

What Does The Future Hold in Ablation

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Disclosures

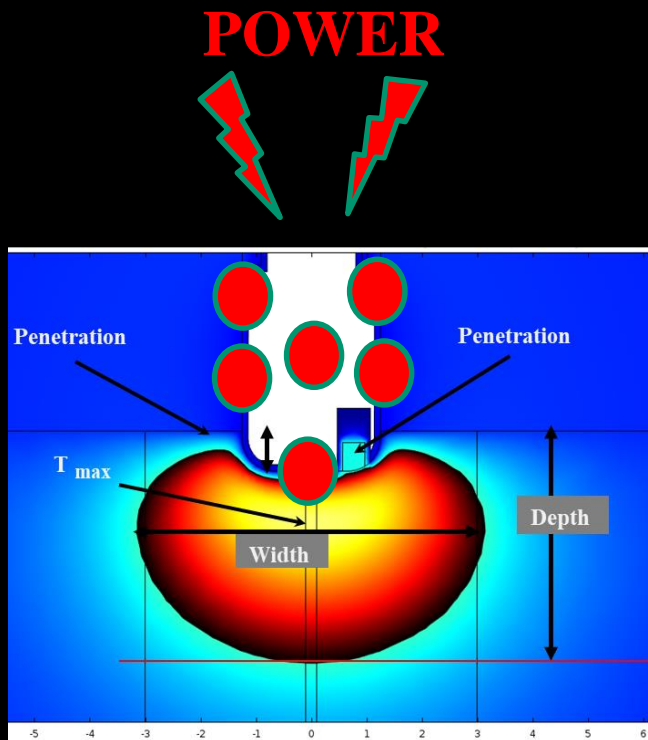
- Research Grants: Biosense Webster, Farapulse, Affera, Vytronus, Medlumics, Luxcath, Cardiofocus, Cardionext
- Consultant: Abbott, Farapulse

This talk discusses various investigational non-FDA approved devices and technologies

The Future of Thermal ablation

Radiofrequency, Laser , Ultrasound

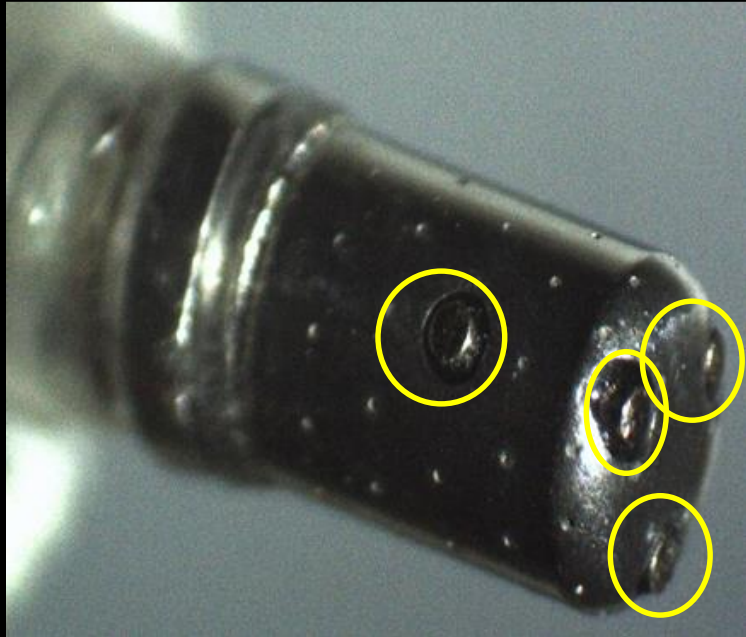
Controlling Lesions Based on “Tissue Temperature”



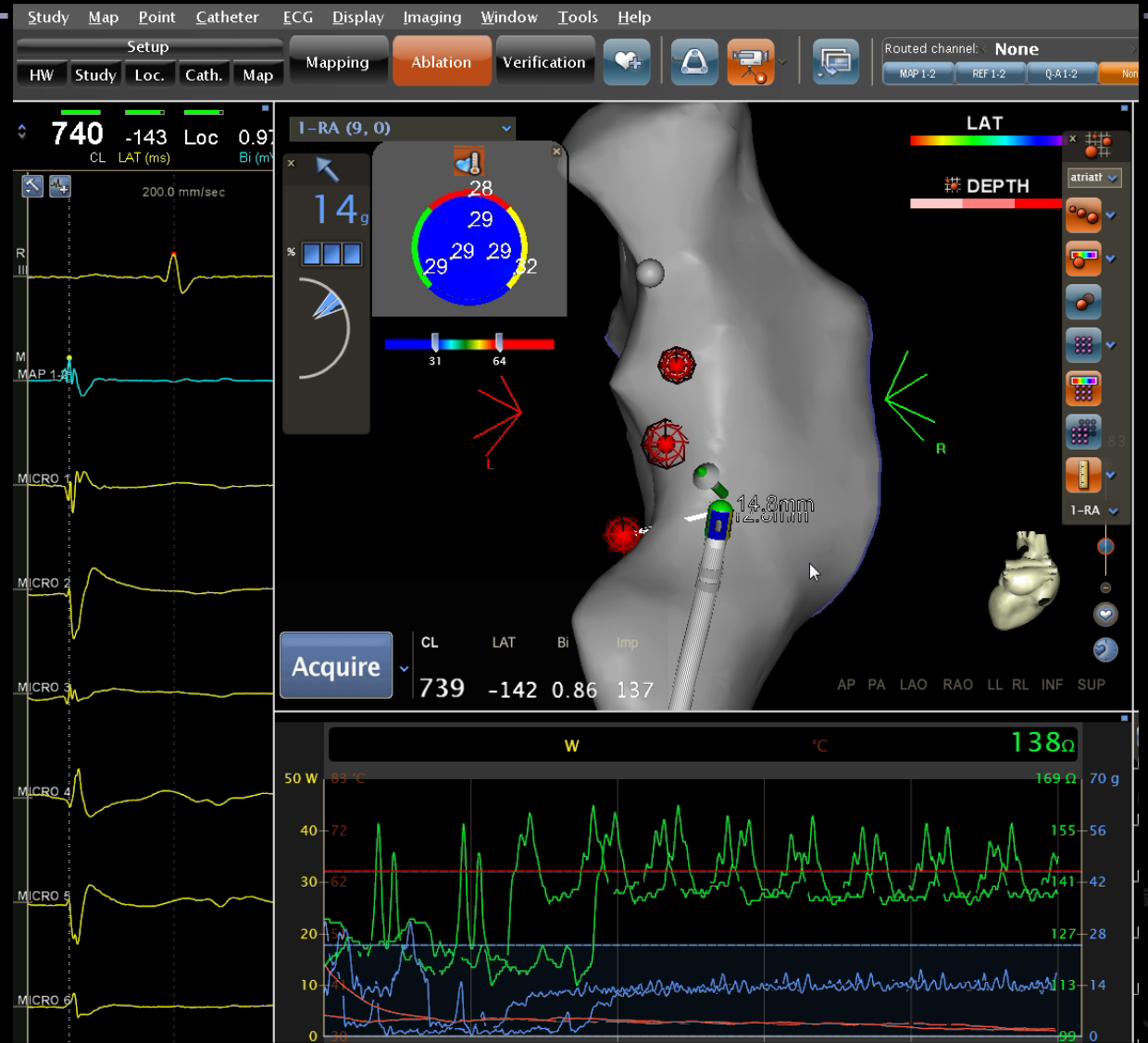
Advantages of Interface Temperature

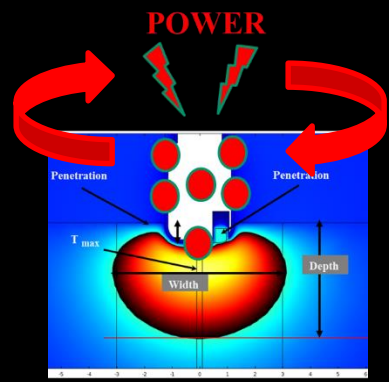
- Another measure of contact- not just force
- Direct measure of mechanism of tissue injury
 - Allows for controlled lesion delivery
 - Avoid char/ steam pops
 - Temperature monitoring – is also stability monitoring

Chamber Specific Lesion Dimension Prediction



Embedded surface temperature sensors in 56 hole porous tip



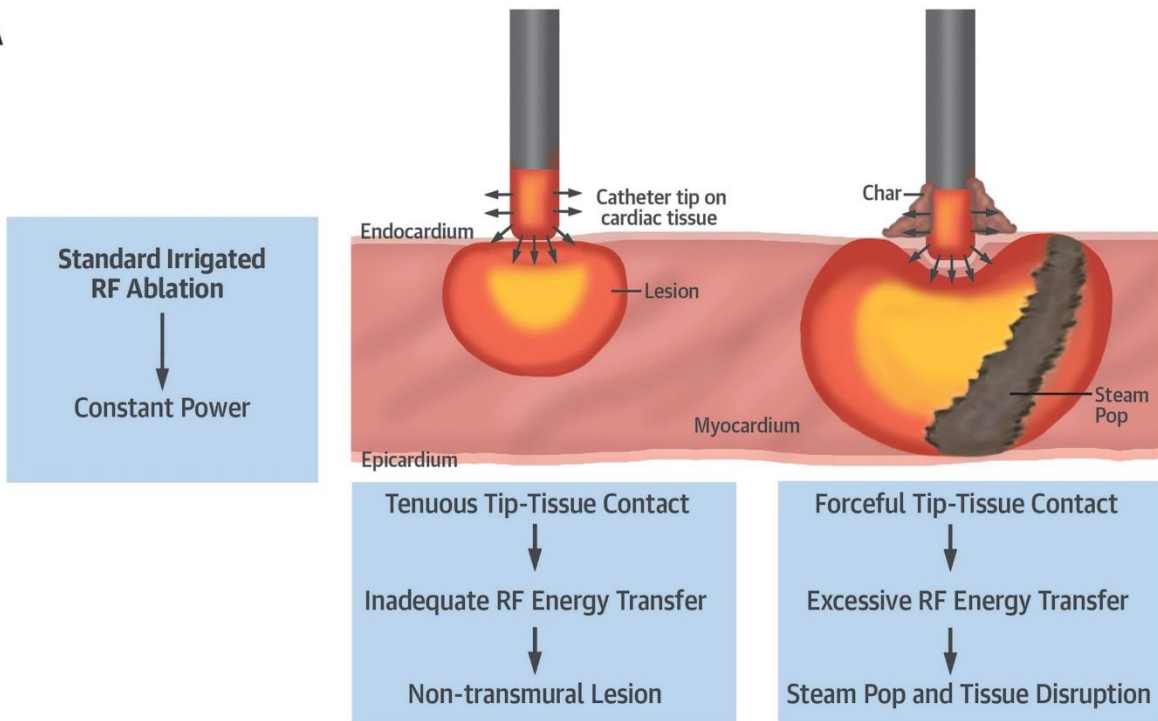


Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation

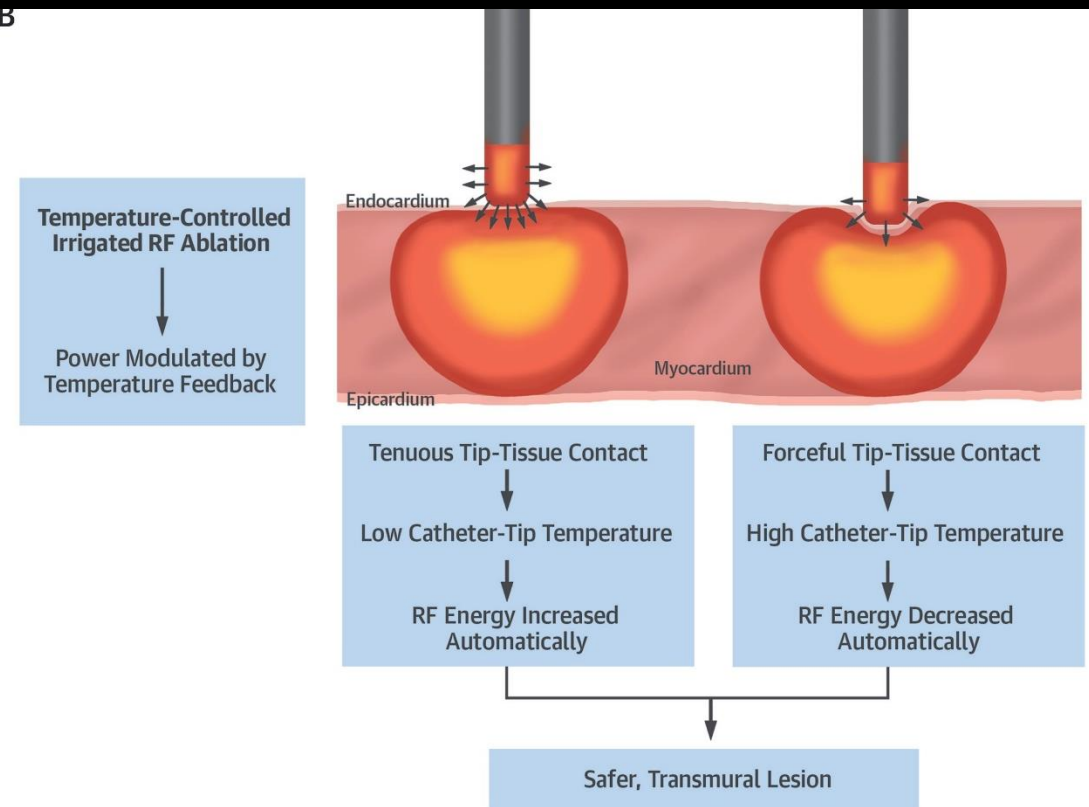


Jin Iwasawa, MD,^a Jacob S. Koruth, MD,^a Jan Petru, MD,^b Libor Dujka, MD,^b Stepan Kralovec,^b Katerina Mzourkova,^b Srinivas R. Dukkipati, MD,^a Petr Neuzil, MD, PhD,^b Vivek Y. Reddy, MD^{a,b}

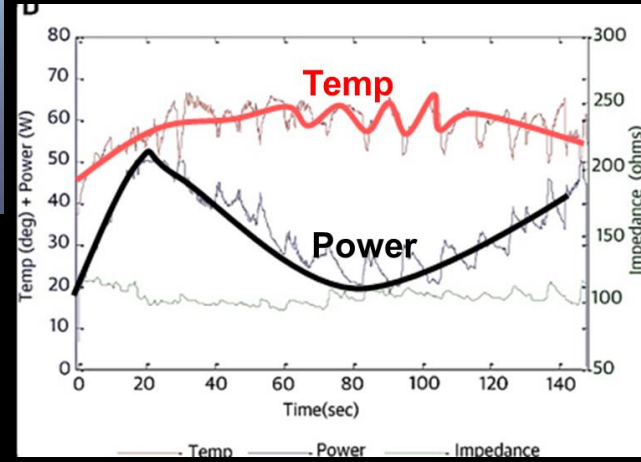
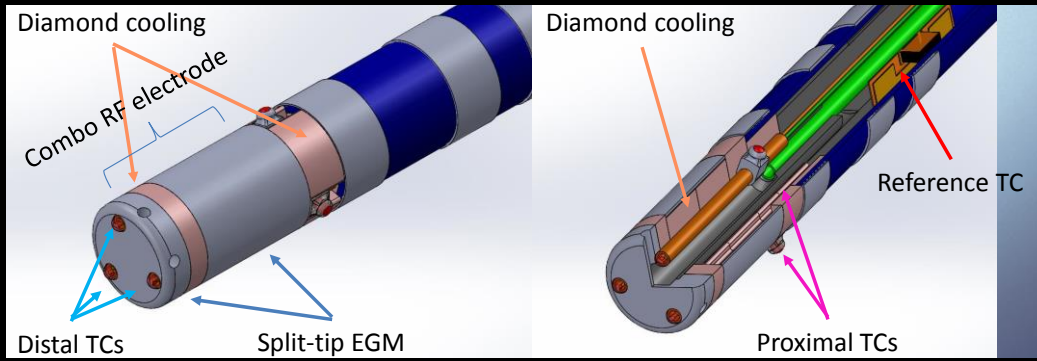
A



B



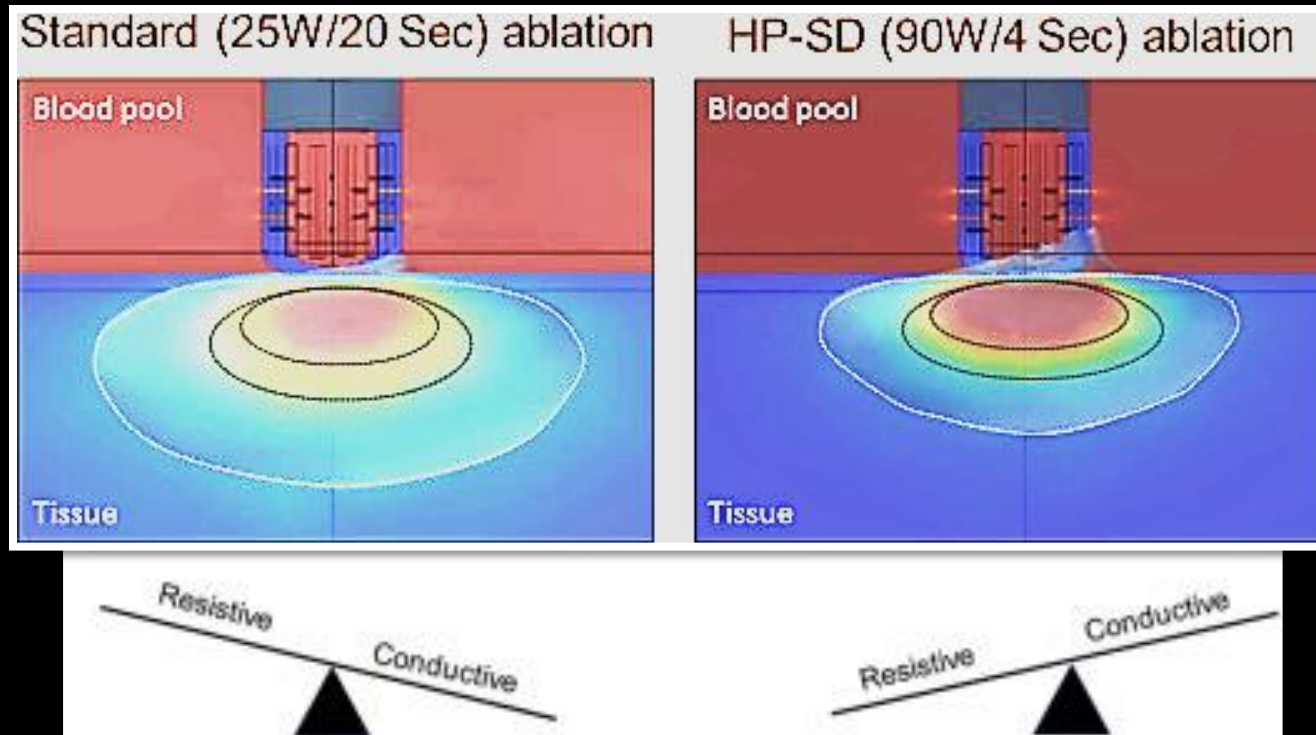
Temperature Controlled-Irrigated RF: Diamond tip ablation



