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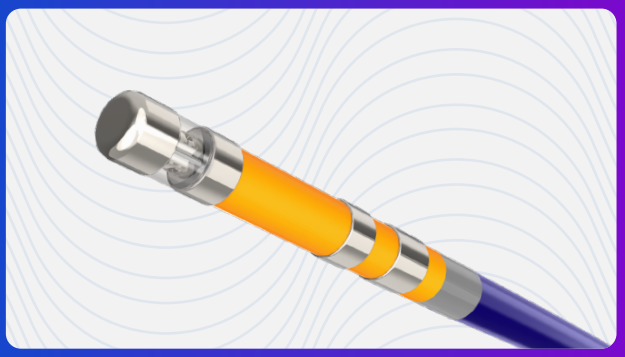
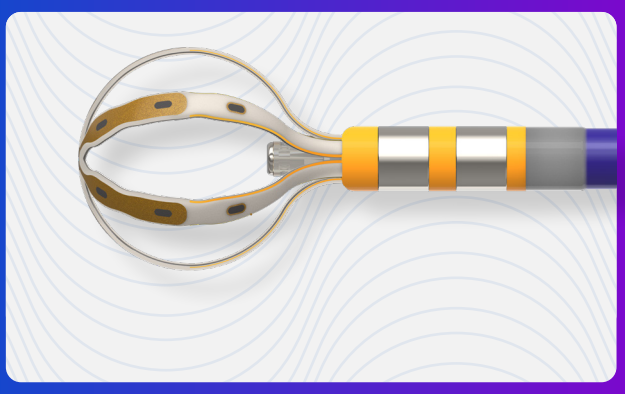
FARAPULSE™
PFA System

Clinical Compendium

The global leader in PFA clinical research





FARAFLEX™ is pending CE Mark. Not available for sale.

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Publication listing by topic

FARAFLEX

Dose-Dependent Ventricular Lesion Formation Using a Novel Large-Area Pulsed Field Ablation Catheter: A Preclinical Feasibility Study

Kueffer T, Casoni D, Goepfert C, et al.

CAUTION: FARAFLEX™ Mapping and Pulsed Field Ablation Catheter. Investigational Device. Limited by Federal (or US) law to investigational use only. Not available for sale.

Heart Rhythm (September 2025), available here

- 7 swine with healthy ventricular myocardium were ablated with FARAFLEX, a novel 8-French large-area focal PFA catheter with 9 mm hexaspline tip, capable of 3D mapping, used to deliver monopolar or bipolar PFA. 1, 2, or 4 applications per site (2.0 kV per application) and survived for 1 week.
- 69 ventricular lesions were analyzed (40 = 58% monopolar; 29 = 42% bipolar).
- The lesion depth at day 7 (bipolar) was; 1 application: median 4.8 mm (IQR 4.1-5.6 mm), .2 mm (IQR, 5.0–6.2 mm) for 2 applications, and 4 applications: median 5.5 mm (IQR 5.0-6.2 mm) (p= 0.06).
- The lesion depth with monopolar was; 1 application: median 4.9 mm (IQR 4.4-5.2 mm), 6.1 mm (IQR, 5.3–7.1 mm) for 2 applications, and 4 applications: median 6.5 mm (IQR 5.9-6.9 mm) (p = 0.002).
- The median lesion width was ~20.6 mm (range 11.5-41.6 mm) for monopolar and ~21.9 mm (range 13.1-39.8 mm) for bipolar.
- Lesion borders sharply demarcated with myocardial fibrosis observed and vessels and nerves were largely preserved.

FARAWAVE™ case studies

- Abdrkhmanov, et al. Early Experience with Pulsed Field Ablation for Atrial Fibrillation in Central Asia: A Case Series
- Adeliño, et al. Mitral Isthmus Ablation with Pulsed-Field Technology: The Flower Power

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE™ PFA System
- Adeliño, et al. Pulsed-Field Ablation of Recurrent Right Atrial Tachycardia: Expanding the Use of Electroporation Beyond Atrial Fibrillation

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Adragão, et al. Pulsed-Field Ablation vs Radiofrequency Ablation for Ventricular Tachycardia: First in-Human Case of Histologic Lesion Analysis

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Al Sakan, et al. Termination of Superior Vena Cava- Focal Atrial Tachycardia Using FARAWAVE Pulse Field Ablation: A Case Report
- Ali Ellejmi, et al. Superior Vena Cava Isolation using a Multielectrode Pulsed Field Ablation Catheter

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Anna-Sophie, et al. Prolonged asystole after conversion to sinus rhythm during pulmonary vein isolation with pulsed field ablation. A Case Report.
- Arai, et al. Pulsed-Field Ablation for Non-Pulmonary Vein Foci of Immediate Recurrence of Atrial Fibrillation Originating from the Left Arial Inferior Wall Directly Adjacent to the Esophagus

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Ascione, et al. A Posterior Wall Resistant to Electroporation Finally Blocked with Vein of Marshall Ethanol Infusion

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Audiat, et al. Interference from Lobe-and-Disc Left Atrial Appendage Occluder Affecting Left Superior Pulmonary Vein Pulsed Field Ablation
- Bianchini, et al. Pulsed-Field Ablation of Pulmonary Vein and Left Atrial Posterior Wall Combined with Left Atrial Appendage Occlusion as Single Procedure

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Botros, et al. Concomitant Pulmonary Vein Isolation with Pentaspline Pulsed-Field Ablation and Left Atrial Appendage Occlusion via Internal Jugular Venous Approach: First US Report
- Chatani, et al. Initial Experiences and Technical Insights of Pulmonary Vein Isolation with FARAPULSE Pulsed Field Ablation in Patients Implanted with WATCHMAN Left Atrial Appendage Closure Devices: The First Report in Japan
- Chen, et al. Pulsed Field Ablation as First-Line Treatment to Reduce Atrial Fibrillation Burden Documented by Pacemaker
- *WARNING: Implantable pacemakers and implantable cardioverter/defibrillators may be adversely affected by irreversible electroporation current.
- Chen, et al. Pulsed Field Ablation as First Line “Efficient” Rhythm Control for Atrial Fibrillation Complicated with Heart Failure: Proof of Concept
- Chen, et al. Pulsed Field Ablation of Incessant Superior Vena Cava–Triggered Atrial Fibrillation: Watch Out for the Sinoatrial Node

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Chen, et al. Pulsed Field Ablation for Paroxysmal Atrial Fibrillation in a Dextrocardia Case: A First-in-Human Experience

Case studies

- De Becker, et al. Severe Coronary Spasm Occurring Remotely from Pulsed Field Application during Right Inferior Pulmonary Vein Isolation
- De Sliva, et al. Pulsed Field Ablation of Ventricular Arrhythmias Arising from Intracavitary Structures: Insights from a Clinical Case Series
- Della Rocca, et al. Transient Inferior ST-Segment Elevation and Ventricular Fibrillation After Cavotricuspid Isthmus Pulsed-Field Ablation

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Denysiuk, et al. Pulmonary Vein Isolation with Pulse Field Ablation and Oral Anticoagulant use in Patients with Factor VII Deficiency-Review of Literature and Case Report
- Ebrahimi, et al. Pulsed Field Ablation for Atrial Fibrillation when in Proximity to LAA AtriClip: the LAA-Clip Does Not Inhibit the Pulse
- Farina, et al. ST Segment Elevation in Pulsed Field Ablation for Atrial Fibrillation: A Case Report
- Fassini, et al. Ventricular Tachycardia Ablation with Pentaspline Pulsed Field Technology in Two Patients with Ischemic Cardiomyopathy
- Franceschi. et al. First Electromyographic Monitoring of a Progressive Phrenic Nerve Palsy in a Pulsed Field Ablation Procedure
- Gaggiotti, et al. Tissue Oedma Following Pulsed Field Ablation Recognized During a Concomitant Left Atrial Appendage Closure Procedure. A Case Report.
- Gardziejczyk, et al. Pulse-Field Ablation using Penta-Spline Catheter as a Bail-Out Strategy for Peri-Mitral Flutter Related to the Left Atrium Anterior Wall Scar

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Ghajar, et al. Severe Hemolysis After Moderate-Dose Pulsed Field Application (48 Pulses) for Atrial Fibrillation/Flutter: A Cautionary Tale
- Goto, et al. Pulsed Field Ablation for Pulmonary Vein Isolation Provoked Ganglionated Plexus-Mediated Vagal Atrial Fibrillation
- Gunawardene, et al. Word of Caution: Clinical Apparent Coronary Spasm following Pulsed Field Cavotricuspid Isthmus Ablation despite Nitroglycerin Prophylaxis
- Gupta, et al. Sequential Isolation of Persistent Left Superior Vena Cava and Right Superior Vena Cava Using Pulsed-field Ablation with a Pentaspline Catheter for Recurrent Persistent Atrial Fibrillation
- Hanley, et al. Pulsed Field Ablation in a Patient with Ventricular Arrhythmia Storm Receiving Mechanical Circulatory Support
- Harmouch, et al. An Antiquated Concept in the Novel Era of Ablation: Zero-fluoroscopy Pulsed Field Ablation for Treatment of Atrial Fibrillation
- Haskova, et al. Case Report: Pulsed Field Ablation for Epicardial Right-Sided Accessory Pathway
- Heeger, et al. Streamlined Concomitant Pulse Field Ablation-Based Pulmonary Vein Isolation and Left Atrial Appendage Occlusion via a Single Venous Access Approach: A Case Report
- Iacopino, et al. Lesion Effects in Terms of Local Impedance Variations after Pulsed-Field Ablation During Pulmonary Vein Isolation: A Case Report
- Jáuregui, et al. Thrombin Inhibition during Pulmonary Vein Isolation using Pulsed Field Ablation
- Katrapati, et al. Pulsed Field Ablation for Incessant Scar-Related Ventricular Tachycardia: First U.S. Report
- Kerley, et al. Refractory Inappropriate Sinus Tachycardia Treated with Pulsed-Field Ablation of the Sinus Node: A Breath of Fresh Air

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Case studies

- Kiang, et al. Catheter-Based Disarticulation of the Epicardial Right Ventricular Free Wall with Endocardial Pulsed Field Ablation in Arrhythmogenic Cardiomyopathy.
- Koruth, et al. Selective Sparing of Purkinje Fibres with Pulsed-Field Myocardial Ablation
- Krzowski, et al. Combination of the Pulsed Field Ablation with EnSite Precision Cardiac Mapping System in the Treatment of Atrial Fibrillation
- Laczay, et al. Pulmonary Vein Isolation with Pentaspline Pulsed Field Ablation Catheter From an Axillary Venous Approach in a Patient with Interrupted Inferior Vena Cava: First US Report
- Lampert, et al. A Novel Etiology for Automatic Mode Switching and Ventricular Noise Reversion Alerts: Pulsed Field Ablation
- Lozano-Granero, et al. Case Series of Ventricular Tachycardia Ablation with Pulsed Field Ablation: Pushing Technology Further Into the Ventricle

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- Lozano-Granero, et al. Electroporation Saves the Day Again: Pulsed-Field Ablation for Phrenic Nerve-Sparing in Right Atrial Tachycardia

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- Lustig, et al. Left Atrial Substrate Modification for Long-Standing Persistent Atrial Fibrillation and Left Atrial Macro- or Micro-Reentrant Tachycardia Using a Single-Shot Pulsed Field Ablation System—A Case Series
- Luther, et al. Diffuse Right Coronary Artery Spasm Occurring 45 Minutes after Pulsed Field Ablation for Atrial Fibrillation
- Martin, et al. First Worldwide use of Pulsed-Field Ablation for Ventricular Tachycardia Ablation via a Retrograde Approach

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- Maury, et al. Transient Loss of Capture after Pulse Field Ablation due to Pacing Threshold Elevation

  *WARNING: Implantable pacemakers and implantable cardioverter/defibrillators may be adversely affected by irreversible electroporation current.
- Maury, et al. Intrapulmonary Haemorrhage during Pulsed Field Ablation
- Medeiros de Vasconcelos, et al. Incessant Atrial Tachycardia Associated to Atrial Septal Aneurysm Treated by Pulsed Field Ablation
- Menè, et al. Pulsed Field Ablation of a Persistent Left Superior Vena Cava in Recurrent Paroxysmal Atrial Fibrillation and Its Effect on the Mitral Isthmus: A Case Report

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- Miraglia, et al. Unexpected Fused Posterior Wall Lesions after Pulsed-Field Pulmonary Vein Isolation
- Misonou, et al. First Clinical Insights into Pulsed Field Ablation for Pulmonary Vein Stumps
- Mittal, et al. Pulsed Field Ablation in Common Inferior Pulmonary Trunk
- Mizutani, et al. A Simple Technique for Manipulating a Pentaspline Pulsed Field Ablation Catheter to Select Right Inferior Pulmonary Vein using Vertebral Body Alignment
- Mol, et al. A Superior Right Jugular Approach to Perform Pulmonary Vein Isolation using FARAPULSE Pulsed-Field Ablation
- Muthu, et al. Ablation of Premature Ventricular Complexes Originating from Papillary Muscle using Pulsed Field Energy: The First in USA Experience
- Nouraee, et al. Pulsed Field Ablation of Atrial Fibrillation in the Setting of Pulmonary Vein Stents: A Case Report

Case studies

- Ohn, et al. Transient Conduction Disturbance During Pulsed-Field Ablation for Atrial Fibrillation in a Patient with Pre-existing Conduction Disease
- Ouss, et al. First in Human Pulsed Field Ablation to Treat Scar-Related Ventricular Tachycardia in Ischemic Heart Disease: A Case Report

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- Papakonstantinou, et al. Breaking Barriers in Atrial Ablations: Pulsed Field Ablation over Left Atrial Scar Lesions
- Prajapatai, et al. Rescuing Failed Radiofrequency Ablation: Pulsed Field Ablation in Ventricular Tachycardia
- Rattanawong, et al. Isolating the Superior Vena Cava and Right Atrial Appendage by Pulsed Field Ablation
- Rattka, et al. Pulsed Field Ablation of Refractory Alternating Atrial Fibrillation and Atrial Flutter Using ImpellaCP in a Patient with Cardiogenic Shock: A Case Report
- Rauber, et al. Zero-Fluoroscopy Ablation with Multielectrode Pulse Field Ablation System: Case Series
- Ruwald, et al. Pulsed Field Ablation of the Cavotricuspid Isthmus using a Multispline-Electrode Pulsed Field Ablation Catheter

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- Sanborn, et al. Failure of Transmural Posterior Wall Isolation by Pulse Field Ablation Demonstrated with Epicardial Mapping
- Schaack, et al. Severe ST-Segment Elevation and AV Block During Pulsed Field Ablation due to Vasospastic Angina – A Novel Observation
- Schmidt, et al. Single Shot Electroporation of Premature Ventricular Contractions from the Right Ventricular Outflow Tract

  *Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System
- Schoof, et al. Pulsed Field Ablation for Rhythm Control in Acute Heart Failure and Extracorporeal Membrane Oxygenation: A Case Report
- Scripcariu, et al. PulsedField Ablation of Atrial Fibrillation using the Farapulse System through the Jugular Vein: A Case Series of Two Patients
- Shokr, et al. De Novo Ablation of premature ventricular complexes originating from posteromedial papillary muscle with pulsed field energy using a Pentaspline catheter. The first case series in in the United States
- Sky, et al. Pulsed Field Ablation Through an Atrial Shunt Device

  *The evidence base for use of an atrial shunt device and irreversible electroporation current is limited
- Shen, et al. Pulsed Field Ablation of Atrial Tachyarrhythmia Originating from Atrial Aeptal Aneurysm
- Sousonis, et al. Pulsed Field Ablation of Spatiotemporal Electrogram Dispersion Following Pulmonary Vein Isolation and Left Atrial Linear Lesions for Persistent Atrial Fibrillation: A Case Report
- Takai, et al. Unintended Isolation of the Left Atrial Appendage: A Rare Complication of Pulsed-Field Ablation
- Tampakis, et al. Pulsed Field Ablation of a Focal Atrial Tachycardia from the Superior Vena Cava in Proximity to the Phrenic Nerve: A Case Report
- Tokohu, et al. Pulsed Field Ablation for Persistent Superior Vena Cava: New Solution for an Old Problem

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- Urbanek, et al. First Pulse Field Ablation of an Incessant Atrial Tachycardia from the Right Atrial Appendage

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- Vasquez, et al. Successful Ablation of Premature Ventricular Complexes Arising from the Posteromedial Papillary Muscle using Pulse Field Ablation

Case studies

- Vazquez-Calvo, et al. Pulse Field Ablation for Persistent Atrial Fibrillation: Targeting the Persistent Superior Vena Cava
- Yamano, et al. Assessment of Pulmonary Vein Isolation by Local Potentials in FARAPULSE Pulsed Field Ablation System
- Zhou, et al. Pulsed-Field-Ablation for Atrial Fibrillation in a Patient With Left Atrial Appendage Occlusion Device
- Żuchowski, et al. Pulmonary vein isolation with pulsed field ablation in a patient with mechanical mitral and aortic valve prostheses

2025 clinical publications

Real-world Experience with the Pentaspline Pulsed Field Ablation System: One-Year Outcomes of the FARADISE Registry
Boersma LVA, Széplaki G, Dello Russo A, et al.

EP Europace (September 2025), available here

- Prospective, real-world registry including 1,158 AF patients treated with FARAPULSE across 48 centers in 21 countries with 65% PAF patients with 90% de novo procedures.
- PVI-only was performed in 80.8% of PAF patients vs 57.5% of non-PAF ($p < 0.01$).
- Median procedure time was 51 [40–70] min, LA dwell time was 31 [24–41] min, and fluoroscopy time was 12 [8–17] min.
- The SAE rate (within 7 days and up to 12 months) was 1.5%, not differing by AF type or lesion set strategy.
- One-year clinical effectiveness (freedom from atrial arrhythmia or arrhythmia-related intervention after blanking period) was 80.8% for PAF and 67.7% for non-paroxysmal AF.
- Within each AF indication (PAF vs non-PAF), ablation strategy (PVI-only vs PVI+) did not significantly affect 1-year effectiveness (paroxysmal: 81.2% PVI-only vs 79.0% PVI+; non-PAF 67.5% vs 67.7%.
- Operator experience showed procedural efficiency improved over time, but 1-year effectiveness was consistent regardless of operator experience.

Hemolysis and Myocardial and Neural Injury After Monopolar Pulsed Field Ablation Using a Novel Lattice-Tip Catheter to Treat Atrial Fibrillation
Gold C, Pratz P, Falagkari A, et al.

EP Europace (September 2025), available here

- All PFA platforms showed post-procedural hemolysis. The decrease in haptoglobin was most pronounced in the FARAPULSE system. Affera: −13.8 ± 18.5 mg/dL, PulseSelect: −36.8 ± 35.9 mg/dL and FARAPULSE: −60.7 ± 26.3 mg/dL ($p < 0.001$).
- Δ Troponin (hs-cTnT): Affera 1,537 pg/ml (IQR 580) vs PulseSelect 970 pg/ml (IQR 1023) vs FARAPULSE 1,051 pg/ml (IQR 592) ($p = 0.180$)
- Δ CK was greater for Affera (232 ± 168 U/L) vs PulseSelect (153 ± 132 U/L) and vs FARAPULSE (102 ± 144 U/L).
- Δ CK-MBf for Affera was 28.5 ± 15.3 U/L vs PulseSelect 14.6 ± 12.4 U/L vs FARAPULSE 13.6 ± 10.5 U/L ($p = 0.055$).
- Neural injury (S100): Increased in PulseSelect and FARAPULSE groups post-ablation; no increase in S100 in Affera group.
- There were no hemolysis-related renal complications reported with any system.

Patient Comfort and Response Pattern Following Pulsed-Field Ablation Compared to Radiofrequency Ablation for Atrial Fibrillation
Hashim U, Patel R, Demo H, et al.

Journal of Cardiovascular Electrophysiology (September 2025), available here

- Retrospective study of 200 patients (100 PFA, 100 RFA) undergoing AF ablation under general anesthesia.
- Emergency department (ED) visits within 30 days were significantly higher in RFA group (17%) vs PFA group (6%, $p < 0.05$).
- RFA ED visits driven by shortness of breath (29%), palpitations (23%), dizziness (18%), and other complaints (30%).
- There was no difference in post-procedural pain scores (RFA 1.70 vs PFA 1.57, $p = 0.61$), analgesic use in recovery area, 36% in RFA vs 27% in PFA ($p = 0.26$) or care team encounters (calls, visits) within 4 weeks post-procedure: 57% RFA vs 44% PFA ($p = 0.20$).

2025 clinical publications

Differential Subclinical Hemolysis After Pulsed Field Ablation Using the FARAPULSE Pentaspline Catheter Versus the PulseSelect Circular Multielectrode Array Catheter
Kuraoka S, Nozoe M, Mannoji H, et al.

Heart Rhythm O2 (September 2025), available here

- Retrospective analysis of hemolysis biomarkers in patients undergoing AF ablation with RFA (n =15), FARAPULSE (n = 39) vs PulseSelect (n = 66).
- The biomarkers measured to characterize hemolysis in both PFA groups were comparable, mild and subclinical with no procedural limit on the number of applications.

Acute Durability of Cavotricuspid Isthmus Block After Pulsed Electric Field Ablation: Randomized Comparison of Two Pentaspline Catheter Configurations (SECTION Trial)
Stojadinović P, Wichterle D, Bulava A, et al.

EP Europace (September 2025), available here

- 178 patients were randomized 1:1 to basket vs flower configurations of the pentaspline PFA catheter for cavotricuspid isthmus (CTI) ablation with the groups having comparable baseline characteristics.
- There was superior procedural efficiency in the flower group with fewer applications required to achieve a CTI block (3.4 ± 3.1 vs 8.0 ± 4.1, $p < 0.001$), shorter time to block (96 ± 289 vs 177 ± 192 s, $p < 0.001$), and fewer total applications (10.1 ± 3.4 vs 13.3 ± 5.1, $p < 0.001$).
- Acute reconduction occurred in 20% of cases but was significantly lower in the flower group (6% vs 32%, $p < 0.001$).
- Plasma free hemoglobin (hemolysis) was lower in the flower group and one case of transient ST elevation occurred in the flower group without clinical sequelae. .

Learning Curve and Procedural Efficiency of Zero-Fluoroscopy Pulsed-Field Ablation for Atrial Fibrillation
Pérez-Pinzón J, Villarreal D, Ma M, et al.

Heart Rhythm (August 2025), available here

- Data from 827 de novo FARAPULSE procedures.
- Zero-fluoroscopy procedure time was significantly reduced with PFA compared with RFA (225 minutes), particularly during PVI + PWA (PVI 216 minutes; PVI 1 PWA 228 minutes) ($p < .001$).
- The learning curve for zero-fluoroscopy PFA did not vary by physician or years of experience and plateaued after 114 total PFA cases.
- Mixed-effects model analysis found that each additional PFA case performed reduced procedure time by 0.5 minutes ($p < .001$).

Cardiac Biomarkers Temporal Dynamics after Radiofrequency and Pulsed-Field Catheter Ablation of Atrial Fibrillation
Casella M, Valeri Y, Compagnucci P, Villarreal D, Ma M, et al.

Heart Rhythm (August 2025), available here

- Blood samples were taken from 69 consecutive AF patients treated with FARAPULSE at baseline, 3h, 24h, and 48h post-ablation. 14 biomarkers were assessed, including hs-cTnI, CK-MB, myoglobin, CRP, NT-proBNP, ferritin, and hemoglobin.
- Biomarkers of myocardial injury (hs-cTnI, myoglobin, CK-MB) showed a rapid, significant peak at 3 hours, followed by decline at 24h and 48h.
- Ferritin increased early (3h), peaked at 24h, declined by 48h.

2025 clinical publications

- WBC rose at 3h and gradually dropped over 24-48h; CRP increased more slowly and peaked at 48h.
- Small but significant decreases post-ablation were seen in hemoglobin & hematocrit but remained within normal range.
- No significant differences in the myocardial injury or inflammatory biomarker kinetics between patients who had ablation limited to PVs vs those with PVI+ lesion sets, except CRP at 3h was higher in extended ablation group (0.86 vs 0.54 mg/dL; p = 0.035).
- There were no major procedural or anesthesia-related events reported.

High Incidence of Phrenic Nerve Injury in Patients Undergoing Pulsed Field Ablation for Atrial Fibrillation
Chéhirlian L, Koutbi L, Mancini J, et al.

Heart Rhythm (August 2025), available here

- 69 consecutive patients were treated with FARAPULSE, 60.9% PAF and 39.1% PersAF.
- Right phrenic nerve function was monitored intra-procedurally using compound motor action potential (CMAP) during ablation.
- Phrenic nerve injury (PNI) occurred in 26/64 patients (40.6%) during the procedure with incomplete recovery at end of procedure in 12 patients (18.8%).
- PNI incidence at discharge was 24% (6/25) with persistent incomplete PNI.
- Follow-up fluoroscopy (for patients in that sub-group) confirmed recovery in 4 of 5 reassessed; 1 patient had persistent dysfunction at 3 months.
- Most PNI events occurred during ablations targeting the right superior pulmonary vein (RSPV) (80.8%), followed by the right inferior vein (11.6%), both RSPV+RIPV (7.7%), and superior vena cava (7.7%).

