



Séminaire
Winter Arrhythmia
School
Annual Cardiac Arrhythmia Meeting
Division of Cardiology, University of Toronto

Review of current clinical research projects involving magnetic navigation systems

Dr. Paul Brathwaite

VP of Research and Development

Stereotaxis, Inc.

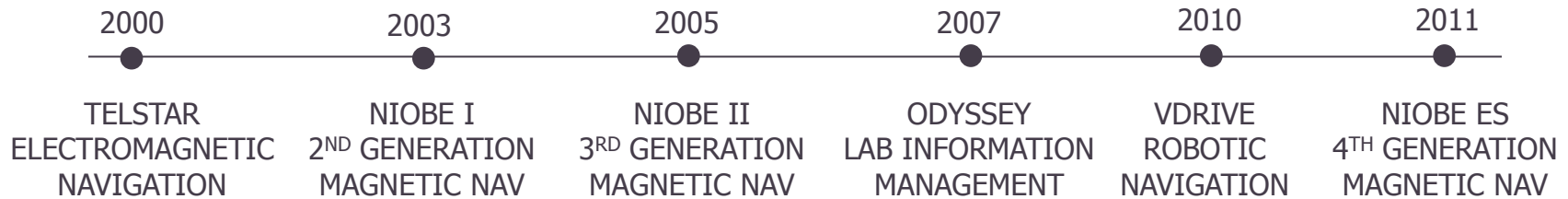


14th Annual
Collingwood, Ontario,
February 10 -12, 2017



Evolution of Robotic EP Technology

History of Innovation Firsts





Current Product Portfolio

Niobe® ES



Only commercialized technology to precisely steer cardiac catheter tip using computer controlled, externally applied magnetic fields

Odyssey®



Pioneering IT solution providing real-time data access and integration in interventional labs

Vdrive™



One-of-a-kind system providing remote, mechanical manipulation of numerous disposable interventional devices for optimized use in Niobe lab

Disposables/Service



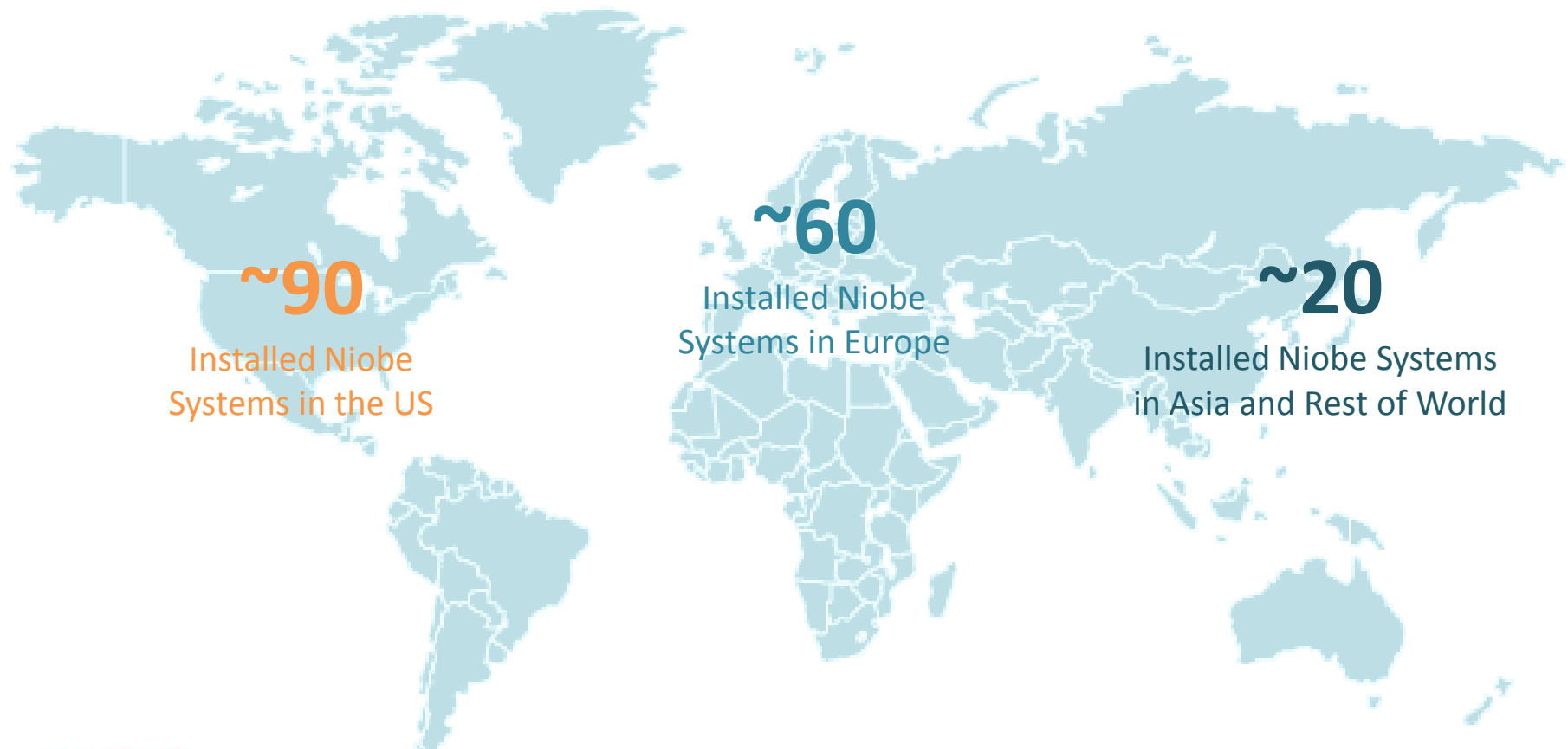
QuikCAS™ (proprietary, automated catheter advancement system) & Vdrive disposables



