Medtronic

PULSED AF[1] Pivotal Trial Overview

The PulseSelect™ pulsed field ablation (PFA) system is limited to investigational use only and is not approved for commercial use in any geography. CE Mark pending.

Trial design and study population

Trial design

Paired single arm. Prospective, nonrandomised clinical study.

Global multicentre study

9 countries: Austria, Belgium, France, Spain, Netherlands, United States, Canada, Australia, Japan.
41 sites
67 operators
300 subjects

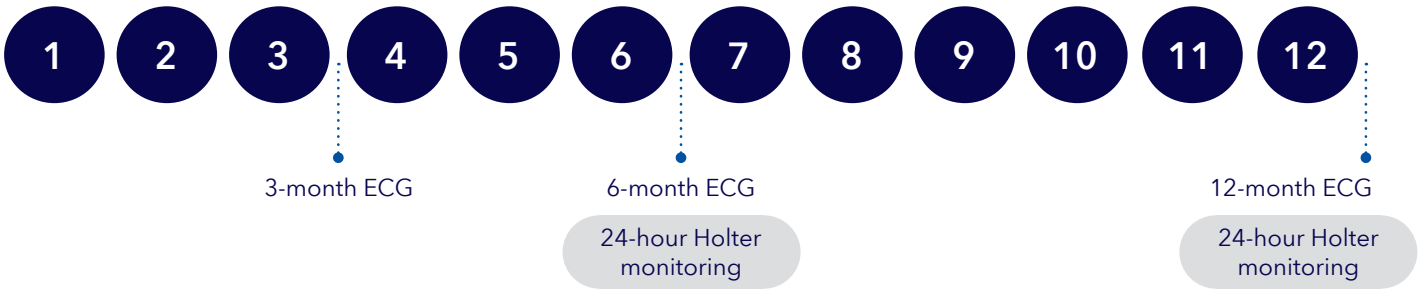
150 Paroxysmal (PAF)
150 Persistent (PsAF)

300 patients

The study population included recurrent symptomatic paroxysmal and persistent atrial fibrillation patients refractory to class I or III antiarrhythmic drugs.

96% (287) of patients completed 12-month follow-up.

Rigorous arrhythmia monitoring



Trial outcomes

PULSED AF evaluated the safety and effectiveness of the PulseSelect™ Pulsed Field Ablation System for the treatment of patients with paroxysmal or persistent atrial fibrillation.

0 Esophageal events

0 PV stenosis

0 Phrenic nerve injury

0 Coronary artery spasm

Primary safety endpoint

0.7%

Primary adverse events (95% CI, 0.1 to 4.6%)

Performance goal of < 13%

1/300 Cerebrovascular accident
1/300 Tamponade
0/300 Transient ischemic attack
0/300 Major bleeding
0/300 Myocardial infarction
0/300 Pericarditis
0/300 Vagal nerve injury
0/300 Systemic pulmonary embolism
0/300 Pulmonary edema
0/300 Vascular access complications
0/300 Cardiovascular hospitalisation
0/300 Death

Quality-of-life scores improved post-ablation compared to baseline

AFEQT score improved by 29.4 (95% CI, 25.8 to 33.1) and 29.0 (95% CI, 25.5 to 32.5) points in the paroxysmal and persistent populations respectively from baseline to 12 months.

EQ-5D-5L score improved by 0.05 (95% CI, 0.02 to 0.08) points in paroxysmal **and 0.06 (95% CI, 0.04 to 0.09)** points in persistent atrial fibrillation patients.

