

Cardioscopically Guided Beating Heart Surgery: Paravalvular Leak Repair

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Purpose. There remains a paucity of direct visualization techniques for beating-heart intracardiac procedures. To address this need, we evaluated a novel cardioscope in the context of aortic paravalvular leaks (PVLs) localization and closure.

Description. A porcine aortic PVL model was created using a custom-made bioprosthetic valve, and PVL presence was verified by epicardial echocardiography. Transapical delivery of occlusion devices guided solely by cardioscopy was attempted 13 times in a total of three pigs. Device retrieval after release was attempted six times. Echocardiography, morphologic evaluation, and delivery time were used to assess results.

Evaluation. Cardioscopic imaging enabled localization of PVLs via visualization of regurgitant jet flow in a paravalvular channel at the base of the prosthetic aortic valve. Occluders were successfully placed in 11 of 13 attempts (84.6%), taking on average $3:03 \pm 1:34$ min. Devices were cardioscopically removed successfully in three of six attempts (50%), taking $3:41 \pm 1:46$ min. No damage to the ventricle or annulus was observed at necropsy.

Conclusions. Cardioscopy can facilitate intracardiac interventions by providing direct visualization of anatomic structures inside the blood-filled, beating-heart model.

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While intracardiac imaging has advanced in recent years, the positioning and deployment of devices remain challenging and success hinges on the experience level of the clinical team. Closure of PVLs in a beating heart is a specific example of such a challenge. PVL is a complication that can occur after both surgical and transcatheter prosthetic valve implantations. Their repair usually involves delivering one or more occluders into the leak to reduce or eliminate regurgitant flow [1]. Occluder deployment inside PVLs is currently performed using combinations of computed tomographic angiography, fluoroscopy, and transesophageal echocardiography and requires an experienced interdisciplinary team of

cardiovascular interventionists and imaging experts [1, 2]. Direct imaging of the valve annulus could substantially improve procedural success and reduce interventional time if it enables leak localization, visualization during deployment, and evaluation of potential interference with valve function. Cardioscopy (i.e., endoscopy within the blood-filled heart) can provide these capabilities. In this article, we describe the design of a handheld cardioscope that incorporates a working channel for deployment of various tools, and we demonstrate localization and repair of PVLs using a transapical approach in a swine model.

Technology

Using endoscopy inside the blood-filled heart involves creating an optically clear path between imaging system

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The Video can be viewed in the online version of this article [<http://dx.doi.org/10.1016/j.athoracsur.2017.03.028>] on <http://www.annalsthoracicsurgery.org>.

and tissue. Early cardioscopes used toroidal balloons pressed against tissue and cleared of blood by a continuous saline flow [3]. Alternative approaches have used clear plastic optical windows that are pressed against the tissue to exclude the blood. These devices have provided intracardiac images of unprecedented resolution [4, 5].

In the design presented here, a chip-based camera and a light-emitting diode for illumination are embedded in an optical window composed of soft, optically clear silicone that incorporates a working channel for device delivery (Fig 1). Since the image and illumination are transmitted electronically through small-diameter wires, the cardioscope can be integrated easily into both catheters and handheld surgical tools. Saline flow is also not necessary for tissue visualization through the clear silicone. Irrigation is provided through the working channel, however, to prevent blood backflow and to enable tool visualization inside the channel.

The cardioscope design in Figure 1 has a diameter of 10 mm, but is scalable to achieve a specified field-of-view diameter and to accommodate various delivery routes (e.g., transfemoral or transapical). A 1-mm³ complementary metal oxide semiconductor camera and 1.6 × 1.6 × 0.5 mm light-emitting diode are molded inside the optical window, which also contains a 2.3-mm internal diameter working channel. The working channel is positioned off center to facilitate device delivery around the outer edge of the annulus, and its walls are transparent inside the optical window to enable device visualization inside the channel during delivery. The cardioscope is mounted on a straight, 5-mm diameter, 35-cm-long handheld catheter. For PVL closure, the occlusion device is loaded inside a transparent delivery cannula that is advanced through the working channel. Both the handheld cardioscope and delivery cannula have integrated Luer lock male fittings for saline infusion to eliminate air bubbles and to clear blood from the channel.

