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Mitral Valve Leaflet Modification: A Working Group Position Statement on Best Practices and Step-by-Step Guide

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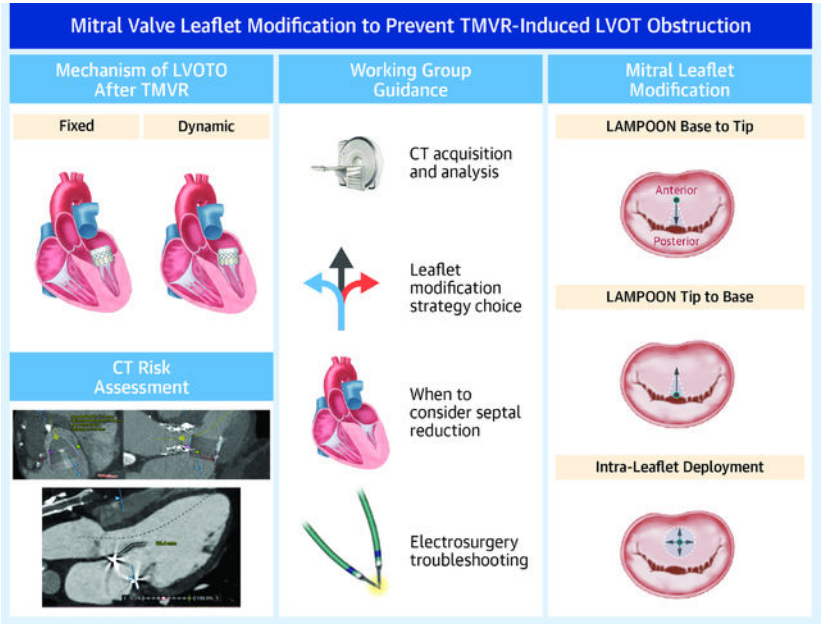
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Abstract

Left ventricular outflow tract (LVOT) obstruction is a potentially lethal complication of transcatheter mitral valve replacement (TMVR). The risk of LVOT obstruction can reliably be identified on pre-procedural cardiac CT. Intentional laceration of the anterior mitral leaflet to prevent outflow obstruction (LAMPOON) and related techniques effectively prevent TMVR-induced LVOT obstruction, thereby expanding the treatable patient population. However, perceived technical complexity, the absence of purpose-built devices, and limited training opportunities have hindered the widespread adoption of mitral leaflet modification. This document

synthesizes international experience to provide contemporary best-practice guidance for mitral leaflet modification. This state-of-the-art review details transcatheter electrosurgery principles, CT-based risk analysis and procedural planning, a step-by-step guide to the LAMPOON technique, tips for managing uncommon challenges, and guidance on post-procedural care. These contemporary best practices can help operators achieve or maintain proficiency.

Central Illustration:



Summary of key concepts relating to mitral leaflet modification reviewed in this position statement.

Keywords

Transcatheter mitral valve replacement; Left ventricular outflow tract obstruction; LAMPOON; Computed tomography; Leaflet modification; Transcatheter electrosurgery

Background

Transcatheter mitral valve replacement (TMVR) offers an option for patients at high-surgical risk in whom transcatheter mitral edge-to-edge repair (TEER) is unsuitable.¹ Left ventricular outflow tract obstruction (LVOTO) is a potentially fatal complication when the transcatheter heart valve (THV) displaces the anterior mitral leaflet (AML) toward the interventricular septum, limiting ventricular blood ejection.² Early series reported LVOTO in up to 40% of patients.^{3–5} Despite improved screening, the risk of LVOTO remains the most common contraindication to TMVR.⁶

TMVR-induced LVOTO can be a fixed obstruction, such as when the THV itself blocks blood ejection, and can be dynamic, such as when an overhanging anterior mitral leaflet

(AML) causes variable obstruction depending on loading conditions that alter LVOT geometry.

Two complementary strategies mitigate LVOTO risk: intraprocedural modification of the pre-existing native or bioprosthetic anterior mitral leaflet, and preparatory septal reduction therapy (SRT).^{5,7–13} Mitral leaflet modification presupposes that the intended transcatheter heart valve (THV) has an uncovered stent frame ('open cells') on its ventricular aspect that permits blood flow if it is in the path of the LVOT, so long as it is not covered by the AML. Currently the only such valves are balloon expandable prostheses. Leaflet modification is performed at the time of TMVR. SRT requires several weeks of myocardial healing, which entails transient swelling and subsequent remodeling, and therefore a delay before TMVR. The two can be used alone or together to achieve the required LVOT dimensions.

This document provides step-by-step guidance on assessing LVOTO risk and performing AML modification during TMVR (Central Figure), based on aggregated experience from 30 international expert operators. These recommendations, combined with reverse proctoring and observed cases, provide a basis for operator proficiency.^{14,15}

Methodology

We aggregated international TMVR leaflet modification experience. Our recommendations are based on a modified-Delphi consensus development framework through three iterative email rounds.^{16,17} We obtained structured input from 30/38 (79%) experienced mitral leaflet modification operators on 3 continents.

Round 1 solicited open-ended recommendations consolidated into proposed statements. Rounds 2–3 assessed concurrence (accept/tolerate/reject) and confidence (4-point scale). Statements that received a decision-confidence score <0.6 triggered iterative revisions. Final position statements were endorsed when scores exceeded 0.6. Resulting scores are shown in Table 1.

Patient Selection: Who Benefits

TMVR indications and implant techniques are described elsewhere.^{1,18,19} Generally, there are four broad categories of TMVR defined by the antecedent mitral annulus. These categories, valve in valve, valve in ring, valve in mitral annular calcification (MAC), and valve in native annulus with a dedicated prosthesis, are relevant to mitral leaflet modification as they have implications on the utility and feasibility of different modification strategies as will be discussed below. Ultimately, patient selection for leaflet modification is largely anatomic, based on CT angiography.

CT analysis and predictors of LVOT obstruction

CT analysis is a foundational skill for TMVR operators and should not be delegated to others. It reveals patient-specific detail and depicts 3-dimensional anatomic relations. Multiplanar viewing tools are widely available, but *curved* multiplanar reconstruction (see below) across multiple cardiac phases is important and available from multiple vendors

(e.g. Pie Medical *3mensio*, Circle cardiovascular *cvi42*, Canon *Vitrea*, FEops *HEARTguide*, Materialise Enlight *Mimics*, TeraRecon, *Intuition*, etc) in addition to an open-source option (<https://horosproject.org/>).

Three CT-derived measurements predict LVOT obstruction: the “neoLVOT”, “skirt-neoLVOT” and anterior mitral leaflet length. Other factors such as aorto-mitral angle are typically less informative.

Acquisition

High-quality ECG-gated contrast-enhanced CT is required. The full cardiac cycle should be reconstructed to permit measurement at end-systole, when the LVOT is smallest and septal thickness greatest. End-systole typically occurs at 30–50% of the R-R interval, but gating errors occur, so all phases should be inspected. Slice thickness and in-plane resolution should be ≤ 1 mm for decision making.

Cardinal planes and simulated (virtual) valve implantation

CT planning uses curved multiplanar reconstruction to visualize the LVOT along the path of blood ejection. The first step is to define the mitral and the aortic annuli (Figure 1, panel A). The LVOT centerline is a curved line between the center of the aortic annulus and the apical left ventricle (Figure 1, panel B).

Next overlay a simulated (“virtual”) THV at the mitral annulus having the required diameter, height, and “skirt height.” The skirt height defines the annular aspect of the THV that has fabric-covered or closed-cells; the skirt height will be the same as the THV height if there are no open cells on the ventricular aspect. The THV is then manipulated to approximate the intended implant depth and orientation. This position needs confirmation in both antero-posterior and medial-lateral orientation. For a balloon-expandable THV this position is typically 75–80% ventricular, which means that after full expansion, the entire THV stent frame is 20–25% atrial and 75–80% ventricular in the projection that corresponds with the TEE 3-chamber view (Figure 1, panel C). In native mitral valves and in prior annuloplasty bands, the THV may be displaced anteriorly by posterior cardiac structures. While performing a CT analysis, it is prudent to plan for an anticipated “worst case” rather than “optimal” simulated valve position, since the ultimate valve implant depth and angulation may differ from what is desired.

Position statements:

Cardiac CT angiography is essential to measure neoLVOT area, skirt neoLVOT area and anterior mitral leaflet length. Cardiac CT angiography should include all phases of the cardiac cycle so that measurements can be made on the smallest end-systolic dimensions despite potential gating errors. Slice thickness and in-plane resolution should be ≤ 1 mm.

NeoLVOT

The neoLVOT is the smallest end-systolic two-dimensional cross section of the LVOT following TMVR.²⁰ After simulating THV implant position, planners “scroll” up and down

along the LVOT centerline examining the cross-sectional plane that is orthogonal to the centerline. The predicted neoLVOT is the smallest LVOT cross-sectional area between the virtual THV and the ventricular septum and is typically found at the apical-most anterior edge of the virtual THV. This cross section is traced and the corresponding area is reported in square millimeters (Figure 1, panel C).²⁰

The neoLVOT predicts fixed LVOT obstruction following TMVR without leaflet modification. NeoLVOT-thresholds below 200 mm² predict LVOT obstruction that is often fatal.^{4,14,15,20–22} However, for active patients, a larger neoLVOT >250mm² maybe necessary to avoid functional LVOTO during activity. In other words, a neoLVOT of 200 mm² may define procedural survivability but may not be sufficient for improved quality of life following the TMVR.²²

Position statements:

The neoLVOT area predicts LVOT area after TMVR without leaflet modification. A neoLVOT area <200mm² predicts risk of important or life-threatening LVOTO after TMVR. In active patients, a neoLVOT area >250mm² may be required to avoid functional LVOTO. These thresholds should prompt consideration for pre-emptive leaflet and/or septal reduction therapy before TMVR.

Skirt-neoLVOT

The skirt-neoLVOT represents the smallest end-systolic LVOT area after AML laceration, measured at the fabric-covered portion of the THV frame.^{4,23}

The skirt-neoLVOT is identified by continuing the procedure outlined above for neo-LVOT but continuing to “scroll” basally from the neoLVOT position along the cross-sectional plane orthogonal to the (curved) LVOT centerline, until the plane intersects the ventricular-most anterior edge of the fabric skirt of the virtual THV (Figure 1, Panel D). For newer prostheses with no open cells on the ventricular aspect of the valve frame, the neoLVOT and skirt-neoLVOT will be the same. LAMPOON-split anterior mitral leaflets splay around implanted THVs, effectively allowing blood to flow through at least two valve frame cells.²² (Figure 2)

A skirt-neoLVOT of ≤200 mm² risks LVOTO despite leaflet modification and should prompt consideration for a preemptive septal reduction therapy (SRT) to enlarge the LVOT. Similar to neoLVOT, active patients may require a skirt-neoLVOT > 250 mm² to avoid functional LVOTO.²²

These thresholds are not adjusted for body surface area, sex, age, myocardial mass, or loading conditions; higher values may be necessary in individual patients. Importantly, small changes in anterior-posterior angulation (“canting”) of the THV can significantly alter the neoLVOT. (Figure 3) Lastly, the shape and rigidity of the intended prosthesis may be important in understanding the neoLVOT. The current values presuppose a cylindrical prosthesis.

Position statements:

The skirt neoLVOT area predicts LVOT area after TMVR with leaflet modification. Skirt neoLVOT area represents expected area after leaflet modification minus the area which will be occupied by the closed cells or fabric skirt of the THV itself. Skirt neoLVOT <200mm² should prompt consideration for pre-emptive septal reduction therapy (SRT) before TMVR. In active patients, a skirt neoLVOT area >250mm² may be required to avoid functional LVOTO.

