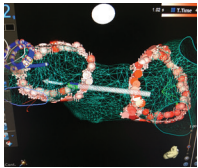
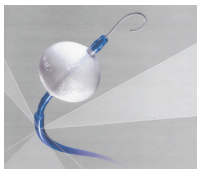


FLORIDA ELECTROPHYSIOLOGY ASSOCIATES®



**CRYOABLATION, RADIOFREQUENCY ABLATION, OR THE CONVERGENT
PROCEDURE: WHICH PROCEDURE FOR WHICH PATIENT?**

Robert S. Fishel, MD, FACC



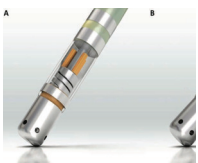
**CRYOBALLOON ABLATION FOR TREATMENT OF PAROXYSMAL ATRIAL
FIBRILLATION**

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**A NEW TOOL TO REDUCE MORTALITY FROM LEAD
EXTRACTION SVC TEARS**

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CONTACT FORCE SENSING TECHNOLOGY

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LEFT ATRIAL APPENDAGE OCCLUSION

Matthew J. Kolek, MD, MSc

We are Florida's largest physician practice of Cardiac Electrophysiologists.

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CRYOABLATION, RADIOFREQUENCY ABLATION, OR THE CONVERGENT PROCEDURE: WHICH PROCEDURE FOR WHICH PATIENT?



Robert S. Fishel, MD, FACC

A patient comes to see you with PAF. She is a 73 year old female with monthly episodes of PAF. The patient has a history of a previous radiofrequency ablation procedure for atrial fibrillation 8 years earlier. Prior to the previous ablation she had been having multiple daily episodes of A. fib. She has been completely A. fib free since then until a few months ago when PAF resumed this time on a once per month frequency. Medical therapy for her newly recurrent PAF has failed. What is the best approach today?

- A. Cryoablation of atrial fibrillation**
- B. Repeat Radiofrequency ablation of atrial fibrillation**
- C. The Hybrid or “convergent” procedure**

Don't know the answer? You're not alone. However, one thing's for sure; with atrial fibrillation, one size does not fit all. Selecting the correct procedure for the correct patient will maximize your patients chance of success. So which procedure is best? To answer that, we need to understand a little about what each procedure really does to the patient.

Cryoablation (Cryo): Cryoablation utilizes a cryoballoon catheter which is inserted into the left atria via a 15fr steerable sheath. The balloon contains an internal refrigeration system in which liquid nitrous oxide is pumped into the balloon after it has been inserted and blown up in the ostia of a pulmonary vein. The balloon is double walled for safety. Cooling of the balloon results in an ice ball forming around the circumference of the balloon and also extending into the lumen of the occluded pulmonary vein. In this procedure each pulmonary vein is frozen over a period of several minutes typically resulting in isolation of the vein and destruction of most of the myocardium inside the vein, not just the rim of tissue at its ostia. As such, cryoballoon ablation is an excellent technique for pulmonary vein isolation in relatively young patients with paroxysmal atrial fibrillation and otherwise a structurally normal heart. Advantages of this technique are that results are repeatable between operators and there is a relatively short learning curve for performing this procedure. This procedure is thus often performed with relatively new ablation operators. Clinical data shows 69.9% of patients are free of PAF after a single cryoablation procedure (versus only 7.3% of drug treated patients)ⁱ. Newer balloon technology and better user experience has increased the success rate of a single cryoablation to over 80% with complication rates well under 5% at experienced centers.

Still, there are some issues with doing CRYO in every patient with A Fib. The sheath used in this procedure is 15 French resulting in a residual ASD or septal defect in 17% of patientsⁱⁱ. The ice ball formed during ablation here has the potential to damage collateral structures including the esophagus and the phrenic nerve. In the original Cryo trial, 11.2% of patients ablated suffered from post-ablation phrenic nerve palsyⁱ. Experienced operators (experience here counts) utilizing nerve protection techniques have a much much lower phrenic nerve palsy rate as well as a low overall complication rate

Moreover this technique only isolates the pulmonary veins and nothing more. As such it is unlikely to result in success in patients who already have undergone pulmonary vein isolation. PAF in these patients is often times originating and/or being driven by secondary inductor/driver sites such as the LA posterior wall, the inferior apical LA, the SVC or the LA appendage. Cryoablation also is not indicated for, nor does it work particularly well for, persistent atrial fibrillation. In these patients, the left atria contains widespread drivers. Multiple additional blocks of myocardium (such as the LA posterior wall) need be isolated to achieve acceptable success rates in persistent A fib procedures. Patients with pulmonary vein anatomy variants (seen in about 25% of the population) are poor candidates for cryo as incomplete or impossible balloon apposition of the veins is often seen. Elderly patients, patients with dilated left atria above 4.5cm and patients with significant valvular heart disease also typically fare poorly with cryo. Finally, since about 1/3 of PAF patients also have right atrial flutter, additional catheters often need to be opened for a cryoablation resulting in little or no profit to the sponsoring hospital facility. Still for typical lone P.A.F. Patients, CRYO in

experienced hands can be an excellent initial ablation choice – and in some of these patients, it might be the ideal initial choice.

