Robotic Magnetic Navigation: Focus on VT and the Future of EP

A Return to First Principles

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Disclosures

A. Consulting Fees/Honoraria:
Stereotaxis Inc., Biosense Webster Inc., St. Jude Medical/Abbott Inc.,

B. Equity Interests/Stock Options - Non-Public:
Talon Surgical Inc., Acutus Medical Inc.

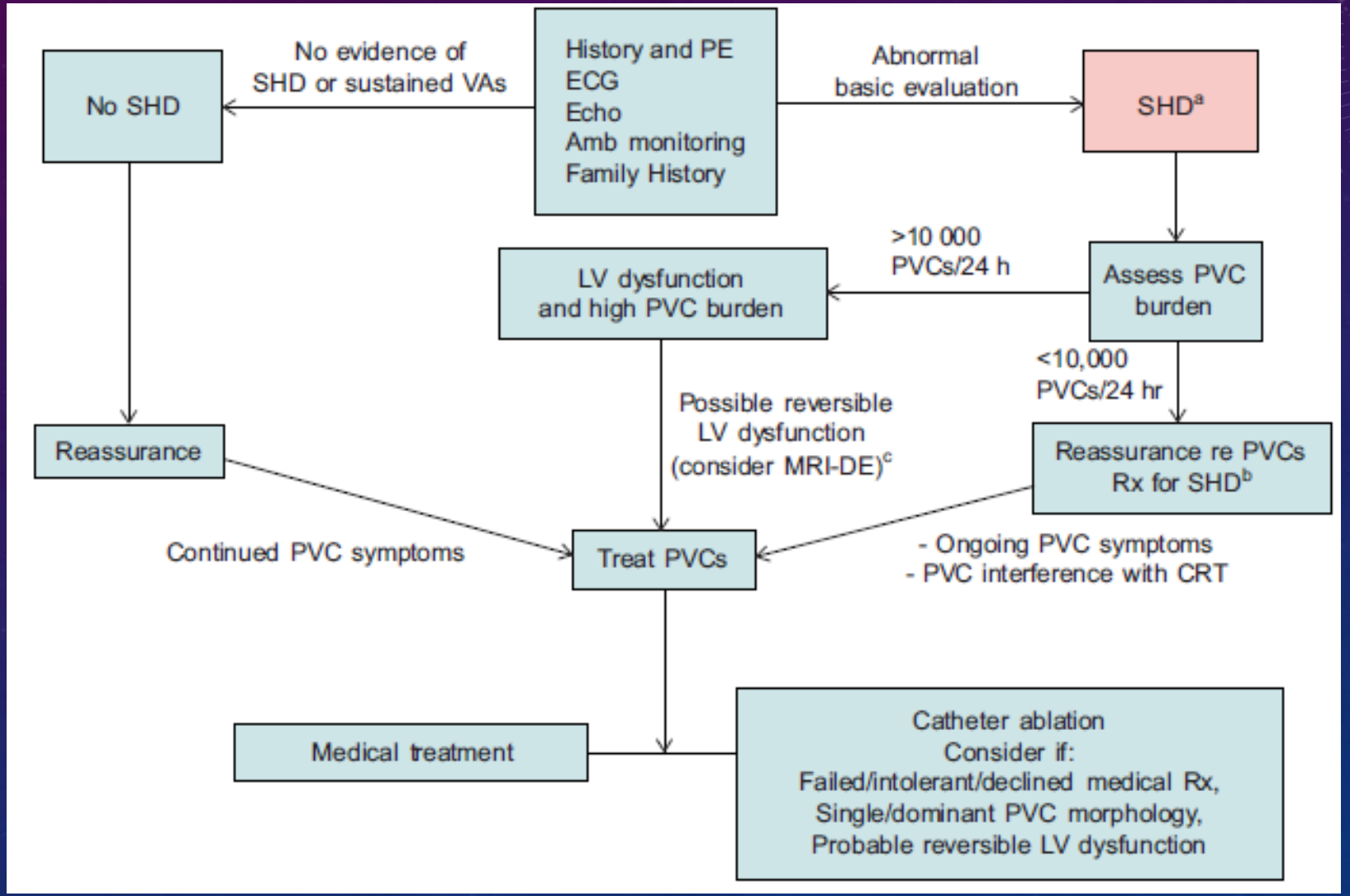
C. Officer, Trustee, Director, Committee Chair, or Any Other Fiduciary Role:
Board Member, Society for Cardiac Robotic Navigation

MEET DAN MARTIN

- Lamin A/C gene (LMNA) associated cardiomyopathy
- 7 years of arrhythmia management in conjunction with heart failure management
- 3 Ablations for Afib leading to eventual AVN ablation and CRT-D
- 4 ablations for ventricular arrhythmias including Sustained VT and PVCs
  - 2 procedures involving percutaneous epicardial mapping and ablation
  - 1 procedure involving intracoronary ethanol infusion
- Managed until Heart Transplant

EHRA/HRS/APHRS EXPERT CONSENSUS ON VENTRICULAR ARRHYTHMIAS

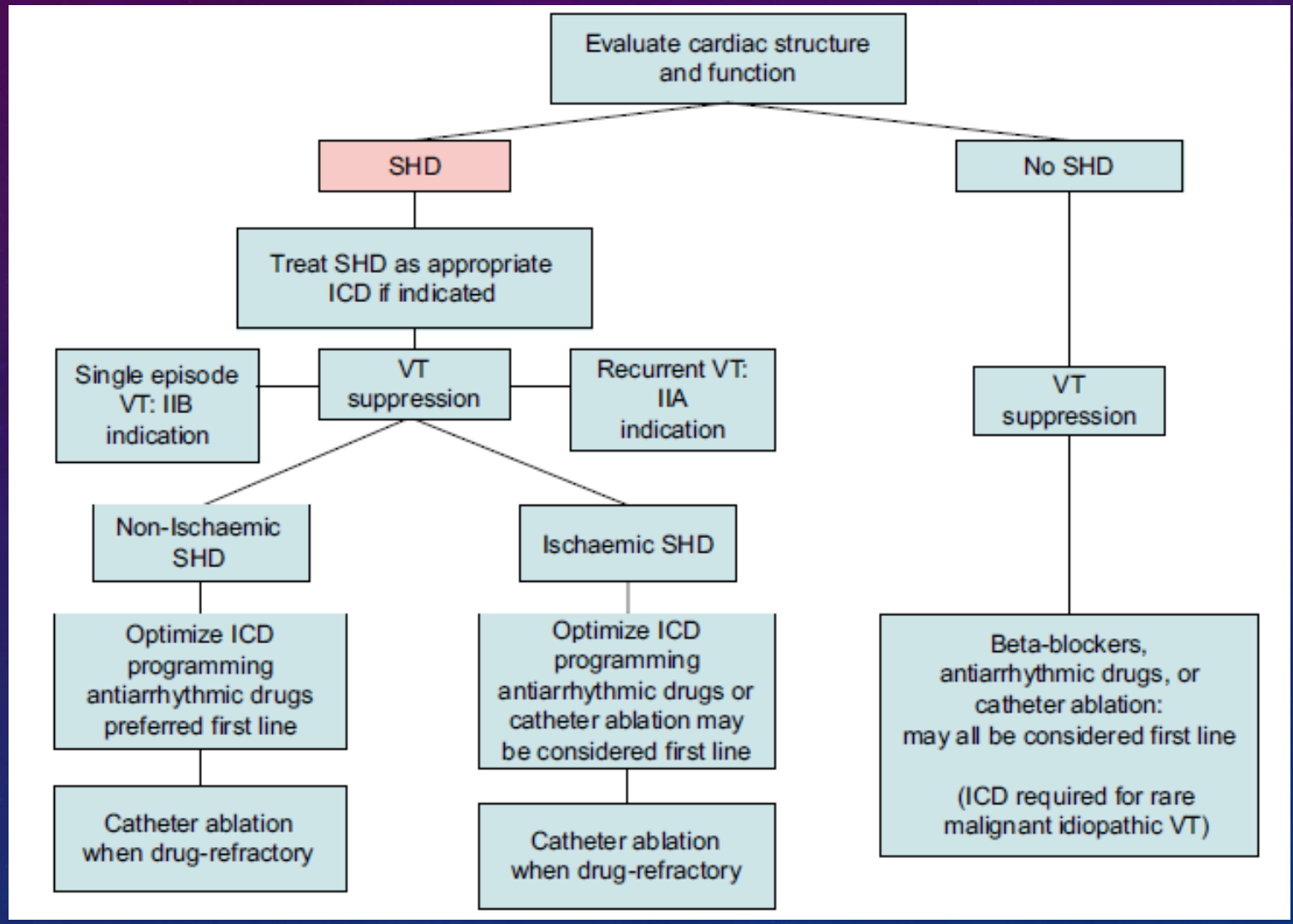
Figure 1 Management of PVCs.



Heart Rhythm, Vol 11, No 10, October 2014

EHRA/HRS/APHRS EXPERT CONSENSUS ON VENTRICULAR ARRHYTHMIAS

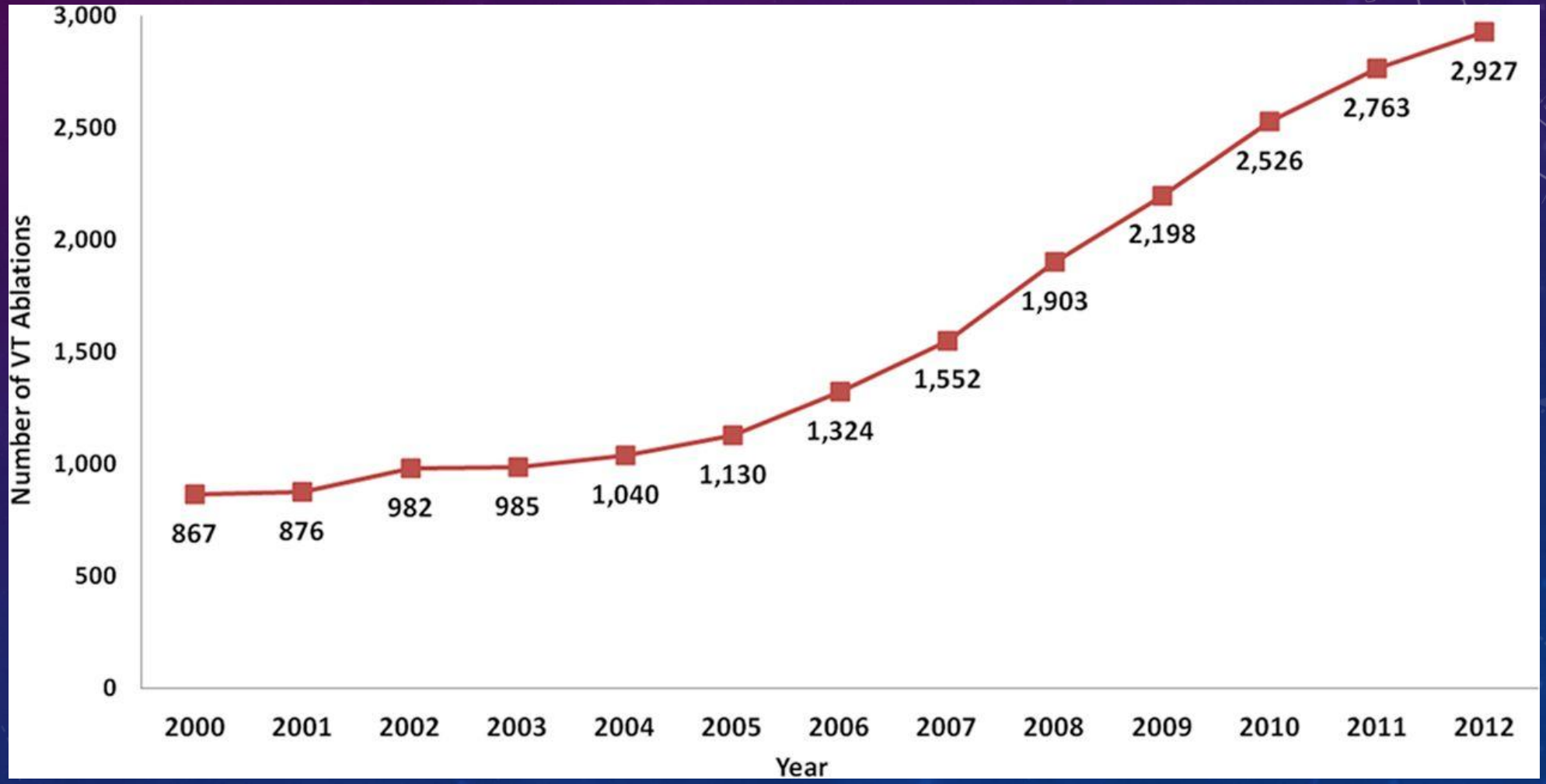
Figure 5 Sustained monomorphic ventricular tachycardia evaluation and management



Heart Rhythm, Vol 11, No 10, October 2014

TRENDS AND OUTCOMES OF CATHETER ABLATION FOR VENTRICULAR TACHYCARDIA IN A COMMUNITY COHORT

Omair K. Yousuf, Robbert Zusterzeel, William Sanders, Daniel Caños, Carmen Dekmezian, Henry Silverman, Hugh Calkins, Ronald Berger, Harikrishna Tandri, Saman Nazarian and David G. Strauss



JACC: Clinical Electrophysiology Volume 4, Issue 9, September 2018 DOI: 10.1016/j.jacep.2018.06.020

VENTRICULAR ARRHYTHMIA PROGRAM KEYS

- Broad Skillset
  - Ventricular tachycardia in structural and idiopathic CM
  - PVCs as adjunctive for CHF management and patient symptoms
  - Strong team: Anesthesia, Lab Staff, Interventional/surgical providers, Heart Failure Specialists, Cardiac Imaging
  - Percutaneous epicardial access, mapping and ablation
  - Appropriate use of percutaneous circulatory support (now very rare)

- Buy-In of Referring Providers:
  - Currently approximately 15% of our ablation procedures at Intermountain
  - Personally approximately 30%
  - Highly integrated with Heart Failure Program
  - Regional referrals, including from other EPs
    - Idaho, Wyoming, Nevada, Arizona, Oregon

- Halo Effect
  - Broad awareness tracks referrals for complex coronary and structural interventions and advanced therapies for heart failure

THE INTERNATIONAL VT ABLATION CENTER COLLABORATIVE GROUP (IVTCC)

- 12 International VT Ablation Centers
- 2,061 patients retrospectively analyzed in centralized database

Brigham and Women's Hospital, Boston, MA

Dokkyo Medical University Koshigaya Hospital, Saitama, Japan

Intermountain Heart Institute, Intermountain Medical Center, Murray, UT

Hospital of the University of Pennsylvania; Philadelphia, PA:

Hospital San Raffaele, Milan, IT

St. Luke's Health System/Texas Heart Institute, Houston and University of Texas Health Science Center, Houston, TX

Texas Cardiac Arrhythmia Institute, St. David's Medical Center; Austin, TX

University of California, Los Angeles, Cardiac Arrhythmia Center, Los Angeles, CA

University of Kansas Medical Center, Kansas City, KS

University of Colorado, Aurora, CO

University of Maryland Medical Center, Baltimore, MD

University of Minnesota Medical Center, Minneapolis VA Medical Center, Minneapolis, MN

IVTCC MAJOR PUBLICATIONS

1. Tung R, et al. Freedom from recurrent ventricular tachycardia after catheter ablation is associated with improved survival in patients with structural heart disease: An International VT Ablation Center Collaborative Group study. *Heart Rhythm. 2015;*12(9):1997-2007.

2. Frankel DS et al . Sex and Catheter Ablation for Ventricular Tachycardia: An International Ventricular Tachycardia Ablation Center Collaborative Group Study. *JAMA Cardiol*. 2016;1(8):938-44..

3. Santangeli P, et al, International VTACCG. Early Mortality After Catheter Ablation of Ventricular Tachycardia in Patients With Structural Heart Disease. *J Am Coll Cardiol. 2017*;69(17):2105-15.

4. Turagam MK, et al. Hemodynamic Support in Ventricular Tachycardia Ablation: An International VT Ablation Center Collaborative Group Study. *JACC Clin Electrophysiol. 2017*;3(13):1534-43.

5. Tzou WS et al. Outcomes after repeat ablation of ventricular tachycardia in structural heart disease: An analysis from the International VT Ablation Center Collaborative Group. *Heart Rhythm. 2017*;14(7):991-7.

6. Tzou WS,et al. Ventricular Tachycardia Ablation in Severe Heart Failure: An International Ventricular Tachycardia Ablation Center Collaboration Analysis. *Circ Arrhythm Electrophysiol. 2017*;10(1).

7. Vakil K et al . Ventricular Tachycardia Ablation in the Elderly: An International Ventricular Tachycardia Center Collaborative Group Analysis. *Circ Arrhythm Electrophysiol. 2017*;10(12).

8. Vaseghi M, et al. Outcomes of Catheter Ablation of Ventricular Tachycardia Based on Etiology in Nonischemic Heart Disease: An International Ventricular Tachycardia Ablation Center Collaborative Study. *JACC Clin Electrophysiol. 2018*;4(9):1141-50.

9. Vergara P, et al. Successful ventricular tachycardia ablation in patients with electrical storm reduces recurrences and improves survival. *Heart Rhythm. 2018*;15(1):48-55.

10. Vergara P, et al. Predictive Score for Identifying Survival and Recurrence Risk Profiles in Patients Undergoing Ventricular Tachycardia Ablation. *Circ Arrhythm Electrophysiol. 2018*;11(12):e006730.

DAN MARTIN: POST TRANSPLANT

Demonstrated ability to care for these patients creates community, regional, national awareness as a CV Center of Excellence

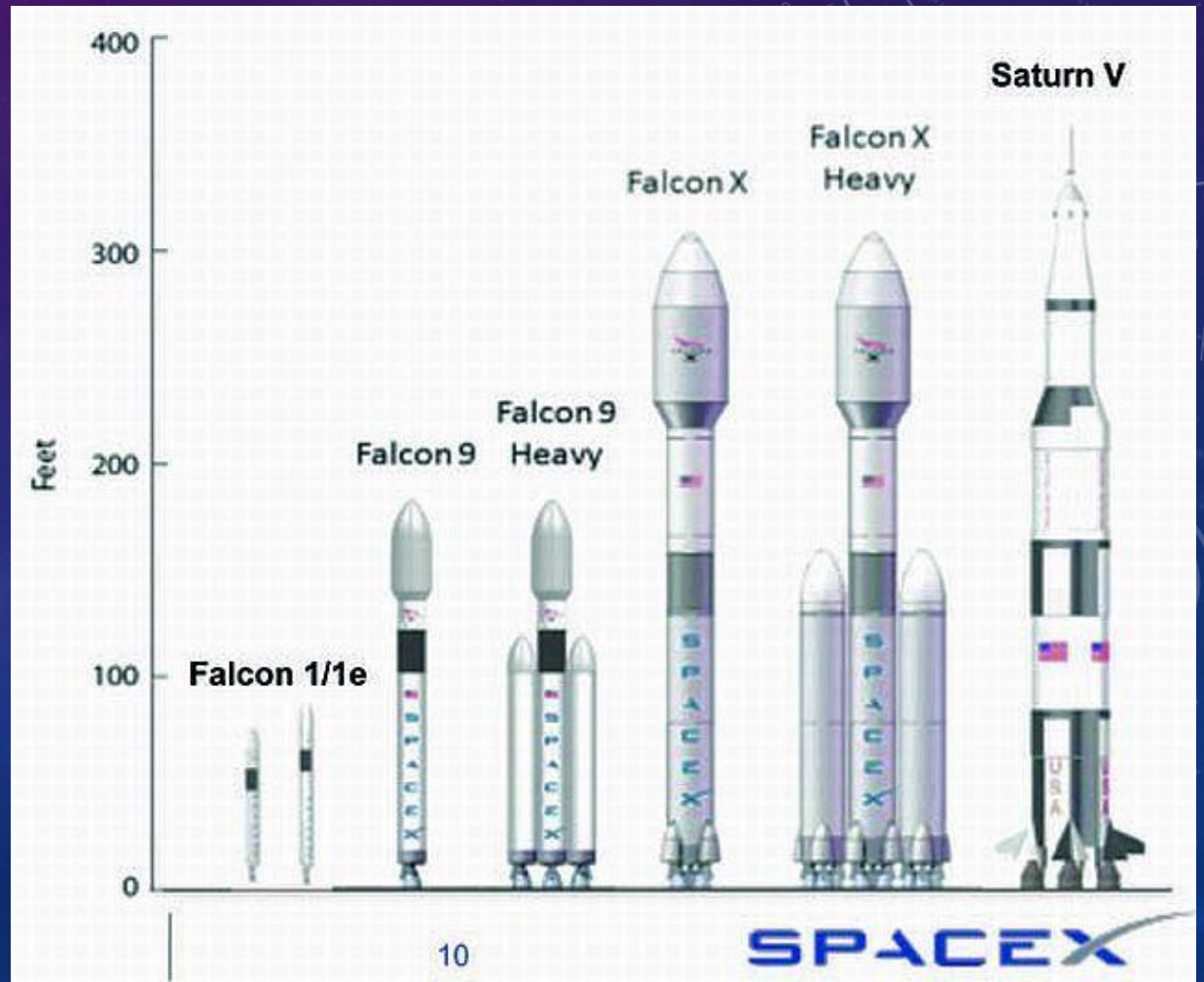
What are the technologies that enable this important work?

THE OBJECTIVE: CHANGE HUMANITY BY GOING TO MARS

THE OBJECTIVE: MARS

- The Falcon Heavy of SpaceX is a significant advance, but is a clear evolution from long existing technology

Recall that the Saturn V Rocket system, larger and more powerful than the Falcon Heavy, took humans to the moon 50 years ago.



THE PARADIGM SHIFT

THIS is the Revolution in space flight:
Reusability creates the economics for success

ELON MUSK: TED TALK

"Well, I do think there's a good framework for thinking. It is physics…first principles reasoning….boil things down to their fundamental truths and reason up from there, as opposed to reasoning by analogy…which essentially means copying what other people do with slight variations."

https://mayooshin.com/first-principles-thinking/

FUNDAMENTAL PRINCIPLES

- Optimal Patient Outcomes
  - **Safety**
    - Risk of collateral damage (perforation, esophagus etc..)
    - X Ray Exposure
    - Time under sedation/anesthesia
  - **Efficacy**
    - Ablation lesion quality
    - Accurate Navigation
    - Optimized Mapping
    - Enhanced Understanding of Underlying Mechanisms

FUNDAMENTAL PRINCIPLES

- Optimal Process
  - **Operators**
    - Time of procedure including setup
    - Facilitation of rapid/accurate mapping and ablation
    - Minimize fatigue and operator injury
  - **System**
    - Cost
    - Integration with associated technology
    - Platform flexibility for future innovation

ASSUMPTIONS ABOUT MAPPING AND ABLATION (A FEW OF MANY…)

- Human hands must direct catheter movement in the heart: “Feel”
- We must know the contact force in order to perform effective mapping and RF ablation
- There must be a trade off between high density EP mapping and high accuracy anatomical mapping with real-time, full chamber mapping
- Remote/Robotic technologies can be evaluated as a whole when compared with manual technologies
- Robotic procedures in EP will remain time consuming, expensive, and not proven to be better than what can be done now

Improvements to our current systems continue to build upon the platform of stiff pull-wire catheters and limited zone mapping

The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study

Vivek Y. Reddy, MD,* Dipen Shah, MD, FHRS,† Josef Kautzner, MD,‡ Boris Schmidt, MD,‡‡
Nadir Saoudi, MD, PhD, FHRS,§ Claudia Herrera, MD, Pierre Jaïs, MD, PhD,¶
Gerhard Hindricks, MD, PhD,# Petr Peichl, MD,‡ Aude Yulzari, MS,** Hendrik Lambert, PhD,**
Petr Neuzil, MD, PhD,†† Andrea Natale, MD, PhD, FHRS,‡‡ Karl-Heinz Kuck, MD, PhD, FHRS§§

CONCLUSIONS:

- CF during catheter ablation for AF correlates with clinical outcome.
- Arrhythmia control is best achieved when ablation lesions are placed with an average CF of 20 g
- Clinical failure is universally noted with an average CF of 10 g.