Ablation in Persistent Atrial Fibrillation: High Long-Term Success with Pulsed Field Ablation Using a Strict Protocol
Chorin E, Frydmann S, Schwarts AL, et al.

Heart Rhythm (August 2025), available here

- Prospective single-center PersAF study of 109 patients with FARAPULSE with a strict protocol (PVI + PWA + additional lesion sets beyond PVs).
- The 12-month freedom from any atrial arrhythmia (AF/AT/AFL ≥ 30s) after a 2-month blanking period was 72%.
- Long-term success was somewhat higher in the early-PersAF group (AF duration ≥ 7 days but ≤ 3 months) compared to the >3-month group.

One-Year Clinical and Safety Outcome of Obese Patients Undergoing Pulmonary Vein Isolation for Atrial Fibrillation with Pulsed Field Ablation or Cryoballoon Ablation: A Propensity-Matched Analysis
Feickert S, Wagner S, Biernath K, et al.

Heart Rhythm (August 2025), available here

- Retrospective propensity-matched study of obese AF patients (BMI > 30 kg/m^2) undergoing de novo PVI with either FARAPULSE or CBA.
- Post-matching results showed significantly lower AF recurrence in the PFA group (25%) compared with the CBA group (42.9%, p = 0.02).
- Procedures were significantly more efficient with PFA with the total procedural time of 46.8 min (PFA) vs 69.3 min (CBA) (p < 0.01), LA dwell time: 33.8 min (PFA) vs 49.7 min (CBA) (p < 0.01).
- Safety outcomes were similar across groups with no significant differences in complication rates. .

2025 clinical publications

Comparison of 30-Day Readmission and Same-Day Discharge Rates in Patients Undergoing Pulsed Field versus Radiofrequency Ablation for Atrial Fibrillation: A Multicenter Analysis
Garapati SS, López-Martínez H, Murthy MK, Younis A, et al.

Heart Rhythm (August 2025), available here

- Multicenter registry comparing PFA vs RFA for AF, 345 FARAPULSE patients vs 352 RFA patients.
- Same-day discharge (SDD) rates were 4.5% for PFA vs 11.0% for RFA.
- Major complications (stroke, TIA, etc.) were 0% in SDD groups for both PFA and RFA.
- Minor complications were 0.5% for PFA SDD, 1.1% for non-SDD PFA and 1.6% for both RFA SDD and non-SDD.
- All-cause 30-day readmission rate was 1.4% in PFA SDD vs 2.4% in RFA SDD (p = 0.54).
- Predictors of same-day discharge in PFA cohort included lower CHA_2DS_2-VASc score (OR 0.754; 95% CI 0.663-0.858; p < .001), and being < 80 years old (being octogenarian reduced likelihood of SDD: OR 0.265; 95% CI 0.105-0.666; p = 0.005).
- Same-day discharge was more common with PFA than RFA, with low readmission and complication rates.

Esophageal Endoscopic Findings After Pulmonary Vein and Posterior Wall Isolation Using Pulsed Field Ablation: Results from the Eso-PFA Study
Gunawardene MA, Middeldorp M, Pape U-F, et al.

EP Europace (August 2025), available here

- Prospective observational cohort of 106 AF patients that had FARAPULSE ablation (PVI+PWA) with 94% having PersAF.
- Median procedure time was 78 minutes and the mean number of applications was 50 ± 19 for PVI and 21 ± 9 on the PW.
- Endoscopic findings the day after ablation were that 0/106 patients had any thermal, ablation-related esophageal lesions.
- There were no ablation related esophageal adverse events reported out to 606 days.
- The durability of PW in a subset of patients (n=14) with a reablation found durable PWA in 11/14 (78%) with 3/14 showing regression.
- The arrhythmia recurrence rate was 34% (36/106).

Pulsed-Field Ablation for Persistent Atrial Fibrillation in the EU-PORIA Registry
Hirokami J, Chun KRJ, Bordignon S, et al.

IJC Heart & Vasculature (August 2025), available here

- 220 patients with PersAF undergoing PVI only at a tertiary referral center: 113 (51%) received PFA and 107 (49%) underwent CBA.
- Median procedure time was 49 minutes for PFA vs 60 minutes for CBA (p < 0.001).
- Median LA dwell time: 34 minutes (PFA) vs 37 minutes (CBA) (p < 0.001).
- Median fluoroscopy time: 9 minutes (PFA) vs 11 minutes [8–16] (cryo) (p = 0.008).
- One-year recurrence-free survival: 72% (PFA) vs 60% (cryo) (Log-rank p = 0.079).
- More patients converted from PersAF to PAF following PFA vs cryo: 68% vs 37%, respectively (p = 0.011).

2025 clinical publications

Pulsed-field ablation versus cryoballoon ablation in patients with persistent atrial fibrillation
Isenegger C, Arnet R, Jordan F, Knecht S, Krisai P, et al.

IJC Heart & Vasculature (August 2025), available here

- 220 patients with PersAF undergoing PVI only at a tertiary referral center: 113 (51%) received PFA and 107 (49%) underwent CBA.
- Median procedure time was 49 minutes for PFA vs 60 minutes for CBA ($p < 0.001$).
- Median LA dwell time: 34 minutes (PFA) vs 37 minutes (CBA) ($p < 0.001$).
- Median fluoroscopy time: 9 minutes (PFA) vs 11 minutes [8–16] (cryo) ($p = 0.008$).
- One-year recurrence-free survival: 72% (PFA) vs 60% (cryo) (Log-rank $p = 0.079$).
- More patients converted from PersAF to PAF following PFA vs cryo: 68% vs 37%, respectively ($p = 0.011$)

Posterior Wall Involvement During Pulmonary Vein Isolation Using the Farapulse System
Izquierdo de Francisco MT, Navarro-Manchon J, Cano Perez O, et al.

Journal of Arrhythmia (August 2025), available here

- 76 consecutive patients referred for PVI and treated with the FARAPULSE PFA system were included in this study.
- Voltage and activation maps were performed before and after PVI with FARAPULSE.
- 12 patients (15%) had a "narrow corridor" in the PW (defined as healthy tissue, voltage > 0.5 mV, width < 20 mm) remaining between ablation lesions and 18 patients (23%) demonstrated "fusion" on the PW (when ablation lesions from opposite carinas connected).
- The only independent predictor of posterior wall involvement (fusion or narrow corridor) was a shorter "middle inter-carinas line" length: 62 ± 2 mm in patients with involvement vs 71 ± 3 mm in those without; $p = 0.0001$.
- Using ROC analysis, a cutoff of 65 mm for middle inter-carinas line length provided ≈80% sensitivity and ≈70% specificity for predicting involvement.
- Narrow corridor (< 10 mm) was associated with slow conduction velocity (below 0.7m/s) across that corridor.
- Either a narrow corridor or fusion was not associated with atrial fibrillation recurrence in follow-up.

Beyond the Learning Curve: How Operator Experience Affects Pulsed-Field Ablation Outcomes
Küffer T, King R, Maurhofer J, et al.

Heart Rhythm (August 2025), available here

- 1,008 patients undergoing de novo FARAPULSE ablation. 3D-EAM) used in 457 (45%) of cases.
- There was a significant reduction in procedure and fluoroscopy time after ~20 procedures per operator.
- Freedom from arrhythmia recurrence at 12 months was similar during (<-20 cases) vs after the learning curve (≥ 20 cases), 65% vs 68% ($p = 0.52$).
- Use of 3D-EAM did not significantly change 12-month arrhythmia-free outcomes, 69% without 3D-EAM vs 64% with 3D-EAM ($p = 0.50$).
- PVI durability for operators with < 60 PVI cases was 61% (201/332 veins); with ≥ 60 cases, durability increased to 73% (82/112 veins) ($p = .017$).

2025 clinical publications

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

*Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

La Fazia V.M., Mohanty S., Gianni C., et al.

Circulation: Arrhythmia and Electrophysiology (August, 2025), available here

- 236 consecutive patients undergoing repeat AF ablation with attempts at coronary sinus isolation, LAA isolation, and MI ablation using FARAPULSE.
- Acute CS isolation was achieved in 147/236 (62.2%) patients, LAA isolation was achieved in all patients (100%), and MI block was achieved in all patients acutely.
- After a 20-minute waiting period + adenosine challenge there was dormant conduction in the CS in 52 (26.4%) patients, dormant conduction in the LAA in 4 (1.7%) patients and regression of MI block in 35 (14.8%) patients.
- Chronic (3-month) remapping during LAA occlusion procedure showed durable CS isolation in 3/236 (1.3%) of patients, durable LAA isolation in 10/236 (4.6%) of patients and durable MI block in 13/236 (5.5%) of patients.

Predictors of Atrial Fibrillation Freedom Postablation with the Pentaspline Pulsed-Field Ablation Catheter: Subanalysis of the ADVENT Study

Mountantonakis SE, Gerstenfeld EP, Mansour M, et al.

Heart Rhythm (August 2025), available here

- In the ADVENT trial (n = 607) treatment failure occurred in 26.7% of PFA-treated patients versus 28.7% in thermal ablation (RF or cryoballoon).
- The most common mode of failure was arrhythmia recurrence (73.8% PFA vs 76.5% thermal), with similar rates of non-AF arrhythmias (12.1% vs 14.6%).
- Prior failure of Class I/III antiarrhythmic drugs (AADs) was associated with better outcomes after PFA.
- Shorter left atrial dwell time was linked to higher success.
- A non-significant trend toward better outcomes was observed for patients enrolled in the second half of the trial (success rate 75.5% vs 69.9%; p = 0.17), suggesting a possible operator learning curve effect.

Incidence of Laboratory-Defined Severe Intravascular Haemolysis Across Commercially Available Pulsed Field Ablation Technologies for Atrial Fibrillation

Mountantonakis SE, Beccarino N, Patel H, et al.

EP Europace (August 2025), available here

- 245 patients undergoing PFA (48.2% PersAF) with Sphere-9, lattice-tip (LT, n = 62), FARAPULSE pentaspline (PS, n = 108), and PulseSelect circular array (CA, n = 75).
- Severe intravascular hemolysis (IH), defined as post-procedure free plasma hemoglobin > 100 mg/dL, was significantly different across systems: PS 37.0%, CA 26.1%, LT 14.7% (p = 0.002).
- Independent risk factor for IH was the use of the PS system (p = 0.001). Within PS group specifically, a higher number of PFA lesions modestly increased risk (p = 0.049).
- Despite 17–37% incidence of IH by laboratory criteria, no patients developed clinically significant renal impairment.

2025 clinical publications

Risk of Acute Pericarditis Following Pulsed-Field Ablation Pulmonary Vein Isolation
Pérez-Pinzón J, Yang S, Maher T, et al.

EP Europace (August 2025), available here

- 322 patients underwent FARAPULSE ablation and 1,750 underwent RFA.
- Suspected acute pericarditis (meeting only one ESC criteria) occurred in 14 PFA patients (4.3%) and 60 RFA patients (3.4%).
- Symptoms were remotely managed in 50% of PFA cases and via unplanned outpatient evaluation in 36% of cases.
- There was no significant difference in triage strategies or the need for a revisit owing to persistent symptoms between PFA and RFA.

Safety and Efficacy of Pulsed Field Ablation for Cavotricuspid Isthmus-Dependent Flutter: A Systematic Literature Review
Rodriguez-Riascos JF, Vemulapalli HS, Muthu P, et al.

Journal of Cardiovascular Electrophysiology (August 2025), available here

- Meta-analysis of 11 studies including pooled data from 155 patients undergoing PFA for CTI-dependent atrial flutter.
- Mean number of PFA applications per CTI was 7.78.
- ST-segment elevation occurred in 0.04% of patients.
- Subclinical coronary vasospasm was observed in 45% of patients undergoing periprocedural coronary angiography.
- Prophylactic nitrate use trended toward reducing subclinical vasospasm ($p = 0.059$).
- Twelve individual case reports assessed with six including complications such as ST elevation or conduction disturbances.

Repeat Procedures After Pulsed Field Ablation for Atrial Fibrillation: MANIFEST-REDO Study
Scherr D, Turagam MK, Maury P, et al.

Europace (August 2025), available here

- Multicenter cohort of 427 patients (mean age 64 ± 11 years; 37% female) undergoing repeat ablation after initial PFA for recurrent AF or atrial tachycardia with these recurrent arrhythmia types: paroxysmal AF 51%, persistent AF 30%, atrial tachycardia 19%.
- Pulmonary vein reconnection rates at redo: LSPV 30%, LIPV 28%, RSPV 33%, RIPV 32%.
- 45% of patients had all PVs durably isolated at repeat procedure onset; prior use of any imaging/mapping modality was linked to higher PVI durability.
- Primary effectiveness endpoint was 65% overall; outcomes differed by arrhythmia type: PAF 65%, PersAF 56%, AT 76% ($p = 0.04$) and the procedural complication rate was 2.8%.
- Persistent AF as the recurrent arrhythmia predicted higher risk of AF/AT recurrence post-redo ($p = 0.045$).

Pulsed-field Ablation for Paroxysmal and Persistent Atrial Fibrillation: A Single-center Experience
Albasiri S, Arafat AA, Al Fagih A, et al.

Heart Views (July 2025), available here

- 33 patients, the LA ablation time was 45.4 ± 18 min; fluoroscopy time 33.5 ± 15.6 min and the total procedure time was 77.6 ± 19.7 min.
- There were no reported procedural or short-term complications at 3- and 6-month FU.
- 1 patient had AF recurrence and 1 patient developed AFL at 9 months and had a redo ablation.

2025 clinical publications

Endocardial Atrial Lesion Characteristics With Pentaspline Pulsed Field Ablation: Insights From Serial Mapping in Patients

Banai A, Dukkipati SR, Watanabe K, et al.

Journal of Cardiovascular Electrophysiology (July 2025), available here

- 25 patients were treated with FARAPULSE (31 mm), PVI (n = 16), PWA (n = 6), and LA roof (n = 3), with 1 or 2 applications per location.
- 5 minutes post-ablation, 3 of 16 PVs (12.5%) reconnected, showing asymmetric, band-like perivenous lesions.
- Posterior LA "flower pose" applications were irregular; mean lesion dimensions among smallest for posterior LA: ~14.9 mm and 17.7 mm.
- Isolation area regression between 1 minute and 5 minutes: for PVs, from 6.7 ± 6.0 cm^2 to 1.3 ± 1.5 cm^2; posterior wall lesions showed less regression (median ~2.9 vs 2 cm^2).
- Roof applications with two doses produced lesions that were circular, "doughnut-shaped," or minimal footprints. Flower pose CTI lesion widths along CTI line had medians: 43.1, 21.3, 24.9 mm depending on orientation and dosing.

Countrywide Introduction of Pulsed Field Ablation for the Treatment of Atrial Fibrillation: Acute Results from the FRANCE-PFA Registry

Chaumont C, Laredo M, Thomas O, et al.

Heart Rhythm O2 (July, 2025), available here

- Nationwide prospective registry including 5223 patients across 33 French centers undergoing de novo AF ablation with FARAPULSE, 55.4% PAF.
- Median procedure time = 54 minutes.
- The major complication rate was 0.96% with reports of atrio-esophageal fistula, PV stenosis, or symptomatic phrenic nerve palsy reported past hospital discharge.

Complications Associated with Pulsed Field Ablation vs Radiofrequency Catheter Ablation of Atrial Fibrillation

Cho MS, Lee S-R, Black-Maier E, et al.

Journal of the American College of Cardiology (July 2025), available here

- The MAUDE database was reviewed between January 1, 2024 through July 31, 2024, comparing complications with commercial PFA vs RFA for AF ablation.
- A total of 1,237 reports were analyzed (clinical complications and catheter malfunctions) and for clinical complications PFA (n = 156) and RFA (n =315) and catheter malfunctions, PFA 336, RFA 430.
- Most common PFA complications were pericardial effusion, vasovagal response, hemolysis and for RFA, pericardial effusion, ischemic stroke, esophageal damage.
- There was a lower proportion of deaths in PFA vs RFA (2.6% vs 8.9%, p = .010), higher hemolysis in PFA, 9.0% in PFA vs 0% in RFA (p < .001), higher proportion of coronary events in PFA, 5.8% in PFA vs 0.6% in RF (p < .001), more vasovagal responses in PFA, 14.1% in PFA vs 0% in RF (p < .001), greater esophageal damage with RFA, 0% in PFA vs 4.1% in RF (p < .001) and pulmonary vein stenosis: 0% in PFA vs 1.9% in RF (p = 0.184) and mechanical problems were more frequent with PFA vs RF (87.2% vs 17.2%, p < 0.001).

2025 clinical publications

Markers of Apoptosis and Cardiac Necrosis During the Acute Phase of Catheter Ablation Using Radiofrequency and Pulsed-Field Energy
Hassouna S, Hozman M, Bacova B, et al.

Biomarkers (July 2025), available here

- Prospective, randomized study with 65 patients undergoing PVI, 33 treated with FARAPULSE and 32 with RFA.
- Pre- and post-procedure myocardial necrosis was looked at via troponin I, and apoptosis via soluble cleaved caspase-3 and Fas ligand were measured.
- Troponin I (1 day post-procedure): PFA group: median 10,102 ng/L and RFA group: median 1,006 ng/L, RFA was significantly lower than PFA.
- No significant increase in post-procedure apoptosis markers (caspase-3, Fas ligand) in the PFA group and no differences between PFA vs RFA groups in apoptotic marker levels at day 1.

Pulmonary Vein Isolation with Radiofrequency Ablation and Pulsed Field Ablation: A Follow-Up with Real-World Data
Krzowski B, Dźwinacka J, Peller M, et al.

Polish Archives of Internal Medicine (July 2025), available here

- Retrospective analysis of 210 patients with AF (76.2% PAF) undergoing PVI, 108 with FARAPULSE vs 102 with vHPSD RFA.
- Procedural times were 55 minutes (PFA) vs 115 minutes (RFA) ($p < 0.001$).
- Deep sedation (PFA) vs conscious sedation (RF), remifentanil dose: 0.2 mg versus 0.5 mg ($p < 0.001$).
- Recurrence of atrial arrhythmias during blanking period: 32.7% (PFA) vs 28.7% (RFA) ($p = 0.55$).
- Recurrence after blanking period was 34.6% (PFA) vs 33.7% (RFA) ($p > 0.99$) and AE rates were similar between groups.

Renal Safety of High-Dose Pulsed Field Ablation of Atrial Fibrillation: A Prospective Real-World Analysis
Martinez J, Challapalli M, Hutchinson M, et al.

Heart Rhythm (July 2025), available here

- 115 consecutive patients ablated with FARAPULSE had had hemolysis and renal markers tested pre-procedure and 24 hours post-procedure.
- Biochemical evidence of hemolysis was seen in all patients and acute kidney injury (AKI) occurred in 8 patients (7%); only 1 had clinically significant renal dysfunction.
- The AKI group had mean number of applications, 88.25 ± 35.37 vs 70.12 ± 16.94 in non-AKI group ($p = 0.5$).
- Change in serum creatinine (SCr) 24 hours post-procedure was comparable across quartiles of application counts (PFA applications grouped into quartiles) ($p = 0.1$).
- Approximately 140 PFA pulses were required to produce a 0.3 mg/dL increase in SCr meeting AKI criterion.

Termination of Atrial Arrhythmia and Restoration of Sinus Rhythm during Pulsed Field Ablation with a Pentaspline Catheter in Patients with Persistent Atrial Fibrillation
Moltrasio M, Iacopino S, Solimene F, et al.

EP Europace (July 2025), available here

- 335 patients with PersAF, 94 (28.1%) with LS PersAF had ablation with FARAPULSE.
- PVI was eight applications per vein; additional non-PV ablation in 60.6% (n = 203) of cases.
- Rhythm at the end of the procedure, 20% (n = 67) in sinus rhythm from start (via prior electrical cardioversion), 3.3% (n = 11) began in AF, remained in AF at end and 76.7% (n = 257) began in AF and achieved termination of atrial arrhythmia and restoration of sinus rhythm (TASR) during the procedure.

- Of those 257 who achieved TASR, 33.1% (n = 85) did so directly through PFA application without need for electrical cardioversion.
- LS PersAF was significantly associated with lower likelihood of achieving TASR (p = 0.0195).
- During median follow-up of 361 days, AF recurrence did not significantly differ between those who achieved TASR vs those who did not (14.2% vs 24.4%; p = 0.0729).
- However, recurrence of any atrial arrhythmia was significantly lower in TASR patients (82.4% vs 70.9%; p = 0.0491).

Pulsed Field Ablation in the Elderly by a Pentaspline Multielectrode Catheter: Safety, Efficacy, and Comparison with Cryoballoon and Radiofrequency Devices

Nakasone K, Della Rocca DG, Magnocavallo M, et al.

Heart Rhythm (July 2025), available here

- Study included 983 patients aged over 75 years undergoing catheter ablation: 221 received PFA with FARAPULSE, 216 received CBA and 546 received RFA.
- Procedure time was significantly shorter with PFA (72 ± 30 minutes) compared to CBA (77 ± 27 minutes) and RFA (99 ± 23 minutes), p < 0.001.
- Extrapulmonary vein ablation was performed in 74.2% of PFA cases, 9.7% of CBA cases, and 42.1% of RFA cases; p < 0.001.
- The major complication rate was 1.01% and minor complications were observed in 1.4% of PFA, 5.1% of CBA, and 3.5% of RFA cases (p = 0.093).
- One-year atrial tachyarrhythmia freedom in the propensity score–matched population: 77.2% with PFA, 80.8% with CBA, and 74.9% with RFA (p = 0.52).

Real-time Detection of Microembolic Signals Using Carotid Echocardiography: A Comparative Study of 3 Pulsed-Field Systems

Shiomi S, Tokuda M, Takato U, et al.

Heart Rhythm (July 2025), available here

- 33 patients undergoing PF ablation for AF were studied: 11 with FARAPULSE, 11 with PulseSelect, 11 with VARIPULSE.
- Carotid echocardiography was used intra-procedurally to detect microembolic signals (MESs); cerebral MRI performed 1 day post-procedure for silent cerebral events/lesions (SCEs/SCLs).
- MES count during PV isolation: FARAPULSE: 61 ± 45, PulseSelect: 472 ± 337, VARIPULSE: 858 ± 266.
- FARAPULSE had significantly fewer MESs than both PulseSelect (p = 0.01) and VARIPULSE (p < 0.001).
- Among the 3 PFA systems: VARIPULSE produced the most MESs overall, especially in inferior pulmonary veins; PulseSelect showed high MES count initially (left superior PV), which then decreased with subsequent veins.
- SCEs/SCLs (silent cerebral events/lesions): VARIPULSE: multiple SCEs/SCLs in 4/11 patients (36%), FARAPULSE: 1 patient had an SCE/SCL, PulseSelect: 0 patients had SCEs/SCLs.

Safety of Same-Day Discharge Following Pulsed-Field Ablation Versus Radiofrequency Ablation: A Comparative Analysis

Watfa A, Younis A, Mdaihly M, et al.

Pacing and Clinical Electrophysiology (July 2025), available here

- 2,027 patients total, 955 underwent FARAWAVE ablation and 1,072 underwent RFA AF ablation.
- 21.7% of PFA patients were discharged same day vs 11.8% of RFA patients.
- The major complication rate in non-SDD patients was 0.5% in PFA vs 1.1% in RFA.
- 30-day readmission rates among SDD patients were PFA 1.4% vs RFA 2.4% (p = 0.54).
- The predictors of SDD in PFA group were lower CHA_2DS_2-VASc score (p < 0.001) and being < 80 years old; octogenarians had much lower odds of SDD (p = 0.005).

2025 clinical publications

Electrophysiologic Characteristics and Durability of Index Pulsed Field Ablation Lesions from Redo Procedures for Atrial Arrhythmia Recurrences

Yokoyama M, Vlachos K, Fitzgerald J, et al.

Heart Rhythm (July 2025), available here

- 180 patients (127 with PAF; 53 PersAF) underwent AF ablation with FARAPULSE.
- Durability of PVI and linear lesions was assessed in a subgroup of 23 patients who underwent a redo procedure.
- 11 of 14 patients and 8 of 14 patients with persistent atrial fibrillation underwent posterior line and mitral isthmus line ablation, respectively, during the index PFA procedure.
- Patients who underwent MI ablation received an adjunctive ethanol infusion into the vein of Marshall (Et-VOM), whereas 5 patients received a RFA touch-up.
- PV reconnection was observed in 10 of 23 patients (43.5%) and in 17 of 89 PVs (19.1%).
- In patients who had both PVI and a posterior line ablation that remained blocked during the redo procedure, no gaps were observed at the posterior aspect of the PVs.
- Posterior line reconnection was observed in 2 of 11 patients. The number of PFA deliveries during the index procedure was significantly lower in these patients (10.0 ± 2.8 vs 15.9 ± 3.2 p = .040).
- Mitral isthmus line reconnection was observed in all 8 patients, including 4 patients with MI dependent AT.

Direct Comparison of Two Commercially Available Pulsed Field Ablation Systems for Atrial Fibrillation; Procedure Characteristics and Acute Outcomes

Abeln B. G. S., Van Der Graaf M., Musat D. L., et al.