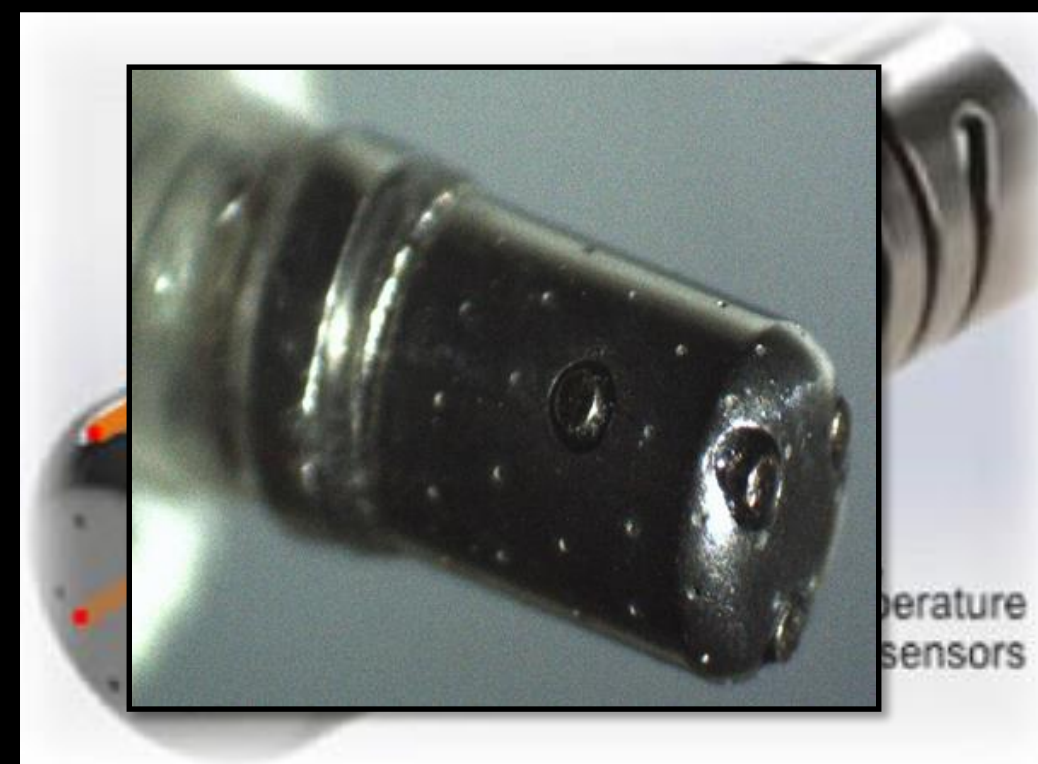
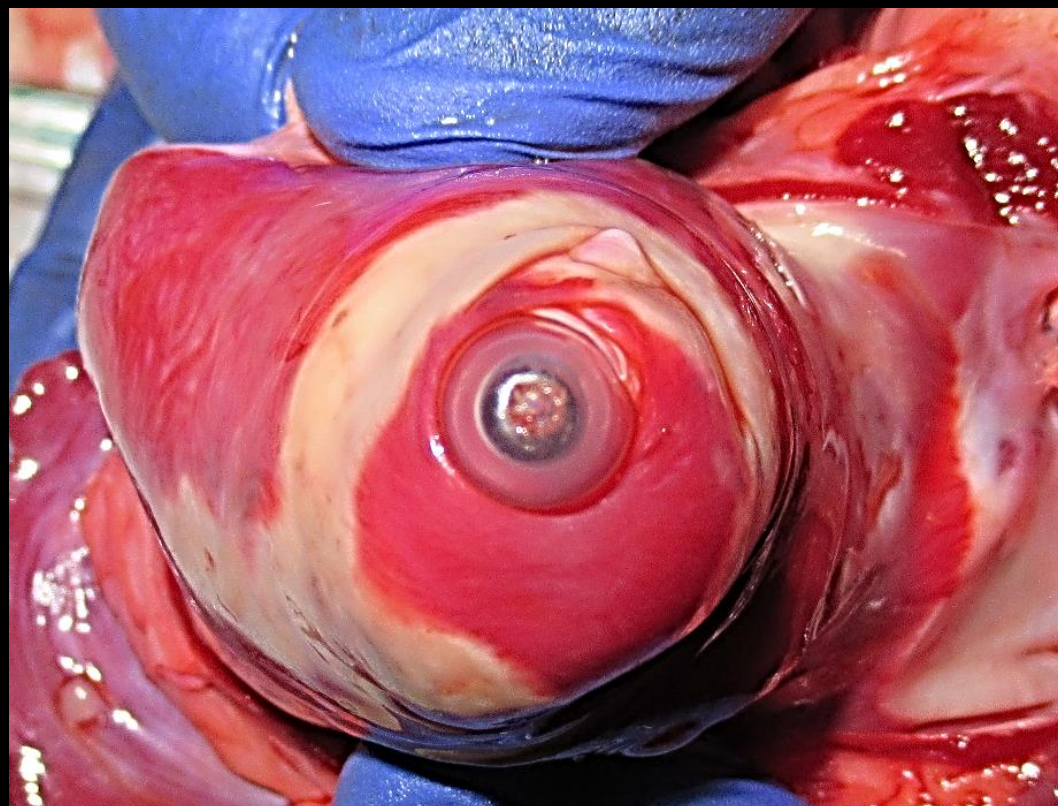
- Diamond-tip radiofrequency (RF) irrigated catheter
- Six thermocouples

	Study Group (n = 35)	Control Group (n = 35)	p Value
No. of ablation lesions per patient	83.6 ± 13.2	151.6 ± 38.2	<0.001
Left PV lesion set	37.9 ± 8.8	60.2 ± 18.2	<0.001
Right PV lesion set	46.1 ± 9.5	91.3 ± 26.0	<0.001
RF application time per point, s	18.8 ± 1.9	35.1 ± 4.1	<0.001
Left PV lesion set	17.6 ± 1.9	33.8 ± 5.4	<0.001
Right PV lesion set	19.7 ± 2.4	35.8 ± 4.2	<0.001
Total RF application time per patient, min	26.3 ± 5.2	89.2 ± 27.2	<0.001
Left PV lesion set	11.2 ± 3.3	34.4 ± 13.1	<0.001
Right PV lesion set	15.1 ± 3.7	54.8 ± 17.9	<0.001
Fluoroscopy time, min	11.2 ± 8.5	19.5 ± 6.8	<0.001
Average impedance drop, Ω	13.1 ± 3.5	8.1 ± 2.1	<0.001
Average power, W	36.3 ± 2.6	31.2 ± 2.5	<0.001

Irrigated RF and Atrial Ablation.....



Fast Ablation: Right Superior PV Isolation 90W/4 Seconds



Pulmonary Vein Isolation With Very High Power, Short Duration, Temperature-Controlled Lesions



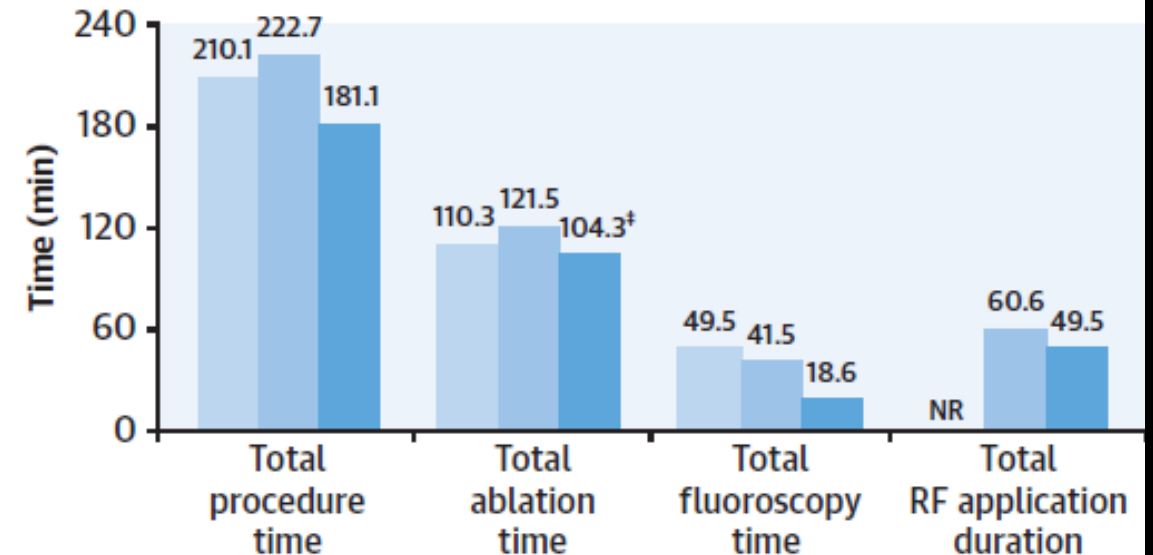
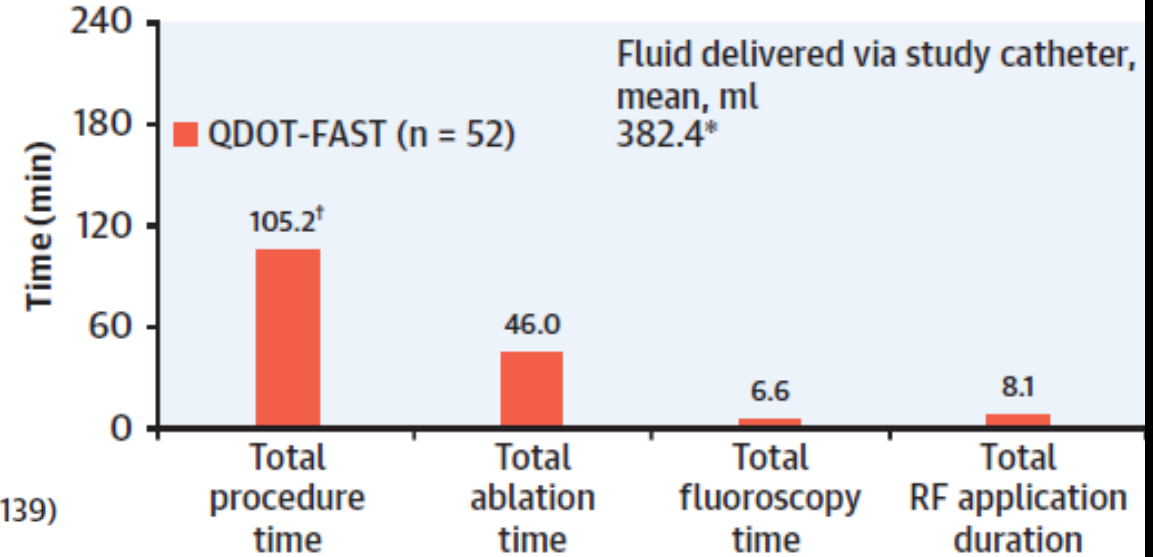
The QDOT-FAST Trial

Vivek Y. Reddy, MD,^{a,b} Massimo Grimaldi, MD,^c Tom De Potter, MD,^d Johan M. Vijgen, MD,^e Alan Bulava, MD, PhD,^f Mattias Francis Duytschaever, MD,^g Martin Martinek, MD,^h Andrea Natale, MD,ⁱ Sebastien Knecht, MD, PhD,^g Petr Neuzil, MD, PhD,^b Helmut Pürerfellner, MD^h

Q-dot - vHPSD

- 52 PAF pts
- Procedure time = 105 mins
- Fluoroscopy = 6.6 mins
- 79% PVI with vHPSD alone

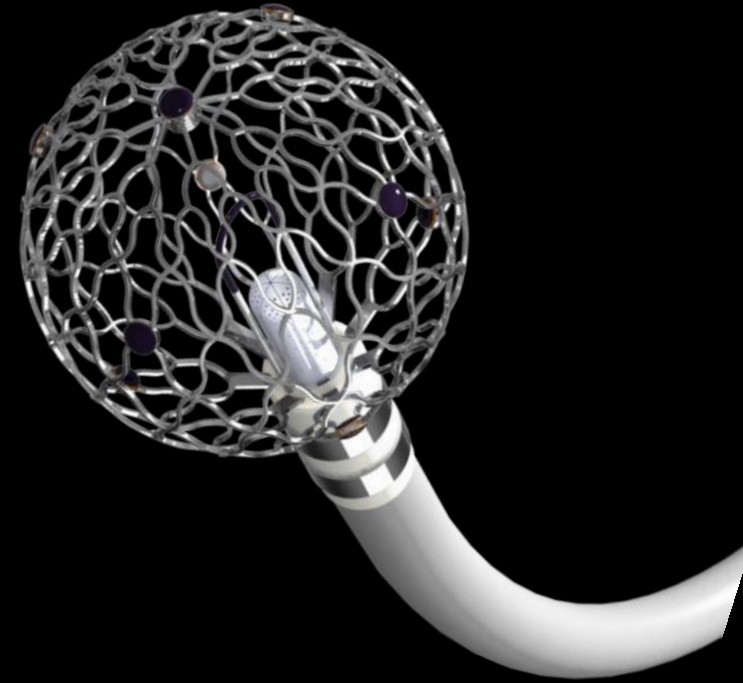
■ THERMOCOOL AF (n = 139)
■ SMART-AF (n = 160)
■ SMART-SF (n = 159)



Lattice Ablation (Sphere 9) Catheter

Combined ablation and mapping catheter

- 8F bidirectional deflectable - expandable conductive nitinol mesh
- Diameter- 9mm with 9 Temp sensors/mini electrodes
- Central irrigation

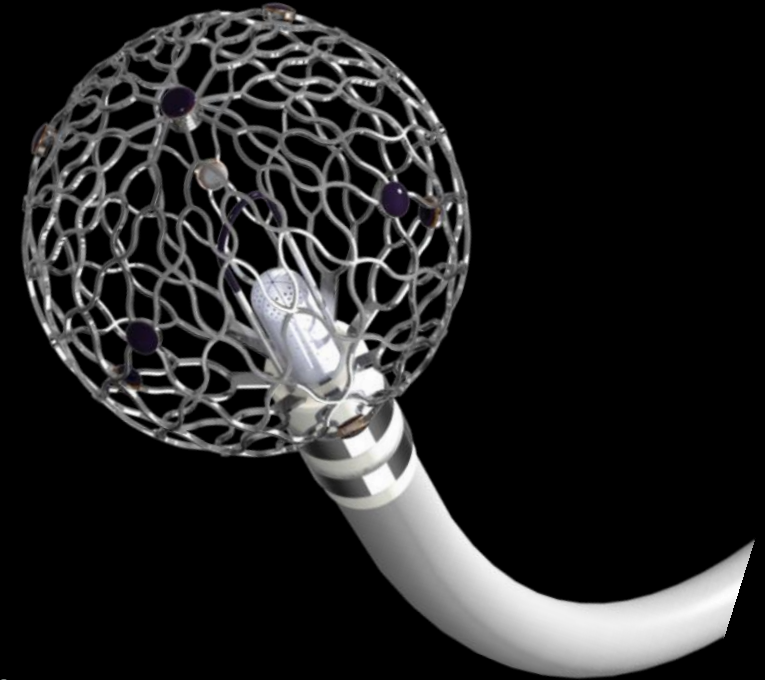


Lattice Ablation (Sphere 9) Catheter

Temperature controlled irrigated RF

- Mini electrodes + Central electrode
- Tissue stability- Compressible
- Faster, Wider, Deeper lesions

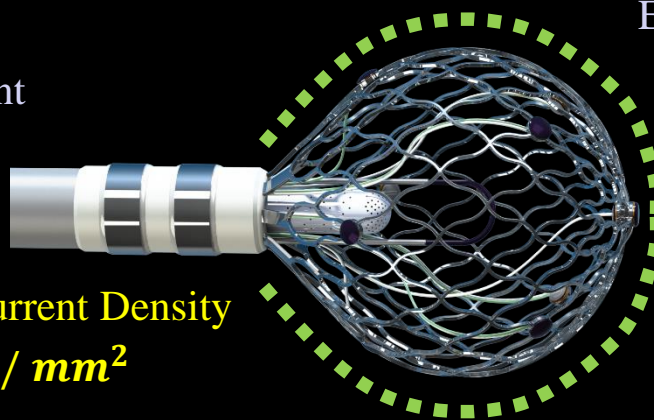
- Electroanatomical mapping - magnetic sensor
- Anatomy acquisition - respiratory gating
- Contact : Impedance between microelectrodes and center electrode



Wide Tip RF delivery

$$\text{Average Current Density} = \frac{\text{Current}}{\text{Surface Area}} = \frac{I}{S}$$

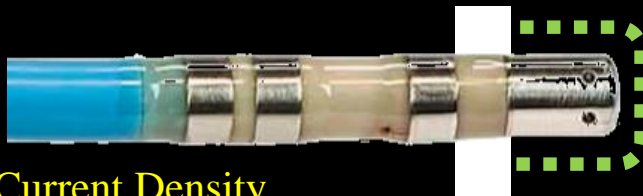
Max Current
 $I \cong 2.75A$



Effective Surface Area
 $S \cong 275mm^2$

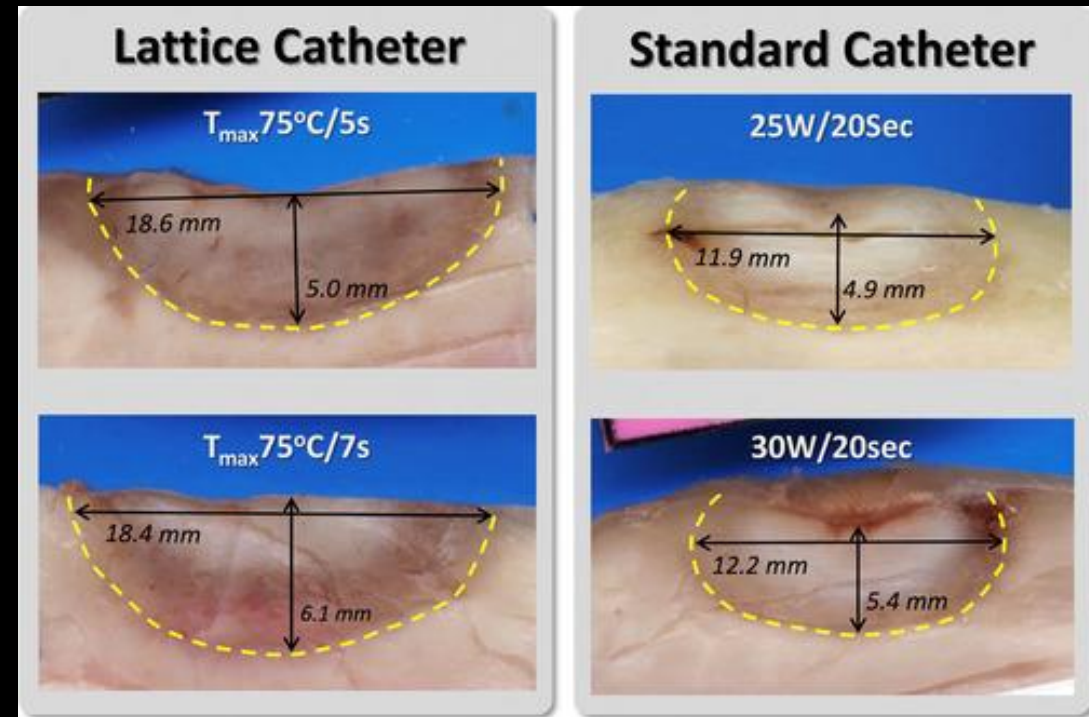
Average Current Density
 $\frac{I}{S} \cong 10mA/mm^2$

