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**CONTEMPORARY TRENDS AND WORKFLOWS IN PULSED FIELD
ABLATION: THE ALLINA HEALTH MINNEAPOLIS HEART INSTITUTE
EXPERIENCE COMPARED TO THE CCB GERMAN EXPERIENCE :
SIMILARITIES AND DIFFERENCES**

- Julian Chun, MD
- Boris Schmidt, MD
- Jay Sengupta, MD
- Edwin Zishiri, MD

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Discussion outline

- Historical perspective for AF ablation and techniques and literature.
- Overview of PFA programs and current procedural volumes at each center
- Patient selection and referral patterns
- Procedural workflow, technology platforms, and ablation strategies with a focus on workflow for AF ablation in Germany and how that differs from typical practice in the United States.
- Clinical outcomes, safety, and complication management
- Challenging cases, lessons learned, and practical pearls.
- Discussion about choosing PFA form factors and platforms and the evidence behind each system.
- Ongoing research initiatives and opportunities for future collaboration



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Historical Perspective

MODIFICATION OF THE MAZE PROCEDURE FOR ATRIAL FLUTTER AND ATRIAL FIBRILLATION
I. Rationale and surgical results

The original maze procedure was described for the treatment of patients with atrial fibrillation who had an unacceptable incidence of two problems: (1) the frequent inability to generate an appropriate sinus tachycardia in response to maximal exercise and (2) occasional left atrial dysfunction. In an effort to overcome these problems, we modified the original technique (maze I) twice. The results of these modifications culminated in the maze III procedure, which is associated with a higher incidence of postoperative sinus rhythm, improved long-term sinus node function, fewer pacemaker requirements, less arrhythmia recurrence, and improved long-term atrial transport function. In addition, the maze III procedure is technically less demanding than either the maze I or maze II procedure. Therefore, the maze III procedure is now the technique of choice for the management of medically refractory atrial fibrillation. (J THORAC CARDIOVASC SURG 1995;110:473-84)

James L. Cox, MD, John P. Boineau, MD, Richard B. Schuessler, PhD, Robert D. St. Jacques, MD, and Frederick C. Lipman, MD, St. Louis, Mo.

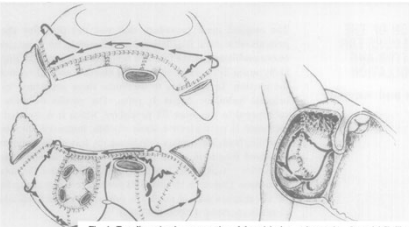


Fig. 1. Two-dimensional representation of the original maze I procedure for atrial fibrillation. In the left panel, the atria are depicted as if viewed from the posterior direction with the back of both atria in the lower panel. The atria are then divided in a sagittal plane and the anterior half of the atria are "flipped" up in the upper panel. The right panel shows the surface of the right atrial septum. Both atrial appendages are excised and the pulmonary veins are isolated. Appropriately placed atrial incisions not only interrupt the conduction routes of the most common reentrant circuits, but they also direct the sinus impulse from the SA node to the atrioventricular node along a specified route. The entire atrial myocardium (except for the atrial appendages and pulmonary veins) is electrically activated, which preserves postoperative atrial transport function. (From Cox JL, Fishback Applications of the Maze Procedure for Atrial Fibrillation [Invited Editorial]. Reprinted with permission from The Society of Thoracic Surgeons. Ann Thorac Surg 1995;55:578-80.)

SPONTANEOUS INITIATION OF ATRIAL FIBRILLATION BY ECTOPIC BEATS ORIGINATING IN THE PULMONARY VEINS

Michel Haissaguerre, M.D., Pierre Jais, M.D., Denis C. Shah, M.D., Arthur Tassabehji, M.D., Muelzer Hohn, M.D., Gilles Quinon, M.D., Stéphane Garrigue, M.D., Alain Le Mourou, M.D., Philippe Le Maitre, M.D., and Jacques Clementy, M.D.

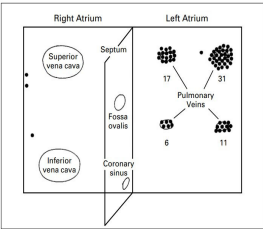
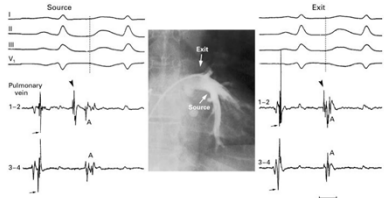


Figure 1. Diagram of the Sites of 60 Foci Triggering Atrial Fibrillation in 45 Patients. Note the clustering in the pulmonary veins, particularly in both superior pulmonary veins. Numbers indicate the distribution of foci in the pulmonary veins.

Haissaguerre, M et al. "Spontaneous initiation of atrial fibrillation by ectopic beats originating in the pulmonary veins." The New England journal of medicine vol. 339,10 (1998)



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AF Technology Evolution

1998

Source

Exit

Pulmonary vein

1-2

3-4

RF Catheter technologies:

- Closed Irrigation RF
- Open Irrigation RF 2001
- Contact Force Sensing catheters RF 2014
- Flexible tip Irrigated catheter RF 2016
- DiamondTemp Ablation System RF 2020
- Upgraded Platinum tipped RF catheters to Diamond tipped RF catheters
- Improved Heat Transfer
- Devastated EP Lab cost per case
- High Density Mapping catheters
- PentaRay, OctaRay, HD

Mapping System Technologies

- Biosense CARTO
- EnSite NAVx
- Boston Scientific Rhythmia
- ToperaMedical RhythmView (defunct/disgraced)

Ablation Systems

- RF systems by multiple vendors
- CryoAblation (ArcticFront, POLARx)
- LaserBalloon (HeartLight X3)
- High Intensity Focused Ultrasound (PhoRhythm)

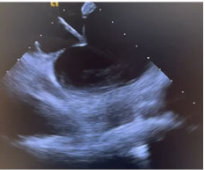
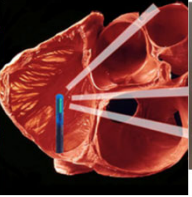
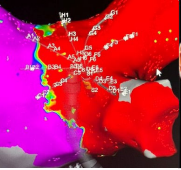
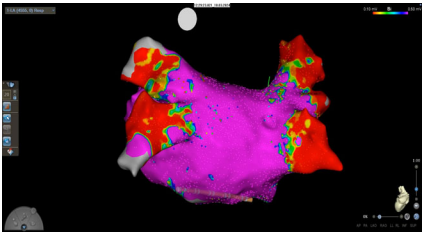
Present

Electro-anatomic Mapping

Imaging

Catheter form factors

Ablation technology



Haissaguerre, M et al. "Spontaneous initiation of atrial fibrillation by ectopic beats originating in the pulmonary veins." *The New England Journal of medicine* vol. 339,10 (1998)

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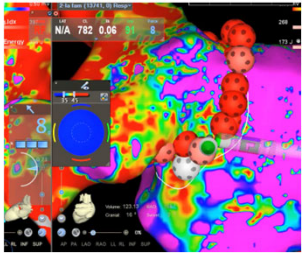
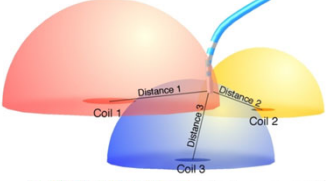
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Diagnostics: 3D Mapping

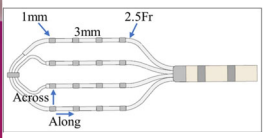
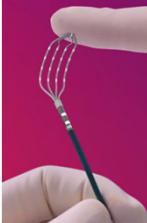
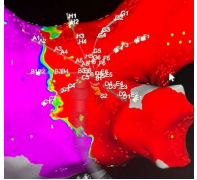
Mapping Systems



Magnetic Fields and Sensors



Mapping Catheters



Indian Pacing Electrophysiol J. 2008 Feb 1;8(1):32-50.

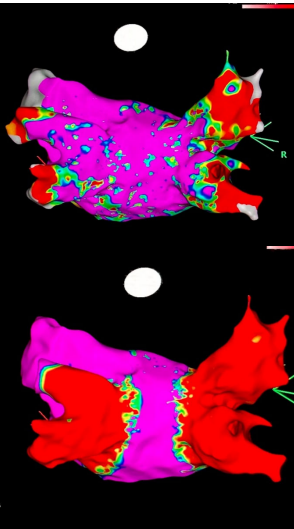
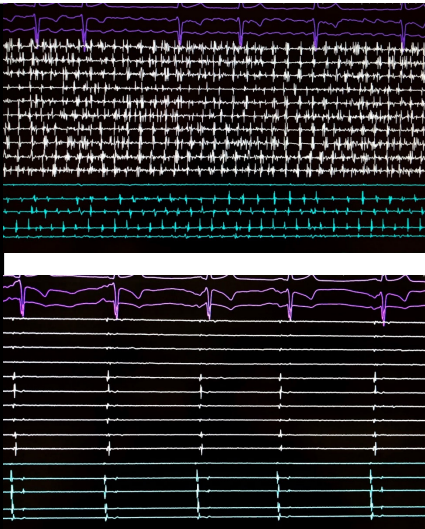
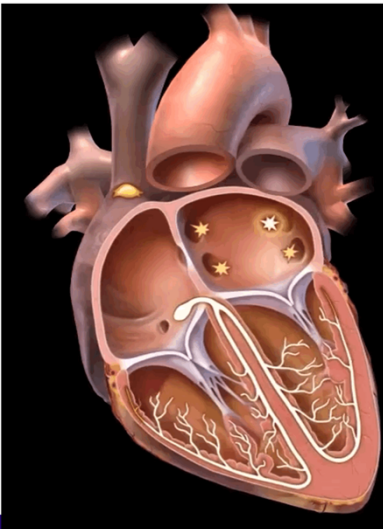
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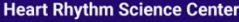
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Atrial Anatomy and Pathophysiology relevant to AF ablation



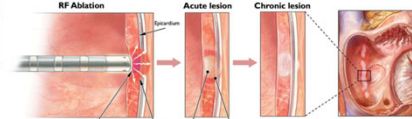
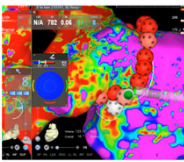
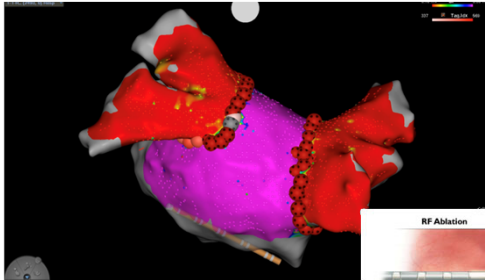


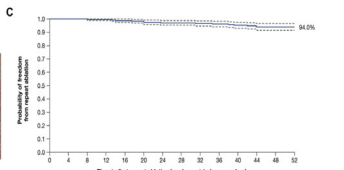
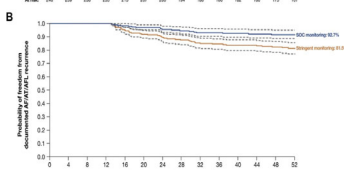
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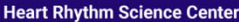
RF Ablation Success

- Ablation index
 - Incorporates contact force, power, and time as an objective surrogate marker of ablation lesion quality

- At 12 months, freedom from documented AF/AFL/AT
 - 93% per standard-of-care monitoring







Di Biase L, Monir G, Melby D, Tabareaux P, Natale A, Mamyry H, Athill C, Delgaster C, Patel A, Gentilek P, Liu C, Arkins J, McSherry HT Jr, Osorio J, SubPOINT Postoperative Trial Investigators. Composite Index Tagging for PVI in Paroxysmal AF: A Prospective, Multicenter Postoperative Study. JACC Clin Electrophysiol. 2022 Sep 6;9(9):1077-1089.

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Who should have early rhythm control strategy with ablation?

- Patients with **symptoms** related to atrial fibrillation despite adequate rate control
 - If asymptomatic, consider early cardioversion and revisit
- Patients with **LV dysfunction and congestive heart failure** that may be tachycardia-mediated or afib-mediated cardiomyopathy
- **Younger patients to prevent comorbidity**
 - Prevent progression
- Patients on **anti-arrhythmic drug therapy with side effects**
- Patients with **bradycardia limiting medical therapy**; ablation may defer need for permanent pacing



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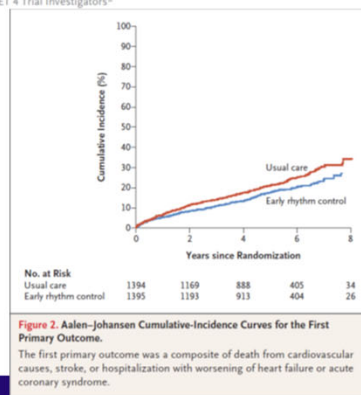
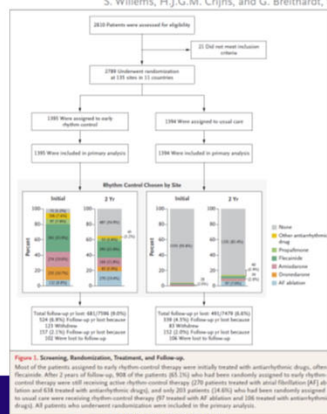
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The NEW ENGLAND
JOURNAL of MEDICINE

ESTABLISHED IN 1812
OCTOBER 1, 2020
VOL. 383 NO. 14

Early Rhythm-Control Therapy in Patients with Atrial Fibrillation

P. Kirchhof, A.J. Camm, A. Goette, A. Brandes, L. Eckardt, A. Elvan, T. Fetsch, I.C. van Gelder, D. Haase, L.M. Haegeli, F. Hamann, H. Heidbüchel, G. Hindricks, J. Kautzner, K.-H. Kuck, L. Mont, G.A. Ng, J. Rekosz, N. Schoen, U. Schotten, A. Suling, J. Taggeselle, S. Themistoclakis, E. Vettorazzi, P. Vardas, K. Wegscheider, S. Willems, H.J.G.M. Crijns, and G. Breithardt, for the EAST-AFNET 4 Trial Investigators*



The trial was stopped for efficacy at the third interim analysis after a median of 5.1 years of follow-up per patient. A first-primary-outcome event occurred in 249 of the patients assigned to early rhythm control (3.9 per 100 person-years) and in 316 patients assigned to usual care (5.0 per 100 person-years) (hazard ratio, 0.79; 96% confidence interval, 0.66 to 0.94; $P=0.005$).



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2023 Expert Guidelines

New: Catheter ablation of AF as first-line therapy in selected patients →

Recommendations for AF Catheter Ablation Referenced studies that support the recommendations are summarized in the Online Data Supplement.		
COR	LOE	Recommendations
1	A	1. In patients with symptomatic AF in whom anti-arrhythmic drugs have been ineffective, contraindicated, not tolerated or not preferred, and continued rhythm control is desired, catheter ablation is useful to improve symptoms. ^{1–10}
1	A	2. In selected patients (generally younger with few comorbidities) with symptomatic paroxysmal AF in whom rhythm control is desired, catheter ablation is useful as first-line therapy to improve symptoms and reduce progression to persistent AF. ^{11–16}



José A. Joglar. Circulation. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation. DOI: (10.1161/CIR.0000000000001193)
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Despite good ablation techniques there are still challenges with recurrent atrial arrhythmias

- Pulmonary vein reconnection
- Arrhythmia Variants
- Atrial Substrate
 - Different phenotypes
 - Atrial myopathy
 - Isolated or related to concomitant cardiac disease including valvular or HFpEF or cardiomyopathy
- Atrial Fibrillation Progression
 - Patient-specific risk factors
 - Lifestyle and Genetics



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Electroporation

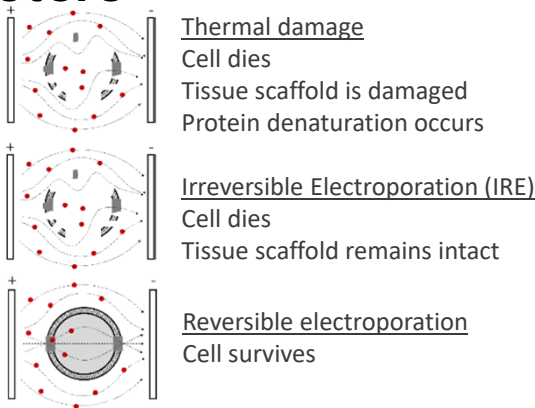
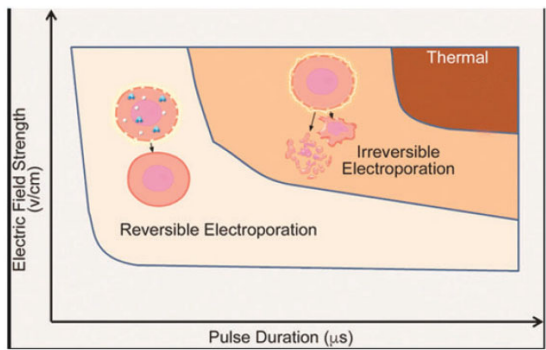
- Non-thermal energy that limits collateral damage
- DC power supply to charge capacitors
 - Discharged, or pulsed, with the help of a high voltage switch
- Delivered between two or more electrodes creating an electric field
- Pulses are in nano- to millisecond range
- Voltage applied in the range of hundred to tens of kilovolts
- Electric field orientation can be monopolar, bipolar, or omnipolar



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Electroporation “zone” depends on electric pulse parameters



- Each zone has distinct effects on target tissue
- Sugrue, A., Maor, E., Del-Carpio Munoz, F., Killu, A. M., & Asinvaltham, S. J. (2022). Cardiac ablation with pulsed electric fields: principles and biophysics. EP Europace.



Basics of Pulsed Field Ablation | Medtronic CAS | August 2023

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Pulsed field ablation and irreversible electroporation

Pulsed field ablation

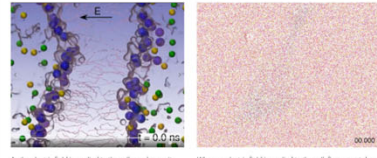
The use of pulsed electric fields to ablate cardiac tissues, through the mechanism of irreversible electroporation.



PulseSelect PFA catheter

Irreversible electroporation

The mechanism of killing tissue through exposure to high electric field gradients that induce a permanent, hyper-permeabilization of the cell membranes, leading to cell death.



As the electric field is applied to the cell membrane, it becomes permeabilized.

When an electric field is applied to the cell, fluorescent dye enters the cell due to permeabilization. The cell is visualized seconds after exposure to electric field.

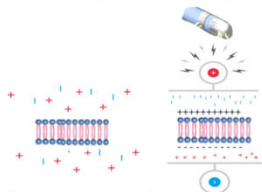
Image courtesy of Medtronic and Prof. Subbotin, University of California. For Research purposes only.

8 PulseSelect™ PFA system APP training | June 2024

Medtronic

Principle of Pulsed Field Ablation (PFA)¹

- Delivery of a **sub-second burst of high-voltage direct current pulses** (microseconds) through the electrode(s) of a catheter creating a **high intensity electric field**
- When the transcellular electrical field is above the **tissue-specific threshold**, nanopore formation will occur



Cellular impact depends on pulse amplitude & duration

Time	Effect
t=0.5ms	No pores form (subclinical effect)
t=40ms	Transient pores form (reversible)
t=10s	Pores form and trigger cell death (irreversible)

Pre-treatment | **Pulse Delivery** | Time

J&J MedTech Electrophysiology 4

Non-thermal energy that limits collateral damage

DC power supply to charge capacitors which are discharged, or pulsed, with the help of a high voltage switch

Delivered between two or more electrodes creating an electric field

Pulses are in nano- to millisecond range

Voltage applied in the range of hundred to tens of kilovolts

Electric field orientation can be monopolar, bipolar, or omnipolar

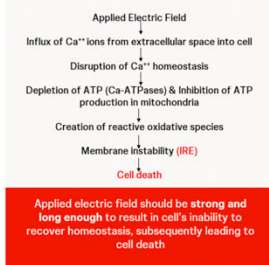
Sugrue, A., Maor, E., Del-Carpio Munoz, F., Killu, A. M., & Asirvatham, S. J. (2022). Cardiac ablation with pulsed electric fields: principles and biophysics. EP Europace.



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Technology Presentation
System with SpH

Mechanism of Cell Death with PFA^{2,3}



Cell death

Applied electric field should be **strong and long enough** to result in cell's inability to recover homeostasis, subsequently leading to cell death.



PFA*

Apoptosis, necrosis, necroptosis



RF

Coagulative necrosis (due to lack of blood supply)



Cryo

Direct cell injury and vascular injury, leading to necrosis

*There is some variability in the cell death mechanism depending on the parameters of the electric field applied

J&J MedTech Electrophysiology 5

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Case presentation MHI

- 62 year-old female with atrial fibrillation and typical atrial flutter
 - Diagnosed 2010
 - Treated with sotalol and subsequently underwent complex RFA ablation in 2016 with pulmonary vein antral isolation and CTI line ablation
 - Recurrent arrhythmias in 2018 with restoration of PV isolation and atypical atrial flutter ablation (LA roof)
 - Comorbidities include hypertension, obesity, obstructive sleep apnea
- Recurrent arrhythmia 12/2021
- Transitioned to dofetilide for anti-arrhythmic therapy
- Recurrent atypical atrial flutter in 2024



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ECG



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Ablation 1/11/24

- SF Smart Touch ablation catheter with Octaray multielectrode mapping
- Ablation strategy to re-isolate right sided pulmonary veins and fortify roof line, elimination of complex fractionated electrograms LA septum
- High energy, short duration lesions
- Avoid esophageal injury and phenic nerve injury with anatomical assessment, temperature monitoring, pacing maneuvers

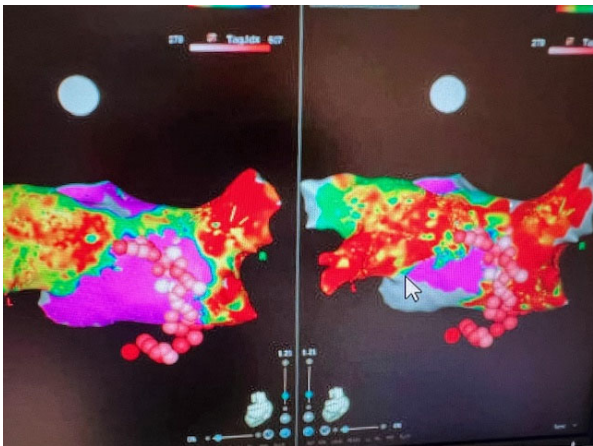


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AF Ablation challenges

- Over they years multiple procedures and operators with RFA
- Pulmonary veins and thick tissue often require repeat ablation
- Progression of atrial myopathy and underlying substrate
- Additional linear and focal lesions necessary to treat subsequent arrhythmia mechanisms



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Recurrent Arrhythmia

- From PCP:
 - “She is frustrated that she keeps going into atrial flutter. She is very sensitive to the rapid heart rate, especially if she gets above 120 bpm. She does not feel safe walking up a flight of stairs because she becomes winded. She feels that some of her doctors are giving up on her because she has been told that there might not be much else they can do for her atrial arrhythmias.”
- Ablation 10/17/2024
 - Successful ablation of roof-dependent left atrial atypical atrial flutter using an epicardial substrate requiring deep ablation along posterior aspect of the roof near the RSPV
 - Atrial flutter repeatedly terminated with ablation but re-inducible; given inability to get deeper lesions, broaden linear ablation but limited by esophageal proximity.



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Recurrent Arrhythmia within 2 months

- Options
 - RF ablation options exhausted
 - Anti-arrhythmic options are limited and fraught with side effects and toxicity
 - Pacing (conduction system versus CRT) and AVJ ablation
 - PFA
 - Would this system be able to identify complex arrhythmia circuit?
 - Would PFA be effective where RFA has repeatedly failed?



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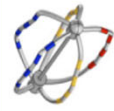
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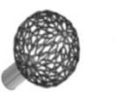
(A) Penta-spline basket



(B) Circular catheter



(C) Nitinol 9 mm sphere



(D) Nitinol large 1-shot sphere



(E) Flexible splines



(F) Balloon







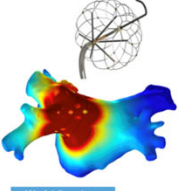




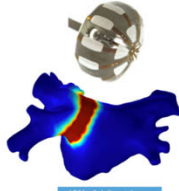




High energy catheter with broad delivery



Low energy catheter with targeted delivery



1% of delivered power goes into target



15% of delivered power goes into target



computer models

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Pulsed Field Ablation to Treat Paroxysmal Atrial Fibrillation: Safety and Effectiveness in the AdmiRE Pivotal Trial

Vivek Y. Reddy, MD; Hugh Calkins, MD; Moussa Mansour, MD; Oussama Wazni, MD; Luigi Di Biase, MD, PhD; Marwan Bahu, MD; David Newton, MD; Christopher F. Liu, MD; William H. Sauer, MD; Sandeep Goyal, MD; Vivek Iyer, MD; Devi Nair, MD; Charles Athill, MD; Ayman Hussein, MD; Patrick Whalen, MD; Daniel Melby, MD; Andrea Natale, MD; on behalf of the AdmiRE Trial Investigators

Circulation. 2024;150:1174–1186. DOI: 10.1161/CIRCULATIONAHA.124.070333

Minneapolis Heart Institute,
Minneapolis, MN

Daniel Melby

Jay Sengupta

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Figure 1. Patient disposition.
Patient flow chart for both the pilot and pivotal phases. mITT indicates modified intention-to-treat; and PP, per protocol.

Figure 2. Kaplan-Meier estimates of effectiveness outcomes.
Kaplan-Meier estimates for 12-month freedom from primary effectiveness end point (PEE) failure (A), atrial fibrillation/atrial tachycardia/atrial flutter (AF/AT/ATFL) recurrence (B), AF/AT/ATFL recurrence off class I or II antiarrhythmic drugs (AADs) (C), and repeat ablation (D).

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FARAPULSE has Over a Decade of PFA Development for AF Ablation

Pre-Clinical
~800 Pre-Clinical Subjects
Prototyping, Testing, Device Iteration

Clinical
~150 Clinical Patients
IMPULSE, PERCAT & PERCAT II

Commercial Experience
>125,000 Global Patients

NAVIGATE-PF
FDA Approval
MANIFEST-17K Results
ADVENT Results
ADVANTAGE First Patient Enrolled
ADVENT CE Mark
First Patient Enrolled

Achieving 96% durable PVI* required optimizing the waveform AND dosing

FARAPULSE Optimized Biphasic - 96% PVI Durable Isolation at ~3 months*			
Cohort	N	Acute PVI (% PVI)	Durable PVI (% PVI)
Monophasic General anesthesia & paralytics	11	100%	85%
Biphasic Waveform eliminated need for GA	55	100%	94%
Optimized Biphasic	44	100%	96%

*% of individual veins isolated, based on HD mapping at ~3 months

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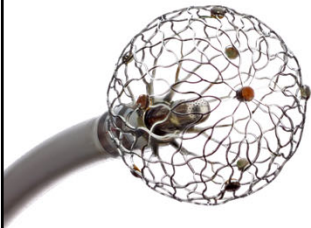
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All-in-one Sphere-9™ catheter

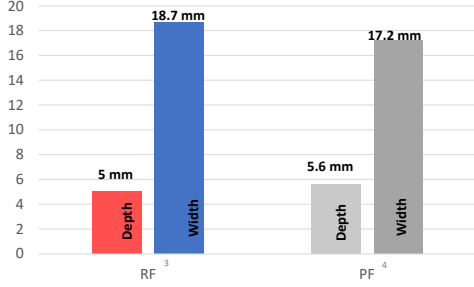
Serves as both multipolar mapping catheter and ablation catheter
Lattice structure larger and more stable than standard point-by-point catheter
Integrated mapping system high fidelity and computational power
Efficient mapping and lesion delivery with larger footprint and deeper tissue penetration
No wait time between applications
General anesthesia with PFA

• Key principles of wide-area focal ablation



4 sec
Pulsed field
Unipolar, biphasic waveform to cause cell death by irreversible electroporation

5 sec
Radiofrequency
Temperature-controlled RF delivery



Modality	Depth (mm)	Width (mm)
RF ³	5	18.7
PF ⁴	5.6	17.2

1. Anter E, et al. JACC Clin Electrophysiol. 2020;6:507-519.
2. Barkagan M, et al. Circ Arrhythm Electrophysiol. 2019;12:e007090.
3. Medtronic data on file (S6585), GLP study.
4. Yavin HD, et al. Circ Arrhythm Electrophysiol. 2021;14:e010375.



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A Focal Ablation Catheter Toggling Between Radiofrequency and Pulsed Field Energy to Treat Atrial Fibrillation

Vivek Y. Reddy, MD,a,b Petr Peichl, MD, PhD,c Elad Anter, MD,d Gediminas Rackauskas, MD, PhD,e Jan Petru, MD,a Moritoshi Funasako, MD,a Kentaro Minami, MD,a Jacob S. Koruth, MD,b Andrea Natale, MD,f Pierre Jais, MD,g Germanas Marinskis, MD, PhD,e Audrius Aidietis, MD, PhD,e Josef Kautzner, MD, PhD,c Petr Neuzil, MD, PhD

JACC: Clinical Electrophysiology Vol. 9 No. 8 2023 pp 1786-1801

- First-in-Human
- Prospective
- Single Arm
- Lattice tip PF/RF Catheter
- 3 centers/2 countries
- 14 operators
- Funding: Affera, Inc

- 178 patients
 - 61% PersAF
 - 39% PAF
- PVI +/- Lines
- PF/PF vs PF/RF
- Pulsed Waveforms:
 - PULSE1
 - PULSE2
 - PULSE3

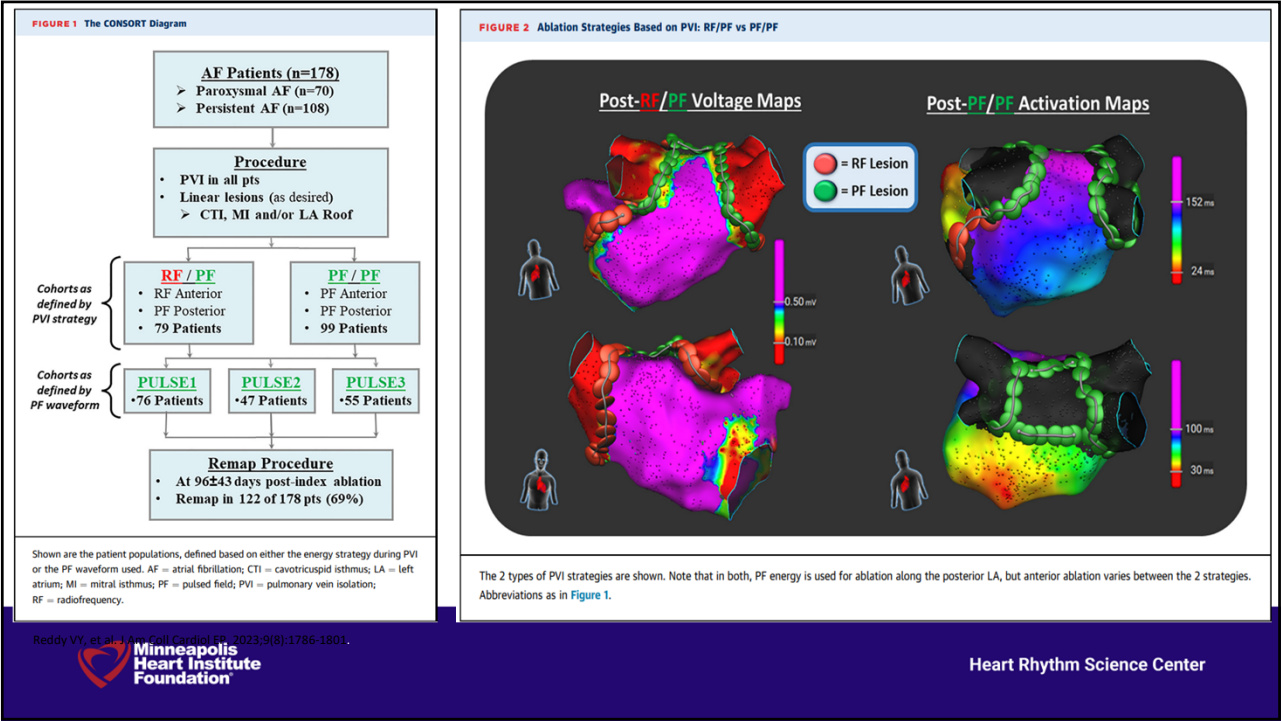
- Remapping planned at 75d
- EGD 1-5 days post ablation
- Brain MRI post ablation
- Cardiac CTA
- Holter monitoring
- Transtelephonic monitoring
- Endpoints:
 - Acute PV isolation
 - Durable PV isolation
 - Linear lesion durability
 - Freedom from AF
 - Safety measures

Reddy VY, et al. J Am Coll Cardiol EP. 2023;9(8):1786-1801.

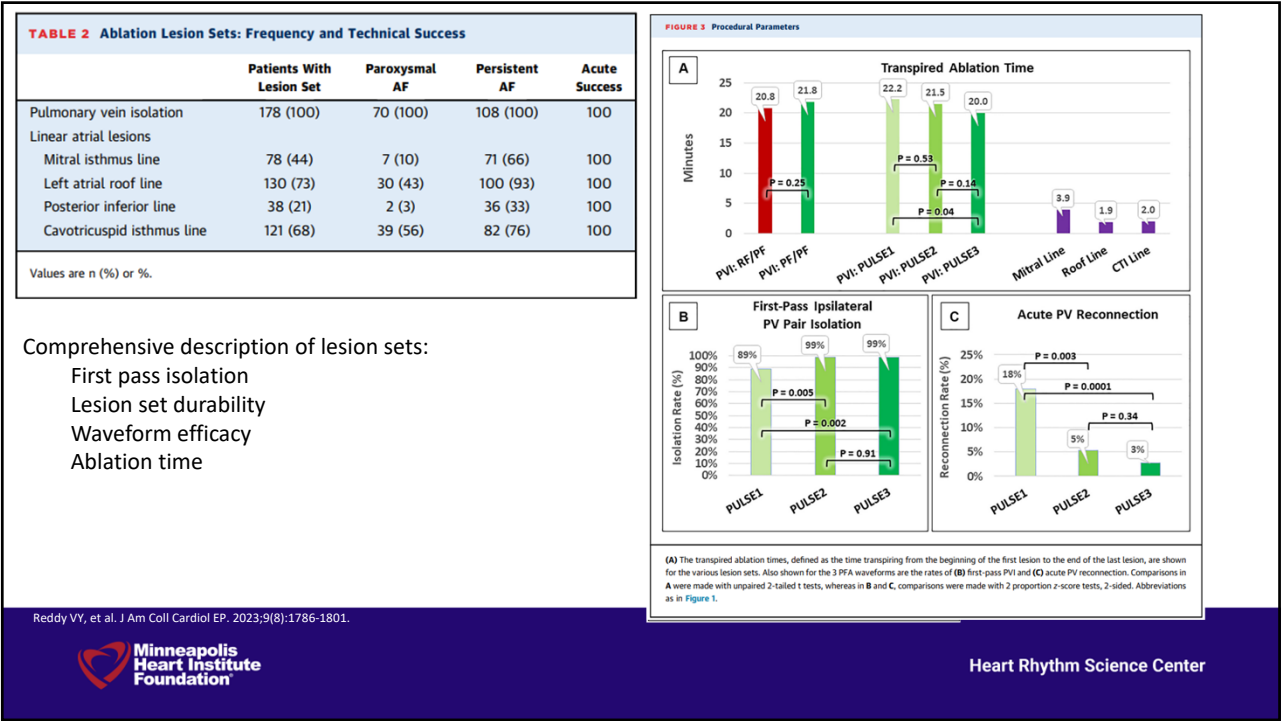


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TABLE 4 Major Adverse Events

	CEC Definition of Primary Adverse Events ^a	Alternate Definition of Adverse Events ^b
Death	0	0
Myocardial infarction	0	0
Pulmonary vein stenosis	0	0
Persistent diaphragmatic paralysis	0	0
Atrioesophageal fistula	0	0
Transient ischemic attack	0	0
Stroke/cerebrovascular accident	0	0
Thromboembolism	0	0
Cardiac tamponade/perforation	0	1 (0.6) ^c
Pneumothorax	0	0
Major vascular access complications	0	1 (0.6) ^d
Pulmonary edema	0	0
Hospitalization	1 (0.6) ^e	0
Heart block	0	0

Values are n or n (%). ^aData Safety Monitoring Board-adjudicated device-related adverse events occurring within 7 days of the procedure except pulmonary vein stenosis and atrioesophageal fistula, which are evaluated through study exit. ^bThis represents a conventional definition of adverse events that is more focused on procedure-related complications, regardless of the relationship to the investigational device technology. ^cRelated to a difficult transeptal puncture procedure requiring radiofrequency energy being applied to the transeptal needle (as adjudicated by the CEC). ^dGroin hematoma requiring surgical intervention. ^eHospitalization for an inflammatory pericardial effusion not requiring catheter/surgical intervention but instead treatment with anti-inflammatory medications.

CEC = Clinical Events Committee.

TABLE 5 Summary of Prospective Safety Assessments

	Full Cohort (n = 178)	RF/PF _{PRE} (n = 36)	RF/PF _{POST} (n = 43)	PF/PF (n = 99)
Esophageal observations				
Any esophageal abnormality		3 (8.3)	0 (0)	0 (0)
Minor erythema		3 (8.3)	0 (0)	0 (0)
Moderate erosion		0 (0)	0 (0)	0 (0)
Ulceration		0 (0)	0 (0)	0 (0)
Phrenic nerve injury				
Fluoroscopy at the end of the procedure	0 (0)			
Fluoroscopy at ~3-month redo procedure	0/122 (0)			
Brain MRI findings				
SCE (DWI-positive/FLAIR-negative)	7 (7.9)			
SCL (DWI-positive/FLAIR-positive)	6 (6.7)			
Pulmonary vein stenosis				
EAM at ~3-month redo procedure	0/107 (0)			
CT scanning at ~3 months	0/77 (0)			

Values are n (%) or n/N (%).

