

**NAVIGATE-PF trial**

**Acute and chronic  
validation of FIELDTAG™  
Technology on the  
FARAVIEW™ Software  
Module**



**FARAPULSE™**  
PFA Platform





## OBJECTIVE

- ▶ Assess the acute and chronic accuracy of FIELDTAG™ Technology on the FARAVIEW™ Software Module in visualizing pulsed field energy delivery by the FARAWARE™ NAV Pulsed Field Ablation (PFA) Catheter, using data from the NAVIGATE-PF feasibility study (NCT06175234).

## FIELDTAG Technology

- ▶ Enables visualization of PFA energy throughout the entire PVI workflow via the FARAVIEW Nav Catheter, allowing for estimation of the size, shape, and intersection of ablation overlap with the anatomical shell.

## METHODS

### ▶ NAVIGATE-PF

- NAVIGATE-PF was a multi-center, first-in-human feasibility study that consisted of 2 phases.

### ▶ Phase I (acute assessment):

- Phase 1 included 30 patients that underwent PV isolation, with 30% also receiving posterior wall ablation.
- PFA markers were placed during PFA application and high-quality, post-ablation HD maps with INTELLAMAP ORION™ Mapping Catheter were completed in 15 pts. PFA markers were overlaid on the HD map and contours were drawn at the outer border of the low voltage areas (defined as  $\leq 0.5\text{mV}$ ) where at least 2 overlapping PFA markers were dropped.

### ▶ Phase II (chronic assessment):

- Phase 2 had 20 patients at 1 center to evaluate chronic lesion durability and alignment between acute PFA marker locations and chronic low voltage borders. Results from one patient are described here.

### ▶ PFA markers:

- The distance between the PFA marker and the low voltage border of the acute lesion was calculated for 5, 6, and 7 mm PFA markers sizes in both phases.

