

First-in-human case of repeat pulmonary vein isolation by targeting visual interlesion gaps using the direct endoscopic ablation catheter after single ring pulmonary vein isolation



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Introduction

Gaps between radiofrequency (RF) ablation lesions are the culprits for failed pulmonary vein isolation (PVI) leading to recurrent atrial arrhythmias. The ability to directly visualize in real time and eliminate interlesion gaps may improve the success of RF ablation by achieving contiguous linear ablation lesion sets. We aimed to describe to the best of our knowledge the first reported clinical case using the direct endocardial visualization (DEV) ablation catheter (Voyage Medical Inc., Redwood City, CA) to successfully reisolate pulmonary veins (PVs) by visually targeting interlesion gaps under direct endoscopic visualization during a clinical trial undertaken at our institution.

The DEV catheter uniquely delivers RF energy using the virtual electrode.¹ The virtual electrode can be conceptualized as the intervening saline column within the hood aperture in contact with the endocardial surface, thus preserving visualization of the target endocardium during ablation. The fiberoptic camera is located at the distal hood to visualize the endocardial surface as blood is purged away by the saline irrigation to create an unobstructed field of view (FOV).¹

Case report

A 60-year-old man with recurrent drug-refractory symptomatic paroxysmal atrial fibrillation (AF) was referred for

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ABBREVIATIONS AF = atrial fibrillation; DEV = direct endocardial visualization; EAM = electroanatomic; EGM = electrogram; FOV = field of view; IR = infrared; LSPV = left superior pulmonary vein; NFUS = near-field ultrasound; PV = pulmonary vein; RF = radiofrequency; VGLA = visually guided laser ablation (Heart Rhythm Case Reports 2015;1:279–284)

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repeat PVI. His debilitating symptoms had returned despite multiple electrical cardioversions and pharmacologic therapies necessitating a repeat ablation. He had a mildly dilated left atrium (LA) and normal left ventricular systolic function. An initially successful single-ring PVI ablation had been performed 6 months earlier using a conventional irrigated-tip catheter.²

Ablation procedural details

An 8.5Fr medium-curve Agilis sheath and 8.5Fr SL1 guiding sheath were used to perform double transeptal punctures using a Brockenbrough needle. The Agilis was upgraded to a 14Fr sheath to accommodate the DEV catheter. The 3-dimensional electroanatomic (EAM) geometry was created using NavX (St. Jude Medical Inc., St. Paul, MN) and Lasso catheters at baseline in order to subsequently validate the map created by the direct visualization catheter. Activation mapping was performed using the 4 metal plate contact electrodes configured to provide 4 pairs of contact bipolar electrograms (EGMs) across the distal hood face apposed to the endocardial surface. [Online Supplemental Movie 1](#) is a fluoroscopic recording in the right anterior oblique view of the circular mapping catheter (Halo, Biosense Webster Inc., Diamond Bar, CA) positioned in the left superior pulmonary vein (LSPV) and the DEV catheter positioned close to the ostium of the LSPV. A 5-mm decapolar catheter was positioned in the coronary sinus. A temperature probe was used to monitor esophageal temperature during ablation.

PVI using the DEV ablation catheter integrated with 3-dimensional EAM and bipolar EGMs

Figure 1 shows the FOV through the DEV catheter (2.8-mm central hood aperture and 6.8-mm diameter) to enable visual mapping of the anatomic gap. An activation map of the LA created using the contact bipolar EGMs of the DEV catheter revealed earliest competing activation on the mid-posterior LA wall.

KEY TEACHING POINTS

- Direct Endoscopic Ablation Catheter utilized a fiberoptic camera at the distal hood to visualize endocardial surface as blood is purged away by the saline irrigation to create an unobstructed field of view (FOV).
- Real-time full-color direct endocardial visualization of partially or non-ablated inter-lesion gaps associated with contact bipolar EGM signals of surviving myocardium was clinically feasible. Electrically reconnected gaps were visually and electrically mapped.
- Electrically reconnected visual gaps were successfully ablated by delivering radiofrequency energy using the virtual electrode under visual guidance that resulted in electrical re-isolation of the pulmonary veins and posterior left atrium following prior single ring pulmonary vein isolation procedure.

Visual mapping of the anatomic gap correlated with earliest electrical conduction into the single ring.

