



1

PFA for PAF +/- LAAC (Watchman)

Jay Sengupta, MD, FACC, FHRS

Minneapolis Heart Institute Foundation

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2

Disclosures

- I participate in industry-sponsored trials and investigator-initiated trials with the Minneapolis Heart Institute Foundation and consulting and educational events for:
 - Medtronic
 - Boston Scientific
 - Abbott Vascular

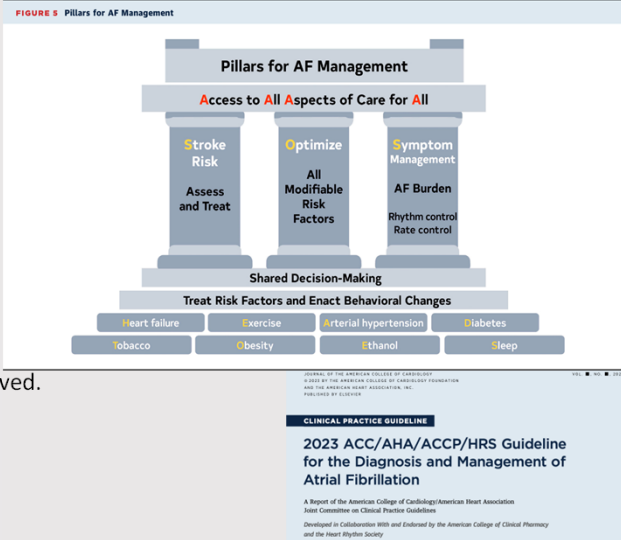


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3

Atrial fibrillation crossroads

- Management has improved.
 - Understanding of atrial fibrillation origins
 - Target risk factors and associated cardiac conditions
 - Tailor options for optimal outcomes
 - Therapies: ablation, device, medication
- Catheter ablation and stroke management options have evolved.
 - Growing list of approaches
 - Alternatives to anticoagulation when applicable
 - Provide context and deep dive
 - Share EP perspective as we perform procedures



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4

Special Thanks to our EP Ecosystem

MHI+MHIF

- Cutting edge clinical options
- Acquisition and use of latest technologies
- Research capability
 - Investigator-initiated and Industry-sponsored multi-center clinical trials
- Quality Improvement
- Research Scholars and Fellows
- Every person involved in EP has played a role



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5

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 Detlev G. Lippman, MD, St. Louis, Mo.

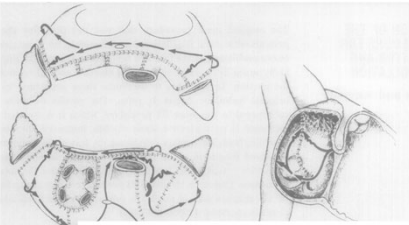


Fig. 1. Two-dimensional representation of the original maze I procedure for atrial fibrillation. In the left panel, the atria are depicted as if viewed from the posterior direction with the back of both atria in the lower panel. The atria are then divided in a sagittal plane and the anterior half of 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, Frishman 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 Taniguchi, M.D., Mueler 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.

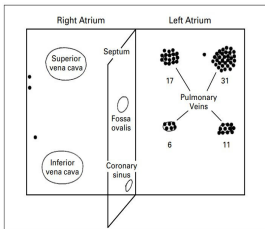
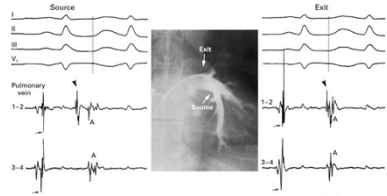


Figure 1. Diagram of the Sites of 60 Foci Triggering Atrial Fibrillation in 45 Patients. Note the clustering in the pulmonary veins, particularly in both superior pulmonary veins. Numbers indicate the distribution of foci in the pulmonary veins.

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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6

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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7

Diagnostics: 3D Mapping

Mapping Systems

Magnetic Fields and Sensors

Distance 1

Distance 2

Distance 3

Coil 1

Coil 2

Coil 3

Mapping Catheters

1mm

3mm

2.5Fr

Across

Along

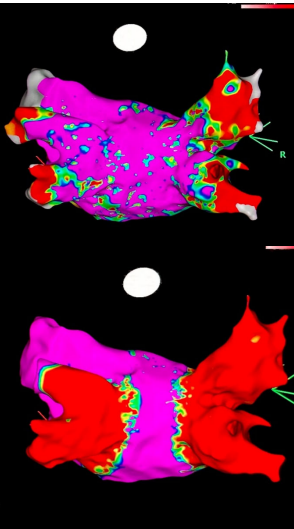
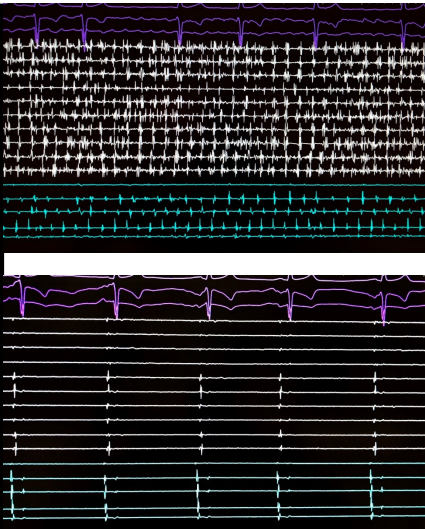
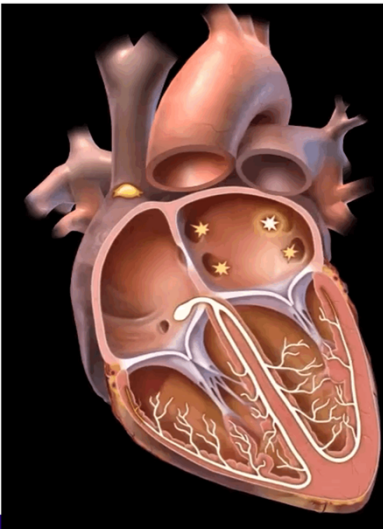
Indian Pacing Electrophysiol J. 2008 Feb 1;8(1):32-50.

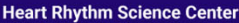

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8

Atrial Anatomy and Pathophysiology relevant to AF ablation



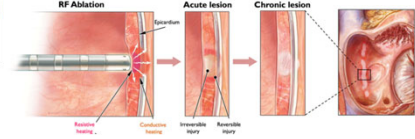
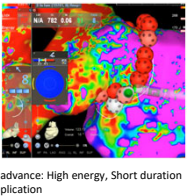
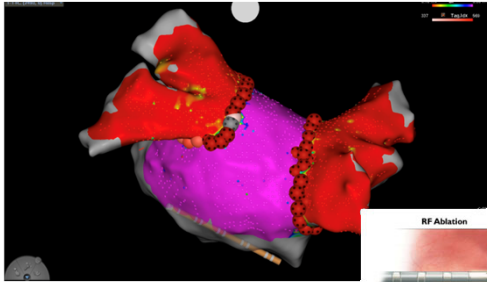


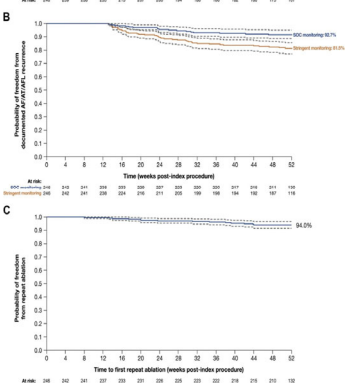
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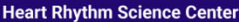

RF Ablation Success

- 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, Mamyam H, Athil 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. 2023 Sep 6;9(9):1077-1089.

10

5 of 45

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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11

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. Haegels, 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*

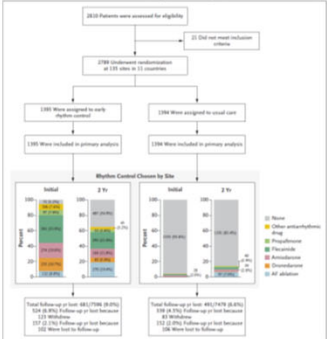


Figure 1. Screening, Randomization, Treatment, and Follow-up.

Most of the patients assigned to early rhythm-control therapy were initially treated with antiarrhythmic drugs, often flecainide. After 2 years of follow-up, 108 of the patients (8%) who had been randomly assigned to early rhythm-control therapy were still receiving active rhythm-control therapy (270 patients treated with antiarrhythmic [AF] drugs and 624 treated with antiarrhythmic drugs), and only 200 patients (14.4%) who had been randomly assigned to usual care were receiving rhythm-control therapy (97 treated with AF ablation and 103 treated with antiarrhythmic drugs). All patients who underwent radiofrequency catheter ablation were included in the primary analysis.

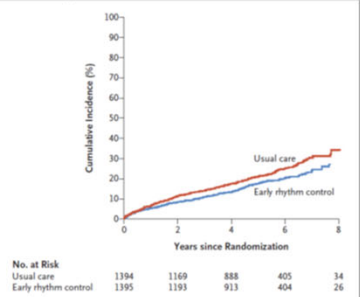


Figure 2. Aalen-Johansen Cumulative-Incidence Curves for the First Primary Outcome.

The first primary outcome was a composite of death from cardiovascular causes, stroke, or hospitalization with worsening of heart failure or acute coronary syndrome.

No. at Risk	0	2	4	6	8
Usual care	1394	1169	888	405	34
Early rhythm control	1395	1193	913	404	26

12

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, contra-indicated, 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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13

Thanks Everyone!

I think we’re done here! Great job!



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14

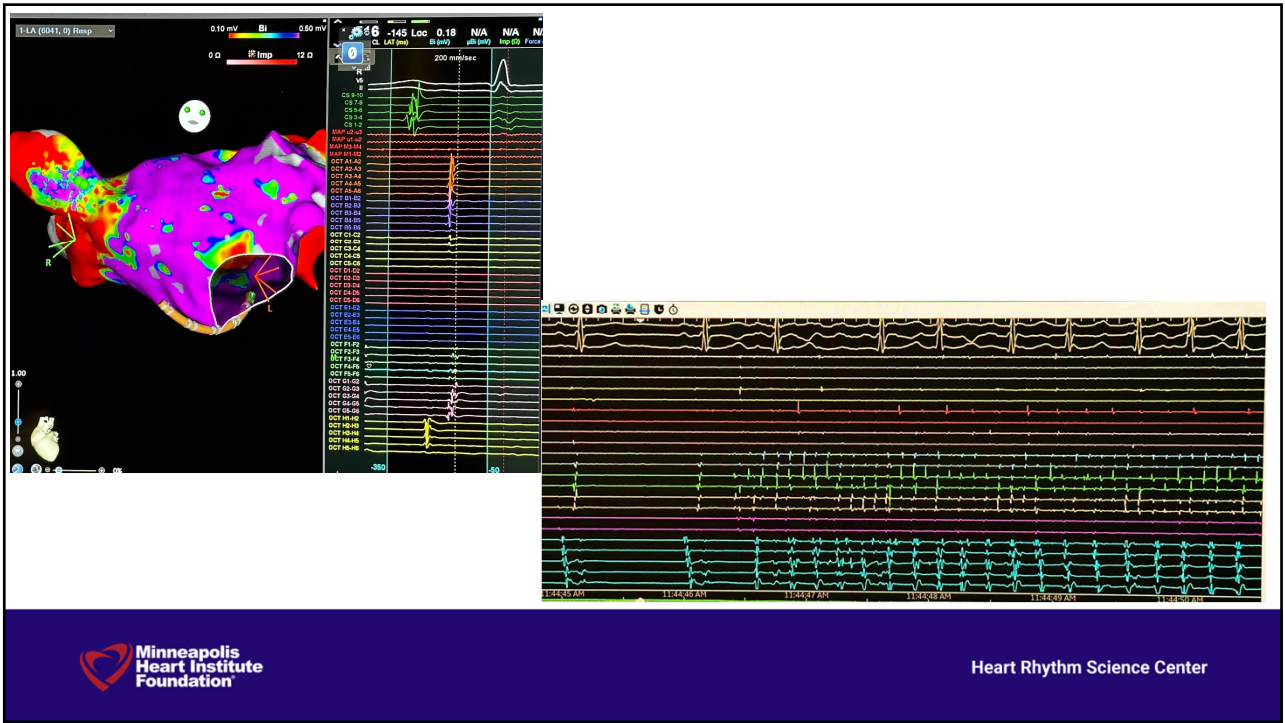
Not so fast... The case of recurrent atrial arrhythmias

