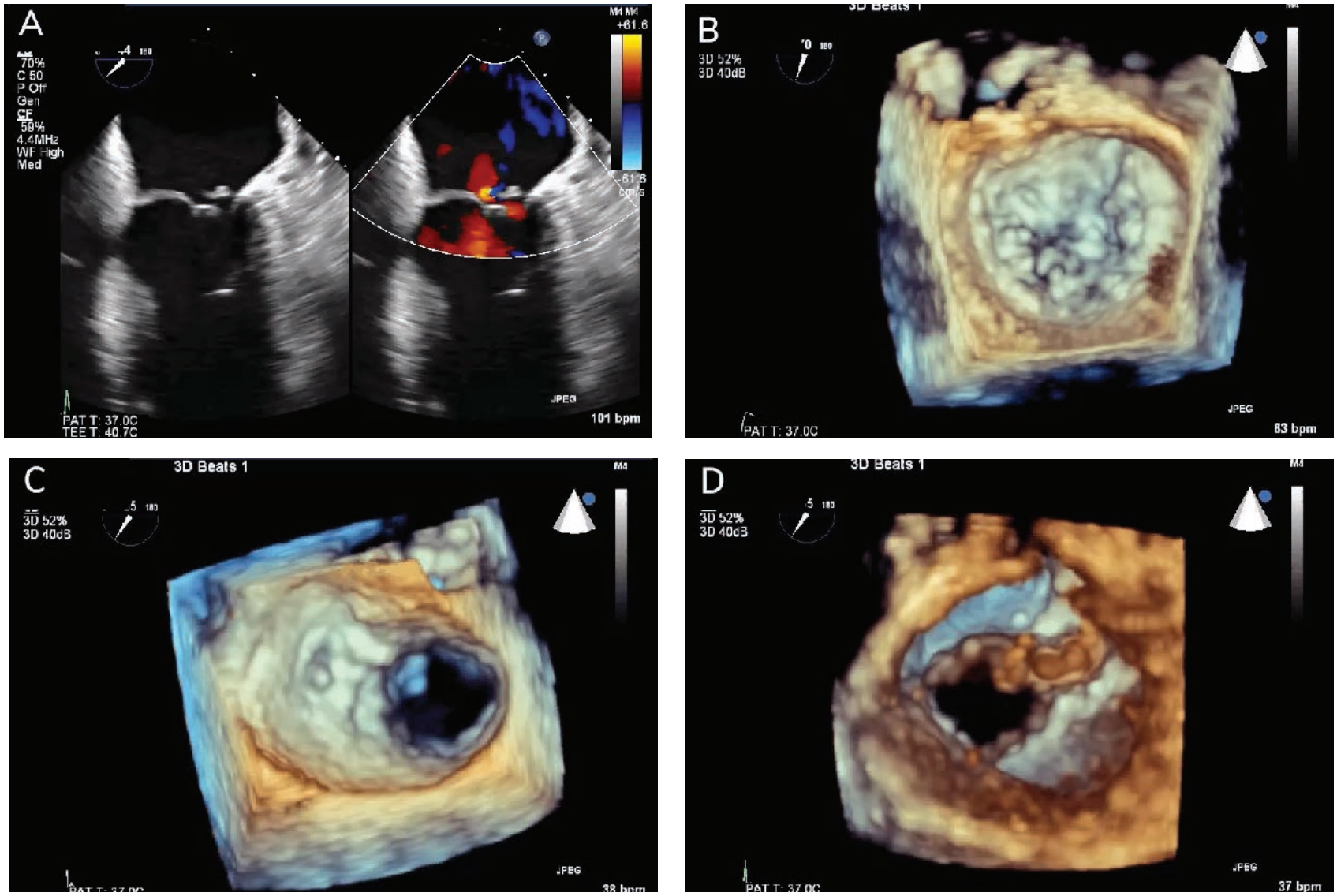


Figure 14 (video). Example: Addressing Flail P1 Leaflet

(A) Mid-esophageal bicommissural 2D view with comparative CFD on the right showing a flail P1 leaflet with its eccentric jet. (B) 3D en face view of this flail P1 leaflet after deployment of the first clip showing an asymmetric opening of the MV with significant residual lateral defect, (C) which is sealed by the second clip. (D) 3D view of the same patient after release of the second clip, viewed from the LV.

Final orifice size and geometry can be evaluated best in either full-volume or 3D zoom. The en face LV 3D view may be helpful when more than one MitraClip is deployed to verify the correct side-by-side positioning of the clips before clip release. While a symmetric double-orifice MV is typically created with central jets, commissural jets are typically associated with the creation of asymmetric orifices. The residual mitral orifice(s) area(s) can be measured by planimetry using the 3D software (Figure 15).

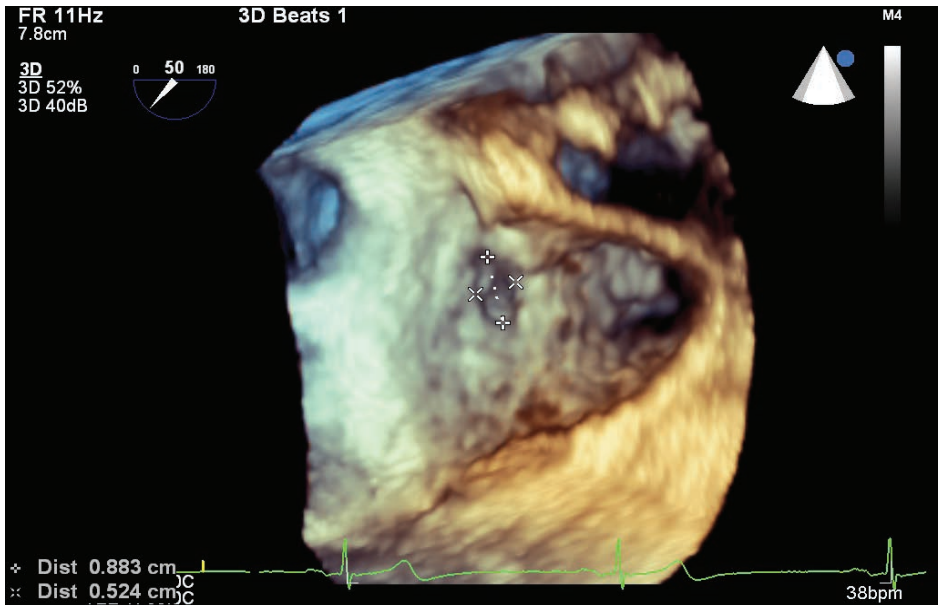


Figure 15. Residual Orifice After First Clip

3D zoom en face frame (from the same patient as shown in Figure 14) showing a residual lateral orifice after the first clip of a patient with P1 prolapse

MR reduction should be evaluated with similar hemodynamics to the beginning of the procedure, therefore vasopressors may be used as required to ensure an adequate blood pressure to evaluate residual MR.

Withdraw the CDS into the SGC while maintaining constant visualization of the distal part of the CDS. After removing the SGC from the LA into the RA, evaluate the interatrial septum. Iatrogenic atrial septal defect (iASD) is a well-known consequence of TEER because of the large size of the SGC. The shape and dimensions of the defect may be readily assessed on 3D TEE, and if percutaneous closure of the iatrogenic ASD is deemed necessary, 3D TEE can guide its closure.[12,13]

BOX 3. FINAL IMAGING EVALUATION CHECKLIST

1. Assess MV morphology after deployment of MitraClip(s).
2. Determine the severity of residual MR or MS and the origin of residual MR.
3. Assess the need for additional devices.
4. When more than one MitraClip is deployed, verify side-by-side positioning of clips.
5. Guide withdrawal of CDS from the LA and across the IAS after MitraClip deployment.
6. Assess size of iatrogenic ASD and guide closure if necessary.

Imaging of challenging anatomy

Commissural MR

Although commissural MR was excluded from treatment in the early clinical trials for TEER, commissural MR can be successfully treated with a specific transseptal puncture site and careful planning (Figure 16). In cases of flail involving the medial commissure (A3-P3), the interventionalist might choose to perform a more posterior (higher) and inferior transseptal puncture and the angle of the TEE should be adjusted to avoid the shadow of the SGC. This usually can be accomplished by either increasing the angle (160°) or sometimes decreasing it (115°) and torquing the probe at the same time to see both leaflets for capture and confirmation of leaflets' insertion.

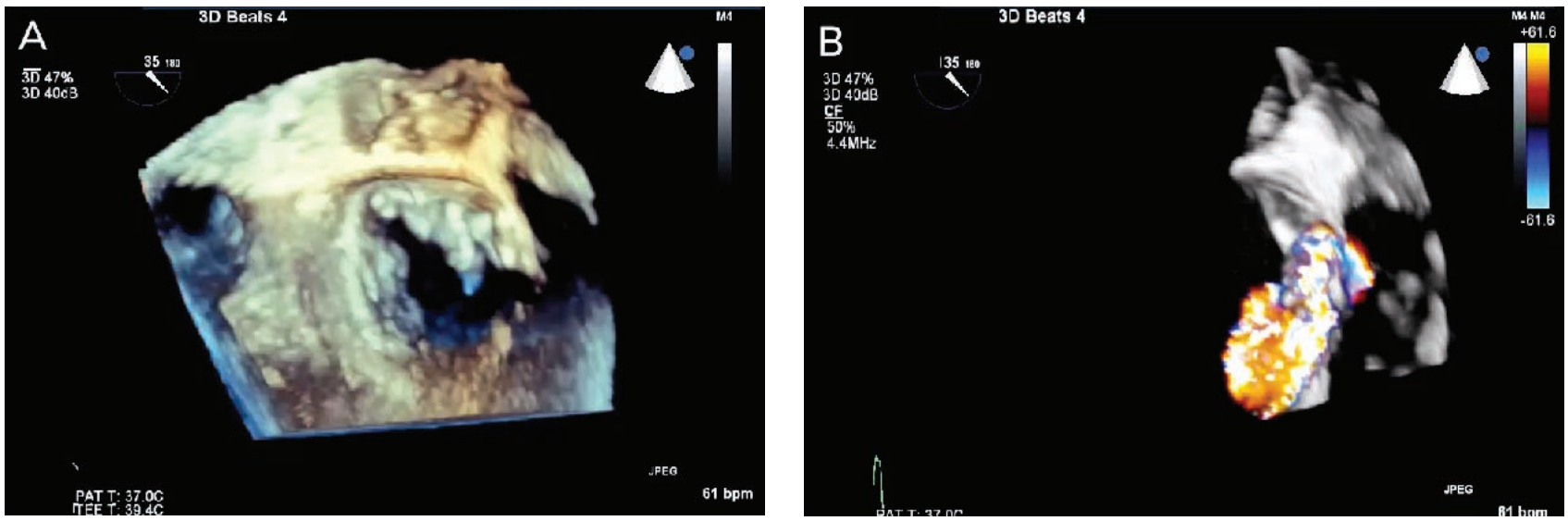


Figure 16 (video). Medial Commissural MR

(A) 3D zoom flail P3-A3 commissure with ruptured chordae and (B) with CFD.

Posterior leaflet clefts

Cleft or deep indentation in the posterior leaflet, usually located between P1 and P2, may preclude successful TEER when associated with significant MR. Three-dimensional TEE is superior to 2D TEE in detecting mitral clefts[14,15] that can be viewed from the atrial and ventricular surface of the MV. Once again, a thorough TEE assessment in the echocardiography laboratory should diagnose this entity and the heart team will evaluate the potential success of the procedure on a case-by-case basis (Figure 17). Mitral cleft traditionally refers to the anterior leaflet with septal chordae attachment. It is important to distinguish this entity from cleft-like indentation (CLI), an expression initially proposed by Mantovani to differentiate between true anterior cleft and large indentation between two posterior scallops, which are not a contraindication to TEER, especially now with the availability of devices with wider arms.

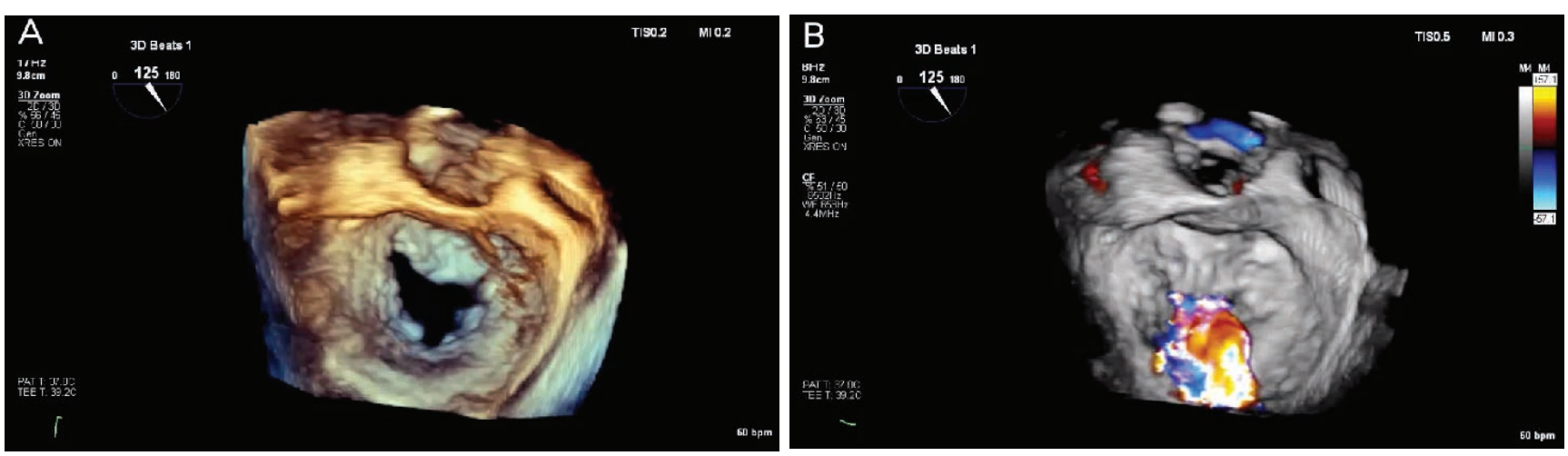


Figure 17 (video). Posterior Leaflet Clefts

(A) 3D zoom of an MV appearing as 3 leaflets or clefts in the posterior leaflet and (B) with CFD. The patient was successfully treated with TEER.

PROCEDURAL PEARLS

- MV area should be measured using 3D from 2 orthogonal planes placed at the tips of the leaflets.
- The choice of the TS puncture site is crucial.
  - The location varies according to the planned grasping area (medial, central, or lateral).
  - X-plane imaging allows for simultaneous visualization of the transseptal needle tip in 2 orthogonal planes.
- Difficult imaging can sometimes be improved with slight lateral tilting of the patient or by placing an inflatable pillow or pressure bag under the patient's right shoulder.
- The trajectory should be established under 2 perpendicular views (called X-plane), with the bicommissural on the left and a long-axis view on the right, or vice versa. Using the "right invert setup button" will facilitate orientation recognition for the team.
- Clip orientation: The arms of the clip should be perpendicular to line of coaptation at the intended site of grasping.
- Grasping is usually performed in long-axis LVOT view. If it is difficult to obtain this view, the bicomm view can be used to identify an optimal LVOT with X-plane imaging.

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CHAPTER 4
A User's Guide to the MitraClip Device

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Overview

The MitraClip device was developed to be an endovascular adaptation of a surgical edge-to-edge mitral valve repair. The surgical technique was described by Alfieri and first used in 1991 to approximate the middle scallops of the anterior and posterior leaflets with a suture, creating a double orifice mitral valve. The endovascular technique was first published in 2003 by St. Goar et al.[3] and described short term results in a porcine model of an endovascular device which restored leaflet coaptation by fastening the leaflets together in a clip. The initial MitraClip device has seen many iterations (Figure 1) including the addition of multiple clip sizes. The currently available system is MitraClip G4 (fourth generation) which is described in this chapter.

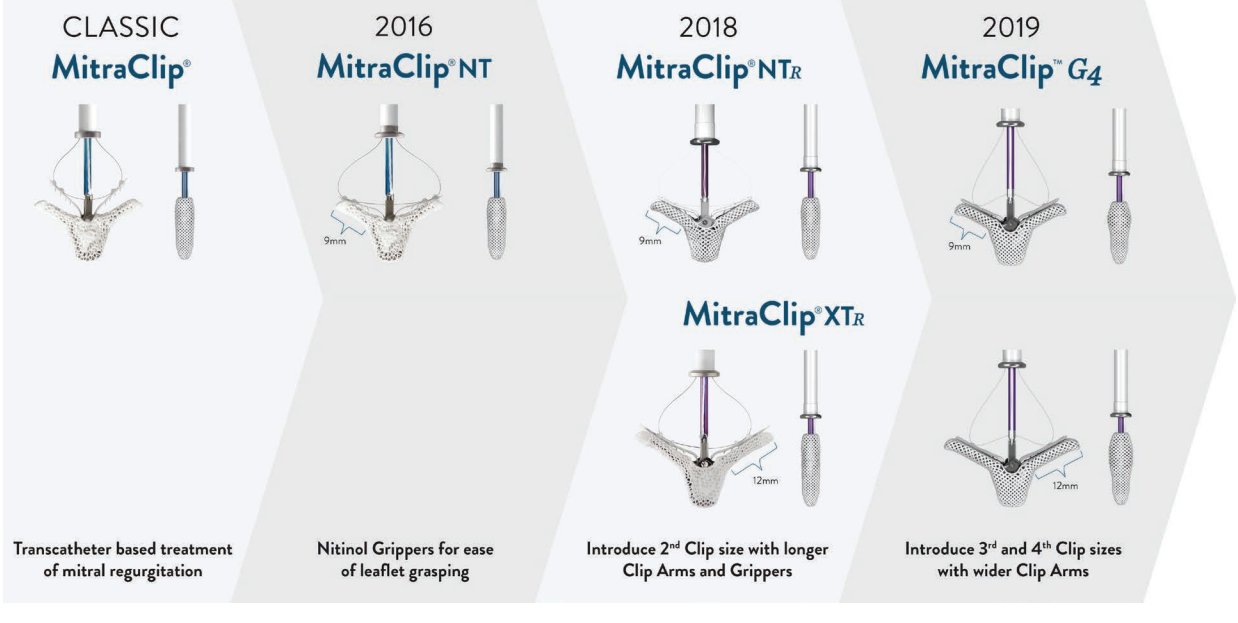

Figure 1. Evolution of the MitraClip Device

Device components

The MitraClip System components include a steerable guide catheter (SGC) and handle, the clip delivery system (CDS), and delivery catheter handle (Figure 2). The stabilizer supports the entire apparatus and facilitates motion.

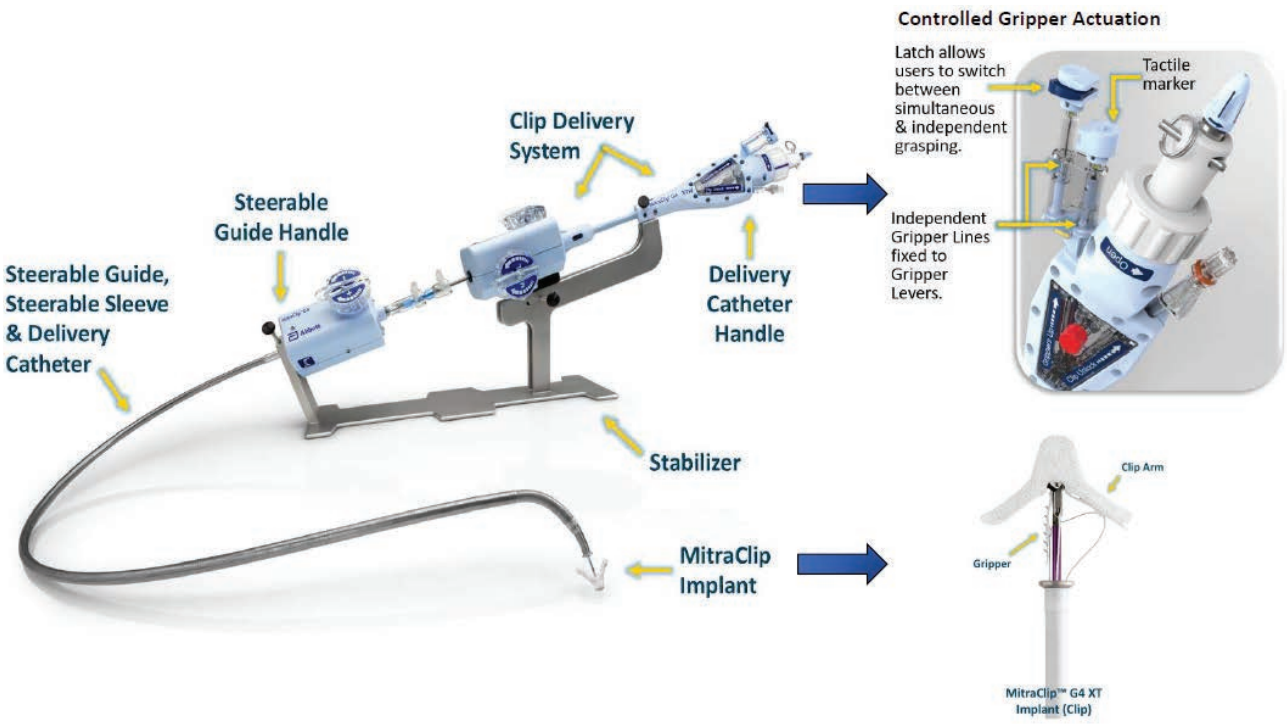

Figure 2. MitraClip G4 System

Steerable guide catheter (SGC)

The MitraClip G4 SGC tapers from 25 Fr at the proximal end to 23 Fr at the distal end. The MitraClip G4 system also offers an incorporated left atrial pressure monitoring port achieved via transduction of the sideport of the SGC intraprocedurally for real time LA pressure monitoring.

The SGC is curved near the distal end and is equipped with one knob (+/-) which permits the additional curving of the distal catheter or removal of the curve as required (Figure 3A). The guide handle can be rotated (Figure 3B) away from (posteriorly) or toward (anteriorly) the operator to move the distal end of the catheter in either direction.

The +/- knob deflects the tip of the SGC. Turning the knob in the plus direction adds additional curve to the tip of the SGC, while turning the knob in the minus direction straightens the tip of the SGC. The knob is positioned in the minus position while advancing through the access site and is then returned to the neutral position for septal crossing. During navigation within the LA, the + knob may be used to direct the SGC tip inferiorly and posteriorly to permit straddling of the CDS in the LA. This typically translates to a loss of height and motion of the device more medial and posterior. The - knob typically extends the SGC tip toward the anterior wall of the LA, providing added height while moving the device more laterally and anteriorly. This is summarized in Table 1.

Table 1. MitraClip Device Component Movements

	ANTERIOR	POSTERIOR	MEDIAL	LATERAL	LOSE HEIGHT ABOVE VALVE	GAIN HEIGHT ABOVE VALVE
Steerable Guide Catheter (SGC)						
Plus (+)		++	+		+	
Minus (-)	++			+		+
Clockwise rotation		++				+
Counter-clockwise rotation	++				+	
Clip Delivery system (CDS)						
Medial (M)			+++		+	
Lateral (L)				+++		+
Posterior (P)		+	+		+	
Anterior (A)	+			+		+
Stabilizer						
Push In (L)				+		
Pull out (M)			+			

The SGC handle body can be rotated clockwise (posterior) and counterclockwise (anterior) to facilitate device positioning more posterior or anterior. This is often employed during grasping to optimize anterior/posterior clip positioning.

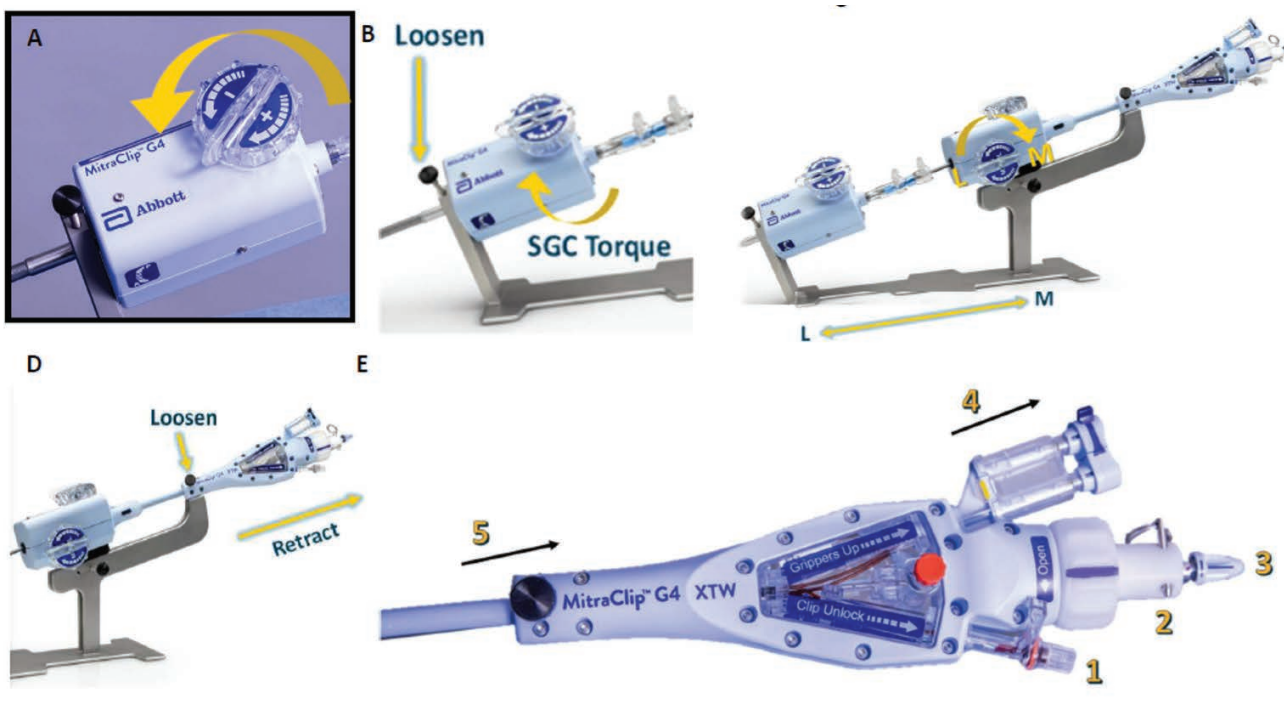

Figure 3. Device Controls

(1) Lock line, (2) Release pin, (3) Actuator knob, (4) Grippers with independent gripping capabilities, and (5) DC fastener

Clip delivery system (CDS)

The CDS must be inserted into the SGC. While maintaining flush on the CDS, and liberally irrigating the SGC hemostatic valve, the CDS is inserted into the SGC by placing the tip of the clip introducer against the SGC hemostasis valve and advancing the introducer into the valve with a continuous motion. The CDS is then advanced, while rotating the clip introducer in small clockwise and counterclockwise motions until the clip is visualized distal to the SGC hemostatic valve.

Next, appropriate keying of the CDS is performed to ensure appropriate device maneuvers. Both the SGC and CDS have blue line markers which must be aligned on insertion using small motions to engage the appropriate grooves to achieve an appropriately keyed insertion. Appropriate "keying" of the SGC and CDS is vital to ensure appropriate M/L and A/P knob function as described below. Should there be any inappropriate maneuvers noted, "mis-keying" should be suspected and managed as outlined in troubleshooting below. The clip introducer should be left fully inserted within the hemostasis valve throughout the period that the CDS is inserted and all stopcocks should be closed to the system aside from those providing continuous flush.

The CDS has a separate set of controls that are complimentary to the SGC to achieve precise device positioning. The CDS sleeve handle has two sets of knobs: (Figure 3C)

- The "M/L knob" moves the sleeve and clip medially or laterally
- The "A/P knob" provides anterior/posterior deflection to the implant and enables optimization of height of the CDS above the leaflets

The addition of M knob will deflect the clip in the medial direction, while L knob will remove medial deflection and move more laterally within the LA. Similarly, advancement of the stabilizer will lead to lateral translation, while retraction will move the system medially. The addition of A knob will help the clip gain height (or "ascend"), while the P knob will help the clip to lose height (or "plummet") toward the valve. These maneuvers can be incorporated in specific advanced steering maneuvers as described in Table 2.

Table 2. Advanced Steering Maneuvers

SITUATION	HOW TO ADJUST
Excessive height *Inadequate delivery catheter travel to advance clip below leaflets*	• Torque guide handle anterior until clip is pointing at aorta • Add (P) knob input (at least 180º of knob input) until clip is redirected to center of valve • Adjust medial/lateral position (intercommissural) • Adjust anterior/posterior position (LVOT)
Inadequate height *Inadequate clip clearance when delivery catheter handle is fully retracted*	• Torque guide handle posterior until clip is pointing at posterior annulus • Add (A) knob input (at least 180º of knob input) until clip is redirected to center of valve • Adjust medial/lateral position (intercommissural) • Adjust anterior/posterior position in (LVOT)
"Aorta hugger" *Delivery catheter biased toward aorta*	• Add (+) knob input to sweep posterior • Adjust medial/lateral position (intercommissural) • Adjust anterior/posterior position (LVOT)

The delivery catheter handle enables clip advancement/retraction/rotation to align the implant on the valve with a locking screw to secure position (Figure 3D). The handle of the CDS (Figure 3E) includes the lock line, release pin, actuator knob, grippers with independent gripping capabilities, and DC fastener to enable leaflet grasping and implant deployment. The lock line is locked by default and must be disengaged to open the clip arms. To unlock the clip, turn the lock lever counterclockwise, withdraw the lock lever until the blue line is visible on the lock lever, and turn clockwise to fix the lock lever in the unlocked position.

The grippers contain frictional elements that engage the leaflet tissue to secure them against the clip arms when lowered. With MitraClip G4, a novel feature called controlled gripper actuation (CGA) enables independent gripper mobilization that facilitates grasping to optimize one leaflet's grasp independently of the other. The distal end of the CDS handle has two gripper levers: one with a tactile marker and one without. Once clip position has been established safely within the LA, identify which gripper is anterior and posterior to facilitate independent grasping and optimization. This can be performed by raising and lowering one gripper while assessing on echocardiography to identify the corresponding anterior or posterior clip arm relative to the tactile or non-tactile gripper lever on the CDS. This should be performed prior to crossing the valve to facilitate optimal grasping.

The arm positioning knob controls the arm position of the clip with clockwise motion closing the clip while counterclockwise motion opens the clip. For optimal results, it is vital to ensure appropriate unlocking/locking, gripper position, and location relative to intracardiac structures prior to opening/closing the clip throughout the clip positioning and grasping sequence.

MitraClip implants

The MitraClip G4 implant is available in 4 different sizes: NT, NTW, XT, and XTW. The width of the regular NT and XT devices is 4 mm and the width of the wide (W) versions (NTW and XTW) is 6 mm. The dimensions are illustrated in Figure 4. Device preparation for both the SGC and CDS requires careful attention to detail while following several sequential steps.

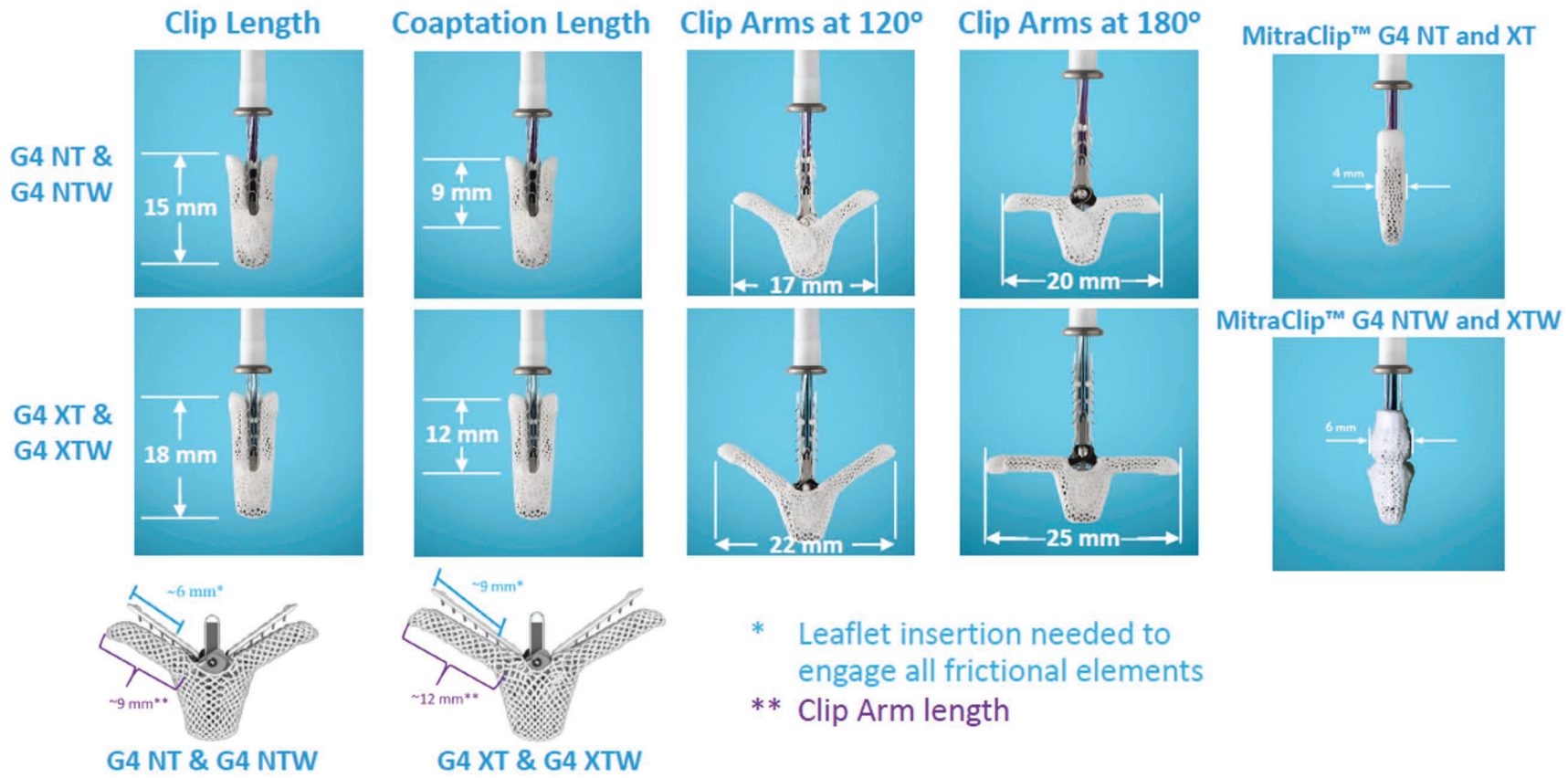

Figure 4. MitraClip Dimensions

Clip deployment

Once leaflet insertion, grasp, and hemodynamics are confirmed, proceed to deployment (Figure 5).

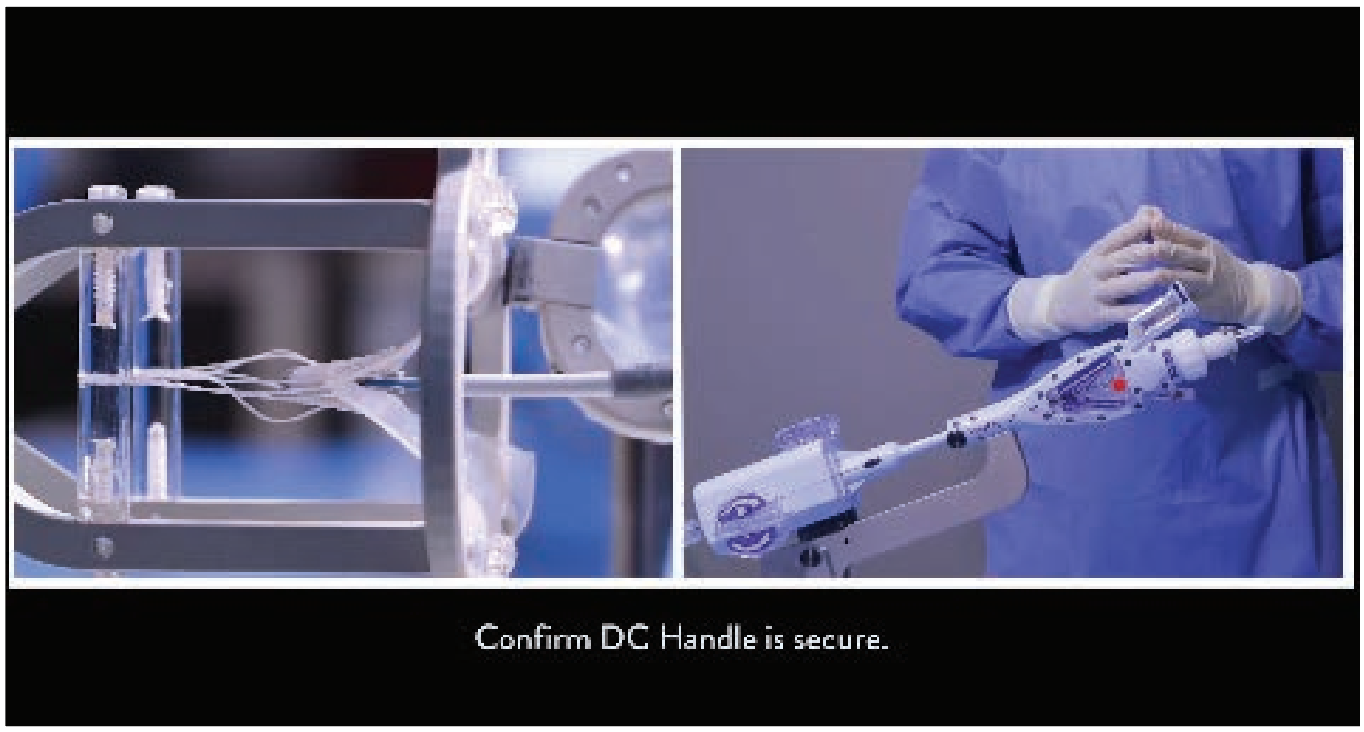

Figure 5. Clip deployment steps

STEP 1.
Establish final arm angle to ensure that the clip locking mechanism holds.

- With the lock lever fully advanced, turn the arm positioner to neutral (note the orientation of the blue line on the arm positioner), followed by another turn in the "open" direction
- The clip arms may open slightly (~5°) and then remain in a stable position. Turn the arm positioner to the "closed" side of the neutral position.

STEP 2.
Remove the lock line

- Remove the lock lever cap and "O" ring and unwrap the two ends of the lock line in a counterclockwise direction. Separate the ends of the lock line and remove the plastic cover from the lines so that no twists or knots are present. Grasp one of the free ends of the lock line, confirm the line moves freely via "flossing," and slowly remove the lock line.

STEP 3.
Establish final arm angle again

STEP 4.
Remove the clip release pin

- Turn the arm positioner to neutral, ensure the release pin moves freely and then remove the release pin from the DC handle.

STEP 5.
Clip deployment

- Turn the arm positioner in the "open" direction until the release pin groove is fully exposed. Turn the actuator knob of the DC handle approximately 8 turns in the direction of the arrow printed on the actuator knob (counterclockwise). Retract the actuator knob approximately 0.5 cm after it is fully unthreaded
- Raise the gripper levers, the clip is now deployed.

Release the DC fastener, and slowly retract the DC handle until the DC radiopaque ring is against the tip of the sleeve. Confirm that the DC handle is fully retracted, and that the clip is stable on both echo and fluoro.

Carefully retract the CDS back into the SGC, being mindful of the distal tip location within the LA. Releasing medial deflection on the M/L knob and + on the SGC is required prior to completely withdrawing the CDS. Ensure the delivery catheter tip is inside the clip introducer by visualizing the proximal sleeve alignment marker just outside the clip introducer, then simultaneously remove the CDS and clip introducer. Cover the guide hemostasis valve with a finger upon CDS removal to prevent air entry while aspirating the guide.

Troubleshooting

Understanding the steps to take when issues are encountered is key to safe and efficacious MitraClip implantation. With the SGC, follow careful de-airing techniques during preparation steps as outlined. During preparation, assessment for air entrainment is critical to note potential valve incompetency prior to introduction into the patient. If air entrainment is noted, exchange the SGC for a new SGC and repeat the preparation steps.

Carefully inspect the clip introducer prior to insertion within the SGC hemostasis valve to avoid potential damage to the valve. Once in the left atrium, if air is noted within the system, initiate liberal aspiration of the system and withdraw the CDS. If the air cannot be removed from the SGC during aspiration, remove the entire unit from the left atrium. Similarly, maintain continuous TEE monitoring for the presence of thrombus on the equipment or intracardiac structures intraprocedurally and if noted, follow aspiration using standard transcatheter techniques.

For the CDS, if there is concern of mis-keying following insertion of the CDS within the SGC, fully close the clip, remove and discard the CDS from the SGC, and prepare and insert a new CDS paying careful attention to the keying process as described. If grippers are not functioning properly, first ensure safe clip positioning away from intracardiac structures or the SGC. Next, unlock and lock the clip, which should free the grippers and enable normal motion. If this does not resolve the issue, remove the CDS and prepare a new CDS. On clip deployment, final confirmation of stable arm positions may demonstrate re-opening of the clip arms beyond 5° of motion. If this occurs, re-check that the lock lever is completely advanced/locked into position, then re-close the clip arms and reassess final arm angle. If the clip arms continue to move from final arm angle, remove the device and prepare a new one.

If difficulty is encountered when releasing the clip, this may be related to coaxiality between the DC shaft and the clip or misalignment of the gripper lines, particularly if separation is achieved from the DC. First confirm the actuator knob is retracted, release pin groove fully exposed, and gripper levels are fully retracted, and then re-attempt release. If not successful, re-secure the DC fastener and reposition the device to improve coaxiality between the DC shaft and clip and repeat release efforts. If unsuccessful, then secure the DC fastener and fully advance the gripper levers. If this still does not work, consider accessing the gripper lines by fully advancing the gripper levers, removing the gripper caps by pulling them off on an angle, and unscrewing the gripper lever screws one at a time. Remove the yellow collet and pull the gripper lever cover tabs outward and retract to remove the gripper lever cover and gripper levers. Then gently pull on the gripper line. If it readily removes, take it out; if not, reassess the CDS and consider removing the CDS, while maintaining the gripper line, followed by removal of the gripper line through the SGC once the apparatus is realigned. If this is unsuccessful, surgical intervention may be required.

PROCEDURAL PEARLS

- The MitraClip device components all have unique functions that enable the operator to steer the clip to the appropriate position.
- A thorough understanding of the components and their resultant actions is paramount to an efficient procedure.

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CHAPTER 5
Procedural Strategy and Planning—Primary MR

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Overview

Transcatheter mitral repair with edge-to-edge technique using MitraClip™ (Abbott Vascular, Menlo Park, CA) is an established therapy for mitral regurgitation (MR) with over 125,000 patients treated.[1] For those with primary (degenerative) MR, MitraClip is indicated (class IIa recommendation) when there is high or prohibitive surgical risk and suitable anatomy is present.[2] In this chapter, we discuss procedural planning and strategy for primary MR with the goal of maximizing clinical effectiveness and safety of the therapy.

CURRENT FDA LABELING FOR MITRACLIP IN PMR

The MitraClip Clip Delivery System is indicated for

- the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+)
- due to primary abnormality of the mitral apparatus [degenerative MR]
- in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease,
- and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

Procedural considerations

Transseptal puncture considerations for primary MR

For patients with primary MR, it is important to measure the distance to the leaflets rather than the mitral annulus for determination of puncture height. Patients with primary MR often have severe leaflet prolapse or flail, leading to the need for grasping relatively higher above the mitral annular plane into the left atrium, requiring a higher transseptal puncture location. As is commonly performed in all MR patients, a puncture height of 4.5 to 5.0 cm above the target pathology, entering at the level of the medial commissure, is preferred. Positioning the entry into the left atrium across the atrial septum at the medial commissure affords the greatest flexibility for matching the orientation of the grasping arms to leaflets in the antero-posterior dimension.

Device choice for creation of coaptation

The choice of the MitraClip device(s) (ie, NT, NTW, XT, and XTW) is made with the goal of matching the patient's specific anatomy. Specific considerations are given to the anatomic lengths of the anterior and posterior leaflets, anticipated number of devices (ie, jet width), and mitral valve area (Table 1).

Table 1. Clip Size Choice Based on Mitral Valve Anatomy

ANATOMICAL CONSIDERATIONS	FAVORS MITRACLIP NT	FAVORS MITRACLIP NTW	FAVORS MITRACLIP XT	FAVORS MITRACLIP XTW
Leaflet length < 9mm	+	+		
Leaflet length ≥ 9mm			+	+
Broad jet		+		+
Smaller valve	+			
Larger valve		+	+	+
Commissural location	+			

During placement, every row of the frictional elements must be engaged with leaflets to reduce risk of tearing, single leaflet device attachment (SLDA), or other injury. There are 4 rows of frictional elements on NT and NTW devices, and 6 rows for the XT and XTW versions in each arm. Figure 1 shows the dimensions of the devices, which should be a particular consideration when anticipating multiple device placement. Leaflet lengths should be a minimum of 4 mm when using NT and NTW devices, and 6 mm when using XT and XTW devices.

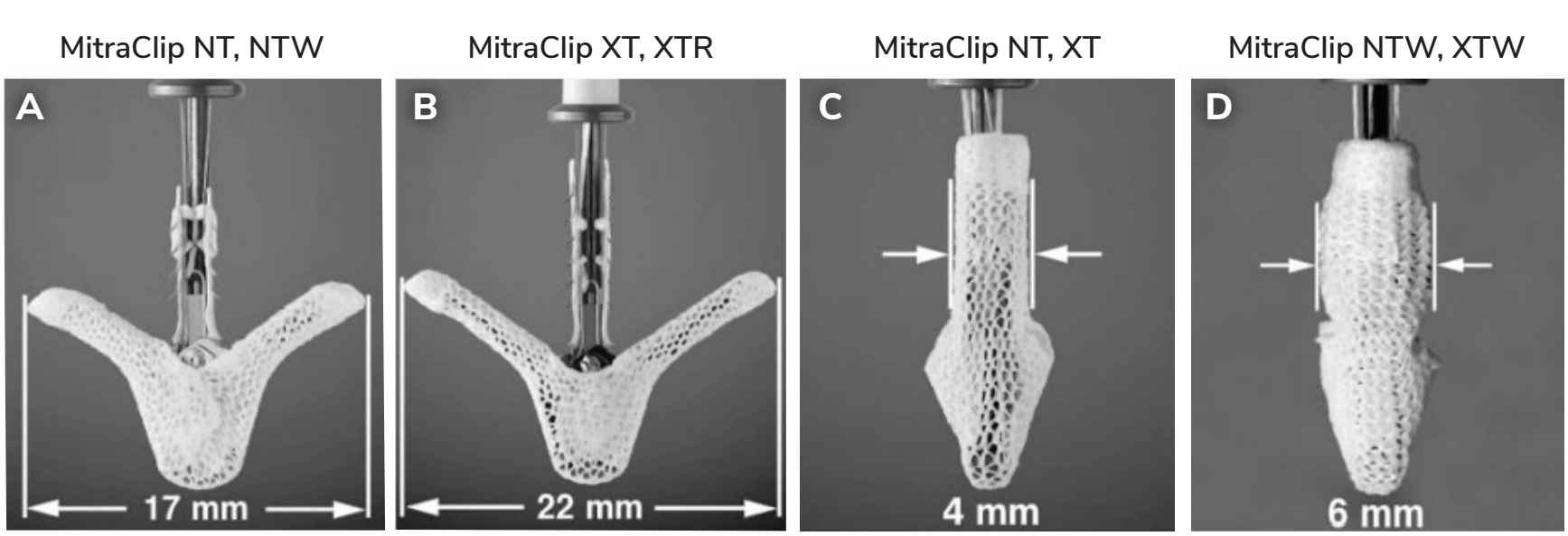
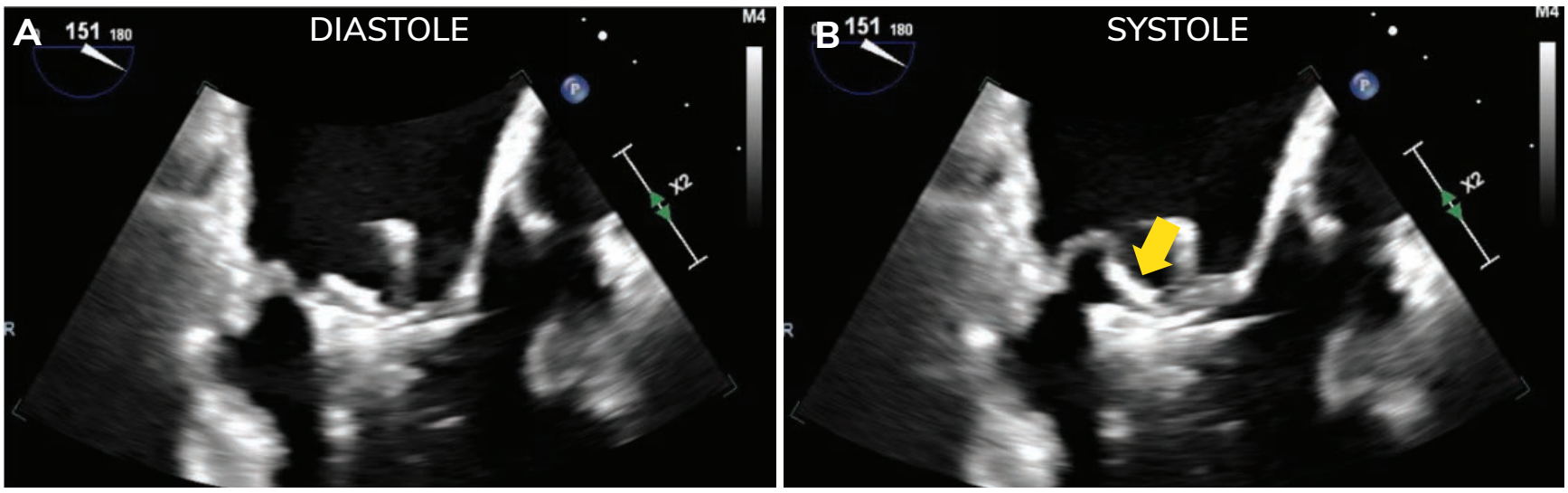


Figure 1. MitraClip Device Dimensions

(A) Distance between arms at 120-degree opening is 17 mm with MitraClip NT or NTW. (B) Distance between arms at 120-degree opening with MitraClip XT or XTR is 22 mm. (C) Width of NT and XT arms is 4 mm, (D) while the width of the NTW and XTW arms is 6 mm.

For all patients, the goal is to restore mitral leaflet coaptation with MitraClip placement. MitraClip historically has been described reductively as a percutaneous Alfieri stitch, and the current moniker of "transcatheter edge-to-edge repair" can easily be misinterpreted. The success of the therapy is not from simply putting the leaflet edges together, but rather from creating longer distances of leaflet contact for coaptation reserve that can successfully resist high left ventricular systolic pressure. Normal mitral valves have coaptation lengths of 7-10 mm as a hindrance against MR; the goal of MitraClip therapy should be to restore a similar coaptation reserve. For primary MR, where there is often prolapse or flail, procedural success is related to reducing leaflet height across any portion of the coaptation plane that either causes or is susceptible to MR. The restoration of coaptation occurs when the device is placed perpendicular to the line of coaptation (ie, no pinwheeling) and there is deep insertion of the leaflets into the arms (ie, no no side biting or side grasping). This best practice is ensured through matching the device size to the leaflet anatomy and regurgitation, monitoring and maintaining device orientation throughout the procedure (above, at, and through the mitral valve), and imaging in multiple planes to ensure appropriate grasping.

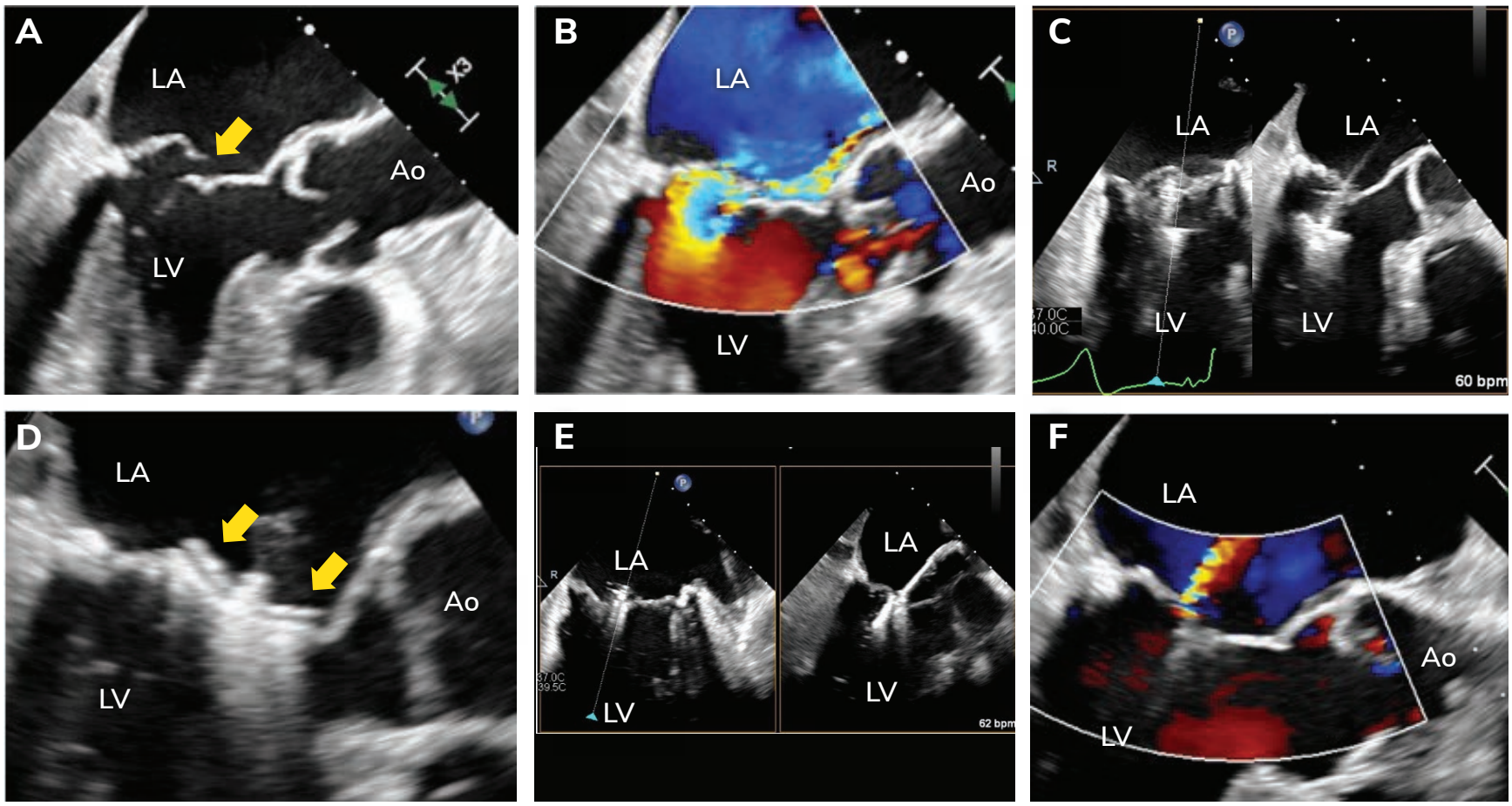


Central Illustration

3-chamber view on TEE shows "gripper sign"—slight lifting of gripper arms during systolic motion of the mitral valve—to ensure leaflets are deeply inserted (arrowhead in B).

Step-by-step technique

1. After performing transseptal puncture at the appropriate location and height above the mitral leaflet pathology and site of intended grasping (see also Chapter 9. Transseptal Puncture), ensure that the patient is fully heparinized and advance the steerable guide catheter (SGC) into the left atrium over an appropriate rail wire. Retract the dilator into the guide, retract the guidewire into the dilator, and then remove the guidewire and dilator simultaneously. De-air and flush the SGC (see Appendix B).
2. Measure pressure in the left atrium. If the pressure is low, consider hemodynamic challenge with phenylephrine to raise the systemic arterial blood pressure to ambulatory levels. Contrary to common belief, primary MR is quite dynamic, and pressure changes with phenylephrine challenge may inform need or a lack of need for additional MitraClip placement during the procedure.
3. Insert the clip delivery system (CDS) into the left atrium, and steer the clip down to the mitral valve using standard techniques (see Chapter 10. Left Atrial Steering, Clip Positioning, and Trajectory). We favor turning tidal volumes to <200 mL/min at this time to minimize the cyclical medial and lateral movements of the CDS that occur with respiration.
4. Unlock and open the clip arms to 120-180° with the arm positioner, and align the arms perpendicular to the mitral line of coaptation on 3D TEE. In the LVOT grasping view, cycle the anterior and posterior grippers independently to check which gripper corresponds to the tactile marker.
5. Entering the left ventricle should be done with the clip closed, especially in flail segments to prevent the free leaflet edge from inadvertently tangling on the gripper elements. Careful use of fluoroscopy (parallax technique) in combination with 2D TEE X-plane imaging should be used to carefully guide the clip into the LV in the intended initial grasp location (See Chaper 11: Clip Alignment and Entering the Left Ventricle). All changes in CDS trajectory should be performed in the LA prior to entering the LV. We recommend steering to either correct an aorta hugger or, in some special situations, intentionally create an aortic trajectory to optimize grasping angles.
6. Open the clip arms to 120° in the LV and check their alignment relative to the line of coaptation (Figure 2, see also Chapter 11). Corrections of alignment while in the left ventricle should be performed only if the movements are very minor. Such rotations risk entanglement of the frictional elements with leaflets and chordae, especially with XT/XTW devices. As these interactions may become apparent only after deployment of the device (eg, pinwheeling, SLDA), the safest practice is to invert the device and retract the clip into the LA to correct major changes of alignment relative to the mitral coaptation plane.



Ao, aorta; LA, left atrium; LV, left ventricle; MR, mitral regurgitation

Figure 2. Use of MitraClip in a Patient with Primary Mitral Regurgitation

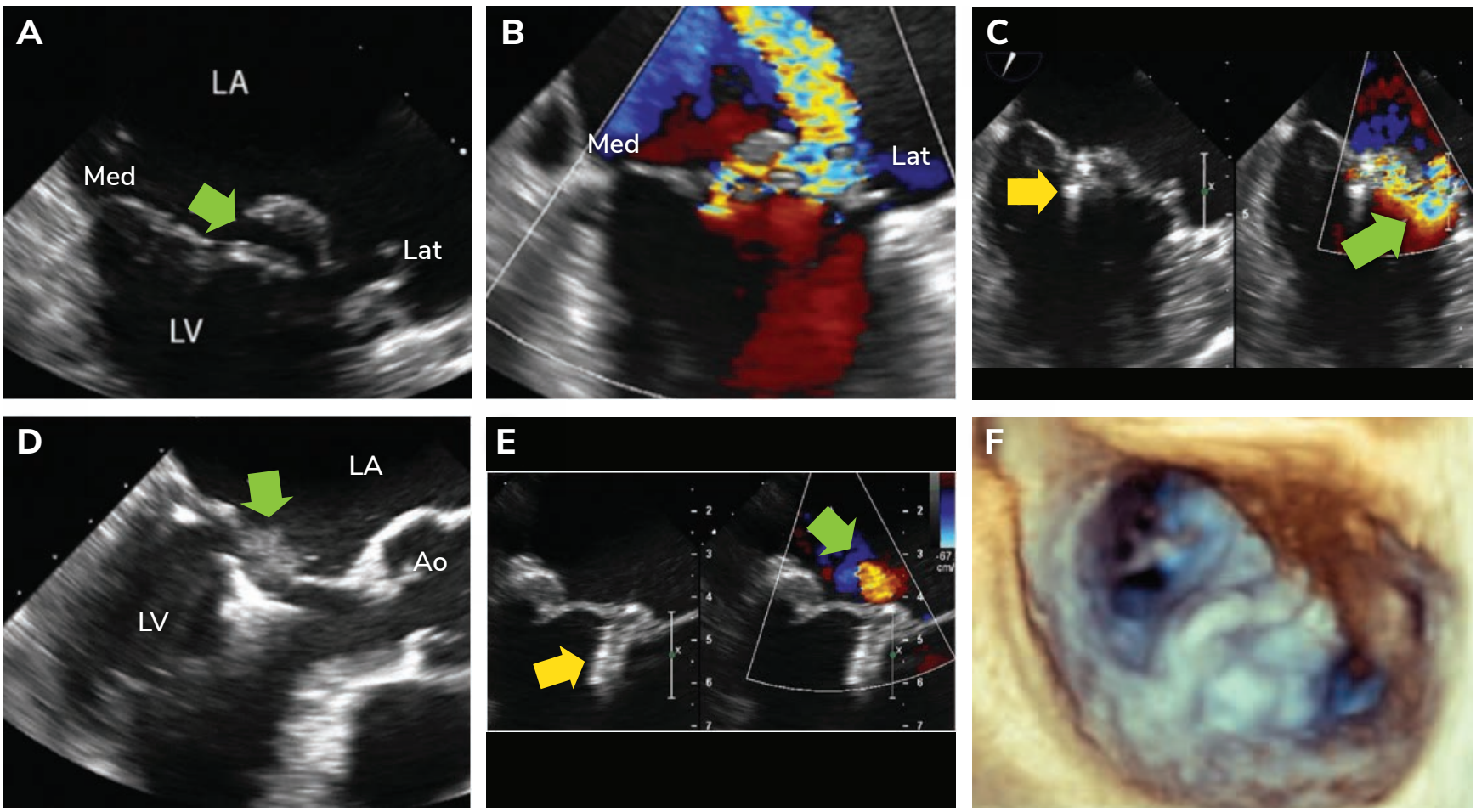
A case with severe MR due to P2 prolapse is shown. (A) Baseline TEE demonstrates P2 prolapse with flail segment (arrow) and (B) severe eccentric MR. (C) After initial alignment with 2D and 3D TEE, the clip is advanced into the left ventricle. (D) Leaflet insertion is performed with confirmation of leaflets between grippers and device arms (arrows). (E) Using multiple imaging views, leaflet insertion with the clip closed to 60 degrees is confirmed. (F) TEE imaging shows mild residual MR after final release.

7. Perform simultaneous grasp of the leaflets while ensuring their deep insertion into the clip arms, and placement of the gripper frictional elements on the atrial side. Look for the "gripper bounce," which is a slight lifting of the gripper arms during systolic motion of the mitral valve, to ensure that leaflets are inserted adequately beneath the gripper arms (Figure 2D). Controlled gripper actuation (ie, CGA or independent grasping) can also be used to optimize leaflet insertion. For primary MR, CGA can help with asymmetry of the coaptation plane, particularly if there is significant discrepancy in the leaflet heights (See Chapter 13. Use of Controlled Gripper Actuation).
8. Use multiple imaging views to confirm leaflet insertion with the clip closed to 60 degrees (Figure 2).
9. Using the commissural view and Doppler color, close the clip arms completely to assess reduction in MR with device placement.
10. Check the mean mitral gradient and corresponding heart rate.
11. Examine residual MR to determine if additional device placement is needed. When deciding whether to treat residual MR, consider its severity, the mitral gradient, the anatomic suitability, and the need to move the current device medial or lateral to make room for additional clip placement. This step requires careful assessment of the surrounding mitral anatomy.
12. Once the effect on MR is satisfied without concern for stenosis, the clip can be deployed and the CDS removed per standard practice.
13. Record final left atrial pressure, and if no further clips are needed, record final TEE imaging.

Special scenarios in primary MR

Large flail or prolapse

Severe prolapse or large flail segments are common in patients with primary MR. These scenarios create challenges due to asymmetry in the grasp and discrepancy in leaflet heights. With meticulous attention to the proper trajectory, clip selection, alignment, and advanced grasping techniques "CGA" (controlled gripper actuation), almost all leaflets can be grasped successfully. If these fundamental techniques fail, other maneuvers may be considered including use of adenosine, rapid ventricular pacing, and the “zip-and-clip” or “anchor clip” strategy. Adenosine (6 to 18 mg intravenously) creates temporary asystole leading to cessation of leaflet motion, with the prolapsed leaflet segment falling into the left ventricle toward the natural state of coaptation. Rapid ventricular pacing “freezes” the leaflets in systole. Although the leaflets become relatively immobile, there may be additional challenges for gripper placement (inadequate leaflet insertion) due to relative loss of height. The “zip-and-clip” or “anchor clip” maneuver is a technique whereby device placement outside of the target pathology or at the edge of a prolapsed segment leads to approximation of coaptation planes within the therapeutic target.[3] Most commonly, the prescribed sequence is device placement first in the commissures or away from the central zone (ie, A2/P2), followed by clipping the central zones, but variations on this sequence are common (Figure 3).



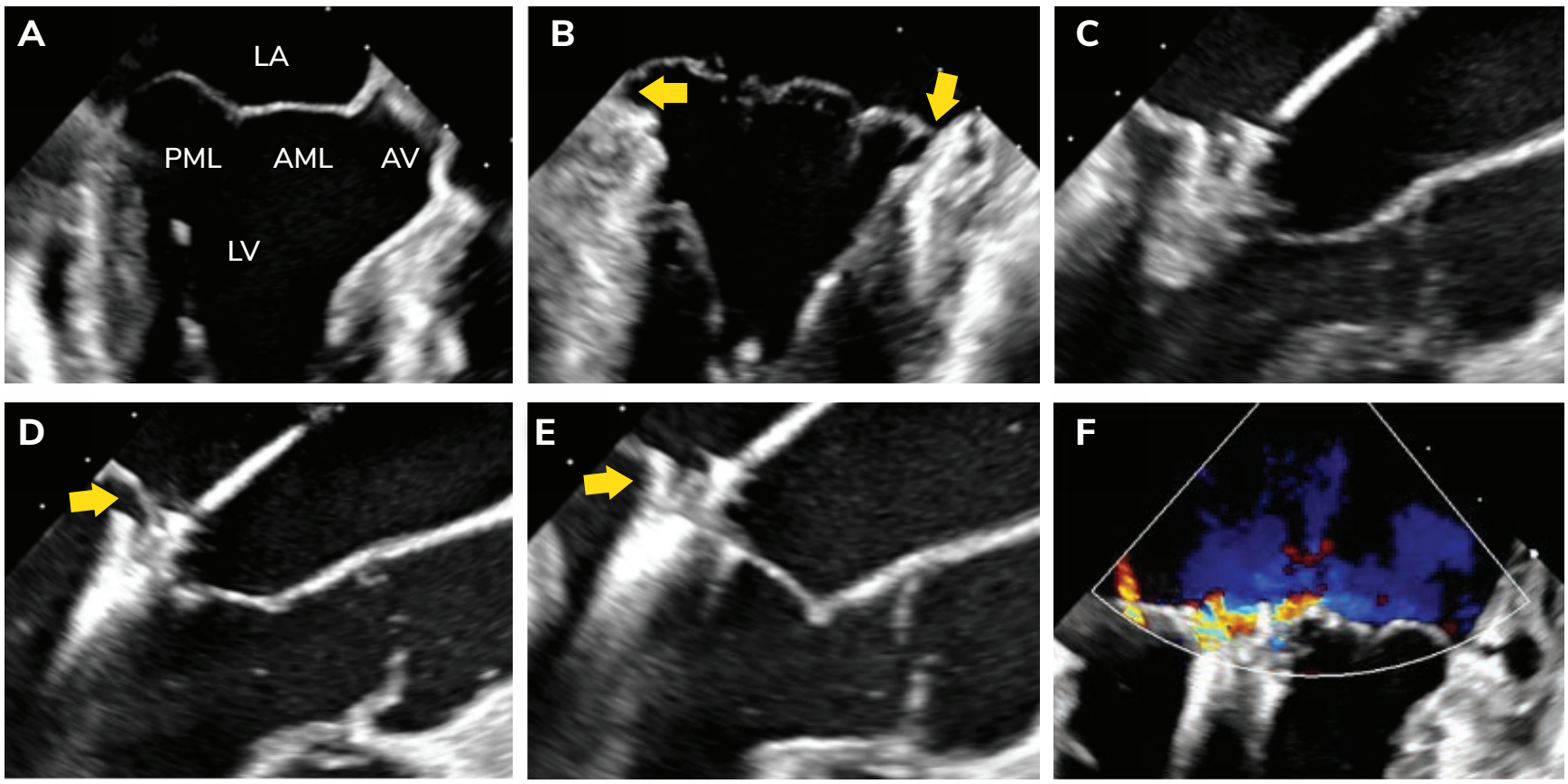
Ao, aorta; LA, left atrium; LV, left ventricle; MR; mitral regurgitation

Figure 3. Zip-and-clip Technique

(A) Very large flail gap of the P2 segment evident by 2D TEE bicomm view at baseline (green arrow). (B) Unsuccessful clip placement attempted laterally, where largest jet present. (C) First clip placed medially to approximate the leaflets, but not necessarily reduce MR (yellow arrow); residual MR still severe (green arrow) after first clip placement. (D) As a result of better leaflet approximation, the large flail gap is no longer seen (green arrow). (E) A second (yellow arrow) and third clip were successfully placed in original flail target area on lateral side of the first clip with minimal residual MR (green arrow). (F) Final 3D imaging of 3 clips shows intact bridge completely reducing the flail segment.

Barlow's disease

Patients with highly degenerative mitral disease involving both leaflets pose challenges due to lack of coaptation across multiple anatomic planes and excessive height of the prolapsed leaflets. Adequate height reduction may not be possible due to the physical limits of the MitraClip device, although multiple device placements can be successful in selected cases (Figure 4). High-quality imaging is needed to ensure adequate leaflet insertion, as residual lift of the surrounding leaflets can make such assessments on TEE difficult.



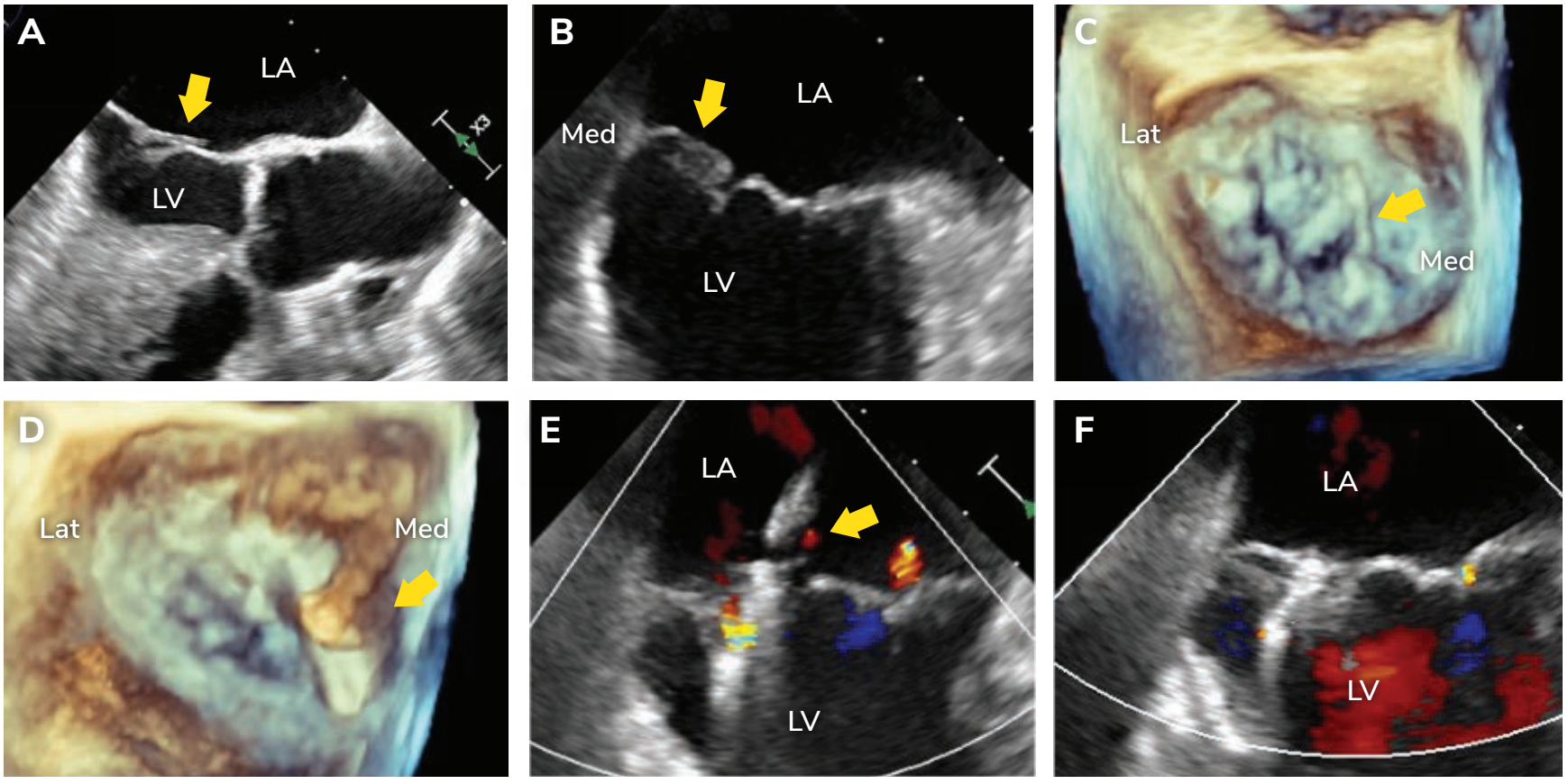
AML, anterior mitral leaflet; AV, aortic valve; LA, left atrium; LV, left ventricle; PISA, proximal isovelocity surface area; PML, posterior mitral leaflet

Figure 4. MitraClip in Patient with Barlow's Disease

(A, B) TEE shows severe, degenerative prolapse and mitral annular dysjunction (atrialization of the mitral hinge point, arrows). (C, D) First clip placed on the medial side of A2-P2 where largest PISA located. Due to severe degeneration, confirmation of insertion difficult in several imaging planes (E) but obtainable with frame-by-frame analysis. (F) Final residual regurgitation was mild after 2 clips.

Commissural mitral regurgitation

Due to the relatively small space and risk for chordal entanglement, special consideration must be given when treating commissural MR. The clip arms should be aligned in the surgeon's view to be perpendicular to the mitral coaptation for leaflet grasping. Thus, for medial commissural pathology, the clip arms are rotated relatively counterclockwise (eg, 10 o'clock to 4 o'clock alignment). For lateral commissural pathology, the clip arms are rotated relatively clockwise (eg, 2 o'clock to 8 o'clock alignment). The device is closed completely (to avoid any chordal entanglement) and advanced into the left ventricle with fluoroscopy and biplane TEE to monitor trajectory simultaneously in both the anterior-posterior and medial-lateral planes. Minimize catheter rotation once the clip arms cross the mitral valve. We open the arms just beneath the leaflets slowly to assess orientation to the targeted coaptation plane. These careful maneuvers and monitoring help to mitigate the risk of chordal entanglement (Figure 5).



LA, left atrium, LV, left ventricle; MR, mitral regurgitation

Figure 5. Commissural Therapy with MitraClip

(A-C) Procedural TEE demonstrates P3 prolapse with ruptured chordae (arrows in A-C). (D) For proper placement, clip arms should be aligned in surgeon's view to be perpendicular to mitral coaptation for leaflet grasping, note 11 o'clock to 5 o'clock alignment. (E) For commissural therapy, arms are rotated either clockwise or counterclockwise depending on whether target is medial or lateral. After single clip placed in the medial flail segment (arrow), (F) residual MR was mild.

PROCEDURAL PEARLS

- Focus on reducing mitral leaflet height and restoring coaptation planes when performing MitraClip in patients with primary MR to achieve optimal reduction in regurgitation.
- Device selection is based on leaflet length, jet width, and size of the mitral valve.
- For complex or large flail segments, consider using multiple clips to adequately treat the diseased segment. Advanced techniques for leaflet grasping such as CGA or the anchor clip technique should be considered.
- Aligment and placement of the MitraClip should be perpendicular to the coaptation planes, with avoidance of pinwheeling and side-biting.

Summary

MitraClip is an established therapy for patients with primary MR when there is high or prohibitive surgical risk and suitable anatomy is present. The goal of MitraClip therapy should be to restore the normal mitral leaflet coaptation reserve. MitraClip device selection should be based on the anatomic lengths of the anterior and posterior leaflets, anticipated number of devices (ie, jet width), and mitral valve area. The key to success is focusing on reducing mitral leaflet height (by grasping the prolapsed segments) and restoring coaptation planes to achieve optimal reduction in regurgitation.