Radiofrequency Ablation (RF): Radiofrequency ablation of atrial fibrillation is the oldest and still the most skill intensive approach to ablating atrial fibrillation. Typically in this technique two 9fr transeptal sheaths are inserted into the LA. One sheath contains a circular mapping catheter and the other a steerable radiofrequency ablation catheter. A 3D reconstruction of the LA is made during this procedure that is entirely unique for that particular patients LA and pulmonary vein sets. Next a series of ablations are delivered to the antral regions of the pulmonary veins isolating all four veins, typically by making two large circles isolating each vein pair as a unit. If there is persistent A fib, or there are no substantial voltages in the pulmonary veins, the ablation can include additional structures such as the LA posterior wall, the right atrial flutter isthmus, the LA mitral flutter isthmus, the LA appendage, etc. With current techniques, there is zero risk of pulmonary vein stenosis (as they are never entered) and the esophagus is annotated with barium to help avoid ablating near it.

Originally approximately 40% of all radiofrequency ablations of PAF needed a repeat procedure either for recurrent PAF or atypical left atrial flutter (which occurred due to gaps in the ablation circles around the veins).

Repeat RF ablation procedures typically were the result of poor cooling of the tip of the ablation catheter (allowing blood to get hot instead of underlying tissue) and lack of stability and contact of the ablation catheter tip with the tissue being ablated. Fortunately, results are far different today due to improvements in catheter design including more efficient tissue-catheter interface cooling and force sensing.

Force sensing represents a major advance in safety and efficacy for RF ablation of atrial fibrillation. This technology works by incorporating a force sensor into the tip of the catheter. The operator gets a graphical force vector showing both the stability and force that the catheter tip has on the underlying tissue. With contact force-sensing technology and adequate force during ablation, 88% of patients who undergo radiofrequency ablation of PAF achieve cure at 1-year follow-upⁱⁱⁱ. The beauty of force sensing is this is a technology which both increases the success rate of the initial procedure and also lowers the complication rate; should excess catheter force occur, the operator gets a warning and can reverse direction prior to a patient complication occurring. The overall serious complication rate seen during A fib ablations at Florida Electrophysiology Associates is well under 1%. RF ablation can also be used for persistent atrial fibrillation procedures in which additional regions of the LA need be isolated, RF can also be used for secondary tachycardias seen during an atrial fibrillation ablation such as right atrial flutter or left atrial reentry. RF can be used in patients with dilated atria, in pulmonary vein variants and for ablation of persistent fibrillation. Thus although RF requires the most skill (and the most work!) in manipulating catheter, it remains a versatile technique which can be used for a wide variety of arrhythmias, in a wide variety of patients with excellent results for most patients with PAF and a low major complications rate.

A typical ablation procedure for PAF using radiofrequency takes about 2 hours and typically requires an overnight stay in the hospital. The procedure is done entirely via femoral venous access and the patients can typically return to work two days later.

The Convergent Procedure: I will state from the start that I am not a fan of this procedure and have a low opinion of it. Unfortunately, many patients who have had it performed would agree with this opinion. The “convergent procedure” describes one of several combined percutaneous and surgical ablation procedures for atrial fibrillation. This is also called a “hybrid procedure”.

One variant of the convergent procedure involves multiple ports placed in both sides of the thorax and mediastinum in which numerous instruments are inserted to destroy parts of the left atria from an external approach. Another variant involves a single thoracoscope placed via a sub-xiphoid approach whereby the LA posterior wall is ablated epicardially. The procedure is called “the convergent” procedure because an electrophysiologist is typically involved in some manner or other. Often times the EP will just perform a right atrial flutter ablation while the surgeon does the rest. In the thoracoscopic version of this procedure, the EP performs a pulmonary vein isolation with the surgeon isolating the LA posterior wall via the thoracoscope. Often times the electrophysiologist who participates in this exercise only knows how to ablate A fib with Cryo and does not have the skills required to perform a persistent atrial fibrillation ablation with RF. A typical patient referred for “the convergent procedure” would thus be a patient with persistent atrial fibrillation whom the electrophysiologist can’t fix with Cryo (cryo is not indicated for persistent atrial

fibrillation). During the procedure, the EP will isolate the pulmonary veins with Cryo and the surgeon will isolate the LA posterior wall (which is a major driver of persistent A fib.) with the thoracoscopic approach.

The net result of all of this is that the patient ends up with a significant amount of pain and morbidity (and occasional mortality) to derive the same lesion set that can be delivered by an operator skilled with conventional radiofrequency ablation in a few extra minutes of time.

