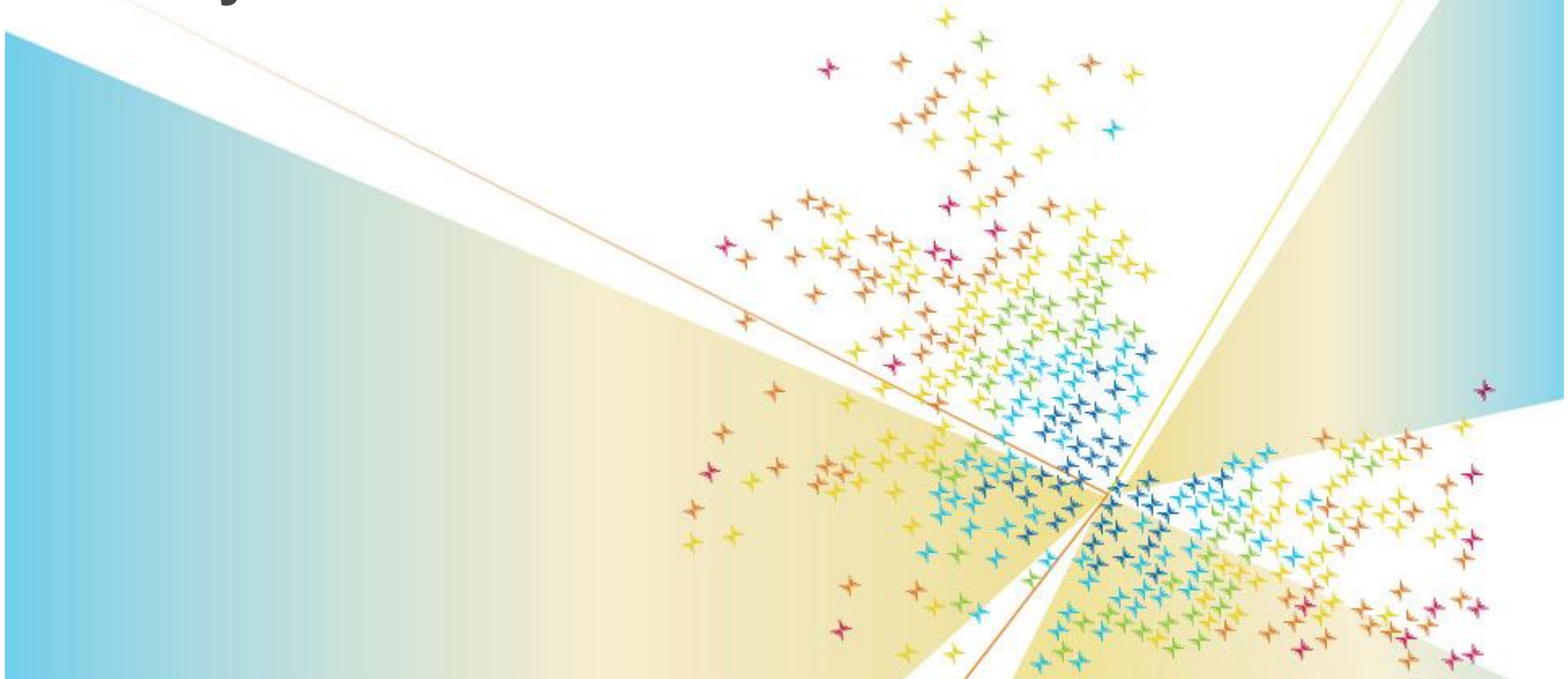


Introduction To Phased RF Technology

Dr Khalameizer Vladimir, Barzilay MC

January 2013



How's it work?

GENius Multi-Channel
RF Ablation Generator
Model #990018



PVAC
Model #990030



MASC
Model #990001

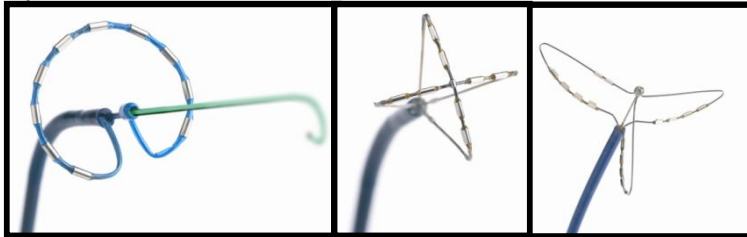


MAAC
Model #990000

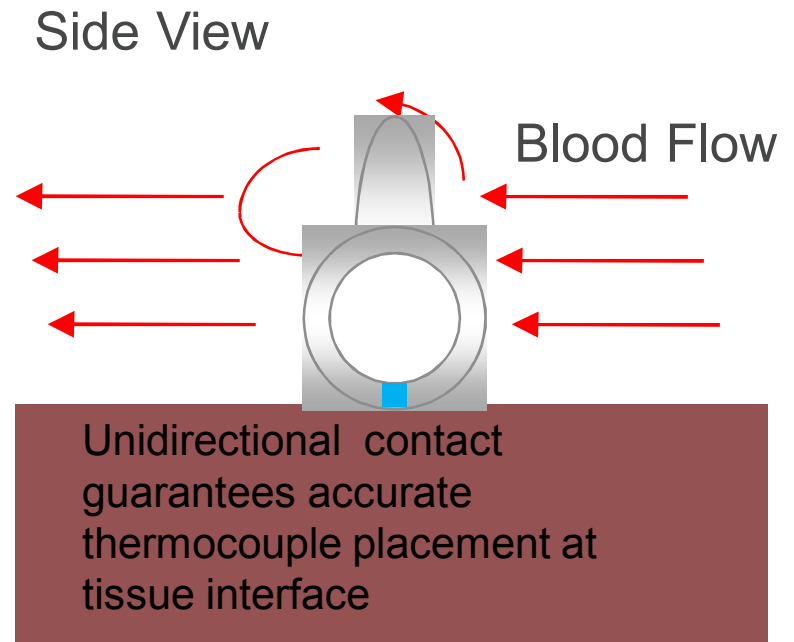


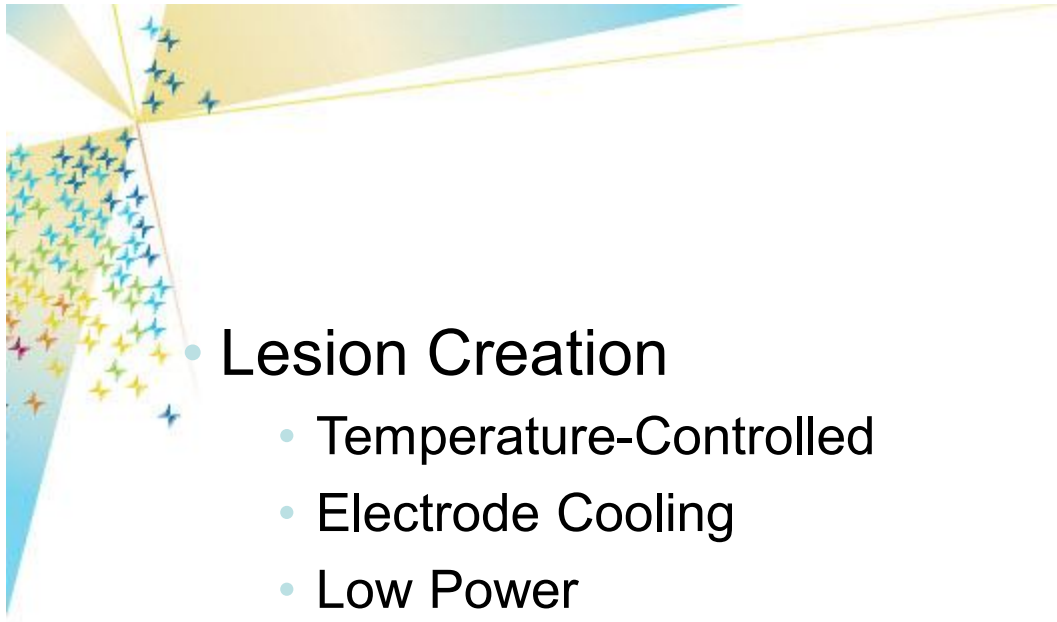
Lesion Creation – Accurate Temp Control

- Temperature driven system with a maximum power limit (10W)



- Anatomically designed catheters
 - Allow accurate measurement of electrode-tissue interface temperature
- Electrode Cooling
 - Finned Electrodes to cool without irrigation
 - Duty-cycled power delivery – cooling during “off” periods





- **Lesion Creation**

- Temperature-Controlled
- Electrode Cooling
- Low Power
- Five Energy modes

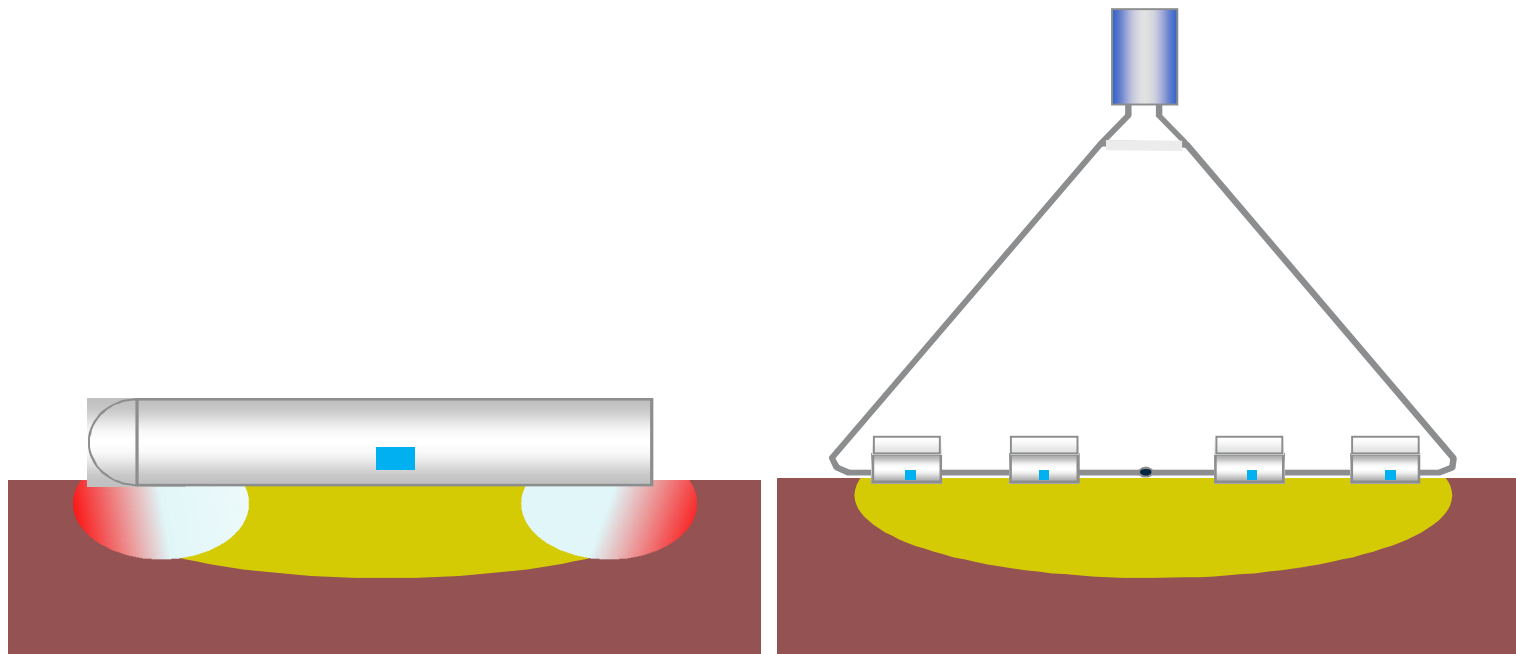
- **Energy Delivery**

- Phased RF Delivery
- Energy Delivery Fields
- Duty Cycles



Lesion Creation – Accurate Temp Control

- Multiple small electrodes in an array
 - Mitigates thermal gradients, ‘hotspots’, overheating – seen with single large electrodes
 - Power output is adjusted at each electrode to achieve target temperature





How can small electrodes with 10W max power create a deep contiguous lesion?

