

MAPPING E DURABILITÀ DELLE LESIONI

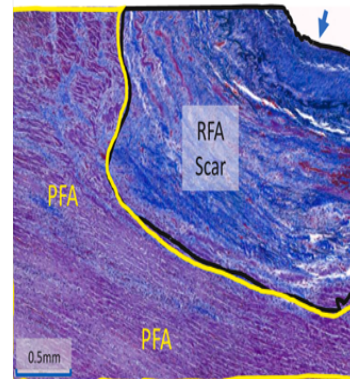
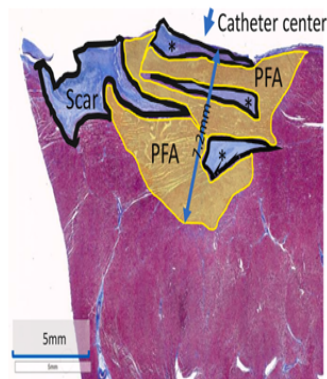
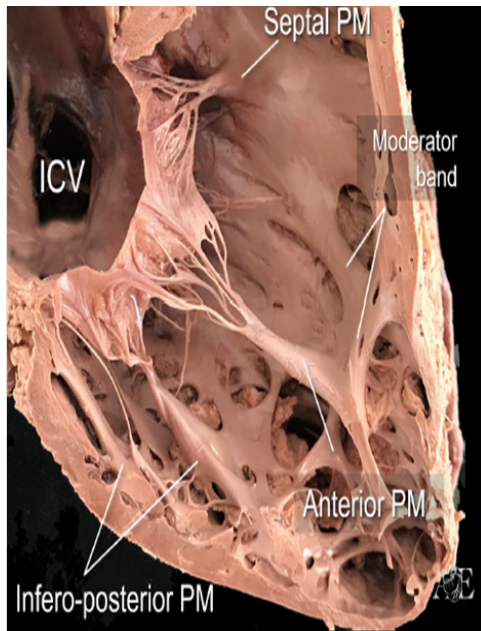
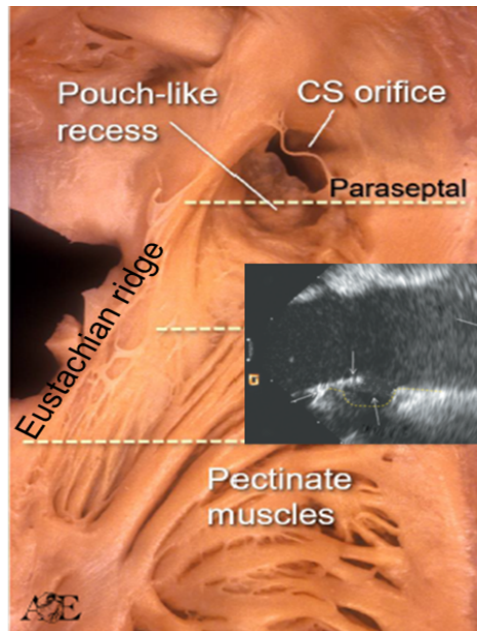
**Migliorare la durabilità dell'isolamento
delle vene polmonari (PVI) nella PFA:
integrazione tra contact sensing e sistemi
di mappaggio avanzati**

Gianfranco Tola



A PARADIGM CHANGE IN LESION FORMATION: **REPRODUCIBLE LESION**

**PFA DOES NOT DEPEND ON ANATOMICAL VARIATIONS:
PROXIMITY TO TISSUE IS CRUCIAL**



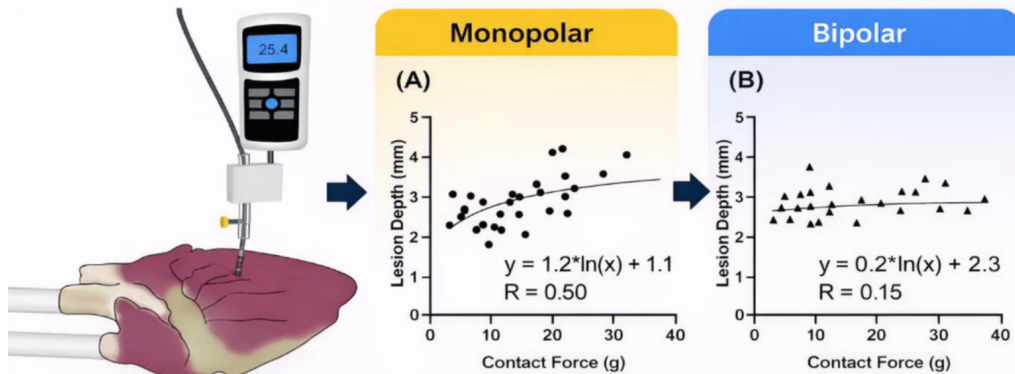
**PFA IS LESS SENSITIVE TO THE NATURE OF
ATRIAL AND VENTRICULAR SUBSTRATES**



CONTACT IS ESSENTIAL IN BOTH BIPOLAR AND MONOPOLAR PFA DELIVERY

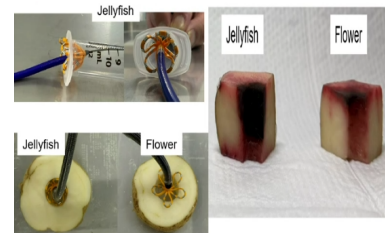
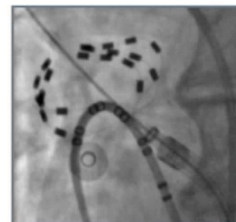
Effects of In Vivo Contact Force on Pulsed-Field Ablation Efficacy in Porcine Ventricles

Taro Koya | Naoto Otsuka | Jason A. Tri | Yang Ying | Elyana Espinoza | Samuel J. Asirvatham | Duy T. Nguyen



INCREASING CONTACT FORCE USING BIPOLAR PFA HAS MINIMAL EFFECTS ON ACUTE LESION

FOR MONOPOLAR PFA, GREATER CF CAN IMPACT LESION DEPTH



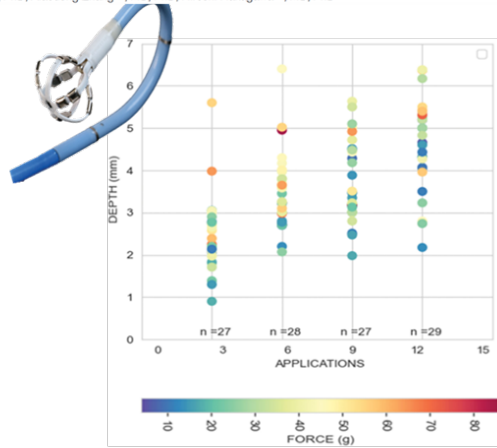
FOR FARAWAVE, INCREASE FORCE LEADS TO SPLINES DEFORMATION AND DISTORTION OF E FIELD



Migliorare la durabilità dell'isolamento delle vene polmonari (PVI) nella PFA: integrazione tra contact sensing e sistemi di mappaggio avanzati

