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ORIGINAL RESEARCH

PVI With CF-Sensing Large-Tip Focal PFA Catheter With 3D Mapping for Paroxysmal AF

Omny-IRE 3-Month Results

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ABSTRACT

BACKGROUND Omny-IRE (A Study For Treatment of Paroxysmal Atrial Fibrillation [PAF] With the OMNYPULSE Catheter and the TRUPULSE Generator; NCT05971693) evaluated safety and effectiveness of a novel large-tip focal, multielectrode, contact force–sensing, pulsed field ablation catheter with electroanatomic mapping integration.

OBJECTIVES This study sought to assess 3-month safety and effectiveness of the platform for treating symptomatic paroxysmal atrial fibrillation.

METHODS Pulmonary vein isolation (PVI) was performed using the OMNYPULSE Platform. Primary effectiveness was adenosine/isoproterenol-proof entrance block. Primary safety was occurrence of primary adverse events. Prespecified patient subsets underwent systematic brain imaging, esophageal endoscopy, cardiac computed tomography/magnetic resonance angiogram, and mandatory 3-month remapping for PVI durability assessment.

RESULTS Of 188 patients enrolled, 136 were included in the per-protocol analysis. Primary effectiveness was 100% (136 of 136). Median (Q1-Q3) procedure, left atrial dwell, total ablation, and total fluoroscopy times were 105.5 (91.0-124.0), 70.0 (56.0-81.5), 46.9 (37.1-58.8), and 5.0 (3.1-9.8) minutes, respectively. The primary adverse event rate was 3.0% (4 of 135 patients with 3-month follow-up; 3 major vascular access complications, 1 pericarditis). Brain imaging ($n = 30$) revealed 1 patient (3.3%) with an asymptomatic silent cerebral event at discharge, which resolved at 1 month without neurological change. No esophageal injury was observed. Computed tomography/magnetic resonance angiogram imaging ($n = 24$) showed no incidences of pulmonary vein narrowing >70%. During remapping, PVI was durable in 84.5% (98 of 116) of veins and 62.1% (18 of 29) of patients. With an optimized workflow, PVI durability improved to 89.3% (75 of 84) and 71.4% (15 of 21) of veins and patients, respectively.

CONCLUSIONS The force-sensing, large-focal pulsed field ablation catheter with 3-dimensional electroanatomic mapping integration showed 100% acute success with a promising safety profile for treating paroxysmal atrial fibrillation. Prespecified remapping showed good PVI durability. (A Study For Treatment of Paroxysmal Atrial Fibrillation [PAF] With the OMNYPULSE Catheter and the TRUPULSE Generator; NCT05971693) (JACC Clin Electrophysiol. 2025;■:■–■)

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ABBREVIATIONS AND ACRONYMS

3D = 3-dimensional
AF = atrial fibrillation
CF = contact force
CT = computed tomography
ITD = intertag distance
mITT = modified intent to treat
MRA = magnetic resonance angiogram
PAE = primary adverse event
PF = pulsed field
PFA = pulsed field ablation
PV = pulmonary vein
PVI = pulmonary vein isolation

Pulsed field ablation (PFA) has emerged as a novel, minimally thermal energy source for the treatment of atrial fibrillation (AF) and other cardiac arrhythmias through the process of irreversible electroporation, with the functional effect of preferential myocardial ablation.[1-3] Compared with thermal ablation, PFA has demonstrated at least similar effectiveness with low rates of complications.[4-11]

A novel large-tip focal, contact force (CF)-sensing, basket catheter (OMNYPULSE Catheter; Biosense Webster, Inc., part of Johnson & Johnson MedTech) has been developed to combine mapping, navigation, and therapeutic capabilities for the creation of wide focal, contiguous PFA lesion sets with enhanced catheter maneuverability and stability. Preclinical studies in swine models demonstrated the feasibility of this large-focal PFA system for both mapping and ablation.[12] The system did not result in any safety concerns, producing no clinically relevant collateral injury to the pulmonary veins (PVs), phrenic nerve, coronary arteries, or esophagus in swine models.[13-15] Ablation resulted in acute isolation of all treated PVs, with contiguous and transmural lesions achieved with shorter intertag distances (ITDs), and dose-related durability through 30 days of follow-up.[12,13,16] Notably, the PFA system provided evidence that there was an impact of CF and PFA dose on lesion size in a preclinical model of PFA, with CF and the number of PFA applications appearing to act synergistically on lesion formation.[17]

The Omny-IRE study (A Study For Treatment of Paroxysmal Atrial Fibrillation [PAF] With the OMNYPULSE Catheter and the TRUPULSE Generator; NCT05971693) was conducted to assess the clinical safety and effectiveness of this novel PFA system for the treatment of patients with symptomatic paroxysmal AF. Acute results, up to 3 months of follow-up, including a remapping study, are presented here.

METHODS

STUDY DESIGN AND POPULATION. The Omny-IRE study was an interventional, prospective, multicenter, single-arm safety and effectiveness study using the OMNYPULSE Bidirectional Catheter in conjunction with the TRUPULSE Generator (Biosense Webster, Inc., part of Johnson & Johnson MedTech). Eligible patients were 18 to 75 years of age, were diagnosed with symptomatic paroxysmal AF, and were identified for AF ablation by pulmonary vein isolation (PVI). Full details of the inclusion and exclusion criteria are summarized in Supplemental Table 1.

The study was reviewed and approved by ethics committees at all participating sites and by national authorities in participating countries. The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practices and the Declaration of Helsinki. All enrolled patients provided written informed consent before study treatment.

ABLATION SYSTEM. The large-focal PFA catheter is a multielectrode, CF-sensing catheter with a distally located, 12-mm-diameter basket cage (**Figure 1A**). The catheter has a deflectable tip designed to facilitate electrophysiological mapping of the heart and to transmit pulsed field (PF) energy to the catheter cage electrodes for ablation purposes. The catheter, which has a 7.5-F shaft with 8-F shaft ring electrodes, is deployed through a 10-F steerable guiding sheath (GUIDESTAR, Oscor Inc.). The catheter comes