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Significant Global Install Base

Over 170 Niobe Systems Installed Globally* with Approximate Geographic Distribution Below...



~90
Installed Niobe
Systems in the US

~60
Installed Niobe
Systems in Europe

~20
Installed Niobe Systems
in Asia and Rest of World

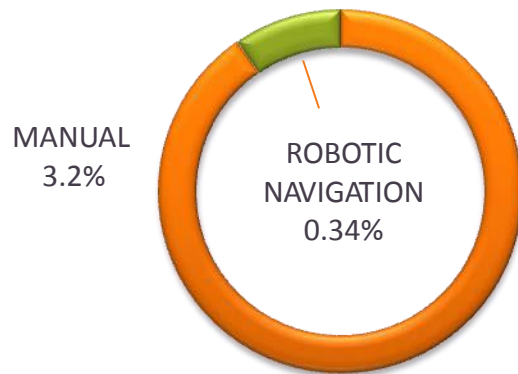
*Niobe ES was released in December 2011. As of 9/30/16 there are 129 Niobe ES systems installed.

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Stereotaxis Robotic Technology – Clinical Evidence

10x Safety Advantage for
Stereotaxis Compared to Manual



Major Adverse Event Rate¹

200+ peer reviewed publications

94% acute success rate for ventricular tachycardia²

92% acute success rate in congenital patients³

90% less x-ray⁴

81% freedom from A-fib at 18 months⁵

49% less radiation exposure over physician career⁶

1. Bauernfeind, et al., Europace 2012
2. Neuzil, et al., STOP-VT Multicenter trial, ESC 2011
3. Ernst, et al., Circ Arrhythmia EP 2011
4. Internal clinical data, HEART Study 2008
5. Pappone, et al., Heart Rhythm 2010
6. Wood, et al., PACE 2008



Clinical Science

- Past Clinical Publications & Research
- Current Research
- Future Research and Opportunities



3-year Clinical Publication History

	2014	2015	2016	2017
Case Studies/Series	5	3	4	-
Reviews	1	2	6	-
Randomized Control Trials (multi &/or single center)	0	0	2 (VERSATILE & RMN guidewire)	1 (MAGNETIC-VT Protocol)
Prospective (registry, observational, randomized no cntrl etc.)	2	7	3	-
Retrospective (registry, consecutive, survey, etc.)	4	3	4	2
Meta-analysis	0	1	1	-
Mentioned in "Methods"	1	2	4	-
Total	13	18	24	

Indication	2014	2015	2016	2017
AF/AFL/CLA*	6	6	6	2
VT/VA*	0	3	2	1
Other* (SHD, CHD, SVT etc.)	0	3	0	0



Scar Homogenization Ablation in Ischemic Cardiomyopathy

Di Biase et al., Poster presented at AHA Scientific Sessions 2015 Nov 7-11; Orlando, FL.