Contact force sensing catheters now standard for manual ablation procedures

Heart Rhythm 2012;9:1789 –1795

WIDE VARIATION IN CONTACT FORCES DURING ABLATION

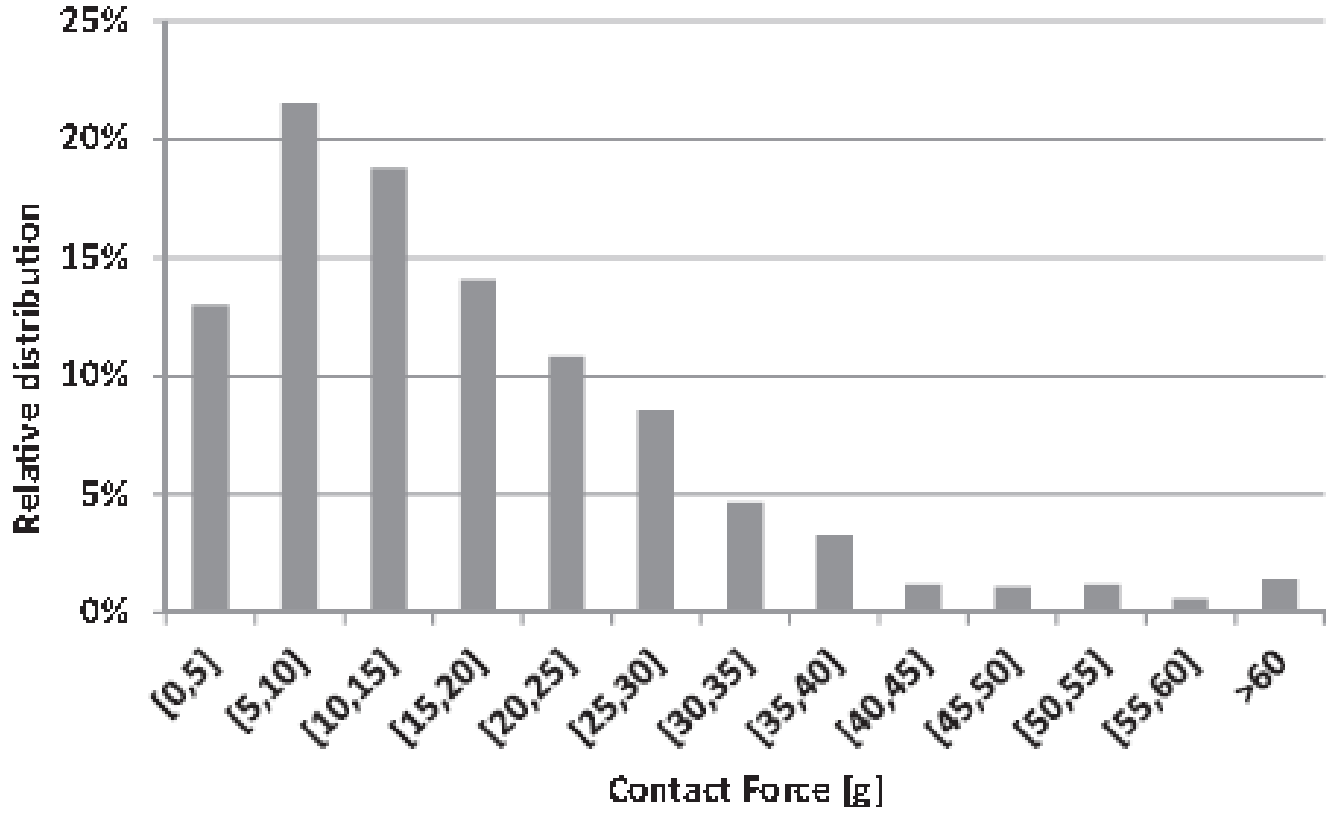
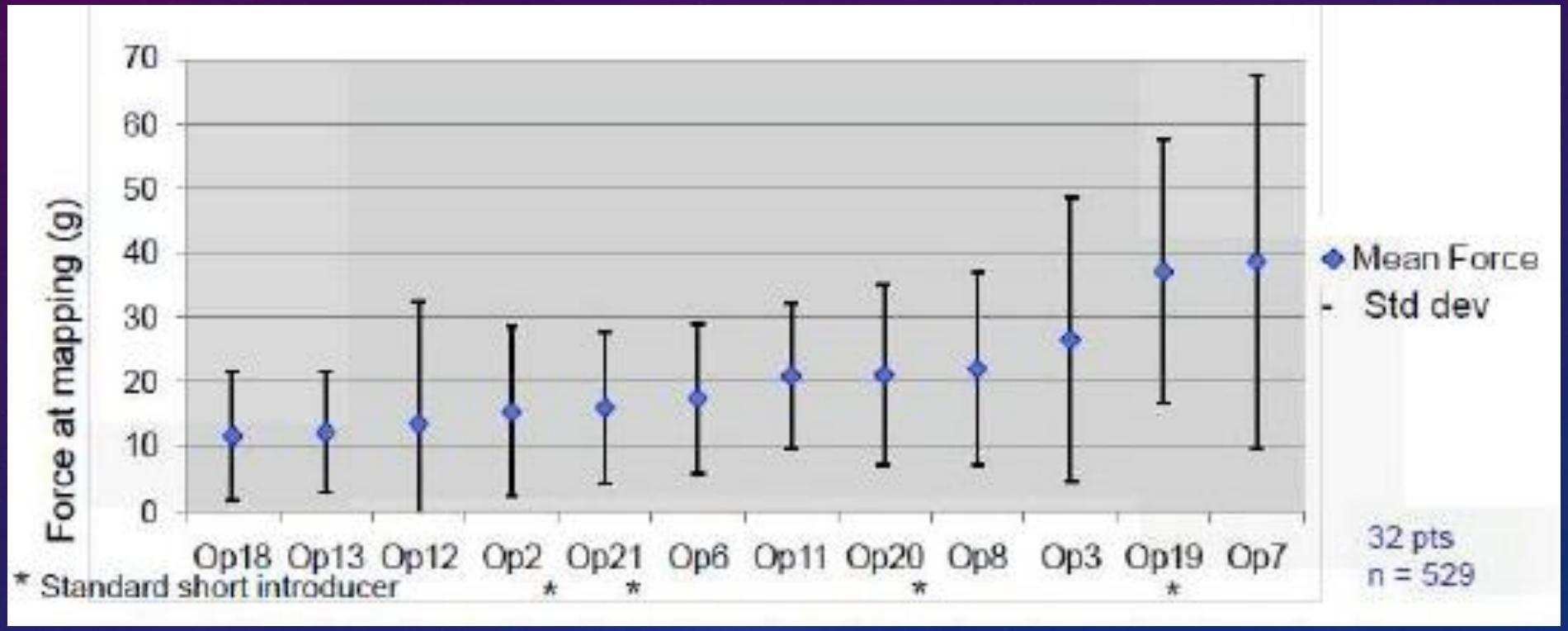


Figure 2 Relative distribution of the average contact force during ablation. Distribution of contact forces for 1017 antral pulmonary vein ablations in 34 patients.

Heart Rhythm 2012;9:1789 –1795

WITHIN OPERATOR VARIABILITY



Shah D, Toccata study, HRS 2009

CONTACT FORCE REALITY

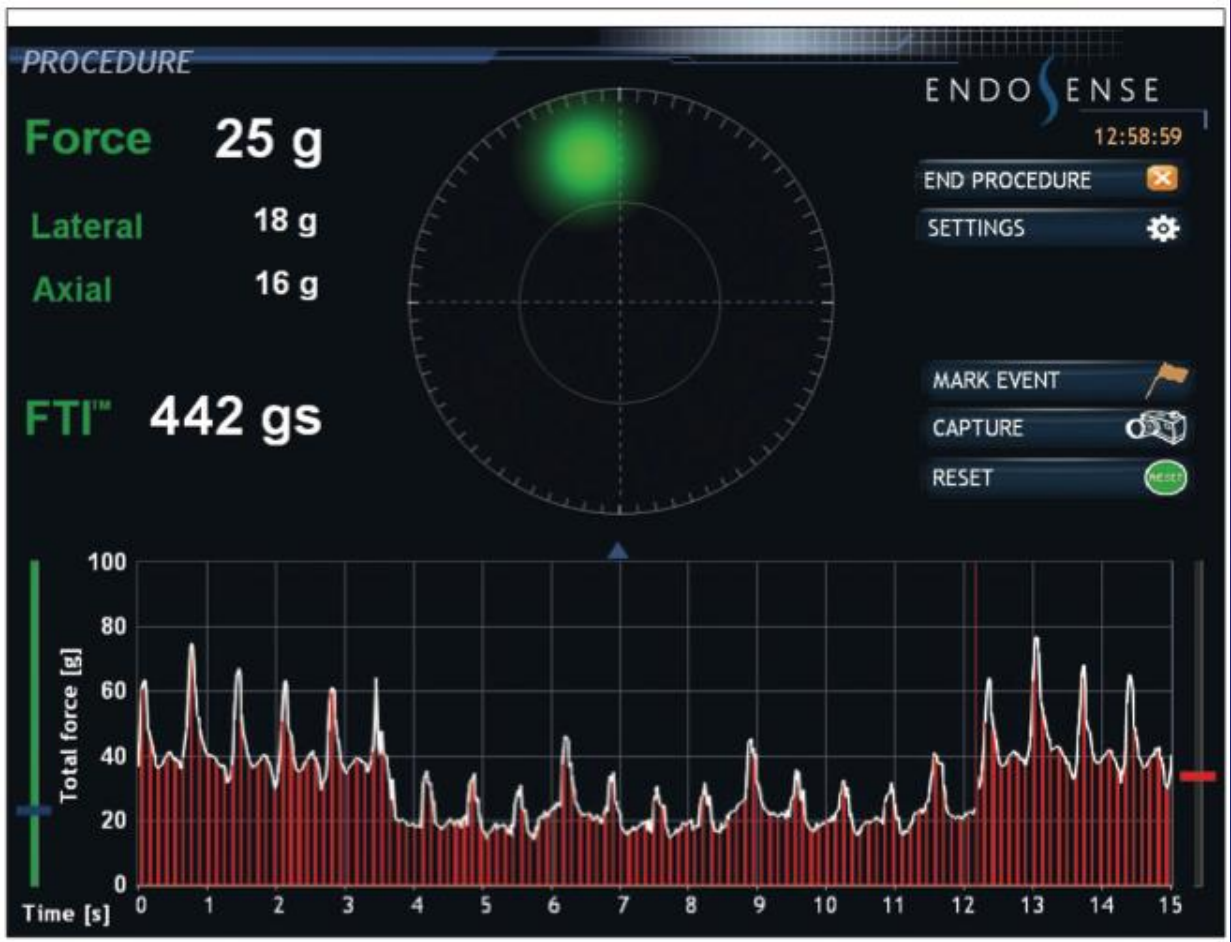
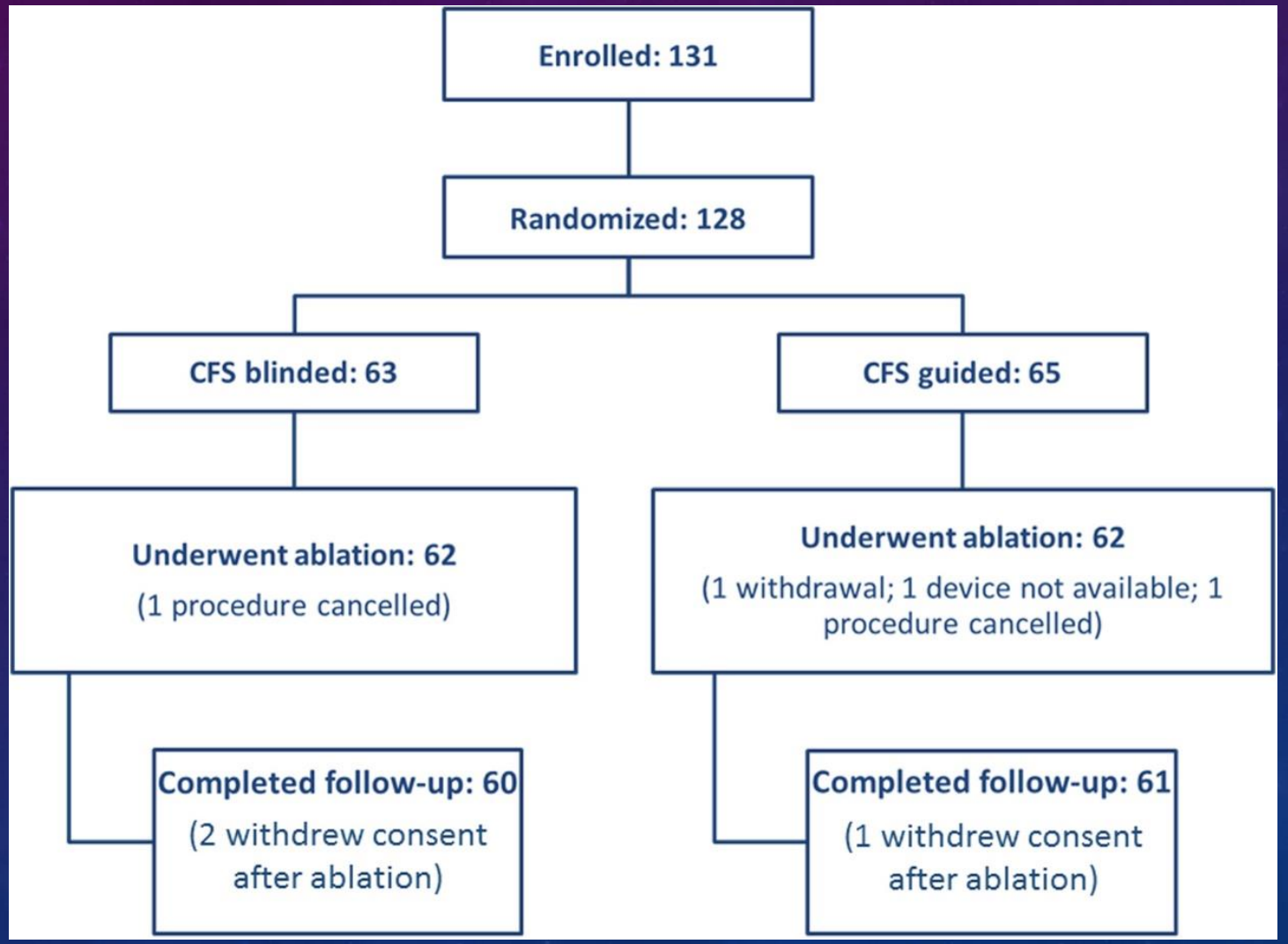


Figure 4: Display indicating the amplitude and direction of the contact force. The total forces are presented at the left side, indicating total force and lateral/axial force. FTI (force time integral) is displayed as well. Below is the curve indicating the total applied contact force over time.

Ferdi Akca and Tamas Szili-Torok, MD, PhD, EP Lab Digest, Volume 12 - Issue 8 - August 2012

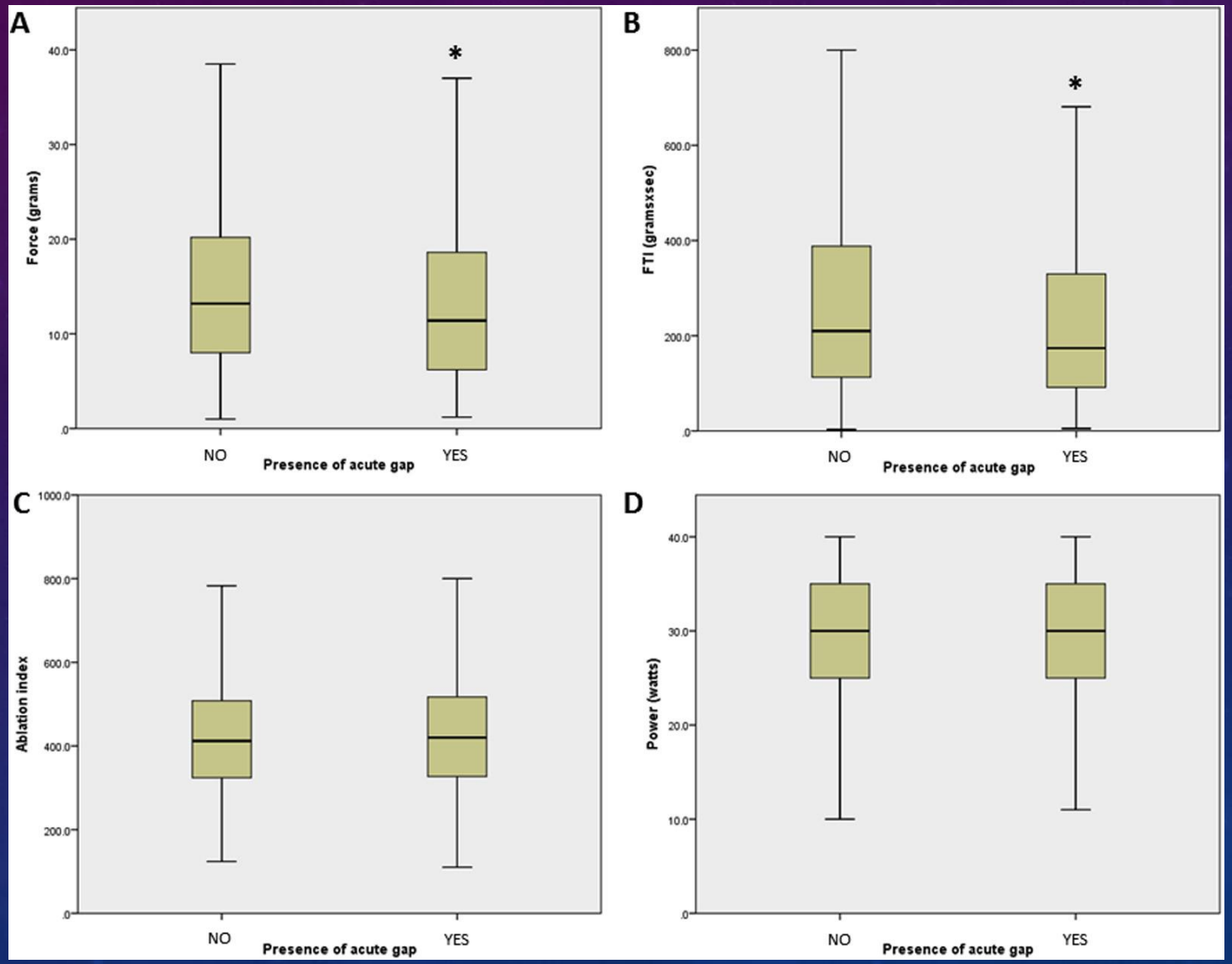
Contact force Sensing for Ablation of Persistent Atrial Fibrillation: A Randomized, Multicenter Trial

Sergio Conti, MD, Rukshen Weerasooriya, MBBS, Paul Novak, MD, Jean Champagne, MD, Hong Euy Lim, MD, Laurent Macle, MD, Yaariv Khaykin, MD, Alfredo Pantano, MD, Atul Verma, MD



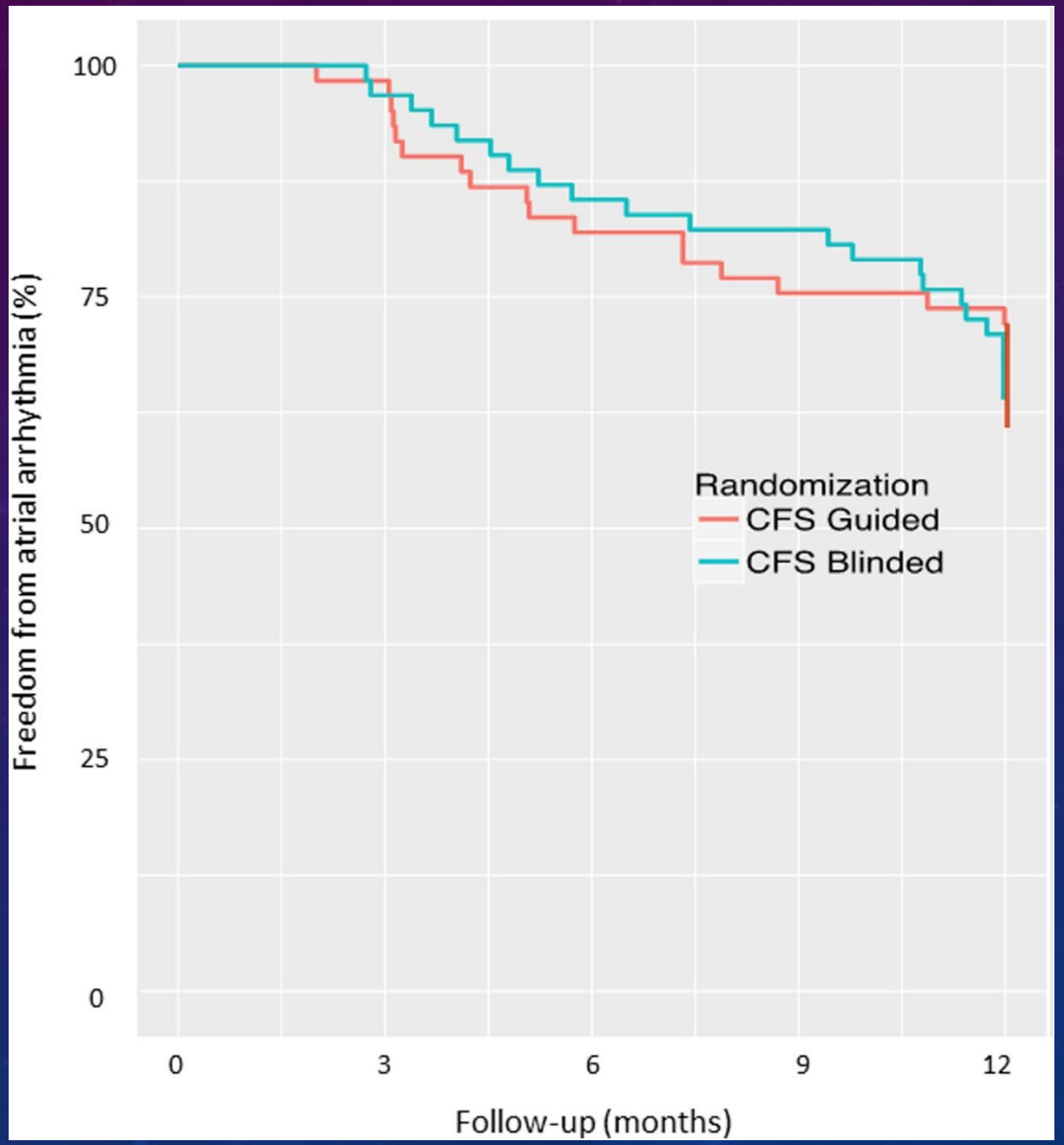
Heart Rhythm DOI: 10.1016/j.hrthm.2017.10.010

Box plots of force (panel A), force time integral or FTI (panel B), ablation index (panel C), and power (panel D) in pulmonary vein and roof line segments that had a conduction gap (YES) versus those that did not have a gap (NO).



Heart Rhythm DOI: (10.1016/j.hrthm.2017.10.010)

One Year Outcomes



Heart Rhythm DOI: (10.1016/j.hrthm.2017.10.010)

A VISUAL


Sharp
Tissue
FPS
Power
DDP
Depth
Dual Fo
Virtual
TDI
Up/Dow
Auto Tis
Color M
2
4
6
Depth
2D
-10 dB
Zoom

MY CONCLUSIONS

- Catheter “feel” in human hands is largely a myth and recent innovations such as contact force sensing inadequately compensate for the inherent limitations of a stiff pull-wire catheter used in a flexible, dynamic system

- These limitations, both in effectiveness and safety, are exacerbated by limited understanding and visualization of the target substrate and surrounding structures

REASONING BY ANALOGY:
ITERATION OF ACCEPTED ASSUMPTIONS AND TECHNOLOGY

What will bring our paradigm shifts??

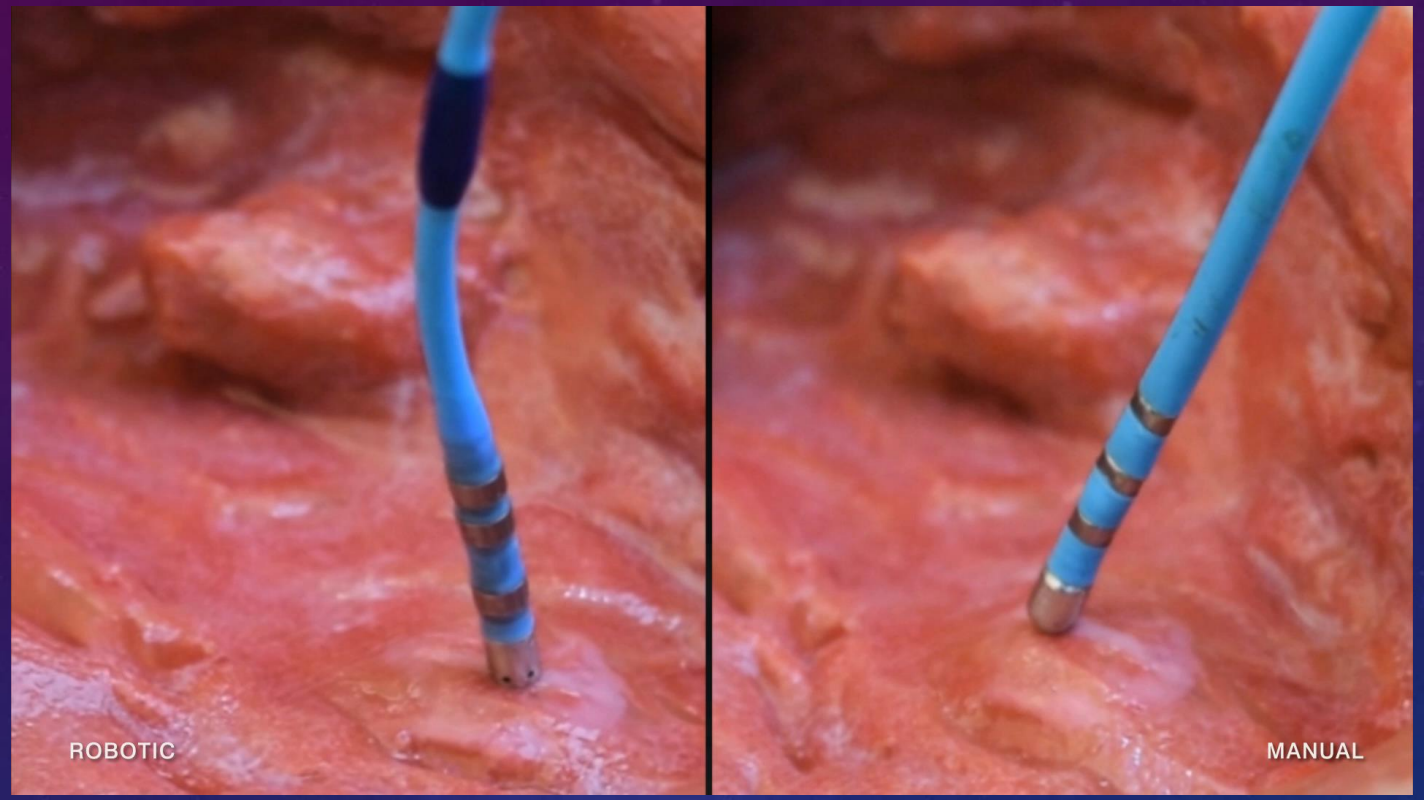
QUESTIONS

- Have we reached the biophysical limits of what can be done with manual pull-wire catheters?
- Can we improve the outcomes and experience for both patients and operators?
- Do remote technologies have the potential to move beyond?
- Will exploring these technologies lead us to a better future?
- Does it make sense to jump in now?

