Absorb Bioresorbable Vascular Scaffold in Complex Coronary Bifurcation Interventions
Insights From an In Vivo Multimodality Imaging Study

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Background—Although bioresorbable scaffolds offer potential advantages compared with metallic drug-eluting stents in the treatment of complex coronary bifurcation lesions, there are concerns that the polymeric scaffold integrity may be compromised. This in vivo study sought to provide insights about the feasibility of performing complex bifurcation stenting with Absorb bioresorbable vascular scaffolds (Abbott Vascular, Santa Clara, CA).

Methods and Results—Twenty New Zealand white rabbits underwent stenting of the nondiseased aortoiliac bifurcation with bioresorbable vascular scaffolds using provisional (PS, n=5), culotte (n=5), modified-T (n=5), or T-and protrusion (n=5) stenting techniques. Angiography, optical coherence tomography, and microcomputed tomography were performed. Angiographic results were excellent without evidence of dissection or side branch (SB) compromise. PS optimally opened the SB ostium without deforming the main vessel (MV) bioresorbable vascular scaffolds, avoiding malapposition, and revealing a single connector fracture in 1 of 5 cases on microcomputed tomography. Culotte stenting resulted in complete bifurcation coverage with extensive segments of double-layered struts and inappropriately apposed struts at the bifurcation level in 3 of 5 cases. On microcomputed tomography, there was MV and SB scaffold distortion at the bifurcation with single strut fractures in 4 of 5 and double fractures in 1 of 5. Modified-T and T-and protrusion resulted in complete bifurcation coverage and in minimal double-strut layers at the neocarina. On microcomputed tomography, no strut fractures were present after modified-T, whereas in 3 of 5 T-and protrusion procedures single strut fractures were noted.

Conclusions—Bifurcation stenting using bioresorbable vascular scaffolds is feasible with excellent angiographic results. PS with additional T-and protrusion whenever needed seems a reasonable approach. Whenever a 2-stent technique is planned, modified T-stenting appears the most promising. (Circ Cardiovasc Interv. 2016;9:e003849. DOI: 10.1161/CIRCINTERVENTIONS.116.003849.)

Key Words: angiography ■ drug-eluting stents ■ optical coherence tomography ■ rabbits ■ stent

Treatment of coronary bifurcation lesions is common in everyday practice and accounts for ≤20% of all percutaneous coronary interventions. The treatment of these lesions with drug-eluting stents, especially when a double-stent technique is used, remains challenging and is associated with a lower procedural success and a higher rate of long-term adverse cardiac events such as stent restenosis and thrombosis. Bioresorbable vascular scaffolds may offer potential advantages compared with metallic drug-eluting stents, aiming at restoring vessel patency without implanting a permanent prosthesis, which may be especially beneficial in bifurcation treatment. This new technology could theoretically eliminate the late and very late stent thrombosis observed after deployment of metal drug-eluting stents because, at some point, the physical material that could potentially provide a nidus for a stent-related thrombotic event completely disappears. The most widely studied bioresorbable stent, the Absorb Bioresorbable Vascular Scaffold (BVS; Abbott Vascular, Santa Clara, CA), has recently been introduced for the treatment of coronary artery disease, and data are now available supporting the use of this scaffold in type A stable coronary artery lesions and more recently also in calcified coronary lesions, acute coronary syndromes, and acute ST-segment–elevation myocardial infarctions. However, the Absorb BVS has yet to be evaluated in patients with true bifurcation lesions because of inherent limitations, such as bulky profile, limited expansion capacity, and length of time for complete reabsorption. More specifically, there are concerns that the integrity of the polymeric scaffold may be compromised, resulting in strut fractures and the BVS unraveling, by common techniques...
WHAT IS KNOWN

- There are data supporting the use of the Absorb everolimus-eluting bioresorbable vascular scaffold, the most widely studied bioresorbable scaffold, in the treatment of noncomplex coronary lesions.
- The use of the Absorb bioresorbable vascular scaffold has yet to be evaluated in more complex coronary lesions and more specifically, in complex bifurcation lesions.

