

Leaflet Modification in Transcatheter Treatment of Valvular Heart Disease

Rationale and technical tips for aortic leaflet, mitral leaflet, and septal modification with BASILICA, LAMPOON, and SESAME.

By Roosha Parikh, MD, FACC, FASE, FSCCT, FSCMR, FASNC, and Jaffar M. Khan, MD, PhD

Techniques for leaflet modification have not only expanded therapeutic options for many patients who were previously ineligible for transcatheter therapies but also have expanded the skill set of structural interventionalists to include interventional “surgery.” Typically using commercially available tools and the application of transcatheter electrosurgery, the interventionalist can cut, resect, or modify valve tissue and myocardium, either as definitive therapy or to enable other transcatheter procedures.¹ In this article, we provide a broad overview of aortic leaflet, mitral leaflet, and septal modification, with a focus on general techniques and rationale. References to detailed step-by-step guides are provided throughout.

AORTIC LEAFLET MODIFICATION

Coronary artery obstruction is a rare but often fatal complication of transcatheter aortic valve replacement (TAVR), and the risk of coronary obstruction is highest when TAVR is performed in bioprosthetic valves with externally mounted leaflets or in failed transcatheter heart valves (THVs).^{2,3} The BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) technique involves cutting the aortic leaflet prior to TAVR to prevent coronary obstruction (Figure 1).⁴

Who Needs It?

A standardized approach is recommended to screen for coronary obstruction risk across diseased native valves, surgical bioprosthetic valves, and THVs.⁵ First, the neo-skirt plane is identified by demarcating the

height of the diseased leaflets when they are displaced by the THV. For both native and bioprosthetic valves, this will be the height of the commissural attachments, which is the maximum height the leaflets can be displaced. If the neo-skirt height plane is higher than the level of the coronary arteries, the distance from the implanted THV to the coronary artery and from the implanted THV to the aortic wall (ie, virtual valve-to-coronary distance [VTC] and virtual valve-to-aorta distance [VTA], respectively) should be simulated and measured. If the VTC is < 4 mm or the VTA is < 2 mm, there is increased risk of coronary obstruction, and BASILICA should be considered.

How Does It Work?

When the aortic leaflet is cut down the middle, it splays when pushed aside during TAVR. If the cut is aligned to the coronary artery, it splays away from the coronary, preserving flow. If sinus sequestration is the predicted mode of obstruction, a central split will result in maximal splay and therefore maximal flow into the sinus.

How to Do It

Using commercially available equipment. BASILICA using commercially available equipment off label has been studied in a prospective trial and real-world registries.^{6,7} The technique involves traversing the base of the target aortic leaflet, from the aorta to left ventricular outflow tract (LVOT), with a 300-cm stiff guidewire that is electrified at 30 to 50 W through a standard electrosurgery generator. The guidewire is then snared in the LVOT, the midsection of the guidewire is denuded and

