



PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

**ROMA**

Centro Congressi  
di Confindustria

Auditorium  
della Tecnica

9<sup>a</sup> Edizione

30 Settembre  
1 Ottobre  
2022



## Sicurezza ed efficacia nell'ablazione della fibrillazione atriale con la tecnologia dell'elettroporazione

*Massimo Grimaldi*



*Ospedale “F. Miulli”  
Acquaviva delle Fonti -  
Bari*

# Conflitto d'interesse

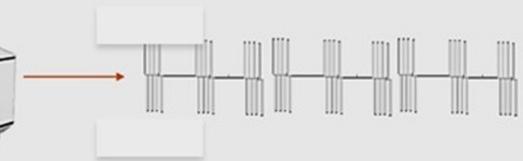


## Massimo GRIMALDI

negli ultimi due anni ho avuto i seguenti rapporti anche  
di finanziamento con soggetti portatori di interessi  
commerciali in campo sanitario:

Bayer, Biosense Webster, Boehringer Ingelheim,  
Daiichi Sankyo, Dompè, Pfizer BMS.

PEF Energy is delivered in a series of short, high-voltage, bipolar, biphasic pulses lasting fractions of a second



Non-Thermal  
Ablation

Non-Thermal ablation minimizes the risk of typically thermal induced risks and harms



Char



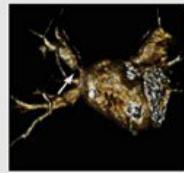
Steam Pop



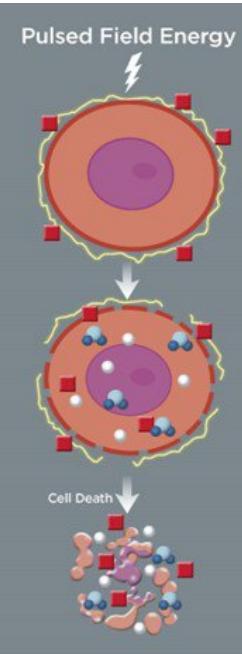
AEF



Phrenic Nerve  
Palsy

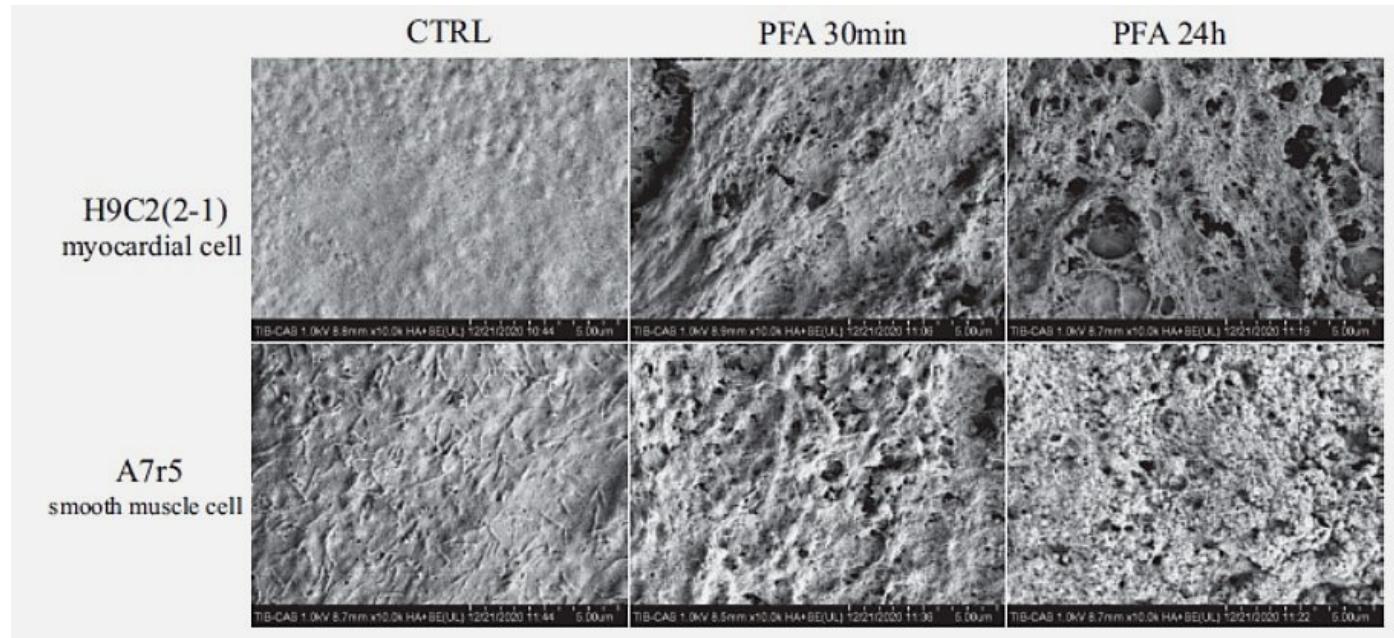


PV Stenosis



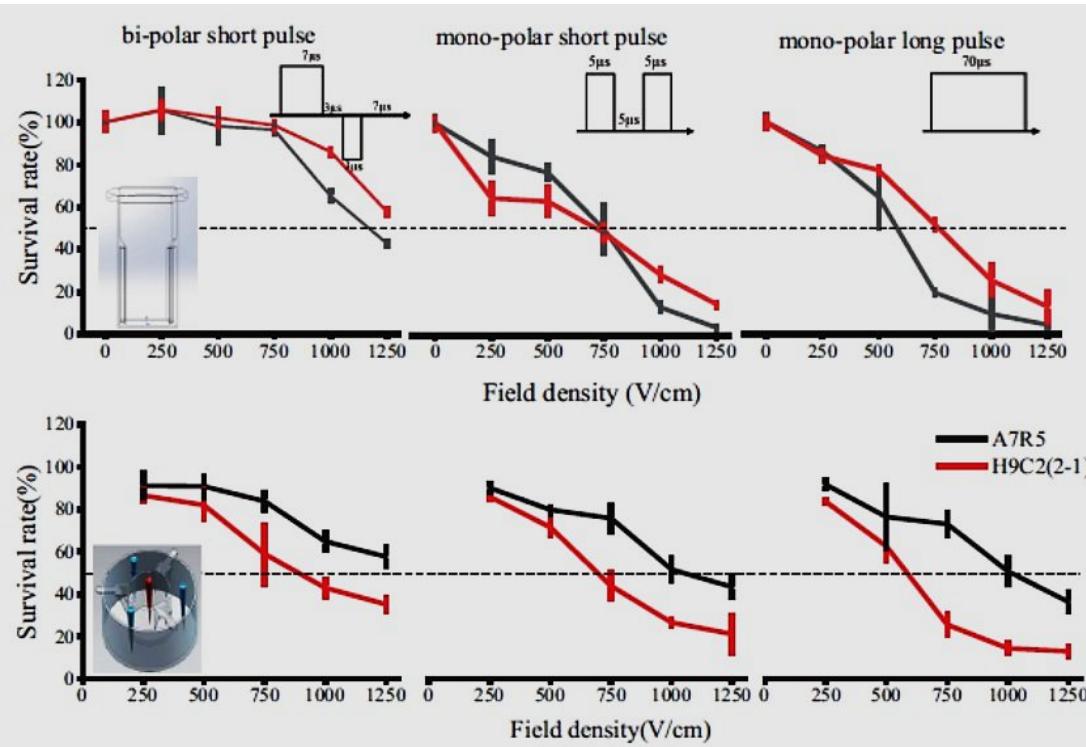
# Study on Optimal Parameter and Target for Pulsed-Field Ablation of Atrial Fibrillation

Xuying Ye<sup>1,2</sup>, Shangzhong Liu<sup>3</sup>, Huijuan Yin<sup>4</sup>, Qiang He<sup>2</sup>, Zhixiao Xue<sup>3,5\*</sup>, Chengzhi Lu<sup>1,2\*</sup>  
and Siying Su<sup>5</sup>