CURRENT APPROACHES TO REMOTE PROCEDURES

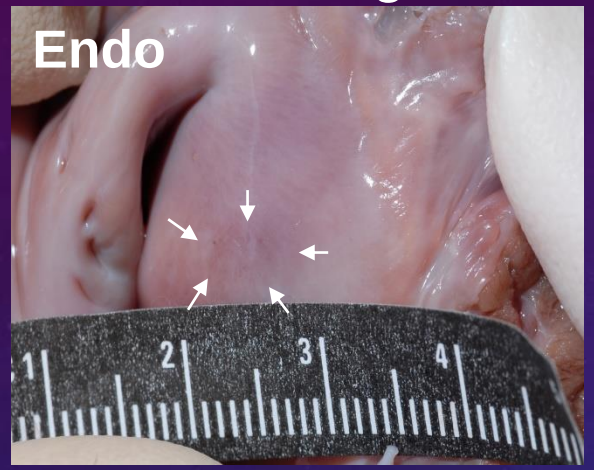
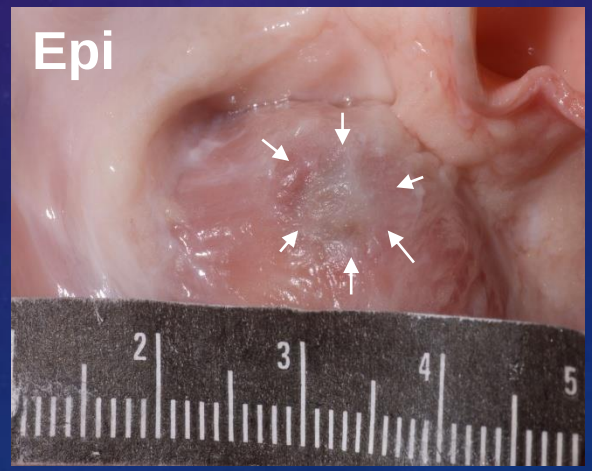
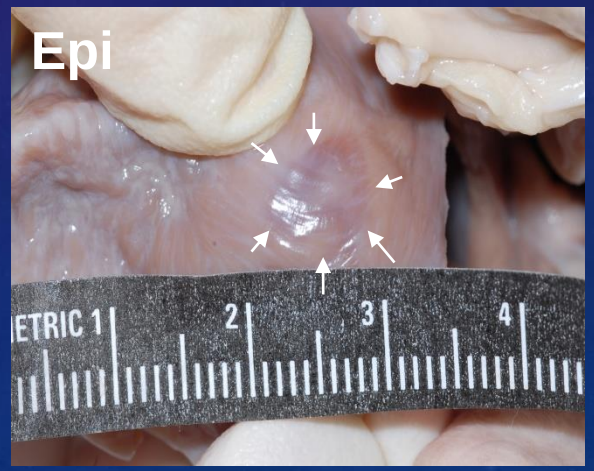
- Remote manipulation of existing tools and novel tools requiring advanced control systems
  - Rely on traditional “Pushing” biophysics
- Remote manipulation of novel tools (i.e. magnetic responsive catheters) based upon alternative biophysics with direct catheter tip control
  - Rely on “Pulling” biophysics
- Remote energy source (i.e. external beam radiation)
  - Limited currently to severe ventricular arrhythmia

ALTERNATE BIOPHYSICS OF MAGNETIC NAVIGATION



- Constant, stable, focal contact
- Safe movement
- Access to difficult anatomy

Impact of Measured Contact Force on Lesion Formation

Force < 10 grams	Force 10-20 grams	Force ≥ 20 grams
		
		
12/30 (40%) transmural	28/32 (88%) transmural	17/22 (72)% transmural

Courtesy T. Jared Bunch MD (porcine model, Mayo)

Comparison of Catheter Stability between Magnetically Guided and Manual Cooled-Tip Ablation Catheters

Karl-Heinz Kuck, MD et al. Heart Rhythm 2008;5(5):S225 (PO3-44)

- Compared mechanical behavior and lesions created between magnetic (RMT) and manual (CONV) cooled-tip ablation catheters in 2 clinically relevant bench models.
- Results from the Beating Heart phantom showed that RMT at 10g of contact force created equivalently sized lesions to CONV at 40g of force ($p > 0.05$).
- CONV stability was increased only by increasing applied force
- RMT achieved stability in the BH model at lower initial contact forces.

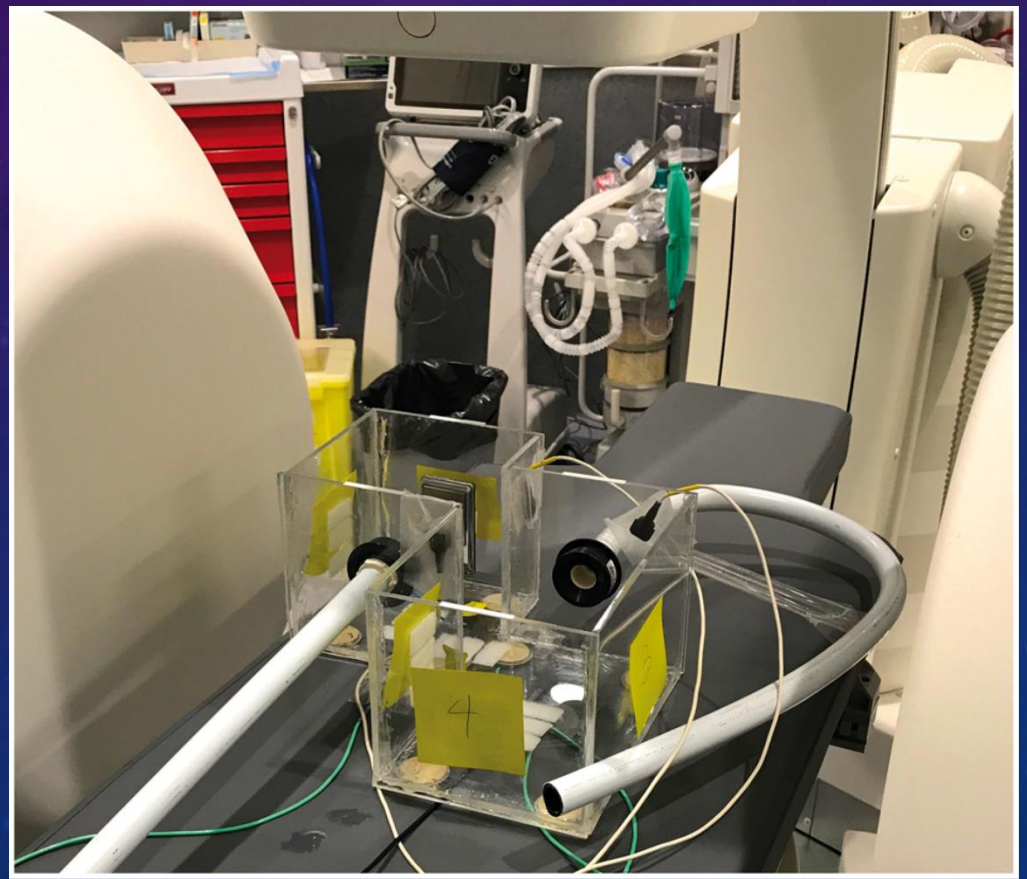
Conclusions:

These results support the hypothesis that stability coupled with lower contact force can produce efficacious lesions while conferring a potential safety advantage of reduction in risk of force-related injury.

CONTACT FORCE WITH MAGNETIC-GUIDED CATHETER ABLATION

FRANCIS BESSIE`RE, CHRISTOPHER ZIKRY, LENA RIVARD, KATIA DYRDA, PAUL KHAIRY
EUROPACE. 2018;20(SUPPL_2):II1-II4. DOI:10.1093/EUROPACE/EUY006

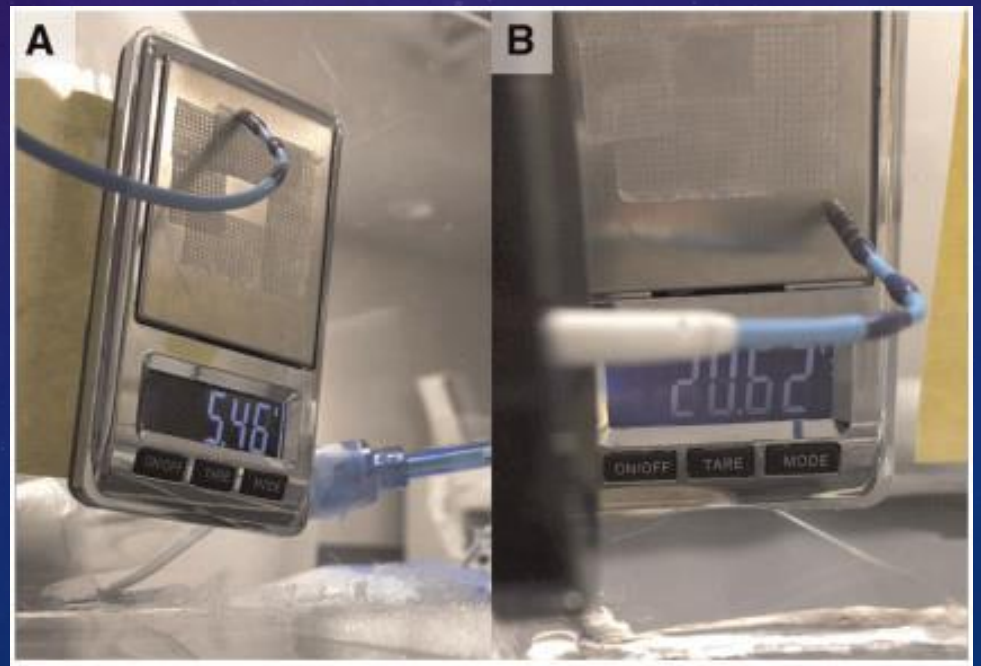
- Plexiglass model with an integrated scale fashioned to mimic transvenous and retrograde access to sites in the right atrium and right and left ventricles.



CONTACT FORCE WITH MAGNETIC-GUIDED CATHETER ABLATION

FRANCIS BESSIE`RE, CHRISTOPHER ZIKRY, LENA RIVARD, KATIA DYRDA, PAUL KHAIRY
EUROPACE. 2018;20(SUPPL_2):II1-II4. DOI:10.1093/EUROPACE/EUY006

- Magnetic fields of 0.08 and 0.10 T provide stable catheter contact forces, as reflected by the small variability between measurements.
- The average contact force is approximately 6g without a sheath and increases to 20g with a long sheath positioned at the entrance of the chamber of interest.



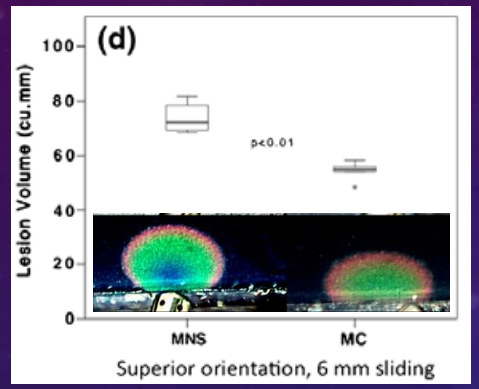
MAGNETIC GUIDANCE VS. MANUAL CONTROL: COMPARISON OF LESIONS

BHASKARAN ET AL, J INTERV CARD ELECTROPHYSIOL, 44(1):1-8, OCTOBER 2015

MAGNETIC GUIDANCE VS. MANUAL CONTROL: COMPARISON OF LESIONS

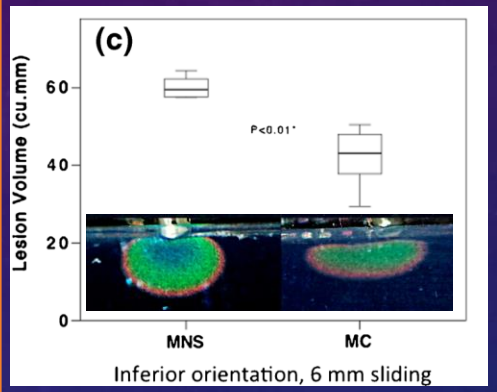
BHASKARAN ET AL, J INTERV CARD ELECTROPHYSIOL, 44(1):1-8, OCTOBER 2015

Superior Approach



A statistically significantly higher lesion volume is produced by MNS (74.1 mm^3) when compared to MC (54.2 mm^3).

Inferior Approach

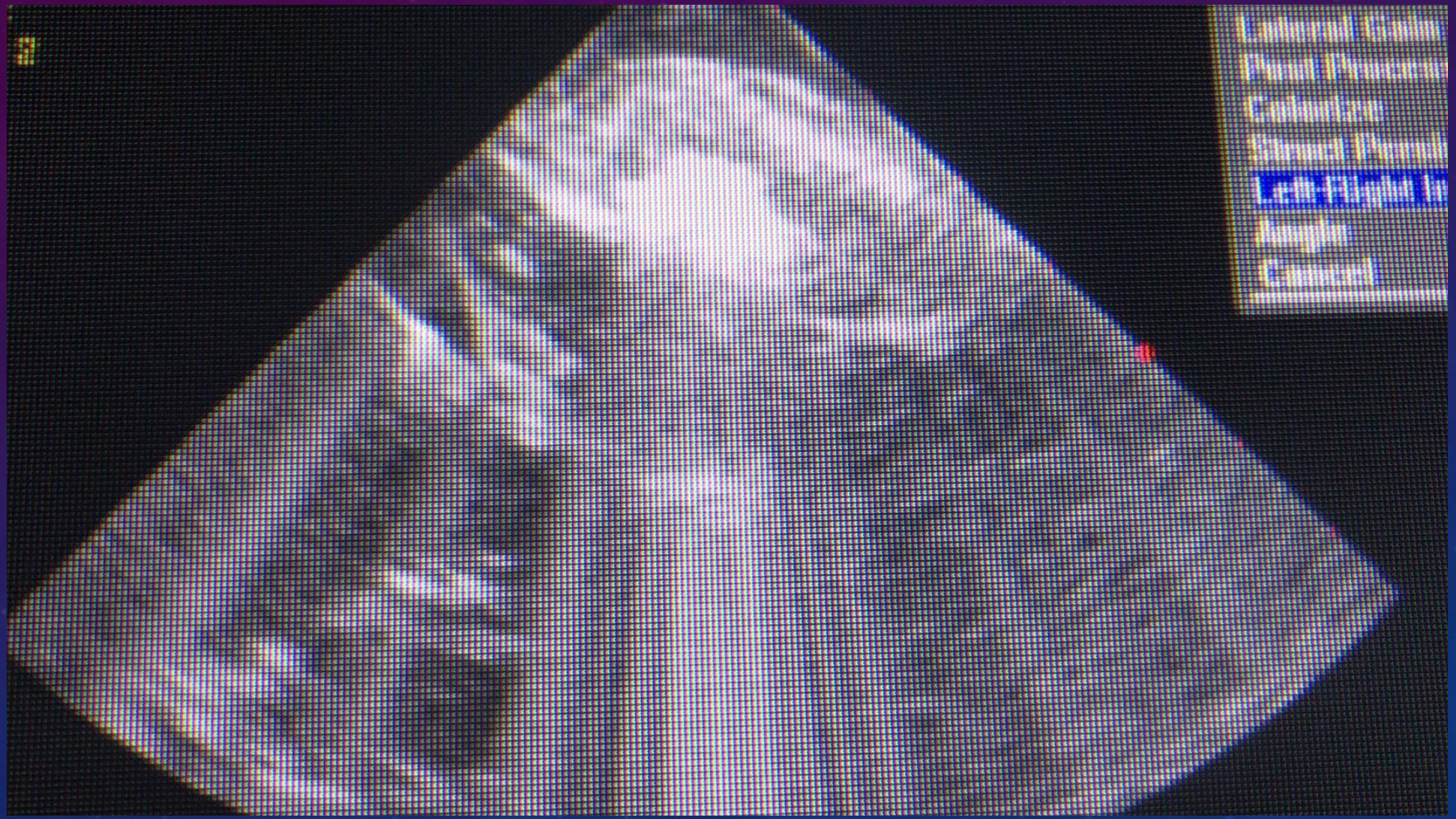


A statistically significantly higher lesion volume is produced by MNS (60.2 mm^3) when compared to MC (42.8 mm^3).

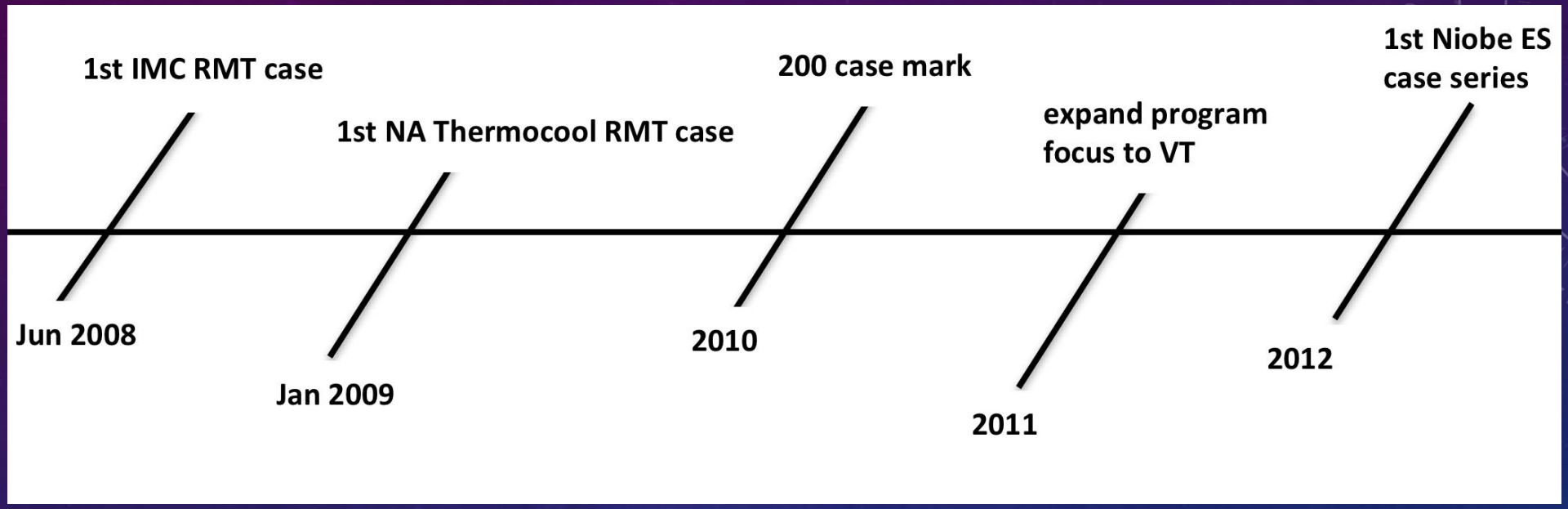
Conclusion

The manual catheter slid across the surface 5.5 mm while the magnetic catheter maintained stable focal contact. This resulted in larger lesion sizes for the Niobe™ magnetic navigation system.

UNIQUE BIOPHYSICS OF CONTINUOUS CONTACT



INTERMOUNTAIN EXPERIENCE



2019

- Overall Experience: Over 1000 procedures
- 1st choice for PVC/VT Cases: over 400 procedures
- Current “Everyday, Everything Use”

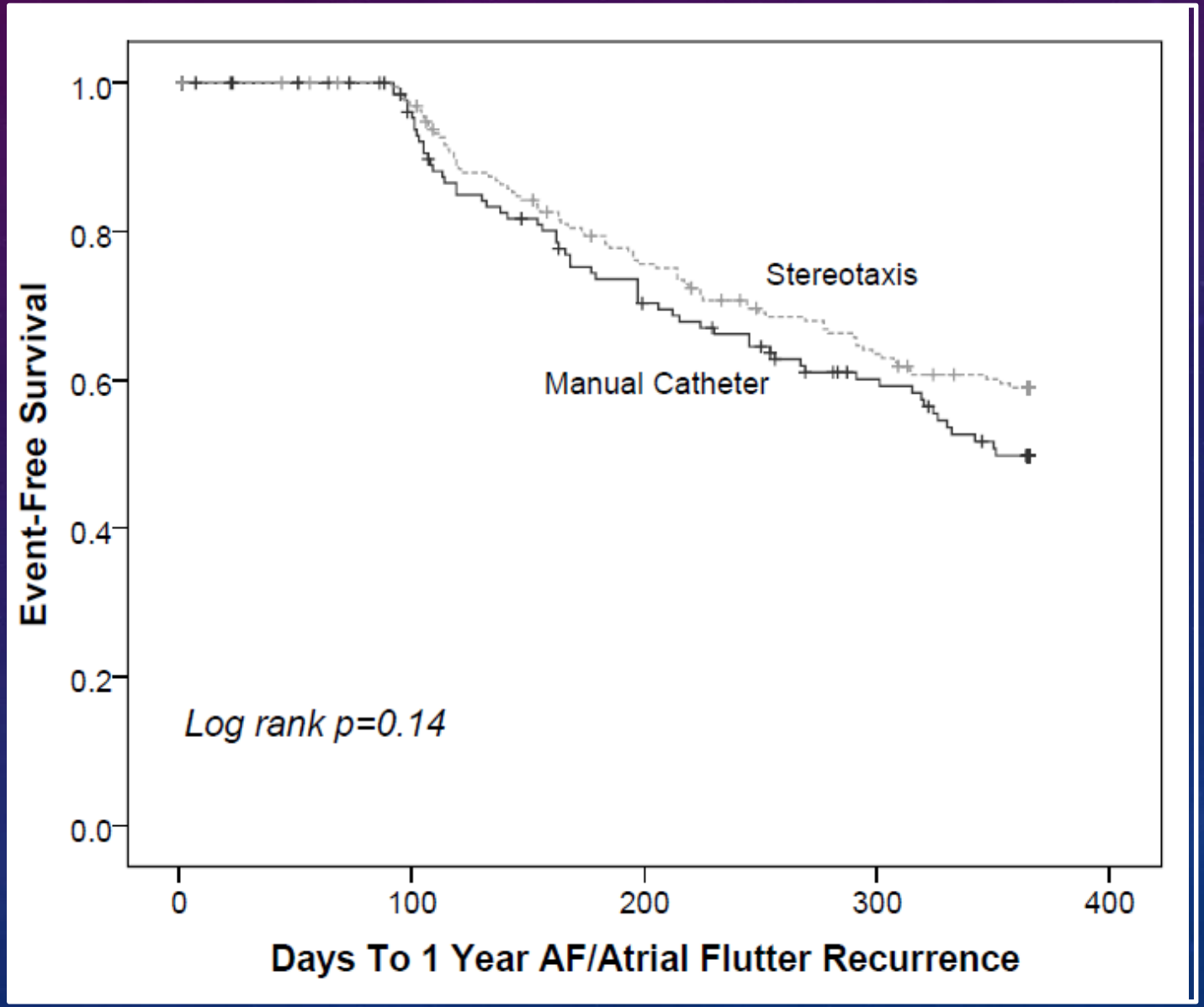
A COMPARISON OF REMOTE MAGNETIC IRRIGATED TIP ABLATION VERSUS MANUAL CATHETER IRRIGATED TIP CATHETER ABLATION WITH AND WITHOUT FORCE SENSING FEEDBACK

J. PETER WEISS MD[1], HEIDI T. MAY PHD[1], MSPH, TAMI L. BAIR BS[1], BRIAN G. CRANDALL MD[1], MICHAEL J CUTLER DO, PHD[1], JOHN D. DAY MD[1], JEFFREY S. OSBORN MD[1], CHARLES MALLENDER MD[1]. T. JARED BUNCH MD[1,2]

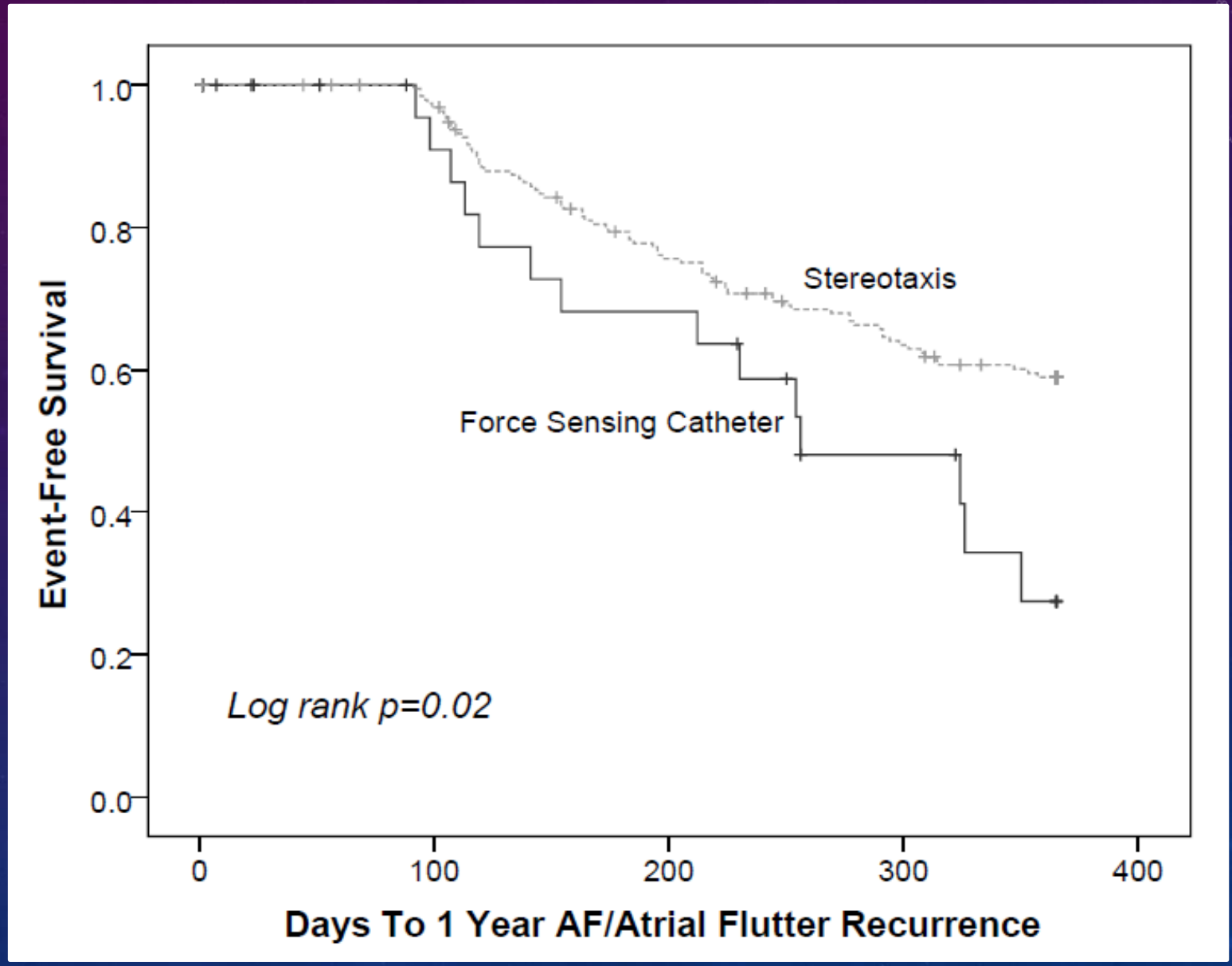
- Single center cohort of patients undergoing Afib ablation
- 627 patients who underwent catheter ablation with either a manual irrigated tip catheter: (312, 49.8%) or by RMN: (315, 50.2%)
- Patients treated with CF (59) were analyzed separately
- 1 and 3 years endpoints included death, HF hospitalization, stroke, TIA, and atrial flutter or AF recurrence.

Journal of Cardiovascular Electrophysiology
Volume 27, Issue S1, March 2016, Pages S5–S10

RMT (N=315) VS. MANUAL CATHETER (N=312)



RMT(N=315) VS. FORCE SENSING (N=59)



RESULTS

- 1 and 3 years endpoints of death, HF hospitalization, stroke, TIA, and atrial flutter or AF recurrence were statistically similar between manual and RMN treated groups.

- Fluoroscopy times were significantly lower in the RMN group compared to the manual ablation group (8.47±0.45 versus 9.63±4.06 minutes, $p<0.0001$).

- CF guided patients had 1 year recurrence rate of AF/atrial flutter statistically identical to patients treated with RMN (36.8% vs. 38.6% ($p=1.00$).

