



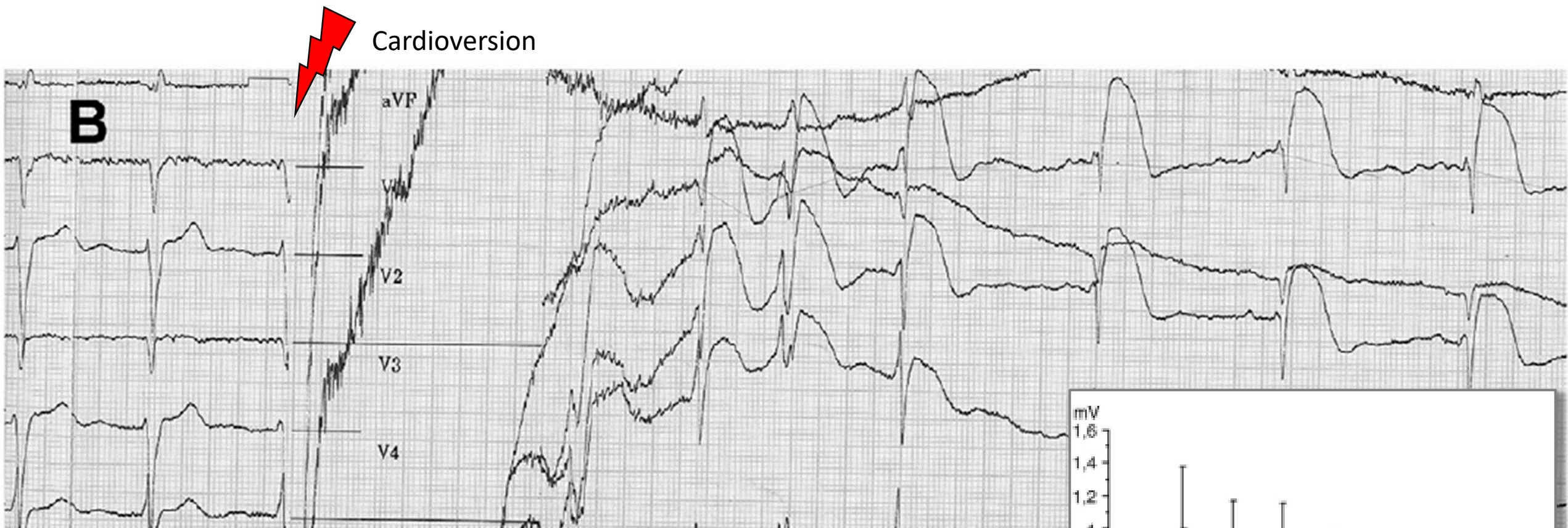
Electroporation de la fibrillation auriculaire: vers une ablation parfaite

Gabriel LAȚCU

Chef de Service Adjoint
Centre Hospitalier Princesse Grace
Monaco
EHRA Training Center

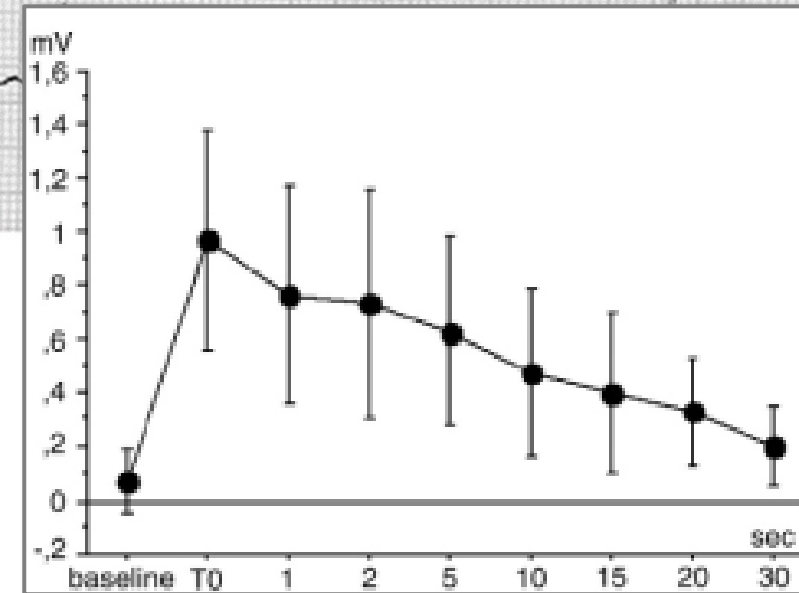


Adj Asst Professor of Medicine
Perelman School of Medicine
University of Pennsylvania



46% of patients after external DC shocks

“This sustained depolarization was suspected by Jones et al. to be caused by alterations in the electrical properties of the cellular membrane secondary to microbreaks, a phenomenon called “electroporation” which can last from a few seconds to minutes according to the model studied.”

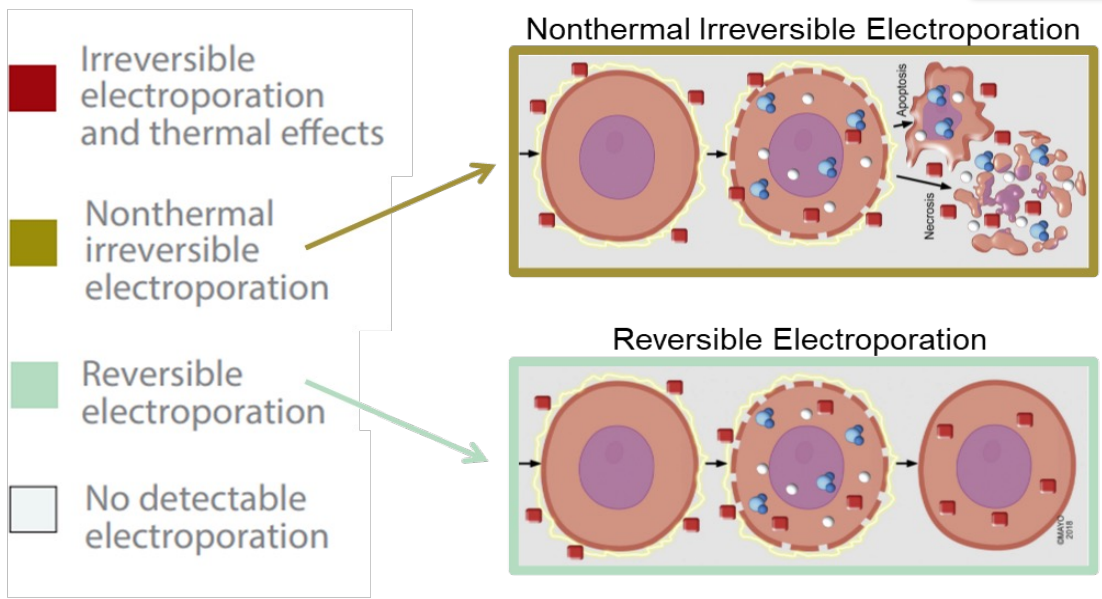
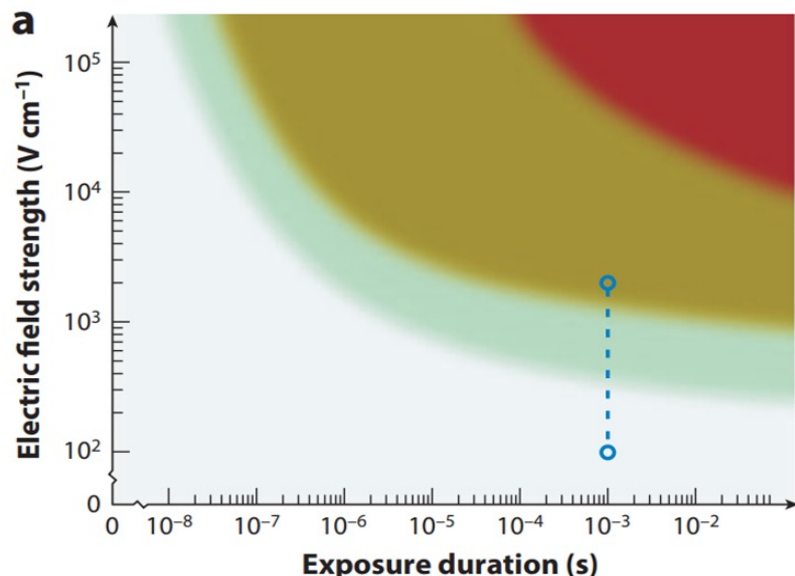
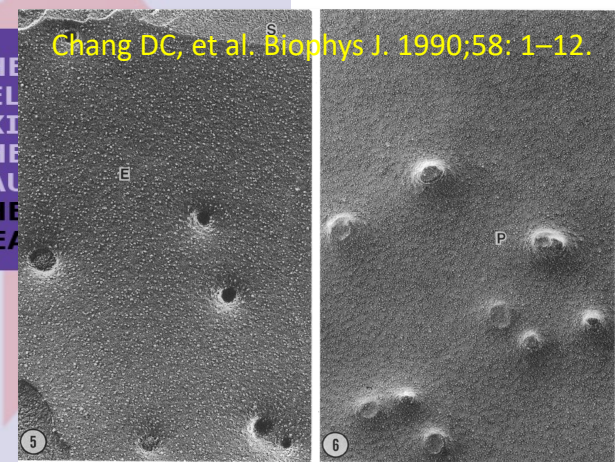
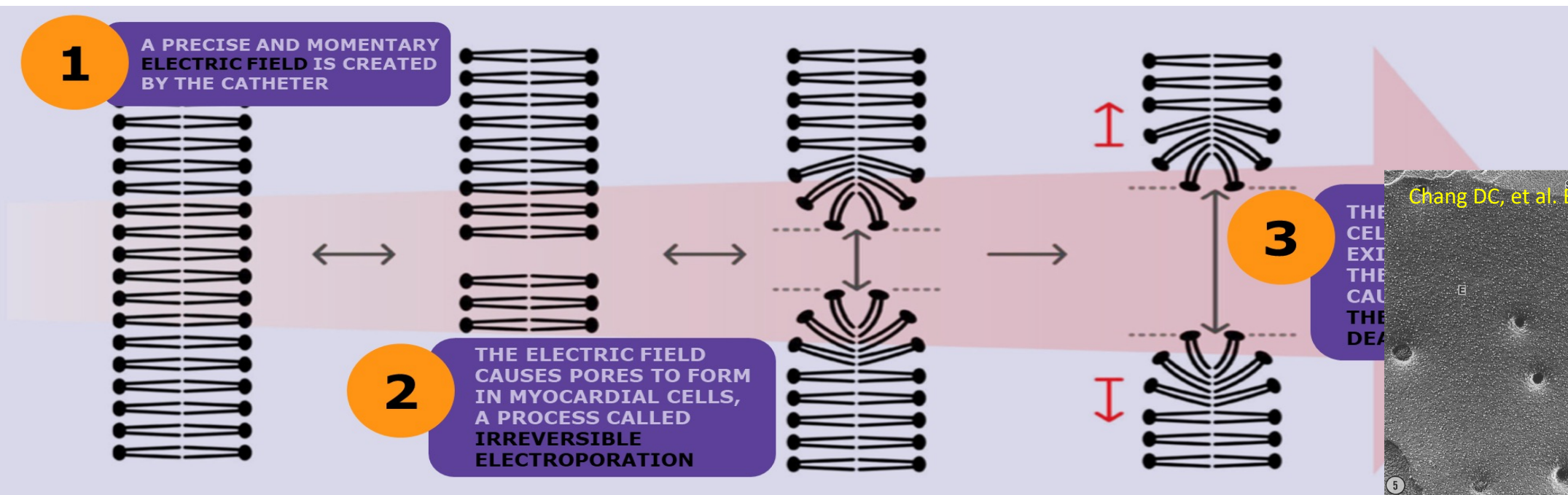




