

First clinical experience using a pentaspline pulse field ablation catheter with integrated electroanatomic 3-dimensional mapping for pulmonary vein isolation

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Pulsed field ablation (PFA) has emerged as a major breakthrough in the setting of atrial fibrillation (AF) ablation, reducing potential complications associated with thermal energy while maintaining comparable efficacy. Recently, the pentaspline PFA catheter (FaraWave NAV; Farapulse, Boston Scientific) has been integrated with the OPAL HDx mapping system, enabling electroanatomic 3-dimensional (3D) reconstruction of left atria and dynamic visualization of shape and contact during ablation.

This multicenter observational study assessed the feasibility, workflow, procedural, and safety data of the novel Faraview integrated mapping technology within the Farapulse PFA catheter for AF ablation.

Patients were stratified into 3 groups according to the mapping approach:

- 1) Integrated Faraview 3D mapping system (FAR)
- 2) Standard approach without a 3D mapping system (STD)
- 3) Nonintegrated 3D mapping system (MAP)

Differences among the 3 groups were balanced with 1:1:1 nearest-neighbor propensity-score matching without replacement.

Only patients undergoing their first ablation targeting pulmonary vein isolation (PVI) were included; those receiving additional lesions outside the pulmonary veins or repeated ablation were excluded.

From the ATHENA registry, 1395 consecutive patients across 12 centers were included: 1319 (94.6%) from the historical control group (July 2022 to April 2025: 1105 STD [79.2%], 214 MAP [15.4%]) and all 76 first cases (5.4%) treated with the integrated 3D mapping system from April 2025 to May 2025. All the cases in the MAP group were performed using pre-/postmapping with a high-density mapping catheter (Octaray/Pentarray, HD Grid, and Orion).

After propensity-score matching, 228 patients were evaluated (82.5% with paroxysmal AF; 25.9% female; mean age 64 ± 9 years; LVEF 58% ± 7%; 76 in each group).

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The overall mean electrophysiology laboratory utilization time (from patient entering to leaving the laboratory), technical support time (from engineer/technician entering to leaving the laboratory), skin-to-skin time, and fluoroscopy time were 104 ± 37 minutes, 93 ± 38 minutes, 69 ± 26 minutes, and 15.7 ± 7 minutes, respectively. The mean number of PFA deliveries was 39.8 ± 10 . FAR procedures had similar electrophysiology laboratory utilization and skin-to-skin time, shorter fluoroscopy time, and longer support time than STD procedures, whereas all procedural times were shorter than MAP procedures. In the FAR group, the number of PFA deliveries was higher than both STD and MAP procedures (Figure 1A).

Operator feedback in the FAR group revealed that planned strategies were often adjusted. The mean number of actual PFA deliveries per patient was significantly higher than the number initially planned (44.8 ± 11 vs 40.6 ± 9 ; $P < .001$; mean difference 4.2 ± 8). More deliveries than planned occurred in 61.8% of cases, equal in 18.4%, and fewer in 19.7% (Figure 1B).

A standard PVI strategy (4-basket/4-flower configuration per vein) was performed in 32 cases (42.1%), whereas 44 (57.9%) received additional lesions. Of these, 22.7% were consolidative (same site), 52.3% extensive (adjacent regions), and 25% combined.

The initial use of the Farapulse PFA catheter, incorporating electroanatomic mapping (EAM) technology, significantly reduced procedure duration time compared with third-party systems, while maintaining efficiency comparable with fluoroscopy-only PFA, even in a learning curve context. This finding cannot be attributed solely to the use of a single catheter for mapping and ablation but also to reduced reliance on technical support during the procedure. This new technology demonstrated flexibility, agility, and ease of use with minimal influence of the learning curve on acute out-

comes, consistent with previous reports using the first-generation pentaspline catheter.^{1,2}

Beyond its contribution to shortening procedure duration, this new integrated technology demonstrates a significant reduction in radiation exposure compared with third-party EAM systems. This advantage is likely attributable to the system's enhanced accuracy in 3D anatomic reconstruction and real-time catheter navigation, which minimized fluoroscopy to verify catheter position and contact. Although the Farawave mapping does not enable detailed electroanatomic reconstruction compared with high-density catheters, this limitation may not affect AF ablation when targeting only the pulmonary veins. In addition, elimination of catheter exchanges—typically requiring fluoroscopy—contributed to reductions in skin-to-skin and laboratory utilization times.

The enhanced precision provided by the integrated real-time electroanatomic navigation and lesion assessment tools also seems to facilitate a more individualized ablation strategy. This may improve catheter positioning and further decrease fluoroscopy use, primarily reflected in a greater number of PFA applications aimed at consolidating and extending PVI.