- 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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15

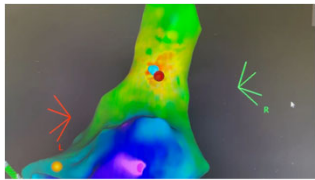


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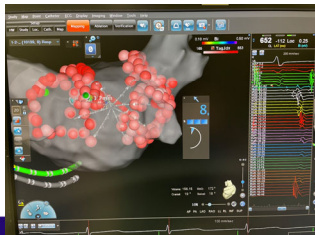
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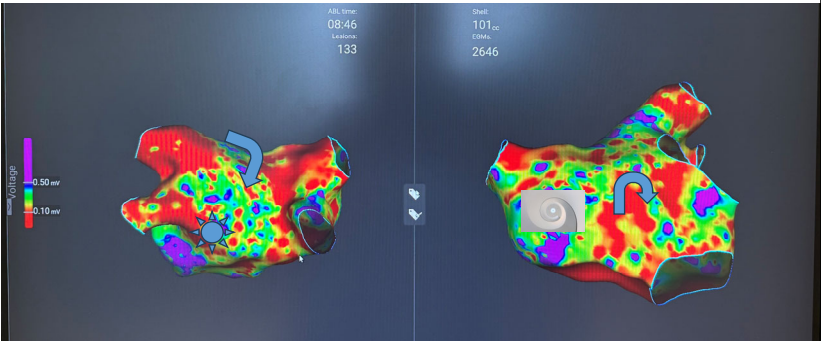
Arrhythmia Types



Non-PV triggers
and PACs



Micro-reentry and Macro-reentry atypical variants of atrial flutter
Atrial tachycardia

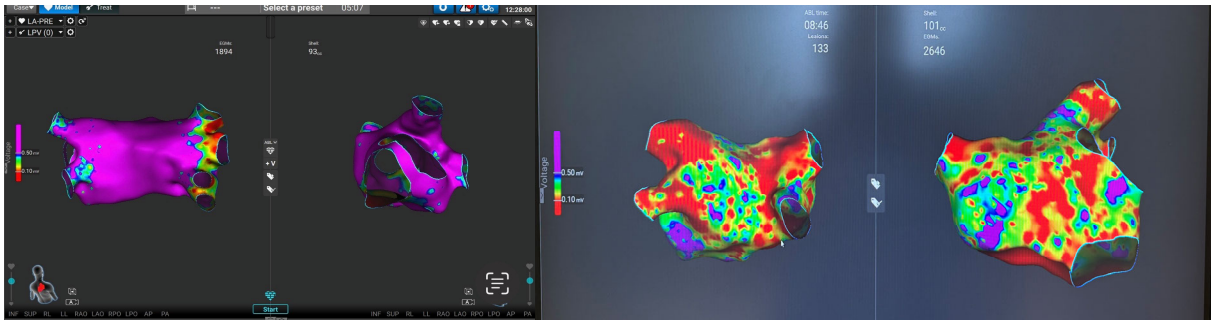


Rotors and Drivers



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AF pattern and burden/Paroxysmal versus Persistent often discordant with substrate



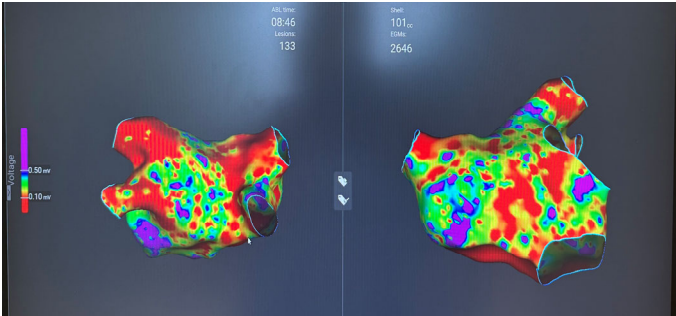
Early referral regardless of AF burden



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No two patients or atria are the same

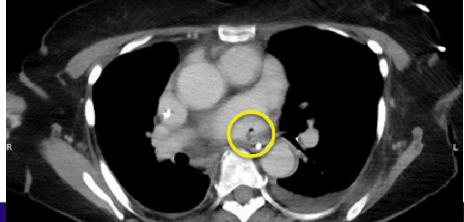
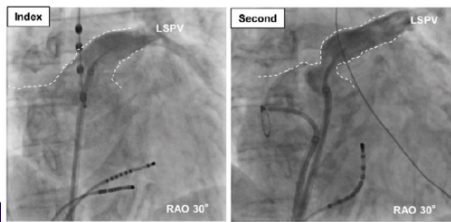
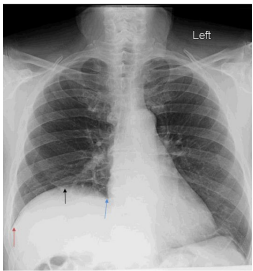
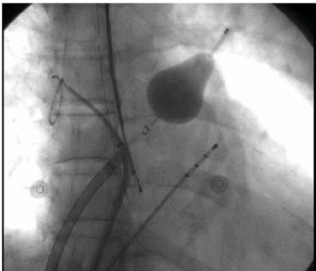
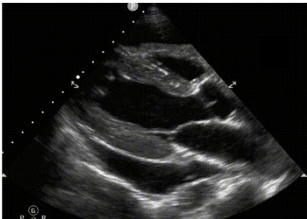
- Clinical impact (QOL, palpitations, CM/HF)
- Imaging (Echo, CT, MRI)
- Intra-procedural data
 - Hemodynamic
 - LA volume
 - Voltage substrate (fibrosis)
 - Electrical substrate (activation, rotors, and drivers)
 - Arrhythmia types (AF, Aflutter, AT) and activation substrate
 - Other arrhythmias associated with symptoms, e.g., PVCs, SVT



21

The Fire and Ice Saga

- Complications with Balloons, multi-electrode array catheters, and thermal energy:
 - Cardio-Embolic Events
 - Effusion/Tamponade
 - PV stenosis
 - Phrenic Nerve Palsy
 - Atrio-Esophageal Fistula



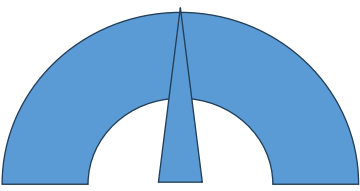
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Afib ablation strategies:

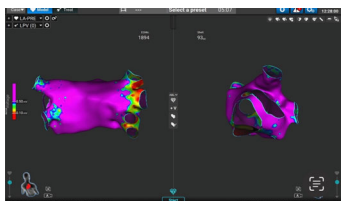
- PV isolation only
- PV isolation + fibrotic areas
- PV isolation + inducible arrhythmia
- PV isolation + linear ablations
- PV isolation + boxed lesion set (posterior wall isolation)
- PV isolation + rotors/drivers
- PV isolation + empiric SVC isolation + LAA isolation + mitral isthmus line + CS isolation + CTI line ablation
- Ablate until no signal exists in LA

Wherever you can put an ablation catheter!

Recurrence



Cure



Move the needle and thread the needle:
Refer early
Understand targets beyond PVs
Ablate with something other than Fire and Ice?

Less ablation

More ablation

Atrial fibrillation


Atrial flutter/tachycardia

Circulation: Heart Failure, Volume 10, Issue 5, May 2012; Page e003855
<https://doi.org/10.1161/CIRCHEARTFAILURE.117.003855>
Images and Case Reports in Heart Failure

**Stiff Left Atrial Syndrome After Multiple Percutaneous Catheter Ablations
Role for Invasive Hemodynamic Exercise Testing**

Marcus A. Urey, MD, Douglas Darden, MD, Douglas Stoller, MD, Mark H. Drazner, MD, MSc, Vernon Horn, MD, Satyam Sarma, MD, and Benjamin D. Levine, MD

Non-compliant LA, pressure-volume relationship steepens accounting for large V waves and pulmonary congestion



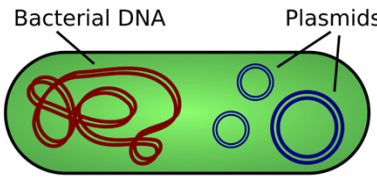
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23

What do plasmids, potatoes, and atrial tissue have in common?

Bacterial DNA

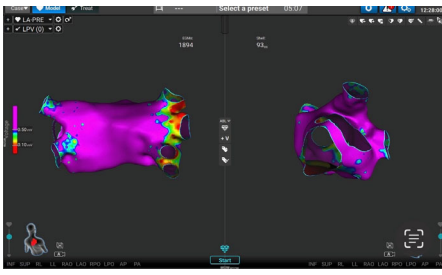
Plasmids






Boise researchers are shocking potatoes with electricity. Can it help Idaho's ag industry?

Elizabeth Walsh
Thu, July 18, 2025 at 10:55 AM CDT · 3 min read





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24

Electroporation

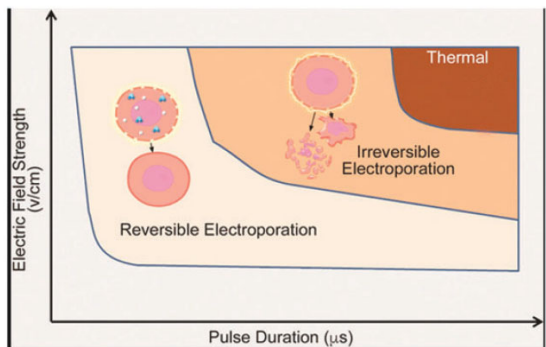
- Non-thermal energy that limits collateral damage
- DC power supply to charge capacitors
 - Discharged, or pulsed, with the help of a high voltage switch
- Delivered between two or more electrodes creating an electric field
- Pulses are in nano- to millisecond range
- Voltage applied in the range of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



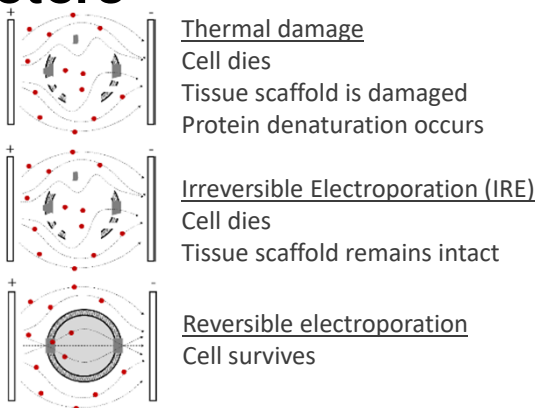
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25

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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26

26

Pulsed field ablation and irreversible electroporation

Pulsed field ablation

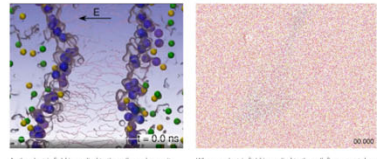
The use of pulsed electric fields to ablate cardiac tissues, through the mechanism of irreversible electroporation.



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.

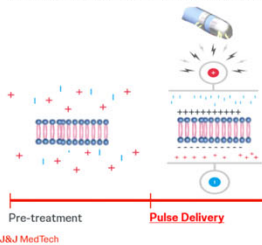
Image courtesy of Medtronic and Prof. Subbotin, University of California. For Research purposes only.

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



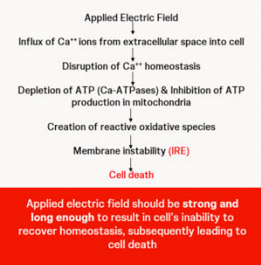
Cellular impact depends on pulse amplitude & duration

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)

Time

1 J&J MedTech 2 Electrophysiology 4

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



Applied Electric Field

Influx of Ca²⁺ ions from extracellular space into cell

Disruption of Ca²⁺ homeostasis

Depletion of ATP (Ca-ATPases) & Inhibition of ATP production in mitochondria

Creation of reactive oxidative species

Membrane instability (IRE)

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

1 J&J MedTech 2 Electrophysiology 5

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.