WHAT THE STUDY ADDS

- In a nondiseased in vivo bifurcation model, commonly used complex bifurcation techniques can be performed using the Absorb bioresorbable vascular scaffold with excellent angiographic results.
- Angiography and optical coherence tomography are not reliable in detecting the presence of scaffold distortion in the form of strut fracture(s), as determined by microcomputed tomography, after complex bifurcation stenting.
- The modified-T technique, where the side branch is stented first, seemed to be the most promising and safest option in the treatment of complex bifurcation lesions with 2 bioresorbable vascular scaffolds.

required during 2 stent bifurcation techniques, such as recrossing, proximal optimization, and kissing balloon dilations. Limited but important data are available from bench testing providing vital insights into deployment, side branch dilatation, and postdilatation strategies. Ex vivo bench testing evaluating the performance of BVS in complex bifurcation techniques is limited to a small study using a synthetic arterial model where microcomputed tomography (micro-CT) was performed, though without correlation with angiography and optical coherence tomography (OCT).

We wished to investigate the feasibility of using Absorb BVS in commonly used simple (provisional) and complex (T-and protrusion [TAP], modified-T, and culotte) bifurcation techniques.

The results of this in vivo study, using multimodality imaging including OCT and micro-CT, will provide insights that will aid the application of these absorbable scaffolds in diseased human coronary bifurcations.

Methods

The study was approved by the Ethics Committee for Animal Experimentation (KU Leuven, Belgium), and carried out in accordance with the Guide for Care and Use of Laboratory Animals (National Institutes of Health). The experiments were performed in an in vivo rabbit nondiseased aortoiliac bifurcation model. Under general anesthesia (Xylazine and Ketamine), 20 New Zealand adult white rabbits (weight 3.5–4.4 kg) underwent bifurcation interventions of the aortoiliac bifurcation. The vessel diameter of the distal aorta and iliac arteries in the New Zealand White rabbit are suitable for the implantation of 3.0-mm Absorb BVS, allowing proximal optimization in the distal aorta ≥3.4 to 3.5 mm. The aortoiliac bifurcation has an angle of ≤70°, as measured from the axis of the main vessel (determined in all experiments as aorta to right iliac artery) to the axis of the origin of the side branch (determined as the left iliac artery). Arterial access was achieved by denuding the left or right carotid artery and introducing a 45-cm 6Fr Check-flo Introducer (Cook Medical, Bloomington, Indiana) to the distal descending aorta. Heparin (Leo, 5000 IU) was administered intra-arterially.

The Absorb BVS is laser cut from a tube of the poly (l-lactic) acid polymer and is coated with a thin layer of drug/polymer matrix composed of everolimus and poly (l-(d,l)-lactic) acid polymer mixture. There are 2 radio-opaque platinum markers to facilitate positioning and postdilatation strategies. In this study, the second-generation BVS (Revision 1.1), with 3.0x28 mm dimensions, were implanted in single- or 2-stent strategies. This BVS consists of 157-μm struts. Balanced middle-weight guidewires and choice floppy extrasupport guidewires (Abbott Vascular) were used for all procedures. Mini Trek and noncompliant Trek balloon catheters (Abbott Vascular) were used for recrossing and postdilatation, respectively. After set up angiography, the bifurcation procedure commenced. After completion of the experiment, the animal was euthanized.

Bifurcation Techniques

We performed provisional stenting (n=5), modified T-stenting (n=5), TAP stenting (n=5), and culotte stenting (n=5). Proximal optimization technique (POT) with 3.5-mm noncompliant balloons and final mini-kissing balloon postdilatation (mini-KBPD) with 3.0-noncompliant balloons was performed in all procedures at appropriate low pressures with techniques that have been evaluated by ex vivo bench testing and that best respect the characteristics of this poly (l-lactic) acid–based BVS scaffold and avoid significant distortion or disruption of the scaffold rings and hoops. In the mini-KBPD, the proximal marker of the SB 3.0 noncompliant balloon was positioned in the MV immediately proximal to the SB ostium, therefore protruding only a short segment into the MV, with the MV 3.0 noncompliant balloon positioned conventionally from proximal MV to distal MV across the bifurcation (Movie I in the Data Supplement).