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CHAPTER 6
Procedural Strategy and Planning – Secondary MR

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Overview

The Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) trial (ClinicalTrials.gov identifier: NCT01626079) studied patients with medically refractory heart failure and secondary/functional mitral regurgitation (SMR).[1] Lessons from COAPT included the value of strict adherence to guideline-directed medical therapy (GDMT), as well as ensuring that patients had moderate-severe and severe SMR. Based on these results, MitraClip received regulatory approval in 2019 for treatment of moderate-to-severe and severe SMR despite GDMT, resulting in increasing interest in this technology and procedure. This chapter reviews the procedural considerations for MitraClip treatment of SMR including patho-anatomic considerations, selection of device size, and procedural steps.

CURRENT FDA LABELING FOR MITRACLIP IN SMR

The MitraClip™ System, when used with maximally tolerated GDMT, is indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation

- MR ≥ Grade III per American Society of Echocardiography criteria
- in patients with a left ventricular ejection fraction (LVEF) ≥ 20% and ≤ 50%
- and left ventricular end-systolic dimension (LVESD) ≤ 70 mm
- whose symptoms and MR severity persist despite maximally tolerated GDMT

as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease.

General procedural planning considerations for patients with SMR

Since by definition, patients with SMR have underlying left ventricular systolic dysfunction, optimal GDMT and cardiac resynchronization therapy (CRT) should be pursued with due diligence before proceeding with TEER therapy. Another way of looking at it is that GDMT potentiates the benefit seen with TEER in SMR. Operators must also be wary of concomitant tricuspid valvular regurgitation (TR), since patients with severe concomitant TR may benefit less from TEER. There should be careful coordination with the anesthesia team since these patients may have hemodynamic compromise after induction for general anesthesia, and inotropic or pressor infusions may be necessary in the peri-procedure period. A right heart catheterization may identify patients with marginal baseline hemodynamics that would need to be tuned up to optimize the results. Patients with SMR may also develop afterload mismatch after reduction of MR with TEER that can necessitate longer postprocedural inotropic support.

Patient selection for TEER for SMR

In the COAPT trial, once patients met the inclusion and exclusion criteria, final anatomic suitability for TEER therapy was determined by the heart team performing the procedure. Recently, there have been efforts to define a group of patients in whom TEER therapy is almost always unsuitable by expert consensus. The Heart Valve Collaboratory (HVC) has suggested anatomic characteristics conferring unsuitability for transcatheter edge-to-edge repair (TEER) of the mitral valve which include:[2]

- Posterior leaflet length <5 mm in the desired grasping location
- Many patients with a baseline mean mitral gradient >5 mmHg (although gradient is the result of a complex interplay of factors that go into the development of stenosis, including severity of MR, cardiac output, and mitral valve orifice area)
- Mitral valve area <3.5 cm^2
- Severe mitral annular calcification with mitral stenosis or calcium extension into the leaflets, or restricted leaflet motion
- Severe Barlow's disease with multiple jets
- MR primarily due to the presence of clefts

Additional considerations include:

- Presence of calcium (there should be at least 5 mm of distal mitral leaflet tip without calcification to grasp)
- Excessive tethering or wide coaptation gaps unsuitable for grasping
- Leaflet thickness and motion
- Left atrium size
- Interatrial septum anatomy

While these criteria are not absolute contraindications, they are suggested guidelines for predicting technical success and procedural difficulty.[2,3,4]

Table 1 summarizes key criteria that may reflect the unsuitability of TEER for SMR.

Table 1. Characteristics Associated with Unsuitability for TEER for SMR

Baseline echocardiographic characteristics associated with stenosis following TEER	• Severe mitral annular calcification with elevated baseline mean mitral gradient (proceed with caution if gradient > 5 mmHg) or calcium extension into leaflets • Small mitral valve area <3.5 cm^2
Baseline echocardiographic characteristics associated with residual regurgitation following TEER	• Posterior leaflet length (<5 mm in the desired grasping location)
Characteristics associated with inability to technically perform TEER	• Inadequate mitral valve visualization, particularly grasping views • Anatomic access issues preventing transseptal and venous access
Characteristics associated with futility in performing TEER	• Patients with less than moderate-to-severe MR • Patients with less than 12 months of expected survival

Procedural considerations

Transseptal puncture

While a superior and posterior transseptal puncture is usually ideal for primary mitral regurgitation (PMR) pathologies, a targeted transseptal approach can be taken for SMR with consideration for leaflet restriction and pathology location.[4] In more restricted leaflets, a lower transseptal puncture to mitral valve annulus height (3.5 cm-4 cm) may be better suited to reach the coaptation site for valve pathology, which is often below the plane of the mitral annulus (Figure 1).[5,6] The absolute transseptal puncture height above the site of leaflet pathology and intended grasping location should be the standard 4.0 to 5.0 cm.

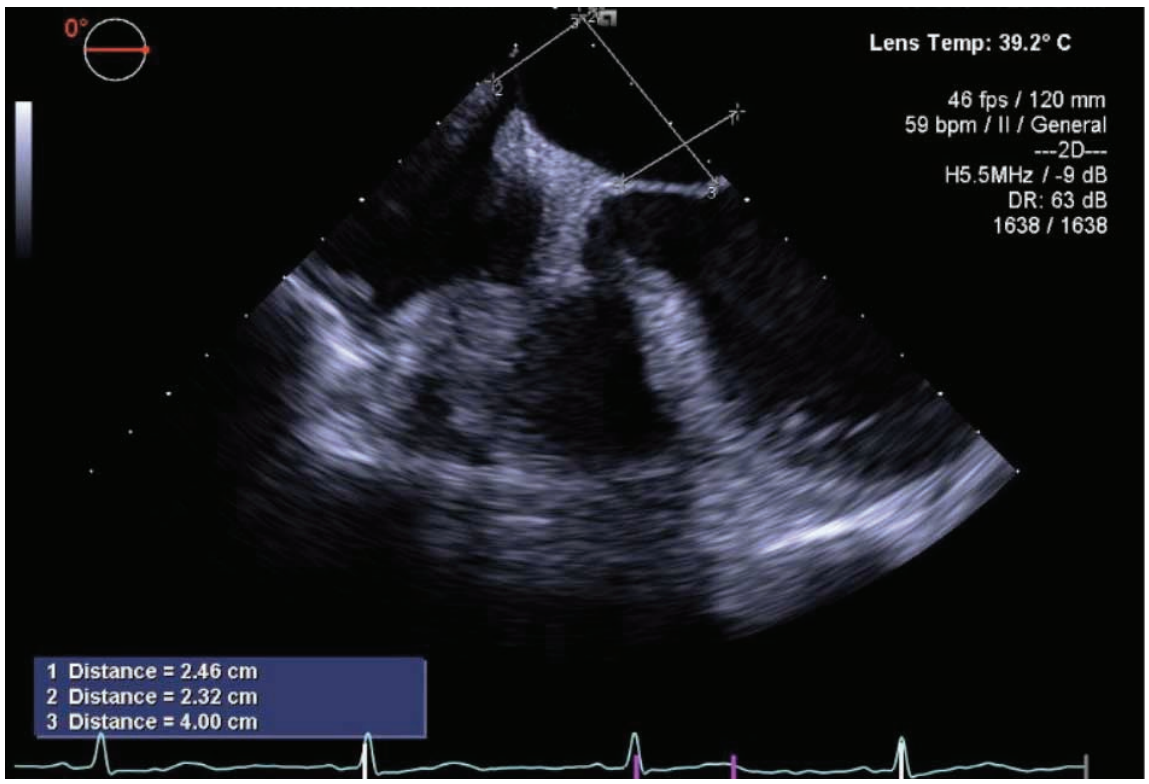


Figure 1. Lower Transseptal Puncture in SMR with More Restricted Leaflets

In SMR with more restricted leaflets, a lower transseptal puncture to mitral valve annulus height (3.5cm-4cm) may be better suited to reach the coaptation site for valve pathology, which is often below the plane of the mitral annulus.

Clip selection

The 4th generation (G4) MitraClip device offers 4 clip options: NT, NTW, XT, and XTW as shown in Figure 2.

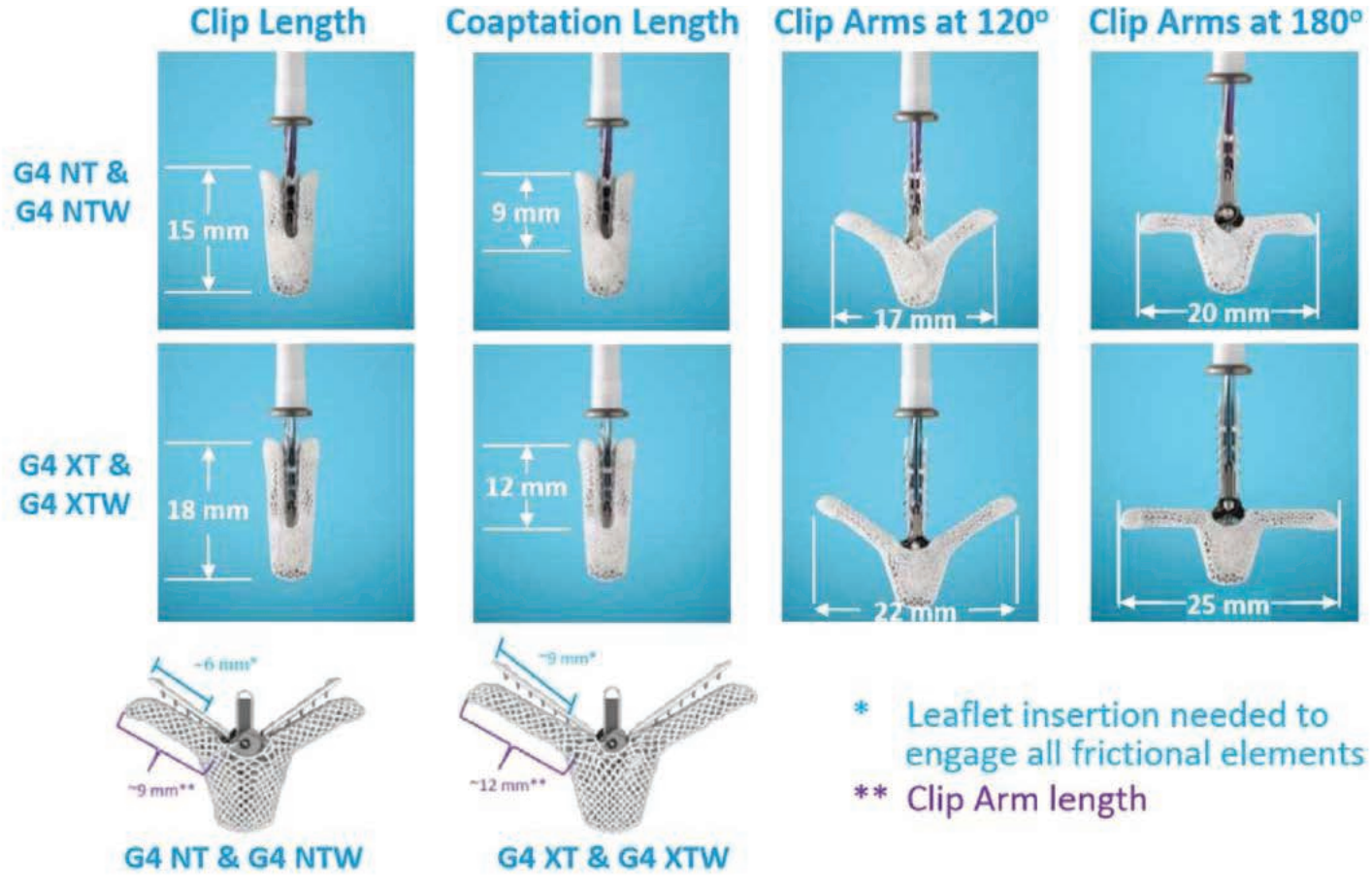


Figure 2. G4 MitraClip Devices

The NT clip has 9 mm arms and an effective gripper length of 6 mm. The XT clip has 12 mm arms and an effective gripper length of 9 mm.[7] The NTW and XTW are 6 mm in width (compared to 4 mm width of NT and XT), which can grasp more leaflet tissue for more apposition and, in theory, more MR reduction. This may lead to lower force applied per unit area on the leaflet and fewer clips utilized, but with greater tissue apposition and therefore smaller residual orifices.[7] Table 2 suggests a generalized approach to determining clip selection based on anatomy.

Location and size of the regurgitant jet in secondary MR can often be a guide for clip selection. In the setting of a dilated cardiomyopathy or annular dilatation in atrial secondary MR, the regurgitant jet is often wide and central. In such cases, starting with a wide clip (NTW, XTW) may provide better restoration of leaflet coaptation and prevent the need for additional clips. The choice between NTW and XTW will be determined by the leaflet length. The posterior leaflet is often more tethered and shorter than the anterior leaflet, therefore assessment of the posterior leaflet length in the grasping view at the site of clip implantation is important for clip selection.

Table 2. Considerations for MitraClip G4 Clip Selection

	Leaflet length in desired grasping zone <9 mm	Commissural jet	Large mitral valve area
NT Width: 4 mm Arms: 9 mm Effective gripper length: 6 mm	+	+	
NTW Width: 6 mm	+		+
XT Width: 4 mm Arms: 12 mm Effective gripper length: 9 mm			+
XTW Width: 6 mm			+

Intra-procedural imaging: importance of the 3D en face view

Once positioned in the left atrium, LVOT, bicomm, and 3 dimensional (3D) en face views with and without color can direct clip alignment, test trajectory, and identify which gripper line corresponds to which leaflet. Once the desired location for the trajectory angle is established, it is helpful to fluoroscopically save the radiographic position as an additional reference image (Figure 3). Alignment is critical for success in SMR TEER therapy since the posterior leaflet is often short and precise alignment is required for adequate posterior leaflet insertion. Chapter 11. Clip Alignment and Entering the Left Ventricle.

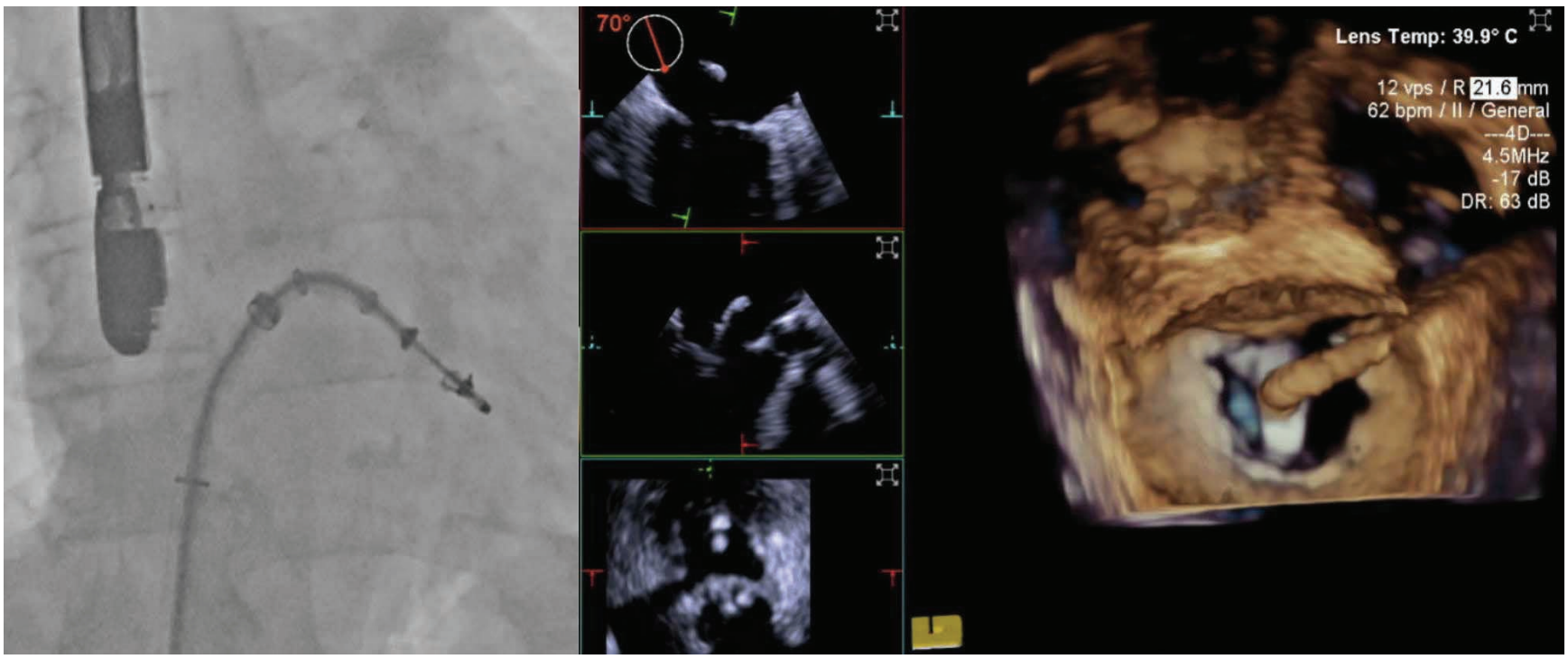


Figure 3. 3D En Face View

3D en face view used to check position and trajectory to optimize angle of attack on coaptation line of valve pathology, and saved as geographic reference marker to ensure no rotation has occurred while moving into the left ventricle.

Grasping

The 2 dimensional (2D) left ventricular outflow tract (LVOT) view is best for grasping, which may be assisted by a short breath hold.[6] The insertion of the posterior leaflet is usually best seen in this LVOT view, while the insertion of the anterior leaflet can also be seen in the 4 chamber view.

In secondary MR, the mechanism of MR may be an isolated restricted posterior leaflet, a large central regurgitant jet in annular dilatation, or bi-leaflet tethering due to papillary muscle displacement. The strategy for leaflet grasping therefore varies accordingly.

In the setting of a restricted posterior leaflet, the leaflet often appears short in the LVOT view and grasping with adequate leaflet insertion can be challenging. The regurgitant jet is often located at the medial segment of A2-P2, therefore appropriate clip alignment should be achieved in the 3D en face view and trajectory should be confirmed to avoid traveling too medial. Once in the ventricle, it may be helpful to attempt the grasp with anterior rotation on the SGC and then gradually rotate the SGC posteriorly to grab as much of the posterior leaflet as possible and then drop the grippers. It is important in SMR to not withdraw the clip to higher than the level of the mitral annulus or both leaflets may be lost due to the tethering.

With the 4th generation MitraClip device, independent grasping of anterior and posterior leaflets can be particularly efficacious in SMR with restricted leaflets and large coaptation gaps. (See Chapter 13. Use of Controlled Gripper Actuation). Additionally, leaflet insertion can be optimized either unilaterally or bilaterally without repeating the entire grasping sequence. Leaflet insertion can be measured with the grippers down and the clip locked but in the open 60-120 degree position by measuring the length of the visible leaflet outside the clip versus total leaflet length (Figure 4). In general, at least 6 mm of leaflet insertion is considered adequate to minimize the risk of single leaflet device attachment (SLDA).[4]

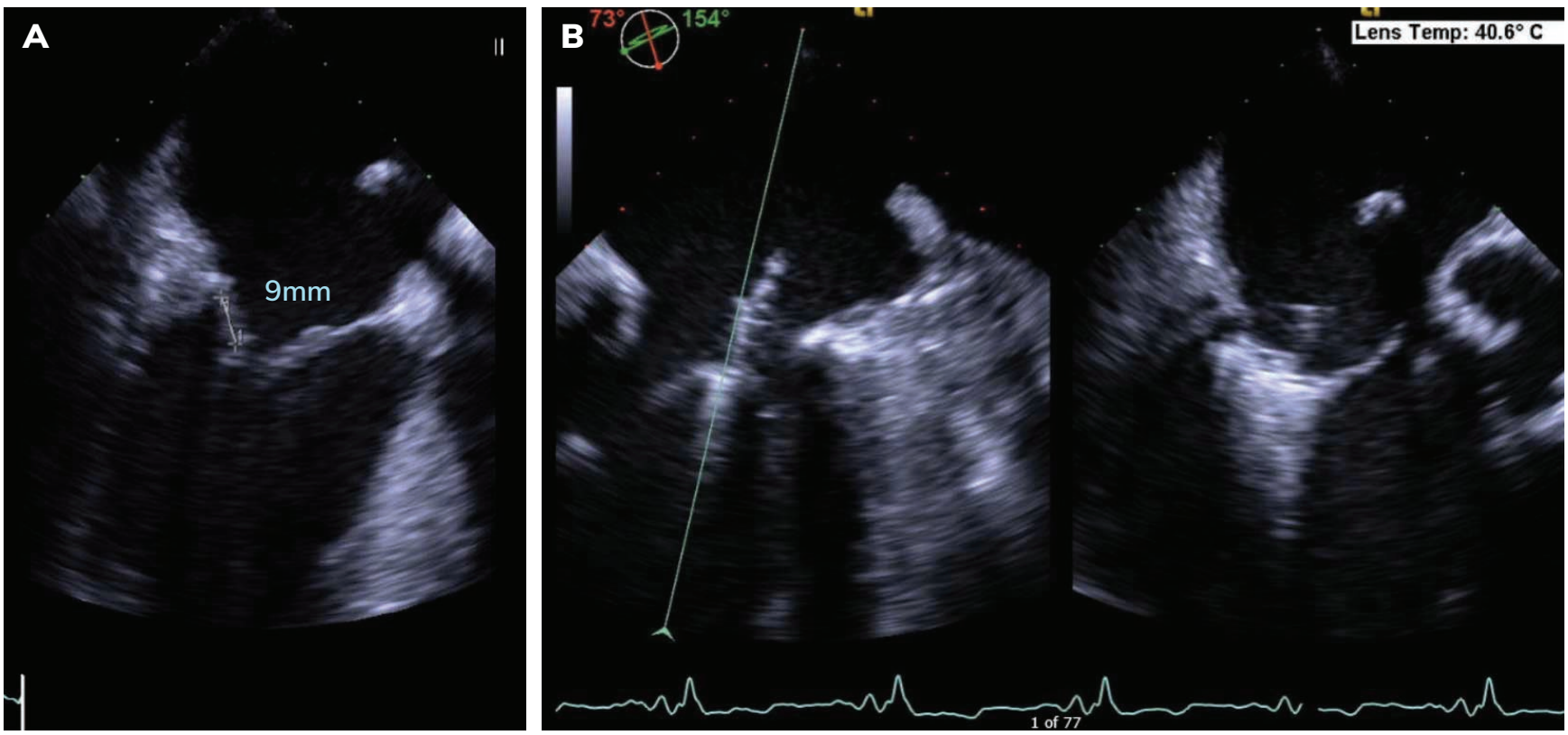
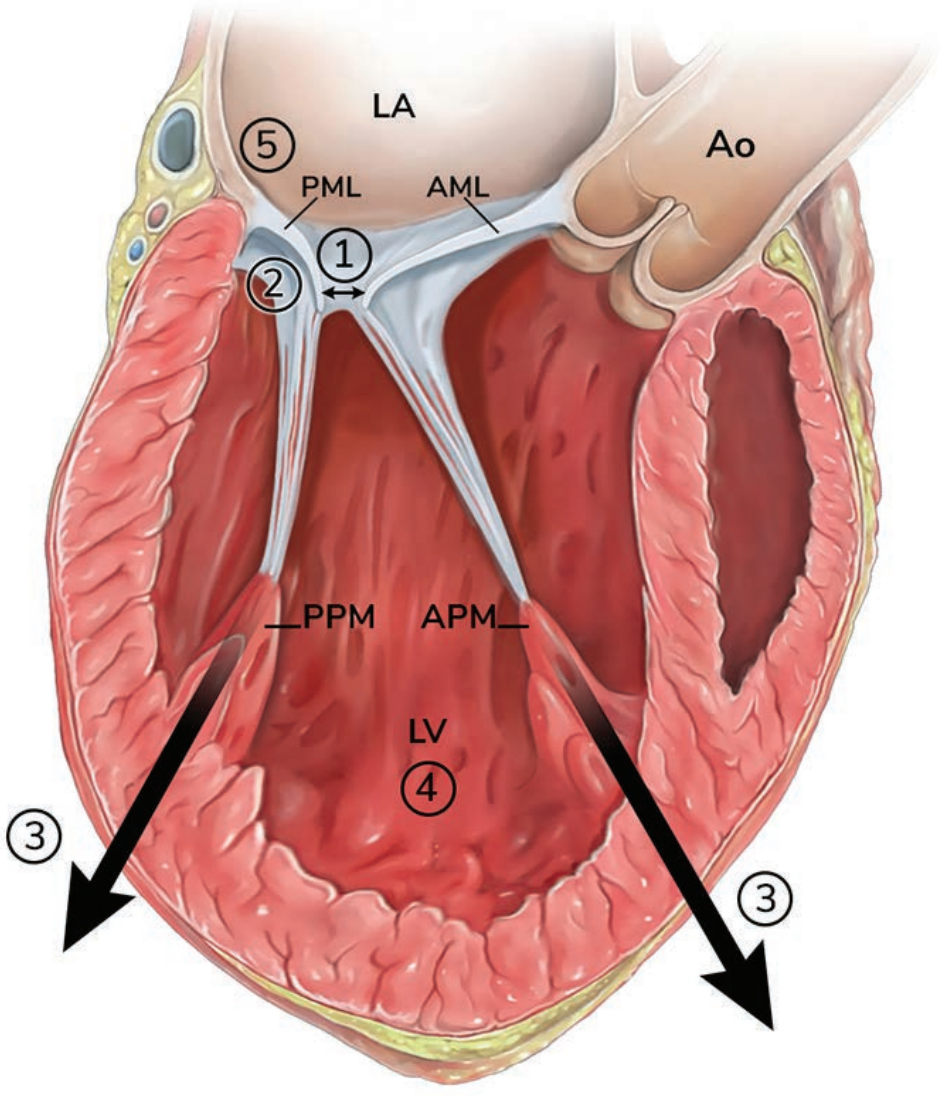


Figure 4. Grasping

(A) Baseline measurement of posterior leaflet length is 9 mm. (B) Once NTW clip is positioned with grippers down and locked, but with clip in open 180-degree position, compare the amount of length within grippers versus outside of grippers to assess leaflet insertion. As seen in the rightmost image, most of the leaflet is secured by the gripper.



Central illustration. Anatomic Challenges to MitraClip Therapy in Secondary MR

(1) Large coaptation gaps with broad MR jet; (2) short tethered posterior leaflet makes leaflet grasping difficult; (3) apical and outward displacement of papillary muscles creates ventricular leaflet tethering; (4) decreased LV function; (5) mitral annular dilation

Assessment of residual MR and considerations for additional clip placement

Before the MitraClip is released, echocardiographic assessment includes appraisal of any residual MR, pulmonary vein flow pattern, and mean mitral gradient. Biplane imaging through any residual proximal isovelocity surface area (PISA) jets can be helpful to understand presence and mechanism of residual MR. If jets are identified on both sides of the clip, it may be necessary to displace the clip more medially to isolate the residual jet completely on the lateral side, after which a second clip may be added laterally to the first. Choice of the second clip will depend on the location and size of the residual jet and leaflet length in the targeted grasping area, as discussed previously.

Hemodynamic assessment with the pressure manifold connected to the guide sheath should include assessment of V wave and LA pressure to assess improvement. Placement of additional MitraClip devices should anticipate the added gradient from a second or third clip, however this is often balanced by the reduction in the flow gradient from reducing MR. To minimize the impact of additional clips on the residual valve orifice, placement of the clips should be close to the first clip, also limiting the possibility of a jet between the clips.

The additional devices should be advanced into the LV in closed position to ensure there is no interaction with the released first device. In certain uncommon situations, the additional MitraClip device may intentionally not be closed entirely to avoid a higher residual gradient caused by more complete tissue coaptation from the device, although this must be done with great care to avoid the risk of SLDA. In general, leaving a clip anything less than completely closed is not recommended.

Potential complications

Multiple echocardiographic views should be obtained prior to final release to ensure that leaflet insertion and tissue bridging is adequate to prevent single leaflet device attachment. Heart rate and blood pressure can be manipulated intraprocedurally to assess the dynamic nature of any created stenosis and residual MR. Chordal entanglement should be avoided by minimizing device manipulation below the mitral valve and not advancing the system deep into the LV. Multiple leaflet grasps may lead to leaflet injury and should be avoided if possible.

PROCEDURAL PEARLS

- Patients with SMR should be on optimal GDMT before undergoing TEER.
- Pre-procedural echocardiographic examination is critical in understanding leaflet anatomy and the regurgitant jets to optimize patient selection for this procedure.
- 3D en face views intraprocedurally can be efficiently utilized while the system is optimally positioned in the left atrium to confirm position, alignment, and trajectory to the desired scallop location.
- Independent leaflet grasping can be advantageous particularly in SMR with restricted leaflets.

Summary

Transcatheter mitral valve repair with the MitraClip is an option that should be considered for SMR patients who remain symptomatic despite GDMT. With appropriate pre-procedural and intra-procedural planning, the procedure is safe and efficacious.

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PART III

Transcatheter Mitral Leaflet Valve Edge-to-Edge Repair Procedure “Step-by-Step”

CHAPTER 7

Procedural Decision-Making Algorithm for TEER

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Overview

The MitraClip procedure is a complex, multistep procedure that requires advanced skills to achieve optimal outcomes. These skills include a detailed understanding of normal and diseased mitral valve anatomy, imaging with transesophageal echocardiography (TEE), and the multiple steps and nuances of delivering and deploying one or more MitraClips to the appropriate locations on the mitral valve leaflets.

In such a complex procedure, operator experience is important for optimal outcomes. With experience comes the knowledge of how to approach the procedure, identify challenges, and perform troubleshooting as required. In short, with experience comes the ability to apply critical thinking to the TEER procedure. Critical thinking—as described by Michael Scriven and Richard Paul at the 8th Annual International Conference on Critical Thinking and Education Reform—is the intellectually disciplined process of actively and skillfully conceptualizing, applying, analyzing, synthesizing, or evaluating information gathered from observation, experience, reflection, reasoning, or communication, as a guide to action. With assistance from the authors of this ebook, we have attempted to harness the collective knowledge, experience, and critical thinking of some of the best operators in the world to bring a simple, systematic approach to the procedure to standardize the technique and improve procedural and patient outcomes.

Algorithm link

The interactive decision-making algorithm (link below) allows the reader to proceed through a MitraClip procedure from start to finish, prompting critical thinking at each step and suggesting best practices throughout. The algorithm presents a series of questions to ponder at each phase of the procedure and suggests potential actions to optimize each step. It is our hope that this algorithm will lead operators through the procedure, assisting them to make the necessary adjustments to achieve the desired result. This decision-making algorithm is interwoven into the chapters of the eBook as described below and an exploded view of the algorithm can be downloaded from the Appendix.

TEER Procedural Decision-Making Algorithm →

Procedural steps and key questions

The MitraClip procedure can be divided into 5 steps:

1. **Transseptal puncture (Chapter 9).** The focus for transseptal puncture (TSP) is understanding the mitral valve pathology being treated and selecting an appropriate puncture site and height to achieve optimal outcomes.
2. **Left atrial steering (Chapter 10).** The goal of left atrial steering is to establish optimal trajectory and alignment of the MitraClip prior to entering the left ventricle to maximize procedural success and reduce risk of complications. Optimal trajectory and alignment are critical as they facilitate leaflet grasping with the fewest attempts, reduce the risk of interaction with intraventricular structures, and reduce complications such as chordal entanglement or the need to invert and retract the clip back into the left atrium.
3. **Clip positioning and entering the LV** (Chapter 10 and Chapter 11). Procedural success and MR reduction is dependent on the ability to place a clip at the appropriate place on the valve and perpendicular to the line of coaptation at the target location. In addition, rapid appreciation of clip movement or rotation upon entering the LV is critical to avoid entanglement in the subvalvular apparatus and efficiently grasp the leaflet.
4. **Leaflet grasping** (Chapter 12). The keys to a successful grasp are preparation prior to entering the ventricle and ensuring the target grasp location is clear. Once the clip is in the ventricle and a grasp has been attempted, it is crucial to evaluate the quality of the grasp as well to understand failed grasp attempts and how to correct.
5. **Assessment for additional clips** (Chapter 12). Decisions regarding additional clips need to be made once a successful grasp with appropriate leaflet insertion has been made. Prior to adding another clip, confirm reduction in MR severity with the first clip, and ideally, that the jet has been isolated to one side of the clip. In some cases, the first clip may serve to approximate the mitral leaflets to permit grasping with another clip.

At each step, key questions arise (Table 1) and challenges may occur, which if not sufficiently managed, can create complexity and difficulty in achieving optimal procedural success.

Table 1. Key Questions at Each Procedural Step

PROCEDURAL STEP	KEY QUESTIONS
Transseptal puncture (Chapter 9)	• What is the etiology of MR? • Where is the leaflet pathology?
Left atrial steering (Chapter 10)	• What is the morphology of the left atrium? • What is the trajectory of the clip on the bicommissural view? • Do you have sufficient CDS length to travel into the LV? • Do you have sufficient height above the valve to pull back during grasping? • Do you have an “aorta hugger”?
Clip positioning (Chapter 10) (Chapter 11)	• Is the clip perpendicular to the line of coaptation at the target location? • Is the CDS shaft perpendicular to the annular plane?
Leaflet grasping (Chapter 12)	• Has there been rotation of the clip arms after entering the LV? • Is the shaft of the CDS in the regurgitant jet? • Is there adequate leaflet insertion for the clip used? • Is there evidence of MR reduction?
Additional clips (Chapter 12)	• Is there residual MR? • What is the location of the residual MR? • What is the mitral valve gradient?

TEER Procedural Decision-Making Algorithm →

CHAPTER 8

Vascular Access

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Overview

Large bore vascular access is the first step for transcatheter edge-to-edge repair (TEER). This important step is focused on identification of the femoral vein, safe puncture (ideally using ultrasound guidance) and the modified Seldinger technique, venous pre-closure, and hemostasis at the end of the procedure.

Procedural considerations

Venous access for TEER is most commonly performed via the right femoral approach, and this is the approach that will be discussed here. Ultrasound-guided access is the standard approach for large bore access, both venous and arterial.

The key steps for vascular access for TEER (which are discussed in more detail below) include:

- Identify the vessel and its branches using ultrasound and select a target puncture site free of large branches.
- Puncture the vein using a standard front wall needle, wire and dilate the vessel, and insert the sheath. At this point, the vessel may be "pre-closed" using 1 or 2 Perclose ProGlide™ vascular closure devices (Abbott Vascular).
- Dilate the venous access to allow insertion of the MitraClip 25 Fr outer diameter steerable guide catheter (SGC).
- Once the procedure is complete, achieve venous hemostasis by locking the Perclose sutures or using a figure-of-8 suture (Figure 1). Manual compression can also be used, however in the setting of an elevated activated clotting time (ACT) this may be prolonged.

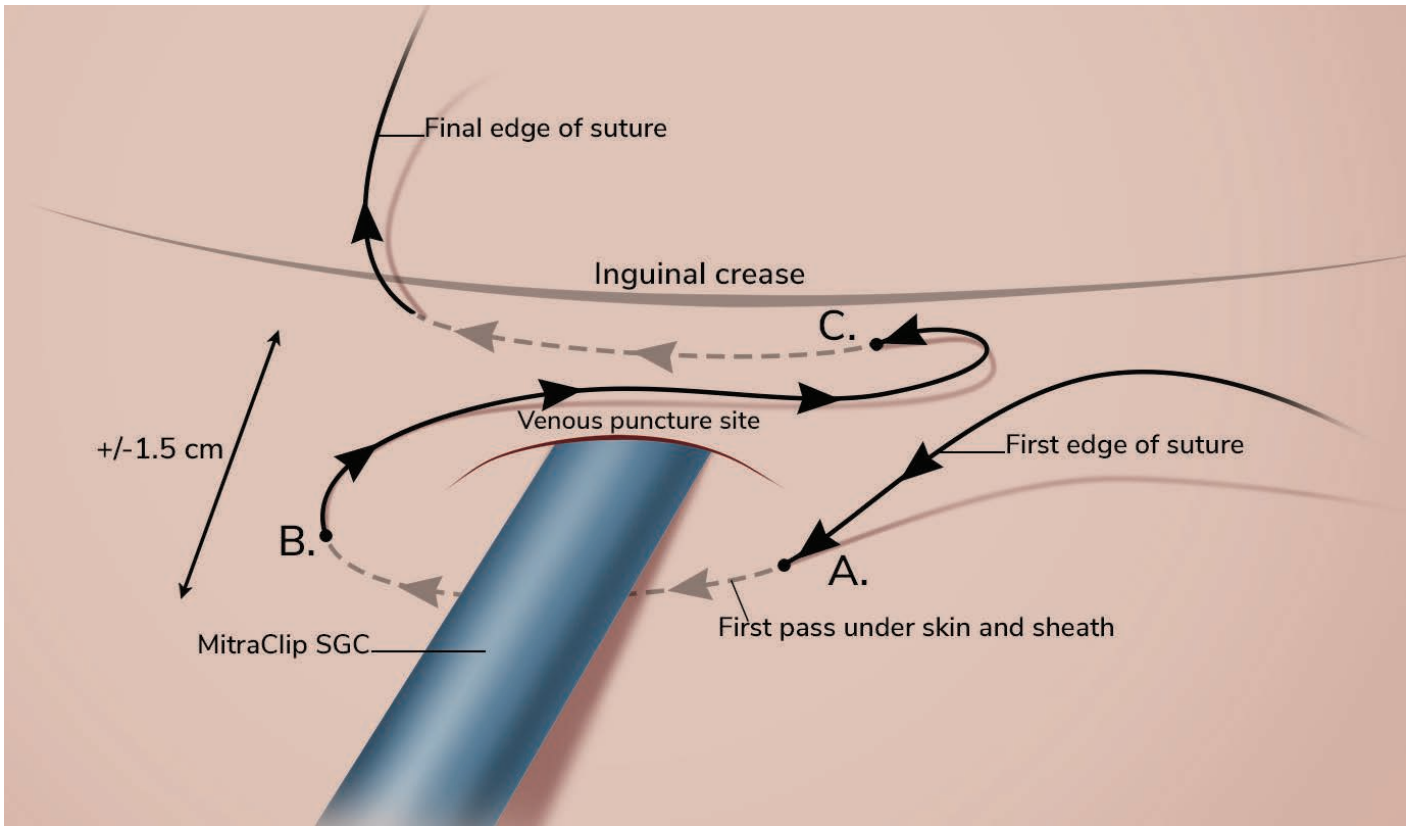


Figure 1. Figure-of-8 Suture

(A) Pass a 2-0 or 1-0 silk suture on a large needle subcutaneously from medial to lateral (or vice versa) below the MitraClip SGC (or from proximal to distal on the right side of the puncture site) and then (B) cross over above the SGC to (C) pass subcutaneously from medial to lateral again more proximately (or from proximal to distal on the left side of the puncture site). Cut the needle and tighten and secure the 2 ends when the sheath is removed. The femoral artery vessels shouldn't catch if the access anatomy is previously visualized with ultrasound.

A recent prospective registry compared the Perclose ProGlide and figure-of-8 methods of hemostasis following ablation. Both methods improved time to hemostasis, time to ambulation, and permitted more same-day discharge compared to manual compression. There were no differences in complications among the three groups.[1] Perclose ProGlide is indicated for closing femoral venous access sites using 5-24 Fr sheaths (up to 29 Fr outer diameter), and it is commonly used. For sheath sizes greater than 8 Fr, it is advisable to use at least one device with a pre-close technique, as shown in the video in Figure 2.

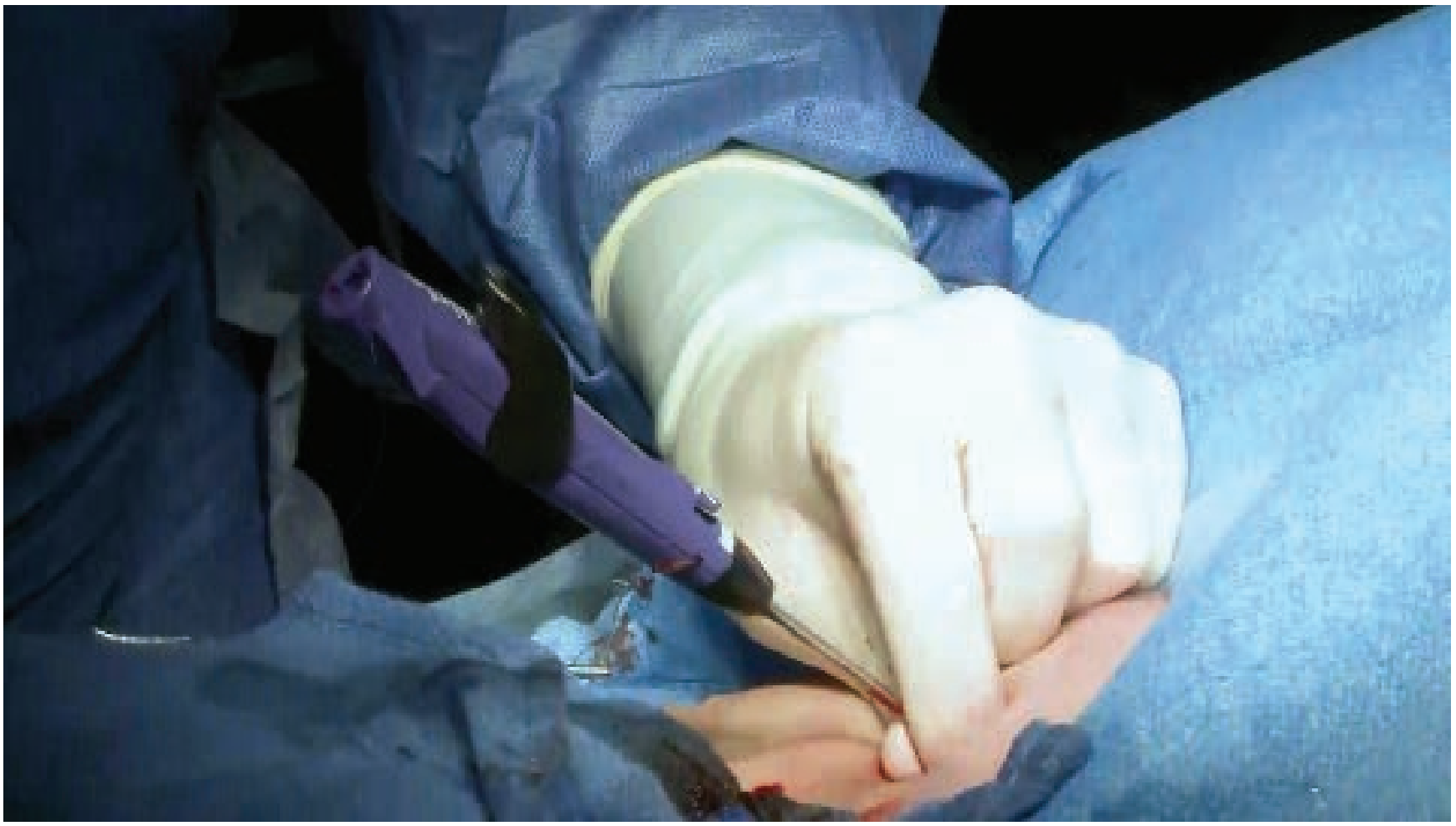
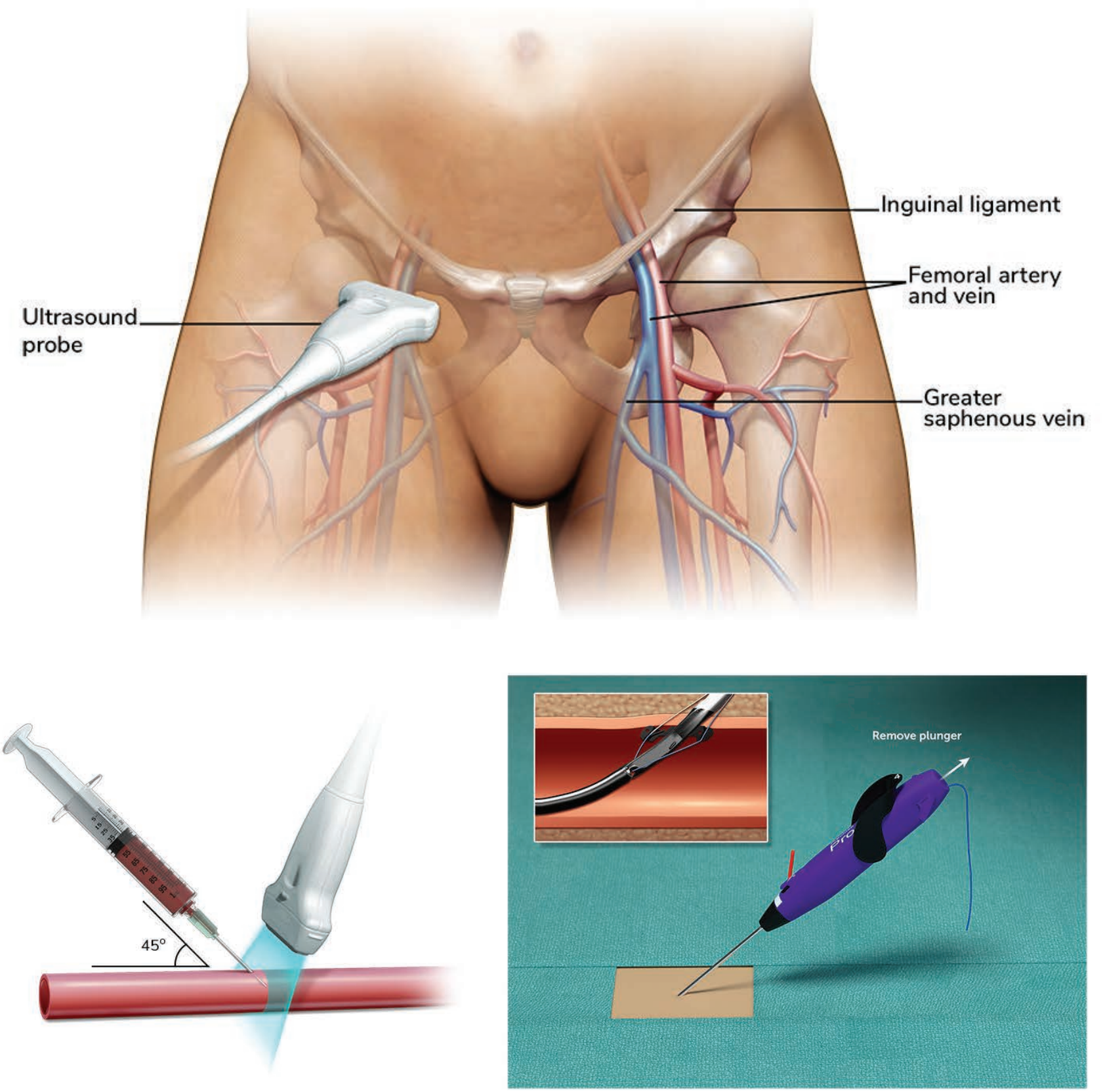


Figure 2. Perclose ProGlide Pre-close Technique (video)

Step-by-Step Technique

As shown in the video in Figure 2, the steps below describe the technique for performing an ultrasound-guided femoral venous puncture and vessel pre-closure using the Perclose ProGlide vascular closure device prior to inserting MitraClip. The box summarizes the equipment required for this technique.



Central Illustration

EQUIPMENT FOR TRANSFEMORAL VENOUS ACCESS FOR MITRACLIP PROCEDURE

Ultrasound

- Vascular ultrasound probe that provides a high-quality image with an adjustable depth of the field of view from 1.5 to 6 cm. The axial and sagittal views are the most useful.

Venous puncture

- Ultrasound gel-filled sterile sleeve
- Superficial (25G needle) and deep (22G needle) local anesthesia: 10 mL of Xylocaine® 2% (5 mL) / Marcaine® 0.5% (5 mL) in each syringe.
- 18G femoral needle attached on a syringe
- 0.035-inch J-curved guidewire
- Scalpel and surgical mosquito forceps to spread the skin and the subcutaneous tissue
- 7 Fr femoral introducer
- Multiple dilators (eg, 16 Fr and 20 Fr) to use after the transseptal puncture, just before introducing the MitraClip steerable guide catheter

Pre-close

- 1 or 2 Perclose ProGlide vascular closure devices

1. **Identify anatomic landmarks.** Begin ultrasound assessment of the vascular structures in the axial plane near the ideal puncture site, which is 2-3 cm below the inguinal crease. The inguinal crease represents the course of the inguinal ligament and should remain the upper limit of the puncture site. The femoral vein can be easily identified as a compressible vascular structure that is medial to the femoral artery. Color Doppler can be used to discriminate between the two structures in the event of significant tricuspid regurgitation. The femoral artery bifurcation can also be identified to distinguish between the artery and vein. The vein is often posterior to the superficial femoral artery. Anastomosis of the long saphenous vein into the femoral vein is a bit lower and should be avoided for the puncture. The optimal site for vascular access will be free from branches and not posterior to the artery to avoid inadvertent arterial puncture.
2. **Under ultrasound guidance, perform superficial and deep local anesthesia** with 10 mL of Xylocaine 2% (5 mL) and Marcaine 0.5% (5 mL) in each syringe. Local anesthesia is helpful even in the setting of general anesthesia for patient comfort post-procedure.
3. **Under ultrasound guidance, use a front wall needle (18G), with or without a syringe, to access the vessel.** Align the probe perpendicular to the vein to create a circular image. Insert the needle in the center of the probe and at a distance of 0.5 cm to 1 cm, with an angulation of approximately 45°. To avoid complications, it is important to follow the course of the needle tip including tilting the ultrasound probe until the needle tip appears in the vein, confirmed by blood aspiration.
4. **Introduce a 0.035-inch J-curved guidewire into the vein** via the needle. The needle angle may need to be reduced for guidewire insertion.
5. **Use ultrasound imaging to confirm the position of the guidewire in the vein** in the axial/longitudinal axis.

6. **Make an incision at the needle puncture site and open the subcutaneous tissue** using blunt dissection with surgical forceps.
7. **To proceed with vessel pre-closure, dilate the vein using a 7 Fr femoral introducer** to facilitate passage of the Perclose device. Two Perclose ProGlide vascular closure devices are indicated for 24 Fr (up to 29 French outer diameter) access.
8. **Insert the first Perclose ProGlide** with the marker lumen oriented at 12 o'clock in the vein, confirmed by a blood return in the marker lumen (sometimes helped by a manual abdominal pressure to increase the venous return). If using a single Perclose, deploy at the 12 o'clock position. If using 2 Perclose devices, rotate 30° laterally so that the marker lumen is oriented to 11 o'clock. (Figure 3) After retraction against the inner wall of the vein, stabilize the device closure at a 45° angle.
9. **After suture deployment, remove the Perclose** until the guidewire port is visualized. Place the longer suture (rail suture with visible knot) and the shorter suture (non-rail suture) together on the operative field and cover with a wet towel. Reinsert the 0.035-inch J-curved guidewire through the guidewire port to the inferior vena cava and remove the Perclose device.
10. **If using 2 closure devices, insert the second Perclose ProGlide into the vein**, confirming blood return in the marker lumen, and rotate 30° medially so that the marker lumen is oriented to 1 o'clock as shown in Figure 3. Deploy sutures as previously described, fix together on the operative field, and cover with a wet towel. Reinsert the 0.035-inch guidewire into the vein via the guidewire port and remove the second device.

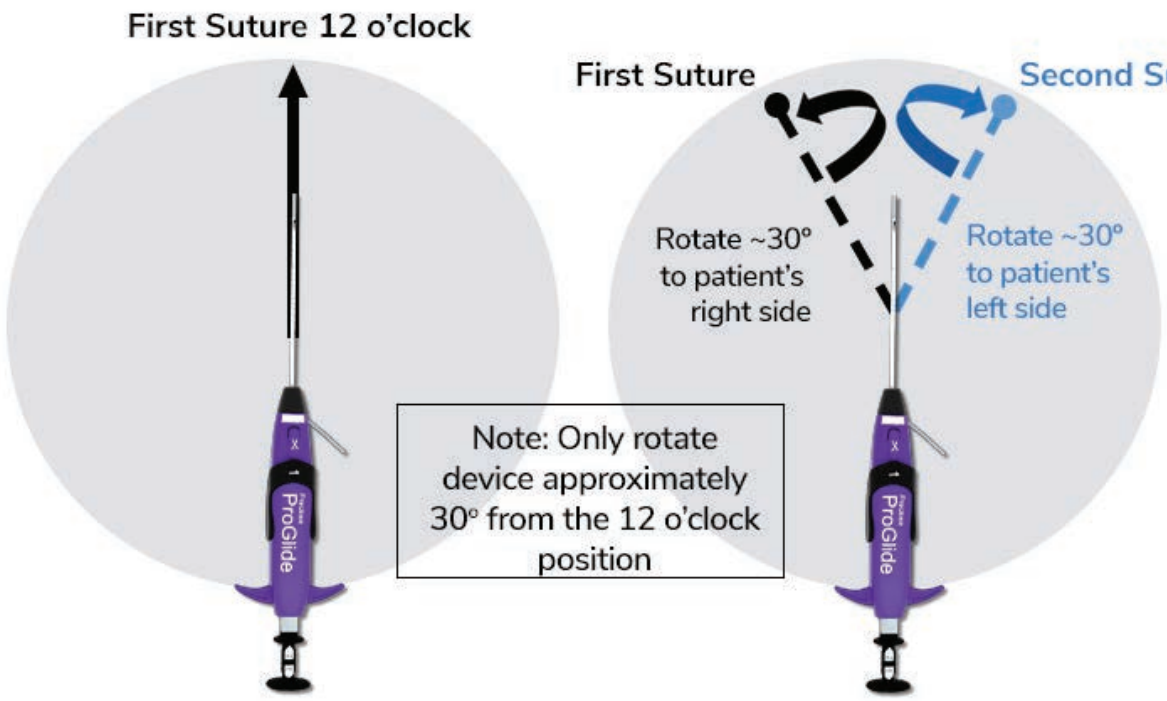


Figure 3. Successive Perclose ProGlide Rotation

11. **Insert a 7 Fr femoral introducer to begin the procedure.** Following transseptal puncture, dilators may be used (14 Fr Inoue dilator, 16 Fr and 20 Fr dilators) prior to introducing the MitraClip SGC.
12. **Once the MitraClip procedure is complete, remove the SGC and achieve hemostasis.** To tighten and lock the Perclose sutures, pull the first suture placed to slide the knot to the vessel wall. The knot is advanced using the knot pusher and the sutures are locked by pulling on the short suture while maintaining tension on the longer suture. Manage the second suture similarly and cut the sutures. If minor bleeding persists, a figure-of-8 stitch is appropriate.

Potential complications

Multiple studies have shown negligible intraprocedural mortality and a low procedural complication rate for MitraClip procedures. A 2019 study documented the requirement of blood transfusion in 12% of the patients, mainly caused by bleeding related to vascular access during the procedure.[2] A major complication related to vascular access may require an intervention, such as venous stenting or vascular surgical repair, but this is rare. It is however, important to have access to the necessary equipment, such as peripheral balloons or covered peripheral stents, if needed. Rapid diagnosis is paramount, and unexplained hypotension should be evaluated for vascular access bleeding or retroperitoneal bleeding using the appropriate imaging modalities, primarily CT imaging.

PROCEDURAL PEARLS

- Procedural complication rate for a MitraClip procedure is low, except for access site bleeding.
- Ultrasound-guided access of the femoral vein significantly improves the vascular complication outcomes and reduces puncture time, inadvertent arterial puncture risk, and postprocedural groin pain.
- Vascular closure with Perclose ProGlide or a figure-of-8 stitch improves the time to hemostasis, ambulation, and reduces length of stay compared to manual compression.
- Right venous access allows a straighter position in the right atrium, facilitating transseptal puncture. It may be more difficult to engage the septum and track the transseptal system into the left atrium from the left femoral venous approach.
- If it is necessary to access the right atrium from left venous access, the route is longer and more tortuous. The left approach places the needle more parallel to the fossa ovalis (rather than perpendicular) with an increased risk of interatrial septal dissection. In cases of left femoral access, a more curved transseptal catheter or transseptal needle may assist reaching the fossa ovalis to perform the transseptal puncture.[3]

Summary

The standard of care for large bore vascular access is ultrasound-guided puncture. Hemostasis can be adequately achieved using Perclose ProGlide with a pre-closure technique or a figure-of-8 suture at the end of the procedure. All efforts should be made to ensure safe vascular access to reduce morbidity and prolonged hospitalization and avoid vascular complications.

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3. Edupuganti MMR, Mutlu D, Mego DM, et al. MitraClip deployed via left femoral vein in an 85-year-old woman with mitral regurgitation. *Tex Heart Inst J.* 2019;46(3):195-8.

CHAPTER 9

Transseptal Puncture

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Overview

Techniques and tools for targeted transseptal puncture (TSP) continue to be refined as the number of electrophysiologic and structural heart procedures escalates. Precise TSP is vital to the success of these procedures. This chapter discusses procedural steps, contemporary equipment, potential complications, and special considerations for TSP as it relates to mitral transcatheter edge-to-edge repair (TEER).

Procedural considerations

Transseptal puncture for TEER

The TSP and subsequent left atrial crossing point determines the height and position of the MitraClip® steerable guide catheter (SGC). The height is referred to as the distance of the MitraClip guide catheter to the intended grasp site (which can be above, at, or below the mitral annular plane). An optimal TSP is one that permits sufficient height above the valve to withdraw the Clip Delivery System (CDS) to the annular plane during grasping and is positioned to permit an optimal CDS trajectory.

Choice of TSP site will depend on the mitral valve pathology being treated. In primary MR with leaflet prolapse or flail, an ideal puncture will be higher to permit retraction of the CDS to the prolapse or flail segment. In secondary MR with leaflet tethering, a lower puncture may be required to allow sufficient travel of the CDS into the ventricle. A rough guide is approximately 4.5–5.0 cm above the mitral annular plane for primary MR and 4.0–4.5 cm for secondary MR.

For example, a low puncture in the setting of primary MR with leaflet flail may not allow sufficient height to grasp the flail leaflet and an inappropriate anteriorly positioned puncture may result in a trajectory that parallels the aorta (aorta hugger) affecting the ability to achieve perpendicularity to the coaptation plane. A non-targeted TSP can increase procedural difficulty with guide positioning and clip delivery.

Pertinent anatomic considerations

For optimal TSP, a thorough understanding of the 3-dimensional (3D) anatomy of the interatrial septum (IAS)/fossa and its relationship to the surrounding cardiac structures is essential (Figure 1).

To guide TSP for TEER the IAS is first visualized in the bicaval view under transesophageal echocardiography (TEE). The bicaval view lays out the superior to inferior access. The short axis view shows the IAS in an anterior to posterior axis between the aortic valve and posterior atrial wall. Importantly, the short axis view is not perpendicular to the bicaval view.

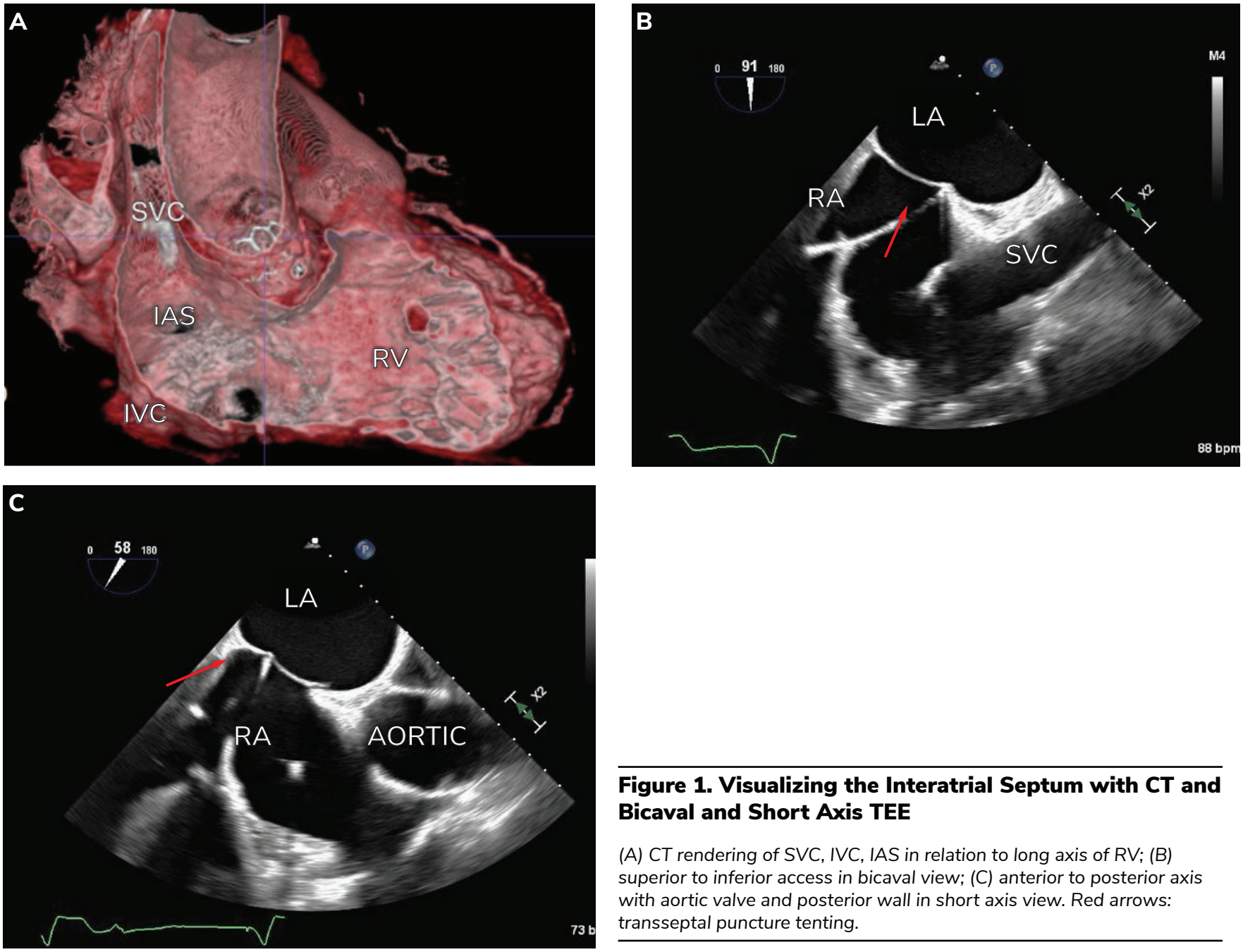
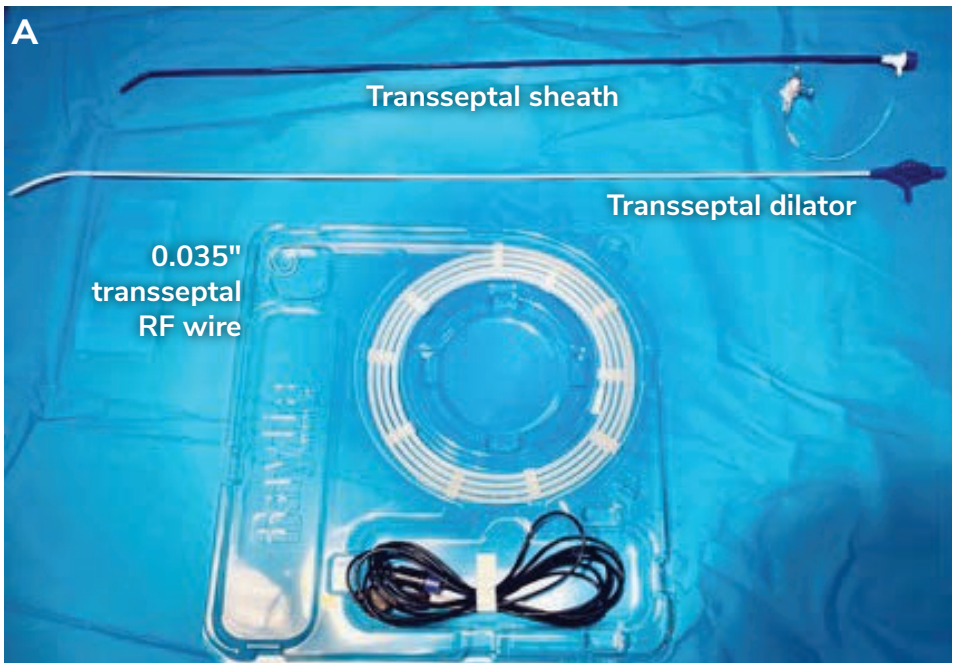


Figure 1. Visualizing the Interatrial Septum with CT and Bicaval and Short Axis TEE

(A) CT rendering of SVC, IVC, IAS in relation to long axis of RV; (B) superior to inferior access in bicaval view; (C) anterior to posterior axis with aortic valve and posterior wall in short axis view. Red arrows: transseptal puncture tenting.

Equipment

A transseptal system—traditionally a sheath and dilator along with a needle and a left atrial (LA) rail wire—is required to perform TSP for TEER. Currently, TSP sheath and dilator systems are available from many different manufacturers (eg, St Jude, Medtronic, Baylis) with differing fixed distal curves and shapes. However, the principle of a sheath/dilator combination remains the same. The contemporary needle selection consists of either a mechanical or radiofrequency (RF) system. Although traditional transseptal sheaths have used a 0.032" wire, technological advancements have also allowed for certain manufacturers to add RF to the distal end of a pre-shaped pigtail 0.035” wire (Baylis VersaCross®) to replace the standard mechanical or RF needle. Other less frequently used options include a pre-shaped mechanical wire (eg, SafeSept®), a steerable mechanical needle, or use of a steerable sheath with any type of needle.



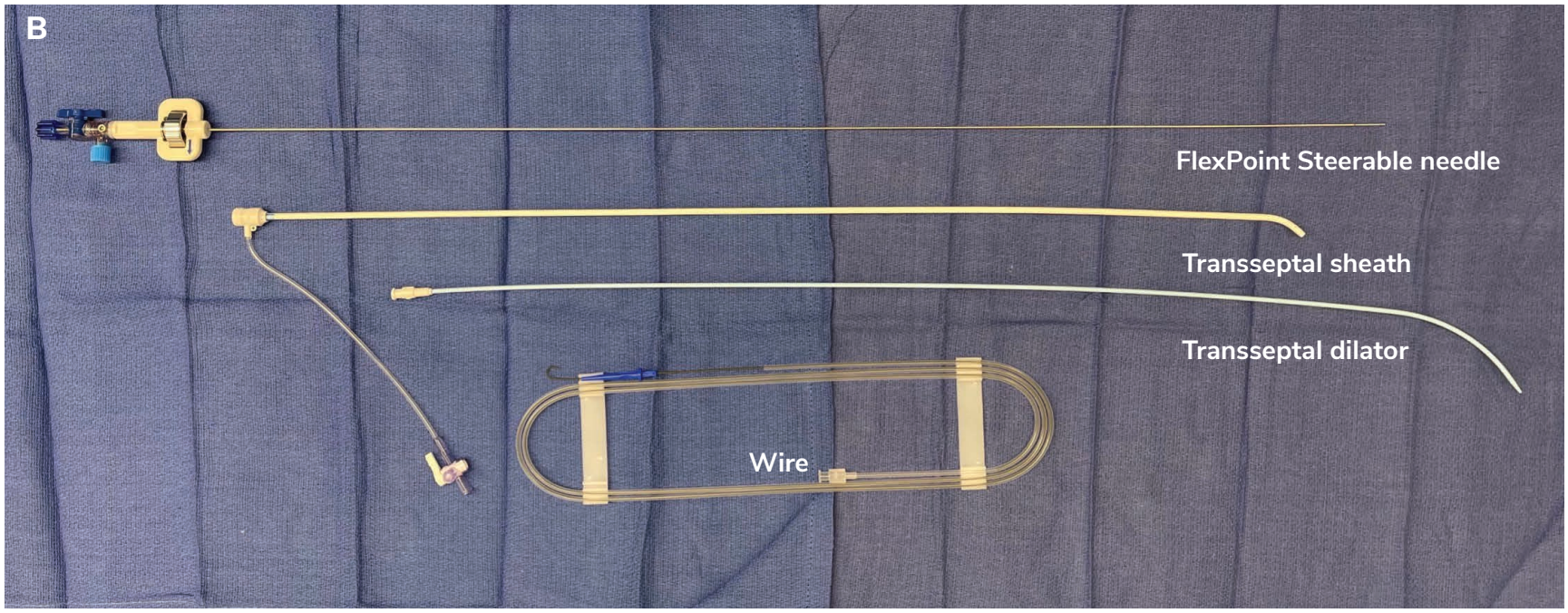


Figure 2. TSP Equipment

(A) Baylis VersaCross Transseptal system; (B) Indian Wells FlexPoint® Steerable Transseptal Needle system

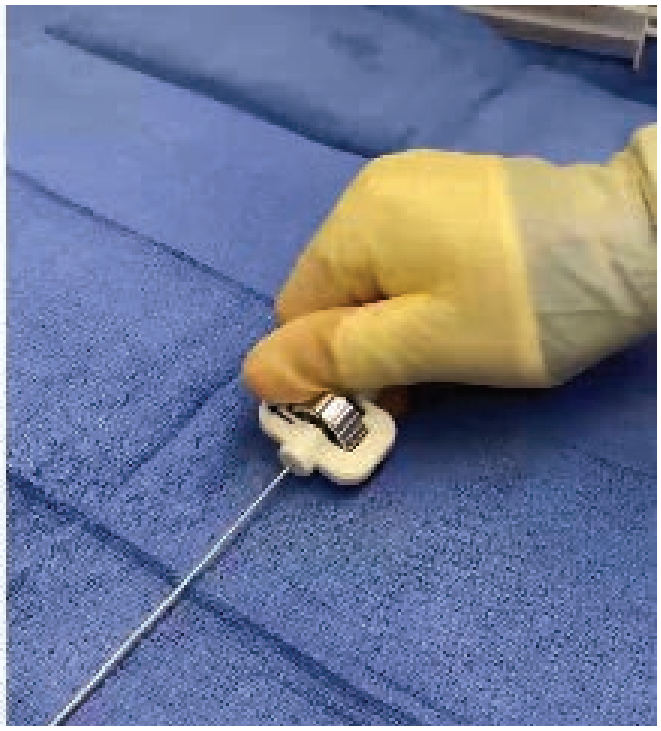


Figure 3 (videos). Indian Wells FlexPoint Steerable Needle

The VersaCross system is the newest development in transseptal technology and offers improvements in several categories. The traditional TSP systems are 0.032” compatible, unlike most other equipment in the catheterization laboratory that is 0.035” compatible. The VersaCross system is 0.035” compatible and serves as both the transseptal “needle” and the LA rail wire after crossing, further streamlining the transseptal process and increasing the overall efficiency of the procedure.

Regardless of the equipment chosen, the most important part of the transseptal procedure is adequate visualization by TEE and selection of the appropriate TSP site for the pathology.

Step-by-step TSP technique

After successfully obtaining venous access and administering IV heparin, begin the steps of TSP (summarized in Table 1). We recommend giving at least one-half the loading dose of heparin upon gaining venous access to prevent clot formation, although many users will give a full loading dose after venous access.

Advance the supplied J wire up from the inferior vena cava (IVC) into the superior vena cava (SVC) and advance the transseptal sheath and dilator system over the wire into the SVC. The wire is then removed and the needle or RF wire is advanced to just proximal to the tip of the dilator. Under fluoroscopic guidance, slowly pull back the system as a unit (Figure 4) from the SVC into the right atrium (RA) with the sidearm of the sheath pointed in the 4 to 5 o’clock position, which usually allows the system to be more perpendicular to the IAS on initial engagement.

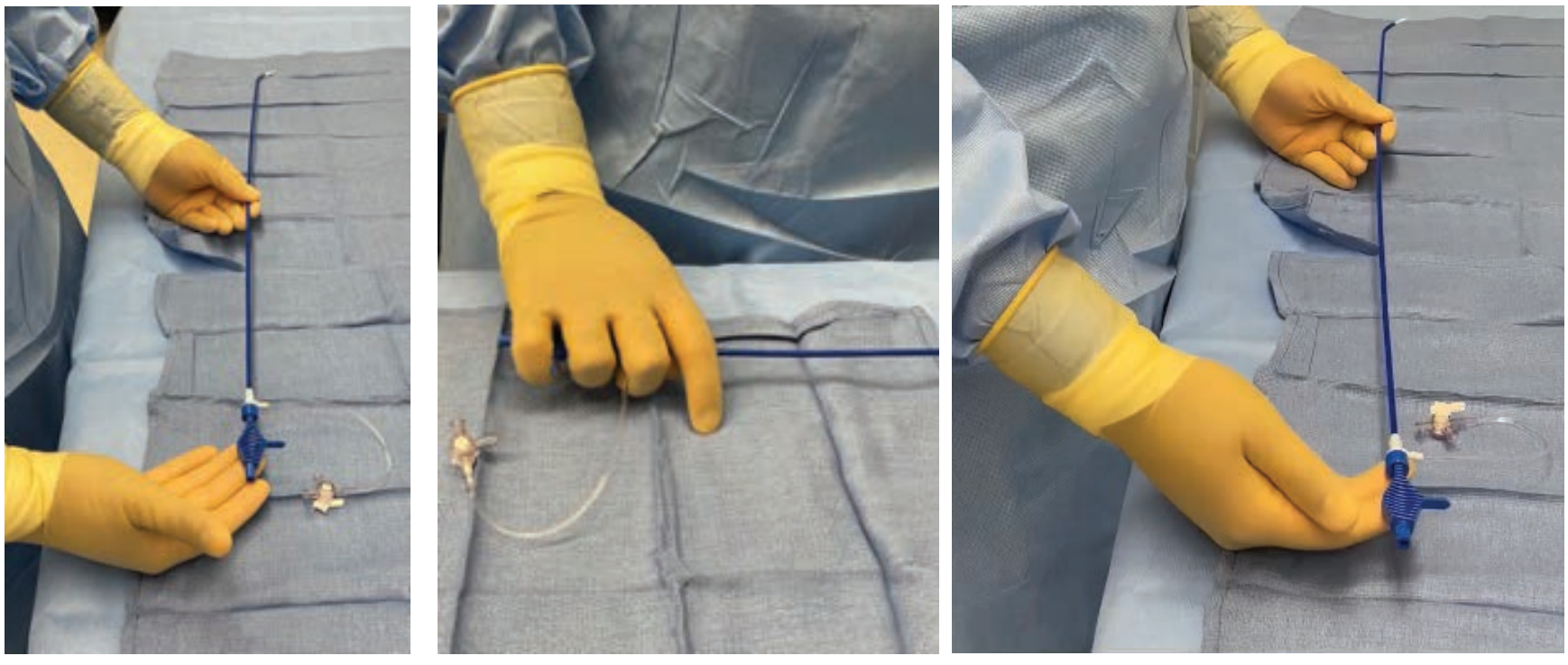


Figure 4 (video). Gripping Technique for Transseptal Sheath and Dilator System

Grip and rotate clockwise.

Fluoroscopically, two drops may be observed. The first drop is noted as the system drops from the SVC into the RA. The second drop occurs as the system falls into the fossa ovalis from the superior RA (Figure 5).

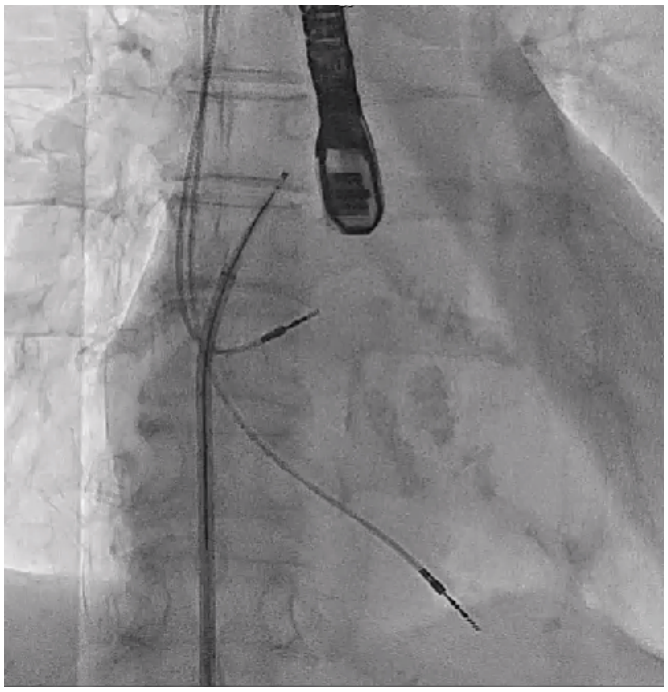


Figure 5 (video). Dropping into the RA, Then Fossa

Observe the tent of the system by TEE in the bicaval view to assess the superior-inferior position, and then use the short axis view to assess the anterior-position position. For TEER, the ideal position for central mitral regurgitation (MR) pathology would be the midpoint in the bicaval view. If the tent is not clearly seen, rotate the TEE probe anteriorly or posteriorly (clockwise or counterclockwise) to find the tent and then adjust the transseptal system to reach the true bicaval plane. Once the appropriate bicaval position is achieved, the TEE can then be set to the short axis view at the level of the aortic valve, providing the anterior-posterior axis for the transseptal puncture location. Torquing the TSP system clockwise will direct it posteriorly while torquing counterclockwise will direct it anteriorly. The ideal position for the standard central MR patient in this axis would be posterior of the midpoint (in the short axis view).