The activation map showed the earliest competing activation represented by the white strip was located on the mid-posterior LA wall. This was targeted first and ablated under visual guidance. After abolition of the visual gap, the next earliest breakthrough was localized to the anterior aspect of the left PV/left atrial appendage (LAA) ridge. The fractionated PV potentials recorded by the hood-face electrodes at the ridge suggested a region of electrically reconnected tissue (Figure 2A). EGMs recorded in this region correlated with the visually pink gap of residual viable endocardium as seen through the FOV (see Online Supplemental Movie 2). This was characteristic for an electrically reconnected anatomic gap on the old ablation line flanked by regions of old electrically inert ablated scar. Chronically ablated scar appeared as white endocardial tissue through the FOV over the left PV ridge (Figure 2B).

Abolition of visual gap by RF ablation delivered via the virtual electrode successfully electrically reisolated both sets of PVs

RF ablation lesions were delivered via the virtual electrode of the DEV ablation catheter targeting the visual anatomic gap with the earliest fractionated EGM signals. A Stockert RF generator (Biosense Webster) was used to deliver RF power titrated from 7 W up to 15 W for durations of 20 to 40 seconds. A saline irrigation rate of 10–15 mL/min was used during visual mapping, and a higher irrigation rate of 25 mL/min was delivered during ablations using the CoolFlow pump (Biosense Webster).

Figure 2 highlights the real-time correlations between (1) direct full-color endoscopic visualization of the pink inter-lesion gap between ablated tissue; (2) bipolar EGMs

recorded at the gap indicative of electrical conduction and tissue viability; and (3) ablation lesions delivered by the DEV catheter localized on the NavX EAM map. When interpreted in conjunction, these images were helpful in the guidance and delivery of RF energy at the targeted gap to successfully electrically re-isolate the PVs as well as the posterior LA wall.

Confirmation of PVI with dissociated signals and differential pacing in the LAA confirming far-field appendage signals

Figure 3A shows the absence of EGM from the DEV catheter positioned within the LSPV, confirming successful re-isolation. The acutely blanch whitish appearance of the ablated gap at this location after electrical re-isolation as seen through the FOV is represented (Figure 3A). The patient reverted to normal sinus rhythm during ablation at the LSPV/LAA ridge. At 12-month follow-up, the patient remained asymptomatic and had documented arrhythmia-free 7-day Holter monitoring.

Discussion

Voyage IRIS DEV ablation catheter

Voyage Medical Inc was a startup company founded in late 2006. It received 3 rounds of venture funding through 2012. The initial funding was in support of a system developed to guide transseptal puncture under direct visualization.³ This

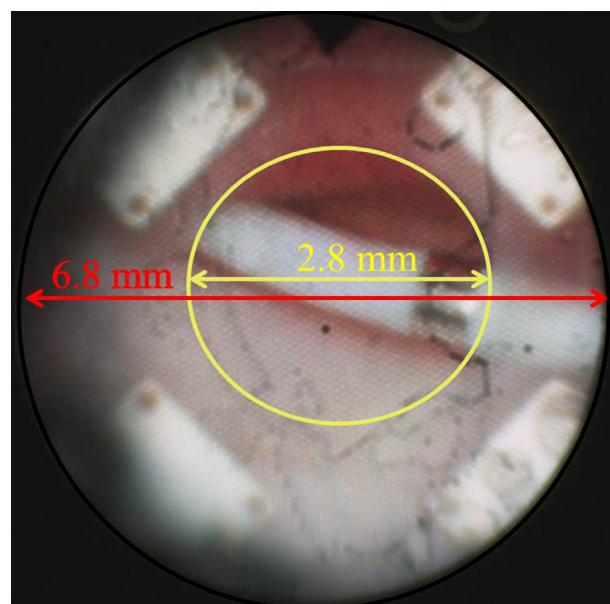


Figure 1 Field of view (FOV) through the direct endocardial visualization catheter measuring 2.8 mm across the central hood aperture and 6.8-mm-diameter hood face. The FOV facilitates visual mapping for the anatomic gap of electrical reconnection embedded in the region of earliest activation. Local endocardial tissue electrogram (EGM) signals were recorded by 4 metal-plate contact electrodes situated on the hood face. The electrodes were configured by an EP recording system (Prucka) to provide 4 pairs of contact bipolar EGMs across the hood face and displayed on the EP recording system (Prucka). A Lasso electrode is seen in contact with the left superior pulmonary vein tissue in the FOV.