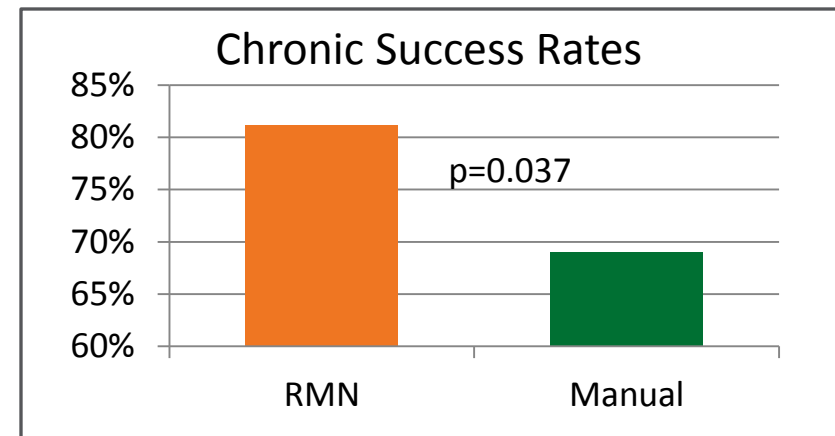
Circulation. 2015; 132: A14384

Study Aim

Compare procedural benefit and outcomes of patients with ischemic cardiomyopathy (IC) undergoing VT ablation with remote magnetic navigation (RMN) versus a manual approach.

Methods

Multi-center study of 218 consecutive patients with scar size $> 60 \text{ cm}^2$ undergoing scar homogenization with either RMN (n=138) or manual (n=80) ablation.



RMN ablation in patients with IC and a scar size greater than 60 cm^2 have a significantly higher success rate than manual approach.



Efficacy and Safety of Atrial Fibrillation Ablation Using Remote Magnetic Navigation: Experience from 1,006 Procedures.

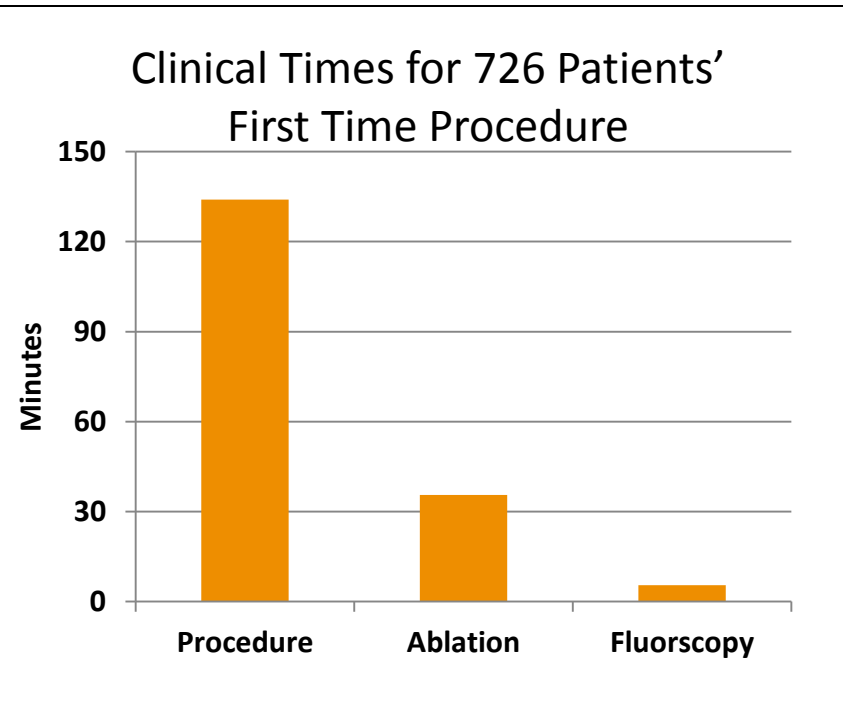
Jin, et al., *J Cardiovasc Electrophysiol.* 2016; 27 Suppl. 1:S23-8.

Study Aims

Evaluate the rate of peri-procedural complications; assess the procedural outcomes of PAF and PerAF patients undergoing RMN-guided ablation; and to compare the procedural outcomes between patients undergoing first and repeat ablations.

Methods

Single center, prospective registry of 726 patients coming in for their first AF ablation and any repeat .



RMN procedure times are 134 ± 35 min, using 5.4 ± 3.7 min of fluoroscopy, and 36 ± 17.1 mins of ablation time in 726 first time procedures with only 0.6% complication rate reported for 1006 procedures.

