



FARAPULSE™

Pulsed Field Ablation System

Clinical Compendium



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CLINICAL PUBLICATIONS

2022

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).

KEY TAKEAWAY: In a real-world setting, the FARAWAVE catheter LA dwell time was 23 ± 9 min with a low number of procedural complications. The one-year freedom from recurrence rate was 90% in PAF patients and 60% in PERS AF patients.

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.

KEY TAKEAWAY: The rate of MRI detected asymptomatic thromboembolic SCE/SCL was 3%. The lesion completely regressed at 40 days and no patient showed neurological deficit.

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 & 3 had PAF w/out 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 & 3 lasted a few seconds).

KEY TAKEAWAY: 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.

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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, Boris 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.

KEY TAKEAWAY: In a real-world use setting, FARAPULSE had a high rate of acute PVI, low procedure time and a low rate of PFA specific complications.

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.

KEY TAKEAWAY: PVI with FARAWAVE resulted in significantly larger acute antral lesions versus cryoballoon when measured with high-density voltage mapping.

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:

<https://www.ahajournals.org/doi/pdf/10.1161/CIRCEP.121.010817>

- 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.

KEY TAKEAWAY: Real world use of the FARAWAVE catheter showed a short learning curve with effective, efficient (38 ± 13 min) and safe procedures.

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.

KEY TAKEAWAY: Proper catheter placement is important to achieve a circumferential antral PV lesion and to prevent posterior wall and roof ablation.

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.

KEY TAKEAWAY: FARAWAVE PFA for PVI in a real-world setting appeared to be safe and feasible with short FARAWAVE catheter left atrial dwell times.

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 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.
- Mean and median post-procedural Troponin levels were significantly higher in the PFA group compared to the RF and cryo groups with no significant difference between the RF and cryo groups.

KEY TAKEAWAY: Post-procedure Troponin T levels with PFA were 1.6x and 1.9x higher vs RF and Cryo, respectively. This may be a surrogate for larger lesions or more myocardial cell death.

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: [DOI: 10.1111/jce.15349](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.

KEY TAKEAWAY: 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

Does pulsed field ablation regress over time? A quantitative temporal analysis of pulmonary vein isolation

Kawamura I, Neuzil P, Shrivamurthy 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 paroxysmal atrial fibrillation underwent PVI using a biphasic PFA waveform delivered through a dedicated, variably deployable multielectrode basket/flower catheter.
- 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.

KEY TAKEAWAY: In this study, the level of PV antral isolation after PFA with a multielectrode PFA catheter persists 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 paroxysmal atrial fibrillation (AF) undergoing pulmonary vein (PV) isolation 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.

KEY TAKEAWAY: In this study, pulsed field ablation induces large acute LGE without microvascular damage or intramural hemorrhage. Most LGE lesions disappear in the chronic stage, suggesting a specific 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), paroxysmal atrial fibrillation 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.

KEY TAKEAWAY: In this study, PVI with a “variable distal end morphology” PFA catheter results in excellent PVI durability and acceptable safety with a low 1-year rate of atrial arrhythmia recurrence.

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), paroxysmal atrial fibrillation (PAF) patients underwent PVI with a multi-electrode pentaspline PFA catheter using a biphasic waveform, and after 75 days, detailed voltage maps were created during protocol-specified remapping studies.
- Comparative voltage mapping data were retrospectively collected from consecutive PAF patients who (i) underwent PVI using thermal energy, (ii) underwent reablation 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.

KEY TAKEAWAY: In this study, catheter-based PVI with the pentaspline PFA catheter creates chronic PV antral isolation areas as encompassing as thermal energy ablation.

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 paroxysmal AF patients undergoing PVI with PFA (N= 18, FARAPULSE) or thermal methods (N= 23, 16 radiofrequency, 7 cryoballoon).
- Oesophageal 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 oesophageal lesions (43%), all observed in patients showing direct contact between the oesophagus and the ablation sites. Oesophageal lesions were observed in no patient ablated with PFA (0%, $P < 0.001$ vs. thermal methods), despite similar rates of direct contact between the oesophagus 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 oesophageal and aortic LGE in all patients.

KEY TAKEAWAY: In this study, PFA does not induce any signs of oesophageal injury on CMR after PVI. Due to its tissue selectivity, PFA may improve safety for catheter ablation of AF.

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. Thus, it holds a promise to become a 'perfect' energy source for cardiac ablation to treat arrhythmias.
- 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 exceptionally low rate of those complications that are 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.
- As the reports confirming its safety and efficacy build up, there seems to be no way that the promise of pulsed field ablation could end in a blind alley.

KEY TAKEAWAY: Promising intraprocedural PFA results for atrial fibrillation ablation had recently been supported by 1-year clinical follow-up data with the pleasing success rate. It is likely that PFA with a circumferential lesion catheter design will become the dominant modality for PVI in the foreseeable future. True focal PFA, with solid tip catheters is being investigated in animal labs while we still await FIH reports. This will provide ability to widen the application for ventricular arrhythmias ablation.

