



Meeting Highlights Journal of Atrial Fibrillation

14th Annual Boston Atrial Fibrillation Symposium Proceedings – Technology Round Up

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What started off as a small, cozy meeting of electrophysiologists thinking about atrial fibrillation (AF) evolved into a major annual program that draws more audience every year? Thanks to the vision of Dr. Jeremy Ruskin (Massachusetts General Hospital, Boston) who started this program and continues to direct it very effectively to this day. Over the last few years, industry has used this as a good platform to showcase some of their latest technology in AF therapy. Several products ranging from radiation protection devices to most advanced mapping and ablation systems have been displayed at the Boston World Trade Center.

Sachin Vadodaria, Director , Marketing for St. Jude Medical was very excited about their new AF technologies. Their latest additions included – **BRK-XS**® Transseptal puncture needle that has a primary bevel at a more acute angle (30 degrees) and two back bevels that combine to form a distinct point on the tip of the needle. This is an improvement from their prior version and was found to have significant reduction in force needed to cross the interatrial septum in in-vitro studies. This is currently FDA approved and may be a good option for septa that are tough and scarred. Steerable transseptal sheath called the **Agilis NxT**® has 52 mm distal curve that could help the ablation or mapping catheters reach

difficult areas of the left atrium. Clinical studies using the prior version of the Agilis sheath was found to be safe and efficacious than the conventional fixed curve (Mullins) transseptal sheaths.¹ Effective left atrial navigation especially for operators early on their learning curve could be difficult and this sheath may facilitate that. This sheath could definitely find some use in severely enlarged and rotated hearts with difficult to reach pulmonary veins to ensure better catheter stability. The additional operational benefit compared to the additional costs over a fixed curve sheath for routine use is yet to be tested. St. Jude also introduced a new high density multi ringed spiral mapping catheter called Reflexion HD®. This is a unique20 pole catheter on the same platform as their **Reflexion spiral** circular mapping catheter with bidirectional curve but fixed diameter. Clinical utility may come in for high density left atrial mapping. This catheter could be used like a traditional circular mapping catheter to guide pulmonary vein isolation and specifically for complex fractionated electrogram mapping. It may help improve the speed and accuracy of left atrial maps considerably. H Curve - TV is their new H-curve catheter with improved flexibility and adjustable tricuspid valve diameter that works like a Halo catheter for right atrial ablations (cavotricuspid

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Agilis NxT ©

isthmus). There was a few other interesting technologies related t o3D mapping that is pipeline pending FDA approval. **Ensile Velocity**® is one such system with better processor speed and improved efficacy. This carries the version 9.0 of the Ensite NavX software with the attached bells and whistles.

Bard Electrophysiology displayed the new 5 mm tip Scorpion 2® (4 pole2-5-2 mm separation) ablation catheter. The unique feature of this catheter is a bidirectional tip with proximal and distal curve control on a single handle with a curve control lock. This feature of the catheter tip could potentially help better tissue contact with parallel contact to tissue. In some of the cavotricuspid isthmuses, adequate tissue contact could be a challenge and this catheter could help stability. In the era of open irrigated catheters, the role for this catheter is yet to be tested. Efficacy data for this catheter system compared to the currently available 4mm, 8mm non irrigated and open irrigated catheters is not available.

Lechnologies Research Inc. showcased their new AfibAlert®external heart rhythm monitor marketed to target AF patients. It seems to work on similar platform like most of the existing external



Scorpion ©



Reflexion HD ©

Reflexion Spiral ©

monitoring systems with two wrist EKG patches and the finger insert for pulse check. It has six memory slots in its cascading memory system that has the capability of storing one baseline EKG and five recordings with new data replaces the old. Life Watch Inc had recently released its ambulatory cardiac telemonitor (ACT III) for AF monitoring with extended memory, greater portability along with their online AF monitoring program. Mednet, Cardio Labs and Cardionet are some of the other companies that have similar technologies. To add to the existing list of monitoring related companies, Cardiostaff Corp from Austin, TX brings in their mini digital recorder and 30 day event recorder.