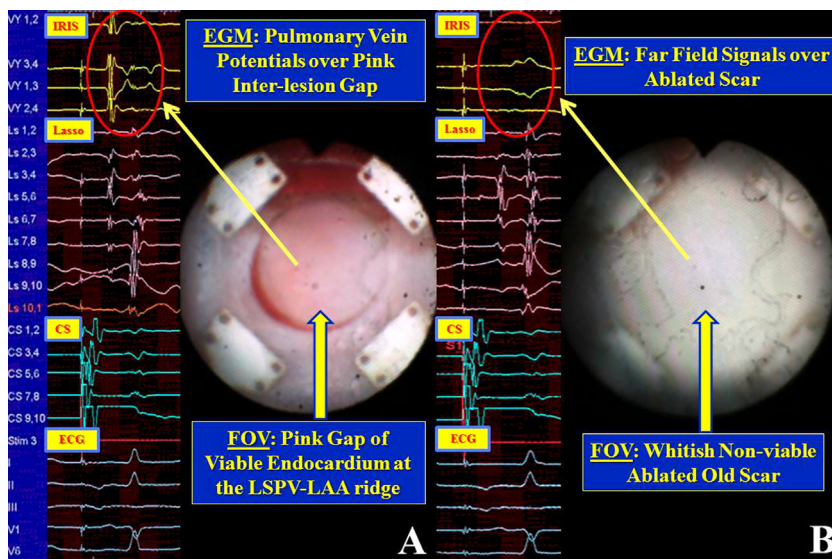


Figure 2 A: Electrogram (EGM) captured by direct endocardial visualization DEV hood-face electrodes at the anterior left superior pulmonary vein (LSPV)/ left atrial appendage (LAA) ridge. Pulmonary vein potentials were recorded over pink viable endocardium at the site of the interlesion gap (between regions of partially blanched tissue). B: Chronically ablated scar during visual mapping adjacent to the ridge. The electrode bipolar EGM shows attenuated amplitude signals corresponding to fully blanched whitish endocardial tissue as seen through the field of view (FOV). CS = coronary sinus.

was followed by the completion of a 10-patient feasibility study for cavotricuspid isthmus flutter ablation by Dr. Petr Neuzil and Dr. Vivek Reddy at Na Homolka Hospital, Czech Republic, in 2008.⁴

The company subsequently enrolled approximately 50 patients in clinical feasibility trials between 2009 and 2012 for ablation of cavotricuspid isthmus flutter and paroxysmal AF. The patients were enrolled and treated in Bordeaux, France, the Czech Republic, and Westmead Hospital in Sydney, Australia. The company was in the process of

implementing an improved CMOS image sensor, but when financing became an overwhelming challenge the company ceased operations in early 2013.

Advantages of DEV

It was clinically feasible to identify partially or nonablated interlesion gaps associated with EGMs of surviving myocardium. An important consideration was that direct visualization provided real-time assessment of tissue contact, which was superior to relying on indirect modalities

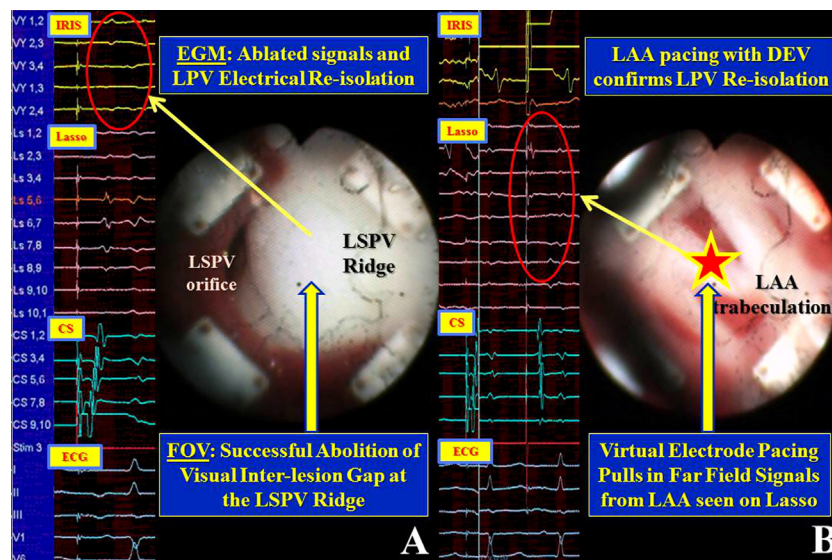


Figure 3 A: Electrograms (EGMs) consistent with electrical reisolation of the left-sided pulmonary veins after successful abolition of visual interlesion gaps at the left superior pulmonary vein (LSPV) ridge. The region was ablated using the virtual electrode of the direct endocardial visualization (DEV) catheter, and the previously pink appearance of the gap is replaced by blanched whitish color ablated myocardium seen on the field of view (FOV) after successful pulmonary vein reisolation. B: Endocardial trabeculae appearance of the left atrial appendage (LAA) as seen through the FOV. Differential pacing was performed using the virtual electrode while the DEV catheter was positioned in the LAA. Upon pacing through the saline bridge of the virtual electrode, the far-field signals on the Lasso were seen to be pulled in from the LAA.