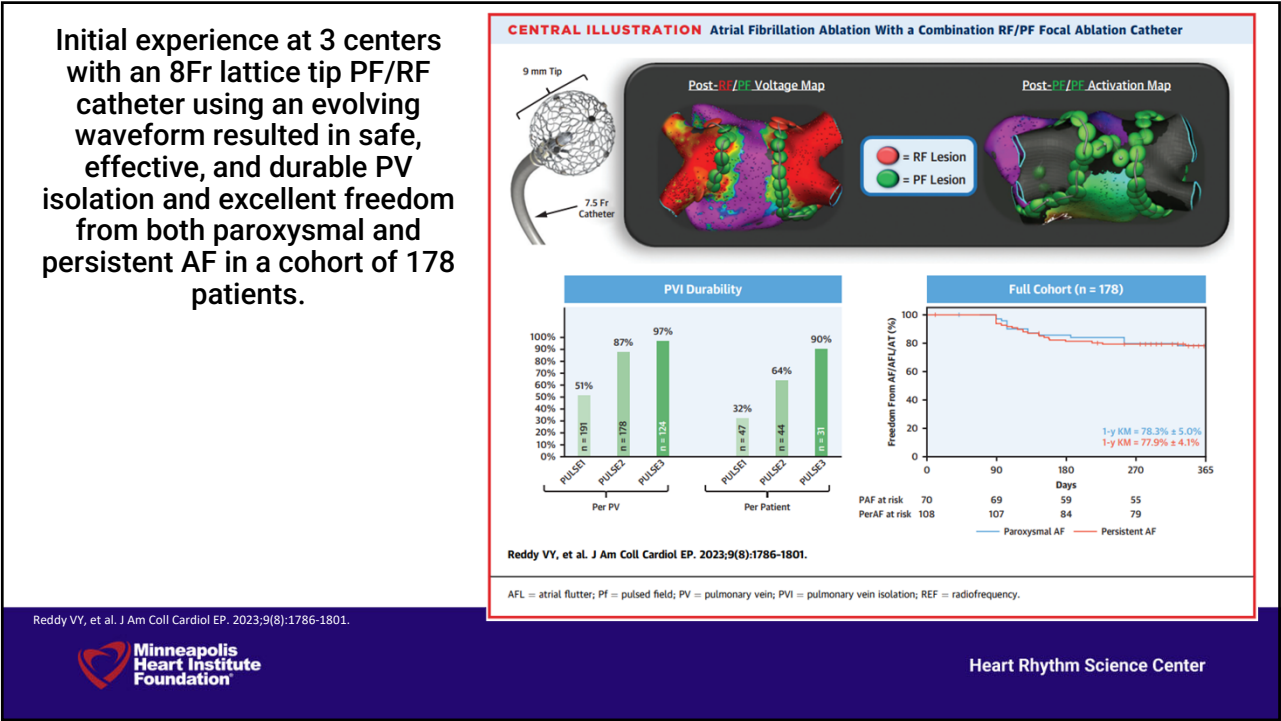
CT = computed tomography; DWI = diffusion weighted imaging; EAM = electroanatomic mapping; FLAIR = fluid-attenuated inversion recovery; SCE = silent cerebral event; SCL = silent cerebral lesion; other abbreviations as in Table 1.

Reddy VY, et al. J Am Coll Cardiol EP. 2023;9(8):1786-1801.



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Non inferior to Contact force sensing RF catheters

nature medicine

Article

Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial

Received: 4 April 2024 A list of authors and their affiliations appears at the end of the paper

Accepted: 26 April 2024

Article

<https://doi.org/10.1038/s41591-0>

Table 2 | Primary effectiveness endpoint summary

Component	Investigational (n=210)*	Control (n=202)*
Composite primary effectiveness success, n (%)	155 (73.8%)	133 (65.8%)
95% CI of success rate	(67.5%, 79.3%)	(59.1%, 72.0%)
Difference (95% CI)	8.0% (-0.5% to 16.8%)	
Farrington-Manning non-inferiority test P value ^b	P<0.0001	
Primary effectiveness first failure mode ^c , n (%)		
Inability to isolate all targeted pulmonary veins during the index procedure	0 (0.0%)	0 (0.0%)
Any left atrial ablation done with non-assigned study device during the index procedure	0 (0.0%)	2 (1.0%)
Any repeat ablation or surgery for AF/AT/AFL recurrence after the index procedure	2 (1.0%)	5 (2.5%)
Direct current cardioversion for AF/AT/AFL recurrence during the effectiveness evaluation period	2 (1.0%)	1 (0.5%)
Documented AF/AT/AFL recurrence during the effectiveness evaluation period	47 (22.4%)	51 (25.2%)
Initiation of new class I/III anti-arrhythmic drug during the effectiveness evaluation period or class I/III anti-arrhythmic drug initiation increase from the historic maximum ineffective dose	4 (1.9%)	10 (5.0%)

AF, atrial flutter; AT, atrial tachycardia. * Two patients in the investigational arm and six patients in the control arm were excluded from the primary effectiveness analysis due to incomplete follow-up without experiencing any failure event. ^b For patients with multiple reasons for failure, only the first occurrence is reported. ^c Based on a pre-defined order of events.

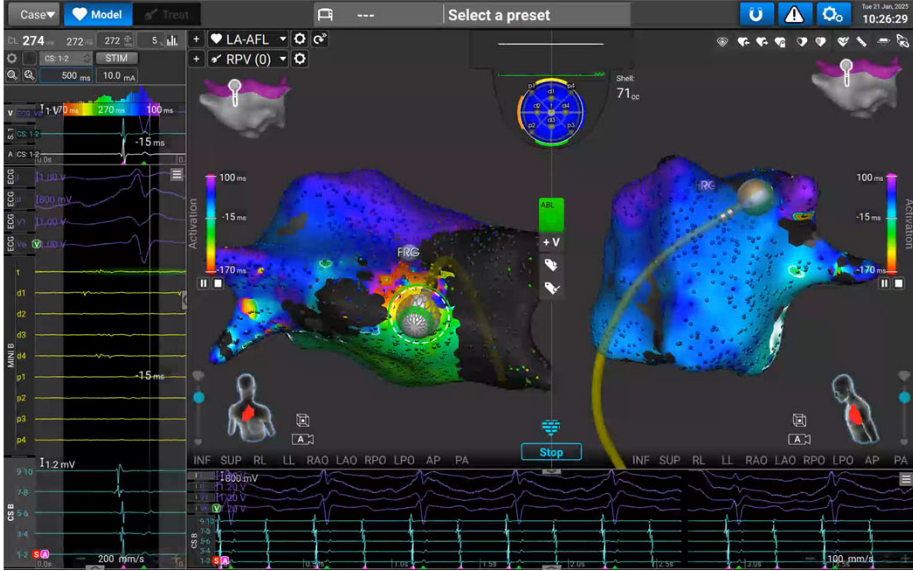
Discussion

The SPHERE Per-AF trial was a randomized, single-blind, non-inferiority trial of patients with persistent AF comparing an all-in-one mapping and dual-energy (radiofrequency and pulsed field) large-footprint ablation catheter to conventional radiofrequency ablation (Extended Data Fig. 1). The investigational system was non-inferior to the conventional system in both safety and effectiveness. The investigational system was superior to the conventional system in measures of procedural efficiency, with shorter procedural duration, time from the first-to-last application and total energy application time.



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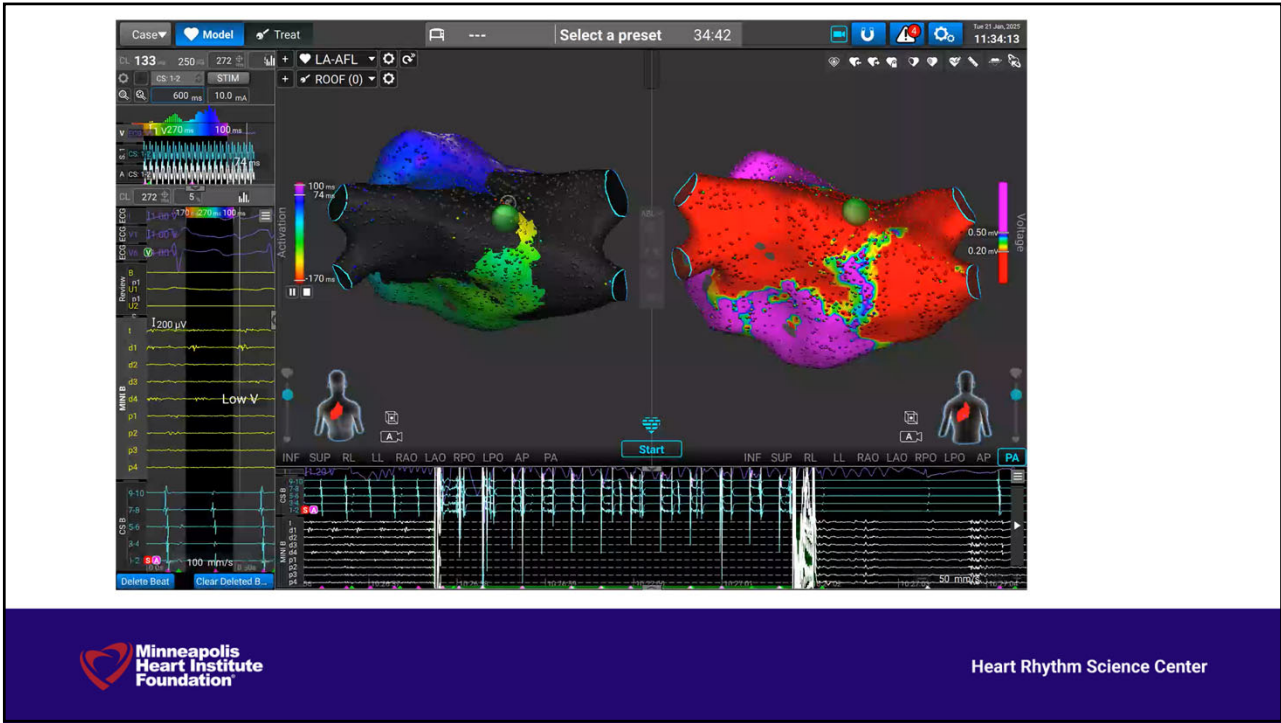
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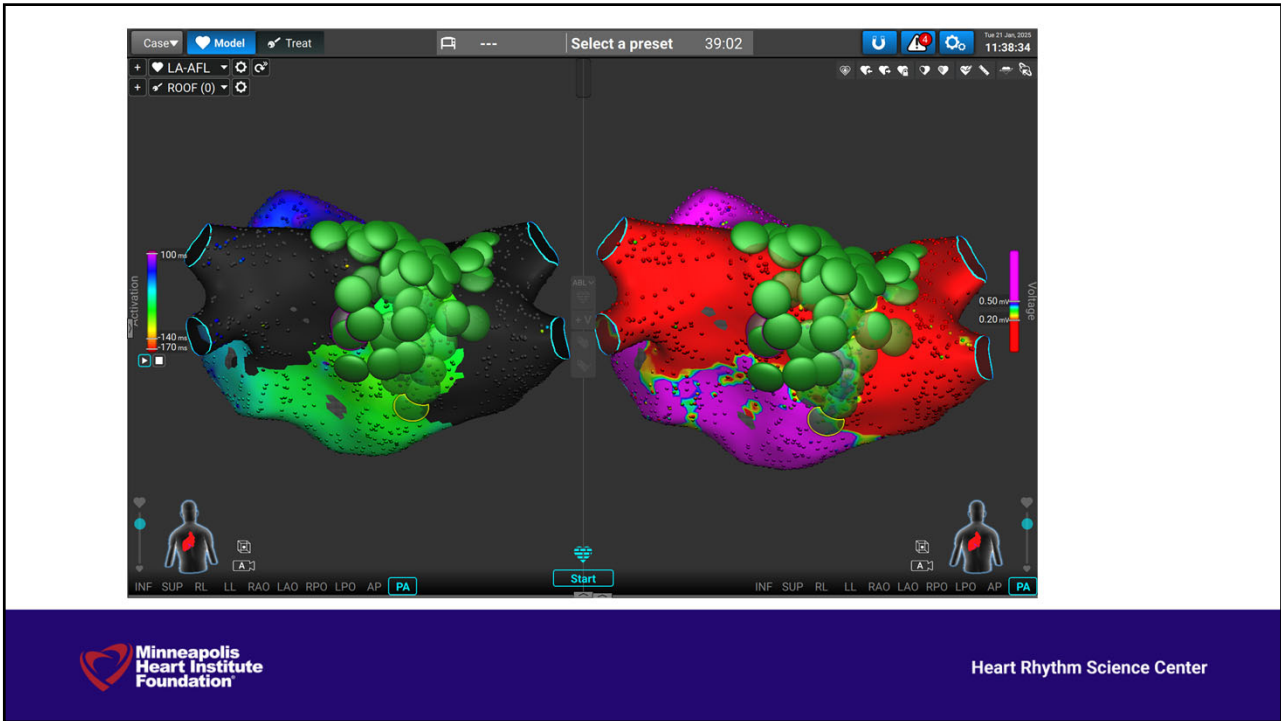


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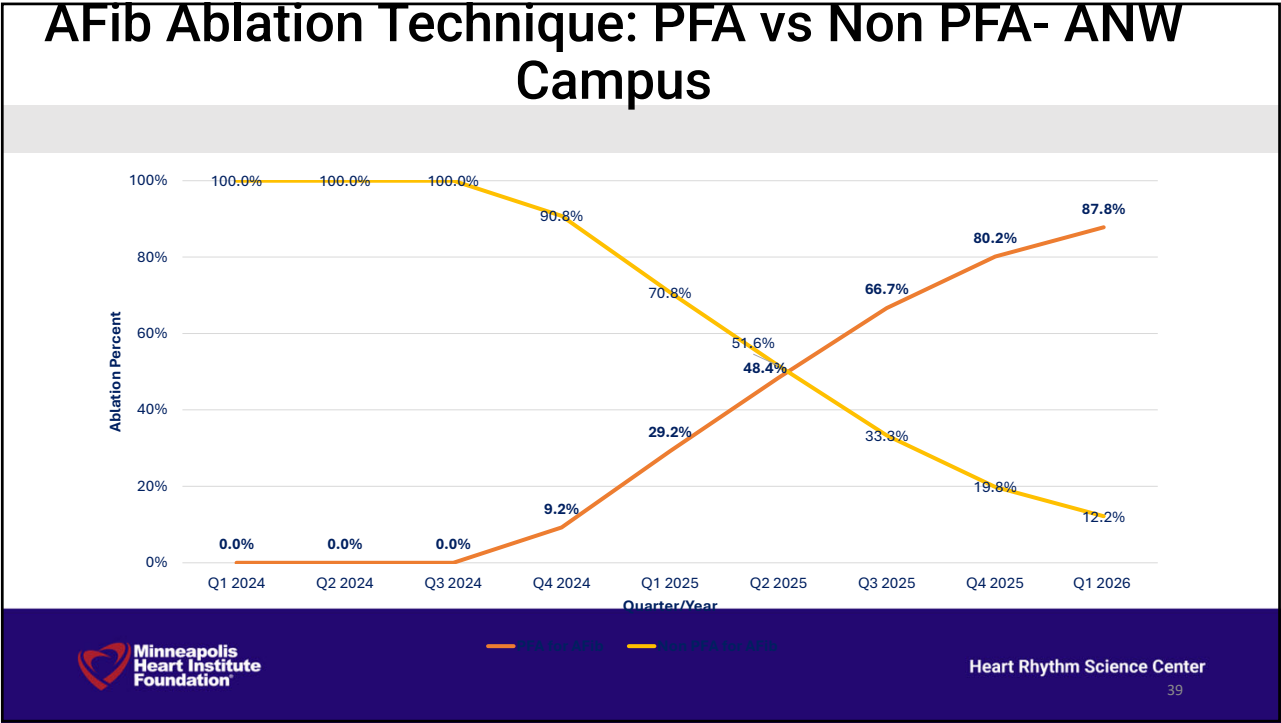
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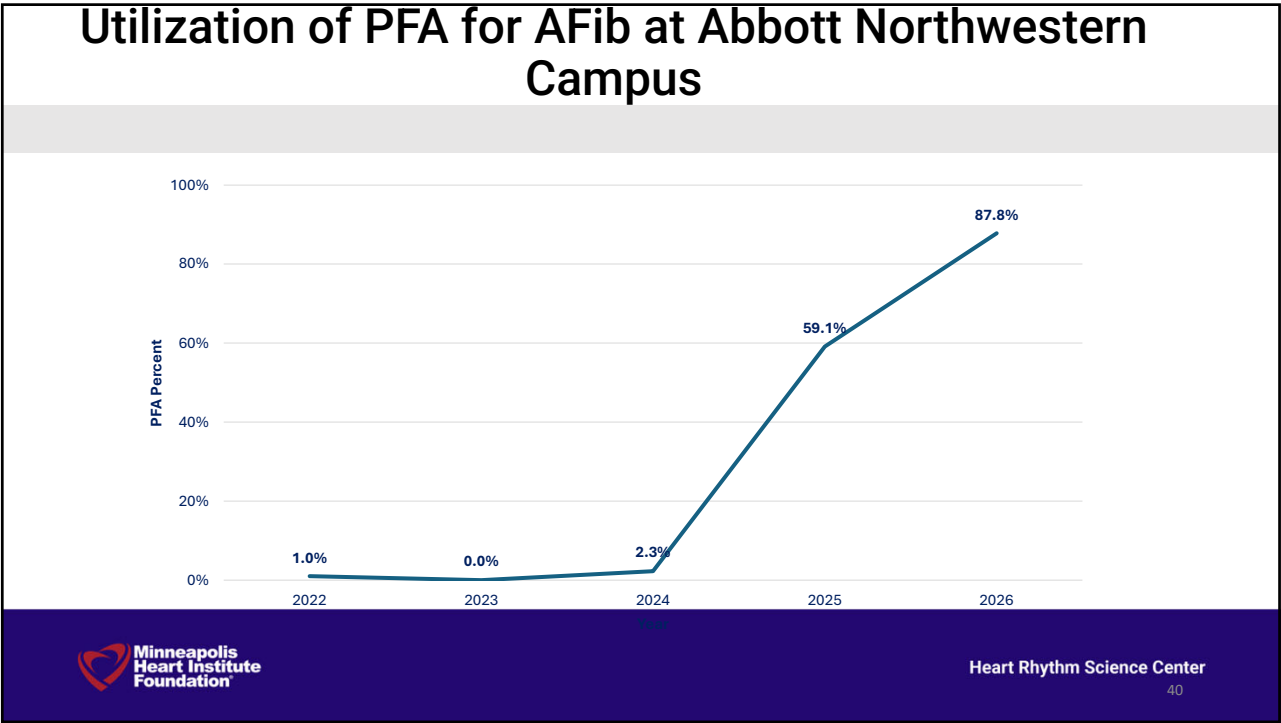
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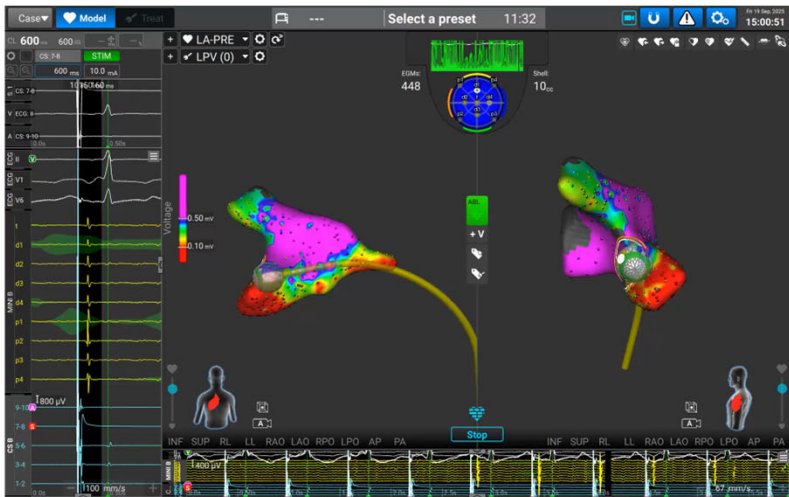
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Are there PFA pitfalls?

- Vasospasm
- Bradycardia/vagal effects
- Over-the-wire systems
 - Increased fluoroscopy
- Hemolysis/increased fluids
- Conduction system risk
- Need for general anesthesia
- Embolic events
 - Large sheaths
 - Changing catheters
- Device-device interactions
- Off-label use
- Form-factor-target mismatch



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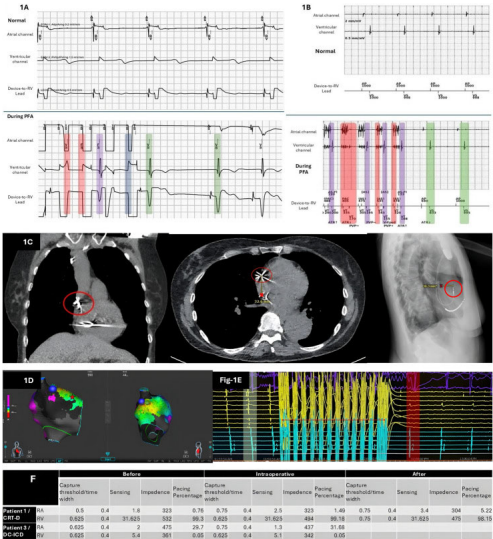


Heart Rhythm O2
Available online 12 September 2025

Pulsed-Field Ablation and Device-Device Procedural Interactions with Cardiac Implantable Electronic Devices

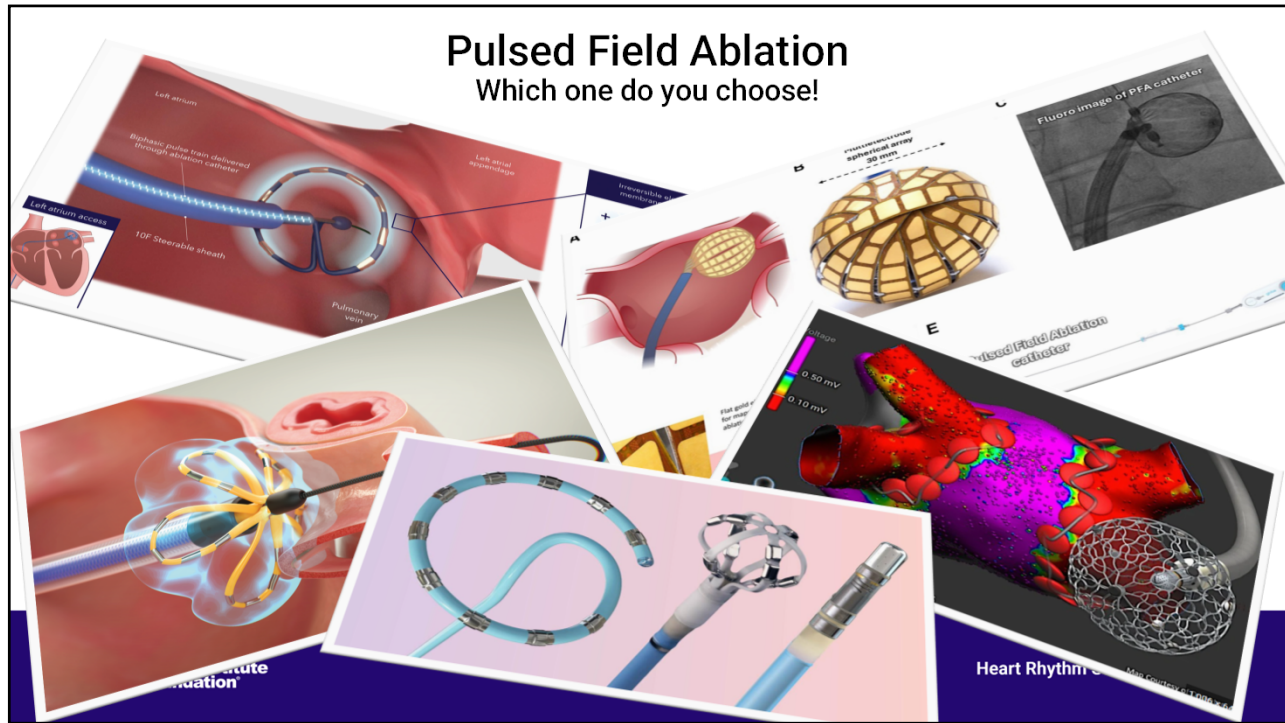
Kerollos Abdelsayed¹, Michael C. Downey^{2,3}, Ali Bahbah¹,
Mariam Tarek Desouki¹, Dawn Witt¹, Edwin Zishiri^{1,2},
Scott Sharkey^{1,2}, Raed H. Abdelhadi^{1,2}, Jay D. Sengupta^{1,2}

<https://doi.org/10.1016/j.hroo.2025.09.005>



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ESC
<https://doi.org/10.1093/europace/euag046>

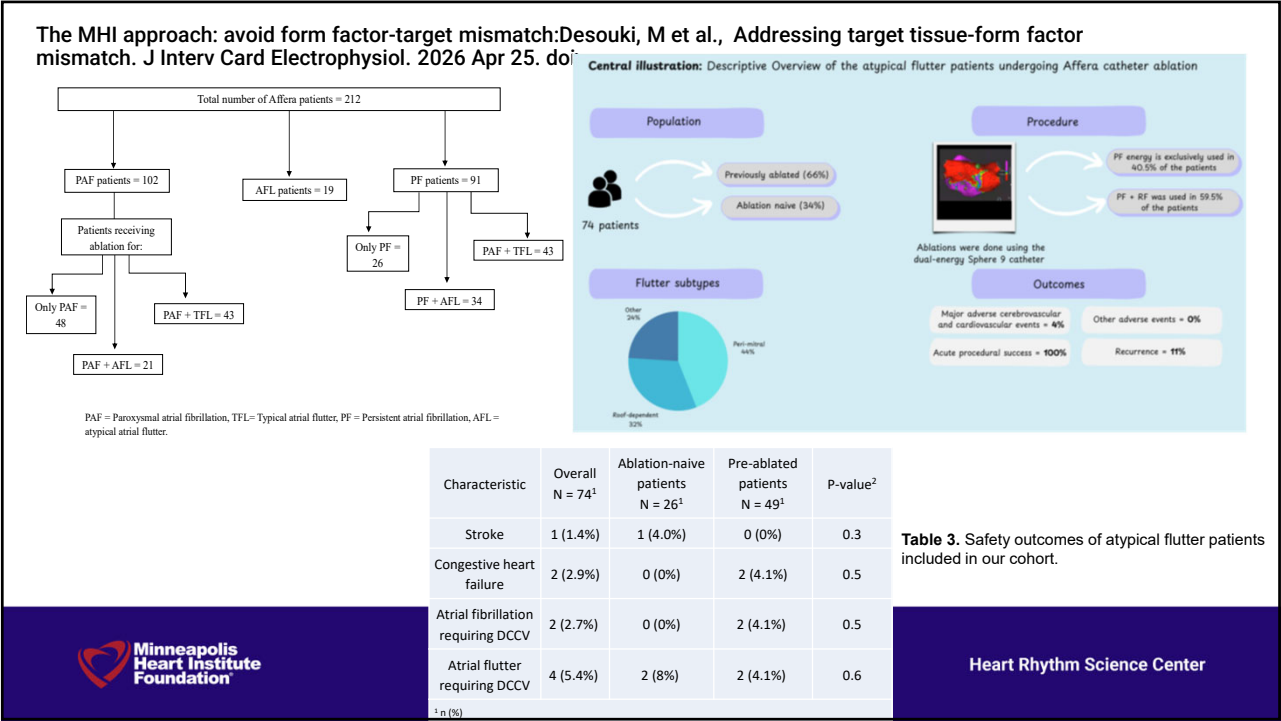
Lattice-tip vs. standard irrigated focal-tip catheter for radiofrequency ablation of the cavotricuspid isthmus - the LINEAR randomized trial

Stylianou Tzeis ¹*, Dimitrios Asvestas ¹, Vasileios Sousonis ¹, Emmanouil Vavouris ¹, Paschalis Karakasis ², Dimitrios Charitos ¹, Stavros Karanikas ¹, Konstantinos Pamporis ², Panos Vardas ², and Konstantinos Vlachos ²

¹Department of Cardiology, Mitera Hospital, 6 Erythrou Stavrou str, 151 23, Marousi, Athens, Greece; and ²7th Cardiology Department, Hippias Hospital, Athens, Greece

Received 11 February 2026; accepted after revision 5 March 2026; online publish-ahead-of-print 14 April 2026

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Dual Energy PFA and RFA with Affera and other systems

- Dual energy RFA and PFA
 - PFA with excellent safety profile given cardioselectivity
 - Avoid pulmonary vein stenosis, esophageal injury, permanent phrenic nerve damage
 - Avoid hemolysis
 - RFA for areas near vascular anatomy (cavotricuspid-isthmus and mitral isthmus)
 - Caution regarding vasospasm with PFA
 - Can use PFA with nitro protocol
- Preferential use of PFA in left atrium
 - Target paroxysmal atrial fibrillation, persistent atrial fibrillation, atypical atrial flutter, repeat ablations
 - Potential for stacking lesions for depth or targeting of alternate tissue types, e.g., parasympathetic ganglia
- Use for ventricular tachycardia ablation in development
 - Huge potential given depth of energy delivery

Minneapolis Heart Institute Foundation

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ORIGINAL RESEARCH

VENTRICULAR TACHYCARDIA

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 Srochek, MD, PhD, Justin Z. Lee, MD, Roy Cheng, MD, Shady Nabholz, MD, Nolan High, CNP, CCSK, Nina Verma, MD, PhD, Arman A. Hossain, MD, Tyler Tager, MD, Mohamed Kari, MD, Mandey Bhargava, MD, Walid I. Saliba, MD, Oussama M. Wazni, MD, MBA, Pasquale Santangeli, MD, PhD

ABSTRACT

BACKGROUND: Catheter ablation of ventricular arrhythmias (VA) with conventional small-tip radiofrequency ablation (RFA) catheters is limited by inadequate lesion size and small footprint design.

OBJECTIVES: This early U.S. experience investigated procedural and clinical outcomes of VA ablation with a lattice-tip wide footprint catheter that allows toggling between RFA and pulsed field ablation (PFA).

METHODS: The Cleveland Clinic VT (CLEAR-VT) Registry is a prospectively maintained registry of consecutive patients undergoing catheter ablation of VAs. Patients undergoing catheter ablation of VA with an RFA/PFA lattice-tip catheter (Sphere-9, Medtronic) between January and September 2025 were analyzed.

RESULTS: A total of 59 patients (median age 70 years; mean left ventricular ejection fraction 36.3% ± 12.3%) underwent ablation of VA using the lattice-tip catheter during the study period. Of these, 50 (85%) had scar-related ventricular tachycardia (VT) (28 with ischemic, 19 with nonischemic, and 3 with mixed cardiomyopathy), and 9 (15%) had frequent premature ventricular contractions (PVCs). Acute procedural success, defined as non-inducibility of any VT (including noninducible VTs with cycle length >240 milliseconds) or complete PVC suppression, was achieved in 78% and 100% of patients, respectively. After a median follow-up of 100 days (IQR: 33–172 days), VT recurred in 9 patients (15%), and death/heart transplantation/left ventricular assist device implantation occurred in 6 patients (10%). At 6 months, the Kaplan-Meier estimated VT-free survival was 69.8% (95% CI: 54.0%–90.3%), the Fine-Gray cumulative incidence of VT recurrence, accounting for competing risks, was 28.4% (95% CI: 11.0%–45.8%). No patient with PVCs had recurrence after a median follow-up of 54 days (IQR: 40–71 days). Three major procedure-related complications occurred, including 2 major bleeding events and 1 implantable cardioverter-defibrillator system failure after PFA application approximately 7.5 mm from the tip of a left ventricular pacing lead (which required intra-operative device generator change).

CONCLUSIONS: In this first U.S. series, catheter ablation of VAs with a Lattice-Tip RFA/PFA catheter appeared effective and generally safe. Caution should be exercised when applying PFA in proximity to exposed conductors of implantable cardiac devices. (JACC Clin Electrophysiol. 2026;10:1846–1862) The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

JACC: CLINICAL ELECTROPHYSIOLOGY VOL 10, NO 8, 2026

AUGUST 2026 1846–1862

Dasa et al

1847



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Clear VT registry

Sphere-9 Lattice-Tip Catheter



9 mini electrodes (0.7 mm) on spherical lattice surface

RFA Radiofrequency

PFA Pulsed Field

CRITERIA

• Anticipated Large Target Substrate Area (Multisegment Scar Involvement at Imaging)

• Prior Failure of Conventional RFA

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

CLEAR-VT Registry, Jan-Sep 2025

N = 59

Scar-related VT

• Ischemic (n = 28)

• NCM (n = 19)

• Mixed (n = 3)

Frequent PVCs

• Lateral VOT (n = 4)

• LV papillary muscles (n = 4)

• RV moderator band (n = 1)

70 y Median Age

36% Mean LVEF

90% Prior VT Ablation

68% Arrhythmone

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% (19.5%–24.5%)

Postablation PVC Burden 3.5% (1.7%–3.8%)

Median follow-up: 54 days

6-Month KM VT-Free Survival 69.8%

95% CI: 54.0%–90.3%

Median follow-up: 100 days

Death

8%

Transplant/LVAD

4%

Major Complications

6%

Dasa O, et al. JACC Clin Electrophysiol. 2026;10(8):1846–1862.

Continued on the next page



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New frontiers—clinical: does it move the needle?

- PFA in one-shot and focal form factors have opened up new possibilities for patients with complex atrial arrhythmias
 - Potentially more durable pulmonary vein isolation
 - More capability to address complex anatomy and refractory arrhythmias
 - Greater efficiency but with it comes more complex cases and higher number of cases
 - No PV stenosis, esophageal injury, rare permanent phrenic injury
 - May preserve LA extracellular architecture (non-thermal cell death)
 - Unconventional cases
- When we can achieve reproducible and durable PV isolation, the question becomes what else will be necessary to improve outcomes?
 - AF pathophysiology and drivers
 - Atrial myopathy
 - Patient-specific factors



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New frontiers—institutional and research

- Application potential is limitless
 - True value when integrated with deeper understanding of atrial fibrillation drivers
 - **Ripple technology (Melby+Biosense/JJ)**
 - **Cortex (proprietary algorithm to identify active AF sources, Boston Scientific)**
 - **Volta Medical (AI and Machine Learning)**
- How does PFA fit in our research portfolio?
 - Investigator-initiated studies
 - Industry-sponsored trials
 - Advance the science and establish our footprint on best practices
- Use of PFA may also revolutionize ventricular arrhythmia ablation
 - PFA modules need to be developed from ground level
 - Research, development, and innovation



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AF Studies at MHI/MHIF

Study Name	Investigator	Description	Status
OMNY-AF	Daniel Melby, MD	Evaluating safety and efficacy of BWI OMNYPULSE PFA platform in patients with symptomatic paroxysmal AF who failed at least one AAD (class I or III)	Completed enrollment q2 2026
ADVANCE AF	Daniel Melby, MD	Prospective, multi-center single-arm study designed to evaluate the effectiveness of ablation of novel Ripple Frequency Map identified atrial fibrillation drivers for treating persistent atrial fibrillation	Completed enrollment
AURA Registry	JoEllyn Moore, MD	Single center registry of patients undergoing AF ablation using RFA or PFA starting in December 2024. We aim to evaluate the long-term efficacy of both modalities, to date nearly 400 patients have been included	Enrolling
SPHERE PER-AF PAS	Edwin Zishiri, MD	Post-approval study to evaluate long-term effectiveness and safety of Sphere-9 Catheter and Affera Ablation System for treatment of persistent AF	Completed enrolment q1 2026
SPHERE-360 PAF IDE	Jay Sengupta, MD	Prospective study to evaluate the safety and effectiveness of the Sphere-360 Catheter and Affera Mapping and Ablation System for treating paroxysmal atrial fibrillation (PAF).	Complete enrolment q22026

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Future directions

- The right target, the right energy, the right form factor
 - PFA dominant approach with RFA near vessels and conduction system
- Understand the atrial fibrillation phenotype
 - Clinical risk factors, atrial substrate, concomitant cardiac disease, new medication impact
 - Clinical designations are often discordant with findings from procedure
- Paroxysmal atrial fibrillation with normal LA size and voltage
 - Durable, safe, efficient pulmonary vein isolation with PFA
- Persistent atrial fibrillation or paroxysmal patient with advanced substrate
 - Pulmonary vein isolation + targeted ablation (substrate and electrical drivers) with PFA+RFA
- Concomitant afib ablation and LAAC for bleeding risk and lifestyle
- Alternatives to anticoagulation as management success improves (Wearables, discontinuation of OAC)

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ENDO- EP VT Cases with 3.5 mm RF/ PF Catheter (Tactiflex Duo)

- 69 year old man chronic systolic heart failure with LVEF of 20% due to cardiac sarcoidosis had 2 previous RF ablations but continued to have VT. Brought to the lab for repeat ablation



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Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

Effect of Sequential, Colocalized Radiofrequency and Pulsed Field Ablation on Cardiac Lesion Size and Histology

Atul Verma, MD, Jennifer Maffre, MSBATS, Tushar Sharma, MD, Salman Farshchi-Heydari, MD

Circ Arrhythm Electrophysiol. 2025;18:e013143. DOI: 10.1161/CIRCEP.124.013143

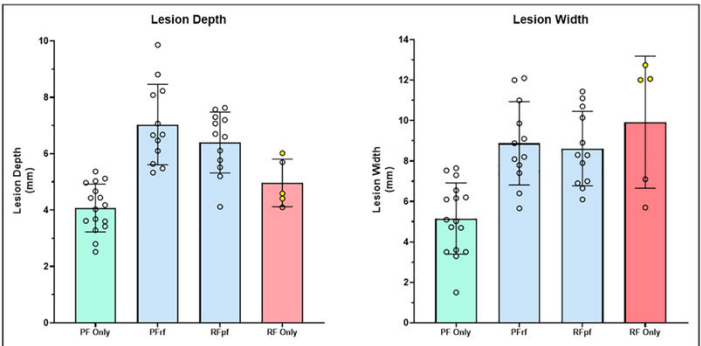


Figure 2. Correlation of lesion depth and width to applied ablation mode.



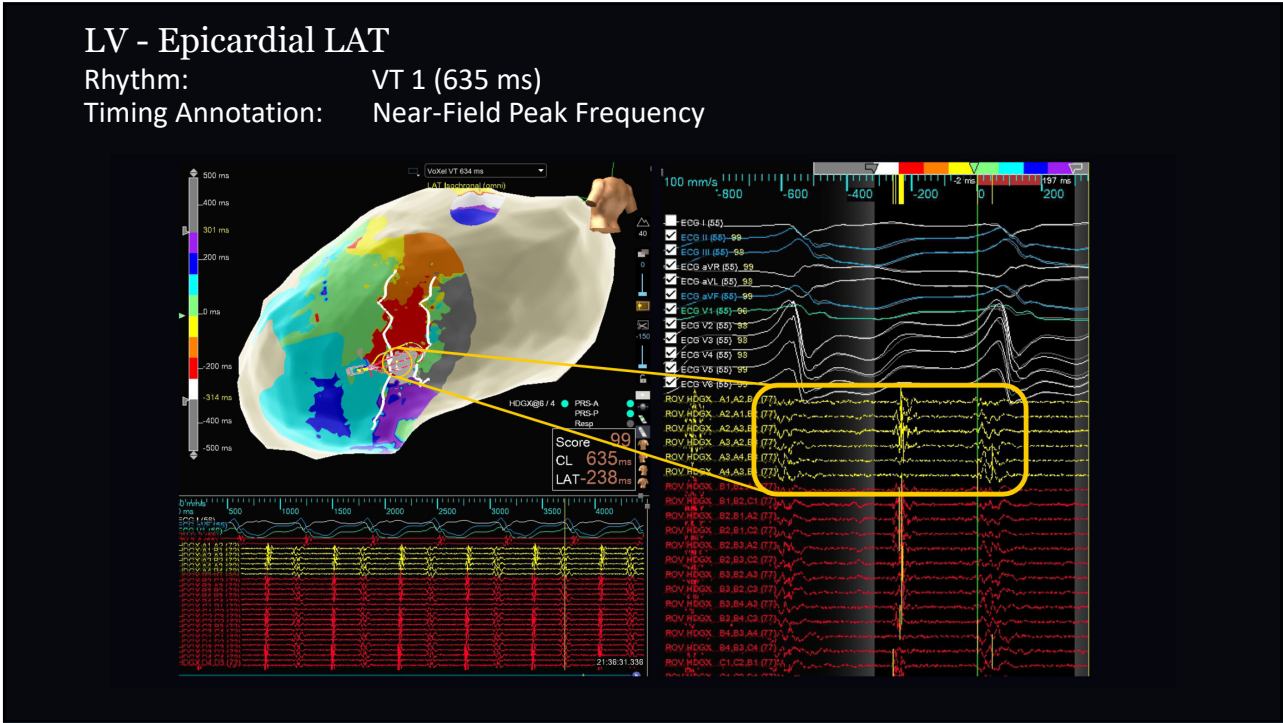
Figure 1. Triphenyl tetrazolium chloride staining of ablated tissue.