# Study on Optimal Parameter and Target for Pulsed-Field Ablation of Atrial Fibrillation

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Energia

Dimensioni elettrodi

Distanza fra elettrodi

Combinazioni fra più elettrodi

Durata singolo impulso

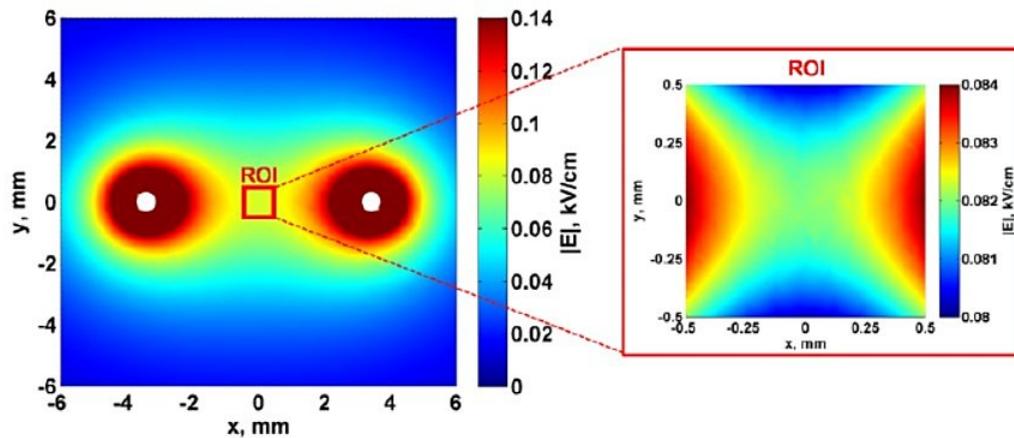
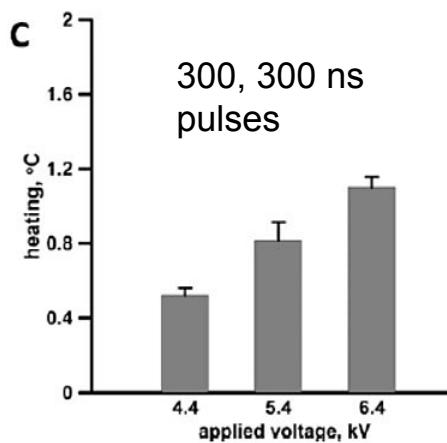
Numero impulsi

Numero di treni di impulsi

Intervallo fra treni di impulsi

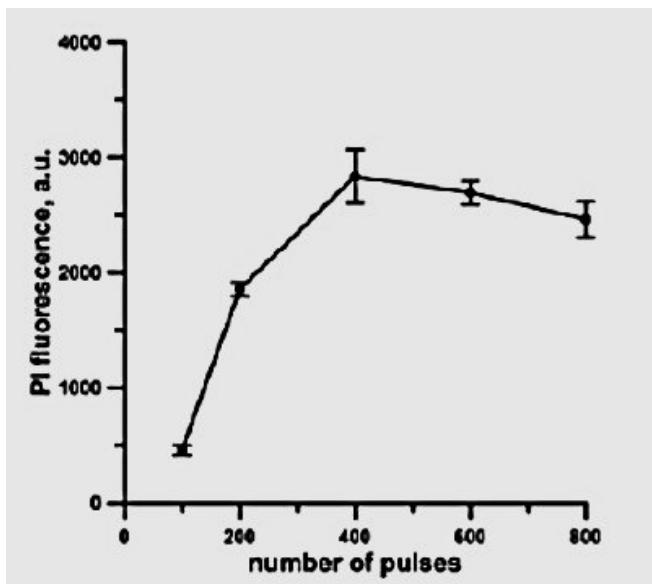
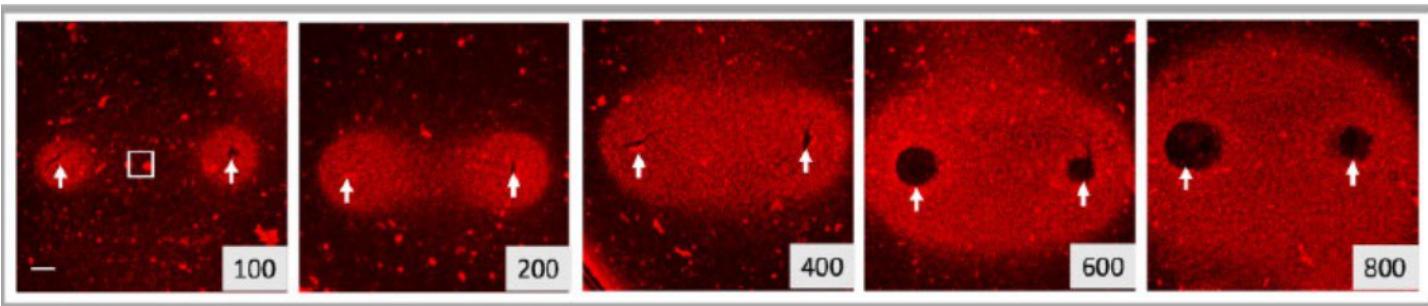
# Electro Effect Fields

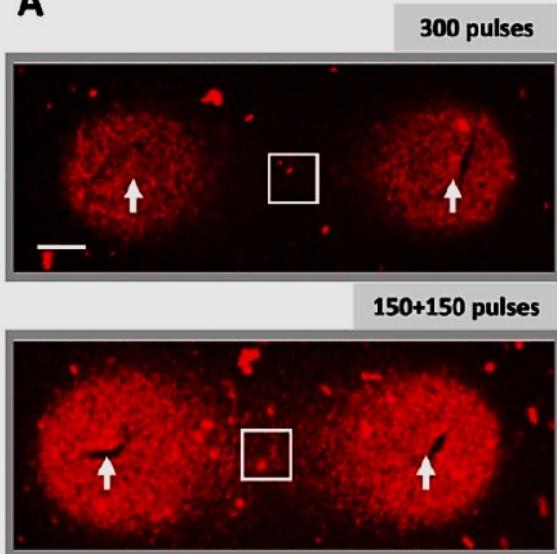
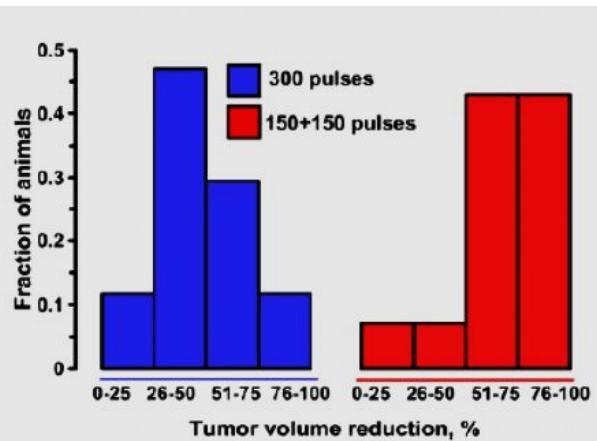
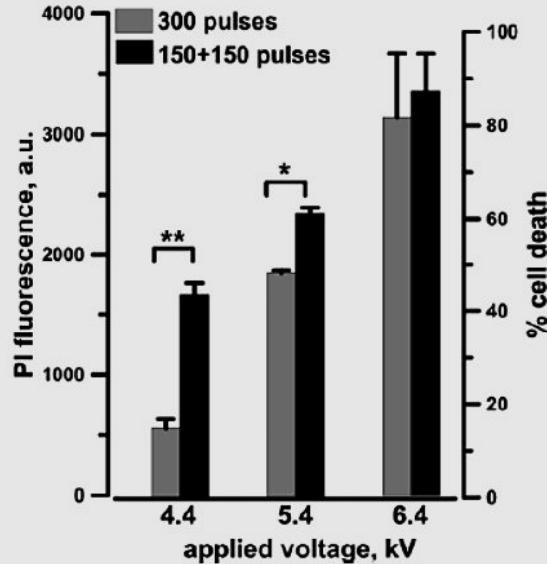
Claudia  
Maura C  
Shu Xia

**A****B****C**

96

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**A****B**

# PFA Ablation System

Multi-channel IRE generator



10-Electrode circular IRE catheter



- ⌚ Delivers trains of high-voltage, bipolar, short-duration pulses on separate channels to multi-electrode circular catheter
- ⌚ Each pulse delivered as a square wave, with positive and negative phases separated by brief delay

IRE, irreversible electroporation; PFA pulsed field ablation.

