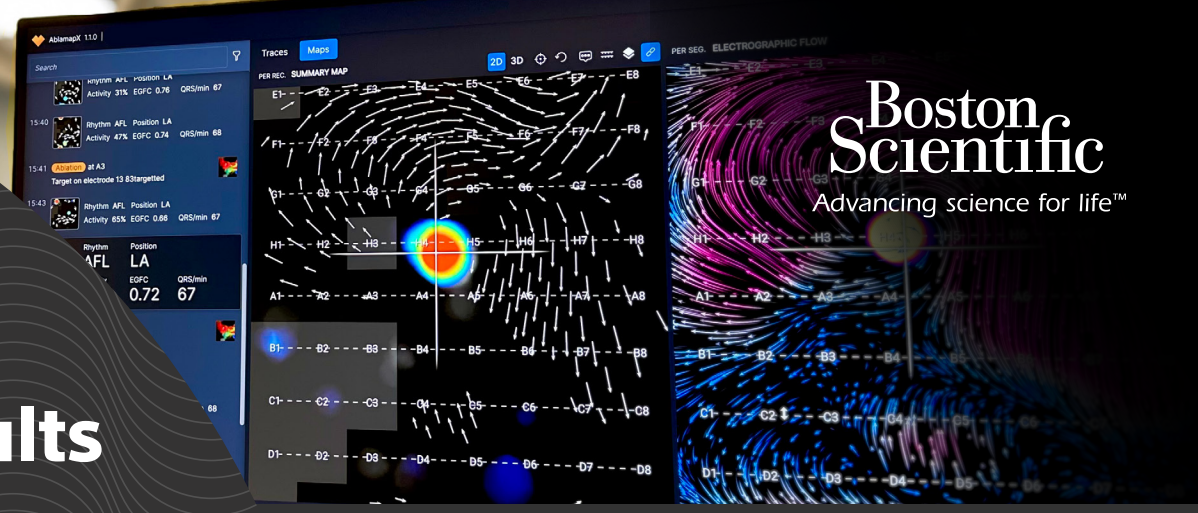

FLOW-AF Clinical Trial Results

Boston Scientific
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FLOW-AF demonstrated the potential of EGF mapping to improve outcomes and guide future AF ablation strategies

A Randomized Trial of Electrographic Flow-Guided Redo Ablation for Nonparoxysmal Atrial Fibrillation (FLOW-AF) NCT06260670

OBJECTIVE AND STUDY DESIGN

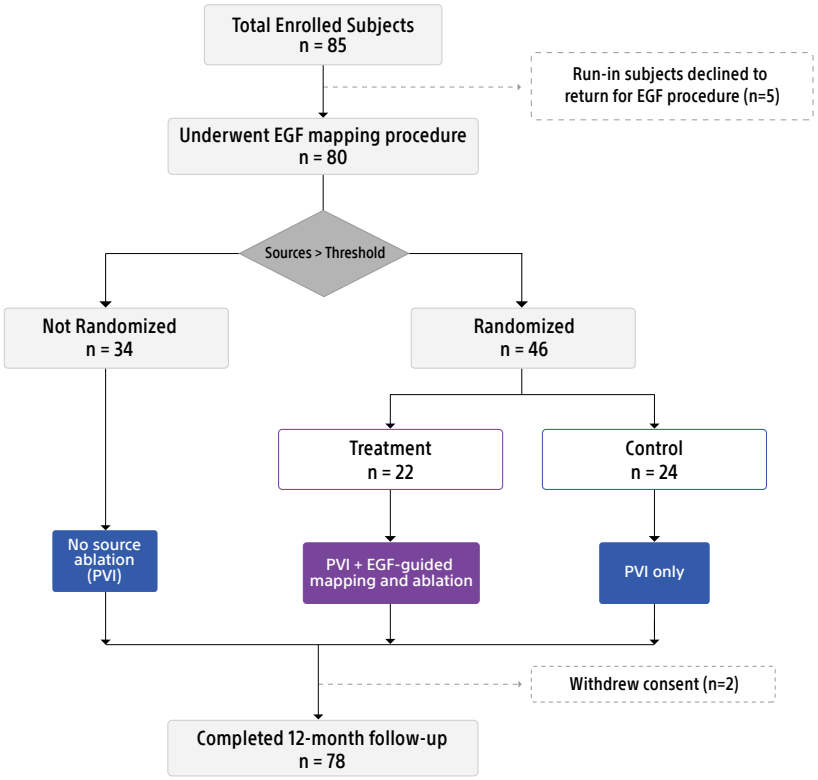
FLOW-AF was a prospective, multicenter, randomized controlled trial that evaluated the safety and effectiveness of Electrographic Flow (EGF) mapping in guiding RF ablation in a non-paroxysmal redo population. Data from this trial was used to support the 510(k) clearance for the OPTIMAP™ System, a diagnostic catheter and software platform.