including tactile sensations, fluoroscopy, and EAM maps. Furthermore, contact bipolar EGM signals provided additional useful local tissue electrophysiologic information in terms of amplitude and timing when the hood face (electrode) attained good apposition with the endocardial interface. Evaluation of local EGM amplitude, morphology, and timing were valuable aids during mapping and ablation to optimize lesion creation at the target anatomic site. During our limited experience, we determined that the ability to observe real-time blanching was advantageous because one could ensure that visually contiguous lesions had been created before proceeding to the next linear ablation. Termination of RF delivery was possible upon observing evidence of overheating, which included the formation of visualized steam bubbles at the electrode–tissue interface and thrombus formation as seen through the FOV, which were used as visual cues to terminate RF ablation.

Other direct visualization ablation technologies

Two visualization catheters have been previously described: the laser endoscopic ablation system (CardioFocus Inc., Marlborough, MA) and the fiberoptic infrared (IR) endoscope system (CardioOptics Inc., Boulder, CO).

The CardioOptics system uses a steerable fiberoptic IR endoscope on a 7Fr flexible catheter that is percutaneously deployed to visualize through flowing blood. The IR endoscope (2900-fiber imaging bundle, wavelength 1620 nm, frame rate 10–30 per second, 320 × 256 pixels) was advanced to the coronary sinus ostium and branches by direct visualization of anatomic landmarks by Nazarian et al⁵ in a closed-chest canine model. Knight et al⁶ successfully deployed the IR endoscopic catheter to directly visualize the electrode–endocardial interface during RF ablation and characterized ablation lesion formation. However, clinical endocardial visualization using IR wavelengths has the disadvantage of losing color fidelity and limited penetrance.

A balloon-tipped fiberoptic endoscope was initially used to visualize the ostium of the coronary sinus and RF lesion formation.⁷ The latex balloon covering the distal tip provided a visual field of 15–20 mm in diameter when the balloon was inflated to a volume of 7–10 mL. Use of the fiberoptic direct visualization catheter for guiding endocardial RF lesion placement, estimating lesion size, and identifying interlesion gaps was subsequently described by Eversull et al⁸ in an ovine model.

CardioFocus is the latest generation of novel laser balloon ablation systems developed for performing PVI for the treatment of AF. This visually guided laser ablation (VGLA) catheter is a compliant, nonsteerable, variable-diameter balloon that delivers laser energy around the PV ostium under real-time endoscopic visualization. A fluid-filled balloon is cooled with continuous circulating saline that clears the blood in front of the catheter to create a bloodless balloon–tissue interface for ablation. FOV is obtained through a 500- μ m diameter 2Fr fiberoptic endoscope positioned proximal to the balloon. Endoscopic real-time visualization permits assessment of tissue blanching and

optimization of deployed balloon placement at the target PV antrum as efficacy of laser balloon ablation is dependent on good contact around the balloon circumference.^{9,10} An arc generator guided by endoscopic visualization emits a green targeting laser beam projected in arcs of approximately 30° onto the balloon–tissue contact. A diode laser delivers 980-nm laser energy to create point-by-point lesions at the target site using 5.5–18 W for 20–30 seconds depending on tissue depth and proximity to the esophagus.¹¹

Dukkipati et al¹² reported VGLA resulted in a high rate of durable PVI with a similar clinical efficacy to that of RF ablation in a multicenter, multioperator clinical study. More recently, the results of the first 200-patient multicenter clinical experience using VGLA for PVI in paroxysmal AF patients involving 33 operators across 15 centers showed 98.8% of targeted PVs were isolated.¹³ There were no complications involving stroke/transient ischemic attack, atrio-esophageal fistulas, or significant PV stenosis. Cardiac tamponade was reported in 2% and phrenic nerve palsy in 2.5%. Importantly, 60.2% (95% confidence interval 52.7%–67.4%) were free from atrial arrhythmias after 1 or 2 procedures off medications, suggesting the VGLA catheter has a efficacy and safety profile similar to that of RF ablation for PVI.¹³ However, as with any new technology, there is an operator learning curve. A limitation of the VGLA catheter is its limited ability to assess lesion depth and determine whether a transmural lesion has been created.

Challenges and limitations with direct visualization systems

DEV using a catheter has been introduced with a variety of different technologies. The critical difficulty with endocardial visualization is the presence of blood obscuring the endocardium. This difficulty has been addressed by either imaging using IR wavelengths that penetrate through blood for short distances or evacuating blood from the FOV using a balloon or continuous saline irrigation.