Central zone: coagulative necrosis/melted and necrosed myofibrils c/w RFA
Dark zone: consistent contraction band necrosis, Nuclear pyknosis, and hemorrhage

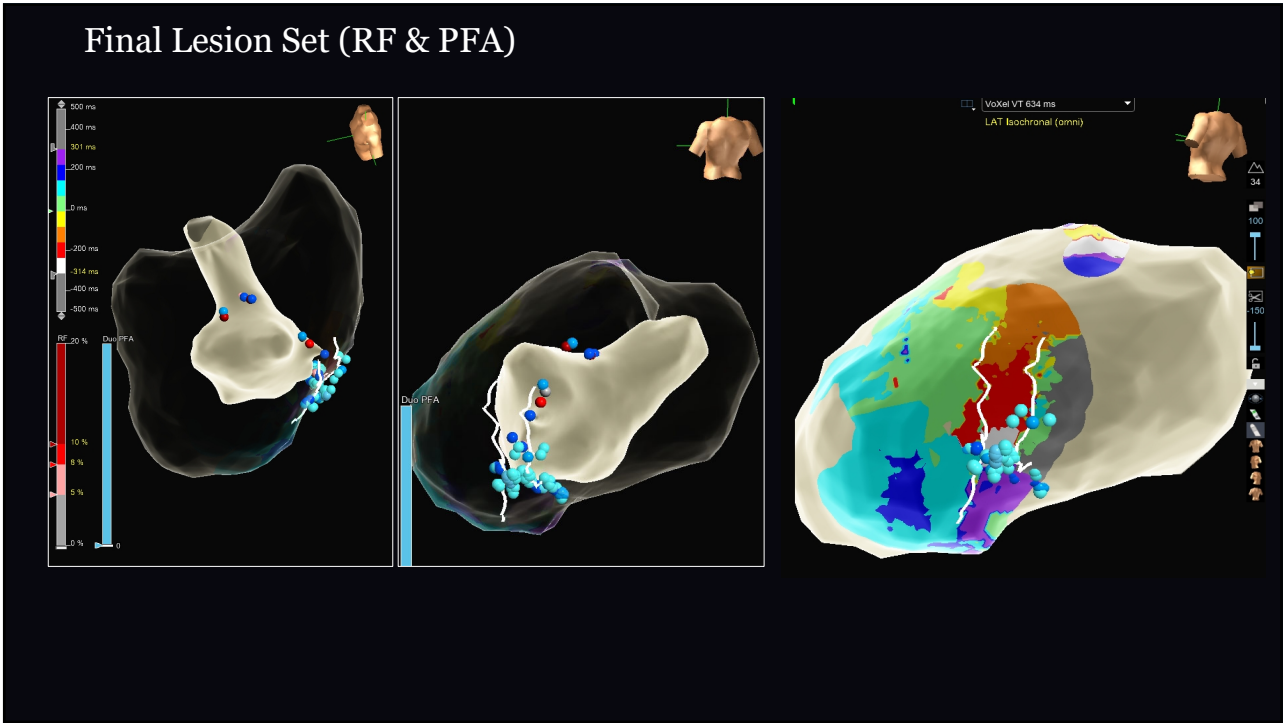


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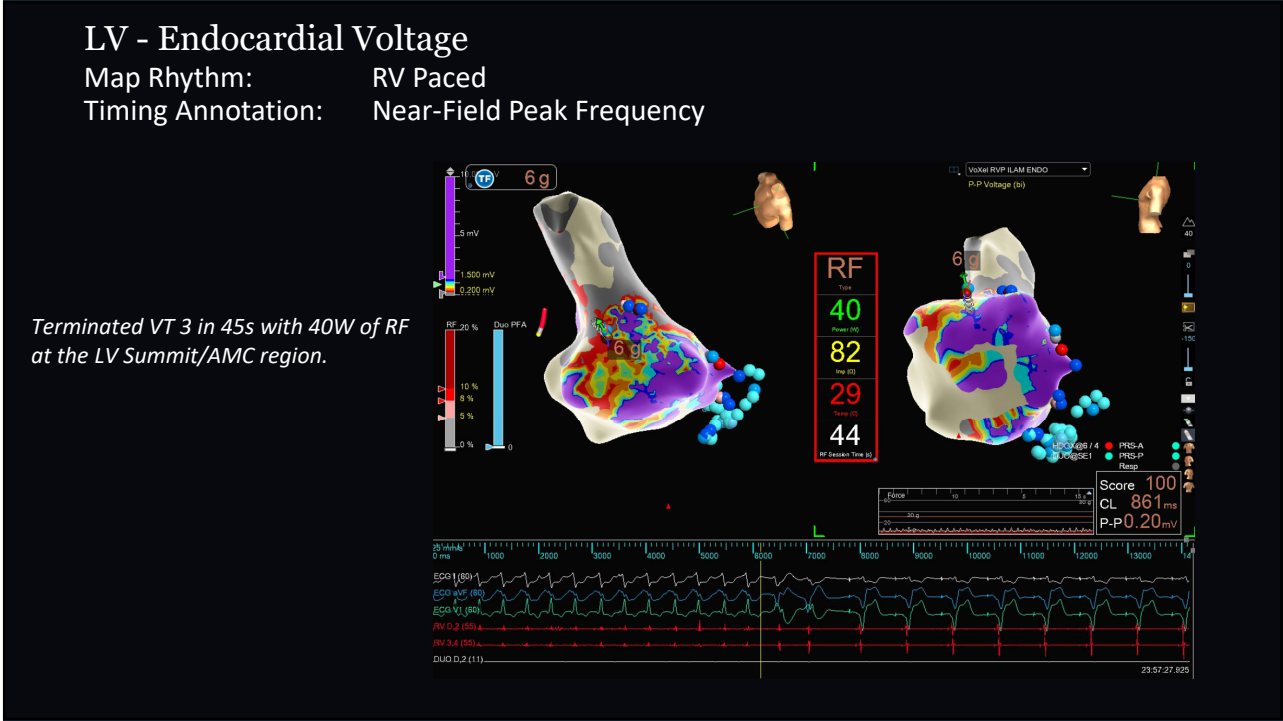
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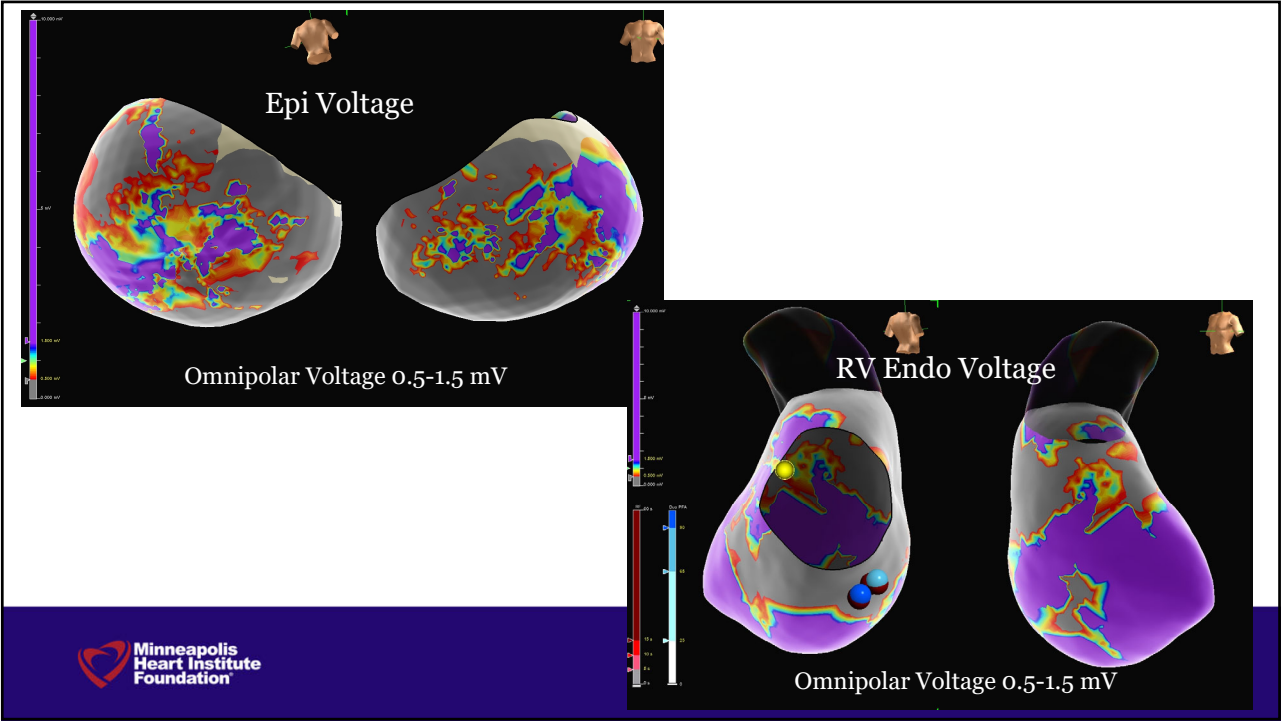
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Brief History

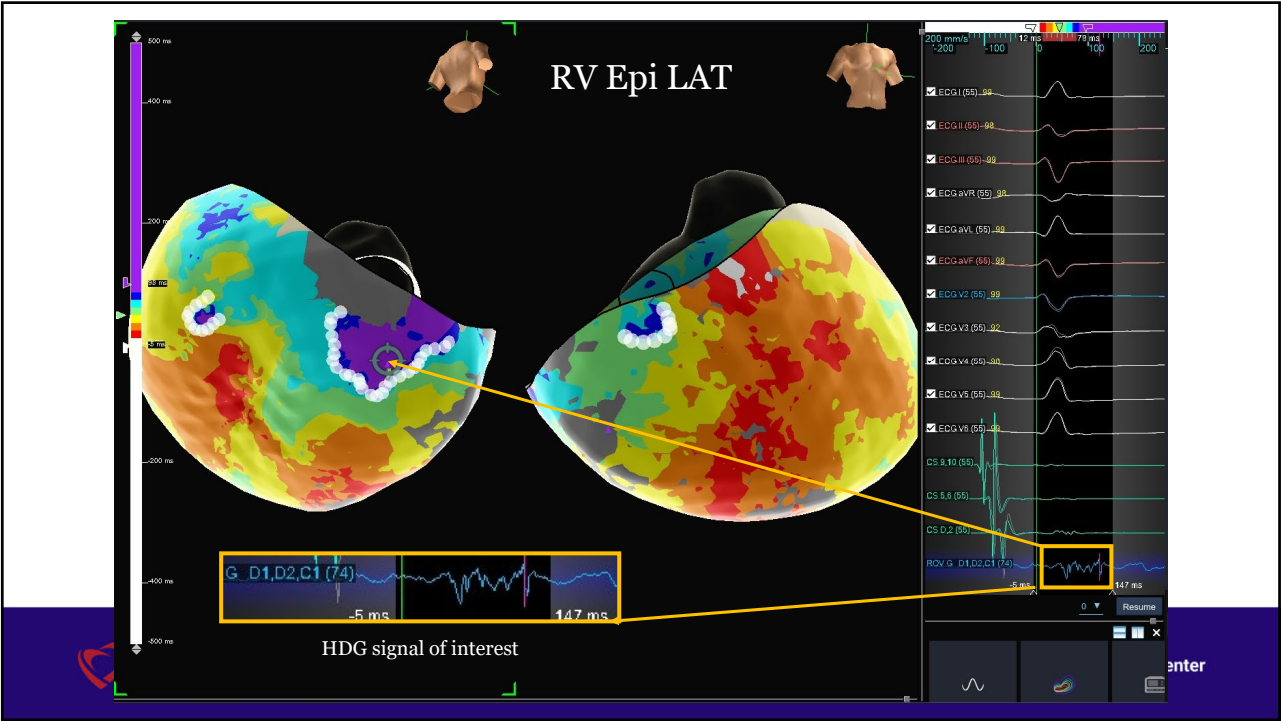
- 39 year old woman with PK2P gene mutation associated arrhythmogenic right ventricular cardiomyopathy who presents for a redo ablation procedure for recurrent ventricular tachycardia. She had had two previous ablations in the preceding months and had recurrent admissions to the hospital with VT despite antiarrhythmics

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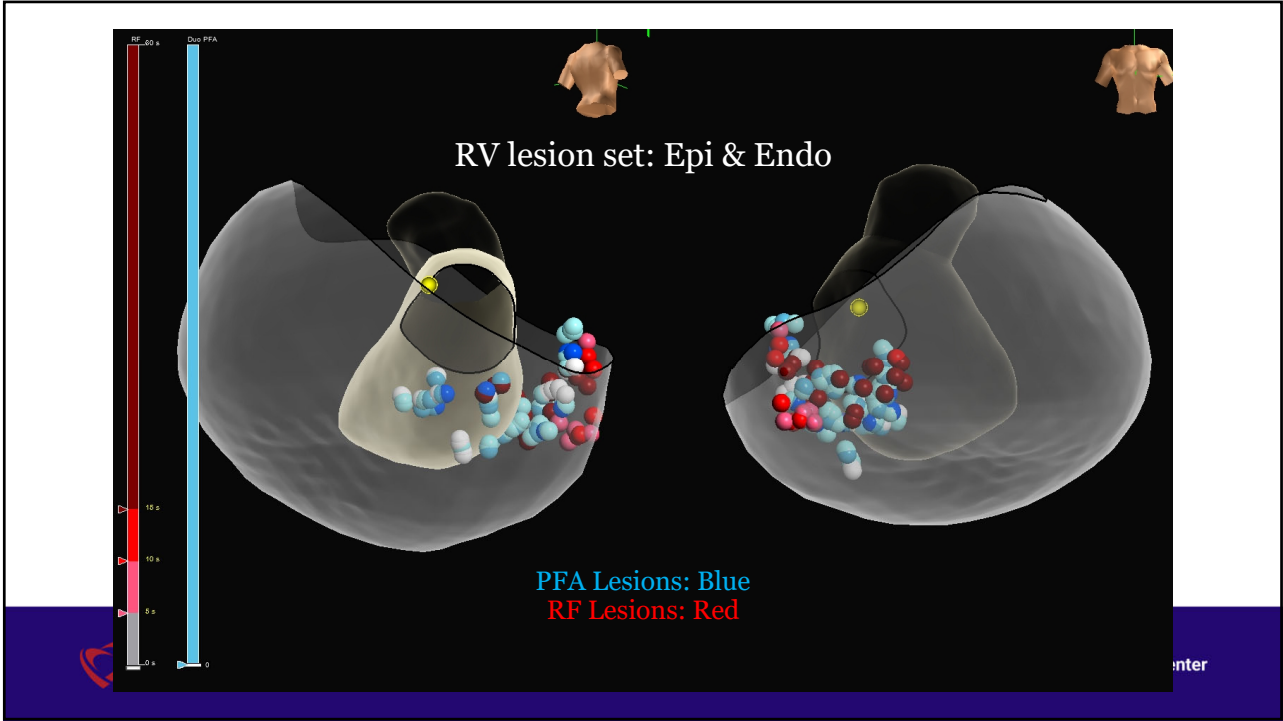
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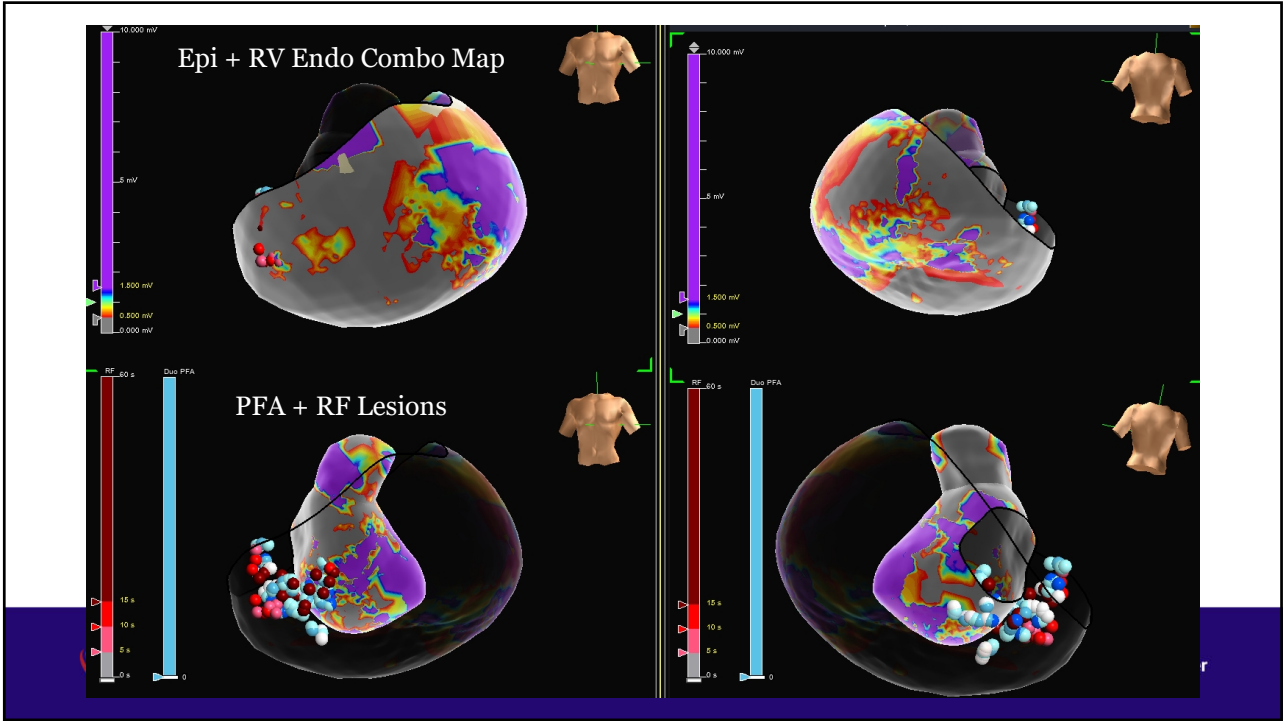
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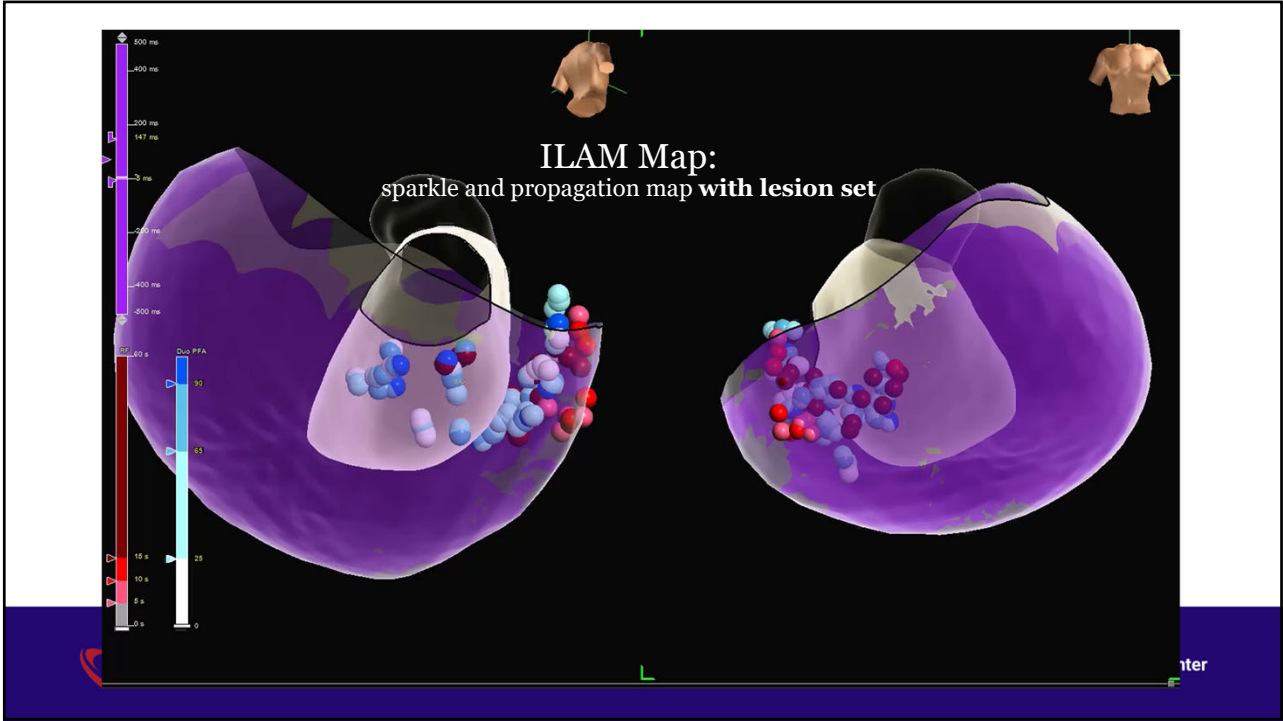
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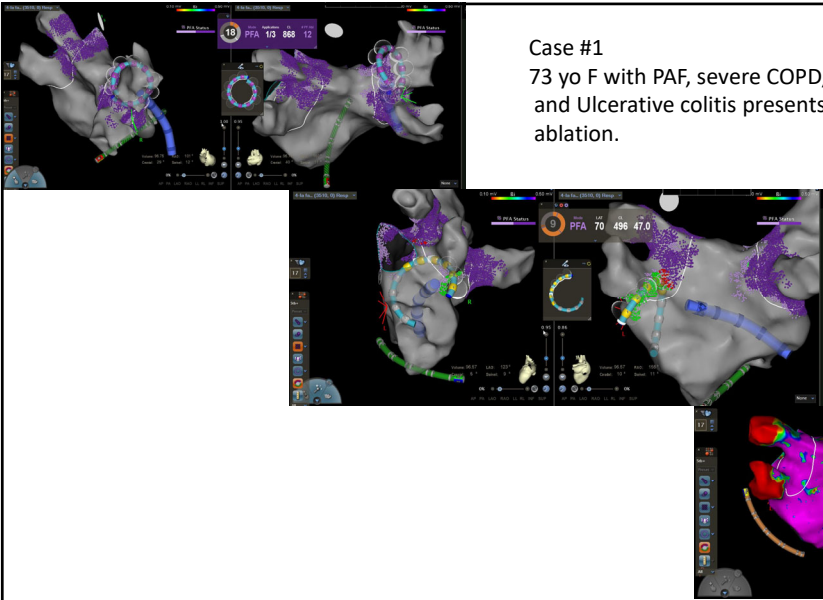


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- Additional cases if time permits

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Case #1
73 yo F with PAF, severe COPD,
and Ulcerative colitis presents for
ablation.

The VARIPULSE™ Platform





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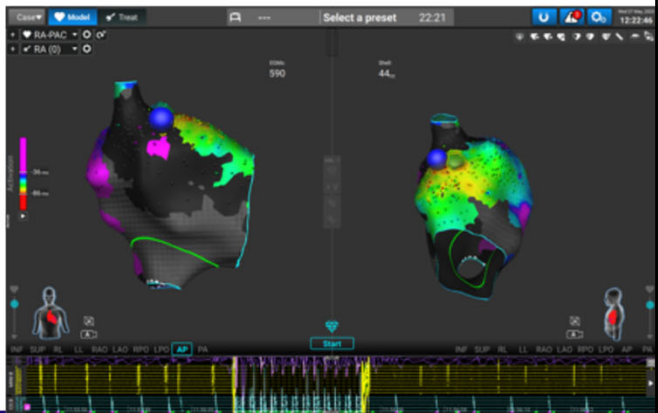
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S.G. 70 yo F with non-ischemic cardiomyopathy,
possibly LMNA gene-related, complex atrial arrhythmias including
Afib, atrial flutter, PACs, and she also has PVCs.
ICD implant for primary prevention and to facilitate atrial-pacing and medical therapy

No AF after RFA ablation but frequent bigeminal, symptomatic PACs originating from high Crista,
near arcuate ridge and in close proximity to phrenic nerve

Presents for ablation with focal PFA

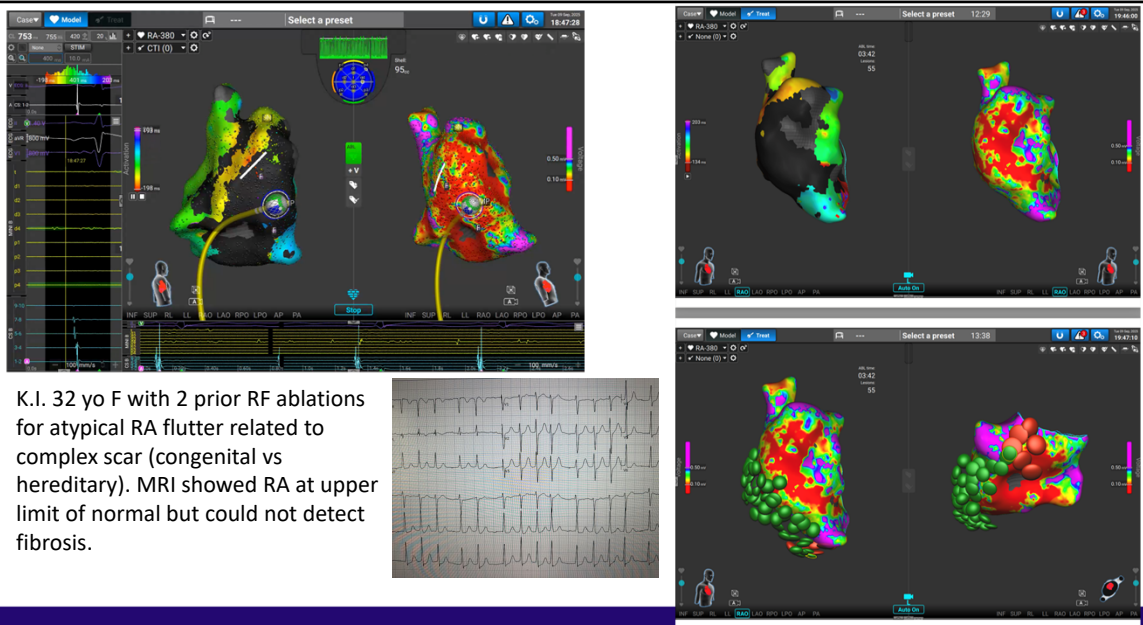
Symptomatically improved post PAC ablation
EF stable and on GDMT
No plans for PVC ablation which would require retrograde
approach given extensive descending aortic atheroma





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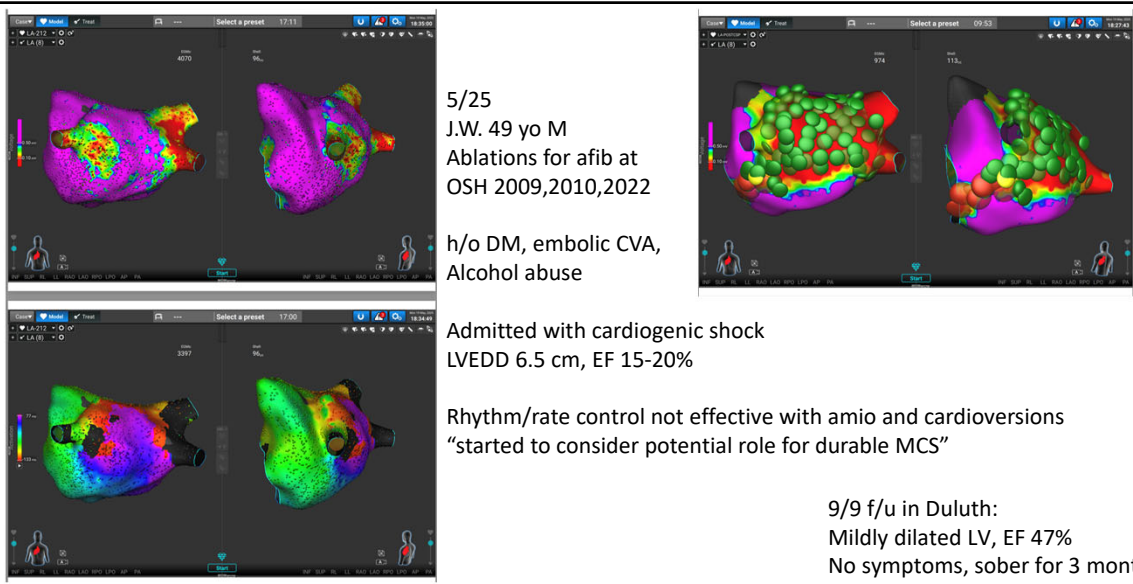
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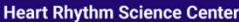
K.I. 32 yo F with 2 prior RF ablations for atypical RA flutter related to complex scar (congenital vs hereditary). MRI showed RA at upper limit of normal but could not detect fibrosis.



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5/25
J.W. 49 yo M
Ablations for afib at OSH 2009,2010,2022
h/o DM, embolic CVA, Alcohol abuse
Admitted with cardiogenic shock
LVEDD 6.5 cm, EF 15-20%
Rhythm/rate control not effective with amio and cardioversions
“started to consider potential role for durable MCS”
9/9 f/u in Duluth:
Mildly dilated LV, EF 47%
No symptoms, sober for 3 months
No plans for LVAD or ICD currently



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ORIGINAL RESEARCH

Pulsed-Field Ablation of Atrial Flutter

Insights From a Large Volume U.S. Center

Joe Demian, MD, Arwa Younis, MD, Oussama M. Wazni, MD, MBA, Pasquale Santangeli, MD, PhD, Mohamed M. Dabbas, MD, Adelle Waffa, MD, Bryan Baranowski, MD, Hiroshi Nakagawa, MD, Tyler L. Taigen, MD, Niraj Varma, MD, PhD, Koji Higuchi, MD, Thomas D. Callahan, MD, Mohamed Kari, MD, Mina K. Chung, MD, Jakub Sroubek, MD, Justin Z. Lee, MD, Mandeep Bhargava, MD, Walid I. Saliba, MD, Ayman A. Hussein, MD

Ablation equipment	
Mapping system	
EnSite Precision	148 (47.59)
CARTO 3	146 (46.94)
RHYTHMIA HDx	17 (5.47)
Mapping catheter	
Advisor HD Grid	148 (47.59)
PENTARAY	79 (25.40)
OCTARAY	67 (21.54)
INTELLAMAP ORION	17 (5.47)

CENTRAL ILLUSTRATION Outcomes of Atrial Flutter Ablation Using Pulsed-Field Ablation

Pulsed-Field Ablation of Atrial Flutter: Safety and Efficacy Across Different Substrates

Population	Procedure	Outcomes
311 Patients 368 Atrial Flutters	Main Ablation Strategy Pulsed-field ablation (All Flutters)	Acute Procedural Success 96.5%
		CTI-dependent 99.5% Perimitral 82.9%
	Adjunctive Radiofrequency Ablation 13 Flutters	Adverse Events 1%
	1 CTI-dependent 12 Perimitral	Follow-up 175 days (IQR: 132-244)
		Recurrence 3.9%
		Death 0
		CTI-dependent 1.5%
		Perimitral 10%

PFA is a safe and effective modality for AFL ablation, achieving high acute success rates and favorable safety outcomes.

Demian J, et al. JACC Clin Electrophysiol. 2025;■(■):■-■.

Summary of the procedural approach and outcomes of atrial flutter (AFL) ablation using pulsed-field ablation (PFA) in a cohort of 311 patients with 368 AFL circuits. PFA was employed as the primary ablation strategy across all AFL subtypes, with adjunctive radiofrequency ablation required in 13 cases, primarily in perimitral flutters. Acute procedural success with PFA alone was high at 96.5%. Flutter recurrence following PFA was low overall (3.9%), with higher rates in perimitral circuits (10%). These findings highlight the effectiveness of PFA in achieving durable conduction block, especially in cavotricuspid isthmus (CTI)-dependent circuits, and support its use as a safe and efficient modality for AFL ablation. ICE = intracardiac echocardiography.

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Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

Feasibility and Safety of Pulsed Field Ablation for Coronary Sinus and Left Atrial Appendage Isolation and Mitral Isthmus Ablation: Acute and Chronic Findings

Vincenzo Mirro La Fata¹, MD, Sanghamitra Mahapatra², MD, Carlo Gianni³, MD, Elia Zili⁴, MD, Nicola Plesio⁵, MD, Giuseppe DiLandro⁶, MD, Preeti Gera⁷, MD, Domenico G. Della Rocca⁸, MD, Weeranan Dechayaporn Boon⁹, MD, J. David Blankenship¹⁰, MD, Robert Horton¹¹, MD, Aron Aronson¹², MD, Luigi D. Basso¹³, MD, Andrea Natale¹⁴, MD

Circ Arrhythm Electrophysiol. 2025;18:e014026. DOI: 10.1161/CIRCEP.125.014026

Figure 3. Left atrial appendage isolation.
Intracardiac echocardiography (top) and fluoroscopic images (bottom) showing the pentaspline catheter at the ostium of the left atrial appendage. The left panels display the catheter in the flower configuration, while the right panels show the basket configuration.

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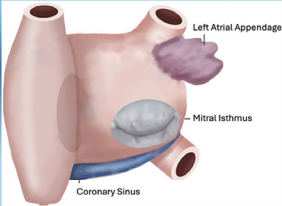
Study Population

236 consecutive patients with long-standing persistent AF

Previous failed AF ablation with PV and PW isolated

CS and LAA isolation and MI ablation using the Pentaspline PFA catheter

Procedural Outcomes



Isolation/Block	Acute	Post-Adenosine	3 Months
LAA	100%	98.3%	4.6%
CS	62.2%	40.2%	1.3%
MI	100%	85.2%	5.5%

Conclusion

PFA achieves acute isolation of extra-PV targets, but long-term durability remains limited



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Proposed Agenda – Visit to CCB Frankfurt

Date: September 22, 2026

Time: 09:00–14:00

Location: Markus Krankenhaus Frankfurt, Wilhelm-Epstein-Straße 4, Building F, 2nd Floor, Conference Room G 250



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Time

09:00–09:15

09:15–09:30

09:30–09:45

09:45–10:00

10:00–11:00

11:00–12:00

12:00–13:00

13:00–13:20

13:20–13:40

13:40–14:00

Agenda

Welcome and introduction

Introduction to CCB Frankfurt: structure, procedures, volumes and key areas of expertise

German healthcare system compared with the U.S. healthcare system

Coffee break

Group Rotation I: Group A – live case observation in the EP lab; Group B – interactive case discussion

Group Rotation II: Group B – live case observation in the EP lab; Group A – interactive case discussion

Lunch break

Current and emerging technologies in electrophysiology

Contemporary treatment strategies: patient selection and clinical decision-making

Final discussion, key takeaways and closing remarks

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Organisation CCB



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History and Present of CCB

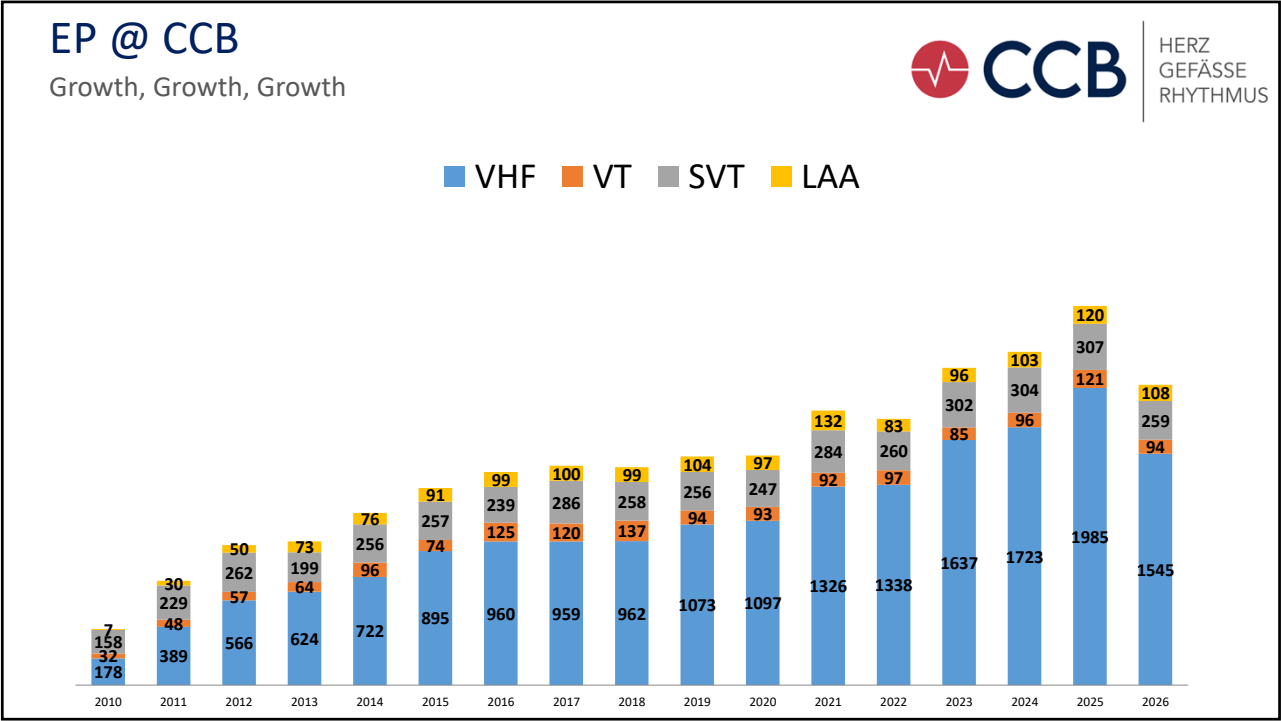


CCB

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- Founded 1978
 - Outpatient PCI since 1985
 - CIED Department 1996
 - CCB @ Markus Hospital 2001
 - Imaging Department 2002
 - First CPU in Germany 2003
 - „Herzwerk“ Cardiac Rehab facility 2008
 - EP Depart. @ Markus Hospital 2010
 - Force CT 2014
 - Clinical Chemistry and Hemastosiology 2014
 - Outpatient Clinic Bad Soden 2019
- | | |
|------|----------------------|
| • 45 | Cardiologists |
| • 2 | Angiologists |
| • 1 | Vascular Surgeon |
| • 3 | Radiologists |
| • 2 | Diabetes Specialists |
| • 6 | Cardiology Trainees |

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Current and Emerging Technologies

Boris Schmidt, Frankfurt/Main, Germany

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Current PFA Technologies

Disclosures

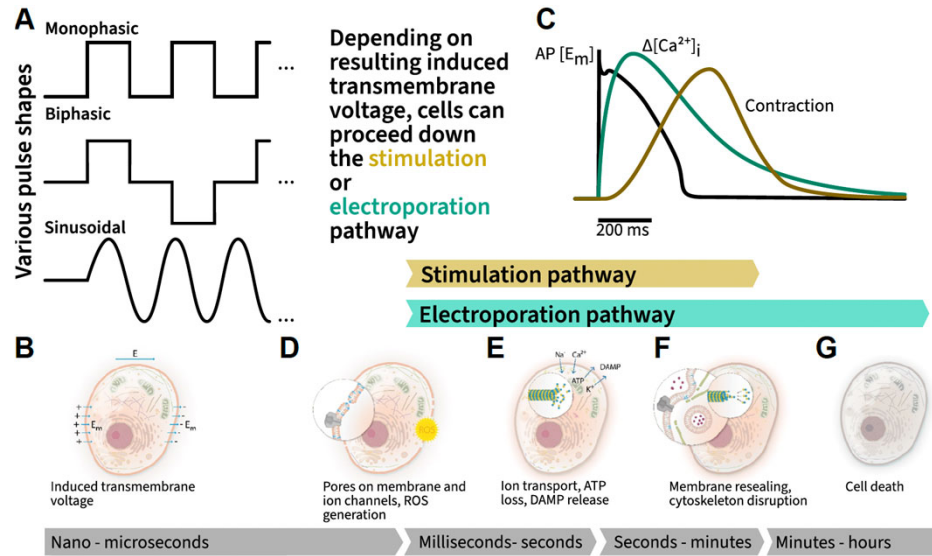


Company	COI
Abbott	Ad Board, Research grant, Speaker Fee
Biosense Webster	Ad Board, Research grant, Speaker Fee
Boston Scientific	Ad Board, Research grant, Speaker Fee
Farapulse	Ad Board, Research grant, Speaker Fee
Medtronic	Research grant, Speaker Fee

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Current PFA Technologies

Basic PFA Principles – Physiological response to PFA



Miclavcic D et al. HeartRhythm (2025) in press

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Current PFA Technologies

Basic PFA Principles – Waveform and others...

