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6-Month Clinical and Angiographic Outcomes of a Novel Radiopaque Sirolimus-Eluting Bioresorbable Vascular Scaffold

The FANTOM II Study

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ABSTRACT

OBJECTIVES The purpose of this study was to evaluate the outcomes of the novel Fantom coronary bioresorbable scaffold at 6 months.

BACKGROUND The Fantom sirolimus-eluting bioresorbable scaffold incorporates a unique proprietary iodinated, polycarbonate copolymer of tyrosine analogs that is radiopaque, with thin struts (125 μm) that facilitate device delivery and precise target lesion treatment.

METHODS The 6-month outcomes and performance of the Fantom scaffold were evaluated in 117 patients with single de novo native coronary artery lesions of length ≤20 mm and reference vessel diameter 2.5 to 3.5 mm. The primary angiographic endpoint was mean late lumen loss at 6 months measured by quantitative coronary angiography. Procedural outcomes were categorized as short-term technical success, short-term procedural success, and clinical procedural success. The primary clinical endpoint was major adverse cardiac events at 6 months, the composite of cardiac death, myocardial infarction (MI), or clinically driven target lesion revascularization (TLR).

RESULTS Short-term technical success, short-term procedural success, and clinical procedural success were achieved in 96.6%, 99.1%, and 99.1% of patients, respectively. Mean 6-month in-stent late lumen loss was 0.25 ± 0.40 mm (n = 100). Binary restenosis was present in 2 patients (2.0%). Major adverse cardiac events within 6 months occurred in 3 patients (2.6%), including no deaths, 2 MIs, and 2 TLRs (1 patient had both an MI and TLR). Scaffold thrombosis occurred in 1 patient (0.9%).

CONCLUSIONS The clinical results from 117 patients enrolled in cohort A of the multicenter FANTOM II (Safety & Performance Study of the FANTOM Sirolimus-Eluting Bioresorbable Coronary Scaffold) study demonstrate favorable 6-month outcomes of this novel device in the treatment of noncomplex coronary artery disease. (J Am Coll Cardiol Intv 2017;10:1832–8) © 2017 Published by Elsevier on behalf of the American College of Cardiology Foundation.

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By restoring vasomotion and normal vascular adaptive responses, and by removing the nidus for ongoing inflammation, strut fracture, and neoatherosclerosis inherent with permanent metallic drug-eluting stents (DES) (1), bioresorbable vascular scaffolds (BRS) offer the potential to improve long-term event-free survival in patients with coronary artery disease. Several bioresorbable materials have been used for coronary artery scaffolds (2). The performance and outcomes of 2 poly L-lactic acid (PLLA)-based BRS have been demonstrated within 1 year of implantation, resulting in commercialization in Europe (3,4). However, first-generation PLLA-based BRS have several important limitations compared with contemporary metallic DES. Unlike metal stents, they are not radiopaque, requiring small markers to delineate the proximal and distal ends of the scaffold. As a result, precise placement can be challenging, especially when overlap is required. Second, the relatively thick struts (~150 μm, necessary to preserve radial strength) increase device profile and reduce deliverability. Thicker struts also delay endothelialization, and have been associated with higher rates of restenosis and thrombosis (5–7). Third, several BRS have limited expansion capability and are prone to fracture if overexpanded during the implantation process. Fourth, some BRS require storage at cold temperature. Finally, the 2 currently available PLLA-based BRS must be deployed with a stepped balloon inflation technique (e.g., 2 atm increase every 5 s), which may cause ischemia and prolongs procedural time.

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To address these limitations, a novel sirolimus-eluting BRS, the Fantom (REVA Medical, San Diego, California), had been developed. The Fantom is composed of a unique radiopaque polymer that has thin struts, excellent radial strength, and favorable expansion properties. The multicenter FANTOM II (Safety & Performance Study of the FANTOM Sirolimus-Eluting Bioresorbable Coronary Scaffold) study was performed to evaluate the outcomes of this new device in 240 patients with coronary artery disease. The present report contains the principal results of the Cohort A group (n = 117).