Technology Presentation System with SpH

27

(A) Penta-spline basket

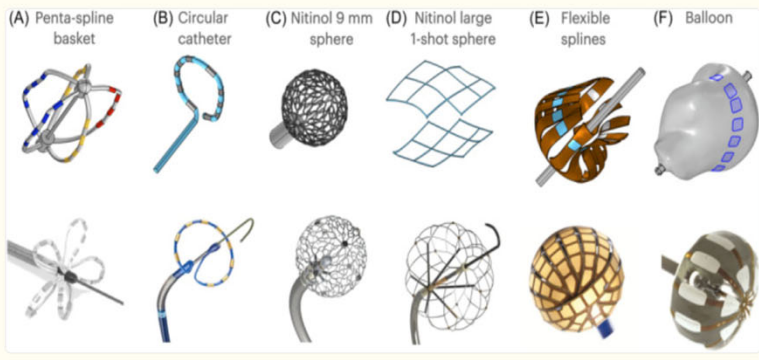
(B) Circular catheter

(C) Nitinol 9 mm sphere

(D) Nitinol large 1-shot sphere

(E) Flexible splines

(F) Balloon



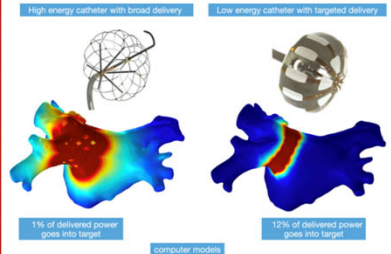
1 J Cardiovasc Electrophysiol. 2024 Oct 16;35(10):2190-2195. doi: 10.1111/jce.15442.

Comparison of efficiency of PFA catheter designs by computer modeling

Andrés Rodríguez, C. Rodríguez

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

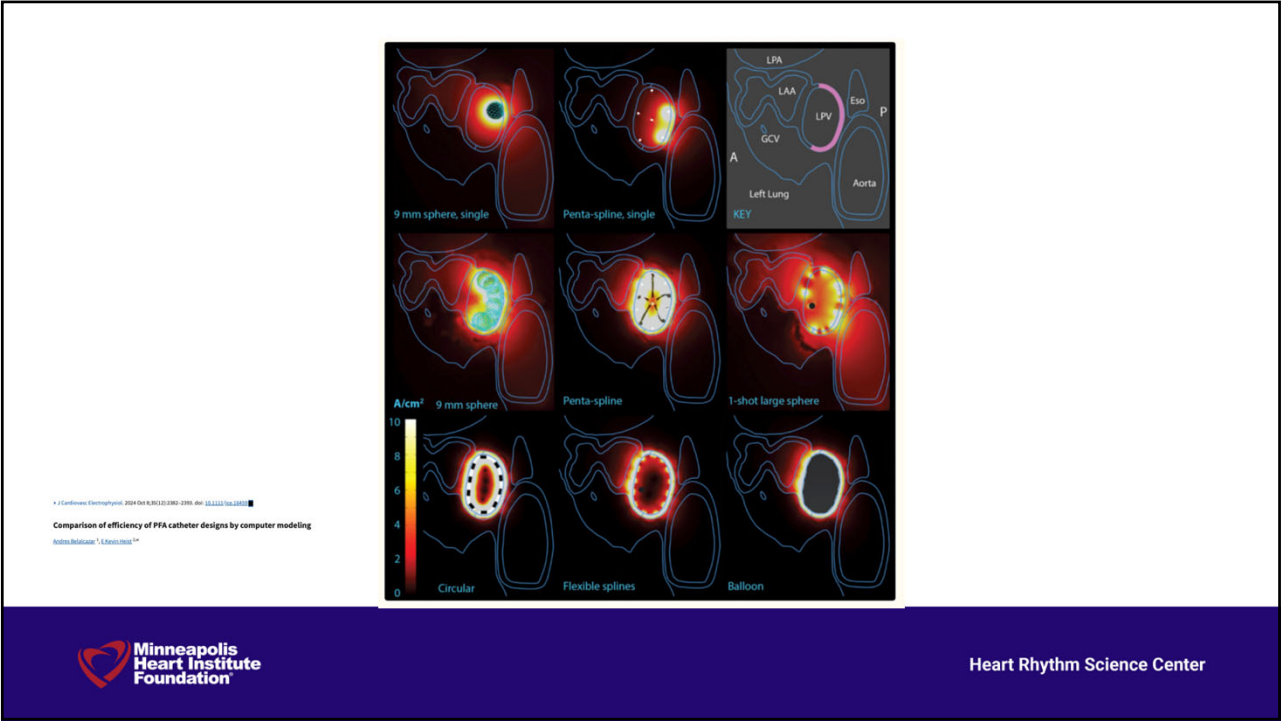
Form factor importance: safety, energy waveforms, directionality, strategy (one-shot versus focal), efficiency, targets



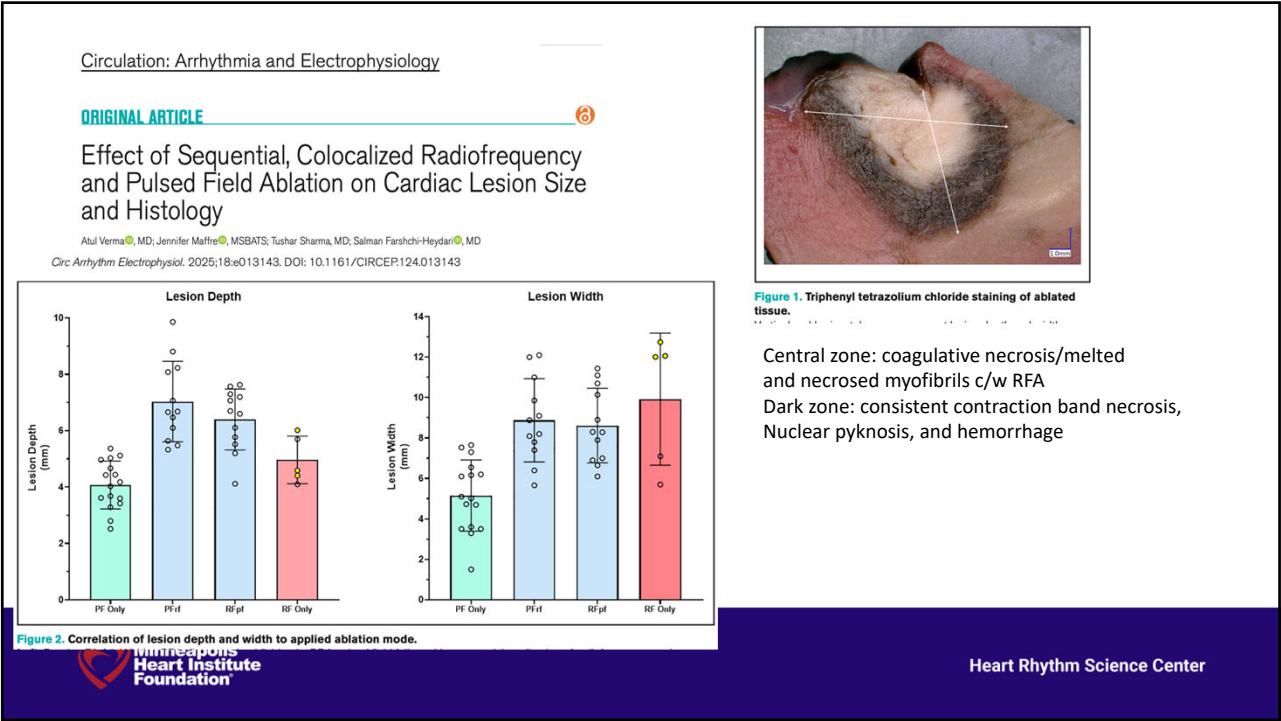
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28

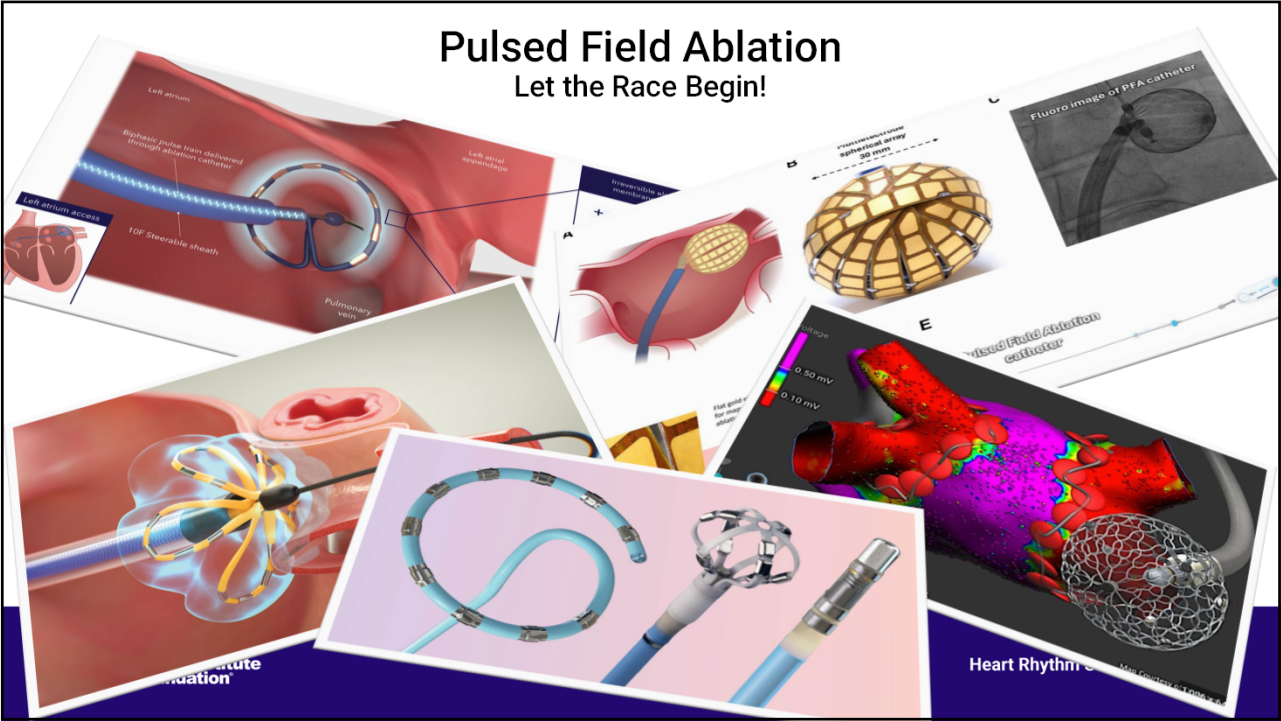
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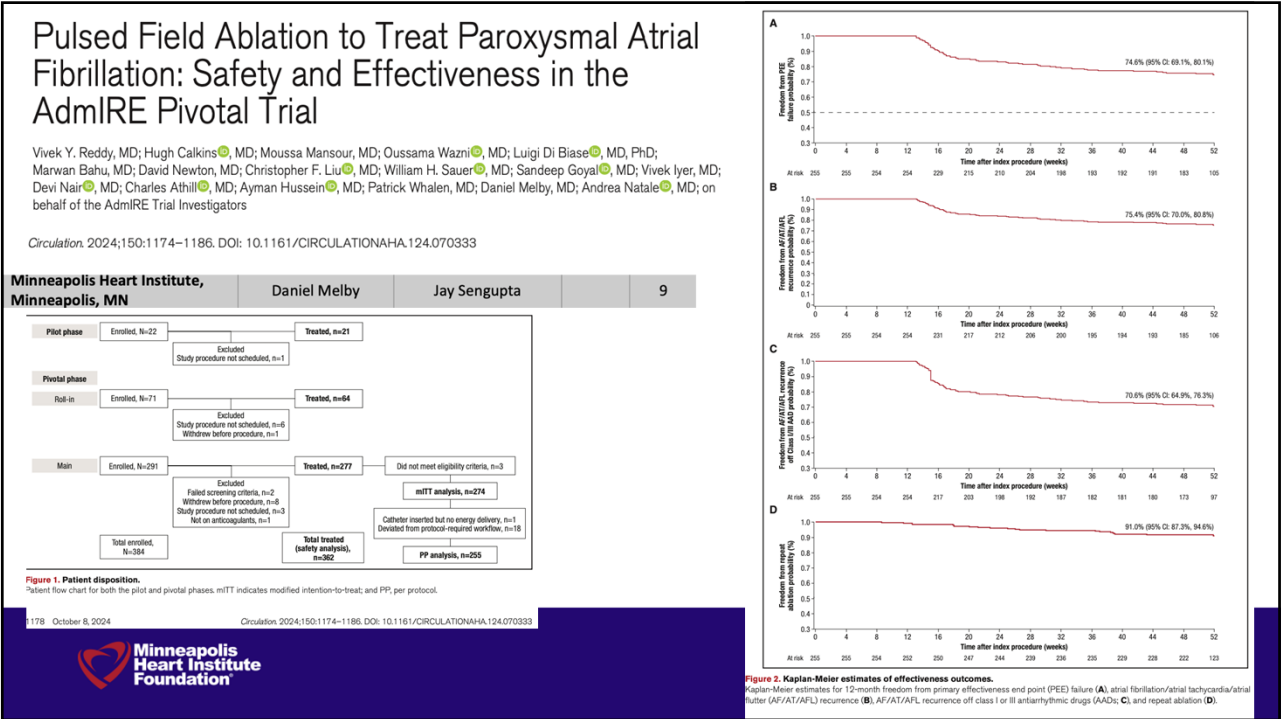
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34