Pulsed Field Ablation Index–Guided Ablation for Lesion Formation: Impact of Contact Force and Number of Applications in the Ventricular Model

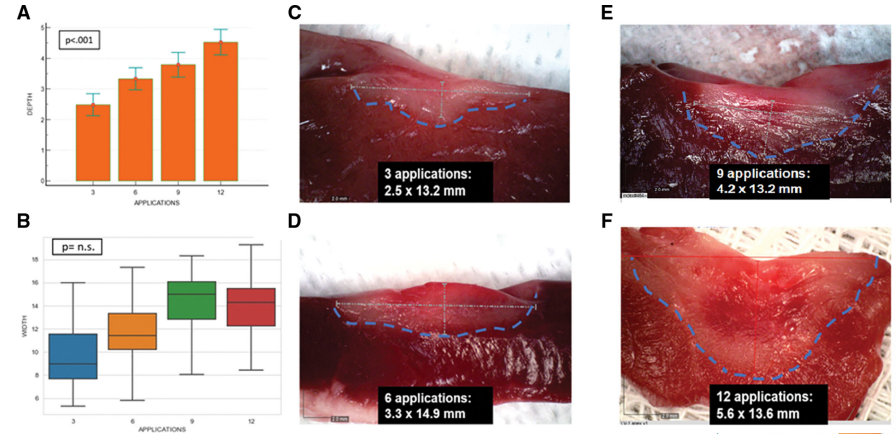
Luigi Di Biase¹, MD, PhD; Jacopo Marazzato², MD, PhD; Assaf Govari, PhD; Andreas Altman³, MS; Christopher Beeckler, BS; Joe Keyes⁴, PhD; Tushar Sharma, MD; Ylio Gruppiso, RT; Fengwei Zou⁵, MD; Masafumi Sugawara⁶, MD; Atsushi Ikeda, MD, PhD; Farshad Raissi⁷, MD, MPH; Rahul Bhardwaj⁸, MD; Jonathan C. Heu⁹, MD, MAS; Mark Lee¹⁰, MD; Rajesh Banker¹¹, MD; Sanghamitra Mohanty¹², MD; Andrea Natale¹³, MD; Qi Chen, DVM; Paras Parikh¹⁴, PhD; Xiaodong Zhang¹⁵, MD, PhD; Hiroshi Nakagawa¹⁶, MD, PhD



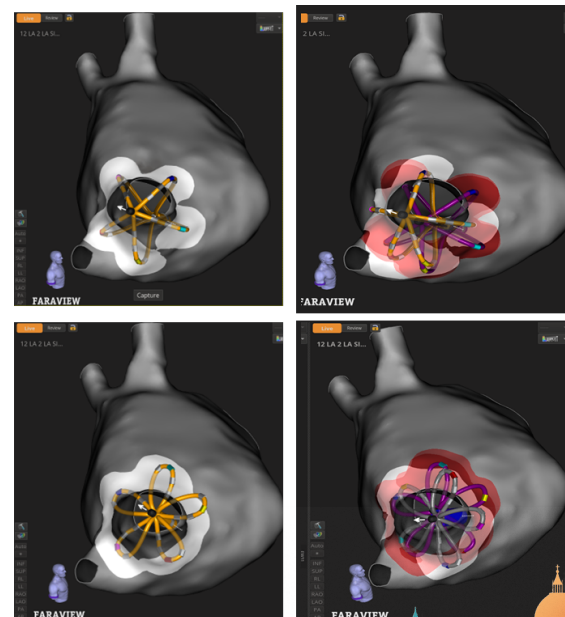
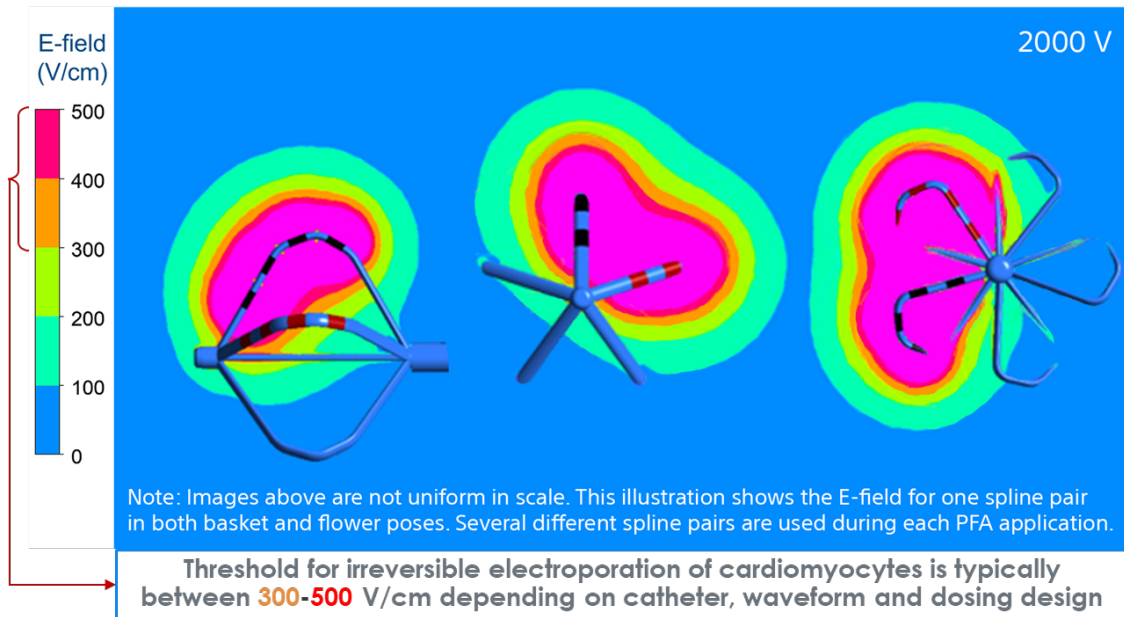
while the relationship between CF and lesion depth ($y=2.882+0.0209x$; $r^2=0.08$; $P=0.0024$) and CF and lesion width ($y=10.633+0.0422x$; $r^2=0.04$; $P=0.0043$) were weakly linearly related, the combination of the PFA