There is currently no good data comparing this procedure to standard RF (or even to simple Cryo) in terms of its success, complication rate or patient satisfaction. Having redone several of these patients myself, I can tell you the patients I have encountered (admittedly a select group with continued issues) don't have anything good to say about the experience or the results. A systematic study of the limited data available on this approach shows a 59.3% success rate for the thoracoscopic convergent approach (the variant currently being widely touted by hospitals in the state of Florida) with an 8.6% death or major complication rate - hardly inspiring^{iv}.

Although this procedure is available at some academic institutions, most major academic medical centers have at this time not endorsed this approach. One thing this procedure does do well is increase reimbursement for the facility. This is billed by the hospital under an open heart surgery code set and the facility thus gets paid a whole lot more to do this than a conventional RF ablation procedure. This might explain why many non-academic for profit hospitals are expending significant resources marketing this procedure on-line. Not the reason to refer a patient.

So back to the initial question as to which procedure is right to choose for our patient who now has recurrent PAF years after a successful RF ablation and pulmonary vein isolation. **The correct answer would be B: a repeat RF ablation.** The patient already had her four pulmonary veins isolated years earlier and had an excellent result from that procedure with elimination of her multiple daily episodes of PAF (indicating that the pulmonary veins were correctly isolated at the time and did jail the trigger for her PAF at that time). The A fib which is occurring now is likely from a new inductor site, most likely the LA posterior wall. A Cryoablation now would only ablate the pulmonary veins - which were already ablated with good results years ago. A hybrid procedure has no place here in my opinion.

Addendum: Unfortunately this particular patient was referred to an electrophysiologist for a cryoablation. This was performed and resulted in no improvement to her A. fib which (given the excellent response to the first ablation years earlier) is likely now from a non-pulmonary vein trigger site. She is scheduled to undergo an RF ablation to include isolation of the LA posterior wall and the SVC (both important secondary drivers for PAF) some time in the future.

ⁱJ Am Coll Cardiol. 2013;62(16):1491-1492. doi:10.1016/j.jacc.2013.07.017

ⁱⁱJ Am Coll Cardiol. 2013;62(16):1491-1492. doi:10.1016/j.jacc.2013.07.017

ⁱⁱⁱMarijon E, Fazaa S, Narayanan K, Guy-Moyat B, Bouzeman A, Providencia R, et al (2013) Real-time contact force sensing for pulmonary vein isolation in the setting of paroxysmal atrial fibrillation: procedural and one-year results. Journal of Cardiovascular Electrophysiology (published online October 2013).

^{iv}Electrophysiologic Perspective on Hybrid Ablation of Atrial Fibrillation, Faisal F. Syed, MBCnB, Hakan Oral, MD, Journal of Atrial Fibrillation, Volume 8, Issue 4, Jan 2016

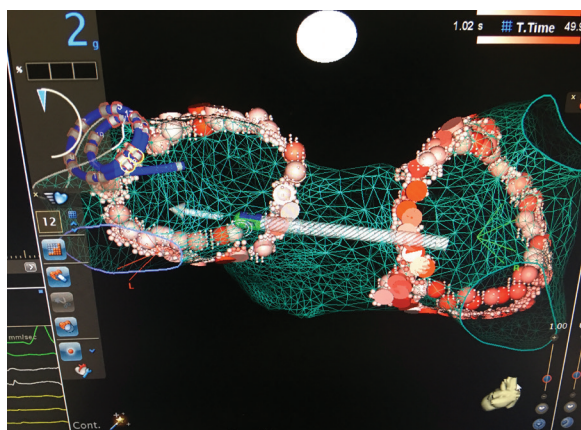


Figure 1: Radiofrequency ablation of both pulmonary vein pairs as performed at JFK Medical Center with bilateral isolation of both vein pairs using force sensing and force-time interval tagging.

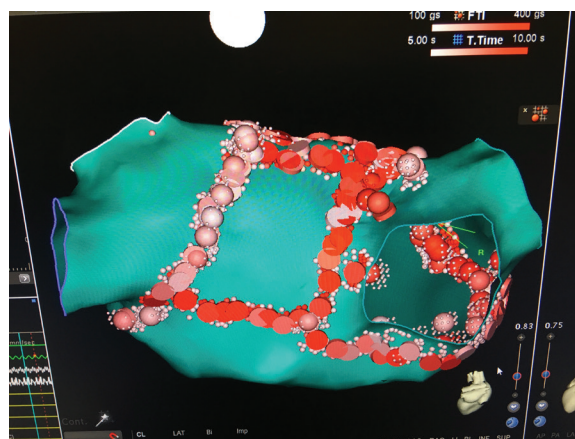


Figure 2: Isolation of the left atrial posterior wall during an ablation for persistent atrial fibrillation; the same lesion set as “the convergent procedure” (i.e. isolation of the posterior LA wall) added an additional 12 minutes to this radiofrequency ablation procedure.