Max Current @50W & 110Ω
 $I \cong 0.67A$



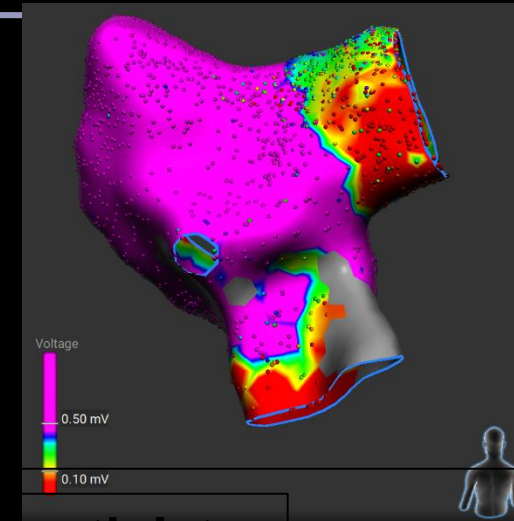
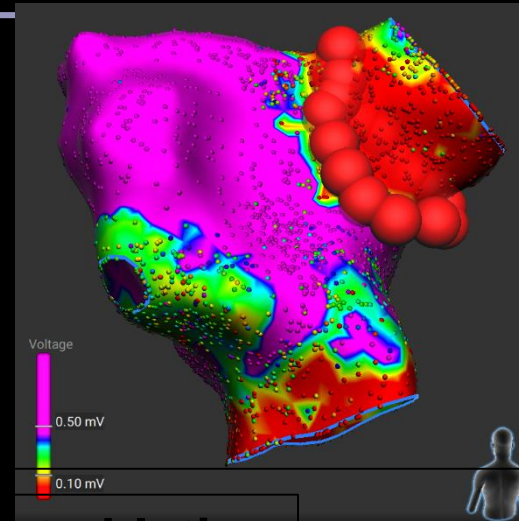
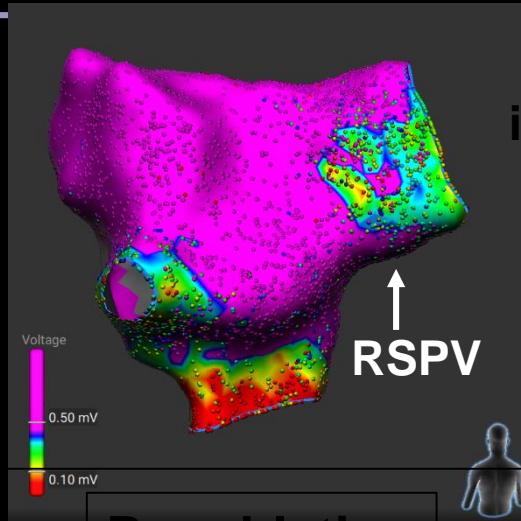
Effective Surface Area
 $S \cong 28mm^2$

Average Current Density
 $\frac{I}{S} \cong 24mA/mm^2$

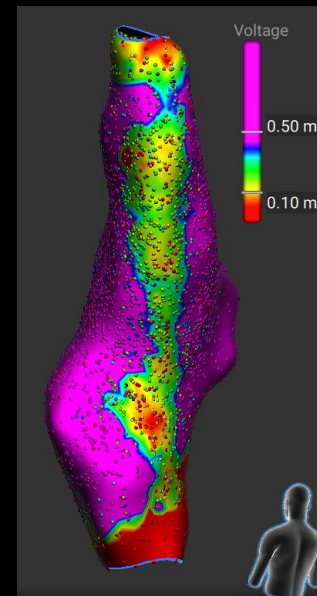
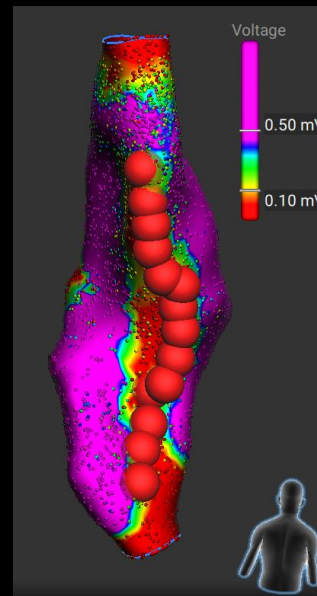
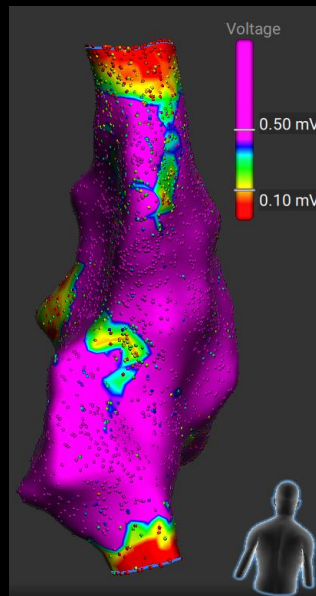


A Novel Radiofrequency Platform Allowing High Current at Low Density for Rapid, Titratable, and Durable Lesions
 Michael Barkagan, Elad Anter

Preclinical Swine Survival

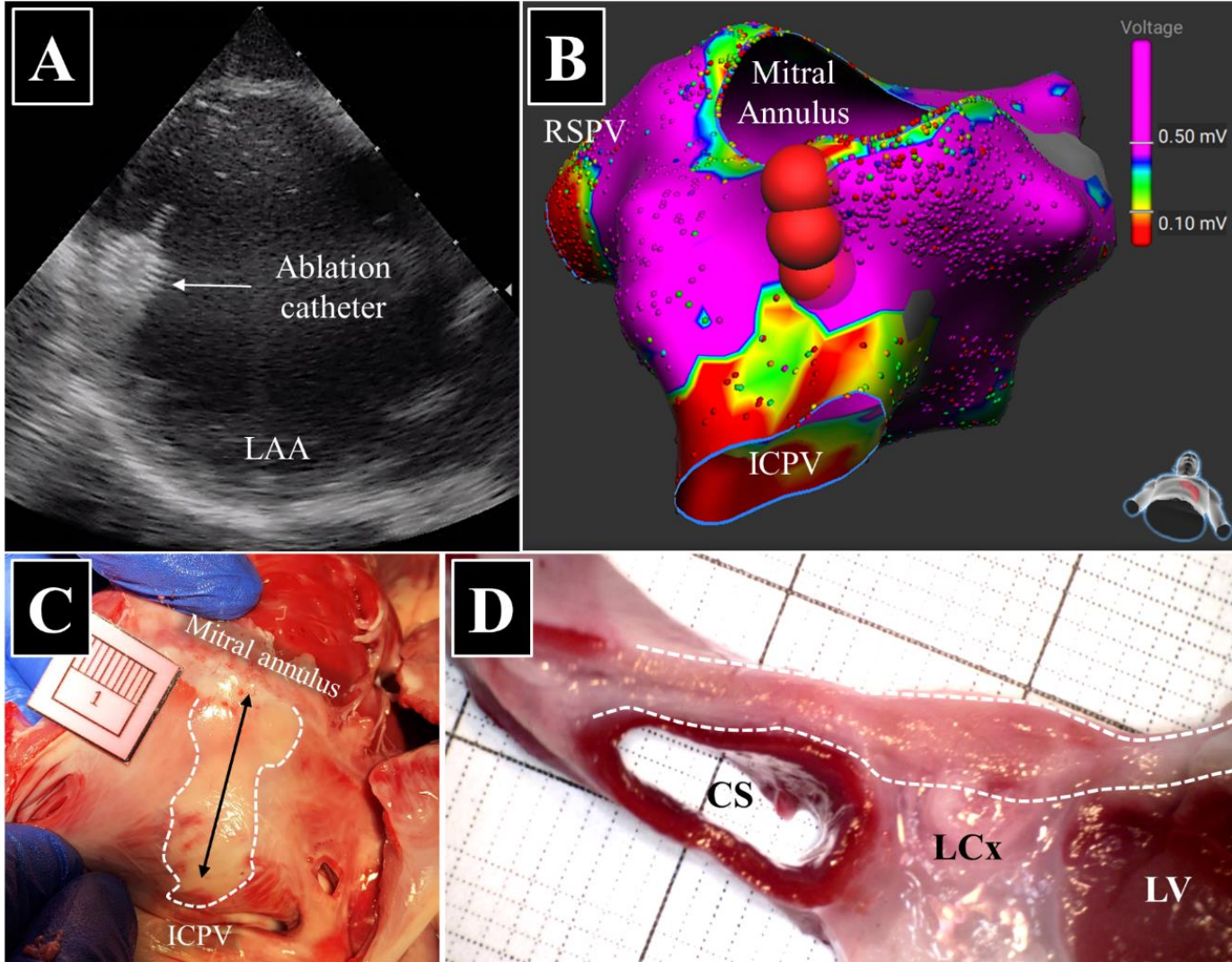


Koruth, Kuroki,
Reddy 2019
(Under
Review)



Preclinical

Koruth, Kuroki,
Reddy 2019
(Under Review)

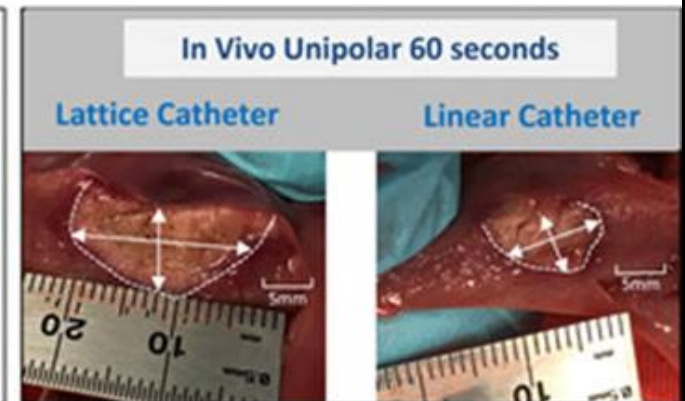
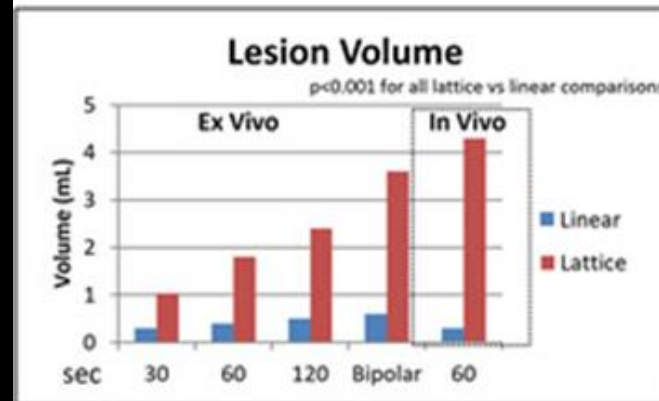
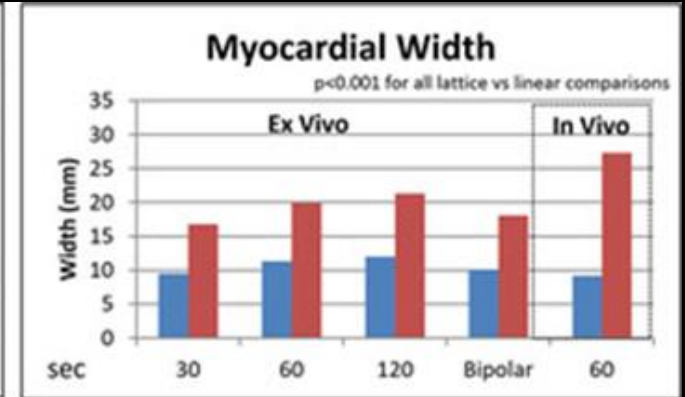
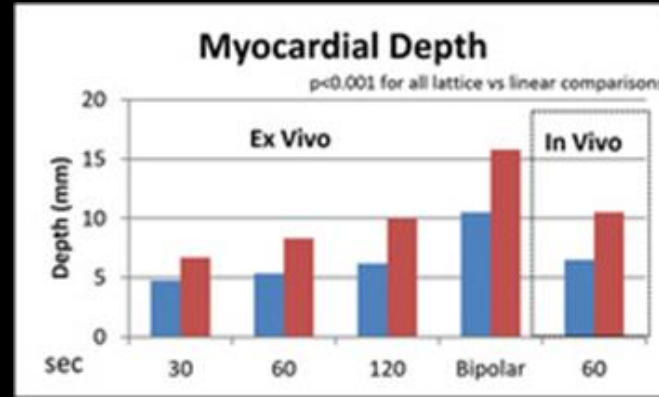
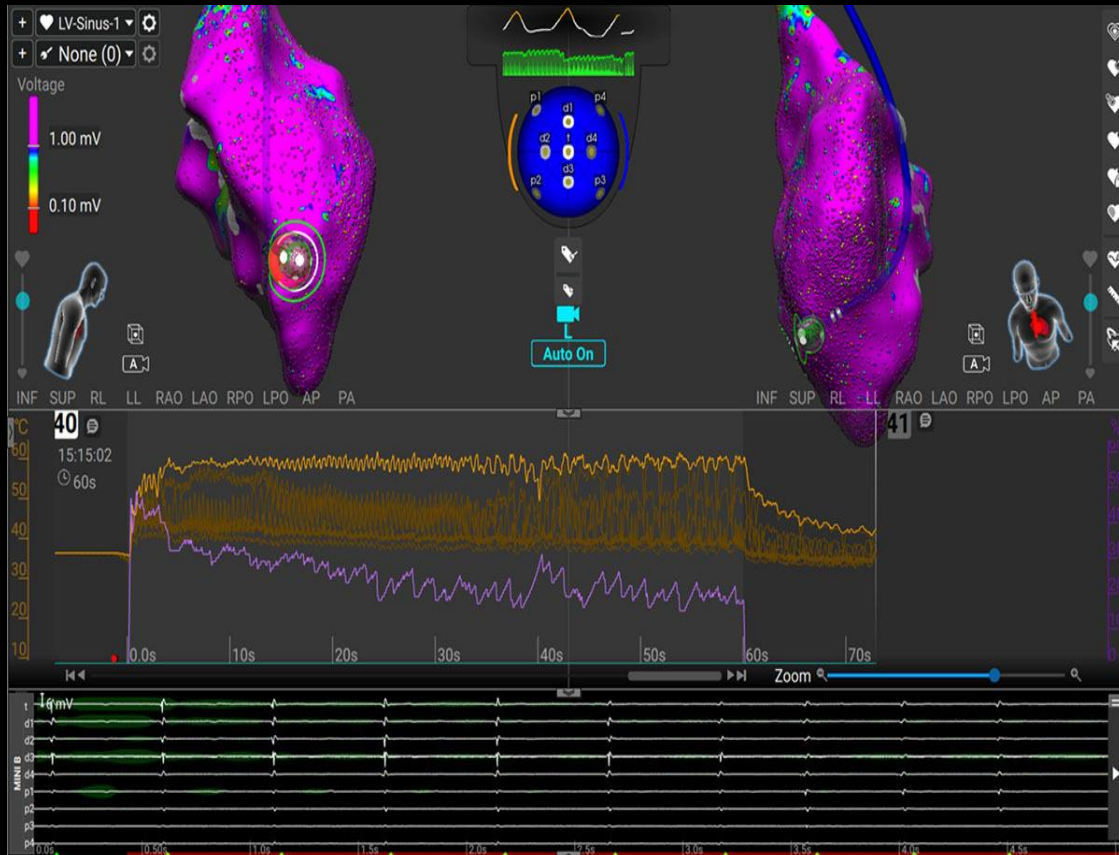


Rapid Pulmonary Vein Isolation using an Irrigated Temperature-Controlled Lattice Ablation Catheter: A First-in-Human Clinical Experience HRS 2019- Vivek Reddy et al



Slide: Courtesy
Reddy / Neuzil
2019

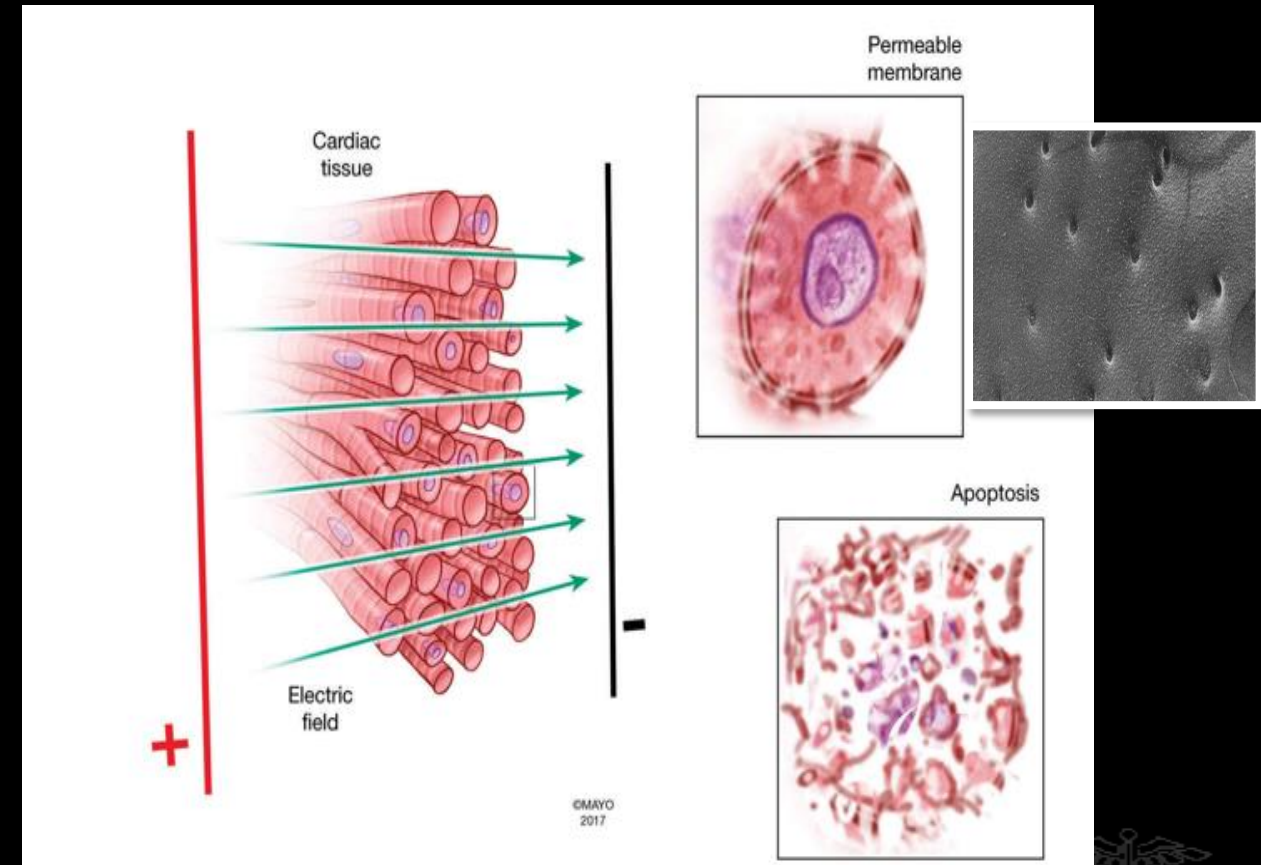
Novel Irrigated Temperature-Controlled Lattice Ablation Catheter for Ventricular Ablation A Preclinical Multimodality Biophysical Characterization. Shapira-Daniels, Anter E et al