1. Provisional stenting with mini-KBPD (Figure 1A). The main vessel (distal aorta to right iliac artery) was wired and a 3.0x28 mm BVS (the stent diameter was chosen for the diameter of the distal segment of the main vessel) was deployed in the main vessel (MV) at 10 atmospheres, covering the side branch (SB, left iliac artery). A second guidewire was used to recross through the struts covering the side branch, aiming to enter the side branch through the most distal cell possible. After POT with a 3.5-mm noncompliant balloon to 16 atmospheres, a mini-KBPD was then performed with a noncompliant 3.0–12 mm balloon in the side branch and a noncompliant 3.0x12 mm balloon in the MV, both inflated to 5 atmospheres.

2. Culotte stenting with mini-KBPD (Figure 1B). After wiring the SB, a 3.0x28 mm BVS was deployed at 10 atmospheres, mostly in the side branch and 8 to 10 mm in the proximal MV. POT was performed with a 3.5 noncompliant balloon (at 16 atmospheres), followed by recrossing into the distal MV with a second guidewire (most distal cell possible) and opening the struts with a 2.0-mm balloon at 10 atmospheres. A 3.0x28 mm BVS was then placed across the dilated cell into the distal MV, with the proximal portion completely covering the proximal main vessel segment of the SB scaffold, and after removal of the SB wire, was deployed at 10 atmospheres. POT with a 3.5 noncompliant balloon at 16 atmospheres was repeated paying attention not to place the balloon past the proximal shoulder of the carina. The SB was then rewired, struts opened with a 1.5 to 2.0-mm balloon, sequential postdilatation performed with 3.0x12 noncompliant balloons in both MV and SB to 10 atmospheres and to complete the procedure, a mini-KBPD was performed to 5 atmospheres.

3. Modified-T stenting with mini-KBPD (Figure 1C). This is a slight adaptation of the technique recently described by van Mieghem et al. After wiring both vessels, a 3.0x28 mm BVS...
is positioned in the SB with a 3.0×12 noncompliant balloon parked in the MV as a bumper to help mark the carina of the bifurcation. The proximal marker of the BVS in the SB is set at the lower shoulder of the carina (Figure 1C, red arrow), after which the BVS is deployed at 10 atmospheres. The SB delivery system and wire are removed and the 3.0 noncompliant balloon in the MV is inflated to 12 atmospheres causing a mini-crush of the slightly protruding SB BVS. Subsequently, a 3.0×28 mm BVS is placed in the MV (at 10 atmospheres) followed by POT with a 3.5 noncompliant balloon (at 16 atmospheres). The SB is rewired aiming to cross through the most distal cell and dilated with a 1.5 or 2.0 mm balloon at 10 atmospheres. A 3.0×28 mm BVS was then advanced into the SB. A 3.0×12 mm balloon was positioned in the MV covering the side branch. The proximal BVS balloon marker was then lined up with the carina (the scaffold would, therefore, protrude ≈ 1 mm into the MV), and the BVS was deployed at 10 atmospheres. The delivery balloon was then withdrawn 2 to 3 mm, the 3.0×12 noncompliant balloon in the MV was inflated to 12 atmospheres balloon followed by a mini-KBPD at 5 atmospheres.

Assessment of the Bifurcation Techniques
All procedures were assessed by angiography, OCT, and micro-CT

Angiography
The different deployment and postdilatation sequences tested were observed and recorded fluoroscopically. At the completion of the bifurcation procedure, and before OCT, a final cine angiogram was taken after intravenous nitroglycerin.

Optical Coherence Tomography
OCT pullbacks were recorded in vivo using the Ilumien IV OCT system and Dragonfly™ catheters or the Optis system with DragonFly Duo catheters (St. Jude Medical, St. Paul, MN). The Ilumien system acquires images at a frame rate of 100 images per second of a segment of 54 mm long. The Optis system is able to acquire images at a frame rate of 180 frames/s, with pullbacks of 75 mm long. Imaging specifications, according to the manufacturer, are an axial resolution of 20 μm and a lateral resolution of 25 to 60 μm. All pullbacks were acquired at the default speed of 20 mm/s. Intravascular optical coherence tomography imaging was

Figure 1. Overview of the main steps in the 4 bifurcation techniques assessed. mini-KBPD indicates mini-kissing balloon postdilatation; MV, main vessel; NC, noncompliant; POT, proximal optimization technique; SB, side branch; atm, atmospheres; SDB, stent delivery balloon; and TAP, T-and protrusion.
performed during manual flush with a diluted contrast medium (Iomeron, Bracco SPA, Milan, Italy) for blood clearance. All images were stored for off-line analysis.