Journal of Cardiovascular Electrophysiology (June 2025), available here

- 402 patients with PAF or PersAF undergoing de novo AF ablation, 56.5% were treated with FARAPULSE and 44.0% with PulseSelect.
- Median procedure time was significantly shorter with FP: 36.0 min vs PS: 49.0 min ($p < 0.001$).
- Major adverse events were rare and similar between groups and minor vascular access site complications were more common in the FP group (11.9%) than the PS group (1.1%, $p < 0.001$).

PulsedField Ablation for Atrial Fibrillation with a Novel Simplified Protocol: The PFA Dose Study

Badertscher P, Isenegger C, Arnet R, et al.

Heart Rhythm (June 2025), available here

- 245 patients underwent first-time PFA PVI using FARAWAVE with 96 in the simple PFA group and 149 in the standard PFA group.
- Simple protocol: 4 applications per PV (2 basket, 2 flower); Standard: 8 applications per PV.
- Median procedure durations: simple 40 min; standard 53 min ($p < 0.001$).
- Median LA dwell times: simple 22 min; standard 37min ($p < 0.001$).
- Median fluoroscopy times: simple 9 min; standard 11 min ($p < 0.001$).
- Procedural complications: none in simple or extended dosing groups; 4 events in standard group ($p = 0.303$).
- The freedom from AA recurrence at 373 days was: simple 79%; standard 77% ($p = 0.767$).

2025 clinical publications

Pulsed-Field Ablation of Atrial Flutter: Insights From a Large Volume U.S. Center
Demian J, Younis A, Wazni OM, et al.

JACC: Clinical Electrophysiology (June 2025), available here

- 311 patients underwent ablation of 368 atrial flutter (AFL) circuits using FARAPULSE guided by ICE.
- Acute procedural success with PFA alone was 96.5%, CTI dependent AFLs was 99.5% and perimitral AFLs was 85.4%.
- Adjunctive RFA was required in 3.5% of circuits, primarily for perimitral flutters.
- 99% freedom from procedure-related adverse events.
- Over a median follow-up of 175 days, AFL recurrence occurred in 14 circuits (3.9%), CTI AFLs, 98.5% recurrence-free and perimitral AFLs, 90% recurrence-free.

Pulsed-Field vs Thermal Catheter Ablation of Atrial Fibrillation in Patients With Hypertrophic Cardiomyopathy
Gribissa S, Kueffer T, Knecht S, et al.

JACC: Clinical Electrophysiology (June 2025), available here

- 109 patients with HCM undergoing first-time AF ablation: 58 treated with FARAPULSE and 51 with thermal ablation (RF or cryoballoon).
- Extra-PV ablation was performed in 62% of PFA cases vs 18% of thermal cases.
- Median procedure time was 81 min for FARAPULSE vs thermal 132 min, $p < 0.0001$.
- Post-procedural heart failure: 0 in PFA group vs 4 in thermal group, $p = 0.03$
- 12-month freedom from atrial arrhythmia: 57% overall; PFA was associated with less recurrence vs thermal, $p = 0.03$.
- In the thermal group, extra-PV ablation was linked to more recurrence, $p = 0.02$, whereas it was not with PFA $p= 0.91$.

Safety and Feasibility of Pulsed Field Ablation with a Pentaspline Catheter in Patients with Cardiac Implantable Electronic Devices: A Multicenter Experience
Iacopino S, Tondo C, Bianchi S, et al.

EP Europace (June 2025), available here

- Study included patients with AF who had cardiac implantable electronic devices (CIEDs), undergoing PFA with FARAPULSE, device types included a variety of pacemakers, ICDs, CRT devices.
- After PFA procedures, no damage to electronic components or leads was observed.

Incidence and Characteristics of Superior Vena Cava Impact After Pulsed-Field Ablation of the Right Pulmonary Veins

*Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

Matsuura H, Kamakura T, Oshima T, et al.

Journal of Cardiovascular Electrophysiology (June 2025), available here

- 68 consecutive patients who underwent PVI with Varipulse (n = 17), PulseSelect (n = 26), and FARAPULSE (n = 25).
- Right atrial mapping was performed both before and after PVI to assess the impact on the superior vena cava (SVC).
- After PFA, a new low-voltage area (< 0.5 mV) ≥ 0.5 cm^2 in the SVC appeared in 56 patients (82.4%), including whole circumferential SVC impact in 10 patients (14.7%).
- Incidence of SVC impact by PFA system, Varipulse (52.9%), PulseSelect (96.2%) and FARAPULSE (88.0%).

- SVC deformity (crescent-shaped SVC) and anatomical distance between RSPV and SVC were associated with greater SVC impact; patients with SVC deformity had a significantly higher incidence of whole circumferential SVC impact vs those without (38.5% vs 9.1%, p = 0.018).

Characterization of Acute Residual Pulmonary Vein Connections Using Electroanatomical Mapping During Pulsed-Field Ablation of Atrial Fibrillation

Mills MT, Sommer P, Day J, et al.

Heart Rhythm (June 2025), available here

- 535 patients underwent PVI with PFA and had and 3D-EAM from 48 centers (89 operators), n = 375 (PAF) and n = 160 (PersAF). FARAPULSE was used in 72.7% of cases and PulseSelect in 27.3%.
- The mean procedure time was 75.9 ± 31.9 minutes and the mean mapping time was 8.4 ± 5.2 minutes.
- Bilateral first-pass isolation (FPI) achieved in 75.1% overall (PAF: 77.1%; PersAF: 70.6%; p = 0.126).
- Individual pulmonary vein (PV) FPI rate: 92.7% (1834 out of 1978 PVs).
- Residual PV connections (excluding common PVs) more frequent in superior veins vs inferior (8.9% vs 3.8%; p < 0.001), especially in the left superior PV (10.1%).
- Predictors of achieving FPI were standard four-vein anatomy (p = 0.021) and use of the FARAPULSE vs PulseSelect (p < 0.001).

Head-to-head Comparison of Pulsed-Field Ablation, High-Power Short-Duration Ablation, Cryoballoon and Conventional Radiofrequency Ablation by MRI-Based Ablation Lesion Assessment

Regany-Closa M, Pomes-Perez J, Invers-Rubio E, et al.

Journal of Interventional Cardiac Electrophysiology (June 2025), available here

- 138 patients undergoing first-time PVI-only for PAF: 43 RFA, 40 CBA, 30 HPSD and 25 FARAPULSE.
- LGE-CMR at 3 months: PFA had the lowest proportion of complete PV-encircling lesions (12%) vs HPSD 40%, RFA 26%, CBA 24% (p = 0.0069).
- Lesion width: PFA 12.7 mm, HPSD 10.9 mm, RFA 8.7 mm, CBA 13.3 mm (p < 0.0001).

Pulsed-Field Ablation With a Pentaspline Catheter for Ventricular Arrhythmias: First US Series

*Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

Younis A, Demian J, Baranowski B, et al.

Heart Rhythm (June 2025), available here

- 11 patients underwent FARAPULSE ablation for either PVCs (n = 2) or ventricular arrhythmias (n = 9).
- FARAPULSE was used for large footprint VT substrate ablation or as a bail out for failed RFA.
- The median number of PFA applications was 29 (16-51) with RFA touch-up applications.
- VT and PVC non-inducibility was achieved in all patients with no peri-procedural complications.
- At a follow-up of 219 days, there were 3 recurrences (2 VT, 1 PVC) managed with AAD adjustments.

Pulsed-Field Ablation Beyond Pulmonary Vein for Persistent Atrial Fibrillation: Efficacy and Impact on Left Atrial Function

Zaher W, Marcon L, Della Rocca DG, et al.

Journal of Interventional Cardiac Electrophysiology (June 2025), available here

- 93 PersAF patients had PVI + PVI+ with FARAPULSE: posterior wall 100%, anterior roof 50.5%, mitral isthmus 22.6%, anterior wall 36.6%, right atrial applications 8.6%.
- No serious procedure-related adverse events were reported.
- At 1-year 82.8% of patients were free from atrial arrhythmia recurrence with 77.9% off AADs.

- There was significant reduction in A-wave velocity of mitral inflow and altered E/A ratio and no change in LA compliance markers (LA reservoir strain and LA stiffness index [LASI]).
- In the subgroup with PersAF > 3 months, there was improvement from baseline observed in LASI and left ventricular ejection fraction.

Extent of Myocardial Injury after Pulmonary Vein Isolation Using Three Different Pulsed Field Ablation Systems

Badertscher P, Brügger, J, Isenegger C, et al.

Heart Rhythm (May 2025), available here

- Study compared myocardial injury after PVI across three PFA systems: FARAPULSE pentaspline catheter system (PCS), PulseSelect loop catheter system (LCS), and Varipulse variable-loop circular catheter (VLCC).
- VLCC PFA was associated with significantly less myocardial injury, with hs-cTnT levels less than half of those recorded in PCS and LCS groups.
- PCS and LCS created larger volumes of cardiac tissue damage compared with VLCC, which may contribute to more durable PVI.
- hs-cTnT levels in PCS and LCS groups were consistent with prior PFA injury studies, while VLCC levels were considerably lower and comparable to values previously reported after thermal ablation.
- VLCC caused significantly lower myocardial injury than PCS or LCS.

Learning Curve of Pulsed Field Ablation for Atrial Fibrillation: Insights from a United States Center

Badin A, Billakanty SR, Nemer DM, et al.

Journal of Interventional Cardiac Electrophysiology (May 2025), available here

- Retrospective analysis of 192 consecutive PFA cases (57.3% PAF, 37.5% PersAF, 5.2% long-standing PersAF) performed by nine operators at a US center with FARAPULSE.
- Acute procedural success of 99.5%; complication rate was 1.6% (three access-site hematomas).
- For PVI-only procedures: mean procedure time was 47.6 ± 20.9 min, fluoroscopy time was 12.1 ± 7.4 min, and mean PFA applications were 36.7 ± 5.7.
- A significant improvement in procedural efficiency over time was observed even when accounting for EAM usage, total procedure time: reduced from 85.7 to 61.1 min ($p < 0.001$) and fluoroscopy time reduced from 17.4 to 11.8 min ($p < 0.001$).

Comparison of Hemolysis with Different Pulsed Field Ablation Systems

Kawamura I, Miyazaki S, Kato R, et al.

Heart Rhythm (May 2025), available here

- Ablation was performed with PulseSelect (n = 38), FARAPULSE (n = 38), and CBA (n = 14) with no significant difference in the number of applications between PFA devices.
- FARAPULSE had significantly higher post-procedure hemolysis markers (LDH, total bilirubin, free hemoglobin) than PulseSelect ($p < 0.001$). More patients in the FARAPULSE group had low-level haptoglobin.
- No significant difference in hemolysis biomarkers between PulseSelect and CBA.
- Both PFA systems showed significantly higher creatine kinase levels vs CBA, but no difference was found between PFA systems and no patients had acute kidney injury.

2025 clinical publications

Ensuring Catheter-Tissue Contact with Intracardiac Echocardiography During Pulsed-Field Ablation Improves Procedure Outcome in Patients with Atrial Fibrillation

Mohanty S, Casella M, Doty B, et al.

Heart Rhythm (May 2025), available here

- PAF and PersAF patients were classified as the ICE group if ICE was used for the assessment of catheter-tissue contact (n = 310) or the fluoro group if fluoroscopy-guided ablation was used (n = 286).
- At 1 year follow-up arrhythmia recurrence was found in 39 (12.6%) and 64 patients (22.3%) in the ICE and fluoro groups, respectively (p = .002).
- 39 patients in the ICE group and 54 patients (84%) in the fluoro group received repeat ablation.
- At the redo procedure, reconnection of previously ablated structures was detected in 4 of 39 (10.3%) and 32 of 54 patients (59.2%) in the ICE and fluoro groups, respectively (p < .001).
- Fluoroscopy-guided ablation was found to be an independent predictor of reconnection (p < .001) and recurrence (p = .021).

Pulsed Field Ablation for Persistent Atrial Fibrillation: 1-Year Results of ADVANTAGE AF

Reddy VY, Gerstenfeld EP, Schmidt B, et al.

Journal of the American College of Cardiology (May 2025), available here

- 339 patients with PersAF (n = 260) underwent PVI and PWA with FARAWAVE.
- Primary safety endpoint (serious adverse events over 12 months): 2.3% (upper 97.5% CI 5.1%), meeting the 12% performance goal which included pericarditis (n = 1), myocardial infarction (n = 1), pulmonary edema (n = 4); no tamponade, stroke, PV stenosis, or esophageal fistula
- Primary effectiveness endpoint (freedom from atrial tachyarrhythmia recurrence, redo ablation, cardioversion, or AAD escalation post-blanking): 63.5% (lower 97.5% CI 57.3%) at 12 months, met the 40% effectiveness goal.
- Freedom from symptomatic AF recurrence: 85.3%; improved to 91.4% when operator experience ≥3 procedures.
- For patient that had a repeat ablation (4.6%) the PV durability was 84.4% of veins (68.8% of patients); Posterior wall durability was 68.8%.
- Patients with atrial arrhythmia burden < 0.1% had significantly fewer hospitalizations, cardioversions, re-ablations, and better quality of life compared to those with ≥ 10% burden.

Safety and Effectiveness of Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation Patients: One-Year Single-Center Experience

Reis Santos R, Bello R, Santos PG, et al.

Revista Portuguesa de Cardiologia (May 2025), available here

- 123 patients underwent PVI with FARAPULSE (52% PAF, 17% redo ablation) with a median procedure time of 83 min and fluoroscopy time of 11.6 min
- Posterior wall isolation was performed in 43 patients (35%).
- Acute cardiac tamponade occurred in 2 patients (1.6%), vascular complications in 4% (3 femoral hematomas, 1 pseudoaneurysm, 1 arteriovenous fistula).
- Over a median 290 days, 9% of patients experienced AF recurrence (2 with paroxysmal AF, 9 with persistent AF).

2025 clinical publications

The Olive Strategy Improved Pulmonary Vein Isolation Durability With the Pentaspline Pulsed Field Catheter

Schaack D, Urbanek L, Kheir J, et al.

Europace (May 2025), available here

- 400 patients, 60.2% PAF, were treated with the Olive Strategy, adding two additional "olive" configuration PFA applications (total 10 per PV: 4 flower, 4 basket, 2 olive).
- 100% acute PVI success, with mean procedure time 33.7 min and fluoroscopy time 7.5 min.
- Procedure-related complications: 11 of 400 (2.75%); no cases of acute kidney injury or PV stenosis; mean pre- to post-eGFR stable (72.25 to 73.09 ml/min/1.73 m^2; p = 0.19).
- In repeat procedures, PV reconnections occurred in 3 of 22 patients (13.6%) after Olive PFA vs 36 of 80 (45%) after conventional PFA (p = 0.007); overall PV reconnection rate 4.6% (4/87) vs 20.2% (64/317) for conventional (p < 0.001).
- Arrhythmia-free survival at 180 days was 86% in the Olive group vs 87.3% in the propensity-matched conventional patients (p = 0.75).

Acute Outcomes of Cryoballoon vs. Circular vs. Pentaspline Pulsed Field Ablation Catheters in Combined Pulmonary Vein Isolation and Roof Line Ablation

Yogarajah J, Hutter J, Kahle P, et al.

Journal of Interventional Cardiac Electrophysiology (May 2025), available here

- 125 patients with PersAF and LA enlargement were enrolled, CBA (n = 65), FARAPULSE (n = 30), and PulseSelect (n = 30).
- Roof-line (LARA) applications: CBA required fewer applications for roof line ablation than PFA systems (CBA 4 vs FARAPULSE 8 vs PulseSelect: 10; p < 0.001).
- Conduction block across the roof line was confirmed in 95% of CBA and 100% in both PFA groups (p = 0.421).
- CBA procedure time was 87.0 min, FARAPULSE – 64.0 min, PulseSelect – 68.0 min (p < 0.001).
- CBA had shorter fluoro times (12.2 min) vs PFA groups (15.3 and 15.1 min); p = 0.002.
- Adverse events were rare and mostly minor, 3 complications in CBA vs 1 in PFA groups; p = 0.493.

Pulsed Field Ablation for Atrial Fibrillation in Patients with Cardiac Implantable Electronic Devices

Abbas M, Emami M, Kamsani SH, et al.

Heart Rhythm (April 2025), available here

- Among 329 PFA procedures over 24 months using four PFA systems, 35 were performed in patients with cardiac implantable electronic devices (CIEDs).
- Pre- and post-procedural interrogation of CIEDs revealed no significant changes in lead impedance, pacing thresholds, or sensing parameters.
- Real-time device interrogation identified PFA-related electrical noise, with ventricular pacing inhibition of 2.5 s to 3.7 s in 2 patients, and atrial pacing inhibition of 2.1 s in 1 patient.

Insight Into Early Recurrences After Pulsed-Field Ablation for Atrial Fibrillation: Results from a Multicenter Experience

Bisignani A, Solimene F, Iacopino S, et al.

Journal of Cardiovascular Electrophysiology (April 2025), available here

- 620 consecutive patients (PAF and early PersAF) underwent de novo FARAPULSE ablation. Early recurrence was defined as arrhythmia >30 s during a 3-month blanking period; recurrence after 3 months was considered late.
- Early recurrence occurred in 44 patients (7.1%) at a median of 56 days post-ablation.

2025 clinical publications

- Larger left atrial volume index (LAVi) was an independent predictor of early recurrence (p= 0.0034).
- 113 patients (18.2%) had late recurrence.
- Predictors of late recurrence: age (p = 0.0077), sleep apnea (p = 0.002), and early recurrence (p < 0.0001).

Pulsed Field Ablation Based Pulmonary Vein Isolation Utilizing a Simplified Approach or a Standard Approach—Insights from the Fast and Furious PFA Study

Heeger CH, Zetzsch L, Eitel C, et al.

Journal of Interventional Cardiac Electrophysiology (April 2025), available here

- 50 consecutive AF patients underwent first-time PFA under deep sedation, split into 25 standard approach (dual-femoral access + 3D mapping + CS catheter) and 25 FAST simplified approach (single femoral/transseptal access + single catheter + closure system).
- The median procedure time was significantly shorter in the FAST approach, 26 min vs standard 65 min (p < 0.0001).
- The median fluoroscopy time was significantly shorter in the FAST approach 5 min vs standard 12 min (p < 0.001).
- The 12-month freedom from AF recurrence was 77% in the FAST approach vs 81% in the standard approach (p = 0.856).
- There were no differences in severe adverse events and minor complications between groups.

NEMESIS-PFA: Investigating Collateral Tissue Injury Associated with Pulsed Field Ablation

Lakkireddy D, Katapadi A, Garg J, et al.

JACC: Clinical Electrophysiology (April 2025), available here

- Multicenter observational registry including 871 patients (59.4% PAF) who underwent AF ablation with either PFA (n = 773) or RFA (n = 98).
- Compared to RF ablation, PFA resulted in significantly greater median increases of: cardiac troponin (p < 0.001), lactate dehydrogenase (p < 0.001), free plasma hemoglobin (p < 0.001), haptoglobin decrease p < 0.001, hemoglobin drop (p < 0.001), creatinine (p = 0.007) and left atrial ejection fraction (LAEF) drop (p < 0.001).
- Biomarker elevations were dose-dependent magnified with increased numbers of PFA applications and varied by catheter system.

Results of ICE-Guided Isolation of the Superior Vena Cava With Pulsed Field Ablation

Pierucci N, La Fazia VM, Mohanty S, et al.

JACC: Clinical Electrophysiology (April 2025), available here

- 616 consecutive patients underwent PVI but SVC isolation with FARAPULSE under ICE guidance, 67.4% PersAF.
- SVC isolation was achieved in 100% (616/616) of patients.
- For the first 10 patients, “flower” configuration was used; in the remaining 606, “basket” configuration with 4 PFA applications used for isolation.
- Mean number of PFA applications 60.8 ± 24 with a procedure time of 77.9 ± 24.7 min.
- In the first 10 (flower config) there were 2 transient sinus node injuries and 2 episodes of phrenic nerve-stunning (all resolved peri-procedurally.
- In the basket configuration group (remaining 606): 1 phrenic nerve-stunning episode occurred and resolved before end of procedure; no permanent sinus node injury or phrenic nerve paralysis at discharge or at 2-month follow-up.

2025 clinical publications

Pulsed Field Ablation of Persistent Atrial Fibrillation With Continuous Electrocardiographic Monitoring Follow-Up: ADVANTAGE AF-Phase 2

Reddy VY, Gerstenfeld EP, Schmidt B, et al.

Circulation (April 2025), available here

- Prospective, multicenter, single-arm study including 255 patients with PersAF undergoing PVI and PWA using FARAWAVE. 141 (55.3%) also received CTI ablation with the FARAPOINT™ PFA Catheter with IV nitroglycerin prophylaxis.
- Acute success: 99.6% for PVI and 100% for PWA; CTI ablation achieved bidirectional block in 98.6%, with no procedural complications.
- Median procedure time: 105 ± 36 minutes; LA dwell time: 59 ± 24 minutes; CTI duration: 8 ± 13 minutes; mean PF applications: 18 ± 6, NTG dose: 4 ± 2 mg IV.
- Continuous ICM-based follow-up over 12 months revealed: 73.4% freedom from atrial arrhythmia (AA) using traditional intermittent monitoring analogue with a 2.4% adverse event rate.
- The freedom from AFL was 97.2%. 52.0% of patients had no AA episodes ≥ 30 seconds; 94.0% had no AA lasting over 24 hours.
- One-year effectiveness defined as AA burden ≤ 0.1%: 71.6%; for episodes shorter than 1 hour: 70.0%.

COOPERATIVE-PFA: A Three-Arm Randomized Controlled Trial

Sochorová V, Kunštátová V, Osmančík P, et al.

Circulation (April 2025), available here

- 127 patients (47.2% PAF) were randomized 1:1:1 to three arms:
  – Arm P: Propofol-opioid deep analgosedation (DAS) (n = 42)
  – Arm R: Remimazolam-ketamine DAS (optimized DAS) (n = 43)
  – Arm TIVA: Total intravenous anesthesia with airway secured (n = 42)
- Primary endpoint—composite of hypoxemia, hypotension, or hypertension requiring intervention or leading to procedure interruption occurred in:
  – 85.7% of Arm P (propofol-opioid DAS)
  – 27.9% of Arm R (optimized remimazolam-ketamine DAS)
  – 66.7% of Arm TIVA (propofol-opioid TIVA) ($p < 0.001$) and in Arm P, all events were hypoxemia; in Arm TIVA, all were hypotension, Arm R had mixed events (hypoxemia 50%; hypotension 66.7%).
- Procedural times, serious adverse event rates, and patient satisfaction were comparable across all three groups.

Redo Ablation Procedures to Treat Recurrent Atrial Arrhythmias via a Pentaspline Pulsed Field Ablation Catheter: A Prospective, Multicenter Experience

Cespón-Fernández MC, Della Rocca DG, Magnocavallo M, et al.

Journal of Interventional Cardiac Electrophysiology (March 2025), available here

- 117 patients underwent redo AF ablation with FARAPULSE in 3 centers (Group 1: SR = 64; Group 2: AFL/AT = 18; Group 3: AF = 35).
- PV re-isolation was performed in 71.9% of Group 1 and 72.2% of Group 2.
- FARAPULSE terminated all non-CTI dependent flutters and 45.7% of AF cases.
- The major complication rate was 0.9% (n = 1).
- Freedom from atrial tachyarrhythmias at 12 months was 78.3%, with no significant differences between groups (Group 1: 85.7%; Group 2: 77%; Group 3: 65.5%; $p = 0.053$)
- Compared to RFA redo ablations, PFA showed similar arrhythmia-free outcomes with significantly shorter procedural and LA dwell time

2025 clinical publications

An Approach to Electroanatomical Mapping with a Pentaspline Pulsed Field Catheter to Guide Atrial Fibrillation Ablation

Mills MT, Calvert P, Phenton C, et al.

Journal of Interventional Cardiac Electrophysiology (March 2025), available here

- 22 patients (45% female; mean age 63 ± 13 years; 55% with paroxysmal AF; 27% were redo procedures).
- EAM increased mean procedure time to 108 min (vs. 68 min in fluoroscopy-only cases) with no change to fluoroscopy time despite mapping addition.
- Three potential advantages for FARAPULSE mapping were identified:
  - (1) The technique helped identify incomplete PVI after index ablation.
  - (2) In the 4 cases mapped with both the PFA and grid-style catheters, voltage maps appeared concordant.
  - (3) The technique helped facilitate PWA and identify inadvertent partial PWA.

Pulsed Field or Cryoballoon Ablation for Paroxysmal Atrial Fibrillation (SINGLE SHOT CHAMPION Trial)

Reichlin T, Kueffer T, Badertscher P, et al.

