

Aritmologia interventistica 3D

Innovazione tecnologica
nell'ablazione
di tachicardia ventricolare

Corrado Carbucicchio



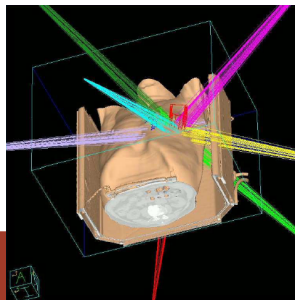
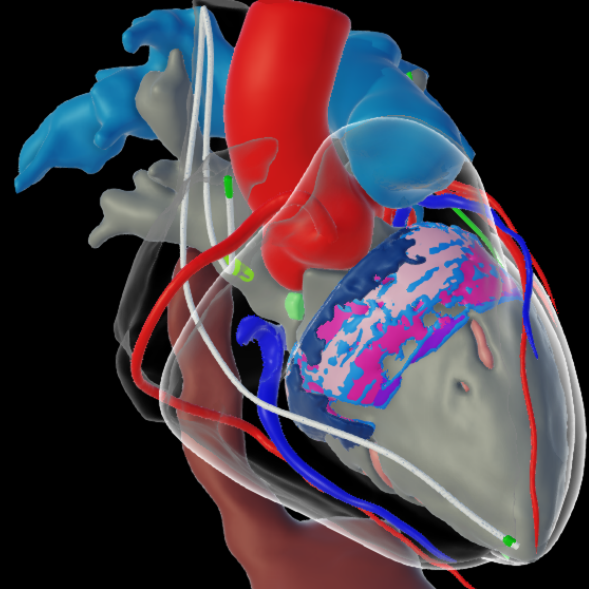
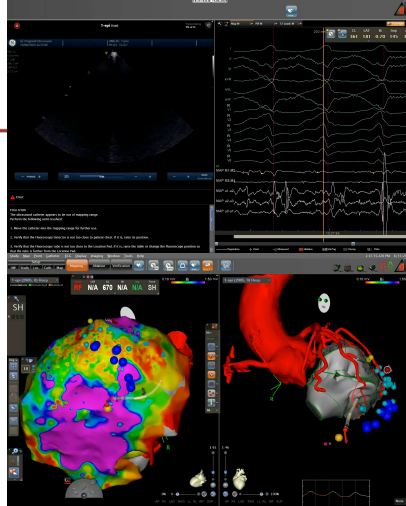
What is new?

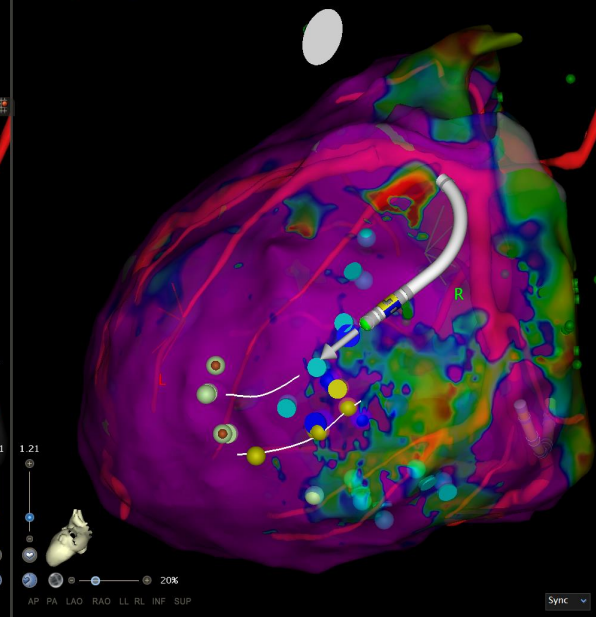
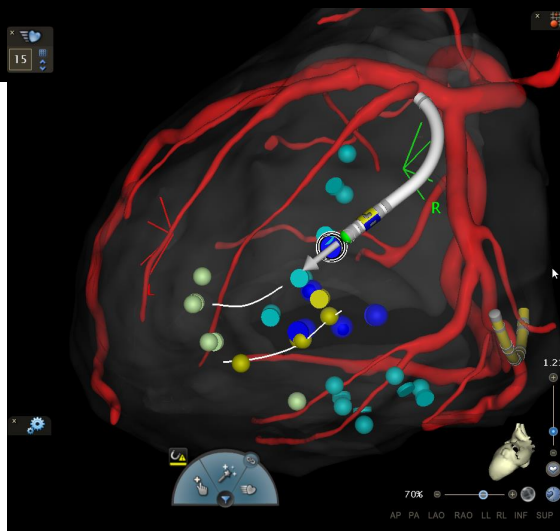
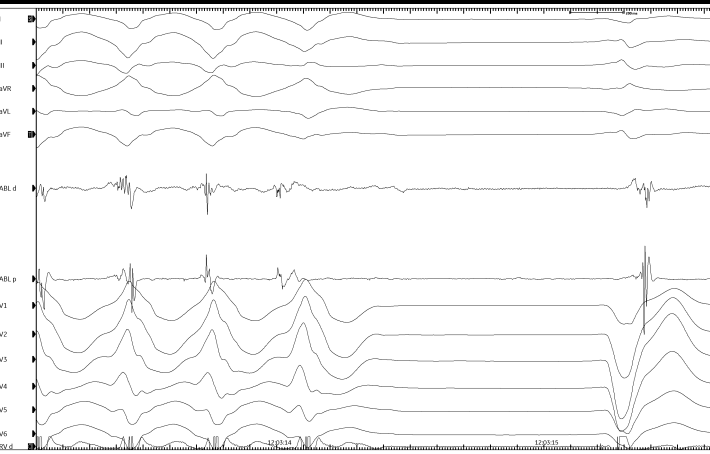
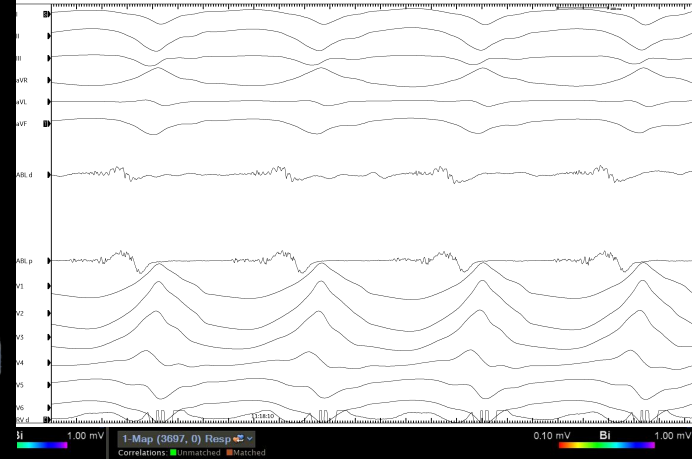
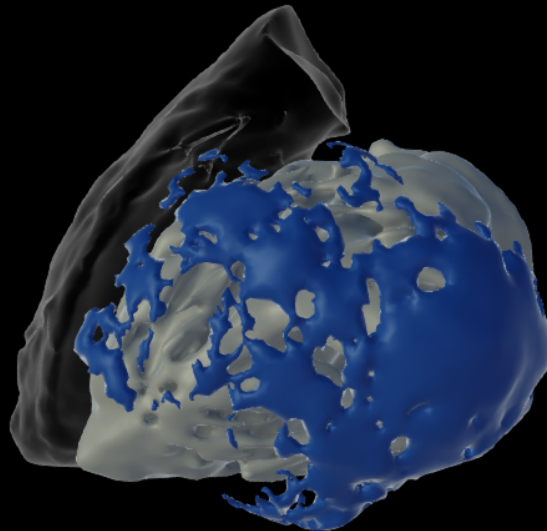
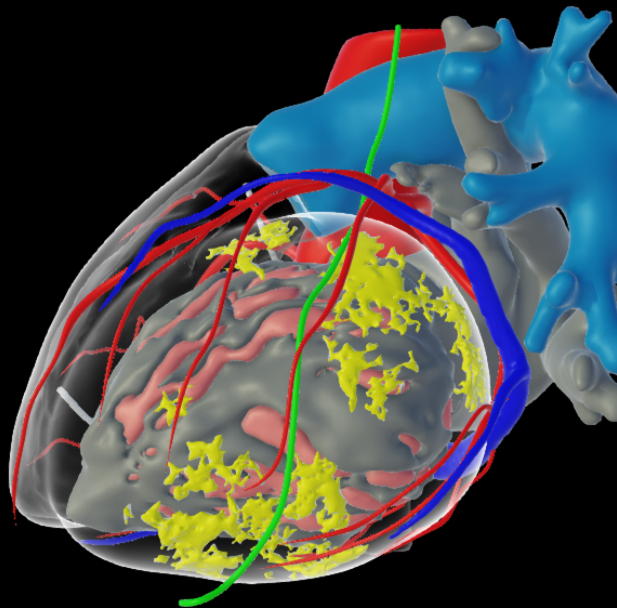
Innovative 3D mapping
(structural and functional substrate
analysis)

