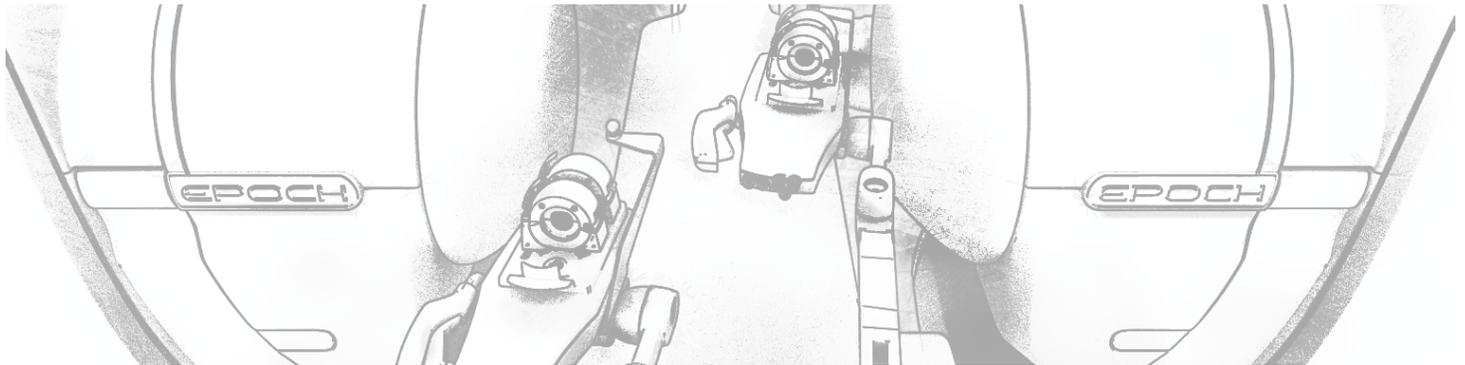


STEREOTAXIS NEWS

JULY 2016

VOLUME 2 ISSUE 1



HEART RHYTHM 2016



In May, Stereotaxis participated in Heart Rhythm Society's (HRS) 37th Annual Scientific Sessions. Attendees from around the world gathered in San Francisco, CA for the four-day conference learning the latest science, education and technology and networking with some of the greatest minds in the electrophysiology field.

In the Stereotaxis exhibition booth, visitors had the opportunity experience the latest Navigant™ software simulator as well as manipulate the movement of a magnetic catheter through a simulated beating model of the heart.

On May 6, over 130 attendees joined the Rhythm Theatre Symposium session chaired by Dr. Mauricio Arruda (University Hospitals Case Medical Center, Cleveland, OH). Dr. Luigi Di Biase (Albert Einstein College of Medicine at Montefiore Hospital, Bronx, NY) presented **VT Ablation... Scar or Arrhythmia? Man or Machine?** where he described VISTA trial results on ablating scar vs. arrhythmia and the latest data on ischemic VT ablation results (magnetic vs. manual). Dr. Tamas Szili-Torok (Erasmus MC, Rotterdam, Netherlands) led the discussion on **Is There Still Room for Manual Ablation in VT?** and focused on the new global randomized trial, Magnetic-VT, as well as results from recently published VT studies comparing magnetic and contact force catheters. Dr. Hiroshi Nakagawa (Oklahoma University Medical Center, Oklahoma City, OK) closed the session with **What Innovation Comes Next in Magnetic Navigation?** with his research and insight on contact confirmation for magnetic catheter (using bipolar impedance) and shared a development progress on Magnetic Ablation Index (MAI) for lesion prediction.



Luigi Di Biase, MD, PhD
Section Head of Electrophysiology at a
Associate Professor, Albert Einstein Col
Hospital, Bronx, NY
Adjunct Associate Professor, Department
University of Texas, Austin
Senior Researcher, Texas Cardiac Arrhythmia
Program, University of Texas at Austin
Professor of Cardiology, University of Texas at Austin

CARDIOSTIM 2016

This year's EHRA Cardioslim congress was held at the Nice Acropolis Center in Nice, France. Stereotaxis proudly participated in this scientific session with several activities including: an interactive booth showcasing the latest simulator software and beating heart simulation model.



On Friday, June 10, a joint session with the Society of Cardiac Robotic Navigation (SCRN) was co-chaired by Dr. Sabine Ernst (London, UK) and Dr. Georg Nölker (Bad Oeynhausen, DEU).