Catheter Ablation of VT Using Remote Magnetic Navigation

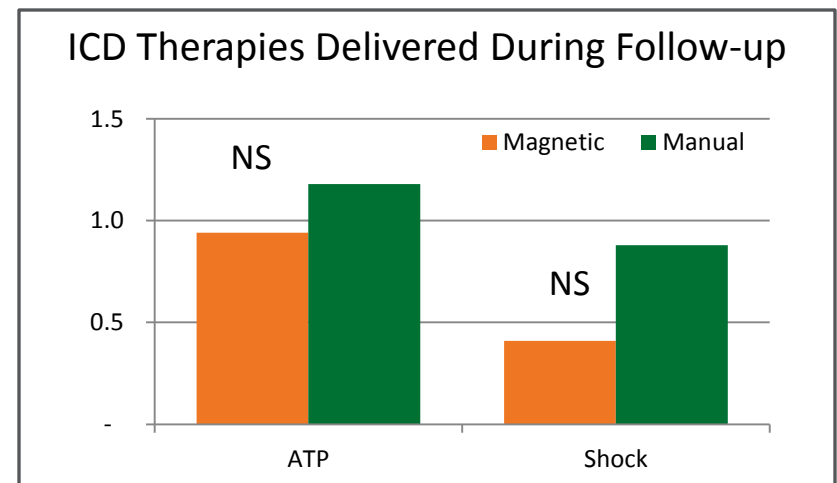
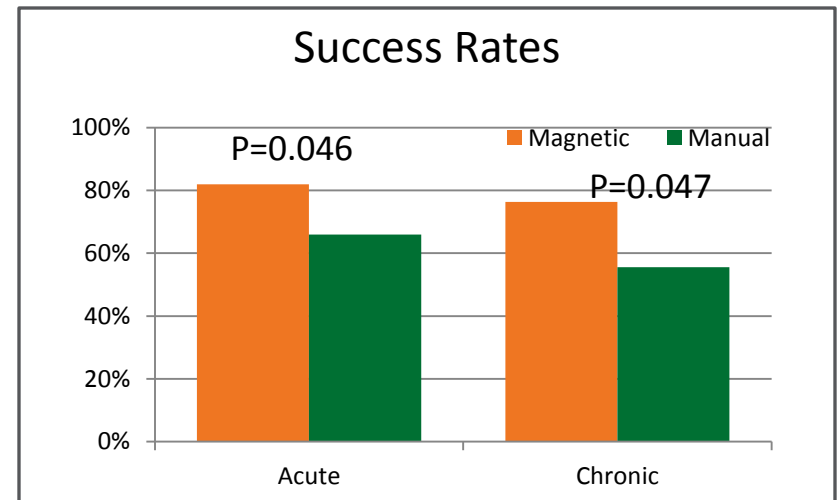
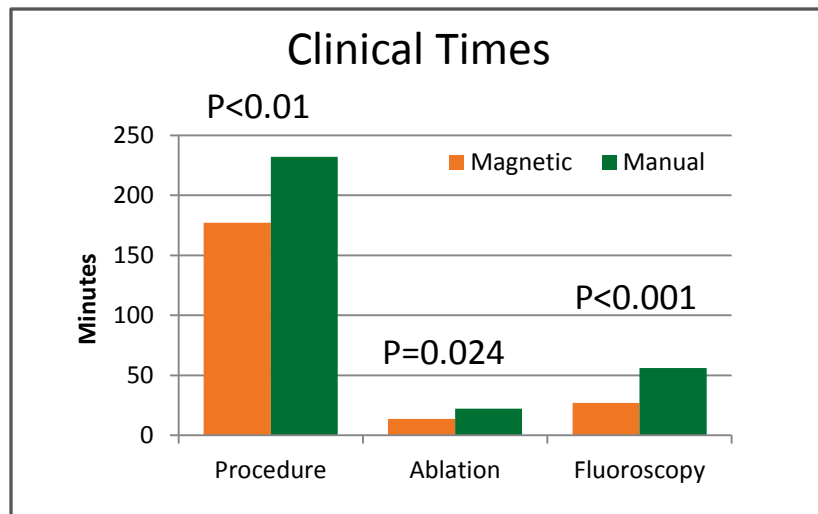
Szili-Torok et al., *J Cardiovasc Electrophysiol*, 2012, 23(9):948-54

Study Aim

Compare acute and late outcomes of VT ablation using a magnetic navigation system (MNS) to manual techniques (MAN).

Methods

A total of 113 consecutive VT patients were included, 72 in the MNS group and 41 in the MAN group. Patients were enrolled over a 32 month period. Mean follow-up was 20 months.



