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FROzEN-AF US IDE Clinical Trial Results

OBJECTIVE

- Evaluate the safety and effectiveness of the Boston Scientific **POLARx™ Cryoablation System** for treatment of symptomatic, drug refractory, recurrent, paroxysmal atrial fibrillation (PAF).

FROzEN-AF TRIAL DESIGN[1]

- Global, prospective, non-randomised, single-arm study (NCT04133168).
- 385 patients (325 primary, 60 roll-in subjects) across 44 sites in 10 countries.
- POLARx™ FIT extension arm[2].
  - 50 patients were treated to collect safety and effectiveness data on the POLARx FIT expandable (28 mm and 31 mm) cryoballoon (CB) catheter.

PROCEDURAL CHARACTERISTICS

- The FROzEN-AF and extension study procedural characteristics are shown in **Table 1**.
- The LA dwell time was 8 minutes shorter and fluoroscopy time was 6 minutes shorter in the FIT extension arm.
- There was an increase in grade 4 occlusion and single-shot success with the 31 mm CB.

Table 1: Procedural Characteristics

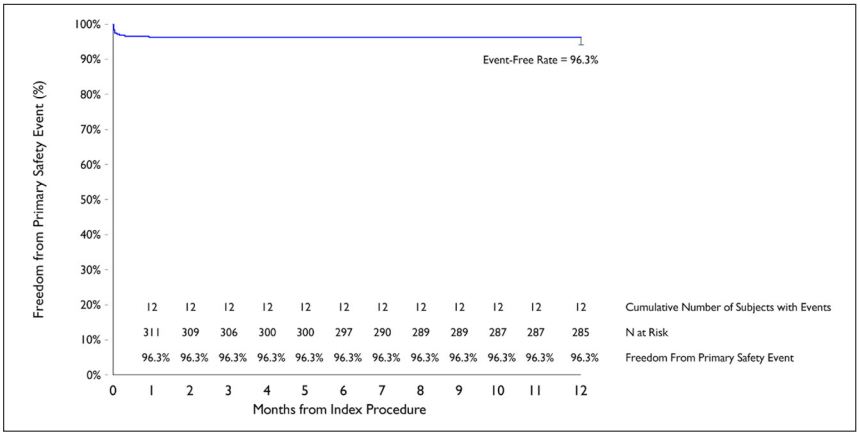
	FROzEN-AF (28 mm balloon)	POLARx FIT Extension Arm (28 mm/ 31 mm balloon)
General Anesthesia (%)	78.5%	100%
Conscious Sedation/MAC (%)	21.5%	-
Procedure Time (min)	91 min	101 min
LA Dwell Time (min)	59 min	51 min
Fluoroscopy Time (min)	13 min	7 min
Grade 3-4 Occlusion* (%)	95.9% (69.9% – Grade 4)	97.7% (66.4% / 77.6% – Grade 4)
Single Shot Success*(%)	55.9%	35.3% / 62.1%

Mean ±
*Only ablations with duration >60s included in ablation counts

PROCEDURAL AND LONG-TERM SAFETY

- The primary safety event-free rate was 96.0%‡ for the FROzEN-AF (12-month) **(Figure 1)** and 100% for the FIT extension arm (12-month).
- There were no reports of moderate or severe PV stenosis, persistent phrenic nerve palsy, or esophageal fistulas in both patient cohorts.

Figure 1. Procedural and Long-term Safety



No reported:
- PV stenosis
- Persistent phrenic nerve palsy
- Esophageal fistulas

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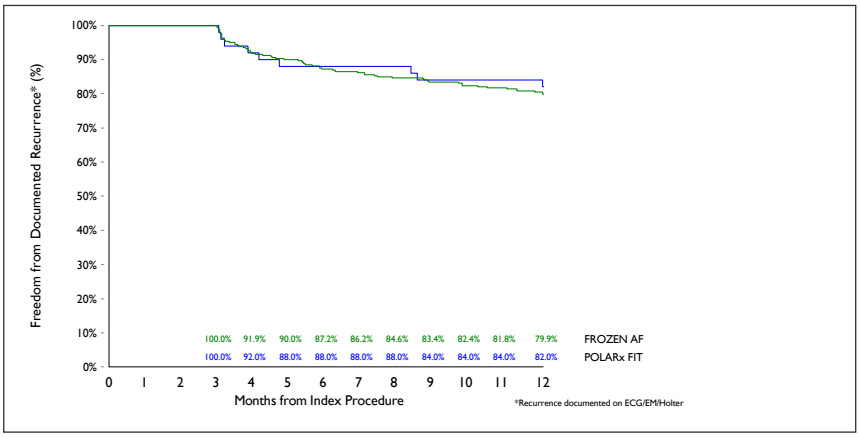
EFFICACY

