

Clinical Trial Update:

Interview with Shephal K. Doshi, MD

Interview by Jodie Elrod



Dr. Shephal Doshi is the Director of Cardiac Electrophysiology and Pacing at Saint Johns Health Center and Director of Cardiac Electrophysiology Research at Pacific Heart Institute in Santa Monica, California. In this interview, he provides information about the ENABLE, PROTECT AF, and POWER trials.

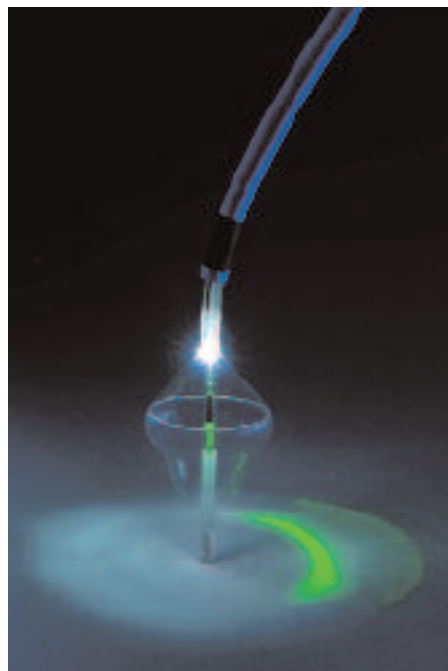


Figure 1. Inside the CardioFocus Ablation Catheter resides a miniature endoscope and a moveable fiber that selectively emits both a 90-degree targeting beam and a matched arc of 980nm light energy. These elements allow the clinician to evaluate and vary the location of energy delivery based on a real-time, full-color view of the pulmonary vein ostium (Image is the property of and was provided by CardioFocus Inc.)

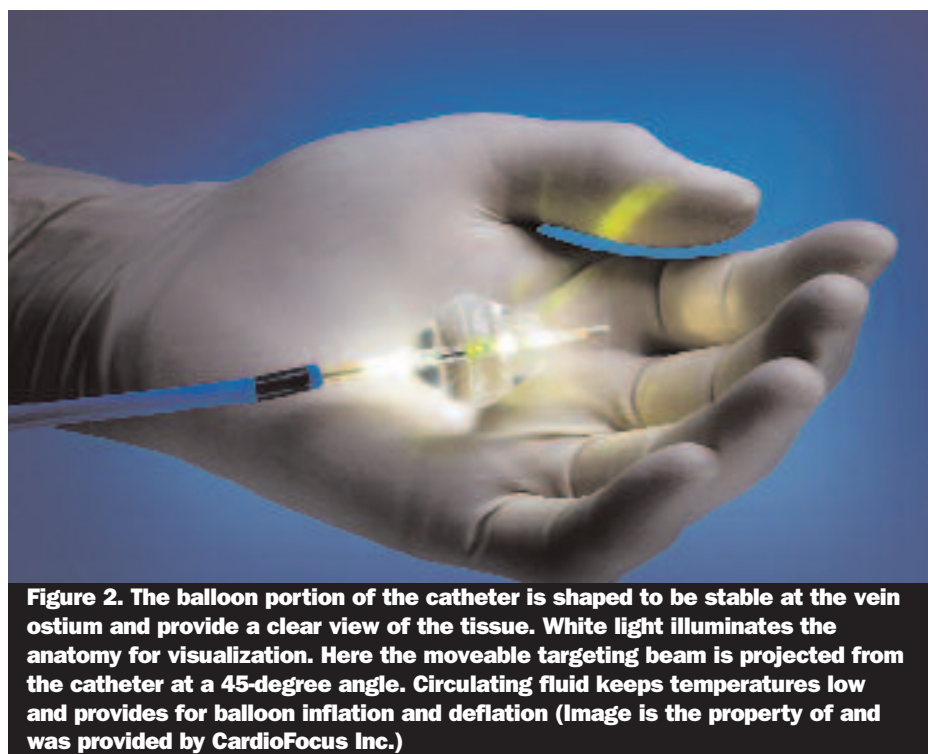


Figure 2. The balloon portion of the catheter is shaped to be stable at the vein ostium and provide a clear view of the tissue. White light illuminates the anatomy for visualization. Here the moveable targeting beam is projected from the catheter at a 45-degree angle. Circulating fluid keeps temperatures low and provides for balloon inflation and deflation (Image is the property of and was provided by CardioFocus Inc.)

Describe the ENABLE trial. What is the purpose of the trial?

The ENABLE (ENdoscopic Ablation using Light Energy) trial is a prospective, randomized, pivotal, multicenter, IDE clinical trial using an investigational endoscopically-guided laser balloon catheter (CardioFocus, Inc.) for the treatment of atrial fibrillation (AF). The study objective is to demonstrate the safety and effectiveness of this visually-guided endoscopic ablation system (EAS) in participants presenting with recurrent, paroxysmal, symptomatic AF by creating electrical isolation of the pulmonary veins (PVI).