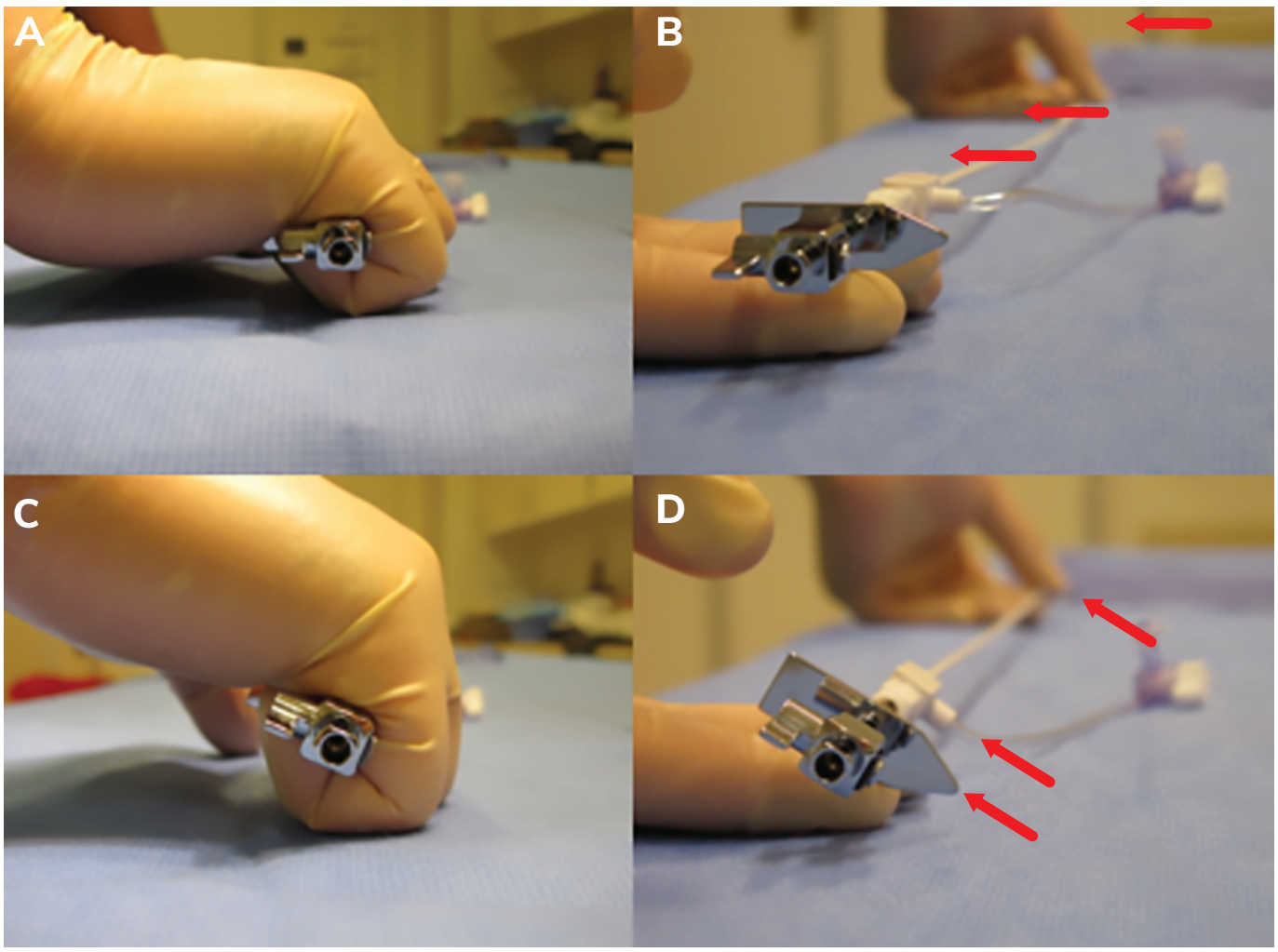
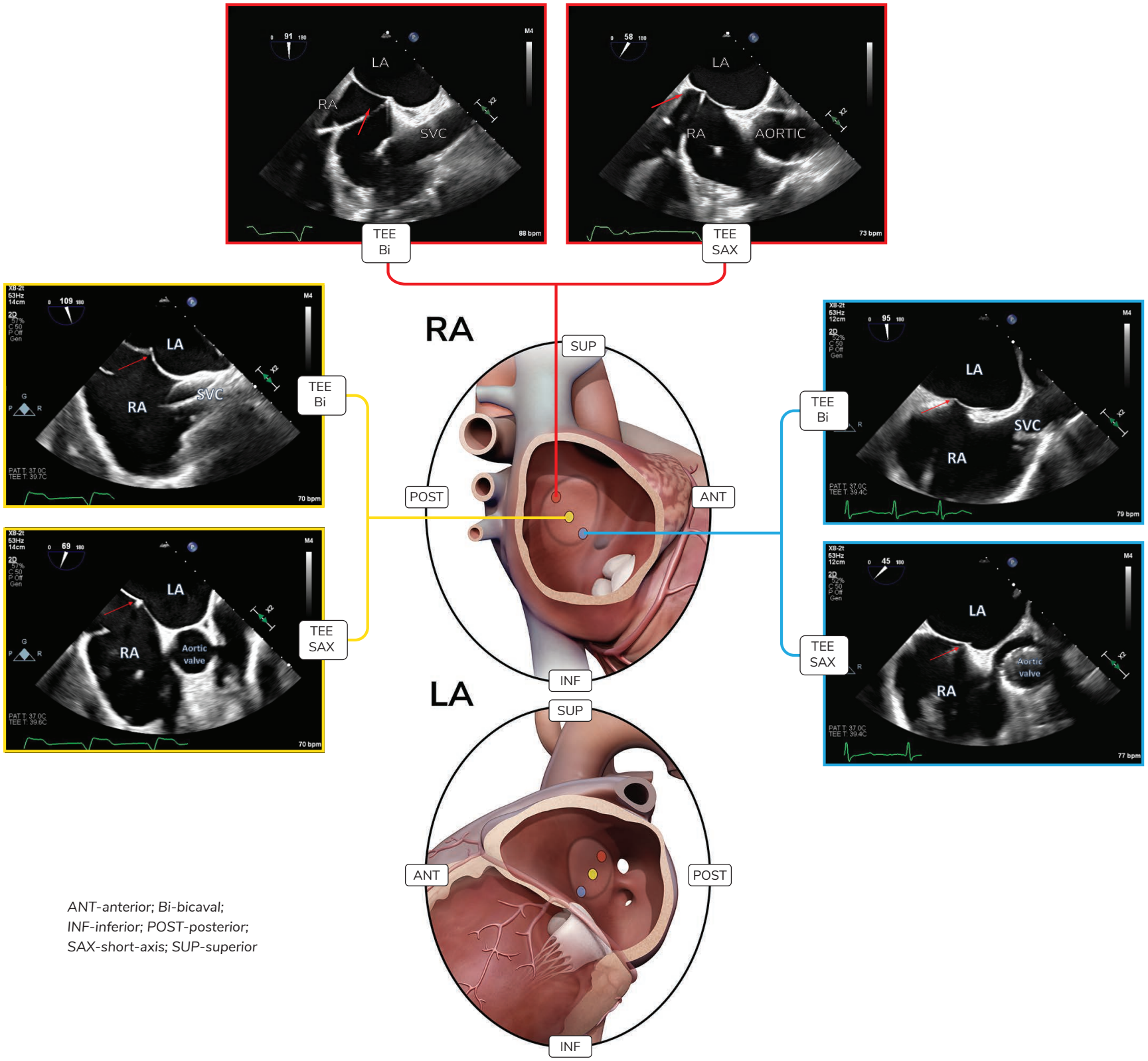


Figure 6. Orientation of Transseptal Needle in Relation to Transseptal Sheath (BRK1 pictured)

Transseptal sheath and needle are moved as a system by rotation. Arrow on the needle should be aligned with the sidearm of the sheath and the curve of the sheath (arrows). (A,B) System in the horizontal (3 o'clock) position. (C,D) System in the 4 o'clock position (arrows), clockwise rotation resulting in slightly more posterior position on the IAS.

After reaching the appropriate anterior-posterior position, it is important to check the bicaval view again to ensure appropriate bicaval position. Sometimes as the system is torqued posteriorly, it can shift in the bicaval view given the elliptical shape of the fossa. (See central illustration of RA/LA views of various tents and accompanying TEE views)



ANT-anterior; Bi-bicaval; INF-inferior; POST-posterior; SAX-short-axis; SUP-superior

Central Illustration. RA/LA View of Various Tents and Accompanying TEE Views

After achieving satisfactory tenting position, change the TEE to the 4 or 5 chamber view and measure the height of the transseptal tent to the mitral valve (MV) pathology (Figure 7). Considering the current MitraClip G4 system, the target transseptal height for optimal results is at least 4.5 cm. Importantly, the mitral valve reference point should be where the grasping will occur. In other words, for patients with primary disease, the MV reference point (where the grasp occurs) is often at or above the mitral annular plane. Conversely, for patients with secondary MR and tethered or restricted leaflets, the MV reference point (and hence the grasp) occurs below the annular plane. One technique to assess height is to draw parallel lines across the mitral annular plane and the transseptal tent plane. The distance between the tent plane and the MV pathology is the estimated transseptal height.

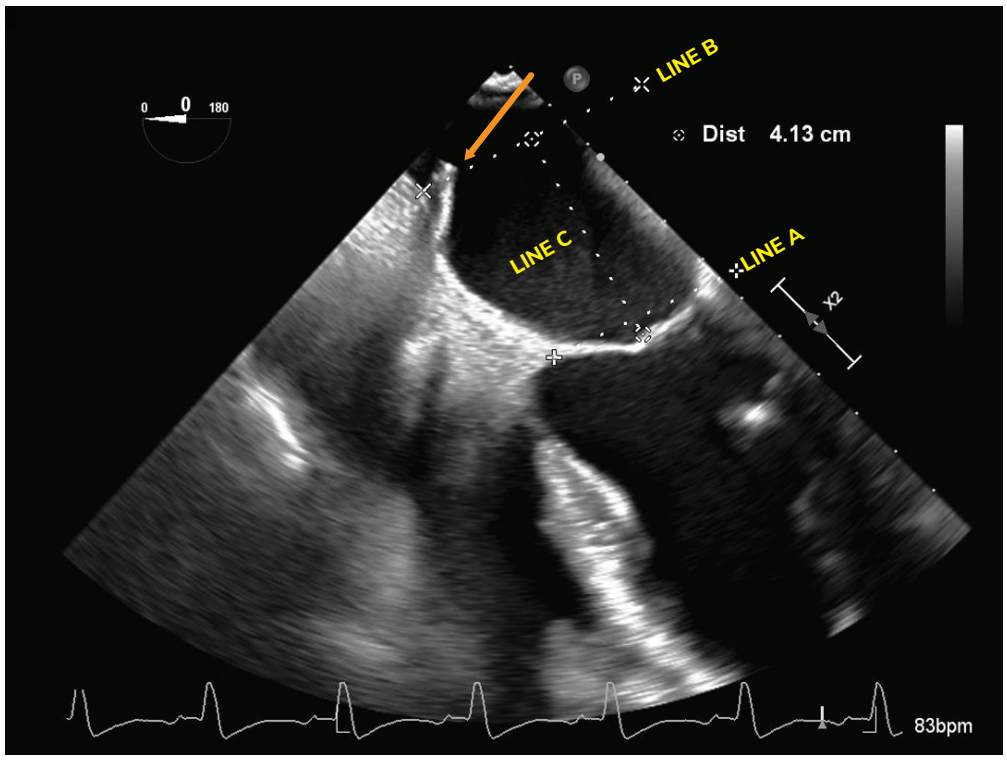


Figure 7. Transseptal Height Measurement (TEE)

First, draw line A across the mitral annulus. Then draw line B parallel to line A, starting from the tent of the transseptal needle (orange arrow). Finally, draw line C perpendicularly connecting line B to the MV pathology. Line C is the transseptal height measurement.

Once optimal transseptal tent and height are achieved and confirmed, return the TEE to the short axis view to prepare for TSP. Make the puncture and advance the system into the LA under TEE and fluoroscopic monitoring while rotating the system away from the posterior LA wall or aorta. Once the transseptal sheath is across into the LA, remove the needle/wire and dilator and thoroughly aspirate and flush the sheath in the usual manner. For other transseptal systems using RF or mechanical needles, advance the transseptal sheath and dilator over the needle. Remove the needle and dilator. An LA sample can then be used to confirm activated clotting time (ACT) greater than 250 seconds and/or further administration of heparin is given if needed.

Table 1. Step By Step Technique Comparing the VersaCross System to Indian Wells and Traditional Transseptal Needles

	BAYLIS VERSACROSS	INDIAN WELLS NEEDLE (IWN)	RF NEEDLE	MECHANICAL NEEDLE
1	Obtain appropriate percutaneous venous access with insertion of an introducer sheath (eg, 8 Fr sidearm sheath). Administer therapeutic systemic anticoagulation; the authors recommend doing so immediately after obtaining access, but a half loading dose can also be given after venous access, with the other half given immediately after transseptal puncture.			
2	Insert the supplied 0.035" wire and place into the SVC.	Insert 0.032” wire and place into SVC.		
3	Remove previously inserted sidearm sheath and advance VersaCross transseptal sheath and dilator over the wire into the SVC.	Remove previously inserted sidearm sheath and insert transseptal sheath over the wire into the SVC.		
4	Remove 0.035" J wire and advance supplied VersaCross RF pigtail wire proximal to the distal tip of the dilator. Alternately, the RF pigtail wire could be advanced initially into the SVC. Connect wire to RF energy source.	Remove the 0.032” wire and insert the transseptal needle just proximal of the dilator tip under fluoroscopy. The needle curve indicator and the sidearm sheath should be pointed in the same direction. For IWN only, rotate the proximal needle curve knob to achieve the desired curve.		
5	Pull the system as a unit down from the SVC into the RA and then the fossa under fluoroscopic and TEE guidance.			
6	Adjust the transseptal tent position using TEE guidance (as described separately) to the desired puncture site. Confirm adequate transseptal height.			
7	Advance the wire a few mm from the distal tip of the dilator. Under TEE guidance, energize the tip as the wire is pushed forward across the septum into the LA. As this wire is advanced, the pre-shaped pigtail shape is immediately formed.	Advance the needle forward beyond the dilator and apply constant steady forward pressure until the needle punctures the interatrial septum and crosses into the LA.	Advance the needle forward beyond the dilator a few mm and apply RF energy.	Advance the needle forward beyond the dilator and apply constant steady forward pressure until the needle punctures the interatrial septum and crosses into the LA.
8	Advance the dilator and sheath over the wire.	Advance the dilator and sheath over the needle into the LA while turning the system away from the important LA structures (ie, to avoid the posterior wall of the left atrium, use a counterclockwise/anterior rotation). As the sheath is advanced, it is important to maintain access to the LA with the needle/dilator.		
9	Walk the dilator out over the wire. Carefully aspirate and flush the sheath.	Remove the needle and dilator while maintaining the position of the transseptal sheath in the LA. Carefully aspirate and flush the sheath. Insert pre-determined LA rail wire. Options include 0.035” wire into the left upper pulmonary vein, 0.035” Safari wire, 0.025” Baylis ProTrack™ pigtail wire.		
10	Carefully remove the transseptal sheath over the wire. Insert the MitraClip Steerable Guide Catheter over the wire and into the left atrium.			

Special considerations

Noncentral MR

When approaching the patient with noncentral mitral regurgitation (MR), the target TSP site may change depending on the location of the MR. Medial MR jets can be more technically challenging. The most important component of TSP in this case is transseptal height. Typically, a posterior and mid bicaval position is the starting point. A mid-inferior and posterior puncture would allow a more direct approach of the medial jet without having to excessively flex the guide catheter if adequate height is achieved. If more height is needed, the bicaval position can be adjusted more superiorly. but advanced CDS maneuvers may be required.

Patients with patent foramen ovale/atrial septal defect

A patent foramen ovale (PFO) is oriented in a superior and anterior direction and does not provide an ideal trajectory for the MitraClip guide. It is not recommended to cross the PFO to enter the LA for TEER. Atrial septal defects (ASD) can also present a challenging situation. Depending on the size and location of the ASD, the operator may be limited. A small ASD may not pose significant issue but a medium or large ASD in a nonideal location is challenging because if TSP is performed in the ideal location, the septum may tear. Instead, in this situation the operator may be obliged to cross the ASD to perform TEER and may need to utilize advanced steering techniques to achieve procedural success. If the ASD is in the ideal position, MitraClip could theoretically be performed through the ASD.

Pre-existing atrial septal or PFO occluder device

With the increasing frequency of structural heart procedures, more patients who are being evaluated for TEER have already undergone procedures such as PFO or ASD occlusion. Depending on the location of the occluder device, it may be possible to perform TSP at an ideal location in the native septum. If the location of the occluder device is at the site of ideal TSP, puncture through the device can be considered. TSP in these scenarios requires careful planning using CT guidance and has been previously described.[1]

Hyperelastic septum

A septum in which more than 1 cm of tenting persists despite adequate forward pressure and advancement of the transseptal needle at the intended puncture site is an important challenge that TEER operators can encounter. In patients with hyperelastic septums, TSP with mechanical needle is especially difficult because adequate forward pressure does not produce a puncture into the left atrium and there is concern that once the needle does finally puncture, a “jump” will occur and the needle may advance too far and injure the distal structures such as the free wall of the left atrium.

Several different methodologies can be applied to try to avoid this potential catastrophic complication. If a BRK needle is being used, the operator can advance the stylet included with the system which may be sufficient to cause a microtear and allow full puncture with the needle. Another method would be to use the back end of a 0.014 inch coronary wire. However, given the significant evolution and predictability of RF technologies, a hyperelastic septum can be overcome with little difficulty.[2,3]

Fibrous septum

Many operators will encounter patients with fibrous interatrial septums that are not readily apparent (eg, post-operative septum). Risk factors for having a fibrous or thick interatrial septum are unknown. Typically in these cases, the TSP is performed as usual, however there may be some difficulty advancing the transseptal sheath and/or guide catheter across the septum. If this is the case, balloon dilation of the septum can be performed with an 8 mm peripheral balloon a priori.[2] The recent introduction of the Baylis Large Access VersaCross system has also aided in easily navigating fibrous septums. With this new system, a dilator and a wire are the only components. After the VersaCross pigtail wire crosses the septum, the distal tip of the dilator is advanced until the septum is slowly dilated with a larger more proximal segment of the dilator (12.5 Fr). The septum can be dilated in this manner to help aid delivery of the MitraClip SGC with little to no resistance (Figure 8).

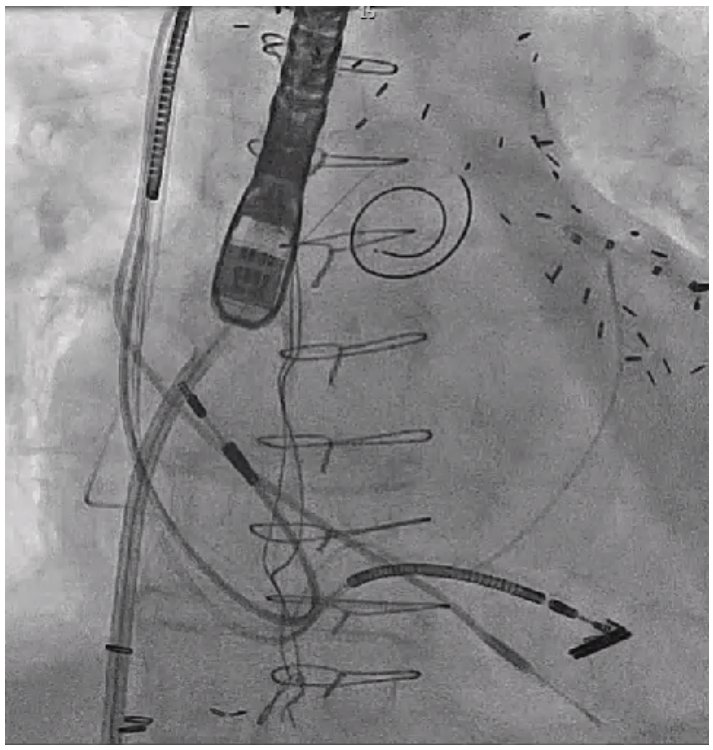


Figure 8 (video). Baylis Large Access Dilation

Iliofemoral tortuosity/enlarged RA

In cases with significant iliofemoral tortuosity, enlarged RA, or when utilizing left sided venous access, there can be difficulty in achieving adequate tenting of the septum as the needle is pulled away from the septal plane. The traditional mechanical and RF needle systems are pre-shaped with a primary bend. A secondary bend can be made 2 to 3 cm proximal to the primary bend, corresponding roughly to the location of the IVC–RA junction (Figure 9). The additional bend facilitates adequate tenting and the targeted TSP can then be achieved as described above.[2] Alternative strategies can include a) use of a more aggressive pre-shaped primary curve system (eg, BRK-1 or C1/D1), b) use of larger profile venous introducer sheaths (eg, 16 Fr x 30 cm) to “straighten out” the tortuous iliofemoral venous system before performing TSP using standard systems or c) in very rare cases, use of a steerable transseptal system (eg, Agilis or Baylis) or a steerable needle may be needed to provide the extra reach.

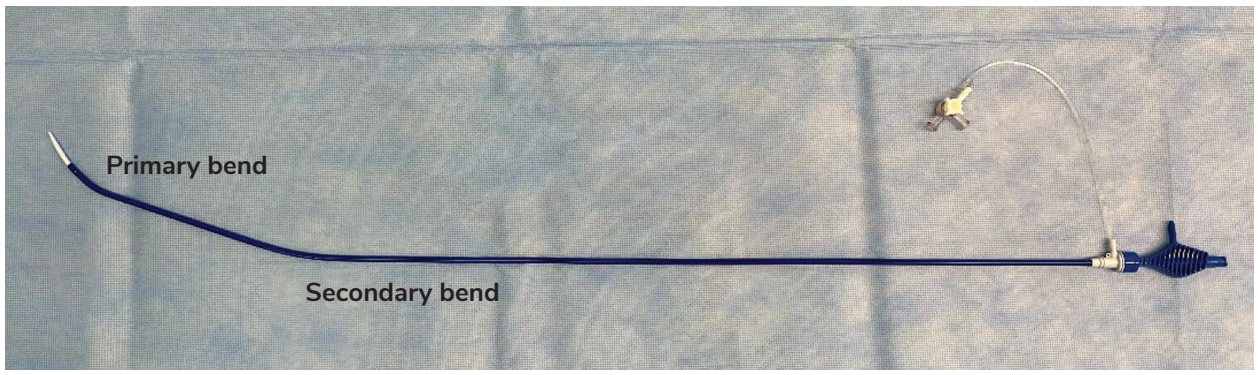


Figure 9. Primary and Secondary bends

Complications

Targeted TSP for structural heart procedures under TEE guidance is generally considered to be a safe procedure. Rates of serious complications are low at 1-2%.[4] Careful patient selection and attention to important procedural details, such as anticoagulation management, are key. Thrombus at the interatrial septum is the only absolute contraindication to TSP, but relative contraindications include marked anatomic abnormalities of the heart or thorax which would greatly increase the risk of injury to surrounding cardiac structures or tissues, and thrombus in either the left or right atrium and associated appendages.

Air embolism. Air embolism can occur during TSP as it does in other cardiac catheterization procedures and can manifest as stroke, coronary ischemia, and cardiac arrest. Extra care must be taken in the aspiration and flushing of the transseptal equipment, the MitraClip guide and delivery system. Treatment for air embolus includes adequate oxygenation, hemodynamic support with intravenous fluids and pressors when necessary, mechanical thrombectomy, and treatment of any associated malignant arrhythmias.[5] With adequate support and treatment, the deleterious effects from an air embolus can be adequately addressed.

Thromboembolism. Thromboembolism, like air embolism, is always a concern for TSP procedures. In a study of MitraClip patients and cerebral embolic protection, 14 patients from 2 centers had embolic protection placed for their MitraClip procedure and all 14 patients and all filters had debris identified that was of possible clinical significance.[6] The authors recommend initial intravenous heparin bolus administration up to target ACT >250 sec immediately after obtaining vascular access and maintaining a therapeutic ACT throughout the procedure. Maintaining a therapeutic ACT throughout will help to reduce the risk for thrombus.

Perforation and tamponade. Perforation and subsequent tamponade can be seen if the transseptal needle is inadvertently advanced and tears the free atrial wall. In this situation, the first consideration should be immediate emergency pericardiocentesis if necessary. Next, the degree of inadvertent free wall tear should be assessed. If no other equipment (eg, sheath, guide) was advanced over the needle at the site of the puncture, immediate reversal of therapeutic anticoagulation and removal of the needle may be adequate. If the guide catheter or other equipment has been advanced over the needle and out into the pericardial space, it is important to not immediately remove them once the problem is recognized. Consideration should be made for surgical removal of the larger bore catheters at this point and in select clinical and anatomic cases closure devices can be considered. Careful and targeted TSP minimizes risk for perforation.

iASD. Lastly, iatrogenic ASD (iASD) post MitraClip is present in every patient. In most patients, there are no significant hemodynamic consequences from the iASD and most will close over time. Rarely, in some patients, large right to left shunting can occur and result in hypoxemia, heart failure, and hemodynamic compromise. Mobile organized fibrinous content on pre-existing right sided hardware (eg, pacemaker leads) may put the patient at risk for paradoxical embolus and iASD closure may be required.[7] Thus far, routine closure of iASD is not supported (see Chapter 14. Evaluation of Iatrogenic ASD and Need for Closure for further discussion).[8]

PROCEDURAL PEARLS

- Therapeutic anticoagulation with intravenous heparin immediately after vascular access is recommended to reduce the chance for thrombus formation on the guidewire or delivery catheter.
- It is important to recognize that if the needle or dilator is tenting the septum too aggressively prior to achieving target location, clockwise or counterclockwise torquing may only lead to pivoting of the system around that point rather than sliding the system across the septum to the desired location. The system may need to be pulled back and disengaged in this case to allow for repositioning.
- Visualizing the needle and its trajectory while crossing will help avoid inadvertent harmful puncture of the posterior LA free wall or aorta.
- Adequate understanding of the anatomy of the interatrial septum/fossa and its relation to the SVC, IVC, aortic valve, and mitral valve is paramount to TSP success. Additionally, understanding of the anatomy assists the operator in maintaining a perpendicular orientation of the transseptal system to the septum, which is important for a safe and successful puncture.

Summary

Targeted and precise TSP is a critical initial step in TEER. The selection and execution of the optimal puncture site for the patient's pathology is paramount to procedural success. A standardized and consistent step-by-step methodical approach to TSP is the key to procedural success.

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CHAPTER 10

Left Atrial Steering, Clip Positioning, and Trajectory

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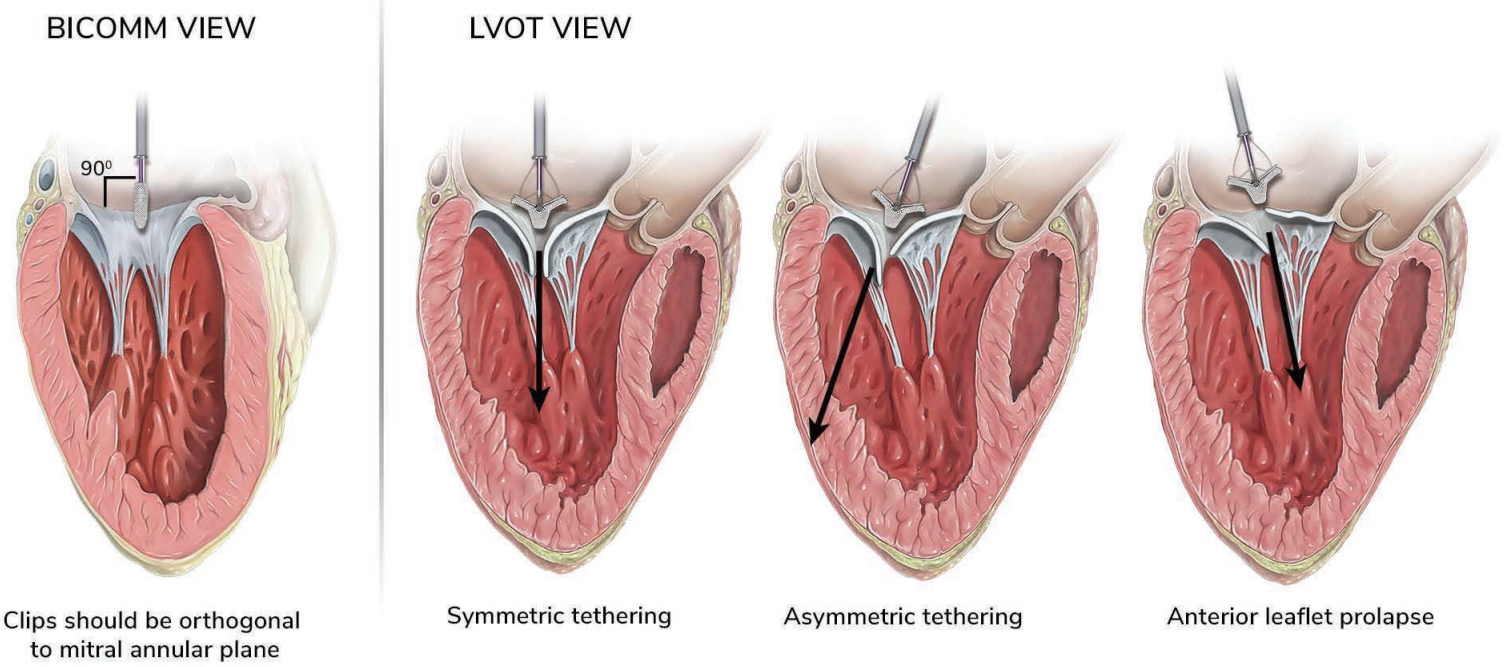
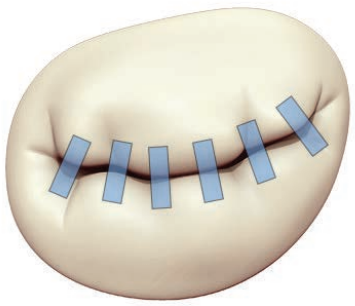
Overview

The goal of left atrial steering and clip positioning is to establish optimal trajectory and alignment of the MitraClip prior to entering the left ventricle to maximize procedural success and reduce risk of complications. After optimal transseptal access is achieved (see Chapter 9. Transseptal Puncture), the steerable guide catheter (SGC) is advanced across the septum. The clip delivery system (CDS) is then inserted and the clip is advanced to the tip of the guiding catheter. Straddle is achieved and M knob with posterior SGC rotation is applied to steer the clip down to the optimal position above the mitral valve. Adjustments are then made to the clip trajectory and alignment to achieve optimal position over the mitral pathology. Optimal trajectory and alignment are critical for procedural success as they facilitate leaflet grasping with the fewest attempts, reduce the risk of interaction with intraventricular structures, and reduce complications such as chordal entanglement or the need to invert and retract the clip back into the left atrium. (see Central Illustration)

Sample Trajectories for Different Pathologies





Clip alignment should follow the line of coaptation

Procedural considerations

TEE guidance is essential for steering and positioning the clip in the left atrium (LA). Appropriate imaging allows visualization and avoidance of interaction with cardiac structures while steering the clip in the left atrium and allows alignment and optimization of clip trajectory. Two-dimensional (2D) TEE imaging is sufficient for most of the steering process and clip alignment, however the use of 3D and multiplanar reconstruction (MPR) imaging can increase procedural efficiency. Evaluation of optimal clip trajectory begins with a good bicommissural (bicomm) view to establish medial and lateral positioning. TEE X-plane imaging from this bicommissural view to a left ventricular outflow tract (LVOT) long axis will establish anterior and posterior trajectory in the grasping view.

Fluoroscopy in the anterior-posterior (AP) or right anterior oblique (RAO) projection is also a valuable tool during the procedure. It is used to determine when the clip delivery system (CDS) and guide have reached optimal "straddle" position. Once clip alignment and trajectory have been confirmed on TEE imaging, an RAO projection is used to create a fluoroscopic bicommissural view and remove any parallax from the clip. This view will help to ensure that trajectory and alignment of the clip are maintained while advancing into the left ventricle (LV) and can help with trajectory of subsequent clips. Minor rotations of the clip that occur while advancing into the ventricle will be rapidly appreciated using fluoroscopy.

It is important to perform all clip alignment maneuvers above valve in the LA to reduce risk of chordal entrapment or interaction with vital LV structures.

Procedural questions during left atrial steering

1. What is the morphology of the left atrium and how will this affect CDS straddle and left atrial steering?
2. What is the trajectory of the clip on the bicommissural view?
3. Do you have sufficient height above the valve to pull back during grasping?
4. Do you have sufficient CDS length to travel into the LV?
5. Do you have an "aorta hugger"?

Step by step technique

After performing transseptal puncture as previously described and advancing the SGC over a stiff wire into the left atrium, remove the wire and dilator under aspiration of the guide catheter and pull back the tip of the SGC to 1 cm across the septum. Once this has been performed, proceed to clip insertion, steering, and clip alignment.

1. Advance the clip to the tip of the guide, advancing it 1 clip length out of the guide under TEE guidance to avoid possible damage to the lateral or posterior atrial wall.
2. Pull back guide until it is 1-1.5 cm across the septum under TEE guidance.
3. Advance the clip and sleeve markers to straddle the guide marker under fluoroscopy.
   This is a good time to evaluate the left atrial morphology and size. *Do you have sufficient space to straddle the CDS on the guide?*

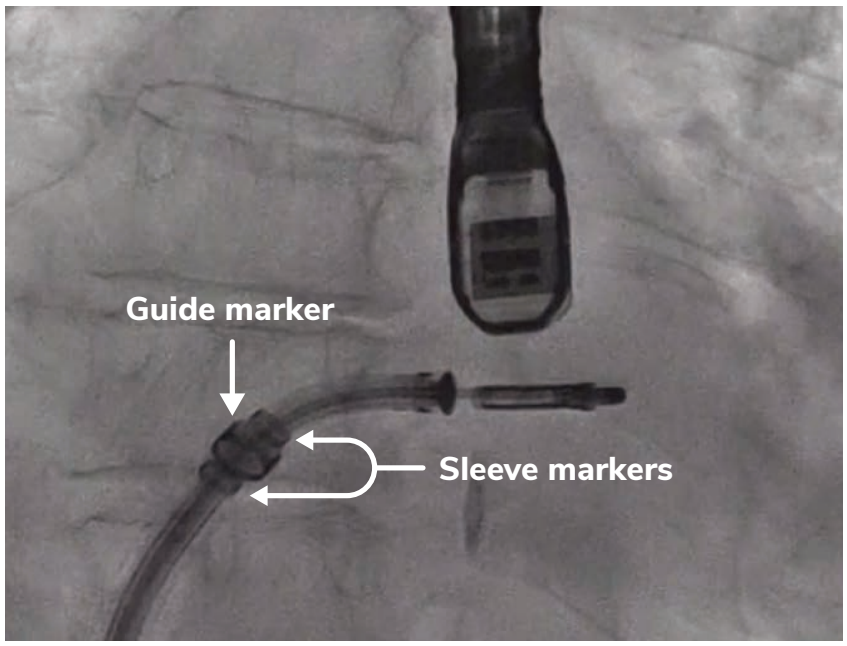


Figure 1. Straddle with Guide Marker Between the Sleeve Markers

There are cases with small left atria where the clip may not be extended to full straddle prior to applying M knob to steer down to the valve without interacting with the walls of the atria. In this case, small amounts of anterior or posterior torque to the SGC can help create some space, typically anterior SGC torque to guide the clip toward the left atrial appendage (LAA) where there is more room.

To complete straddle in a small left atrium, it may be necessary to add + to the SGC or early use of the M knob. Often, the addition of more anterior guide torque will also be necessary.

If still unable to extend to straddle with the CDS, a small amount M knob may be applied as the clip is being advanced (pre M technique) as shown in the video in Figure 2. This will start steering the clip toward the valve and away from the posterior/lateral wall of the atrium. As more room is created, the CDS can be advanced slowly until straddle is reached. This process may need to be completed in steps with careful focus on the clip and the lateral wall of the atrium to avoid interaction with cardiac structures.

As the clip is steered down to the valve, check the straddle intermittently on fluoroscopy and adjust as needed.

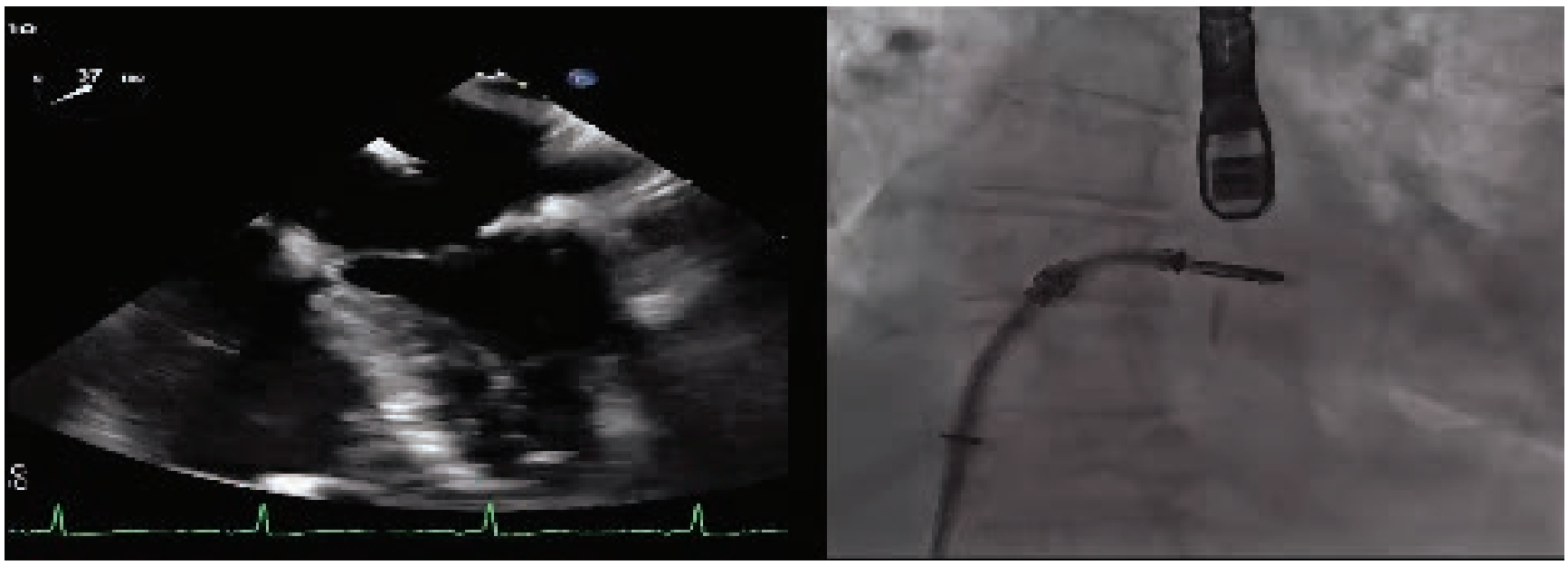


Figure 2 (video). “Pre-M” Required Before Full Straddle Achieved in Setting of Small LA

4. Use M knob to steer the clip down to the mitral valve. TEE should focus on the clip. To avoid interaction with the cardiac structures, simultaneously apply posterior rotation and M to the guide catheter. Once the clip has cleared the ridge between the pulmonary vein and left atrial appendage, X-plane may be used to aid in anterior and posterior steering with the SGC. As the M knob is applied and the clip is steered down toward the mitral annulus, remove slack from the CDS by periodically retracting the CDS handle to create more space. Frequently check fluoroscopy and adjust the straddle accordingly.

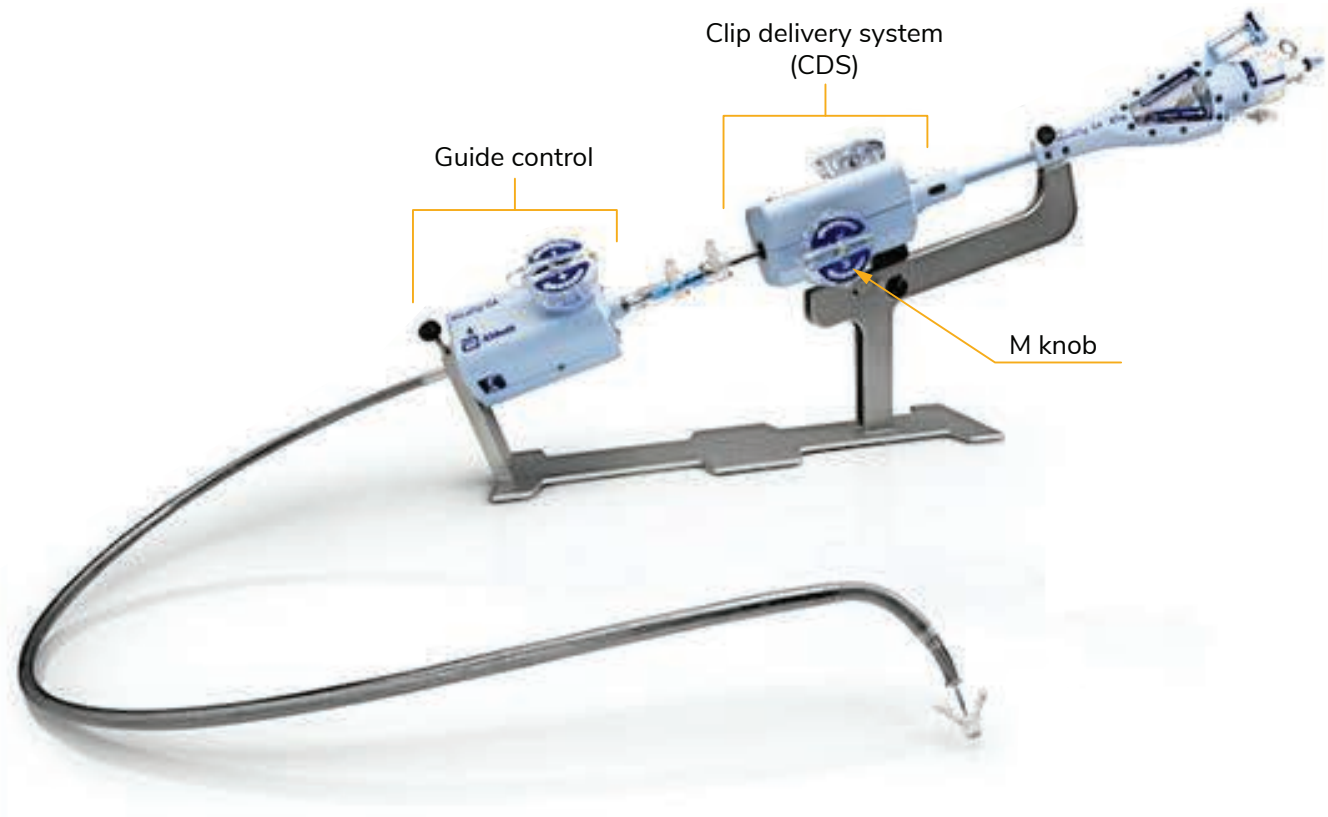


Figure 3. Guide Control and M Knob on the Clip Delivery System

5. Once the clip has been steered down toward the valve, evaluate the trajectory in the bicommissural view. In this view, adjustments can be made with the M knob to ensure a medial/lateral trajectory that is perpendicular to the axis of the mitral valve annulus.

Trajectory can be confirmed by gently advancing the clip and by translating the motion with small back and forth movements of the CDS. Pay special attention to avoid possible medial or lateral dive and adjust the M knob accordingly. More M knob will move the trajectory more medial; less M knob will move the trajectory lateral.

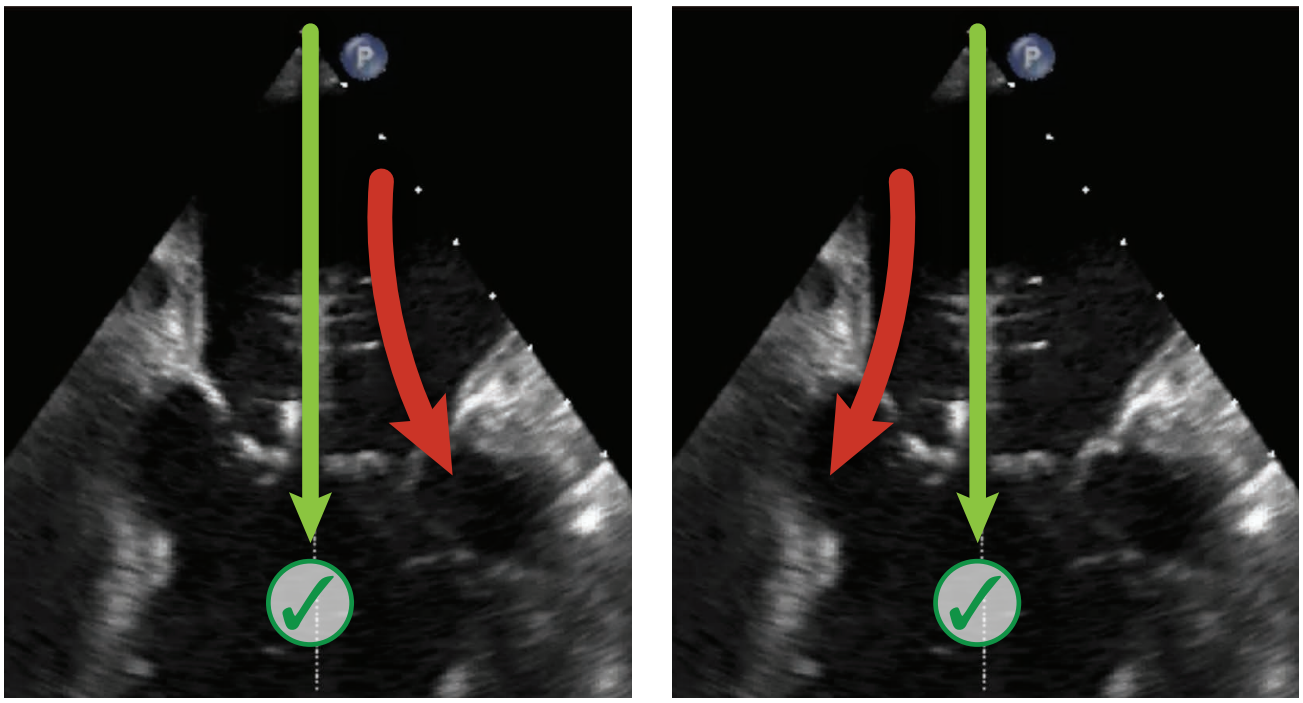


Figure 4. Adjusting Medial and Lateral Trajectory with M Knob

(Left image) Applying more M knob will correct the medial to lateral trajectory (red arrow) to the green arrow perpendicular to the valve annulus and parallel to the axis of the LV. (Right image) Applying less M knob or removing "M", will move the lateral medial trajectory (red arrow) back to the green arrow.

6. Once medial/lateral trajectory has been confirmed, X-plane from the bicommissural view to an LVOT view to evaluate anterior and posterior trajectory.

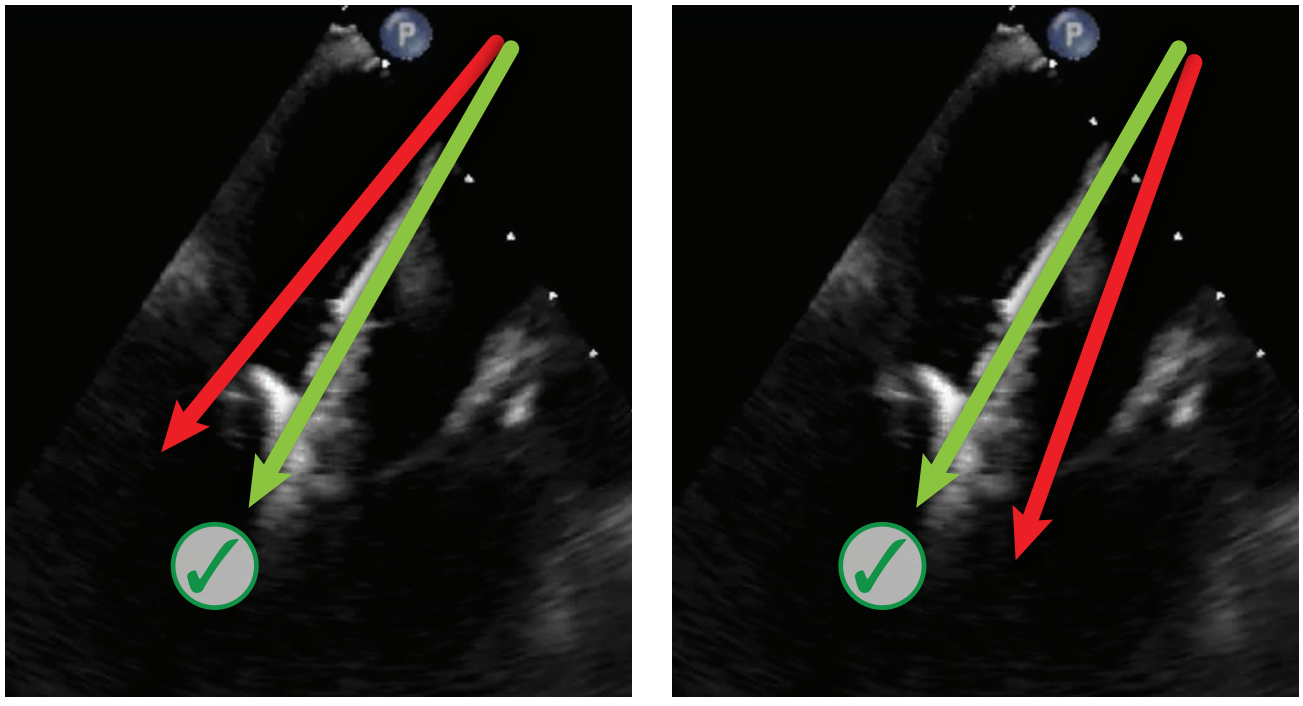


Figure 5. Adjusting Anterior and Posterior Trajectory

(Left image) Trajectory is too posterior (red arrow); anterior torque to the SGC will move the trajectory more anteriorly to the green arrow. (Right image) Trajectory is anterior (red arrow); posterior torque of the SGC will move the trajectory posteriorly to the green arrow.

If the trajectory appears more posterior, rotate the SGC anteriorly to correct the trajectory. Similarly, in the setting of a more anterior trajectory, use posterior rotation of the SGC to make corrections.

7. Once trajectory has been established, position the clip over pathology or the area of largest proximal isovelocity surface area (PISA) in the medial and lateral aspect of the mitral valve on bicommissural view of TEE. The system can be adjusted by pulling the entire clip system, using the stabilizer, back (medial) or by pushing the stabilizer in (lateral).

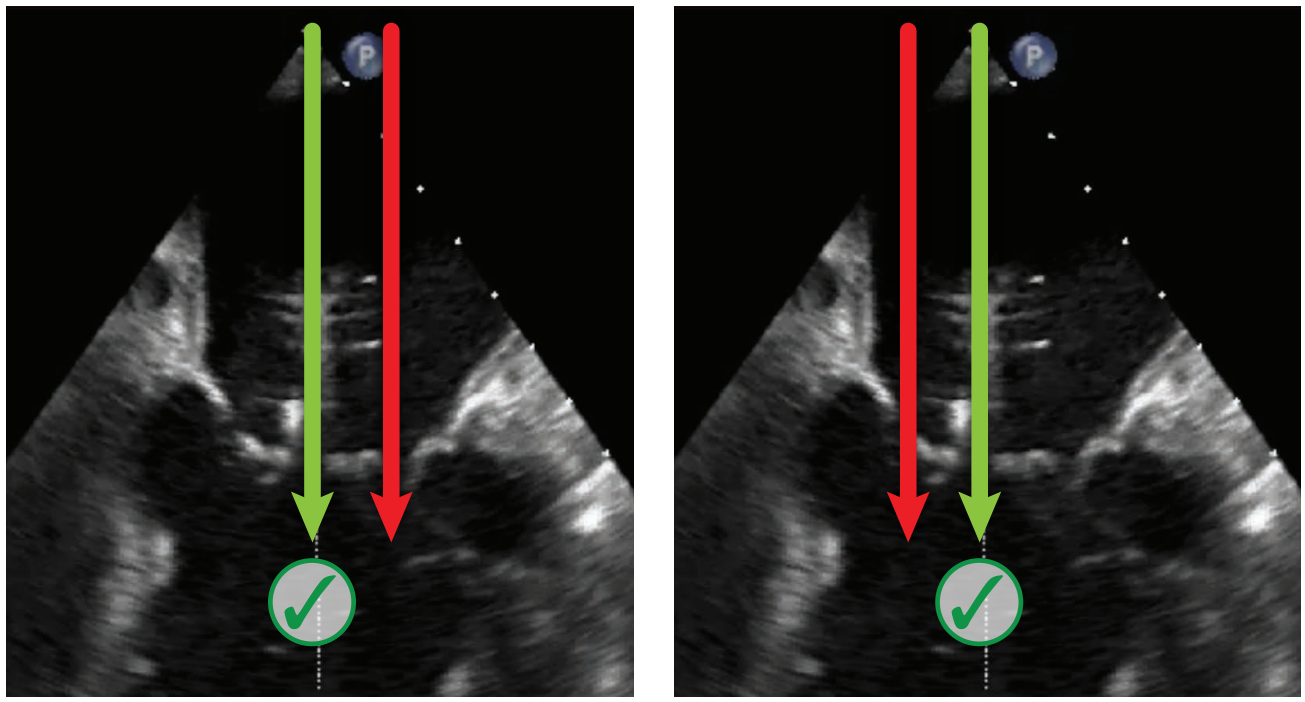


Figure 6. Positioning Clip Over Mitral Valve

(Left image) Clip trajectory is correct but too lateral (red arrow); pulling back on the system moves the clip more medial (green arrow). (Right image) Clip trajectory is correct but too medial (red arrow); pushing the system in moves the clip more lateral (green arrow).

8. Once the clip is positioned, open the clip arms to establish alignment of the clip over the mitral valve using 3D TEE en face view. To adjust clip orientation, rotate the CDS handle clockwise or counterclockwise so that the clip is perpendicular to the line of coaptation of the mitral valve at the area of pathology (see Central Illustration). This angle will change as you go more medial or more lateral on the mitral valve in either the A1/P1 or A3/P3 segments. Pay special attention to TEE during this maneuver and adjust accordingly, as clip rotation will move the clip anterior or posterior.
9. Once the alignment is established, adjust fluoroscopy, typically by coming RAO to remove parallax from the clip. As the clip is advanced and retracted, if this orientation of the clip is maintained on fluoroscopy, the orientation of the clip relative to the valve will remain the same.
10. Close clip arms for crossing into the LV.
11. Slowly advance the clip in the LV, maintaining clip orientation with constant monitoring of TEE and trajectory in the medial/lateral and the anterior/posterior directions. As the clip is advanced, small adjustments may be made as needed. Monitor fluoroscopy constantly to help maintain clip orientation. After the clip is advanced into the LV, proceed with the clip procedure (described elsewhere).

Troubleshooting

Do you have sufficient height above the valve to pull back during grasping?

Depending on the height of the transseptal puncture, specifically in the setting of a low transseptal, you may not have sufficient height above the valve to pull back the clip. This will be more problematic in degenerative etiologies or flail pathology. In this case you will need to gain height, which may be achieved by removing + from the SGC; however, this will move the clip anteriorly and laterally. Posterior SGC torque will be required to gain additional height. If this is unsuccessful, use the A knob, as described below.

1. **Use A knob as your primary method for medial deflection.**
2. Confirm guide position and ensure 10-15 mm guide in the LA. More guide may prove detrimental.
3. Gradually add A knob while maintaining echo visualization of the clip tip in the LVOT/bicomm view (X-plane)
4. As you add A knob, gradually torque the guide posterior. You may need a significant amount of posterior torque to ensure position of the clip away from the LAA.
5. The clip will move anterior and lateral and you will gain height, up to approximately 10 mm.
6. Verify bicomm position and add more M to achieve perpendicular approach to the valve.
7. When you have sufficient height above the valve, proceed cautiously to test additional maneuvers to achieve perpendicularity.

Do you have sufficient CDS length to travel into the LV?

Sufficient CDS length is also dependent on the transseptal puncture. If the puncture is too high you will need to lose height. This can be achieved by adding + to the SGC, however this will result in posterior and medial movement of the clip which will require adjustment. If this is unsuccessful, you may need to use the P knob as described below.

1. **Remove all M deflection from the CDS**.
2. **Add P knob as you rotate the guide anteriorly.** Note: Once you use P knob it becomes the primary method for medial deflection.
3. The clip will move posteriorly and medially, and you will therefore need to rotate the guide anteriorly to maintain position in the center of the valve.
4. Use the stabilizer to perform additional medial and lateral displacement.

Do you have an "aorta hugger"?

Depending on the location of transseptal puncture in the grasping/long axis view of the aorta, the clip trajectory may be close to the anterior wall with a shallow trajectory or an "aorta hugger." It is important to recognize this prior to advancing into the LV for leaflet grasping as it may increase the likelihood of interaction with subvalvular structures in the LV and/or make leaflet grasping more difficult. The aorta hugger may be remedied by applying + knob to the SGC which will lift the trajectory of the clip so that it is better aligned for grasping in the anterior/posterior projection.

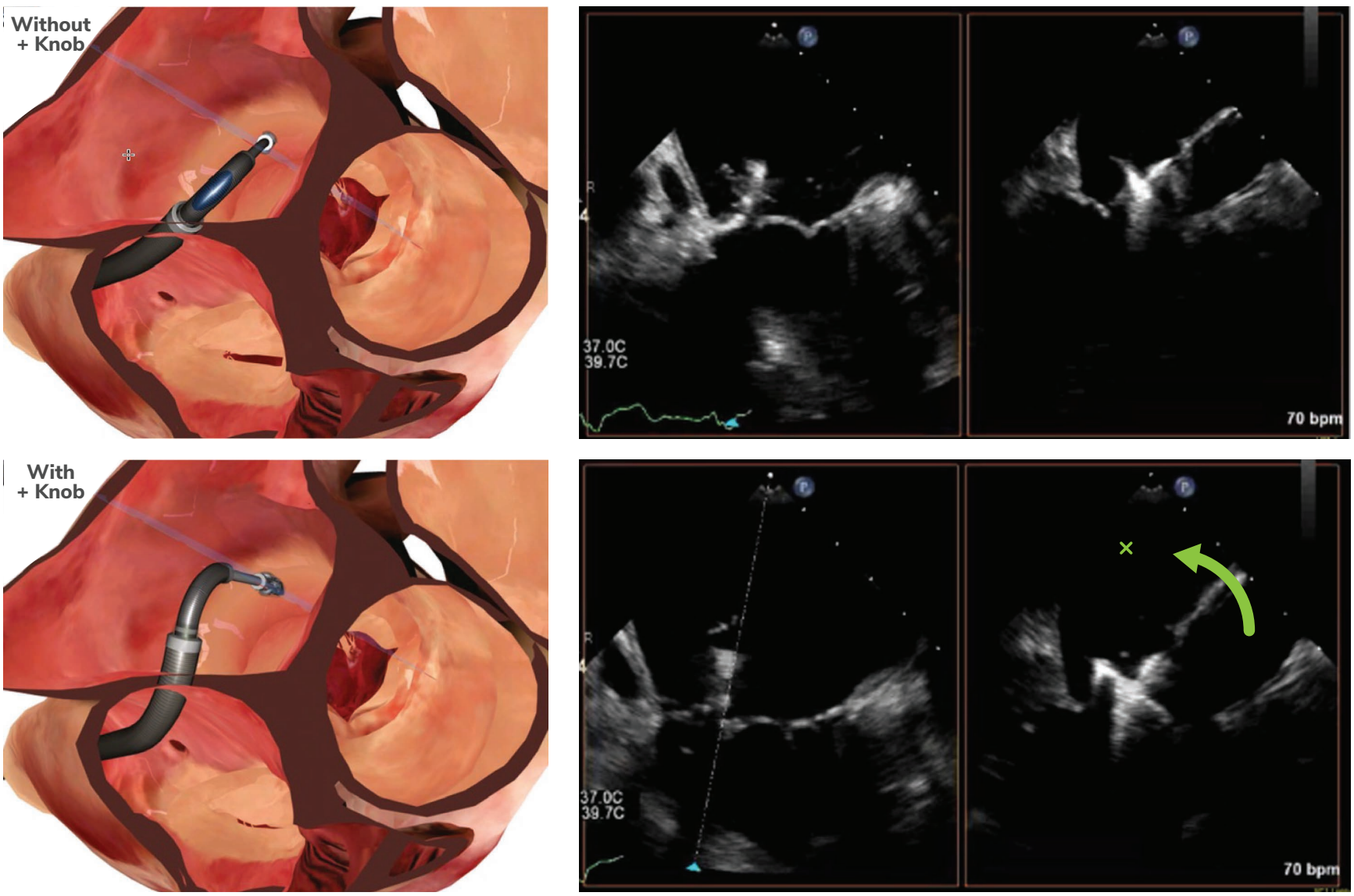


Figure 7. With and Without + Knob

(Top image) Shallow trajectory from anterior to posterior or "aorta hugger" without + knob. (Bottom image) Adding + knob to the SGC corrects the trajectory away from the aorta to a more favorable trajectory.

Procedural Pearls

- While the clip is advanced into the LA and during the alignment and steering down process, communication with the anesthesiologist is important. If the patient can tolerate low tidal volume respiration this should be performed. Low tidal volume respiration will decrease the movement of the heart and its associated structures during respiration to help maintain alignment at the area of pathology, as well as decrease the likelihood of damage and interaction with vital structures.

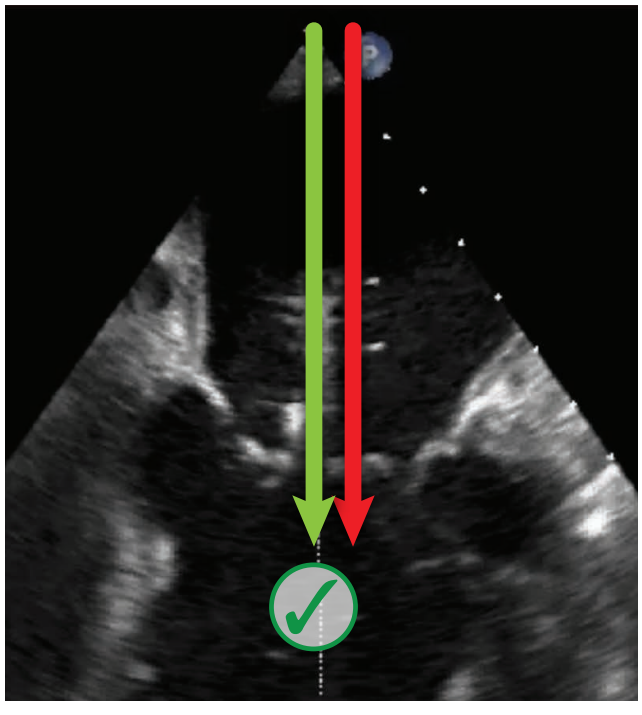


Figure 8. Clip Movement with Breath Hold or Low Tidal Respiration

Clip position at baseline (red arrow); clip moves medial with breath hold or low tidal respiration (green arrow).

- For pathology close to either A1/P1 or A3/P3 segments in the medial or lateral commissures, X-plane often is not orthogonal to the trajectory of the clip and the grasping view will therefore be off access to the pathology of the mitral valve. In these situations, or other difficult imaging situations, it may be beneficial to use the MPR feature of TEE.

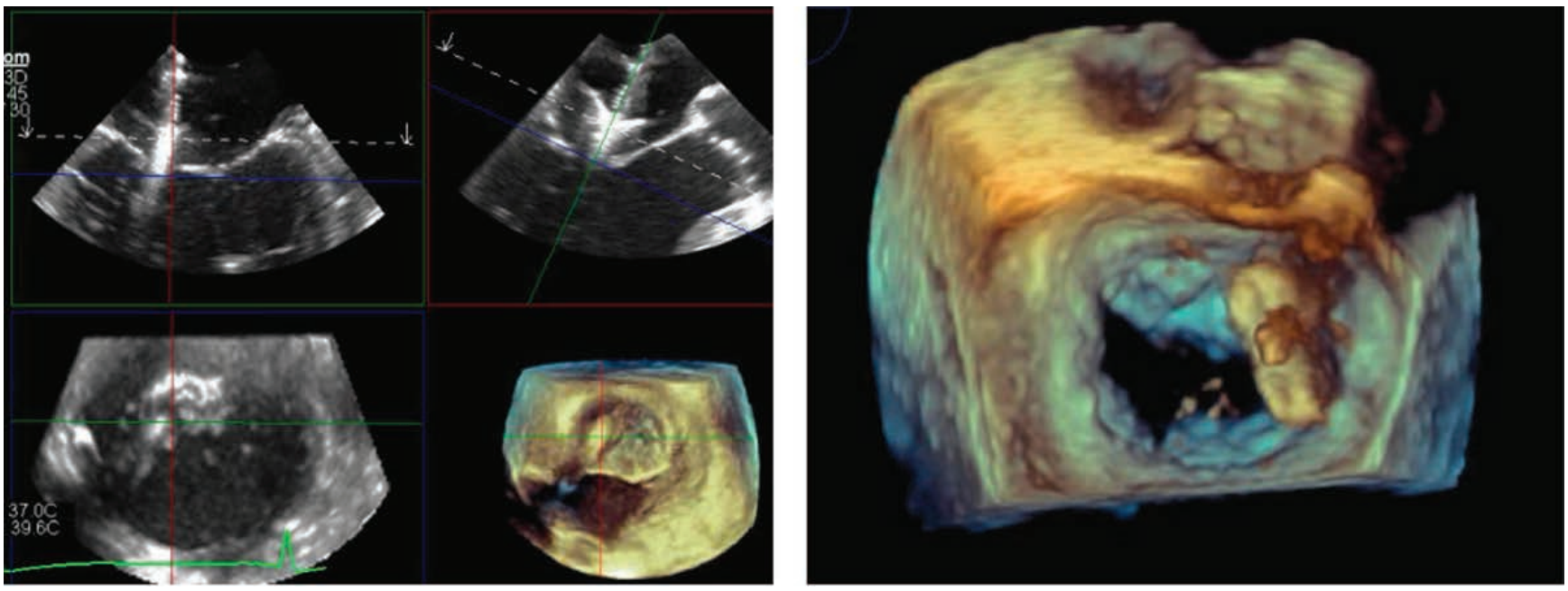


Figure 9. MPR and 3D TEE Views

(Left image) MPR may create a more orthogonal angle in the bicomm view which then allows for more precise trajectory; however, (Right image) clip alignment may be best seen in a dedicated 3D TEE view.

- Other special situations include severe mitral regurgitation with previous annuloplasty ring. The ring often overrides the posterior leaflet, making proper trajectory difficult in this situation. Using the guide alone with + knob with a “clip on a stick” technique will achieve a shallow trajectory (super aorta hugger) to be able to grasp the posterior ring/leaflet.

- Careful use of fluoroscopy will aid in advancing the clip into the LV and maintaining clip orientation. Once clip orientation is established in the en face view in TEE, removing the parallax from the clip arms while maintaining this view of the clip on fluoroscopy will maintain the orientation of the clip as it is advanced into the LV and maintain the proper orientation for grasping, reducing the need for adjustments in the LV. This is done typically by coming to the RAO projection and then adjusting cranially or caudally to attempt to completely remove parallax. This creates a “fluoroscopic bicomm” which is helpful in maintaining clip orientation as it is advanced below the valve, as well as helping with placement and orientation of a second clip if needed.

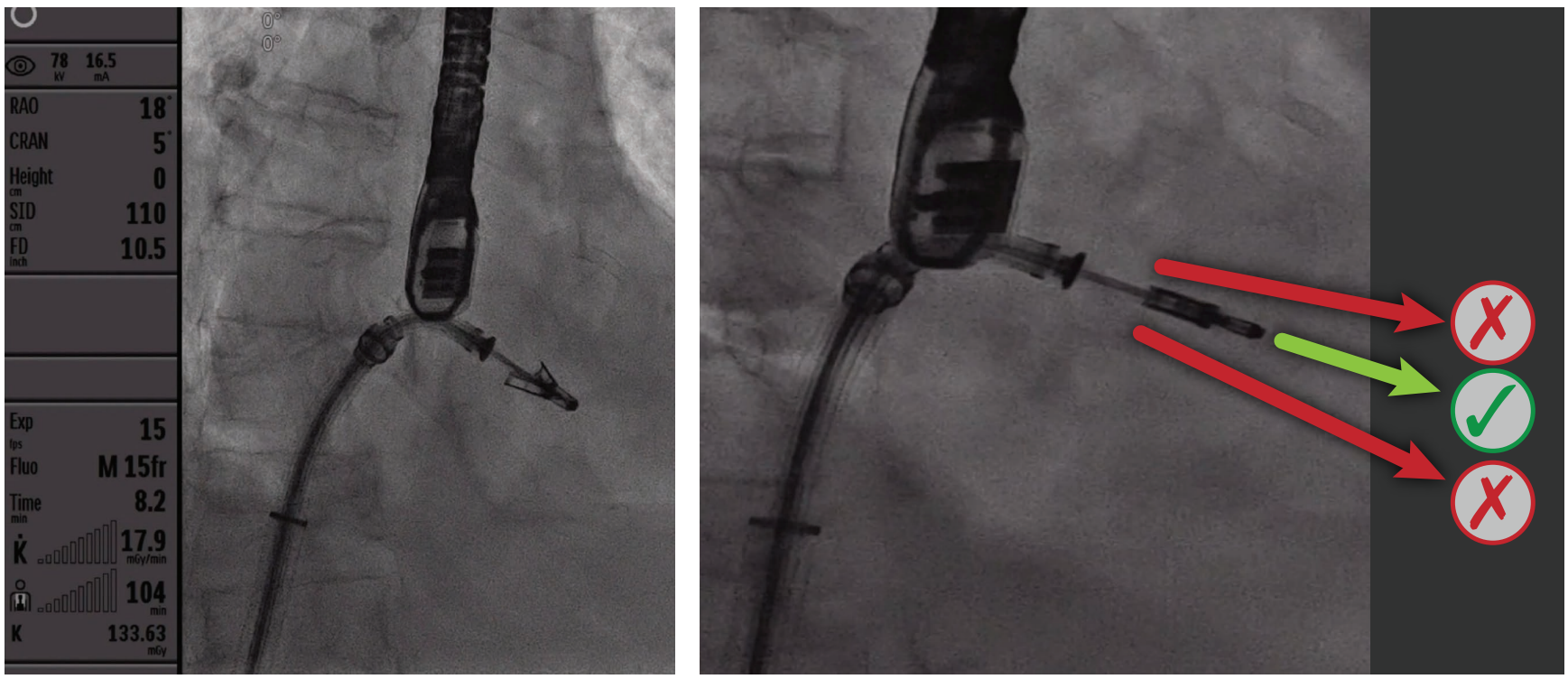


Figure 10. Removing Parallax and Using M Knob for Optimal Entry Trajectory

(Left image) Clip with arms open but parallax not removed. The fluoroscopic angle is changed to superimpose the clip arms (removing parallax) and then the clip is advanced under TEE and fluoroscopy into the LV. (Right image) Correcting from the red arrow trajectories to an optimal fluoroscopic entry trajectory (green arrow) can be achieved by adding or removing M knob.[1]

Summary

Left atrial steering and clip positioning are critical to procedural safety and success. Each step in the MitraClip procedure is built on the prior step. Transseptal puncture is critically important in making clip steering, positioning, and alignment safer and easier to perform, just as proper left atrial steering, positioning, and alignment make clip advancement and grasping safer and are critical to procedural success. Imaging is critically important in left atrial steering, positioning, and alignment. Constant monitoring of TEE while steering to avoid interaction with vital structures is critical for positioning and alignment above pathology and determining proper trajectory. Determining proper alignment, positioning, and trajectory in the left atrium will reduce adjustments needed as the clip is advanced and will reduce adjustments needed when the clip is in the LV. This will reduce the risk of interaction of sub-valvular structures and will ensure optimal grasping leading to greater procedural success.

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CHAPTER 11
Clip Alignment and Entering the Left Ventricle

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Overview

This chapter focuses on the basic principles of clip alignment (or orientation) to the mitral leaflet plane of coaptation by utilizing different imaging modalities including 2D TEE, 3D TEE, and fluoroscopy. It describes the step-by-step procedural techniques involved in achieving the appropriate clip alignment in the left atrium, advancing the clip into the left ventricle under combined TEE and fluoroscopic guidance while minimizing clip rotation, and realigning once in LV. These best practices are required to reduce the risk of chordal entanglement, ensure ideal leaflet grasping, and avoid any folding, tension, or pinwheeling effect on the mitral valve leaflets. Proper alignment minimizes the risk of single leaflet device attachment (SLDA), leaflet tear or perforation, or suboptimal MR reduction due to leaflet distortion.

Procedural considerations

High quality imaging is required to assess for clip alignment in the LA and entering the LV. Optimal views on TEE are the 2D bicommissural (bicomm) view, long-axis LVOT grasping view (orthogonal X-plane of bicomm view), and 3D en face (surgeon's) view with and without color. Fluoroscopy also plays an important complementary role in conjunction with TEE and the concept of clip "parallax" is a valuable learning point. By using fluoroscopy as a guide (the parallax technique) after aligning the clip under TEE, rotation can be minimized while advancing the clip into the LV and during grasping.

Step-by-step technique

1. Once the clip delivery system (CDS) is inserted but before M knob is applied, fluoroscopy is used in the anterior-posterior (AP) projection to rotate the delivery catheter (DC) handle until the clip arms are superimposed. (Figure 1). The change in appearance of the clip that occurs when the arms are superimposed on fluoroscopy has been termed "loss of parallax."[1] The clip is then steered down to the valve in the traditional manner with application of the M knob, posterior guide rotation, and straddling the CDS. When steering down to the valve visualize the lateral wall on TEE to avoid interaction with the coumadin ridge. If parallax is removed early during this process, less clip rotation will be needed to achieve final optimal alignment.

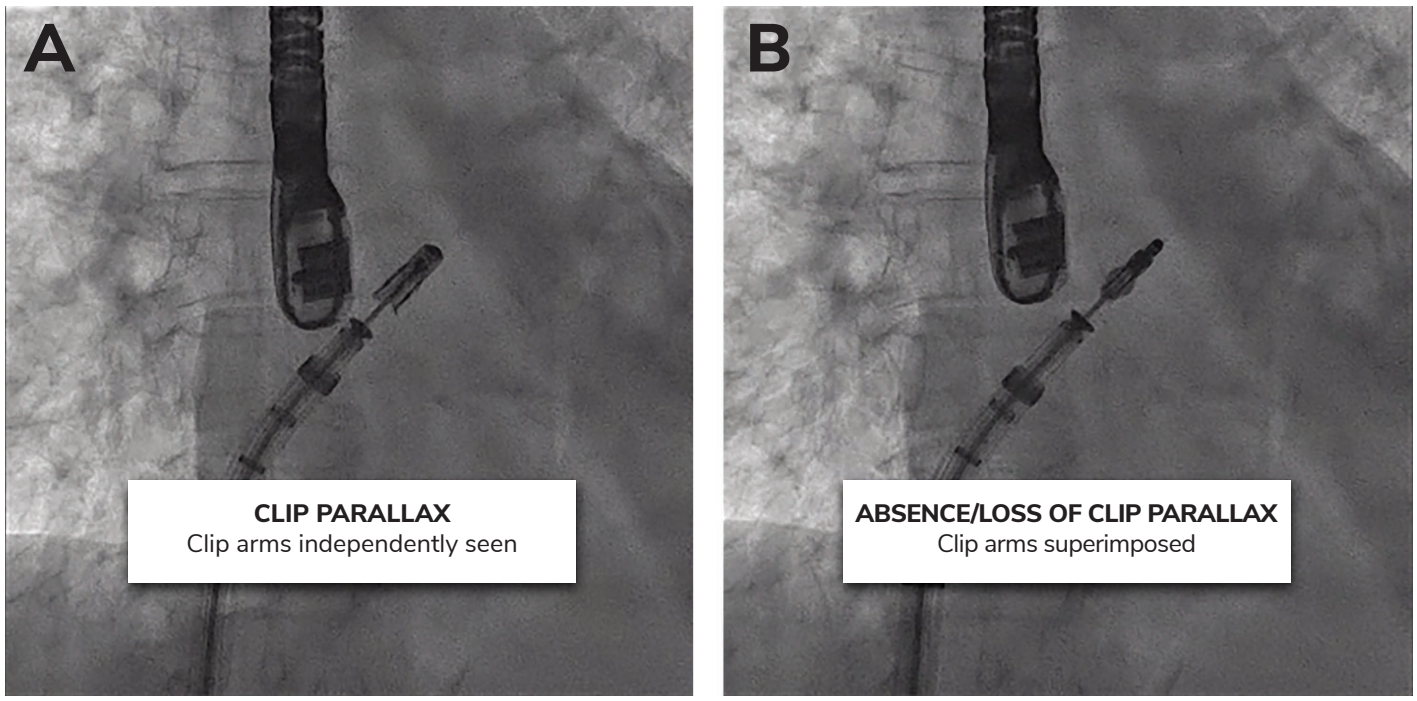

Figure 1. Removal of Parallax

(A) Fluoroscopy in AP projection with parallax (both arms are seen). (B) Rotation of handle removes parallax. (Reproduced with permission from Singh G, Rogers JH, et al.[1])

2. Perform the 2D mid esophageal bicomm view, with apex positioned at 6 o'clock and an orthogonal LVOT view by X-plane, 3D, and 3D color TEE to confirm the clip is perpendicular (orthogonal) to the valve plane and centered over the regurgitant jet at the desired grasping location. (Figure 2).