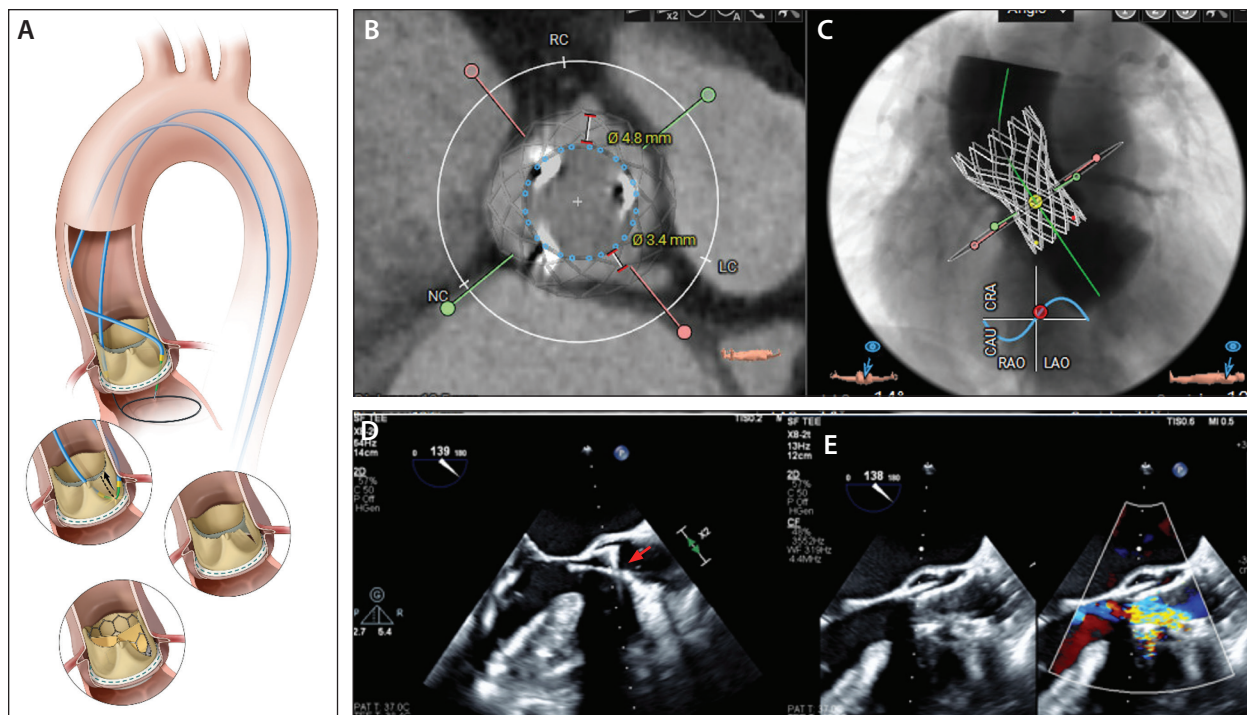
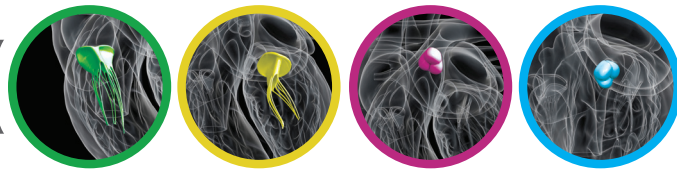


Figure 1. BASILICA: Illustration showing laceration of the left bioprosthesis aortic valve leaflet before TAVR to prevent coronary artery obstruction (A). Cardiac CT showing a virtual VTC distance of 3.4 mm for the left coronary, obtained by simulating a virtual THV and measuring the virtual valve to the coronary ostia (B). CT prediction of fluoroscopic projections with a virtual THV (C). Intraprocedural two-dimensional (2D) transesophageal echocardiogram (TEE) of a bioprosthesis valve in the aortic position with the snaring system and traversal catheter positioned through the “left” cusp of the bioprosthesis valve (red arrow) (D). Intraprocedural 2D TEE assessment of the lacerated bioprosthesis leaflet, with color Doppler showing eccentric aortic insufficiency after bioprosthesis leaflet laceration (E). Illustration in panel A reprinted from JACC: Cardiovascular Interventions, Vol 11, Khan JM et al, Transcatheter Laceration of Aortic Leaflets to Prevent Coronary Obstruction During Transcatheter Aortic Valve Replacement: Concept to First-in-Human, Pages 677-689, Copyright 2018, with permission from Elsevier.

linked to create a flying V configuration to focus charge, and the snared tip is externalized while the flying V is advanced to straddle the leaflet. The guidewire is further electrified at 70 W, under slight tension and with a non-ionic dextrose infusion to lacerate the leaflet.⁸

Using dedicated devices. Two devices dedicated for BASILICA are in clinical trials (NCT04952909, NCT05666713). The ShortCut device (Pi-Cardia) creates a mechanical cut in the leaflet using a blade that engages the leaflet base in a pincer motion and cuts the leaflet as the device is retracted. The Telltale system (Transmural Systems) uses dedicated catheters and an insulated wire and follows the conventional BASILICA sequence to create an electrosurgical cut.

Augmenting leaflet laceration. Increased leaflet splay may be necessary when treating failed and underexpanded THVs. In this case, the base of the leaflet can be ballooned prior to laceration.⁹ Furthermore, the base of the leaflet can be sequentially ballooned to completely

mechanically disrupt the leaflet or enable intraleaflet deployment of the THV.¹⁰

Limitations

As with any advanced technique, there is a learning curve for these procedures, and regular practice is required to maintain skills in these techniques. Inadvertent mechanical leaflet avulsion may cause hemodynamic compromise prior to TAVR and may result in coronary obstruction from the avulsed leaflet flap. Cerebral embolic protection is generally recommended during these procedures.