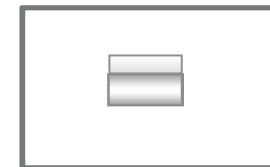
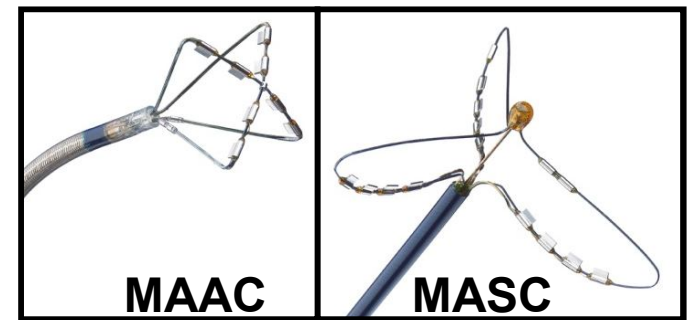
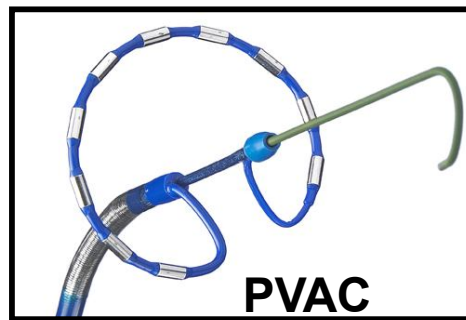
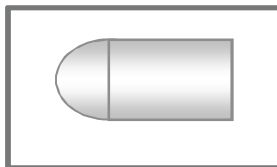
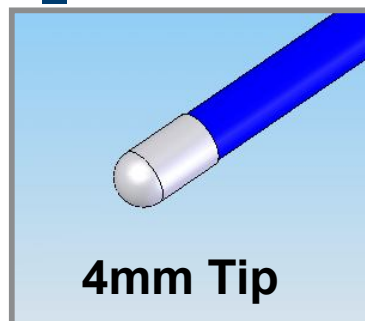
Lesion Creation – Low Power

- Lesion formation is governed by the Current Density

↓ Less Current (Lower Power)

↓ Small Electrodes

$$\text{Current Density} = \frac{\text{Total Current}}{\text{Surface Area}}$$

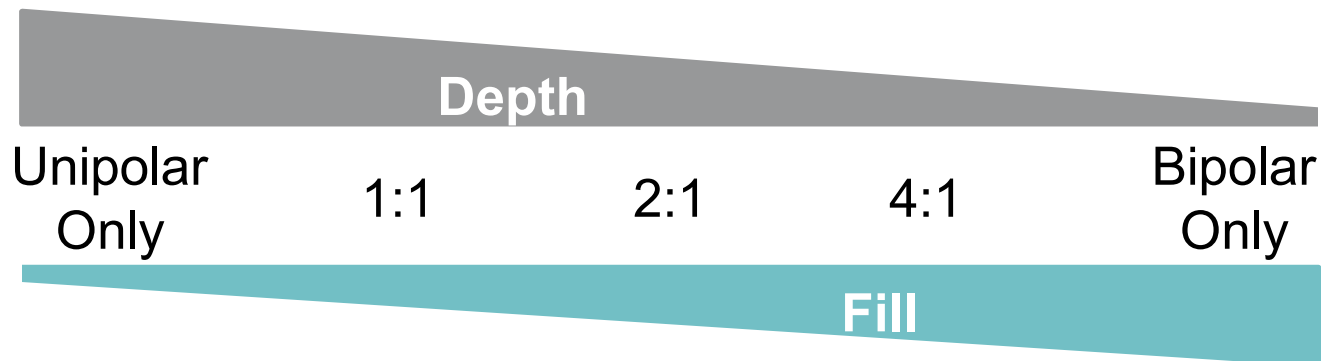




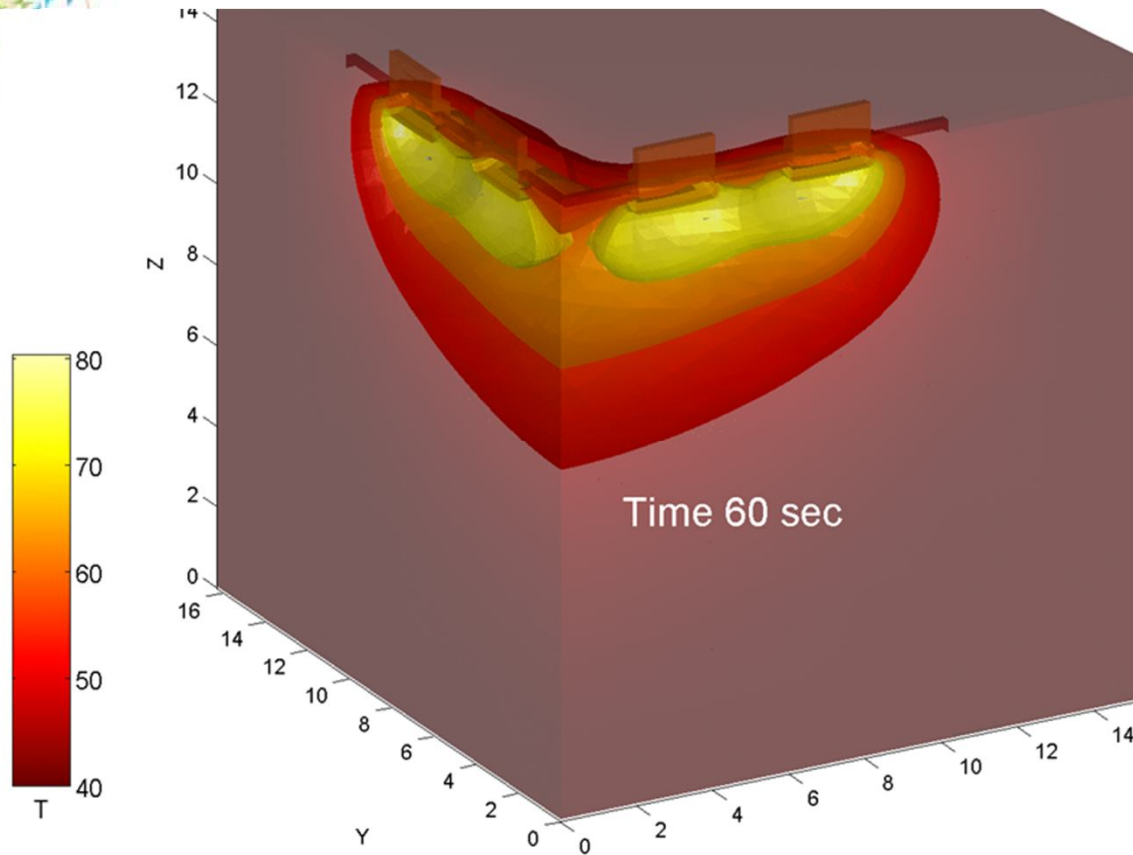
Lesion Creation – Five Energy Modes

- Five different energy modes
 - Unipolar Only
 - 1:1 (50% bipolar, 50% unipolar)
 - 2:1 (66% bipolar, 33% unipolar)
 - 4:1 (80% bipolar, 20% unipolar)
 - Bipolar Only

- Modes allow user to control lesion depth and fill

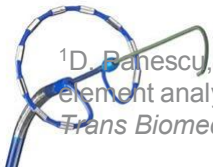


Lesion Creation – Five Energy Modes



MAAC 60° C – 60s
Energy Mode: 1:1

Lesion forms ~50° C
Tissue Discoloration ~60° C ¹

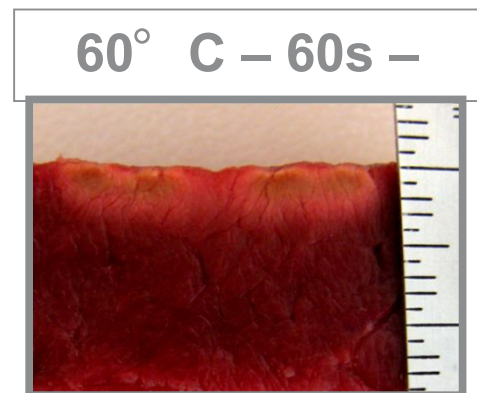
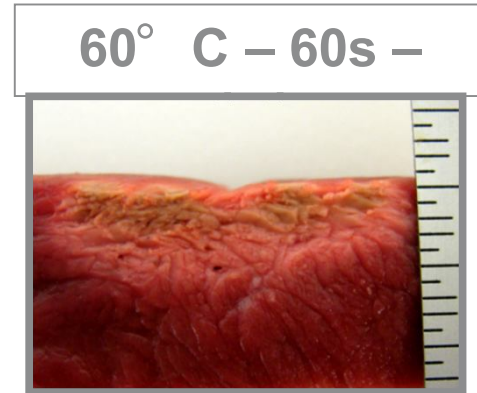
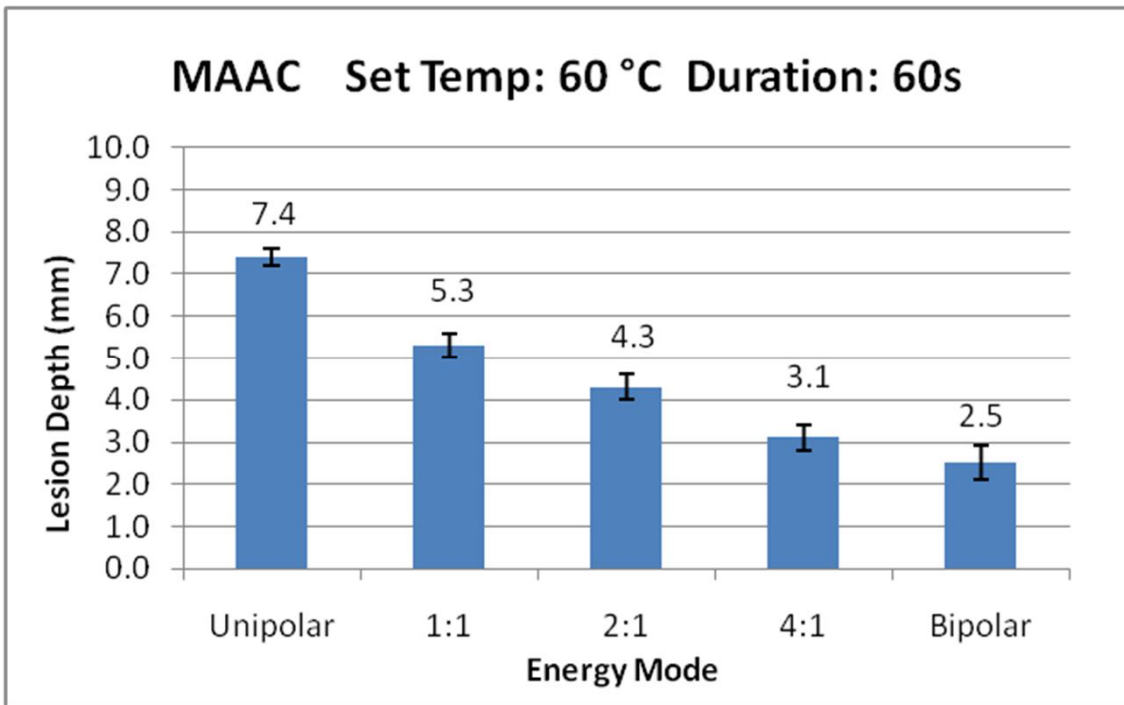


¹D. Banescu, J. Whyne, S. Fleischman, M. Mirotznik, D. Swanson, J. Webster, "Three-dimensional finite element analysis of current density and temperature distributions giving radio-frequency appellation," *IEEE Trans Biomed Eng*, Vol. 42, No. 9, p.879-890, Sep. 1995.