Technique

A porcine model of PVLs was created using custom-designed bioprosthetic valves incorporating features for producing three PVLs spaced approximately 120 degrees apart on the valve rim (Fig 2). The bioprosthetic valves were composed of a three-dimensional printed titanium frame covered with a nonwoven polyester fabric, a suturing ring made of polypropylene felt, and leaflets made from glutaraldehyde-fixed porcine pericardium [6]. Three reinforced gaps in the suturing ring were included to allow paravalvular blood backflow. Valves were

fabricated in several sizes to accommodate to individual porcine anatomies.

After having premedicated and sedated the swine, the thoracic cavity was accessed through a median sternotomy. Epicardial echocardiographic images of the native aortic valve were acquired for prosthetic valve implant size selection. After initiating cardiopulmonary bypass, performing aortic cross-clamping, and starting cardioplegia, a transverse arteriotomy was made in the aortic root to remove the native leaflets and to implant the artificial valve.

With the valve placed, the animal was rewarmed, and the aortotomy repaired followed by cross-clamp release. Partial cardiopulmonary bypass was maintained to ensure hemodynamic and cardiac rhythm stability. Bioprosthetic valve function was then evaluated by epicardial short- and long-axis two-dimensional and color Doppler echocardiography to assess PVL location and size. Two pledgeted purse-string sutures were then placed on the cardiac apex, to stabilize it for introduction of the cardioscope, which was preloaded (Fig 2C) with the delivery cannula containing an occlusion device (AMPLATZER Vascular Plug II, St. Jude Medical, Saint Paul, MN).

The handheld cardioscope was inserted through the apex and navigated to the valve annulus. Once the valve was reached, the catheter was navigated around the valve annulus to identify and inspect each leak. The catheter was then withdrawn from the annulus to just inside the apex. From this position, sequential closure of each PVL was attempted followed by device reloading.

The closure process consisted of the following steps. First, the cardioscope was navigated to the valve annulus and the targeted PVL (Fig 2B) was localized. The working channel was positioned directly over the center of the PVL. The delivery sheath was then extended by approximately 3 mm into the PVL to ensure that the device would expand inside the PVL and not proximal to it. The occluder was then advanced out of the delivery sheath, with the operator being able to feel a pop as each of the three device lobes were released. Finally, the sheath, the device and, if needed, the cardioscope, were slightly retracted until the proximal lobe of the occluder was positioned just inside the ventricle and flush with the annulus (Fig 2D). If device position was satisfactory, it was released. Otherwise, the device was retracted back into its cannula and the process was repeated. The time needed to perform each closure was recorded.

Subsequent to device delivery, cardioscopy was used to inspect device placement. Echocardiography was

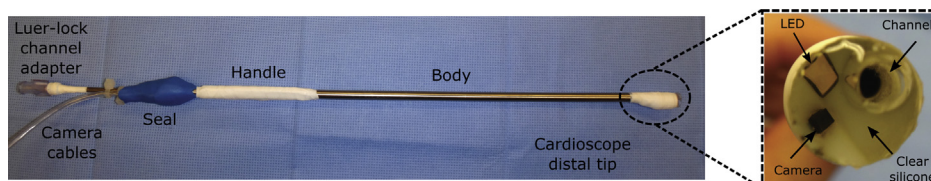


Fig 1. Cardioscope mounted on a handheld catheter for transapical access. (LED = light-emitting diode.)

also used to assess device placement and to evaluate reduction in PVL jet size. We note that blood flow through a properly delivered device can occur before endothelialization.