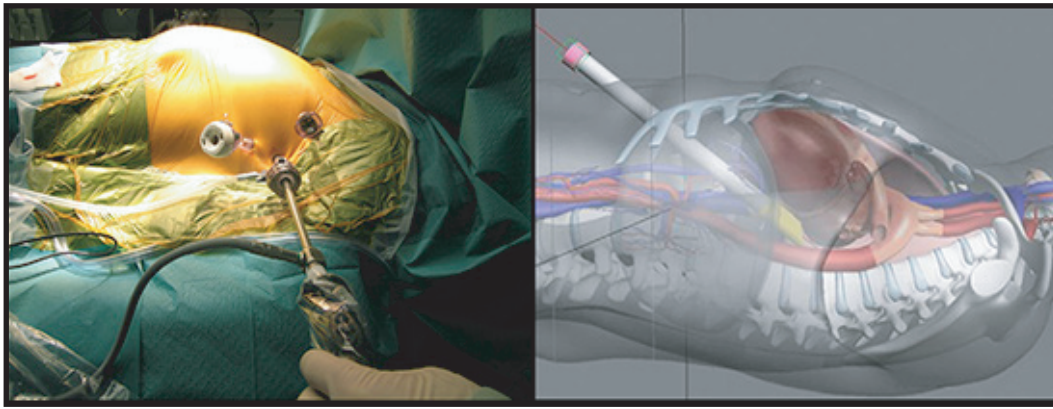


Figure 3: Typical surgical access points for “the convergent” procedure .^{iv}

CRYOBALLOON ABLATION FOR TREATMENT OF PAROXYSMAL ATRIAL FIBRILLATION



Faren R. Angella, MD, FACC

Atrial fibrillation is the most common arrhythmia occurring over age 65. Catheter ablation has been an important tool in treating symptomatic patients who are refractory to medical therapy. There are currently 2 main approaches in catheter based treatment. One is radiofrequency catheter ablation (RFA) and the other is cryoballoon ablation (CB).

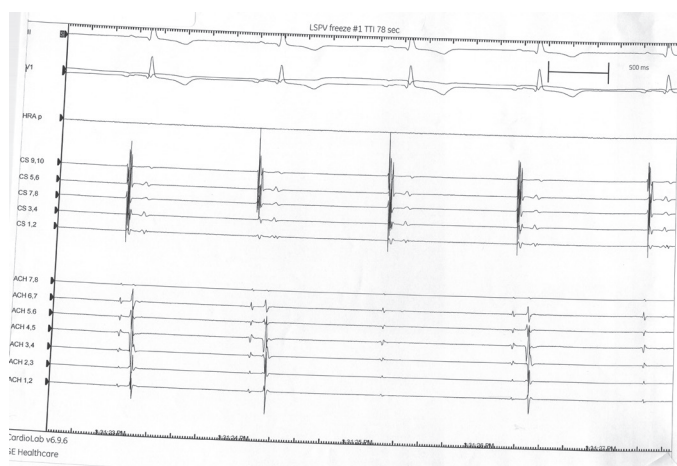
Whereas RFA uses point by point ablation technique to create durable pulmonary vein isolation, CB uses a balloon to create a continuous pattern along the veins without gaps. RFA uses heat to create lesions and CB uses freeze method.

The 1st generation cryoballoon was released in 2010 in the United States and is called Arctic Front, which is owned by Medtronic company based in Minneapolis, MN. For this procedure a balloon is inflated in the left atrium with close proximity to the targeted pulmonary vein. Once the position is verified to be suitable under fluoroscopic guidance by use of contrast (to assure a good seal), then the freeze process will begin. It generally requires 2 freezes per each pulmonary vein to achieve a good result and long term pulmonary vein isolation. With this method there is less risk of thermal injury to the esophagus. However, there is a potential for phrenic nerve injury while freezing the right sided pulmonary veins, especially the right upper pulmonary vein. During the procedure there are ways to monitor the phrenic nerve function. Fortunately, phrenic nerve injury is not permanent and generally recovers with time (it may take up to 6 months for full recovery). CB method is faster and less technically challenging than RFA in achieving the same results.

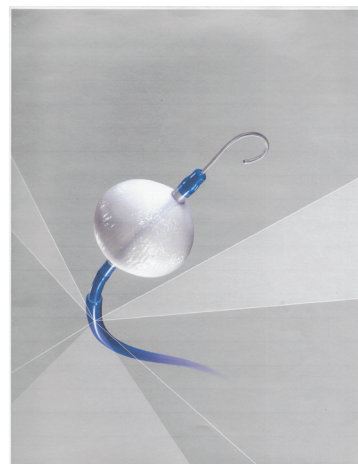
Recently result of Fire And Ice (RFA vs. CB) was published. This was a large randomized multi center study which compared the 2 methods in treating drug refractory symptomatic patients with atrial fibrillation. The study showed that both methods were equally effective (CB was not inferior to RFA). However, analysis of the secondary end points showed that CB group had fewer re-interventions such as repeat ablations and cardioversions in the follow up period.

