One-Year Results of Bioresorbable Vascular Scaffolds for Coronary Chronic Total Occlusions

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The potential of bioresorbable vascular scaffold (BVS) technology has been demonstrated in first-in-man studies with up to 5-year follow-up. This study sought to investigate the 1-year outcomes of the BVS, for the treatment of chronic total occlusions (CTOs), using various imaging techniques. Thirty-five true CTO lesions treated with BVS were included in this prospective study. Scaffolds were deployed after mandatory predilation and intravascular ultrasound analysis. Optical coherence tomography was performed after BVS implantation and at 10 to 12 months. Multislice computed tomography was performed at baseline and at 6 to 8 months. Mean patient age was 61 ± 10 years. The most frequent vessel treated was the right coronary artery (46%). Lesions were classified as intermediate (49%) or difficult/very difficult (26%) according to the Japanese CTO complexity score. Predilation was performed in 100% of lesions, using cutting balloons in 71% of these. The total scaffold length implanted per lesion was of 52 ± 23 mm. All scaffolds were delivered and deployed successfully. Postdilation was undertaken in 63%. By multislice computed tomography at 6 months, we observed 2 cases of asymptomatic scaffold restenosis, subsequently confirmed by angiography. At 12 months, no scaffold thrombosis or major adverse cardiac events were reported. The optical coherence tomography at follow-up showed that 94% of struts were well apposed and covered (5% of uncovered struts and 1% of nonapposed struts), and only 0.6% of struts were nonapposed and uncovered. In conclusion, 1-year results suggest that BVS for CTO is associated with excellent clinical and imaging outcomes. Accurate percutaneous coronary BVS technique might have enabled these promising results. **(Am J Cardiol 2016;117:906–917)**

Drug-eluting stents (DES) have been demonstrated to cause less restenosis than bare-metal stents in chronic coronary total occlusion (CTO) recanalization. However, issues about the safety of DES use in CTO that might affect long-term outcome remain unanswered.[1] Hong et al[2] identified CTO revascularization as an independent predictor of DES late-acquired incomplete scaffold apposition (LAISA) with an incidence of 27.5%. In addition, the main risk of LAISA was its association with late stent thrombosis. Thus, a potential advantage of bioresorbable vascular scaffolds (BVSs) over DES is the resolution of this process with stent dismantling and subsequent resorption.[3–6] In addition, the idea of a "full polymer jacket" with multiple BVS for long CTOs is an appealing one. However, this technology should be noninferior to best-in-class DES.[7–9] This study was conducted to evaluate the safety and feasibility of using Absorb-BVS for the revascularization of CTOs in a real-world population. Consistent with recent published data, we have reported excellent short-term results using BVS in this setting.[10,11] In the present report, we describe the 1-year response to BVS in CTOs using multiple imaging techniques, including multislice computed tomography (MSCT) and optical coherence tomography (OCT, Figure 1).

Methods

The design of the ABSORB-CTO pilot study has been published previously.[10] In our CTO program, before the procedure MSCT, cardiac magnetic resonance imaging, quality of life, and 6-minute walk test are recommended for all patients. From February 2013 until March 2014, 33 patients with 35 true CTO coronary lesions (EuroCTO definition),[12] with vessel reference diameters between 2.5 and 3.5 mm, were enrolled. Major exclusion criteria were lesions located in the left main, true bifurcation lesions with a side branch ≥2.5 mm in diameter by visual assessment, the presence of any contraindication to implantation of a drug-eluting stent and reference vessel diameters. Angiographic target lesion calcification was not a predefined exclusion criteria but was left to operator's discretion. From 49 clinically eligible patients with CTO, 14 patients (28.5%) were excluded because of the predefined angiographic criteria (n = 11: calcification and tortuosity lesions [5], true

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Clinical Trial Registration Information: This study has not been registered at the Clinical Trial Registry.

See page 916 for disclosure information.

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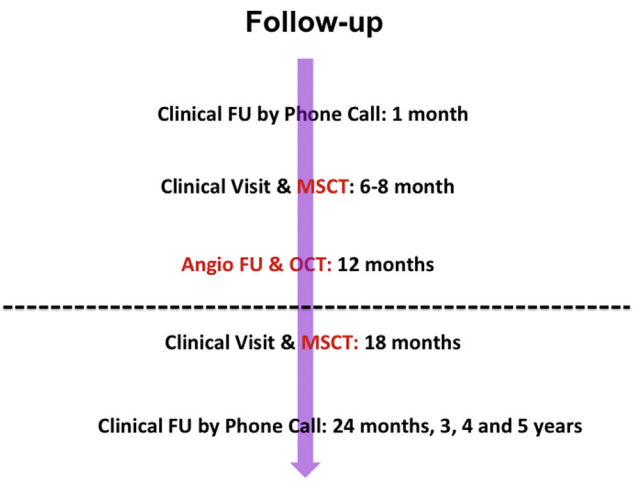

Figure 1. Patient follow-up procedures.

bifurcated lesions with a side branch reference diameter ≥2.5 mm [4], lesions with reference vessel diameter <2.5 mm [n = 1], or ≥4 mm [n = 1]) or because of procedural complications needing bailout stent implantation (n = 3: coronary perforation treated with stent graft, aorto-ostial dissection treated with a 4-mm DES, and distal coronary dissection after BVS implantation treated with 2.25-mm DES).