- The 12-month freedom from documented atrial arrhythmias was 79.9% (AF 82.7%, AFL 96.5%, AT 98.1%) **(Figure 2)**.
- The FIT extension arm 12-month freedom from documented atrial arrhythmias was 82.0% (AF 84%, AFL 94%, AT 100%).
- Electroanatomic mapping (EAM) was used in 184/325 cases; examination of recurrence in these patients revealed a trend (p=0.08) toward higher freedom from recurrence (83.7%) when EAM was used, compared to 75.9% when not.

Figure 2. Freedom from Documented Recurrence of Atrial Arrhythmias



FROzEN (n=325)
12-Month
79.9%

Fit Extension (n=50)
12-Month
82.0%

POLARx FIT VOLTAGE SINGLE-CENTRE EXPERIENCE[3]

- A single-centre characterised lesions with high-density voltage maps on 14 patients (8 ablated with the 31 mm CB and 6 with the 28 mm CB).
- Voltage maps revealed wide antral lesions around all veins (100%).
- Lesion assessment of atrial scar burden revealed a statistically significant difference in the fractional antral scar, 68% (31 mm) vs. 60.5% (28 mm) (p = 0.048) indicating a significantly larger lesion being created by the 31 mm CB **(Figure 3)**.

Figure 3. High Density Maps of Atrial Scar Burder of the 28 mm and 31 mm CB

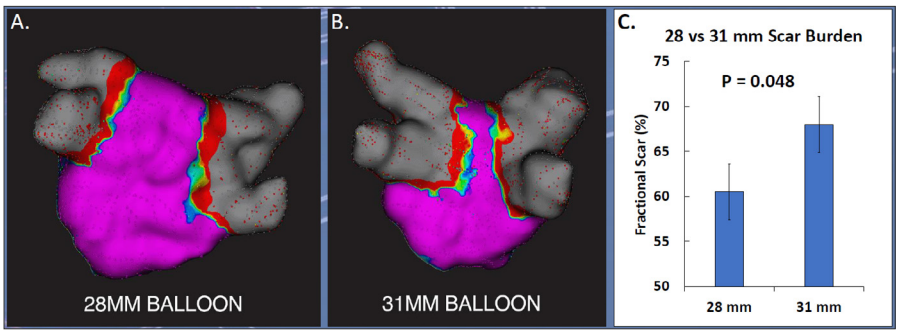


Figure Legend. High-density voltage maps from 28 mm (A) and 31 mm (B). C. scar burden analysis.

CONCLUSION

- The choice of balloon sizes (31 and 28 mm) with **POLARx FIT** may assist in overcoming challenges related to variability in patient PV size and geometry with the 31 mm CB achieving high-grade 3-4 vein occlusion, lowering the LA dwell and fluoroscopy times and increasing the single-shot isolation rate.
- The primary safety event-free rate was 96.0%‡ (FROzEN-AF) and 100% (FIT extension arm) with no reported PV stenosis, persistent phrenic nerve palsy, or esophageal fistulas.
- The documented atrial arrhythmia recurrence rate was low with 20.1% (FROzEN-AF) and 18% (FIT extension) at 12 months.
- In the single-centre experience, **POLARx FIT** produced significantly larger, more antral lesions and the 31 mm balloon and sheath maneuverability allowed greater control of balloon occlusion and lesion placement.

‡Updated analysis with corrected data

1. Ellenbogen KA, Mittal S, Varma N, *et al.* One-year outcomes of pulmonary vein isolation with a novel cryoballoon: Primary results of the FROZEN AF trial. J Cardiovasc Electrophysiol. Online ahead of print.

2. Su, *et al.* Clinical application of a novel 31 mm cryoballoon for pulmonary vein isolation for paroxysmal atrial fibrillation: procedural data from the FIT arm of FROzEN-AF. Presented at: Heart Rhythm Society 2023; May 19-21, 2023; New Orleans, LA, USA.

3. Makati, *et al.* Voltage mapping of a novel 31 mm cryoballoon for pulmonary vein isolation to manage paroxysmal atrial fibrillation: a single center experience. Presented at: AF Symposium 2023; Feb. 2-4, 2023; Boston, MA, USA.

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EP-1576508-AC
CE 0123