Anterior Mitral Leaflet Length

Leaflet length is best measured on CT during a diastolic phase (Figure 1, Panel E). An AML length >20–23 mm may result in leaflet tip overhang beyond the implanted balloon-expandable THV after TMVR. Thresholds are uncertain since overhang depends on THV frame height, implantation depth, and valve canting. Leaflet overhang is a problem most often in valve-in-ring cases with long native AMLs. Mobile overhanging leaflets can cause dynamic LVOTO (Venturi forces) or, less commonly, even interfere with THV leaflet opening and closing. Reduced preload, reduced afterload, and increased inotropy may exacerbate this dynamic LVOTO. Pre-emptive leaflet modification can mitigate both dynamic LVOTO and impaired THV function.

Position statements:

A reasonably mobile anterior mitral leaflet length >20–23 mm may result in leaflet tip overhang after TMVR. Leaflet overhang is based on leaflet length, THV prosthesis height and implant depth of the THV so uncertainty remains about specific leaflet length thresholds. Leaflet overhang risks dynamic LVOTO or impaired THV function. Both can be mitigated with pre-emptive leaflet modification.

CT-planning for procedural fluoroscopy

The leaflet traversal spot and intended line of laceration are selected based on the distribution and volume of leaflet calcification. The traversal target must be calcium-free. Fluoroscopic projection angles, both side- and front views, are selected based on the mitral annular plane (Figure 1, Panel F). Fluoroscopic fiducial markers are selected at these angles, ideally during multi-phasic CT animation, using markers such as calcifications, aortic prostheses, pacemaker leads, bones, etc. These fiducial markers can be valuable to guide leaflet traversal and THV implantation. For valve-in-valve TMVR, the commissural post orientation of surgical bioprosthetic valves is assessed to ensure it does not contribute to LVOTO.

Pre-procedure transesophageal echocardiography

Pre-procedural TEE is valuable, especially for native valve procedures. TEE can demonstrate length and mobility of the AML and an understanding of the dynamic changes in LVOT geometry throughout the cardiac cycle. It can also be useful in understanding

target areas for leaflet traversal. Diagnostic TEE is not considered mandatory for more straightforward procedures, such as valve-in-valve.

Position statements:

Transesophageal echocardiography is a valuable adjunct to CTA, especially for valve-in-ring and valve-in-MAC, to corroborate native anterior mitral leaflet length, mobility, and systolic anterior motion.

Detailed Step-by-Step Technique

Antegrade Base-to-Tip LAMPOON

The default LAMPOON approach is antegrade, positioning catheters from the left atrium, and lacerating the AML A2 scallop from base-to-tip (Figure 4).

TMVR is technically demanding and can be high risk. Risk and complexity increase when combined with leaflet modification. These procedures are best performed in hybrid spaces with intraprocedural TEE, and with the assistance of dedicated cardiac anesthesiologists. Ensuring an adequate supply and detailed understanding of the standard equipment required for leaflet modification is also paramount (Table 2).

The value of cerebral embolic protection has not been established for TMVR with leaflet modification. There were no strokes in the original 30-patient LAMPOON series.⁷ Cerebral embolic protection is used at operator discretion.

Hemodynamic collapse is infrequent after successful LAMPOON because split leaflets continue to coapt, albeit with worsened mitral regurgitation (Figure 5). Prophylactic intra-aortic balloon pump (IABP) is recommended by many operators before leaflet modification, especially when baseline mitral regurgitation is minimal. The hemodynamic burden of catheter-induced leaflet displacement during procedural manipulation may also be reduced with the aid of an IABP. Percutaneous LVAD (e.g., Impella) and extracorporeal membrane oxygenation (ECMO) are rarely required a priori.

Position statements:

- Prophylactic hemodynamic support with an IABP may be considered when performing LAMPOON, particularly when lacerating a native leaflet or when the primary valve lesion is not mitral regurgitation.
- Prophylactic hemodynamic support with ECMO is very rarely necessary for hemodynamic stability.
- Regarding cerebral embolic protection, available data are inadequate to guide decision-making, thus its use during TMVR and leaflet modification should be left to the discretion of the operator.

Access, transseptal puncture, and antegrade LAMPOON “Fulcrum”

A large femoral vein sheath with an inflatable hemostasis valve (DrysealFlex, 26Fr, Gore) allows multiple catheters through a single puncture. TEE-guided transseptal puncture is typically performed in an inferior-posterior location to achieve a transseptal height of 3.0–4.0 cm above the annulus and to facilitate later valve delivery. The transseptal sheath is exchanged for two stiff guidewires to deliver two transfemoral deflectable guiding sheaths (*e.g.*, AgilisNxT, Abbott) into the left atrium (Figure 6, Panel A). A hemostatic valve is attached to each guiding catheter hub. Standard anticoagulation targets an activated clotting time >300.

A key concept in antegrade LAMPOON (both base-to-tip and tip-to-base) is that the two left atrial deflectable guiding sheaths serve as a fulcrum for their respective laceration catheters while they are energized and withdrawn (Figure 7). Alignment of the laceration with the LVOT is achieved via this left atrial fulcrum. Without the fulcrum point, the laceration would otherwise be oblique towards the interatrial septum creating a highly asymmetric split.

Guidewire Rail and LV Snare Position

A veno-arterial guidewire rail helps stabilize the left ventricular snare catheter directly under the AML. The rail is established by advancing a 0.035” balloon-wedge end-hole catheter (BWEC), preferably from the more posterior deflectable guiding sheath, across the mitral orifice (Figure 6, Panel B). Deflection of the BWEC away from the apex toward the LVOT may be facilitated using a Glidewire or by hand-kinking a coaxial 0.035” J-guidewire. Once the BWEC is oriented toward the LVOT, a long (preferably kink-resistant, nitinol) 0.014” guidewire is advanced from the BWEC into the ascending aorta.

This guidewire is ensnared from a retrograde transfemoral 6 or 7Fr aortic guiding catheter (*i.e.* JR4) directing a tri-lobe snare (*e.g.*, Atrieve 18/30 Teleflex or Ensnare 18/30, MeritMedical). Ensnarement is achieved most rapidly at the innominate artery.

To prevent mitral chordal entrapment of the eventual lacerating system, the BWEC is swept in the medial-lateral dimension with the antegrade deflectable guiding sheath to confirm free movement of the ensnared guidewire rail. Preservation of chordal integrity is important for optimizing eventual leaflet splay. Before externalization of the guidewire rail, the snare loading device may be inserted inside the hemostatic adaptor to prevent loss of ensnarement. The snared (arterial) end of the externalized rail guidewire is secured at the groin using forceps to ensure that inadvertent withdrawal does not occur.

The venous end of the guidewire rail then delivers an antegrade transvenous 6–7Fr JL3.5 guiding catheter across the mitral orifice, positioning the same 18/30 tri-lobe snare along the ventricular surface of the target AML scallop (Figure 6, Panel C). Position should be confirmed by TEE.

Some experienced operators no longer employ a veno-arterial rail to maintain the tri-lobe snare in the LVOTO. In such instances, the snare is directed anteriorly through a JR4 guiding

catheter further toward the LV apex. This technique has fewer steps but may make snaring more difficult. It is described further below in the “Mechanical Aortic Valve” section.

Anterior Mitral Leaflet Traversal

The next step is to position a guidewire at the base of the AML A2 scallop for electrosurgical traversal and ensnarement. The more-anterior deflectable guiding sheath directs a 6–8Fr JR4/IM guiding catheter to contact the AML base at a calcium-free traversal point identified on CT. Medial-lateral position is adjusted by the degree of deflection on the deflectable guiding sheath or by pushing it forward (lateral) or drawing it back (medial), whereas basal–apical position is controlled by torque. The approach or “attack” angle for the puncture is controlled by torquing the JR4/IM guiding catheter. Position and contact are confirmed by TEE in 3-chamber and medial-lateral views, or multiplanar 3-dimensional reconstruction. (Figure 8)

Absent purpose-built traversal guidewires, a rigid “CTO” guidewire (AstatoXS 20 or AstatoXS40, Asahi) is prepared for traversal. A 300-cm wire length is required to allow subsequent externalization. These guidewires have an insulating coating on their proximal shafts but are effectively non-insulated distally. They are therefore electrically insulated with a 0.014” microcatheter (Quick-Cross, Phillips)²⁴. This microcatheter maybe 135 or 150 cm but should not be greater than half the length of the wire it is insulating. Insulating guidewire coating is scraped from the proximal guidewire end to make good electrical contact when clamped to an uncoated electrosurgical pencil. The distal 1–2mm of the guidewire extends beyond the tip of the 0.014” microcatheter where it contacts the atrial side of the AML base via the JR4 guiding catheter. Note microcatheter tips are typically ~2mm beyond radiopaque tip markers. Ensure that the guidewire “attack angle” is relatively orthogonal to the AML so that it doesn’t deflect (“skive”) when advanced. The tri-lobe snare is positioned immediately beneath the AML to “receive” the traversing guidewire (Figure 6, Panel D). If catheter positioning and trajectory above the AML do not provide a perpendicular angle to the AML for perforation despite positioning of the mother/daughter catheter system, re-crossing the atrial septum in a more favorable position to establish coaxiality may be valuable.

For electrosurgical traversal, the guidewire is briefly energized (≤ 1 second) during gentle advancement. Typical traversal energy is 50 Watts on the “pure cut” setting, traditionally activated with the yellow switch on the electrosurgical pencil. Electrosurgery generates steam microbubbles evident on TEE; their absence suggests electrical circuit failure. Applying energy for a longer time risks carbonizing the guidewire, reducing its electrosurgical utility, and causing blood clots. Heavy advancement force risks “knuckling” the guidewire, causing potentially hazardous bystander tissue injury. Failure to advance easily when energized suggests calcification at the contact point or electrical circuit failure. Difficult traversals sometimes require longer or higher energy application or D5W flush to displace blood and focus energy delivery onto the guidewire tip.

The energized guidewire should not be advanced more than a few millimeters because electrosurgical traversal beyond the target leaflet is unnecessary. After current is discontinued, the wire may be advanced further to maintain position across the leaflet. TEE should confirm traversal at the intended leaflet base without deflection toward the central

orifice. Once traversal is confirmed, the guidewire is ensnared with the prepositioned tri-lobe snare (Figure 6, Panel E)

Once ensnared, the tip of the wire is withdrawn into the snare catheter 2–3 cm (often referred to as “breaking” the wire). Maintain the guidewire-snare combination in the current fluoroscopic field-of-view while the laceration surface is created (next section)(Figure 6, Panel F). The snare-rail guidewire may then be released and withdrawn through the venous side. The 0.014” microcatheter is withdrawn to within ~5 cm of the proximal guidewire end to expose the Astato segment between the guide catheter and microcatheter tip.

Position statements:

- For traversing the leaflet, a standard telescoping set up would be a deflectable guiding sheath, a curved 6–8Fr guide (typically a JR4, sometimes an IM), a 0.014” microcatheter, and an Astato XS 20 guidewire.
- For traversing the leaflet, 50 watts of energy on the ‘pure cut’ setting without continuous flush infusion is the standard electrosurgical approach but can be modified as needed.

Create the Laceration Element (“Flying-V”)

Creating a proper “Flying-V” leaflet laceration surface is relatively simple in concept and execution though may require some practice.^{25,26} The guidewire is intentionally folded/kinked where it will straddle the leaflet. Electrical energy “wants” to concentrate on the outer “elbow” of the folded/kinked guidewire, where it is not desired. To counteract this effect, electrical insulation is scraped/denuded from the inner “antecubital” surface of the folded/kinked guidewire. The scraping/denudation is ~3mm long, ~120° non-circumferential, and accomplished with the sharp end of a scalpel blade. Folding/kinking is accomplished against the blunt-end of the scalpel blade (Figure 9). Care is required to ensure that the scraped/denuded guidewire is not rotated before folding/kinking, so that the denuded segment aligns with the inner surface. This process can be practiced using common guidewires before attempting LAMPOON.

