FANTOM II Study: 48-Month Follow-up of Safety and Performance Second Generation Bioresorbable Scaffold (Fantom)

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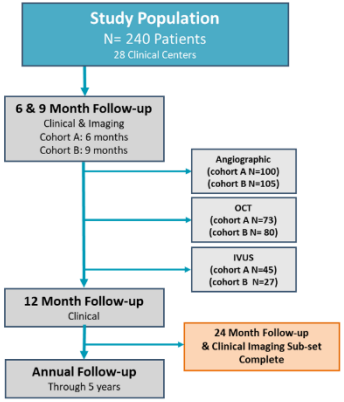
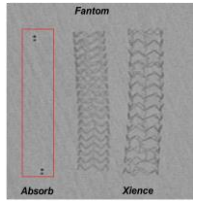
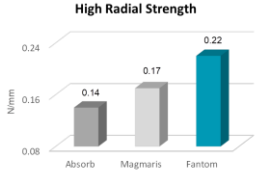
Background

Bioresorbable vascular scaffolds (BRS) provide temporary mechanical support and may help restore normal vessel reactivity, positive remodeling, and reduce chronic inflammation. The Fantom® scaffold (REVA Medical) is a sirolimus-eluting BRS, manufactured from Tyrocore™, a unique radiopaque tyrosine-based polymer scaffold with thinner struts.







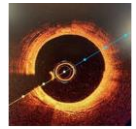
Bench testing on 3.0 mm scaffolds in water at 37°C.

Methods

FANTOM II is a prospective, multi-center, safety and performance study of patients with myocardial ischemia or a positive functional study. The study included patients with single de novo lesions in native coronary vessels ranging in diameter from 2.5 to 3.5 mm and lesion lengths up to 20 mm. The primary objective of the study is to demonstrate safety and performance of the Fantom sirolimus-eluting bioresorbable scaffold by assessing the incidence of Major Adverse Cardiac Events (MACE) and Late Lumen Loss at 6 months, as well as secondary endpoints at 9 month and subsequent up to 5 years.

Results

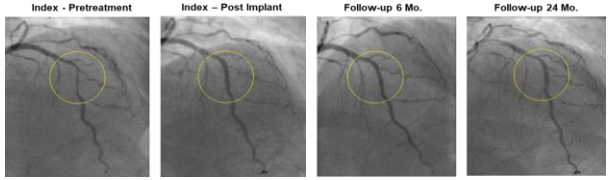
FANTOM II enrolled 240 patients across 28 clinical centers in 8 countries. Two separate sequential cohorts followed patients with a 6-month (Cohort A, N=117) versus 9-month (Cohort B, N=123) angiographic assessment. A sub-set of Cohort A patients, returned for serial angiographic follow-up at 24-month. Acute technical success, acute procedural success, and clinical procedural success were 95.8%, 99.1% and 99.6%, respectively.

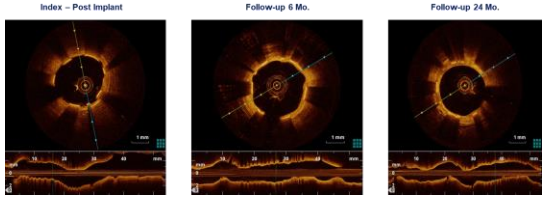


Fantom OCT
4-Year Follow-up

Components of 6-Month Primary Endpoint (ITT): non-Hierarchical	6 Month (n = 240)	12 Month (n = 240)	24 Month (n = 240)	36 Month (n = 240)	48 Month (n = 240)
MACE	2.1% (5)	4.2% (10)	5.0% (12)	5.0% (12)	5.4% (13)
Cardiac Death	0.4% (1)[1]	0.8% (2)[1,2]	0.8 % (2)	0.8 % (2)	1.3% (3)[1,2,3]
MI	1.3% (3)	1.3% (3)	1.7% (4)[4]	1.7% (4)[4]	1.7% (4)[4]
Clinically Driven TLR	0.8% (2)	2.5% (6)	2.9% (7)	2.9% (7)	2.9% (7)
Target Lesion Failure (TLF)	2.1% (5)	4.2% (10)	4.6% (11)	4.6% (11)	5.0% (12)

(1) One patient died between 0-6 months. Exact cause of death not determined. Patient died at home 4 weeks after subsequent TAVI procedure.
(2) One death occurred between 6-12 months. Patient was reported to have died of COPD by treating physician, but cardiac relation could not be excluded.
(3) One death occurred between 4 and 5years. Patient was treated for an occlusion in a non-target vessel and had an IABP implanted, but subsequently died due to cardiogenic shock.
(4) Three target vessel related MIs and one non-target vessel related MI.
(5) Event rate percentages are based upon the full 240 patient cohort in the denominator.





Definite or Probable Scaffold thrombosis (N=240)	
Acute (0 - 1 day)	0% 0)
Sub-acute (2 – 30 days)	0.4% (1)[1]
Late (31 – 365 days)	0% (0)
Very Late (>365 days)	0.8% (2)[2,3,4]

(1) Target lesion was not fully covered with scaffold. Significant untreated stenosis both proximally and distally to the scaffold was present at index procedure. Patient returned 5 days post procedure with a scaffold thrombosis
(2) Clear Protocol Violation: Patient Selection outside of protocol limits: Distal segment of scaffold was in a 2.0mm vessel and the scaffold had significant malapposition that was not corrected at the index procedure
(3) One new event was reported between 24 and 36 months. The patient was treated for a Non-Clinically Driven TLR. The site reported a "Thrombus Flake" at the edge of the scaffold.
(4) Event rate percentages are based upon the full 240 patient cohort in the denominator

Conclusion

FANTOM II confirms the safe and stable performance of the Fantom BRS through 48-months follow up in regards of clinical and angiographic endpoints. Fantom continues to show a stable TLF rate of 5.0% through 4 years.