9 swine, ventricular ablation at Tmax60°C versus 40 W was performed for 60 seconds

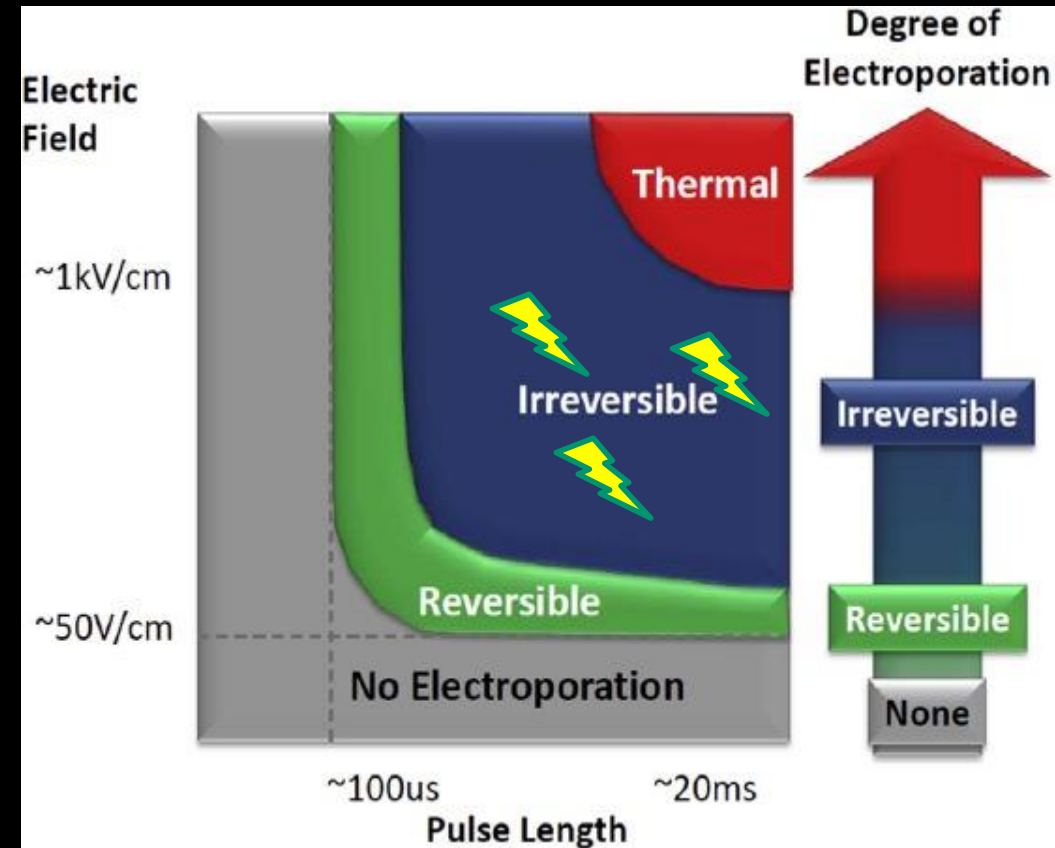
What is Pulsed Field Ablation (IRE)?

- Novel ablation- Ultra-short, high-voltage electrical impulses
- Large increase in the electric field across cell membrane - Nanoscale pores
- Specific thresholds for target tissue
- Permanent nanopores - Cell death



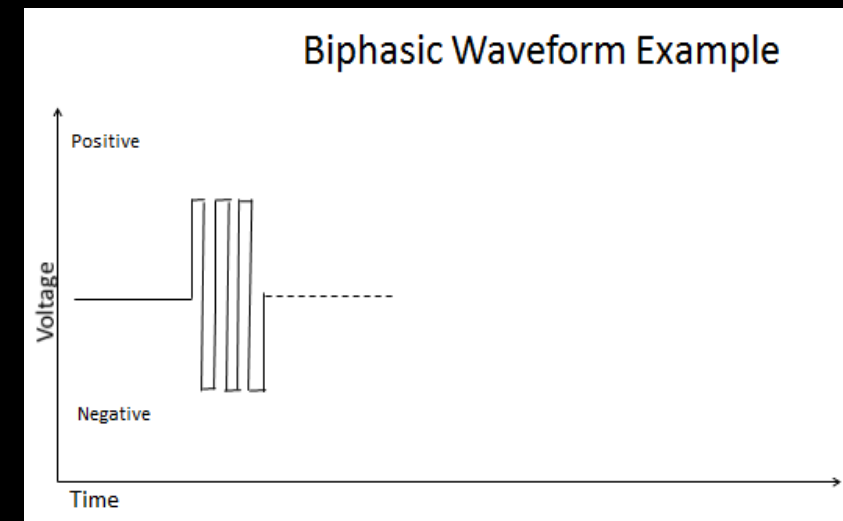
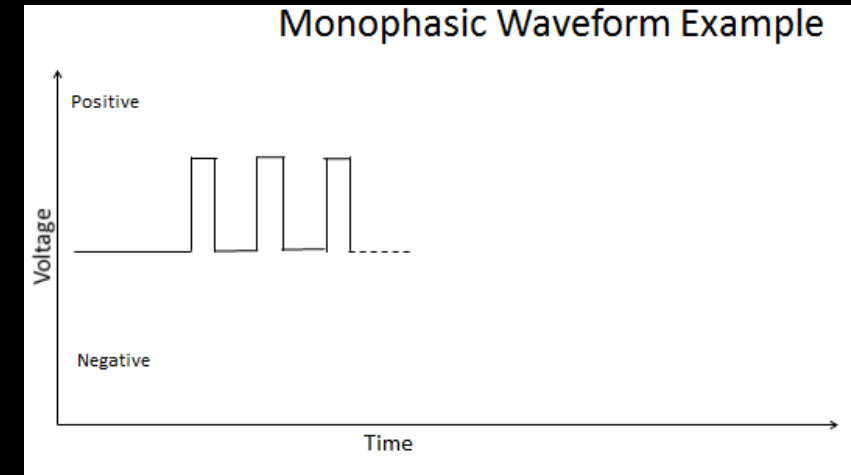
Pulsed Field Ablation

- **Non-thermal ablation** - despite electric field of 1000 V/cm - short duration, limited pulses
- **Effect/Lesion volume** determined by
 - Electric field distribution
 - Tissue specific thresholds
- **Affects only cell membrane:** Extracellular matrix is intact



Pulsed Field Ablation

- IRE -Unipolar pulse (s) applied for a duration of microseconds: ++muscle contractions requiring NM blockade
- IRE- Bipolar pulse : Effective but with less muscular contractions

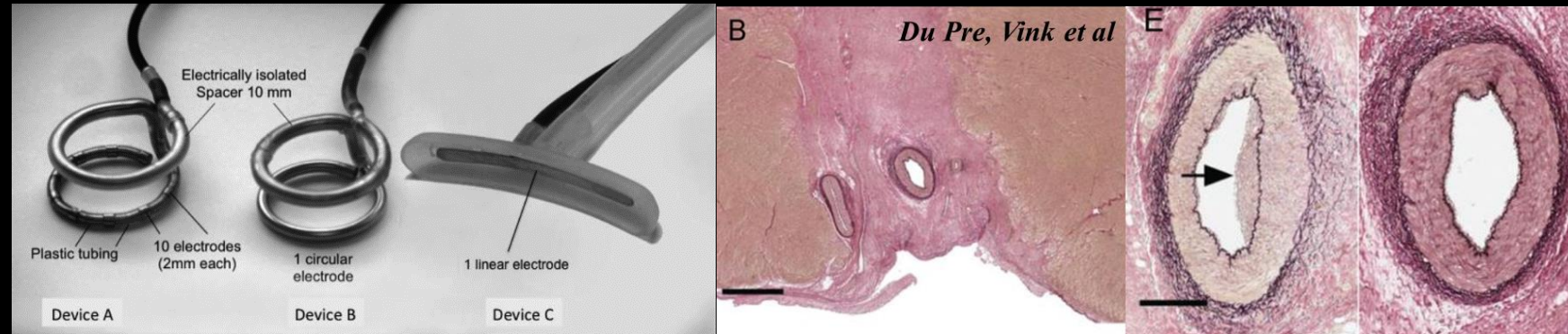


PFA - Ventricular Myocardium

Monophasic - Monopolar

Epicardial ablation

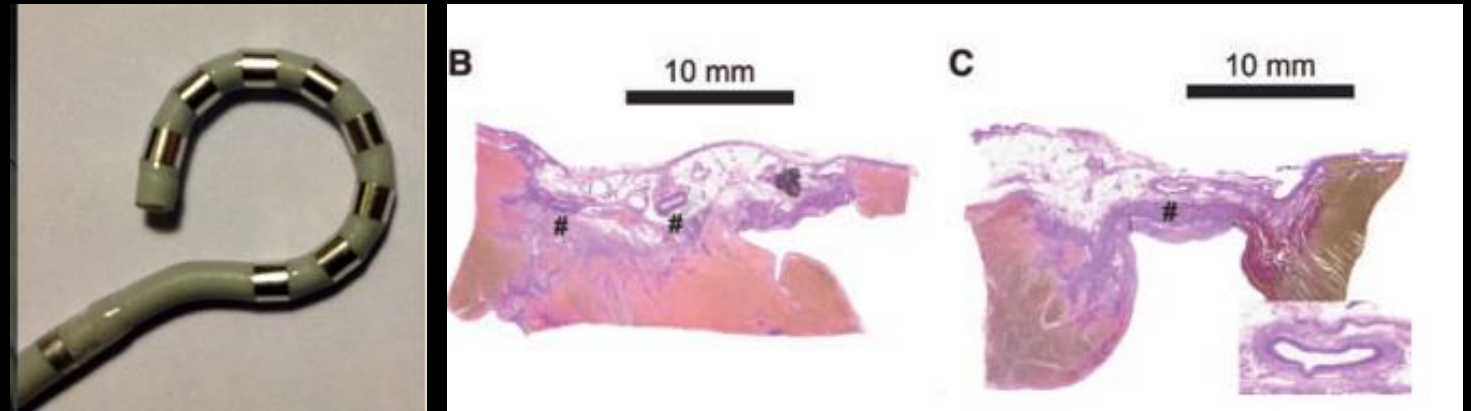
- 50-360 J
- 5/56 arteries :intimal hyperplasia (<50% stenoses)
- 5 direct LAD – no change
- Depth - 6.5 ± 2.7 mm



du Pré BC, Wittkamp FH, et al. Europace 2013 15, 144–149

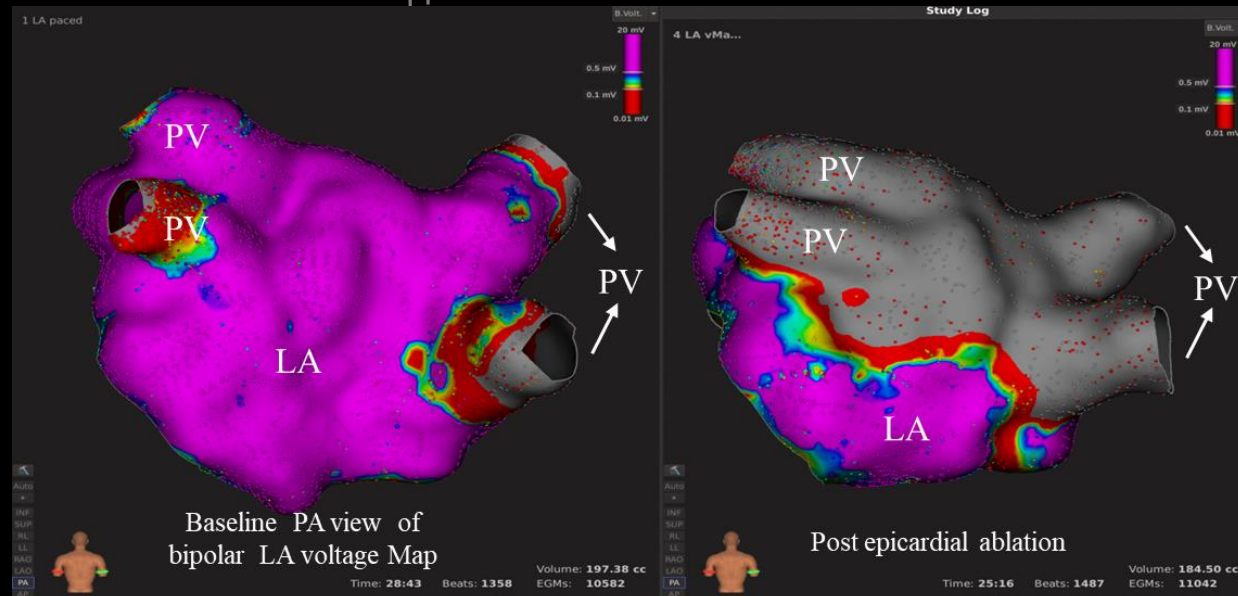
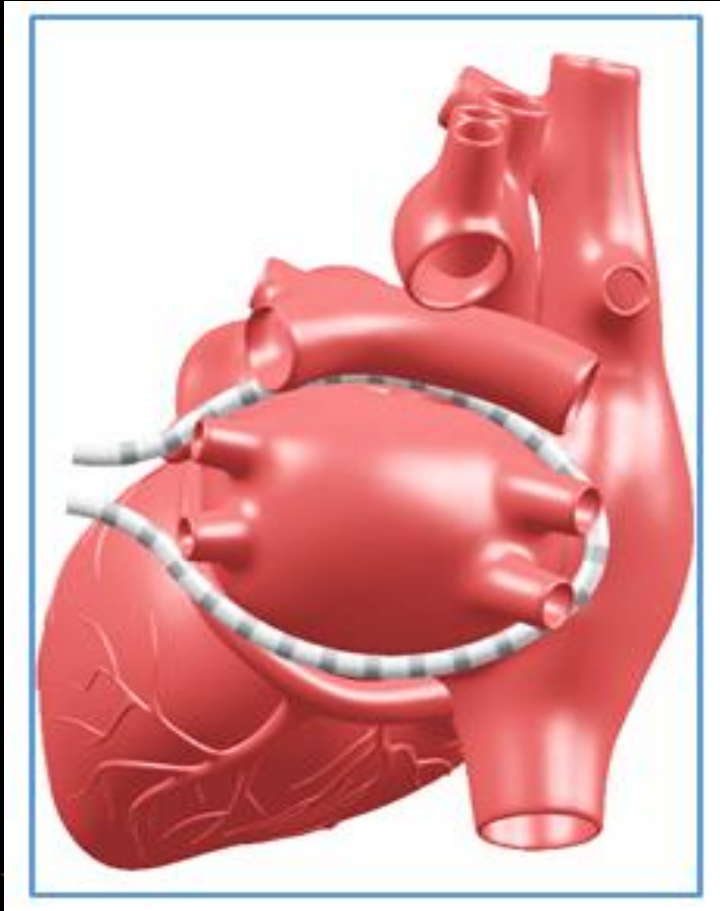
Epicardial ablation:

- 50-200-J
- Depth - 5-12 mm
- Width - 16 -20 mm
- 200-J : Transmural lesions & significant tissue shrinkage were observed



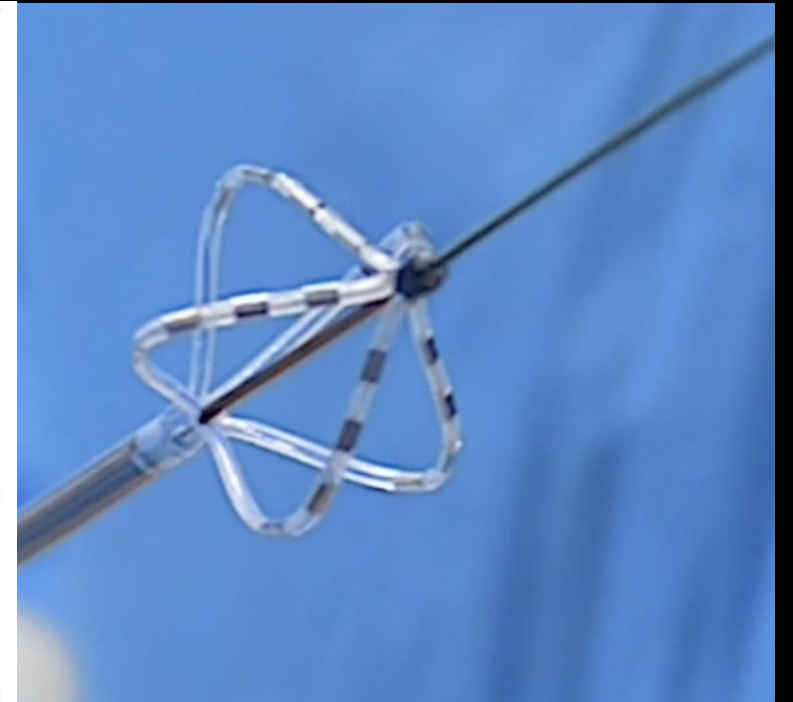
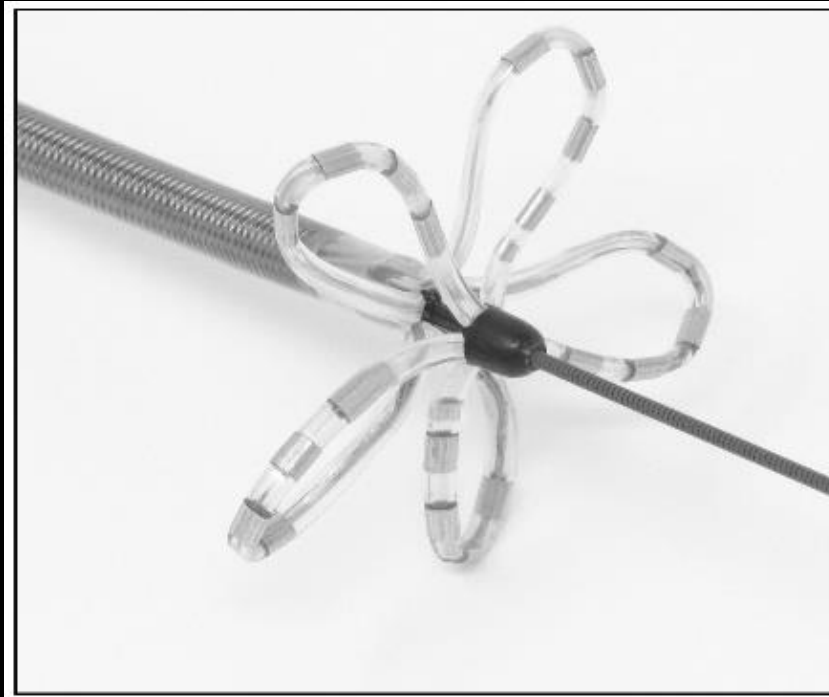
Neven K, Wittkamp F, et al. Circ AE 2014;7:728-733.