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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35

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

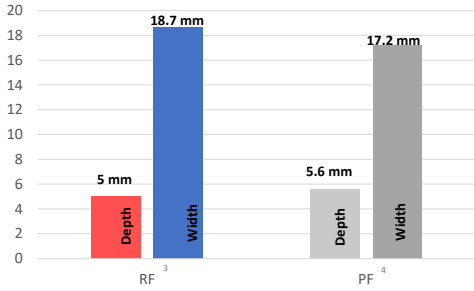
Pulsed field

Unipolar, biphasic waveform to cause cell death by irreversible electroporation

5 sec


Radiofrequency

Temperature-controlled RF delivery



Modality	Parameter	Value
RF ³	Depth	5 mm
	Width	18.7 mm
PF ⁴	Depth	5.6 mm
	Width	17.2 mm

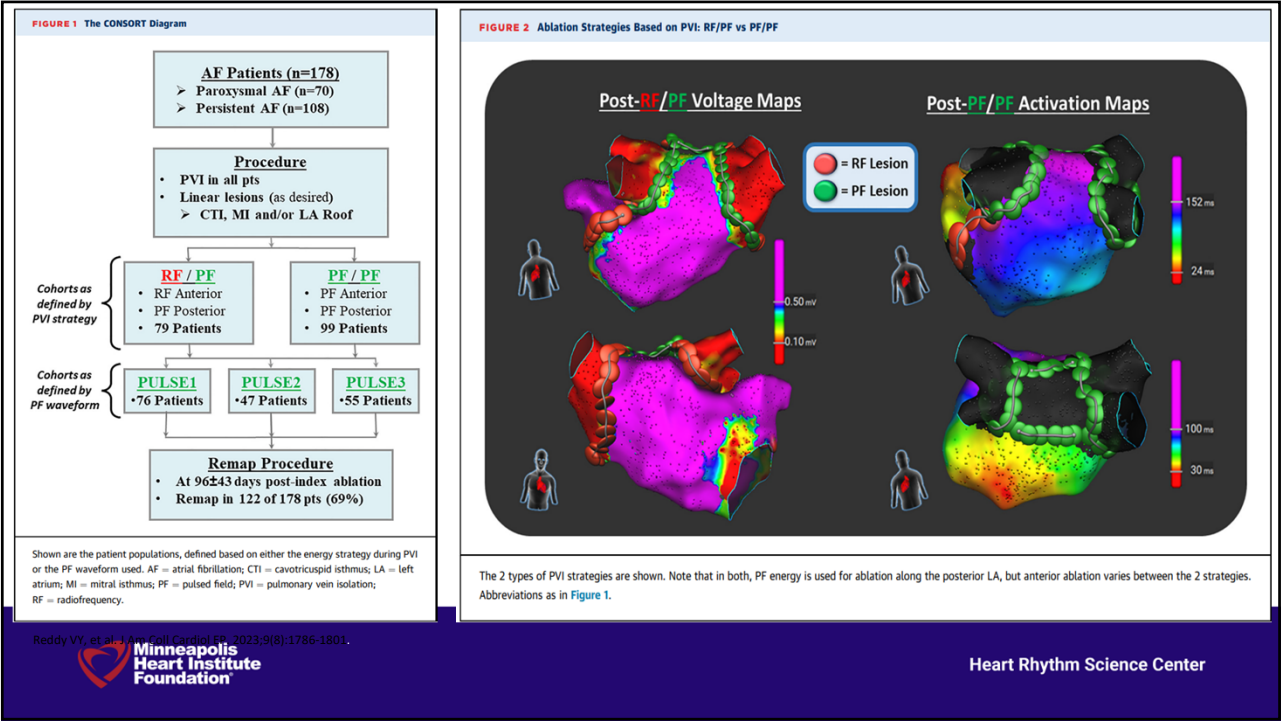
1. Anter E, et al. JACC Clin Electrophysiol. 2020;6:507-519.
2. Barkagan M, et al. Circ Arrhythm Electrophysiol. 2019;12:e007090.
3. Medtronic data on file (56585), GLP study.
4. Yavin HD, et al. Circ Arrhythm Electrophysiol. 2021;14:e010375.



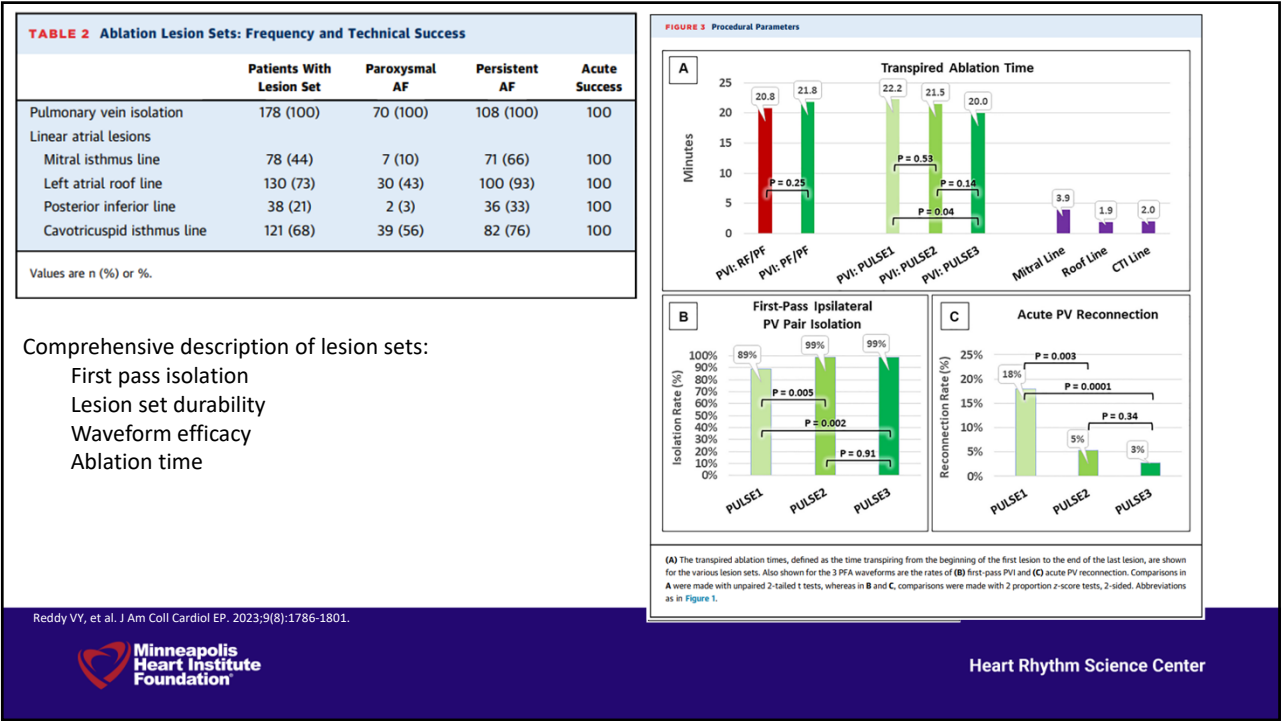
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36

36



37



38

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.




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

39

Initial experience at 3 centers with an 8Fr lattice tip PF/RF catheter using an evolving waveform resulted in safe, effective, and durable PV isolation and excellent freedom from both paroxysmal and persistent AF in a cohort of 178 patients.

CENTRAL ILLUSTRATION Atrial Fibrillation Ablation With a Combination RF/PF Focal Ablation Catheter



Post-^{RF}/PF Voltage Map

Post-^{RF}/PF Activation Map

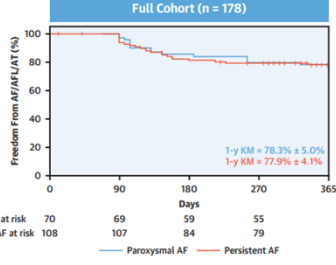
● = RF Lesion

● = PF Lesion

PVI Durability

Group	n	Success Rate
PVISO1	191	51%
PVISO2	178	87%
PVISO3	124	97%
Per Patient		
PVISO1	47	32%
PVISO2	44	64%
PVISO3	31	90%

Full Cohort (n = 178)



1-y KM = 78.3% ± 5.0%


1-y KM = 77.9% ± 4.1%

PAF at risk: 70, 69, 59, 55

PerAF at risk: 108, 107, 84, 79

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

AFL = atrial flutter; PF = pulsed field; PV = pulmonary vein; PVI = pulmonary vein isolation; REF = radiofrequency.



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20 of 45

Google, what are FDA-approved PFA technologies for atrial fibrillation?

AI Overview

FDA-approved Pulsed Field Ablation (PFA) technologies for atrial fibrillation include the **Medtronic PulseSelect™ PFA System**, the **Boston Scientific FARAPULSE™ PFA System**, the **Johnson & Johnson MedTech VARIPULSE™ Platform**, and the **Medtronic Aferra™ Sphere-9 Catheter**. These systems use pulsed electrical fields instead of heat or cold to selectively eliminate cardiac tissue, offering a nonthermal mechanism of action that is designed to be safer for surrounding structures than traditional ablation methods.

Specific FDA-approved PFA Systems

Medtronic PulseSelect™ PFA System:
Approved in December 2023, this system provides a single-shot solution for pulmonary vein isolation (PVI).

Boston Scientific FARAPULSE™ PFA System:
Approved in January 2024, this PFA system provides a cost-effective and simple alternative to thermal ablation.

Johnson & Johnson MedTech VARIPULSE™ Platform:
Approved in November 2024, this platform integrates PFA with the CARTO™ 3 System for advanced mapping and treatment.


Medtronic Aferra™ Sphere-9 Catheter:
Approved in October 2024, this catheter offers a flexible, wide-area focal design for treating patients with atrial fibrillation.

Johnson & Johnson MedTech Receives FDA Approval for the ...
Nov 7, 2024 — Irvine, CA – November 7, 2024 – Johnson & Johnson MedTech, a...

Medtronic receives FDA approval of Aferra™...
Oct 24, 2024 — With this approval, Medtronic is now...

FDA Approves PulseSelect Pulsed Field Ablation System, a Novel ...
Jan 5, 2024 — Kansas City, Missouri – The PulseSelect Pulsed Field Ablation (PFA)...