+

Imaging & imaging integration (scar characterization)

New energy sources
(PFA, STAR)





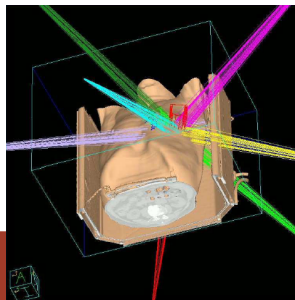
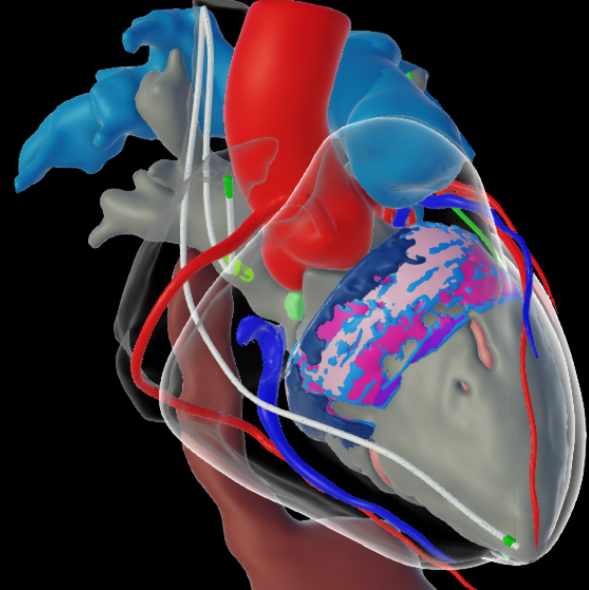
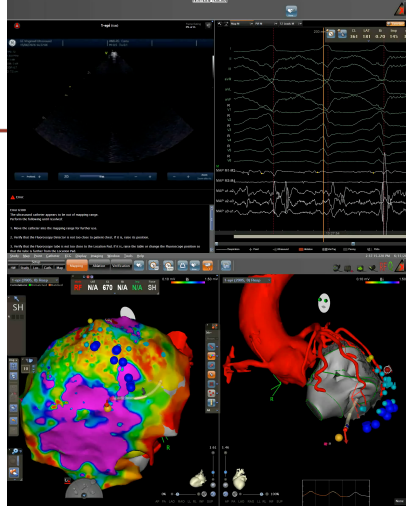
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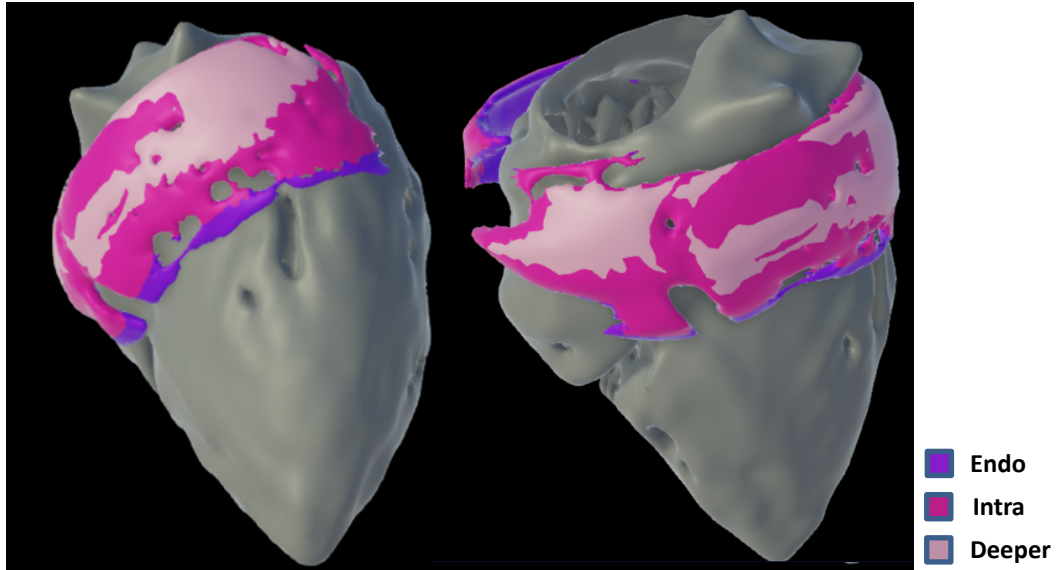
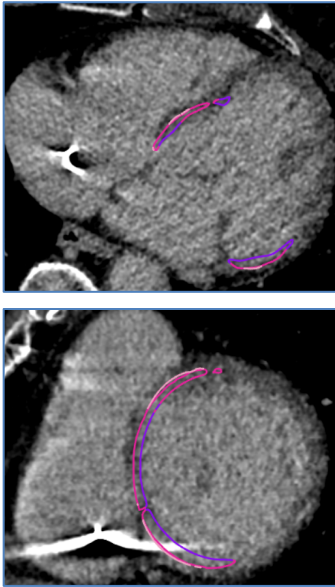