Epicardial Pulsed Electric Field Therapy

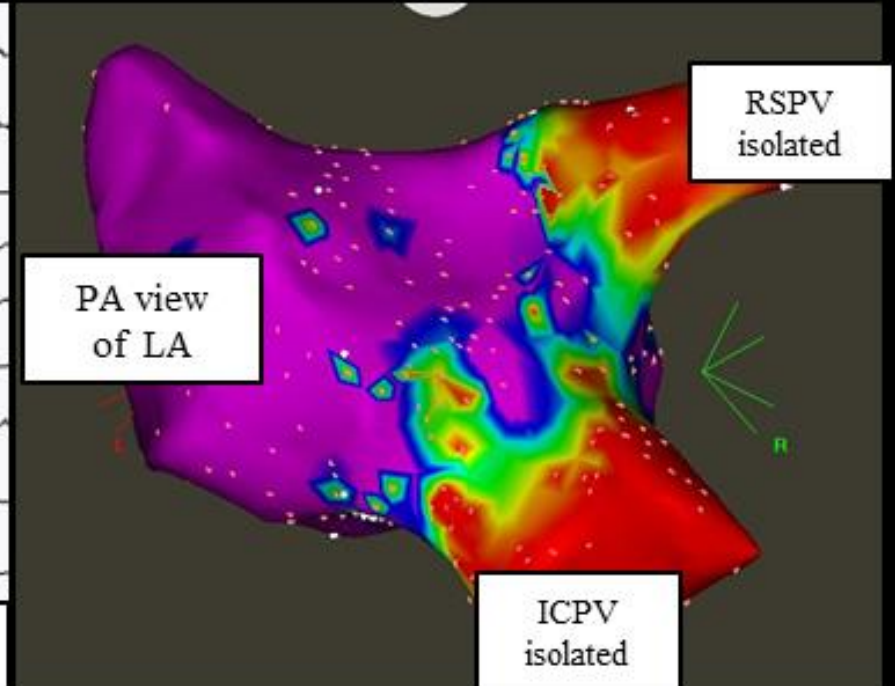
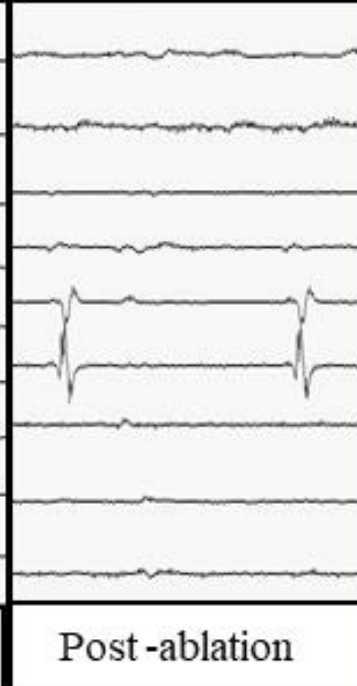
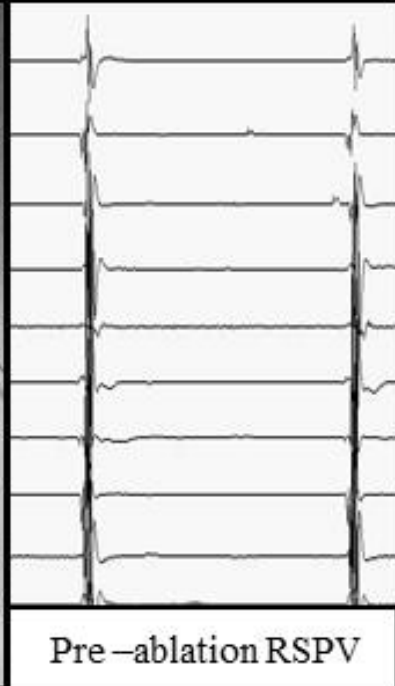
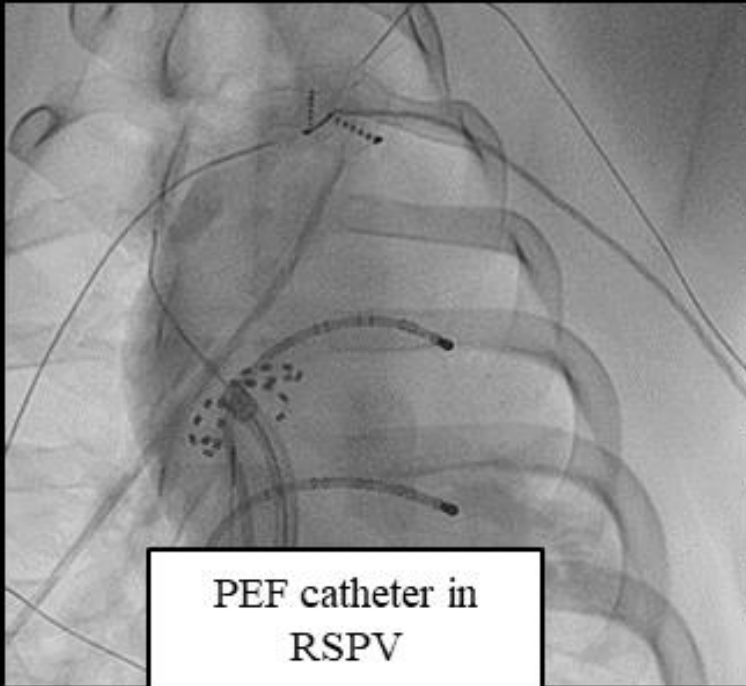


Pulsed Field Ablation: Catheter Design

- 12F OTW pentaspline catheter
- PFA-specific generator
- Bipolar/biphasic waveform
- Farawave/Farapulse



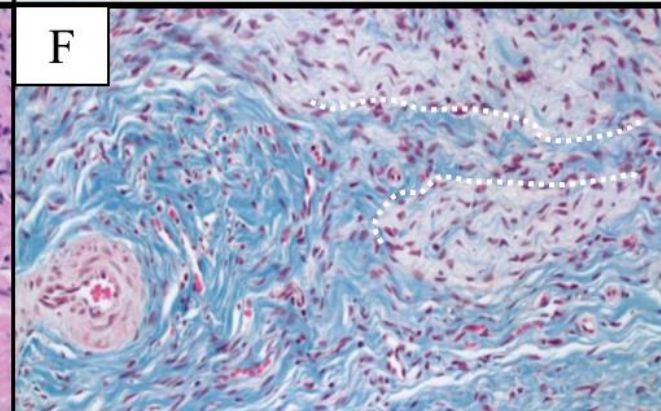
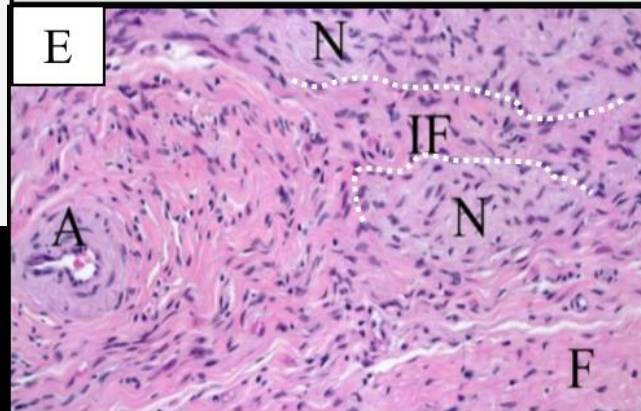
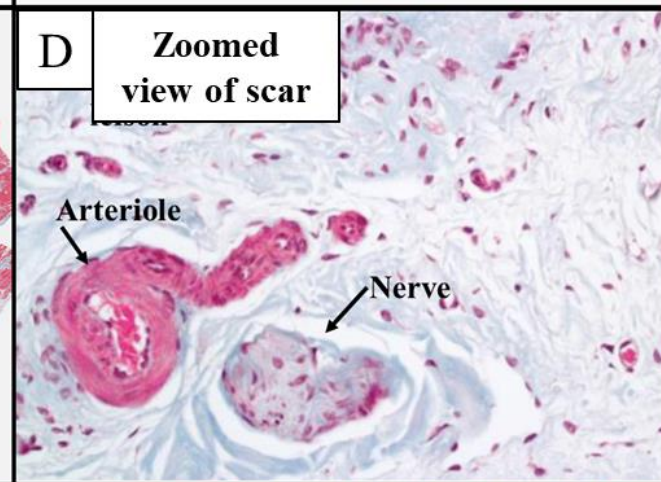
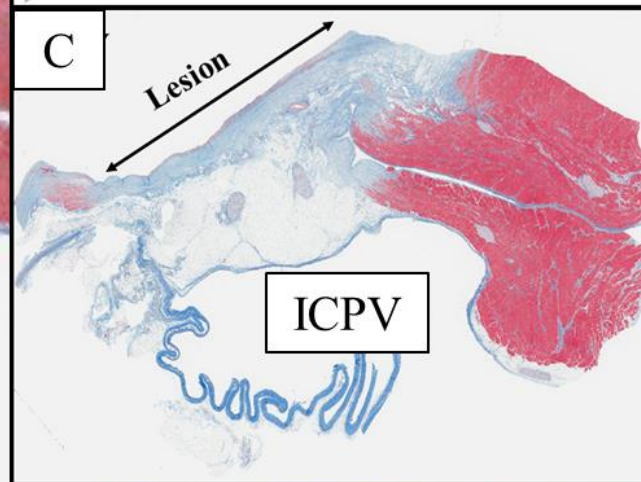
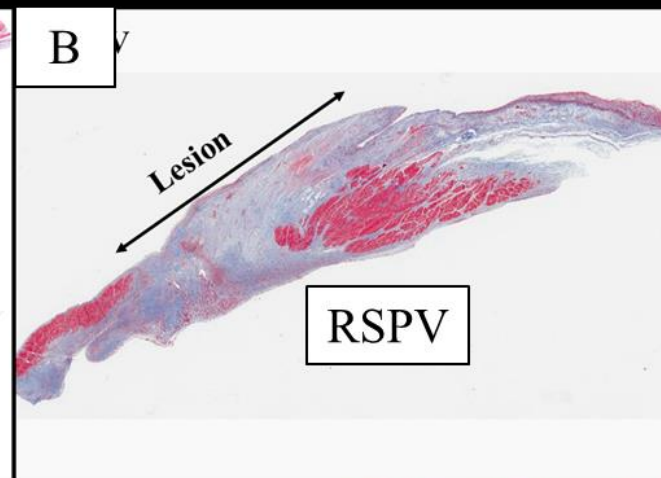
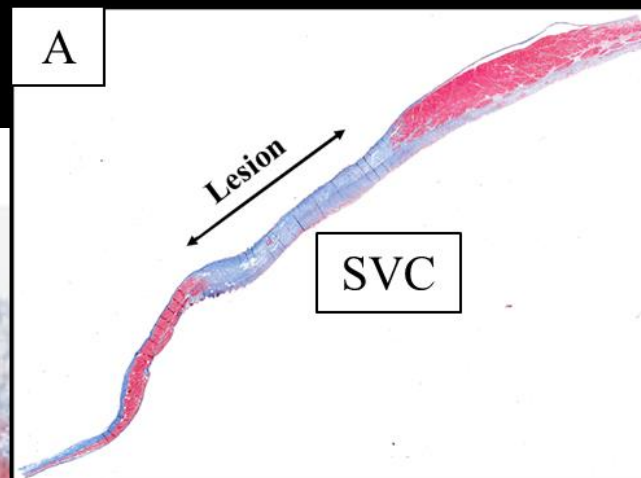
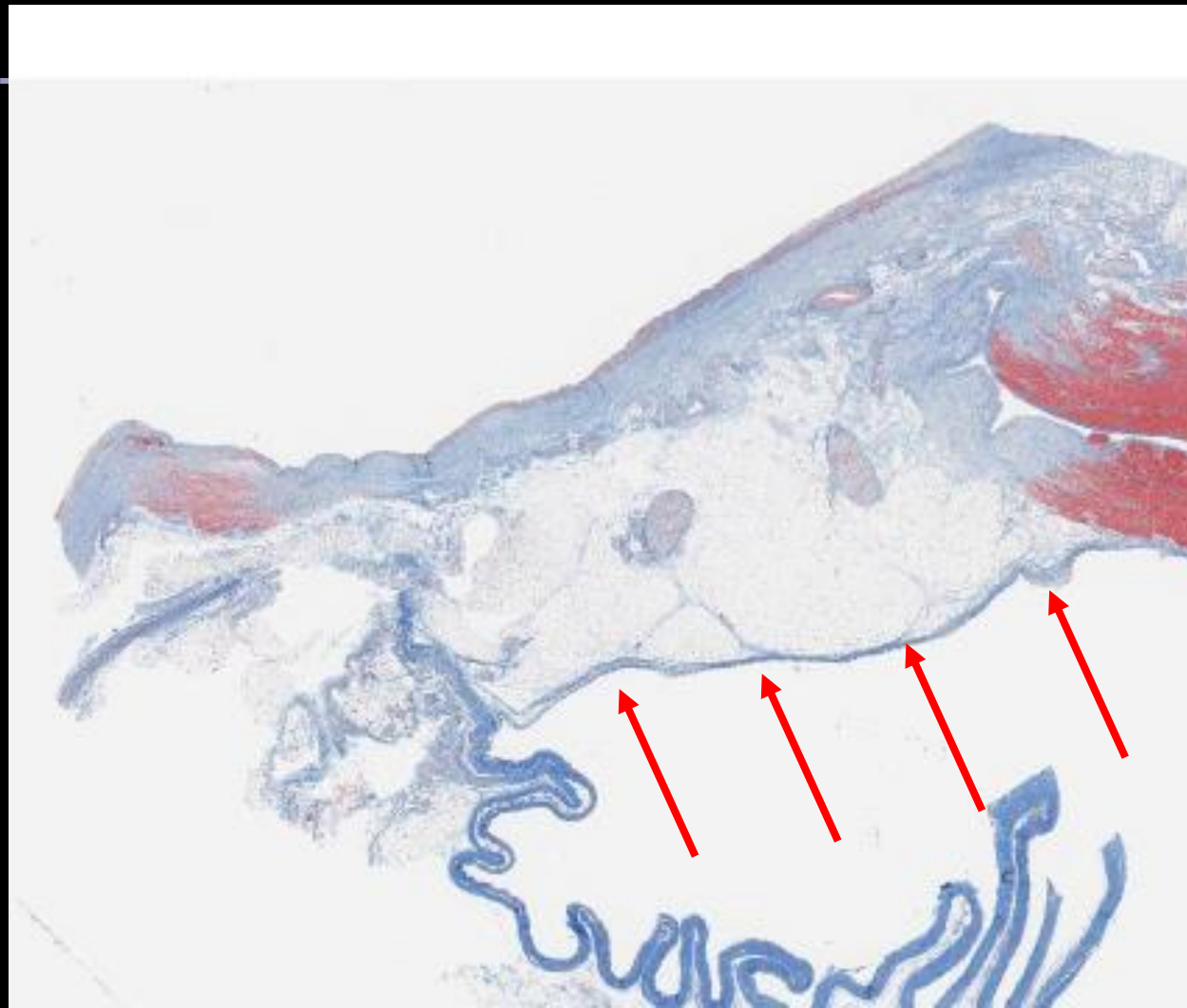
Pre-Clinical Evaluation of Pulsed Field Ablation: Electrophysiological and Histological Assessment of Thoracic Vein Isolation



RSPV ablation → Monophasic waveform-Precordial ST ↑



Jacob Koruth MD, Kenji Kuroki¹, MD, Vivek Reddy MD
(Accepted, *CircEP*)

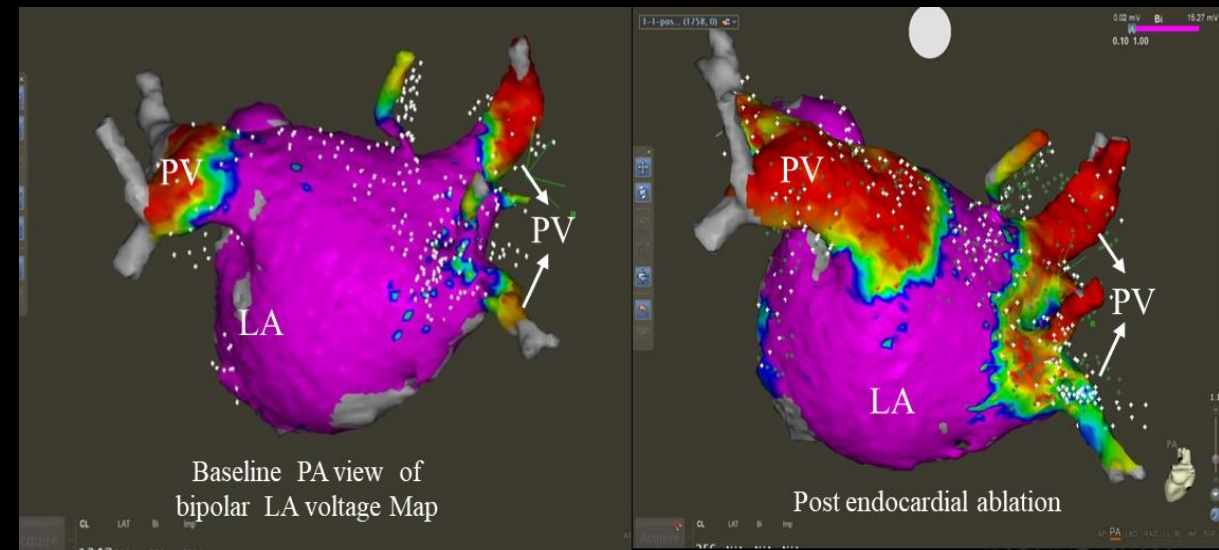
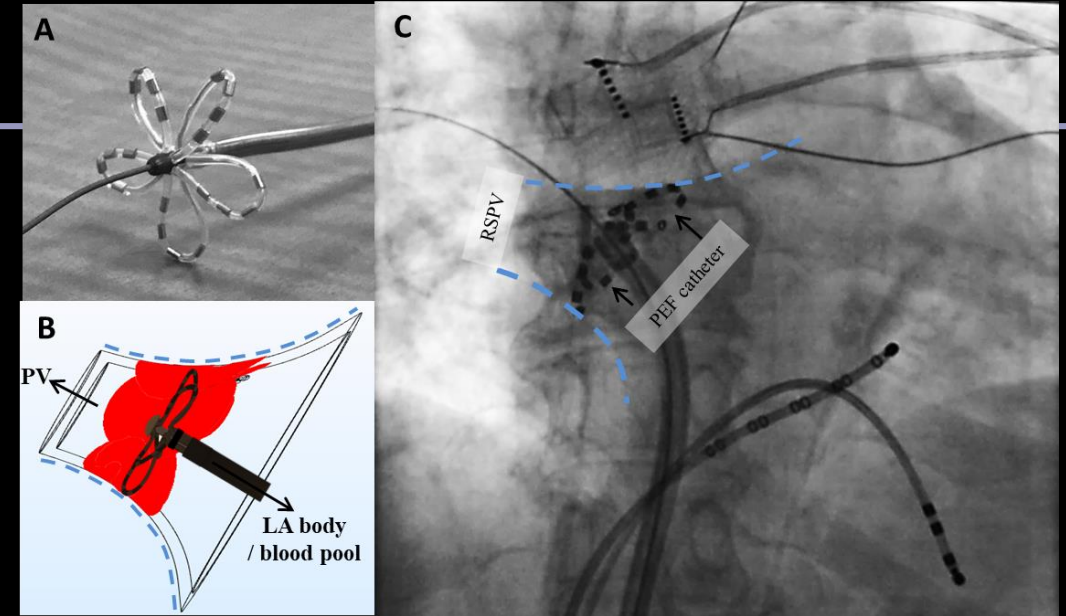


