

STATE-OF-THE-ART PAPER

Percutaneous Transcatheter Closure of Prosthetic Mitral Paravalvular Leaks

Are We There Yet?

Michael S. Kim, MD,* Ivan P. Casserly, MB, BCH, FACC,*† Joel A. Garcia, MD, FACC,*‡ Andrew J. Klein, MD,* Ernesto E. Salcedo, MD, FACC,* John D. Carroll, MD, FACC*

Aurora and Denver, Colorado

A potential complication of mitral valve replacement surgery is the development of a paravalvular leak (PVL). Percutaneous transcatheter closures of PVLs using a wide array of devices have been reported in the literature, although the procedural success rate of this approach remains variable. One major challenge of transcatheter mitral PVL closure lies in the ability to adequately visualize the area of interest to facilitate defect crossing and equipment selection. Furthermore, the current spectrum of devices available for off-label use in the closure of these unique defects remains limited. This review examines the current state of transcatheter prosthetic mitral PVL closure, describes our institution's experience using advanced imaging modalities for procedural guidance, and illustrates some of the limitations associated with using existing devices in transcatheter PVL closure. (*J Am Coll Cardiol Intv* 2009;2: 81–90) © 2009 by the American College of Cardiology Foundation

Paravalvular leak (PVL) is a rare but serious complication of surgical mitral valve replacement (1). Although most PVLs are small, remain asymptomatic, and follow a benign clinical course, larger PVLs with serious clinical consequences (i.e., heart failure, endocarditis, or hemolysis) occur in 1% to 5% of patients who have undergone surgical valve replacement (2), with most clinically significant PVLs occurring in association with prosthetic mitral valves (3). Surgical intervention is recommended in adult patients with symptomatic PVLs, though reoperation is associated with mortality rates approaching 16% (4). Percutaneous transcatheter closure procedures, which are routinely applied in the management of various intracardiac defects and vascular communications (5,6), have been applied to the treatment of PVLs using a variety of techniques (2,7–12). Experience with

transcatheter mitral PVL closure has achieved variable success (Table 1), with reported initial technical success rates of 60% to 90% and a need for repeat intervention in up to 40% of cases (2). In most cases, technical failure results from either the inability to deliver a closure device or device interference with surrounding structures after deployment (e.g., neighboring valve leaflets), and repeat procedures were performed either for the presence of residual leaks or unanticipated device embolization (2,7,13).

One major challenge associated with transcatheter PVL closure is the ability to adequately visualize the defect's three-dimensional (3D) anatomic and spatial characteristics. Suboptimal visualization of defect anatomy contributes to the challenge of multiple technical elements of these procedures such as access to the region of the defect, device selection, and appreciation of device interaction with surrounding structures (e.g., prosthetic valve struts or leaflets, valve inflow). A second challenge lies in the fact that there are no devices currently available that are specifically designed to meet the anatomic and physiologic properties of PVLs. Rather, devices that have been approved by the

*From the University of Colorado Denver, Aurora, Colorado; and the †Denver Veterans Affairs Medical Center and the ‡Denver Health Medical Center, Denver, Colorado. Dr. Carroll is a consultant/investigator for AGA Medical Inc. and a consultant/member of the Speakers' Bureau for Philips Healthcare. Dr. Salcedo is a consultant for Philips Healthcare.

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U.S. Food and Drug Administration for the closure of other cardiovascular defects (e.g., atrial septal defect, ventricular septal defect [VSD], patent ductus arteriosus) are used in an off-label fashion (2,8,13-17).

In this review, we examine the current state of transcatheter closure of prosthetic mitral PVLs and share our experience using advanced imaging technologies to help overcome the previously described technical challenges of image guidance associated with these complex procedures. In addition, by addressing the limitations associated with using existing devices in transcatheter mitral PVL closure, we highlight the need for a PVL-specific closure device.

Technical Approach to Transcatheter Mitral PVL Closure

Transcatheter closures of prosthetic PVLs are often long, technically demanding procedures requiring access to a robust equipment inventory. Because transesophageal echocardiography (TEE) is commonly used for image guidance, general anesthesia is often used for both patient comfort and airway protection. In addition, adequate anticoagulation is required throughout the procedure, and especially after transseptal catheterization, as prolonged equipment dwell times within the patient are common. Finally, the interaction among the interventional cardiologist, echocardiographer, and anesthesiologist is a key component in attaining procedural success.

Transcatheter closure of prosthetic mitral PVLs is performed using either a retrograde or anterograde approach (Fig. 1). The method of approach is determined by several factors. For example, severe paravalvular regurgitation may prevent defect crossing using an anterograde approach, the presence of a mechanical aortic valve precludes a retrograde approach, and the asymmetric size of the end disks of certain closure devices may dictate a specific deployment sequence (Table 2). The equipment selections described later are provided as a guide in implementing the following critical procedural steps for percutaneous mitral PVL closure: 1) positioning an optimally shaped catheter close to the PVL; 2) crossing the PVL with an atraumatic guidewire that is capable of passing through a defect that may contain various angulations and irregularities; 3) advancing a flexible and lubricious surfaced catheter over the guidewire across the defect; 4) replacing this initial guidewire with an extra support wire that is either coiled in a distal location or snared and exteriorized for stability; 5) advancing a device

delivery catheter that is resistant to kinking or significant deformation across the defect; 6) introducing a closure device through the delivery catheter with or without a separate leading guidewire to prevent catheter kinking; and 7) deploying a device while maintaining the option of device retrieval in the setting of suboptimal device stability, malalignment, or undesired interaction on surrounding structures including the prosthetic valve itself.