# Procedural Methods

**Subjects:** N=10 healthy porcine subjects

## Ablation parameters

	Left Atrium	Right Atrium		
Target anatomic region	RSPV and RIPV	Roof	SVC	Posterior wall
Active Electrodes, n	All 10	Up to 10	Up to 10	3–6
Ablation strategy	Circumferential	Segmental	Circumferential	Linear/Line

## Post-ablation follow up

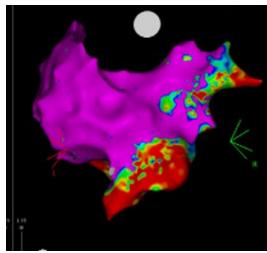
- **Subchronic:**  $7 \pm 3$  days (n=6)
- **Chronic:**  $30 \pm 3$  days (n=4)

## Assessments

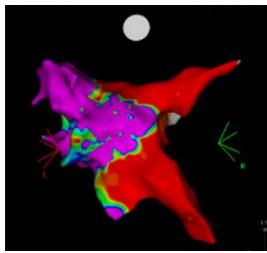
- Intracardiac measurements (ICE)
- Mapping of PV/SVC isolation (PentaRay)
- Gross necropsy and histology

ICE, intracardiac echocardiography; PV, pulmonary vein; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein; SVC, superior vena cava.

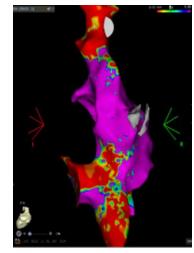
Pre-Ablation



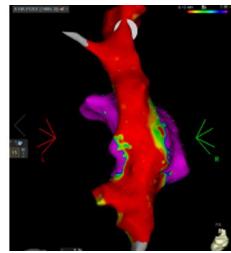
Immediately Post  
Ablation



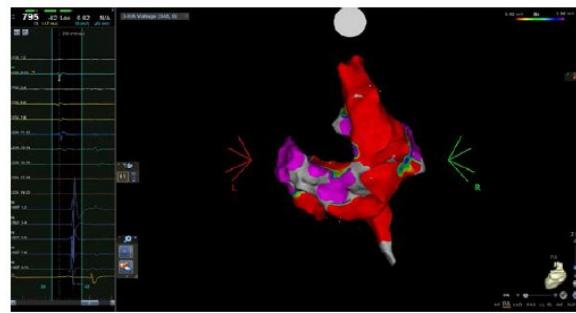
Pre-Ablation



Immediately Post  
Ablation



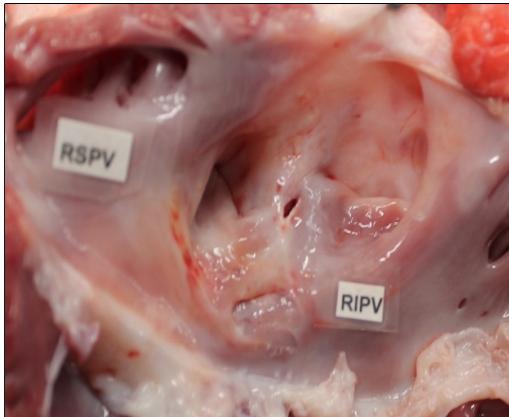
29 days Post Ablation



# Gross Pathology of Ablation Sites

Macroscopic evidence of lesion formation at each site (visible from endocardial surface)

Left atrium



Right atrium

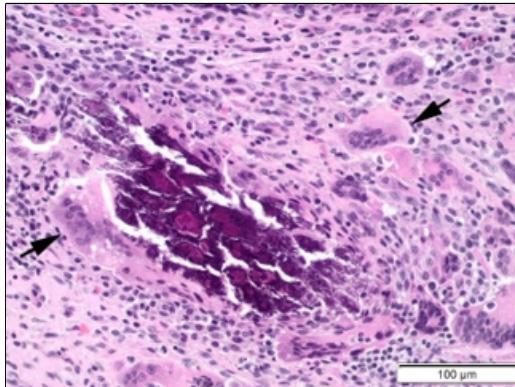


PW, posterior wall; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein; SVC, superior vena cava.

# Subchronic Histology (7±3 Days): RSPV

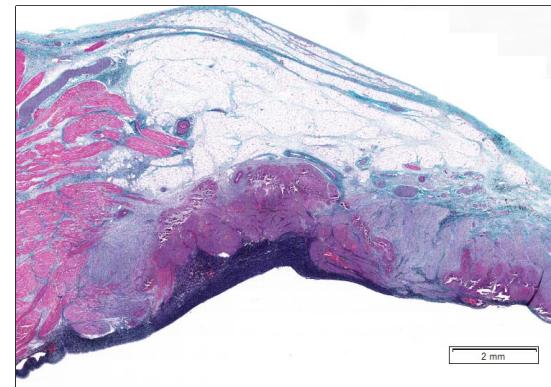
Clear zones of ablation observed, with preservation of tissue architecture  
Some rare occurrences of loss of myocardial fibers and fibrovascular healing:

Mineralization



Inflammatory cell infiltrates including macrophages, lymphocytes and multinucleated giant cells (arrows)

Denaturation

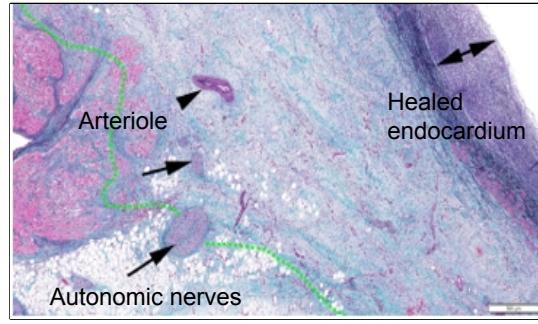


Rare occurrence of slight multifocal denaturation of endocardial elastin and collagen (*stained dark gray/black*)

RSPV, right superior pulmonary vein.

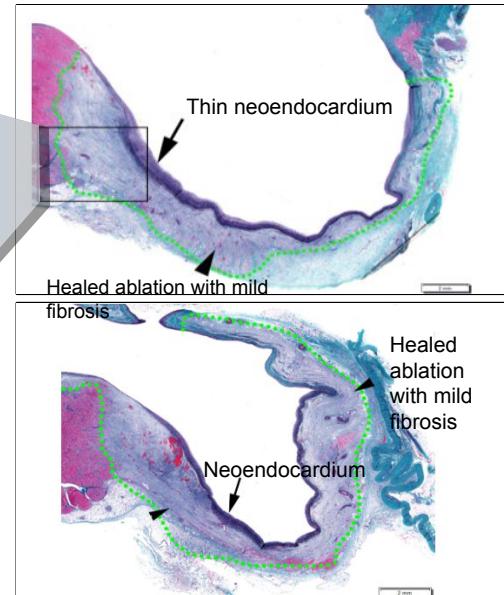
## Chronic Histology (30±3 days): Posterior Wall