Ablation of Atrial Fibrillation With Pulsed Electric Fields

An Ultra-Rapid, Tissue-Selective Modality for Cardiac Ablation

Vivek Y. Reddy, MD,^{a,b} Jacob Koruth, MD,^a Pierre Jais, MD,^c Jan Petru, MD,^b Ferdinand Timko, MD,^d Ivo Skalsky, MD,^d Robert Hebel, MD,^e Louis Labrousse, MD,^f Laurent Barandon, MD,^f Stepan Kralovec,^b Moritoshi Funosako, MD,^b Boochi Babu Mannuva, MD,^b Lucie Sediva, MD,^b Petr Neuzil, MD, PhD^b

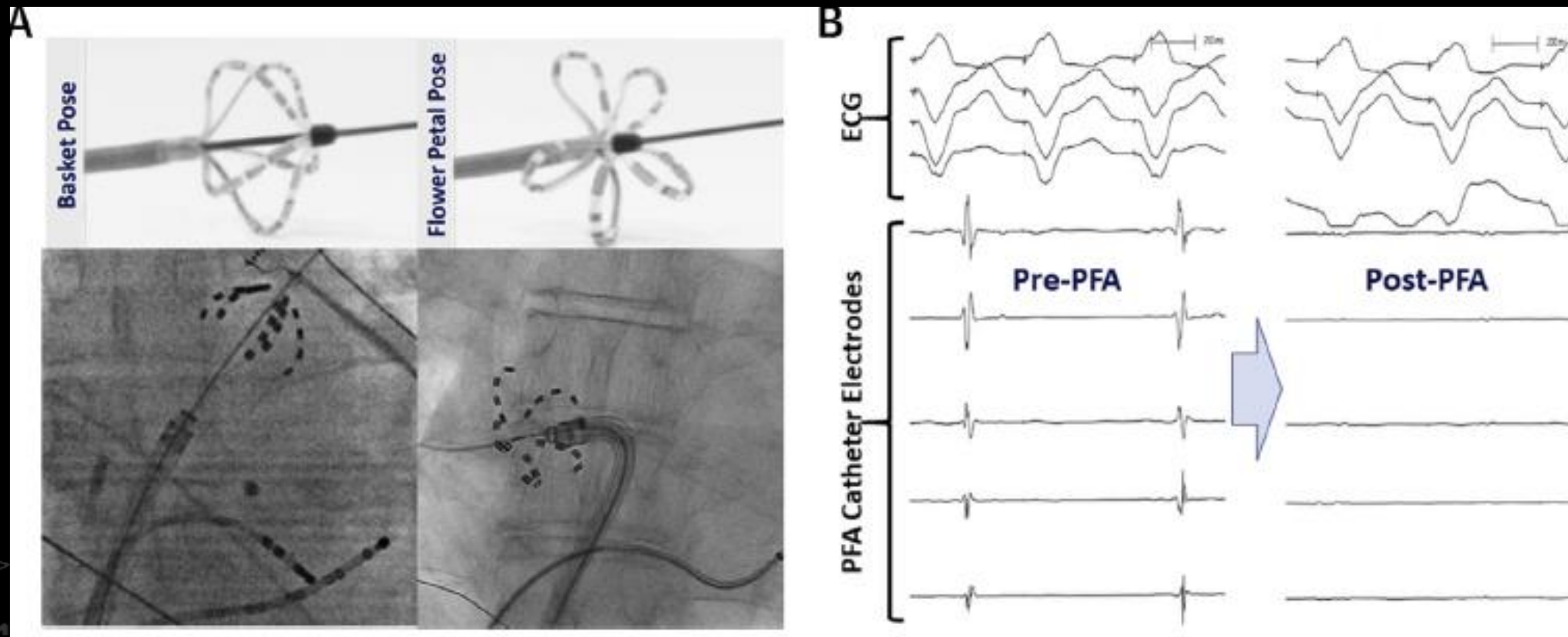
- Acute isolation : 57 PVs in 15 patients
- Mean of 3.26 ± 0.5 lesions/PV
- Procedure : 67 ± 10.5 min
- PEF catheter entry into LA to time of removal: 26 ± 4.3 min
- Total ablation time (was 19 ± 2.5 min (range 16 to 23 min)
- All lesions was <60 s/patient



Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation



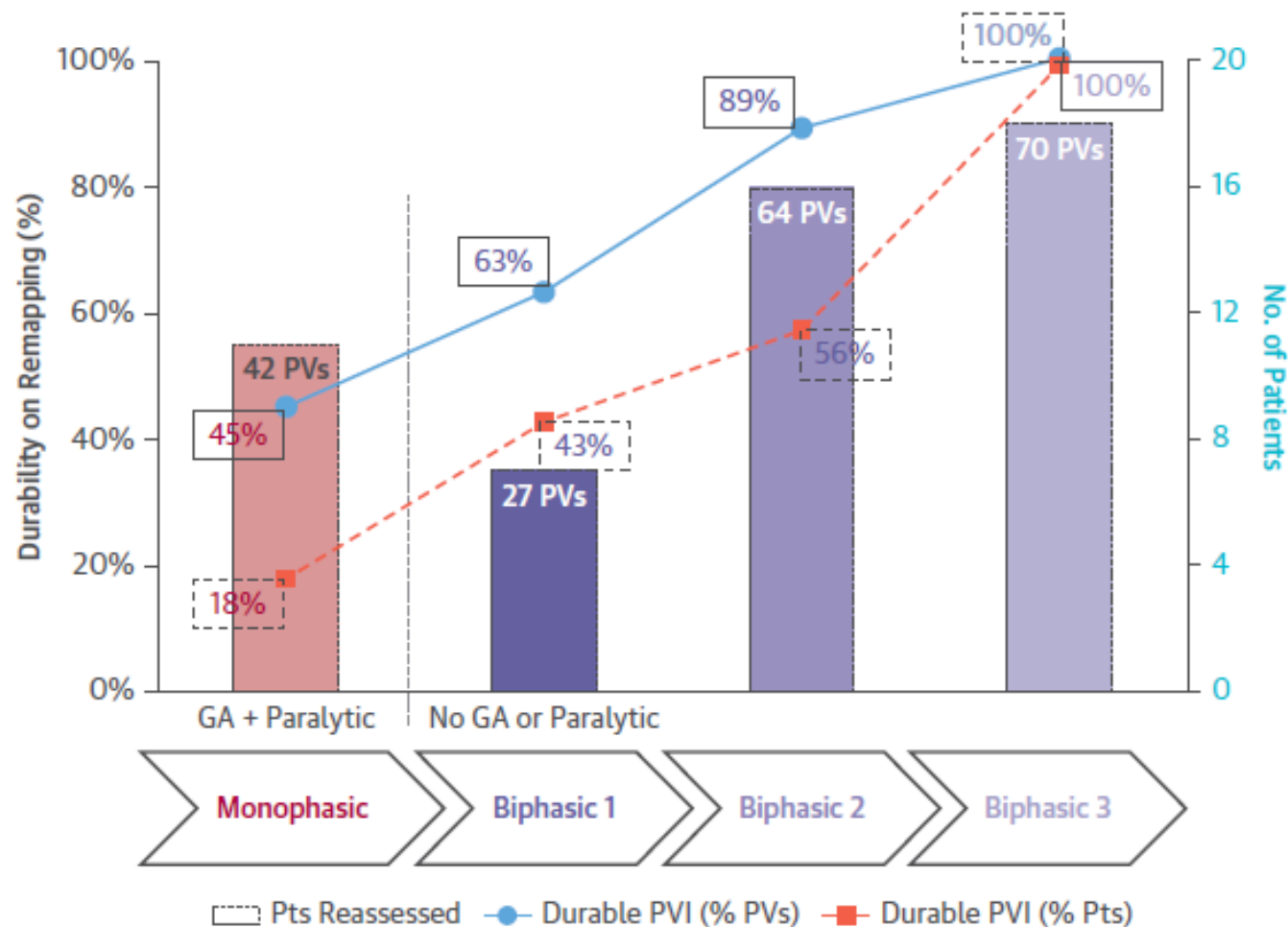
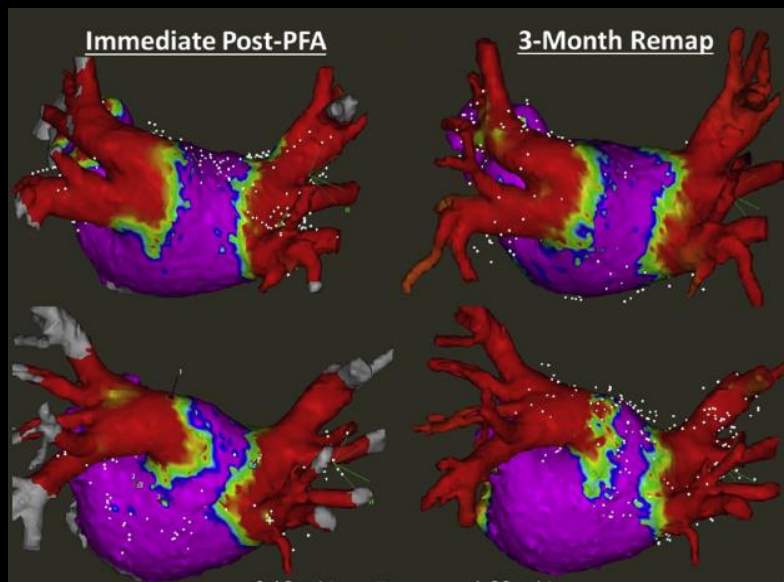
Vivek Y. Reddy, MD,^{a,b} Petr Neuzil, MD, PhD,^a Jacob S. Koruth, MD,^b Jan Petru, MD,^a Moritoshi Funosako, MD,^a Hubert Cochet, MD,^c Lucie Sediva, MD,^a Milan Chovanec, MD,^a Srinivas R. Dukkipati, MD,^b Pierre Jais, MD^c



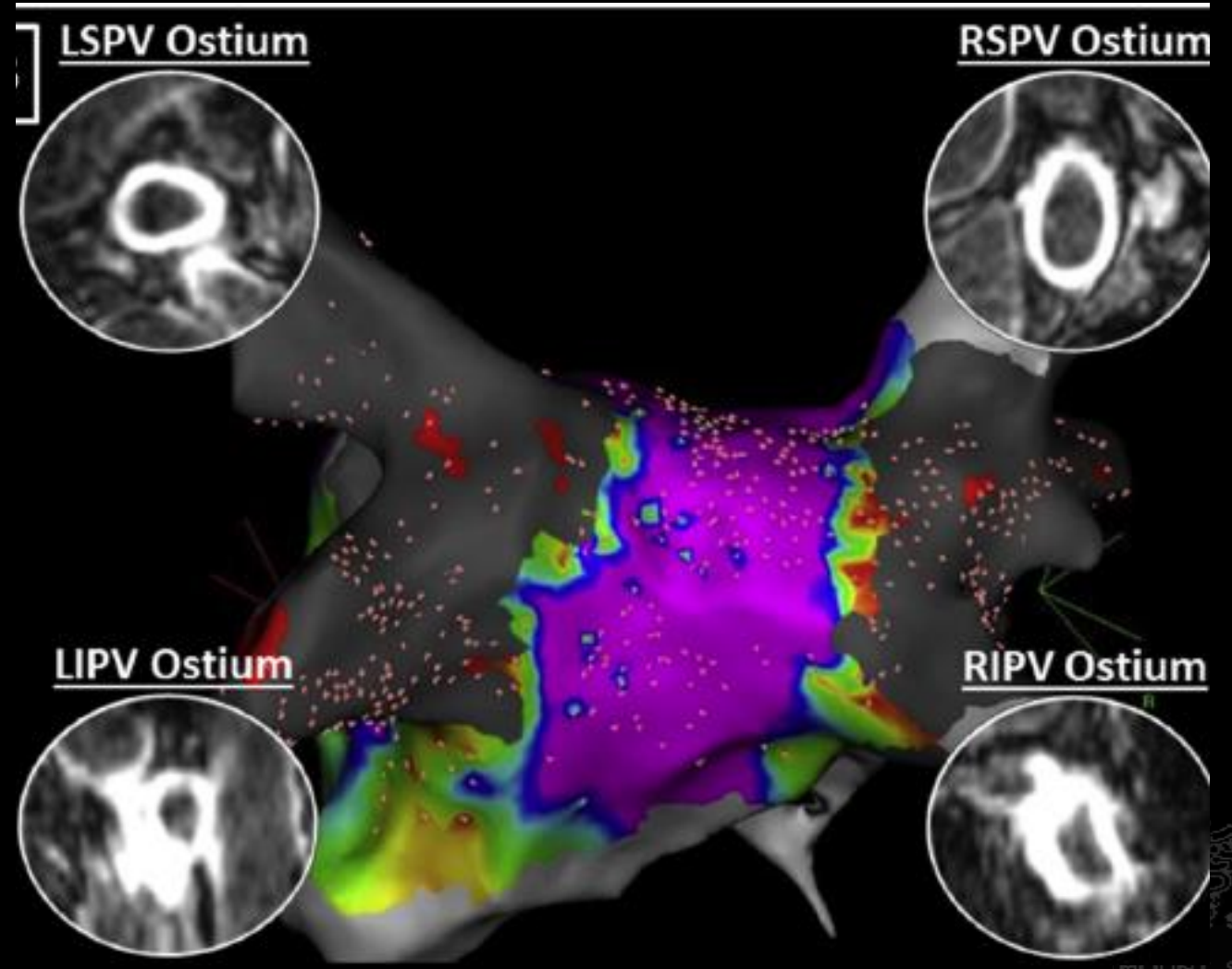
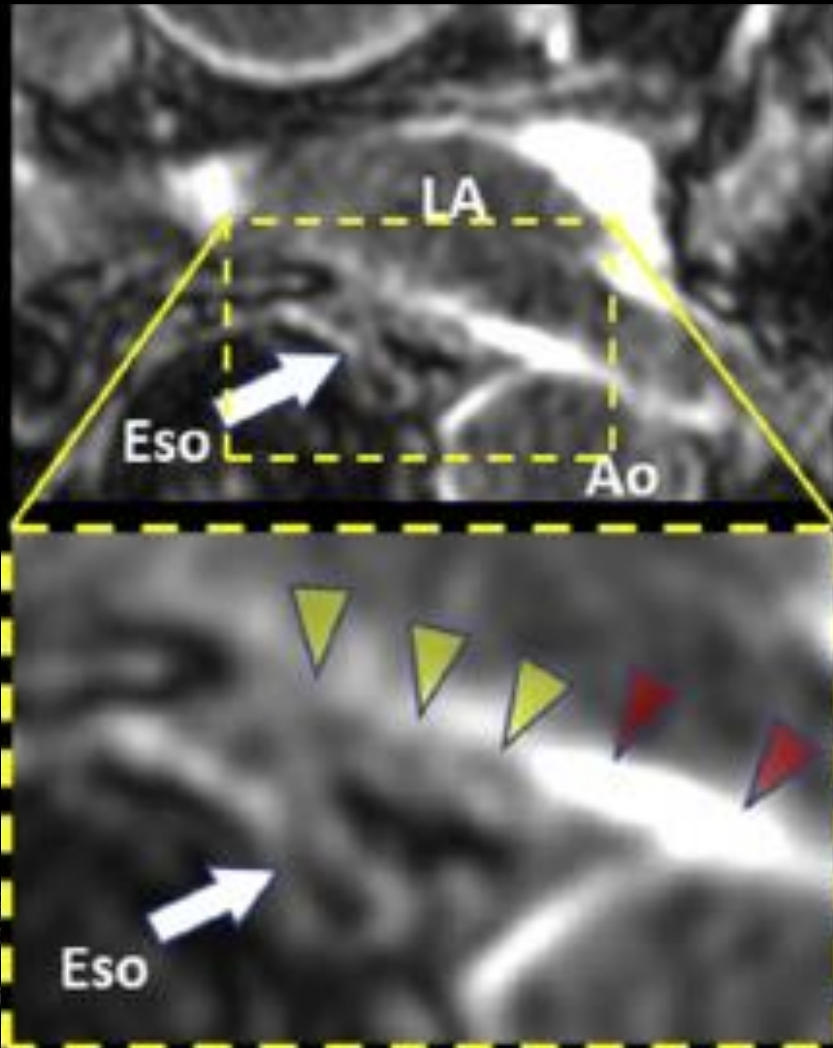
Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation



Vivek Y. Reddy, MD,^{a,b} Petr Neuzil, MD, PhD,^a Jacob S. Koruth, MD,^b Jan Petru, MD,^a Moritoshi Funosako, MD,^a Hubert Cochet, MD,^c Lucie Sediva, MD,^a Milan Chovanec, MD,^a Srinivas R. Dukkipati, MD,^b Pierre Jais, MD^c



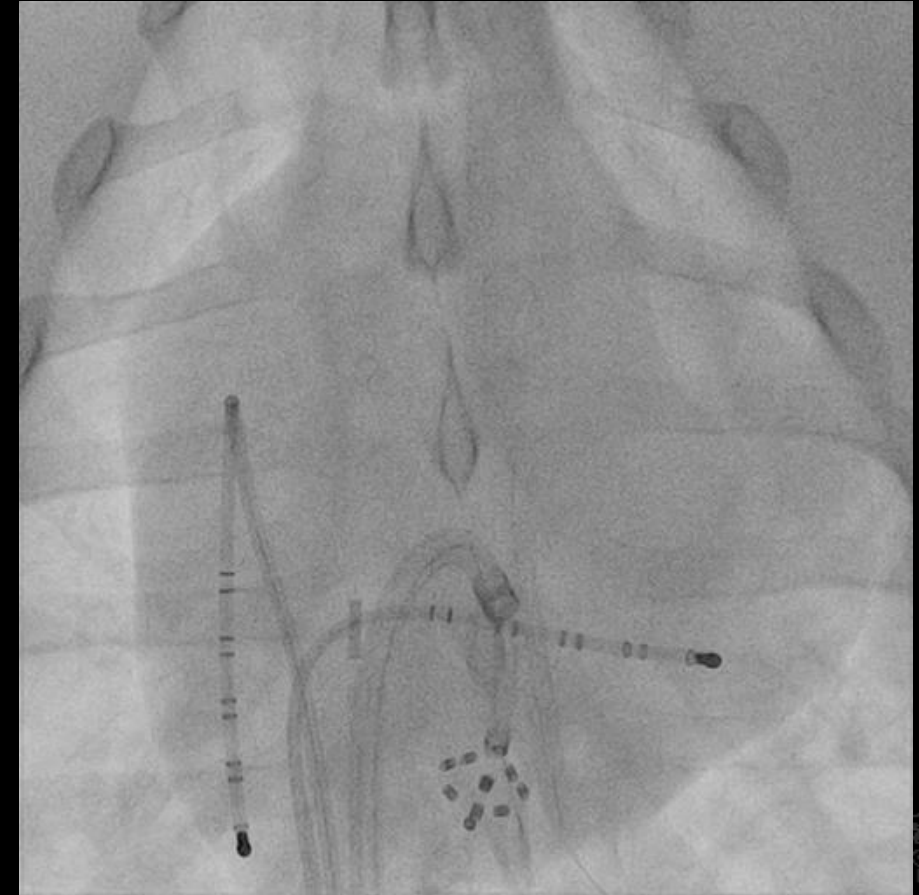
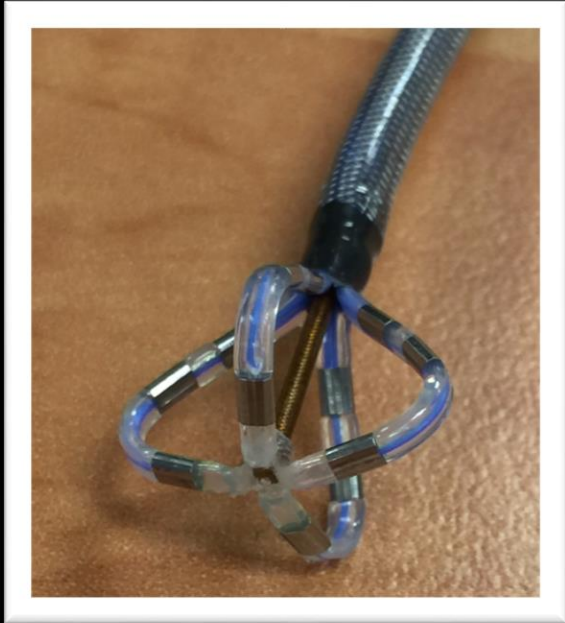
Pulsed Field Ablation: Delayed Enhancement