The much awaited magnetic irrigated catheter from Stereotaxis Inc may finally come to the United States in a few months. Initial clinical experience of this magnetic guided open irrigated catheter in complex left atrial ablations was found to have comparable short term and long term success rates. The earlier attempts of release in the United States were marred by technical problems and the





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concerns regarding char formation at the catheter tip. Currently Biosense Webster manufactures exclusively all the catheters that are compatible with magnetic navigation system. There are other manufacturers who are attempting to work on some of these navigation catheters. They also featured their Odyssey® compact but comprehensive monitor that brings EP recording/monitor, 3D map, intracardiac echo and magnetic navigation to one large screen. This is very user friendly and reduces the desk space in the control room significantly.

Lemer Pax Innovative is a France based company that makes a radiation protection cabin called CATHPAX®. They released their second iteration recently. This is the first alternative to the traditional lead apron/skirt/vest that has been around for several decades. This designed in the shape of a vertical cabin with two holes for the operator's hands at adjustable height. The whole frame is mounted on wheels and can be moved around. A study from Hein Heidubuchel from Lueven, Belgium² clearly shows greater reductions in exposure to head, legs and forearms that typically are not protected by the conventional lead gear. There is no definite data on ergonomic aspects of operator performance. This is definitely worth looking into for high volume operators of prolonged procedures like AF ablation. Kinesiologic impact on the operators is worth studying. Phillips Medical



CATHPAX II ©



Catheter Robotics Navigation System ©

has marketing rights to this system in the United States.

Catheter technology seems to attract companies that have traditionally been in device business. The latest additions are Biotronik and Medtronic. Biotronik has recently release their Alcath Flux Gold®, Trignum® and Lexx® catheters in Europe and are working on feasibility and non-inferiority studies pending FDA approval in the United States. Medtronic acquired Ablation Frontiers, a niche catheter company that makes multisite ablation catheters. Traditionally, RF could be delivered through a single tip limiting the speed of applications in procedures that required extensive ablation. This shortcoming of the traditional catheters was attempted to overcome by new technologies that can burn simultaneously from multiple electrodes. Ablation Frontiers pioneered that new technology releasing catheters of various shapes with strategically located ablation electrodes. The most popular one was a catheter on a circular platform with adjustable diameter for PV isolation. The feasibility study results are encouraging. Medtronic also acquired Cryo Cath Inc, a Canadian company that specializes in cryo ablation. Interestingly, Medtronic had stayed away from catheter technologies for several years despite their early interest (Mariner catheter & Localisa mapping system) while its competitor St. Jude Medical Inc. continued its efforts to consolidate its position in the catheter business.

Biosense Webster Inc., has been in catheter business for more than a decade. They have traditionally done well through their CARTO 3D mapping system and non irrigated and open irrigated cath-



Cardiofocus Laser Balloon Ablation Catheter ©

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eter. Their Thermocool® open irrigated catheter was a major success and had recently received an approval for use in AF ablations by FDA. CARTO Sound integrates intracardiac echo with 3D mapping. CARTO-3 is their latest system with multi catheter visualization capability. Hansen Medical showed their new Sensei robotic navigation system. They gained a significant market share in the United States on the robotic front. Yet another robotic navigation system that operates on much smaller budgets has showcased their system. No major details are available at this point in time. Cardiofocus has brought out their new laser balloon with changes made to the catheter platform and better visibility. To remind the readers, Cardiofocus had prematurely terminated their initial study using the earlier version of their balloon catheter due to complications from cardiac perforation. Steve Sagon, the CEO of Cardiofocus discussed with JAFIB about starting a new feasibility trial in the United States very soon and is trying to recruit some prestigious institutions to do the trial. Catheter Robotics Inc. has developed a new robotic catheter system with remote navigation capabilities. This is in its very early stages of development and no major clinical data is available.

Disclaimer : This is a pure technical review of the products and JAFIB does not endorse any of these products.

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