Show all

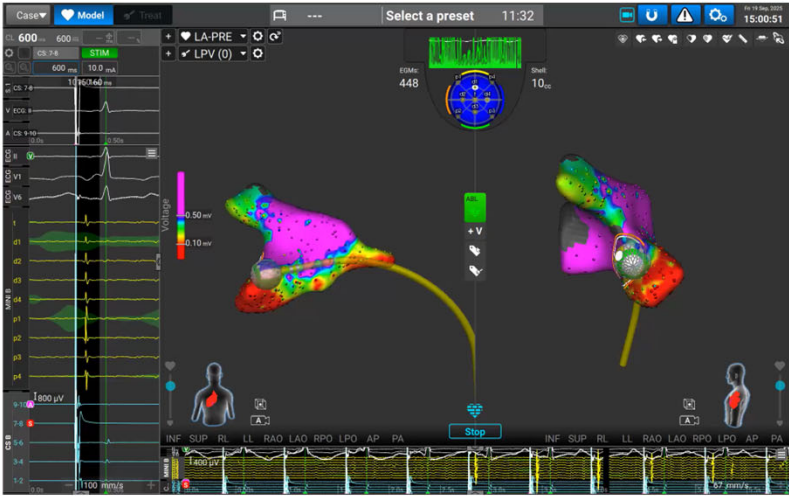



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Are there PFA pitfalls?

- 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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Case 2

- C.R.
 - 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



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C.R.

- 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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47

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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48

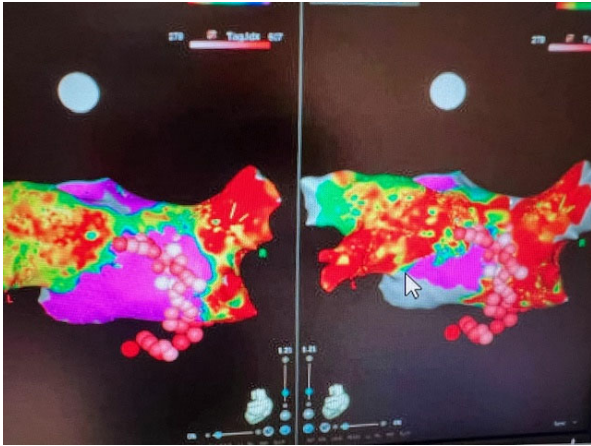
AF Ablation challenges

Over the 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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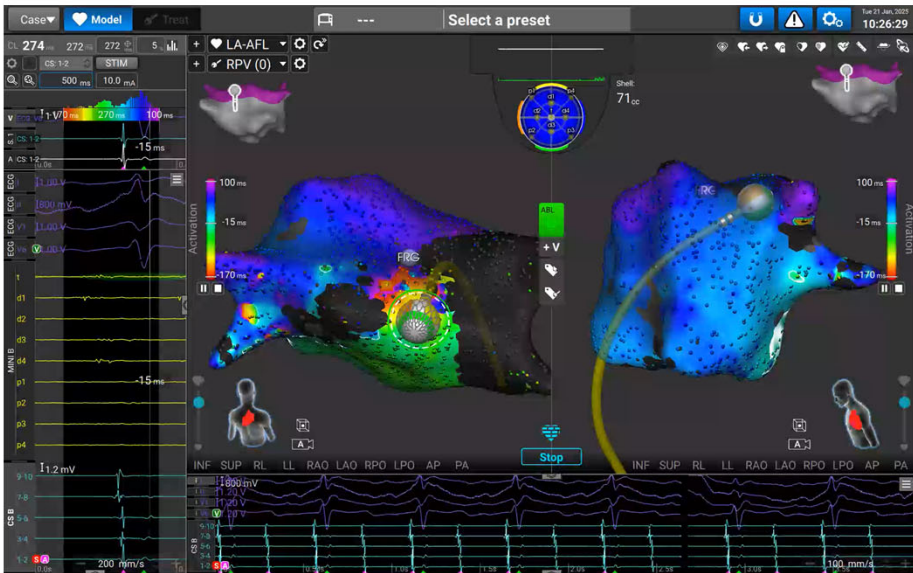
Recurrent Arrhythmia within 2 months

- 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?



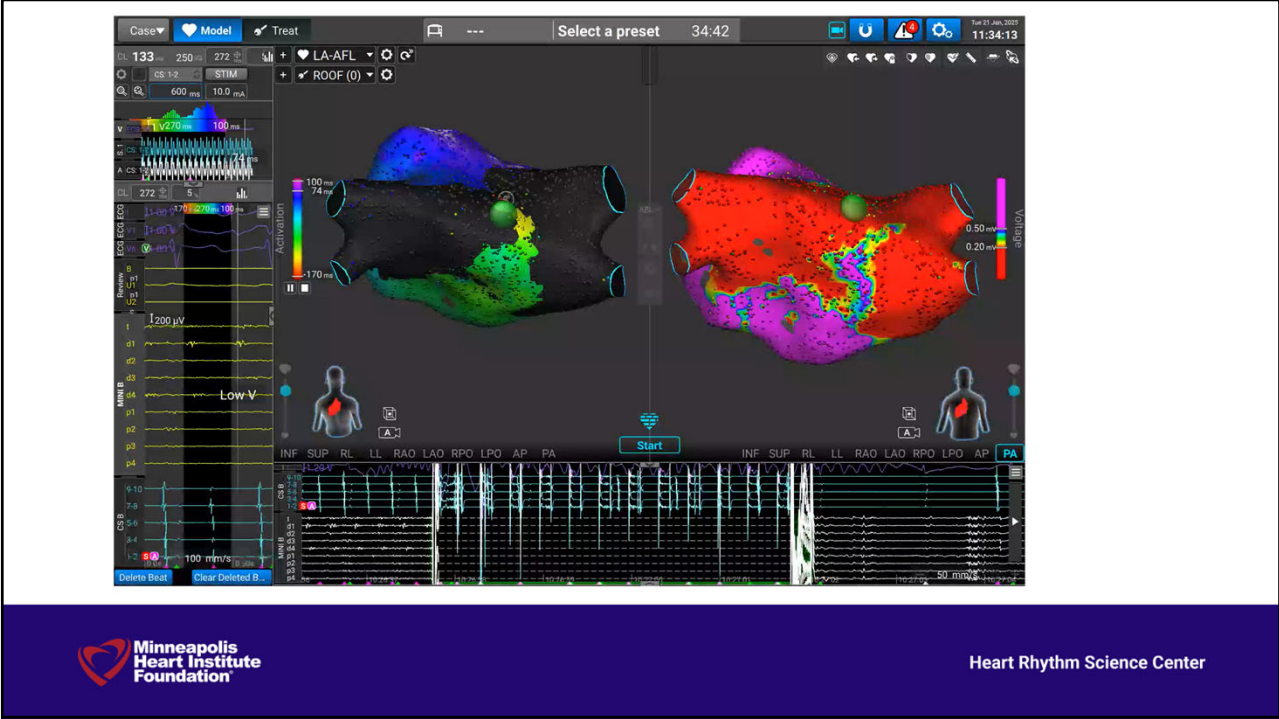
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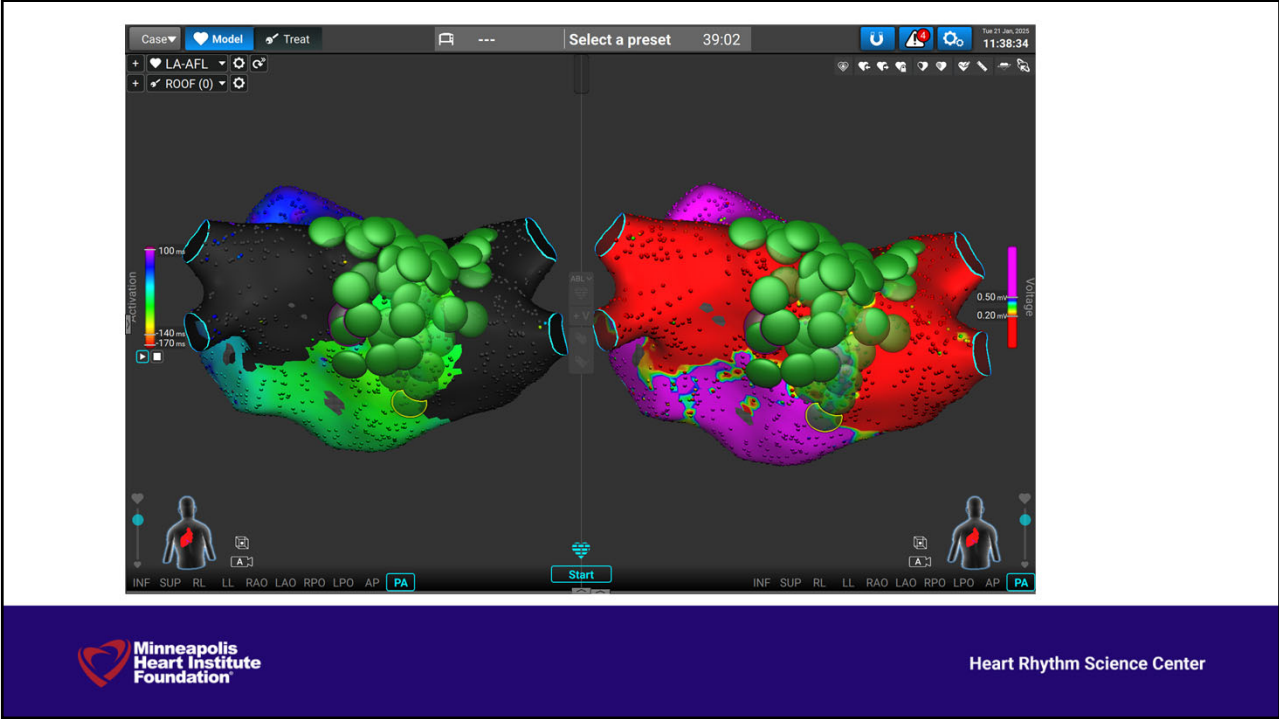


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53



54

Focal PFA and RFA with Affera

- 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



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JACC: CLINICAL ELECTROPHYSIOLOGY
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VOL. ■ NO. ■ 2021

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, Mohamad Mdaibly, MD, Adèle Warfa, MD, Bryan Baranowski, MD, Hiroshi Nakagawa, MD, Tyler L. Taigen, MD, Niraj Varma, MD, PhD, Koji Higuchi, MD, Thomas D. Callahan, MD, Mohamed Kanj, MD, Mina K. Chung, MD, Jakub Stroubek, 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	148 (47.59)
Advisor HD Grid	
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	Acute Procedural Success 96.5% CTI-dependent 99.5% Perimitral 82.9%
Flutter Subtypes 	Main Ablation Strategy Pulsed-field ablation (All Flutters) Adjunctive Radiofrequency Ablation 13 Flutters 1 CTI-dependent 12 Perimitral	Adverse Events 1% Follow-up 175 days (IQR: 132-244) Major 0.64% Minor 0.32% Death 0 Recurrence 3.9% 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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56

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 Mirra La Ferla¹, MD; Sanghamitra Mahapatra², MD; Cecilia Gianni³, MD; Edo Zito⁴, MD; Nicola Penarri⁵, MD; Giuseppe Di Biase⁶, MD; Phoen Gierla Talarmin⁷, MD; Domenico G. Della Rocca⁸, MD; Wenzhuo Daxuegong Bu⁹, MD; J. David Burkhardt¹⁰, MD; Rodney Horvath¹¹, MD; Amr Al-Ahmad¹², MD; Luigi Di Biase¹³, 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.