Electroporation (Pulsed Field Ablation - PFA): physiopathologie de la lesion

Kotnik et al. *IEEE Electrical Insulation Magazine* 28.5 (2012): 14-23.

Chang DC, et al. *Biophys J.* 1990;58: 1-12.



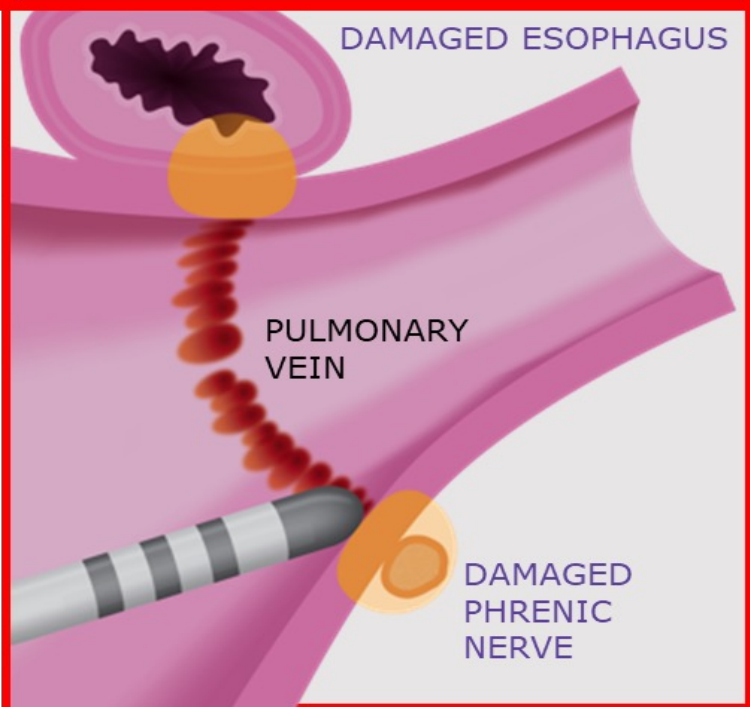
Yarmush et al. *Annual review of biomedical engineering* 16 (2014): 295-320;

Maor, et al. *Heart Rhythm* 16.7 (2019): 1112-1120.

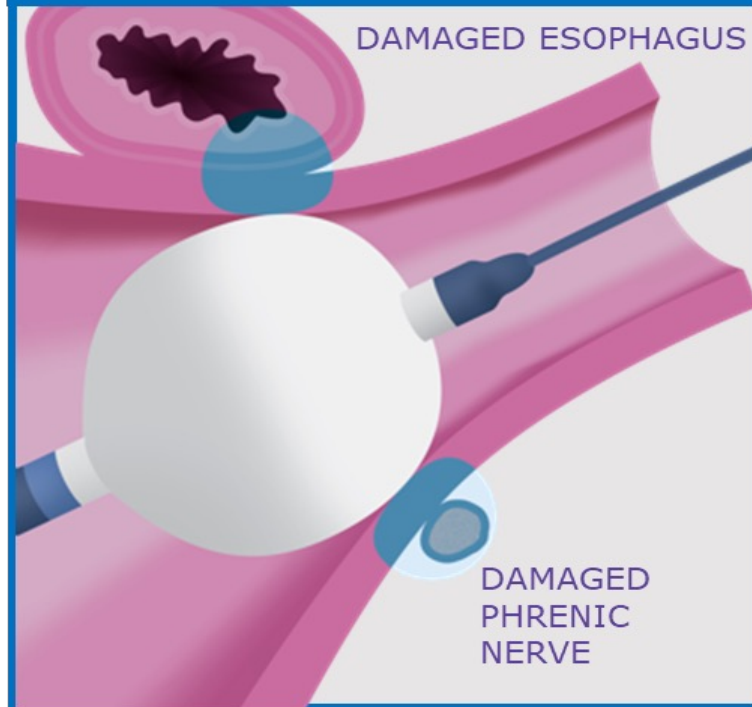


Electroporation (*Pulsed Field Ablation - PFA*) vs energies thermiques

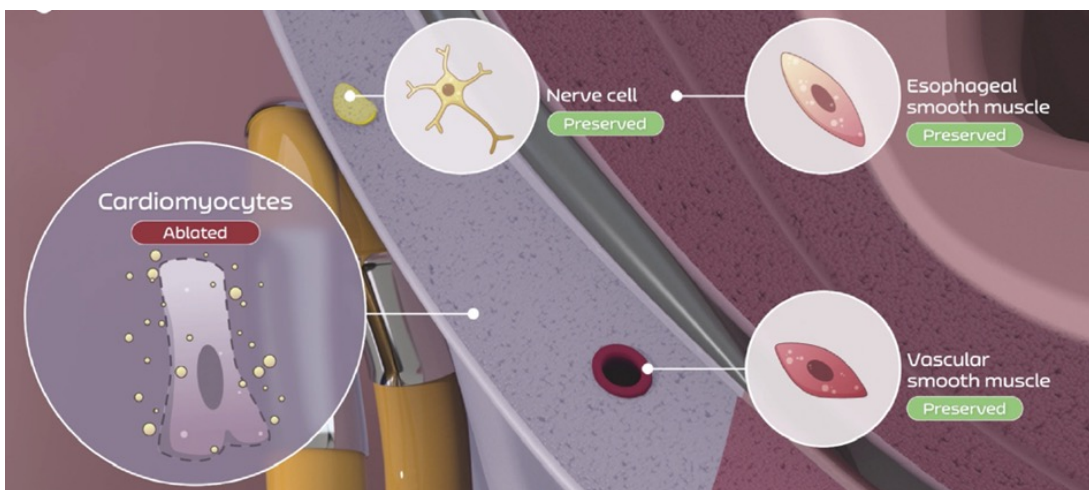
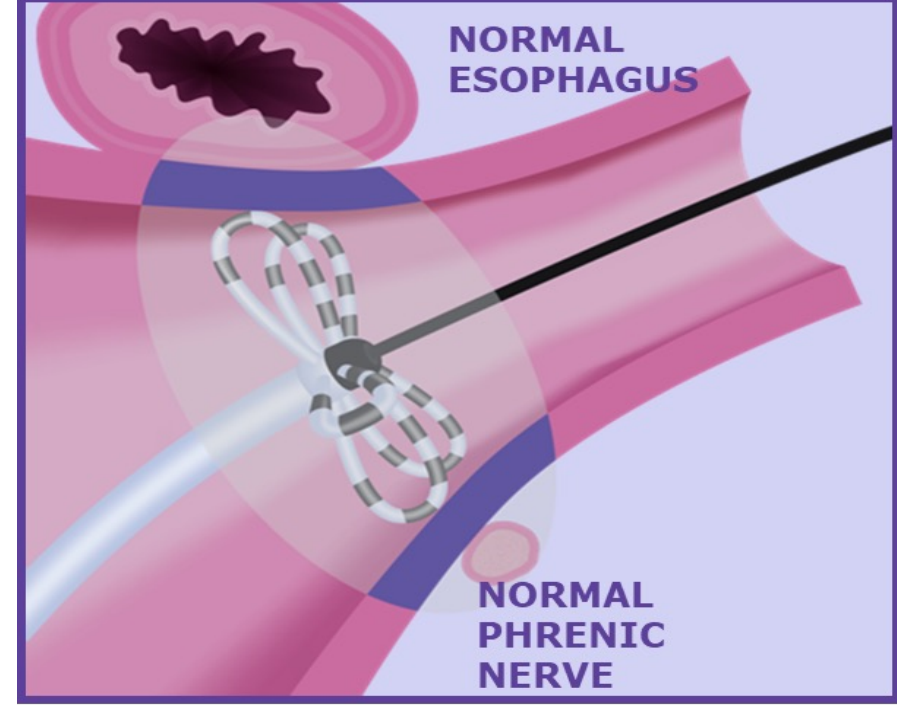
RADIOFREQUENCY ABLATION



CRYOBALLOON ABLATION



PULSED FIELD ABLATION



L'électroporation optimisée est sélective des cardiomyocytes.