In the retrograde approach (Fig. 1A), a diagnostic catheter is advanced into the left ventricle, and a 0.035-inch × 260-cm Terumo floppy Glidewire hydrophilic coated guidewire (Terumo Medical Corporation, Somerset, New Jersey) is used to cross the defect. Depending on the location of the defect, a variety of diagnostic catheters can be used including Judkins left and right coronary catheters (18), vertebral catheters (19), or pigtail catheters modified by cutting off the distal end (8). After the defect is crossed with the Glidewire, the catheter is advanced into the left atrium over the wire. To provide adequate support of the device delivery catheter, an arteriovenous (A-V) wire loop is typically established. In preparation for creating the A-V loop, the floppy Glidewire may be exchanged for a 0.035-inch × 260-cm Terumo stiff-angled Glidewire. A transseptal puncture is performed in the standard fashion using a BRK transseptal needle (St. Jude Medical Inc., St. Paul, Minnesota) and a Mullins sheath (Medtronic Inc., Minneapolis, Minnesota). An Amplatz Gooseneck snare (ev3 Inc., Plymouth, Minnesota) is advanced through the Mullins sheath into the left atrium (typical size: 2 to 4 cm) and is used to snare the stiff angled Glidewire. The Glidewire is then externalized through the Mullins sheath to form a continuous A-V loop. The Mullins sheath is then removed and replaced with the device delivery sheath, which is advanced across the mitral PVL from the venous aspect of the loop into the left ventricle while simultaneously withdrawing the original diagnostic catheter ("chasing the catheter" technique). The closure device is subsequently introduced through the delivery catheter while simultaneously withdrawing the Glidewire ("chasing the wire" technique) and is deployed across the PVL in a standard fashion.

In the anterograde approach (Fig. 1B), a transseptal puncture is performed in the standard fashion using a BRK transseptal needle and a Mullins sheath. A diagnostic catheter is advanced through the Mullins sheath into the left atrium through which a 0.035-inch × 260-cm Terumo floppy Glidewire is delivered and used to cross the defect. Once the defect is crossed with the floppy Glidewire, the catheter is advanced into the left atrium over the wire. At this point, the goal is to deliver a sufficiently supportive wire across the defect into the left ventricle that will allow subsequent transit of the delivery sheath (e.g., 0.035-inch Amplatz ES wire, Cook Medical, Bloomington, Indiana). Typically, this is achieved by the sequential delivery of increasingly supportive catheters (e.g., 4-F Bernstein cath-

Abbreviations and Acronyms

3D = three-dimensional

ASO = Amplatz Septal Occluder device

A-V = arteriovenous

PVL = paravalvular leak

TEE = transesophageal echocardiography

VSD = ventricular septal defect

Table 1. Summary of Published Reports of Transcatheter PVL Closure

Author	Year	PVL Type	Device Used	No. of Defects	Technical Success	Short-/Long-Term Clinical Success	Need for Repeat Procedure
Hourihan et al. (7)	1992	AV	Double-Umbrella Rashkind	4	3 (75%)	2 (50%)	1 (25%)
Moore et al. (19)	2000	MV	Gianturco coil	1	1 (100%)	1 (100%)	0
Eisenhauer et al. (20)	2001	MV	Gianturco-Grifka Vascular Occlusion Device	1	1 (100%)	1 (100%)	0
Kort et al. (8)	2004	MV	Amplatzer Duct Occluder	1	1 (100%)	n/a	0
Webb et al. (12)	2005	AV	Amplatzer Duct Occluder	1	1 (100%)	1 (100%)	0
Pate et al. (2)	2006	MV (9); AV (1)	Amplatzer Septal Occluder, Amplatzer Duct Occluder, coils	10	7 (70%)	4 (40%)	4 (40%)
Hildick-Smith et al. (15)	2007	AV	Amplatzer Muscular VSD Occluder	1	1 (100%)	n/a	n/a
Momplaisir et al. (16)	2007	MV	Amplatzer Septal Occluder	1	1 (100%)	1 (100%)	0
Shapira et al. (17)	2007	MV (9); AV (2)	Amplatzer occluder	13	11 (85%)	6 (46%)	1 (8%)
Sorajja et al. (13)	2007	MV (17); AV (2)	Amplatzer Septal Occluder or Amplatzer Duct Occluder	19	17 (89%)	12 (63%)	0
Cortes et al. (14)	2008	MV	Amplatzer Duct Occluder	27	17 (63%)	10 (37%)	0

AV = aortic valve; MV = mitral valve; n/a = information not available; PVL = paravalvular leaks; VSD = ventricular septal defect.

eter, 6.5-F JB-1 catheter, Cook Medical) over increasingly supportive wires (e.g., floppy Glidewire, stiff Glidewire, Amplatz ES wire). The Mullins sheath is removed and replaced with the device delivery sheath, which is advanced across the PVL into the left ventricle. The closure device is then deployed across the PVL in standard fashion.