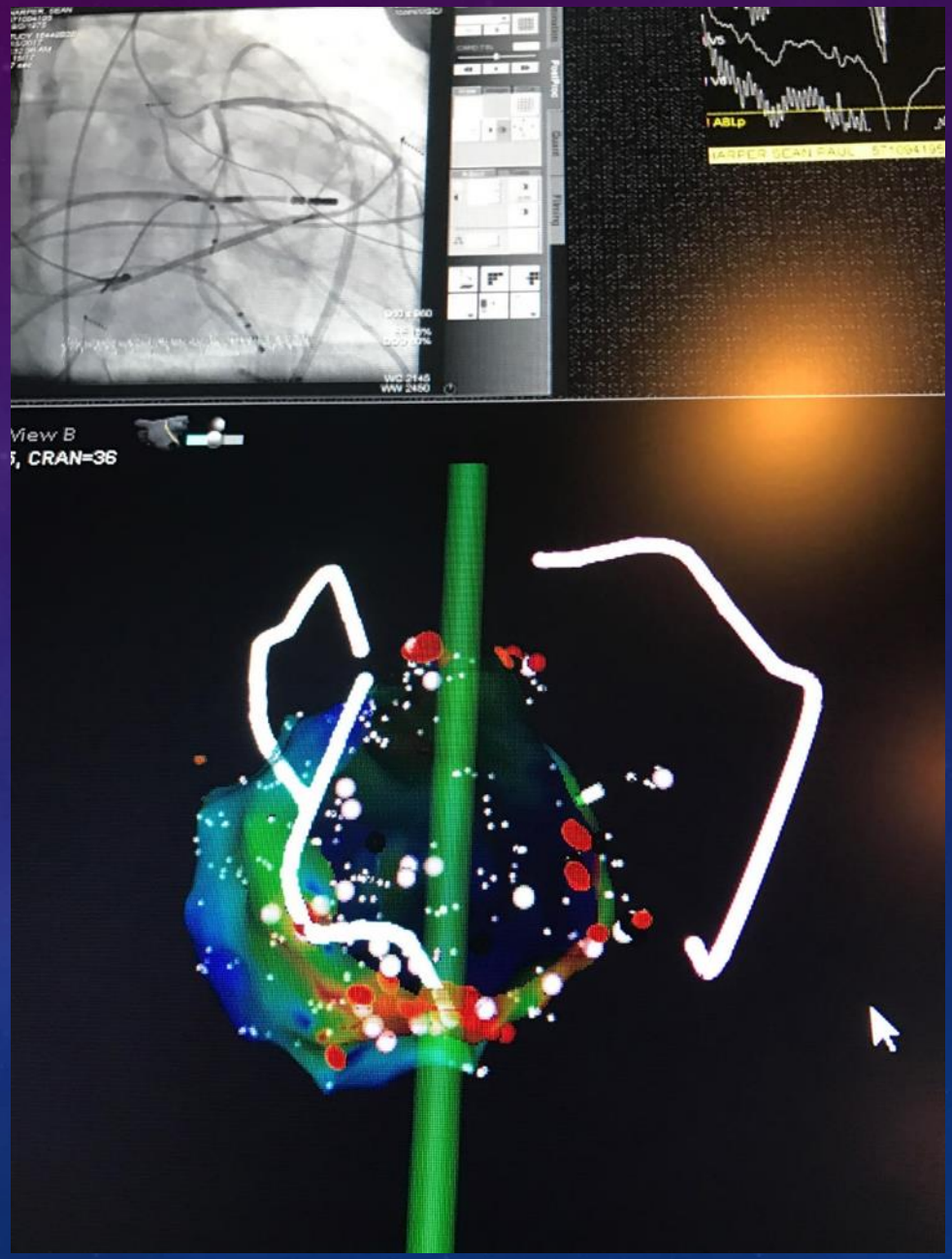
CONCLUSIONS

- RMN results in outcomes similar to manual navigation in this large Afib ablation cohort.
- The addition of CF sensing catheters did not improve relative procedural outcome or safety profile in comparison to traditional manual or RMN guided ablation.

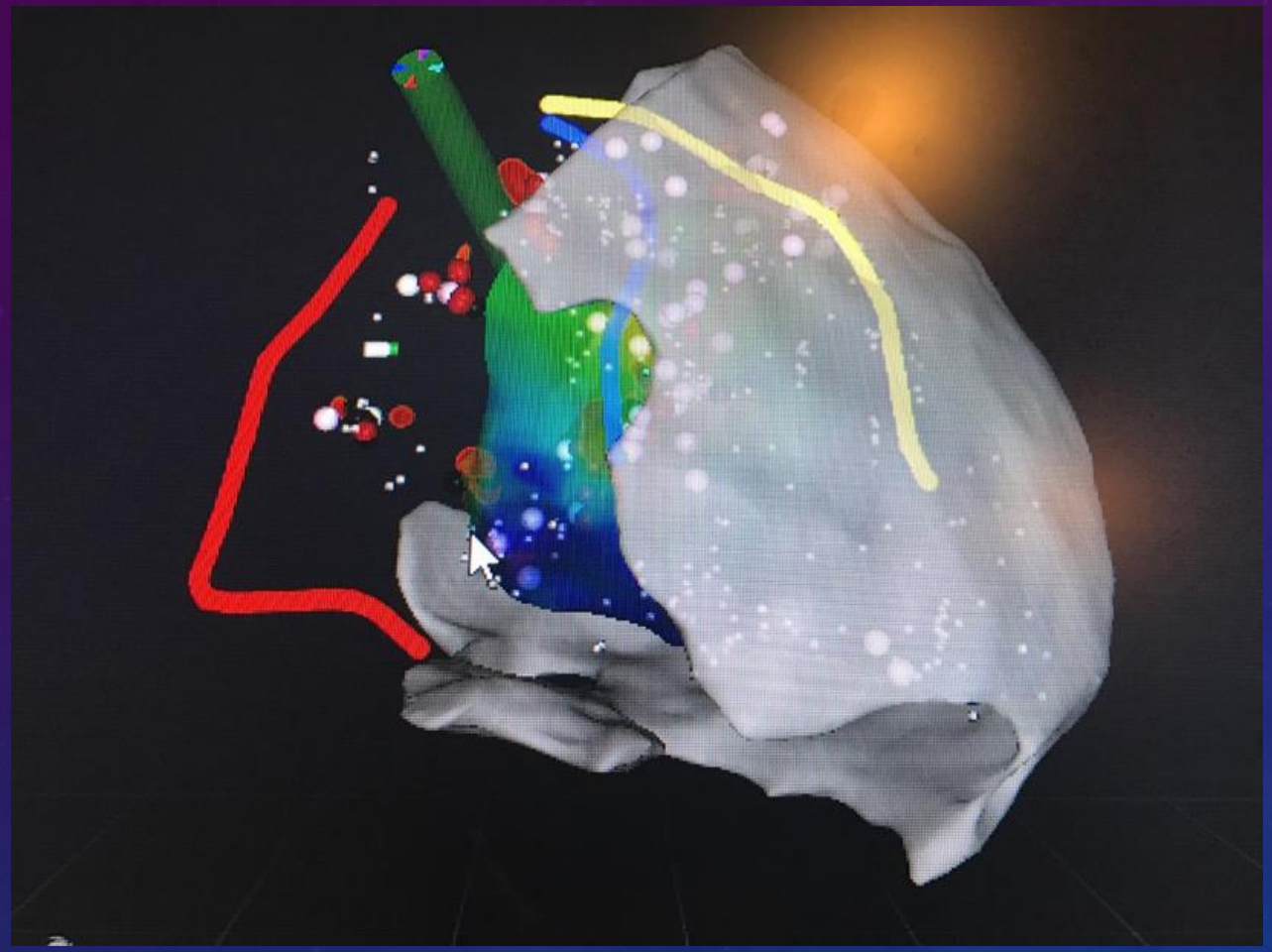
UNIQUE ABILITIES:
“TOUGH PLACES, TOUGH CASES”

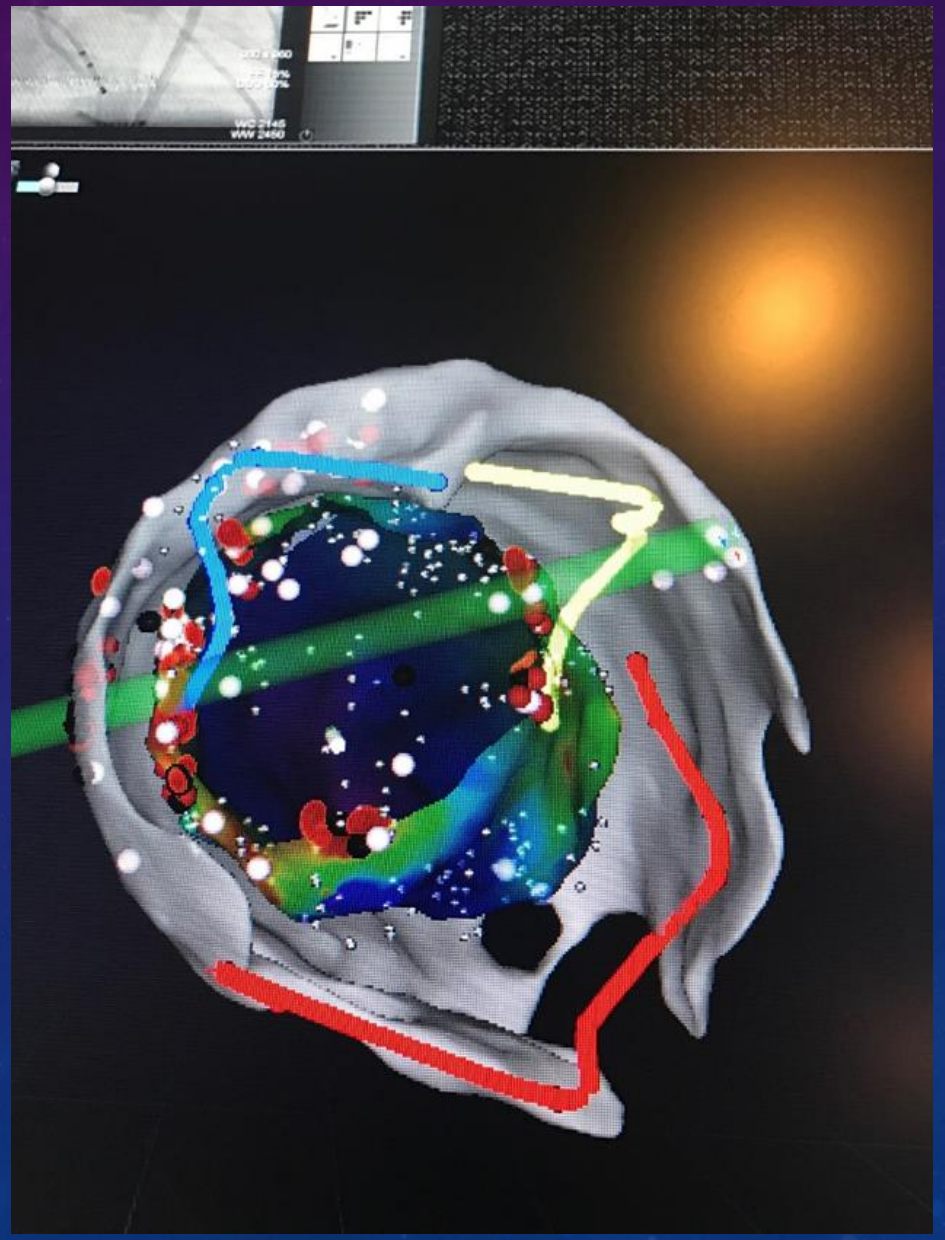
NONISCHEMIC VT ENDO AND EPICARDIAL

Using Point Annotation on Fluoro to outline coronary anatomy

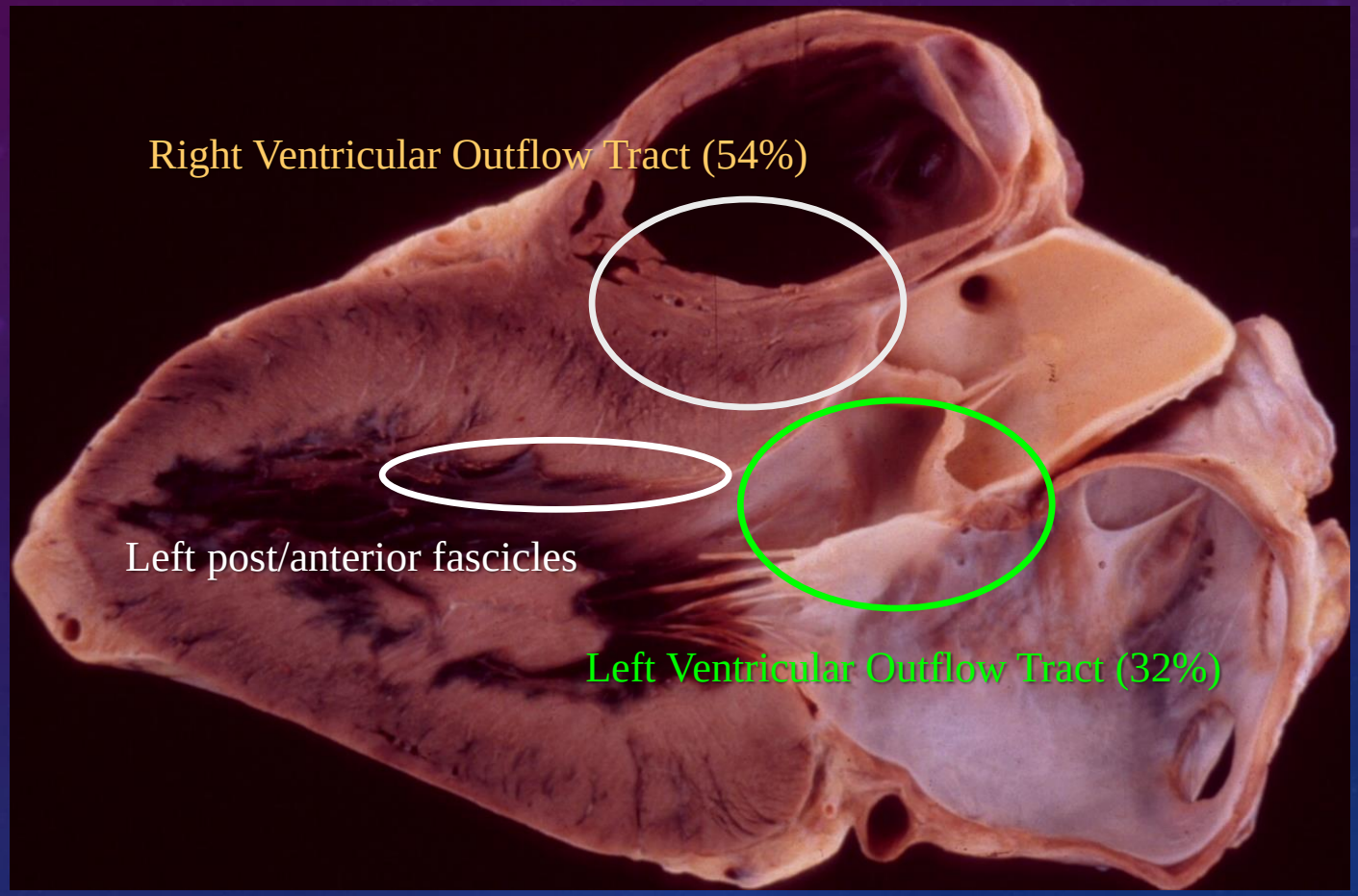


NONISCHEMIC VT ENDO AND EPICARDIAL





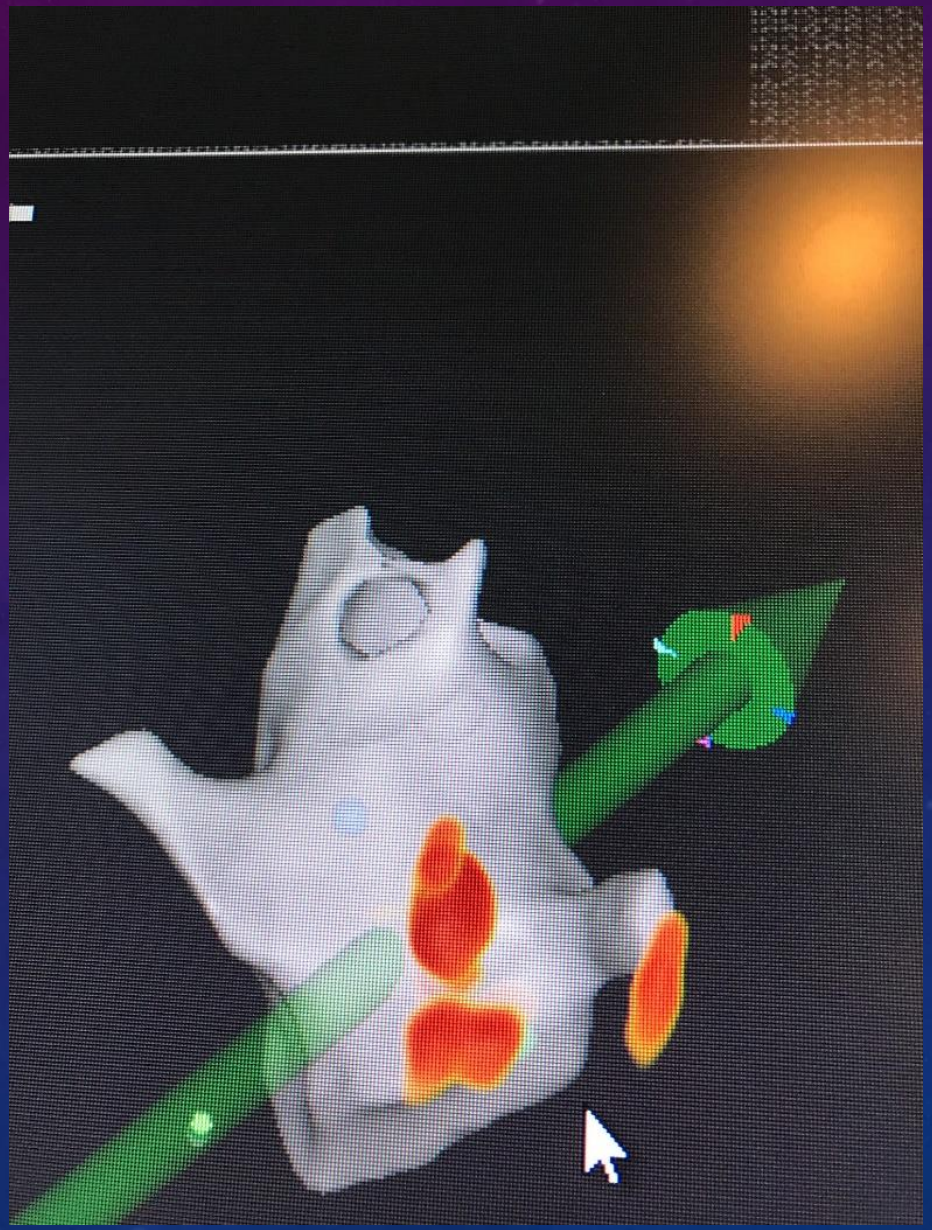
IDIOPATHIC PVCS/VT



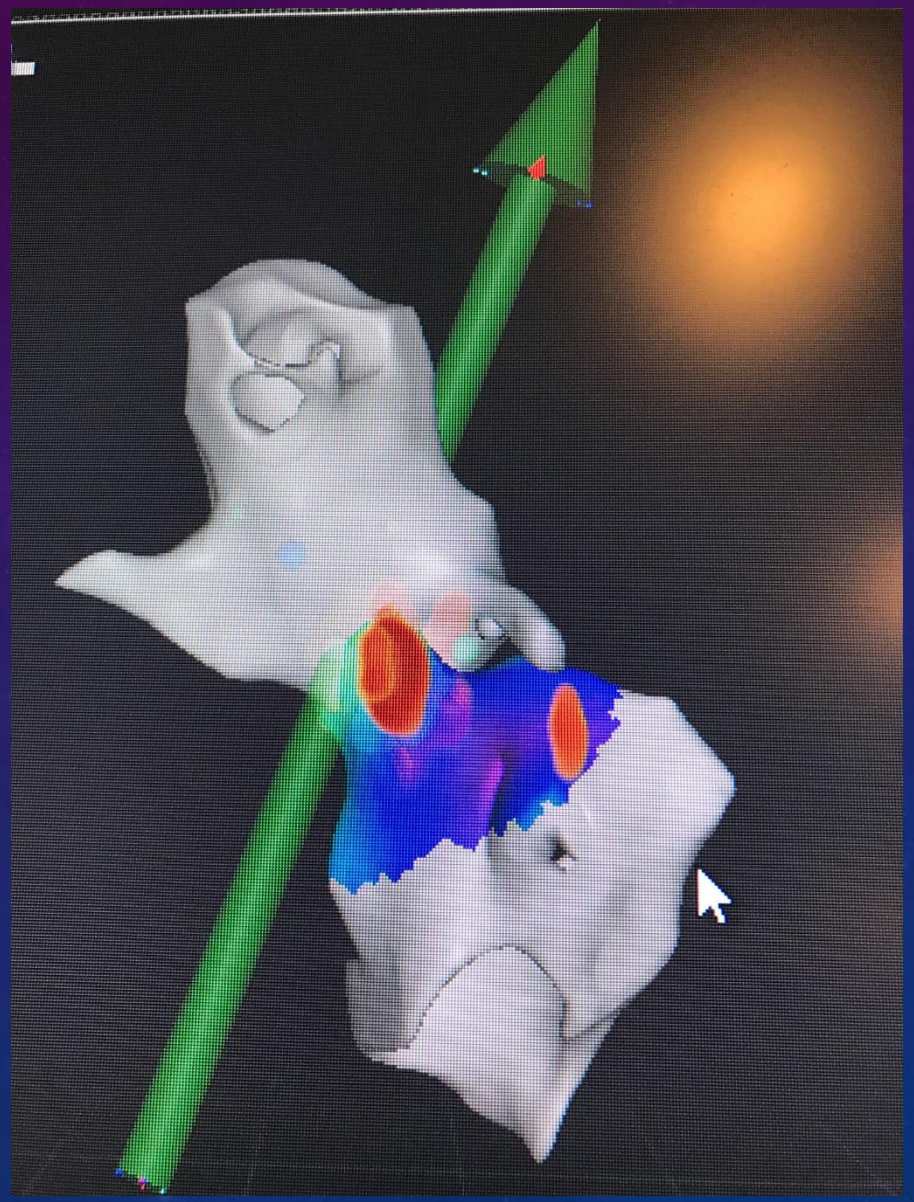
Key: Accurate navigation of complex anatomy