MITRAL LEAFLET MODIFICATION

LVOT obstruction from displacement of the anterior mitral valve leaflet toward the interventricular septum is a leading cause of screen failure for transcatheter mitral valve replacement (TMVR).¹¹ The LAMPOON (laceration of the anterior mitral leaflet to prevent outflow obstruction) tech-

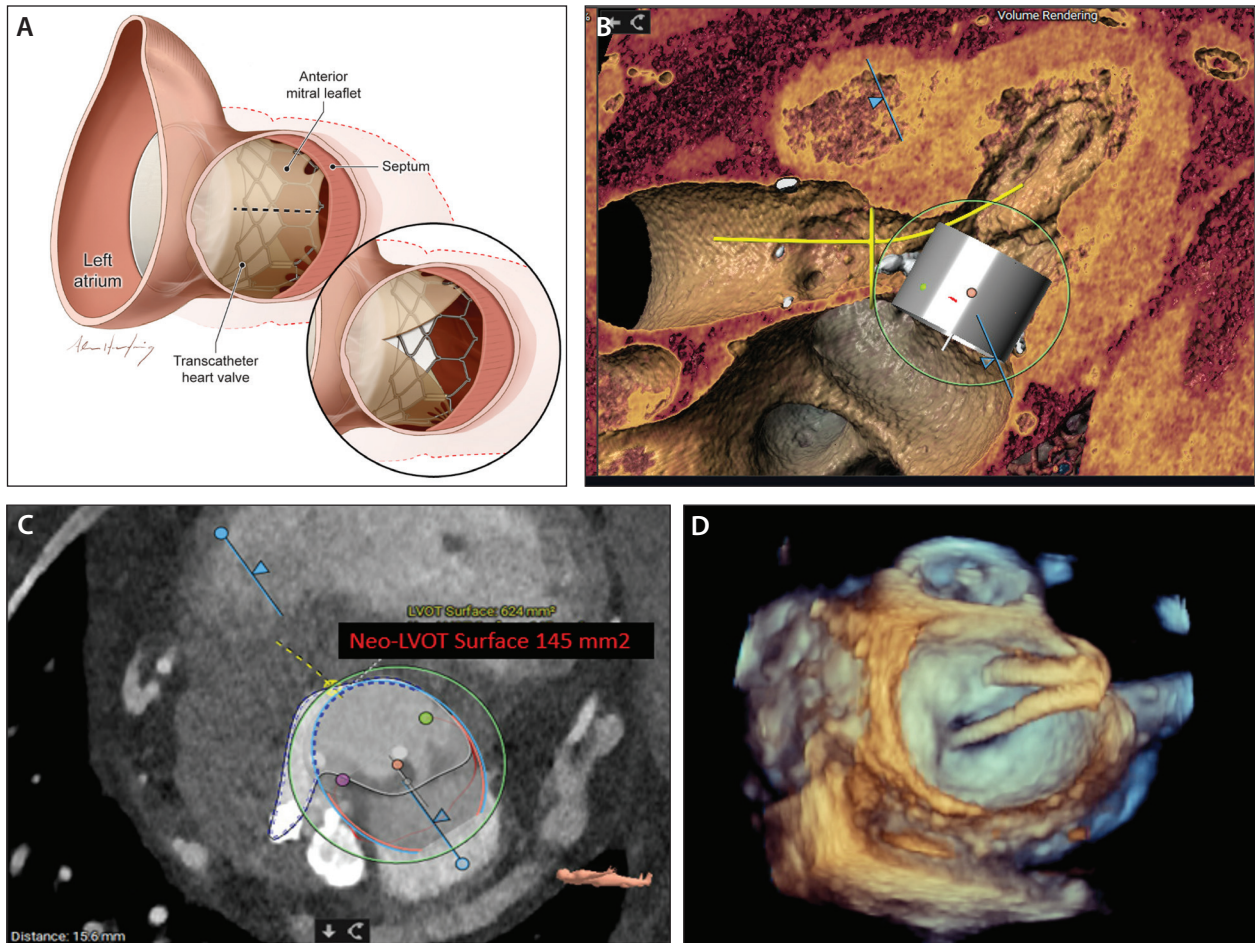
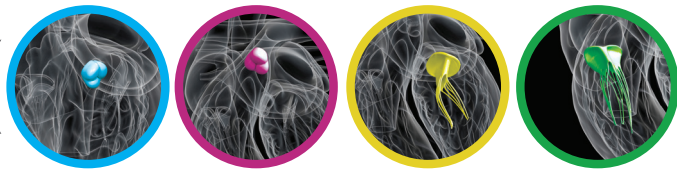