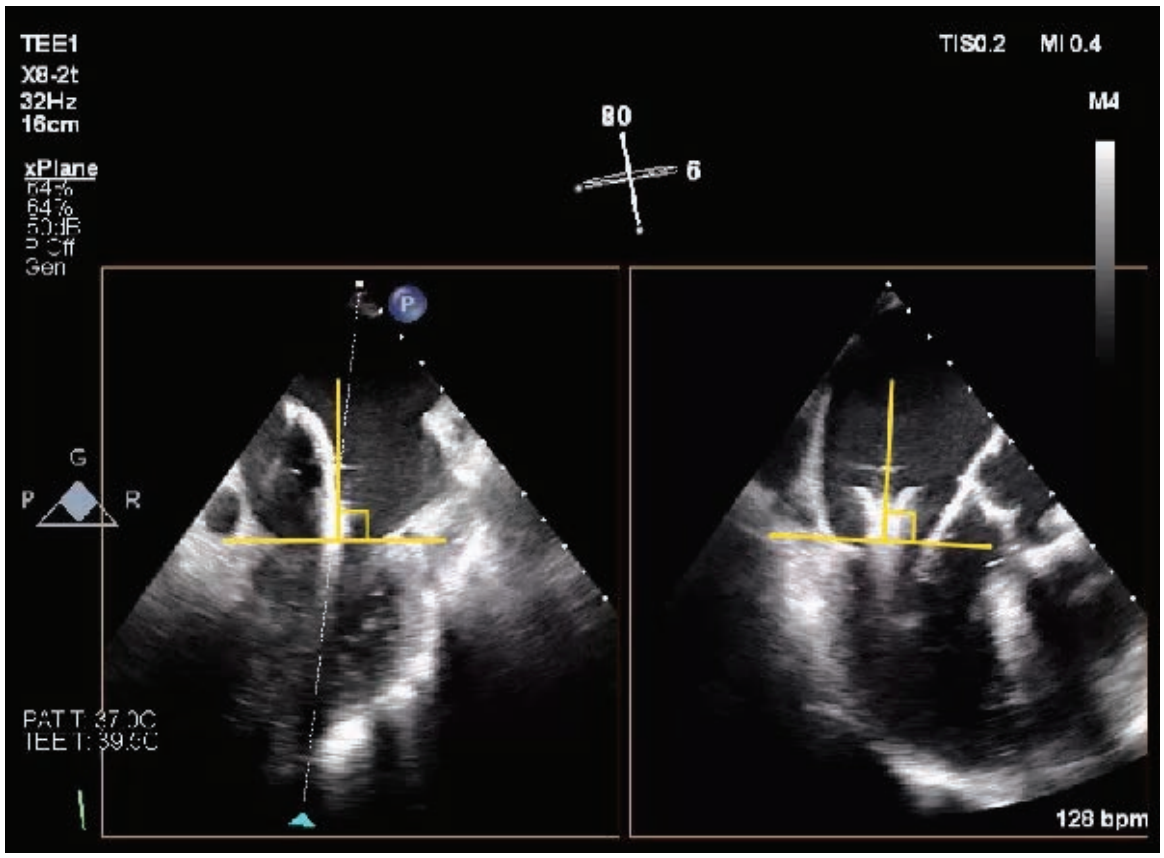

Figure 2. Steering and Orientation with MitraClip in the LA Using 2D TEE

In the bicomm X-plane to LVOT grasping view, the MitraClip CDS in the LA should be perpendicular to the annular plane bicomm view and perpendicular to the grasp plane in the LVOT view.

3. It is important to assess for excess medial deflection of the CDS which can create a medial dive into the LV. Similarly, lack of sufficient medial deflection may result in a lateral dive. By gently advancing and retracting the DC handle the presence of a medial or lateral dive can also be assessed by fluoroscopy and TEE. It is also important to optimize the anterior-posterior trajectory (Figures 3 and 4). This concept is discussed in detail in Chapter 10. Left Atrial Steering, Clip Positioning, and Trajectory.

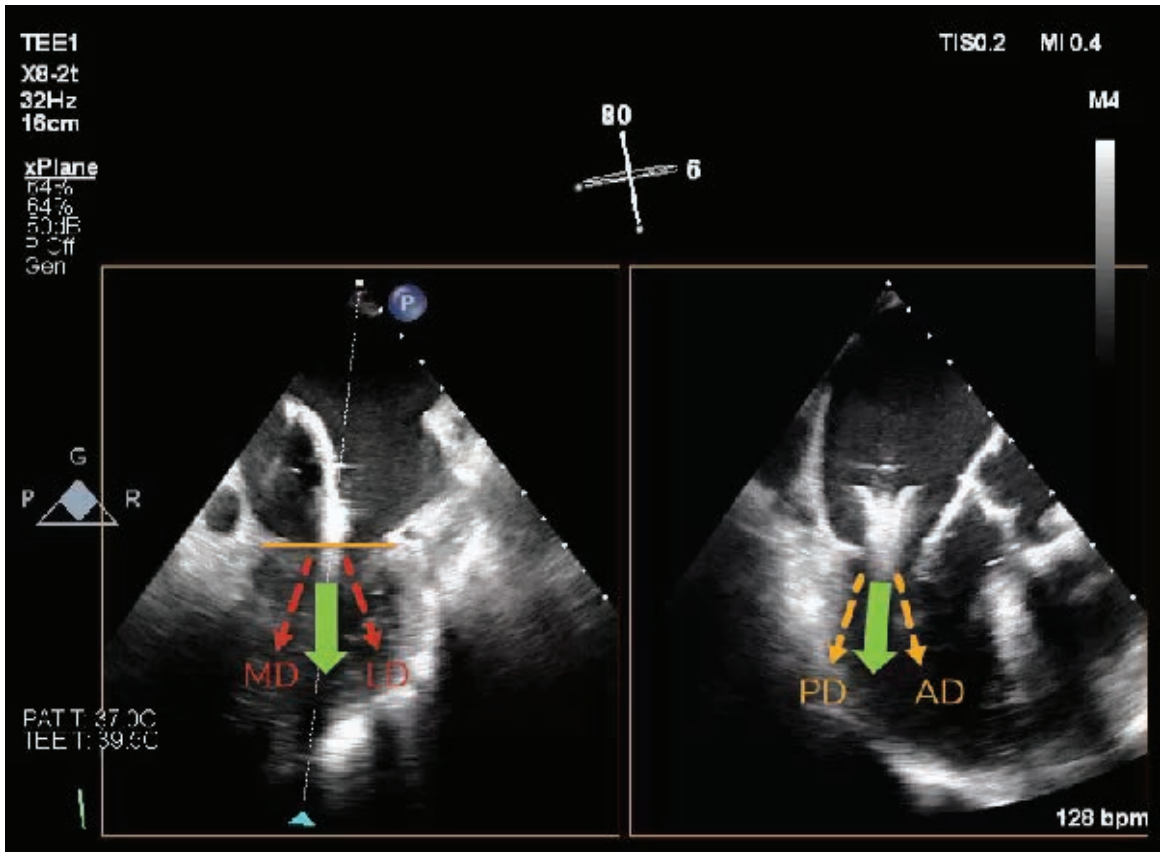

Figure 3 (video). Preparing MitraClip Entry from LA to LV on 2D TEE

The CDS entry from LA to LV should be straight (solid green arrow) on both bicomm and LVOT X-plane view. Adjustments of the CDS and SGC may be necessary to avoid medial or lateral dive (red arrows) on the bicomm view and posterior or anterior dive (yellow arrows) on the LVOT view.

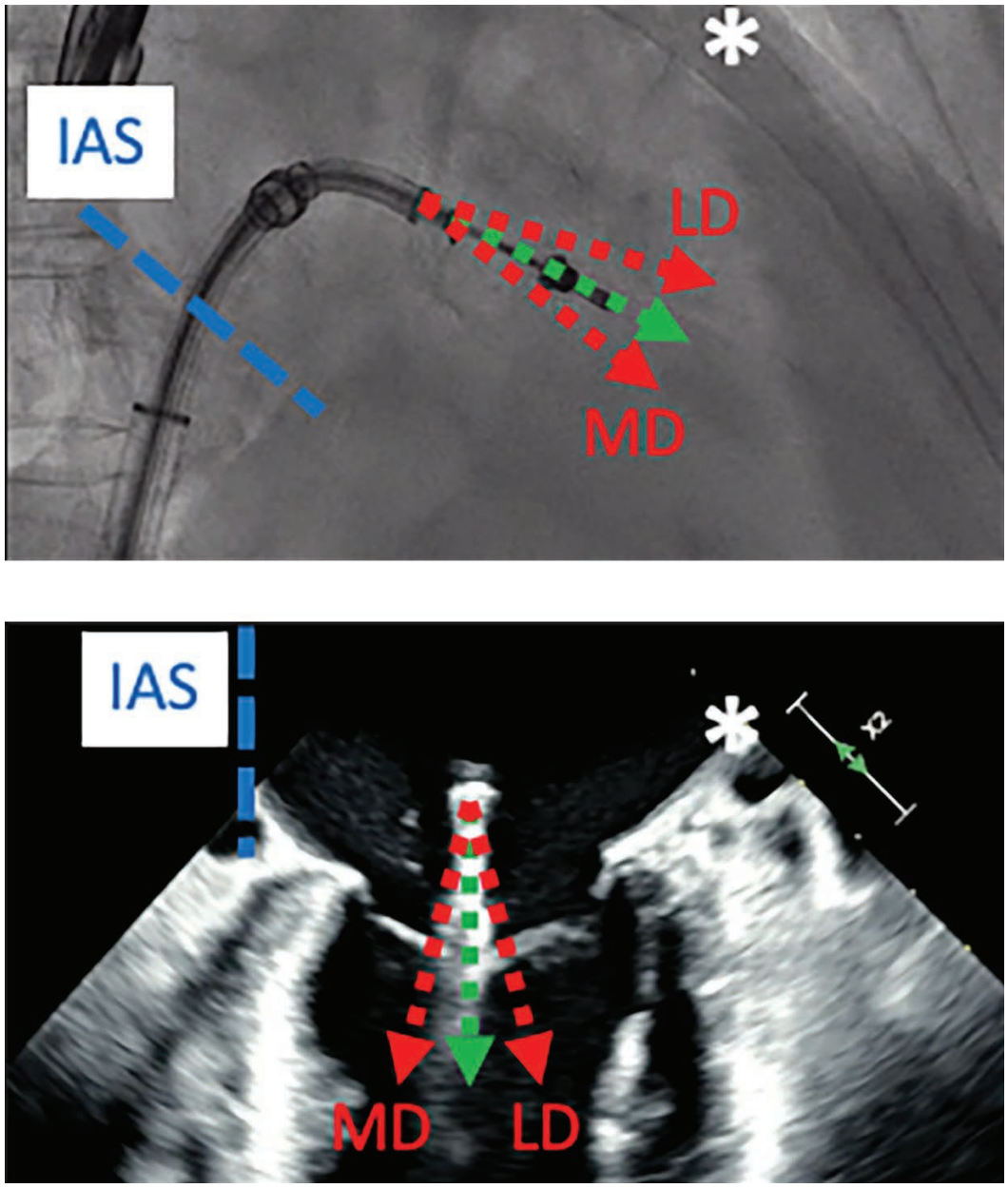

Figure 4. Assessing for Medial and Lateral Dive

(Top panel) Fluoroscopic representation of a medial dive (MD) or a lateral dive (LD), which can be corrected by either increasing or decreasing M knob rotation. (Lower panel) Correlative TEE bicomm view demonstrating medial and lateral dives. Green arrow, optimal trajectory. IAS, interatrial septum. (Reproduced with permission from Singh G, Rogers JH, et al.[1])

4. Once the optimal trajectory is established, clip alignment is established using 3D TEE. The clip arms should be rotated so that they are orthogonal to the plane of coaptation between the anterior and posterior mitral leaflets. Patience is required since there may be "lag" between rotation of the DC handle and actual clip rotation. Ensure appropriate height above the valve to prevent inadvertently entering the ventricle during these maneuvers. It is important to recognize that rotation of the DC handle to align the clip may result in a "radius of deviation." Clockwise rotation of the DC handle results in posterior and medial deviation of the clip. Counterclockwise rotation results in an anterior and lateral deviation (Figures 5 and 6). This concept is important since alignment of the clip may require re-verifying CDS alignment as described in Steps 2 and 3 above.

   Assessment of controlled gripper actuation (CGA) can also be evaluated at this point by performing the "gripper wave" in the LVOT view to identify the gripper arm associated with the tactile marker on the CDS handle. This is performed by unlatching the grippers and gently pressing down on the individual gripper lever with the tactile marker. This will identify the leaflet associated with the tactile marker, anterior or posterior. This maneuver can be repeated with the other gripper to verify proper actuation of both gripper arms. Once completed, raise both grippers and make sure the latch is engaged to enable simultaneous grasping.

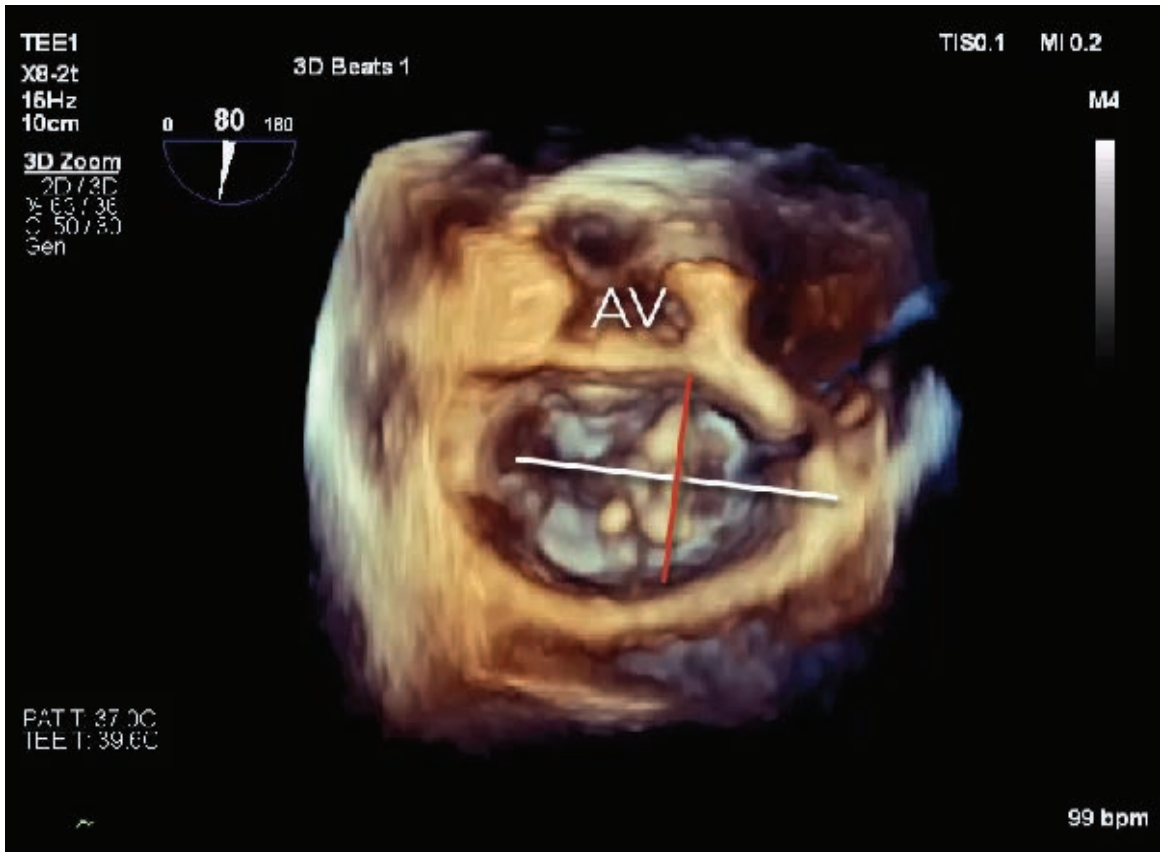

Figure 5 (video). Optimizing MitraClip Alignment in the LA Using 3D TEE

Using 3D en face view of the mitral valve on TEE, the MitraClip (red line) should be oriented perpendicular to the line of coaptation (white line) of the anterior and posterior leaflets at the target grasping area.

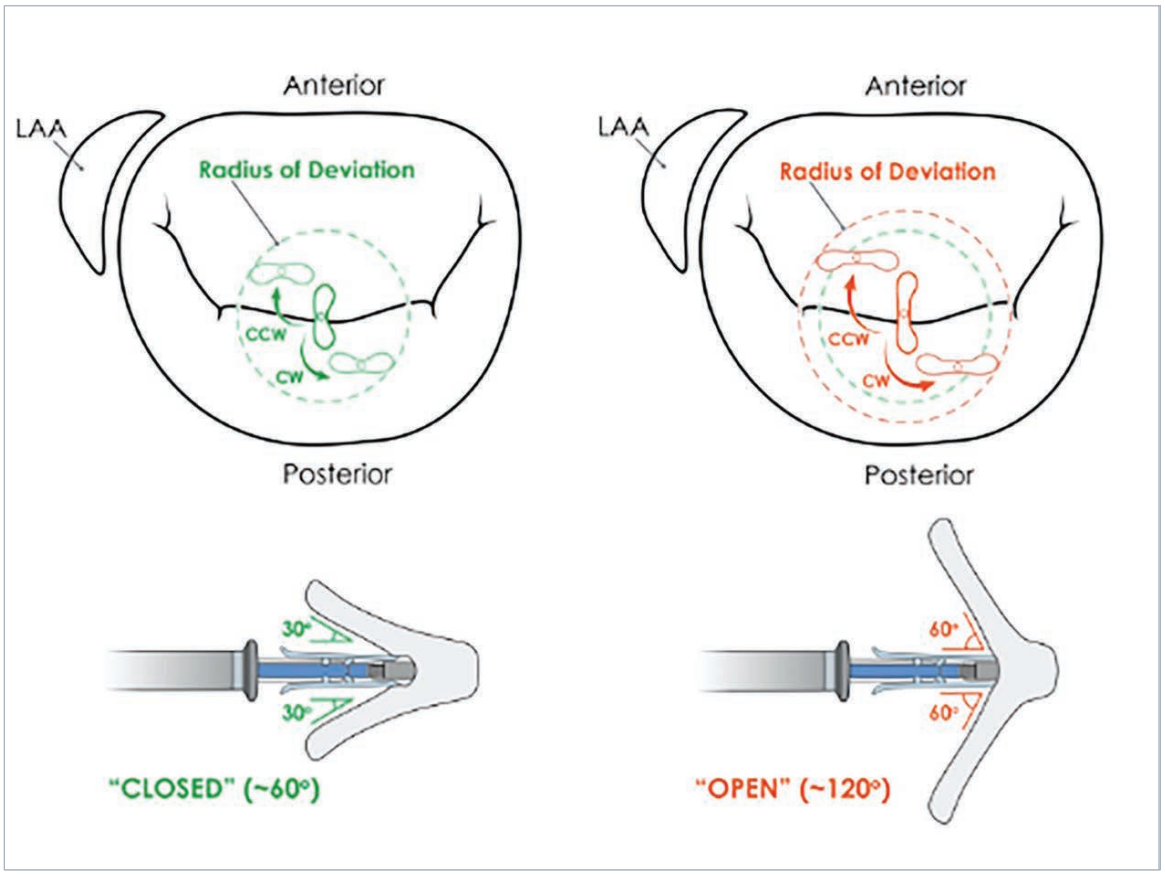

Figure 6. Radius of Deviation with Supravalvular Clip Rotation

Rotation of the DC handle to achieve optimal clip alignment may result in deviation of the clip shaft which may require subsequent realignment. Clockwise (CW) rotation of the DC handle results in posterior and medial deviation. Counterclockwise (CCW) rotation of the DC handle results in anterior and lateral deviation. Note that radius of deviation is less with the clip partially closed at 60° versus opened at 120°. (Reproduced with permission from Singh G, Rogers JH, et al.[1])

5. Once the clip is oriented to the coaptation plane and the operator is ready to enter the LV, the fluoroscopic angle should be adjusted to remove any parallax from the clip. This establishes the proper baseline fluoroscopic appearance of the clip which should be maintained while advancing the clip into the LV. Usually a slight RAO with either cranial or caudal is used to remove the parallax (Figure 7). On TEE, the 2 clip arms should be visible on the grasping view while superimposed with each other on the bicomm view.

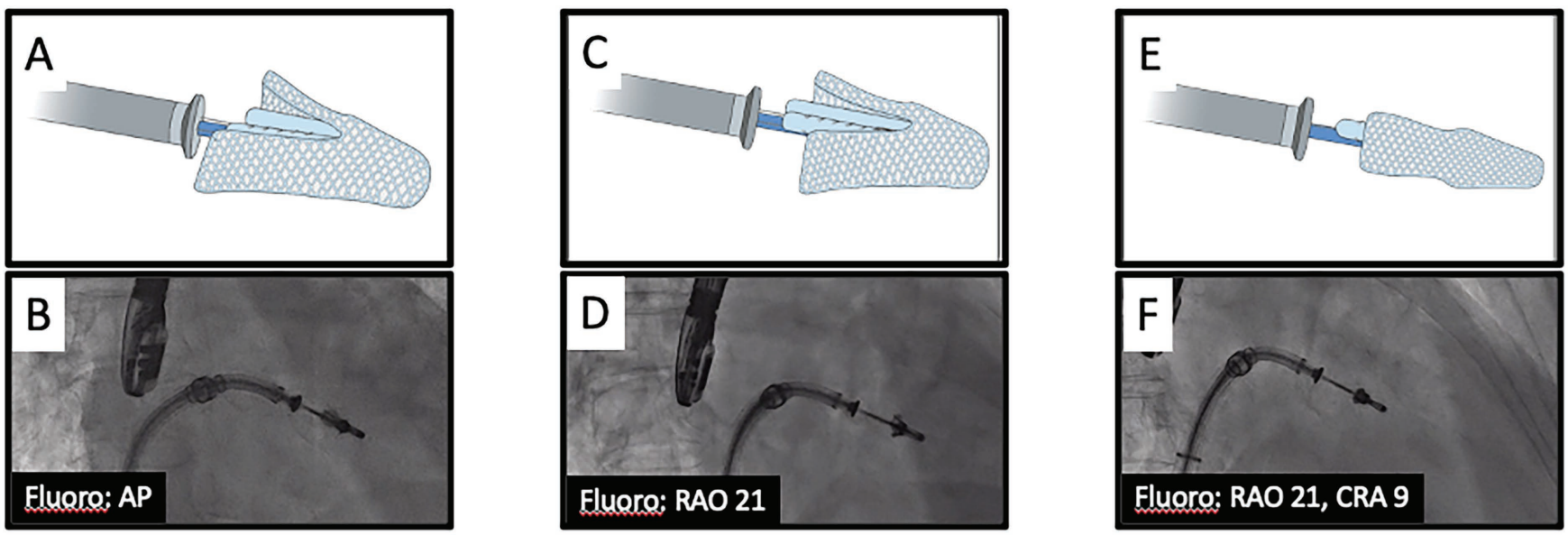

Figure 7. Removal of Parallax Prior to Entering LV

Once the trajectory and supravalvular alignment have been optimized, the fluoroscopic angle (NOT the clip position) is changed to eliminate parallax. (A, B) Baseline clip appearance in AP projection. (C, D) Addition of RAO brings the top of the clip arms into the same plane. (E, F) Addition of cranial angulation perfectly superimposes the clip arms, removing all parallax. (Reproduced with permission from Singh G, Rogers JH, et al.[1])

6. Advance the clip into the LV with arms closed to 60° and watch carefully on TEE and fluoroscopy to ensure that there is no medial or lateral dive, and that clip arms remain superimposed on fluoroscopy to ensure that the clip does not rotate out of alignment. Confirm there is no parallax on TEE as well. No clip arms should be seen in the bicomm view and equal clip arm length seen in the long axis view. (Figures 8 and 9).

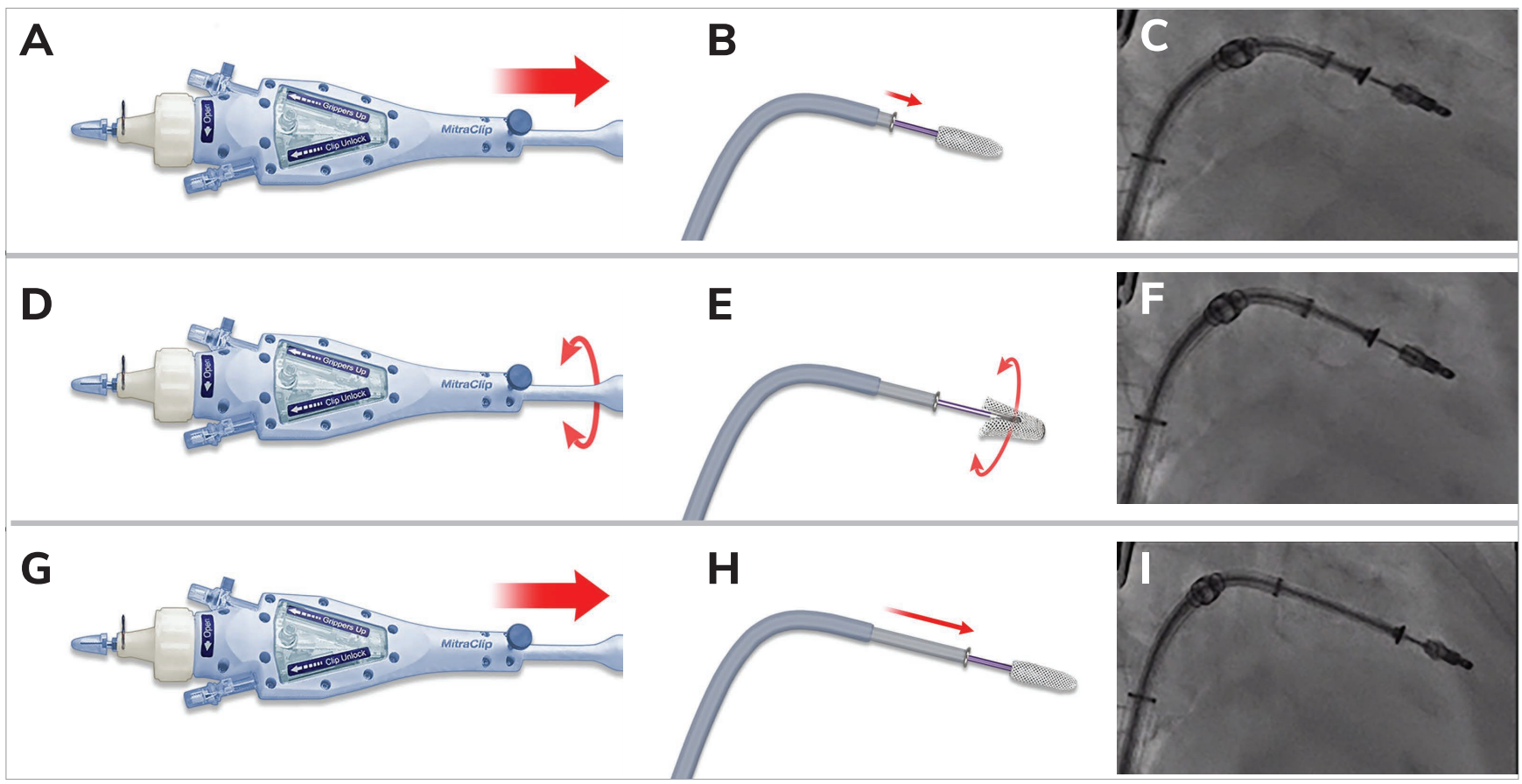

Figure 8. Advancing Clip into LV While Maintaining Fluoroscopic Parallax

(A, B, C) With the clip closed to 60°, the DC handle is advanced forward and the clip begins to enter the LV. (D, E, F) During advancement, the clip may rotate out of alignment and small clockwise or counterclockwise rotations are made with the DC handle to maintain superimposed clip arms without parallax. (G ,H, I) Continue to advance clip until beneath the leaflets. (Reproduced with permission from Singh G, Rogers JH, et al.[1])

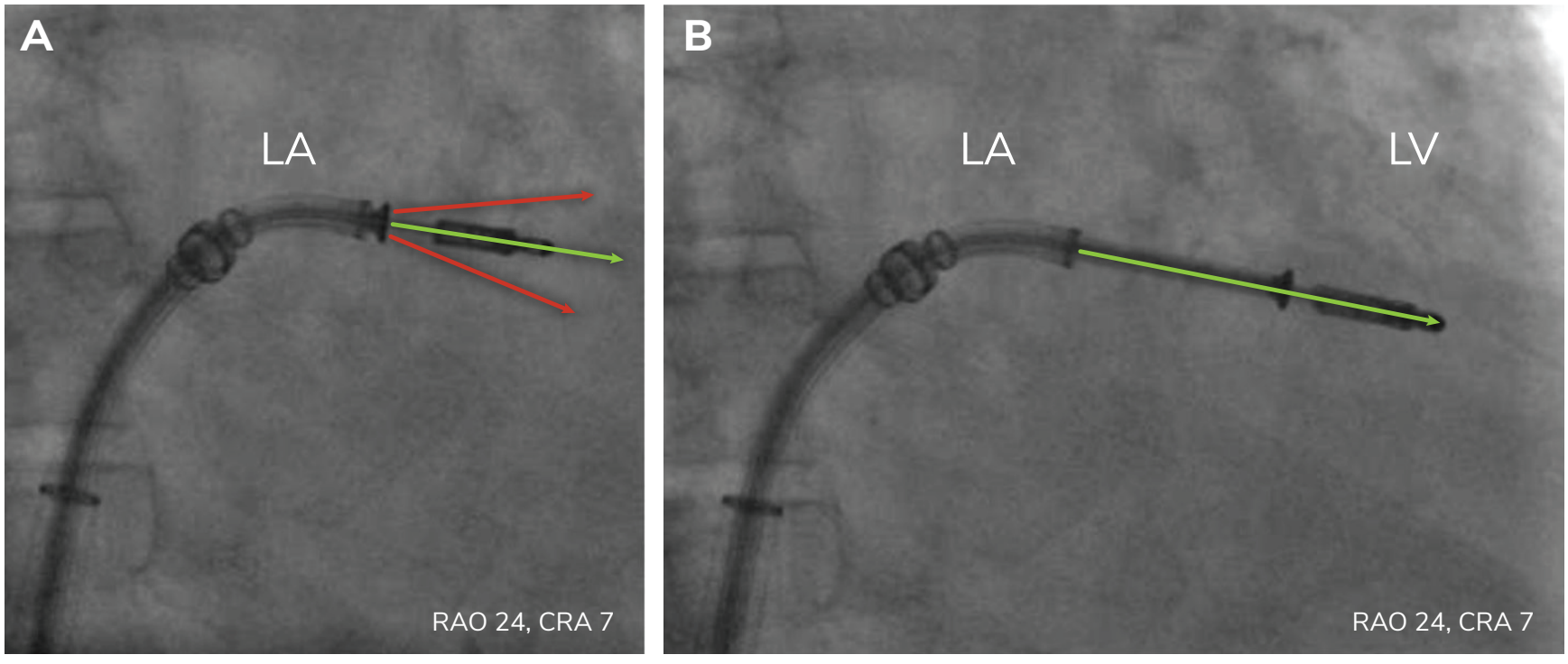

Figure 9. Maintaining MitraClip Trajectory on Fluoroscopy While Crossing Valve from LA to LV

(A) When advancing the MitraClip from LA to the LV, avoid a lateral or medial dive (red arrows). (B) Instead, maintain a straight trajectory (green arrow) under both fluoroscopy and TEE. Also note that clip arms remain superimposed at fluoroscopic angle RAO 24, cranial 7.

7. When entering the LV, the clip may be closed completely if targeting treatment near commissures or if there is a large flail to avoid getting the leaflet caught against the gripper. Using fluoroscopy, check to make sure the clip has not rotated during advancement into the LV. One may need to rotate the DC handle catheter opposite the direction previously rotated (eg, if clockwise before to orient clip, may need to go counterclockwise to avoid clip rotation as it enters LV). Also check to make sure the clip trajectory remains straight and is not diving medial (too much M) or lateral (not enough M) on both fluoro and 2D TEE, as shown in Figure 9.

8. Once in the LV, open the clip arm to 120-150°. Reassess alignment of the clip using 2D and 3D TEE and fluoroscopy before preparing for grasping. The clip appearance on 2D TEE should be maintained (Figure 10). Readjust the fluoroscopic angle again if needed prior to grasping to remove parallax.

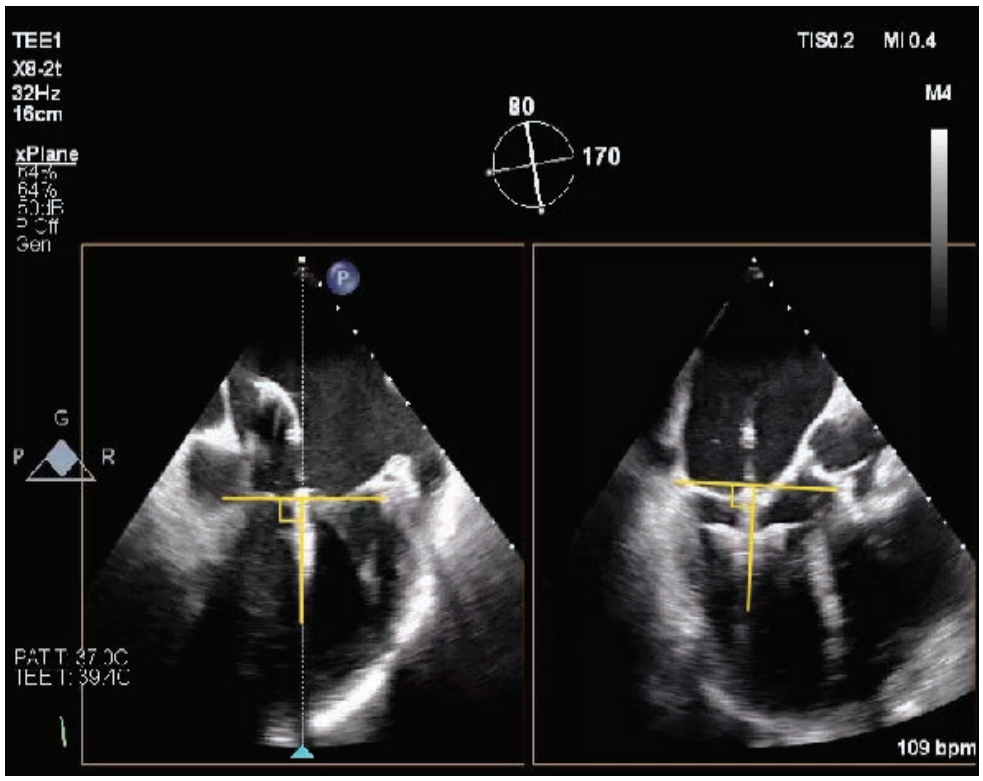

Figure 10 (video). Maintaining MitraClip Orientation in LV on 2D TEE

On the bicomm view, the MitraClip CDS should be perpendicular to the mitral annular plane. When X-plane to LVOT grasping view, the CDS should also typically be perpendicular to the anterior-posterior annular plane.

9. When retracting the DC handle to perform leaflet grasping, maintain the clip orientation on fluoro without parallax (Figure 11) and on 2D TEE (Figure 12). The clip may again want to rotate slightly when retracting the clip to grasp the leaflets. Use small rotational corrections with the DC handle to maintain the fluoroscopic appearance.

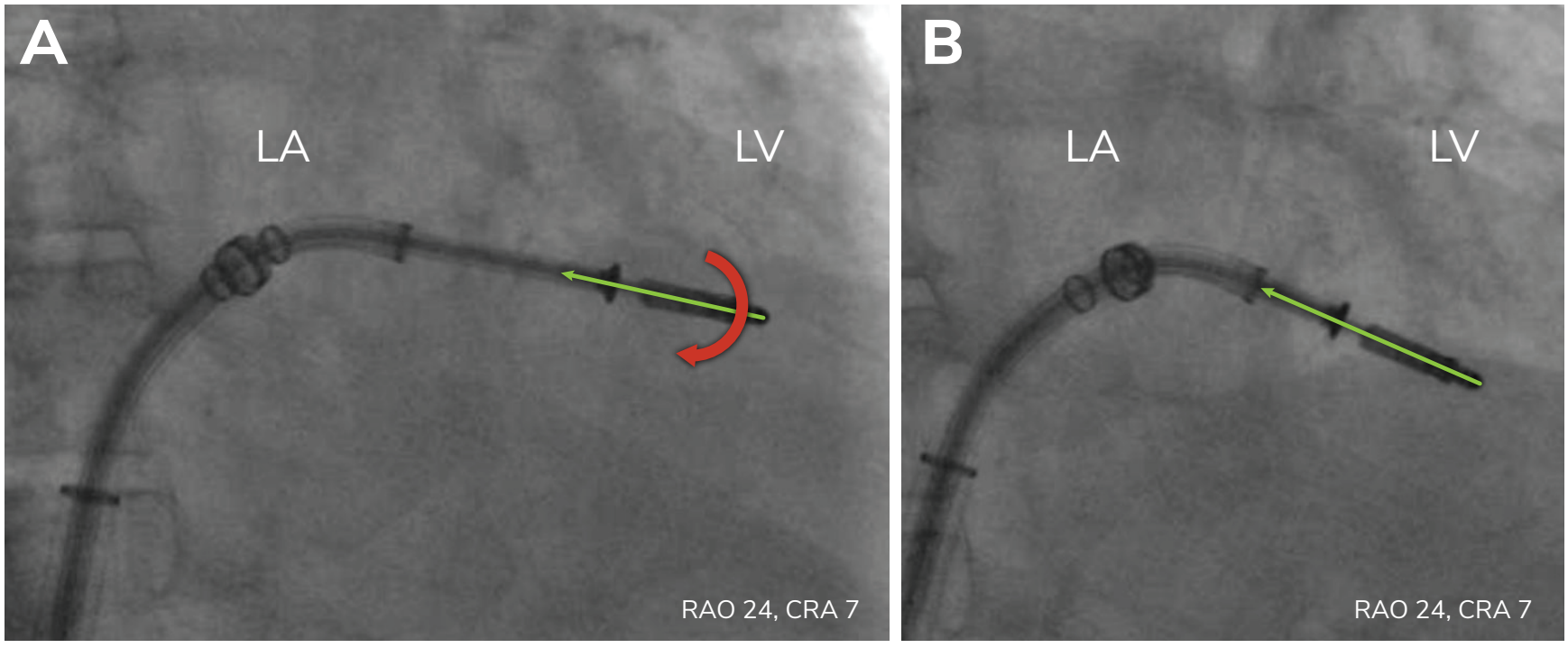

Figure 11. Maintaining MitraClip Orientation During Leaflet Grasping on Fluoroscopy

(A) When pulling back (green arrow) the MitraClip toward the leaflets to begin grasping, ensure on fluoroscopy that the absence of parallax is maintained on the clip. Any rotation (red curved arrow) on the clip during grasping, even if minute, can be seen on fluoroscopy with the emergence of parallax on the clip itself. (B) The goal is to perform the grasp (green arrow) while maintaining optimal clip orientation.

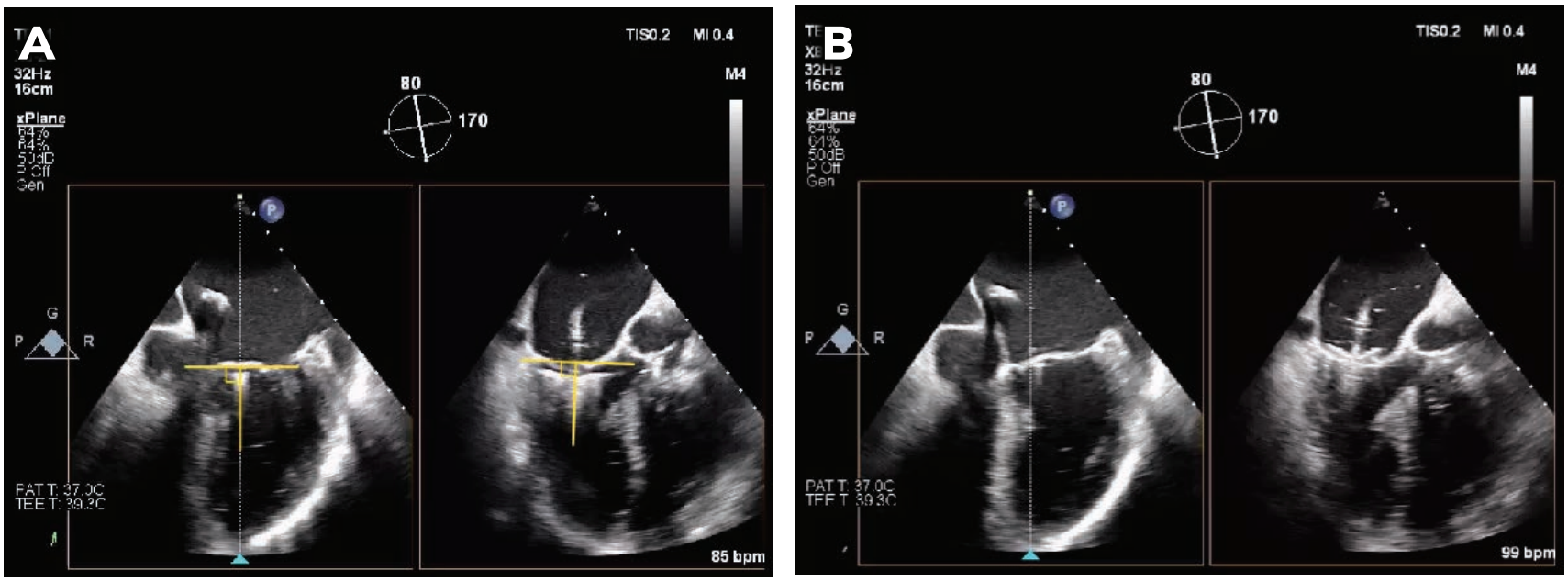

Figure 12 (video). Optimal MitraClip Orientation During Leaflet Grasping on 2D TEE

(A) During leaflet grasping on 2D TEE in conjunction with fluoroscopy, the clip CDS should be perpendicular to the mitral annular plane in the bicomm view and similar to the anterior-posterior annular plane in the X-plane LVOT view. (B) This optimizes clip alignment just as the gripper arms are lowered onto the leaflets.

10. After grasping the leaflets, close the clip arms to 60° and check alignment on 3D TEE a final time. Lock the clip before completely closing the clip arms.

Potential complications

Potential complications and challenges during this step include rotation of the clip and misorientation leading to side-biting or pinwheeling of the leaflets during grasping. Use only gentle and minor rotations of the clip in the LV to re-establish proper orientation in the 2D and 3D TEE and fluoroscopic views. Otherwise, the clip should be inverted and retracted into the LA to reorient the clip before readvancing back into the LV. There is also a chance for the gripper arms to be entangled to the leaflets. Freeing the chord from leaflet entanglement is discussed in Chapter 15. Complications: Single Leaflet Device Attachment, Chordal Entanglement, and Embolization. Gentle manipulation of the CDS, DC handle, or SGC can be attempted, along with gentle clip advancement into the LV to free the leaflet from the gripper. Cycling the grippers up and down can also help.

PROCEDURAL PEARLS

- Do all the clip maneuvers to optimize trajectory, clip alignment, and target grasping location in the LA, not in the LV.
- Watch for appropriate CDS “M knob” deflection to avoid a medial or lateral dive of the clip when entering the ventricle.
- Change the fluoroscopic angle to eliminate parallax before entering LV.
- Check trajectory and alignment and adjust as while entering ventricle as required.
- Watch for rotation of the clip arms while entering LV; use fluoroscopy and make small adjustments to maintain parallax.
- Close the clip while entering LV if a large flail segment or commissural jet is present.
- Constantly maintain optimal clip arm orientation when entering LV and while grasping on both fluoro and TEE since a slight rotation on fluoro may not be seen on TEE. Use fluoro as a reference to prevent inadvertent clip rotation.

Summary

Optimal orientation of the CDS in the left atrium is key before entering the left ventricle to minimize maneuvering of the CDS in the LV. This can be achieved by following a meticulous step-by-step technique using a checklist in conjunction with different imaging techniques such as 2D TEE, 3D TEE, and fluoroscopy.

References

1. Singh GD, Rogers JH, Chen S, et al. Adjunctive use of fluoroscopy during MitraClip implantation reduces procedural complexity: the parallax technique. *Catheterization Cardiovasc Interv.* 2021;97(4):745-54. DOI: 10.1002/ccd.29323. PMID: 33045138.

CHAPTER 12
Leaflet Grasping and Additional Clips

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Overview

Leaflet grasping is a critical step of edge-to-edge leaflet repair before clip deployment. In this chapter we explain how successful execution depends on several preceding steps including ensuring appropriate clip/CDS trajectory, clip orientation, and optimal imaging. The key to a successful grasp is preparation prior to entering the ventricle and ensuring the target grasp location is clear. Once the clip is in the ventricle and a grasp has been attempted, it is crucial to evaluate the quality of the grasp as well to understand failed grasp attempts and how to correct. Finally, we discuss when to invert the clip and return to the left atrium to optimize positioning prior to re-attempting a grasp. Once a grasp has been made, it is important to evaluate the adequacy of leaflet insertion as well as the impact on MR severity. The operator can then decide whether additional clips are required and if the first clip is adequately positioned prior to the placement of the second clip.

Successful leaflet grasping depends on the following:

- Appropriate clip selection
- Appropriate clip/CDS trajectory (see Chapter 10)
- Appropriate clip alignment to the target grasping area (see Chapter 11)
- Adequate imaging of the valve leaflets during the grasp
- Adequate leaflet insertion

Once a grasp is made, evaluate MR reduction. Reposition the clip if necessary and decide whether additional clips are required and at what location.

Procedural considerations

A successful grasp is the culmination of multiple previous steps. In preparation for leaflet grasping, it is crucial to appropriately evaluate the leaflet anatomy, make your clip selection (see Chapter 4, A User's Guide to the MitraClip Device), and choose the target location for your clip.

Prior to leaflet grasping and entering the ventricle, consider the questions in the leaflet grasping preparation checklist in Box 1. If more than one clip is likely to be required, it is often simpler to place the more medial clip first to avoid interaction with the first clip when steering down to the valve.

BOX 1. LEAFLET GRASPING PREPARATION CHECKLIST

- ✓ What is the target location for the first clip?
- ✓ How many clips may be required?
- ✓ What is the valve orifice area?
- ✓ What is the posterior leaflet length at the target grasping location?
- ✓ How much leaflet insertion is required for a secure grasp with the chosen clip?
  - NT/NTW 6 mm leaflet insertion (minimum)
  - XT/XTW 9 mm leaflet insertion (minimum)
- ✓ Is the clip orientation perpendicular to the line of coaptation at the target grasping location? (see Chapter 11, Clip Alignment and Entering the LV)
- ✓ Is the clip trajectory and orientation appropriate for leaflet grasping at the chosen location?

Clip alignment is important for ensuring a successful grasp without causing distortion of the mitral valve anatomy. The clip should be perpendicular to the line of coaptation at the target location. The next step is to ensure appropriate clip/CDS alignment and orientation, and trajectory should be confirmed prior to entering the ventricle. Further confirmation of clip alignment should be made in the left ventricle just prior to grasping. Minor adjustments to alignment may be made in the ventricle, however the need for significant changes should prompt the operator to invert the clip and return to the left atrium.

Once alignment is confirmed, the shaft of the clip should be positioned in the regurgitant jet on the bicommissural (bicomm) view, and a grasp may be attempted by opening the clip to 120° to simultaneously grasp the leaflets in the LVOT view. Prior to entering the LV, the grippers must be identified to permit use of controller gripper actuation (CGA), discussed in Chapter 13. This is performed by unlatching the grippers and depressing the gripper with the tactile marker. This is performed in the LVOT view to identify if the gripper associated with the tactile marker corresponds to the anterior or posterior leaflet. Once this has been successfully performed, the grippers are raised and relatched together. It is recommended to attempt a simultaneous grasp and optimize as required using CGA. The grasp should be evaluated by TEE to verify adequate leaflet insertion and MR reduction. In the case of partial reduction, consider use of additional clips.

To facilitate entry into the LV, some operators suggest the use of a breath-hold/apnea or a reduction in tidal volumes. This may be considered but it is important to evaluate the impact on clip position while entering the LV. Low tidal volumes or apnea may cause the clip to move more medially as it is inserted into the LV, therefore confirming trajectory of the clip under these conditions is recommended to understand clip movement prior to entering the LV.

Entering LV and alignment

1. Enter the LV as described in Chapter 1 with the clip closed to 60° or more. Inserting the clip while open to more than 60° may result in rotation as it encounters the mitral leaflets. This may be more exaggerated with the XT/XTW clips. In the setting of primary MR with prolapse or flail, insertion of the clip while completely closed may prevent excessive clip rotation.
2. During insertion of the clip into the LV, it is suggested to image in both the LVOT grasping view and bicomm view using X-plane imaging.
   - The LVOT grasping view provides information on the anterior and posterior position of the clip as you advance into the LV.
   - The bicomm view allows you to understand whether the clip trajectory is medial or lateral.
3. To evaluate clip rotation when entering the ventricle, first ensure the clip is properly aligned on 3D TEE with the line of coaptation of the mitral valve from the left atrium. Then, rotate the image intensifier RAO and cranial or caudal and store a fluoroscopic image of the clip with arms overlapped (removal of parallax technique, Chapter 11). Rotation of the clip that occurs upon entering the ventricle can then be easily appreciated on the fluoroscopy image by comparing to the stored image. (See Figure 1A and B)

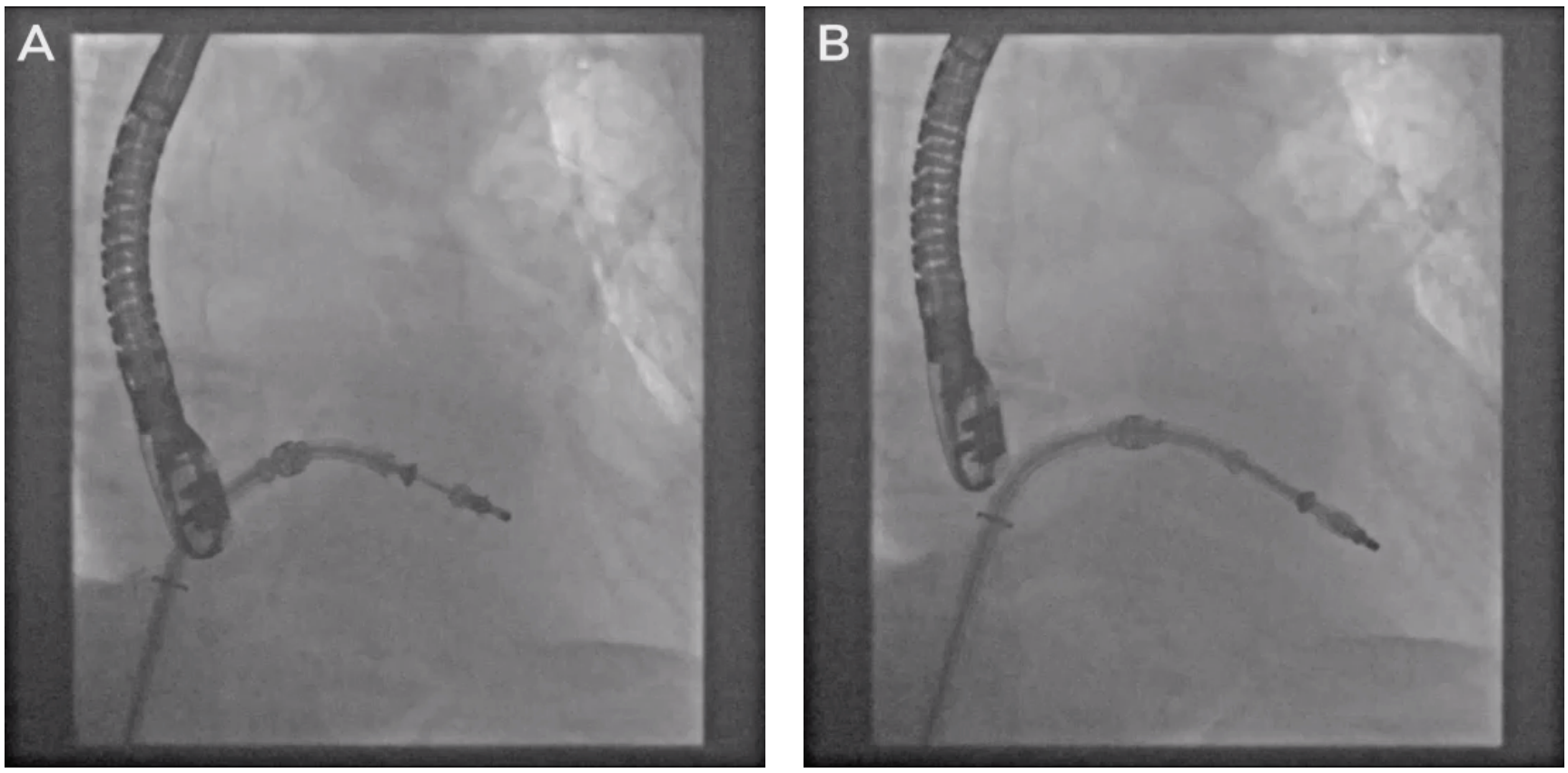


Figure 1 (videos). Clip Orientation on Fluoroscopy

(A) Clip orientation on fluoroscopy in LA, both arms visible with parallax present before correcting fluoroscopic view; (B) After rotating image intensifier, note clip entering LV with correct orientation on fluoroscopy with both arms superimposed (parallax technique).

4. Once inside the LV, reevaluate clip orientation and position of the CDS shaft in relation to the regurgitant jet using the 3D en face view and dropping the gain to visualize the clip arms. Additionally, the clip should be opened to 120° and the arms should be well visualized in the LVOT view and the CDS shaft should be in the jet on the bicomm view. If the orientation and CDS trajectory are appropriate, you may proceed to grasping. (See Figure 2).

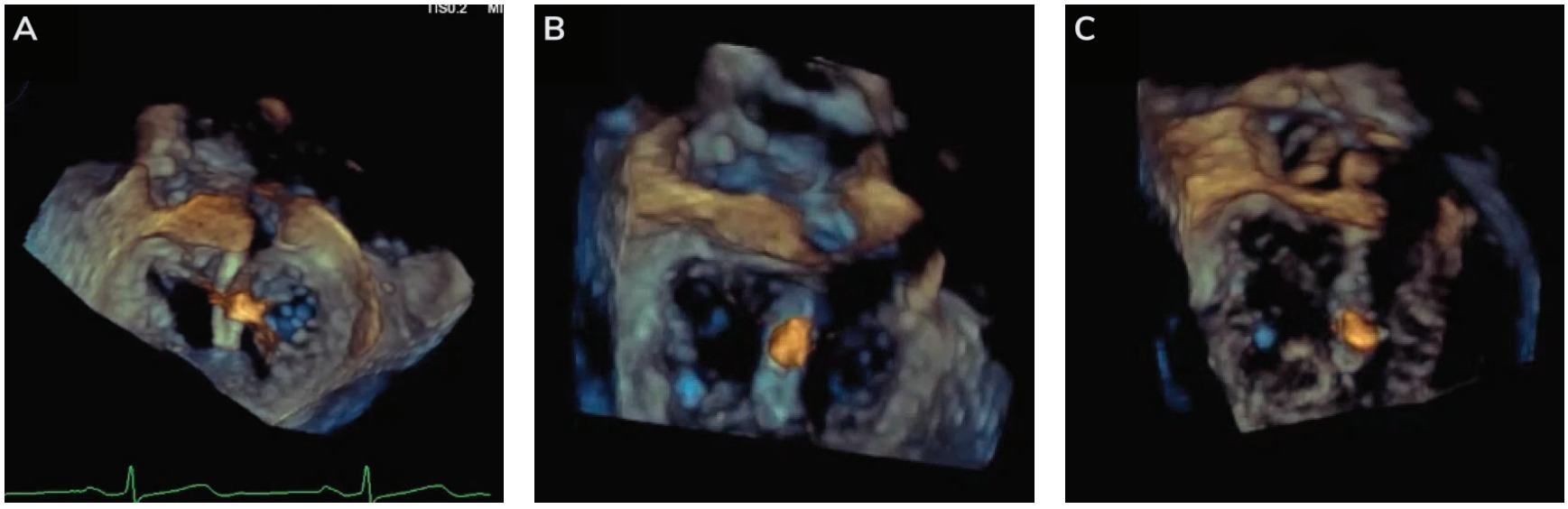


Figure 2 (video). Assessing Clip Alignment

(A) Supravalvular alignment; (B) Subvalvular alignment; (C) After grasp and closure to 60°

Troubleshooting for clip insertion and orientation

If there has been significant clip arm rotation (more than 15°), it may be more prudent to invert the clip and return to the left atrium to make the necessary corrections as shown in Figure 3.

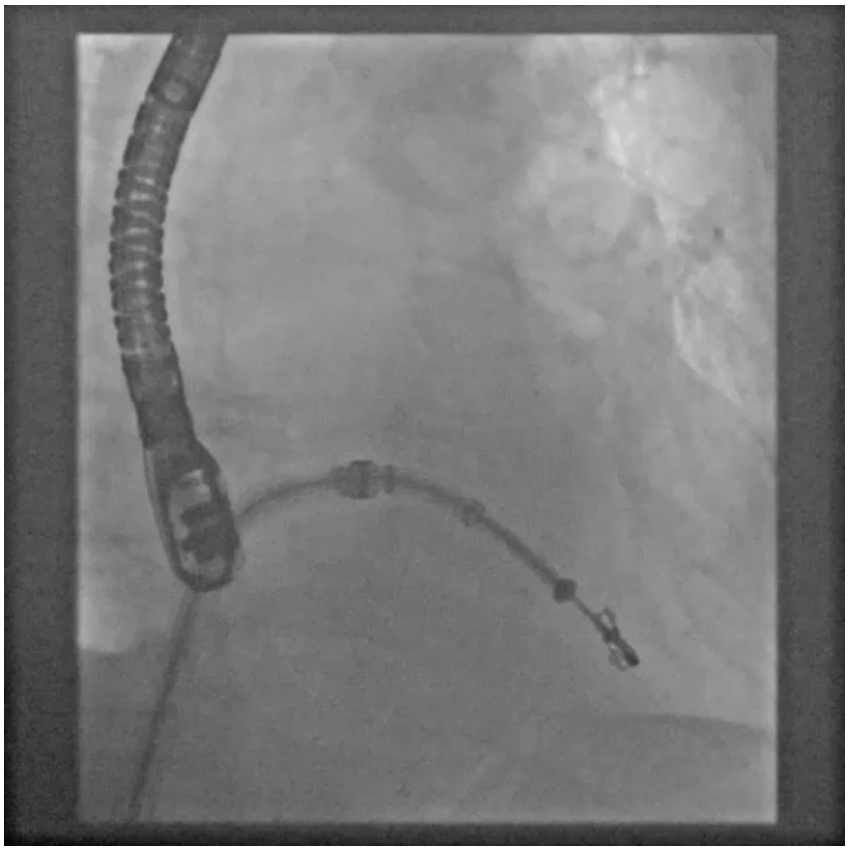


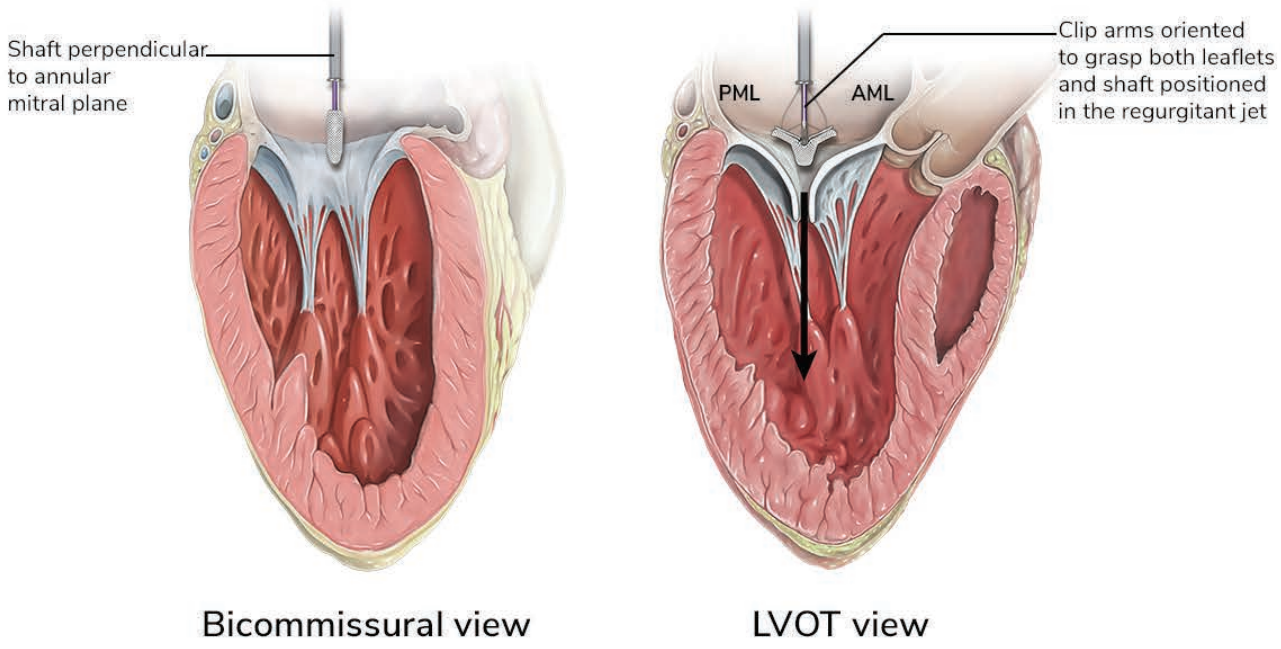
Figure 3 (video). Fluoro of Clip Inverted and Pulled Back into LA

If minor adjustments in clip orientation are required, these may be performed in the ventricle as follows:

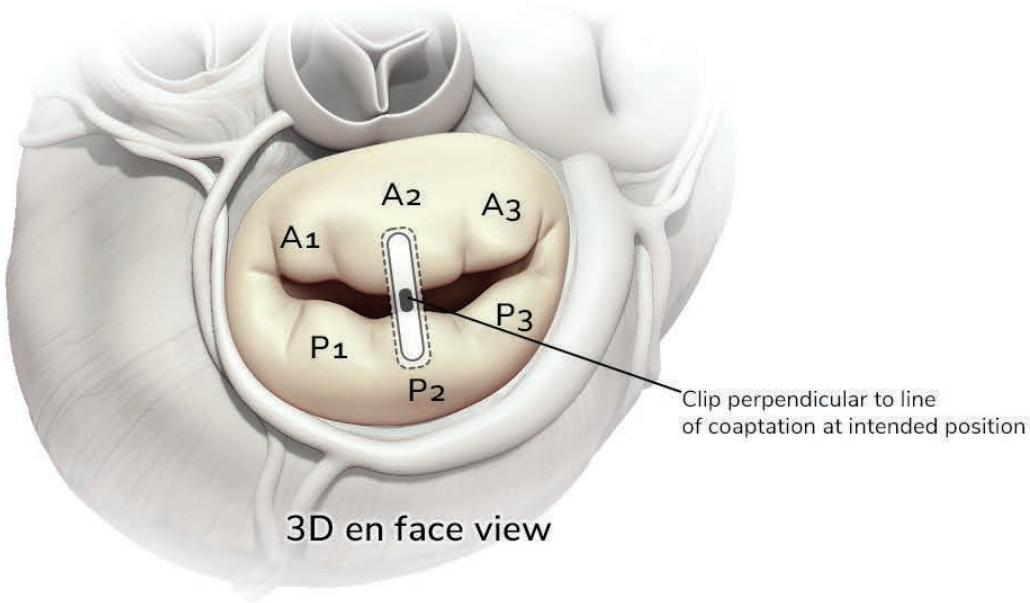
- Ensure you have adequate visualization of the clip in the 3D en face view. Some echo platforms permit additional 2D images of the LVOT and bicomm view simultaneously with the 3D.
- Ensure the clip and grippers are below the level of the leaflets and gently rotate in the desired direction while translating the CDS handle and visualize on echo and fluoro to confirm movement.
- If the clip does not appear to respond to the movements, you may be caught in the chords or have interference from the subvalvular structures. Observe the movement of the clip and guide on fluoroscopy as well. Signs of being stuck include abnormal clip rotation or movement of the guide, or the lack of anticipated guide/device motion despite translated movement of the delivery system. You may also feel resistance. In such cases consider inverting the clip and gently withdrawing back into the left atrium.

If the clip is too medial or lateral, adjustments may be made advancing (move laterally) or retracting (move medially) the stabilizer. This is preferable to adding or removing M in the ventricle. To ensure that there is no chordal interaction when moving the stabilizer, maintain the clip below the leaflets and central on the LVOT view. If there does not appear to be free movement with motion of the stabilizer, consider inverting the clip and returning to the left atrium. Chordal interaction may be difficult to see but may impede movement of the clip in the LV and should be suspected in the case of motion that does not appear to be translated to the clip.

① APPROPRIATE CLIP / CDS TRAJECTORY

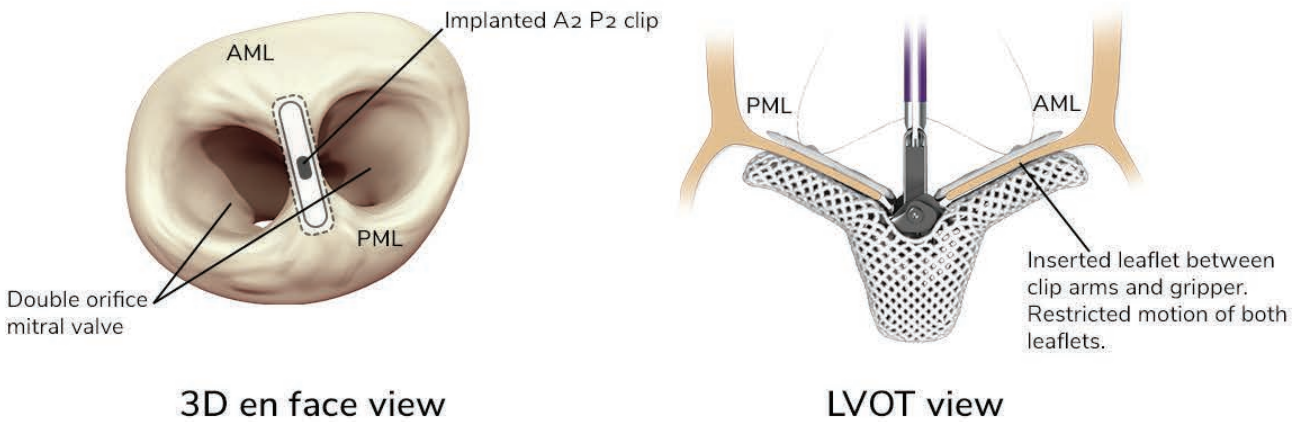


② APPROPRIATE CLIP ORIENTATION



③ ADEQUATE LEAFLET INSERTION

* Simultaneous / Independant leaflet grasp
* Confirm leaflet insertion in multiple views



Central Illustration

Imaging for leaflet grasping

In preparation for grasping, adequate imaging is key to success. Grasping is generally performed in the LVOT view. Prior to grasping ensure you have good visualization of both leaflets as shown in Figure 4. In the case of challenging imaging, consider the following:

- If you are unable to adequately image the full clip arms, recheck clip orientation on 3D en face or transgastric view and return to LVOT.
- Start from a bicomm view and x-plane on the shaft of the CDS to an LVOT view. This is particularly useful in the setting of multiple clips to ensure visualization of the appropriate clip. (Figure 5)
- For placement of a medial clip, consider lowering the TEE probe angle to between 100°-130°.
- For placement of a lateral clip, consider raising the TEE probe angle to between 140°-180°.

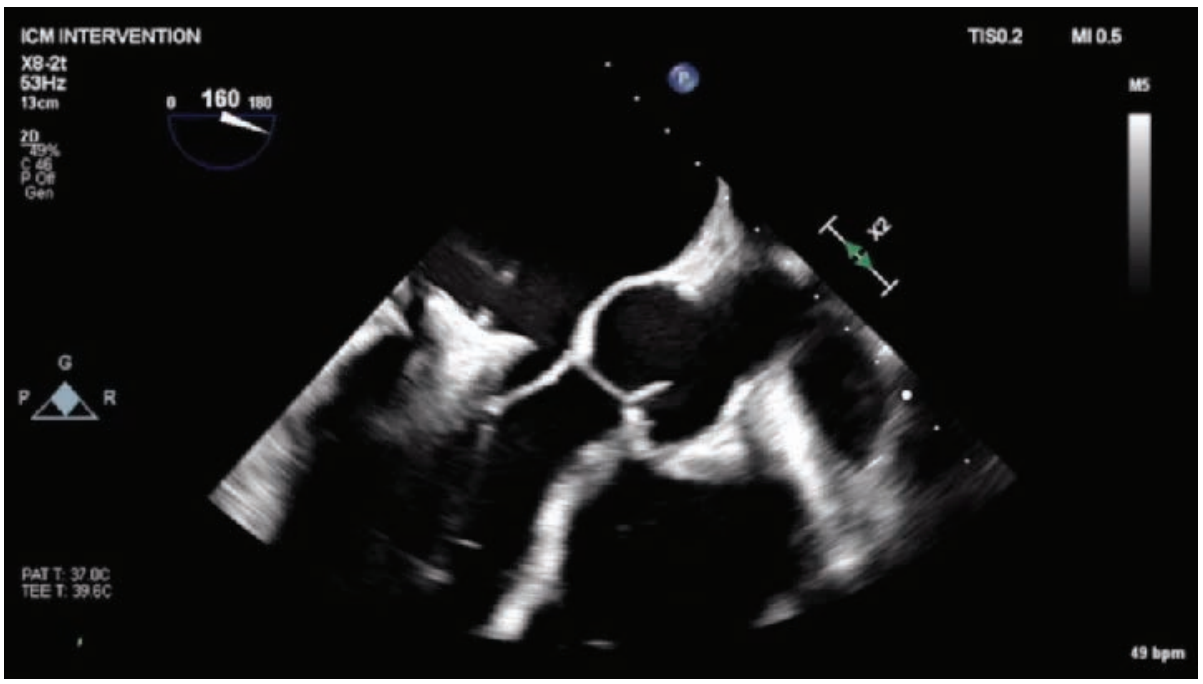


Figure 4 (video). Optimal Grasping View (LVOT)

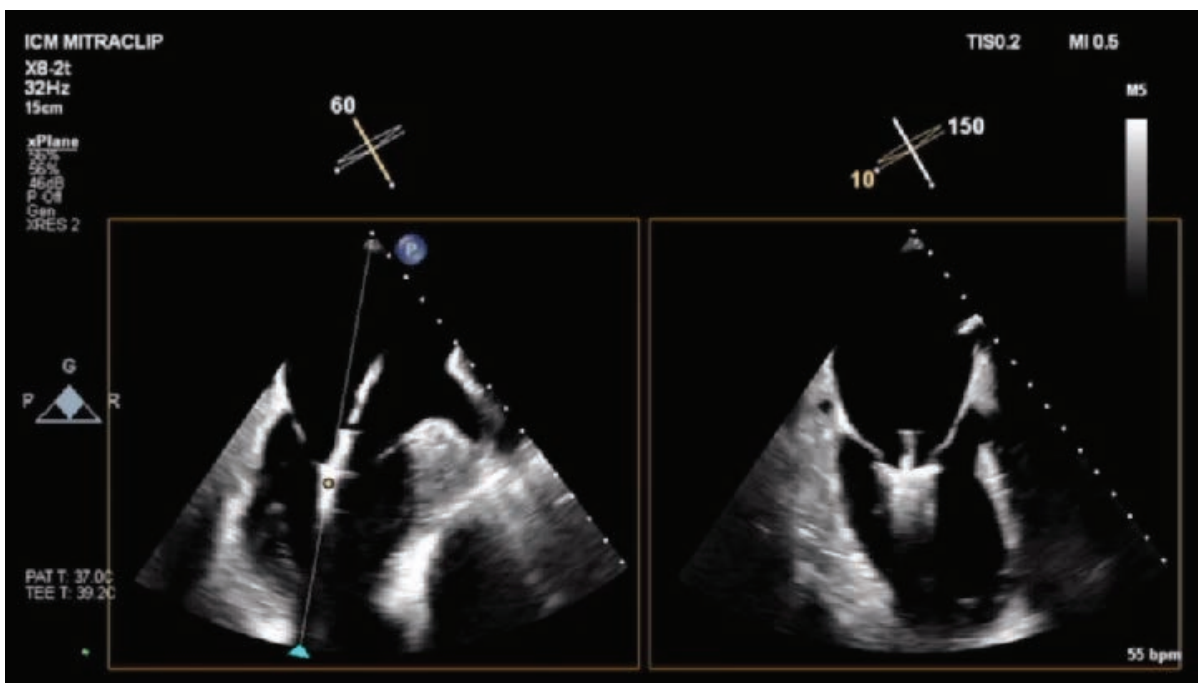


Figure 5 (video). Optimal Grasping View (modified LVOT from bicomm)

Leaflet grasping

1. Simultaneous leaflet grasping is the preferred method despite the availability of controlled gripper actuation. To grasp, slowly retract the CDS handle toward the mitral annulus while visualizing the anterior and posterior leaflets. The leaflets should rest as deep as possible into the "V" of the clip arms prior to dropping the grippers as shown in Figure 6.

- In primary MR with significant prolapse or flail, the clip should be retracted to the mitral annulus and higher to ensure the leaflet is properly captured prior to dropping the grippers.
- In secondary MR with leaflet tethering, the clip is often retracted just to the level of the annulus prior to dropping the grippers.
- In the case of a severely tethered posterior leaflet, you may need to use the CGA function (independent leaflet grasping, Chapter 13) and capture the anterior leaflet first and then gently rotate the guide posterior as the clip is retracted to capture the posterior leaflet. Excessive rotation of the guide may result in distortion of the anatomy of the mitral valve, particularly with the longer arm clips.