To investigate the potential for removal of a device after its release, we inserted 1.7-mm-diameter endoscopic forceps through the working channel in the last two experiments. After positioning the working channel over the screw connector of a deployed device, the connector was grasped with the forceps and the device was pulled out of the PVL. Because the diameter of the forceps precluded the use of the occluder delivery sheath, and to avoid damage to the silicone optical window, the occluder was not withdrawn inside the window. Instead, to remove the device from the heart, the cardioscope was withdrawn through the apical purse string sutures. At the conclusion of each experiment, a euthanasia solution was administered to the animal, and the heart was recovered for postoperative evaluation.

Preclinical Experience

After a series of preliminary experiments to refine the PVL model and delivery protocol [7], the technique described here was performed in a series of animal experiments ($n = 3$). In each experiment, three PVLs were successfully created at the aortic annulus (Fig 2B), as validated using epicardial echocardiography (Figs 3A–C).

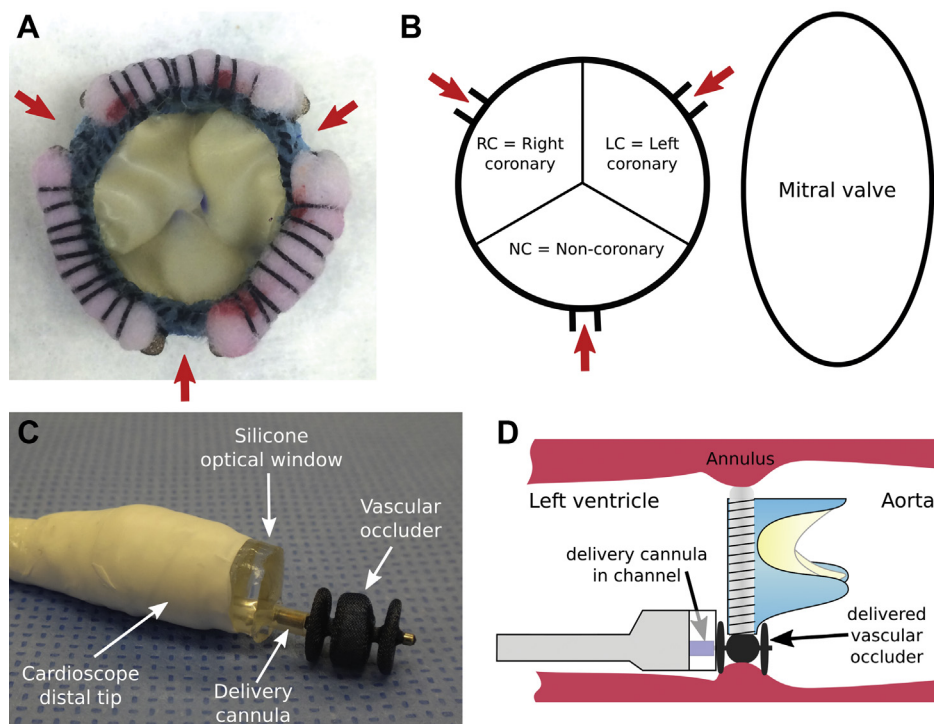
Navigation of the cardioscope tip from the apex to the aortic annulus using only cardioscopic guidance was

performed on initial entry into the heart and, subsequently, for each PVL closure (Fig 4, Video). Navigation around the entire annulus while maintaining cardioscopic visualization for inspection of the three PVLs was intuitive to perform (Video) requiring 54 ± 22 s ($n = 3$). PVLs were localized cardioscopically by identifying diastolic regurgitant blood flow external to the rim of the valve (Fig 4B).

In total, 11 of 13 occluders (84.6%) were successfully deployed and released in PVLs under cardioscopic guidance (Fig 4, Video), (2 of 4 in noncoronary, 4 in right coronary, 5 in left coronary sinuses). The average time to navigate from the apex to the targeted PVL and deliver an occluder was $3:03 \pm 1:34$ min ($n = 13$). In one unsuccessful case, the device was positioned in the PVL, but not released because it was cardioscopically observed to be undersized and shifting in position over the cardiac cycle. In the other case, the remaining native leaflet tissue was covering the PVL channel and acting as a one-way valve. While regurgitant blood flow could be observed to be emerging from the edge of the leaflet tissue, it was not possible to insert the delivery sheath safely through the leaflet tissue. Of the 11 successfully deployed occluders, in 2 cases (18%), the devices were undersized and were found to have dislodged and been lost later in the procedure during cardioscopic and echocardiographic assessment.