Figure 2. LAMPOON: Illustration demonstrating laceration of the anterior mitral valve leaflet from base to tip along the centerline (top image) (A); after LAMPOON TMVR, the split anterior mitral valve leaflet is shown with preserved chordae parting around a Sapien 3 valve (Edwards Lifesciences), preventing LVOT obstruction (bottom image) (A). Three-dimensional (3D) volume-rendered CT with a simulated Sapien 3 valve in a mitral position neo-LVOT trajectory (B). Multiplanar reconstruction view of the neo-LVOT measuring 145 mm² when using a simulated Sapien 3 valve in the mitral position (C). Intraprocedural 3D TEE view of the mitral valve with one guiding catheter positioned that abuts the base of the A2 mitral scallop, while the other is placed retrograde across the mitral valve (D). Illustration in panel A reprinted from JACC: Cardiovascular Interventions, Vol 10, Vasilis C et al, Intentional Percutaneous Laceration of the Anterior Mitral Leaflet to Prevent Outflow Obstruction During Transcatheter Mitral Valve Replacement First-in-Human Experience, Pages 798-809, Copyright (2017), with permission from Elsevier.

nique involves cutting the anterior mitral valve leaflet prior to TMVR to prevent LVOT obstruction (Figure 2).¹²

Who Needs It?

LVOT obstruction risk is most accurately predicted by simulating the neo-LVOT using the intended THV. A neo-LVOT area < 200 mm² portends increased risk of LVOT obstruction. Furthermore, a long anterior mitral leaflet can cause dynamic LVOT obstruction from systolic anterior motion as well as leaflet overhang that can interfere with transcatheter valve function. Typically, LAMPOON works

in combination with a THV that has an open-cell design, allowing blood to flow through it when the anterior mitral leaflet is split or when the risk is from a long leaflet.

How Does It Work?

The anterior mitral valve leaflet is cut down the centerline. The chords are spared, and these pull the cut leaflets apart, splaying them away from the LVOT. This splay is magnified further when the THV is deployed, particularly in the setting of anteroposterior oversizing and flaring in the ventricle.

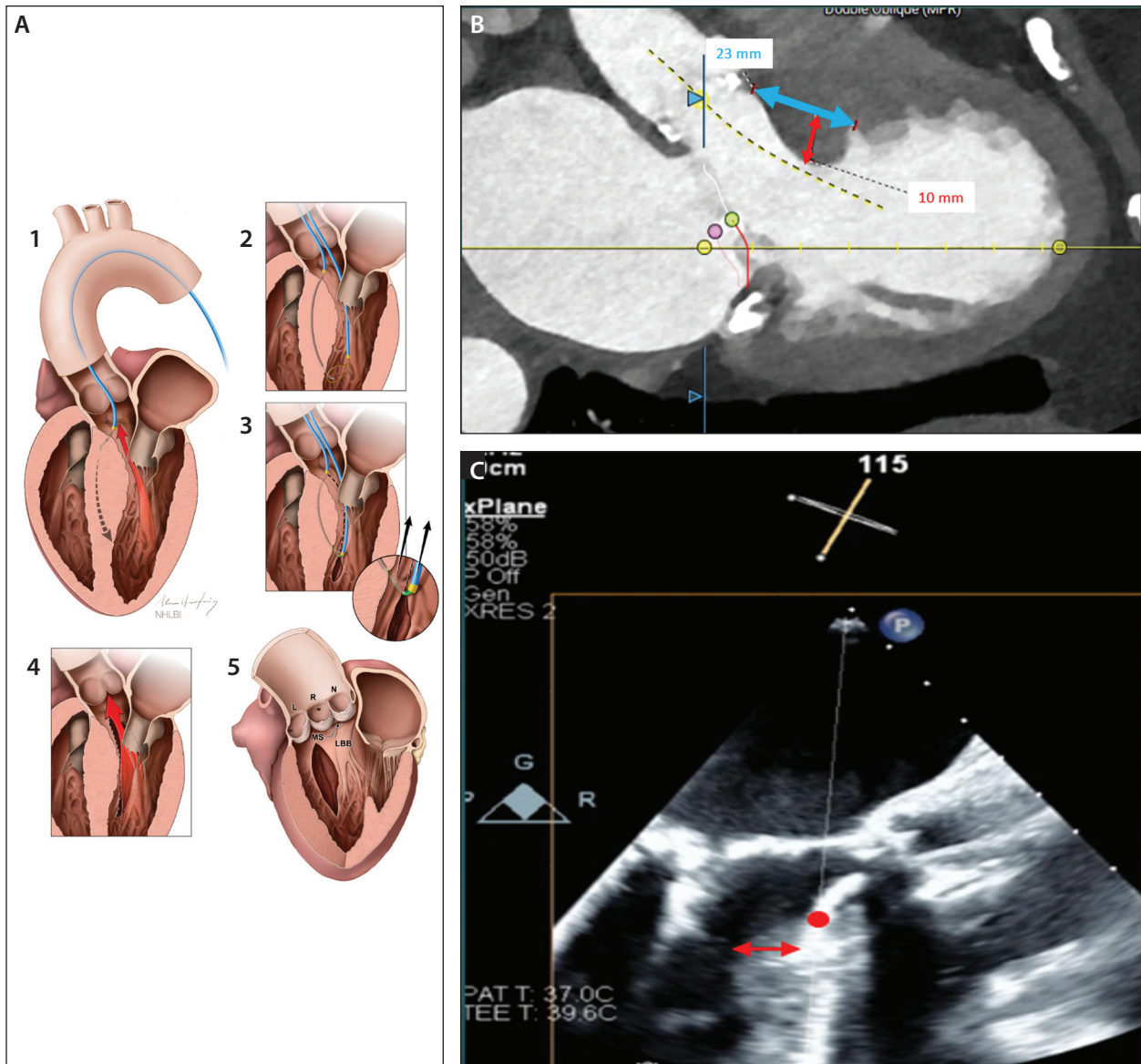
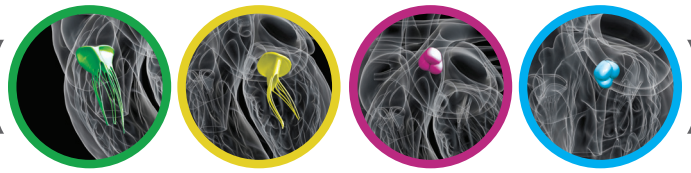
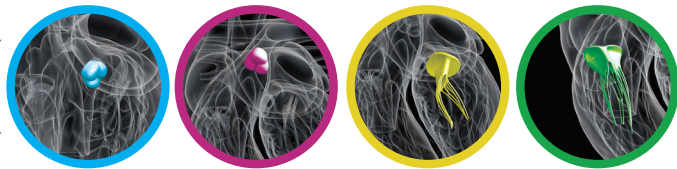