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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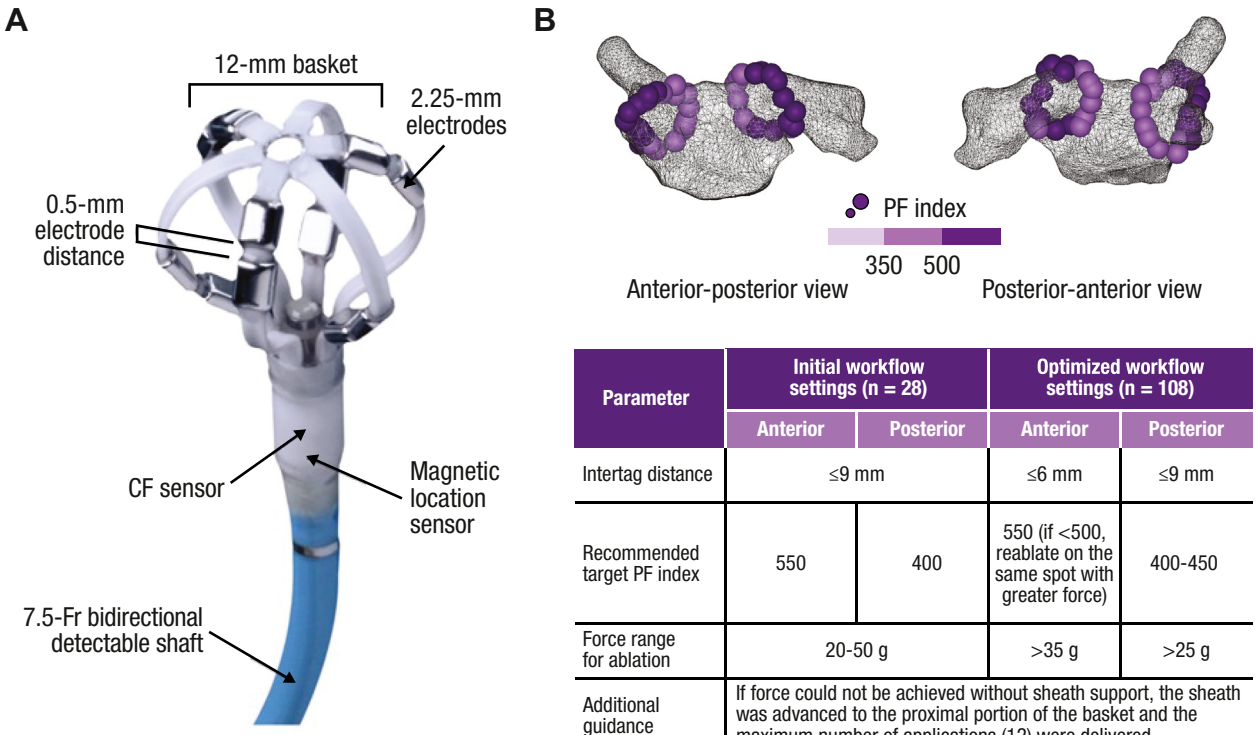
FIGURE 1 Study Catheter and Recommended Workflow



Parameter	Initial workflow settings (n = 28)		Optimized workflow settings (n = 108)	
	Anterior	Posterior	Anterior	Posterior
Intertag distance	≤9 mm		≤6 mm	≤9 mm
Recommended target PF index	550	400	550 (if <500, reablate on the same spot with greater force)	400-450
Force range for ablation	20-50 g		>35 g	>25 g
Additional guidance	If force could not be achieved without sheath support, the sheath was advanced to the proximal portion of the basket and the maximum number of applications (12) were delivered			

The workflow was updated after 28 patients to improve reaching the target index. Reliable force measurements and PF index calculations require adequate distance from the proximal portion of the basket.

(A) Large-focal, CF-sensing PFA catheter. (B) Recommended workflow parameters. CF = contact force; PF = pulsed field; PFA, pulsed field ablation. Images are courtesy of © Biosense Webster, Inc., part of Johnson & Johnson MedTech. All rights reserved.

assembled with an insertion tool located on the shaft to facilitate collapse of the spherical cage and subsequent insertion into the guiding sheath. It has magnetic-based navigation technology, allowing the electroanatomic mapping system (CARTO 3; Biosense Webster, Inc., part of Johnson & Johnson MedTech) to display the location and orientation of the catheter. The catheter has force-sensing technology that provides a real-time measurement of CF between the distal cage of the catheter and the heart wall. The cage is composed of 6 spines, with each spine having 2 electrodes capable of delivering energy, sensing, and pacing. A reference electrode for sensing is located in the base of the cage, and there are 2 advanced catheter location electrodes for shaft visualization of the deflectable segment. The PFA generator that was used in Omny-IRE is a modified version of the PFA generator used in the SmartfIRE (A Study For Treatment Of Paroxysmal Atrial Fibrillation [PAF] With The THERMOCOOL SMARTTOUCH SF Catheter and TRUPULSE Generator) clinical investigation.[6] PF energy is delivered in high-frequency, high-voltage, bipolar, biphasic microsecond pulses. The generator transmits biphasic high-voltage pulses (1,200-1,500 V) to the electrodes on the catheter to perform ablation in bipolar mode, in which the entire basket is energized. Applications (ie, trains of pulses) are delivered in groups of 3 to a maximum of 12 per lesion, with a 1-second delay between pulses. The duration of 12 pulses is approximately 14.5 seconds, depending on the PF index targeted at the physician's discretion.

ABLATION PROCEDURE. Uninterrupted anticoagulation therapy was administered ≥3 weeks before the ablation procedure. Anesthesia or sedation was delivered per standard laboratory procedure. Following transseptal puncture, a left atrial map was created with the large-focal bidirectional PFA catheter (or an alternative commercially available

multielectrode mapping catheter at the investigator's discretion). Confirmation of activated clotting time ≥350 seconds before the start of ablation and systemic anticoagulation with heparin were required. When the investigational catheter was in the body, a continuous infusion of 4 mL/min or 40 mL/min of room temperature heparinized saline (1 unit heparin/1 mL saline) was required during idle and ablation mode, respectively. PVI was subsequently performed using the large-focal PFA catheter with point-by-point ablation to obtain a contiguous lesion set for antral ipsilateral PVI.

The initial workflow settings recommended an ITD ≤9 mm, a target index of 550 for anterior and 400 for posterior, and force range for ablation of 20 to 50 g per preclinical study results showing that lesion size is titrated based on CF and number of applications delivered to target a desired PF index.[17] After the first 28 procedures, the presence of gaps prompted a workflow optimization to recommend an ITD ≤6 mm for anterior and ≤9 mm for posterior left atrium lesions, a target index of 550 for anterior (if <500, reablation of the same location with greater force) and 400 to 450 for posterior, and force of >35 g anterior and >25 g posterior (Figure 1B). If force could not be achieved without sheath support, the sheath was advanced to the proximal portion of the basket and the maximum number of applications (12) were delivered. Reliable force measurements and PF index calculations require adequate distance from the proximal portion of the basket.

Pacing of the phrenic nerve was performed systematically, before and after ablation, to assess for phrenic nerve injury. Confirmation of PVI (entrance block) was performed after adenosine/isoproterenol challenge and, if necessary, additional applications of PF energy were delivered to treat acute reconnections. Cavotricuspid isthmus ablation, performed using a compatible commercially available radiofrequency catheter, was permitted in cases of documented typical atrial flutter. Prophylactic ablation outside the PV region (eg, posterior wall isolation, roof, and mitral valve isthmus) was not allowed. Antiarrhythmic drug management during the study was at the investigator's discretion.

STUDY ENDPOINTS. The primary safety endpoint was the occurrence of primary adverse events (PAEs) within 7 days of the index procedure, including major vascular access complication or bleeding, myocardial infarction, pericarditis, pulmonary edema (respiratory insufficiency), phrenic nerve paralysis, stroke or cerebrovascular accident, transient ischemic attack, thromboembolism, heart block, vagal nerve injury, or gastroparesis; cardiac tamponade or perforation (up to 30 days postprocedure); and PV stenosis (≥70% reduction in PV diameter), atrioesophageal fistula, and device- or procedure-related death (up to 90 days postprocedure).

