FANTOM II Trial

Safety & Performance Study
Final 5 Year Clinical Outcomes

First Report on Final Clinical Outcomes

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Potential conflicts of interest

Speaker's name : Matthias Lutz

☑ I have the following potential conflicts of interest to declare:

Receipt of grants / research support: REVA Medical

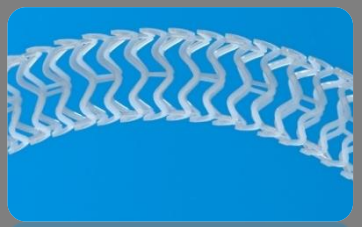
Receipt of honoraria or consultation fees: Abbott, B.Braun Melsungen AG, REVA Medical

Why this study?

Second Generation Fantom Bioresorbable Scaffold

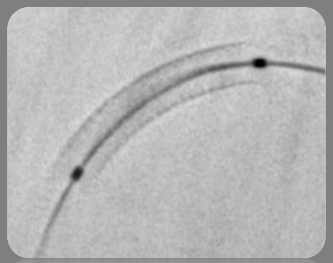
Scaffold Design

- Thin struts: 125 µm
- Enhanced radial strength
- Minimal recoil
- Single-step balloon inflation
- 0.75 expansion over nominal (3.0 mm)



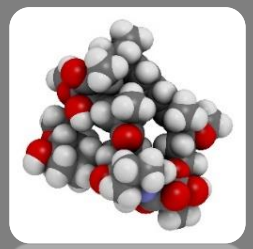
Tyrocore™

- Radiopaque
- Provides strength during healing
- Vessel uncaged in one year
- Complete resorption in ~4 years



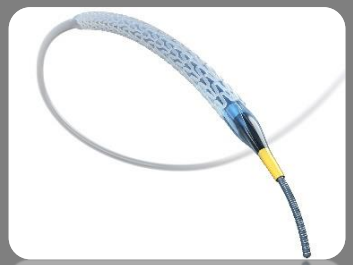
Sirolimus

- First anti-proliferative agent used in drug eluting stents
- Highly lipophilic with broad therapeutic window
- Demonstrated across multiple clinical studies and drug eluting stents



Delivery System

- Semi-compliant nylon balloon
- High 18 atm rated burst pressure
- Rapid exchange
- 1.35 mm crossing profile



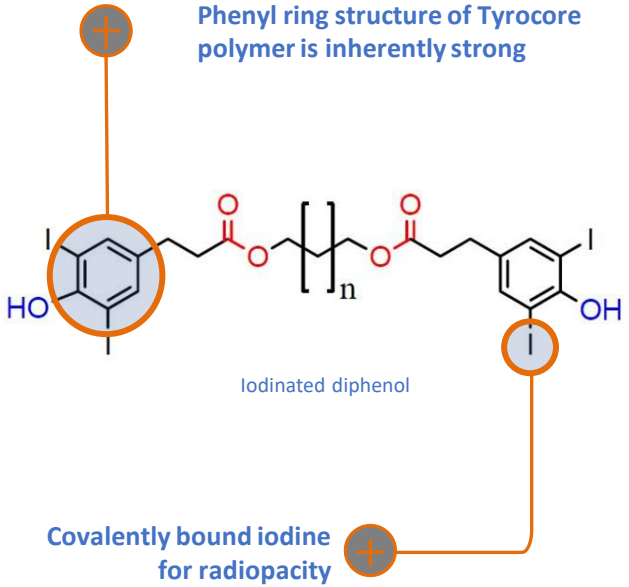
Why this study?

Fantom's Technology: Tyrocore®

Radiopaque, bioresorbable polymer approved for use in medical devices

Tyrocore® Properties

- Proprietary bioresorbable polymer
- Strong for excellent mechanical properties
- X-ray visible, ideal for vascular procedures
- Naturally biocompatible: derived from the tyrosine amino acid
- Polymer properties are tailorable to meet a clinical application by modifying:
  - Strength
  - Flexibility
  - Degradation time
  - Drug delivery profile



