



BEAT PAROX-AF randomised controlled trial: 12-month outcomes

3rd randomised controlled trial on FARAPULSE™ PFA System

Comparable, high 12-month effectiveness | Favourable safety and efficiency

Multicentre European RCT evaluated FARAWAVE™ Pulsed Field Ablation Catheter (n = 145) vs. RF (SMARTTOUCH™, n = 144) for pulmonary vein isolation to treat paroxysmal AF.

- ▶ **9 expert high volume EU centres**
- ▶ **5 countries** (France, Czechia, Germany, Austria, Belgium)
- ▶ **292 patients** (drug-resistant paroxysmal AF)
- ▶ **Enrolment start 2021**
- ▶ **1:1 randomisation, superiority trial**

Primary endpoint: Single-procedure success at 1 year: absence of atrial arrhythmia recurrence on any type of recording (≥ 30 sec), absence of resumption of class I or III AAD, absence of redo ablation in the 12 months (including 2-month blanking period).

Secondary endpoint: At least one procedure-related SAE.

KEY HIGHLIGHTS

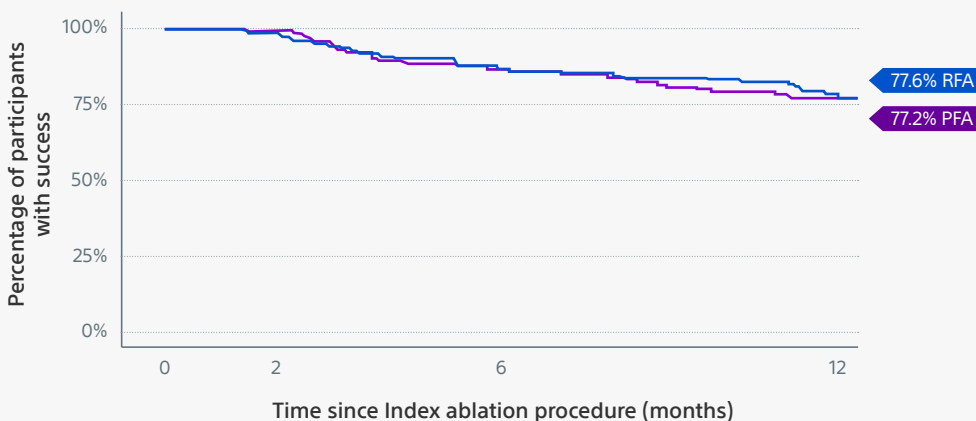
ZERO

PULMONARY VEIN STENOSIS

~ 40 min

reduction in procedure time

12-MONTH PRIMARY EFFECTIVENESS



		Number at risk						
Group		0	2	4	6	8	10	12
PFA		145	144	130	126	122	115	58
RFA		143	141	130	124	122	119	54

Procedure workflow



PFA PVI, high voltage pulsed field energy (2000 V) $\geq 8x$ per vein in 2 configurations (FARAPULSE™)



RF PVI, using contact force catheter (CLOSE protocol*, CARTO™ SMARTTOUCH™)

The Primary effectiveness endpoint to demonstrate superiority of PFA over RF on the rate of 1-year atrial arrhythmia recurrence was not met.

No difference found in the primary effectiveness between FARAWAVE and RF ablation.



BEAT PAROX-AF randomised controlled trial: 12-month outcomes

SAFETY

Clinically relevant serious adverse events with durable consequences	FARAWAVE (n = 145)	RFA (n = 145)
Transient ischemic attack	1	0
Tamponade drained	0	2
Pulmonary vein stenosis >70%	0	2
PV stenosis >50% (post hoc)	0	12

3.4% PFA vs. 7.6% RF procedure-related SAE***

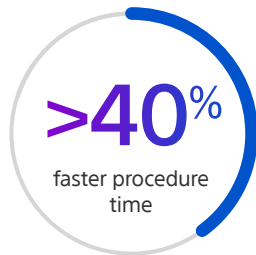
Comparison with other RCTs**

	ADVENT		SINGLE SHOT CH.		BEAT PAROX-AF	
	FARAWAVE (n = 305)	Thermal (n = 302)	FARAWAVE (n = 105)	CBA (n = 105)	FARAWAVE	RFA
TIA/Stroke (%)	0.3	0.3	1.0	0	0.7	0
Tamponade (%)	0.7	0	0	1.9	0	1.4
Atrio-esophageal Fistula (%)	0	0	0	0	0	0
Persistent Phrenic Nerve Palsy (%)	0	0.7	0	0	0	0
Change in PV area (%)	-1	-12	n/a	n/a	n/a	n/a
PV Stenosis > 50 (%)	n/a	n/a	n/a	n/a	0	8.3

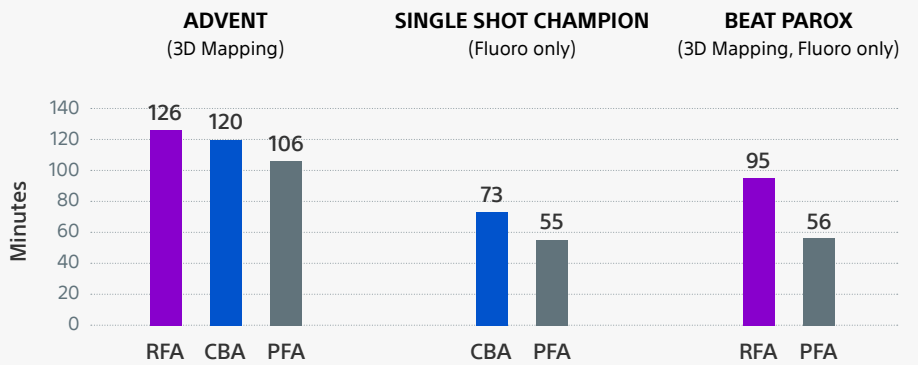
PROCEDURE TIME

Duration of AF procedure, median (IQR)

FARAWAVE (n = 145)	RFA (n = 144)	Adjusted difference (95% CI)
56 min (44,72)	95 min (73,118)	-39 min (-44 to -34)



Comparison with other RCTs**



CONCLUSIONS

BEAT PAROX-AF demonstrated:

- Excellent efficacy of PFA and RFA using the CLOSE protocol*, with no superiority
- PFA was faster, with fewer adverse events (notably 0 PV stenosis)



BEAT PAROX-AF underlined the positive safety profile and high efficiency of FARAPULSE PFA, while showing consistency with previous RCTs on efficacy.

*CLOSE protocol combines an ablation index and ≤6 mm interlesion distance.

**Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

***Post hoc analysis, excluding unrelated hospitalisation.

Jais P, BEAT PAROX AF: a randomized comparison of PFA vs RFA, presented at ESC Aug 2025, Copenhagen.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

© 2025 Boston Scientific Corporation or its affiliates. All rights reserved. EP-2311903-AA C€ 0459