Recovery of released occluders from PVLs was performed successfully in 3 of 6 attempts (2 of 4 from left coronary, 1 of 2 from right coronary sinus [50%]; Fig 5;

Fig 2. Paravalvular leak (PVL) model and device deployment. (A) Bioprosthetic valve incorporating three PVLs. (B) Schematic showing PVL locations as viewed from ventricle. (C) Three-lobed occluder (Amplatzer AVP II) shown extended from delivery cannula as deployed from the cardioscope. (D) Delivery process.



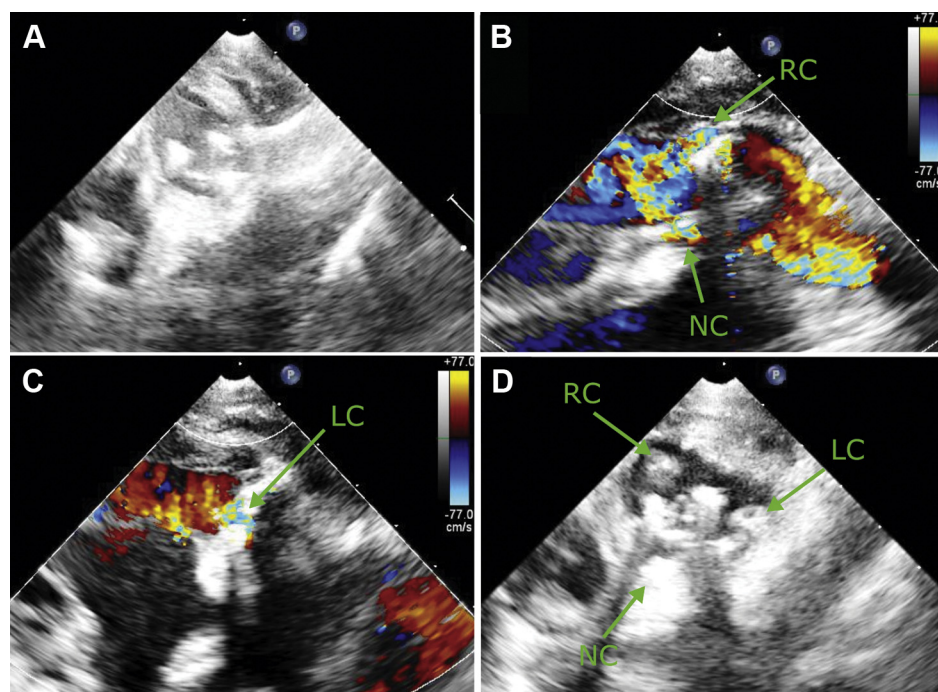
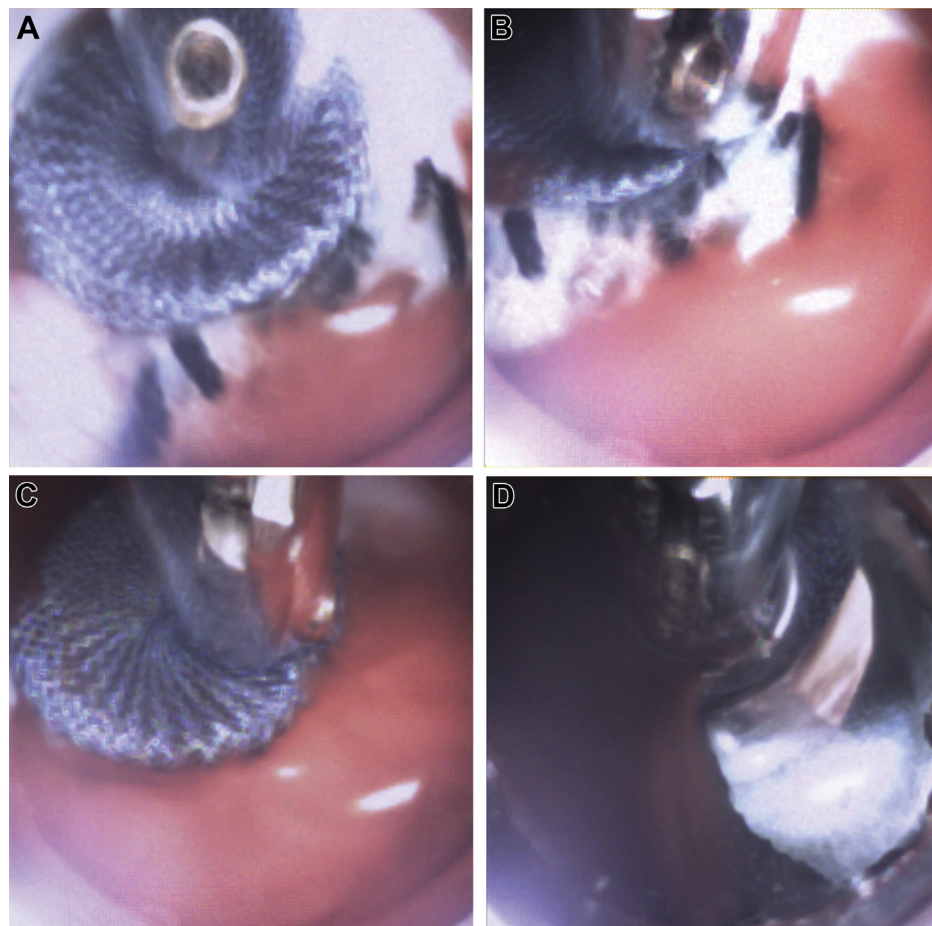