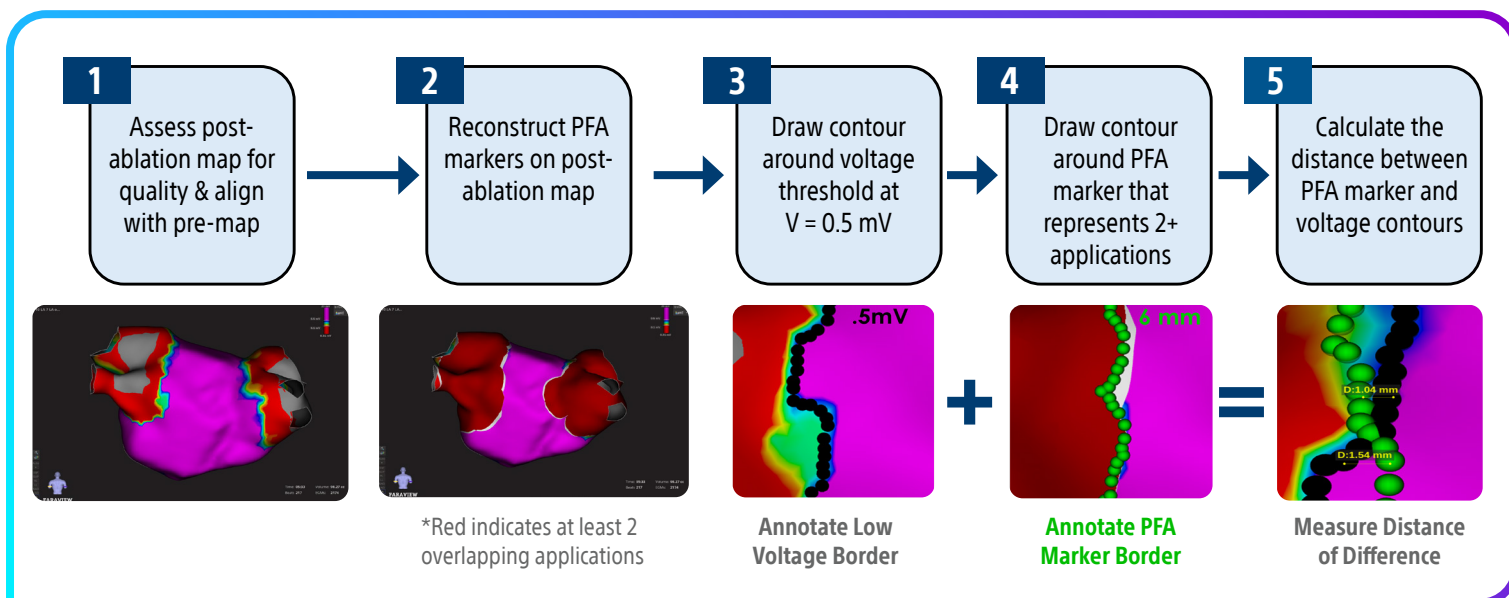


Figure 1. PFA Marker Analysis Methodology

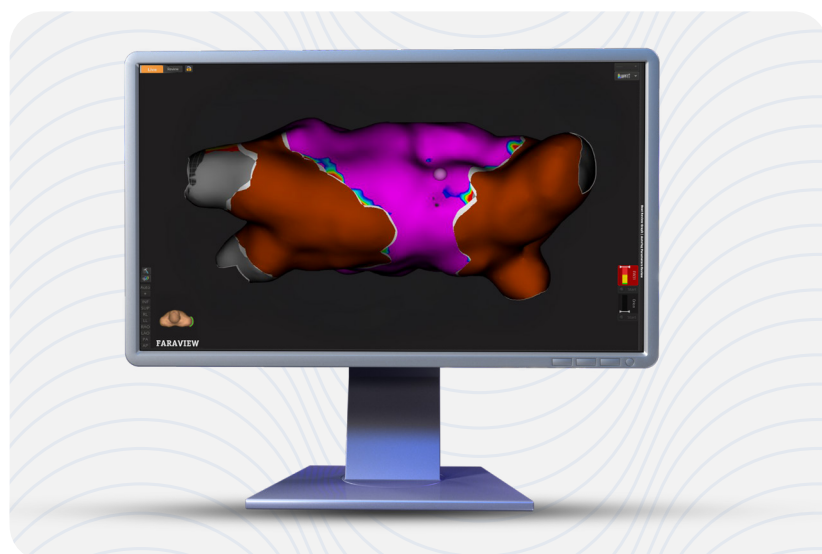


## ACUTE RESULTS - PHASE I<sup>1</sup>

- ▶ The total procedure time was  $95 \pm 20$  min with a LA dwell time of  $52 \pm 22$  min and a fluoroscopy time of  $11 \pm 8$ . The number of PFA applications for PVI was  $43 \pm 4$ .
- ▶ The 5 mm PFA markers were smaller than the lesions. The acute low voltage border extended beyond the 5 mm PFA marker by a median of 1.71 mm.
- ▶ The 6 mm PFA markers were slightly smaller than the lesions. The acute low voltage border extended beyond the 6 mm PFA marker by a median of 0.58 mm.
- ▶ The 7 mm PFA markers were larger than the lesions. The 7 mm PFA marker extended beyond the acute low voltage border by a median of 0.8 mm.

PFA marker size	5 mm	6 mm	7 mm
PFA marker to border zone distance	-1.71 mm	-0.58 mm	0.8 mm

Negative numbers indicate the PFA markers were smaller than the low voltage border

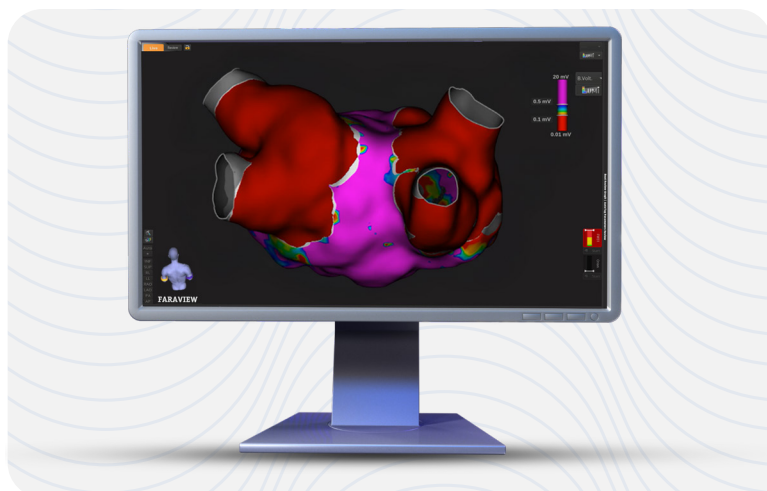


There was strong alignment between 6 mm PFA markers and acute lesion low voltage border zones.

**Figure 2.** 6 mm PFA markers (dark red, indicating at least 2 overlapping PFA applications) overlaid on a high density acute post-ablation voltage map.

## CHRONIC RESULTS - PHASE II<sup>1</sup>

- ▶ In NAVIGATE Phase II, patients had an index ablation and were remapped ~60 days post-index procedure to assess the concordance of FIELDTAG Technology driven acute PFA markers and chronic lesion border zones.
- ▶ Data from a single patient was available at the time of this clinical summary.
- ▶ The 6 mm PFA markers slightly underestimated the chronic lesion size. The 60-day chronic lesion voltage boundary extended beyond the 6 mm PFA marker by a median of 0.32 mm ( $\pm 2.8$ ) mm.



Analysis of a single patient showed strong alignment between the acute 6 mm PFA markers and chronic low voltage border zone created by prior FARAWAVE NAV ablation suggesting minimal lesion regression and that PFA markers driven by FIELDTAG Technology can accurately display the PFA energy field on the atrial anatomy.

**Figure 3.** 6 mm PFA markers (dark red, indicating at least 2 overlapping PFA applications) overlaid on a high density chronic 60-day post-ablation voltage map.

## CONCLUSIONS

- ▶ FIELDTAG Technology can guide ablation without adding significant complexity to the procedure, may assist in dealing with challenging anatomies and may reduce the number of lesions by guiding catheter positioning to achieve appropriate lesion overlap.
- ▶ This is the initial clinical data validating that PFA markers by the FIELDTAG Technology correlated to both acute and chronic lesion location.
- ▶ The 6 mm acute and chronic PFA markers provided an accurate estimation of the FARAWAVE NAV lesions in this initial analysis. The PFA markers were, on average, 0.58 mm smaller than the acute lesion low voltage border and 0.32 mm smaller than the chronic 60-day lesion low voltage border suggesting 6 mm markers may be most appropriate to estimate the PFA field and associated lesion borders.

## NEXT STEPS

- ▶ Further analysis is in progress to understand the translation of the acute PFA markers to chronic lesion formation and lesion durability. Appropriately estimating lesion size could help to optimize ablation strategy/number of lesions.

The strong alignment between PFA markers and chronic ablation lesions indicates that FIELDTAG Technology can accurately visualize the PFA energy field, increasing confidence in catheter positioning and streamlining lesion delivery workflow.



[FARAPULSE Pulsed Field Ablation System  
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