Endocardial visualization using IR wavelengths has the disadvantage of losing color fidelity, but balloon and saline irrigation techniques preserve full-color visualization of the endocardial surface. In the case of the DEV ablation catheter, RF energy delivery using a standard metal contact electrode would directly obstruct the FOV. This led to the concept of using a virtual electrode for RF energy delivery via a saline bridge to the target tissue and simultaneously preserving the FOV during ablation.¹ Unfortunately, 1 of the key limitations for the DEV catheter is the technical difficulties in fixing the hood orthogonal to the tissue surface. This is essential to achieving a good seal between the open hood aperture and the target–tissue interface in order to exclude blood from the FOV, thus preserving RF energy within the virtual electrode and maintaining visualization of the target tissue. Adequate hood aperture–tissue apposition may not be possible at uneven anatomic sites such as trabeculated atrial/ventricular tissue, the LAA ridge, and the orifice of PVs.

FOV is relatively limited despite a 6.8-mm-diameter hood face (Figure 1). Therefore, assessment of the catheter's

overall position within a cardiac chamber is difficult, often requiring concurrent fluoroscopic and EAM imaging guidance. The need to maintain an unobstructed FOV during mapping and ablation has the potential for extra saline volume loading, which may be a contraindication for patients with unstable heart failure, and may necessitate empiric urinary catheterization. In addition, the larger 14Fr diameter sheath may increase the risk for local vascular injury at the site of percutaneous access. Finally, the presence of visual blanching on the endocardial surface did not necessarily imply a transmural lesion; hence, electrical signals were beneficial to rectify the efficacy and adequacy of ablations.

Future technologies to overcome the limitations of direct visualization systems

The ultimate goal is to improve the long-term success of RF ablation and reduce the need for repeat procedures by delivering better lesions that are durable, transmural, and contiguous. However, delivery of more energy to create deeper and more efficacious lesions must be performed without compromising the safety of the procedure. Progress certainly has been made with the refinement of ablation techniques and ongoing development of technologies aimed at achieving better tissue contact during ablation, namely, the use of a long steerable sheath, high-frequency jet ventilation to reduce the negative effects of respiration on catheter stability,^{14,15} and, more recently, real-time contact force catheters integrated with 3-dimensional EAM mapping.^{16–18}

Intracardiac echocardiography monitors lesion formation by detecting increased tissue echogenicity associated with lesion edema on ultrasound images. A recent novel technologic development is the near-field ultrasound (NFUS) ablation catheter, which uses 4 ultrasound transducers at the catheter tip with an 8Fr open-irrigated conventional RF ablation catheter. The NFUS ablation catheter obviates the need for extruding blood from the FOV and may potentially overcome numerous limitation attributed to the visualization catheter by virtue of its ability to assess catheter–tissue contact, determine target tissue thickness, and assess the depth of real-time RF lesion formation. Wright et al¹⁹ demonstrated the practical utility of NFUS imaging to assess lesion size and transmural, as well as visualization of intramyocardial gas formation before steam pop occurrence to improve ablation safety.²⁰

Contact force sensing ablation catheter technologies, such as TactiCath (Biotronik Inc., Berlin, Germany) and Smart-Touch (Biosense Webster), have the potential to obviate the need for visualization to assess tissue contact pressure. Optimal contact force (20–40g) at the electrode–tissue interface can be predictably applied independent of catheter orientation and without the need for direct visual confirmation.^{18,21–25} Furthermore, the integration of imaging technologies, including real-time magnetic resonance imaging and computed tomographic guidance, with contact force sensing catheters may facilitate targeting of interlesion gaps and achieve durable ablation lesion sets. Future advances in real-time imaging visualization of ablation lesions on both

computed tomography^{26,27} and magnetic resonance imaging^{28,29} may be the new paradigm that has the potential to overcome most of the difficulties associated with direct visualization ablation catheters for effective and safe ablations. It is hoped that future technologies will allow the proceduralist to directly visualize lesion formation as energy is being delivered with an imaging modality that possesses high spatial and temporal resolution to readily assess the adequacy of lesion depth, ensures that transmural is achieved with optimal contact force, and accurately targets and then ablates interlesion gaps to create contiguous lesion sets.

In conclusion, interlesion electrically reconnected gaps were visually and electrically mapped under real-time, full-color endocardial visualization. Successful ablation of visual gaps using the virtual electrode under visual guidance resulted in electrical reisolation of the PVs and posterior LA after prior single-ring PVI for paroxysmal AF.

Appendix Supplementary Data

Supplementary data associated with this article can be found in the online version at <http://dx.doi.org/10.1016/j.hrcre.2014.12.009>.

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