Fig 3. Epicardial echocardiography of paravalvular leaks (PVLs). (A) Short-axis view of implanted valve. (B) Long-axis echo color Doppler showing regurgitant jet in right coronary (RC) and noncoronary (NC) sinuses. (C) Long-axis echo color Doppler showing regurgitant jet in the left coronary (LC) sinus. (D) Short-axis view after delivery of closure devices in three PVLs.



Fig 4. Cardioscopic images during paravalvular leak (PVL) closure. (A) View in blood. (B) Localizing PVL by visualization of regurgitation. Inset: Imaged region of valve. Blue fabric appears white in cardioscopic image because of lighting. (C) Device deployment. (D) Device inspection.

Fig 5. Cardioscopic images during device recovery. (A) Positioning device screw connector inside working channel. (B) Forceps grasping screw connector. (C) Device pulled from paravalvular leak. (D) Device removed through apex.



Video). The time to navigate from the apex to the device and to retrieve it from the heart was $3:41 \pm 1:46$ min. In the unsuccessful cases, one device dislodged into the aorta, and a second device slipped from the forceps as it was pulled through the apical purse-string sutures. The third device was pushed deeper into the channel during attempted grasping such that it could not be grasped. Finally, during postmortem assessment, no significant damage to either the annulus or the septum was observed (Fig 6).

Comment

Cardioscopy is a promising imaging modality for beating-heart interventions. In the context of PVL closure, it provided excellent tissue and bioprosthetic valve visualization. PVLs were easily localized by direct imaging of the regurgitant flow, and the integrated working channel enabled device delivery under continuous direct visualization. With PVL closure times just longer than 3 minutes, the approach compares favorably with published reports for which fluoroscopy times alone are 29.9 ± 24.5 min [8]. Although cardioscopy was used exclusively here for device deployment, we anticipate that clinically,