..... Demarcation of healed ablated area



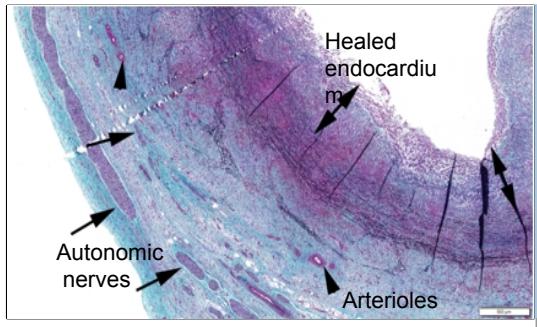
Clearly demarcated healed ablated areas, similar to observations in subchronic tissues

Mineralization/inflammation rarely observed  
(mild in nature)



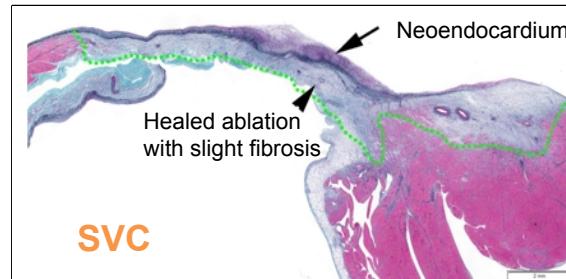
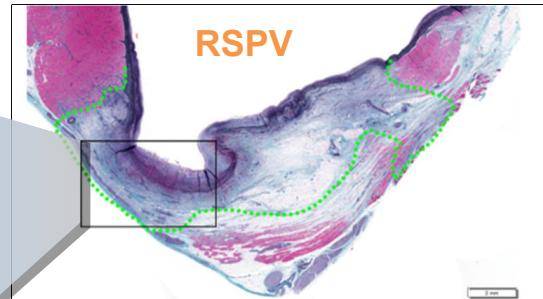
## Chronic Histology (30±3 days): RSPV and SVC

..... Demarcation of healed ablated area



Healed ablated area showed no adverse changes

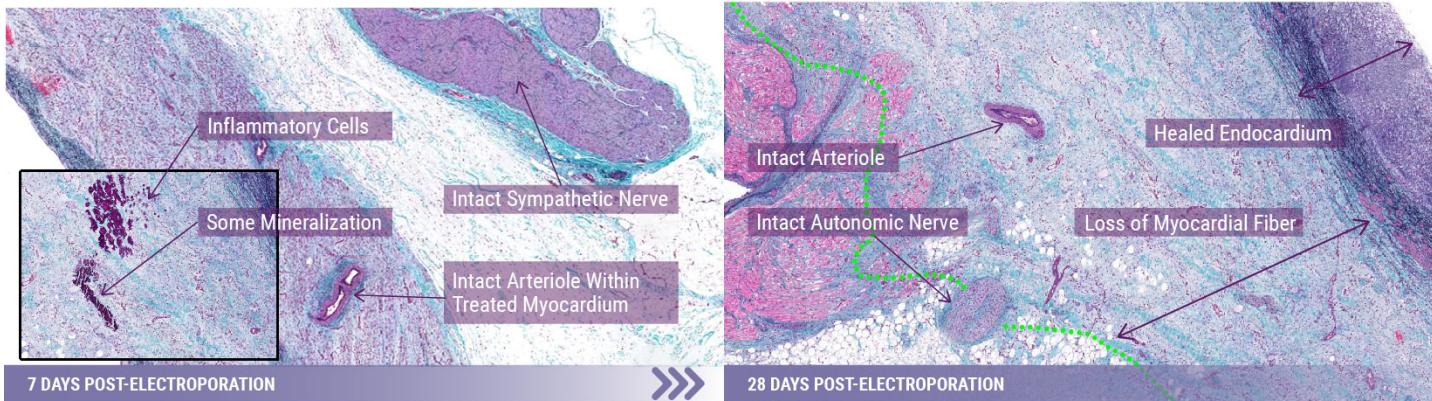
Autonomic nerves and arterioles intact



SVC, superior vena cava; RSPV, right superior pulmonary vein.

# PROGRESSIVE MATURATION OF PFA TREATED ATRIAL CARDIAC LESIONS

The typical histological hallmarks of cell electroporation can be visualized at 7 days with some transient tissue responses that fully heal at 30 days

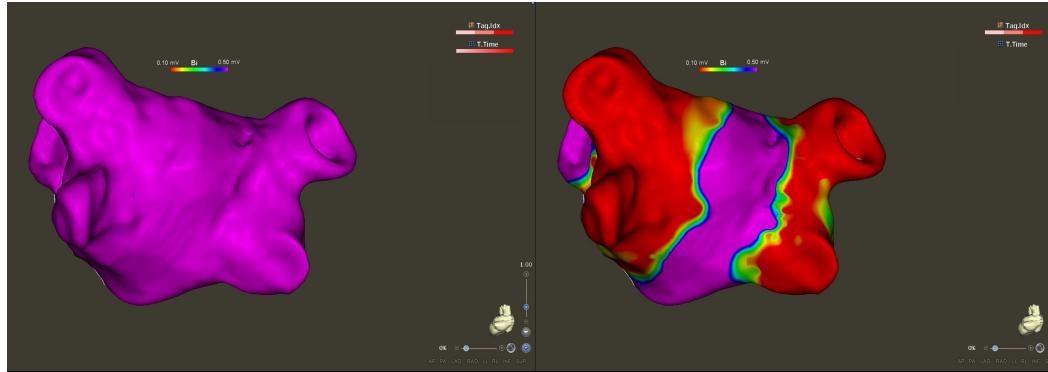


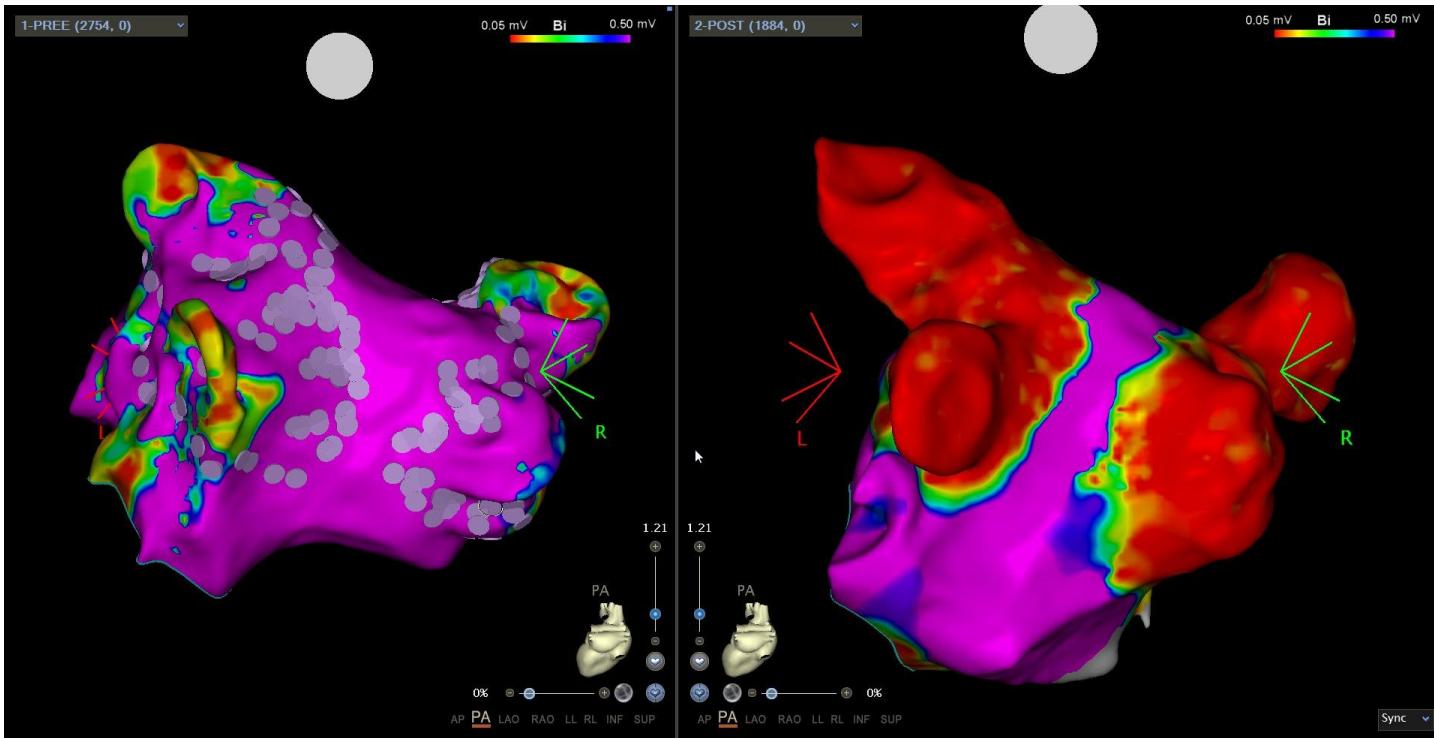
- Loss of myocardial fiber
- Well demarcated lesions
- Intact arterioles and autonomic nerves
- Not mature neoendocardium
- Inflammatory cells
- Slight thermal denaturation
- Rare swollen axons