Endocardial Focal PFA Bipolar and Biphasic

12F Deflectable “FLEX” Catheter

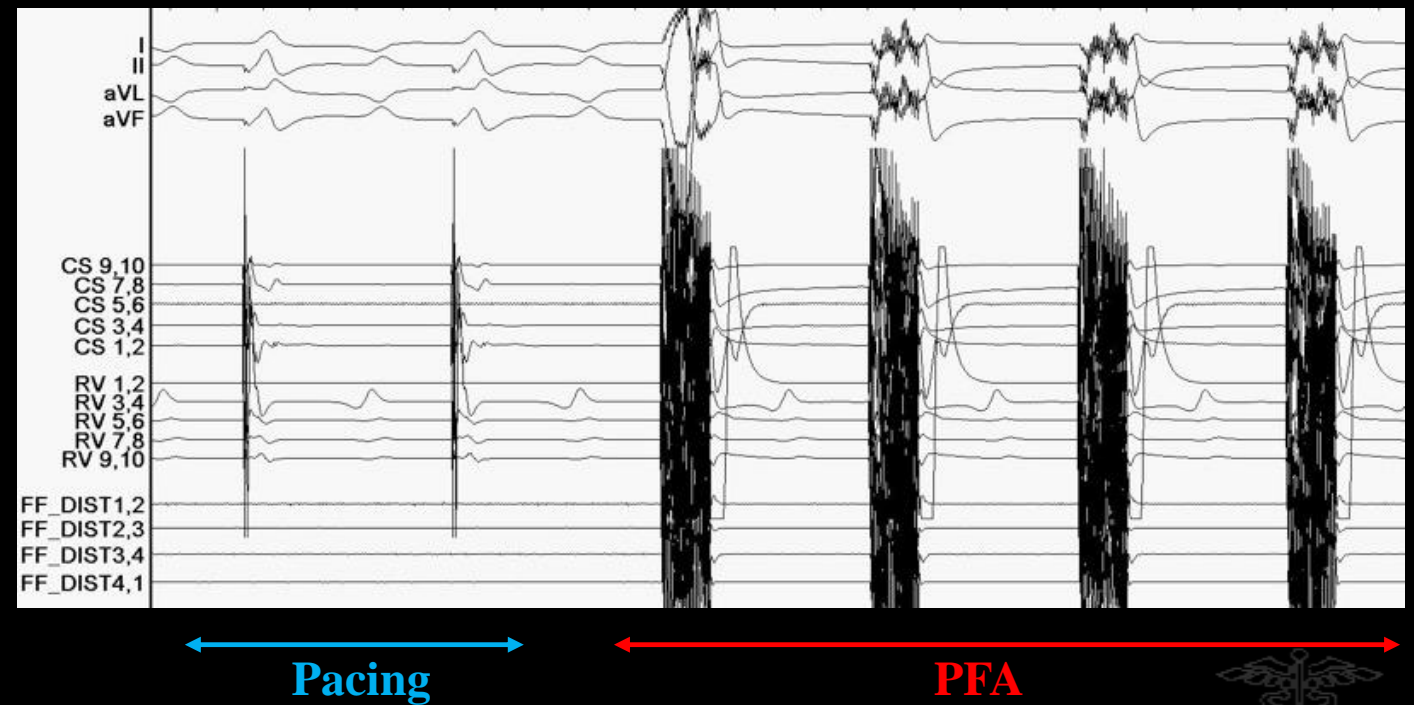
- Four splines / four electrodes each



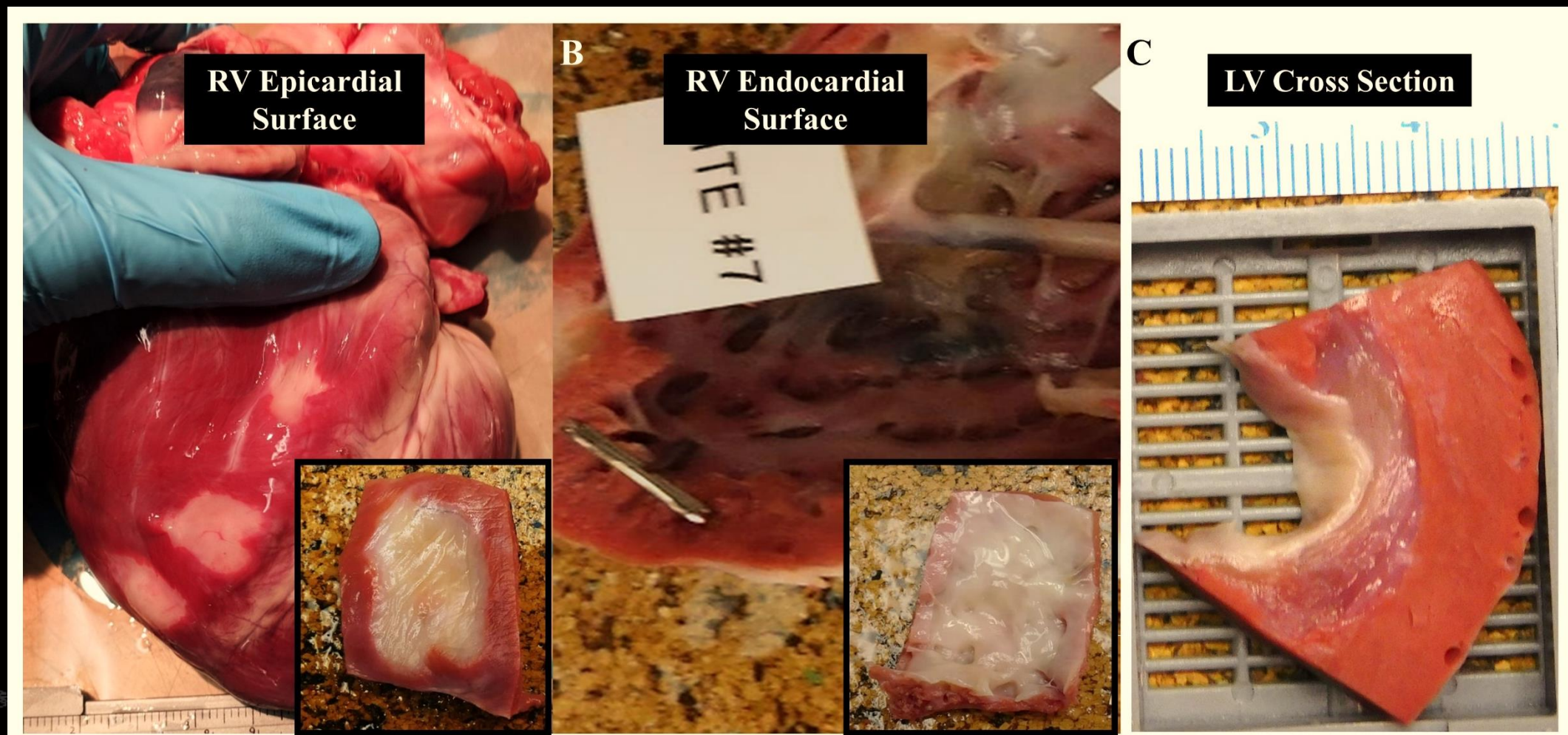
Koruth, Kuroki, Reddy et al- Manuscript accepted Europace

Endocardial Focal PF Ablation

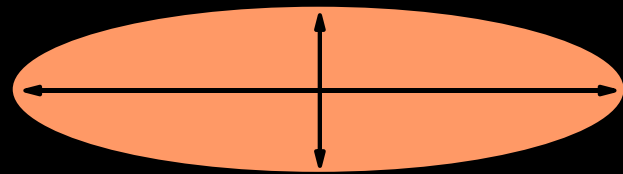
- CS and RV pacing catheters
- Synchronized delivery during joined RV and CS pacing
- Pre- and post-ablation pacing threshold recorded in 2/4 swine:
Pulse width of 2ms pacing through distal bipoles



Endocardial Focal PFA Ablation



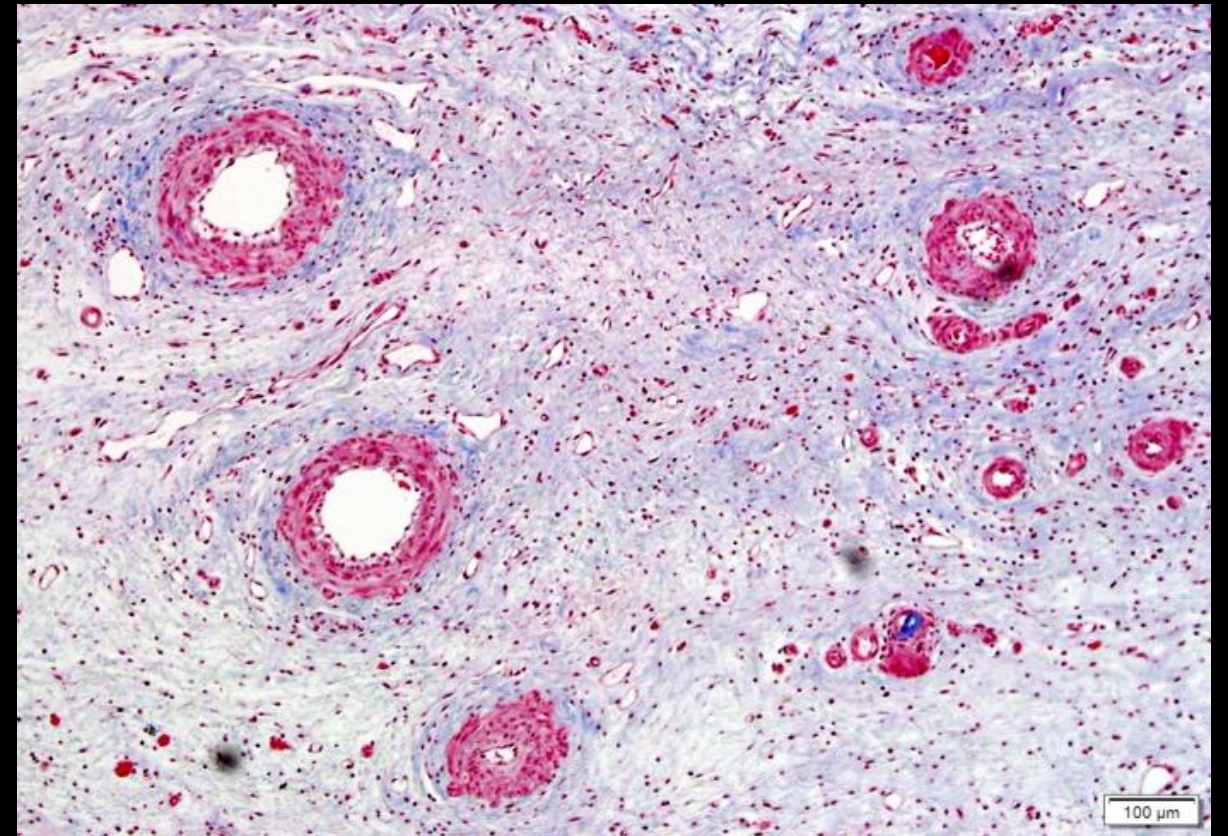
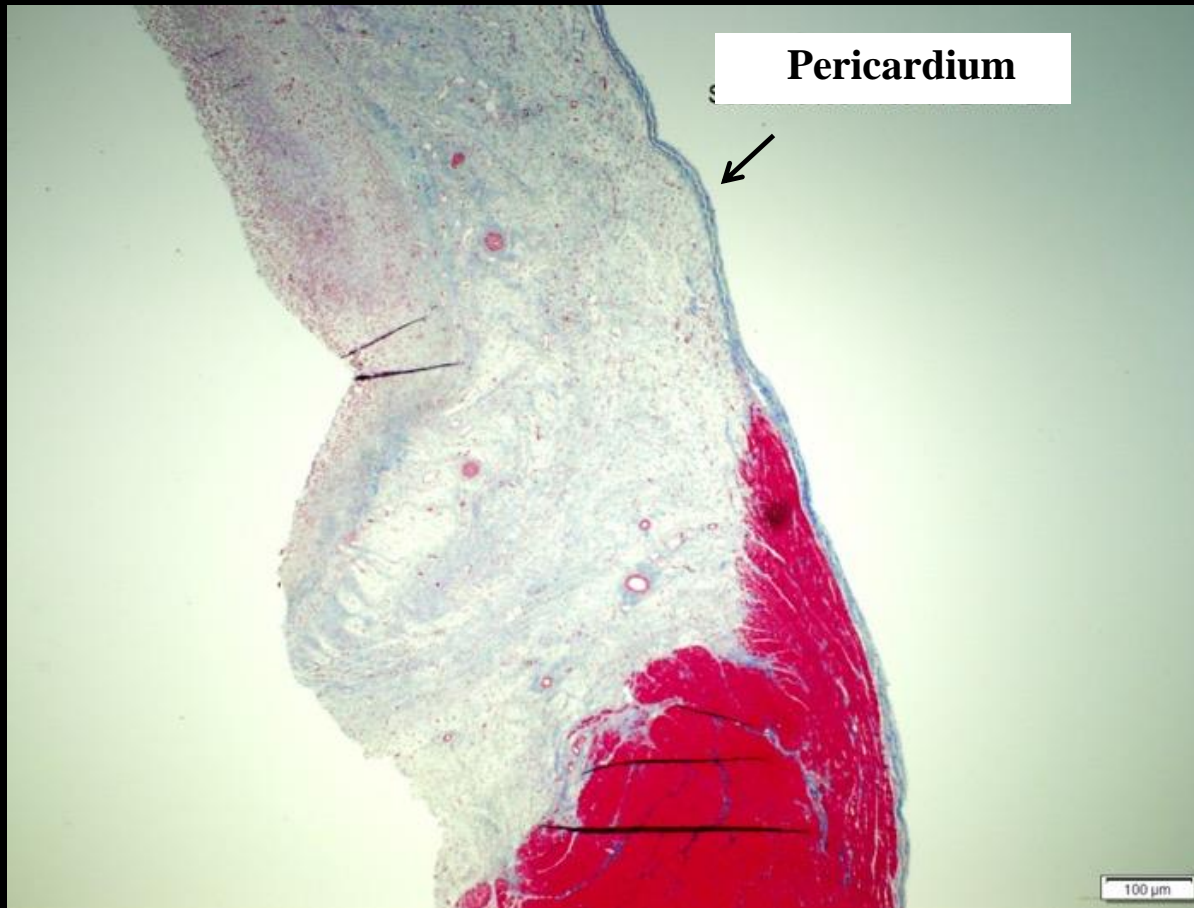
Endocardial Focal PFA Ablation