New England Journal of Medicine (March 2025), available here

- 210 patients with symptomatic, drug-refractory PAF were randomized 1:1 to PFA (FARAPULSE, n = 105) or cryoballoon ablation (Arctic Front Advance, n = 105), all monitored with an ICM.
- Primary efficacy endpoint (recurrence of atrial tachyarrhythmia between day 91–365): 37.1% incidence with PFA vs 50.7% with cryoballoon (difference −13.6 percentage points, 95% CI −26.9 to −0.3; p < 0.001 for noninferiority, p = 0.046 for superiority).
- During the 3-month blanking period (days 1–90): recurrence-free rate was 61.9% (PFA) vs 41.9% (CBA) — 20% reduction (95% CI −33.2 to −6.8).
- Over the full 12 months (days 1–365): recurrence-free rate was 55.2% (PFA) vs 37.0% (CBA) — 18.2% reduction (95% CI −31.5 to −4.9).
- Procedure time: PFA 54.8 ± 22.7 min vs cryo 73.2 ± 26.7 min (PFA was 18 min shorter); LA dwell time: 36.1 ± 16.6 min vs 51.5 ± 20.0 min; troponin day1: 1920 ± 954 ng/L (PFA) vs 1114 ± 419 ng/L (CBA), difference 823 ng/L (95% CI 612–1034).
- Safety event rate occurred in 1 patient (1.0%) in PFA vs 2 (1.9%) in CBA.
- There were no significant differences in hospitalizations, quality of life, or repeat procedures during follow-up.

Posterior Wall Isolation with Pulsed Field Ablation or Radiofrequency Ablation with Vein of Marshall Ethanol Ablation for Repeat Catheter Ablation of Recurrent Atrial Fibrillation

Isenegger C, Krisai P, Knecht S, et al.

Journal of Interventional Cardiac Electrophysiology (February 2025), available here

- 111 patients undergoing repeat catheter ablation for recurrent AF, 73 were treated with PFA PVI + PWA and 38 were treated with RFA PVI + vein of Marshall (VoM) ethanol ablation plus linear lesion set.
- Procedure duration: 64 minutes PFA vs 113 minutes VoM-RFA (p < 0.001).
- Fluoroscopy time: 9 minutes PFA vs 13 minutes VoM-RFA (p < 0.001).
- There was no significant difference in myocardial injury measured by hs-cTnT 24 h post-ablation.
- AF recurrence-free during follow-up (median 226 days): 66% in PFA group vs 59% in VoM-RFA group.
- No major complications in PFA group; VoM-RFA group had one probable allergic reaction.

2025 clinical publications

Comparing Pulsed Field Ablation and Thermal Energy Catheter Ablation for Paroxysmal Atrial Fibrillation: A Cost Effectiveness Analysis of the ADVENT Trial

Padula W V, Paffrath A, Jacobsen C M, et al.

Journal of Medical Economics (January 2025), available here

- Cost-effectiveness model based on randomized ADVENT trial data comparing PFA vs RFA and CBA.
- Over a 40-year period, FARAPULSE provided +0.044 QALYs and saved US $2,871 per patient versus thermal ablation.
- The FARAPULSE estimated payer savings per member per month: $0.00015 (year 1), $0.0059 (year 4), $0.02343 (year 6).
- Anticoagulation and procedural costs were the principal drivers of model uncertainty
- FARAPULSE was as cost-effective as conventional thermal ablation AF and potentially reduces US healthcare payer costs.

2024 clinical publications

Feasibility of Pulsed Field Ablation for Atrial Fibrillation Under Mild Conscious Sedation

Calvert P, Mills MT, Murray B, et al.

Journal of Interventional Cardiac Electrophysiology (December 2024), available here

- 23 patients underwent PFA PVI: 8 with mild conscious sedation (MCS), 15 under general anesthesia (GA).
- 12.5% (1/8) in MCS group required conversion to GA.
- Mean procedure times: MCS 92 ± 12.4 min vs GA 101 ± 17.3 min (p = 0.199). MCS group received 5.12 ± 0.83 mg midazolam and 209 ± 40 µg fentanyl.
- Median intraprocedural pain score in MCS: 45 (IQR 22.5–72.5) on a 0–100 scale.
- Post-procedural groin pain (0 [0–0] vs 5 [0–35]; P = .027) and throat pain (0 [0–0] vs 10 [5–40]; p = .001) were lower in MCS versus GA.

Acute Mitral Block: Pulse Field Ablation Plus Radiofrequency Ablation when compared to Radiofrequency Ablation Plus Vein of Marshall Ethanol Injection

*Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

Cubberley A, AhmadianTehrani AA, Kashyap M, et al..

Journal of Interventional Cardiac Electrophysiology (December 2024), available here

- Retrospective comparison of 53 patients treated with RFA + VOM ethanol (VOM/RFA ALL group) vs 12 patients treated with PVI + posterior wall PFA followed by mitral isthmus and CS RFA (PFA PV+PW/RFA MITRAL group).
- Mitral isthmus block achieved in 92.5% (49/53) of VOM/RFA ALL vs 83.3% (10/12) of PFA PV+PW/RFA MITRAL (p = 0.31).
- Coronary sinus ablation required 50.9% (27/53) in VOM/RFA ALL vs 66.7% (8/12) in PFA PV+PW/RFA MITRAL (p = 0.36).
- Total procedure time and fluoroscopy dose were significantly lower in PFA PV+PW/RFA MITRAL (p = 0.02 and p < 0.01).
- No complications observed in either group (no coronary spasm, pericardial effusion, stroke or AV block).

LA PULSE: Evaluating Left Atrial Function Pre- and Post- Atrial Fibrillation Ablation Using Pulsed Field Ablation

Mahrous N, Blaschke F, Schöppenthau D, et al.

Journal of Clinical Medicine (December 2024), available here

- 34 patients underwent PVI with FARAPULSE (44% PAF).
- Left atrial reservoir strain (LASr) increased significantly from 12.5 ± 5.8% to 21.7 ± 8.1% (p < 0.001).
- Patients with paroxysmal AF exhibited a greater increase in LASr compared to those with persistent AF.
- Mean left atrial volume index decreased, contractile strain increased and conduit strain also improved.

Safety and Efficacy of Pulsed Field Ablation for Atrial Fibrillation in the Elderly: A EU-PORIA Sub-Analysis

Mené R, Sousonis V, Schmidt B. et al.

International Journal of Cardiology (December 2024), available here

- Sub-analysis of the EU-PORIA real-world registry comparing outcomes of PFA in elderly patients (≥ 80 years) versus younger patients.
- Overall procedural complication rates were comparable between the ≥ 80 and < 80 age groups.
- Elderly patients showed a higher incidence of periprocedural stroke compared to younger patients.
- Acute safety outcomes (e.g., vascular complications) remained similar between age groups.

2024 clinical publications

Pulsed field Ablation of Atrial Fibrillation with a Pentaspline Catheter Across National Health Service England centres

Mills MT, Trivedi S, Lovell MJ, Calvert P, et al.

Open Heart (December 2024), available here

- 1,034 procedures performed at nine NHS England centers by 48 operators, 53.1% paroxysmal AF, 89.7% first-time ablations.
- General anesthesia was used in 93.7% of procedures with 63.8% of patients being same day discharge.
- The median skin-to-skin procedure time was 74 min and fluoroscopy time was 20 min.
- EAM used in 15.3% of cases, PWA was performed in 11.0%, and additional RF in 0.6%.
- The acute complication rates were, major (1.3%) and minor (3.1%) with no reported procedural deaths or AEF.

Procedural Characteristics, Safety and Clinical Outcomes of PulsedField Ablation for Pulmonary Vein Isolation in Patients with a Left Common Pulmonary Vein

Jordan F, Knecht S, Isenegger C. et al.

Heart Rhythm (November 2024), available here

- Propensity matching of 208 patients undergoing PVI with FARAWAVE. LCPV group (n = 52) were matched to 156 patients with 2 LPVs.
- Median procedure, LA dwell and fluoro times were comparable along with PVI application number.
- There were no major complications in either group.
- At ~1-year follow-up, arrhythmia-free survival was 85% in the LCPV group vs 80% in the control group (p = 0.051).

Pentaspline Catheter or Cryoballoon for Pulmonary Vein Plus Posterior Wall Isolation in Persistent Atrial Fibrillation: 1-Year Outcomes

Pannone L, Doundoulakis I, Della Rocca DG, et al.

Heart Rhythm (December 2024), available here

- 160 patients with PersAF had de novo ablation of PVI + PWA: 80 with FARAPULSE and 80 with CBA.
- Significantly shorter procedure time, LA dwell time and fluoroscopy time with FARAWAVE.
- 1-year freedom from atrial arrhythmia recurrence was 78.8% for FARAPULSE vs 76.2% for CBA.
- Complication rates were low with no significant difference in safety events.

Comparative Analysis of Real-World Clinical Outcomes of a Novel Pulsed Field Ablation System for Pulmonary Vein Isolation: The Prospective CIRCLE-PVI Study

Katov L, Teumer Y, Bothner C, et al.

Journal of Clinical Medicine (November 2024), available here

- 125 de novo AF patients underwent PVI - 25 were treated with PulseSelect, and 100 were treated FARAPULSE.
- The median procedure times were comparable between groups (FARAWAVE 54.0 min vs PulseSelect 62.0 min; p = 0.14).
- Median total LA dwell times were comparable, FARAWAVE was 37.0 min vs PulseSelect 38.5 min (p = 0.35).
- Median fluoroscopy durations were comparable, FARAWAVE was 16.6 min vs PulseSelect 14.9 min (p = 0.18).
- No procedural complications were reported in either group.

2024 clinical publications

Atrial Fibrillation Ablation During Hospitalization for Acute Heart Failure: Feasibility and Role of Pulsed Field Ablation

Marek J, Stojadinović P, Wichterle D, et al.

Journal of Cardiovascular Electrophysiology (November 2024), available here

- 46 patients underwent AF ablation during hospitalization for acute HF.
- 32 patients received PFA and 14 underwent thermal catheter ablation (13 RFA, 1 CBA).
- Procedure duration: PFA 77 min vs thermal 166 min; $p < 0.001$.
- Fluoroscopy time: PFA 9.5 min vs thermal 3.9 min; $p < 0.001$.
- Arrhythmia-free survival at 1 year: PFA 79% vs thermal 64% ($p = 0.44$).
- Freedom from composite endpoint (AF recurrence, HF hospitalization, death): PFA 76% vs thermal 57% ($p = 0.43$).
- Left ventricular ejection fraction improvement: +24 % ± 2% in first-time HF vs +14 % ± 4% in decompensated HF ($P < 0.001$ and $P = 0.004$, respectively).

Pulsed Field Ablation in Atrial Fibrillation: Initial Experience of the Efficacy and Safety in Pulmonary Vein Isolation and Beyond

Tay JCK, Tarranza JL, Chia SY, et al.

Journal of Cardiovascular Development and Disease (November 2024), available here

- 101 patients underwent FARAPULSE ablation with 29 patients (28.7%) receiving additional posterior wall ablation (PVI + PWA), all achieving acute success.
- One year freedom from atrial arrhythmia: 90.3% (95% CI 83.3–97.3) for PVI-only vs 82.8% (95% CI 68.1–97.4) for PVI + PWA.
- Persistent AF group had 21% recurrence at 12 months vs 10% in paroxysmal AF.
- There were no major complications and PFA applications, LA dwell time, procedure time, fluoroscopy time—were similar between PVI-only and PVI + PWA groups.

Cavotricuspid Isthmus Ablation Using a Pentaspline Pulsed Field Ablation Catheter: Feasibility and Acute Results

Chaumont C, Ollitrault P, Savoure A. et al.

EP Europace (October 2024), available here

- Cohort of 32 patients undergoing combined PVI + CTI ablation, 66% treated with direct flower configuration, 28% with indirect basket, 6% had both.
- A bolus of nitroglycerin (2 mg) was administered via the femoral venous sheath 1–5 min prior to the first PFA application. A minimum of four PFA applications were delivered, with at least two additional applications after achieving CTI block.
- Sinus rhythm restored after first PFA delivery in 89% of patients with ongoing atrial flutter (17/19).
- Median PFA applications: 6 in flower; 6 in basket with acute bidirectional CTI block achieved in 100% of patients.
- Mean time to CTI block 8.2 ± 2.6 min with no reported conduction disturbances, ST-elevation, or hemodynamic instability reported.
- At 6-month followup, 94% (30/32) were symptom-free and in sinus rhythm and the 2 patients that experienced recurrences underwent redo procedures persistent bidirectional block along the CTI.

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Intravascular Haemolysis and Acute Kidney Injury Following Atrial Fibrillation Ablation: A Report Using Two Different Systems for Pulsed Field Ablation

De Smet MAJ, François C, De Becker B, et al.

EP Europace (October 2024), available here

- Prospective cohort of 198 AF patients comparing RF (n = 46), VARIPULSE PFA (n = 94), and FARAPULSE (n = 98) for PVI alone or PVI-plus ablation.
- Across both PFA systems, intravascular hemolysis was observed post-ablation (↓haptoglobin, ↑free Hb, ↑LDH, ↑bilirubin, ↑reticulocytes; all P < 0.0001), no changes were seen with RFA.
- Hemoglobinuria rates 24-hours post ablation: VARIPULSE 15% (PVI-only), 29% (PVI-plus); FARAPULSE 11% (PVI-only), 33% (PVI-plus); RFA rates 3% (PVI-only), 7% (PVI-plus).
- AKI occurred in PFA-treated patients: 8/152 (5.3%), 4 Stage 1 with VARIPULSE, 3 Stage 1 and 1 Stage 3 with FARAPULSE and no AKI in RFA group.
- All patients recovered baseline renal function except the one with Stage 3 AKI (the patient had advanced kidney disease prior to ablation).

Multielectrode Catheter-Based Pulsed-Field Ablation of Persistent and Long-Standing Persistent Atrial Fibrillation

Della Rocca DG, Sorgente A, Pannone L, et al.

EP Europace (October 2024), available here

- 72 patients, 52.8% had PersAF > 6 months and 47.2% had long-standing PersAF.
- PVI, PWA and roof line isolation, plus electrogram-guided substrate modification, terminated AF in 95.8% of patients.
- AF organized into left-sided AFL in 74.2% (46/72), and left AFL was terminated by PFA in 100% of those patients.
- Mean procedure duration was 112 ± 25 minutes with a LA dwell time of 59 ± 22 minutes.
- Major complications occurred in 2 patients (2.8%).
- After 14.9 ± 2.7 months follow-up, the single-procedure success rate was 74.6%, and AF-free survival was 89.2%.

Impact of Overweight and Obesity on Radiation Dose and Outcome in Patients Undergoing Pulmonary Vein Isolation by Cryoballoon and Pulsed Field Ablation

Jungen C, Rattka M, Bohnen J, et al.

IJC Heart & Vasculature (October 2024), available here

- Retrospective analysis of 115 AF patients with BMI ≥ 25 kg/m² (57% overweight, 43% obese) undergoing either PFA-PVI (68%) or CBA-PVI (32%).
- Logistic regression identified obesity (p = 0.006) and CBA-PVI (p < 0.001) as independent predictors of increased radiation exposure.
- Safety outcomes were comparable: PFA 4% vs CBA 0% complications (p = 0.3).
- One-year freedom from AF was similar across BMI categories (overweight 82% vs obese 67%, p = 0.19) and between modalities (PFA vs CBA both 76%, p = 0.42).

Investigating the Role of Electroanatomical Mapping in Single-Shot Pulsed Field Catheter Ablation

Kariki O, Mililis P, Saplaouras A, et al.

Journal of Arrhythmia (October 20204), available here

- 51 atrial fibrillation patients were randomized to PFA with fluoroscopy alone (n = 31) or with additional EAM validation (n = 20).
- Arrhythmia recurrence rates were similar between groups at ~11 months (16.1% vs. 20%, p = 0.72); procedure time was significantly longer with EAM.

- EAM with FARAWAVE found 5 non-isolated pulmonary veins.
- During the follow-up period of 11.2 ± 1.3 months, 4 patients had a redo procedure. In all redo patients there was at least one reconnected PV.

Characterization and Clinical Significance of Hemolysis After Pulsed Field Ablation for Atrial Fibrillation: Results of a Multicenter Analysis

Popa M, Venier S, Menè R. et al.

Circulation: Arrhythmia and Electrophysiology (October, 2024), available here

- Hemolysis and renal function biomarkers were analyzed in blood samples at baseline, at the end of ablation, and 24 hours after ablation in FARAPULSE (n = 145) and RFA (n = 70) patients.
- The ablation procedures had a mean of 61.6 ± 27.4 PFA deliveries and 26.3 ± 15.0 minutes of RFA.
- Hemolysis was detected in 94.3% (PFA) versus 6.8% (RFA) patients.
- Creatinine increase was higher in patients with baseline glomerular filtration rate <50 mL/min than with baseline glomerular filtration rate > 50 mL/min (Δcrea, 27.0 ± 103.1 versus −0.2 ± 12.1 µmol/L; P = 0.010).
- PFA was associated with significantly lower haptoglobin levels, while free plasma hemoglobin, bilirubin and LDH (lactate dehydrogenase) were significantly higher after PFA versus RFA.
- Hemolysis correlated with the number of PFA deliveries, with the highest severity occurring ≥ 54 PFA deliveries

Prediction of Major Intravascular Hemolysis during Pulsed Electric Field Ablation of Atrial Fibrillation Using a Pentaspline Catheter

Stojadinović P, Ventrella N, Alfredová I, et al.

Journal of Cardiovascular Electrophysiology (October 2024), available here

- Prospective study of 60 PAF patients undergoing FARAPULSE ablation, including PVI+ lesions in 73% of cases.
- Following a median of 74 PFA applications, free hemoglobin (fHb) rose from 40 to 493 mg/L ($p < 0.001$), LDH from 3.1 to 6.8 µkat/L ($p < 0.001$), and direct bilirubin from 12 to 28 µmol/L ($p < 0.0001$).
- There was a strong linear correlation between number of PFA deliveries and peak fHb; an optimum cut-off value of 74 applications predicted major hemolysis (fHb >500 mg/L) with 89% sensitivity and 87% specificity.

Comparative Evaluation of 2 Pulsed Field Ablation Systems for Atrial Fibrillation: Insights from Real-World Clinical Implementation and Short-Term Outcomes

Zylla M, Mages C, Rahm A. et al.

Heart Rhythm (October 2024), available here

- The study included the first 40 consecutive patients treated with FARAPULSE and PULSESELECT.
- Overall procedural complications were not significantly different: PULSESELECT 12.5% vs FARAPULSE 7.5% (P = 0.71); most were minor: 10.0% (PS) vs 7.5% (FP).
- Procedure duration, dwell time and fluoroscopy times were similar between catheters.

Variations in Workflow Affecting Cost of Pulsed Field Ablation for Atrial Fibrillation

Badin A, Billakanty SR, Nemer DM, at al.

Heart Rhythm (Sept 2024), available here

- Single-center cost analysis of PFA procedures evaluating variations in workflow components (room setup, equipment use, staffing).

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- The average supply cost of the FARAPULSE ablation procedure was $14,841±1490. Procedures completed with (n = 72) or without (n = 44) 3D EAM and demonstrated different total costs ($1,5613±1393 vs $13,531±150, P<0.001) with cost differential of 15%.
- There were significant cost differences noted among the three major 3D EAM systems.
- Implications suggest that streamlined workflows in high-volume centers may offset upfront capital and device costs associated with PFA.

Pulsed-Field vs. Cryoballoon-Based Pulmonary Vein Isolation: Lessons from Repeat Procedures

Lemoine M, Obergassel J, Jaeckle S. et al.

Europace (September 2024), available here

- Prospective, observational cohort of 550 patients undergoing de novo PVI, n = 191 with PFA and n = 359 with cryoballoon ablation (CBA).
- Redo ablation was performed in 12% of patients in each group (22/191 PFAPVI; 44/359 CBAPVI).
- Pulmonary vein reconnections were found in 73% (38% of total) after PFA-PVI vs. 75% (37% of total) after CBA-PVI.
- Clinical atrial tachycardia rates similar (PFA: 23%; CBA: 16%; p = 0.515); roof lines were more frequent after PFA (36% vs. 11%; p = 0.023).
- Repeat procedure times (87 vs. 93 min; p = 0.446) and fluoroscopy durations (110.9 vs. 11.3 min; p = 0.739) were equivalent between groups.

Pulsed Field Ablation Prevents Left Atrial Restrictive Physiology after Posterior Wall Isolation in Patients with Persistent Atrial Fibrillation

Banai A, Chorin E, Schwartz A, et al.

Heart Rhythm (August 2024), available here

- Thirty-two patients with AF underwent PVI and PWA, during which left atrial mechanical function was evaluated.
- Of the 15 patients in sinus rhythm at the time of ablation, LA strain, active emptying fraction, and expansion index significantly declined at day 1 post-ablation but returned to baseline by 3 months.
- For the entire study group, all measurements of LA function significantly improved after 3 months vs the day after ablation.
- Only 3 of 15 (20%) patients in sinus rhythm at baseline and 4 of 32 (12.5%) of the entire cohort had declined LA strain by 3 months of follow-up.
- At 3 months, 26 (81.8%) patients were free of AF recurrence; 3 patients underwent redo ablation after 4–6 months and persistent PVI and PWI were confirmed in all.

Redefining the Blanking Period after Pulsed-Field Ablation in Patients with Atrial Fibrillation

Mohanty S, Torlapati P, Casella M. et al.

Heart Rhythm (August 2024), available here

- Consecutive FARAPULSE patients (n = 337) undergoing PFA were prospectively followed up for 1 year. Early recurrence was defined as atrial arrhythmia of > 30-second duration during the 3-month blanking period, and any recurrence beyond 3 months was considered as late recurrence.
- Early recurrence was recorded in 53 patients (15.7%): 10 in the first month, 12 in the second month, and 31 in the third month.
- Of the 10 patients having recurrence during the first month, 7 (70%) remained in sinus rhythm after cardioversion whereas 3 (30%) underwent a redo procedure because of late recurrence.

- At 1 year, all patients with recurrence in the second and third months experienced late recurrence; among these patients 10/12 (83.3%) and 27/31 underwent a redo procedure and the remaining 6 patients were in sinus rhythm on AADs.
- The number of patients undergoing a redo procedure for late recurrence was significantly higher if early recurrence occurred in the second or third month versus in the first month (3/10 [30%] vs. 37/43 [86%]; p = 0.03).

Pulsed-Field Ablation for Atrial Fibrillation without the use of Fluoroscopy

Palmeri N, Alyesh D, Keith M. et al.

Journal of Interventional Cardiovascular Electrophysiology (August 2024), available here

- FARAPULSE procedures (n = 50) were completed with a fluoroless approach with 3D EAM and ICE for wire guidance and evaluation of tissue contact.
- Projection lesions were placed with every application of PFA. An average of 41.7 (± 8.5) PFA applications were placed.
- In 100% (50/50) of subjects, acute isolation of the pulmonary veins was achieved.
- There were no complications and compared to the control cohort; the LA dwell time was similar.

Pulsed Field Ablation Prevents Left Atrial Restrictive Physiology after Posterior Wall Isolation in Patients with Persistent Atrial Fibrillation

Banai A, Chorin E, Schwartz A, et al.

Heart Rhythm (August 2024), available here

- Thirty-two patients with AF underwent PVI and PWA, during which left atrial mechanical function was evaluated.
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Safety of Pulsed Field Ablation in more than 17,000 Patients with Atrial Fibrillation in the MANIFEST-17K Study

Ekanem E, Neuzil P, Reichlin T. et al.

Nature Medicine (July 2024), available here

- This safety registry included 17,642 patients treated across 106 centers and 413 operators, encompassing 91.4% of all commercial centers using FARAPULSE.
- The major adverse event rate was < 1% with no reports of esophageal fistula or dysmotility, pulmonary vein stenosis or persistent phrenic nerve injury.
- One of the goals of this registry was to look for any unusual adverse events that would only be apparent after thousands of procedures. Two rare events were noted, coronary spasm and hemolysis.
  - The rate of coronary spasm was (0.14%) with a majority (88%) being proximity-related occurring with off-label use of the catheter during mitral isthmus MI or CTI ablation. There were 3 reports of generalized spasm (0.02%) which is lower than the cited thermal (RFA/CBA) rate of 0.19%.
  - Hemolysis resulting in acute renal failure was rare (< 1 in 1000) and likely manageable with hydration and being aware of number of lesions applied.

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- Evidence of learning curve at both the physician/site level and the EP community was seen in the significant decrease in rates of pericardial tamponade and minor vascular complications and improvements in stroke and transient phrenic nerve paresis rates from the initial MANIFEST-PF[1] registry to MANIFEST-17K.

Safety and Feasibility of Pulmonary Vein Isolation Utilizing Pulsed Field Ablation in Patients with Symptomatic Atrial Fibrillation and Implanted Watchman Devices
Garza I, Al Taii, H, Narayanan A. et al.

Journal of Interventional Cardiac Electrophysiology (July 2024), available here

- FARAWAVE PVI was performed in 7 patients that had previously implanted Watchman devices.
- Watchman devices were implanted at a median time of 534 days prior to the index ablation.
- Ablation was performed with no reported major adverse events (intraprocedural CVA, post-procedural CVA, major or minor bleeding events, device embolization, or cardiac tamponade).
- In 6 of 7 patients, a low-dose direct oral anticoagulant (DOAC) strategy was implemented post-PFA.