Lesion Creation – Five Energy Modes

In-vitro Lesion Characterization: MAAC

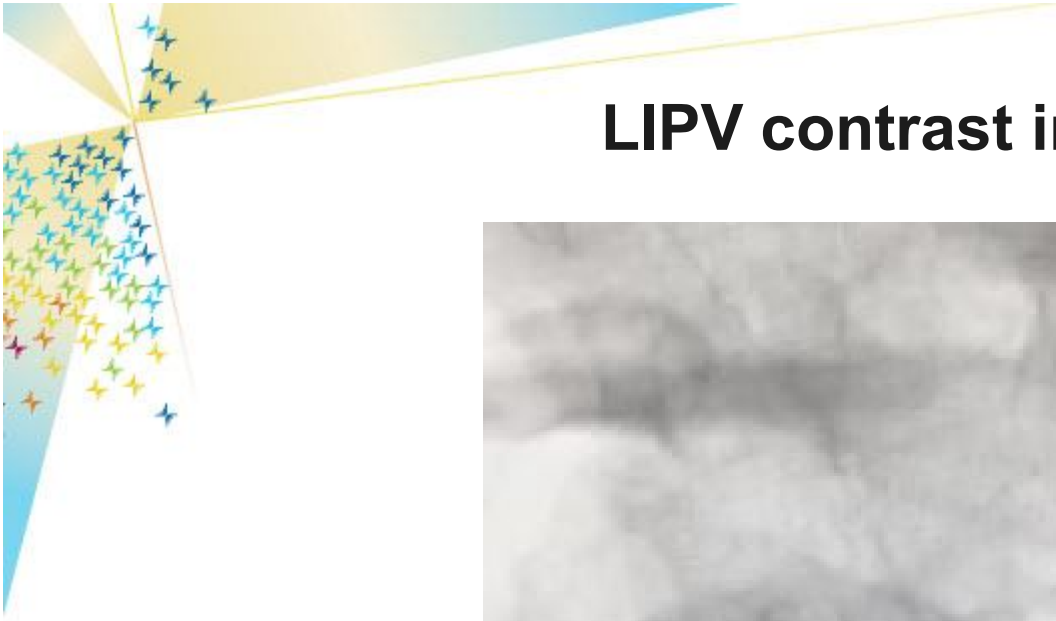
- Lesion Depth Decrease from Unipolar → Bipolar