Callans DJ. JACC 1997; 29:1023-7

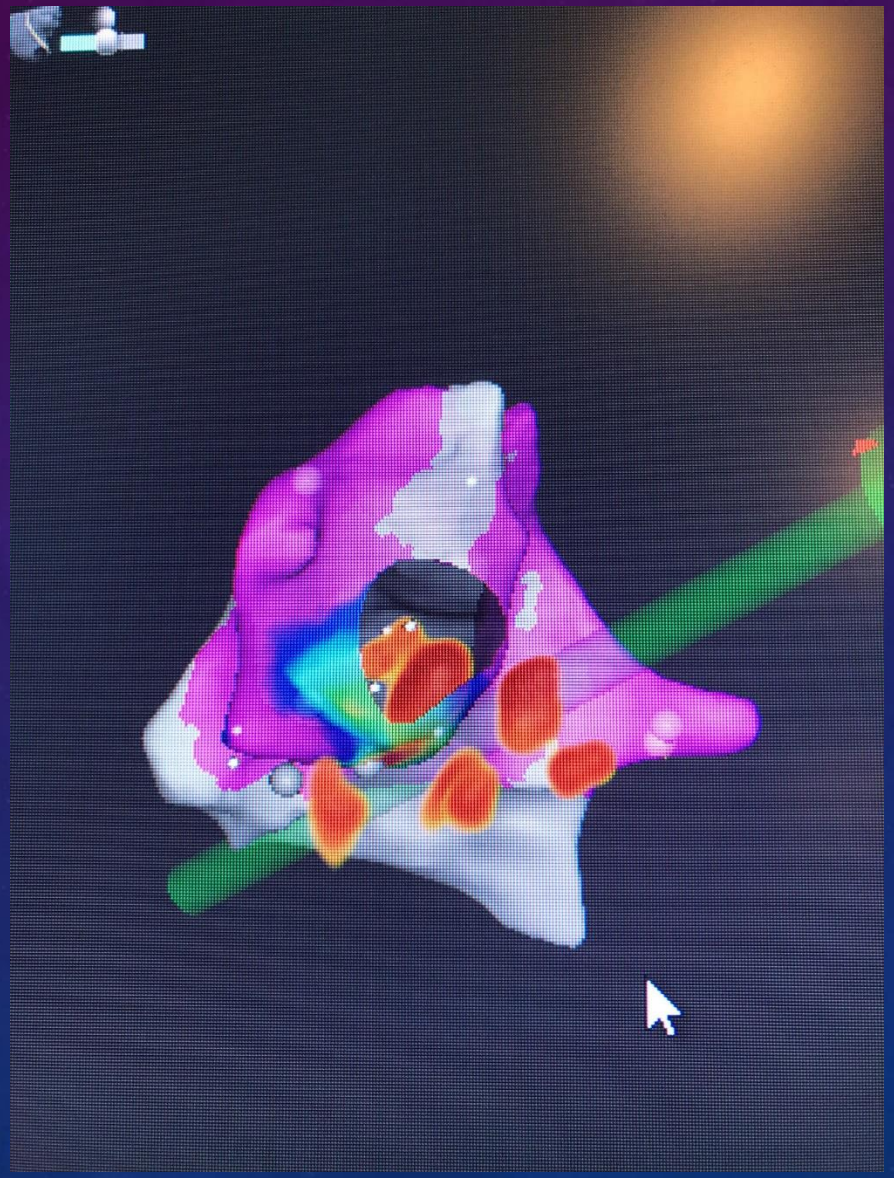
AORTIC ROOT



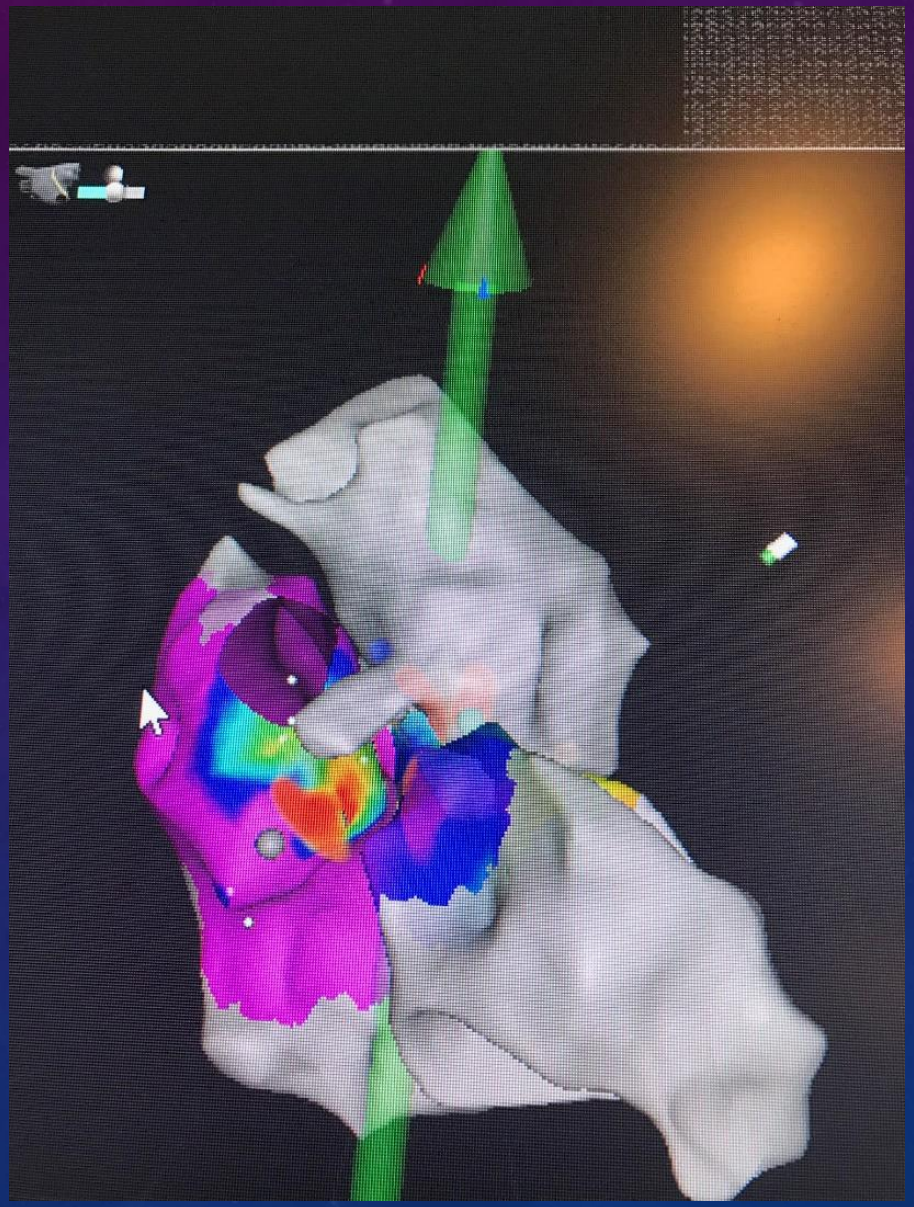
AORTIC ROOT AND BASAL LV



RIGHT VENTRICLE



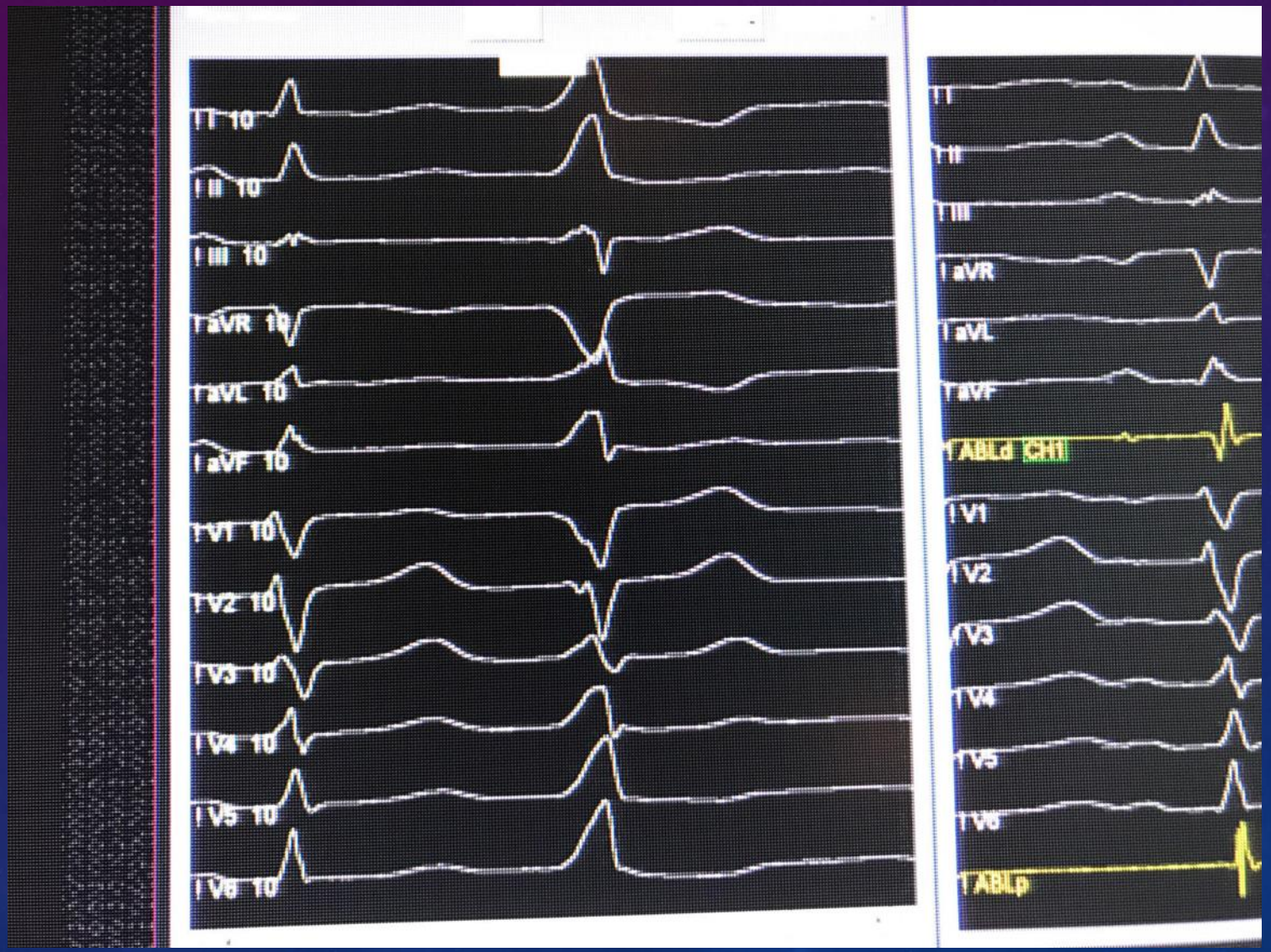
PUT IT ALL TOGETHER



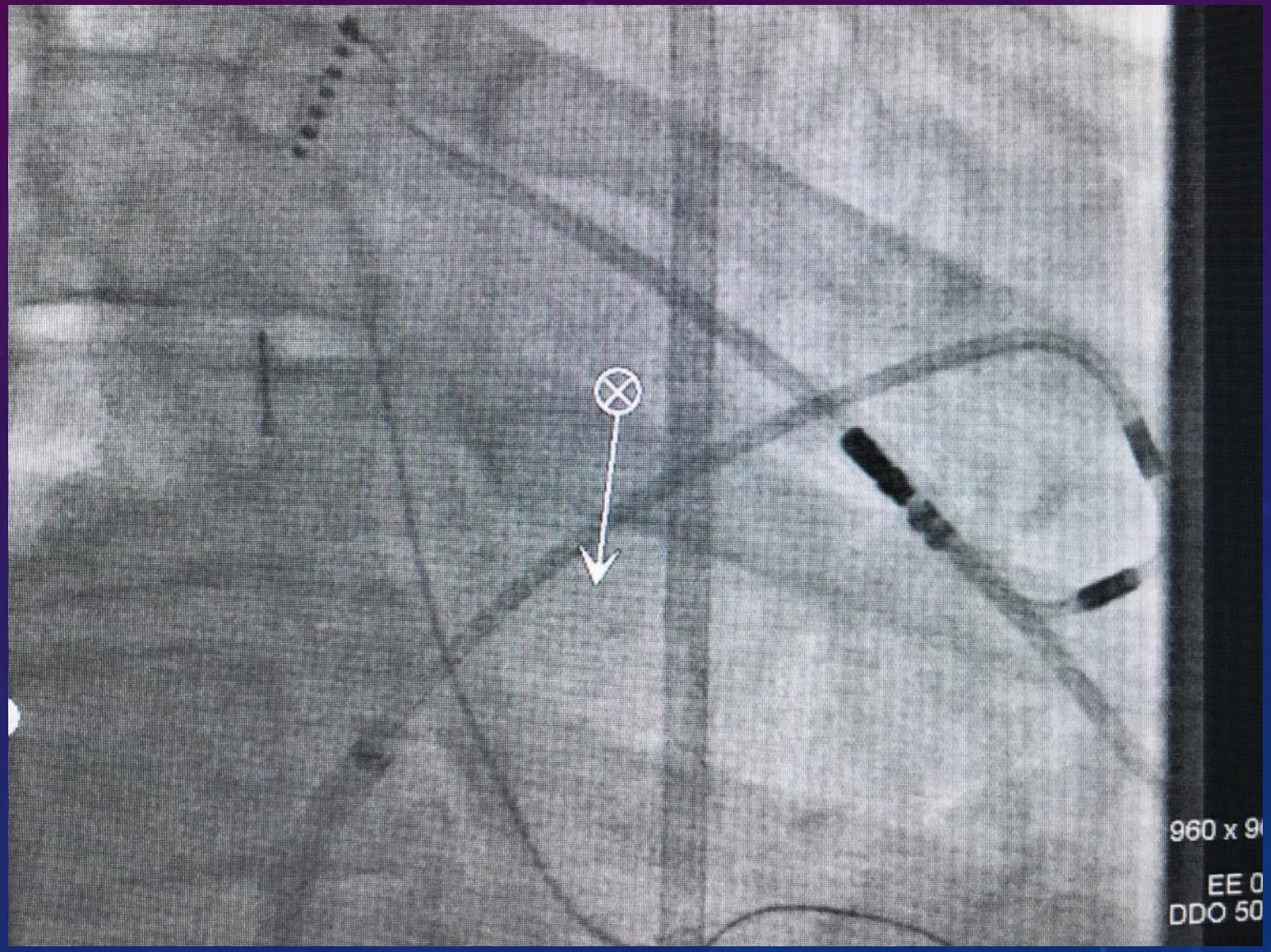
Mapping and Ablation in Aortic Root from Transseptal Approach

- Transseptal Access
- Across Mitral Valve
- Prolapse in LV
- Out Aortic Valve
- 180 Degrees Back to Root

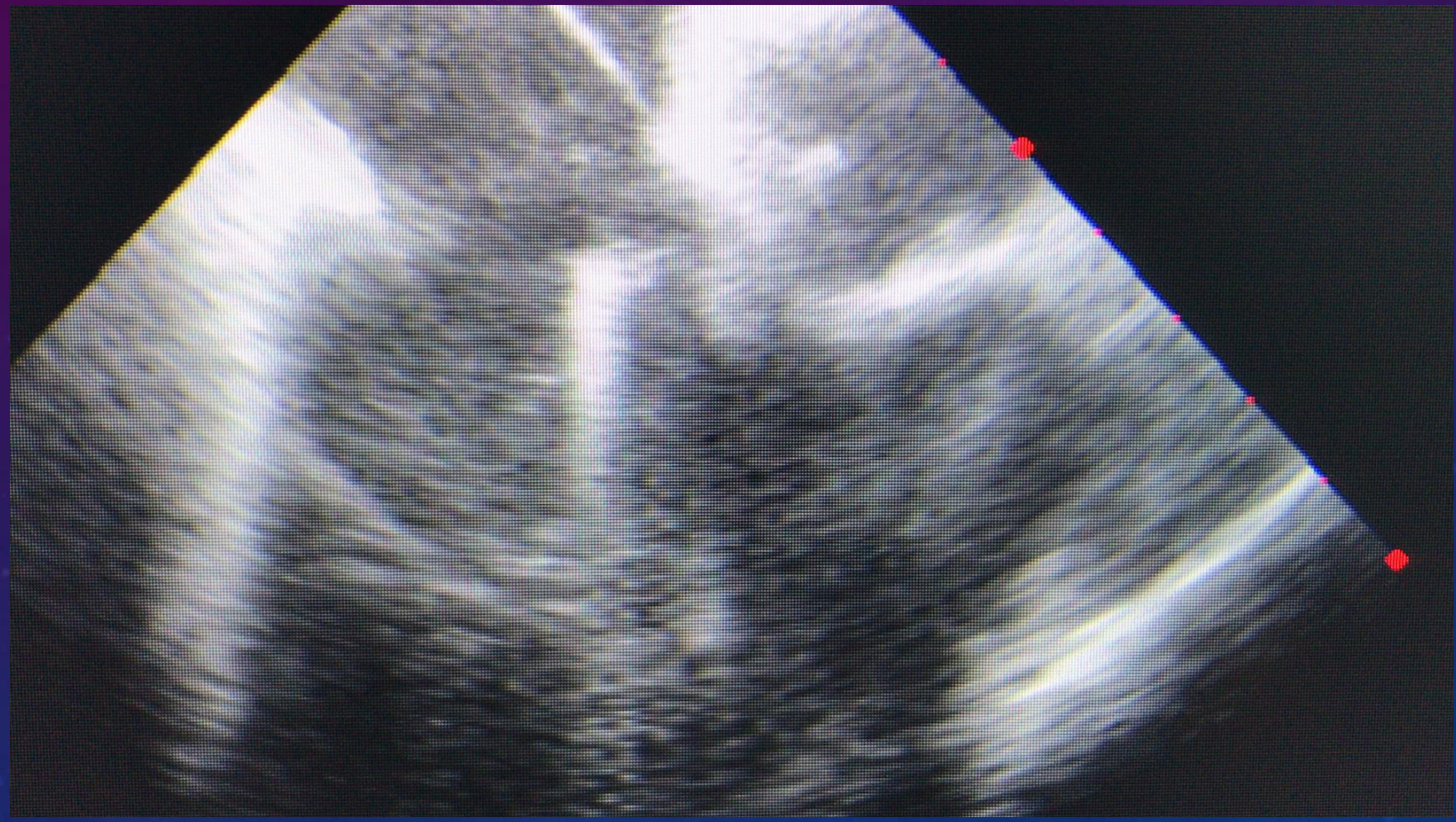
PARA-HISIAN PVCS



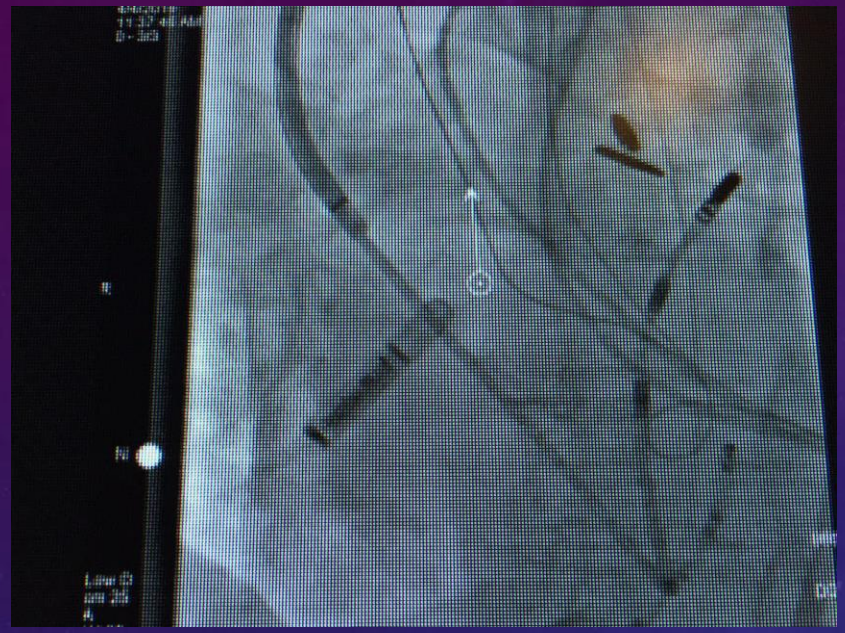
PARA-HISIAN PVCS

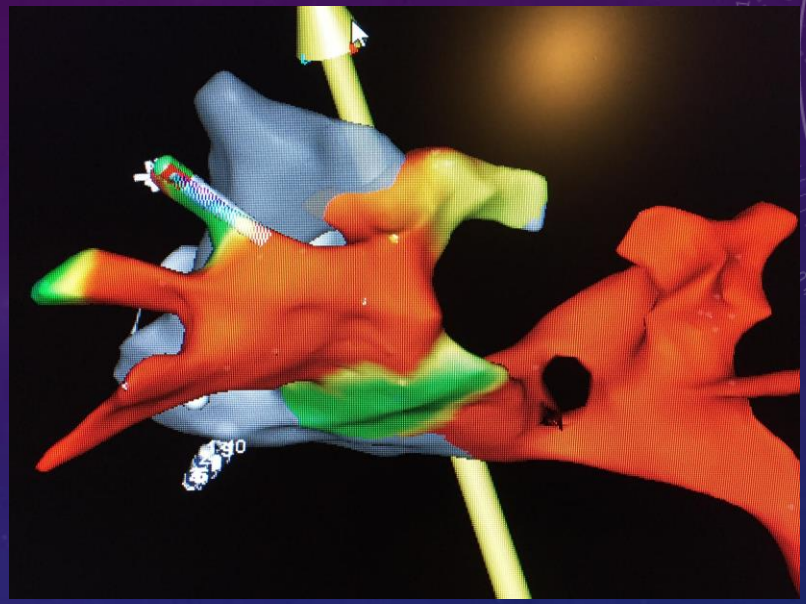


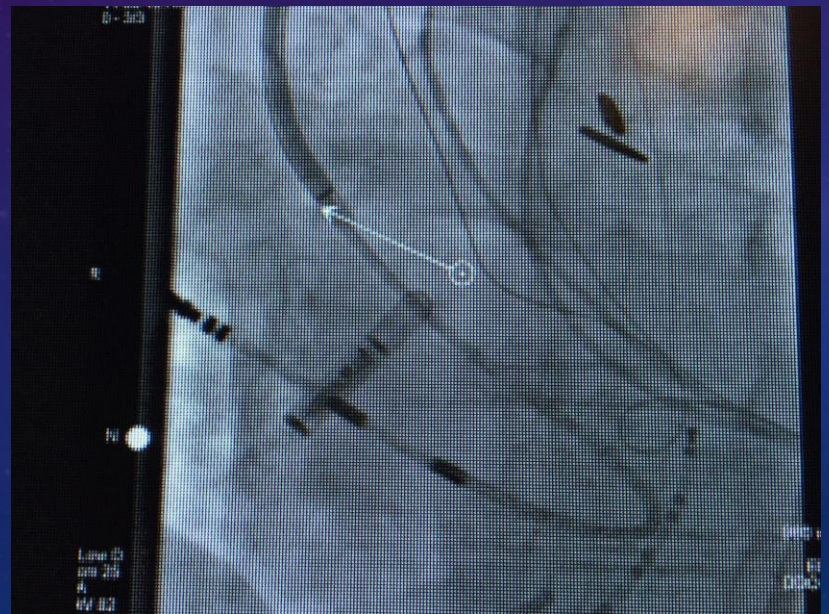
PARA-HISIAN PVCS

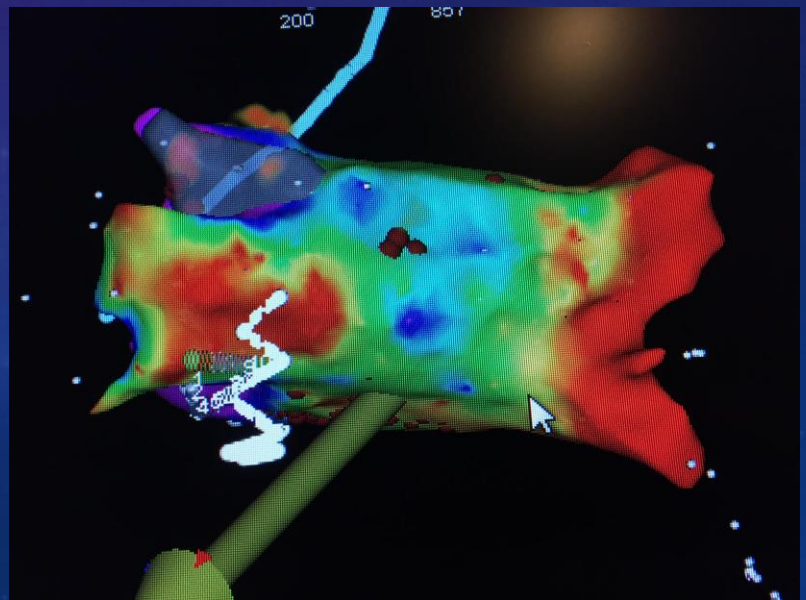


RETROGRADE AORTIC AF ABLATION



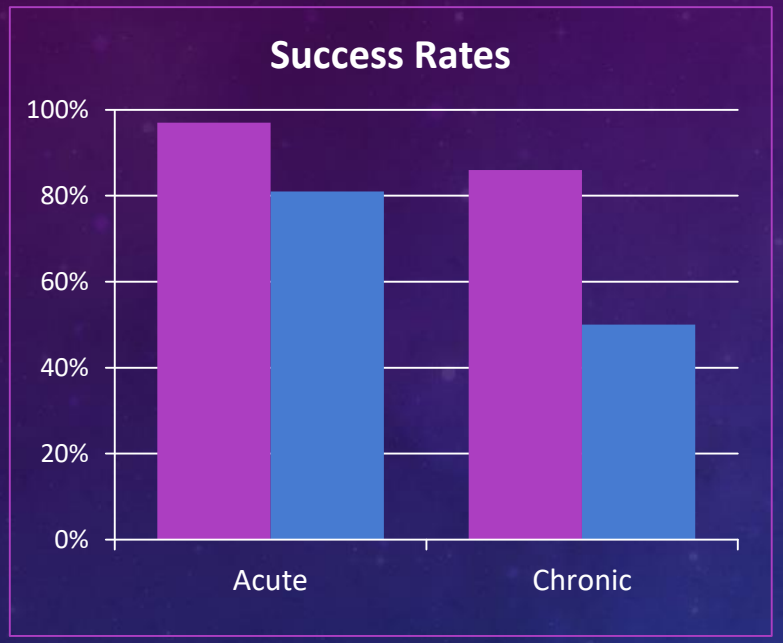


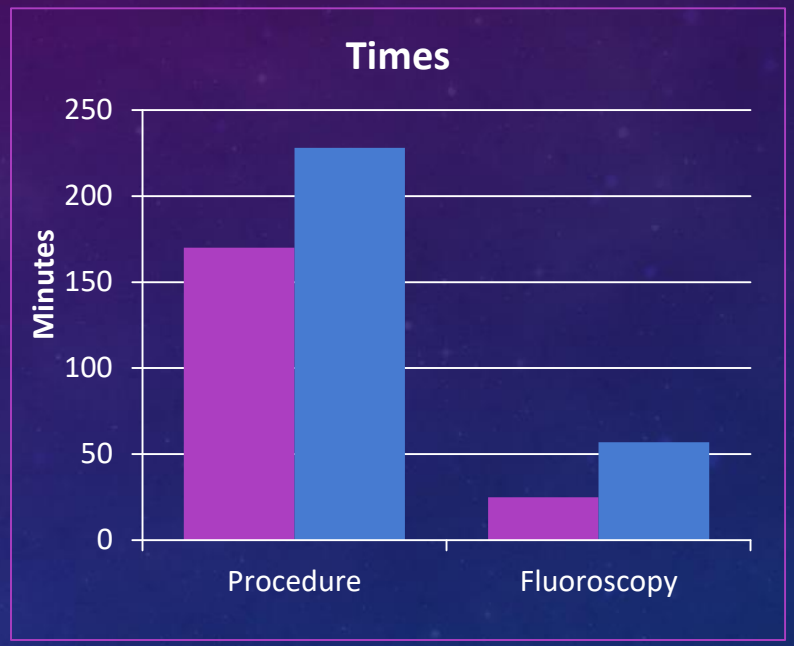




USEFULNESS OF THE MAGNETIC NAVIGATION SYSTEM IN ABLATION OF VT

SCHWAGTEN ET AL, EUROPEAN HEART JOURNAL, 2010:31(ABSTRACT SUPPLEMENT):932



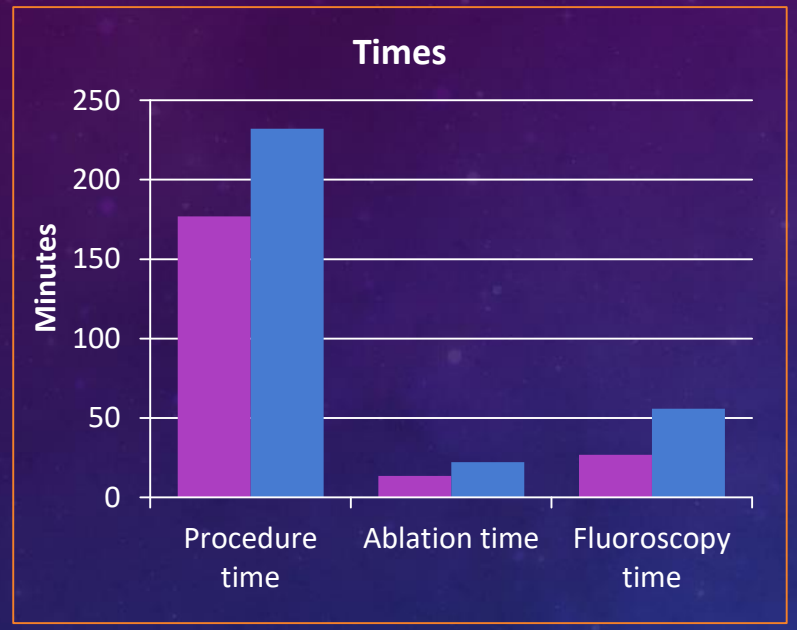


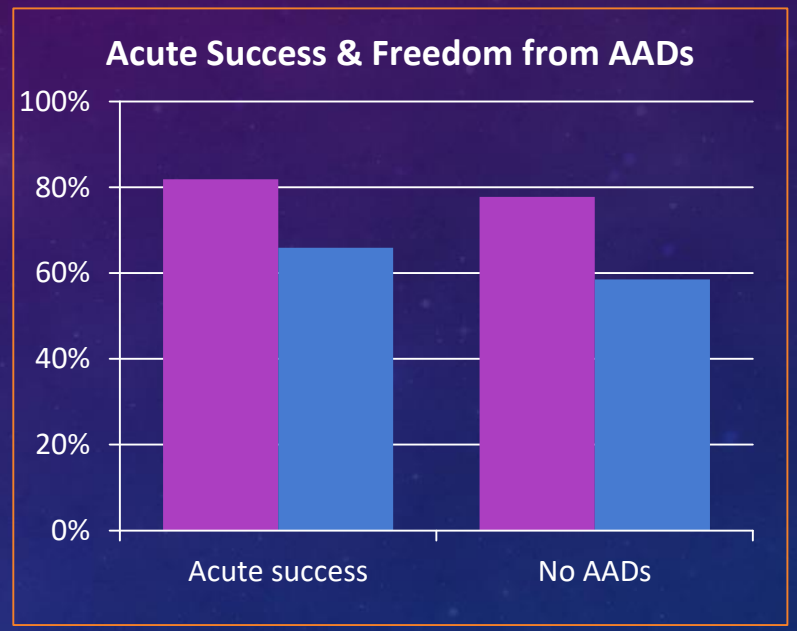
Magnetic Manual

Compared 37 procedures with magnetic navigation (12 month follow-up) to 27 procedures performed with pull-wire catheters (8 month follow-up).