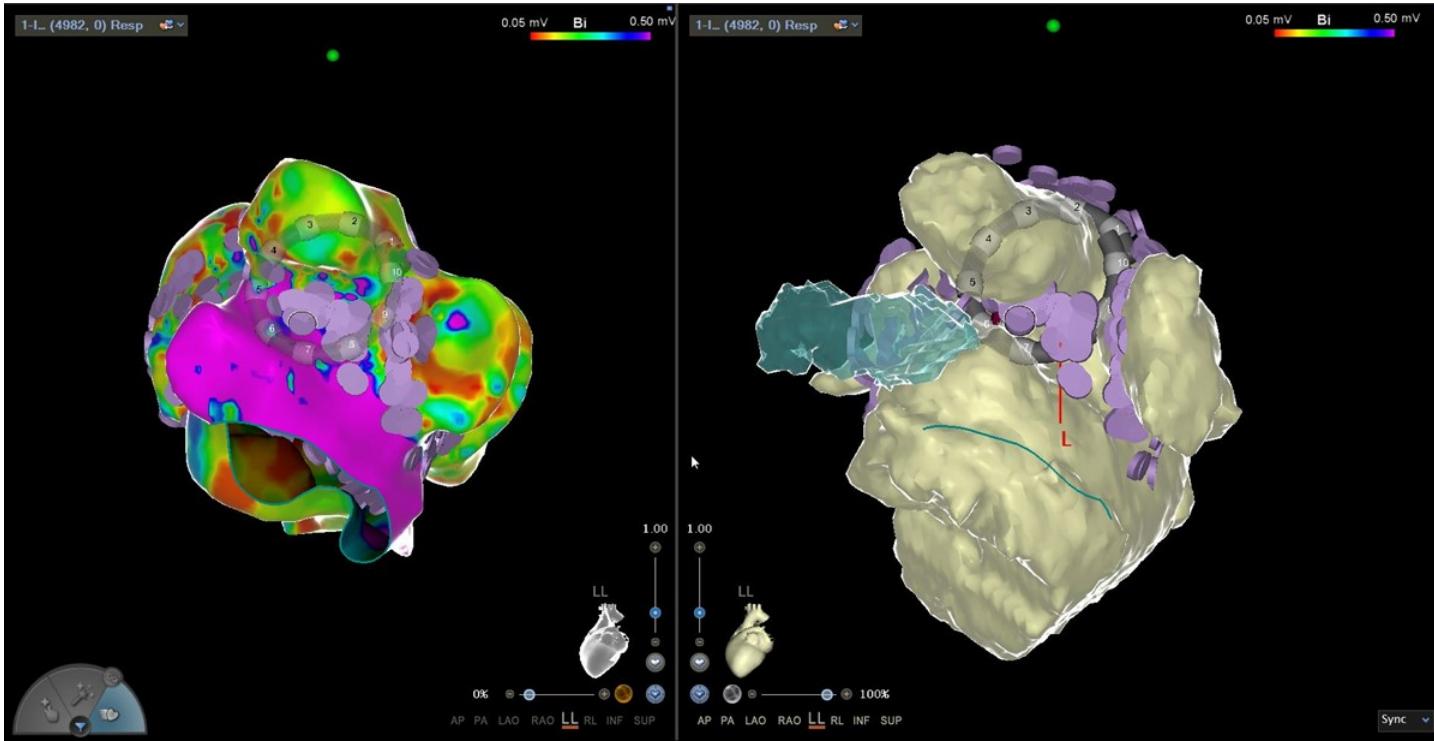
- Loss of myocardial fiber
- Well demarcated lesions
- Intact arterioles and autonomic nerves
- Resolved inflammation, mineralization, etc.
- Mature healed endocardium