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Unwanted effects/Side effects

- Cardiovascular spasm
- Hemolysis
- Stroke, TIA, silent cerebral lesions
- Bubble formation
- Muscle contraction
- Nerve damage
- Pain
- Local heating/temperature increase
- Coughing
- ...

Intended outcome

- Cell death
- Lesion depth
- Transmurality
- Size
- Predictability
- Reproducibility
- ...

Pulse parameters:

PFA waveform

- Catheter design
- Vectoring
- Contact
- Number of applications
- Workflow/protocol
- Repositioning
- Irrigation
- ...

	Lesion Depth	Stunning	Heating	Electro-chemistry	Pain	Neuro-muscular stimulation	Arrhythmogenic
Pulse Amplitude	↑↑	↑	↑↑	↑	↑	↑	↑
Pulse Width	↑	↑	↑	↑↑	↑↑	↑↑	↑↑
Number of Pulses	↑	↑	↑	↑↑	↑	↑	↑
Monophasic Pulse	↑	↑	—	↑↑	↑	↑	↑
Biphasic Pulse	↓	↓	—	↓↓	↓	↓	↓
Interphase delay	?	↑	↓	—	↑	↑	↑
Interpulse delay	↑	?	↓	—	↑↑	↑↑	↑↑
Intertrain delay	—	—	↓↓	—	—	—	—

Vermas A et al. HeartRhythm (2026) in press

Current PFA Technologies

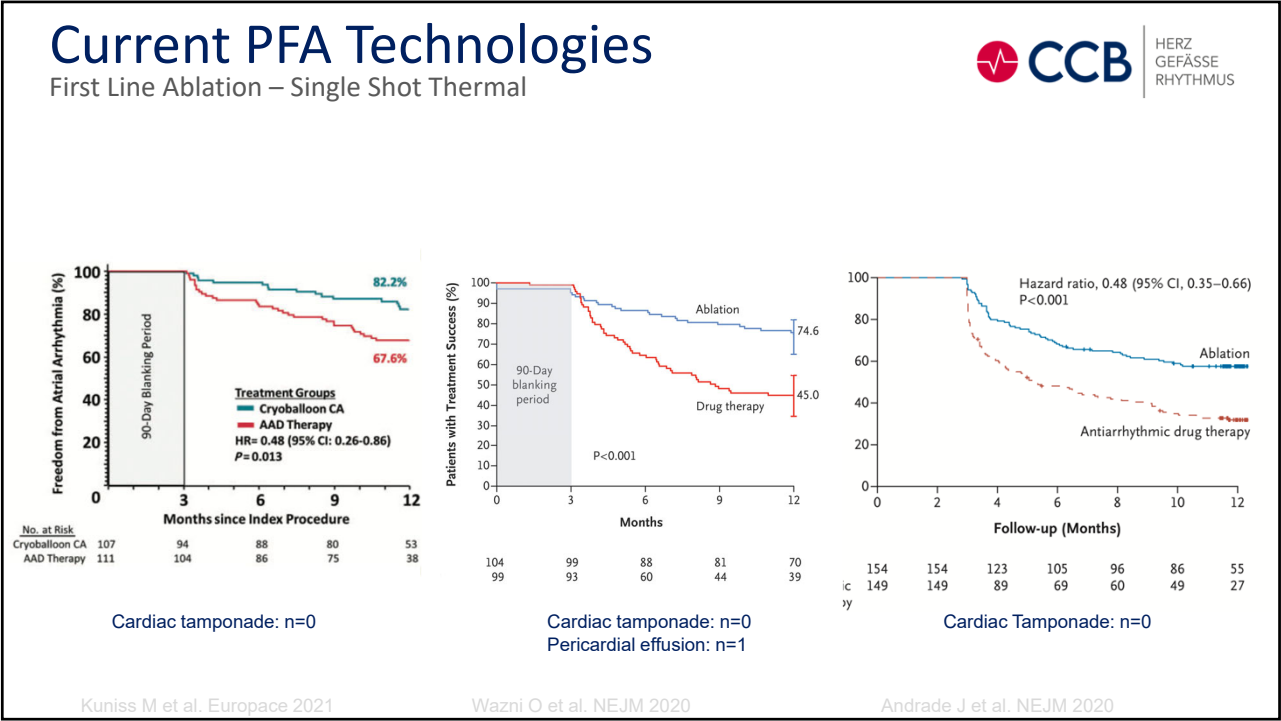
Pulmonary Vein Isolation

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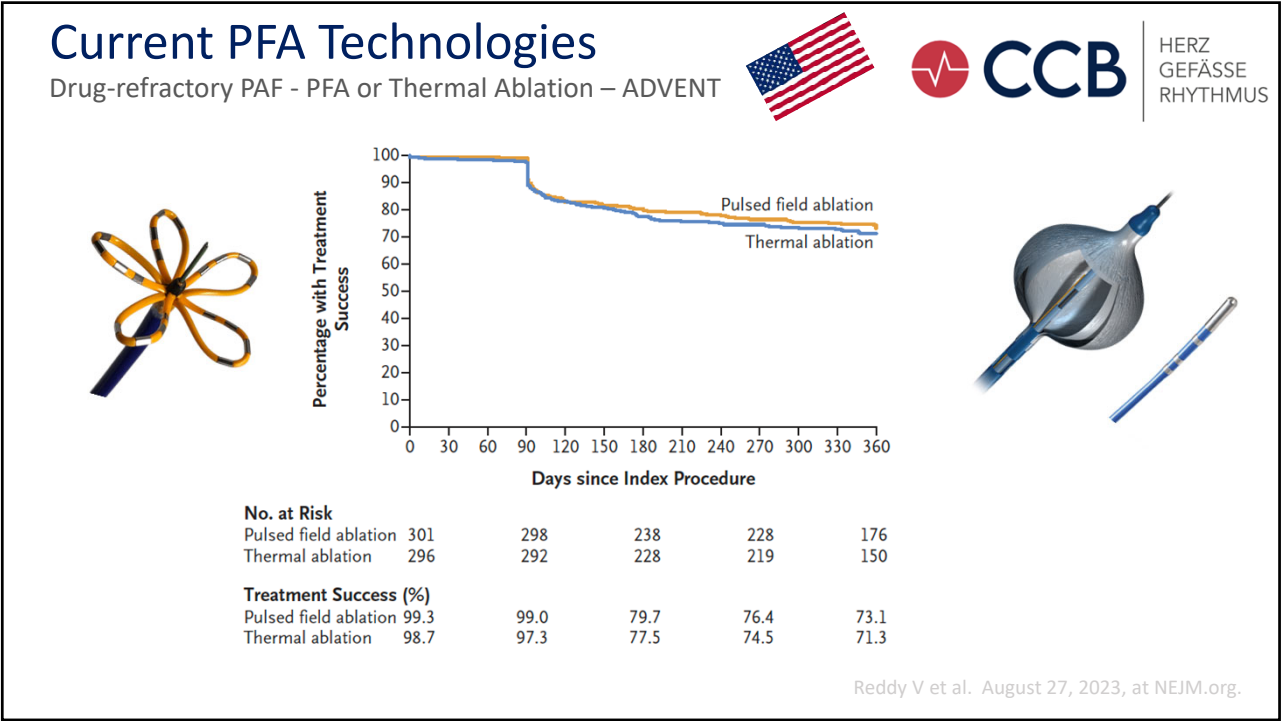
LPVs
LAA
RPVs
MA

In patients undergoing ablation for AF, PVI is recommended as the primary lesion set for all patients unless a different specific trigger is identified. (LOR Class I A)

Joglar et al. Circulation. 2023



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Current PFA Technologies

Paroxysmal AF – PFA or Cryo ?

The NEW ENGLAND JOURNAL of MEDICINE





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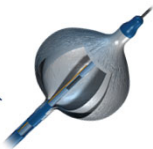
ORIGINAL ARTICLE

Pulsed Field or Cryoballoon Ablation for Paroxysmal Atrial Fibrillation



N=210

R
1:1



1° EFFICACY ENDPOINT: FIRST RECURRENCE OF AT/AF

1° SAFETY ENDPOINT: PROCEDURE RELATED SAE

Reichlin T et al. March 31, 2025, at NEJM.org.

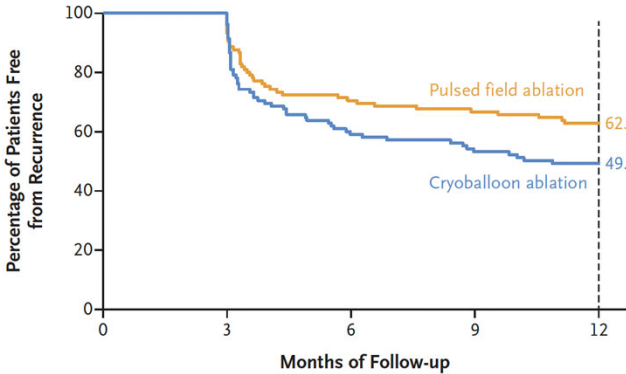
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Current PFA Technologies

Paroxysmal AF – Single Shot Champion



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Percentage of Patients Free from Recurrence

Months of Follow-up

Pulsed field ablation

Cryoballoon ablation

62.9

49.3

Difference in cumulative incidence, -13.6 percentage points (95% CI, -26.9 to -0.3)

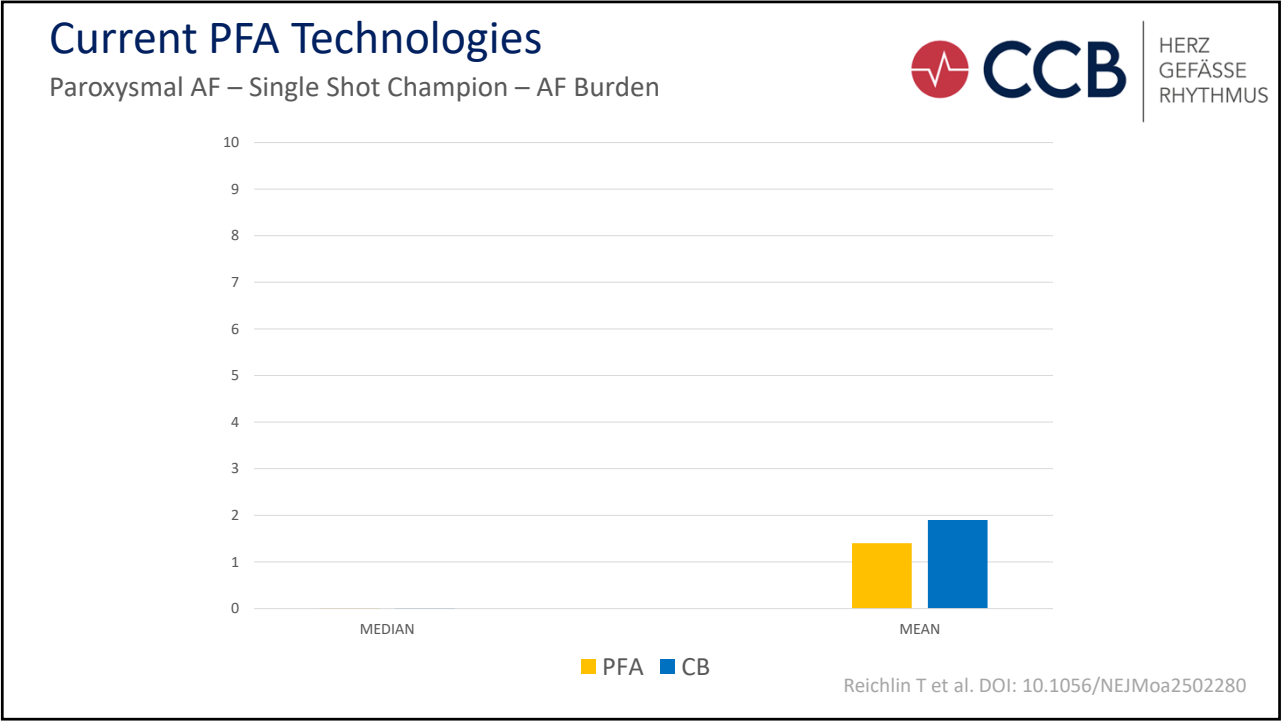
No. at Risk (%)

Pulse field ablation	105 (100)	98 (93)	74 (70)	70 (67)	66 (63)
Cryoballoon ablation	105 (100)	101 (96)	62 (59)	54 (51)	50 (48)

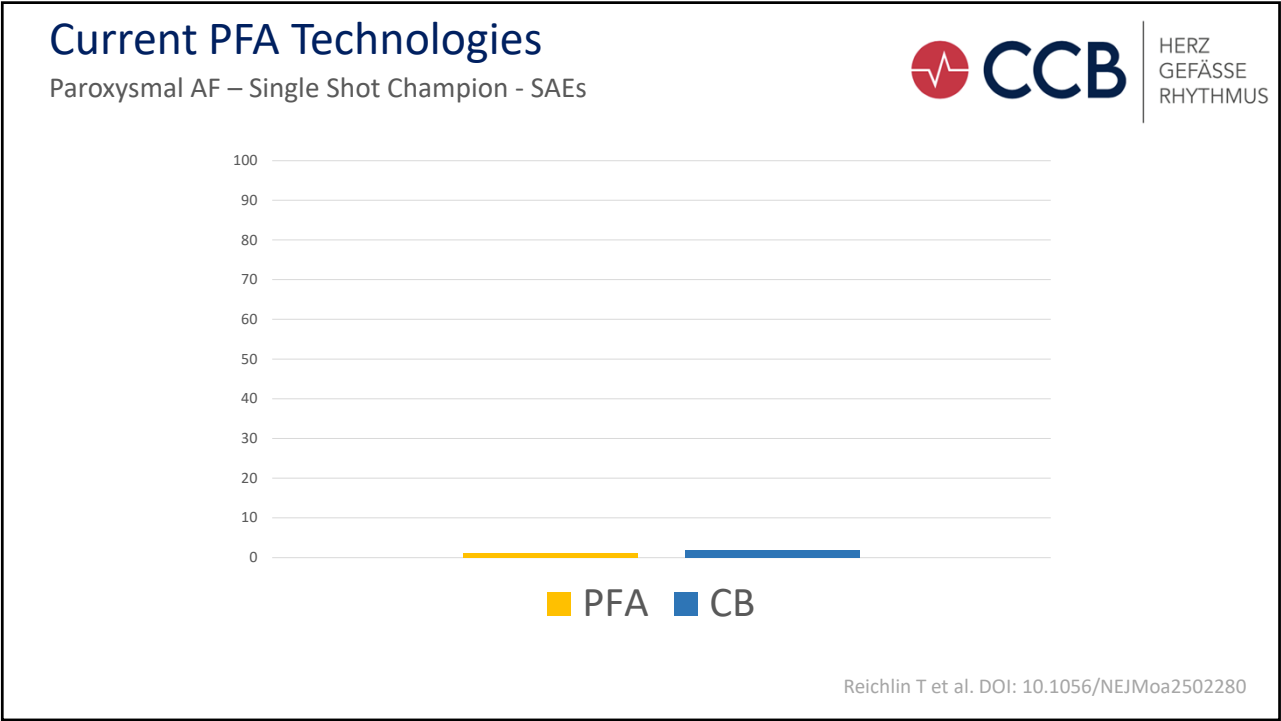
Reichlin T et al. DOI: 10.1056/NEJMoa2502280

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Current PFA Technologies

Device Overview



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Single Shot PVI Tools

Table 2 Overview of contemporary circumferential PVI tools

Farapulse™ Boston Scientific	Pulsaflex™ Medtronic	Inspire™ Biosense Webster	Globe PF™ Kardium	Vital™ Abbott	Sphere 360™ Medtronic	Adagio Adagio	Lotus™ Lifetech	ColFX™ Polar Bioscience
Diameter 31/35 mm	25 mm	25-35 mm	30 mm	28 mm	28 mm	25 mm variable	28/31 mm	30 mm
Size 12F	9F	8.5F	10F	13F	7.5F	8.5F	12F	11F
Over the wire	No	No	No	Yes	Yes	No	No	No
PVI ****	****	****	****	****	****	***	****	****
Non-PV lesions/versatility	**	**	**	*	*	**	**	**
Clinical experience	****	***	**	*	*	*	No	*
Ablation mode	Bipolar	Bipolar	Bipolar	Bipolar	Monopolar	Bipolar	Bipolar	Bipolar
Dedicated 3D mapping	No	No	Yes	Yes	No	No	No	No
Approval	EU/USA	EU/USA	EU/Japan	No	No	No	No	No

Large FOOTPRINT / Focal PFA

Table 3 Overview of focal point-by-point large/intermediate footprint PFA catheters and a specific generator enabling PFA using conventional RF catheters

Sphere 9™ Medtronic	Omnipulse™ Biosense Webster	Farapulse™ Boston Scientific	LFC Centauri	Centauri
Diameter 9 mm	12 mm	10 mm	10 mm	33-4 mm
Size 8F	7.5F	12F	8.5F	8F
Catheter deflection	Bidirectional	Bidirectional	Unidirectional	Unidirectional/bidirectional
PVI ****	****	****	NA	****
Non-PV lesions/versatility	****	****	NA	****
Clinical experience	***	+	No	**
Ablation mode	Monopolar	Bipolar	Monopolar	Monopolar
PFARIC	Yes/Yes	Yes/No	Yes/No	Yes/Yes
Dedicated 3D mapping	Yes	Yes	multiple	multiple
Approval	EU	No	No	EU

Several systems are currently under investigation; thus, scientific references are not always available. The assessment of clinical applicability is based on the authors' opinion. For more details, please see text. PVI, pulsed field; PFA, pulsed field ablation; PVI, pulmonary vein isolation; RF, radiofrequency; RNC, radiofrequency current.

Chun KRJ et al. Europace (2024) 26, euae134

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Current PFA Technologies

Single Shot Devices – Circular Catheters

STUDY DESIGN

13
EUROPE & CANADA
CENTERS

226
PATIENTS

WITH DRUG-REFRACTORY SYMPTOMATIC
PAROXYSMAL ATRIAL FIBRILLATION

95 (42.1%) male, 131 (57.9%) female, 53.9 (SD 10.6) years
78.5 (SD 10.4) mm Ld, 36.6 (SD 10.2) mm Ld, 36.6 (SD 10.2) mm Ld

PROCEDURAL DATA

CHARACTERISTICS	WAVE I	WAVE II
Procedure time, min	82.4	70.1
LA dwell time, min	46.2	44.7
Fluoroscopy time, min	9.8	7.9

PRE- VS. POST-ABLATION VOLTAGE MAP
SHOWING LEVEL OF ISOLATION
(WAVE I & II)

PRE-ABLATION

POST-ABLATION

CLINICAL OUTCOMES

PRIMARY ADVERSE EVENTS (WAVE I & II)

0% NO PV STENOSIS, ESOPHAGEAL THERMAL LESIONS, AE, FISTULA, THROMBOEMBOLISM, TIA, OR MYOCARDIAL INFARCTION

12-MONTH EFFECTIVENESS (WAVE II)

70.9% 12-MONTH FREEDOM FROM PRIMARY EFFECTIVENESS FAILURE

78.9% CLINICAL SUCCESS

92.3% FREEDOM FROM REPEAT ABLATION

Trial design & study population

Prospective, global, multi-center, non-randomized paired single-arm trial

Global multicenter study

- 9 countries
- 41 sites
- 67 operators

300 patients enrolled

150 Paroxysmal, 150 Persistent

Symptomatic AF patients refractory to class I or III AADs

96% (287) of patients completed 12-month follow-up

Safety outcomes

0 Esophageal events

0 PV stenosis

0 Phrenic nerve injury

Safety 0.7% Primary adverse events

0 PV stenosis

0 Phrenic nerve injury

0 PV stenosis

0 Phrenic nerve injury

Efficacy outcomes

80% PAF Freedom from symptomatic AF/AFL

70% PAF Freedom from AF/AFL

81% PAF Freedom from AF/AFL

62% PAF Freedom from AF/AFL

Primary efficacy outcome

Secondary efficacy outcome

Primary efficacy outcome

Secondary efficacy outcome

Procedural data

	PAF	PSP
Time between first and last application (min)	58±28	64±28
Total pulsed field ablation energy delivery (sec)	25±8	29±10

Rigorous arrhythmia monitoring

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

Duytschaever M et al. Circ Arrhythm Electrophysiol. 2023;16:e011780.

Verma A et al. Circulation.2023 May 9;147(19):1422-1432.

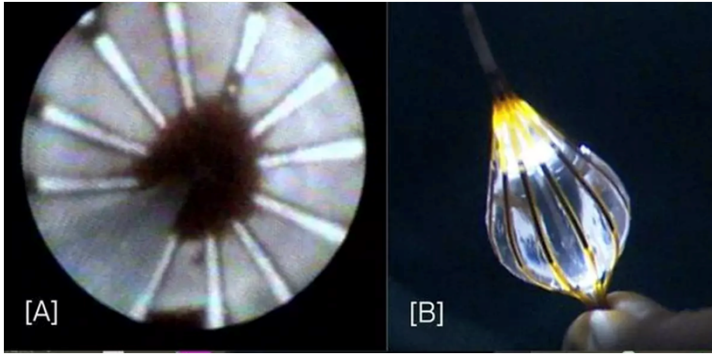
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Current PFA Technologies

Single Shot Devices – „Balloon“ Solutions





6-MONTH RESULTS OF THE VOLT CE MARK STUDY

150 PAF + PersAF Subjects
11 Sites

99.1% ACUTE EFFECTIVENESS
PVI confirmation after 20-minute wait period

17.6±5.7 TOTAL PFA APPLICATIONS/PATIENT
Baseline 2 applications, maximum of 8 applications per vein

88.2% PAF
76.7% PersAF

6 MONTH EFFECTIVENESS
Free from documented AF/AFL/AT recurrence

2.7% PRIMARY SAFETY
2 vascular access/major bleeding complications, 1 cardiac tamponade, 1 pneumonia

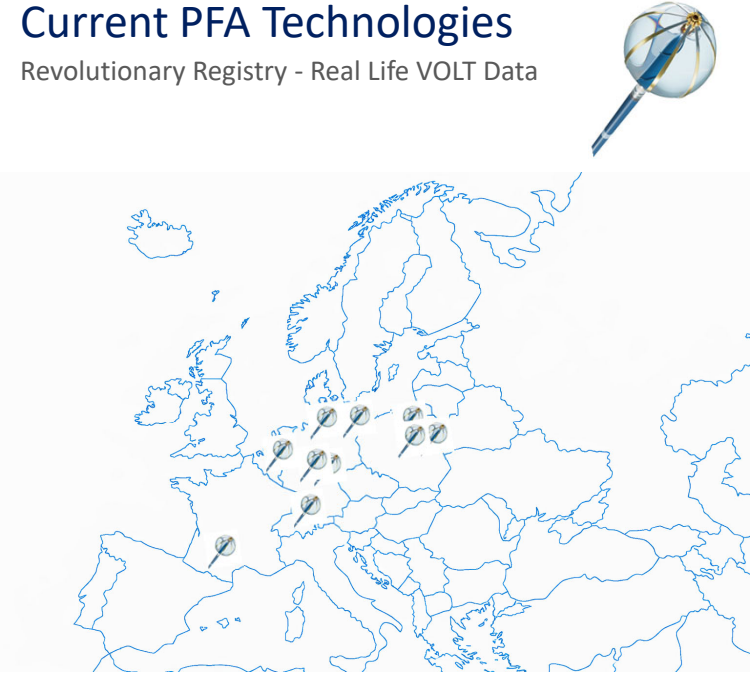
Reddy V et al. Jacc 2026 .

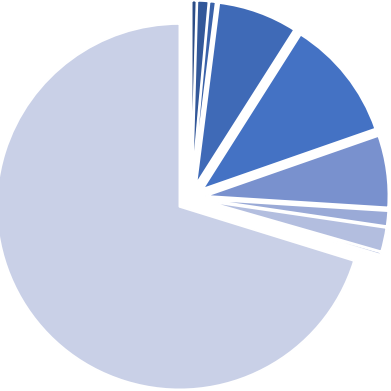
Tilz RR et al. EP Europace, Volume 27, Issue 4, April 2025,.

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Current PFA Technologies

Revolutionary Registry - Real Life VOLT Data





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Current PFA Technologies

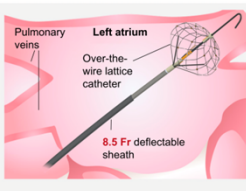
Single Shot Devices – Monopolar Array





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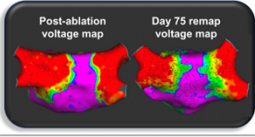
First-in-human clinical trial
Symptomatic drug-refractory paroxysmal atrial fibrillation
N = 85



3-month remapping: PV durability

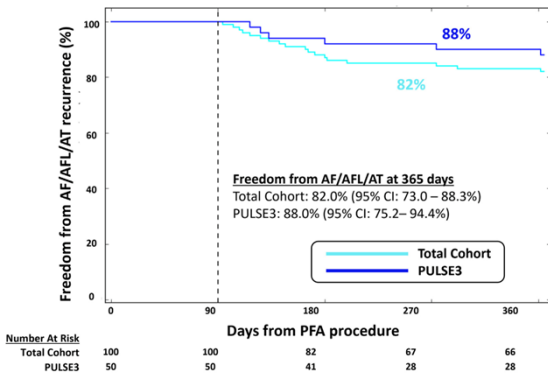
Group	PVI durability (%)
Total cohort	90%
Pulse 3	99%
Total cohort	77%
Pulse 3	96%

3-month remapping: Voltage maps



Weekly TTM schedule:
Visit day 10, Visit day 75 (Optional remap), Visit month 6 (48-hour holter), Visit month 12 (48-hour holter).
Weekly TTM 8 weeks post 90-day blanking period, monthly, and symptomatic TTM thereafter.

Metric	Value
Primary safety event rate	0%
Acute efficacy	100%
12M freedom from atrial arrhythmia with pulse 3	100%
12M freedom from atrial arrhythmia in total cohort	81.8%



Freedom from AF/AFL/AT at 365 days
Total Cohort: 82.0% (95% CI: 73.0 – 88.3%)
PULSE3: 88.0% (95% CI: 75.2 – 94.4%)

Days from PFA procedure	Total Cohort	PULSE3
0	100	100
90	100	100
180	82	88
270	67	88
360	66	88

- 4.7 applications per PV
- 99% General Anaesthesia

Reddy VY et al. Heart Rhythm. 2025 Oct;22(10):2551-2561.

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Current PFA Technologies

Nanosecond PFA – The new Hype



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Nanosecond PFA for Paroxysmal AF: High Efficacy and Safety at 12 Months

STUDY POPULATION



166 Patients
Paroxysmal Atrial Fibrillation

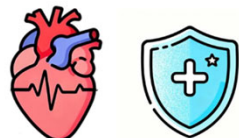
INTERVENTION: nsPFA



SCENA-AF Trial
Nanosecond PFA for PVI

Reduced Anesthesia Burden
92.77% under Conscious Sedation

12-MONTH OUTCOMES



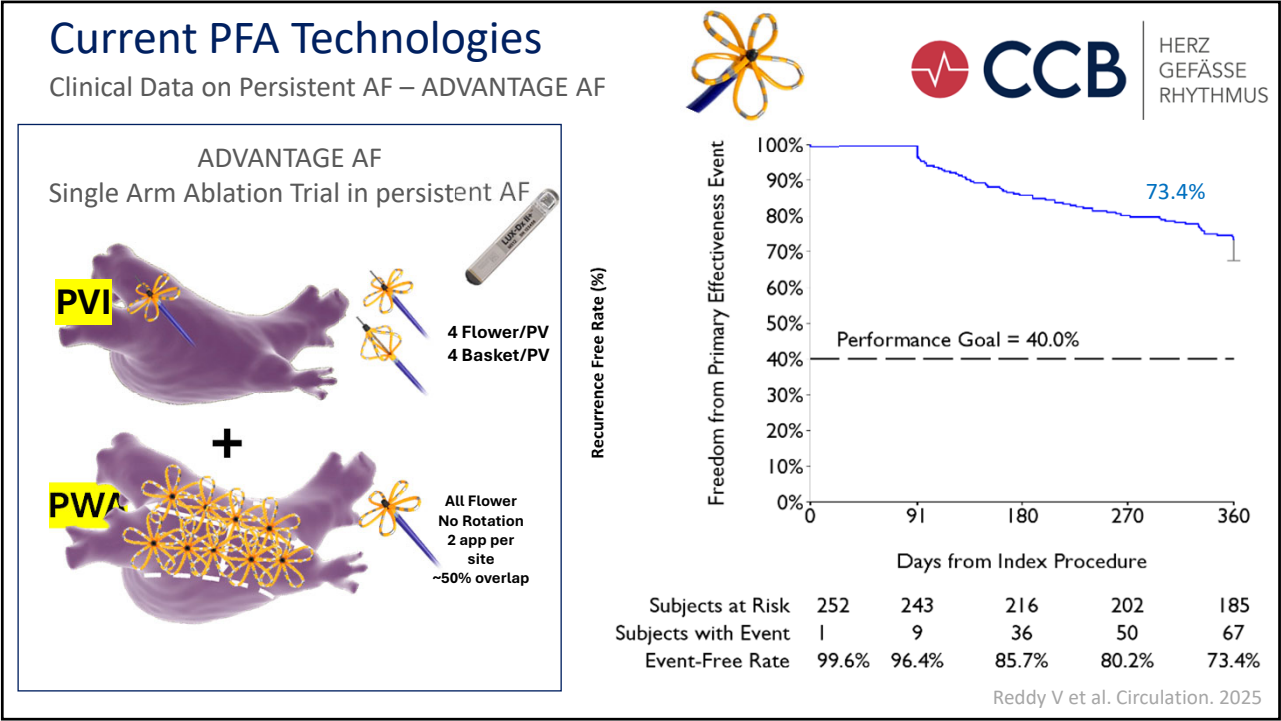
High Efficacy
88.49% Free from Atrial Arrhythmia

Favorable Safety
0% Major Complications

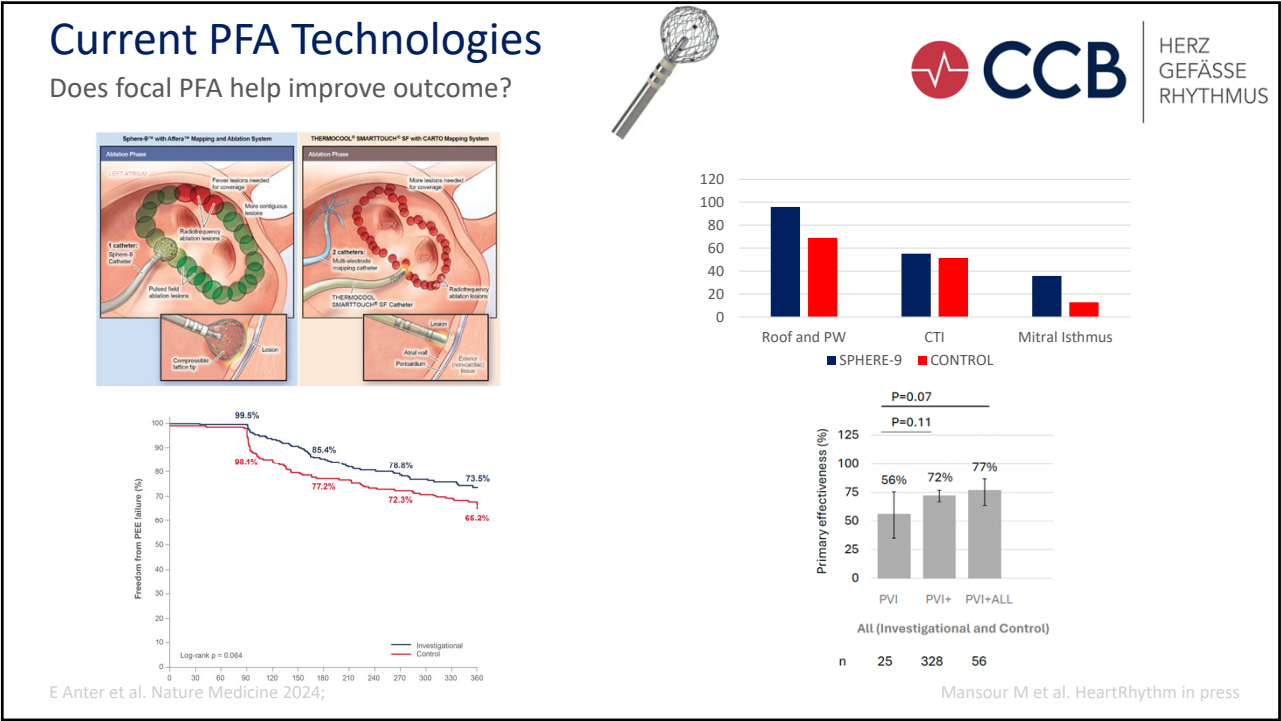
Xie S et al. Circ Arrhythm Electrophysiol 2025

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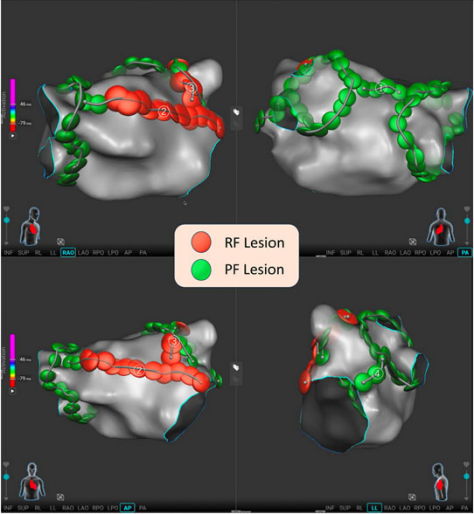
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Current PFA Technologies

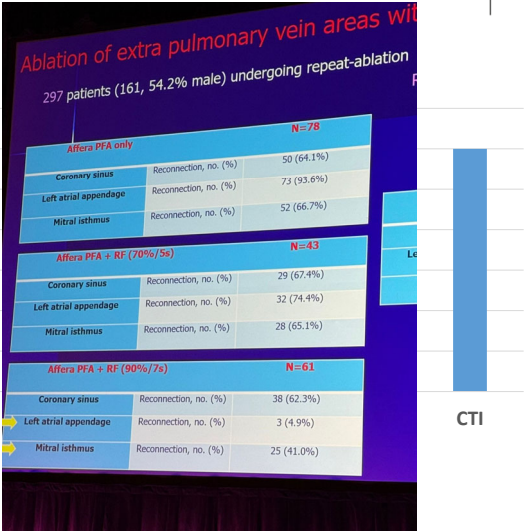
Does focal PFA help improve outcome?



Hirokami J et al. Heart Rhythm. 2025 Jul;22(7):e40-e50.



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Site	Reconnection, no. (%)
Coronary sinus	50 (64.1%)
Left atrial appendage	73 (93.6%)
Mitral isthmus	52 (66.7%)

Site	Reconnection, no. (%)
Coronary sinus	29 (67.4%)
Left atrial appendage	32 (74.4%)
Mitral isthmus	28 (65.1%)

Site	Reconnection, no. (%)
Coronary sinus	38 (62.3%)
Left atrial appendage	3 (4.9%)
Mitral isthmus	25 (41.0%)

CTI

Natale A et al. AF Symposium 2026

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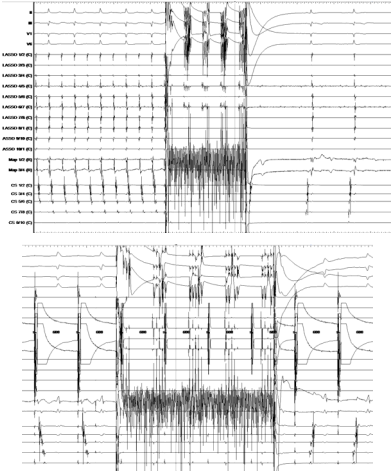
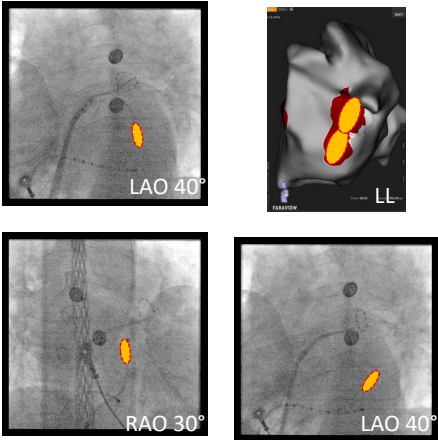
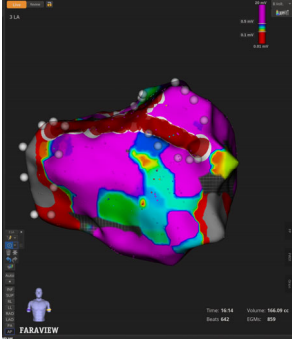
Current PFA Technologies

Does focal PFA help improve outcome?