Presenting physicians included:
P. Ricard (Nice, FRA)
D. Bastian (Nürnberg, DEU)
B. Schwagten (Antwerp, BEL)
G. Tomassoni (Lexington, USA)
T. Szili-Torok (Rotterdam, NLD)

Other 2016 Scientific Sessions Around The World

Gulf EP Live Congress (January 8-9)

Each year since 2014, the “crème de la crème” of the EP community converge in Dubai to educate and exchange findings on the growing application of cardiac EP in the Gulf countries. Prior to the establishment of the Gulf EP Live Congress, experts in the region would have had to travel to Europe or the United States for scientific exchange. Supported by the United Arab Emirates (UAE) Minister of Health, who sees the UAE becoming “a major hub and benchmark of cardiac EP,” this scientific meeting convened at the Dubai Mall and was also streamed live.

At this year’s Gulf EP Live, Dr. Sabine Ernst (Royal Brompton Hospital, London, UK) transmitted a live presentation from London highlighting an epicardial ARVD (VT) case viewed by attendees and online participants.



EP LIVE (March 3-4)

EP Live is a CME accredited EP educational event hosted by St. David’s Medical Center (Austin, TX).

EP Live is a unique course in that it largely educates attendees via live procedures. Among the many live cases throughout the event, Dr. J. David Burkhardt utilized the remote magnetic navigation platform to treat a very complex case. This young patient was diagnosed with arrhythmogenic right ventricular dysplasia (ARVD)/cardiomyopathy with a complex endo-epicardial intramural scar. The patient had an ICD and experienced frequent VT and PVC.

Dr. Burkhardt demonstrated his finesse with the Niobe™ system; he built dense and precise maps and ablated densely homogenize targeted scar tissue. The patient was treated effectively, efficiently and successfully; the VT was not inducible at the end of the two-hour procedure.

Throughout the entire course, all live cases were transmitted from the procedure rooms to the auditorium using Stereotaxis’ Odyssey™ solution.

International AF Symposium (January 14-16)



The 21st annual International AF Symposium took place in Orlando, Florida. In addition to participating as an exhibitor, Stereotaxis presented a Product Theatre Symposium. The symposium was moderated by Dr. Andrea Natale (St. David’s Medical Center, Austin, TX) and presented by Drs. Tamas Szili-Torok (Erasmus MC, Rotterdam, Netherlands), Michael Porter (Saint Joseph Hospital, Denver, CO) and Luigi Di Biase (Albert Einstein College of Medicine at Montefiore Hospital, Bronx, NY).

In addition to learning about the latest clinical findings using RMN and novel techniques, attendees were introduced to the latest clinical research and novel techniques for remote magnetic navigation. Dr. Natale also shared an overview of the Stereotaxis MAGNETIC-VT study.

Read about the MAGNETIC-VT Study on page 4

MUAC (March 17-19)

The annual Monaco-USA Ablation Course took place again this year at Monaco. This clinical partnership and educational event between The Princess Grace Hospital (Monaco) and the University of Pennsylvania (Philadelphia, PA) is the largest gathering of EP fellows around the globe.



This year, attendees were exposed to remote magnetic navigation technology through a live procedure and scientific presentation.

Dr. Gabriel Latcu (Princess Grace Hospital, Monaco) completed a complex VT with PVCs procedure where he navigated to the left ventricle through retrograde access using a RMT (remote magnetic technology) catheter and the right ventricle using the V-CAS Deflect™ system. The ability to reach and map these hard-to-reach areas of the heart, including the cusp, demonstrated the superiority of the RMT catheter.

Dr. Sabine Ernst delivered a presentation on “Advanced catheter ablation techniques in complex congenital heart diseases” in which she highlighted the ability to steer the magnetic catheter from the tip rather than the end, allowing access to difficult anatomy. Numerous case examples, that otherwise would not have been possible without RMN, were shown – all demonstrated high success rates coupled with low x-ray doses.

In The News

CONTINUING OUR PARTNERSHIP

Philips and Stereotaxis have agreed to collaborate on developing an interface between the Niobe™ magnetic navigation system and Philips' cardiovascular x-ray system, the Allura Xper FD10 version R8.2. The Allura Xper FD10 is a ceiling-suspended system offering rotational scan for 3D images, low-dose x-ray, and storage and retrieval of multi-modality cardiology information. The main features of the 8.2 system are the support of a new FD20 image detector as well as a new x-ray generator. The new interface will enable interoperability of Stereotaxis' Niobe™ magnetic navigation system with the latest version of Philips' cardiovascular X-ray system, Allura Xper FD10 version R8.2 system. This new interface is expected to be available in major global markets in 2016.



NEW LAUNCHES AROUND THE WORLD

The Stereotaxis Niobe™ magnetic navigation system continues its footprint around the world. In recent months, new systems have been installed in:

- University Medical Center New Orleans (New Orleans, Louisiana, USA)
- Centre Hospitalier Régional Universitaire de Nancy (Nancy, France)
- Montreal Heart Institute (Montreal, Quebec, Canada)



DR. ANDREA NATALE SITS DOWN WITH EP LAB DIGEST TO DISCUSS THE VALUE AND POTENTIAL OF REMOTE MAGNETIC NAVIGATION IN EP

In the May 2016 issue of EP Lab Digest, Dr. Andrea Natale from Texas Cardiac Arrhythmia Institute at St. David's Medical Center shared his views and insights about his use of remote magnetic navigation (RMN) for the treatment of complex arrhythmia.