The OCT analyses were assessed for the proximal MV, ostial distal MV (first 5 mm from carina toward distal MV), and ostial SB (first 5 mm from carina toward SB) region separately. The luminal and abluminal scaffold areas were drawn after the endoluminal and abluminal surface of the polymeric struts, respectively. The luminal and abluminal mean scaffold diameters were subsequently measured.

In each of the specified segments, the smallest scaffold area (the minimal scaffold area) and the shortest mean scaffold diameter (the minimal scaffold diameter) were reported, for both the luminal and abluminal surfaces. Stent fracture was suspected in the presence of isolated struts lying unopposed in the lumen with no connection to expected/adjacent strut pattern. Struts were classified as well apposed or as incompletely apposed. Because the BVS is transparent to the near-infrared light of the OCT catheter, incomplete strut apposition was defined as the presence of struts separated from the underlying vessel wall.

**Microcomputed Tomography**

After the completion of the bifurcation procedure and OCT examinations, the animal was euthanized and the aortoiliac bifurcation was dissected out and stored in a 4% formaldehyde solution. Thereafter, micro-CT was performed using the SkyScan 1076 in vivo micro-CT (SkyScan Bruker-microCT, Kontich, Belgium). Two-dimensional reconstructions were made with Bruker SkyScan NRecon 1.6.9.8, whereas 3-dimensional (3D) volume rendering was performed with Bruker SkyScan CTvox 3.0.0. The 2D and 3D micro-CT analyses were assessed for the proximal MV, distal MV, SB, and bifurcation segments separately. For each segment, the presence and location of strut fractures (hoop or connector) and possible associated luminal compromise was reported. The presence of a good aperture toward the SB was also evaluated.

**Statistical Analysis**

The data are presented as mean±SD. Differences in scaffold areas and scaffold diameters between the 4 stenting groups were compared with the nonparametric Kruskal–Wallis test (1-way ANOVA on ranks). Pairwise follow-up analysis was performed using Dunn Multiple Comparison test. Given the small sample sizes and exploratory nature of the experiments only overall comparison results between the 4 groups are provided. Statistical analyses were performed using Graphpad PRISM statistical software version 5.01 (Graphpad Software Inc. La Jolla, CA). All results were from 2-sided tests and a P value of <0.05 was considered significant.

**Results**

A total of 35 Absorb BVS 1.1 were successfully delivered and implanted in 20 rabbits without any complication, and with a procedure success of 100%. In all bifurcation procedures (n=20), the angiographic results (Movie I in the Data Supplement; example of step by step angiographic assessment of Modified T stenting) were excellent with no evidence of dissection or SB compromise. Re-crossing through BVS struts with guidewires was always successful and subsequent crossing with balloons, and a second BVS (only in TAP+culotte procedures) was smooth. On mini-KBPDP, the 3.0 noncompliant balloons showed waisting as the scaffold constrained their expansion at low pressure. OCT and micro-CT data are presented in Tables 1 and 2, respectively.

**Optical Coherence Tomography**

There were no significant differences in luminal and abluminal minimal scaffold areas and luminal and abluminal minimal scaffold diameters between the 4 stenting techniques at the level of the proximal MV, and distal ostial MV (Table 1). As a result of a double layer of struts in the proximal MV, the luminal scaffold area in the culotte technique (7.6±0.8 mm²) was smaller than in the provisional (8.3±0.8 mm²), modified T (8.4±1.5 mm²), and TAP technique (8.4±0.2 mm²); however, the difference in this small number of procedures was not significant (P=0.44). Of note, there was a significant difference in luminal minimal scaffold area (6.7±0.9 mm² versus 5.5±0.3 mm², P=0.0167) and luminal minimal scaffold diameter (2.9±0.2 mm versus 2.6±0.1 mm, P=0.0167) at the level of the ostial SB scaffold between the TAP and culotte procedures, respectively, with larger luminal areas and diameters after TAP stenting. Although numerically the luminal scaffold areas and diameters were also larger in the Modified T group compared with the culotte group, this did not reach statistical difference. There was no significant difference in abluminal measurements between the groups at the level of the SB ostium.

