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Real-World Outcomes of Concomitant Pulsed Field Ablation and Left Atrial Appendage Closure: Acute Safety, Feasibility, and 3 Month Implantation Results from ALIGN-AF[1]

Real-world results demonstrated a strong safety profile and high LAA closure, supporting **FARAWATCH™ — a concomitant FARAWAVE™ PFA and WATCHMAN FLX™ Pro procedure, as a practical, contemporary approach for AFib patients eligible for both therapies.**

STUDY DESIGN

- ALIGN-AF is a prospective real-world registry, within the DISRUPT-AF registry, evaluating real-world outcomes of combined AFib ablation and left atrial appendage (LAA) closure with the FARAWAVE PFA Catheter and WATCHMAN FLX Pro Device.
- This analysis included 122 patients at 12 sites with 24 operators, and assessed peri-device leaks between 45 and 90 days following implant.
- Additional analysis will assess freedom from stroke and documented atrial arrhythmia recurrence at 1 year and freedom from late-onset procedure or device related complications.

ACUTE RESULTS

- 100% acute ablation and LAAC procedural success
- 2.5% procedure related serious adverse events (3/122)
- No significant change in LAA orifice diameter (0.3 ± 1.6 mm) pre- and post-ablation (n=103)
- 94.1% of patients showed no new LAA edema after FARAWAVE ablation

45-90 Day Follow-up

- 90.6% complete seal (0 mm) of the LAA between 45-90 days follow-up, with no leaks >3 mm
- No reported device related thrombus or device shift among evaluated implants
- Of the 5.9% of patients with post-ablation edema, implant success remained unaffected, with leak-free, stable devices at follow-up

Patient Characteristics	
Number of Patients	122
Sex, % Female	52.9 (64)
Age, Mean	74.2 ± 6.8
Vascular Comorbidities	
Vascular Disease	45.1 (55)
Prior Stroke	18.0 (22)
HAS-BLED	2.6 ± 1.2
CHA_2DS_2-VASc	4.1 ± 1.3
Atrial Fibrillation Indication, % of Patients	
Paroxysmal Atrial Fibrillation	66.4 (81)
Persistent Atrial Fibrillation	33.6 (41)
LA Diameter, cm	4.2 ± 0.7
Cardiac Function, % Ejection Fraction	56.1 ± 8.9

Data presented as mean ± standard deviation or % (n).

45-90 Day Follow-Up (n=106)	
Time to Follow Up, Days	66.3 ± 30.7
Clinically Relevant Closure (Leak ≤ 3mm)	100.0 (106)
Complete Seal	90.6 (96)
Leak 0 - 3 mm	9.4 (10)
Leak > 3 mm	0.0 (0)
Device Related Thrombus	0.0 (0)
Device Shift	0.0 (0/92)
Drug Regimen at Time of Follow Up	
Antiplatelet Use Alone	19.8 (22)
OAC Use Alone	34.2 (38)
Antiplatelet + OAC Use	29.7 (33)

Data presented as mean ± standard deviation or % (n). 45–90-day imaging modality: 77.4% (n=82) TEE, 22.6% (n=24) CT.

94.1% NO LAA EDEMA AFTER FARAWAVE PFA ABLATION

90.6% WATCHMAN FLX Pro COMPLETE SEAL (0 mm)

1. Al-Ahmad, A., et al. (2026). Real-World Outcomes of Concomitant Pulsed Field Ablation and Left Atrial Appendage Closure: Acute Safety, Feasibility, and 3 Month Implantation Results from ALIGN-AF. Presented at HRS 2026.

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FARAPULSE™ Pulsed Field Ablation System Indications, Safety, and Warnings

https://www.bostonscientific.com/en-US/products/catheters--ablation/farapulse/farapulse-indications.html

WATCHMAN FLX™ Pro LACC Device Implanter Indications, Safety, and Warnings

https://www.watchman.com/en-us-implanter/watchman-flx-pro-brief-summary.html



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