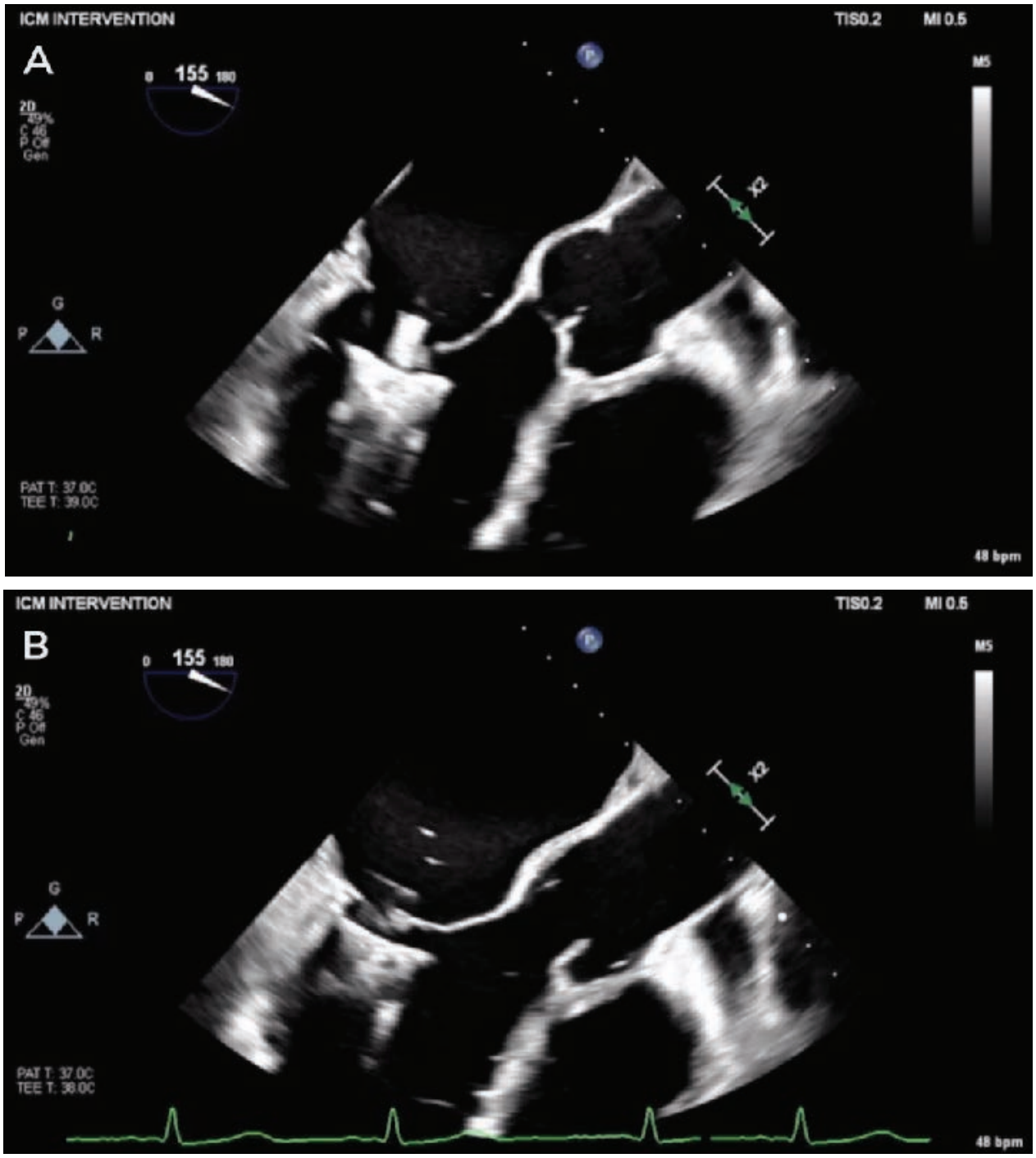


Figure 6 (video). Successful Grasp With Good Leaflet Insertion

2. When performing the grasp, consider using a long TEE acquisition (10-20 seconds) to completely capture the entire grasp sequence which can later be reviewed as needed to confirm both leaflets are inserted (Figure 7). Once the grippers have been dropped, close the clip to 60° and relock. Release the tension as the clip is gently advanced forward into the ventricle.

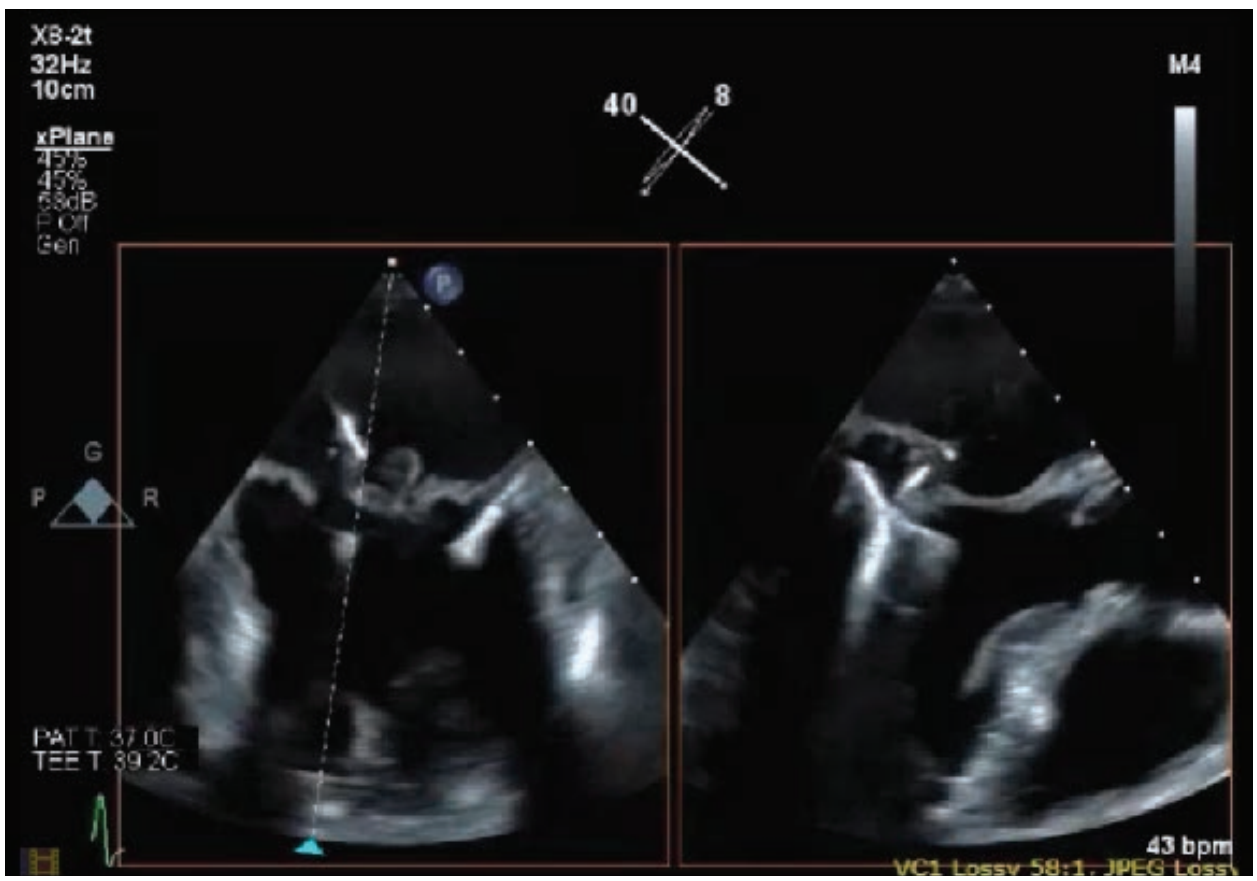


Figure 7 (video). Confirm Adequate Leaflet Insertion

3. Verify leaflet insertion by imaging from the bicomm view and x-plane on the CDS shaft to the LVOT view and sweeping from medial to lateral to validate adequate leaflet insertion as shown in Figure 8. Depending on the clip used, 6-9 mm of leaflet insertion is recommended. If this is not the case, release and reattempt the grasp.

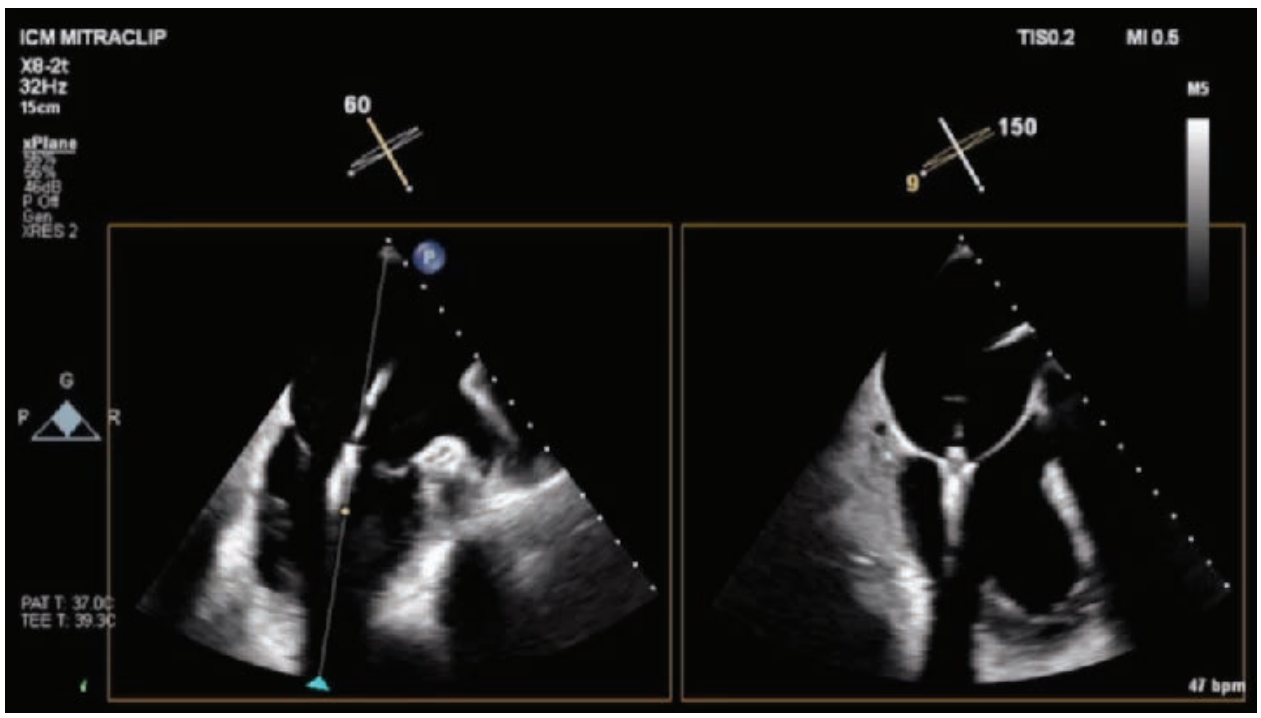


Figure 8 (video). Confirm Adequate Leaflet Insertion

4. Once leaflet insertion is confirmed, close the clip on the bicomm view with color to assess reduction in MR severity as shown in Figure 9.

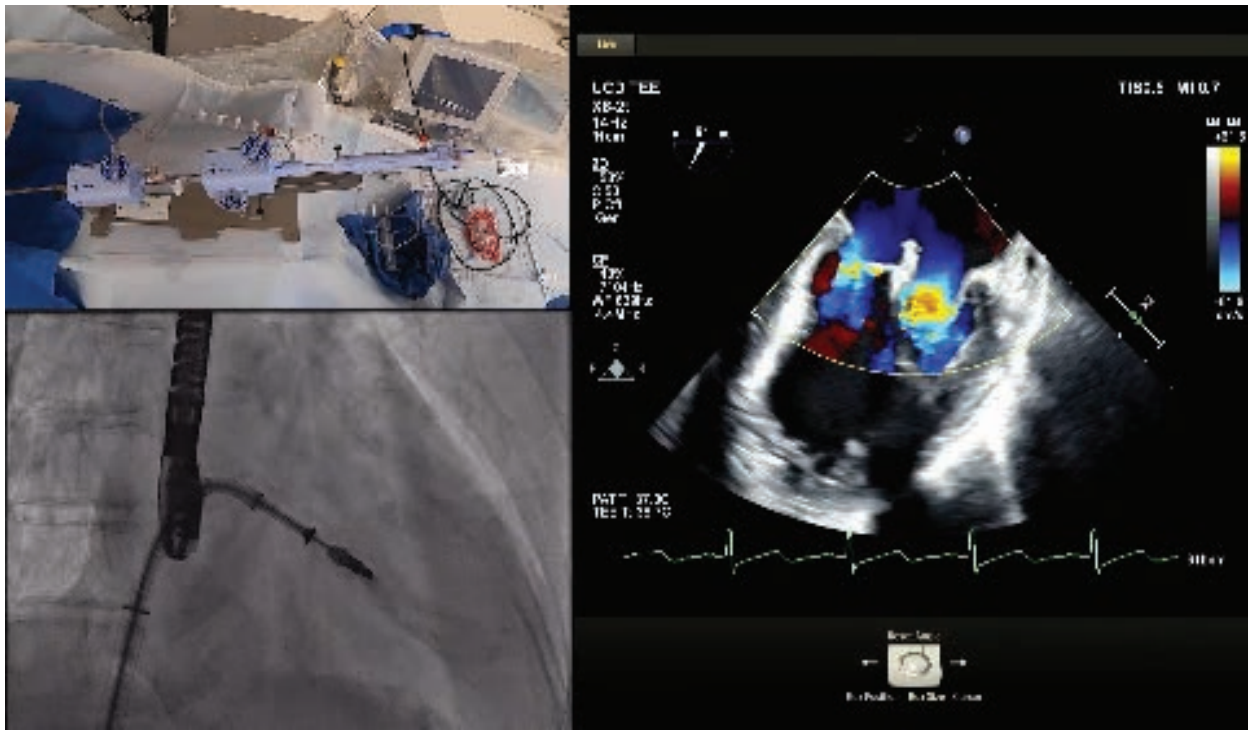


Figure 9 (video). MR Reduction

Troubleshooting for leaflet grasping

If there is adequate reduction MR 1+ or less and the gradient is acceptable, the clip may be deployed, and MR re-evaluated using 2D and 3D echo (Figure 10).

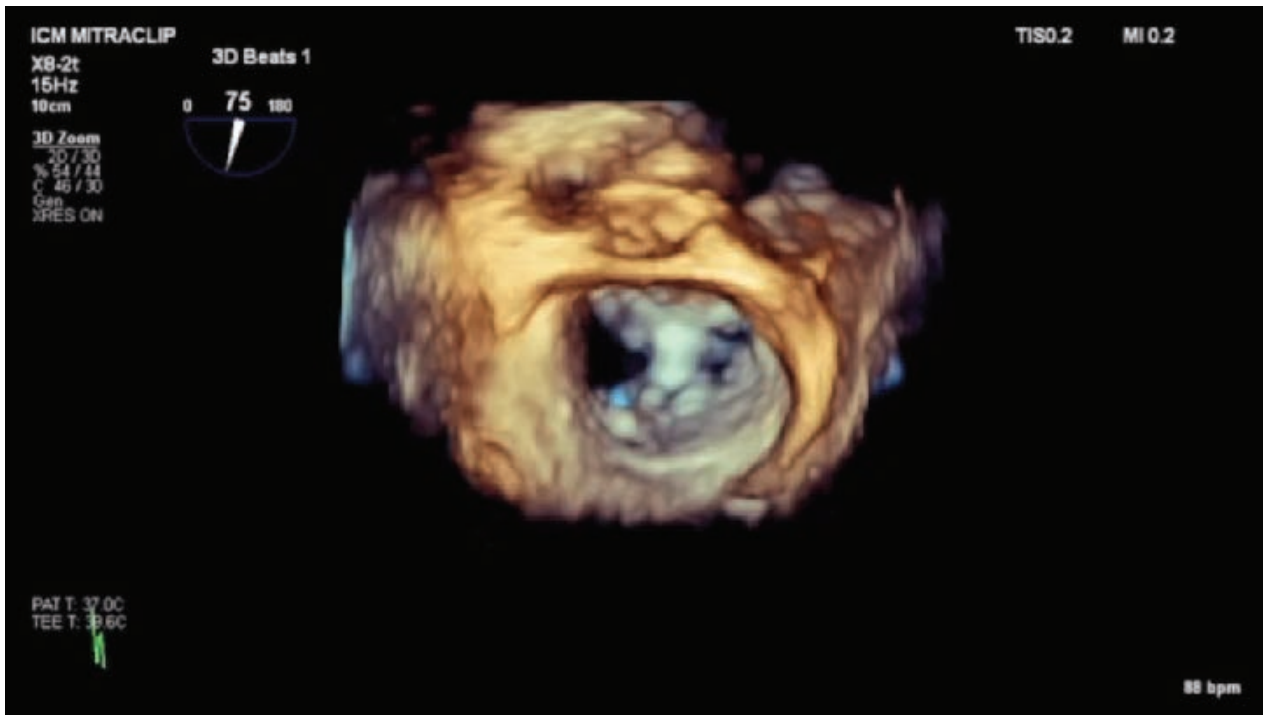


Figure 10 (video). Successful Grasp 3D

If there is some reduction in MR but still significant residual MR, appropriate clip alignment should be confirmed prior to considering additional clips.

- It is important to assess the residual MR, the location of the jet, and the presence of anatomic distortion on 3D. In some cases, distortion of the anatomy by a clip that is not properly aligned to the line of coaptation may cause residual MR.
- Ideally in the case of additional clips, the jet should be isolated to one side of the clip. For example, if there is MR reduction after the first clip, but the clip splits the residual jet, consider moving the clip medially to isolate the jet to the lateral side and then add another clip laterally to the first.

If there is no reduction in MR, re-evaluate the leaflet insertion and release and reattempt the grasp. The video in Figure 11 demonstrates loss of posterior leaflet insertion on 3D en face imaging following the grasp.

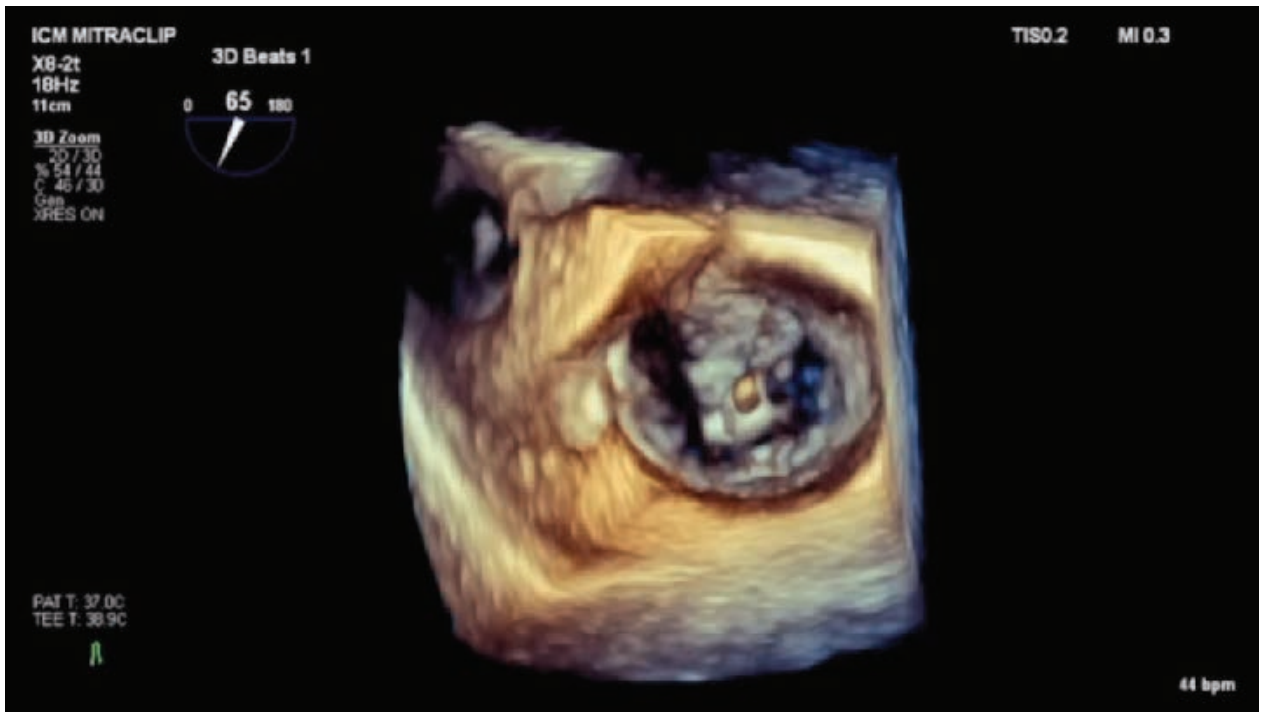


Figure 11 (video). Single Leaflet Device Attachment 3D

Following clip closure, assess the mitral valve gradient prior to clip deployment or decision making for an additional clip.

- If the mitral valve gradient is <4 mmHg and no significant residual MR, deploy the clip.
- If the mitral valve gradient is <4 mmHg and there is significant residual MR requiring additional clips, deploy and reassess the MR and gradient. In the setting of significant residual MR, this gradient may reflect the increased flow across the valve rather than significant stenosis.
- If the mitral valve gradient is high (>7 mmHg) with other signs of mitral stenosis, you may need to consider repositioning the clip or removing it to avoid mitral stenosis.

Additional clips

Additional clips may be required to optimize MR reduction or stabilize a clip in the case of significant leaflet prolapse or flail. In either case the following questions should be considered for clip selection and deployment strategy.

1. What was the first clip used (NT, XT, NTW, XTW)?

- In some cases, such as the addition of a clip at A2 P2 lateral to the first clip, the choice of clip will likely be the same as the first to match the anatomy.
- Choice of a wide or regular clip will depend on the initial mitral valve area, residual jet width, and mitral valve gradient.

2. What is the mitral valve gradient after the first clip deployment?

- If the gradient is not elevated after the first clip, a wide clip may be used as the second clip.
- In the setting of an elevated gradient, a regular clip placed close to the first is likely to have the least impact on mitral valve gradient.

3. Where is the intended location of the second clip (medial, lateral, commissural)?

- If the intended location of the second clip is medial or lateral, it is important to evaluate the size of the orifice and neighboring structures to avoid clip entrapment in the chords and select your clip accordingly.
- If the intended location is near the commissures, it is advisable to use an NT clip to avoid chordal entrapment.

Tips for additional clips

When placing more than one clip:

- Consider placing the second clip as close as possible to the first. To avoid clip-clip interaction or entrapment, keep in mind that the device material extends beyond its fluoroscopic signature.
- Clip orientation should be appropriate for the target grasping area and will not necessarily be the same as the first clip.
- The second clip should be advanced closed into the ventricle just below the leaflets prior to opening.
- For a lateral second clip, advance slightly lateral to the first, observing the trajectory on fluoroscopy and echo and avoid interaction with the first clip. To move slightly lateral, use the stabilizer rather than removing M knob.
- Fluoroscopy is very helpful when inserting a second clip to evaluate distance from the first and clip orientation as shown in Figure 12.

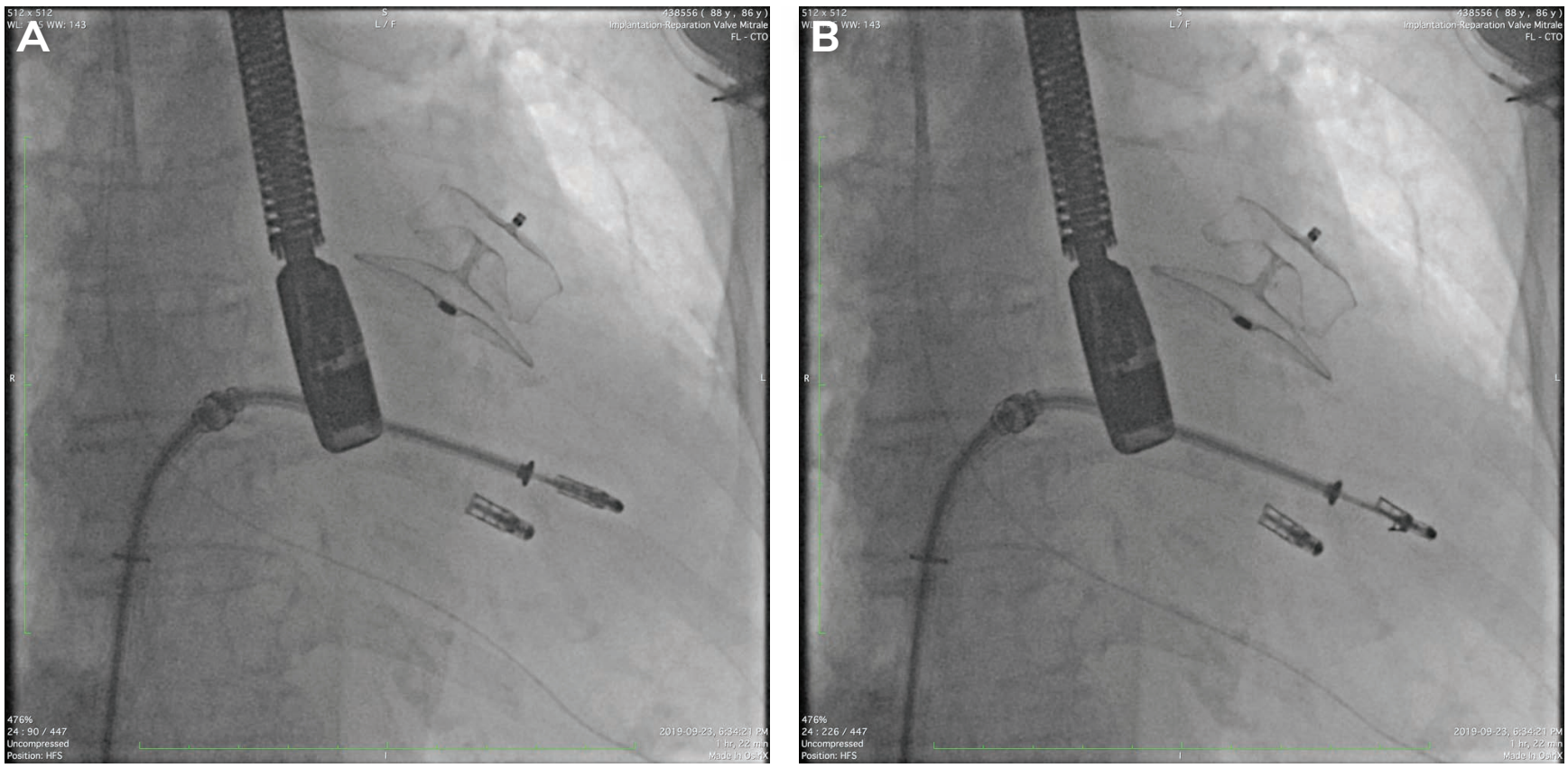


Figure 12. Guidance for Second Clip using Fluoroscopy

(A) Second clip advanced laterally to the first with the clip closed; note orientation of clip on fluoro is similar to first clip. (B) Clip is opened to grasp once in the ventricle, there has been no clip rotation. (C) Leaflet grasp on fluoro; note the height of the clip is similar to the more medial clip; (D) Complete closure of the second clip.

PROCEDURAL PEARLS

- Never make major changes in the ventricle, such as clip orientation or trajectory. If medial or lateral changes are required, use the stabilizer rather than add or remove “M” in the ventricle.
- For changes in trajectory, invert the clip and return to the left atrium prior to adding +/- to the guide or adding/removing “M.”
- Use fluoroscopy (parallax technique) to maintain clip alignment while entering the LV and grasping.
- Be gentle with clip movements. Do not overly turn the clip in the ventricle as this may cause chordal entanglement.
- With large clips, it may be a “one way trip.” The XT/XTW clips may be difficult to invert and remove, therefore optimize clip trajectory and orientation and be sure before entering the ventricle. Consider entering the ventricle with these clips closed.
- Record the entire grasp sequence as a long TEE acquisition to verify leaflet capture and intraprocedural review.
- Systematic assessment of leaflet insertion is your best defense against SLDA. Be sure you have enough leaflet insertion prior to clip deployment.

CHAPTER 13
Use of Controlled Gripper Actuation

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Overview

A key advance of the 4th generation MitraClip® system is the ability to raise and lower the 2 leaflet grippers independently. This process, called "controlled gripper actuation," allows for various maneuvers that can facilitate leaflet grasping and improve leaflet insertion, thereby improving procedural success and outcomes while shortening procedure duration. There are four approaches to controlled gripper actuation as shown in Figure 1.

- **Simultaneous grasping** - akin to the standard approach to leaflet grasping used with prior generation MitraClip systems
- **Confirmation of leaflet grasp** - after grasping both leaflets, a single gripper is raised to verify that a sufficient amount of leaflet tissue is engaged above the ipsilateral arm and then re-lowered
- **Optimization of leaflet grasp** - more leaflet tissue is incorporated into the grasp after simultaneous grasping by raising one gripper, maneuvering the clip system, and re-lowering the gripper
- **Independent leaflet grasping** - each leaflet is grasped one at a time

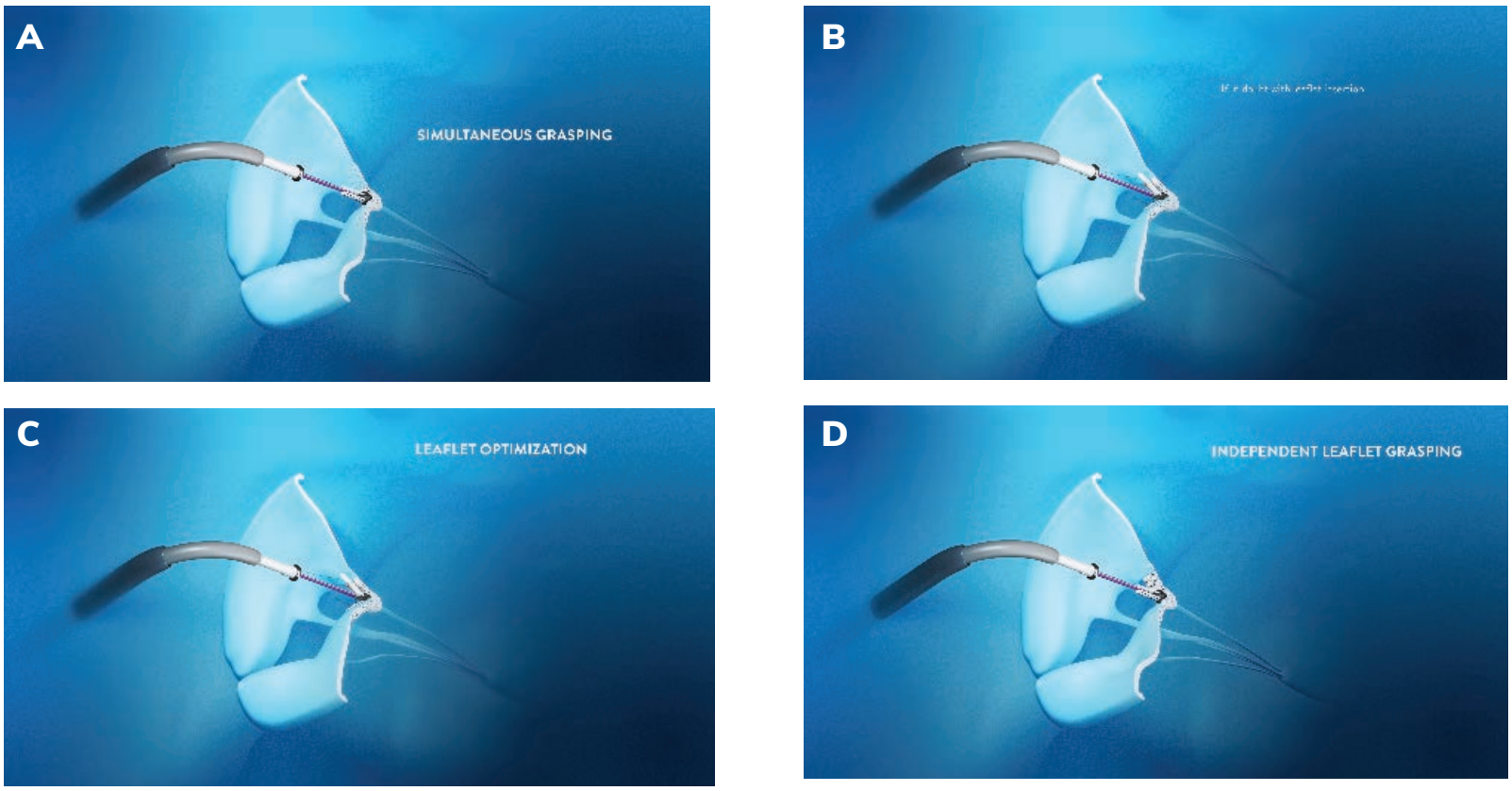


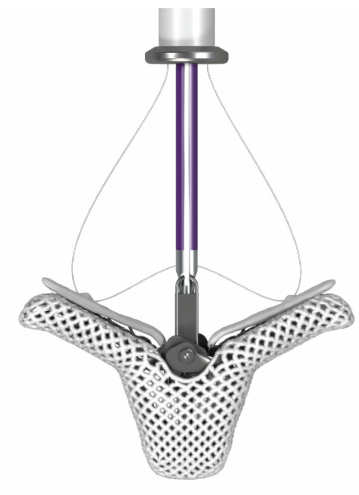
Figure 1 (videos). Controlled Gripper Actuation

(A) Simultaneous gripper actuation; (B) confirmation of leaflet grasp; (C) optimization of leaflet grasp; (D) independent leaflet grasp

In this chapter we describe the appropriate application of these 4 approaches and review potential pitfalls and possible complications.

G4 gripper levers overview

The grippers of the MitraClip G4 system are controlled by two levers at the proximal end of the handle, as shown in Figure 2. Engaging the blue latch fixes the two levers as a single unit and both grippers will drop when the levers are depressed, or both will be raised when the levers are withdrawn. When the latch is disengaged, each lever can be depressed and retracted separately, allowing for independent actuation of each gripper.



BOTH GRIPPERS LOWERED

ONE GRIPPER LOWERED AT A TIME

Figure 2. MitraClip G4 System Gripper Levers

Two gripper levers are located at the proximal end of the delivery catheter (DC) handle. The grippers can be raised and lowered individually by actuating their respective levers when the blue latch (blue arrow) is open and disengaged. When the two levers are fully raised or lowered and at the same height the blue latch can be closed and engaged and the two levers act as a single unit. A tactile marker (red arrow) is used to correlate that specific lever with either the anterior or posterior leaflet by cycling that gripper once the clip is open and positioned perpendicular to the plane of leaflet coaptation above the mitral valve and noting the arm associated with that gripper on echocardiography.

The position of each gripper relative to the anterior or posterior leaflet should be defined before the clip is advanced into the left ventricle, referred to as the “gripper wave.”

1. Open the clip and orient it perpendicular to the coaptation line in the 3D en face view.
2. Disengage the latch and depress the lever with the tactile marker.
3. Using either the echocardiographic long axis view (ie, “grasping view”) or the 3D en face view, note which leaflet is associated with that gripper (ie, either anterior or posterior).
4. Raise the gripper and re-engage the latch to prepare for simultaneous grasping.

Controlled gripper actuation approaches

Simultaneous grasp

Simultaneous grasping should be the default initial approach.

1. Confirm that the gripper latch is fully engaged.
2. Open the clip to 120° below the leaflets and confirm perpendicularity to the plane of coaptation.
3. Retract the DC to engage both the anterior and posterior leaflets, lower the grippers as a unit onto the leaflets, and slowly close the clip to 60° and lock.
4. Confirm leaflet insertion and completely close the clip while slightly advancing the DC handle to release tension.

Leaflet grasp confirmation

Occasionally it can be difficult to confirm the amount of leaflet insertion after simultaneous grasping and closure of the clip to 60° or more. Controlled gripper actuation (CGA) provides the freedom to confirm grasp quality without the danger of losing the grasp and having to reapproach the leaflet for another grasp.

To confirm leaflet grasp using CGA:

1. Open the clip to 120° without raising the grippers.
2. Obtain an echocardiographic view that clearly demonstrates the clip arms and respective leaflets.
3. Disengage the gripper latch.
4. Raise the gripper corresponding to the leaflet for which insertion is in doubt (as determined at the time of initial clip orientation above the valve).
5. Assess leaflet insertion using multiple echocardiographic views.
6. Once leaflet insertion is confirmed, re-lower the gripper, re-engage the gripper latch, and close the clip to 60°. Reassess final insertion before closing the clip completely. If leaflet insertion is sub-optimal, CGA can be used for leaflet grasp optimization (see below).

Leaflet grasp optimization

If necessary, the operator can optimize leaflet insertion after the clip has been opened to 120° and the gripper of the leaflet in question has been raised (Figures 3 and 4). Through subtle rotation of the steerable guide catheter (SGC) toward the leaflet, more leaflet tissue can be engaged within the “V” of the clip resulting in greater leaflet insertion.

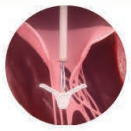
1. Rotate the SGC clockwise to engage more of the posterior leaflet, and counterclockwise to engage more of the anterior leaflet. Occasionally the DC handle will need to be slightly advanced so that the arm can “scoop” under the leaflet as the SGC is rotated, or slightly withdrawn to engage more of the leaflet. Any manipulation of the SGC and the DC handle should be slow and incremental to avoid excessive tension on the opposite leaflet, which can lead to loss of leaflet insertion or leaflet damage.
2. Once the clip arm is underneath a sufficient length of leaflet, lower the gripper and re-engage the gripper latch.
3. Close the clip arms to 60°, lock the clip, and reassess insertion before closing the clip completely.

CHECK AND CONFIRM

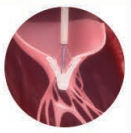
1. Imaging quality
2. Clip arms perpendicularity to line of coaptation throughout grasping sequence
3. Perpendicular DC trajectory

SIMULTANEOUS GRASPING

1. Retract the DC to grasp both anterior and posterior leaflet
2. Lower the grippers onto the leaflets
3. Slowly close the clip to 60



4. Advance the clip a few millimeters into the LV to release tension
5. Check leaflet insertion assessment



If leaflet insertion is questionable:

CHECK AND CONFIRM

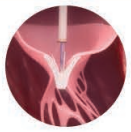
1. Imaging quality
2. Clip arms perpendicularity to line of coaptation throughout grasping sequence
3. Perpendicular DC trajectory

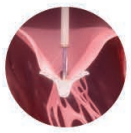
If any of these are not acceptable, release grasp and attempt Simultaneous Grasping again

If these are acceptable, consider to attempt Independent Leaflet Re-Grasp to optimize leaflet insertion

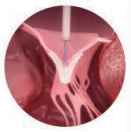
INDEPENDENT LEAFLET RE-GRASP

1. Raise the gripper associated to the leaflet whose insertion you intend optimize
2. Open the clip to 120°
3. Slightly adjust clip positioning without increasing tension on the leaflet
4. Re-lower the previously raised gripper





5. Slowly close the clip to 60 degrees and release tension on the DC, and secure the DC fastener
6. Verify leaflet insertion
7. Lock the clip—slowly close the clip just until the leaflets are coapted and MR is sufficiently reduced and release tension on the DC



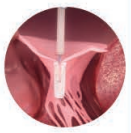
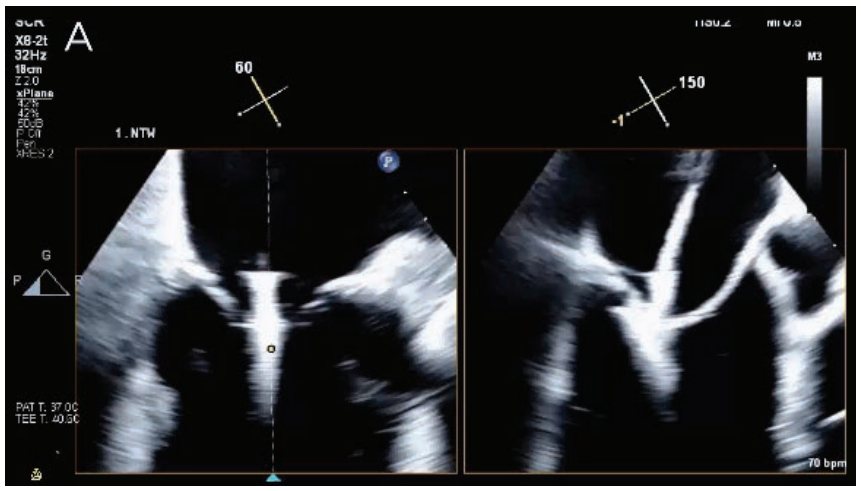
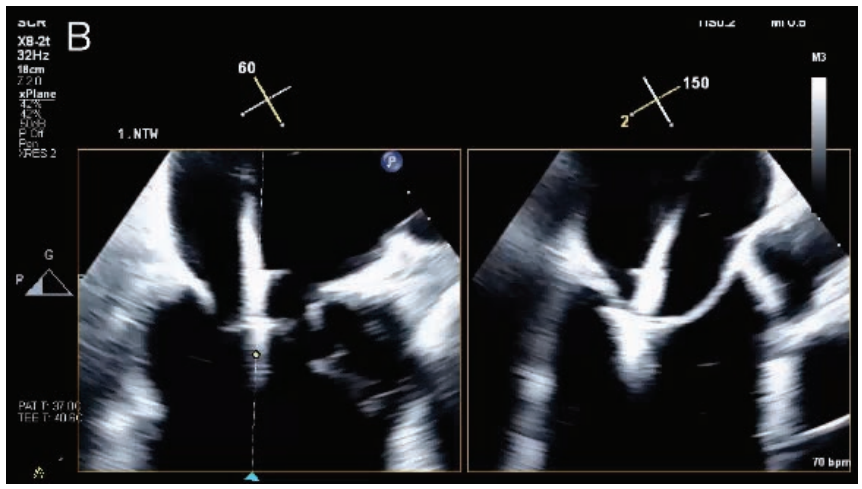
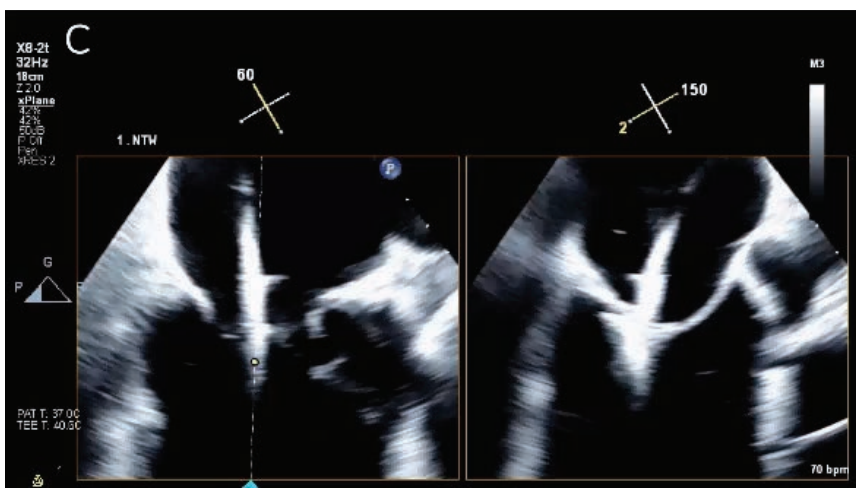


Figure 3. Controlled Gripper Actuation Technique to Optimize Leaflet Insertion







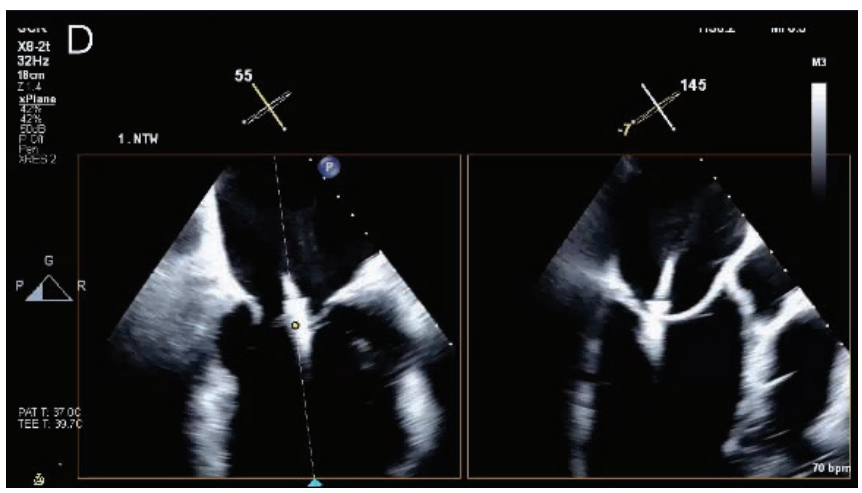


Figure 4 (videos). Simultaneous Grasp Followed by Leaflet Optimization

A 60-year-old male with heart failure with reduced ejection fraction underwent TEER for severe symptomatic functional MR despite guideline directed medical therapy. An NTW clip was selected due to adequate leaflet coaptation and to reduce leaflet tension. (A) After simultaneous grasping, the anterior leaflet is immobile, while there is persistent movement of the posterior leaflet raising the suspicion of insufficient leaflet tissue within the arm of the clip. (B) The posterior gripper is raised while the arms are open to approximately 120°, and the guide gently rotated clockwise, and the handle slightly withdrawn to optimize posterior leaflet insertion. (C) The posterior gripper is dropped again, with clear evidence of improved leaflet insertion. (D) After the clip is closed, there is no mobility of the posterior leaflet and leaflet insertion has been optimized.

Independent leaflet grasping

Independent leaflet grasping can be attempted when initial grasping and optimization does not result in sufficient leaflet insertion (Figure 5). This situation can occur when there is minimal vertical coaptation, or when both leaflets cannot be adequately grasped because of differential leaflet height in the setting of unilateral leaflet restriction or prolapse. Simultaneous grasping and optimization should always be attempted first to avoid potential complications due to excessive leaflet tension that might occur during independent grasping. If independent grasping is used, clip trajectory and alignment are critical and must be maintained to grasp opposing segments of the anterior and posterior leaflet. If the clip is not aligned or rotates between independent grasps, there is the risk of distorting the valve coaptation ("pinwheeling") which may result in suboptimal mitral regurgitation (MR) reduction, or in some cases, increased MR.

1. Raise both grippers, open the arms of the clip to 120°, and disengage the gripper latch to allow for independent gripper lowering.
2. Move the clip near both leaflets, rotate the SGC, and retract the DC handle to engage the first leaflet enough to obtain sufficient insertion. Then drop the gripper associated with that leaflet. In general, first grasp the leaflet that was most challenging to grasp during the initial attempt at simultaneous grasping – this is usually the more (relatively) retracted leaflet.
3. Slowly make subtle adjustments to the SGC (ie, rotation and retraction) to engage the arm under the other leaflet and drop that gripper when sufficient leaflet tissue falls on top of the arm.
4. Drop the gripper, close the gripper latch, and close the arms to 60° while releasing tension with the DC handle.
5. Lock the clip and verify leaflet insertion with multiple echocardiographic views. Confirm that the original leaflet that was grasped is still adequately inserted.
6. Perform leaflet confirmation and optimization of either or both leaflets using CGA as described above.

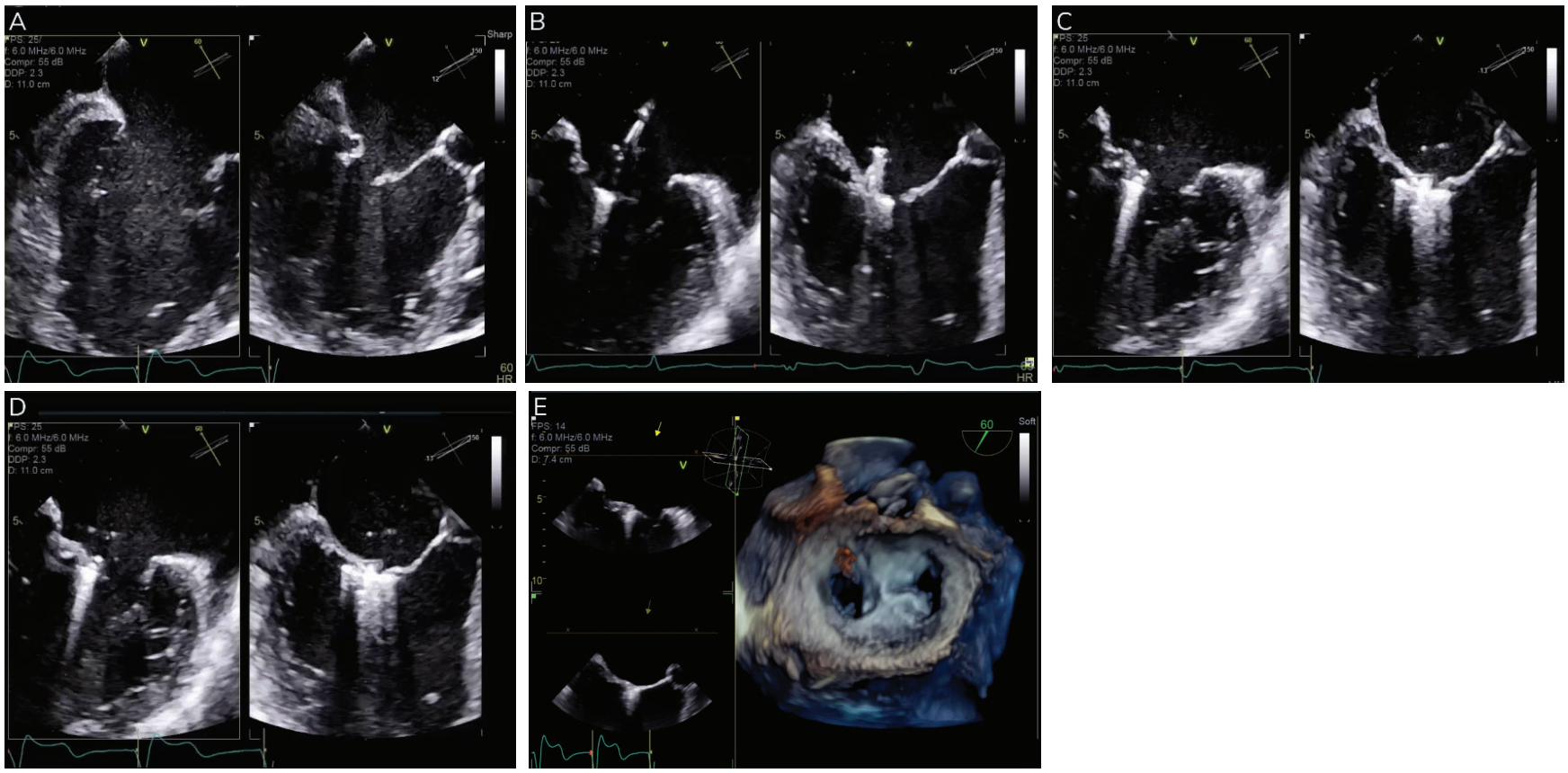


Figure 5 (videos and image). Independent Leaflet Grasping

A 60-year-old female with heart failure with reduced ejection fraction, atrial fibrillation, diabetes mellitus, and morbid obesity presented with NYHA Class IVa symptoms despite optimal medical therapy. The MR mechanism was primarily functional, although the leaflets were also thickened and calcified, with modest redundancy of P2. The mean gradient was 2.5 mmHg, and the 2D planimetered valve area was 4.3 cm^2. An NTW clip was chosen given the lack of substantial leaflet redundancy or mobility, what appeared to be adequate vertical leaflet coaptation, and a relatively small valve area. However, both leaflets could not be grasped simultaneously due to a mild aorta hugger, the differential height of the restricted anterior leaflet and the redundant leaflet, and significant annular dilation. (A) Mitral valve anatomy at baseline. (B) The NTW was manipulated under the posterior leaflet, and the posterior gripper dropped, capturing a sufficiently large segment of posterior leaflet. (C) The SGC was then carefully rotated counterclockwise, and the DC handle retracted so that the anterior leaflet lay fully on the other clip arm. (D) The anterior gripper was dropped, and the arms of the clip closed. (E) 3D en-face view demonstrates excellent tissue bridge and double orifice valve.

Pitfalls and potential complications

Independent leaflet grasping, and to a lesser extent leaflet grasp optimization, can place substantial tension upon the leaflet that is grasped initially. Adjustments with the SGC must be slow and minimal. Independent grasping should only be considered after attempting simultaneous grasping and leaflet optimization (if necessary). If an NT/NTW clip is being used and simultaneous grasping with optimization fails, consider “upsizing” to an XT/XTW if there is adequate leaflet length rather than performing aggressive independent grasping maneuvers. After leaflet optimization or independent grasping, remember to carefully re-assess leaflet insertion within the original gripper (ie, the one kept closed during optimization or the first leaflet to be grasped during independent grasping) as leaflet insertion may have been affected by the tension incurred by SGC manipulation.

Independent grasping should not be used to compensate for an extreme “aorta hugger.” Such a scenario can cause large differences in the height at which the arms engage the anterior and posterior leaflets and in the length of leaflet tissue that can be engaged by the arms. While this makes simultaneous grasping/leaflet optimization challenging, it also will result in a large amount of tension in the case of successful independent grasping. This can lead to leaflet tearing and/or single leaflet device attachment.

Finally, tension may build up in the guide from the torquing maneuvers if they are substantial, and when the clip is released, the operator should be prepared to compensate accordingly (ie, rotate the guide in the opposite direction from what was required during independent grasping).

It is also important to verify clip position and orientation on the 3D en face view once leaflet optimization or independent grasping has been performed to assess distortion of the valve leaflets or "pinwheeling" which may result in regurgitant jets on both sides of the clip. If significant distortion of the anatomy is identified, it may be best to release the grasp and attempt again. Keep in mind that distortion is magnified when using the XT/XTW due to the longer clip arms.

PROCEDURAL PEARLS

- Always attempt simultaneous grasping first before moving to the controlled gripper actuation feature.
- Clip alignment and trajectory are critically important to achieve and maintain when using CGA to prevent distorting the coaptation zone by grasping non-apposing anterior and posterior leaflet segments ("pinwheeling")
- When utilizing CGA, all MitraClip adjustments must be done very slowly and gently to prevent injury to the leaflets.

Conclusions

Controlled gripper actuation represents a significant technical evolution of the MitraClip system. It offers the operator greater confidence in confirming adequate leaflet tissue insertion, provides an efficient way to optimize questionable grasps, and may improve technical success in the setting of complex anatomies. Whether this and other advances incorporated in the G4 system translate into improved procedural and clinical outcomes will be evaluated in the ongoing, prospective, EXPAND G4 global observational registry (clincialtrials.org identifier, NCT04177394).

CHAPTER 14

Evaluation of Iatrogenic ASD and Need for Closure

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Overview

Due to the large size of the transseptal sheath in MitraClip™ (23 French at the interatrial septum), there is a risk of developing persistent iatrogenic atrial septal defects (iASDs) after the procedure. We have previously estimated the prevalence of persistent iASDs to be approximately 27% when evaluated at 12 months.[1] Some reports of persistent iASDs due to transseptal puncture have suggested a neutral effect on outcomes, although many such studies were with smaller sheaths for non-mitral valve procedures.[1-4] More recently, persistent iASDs have been associated with adverse outcomes in observational studies, including increased mortality, heart failure symptoms, and associated hospitalizations, as well as pulmonary hypertension.[5,6] As studies have been observational in nature, is not clear if persistent iASDs are markers or mediators of poor prognosis. In our observational study, patients who required iASD closure had low 30-day mortality but higher one year mortality, which may have been related to substantial comorbidities.[7]

Assessment of iASD and indications for closure

Patients who undergo MitraClip have transesophageal echocardiogram (TEE) guidance at the time of their procedure, and we routinely assess iASDs at the end of the procedure to help determine need for closure. Both 2 dimensional (2D) and 3D echo can be utilized to help assess size of the iASD as can the dimensions of the largest color flow width on color flow Doppler in the bicaval and short axis views (Figure 1).

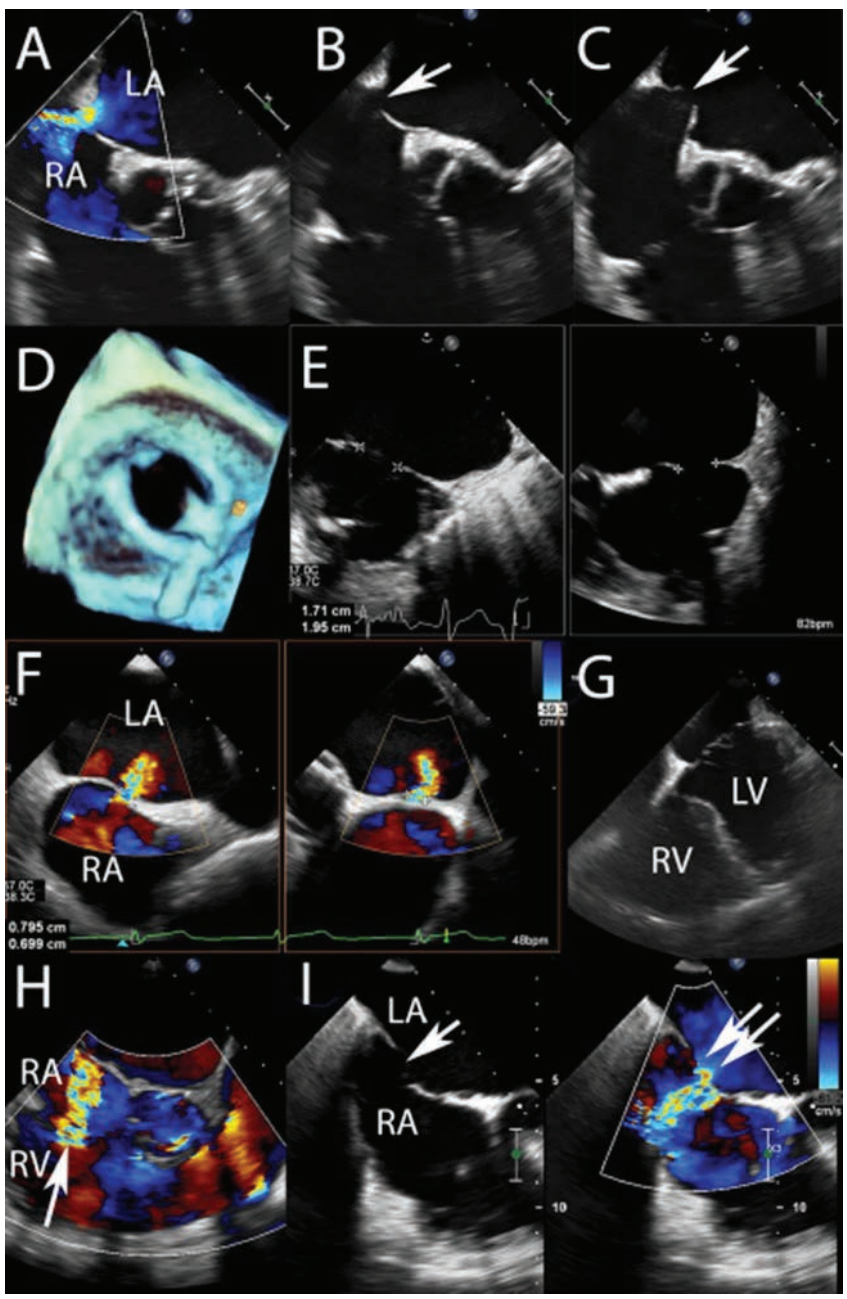


Figure 1. Iatrogenic ASD Closure Case Examples

(A-C) Thin, aneurysmal interatrial septum with iASD after MitraClip unlikely to close spontaneously (A, left to right shunt on color Doppler; B and C, interatrial septal motion with respiration, arrows). (D-E) Large iASD after transseptal mitral valve-in-valve replacement (D, 3D TEE with large iASD en face; E, large diameter iASD 1.71 x 1.95 cm biplane TEE). (F) Continuous right to left shunt. (G) Severe right ventricular enlargement in patient with iASD. (H-I) Large iASD with left to right shunt in setting of severe tricuspid regurgitation (TR). (H, severe TR, arrow; I, large iASD, arrow; left to right shunt, double arrow).

The degree of shunting can also be subjectively assessed via color flow Doppler. Right heart catheterization, if performed, may aid in decision making. Current ACC/AHA guidelines on ASDs pertain only to congenital ASDs, not iatrogenic ASDs. In general, closure has been proposed for high risk iASDs including those that are large (>10 mm) and unlikely to close spontaneously, have significant left to right shunting, right to left shunting with hypoxemia, significant right ventricular dysfunction, risk of paradoxical embolus (for instance in the presence of pacemaker leads with fibrinous attachments), severe TR creating excessive right to left shunting, pulmonary hypertension, aneurysmal septum, and young age.[3] There are no established metrics to define significant right to left or left to right shunting, and ultimately the decision to close is left to the operator's best clinical judgement. We reviewed all cases at our institution that underwent transcatheter iASD closure after transseptal mitral valve procedures, and the most common indications for closure were large iASD, significant left to right shunting by color flow Doppler, and pulmonary hypertension (Figure 2).[7]

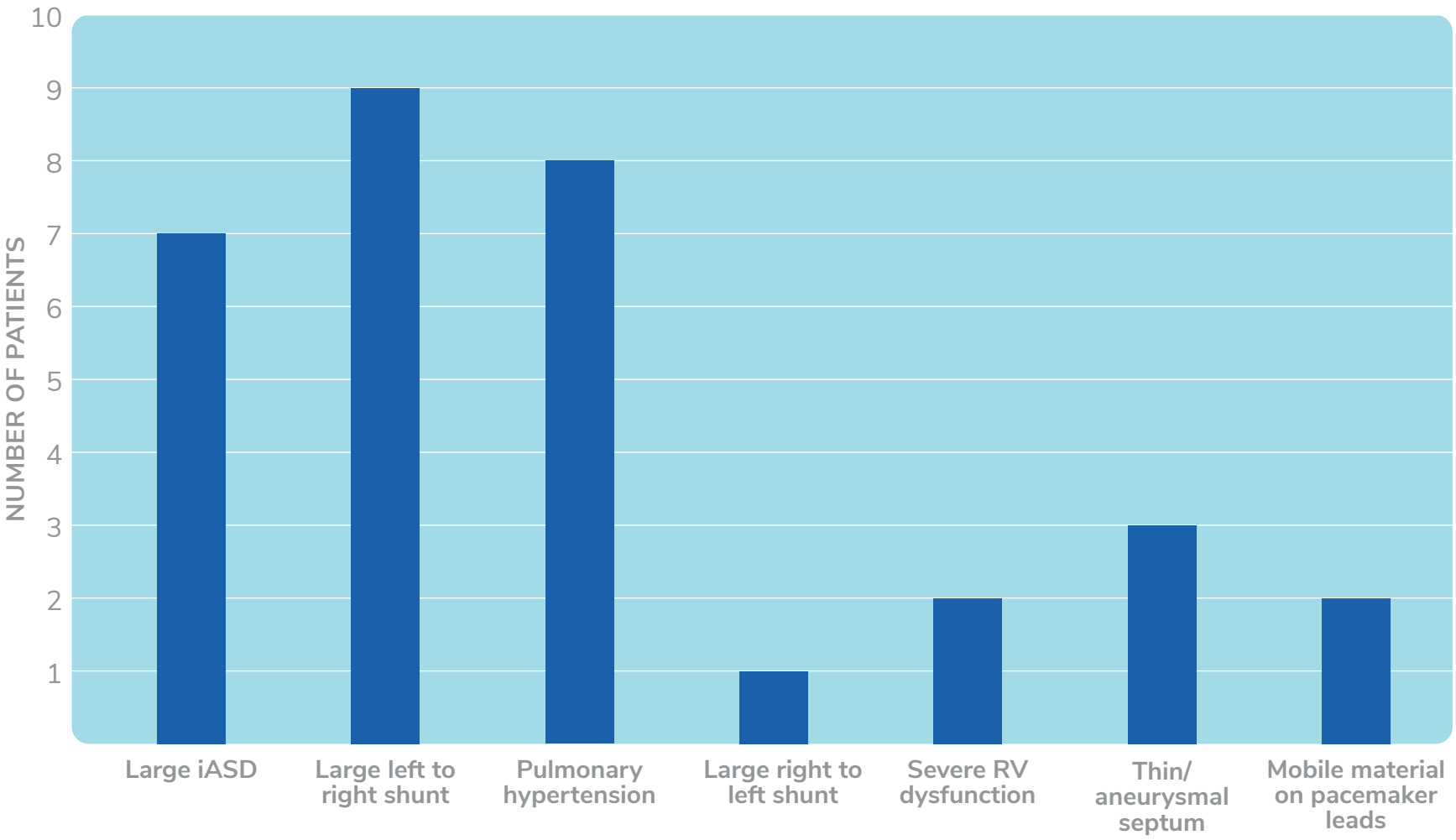
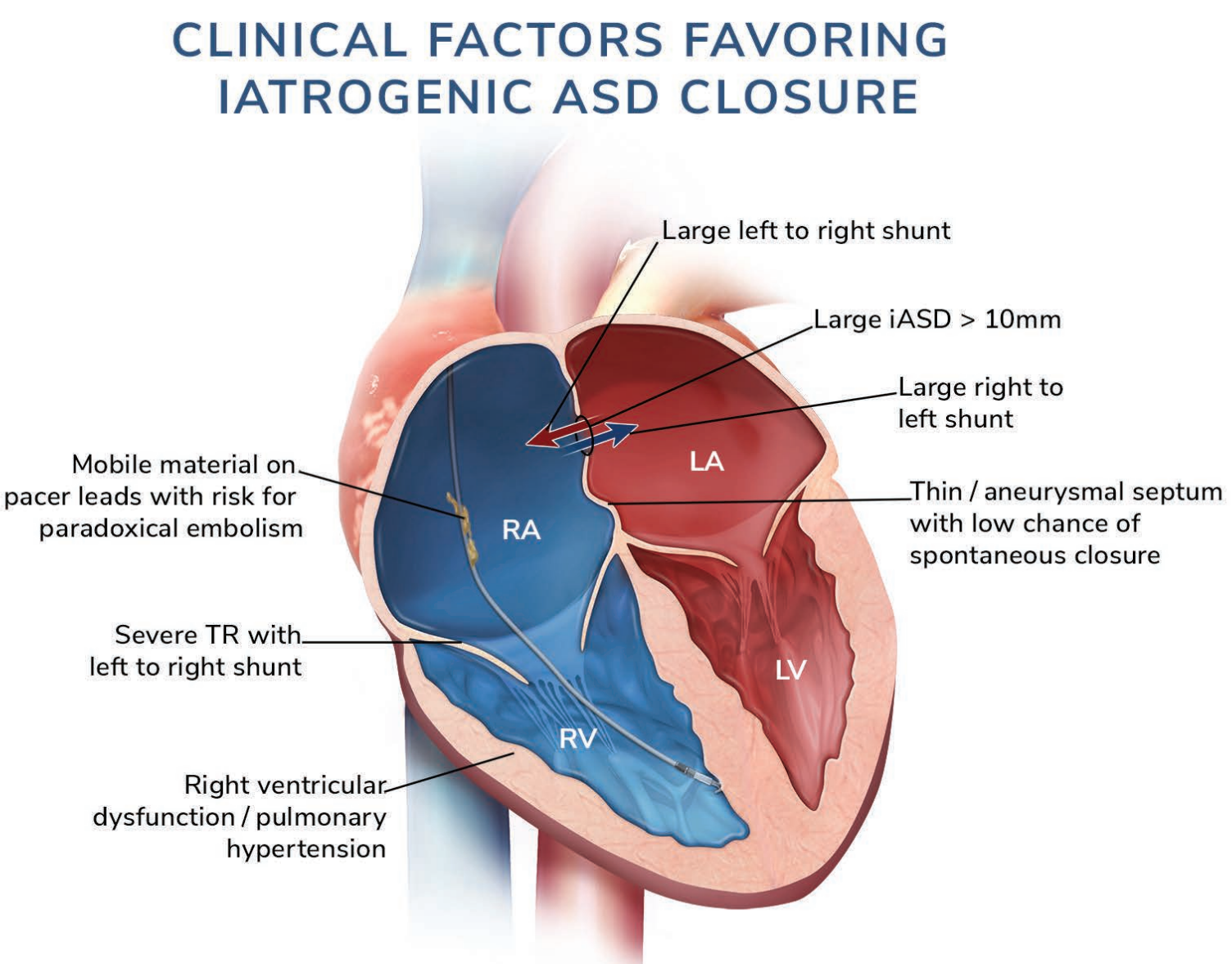


Figure 2. Indications for iASD Closure



iASD closure considerations

Closure of an iASD requires TEE or intracardiac echo (ICE) guidance. While there are currently two devices on the market in the United States in use for ASD closure, the Gore® Cardioform Septal Occluder (W. L. Gore & Associates, Inc., Newark, DE, USA) with its premounted delivery system, does not provide enough length to be extended beyond the MitraClip steerable guide sheath, and thus cannot be used unless the guide sheath is removed and replaced, in which case a standard technique can be used. The Amplatzer™ Septal Occluder (Abbott, Abbott Park, IL, USA) has a system that allows for gaining extra length in the delivery system and thus is the preferred device if deploying through the steerable guide sheath. The device waist size selected is typically 1-2 mm larger than the maximal color flow Doppler width, although in selected cases balloon sizing may be used.[8] Once deployed, TEE should be used to evaluate for mitral regurgitation and impingement on the aortic root. Other potential complications of closure which may rarely occur include device embolization (typically occurring within 24 hours), new onset atrial arrhythmias, and thromboembolic events. In general, the smallest sized occluder possible should be used to close an iASD to minimize the footprint on the interatrial septum, and to allow room for repuncture in the future. Recrossing of both Amplatzer and Gore septal occluders is feasible but technically challenging.

Closure techniques

If using the Gore Cardioform Septal Occluder, the MitraClip steerable guide must first be removed, after which the Gore delivery system can be advanced into the LA and the iASD closed using standard technique.

For the Amplatzer Septal Occluder, the standard technique is to advance the TorqVue™ delivery sheath (Abbott, Abbott Park, IL, USA) via fluoroscopy into the left atrium over an Amplatzer™ stiff wire (Abbott, Abbot Park, IL, USA) placed in the left upper pulmonary vein.[8] After removing the wire, the device is advanced through the delivery sheath until the left atrial disk is deployed into the left atrium, which is then pulled against the septum. The right atrial disk is then deployed. When used for iASD closure, it is important to note that the TorqVue™ delivery catheter is shorter than the steerable guide sheath for the MitraClip (Figure 3).

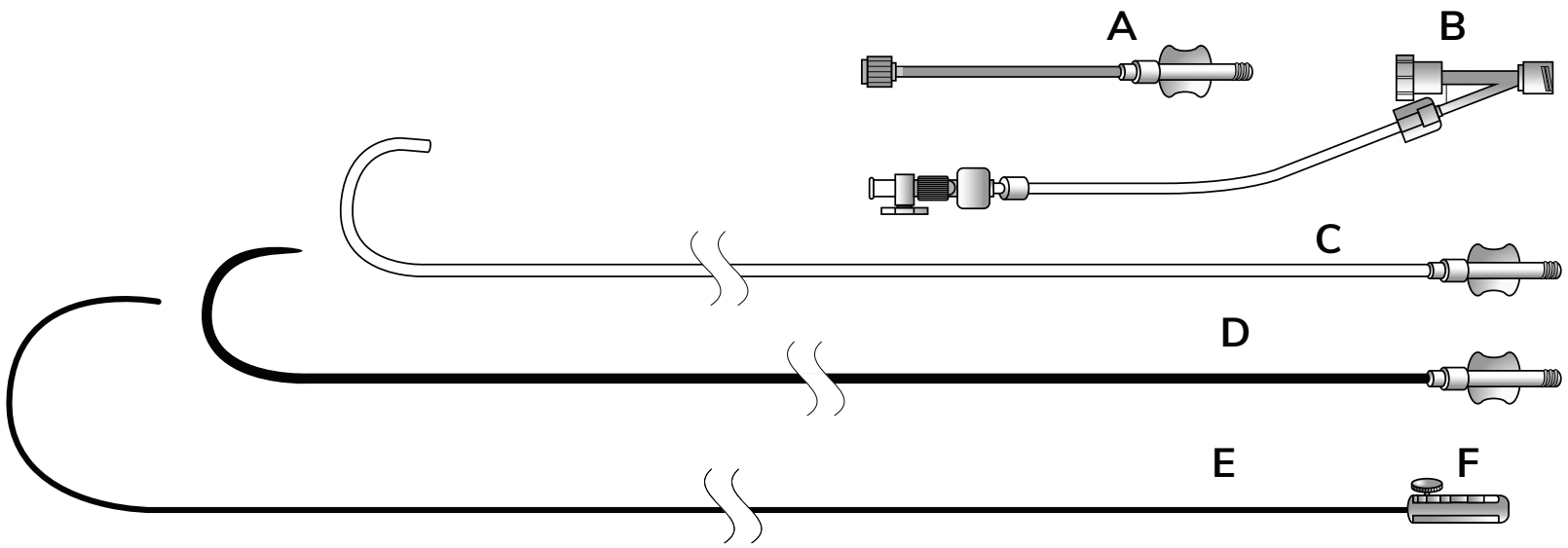
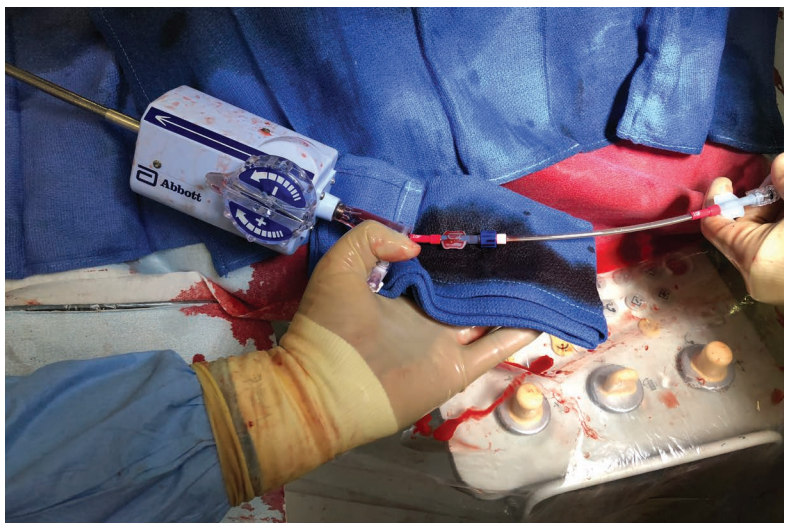
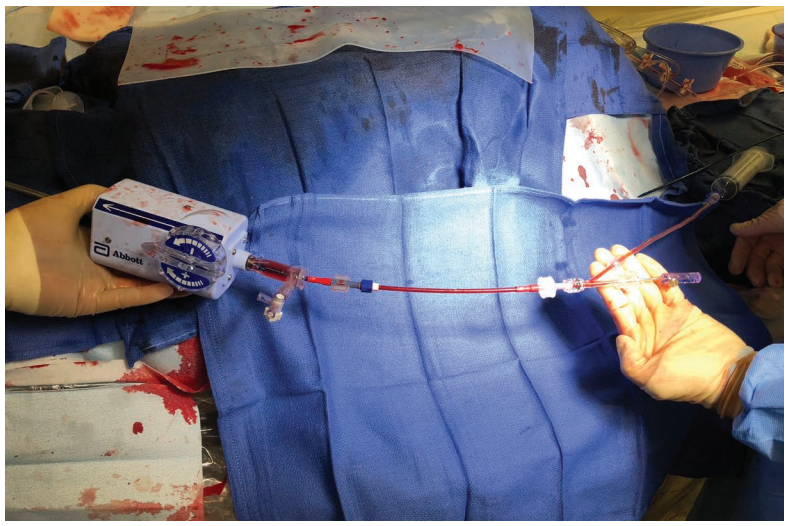


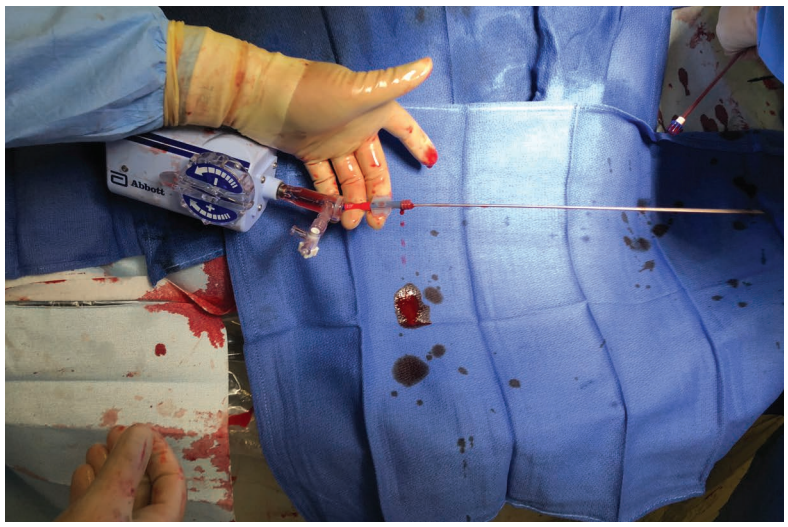
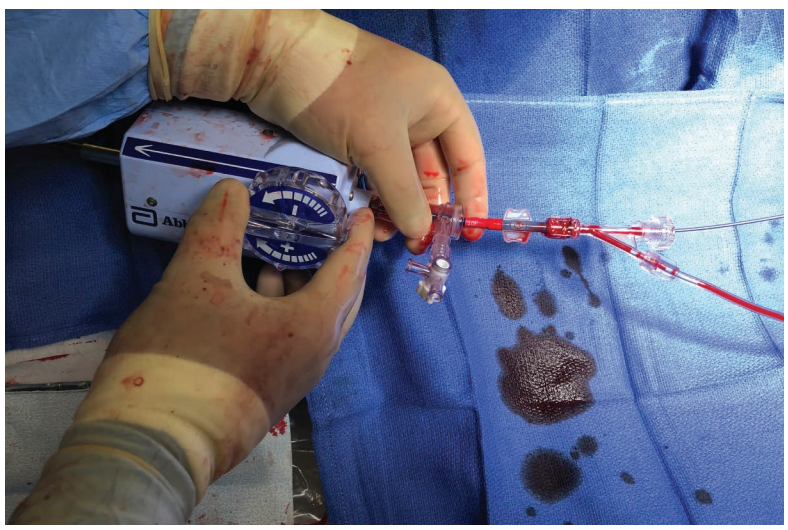
Figure 3. Amplatzer TorqVue Delivery System Components

A. Loader – Introduces an AMPLATZER device into the sheath
B. Hemostasis valve with extension tube and stopcock – Allows flushing of the delivery system and controls blood backflow
C. Sheath – Provides a pathway through which and AMPLATZER device is delivered
D. Dilator – Eases penetration of tissue and minimizes vessel trauma
E. Delivery cable – Attaches to the device to control its movement through the sheath
F. Plastic vise – Attaches to the delivery cable and serves as a handle for disconnecting (unscrewing) the delivery cable from a device

The delivery cable, at 120 cm, is longer than the steerable guide sheath, however, the loading system adds an extra 20 cm to the length of the TorqVue delivery sheath. Therefore, there is a need to gain length in the system for the septal occluder to come out the end of the steerable guide sheath if this is being used for deployment of the ASD occluder device.