**Provisional Stenting With Mini-KBPDP (n=5)**

Single (provisional) stent procedures with mini-KBPDP optimally opened the SB ostium without deforming the MV BVS. As a result of the mini-KBPDP, there was excellent scaffolding at the SB ostium with no detachment of the MV scaffold opposite the SB ostium. In just one case, there were several incompletely apposed struts present in the proximal MV scaffold (Figure 2). A single-strut fracture was clearly identified in 1 case, resulting in an intraluminal strut overhanging and protruding into the SB (Figure 3A).

**Culotte Stenting With Mini-KBPDP (n=5)**

Inherent to the technique, culotte stenting resulted in a double layer of struts in the proximal MV (Figure 4). There were no inappropriately apposed struts in the proximal MV, distal MV, or SB. In 1 of 5 cases of culotte stenting, there was an excellent OCT result at the level of the bifurcation with complete coverage of the SB ostium and carina and no evidence scaffold malapposition. In the other 4 cases, there were circumferentially inappropriately apposed struts affecting MV and SB BVS (n=2), inappropriately apposed struts affecting only the MV opposite the SB (n=1) and inappropriately apposed struts affecting only the SB at the level of the proximal bifurcation (n=1). Only in one case a strut fracture was clearly identifiable, protruding into the lumen at the level of the neocarina (Figure 3B).

**Modified-T Stenting With Mini-KBPDP (n=5)**

In 1 case, there were several inappropriately apposed struts in the proximal MV scaffold. In 4 of 5 cases, there was complete coverage of the SB ostium and carina (Figure 5). In 1 case, there was a short uncovered segment in the SB at the level of the bifurcation, as a result of a slightly too distal deployment of the SB BVS. Modified T stenting resulted in a layer of single struts at the carina and a short segment of double-layered struts at the proximal SB ostium. In 3 of the 5 procedures, there was a short segment of inappropriately apposed struts in the SB BVS at the level of the bifurcation. All MV scaffold struts were well apposed at the level of the bifurcation.

**TAP Stenting With Mini-KBPDP (n=5)**

In 1 case, there were several inappropriately apposed struts in the proximal MV scaffold (Figure 6). In all 5 cases, there...
was an excellent OCT result with complete coverage of the SB ostium and carina and no evidence of malapposition. TAP stenting resulted in a layer of double struts at the neocarina and a short segment of double-layered struts at the proximal SB ostium. In 1 of the 5 procedures, there was a short segment of inappropriately apposed struts in the SB BVS at the level of the bifurcation. All MV scaffold struts were well apposed at the level of the bifurcation.

### Three-Dimensional Microcomputed Tomography

In all 20 stenting procedures, POT was performed with a 3.5-mm noncompliant balloon to 16 atmospheres and, in keeping with previous bench testing studies, this did not result in any strut fractures affecting the proximal MV scaffolds on micro-CT. Furthermore, there were no strut fractures identified in the distal MV or SB (Table 2). In 8 of the 20 stenting procedures, single-strut fractures were identified, whereas after only 1 procedure (culotte stenting) multiple (n=2), strut fractures were identified. All strut fractures occurred at the level of the bifurcation affecting the MV scaffold (n=5), SB scaffold (n=3), or both (n=1). There was no evidence of significant compromise to the integrity (unraveling) of the scaffolds following any of the 20 procedures.

#### Provisional Stenting With Mini-KBPD (n=5)

All provisional procedures produced excellent results on 3D micro-CT assessment with excellent scaffolding of the proximal MV, the bifurcation segment, the distal MV, and good SB aperture. In 1 of the 5 procedures, a connector fracture was identified, in the segment overlying the SB, with protrusion of the strut into the SB lumen (Figure 3A; Movie II in the Data Supplement).

#### Culotte Stenting With Mini-KBPD (n=5)

On 3D micro-CT, all culotte procedures produced excellent scaffolding of the proximal MV, distal MV, SB, bifurcation segment, carina and maintained good SB aperture. Strut fractures were identified following all 5 culotte procedures affecting the bifurcation segment; in 4 cases, there were single-strut fractures, whereas in 1 case, there was a double-strut fracture. The single-strut fractures affected the MV scaffold in 2

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### Table 1. Optical Coherence Tomographic Findings

<table>
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<th>Provisional (n=5)</th>
<th>Culotte (n=5)</th>
<th>Modified-T (n=5)</th>
<th>TAP (n=5)</th>
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<td>Luminal scaffold area, mm²</td>
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<td>5.5±0.3</td>
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<td>1/5 (1/5)</td>
<td>1/5 (0/5)</td>
<td>0/5 (0/5)</td>
<td>0/5 (3/5)</td>
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2D indicates 2-dimensional; micro-CT, microcomputed tomography; MV, main vessel; OCT, optical coherence tomography; SB, side branch; and TAP, T-and protrusion.