The tip of the 0.014” microcatheter is fixed in place 1–2 mm proximal to this denuded segment and serves as electrical insulation and a fluoroscopic marker. The microcatheter position is “locked” either with a preloaded 0.035” torque device on the shaft and 0.014” torque device on the guidewire abutting the microcatheter hub or with surgical hemostat forceps (e.g. “Kelly clamps”). Recognize that the radiopaque tip marker on the 0.014” microcatheter is 1–2mm from its tip.

Improper “Flying-V” configurations include denudation mal-aligned with the inner-surface of the kink; denudation too long (longer than ~3mm), circumferential, or not centered on the kink; kinks with excessive radius of curvature (round instead of sharp kinks); microcatheters abutting or covering the kink rather than offset 1–2mm; and guiding catheters or microcatheters too-far from (therefore insufficiently insulating) the Flying-V. Appropriate

Flying-V configurations may also be ineffective if pulled asymmetrically at the time of laceration so that the denuded lacerating surface no longer contacts the target leaflet.

Positioning for Laceration

Locked in place, the microcatheter and Flying-V are advanced across the anterior mitral leaflet as one unit by externalizing the distal ('broken') end of the guidewire through the snare guide. Properly positioned, the kinked Flying-V self-oriens around the leaflet at its traversal point (Figure 6, Panel H). Once externalized, the guidewire shaft is clamped against the guiding catheter hub using multiple 0.014" torque devices or snaps. The "proximal" denuded guidewire shaft is clamped to an uncoated electrosurgery pencil.

The transseptal deflectable guiding sheath tips are positioned against each other in the central left atrium, to serve as a midline fulcrum. The deflectable guiding sheaths are held in place (usually by a second operator) while laceration is performed via traction on the nested guiding catheters, microcatheter, and Flying-V as one unit. A "dry run" is helpful before electrosurgical laceration to remove slack from the catheter system, and to alert staff to next steps including preparation of the valve for subsequent implantation. Excessive traction while not lacerating can induce severe mitral regurgitation.

Laceration

During laceration, electrosurgical energy is applied at 70W while the primary operator pulls both guidewire limbs in a controlled, symmetric fashion to slice from the base to the tip of the leaflet. While energized, the Flying-V is flooded via both guiding catheters with 5% dextrose (~2–5mL/s, delivered simultaneously from two 60mL syringes with extension tubing) in water (not saline) to displace blood, focus energy application, reduce guidewire carbonization, and reduce clotting. Steam microbubbles should be evident on TEE.

Operators should apply traction symmetrically to both guidewire limbs and ensure that neither microcatheters nor guiding catheters interpose between the Flying-V and the target leaflet. In some instances, the deflectable guiding sheaths will be drawn down to the leaflet leaving little room to further withdraw the nested catheters. In such scenarios, rather than pulling on the deflectable guiding sheaths also, which will naturally draw the laceration medially, posterior deflection (clockwise torque) of the deflectable guiding sheaths may allow for increased height and improved vector forces ensuring that the laceration, when performed, traverses in a straight line from the base to the tip of the leaflet along A2 and does not deviate tangentially towards the medial commissure and intra-atrial septum.

Laceration typically requires 2–5s of energy application, depending on leaflet thickening, calcification, and electrosurgery efficiency. Excessive traction risks leaflet avulsion, flail, and embolization. Flush should be refilled as needed.

Successful laceration is evident on TEE as leaflet splay and regurgitation. After successful laceration, LAMPOON equipment is removed except for one transseptal guiding sheath used to initiate valve implantation.

Position statements:

- For lacerating the leaflet, 70 watts of energy on the ‘pure cut’ setting with continuous 5% dextrose water flush infusion to better insulate both limbs of the Flying-V and minimize char and thrombus formation is the standard electrosurgical approach.

Role of procedural TEE

Transesophageal echocardiography is invaluable to guide key procedural steps including traversal location, ensnarement, freedom from chordal entrapment after the traversing guidewire is ensnared (Figure 10, Panel A & B), mitral regurgitation from tension on the AML prior to laceration (Figure 10, Panel C), steam microbubbles indicating electrosurgical energy delivery (Figure 10, Panel D), success of laceration (Figure 10, Panel E & F), THV deployment position, and residual LVOTO and paravalvular leak.²⁷ TEE can corroborate or refute concerns over long AML leaflets that cause post-TMVR leaflet overhang and dynamic LVOTO. TEE is also essential to confirm successful laceration (with valvular regurgitation) after tip-to-base LAMPOON, because electrosurgical failure may not be evident on fluoroscopy alone.

Balloon-assisted LAMPOON

When skirt-neoLVOT is low or borderline, some operators prefer to enlarge the basal-most aspect of the LAMPOON laceration. Balloon-assisted LAMPOON may enhance leaflet splay.^{28,29} In this variant, a non-compliant balloon (typically 4×20 mm) is inflated antegrade across the leaflet traversal point immediately after ensnarement of the traversal guidewire (following removal of the antegrade microcatheter) (Figure 6, Panel G). The balloon catheter is then withdrawn and replaced with the 0.014” microcatheter before the Flying-V is created.

Antegrade Tip-to-Base LAMPOON

Tip-to-base LAMPOON is a simplified variant that omits the mitral leaflet traversal step (Figure 4).³⁰ It may be suitable to lacerate leaflets when the aorto-mitral curtain is protected by bioprosthetic surgical valves, by complete mitral annuloplasty rings, or to rescue dynamic LVOTO caused by leaflet overhang in TMVR.³¹ Tip-to-base LAMPOON may also be useful when two surgical bioprosthetic leaflets need laceration based on surgical prosthesis mal-alignment.³² There is limited experience with this technique inside a prior balloon-expandable TMVR. Disadvantages include difficulty “binding” the Flying-V to the AML tip for stable positioning before laceration, accordion-like “bunching” of mobile AML tips confounding actual laceration (Figure 11), difficulty recognizing laceration failure, and difficulty controlling and assuring the basal extent of laceration. Rarely, operators have injured the aortic valve by inadvertently displacing the Flying-V towards the LVOT during electrification. Therefore, tip-to-base LAMPOON should only be used when there is ample anatomic space to protect the aortic leaflets.

In tip-to-base LAMPOON, laceration is performed using the veno-arterial guidewire rail. Only a single transseptal deflectable guiding sheath is employed. The rail is established

exactly as in base-to-tip LAMPOON using a BWEC. The rail employs an AstatoXS 300cm guidewire. The Flying-V and 0.014" microcatheter configuration are prepared after ensnarement as described above. Bystander structures, especially the aortic valve, are protected using retrograde and antegrade 6–8Fr JR4 guiding catheters kept close to the Flying-V. The antegrade deflectable guiding sheath is typically advanced to the base of the mitral leaflet where it serves as a fulcrum during laceration. Medial-lateral position is controlled by the degree of deflection of the deflectable guiding sheath that serves as a fulcrum.

Electrosurgical tip-to-base laceration is performed at 70W with D5W flush, as in conventional base-to-tip laceration.^{30,31} To ensure protection of the aortic valve, the retrograde catheter should be connected to hemodynamic monitoring throughout the preparation and laceration process. A left ventricular pressure wave form confirms the catheter is insulating the aortic leaflets from the Flying-V.

Position statements:

- Tip-to-base LAMPOON is less technically complex than base-to-tip LAMPOON although also less precise. Tip-to-base LAMPOON should be confined to cases where the aorto-mitral curtain is protected by a prosthesis (such as a complete annuloplasty ring, prosthetic sewing ring), the aorto-mitral curtain is long enough that there is ample space to protect the aortic leaflets while applying the Flying-V, and the risk of LVOTO is borderline. Tip-to-base LAMPOON may be helpful when multiple lacerations are intended, such as around a surgical valve commissural post, or to treat dynamic LVOTO after TMVR.
- In tip-to-base LAMPOON, if there is not ample evidence of leaflet laceration, the laceration can be repeated after verifying electrosurgical connections and Flying-V position; otherwise conversion to an alternate strategy should be considered.
- LAMPOON (tip-to-base or base-to-tip) may not be effective for valve-in-valve if the surgical bioprosthesis is unfavorably aligned with a commissural suture post in the LVOT. Further validation of 'double cutting' techniques as a possible solution is required.

Intra-leaflet Deployment TMVR

First described in the literature as BATMAN³³ and CLEVE³⁴, intra-leaflet deployment obviates electrosurgical laceration. This option may be desirable so long as the aorto-mitral curtain is protected. Prospective study of intra-leaflet deployment has not been performed. However, a large multicenter registry of ILD utilizing self-reported outcomes demonstrates excellent safety and efficacy amongst experienced operators.³⁵ Features of this procedure that remain unclear include the extent and direction of leaflet tearing that may occur during balloon dilatation. Mechanically tearing the leaflet to the orifice with balloons is not the goal

of balloon dilatation. The intention is to create a large enough hole in the AML to facilitate delivery of the valve across the leaflet.

Intra-leaflet deployment utilizes multiple steps described in detail above in the “Anterior Mitral Leaflet Traversal” section. Specifically, it requires standard basal electrosurgical traversal as in base-to-tip LAMPOON. Insufficiently basal traversal risks LVOTO. Inadequate medial-lateral position risks eccentric laceration that mobilizes a large residual leaflet flap causing LVOTO.

Once the guidewire has traversed the AML in an appropriate position, balloon predilatation is performed before valve delivery, serially with a ~4mm and ~12mm balloon. Larger holes are likely to lead to complete AML disruption. Multiple balloon dilatations using incrementally larger balloon sizes between 4 and 12mm is typically not required. However, following dilation with the 4 mm balloon, the traversal wire should be exchanged for the desired 0.035” valve delivery guidewire. The valve delivery guidewire should be positioned through a stiff catheter, such as 5Fr MP guiding catheter, rather than through a 0.035” microcatheter to avoid displacement from the AML when delivering a pre-shaped, stiff guidewire. Once the valve delivery guidewire is in place, the 12 mm balloon can be delivered. The large hole created in the leaflet may cause more acute mitral regurgitation than does linear laceration since the hole cannot coapt during systole (as demonstrated in Figure 5). Therefore, it is advisable to pre-dilate the atrial septum to prepare for THV delivery before the final leaflet predilatation (this can be performed with the 12 mm balloon prior to advancing it through the AML). Following these maneuvers, TMVR is performed within the balloon-dilatated hole in the AML (Figure 12).

Some operators have described performing leaflet traversal for intra-leaflet deployment using a dedicated 0.035” electrosurgery guidewire (e.g., VersaCross, Boston Scientific or Nykanen RF Wire, Baylis). This strategy avoids exchanging an initial 0.014” traversal guidewire for the eventual 0.035” valve delivery guidewire. It also allows for immediate use of 0.035” lumen peripheral balloons. Nevertheless, we discourage this strategy for new operators because it risks injury to bystander structures that might otherwise be inconsequential using 0.014” guidewires. Additionally, 0.035” balloons have a larger crossing profile than comparably sized 0.014” balloons, making them more challenging to deliver in a heavily calcified leaflet. Doddering with a 0.035” microcatheter first may facilitate initial balloon delivery.

Anecdotally, two complications of intra-leaflet deployment should be considered. First, circumferential balloon rupture during predilation can result in a non-collapsible fragment of the balloon on the ventricular side of the leaflet. This balloon fragment maybe larger than the hole in the AML if the balloon rupture occurs prior achieving its maximal diameter. Aside from surgery, no clear solution exists, so care should be taken to choose balloons less likely to rupture. Cutting the proximal hub off the ruptured balloon allows for delivery of a guide catheter over the balloon. Countertraction at or across the leaflet may facilitate removal of the balloon fragment. Second, an inability to deliver the valve across the AML despite pre-dilation of the leaflet can be very challenging. This may occur from interaction between leaflet calcium and the scaffolding of the TMVR or when the leaflet deflects

ventriculally away from the nose cone of the valve creating suboptimal geometry for valve delivery. If it is feasible to withdraw the valve back to the right atrium to make space, re-ballooning the AML from a second deflectable guiding catheter directed through the iatrogenic ASD and AML hole in a “buddy balloon” fashion would typically be the next step.