Currently there are no catheters approved in the United States for the ablation of AF. This trial is designed to assess the efficacy and safety of this new technology, as well as measure freedom of documented atrial fibrillation symptoms for 1 year post treatment.

What are the start and end dates? When did enrollment begin? How many patients do you expect to treat?

The study has already begun enrollment. We enrolled and performed the first visually-guided laser balloon ablation for AF in the United States in mid March of this year. There will be up to 20 study sites. Approximately 180 patients will be randomized to laser balloon ablation versus antiarrhythmic drug therapy (AAD). Patients who develop AF on AAD therapy can cross over to EAS ablation. Again, the primary effectiveness endpoint is freedom of documented atrial fibrillation symptoms for 1 year post treatment.

Describe endoscopic catheter ablation with the use of the investigational video camera.

As real-time intracardiac imaging for ablation has been clinically limited to ultrasound technology, we have had to rely on image integration with CT scan/MRI/fluoroscopy and 3D mapping tools to “visualize” the areas where we ablate.

However, in this study we are investigating the use of a ~500 micron (~2 French) diameter endoscopic camera with a wide field of view. It provides a direct view into the left atrium on the front, side and part of the back of the balloon. Balloon contact with the tissue can then be observed. Using these “live” images, we can adjust the actual location of the projected energy, essentially “aiming the laser.”

In this study, the EAS catheter is seated and inflated at the ostium of the PV. An “aiming” beam is displayed onto the surface, and using the endoscope, is adjusted to desired locations. The laser is then discharged over this surface, creating “arcs” of ablation. The laser energy for the system is delivered through a diode laser system. PVI is documented in all veins at 30 minutes post ablation.

Describe the first case treated at your institution. How long did the case take?

The first case was a man in his late 50s who had been experiencing symptomatic arrhythmia for over a year. He was diagnosed with paroxysmal atrial fibrillation. He had tried and failed antiarrhythmic drugs, and continued to be very symptomatic, having a few episodes a day that lasted several minutes at a time to hours.

His symptoms were primarily palpitations, fatigue, difficulty sleeping, and occasional lightheadedness. Previously he had been a very active man, but was now having breakthrough arrhythmias on three medications. He was also on anticoagulation with warfarin. All these things significantly affected his quality of life. Therefore, he was looking for a more curative approach to treating his atrial fibrillation.

We discussed with him the different options of catheter ablation and the risks associated with it, including but not limited to: stroke, pulmonary vein stenosis, and injury to the esophagus. He had done his own research and was also concerned about the risks associated with RF “spot” ablation catheters, including thrombus formation and inconsistent lesion formation.

We discussed with him an alternative approach, specifically the ENABLE trial with the use of an endoscopically-guided laser balloon, with direct visualization of the surface to have laser ablation. The patient was very interested and enrolled in the study. He was randomized to the treatment (laser ablation) arm.

The procedure, from the point when we started to laser to when we finished, including a 30-minute waiting period to document persistent PVI, took a little over three hours.

Who can participate in this trial?

The ENABLE trial is geared for patients between the ages of 18 and 65. It is designed for symptomatic paroxysmal to recently persistent AF patients. Specifically, we are looking for patients who have “trigger”-based atrial fibrillation. Most experts agree that the majority of paroxysmal AF cases are related to triggers from the pulmonary veins. The focus of the ENABLE trial will be to study how PVI using this visually-guided endoscopic ablation system will affect this population of patients.

Patients with chronic or permanent AF are not being studied in the ENABLE trial, as their AF is thought to have a more significant role of substrate changes; it is unknown whether PVI can provide significant efficacy.

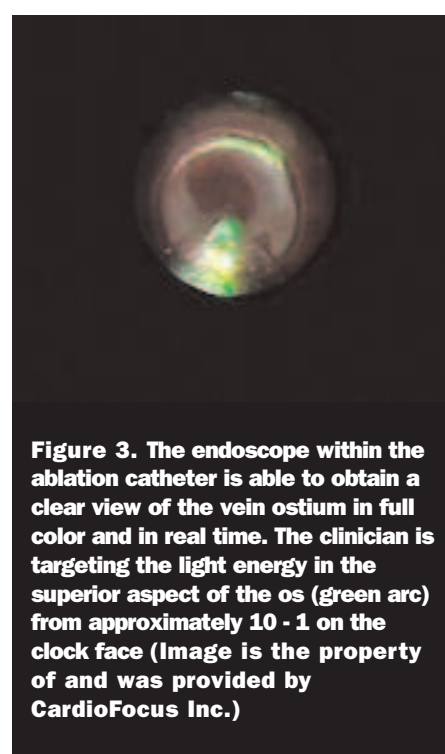


Figure 3. The endoscope within the ablation catheter is able to obtain a clear view of the vein ostium in full color and in real time. The clinician is targeting the light energy in the superior aspect of the os (green arc) from approximately 10 o'clock (Image is the property of and was provided by CardioFocus Inc.)