New energy sources

Rationale for the use of new technologies: efficacy, safety, efficiency, feasibility



cCT post-processing: septal scar



Courtesy of In-Heart

Pulsed Field Ablation (NO DISCLOSURE)

Non-thermal, cell-selective ablation causing irreversible electroporation

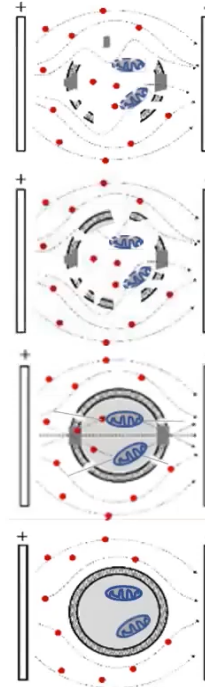
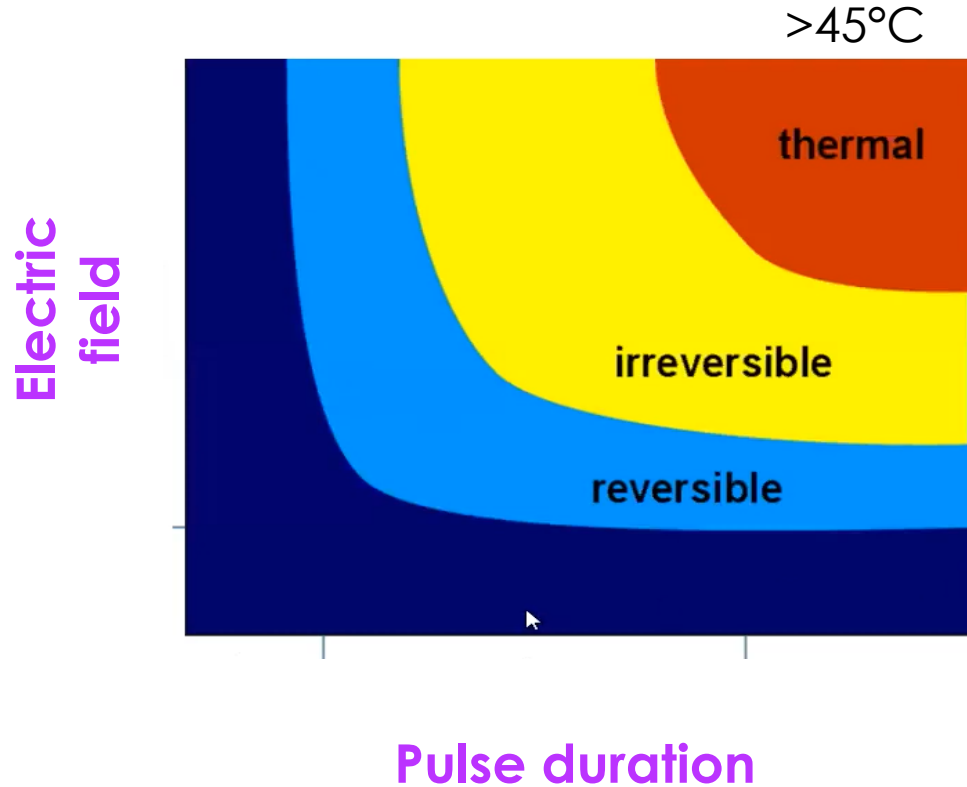
Adopted from cellular biology

High voltage (mmsec – nsec) electrical pulses create an electric field:
membrane lesion – loss of omeostasis- apoptosis

No usual thermal lesion (collagen, cellular matrix, vascular structures preserved)

Relative high tissue-selectivity (cellular dimensions and metabolism, intracellular matrix)





Thermal damage

Cell dies
Tissue scaffold is damaged
Protein denaturation occurs

Irreversible electroporation

Cell dies
Tissue scaffold remains intact

Reversible electroporation

Cell survives
(room for Pulsed Field Mapping ?)