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

September 2025 673

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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

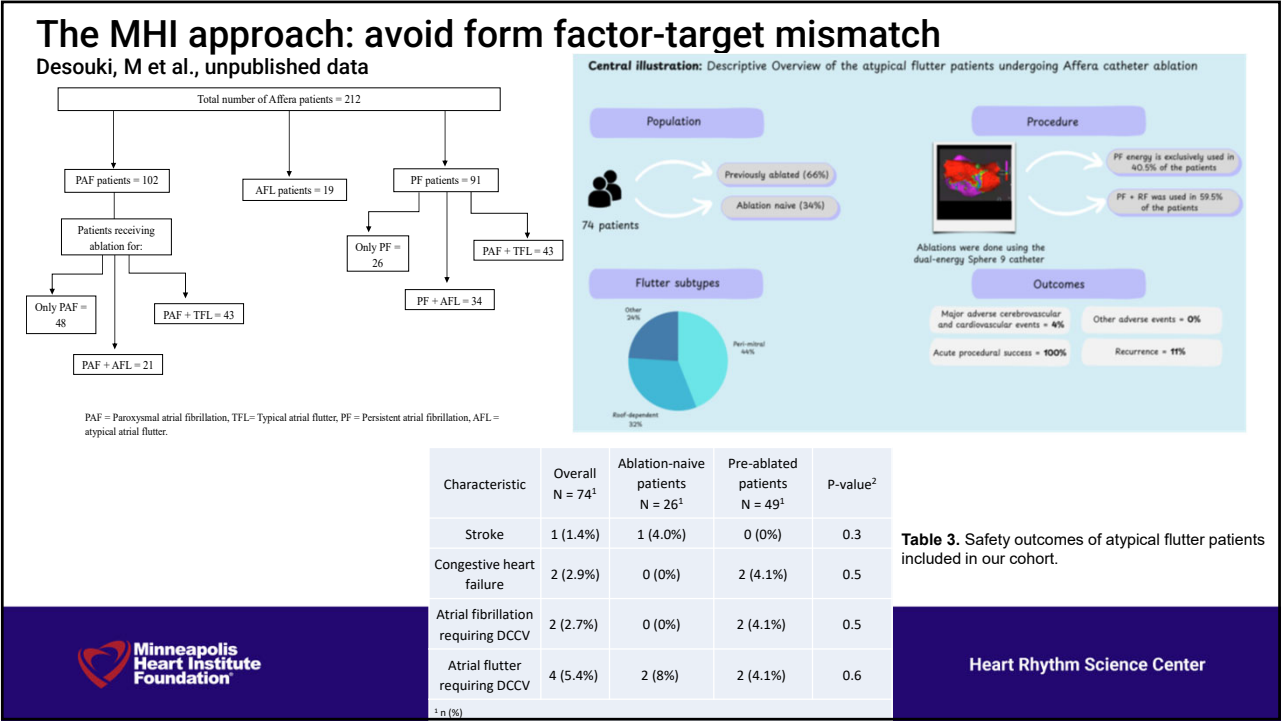
Isolation/Block	Acute	Post-Adenosine	3 Months
LAA	100%	98.3%	4.6%
CS	62.2%	40.2%	1.3%
MI	100%	85.2%	5.5%

Conclusion

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

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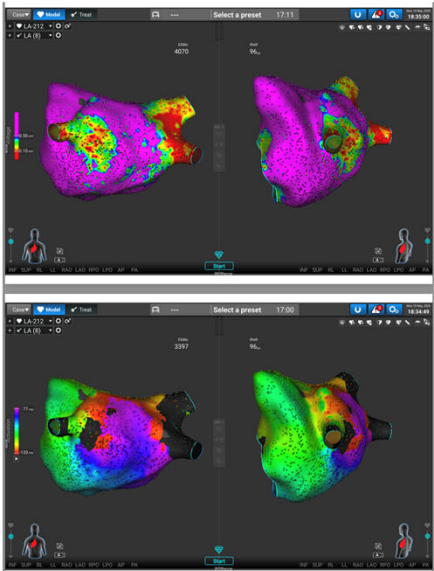
59

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
- With PV isolation durability, question becomes what else will be necessary to improve outcomes
 - AF pathophysiology and drivers
 - Atrial myopathy
 - Patient-specific factors

Minneapolis Heart Institute Foundation **Heart Rhythm Science Center**

60




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%

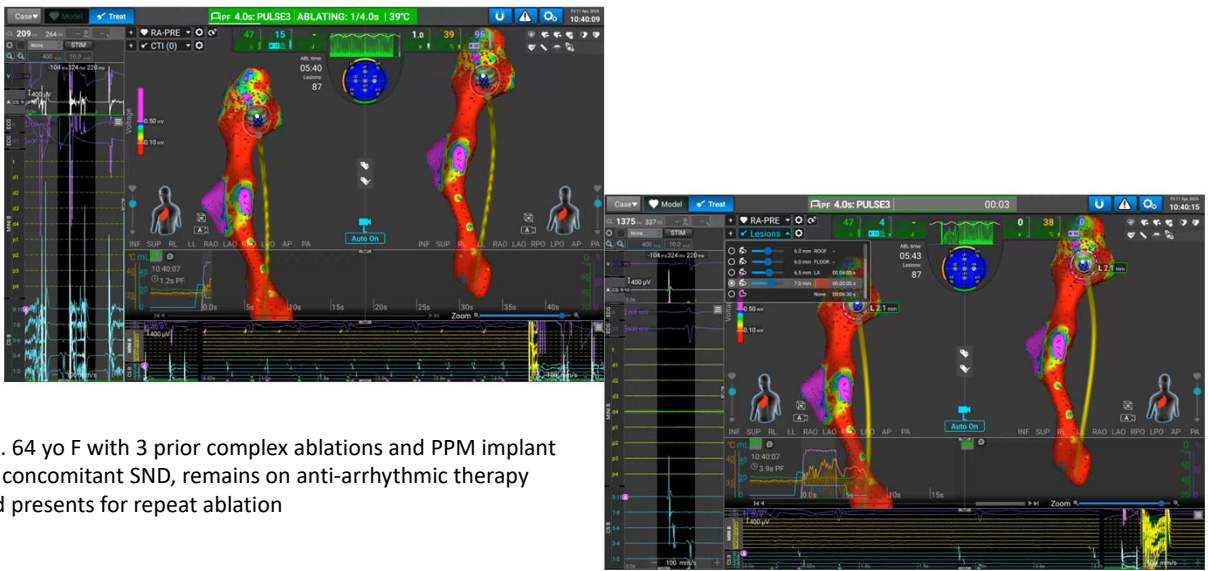
Rhythm/rate control not effective with amio and cardioversions
“started to consider potential role for durable MCS”

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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S.G. 64 yo F with 3 prior complex ablations and PPM implant
for concomitant SND, remains on anti-arrhythmic therapy
and presents for repeat ablation



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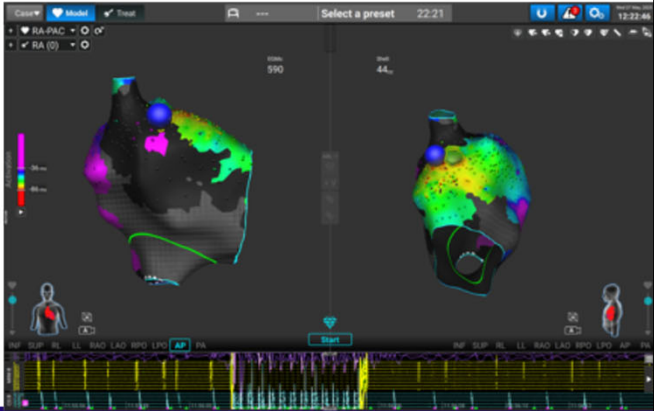
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S.G. 70 yo F with non-ischemic cardiomyopathy, possibly LMNA gene-related, complex atrial arrhythmias including Afib, atrial flutter, PACs, and she also has PVCs. ICD implant for primary prevention and to facilitate atrial-pacing and medical therapy

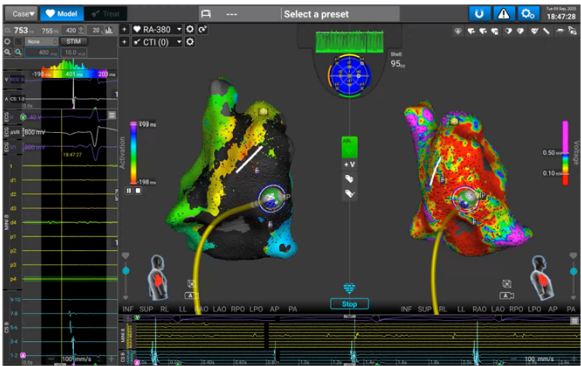
No AF after RFA ablation but frequent bigeminal, symptomatic PACs originating from high Crista, near arcuate ridge and in close proximity to phrenic nerve

Presents for ablation with focal PFA

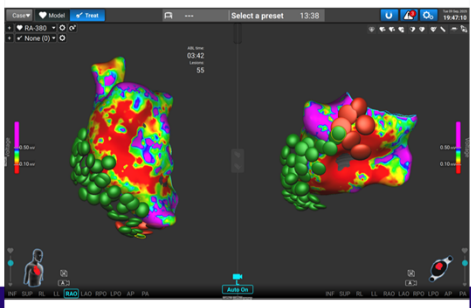
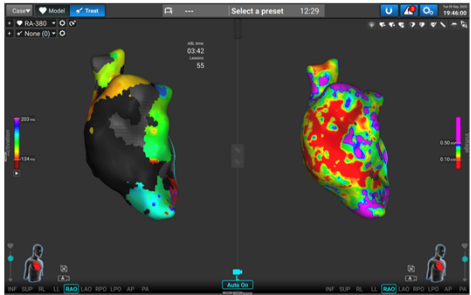
Symptomatically improved post PAC ablation
EF stable and on GDMT
No plans for PVC ablation which would require retrograde approach given extensive descending aortic atheroma



63



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.



64

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)	Enrolling
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	Enrolling
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	Anticipated start by end of 2025
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).	Anticipated 2026

66

Thanks Everyone!

I think we’re done here! Great job!



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67

Not so fast...

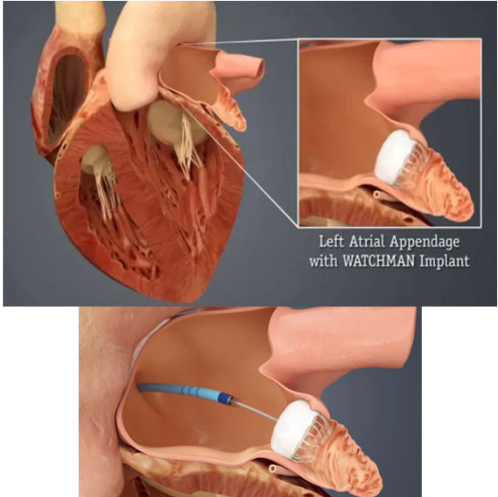
“But Doctor, do I need to stay on my blood thinner?”



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Percutaneous Left Atrial Appendage Occlusion



Left Atrial Appendage with WATCHMAN Implant

Percutaneous LAAC

"BALL" - TYPE		"DISC" - TYPE		Suture
Watchman	WaveCrest	Amplatzer	Lambre	Lariat
Watchman FLX Pro		Amulet	Omega	
In development				
CLAAS	LAMINAR			



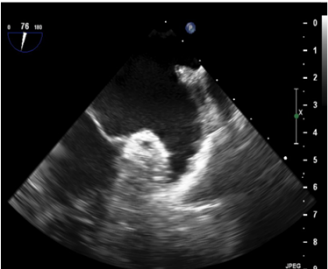
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69

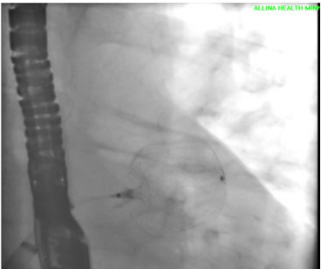
WATCHMAN development

Special thanks to Dr. Robert Van Tassel and Dr. Robert Hauser
Allina Health Minneapolis Heart Institute

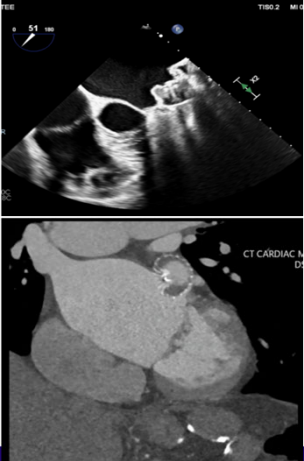
Before Implant




During Implant



After Implant





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70

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CODEN: JACCDE
CLINICAL PRACTICE GUIDELINE

**2023 ACC/AHA/ACCP/HRS Guideline
for the Diagnosis and Management of
Atrial Fibrillation**

A Report of the American College of Cardiology/American Heart Association
Joint Committee on Clinical Practice Guidelines
Developed in Collaboration With and Endorsed by the American College of Clinical Pharmacy
and the Heart Rhythm Society