CB can be used in symptomatic patients with paroxysmal atrial fibrillation that are not responding to antiarrhythmic therapy. It is generally not recommended in patients with persistent or permanent atrial fibrillation, since those patients would require further ablations along the posterior wall and roof of the left atrium, which can not be done by CB. Those patients would benefit from RFA which can create linear lesions.

In summary, CB is indicated in any symptomatic patient with atrial fibrillation that does not respond to medical therapy. It is a safe and effective procedure with lower risk and equal efficacy to RFA, with fewer repeat ablations and cardioversions. Also it is faster and less technically challenging.



This tracing shows pulmonary vein isolation during cryoballoon.



Cryoballoon

A NEW TOOL TO REDUCE MORTALITY FROM LEAD EXTRACTION SVC TEARS



Vlad Rankovic, MD, FACC

The most feared complication by every physician performing extractions of cardiac implanted electronic device (CIED) leads is a tear of the superior vena cava (SVC). In general, lead extraction with the proper tools has been proven to be safe and an effective way to manage CIED leads. The clinical success rate for lead removal is approximately 97.7% based on multiple studies with only 1.4 % of patients experiencing a major adverse event. In terms of SVC tears, it is estimated that they occur in less than 0.5 % of extraction procedures. However, an SVC tear can often be fatal due to the rapid blood loss and inability to maintain any reasonable hemodynamic stability. Seconds count and there is a narrow window of time during which a cardiothoracic surgeon can intervene.

The risk of SVC tear for a particular patient can be difficult to estimate. Pacemaker leads and particularly the coils of ICD leads can have significant adhesions in the SVC, which is composed of very thin membranous tissue. Obviously, the older the leads, the greater the chance of scarring however, the amount of adhesions is greatly variable between patients. Despite vast extraction experience by an operator and careful handling of the extraction instruments, a tear can be unpredictable and sometimes inevitable.

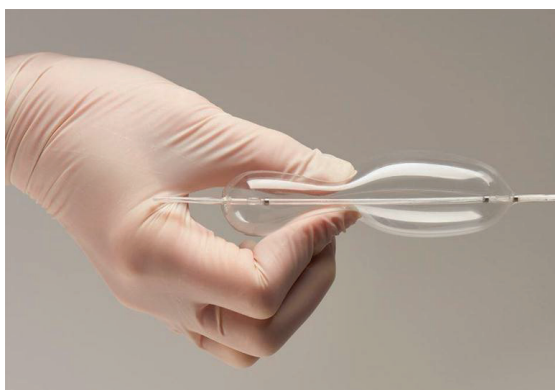
Fortunately, there is now help in reducing mortality from this catastrophic complication. The Spectronetics Corporation has produced the Bridge Occlusion Balloon for the purpose of reducing blood loss and providing hemodynamic stability during a SVC tear. The balloon is designed for rapid deployment in the SVC, producing homeostasis for up to 45 minutes, and allowing the cardiothoracic surgeon time to properly repair the tear.

The attached photos show an actual Bridge Occlusion Balloon along with a fluoroscopy image of the balloon being inflated during a case. At the start of the extraction procedure, a guide wire is placed from the right femoral vein to the internal jugular vein, providing a rail for the balloon. In case a suspected tear occurs, the balloon can be deployed in less than two minutes. The balloon is a "one size fits all", designed to accommodate the size of most SVCs. The balloon is injected with up to 60 cc of 80:20 saline and contrast

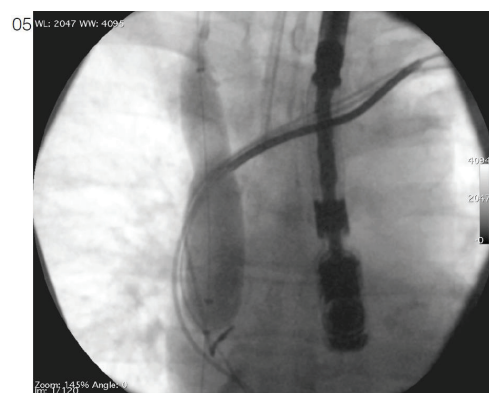
with a proximal radiopaque marker being aligned with the SVC/RA junction. Tested in pig models, the Bridge balloon stopped 90% of blood loss and provided 30-45 minutes of acceptable hemostasis.

One of the primary concerns with occlusion of the SVC is neurologic safety. If blood can't return to the heart, can freshly oxygenated blood reach the brain? Multiple studies using animal models have demonstrated zero observations of neurologic issues with inflation of the Bridge Occlusion Balloon for even up to 45 minutes. Fortunately, the internal thoracic, intercostal, hemiazygos, and lumbar veins provide alternate pathways for blood drainage.