The decision to establish a continuous A-V loop when using the anterograde approach to transcatheter closure of mitral PVLs primarily depends on the anatomy of the defect. For example, in situations where numerous and/or acute angles are encountered while crossing the defect, thereby raising concerns of either difficulty in transit of the delivery sheath across the PVL or excessive kinking of the delivery sheath once delivered, the operator may choose to establish an A-V loop to enhance overall stability during

delivery catheter advancement. In cases where an A-V loop is created, the Terumo floppy Glidewire is advanced around the left ventricular apex and through the aortic valve into the ascending aorta. An Amplatzer Gooseneck snare is then advanced via the common femoral artery to the level of the ascending aorta and is used to snare the Glidewire. The Glidewire is then externalized through the common femoral artery sheath, thereby establishing a continuous A-V loop.

Choice of PVL Closure Device

Presently, there is no device approved by the U.S. Food and Drug Administration for use in the closure of mitral PVLs. As a result, off-label use of other available devices remains the only percutaneous therapeutic option (Table 2), though

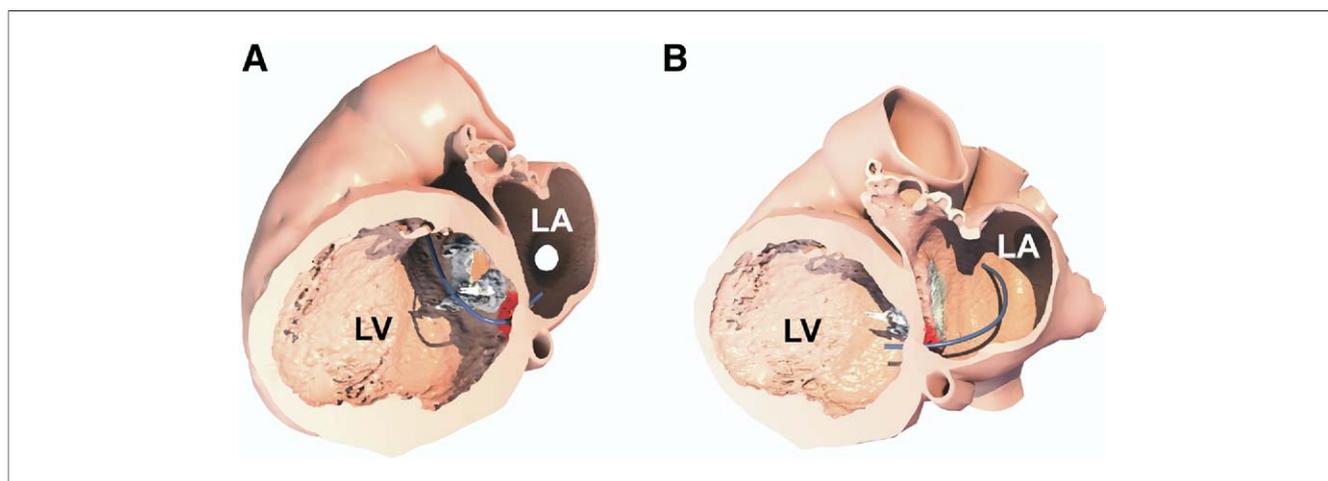
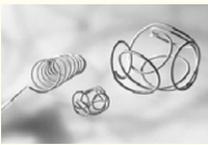


Figure 1. Approaches to Transcatheter Prosthetic Mitral PVL Closure

(A) Retrograde approach. (B) Anterograde approach. The **white highlight** indicates the prosthetic mitral valve. The **red highlight** indicates the paravalvular defect. LA = left atrium; LV = left ventricle; PVL = paravalvular leaks.

Table 2. Comparison of Current Devices Most Commonly Used in Transcatheter PVL Closure

					
	Amplatzer Septal Occluder	Amplatzer Muscular VSD Occluder	Amplatzer Duct Occluder	Amplatzer Vascular Plug	Vascular Coils
Low profile	+	++	+++	+++	+++
Stability	+++	++	+	+	+
Resistance to hemolysis	+	++	++	+	++
Clinical experience	+++	+++	+++	+	+
Delivery approach	Anterograde or retrograde	Anterograde or retrograde	Anterograde only	Anterograde or retrograde	Anterograde or retrograde

Ao = aorta; LA = left atrium; PA = pulmonary artery; RA = right atrium; +++ = very favorable; ++ = moderately favorable; + = least favorable; other abbreviations as in Table 1.

this option should be considered only after the patient has been comprehensively informed of the potential risks and benefits of off-label device use. Although various devices including umbrella devices (7), vascular occluding devices (20), and coils (19), have been used, the Amplatzer family of devices (AGA Medical Inc., Plymouth, Minnesota) has gained popularity as the most frequently employed devices for PVL closure (8,16,17), and further discussion will be limited to this group of devices.