The primary effectiveness endpoint was the electrical isolation of clinically relevant targeted PVs as evidenced by patient-level confirmation of entrance block after adenosine/isoproterenol challenge at the end of the index ablation procedure. The use of a nonstudy device to achieve PVI was considered an acute procedural failure. Patients who had the study catheter inserted but did not undergo ablation due to study device–related reasons were considered acute effectiveness failures. Patients who were discontinued due to nonstudy device–related reasons (eg, pump, other equipment, or anatomy that precluded treatment with the investigational system or a commercially available device) were considered to be missing the acute effectiveness endpoint outcome, as entrance block would not be achieved by the study device.

PRESPECIFIED SUBSETS FOR SAFETY AND PV DURABILITY ASSESSMENT. To further delineate safety and assess lesion durability, the same group of patients underwent additional assessments for neurological evaluation and cerebral lesion, esophageal endoscopy for esophageal injury, cardiac computed tomography (CT) or magnetic resonance angiogram (MRA) imaging for PV stenosis, and mandatory remapping for PVI durability assessment. For the PVI durability assessment, patients underwent repeat electroanatomic creation of paced activation and bipolar voltage maps at 75 days (±15 days) after the index ablation to verify isolation durability of the treated PV, using the same mapping catheter as that used during the index ablation procedure (Table 1). If reconnections were identified in the remapping procedure, additional ablations could be performed at the investigator's discretion with the investigational ablation system. If the additional ablations could not be achieved with the investigational ablation system, a commercially approved and compatible radiofrequency catheter and generator could be used.

STATISTICAL METHODS. As specified in the protocol, the first 2 patients for each ablating physician were considered roll-in patients to verify consistent workflow of study device components and to minimize any learning curve effects; these patients were not included in the main study analyses. The safety analysis set consisted of all enrolled patients who had the study catheter inserted, regardless of energy

delivery. The modified intent-to-treat (mITT) analysis set, which was used for the primary safety endpoint analysis, consisted of enrolled patients who met the eligibility criteria and had the study catheter inserted. The per-protocol analysis set, used to evaluate the primary effectiveness endpoint, consisted of patients who underwent ablation using PF energy via the study ablation system, were treated for the study-related arrhythmia, and had no major protocol deviations that would affect the integrity of the safety and effectiveness data. The neurological assessment, esophageal endoscopy, cardiac CT/MRA, and PVI durability subsets included patients who completed the necessary additional assessments.

The primary safety endpoint was evaluated in the mITT analysis set using an exact test for a binomial proportion at a 1-sided significance level of 2.5%. If the upper bound of the exact 2-sided 95% CI of the primary safety endpoint rate was less than the performance goal of 12%, the study would be considered to have demonstrated safety.

The primary effectiveness endpoint was evaluated in the per-protocol analysis set using the exact test for a binomial proportion at a 1-sided significance level of 2.5%. If the lower bound of the exact 2-sided 95% CI of the primary effectiveness endpoint rate was greater than the performance goal of 90%, the study would be considered to have demonstrated effectiveness.

The baseline characteristics, safety and effectiveness outcomes, and subset analyses were summarized descriptively. All statistical analyses were performed using SAS 9.4 or SAS Studio 3.8 (SAS Institute Inc.).

TABLE 1 Schedule of Assessments in a Prespecified Subset of Patients for PV Durability and Safety

	Preprocedure (≤72 h)	Postprocedure (≤72 h)	1 Month	3 Months
Neurological				
Cerebral MRI	X	X	X[a]	X[a]
Neurological examination	X	X	X[a]	X[a]
NIHSS	X	X	X[a]	X[a]
mRS	X		X	X[a]
MMSE	X		X	X[a]
Esophageal injury				
Esophageal endoscopy		X		
PV stenosis				
Cardiac CT/MRA	X[b]			X[c]
PVI durability				
3D electroanatomic remap				X[d]

[a]Performed if neurological symptoms and/or cerebral ischemic lesions were identified in a prior evaluation. [b]CT/MRA to be completed within 6 months before the index ablation procedure (for all patients). [c]Performed at the 3-month follow-up visit or any other point in time when the patient presents with symptoms of PV stenosis (for all patients). [d]75 days postprocedure (±15 days).

3D = 3-dimensional; CT = computed tomography; MMSE = Mini-Mental State Examination; MRA = magnetic resonance angiogram; MRI = magnetic resonance imaging; mRS = modified Rankin scale; NIHSS = National Institutes of Health Stroke Scale; PV = pulmonary vein; PVI = pulmonary vein isolation.