There have already been several clinical cases during which the Bridge Occlusion Balloon has been successfully deployed, allowing the surgeon ample time to repair the SVC with the patients surviving and doing well. The Bridge Occlusion Balloon does not change the usual necessary precautions needed for a lead extraction (e.g. an experienced operator/team and proper cardiothoracic surgical back-up) however, it is an important step towards achieving the goal of zero mortality with CIED lead extraction procedures.

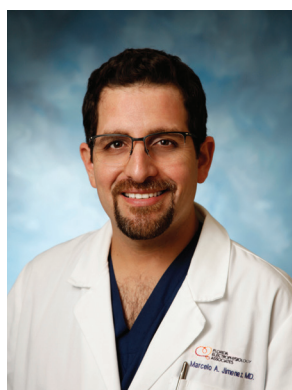


The Spectronetics Bridge Occlusion Balloon



Fluoroscopy of Bridge Occlusion Balloon deployment in a patient.

CONTACT FORCE SENSING TECHNOLOGY



Marcelo A. Jimenez, MD, FHR

In order to achieve durable clinical benefit from catheter ablation of cardiac arrhythmias, it is necessary to create contiguous and transmural lesions in specifically targeted locations.

Lesion formation during radiofrequency catheter ablation of cardiac tissue depends on biophysical parameters including power delivery, duration of energy application, tissue temperature, ablation catheter tip size and orientation and electrode-tissue contact force¹.

The majority of these parameters have long been controlled by the electrophysiologist in an objective and reproducible manner, but until recently, perceived tissue contact has been based on subjective operator dependent tactile feedback, fluoroscopic evidence, and electrogram changes.

Effective and durable lesions cannot be accomplished without adequate contact force. Conversely, excessive contact force is associated with inadvertent deep tissue heating and an increased risk of deep steam pop with possible perforation/tamponade and injury to adjacent tissue, such as esophageal, pulmonary and phrenic nerve injury.

Recently, catheters equipped with contact force sensing technology have been developed for radiofrequency ablation. The most commonly used point-by-point radiofrequency contact force sensing catheter systems

are THERMOCOOL® SmartTouch® (Biosense Webster, Diamond Bar, CA) and TactiCath® (St. Jude Medical, St Paul, MN)

THERMOCOOL® SmartTouch® uses electromagnetic location technology to detect movement between a precision spring (mounted within the tip of a 3.5 mm externally irrigated radiofrequency ablation catheter) and three location sensor coils also mounted within the shaft of the catheter. These movements are sampled every 50 msec and calibrated to produce a contact force reading (in grams) that is averaged over 1 sec².

TactiCath® estimates axial and lateral contact force by examining the wavelength of the light emitted from fiber-optic tubes embedded within an open irrigated-tip ablation catheter. Forces applied at the tip of the catheter result in micro-deformation of optical fibers and changing in the wavelength of the light proportional to the force applied (with a sensitivity of 1 gram)².

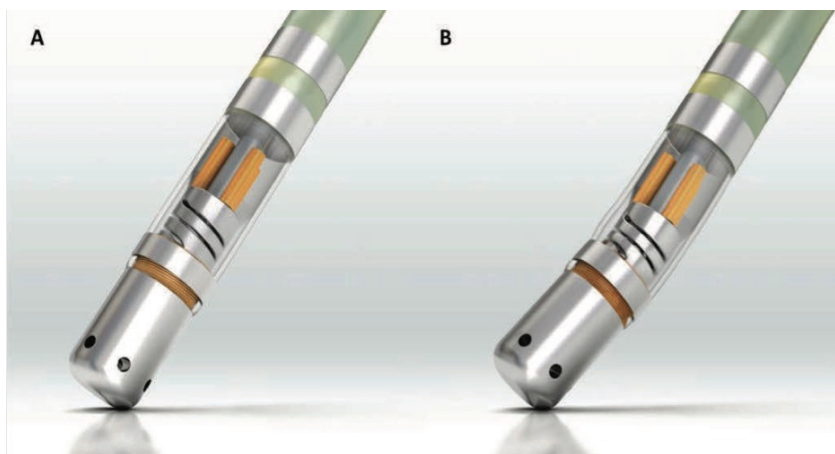
The safety and effectiveness of the THERMOCOOL® SMARTTOUCH® Catheter were evaluated as part a prospective, multicenter study called the SMART-AF Trial³. Patients with drug-resistant symptomatic paroxysmal atrial fibrillation were enrolled. One-year results from the trial showed that patients experienced a 74% overall success rate after ablation with the THERMOCOOL® SMARTTOUCH® Catheter. While the overall success rate was comparable to historical results from other trials, data from the SMART-AF trial provided further evidence that it is the consistent and stable application of contact force on cardiac tissue that positively impacts the efficacy of the procedure in this patient population. Importantly, post-Hoc analysis data from the trial demonstrated higher success rates the longer the operator stayed within a targeted contact force range, with one-year results demonstrating an 88% success rate when physicians stayed within a targeted range greater than or equal to 85% of the time.