Intra-leaflet deployment does not require snaring of the leaflet traversal wire. This is generally considered an advantage as it is fewer steps. However, snaring the traversal wire does provide confirmation that the wire is in the left ventricle and thus, in the context of intra-leaflet deployment, care must be taken to confirm that the wire has not been advanced across the membranous septum or elsewhere prior to ballooning.

Intra-leaflet deployment has been anecdotally reported in ViMAC.^{36–41} This has been understudied systematically and we do not recommend this strategy given the potential risk of injury to the aortomitral curtain.

It is unclear whether intraleaflet deployment releases more or less embolic debris compared with LAMPOON, or whether the indications differ for cerebral embolic protection.

Position statements:

- Intra-leaflet valve deployment has been safely performed, particularly in valve-in-ring and valve-in-valve, but further study is required before broad adoption, particularly for valve in MAC or valve in incomplete ring scenarios.

Heavily Calcified Anterior Mitral Leaflet

Leaflet calcification confounds traversal and laceration. But successful traversal allows either laceration or alternative intra-leaflet valve deployment (see above).

Tip-to-base LAMPOON is not advisable in the setting of heavy leaflet calcification because calcium impedes laceration as does accordion-like leaflet “bunching”. Furthermore, the laceration trajectory is difficult to control in such settings, leading to medial or lateral electrosurgical laceration or even mechanical tearing.

In the face of severe leaflet calcification, finding a non-calcified spot for traversal is paramount and is typically achieved via TEE. Rarely, some operators undertake “classic” retrograde base-to-tip LAMPOON. While more technically demanding than antegrade LAMPOON, the retrograde aortic guiding catheters intrinsically directly orient the laceration along the LVOT towards the aortic valve.⁴⁰ Retrograde LAMPOON does not obviate issues with finding a calcium free zone for leaflet traversal but it can avoid catheter interaction with bulky calcification on the atrial side of the leaflet. Another technique variant is traversal using an electrosurgical 0.035” wire (*e.g.* Versa Cross, Boston Scientific or Nykanen RF Wire, Bayliss), which is attractive in simplicity but renders off-target traversal more dangerous.

Position statements:

- Base-to-tip LAMPOON is more effective in patients at higher risk of LVOTO, or with a higher burden of leaflet calcification, because it can achieve a more predictable laceration all the way to the base of the leaflet.
- Tip-to-base LAMPOON may not be effective in the presence of leaflet calcification because the leaflet may “accordion” rather than lacerate or the Flying-V may be deflected to a commissure. These can result in an incomplete or eccentric leaflet laceration.

Mechanical Aortic Valve

Mechanical aortic valves preclude establishing the veno-arterial guidewire rail that facilitates positioning of the LV snare guiding catheter. In such scenarios, an antegrade transseptal JR4 guide catheter is typically used to deliver the snare towards the LV apex and torqued anteriorly. A gentle secondary bend 10mm from the tip of the traversing AstatoXS guidewire can facilitate ensnarement. Alternatively, ILD does not require ensnarement of the traversal wire and thus may be an appealing option if the context is otherwise permissible.

Double Orifice Mitral Valve: ELASTA-Clip and FRONTEER

These techniques are employed to reconstitute a single mitral orifice and can be used in the context of a prior mitral edge to edge repair device or Alfieri stitch. ELASTA-Clip is performed with two deflectable guiding sheaths in the LA, one medial and the other lateral to the clip. Each delivers a JR4 guiding catheter through their respective mitral orifice, each oriented towards the other. An AstatoXS 300 cm guidewire is advanced through one and ensnared with a tri-lobe snare through the other. The Flying-V is delivered in similar fashion to tip-to-base LAMPOON.^{42–45}

The key procedural step is to position the Flying-V anterior to the TEER device or Alfieri stitch. It is accomplished by torquing each deflectable guiding sheath anteriorly and maintaining this anterior position until laceration. The desired final position of the retained clip is abutting the posterior wall of the left ventricle away from the LVOT thus lacerating the AML is always the desired target. The *en face* (LAO caudal) projection, and TEE, serve to fine-tune the Flying-V position close to the device(s). Electrosurgical laceration is performed in standard fashion at 70W with D5W flush.

Clip removal may be indicated when retained bulky or multiple TEER devices along the posterior wall may be undesirable or unsuitable for specific THVs or their anchors. Fully percutaneous Removal Of Non-functional TEER (FRONTEER)^{46 47} is an option to extract TEER devices using a retrieval device (ÖNÖ Retrieval device, Onocor) through a large venous introducer sheath. This technique is performed using the same principles as ELASTA-Clip, with the following sequence: first, lacerate one leaflet from the TEER device; second, ensnare the device; third, lacerate the other aspect of the TEER device; finally, extract the device. Occasionally more than 2 lacerations are required if subvalvular structures have also fibrosed onto the exterior of the TEER device(s).

Safety, Troubleshooting, and Bailouts

Many TMVR procedures, with or without concomitant electrosurgery, are high risk—particularly ViMAC cases. This underscores the importance of careful patient selection and balancing potential benefit against procedural risk (see “Patient Selection”). Procedural risk often increases when electrosurgical steps do not proceed as planned. Common challenges and mitigation strategies are outlined below.

Insufficient NeoLVOT and Septal Reduction Therapy

For specific anatomies, mitral leaflet modification alone may be insufficient to preserve a large enough LVOT. In such circumstances, antecedent septal reduction therapy (SRT) will be required. A detailed discussion of SRT is beyond the scope of this manuscript, although multiple SRT techniques have been described. Transcatheter alcohol septal ablation^{5,10,48} is technically straightforward but may be insufficiently basal. Transcatheter septal myotomy (septal scoring along midline endocardium, SESAME)^{13,49} is more complex. SRT with unipolar and bipolar radiofrequency ablation using cardiac electrophysiology catheters and mapping systems have been reported^{50,51} but not widely replicated.⁵²

All SRT techniques require as long as a month for remodeling and healing. Repeat cardiac CTA is required to measure the resulting neoLVOT and skirt-neoLVOT to determine feasibility of TMVR.

Position statements:

- Particularly for valve-in-MAC, SRT may be considered pre-emptively even when the skirt neoLVOT is $\geq 200\text{mm}^2$ in cases of high complexity (e.g. the valve frame is expected to touch the septum, the anterior mitral leaflet is heavily calcified, etc). In this scenario, operators must balance the risks of pre-emptive SRT (e.g. need for a permanent pacemaker, delays in care) against the risks of unanticipated LVOT obstruction or potential need for a second valve.
- Following septal reduction therapy performed in anticipation of TMVR, cardiac CT angiography should be repeated to analyze for neoLVOT and skirt neoLVOT areas. This CTA should be performed at least 30 days after septal reduction therapy to allow for tissue remodeling.

Traversal failure

After a failed attempt at leaflet traversal, operators should confirm electrosurgery microbubbles (not flush microbubbles) are visualized on TEE. Failure to visualize bubbles indicates electrosurgery failure such as faulty connection between guidewire and electrosurgery pencil, dispersive electrode making poor contact to patient or electrical coupling of the dispersive electrode with nearby metallic implants such as prosthetic hip, or electrosurgery generator fault.

Prolonged electrification of the *Astato* guidewire, for example in the course of multiple attempted traversals, may carbonize the guidewire tip (develops “char”) and impede energy transmission. Replacing the guidewire may be necessary.

Otherwise, small movements in catheter position away from the prosthetic sewing ring or towards a non-calcified spot in the leaflet are likely the most productive next steps. One can also consider increasing the energy setting from 50 to 70 Watts and adding 5% dextrose flush as noted above.

Traversal burns into incorrect structures.

Buckling of the guidewire tip can create a linear laceration on whatever tissue is contacted, including the anterior wall of the left atrium. Any wire buckling during advancement should always prompt immediate cessation of radiofrequency energy.

Following appropriate traversal of the mitral leaflet, if the guidewire is advanced too far forward with on-going radiofrequency current, the guidewire may enter the interventricular septum potentially causing ventricular tachycardia or ventricular fibrillation. Care should be taken to only advance the guidewire 1 cm or less through the leaflet while energy is applied.

Laceration

For LAMPOON, laceration of the leaflet is predicated on tissue vaporization. Mechanical tearing or avulsion of the leaflet from excessive pulling can lead to hemodynamic compromise and less-effective procedures. The typical causes are excessive calcification or electrosurgery failure.²⁴ One should ensure that the microcatheter has not slipped forward over the Flying-V thereby inadvertently insulating the leaflet. Changing the degree of bend or position of the deflectable guides can alter the trajectory of the laceration such that it may find a less calcified pathway. Increasing the radiofrequency current to 90 Watts can be considered if all other aspects have been confirmed.

Need for a Second Valve

If the TMVR is placed or migrates too far into the atrium, there may be substantial regurgitation through the open cells of the THV at the level of the annulus. There may also be concern for further migration or even embolization of the THV. In both circumstances, a second THV deployed with a more ventricular position is the primary solution. A second valve will largely negate the benefit of LAMPOON on the neoLVOT since the open cells on the ventricular aspect of the initial THV will be covered by its own leaflets as they are trapped between the first and second THV. Thus, the decision to deploy a second THV inside the first should be carefully considered based on the clinical scenario and original neoLVOT measurements. If the first THV migrated substantially such that it is very atrial, a second valve may not be as much of a concern since the covered cells will not extend far into the LVOT.

Post-Procedure Management

Surveillance

Echocardiographic surveillance following TMVR is the same irrespective of leaflet modification. Serial assessment of LVOT gradient should be performed by TTE in addition to the procedural direct hemodynamic measurements. In the immediate follow up period, the left ventricle will typically be more hyperdynamic when the patient is not under general anesthesia, but the patient will likely also be less volume depleted when not fasting. These countervailing forces can result in unpredictable differences in the LVOT gradient compared with intraprocedural measurements. Relevant thresholds are extrapolated from experience with obstructive hypertrophic cardiomyopathy and include a peak LVOT gradient increase of >10 mmHg to at least 30 mmHg for clinically significant LVOTO and at least 50 mmHg for critical LVOTO.⁴ Medical management to limit dynamic LVOTO should include avoiding inotropic agents in favor of vasoconstrictors (phenylephrine and vasopressin) for blood pressure support and repleting blood and volume liberally for hypotension. Intravenous beta blockers can be used in the context of acute LVOTO as tolerated. Rescuing clinically significant LVOTO post-implant is more challenging and less desirable than preparatory alcohol septal ablation, salvage tip-to-base LAMPOON, or SESAME.

Beyond echocardiographic assessment, we encourage surveillance for blood markers of hemolysis, such as haptoglobin, lactate dehydrogenase, bilirubin, schizocytes, reticulocyte count and/or plasma free hemoglobin.⁵³ Turbulent flow across exposed THV cells is usually evident on echocardiography following mitral leaflet modification and may contribute to hemolysis. A low-level of biochemical hemolysis is expected, but pigment nephropathy should prompt further investigation, including a TEE to explore the possibility of paravalvular leak. Supportive management is likely the best course of action, but occasionally SRT may be required to restore laminar flow and reduce hemolysis.

As is readily apparent, the care of a post-TMVR patient does not end with the conclusion of the valve implantation. Substantial cooperation from the hospital system to support a multi-disciplinary team of cardiologists, intensivists, cardiac imaging specialists, nephrologists, and others is required to successfully navigate these complex patients from hospital to home.

Conclusion:

Managing the risk of LVOT obstruction remains a central challenge in TMVR. A dedicated CT assessment, including predicted neoLVOT, skirt neoLVOT, and anterior mitral leaflet length is essential for anticipating obstruction. Contemporary balloon-expandable valves permit flow through the ventricular aspect of the frame following leaflet modification. Thus, base-to-tip LAMPOON, tip-to-base LAMPOON, and ILD can effectively mitigate LVOT obstruction when performed correctly. This manuscript outlines key procedural steps to support the adoption and optimization of mitral leaflet modification strategies.

