FIRST REPORT OF LONG-TERM (3-YEAR) CLINICAL OUTCOMES IN PATIENTS TREATED WITH PULSED FIELD ABLATION FOR PAROXYSMAL ATRIAL FIBRILLATION

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Background: Pulsed field ablation (PFA) has gained prominence due to its enhanced safety profile, durable pulmonary vein isolation (PVI), and high 1-year rates of freedom from recurrent paroxysmal AF. However, the long-term (beyond 1 year) safety and efficacy outcomes of PFA in paroxysmal patients remains unknown.

Objective: To assess 3-year clinical safety and efficacy outcomes of PFA for paroxysmal AF.

Methods: In 3 multicenter trials (IMPULSE - NCT03714178, PEFCAT - NCT03714178, PEFCAT2 - NCT04170608), of similar design and utilizing a multielectrode penta-spline PFA catheter (Farawave, Farapulse Inc; Figure 1), paroxysmal AF patients underwent PVI. A protocol-driven remapping procedure at 2-3 months assessed PVI durability, and standardized rhythm monitoring to 1 year. Following study exit, patients returned to institutional standard-of-care monitoring. At a recent timepoint, 7-day Holter monitors and symptom and safety assessments were performed.

Results: The overall patient cohort included 121 patients enrolled at 3 centers. Long-term safety data is available for 112 of 121 patients, with follow-up of 1049 ± 205 days. Patients had no long-term ablation-related adverse events - including no deaths (1 patient had a brain tumor treated with radiation). Long-term efficacy data is available for 81 of 121 patients, with follow-up to 1116 ± 193 days. Repeat catheter ablation after the 1 year time point was performed on 10 of 78 (12.8%) patients. The mean time to re-ablation was 934 ± 269 days. Of these 10 patients, 3 patients had initially received the optimized PFA waveform at the index procedure - all PVs had remained isolated at both the protocol-mandated remapping procedure, as well as at the late re-ablation procedure. The remaining 7 patients had initially received the index PVI procedure with an early version of the PFA waveforms.

Data at re-ablation was available for 6 of the 7 patients: 1 patient had 2 PVs reconnected, 3 patients had 1 PV reconnected, and 2 patients had durable PVI.

Conclusion: In this long-term (3 years) evaluation of PFA, there were no untoward late safety events, and efficacy appears to remain good. During redo procedures, patients initially receiving the optimized PFA waveform retained durable PVI, while the patients receiving the earlier waveforms had a higher rate of PV reconnections.

SIX-MONTH FOLLOW-UP OF FIRST REAL-WORLD EXPERIENCE WITH PULMONARY VEIN ISOLATION USING PULSED FIELD ABLATION FOR PAROXYSMAL ATRIAL FIBRILLATION

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Background: Catheter ablation for AF using thermal energy can cause collateral damage. Pulsed field ablation (PFA) is a novel nonthermal energy source. Only a few small clinical studies have been published.

Objective: We report on the first real-world experience with 6-month follow-up with PVI with PFA for paroxysmal AF.

Methods: Pre and post ablation, phrenic nerve function was assessed. A high-density LA bipolar voltage map was created. All PVs were individually isolated using a steerable sheath and a penta-spline over-the-wire PFA catheter. After ablation, mapping was repeated to assess lesion formation. Patients had a scheduled follow-up visit at days 30, 90 and 180 after ablation.