Long-Term Anticoagulation Contraindicated	COR	LOE	Recommendations
Severe bleeding due to a nonreversible cause involving the gastrointestinal, pulmonary, or genitourinary systems	2a	B-NR	1. In patients with AF, a moderate to high risk of stroke (CHA ₂ DS ₂ -VASC score ≥2), and a contraindication (Table 14) to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAAO (pLAAO) is reasonable. ¹⁻⁴
Spontaneous intracranial/intraspinal bleeding due to a nonreversible cause Serious bleeding related to recurrent falls when cause of falls is not felt to be treatable	2b	B-R	2. In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive. ^{1-3,5,6}



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71

Evidence compared to OAC: non-inferior

Summary Plot of Clinical Outcomes

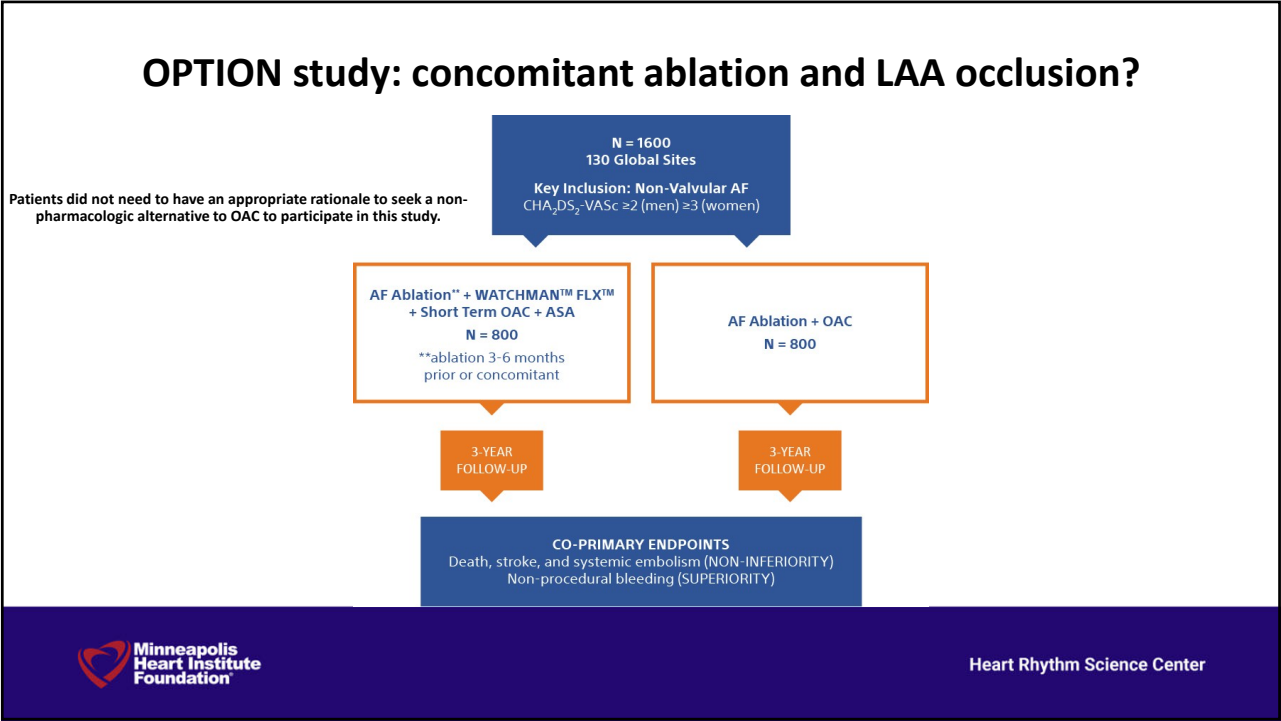
	LAAC	OAC	Risk Ratio	95% CI	p Value
All Stroke or SE	6.1% (57/933)	5.8% (34/583)	0.98	0.65–1.48	0.92
Ischemic Stroke or SE	5.6% (52/933)	3.6% (21/583)	1.48	0.89–2.46	0.13
Ischemic Stroke or SE >7 days	4.7% (44/933)	3.6% (21/583)	1.27	0.76–2.14	0.37
Hemorrhagic Stroke	0.5% (5/933)	2.4% (14/583)	0.22	0.08–0.58	0.002
Cardiovascular Mortality	5.4% (50/933)	8.2% (48/583)	0.65	0.44–0.95	0.03
All-Cause Mortality	14.3% (133/933)	17.8% (104/583)	0.78	0.62–0.99	0.04
Major Bleeding	10.5% (98/933)	11% (64/583)	0.89	0.66–1.20	0.46
Nonprocedure-Related Major Bleeding	6.2% (58/933)	11.1% (65/583)	0.53	0.38–0.74	0.0002

0.01 0.1 Favors LAAC 1 Favors OAC 10
Risk Ratio 95% CI



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72



73

WATCHMAN FLX

- Studied for an expanded indication as a first line therapy versus NOAC for NVAf patients after AF ablation
- Assess long-term safety and efficacy of WATCHMAN at 3 years compared to standard of care
- Primary Efficacy Endpoint (Non-inferiority)
 - Stroke, all-cause mortality, systemic embolism
- Primary Safety Endpoint (Superiority)
 - Non-procedural bleeding (ISTH major bleeding and clinically-relevant non-major bleeding)
- Secondary Safety Endpoint (Non-inferiority)
 - ISTH major bleeding (including procedural bleeding)

Minneapolis Heart Institute Foundation

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74



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

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75

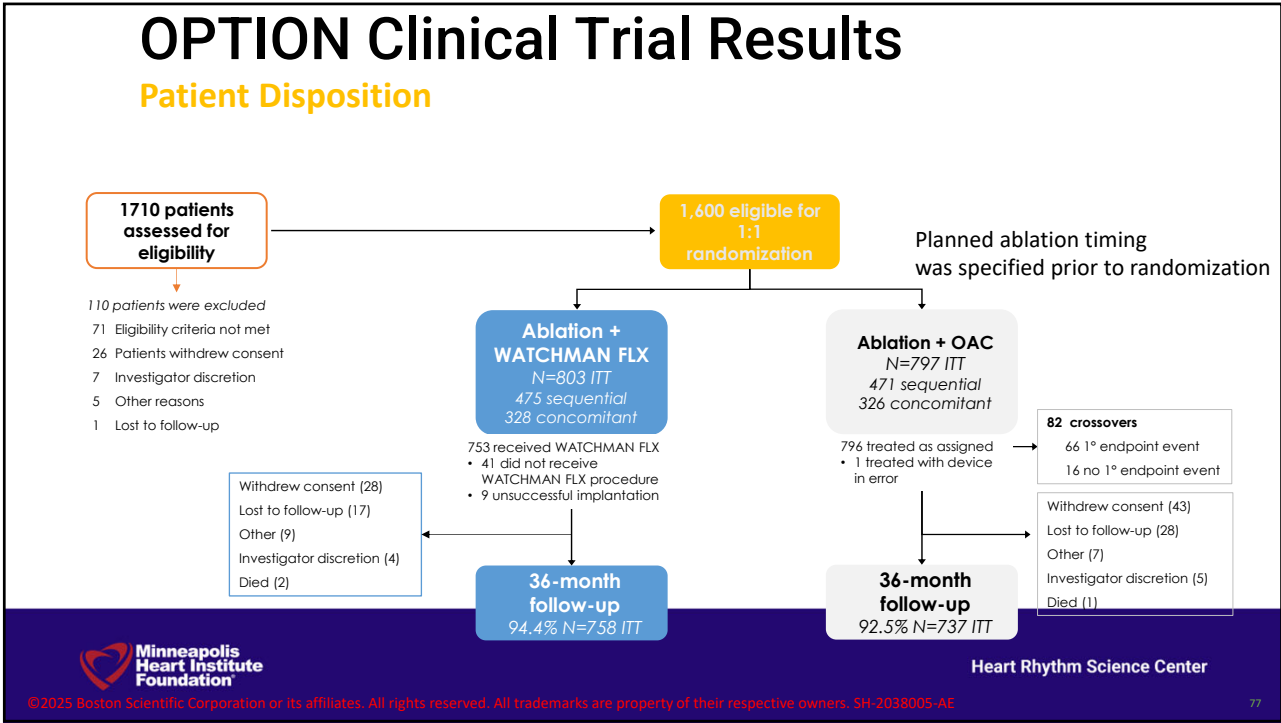
Protocol-mandated regimens

- Control group patients prescribed DOAC or warfarin for duration of trial
 - OAC group had 95% DOACs after cardiac ablation.
- Device group patients were prescribed a 3 month course of DOAC or warfarin plus aspirin and then aspirin only for duration of the trial
- OAC use over the duration of the trial was assessed
 - Captured as the number of patients who were taking OAC at any given time