Next-Generation Atrial Fibrillation Ablation: Clinical Performance of Pulsed-Field Ablation and Very High-Power Short-Duration Radiofrequency
Soubh N, Gronwald J, Haarmann H, et al.

Journal of Interventional Cardiac Electrophysiology (July 2024), available here

- This was a retrospective analysis of 82 AF patients receiving FARAPULSE (n = 52) or vHPSD-RF (90 W, 4 s) (n = 30).
- AF recurrence occurred in 4 patients following PFA and 5 patients following vHPSD-RF at 6 months.
- The total procedure duration and the left atrial dwell time were significantly shorter in the PFA group and the fluoroscopy time were significantly greater in the PFA group.

How to Perform Pulmonary Vein Isolation using a Pentaspline Pulsed Field Ablation System for the Treatment of Atrial Fibrillation
Badertscher P, Knecht S, Rosso R. et al.

Heart Rhythm (June 2024), available here

- Published guide on how to use the FARAWAVE catheter.

Pulsed Field vs Very-High Power Short-Duration Radiofrequency Ablation for Atrial Fibrillation: Results of a Multicenter, Real-World Experience
Della Russo A, Compagnucci P, Anselmino M. et al.

Heart Rhythm (June 2024), available here

- FARAPULSE (n = 192) was compared to vHPSD (n = 342) in PAF (n = 368) and PersAF (n = 166) patients.
- FARAPULSE procedures were significantly shorter than vHPSD (70 min vs 100 min) but had longer fluoro times.
- FARAPULSE procedures were performed more often under general anesthesia.
- Safety events were similar between groups FARAPULSE (4%), vHPSD (3%) with a similar 12-month freedom from recurrent atrial tachycardias; FARAPULSE (75%) and vHPSD (76%).

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Pulsed Field Ablation of Atrial Fibrillation and Atrial Tachycardia in Adult Patients with Congenital Heart Disease
Krause U, Bergau L, Zabel M. et al.

Circulation: Arrhythmia and Electrophysiology (June, 2024), available here

- 21 patients with various types of congenital heart disease (mild, n = 2 (10%); moderate, n = 15 (71%); and severe, n = 4 (19%) were enrolled.
- Follow-up was 6 months. Sustained post-procedure macro reentrant AT was noted in n = 2/21 (9.5%) of the total cohort within 48 hours after PFA, though only observed in patients with left atrial ablation (2/18, 11%).
- No recurrences of AT were seen in patients with right atrial ablation only, and no recurrence of AF was observed in any patient.

Superior Vena Cava Isolation using a Pentaspline Pulsed-Field Ablation Catheter: Feasibility and Safety in Patients Undergoing Atrial Fibrillation Catheter Ablation
Ollitrault P, Chaumont C, Font, J. et al.

Europace (June 2024), available here

- SVC isolation was performed using a standardized workflow in 105 patients with FARAPULSE. Acute isolation was achieved in 105/105 (100%) of patients after 6 ± 1 applications.
- Transient phrenic nerve stunning occurred in 67/105 (64%) of patients, all of which resolved during the procedure.
- Transient high degree sinus node dysfunction occurred in 5/105 (4.7%) of patients with no recurrence at the end of the procedure and until discharge.
- There were no reported complications when followed up with at 3-months.

Procedural Efficiency is Enhanced Combining the Pentaspline Pulsed Field Ablation Catheter with Three Dimensional Electroanatomical Mapping System for Pulmonary Vein Isolation
Zamponi A, Olson J, Scheel S. et al.

Journal of Interventional Cardiac Electrophysiology (June 2024), available here

- PAF or Pers AF (n = 248) patients undergoing PVI with FARAPULSE were compared. The control group (n = 104) received conventional FARAPULSE ablation with fluoroscopic guidance alone, while the intervention group (n = 144) underwent PVI with FARAPULSE with 3D-EAM integration.
- In the 3D-EAM-PFA group, procedural time was 63.3 ± 14.3 min, compared to 65.6 ± 14.9 min in the control group.
- The 3D-EAM group experienced significantly reduced FT (9.7 ± 4.4 min vs 16.7 ± 5.2 min) and compared to the control group, respectively.
- No major complications were observed in either group.

National Workflow Experience with Pulsed Field Ablation for Atrial Fibrillation: Learning Curve, Efficiency, and Safety
Bisignani A, Schiavone M, Solimene F. et al.

Journal of Interventional Cardiac Electrophysiology (May 2024), available here

- Consecutive AF patients n = 752 (66.9% PAF) patients underwent ablation with FARAPULSE.
- A total of 62.5% of procedures were performed by operators that had performed > 20 PFA procedures.
- Both time to PVI and fluoroscopy time significantly improved after 10 procedures with a trend toward procedure time reduction.
- FARAPULSE procedure skin-to-skin time was lower than the historical skin-to-skin time in 217 (62.4%) procedures; it was similar in 112 (32.2%) cases and higher than the historical procedures in 19 (5.5%) with no major complications reported.

2024 clinical publications

Pulsed Field Ablation with the Pentaspline Catheter Compared with Cryoablation for the Treatment of Paroxysmal Atrial Fibrillation in the UK NHS: A Cost-Comparison Analysis
Duxbury C, Begley D, Heck P. et al.

BJM (May 2024), available here

- A cost-comparison model was developed to compare the expected 12 month costs of AF ablation with either FARAPULSE or CBA for a single patient.
- Costs for a single patient treated with FARAPULSE were −3% (−£343) less over 12 months than those who received treatment with CBA.
- PFA was associated with 16% higher catheter costs but the reduction in repeat ablation reduced cost by over 50% and the cost of managing complications was −£211 less in total for FARAPULSE vs CBA.

Safety and Effectiveness of Additional Left Atrial Posterior Wall Ablation using Pulsed Field Ablation for Persistent and Long-Standing Persistent Atrial Fibrillation Patients
Kordić L, Sikirić I, Brešković, T. et al.

Journal of Cardiovascular Electrophysiology (May 2024), available here

- The long-term AF/AFL/AT recurrence was assessed with a retrospective observational study of 94 patients with half of the patients having LS-PersAF.
- There was AF/AFL/AT recurrence in 50 patients (54.3%) with an increase in PW low-voltage areas and AF classification being associated with arrhythmia recurrence.
- FARAPULSE PVI+PWA had the best outcome in PersAF patients without extensive LA fibrosis.
- The addition of PWA + PVI using FARAPULSE was safe in this study and did not significantly increase ablation time.

Pulsed Field Ablation in Patients with Cardiac Implantable Electronic Devices: An Ex Vivo Assessment of Safety
Lennerz C, O'Connor M, Schaarschmidt C. et al.

Journal of Interventional Cardiac Electrophysiology (May 2024), available here

- FARAWAVE was tested on 44 CIEDs (16 pacemaker, 21 ICDs, 7 CRT-P/D) with 1980 PFA applications (45 per CIED) < 5 cm from the lead tip and < 15 cm from the generator.
- All devices were checked before and after PFA application for proper sensing and pacing functionality.
- There was no change in device settings, functionality and electrical parameters, and there was no macroscopic damage to the devices.
- Clinically relevant EMI appeared with oversensing and pacing inhibition but not tachycardia detection.
- Bipolar PFA appears safe and does not result in damage to CIEDs or leads. Clinically relevant EMI does occur, but appropriate peri-procedural programming may mitigate this. In vivo studies are needed to confirm the findings.

Nitroglycerin to Ameliorate Coronary Artery Spasm During Focal Pulsed-Field Ablation for Atrial Fibrillation
Malyshev, M, Neuzil P, Petru J. et al.

JACC: Clinical Electrophysiology (May 2024), available here

- The FARAPOINT catheter was used for cavo-tricuspid isthmus (CTI) ablation.
- Angiography of the right coronary artery was performed before, during, and after PFA.
- Beyond no nitroglycerin (n = 5), and a few testing strategies (n = 8), 2 primary nitroglycerin administration strategies were studied:
  – Multiple boluses (3-2 mg every 2 min) into the right atrium (n = 10)

– A bolus (3 mg) into the right atrium with continuous peripheral intravenous infusion (1 mg/min; n = 10).
- Without nitroglycerin, CTI ablation provoked moderate-severe vasospasm in 4 of 5 (80%) patients.
- With repetitive nitroglycerin boluses, severe spasm did not occur, and mild-moderate vasospasm occurred in only 2 of 10 (20%) with no patients experiencing ST-segment changes.
- Using the bolus + infusion strategy, severe and mild-moderate spasm occurred in 1 and 3 of 10 patients (aggregate 40%).

Pulsed-Field Ablation for Repeat Procedures after Failed Prior Thermal Ablation for Atrial Fibrillation
Maurhofer J, Tanner H, Kueffer T. et al.

Heart Rhythm O2 (May 2024), available here

- There were 186 patients undergoing a repeat ablation procedure with FARAPULSE.
- The prior ablation modality was radiofrequency in 129 patients (69.4%), cryoballoon in 51 (27.4%), and epicardial ablation in 6 (3.2%).
- During the redo procedure, 258 of 744 PVs (35%) showed reconnections.
- Additional antral ablations were applied in 236 of 486 still isolated veins (49%) and posterior wall ablation was added in 125 patients (67%).
- Major complications occurred in 1 patient (transient ischemic attack 0.5%).
- KM Freedom from arrhythmia recurrence was 78% after 6 months and 54% after 12 months.

Comparison of Cerebral Safety Following Atrial Fibrillation using Pulsed Field and Thermal Ablation: Results of the Neurological Assessment Subgroup in the ADVENT Trial
Patel C, Gerstenfeld E, Gupta S. et al.

Heart Rhythm (May 2024), available here

- In the ADVENT trial a total of 77 patients with PAF were enrolled at 6 centers; 71 had analyzable scans (34 PFA; 37 thermal ablation).
- The initial center review identified 6 PFA and 4 thermal scans as SCE/SCL positive. In a blinded core lab, 3 PFA and 0 thermal SCE/SCL findings were confirmed.
- MRI findings revealed one patient with 2-4 mm SCEs, one patient with a 3 mm SCE, and one patient with 2 SCLs (5.5 mm and 11 mm).
- All mRS and NIHSS scores were 0 prior to discharge and at 90-day follow-up.
- There were only two neurological safety events (1 TIA [PFA]) and 1 stroke (thermal) in the ADVENT study, neither of which was part of the NAS.

Pulsed Field vs Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation: Recurrent Atrial Arrhythmia Burden
Reddy V, Mansour M, Calkins H. et al.

Journal of the American College of Cardiology (May 2024), available here

- The impact of post-ablation AA burden on outcomes was assessed as well as the effect of ablation modality on AA burden in the ADVENT clinical trial.
- AA burden was calculated from percentage AA on Holters (6 and 12 months) and transtelephonic electrocardiogram monitors (weekly and symptomatic monitoring).
- From 593 randomized patients (299 FARAPULSE, 294 thermal), using aggregate PFA/thermal data, an AA burden exceeding 0.1% was associated with a significantly reduced quality of life and an increase in clinical interventions (i.e. redo ablation, cardioversion, and hospitalization).
- Compared with thermal ablation, FARAPULSE ablation more often resulted in an AA burden less than the clinically significant threshold of 0.1% AA burden.

2024 clinical publications

Impact of Left Atrial Posterior Wall Ablation During Pulsed-Field Ablation for Persistent Atrial Fibrillation: A MANIFESTPF Registry SubStudy
Turagam MK, Neuzil P, Schmidt B. et al.

JACC: Clinical Electrophysiology (May 2024), available here

- Retrospective sub-study of the MANIFESTPF registry comparing PFA with PVI vs PVI + PWA in persistent AF patients.
- Analysis included 547 patients: 131 received PVI + PW ablation (24%), the remaining had PVI only
- One-year arrhythmia-free survival: 66.4% for PVI + PWA vs 73.1% for PVI-only (P = 0.68), with no significant difference.
- Major adverse event rates were low and comparable: PVI + PWA 2.2% vs PVI, 1.4% (p = 0.51).

Autonomic Effects of Pulsed Field vs Thermal Ablation for Treating Atrial Fibrillation: Sub analysis of ADVENT
Gerstenfeld E, Mansour M, Whang W. et al.

JACC: Clinical Electrophysiology (May 2024), available here

- Baseline heart rate (HR) was acquired from a pre-ablation 12-lead ECG. Follow-up HRs, as well as heart rate variability (HRV: SDNN, SDANN) metrics, were derived from 72-hour Holter monitors at 6 and 12-months.
- This ADVENT sub-study included 379 PAF patients undergoing FARAPULSE (n = 194) or thermal ablation (n = 185; n = 102 RFA, n = 83 CBA) completing 6 and 12-month Holter monitoring.
- Compared to FARAPULSE, thermal patients had significantly greater increases in HR from baseline to 6 months and 12 months. This increase in HR at 6- and 12 months was similar between CBA and RFA.
- Based on the study metrics, HRV was significantly lower at both 6 and 12 month after thermal ablation compared to FARAPULSE.

Acute Kidney Injury after Catheter Ablation of Atrial Fibrillation: Comparison between Different Energy Sources
Jordan F, Knecht S, Isenegger C, et al.

Heart Rhythm (April 2024), available here

- 2,570 patients were treated with RFA (n = 1707), CBA (n = 557), or FARAPULSE (n = 306) and blood samples were collected to assess hemolysis indicators.
- AKI was found in 73 (4.3%), 10 (1.8%) and 3 (1.0%) patients treated with RFA, CBA and FARAPULSE, respectively.
- There was a statistically significant positive correlation in the RFA group for ablation duration and the creatinine level after the procedure with no correlation between CBA or FARAPULSE.
- At least two hemolysis indicators (bilirubin, LDH or urea levels) were elevated the day after the procedure in 12.4%, 11.8% and 13.5% in the RFA, CBA and FARAPULSE groups.
- Overall, there was a very low incidence of AKI for FARAPULSE (1.0%), which was lower than for the other energy sources. Unspecific hemolysis indicators such as LDH were elevated in one-third of patients after all ablation modalities and dialysis was never necessary.

2024 clinical publications

Durability of Pulmonary Vein Isolation Using Pulsed-Field Ablation: Results from the Multicenter EU-PORIA Registry

Kueffer T, Bordignon S, Neven K, et al.

JACC: Clinical Electrophysiology (April 2024), available here

- In the EU-PORIA registry 1,184 patients (62% paroxysmal atrial fibrillation) underwent de novo ablation with FARAPULSE with 272 (23%) having an arrhythmia recurrence.
- There were 144 (53%) redo procedures at a median of 7 months after the first ablation.
- Three-dimensional EAM identified 404 of 567 pulmonary veins (71%) were durability isolated with 54 patients (38%) all having their pulmonary veins durably isolated.
- Prior operator experience with CBA was associated with a higher PVI durability compared to operators with only RFA experience. Operator experience and device size had no impact on lesion durability.

Pulsed-Field vs. Cryoballoon vs. Radiofrequency Ablation: Outcomes After Pulmonary Vein Isolation in Patients with Persistent Atrial Fibrillation

Kueffer T, Stettler, R, Maurhofer J. et al.

Heart Rhythm O2 (April 2024), available here

- A total of 533 patients with PersAF underwent PVI using FARAPULSE (n = 214, 39%), CBA (n = 190, 36%), or RFA (n = 129, 24%).
- Procedures with FARAPULSE guided by fluoroscopy were shorter than those with CBA, and procedures with FARAPULSE in combination with 3-D electroanatomic mapping were shorter than those with RFA.
- Safety events occurred in 2.3%, 2.6%, and 0.8% in the FARAPULSE, CBA, and RFA groups, respectively.
- The 1-year confounder-adjusted estimate for freedom from atrial arrhythmias was 62.1% for CBA, 55.3% for FARAPULSE, and 48.3% for RFA.

Role of 3D Electro-Anatomical Mapping on Procedural Characteristics and Outcomes in Pulsed-Field Ablation for Atrial Fibrillation

Badertscher P, Teodor Serban T, Isenegger C. et al.

Europace (March 2024), available here

- 197 consecutive patients were included with 127 patients (64%) with PVI + mapping and 70 patients (36%) with no mapping. Baseline characteristics were similar between the groups.
- The median procedure time, left atrial dwell time, and the fluoro time for the mapping vs. the non-mapping group were 55 min vs. 28 min; 38 min vs 15 min; and 11 min vs 8 min, respectively.
- 9% (11/127 patients) of the mapping group had at least 1 PV incompletely isolated and required additional applications.
- There were two complications in the mapping group (one stroke, one coronary artery air embolism), and none were observed in the non-mapping group.
- The recurrence rate of atrial arrhythmias during a median follow-up of 267 days was 14% in the mapping group and 17% in the non-mapping group.

Evaluating Autonomic Outcomes After Pulmonary Vein Isolation: The Differential Effects of Pulsed-Field and Radiofrequency Energy

Valeriano C, Buytaert D, Addeo, L. et al.

Heart Rhythm (April, 2024), available here

- A total of 105 patients were included (PF:35; RFA:70) with the 2 cohorts having similar baseline characteristics.
- In the RF group, HR significantly increased when compared to baseline and the difference persisted after 3 months. This change in HR was not observed in the FARAPULSE group.
- Additionally, the RF cohort exhibited significantly lower HRV indices 3 months after PVI.
- FARAPULSE PVI did not result in an increase in HR and the HRV is notably higher following FARAPULSE ablation suggesting PFA has a limited influence on the autonomic nervous system.

2024 clinical publications

Prospective 1-Year Results of Atrial Fibrillation Ablation using the Pentaspline Pulsed Field Ablation Catheter: The Initial French Experience
Chaumont C, McDonnell E, Boveda S. et al.

Archives of Cardiovascular Disease (March 2024), available here

- There were 311 patients included (PAF = 53%, PersAF = 35%, LS PersAF = 11%). Additional non-pulmonary vein pulsed field ablation applications were performed in 104/311 patients.
- One-year freedom from arrhythmia recurrence was 77.6% in the overall population and was significantly higher in patients with PAF (88.4%) compared to PersAF (69.7%) and those with LS PersAF (49.0%).
- The major complication rate was 2.6% (tamponade n = 4, stroke n = 2, and coronary spasm n=1).

Pentaspline Pulsed Field Ablation Catheter Versus Cryoballoon for Atrial Fibrillation Ablation: Results from a Prospective Comparative Study
Chaumont, Hayoun, C, Savoure A. et al.

Journal of the American Heart Association, (March 2024), available here

- PVI-only patients were either treated with FARAPULSE or CBA with the choice of the energy was based on patients' preference between general anesthesia (PFA) and local anesthesia (CBA).
- A total of 301 patients (PAF = 220) a first PVI procedure performed using PFA (n = 151) or cryoballoon (n = 150).
- Procedure duration was significantly longer in the cryoballoon group. Transient and persistent phrenic nerve injuries were observed in the CBA group only (13/150 and 2/150, respectively).
- One-year freedom from atrial arrhythmia was significantly higher in the FARAPULSE group compared with the CBA group (87.9% versus 77.7%).

Pulsed Field Ablation Technology for Pulmonary Vein and Left Atrial Posterior Wall Isolation in Patients with Persistent Atrial Fibrillation
Schavone M, Solimeme, F, Maltraso, M. et al.

Journal of Cardiovascular Electrophysiology (March 2024), available here

- Patients undergoing pulmonary vein isolation (PVI) alone, PVI + PWI and redo procedures were compared.
- There were 249 patients; 21.7% had LS PersAF, PWI was performed in 57.6% of cases, with 15.3% being redo procedures.
- Median procedure times did not differ between groups. No major complications occurred, with a 2.4% minor complication rate.
- During a median follow-up of 273 [191–379] days, 41 patients (16.5%) experienced recurrence with a mean time to recurrence of 223 ± 100 days and no difference across ablation strategies.

Contemporary Catheter Ablation of Complex Atrial Tachycardias after Prior Atrial Fibrillation Ablation: Pulsed Field vs Radiofrequency Current Energy Ablation Guided by High-Density Mapping
Gunawardene M, Harloff T, Jularic M. et al.

Europace (March 2024), available here

- Atrial tachycardia (AT) patients were matched 1:1 to RFA (n = 28) vs FARAPULSE (n = 28). Ablation was performed at the assumed critical isthmus with additional ablations, as necessary.
- A total of 77 AT (n = 67 LAT, n = 10 RAT; 77% macro-re-entries) occurred with n = 32 LAT in the PFA group and n = 35 LAT in the RFA group.
- Of all LAT, 94% (PFA group) vs. 91% (RFA group) successfully terminated to sinus rhythm or another AT. Procedure times were shorter for FARAPULSE and fluoroscopy times longer. There were no major complications.
- After one-year follow-up, estimated arrhythmia free survival was 63% (PFA group) and 87% (RFA group).

2024 clinical publications

Procedural Performance and Outcome after Pulsed Field Ablation for Pulmonary Vein Isolation: Comparison to a Reference Radiofrequency Database
De Becker B, El Haddad M, De Smet M, et al.

European Heart Journal (March, 2024), available here

- Patients were propensity matched, 161 CLOSE protocol guided RFA patients from the PowerPlus study and 161 PFA guided PAF or PersAF patients with FARAPULSE.
- Procedure time was significantly shorter in the FARAPULSE group (47 min vs 71 min for RFA) with the fluoroscopy time being significantly longer in the FARAPULSE group (15 min PFA vs 11 min RFA).
- One serious adverse event occurred (TIA) in a patient with thrombocytosis in the FARAPULSE group.
- During a 6-month follow-up period, 24 (15%) FARAPULSE and 27 (17%) RFA patients experienced recurrence with 20 (12%) FARAPULSE repeat procedures and 11 (7%) RFA.
- HDM revealed that 7/20 (35%) patients in the FARAPULSE and 2/11 (18%) patients in the RFA group had all 4 PVs durably isolated.

Durability of Pulmonary Vein Isolation Using Pulsed-Field Ablation: Results from the Multicenter EU-PORIA Registry
Kueffer T, Bordignon S, Neven K, et al.

JACC: Clinical Electrophysiology (February, 2024), available here

- 1,184 patients (62% PAF) had a PVI procedure using FARAPULSE. 272 (23%) patients had an arrhythmia recurrence.
- Of these, 144 (53%) underwent a left atrial redo procedure a median of 7 months post-ablation.
- 3D electro-anatomical maps identified 404 of 567 pulmonary veins (71%) with durable isolation.
- Physicians with experience with CBA had a significantly higher PVI durability rate compared to operators with only RFA experience (76% vs 60%).
- The operators' experience in AF ablation (≤ 5 vs > 5 years) or the size of the PFA device used (31 mm vs 35 mm) did not have an impact on lesion durability in redo patients.

Does Acute Coronary Spasm from Pulsed Field Ablation Translate into Chronic Coronary Arterial Lesions?
Malyshev Y, Neuzil P, Petru J, et al.

JACC: Clinical Electrophysiology (February, 2024), available here

- Single-center study where patients had coronary angiography performed who previously had vasospasm during FARAPULSE ablation to determine long-term effects of PFA on coronary arteries.
- Coronary vasospasm occurred during FARAPULSE ablation in 30 patients.
- The spasm was localized as follows:
  - Adjacent to the RCA in 21 pts during CTI ablation with either FARAWAVE (38%) or FARAPOINT (62%) catheters.
  - Adjacent to the left circumflex artery in 8 patients.
- Intracoronary nitroglycerin helped resolve the vasospasm in 18 patients, whereas it spontaneously resolved in the remaining 12 patients with one patient (3.3%) having transient ST-segment depression.
- Coronary angiography was performed after a median of 11 months post-ablation.
- No patients (0 of 30) had new coronary irregularities or stenosis at the site of previous vasospasm, whether the initial PFA procedure had been performed with FARAWAVE or FARAPOINT.
- This was an initial description of favorable long-term safety of FARAPULSE PFA when performed in close proximity to coronary vessels.

2024 clinical publications

Pulmonary Vein Narrowing after Pulsed Field Versus Thermal Ablation
Mansour M, Gerstenfeld E, Patel C, et al.

Europace (February, 2024), available here

- ADVENT was a randomized, single-blind study comparing FARAPULSE with thermal ablation (RFA and CBA) to treat PAF. Pulmonary vein diameter and aggregate cross-sectional area were measured at baseline and 3 months with imaging.
- The pre-specified, formally tested, secondary safety endpoint found significantly less PV narrowing after PFA (-0.9%) vs thermal ablation (-12%). No subject had significant (≥ 70%) PV stenosis.
- The aggregate PV cross-sectional area change was primarily driven by the RFA sub-cohort (–19.5%) vs CBA sub-cohort (–3.3%).
- Almost half of all PFA PV diameters did not decrease, but the majority (80%) of RF PVs decreased, regardless of PV anatomic location.

Long-Term Outcomes of the Pentaspline Pulsed-Field Ablation Catheter for the Treatment of Paroxysmal Atrial Fibrillation: Results of the Prospective, Multicentre FARA-Freedom Study
Metzner A, Fiala M, Vijgen J, et al.