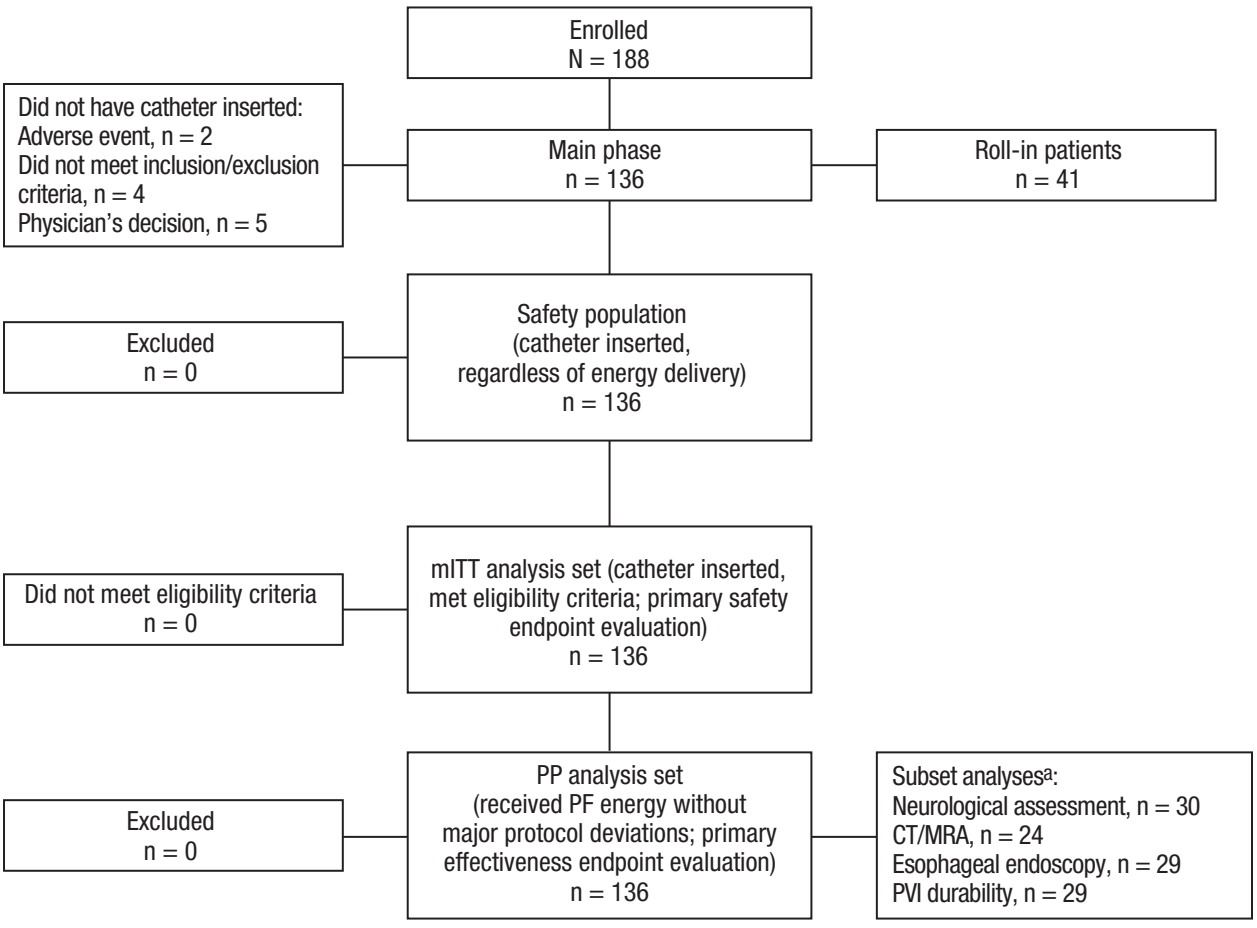
RESULTS

PATIENT CHARACTERISTICS. Between September 2023 and August 2024, 188 patients were enrolled across 13 centers, with procedures performed by 21 operators. The main phase of the study included the 136 patients who comprised the safety, mITT, and per-protocol analysis sets (Figure 2). Baseline characteristics of patients included in the roll-in and main study phases are shown in Table 2. Baseline characteristics were generally comparable between the groups. Roll-in patients had a longer diagnosis-to-ablation time, a higher incidence of failed Class II/IV antiarrhythmic drugs, more prior thromboembolic events, and a higher incidence of diabetes. Roll-in patients were also slightly older, had more patients with a CHA_2DS_2-VASc (congestive heart failure, hypertension, age ≥75 years [doubled], type 2 diabetes, previous stroke or thromboembolism [doubled], vascular disease, age 65-75 years, and sex category) score ≥3, had a lower incidence of obstructive sleep apnea, and had a less frequent history of typical right atrial flutter. The mean (SD) age for the main phase group was 59.8 (9.6) years, 94 of 136 (69.1%) patients were male, and the mean (SD) CHA_2DS_2-VASc score was 1.6 (1.2). Systemic hypertension and hypercholesterolemia were the most frequent cardiovascular comorbidities reported in 79 (58.1%) and 68 (50.0%) main phase patients, respectively.

PROCEDURAL DATA. Procedural data for the per-protocol analysis set are summarized in Table 3. The large-focal PFA catheter was used to create the preablation 3-dimensional (3D) electroanatomic map in 135 of 136 (99.3%) procedures, and a multipolar mapping catheter (PENTARAY; Biosense Webster, Inc., part of Johnson & Johnson MedTech) was used to create the preablation map in 1 of 136 (0.7%) procedures. Median (Q1-Q3) total procedure, left atrium dwell, total ablation, and total fluoroscopy times were 105.5 (91.0-124.0), 70.0 (56.0-81.5), 46.9 (37.1-58.8), and 5.0 (3.1-9.8) minutes, respectively. A median (Q1-Q3) of 61.0 (47.0-74.5) PF ablations was reported. No procedures used a nonstudy catheter to achieve PVI. Five patients received radiofrequency ablation of cavotricuspid isthmus line during the index procedure.

The compliance rate for patient follow-up was 100% for the 7-day and 1-month visits and 99.3% for the 3-month follow-up visit.

FIGURE 2 Patient Disposition



[a]A group of 31 patients was enrolled in protocol-defined subset analyses regardless of symptoms. Only those completing mandatory tests for the specific assessment were included in the corresponding analysis. CT = computed tomography; mITT = modified intent to treat; MRA = magnetic resonance angiogram; PP = per protocol; PVI = pulmonary vein isolation; other abbreviation as in Figure 1.

SAFETY. A total of 4 PAEs in 4 patients were identified in the 135 patients in the mITT analysis set with ≥3 months of follow-up (4 of 135 [3.0%]; Table 4). The primary safety endpoint was met because the upper bound of the exact 2-sided 95% CI was 7.4%, which was lower than the prespecified performance goal (12%). The PAEs were major vascular access complications (3 patients [2 events reported on the day of procedure, 1 event the day after the procedure], all resolved) and pericarditis (1 patient [reported the day after the procedure], resolved). All PAEs were determined to be procedure related based on Clinical Events Committee adjudication.

EFFECTIVENESS. Following adenosine/isoproterenol challenge during the index procedure, 16 of 545 (2.9%) targeted veins in 10 of 136 (7.4%) patients showed acute reconnection. After touch-up, acute procedural success was 100% (PVs, 545 of 545; patients, 136 of 136). The primary effectiveness endpoint was met because the patient-level lower bound of the exact 2-sided 95% CI was 97.3%, which exceeded the prespecified performance goal (90%).

SUBSET ANALYSES. Neurological assessment for cerebral lesions. Of the 30 patients included in the neurological assessment analysis, none had cerebral lesions at baseline. At the discharge assessment, 1 of 30 (3.3%) patients had an asymptomatic cerebral microembolic lesion located in the right-side cerebellum. An investigation suggested that 5 intraprocedural catheter exchanges may have resulted in the introduction of bubbles during the case. The mean (SD) catheter exchange for the study population was 1.3 (0.8), but multiple exchanges were needed in this case because of the presence of gaps after

TABLE 2 Baseline Characteristics

Parameter	Roll-in (n = 41)	Main Phase (n = 136)
Age, y, mean (SD)	61.4 (11.2)	59.8 (9.6)
Male	25 (61.0)	94 (69.1)
CHA_2DS_2-VASc score, mean (SD)	2.1 (1.6)	1.6 (1.2)
0	5 (12.2)	25 (18.4)
1-2	24 (58.5)	85 (62.5)
≥3	12 (29.3)	26 (19.1)
Diagnosis-to-ablation time, mo, mean (SD)	60.0 (93.9)	54.2 (74.3)
DCCV in past 12 months for paroxysmal AF	7 (17.1)	29 (21.3)
History of typical right atrial flutter	1 (2.4)	6 (4.4)
LVEF, %, mean (SD)	59.5 (5.1)	59.0 (5.5)
LA diameter, mm, mean (SD)	40.4 (6.0)	39.6 (5.5)
Failed Class I/III antiarrhythmic drug at baseline	25 (61.0)	84 (61.8)
Failed Class II/IV antiarrhythmic drug at baseline	22 (53.7)	50 (36.8)
Cardiovascular medical history	31 (75.6)	106 (77.9)
Hypertension	25 (61.0)	79 (58.1)
Hypercholesterolemia	18 (49.3)	68 (50.0)
Coronary disease	3 (7.3)	14 (10.3)
Congestive heart failure Class II	3 (7.3)	13 (9.6)
Prior thromboembolic events	3 (7.3)	4 (2.9)
Type 2 diabetes	5 (12.2)	9 (6.6)
Obstructive sleep apnea	1 (2.4)	12 (8.8)

Values are n (%) unless otherwise indicated.

