

## RESEARCH LETTER



# Lesion Durability Using a Circular Pulsed Field Ablation Catheter and Novel Mapping-Navigation System

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**P**ulsed field ablation (PFA) is being widely adopted for the treatment of atrial fibrillation due to potential safety benefits over traditional thermal ablation. One challenge posed by PFA is the inability to acutely confirm durable lesion formation. Immediate loss of electrograms after PFA may be due to regions of reversible electroporation, where acute hyperpolarization of cell membranes leads to cardiomyocyte stunning.<sup>1</sup> Accordingly, a better understanding of chronic lesion formation and procedural best practices to achieve durable pulmonary vein isolation (PVI) across PFA systems is needed.

This prospective, first-in-human study evaluated the long-term durability of PVI using the 25-mm circular PulseSelect PFA catheter integrated into the Affera mapping system (Medtronic). This study was conducted in accordance with the Declaration of Helsinki after receiving Ethics Committee approval (Vilniaus Regioninis Biomedicinių Tyrimų Etikos Komitetas) and informed patient consent. Patient-level data cannot be shared due to privacy restrictions; deidentified, aggregated data may be available from the corresponding author upon reasonable request.

In total, 15 patients with atrial fibrillation (67% male, 87% paroxysmal, 60.7±8.0 years, left atrial diameter: 41.9±4.2 mm, and CHA<sub>2</sub>DS<sub>2</sub>-VASc score: 1.8±1.3) were enrolled at a single center (Vilnius University, Lithuania) and treated by 3 operators. Procedures were performed using general anesthesia and paralytics. The catheter was visualized on an investigational hybrid impedance

and magnetic electroanatomic mapping system (Affera). All operators used intracardiac echocardiography to confirm catheter-tissue contact, with one operator placing the intracardiac echocardiography catheter in the left atrium.

Acute PVI, evaluated by entrance and exit block after a 20-minute wait or adenosine infusion, was achieved in 15 of 15 patients with an average of 52±12 applications (19±4 ostial, 33±13 antral; range: 41±7–58±6 across operators). All operators placed more lesions in the vein antrum versus ostium (ratio: 1.7) to achieve wide antral ablation. However, significant variation was observed in how operators defined ostial and antral deliveries. An average of 25±9, 13±2, 11±2, 15±5, 13±4, and 8 applications were placed to isolate the left common (n=6), left superior (n=9), left inferior (n=9), right superior (n=15), right inferior (n=15), and 1 right middle PV, respectively. No serious adverse events were observed.

To assess PVI durability, invasive remapping was completed in 15 of 15 patients 74.7±19.9 days after the index PVI. A total of 52 of 55 (95%) PVs were durably isolated, and 14 of 15 patients (93%) had all PVs durably isolated at the time of remap (confirmed by high-density mapping and entrance/exit block testing; Figure). All 3 reconducting PVs were observed in a single patient (47-year-old male with paroxysmal atrial fibrillation, left atrial diameter: 46 mm, CHA<sub>2</sub>DS<sub>2</sub>-VASc score: 0, and body mass index: 29 kg/m<sup>2</sup>). Conduction into the PV was observed anteriorly and on the carina of the left-sided

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## Nonstandard Abbreviations and Acronyms

<b>PFA</b>	pulsed field ablation
<b>PVI</b>	pulmonary vein isolation

PVs. Conduction was also observed in the right inferior PV via a small patch of viable tissue located posteriorly in the antrum. There was no obvious technical or anatomic cause for PV reconnection in this patient. A single patient (56-year-old male with paroxysmal atrial fibrillation) had early (day 72) atrial tachycardia/atrial flutter recurrence; all PVs were durably isolated. There have been no other documented atrial arrhythmia recurrences over a mean follow-up of  $237 \pm 62$  days.

Previous studies have evaluated lesion durability with PFA catheters during protocol-mandated invasive remapping  $\approx 75$  to 90 days after the index procedure. The 95% per-PV durability rate observed here is within the upper range previously reported for optimized PFA systems (87%–99%).<sup>1–4</sup> How these durability results will translate into long-term clinical success is still being elucidated.