No effect

Intact cell



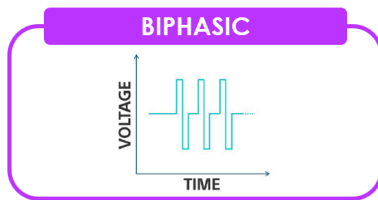
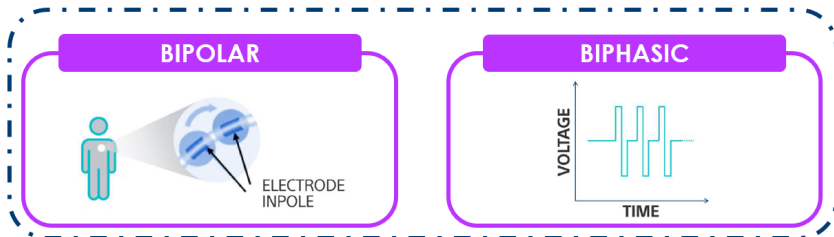
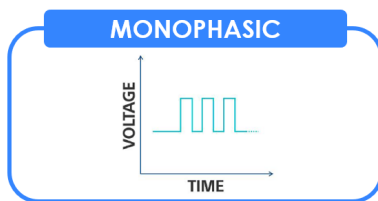
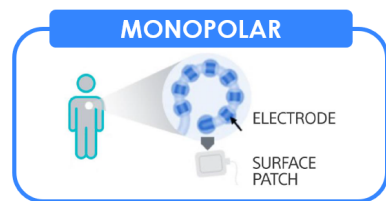


PFA Mechanism of Action

Not all PFA systems are the same

Boston
Scientific

Each PFA system is highly parameter dependent



CATHETER DESIGN

Electrode spacing
Electrode count
Electrode geometry

PROPRIETARY PULSE

Width/duration
Frequency/count
Amplitude/strength

BIOPHYSICS

Target cell proximity
Target cell orientation
Target cell type

= varietà di protocolli

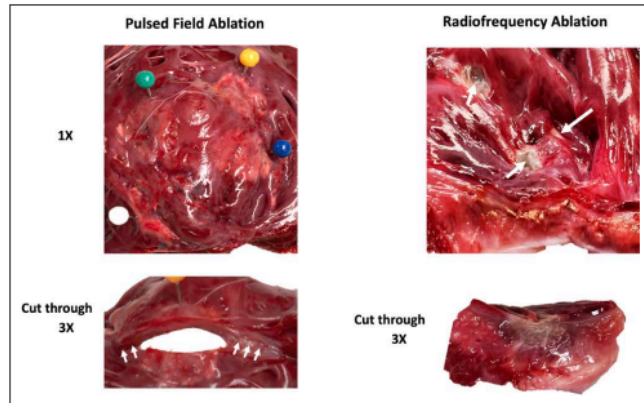


Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

Effect of Pulsed-Field and Radiofrequency Ablation on Heterogeneous Ventricular Scar in a Swine Model of Healed Myocardial Infarction

Arwa Younis , MD; Israel Zilberman , DVM; Alison Krywanczyk , MD; Koji Higuchi , MD; Hagai D. Yavin , MD; Jakub Sroubek , MD, PhD; Elad Anter , MD



- In scar areas, PFA-induced lesions extend more consistently to the subepicardium through fat and collagen, eliminating viable myocardium
- The limit of RF penetration was attributed to the lower temperature reached by infarcted tissue compared to healthy tissue at deeper infarct layers



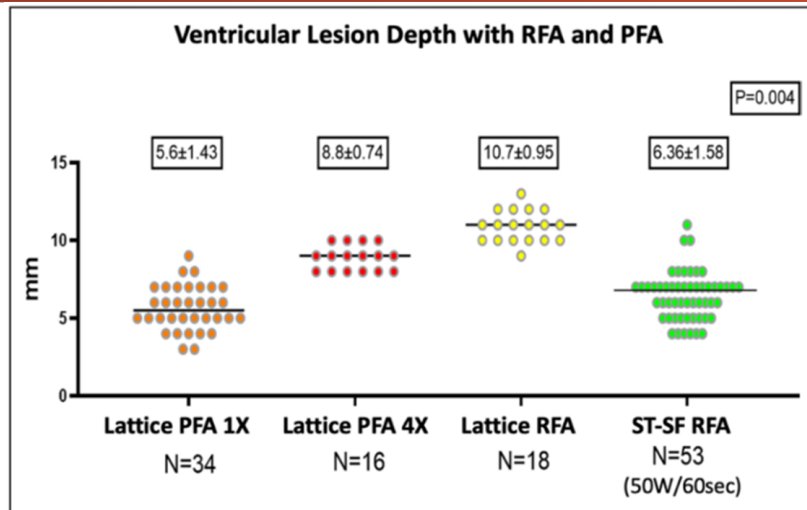
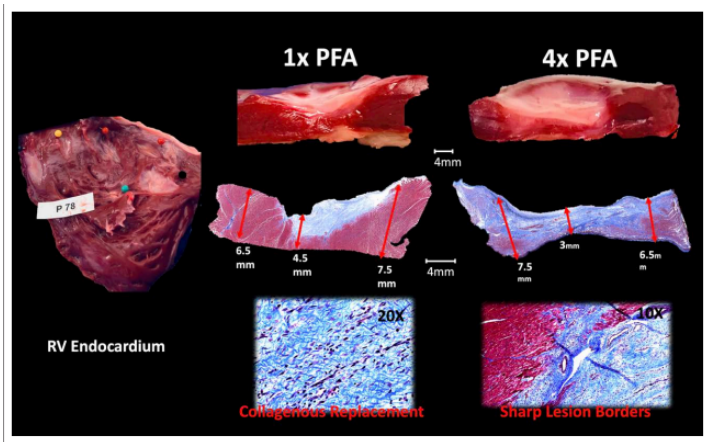
Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

Pulsed-Field Ablation in Ventricular Myocardium Using a Focal Catheter

The Impact of Application Repetition on Lesion Dimensions

Hagai D. Yavin MD; Koji Higuchi MD; Jakub Sroubek MD, PhD; Arwa Younis, MD; Israel Zilberman, DVM; Elad Anter MD



«Application repetition»

PFA vs. RFA lesions

Does the sequence matter ?