METHODS

DEVICE DESCRIPTION. The sirolimus-eluting Fantom BRS is made principally from an iodinated, polycarbonate copolymer of tyrosine analogs (desaminotyrosine [DAT]), and biocompatible hydroxyesters (8–10). The scaffold is constructed as a series of hoops with interconnecting rings (Figure 1). Strut thickness is 125 μm. The design and structural properties of the polymer afford radial strength comparable to or greater than contemporary metallic DES, with low rates of recoil (data on file, REVA Medical). Iodine atoms covalently bound to the backbone of poly (DAT carbonate) scatter x-rays and impart radiopacity due to their greater mass. Scaffold radiopacity is thus equivalent to currently marketed cobalt chromium drug-eluting metal stents (Figure 2). In addition, this material allows the Fantom scaffold to be rapidly inflated to the desired pressure during deployment in the same manner as a metal stent, without stepped inflation. Sirolimus (115 μg dose per 3.0 × 18-mm scaffold) is incorporated in the polymeric matrix; >60% of the drug is eluted within the first 30 days. The scaffold maintains radial strength through the critical healing period of 3 to 4 months and then completely degrades over 36 to 48 months, with the byproducts renally excreted. The Fantom scaffold is pre-mounted on a semicompliant balloon of a rapid exchange delivery catheter and is 6-F guide catheter and 0.014-inch guidewire compatible. The scaffold can be expanded 0.75 mm above nominal with a minimal risk of fracture. Fantom is stored at room temperature and requires no special handling. For the present study, the Fantom scaffold was available in 3 sizes (diameter and length): 2.5 × 18.0 mm, 3.0 × 18.0 mm, and 3.0 × 24.0 mm.

STUDY DESIGN AND POPULATION. The FANTOM II study enrolled patients with coronary artery disease and clinical or functional evidence of myocardial ischemia. By protocol, each patient was to have a single de novo native coronary artery lesion with visually assessed reference vessel diameter (RVD) 2.5 to 3.5 mm and with lesion length ≤20 mm. The pre-treatment diameter stenosis was required to be ≥50% and <100%. Principal clinical exclusion criteria included myocardial infarction within 72 h of the procedure with either creatine kinase-myocardial band (CK-MB) or troponin not returned to within 2× upper normal value; allergy to tyrosine-derived polycarbonate or sirolimus and its

FIGURE 1 The Fantom Sirolimus-Eluting Bioresorbable Scaffold

ABBREVIATIONS AND ACRONYMS

BRS = bioresorbable scaffold
DES = drug-eluting stent(s)
ITT = intention-to-treat
LLL = late lumen loss
MACE = major adverse cardiac events(s)
MI = myocardial infarction
MLD = minimum lumen diameter
PLLA = poly L-lactic acid
QCA = quantitative coronary angiography
RVD = reference vessel diameter
TLR = target lesion revascularization

FIGURE 2 Radiopacity of the Fantom Scaffold Compared to the Absorb Bioresorbable Scaffold and the Xience Metallic Stent

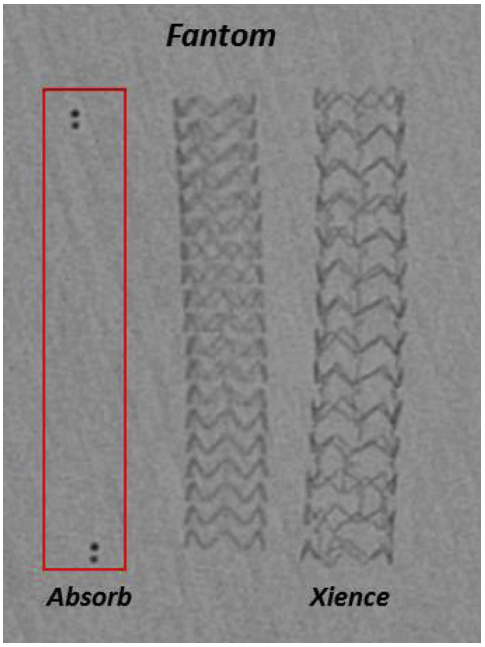


TABLE 1 Baseline Clinical Characteristics of the Cohort A Patients (n = 117)