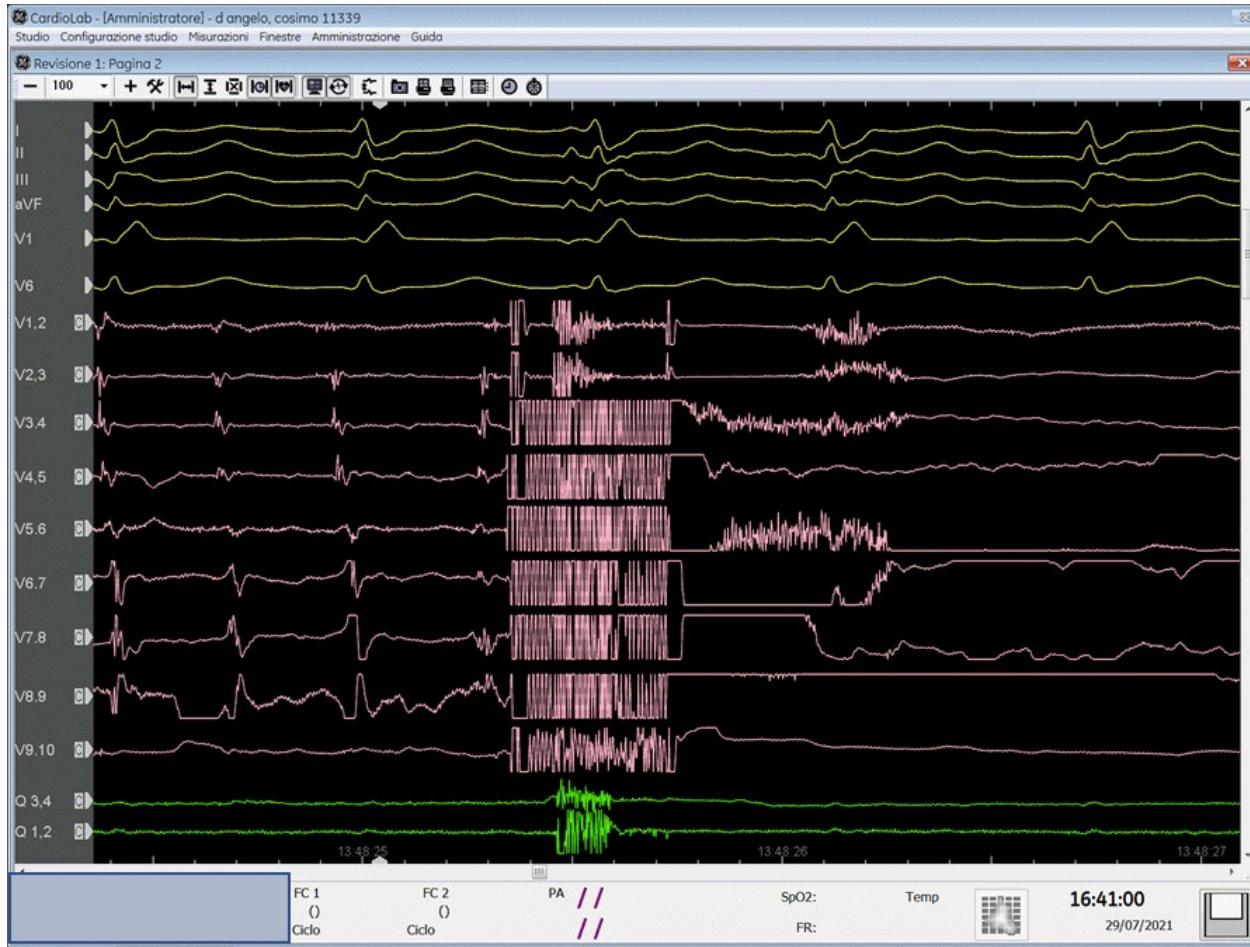
## The insPIRE Study

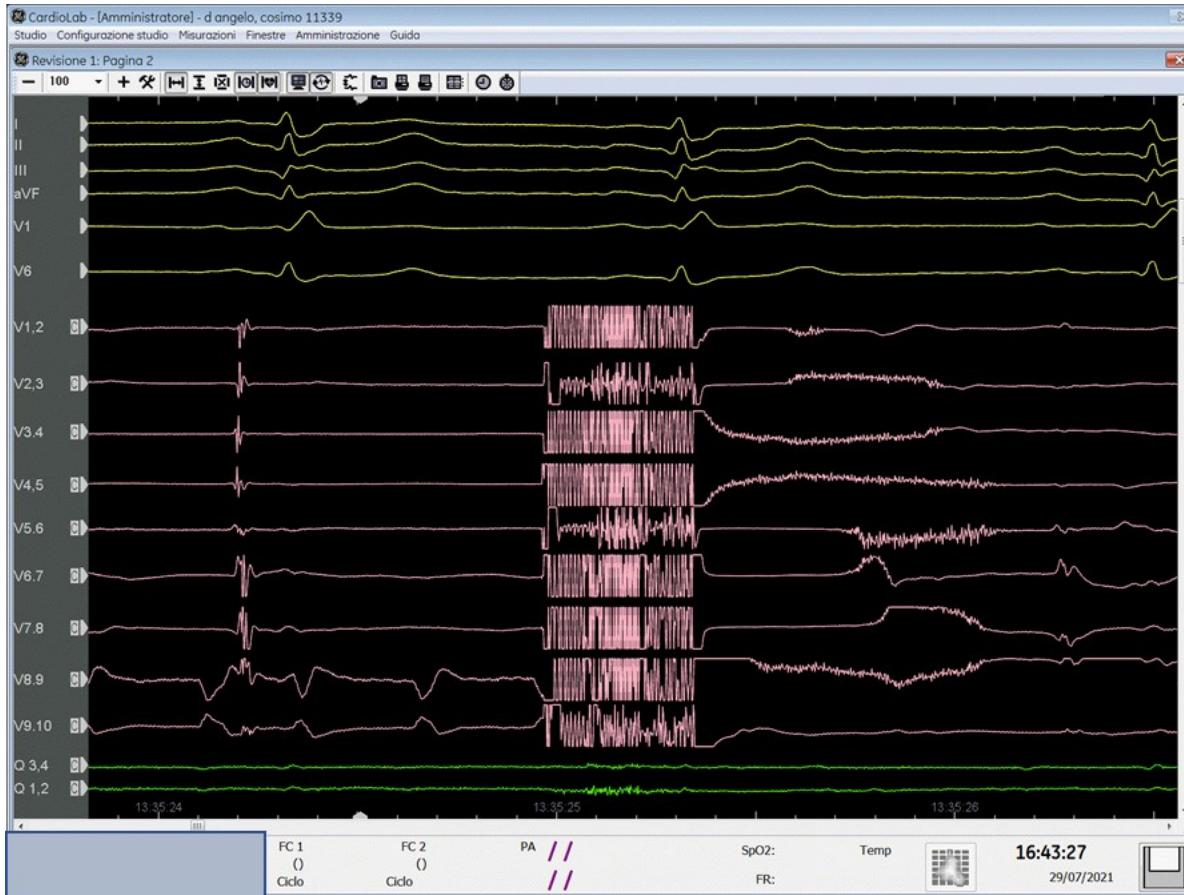
A Study for Treatment of Paroxysmal Atrial Fibrillation (PAF) by  
Pulsed Field Ablation (PFA) System with Irreversible Electroporation











# Pulsed Field Ablation of Paroxysmal Atrial Fibrillation

## 1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II

Vivek Y. Reddy, MD,<sup>a,b</sup> Srinivas R. Dukkipati, MD,<sup>b</sup> Petr Neuzil, MD, PhD,<sup>a</sup> Ante Anic, MD,<sup>c</sup> Jan Petru, MD,<sup>a</sup>