Combined RF + PFA treatment

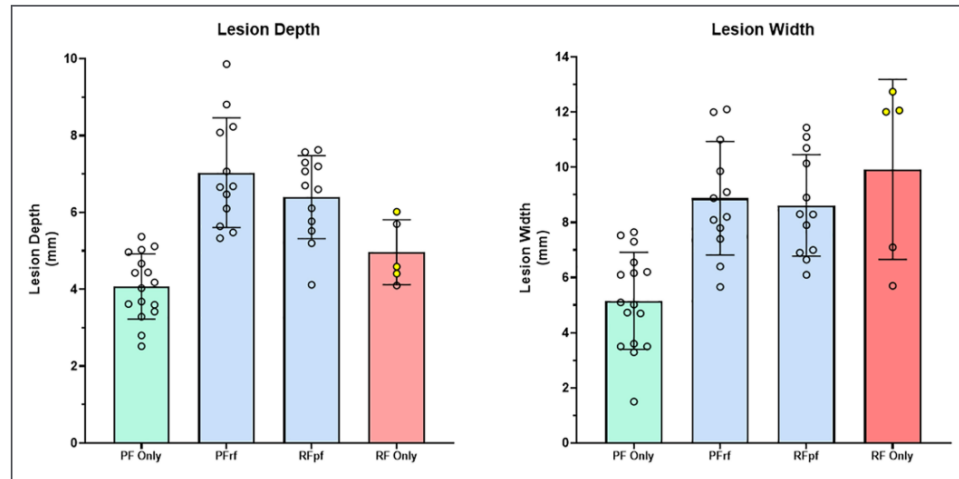
Table 1. Number, Type, and Distribution of Lesions Delivered in Animal Subjects ([Table view](#))

LV							RV					
	PFA	RFpf	PFrf	RF-only	SP	TM	PFA	RFpf	PFrf	RF-only	SP	TM
Animal 1	2	2	2			0	3	4	2	1		2 (1 PFrf and 1 PF)
Animal 2	2	3 (1 SP)	3	1	1	1 RFpf	2	2 (1 SP)	3 (1 SP)		2	4 (2 PFrf and 2 RFpf)
Animal 3	2	3	2	1		1 RFpf	2	2	2	1		2 (1 PFrf and 1 RFpf)
Animal 4	2	2	2			1 RFpf	4	3	3 (2 SP)	1	2	4 (1 PF, 1 PFrf, and 2 RFpf)

LV indicates left ventricle; PF, pulsed field; PFrf, pulsed field followed by sequential application of radiofrequency on the same location; RF, radiofrequency; RFpf, radiofrequency followed by sequential application of pulsed field on the same location; RV, right ventricle; SP, steam pop; and TM, transmural.

Table 2. Average Ablation Index of Applied PF and Combination RF/PF Lesions ([Table view](#))

Group	Ablation type	Average index
PF-only	PFA	318.5±18.2
RF followed by PF	RF	423.3±55.5
	PFA	313.0±19.6
PF followed by RF	RF	408.7±63.8
	PFA	322.3±18.3
RF alone	RF	408.6±20.1



PF indicates pulsed field-only; PFrf, pulsed field followed by sequential application of radiofrequency on the same location; RF, radiofrequency-only; and RFpf, radiofrequency followed by sequential application of pulsed field on the same location.

Both combination ablations were significantly wider and deeper than PF alone ($P<0.0001$).



TactiFlex™ Duo Ablation Catheter, Sensor Enabled™; Abbott



Diameter **4 mm**
Size **8.5**
Ablation mode **Unipolar, Biphasic**
PF/RF **Yes/Yes**
Dedicated 3D mapping **Yes**

CENTAURI System (delivery of focal monopolar energy through standard irrigated contact force ablation catheters) (CardioFocus)



Dual Energy THERMOCOOL SMARTTOUCH™ SF Platform, Biosense Webster

Diameter **3,5 mm**
Size **8.5 Fr**
Ablation mode **Unipolar, Biphasic**
PF/RF **Yes/Yes**
Dedicated 3D mapping **Yes**



Sphere-9 Medtronic



Diameter **9 mm**
Size **8 Fr**
Ablation mode **Unipolar, Biphasic**
PF/RF **Yes/Yes**
Dedicated 3D mapping **Yes**



Farapoint™ Pulsed Field Ablation Catheter, Boston

Diameter **2,5 mm**
Size **8 Fr**
Ablation mode **Bipolar, Biphasic**
PF/RF **Yes/No**
Dedicated 3D mapping **Yes**





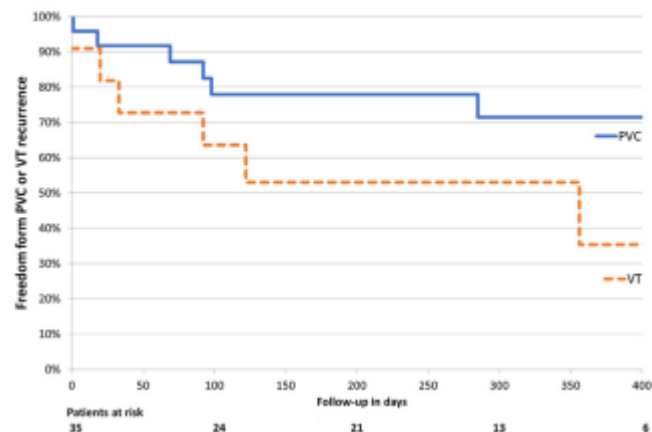
Feasibility and midterm effectiveness of focal pulsed field ablation for ventricular arrhythmias ^e