RMN ablation procedures have significantly higher success rates and lower clinical times.



Substantial superiority of Niobe ES over Niobe II system in remote-controlled magnetic pulmonary vein isolation

Da Costa et al., Int J Cardiol. 2017; 230:319-23

Study Aim

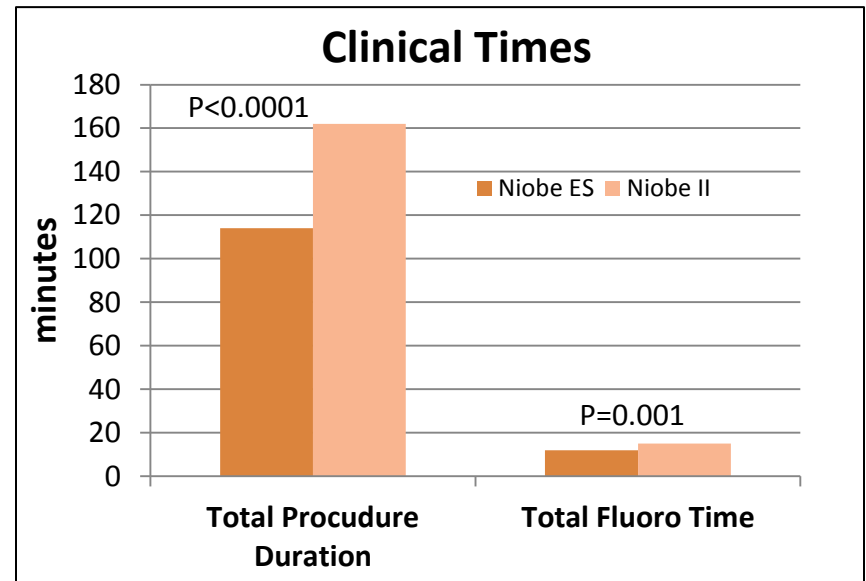
Evaluate the efficacy and extent of fluoroscopic exposure and procedure duration comparing the Niobe ES to the Niobe II

Methods

A total of 92 consecutive AF patients were included in the Niobe ES (71% Paroxysmal) and 92 consecutive patients in the Niobe II group (60% Paroxysmal). 1^o endpoint was PVI confirmation. Also measured was total procedure duration, fluoro exposure, mapping and RF delivery.

Conclusions

100% acute success for PVI in both groups and approximately 30% significant reductions in procedure and fluoroscopy times in the Niobe ES group.



Niobe ES had significantly lower fluoroscopy and procedure times than the Niobe II.



Current STXS Research

- MAGNETIC VT, NCT02637947
 - Large population (386), RCT
 - 15 sites spanning the globe
 - ischemic cardiomyopathy with LVEF of $\leq 35\%$
- Magnetic Ablation Index – MAI (Pre-clinical)
 - Validation
 - Supporting Data for FDA submission
- Early stage discussions

MAGNETIC-VT Study



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Study Advisory Committees

- Independent clinical event and data safety committees will adjudicate adverse events and provide oversight and monitoring of the study progress
- Study Steering Committee will provide expertise on the study protocol, execution and publication of the study results. Members will include: Dr. Andrea Natale, Dr. Roderick Tung, Dr. Tamas Szili-Torok, Dr. Luigi Di Biase, and Ken Lock (Stereotaxis, Inc.)



Dr. Andrea Natale



Dr. Roderick Tung



Dr. Tamas Szili-Torok



Dr. Luigi Di Biase



Participating Centers

***Pramesh Kovoor, MD**
Westmead Hospital, AUS



Andrea Natale, MD
St. David's Medical Center, USA
Roderick Tung, MD
The University of Chicago Medicine, USA
Adam Berman, MD
Georgia Health Sciences University, USA
Dhanunjaya Lakkireddy, MD
The University of Kansas Hospital, USA
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ZNA Middelheim, Belgium
***Muchtiar Khan MD**
OLVG, Netherlands
***Christian de Chillou**
CHRU Nancy, France