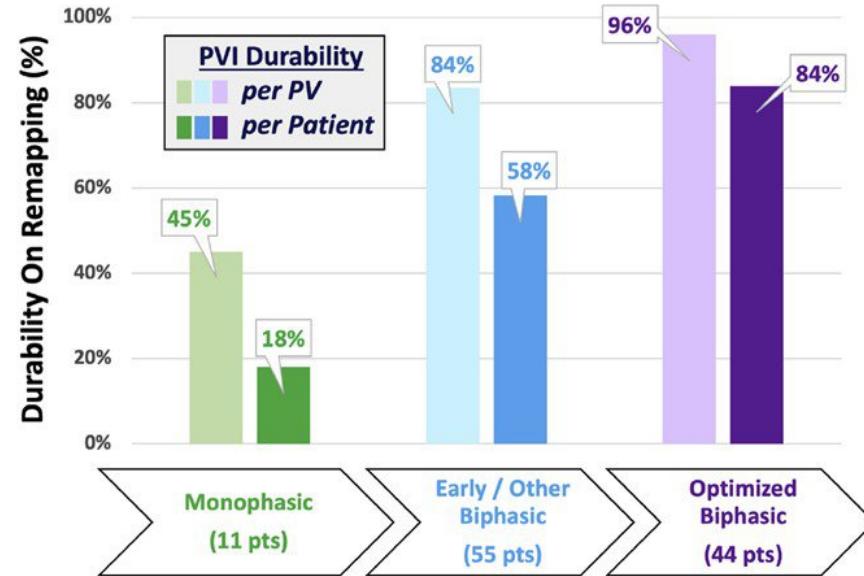


JACC 2021

**TABLE 2** Procedural Characteristics

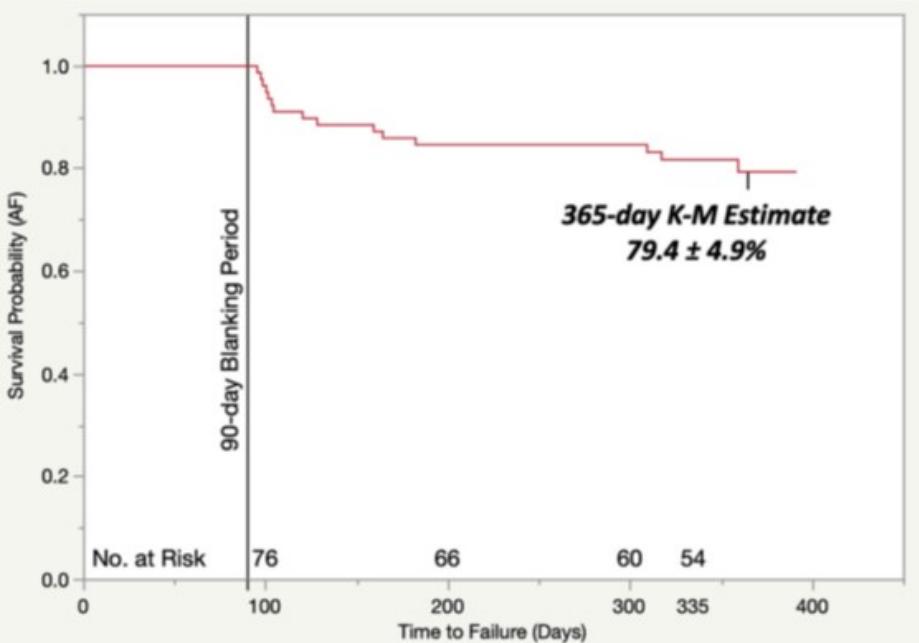
	Total Cohort (N = 121)*	Monophasic PF Waveform (n = 15)	Biphasic PF Waveforms	
			Early/Other (n = 57)	Optimized (n = 49)
PVI success	475/475 (100)	57/57 (100)	223/223 (100)	195/195 (100)
Number of lesions/PV				
Combined PVs	7.2 ± 2.2	3.3 ± 0.5	6.9 ± 1.6	8.7 ± 1.5
LCPV	12.9 ± 6.1	6.3 ± 0.6	10.2 ± 2.5	18.5 ± 4.7
LSPV	7.3 ± 2.4	3.0 ± 0.0	7.1 ± 2.0	8.6 ± 1.7
LIPV	6.9 ± 2.2	3.0 ± 0.0	6.5 ± 1.5	8.5 ± 1.6
RSPV	7.2 ± 2.4	3.4 ± 1.1	7.1 ± 2.1	8.5 ± 1.6
RIPV	6.9 ± 2.5	3.0 ± 0.0	6.5 ± 2.1	8.6 ± 1.6
Procedure time, min	96.2 ± 30.3	84.1 ± 13.1	98.4 ± 34.0	97.2 ± 29.1
Mapping time, min	19.3 ± 12.0	23.6 ± 10.0	17.9 ± 11.0	19.0 ± 13.5
Catheter dwell time, min*	34.4 ± 15.8	27.3 ± 4.1	36.8 ± 19.6	33.7 ± 12.2
Fluoroscopy time, min	13.7 ± 7.8	12.2 ± 4.0	14.4 ± 8.8	13.4 ± 7.6
CTI block success	4/4 (100)	—	—	4/4 (100)
Catheter dwell time, min†	8.5 ± 7.7	—	—	8.5 ± 7.7

**FIGURE 4** Durability of PV Isolation With Pulsed Field Ablation

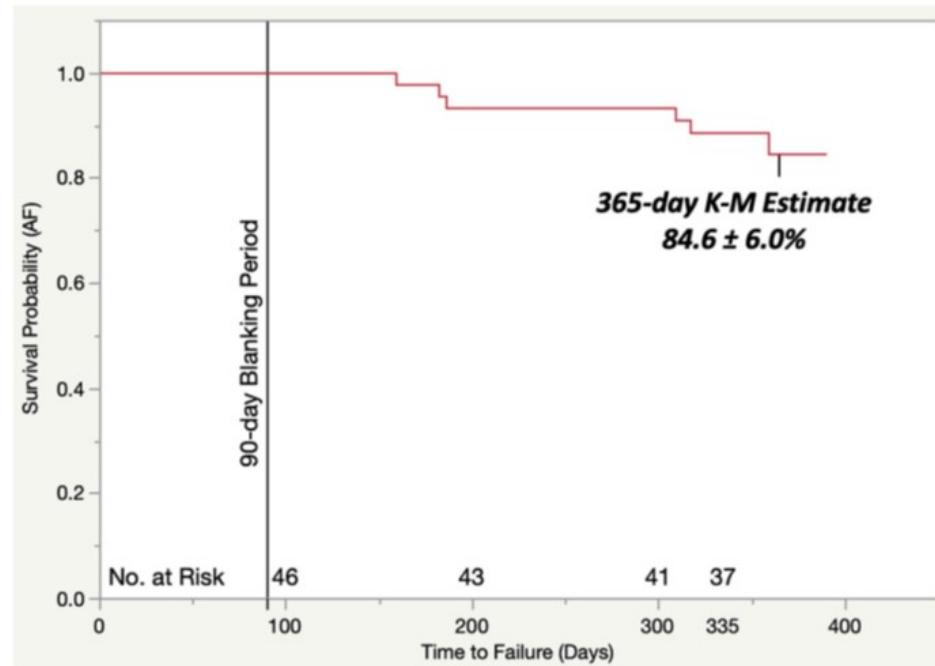


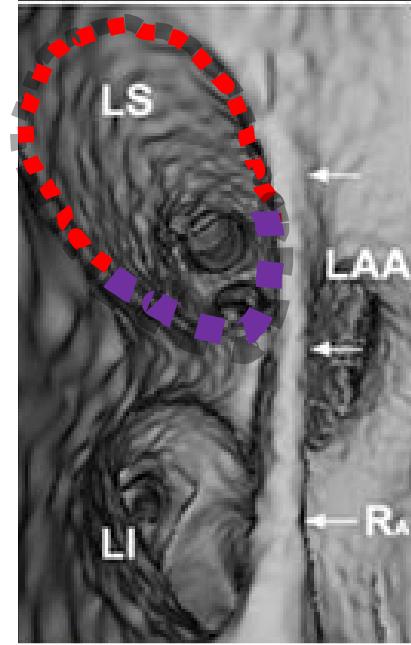
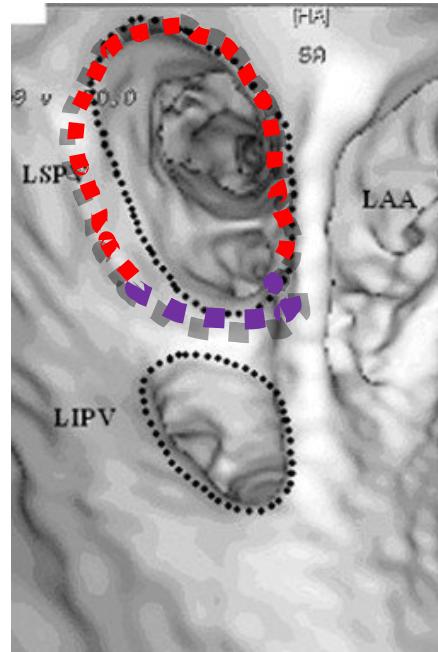
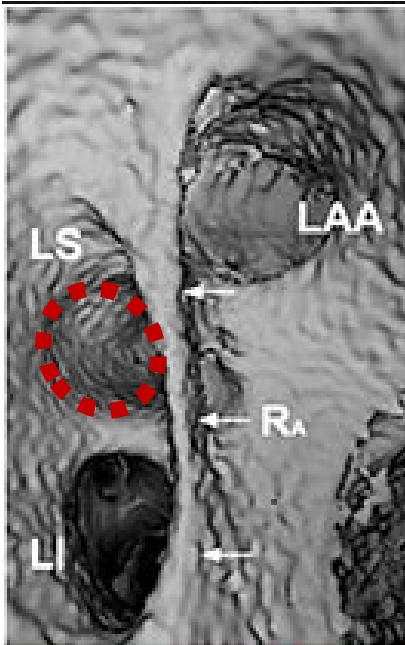
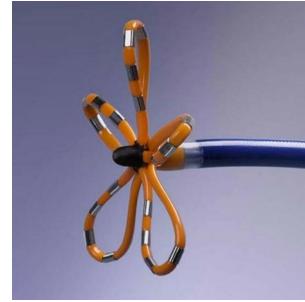
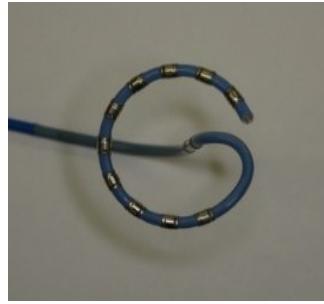
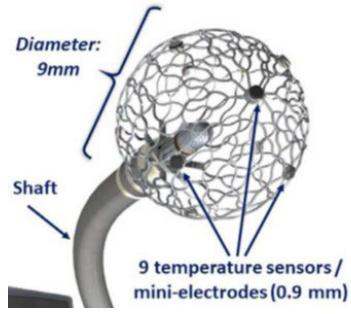
**A**