CATHETER ABLATION OF VT USING REMOTE MAGNETIC NAVIGATION

SZILI-TOROK ET AL, J CARDIOVASC ELECTROPHYSIOL, 2012 SEP, 23(9):948-54





Magnetic Manual

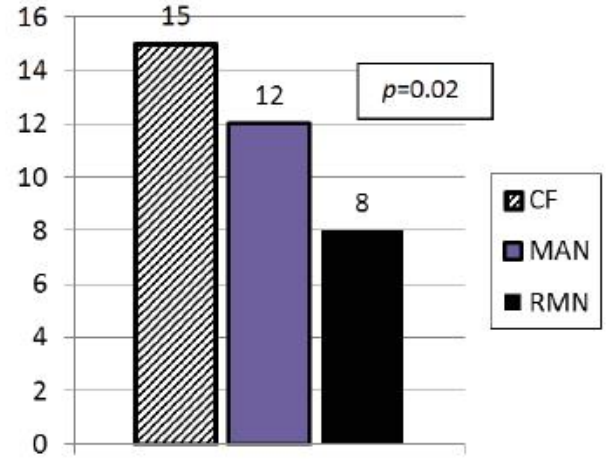
A consecutive case-control study involving 113 patients

Safety and Clinical Outcome of Catheter Ablation of Ventricular Arrhythmias Using Contact Force Sensing: Consecutive Case Series

HENDRIKS, A. A., AKCA, F., DABIRI ABKENARI, L., KHAN, M., BHAGWANDIEN, R., YAP, S.-C., WIJCHERS, S. and SZILI-TOROK, T. (2015), J Cardiovasc Electrophysiol, 26: 1224–1229. doi:10.1111/jce.12762

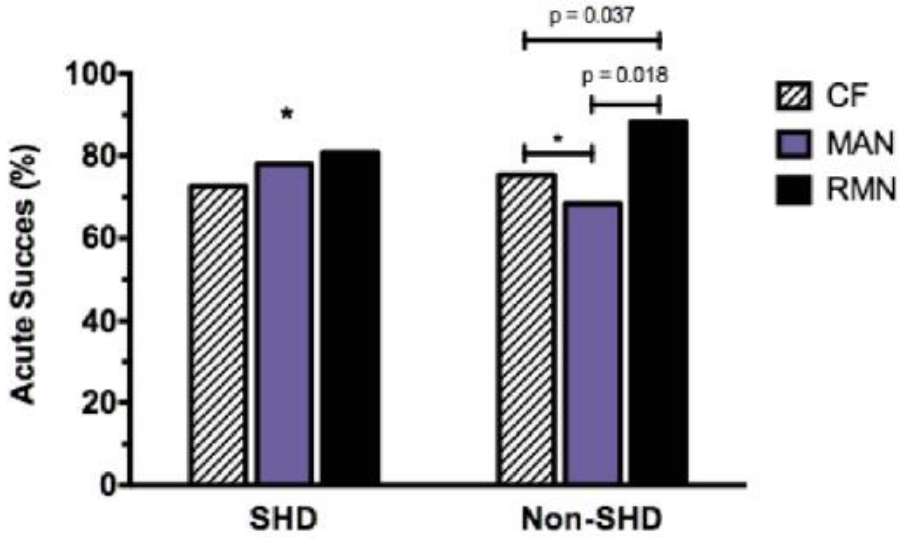
Results

SECTION 1: MAIN FINDINGS



Procedure Outcomes

The RMN group had fewer RF applications (p=0.02).



Acute Success

For structural heart disease (SHD), there were no statistically significant differences between acute success outcomes: CF (73%), MAN (78%), RMN (81%). For Non-SHD, acute success for RMN was statistically higher compared to both of the other groups: CF (68%), MAN (62%), RMN (88%). Note that the p–values above are both below $p<0.05$ indicating statistical significance (RMN vs. CF (20% difference) and RMN vs. MAN (26% difference)).

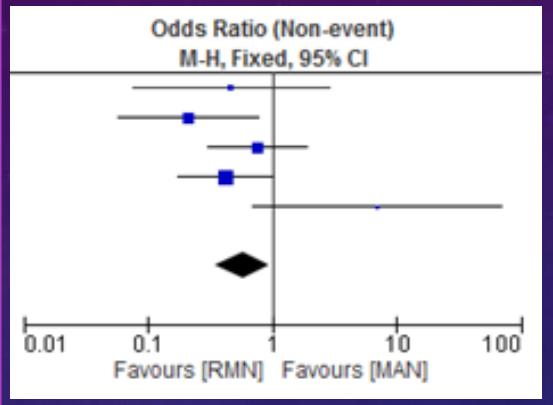
Manual Navigation vs. Remote Magnetic System for VT Ablation

Gunda et al, literature review presented at HRS 2015

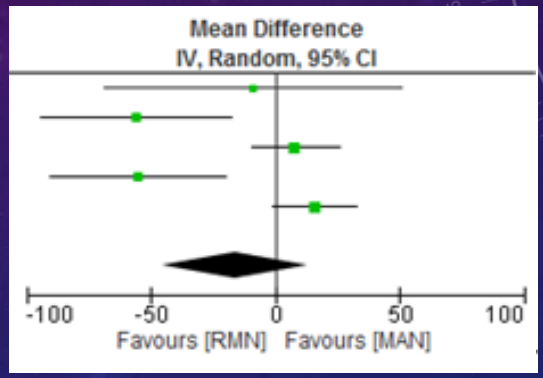
Overview

A meta-analysis of five studies including 356 patients.

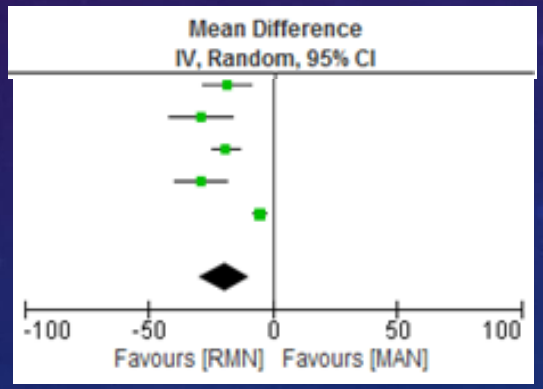
Acute Success



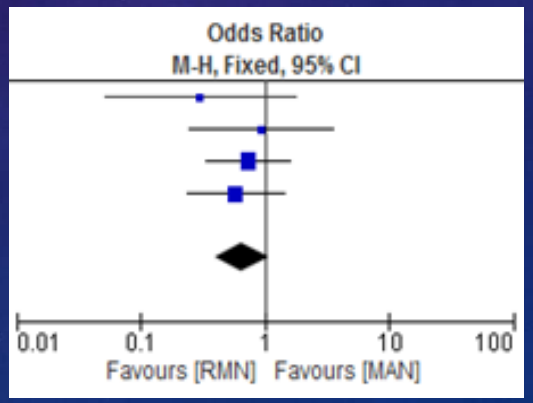
Procedure Time



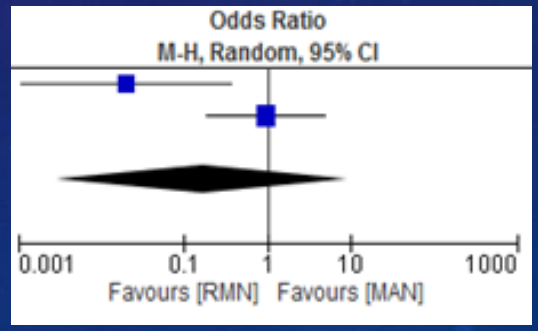
Fluoroscopy Time



Recurrence



Pericardial Effusion Incidence

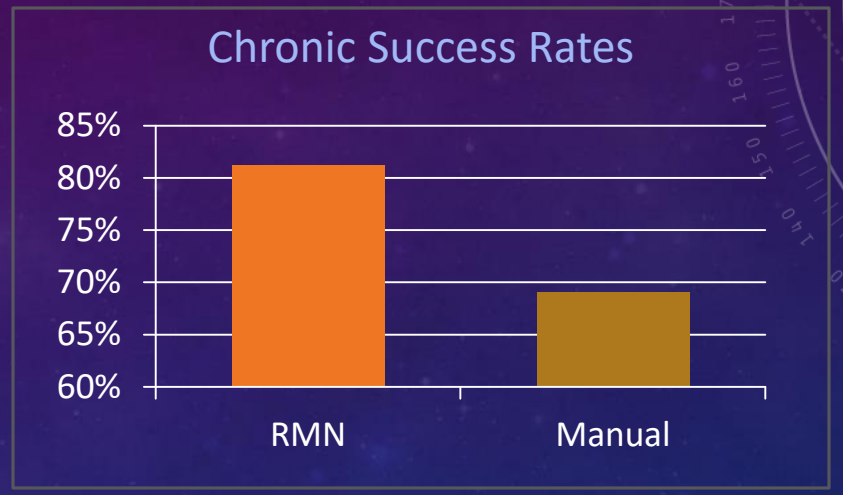


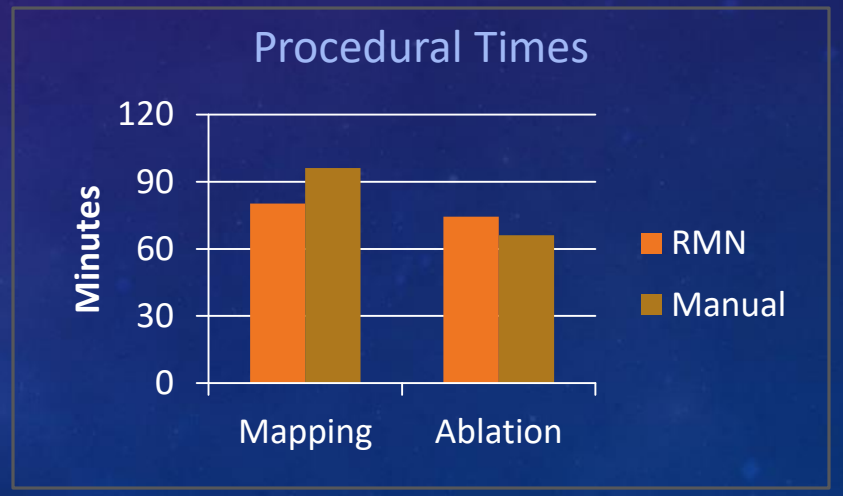
Scar Homogenization Ablation in Ischemic Cardiomyopathy

Di Biase et al, Circulation.2015; 132: A14384

Methods & Results

Multi-center study of 218 consecutive patients with scar size > 60 cm^2 undergoing scar homogenization with either RMN (138 pts) or manual (80 pts) ablation. Density of the substrate map was higher in RMN group than manual (553±118 vs 347±97, p<0.001). Mean follow-up was 15.4±6.8 months.





Conclusion

Using RMN in pts with IC and a scar size greater than 60 cm^2 increases success rate at follow up when compared to manual ablation.

Remote Magnetic Navigation: A Focus on Catheter Ablation of Ventricular Arrhythmias

PHILIP AAGAARD, M.D., Ph.D.,* ANDREA NATALE, M.D., F.A.C.C., F.H.R.S., F.E.S.C.,†,§,¶,#,,**,†† DAVID BRICENO, M.D.,* HIROSHI NAKAGAWA, M.D., Ph.D.,‡‡ SANGHAMITRA MOHANTY, M.D.,† CAROLA GIANNI, M.D.,† J. DAVID BURKHARDT, M.D.,† and LUIGI DI BIASE, M.D., Ph.D., F.A.C.C., F.H.R.S.*,†,‡,§

TABLE 1

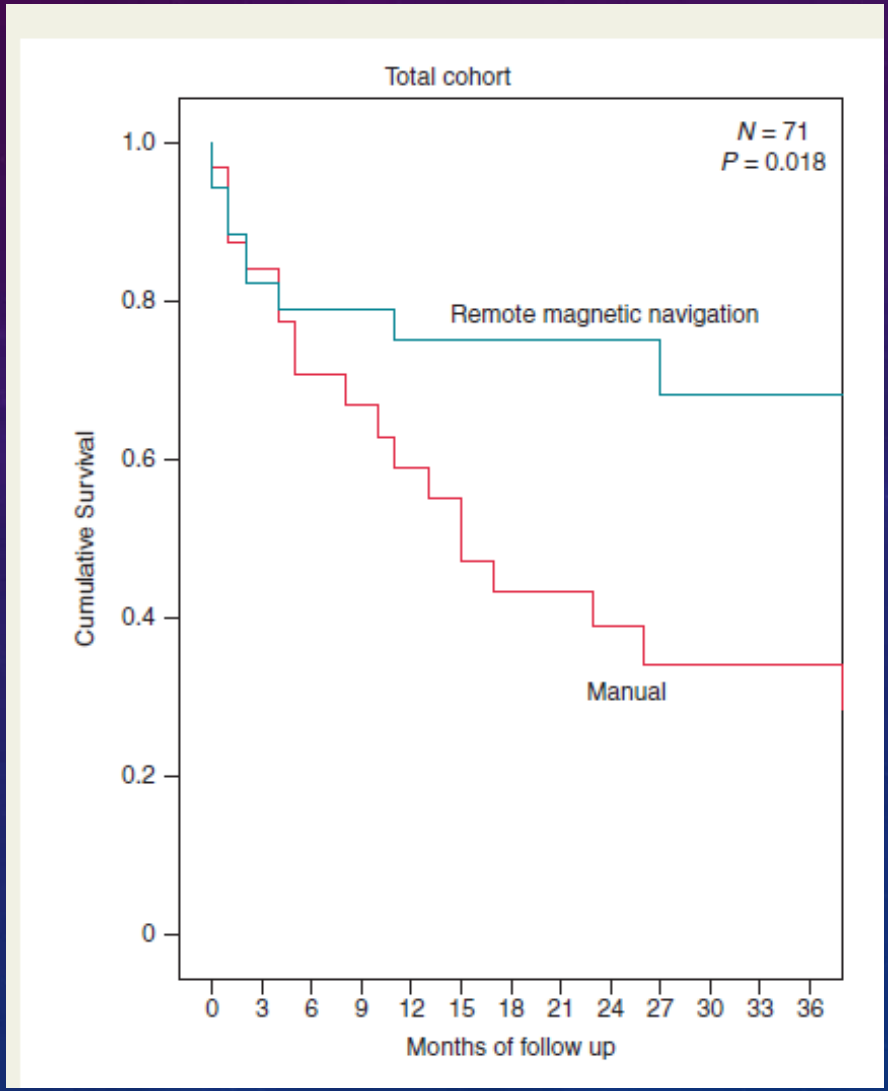
Comparison of Manual versus Remote Navigation for VT Ablation

Parameter	Manual versus RMN
Efficacy	Similar
Safety	Favors RMN
Radiation exposure	Favors RMN
Fluoroscopy times	Favors RMN
Procedure time	Favors RMN
Access to difficult anatomy	Favors RMN

J Cardiovasc Electrophysiol, Vol. 27, pp. S38-S44, March 2016)

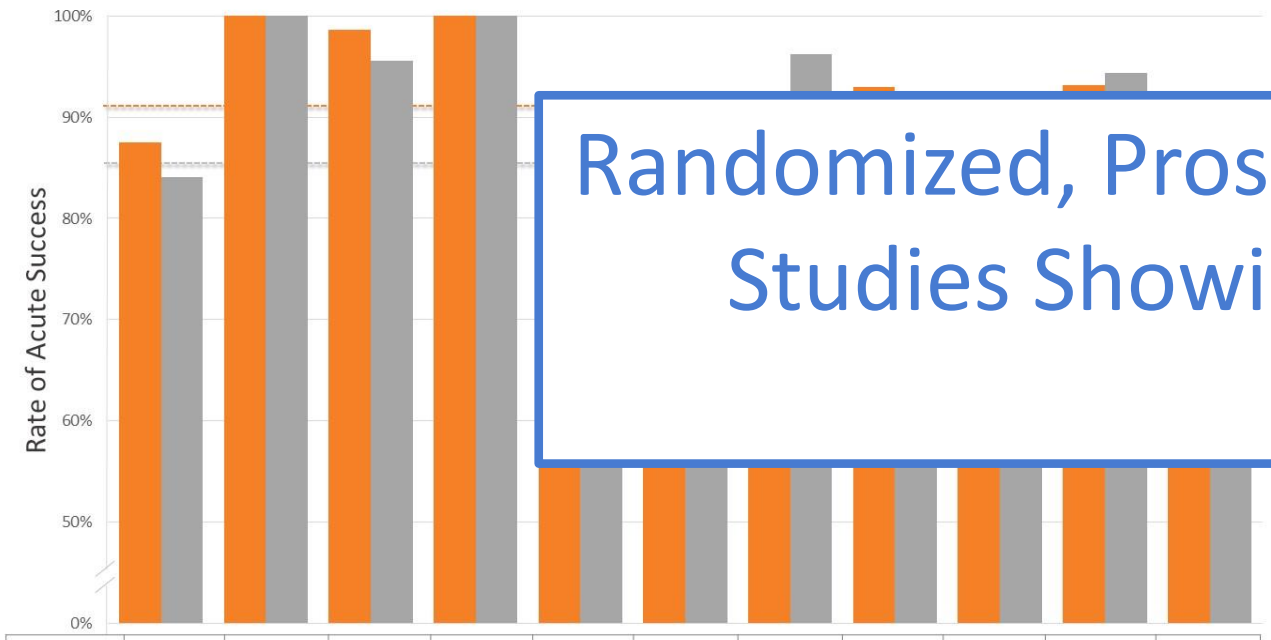
EARLY AND LONG-TERM OUTCOMES AFTER MANUAL AND REMOTE MAGNETIC NAVIGATION-GUIDED CATHETER ABLATION FOR VENTRICULAR TACHYCARDIA

P. KOVOOR ET AL. EUROPACE. 2018;20(SUPPL_2):II11-II21. DOI:10.1093/EUROPACE/EUY057



Multi-procedure freedom from VT leading to implanted defibrillator shock, re-hospitalization, or repeat catheter ablation and death of any cause.

DOES THIS WORK?
IS THERE SUPPORTING CLINICAL DATA?



Study	Qiu, et al.[17]	Kataria, et al.[16]	Lim, et al.[14]	Reents, et al.[13]	Kawamura, et al.[12]	Hendriks, et al.[7]	Akca, et al.[5]	Roudijk, et al.[4]	Dinov, et al.[3]	Kim, et al.[2]	Szili-Torok, et al.[1]
Year	2018	2017	2017	2017	2017	2015	2013	2013	2012	2012	2012
No. Patients	152	336	443	218	51	239	163	62	102	145	113
Arrhythmia Type(s)	PVC	AF	AF	SVT	VT	VT	AF, SVT, VT	SVT	VT	AP	VT

Rates of acute success with RMN (orange) vs. manual navigation (gray) in head-to-head publications of >50 patients from 2012-2018.
Studies which did not report acute success data were excluded. [6, 8, 9, 10, 11, 15]
AF=Atrial Fibrillation, VT=Ventricular Tachycardia, SVT=Supraventricular Tachycardia, PVC=Premature Ventricular Contraction, AP=Accessory Pathway-Mediated Tachycardia

- More than 350 publications since 2012
- ead to
- 25 with more than 50 patients per group
- VT, PVCs, Afib, SVT, Congenital procedures

Randomized, Prospective, Multicenter Studies Showing Superiority??

RANDOMIZED TRIAL

MAGNETIC VT study: a prospective, multicenter, post-market randomized controlled trial comparing VT ablation outcomes using remote magnetic navigation-guided substrate mapping and ablation versus manual approach in a low LVEF population

Luigi Di Biase[1,2,3,4] · Roderick Tung[5] · Tamás Szili-Torok[6] · J. David Burkhardt[1] · Peter Weiss[7] · Rene Tavernier[8] · Adam E. Berman[9] · Erik Wissner[10] · William Spear[10] · Xu Chen[11] · Petr Neužil[12] · Jan Skoda[12] · Dhanunjaya Lakkireddy[13] · Bruno Schwagten[14] · Ken Lock[15] · Andrea Natale[1,3,16,17,18,19,20] · on behalf of MAGNETIC VT investigators

"The MAGNETIC VT trial will assess if VT ablation using the Niobe™ES magnetic navigation system results in superior outcomes compared to a manual approach in subjects with ischemic scar VT and low ejection fraction."

https://clinicaltrials.gov/ct2/show/study/NCT02637947

J Interv Card Electrophysiol
DOI 10.1007/s10840-016-0217-3

2019 HRS/EHRA/APHRS/LAHRS EXPERT CONSENSUS STATEMENT ON CATHETER ABLATION OF VENTRICULAR ARRHYTHMIAS

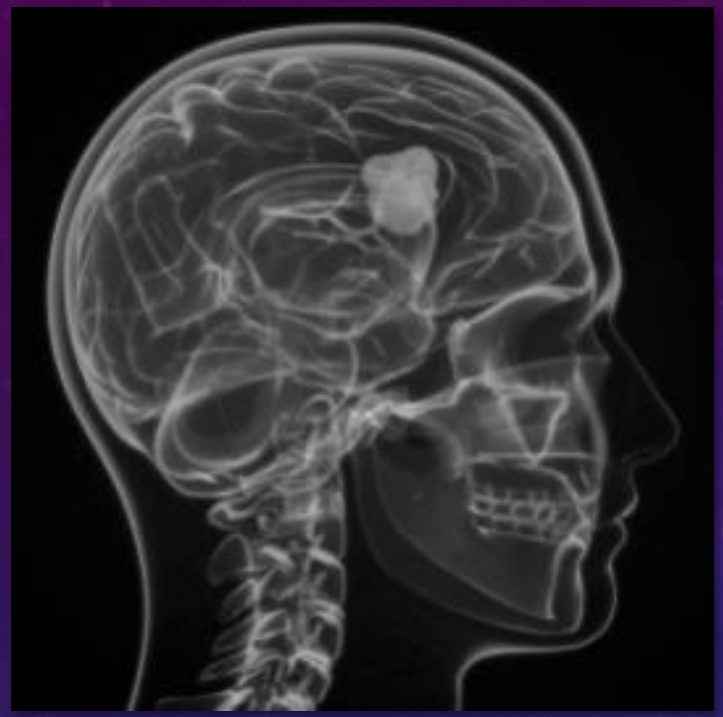
Cronin et al. Catheter Ablation of Ventricular Arrhythmias: In press, Heart Rhythm, Vol -, No -, - 2019

8.7. Electroanatomical Mapping Systems and Robotic Navigation

Recommendations for the use of EAM systems and remote navigation in ablation procedures for VAs

COR	LOE	Recommendations	References
I	B-NR	1. In patients with VA due to SHD undergoing an ablation procedure, EAM is useful.	S8.7.1–S8.7.9
IIa	B-NR	2. In patients with idiopathic VA undergoing an ablation procedure, EAM can be useful.	S8.7.4,S8.7.6
IIa	B-NR	3. In patients undergoing an ablation procedure for VA, magnetic catheter navigation can be useful to reduce fluoroscopy use.	S8.7.10–S8.7.14

PHYSICIAN RISK FACTORS OF MANUAL INTERVENTIONAL MEDICINE



OCCUPATIONAL CANCER RISK

85% of interventional cardiologists with brain tumors presented with the mass on the left side of their brain, the side most often facing the x-ray source.[1]

LOSS OF VISION

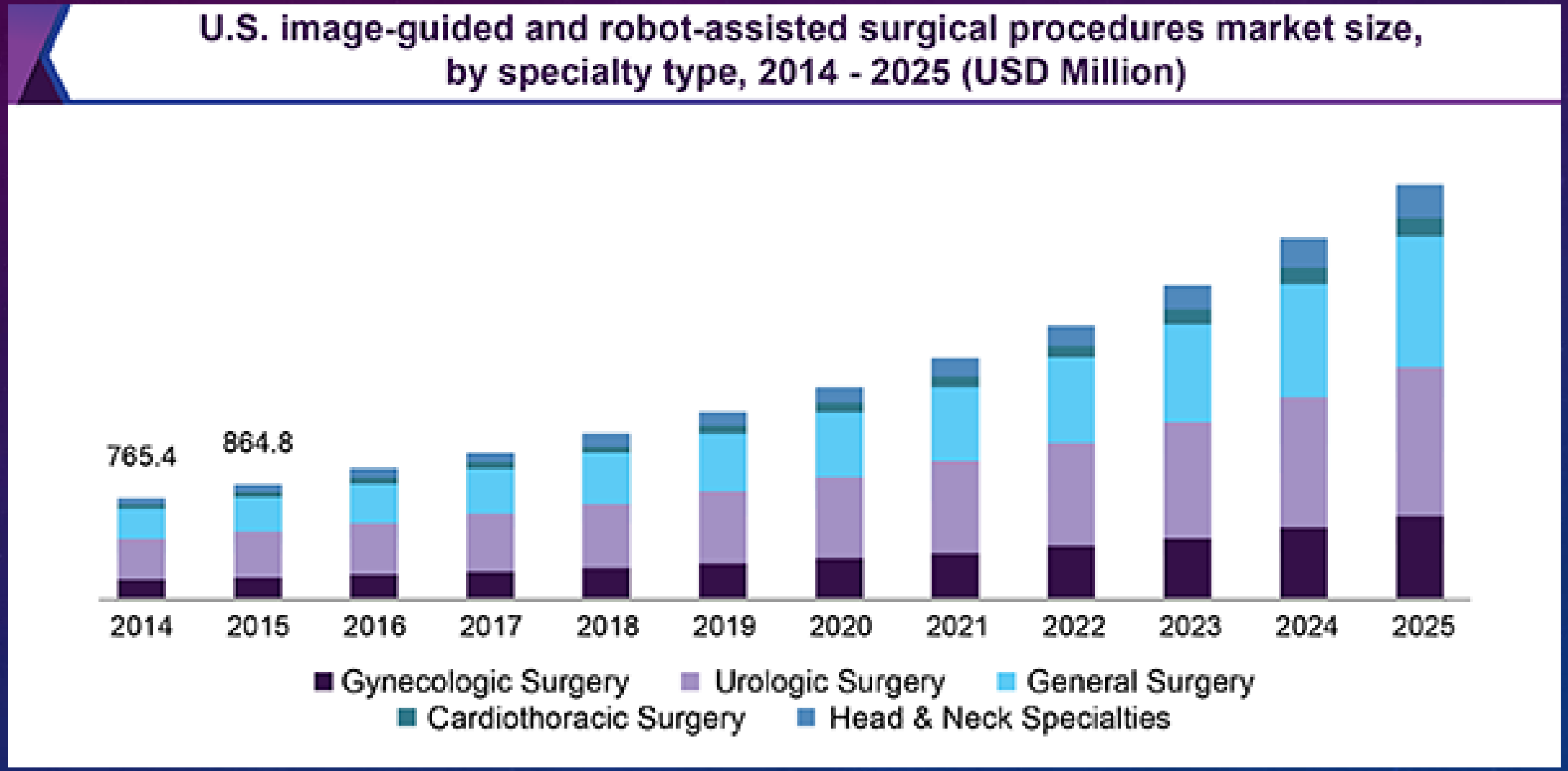
50% of interventional cardiologists and 41% of cardiac cath nurses and technicians had significant posterior subcapsular lens changes.[2]

