



CLINICAL SUMMARY

Re-Ablation of Atrial Fibrillation Targeting Electrogram Dispersion in Patients with Isolated Veins: The RESTART Trial

Hummel, et al. Heart Rhythm 2026; DOI: 10.1016/j.hrthm.2026.01.042

Objective

To evaluate the effectiveness of a personalized artificial intelligence (AI)-guided spatio-temporal dispersion mapping and ablation in patients undergoing a repeat ablation and whose PVs remain isolated from prior ablation procedures.

Patient Population

213 symptomatic AF patients who had undergone a previous catheter ablation were consented by 29 operators at 20 centers (16 in the US and 4 in Europe) between March 2023 and April 2024.

Interventional, single arm, prospective, non-randomized trial

Patient Characteristics:

Age: 68.1 ± 9.0 years

Sex: 35 women (36%); 61 men (64%)

Medical history: Obesity - BMI > 30 (51% - 49 patients); Hypercholesterolemia (44% - 42 patients); Sleep apnea (46% - 44 patients)

AF Type:

41% Paroxysmal AF (39 patients)

53% Persistent AF (51 patients)

6% Long-standing persistent AF (6 patients)

Prior ablation per patient: 1.6 ± 0.7 (54% had 1 prior ablation; 33% had 2 prior ablations, 11% had 3 prior ablations and 1 patient had 4 prior ablations)

Mean AF history: 8.2 ± 6.3 years

Mean CHA₂DS₂-VASc score: 2.6 ± 1.5

Key Takeaways

- **83% of patients** experienced **freedom from documented AF** after a single procedure at 12 months
- **70% of patients** experienced **freedom from any atrial arrhythmia** after a single procedure at 12 months
- **AF termination** during ablation was achieved in **54% of patients**
- **Right atrial dispersion** was identified in **59% of patients**
- The procedure was associated with low complication rates and **improvements in quality of life** metrics (AFEQT and SF-36 scores)

Methods

At the beginning of the ablation procedure, assessment of PVI for bi-directional conduction block at each pulmonary vein
Patients with PV reconnection were withdrawn from the study

AI assisted identification of spatio-temporal dispersion regions (Volta AF-Xplorer™ system) on bi-atrial 3D maps

Ablation of spatio-temporal dispersion regions with RF energy

Connection of ablated areas to an electrically neutral structure
Empiric anatomical ablation lines were not allowed

Procedure endpoint: sinus rhythm conversion by ablation.
If AF or AT persisted, cardioversion was recommended

Follow-up

Office visits at 3, 6, and 12 months including 12-lead ECG

Monitoring: 24-hour (24%) minimum, 2 to 7-day (25%), 14 to 30-day (16%) Holter, cardiac implantable device (26%)

Quality of life questionnaires (AFEQT and SF-36)

Fig. 1: AI-Guided Tailored Ablation Strategy (Tailored-AF-like)

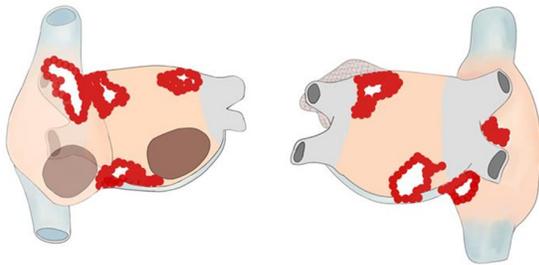
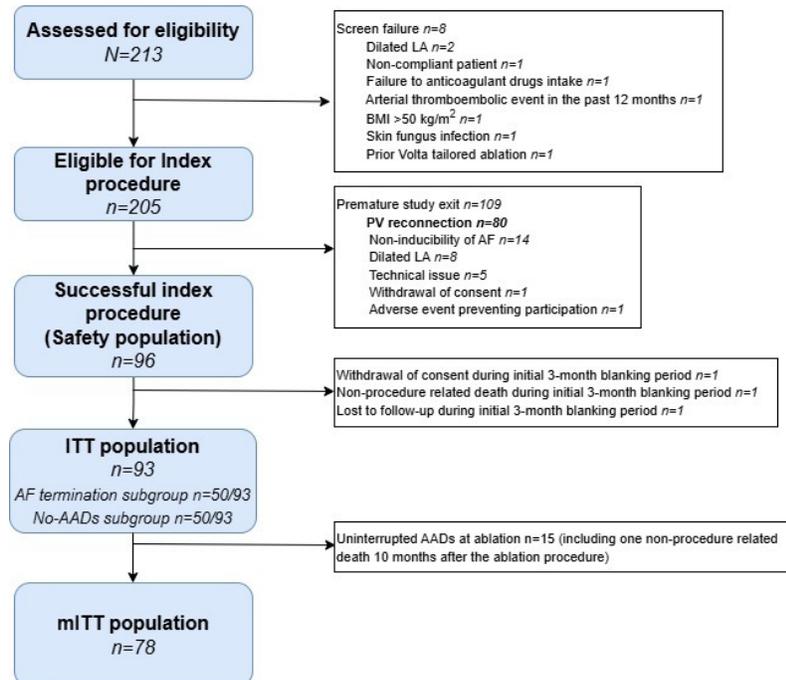