Table 1. Steps for Deploying ASD Closure Device Through the Steerable Guide Sheath

 	1. Load the TorqVue catheter into the guide sheath and advance it as far as possible.
	2. Attach the short loading catheter to the TorqVue catheter using a wet-to-wet connection in the standard fashion.
	3. Once the delivery cable has been advanced as far as possible, the occluder is still within the guide sheath. (The working length of a MitraClip steerable guide is 80 cm plus 20 cm of the steering handle and the hemostasis valve, plus the extra 20 cm of the loading catheter and hemostatic valve leaves the device just inside the steerable guide.)

	4. Remove the plastic torque vise from the delivery cable, then, with the external end of the system held below the level of the left atrium to reduce the risk or air entrainment, remove the short loading catheter and hemostatic valve.
	5. Replace the hemostatic valve without the short loading catheter. This allows for shortening the delivery system by about 15 cm and allows the ASD occluder device to be pushed out the end of the guide sheath. Then, use the standard technique of deployment to occlude flow across the iatrogenic ASD. We have demonstrated in a case series that shortening the delivery system by removing the loading portion is safe and did not lead to any complications.[9]

Post iASD closure management

Dual-antiplatelet therapy is recommended for at least 3-6 months after iASD closure while the device endothelializes with lifelong aspirin administered thereafter. Endocarditis prophylaxis should also be the standard for dental procedures for a minimum of 6 months. If the left atrium needs to be re-accessed, this can be done through an adjacent portion of the septum (eg, inferoposteriorly) or even through the closure device if needed (see Chapter 9. Transseptal Puncture).

Summary

Closure of an iASD at the conclusion of large bore transseptal structural heart procedures is not a common occurrence but persistence of a defect has been linked with worsened outcomes in certain cases. Consideration should be given to closing the iASD in cases where the iASD is large (>10 mm and unlikely to close spontaneously), and in cases with significant left to right shunting, right to left shunting with hypoxemia, significant right ventricular dysfunction, risk of paradoxical embolus (presence of pacemaker leads with embolic-prone material), aneurysmal septum, and young age. In cases where closure of the defect is desired prior to removing the large bore transseptal guide sheath one must understand whether there is enough length on the delivery cable. We have described techniques to allow for delivery of the closure device when there may initially not be enough length on the delivery cable for deployment.

PROCEDURAL PEARLS

- If closing iatrogenic ASD through the MitraClip guide, use the Amplatzer Septal Occluder system which has a delivery cable long enough for the MitraClip guide.
- If closure is not performed through the MitraClip guide, the guide may be removed, a new femoral sheath may be placed, and any commercial ASD closure system may be used.

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CHAPTER 15

Complications: Single Leaflet Device Attachment, Chordal Entanglement, and Embolization

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Overview

Major complications of transcatheter edge-to-edge repair (TEER) of the mitral valve have included single leaflet device attachment, device embolization, tamponade, myocardial infarction, urgent open mitral valve surgery, acute stroke, and vascular injury. Since the first use of the MitraClip™ (Abbott, Abbott Park, Illinois) in 2003, there have been several advances in the technology and improvements in operator technique, and the incidence of these major complications has decreased over time.[1-10]

The risk for complications such as single leaflet device attachment, chordal entanglement, and device embolization can be mitigated with good technique and decision making. Nevertheless, these complications can occur in the best of circumstances, so having a familiarity with the causes and techniques to manage them will help ensure optimal outcomes for patients.

Single leaflet device attachment

The most common and potentially avoidable complication of mitral valve TEER is the detachment of one of the mitral leaflets from the clip device. This has been variously called single leaflet device attachment (SLDA),[2-15] single leaflet detachment,[16-18] partial clip detachment, loss of leaflet attachment,[19] or partial leaflet detachment.[1] This complication occurs in 1-5% of patients[1-9,20] and most often within the first 30 days of the procedure. It is recognized on follow-up echocardiography or by symptoms associated with recurrent mitral valve regurgitation.[6]

SLDA is due to either failure of the device to capture or hold onto a leaflet or tearing off of the captured leaflet from the mitral valve; a check of the lock before releasing the device should prevent this. SLDA represents a spectrum of presentations associated with partial or complete clip detachment. Partial SLDA can present as new leaflet prolapse from tissue slippage, or leaflet perforation and tearing.[11]

Echocardiographic and fluoroscopic criteria have been proposed to help identify complete SLDA based on one of the following:[6]

- Demonstration of complete separation between device and leaflet tissue
- Absence of a diastolic tissue bridge
- New excessive leaflet mobility or mitral regurgitation following TEER

Leaflet Injury	**Tear**	Disruption of leaflet integrity reaching the leaflet edge.
	Perforation	Disruption of leaflet integrity NOT reaching the leaflet edge.
	Shape Distortion	Shape distortion affecting leaflet coaptation, without disruption of the leaflet integrity. Examples include, but are not limited to, leaflet folding, tension/pinwheeling, etc.
Single Leaflet Device Attachment (SLDA)*	**Criteria 1**	Confirmation of complete SLDA at surgery or autopsy.
	Criteria 2	Echocardiographic or fluoroscopic demonstration of complete separation of device and a single leaflet tissue.
	Criteria 3	3.1 - Failure to demonstrate diastolic tissue bridge. 3.2 - Color Doppler demonstration of significant MR through the device/leaflet interface. 3.3 - New excessive leaflet mobility following device deployment.
Chordal Entrapment (CE)	**Partial leaflet insertion and/or chordal rupture**	Only one clip arm gripping chordae.
	Complete Entrapment	Both clip arms tangled/ gripping chordae.

*
– Definite SLDA: Fullfillment of criteria 1 or 2 or 3 (all 3.1, 3.2, and 3.3).
– Likely SLDA: Partial fullfillment of criteria 3. Criteria 3.1 must be met, with either 3.2 or 3.3 (not both).
– Unconfirmed SLDA: Failure to meet criteria for Definite or Likely SLDA.

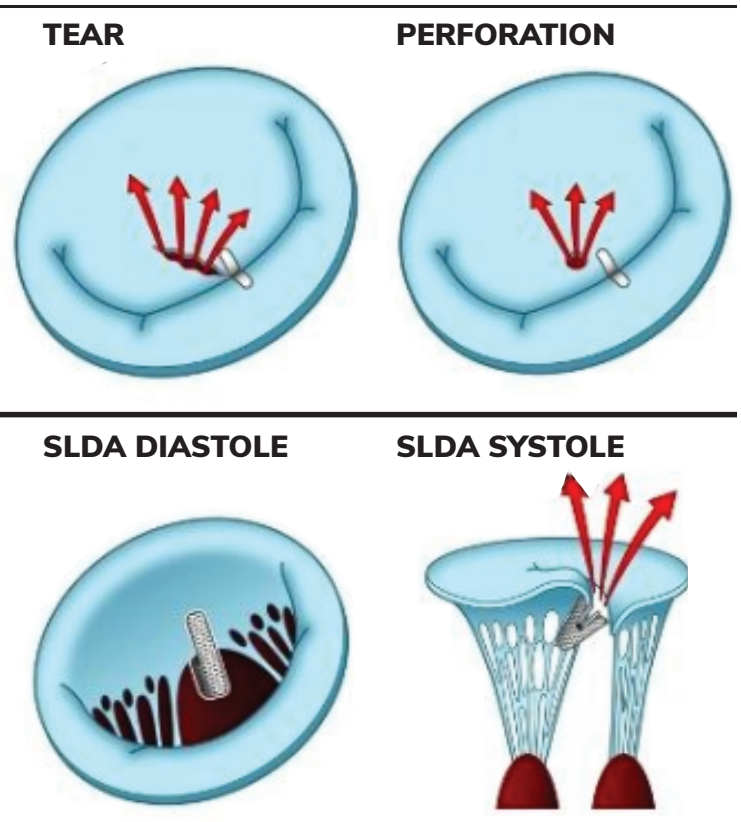


Figure 1. Echocardiographic Criteria for Partial and Complete SLDA, Leaflet Tears and Perforation, and Chordal Entrapment[6]

(used with permission)

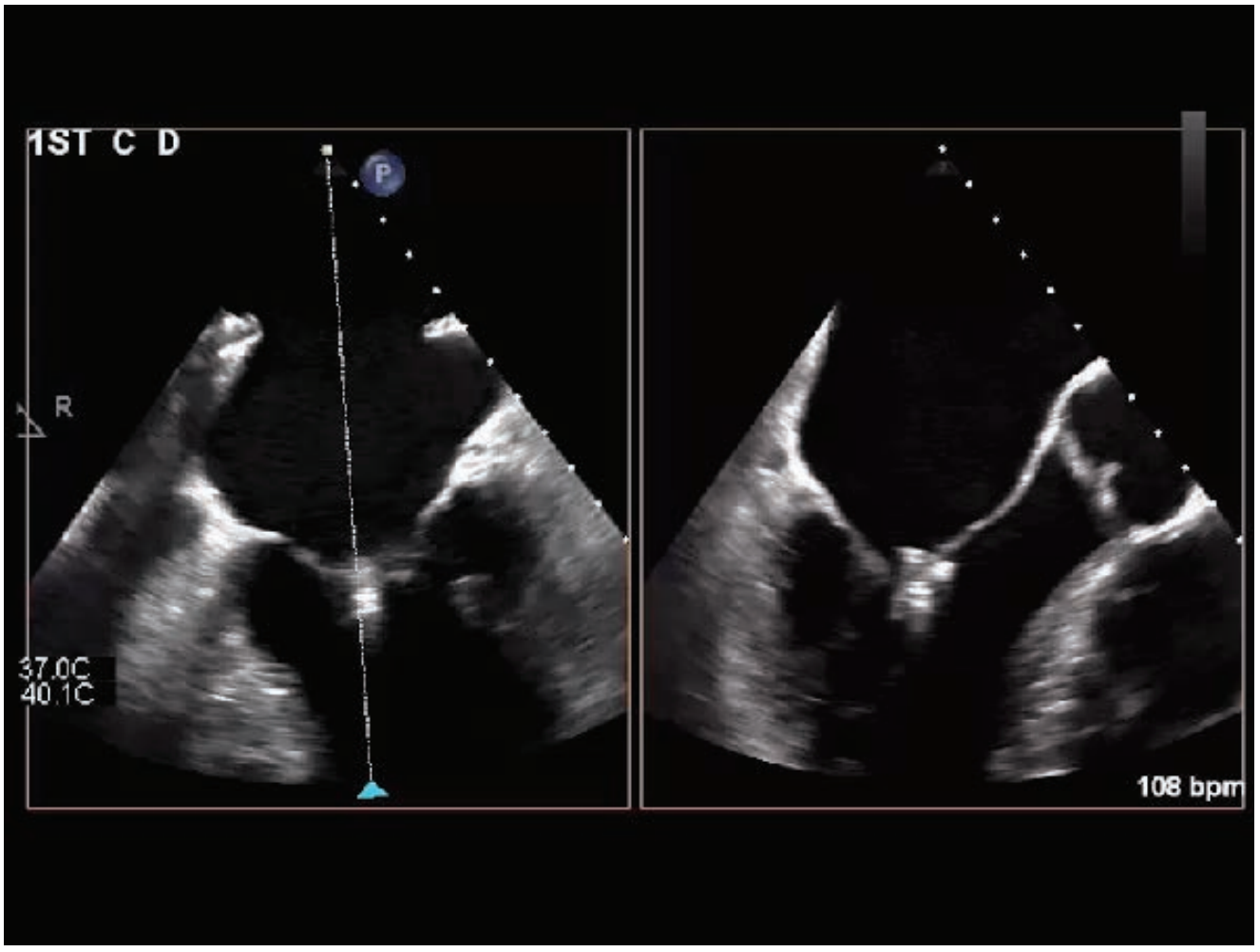


Figure 2 (video). Transesophageal Echo of SLDA with Clip Attached to Anterior Leaflet

The risk for SLDA can be reduced with proper technique and operator judgment, and can be mitigated by recognizing anatomic risk factors, optimizing device visualization during grasping and assessment after clip closure, and avoiding suboptimal device placement. The earliest experience with TEER in ACCESS-EU reported a 4.8% incidence of SLDA. In the EVEREST II study there were no embolizations, but 9 cases of SLDA (5%) in the first 12 months,[4] and one SLDA at long-term follow-up treated successfully with a second clip.[20] In contrast, 7-years later COAPT reported only two patients (0.7%) with SLDA, albeit with one case of device embolization (0.3%).[2] In the real-world EXPAND registry of 1041 patients who underwent therapy in 2018-2019, overall SLDA occurred in 26 (2.5%) patients, with 24 having isolated SLDA and two who had both SLDA and leaflet injury. Leaflet perforations/tears were seen in 1.1% of patients.[6]

The causes for SLDA are numerous, but generally fall into the major categories of inadequate leaflet capture, excessive clip-leaflet tension, and/or poor tissue quality causing leaflet tearing. The majority of SLDA involve detachment from the posterior mitral valve leaflet[6] (Table 1). SLDA may also be caused by chordal entanglement.

Table 1. Causes for SLDA

CAUSE FOR SLDA	SPECIFIC EXPLANATION
Inadequate leaflet capture	• Poor echo imaging[21] • Short leaflet (NTR <6 mm, XTR <9 mm) • Gripper below leaflet
Poor tissue quality	• Thin leaflet[13] • Connective tissue disorder[15] • Myxomatous leaflet • Steroid use[23] • Calcified leaflet or annulus[7]
Excessive clip-leaflet tension	• Severe mitral annular dilation[12] • Use of individual grippers and aggressive anterior or posterior torque • Cardioversion[23] • Device malrotation
Chordal entanglement	• Gripper and clip arm attached to mitral valve chords

SLDA due to inadequate leaflet capture

Visualization of the gripper arms and clip arms is critical during device deployment to ensure the mitral leaflets have been adequately captured by the device. Suboptimal echocardiographic visualization during gripper deployment, clip arm closing, and evaluation prior to clip release can all lead to SLDA.[21] It may be difficult to see both leaflets simultaneously and sometimes difficult to image the relationship of the device to one or the other leaflet, especially in commissural deployments.

Echo imaging should document:

- Reduction in mitral regurgitation
- Reduced movement of the leaflets that remain above the clip arms during diastole
- Stable tissue bridge in systole and diastole

There may be partial leaflet capture, however, which might fulfill criteria for clip deployment but inadequate tissue to maintain clip attachment during the tensioning of the leaflet through the cardiac cycle. For this, visualizing and saving the gripper deployment and clip arm closure is helpful to review how much tissue was captured. The MitraClip Indications For Use recommends that a leaflet length of at least 6 mm be captured by each clip arm of the MitraClip NT system and 9 mm for the XT system.[22] Case 1, shown in Figure 3, illustrates a short posterior leaflet measuring 6 mm in length which lead to SLDA after placement of an NTR device, despite appropriate imaging demonstrating adequate tissue capture.

Additionally, the grippers can be inadvertently deployed beneath the leaflets, on the ventricular side. This may occur if the device is not positioned correctly, or if the grippers are entangled with the mitral valve chords during device manipulation prior to being deployed.

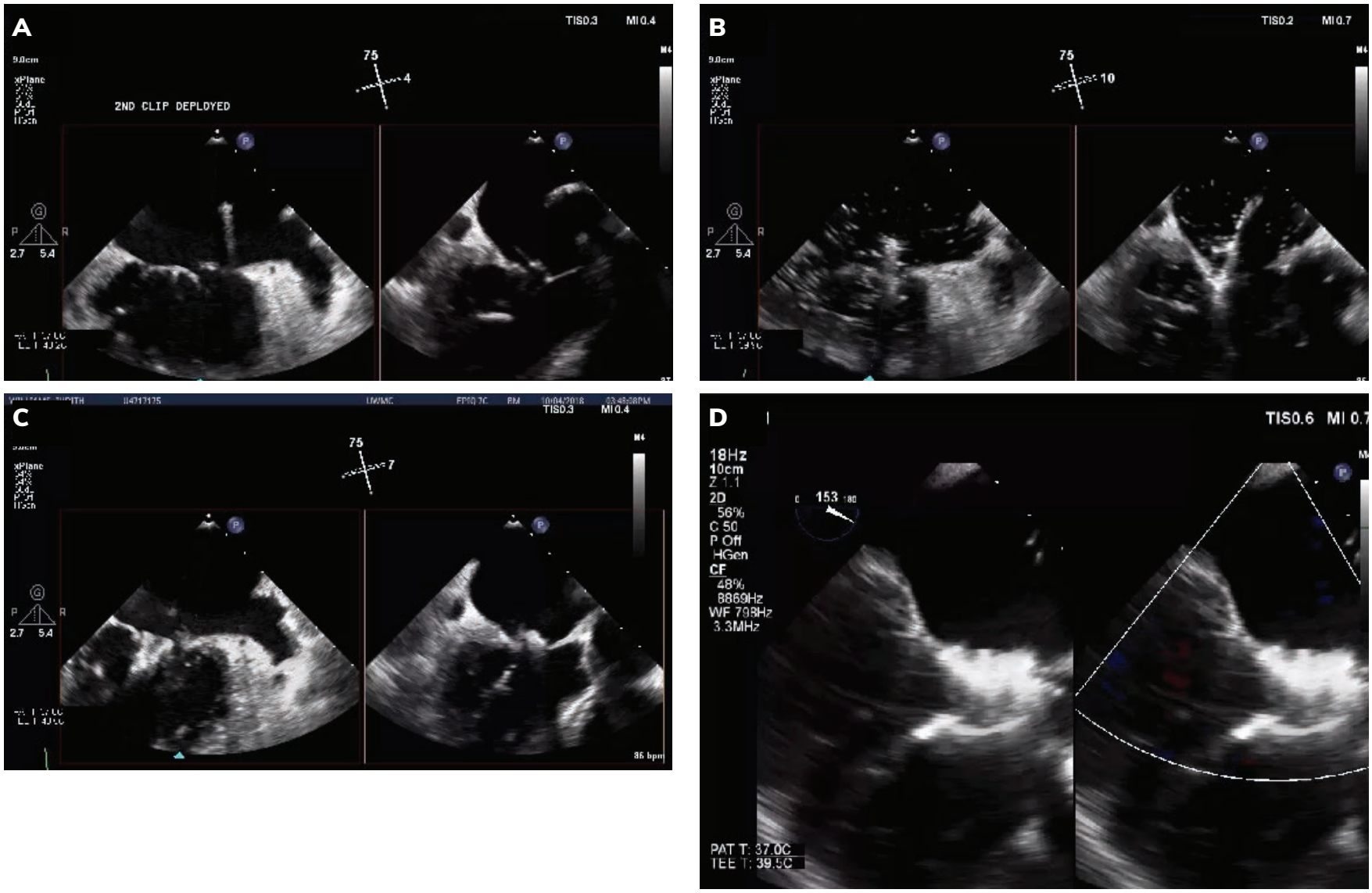


Figure 3 (video). Case 1: Short Leaflet and SLDA

(A) Large A1/A2 flail following two TEER devices with remaining small A1 flail with a short corresponding posterior (P1) leaflet. (B) Adequate tissue capture. (C) SLDA with evidence for tearing of the P1 leaflet tip. (D) Placement of an Abbott St. Jude Amplatzer atrial septal occluder device with residual regurgitation in the lateral commissure.

SLDA due to poor tissue quality

The appearance of the mitral leaflet tissue should be evaluated when considering TEER, as poor tissue quality can lead to complications along a continuum from leaflet injury to partial leaflet detachment to complete SLDA.

Case reports and registries have described SLDA associated with:

- Thin leaflets[13]
- Short leaflets[6,13]
- Connective tissue disorders[15]
- Steroid use[23]
- Severely calcified leaflets or mitral annular calcification[6,7]

Operators should be aware of characteristics of the mitral leaflet that may predispose to SLDA, although in many patients this may not change the ultimate clinical decision to go forth with the procedure. Thin or short leaflets may influence device size or the decision to use more than one device to buttress the first device and help distribute the load across a wider segment of the leaflet.

SLDA due to excessive clip-leaflet tension

The transcatheter mitral repair devices work by pulling the anterior and posterior leaflets together, which places tension on both leaflets. In patients with a flail leaflet in primary mitral regurgitation or a severely dilated annulus, the coaptation gap can be quite large. While the current transcatheter technologies can effectively treat such patients, maneuvers employing independent gripper mechanisms to grasp one leaflet and torque the system toward the other leaflet may increase the tension on each of the leaflets.

The clip arms of the new generation MitraClip XTR are 3 mm longer than the previous clip arms and allow more tissue to be captured and greater reach across larger coaptation gaps in anatomically challenging patients. A single-center study of 107 patients treated with the XTR system reported SDLA in 3.7% and leaflet injury in 1.9% which required surgery in 4 of these 6 patients.[8] In a retrospective comparison of the XTR system with the shorter NTR system, the overall incidence of leaflet injury was higher for patients with the XTR device (XTR 14.6% vs. NTR 1.7%, p = .01). There were 4 (7.3%) acute leaflet tears associated with the XTR device, and only 1 (1.7%) with the NTR (p = 0.15). The incidence of SLDA among patients with the XTR device was 3 (5.5%), while there were no patients with SLDA among the NTR group (p = 0.07).[5]

As shown in Case 2 (Figure 4), device malrotation, where the clip is not perpendicular to the leading edges of the anterior and posterior leaflets, may have contributed to a case of SLDA at our center. A case of SLDA has been reported in a patient with mitral regurgitation due to atrial fibrillation associated with a severely dilated left atrium and severe mitral annular dilation.[12] A device was placed with good tissue capture, but the authors suggest that as a result of the dilated annulus and leaflet malcoaptation, the edge-to-edge repair required significant tension to be placed on the posterior leaflet, leading to SLDA and damage to the posterior leaflet.

There have also been two cases of SLDA that occurred immediately after cardioversion, presumably due to the leaflet-device tension incurred by the acute increase in ventricular pressure.[23] The purported benefit of the central spacer used in the Edwards Scientific Pascal repair system is to bridge the coaptation gap and reduce stress on fragile leaflets. Nevertheless, even with limited use, SLDA has been reported with this device as well.[7,13]

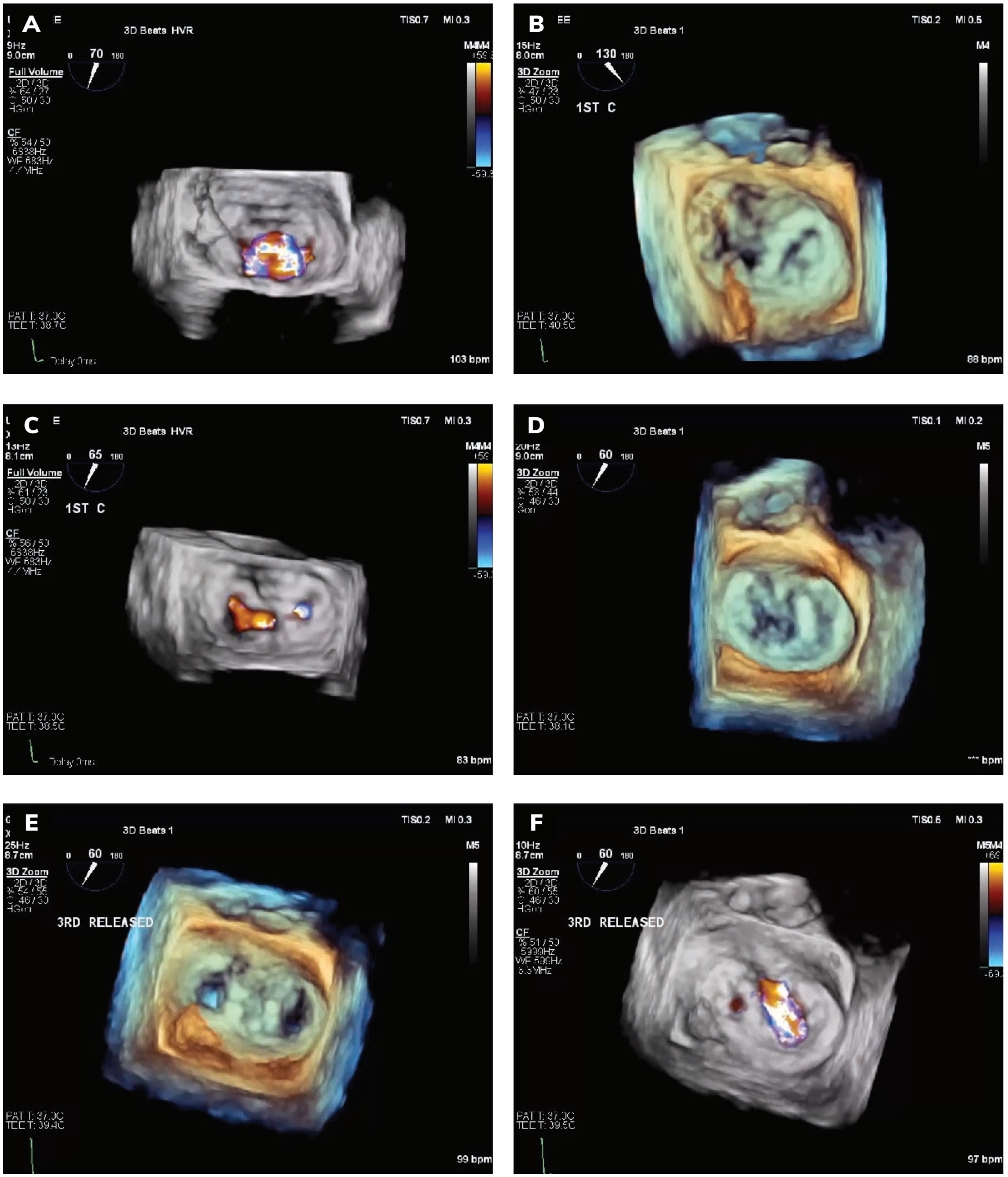


Figure 4 (video). Case 2: Malrotation and SLDA

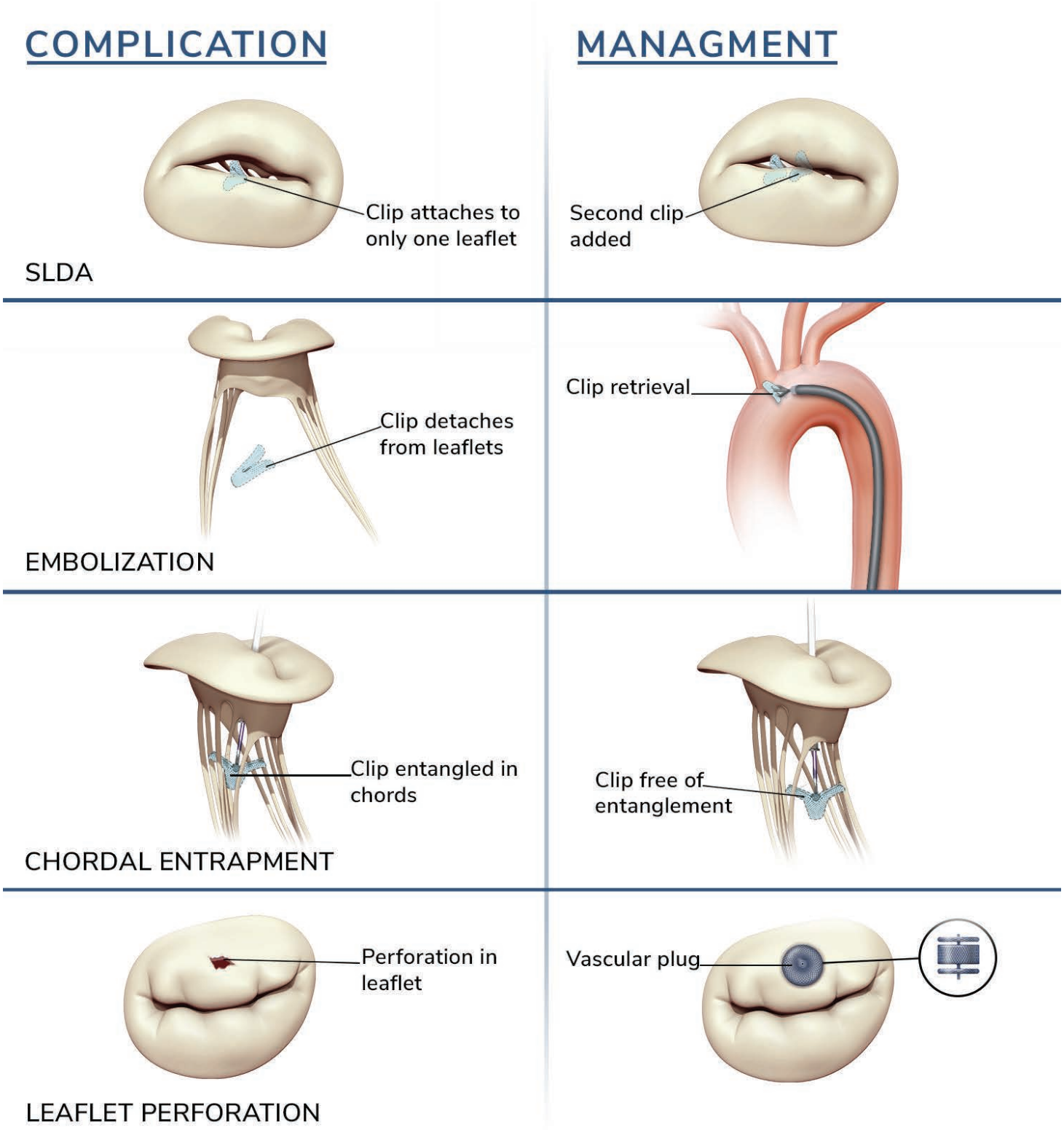
(A) Baseline severe secondary mitral regurgitation originating from the medial aspect of A2/P2. (B) TEER of the medial regurgitant jet, with deployment of a MitraClip with a clockwise malrotation. (C) TEER with satisfactory reduction in MR. (D) Two weeks after the procedure the patient experiences recurrent heart failure symptoms and a TEE shows SLDA. (E, F) SLDA treated with clips alongside the detached clip.

SLDA management

Treatment of SLDA is generally recommended due to the significant resultant mitral valve regurgitation and the risk for device embolization. Treatment may entail:

- Additional TEER devices
- Vascular occluders
- Surgical repair

Additional TEER devices. The most common way SLDA is managed is by adding additional clips alongside the detached clip.[5,11,13,17-19,24,25] (central illustration). In addition to treating the mitral regurgitation, this maneuver serves to stabilize the mitral valve leaflets, thereby reducing excessive motion in the region adjacent to the clip, and provide direct mechanical contact that stabilizes the SLDA device.



Central Illustration: SLDA Management

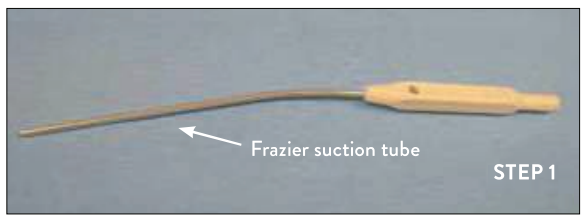
Vascular occluders. In attempting to stabilize the SLDA clip, a significant residual leak may form between the new clips and the detached device. Treatment of the focal regurgitation has been described using vascular plugs,[11,16] but the risk for further complications and the long-term outcome of this approach is unknown. As with paravalvular mitral leaks, incomplete treatment of the regurgitation caused by SLDA using more clips or a vascular plug can lead to high velocity jets that can cause hemolytic anemia,[14] as shown in Case 1 in the video in Figure 4F.

Surgical repair. Open valve surgery[1,8,12,19] followed by valve replacement or repair has been successfully reported to treat SLDA. The clip mechanism of the MitraClip can be released by using a suture to pull up on the lock harness while applying force to pry open the clip arms (Figure 5). More often, however, the clip and leaflet need to be surgically excised. This has been accomplished using a minimally invasive approach with a robotic system to remove the clip and perform mitral annuloplasty, edge-to-edge repair, and placement of artificial chordae.[15]

CLIP UNLOCK TECHNIQUE

RECOMMENDED ACCESSORIES:

1. 8 Fr suction tube such as Frazier suction tube.
2. 30" (76.2 cm) long braided suture such as 2-0 Tevdek II suture.

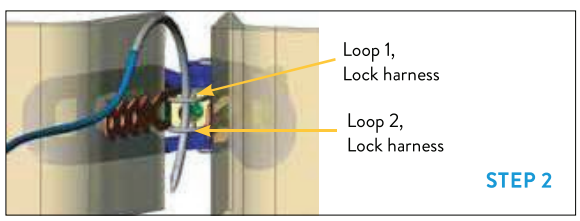


STEP 1

Remove the 'stylet' within the suction tube, then straighten as desired.

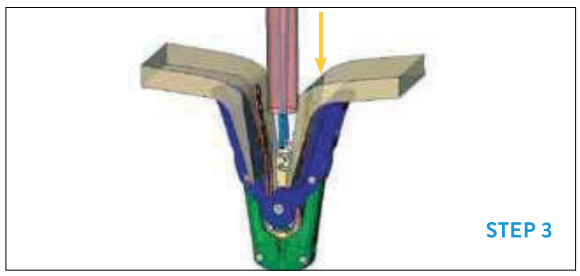
STEP 2

Use the needle end to pass the 2-0 suture [at least 30" (76.2 cm) long] through both loops of the lock harness. Remove the needle from the suture.



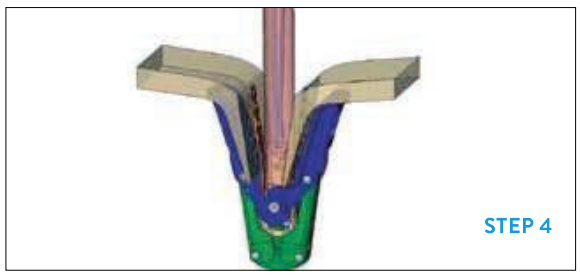
STEP 3

Use suction to assist advancing the 2-0 suture through the suction tube. Hold both ends of the suture, then advance the suction tube toward the clip.



STEP 4

Fully advance suction tube into clip while tensioning sutures. This suture tension should unlock the clip. Clamp suture to maintain tension.



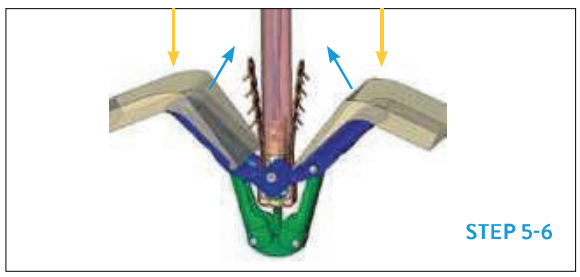
STEP 5

Using a blunt instrument, apply pressure (shown by yellow arrows) on atrial surface to open clip arms to approximately 90°.

- If clip is difficult to open, squeeze tips of arms together while maintaining tension on suture, then reapply pressure on atrial surface to open clip arms to approximately 90°.

STEP 6

After opening the clip, lift the grippers (in direction shown by blue arrows). With the grippers lifted, extract the leaflet, then remove the clip.



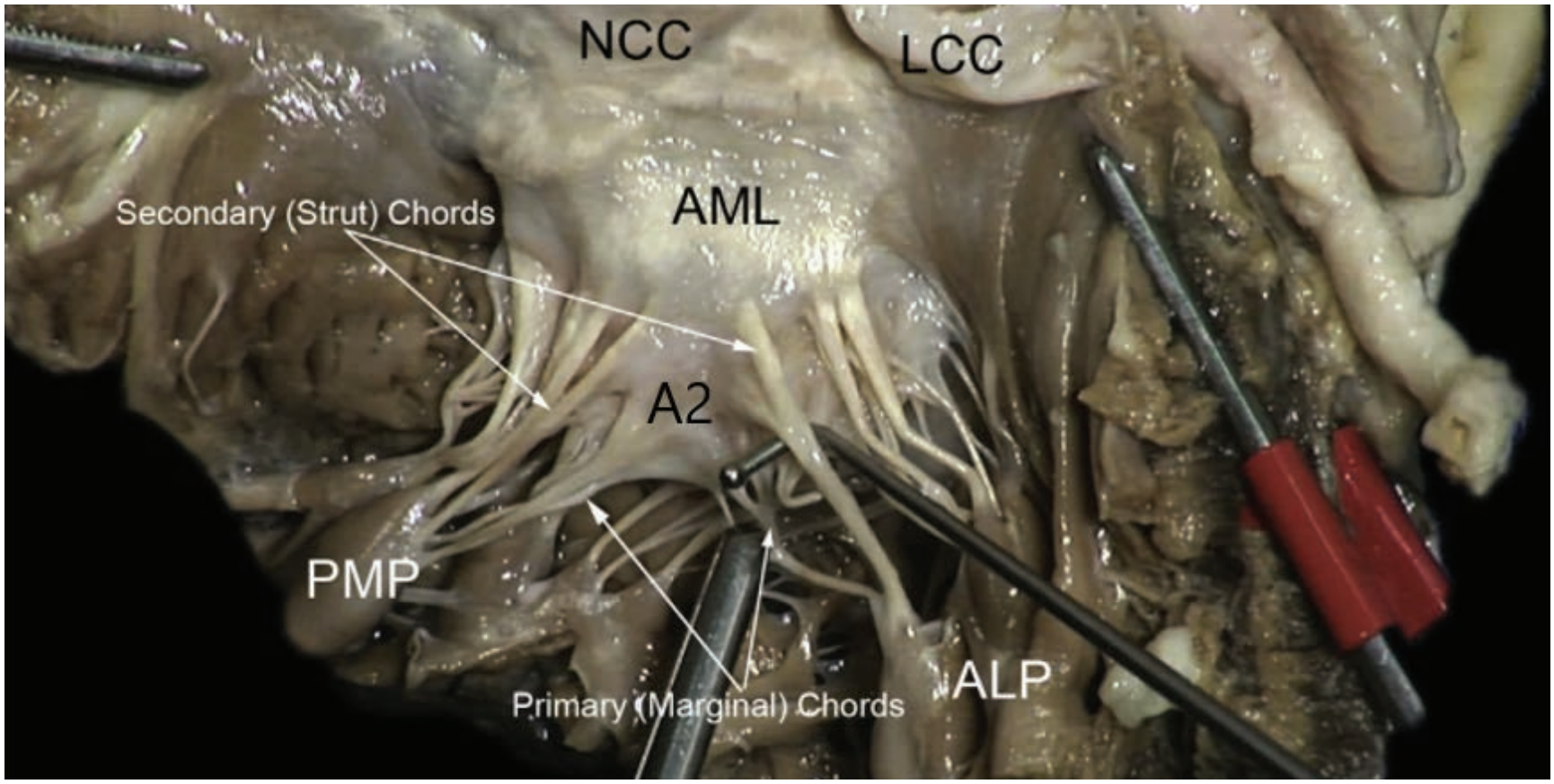
Source: MitraClip Device Explant Report, Version 1.0, March 1, 2010 (IDE G030064 / PMA - M080023-M004).

Figure 5. MitraClip Explant Recommended Procedure: Clip Unlock Technique

(used with permission from Abbott)

Chordal entanglement

The mitral apparatus consists of the mitral valve leaflets, the annulus, chords, and papillary muscles. Chordae tendinae include primary and secondary chords (Figure 6). Primary chords attach directly to the free edge of the anterior and posterior mitral leaflets. Secondary chords attach to the body of the leaflets. The center of the mitral valve, at the A2/P2 coaptation, typically is free of chordal attachments and is sometimes referred to as the 'chord free zone.' Any medial or lateral deviation from the center of the A2/P2 coaptation has significant chordae, hence the higher risk for chordal entanglement in the mitral valve commissures. Furthermore, extensive variability in the anatomy of chordal structure presents an important challenge that needs to be carefully evaluated at the time of the procedure.*ALP- anterolateral papillary muscle; AML- anterior mitral leaflet; LCC- left coronary cusp; NCC- non-coronary cusp;*



PMP- posteromedial papillary muscle

Figure 6. Mitral Valve with Chordal Attachments

Pathologic specimen demonstrating the relationship between the anterior mitral leaflet and primary and secondary chords. The center of the leaflet (A2) is relatively free of chords.

Operators must exercise caution to avoid entanglement of the clip arms or grippers with mitral valve chords. While several maneuvers may allow a safe removal of the TEER device if entanglement occurs, it may result in cardiac injury, inability to remove the device, and conversion to surgical intervention. While surgical bailout in contemporary TEER is very low, chordal entanglement and attempts to remove a device can cause chordal and papillary muscle rupture, or leaflet rupture leading to severe acute mitral regurgitation. In one study of patients with failed TEER undergoing surgery, 3 of 9 patients had papillary or chordal rupture as the cause for recurrent mitral regurgitation. Such patients can present emergently with cardiogenic shock, associated with a high 33% surgical mortality.[26]

Causes and prevention strategies

Several anatomic characteristics and procedural factors are anecdotally associated with a higher risk of entanglement with the subvalvular apparatus (Table 2). In the pre-procedural planning stage, a careful and thorough assessment should identify the presence of primary or secondary chords at the intended grasping site.

Table 2. Anatomic and Procedural Factors That May Increase the Risk of Entanglement with the Mitral Subvalvular Apparatus

ANATOMIC FACTORS	PROCEDURAL FACTORS
• Small ventricle • Treatment of MR in the medial or lateral commissure • Multiple primary chords at the site of grasping	• Rotation and manipulation of the device in the ventricle • Inadvertent rotation of the device while advancing into the ventricle • Deployment of multiple clips • Excessive opening of the device arms in the ventricle

Strategies for reducing the risk of entanglement with mitral valve chords include:

- Assessing the device trajectory
- Adjusting device orientation before and during valve crossing
- Avoiding excessive opening or premature deployment of device apparatus

Assessing the device trajectory (Figure 7A). As the device is advanced across the mitral valve, unplanned medial or lateral movement can lead to the device becoming entangled in the dense chords in the commissures. Attempts to correct the device position in the ventricle further increases the risk of chordal entanglement. Prior to crossing the mitral valve, using the bi-plane function of the TEE, small back and forward motions are used to evaluate the medial-lateral and anterior-posterior dive of the device to ensure coaxial advancement across the valve. For further discussion of this topic, see Chapter 10. Left Atrial Steering, Clip Positioning, and Trajectory.

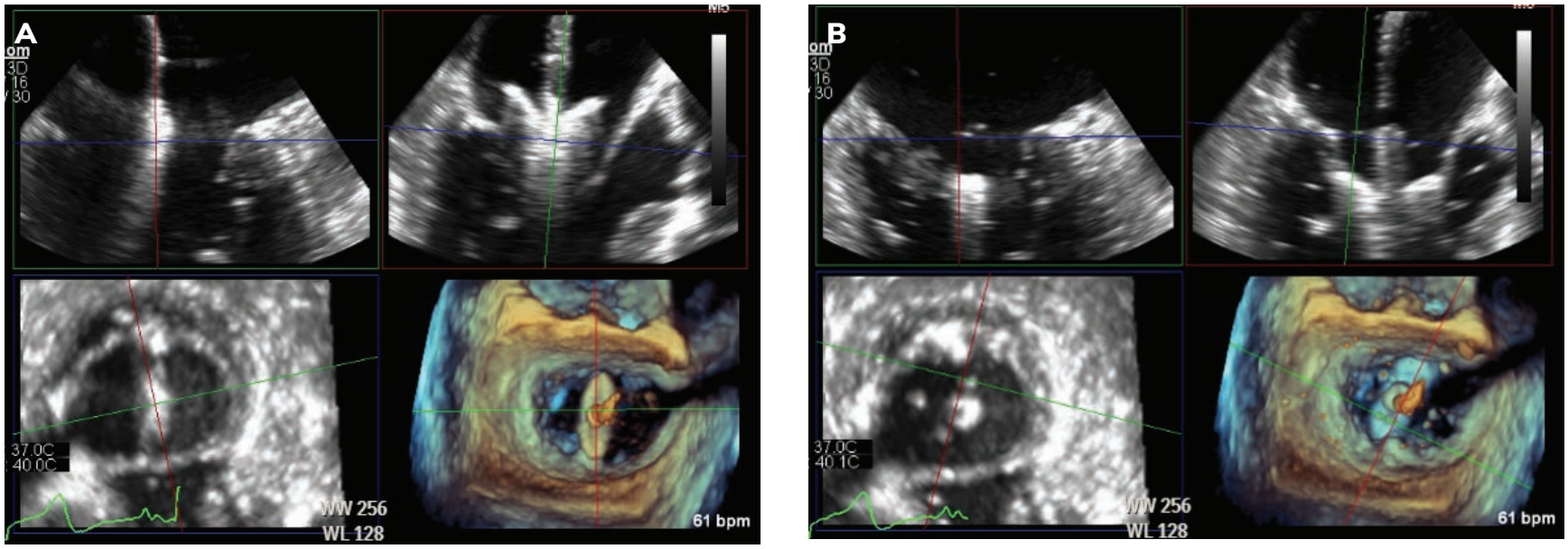


Figure 7. Multi-plane TEE Images of the MitraClip Device

Commissural, long-axis, short-axis, and 3-D views of the MitraClip device (A) prior to crossing the mitral valve, and (B) during travel from the atrium to the ventricle. Careful inspection of these images demonstrates two problems with this set up. First, there is excessive anterior dive, as seen in the top right image of panel B. Second, there is undesired clockwise device rotation as the MitraClip travels from the atrium to the ventricle, as seen in the 3-D surgeon's view image of the mitral valve in panel B. Recognition of these two problems prior to delivering the MitraClip into the ventricle allows for retraction of the device into the atrium and correction of the anterior dive and untoward clockwise rotation. Delivery of the device across the valve without correcting these errors would result in excessive manipulation of the device in the ventricle, thereby increasing the risk of entrapment with subvalvular structures.

Adjusting device orientation before and during valve crossing (Figure 7B). Minor adjustments in device rotation can generally be safely performed in the ventricle; however, excessive device rotation is strongly discouraged as this can result in chordal entanglement. Furthermore, it is not uncommon for the device to rotate as it is advanced. TEE multi-plane view is used to carefully optimize the rotation of the TEER device in the atrium and as it travels into the ventricle. Recognition of unfavorable device trajectory or malrotation of the device at this stage should be corrected and/or the device retracted into the atrium, if significant malrotation is observed. Extensive rotation in the ventricle, especially in the medial and lateral commissures, is one of the main causes for chordal entanglement.

Avoiding excessive opening or premature deployment of device apparatus (Figure 8). During leaflet capture, the device arms should be open to approximately 120 degrees (each arm 60 degrees from the delivery catheter). Maneuvering the clip in the ventricle with clip arms open beyond this angle increases the risk of interaction and entrapment with subvalvular structures. With the longer clip arms of the MitraClip XTR or Pascal devices, this risk is further increased. Additionally, premature release of the leaflet grip arms may lead to their entanglement with the chordal apparatus while the device is in the ventricle.

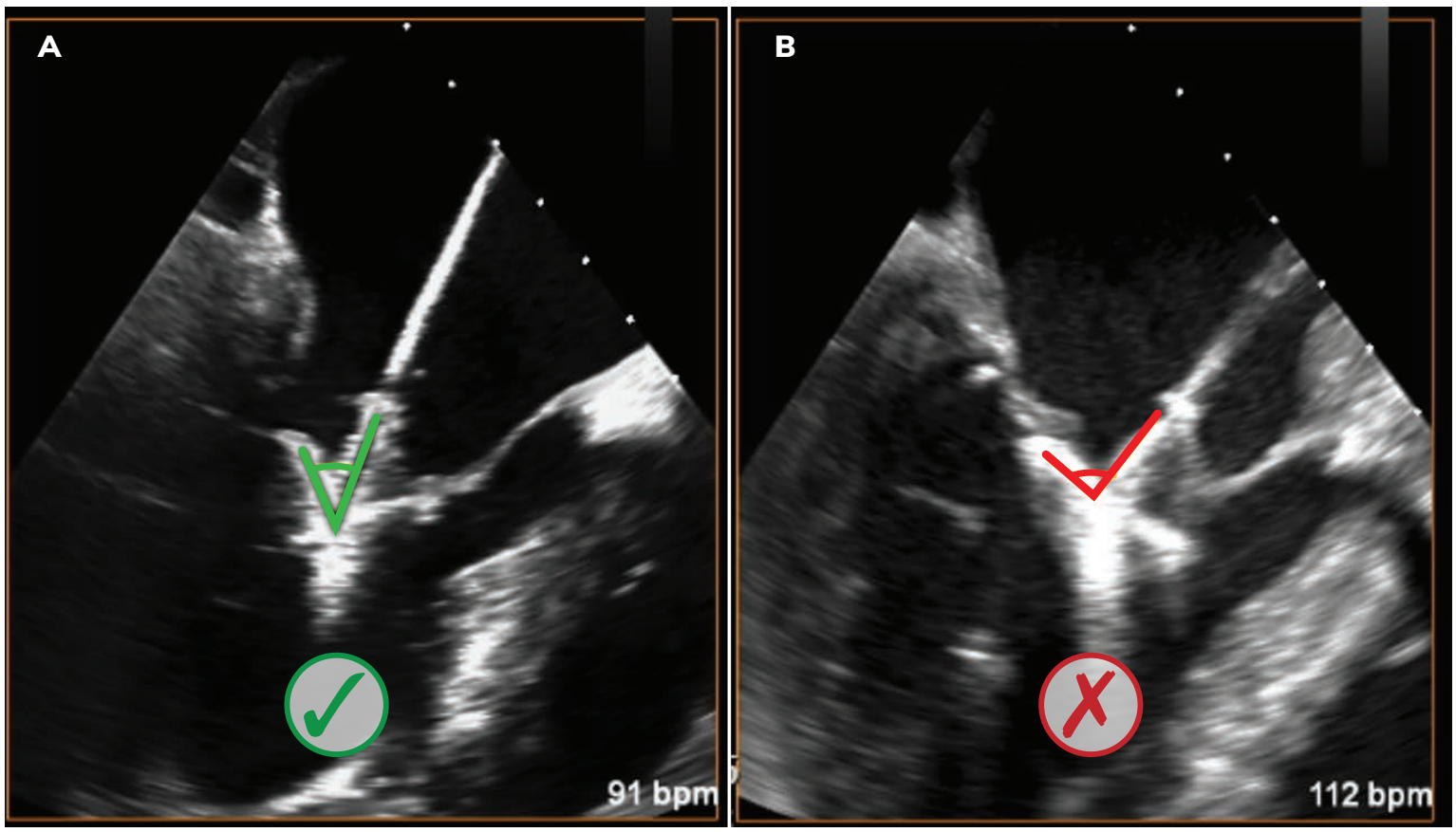


Figure 8. TEE Images of MitraClip Prior to Grasping Mitral Valve Leaflets

(A) Appropriate opening of the device, with an approximate angle of 60 degrees between the delivery catheter and each grasping arm. (B) Excessive opening of the device arms, with an almost 90-degree angle between each grasping arm, increases the risk of interaction with subvalvular apparatus and entanglement with chords.

Identifying chordal entanglement

Identifying chordal entanglement can often be quite challenging. The first clue may be a lack of responsiveness from the TEER device as the operator attempts to manipulate the device in the ventricle. This can be confirmed using fluoroscopy and TEE, which may show the device moving only slightly as the operator attempts to advance, retract, or rotate the device. Chordae can sometimes be seen entangled with clip arms or grippers on TEE (Figure 9).[6]

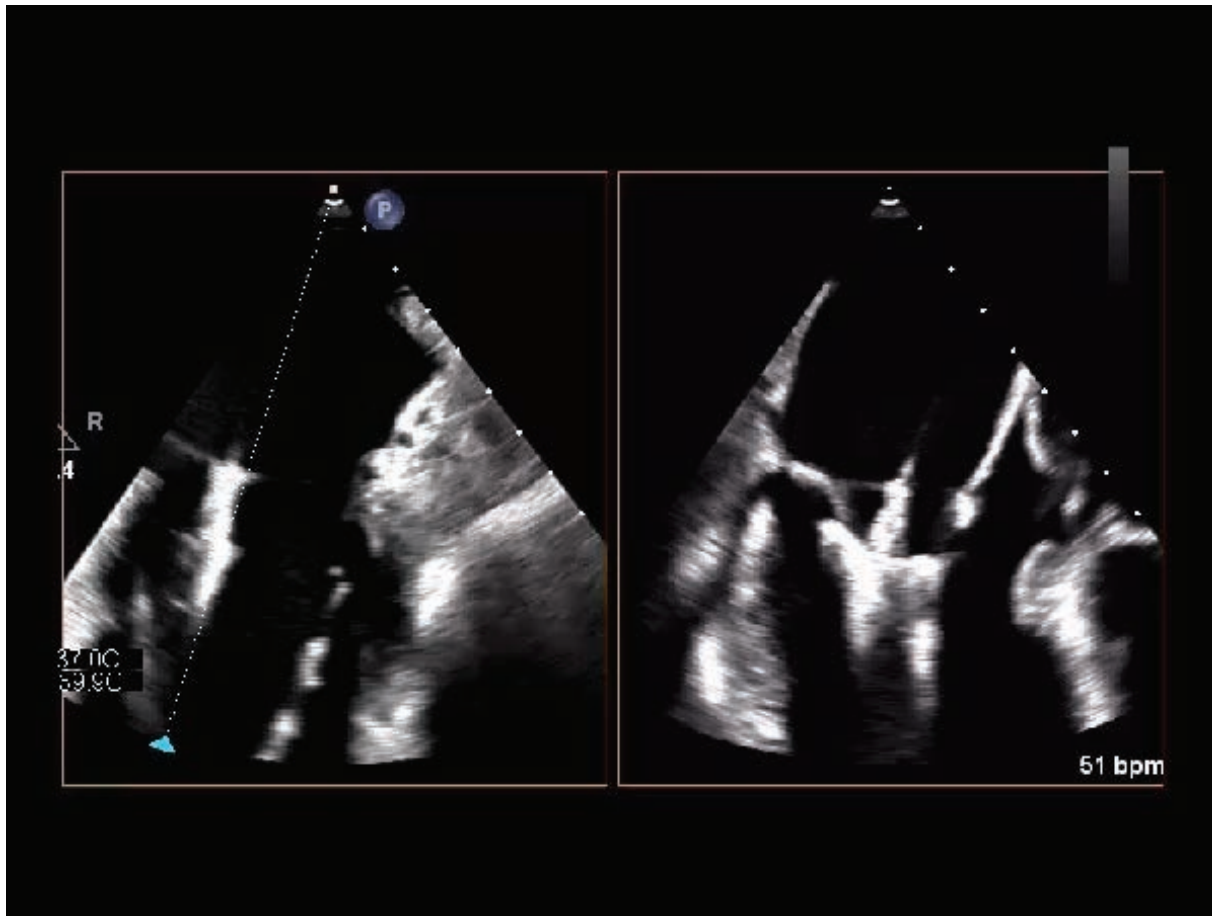


Figure 9 (video). Clip with Gripper and Clip Arm Entangled with Anterior Leaflet Chordae

Managing chordal entanglement

Once chordal entanglement is confirmed, the operator needs to proceed carefully to avoid worsening entanglement. Similarly, attempts to pull the MitraClip forcefully back into the atrium when resistance is met are also ill-advised. This maneuver may result in tearing of the chords, papillary muscle rupture, or leaflet injury.

Disentangle device. Very gentle and very small movements of the system are favored in attempting to dislodge the TEER device from the chords. An operator can potentially 'reverse' the set of movements that lead to the entanglement. Thus, it is important to remember the series of moves that preceded the entanglement. For example, if the operator had just pulled the device upward, made a slight counterclockwise rotation, and pulled it medially, then the operator should move the device laterally, make a slight clockwise rotation, and push the device inward. Sometimes by slightly torquing the delivery system back and forth anteriorly and posteriorly with careful rotation of the arms, or 'jiggling' the device, the clip arms will pull away from the chordal structures. These maneuvers should be performed with extreme care and thoughtfulness, as it is possible to further entangle the device with each movement.

Eversion and retraction into the atrium. If maneuvers to disentangle the device are unsuccessful, the MitraClip must be everted in preparation for retrieval of the device back into the atrium (Figure 10).

1. Under direct visualization using TEE guidance and fluoroscopy, slowly open the MitraClip arms to the everted position, 270-degree angle.
2. Once everted, slowly retract the device handle to bring the device across the mitral valve, into the left atrium, in the everted position using TEE and fluoroscopy to confirm that the device is moving freely (Figure 11). If resistance is met, attempt advancing the device back into the ventricle, rotating the device slightly, and gently 'jiggling' it.

3. Once the device is withdrawn, carefully assess the mitral valve with TEE for any damage to the valvular structures.
4. Perform an assessment of clip functionality to ensure that it remains fully operational before reattempted grasping using the clip.

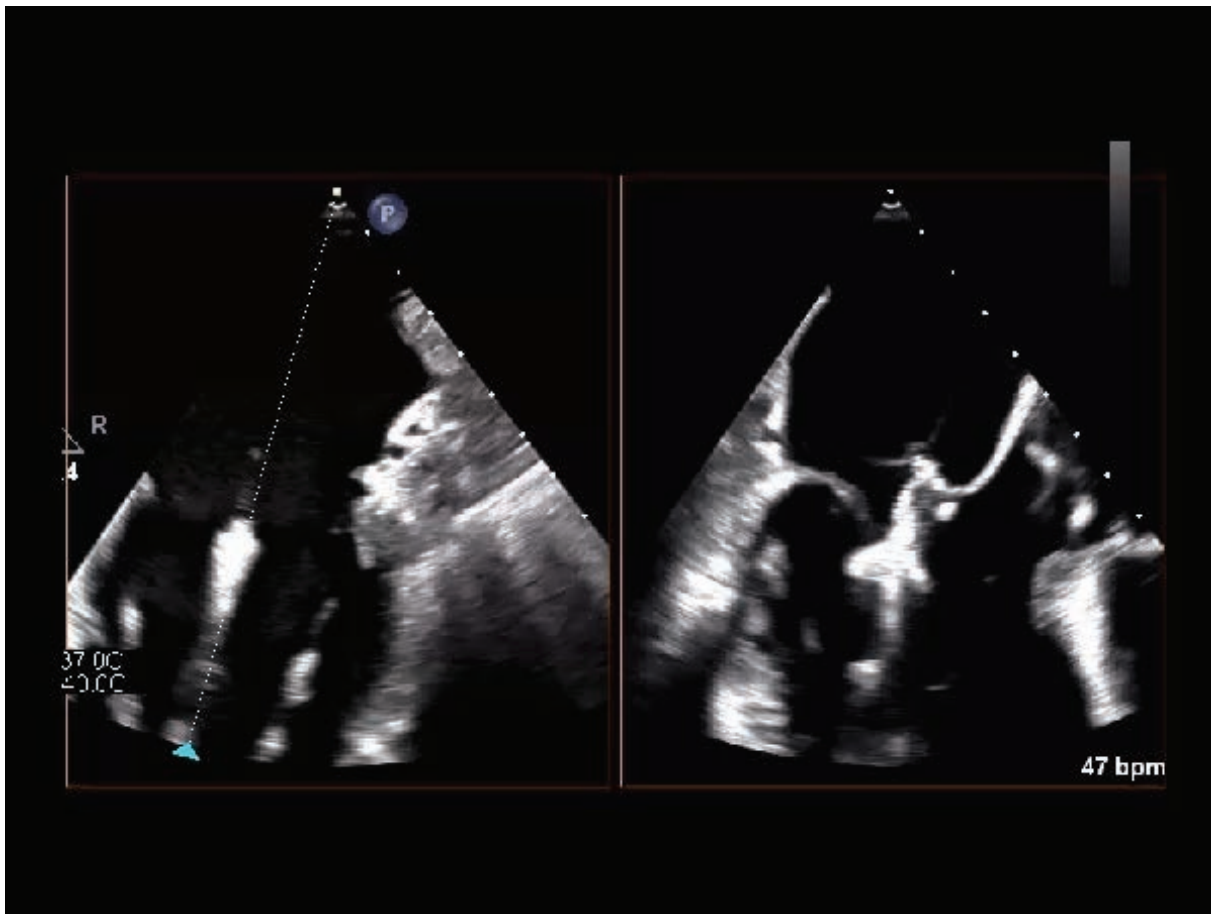


Figure 10 (video). Eversion of Clip and Withdrawal into Atrium

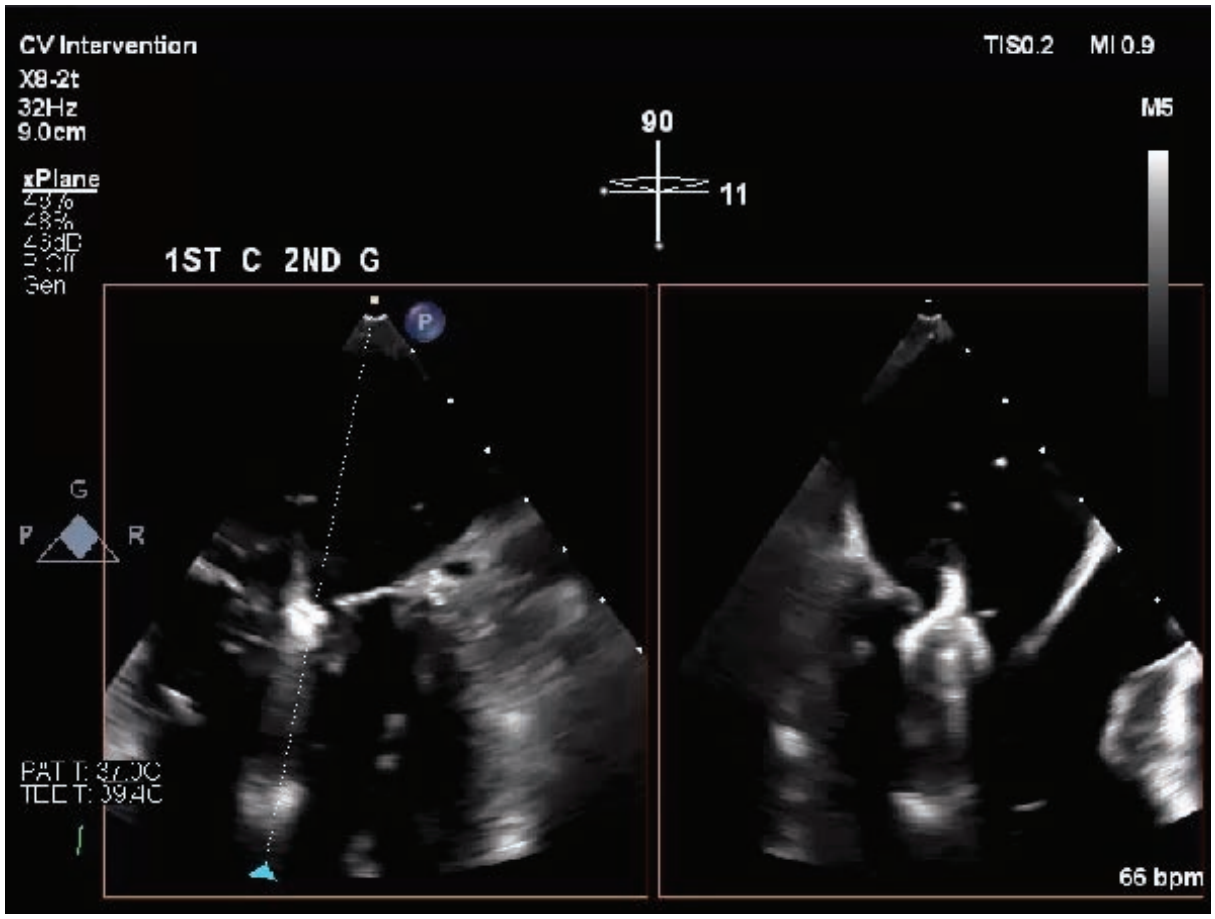


Figure 11 (video). Chordal Damage and Tearing While Trying to Disentangle a Clip from the Posterior Chordae

Device embolization

Device detachment from one leaflet is one of the most common complications of TEER of the mitral valve, but complete device detachment and embolization occurs infrequently, with clinical studies reporting a rate of zero or <1%.[1-10,20] TEER device embolization happens most commonly during the procedure, but late embolization days or even months after the index procedure has been reported.[27-29] By virtue of the device being deployed in the arterial system, embolization results in migration of the device to a major peripheral artery (Figure 12). Cases of device embolization to the axillary, renal, and coronary arteries have been reported.[27-29] The clinical consequence of device embolization to a peripheral artery is ischemia in the limb or organ perfused by the artery.

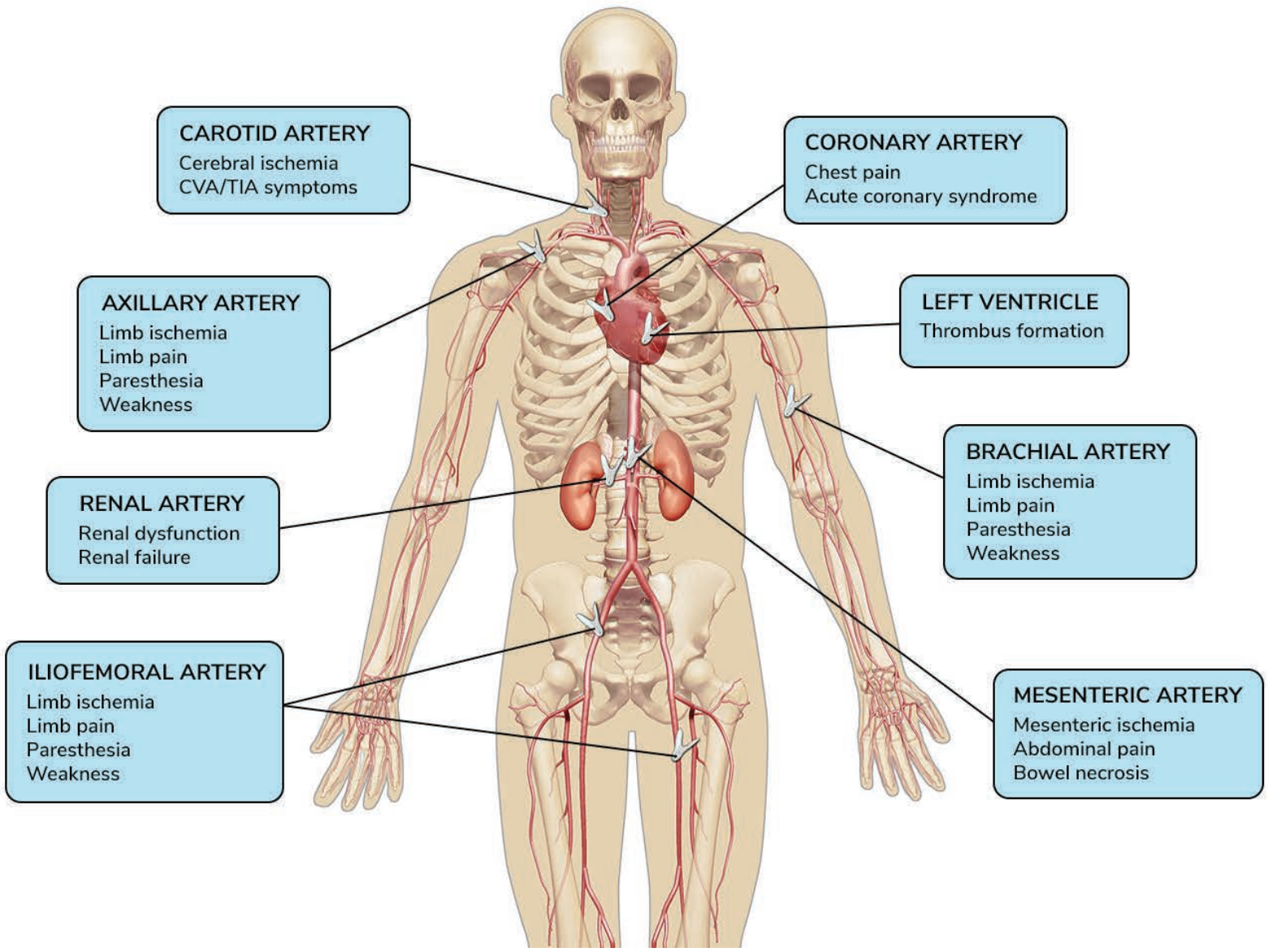


Figure 12. Clip Embolization and Potential Clinical Consequences

Prevention strategies for device embolization

The risks for complete embolization are similar to that of SLDA and the best practices described in the section on SLDA apply here. Untreated SLDA during a procedure potentially leads to an unstable device that is more likely to embolize. Checking the locking mechanism prior to removing the lock or gripping lines helps prevent embolization due to device failure, and if needed, the attached lines can be used to pull the device back to the delivery system for retrieval.[25] Otherwise, the device needs to be retrieved percutaneously with snares or surgically.

Management of device embolization

There are no guidelines on the management approach to device embolization. The small number of cases reported in the literature precludes generalization of an optimal treatment strategy. As such, treatment is generally individualized to each scenario. Device retrieval via a percutaneous approach or an open surgical approach are the two management options. If a percutaneous approach is pursued, extreme care must be taken when snaring and retrieving the device to avoid re-embolization. The approach for device retrieval after embolization is delineated below.

Snaring device from left atrium

In the event of intraprocedural device embolization to the atrium, device retrieval can be accomplished as follows.[25]

1. The steerable guide catheter for the TEER system can be left across the atrial septum and the dials on the sheath can be used to direct the tip toward the embolized device. The working length of the 24 Fr guide catheter for the MitraClip is 80 cm and the inner shaft diameter is 16 Fr (5.5 mm) and will allow for one or two 100-120 cm 6 Fr catheters to be passed. This is too long to allow passage of a commercially available steerable sheath.
2. If the TEER guide catheter cannot be used, remove the guide catheter, and place a large bore venous sheath (at least 16 Fr, but a 24 or 26 Fr is ideal for hemostasis and optimizing the chances for clip retrieval). Use TEE guidance and a transseptal system to re-engage the iatrogenic ASD and place a steerable sheath (eg, Agilis, Direx, FlexCath).
3. Using a JR4 catheter, a 20-30 mm snare can be used to capture the device. If the device is moving around the atrium, a second snare or catheter may be needed to pin down the device so the primary snare can capture it.
4. Retract the device into the sheath.

    - If using the 24 Fr TEER guide sheath it may be possible to orient the device to retrieve it into the guide sheath in the left atrium. When using a single snare, the MitraClip may not have the proper orientation and may get caught on the TEER guide sheath (Figure 13). A second snare can be advanced through the guide to snare the device and help align the clip for retrieval into the sheath.
    - If using a smaller 8.5-10 Fr steerable sheath, the clip will need to be pulled back across the atrial septum and into the large venous sheath. See two snare technique as described below (Figure 15).

Figure 13. Clip Caught on Guide Sheath During Retrieval

From: Stripe BR, Singh GD, Smith T, Rogers JH. Retrieval of a MitraClip from the left atrium using a two-snare technique: Case report and review of the literature. Catheter Cardiovasc Interv. 2020;96(1):210-214.

Figure 14 (video). Clip Caught on Sheath Using a Single Snare

From: Stripe BR, Singh GD, Smith T, Rogers JH. Retrieval of a MitraClip from the left atrium using a two-snare technique: Case report and review of the literature. Catheter Cardiovasc Interv. 2020;96(1):210-214.

Figure 15 (video). Device Retrieval Using 2 Snares

From: Stripe BR, Singh GD, Smith T, Rogers JH. Retrieval of a MitraClip from the left atrium using a two-snare technique: Case report and review of the literature. Catheter Cardiovasc Interv. 2020;96(1):210-214.

Snaring device from peripheral arterial site

If a device has embolized to the left ventricle or a peripheral artery, a percutaneous approach for device retrieval may be attempted.

1. Obtain large bore arterial access, preferably via the femoral artery. Use of a 26 Fr sheath through the femoral vein has been previously described.[25] A 16 Fr arterial sheath may be adequate to snare a device if it is coaxial with the sheath and has remained in the closed position after embolization.
2. Use a guide catheter with a J-wire to access the peripheral artery where the device is lodged. Selection of a catheter shape depends on which artery is being accessed. A JR4 provides a neutral shape and is a reasonable starting point for most peripheral arteries.
3. Through the catheter, deliver a snare to capture the device. Successful use of a 25 mm and 30 mm Amplatz goose neck snare has been previously described.[25,28] If a single snare is used, the MitraClip may not enter the large bore sheath if it is snared in the center. This is due to a "T" configuration that prevents it from entering the large bore sheath (Figure 14). A 2-snare technique to provide additional support and reduce the risk of device re-embolization has been reported and is encouraged.[25] The 2-snare approach may require two operators. Of note, a bioptome proves too small to securely grasp the embolized device and is not a recommended strategy.
4. Following successful snaring of the embolized device, slowly retrieve the device to the large bore sheath. The device may be retracted into the sheath, depending on device orientation and sheath size. A 2-snare technique may be necessary to reorient the device to retract it into the sheath. (Figure 15) Alternatively, surgical cutdown may be necessary to remove the device from the body.

Summary

- Meticulous intra-procedural imaging with clear visualization of the device, leaflets, and subvalvular apparatus reduces the risk of complications during device delivery and deployment in TEER.
- SLDA is one of the most common complications of TEER and placing new clips alongside detached device is the preferred treatment for SLDA.
- Operators need to be familiar with the techniques to managed entangled and embolized TEER devices.

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CHAPTER 16
MitraClip After Surgical Mitral Valve Repair

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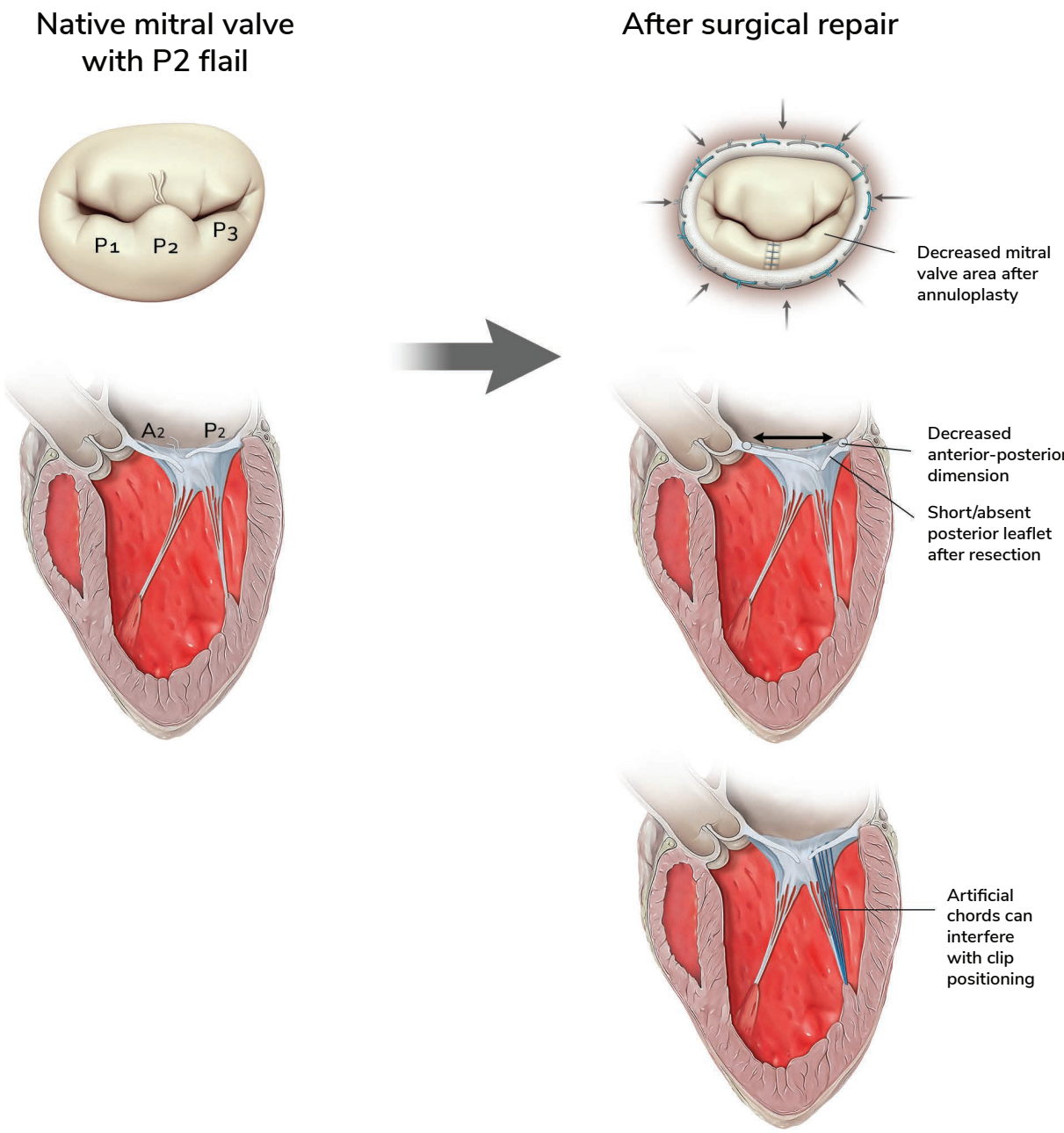
Background

Surgical mitral valve repair for primary MR generally consists of chordal replacement, leaflet resection, and annuloplasty. For secondary MR, surgical repair consists of an annuloplasty ring and sometimes cleft closure. When patients have recurrent MR after mitral valve surgery, several options exist to recorrect MR.