ORTHOPEDIC BURDEN

49% of interventional cardiologists have suffered one or more orthopedic injuries as a direct result of their work in the cath lab.[3]

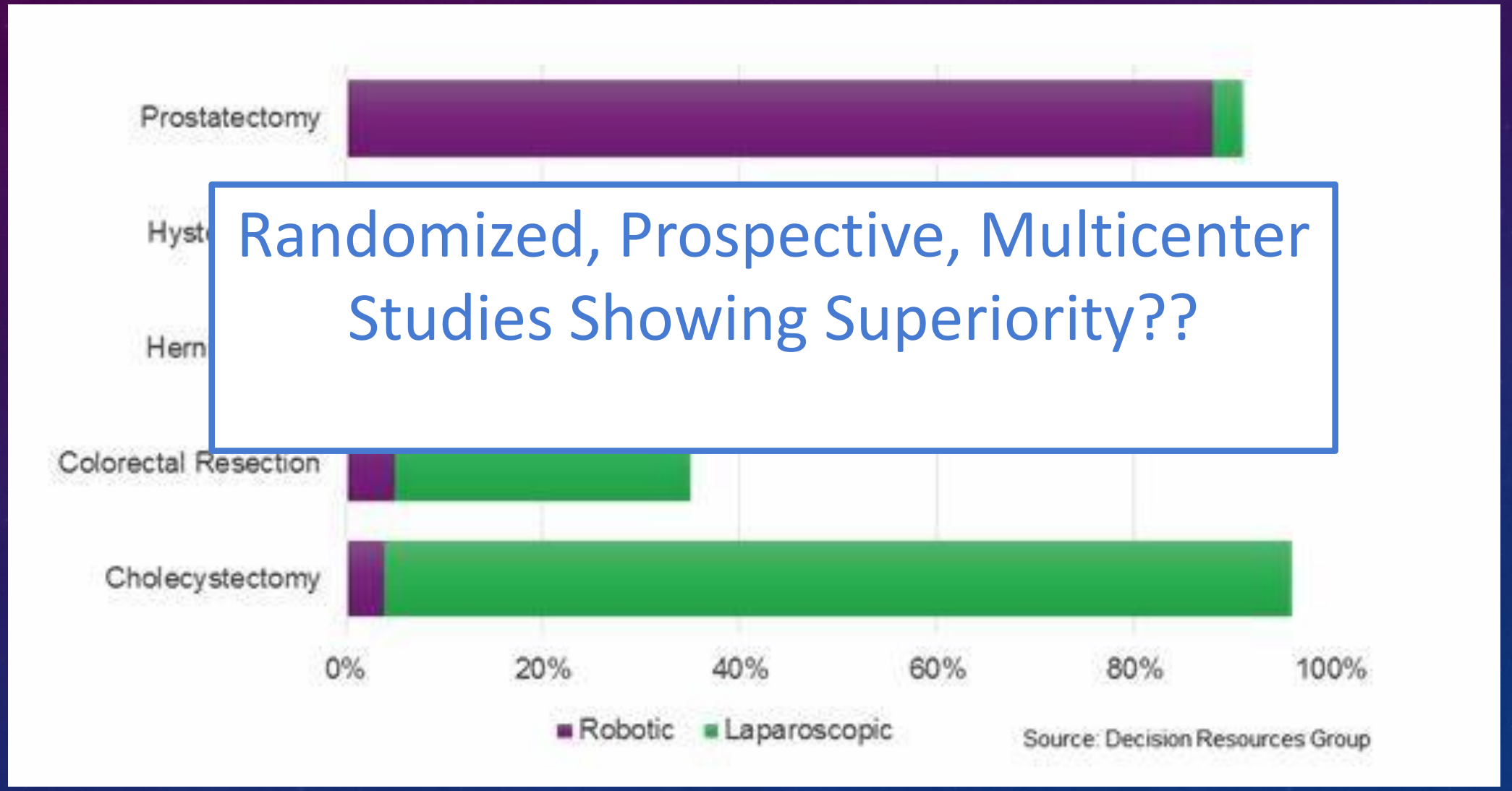
RoboticEP.com

ROBOTIC PRESENCE IN OTHER AREAS OF MEDICINE



https://www.grandviewresearch.com/industry-analysis/image-guided-and-robot-assisted-surgery-market

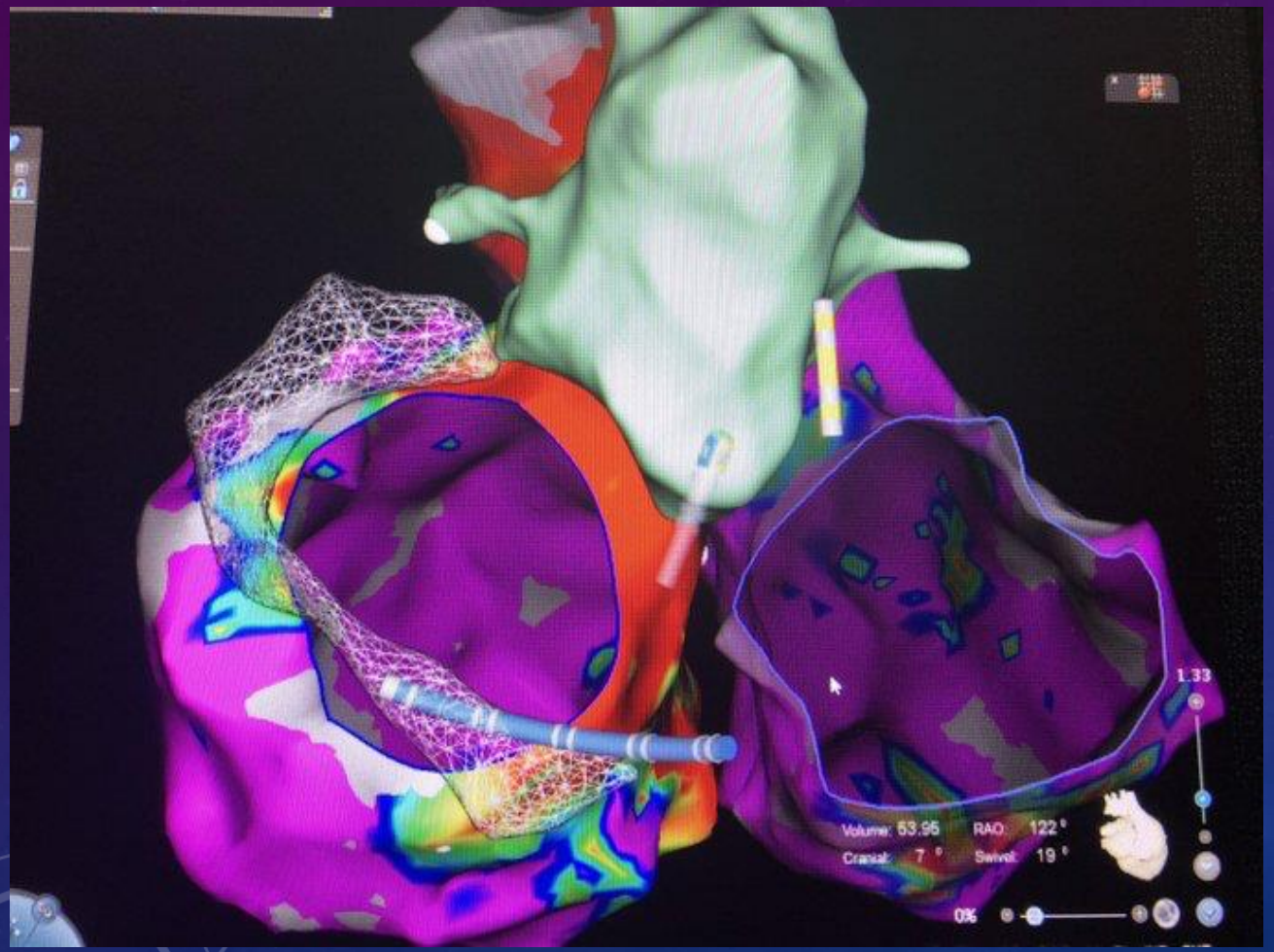
ROBOTIC PROCEDURE PENETRATION, U.S., 2016

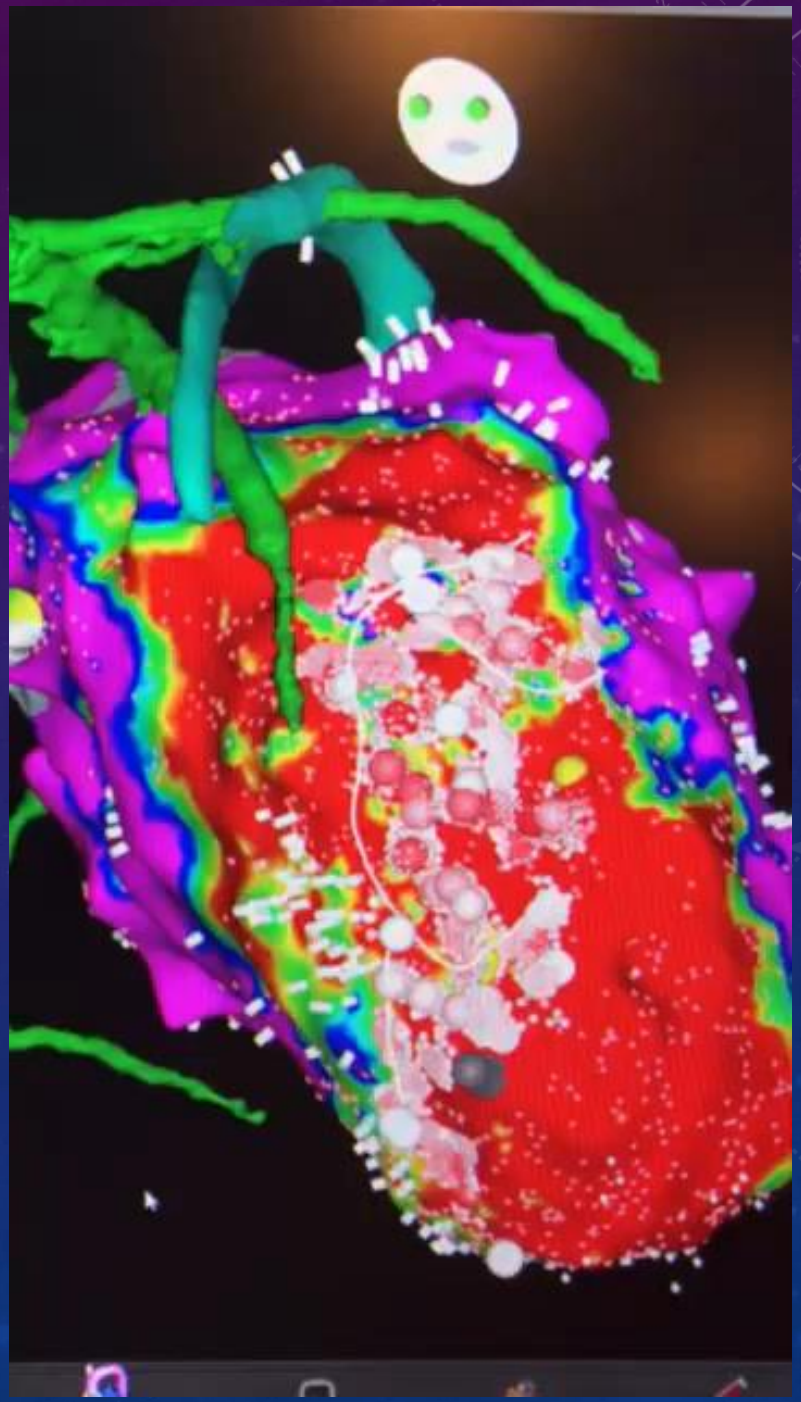


Randomized, Prospective, Multicenter Studies Showing Superiority??

https://www.meddeviceonline.com/doc/considerations-for-conquering-the-u-s-robotic-surgery-market-0001

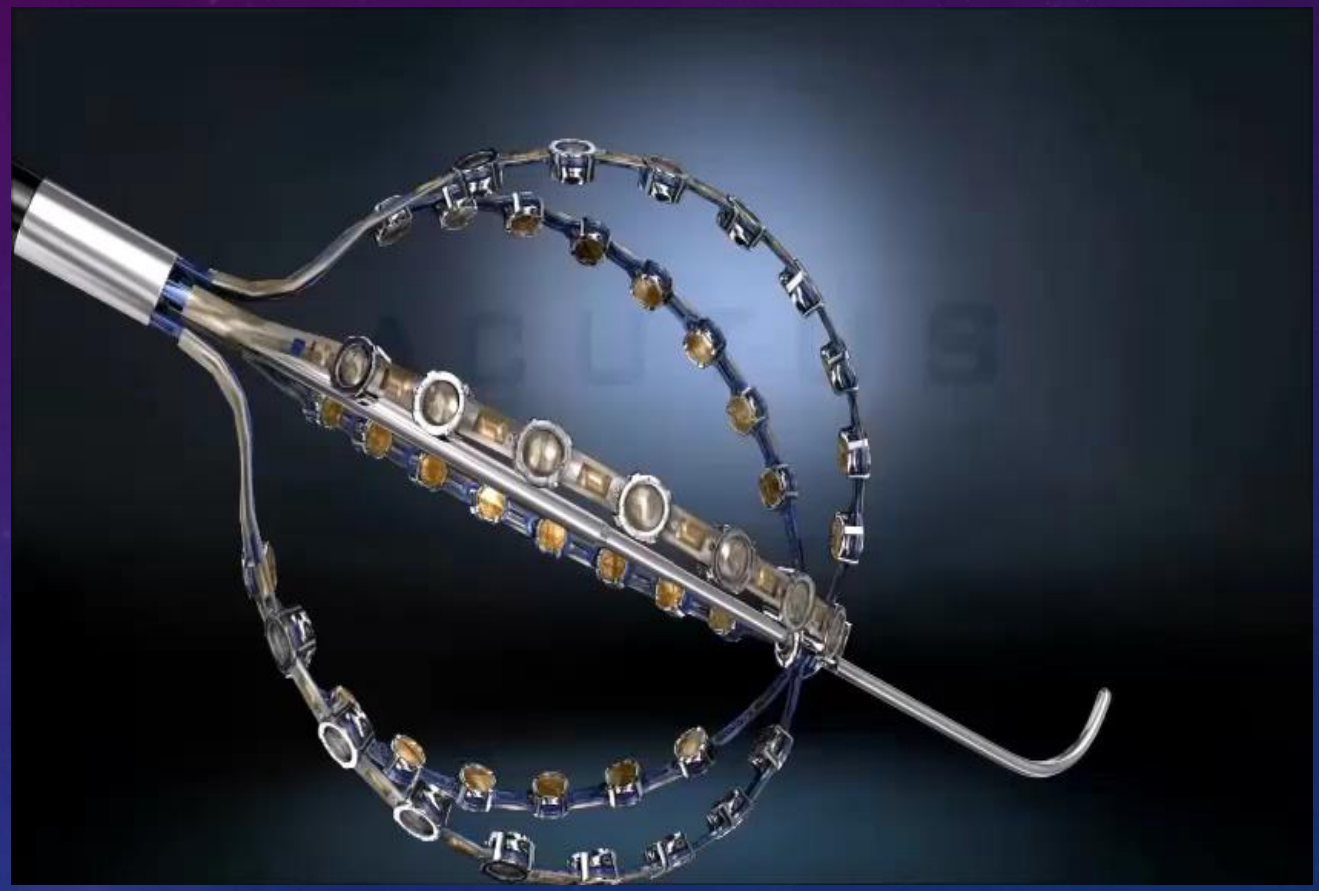
ADVANCED MAPPING





ACUTUS: ACQMAP®

- Anatomical Mapping
  - 48 Ultrasound transducers
  - 115,000 points/minute
  - Full chamber anatomy, few minutes, reproducible
  - Eventual visibility of secondary tissue characteristics and structures*
- Electrophysiological Mapping
  - 48 sensors: noncontact dipole density mapping: high definition
  - Immediate full chamber high density representation of stable and unstable arrhythmias
  - Contact mapping capable



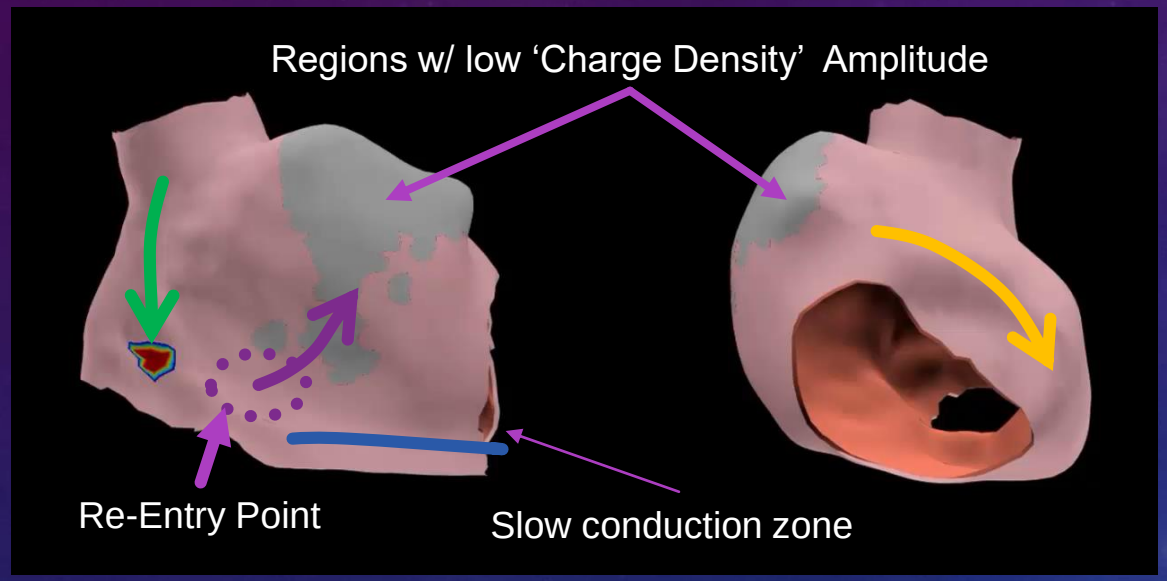
Stand-alone, open platform system

*This presentation may discuss technology which is off-label and/or not for sale in the U.S.

ACUTUS SUPERMAP

RAPID, HIGH DENSITY, FULL CHAMBER, MULTI-CIRCUIT MAPPING

SuperMap

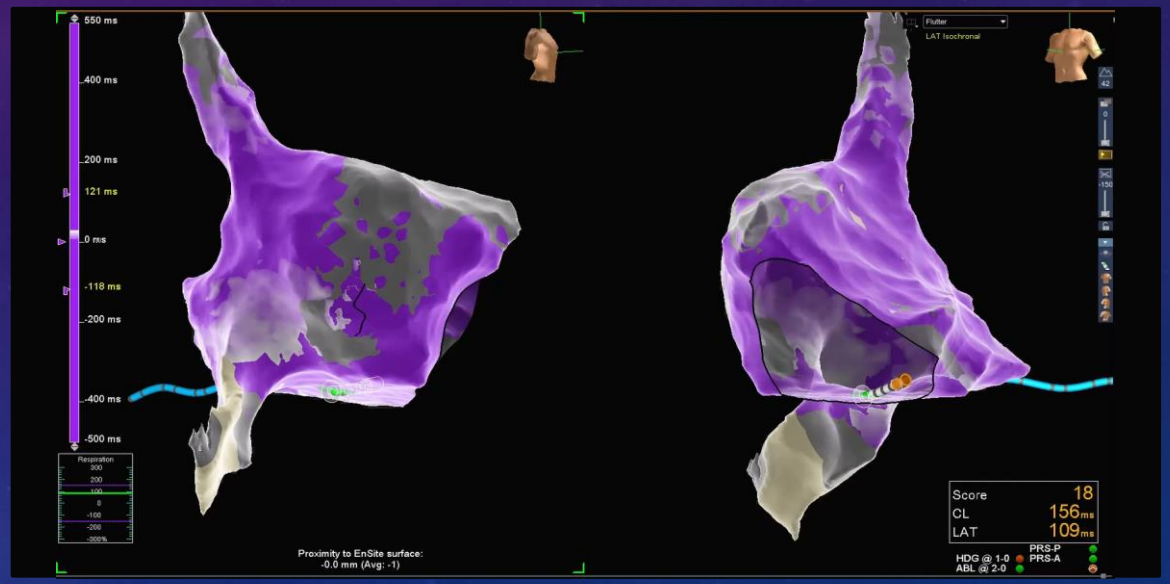


2 min and 36 sec of recording

55,000,000 in each 5 seconds

11,000,000 signals/sec

HD Grid*



15 min and 31 sec of recording

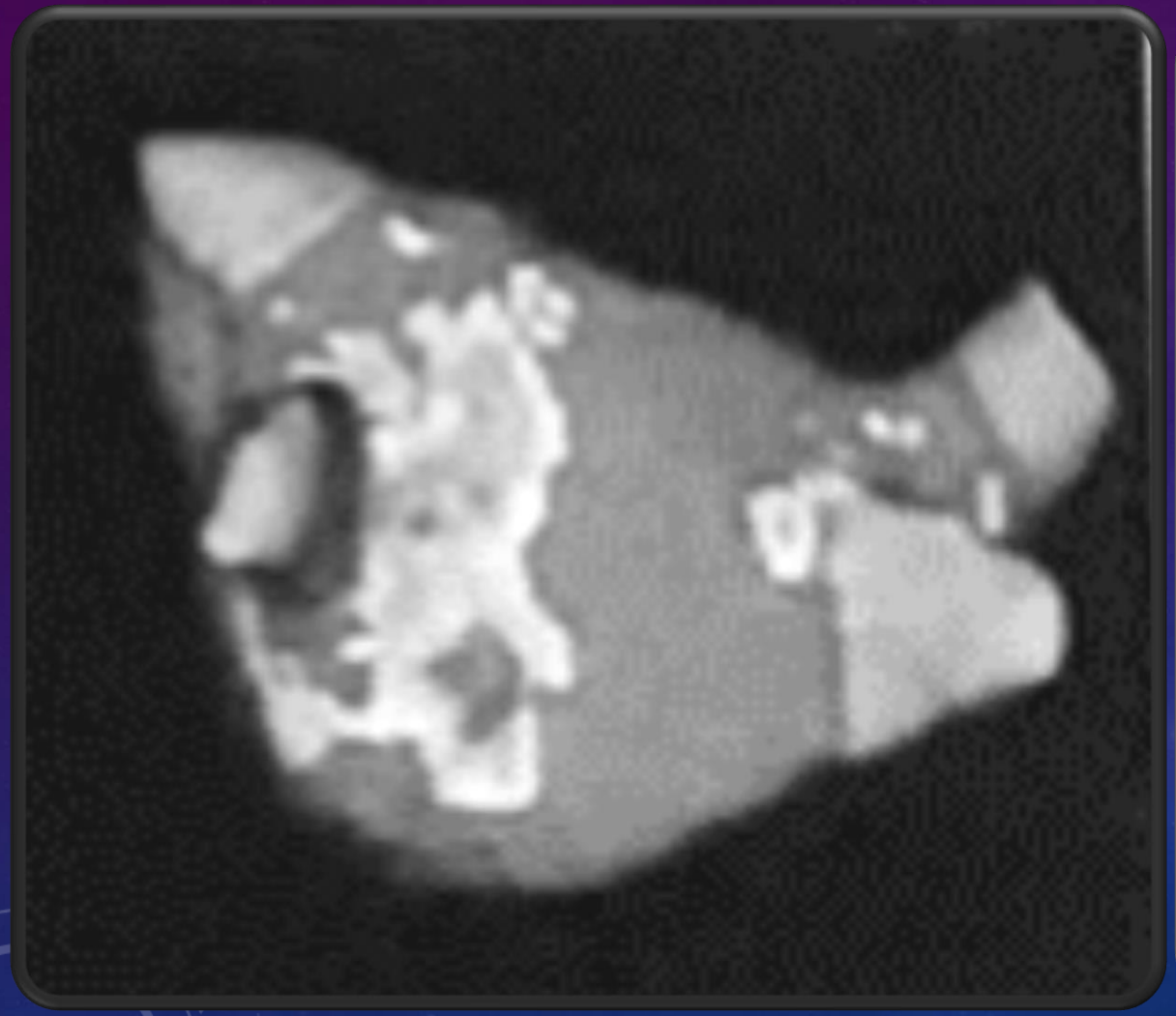
24,978 EGM's

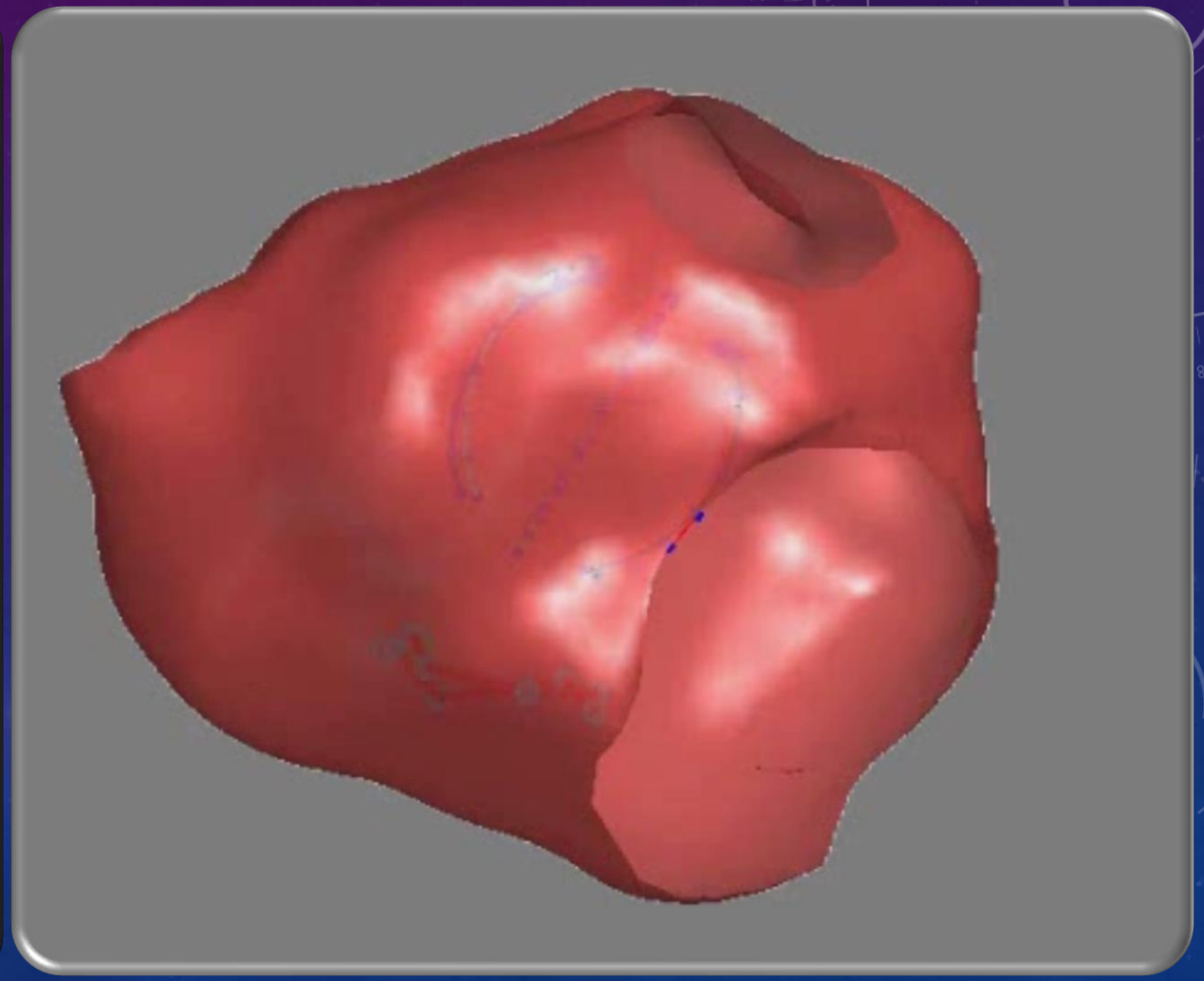
31 signals/sec

This presentation may discuss technology which is off-label and/or not for sale in the U.S.