12-month effectiveness data

Freedom from any atrial arrhythmias recurrence of ≥ 30 seconds

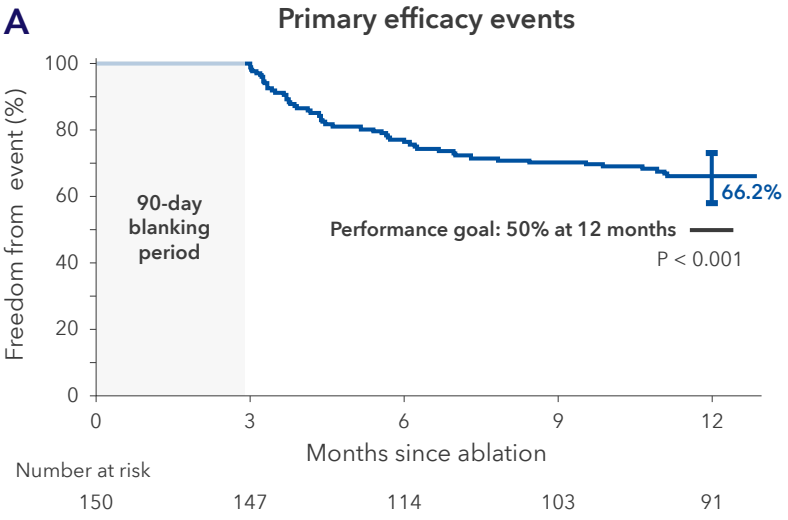
70%
PAF

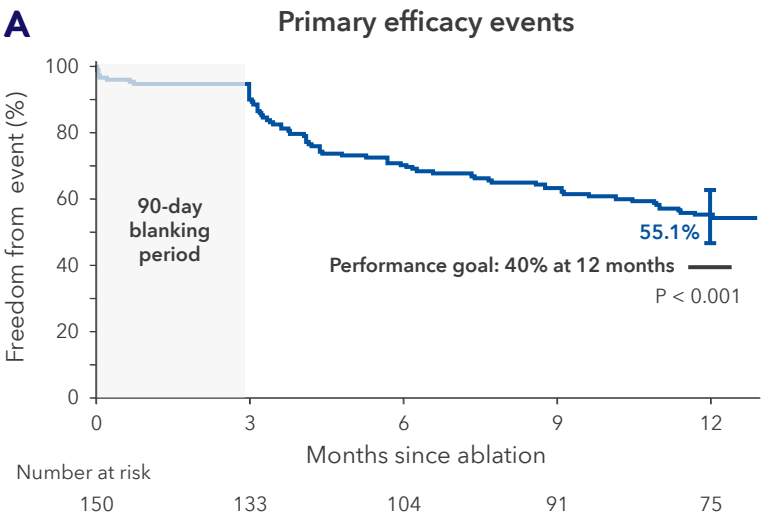
(95% CI, 57.9 to 73.2)

62%
PsAF

(95% CI, 46.7 to 62.7)

Primary effectiveness
Acute procedure failure, AF/AFL/AT recurrence, cardioversion, repeat ablation, new/re-initiated/increased AADs, any subsequent AF surgery





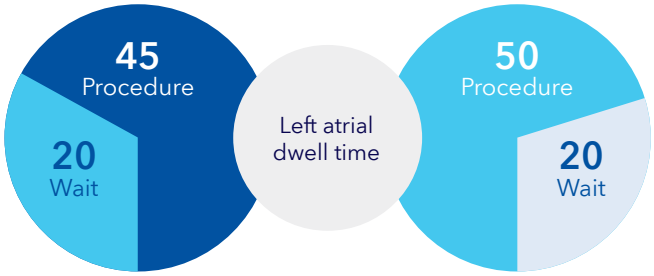
Clinical success

Freedom from recurrence of any symptomatic atrial arrhythmias (post-hoc analysis)

80%
PAF

81%
PsAF

Procedural data (ancillary endpoints)

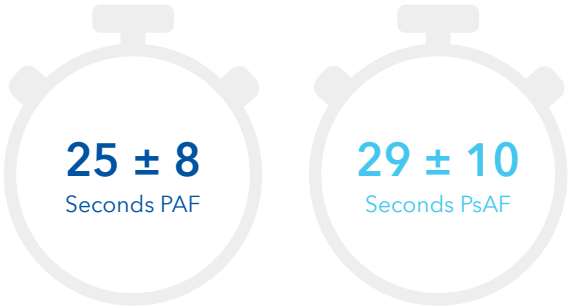


Paroxysmal
65 ± 29 minutes

Persistent
70 ± 31 minutes

Procedure times under 50 minutes

when excluding the 20-minute trial-mandated wait period.



Total PFA energy delivery under 30 seconds

Parameter	Paroxysmal (n = 150)	Persistent (n = 150)
Skin-to-skin procedural time (min)†	134 ± 50	145 ± 60
Device left atrial dwell time (min)‡	65 ± 29	70 ± 31
Fluoroscopy time during procedure (min)	26 ± 17§	29 ± 21

The PulseSelect™ system was used in conjunction with multiple commercially available mapping systems.

Plus–minus values are means ±SD, with median (interquartile range) also presented.

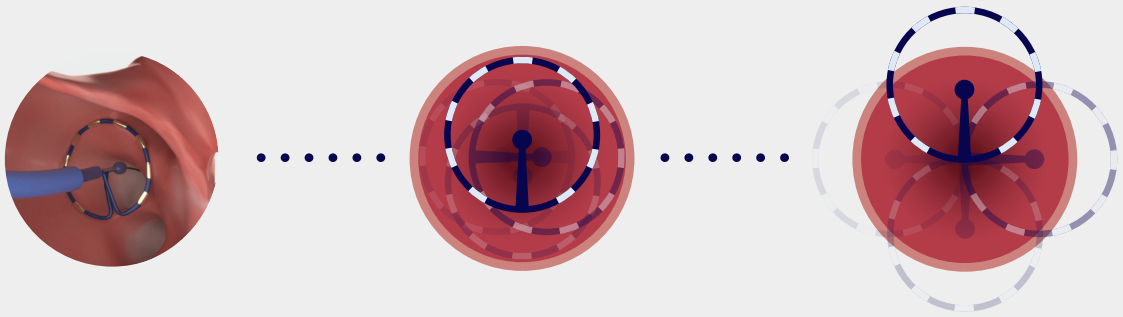
†Skin-to-skin procedure time is from first sheath inserted to last sheath pulled out – this includes transfer time to recovery room and sheath pulling time.

‡Left atrial dwell time and time from first to last application includes the protocol-mandated 20-minute wait period and any post-ablation mapping time.

§Data were available for 149 patients.

Stepwise ostial-antral approach

- Four pulse trains delivered per application
- One application per catheter position
- A minimum of 8 applications per vein is recommended to achieve pulmonary vein isolation.



Over-the-wire catheter positioning

Ostial applications
Stepwise catheter rotation for overlapping lesions

Antral applications
Stepwise catheter rotation for overlapping lesions

[1] Verma A, Haines DE, Boersma LV, et al. Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial. *Circulation*. May 9, 2023;147(19):1422–1432.

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