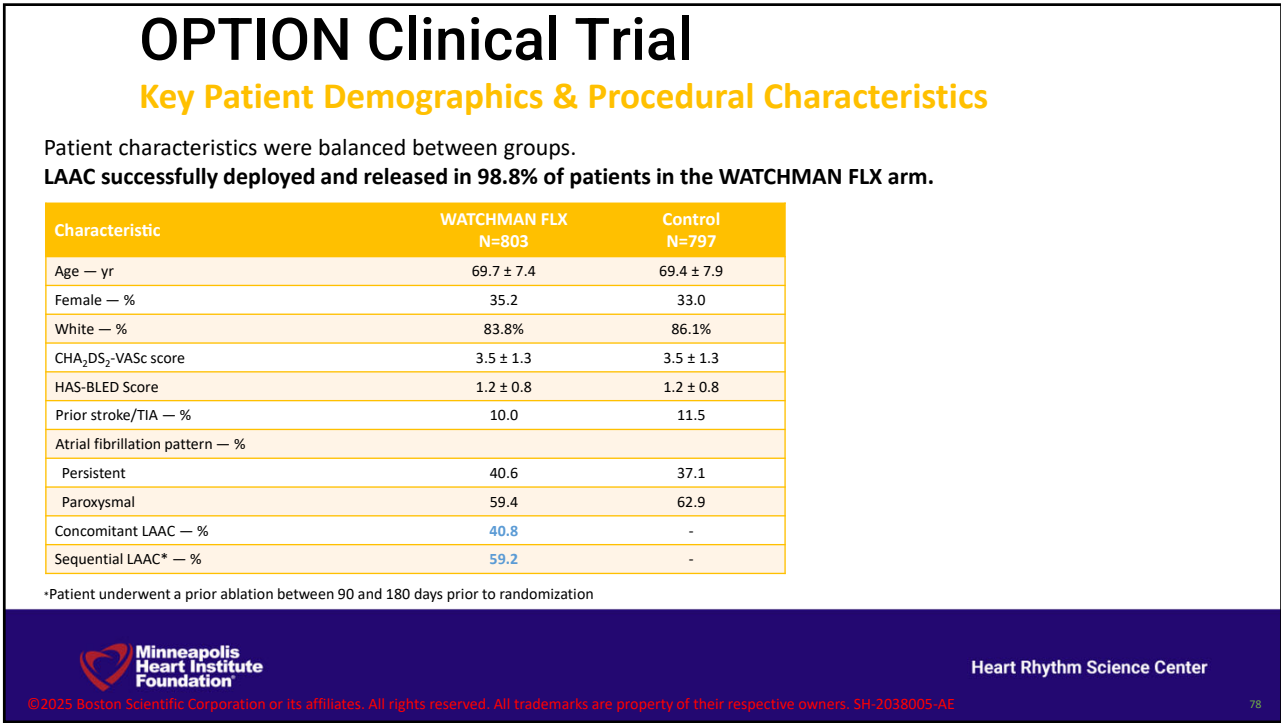


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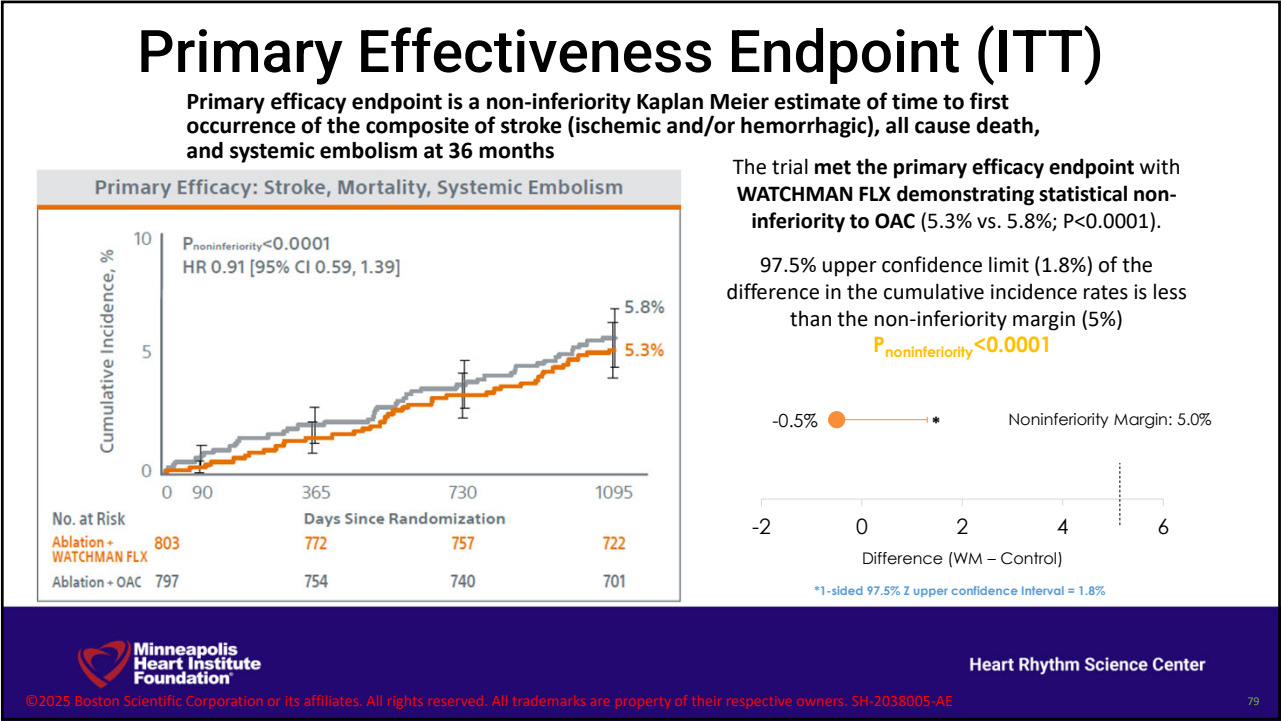
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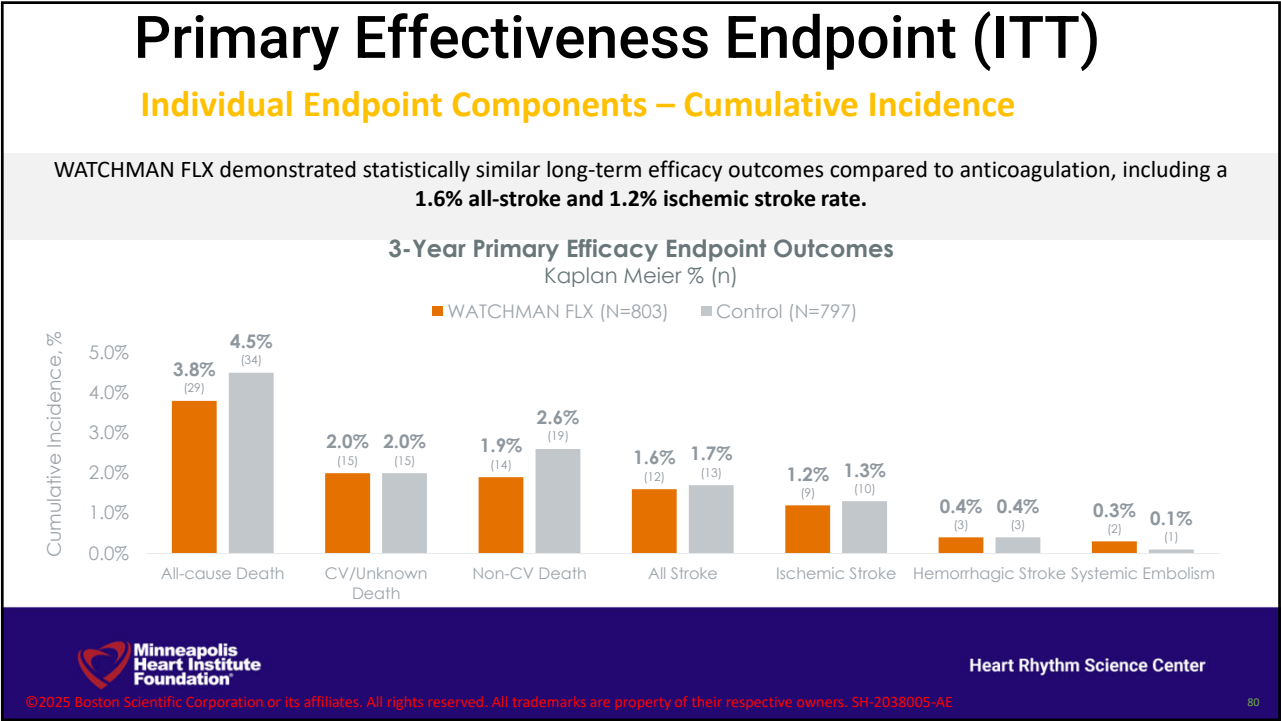
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78



79



80

OPTION Conclusions

Primary efficacy and safety endpoints met

Secondary Safety Endpoint (major bleeding including procedural) demonstrating statistical non-inferiority to OAC met

The primary endpoints showed the WATCHMAN FLX™ device was **non-inferior to OAC at 36 months, with a superior safety profile**

Procedural event within 7 days similar in Ablation + Watchman FLX (2.1%) vs Ablation + OAC (2.7%)

Primary Efficacy Endpoint: Non-inferiority Met

Primary Efficacy: Stroke, Mortality, Systemic Embolism

Cumulative Incidence, %

HR 0.91 [95% CI 0.59, 1.39]

No. at Risk

Days Since Randomization	0	90	365	730	1095
Ablation + WATCHMAN FLX	803	772	757	722	722
Ablation + OAC	797	754	740	701	701

Primary Safety Endpoint: Superiority Met

Primary Safety: Non-procedural Bleeding

Cumulative Incidence, %

HR 0.44 [95% CI 0.33, 0.59]

No. at Risk

Days Since Randomization	0	90	365	730	1095
Ablation + WATCHMAN FLX	803	749	728	681	681
Ablation + OAC	797	701	657	598	598

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81

Concomitant & Sequential Cohort Sub-analysis

Concomitant Subgroup 3-Year Clinical Outcomes

Concomitant LAAC with WATCHMAN FLX demonstrated similar long-term stroke protection to anticoagulation, including a **1.6% ischemic stroke rate at 3 years**.

Concomitant Cohort 3-Year Outcomes

Kaplan Meier % (n)

Outcome	WATCHMAN FLX Concomitant (N=328)	OAC (N=326)
All-cause Death	5.4% (17)	5.4% (17)
All Stroke	2.3% (7)	2.5% (8)
Ischemic Stroke	1.6% (5)	1.6% (5)
Hemorrhagic Stroke	0.6% (2)	0.3% (1)
Systemic Embolism	0.0% (0)	0.3% (1)
ISTH Bleeding	9.2% (29)	13.3% (42)
Major Bleeding	5.1% (16)	4.1% (13)
Clinically Relevant Non-major Bleeding	4.4%* (14)	10.8% (34)

Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2025.

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82

41 of 45

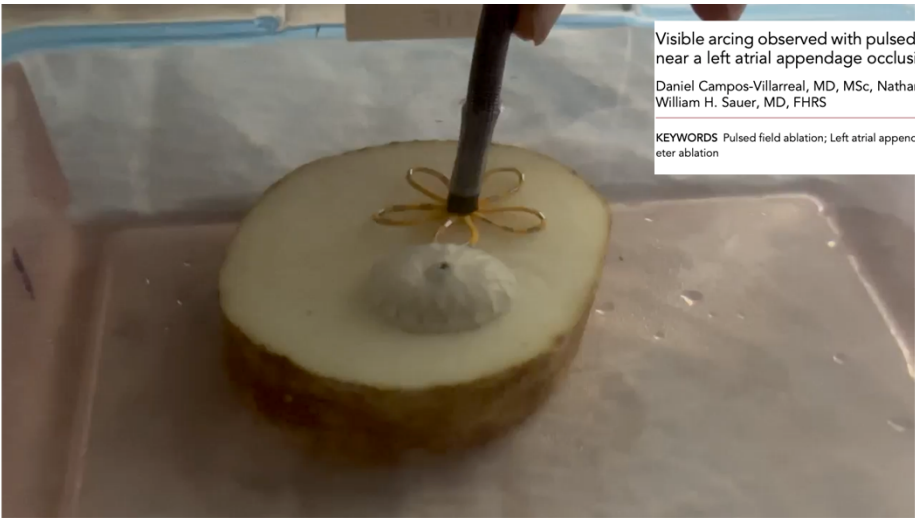
CMS



- New MS-DRG 317 (concomitant left atrial appendage closure and cardiac ablation) for percutaneous LAAC and ablation to treat atrial fibrillation effective 10/1/2024 to address higher average costs and slightly longer lengths of stay
- Includes pulsed field ablation in the coding logic along with RFA and cryotherapy energy sources
- No strict requirement for typical WATCHMAN rationale



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83



Visible arcing observed with pulsed field ablation applications delivered near a left atrial appendage occlusion device  

Daniel Campos-Villarreal, MD, MSc, Nathaniel A. Steiger, MD, Maxwell Coll, MD, William H. Sauer, MD, FHRS

KEYWORDS Pulsed field ablation; Left atrial appendage occlusion device; Electrical arcing; Implanted metallic device; Catheter ablation

Heart Rhythm 2025; ■ 11 © 2025 Published by Elsevier Inc. on behalf of Heart Rhythm Society.

The work continues...



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84

CARTO™ 3 System Integration Procedural Efficiency¹

Parameter	Pivotal phase (n=277)
Procedure time, min	90.0 (65.0–119.0)
Procedure time for PVI, ^c min	81.0 (61.0–112.0)
Transpired PFA time, ^d min	31.0 (24.8–40.9)
Fluoroscopy time, min	7.1 (0.0–14.3)

Table 2. Procedural end points atypical flutter patients who underwent Aflera catheter ablation.

Total number of patients = 10	
Procedural end points	
Procedure time, minutes	112 ± 21
Fluoroscopy time, minutes	13.6 ± 4.5
Fluoroscopy dose, mGy	477 ± 299
Total ablation time, seconds	370 ± 239
Transeptal mean left atrial pressure, mmHg	11.1 ± 7.56




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85

Concomitant PFA-Watchman workflow

- General anesthesia; Measure LAA dimensions at outset
- Isolate right sided veins and then left-side; Ablate inducible arrhythmias and targets
- Plan transeptal puncture based on optimal trajectory for LAAC
- Anticipate potential to upsize to ensure no PDL
- TruSteer™ deflectable sheath allows for greater maneuverability
- ACT goal 400-450 with uninterrupted anticoagulation
- Drs. Desouki, Ergando, Hamid reviewing dimensions and impact of PFA on ridge/edema
- Three months of OAC may be necessary post-procedure
- Is there a role for isolating LAA? Outcomes with newest generation Watchman FLX Pro?



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86

Translation to practice

- Thus far concomitant procedures are patients who have a rationale for Watchman due to bleeding or bleeding risk
- All procedures were formed with PFA (Farapulse or Affera)
- This is fundamentally a different population than the OPTION trial population
 - **Often derived from patients referred for WATCHMAN**
- Protocols have evolved including avoiding aspirin for 45 day period and maintaining OAC for at least 2 months post procedure
- Outcomes may be different in these groups
- Devise best-practice work-flow and understand impact of PFA on Watchman placement



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87

State of the art 10/6/25 at 7:50 am CST

- 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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88

Thank you



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89

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90