Figure 3. SESAME: Illustration depicting the SESAME procedure (A), where a guidewire is navigated through the interventricular septum (A1) then completes the intramyocardial trajectory and reenters the left ventricle cavity into a snare (A2). A lac-erating surface is then electrified to create the myotomy (A3) leading to muscle splay and increased space in the LVOT, with increased blood flow (A4-A5). Cardiac CT showing trajectory of the neo-LVOT (yellow dotted line), length of the thickened basal interventricular septum targeted for wire traversal (blue arrow), and planned guidewire depth (red arrow) (B). Intraprocedural TEE (long-axis view) showing the guidewire navigating through the interventricular septum intramyocardially (red dot) and the depth of the guidewire in the septum (red arrow) (C). Illustration in panel A reprinted from Khan JM et al, Transcatheter Myotomy to Relieve Left Ventricular Outflow Tract Obstruction: The Septal Scoring Along the Midline Endocardium Procedure in Animals, *Circulation: Cardiovascular Interventions*, Volume 15, Issue 6.

How to Do It

LAMPOON is currently performed using commercially available equipment. Dedicated devices for BASILICA could potentially be repurposed for transseptal delivery for LAMPOON, but these have not yet been applied

in patients. LAMPOON was originally performed from the retrograde aortic approach, and this approach was studied in a prospective trial.¹³ However, contemporary practice is to perform LAMPOON from the antegrade transseptal approach due to greater ease of use.¹⁴



VALVULAR INTERVENTIONS

Tip-to-base LAMPOON. In the setting of valve-in-valve or valve-in-complete ring TMVR, lacerating the leaflet from tip to base is the preferred method. A venoarterial rail is created after transseptal puncture, delivery of a guidewire through the mitral and aortic valves along a chord-free trajectory, and snaring the guidewire in the aorta from the femoral artery. A flying V is created (as in BASILICA) and delivered to the mitral valve leaflet tip while externalizing the snared tip of the guidewire. The left atrial catheter is positioned at the center of the mitral leaflet under echocardiographic and fluoroscopic guidance. Tension is applied to both limbs of the guidewire during electrification at 70 W and dextrose flush until the guidewire meets the sewing ring. The cut is confirmed on echocardiography prior to equipment disassembly and TMVR.¹⁵