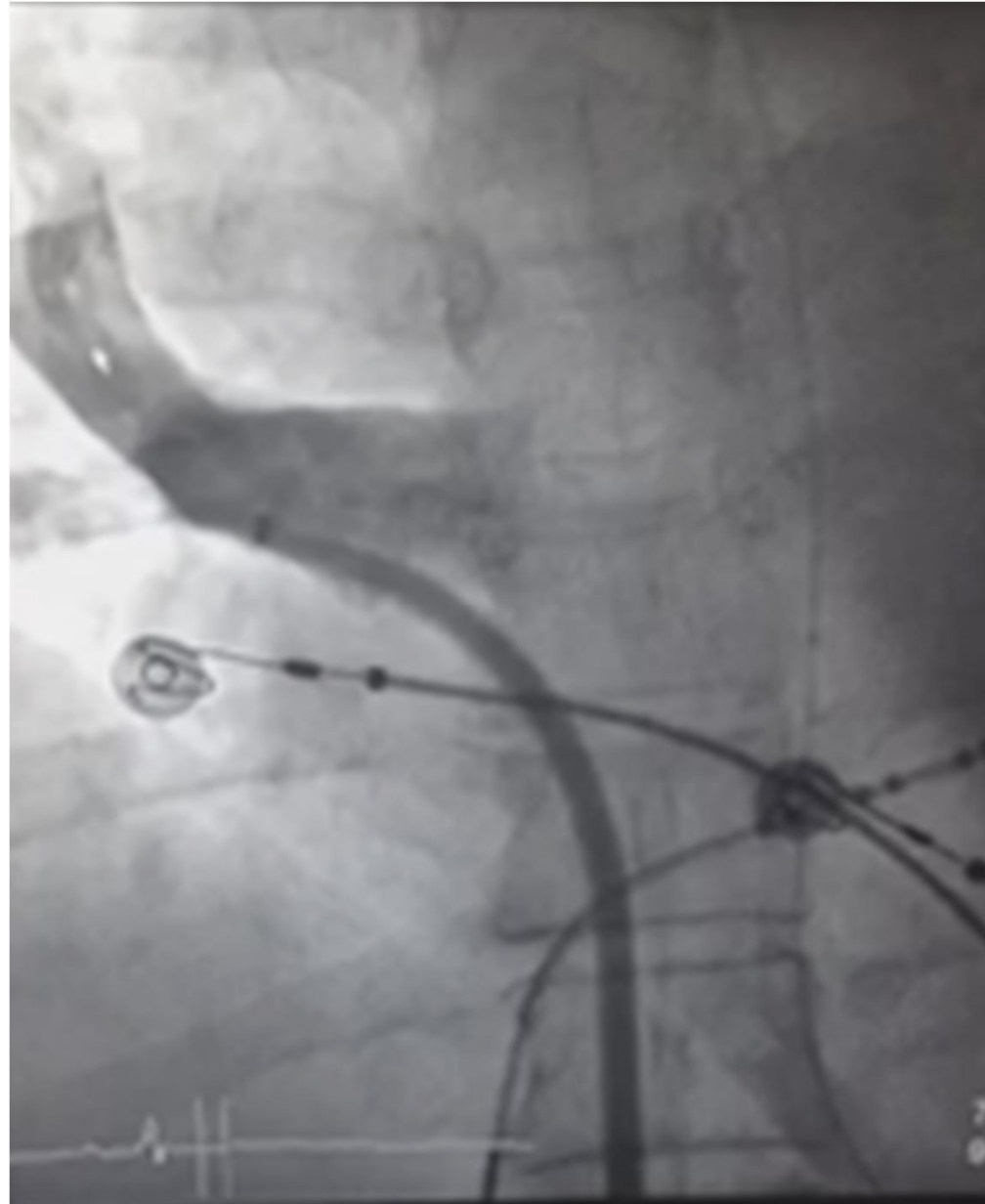
LSPV contrast injection



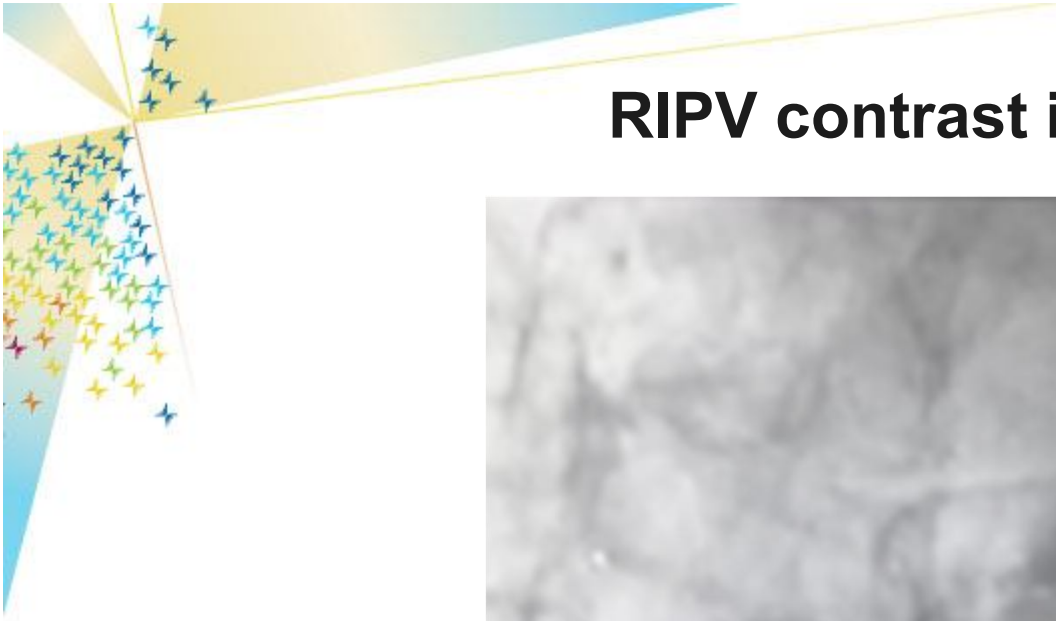
LIPV contrast injection

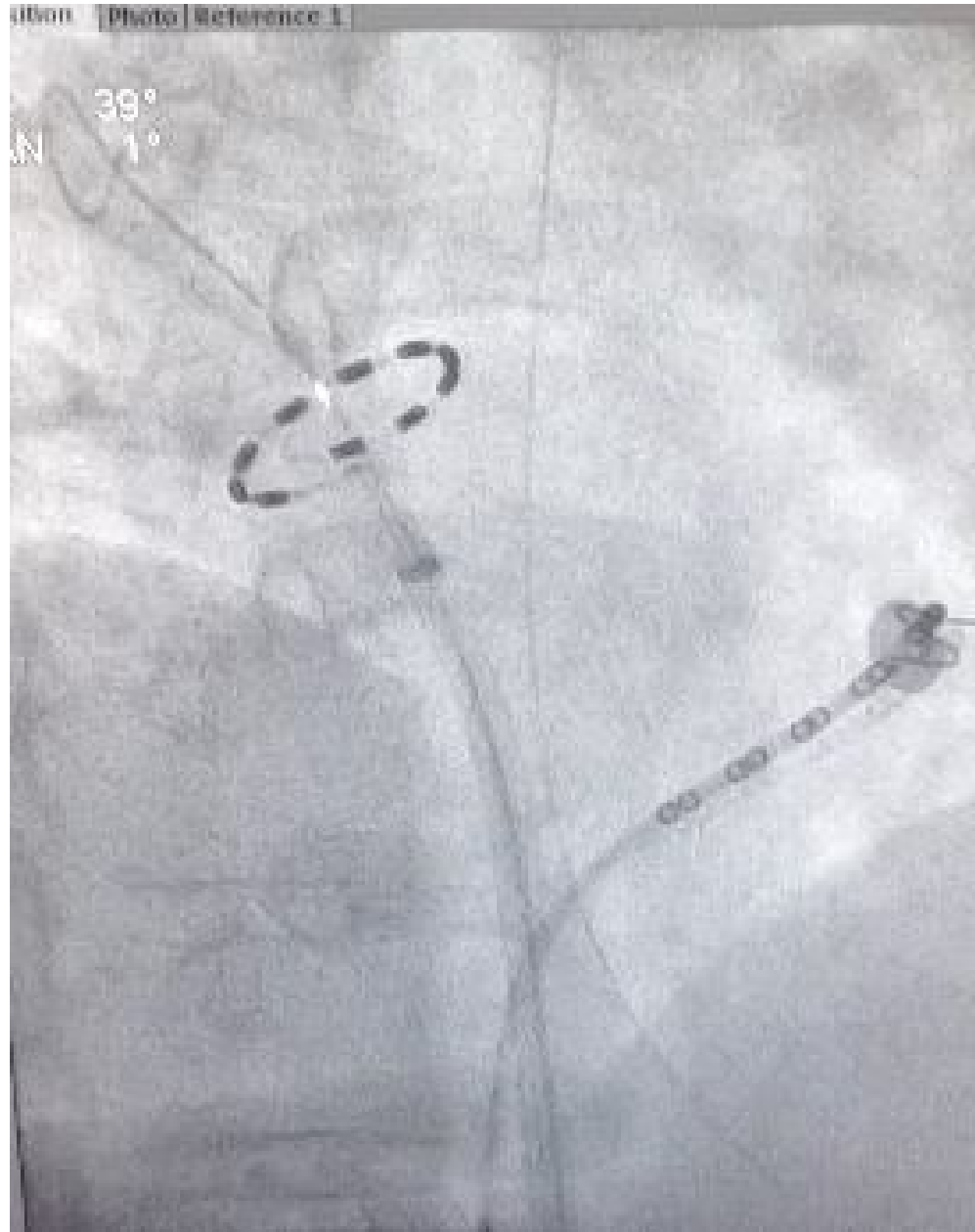
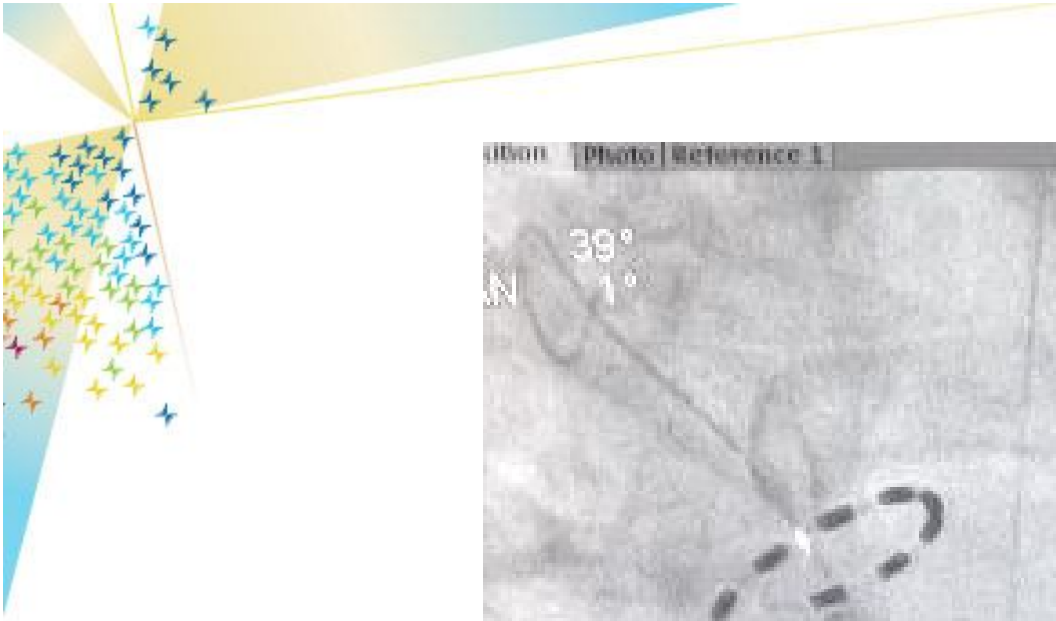


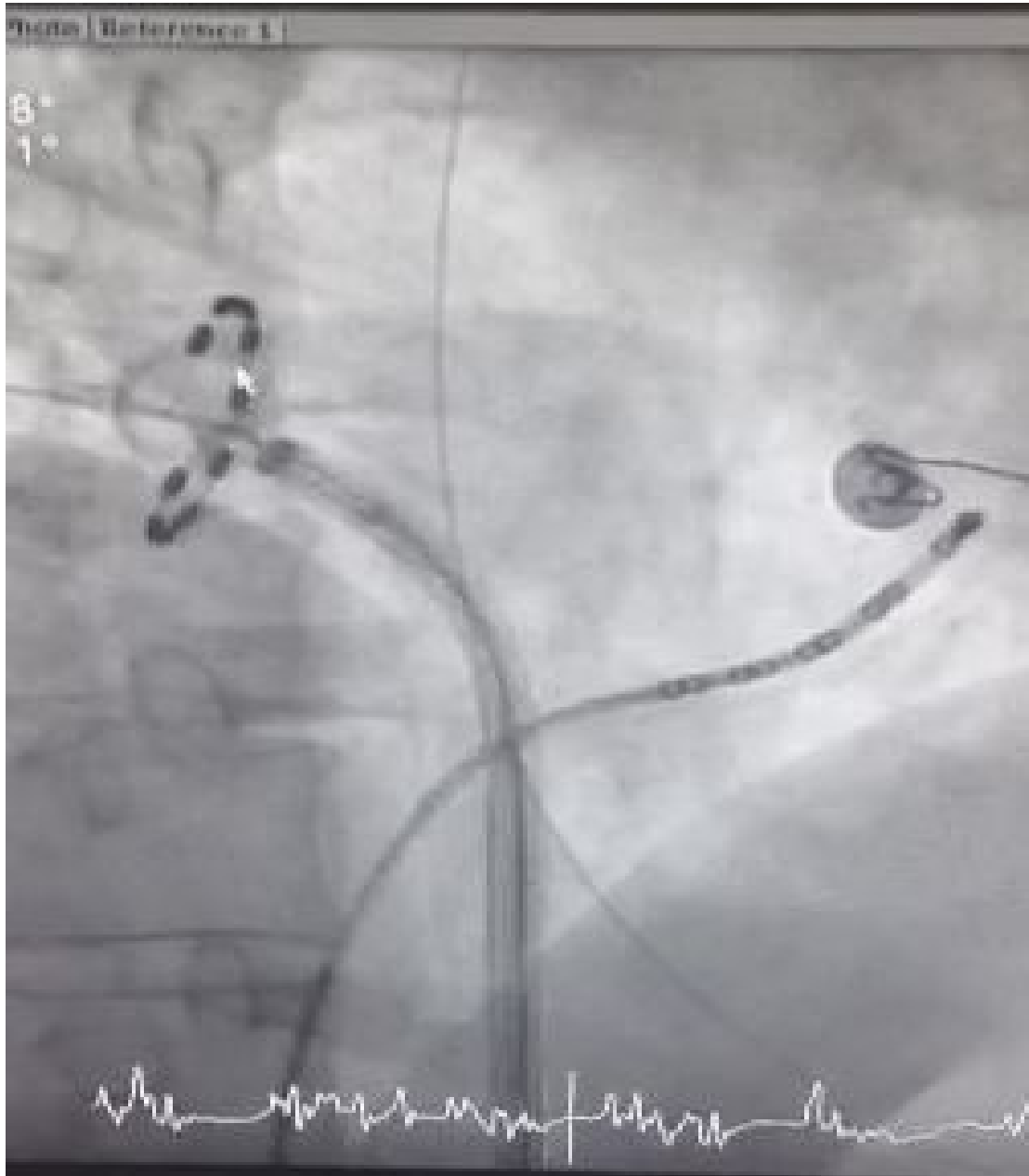
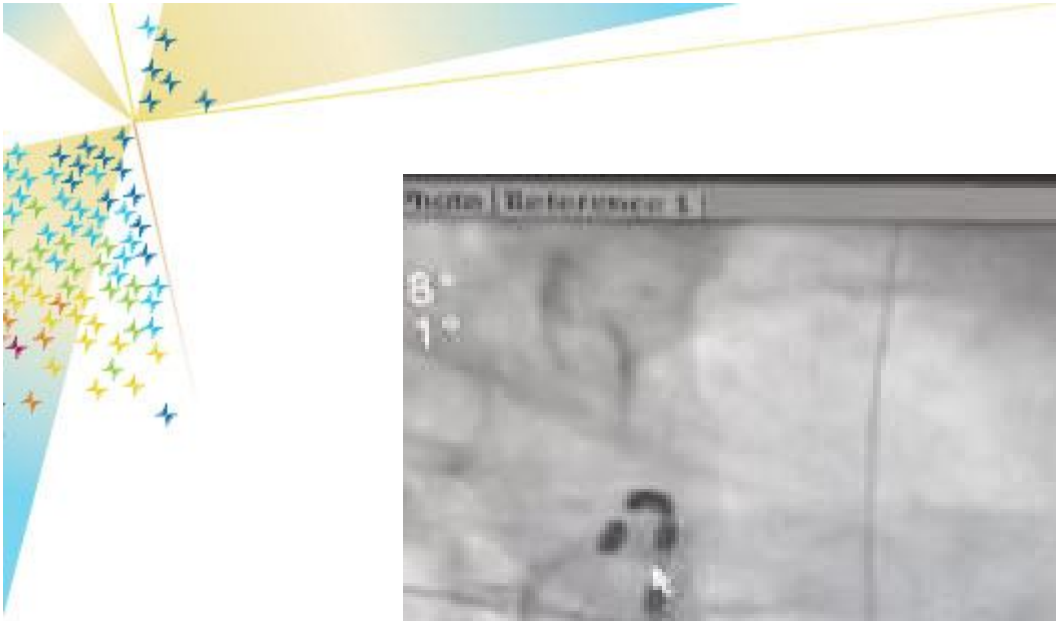
RSPV contrast injection