Martin H. Ruwald, MD, PhD, DMSc, Arne Johannessen, MD, DMSc, Rene Worck, MD, PhD, Morten Lock Hansen, MD, PhD, Martin Haugdal, MSc, Jim Hansen, MD, DMSc

Table 3 Follow-up data

	Total (N = 35)	PVC (n = 24)	VT (n = 11)
Follow-up time, d	288 ± 149	293 ± 154	230 ± 132
Long-term success	24 (69)	18 (75)	5 (45)
Reablations	5 (14)	1	4
Time to recurrence, d	71 ± 102	56 ± 44	104 ± 132

Recurrence free survival after PFA



- TactiFlex™ Duo Ablation Catheter, Sensor Enabled™

EYEBROW IDENTIFICATION, CALIBRI, 14PT REGULAR

PI Algorithm Parameters

1. Number of bursts

NOMINAL THERAPY
5 bursts at 2400 V

LOW THERAPY
10 bursts at 2100 V

1

Total
number of
bursts
applied

2. Contact Force

% TIME THAT CF ≥ 5 g
Consistency

Measures **TIME** Contact Force
is equal to or above 5 g.

May require an average of 10 g-
20 g to achieve a minimum
consistency of ≥ 5 g

2

Tissue
contact

3. Intracardiac Impedance

**CHANGE IN LOCAL BIPOLAR
IMPEDANCE OVER THE
THERAPY APPLICATION**

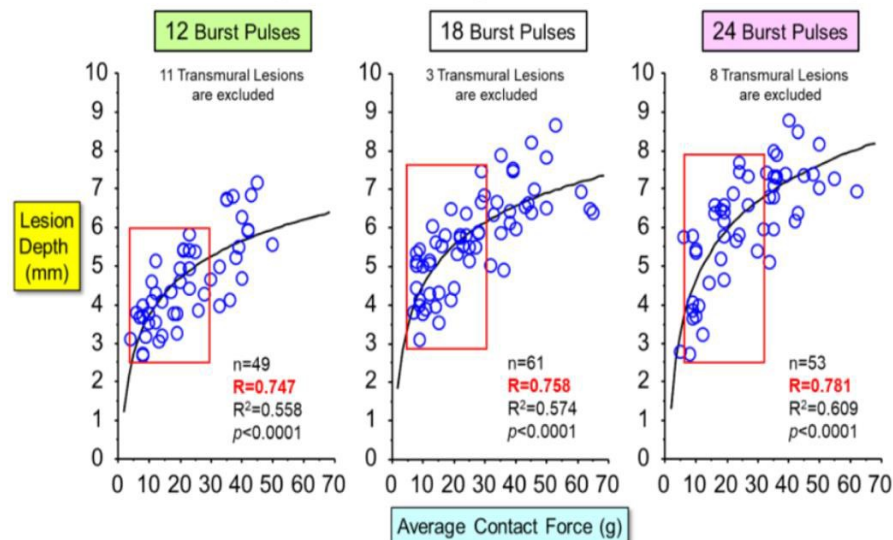
PI uses impedance data from electrode
1 and 2 on the TactiFlex™ Duo Ablatio
Catheter, Sensor Enabled™

3

Local
tissue
response

- Dual Energy THERMOCOOL SMARTTOUCH™ SF Platform

Relationship Between Average Contact Force and Lesion Depth



Safety and efficacy of a lattice-tip catheter for ventricular arrhythmia ablation: the AFFERA Ventricular Arrhythmia Ablation Registry (AVAAR)

Frédéric Sacher ^{1*}, Andrea Sarkozy ², Helmut Pürerfellner ³,
Alexandra Steyer ⁴, Jonathan Lyne ⁵, Charlène Coquard ⁶, Romain Tixier ¹,
Nicolas Combes⁷, Michel Haissaguerre ¹, Michalis Efremidis⁸,
Josselin Duchateau ¹, Victor Castro Urda ⁹, Claire A. Martin ^{10,11},
Marc Lemoine ¹², Alejandro Carta Bergaz ¹³, Frank Bogun ¹,
Nick Linton ¹⁴, Nicolas Derval ¹, Filip Schlosser ¹⁵, Thomas Pambrun ¹,
Jan Petru¹⁶, Meleze Hocini ¹, Luigi Pannone ², Martin Mudroch ¹⁶,
Josef Kautzner ¹⁵, Pierre Jais ¹, Tobias Reichlin ¹⁷, Petr Neuzil ¹⁶, and
Petr Pechl ¹⁵

A total of 126 patients (18% female; mean age 59 ± 16 years) underwent VA ablation using the lattice-tip catheter during the inclusion period.

Ablation indications included **ventricular tachycardia** (VT) in 99, **premature ventricular complexes** (PVCs) in 23, and **ventricular fibrillation** (VF) in 4 patients.

After a mean follow-up of 5.6 ± 3.7 months, absence of recurrence was 78% for PVC, 70% for VT, and 100% for VF.

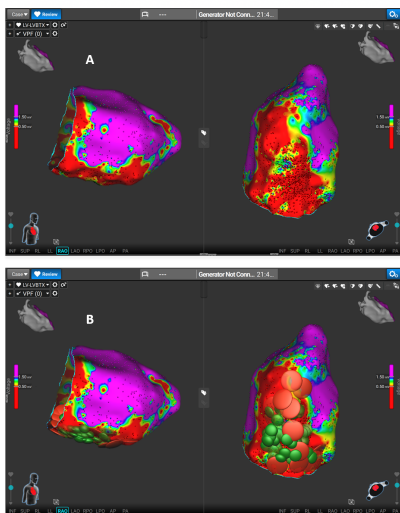
Short-term efficacy seems promising with an absence of ventricular arrhythmia (VA) recurrence in 36/45 (80%) patients for de novo VA ablation and **55/81 (68%) for redo procedures**.