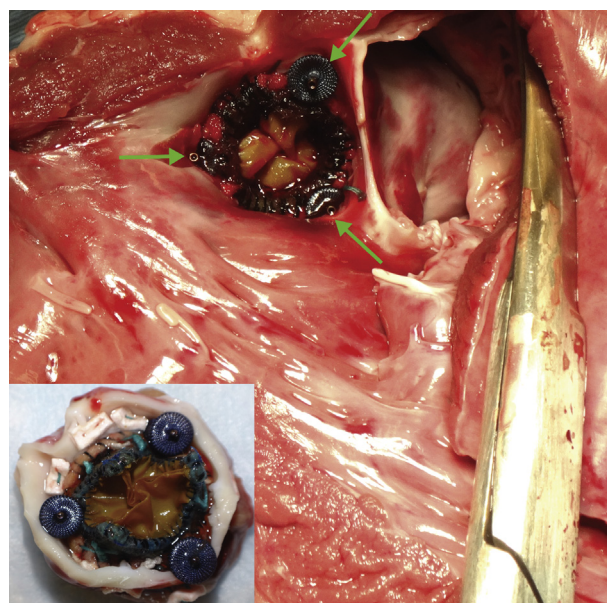


Fig 6. Postoperative assessment of device placement (arrows) viewed from ventricle (anterior mitral leaflet resected). Inset: aortic view.

additional imaging modalities would be needed, but that their need would be reduced.

The demonstration of cardioscopic technology on a straight, transapically introduced instrument was designed to simplify testing. The scalable design can be adapted for transfemoral access, which is often preferred for PVL closure [1, 2]. Furthermore, the direct visualization during occluder delivery provided by cardioscopy may be equally applicable to the deployment of many valve replacement and repair devices.

Study limitations included some variability in our PVL model such that a few PVLs were larger than the devices we had on hand. This led to two instances of device dislodgement, which could be prevented through placement of larger devices. In addition, the technique of forceps-based device retrieval was intended to illustrate the potential for cardioscopically guided retrieval, but would require modification for clinical applicability.

Disclosures and Freedom of Investigation

This work was supported by the National Institutes of Health under grant R01HL124020. The authors had freedom of investigation and full control of study design, methods used, outcome parameters and results, data analysis, and production of the written report. Animal experiments were conducted under a protocol approved by the institutions animal care and utilization committee of Boston Children's Hospital.

References

1. Nietlisbach F, Maisano F, Sorajja P, Leon MB, Rihal C, Feldman T. Percutaneous paravalvular leak closure: chasing the chameleon. *Eur Heart J* 2016;37:3495–502.
2. Sharma S, Kliger C, Jelnin V, Ruiz C. Paravalvular leak closure: the apical approach. *Cardiac Int Today* 2014;March/April:48–52.
3. Uchida Y. Recent advances in percutaneous cardioscopy. *Curr Cardiovasc Imaging Rep* 2011;4:317–27.
4. Vasilyev NV, Martinez JF, Freudenthal FP, Suematsu Y, Marx G, del Nido PJ. Three-dimensional echo and videocardioscopy-guided atrial septal defect closure. *Ann Thorac Surg* 2006;4:1322–6.
5. Padala M, Jimenez JH, Yoganathan AP, Chin A, Thourani VH. Transapical beating heart cardioscopy technique for off-pump visualization of heart valves. *J Thorac Cardiovasc Surg* 2012;144:231–4.
6. Rosa B, Machaidze Z, Shin B, et al. A low cost bioprosthetic semilunar valve for research, disease modeling and surgical training applications. *Interact Cardiovasc Thorac Surg*. In press.
7. Machaidze Z, Rosa B, Mencattelli M, et al. TCT-246 cardioscopy-guided repair of aortic paravalvular leak in porcine beating heart model. *J Am Coll Cardiol* 2016;68:B100.
8. Ruiz C, Jelnin V, Kronzon I, et al. Clinical outcomes in patients undergoing percutaneous closure of periprosthetic paravalvular leaks. *J Am Coll Cardiol* 2011;58:2210–7.

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