Age, yrs	62.7 ± 9.7
Male	82 (70.1)
Risk factors	
Diabetes	25 (21.4)
Cigarette smoking	59 (50.4)
Hypertension	90 (76.9)
Hyperlipidemia	83 (70.9)
Family history of coronary artery disease	45 (38.5)
Medical history	
Peripheral vascular disease	5 (4.3)
Previous myocardial infarction	31 (26.5)
Prior coronary artery bypass graft surgery	7 (6.0)
Left ventricular ejection fraction <40%	0 (0.0)*

Values are mean ± SD or n (%). *Measured in 112 patients.

structurally related compounds; hepatic impairment, kidney failure, coagulopathy, or any comorbidity that reduces life expectancy to ≤24 months. Principal angiographic exclusion criteria included excessive proximal tortuosity; target lesion is a bifurcation with side branch >1.5 mm diameter, is ostial, moderately or severely calcified, thrombotic, has in-stent restenosis, or is supplied by a patent distal graft; left ventricular ejection fraction of <40% or a >50% diameter stenosis is present proximal or distal to the target lesion that will not be treated. The investigation was approved by the ethics committee at each participating center, and all patients provided written, informed consent. The study is registered as NCT02539966.

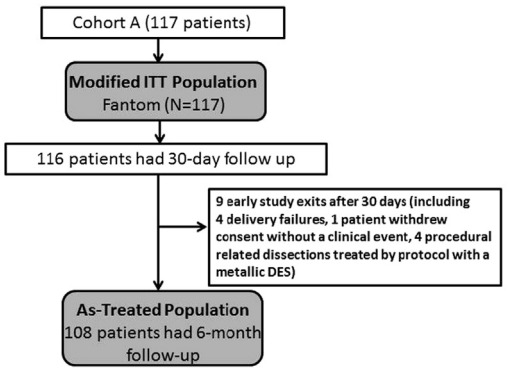
In the FANTOM II study, 240 patients were enrolled at 28 clinical centers in 8 countries in 2 angiographic follow-up cohorts: Cohort A: angiographic follow-up at 6 months (n = 117); and Cohort B: angiographic follow-up at 9 months (n = 123). Patients enrolled in the FANTOM II study will be followed for a total of 5 years with planned follow-up assessments at 1, 6, 12, 24, 36, 48, and 60 months. Up to 25 patients in each cohort will undergo routine repeat angiography at either 24 or 48 months. The present report describes the principal clinical and angiographic outcomes of the Cohort A group (n = 117). Follow-up of Cohort B (n = 123) is ongoing.

TREATMENT PROCEDURE. Lesions were pre-dilated with noncompliant or semicompliant balloons that were not <0.25 mm smaller than the RVD. Scoring and cutting balloons were allowed for lesion preparation, but rotational atherectomy was not. The Fantom scaffold was deployed at the lesion site in a standard single-step inflation procedure directly to its intended diameter. Only 1 Fantom was used to cover each target lesion. If the device was shorter than required, or an edge dissection occurred requiring treatment, an overlapping metallic DES was used for complete lesion coverage. Dual antiplatelet therapy with aspirin plus clopidogrel, ticagrelor, or prasugrel was prescribed to all patients for 12 months.

ENDPOINTS AND DEFINITIONS. The modified intention-to-treat (ITT) population was defined as all patients who had an attempt was made to implant a Fantom scaffold. The as-treated population included all patients who received a Fantom scaffold and remained in the study through 6 months. The analysis population flowchart is provided in Table 1. The primary angiographic measure was in-stent late lumen loss (LLL) at 6 months, as assessed by quantitative coronary angiography (QCA), defined as the difference between the post-procedure minimal lumen diameter (MLD) and the MLD at 6-month follow-up (3). The primary clinical endpoint was major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction (MI) (defined as CK-MB >5× upper limit of normal within 48 h of procedure, or any cardiac biomarker elevation with clinical or electrocardiographic evidence of ischemia beyond 48 h) or clinically driven target lesion revascularization (TLR).