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Abbreviations

AML	anterior mitral leaflet
BWEC	balloon wedge endhole catheter
CTA	computed tomography angiography
ECMO	extracorporeal membrane oxygenation
ELASTA-Clip	Electrosurgical Laceration and Stabilization of MitraClip
FRONTEER	Fully percutaneous Removal Of Non-functional TEER
ILD	intra-leaflet deployment
LAMPOON	Laceration of the anterior mitral leaflet to prevent left ventricular outflow tract obstruction
LVOT	left ventricular outflow tract
LVOTO	left ventricular outflow tract obstruction
MPR	multiplanar reconstruction
PVL	paravalvular leak
SESAME	septal scoring along midline endocardium
SRT	septal reduction therapy
TEER	transcatheter edge-to-edge repair
TEE	transesophageal echocardiography
THV	transcatheter heart valve
TMVR	transcatheter mitral valve replacement
ViMAC	valve-in-mitral annular calcification
ViR	valve-in-ring.

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Highlights

- LVOT obstruction is a key TMVR limitation.
- Leaflet modification facilitates TMVR if there is a patent framework on the ventricular aspect of the prosthesis.
- Mastery of CT analysis and procedural steps are key to optimizing leaflet modification procedures
- Novel TMVR designs enabling leaflet modification are an area for development

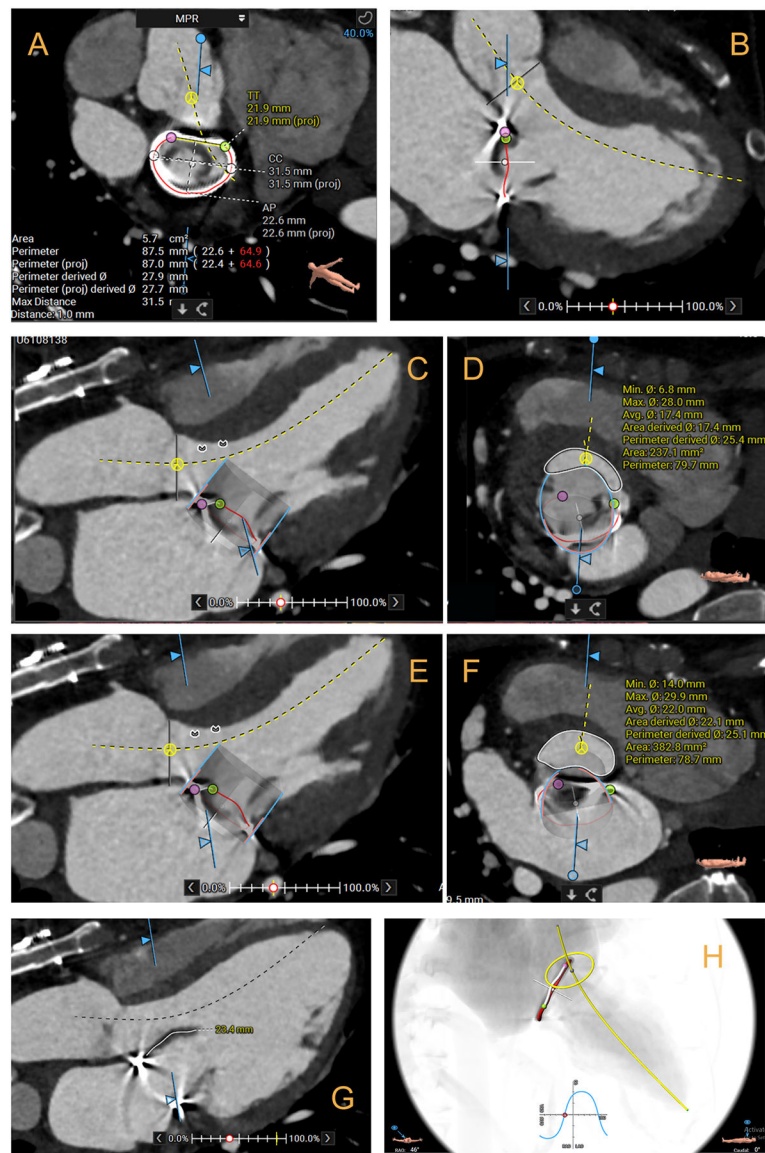


Figure 1. Step by Step CT Analysis to Determine Need for Leaflet Modification:

Panel A: the mitral annulus is traced and measured. The mitral annulus is defined in red with a white segment for the inter-trigone region. Panel B: an LVOT center line is drawn (yellow) and the aortic valve plane is identified. Panel C: a simulated THV is inserted into the mitral annulus and positioned 75% ventricular. Moving along the LVOT centerline in the 3-chamber view with the blue crosshairs provides a corresponding short axis view (panel D). Panel D: the neoLVOT is traced at the ventricular edge of the simulated THV. Panel E: the same process is performed to find the skirt neoLVOT by moving the cross hairs to the ventricular edge of the covered aspect of the simulated THV as predefined (designated as pink on the simulated THV). Panel F: corresponding short axis to the blue cross hairs in Panel E allows for tracing of the skirt neoLVOT. Panel G: anterior mitral leaflet length is best defined in a diastolic phase and can be measured with a curved measuring tool. Panel H: fluoroscopic angles can be identified that provide coplanar views for the mitral annulus (red)

while the aortic annulus and LVOT center line are also seen (yellow). CT images courtesy of JMM.

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Figure 2. Demonstration of LAMPOON Effect:

Cadaveric specimen viewed from the aorta demonstrating splay of the anterior mitral leaflet across an implanted THV following ex vivo LAMPOON. Red * designate the anterior mitral leaflet. LVOT: left ventricular outflow tract. Image courtesy of SS.

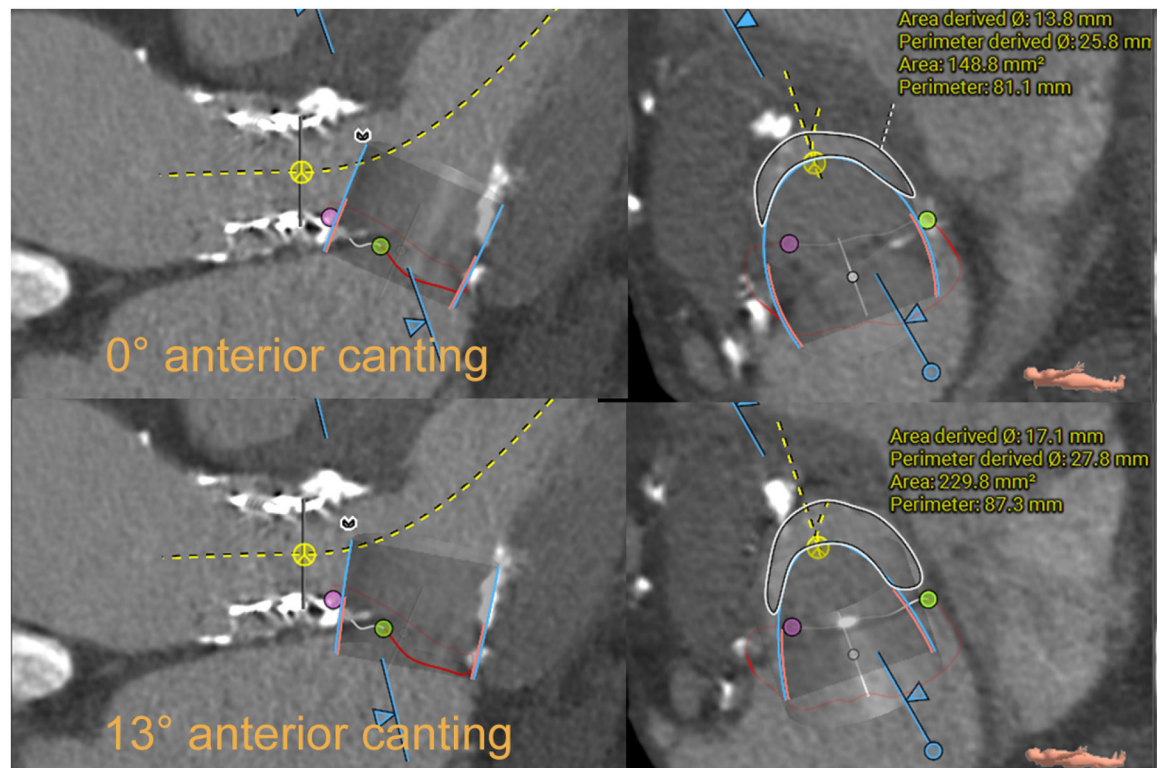


Figure 3. Impact of Prosthesis Positioning on neoLVOT:

Repeated CT analysis for neoLVOT measurements. All conditions were preserved except for canting the simulated THV 13 degrees anteriorly so that it is more in-line with the posterior wall of the ventricle. This forced valve reorientation would be expected from the interaction of the posterior wall and the shoulder of the deployment balloon. This canting results in a change in predicted neoLVOT from 149mm² to 230mm². CT images courtesy of JMM.

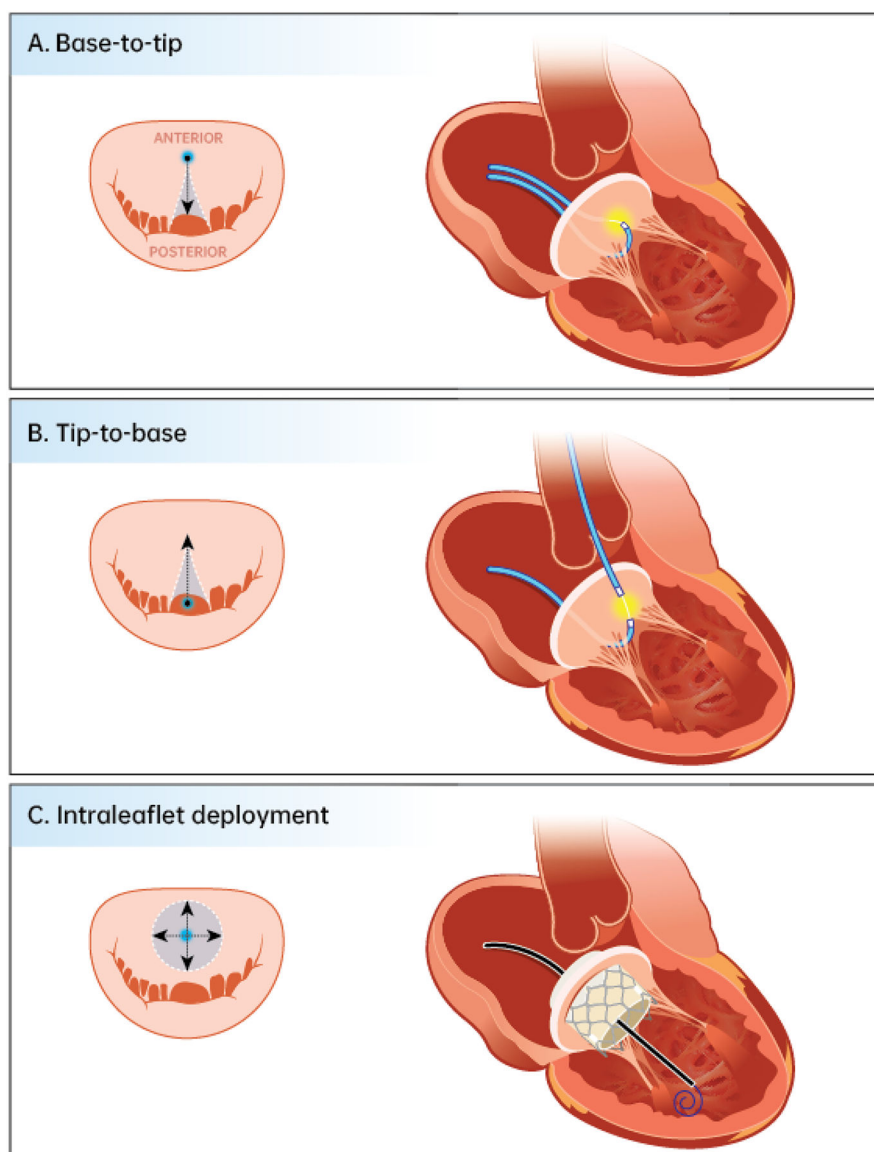


Figure 4. Primary Leaflet Modification Modalities:

Panel A: Base-to-tip LAMPOON; Panel B: Tip-to-base LAMPOON; Panel C: intra-leaflet deployment.