*The comparison of side branch luminal scaffold area between the culotte group and the TAP group carried the P value.
†The comparison of side branch luminal mean scaffold diameter between the culotte group and the TAP group carried the P value.
cases and the SB scaffold in 2 cases. The double-strut fracture affected both an MV scaffold strut and an SB scaffold strut. Overall, the hoops (n=4) were more frequently affected than the connectors (n=2). In 1 case, a hoop fracture affecting the MV scaffold caused luminal compromise of the SB at the level of the carina (Figure 7A and 7B). The other 5 fractures did not cause significant luminal compromise (Figure 7C and 7D) as they fell outward, away from the lumen (Movie III in the Data Supplement).

**Modified-T Stenting With Mini-KBPD (n=5)**
All modified T procedures produced excellent scaffolding of the proximal MV, distal MV, SB, bifurcation segment, carina and maintained good SB aperture. No overt strut fractures were identified (Movie IV in the Data Supplement).

**TAP Stenting With Mini-KBPD (n=5)**
All TAP procedures produced excellent scaffolding of the proximal MV, distal MV, SB, bifurcation segment, carina and...
maintained good SB aperture. On micro-CT, however, there was evidence of scaffold distortion with single-strut fractures being present in 3 of the 5 procedures at the level of the bifurcation. The strut fractures affected the MV scaffold in 2 cases and the SB scaffold in 1 case. These single fractures affected only the hoops and did not give rise to luminal compromise (Movie V in the Data Supplement).

**Discussion**

This is the first in vivo study to investigate the feasibility of performing complex bifurcation stenting with the Absorb BVS by correlating findings on angiography, OCT and micro-CT.

The main findings of this study are (1) in this nondiseased in vivo aortoiliac bifurcation model, commonly used complex bifurcation techniques can be performed using the polymeric Absorb BVS with excellent angiographic results. (2) Side branches can be wired with workhorse wires through single- and double-scaffold strut layers and the SB ostium can be crossed without difficulty with a balloon or second BVS through an opened BVS cell in this in vivo model. (3) Provisional, TAP, and modified-T stenting techniques produced acceptable OCT results with minimal malapposition, whereas the culotte technique more frequently resulted in significant malapposition at the level of the bifurcation; (4) angiography and 2-dimensional OCT are infrequently (only 2 out of 9 cases in this study) able to detect the presence of strut fractures, as determined by micro-CT (the gold standard), as there is significant overlap of scaffold struts in the bifurcation segment and the fractured struts tend not to protrude into the lumen. (5) In all culotte stenting procedures and the majority of TAP stenting procedures, single connector or hoop fractures were present at the level of the bifurcation. In 1 culotte procedure, a double fracture was present. Although these strut

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**Figure 4.** Optical coherence tomography (OCT) assessment after culotte stenting. 
A, 3-Dimensional microcomputed tomography reconstruction identifying the sites of the OCT cross sections. There is good strut apposition in the proximal (I) and distal (V) main vessel (MV). At the level of the proximal bifurcation (II), there is a double layer of malapposed struts (white arrows). The neocarina (white*), composed of a double layer of struts, is present at the MV side (III) and side branch (SB) side (IV), with evidence of incomplete strut apposition affecting the MV struts (III, white arrows).

**Figure 5.** Optical coherence tomography (OCT) assessment after modified-T stenting. 
A, 3-Dimensional microcomputed tomography reconstruction identifying the sites of the OCT cross sections. There is good strut apposition in the proximal (I) and the distal (V) main vessel (MV). Strut apposition is excellent in the proximal bifurcation segment (II) with a short segment of double-strut layer (white arrowheads) on the side branch (SB) side. The neocarina (white*), composed of a single-strut layer, is present at the MV side (III) and SB side (IV), with no evidence of inappropriately apposed struts.
fractures infrequently caused luminal compromise, the long-term effects are unknown.