Short-term performance was also evaluated in 3 separate categories. Short-term technical success was defined as successful delivery and deployment of the scaffold in the intended location without device-related complications. Short-term procedural

FIGURE 3 Cohort A Patient Flow Chart



success was defined as short-term technical success with a residual stenosis of ≤50% with no in-hospital MACE. Clinical procedural success was defined as short-term procedural success with no MACE through 30 days post-intervention.

DATA COLLECTIONS AND ANALYSIS. The investigators or research coordinators at each clinical center entered all study data into a web-based electronic data capture system. Data accuracy was source document verified by independent site monitors. All MACE were adjudicated by an independent clinical events committee (Yale Cardiovascular Research Group, New Haven, Connecticut). Procedural and follow-up angiograms were assessed at an independent angiographic core laboratory (Yale Cardiovascular Research Group).

STATISTICAL METHODS. The present single-arm study was designed to establish preliminary results in terms of safety and efficacy of the Fantom scaffold, and to provide guidance for a largescale, pivotal randomized trial. A total of 240 patients were enrolled to provide an acceptable SD for the late loss primary angiographic endpoint and to exclude major safety issues. Formal power analysis was not performed. The primary outcomes were assessed in both the modified ITT population and the as-treated population. Categorical variables are presented as counts and percentages, and continuous variables are presented as mean ± SD.

RESULTS

PATIENT CHARACTERISTICS. Between March 2015 and March 2016, 240 patients were enrolled at 28 clinical centers in 8 countries in the FANTOM II study. The Cohort A study group included 117 patients, whereas the Cohort B study group included 123 patients. The results from Cohort A are provided herein (Figure 3). All 117 Cohort A patients were included in the modified ITT analysis population. Outcomes were also analyzed in 108 patients who comprised the as-treated population. The reasons for excluding 9 ITT patients from the as-treated cohort were as follows: study device not implanted (patient followed for only 30 days per protocol, n = 4); withdrawal of consent at 1 month (n = 1); study device overlapped with a metallic DES to cover an edge dissection after post-dilatation (patient followed for only 30 days per protocol, n = 4).

TABLE 2 Baseline QCA (n = 115 Patients and Lesions*)

Target coronary artery	
Left anterior descending	57 (49.6)
Left circumflex	36 (31.3)
Right	22 (19.1)
Lesion location within vessel	
Proximal	45 (39.1)
Mid	60 (52.2)
Distal	10 (8.7)
Baseline morphology	
Eccentric	26 (22.6)
Angulation >45°	15 (13.0)
Thrombus	1 (0.9)
Moderate or severe tortuosity	13 (11.3)
Moderate or severe calcification	7 (6.1)
Ulceration	2 (1.7)
Aneurysm	1 (0.9)
ACC/AHA lesion class	
Type A	28 (24.3)
Type B1	49 (42.6)
Type B2	38 (33.0)
Type C	0 (0.0)
Quantitative measures	
RVD, mm	2.68 ± 0.37
MLD, mm	0.79 ± 0.29
Diameter stenosis, %	70.3 ± 10.4
Lesion length, mm	11.08 ± 3.41

Values are n (%) or mean ± SD. *Two baseline angiographic images were not analyzable.

ACC/AHA = American College of Cardiology/American Heart Association; MLD = minimum lumen diameter; QCA = quantitative coronary angiography; RVD = reference vessel diameter.

As shown in Table 1, the mean age was 62.7 years; 70.1% were male and 21.4% had diabetes. All 117 patients were in the modified ITT population; each patient had 1 lesion treated. Baseline QCA is shown in Table 2. Mean RVD was 2.68 mm, and mean lesion length was 11.08 mm. Procedural data are shown in Table 3. Pre-dilatation was performed in all cases, and post-dilatation was performed in 76.1% at a mean pressure of 16.6 atm.