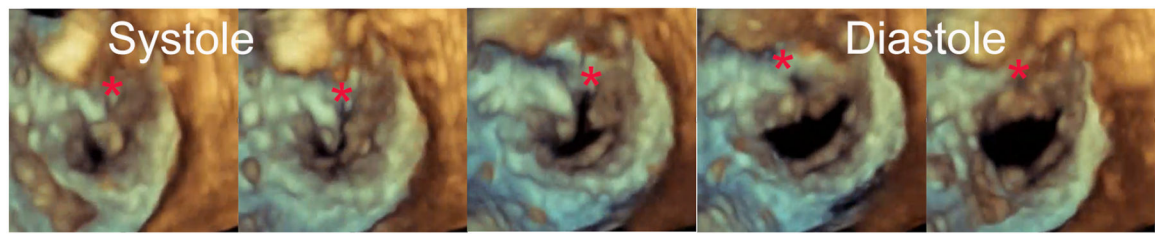


Figure 5. Anterior Mitral Leaflet Movement during Cardiac Cycle Following LAMPOON: Transesophageal echo demonstrating continued mitral leaflet coaptation in systole following successful LAMPOON. A red * denotes the basal edge of the LAMPOON laceration in each panel. Echo images courtesy of JMM.

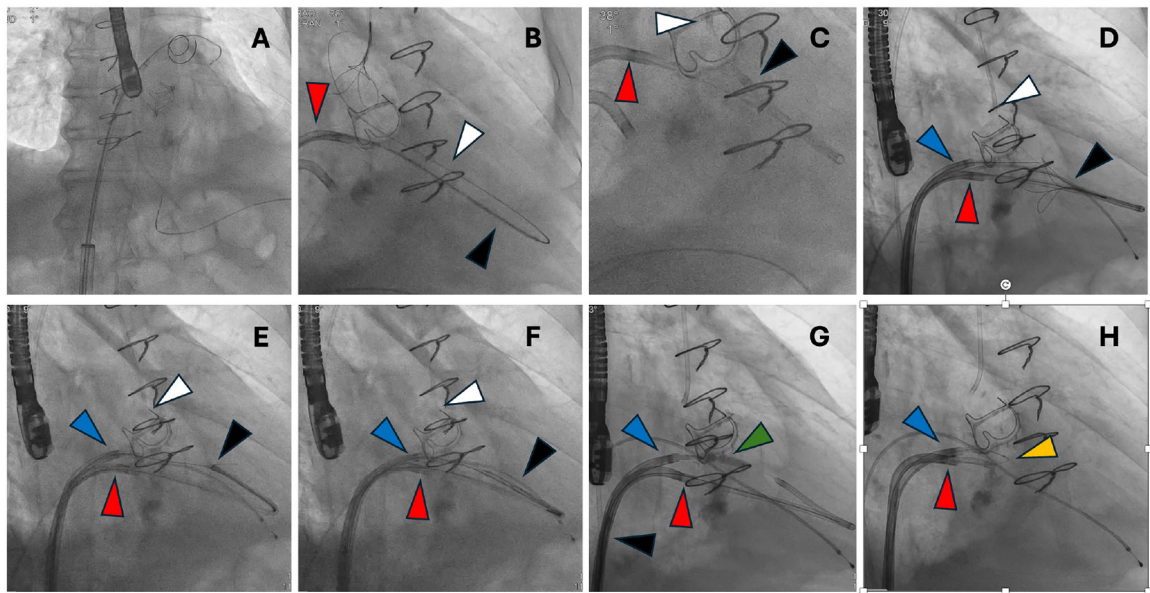


Figure 6. Base to Tip LAMPOON Steps:

Fluoroscopy demonstrating step by step process of base to tip LAMPOON. Panel A: Following transeptal puncture, 2 wires are placed in the left upper pulmonary vein to deliver to 2 deflatable guiding sheaths. B: Through the more posterior guide sheath (Red Arrow) a balloon wedge endhole catheter (black arrow) is delivered through the mitral orifice and redirected to the LVOT via a guidewire (white arrow). A snare is seen in the aortic root in anticipation of creating a venous-arterial rail with a 300 cm 0.014" wire. Panel C: With the venous-arterial rail in place via a 6 French JR4 guide in the ascending aorta (white arrow), the balloon wedge catheter is removed and a 7 French JL3.5 guide catheter (black arrow) is delivered over the venous-arterial rail via the deflatable sheath (red arrow) to the LVOT in order to deliver a 3 loop snare catheter adjacent to the AV rail. Panel D: Via the posterior deflatable sheath (red arrow) the 3 loop snare and JL3.5 guide catheter (black arrow) are held in the LVOT underneath the anterior mitral leaflet via the venous-arterial rail (white arrow) while a JR4 guide catheter is delivered to the base of A2 via the anterior deflatable guide sheath (blue arrow) through which a 300 cm Astato 20 wire is seen having punctured the anterior mitral leaflet. Panel E: In this same configuration of catheters, the Astato wire is snared by the 3-loop snare in the JL3.5 (black arrow). Panel F: The 3-loop snare and Astato wire are withdrawn 3–5 cm into the JL3.5 guide catheter (black arrow) but not yet externalized. Once the Astato is secured in this position, the venous-arterial rail (white arrow) can be withdrawn. Panel G: Keeping the Astato secured in the JL3.5 guide catheter (black arrow), the microcatheter insulating the Astato is removed from the JR4 and anterior deflatable sheath (blue arrow) and a 4.0×20 mm non-compliant coronary balloon (green arrow) is delivered over the Astato and across the anterior mitral leaflet for balloon-assisted LAMPOON. Panel H: After withdrawing the coronary balloon, a Flying-V is created and delivered via the anterior deflatable sheath (blue arrow) while the snare is withdrawn from the JL3.5 in the posterior deflatable sheath (red arrow) thereby externalizing the Astato and delivering the Flying-V (orange arrow) across the anterior mitral leaflet in anticipation of laceration. Images courtesy of JMM.

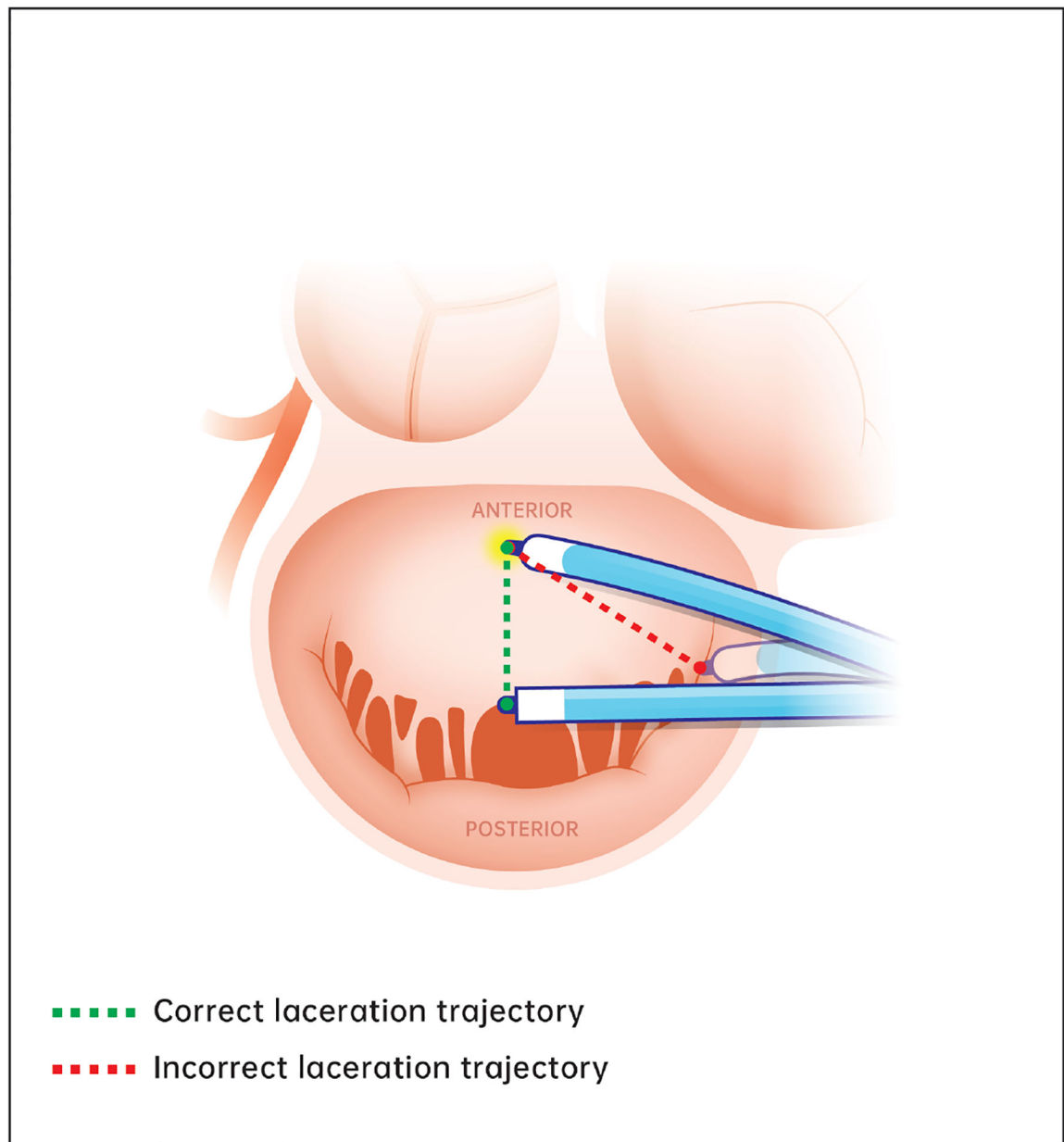


Figure 7. Optimizing Laceration Trajectory:

Illustration of the mitral valve from a "surgeon's view" demonstrating the role of the deflectable guiding sheaths in providing a fulcrum to direct the laceration orthogonal to the line of coaptation rather than eccentrically towards the septum