Beyond the biophysical effects of the ability to monitor contact force, there is evidence that an optimal catheter tip-to-tissue contact force during radiofrequency catheter ablation of atrial fibrillation affects procedural parameters by significantly reducing procedure duration and fluoroscopy time, without increasing the acute and mid-term complication rates^{4,5}.

In support of this, a recent study found that contact force sensing technology using the THERMOCOOL® SMARTTOUCH® catheter was able to significantly reduce ablation and procedural times during pulmonary vein isolation for atrial fibrillation. Energy delivery was substantially reduced by avoiding radiofrequency delivery in areas with insufficient contact force⁶.

Catheters equipped with contact force technology have become the standard of care for catheter ablation of atrial fibrillation. The objective feedback is invaluable and has helped to create more effective lesions resulting in improved clinical outcomes.

The future of catheter ablation technology lies in determining the optimal combination of contact force, duration of energy delivery and selected power that achieves durable transmural lesions. Indices that weigh all these parameters as well as tissue thickness are in the process of being developed and validated. Catheter ablation of cardiac arrhythmias is evolving to be less dependent on subjective parameters, an evolution that could not have occurred without the advent of contact force sensing technology.

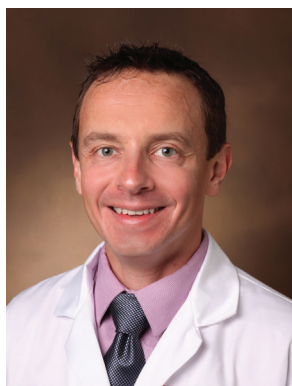


The Thermocool Smarttouch ablation catheter senses the amount of force the physician is using during an ablation. (a) Non-deflected and (b) deflected catheter tip. (Reproduced with permission from Biosense Webster, Diamond Bar, CA, USA).

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LEFT ATRIAL APPENDAGE OCCLUSION



Matthew J. Kolek, MD, MSc

Atrial fibrillation is the most common arrhythmia encountered in cardiology practice. In the United States greater than 5 million people have atrial fibrillation. For most of these patients treatment involves treating the symptoms related to atrial fibrillation as well as prevention of stroke. The large majority of these patients carry an increased risk for stroke. In patients with nonvalvular afib 90% of strokes originate in the left atrial appendage – a muscular sac extending off of the lateral left atrium. The risk of stroke can be quantified with stratification with CHADS2 or CHADSVASC

scores which take into account other predisposing factors such as age, sex, diabetes, vascular disease and congestive heart failure as well as previous strokes. Until recently the predominate way of reducing the risk of stroke in patients with afib was through use of anticoagulants.

On the basis of data from large, prospective randomized controlled trials, oral anticoagulants such as warfarin, factor Xa inhibitors, and direct thrombin inhibitors have become the current standard of care to reduce the risk of stroke in patients with risk factors. Studies on Coumadin have demonstrated multiple pitfalls in its use for atrial fibrillation including patients spending a significant time outside the therapeutic window with increased bleeding risk if INR too high and increased stroke risk if too low. In addition frequent nonadherence to therapy of up to 40%. Coumadin tops the list of emergency hospitalizations for older Americans. While NOACs have improved compliance they carry a 3-4% bleeding risk per year. Up to 40% of patients at increased risk from stroke are not receiving anticoagulation due to absolute or relative intolerance -with a higher percentage of nontreatment in the elderly who may benefit most.

Mechanical approaches to LAA occlusion have been used for more than a half-century in cardiac surgery. Initial surgical techniques, typically performed concomitantly with mitral valve surgery or surgical maze procedures, were challenged by the fragility of the LAA, with mechanical complications resulting in hemorrhage during surgical suturing or stapling. Also, surgical closure of the LAA was often incomplete. Several studies suggest the rate of closure of the left atrial appendage is 23-70% dependent on method but lack of appropriate follow up and continued presence of significant part of left atrial appendage raise concerns about the discontinuation of pharmacological anticoagulation and overall success of procedure.

On the basis of the lessons from surgical closure and a continued belief that elimination of the LAA as a source of systemic thromboembolism could be an effective alternative to pharmacological anticoagulation for patients with AF, a Nitinol plug with a fabric component was developed which could be inserted via femoral puncture and transeptal catheterization. This is the WATCHMAN device. Two large randomized clinical trials the PROTECT-AF study and PREVAIL study enrolling 1200 patients have demonstrated the noninferiority to Coumadin of the watchman device in preventing ischemic stroke in patients at high risk for stroke. The Protect AF study enrolled 800 patients and demonstrated a 60% reduction in stroke risk compared to coumadin and the PREVAIL trial enrolled 400 patients with an identical stroke risk compared to Coumadin and demonstrated safety of implantation techniques.

