Boston Scientific
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POLARx™ Cryoablation Balloon Catheter | POLARx™ FIT Cryoablation System

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-randomized, single arm study (NCT04133168)
- 385 patients (325 primary, 60 roll-in subjects) across 44 sites
- **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.
  - All patients were treated with at least one application of the 31 mm CB

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 5.7 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

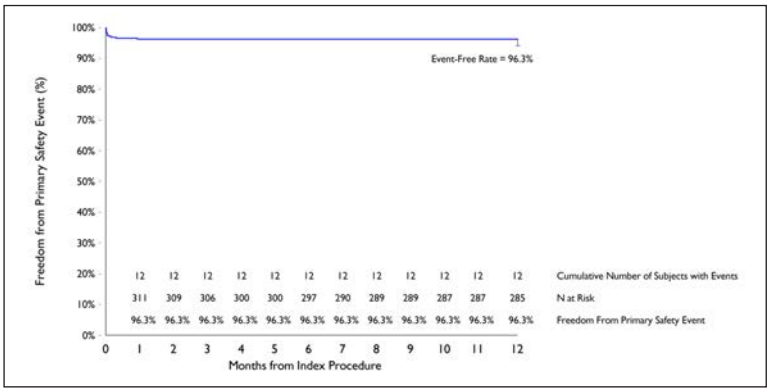
	FROzEN-AF (28 mm Balloon)	POLARx FIT Extension Arm (28 mm / 31 mm balloon)
General Anesthesia (%)	78.5%	100%
Conscious Sedation/MAC (%)	21.5%	-
Procedure Time (min)	91 ± 41 min	101 ± 59 min
LA Dwell Time (min)	59 ± 33 min	51 ± 22 min
Fluoroscopy Time (min)	12.9 ± 11.2 min	7.2 ± 11.3 min
Grade 3-4 Occlusion* (%)	95.9% (69.9% – Grade 4)	97.8% (67.3% / 80.8% – Grade 4)
Single Shot Success* (%)	55.9%	35.3% / 62.1%

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

PROCEDURAL AND LONG-TERM SAFETY

- The primary safety event-free rate was 96.3% for the FROzEN-AF (12-month) and 100% for the FIT extension arm (6-month) patients (Figure 1)
- 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

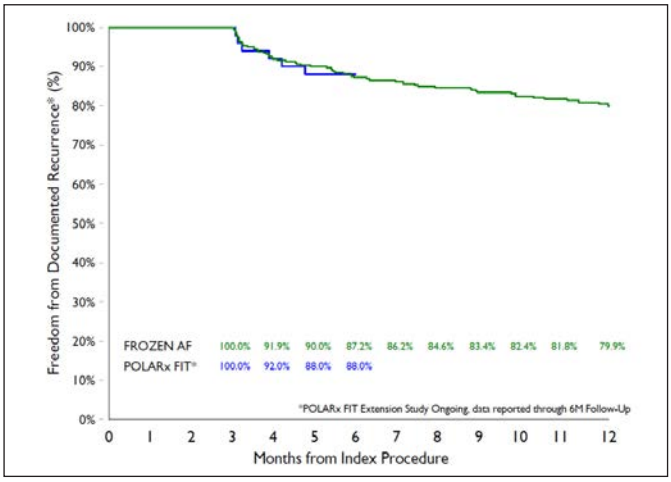


No reported:
- PV stenosis
- Persistent phrenic nerve palsy
- Esophageal fistulas

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 6-month freedom from documented atrial arrhythmias was 88.0%

Figure 2. Freedom from Documented Recurrence of Atrial Arrhythmias



FROzEN (n = 325)
12-Month
79.9%

FIT Extension (n = 50)
6-Month
88.0%

POLARx™ FIT Voltage Mapping Single Center Experience[3]

- A single center characterized 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 Burden of the 28 mm and 31 mm CB

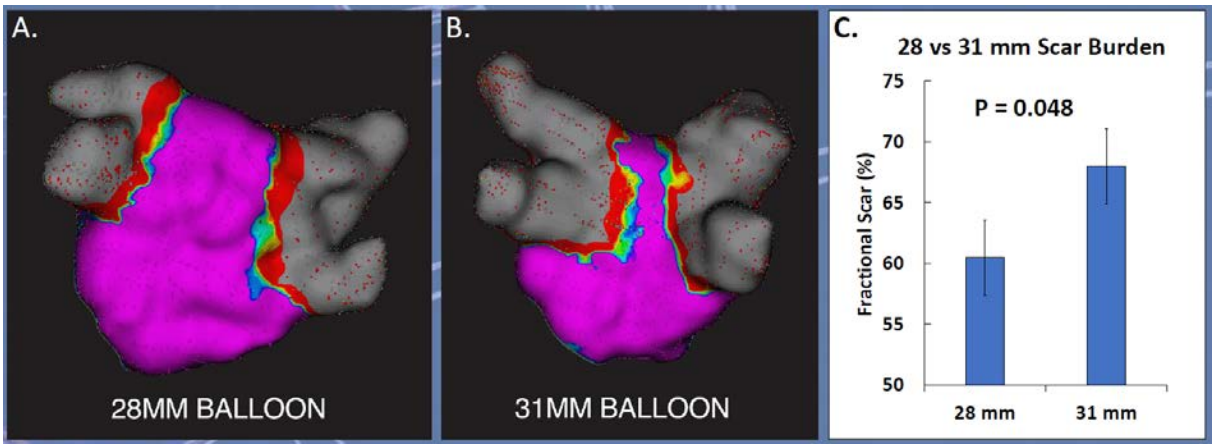


Figure Legend. High density voltage maps from 28 mm (A) and 31 mm (B). C. scar burden analysis.

CONCLUSIONS

- 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 96.3% (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) at 12 months and 12% (FIT extension) at 6 months
- In the single center 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

1. Ellenbogen et al. One-Year Outcomes of Pulmonary Vein Isolation with a Novel Cryoballoon in 325 Patients: Primary Results of the FROzEN-AF Trial. HRS 2023.
2. Su et al. Clinial Application of a Novel 31 mm Cryoballoon for Pulmonary Vein Isolation for Paroxysmal Atrial Fibrillation: Procedural Data from the FIT arm of FROzEN-AF. HRS 2023.
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. AFS 2023.

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