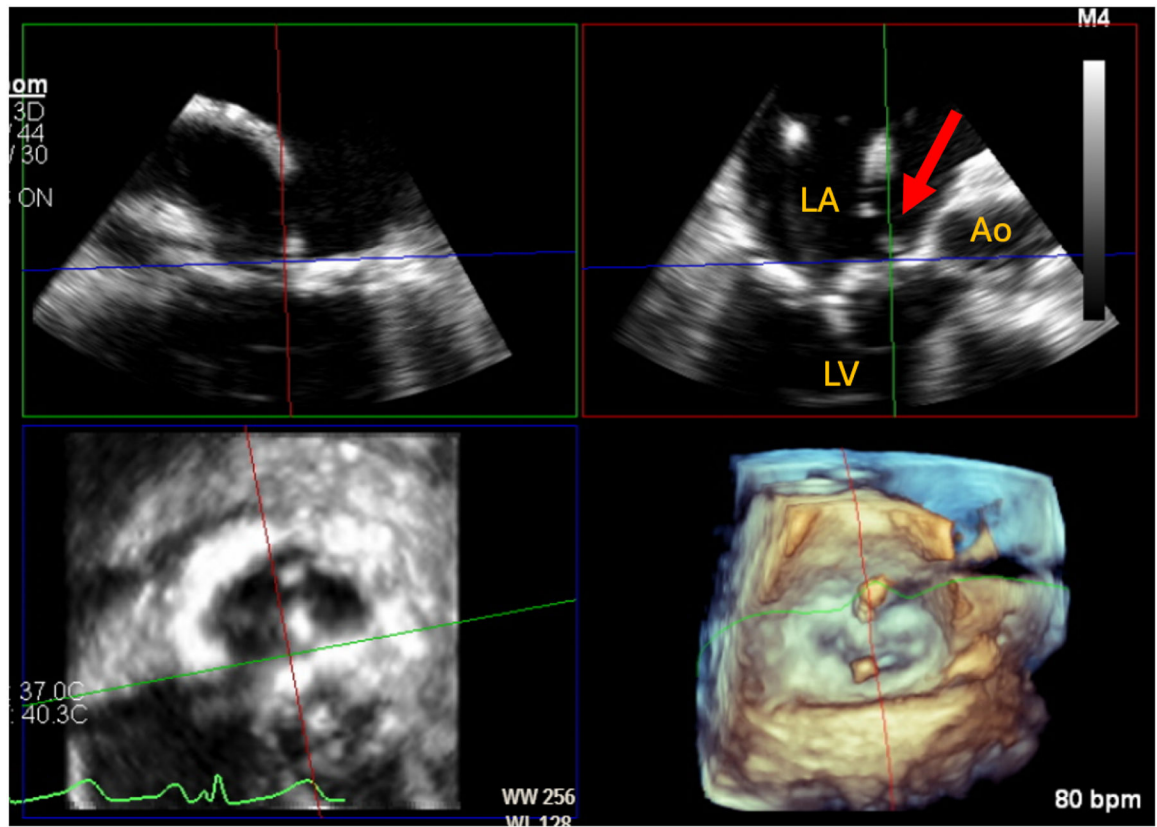


Figure 8. Transesophageal Echo Facilitates Positioning for Leaflet Traversal:

Transesophageal echo multiplanar reconstruction demonstrating catheter positioning prior to leaflet traversal. The red arrow in the upper right image demonstrates the JR4 guiding catheter positioned at the base of the AML just below the aortic valve. The 3D reconstruction (lower right) and left sided images confirm positioning in the center of the A2 scallop. TEE images courtesy of DE

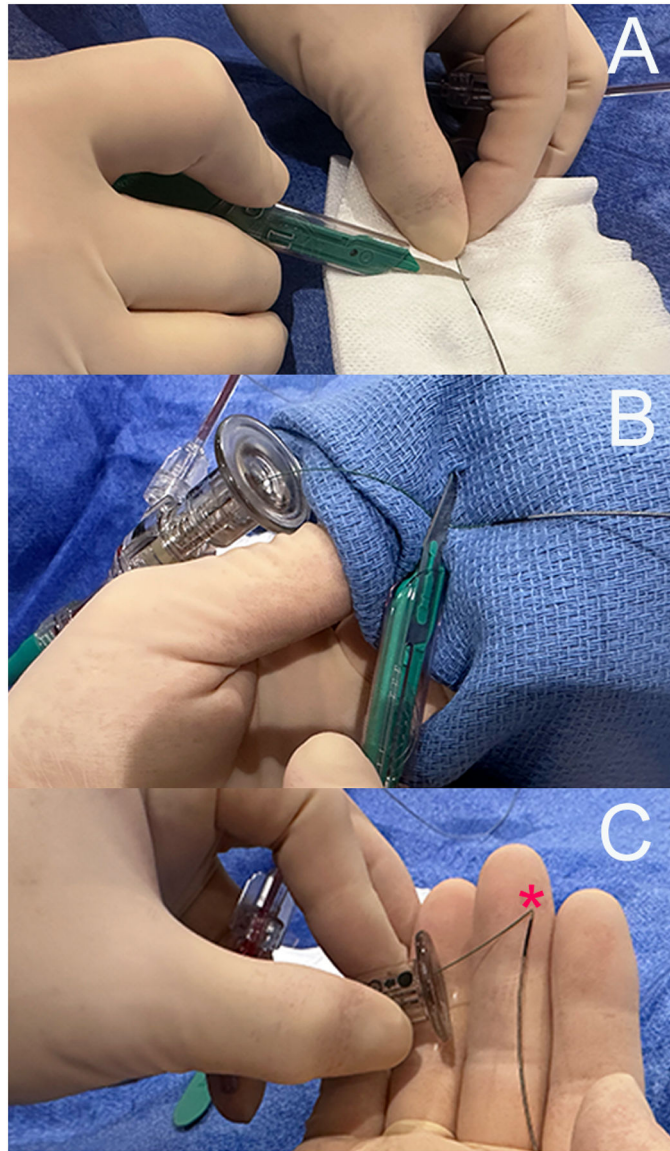


Figure 9. Steps for Creating the Flying-V:

Panel A: denuding 1–3 mm of insulation from the Astato guidewire using the sharp side of a scalpel. Black arrows point to denuded surface of the wire. B: Creating a kink in the wire at the denuded position using the blunt side of the scalpel. C: A fully formed “Flying-V” lacerating surface is denoted by the red *. Images courtesy of JMM.

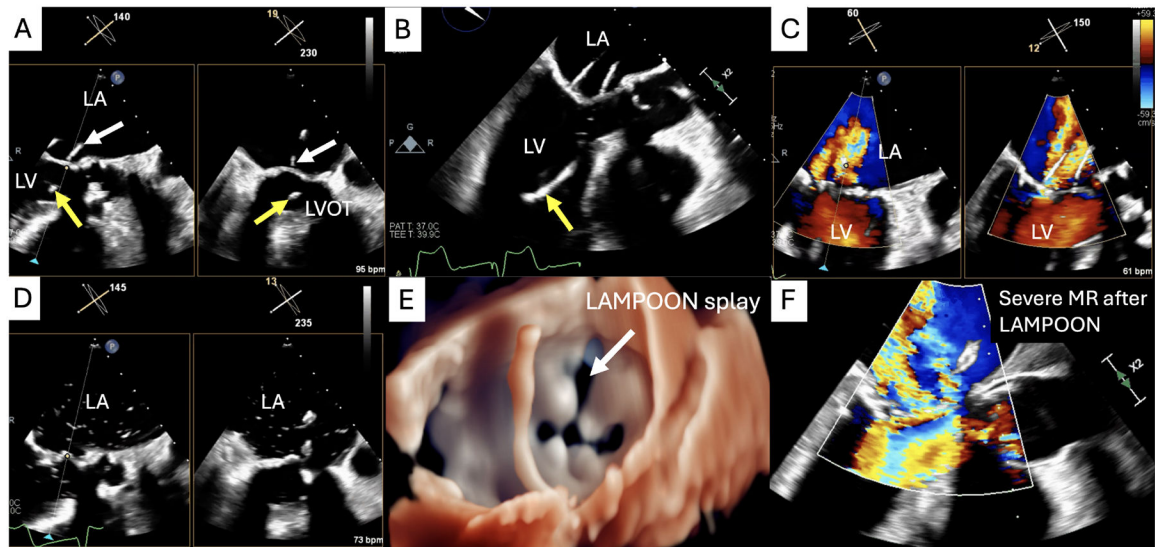


Figure 10. Key Transesophageal Images During Base to Tip LAMPOON:

Panel A: Biplane TEE demonstrating the catheter/wire tip positioned at the base of the AML (white arrow) before traversal. Snare established in LVOT (yellow arrow). Panel B: 2D Long axis view showing ensnared but relaxed Flying-V in LV (yellow arrow). Panel C: 2D color Doppler biplane view demonstrating iatrogenic MR due to tension on the Flying-V tenting the MV leaflets open prior to laceration; this can be alleviated by relaxing tension on the Flying-V. Panel D: 2D biplane image during leaflet laceration with microbubbles in LA and LV confirming an active radiofrequency current. Panel E: 3D view from the LV perspective demonstrating the AML splay (white arrow) after LAMPOON. Panel F: 2D TEE color Doppler long axis view showing the resulting massive MR after laceration of the AML. LA = left atrium; LV = left ventricle; Ao = aorta; MV = mitral valve; MR = mitral regurgitation. Images courtesy of GBM

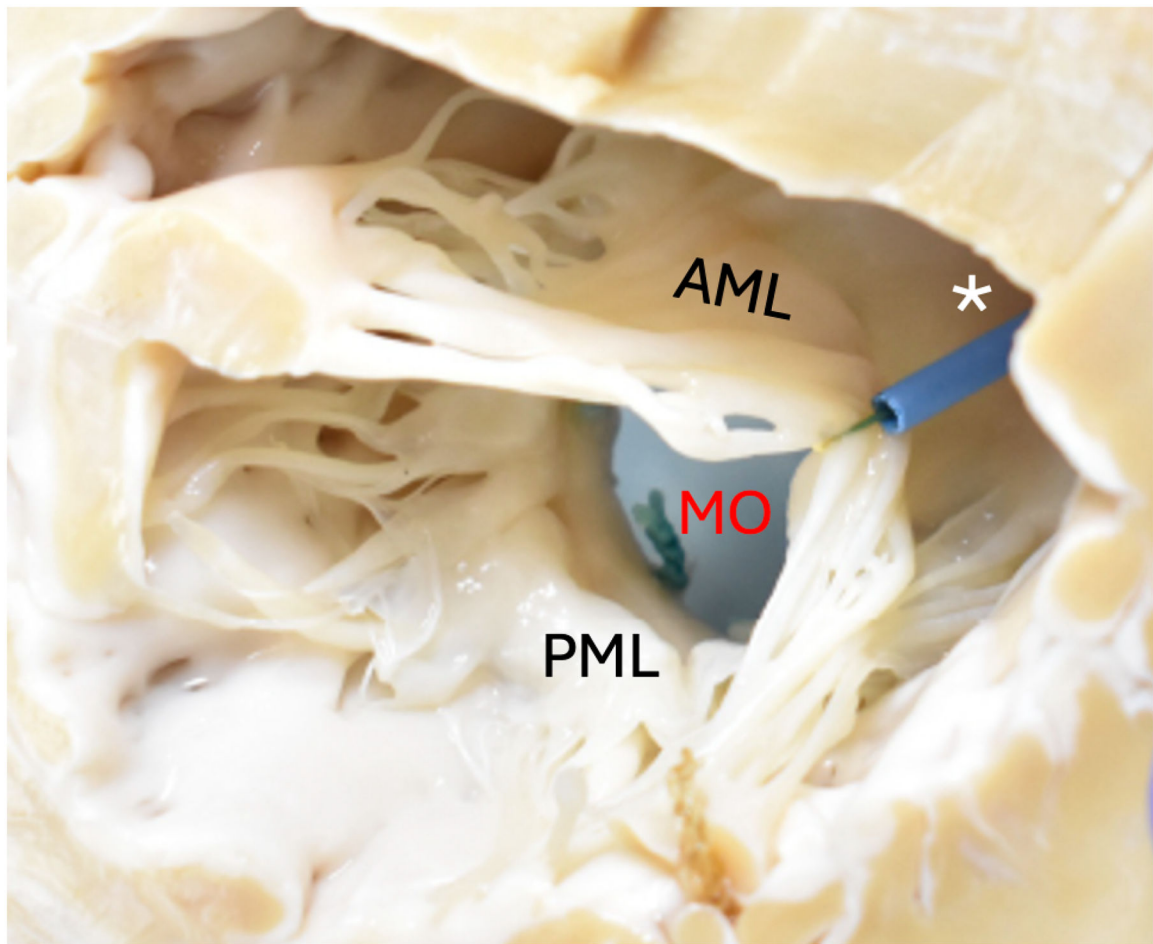


Figure 11. Inadvertent Bunching of the Anterior Mitral Leaflet:

A cadaveric specimen viewed from the ventricle demonstrating anterior mitral leaflet bunching rather than lacerating in a tip-to-base LAMPOON configuration. AML: anterior mitral leaflet; MO: mitral orifice; PML: posterior mitral leaflet; white * designates the left ventricular outflow tract. Images courtesy of SS.