Reddy VY et al. *J Am Coll Cardiol.* 2019;74(3):315-26.
Reddy et al. *JACC: Clinical Electrophysiology* 7.5 (2021): 614-627.



FARADRIVE Steerable Sheath



FARAWAVE PFA Catheter

FLOWER

- Antral positioning
- Radially widest lesion

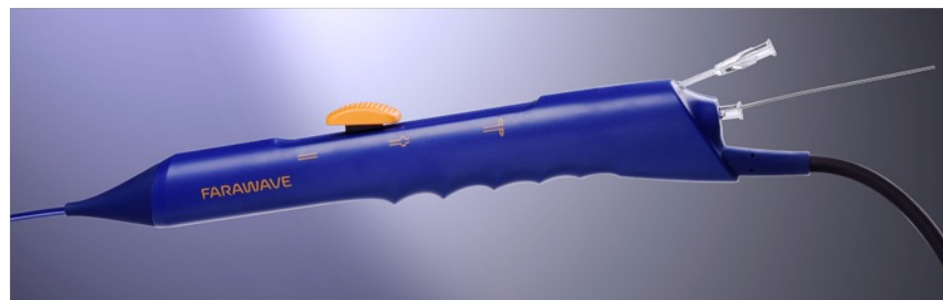


BASKET

- Ostial positioning
- Self-centering capability



5 splines, each with 4 active electrodes
3rd electrode available for pacing and recording EGMs



FARASTAR PFA Generator

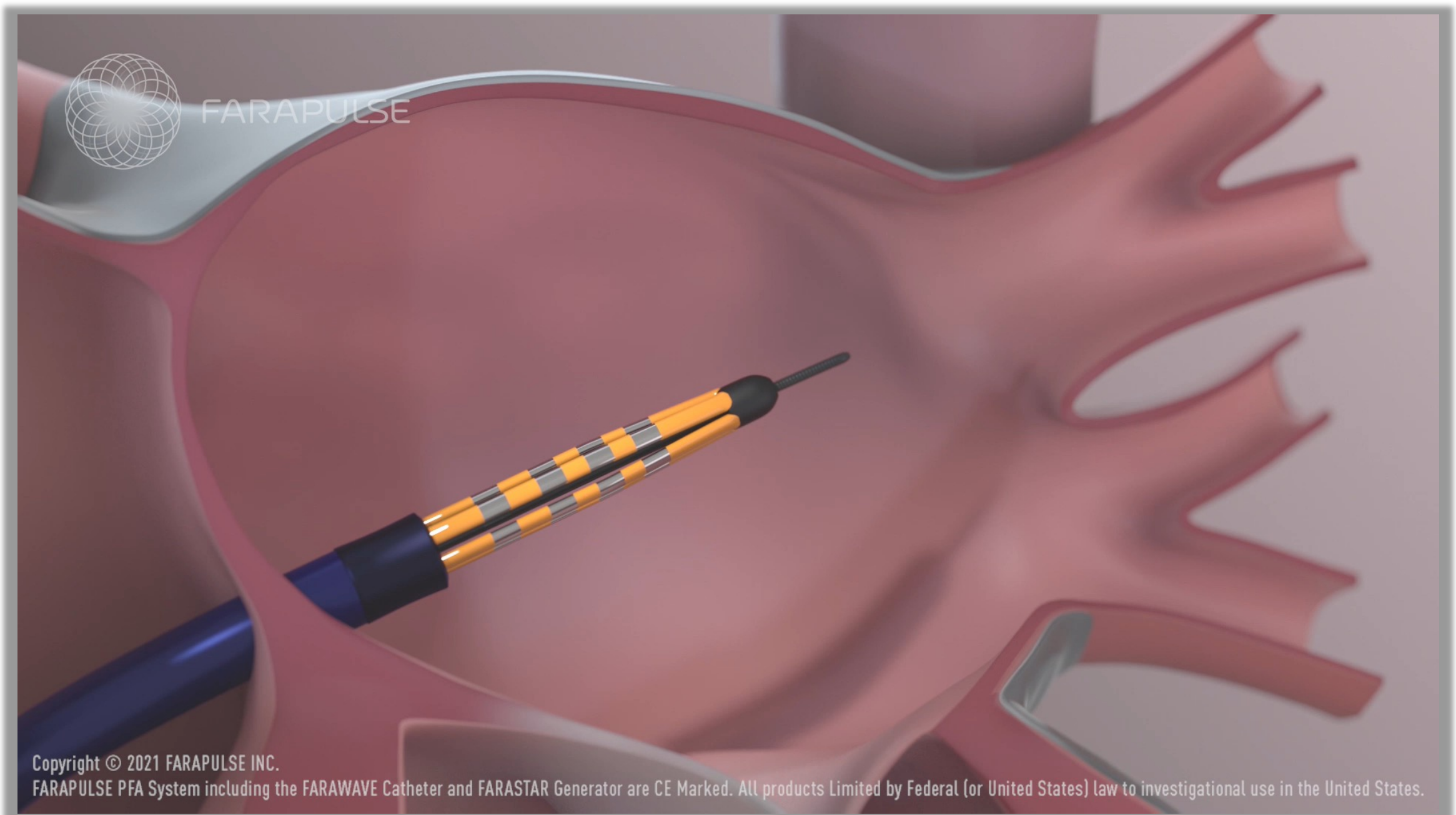


FARAFLEX *Large-area Focal*



FARAPOINT *Precision Focal*

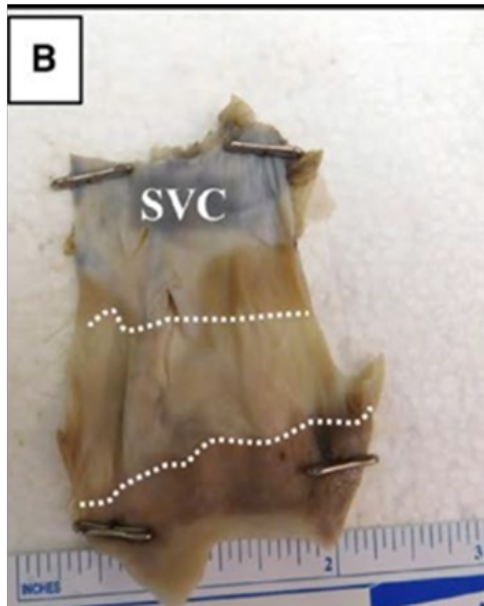




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FARAPULSE PFA System including the FARAWAVE Catheter and FARASTAR Generator are CE Marked. All products Limited by Federal (or United States) law to investigational use in the United States.



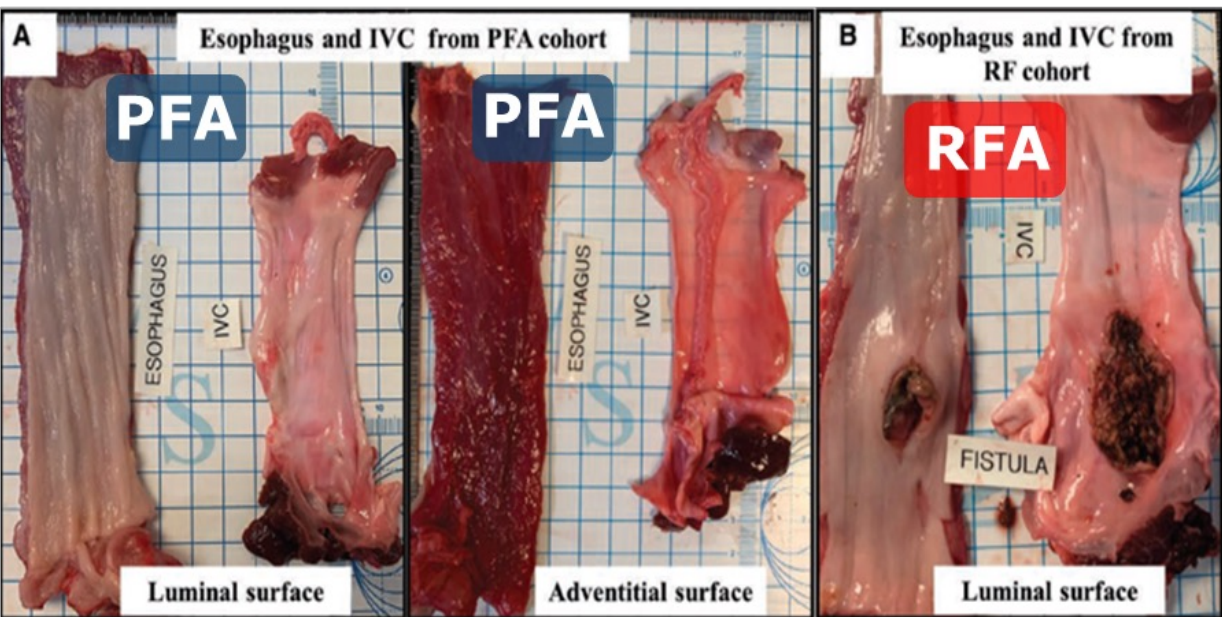
LESION DURABILITY¹



Biphasic PFA demonstrated:

- Favorable safety with a myocardial-specific ablation
- **Durable lesions at 63 ± 3 days: 12/12 PVs & 6/6 SVCs**

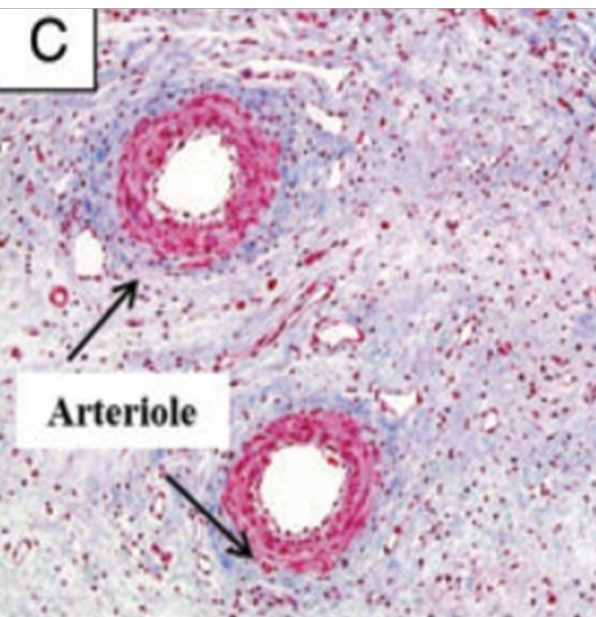
ESOPHAGEAL SAFETY²



Comparison of PFA and RFA effects on the esophagus at 25 days post-procedure

PFA	RFA
<ul style="list-style-type: none">• No esophageal lesions (0/6)• No histopathological changes observed	<ul style="list-style-type: none">• Esophageal injury occurred in all animals (4/4)• 1.5 mucosal lesions / animal

NERVE & VASCULAR SAFETY³



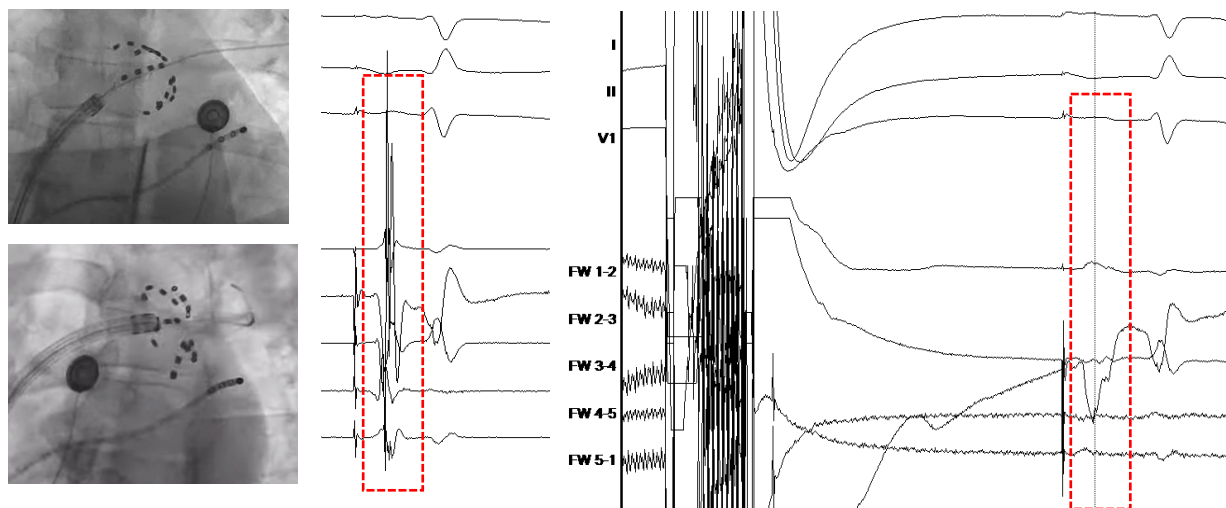
After focal, ventricular PFA, histology revealed:

- **Homogeneous fibrosis &**
- **Evidence of spared nerves and vessels**

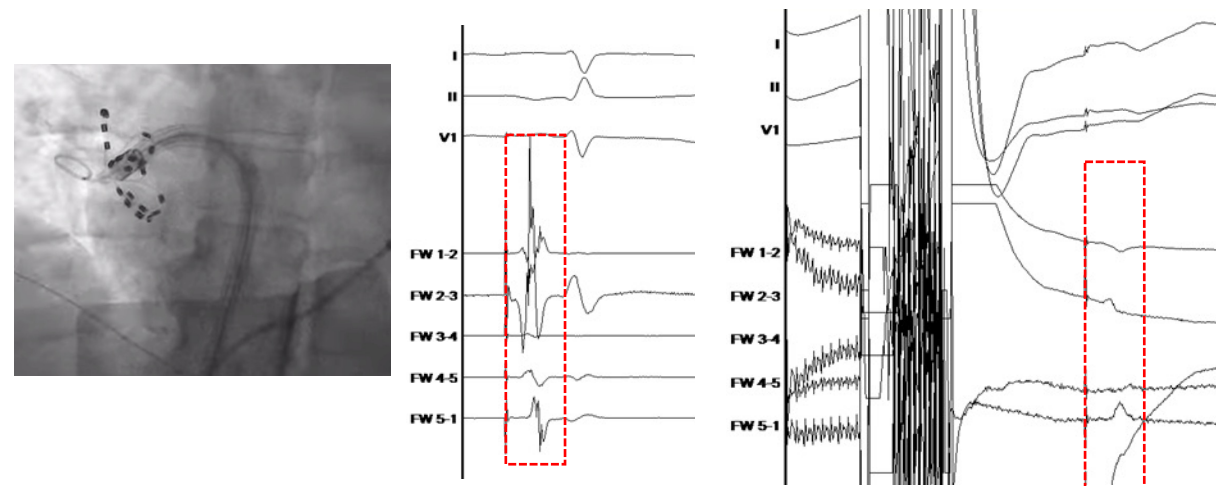
Koruth et al. *Circulation AE*. 2019; 12:e007781
Koruth et al. *Circulation AE*. 2020; 13:e008303
Koruth et al. *EP Europace* 22.3 (2020): 434-439.