CONTACT IS ESSENTIAL AND SHOULD BE PERPENDICULAR TO THE TISSUE

DEPTH OF LESION INCREASES WITH APPLICATIONS

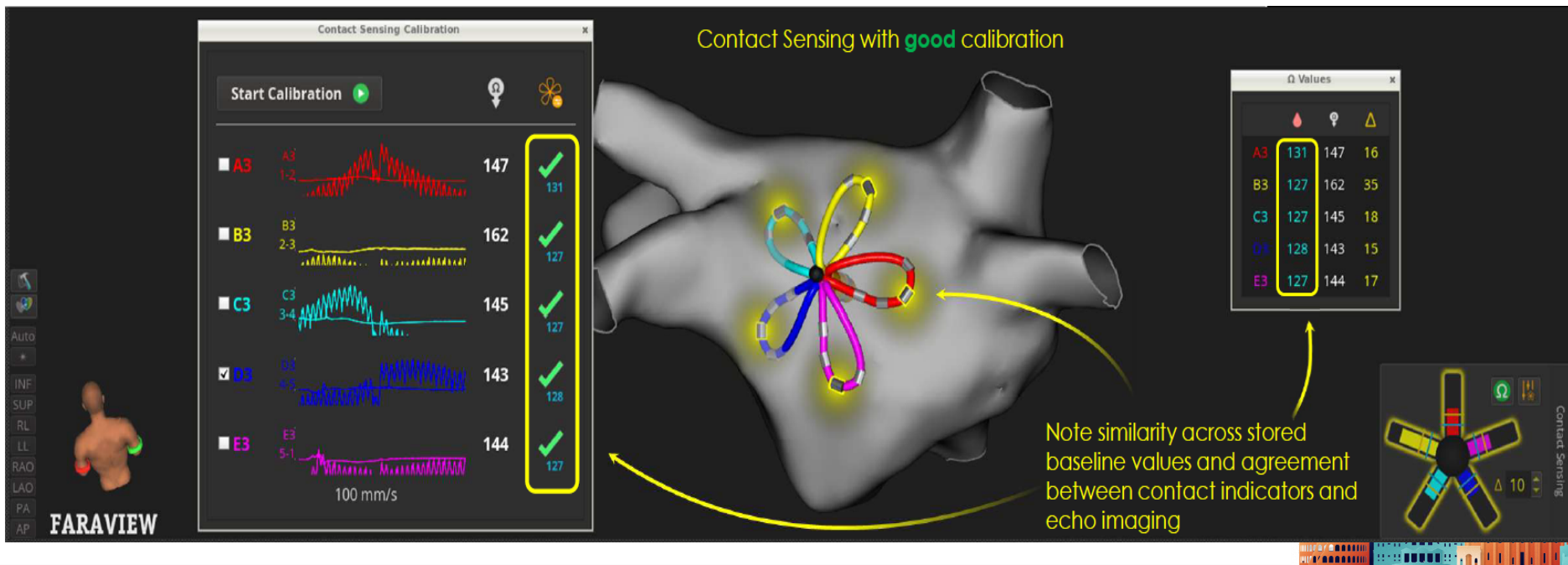


MAPPING PROXIMITY INDICATOR OF CHRONIC LESION: Intersection of the estimated PFA field volume & anatomy prior to PFA delivery



Contact Sensing: *REAL LOCAL IMPEDANCE* with FARAWAVE

Contact Sensing is an impedance-based metric that exhibits differences blood vs tissue



Contact Sensing: *REAL LOCAL IMPEDANCE* with FARAWAVE

NAVIGATE PF:

Feasibility study of FARAVIEW™

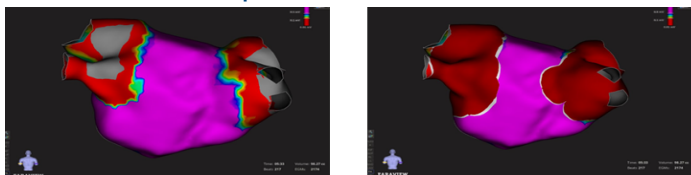
Visualization and chronic assessment of electrical field tags for pulsed field ablation of pulmonary veins with the second-generation pentaspline catheter

Authors: Vivek Y. Reddy, Ignacio Garcia Bolao, Noel Fitzpatrick, Petr Neuzil, Ramón Albarrán Rincón, Evripidis Mikos, Silvia Canepa, Tobias Oesterlein, Brendan Koop, Sarah Gutbrod, Gabor Szeplaki



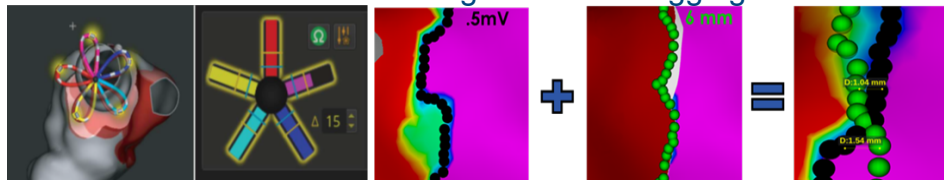
PHASE 1

To establish best practices for use of the FARAVIEW

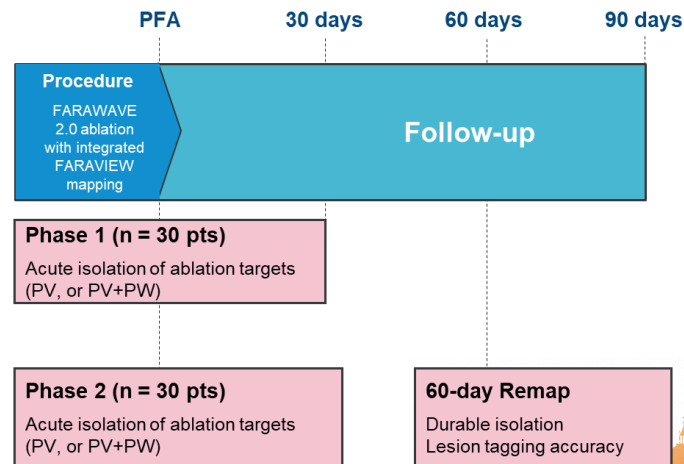


PHASE 2

To evaluate contact sensing and lesion tagging features



Study Timeline



Contact Sensing: *REAL LOCAL IMPEDANCE* with FARAWAVE

NAVIGATE PF:

Feasibility study of FARAVIEW™

Visualization and chronic assessment of electrical field tags for pulsed field ablation of pulmonary veins with the second-generation pentaspline catheter