## Freedom from AF: Single Procedure

**C**

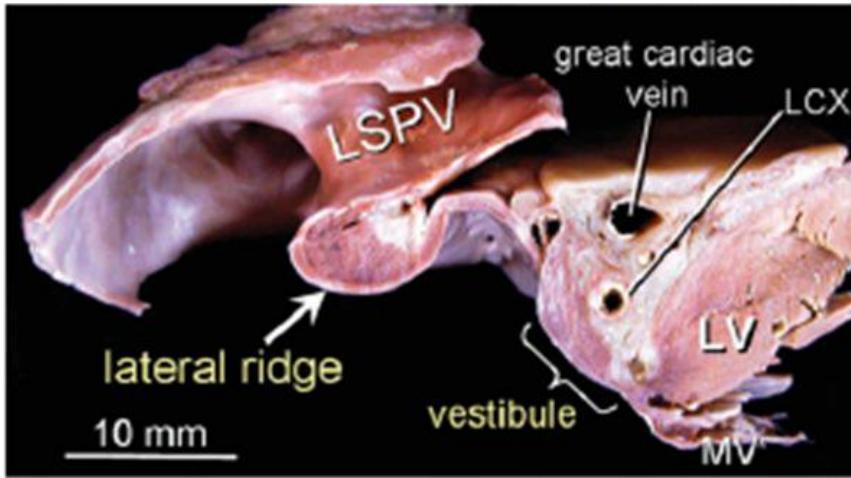
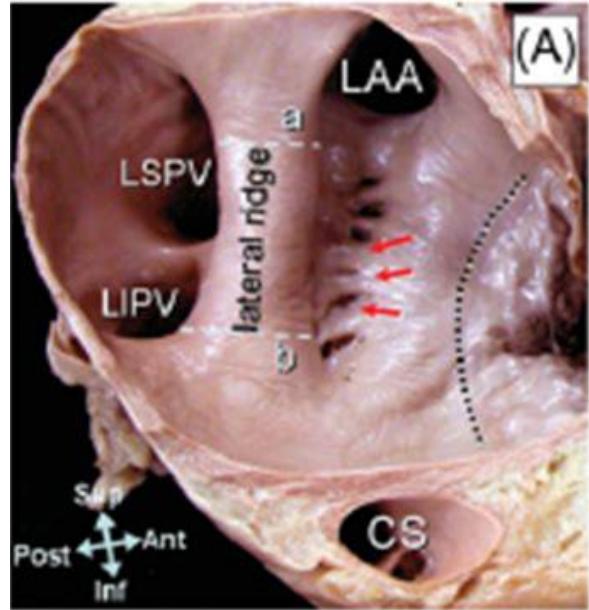
## Freedom from AF: PFA-OW Cohort





# The architecture of the left lateral atrial wall: a particular anatomic region with implications for ablation of atrial fibrillation

José Angel Cabrera<sup>1</sup>, Siew Yen Ho<sup>2\*</sup>, Vicente Climent<sup>3</sup>, and  
Damián Sánchez-Quintana<sup>3</sup>



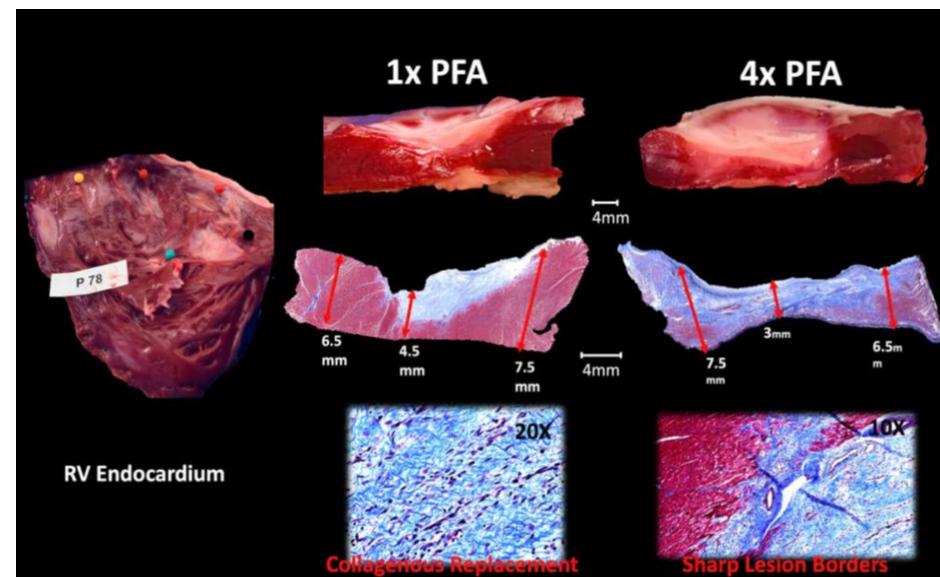
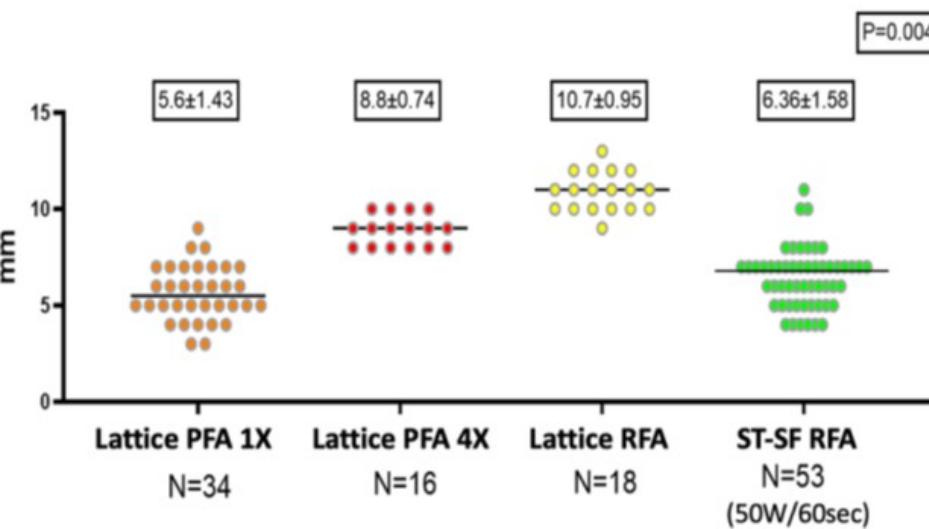
## ORIGINAL ARTICLE

# Pulsed-Field Ablation in Ventricular Myocardium Using a Focal Catheter

## The Impact of Application Repetition on Lesion Dimensions

Hagai D. Yavin<sup>1</sup>, MD; Koji Higuchi<sup>2</sup>, MD; Jakub Sroubek<sup>1</sup>, MD, PhD; Arwa Younis, MD; Israel Zilberman, DVM;  
Elad Anter<sup>1</sup>, MD

### Ventricular Lesion Depth with RFA and PFA



# CONCLUSIONI

## LUCI

Elevato profilo di sicurezza per organi vicini

Rapidità

Possibilità di single shot con basso rischio

Notevole margine di miglioramento

## OMBRE

Efficacia a medio e lungo termine

Follow up a lungo termine di tessuto vascolarizzato con ampia necrosi

Difficoltà nell'individuare aree non correttamente trattate

Difficoltà del device single shot in anomalie particolari

Insorgenza di aritmie diverse da FA

Anestesia generale o sedazione