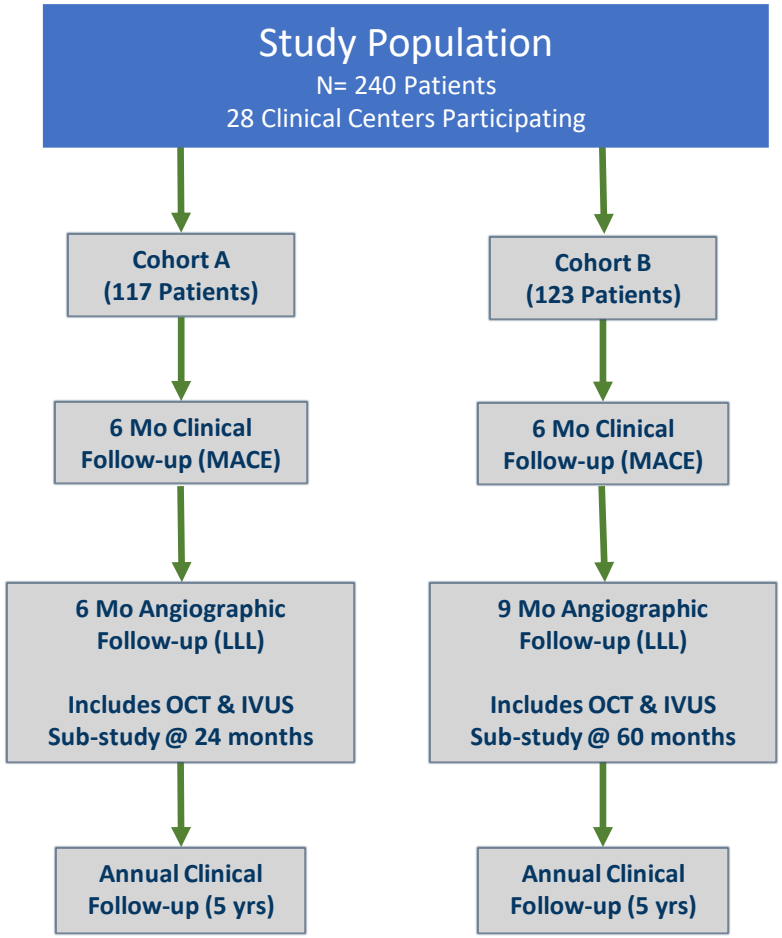
What did we study?

Study Design

- Safety and Performance Trial
- 240 patients in 2 cohorts
- 2.5mm to 3.5mm vessels
- Lesion length ≤ 20mm
- Angiographic follow-up
  - Cohort A: 6 months 117 Pts.
  - Cohort B: 9 months 123 Pts.
- Serial imaging sub-studies
  - Cohort A: 24 months (25 Patients)
  - Cohort B: 60 months (25 Patients)