Moreover, this approach may promote the creation of wider and more contiguous antral lesions, which are recognized as predictors of long-term efficacy in PVI.³⁻⁵

The primary limitation of this study is its observational design. Although the aim was to evaluate the performance of the novel technology in the acute setting, the absence of follow-up data limits the ability to draw conclusions regarding long-term efficacy. Finally, the presumed advantage of tissue-contact assessment in the FAR group was not directly evaluated against the MAP group, in which contact index tools were not applied in this subset of patients.

This initial real-world experience with the novel pentaspline PFA catheter integrated with EAM capabilities demonstrated

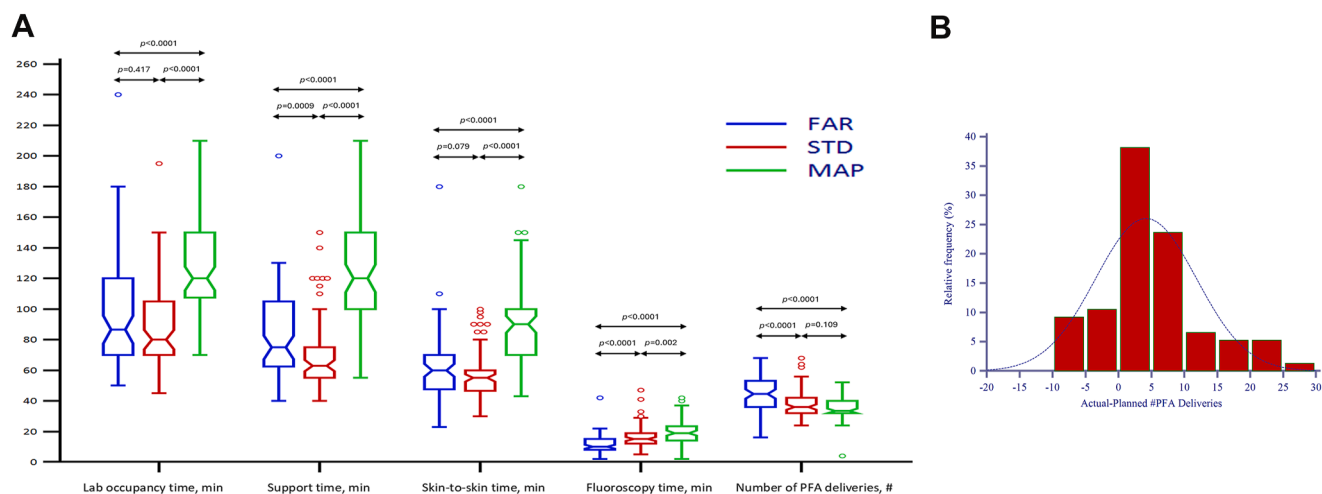


Figure 1

A: Procedural times and number of PFA deliveries among groups. Laboratory occupancy time, support time, skin-to-skin time, fluoroscopy time, and number of PFA deliveries were compared among matched cohort study groups (FAR, STD, and MAP). B: Mean difference of the number of actual vs planned PFA deliveries per patient. The red bar represents the relative frequency (%) of the difference between the actual and the planned number of PFA deliveries. The dotted blue curve represents the theoretical normal distribution of relative frequency. FAR = integrated Faraview 3D mapping system; MAP = nonintegrated 3D mapping system; PFA = pulsed field ablation; STD = standard approach without a 3D mapping system.

a simplified workflow for PVI compared with third-party EAM systems. This technology was associated with shorter procedural times and reduced radiation exposure.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

Clinical trial registration

Advanced Technologies for Successful Ablation of AF in Clinical Practice. URL: <http://clinicaltrials.gov/>. Identifier: NCT05617456.

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References

1. Rordorf R, Bianchi S, Dello Russo A, et al. Conventional pulsed-field ablation versus pulsed-field ablation with non-integrated three-dimensional mapping for paroxysmal and persistent atrial fibrillation ablation. *J Interv Card Electrophysiol* 2025. Epub ahead of print.
2. Bisignani A, Schiavone M, Solimene F, et al. National workflow experience with pulsed field ablation for atrial fibrillation: learning curve, efficiency, and safety. *J Interv Card Electrophysiol* 2024;67:2127–2136.
3. Gasperetti A, Assis F, Tripathi H, et al. Determinants of acute irreversible electroporation lesion characteristics after pulsed field ablation: the role of voltage, contact, and adipose interference. *Europace* 2023;25:euaad257.
4. Proietti R, Santangeli P, Di Biase L, et al. Comparative effectiveness of wide antral versus ostial pulmonary vein isolation. *Circ Arrhythm Electrophysiol* 2014; 7:39–45.
5. Kuck KH, Hoffmann BA, Ernst S, et al. Impact of complete versus incomplete circumferential lines around the pulmonary veins during catheter ablation of paroxysmal atrial fibrillation. *Circ Arrhythm Electrophysiol* 2016;9:e003337.