Base-to-tip LAMPOON. Base-to-tip LAMPOON is preferred in the setting of a native mitral valve or incomplete ring when there is no adequate backstop to atrial progression of wire laceration. Two deflectable transseptal sheaths are used: one for traversal from the left atrium to the LVOT through the base of the anterior mitral valve leaflet and the other for snaring in the LVOT. After traversal, the flying V is delivered to straddle the mitral leaflet. The vector of laceration is determined by aligning the two deflectable sheaths along the midline of the mitral leaflet. Laceration is performed by applying tension of both limbs of the guidewire during electrification at 70 W.¹⁶

Limitations

There is a learning curve for these procedures, and maintaining skills requires a certain regularity in performing them. In the setting of a small neo-LVOT, LAMPOON can only help when using a THV with an open-cell design.

MYOCARDIAL MODIFICATION

The techniques of guidewire traversal, snaring, and laceration described for valve leaflet laceration have been applied to the myocardium to augment the LVOT. The SESAME (septal scoring along the midline endocardium) procedure can be used to prevent LVOT obstruction from TMVR and also as septal reduction therapy for patients with obstructive hypertrophic cardiomyopathy (oHCM) (Figure 3).¹⁷

Who Needs It?

Septal reduction therapy should be considered for patients with oHCM and provokable gradients of ≥ 50 mm Hg despite optimal medical therapy. Given that SESAME is a novel therapy, it is generally reserved

for patients who either are not candidates or do not wish to undergo surgical myectomy or transcatheter alcohol septal ablation. SESAME is also used prior to TMVR to augment the LVOT in patients at risk of LVOT obstruction. Unlike LAMPOON, SESAME is agnostic to TMVR design.

How Does It Work?

SESAME is a myotomy without myectomy. In other words, a cut is made in the muscle without excision of muscle tissue, replicating the original surgery for oHCM. After muscle laceration, the muscle splays, creating increased room in the LVOT. The splay is greater with greater depth of laceration and is theoretically greater when cutting across circumferential muscle fibers. The muscle remodels over the subsequent weeks to further augment LVOT area.

How To Do It

A stiff guidewire is buried into the basal interventricular septum from a retrograde approach across the aortic valve. The guidewire is shaped and reinserted through a microcatheter and then navigated through the myocardium using echocardiography to determine the depth and length of myocardium traversed. The guidewire is directed to reenter the left ventricular cavity, where it is snared. The flying V is created and advanced through the myocardium while the snared guidewire tip is retrieved. The guidewire is electrified at 50 to 70 W while traction is applied to both ends of the guidewire, resulting in myocardial laceration.

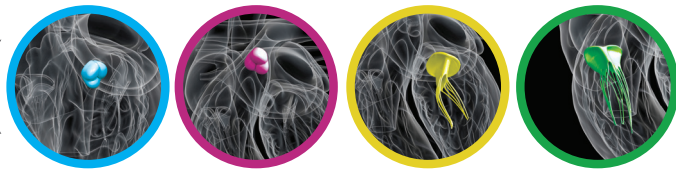
Limitations

The procedure is novel, has not been studied prospectively, and long-term outcomes are unknown. However, the targeted nature of therapy in precisely directing the percutaneous myectomy is attractive in terms of safety, avoidance of the conduction system, and effectively reducing the septal bulge at the intended location.¹⁸

FUTURE DIRECTIONS

The need for these procedures is increasing as increasingly complex patients are being treated. Need for BASILICA and its variants is set to increase exponentially as cases of redo TAVR increase. Dedicated TMVR devices have been associated with high screen failure rates, but compatibility with LAMPOON or pairing with SESAME may significantly improve treatment rates. These dedicated devices are in development, which will increase the accessibility of these procedures. ■

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VALVULAR INTERVENTIONS

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Roosha Parikh, MD, FACC, FASE, FSCCT, FSCMR, FASNC

Associate Director of Cardiac CT
Associate Program Director of Cardiovascular
Imaging Fellowship Program
Assistant Professor of Medicine
Advanced Imaging Cardiologist
St. Francis Hospital and Heart Center
Roslyn, New York
roosha.parikh@chsli.org

Disclosures: Consultant for HeartFlow.

Jaffar M. Khan, MD, PhD

Director of Cardiovascular Innovation
Director of Interventional Electrosurgery
St. Francis Hospital and Heart Center
Roslyn, New York
jaffar.khan@chsli.org

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