SHORT-TERM PERFORMANCE. Short-term technical success, short-term procedural success, and clinical procedural success were achieved in 96.6% (113 of 117), 99.1% (112 of 113), and 99.1% (111 of 112),

TABLE 3 Procedural Data (n = 117 Patients and Lesions)

Pre-dilatation performed	117 (100.0)
Cutting/scoring balloons	6 (5.1)
Scaffold/stent implantation, any, per patient	117 (100.0)
Fantom scaffolds	113 (96.6)
Metallic DES	4 (3.4)
Bare-metal stents	0 (0.0)
Fantom implantation (n = 113)	
Mean diameter, mm	2.89 ± 0.21
Mean length, mm	18.05 ± 0.56
Mean pressure, atm	13.1 ± 3.0
Post-dilatation performed (all lesions)	89 (76.1)
Mean largest balloon diameter, mm	3.17 ± 0.37
Mean pressure of largest balloon, atm	16.6 ± 4.1
Intravascular imaging used*	108 (92.3)

Values are n (%) or mean ± SD. *Optical coherence tomography or intravascular ultrasound was used.

respectively. There were 4 cases of scaffold delivery failure in patients who had the target vessels or lesions were heavily calcified, or diffusely diseased and located distally in vessels with RVD smaller than indicated for the device. These cases were excluded by protocol definitions from the short-term procedural and clinical procedure success analysis. In addition, there was 1 case of a periprocedural MI that was excluded from the clinical procedural success analysis because it was accounted for in the short-term procedure success results.

ANGIOGRAPHIC RESULTS. Post-procedural and 6-month QCA results are shown in Table 4. Angiographic follow-up was completed in 101 patients (86.3%), and paired angiograms for LLL analysis were available in 100 patients (a baseline image was not available in 1 case). The primary angiographic endpoint of mean in-stent LLL at 6 months was 0.25 ± 0.40 mm. The mean in-segment LLL in was 0.17 ± 0.34 mm. The cumulative frequency distribution curve is presented in Figure 4. Only 2 patients (2.0%) had in-stent or in-segment binary restenosis.

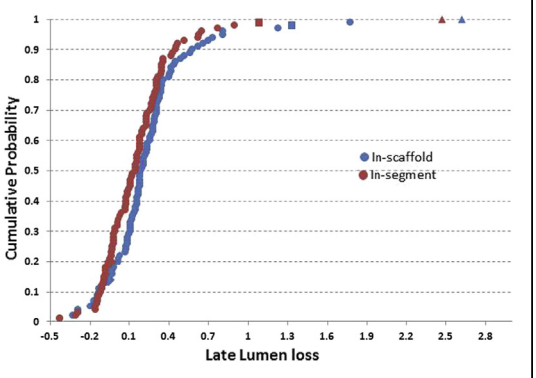
CLINICAL OUTCOMES. There were 108 patients remained in the study through 6 months. The primary clinical endpoint of 6-month MACE occurred in 2.6% and 2.8% of patients in the modified ITT and as-treated populations, respectively (Table 5). A total of 2 MIs and 2 clinically driven TLRs occurred in 3 patients (1 patient had both an MI and TLR). One patient was enrolled with 2 lesions in the target vessel (a protocol violation); 1 lesion was treated with Fantom, and 1 with a metallic DES. After Fantom scaffold deployment, 2 more DES were deployed to cover a proximal dissection and an intramural hematoma distal to the target lesion. A periprocedural MI developed. The second MI was due to a Fantom scaffold thrombosis on day 5, likely related to an untreated significant residual edge stenosis, successfully treated with PCI. This was the only definite or probable scaffold thrombosis that occurred (rate 0.9%). The second TLR occurred in a patient with