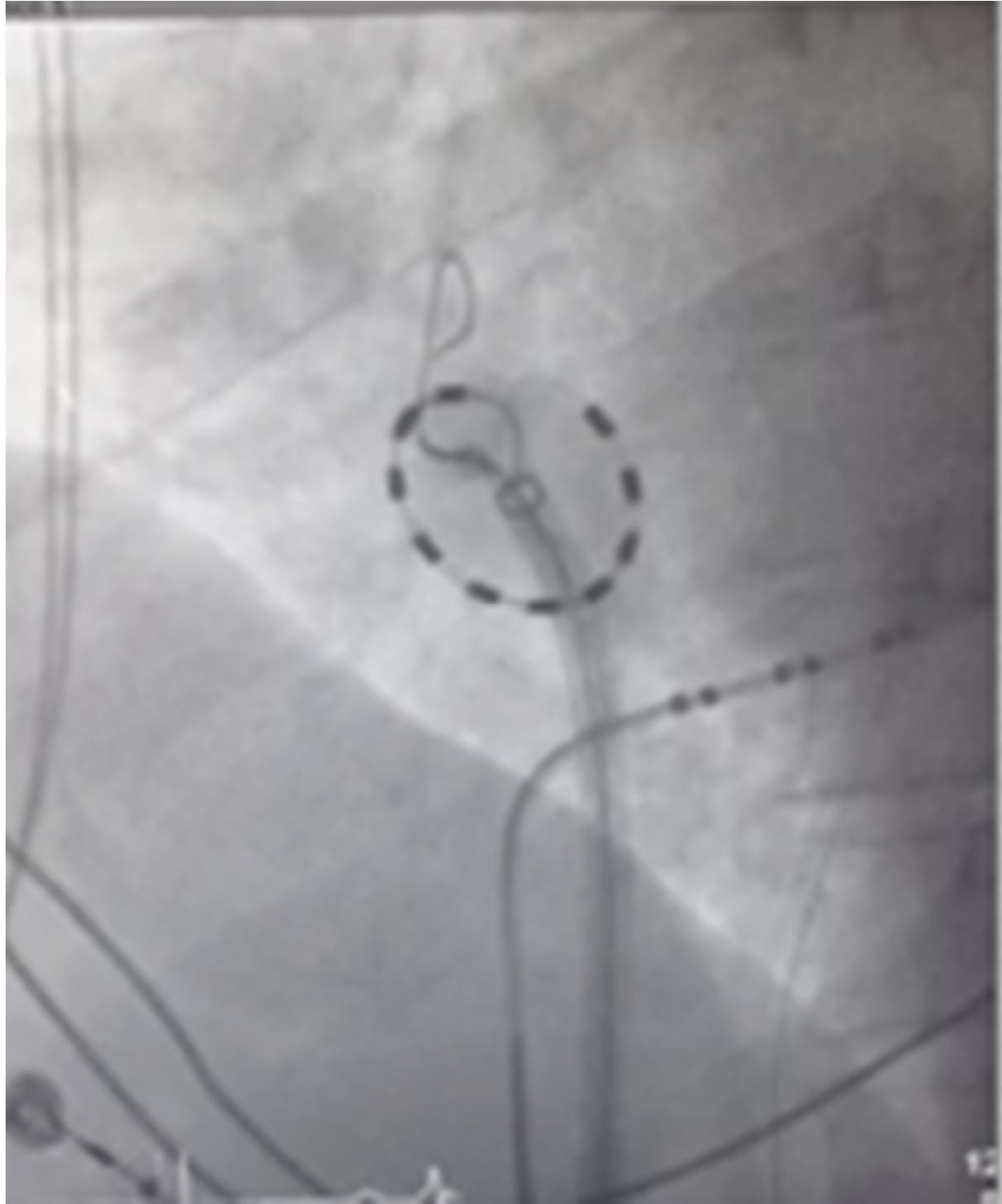


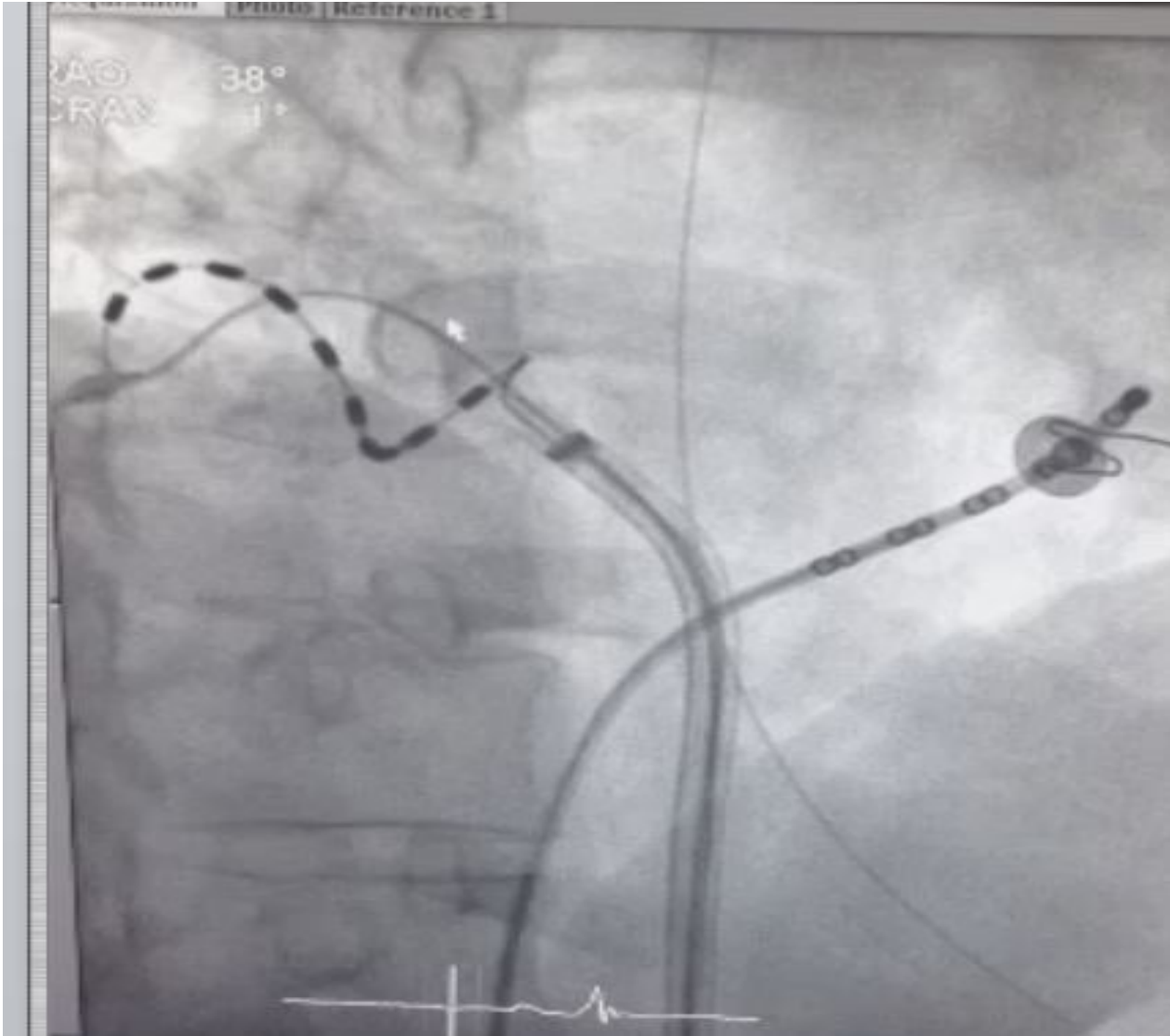
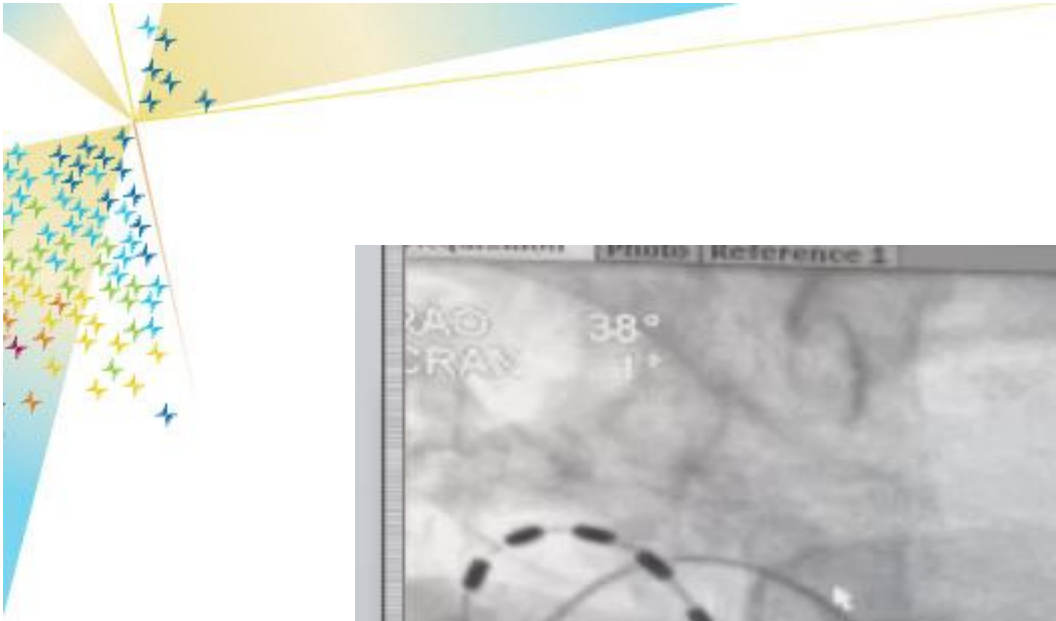
RIPV contrast injection