A careful examination of the PVL anatomy, the relationship of the defect to surrounding structures, and the planned procedural approach, so that the device with the most appropriate characteristics is chosen, is critical to procedural and clinical success. Specifically, the length and diameter of the defect will determine the ideal waist length and diameter of the device, respectively. Therefore, the Amplatzer Septal Occluder (ASO) device (waist length: 3 to 4 mm) is better suited for shorter paravalvular defects, while the Amplatzer Muscular VSD Occluder (waist length: 7 mm) and Amplatzer Duct Occluder (waist length: 5 to 8 mm) are better suited for longer paravalvular defects. The distance of the PVL from adjacent valve struts or leaflets helps determine the maximum disk size that can be tolerated without impingement on adjacent structures. In this regard, the ASO device has the greatest difference (12 to 14 mm) between the waist and the disk (i.e., the left atrial disk) diameters, whereas the Muscular VSD Occluder (5 to 8 mm) and Duct Occluder (5 to 8 mm) devices have less of a difference between the waist and disk diameters and would be better suited in situations where the distance between the PVL and adjacent critical structures is small. Finally, whereas all of the Amplatzer devices can be deployed using an anterograde approach, the Duct Occluder should not be deployed using a retrograde approach, because the single retention disk of this device in this situation would rest on the left atrial side of the PVL, and the pressure difference

between the left ventricle and atrium would result in a prohibitive risk of embolization.

Advanced Image Guidance With 3D Echocardiography

In transcatheter PVL closure, as in all structural heart disease interventions, visualizing the 3D anatomy of the region of interest and its spatial orientation to surrounding structures is a critical component of successful and safe intracardiac device implantation. The ability to adequately visualize and appreciate these 3D relationships using 2-dimensional imaging modalities (e.g., fluoroscopy, TEE, intracardiac echocardiography), however, remains a formidable challenge. Three-dimensional echocardiography has recently gained popularity as a noninvasive method of evaluating structural heart defects (21). In the case of transcatheter mitral PVL closure, the enhanced appreciation of both the complex 3D anatomy (18) as well as the spatial orientation of PVLs provided by 3D echocardiography offers several potential benefits in facilitating procedural success.

Although 3D echocardiography represents a technology in constant evolution with definite limitations (i.e., relatively slow 30 frames/s acquisition rate of 3D imaging, lack of standardized 3D views, steep learning curve in both understanding and appropriately integrating 3D images in a procedural environment), its potential to both complement existing imaging modalities as well as enhance procedural success holds significant promise. In our laboratory, we have used real-time 3D transthoracic echocardiography and real-time 3D TEE both to define defect anatomy as well as to guide transcatheter PVL closure. All 3D echocardiography studies are performed using an iE33 ultrasound system (Philips Healthcare, Andover, Massachusetts). Real-time 3D TEE is performed using an X7-2t TEE transducer

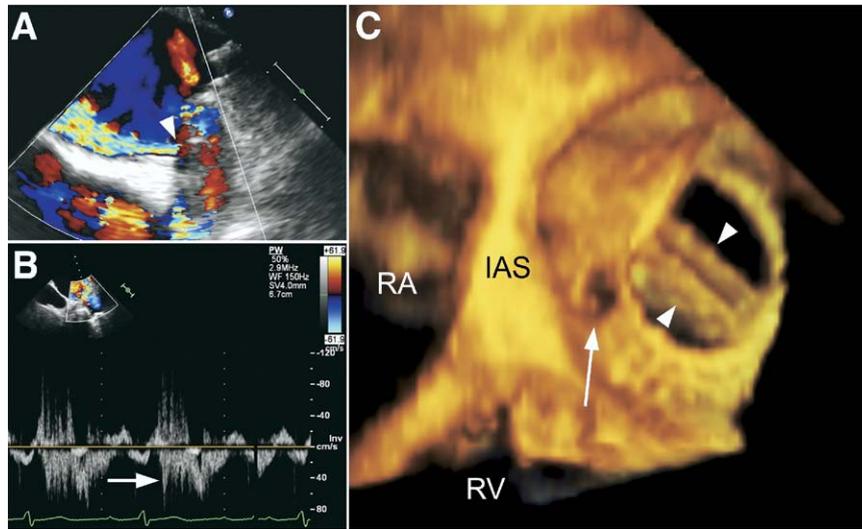


Figure 2. Multidimensional Echocardiographic Evaluation of a Prosthetic Mitral PVL

(A) A 2D TEE demonstrating the paravalvular defect (arrowhead) with severe paravalvular regurgitation. (B) A 2D TEE pulse wave Doppler demonstrating marked systolic flow reversal (arrow) in the right upper pulmonary vein. (C) Real-time 3D TEE volumetric reconstruction demonstrating the anteromedial location of the paravalvular defect (arrow) and mechanical mitral valve leaflets (arrowheads). IAS = interatrial septum; PVL = paravalvular leak; RA = right atrium; RV = right ventricle; TEE = transesophageal echocardiography; 2D = 2-dimensional; 3D = 3-dimensional.