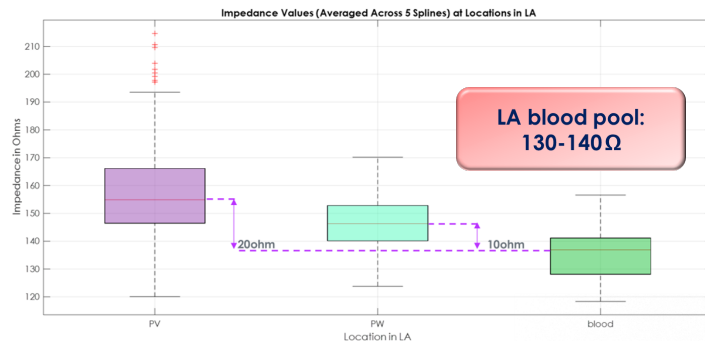
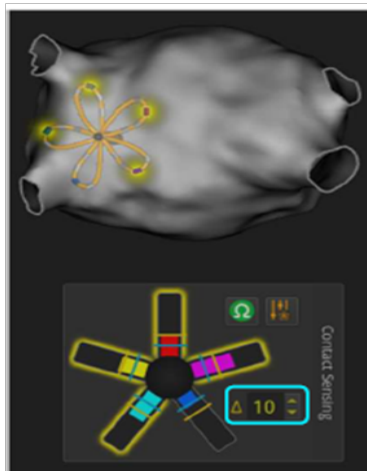
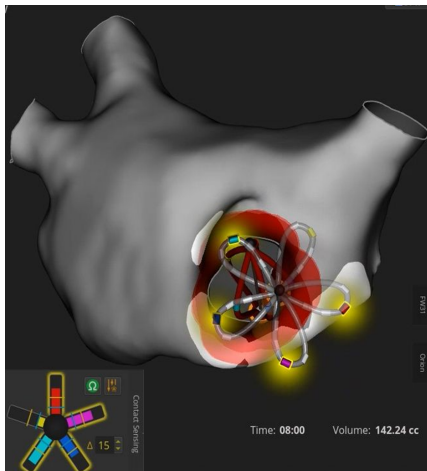
Authors: Vivek Y. Reddy, Ignacio Garcia Bolao, Noel Fitzpatrick, Petr Neuzil, Ramón Albarrán Rincón, Evripidis Mikos, Silvia Canepa, Tobias Oesterlein, Brendan Koop, Sarah Gutbrod, Gabor Szeplaki



PV contact:
 $>160 \Omega$
 $(> 15-20 \Omega \text{ blood pool})$

Posterior Wall contact:
 $>150 \Omega$
 $(> 10 \Omega \text{ blood pool})$

**Measured local impedance values
are dependent on Anatomical location**



Variability across patients is expected. Values outside this range can still be considered normal, depending on individual patient characteristics.

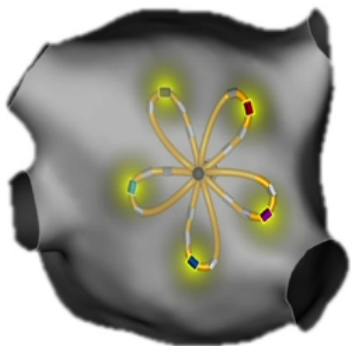


Contact Sensing: *REAL LOCAL IMPEDANCE* with FARAWAVE

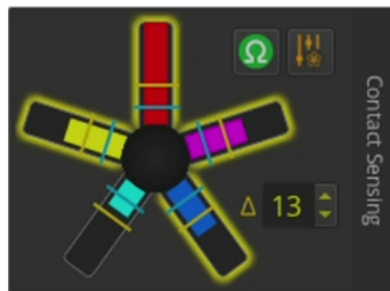
Contact Sensing GUI elements

EXAMPLE

FW Glowing Electrodes



Impedance Bar Widget



Data table

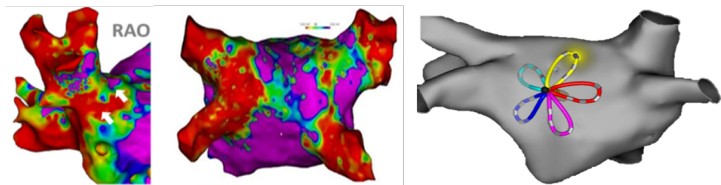
A3	127	183	56
B3	126	150	24
C3	125	131	6
D3	131	150	19
E3	127	152	25

Calibration Window

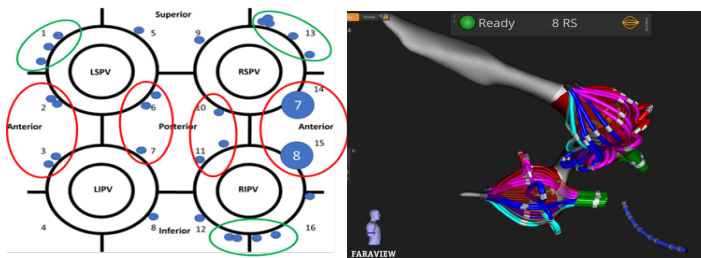


WHAT BENEFITS CAN IT BRING?