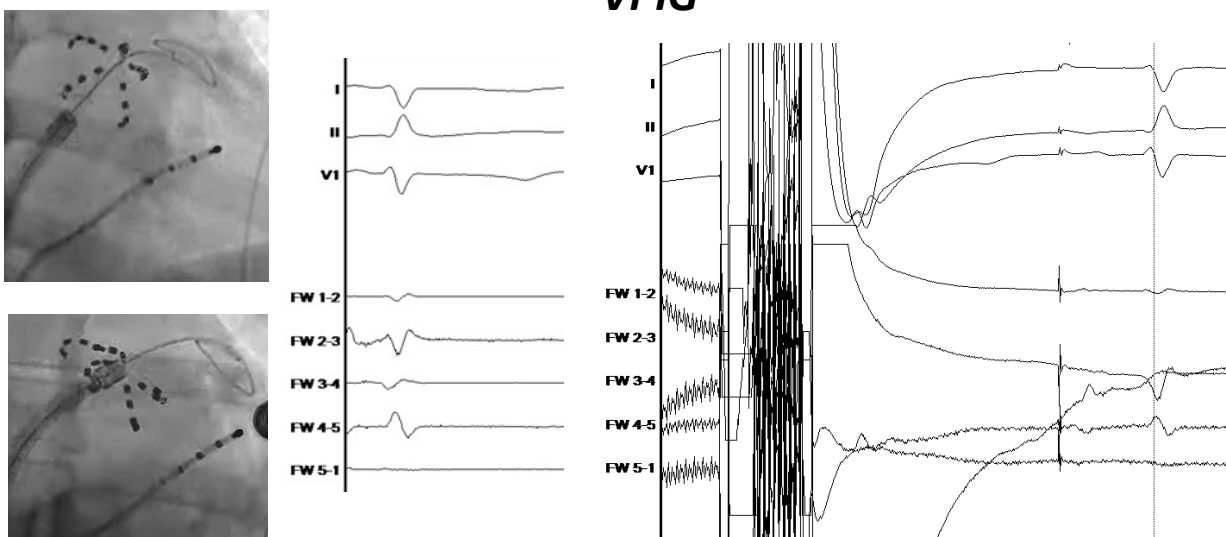
VPSG



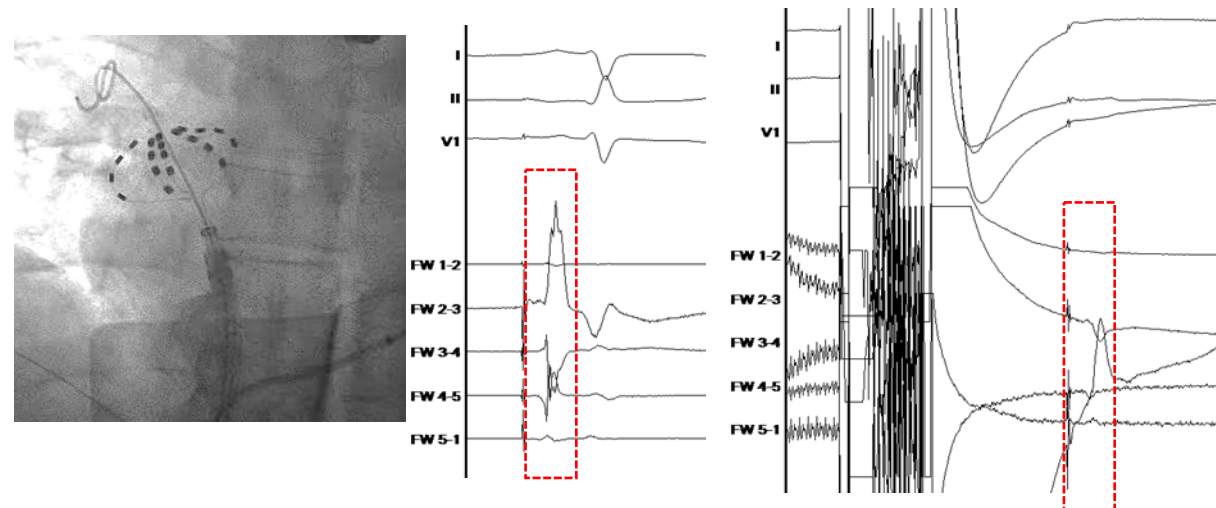
VPID

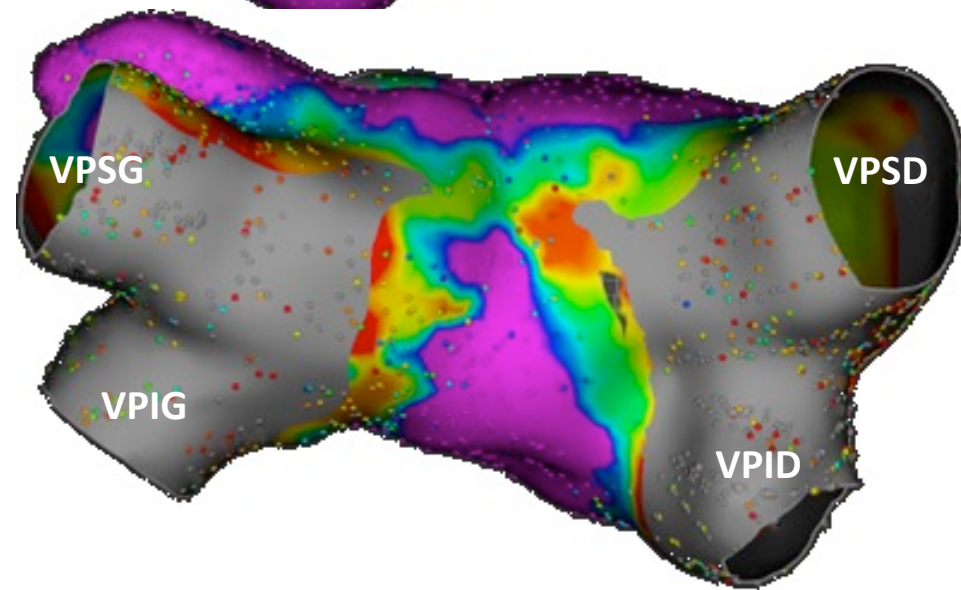
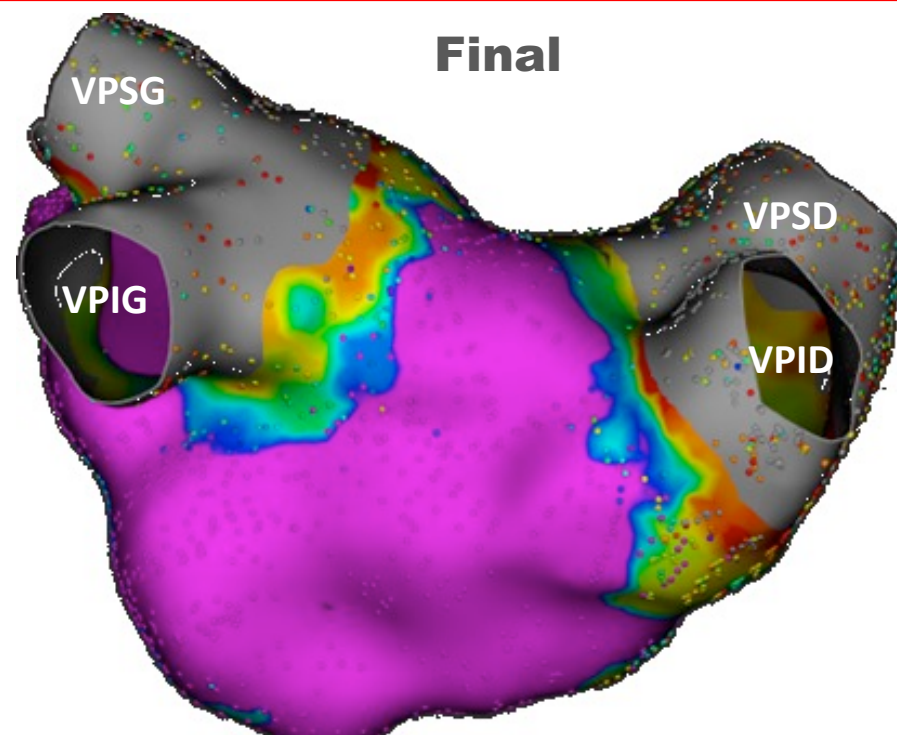
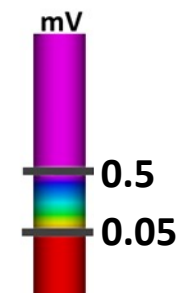
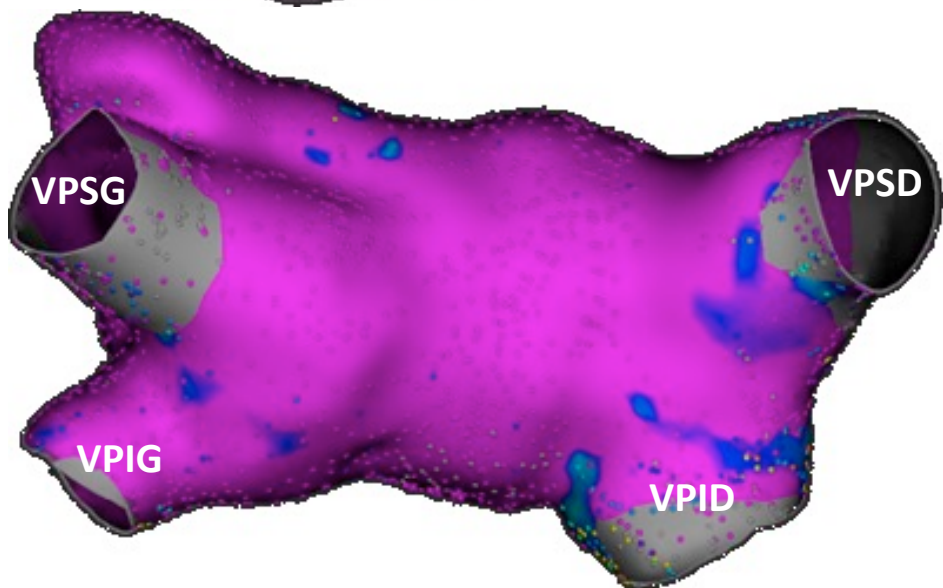
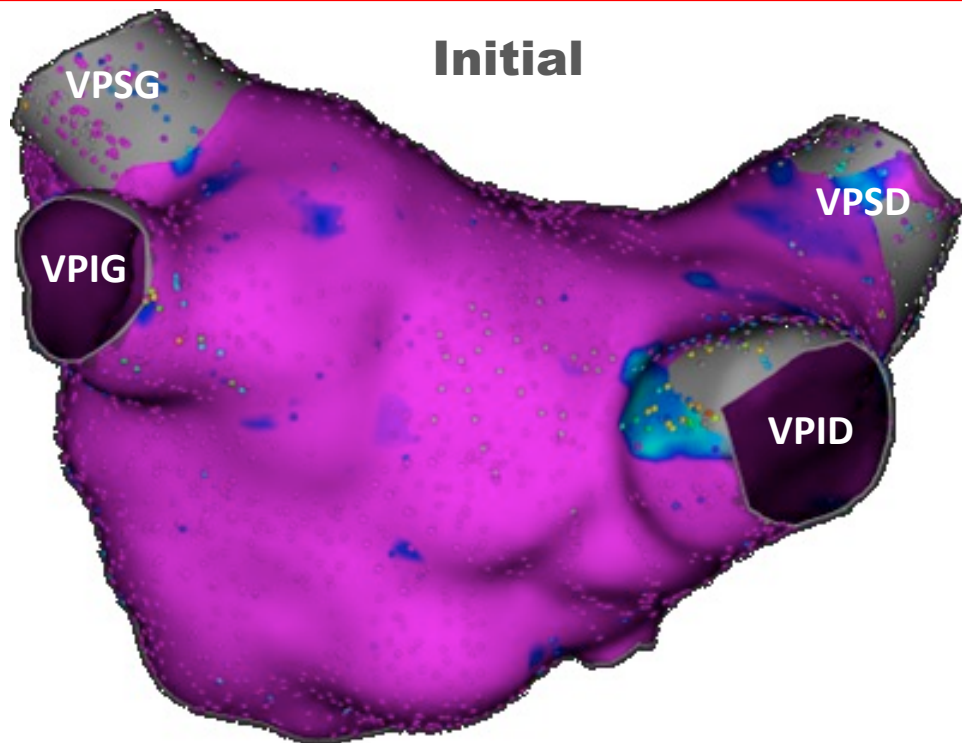