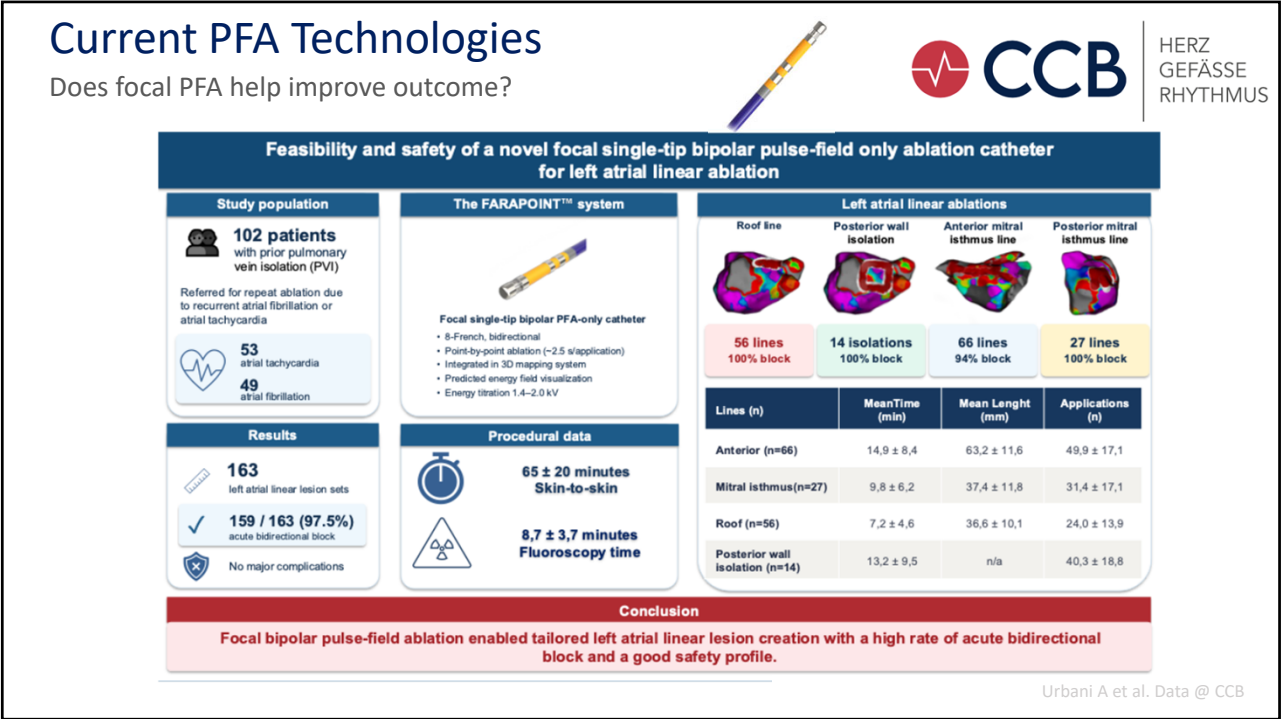


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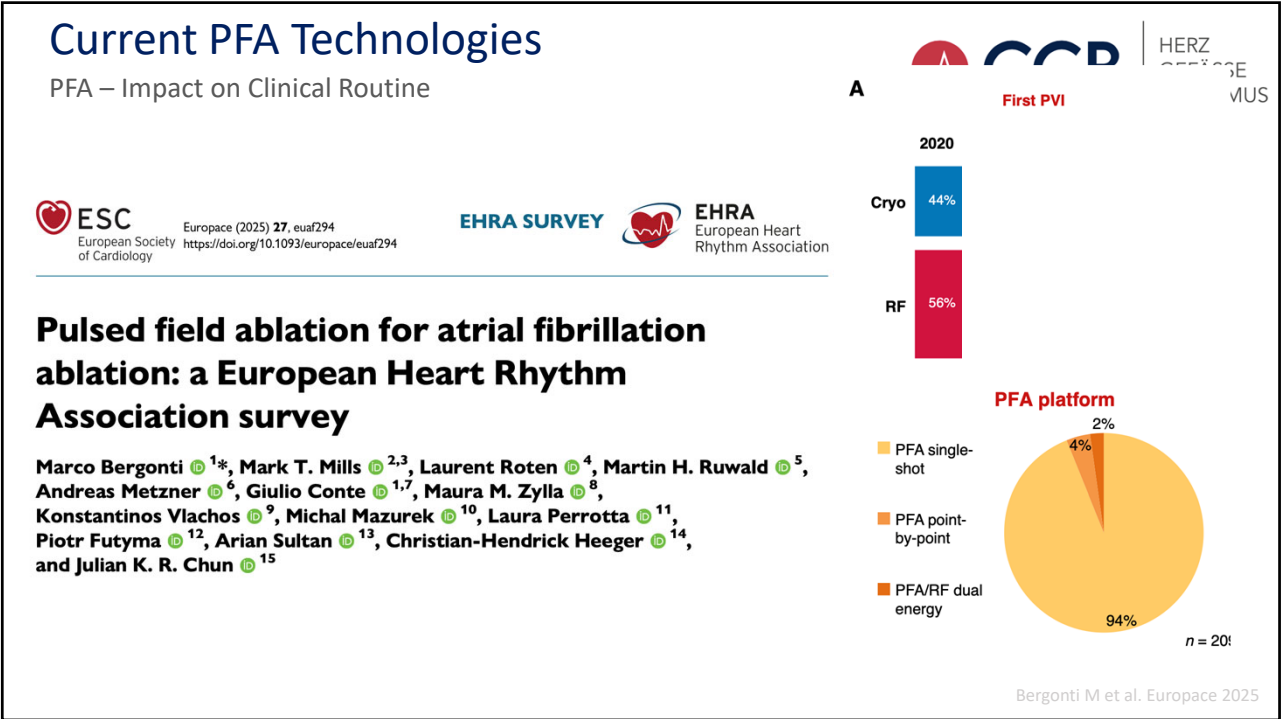


Data @ CCB

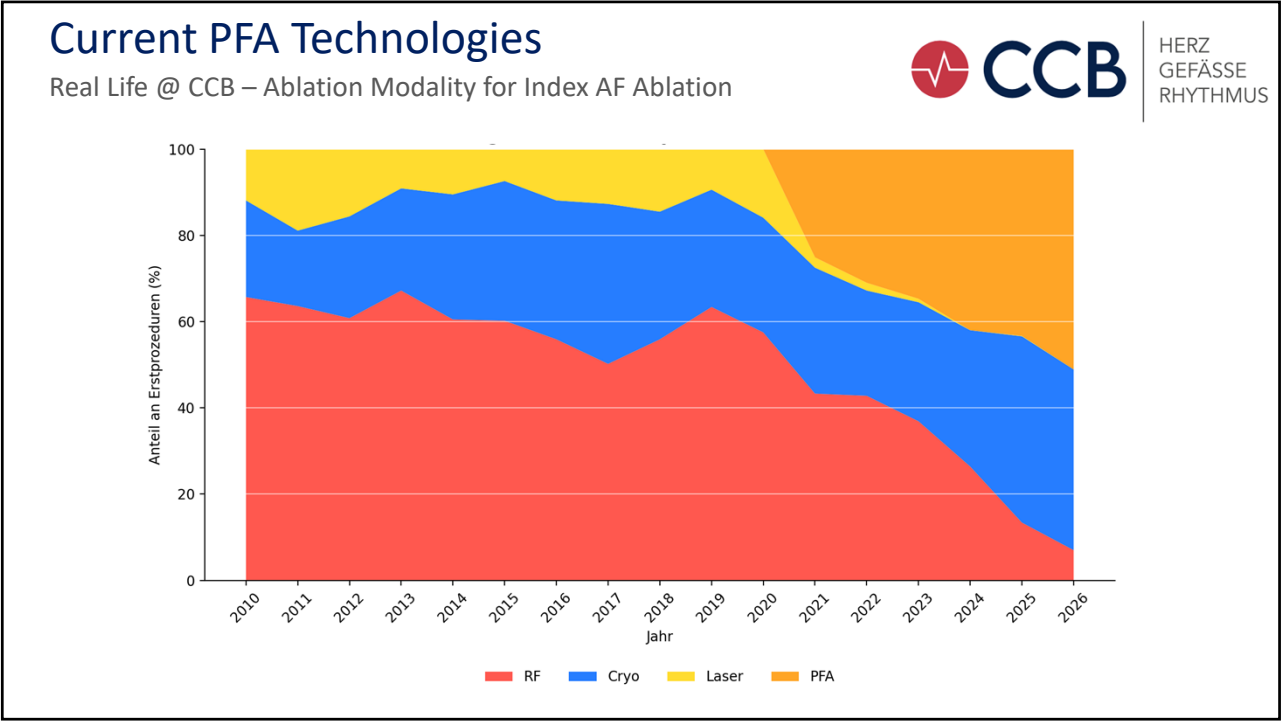
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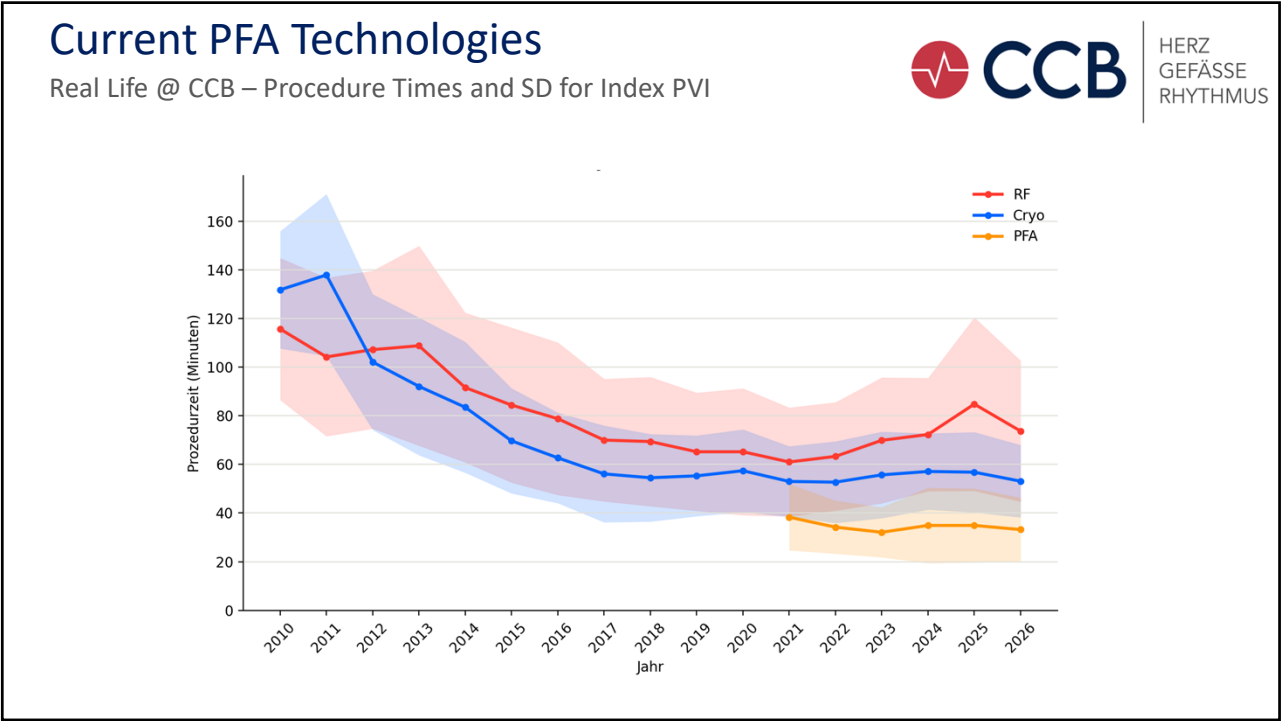
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Current PFA Technologies

Outpatient Ablation – The new Now



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Feasibility and Safety of Ambulatory Atrial Fibrillation Ablation

Results from a Prospective Single-Centre Study

STUDY DESIGN

- Prospective, single centre, observational study
- January-April 2026
- 200 consecutive patients undergoing index AF ablation within an ambulatory pathway
- No stringent pre-procedural selection criteria

AMBULATORY AF ABLATION PATHWAY

Pre-procedure → Ablation procedure → Post-procedure monitoring → Discharge → Follow-up 30 days

Pre-procedure: Clinical evaluation and laboratory tests

Ablation procedure: Single-shot PVI (Cryoballoon, PFA Farapulse or Volt), Two femoral venous access

Post-procedure monitoring: 2-4 h observation in monitored recovery area

Discharge: Discharge after clinical reassessment

Follow-up 30 days: Structured telephone interview and review of clinical records

PROCEDURAL PROTOCOL

Anticoagulation. Heparin 100 IU/Kg before venous access; ACT>300 s throughout procedure

Access and Hemostasis. Femoral venous access under ultrasound guidance. Figure-of-eight suture

Sedation protocol. Midazolam, Fentanyl and Propofol

Safety check. TTE at the of the procedure and before discharge

PATIENTS AND PROCEDURAL CHARACTERISTICS (n=200)

- Male, 59%
- Paroxysmal AF, 58%
- Age, 66 (59-73) Years
- BMI, 28 (25-33) Kg/m²
- LVEF, 60±8 %

PROCEDURE DURATION, 43 (35-50)

Energy source,

- Cryoballoon 53%
- PFA – Farapulse 34%
- PFA – Volt 13%

Heparin dose, 104 (98-120) IU/Kg

Propofol dose, 4.7 (3.7-5.6 mg/Kg)

POST-PROCEDURAL COURSE

Post-procedural observation time 4:22 (3:30-5:012) hours

Overall stay duration 5:25 (4:30-6:11) hours

Conversion to overnight stay

n=8	4%
- Patient preference	n=5 2.5%
- Groin bleeding	n=2 1%
- Procedure-related complications	n=1 0.5%

30-DAY OUTCOMES

30-day follow up completion 174/192 90.6%

Healthcare contact

- Within 24 hours	5/174 2.9%
- Within 30 days	40/174 23%
- Requiring hospitalization	5/174 2.9%

Symptoms reported:

- Palpitations
- Groin access-site complains
- Chest pain
- Others

High patient-perceived safety and acceptance

CONCLUSIONS

In this all-comer population, ambulatory AF ablation was feasible, safe, and applicable to most patients. Low rates of clinically relevant adverse events and high patient-perceived safety support the implementation of ambulatory AF ablation in routine clinical practice.

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Current PFA Technologies

Ablation in an Ambulatory Surgical Center



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Selection

- 4 patients per day
 - First-do PVI
 - Age <80
 - Patient consent

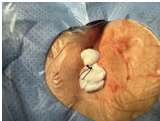
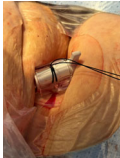
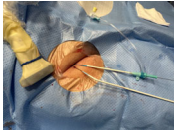
Procedure

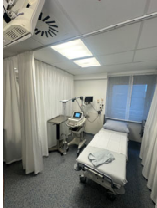
- Single Shot Technology
 - 2 US venous puncture
 - ACT>350s
 - Z-suture

After Care

- Telemetry, NIBP, SpO₂
- Bed rest (2) - 4h
- Suture removal
- „Ambulation test“
- Echo pre d/c
- NOAC cont'd







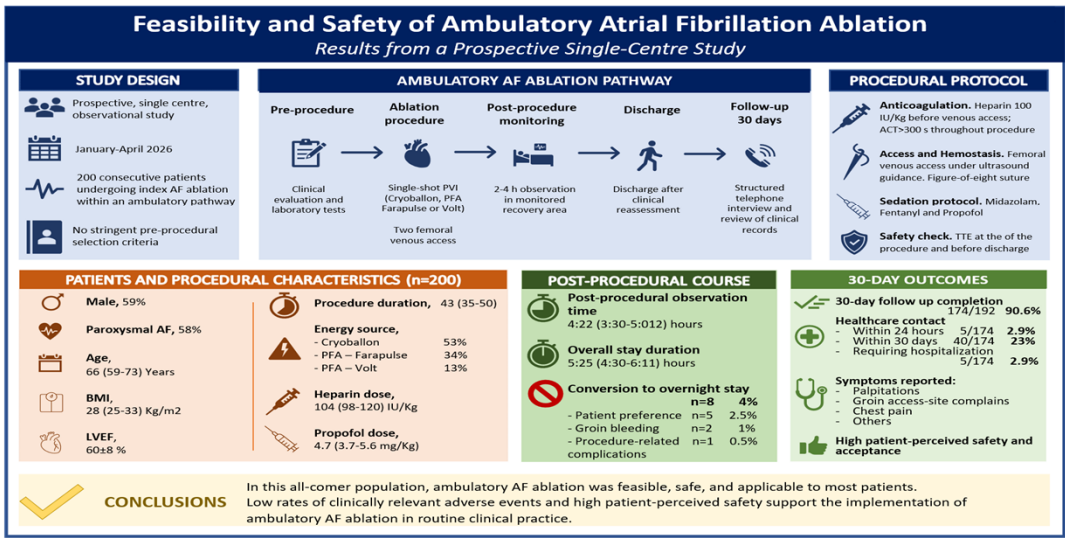
102

Current PFA Technologies

Outpatient Ablation – The new Now



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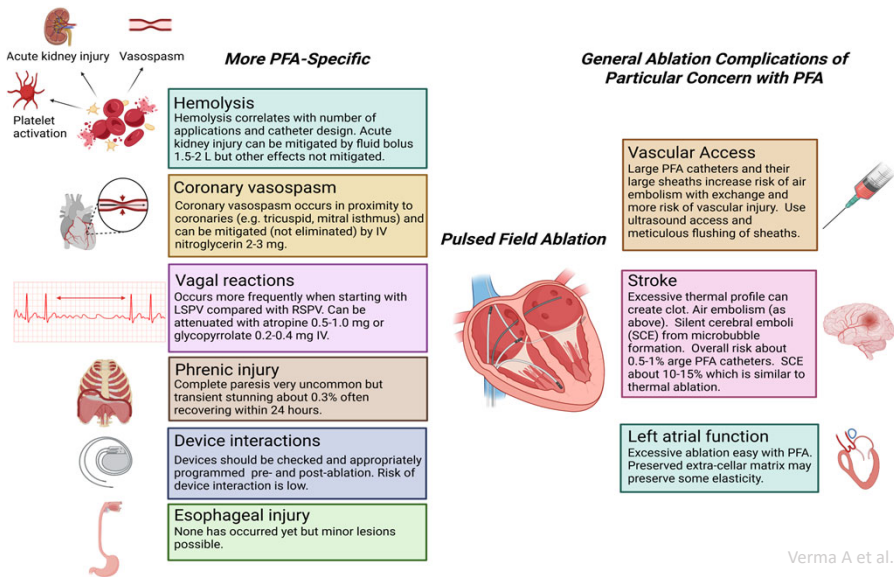
103

Current PFA Technologies

Spectrum of Side Effects



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RHYTHMUS



Verma A et al. Heart Rhythm in press

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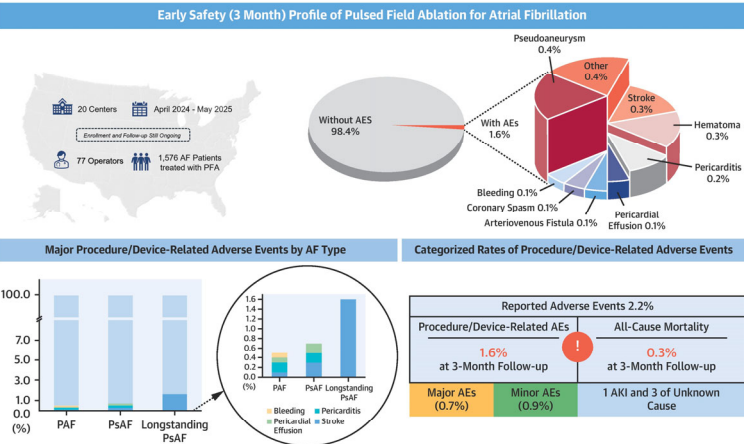
Current PFA Technologies

SAFETY of Pentaspline PFA in Early US Experience (n=1576)



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RHYTHMUS

CENTRAL ILLUSTRATION: Safety Profile Using Pulsed Field Ablation in Real-World DISRUPT-AF Registry



Wong EA, et al. JACC Clin Electrophysiol. 2026;10.1016/j.jacep.2026.04.032

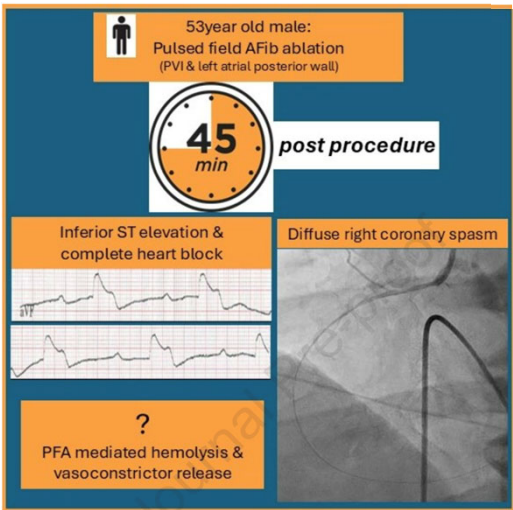
105

Current PFA Technologies

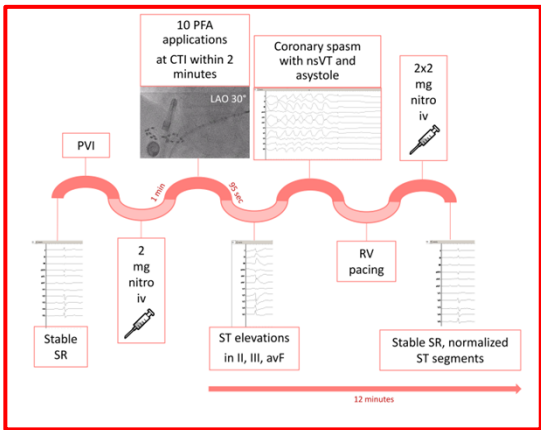
Coronary Spasm – Variable Time Course



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GEFÄSSE
RHYTHMUS



Luther V et al. Heart Rhythm (2025)



Gunawardene MA et al. EHJ - Case Reports (2024) 8

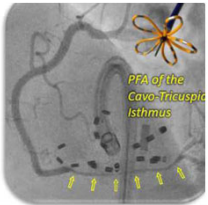
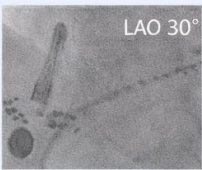
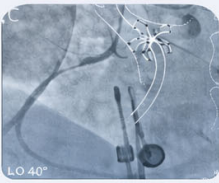
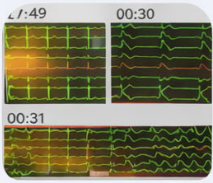
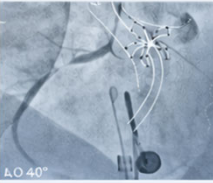
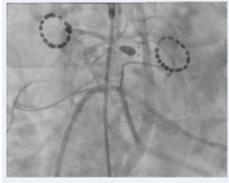
106

Current PFA Technologies

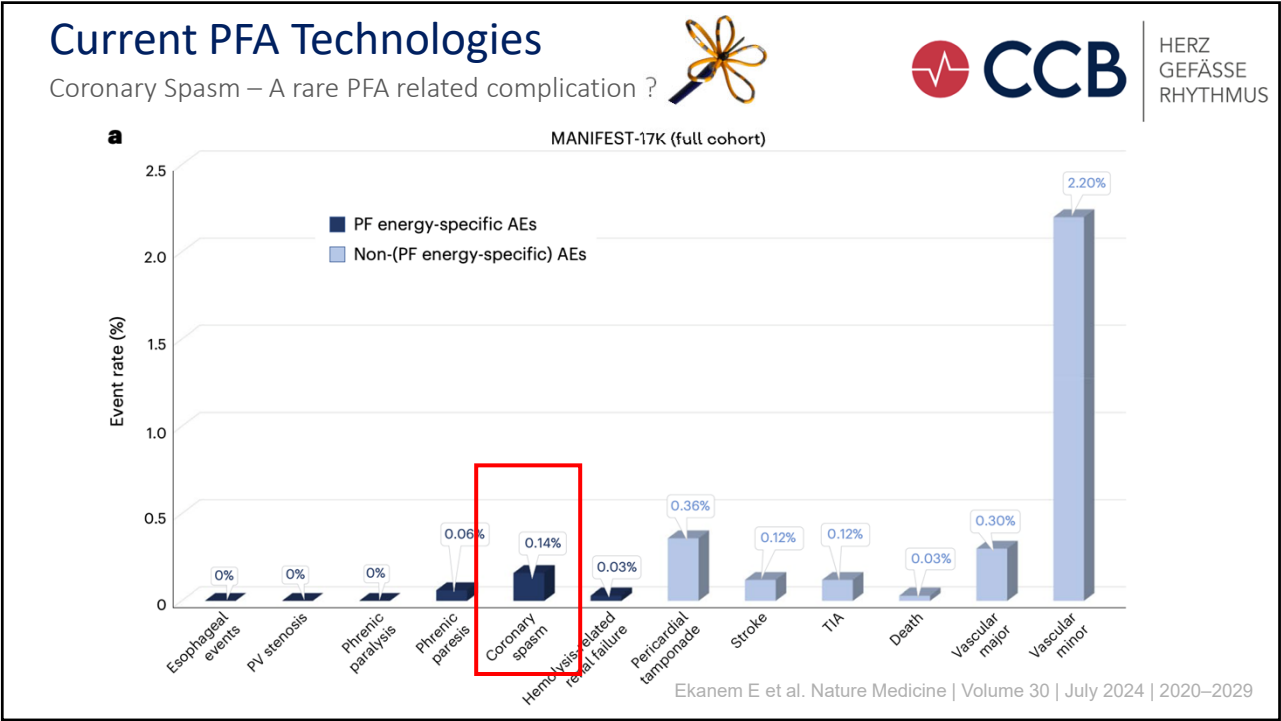
Coronary Spasm – Typology



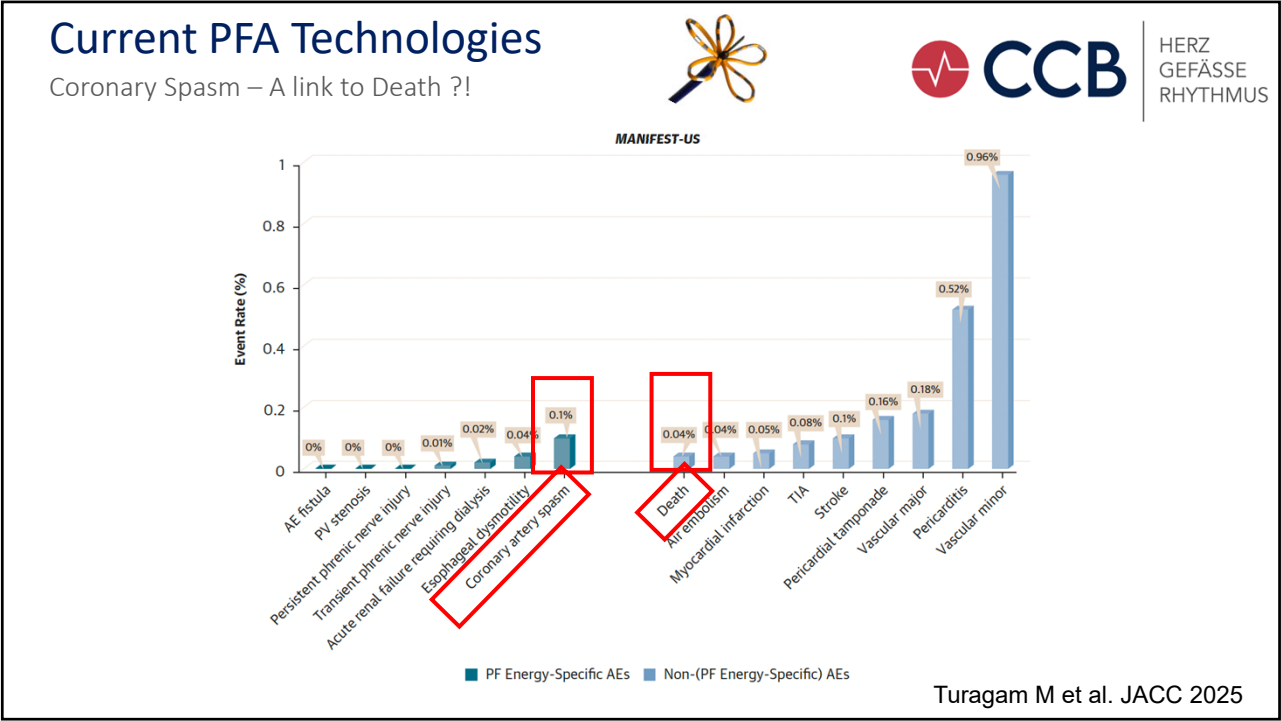
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	 Immediate Spasm	 Delayed Spasm	 Localized Spasm	 General Spasm
 Proximity-related	 PFA of the Cavo-Tricuspid Isthmus	 LAO 30°		
 Non-Proximity related	 LAO 40°	 LAO 40°	 LAO 40°	

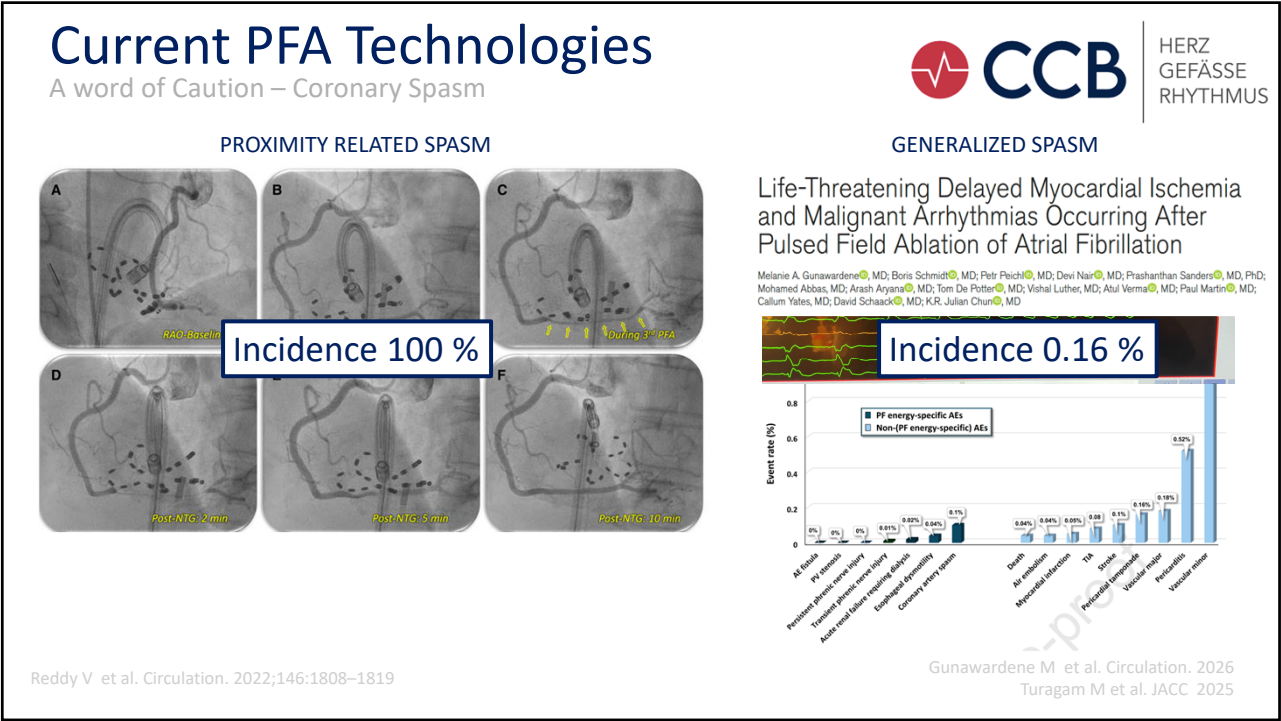
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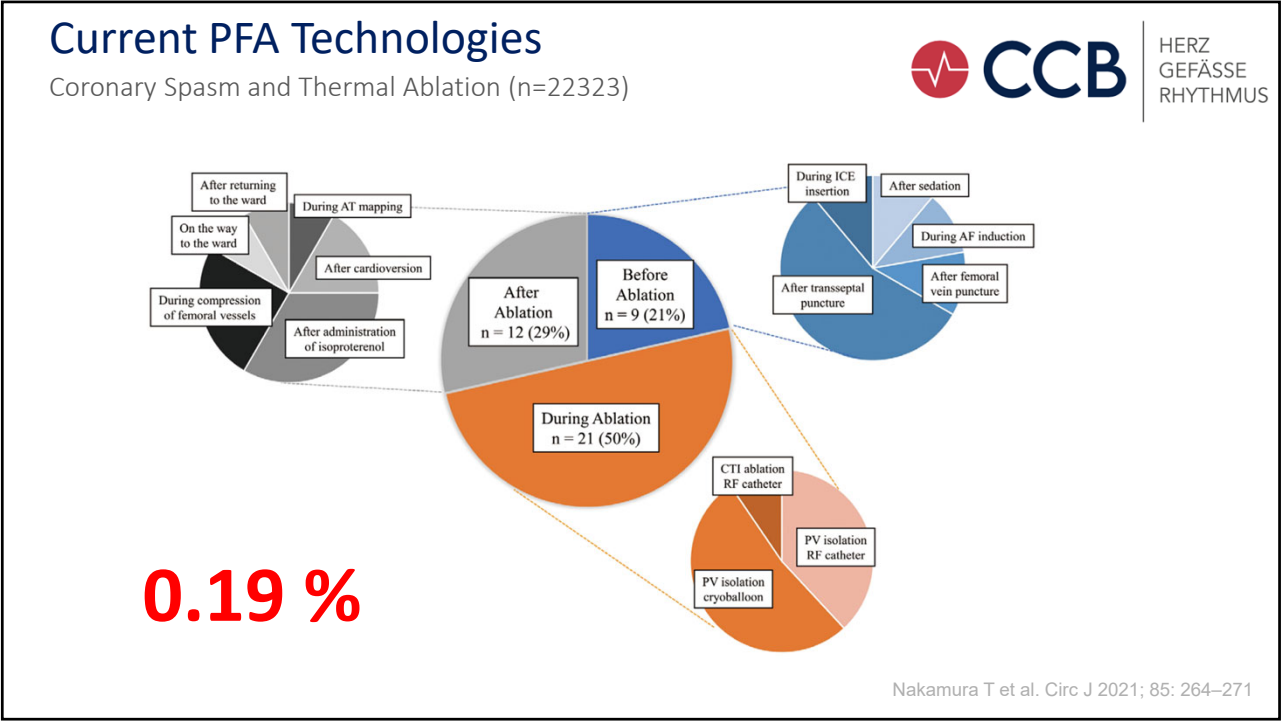
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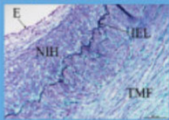
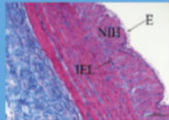
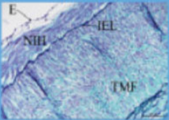
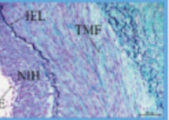
111

Current PFA Technologies

Proximity related Coronary Spasm independent of PF waveform

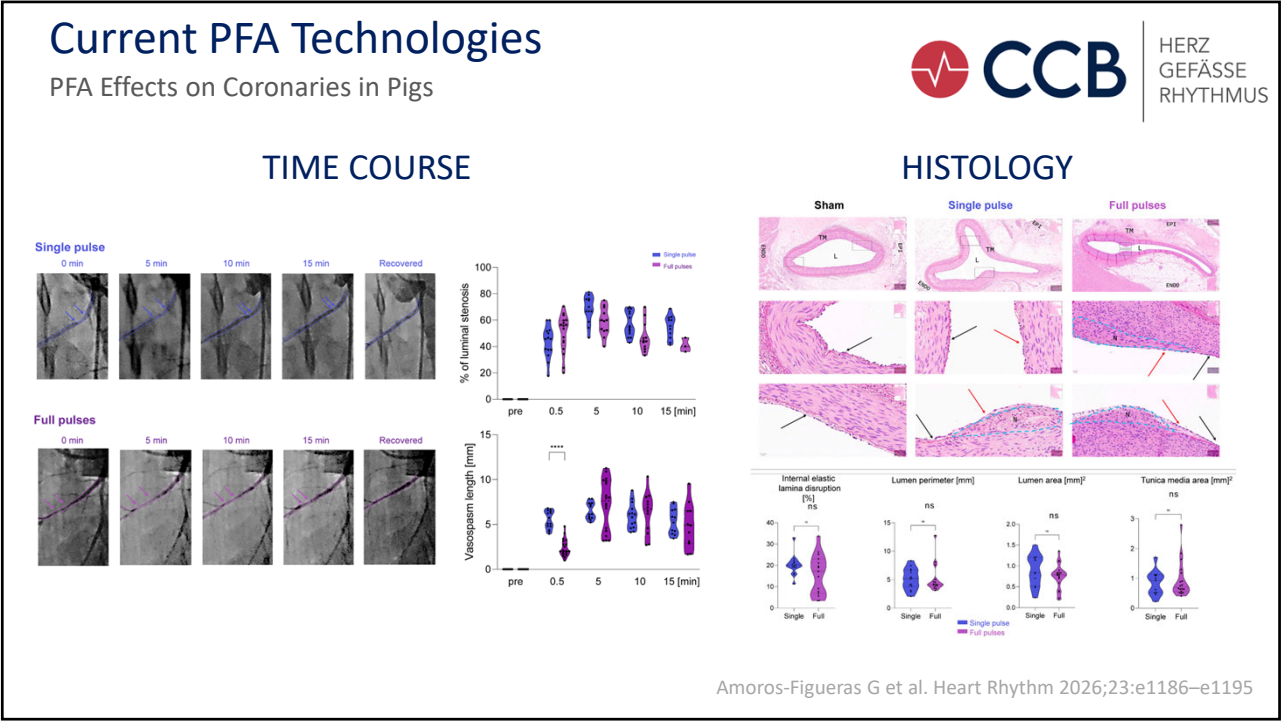


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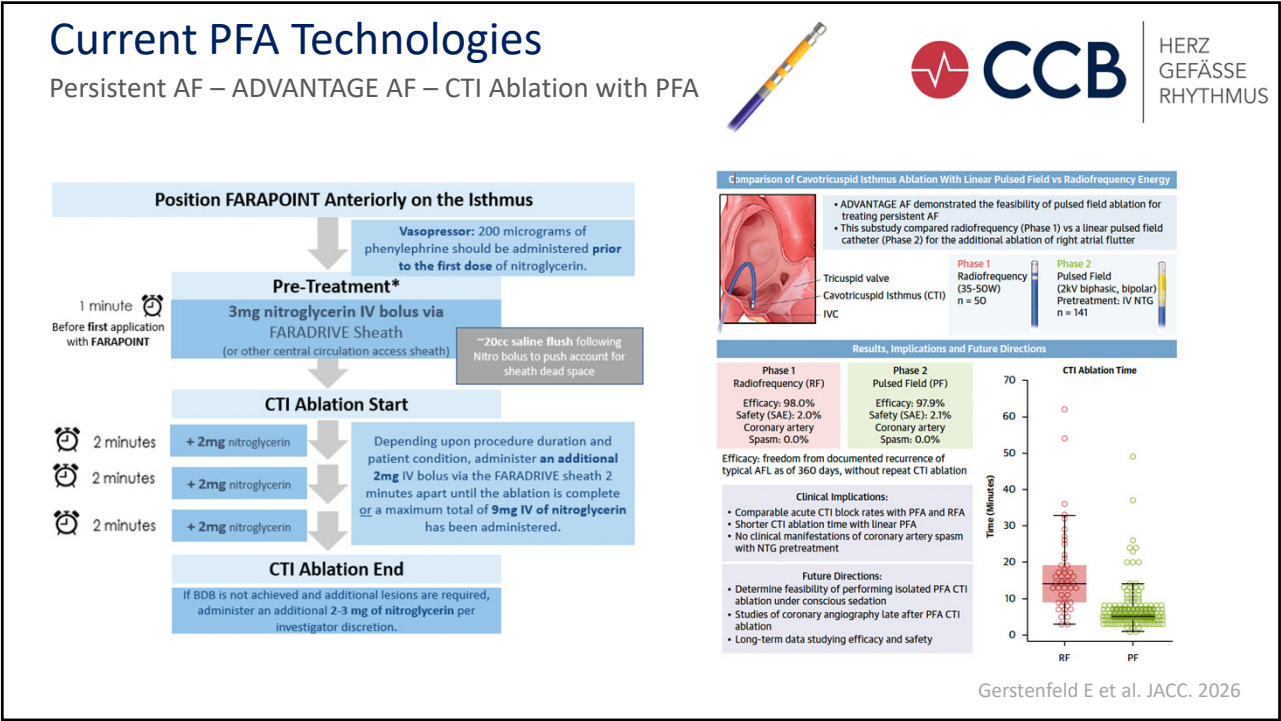
	Group 1-Monopolar PFA 1.4 kV	Group 2-Monopolar PFA 2 kV	Group 3-Bipolar PFA 2 kV	Group 4-RF
Median Number of PFA/RF Applications	5	7	7	12
Mean Acute Luminal Reduction on CA Angiography	-58.5%	-68.8%	-66.6%	+10.2%
Mean Chronic (1 month) Luminal Reduction on CA Angiography	-3.6%	+0.6%	-6.19%	+11.7%
Chronic (1 month) Neointimal Hyperplasia	2/3 animals 1 Minimal; 1 Mild 	2/3 animals 1 Minimal; 1 Mild  *same stain, different coloring	1/3 animals 1 Minimal 	2/3 animals 1 Minimal; 1 Mild 

Gerstenfeld EP et al. Jacc EP 2026;12(3): 528-37.