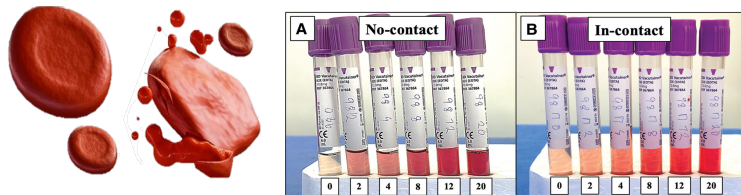
MAGGIORE EFFICACIA DI LESIONE



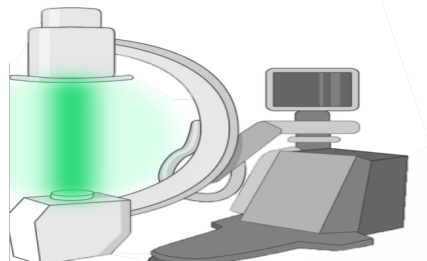
RIPRODUCIBILITA' DELLA LESIONE



MENO EMOLISI



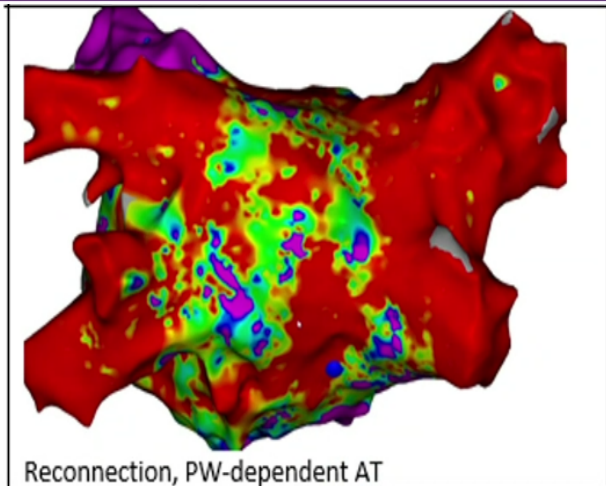
MENO X-RAY



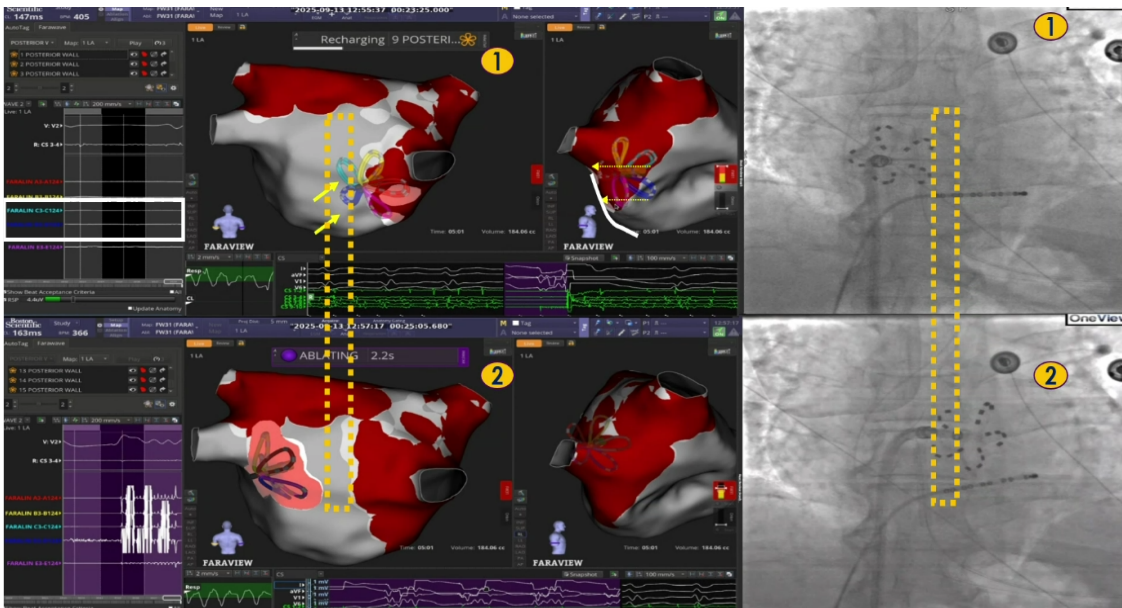
FAR FIELD IMPEDANCE

Posterior wall ablation by pulsed-field ablation: procedural safety, efficacy, and findings on redo procedures

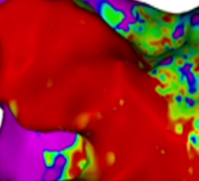
Thomas Kueffer^{1,2}, Hildegard Tanner¹, Antonio Madaffari¹, Jens Seiler¹, Andreas Haerberlin^{1,2}, Jens Maurhofer¹, Fabian Noti¹, Claudia Herrera¹, Gregor Thalmann¹, Nikola A. Kozuharov¹, Tobias Reichlin¹, and Laurent Roten^{1*}



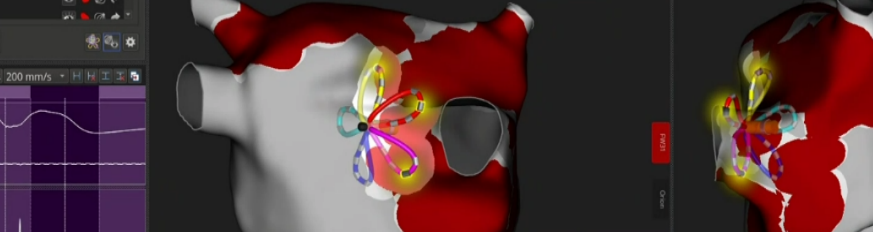
COMMON GAPS IN POSTERIOR WALL ISOLATION WITH FARAPULSE: NOT ALL SPLINES ARE IN CONTACT DURING PWI



Posterior wall ablation by pulsed-field ablation: procedural safety, efficacy, and findings on redo procedures



Reconnection, peritumoral AT



Migliorare la durabilità dell'isolamento delle vene polmonari (PVI) nella PFA: integrazione tra contact sensing e sistemi di mappaggio avanzati

Optimized Workflow for Pentaspline PFA and Its Impact on PVI Durability: Evidence From Systematic Remapping



Paroxysmal or persistent AF patients
Index PVI procedures using pentaspline PFA catheter
Fluoroscopy-only and Fluoro+EAM guided ablation
>30-day systematic remapping



No prior cardiac CT or intraprocedural imaging
Propofol-based deep sedation (Propofol)
Same-day discharge
Progressive workflow refinement (3 Phases) to increase PVI durability



118 patients enrolled, 94 remapped
PVI durability (per vein / per patient):

Phase 1: 89.8% / 60.0%
Phase 2: 92.9% / 76.5%
Phase 3: 99.2% / 96.7%

Phase 1

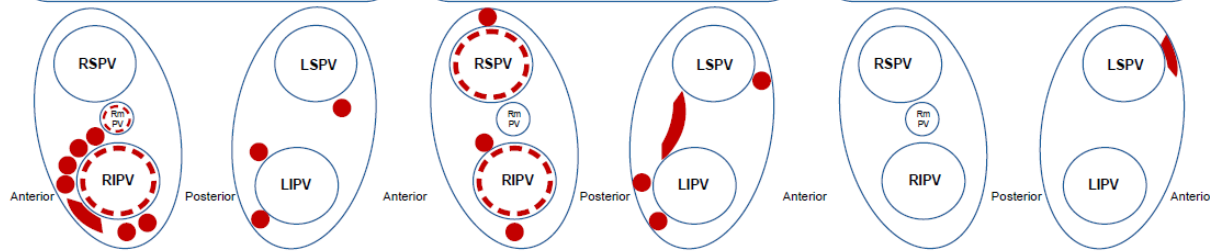
- Systematic use of orthogonal projections prior to applications
- Reference image of first application in both basket and flower configurations to guide subsequent positions covering non-treated areas
- Position stability check after each application
- Re-initiation of application pairs if suspected catheter displacement or >30 seconds since first application

Phase 2

- Additional applications to right-sided carina from both superior and inferior vein
- Sheath-catheter separation for applications in inferior PVs in flower configuration

Phase 3

- Additional applications to left-sided carina from both superior and inferior vein
- Electroanatomic mapping guidance with systematic, impedance-based assessment of planar spline distribution
- Segmental, "quadrant-guided" applications if suspected non-planar spline distribution



Optimized workflow for pentaspline PFA and its impact on PVI durability: evidence from systematic remapping

Daniel Rodríguez-Muñoz ^{1,2*}, Lucía Cobarro Gálvez ^{1,2}, Ez Aldin Rajjoub Al-Mahdi ^{1,2}, Isabel López-Alacid ^{1,2}, Javier Ramos Jiménez ^{1,2}, Álvaro Marco del Castillo ^{1,2}, Luis Borrego Bernabé ^{1,2}, Martín Negreira Caamaño ^{1,2,3}, Lorena Gómez Burguño ^{1,2}, Fernando Arribas Ynsaurriaga ^{1,2,4,5}, and Rafael Salguero-Bodes ^{1,2,4,5}