AF = atrial fibrillation; CHA_2DS_2-VASc = congestive heart failure, hypertension, age ≥75 years (doubled), type 2 diabetes, previous stroke or thromboembolism (doubled), vascular disease, age 65-75 years, and sex category; DCCV = direct current cardioversion; LA = left atrial; LVEF = left ventricular ejection fraction.

TABLE 3 Procedural Characteristics (PP Analysis, n = 136)

Conscious sedation	2 (1.5)
General anesthesia	134 (98.5)
Total procedure time, min	105.5 (91.0-124.0)
Catheter type used for LA map[a]	
OMNYPULSE catheter	135 (99.3)
PENTARAY catheter	1 (0.7)
CT integration	1 (0.7)
Esophageal monitoring	
Esophageal temperature probe	10 (7.4)
Esophageal visualization with CARTOSOUND and/or ICE	13 (9.6)
LA mapping time, min	9.0 (7.0-13.0)
Total fluoroscopy duration, min	5.0 (3.1-9.8)
Diagnostic fluoroscopy duration	3.0 (1.9-4.9)
PF applications fluoroscopy duration	4.1 (2.5-7.8)
LA dwell time, min	70.0 (56.0-81.5)
Total ablation duration, min[b]	46.9 (37.1-58.8)
Total PF ablation time, s[b,c]	175.8 (135.0-210.2)
Number of PF ablations	61.0 (47.0-74.5)
Fluid delivered via the study catheter, mL	1,200.0 (1,000.0-1,700.0)

Values are n (%) or median (Q1-Q3). [a]Allow for multiple selection. [b]Data derived from generator data. [c]Total energy delivery time, defined as the sum of all energy ablations, excluding idle/navigating time when energy is not applied. Up to 12 applications make up 1 ablation.

ICE = intracardiac echocardiography; PF = pulsed field; PP = per protocol; other abbreviations as in Tables 1 and 2.

required conduction evaluation using a commercially approved mapping catheter. At 1-month follow-up, a repeat scan showed that the lesion had resolved.

Esophageal endoscopy. Esophageal endoscopy was performed at 1 to 3 days postablation in 29 patients. No (0 of 29 [0%]) esophageal thermal lesions were observed.

PV stenosis. Of the 101 veins in 24 patients in this subset, 39 (38.6%) PVs showed no narrowing, and 62 (61.4%) PVs showed mild narrowing (reductions in diameter ≤50%) compared with baseline at the 3-month CT/MRA. There were no instances of moderate (>50%-70%) or severe (>70%) PV narrowing. At the patient level, 2 of 24 (8.3%) patients had no PV narrowing and 22 of 24 (91.7%) patients showed mild narrowing (reductions in diameter ≤50%) at the 3-month follow-up. At the PV level, most mild PV narrowing was under 10% (Supplemental Table 2).

PVI durability. A prespecified subset of 29 patients, treated at 7 centers by 9 operators, underwent mandatory 3D electroanatomic remapping, with the same multielectrode mapping catheter as used during the index procedure, at a mean (SD) of 81.7 (9.1) days postablation. Activation and voltage mapping were combined to assess vein isolation, and all reconnections were reablated with the investigational catheter. A post hoc analysis showed that a median (Q1-Q3) ITD of 4.6 (3.2-5.8) mm was used for the lesions created during the index procedures.

At the time of the remapping study, 26 of 29 (89.7%) patients were free of atrial tachyarrhythmia. Durable PVI was observed in 98 of 116 (84.5%) veins and 18 of 29 (62.1%) patients. In optimized workflow cases (n = 21), durable PVI was verified in 75 of 84 (89.3%) veins and 15 of 21 (71.4%) patients. In arrhythmia-free cases (n = 26), durable PVI was verified in 93 of 104 (89.4%) veins and 18 of 26 (69.2%) patients. A representative example of durable isolation in all 4 veins is given in Figure 3.

Overall, reconnection was observed in 11 patients and 18 veins. Reconnection of 1 vein only, 2 veins, or ≥3 veins was observed in 7, 2, and 2 patients, respectively. The spatial distribution of reconnection is shown in Figure 4.

Overall, 36 regions revealed a conduction gap (3.3 gaps per patient). There were more reconnections at right-sided veins (22 vs 14 gaps), with a trend toward more reconnection at the anterior and posterior carina.

In 33 of 36 gaps, the region of reconnection corresponded to a region containing an ITD of ≥6 mm

TABLE 4 Summary of PAEs (mITT Analysis Set, n = 136)

	n (%)[a]	Relationship to Study Catheter/Generator[b]
PAEs (≤7 days postablation)[c]	4 (3.0)[d]	
Atrioesophageal fistula	0	
Phrenic nerve paralysis (permanent)	0	
PV stenosis	0	
Cardiac tamponade/perforation	0	
Stroke/cerebrovascular accident	0	
Transient ischemic attack	0	
Major vascular access complication/bleeding	3 (2.2)	Not related/not related
Thromboembolism	0	
Myocardial infarction	0	
Pericarditis	1 (0.7)	Probable relationship/not related
Heart block	0	
Pulmonary edema (respiratory insufficiency)	0	
Vagal nerve injury/gastroparesis	0	
Death (device or procedure related)	0	

[a]PAEs were evaluated in 135 patients because 1 patient without ≥3 months of follow-up who did not experience a PAE was excluded from the analysis. [b]All PAEs were deemed procedure related. [c]Device- or procedure-related death, PV stenosis, and atrioesophageal fistula that occurred at 7 to 90 days and cardiac tamponade/perforation that occurred within 30 days postablation were also considered as PAEs. Phrenic nerve paralysis was considered a PAE if specified symptoms had not improved at the 3-month visit. [d]The upper bound of 2-sided 95% CIs is 7.4%, less than the prespecified performance goal of 12%.

mITT = modified intent to treat; PAE = primary adverse event; other abbreviation as in Table 1.

during the index procedure (9.3 ± 1.7 mm). A representative example is given in Supplemental Figure 1. In this patient, the left superior pulmonary vein was reconnected due to a gap at the posterior roof of the left circle. Revisiting the ablation tags at the index map revealed an ITD of 7 mm at that same region.