(Philips Healthcare). Our experience has shown that when combined with the information derived from existing 2-dimensional imaging modalities, 3D echocardiography enhances effective catheter navigation by clearly defining the spatial location of the defect relative to surrounding intracardiac structures (Fig. 2). With the recent availability of real-time 3D TEE, we are now able to effectively employ live 3D image guidance to facilitate both catheter navigation and defect crossing (Fig. 3) without the need for time-intensive offline reconstruction. In addition, 3D echocardiography can be used immediately post-PVL closure (Fig. 4) to assess device stability and interaction with surrounding structures (e.g., prosthetic valve struts, mechanical leaflets).

Pre-Procedural Planning With Rapid Prototyping

Rapid prototyping, a method by which 2-dimensional images are processed into 3D physical models, has provided physicians the opportunity to more clearly understand complex anatomic and spatial relationships as well as effectively predict potential procedural complexities by allowing physical visualization of device-anatomy orientation in 3D space (5,22). As such, it represents a novel technology that will likely play a major role in the patient-specific planning of various, complex catheter-based interventions. We are currently investigating the utility of rapid prototyping in the clinical evaluation and planning of catheter-based interventions for complex structural heart defects, including percu-

taneous mitral PVL closure. In 1 of our patients with a prosthetic mitral PVL, rapid prototyping technology was used to create a 3D physical heart model that clearly demonstrated a paravalvular defect located in the posterolateral position (Fig. 5A). In addition, using the model as a reference for device sizing, it was determined an 11-mm ASO device would achieve defect closure without compromising surrounding anatomic or valvular structure and function (Fig. 5B). Deployment of subsequently larger devices within the model demonstrated significant physical deformation of the left ventricular disk and/or impingement on mitral valve inflow. Using both the model as a procedural guide and 3D echocardiography for image guidance, the patient subsequently underwent a technically successful transcatheter PVL closure with an 11-mm ASO device. Although this represents only 1 example of the potential utility of rapid prototyping in the care of patients with complex structural heart disease, as our understanding of this unique technology continues to evolve, so will its application in the care of patients with all types of both congenital and acquired structural heart defects.

Limitations of Currently Available Devices

The devices currently being used in an off-label manner for PVL closure are associated with both immediate and delayed technical failure (Table 1). Immediate failure is most commonly caused by device impingement on adjacent critical structures, and delayed failure is typically due to device

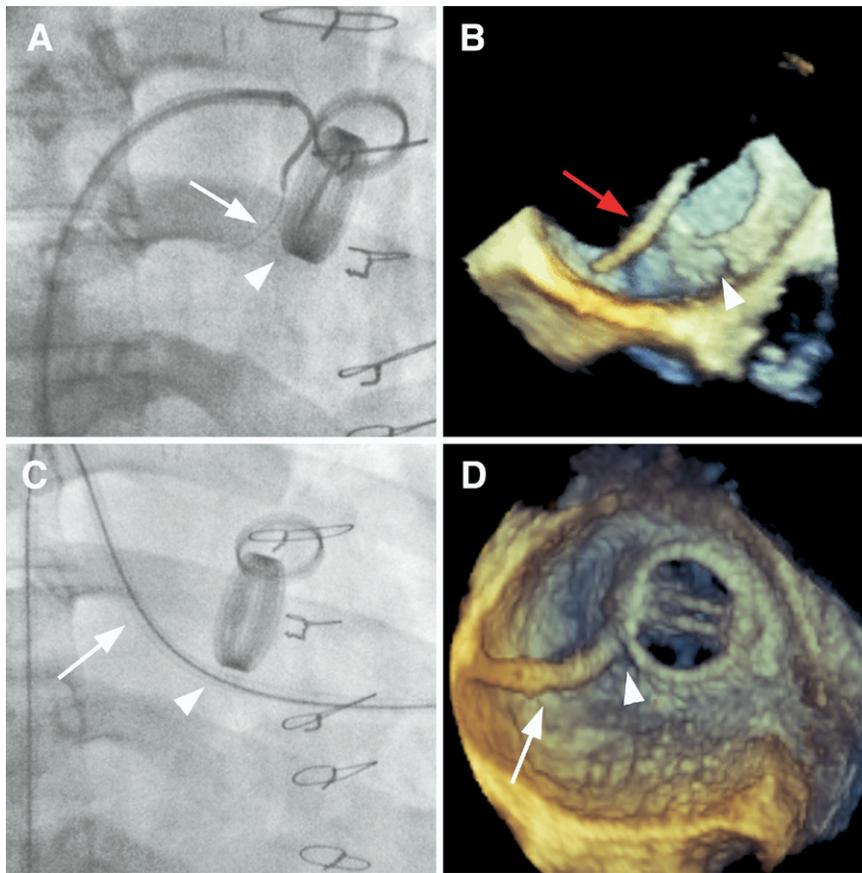


Figure 3. Multimodality Image Guidance of Transcatheter PVL Closure

Fluoroscopic visualization (A) and real-time 3D TEE volumetric reconstruction (B) of the floppy Glidewire (white arrows) and JB-1 catheter (red arrow) in relation to the paravalvular defect (arrowheads). Fluoroscopic visualization (C) and real-time 3D TEE volumetric reconstruction (D) of the delivery system catheter (arrows) across the paravalvular defect (arrowheads). Abbreviations as in Figures 1 and 2.