VPIG



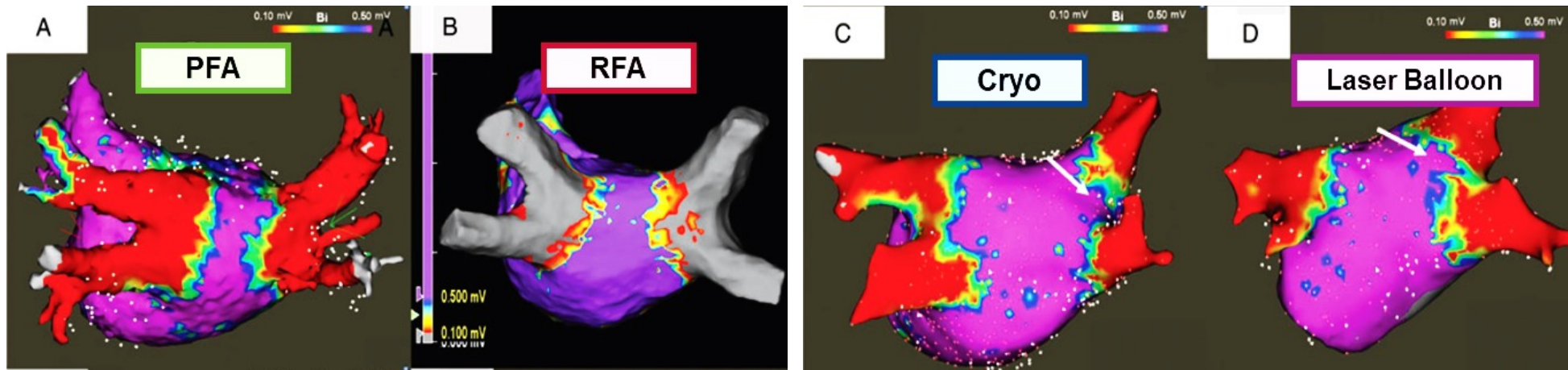
VPSD







Résultat aigu



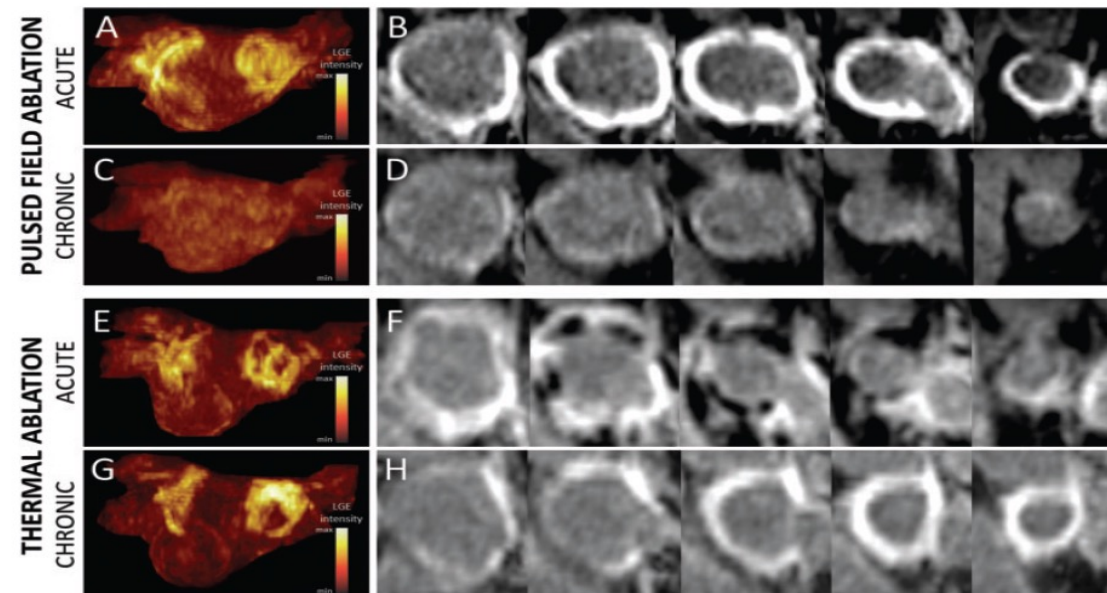
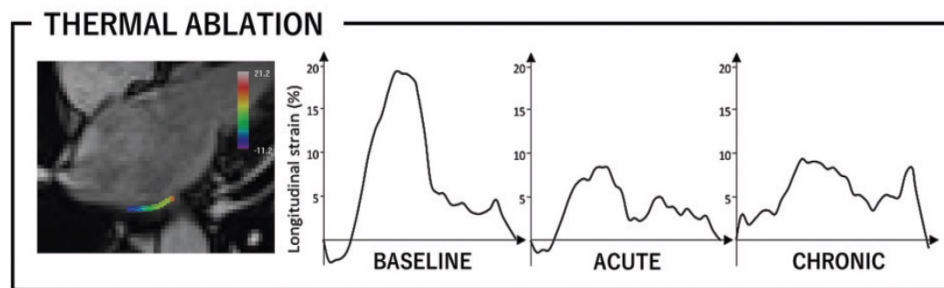
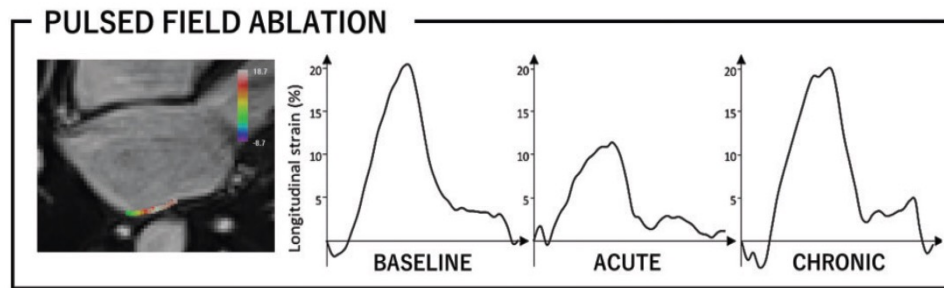
Kawamura et al. *EP Europace* 23.11 (2021): 1757-1766.

IRM x 3: PFA (18) vs RF (16) vs cryo (7)

Prior to PVI ablation (**BASELINE**),
<3 hours post-PVI (**ACUTE**),
3-months post-PVI (**CHRONIC**)

PFA

- Modifications tissulaires plus homogènes
- Pas d'hémorragie intra pariétale, pas de changement microvasculaire
- Récupération strain PV antrum et fonction systolique OG
- A la phase chronique moins de rehaussement tardif de gadolinium

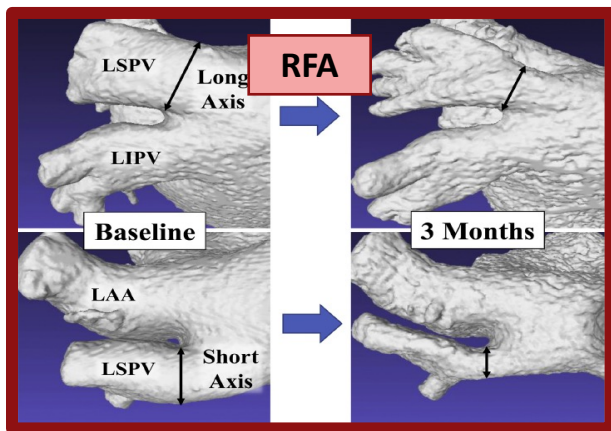
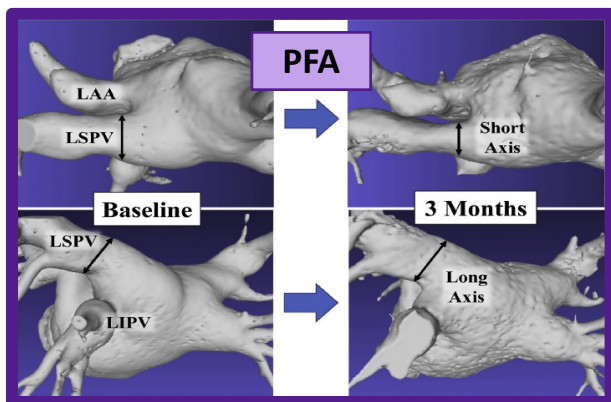


Nakatani et al. *EP Europace* 23.11 (2021): 1767-1776.