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External Research*

- **MRICEMAN**, NCT02639793, Helsinki University (not recruiting)
(RMN, Cryo, MAN)
- Manual Compared to Magnetic Navigation in Ablation for Atrial Fibrillation, NCT01407588, St. Olavs Hospital (ongoing not recruiting)
- **MAGNA** Magnetic Navigation for Contrast and Radiation Reduction, NCT01276808, Onze Lieve Vrouwe Gasthuis (recruiting)
- **MAGMA-AVNRT** Magnetically Navigated vs. Manually Guided Radiofrequency in Atrioventricular-node-reentry-tachycardia, NCT00875914, Deutsches Herzzentrum München (completed)
- **MAGNA-AF** Remote MAGNetic Catheter Ablation for Atrial Fibrillation, NCT02587624, Paracelsus Medical University (recruiting)
- **RAS** Radiofrequency Ablation of Symptomatic Frequent Ventricular Premature Complexes in Pediatric Population, NCT02772354, N.I. Pirogov Russian National Research Medical University (recruiting)



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CURRENT / FUTURE MN FEATURES

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From Remote to Automated

Investing in New Software Developments to Help Fulfill Promise of Complete Automation

Stereotaxis has pioneered a path with Niobe Epoch enabling **fully remote capability** bringing numerous benefits to physicians/patients. We continue to invest to enhance the 'Stereotaxis experience' for physicians as we strive to reach our goal of **fully remote automation**, and here are some recent advancements:

Ablation History

Unique, real-time cardiac mapping application displays integrated history of ablation catheter's power output and time at locations accessed during Niobe procedure

Navigant™

Navigant™ user interface includes enhancements to the Ablation History module that are designed to improve accuracy by compensating for movement during the respiratory cycle

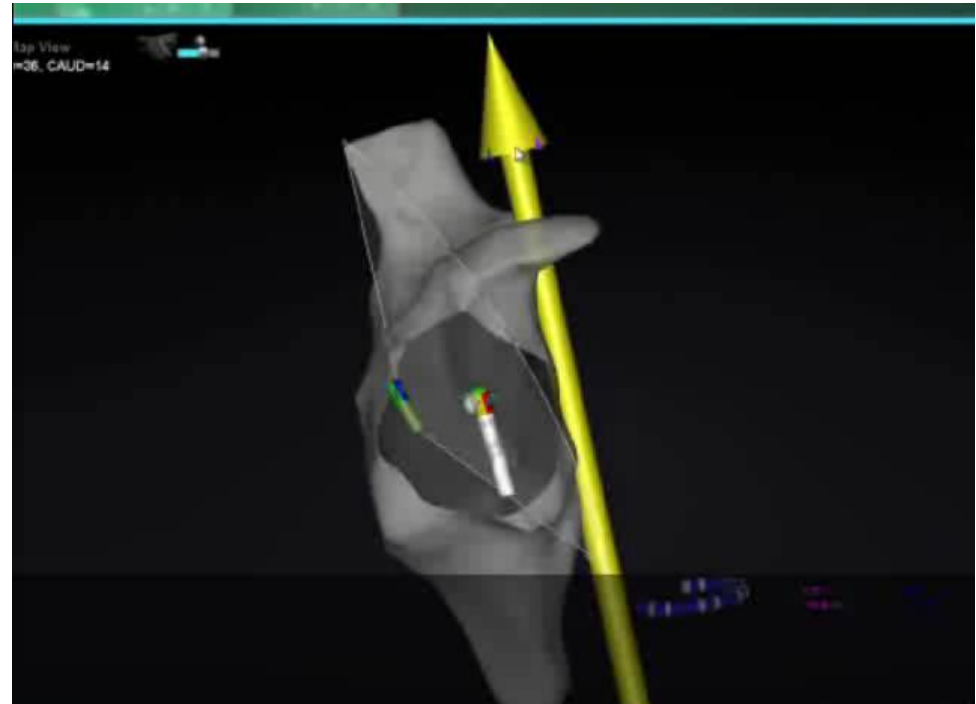
Vmotion™ Automation

Vmotion™ Automation features improve operator efficiency by providing automatic orientation of an Intracardiac Echocardiography (ICE) catheter offering a continuous view of the ablation catheter