When asked to describe what has continually attracted physicians in his practice to RMN, Dr. Natale responded with, "In Austin, we have access to the newest technologies available for treating VT. Most of our physicians doing VT ablation use RMN technology from Stereotaxis, because it allows them to handle the procedure in a more relaxed fashion. The manual procedure can last several hours and requires the physician to stand at the table, which can be tiring. With RMN

technology, you can sit at the remote control panel and create the map. Especially in structurally complex heart disease patients who have a large scar area that needs to be addressed, we have found the map is usually more accurate with Stereotaxis. The ablator also tends to do a better job at obliterating all the relevant channels in patients with a complex large scar area, compared to a manual approach. When comparing the manual approach vs the magnetically guided approach, we have data to support the importance of magnetic navigation in patients with a large scar area."



Read the full interview here:

<http://www.eplabdigest.com/articles/Value-and-Potential-Remote-Magnetic-Navigation-EP-Interview-Dr-Andrea-Natale>

MARIA'S JOURNEY TO ALLEVIATING HER ARRHYTHMIA



Photo credit: Deborah Heart and Lung Center

Watch her journey and story and hear how her life was restored by Deborah Heart and Lung Center with the Niobe™ magnetic navigation system.

"For her entire life, Maria has dealt with abnormal rhythms in her heart. As she has aged, the problem has worsened, leading to life-threatening complications."

Maria's quality of life was greatly affected; she was often dizzy, unable to walk and shop. In one incident, she fainted in front of her four year old Granddaughter because of her heart beating too fast. She had been in and out of several hospitals. Determined to make a change, Maria selected Dr. Raffaele Corbisiero at Deborah Heart and Lung Center (Browns Mills, NJ). When she woke up from the anesthesia, her heart was beating normally, Maria couldn't believe it – she even took a picture of it to remember the moment.

"...she knew immediately she was fixed...when you can cure somebody and take care of a problem like this, that's affected somebody's life, it kind of makes you smile."

Raffaele Corbisiero, MD, FACC



<http://demanddeborah.org/2015/11/maria-jeloneks-patient-journey/>

Latest Scientific Publications

MAGNETIC-VT Study: A Multi-center Randomized Superiority Study On Ventricular Tachycardia Ablation Outcomes

Stereotaxis has initiated its first prospective, multi-center, randomized clinical study to compare radiofrequency ablation outcomes generated using its Niobe™ remote magnetic navigation system to manual approaches in ischemic scar ventricular tachycardia (VT) patients.

The study is by Global Principal Investigator Dr. Andrea Natale (Texas Cardiac Arrhythmia Institute of St. David's Medical Center, USA), along with Co-Principal Investigators Dr. Tamas Szili-Torok (Erasmus Medical Center, Netherlands), and Dr. Roderick Tung (The University of Chicago Medicine, USA). Ten hospitals have confirmed participation.



Andrea Natale



Tamas Szili-Torok



Roderick Tung

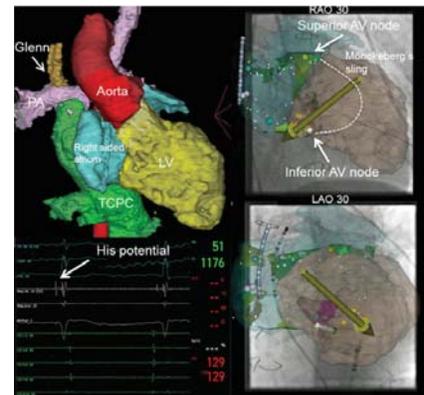
JCE releases Special Issue dedicated to Remote Magnetic Navigation

The Journal of Cardiovascular Electrophysiology (JCE), leading journal devoted to the study of the electrophysiology of the heart, has released a Special Issue dedicated to RMN. This supplement is the first in EP clinical literature to focus solely on the remote magnetic navigation technology. Seven peer-reviewed papers are featured, involving over 50 unique authors were involved.

For complimentary access to this Special Issue (March 2016, Volume 27, Issue S1, Pages S3-S56), click here.