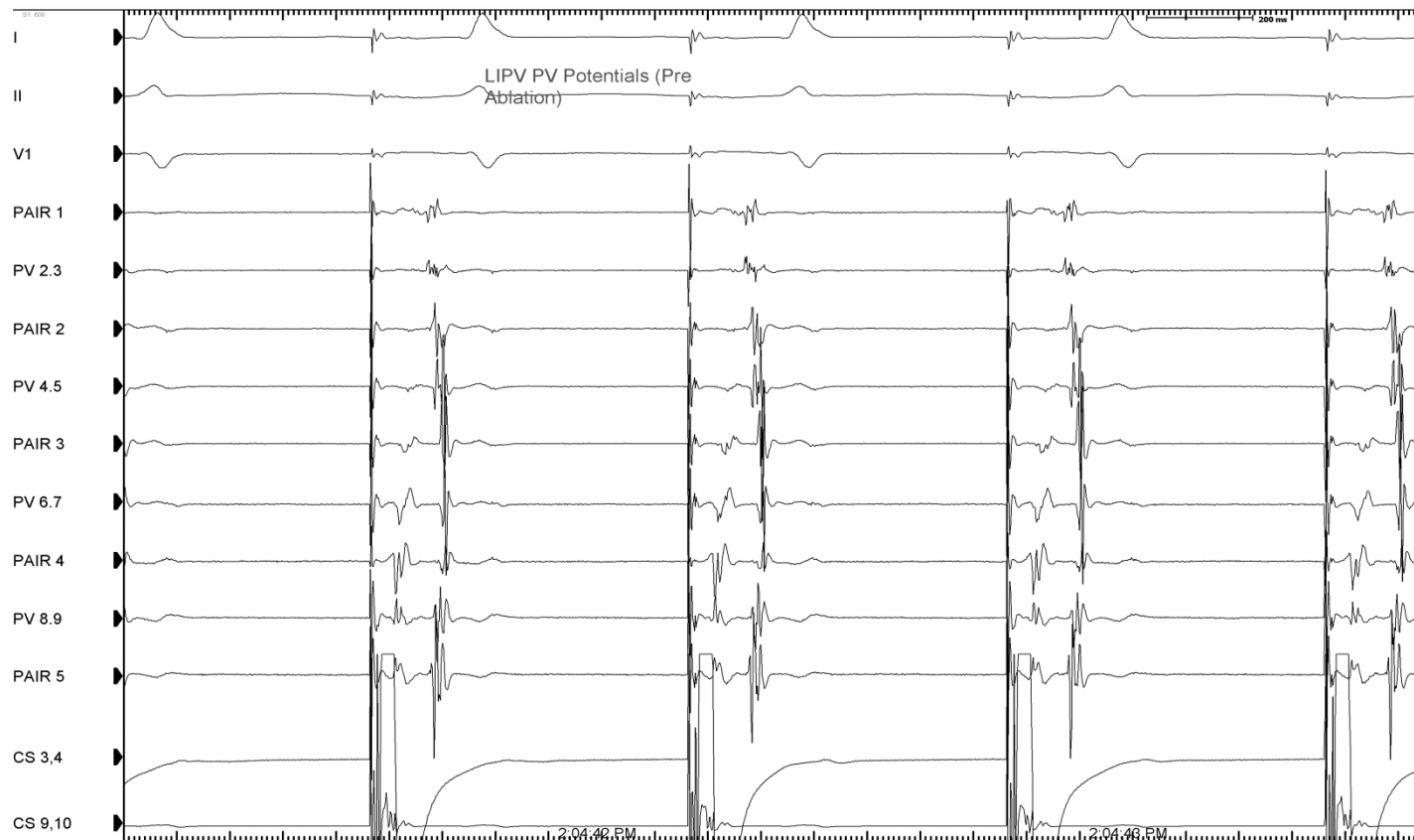




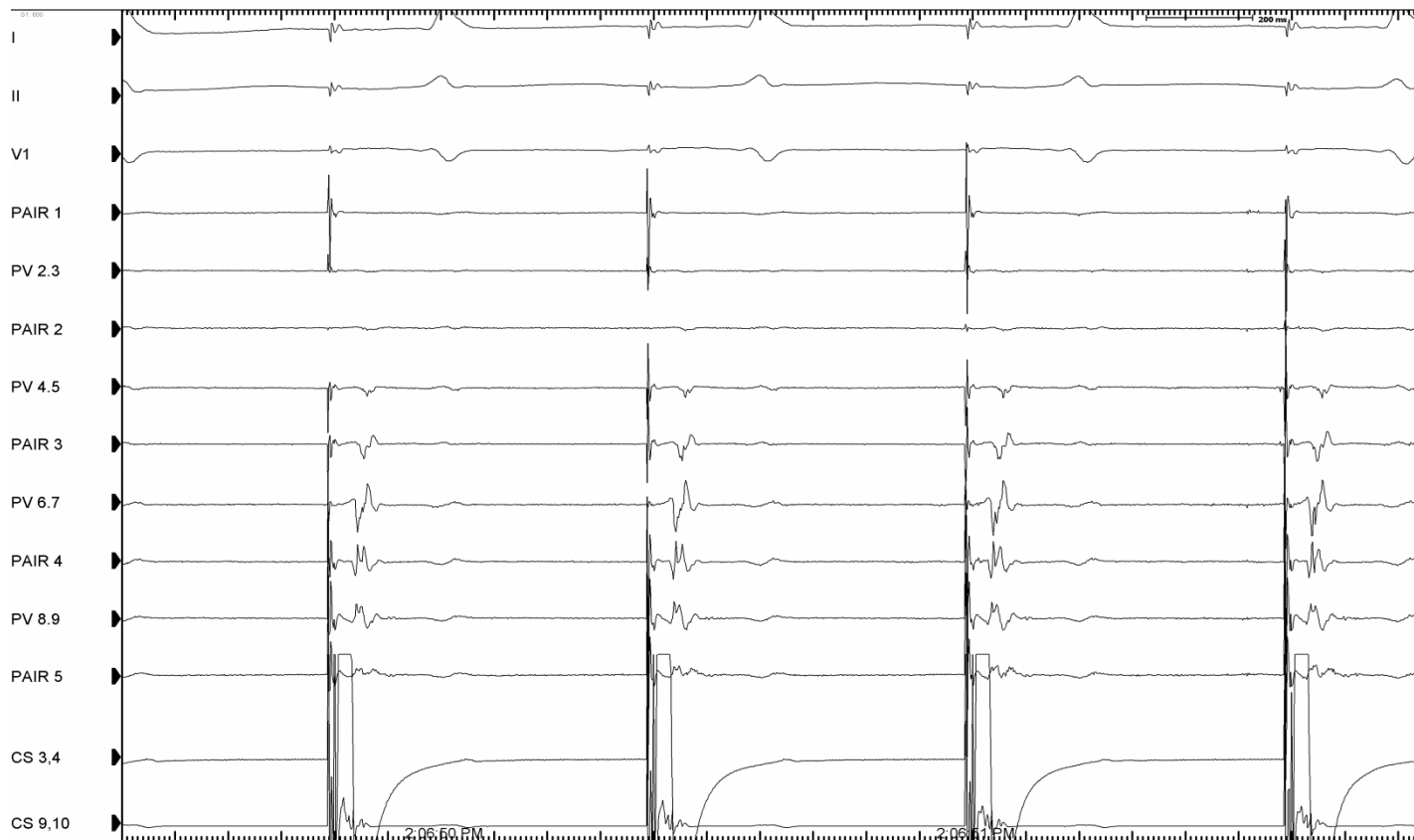
PV SIGNALS



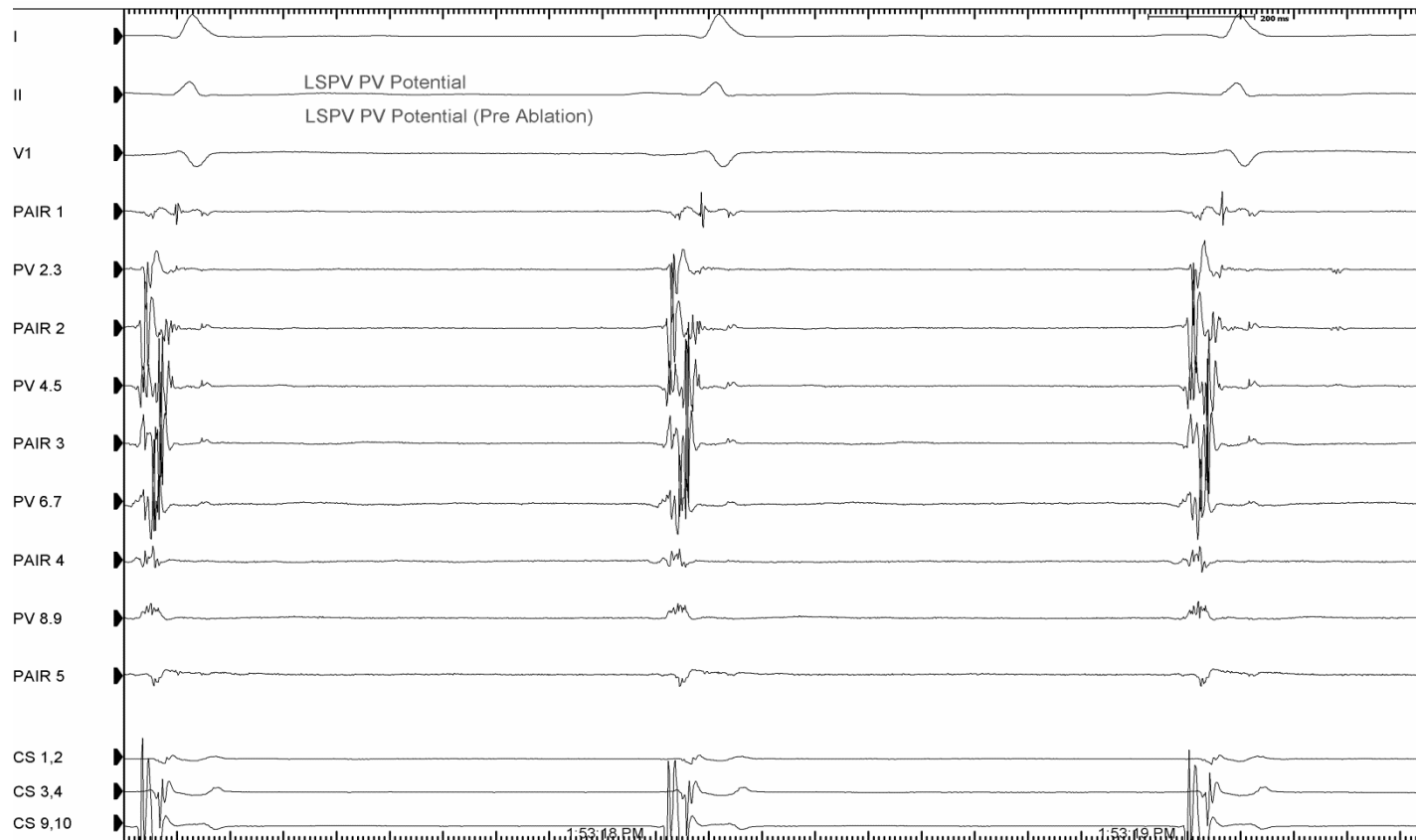
PV potential during pacing from distal CS (pre ablation)



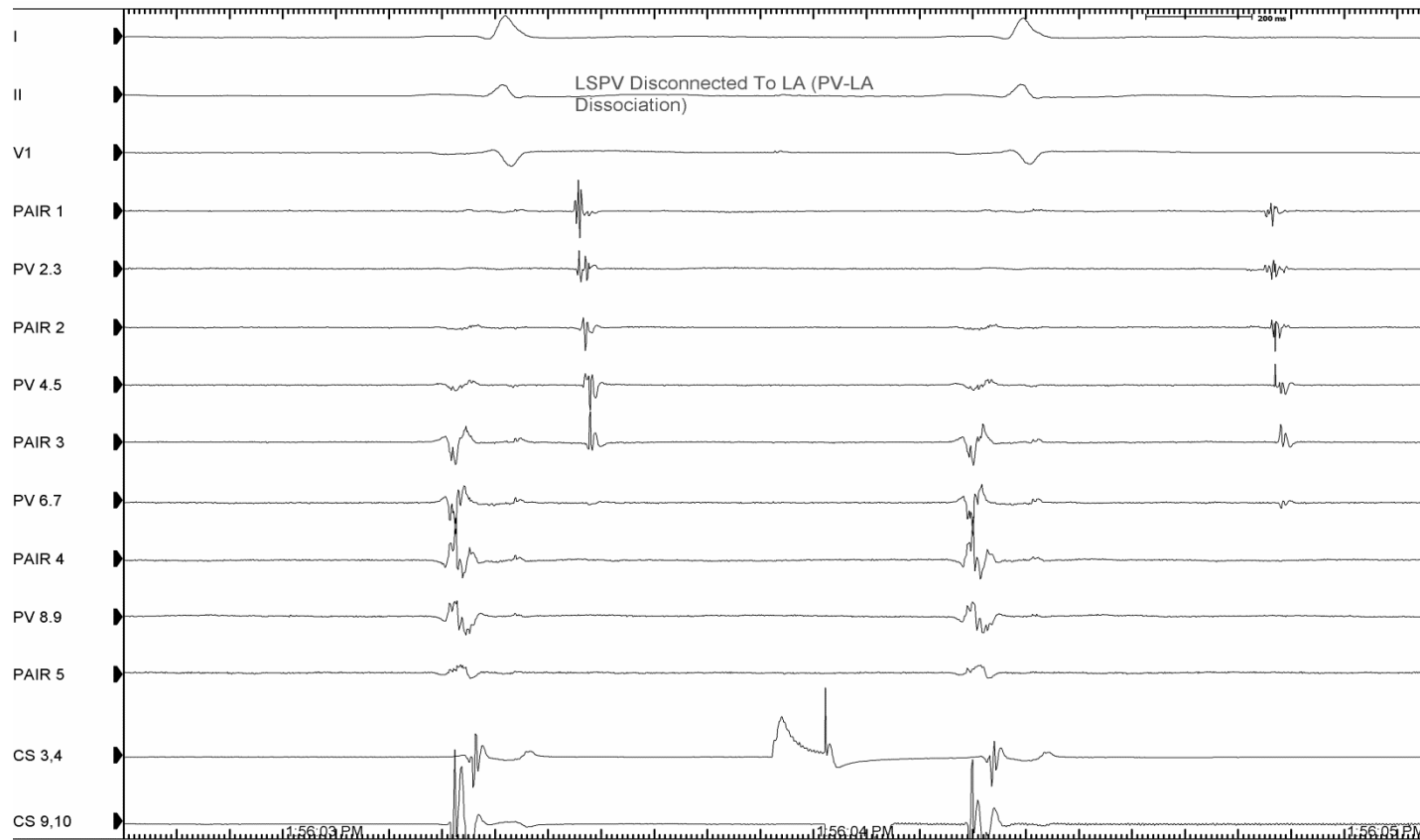
No PV signals during pacing from distal CS (post ablation)



