Review of current clinical research projects involving magnetic navigation systems

Dr. Paul Brathwaite
VP of Research and Development
Stereotaxis, Inc.
Evolution of Robotic EP Technology

History of Innovation Firsts

- 2000: TELSTAR ELECTROMAGNETIC NAVIGATION
- 2003: NIOBE I 2ND GENERATION MAGNETIC NAV
- 2005: NIOBE II 3RD GENERATION MAGNETIC NAV
- 2007: ODYSSEY LAB INFORMATION MANAGEMENT
- 2010: VDRIVE ROBOTIC NAVIGATION
- 2011: NIOBE ES 4TH GENERATION MAGNETIC NAV

14th Annual Winter Arrhythmia School
Collingwood, On
February 10-12, 2017
## Current Product Portfolio

<table>
<thead>
<tr>
<th>Niobe® ES</th>
<th>Odyssey®</th>
<th>Vdrive™</th>
<th>Disposables/Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only commercialized technology to precisely steer cardiac catheter tip using computer controlled, externally applied magnetic fields</td>
<td>Pioneering IT solution providing real-time data access and integration in interventional labs</td>
<td>One-of-a-kind system providing remote, mechanical manipulation of numerous disposable interventional devices for optimized use in Niobe lab</td>
<td>QuikCAS™ (proprietary, automated catheter advancement system) &amp; Vdrive disposables</td>
</tr>
</tbody>
</table>

**14th Annual Collingwood, Ontario, February 10-12, 2017**
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.
Stereotaxis Robotic Technology – Clinical Evidence

10x Safety Advantage for Stereotaxis Compared to Manual

- 200+ peer reviewed publications
- 94% acute success rate for ventricular tachycardia\(^2\)
- 92% acute success rate in congenital patients\(^3\)
- 90% less x-ray\(^4\)
- 81% freedom from A-fib at 18 months\(^5\)
- 49% less radiation exposure over physician career\(^6\)

2. Neuzil, et al., STOP-VT Multicenter trial, ESC 2011
4. Internal clinical data, HEART Study 2008
5. Pappone, et al., Heart Rhythm 2010
Clinical Science

• Past Clinical Publications & Research
• Current Research
• Future Research and Opportunities
### 3-year Clinical Publication History

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
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<tbody>
<tr>
<td>Case Studies/Series</td>
<td>5</td>
<td>3</td>
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<td>Reviews</td>
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<tr>
<td>Randomized Control Trials</td>
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<td>0</td>
<td>2 (VERSATILE &amp; RMN guidewire)</td>
<td>1 (MAGNETIC-VT Protocol)</td>
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<td>Prospective (registry,</td>
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<td>ctrl etc.)</td>
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<td>Retrospective (registry,</td>
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<tr>
<td>Mentioned in “Methods”</td>
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<td><strong>Total</strong></td>
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### Indication

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<th>2014</th>
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<tbody>
<tr>
<td>AF/AFL/CLA*</td>
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<td>6</td>
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<tr>
<td>VT/VA*</td>
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<tr>
<td>Other* (SHD, CHD, SVT etc.)</td>
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</table>
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 cm² undergoing scar homogenization with either RMN (n=138) or manual (n=80) ablation.

Chronic Success Rates

RMN ablation in patients with IC and a scar size greater than 60 cm² have a significantly higher success rate than manual approach.

**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). 1º 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 ≤35%

• Magnetic Ablation Index – MAI (Pre-clinical)
  – Validation
  – Supporting Data for FDA submission

• Early stage discussions
MAGNETIC-VT Study

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.)

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 Lakireddy, MD
The University of Kansas Hospital, USA

J. Peter Weiss, MD
Intermountain Medical Center, USA

William Spear, MD
Advocate Christ Medical Center, USA

*Jim Cheung, MD
NY Pres./Cornell, 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

Bruno Schwagten MD, PhD
ZNA Middelheim, Belgium

*Muchtiar Khan MD
OLVG, Netherlands

*Christian de Chillou
CHRU Nancy, France
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)

* found on clinicaltrials.gov
CURRENT / FUTURE MN FEATURES
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

Path of CS Catheter

Linear Auto Ablation

Excised heart showing lesion line
Looking Forward

Auto Ablate
- Computer controlled catheter movement during RF delivery

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

Fully automated execution of physician defined ablation strategies

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
  • ken.lock@stereotaxis.com
– Dustie Butteiger, Mngr. Research and Clinical Affairs
  • dustie.butteiger@stereotaxis.com
– Taylor Tso, CRA
  • taylor.tso@stereotaxis.com
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OUTCOMES PROVEN.
SAFETY UNDOUBTED.