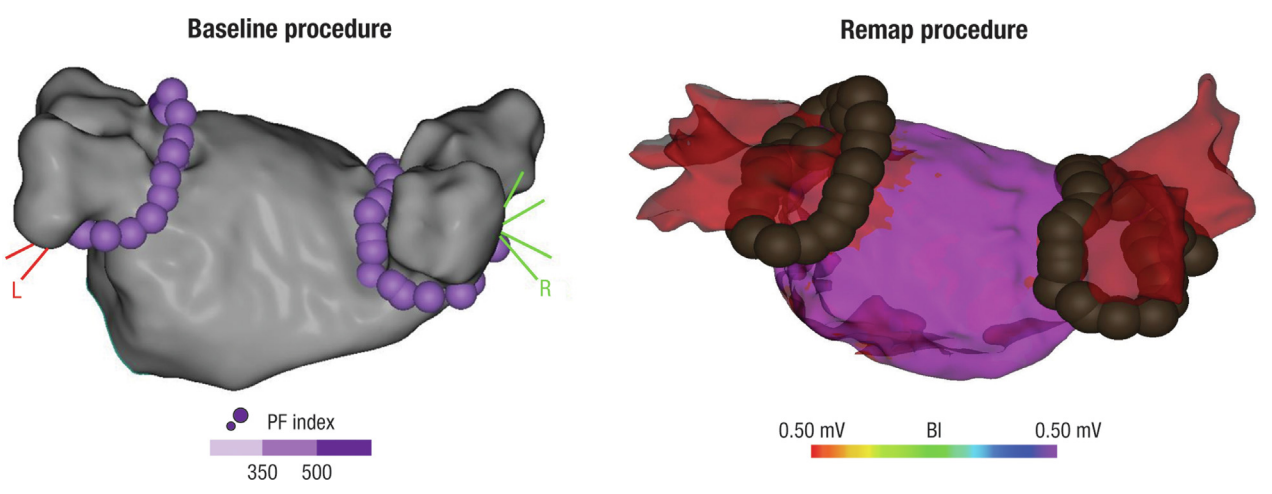
In 3 of 36 gaps, reconnection occurred in a region that was ablated with a PF index of ≥400 of 550 and ITD ≤6 mm. A representative example is given in Supplemental Figure 2. In this patient, the right superior PV and right inferior PV were reconnected due to a gap at the anterior carina at the right circle. Revisiting the ablation tags at the index map revealed a PF index of ≥550 and ITD of ≤6 mm.

DISCUSSION

This first-in-human study of the large-tip focal, CF-sensing PFA catheter in conjunction with the dedicated PFA generator showed promising initial results, with an acute success rate of 100%, median total procedure and total fluoroscopy times of approximately 106 and 5 minutes, respectively, and a low rate of PAEs (3%). Safety was further demonstrated by no incidences of severe PV stenosis or esophageal injury and a single asymptomatic, self-resolving neurological lesion in prespecified subsets of patients. Remapping in a subset of patients showed durable PVI in 85% of veins at 3 months (Central Illustration). Twelve-month data from this study will provide further information on long-term freedom from arrhythmia and repeat ablation and will assess the long-term safety of the ablation system.

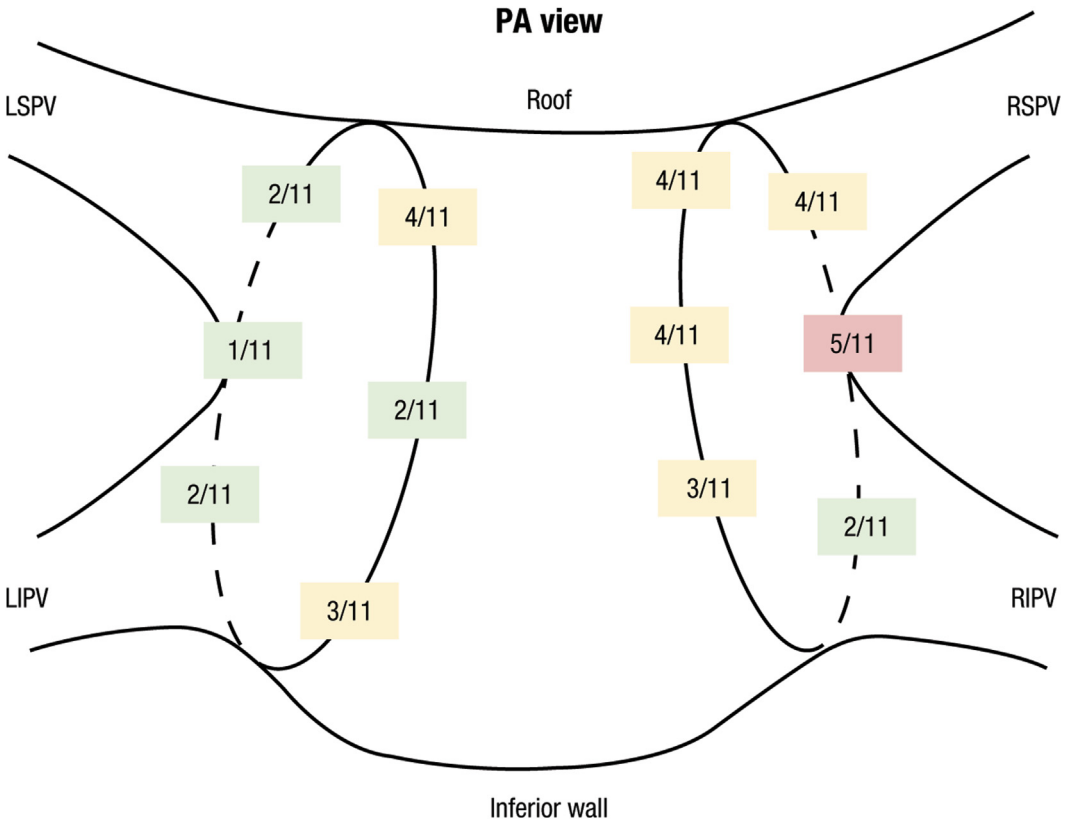
The median total procedure and fluoroscopy times (106 and 5 minutes, respectively) reported in the current study were similar to those in the recent SmartfIRE (108 and 4 minutes, respectively) and Sphere-9 (Safety and Performance Assessment of the

FIGURE 3 Representative Example of Durable Isolation in All 4 PVs



Left, index procedure. Right, voltage map during remapping procedure. BI = bipolar; PV = pulmonary vein; other abbreviations as in Figure 1. Images are courtesy of Biosense Webster, Inc, part of Johnson & Johnson MedTech. All rights reserved.

FIGURE 4 **Reconnection Distribution During Remapping Studies**



Distribution of reconnections seen in 11 of 29 subset patients. More reconnections were seen at right-sided veins, with a trend toward more reconnection at the anterior and posterior carina. LIPV = left inferior pulmonary vein; LSPV = left superior pulmonary vein; PA = posteroanterior; RIPV = right inferior pulmonary vein; RSPV = right superior pulmonary vein. Images are courtesy of © Biosense Webster, Inc., part of Johnson & Johnson MedTech. All rights reserved.

Sphere-9 Catheter and Affera Mapping and RF/PF Ablation System) (99 and 4 minutes, respectively) studies of dual-energy radiofrequency and PFA focal ablation catheters.[6,8] By contrast, total procedure and fluoroscopy times were shorter in the current study than those reported for the optimized PFA workflow in the ECLIPSE AF (Safety & Clinical Performance Study of Catheter Ablation With the Centauri System for Patients With Atrial Fibrillation) study of focal PFA with CF-sensing solid-tip ablation catheters (137 and 10 minutes, respectively).[4] The acute procedural success rate of 100% with 97% of PVs ablated without acute reconnections demonstrated in the current study compares favorably with those shown in the SmartfIRE, Sphere-9, and ECLIPSE AF studies.[4,6,8]

The current study showed a low rate of PAEs (3.0%), consisting of 3 major vascular access complications and 1 pericarditis, which were all deemed related to the study procedure. These safety findings compare favorably with those reported in other PFA studies, which ranged from 0.6% in the Sphere-9 study to 4.4% in the SmartfIRE study and 4.9% in the ECLIPSE study.[4,6,8] Although PFA energy is associated with a lower risk of collateral tissue damage compared with thermal ablation, there is still a risk of adverse events related to the procedure and catheter manipulation,[7,18] such as the vascular access injuries seen in the current study. We would expect that as PFA catheters and integrated systems are more widely adopted, experience with their use will increase, and further improvements in safety will be seen.