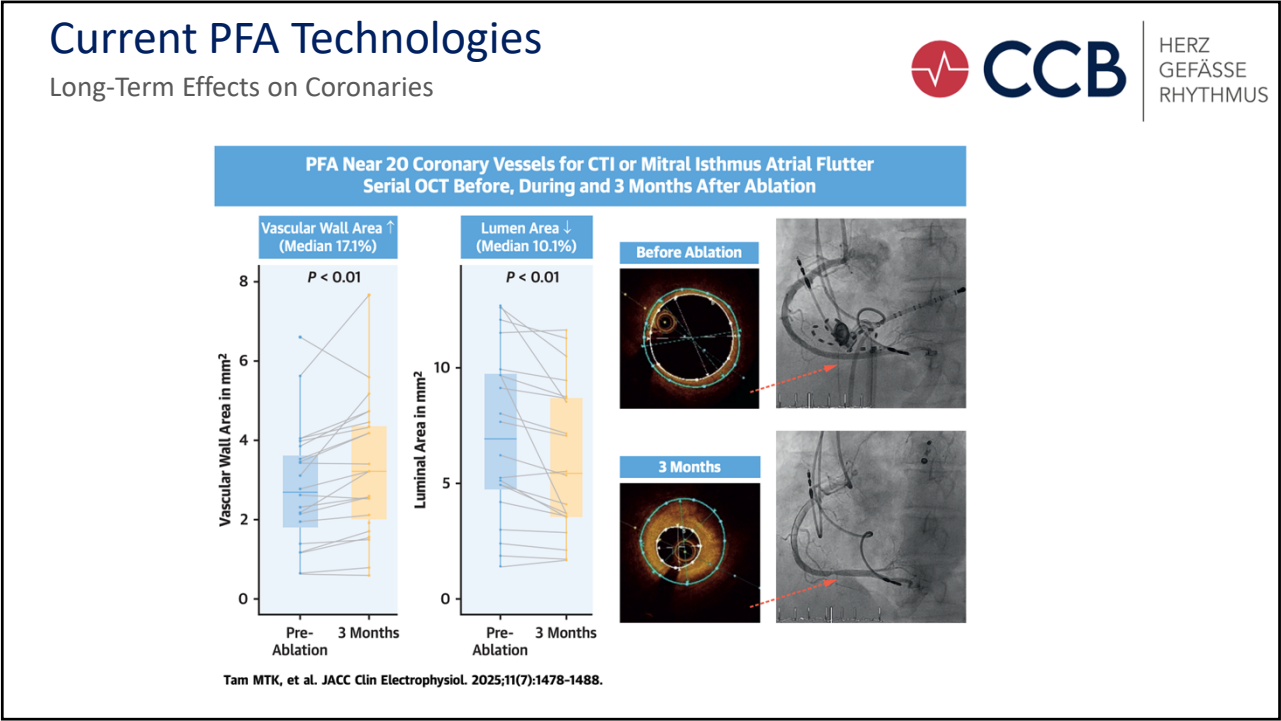
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Current PFA Technologies

Conclusion



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- Non-thermal PFA offers broad therapeutic window
- Large number of existing technologies at different stages in the development
- Increasing set of data from controlled trials
- Different form factors for all (?) arrhythmias
- Word of Caution – Coronary Spasm but rare !

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CATHETER ABLATION OF AF – THE GERMAN PERSPECTIVE

Prof. Dr. Kyoung-Ryul Julian Chun
CCB Frankfurt am Main
j.chun@ccb.de

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CATHETER ABLATION – THE GERMAN PERSPECTIVE



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Disclosures

Company	COI
Medtronic	Ad Board, Research grant, Speaker Fee Research grant
Boston Scientific	Ad Board, Research grant, Speaker Fee
Abbott	Ad Board, Research grant, Speaker Fee Research grant
J&J Medtech	Ad Board, Research grant, Speaker Fee
AstraZeneca	Speaker Fee

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CATHETER ABLATION – THE GERMAN PERSPECTIVE



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AGENDA

German Health Care System



Procedural Workflow Considerations

- Sustainability   
- Sedation/GA 
- Mapping 
- Ablation   

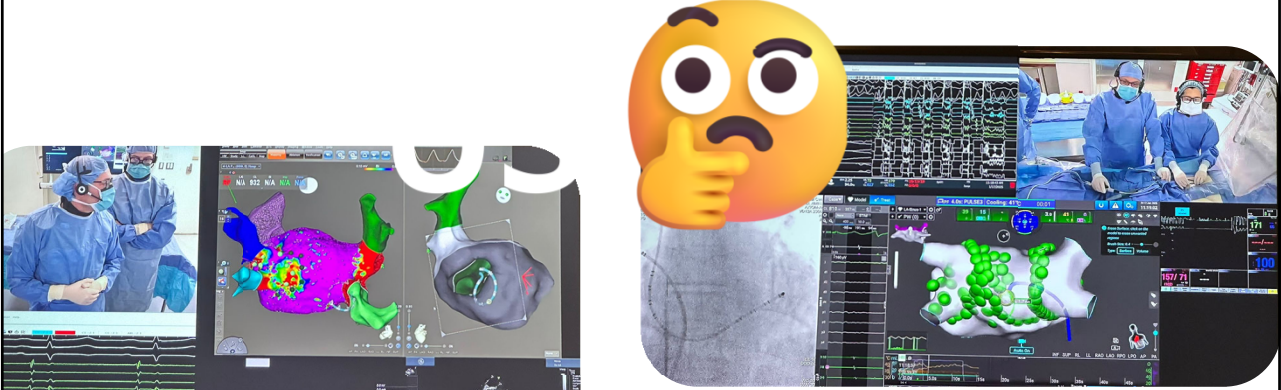
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WORKFLOW AF ABLATION: GERMANY vs. USA



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HOW MUCH TECHNOLOGY IS REALLY NEEDED?



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CATHETER ABLATION – THE GERMAN PERSPECTIVE



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John Doss CFA, CPA

@JohnDoss1

X.com

I paid \$42K for a family plan and had a procedure from Dr. [REDACTED] Cardiology and Electrophysiology at NYU Langone for \$500K. My co-pay was \$300. So it all works out.

Übersetzung zeigen

02:57 · 07.10.25 · 5,5K Mal angezeigt

13

1

28

07:30

Post



John Doss CFA, CPA @JohnD... · 07.10.25

Hmm...I'm not certain what kind of doctor you are, but we will agree to disagree.

2

97



Dr. Shane @docshane · 07.10.25

I'm a primary care physician practice for over 20 years most that on direct care. Hospital prices are an illusion to strike fear in the hearts of man. There's zero change someone's insurance is paying \$500K for a heart ablation procedure. That's like the fees of a heart transplant.

1

1

69



John Doss CFA, CPA @JohnD... · 07.10.25

Ok...I'm lying. Dude get a life. Dr. Chinitz is one of the top cardiologists in the world.

1

68



Dr. Shane @docshane · 07.10.25

It's ok. Not saying you're lying. I'm saying the hospital is. They are screwing the people over. They're in league with the insurance companies to keep prices going up. Thanks for the dialogue. Best of luck out there.

1

2

60



daniinbluend @daniinbluend · 08.10.25

Evartlv. Hnen. mau "hill" \$500k hut I doubt

Deine Antwort posten

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CATHETER ABLATION – THE GERMAN PERSPECTIVE



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Frankfurt



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CATHETER ABLATION – THE GERMAN PERSPECTIVE

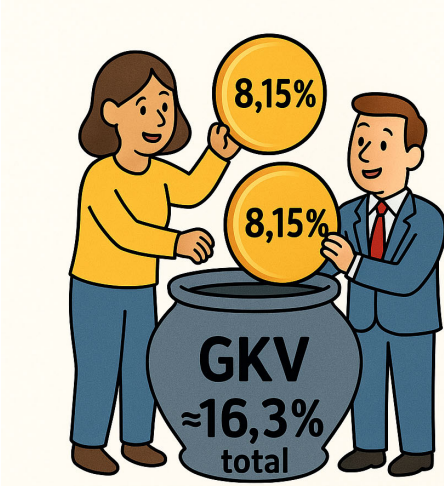


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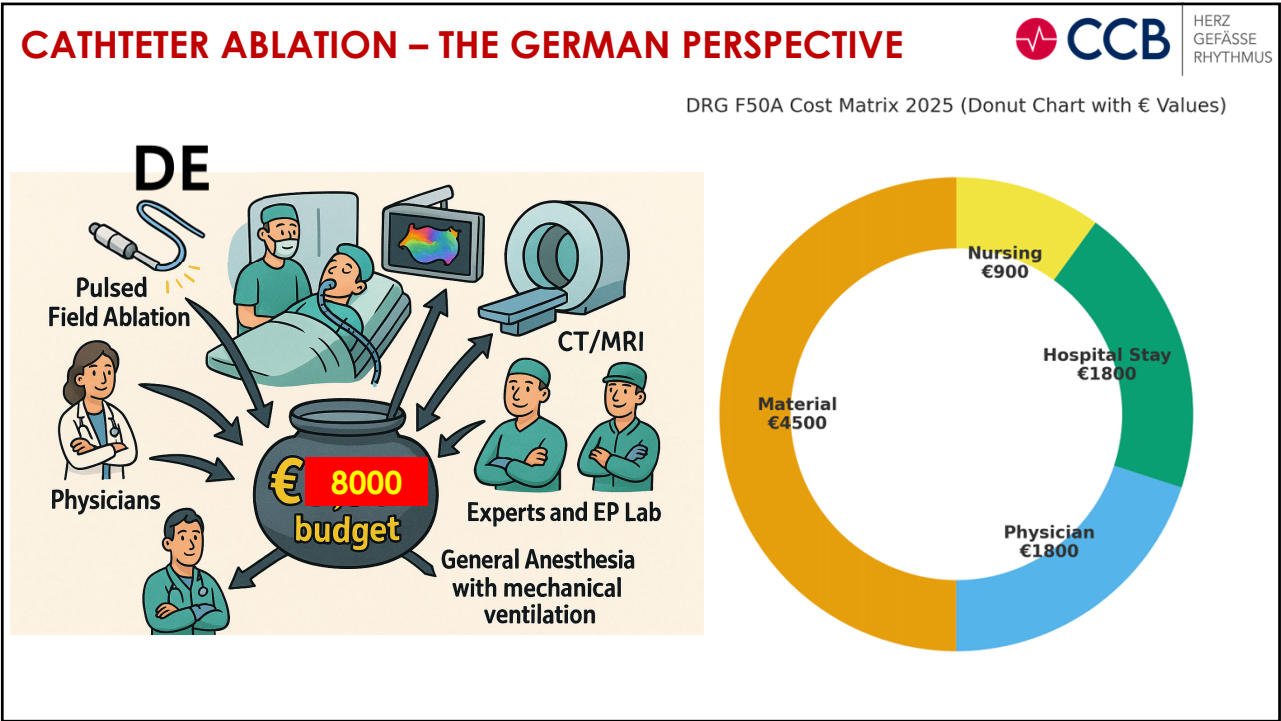
**PRIVATE
INSURANCE**



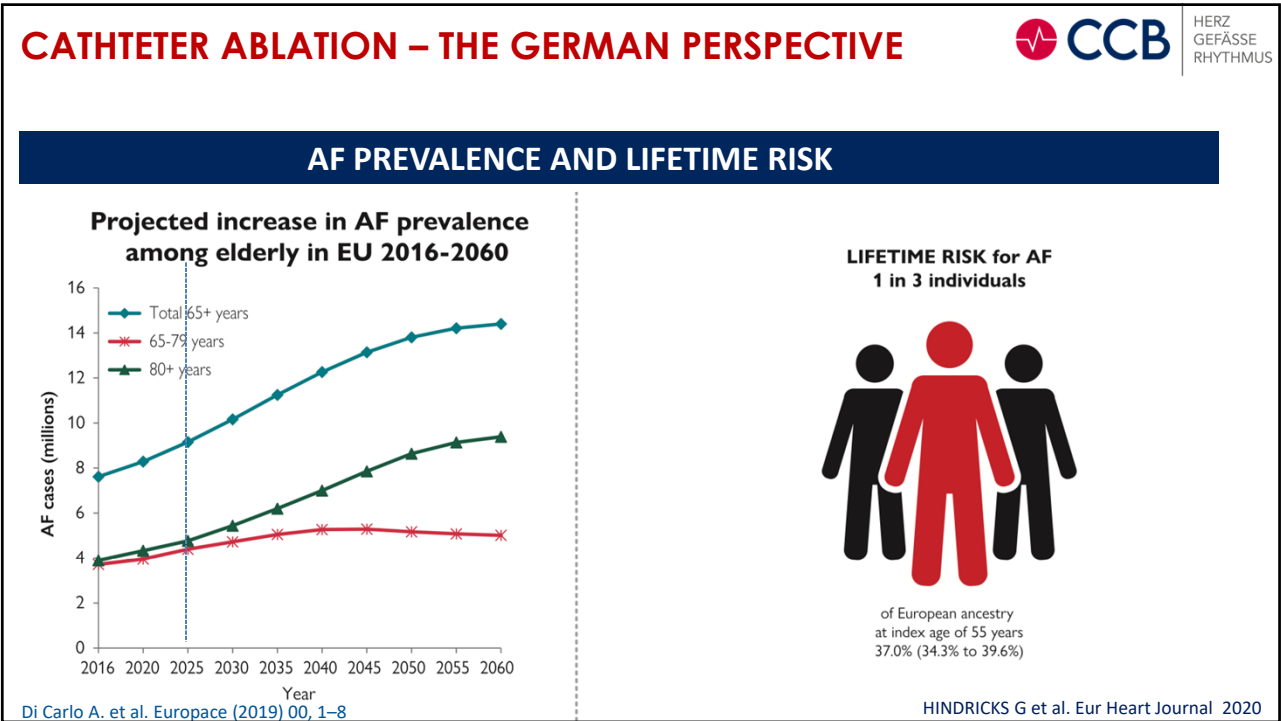
Variable

SAME BENEFITS F ALL

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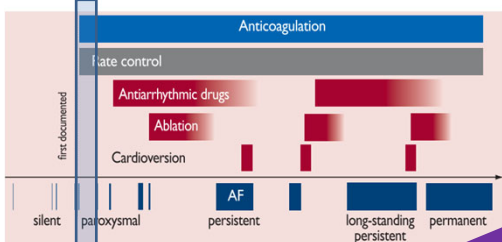
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CATHETER ABLATION – THE GERMAN PERSPECTIVE



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RATE vs. RHYTHM CONTROL



	Rhythm Control (n=682)	Rate Control (n=682)
First episode AF	37	37
Paroxysmal AF (%)	36	35
Persistent AF (%)	27	27
Median Days to enrollment	36	36

EAST TRIAL (n=2780)

Rhythm Control vs. Rate Control

Kirchhof P et al. NEJM 2020

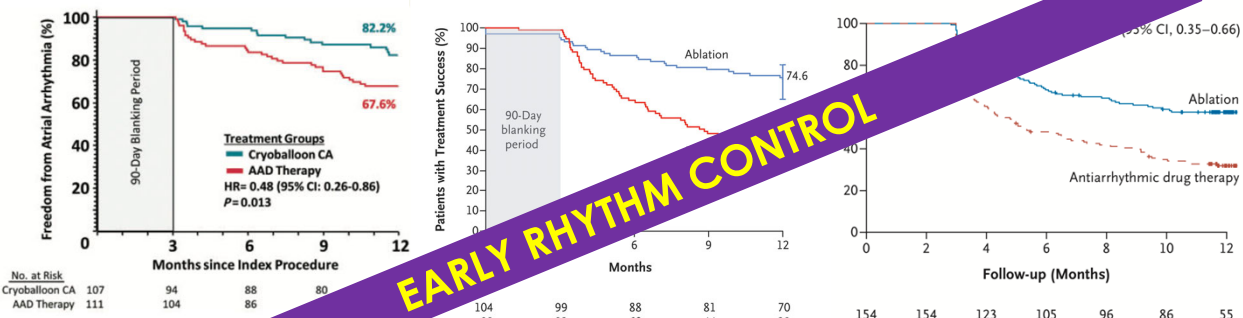
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CATHETER ABLATION – THE GERMAN PERSPECTIVE



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FIRST LINE Cryo PVI vs. AAD (3 RCT, >700 pts)



Section 7.2—Rhythm Management in patients with AF 2020

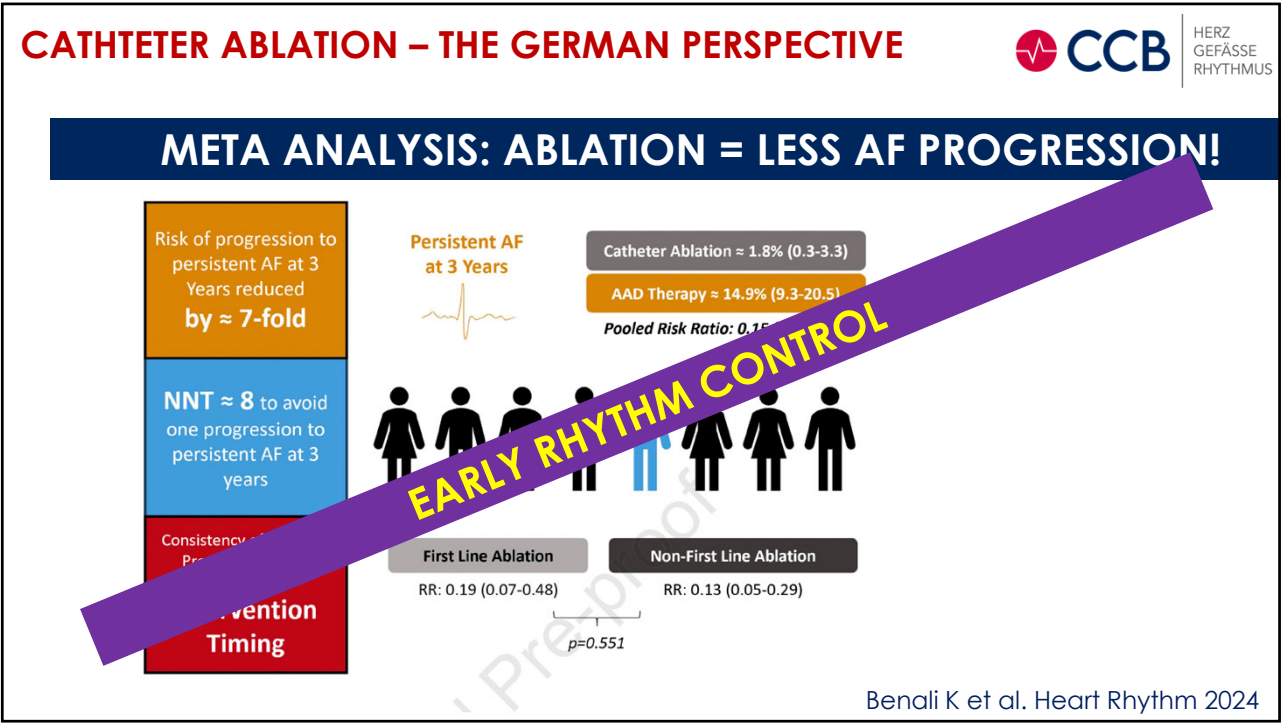
AF catheter ablation may be considered as first-line rhythm control therapy to improve symptoms in selected patients with symptomatic:

- Paroxysmal AF episodes.

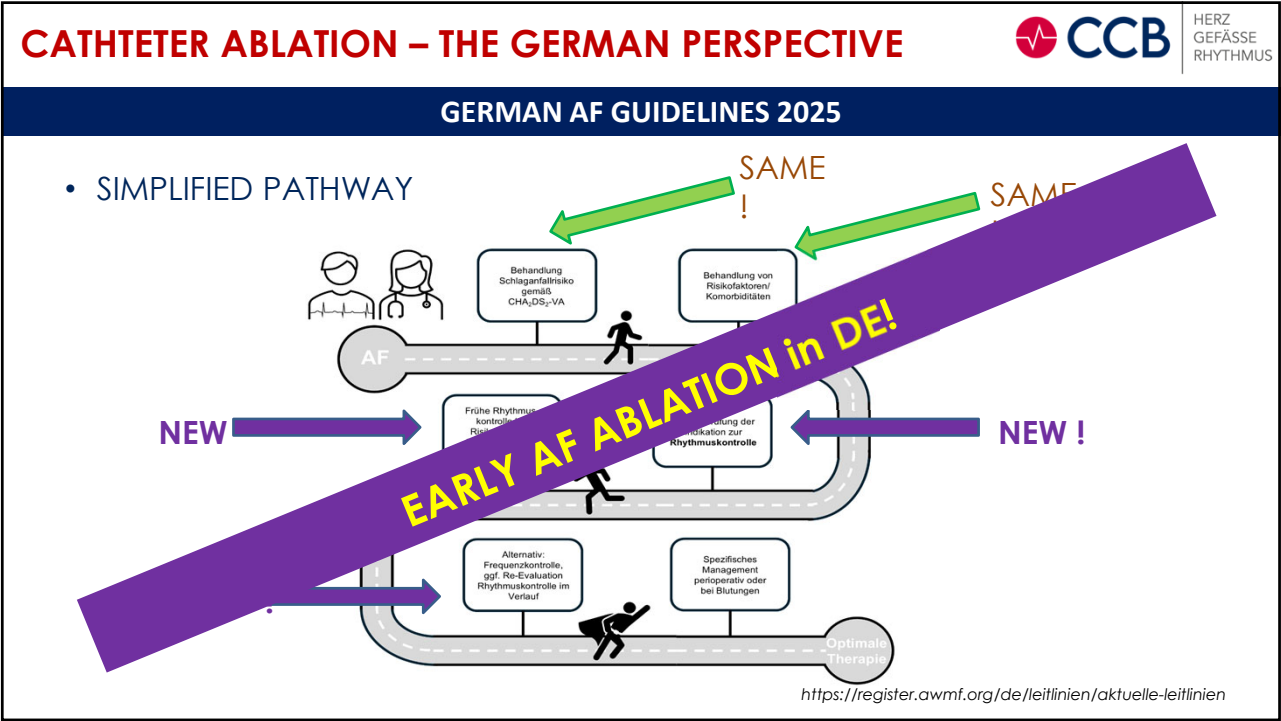
2024

Catheter ablation is recommended as a first-line option within a shared decision-making rhythm control strategy in patients with paroxysmal AF, to reduce symptoms, recurrence, and progression of AF.

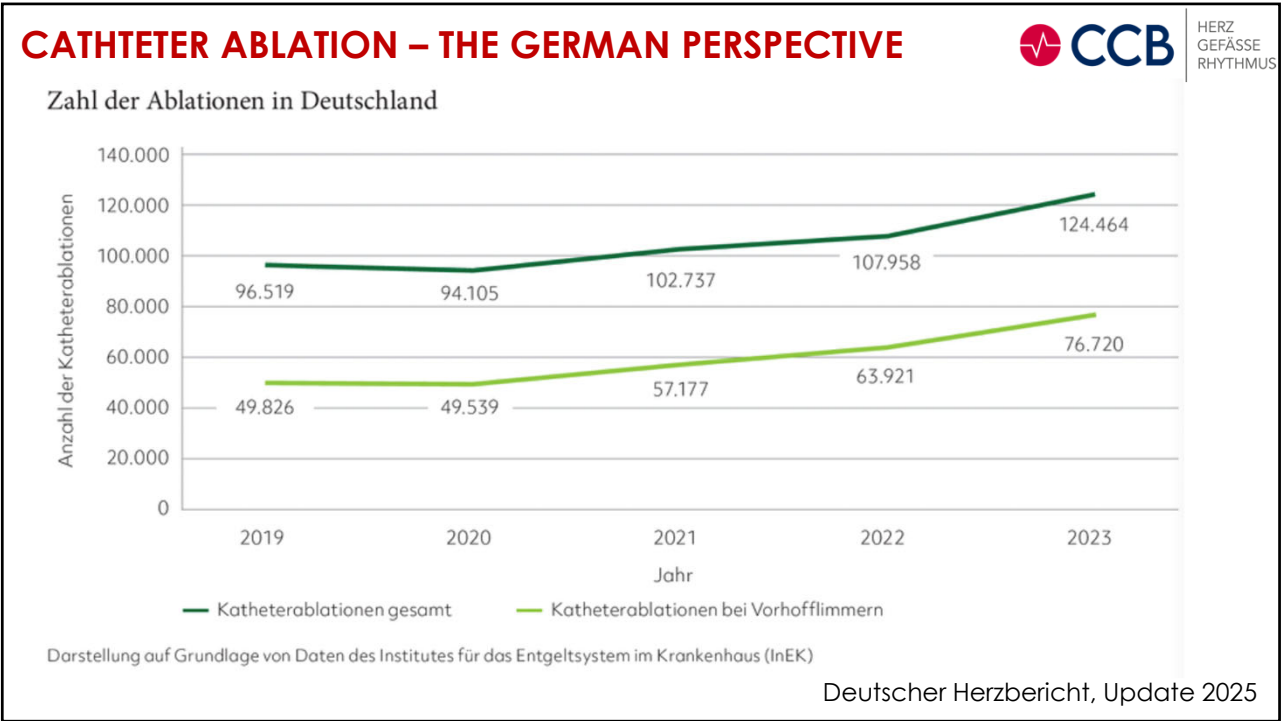
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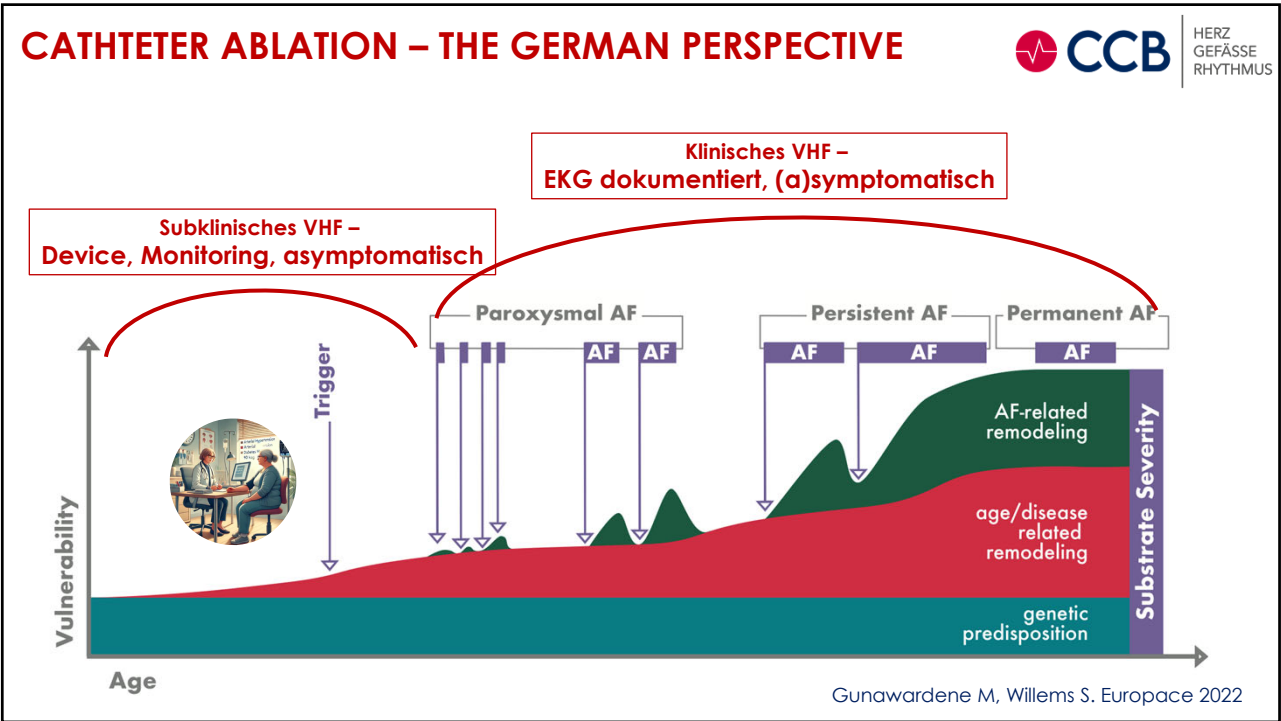
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CATHETER ABLATION – THE GERMAN PERSPECTIVE

AF + HFpEF
via Emergency Room

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Reprocessing of EP material is a MUST!

ONE AF ABLATION = 76,9kg CO₂ = 700.000 km Car Drive

Europace (2023) 25, 331–340
<https://doi.org/10.1093/europace/euac160>

CLINICAL RESEARCH

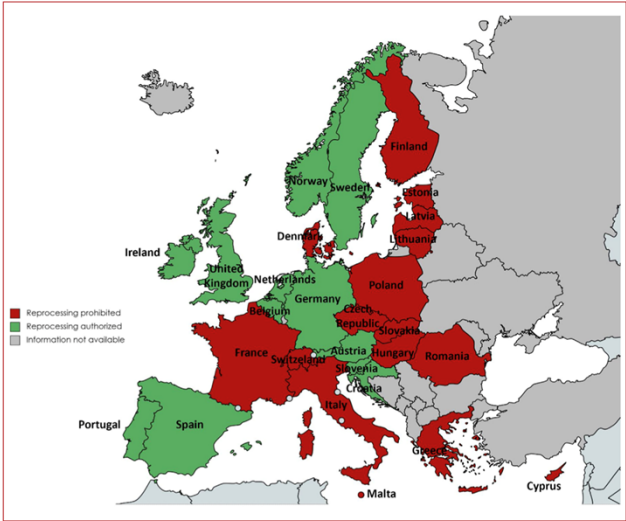
Carbon footprint of atrial fibrillation catheter ablation

Geoffroy Dita¹, Pierre-Jean Cottinet², Minh Quyen Le², Daniel Grinberg^{3,4}, Josselin Duchateau⁵, Kévin Gardey¹, Arnaud Dulac¹, Antoine Delinière^{1,4}, Christelle Haddad¹, Julie Boussuge-Roze⁵, Frédéric Sacher⁵, Pierre Jaïs⁵, Philippe Chevalier^{1,4}, and Francis Bessière^{1,4*}

¹Department of Electrophysiology, Hôpital Cardiologique Louis Pradel, Hospices Civils de Lyon, 28 avenue du Doyen Lepine, 69500 Bron, France; ²INSA-Lyon, LGEF, Université de Lyon, 20 Av. Albert Einstein, 69100 Villeurbanne, France; ³Department of Cardiac Surgery, Hôpital Cardiologique Louis Pradel, Hospices Civils de Lyon, 28 avenue du Doyen Lepine, 69500 Bron, France; ⁴Université Claude Bernard Lyon 1, Faculté de Médecine Lyon Est, 8 avenue Rockefeller, 69003 Lyon, France; and ⁵Department of electrophysiology, CHU Bordeaux, Université de Bordeaux, IHU LIRYC, Av. du Haut Lévéque, 33600 Pessac, France

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Reprocessing of EP material is a MUST!