2020

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 is a single-arm study evaluating biphasic, bipolar PFA using a multispline catheter 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 multispline PFA catheter alone. Using the focal PFA catheter, acute cavotri cuspid isthmus block was achieved in 13 of 13 patients.
- Post-procedure esophagogastroduodenoscopy 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.

KEY TAKEAWAY: In this study, the unique safety profile of PFA potentiated efficient, safe, and durable PVI and LAPW ablation. This extends the potential role of PFA beyond paroxysmal to persistent forms of AF. Lesion reassessments at 3 months revealed durable lesions.

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 paroxysmal atrial fibrillation 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.

KEY TAKEAWAY: In this study, unlike after RFA, the incidence and severity of PV narrowing/stenosis after PV isolation is virtually eliminated with PFA.

2019

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 paroxysmal atrial fibrillation.
- 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.

KEY TAKEAWAY: In this study, FARAPULSE PFA preferentially affected myocardial tissue, allowing facile ultra-rapid PV isolation with excellent durability (3 months remapping) and chronic safety.

2018

Ablation of Atrial Fibrillation With Pulsed Electric Fields: An Ultra-Rapid, Tissue-Selective Modality for Cardiac Ablation

Reddy VY, Koruth J, et al.

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

- First acute clinical experience of atrial fibrillation ablation with PFA, both epicardial box lesions during cardiac surgery, and catheter-based PV isolation.
- PFA was performed using a custom over-the-wire endocardial catheter for percutaneous transeptal 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.

KEY TAKEAWAY: In this study, ultrarapid PFA-based PV and LA ablation is both feasible and safe and is associated with excellent acute efficacy.

PRECLINICAL PUBLICATIONS

2022

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.

KEY TAKEAWAY: 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

Pulsed Field Ablation Versus Radiofrequency Ablation: Esophageal Injury in a Novel Porcine Model

Koruth JS, Kuroki K, Kawamura I, et al.

Circulation: Arrhythmia and Electrophysiology (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.

KEY TAKEAWAY: Dr. Koruth et al describe a novel porcine model simulating clinical conditions for esophageal damage caused by endocardial ablation. Six subjects treated with FARAPULSE PFA revealed no esophageal injury while radiofrequency ablation caused grossly observable and severe injury.

2019

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.

KEY TAKEAWAY: Dr. Koruth et al compares lesion durability and collateral injury following preclinical pulmonary vein isolation with FARAPULSE PFA (monophasic and biphasic) and radiofrequency. Nerve and PV damage was observed only with radiofrequency ablation and biphasic PFA yielded optimal lesion durability among the three cohorts.

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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 28.6mm respectively.
- In PFA lesions, fibrous tissue homogeneously replaced myocytes without overlying thrombus. When present in the lesion zone, nerve fascicles and vasculature were preserved.

KEY TAKEAWAY: Report on a series of porcine subjects treated with the novel FARAPULSE FARAFLEX focal PFA catheter. Ventricular tissue targeted for ablation demonstrated lesions with clinically relevant dimensions and spared collateral structures such as vasculature and nerves.

ABSTRACTS

2021

Cerebral safety after pulsed field ablation for symptomatic atrial fibrillation ablation

Reinsch N, Fueting AV, Höwel D, et al.

Clin Res Cardiol (2021). 10.1007/s00392-021-01933-9

Pulsed field ablation for atrial fibrillation is safe for the bronchial system

Höwel D, Fueting AV, Reinsch N, et al.

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Patient discomfort following pulsed field ablation for paroxysmal atrial fibrillation - an assessment of chest and groin pain using Numeric Rating Scale

Füting A, Neven K, Höwel D, et al.

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Cardiac enzyme kinetics as marker for myocardial damage after pulsed field ablation for paroxysmal atrial fibrillation

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First real-world experience with pulmonary vein isolation using pulsed field ablation for paroxysmal atrial fibrillation

Neven K, Füting A, Höwel D, et al.

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Pulsed field ablation for atrial fibrillation is safe for the esophagus

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Pulsed Field Ablation For Paroxysmal Atrial Fibrillation Using An Optimized Biphasic Waveform: Recurrence Of Atrial Arrhythmias

Neuzil P, et al.

B-AB06-01, *Heart Rhythm*; May 2021, 18(8), S1-S540 (abstr)

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Sung Il ,et al.

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Focal PFA For Linear Atrial Lesions-a Preclinical Feasibility Assessment

Kawamura I, et al.

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Reddy VY, et al.

D-PO01-170, *Heart Rhythm*; May 2020, 17(5), S1-S622

Best Abstract Award - PFA vs. RF: Esophageal Effects in a Novel Preclinical Model

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PO05-104, *Heart Rhythm*; 11(5), S451-492 (abstr)

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