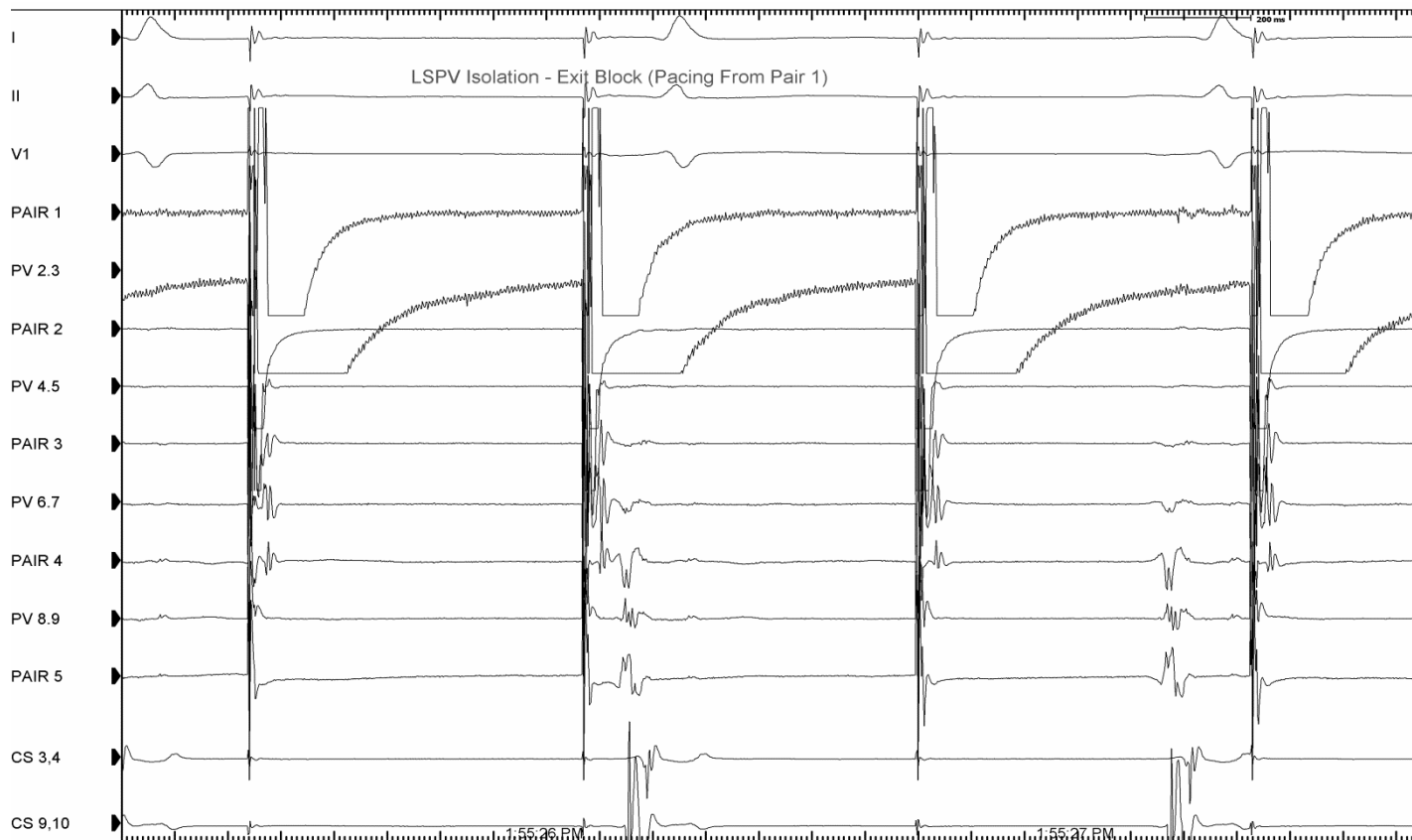
PV signals during SR (pre ablation)



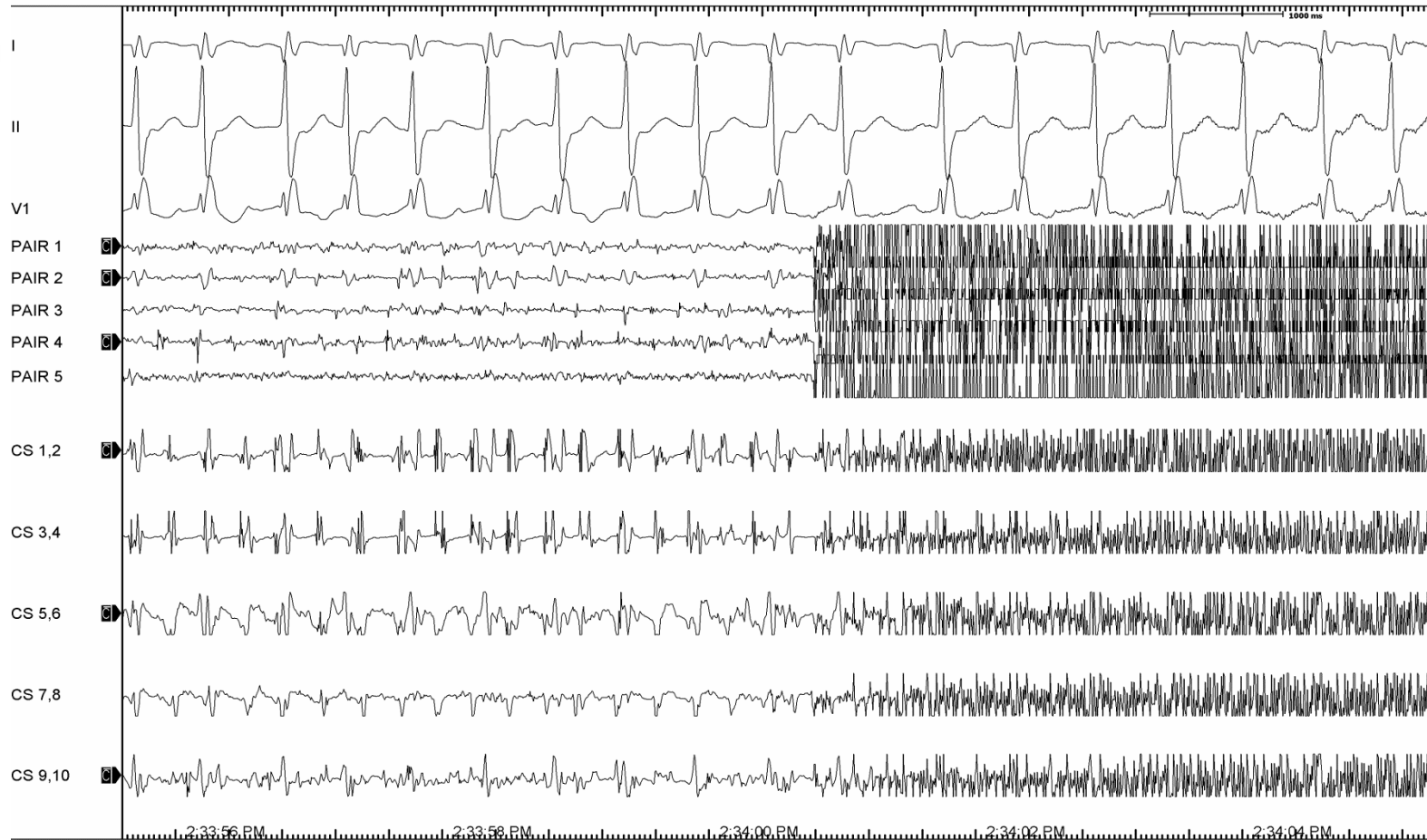
PV – LA signals dissociation (post ablation)



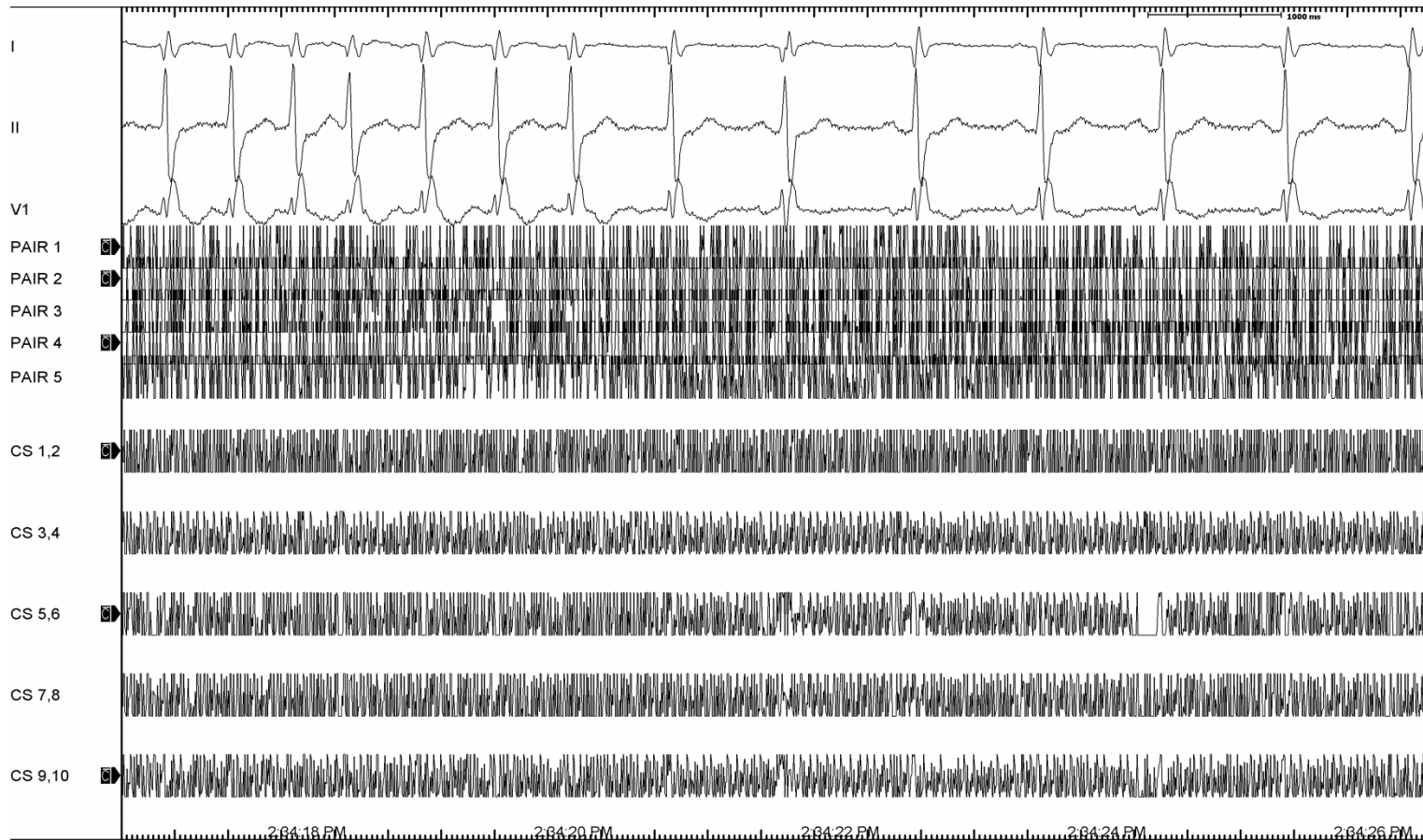
PV Isolation - **Exit** Block (pacing from the vein)