The trial

- Demonstrated OPTIMAP's ability to identify extra-pulmonary vein AF sources and guide RF ablation to improve AF recurrence
- Showed that EGF-guided mapping and ablation met effectiveness and safety endpoints

Patients

- Documented, symptomatic PerAF or LS-PerAF
- Redo patients with at least 1 prior AF ablation including pulmonary vein isolation (PVI)



METHODS

- After confirming or retouching PVI, 1-minute panoramic EGF maps were recorded in standardized bi-atrial basket positions.
- Patients with EGF-identified source activity (n = 46) were randomized 1:1 to:
  - PVI + EGF-guided mapping and ablation (treatment group; n = 22)
  - PVI only (control group; n = 24)

The OPTIMAP system is 510(k) cleared and is not yet available for sale in the United States.

Patient Group	Treatment (PVI + EGF)	Control (PVI only)
Randomized	22	24
Completed 12-month follow-up	21	23
Per-protocol population (analyzed)	**19**	**21**

Per-protocol population includes patients who received assigned treatment without major deviations and were used for primary effectiveness analysis

Primary endpoints

- **Primary Safety:** Freedom from procedure-related serious adverse events (SAEs) through 7 days following redo procedure
- **Primary Effectiveness:** Successful elimination of significant sources of excitation*

*Defined as reduction of the source activity (SAC) of the leading source to <26.5%

KEY RESULTS

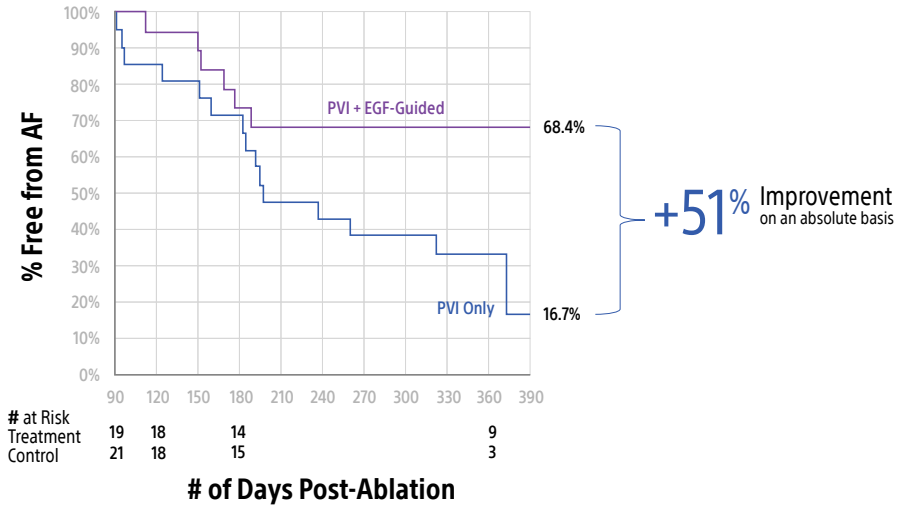
Patients with active sources who received PVI + EGF mapping and source ablation had **51%** improvement in freedom from AF on an absolute basis.

51% Improvement in freedom from AF

Freedom from AF at 12 months

68.4% in PVI + EGF mapping and ablation group vs. 16.7% in PVI alone control group (p = 0.042)

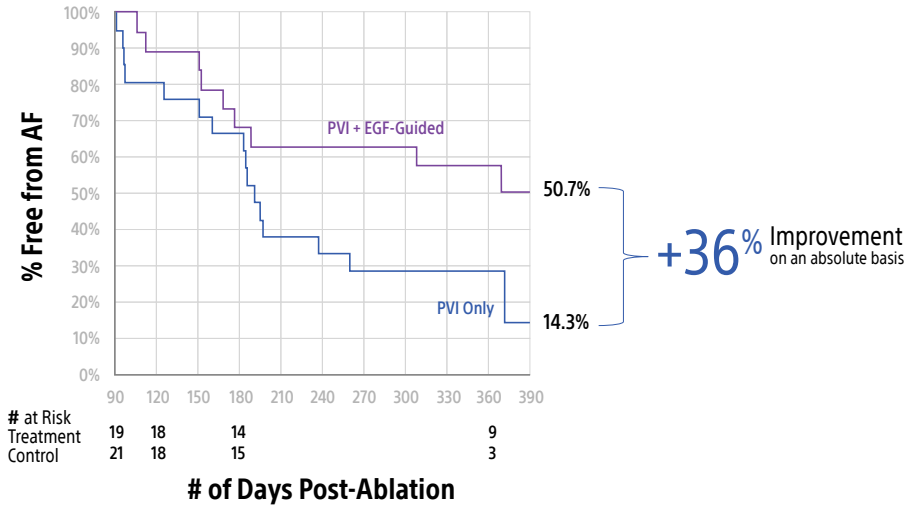
Kaplan-Meier Plot for Freedom from AF for EGF-Guided Mapping and Ablation vs. Control