The second generation of Absorb-BVS comprises a poly-L-lactide backbone coated with a thin layer of a 1:1 mixture of poly-D, L-lactide polymer that contains and controls the release of the antiproliferative drug everolimus. Both poly-L-lactide (backbone) and poly-D, L-lactide (coating) are fully bioresorbable and degrade to lactic acid over 3 years.[13]

Two experienced CTO operators performed all procedures (Figure 1). After crossing the CTO with the guidewire, balloon dilation was performed first with small balloon sizes (1.5 or 2.0 mm). All patients underwent intravascular ultrasound (IVUS) before device implantation with 2 objectives: (a) to analyze the morphologic and anatomical characteristics of the lesion (fibrocalcific or calcified plaques

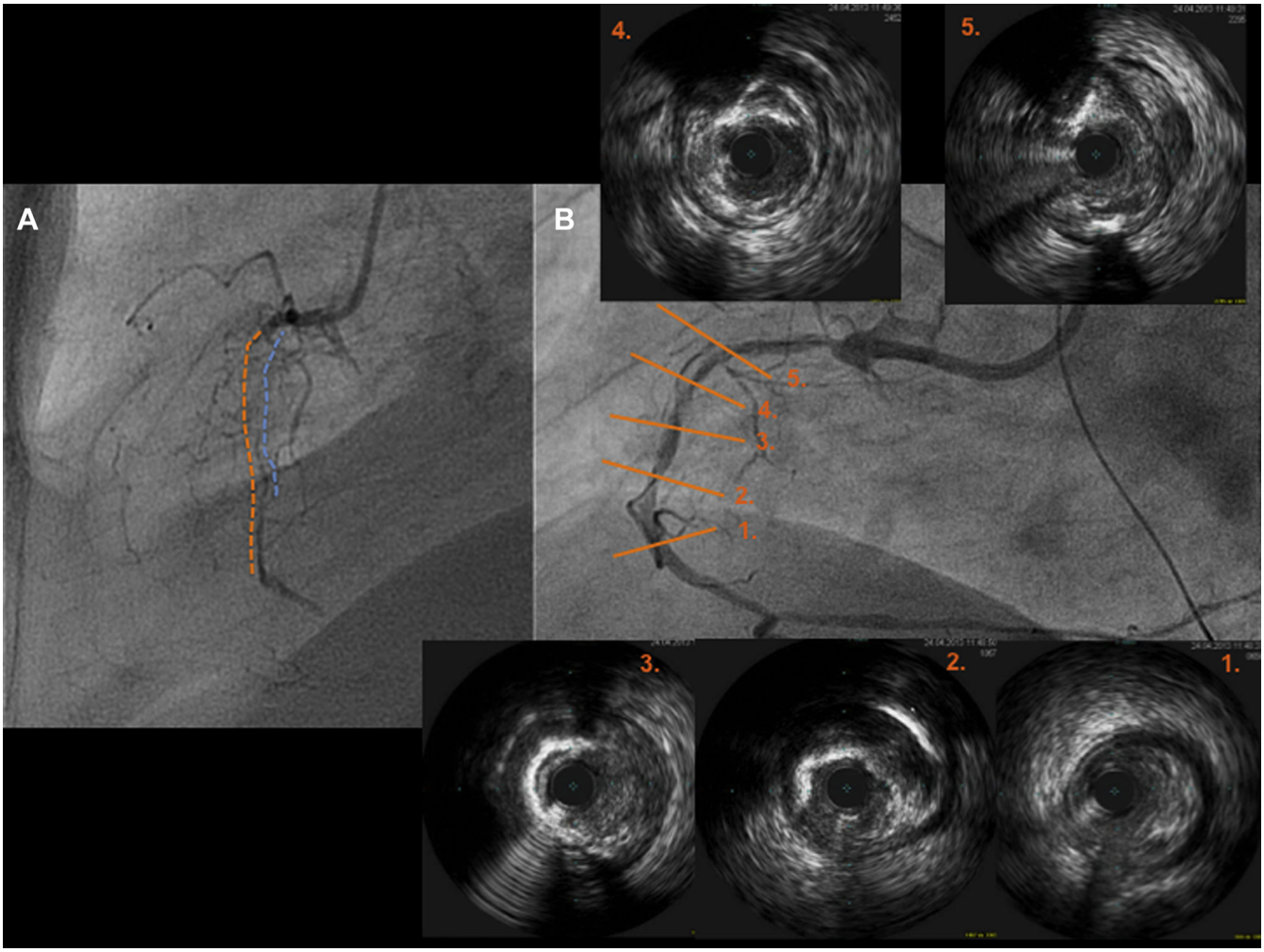

Figure 2. Representative complex CTO case of the mid-right coronary artery treated with 2 overlapped Absorb-BVSs. Preprocedure angiography showed a long, calcified CTO lesion, without a clear stump, grade 3 on the J-CTO score of complexity *(A)*. After predilation with small balloons *(B)*, IVUS assessment was performed showing a moderately calcified lesion. Therefore, 2.5- and 3.0-mm cutting balloon predilation was performed.