Width
22.7+3.3mm

Depth
4.8+1.9mm

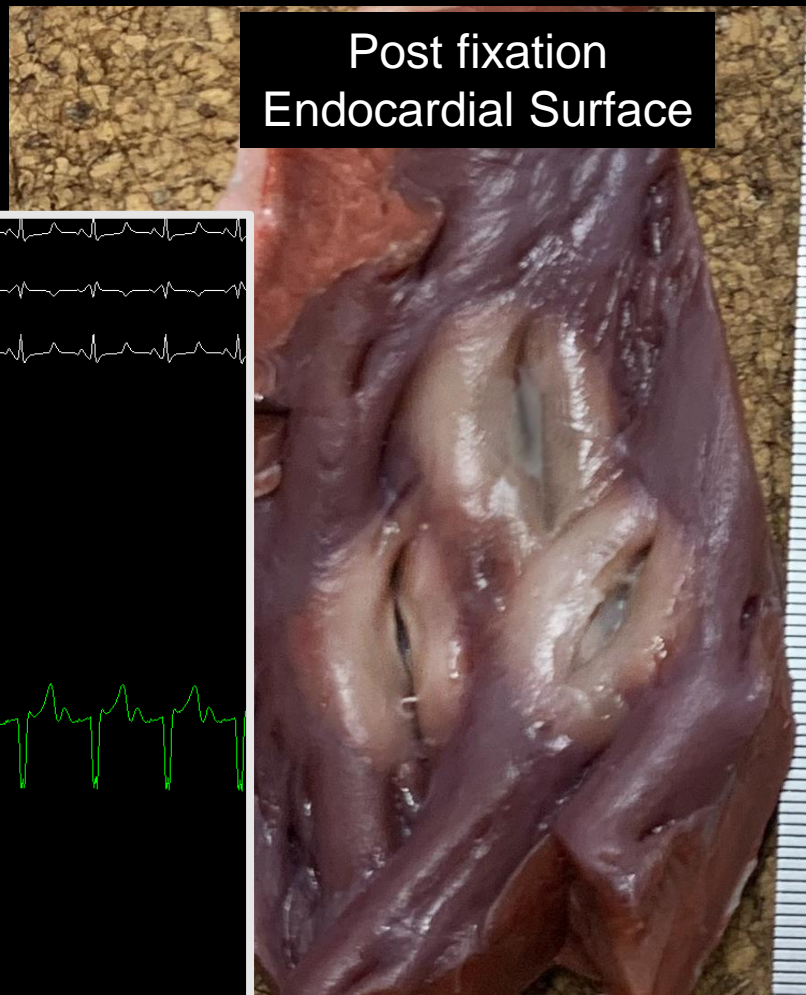
Histological Findings - Focal PFA



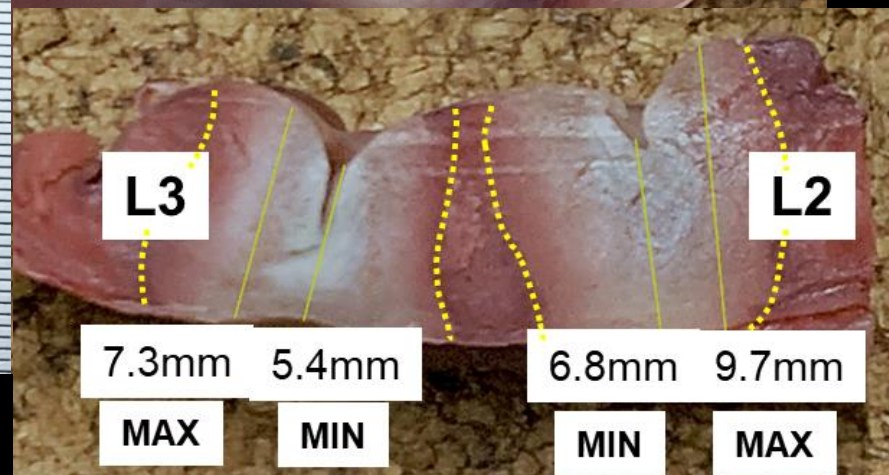
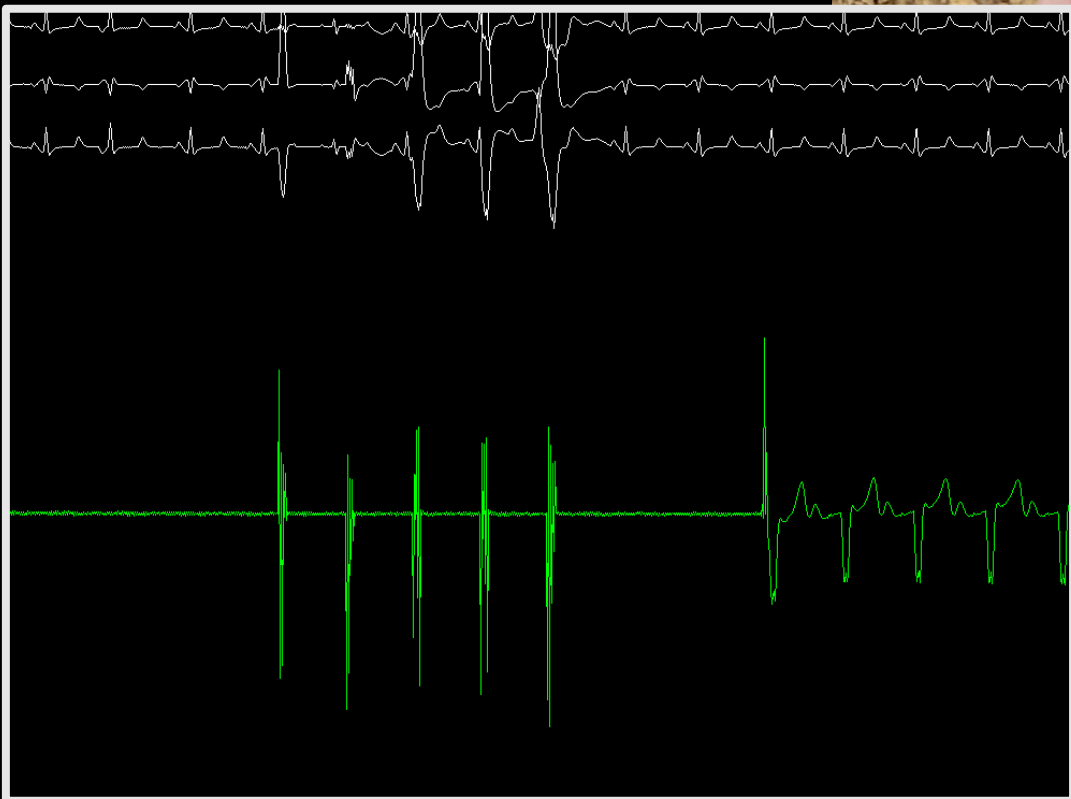
8F Deflectable "POINT" Catheter



Post fixation
Endocardial Surface



Post fixation
Epicardial Surface

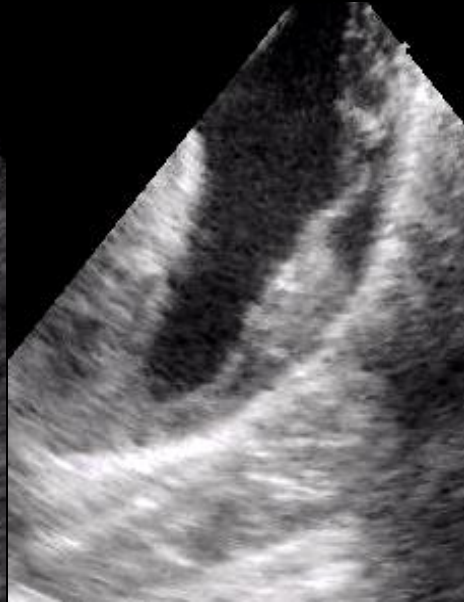
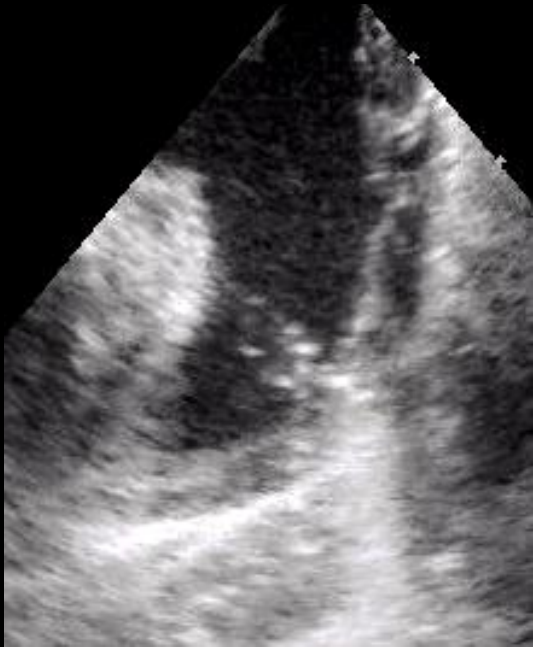


Pulse Field Ablation- ICE Imaging

During ablation

Immediate
Post-ablation

10 mins
Post-ablation



- Echodense lesion immediate post ablation
- Echodensity/edema progresses over time

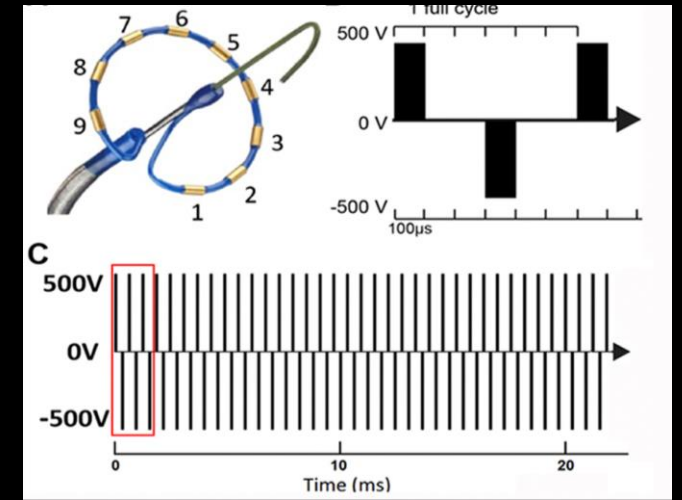
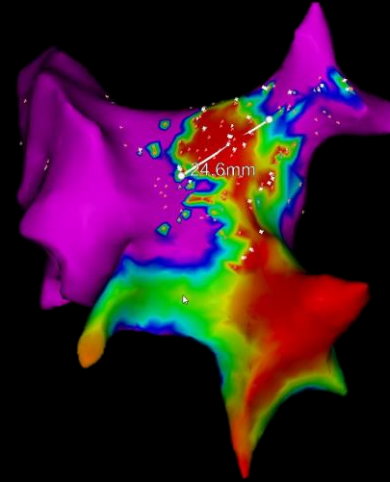
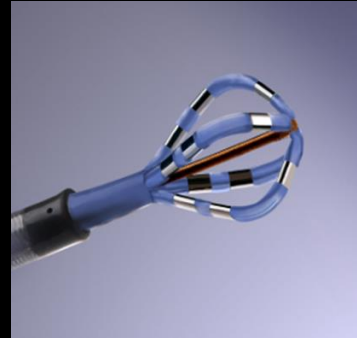
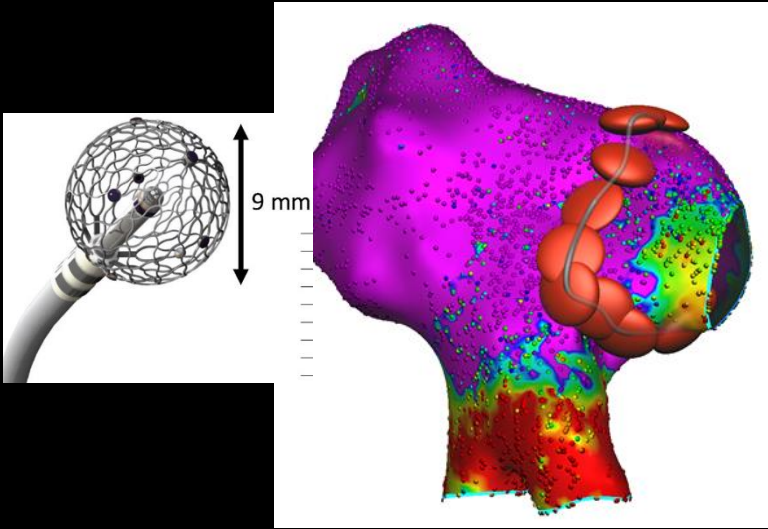


MOUNT SINAI
SCHOOL OF
MEDICINE



MOUNT SINAI
SCHOOL OF
MEDICINE

What's out there in PFA?

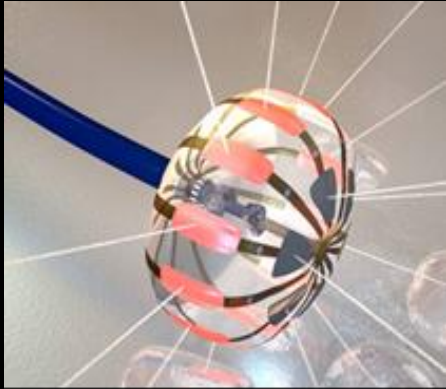


RF Balloon Ablation Catheter

Visually-Guided, Titrate-able RFA

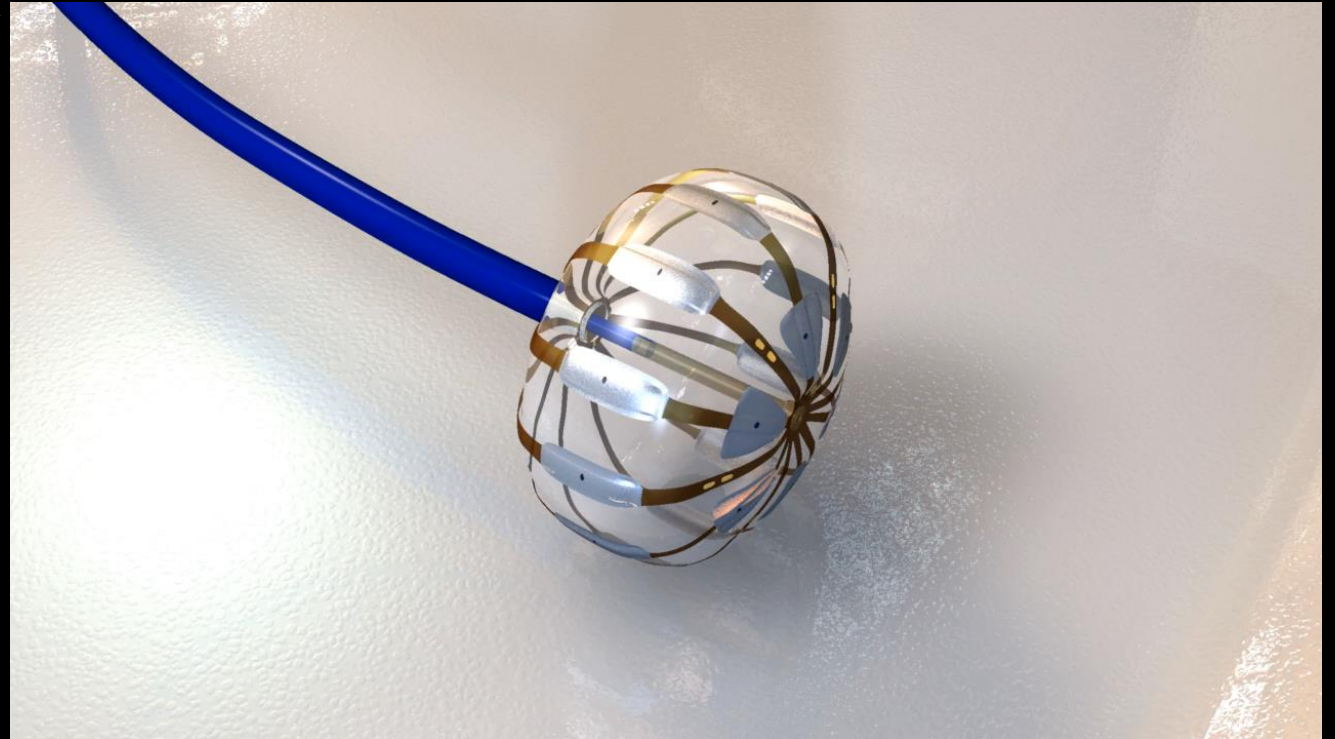
One Shot Multipoint Irrigated RF

May improve procedural
efficiency



Built-in Cameras

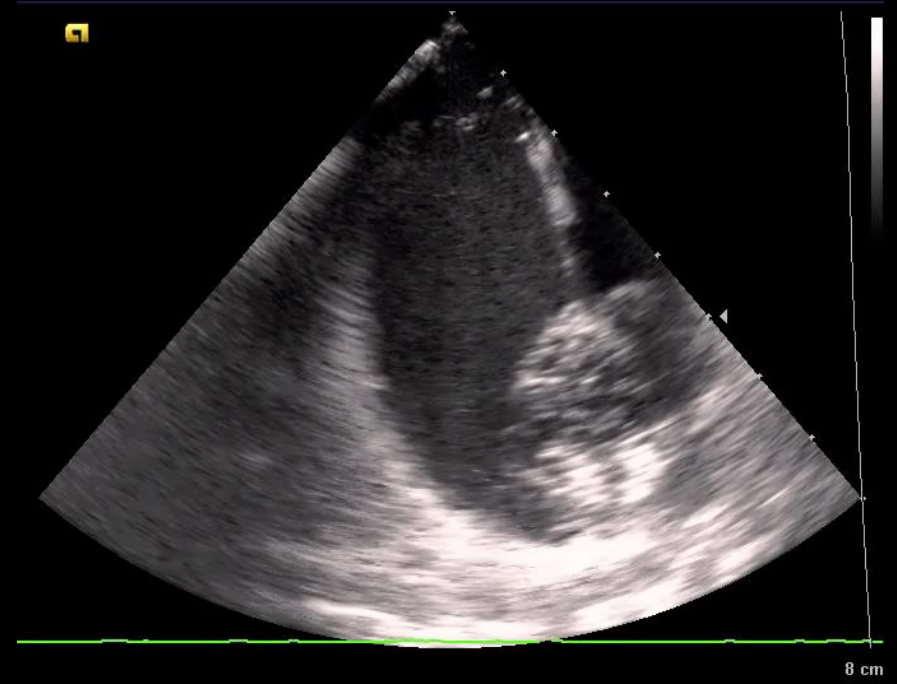
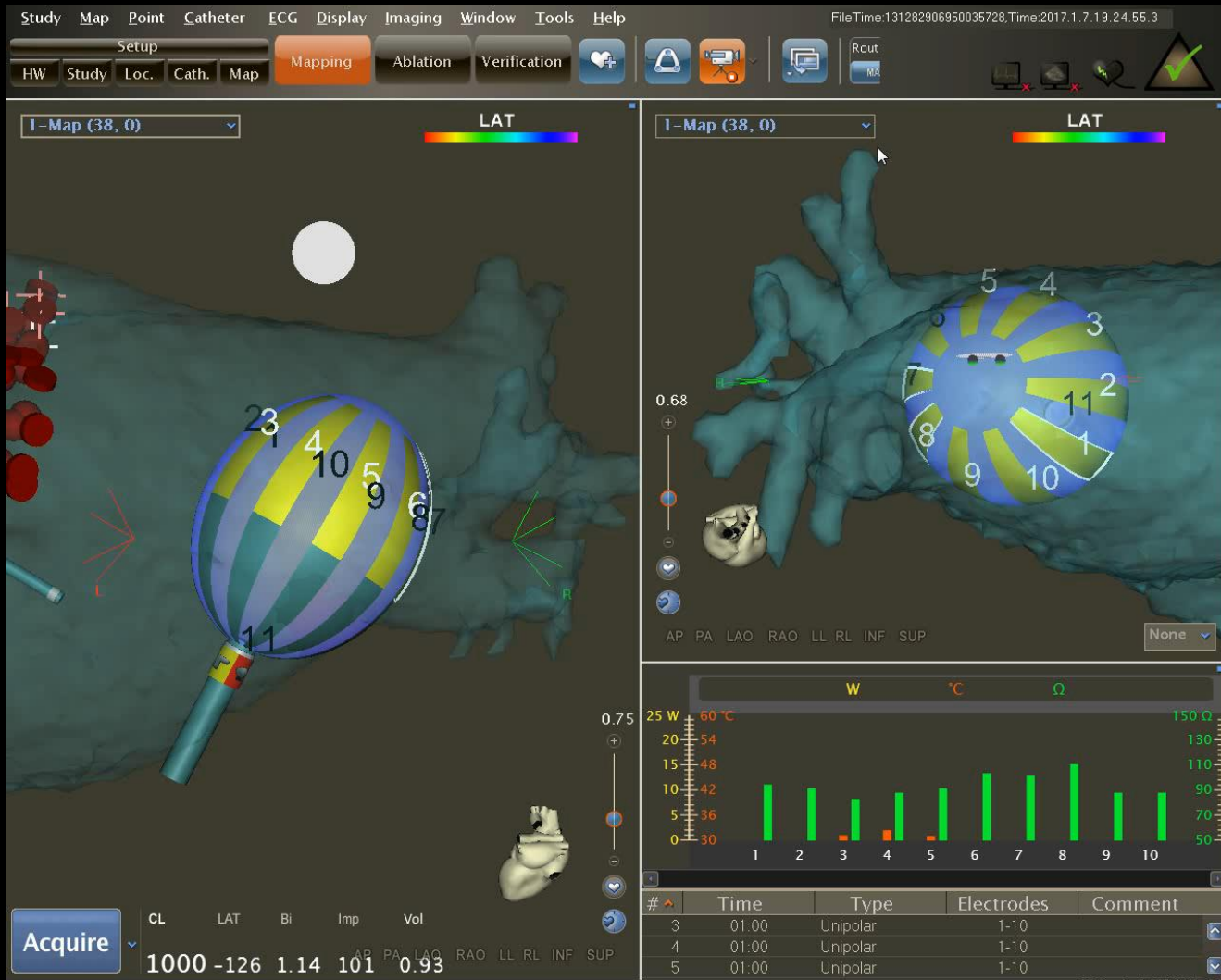
Validation of
electrode
contact via real-
time direct
visualization



**Integrated Mapping and
Pacing**

Multi-Electrode Balloon Ablation Catheter

Helios: Directionally-Titratable RF Energy



Visually-Guided Laser Balloon

Next-Gen Improvements → Shorten Procedure Time

- **Gen 2: Excalibur**
 - More Compliant Balloon
 - Goal: Easier, faster, maximal balloon-tissue conformance
- **Gen 3: X3 RAPID**
 - Continuous ablation at higher power → ‘drag and burn’ lesion
 - Dose-equivalent to current titration
 - Controlled by single-axis motor
 - Goal: Isolate PV < 3 minutes of ablation ... *but preserve ability to titrate energy along balloon circumference*