<http://www.stereotaxis.com/clinical-science/jce-special-issue/>



Participating Sites



Andrea Natale, MD
St. David's Medical Center, USA

J. Peter Weiss, MD
Intermountain Medical Center, USA

Erik Wissner, MD
Advocate Christ Medical Center, USA

Adam Berman, MD
Georgia Health Sciences University, USA

Dhanunjaya Lakkireddy, MD
The University of Kansas Hospital, USA

Roderick Tung, MD
The University of Chicago Medicine, USA



Tamas Szili-Torok, MD, PhD
Erasmus MC, Netherlands

Xu Chen, MD
Rigshospitalet, Denmark

Petr Neuzil, MD, PhD
Nemocnice Na Homolce, Czech Republic

Rene Tavernier, MD, PhD
Algemeen Ziekenhuis, Belgium

Complete List of Studies

- Remote Magnetic Navigation for Catheter Ablation in Patients with Congenital Heart Disease (Roy, et al.)
- A Comparison of Remote Magnetic Irrigated Tip Ablation versus Manual Catheter Irrigated Tip Catheter Ablation With and Without Force Sensing Feedback (Weiss, et al.)
- Catheter Ablation of Ischemic Ventricular Tachycardia with Remote Magnetic Navigation: STOP-VT Multicenter Trial (Skoda, et al.)
- Remote Magnetic Navigation: A Focus on Catheter Ablation of Ventricular Arrhythmias (Aagaard, et al.)
- Safety and Long-Term Outcomes of Catheter Ablation of Atrial Fibrillation Using Magnetic Navigation versus Manual Conventional Ablation: A Propensity-Score Analysis (Adragão, et al.)
- Vdrive Evaluation of Remote Steering and Testing in Lasso Electrophysiology Procedures Study: The VERSATILE Study in Atrial Fibrillation Ablation (Nölker, et al.)
- Efficacy and Safety of Atrial Fibrillation Ablation Using Remote Magnetic Navigation: Experience from 1,006 Procedures (Jin, et al.)



For more information

<https://clinicaltrials.gov/ct2/show/NCT02637947>

Latest Scientific Publications

Section of Arrhythmias, Lund University Hospital, Lund, Sweden

Comparison of remote magnetic catheter navigation with manual technique for catheter ablation of complex left atrial arrhythmias—a single center long-term follow-up study

Yuan, et al.

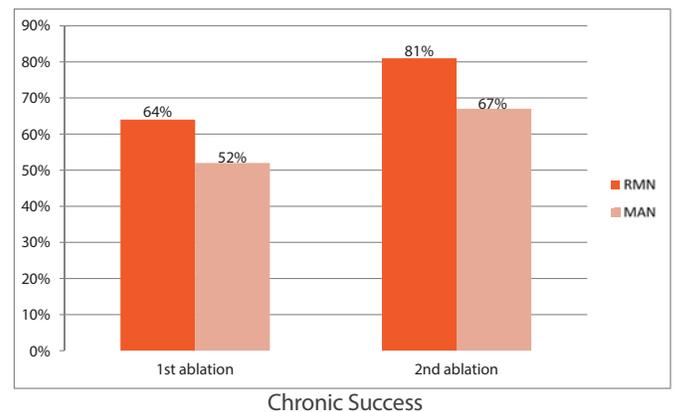
Objective

Earlier generations of the Niobe™ remote catheter navigation system have reported inconsistent results. This study aims to evaluate the efficacy and outcomes of the latest generation *Niobe* ES RMN for CLA ablation in a large patient population with long-term follow-up.

Patient Distribution: RMN: 112 Patients (40 Persistent, 72 Paroxysmal) MAN : 102 Patients (33 Persistent, 59 Paroxysmal)
Follow up: 3, 6, 12, 24, 36 months
Endpoint: PVI in Paroxysmal CLA, PVI + CFAE for Persistent CLA

Results

- Fluoroscopy time and X-ray doses were significantly lower in RMN vs. MAN by 34% and 38% respectively ($P < 0.05$)
- Procedure time showed no significant difference between RMN (205 min.) and MAN (197 min.)
- Major complications were fewer in the RMN group than the manual group (1 PV stenosis vs. 3 cardiac tamponades)
- In long-term follow-up (33 +/- 8 RMN and 42 +/- 9 MAN months) there was significantly better clinical efficacy with RMN ($P < 0.05$)



From Dr. Shiwen Yuan, Associate Professor of Cardiology at Lund University:

“The *Niobe* system enables **enhanced cardiac mapping, precise catheter positioning, access to difficult-to-reach anatomy**, and significantly lower radiation exposure—all critical factors in achieving safe and effective transmural lesions.”

“On a personal note, the convenience and ease of use associated with the *Niobe* system alleviates much of the physical burden related to these complex procedures, **enabling me to continue practicing electrophysiology longer than expected**,” said Dr. Yuan, who performed his first procedure using the *Niobe* system in late 2011 and has since completed more than 300 cases.

Conclusion

“The latest RMN technique [*Niobe* ES] is associated with **lower radiation exposure** and **clearly better clinical outcomes** as compared with data using manual technique...”

- Yuan, et al.