RESEARCH LETTER

Initial Experience With a Dual-Energy Lattice-Tip Catheter for Ventricular Tachycardia Ablation: Procedural Feasibility and Emerging Safety Warning

Nicoletta Ventrella¹, MD; Mariano Sabatino, MD; Lorenzo Bianchini², MD; Marco Schiavone³, MD, PhD;
Andrea Dell'Aquila⁴, MD; Fabrizio Tundo⁵, MD, PhD; Maria Elisabetta Mancini⁶, MD; Gianluca Pontone⁷, MD, PhD;
Claudio Tondo⁸, MD, PhD*; Corrado Carbucichio⁹, MD*



	Patient #1	Patient #2	Patient #3	Patient #4	Patient #5	Patient #6	Patient #7
Pre-procedural imaging	CT	CT	CT	CT	CT	CT	CMR
Target scar location	Infero-basal IVS	Mitro-aortic continuity	Antero-basal IVS	Inferior wall (basal)	Mid-basal IVS	Antero-basal IVS	RVOT
Indication for AFFERA	Deep septal substrate	Redo ablation	Deep septal substrate; pericardial space not accessible	Intramyocardial substrate; pericardial space not accessible	Deep septal substrate	Redo ablation	Redo ablation; challenging pericardial access
Type of SHD	DCM	DCM	CAD	CAD	DCM	DCM	ACM
Previous ablation	No	Yes	No	No	Yes (stereotactic radiotherapy)	Yes	Yes
PAINESD score	22	11	NA	12	22	11	5
Procedural time (min)	210	310	175	180	280	390	150
# EAM points	6216	3968	4320	3005	4572	4707	4514
# RF applications	0	4	8	18	71	/	8
# PFA applications	81	44	61	82	20	/	11
Any abnormal electrograms attenuation >75% after RF	NA	Yes	Yes	Yes	Yes	NA	No
Abnormal electrograms elimination	Yes	Yes	Yes	Yes	Yes	NA	No
Clinical VT inducibility at the end of the procedure	No	No	No	No	No	No	Yes

Early U.S. Experience With Catheter Ablation of Ventricular Arrhythmias With a Dual-Energy Lattice-Tip Catheter

Insights From the CLEAR-VT Registry

Osama Dasa, MD, PhD, Arwa Younis, MD, Koji Higuchi, MD, PhD, Jakub Sroubek, MD, PhD, Justin Z. Lee, MD, Roy Chung, MD, Shady Nakhla, MD, Nolan Hight, CNP, CCDS, Niraj Varma, MD, PhD, Ayman A. Hussein, MD, Tyler Taigen, MD, Mohamed Kanj, MD, Mandeep Bhargava, MD, Walid I. Saliba, MD, Oussama M. Wazni, MD, MBA, Pasquale Santangeli, MD, PhD

CENTRAL ILLUSTRATION: Continued

ABLATION STRATEGY

Dual-Energy Sequential Protocol

- High-Density Substrate Mapping**
3D electroanatomic map; scar by ICE wall thinning/hypokinesia + low bipolar voltage
- RFA - First-Line Ablation Modality**
Activation/entrainment for tolerated VTs; substrate modification for unstable VTs
- PFA - Adjunctive in Dense Scar**
Wall thinning, absent contractility on ICE + low bipolar voltage; avoided at scar border zone
- Acute Endpoint**
VT: Noninducibility of clinical/nonclinical VT (CL >240 ms) + abolition of abnormal EGMs
PVC: Complete PVC suppression

SAFETY CONSIDERATIONS

- ICD Device Failure (PFA)**
PFA ~7.5 mm from LV pacing lead → ICD generator failure. Intraoperative device change required.
- 2 Major Bleeding Events**
Periprocedural hemorrhagic complications not device-related.
- Catheter Entrapment**
Sphere catheter trapped in mitral/tricuspid valve apparatus; resolved by recapture into long sheath via transseptal/transfemoral venous approach.
- Epicardial Fat Entrapment**
Epicardial fat entrapped within the sphere with epicardial mapping. Catheter changed to remap endocardium to minimize embolization risk.
- Steam Pops**
RFA (7s) typically at the scar border zone. No preceding steep increase in temperature.
- No Coronary Vasospasm / No Clinical Hemolysis**
Epicardial PFA >1 cm from major coronary arteries.

CENTRAL ILLUSTRATION: Summary of Study Findings

Sphere-9 Lattice-Tip Catheter



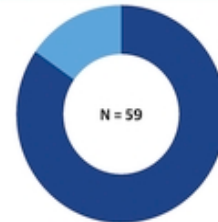
9 mini electrodes (0.7 mm) on spherical lattice surface

RFA
Radiofrequency

PFA
Pulsed Field

STUDY POPULATION, N = 59 (18% of VA Ablations)

CLEAR-VT Registry, Jan-Sep 2025



- Scar-related VT**
 - Ischemic (n = 28)
 - NICM (n = 19)
 - Mixed (n = 3)
- Frequent PVCs**
 - Lateral LVOT (n = 4)
 - LV papillary muscles (n = 4)
 - RV moderator band (n = 1)

CRITERIA

- Anticipated Large Target Substrate Area (Multisegment Scar Involvement at Imaging)
- Prior Failure of Conventional RFA

70 y Median Age	36% Mean LVEF	30% Prior VT Ablation	68% Amlodarone
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ACUTE & FOLLOW-UP OUTCOMES

