FANTOM II Trial: Safety & Performance Study of the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold – 24-Month Follow-up Clinical Outcomes Final Results

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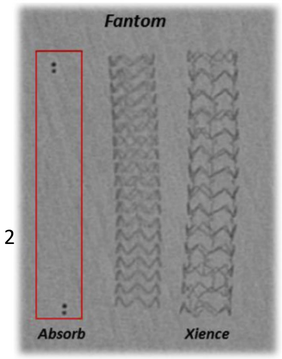
Background

Bioresorbable vascular scaffolds (BRS) may help restore normal vessel reactivity, positive remodeling, and reduce chronic inflammation. However, 1st generation BRS had some safety concerns.[1]

Methods

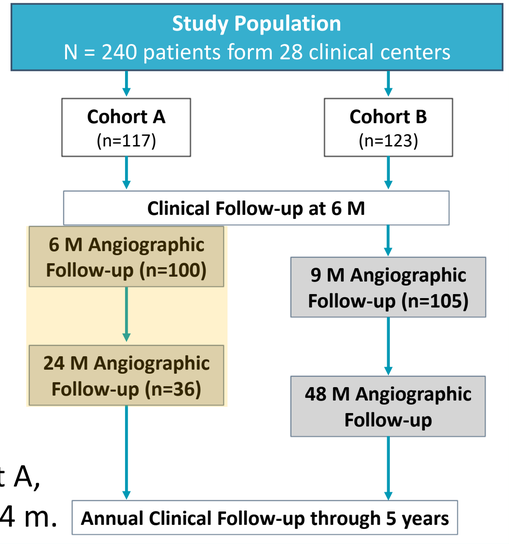
Fantom BRS (REVA Medical)



- ✓ **Thin struts:** 125 µm
- ✓ **Sirolimus-eluting:** completely resorption ~4 years
- ✓ **Best-in-class radial strength**
- ✓ **Minimal fracture risk:** can be expanded 0.75 mm above nominal [2]
- ✓ **Radiopaque:** tyrosine polycarbonate (Tyrocore™)
- ✓ **Stable:** for room temperature shipping and storage

FANTOM II Trial

- 240 patients in 2 cohorts
- 2.5 to 3.5 mm vessels
- Lesion length ≤ 20 mm
- Angiographic follow-up (6 and 9 months)
- Serial imaging sub-study (24 and 48 months)
- IVUS and OCT sub-study
- Independent assessment for images and events



- Here, we present angiographic analysis in cohort A, and clinical endpoints in total cohorts at 6 and 24 m.

Results

Patient Characteristics

Variable	All patients (n=240)
Age (years)	62.7±10.1
Male	169 (70%)
Hypertension	177 (74%)
Diabetes	57 (24%)
Hyperlipidemia	170 (71%)
Current/former smoker	143 (60%)
Prior PCI	105 (44%)
Prior CABG	7 (3%)
Prior MI	63 (26%)

Lesion Characteristics

Variable	All lesions (n=238)
Total lesion location	
LAD	116 (49%)
LCX	74 (31%)
RCA	48 (20%)
ACC/AHA Lesion Class	
Type A	44 (19%)
Type B1	118 (50%)
Type B2	70 (29%)
Type C	6 (3%)

Acute Procedural Outcomes

Acute Technical Success (1)	95.8%
Acute Procedural Success (2)	99.1%
Clinical Procedural Success (3)	99.6%

(1) Defined as successful delivery and deployment of the intended scaffold in the intended lesion without device related complications.

(2) Defined as acute technical success (see definition above), resulting in a residual stenosis of ≤50% with no immediate (in-hospital) MACE.

(3) Defined as acute procedural success (see definition above), with no MACE 30 days post-intervention and with a final diameter stenosis ≤50%

Clinical Endpoints (modified ITT): non-Hierarchical	6 Months (n = 240)	24 Months (n=240)
MACE	2.1% (5)	5.0% (12)
Cardiac Death	0.4% (1)	0.8% (2)
MI	1.3% (3)	1.7% (4)
Target Vessel		1.3% (3)
Non-Target Vessel		0.4% (1)
Clinically Driven TLR	0.8% (2)	2.9% (7)

In-Scaffold Analysis	Baseline (n=238)	Cohort A 6 Mo. (n=100)	Cohort A 24 Mo. (n=36)
RVD (mm)	2.71±0.37	2.70±0.36	2.67±0.33
MLD (mm)	0.82±0.31	2.23±0.41	2.18±0.48
Diameter Stenosis (%)	69.5±11.0	15.3±15.2	15.1±17.9
Acute Gain (mm)	1.68±0.41		
Acute Recoil (%)	4.0±8.3		
Mean LLL (mm)		0.25±0.40	0.23±0.49
In-Segment Analysis			
Mean LLL (mm)		0.17±0.34	0.21±0.49

There were 2 definite or probable scaffold thrombosis (0.8%), 1 in sub-acute and 1 in very late.

Conclusion

FANTOM II demonstrates safe and stable performance of the Fantom BRS at 24 months

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Reference: 1. EuroIntervention. 2017;13:734-50. 2. JACC Cardiovasc Interv. 2017;10:1832-8.