Sacher F et al. Archives of Cardiovascular Disease 117 (2024) 224–231

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CATHETER ABLATION – THE GERMAN PERSPECTIVE



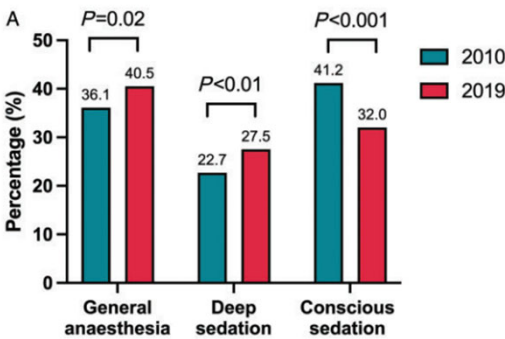
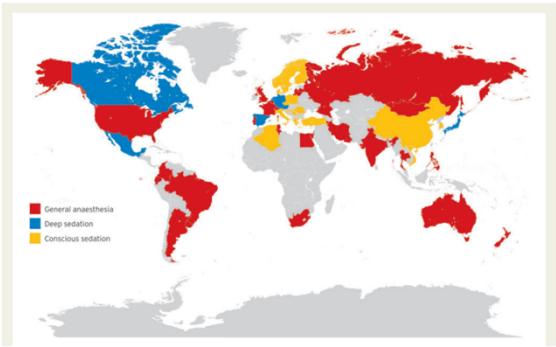
ESC
European Society
of Cardiology

Europe (2021) 33, 2039–2045
https://doi.org/10.1093/eurpace/euab154

EHRA SURVEY

Worldwide sedation strategies for atrial fibrillation ablation: current status and evolution over the last decade

Rodríguez García^{1,2,4}, Victor Waldmann⁵, Philippe Vanduyndhoven⁴,
Martina Nesi⁶, Márcio Jansen de Oliveira Figueiredo⁷, Kumar Narayanan⁷,
Giulio Conte⁸, Jose M. Guerra⁹, Serge Boveda^{10,11}, and David Duncker¹²



- GA worldwide most common (further increasing)
- Followed by deep sedation (further increasing)
- Conscious sedation (declining)

García R et al., Worldwide sedation strategies for atrial fibrillation ablation: current status and evolution over Europe, 2021 Dec 7;33(12):2039–2045. doi: 10.1093/eurpace/euab154

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WORKFLOW AF ABLATION: GERMANY vs. USA



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Analgosedierung in der Kardiologie

Konsensuspapier der DGK u. DGE für 2024

Roland R. Tilz^{1,2} · Sonja ... · R. J. Chun⁴ · Christian Frerker^{2,5} · Luise Gaede⁶ · Daniel Steven ... · Tiefenbacher^{8,11} · Lars Eckardt¹¹ · Michael Sander¹³ · Bernh ... · Frank Wappler¹⁵ · Vera von Dossow⁹ · Holger Thiele^{10,12}

NAPS = Nurse Assisted Propofol Sedation

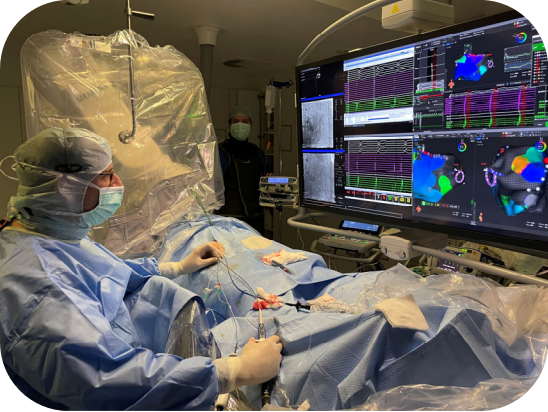
Die Kardiologie 2024, <https://doi.org/10.1007/s12181-023-00658-5>

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WORKFLOW AF ABLATION: GERMANY vs. USA

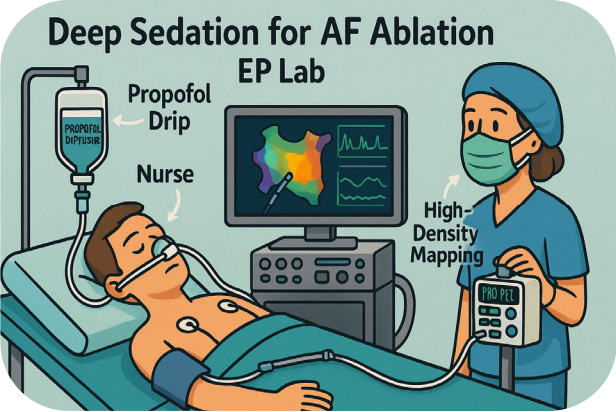


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Deep Sedation for AF Ablation

EP Lab



Propofol Drip

Nurse

High-Density Mapping

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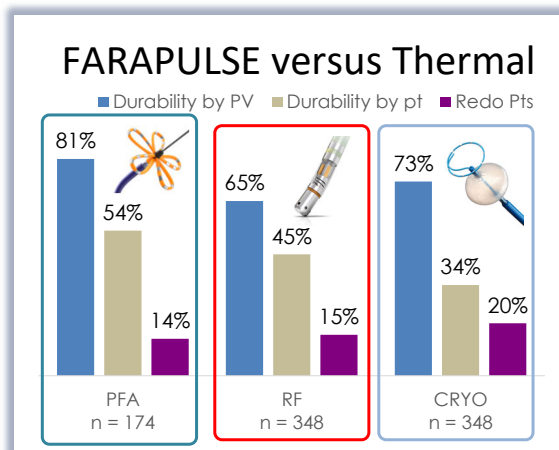
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WORKFLOW AF ABLATION: GERMANY vs. USA

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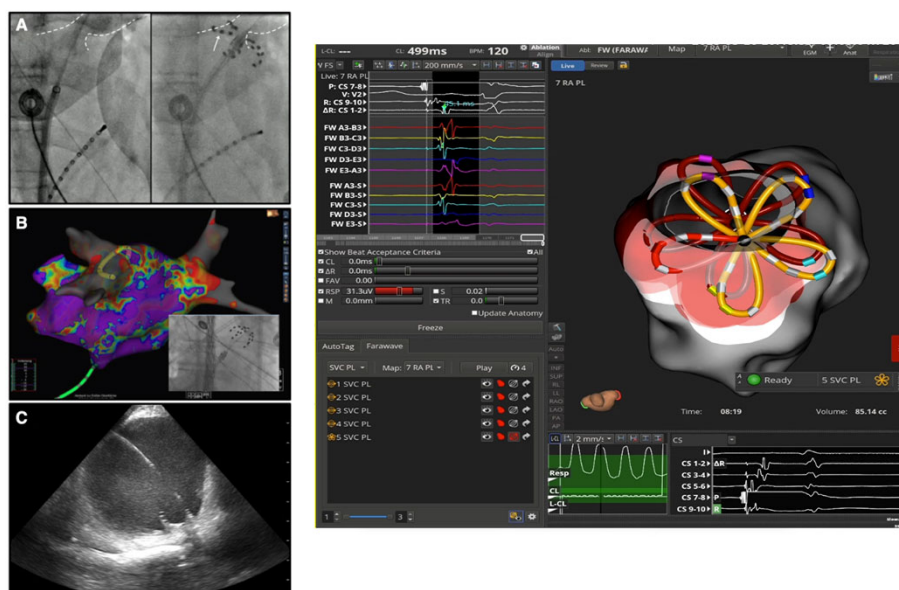
PVI durability improved in “real life”

- Propensity-score matched comparison of patients undergoing PVI
- Room for improvement!
- FARAPULSE had significantly higher PV durability compared to RF and Cryo ($p = 0.01$)

Della Rocca DG, et al. *Europace*. Jan 20 2024;doi:10.1093/europace/euae016

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WORKFLOW AF ABLATION: GERMANY vs. USA

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WORKFLOW AF ABLATION: GERMANY vs. USA



ESC

European Society of Cardiology

Europace (2024) 26, euae075

<https://doi.org/10.1093/europace/euae075>

RESEARCH LETTER



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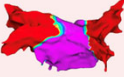
Role of 3D electro-anatomical mapping on procedural characteristics and outcomes in pulsed-field ablation for atrial fibrillation

Patrick Badertscher ^{1,2,*†}, Teodor Serban ^{1,2†}, Corinne Isenegger^{1,2}, Philipp Krisai ^{1,2}, Gian Voellmin ^{1,2}, Stefan Osswald ^{1,2}, Sven Knecht ^{1,2}, Christian Sticherling ^{1,2}, and Michael Kühne ^{1,2}

Fluoroscopy Time: Mapping vs. Non-Mapping 11 vs. 8min

Mapping


N = 127



Non-mapping


N = 70



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WORKFLOW AF ABLATION: GERMANY vs. USA



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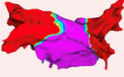

N = 197
Patients with AF undergoing PFA PVI



Fluoroscopy Time: Mapping vs. Non-Mapping 11 vs. 8min

Mapping


N = 127



Non-mapping

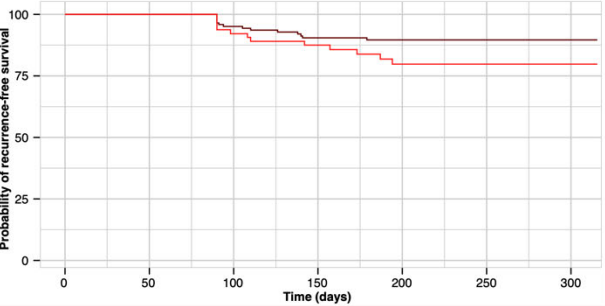

N = 70



Median follow-up: 267 (164–419) days

Recurrence-free survival after 1 year

Method of ablation — Mapping — Non-mapping

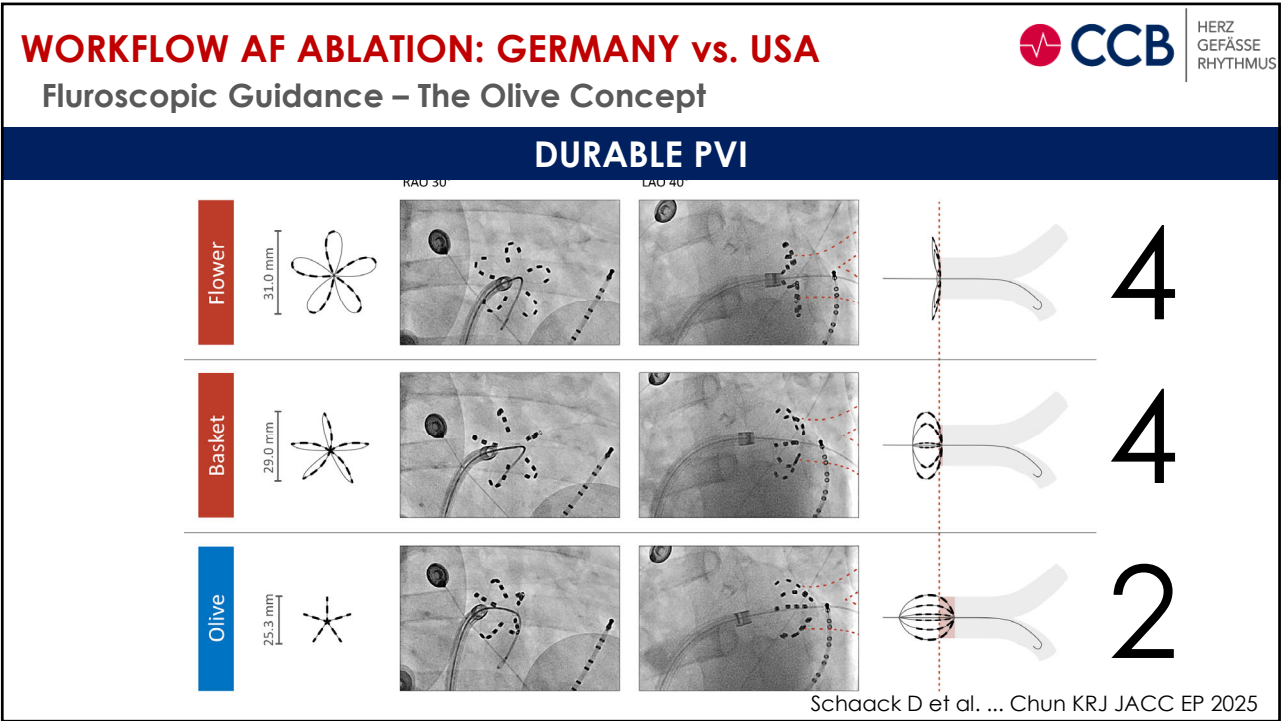


Method of ablation	Probability of recurrence-free survival (%)
Mapping	~90
Non-mapping	~80

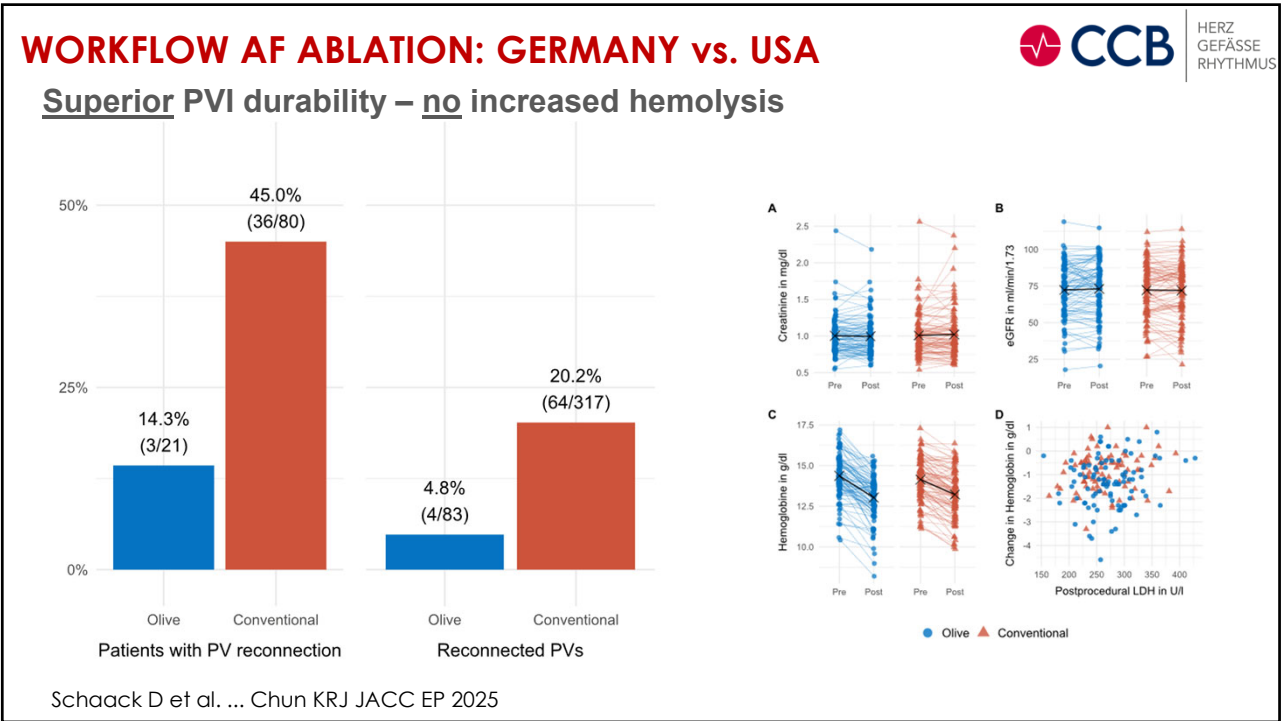
	Mapping	Non-mapping
Total procedure duration, min	55 (45–67)	28 (23–35)
LA dwell time, min	38 (30–49)	15 (11–21)
Recurrence	18 (14%)	12 (17%)
Redo-procedures	9 (7%)	6 (9%)
Reconnected PVs	6/9 (67%)	4/6 (67%)

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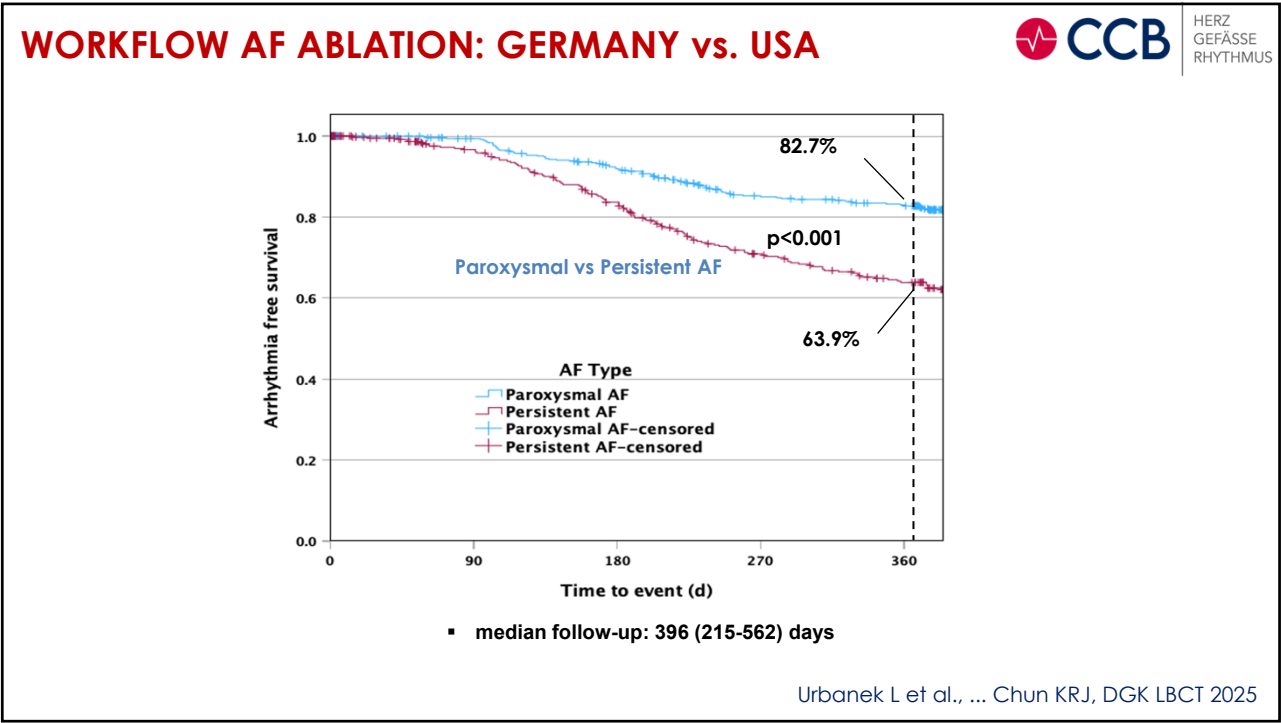
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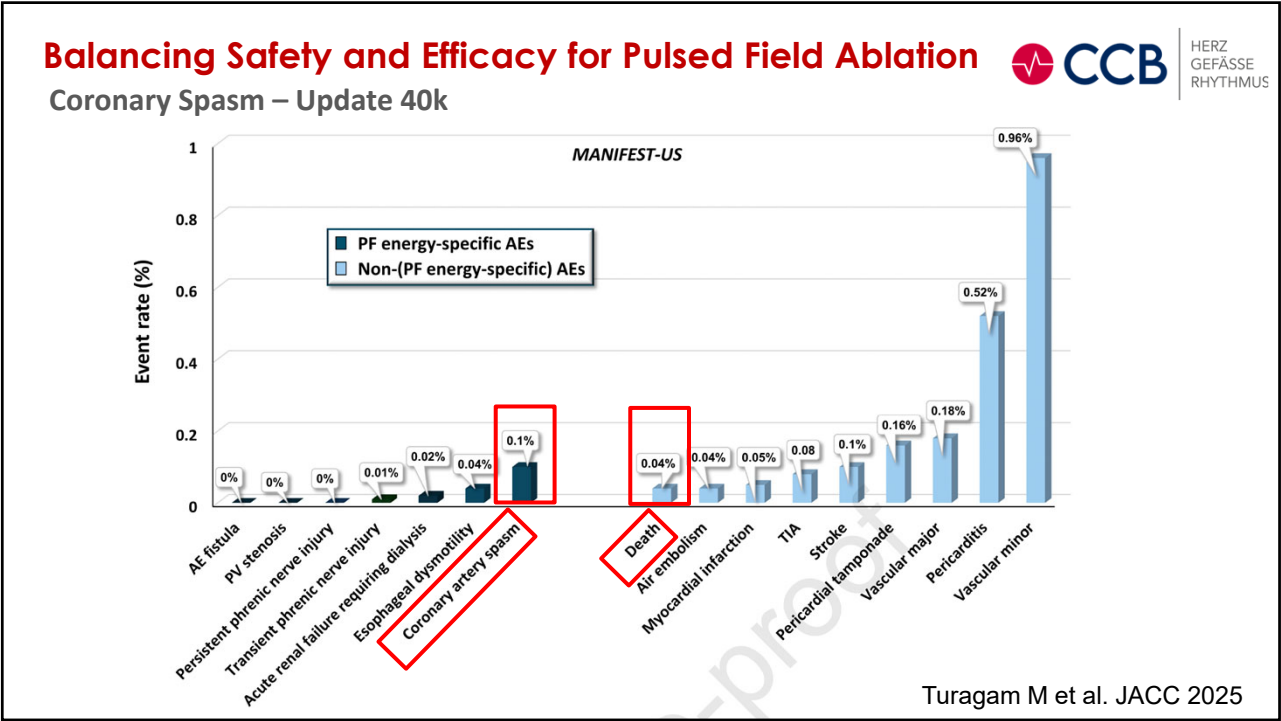
149



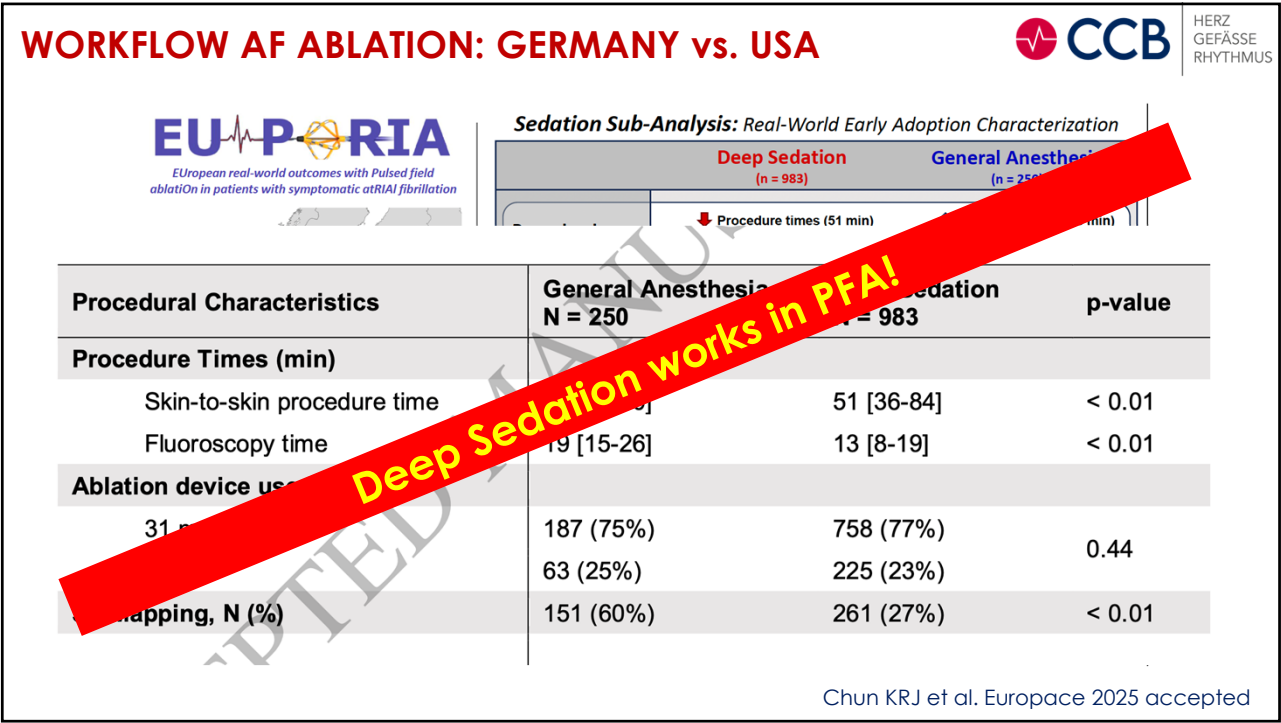
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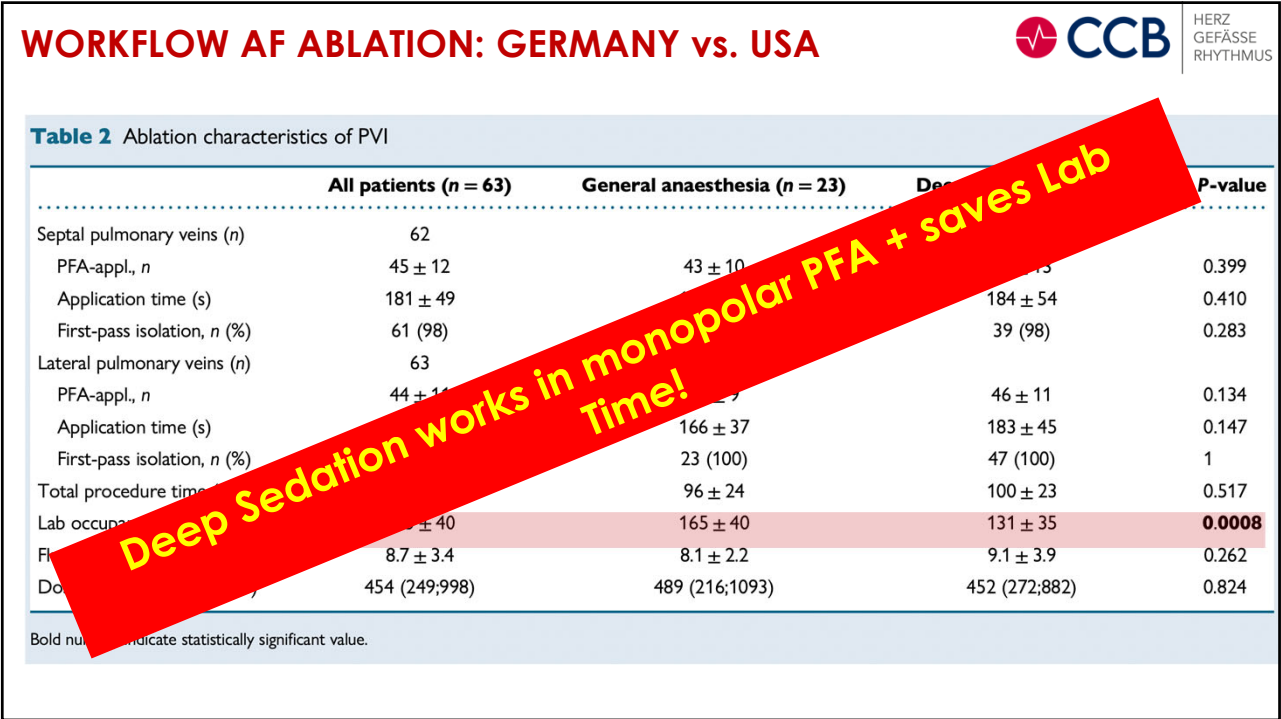
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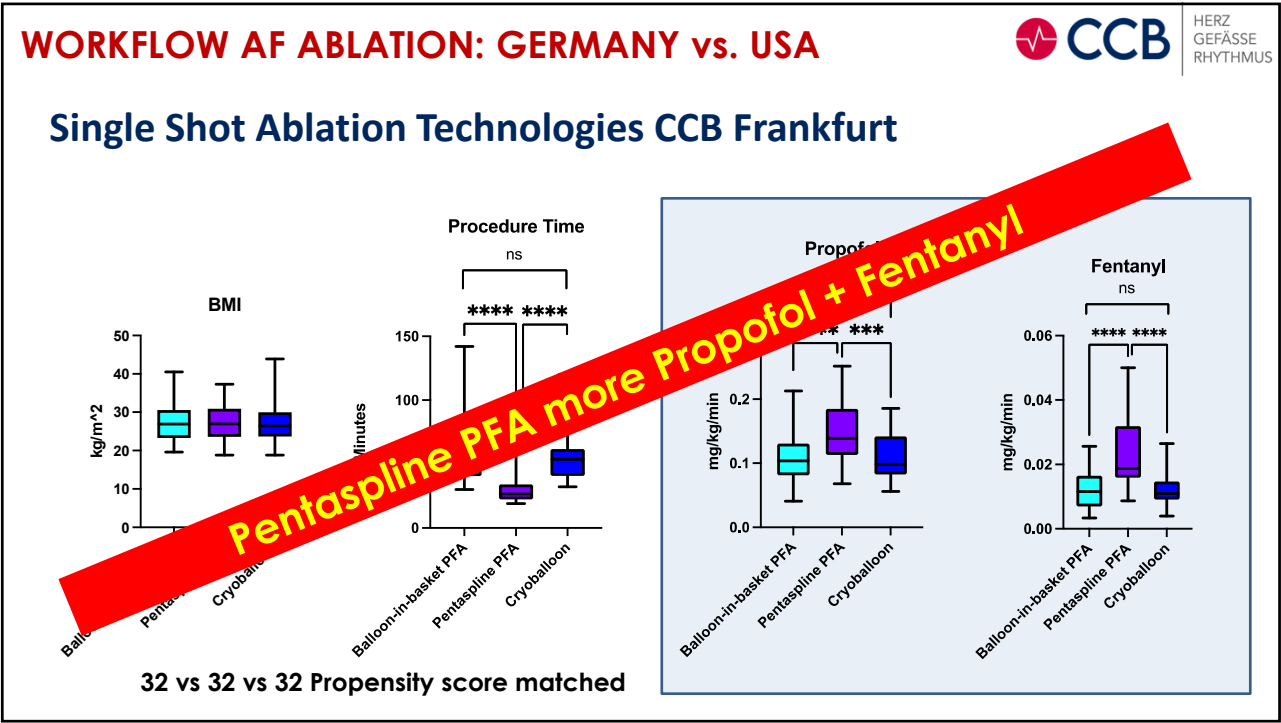
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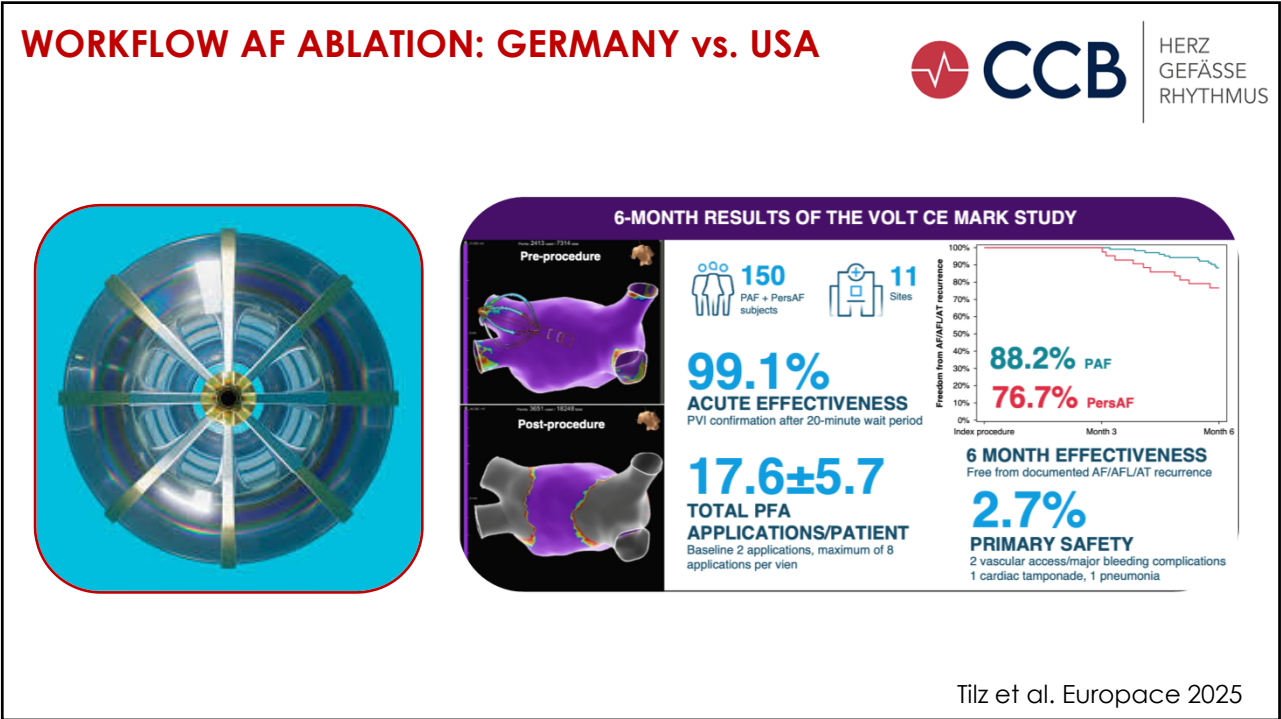
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156



157



158

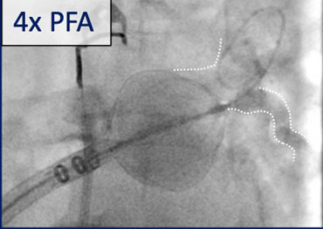
WORKFLOW AF ABLATION: GERMANY vs. USA



HERZ
GEFÄSSE
RHYTHMUS

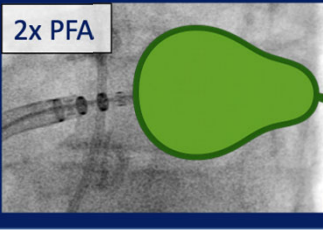
1. Fully inflated balloon, occlusion guided

4x PFA



2. Partially deflated balloon, PEAR

2x PFA



 All PVs isolated in all-comer AF patients with the PEAR workflow (n=50)

 Procedure time: 50 minutes (IQR 41–50)

 Fluoro time: 7.2 minutes (IQR 5.8–11.4)

 Six operators, no significant learning curve

 Versatility: additional ablation and concomitant left atrial appendage closure in 7 patients

 No complications

 Minimal hemolysis profile

Data @CCB Frankfurt

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WORKFLOW AF ABLATION: GERMANY vs. USA



HERZ
GEFÄSSE
RHYTHMUS

Mr A.S. 63 years
Persistent AF, Cardioversion 06/2025
Z.n. Subduralhämatom links, 29.07.2024 unter OAK
3 VD, CAD, regular LV function
HFpEF
CKD II

CRF: HTN, exNikotin, Adepts

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Page 80 of 96

The diagram shows a horizontal beam of length 120 cm. A triangular load starts at 0 at the left end and increases linearly to 8 at the right end. A point load of 12 is applied at the right end. The internal force diagrams are shown at two sections: 0° and 120 cm. At 0°, the shear force is 0, the bending moment is 0, and the axial force is 0. At 120 cm, the shear force is 0, the bending moment is 0, and the axial force is 0.

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WORKFLOW AF ABLATION: GERMANY vs. USA



HERZ
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RHYTHMUS

23.10.2025
08:59:00



90.0 KV CARD
93.9 mA 7.5 B/s

A

Coro super LD

FL(-) EP xCARE

0 1.0

Gy

00:01:20

5 mGy

1%

00:00

Wiedergabe

163

LIVE IN THE BOX – BALLOON PREP + START RIPV



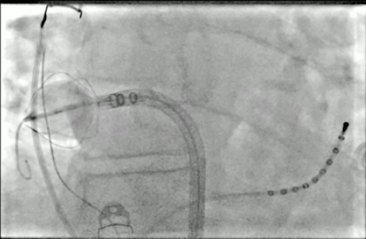
HERZ
GEFÄSSE
RHYTHMUS



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ONE STOP SHOPPING – RIPV 4+2 THEN TO RSPV



23.10.2025
09:15:34
9 - 123

VD12A 241011
HFS
fcom/fff

89.4 kV
241.0 mA
6.0 B/s

FLUO Card
cm 25
D 25
RAO 30° / 0°

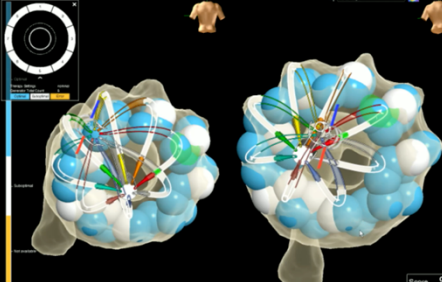
KA 15%
DOO 70%

Wiedergabe
FM 1800
FS 2100

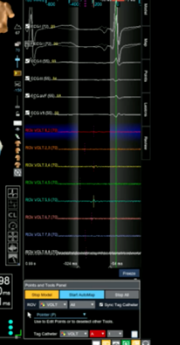
Referenz gespeichert

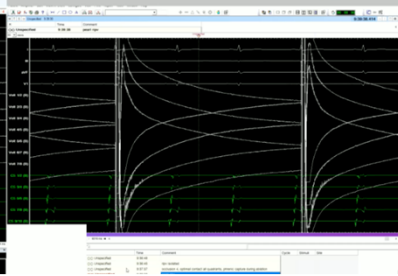
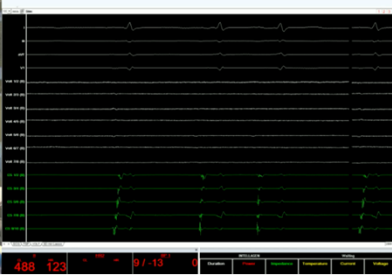
00:00

31 mGy
249.26 µGymf
2%



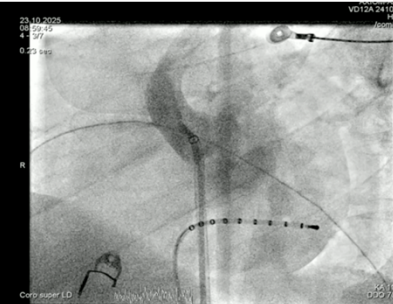
Score
98
C: 730
LAT: 191





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ONE STOP SHOPPING - RSPV to LSPV



23.10.2025
09:17:45
4 - 97

VD12A 241011
HFS
fcom/fff

89.4 kV
241.0 mA
6.0 B/s

FLUO Card
cm 25
D 65
LAO 40° / 0°

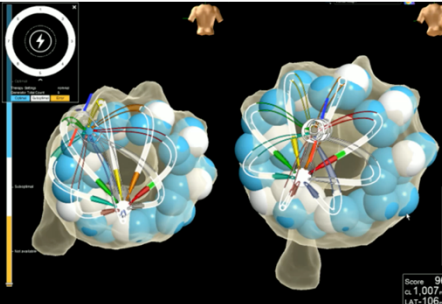
KA 11%
DOO 70%

Wiedergabe
FM 2000
FS 2004

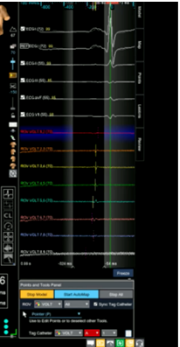
Referenz gespeichert

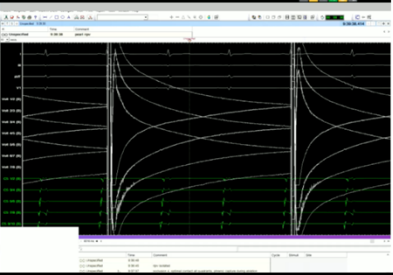
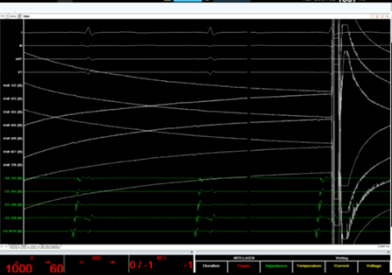
00:00

31 mGy
249.26 µGymf
2%



Score
96
C: 1,007
LAT: 106



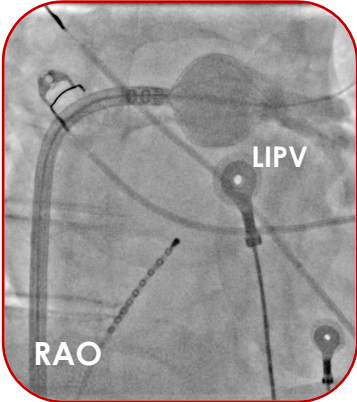


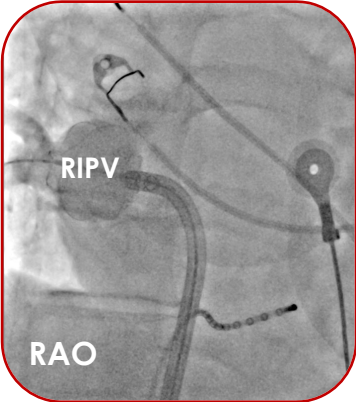
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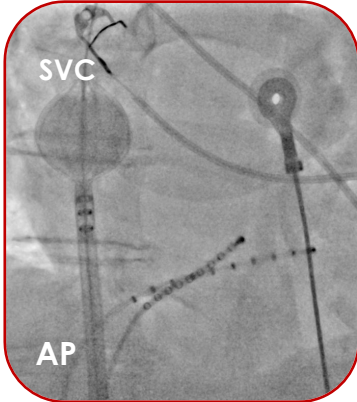
WORKFLOW AF ABLATION: GERMANY vs. USA

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RHYTHMUS

FLUORO ONLY







167

WORKFLOW AF ABLATION: GERMANY vs. USA

HERZGEFÄSSE
RHYTHMUS

CCB Frankfurt VOLT Experience

CCB Frankfurt: VOLT Balloon AF Ablation, n=83	
Procedure Time (min)	52 ± 22
Fluoro Time (min)	8,8 ± 4,4
Fluoro Dosage (µGym2)	506,5



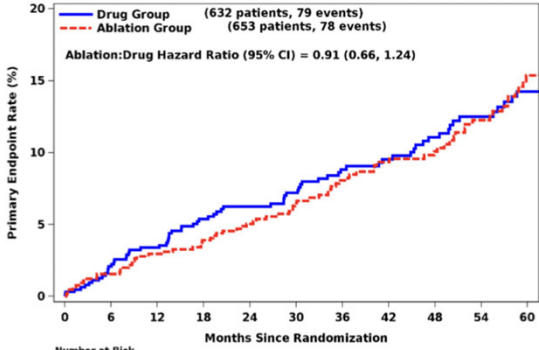
168

WORKFLOW AF ABLATION: GERMANY vs. USA



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RHYTHMUS

(A) North America



Primary Endpoint Rate (%)

Months Since Randomization

Number at Risk

Months	0	6	12	18	24	30	36	42	48	54	60
Drug Group	632	605	585	562	520	472	417	375	332	281	212
Ablation Group	653	631	618	604	562	500	448	401	354	295	208

American Heart Journal

Volume 270, April 2024, Pages 103-116

Clinical Investigations

Regional differences in outcomes with ablation versus drug therapy for atrial fibrillation: Results from the CABANA trial ☆,

Riccardo Cappato MD ^a, Daniel B. Mark MD, MPH ^b, Adam P. Silverstein MS ^b, Peter A. Noseworthy MD ^c, Gianluca Bonitta PhD ^d, Jeanne E. Poole MD ^e, Jonathan P. Piccini MD ^b, Tristram D. Bahnson MD ^b, Melanie R. Daniels BA ^b, Hussein R. Al-Khalidi PhD ^b, Kerry L. Lee PhD ^b, Douglas L. Packer MD ^f, CABANA Investigators

Cappato R et al. Am H Journal 2024

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WORKFLOW AF ABLATION: GERMANY vs. USA

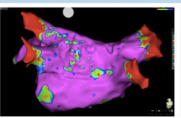


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CENTRAL ILLUSTRATION: Long-Term Outcomes of Repeat Ablation Procedures

Atrial Fibrillation Ablation

2,194 patients with paroxysmal and persistent atrial fibrillation (AF) underwent ablation

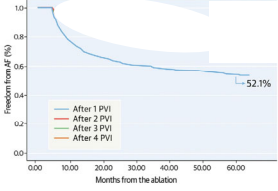


Repeat Ablation

1,052 patients with AF recurrences:

- 576 underwent a second ablation
- 103 a third ablation
- 20 a fourth ablation

Outcomes at 5-Year Follow-Up



Per-Procedure and Cumulative Success Rates Post-Ablation	1st ablation success (%) n=2,194	2nd ablation success (%) n=576	3rd ablation success (%) n=103	4th ablation success (%) n=20
Paroxysmal AF	56.2%	56.9%	60.4%	41.7%
Persistent and long-standing persistent AF	44.4%	56.6%	59.3%	37.5%
Freedom from AF after 1 ablation n=2,194	56.2%	69.3%	69.8%	70.1%
Freedom from AF after 2 ablations n=2,194	44.4%	60.4%	61.5%	61.8%

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WORKFLOW AF ABLATION: GERMANY vs. USA

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JOURNAL ARTICLE

ACCEPTED MANUSCRIPT

Contemporary Strategies for Repeat Ablation of Atrial Fibrillation: A European Heart Rhythm Association Survey

Sergio Conti , Ante Anic, Giulio Conte, Christian Heeger, Jarkko Karvonen, Andreas Metzner, Mark T Mills, Martina Nesti, Diego Penela, Rui Providencia, Laurent Roten, Martin H Ruwald, Kostantinos Vlachos, Maura M Zylla, Julian K R Chun

EP Europace, euaf231, <https://doi.org/10.1093/europace/euaf231>

Published: 22 September 2025 Article history ▼

Conti S et al. Europace 2025

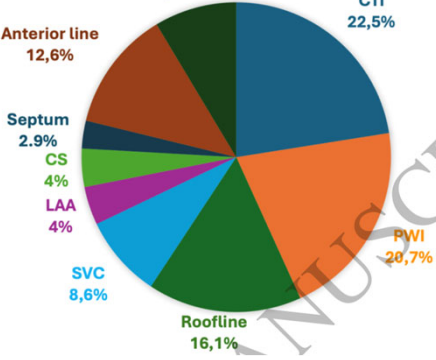
171

WORKFLOW AF ABLATION: GERMANY vs. USA

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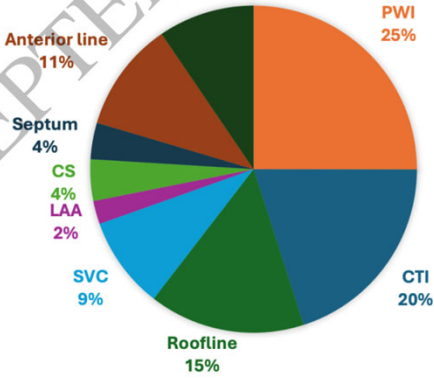
What means PVI + ?