TABLE 4 Post-Intervention and 6-Month Follow-Up QCA

	Post-Procedure (n = 112 Patients and Lesions)	6-Month Follow-Up (n = 100 Patients and Lesions)
RVD, mm	2.75 ± 0.40	2.70 ± 0.36
In-stent/scaffold		
MLD, mm	2.47 ± 0.37	2.23 ± 0.41
Diameter stenosis, %	7.6 ± 9.7	15.3 ± 15.2
Short-term gain, mm	1.67 ± 0.41	–
Late loss, mm	–	0.25 ± 0.40
Binary restenosis, %	–	2 (2.0)
In-segment (device + 5-mm margins)		
MLD, mm	2.27 ± 0.39	2.11 ± 0.42
Diameter stenosis, %	17.1 ± 8.4	21.7 ± 13.2
Short-term gain, mm	1.47 ± 0.43	–
Late loss, mm	–	0.17 ± 0.34
Binary restenosis, %	–	2 (2.0)
Acute recoil, %	2.9 ± 8.8	–

Values are mean ± SD or n (%).
Abbreviations as in Table 2.

FIGURE 4 Cumulative Frequency Distribution Curves for In-Scaffold and In-Segment Late Lumen Loss



The in-stent and in-segment LLL numbers of three MACE are indicated by three symbols. The **triangle symbols** represent the LLL values (2.62 mm in-stent and 2.47 mm in-segment) for the patient who had a subacute thrombosis with MI and TLR on day 5. The **square symbols** represent the LLL values (1.33 mm in-stent and 1.08 mm in-segment) for the patient who underwent a TLR at 6 months. The **diamond symbols** represent the LLL values (-0.06 mm in-stent and -0.06 mm in-segment) for the patient who had a post-procedure MI. LLL = late lumen loss; MACE = major adverse cardiac events(s); MI = myocardial infarction; TLR = target lesion revascularization.

recurrent angina at 6 months. Angiography demonstrated a diffuse in-stent restenosis (68.8% diameter stenosis), and repeat PCI was successfully performed.

DISCUSSION

The sirolimus-eluting Fantom BRS is a novel technology that is characterized by its thin struts, rapid and broad expansion capability, and most uniquely, its radiopacity. The Cohort A results from the FANTOM II study have demonstrated that the Fantom scaffold is capable of treating noncomplex de novo native coronary artery lesions with low LLL and MACE at 6 months.

The angiographic performance of the Fantom was similar to that achieved with contemporary metallic DES and other BRS. The mean in-stent late lumen loss at 6 months was 0.25 ± 0.40 mm. In the types of lesions enrolled in the present study, 6-month in-stent LLL values with metallic DES have ranged from approximately 0.11 mm with everolimus-eluting stents to 0.36 mm with paclitaxel-eluting stents and to 0.61 mm with fast-release zotarolimus-eluting metal stents at 6 to 8 months (11-13). Similarly, 6-month in-scaffold LLL have been reported to be 0.44 mm, 0.19 mm, 0.20 mm, and 0.44 mm with the Absorb BVS 1.0 (Abbott Vascular, Santa Clara, California), Absorb BVS 1.1 (Abbott Vascular), DESolve (Elixir Medical, Sunnyvale, California), and DREAMS-2 (Biotronik, Bülach, Switzerland) BRS, respectively (3,14-16). Only 2 cases (2.0%) of binary angiographic restenosis occurred with Fantom in this study. The Fantom BRS would thus appear to be an effective antirestenotic device.

The Fantom scaffold demonstrated promising outcomes at 6 months, with a low rate of MACE (2.6% in the ITT population and 2.8% in the as-treated population), and only 1 scaffold thrombosis occurred, which was likely technique-related. In comparison, CE Marked commercially available BRS have demonstrated a 6-month MACE rate ranging from 3.0% to 5.0% (3,15,17,18). The short-term technical success and short-term procedural success rates were also high at 96.6% and 99.1%, at least as good as with the other BRS, which ranged from 93% to 94% (19). Mean measured recoil was low at 2.9%, comparable within the range encountered with BVS 1.0 (6.9%), BVS 1.1 (6.7%), and current metallic DES (4.3%) (20).