CT: taille ostium VP: PFA (37) vs RF (43)

Baseline et à 3 mois



MRI-gadolinium: œsophage:

**PFA (18) vs
ablation thermique (23)**
< 3h de l'ablation

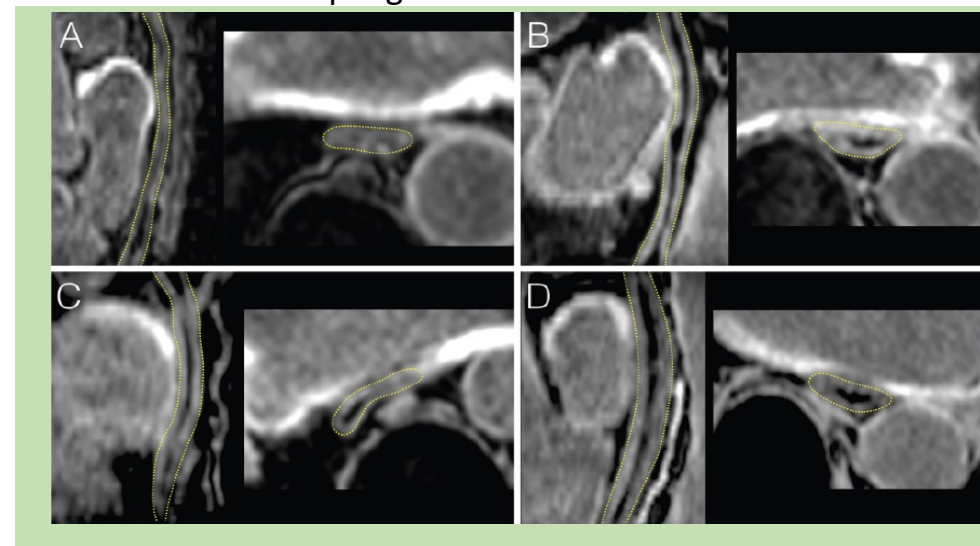
IRM cérébrale:
pas de lacune 16/18

Reddy et al. *JACC: Clinical Electrophysiology* 7.5 (2021): 614-627

29/30: presented at DGK
2021. *Clin Res Cardiol* (2021).
10.1007/s00392-021-01933-9
Abstract 190

PFA

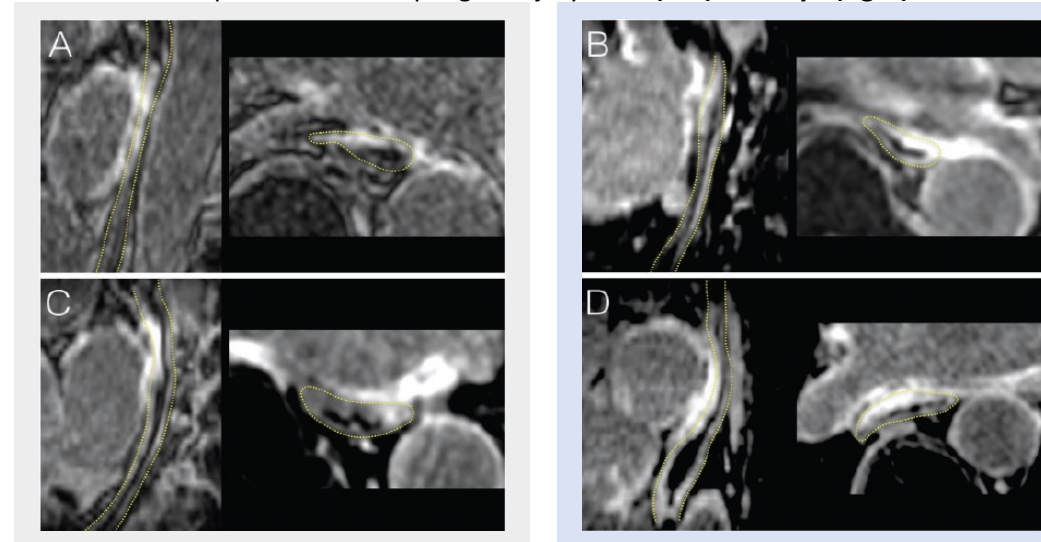
No esophageal lesions were observed



Thermal Ablation

Esophageal lesions were observed in 43% (10/23) patients

Examples of acute esophageal injury in RF (left) and Cryo (right)

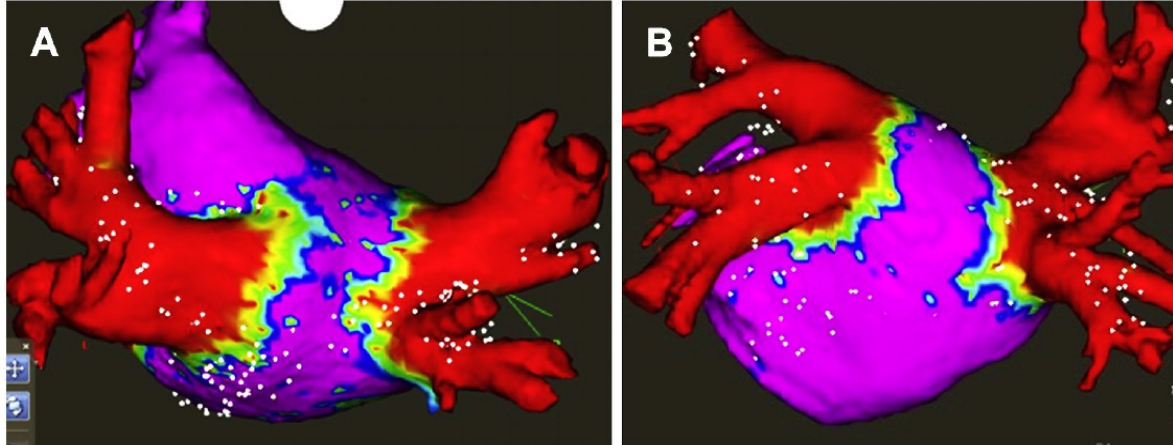


	PFA	RFA
By PV	0% (0/133)	12% (20/166)
By Patient	0% (0/37)	32.5% (14/43)