***Abbott Medical Inc.**

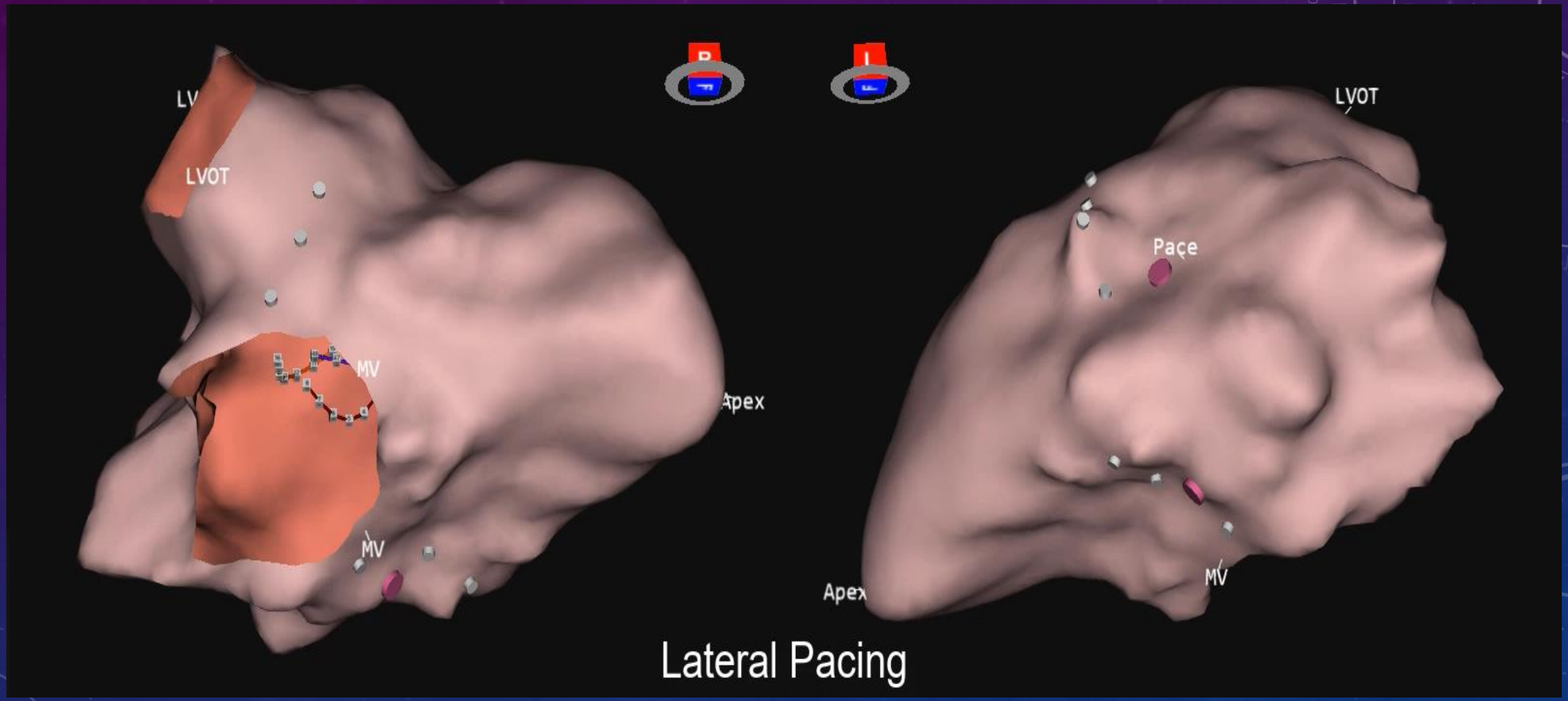
ULTRASOUND IMAGING CAPABILITY OF ACQMAP SYSTEM: WHAT CAN WE ADD TO ACTIVATION MAP SUBSTRATE?





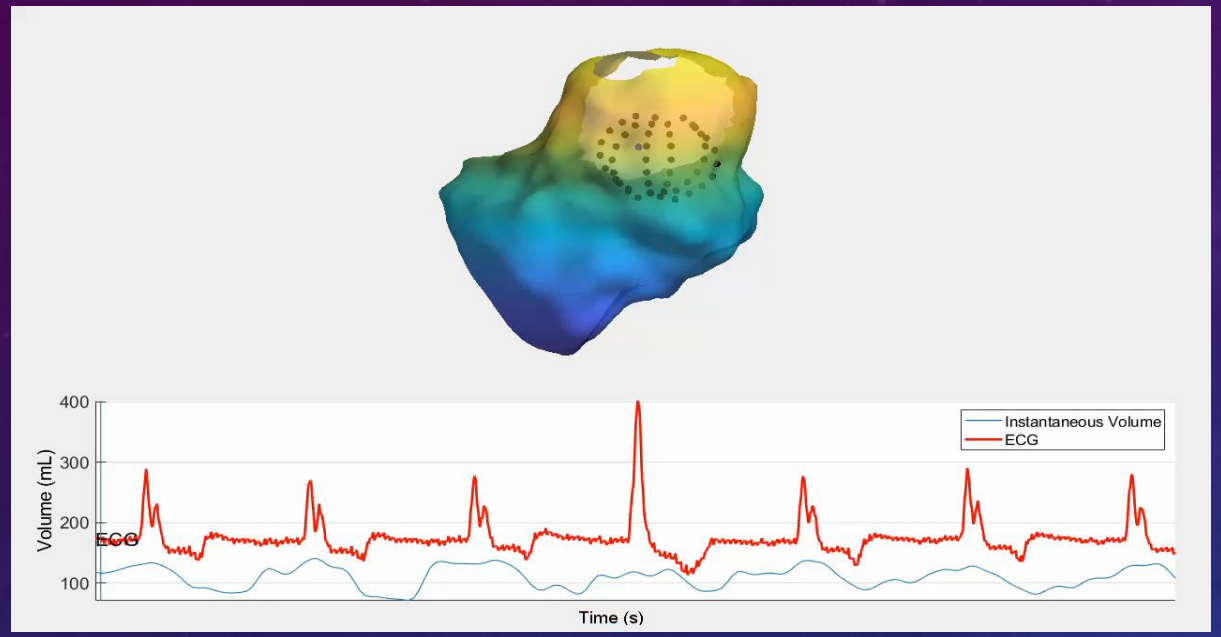
Advanced research and concepts, technology not available for sale in the US

EARLY LV PACING STUDY (ANIMAL MODEL)

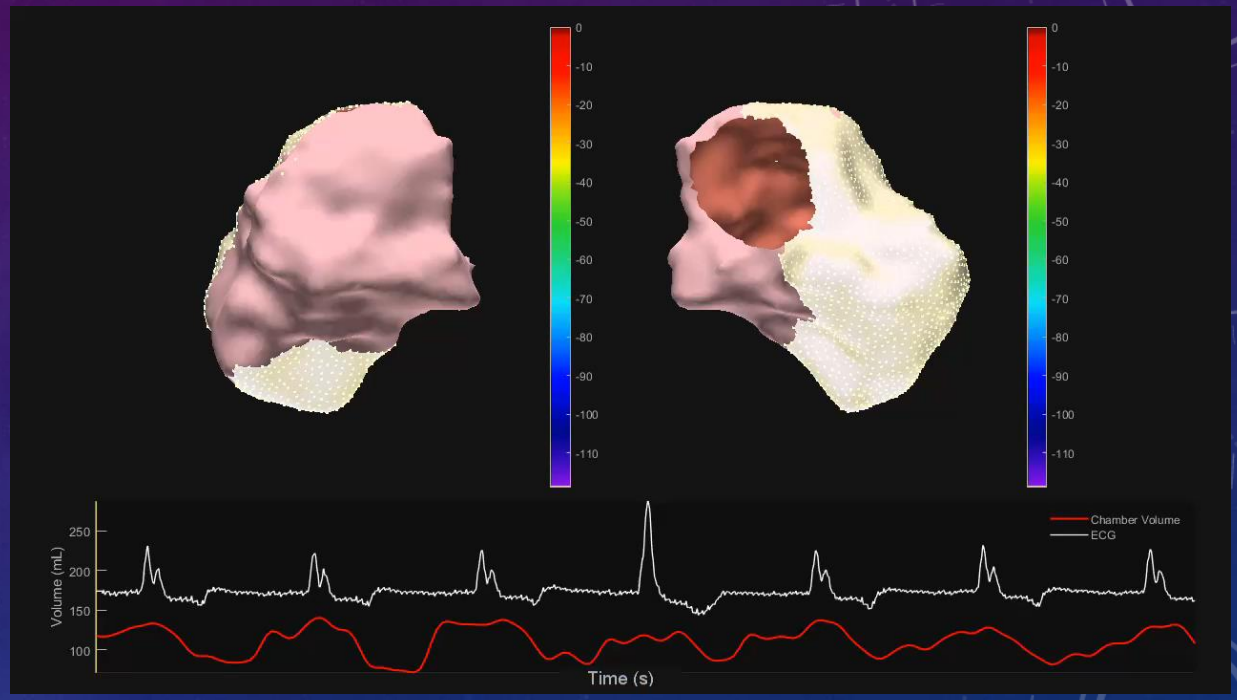


Advanced research and concepts, technology not available for sale in the US

What's Next?
Electro-functional diagnostics and VT



Real Time Wall Motion



Electro-Functional Representation

Advanced research and concepts, technology not available for sale in the US

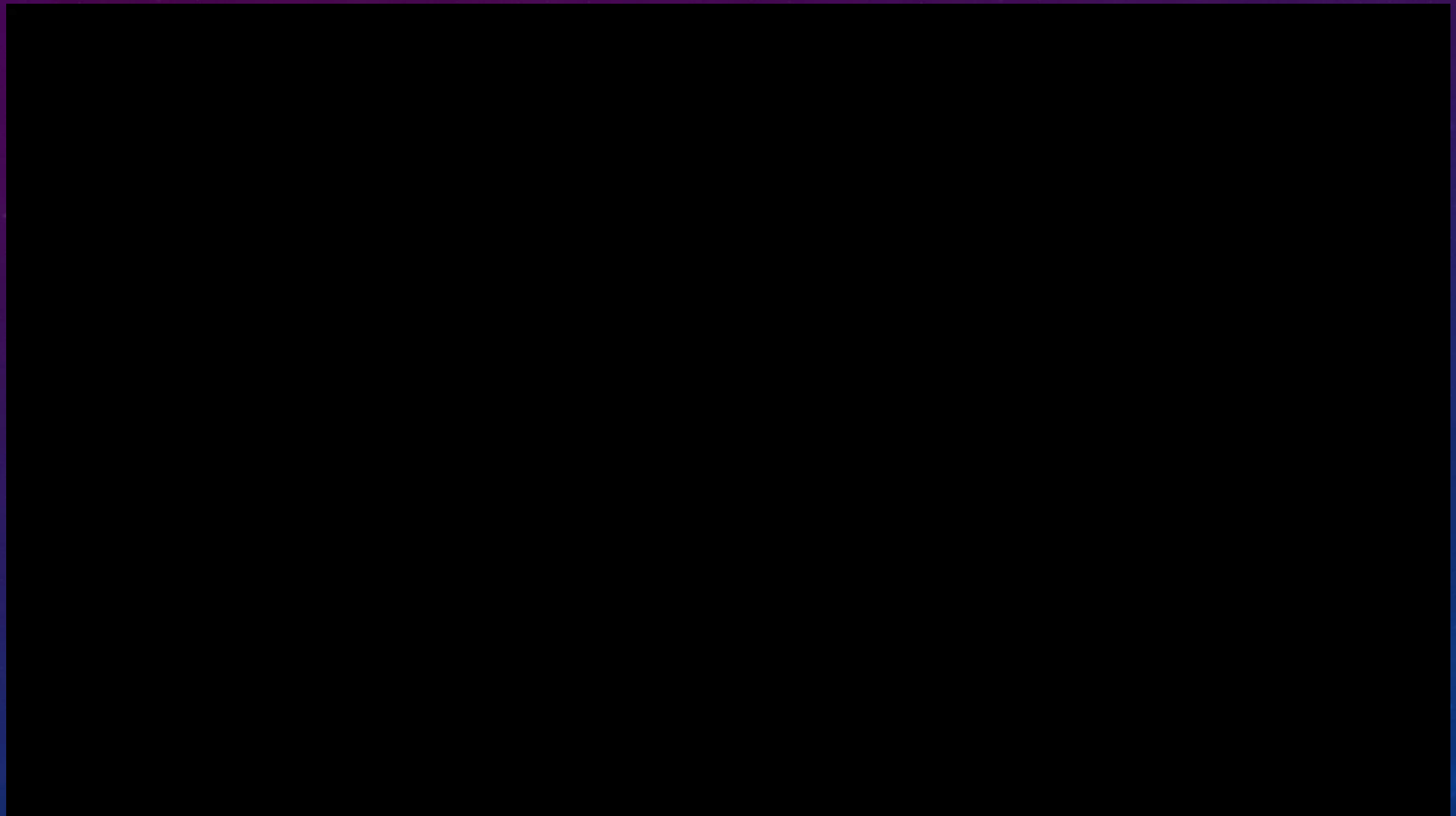
WHAT IS NEXT FOR OPTIMAL MAPPING AND ABLATION?

- We have technology that allows us to accurately navigate
- We have technology that allows us to ablate with reproducible effectiveness and safety

- Improved visualization of underlying electrophysiology
- Accurate real-time anatomy of chamber and surrounding structures
- Target Tissue Characterization

Automation???

STEREOTAXIS AND ACUTUS INTEGRATION



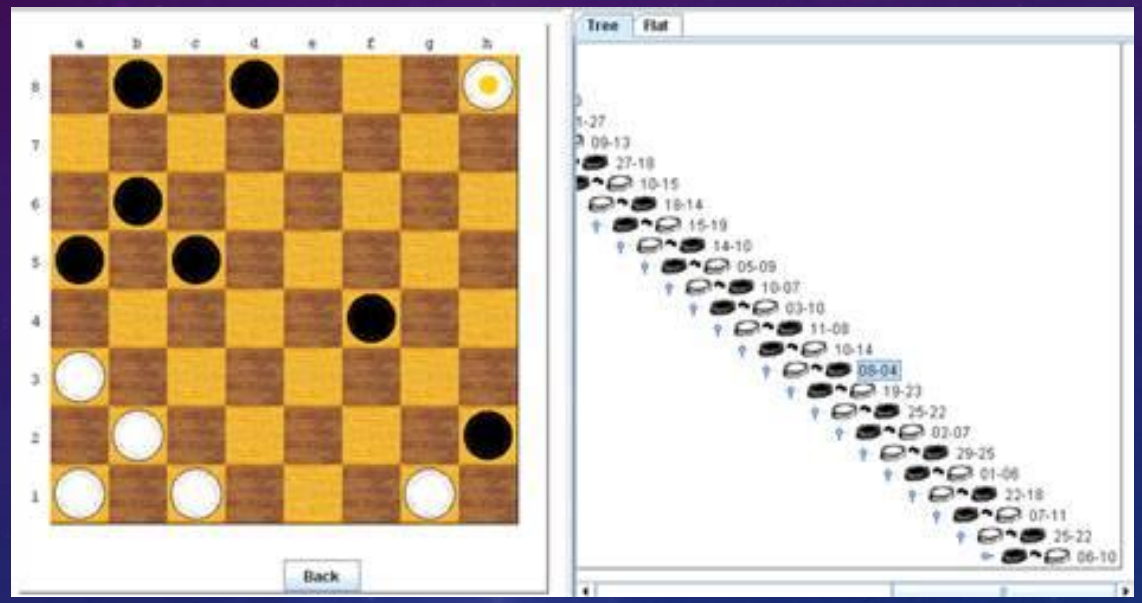
WHY MOVE TOWARDS AUTOMATION IN EP/CV?

"As technology advances, human error in manufacturing becomes more and more visible every day. Human error is responsible for more than 80 percent of failures and defects"

Dr. Ginette M. Collazo, https://learnaboutgmp.com/good-manufacturing-practices-cgmp/the-top-7-how-to-reduce-manufacturing-human-error/

HARDWARE AND AI CAPABILITIES EVOLVING RAPIDLY

- 1989: Chinook, created by computer scientists from the University of Alberta beat the world's checkers champion



- 2007: By playing out every possible move — about 500 billion billion in all — the computer proved it can never be beaten.

http://www.nbcnews.com/id/19839044/ns/technology_and_science-innovation/t/checkers-computer-becomes-invincible/#.W-5OU8LHxEY

HARDWARE AND AI CAPABILITIES EVOLVING RAPIDLY

- 1997: IBM's Deep Blue supercomputer defeated chess Grand Master Gary Kasparov

HARDWARE AND AI CAPABILITIES EVOLVING RAPIDLY

- **Go: 1 million trillion trillion trillion trillion more configurations than chess. 10 followed by more than 300 zeroes – More possible GO game configurations than there are subatomic particles in the known universe**
- **2016 AlphaGo wins 4/5 matches versus 18-time world champion Lee Sedol**

HARDWARE AND AI CAPABILITIES EVOLVING RAPIDLY

- 2017: AlphaZero AI (Google)
- Its machine-learning approach is given no human input apart from the basic rules of chess. The rest it works out by playing itself over and over with self-reinforced knowledge.
- In four hours of learning defeats the worlds best chess AI program

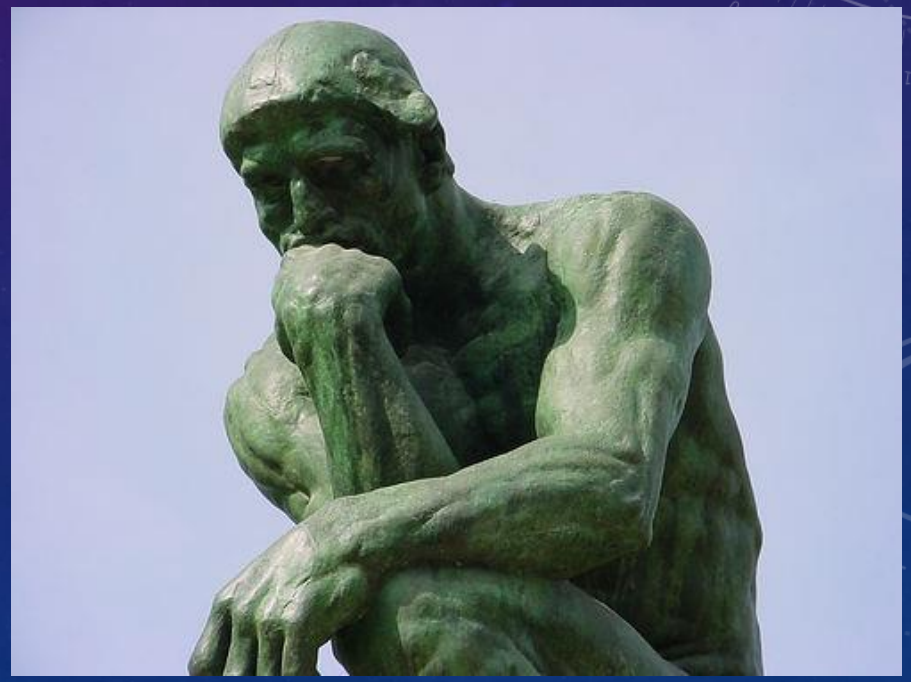
Once technology bests humans at a task, it leaves us behind rapidly and never looks back

https://www.theguardian.com/technology/2017/dec/07/alphazero-google-deepmind-ai-beats-champion-program-teaching-itself-to-play-four-hours

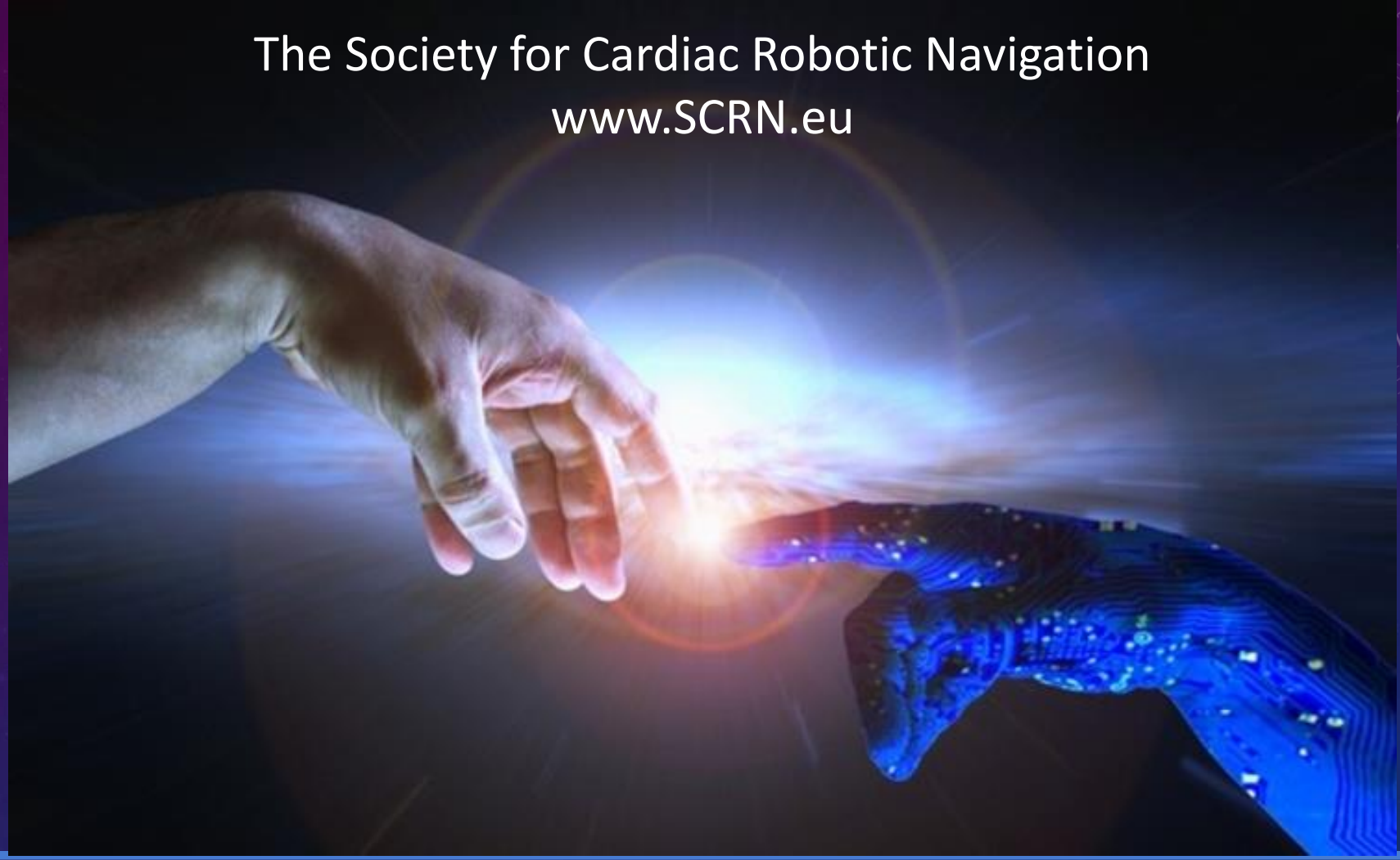
SHIFT THE PARADIGM

- We have become excellent technicians in order to overcome the inerent limitations of existing technology
- In virtually every industry, advances in hardware and software have superseded human manual abilities alone
- Have we reached a point where this is worth focused exploration
- Are we going to be ready to teach the next generation?
  - Certificate pathway in Robotic Navigation
  - Society for Cardiac Robotic Navigation: www.SCRN.eu

REDUCE EMPHASIS ON PHYSICIANS AS TECHNICIANS: ENABLE PHYSICIANS TO BE SCIENTISTS, COMMUNICATORS AND PHILOSOPHERS



The Society for Cardiac Robotic Navigation
www.SCRN.eu



Kasparov:
“AI will help us to release human creativity. Humans won’t be redundant or replaced, they’ll be promoted.”

https://www.theregister.co.uk/2018/05/10/heres_what_garry_kasparov_an_old_world_chess_champion_thinks_of_ai/