Freedom from AF/Atrial Tachycardia (AT)/Atrial Flutter (AFL) at 12 months:

50.7% vs 14.3% in PVI + EGF mapping and ablation group vs. PVI alone control group (p = 0.103)

Kaplan-Meier Plot for Freedom from AF/AT/AFL for EGF-Guided Mapping and Ablation vs. Control



KEY RESULTS

95%

Primary Effectiveness Outcome

(19/20) of patients in the PVI+ EGF-guided mapping and ablation treatment arm achieved source elimination on repeat EGF mapping.

EGF-guided mapping achieved the primary efficacy endpoint of successful source ablation.

97.2%

Primary Safety Outcomes

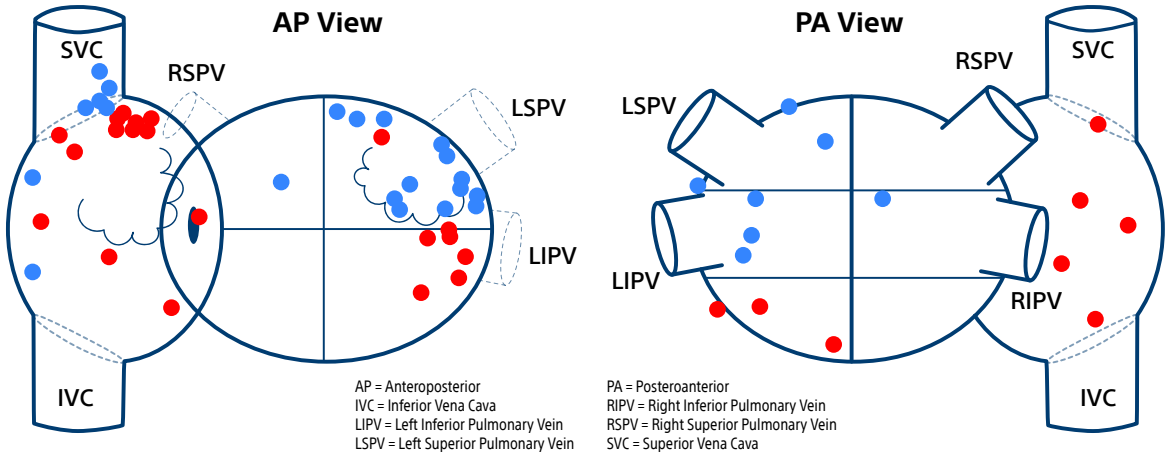
PVI+ EGF mapping and ablation showed a 97.2% freedom from SAEs at 7 days.

There was no significant difference in procedure-related SAEs between the PVI only and PVI + EGF mapping and source ablation groups (p = 1.000).

Does standard ablation fail to target clinically relevant AF sources?

EGF mapping identified sources in both the left and right atria.
49% of those sources were located outside of standard lesion set areas.

Anatomic distribution of sources identified in FLOW-AF (n=46 patients)



KEY: Source within standard lesion set area | Source outside of standard lesion set area

Boston Scientific adjusted source colors post study

Lesion Set Type	# of Sources within the Lesion Set	% of Sources within the Lesion Set
WACA	9	16%
Posterior Box Isolation	2	4%
Roof Line	4	7%
Anterior Line	1	2%
LAA Isolation	5	9%
SVC Isolation	5	9%
Intercaval Isolation	2	4%
Total	28	51%

Boston Scientific data on file

49%

of sources were in areas **not addressed** by standard lesion sets

KEY TAKEAWAYS

EGF-guided mapping and ablation improved freedom from AF recurrence

PVI + EGF mapping and ablation improved 12-month AF-free survival among patients with sources by **51%** compared to PVI alone.

Targeted ablation of EGF-identified sources was feasible, effective and safe

95% of patients in the EGF group achieved successful source elimination of highly active sources, confirming the feasibility of targeted source ablation. There was no significant difference in safety outcomes between treatment and control groups.

EGF mapping revealed sources in non-standard ablation regions

49% of sources were located outside of standard lesion set areas—including in both atria—suggesting that EGF may uncover AF drivers missed by conventional approaches.

Findings are hypothesis-generating and warrant further study

The presence of clinically relevant AF sources in non-standard regions may help explain why some patients do not respond to PVI and/or empiric lesion sets alone, pointing to a potential role for EGF-based personalized ablation strategies.

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