Acute VT Noninducibility	78%
Abnormal EGM Elimination	100%
Acute PVC Suppression	100%
VT Recurrence (follow-up)	18%
PVC Suppression	100%

Preablation PVC Burden 20.4% (15.5%-24.5%)
Postablation PVC Burden 3.5% (1.7%-3.8%)
Median follow-up: 54 days

VT Cohort

Death	8%
Transplant/LVAD	4%
Major Complications	6%

6-Month KM VT-Free Survival 69.8%
95% CI: 54.0%-90.3%
Median follow-up: 100 days

50pts. RF + PFA

No transmural by PFA

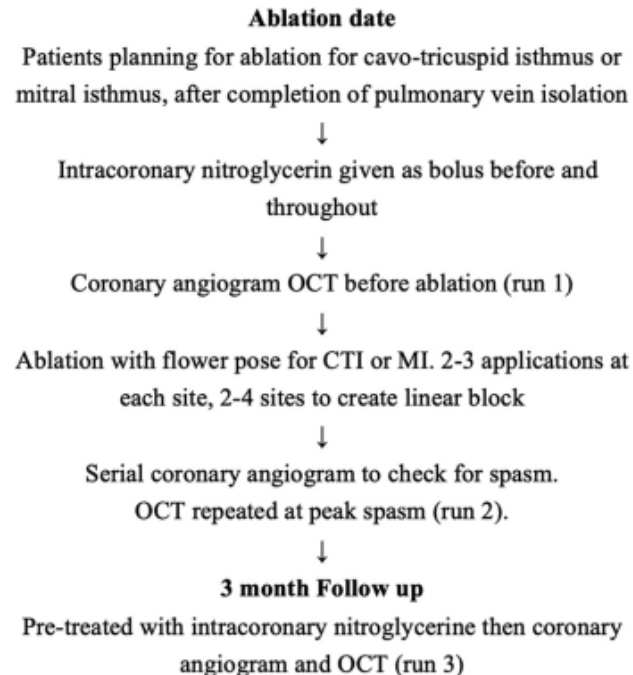
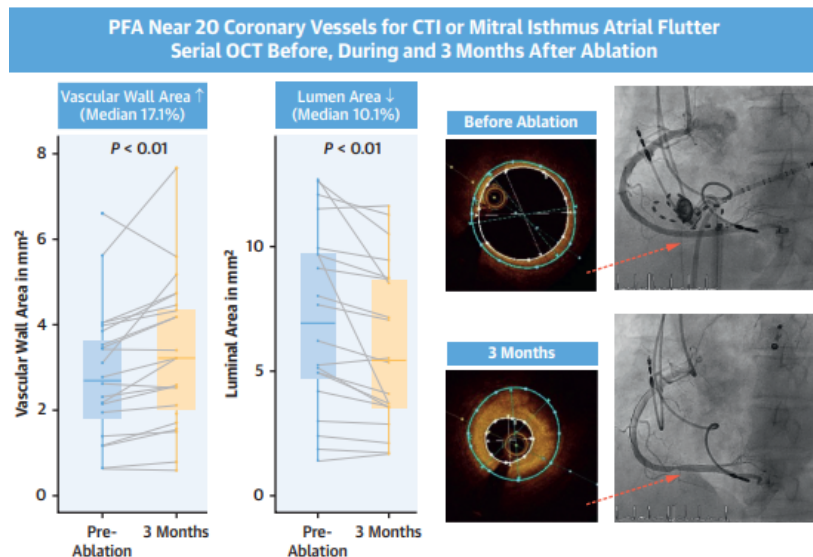
Mapping conditioned by catheter design



Effect of Pulsed-Field Ablation on Human Coronary Arteries

A Longitudinal Study With Intracoronary Imaging

Mark T.K. Tam, MBChB, Joseph Y.S. Chan, MBBS, Chin Pang Chan, MBChB, Eugene B. Wu, MD, Angel Lai, PhD, Alex C.K. Au, MBChB, Wai Kin Chi, MBChB, GuangMing Tan, MBChB, Bryan P. Yan, MD



PFA of the CTI and MI is associated with acute spasm, and mild narrowing of the coronary arteries at 3 months



PFA

Lot of data...

...still limited scientific and clinical evidence...

...need for clarity

...high expectations



RADIATE-VT clinical trial

• Cardiac **RAD**ioablation versus repeat catheter **Abl**ation:

a pivotal randomized clinical **Trial** **E**valuating safety and efficacy for patients with high-risk refractory **V**entricular **T**achycardia

Study Design

Up to 380 participants with high-risk, refractory ventricular tachycardia (VT) will be enrolled at up to 30 sites.

Participants will be randomized 1:1 between 2 treatment arms:

- Repeat standard-of-care catheter ablation
- Cardiac radioablation with Varian's CRA system

Eligibility criteria

Patients with refractory VT who meet the following criteria may be eligible:

- Ischemic and/or nonischemic cardiomyopathy
- Recurrent sustained monomorphic VT
- LVEF $\leq 49\%$
- Previously underwent a catheter ablation for VT
- Have failed or are intolerant to amiodarone
- Have an implantable cardioverter-defibrillator (ICD)
- Medically and technically a candidate for catheter ablation

Outcomes measures

The primary objective of the RADIATE-VT clinical trial is to demonstrate that treatment with Varian's CRA system is safer than and as effective as catheter ablation in participants with high-risk refractory VT.

The secondary objectives are to compare quality of life and VT burden reduction between the two treatments.

Innovative GATing approach in PROton therapy for Ventricular Tachycardia (i-GATE PRO VT)

First-in-Human clinical investigation focusing on

Proton Stereotactic Arrhythmia Radiotherapy (STAR) delivered with **CardioKit** (investigational gating system) to treat refractory VTs (*STRAMI-Like Pts*)

CardioKit system combines cardiac and respiratory gating to improve targeting accuracy during proton STAR.

Thank you !

corrado.carbucicchio@ccfm.it