On March 13, 2015, the FDA issued an approval for the WATCHMAN device. The approval specified indications for use in patients with nonvalvular AF who are 1) at increased risk of stroke and systemic embolism based upon CHADS2 or CHA2DS2-VASc scores; 2) deemed by their physicians to be suitable for warfarin therapy; and 3) have an appropriate rationale to seek a non-pharmacological alternative to warfarin, taking into account the safety and efficacy of the device compared with warfarin

At Florida Electrophysiology associates we were the first in palm beach county to implant the Watchman device as part of the PREVAIL trial and the first to implant in palm beach county once the device became clinically available. We are currently one of a select group of centers across the country offering this device due to our participation in the initial ground breaking research. Current protocol is to perform a screening tee to confirm absence of thrombus and anatomy suitable for watchman device. In most patients this can be done the day of the procedure but for high risk patients it can be done up to several weeks prior to the procedure. The patient is placed under general anesthesia and transeptal catheterization is performed and watchman is place in the left atrial appendage under fluoroscopic and echocardiographic guidance. Successful placement is achieved in greater then 95% of patients attempted. Post procedure standard protocol is to start patients on anticoagulation with NOAC or Coumadin the day of the procedure and asa. At 45 days a repeat TEE is performed and if the watchman is well seated and appropriate closure is in place the patient is placed on asa and plavix for 6 months. Over 95% of patients stop anticoagulation with NOAC or Coumadin at 45 days. The ASAP data suggests that asa and plavix alone is likely sufficient post watchman and we have done many patients without need for Coumadin or NOAC post procedure.



2d echo with color Doppler demonstrating successful watchman placement in left atrial appendage



Watchman LAAC closure device - Nitinol frame with 10 anchors covered by 160 micron PET cap

The Complex Ablation and Device Specialists

For twenty years, Florida Electrophysiology Associates has maintained their status as South Florida's premiere cardiac electrophysiologists practice. With over 70 years of combined experience, FEA is by far the most dedicated group of heart rhythm specialists in the state. Every physician in this practice is board certified in both cardiology and clinical cardiac electrophysiology.

Our practice is affiliated with many hospitals including, JFK Medical Center, Delray Medical Center, Bethesda Health System, Wellington Regional Medical Center, Palms West Hospital, Good Samaritan Medical Center, St. Mary's Medical Center, Palm Beach Gardens Medical Center, Jupiter Medical Center, Northwest Medical Center and Westside Regional Medical Center.

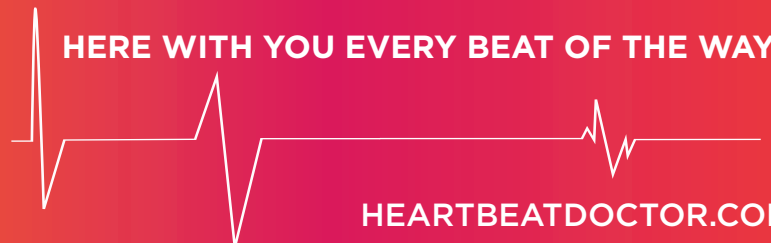
Our mission is to provide compassionate, ethical and quality care to patients with cardiac arrhythmias. Today, essentially all disorders of the heart's rhythm are amenable to treatment - and many heart rhythm disorders can be permanently cured. Our philosophy is to treat patients the way we, ourselves, would want to be treated.



We are Florida's largest physician practice of Cardiac Electrophysiologists.

Robert S. Fishel, MD, FACC
Faren R. Angella, MD, FACC
Vlad Rankovic, MD, FACC
Marcelo A. Jimenez, MD, FHRS
Matthew J. Kolek, MD, MSc

HERE WITH YOU EVERY BEAT OF THE WAY



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FLORIDA
ELECTROPHYSIOLOGY
ASSOCIATES.

180 JFK Dr., Suite 311
Atlantis, FL 33462

Office Hours: Monday-Friday 9am-5pm
Office: (561) 434-0353
Fax: (561) 357-0869
Toll Free: 1-888-VTACHMD
Patient Care: (561) 983-6514
Monitoring: (561) 983-6407
New Patient Appointments: (561) 983-6474
Surgical Scheduling: (561) 983-6411
Medical Records : (561) 983-6513
Billing: (561) 983-6175
Research: (561) 983-6492
Marketing: (561) 577-6737
Office Manager: (561) 983-6175
General Inquiries:
info@heartrhythmexperts.com
Appointments:
appt@heartrhythmexperts.com
Medical Records:
questions@heartrhythmexperts.com

LOCATIONS

Lake Worth
180 JFK Drive, Suite 311
Atlantis, FL 33462

Jupiter
1004 S. Old Dixie Hwy, Suite 303
Jupiter, FL 33458

Boynton / Delray
10151 Enterprise Ctr. Blvd., Ste 202
Boynton Beach, FL 33437

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and Clinical Cardiac Electrophysiology.

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