**Scaffold Integrity Compromise: Strut Fractures**

In 9 of the 20 bifurcation stenting procedures, strut fractures were clearly identified on micro-CT. When correlating micro-CT and OCT findings, only 2 fractures were easily identifiable on OCT as the affected struts lay clearly intraluminal (Figure 3). In 2 other cases, there is merely a suspicion on OCT that there is a fracture, whereas 5 fractures, clearly identifiable on micro-CT, were not apparent on OCT as the affected struts fell outward and did, thus, not protrude into the lumen. As disrupted BVS struts cannot be visualized by angiography, and in the majority of cases also not by intravascular imaging in the form of OCT, it is consequently not possible to be sure of scaffold integrity after completion of a 2-stent bifurcation procedure using BVS. These observations, thus, provide a word of caution that OCT, although an excellent aid in guiding interventions, does not provide a precise and all-encompassing evaluation of the integrity of implanted scaffolds.

### Table 2. Three-Dimensional Micro-Computerized Tomography Findings

<table>
<thead>
<tr>
<th></th>
<th>Provisional (n=5)</th>
<th>Culotte (n=5)</th>
<th>Modified-T (n=5)</th>
<th>TAP (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal main vessel scaffold</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strut fracture present</td>
<td>0/5</td>
<td>0/5</td>
<td>0/5</td>
<td>0/5</td>
</tr>
<tr>
<td>Distal main vessel scaffold</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strut fracture present</td>
<td>0/5</td>
<td>0/5</td>
<td>0/5</td>
<td>0/5</td>
</tr>
<tr>
<td>Side branch scaffold</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strut fracture present</td>
<td>...</td>
<td>0/5</td>
<td>0/5</td>
<td>0/5</td>
</tr>
<tr>
<td>Bifurcation segment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good aperture toward SB</td>
<td>5/5</td>
<td>5/5</td>
<td>5/5</td>
<td>5/5</td>
</tr>
<tr>
<td>Multiple strut fractures present</td>
<td>0/5</td>
<td>1/5</td>
<td>0/5</td>
<td>0/5</td>
</tr>
<tr>
<td>MV+SB scaffold affected</td>
<td>...</td>
<td>1/5</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Single strut fracture present</td>
<td>1/5</td>
<td>4/5</td>
<td>0/5</td>
<td>3/5</td>
</tr>
<tr>
<td>MV scaffold affected</td>
<td>1/5</td>
<td>2/5</td>
<td>0/5</td>
<td>2/5</td>
</tr>
<tr>
<td>Hoop</td>
<td>0/5</td>
<td>2/5</td>
<td>...</td>
<td>2/5</td>
</tr>
<tr>
<td>Connector</td>
<td>1/5</td>
<td>0/5</td>
<td>...</td>
<td>0/5</td>
</tr>
<tr>
<td>SB scaffold affected</td>
<td>...</td>
<td>2/5</td>
<td>0/5</td>
<td>1/5</td>
</tr>
<tr>
<td>Hoop</td>
<td>...</td>
<td>1/5</td>
<td>...</td>
<td>1/5</td>
</tr>
<tr>
<td>Connector</td>
<td>...</td>
<td>1/5</td>
<td>...</td>
<td>0/5</td>
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<tr>
<td>Luminal encroachment</td>
<td>1/1</td>
<td>1/5</td>
<td>0/5</td>
<td>0/3</td>
</tr>
</tbody>
</table>

MV indicates main vessel; SB, side branch; and TAP, T-and protrusion.
Furthermore, although the clinical sequelae of single-strut fractures are unknown, it is somewhat concerning that in this nondoiseased noncalcified model strut fractures were present in >50% (8 of 15) of 2-stent bifurcation procedures, despite rigorous adherence to manufacturer guidelines in terms of scaffold deployment and postdilatation, and also in accordance with important procedural insights gained from in-vitro bench-testing regarding deployment, side branch dilation, and postdilatation strategy. When using metal stents in human diseased fibrotic or calcified bifurcation lesions, adequate stent expansion is frequently only obtained at relatively high postdilatation pressures. If these strategies are transferred to scaffolds, multiple scaffold strut fractures, probably not visible on angiography or OCT, will result with potential unraveling of the scaffold and increased likelihood of adverse clinical events. Aggressive predilatation, aiming at full balloon opening with no indentations, will be extremely important to allow adequate scaffold expansion at the suggested safe postdilatation pressures. If these strategies are transferred to scaffolds, multiple scaffold strut fractures, probably not visible on angiography or OCT, will result with potential unraveling of the scaffold and increased likelihood of adverse clinical events. Aggressive predilatation, aiming at full balloon opening with no indentations, will be extremely important to allow adequate scaffold expansion at the suggested safe postdilatation pressures.