FANTOM II

Study Design and Endpoints

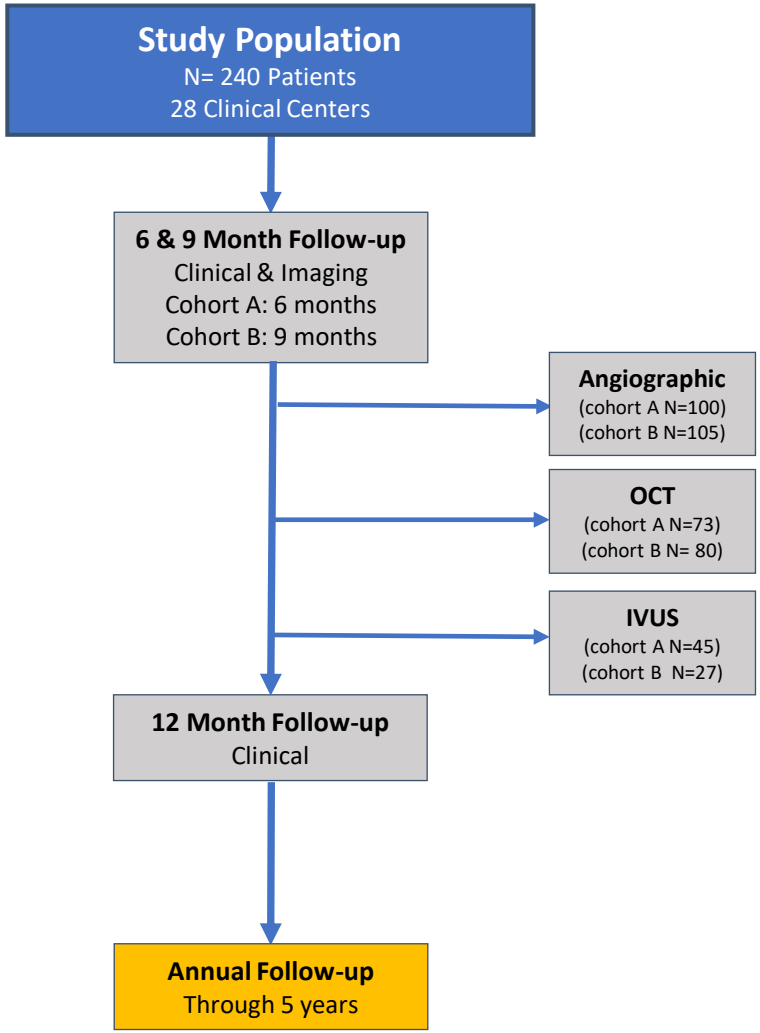


How was the study executed?

FANTOM II Study Investigators

- Australia
  - Dr. Muller, Dr. Jepson, Dr. Walters
- Belgium
  - Dr. De Bruyne
- Brazil
  - Dr. Feres, Dr. Costa, Dr. Chamie, Dr. Perin
- Denmark
  - Dr. Christiansen, Dr. Tilsted, Dr. Okkels-Jensen
- France
  - Dr. Carrié, Dr. Chevalier, Dr. Fajadet, Dr. Collet
- Germany
  - Prof. Frey, Dr. Lutz, Dr. Weber-Albers, Dr. Achenbach, Dr. Kische, Dr. Ince, Prof. Brachmann, Dr. Naber
- Netherlands
  - Dr. Amoroso, Dr. Wykrzykowska, Dr. Daemen
- Poland
  - Dr. Dudek, Dr. Kochman, Dr. Koltowski, Dr. Lesiak, Dr. Wojdyla

How was the study executed?



FANTOM II – Cohorts A & B

Patient Flow and Baseline Characteristics

Patient Characteristics (N=240)	
Patient Age (average years)	62.7 ± 10.1
Male	70.4%
Diabetes	23.8%
Current/Former Smoker	59.6%
Hypertension	73.8%
Hyperlipidemia	70.8%
Prior PCI	43.8%
Prior CABG	2.9%
Prior MI	26.3%
Recent LVEF <40%	0.0% (N=231)

What are the essential results?

FANTOM II – Cohorts A & B

Lesion Characteristics and Procedural Outcomes

Lesion Characteristics

Target Lesion Location (n=238)[1]	
LAD	48.7% (116)
LCX	31.3% (74)
RCA	20.2% (48)

ACC/AHA Lesion Class (n=238)[1]	
Type A	18.5% (44)
Type B1	49.6% (118)
Type B2	29.4% (70)
Type C	2.5% (6)

Procedural Outcomes

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 percent with no immediate (in-hospital) MACE.

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

(1) Two pre-procedure angiograms were not available

What are the essential results?

FANTOM II (Cohorts A&B)

60-Month Clinical Outcomes

Components of 6-Month Primary Endpoint (modified ITT): non-Hierarchical	6 Month (n = 240)	12 Months (n = 240)	24 Months (n=240)	36 Months (n=240)[6]	48 Months (n=240)[6]	60 Months (n=240)[6]
MACE	2.1% (5)	4.2% (10)	5.0% (12)	5.0% (12)	5.4% (13)	6.3% (15)
Cardiac Death	0.4% (1)[1]	0.8% (2)[1,2]	0.8 % (2)	0.8 % (2)	1.3 % (3)[1,2,3]	1.7 % (4)[1,2,3,4]
MI (All MI Events)	1.3% (3)	1.3% (3)	1.7% (4)[5]	1.7% (4)[5]	1.7% (4)[5]	1.7% (4)[5]
Clinically Driven TLR	0.8% (2)	2.5% (6)	2.9% (7)	2.9% (7)	2.9% (7)	3.3% (8)
TLF	2.1% (5)	4.2% (10)	4.6% (11)	4.6% (11)	**5.0% (12)**	**5.8% (14)**

(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 3 and 4 years. Patient was treated for an occlusion in a non-target vessel and had an IABP implanted, but subsequently died due to cardiogenic shock.
(4) One death occurred between 4 and 5 years. Patient suffered from several comorbidities including end-stage COPD, pulmonary fibrosis, and dementia.
(5) Three target vessel related MIs and one non-target vessel related MI.
(6) Event rate percentages are based upon the full 240 patient cohort in the denominator.