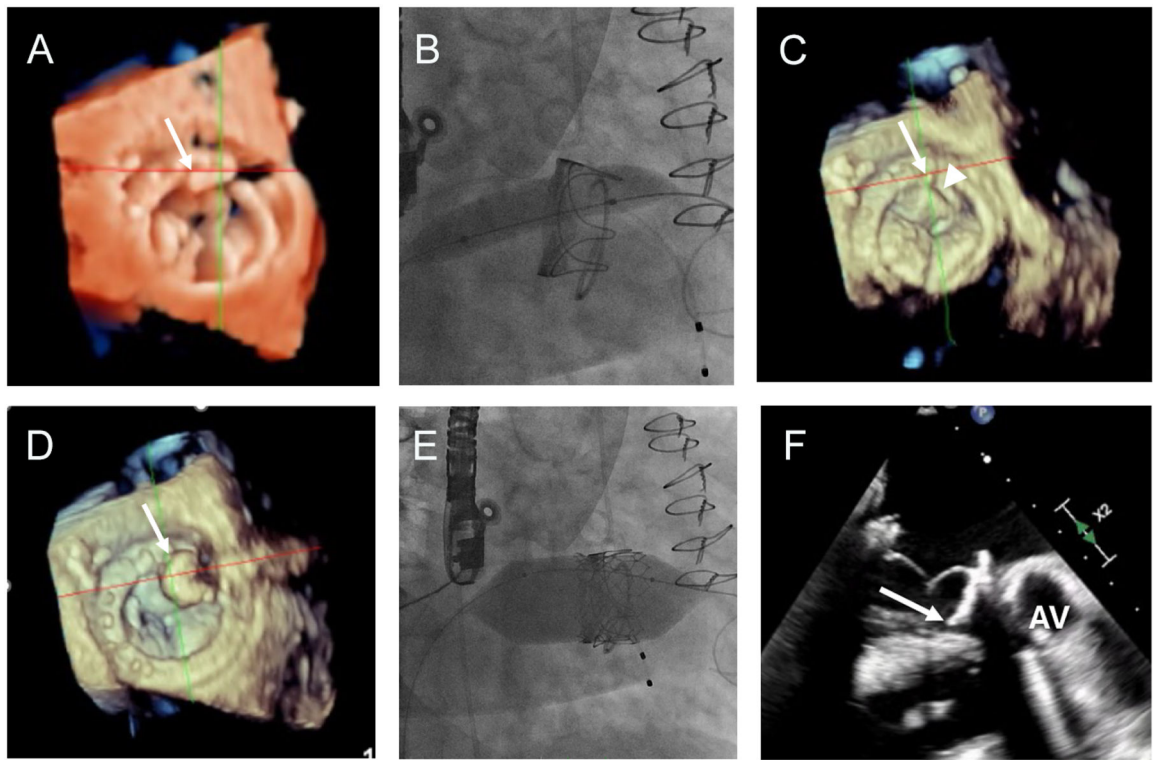


Figure 12. Intraleaflet Deployment of a Mitral Valve-in-Valve:

Panel A: Puncture at the middle/base of the anterior leaflet (arrow) as seen on 3D TEE.

Panel B: Dilation of the leaflet using a 12mm balloon. Panel C: wire position maintained across the leaflet (arrow) and the base of the leaflet “freed” from the annular frame (arrowhead).

Panel D: 3D TEE demonstrating the THV positioned within the leaflet perforation (arrow). Panel E: fluoroscopy of TMVR post-dilated. Panel F: 2D TEE image demonstrating proximity of the THV frame (arrow) to the Interventricular septum just beneath the aortic valve (AV). 2D: two-dimensional; 3D: three-dimensional; AV: aortic valve; THV: transcatheter heart valve. Images courtesy of AK.

TABLE 1:**Position Statements Survey Weights**

Position Statement	N	% Accept	% Tolerate	% Reject	Confidence Level	Decision- confidence Score
Cardiac CT angiography is essential to measure neoLVOT area, skirt neoLVOT area and anterior mitral leaflet length. Cardiac CT angiography should include all phases of the cardiac cycle so that measurements can be made on the smallest end-systolic dimensions despite potential gating errors. Slice thickness and in-plane resolution should be $\leq 1\text{mm}$.	30	97%	3%	0%	94%	0.92
The neoLVOT area predicts LVOT area after TMVR without leaflet modification. A neoLVOT area $<200\text{mm}^2$ predicts risk of important or life-threatening LVOTO after TMVR. In active patients, a neoLVOT area $>250\text{mm}^2$ may be required to avoid functional LVOTO. These thresholds should prompt consideration for pre-emptive leaflet and/or septal reduction therapy before TMVR.	30	97%	3%	0%	94%	0.92
The skirt neoLVOT area predicts LVOT area after TMVR with leaflet modification. Skirt neoLVOT area represents expected area after leaflet modification minus the area which will be occupied by the closed cells or fabric skirt of the THV itself. Skirt neoLVOT $<200\text{mm}^2$ should prompt consideration for pre-emptive septal reduction therapy (SRT) before TMVR. In active patients, a skirt neoLVOT area $>250\text{mm}^2$ may be required to avoid functional LVOTO.	30	93%	3%	3%	88%	0.83
A reasonably mobile anterior mitral leaflet length $>20\text{--}23\text{ mm}$ may result in leaflet tip overhang after TMVR. Leaflet overhang is based on leaflet length, THV prosthesis height and implant depth of the THV so uncertainty remains about specific leaflet length thresholds. Leaflet overhang risks dynamic LVOTO or impaired THV function. Both can be mitigated with pre-emptive leaflet modification.	30	97%	3%	0%	92%	0.88
Transesophageal echocardiography is a valuable adjunct to CTA, especially for valve-in-ring and valve-in-MAC, to corroborate native anterior mitral leaflet length, mobility, and systolic anterior motion.	30	100%	0%	0%	98%	0.98
Prophylactic hemodynamic support with an IABP may be considered when performing LAMPOON, particularly when lacerating a native leaflet or when the primary valve lesion is not mitral regurgitation.	30	90%	3%	7%	91%	0.77
Prophylactic hemodynamic support with ECMO is very rarely necessary for hemodynamic stability.	30	100%	0%	0%	97%	0.97
Regarding cerebral embolic protection, available data are inadequate to guide decision-making, thus its use during TMVR and leaflet modification should be left to the discretion of the operator.	30	90%	10%	0%	96%	0.86
For traversing the leaflet, a standard telescoping set up would be a deflectable guiding sheath, a curved 6–8Fr guide (typically a JR4, sometimes an IM), a 0.014" microcatheter, and an Astato XS 20 guidewire.	30	97%	3%	0%	99%	0.96
For traversing the leaflet, 50 watts of energy on the 'pure cut' setting without continuous flush infusion is the standard electrosurgical approach but can be modified as needed.	30	97%	3%	0%	94%	0.91
For lacerating the leaflet, 70 watts of energy on the 'pure cut' setting with continuous 5% dextrose water flush infusion to better insulate both limbs of the Flying-V and minimize char and thrombus formation is the standard electrosurgical approach.	30	93%	3%	3%	96%	0.93
Tip-to-base LAMPOON is less technically complex than base-to-tip LAMPOON although also less precise. Tip-to-base LAMPOON should be confined to cases where the aorto-	30	100%	0%	0%	95%	0.95

Position Statement	N	% Accept	% Tolerate	% Reject	Confidence Level	Decision- confidence Score
mitral curtain is protected by a prosthesis (such as complete annuloplasty ring, prosthetic sewing ring), the aorto-mitral curtain is long enough that there is ample space to protect the aortic leaflets while applying the Flying-V, and the risk of LVOTO is borderline. Tip-to-base LAMPOON may be helpful when multiple lacerations are intended, such as around a surgical valve commissural post, or to treat dynamic LVOTO after TMVR.						
In tip-to-base LAMPOON, if there is not ample evidence of leaflet laceration, the laceration can be repeated after verifying electrosurgical connections and Flying-V position; otherwise conversion to an alternate strategy should be considered.	30	97%	0%	3%	94%	0.88
LAMPOON (tip-to-base or base-to-tip) may not be effective for valve-in-valve if the surgical bioprosthesis is unfavorably aligned with a commissural suture post in the LVOT. Further validation of 'double cutting' techniques as a possible solution is required.	30	90%	7%	3%	89%	0.78
Base-to-tip LAMPOON is more effective in patients at higher risk of LVOTO, or with a higher burden of leaflet calcification, because it can achieve a more predictable laceration all the way to the base of the leaflet.	30	100%	0%	0%	95%	0.95
Tip-to-base LAMPOON may not be effective in the presence of leaflet calcification because the leaflet may "accordion" rather than lacerate or the Flying-V may be deflected to a commissure. These can result in an incomplete or eccentric leaflet laceration.	30	100%	0%	0%	95%	0.95
Intra-leaflet valve deployment has been safely performed, particularly in valve-in-ring and valve-in-valve, but further study is required before broad adoption, particularly for valve-in-MAC or valve-in-incomplete ring scenarios.	30	90%	10%	0%	91%	0.83
Particularly for valve-in-MAC, SRT may be considered pre-emptively even when the skirt neoLVOT is $\geq 200\text{mm}^2$ in cases of high complexity (e.g. the valve frame is expected to touch the septum, the anterior mitral leaflet is heavily calcified, etc). In this scenario, operators must balance the risks of pre-emptive SRT (e.g. need for a permanent pacemaker, delays in care) against the risks of unanticipated LVOT obstruction or potential need for a second valve.	30	100%	0%	0%	91%	0.91
Following septal reduction therapy performed in anticipation of TMVR, cardiac CT angiography should be repeated to analyze for neoLVOT and skirt neoLVOT areas. This CTA should be performed at least 30 days after septal reduction therapy to allow for tissue remodeling.	30	100%	0%	0%	94%	0.94
Mean Strength key: ≥ 0.60 — <i>Recommend</i> 0.30 – <0.60 — <i>Suggest</i> < 0.30 — <i>Continued controversy</i>						

Table 2:
Common Products Used in Mitral Leaflet Modification Procedures

Product	Manufacturer	Specifications	Purpose
Balloon Wedge Endhole Catheter	Arrow; Teleflex	6 French, 0.035" lumen	Creating an V-A rail
JR4 Guiding catheter	multiple	6 French	Delivering aortic snare
Tri-lobed snare	Atrieve: Teleflex; EnSnare: Merit Medical	18×30 mm	1. Aortic snare for V-A rail. 2. LV snare for Flying V
Externalization wire	R350: Teleflex; RG3: Asahi	kink-resistant, > 300 cm	Externalized wire for V-A rail
JL3.5 Guiding Catheter	multiple	7 French	Deliver trilobe snare to LVOT over the V-A rail
Deflectable guiding sheathes	AgilisNxT: Abbott; DiRex: Boston Scientific; Nagare: Terumo	8.5Fr ID	Delivering, positioning catheters in LA
Non-wire braided Microcatheter	Quickcross: Phillips	0.014" lumen	insulating electrosurgical wire
Traversal wire	Astato XS20, Asahi	300 cm	Becomes Flying V
Positioning Catheter	IMA; JR: Multiple. SuperCross 120: teleflex. 125 cm Angled Glide Catheter: Terumo.	typically 6 Fr	Positioning traversal wire at the base of A2
4 × 20 mm non-compliant balloon	multiple	0.014" lumen	1. BA-LAMPOON. 2. initial balloon ILD
12 × 40 mm OTW balloon	multiple	0.035" lumen, 135 cm shaft	Ballooning the AML and the septum

V-A: veno-arterial; LA: left atrium; ILD: intraleaflet deployment; AML: anterior mitral leaflet