Europace (February, 2024), available here

- FARA-Freedom (NCT05072964) was a prospective, non-randomized, single-arm, multicenter study of 179 PAF patients at 13 centers across 6 European countries.
- FARA-Freedom procedures were efficient (71.9 ± 17.6 min) with a left atrial dwell time of 41 minutes (inclusive of the 20-minute waiting period) and 11.5 minutes of fluoroscopy.
- The freedom from the primary safety event rate in FARA-Freedom was 98.9%. There were no reports of coronary spasm, persistent phrenic nerve palsy, PV stenosis, or AE fistula.
- The freedom from the primary effectiveness event rate was 66.6%. The monitoring compliance was high with an 88.4% compliance with weekly event monitoring and 90.3% with 72-hour Holter monitoring.
- In this study, FARAPULSE was found to be effective and safe with rigorous endpoint definitions and high monitoring compliance.

Acute Kidney Injury Resulting from Hemoglobinuria after Pulsed-Field Ablation in Atrial Fibrillation: Is It Preventable?
Mohanty S, Casella M, Compagnucci P, et al.

JACC: Clinical Electrophysiology (February, 2024), available here

- Patients were split into two groups, group 1 was patients who did not receive post-ablation hydration immediately after the procedure (n = 28), the remainder of study patients received planned fluid infusion (0.9% sodium chloride ≥2 L) after the procedure (n = 75).
- Of the 28 patients in group 1, 21 (75%) experienced hemoglobinuria during the 24 hours after catheter ablation and their post-ablation serum creatinine (S-Cr) was significantly higher than the baseline value in those 21 patients.
- Of those 21 patients, 4 (19%) had S-Cr >2.5 mg/dL. The mean number of PF applications was significantly higher in those 4 patients than in the other 17 patients experiencing hemoglobinuria.
- In the second group of patients who received fluid infusion, no significant changes in S-Cr were noted.
- In multivariable analysis, both hydration and number of PFA applications were independent predictors of post-procedure acute kidney injury.

2024 clinical publications

Peri-Procedural Intravascular Hemolysis during Atrial Fibrillation Ablation: A Comparison of Pulsed-Field with Radiofrequency Ablation
Osmancik P, Bacova B, Herman D, et al.

medRxiv (February, 2024), available here

- 70 PAF patients were enrolled, 47 patients in the PFA group (22 PVI only, 36.4±5.5 PFA applications vs 25 PVI plus additional ablations, 67.3±12.4 PFA applications). 23 patients underwent RFA.
- Compared to baseline, the RBCμ concentration increased ~ 12-fold post-PFA and returned to baseline by 24 h. This increase was significantly greater in PVI-plus compared to PVI-only patients.
- There was also a significant peri-procedural increase in RBCμ after RFA.
- At 24 h with PFA, the concentration of LDH and indirect bilirubin increased, and haptoglobin significantly decreased.
- At 24 h with RFA, there were smaller significant changes in LDH and haptoglobin with no change in bilirubin.

Impact of Left Atrial Posterior Wall Ablation during Pulsed Field Ablation for Persistent Atrial Fibrillation: A MANIFEST-PF Registry Sub-Study
Turagam M, Neuzil P, Schmidt B, et al.

AF Symposium (February, 2024), available here

- 131/547 PersAF (24%) patients in MANIFEST-PF received adjunctive left atrial posterior wall (LAPW) ablation.
- Compared to PVI-alone, patients receiving adjunctive LAPW ablation were younger, had a lower CHA_2DS_2-VASc score, and were more likely to receive mapping and ICE imaging.
- The 1-year Kaplan-Meier estimate for freedom from atrial arrhythmias was similar between groups (PVI+LAPW: 66.4% vs PVI: 73.1%).
- After propensity matching, the 1-year effectiveness remained similar between groups (PVI+LAPW: 71.7% vs. PVI: 68.5%).
- There was no significant difference in major adverse events between the groups (2.2% vs 1.4%).

Left Atrial Posterior Wall Isolation Using Pulsed-Field Ablation: Procedural Characteristics, Safety, and Mid-Term Outcomes
Badertscher P, Mannhart D, Weidlich S, et al.

Journal of Interventional Cardiac Electrophysiology (January, 2024), available here

- 100 patients underwent PFA-PVI with PWI with FARAWAVE.
- Median procedure time was 66 (IQR: 59-77) min, and fluoroscopy time was 11 (8–14) min.
- PWI using PFA was achieved in 100% of patients with a median of 19 (IQR: 14-26) applications with no reported major complications.
- Recurrent AF/AT was noted in 15 patients (15%) during a median follow-up of 144 days.

2024 clinical publications

A Zero-Exchange Approach for Left Atrial Access in Pulmonary Vein Isolation with Pulsed Field Ablation
Bejinariu A, Spieker M, Makimoto H, et al.

Journal of Cardiovascular Electrophysiology (February, 2024), available here

- Transeptal puncture (TSP) was performed with transesophageal echocardiography guidance in 166 patients, using the FARADRIVE sheath and a 98 cm matched Brockenbrough needle.
- The median duration of the procedure was 60 min, median time to TSP was 15 min.
- In one patient a non-TSP related pericardial tamponade occurred which was managed with pericardial puncture.
- Direct TSP with skipping sheath exchange using the large diameter FARADRIVE sheath was safe, feasible, and reduced costs.

Pulsed-Field Ablation of Atrial Fibrillation: Kinetics of Release of Multiple Cardiac Biomarkers
Casella J, Compagnucci P, Malacrida M, et al.

Journal of Interventional Cardiac Electrophysiology (January, 2024), available here

- 72 patients were treated with FARAPULSE. Blood samples were evaluated for 14 cardiac biomarkers for stress, myocardial fibrosis, inflammation and coagulation activity 3, 24, and 48 hours after ablation.
- CK-MB, hs-cTnI, myoglobin, and WBC levels displayed an increase at 3 hours post-ablation, followed by a decline towards lower values within 24 h. C-reactive protein peaked at 48 hours, exhibiting a gradual increase over time.
- Markers of hemolysis and potential end organ damage exhibited fluctuations within the normal range for this population.
- Following the procedure, markers indicating coagulation activity, such as hemoglobin, hematocrit, and platelet count, exhibited a decline which was similar to other ablation energies.
- There appeared to be no correlation between cardiac enzyme elevations and extension of PFA beyond the PVs.

Pulsed Field Ablation of the Right Superior Pulmonary Vein Prevents Vagal Responses Via Anterior Right Ganglionated Plexus Modulation
Del Monte, M, Della Rocca D, Pannone, L, et al.

Heart Rhythm (January, 2024), available here

- In 40 patients, PVI was performed first ablating the left superior pulmonary vein (LSPV-first group). In 40 patients the RSPV was targeted first, followed by left PVs and right inferior PV (RSPV-first group). Heart rate (HR) and extracardiac vagal stimulation (ECVS) were evaluated at baseline, during PVI, and post-ablation to assess GP modulation.
- Significantly more vagal responses occurred in the LSPV-first group, 31 (78%) patients and 5 (13%) occurred in the RSPV-first group.
- Temporary pacing was needed in 14 (35%) patients in the LSPV-first group and 3 (8%) in the RSPV-first group. RSPV isolation was associated with similar acute HR increase in the two groups.
- No significant residual changes in HR or ECVS response were documented in both groups at the end of the procedure.

2024 clinical publications

Pulsed Electric Field, Cryoballoon, and Radiofrequency for Paroxysmal Atrial Fibrillation Ablation: A Propensity Score-Matched Comparison
Della Rocca D, Marcon L, Magnocavallo M, et al.

Europace (January, 2024), available here

- PVI-only ablation outcomes via FARAPULSE, CBA and RFA were propensity score matched yielding 174 PFA, 348 CRYO, and 348 RF patients.
- There were significant differences in first-pass isolation; 98.8% of pulmonary veins (PVs) with PFA, 81.5% with CBA, and 73.1% with RFA.
- Procedure and dwell times were significantly shorter with PFA, and 3D mapping system usage led to a significant reduction in fluoroscopy exposure with RFA.
- Overall complication rates were 3.4% (n = 6) with PFA, 8.6% (n = 30) with CBA, and 5.5% (n = 19) with RFA.
- The one-year Kaplan–Meier estimated freedom from any atrial tachyarrhythmia was 79.3% with PFA, 74.7% with CBA, and 72.4% with RFA. Freedom from AF was 85.5% with PFA, 78.5% with CBA, and 77.4% with RF.
- Among 145 repeat ablation procedures, PV reconnection rate was significantly different: 19.1% after PFA, 27.5% after CBA, and 34.8% after RFA.
- The most common site of PFA reconnection was the left superior PV (27.3%) consistently involving the anterior aspect and the carina of the vein.

Impact of Pulsed Field Ablation on Intraluminal Esophageal Temperature
Kirstein B, Heeger C, Vogler J, et al.

Journal of Cardiovascular Electrophysiology (January, 2024), available here

- Median intraluminal esophageal temperature change was statistically significant and increased by 0.8 ± 0.6 °C.
- A TESO increase ≥ 1° C was observed in 10/43 (23%) patients. The highest TESO measured was 40.3°C.
- All patients remained asymptomatic, and no atrio-esophageal fistula was reported on follow-up.

Posterior Wall Ablation by Pulsed-Field Ablation: Procedural Safety, Efficacy and Findings on Redo Procedures
Kueffer T, Tanner H, Madaffari A, et al.

Europace (January, 2024), available here

- Posterior wall ablation was performed in 215 patients (67% redo procedures) and was successful in all patients by applying a median of 36 PFA lesions.
- The rate of severe adverse events was 0.9%; one cardiac tamponade, and one vascular access complication.
- Median follow-up was 7.3 months. The one-year arrhythmia-free Kaplan–Meier analysis was 53%.
- A redo procedure was performed in 26 patients (12%) after a median of 6.9 months and showed durable PWA in 22 patients (85%) with minor lesion regression.
- There was posterior wall reconnection in four patients with three (75%) having roof-dependent AT.

2024 clinical publications

Efficacy of Intravenous Nitrates for the Prevention of Coronary Artery Spasm During Pulsed-Field Ablation of the Mitral Isthmus

*Ablation beyond pulmonary vein isolation and posterior wall ablation is outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

Menè R, Boveda S, Della Rocca DG, et al.

Circulation: Arrhythmia and Electrophysiology (January 2024), available here

- 182 patients had mitral isthmus (MI) ablation, 79 patients were pretreated with isosorbide dinitrate (ISDN+) and 103 in a historical control group without pretreatment (ISDN−).
- Baseline features (including coronary artery disease and prior angioplasty) were similar between ISDN+ vs ISDN− groups.
- PVI and PWA was successful in 100% of cases; bidirectional block across the mitral isthmus documented in 179 of 182 patients (98.3%).
- Number of PFA applications delivered on the MI was higher in ISDN+ group: median 14 (IQR: 11–39) vs 12 (IQR: 8–28) in ISDN− group; p = .018.
- Coronary artery spasm (CAS) incidence: 10 of 103 patients (9.7%) in ISDN− group vs 0 of 79 (0%) in ISDN+ group; P = .005.
- In the combined MI + CTI (cavotricuspid isthmus) applications, no drug-related hypotension or allergic reactions occurred in pretreated patients. Adjunct complications in the ISDN− group included air embolism (n = 1), cardiogenic shock (n = 1), non-sustained VT (n =1), and oxygen desaturation (n = 1) before first PFA on MI.

Pulsed Field Ablation and Cryoballoon Ablation for Pulmonary Vein Isolation: Insights on Efficacy, Safety and Cardiac Function

Rattka M, Mavrakis E, Vlachopoulou D, et al.

Journal of Interventional Cardiac Electrophysiology (January, 2024), available here

- 141 consecutive AF patients were treated with PFA (n = 94) or CBA (n = 47).
- At 1 year, 70% of the PFA patients and 61% of the CBA patients were free from AF/AT.
- After PFA, there was a significant improvement in left atrial volume index.
- PFA and CBA had similar efficacy outcomes, but PFA might induce left atrial reverse remodeling and contribute to left ventricular systolic function.

Pulsed Field versus Cryoballoon Ablation for Atrial Fibrillation: A Real-World Observational Study on Procedural Outcomes and Efficacy

Mileen R. D. van de Kar M, Slingerland S, Steenbergen G, et al.

Netherland Heart Journal (January, 2024), available here

- Retrospective cohort study conducted at a high-volume center comparing CBA and PFA in the real-world setting.
- 1,714 procedures were analyzed: 1,241 in the CBA group and 473 in the PFA group.
- The CBA group had a significantly higher incidence of phrenic nerve palsy compared with the PFA group (15 vs 0).
- The procedure duration was significantly shorter in the PFA group (95.0 vs 74.0 min).

2024 clinical publications

Severe Acute Kidney Injury Related to Hemolysis After Pulsed Field Ablation for Atrial Fibrillation
Venier S, Vaxelaire N, Jacon P, et al.

Europace (January, 2024), available here

- Acute kidney injury (AKI) occurred in 2 patients which was secondary to acute and severe hemolysis after a PFA procedure.
- 68 consecutive patients had a blood sample the day after the procedure for the assessment of hemolysis indicators.
- FARAPULSE was used with a total number of median applications of 64.
- Nineteen patients (28%) showed significantly depleted haptoglobin levels with a significant inverse correlation between the plasma level of haptoglobin and the total number of applications.
- Two groups were compared:
  - The hemolysis+ group (haptoglobin < 0.04 g/L) vs. the hemolysis– group.
  - The number of applications was significantly higher in the hemolysis+ group (75) vs the hemolysis– group (62).
  - More than 70 applications seem to have better sensitivity and specificity to predict hemolysis.

2023 clinical publications

Efficacy and Safety of Pulmonary Vein Isolation with Pulsed Field Ablation vs Novel Cryoballoon Ablation System for Atrial Fibrillation
Badertscher P, Weidlich S, Knecht S, et al.

Europace (December, 2023), available here

- 181 AF patients underwent PVI (PFA = 106) and (CBA = 75).
- The median procedure, left atrial dwell, and fluoroscopic times were similar between the PFA and the CB group; 55 min vs 58 min, 38 min vs 37 min, and 11 min vs 11 min, respectively.
- Three procedural complications were observed in the PFA group (two tamponades, one temporary ST elevation) and 3 complications in the CB group (3 reversible phrenic nerve palsies).
- During the median follow-up of 404 days, AF recurrence was similar in the PFA (24%) group and the CB (30%) group.

Pulsed Field Ablation of Atrial Fibrillation: An Initial Australian Single-Centre Experience
Lee X, Freeman B, Gunthorpe N, et al.

Heart, Lung and Circulation (December, 2023), available here

- 100 FARAPULSE procedures were performed in 97 patients under GA with a median procedure time of 74 minutes.
- At median follow-up of 218 days, the Kaplan-Meier estimate for freedom from atrial arrhythmias at 180 days was 87%.
- Two (2%) pseudoaneurysm vascular access complications occurred. There were no reported thromboembolic complications, stroke, phrenic nerve palsy, pulmonary vein stenosis, atrio-esophageal fistula, or pericardial tamponade.

Myocardial Injury and Inflammation Following Pulsed-Field Ablation and Very High-Power Short-Duration Ablation for Atrial Fibrillation
Popa M, Bahlke F, Kottmaier M, et al.

Journal of Cardiovascular Electrophysiology (December, 2023), available here

- 179 patients with paroxysmal AF received de novo PVI with standard power RFA (30–40 W/20–30 s, n = 52), power-controlled HPSD (70 W/5–7 s, n = 60), temperature-controlled HPSD (90 W/4 s, n = 32), and FARAPULSE PFA (n = 35).
- High-sensitivity cardiac troponin T (hs-cTnT), creatine kinase (CK), CK MB isoform (CK-MB), and white blood cell (WBC) count were determined before and after ablation.
- Post-ablation hs-cTnT release was significantly higher with PFA, HPSD-70W, and HPSD-90W than with standard RFA.
- CK and CK-MB release was increased with PFA by 3.4-fold and 5.8-fold, respectively, as compared to standard RFA.
- PFA was associated with the lowest elevation in WBC compared to standard RFA, HPSD-70W, and HPSD-90W.
- PFA was associated with the highest myocardial injury and the lowest inflammatory reaction compared to the other energies tested.

2023 clinical publications

Intracardiac Echocardiography–Guided Pulsed-Field Ablation for Successful Ablation of Atrial Fibrillation: A Propensity-Matched Analysis from a Large Nationwide Multicenter Experience
Dello Russo A, Tondo C, Schillaci V, et al.

Journal of Interventional Cardiac Electrophysiology (November, 2023), available here

- 556 patients were analyzed: 357 (66%) with paroxysmal AF, 499 (89.7%) undergoing de novo PVI.
- ICE-guided procedures ($n = 138$) were propensity matched with patients with a standard approach ($n = 138$).
- There were no differences in procedural metrics and no major procedure-related adverse events were reported.
- ICE-guidance of PFA was not associated with an improvement in procedural metrics.

Pulsed-Field Ablation Does Not Induce Esophageal and Periesophageal Injury—A New Esophageal Safety Paradigm in Catheter Ablation of Atrial Fibrillation
Grosse Meininghaus D, Freund R, Koerber B, et al.

Journal of Cardiovascular Electrophysiology (November, 2023), available here

- 20 FARPULSE patients were compared to a previous cohort of 57 patients who underwent thermal ablation (33 CBA, 24 RFA).
- Following PFA, there were no mucosal lesions, food retention, or ablation induced vagal nerve injury; 4 patients showed periesophageal edema.
- After thermal ablation, 33/57 (58%) showed esophageal or periesophageal injury; 4/57 mucosal lesion, 18/57 food retention, 17/57 vagal nerve injury and 20/52 edema.
- In contrast to thermal methods, PFA was not associated with the same amount of esophageal injury.

Pulsed-Field Ablation Does Not Worsen Baseline Pulmonary Hypertension Following Prior Radiofrequency Ablations
Mohanty S, Della Rocca D, Torlapati P, et al.

JACC: Clinical Electrophysiology (November, 2023), available here

- 28 non-PAF patients with pulmonary hypertension (PH) that failed >1 RFA were treated with FARAPULSE and propensity matched to 28 AF patients treated with a repeat RFA after a failed procedure.
- The groups had comparable baseline mean pulmonary artery pressures (mPAP).
- After adjustment for baseline mPAP, the least-squares means change at 3 months after ablation was –1.71 ± 1.03 mm Hg and 19.67 ± 1.03 mm Hg in PFA and RFA.
- The RFA group had significantly higher mPAP than in the PFA group with the post-ablation mPAP values increased in all (100%) of the RFA patients, and it either remained unchanged or was reduced in most (89.3%) of the PFA patients.
- In this propensity-matched population, no worsening of mPAP was detected following PFA in patients with PH undergoing a repeat procedure for recurrence.

2023 clinical publications

Myocardial Damage, Inflammation, Coagulation, and Platelet Activity During Catheter Ablation Using Radiofrequency and Pulsed-Field Energy
Osmancik P, Bacova B, Hozman M, et al.

JACC Clinical Electrophysiology (November, 2023), available here

- 65 AF patients were treated (PFA = 33) and (RFA = 32) with both groups being similar in baseline characteristics.
- Procedure and LA dwell times were substantially shorter in the PFA group (55 min vs 151 min and 36 min vs 116 min).
- Peak troponin release was substantially higher in the PFA group and both PFA and RFA were associated with similar extents (> 50%) of platelet and coagulation activation.
- Despite 10 times more myocardial damage, pulsed-field ablation was associated with a similar degree of platelet/coagulation activation, and slightly lower inflammatory response.

Durability of Pulmonary Vein Isolation for Atrial Fibrillation. A Meta-Analysis and Systematic Review
Serban T, Mannhart D, Abid Q, et al.

Europace (November, 2023), available here

- Metanalysis of 19 studies investigating 1050 patients (mean age 60 years, 31% women, time to remap 2–7 months) were included.
- In a pooled analysis, 99.7% of the PVs and 99.4% of patients were successfully ablated at baseline and 75.5% of the PVs remained isolated and 51% of the patients had all PVs persistently isolated at follow-up across all energy sources.
- In a pooled analysis of the percentages of PVs durably isolated during follow-up, the estimates of RFA were the lowest at 71%, but comparable with CBA (79%).
- Higher durability percentages were reported in PVs ablated with laser-balloon (84%) and PFA (87%).

Clinical Outcomes by Sex After Pulsed Field Ablation of Atrial Fibrillation
Turagam M, Neuzil P, Schmidt B, et al.

JAMA Cardiology (November, 2023), available here

- Of 1568 patients with AF who underwent PFA, female patients, as compared with male patients, were older, had more paroxysmal AF and fewer comorbidities such as coronary disease, heart failure, and sleep apnea.
- The 1-year Kaplan-Meier estimate for freedom from atrial arrhythmia was similar in male (79.9%) and female (76.3%) patients with no significant difference in acute major adverse events between groups.

Pulsed-Field Versus Cryoballoon Ablation for Atrial Fibrillation—Impact of Energy Source on Sedation and Analgesia Requirement
Wahedi R, Willems S, Feldhege J, et al.

Journal of Cardiovascular Electrophysiology (November, 2023), available here

- 100 PVI patients (PFA (n = 50), CBA (n = 50)) underwent PVI ablation.
- Requirement of propofol, midazolam, and sufentanyl was significantly higher in the PFA group compared to CBA.
- Sedation-associated complications did not differ between both groups.
- Non-sedation-associated complications procedure times did not differ between groups.

2023 clinical publications

A Real-World Case–Control Study on the Efficacy and Safety of Pulsed Field Ablation for Atrial Fibrillation
Yang M, Wang P, Hao Y, et al.

European Journal of Medical Research (November, 2023), available here

- 36 AF patients were treated with PFA and 36 patients with RFA.
- There were no significant differences in patient baseline demographics or AAD usage.
- The ablation time in the PFA group was markedly shorter than RFA.
- At 6 months, there was no statistically significant difference in efficacy.
- In this study, PFA was safe, efficient, and had a short learning curve.

Coronary Artery Spasm During Pulsed Field vs Radiofrequency Catheter Ablation of the Mitral Isthmus
Zhang C, Neuzil P, Petru J, et al.

JAMA Cardiology (November, 2023), available here

- 26 patients underwent PVI with either PFA (n = 17) or RFA (n = 9) along the mitral isthmus ablation.
- Coronary spasm was observed in 7 of 17 patients (41.2%) undergoing PFA: in 7 of 9 (77.8%) when the mitral isthmus ablation line was situated superiorly and in 0 of 8 when placed inferior.
- Coronary spasm did not occur in any of the 9 patients undergoing RFA.
- 5 patients received crossover PFA after RFA failed to achieve conduction block, coronary spasm occurred in 3 (60%).
- Most instances of spasm (9/10, 90%) were subclinical, with 2 (20%) requiring nitroglycerin administration. The median time to resolution of spasm was 5 minutes.

Versatility of the Novel Single-Shot Devices: A Multicenter Analysis
Cespón-Fernandez, M, Della Rocca D, Almorad A, et al.

Heart Rhythm (October, 2023), available here

- Procedural data from 12 electrophysiologists experienced with balloon technologies was analyzed for a total of 480 procedures (240 balloons, 120 FARAPULSE and 120 HELIOSTAR).
- During the follow-up period of 6.86 ± 3.82 months, there were 11 atrial tachyarrhythmia recurrences (9.17%) in the HELIOSTAR group and 8 (6.67%) in the FARAPULSE group after the 3-month blanking period.
- The number of cases needed to become confident with the new technology, we found a mean number of 10 and 17 procedures for FARAPULSE and HELIOSTAR.

Investigating Deep Sedation with Intravenous Ketamine in Spontaneous Respiration during Pulsed-Field Ablation
Iacopino S, Filannino P, Artale P, et al.

Journal of Cardiothoracic and Vascular Anesthesia (October, 2023), available here

- The sedation protocol was the intravenous administration of fentanyl (1.5 mg/kg) and midazolam (2 mg) at low doses before local anesthesia with lidocaine.
- A ketamine adjunct (1 mg/kg) in 5-minute boluses was injected about 5 minutes before the first PFA delivery.
- 117 patients underwent ablation with a PFA LA dwell time of 24 ± 7 minutes.
- The mean time under sedation was 54.9 ±6 minutes, with 92 patients (79%) being sedated for <1 hour.
- The satisfaction level was found acceptable by both the patient and the primary operator in all procedures.

2023 clinical publications

Comparison of Pulsed-Field Ablation versus Very High-Power Short Duration-Ablation for Pulmonary Vein Isolation
Wörmann J, Schipper J, Lüker J, et al.

Journal of Cardiovascular Electrophysiology (October, 2023), available here

- Study that compared the procedural outcome data for PVI between FARAWAVE and very high-power short duration (vHPSD) defined as 70W/7 sec lesions or 70W/5 sec for posterior wall.
- There were 57 patients in each group.
- The FARAWAVE group had significantly shorter procedure duration (65 ± 17 min) versus the vHPSD (95 ± 23 min) with longer fluoroscopy times (15 ± 5 min) vs 12 ± 3 min for vHPSD.
- The freedom from arrhythmia recurrence at a median of 125 days was 80.7% in the FARAWAVE arm versus 77.2% in the vHPSD group.
- Safety event rates were low with 2 tamponades occurring in the FARAWAVE group and 2 groin bleeds in the vHPSD group. One clinically non-significant PV stenosis occurred in the vHPSD group.