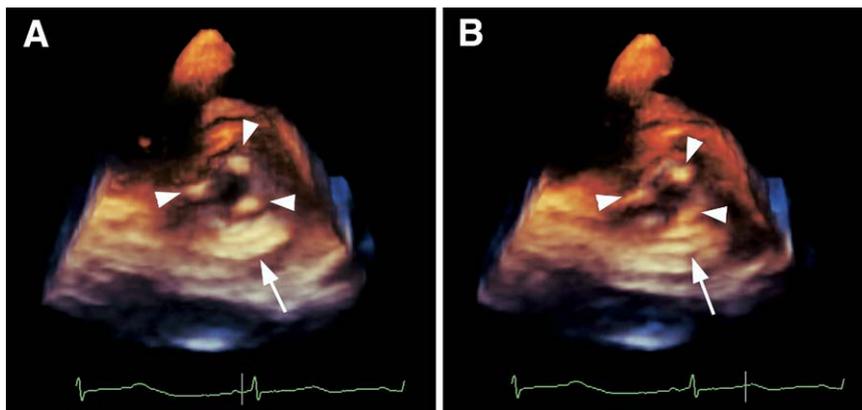


Figure 4. Post-PVL Closure 3D TTE Evaluation of Device Morphology

Volumetric reconstruction following device implantation at end-diastole (A) and end-systole (B) demonstrating an absence of device (arrows) impingement on the neighboring prosthetic valve struts (arrowheads). TTE = transthoracic echocardiography; other abbreviations as in Figures 1 and 2.

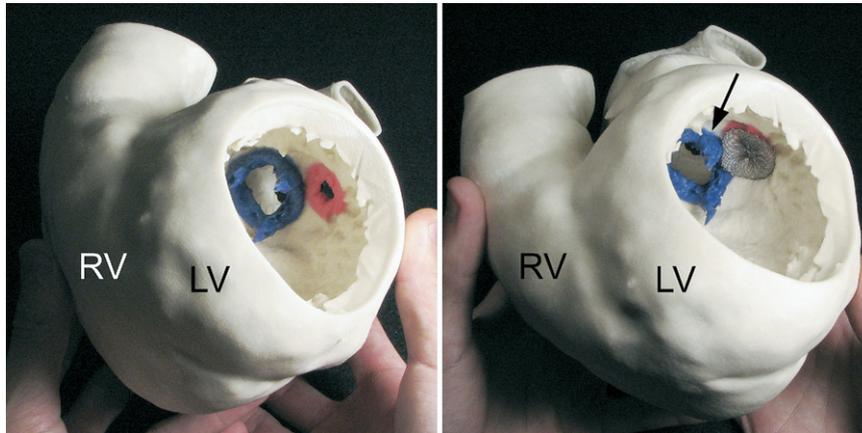


Figure 5. Physical Model Application in a Prosthetic Mitral PVL

(A) View from the left ventricle illustrating a posterolaterally located prosthetic mitral paravalvular defect (red highlight). (B) Amplatzer Septal Occluder device placed through the defect, demonstrating that the occluder device neither interferes with adjacent prosthetic valve struts (arrow) nor obstructs valve inflow. The blue highlight indicates the mitral bioprosthesis. The red highlight indicated the paravalvular defect. Abbreviations as in Figures 1 and 2.

embolization. These failures are connected in that with the current generation of Amplatzer devices, improved device stability is achieved at the expense of increased device profile, and vice versa (i.e., devices with larger waists and terminal disk sizes that provide enhanced stability and protection from distal embolization have larger profiles that are more likely to impinge on adjacent structures). Even after trial and error with different device types and sizes, a device that strikes the balance between stability and profile may not be found. For example, in 1 of our patients with a PVL of a mechanical mitral prosthesis, although variably sized ASO and Amplatzer Muscular VSD Occluder devices were successfully deployed across the PVL, they could not

do so without impinging on the neighboring prosthetic valve leaflet (Figs. 6 and 7). Although smaller devices avoided this leaflet impingement, they failed to remain seated in the defect during push-pull testing and thus could not be released due to fear of device embolization. The patient subsequently underwent surgical repair of the PVL with a Gore-Tex (W.L. Gore & Associates, Flagstaff, Arizona) patch, but developed recurrent heart failure post-operatively due to a persistent PVL complicated by transfusion-requiring hemolysis. This case in particular further highlights the truly suboptimal therapeutic options (both percutaneous and surgical) that are currently available for treating patients with this unique pathology.