Which Bifurcation Technique Can be Proposed?
Provisional single stenting is the default strategy in coronary bifurcation lesions, and this remains the case when using BVS. Both the TAP and culotte techniques require the crossing and expansion of a second scaffold through a dilated cell of an already deployed scaffold. It is possible that during this maneuver the scaffolds can be damaged, resulting in distortion and fractures. Although bench testing has confirmed the safety of inflating a 3.0 mm noncompliant balloon ≤10 atmospheres through the side hole of a 3.0 mm scaffold, expanding a 3.0 mm BVS (3.0 mm semicompliant balloon+circumferential layer of 157-µm struts) at 10 atmospheres may compromise the integrity of either BVS. Furthermore, it would appear that when deploying one scaffold through another scaffold (TAP and culotte procedures), the hoops undergo the most strain and are most susceptible to fracturing than the connectors. Although culotte stenting resulted in excellent angiographic results, the OCT and micro-CT results in this nondoiseased bifurcation model were unsatisfactory with significant malapposition, scaffold distortion, and single or double-strut fractures at the level of the bifurcation core. Moreover, a culotte strategy with 2 BVS leaves the patient with a significant segment in the proximal MV and bifurcation core with a thick (314 µm) double layer of scaffold struts, seriously affecting on scaffold expansion and residual minimal luminal area. In our opinion, culotte stenting with 2 BVS should, therefore, not be recommended in clinical practice.

Except for the sequence of scaffold positioning, degree of strut overlap, proximal optimization and mini-kissing post-dilatation strategies are similar between the TAP and modified-T stenting. Interestingly, no strut fractures were present after the modified-T stenting yet in 60% of the TAP stenting procedures, single-strut fractures were clearly identified on micro-CT. In the modified T technique, technically a mini-mini crush, there is only a minimal layer of double-scaffold struts. Furthermore, in this technique, the SB will be stented before the MV avoiding the need to pass one Absorb BVS.
through another Absorb BVS, thereby reducing further potential damage to the integrity of the scaffolds. The downside of the modified-T (and also TAP) technique may be the difficulty in optimally positioning the SB scaffold, to minimize neocarina formation while avoiding suboptimal lesion coverage at the ostium of the SB, as occurred in one of our cases. The use of multiple angiographic projections and an optimal interpretation of the interplay of bifurcation angle and radiopaque markers with BVS may improve implantation success. In our analysis, the modified-T technique seemed to be the most promising and safest option in the treatment of complex bifurcation lesions with 2 BVS. These findings will need to be confirmed in clinical studies.

Limitations

Although in vivo preclinical testing provides valuable insights that may aid in improving clinical practice, the nondiseased model used may not accurately predict scaffold behavior in human subjects. The rabbit aortoiliac bifurcation model has a relatively high-angle bifurcation (≈70°) and does, therefore, not allow assessment of the performance of the evaluated stenting techniques at lower or even higher angles, consequently results cannot be translated into all bifurcations. This study included a relatively small number of animals that may not allow us to identify significant differences between the treatment groups.

Conclusions

The introduction of fully bioresorbable vascular scaffolds represents an appealing technology for the management of simple and complex coronary artery disease. This in vivo preclinical study provides valuable insights into the opportunities and limitations of the BVS in coronary bifurcations. In a nondiseased rabbit bifurcation model, it was feasible to perform complex bifurcation stenting using Absorb BVS with excellent angiographic results. Provisional stenting of the main vessel with additional TAP stenting whenever needed seems a reasonable standard approach for most bifurcation lesions. Whenever a 2-stent technique is planned from the outset, modified T-stenting was the most promising. Finally, based on scaffold behavior in our analysis, a culotte strategy with current generation BVS should rather be avoided.

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Disclosures

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References


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