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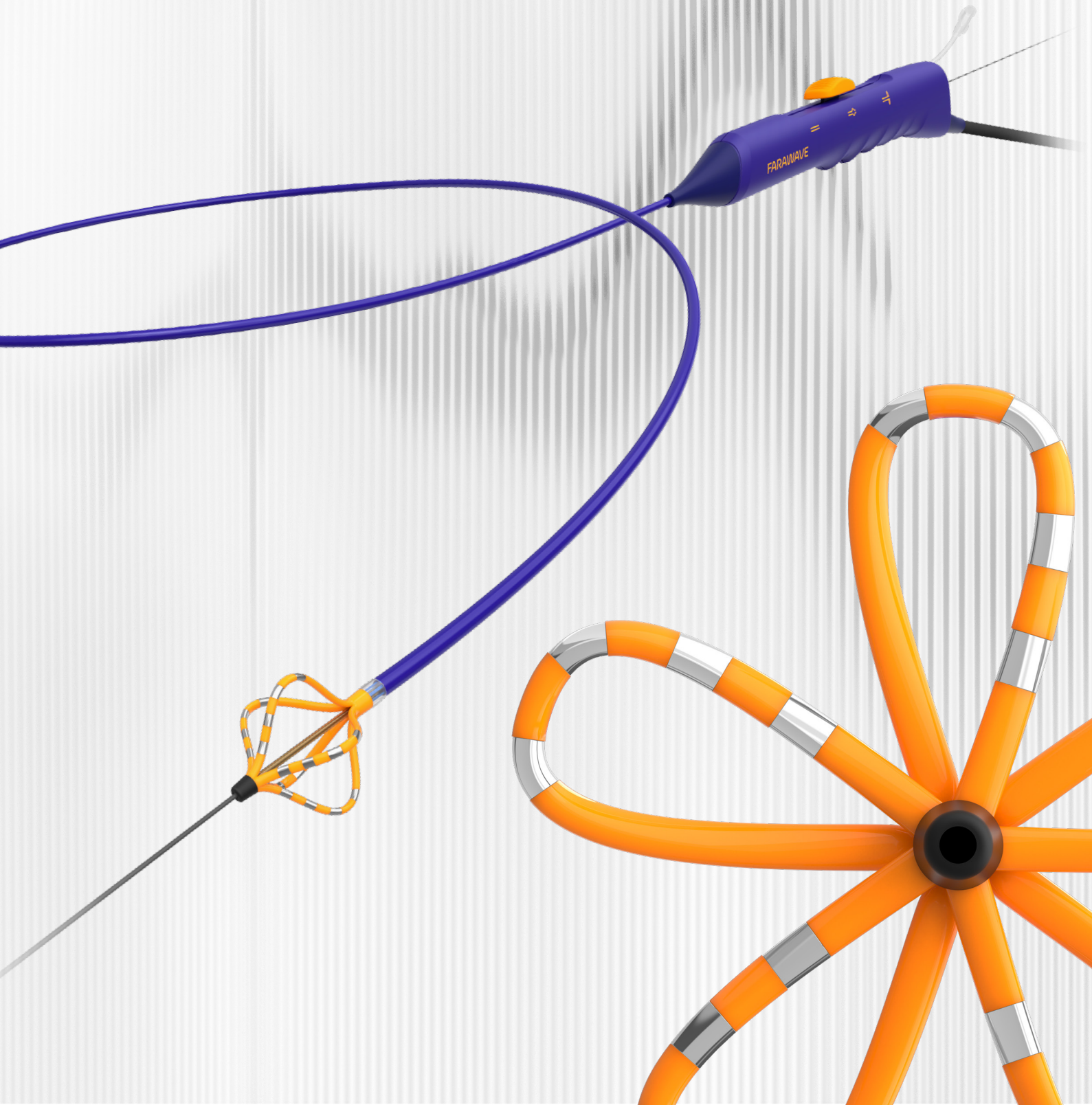
FARAPULSE™

Pulsed Field Ablation System

Clinical Compendium



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*Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE™ PFA Catheter with the FARAPULSE PFA System

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2024 CLINICAL PUBLICATIONS

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.
- 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, Ross R. et al.

Heart Rhythm (June 2024), available here

- Published guide on how to use the FARAWAVE catheter.

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Pulsed Field versus 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%).

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 with 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.

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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 2-4mm SCEs, one patient with a 3mm SCE, and one patient with 2 SCLs (5.5mm and 11mm).
- 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.

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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.

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 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.

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

- 2570 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 1/3 of patients after all ablation modalities and dialysis was never necessary.

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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, Steller, 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, Addelo, 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, Savour 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 Versus Radiofrequency Current Energy Ablation Guided by High-Density Mapping

Gunawardene M, Tim 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-reentries) 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 PFA for Pulmonary Vein Isolation: Comparison with a Reference RF 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 FAFAPULSE 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 in patients 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 pts.
- 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%).

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.

2024 CLINICAL PUBLICATIONS

Left Atrial Posterior Wall Isolation Using Pulsed-Field Ablation: Procedural Characteristics, Safety, and Mid-Term Outcomes

Badertscher P, Mannhart D, Weidlich S, et al.

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

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

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

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-h 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

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

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.
- 1714 procedures were analyzed: 1241 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).

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 versus 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 (1mg/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: Procedural 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, Cespon Fenandez 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.

- 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 mins 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.

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

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.

- 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 > .999).
  - Significantly less pulmonary vein cross-sectional narrowing compared to thermal ablation (posterior probability > .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, Kirstei 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 is outside the use of labeled indication of the FARAWAVE PFA Catheter with the F ARAPULSE 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.

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

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.

PFA for Treatment of AF in Patients with Congenital Anomalies of Cardiac Veins
Castiglione A, Küffer T, Gräni C, et al.

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

Journal of Cardiovascular Electrophysiology (March, 2023), available

- 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.

Effects of Pulsed Field Ablation on Autonomic Nervous System in Paroxysmal Atrial Fibrillation: A Pilot Study
Guo F, Wang J, Deng Q, et al.

Heart Rhythm (March, 2023), available here

- Nerve injury biomarkers and DW-MRI were conducted on 18 patients in a pilot study.
- Serum nerve injury biomarkers did not differ between pre- and post--ablation. Heart rate variability did not differ and there were no acute cerebral microemboli events.
- FARAPULSE PVI did not induce nerve injury in this study.

2023 CLINICAL PUBLICATIONS

Visualization of Fibroblast Activation Using 68Ga- 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.

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 is 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.

*PRECAUTION: 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 is 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.

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).

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, Nation 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 Ultra-High-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 nonablated 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 reisolated 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 under-went 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 biphasic, bipolar 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
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
Reddy VY, Koruth J, 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 and surgical box lesions were successful in 6 of 7 patients (86%) 2 lesions/patient. No complications.

2024 PRECLINICAL PUBLICATIONS

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.
- 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 V, Santos-Gallego C, 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.
- 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 vs Radiofrequency Ablation: Esophageal Effects in a Novel Preclinical Model
Koruth JS, Kuroki K, Kawamura I, et al.

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

- A novel preclinical model was created to nonsurgical 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 fistula.

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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