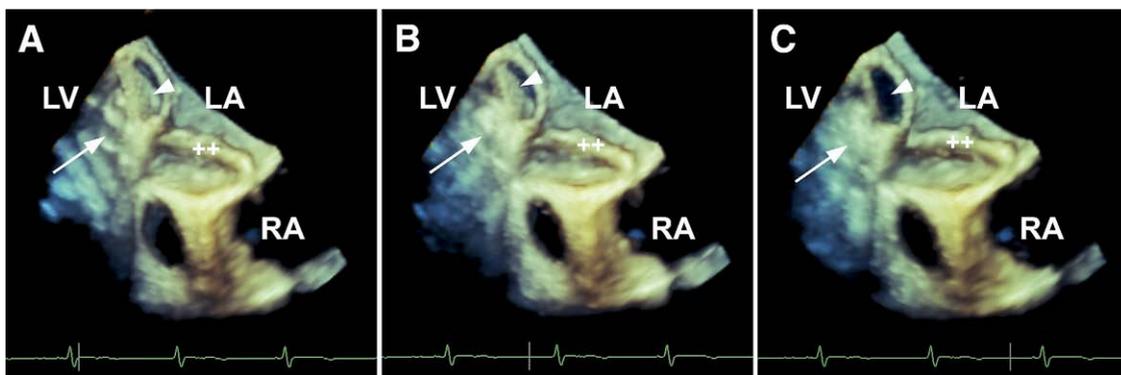


Figure 6. Real-Time 3D TEE Volumetric Reconstruction of ASO Device Interaction With a Mechanical Mitral Valve Following Disk Deployment on the LV Side

(A) Mechanical leaflet physiologically closed during systole. (B) Leaflet impingement is present during diastole. (C) Repositioning of the device results in normal leaflet motion but obstruction to mitral inflow persists. (Crop plane is oriented through the mechanical mitral valve, parallel and between the leaflets.) Arrows indicate placement of ASO device disk deployed in LV. The arrowheads indicate the mechanical valve leaflet. ++ mark the delivery system catheter across the paravalvular defect. ASO = Amplatzer Septal Occluder; other abbreviations as in Figures 1 and 2.

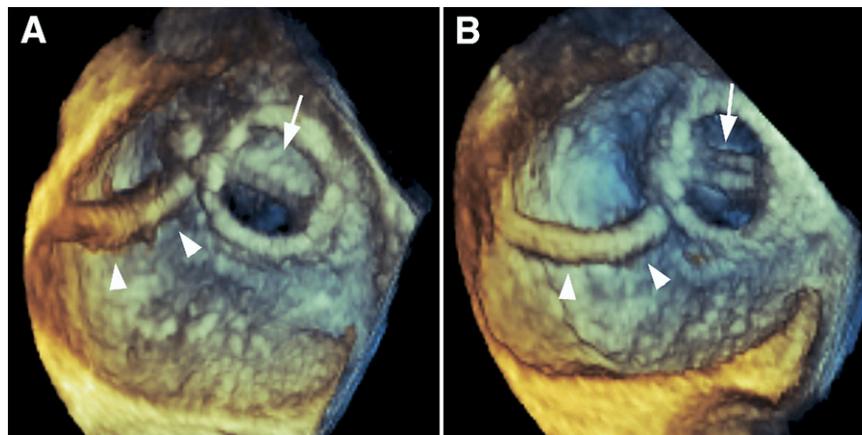


Figure 7. Real-Time 3D TEE Volumetric Reconstruction of Amplatzer Muscular VSD Occluder Device Impingement on a Mechanical Valve Leaflet Following Deployment of the LV Disk

(A) Leaflet impingement (**arrow**) using a 12-mm Muscular VSD Occluder device. (B) Normal functioning leaflet (**arrow**) using an 8-mm Muscular VSD Occluder device. **Arrowheads** show the delivery catheter. VSD = ventricular septal defect; other abbreviations as in Figures 1 and 2.

In addition, although the PVL closure procedure may be technically successful, vigilant monitoring for unsuspected or rare procedural complications is crucial as current devices were not originally designed for use in this pathophysiologic setting. For example, 1 of our patients underwent a successful prosthetic mitral PVL closure with an ASO device, but the post-closure Doppler exam revealed a residual shunt through the closure device (Fig. 8). Over the course of several weeks, the patient developed progressively discolored urine that ultimately evolved into hemolysis requiring transfusion and pigment-induced nephropathy with renal failure (23), a rarely reported complication of percutaneous device implantation (24–26). Despite cessation of all anticoagulant and antiplatelet agents, the residual flow through the device and hemolysis requiring transfusion persisted, necessitating surgical repair with a Gore-Tex patch resulting in minimal paravalvular regurgitation and major reduction of hemolysis and pigment-induced nephropathy.

Designing New Equipment and Devices

Based on this discussion, there is clearly a need to engineer a closure device designed specifically for mitral PVLs. Given the close proximity of paravalvular defects to prosthetic valve sewing rings and leaflets (either mechanical or porcine), the ideal device would be low in profile. Unlike many existing closure devices, this defect-specific device would also avoid the need for anchoring end disks to avoid potential inflow/outflow obstruction and/or valve leaflet impingement. Furthermore, in light of both the contractile and hemodynamic forces generated by the left ventricle, the ideal closure device would also be designed of a material capable of conforming to the dynamic morphology of the