Contact Detection

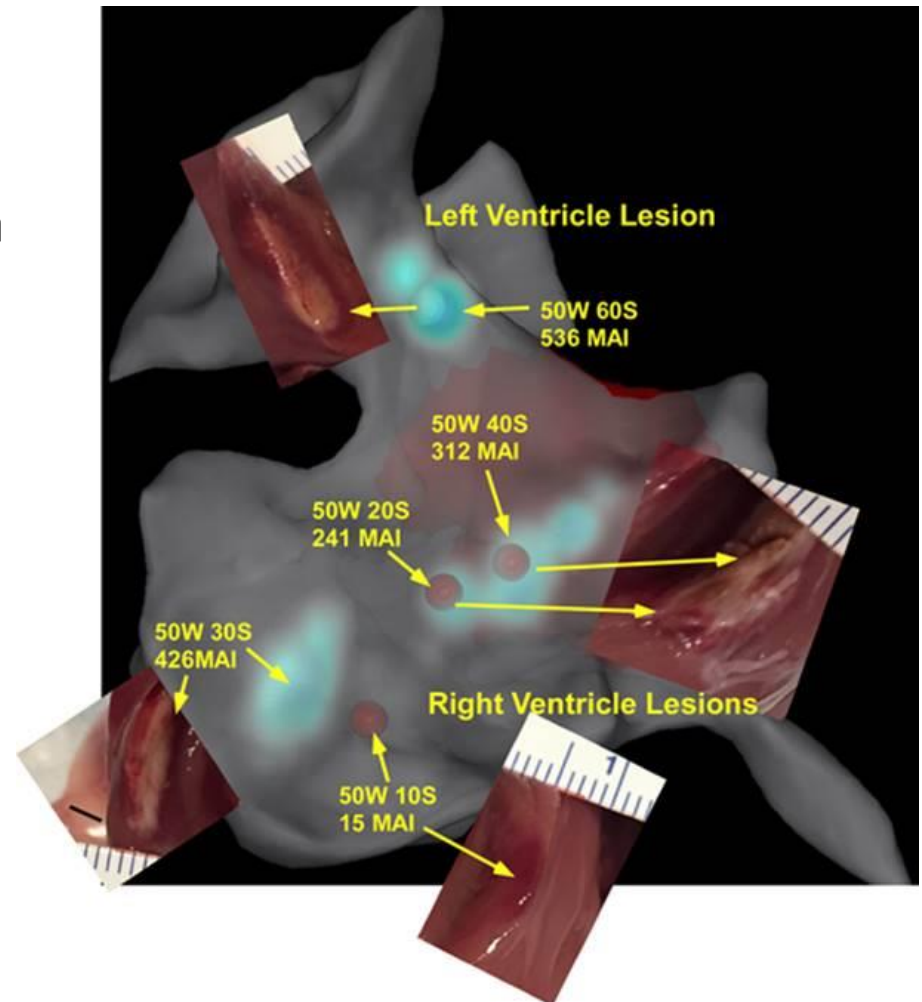
- Detect tissue contact using bipolar impedance
- Display as a binary Yes/No indication
- Information will be integrated into other aspects of the system
 - Energy delivery tracking (Ablation History)
 - Automations





Magnetic Ablation Index

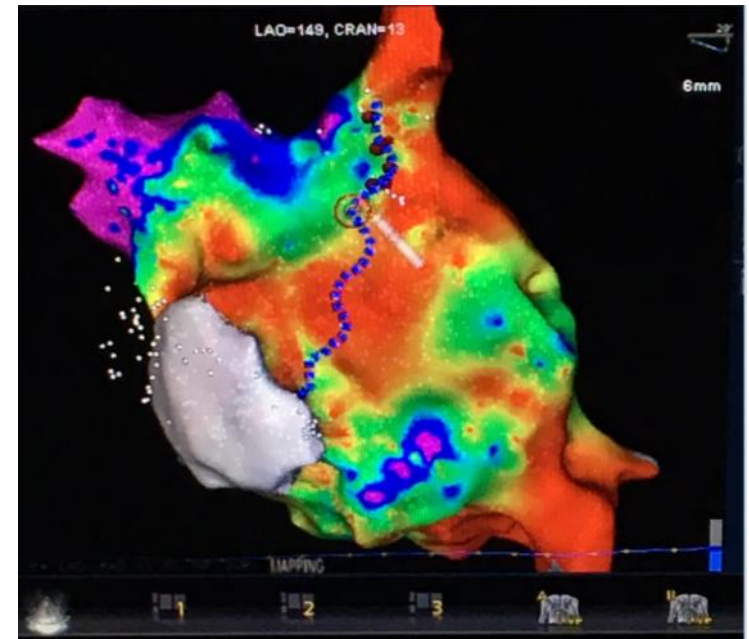
- Modification of Ablation History based on Contact Detection and Prof. Nakagawa lesion study data
- Modeled to more closely match the biophysics of lesion creation
- Good correspondence between lesion model and excised animal heart lesions