Pulsed-Field Ablation Versus Single Catheter High-Power Short-Duration Radiofrequency Ablation for Atrial Fibrillation: Procedura-l Characteristics, Myocardial Injury and Midterm Outcomes
Badertscher P, Weidlich S, Serban T, et al.

Heart Rhythm (September, 2023), available here

- Compared FARAPULSE to high-power short-duration (HPSD) RF looking at efficiency, safety, myocardial injury and midterm outcomes.
- 115 patients (56% paroxysmal) underwent ablation, 52 patients had FARAPULSE ablation and 63 had HPSD RF ablation.
- PFA procedures were significantly shorter (PFA, 58 [53-71] minutes vs HPSD, 83 [71-99] minutes with significantly longer fluoroscopy times (PFA 13 [10-16] minutes vs HPSD 2.2 [1.3-3.6]).
- The postoperative troponin levels were significantly higher in the PFA group (1540 ng/l [1010-1980]) vs HPSD (897 ng/l [725-1240]).
- The AF recurrence free rate at 6 months was 85% for the PFA group and 65% for the HPSD group.
- PFA procedures were shorter, there were higher cardiac troponin levels, and the AF-free survival during mid-term follow-up was similar.

Quantitative Assessment of Transient Autonomic Modulation after Single-Shot Pulmonary Vein Isolation with Pulsed-Field Ablation
Del Monte A, Cespón Fernández M, Vetta G, et al.

Journal of Cardiovascular Electrophysiology (September, 2023), available here

- Assessed the effects of FARAPULSE ablation on the ganglionated plexi and autonomic nervous system (ANS) by looking at the degree of acute vagal modulation induced immediately following FARAPULSE ablation.
- De novo PVI patients treated with FARAPULSE (n = 40) or cryoballoon (n = 36) were assessed with extracardiac vagal simulation (ECVS) to capture the effects of ablation. To capture any transient effects, the subgroup was assessed before PVI, immediately after PVI and 10 minutes after the last ablation application.
- Baseline values were similar, but the vagal response induced by ECVS almost disappeared in the thermal group but persisted in the FARAPULSE group. Intraprocedural vagal reactions occurred more frequently with FARAPULSE than thermal. The heart rate 24-hour post ablation increased more with thermal than PFA ablation.

2023 clinical publications

- In the subgroup with repeated ANS modulation assessment, PFA had a significant acute suppression of vagal response immediately after ablation which recovered almost completely within a few minutes after ablation.
- FARAPULSE was found to be associated with only transitory, short vagal effects on the ANS.

Left Atrial Posterior Wall Isolation with Pulsed Field Ablation in Persistent Atrial Fibrillation
Gunawardene M, Frommeyer G, Ellermann C, et al.

Journal of Clinical Medicine (September, 2023), available here

- Persistent AF patients were treated with PVI + (n = 16) or PVI + posterior wall isolation (n = 59) with FARAWAVE with 32 patients being de novo and 43 patients were repeat ablation patients.
- In the redo cohort, 67% of all PVs were isolated.
- PVI + PWI had an average procedure time of 91 ± 30 min and two minor complications occurred.
- The 354 ± 197-day freedom from atrial arrhythmias (allowing AADs) in the PVI + PWI cohort was 79.3%.
- PWI guided by FARAPULSE had favorable outcomes with a low number of complications.

Pulsed-Field vs. Cryoballoon vs. Radiofrequency Ablation: A Propensity Score Matched Comparison of One-Year Outcomes after Pulmonary Vein Isolation in Patients with Paroxysmal Atrial Fibrillation
Maurhofer J, Kueffer T, Madaffari A, et al.

Journal of Interventional Cardiac Electrophysiology (September 2023), available here

- CBA and RFA AF patients were propensity matched to PFA, (PFA, n = 40), (CBA, n = 80) and (RFA, n = 80).
- Median procedure times were the shortest with CBA (75 min), followed by PFA (94 min) and RFA (182 min), with RFA having the lowest fluoroscopy dose.
- After 1-year of follow-up, freedom from any atrial arrhythmia was 85% for PFA, 66.2% for CBA, and 73.8% for RFA.
- With propensity-matched patients, the results were favorable for the initial use of PFA versus CBA and RFA.

Long-Term Clinical Outcomes of Pulsed Field Ablation in the Treatment of Paroxysmal Atrial Fibrillation
Musikantow D, Neuzil P, Anic A, et al.

JACC: Clinical Electrophysiology (September, 2023), available here

- The first long-term safety and recurrence outcomes for the FARAPULSE PFA system in clinical trial patients.
- 121 PAF patients were treated during these feasibility studies (IMPULSE, PEFCAT, PEFCAT II), of which 49 patients were treated with the optimized waveform ("Biphasic II"). DOI: 10.1016/j.jacep.2021.02.014
- 116 patients were included in long-term follow-up with a mean follow-up duration of ~4 years (49 +/- 7 months).
- No new adverse events were reported.

2023 clinical publications

- ***All Follow-Up Results (Years 1-5)*** - With the optimized biphasic waveform, there was an 81% (38/47) freedom from AF/AFL recurrence.
- ***Late Recurrence Follow-Up Analysis (Years 2-5) - 95%*** freedom from AF/AFL/AT (optimized biphasic waveform).

Early Recurrences Predict Late Therapy Failure after Pulsed Field Ablation of Atrial Fibrillation
Plank K, Bordignon S, Urbanek L, et al.

Journal of Cardiovascular Electrophysiology (September, 2023), available here

- 231 AF patients (55% paroxysmal) were analyzed for a medial follow-up of 367 days.
- 46 (21%) experienced early recurrence of atrial tachyarrhythmia (ERAT) after a median of 23 days post-ablation.
- The KM estimated freedom from AF/AT was 74.2% at 1 year, 81.8% for paroxysmal and 64.8% for persistent AF.
- Multivariate analysis found that ERAT and female sex were independent predictors of late recurrence.

Characterization of Durability and Reconnection Patterns at Time of Repeat Ablation after Single-Shot Pulsed Field Pulmonary Vein Isolation
Ruwald M, Haugdal M, Worck R, et al.

Journal of Interventional Cardiac Electrophysiology (September, 2023), available here

- The pulmonary vein durability rate was 69% in repeat ablation patients (n = 26) that had a FARAPULSE procedure an average of 292 ± 119 days after the de novo ablation.
- Patients who underwent posterior wall isolation had a durable PW isolation rate of 80% (4/5).
- Reconnection was observed in the LSPV (27%), LIPV (19%), RSPV (35%), RIPV (42%) with the gaps significantly clustered in the right-sided anterior carina compared to other regions.

Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation
Reddy VY, Gerstenfeld EP, Natale A, et al.

New England Journal of Medicine (August, 2023), available here, supplement available here

- The ADVENT Pivotal Trial was the first randomized clinical trial that directly compared FARAPULSE™ PFA to standard-of-care thermal ablation devices (force-sensing radiofrequency [RFA] or cryoballoon ablation [CBA]), for the treatment of paroxysmal atrial fibrillation (PAF).
- It included an experienced group of thermal ablators with limited clinical experience with the novel FARAPULSE technology.
- In this RCT, FARAPULSE demonstrated:
  - Non-inferiority for both the primary safety and effectiveness outcomes compared to thermal ablation technology (posterior probability > 0.999).
  - Significantly less pulmonary vein cross-sectional narrowing compared to thermal ablation (posterior probability > 0.999).
  - Significantly shorter procedure times, reduced LA dwell time and total ablation time versus thermal ablation. Lower standard deviations across these characteristics also indicate less variability within the PFA procedures.

2023 clinical publications

Comparison of Pulsed Field Ablation and Cryoballoon Ablation for Pulmonary Vein Isolation
Schipper H, Steven D, Lüker J, et al.

Journal of Cardiac Electrophysiology (August, 2023), available here

- Retrospective analysis of de novo paroxysmal or persistent AF PVI with FARAWAVE (PFA) (n = 54) and the POLARx Cryoballoon (CBA) (n = 54).
- The total procedure times excluding the LA mapping were significantly shorter for the PFA group (58.0 ± 12.5 min) vs CBA (73.0 ± 24.8 min). Fluoroscopy time was significantly longer in the PFA arm. Subgroup analysis showed a significant reduction in procedure time with continued use of FARAPULSE.
- At 273 ± 129 days, the arrhythmia recurrence free rate was similar for both devices, 74% for PFA and 72% for CBA.
- HR changes between baseline and 3-month follow up did not differ between both groups (PFA: 4 ± 8 beats/min, CBA: 4 ± 11 beats/min).

Pulsed Field Ablation-Based Pulmonary Vein Isolation Using a Simplified Single-Access Single-Catheter Approach — The Fast and Furious PFA Study
Tilz R, Vogler J, Kirstein B, et al.

Circulation Journal (August, 2023), available here

- 50 paroxysmal (56%) and persistent AF patients underwent wide area circumferential ablation (WACA) with FARAPULSE.
- The mean procedure time was 27.4 ± 6.6 min with a mean LA dwell time of 14.4 ± 5.5 min.
- The mean time to ambulation was 3.3 ± 3.1 hours with a low rate of periprocedural complications.
- At a mean follow-up of 6.5 ± 2.1 months, 82% (41/50) patients remained in sinus rhythm.

Pulsed-Field Ablation on Mitral Isthmus in Persistent Atrial Fibrillation - Preliminary Data on Efficacy and Safety
Davong B, Adeliño R, Delasnerie H, et al.

*Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System.

JACC: Clinical Electrophysiology (July, 2023), available here

- PVI, posterior wall (PW) and mitrial isthmus (MI) ablation were performed in 45 patients with persistent AF.
- The acute success of PVI, PW isolation, and MI block was 100%.
- There were 2 (4.4%) coronary artery spasms which were reversible after intravenous nitrate infusion.
- During a mean follow-up of 107 ± 59.5 days, there was a 20% rate of arrhythmia recurrence.

2023 clinical publications

Pulmonary Vein Isolation Durability and Lesion Regression in Patients with Recurrent Arrhythmia after Pulsed Field Ablation
Kueffer T, Stefanova A, Madaffari A, et al.

Journal of Interventional Cardiac Electrophysiology (July, 2023), available here

- Redo ablation was performed on 29/341 (8.5%) of patients for arrhythmia recurrence.
- At 6 months post-index ablation, mapping identified 69/110 (63%) durable PV isolation. In 6 (21%) all PVs were durability isolated.
- PV reconnections were often found on the right-sided veins and on the anterior aspects of the upper veins.
- Importantly, only minor regression was observed between the index and redo procedures (median of 3 mm).

Acute Lesion Extension Following Pulmonary Vein Isolation with Two Novel Single Shot Devices: Pulsed Field Ablation versus Multielectrode Radiofrequency Balloon
My I, Lemoine M, Butt M, et al.

Journal of Cardiovascular Electrophysiology (July, 2023), available here

- Compared lesion formation and lesion extent (measured with mapping and biomarkers) between FARAPULSE and HELIOSTAR (multi-electrode RF balloon).
- 60 paroxysmal patients (28 PFA, 32, RF balloon) underwent PVI, high-density mapping and Troponin I was quantified.
- The posterior wall ablation area was significantly larger in the PFA group.
- In a subset of 38 patients, the serum Troponin was significantly higher in the PFA group, likely due to it creating larger lesions.

Pulsed Field Versus Cryoballoon Pulmonary Vein Isolation for Atrial Fibrillation: Efficacy, Safety, and Long-Term Follow-Up in a 400-Patient Cohort
Urbanek L, Bordignon S, Schaack D, et al.

Circulation: Arrhythmia and Electrophysiology (July, 2023), available here

- 400 patients were treated with FARAPULSE (n = 200) or cryoballoon ablation (CBA) (n = 200).
- The mean procedure times were significantly shorter in the FARAPULSE group (34.5 [29-40] mins) vs CBA (50 [45-60] mins) with similar fluoroscopy times.
- The overall procedural complication rates were 6.5% in the CBA and 3.0% in the FARAPULSE group driven by a higher rate of phrenic nerve palsy in the CBA group.
- The 1-year freedom from arrhythmia recurrence rates in paroxysmal AF were similar with 83.1% in the CBA group and 80.3% in the FARAPULSE group.

2023 clinical publications

European Real-World Outcomes with Pulsed Field Ablation in Patients with Symptomatic Atrial Fibrillation - Lessons from the Multicenter EU-PORIA Registry
Schmidt B, Bordignon S, Neven K, et al.

EURPOACE (July, 2023), available here

- Registry to study the real-world adoption, workflow, acute and long-term outcomes after pulsed field ablation (PFA) in an all-comer atrial fibrillation (AF) patient population in high-volume European centers, inclusive of learning curve.
- This registry demonstrated consistent, short procedure times with a median of 58 minutes despite a large number of operators with varied experience and workflow.
- There was a low rate of safety events (3.6%) and promising one-year efficacy rate (74%) in a large spectrum of AF patients.
- Operator experience and previous primary ablation modality did not have an effect on the one-year AF/AT recurrence rates showing a rapid adoption of the technology by new operators and prior RF and cryo users.
- A small subset of 149 patients (12%) returned for repeat ablation during follow-up. In these patients, EAM revealed a high rate of PVI with 72% of pulmonary veins being durably isolated.

Electrophysiological Findings during Re-Do Procedures after Single-Shot Pulmonary Vein Isolation for Atrial Fibrillation with Pulsed Field Ablation
Magni F, Scherr D, Manninger M, et al.

Journal of Interventional Cardiac Electrophysiology (May, 2023), available here

- Patients who had a de novo procedure with FARAWAVE that had recurrence and subsequent repeat ablation (14/447) procedures were analyzed. The mean time to recurrence was 4.9 ± 1.9 months.
- PV reconnection was found in zero (35.7%), one (21.4%), two (14.3%) or three (28.6%) of patients.
- Durable PVI was observed in over 1/3 of redo patients. The most common arrhythmia recurrence following PVI only was AF. Concomitant (35.7%) or isolated AFL/AT (14.3%) recurrence was observed in 50% of patients.

Lesion Formation Following Pulsed Field Ablation for Pulmonary Vein and Posterior Wall Isolation
Sohns C, Fink T, Braun M, et al.

PACE (May, 2023), available here

- Lesion formation was assessed with late gadolinium enhancement CMR (LGE-CMR) 3 months after FARAPULSE ablation.
- In 10 patients, PVI and posterior wall isolation (PWI) was performed with FARAWAVE. The mean procedure duration was 62 ± 7 min with a mean LA dwell time of 13 ± 2 min.
- The mean LA scar burden was 8.1 ± 2.1% with a mean scar width of 12.8 ± 2.1 mm. At 7 months, 9/10 (90%) of patients were recurrence-free.
- LGE CMR analysis found homogenous and continuous lesion patterns with no evidence of PV stenosis or collateral damage to adjacent structures.

2023 clinical publications

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Safety and Effectiveness of Pulsed Field Ablation to Treat Atrial Fibrillation: One-Year Outcomes From the MANIFEST-PF Registry
Turagam MK, Neuzil P, Schmidt B, et al.

Circulation (May, 2023), available here

- Multi-national retrospective survey of all patients treated with FARAPULSE from 24 EU centers (77 operators), 1,568 patients.
- Low complication rates; 1.9% major complication rate and 4.0% minor complication rate with no reported esophageal damage or PV stenosis.
- There was an 81.6% 1-year freedom from AF/AFL/AT for paroxysmal AF patients with no difference in recurrence-free outcomes based on the procedural volume (PFA procedure numbers).

2023 clinical publications

Bronchial Safety After Pulsed Field Ablation for Paroxysmal Atrial Fibrillation
Füting A, Reinsch N, Brokkaar L, et al.

Circulation: Arrhythmia and Electrophysiology (April, 2023), available here

- Respiratory tract CT scans were performed on 60 patients post- FARAPULSE ablation to look for bronchial damage with either straight-tip (n = 30) or J-tip (n = 30) guidewires.
- In 12/30 patients with the straight-tip, extra-stiff guidewire, small amounts of old blood without active bleeding were detected with no evidence of thermal lesions. There was no clinical relevance at 30 days post-procedure.
- Use of the straight-tip guidewire may lead to asymptomatic bronchial damage which was not detected when the J-tip guidewire was used.

Pulsed Field Ablation to Treat Atrial Fibrillation: Autonomic Nervous System Effects
Musikantow DR, Neuzil P, Petru J, et al.

JACC: Clinical Electrophysiology (April, 2023), available here

- Heart rate was assessed pre and post PVI using FARAPULSE (n = 40), Cryoablation (n = 40) and radiofrequency (n = 40) PVI ablation to understand the impact of pulsed field ablation on the ganglionated plexi (GP).
- Between baseline and 3 months, heart rates increased by 8.9 ± 11.4 (RF), 11.1 ± 9.4 (CB), and -0.1 ± 9.2 (PFA) beats/min.
- Unlike thermal ablation, FARAPULSE PFA had minimal effects on the GPs.

Pulsed Field Ablation for Treatment of Atrial Fibrillation in Patients with Congenital Anomalies of Cardiac Veins
Castiglione A, Küffer T, Gräni C, et al.

Journal of Cardiovascular Electrophysiology (March, 2023), available here

- Five patients with congenital anomalies were treated with FARAPULSE.
- PVs were isolated with no phrenic nerve palsy or other complications.
- Pre-procedural imaging and 3D mapping was found to be well-suited, efficient, and versatile in AF patients with anomalous cardiac veins.

Visualization of Fibroblast Activation Using ^{68}Ga- FAPI PET/CT after Pulmonary Vein Isolation with Pulsed Field Compared with Cryoballoon Ablation
Kupusovic J, Kessler L, Bruns F, et al.

Journal of Nuclear Cardiology (March, 2023), available here

- Fibroblast activation was used as a surrogate for ablation damage after FARAPULSE(n = 15) and CBA (n = 11) ablation.
- Fibroblast activation tissue response was less pronounced in the PFA patient cohort vs CBA.

2023 clinical publications

A Randomized Controlled Trial of Pulsed Field Ablation versus Standard-of-Care Ablation for Paroxysmal Atrial Fibrillation: The ADVENT Trial Rationale and Design
Reddy VY, Lehmann JW, Gerstenfeld EP, et al.

Heart Rhythm O2 (March, 2023), available here

- The ADVENT (Randomized Controlled Trial for Pulsed Field Ablation versus Standard of Care Ablation for Paroxysmal Atrial Fibrillation) trial was a multicenter, prospective, single-blind, randomized controlled trial comparing PVI using PFA vs conventional thermal (cryoballoon and contact force radiofrequency) ablation for the treatment of drug-resistant paroxysmal AF.

Pulsed Field Ablation in Real-World Atrial Fibrillation Patients: Clinical Recurrence, Operator Learning Curve and Re-Do Procedural Findings
Ruwald MH, Johannessen A, Lock Hansen M, et al.

Journal of Interventional Cardiac Electrophysiology (February, 2023), available here

- 121 patients underwent PVI with FARAPULSE. The mean procedure time was significantly reduced from the initial cases from 85 ± 34 min to 72 ± 18 min.
- There was one phrenic nerve palsy with partial remission at follow-up. The KM event-free estimate at 365 days was 80% (88% paroxysmal, 69% persistent).
- In 5/8 re-do procedures, the gaps were primarily located in the right pulmonary veins.

2022 clinical publications

Pulsed-Field Ablation for the Treatment of Left Atrial Reentry Tachycardia
Kueffer T, Seiler J, Madaffari A, et al.

*Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

Journal of Interventional Cardiac Electrophysiology (December, 2022), available here

- Left atrial reentry tachycardia were treated with FARAPULSE (n = 22).
- Lesion used to treat the ATs included, 20 roof lines, 13 anterior lines, and 6 mitral isthmus lines with no reported complications.

Findings from Repeat Ablation using High-Density Mapping after Pulmonary Vein Isolation with Pulsed Field Ablation
Tohoku S, Chun J, Bordignon S, et al.

EUROPACE (November, 2022), available at here

- In redo patients initially treated with FARAPULSE using the 5S strategy, the incidence of pulmonary vein (PV) reconnection was assessed (inclusive of learning curve).
- Among the 360 patients, 25 patients (19 paroxysmal) underwent a redo procedure in 6.1 ± 4 months.
- The PV durable isolation rate was 90.9% as assessed by high-density mapping.
- The mechanism of all but one atrial tachyarrhythmia was macro-reentry.
- The mean % of isolated posterior wall surface area was 72.7 ± 19.0%.
- There was a low rate of PV reconnection (9.1%) in redo patients and the unique features of the FARAWAVE catheter design and optimized workflow enabled wide antral lesion creation without regression over time.

Pulsed Field Ablation-Based Pulmonary Vein Isolation in Atrial Fibrillation Patients with Cardiac Implantable Electronic Devices: Practical Approach and Device Interrogation (PFA in CIEDs)
Chen S, Chun J, Bordignon S, et al.

*WARNING: Implantable pacemakers and implantable cardioverter/defibrillators may be adversely affected by irreversible electroporation current

Journal of Interventional Cardiac Electrophysiology (November, 2022), available here

- A pilot patient cohort (n = 20) underwent PFA ablation for AF (PVI) with different CIEDs.
- CIEDs included pacemaker, implantable cardioverter-defibrillators (ICD), or cardiac resynchronization therapy plus defibrillator (CRT-D).
- CIED pre- and post-PFA interrogation of the devices showed no significant alterations to the parameters or function of the CIEDs and no lead dislodgement.

Initial Experience with Pulsed Field Ablation for Atrial Fibrillation
Magni F, Mulder B, Groenveld H, et al.

Frontiers in Cardiovascular Medicine (November, 2022), available here

- 100 subjects (80% paroxysmal AF) underwent AF ablation with FARAWAVE.
- The learning curves of 2 operators (junior/senior) who performed >20 procedures showed no difference in procedure time, senior (46.9 ± 9.7 min) and junior (45.9 ± 9.9 min).
- The 2 complications that occurred were bleeding at the access site.

2022 clinical publications

Pulsed Field Ablation in Patients with Complex Consecutive Atrial Tachycardia in Conjunction with Ultra-High-Density Mapping: Proof of Concept

Gunawardene M, Schaeffer B, Jularic M, et al.

*Ablation beyond pulmonary vein isolation and posterior wall ablation are outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

Journal of Cardiovascular Electrophysiology (September, 2022), available here

- Fifteen patients with atrial tachycardia (AT) underwent high density mapping to ID critical sites for AT maintenance.
- FARAWAVE ablation was performed with 100% success, 63% terminated with the first application and 2 ATs in the right atrial requiring RF ablation.
- No procedure-related complications occurred.
- AF/AT free survival was 80% (12/15) after 153 {88-207) days of follow-up.

Pulsed-Field Ablation-Based Pulmonary Vein Isolation: Acute Safety, Efficacy and Short-Term Follow-up in a Multi-Center Real World Scenario

Lemoine MD, Fink T, Mencke C, et al.

Clinical Research in Cardiology (September, 2022), available here

- 138 patients (62% persistent AF) from 2 centers were treated with FARAWAVE.
- Mean procedure time was 78 ± 22 min including pre- and post-procedure HD voltage mapping. FARAWAVE LA dwell time was 23 ± 9 min with a fluoroscopy time of 16 ± 7 min.
- There were 3 groin complications (2.2%), 1 pericardial tamponade (0.7%) and 1 transient ST-elevation (0.7%).
- The one-year freedom from recurrence rate was 90% in paroxysmal patients (n = 47) and 60% in persistent AF patients (n = 82).

Coronary Arterial Spasm During Pulsed Field Ablation to Treat Atrial Fibrillation

Reddy VY, Petru J, Funasako M, et al.

Circulation (September 2022), available here

- 25 FARAPULSE patients had PV isolation, 5 had PWA —no coronary spasm occurred in these groups.
- 20 patients underwent cavotricuspid isthmus (CTI) PFA—100% (5/5) of the first consecutive CTI-treated patients developed severe right coronary artery spasm.
- Spasm was relieved by intracoronary nitroglycerin (typically 1 mg) in 5.5 ± 3.5 minutes.
- Prophylactic administration of nitroglycerin (intracoronary [n = 5, 1 mg] or intravenous [n = 10, 1-2 mg]) prevented all severe spasm.

Cerebral Safety After Pulsed Field Ablation for Paroxysmal Atrial Fibrillation

Reinsch N, Füting A, Höwel D, et al.

Heart Rhythm (September, 2022), available here

- In 30 patients treated with FARAWAVE, National Institute of Heath Stroke Scale (NIHSS) scores were assessed 2- and 30-days post PVI. One day after PVI, DW-MRI and FLAIR imaging was done to document the occurrence of silent cerebral events (SCE)/silent cerebral lesions (SCL).
- NIHSS scores were 0 for all patients. Cerebral MRI scans were normal in 29/30 (97%) of patients. In one patient (3%), a single cerebral lesion was observed. 40-days post-procedure, a follow-up MRI cerebral scan showed complete lesion regression.

2022 clinical publications

Catheter Ablation Induced Phrenic Nerve Palsy by Pulsed Field Ablation—Completely Impossible? A Case Series
Pansera F, Bordignon S, Bologna F, et al.