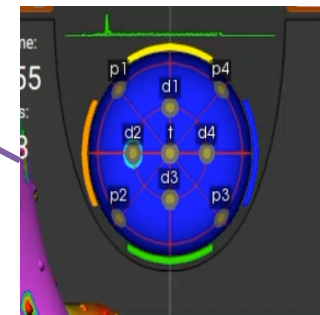
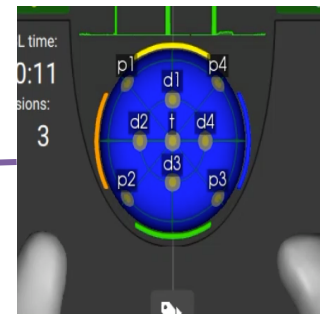
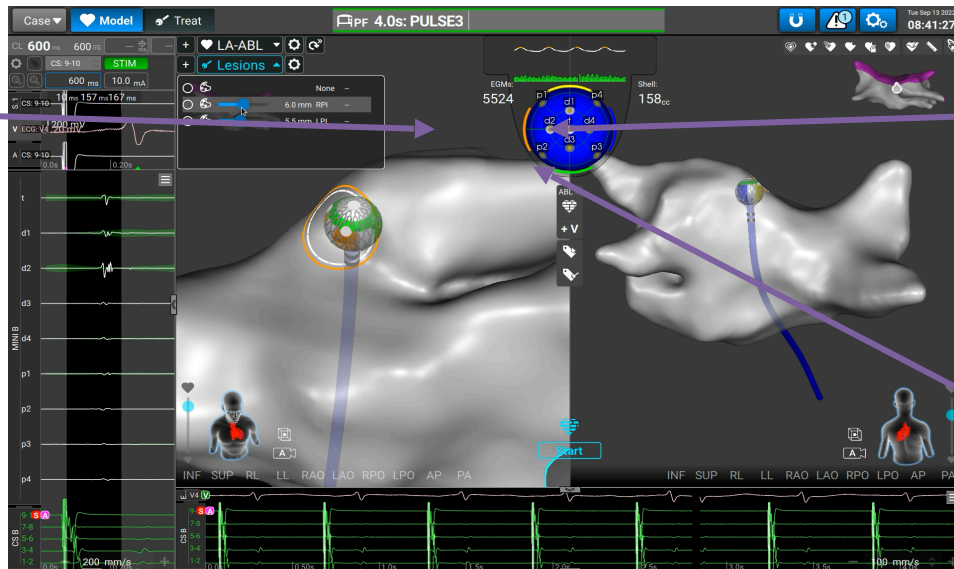
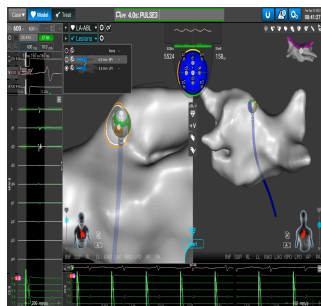
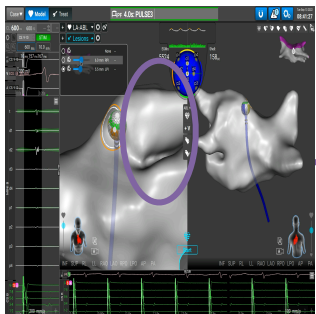
Migliorare la durabilità dell'isolamento delle vene polmonari (PVI) nella PFA: integrazione tra contact sensing e sistemi di mappaggio avanzati

Affera™ Prism-1 Mapping System Software - Features and Functionality

- Local impedance can provide an indication of electrode proximity and orientation

Local Impedance and Temperature Measurements

- Temperature information from each electrode represented with color gradient



PF

RF

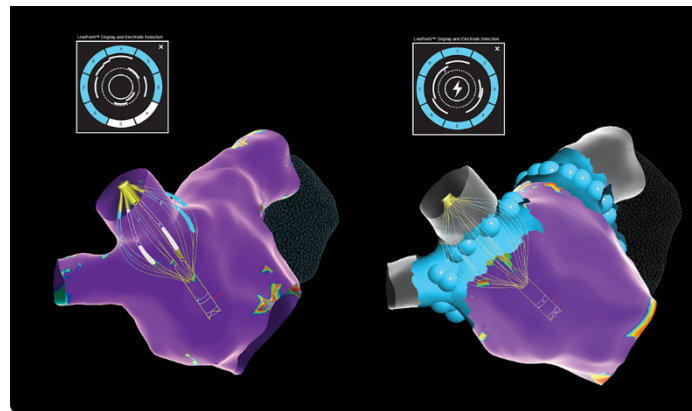
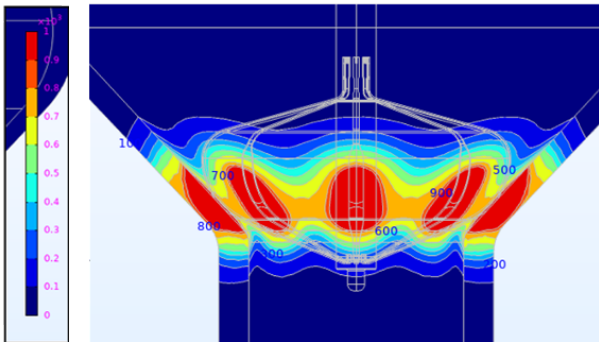


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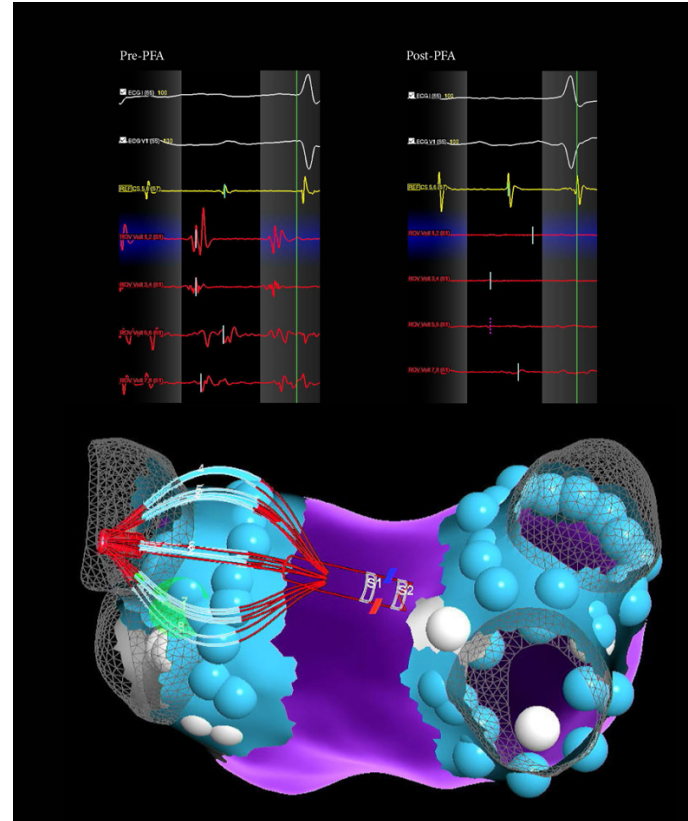
Delivers targeted lesion sets where it matters with an 8-spline balloon-in-basket design that conforms to anatomy and creates a wide-band lesion² for fewer repositions

Gain real-time procedural insight with elegant impedance-based contact visualization through AutoMark and eField integration for precise lesion tracking^{3,4}



