



FARAPULSE™
Pulsed Field Ablation System

Clinical Compendium



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2022 CLINICAL PUBLICATIONS

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 <https://doi.org/10.1093/europace/euac211>

- 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 $72.7 \pm 19.0\%$.
- 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 at:

<https://doi.org/10.1007/s10840-022-01445-0>

- 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 at:

<https://doi.org/10.3389/fcvm.2022.959186>

- 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 (Sept 2022), available at: [DOI: 10.1111/jce.15713](https://doi.org/10.1111/jce.15713)

- 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 (Sept 2022), available at: <https://doi.org/10.1007/s00392-022-02091-2>

- 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, Fütting A, Höwel D, et al.

Heart Rhythm (Sept 2022), available at: <https://doi.org/10.1016/j.hrthm.2022.06.018>

- In 30 patients treated with FARAWAVE, Nation Institute of Health 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 (Sept 2022), available at: <https://doi.org/10.1093/ehjcr/ytac361>

- 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 at: <https://doi.org/10.1093/europace/euac050>

- 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 at: <https://doi.org/10.1007/s10840-022-01359-x>

- 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 ($67.03 \pm 12.69\%$) were significantly larger compared to cryoballoon ($57.39 \pm 10.91\%$).
- 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 at: <https://doi.org/10.1093/europace/euac044>

- 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 at: [LINK](#)

- 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 temperature 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 at: <https://doi.org/10.1093/europace/euac111>

- 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 at: <https://doi.org/10.1093/europace/euac041>

- 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 at <https://doi.org/10.1016/j.hrthm.2022.05.020>

- 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.
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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 at: <https://doi.org/10.1111/jce.15349>

- 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 at: [doi: 10.1016/j.hrthm.2021.02.020](https://doi.org/10.1016/j.hrthm.2021.02.020)

- 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 at: [doi:10.1093/europace/euab155](https://doi.org/10.1093/europace/euab155)

- 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 at: doi.org/10.1016/j.jacep.2021.02.014

- 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 $78.5 \pm 3.8\%$ and $84.5 \pm 5.4\%$, 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 at: [doi:10.1093/europace/euab150](https://doi.org/10.1093/europace/euab150)

- 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 at: [doi:10.1093/europace/euab090](https://doi.org/10.1093/europace/euab090)

- 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 (Jan 2021), available at: [DOI: 10.1097/HCO.0000000000000810](https://doi.org/10.1097/HCO.0000000000000810)

- 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 (Sep 2020), available at: <https://doi.org/10.1016/j.jacc.2020.07.007>

- 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 2020 May, available at: doi.org/10.1016/j.hrthm.2020.04.040

- 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: $0.9\% \pm 8.5\%$ vs. $-11.9\% \pm 16.3\%$; $P < .001$ and short axis: $3.4\% \pm 12.7\%$ vs. $-12.9\% \pm 18.5\%$; $P < .001$).
- 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 (Jul 2019), available at: <https://doi.org/10.1016/j.jacc.2019.04.021>

- 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.
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2018 CLINICAL PUBLICATIONS

Ablation of Atrial Fibrillation with Pulsed Electric Fields

Reddy VY, Koruth J, et al.

JACC-EP (Apr 2018), available at: <https://doi.org/10.1016/j.jacep.2018.04.005>

- 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.

2023 PRECLINICAL PUBLICATIONS

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 at:

<https://doi.org/10.1161/CIRCEP.122.011369>

- 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 (Dec 2022), available at: <https://doi.org/10.1016/j.jacep.2022.09.003>

- 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 at: <https://doi.org/10.1016/j.jacep.2022.03.007>

- 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 FARAWAVE 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 (Jan 2020), available at:
<https://doi.org/10.1161/CIRCEP.119.008303>

- A novel preclinical model was created to nonsurgically assess the response to esophageal injury. This was accomplished by delivering the energy source from within the inferior vena cava, against the esophagus (which was purposefully mechanically deviated towards the IVC).
- Biphasic pulsed field ablation induced no chronic histopathologic esophageal changes, whereas radiofrequency catheter ablation demonstrated a spectrum of esophageal lesions including esophageal ulcers, abscess, and 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 (Dec 2019), available at:
<https://doi.org/10.1161/CIRCEP.119.007781>

- 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 (Dec 2019), available at: <https://doi.org/10.1093/europace/euz341>

- 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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