European Journal Case Report (September, 2022), available here

- Case series on three patients that had FARAWAVE PFA-induced phrenic nerve (PN) injury during PVI. Cases 1 and 3 had PAF without evidence of structural heart disease and case 2 had Pers AF and ischemic cardiomyopathy with preserved ejection fraction.
- Transient right hemidiaphragm palsy was seen during PFA delivery in the RSPV (Cases 1 and 2) and the RIPV (Case 3).
- The palsy lasted < 1 min and was followed by spontaneous full recovery in all cases (Case 1, 40 sec, Cases 2 and 3 lasted a few seconds).
- Transient PN palsy fully recovered rapidly suggesting PN hyperpolarization of neuronal cells or depletion of acetylcholine in the motoric endplate. Further studies are needed to understand the mechanism.

Multi-National Survey on the Methods, Efficacy, and Safety on the Post-Approval Clinical Use of Pulsed Field Ablation (MANIFEST-PF)
Ekanem E, Reddy VY, Schmidt B, et al.

Europace (August, 2022), available here

- The MANIFEST-PF registry was a retrospective survey of 24 centers with 90 operators, 1758 patients that assessed the real-world performance (use case, acute effectiveness, safety) of FARAPULSE.
- Procedure time was 65 min, fluoroscopy time was 13.7 min. There was a 99.9% mean acute PVI success rate.
- There were no esophageal complications reported, no phrenic nerve injury persisting beyond hospital discharge and no reported PV stenosis. There was a 1.6% rate of major complications, a 3.87% rate of minor complications and 0.46% rate of energy-specific adverse events.
- Root-cause analysis showed that most of the pericardial tamponades and stroke were attributable to catheter workflow and manipulation, independent of energy modality. Complications were plotted on a timeline, and it indicated an improvement in complication rate over time.

Pulsed Field Ablation for Pulmonary Vein Isolation: Real-World Experience and Characterization of the Antral Lesion Size Compared with Cryoballoon Ablation
Blockhaus C, Guelker J, Feyen L, et al.

Journal of Interventional Cardiac Electrophysiology (August, 2022), available here

- Single-center study looking at procedural characteristics and the size of acute PVI antral lesions with high-density mapping in 43 patients treated with PFA compared to 20 patients treated with cryoballoon ablation.
- All patients had 100% acute vein isolation with no early reconnections. The acute antral lesion size of PFA lesions (67.03 ± 12.69%) were significantly larger compared to cryoballoon (57.39 ± 10.91%).
- In the PFA group there was no acute phrenic nerve injury, and 1 (4.34%) patient stroke.

2022 clinical publications

Validation of a Multipolar Pulsed-Field Ablation Catheter for Endpoint Assessment in Pulmonary Vein Isolation Procedures
Kueffer T, Baldinger S, Servatius H, et al.

EUROPACE (June, 2022), available here

- In 56 patients undergoing PVI with FARAWAVE, the accuracy of FARAWAVE to detect residual PV connections was assessed with high-density mapping.
- Acute PVI was achieved in 100% of PVs.
- The accuracy of the PV assessment with FARAWAVE was 91%. In 14/213 (6.6% of veins), FARAWAVE incorrectly indicated residual PV conduction due to high-output pace-capture.
- Lowering the output to 5 V/1 ms reduced this observation to 0.9% (2/213) and increased the accuracy to 97%.
- FARAWAVE offered reliable endpoint assessment for PVI and lowering the pacing output increased the accuracy from 91% to 97%.
- At a median of 3.2 months, 3/56 (5.4%) underwent a redo procedure. The durable PV isolation rate was 10/12 (83%).

5S Study: Safe and Simple Single Shot Pulmonary Vein Isolation with Pulsed Field Ablation Using Sedation
Schmidt B, Bordignon S, Tohoku S, et al.

Circulation: Arrhythmia and Electrophysiology (June, 2022), available here

- Single-center study looking at the adoption and the process of streamlining the procedure in the first 191 patients treated with FARAPULSE PFA. Electrogram validation was performed with a circular mapping catheter (CMC) in the first 25 patients, cerebral MRI was performed in 53 patients and esophageal endoscopy was performed in 52 patients.
- Electrogram information was 100% congruent between the CMC and FARAWAVE. PVI rate was 100%. No esophageal temperate rise or esophageal thermal injuries were observed. Two minor strokes occurred in the first 25 patients, likely due to air embolism during catheter exchanges.
- After the first 25 patients, the procedure times were significantly reduced from an average of 46 ± 14 min to 38 ± 13 min. During short-term follow-up, 9% (17/191) of patients had atrial arrhythmia recurrence.

Characterization of Circumferential Antral Pulmonary Vein Isolation Areas Resulting from Pulsed-Field Catheter Ablation
Bohnen M, Weber R, Minners J, et al.

Europace (June, 2022), available here

- In 40 patients, pre- and post-procedure 20-pole circular mapping catheter voltage mapping was done to evaluate PV isolation and area of isolation.
- Isolation gaps were located most frequently in the anterior antral PV segments of the left PVs.
- Additional areas of isolation beyond the antral PV segments were found on the posterior wall and roof regions.

2022 clinical publications

First Experience with Pulsed Field Ablation as Routine Treatment for Paroxysmal Atrial Fibrillation
Füting A, Reinsch N, Höwel D, et al.

Europace (May, 2022), available here

- Single-center 30 patient study looking at phrenic nerve injury and high-density mapping pre-and post-ablation.
- Acute PVI rate was 100%, the median procedure time was 116 min and the FARAWAVE catheter dwell time was 29 min. There was no esophageal or phrenic nerve injury.
- 97% of patients were in sinus rhythm after 90 days.

Troponin Release After Pulmonary Vein Isolation Using Pulsed Field Ablation Compared to Radiofrequency and Cryoballoon Ablation
Krisai P, Knecht S, Badertscher P, et al.

Heart Rhythm (May, 2022), available here

- Troponin T is a measure of myocardial cell death. Troponin T was measured in 60 patients one day before and the morning after PVI ablation with FARAWAVE, radiofrequency or cryoballoon ablation. No additional lesion sets were performed.
- Post-procedure Troponin T levels with PFA were 1.6x and 1.9x higher vs RF and Cryo, respectively with no significant difference between the RF and cryo groups.

Pulsed Field Ablation Combined with UltraHigh-density Mapping in Patients Undergoing Catheter Ablation for Atrial Fibrillation: Practical and Electrophysiological Considerations
Gunawardene M, Schaeffer B, Jularic M, et al.

Journal of Cardiovascular Electrophysiology (March, 2022), available here

- 20 consecutive patients underwent PVI with FARAWAVE. Additional ablations were performed off-label in a sub-set of patients. PFA lesion size and decrease in voltage were assessed with high-density voltage mapping.
- High-density mapping showed PV reconnection in 5 cases (6.25%). Gaps were located at the anterior-superior PV ostia and were successfully closed with additional PFA. Voltage was significantly decreased following PFA with almost no complex electrogram fractionation at the lesion border zones.
- High-density mapping for FARAWAVE PFA lesion showed wide, antral, circumferential lesion with significantly decreased atrial tissue voltage and little evidence of fraction in the lesion border zones.

2021 clinical publications

Does Pulsed Field Ablation Regress Over Time? A Quantitative Temporal Analysis of Pulmonary Vein Isolation
Kawamura I, Neuzil P, Shivamurthy P, et al.

Heart Rhythm (June, 2021), available here

- Patients with PAF underwent PVI with FARAWAVE. A comparison of voltage maps immediately after PFA and at a median of 84 days (interquartile range 69–90 days) later revealed that there was no significant difference in either the left and right-sided PV antral isolation areas or non-ablated posterior wall area.
- The distances between low-voltage edges on the posterior wall were also not significantly different between the 2 time points.
- The level of PV antral isolation after PFA with FARAWAVE persisted without regression.

Pulsed Field Ablation Prevents Chronic Atrial Fibrotic Changes and Restrictive Mechanics After Catheter Ablation for Atrial Fibrillation
Nakatani Y, Sridi-Cheniti S, Cheniti G, et al.

Europace (May, 2021), available here

- Cardiac magnetic resonance was performed pre-ablation, acutely (< 3 h), and 3 months post-ablation in 41 patients with PAF undergoing PVI with PFA (n = 18) or thermal ablation (n = 23, 16 radiofrequency ablations, 7 cryoballoon ablations).
- Tissue changes were more homogeneous after PFA than after thermal ablation, with no sign of microvascular damage or intramural hemorrhage. In the chronic stage, the majority of acute LGE had disappeared after PFA, whereas most LGE persisted after thermal ablation.
- The maximum strain on PV antra, the LA expansion index, and LA active emptying fraction declined acutely after both PFA and thermal ablation but recovered at the chronic stage only with PFA.
- In this study, PFA induced large acute LGE lesions which mostly disappeared in the chronic stage, suggesting a reparative process involving less chronic fibrosis.

Pulsed Field Ablation of Paroxysmal Atrial Fibrillation: 1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II
Reddy VY, Dukkipati SR, Neuzil P, et al.

JACC-EP (May, 2021), available here

- In 3 multicenter studies (IMPULSE, PEFCAT and PEFCAT II), PAF patients underwent PVI using a basket and flower PFA catheter.
- Invasive remapping was performed at 2 to 3 months, and reconnected PVs were re-isolated with PFA or radiofrequency ablation. After a 90-day blanking period, arrhythmia recurrence was assessed over 1-year follow-up.
- In 121 patients, acute PVI was achieved in 100% of PVs with PFA alone.
- PV remapping, performed in 110 patients at 93.0 ± 30.1 days, demonstrated durable PVI in 84.8% of PVs (64.5% of patients), and 96.0% of PVs (84.1% of patients) treated with the optimized biphasic energy PFA waveform.
- The 1-year Kaplan-Meier estimates for freedom from any atrial arrhythmia for the entire cohort and for the optimized biphasic energy PFA waveform cohort were 78.5 ± 3.8% and 84.5 ± 5.4%, respectively.

2021 clinical publications

How Does the Level of Pulmonary Venous Isolation Compare between Pulsed Field Ablation and Thermal Energy Ablation (Radiofrequency, Cryo, or Laser)?
Kawamura I, Neuzil P, Shivamurthy P, et al.

Europace (May, 2021), available here

- In a clinical trial (NCT03714178), PAF patients underwent PVI with FARAWAVE using a biphasic waveform, and after 75 days, detailed voltage maps were created.
- Comparative voltage mapping data were retrospectively collected from consecutive PAF patients who (i) underwent PVI using thermal energy, (ii) underwent re-ablation for recurrence, and (iii) had durably isolated PVs. The left and right PV antral isolation areas and non-ablated posterior wall were quantified.
- There was no significant difference between the PFA and thermal ablation cohorts in either the left- and right-sided PV isolation areas, or the non-ablated posterior wall area.

Pulsed Field Ablation Selectively Spares the Oesophagus During Pulmonary Vein Isolation for Atrial Fibrillation
Cochet H, Nakatani Y, Sridi-Cheniti S, et al.

Europace (February, 2021), available here

- Cardiac magnetic resonance (CMR) imaging was performed before, acutely (< 3 h) and 3 months post-ablation in 41 PAF patients undergoing PVI with PFA (N = 18, FARAPULSE) or thermal methods (N = 23, 16 radiofrequency, 7 cryoballoon).
- Esophageal and aortic injuries were assessed by using late gadolinium-enhanced (LGE) imaging. Phrenic nerve injuries were assessed from diaphragmatic motion on intra-procedural fluoroscopy.
- Acutely, thermal methods induced high rates of esophageal lesions (43%), all observed in patients showing direct contact between the esophagus and the ablation sites.
- Esophageal lesions were observed in no patient ablated with PFA (0%, P < 0.001 vs thermal methods), despite similar rates of direct contact between the esophagus and the ablation sites (P = 0.41).
- Acute lesions were detected on CMR on the descending aorta in 10/23 (43%) after thermal ablation, and in 6/18 (33%) after PFA (P = 0.52). CMR at 3 months showed a complete resolution of esophageal and aortic LGE in all patients.

Pulsed Field Ablation: A Promise That Came True
Ante A, Breskovic T, Sikiric I.

Current Opinion in Cardiology (January, 2021), available here

- Pulsed field ablation is a nonthermal ablative modality that uses short living, strong electrical field created around catheter to create microscopic pores in cell membranes (electroporation). When adequately dosed/configured it shows a preference for myocardial tissue necrosis.
- First-in-human series using pulsed field ablation for atrial fibrillation ablation have been completed and data published for several platforms. Acute safety outcomes are similar across the platforms with a low complication rate for complications typically reported for thermal ablation methods (esophageal injury, pulmonary vein stenosis, phrenic nerve palsy).
- Promising acute data on pulmonary vein isolation had been corroborated with satisfactory 1-year clinical follow-up for a single platform (i.e., FARAPULSE), whereas reports are pending for the rest. Research efforts are being expanded to a development of focal catheters, and therefore, pulsed field ablation application for ventricular arrhythmias.

2020 clinical publications

Pulsed Field Ablation in Patients with Persistent Atrial Fibrillation
Reddy VY, Anic A, Koruth J, et al.

JACC (September, 2020), available here

- PersAFOne was a single-arm study evaluating bi-phasic, bi-polar PFA with FARAWAVE for PVI and LAPW ablation to assess the safety and lesion durability of pulsed field ablation (PFA) for both PVI and LAPW ablation in persistent AF.
- In 25 patients, acute PVI (96 of 96 pulmonary veins) were 100% acutely successful with the FARAWAVE catheter. Using the focal PFA catheter, acute cavotricuspid isthmus block was achieved in 13 of 13 patients.
- Post-procedure EGD and repeat cardiac computed tomography revealed no mucosal lesions or PV narrowing, respectively.
- Invasive remapping at 2 to 3 months demonstrated durable isolation (defined by entrance block) in 82 of 85 PVs (96%) and 21 of 21 LAPWs (100%) treated with the pentaspline catheter.

Ostial Dimensional Changes After Pulmonary Vein Isolation: Pulsed Field Ablation vs Radiofrequency Ablation
Kuroki K, Whang W, Eggert C, et al.

Heart Rhythm (May, 2020), available here

- Data were analyzed from 4 PAF ablation trials using either PFA or RFA.
- Baseline and 3-month cardiac computed tomography scans were reconstructed into 3-dimensional images, and the long and short axes of the PV ostia were quantitatively and qualitatively assessed in a randomized blinded manner.
- PV ostial diameters decreased significantly less with PFA than with RFA (% change; long axis: 0.9% ± 8.5% vs −11.9% ± 16.3%; P < .001 and short axis: 3.4% ± 12.7% vs −12.9% ± 18.5%; P < .001).
- PV narrowing/stenosis was present in 0% and 0% vs 12.0% and 32.5% of PVs and patients who underwent PFA and RFA, respectively.
- In this study, unlike after RFA, the incidence and severity of PV narrowing/stenosis after PV isolation was virtually eliminated with PFA.

2019 clinical publications

Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation: An Ultra-Rapid, Tissue-Selective Modality for Cardiac Ablation
Reddy VY, Neuzil P, Koruth JS, et al.

JACC (July, 2019), available here

- Two trials were conducted to determine whether PFA allows durable pulmonary vein (PV) isolation without damage to collateral structures, in patients with PAF.
- Ablation was performed using proprietary bipolar PFA waveforms: either monophasic with general anesthesia and paralytics to minimize muscle contraction, or biphasic with sedation because there was minimal muscular stimulation. No esophageal protection strategy was used. Invasive electrophysiological mapping was repeated after 3 months to assess the durability of PV isolation.
- 81 patients, all PVs were acutely isolated by monophasic (n = 15) or biphasic (n = 66) PFA. With successive waveform refinement, durability at 3 months improved from 18% to 100% of patients with all PVs isolated. Beyond 1 procedure-related pericardial tamponade no additional primary adverse events over the 120-day median follow-up, including: stroke, phrenic nerve injury, PV stenosis, and esophageal injury.

2018 clinical publications

Ablation of Atrial Fibrillation with Pulsed Electric Fields: An Ultra-Rapid, Tissue-Selective Modality for Cardiac Ablation
Reddy VY, Koruth J, Jais P, et al.

JACC-EP (April, 2018), available here

- The first acute clinical experience of AF ablation with PFA, both epicardial box lesions during cardiac surgery, and catheter-based PVI.
- PFA was performed using a custom over-the-wire endocardial catheter for percutaneous transseptal PV isolation, and a linear catheter for encircling the PVs and posterior left atrium during concomitant cardiac surgery.
- Catheter PV ablation was successful in 15 patients (100%) 57 PVs Using 3.26 lesions/PV.

2025 preclinical publications

Is the Esophagus Spared During Pulsed Field Ablation? Early Histopathology and In Vivo Esophageal Retraction
Nies M, Koruth JS, Mlček M, et al.

Heart Rhythm (June 2025), available here

- In 6 swine (early, n = 4; late, n = 2) under anesthesia and paralysis, the esophagus was manually displaced toward the IVC where FARAPULSE delivered 4 stacked applications at 4–7 sites.
- Animals were sacrificed either early (1 day) or late (14 days), followed by pathologic assessment.
- After 1 day, 3 of 4 animals demonstrated esophageal lesions, measuring 13.3 ± 8.5 mm long, 6.3 ± 5.9 mm wide, and 2.3 ± 0.6 mm deep.
- All lesions were non-transmural, with myocyte degeneration and leucocyte infiltration on histology; the mucosa and blood vessels were spared.
- The 14-day cohort exhibited no lesions upon gross necropsy or histology. During atrial PFA using various catheters, waveforms, and manufacturers, esophageal contraction universally occurred such that it functionally retracted away from the point of ablation.

2024 preclinical publications

Lesion Morphometry of the Pentaspline Pulsed Field Ablation Catheter: Understanding Catheter Pose, Rotation, and Dosing
Watanabe K, Nies M, Reddy VY, et al.

Circulation: Arrhythmia and Electrophysiology (December 2024), available here

- Pre-clinical evaluation (n = 9) studying effects of one or two applications at specific poses (flower, basket) and with/without catheter rotation.
- In 6 SVC using basket pose without rotation: acute electrical isolation achieved in 4/6 veins and no conducation recovery in over 40 minutes, but at 2-day remap (in 3 isolated veins), all had reconnected.
- PVs (3/4) showed similar lesion behavior: acute isolation followed by reconnection.
- Lesion size comparisons: double application vs single application, flower pose, posterior atrium:
  – Double vs single lesion widths: 8.2 ± 2.8 mm vs 6.1 ± 2.0 mm (p = 0.02).
  – Lesion lengths linear ~ 15-16 mm with gaps in many cases.
  – Double flower pose produced wide, confluent lesions (~40×30 mm) where single flower applications yielded narrow lesions with variable gaps.
- In right ventricle flower pose, lesions were flower-shaped, linear with gaps and depths up to ~5 mm.

Hemolysis After Pulsed Field Ablation: Impact of Lesion Number and Catheter-Tissue Contact
Nies M, Koruth J, Mlček M, et al.

Circulation: Arrhythmia and Electrophysiology (June 2024), available here

- In vitro analysis of 76 blood samples ablated with FARAPULSE from 4 swine (36 no-contact, 36 in-contact, and 4 controls) were analyzed.

2024 preclinical publications *(continued)*

- Following ablation, hemolysis was observed in all 12 (100%) PFA experiments (6 no-contact and 6 in-contact) in a dose-dependent manner with more pronounced hemolysis in no-contact positions.
- The in vitro experiments may represent a worst-case scenario limiting the ability to extrapolate these findings to clinical practice.

Comparative Efficacy and Safety of Pulsed Field Ablation Versus Radiofrequency Ablation of Idiopathic LV Arrhythmias
Younis A, Tabaja, C, Kleve R, et al.

JACC: Clinical Electrophysiology (June 2024), available here

- Ten swine were randomized to FARAPULSE or RFA of LV interventricular septum, papillary muscle, LV summit, and LV epicardium
- LV interventricular septum: average PFA depth was 7.8 mm vs RFA 7.9 mm and no adverse events.
- Papillary muscle: average PFA depth 8.1 mm vs RFA 4.5 mm.
- Left ventricular summit: average PFA depth 5.6 mm vs RFA 2.7 mm. Steam-pop and/or ventricular fibrillation in 4 of 12 RFA vs 0 of 12 PFA, no ST-segment changes observed.
- Epicardium: average PFA depth 6.4 mm vs RFA 3.3 mm ($P < 0.01$). Transient ST-segment elevations/depressions occurred in 4 of 5 swine in the PFA arm vs 0 of 5 in the RFA arm.
- Angiography acutely and at 7 days showed normal coronary arteries.
- FARAPULSE produced deeper lesions with fewer steam pops but had higher rates of ST-segment elevations/depressions.

2023 preclinical publications

Efficacy of Pulsed Field vs Radiofrequency for the Reablation of Chronic Radiofrequency Ablation Substrate: Redo Pulsed Field Ablation
Younis A, Buck E, Santangeli P, et al.

JACC: Clinical Electrophysiology (November, 2023), available here

- PFA is highly efficient for ablation following prior RFA, which may be beneficial in patients presenting for redo procedures.
- PFA resulted in lesions in the ventricle that were deeper than RFA when ablating over chronic superficial RFA lesions.

Electrophysiology, Pathology, and Imaging of Pulsed Field Ablation of Scarred and Healthy Ventricles in Swine
Kawamura I, Reddy VY, Santos-Gallego CG, et al.

Circulation: Arrhythmia and Electrophysiology (January, 2023), available here

- 6 swine were infarcted to assess penetration of scar, risk of arrhythmias and lesion imaging evaluation.
- FARAPULSE PFA successfully penetrated scar without significant differences in the lesion depth of infarcted tissue (5.9 ± 1.0 mm) vs healthy (5.7 ± 1.3 mm) myocardium.

2023 preclinical publications *(continued)*

- In ungated QRS PFA applications, sustained ventricular arrhythmias requiring defibrillation occurred in 4/187 (2.1%) applications with zero occurring during gated applications.
- Dark-blood late-gadolinium-enhanced sequences allowed for improved endocardial border detection.

2022 preclinical publications

Effect of Epicardial Pulsed Field Ablation Directly on Coronary Arteries
Higuchi S, Im S, Stillson C, et al.

JACC: Clinical Electrophysiology (December, 2022), available here

- 4 swine, FARAWAVE lesions were delivered directly to the left anterior descending artery, left circumflex artery or normal myocardium.
- Angiography was performed to quantify the degree of coronary artery narrowing and histology was performed at 4 and 8 weeks.
- Acute luminal narrowing immediately after PFA was 47% which gradually resolved over 30 minutes.
- Epicardial lesions had a median depth of 4.1 mm and 87.5% of the arteries had minimal to mild stenosis via neointimal hyperplasia.

Pulsed Field Ablation of Left Ventricular Myocardium in a Swine Infarct Model
Im S, Higuchi S, Lee A, et al.

JACC: Clinical Electrophysiology (June, 2022), available here

- 10 swine were infarcted to evaluate how PFA and RF perform in areas of myocardial scar.
- In myocardial scar, lesion depth was not different between the FAWAVAVE or the FOCAL PFA catheter.
- In myocardial scar, lesion depth was significantly greater for PFA vs RF.
- In a pre-clinical animal model, unlike RF, FARAPULSE PFA was able to effectively ablate surviving islands of myocardium in infarct-related ventricular substrate.

2020 preclinical publications

Pulsed Field Ablation versus Radiofrequency Ablation: Esophageal Injury in a Novel Porcine Model
Koruth JS, Kuroki K, Kawamura I, et al.

Circulation: Arrhythmia and Electrophysiology (January, 2020), available here

- A novel porcine model was created to nonsurgically assess the response to esophageal injury. This was accomplished by delivering the energy source from within the inferior vena cava, against the esophagus (which was purposefully mechanically deviated towards the IVC).
- Biphasic pulsed field ablation induced no chronic histopathologic esophageal changes, whereas radiofrequency catheter ablation demonstrated a spectrum of esophageal lesions including esophageal ulcers, abscess, and fistulas.

2019 preclinical publications

Preclinical Evaluation of Pulsed Field Ablation: Electrophysiological and Histological Assessment of Thoracic Vein Isolation
Koruth JS, Kuroki K, Iwasawa J, et al.

Circulation: Arrhythmia and Electrophysiology (December, 2019), available here

- In this study, the safety, efficacy, and durability of achieving catheter-based electrical isolation of PVI using optimized monophasic and biphasic PFA waveforms and describe procedural and histological characteristics of PFA in swine atrial tissue.
- Both waveforms created confluent myocardial lesions that demonstrated a myocardial-specific ablative effect.
- Biphasic PFA was more durable than monophasic PFA and radiofrequency ablation lesions.

Endocardial Ventricular Pulsed Field Ablation: A Proof-of-Concept Preclinical Evaluation
Koruth JS, Kuroki K, Iwasawa J, et al.

EP Europace (December, 2019), available here

- Assessment of safety and feasibility of FARAPULSE PFA in swine ventricles with a prototype steerable endocardial catheter.
- Gross measurements, available for 28 of 30 ablation sites, revealed average lesion dimensions to be 6.5 ± 1.7 mm deep and 22.6 ± 4.1 mm, with a maximum depth and width of 9.4 mm and 28.6 mm respectively. In PFA lesions, fibrous tissue homogeneously replaced myocytes. When present in the lesion zone, nerve fascicles and vasculature were preserved.

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