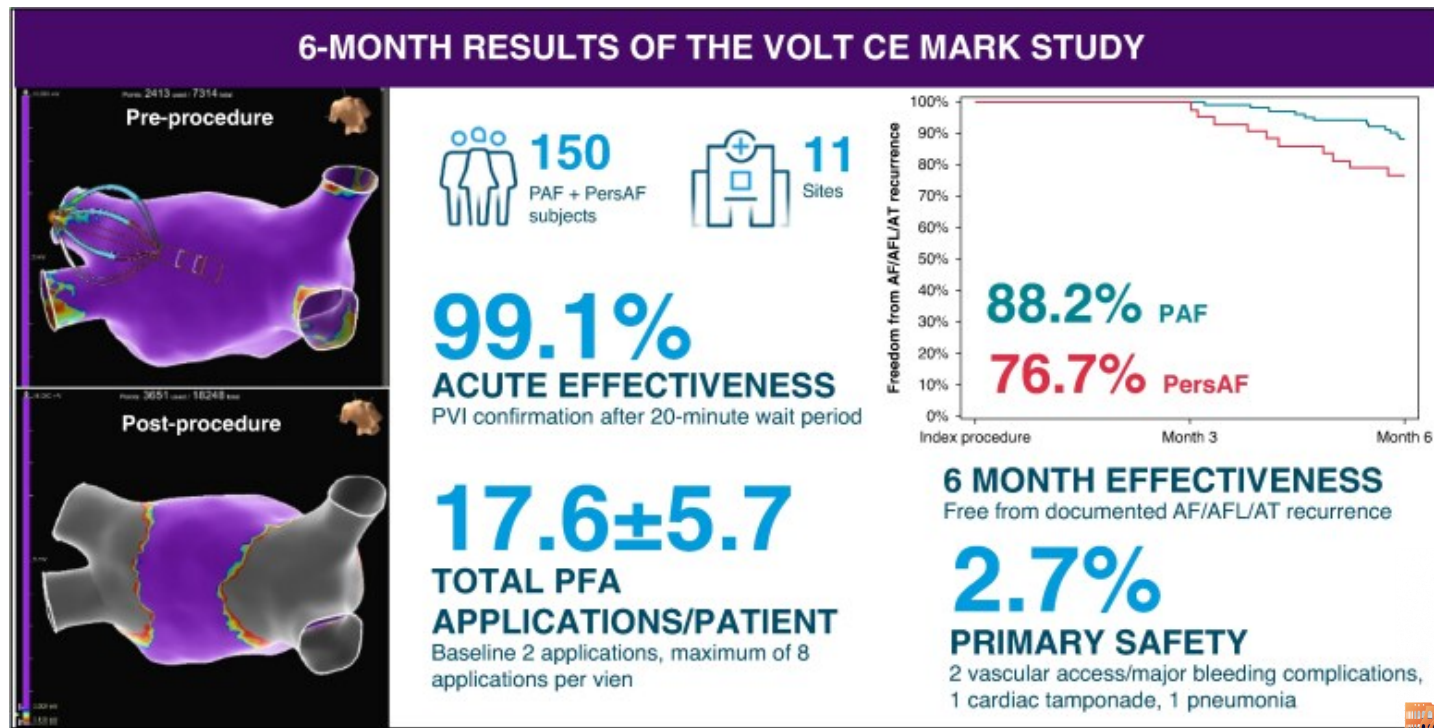
Migliorare la durabilità dell'isolamento delle vene polmonari (PVI) nella PFA: integrazione tra contact sensing e sistemi di mappaggio avanzati

Enables a single-catheter **workflow** for mapping, pacing, and ablating, minimizing catheter exchanges



Migliorare la durabilità dell'isolamento delle vene polmonari (PVI) nella PFA: integrazione tra contact sensing e sistemi di mappaggio avanzati

Safety and effectiveness of the first balloon-in-basket pulsed field ablation system for the treatment of atrial fibrillation: VOLT CE Mark Study 6-month results



Migliorare la durabilità dell'isolamento delle vene polmonari (PVI) nella PFA: integrazione tra contact sensing e sistemi di mappaggio avanzati

ORIGINAL RESEARCH

ATRIAL FIBRILLATION

PVI With CF-Sensing Large-Tip Focal PFA Catheter With 3D Mapping for Paroxysmal AF

Omny-IRE 3-Month Results

CENTRAL ILLUSTRATION: Summary of the Omny-IRE 3-Month Results

Omny-IRE 3-Month Results: PVI With a CF-Sensing, Large-Tip Focal PFA Catheter With 3D Mapping Showed High Acute Success and PVI Durability With a Promising Safety Profile in the Treatment of Paroxysmal AF

Study Design

- 18-75 years of age
- Symptomatic paroxysmal AF



13 Centers in Europe & Canada

21 Operators



136 Patients^a

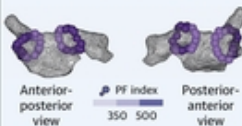
59.8 years, 69.1% male,
1.6 CHA₂DS₂-VASc score

Primary endpoints

- Safety^b: PAEs
- Effectiveness: acute PVI



Ablation Procedure



Target PF index: anterior, 550;
posterior, 400-450
ITD: anterior, ≤6 mm; posterior, ≤9 mm^c

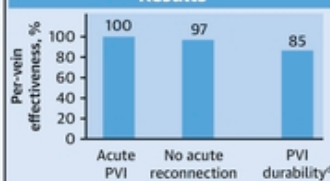
Additional safety assessments (up to 3 months)^b:

- Neurological assessment
- Esophageal endoscopy
- Cardiac CT/MRA

PVI durability assessment (75 days):

- Remapping procedure

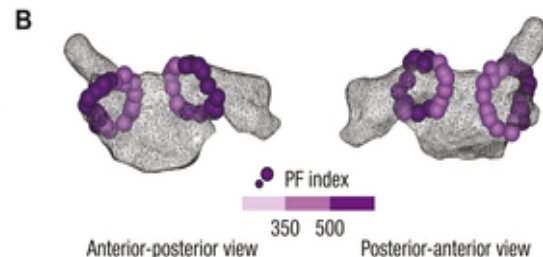
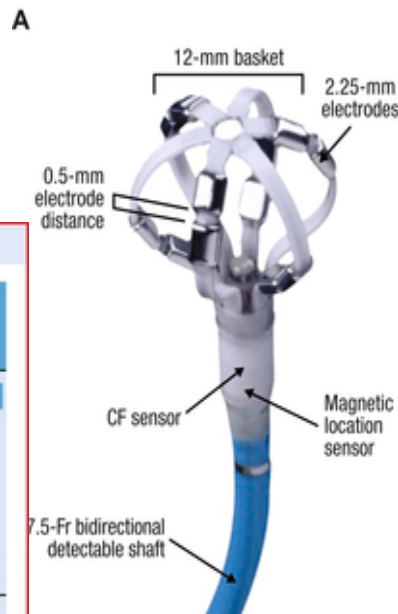
Results



5.0 min Median fluoroscopy time
176 sec Median PFA time^e

Safety

- 3.0% PAEs
- 3 vascular access complications
- 1 pericarditis
- 0 severe PV stenosis
- 0 esophageal injuries
- 1 asymptomatic SCE