What are the essential results?

FANTOM II (Cohorts A&B)
60-Month Clinical Outcomes

No new events between 36 and 60 months

Definite or Probable Scaffold Thrombosis (N = 240 Patients)	
Acute (0 – 1 day)	0.0% (0)
Sub-acute (2 – 30 days)	0.4% (1)[1,4]
Late (31 – 365 days)	0.0% (0)[4]
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 malaposition 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

Why is this important?

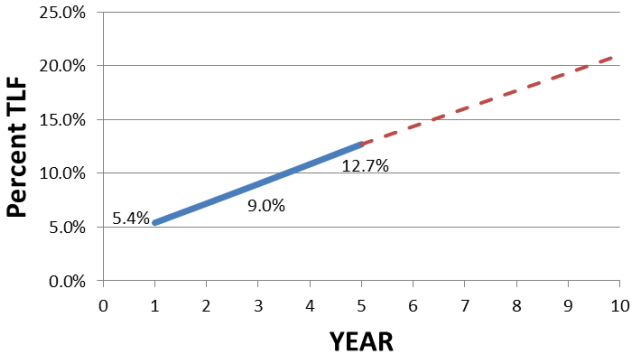
"The ideal of a stent that does its job and disappears is a valuable long-term goal, especially in young patients with long life-expectancy."

EuroPCR 2017 course director Dr. William Wijns

- There are **two distinct requirements for stent/scaffold Implantation** after lesion expansion:
  1) To provide **temporary mechanical support to the artery** during the healing process
  2) To provide a **temporary drug delivery platform** to reduce restenosis
- Permanent Implants are not needed for a temporary role
- The Fantom Encore BRS reduce the risks associated with permanent implants

Risk of Long-term Complications

~2% Increase in Target Lesion Failure Rates Every Year Following Treatment[1]

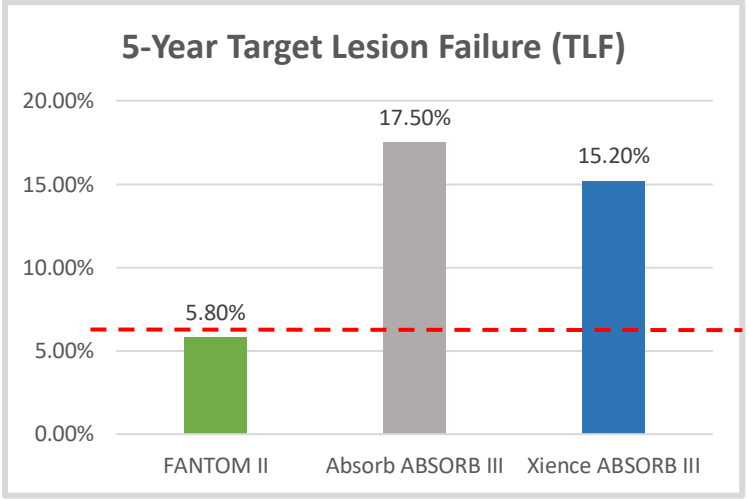


TLF = cardiac death, target vessel MI, ischemic-driven TLR

The essentials to remember

- **The Fantom BRS - as a next generation device - has demonstrated safe and effective clinical outcomes through 5 years**

  - Tyrocore® is a unique material developed specifically for improving coronary artery stenting
  - Excellent Long Term Clinical Outcomes
    1) **TLF = 5.8% through 5 years**
    2) Reduces the Late-Stage Thrombosis risk seen in other BRS



5-Year Clinical Outcomes Comparison

PCRonline.com