Table 1: Procedural characteristics

	STUDY PATIENTS (N=96)
Procedure time (min)	150.0 ± 63.5
AF mapping time (min)	39.8 ± 22.8
Total fluoroscopy time (min)	14.7 ± 11.9
RF time to AF termination (min)	15.8 ± 12.0
Total RF time (min)	26.7 ± 15.7
Patients with dispersion in the LA	77/82 (94%)
Patients with dispersion in the RA	48/82 (54%)
AF termination by ablation	52/96 (54%)
SR conversion by ablation	46/96 (48%)

Fig. 2: Participant flow diagram



Results - ITT population

Endpoints

Freedom from AF (FFAF) after one procedure at 12 months was achieved in 77/93 (83%) patients.

Freedom from any atrial arrhythmia (FFAF/AT) after one procedure at 12 months was achieved in 65/93 (70%) patients.

Sub-group with AF termination

During the index procedure, AF termination by ablation occurred in 50/93 patients (54%).

In this sub-group, after one procedure, the FFAF was 92% and the FFAF/AT was 78%.

Sub-group without AADs

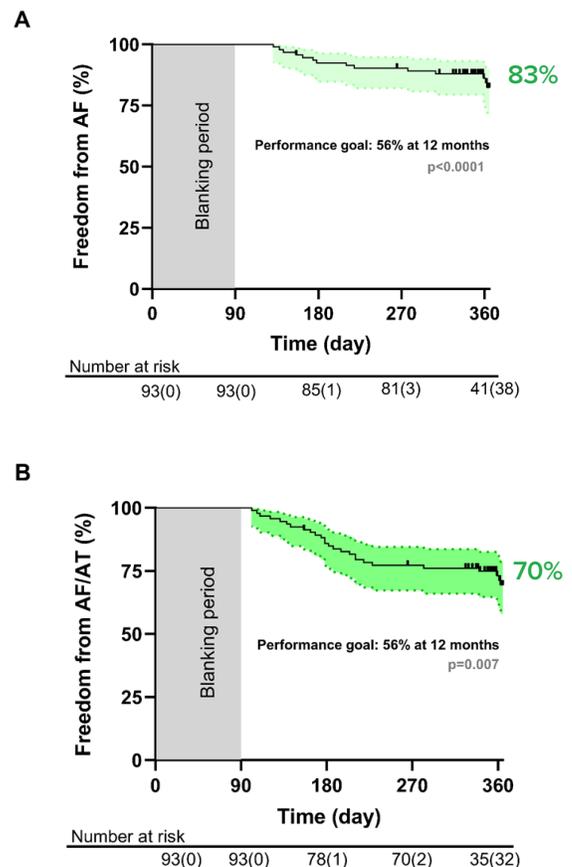
At the time of the index ablation, 15 patients were on AADs; 28 more started AADs later, leaving 50/93 patients in the no-AAD subgroup.

In this sub-group, after one procedure, FFAF was 86% and FFAF/AT was 74%.

Quality of Life

Patients reported an increased AFEQT overall score and SF-36 general health score at 12 months compared to baseline scores at enrollment: AFEQT: 85.8 ± 18.2 vs 66.1 ± 21.7 , $p < 0.0001$; SF-36: 71.6 ± 19.1 vs 64.7 ± 16.8 , $p < 0.01$.

Fig. 3: Kaplan-Meier estimates of the FFAF and FFAF/AT after one procedure at 12 months.



Conclusions

- ✓ Historically, empirical approaches such as repeat PVI, linear ablation, CFAE ablation and low-voltage area modification have yielded modest success in repeat patients.
- ✓ The RESTART trial is the first prospective, multicenter study to demonstrate the safety and efficacy of AI-guided dispersion mapping in patients with recurrent AF despite confirmed durable PVI.
- ✓ FFAF after a single procedure at 12 months, was achieved in 83% of patients and FFAF/AT was 70%.
- ✓ These findings suggest that AI-guided dispersion ablation is a promising strategy for so-called “non-PVI responder” patients.