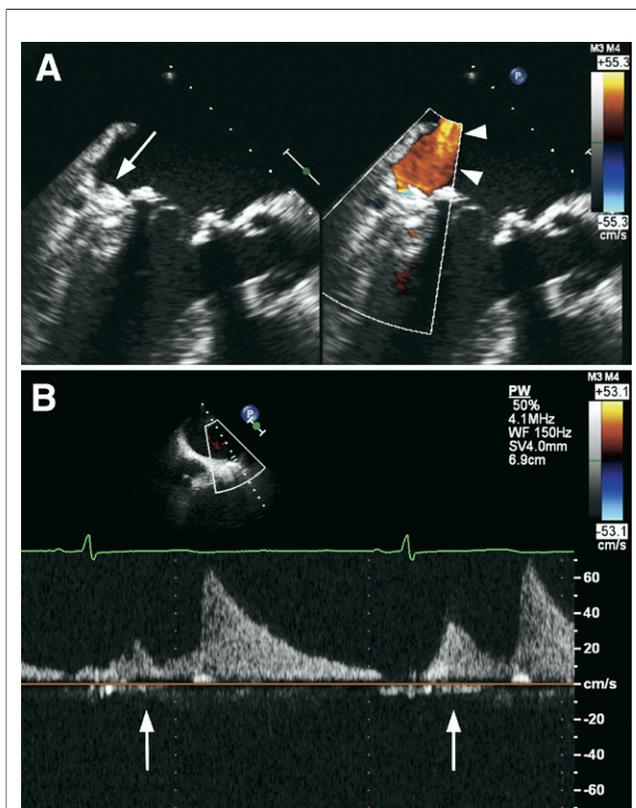


Figure 8. Post-Device Implantation 2D TEE With Doppler

(A) Deployed ASO device (**arrow**) with residual flow by color Doppler (**arrowheads**) through the body of the device. (B) Pulse wave Doppler demonstrating an absence of systolic flow reversal (**arrows**) in the pulmonary veins. Abbreviations as in Figures 2 and 6.

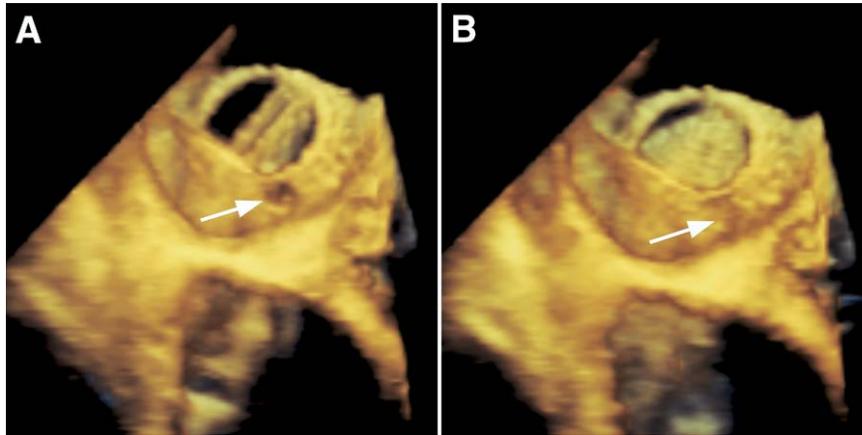


Figure 9. Real-Time 3D TEE Volumetric Reconstruction Illustrating the Dynamic Morphology of the Paravalvular Defect

(A) End-diastole. (B) End-systole. Arrows indicate the paravalvular defect. Abbreviations as in Figure 2.

paravalvular defect observed during systole and diastole (Fig. 9), yet provide enough stability to withstand the significant transdefect pressure gradient across cardiac chambers. In addition, the ideal PVL closure device should be designed to balance the need to seal the defect quickly to reduce the concern for device-mediated hemolysis without posing an increased risk of thrombus formation and subsequent embolic complications. Finally, because of the inherent morphologic variability of PVLs and the relatively small number of patients requiring intervention for these defects, PVL device design may ultimately be based on data obtained from advanced imaging modalities such as 3D echocardiography and rapid prototyping to design true patient-specific or modifiable closure devices.

As the use of advanced image guidance with 3D echocardiography becomes routine in facilitating the performance of these complex procedures, device and equipment manufacturers must focus on developing devices, catheters, and wires composed of “ultrasound friendly” materials (i.e., materials maximizing echogenicity while minimizing refractive/reflective artifacts). For example, our experience has shown that while certain catheters and wires are clearly visualized on 3D echocardiography, wires with hydrophilic coatings (i.e., the Terumo floppy Glidewire) are often invisible by ultrasound. Given that hydrophilic wires are critical components in PVL and other intracardiac defect closure procedures, finding ways to maximize their echogenicity in future design iterations remains an important goal.

Conclusions

Transcatheter mitral PVL closures are one of the most challenging procedures facing interventional cardiologists today. Our experience suggests that the use of advanced image guidance with 3D echocardiography may enhance

immediate technical success. Long-term clinical success, however, ultimately is dictated by the limitations associated with the use of existing devices for PVL closure and the need to design a PVL-specific closure device.

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Reprint requests and correspondence: Dr. John D. Carroll, University of Colorado Denver—Anschutz Medical Campus, Lepirino Office Building, Room 524, 12401 East 17th Avenue, P.O. Box 6511, Campus Box B-132, Aurora, Colorado 80045. E-mail: John.Carroll@ucdenver.edu.

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Key Words: paravalvular leak ■ perivalvular leak ■ mitral valve ■ prosthetic valve ■ 3-dimensional echocardiography ■ percutaneous transcatheter closure ■ rapid prototyping.