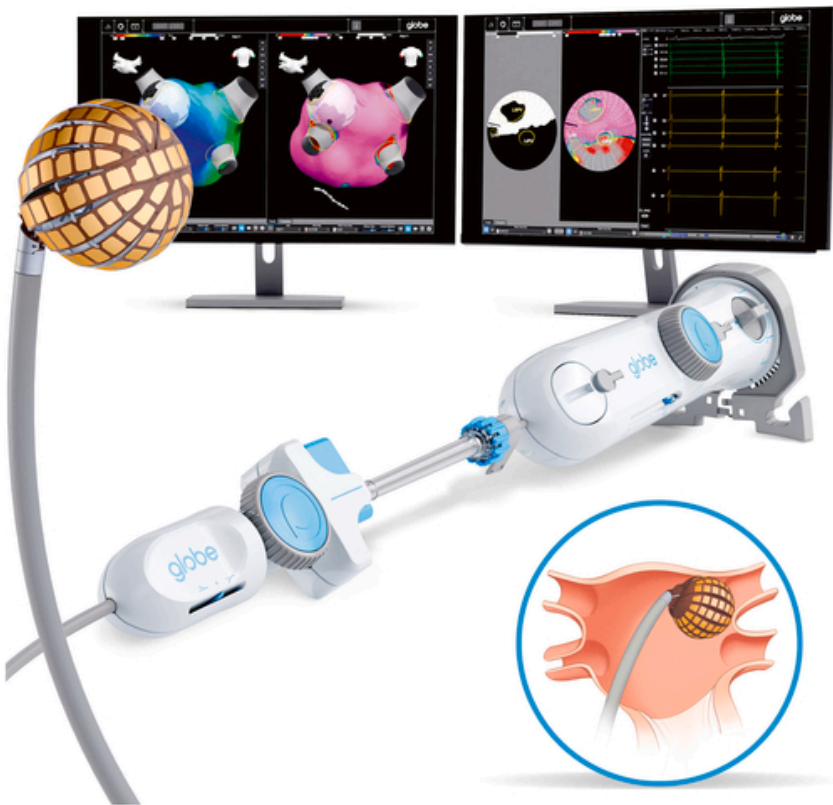
Parameter	Initial workflow settings (n = 28)		Optimized workflow settings (n = 108)	
	Anterior	Posterior	Anterior	Posterior
Intertag distance	≤9 mm		≤6 mm	≤9 mm
Recommended target PF index	550	400	550 (if <500, reablate on the same spot with greater force)	400-450
Force range for ablation	20-50 g		>35 g	>25 g
Additional guidance	If force could not be achieved without sheath support, the sheath was advanced to the proximal portion of the basket and the maximum number of applications (12) were delivered			

The workflow was updated after 28 patients to improve reaching the target index. Reliable force measurements and PF index calculations require adequate distance from the proximal portion of the basket.

Duytschaever M, et al. JACC Clin Electrophysiol. 2025;11(8):1769-1782.

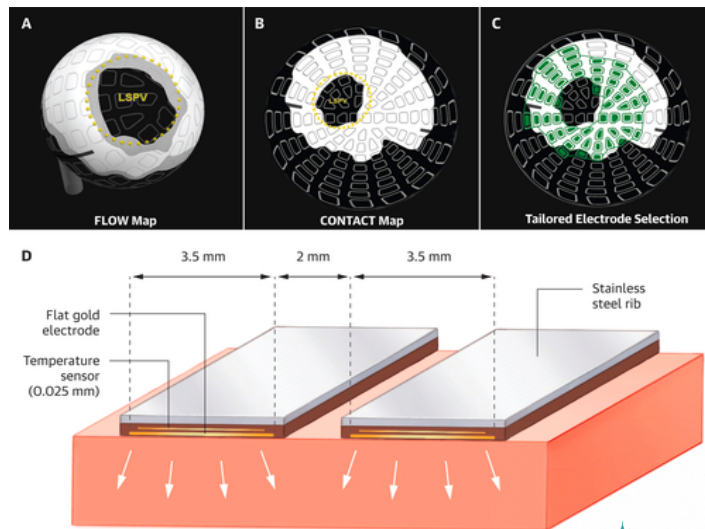


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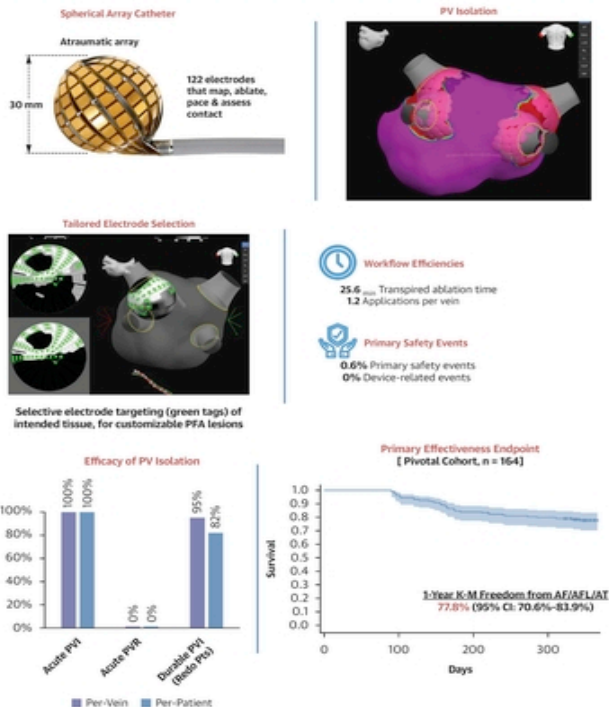
Pulsed-Field Ablation to Enhance the Durability of Pulmonary Vein Isolation and Treat Paroxysmal Atrial Fibrillation

Vivek Y. Reddy, MD,^a Hans Kottkamp, MD,^b Hugh Calkins, MD,^c Devi G. Nair, MD,^d Philipp Sommer, MD,^e Ayman A. Hussein, MD,^f Burghard Schumacher, MD,^g Srinivas Dukkipati, MD,^h Petr Neuzil, MD, PhD,^g Saumil Oza, MD,^h Christopher Woods, MD, PhD,^h Marc W. Deyell, MD, MSc,ⁱ Jose Osorio, MD,^k Atul Verma, MD,^l the PULSAR Investigators



Migliorare la durabilità dell'isolamento delle vene polmonari (PVI) nella PFA: integrazione tra contact sensing e sistemi di mappaggio avanzati

CENTRAL ILLUSTRATION: The Multielectrode Spherical Array PFA Catheter in PULSAR



Reddy VY, et al. JACC. 2026;87(14):1747-1761.

Pulsed-Field Ablation to Enhance the Durability of Pulmonary Vein Isolation and Treat Paroxysmal Atrial Fibrillation

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CONCLUSIONI

L'integrazione del sistema di mappaggio con il contact sensing:

- ✓ Migliora la durabilità delle lesioni
- ✓ Riduce il numero di erogazioni «inefficaci»
- ✓ Aumenta la sicurezza procedurale
- ✓ Aumenta la riproducibilità delle lesioni