Fig. 4: Quality of life

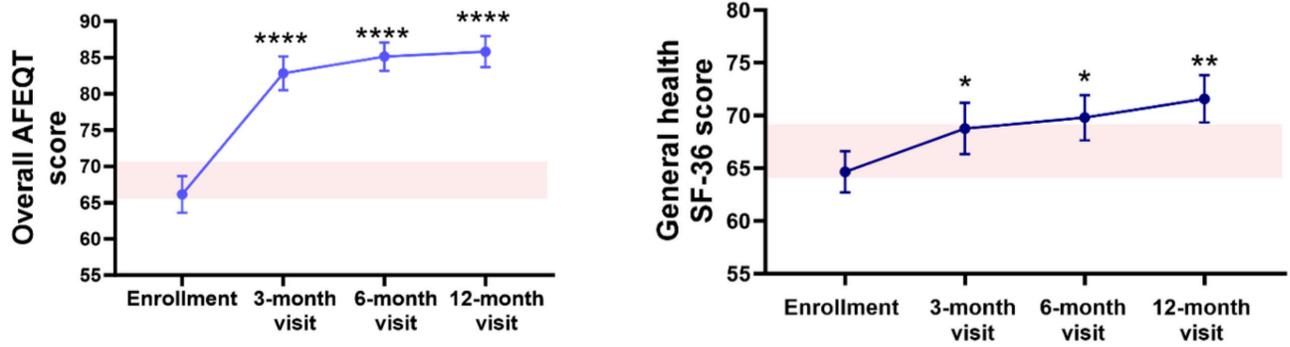
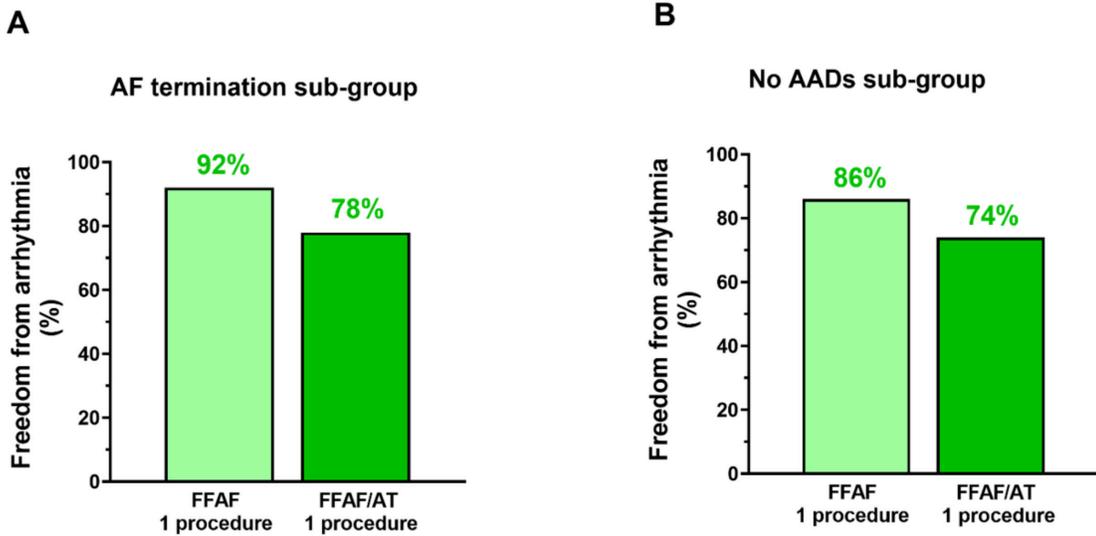


Fig. 5: Sub-group outcomes



ABOUT VOLTA MEDICAL

Volta Medical leverages artificial intelligence to revolutionize interventional cardiac electrophysiology. Its cutting-edge software solutions use machine and deep learning algorithms to assist operators during cardiac ablation procedures. Founded in 2016, Volta Medical is based in Marseille, France.



VOLTA MEDICAL

65 Avenue Jules Cantini
13006 Marseille
FRANCE
contact@volta-medical.com

VOLTA MEDICAL, INC.

225 Dyer St.
Providence, Rhode Island 02903
USA
contact@volta-medical.com

The Volta AF-Xplorer system is a Class IIa Medical Device manufactured by Volta Medical. This product is CE marked by TÜV Rheinland LGA Products GmbH (0197) and FDA cleared. CAUTION: See User Manual/Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Volta Medical® a brand of SUBSTRATE HD SAS - Share capital: 19 925,40 Euros - RCS Marseille 820 967 875

©2026 Volta Medical. All rights reserved. Reproduction or transmission of this document or part of this document in any format or by any means without written permission from Volta Medical is not authorized.