- Patients may have repeat surgery, and often undergo mitral valve replacement since the initial attempt at repair was unsuccessful.
- Transcatheter valve-in-ring therapy can be performed, but this depends on an adequate seal between the valve and annuloplasty ring which is not always possible due to large rings, highly elliptical rings, or risk of left ventricular outflow tract obstruction.
- MitraClip therapy can often be performed after failed mitral valve surgery in patients at high risk for reoperation, but several anatomic and technical factors must be considered. Recent registries have shown that in properly selected patients, TEER can be successfully performed for failed surgical mitral valve repair with a high degree of success.[1]



Central Illustration. Anatomic and Technical Factors

Residual mitral valve area and baseline gradient

Since mitral valve repair can involve leaflet resection (usually the posterior leaflet) and downsizing annuloplasty, the new baseline mitral valve area will be decreased and this may limit the ability to place clips due to risk of mitral stenosis. In some cases, patients will not tolerate even a single MitraClip.

Posterior leaflet length and angle

Since a portion of the posterior leaflet is often resected in surgical repair for primary MR, the resulting posterior leaflet length may be very short (<5 mm) or even absent on TEE imaging. If present, the posterior leaflet is often tethered vertically into the left ventricle. Grasping the posterior leaflet may be challenging and an "aorta hugger" trajectory may be required to grasp the posterior leaflet. In some cases, it may be feasible to grasp the posterior aspect of the annuloplasty ring instead of the posterior leaflet.

Chordal replacement

Patients may have artificial chordae tendineae surgically placed which may be prominent on the leaflet edge and interfere with the ability to grasp the leaflet at that location.

Case 1. MitraClip after robotically-assisted MV repair

A 78-year-old male with severe degenerative mitral regurgitation (DMR) with P2 flail and torn chords underwent robotic mitral valve repair via right chest port access with 2 PTFE chords placed to the posterior leaflet and a 33 mm Duran AnCore Annuloplasty band (Figures 1 and 2).

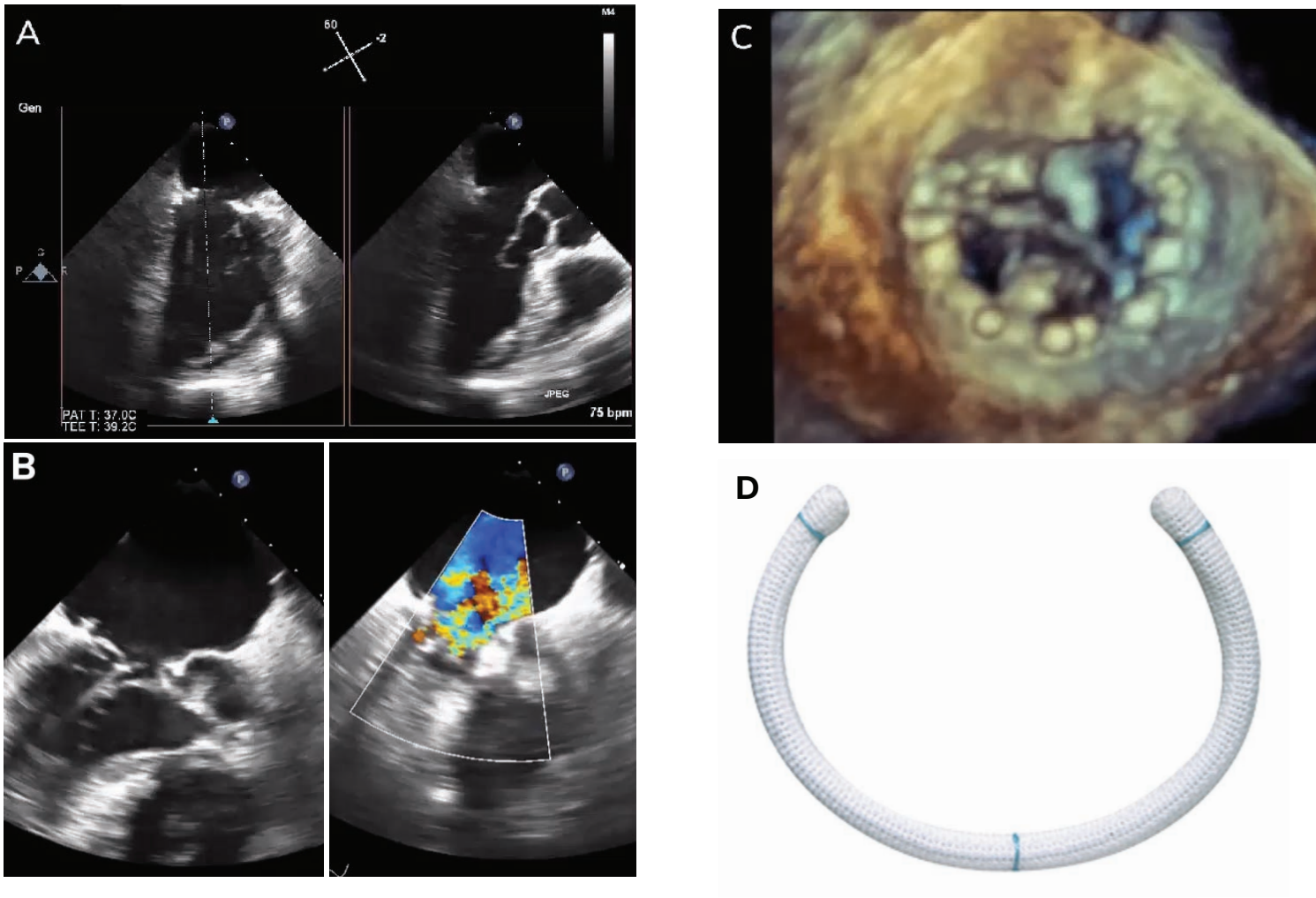


Figure 1 (videos). Case 1 Baseline Images and Duran AnCore Annuloplasty Band

(A) X-plane TEE view of recurrent P2 prolapse, bicomm view (left) and LVOT view (right); (B) TEE LVOT view of P2 flail with severe eccentric MR; (C) 3D TEE enface view; (D) 33 mm Duran AnCore annuloplasty band

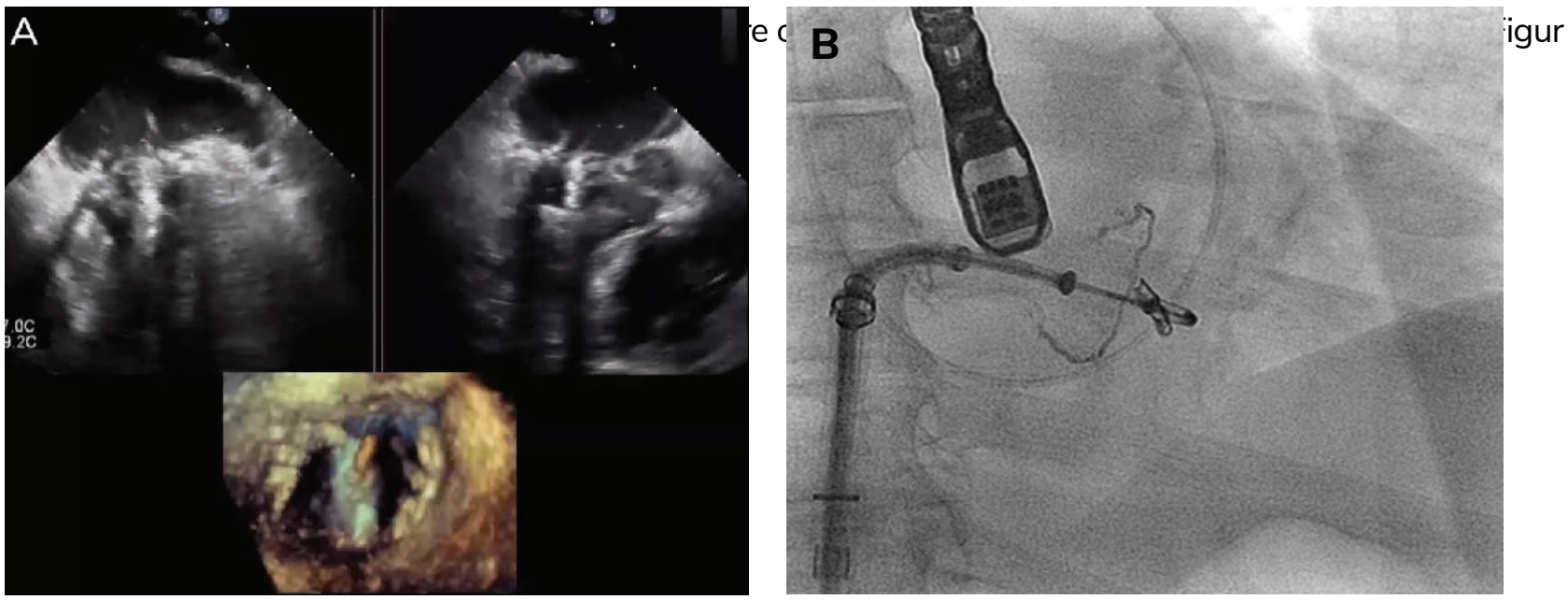


Figure 2 (videos). Case 1 MitraClip Placement

(A) MitraClip aligned, centered over P2, and entering left ventricle in TEE X-plane and 3D enface views; (B) MitraClip centered in annuloplasty ring on fluoroscopy; (C) TEE LVOT grasping view

Six months after surgery the patient was noted to he 3). The patient had successful TEER with placement of a single NT MitraClip and final MR grade trace. Note some shadowing on imaging due to the annuloplasty ring which may require a lower esophageal imaging window for improved leaflet visualization.

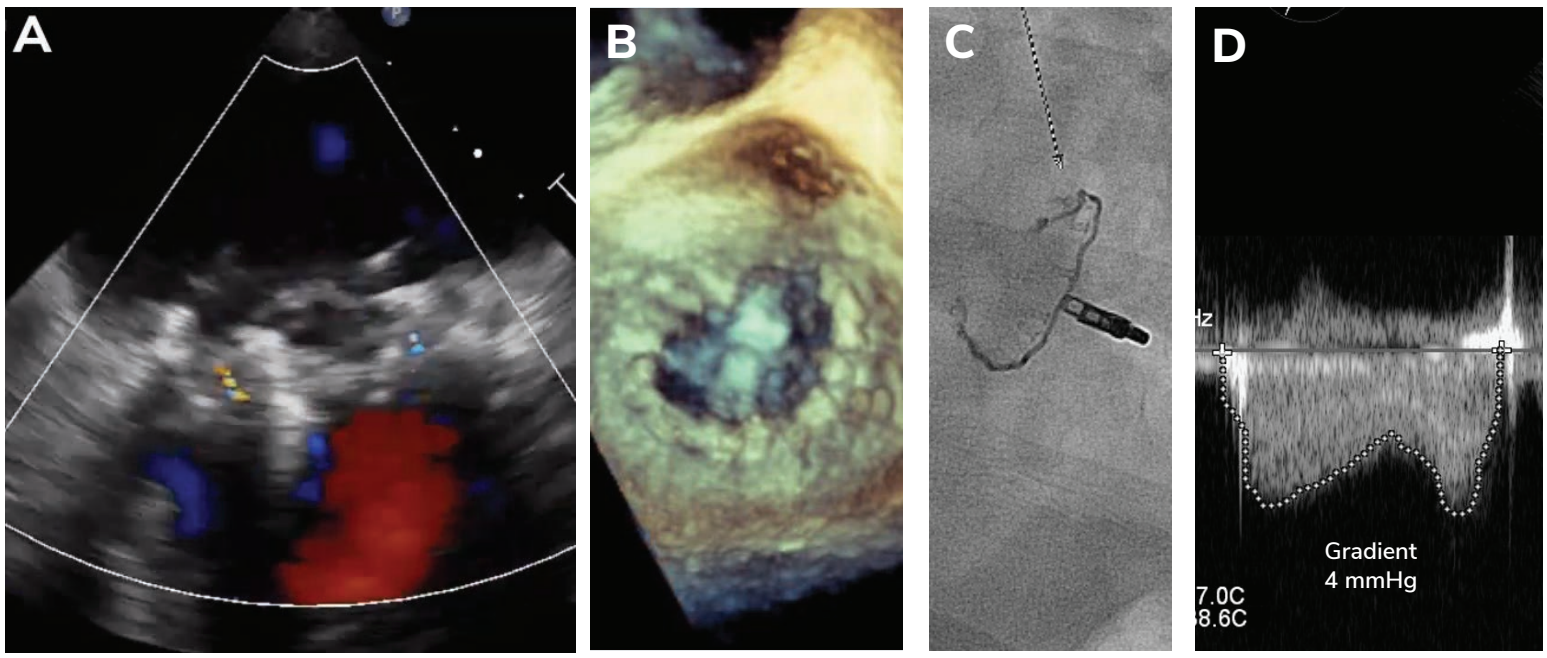


Figure 3 (video). Final Result for Case 1 with Trace Residual MR

(A) Bicomm TEE view with color showing trace residual MR; (B) 3D enface view; (C) Fluoroscopic view; (D) Final mean diastolic gradient 4 mmHg

Case 2. Edge-to-ring technique

A 68-year-old patient with idiopathic thrombocytopenia, severe AI, ascending thoracic aortic aneurysm, and severe MR with ruptured anterior leaflet chordae tendineae underwent surgical correction with median sternotomy and circulatory arrest. The patient had a #27 Magna AVR, #32 Dacron ascending aortic graft, 2 PTFE chords to A2 segment, and a #34 Physio II annuloplasty ring. Of note, the ring has a diameter of 4 mm which is graspable by the MitraClip device (Figure 4).

At 6-month follow-up the patient had recurrent dyspnea and was found to have a normally functioning aortic bioprosthesis, but severe recurrent MR due to severe MR with a highly retracted nongraspable posterior leaflet and failure of the anterior mitral leaflet to coapt. The MR jet was located laterally in the A1/P1 segment.

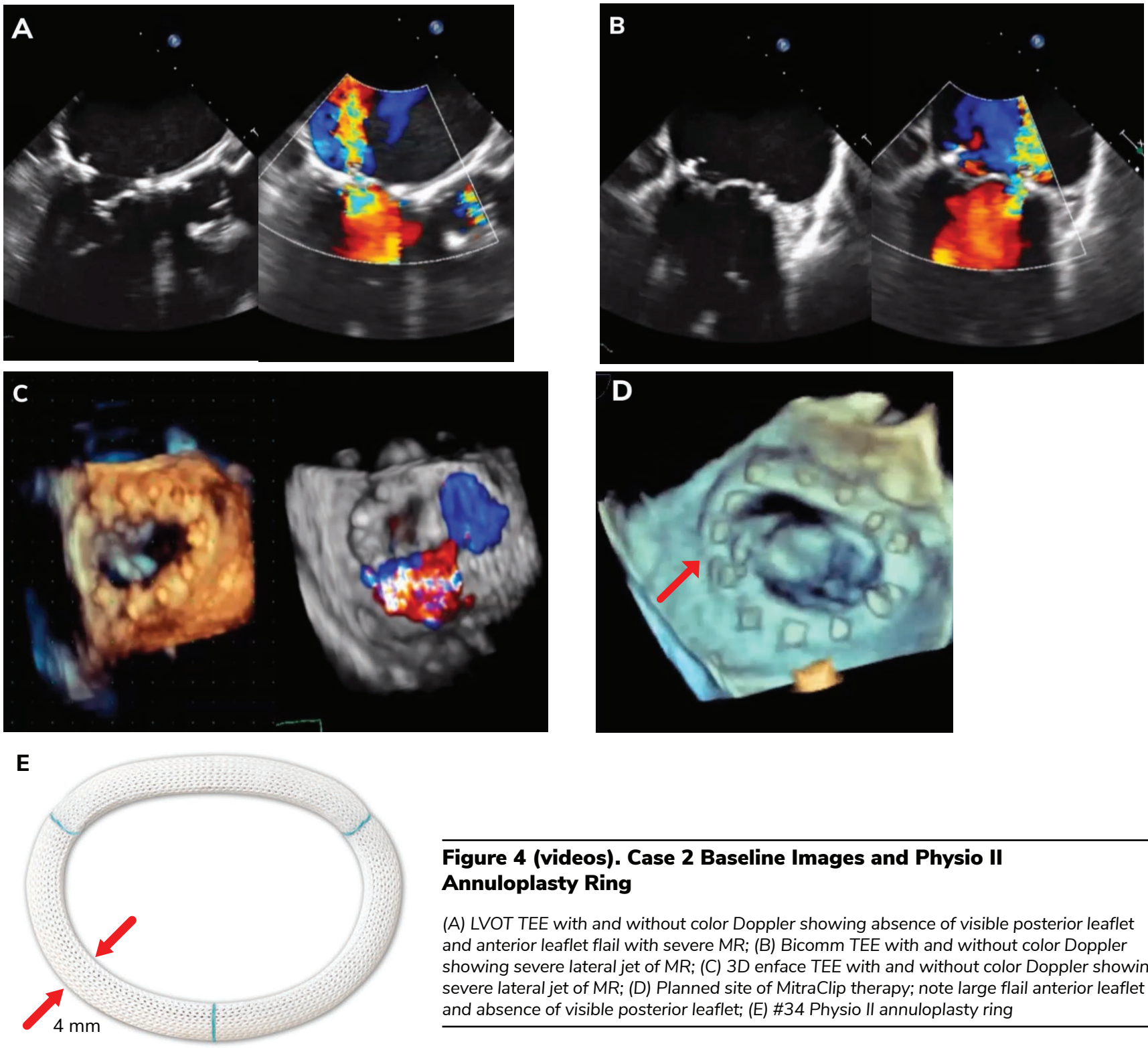


Figure 4 (videos). Case 2 Baseline Images and Physio II Annuloplasty Ring

(A) LVOT TEE with and without color Doppler showing absence of visible posterior leaflet and anterior leaflet flail with severe MR; (B) Bicomm TEE with and without color Doppler showing severe lateral jet of MR; (C) 3D enface TEE with and without color Doppler showing severe lateral jet of MR; (D) Planned site of MitraClip therapy; note large flail anterior leaflet and absence of visible posterior leaflet; (E) #34 Physio II annuloplasty ring

The patient underwent successful TEER with placement of two MitraClip NTs grasping the anterior leaflet and the posterior lateral annuloplasty ring restoring coaptation with reduction of MR from severe to mild, final mean diastolic gradient 6 mmHg (Figure 5). This case illustrates the “edge-to-ring” technique (Figure 6).

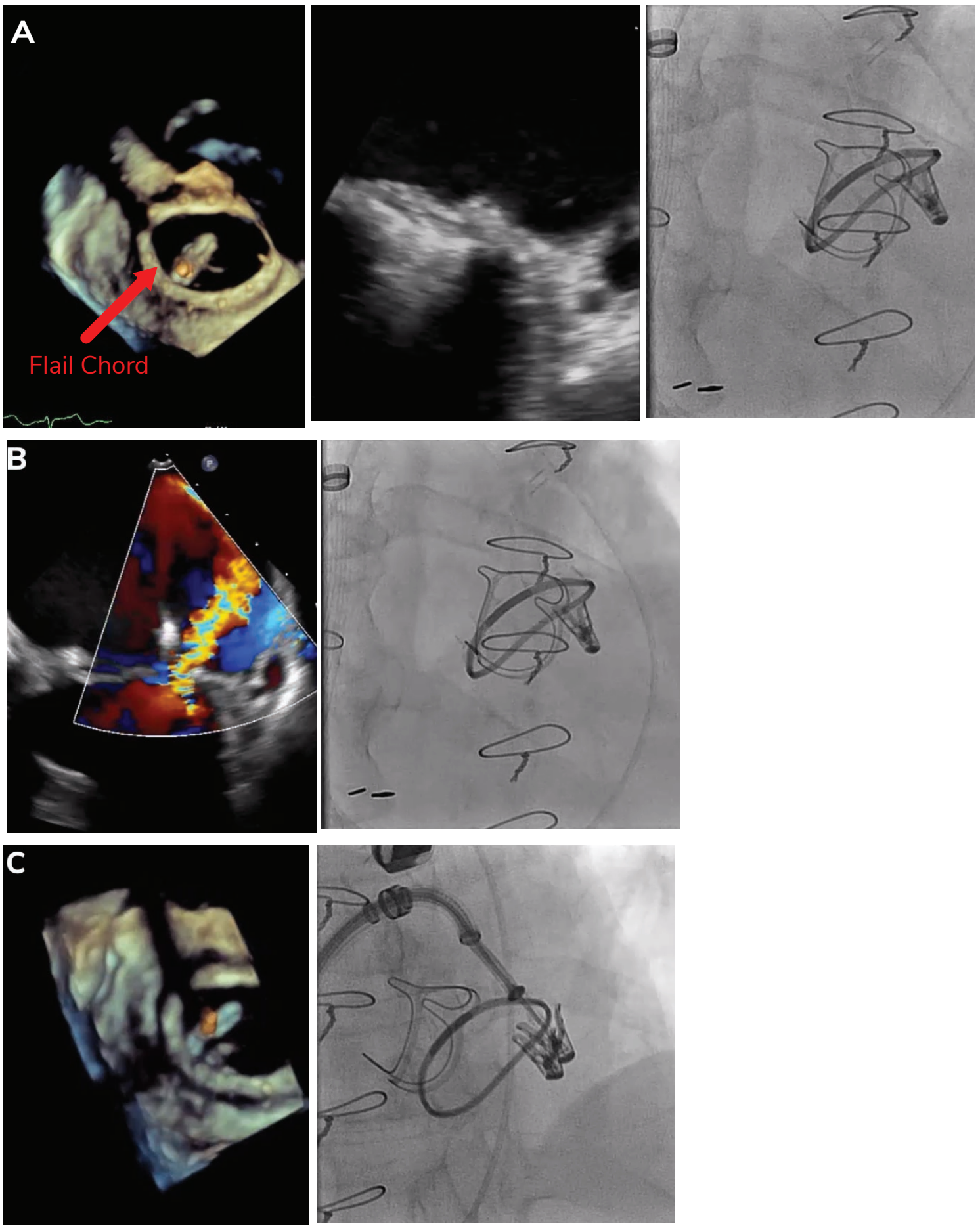


Figure 5 (videos). Case 2 Placement of 2 MitraClips

(A) ***First MitraClip:*** *3D enface showing alignment of clip (left); grasping view of anterior leaflet and posterior ring grasped (middle); fluoroscopic view of clip grasping anterior leaflet and posterior ring. (B)* ***After first MitraClip:*** *Residual jet of MR lateral to first clip after deployment in bicomm TEE view (left) and fluoroscopic view (right). (C)* ***Second MitraClip:*** *3D TEE enface alignment of second MitraClip just lateral to first clip (left) and fluoroscopic view of second MitraClip position (right)*

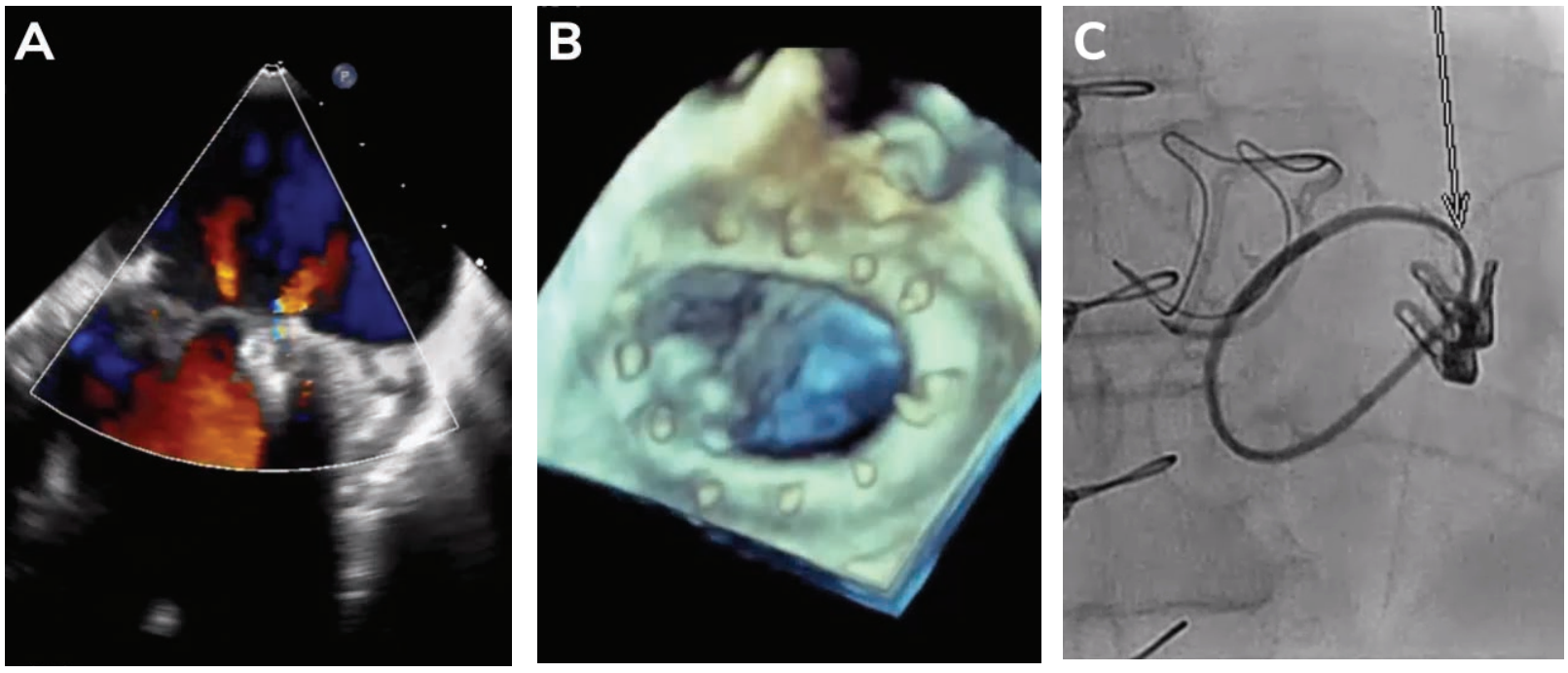


Figure 6 (videos). Final Result for Case 2: V Wave 45 mmHg Reduced to 13 mmHg

(A) Only mild residual MR in bicomm TEE view; (B) 3D enface view of 2 MitraClips attached to posterior lateral segment of annuloplasty ring; (C) Final fluoroscopic view

Case 3. Edge-to-edge repair post-annuloplasty

A 76 year-old woman underwent surgical mitral valve repair for severe degenerative MR with an annuloplasty ring (Physio II, 40mm) and P2 leaflet prolapse resection. Post-procedure MR was reduced to trace. However, the patient presented 6 years later with recurrent symptomatic severe MR. TEE revealed a large posterior leaflet prolapse affecting mainly P1 extending to P2. Baseline mitral mean gradient was 2 mmHg and area was 4.5cm^2 as measured by 3D. No ring dehiscence was observed and left ventricular size and ejection fraction were normal.

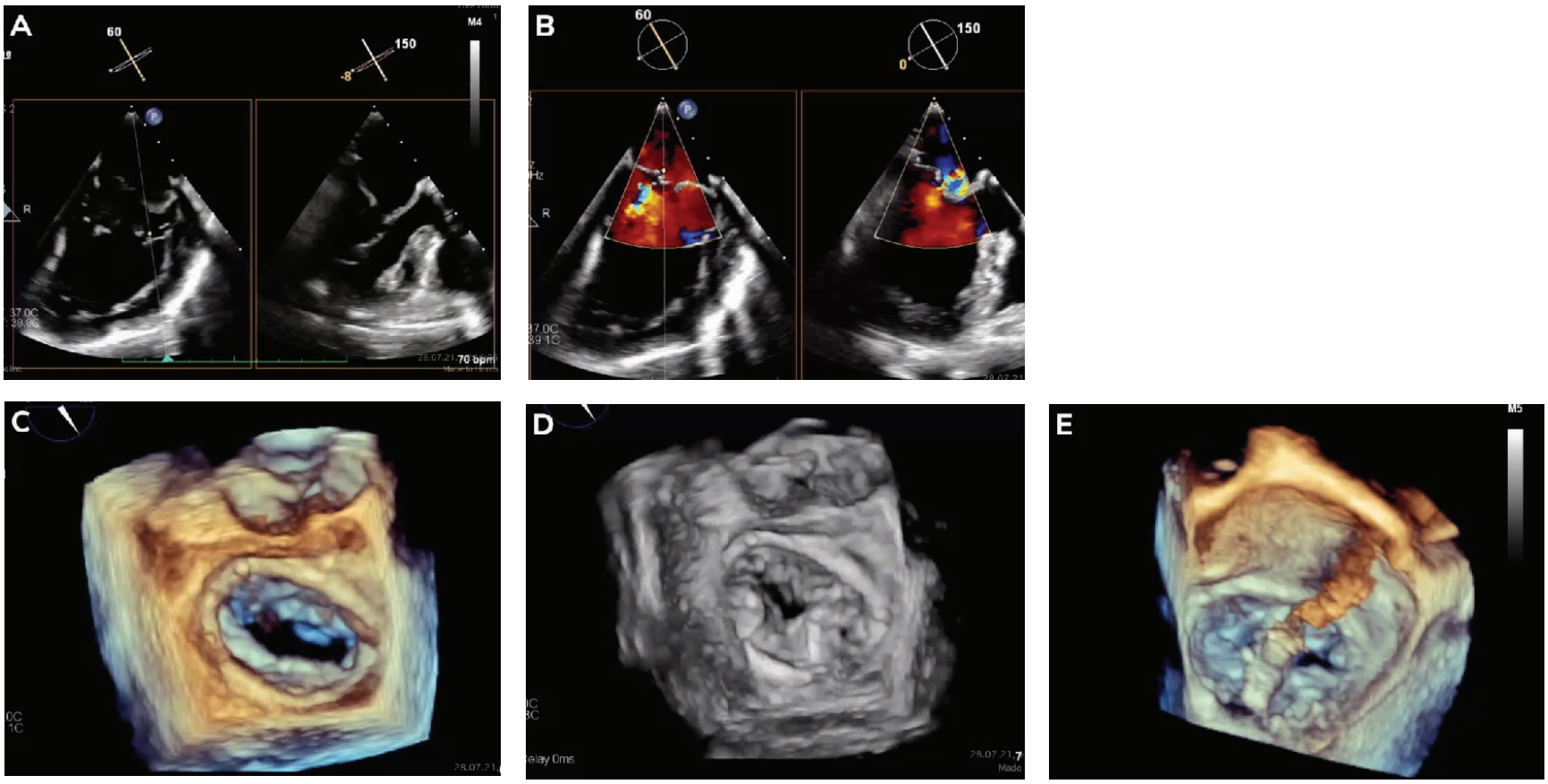


Figure 7 (videos). Case 3 Baseline Images Post-mitral Annuloplasty

(A) TEE demonstrating lateral flail segment post-annuloplasty; (B) TEE with Color Doppler images demonstrating lateral regurgitant jet; (C) TEE 3D enface view demonstrating annuloplasty ring without evidence of dehiscence but flail segment at P1; (D) 3D TEE enface imaging demonstrating regurgitant jet at site of P1 flail; (E) 3D TEE imaging demonstrating alignment of XTW clip at A1P1

Following heart team discussion, TEER was proposed and performed. Given the large coaptation defect (2.5 mm) and long posterior leaflet (≥9 mm), a XTW device was selected. Clip orientation was optimized above the mitral annulus to allow minimal positional changes while in the ventricle. Clip insertion at the P1-A1 junction was performed under fluoroscopic and echocardiographic guidance. MR was reduced to trace with a final mean gradient of 4 mmHg.

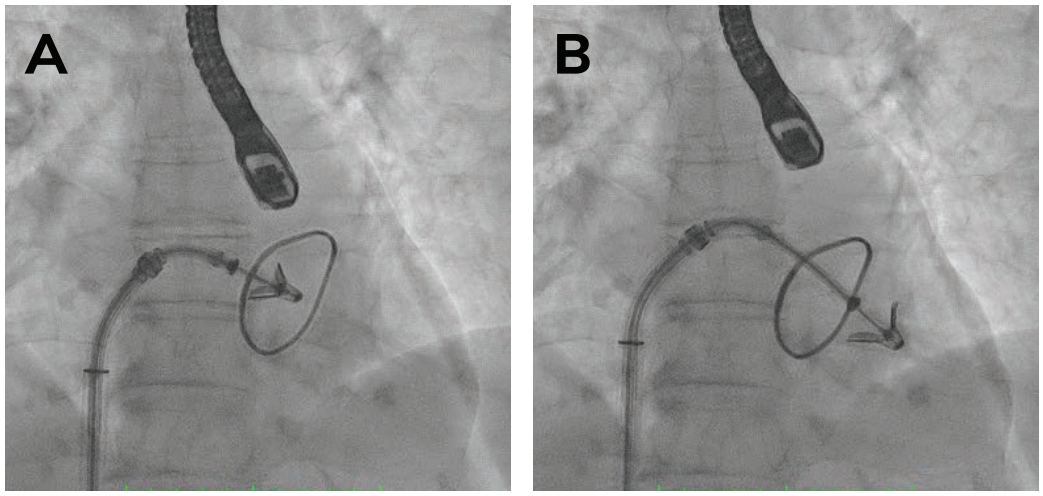


Figure 8. Case 3 MitraClip Placement

(A) Positioning of XTW clip above the valve; (B) Passage of XTW clip into the LV

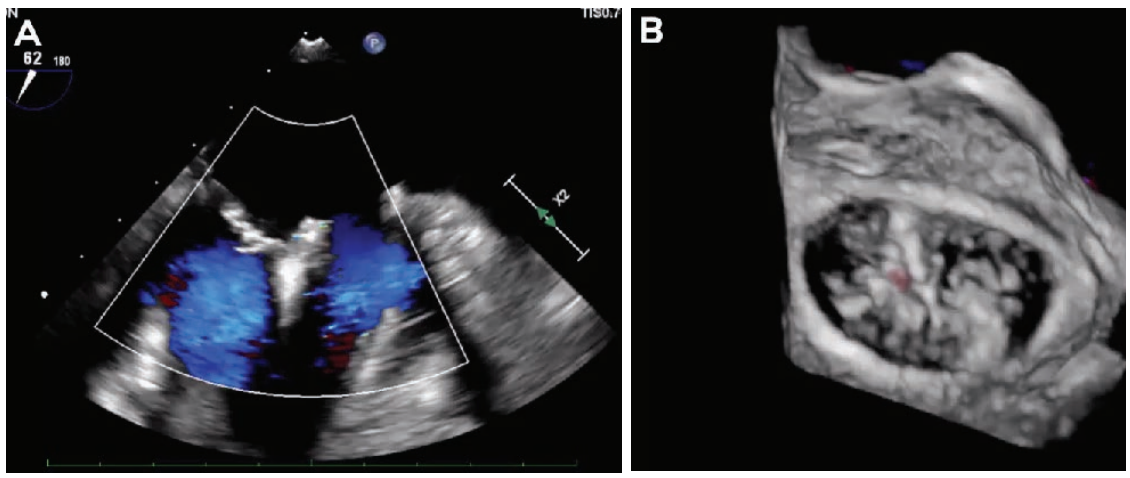


Figure 9 (videos). Final Results for Case 3

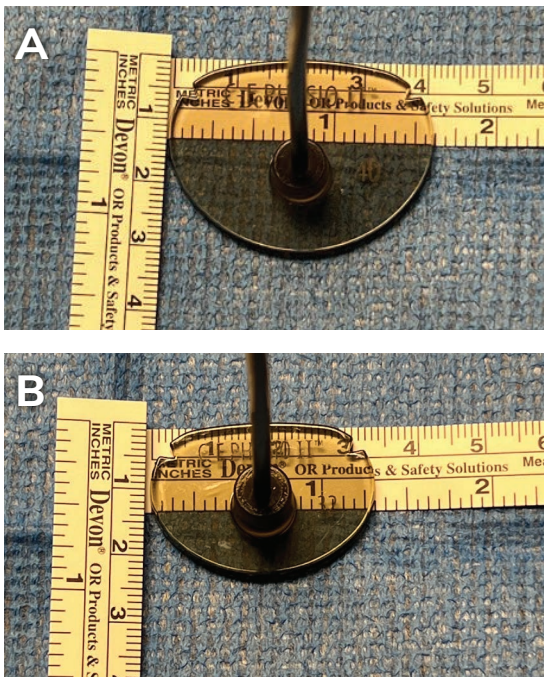
(A) Bicommissural view post clip placement demonstrating no residual MR; (B) 3D enface imaging with color showing excellent procedural result; (C) Final fluoroscopic imaging showing XTW clip position in the mitral valve

Clip-in-ring considerations

The following challenges specific to the Carpentier-Edwards Physio II ring need to be reviewed when considering a clip-in-ring procedure:

1. **Anteroposterior diameter of the annuloplasty ring.** Sizes of Carpentier-Edwards Physio II ring refer to the trigone-to-trigone distance of the ring and range from 24-40 mm. The ring is oval, therefore the anteroposterior dimension is smaller than the trigone-to-trigone distance, and the relationship between these two diameters is not proportional across the ring sizes, as shown in Figure 11. As ring size changes, the anteroposterior dimension decreases to a greater extent than the trigone-to-trigone distance. This must be considered for clip selection, given the wingspan of the devices, and clip insertion into the ventricle. In many cases, the clip may need to be inserted closed into the LV. In the setting of smaller ring sizes, clip choice will be limited as well as the number of clips to minimize the risk of mitral stenosis.

Carpentier-Edwards Physio II Ring Dimensions



RING SIZE (MM)	TRIGONE-TO-TRIGONE DISTANCE (MM)	ANTERIOR-POSTERIOR DIAMETER (MM)
40 mm	40 mm	31 mm
38 mm	38 mm	29 mm
36 mm	36 mm	27 mm
34 mm	34 mm	25 mm
32 mm	32 mm	24 mm
30 mm	30 mm	22 mm
28 mm	28 mm	20 mm
26 mm	26 mm	19 mm

Figure 10. Measurements of CE Physio II Annuloplasty Sizers for Ring Placement

(A) 40 mm annuloplasty ring sizer; (B) 32 mm annuloplasty ring sizer

2. **Clip orientation.** Clip orientation optimization is best performed above the mitral annulus to allow minimal position correction while in the ventricle. If clip reorientation is required, advancing deeper into the ventricle may be needed to avoid interference with the ring, but this increases the risk of chordal interaction.
3. **Reduced orifice.** In case of small rings, higher gradients post TEER-in-ring may occur.
4. **Ring shadowing.** Annuloplasty rings may obscure echocardiographic imaging, in particular affecting posterior leaflet visualization. Shadowing is best addressed by adding more extreme transesophageal probe angulation or using transgastric views.

Conclusion

TEER for recurrent MR after mitral valve repair surgery with annuloplasty is an alternative to redo surgery and may lead to favorable results in selected patients. It is vital to understand clip dimensions and specific challenges related to clip-in-ring procedures to optimize procedural planning and perform a successful and safe procedure.

PROCEDURAL PEARLS

- Consider baseline mitral valve area and gradient to assess risk of mitral stenosis with TEER therapy.
- Carefully assess the anterior and posterior leaflet lengths and imaging quality.
- The posterior leaflet is often the hardest to grasp, and an aorta hugger trajectory may be required.
- If the posterior leaflet cannot be grasped and there is adequate anterior leaflet length, “edge-to-ring” therapy may be possible.
- In some cases, significantly understraddling the CDS and using the “clip on a stick” technique can create the desired aorta hugger (anterior to posterior) clip trajectory.
- In the setting of a previous annuloplasty ring, the size and dimensions of the annuloplasty ring are informative and will dictate the choice of clip size and feasibility of the procedure.

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2. Singh GD, Smith TW, Boyd WD, Rogers JH. Clipping the ring: transcatheter edge-to-ring mitral valve repair in a patient with prior mitral annuloplasty ring. *JACC Cardiovasc Interv.* 2018;11(7). :e55-e58. doi: 10.1016/j.jcin.2017.10.037. Epub 2018 Jan 17.

CHAPTER 17

Future Directions – Practical Guide to Volumetric Intracardiac Echocardiography-guided MitraClip Implantation

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Overview

Transesophageal echocardiographic (TEE) guidance has been the primary imaging modality in guiding the the MitraClip (Abbott Vascular, Santa Clara, CA) procedure. In recent times, improvements in technology have heralded the introduction of volumetric 3-dimensional (3D) live intracardiac echocardiography (vICE) catheters. This has provided a potential alternative/adjunct for patients with severe mitral regurgitation (MR) who have contraindications to TEE imaging. This chapter provides a practical step-by-step guide on how to perform a vICE-guided MitraClip procedure.

Procedural considerations

vICE-guided MitraClip could potentially be considered in the following settings that may preclude TEE imaging:

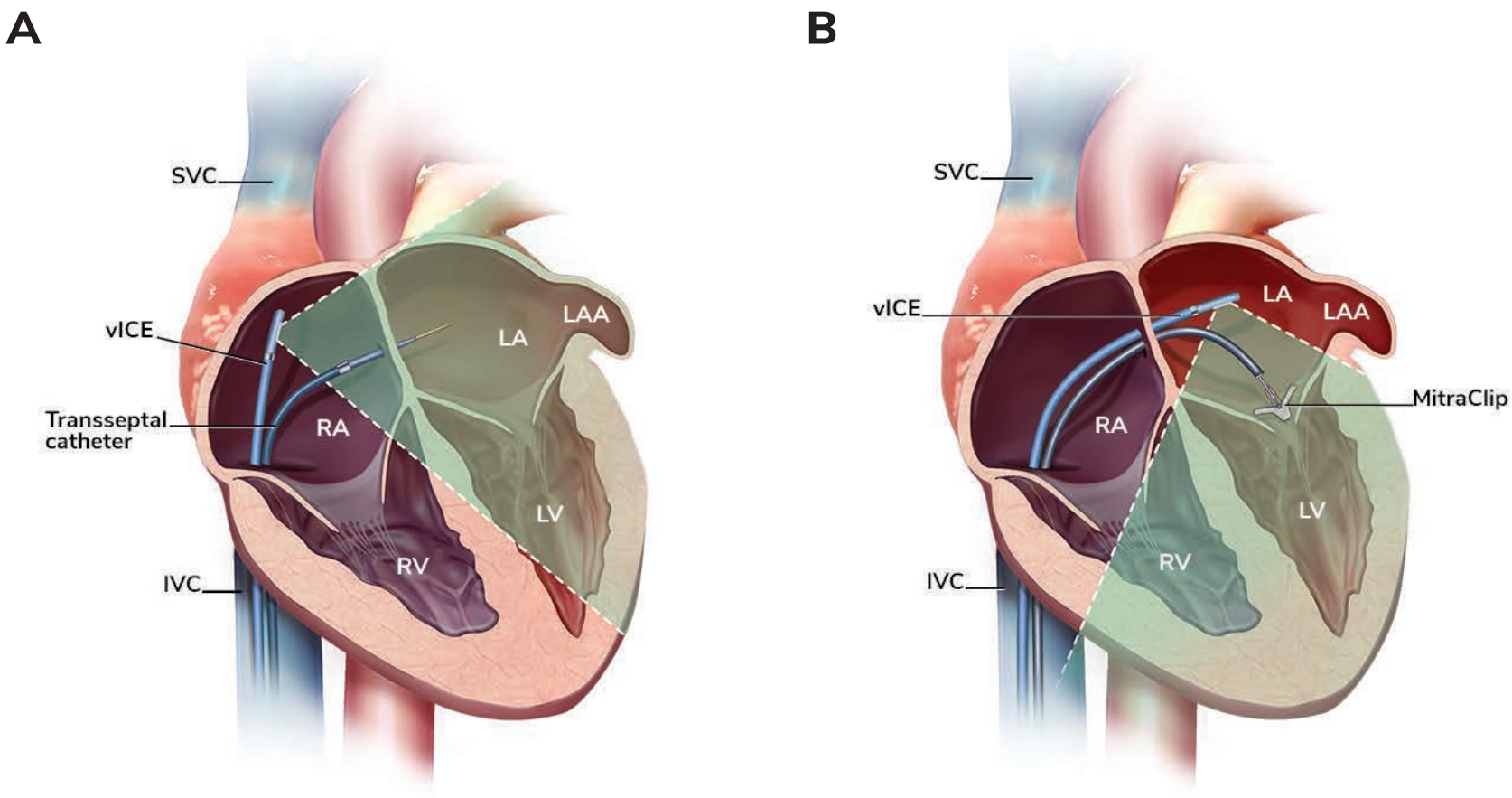
- Esophageal strictures
- Esophageal tortuosity
- Esophageal varices
- Unfavorable esophageal-LA relationship
- Severe scoliosis
- Poor TEE windows
- Inability to tolerate general anesthesia

It is important to have a good understanding of the vICE catheter. The vICE catheter steering planes are similar to the normal ICE catheter. There are basically 4 movement planes:

- A/P knob - flexes the catheter anteriorly/posteriorly
- L/R knob - flexes the catheter left/right
- Handle rotation - rotates the catheter clockwise/counterclockwise (CW/CCW)
- Catheter advancement/retraction - moves the catheter in/out

Other noteworthy characteristics of the vICE catheter:

- The vICE catheter is larger-bore and relatively stiffer than the normal ICE catheter.
- The flexion point is further proximal to the imaging element compared to the normal ICE catheter.
- The vICE catheter is able to perform both multiplanar and live 3D imaging. However, the field of view with multiplanar imaging may be more limited than TEE. For example, the Sieman's vICE catheter field of view is only 90° x 54° compared to the traditional TEE of 90° by 90°. In addition, although the vICE catheter has optimal single plane 2D imaging, there is degradation in 2D quality once multiplanar imaging is utilized in current versions.



Central Illustration. Volumetric ICE (vICE) Catheter Locations For MitraClip Procedure

(A) vICE catheter in right atrium for transseptal puncture and measurement of transseptal puncture height; (B) vICE catheter in superior left atrium for visualization of mitral apparatus and MitraClip system

Step-by-step technique

Vascular access

1. Obtain, contralateral ultrasound-guided left femoral venous access for the introduction of the vICE catheter.
2. Consider pre-closure with 1 Perclose ProGlide™ vascular closure device (Abbott Vascular) for subsequent hemostasis.
3. A long sheath larger than the outer diameter of the vICE catheter is recommended as this will allow for more support and easier maneuverability of the vICE catheter (Figure 1). For example, for the 12.5 Fr Siemans vICE catheter, a 14 Fr long sheath is generally used.

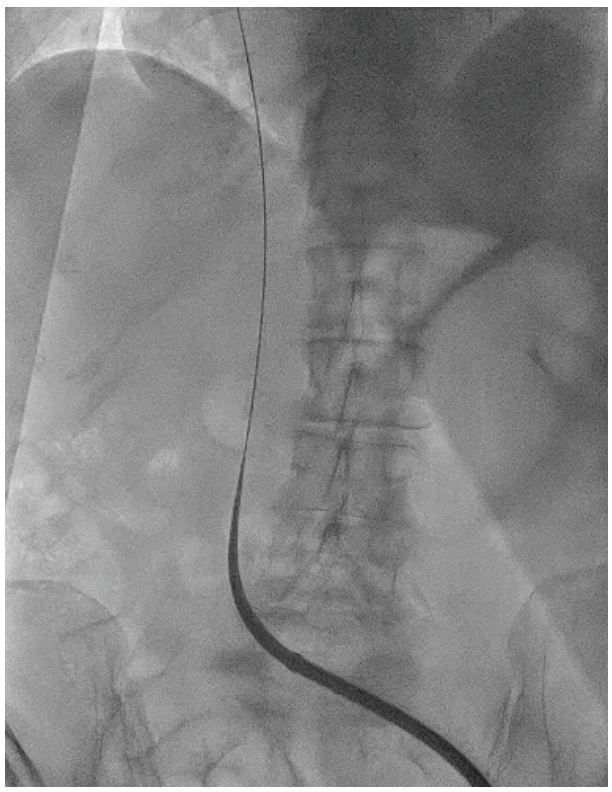


Figure 1 (video). Introduction of Long Sheath for vICE Catheter

Transseptal puncture

1. To aid the transseptal puncture, introduce the vICE catheter into the right atrium under fluoroscopic guidance.
2. Obtain the ICE-equivalent of the traditional TEE bicaval and short-axis views to facilitate the standard superior-posterior puncture (Figure 2). These ICE-equivalent views are routinely used in ICE-guided patent foramen ovale/atrial septal defect closures.

- The bicaval view allows for superior and inferior positioning and is obtained by clockwise rotation of the ICE catheter from the home view until the septum is visualized followed by a slight “P” flexion.
- The short-axis view allows for anterior and posterior position and is obtained by further “P” flexion and clockwise rotation from the bicaval view.

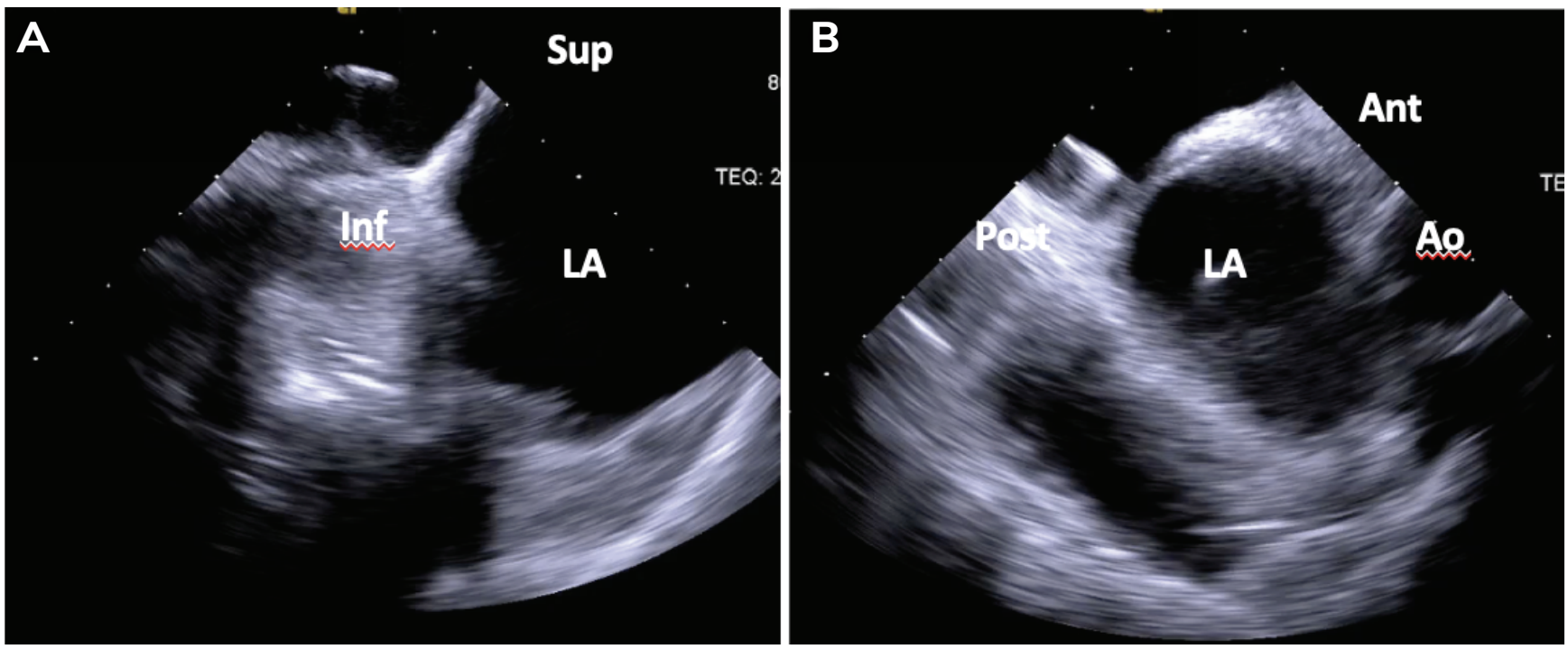


Figure 2. ICE Views for Transseptal Puncture

(A) ICE bicaval view; (B) ICE short-axis view

It may be difficult to assess the height of transseptal puncture above the mitral annulus as you may not be able to simultaneously visualize the transseptal tent and mitral annulus on the same plane.

3. With the tenting first identified in the bicaval view, rotate the catheter counterclockwise until the mitral valve is visualized and estimate the transseptal height by measuring the distance from the approximated tenting location to the mitral annulus (Figure 3).
4. Perform the transseptal puncture in the short-axis view.

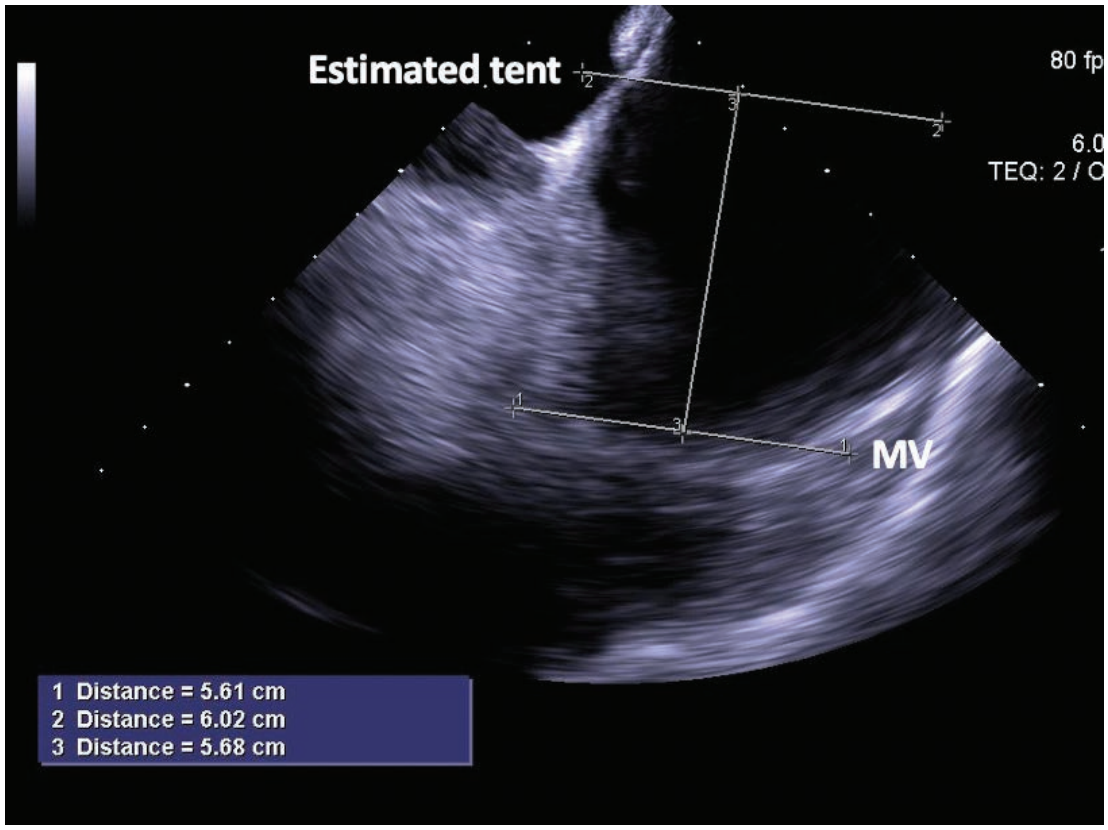


Figure 3. Assessment of Height of Tent Above Mitral Valve

Entry into left atrium

The vICE catheter can be introduced into LA through the same transseptal puncture or a separate puncture, although the same puncture is preferred as it avoids the need of a double transseptal puncture.

1. After the transseptal puncture, advance a pre-shaped pigtail wire (eg, Inoue wire, Safari, Confida wire) into the left atrium (LA) (Figure 4). Alternatively, a stiff J wire can be advanced into the left upper pulmonary vein. The use of a pigtail wire allows for greater stability.
2. Perform a septostomy with a 8x40mm balloon (Figure 5) to allow for the vICE catheter and subsequently the MitraClip steerable guide catheter (SGC) to concurrently transverse through the same puncture in the interatrial septum (IAS).
3. Under fluoroscopy, apply “A” flexion to the vICE catheter to match the trajectory of the wire and gently advance alongside the wire into the LA (Figure 6). In the event of resistance, slight “R/L” knob adjustment or clockwise/counterclockwise rotation may aid in the crossing. In addition, matching the vICE and wire trajectory in both the LAO and RAO fluoroscopic views is helpful.

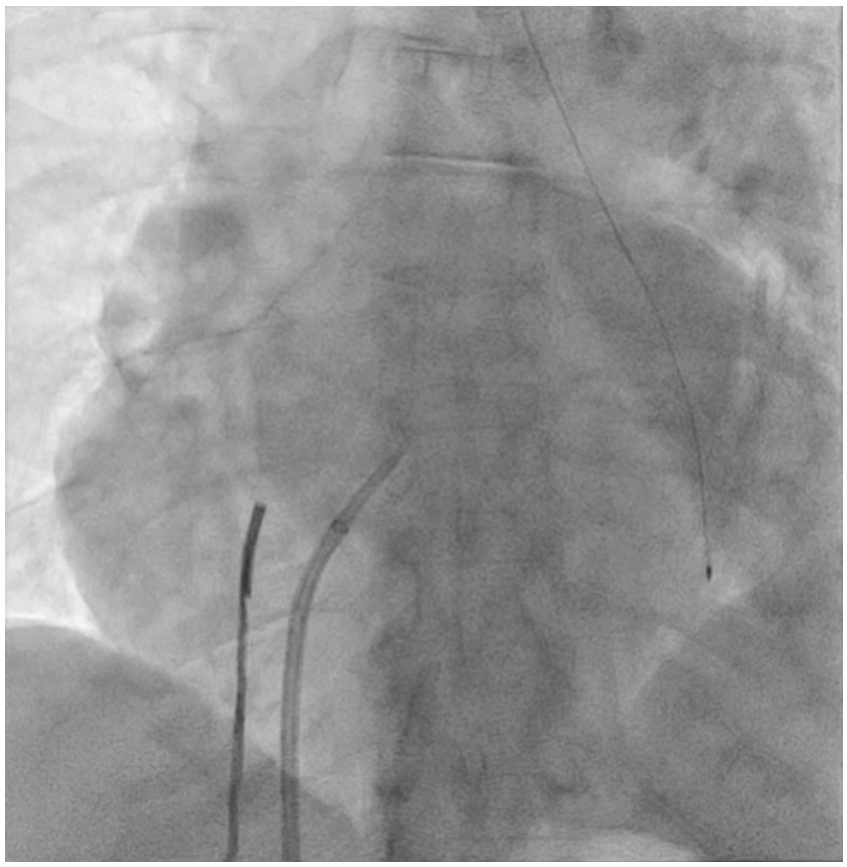


Figure 4 (video). Introduction of Pigtail Wire

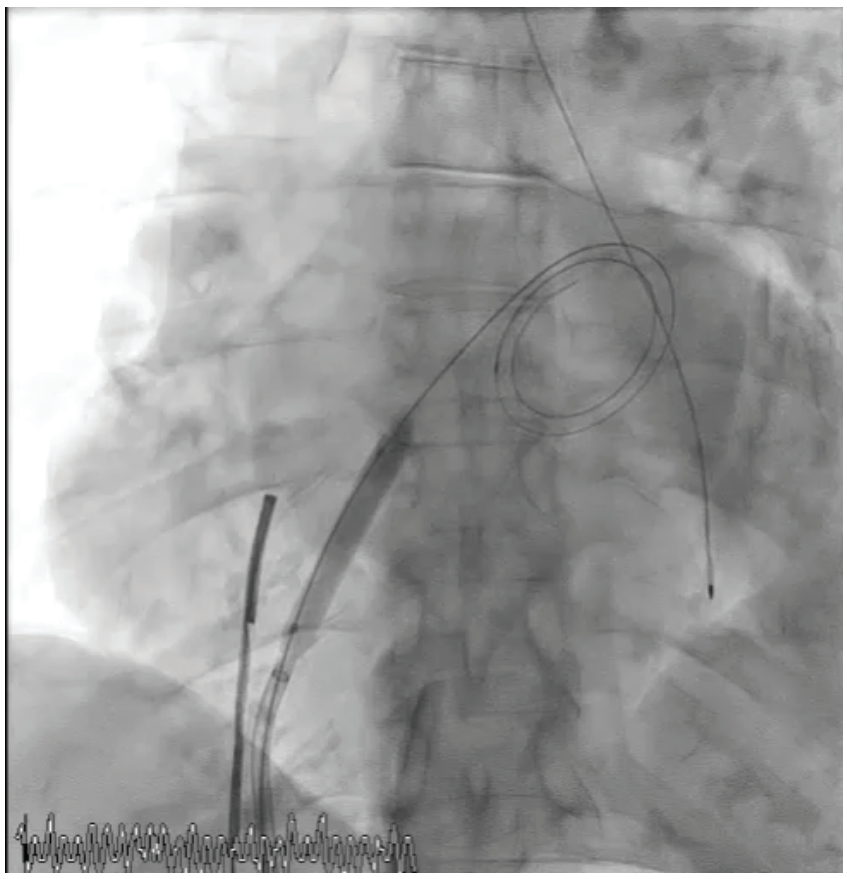


Figure 5 (video). Atrial Septostomy with 8x40mm Balloon

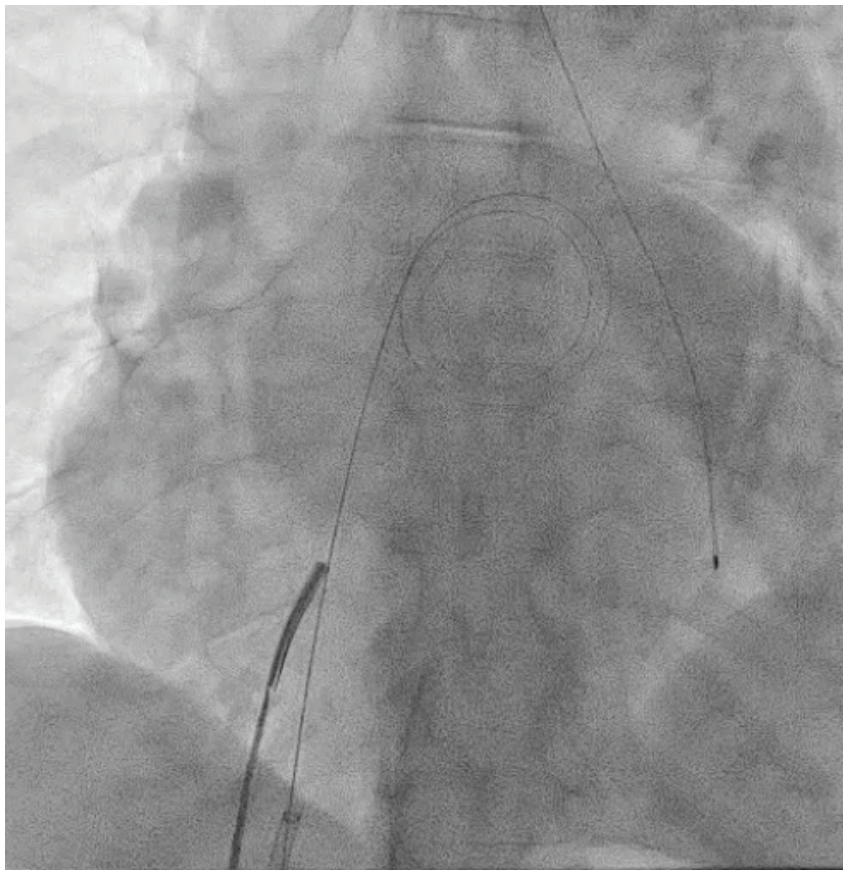


Figure 6 (video). Crossing of vICE Catheter into Left Atrium

Initial ICE assessment

Perform ICE evaluation of the left atrial appendage, pulmonary veins, and mitral valve.

- **Pulmonary veins.** With the ICE catheter in neutral position in the LA, clockwise rotation will image the pulmonary veins with the required color and Doppler images obtained (Figure 7A).
- **Left atrial appendage.** Counterclockwise rotation with a slight "P" flexion will bring the left atrial appendage into view to exclude any thrombus (Figure 7B). The multiplane imaging function can also be used to sweep through the appendage from this view.
- **Mitral valve.** Further counterclockwise rotation will bring the mitral valve into view. Slight adjustment in R/L tilt can be used to acquire the best bicommissural view to obtain color Doppler and multiplane imaging (Figure 7C). The movement and orientation of the vICE catheter to the mitral valve is summarized in Figure 8.

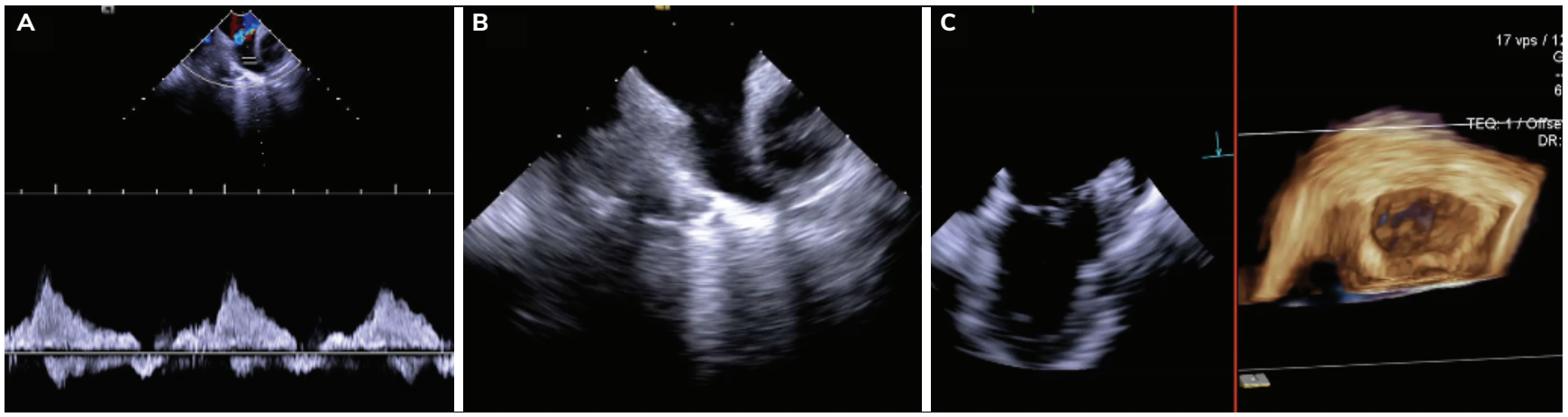


Figure 7. Initial ICE Assessment

(A) Pulmonary veins, (B) left atrial appendage, and (C) mitral valve

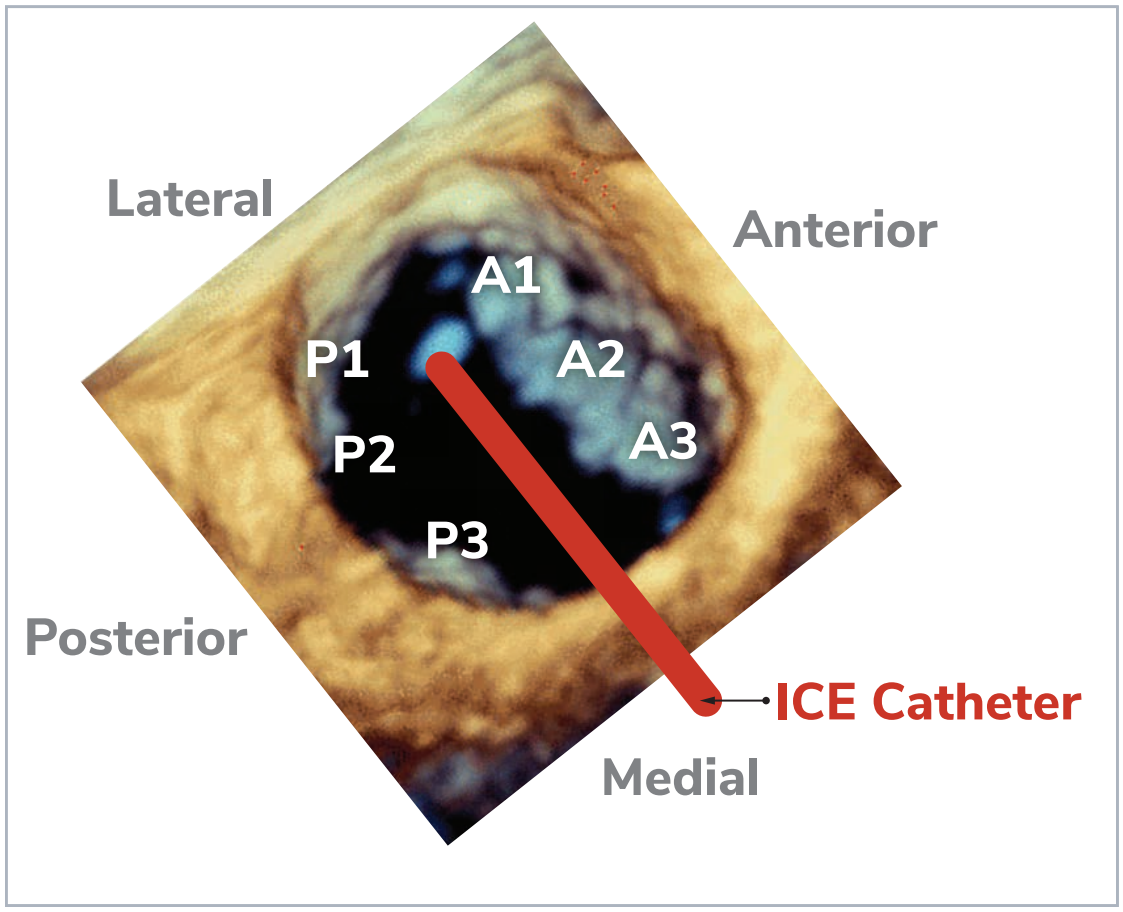


Figure 8. Movement of the ICE Catheter Relative to Mitral Valve

Insertion of SGC and CDS

1. Use a combination of fluoroscopy and tactile feedback to advance the SGC into the left atrium, as the vICE catheter is unable to visualize the SGC coils engaging and crossing the IAS from the LA (Figure 9). Oftentimes, a slight “give” can be felt as the SGC crosses into the LA with a slight “jump” seen on fluoroscopy.

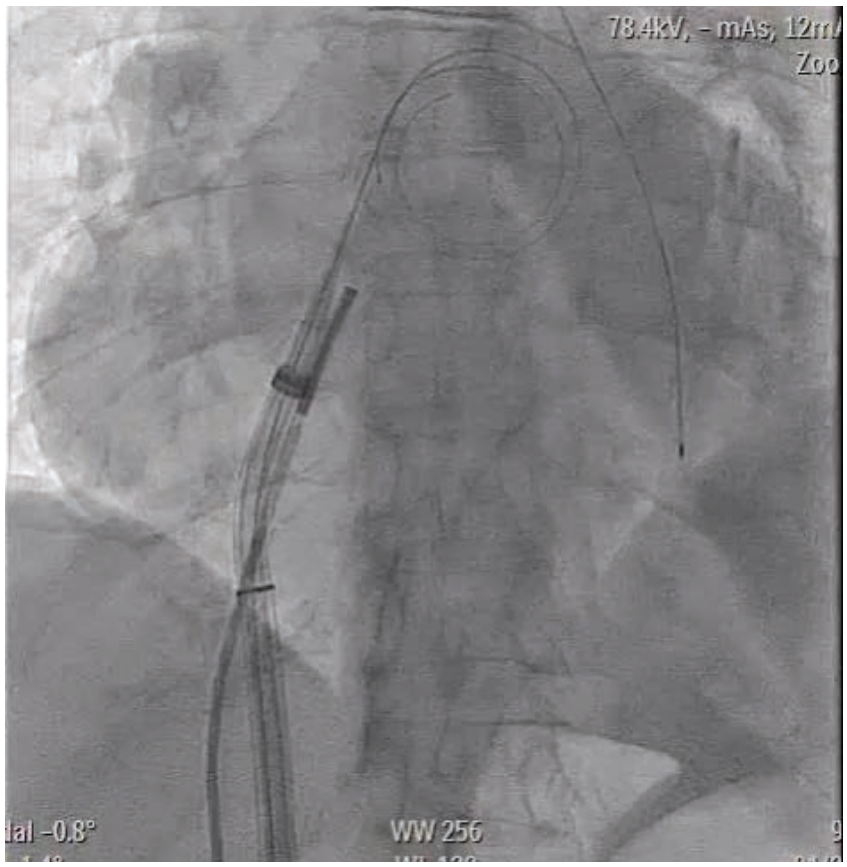


Figure 9 (video). Introduction of Steerable Guide Catheter over Pigtail Wire

2. Confirm the position of the SGC in the center of the LA on the vICE catheter.
3. As the clip delivery system (CDS) is advanced out of the SGC, advance the ICE catheter slightly and rotate CW/CCW to continuously visualize and track the CDS tip.
   - As the M knob is applied to the CDS, this usually requires a CCW rotation of vICE catheter.
   - As posterior torque of SGC is applied, this usually requires CW rotation of the vICE catheter.
4. It is important for the vICE catheter to continuously visualize the CDS tip while steering down to valve and this requires constant fine micro-adjustments of the vICE catheter (Figure 10).
5. On fluoroscopy, the ICE catheter is usually positioned just behind the CDS tip (Figure 11).