STUDY LIMITATIONS. The sample size was modest, but adequate to assess the 6-month angiographic performance of the device. Cohort B will indirectly assess whether the favorable angiographic results from the present study are maintained at 9 months. Although the 6-month event rates were favorable, larger studies are required to more precisely determine clinical outcomes.

TABLE 5 MACE Within 6 Months

Outcome	Modified ITT (n = 117)	As-Treated (n = 108)
MACE	3 (2.6)	3 (2.8)
Death	0 (0.0)	0 (0.0)
MI	2 (1.7)	2 (1.9)
Clinically driven TLR	2 (1.7)	2 (1.9)
Stent thrombosis (ARC definite or probable)	1 (0.9)	1 (0.9)
Definite	1 (0.9)	1 (0.9)
Probable	0 (0.0)	0 (0.0)
Acute (<24 h)	0 (0.0)	0 (0.0)
Subacute (24 h to 30 days)	1 (0.9)	1 (0.9)
Late (30 days to 6 months)	0 (0.0)	0 (0.0)

Values are n (%). Data are nonhierarchical. The modified intention-to-treat (ITT) population includes all patients who had an attempt was made to implant a Fantom scaffold. The as-treated population includes all patients who received a Fantom scaffold and remained in the study at 6 months. Nine subjects were excluded from the as-treated population: 4 were delivery failures, 1 was an early withdrawal of consent, and 4 were protocol-required study exits due to procedural-related dissections that were treated with metallic drug-eluting stents.

ARC = Academic Research Consortium; MACE = major adverse cardiovascular event(s); MI = myocardial infarction; TLR = target lesion revascularization.

Studies with intravascular imaging (ultrasound and optical coherence tomography) are planned to characterize vascular responses to the device. Ongoing long-term follow-up is also required to assess whether late events accrue as bioresorption takes place, as has been observed with other BRS (18). Neither high-risk patients (e.g., ST-segment elevation MI) nor complex lesions were treated in this study; additional investigation is required to assess the outcomes of the Fantom BRS in such patients. A limited matrix of Fantom diameters and lengths were available for this early study, precluding examining the results of overlapping scaffolds. Intravascular imaging was not required in this study but was performed in a substantial proportion of patients and will be reported in the future. Ultimately, comparative randomized trials of Fantom versus other metallic DES and BRS must be performed to examine whether the novel properties of this scaffold translate to improved clinical outcomes.

CONCLUSIONS

The clinical results from 117 patients enrolled in Cohort A of the multicenter FANTOM II study demonstrate favorable 6-month outcomes of this novel device in the treatment of noncomplex coronary artery disease.

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PERSPECTIVES

WHAT IS KNOWN? Currently, commercially available drug-eluting coronary bioresorbable scaffolds have demonstrated safety and effectiveness in treating coronary artery disease without the need of a permanent metal implant. However, these first-generation BRS have limitations including lack of radiopacity, thick struts, requirement for incremental inflation steps, and other disadvantages that have restricted their use for coronary artery intervention.

WHAT IS NEW? The Fantom sirolimus-eluting coronary BRS was designed to overcome many of the limitations of first generation BRS. The Fantom scaffold is radiopaque, is implanted using standard stent-like techniques, and has thinner struts which may further enhance deliverability, accelerate endothelialization and reduce long-term adverse events. The FANTOM II study has demonstrated favorable 6-month outcomes of this novel device in the treatment of noncomplex coronary artery disease.

WHAT IS NEXT? Nine-month clinical and angiographic data from Cohort B of the FANTOM II study is forthcoming, and all 240 patients enrolled in the FANTOM II study will be followed through 5 years. Studies involving intravascular imaging follow-up will be performed to assess vascular responses of the Fantom BRS, and larger clinical studies are planned to examine the comparative outcomes of this device versus other BRS and metallic DES.

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