AutoAblate

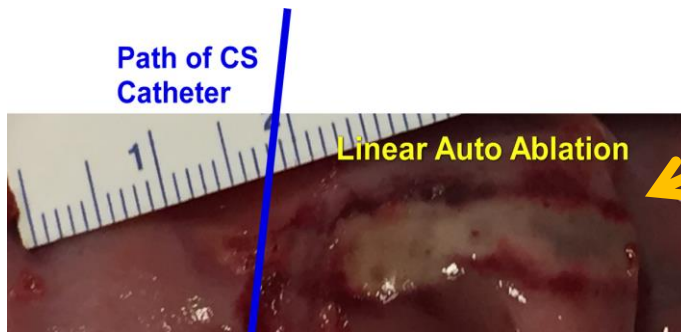
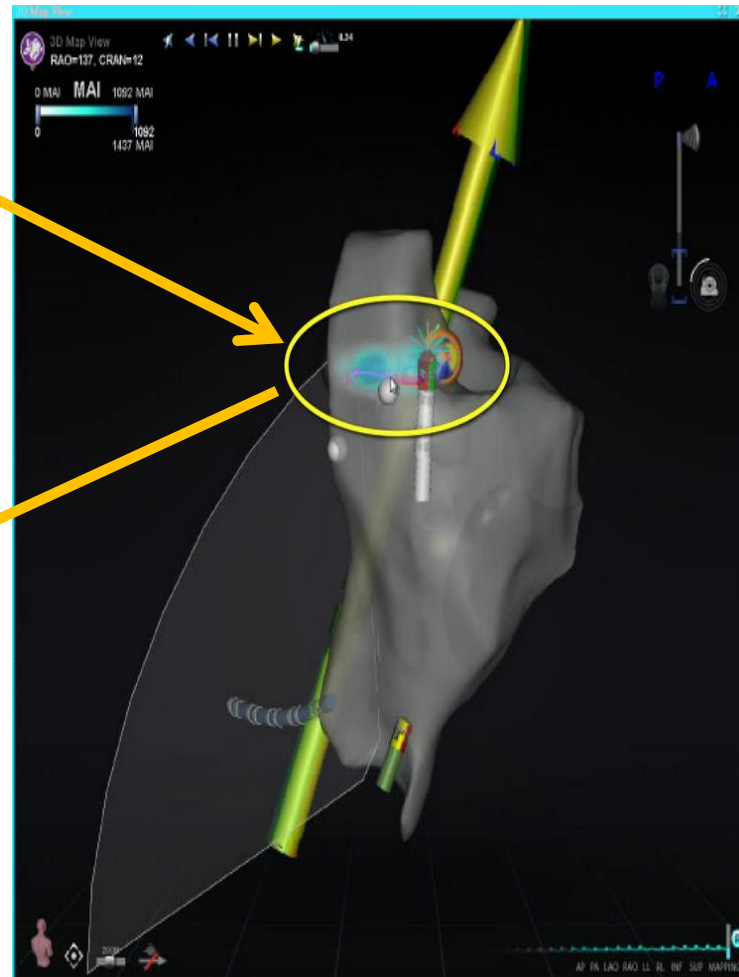
- Automatically execute the physician defined ablation strategy when RF energy is being delivered
- Integrate the features previously described
 - Contact indicator = control energy delivery tracking
 - MAI = physician defined localized endpoint





AutoAblate Example

MAI representation of lesion line



Excised heart showing lesion line



Looking Forward

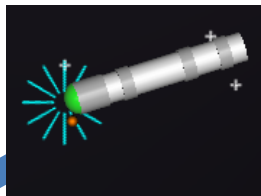
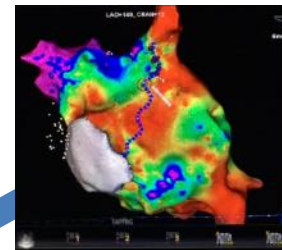
Auto Ablate

- Computer controlled catheter movement during RF delivery

Fully automated execution of physician defined ablation strategies

Contact Indicator

- Reduce anatomic interpolation error
- Enhance automation algorithms
- Refine lesion prediction



Magnetic Ablation Index

- Correlates to lesion formation
- Key part of defining an ablation strategy

On-going Automation Enhancements



Future Outlook

Build a 3 year research and publication strategy pipeline

- Proactively seek collaborations and partnerships for new research
- Enable multicenter collaborations
- Provide STXS Research Grants
- Provide publication support

STXS Clinical Affairs:

- Ken Lock, Sr. Clinical Director
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**EFFICIENCY ESTABLISHED.
OUTCOMES PROVEN.
SAFETY UNDOUBTED.**

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