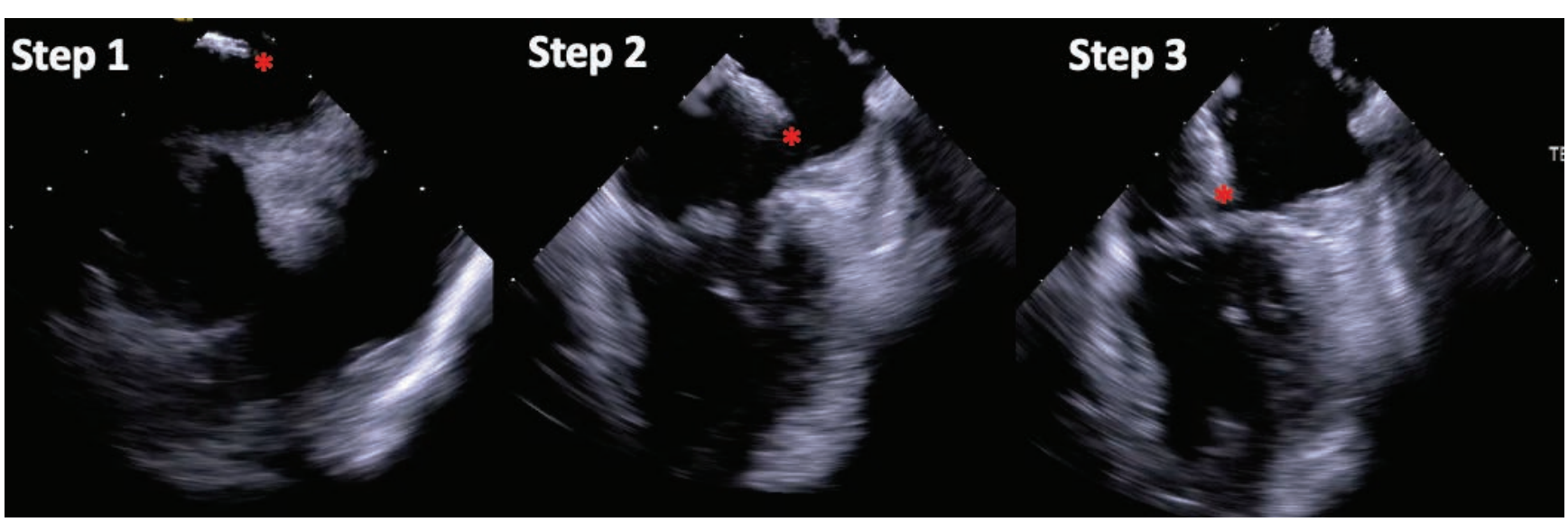


Figure 10. Continous Visualization of CDS Tip (*) While Steering Down to Valve

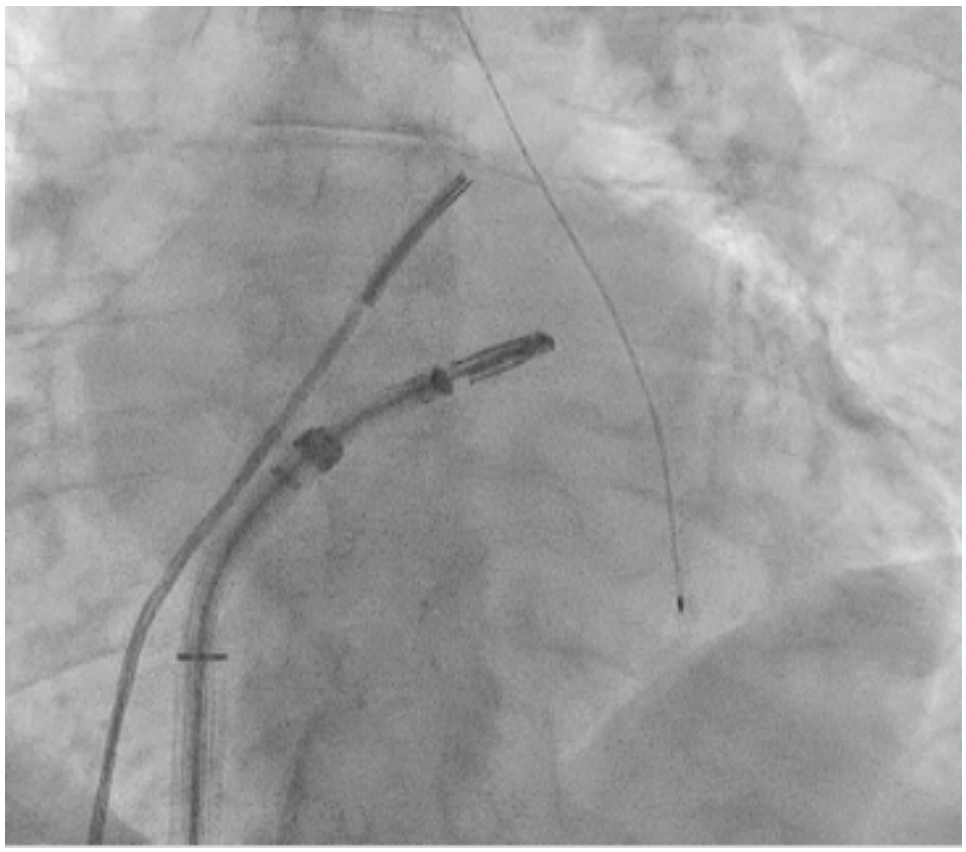


Figure 11. Fluoroscopic Relationship Between vICE Catheter and CDS

Trajectory, clip alignment and leaflet grasping

Similar to TEE-guided MitraClip procedure, the ICE equivalent of the bicommissural, LVOT view and 3D en-face views are required.

- The bicommissural view allows for medial/lateral positioning and is obtained by centering the vICE catheter above the clip on fluoroscopy with a slight "A" flexion and CW/CCW rotation until the clip and valve are seen (Figure 12).
- The left ventricular outflow tract (LVOT) view allows for anterior/posterior positioning and this modified view is usually obtained by doing multiplane imaging (analogous to "X-plane" on TEE) off the bicommissural view (Figure 12). A dedicated LVOT view is possible to obtain but requires more maneuvering.
- 3D imaging is used for clip alignment (Figure 13). This does not require much catheter manipulation beyond having a good bicommissural view. The rest of the fine-tuning occurs on the console.

The LVOT view is used for leaflet grasping and, as mentioned above, this is best obtained by multiplanar imaging off the bicommissural view. Figure 14 shows the visualization of the grasping of the leaflets on ICE. The use of the "circle" tool will allow better identification of the anterior/posterior and medial/lateral orientation. Placing the circle tool on the desired position on the 2D view will show the similar position on the 3D view and vice versa (Figure 15).

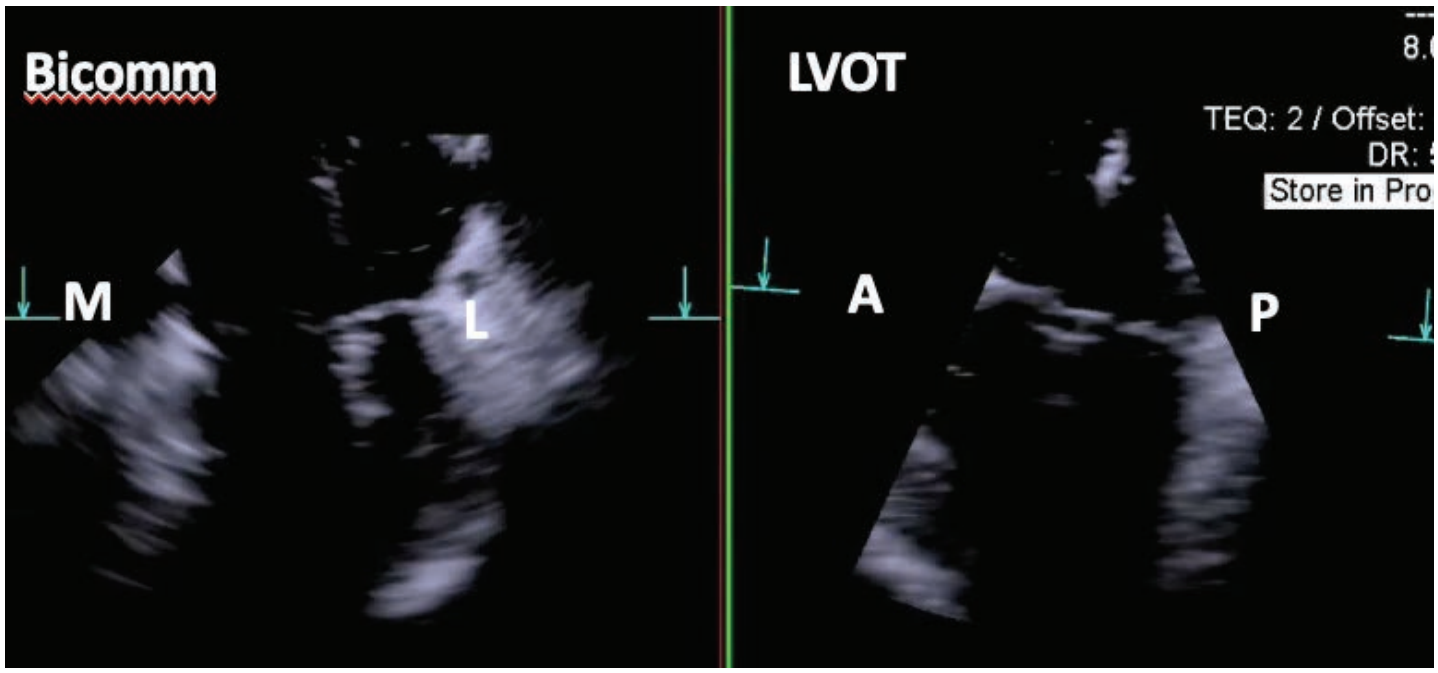


Figure 12. Bicommissural and LVOT View of Mitral Valve for Assessment of Trajectory

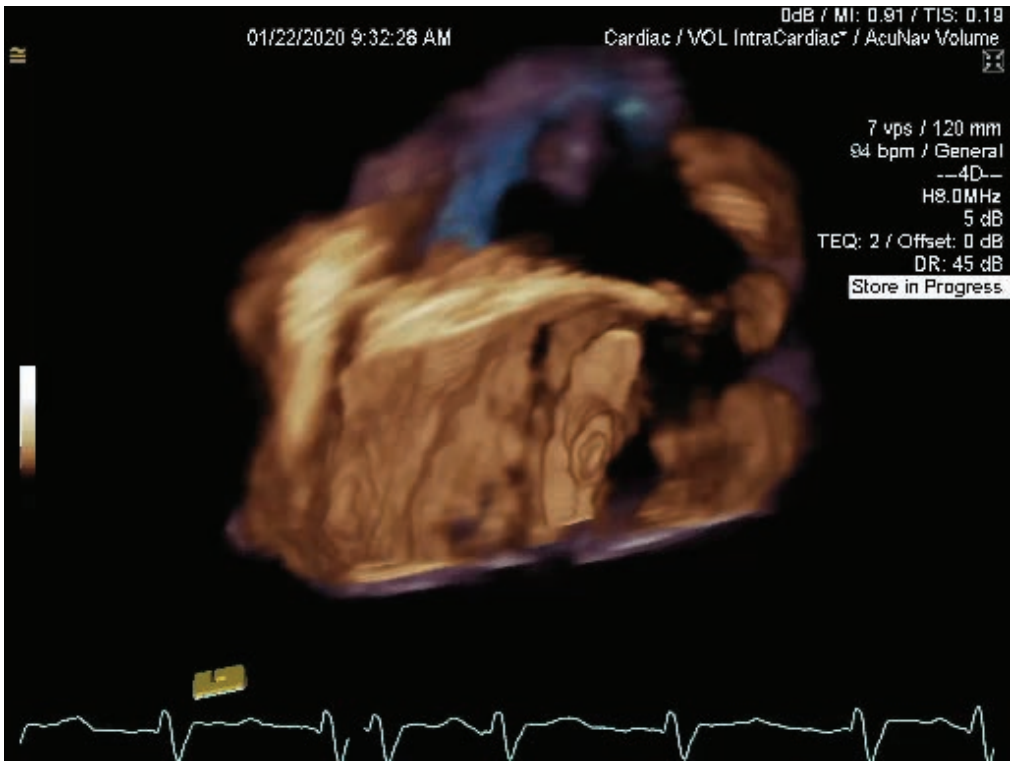


Figure 13 (video). Clip Alignment on 3D Imaging

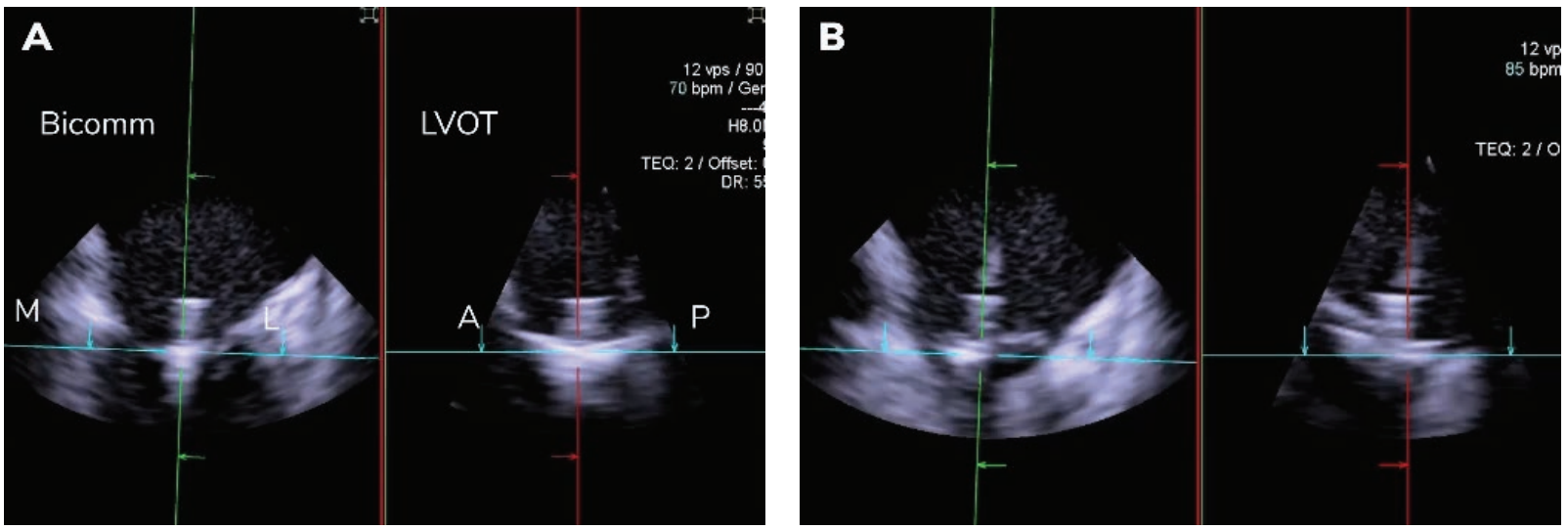


Figure 14 (video). Leaflet Grasping

(A) Independent gripping of posterior leaflet, (B) independent gripping of anterior leaflet, and (C) closing of clip arms

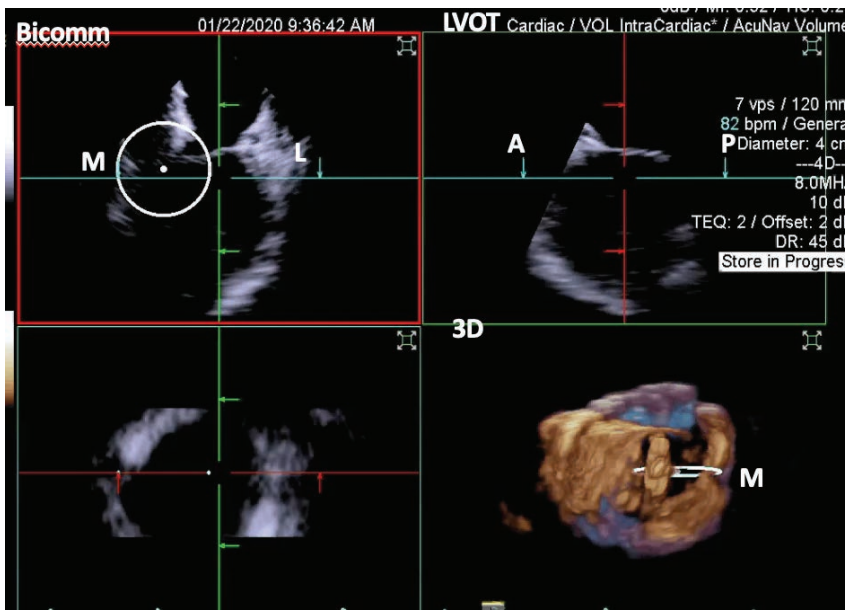


Figure 15. Use of Circle Tool

Final ICE assessment

Final leaflet insertion and MR assessment is similarly performed in both the bicommissural view as well as the LVOT view (Figure 16). Oftentimes, this requires multiplane imaging.

1. Obtain final color Doppler, mitral valve gradients, and pulmonary vein flow assessments.
2. Reassess the IAS after withdrawal of the SGC and vICE catheter from the LA (Figure 17). Closure of the iatrogenic ASD is seldom required except possibly in the setting of R to L shunt with hypoxemia or significant L to R shunt in the setting of signfiicant RV dysfunction.

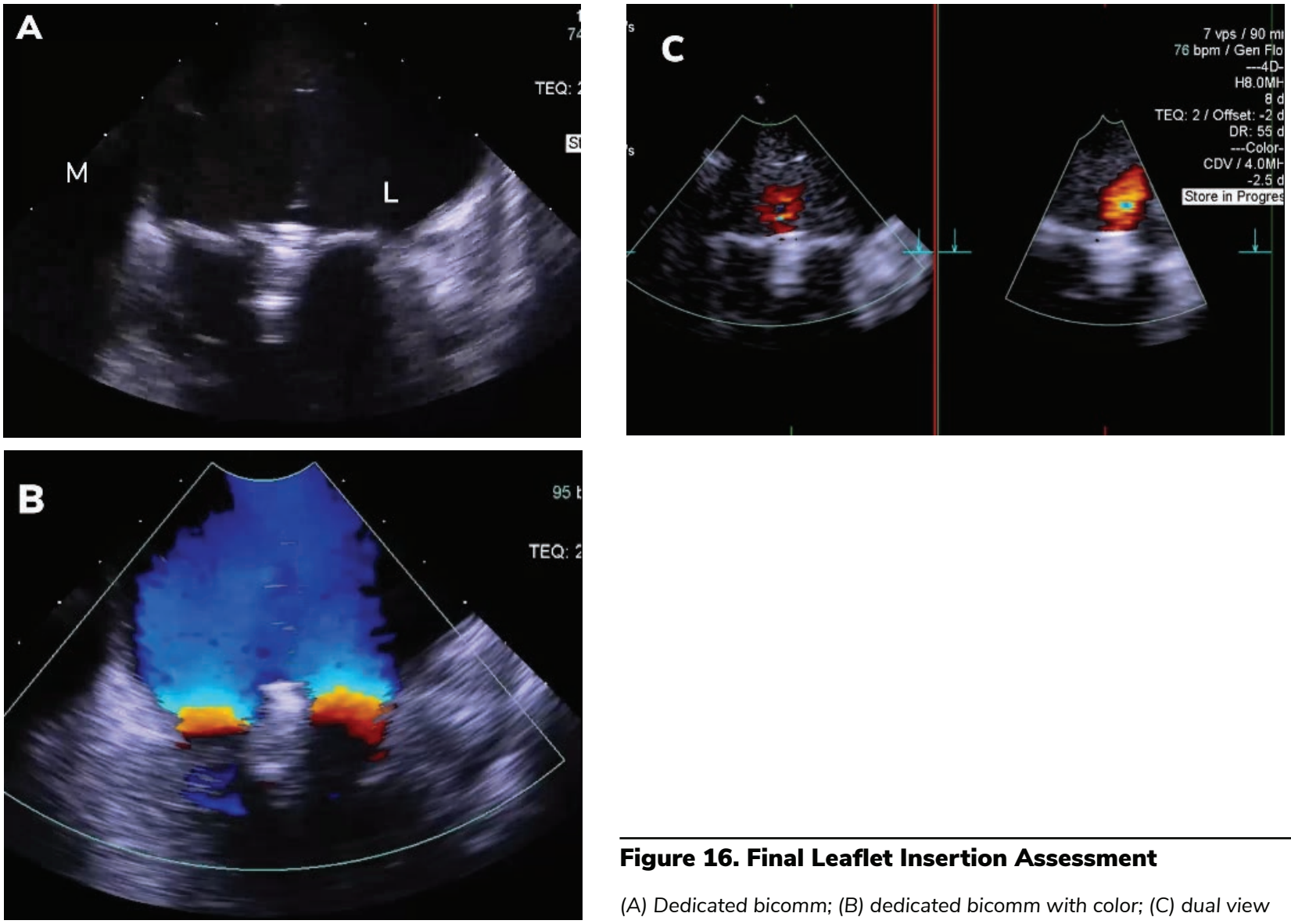


Figure 16. Final Leaflet Insertion Assessment

(A) Dedicated bicomm; (B) dedicated bicomm with color; (C) dual view

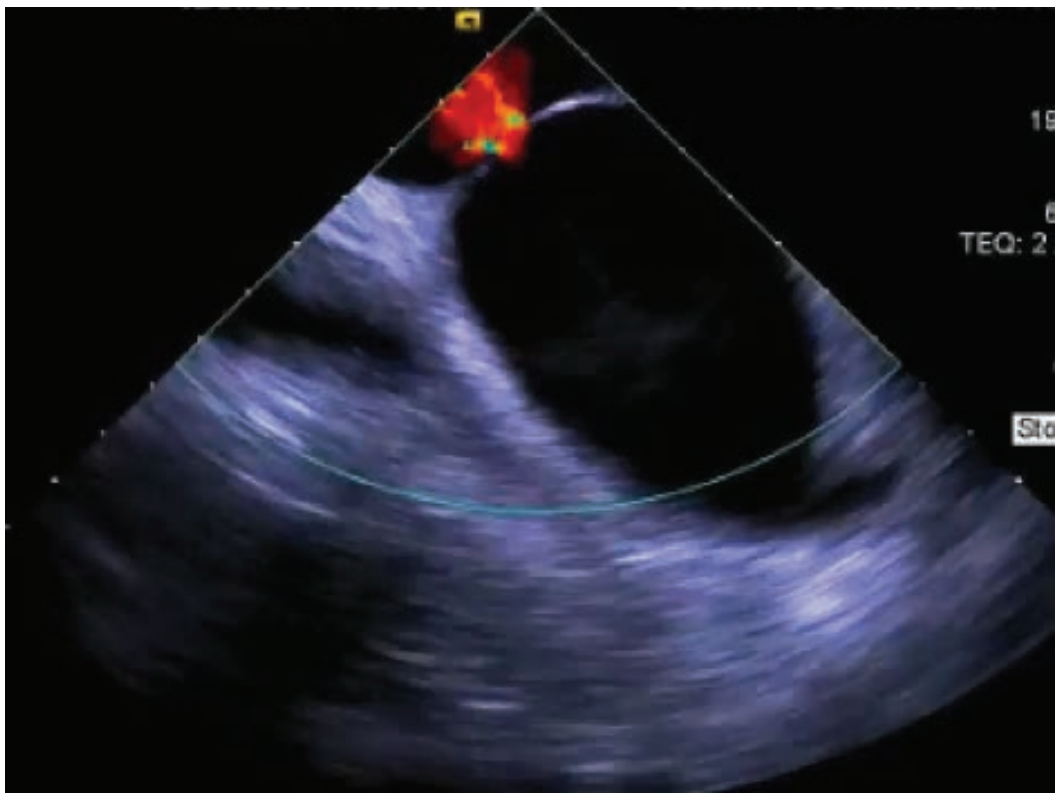


Figure 17 (video). Assessment of IAS

Potential complications

Potential complications specific to the use of the vICE catheter for the MitraClip procedure include:

- Perforation
- Pericardial effusion/tamponade
- Arrhythmias
- Larger iatrogenic ASD
- Vascular access site

Summary

vICE-guided MitraClip implantation is feasible in patients with contraindications to TEE, however, there is a learning curve to overcome. The step-by-step techniques required and the potential challenges of the procedure require experienced operators in both MitraClip and ICE imaging. Nevertheless, with increasing experience and improvements in technology, the role of vICE-guided MitraClip implantation may become more established, potentially avoiding the need for general anaesthesia in future.

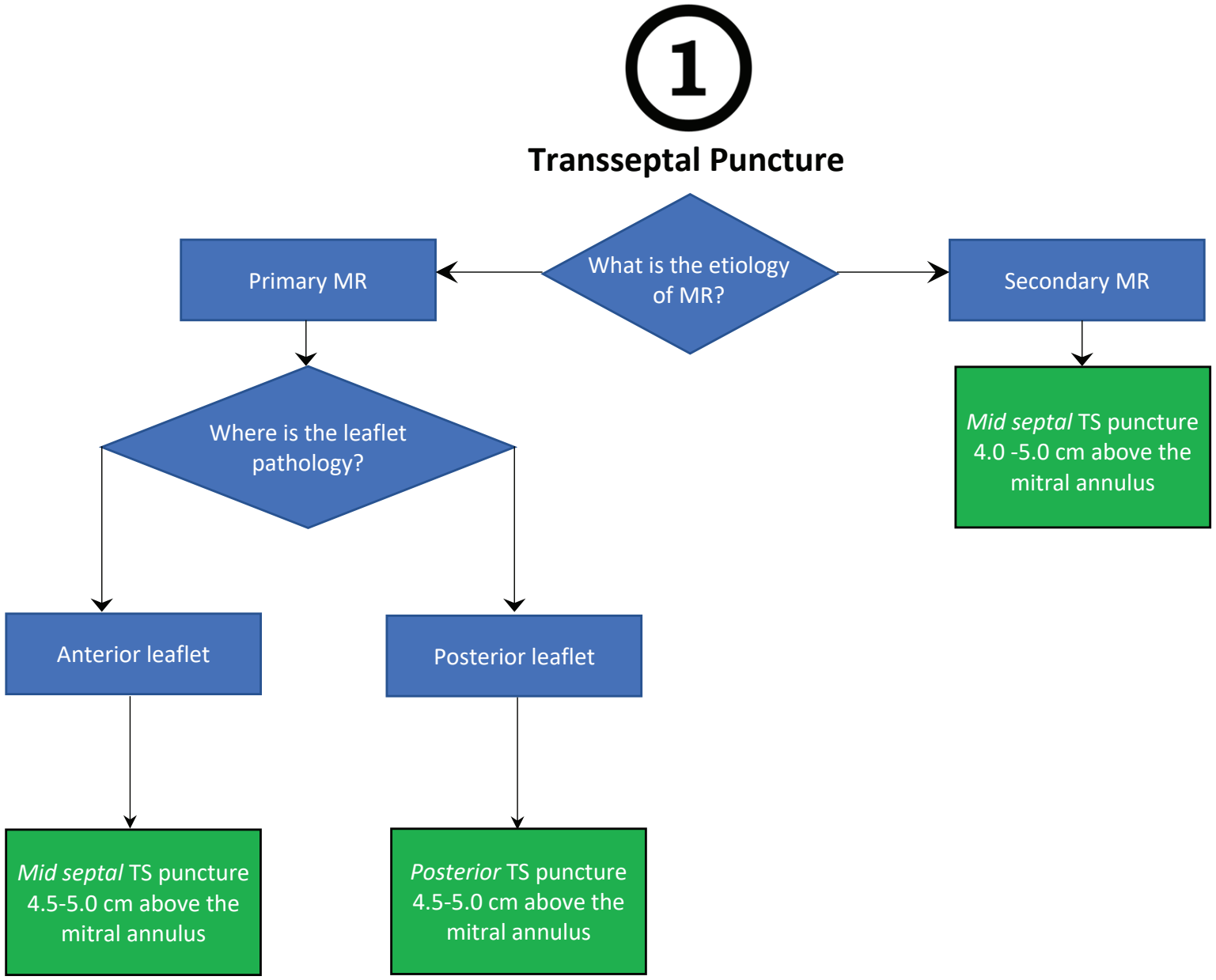
References

1. Yap J, Rogers JH, Aman E, et al. MitraClip implantation guided by volumetric intracardiac echocardiography: technique and feasibility in patients intolerant to transesophageal echocardiography. *Cardiovasc Revasc Med.* 2021 Jul;28S:85-88. doi: 10.1016/j.carrev.2021.01.019. Epub 2021 Jan 22. PMID: 33541810.

APPENDIX A.

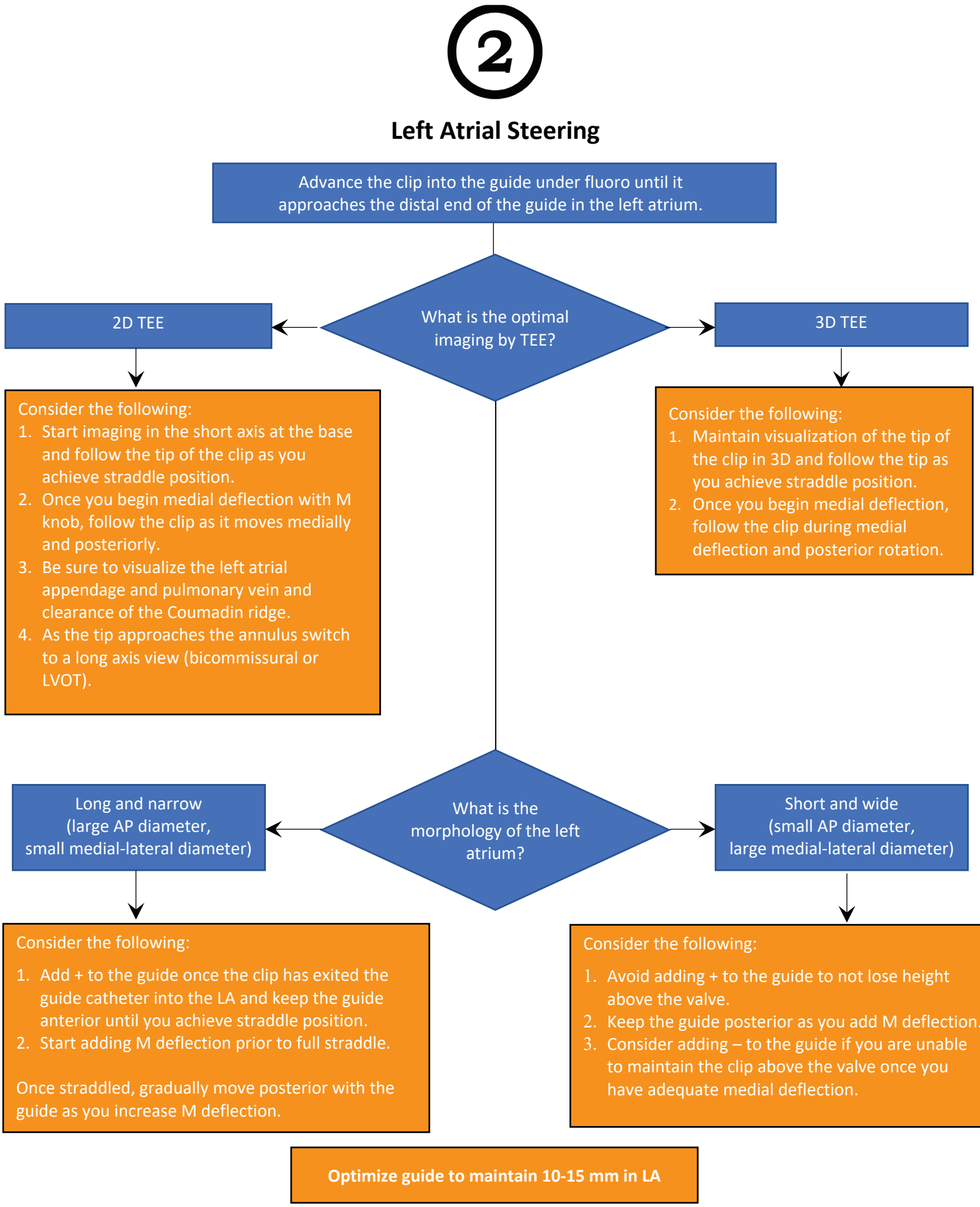
TEER Procedural Decision-Making Algorithm Flowchart

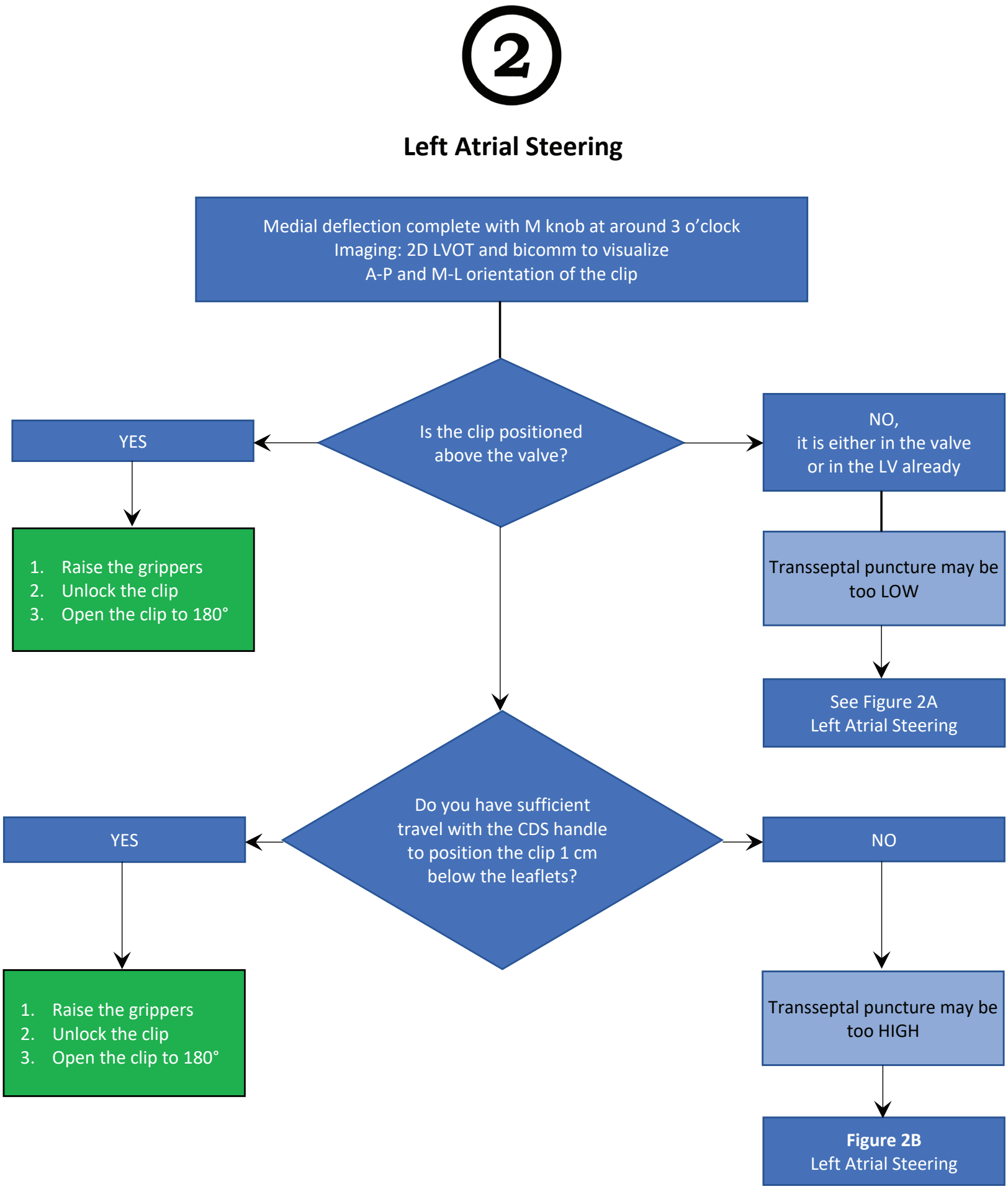
This appendix contains the flowchart for the interactive TEER procedural decision-making algorithm presented in Chapter 7.



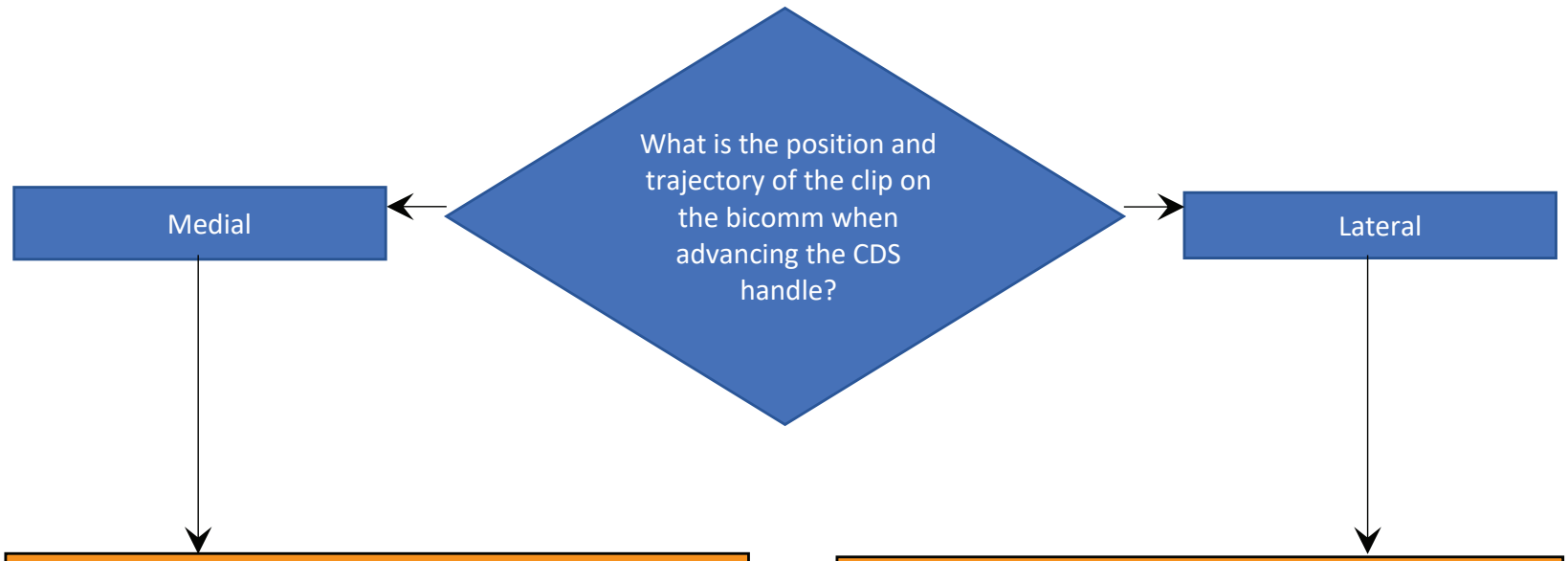
Important Considerations

- Once transseptal puncture has been performed, the septum may be dilated as required using an Inoue dilator or balloon as appropriate and the MitraClip Guide advanced into the left atrium.
- IV heparin should be given following transseptal puncture to maintain an ACT > 250.
- Once the ACT is confirmed to be over 250 the guide may be advanced into the left atrium under TEE imaging in the short axis view.
- Advance the guide 10-15 mm into the left atrium then withdraw the dilator ensuring that the wire remains in place and that the guide is central in the atrium to avoid contact with the left atrial wall.
- Once the dilator is inside the guide, withdraw your wire completely within the dilator and then remove both from the guide under aspiration with a syringe on the guide.


2
Left Atrial Steering
Advance the clip into the guide under fluoro until it approaches the distal end of the guide in the left atrium.
What is the optimal imaging by TEE?
2D TEE
3D TEE
Consider the following:
1. Start imaging in the short axis at the base and follow the tip of the clip as you achieve straddle position.
2. Once you begin medial deflection with M knob, follow the clip as it moves medially and posteriorly.
3. Be sure to visualize the left atrial appendage and pulmonary vein and clearance of the Coumadin ridge.
4. As the tip approaches the annulus switch to a long axis view (bicommissural or LVOT).
Consider the following:
1. Maintain visualization of the tip of the clip in 3D and follow the tip as you achieve straddle position.
2. Once you begin medial deflection, follow the clip during medial deflection and posterior rotation.
What is the morphology of the left atrium?
Long and narrow (large AP diameter, small medial-lateral diameter)
Short and wide (small AP diameter, large medial-lateral diameter)
Consider the following:
1. Add + to the guide once the clip has exited the guide catheter into the LA and keep the guide anterior until you achieve straddle position.
2. Start adding M deflection prior to full straddle.
Once straddled, gradually move posterior with the guide as you increase M deflection.
Consider the following:
1. Avoid adding + to the guide to not lose height above the valve.
2. Keep the guide posterior as you add M deflection.
3. Consider adding – to the guide if you are unable to maintain the clip above the valve once you have adequate medial deflection.
Optimize guide to maintain 10-15 mm in LA

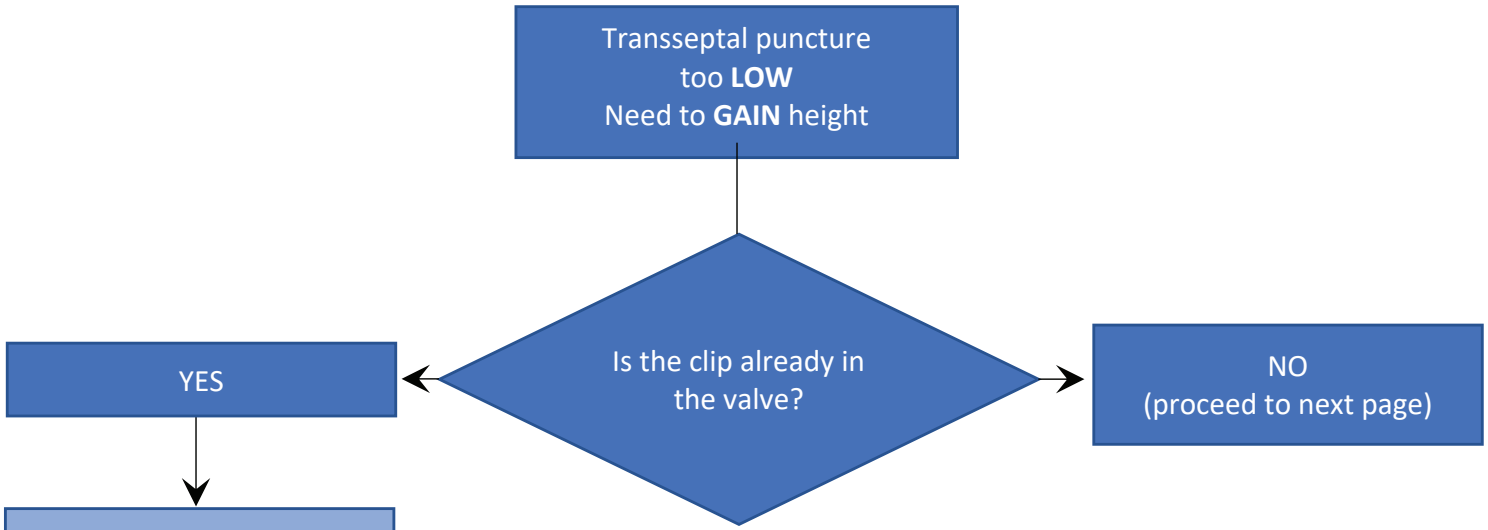

2
Left Atrial Steering
Medial deflection complete with M knob at around 3 o'clock
Imaging: 2D LVOT and bicomm to visualize
A-P and M-L orientation of the clip
Is the clip positioned above the valve?
YES
1. Raise the grippers
2. Unlock the clip
3. Open the clip to 180°
NO,
it is either in the valve
or in the LV already
Transseptal puncture may be too LOW
See Figure 2A
Left Atrial Steering
Do you have sufficient travel with the CDS handle to position the clip 1 cm below the leaflets?
YES
1. Raise the grippers
2. Unlock the clip
3. Open the clip to 180°
NO
Transseptal puncture may be too HIGH
Figure 2B
Left Atrial Steering

Left Atrial Steering – Trajectory



2

Left Atrial Steering (Figure 2A)



Consider the following:

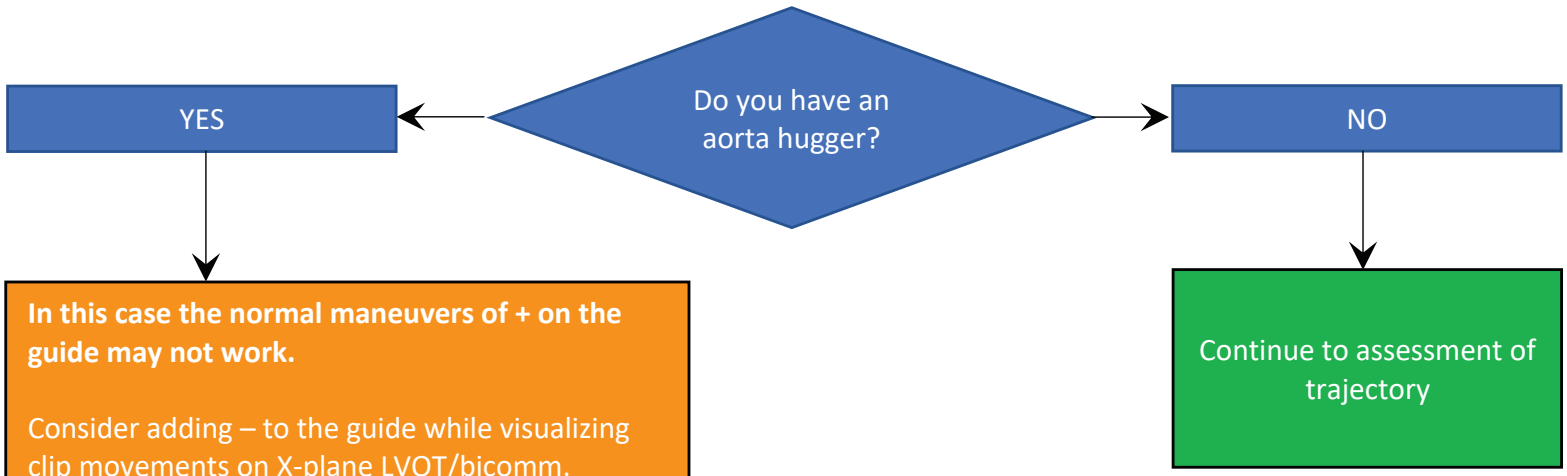
If you already have + on the guide, remove it gently and expect the clip to move anteriorly and laterally so torque the guide posteriorly to get more height.
Note: This may result in an aorta hugger.

OR

Consider the following:

1. **Remove all M deflection** from the CDS while monitoring the movement of the clip on the bicomm and LVOT view (the clip may move more anterior) to place yourself **safely above the valve.**
2. You will now use **A knob as your primary method for medial deflection.**
3. Confirm guide position and ensure 10-15 mm guide in the LA, more guide may prove detrimental.
4. Gradually add A knob while maintaining echo visualization of the clip tip in the LVOT/bicomm view (X-plane).
5. As you add A knob, gradually torque the guide posterior. You may need a significant amount of posterior torque to ensure position of the clip away from the LAA.
6. The clip will move anterior and lateral and you will gain height, up to approximately 10 mm.
7. If you now have sufficient height above the valve proceed cautiously to test additional maneuvers to achieve perpendicularity.

Left Atrial Steering (Figure 2A continued)



In this case the normal maneuvers of + on the guide may not work.

Consider adding – to the guide while visualizing clip movements on X-plane LVOT/bicomm.

If this is unsuccessful, consider adding M (may require up to half a turn).

- Add enough M to see movement of the clip and verify if the movement is helpful.
- The clip may move significantly posterior, but you may lose perpendicularity on the bicomm which will require more A knob and/or movement of stabilizer for medial/lateral positioning.
- Optimization of the trajectory on the bicomm view will be performed using the A knob.

2

Left atrial Steering (Figure 2B)

Transseptal puncture too **HIGH**
Need to **LOSE** height

Fully retract the clip and visualize on the bicomm and LVOT views.

Consider the following:

Add some **+** to the guide to lose some height; this will move the clip posterior and medial and will require anterior adjustment to the guide.

Did this maneuver solve your height issue?

YES

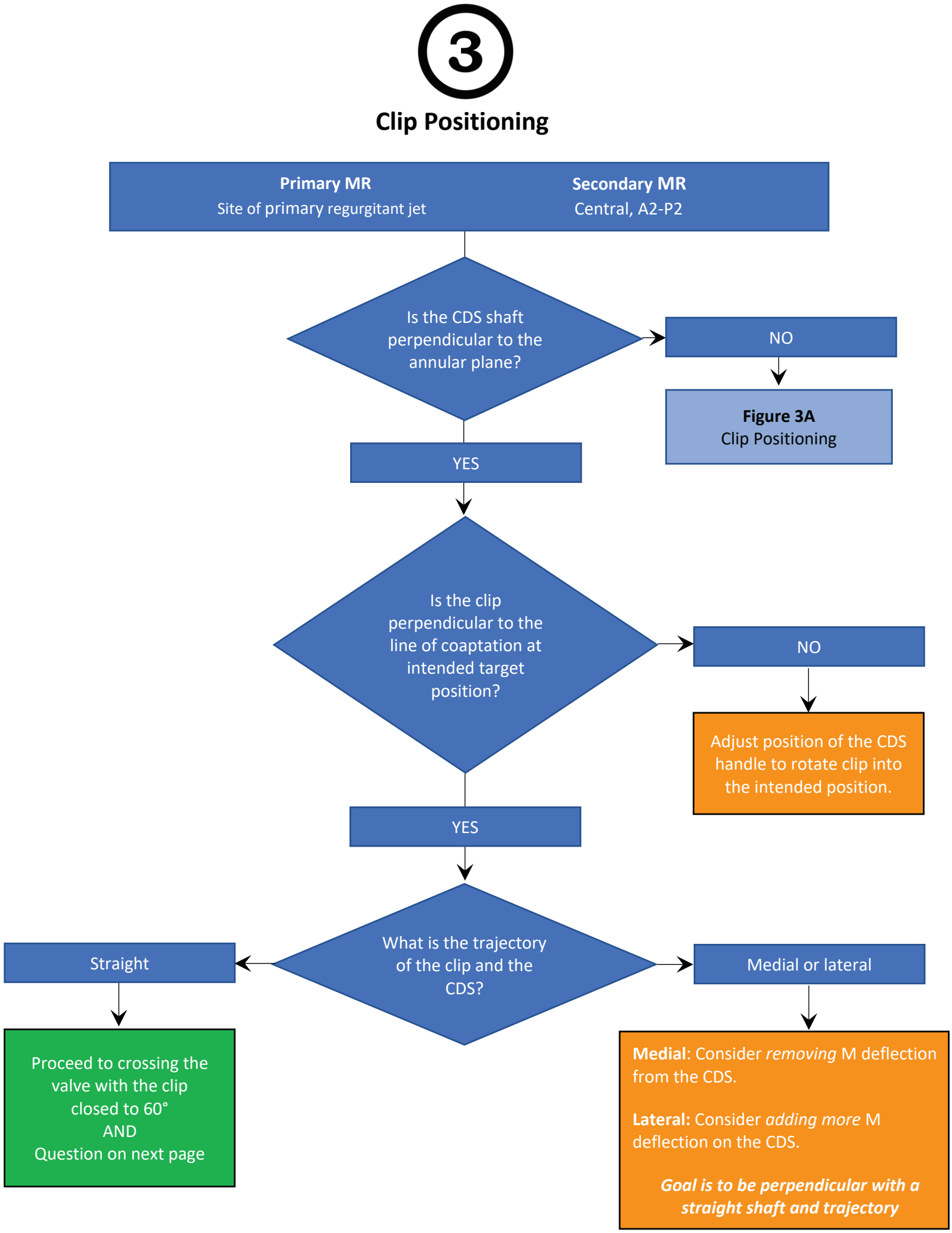
1. Raise the grippers
2. Unlock the clip
3. Open the clip to 180°

NO

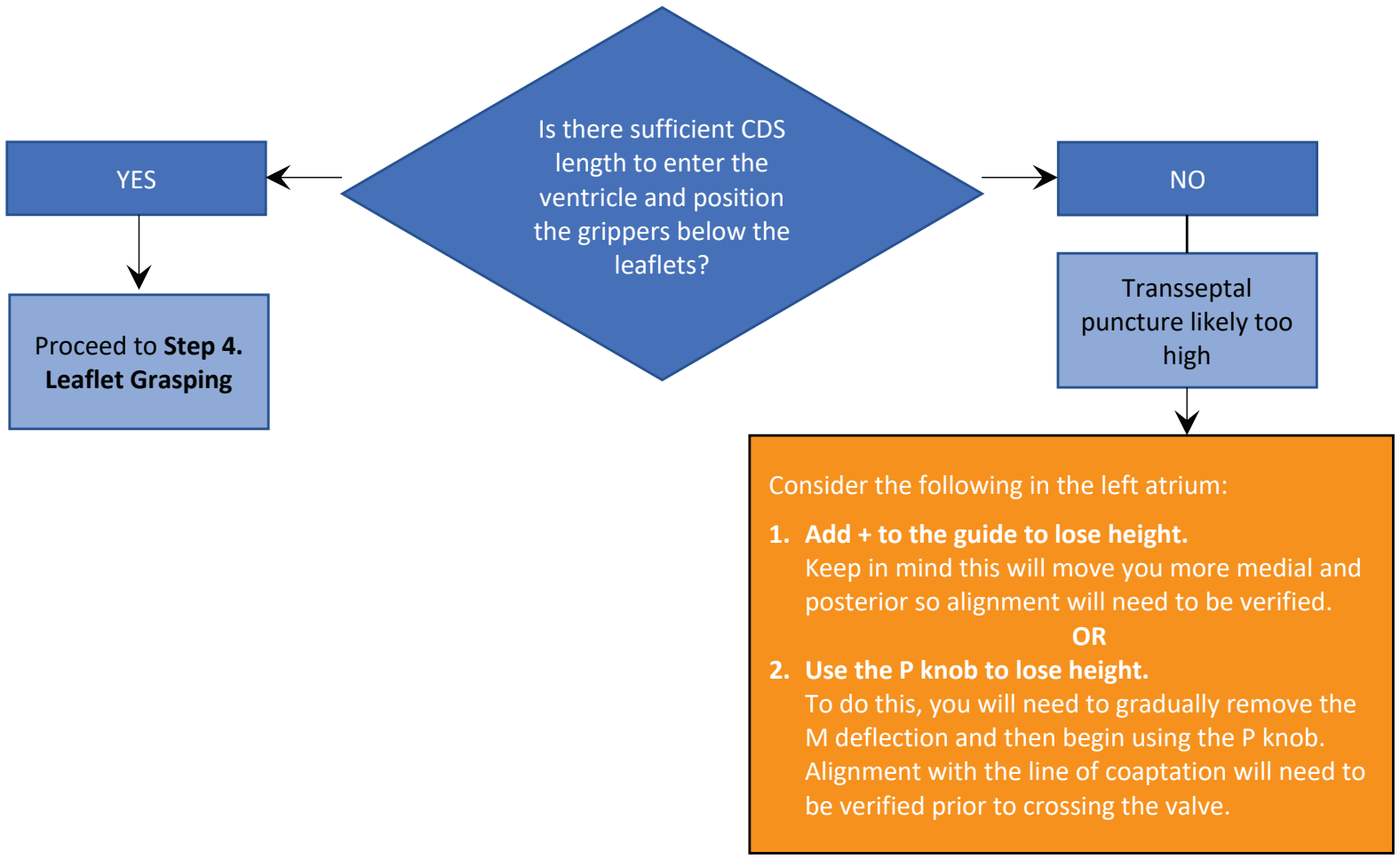
Consider the following:

- **Remove all M deflection from the CDS.**
- **Add P knob as you rotate the guide anteriorly**.
- The clip will move posteriorly and medially therefore you need to rotate the guide anteriorly to maintain position in the center of the valve.
- Additional medial and lateral displacement can be performed with the stabilizer.

P Knob: Once you use this knob it becomes the primary method for medial deflection.


3
Clip Positioning
Primary MR
Site of primary regurgitant jet
Secondary MR
Central, A2-P2
Is the CDS shaft perpendicular to the annular plane?
NO
Figure 3A
Clip Positioning
YES
Is the clip perpendicular to the line of coaptation at intended target position?
NO
Adjust position of the CDS handle to rotate clip into the intended position.
YES
What is the trajectory of the clip and the CDS?
Straight
Proceed to crossing the valve with the clip closed to 60°
AND
Question on next page
Medial or lateral
Medial: Consider removing M deflection from the CDS.
Lateral: Consider adding more M deflection on the CDS.
Goal is to be perpendicular with a straight shaft and trajectory

Clip Positioning



3

Clip Positioning (Figure 3A)

CDS shaft is NOT perpendicular to the annular plane.

What is the position of the CDS shaft relative to the mitral annulus on **LVOT view**?

Directed posteriorly toward posterior annulus

Consider the following:

1. **Remove any + on the guide or add – to the guide .**
   This will move the system more anterior and laterally therefore guide position may need to be adjusted by adding posterior torque.
2. **Add some M deflection or withdraw the stabilizer to maintain appropriate position.**

Directed anteriorly "aorta hugger"

Consider the following:

1. **Add + to the guide.**
   This will move the system more medially but away from the aorta.
2. **Reduce M deflection or advance the stabilizer to maintain appropriate position.**

OR

3. **Add P knob to the CDS.**
   This will move the system more medially so you may need to release some M or advance the stabilizer may be needed to maintain position.

What is the position of the CDS shaft relative to the mitral annulus on **bicomm view**?

Directed medially

Consider the following:

1. **Remove some M deflection.**
   This will move the system more laterally, and needs to be done in the LA.

OR

2. **Advance the stabilizer.**
   Always re-check trajectory after making adjustments to the catheter or stabilizer and confirm perpendicularity to line of coaptation on 3D imaging

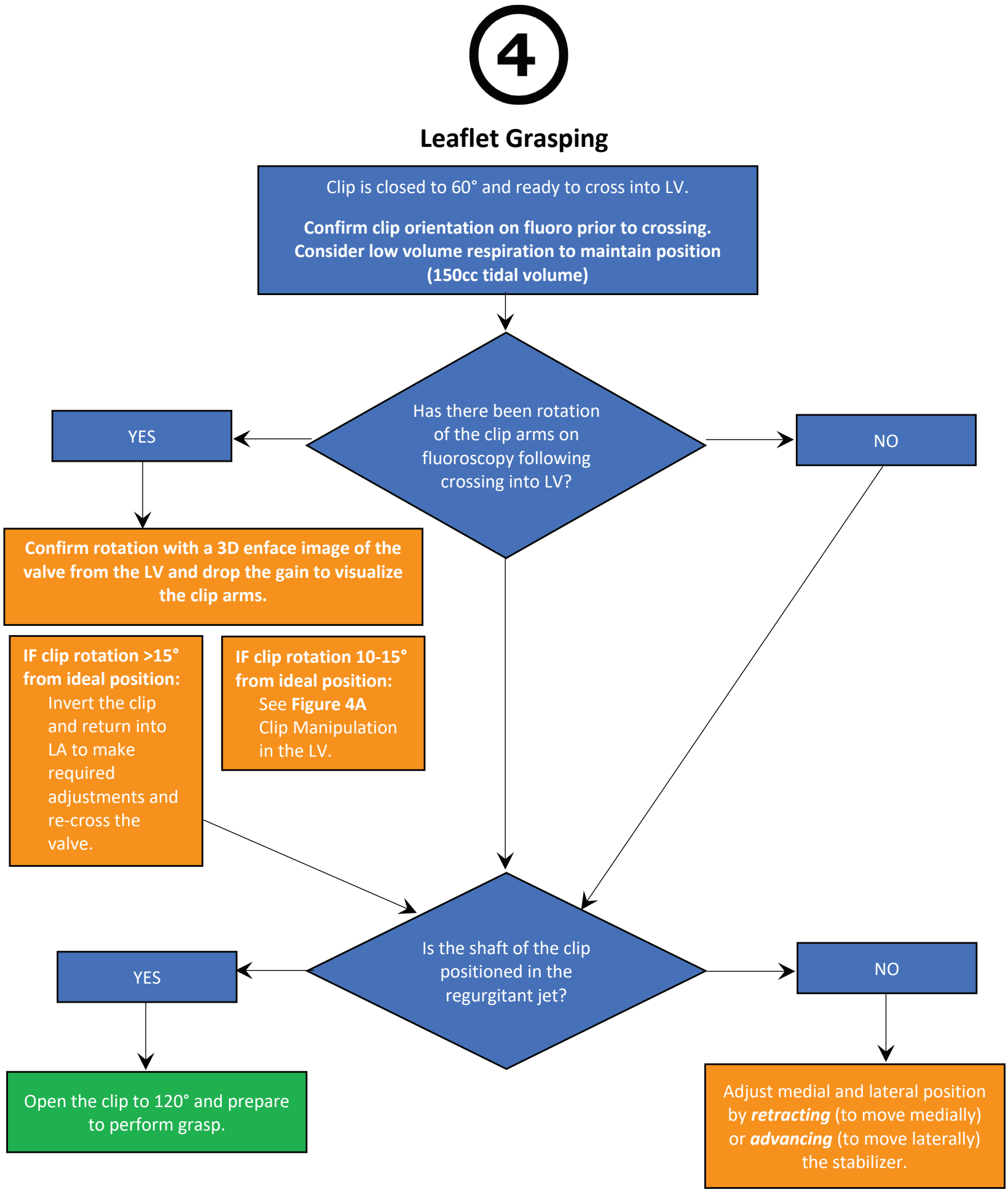
Directed laterally

Consider the following:

1. **Add M deflection on the CDS.**
   This will move the system more medially and posterior therefore position of clip should be verified on LVOT view and guide rotated accordingly.

OR

2. **Add + on the guide.**
   Always re-check trajectory after making adjustments to the catheter or stabilizer and confirm perpendicularity to line of coaptation on 3D imaging.


4
Leaflet Grasping
Clip is closed to 60° and ready to cross into LV.
Confirm clip orientation on fluoro prior to crossing. Consider low volume respiration to maintain position (150cc tidal volume)
Has there been rotation of the clip arms on fluoroscopy following crossing into LV?
YES
NO
Confirm rotation with a 3D enface image of the valve from the LV and drop the gain to visualize the clip arms.
IF clip rotation >15° from ideal position: Invert the clip and return into LA to make required adjustments and re-cross the valve.
IF clip rotation 10-15° from ideal position: See Figure 4A Clip Manipulation in the LV.
Is the shaft of the clip positioned in the regurgitant jet?
YES
NO
Open the clip to 120° and prepare to perform grasp.
Adjust medial and lateral position by retracting (to move medially) or advancing (to move laterally) the stabilizer.

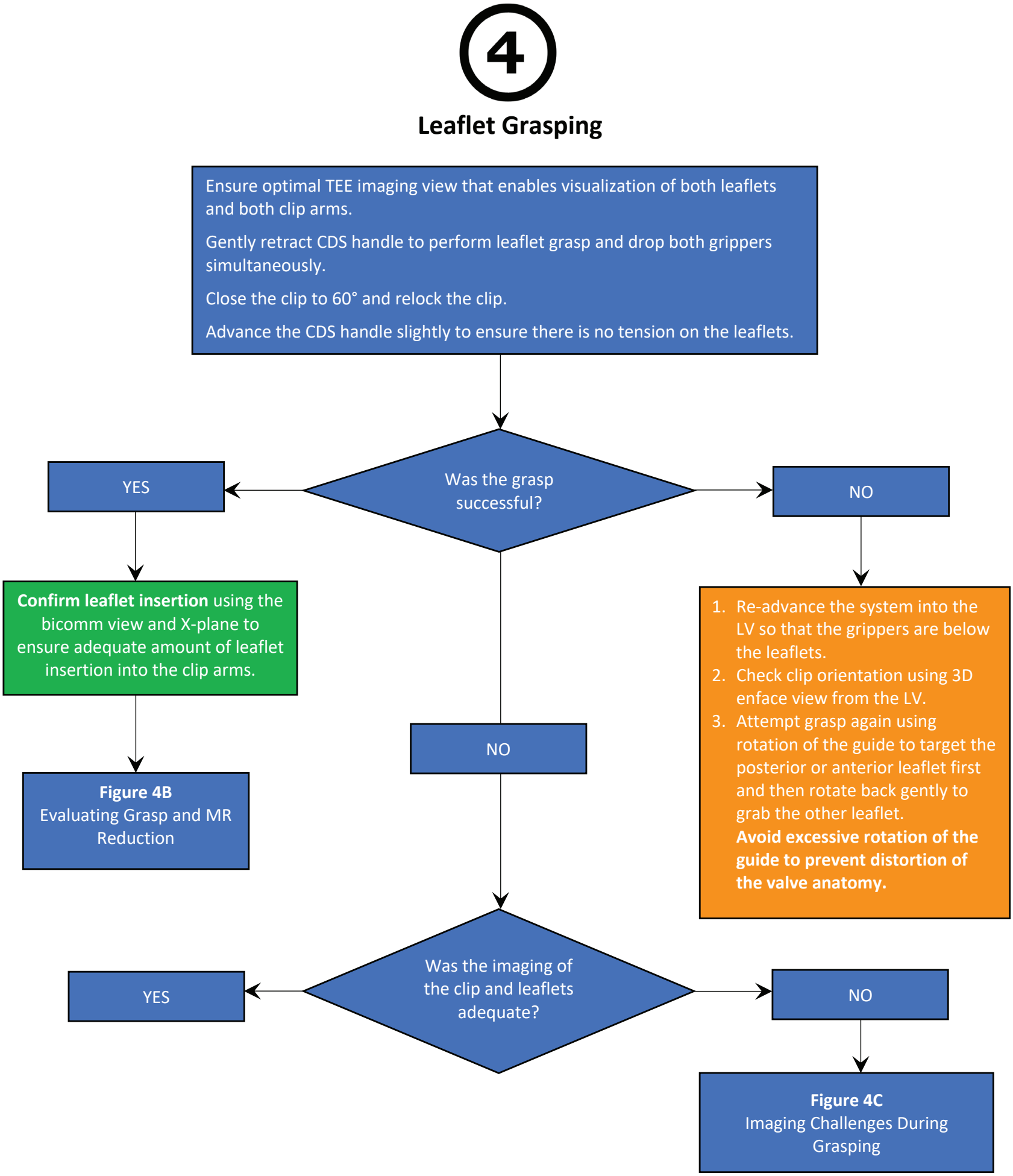


Figure 4B
Evaluating Grasp and MR Reduction

Figure 4C
Imaging Challenges During Grasping

Clip Manipulation in the LV (Figure 4A)

Clip has rotated < 15° and is in the left ventricle.

1. Confirm clip position on **3D enface** from the LV and determine direction of manipulation.
2. Confirm that the clip is free of the leaflets and chords, and that the grippers are below the level of the leaflets on **LVOT view.**
3. Confirm the clip position on the b**icomm view.**

Rotate the clip as required ensuring adequate translation of the CDS and that there is movement of the clip.

Is the clip moving freely with movement and translation of the CDS?

YES

Adjust clip to obtain optimal position on 3D enface view and attempt another grasp.

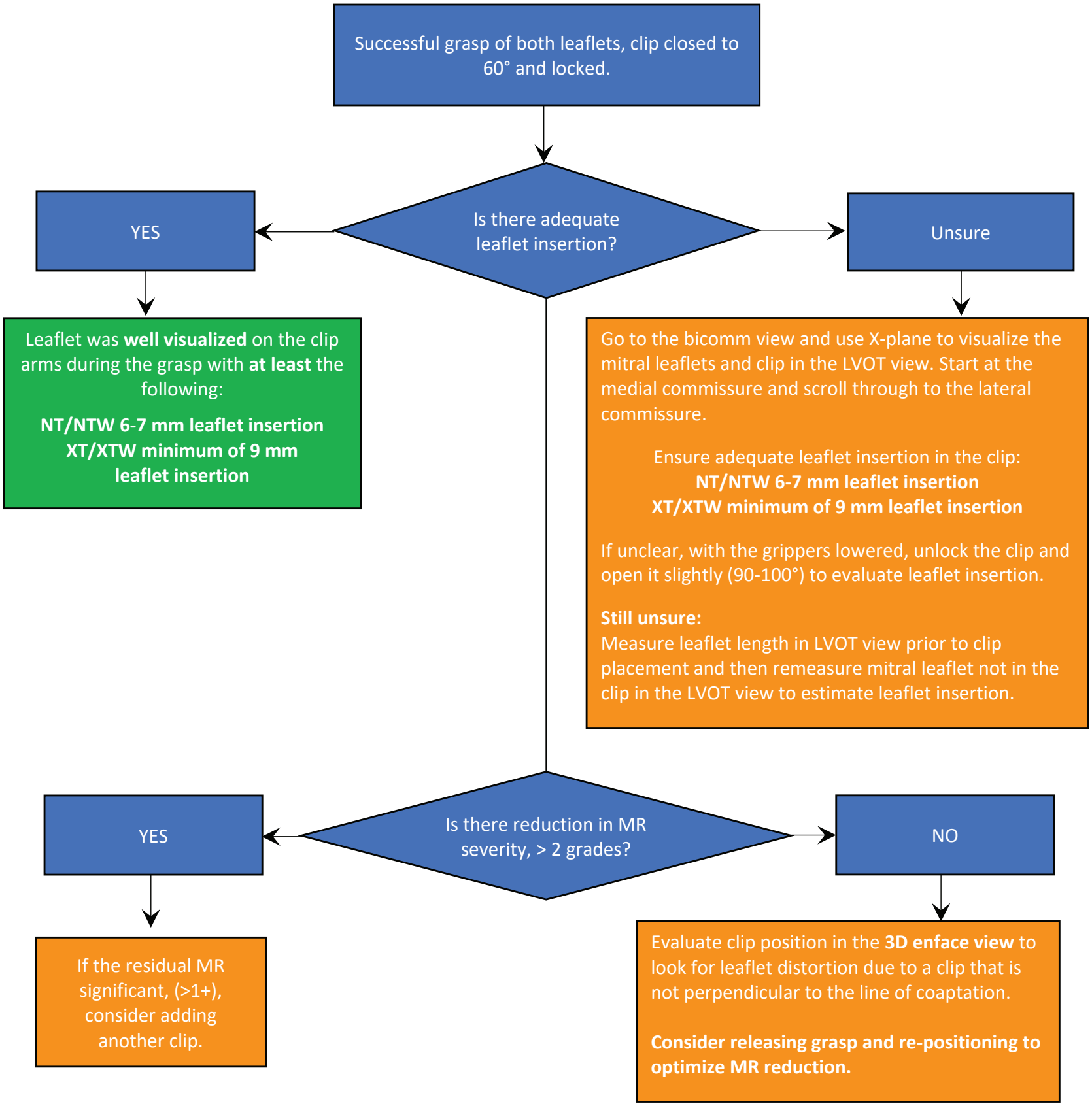
NO

Confirm that the clip is free of the leaflets and chords, and that the grippers are below the level of the leaflets on **LVOT view.**

THEN RE-ATTEMPT.

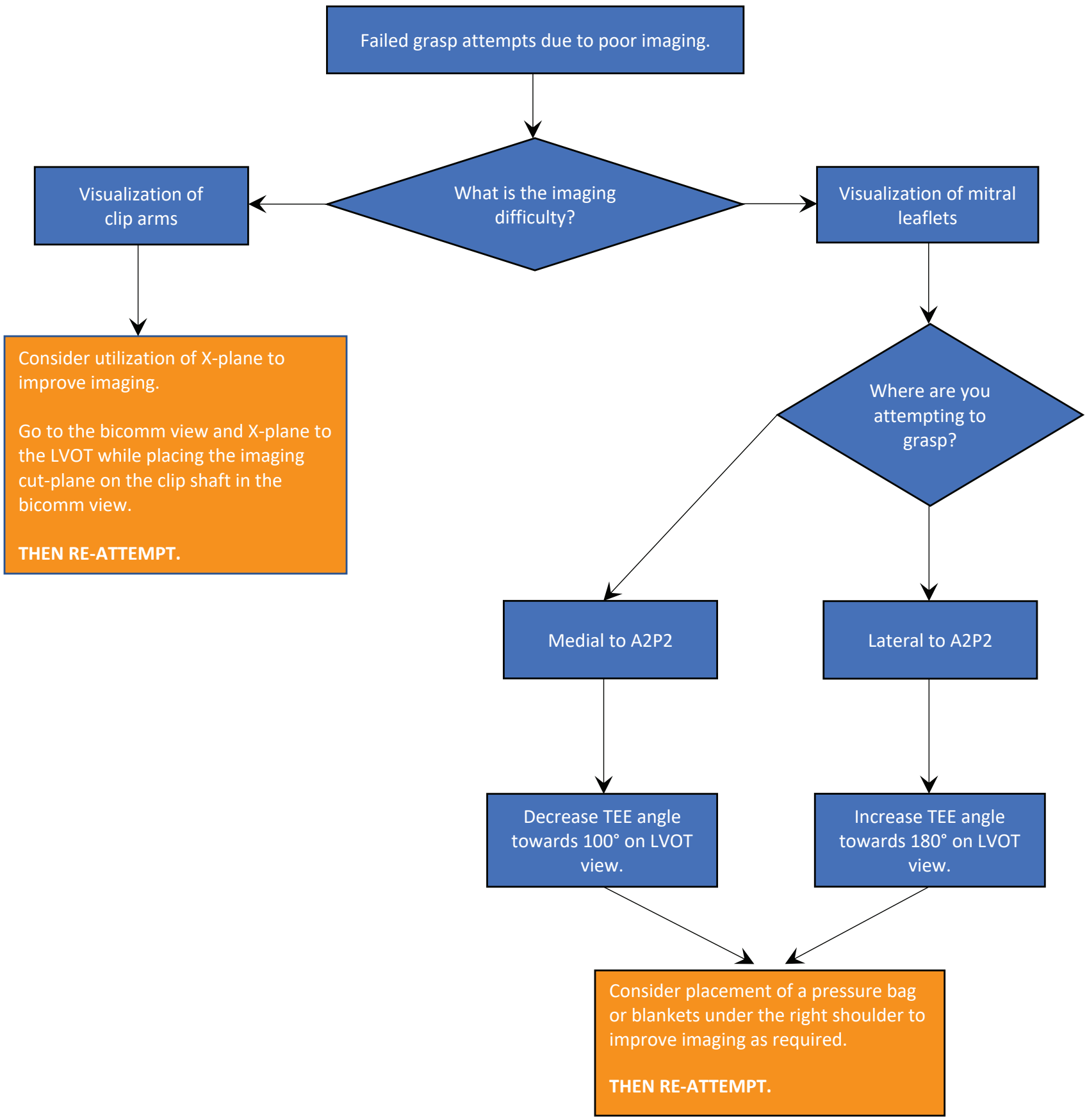
4

Evaluation of Leaflet Grasp and MR Reduction (Figure 4B)

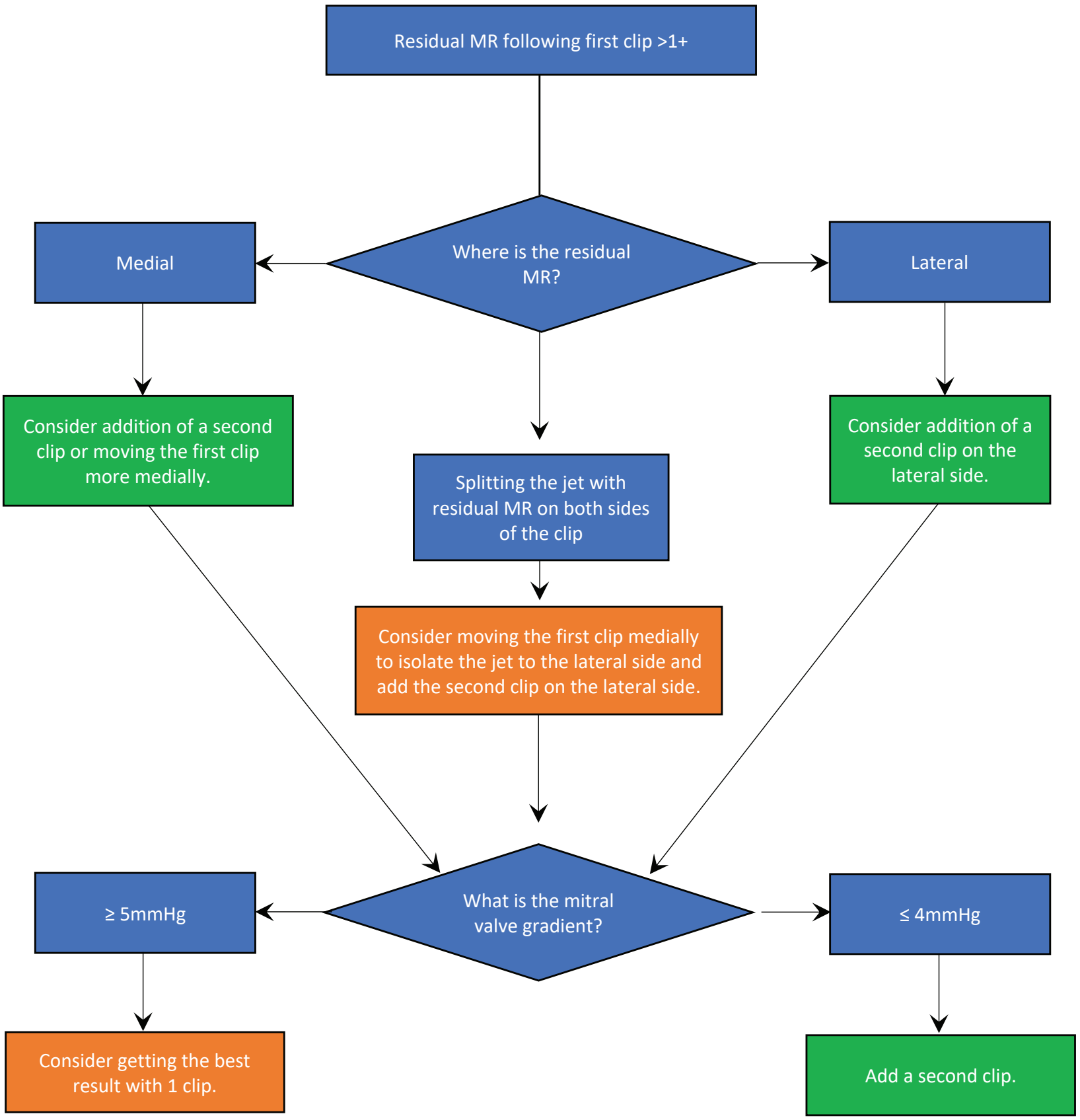


4

Imaging Challenges During Grasping (Figure 4C)



5 Additional Clips



APPENDIX B.

MitraClip Flushing Video


11. Return the Arm Positioner to Neutral.
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