This study reports on the first-in-human use of a PF index to guide ablation with a large-tip focal catheter using a range of 3 to 12 applications. Twelve anterior wall applications were typically required to achieve a PF index of 550, whereas the posterior wall

CENTRAL ILLUSTRATION **Summary of the Omny-IRE 3-Month Results**

Omny-IRE 3-Month Results: PVI With a CF-Sensing, Large-Tip Focal PFA Catheter With 3D Mapping Showed High Acute Success and PVI Durability With a Promising Safety Profile in the Treatment of Paroxysmal AF

Study Design

- 18-75 years of age
- Symptomatic paroxysmal AF

13 Centers in Europe & Canada

21 Operators

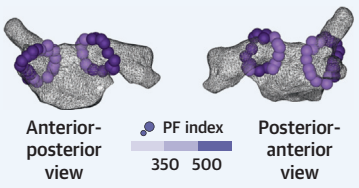
136 Patients[a]

59.8 years, 69.1% male, 1.6 CHA_2DS_2-VASc score

Primary endpoints

- **Safety[b]:** PAEs
- **Effectiveness:** acute PVI

Ablation Procedure



Target PF index: anterior, 550; posterior, 400-450
ITD: anterior, ≤6 mm; posterior, ≤9 mm[c]

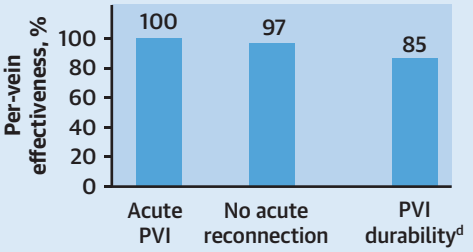
Additional safety assessments (up to 3 months)[b]:

- Neurological assessment
- Esophageal endoscopy
- Cardiac CT/MRA

PVI durability assessment (75 days):

- Remapping procedure

Results



5.0 min Median fluoroscopy time
176 sec Median PFA time[e]

Safety

3.0% PAEs

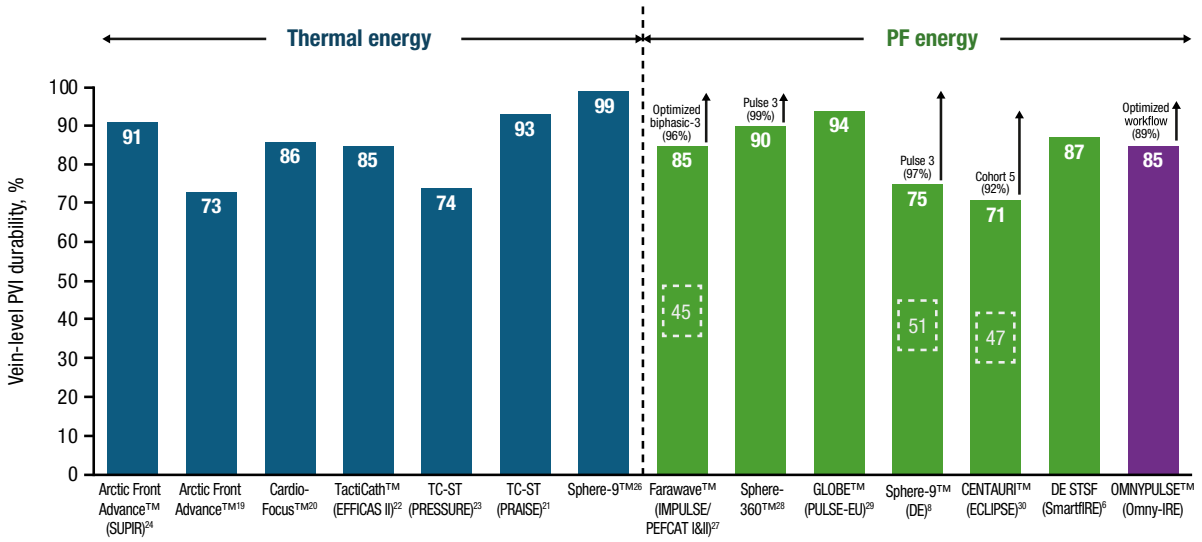
- 3 vascular access complications
- 1 pericarditis
- 0 severe PV stenosis
- 0 esophageal injuries
- 1 asymptomatic SCE

Duytschaever M, et al. JACC Clin Electrophysiol. 2025;■(■):■–■.

[a]Safety, mITT, and PP analysis sets (188 patients enrolled). [b]PAEs were evaluated in the mITT analysis set. Additional safety outcomes were assessed in a subset of 31 patients. Only those completing mandatory tests for the specific assessment were included in the analysis: neurological assessment, n = 30; esophageal endoscopy, n = 29; PV stenosis, n = 24. [c]Optimized workflow implemented after the first 28 cases. [d]Acute PVI refers to confirmed entrance block at the end of the procedure, including touch-ups, if applicable. No acute reconnection refers to the veins where conduction was not seen after adenosine/isoproterenol challenge. Acute PVI and no acute reconnections were evaluated in 136 patients. PVI durability was based on mandatory remapping studies performed at a mean (SD) of 81.7 (9.1) days postablation in 29 patients. [e]Total energy delivery time is defined as the sum of all energy ablations (excluding idle/navigating time when energy is not applied). Up to 12 applications make up 1 ablation. Images are courtesy of © Biosense Webster, Inc., part of Johnson & Johnson MedTech. All rights reserved. 3D = 3 dimensional; AF = atrial fibrillation; CF = contact force; CHA_2DS_2-VASc = congestive heart failure, hypertension, age ≥75 years (doubled), type 2 diabetes, previous stroke or thromboembolism (doubled), vascular disease, age 65-75 years, and sex category; CT = computed tomography; ITD = intertag distance; mITT = modified intent to treat; MRA = magnetic resonance angiogram; Omny-IRE = A Study For Treatment of Paroxysmal Atrial Fibrillation [PAF] With the OMNYPULSE Catheter and the TRUPULSE Generator; PAE = primary adverse event; PF = pulsed field; PFA = pulsed field ablation; PP = per protocol; PV = pulmonary vein; PVI = pulmonary vein isolation; SCE = silent cerebral event.