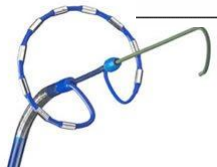
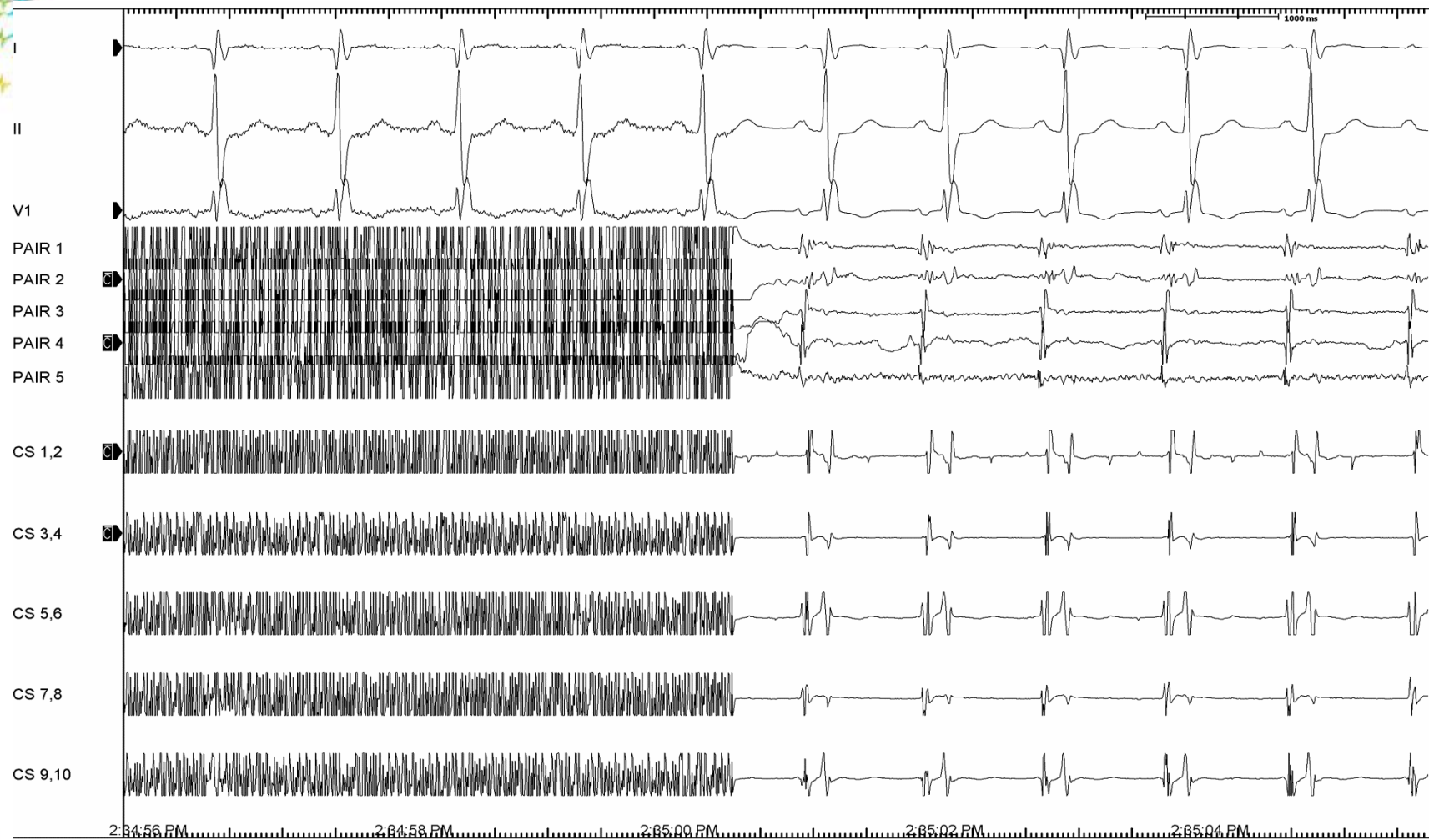
AF Termination During Ablation



AF Termination During Ablation



AF Termination During Ablation





AF Classification:

- Patients total 70
- Paroxysmal AF 51 72.8%
- Persistent AF 16 22.8 %
- Long Standing AF 3 4.3%





Success Rate:

- Patients (N) 70
- No. of procedures 74 (Redo - 4 procedures)
- Parox. AF Success rate 83 %
- Persistent AF Success rate 60%
- Long Standing AF Success rate- 1 patient after one year in SR without AAD, 1 patient in SR with amiodarone, 1 patient still in AF.

Procedure Data:

- Procedure duration (skin to skin) 75+-15 (min)
- X-ray (min) 20+-5 (min)

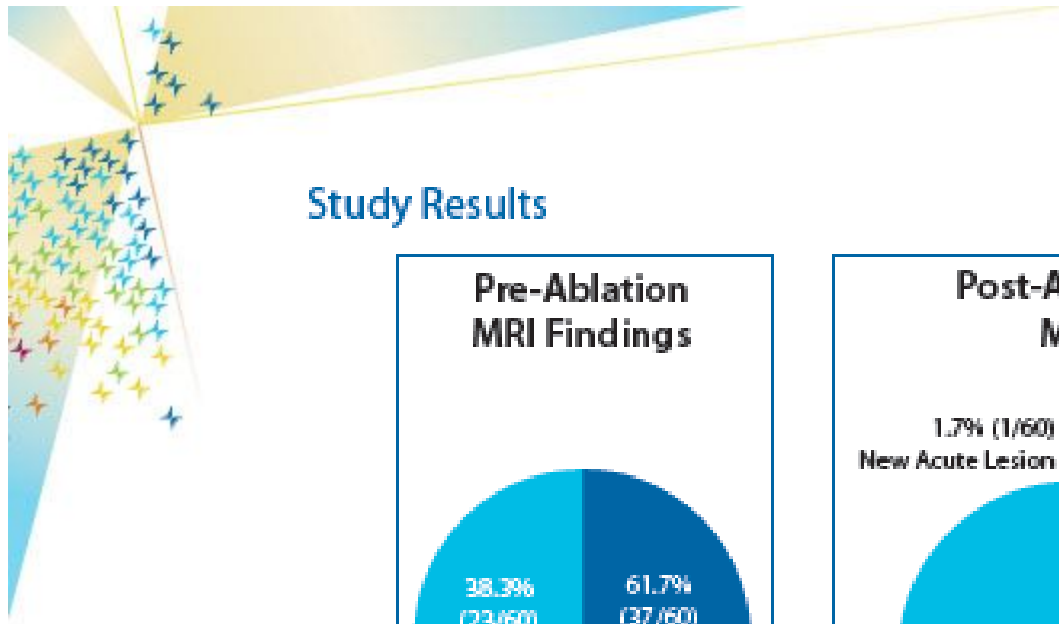




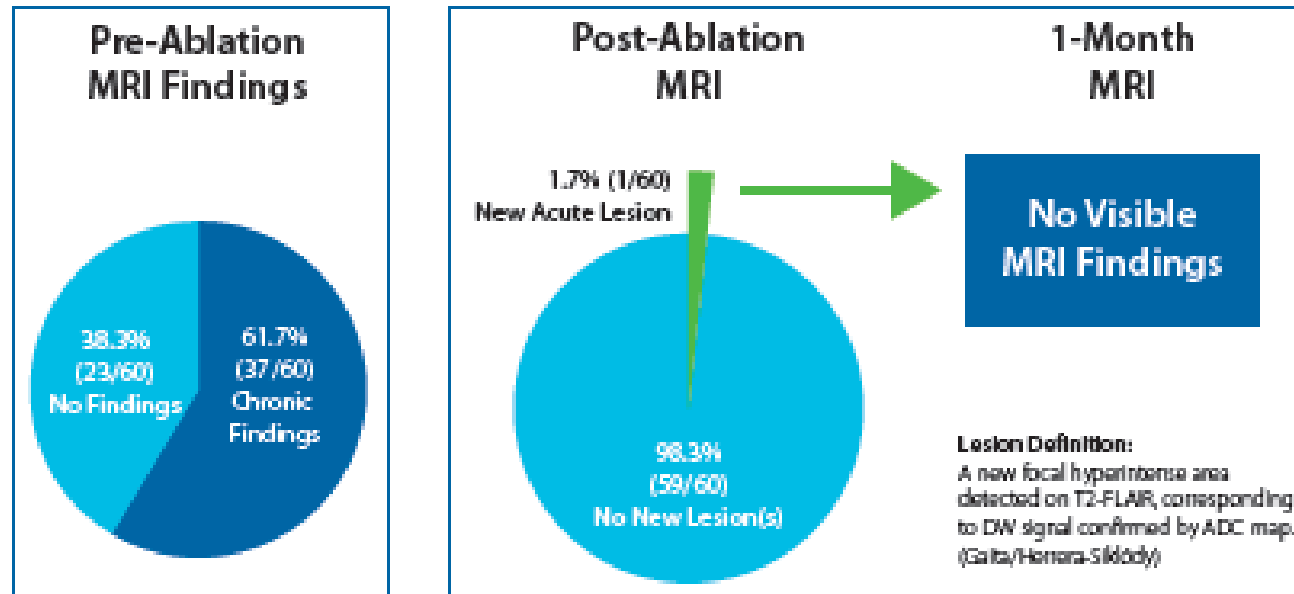
Complications:

- Pseudo Aneurysm – 2 Patients
- No Perforation
- No Tamponade
- No Stroke





Study Results



- Simple procedural changes reduced the ACE rate with PVAC to 1.7%
- No observable change in baseline, post-ablation and 1-month neurological scores (MMSE and NIHSS)

Acute Safety and Effectiveness

Acute Safety Events

- 1.7% (1/60) major complications were reported (groin hematoma requiring intervention)

Acute Effectiveness

- 100% (240/240) of targeted veins were acutely isolated per investigator protocol
- Disabling PVAC electrode 1 or 10 did not impact the number of RF applications per subject from previously published values (28.8 +/- 16.1)⁴⁻⁶



Procedural Mitigations to Reduce Embolic Load

E1:10 Interaction²⁷

- Disable Pair 1 or Pair 5 prior to ablation

Electrode Contact Management²⁸

- Disable electrode pairs with ineffective contact
- Avoid repositioning the catheter during ablation
- Pull catheter away from endocardium to reposition

Sheath Management⁵⁵

- Submerged catheter loading
- Deliberate insertion and withdrawal of the catheter

Anticoagulation^{53,55}

- Continuous anticoagulation (INR>2)
- ACT > 350s