Empirical ablation targets with PV reconnection



Target	Percentage
CTI	22.5%
PWI	20.7%
Roofline	16.1%
SVC	8.6%
LAA	4%
CS	4%
Septum	2.9%
Anterior line	12.6%
VoM	8.6%
CTI (other)	8.6%

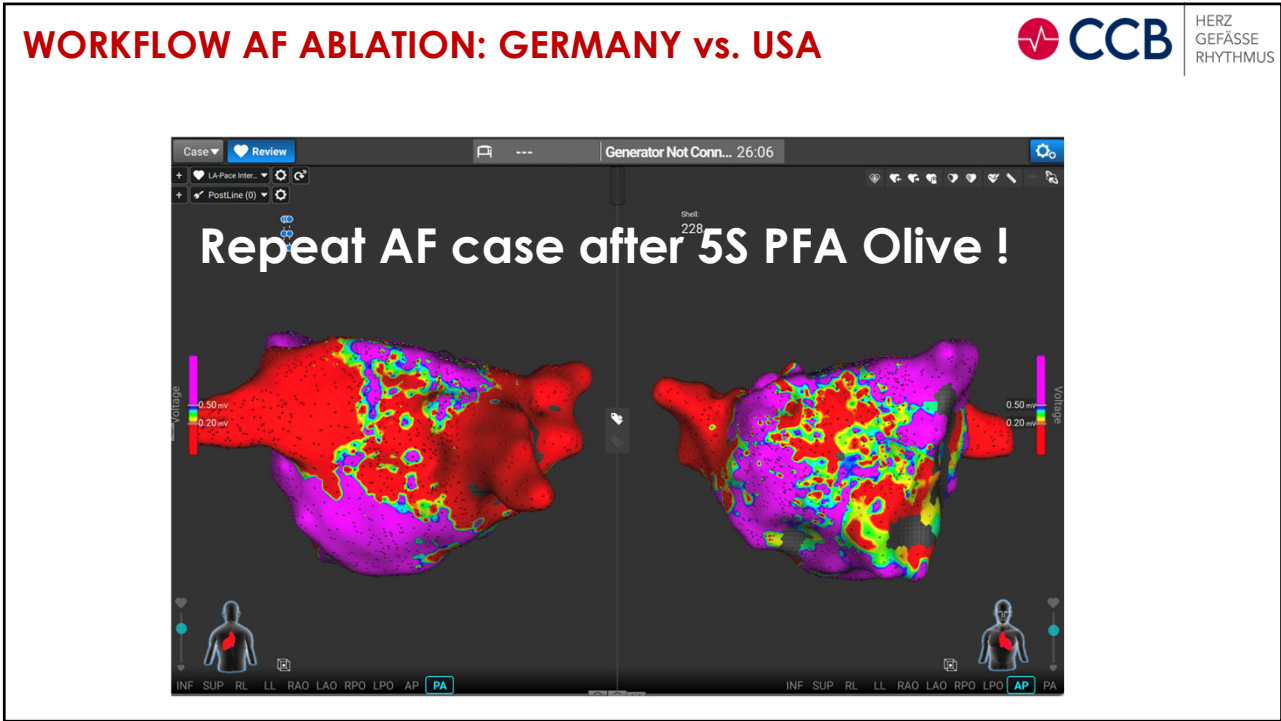
Empirical ablation target without PV reconnection



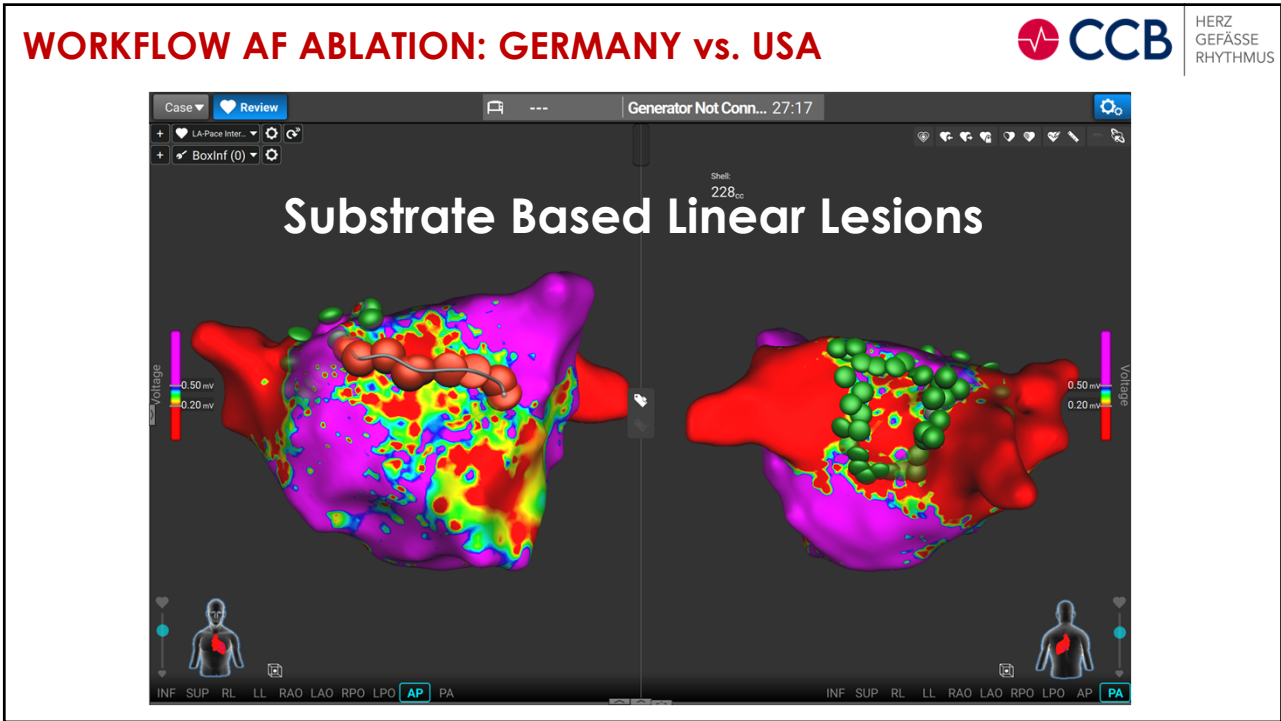
Target	Percentage
PWI	25%
CTI	20%
Roofline	15%
SVC	9%
LAA	2%
CS	4%
Septum	4%
Anterior line	11%

Conti S et al. On behalf of EHRA SIC, Europace 2025

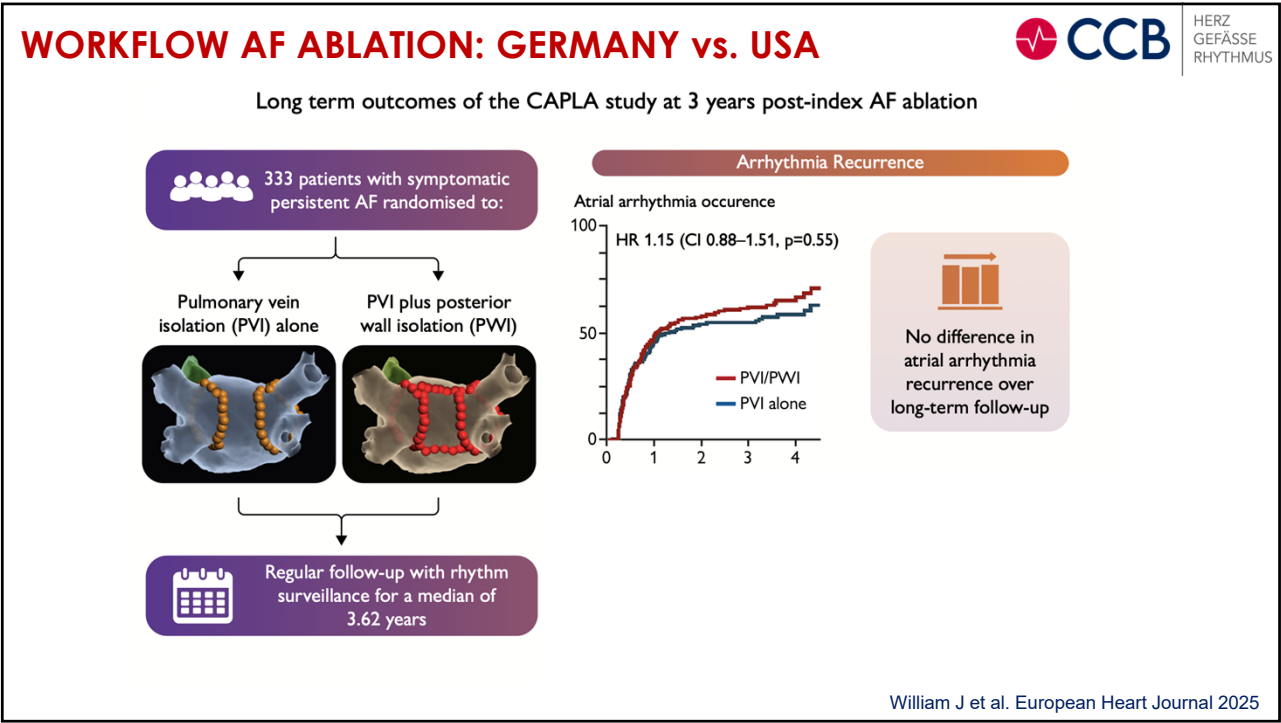
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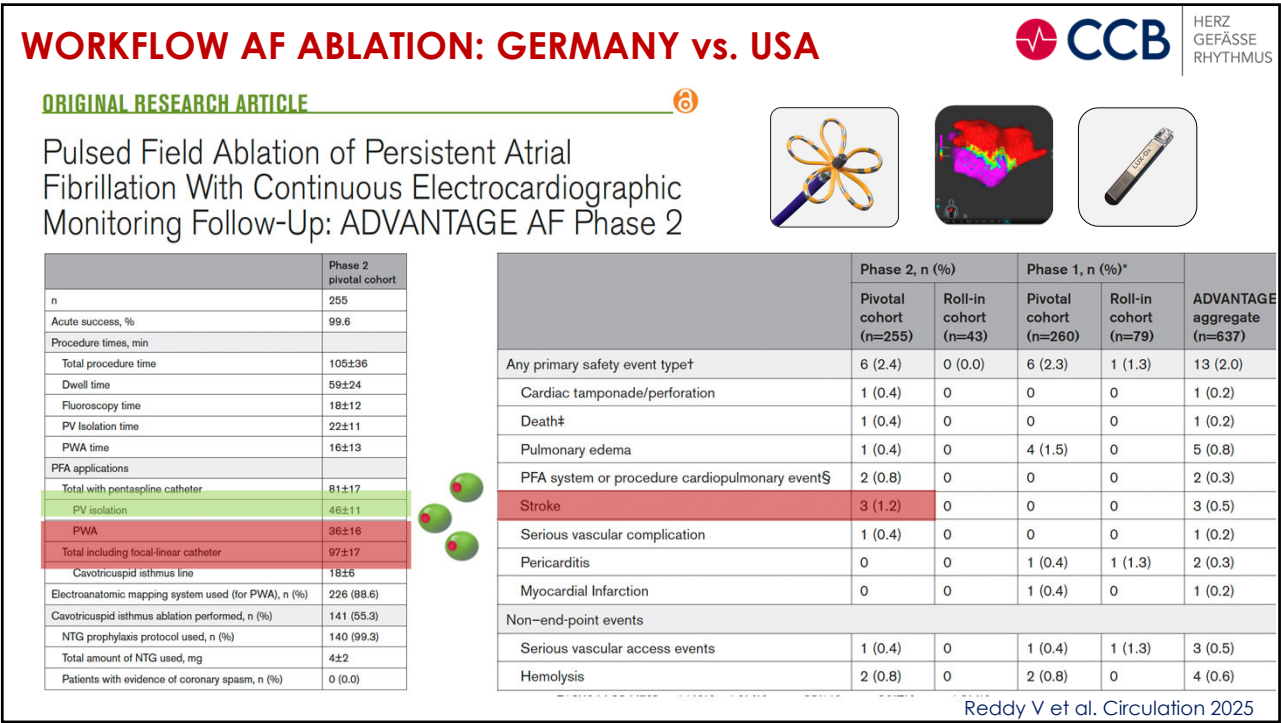
173



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175



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WORKFLOW AF ABLATION: GERMANY vs. USA

Failure of Transmural Posterior Wall Isolation by Pulse Field Ablation Demonstrated With Epicardial Mapping

Baseline

Lesion

Post

Patient 1

NA

NA

Patient 2

Patient 3

CCB

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Sanborn L et al. JACC EP 2025 <https://doi.org/10.1016/j.jacep.2025.08.017>

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WORKFLOW AF ABLATION: GERMANY vs. USA

Pulsed-field ablation versus radiofrequency ablation in patients undergoing repeat catheter ablation for atrial fibrillation

Corinne Isenegger, MD,^{1,2,3} Gianluca Di Bari, MD,^{1,2,3} Rebecca Arnet, MD,^{1,2} Fabian Jordan, MD,^{1,2} David Spreen, MS,^{1,2} Behnam Subin, MD,^{1,2} Philipp Krisai, MD,^{1,2} Sven Knecht, DSc,^{1,2} Nicolas Schaerli, MD,^{1,2} Gian Voellmin, MS,^{1,2} Felix Mahfoud, MD,^{1,2} Christian Sticherling, MD,^{1,2} Michael Kühne, MD,^{1,2,4} Patrick Badertscher, MD^{1,2,4}

Table 3

Additional lesions of patients undergoing catheter ablation for AF using PFA or RFA

Variable	PFA, n = 71	RFA, n = 114	P value
Posterior wall isolation or roof line	51 (93%)	23 (43%)	<.001*
Mitral isthmus line	3 (4%)	15 (13%)	.046*
Cavotricuspid isthmus ablation	5 (7%)	23 (20%)	.015*
Vein of Marshall ethanol ablation	0 (0%)	8 (7%)	.024*
Superior vena cava isolation	0 (0%)	5 (4%)	.158
Extra PVI foci	3 (4%)	1 (1%)	.158
Substrate modification	8 (11%)	11 (10%)	.724

Recurrence-free survival

Method of ablation — PFA — RFA



Probability of recurrence-free survival

p = 0.082

Time (days)

Number at risk

Method of ablation

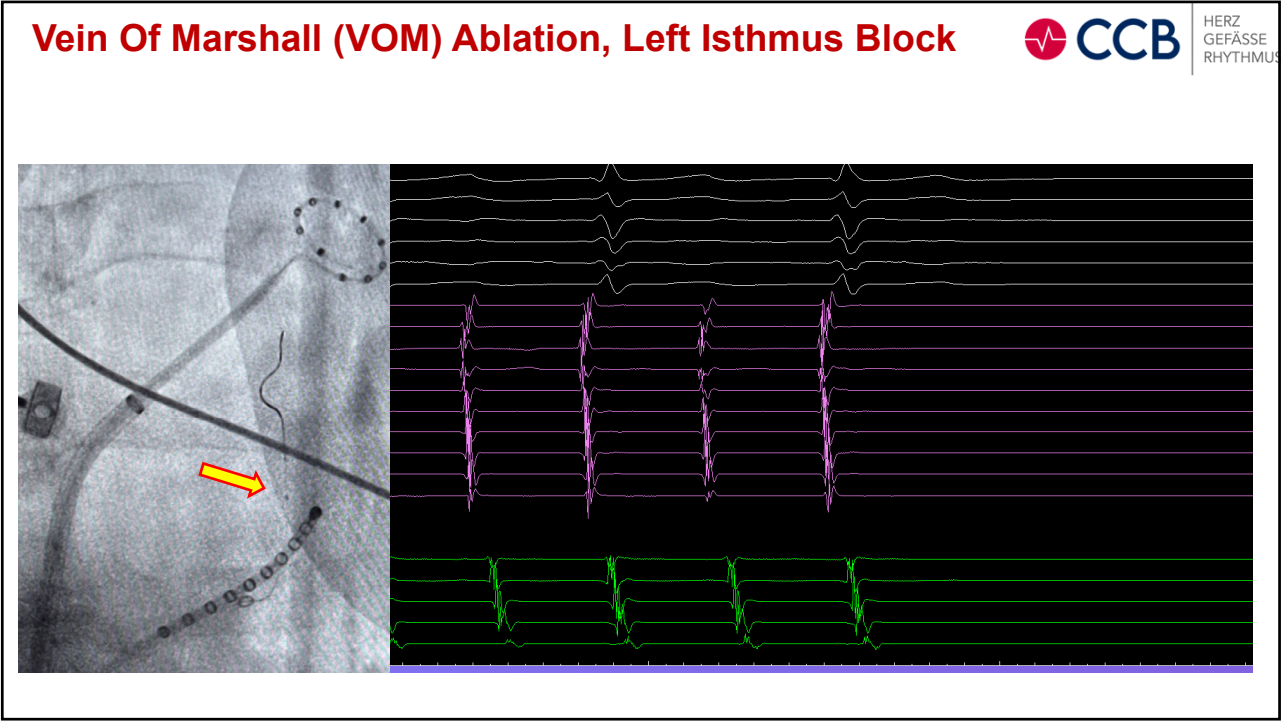
PFA	71	71	71	63	60	57	55	54	51	49	46	45	43
RFA	114	114	114	105	97	94	88	86	83	83	83	80	79

Time (days)

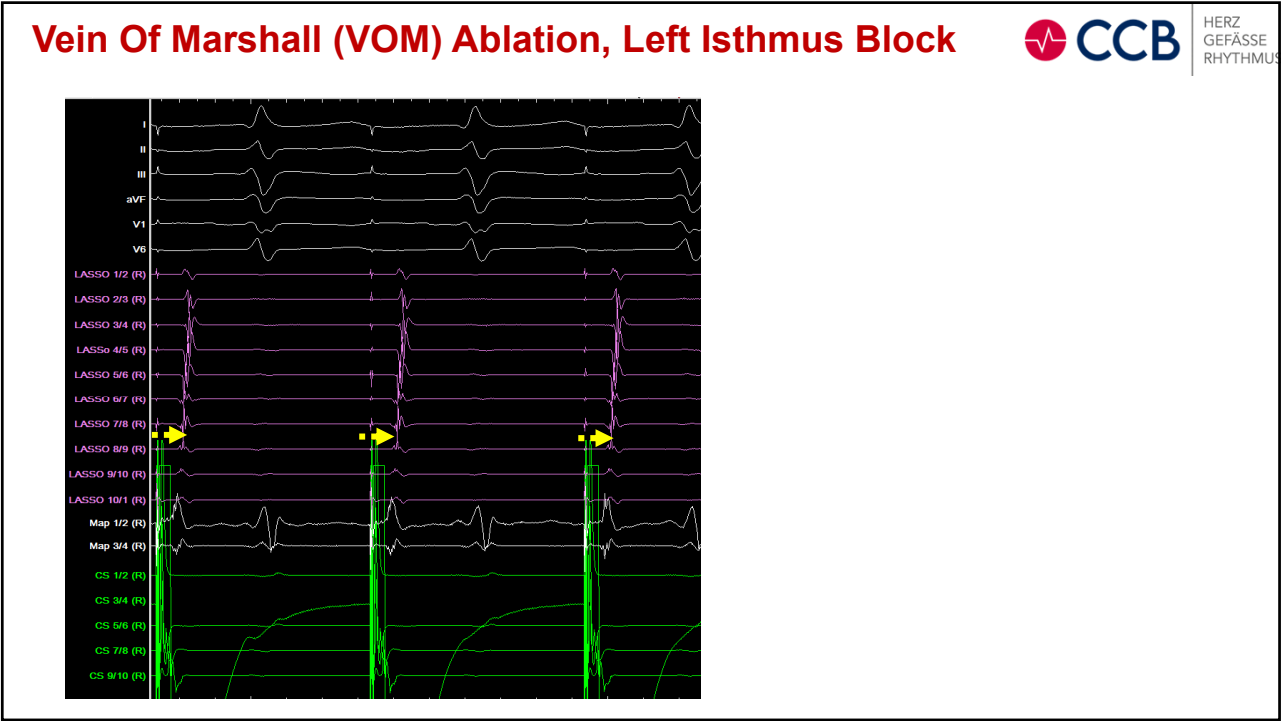
Isenegger C et al. Heart Rhythm O² 2025

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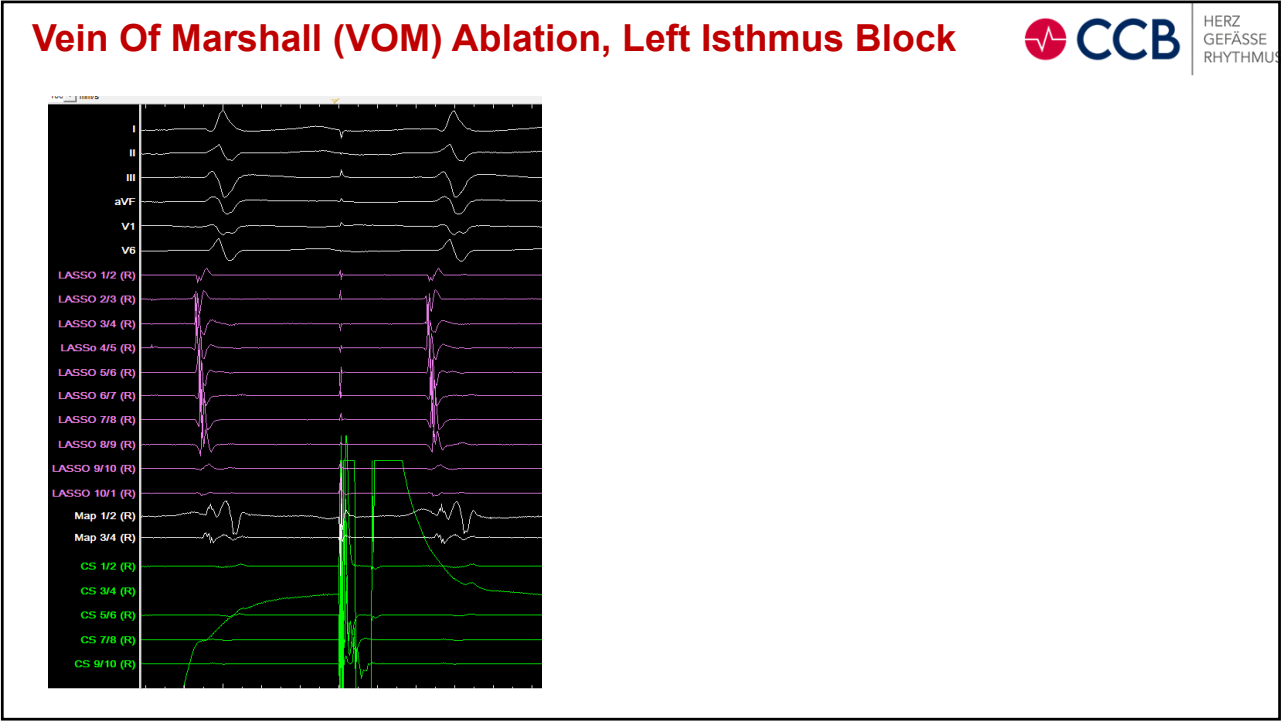
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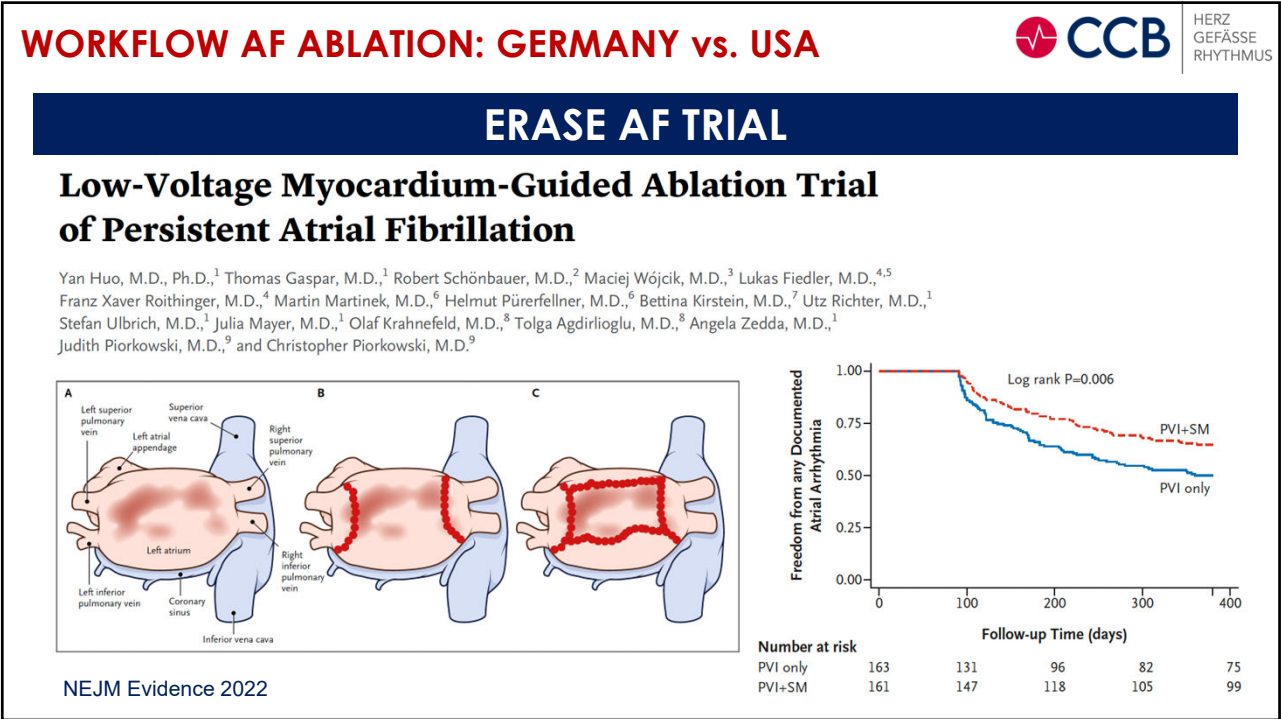
179



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Full Cohort (n = 178)

Freedom From AF/ABL/AT (%)

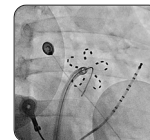
Days

1-y KM = 78.3% $\pm$ 5.0%
1-y KM = 77.9% $\pm$ 4.1%

Paroxysmal AF Persistent AF

Days	Paroxysmal AF at risk	Persistent AF at risk
0	70	108
90	69	107
180	59	84
270	55	79

Deddy VV, et al. J Am Coll Cardiol EP. 2022;9(8):1786-1801.

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WORKFLOW AF ABLATION: GERMANY vs. USA

HERZ GEFÄSSE RHYTHMUS

Feasibility of atrial linear ablation using a lattice tip catheter that toggles between radiofrequency and pulsed-field energy under deep sedation

Jun Hirokami, MD,¹ Fabian Moser, MD,² Boris Schmidt, MD,¹ Stefano Bordinon, MD,¹ Shota Tohoku, MD,¹ David Schaack, MD,¹ Lukas Urbanek, MD,¹ Andrea Urbani, MD,¹ Joseph Kheir, MD,¹ Andreas Rillig, MD,² Bruno Reissmann, MD,² Feifan Ouyang, MD,² Laura Rottner, MD,² Ilaria My, MD,² Marc Lemoine, MD,² Andreas Metzner, MD,² K.J. Julian Chun, MD¹

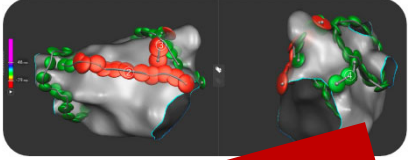


Table 3 Characteristics of linear lesions

	Total ablation n = 55	Posterior MI ablation	Left atrial appendage isolation
Roof-line ablation			
Successful linear lesion, n/total (%)	41/41 (100)	5/6 (83)	1/1 (100)
Success with lattice tip only, n/total (%)	41/41 (100)	5/6 (83)	1/1 (100)
Number of applications	9 ± 4	1/1 (100)	0/0 (0)
Ablation with PF only, n/total (%)	41/41 (100)	0/0 (0)	0/0 (0)
Total ablation time (min)	2.1 ± 1.7	1/1 (100)	3/3 (100)
Posterior wall isolation			
Successful linear lesion, n/total (%)	4/4 (100)	16.0 ± 19.2	36
Success with lattice tip only, n/total (%)	4/4 (100)	15/15 (100)	3/3 (100)
Number of applications	26 ± 34	15/15 (100)	5 ± 1
Ablation with PF only, n/total (%)	26 ± 34	12/12 (100)	12 ± 8
Total ablation time (min)	2.1 ± 1.7	12/12 (100)	1/1 (8)
Anterior MI line ablation			
Successful linear lesion, n/total (%)	29/30 (97)	15/15 (100)	11/11 (92)
Success with lattice tip only, n/total (%)	29/30 (97)	15/15 (100)	5.9 ± 8.3
Number of applications	21 ± 9	1/1 (100)	0/0 (0)
Ablation with PF only, n/total (%)	7/30 (23)	1/1 (100)	0/0 (0)
Total ablation time (min)	7.8 ± 4.5	8	NA
		1/1 (100)	1/1 (100)
		3.5	NA
		3.5	3.5

Acute: linear lesions block!

Hirokami J et al. Heart Rhythm 2024

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WORKFLOW AF ABLATION: GERMANY vs. USA

HERZ GEFÄSSE RHYTHMUS

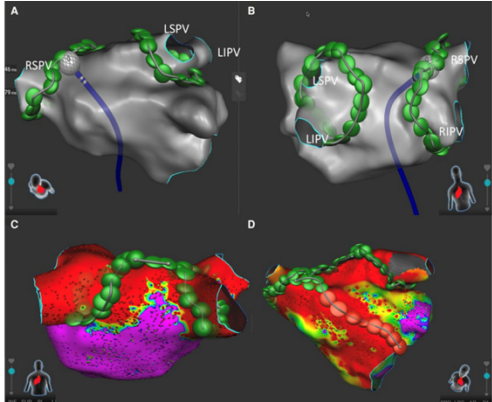
ERASE „Concept“ enriched by PFA

ESC
European Society of Cardiology
Europace (2024) 26, euae129
<https://doi.org/10.1093/europace/euae129>

CLINICAL RESEARCH

Initial real-world data on catheter ablation in patients with persistent atrial fibrillation using the novel lattice-tip focal pulsed-field ablation catheter

Shota Tohoku ^{1,2*}, Stefano Bordinon ¹, David Schaack ¹, Jun Hirokami ¹, Lukas Urbanek ¹, Andrea Urbani ¹, Joseph Kheir¹, Boris Schmidt ^{1,3}, and Kyoung-Ryul Julian Chun ^{1,2*}



Tohoku S et al., ... Chun KRJ Europace 2024

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WORKFLOW AF ABLATION: GERMANY vs. USA

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CCB

Focal PFA/RFC + HD mapping, persistent AF – PVI + Ablation

A

B

C

D

Anterior line

Roof line

AP

PA

Tohoku S et al., ... Chun KRJ Europace 2024

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WORKFLOW AF ABLATION: GERMANY vs. USA

HERZ
GEFÄSSE
RHYTHMUS

CCB

Persistent AF – PVI + Substrate Ablation

Sinus Rhythm

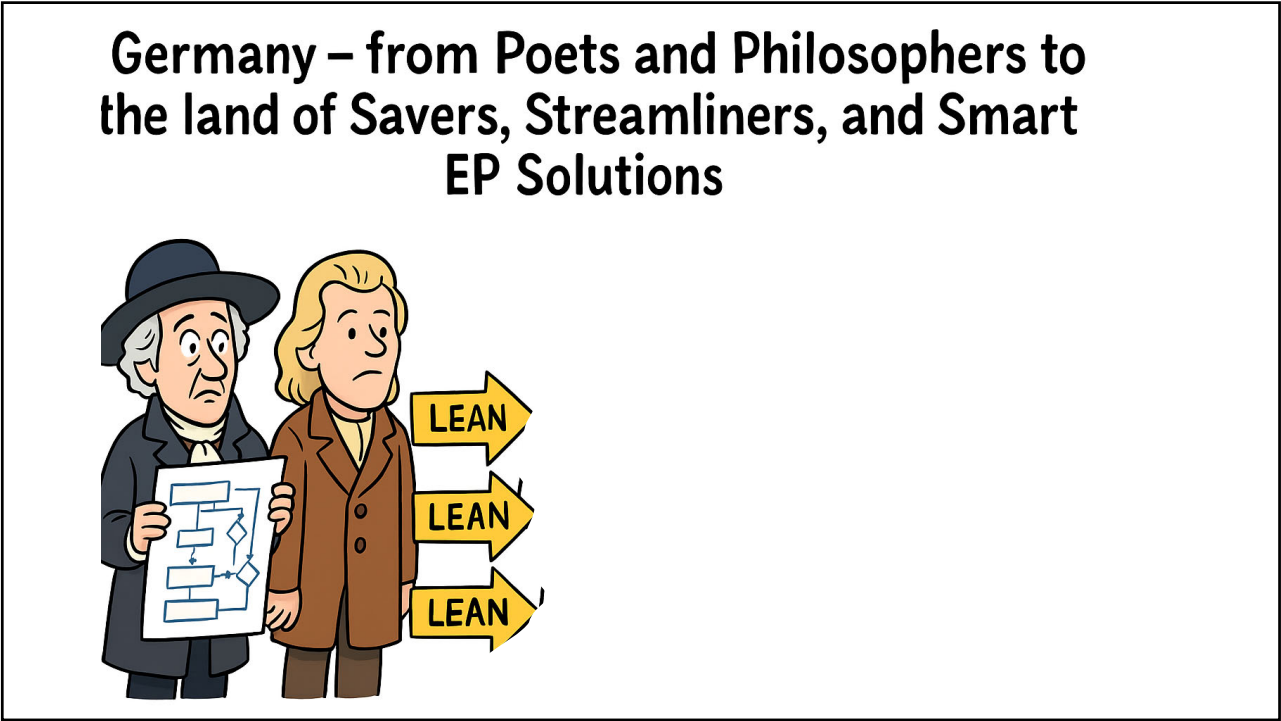
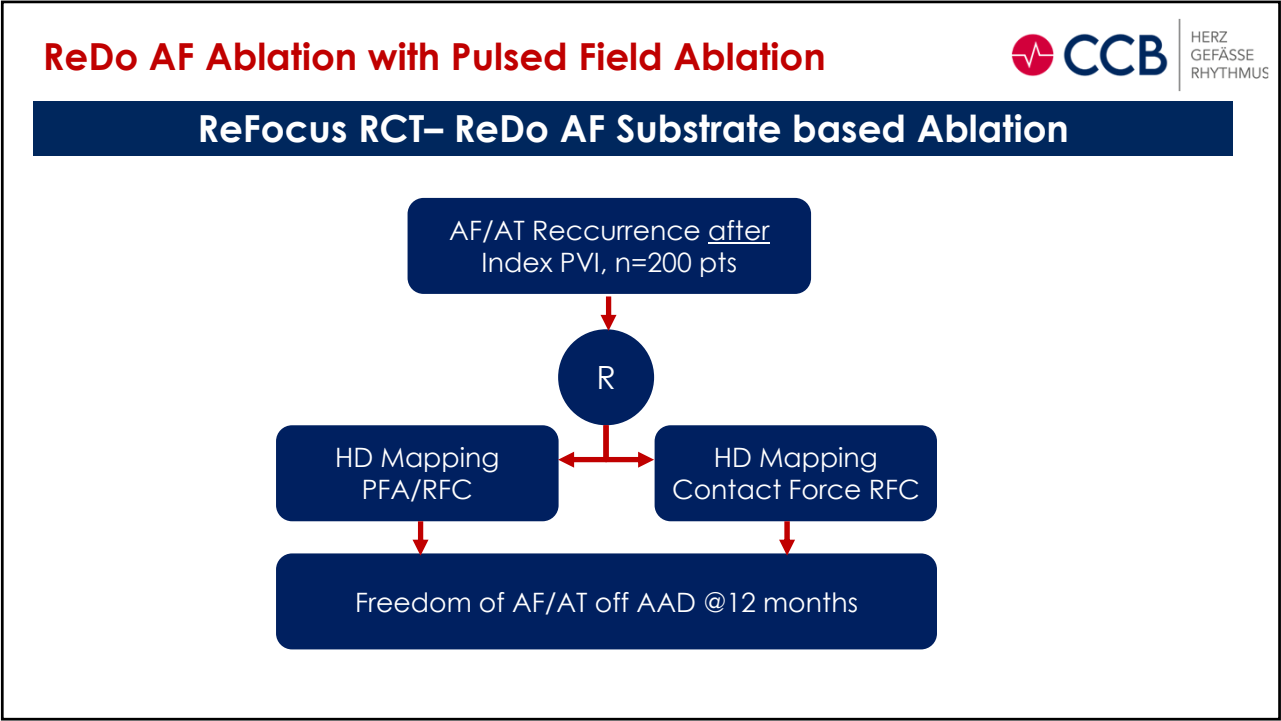
Anterior line
ablation

Pacing from Appendage

Tohoku S et al., ... Chun KRJ Europace 2024 accepted

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