required 8 to 12 applications to achieve a PF index of 400 to 450 depending on CF. Increasing efficacy after workflow improvements, mainly by decreasing the ITD on the anterior wall and requiring higher CF, provided clinical evidence of the need for a tighter lesion set and better CF to achieve deeper lesions in thicker tissues. This workflow adjustment, which is consistent with animal studies showing non-transmurality with increased ITD in thicker tissue,[16] led to a PVI durability of 85% of PVs during mandatory remapping studies for the entire subset and 89% for the patients ablated with the optimized workflow. The PVI durability observed for the first generation of the novel large-tip focal PFA catheter compares favorably with data from previous thermal and PFA studies (**Figure 5**).[4,8,19-30] Although a direct comparison is not possible due to differences in study design and variations in durability assessment timing, PVI durability based on invasive remapping ranged from 74% to 99% in thermal ablation

FIGURE 5 **PVI Durability of Ablation Technologies**



	Cryo	Cryo	Laser	RF	RF	RF	RF	PF	PF	PF	PF and RF	PF	PF and RF	PF
Remap population	PAF (n = 19)	PAF (n = 32)	PAF (n = 52)	PAF (n = 24)	PAF (n = 40)	PsAF (n = 40)	PAF/PsAF (n = 27)	PAF (n = 110)	PAF (n = 60)	PAF/PsAF (n = 43)	PAF/PsAF (n = 122)	PAF/PsAF (n = 80)	PAF (n = 30)	PAF (n = 29)
Protocol mandated	Yes	Yes	Yes	Yes	Yes	Yes	Yes	**No**	**No**	Yes	Yes	Yes	Yes	Yes
Time postindex	3.4 mo	6 mo	6 mo	3 mo	2 mo	8-10 weeks	~3 mo	75 or 90 d	75 d	3 mo	75 d	90 d	75 d	75 d

Percentages of isolated PVs at remapping procedure following index ablation. Bars report the per-vein durability data reported for the entire evaluated cohort. Dotted boxes represent durability reported for initial waveforms. Arrows represent PVI durability observed after waveform or workflow optimizations not prespecified by protocol were implemented in series of patients. DE = dual energy; ECLIPSE = Safety & Clinical Performance Study of Catheter Ablation With the Centauri System for Patients With Atrial Fibrillation; EFFICAS II = Efficacy Study on Atrial Fibrillation Percutaneous Catheter Ablation With Contact Force Support 2; IMPULSE = A Safety and Feasibility Study of the IOWA Approach Endocardial Ablation System to Treat Atrial Fibrillation; Omny-IRE = A Study For Treatment of Paroxysmal Atrial Fibrillation [PAF] With the OMNYPULSE Catheter and the TRUPULSE Generator; PAF = paroxysmal atrial fibrillation; PEFCAT = A Safety and Feasibility Study of the FARAPULSE Endocardial Ablation System to Treat Paroxysmal Atrial Fibrillation; PEFCAT II = Expanded Safety and Feasibility Study of the FARAPULSE Endocardial Multi Ablation System to Treat Paroxysmal Atrial Fibrillation; PRAISE = Pulmonary Vein Reconnection Following Ablation Index-Guided Ablation: a Success Evaluation; PRESSURE = the Effect of Early Repeat Atrial Fibrillation (AF) on AF Recurrence; PsAF = persistent atrial fibrillation; PULSE-EU = Safety and Performance of a Pulsed Field Device for Global Mapping and Ablation of the Left Atrium for the Treatment of Atrial Fibrillation; RF = radiofrequency; SmartfIRE = A Study For Treatment Of Paroxysmal Atrial Fibrillation [PAF] With The THERMOCOOL SMARTTOUCH SF Catheter and TRUPULSE Generator; Sphere-9 = Safety and Performance Assessment of the Sphere-9 Catheter and the Affera Mapping and RF/PF Ablation System to Treat Atrial Fibrillation; STSF = THERMOCOOL SMARTTOUCH SF; SUPIR = Sustained PV Isolation with Arctic Front Advance; TC-ST = THERMOCOOL SMARTTOUCH; other abbreviations as in Figures 1-3.

studies.[21-23,26] For PFA studies, some initial workflows resulted in PVI durability <50%, with improved results observed with workflow optimization.[4,8,27,28] An advantage of protocol-mandated remapping with the current study is that both the index and repeat procedures are mapping based, enabling overlay of the index and repeat maps, thus enhancing the reliability of the study results. In contrast, for ablation systems without this capability (such as cryoablation or nonintegrated PFA systems), PVs may erroneously appear to be isolated on repeat mapping.

IMPLICATIONS FOR FUTURE CLINICAL INVESTIGATIONS. From this experience of the first use of the large-focal PFA catheter in humans, we observed good stability at the anterior and inferior parts of the left circle. Factors contributing to this stability may have included compression of the catheter "cage," the ability to position the catheter deeper in the pulmonary vein without the risk of severe stenosis seen with thermal ablation, and its bipolar nature. Although this study was restricted to PV ablation only, the large-tip focal catheter design and electroanatomic mapping integration may enable more

personalized ablation strategies compared with "regional" or "single-shot" catheters. This large-focal PFA catheter may be suitable for PVI regardless of the PV anatomy and for ablating lines outside the PVs. It may support anatomical procedures in which the catheter allows the operator to deploy lines and then map block. It may also be used in more complex patient-specific procedures, including, for example, catheter mapping of low-voltage zones, dispersion, and atrial tachycardia to first pinpoint the origin of the arrhythmia and then ablate that target. The same catheter can then be used to confirm conduction block postablation. Thus, this large-tip focal PFA catheter may provide versatility across a range of procedures, which should be tested in future clinical investigations. When commercially available and used by a large group of operators, clinical follow-up will allow for further optimization of the workflow and confirmation of the successful safety and effectiveness profile of the ablation system.

STUDY LIMITATIONS. One limitation of this study is its single-arm study design, which precludes direct comparison to thermal or other PFA catheters. Future integration of stability indication with improved technology and workflow may reduce the PV reconnection rate. Although the current results demonstrate successful acute PVI and 3-month PVI durability, longer-term 12-month data are needed to confirm the clinical safety and effectiveness of ablation using the large-focal PFA catheter. The analyses of 3-month PVI durability, cerebral lesions, PV stenosis, and esophageal injury were performed in subsets of the per-protocol analysis set.

CONCLUSIONS

Ablation with the novel large-focal CF-sensing PFA catheter with 3D electroanatomic mapping integration showed 100% acute success with low PV reconnection rates and a promising safety profile in the treatment of paroxysmal AF. Prespecified remapping at 3 months postablation showed favorable PVI durability.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: This first-in-human study demonstrated that use of a novel large-tip focal, multielectrode, CF-sensing PFA catheter (OMNYPULSE) with integrated electroanatomic mapping resulted in a 100% acute PVI success rate, durable PVI in 85% of veins at 3 months, and a low rate of PAEs in patients with symptomatic paroxysmal AF.

TRANSLATIONAL OUTLOOK: By integrating electroanatomic mapping and CF sensing, this novel large-tip focal, basket catheter may allow for more personalized ablation strategies in the treatment of paroxysmal AF.

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KEY WORDS contact force catheter, PF index, pulmonary vein isolation, pulsed field ablation, large-tip focal

APPENDIX For the supplemental tables and figures, please see the online version of this paper.