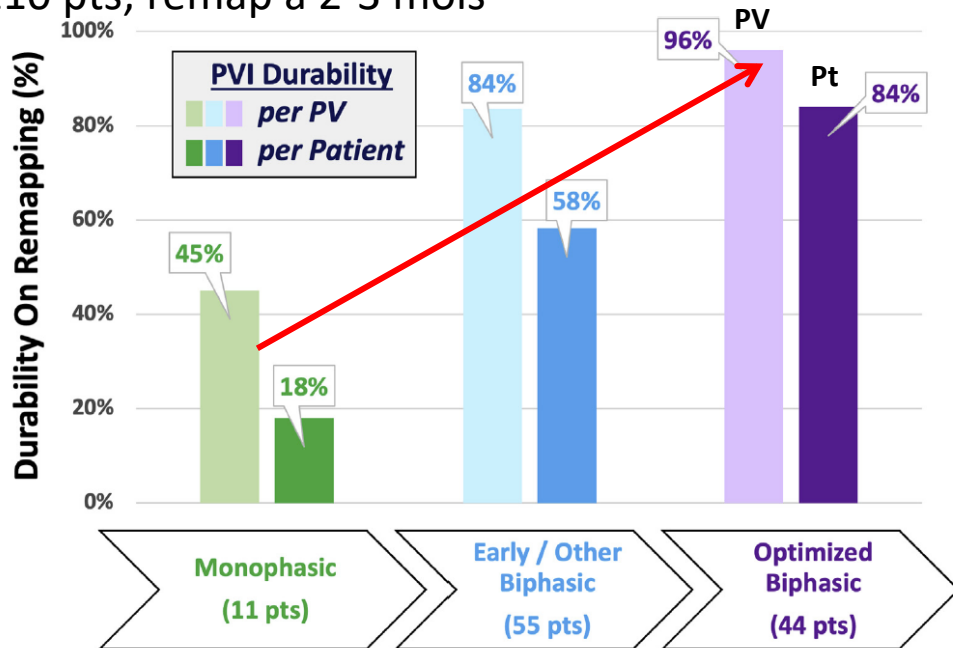


IMPULSE, PEFCAT, PEFCAT II: 121 pts, FA paroxystique

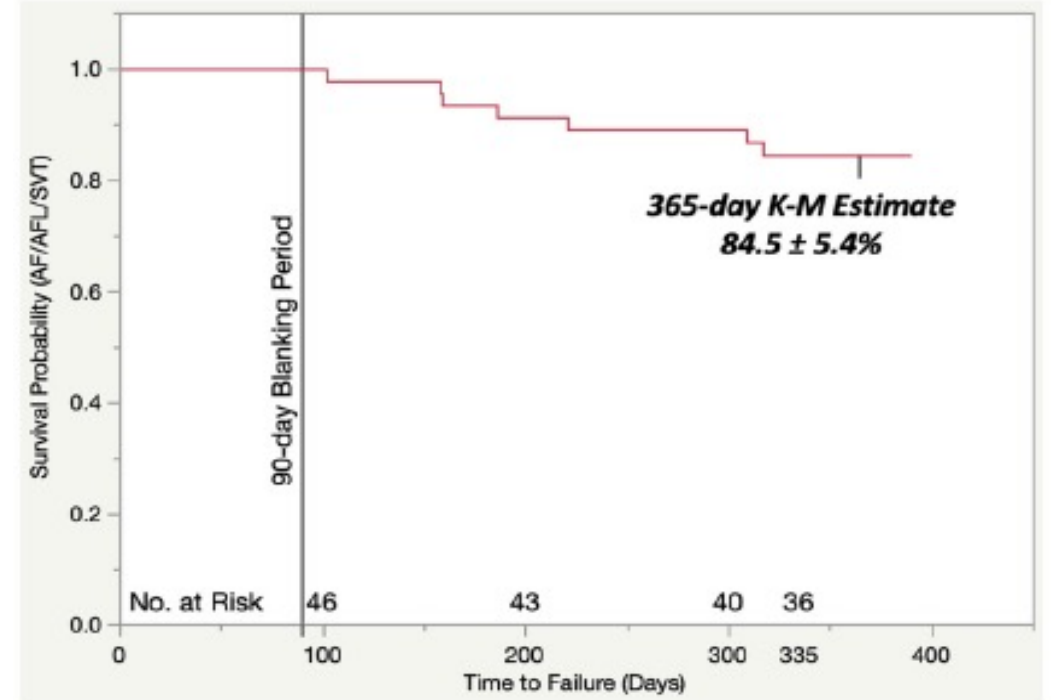
100% acute isolation



110 pts; remap à 2-3 mois



Freedom from AF, AFL or AT: PFA-OW Cohort



Reddy et al. JACC: Clinical Electrophysiology 7.5 (2021): 614-627

**Entre 1^{ère} et 3^e année de suivi: re ablation 12,8%
(les VP toujours déconnectées)**

Presented by D. Pugliese at HRS 2022



Etudes monocentriques *vie réelle*

	Lemoine et al. ¹	Gunawardene et al. ²	Neven et al. ³	Nentwich et al. ⁴	Chun et al. ⁵	Magni et al. ⁶	Neuzil et al. ⁷	Reddy et al. ⁸
Patient Population	PAF + PersAF	PAF + PersAF	PAF	PAF + PersAF	PAF	PAF + PersAF	PAF + PersAF	PAF
# of Patients Treated	31	20	30	50	100	68	412	121
PFA Ablation Strategy	PVI only	PVI + Posterior wall (PW) & mitral isthmus (MI) in a subset of PersAF pts	PVI only	PVI (42%) PVI + PW (58%)	PVI only	PVI (92.6%) PVI + PW (7.4%)	PVI, & PVI + PWI	PVI only
Procedure Time (min)	96 ± 4	123 ± 22	120 ± 21	83 ± 14	41 ± 11	49 ± 21	32.6 (PAF) 56.2 (PersAF)	96.2 ± 30.3*
LA Dwell Time (min)	29 ± 2	49 ± 14				40 ± 19		34.4 ± 15.8
Acute Isolation	115/124 (93%) PVs	80/80 (100%) PVs 9/9 PWs; 2/2 MIs	30/30 (100%) pts	50/50 (100%) pts	388/393 (99%) PVs	68/68 (100%) pts	412/412 (100%) pts	475/475 (100%) PVs
inclusive of pre- and post-PVI voltage mapping						98.8% Freedom from Atrial Arrhythmias, 6.8 months FU		*inclusive of post-PVI voltage mapping

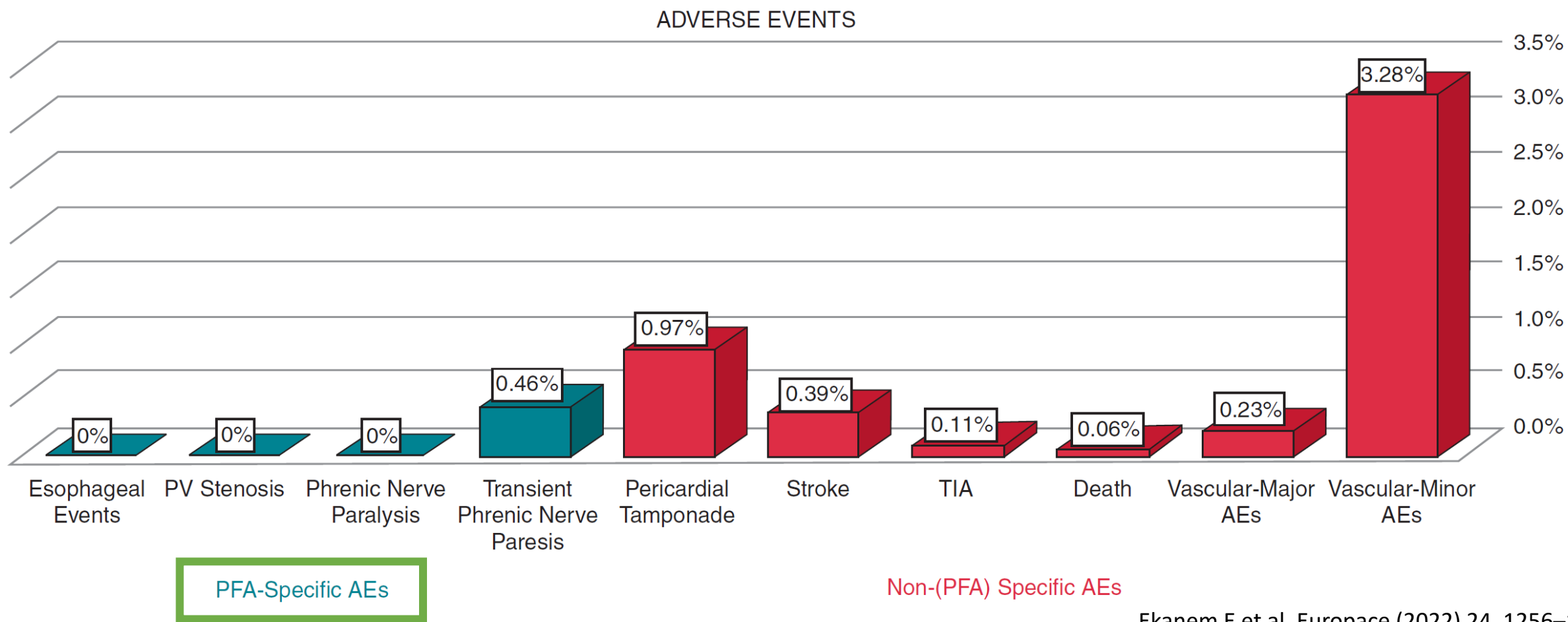
•[1] *Clin Res Cardiol* (2021). 10.1007/s00392-021-01933-9. Abstract 158; [2] *Journal of cardiovascular electrophysiology* (2022). 10.1111/jce.15349; [3] *Clin Res Cardiol* (2021). 10.1007/s00392-021-01933-9 Abstract 237; [4] Presented by Nentwich et al. EHRA 2022. "Acute safety and efficacy outcome of pulmonary vein isolation using pulsed field ablation technology" [5] Presented at DGK 2021, K.R. Julian Chun, World Congress Center, Germany, Sept 30, 2021 [6] Presented by F.T. Magni et al. EHRA 2022. "Initial experience with a novel pulsed field ablation catheter for ablation of atrial fibrillation: procedural findings and acute safety" [7] Presented by P. Neuzil at HRS 2022 "PFA for Paroxysmal and Persistent AF using an optimal waveform: Real Clinical Evidence from a Single Center [8] *JACC: Clinical Electrophysiology* 7.5 (2021): 614-627



Etude multicentrique *via réelle*


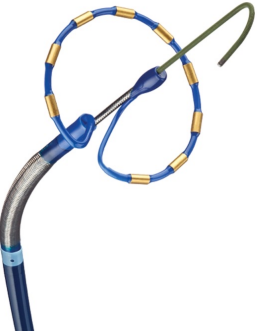


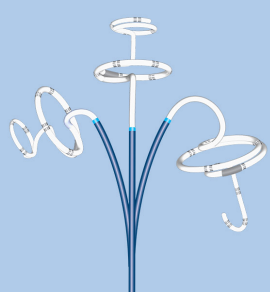


MANIFEST-PF: 24 centres (Europe), 90 opérateurs, 1758 patients

General Anesthesia / Intubation (%)	17.8%
Deep Sedation / No Intubation (%)	82.1%
No. of Transeptal Punctures, n (%)	1 (100%)
PVI success rate (%), mean (min-max)	99.9% (98.9-100)
Procedure Time (minutes), mean (min-max)	65 (38-215)
Fluoroscopy Time (minutes), mean (min-max)	13.7 (4.5-33)
Same Day Discharge (%)	15.8%









Single-Shot PFA

Company	Boston Scientific Farapulse	Medtronic	Medtronic Affera	Biosense Webster	Adagio	Kardium	Utrecht Group Abbott
Device	Farawave	PulseSelect	Sphere-PVI	Varipulse	iCLAS (PFCA)	Globe	
							
Ongoing Clinical Trials	ADVENT IDE BEAT-AF FARA FREEDOM (PMCF)	PULSED AF IDE	SPHERE PVI (FIH)	inspire (CE Mark)	FIH Trial	PULSE-EU (Feasibility)	FIH Trial



Focal PFA

Company	Boston Scientific Farapulse	Medtronic Affera	Acutus	Galaxy Medical
Device	Farapoint	Sphere-9	AcQForce	CENTAURI System
				
Ongoing Clinical Trials	PERSAFONE II (Feasibility) PERSAFONE III (Feasibility)	Sphere-9 IDE Sphere-Per-AF IDE	PFA-AF (EU; CE Mark)	SPACE-AF (Feasibility) ECLIPSE-AF (EU; CE Mark)



Dr Reddy: « Si vous devez avoir pour vous-même une ablation pour de la fibrillation atriale, quelle technologie vous choisiriez: RF, Cryo ou Electroporation? »

Pierre Jais
Bordeaux University Hospital
France



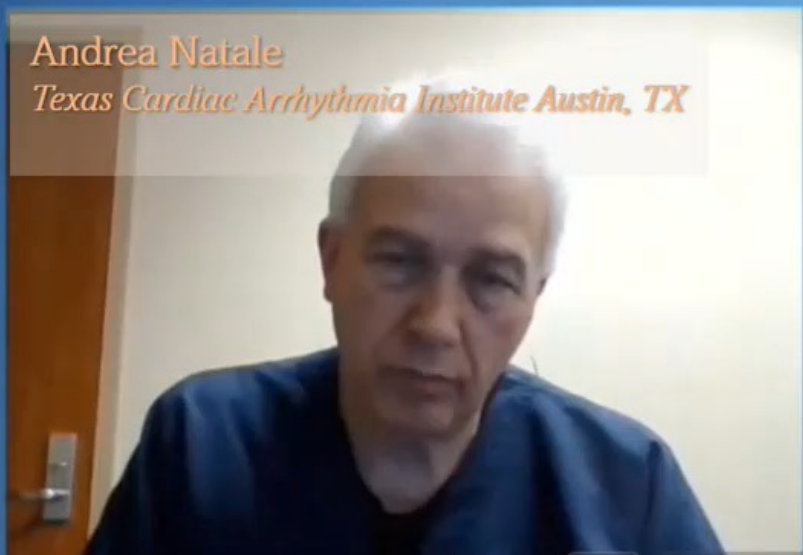
Vivek Reddy
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