The PulseSelect catheter creates a horseshoe-shaped lesion and requires rotation of the catheter between applications to achieve overlapping segments for continuous circumferential lesion formation. Notably, the average number of applications per vein for all 3 operators was higher than the recommended minimum of 8 according to the catheter's instructions for use. In this study, all operators used intracardiac echocardiography, fluoroscopy, and electroanatomic mapping and placed a specific focus on the left atrial ridge and carinal areas. A previous preclinical study demonstrated a linear relation between electrode-tissue proximity and lesion depth, suggesting that tissue contact is critical for ensuring transmural lesion formation.<sup>5</sup> Contact can be visualized on intracardiac echocardiography (by coordinated movement of the catheter array with the cardiac cycle) but also with fluoroscopy (due to displacement of the array's 20° forward tilt). Electroanatomic mapping additionally enables lesion annotation for visualizing optimal overlap between applications and voltage mapping for further insight into lesion creation.

Limitations of this study include a small sample size, participation by select experienced operators, the absence of long-term follow-up, and an inability to

identify the cause of PV reconnections in one patient. While additional studies are needed to confirm the generalizability of these results, the present findings support that durable PVI can be safely and consistently achieved across various workflows.

In conclusion, this is the first study to evaluate the long-term durability of PVI with the PulseSelect PFA system. A high rate of chronic lesion durability was observed across variant PV anatomy and multiple operators.

## ARTICLE INFORMATION

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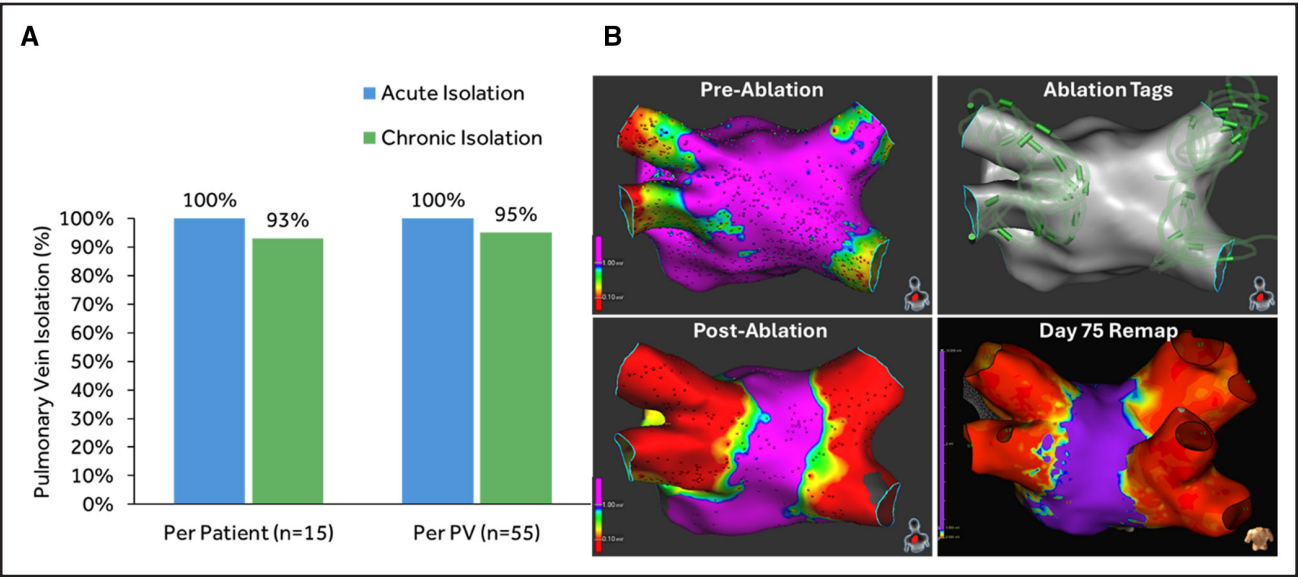
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**Figure. Durability of pulmonary vein (PV) isolation on invasive remapping.**  
**A**, Acute and chronic PV isolation on a per-patient and per-PV basis. **B**, Representative electroanatomical maps preablation, during the ablation procedure showing ablation tags on the Affera mapping system, immediately post-procedure and during the 75-day remap.