Bioresorbable Polymeric Vascular Scaffolds
A Cautionary Tale

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The everolimus-eluting bioresorbable vascular scaffold (BVS, Abbott Vascular, Santa Clara, CA) is an exciting advance in percutaneous coronary intervention (PCI), providing a temporary coronary scaffold for at least 3 months and being resorbed by about 2 years.1–3 Along with patient preference, potential advantages over metallic stents include restored vasomotion, reduced late thrombosis, and unimpaired imaging with computed tomography and magnetic resonance. However, advances in interventional devices may bring new challenges in the early days of the technology.

A 78-year-old man with recent-onset angina was enrolled in the ABSORB Trial Cohort B Group 1.3 An obtuse marginal coronary artery branch measuring by quantitative angiography 3.5 mm upstream and 3.0 mm downstream from a stenosis was predilated with a 2.5-mm balloon. A 3.0×18 mm Revision 1.1 ABSORB BVS (Figure 1) was deployed at 16 atm, and the scaffold was postdilated with a 3.25-mm noncompliant balloon at 24 atm (expected diameter, 3.5 mm). Although the angiographic appearances were good, there was malapposition of the proximal half of the scaffold shown by intravascular ultrasound (IVUS), and more clearly seen with optical coherence tomography (OCT) (Figure 1). After further inflations with a compliant 3.5-mm balloon to 16 atm (expected diameter, 4.0 mm), the angiographic appearances remained satisfactory. However, repeat IVUS and OCT showed persisting strut malapposition, including sections where the struts lay more centrally in the lumen, with strut overlap and loss of the typical strut pattern parallel to the vessel wall (Figures 2 and 3).

The patient at discharge was medicated with aspirin and clopidogrel and was initially well but presented 1 month later with rest pain. Angiographic appearances remained satisfactory, but OCT revealed more extensive scaffold pattern disarray (Figures 2 and 3). A 3.5×18-mm everolimus-eluting metallic stent was successfully deployed within the same segment. One BVS strut was still protruding into the vessel lumen on OCT. Although it is not known whether a single fractured strut protruding into the lumen like a finger is associated with adverse outcomes, the operator chose to deploy a 3.5×8-mm stent to remove this from the lumen. A bare metal stent was chosen to avoid multiple layers of drug-eluting struts. Final 1 angiographic and IVUS appearances were excellent (Figure 2). The patient remains symptom-free 18 months later.

This report demonstrates a limitation of early-generation bioresorbable polymeric scaffolds. There is a high likelihood of scaffold distortion and strut fracture if the current design of the 3.0-mm BVS scaffold is dilated beyond 3.5-mm diameter. Further strut displacement and disarray developed over the month after deployment. Although angiography revealed an apparently patent segment, IVUS and OCT appearances were consistent with strut rupture. Metallic stents were used to trap the polymeric struts against the vessel wall and to restore vessel scaffolding.

It is unclear what caused his rest pain at representation. It may have been secondary to disturbed coronary flow, microthrombus formation, and/or downstream vasospasm. The loss of vessel scaffold, reduced drug delivery, and flow disturbance probably would predispose the lesion to stent thrombosis and restenosis.

Although changes in strut design and alteration in polymeric processing increase the vessel diameter working range and lessen the likelihood of strut rupture, bioresorbable polymeric scaffolds are less forgiving than metallic stents when overexpanded. Objective vessel sizing by on-line quantitative angiography or IVUS, after administration of intra-coronary vasodilators, is recommended for accurate scaffold diameter selection.

Strut discontinuity and malapposition are not evident angiographically. Although IVUS provides some insights, the problem is best detected by OCT. These findings may have particular relevance as more complex lesions, for example, bifurcation stenoses, are treated. OCT may become an integral part of PCI procedures with bioresorbable scaffolds in these lesions. This case provides important insights to help guide the future safe and effective use of bioresorbable polymeric vascular scaffolds.

Disclosures
John Ormiston serves on advisory boards for Abbott Vascular and Boston Scientific and has received minor honoraria.

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Figure 1. A, Stenosis in the obtuse marginal branch of the left circumflex coronary artery before ABSORB bioresorbable vascular scaffold (BVS) implantation; B, artery after deployment of a 3.0×18 mm ABSORB BVS scaffold and after dilatation with a 3.25-mm non-compliant balloon at 24 atm. Panels 1 and 2 are optical coherence tomography cross sections of the artery at the sites indicated in B. The appearance of the struts is box-like without shadowing. At site 1 there is incomplete strut apposition with many struts separated from the vessel wall. At site 2, the struts are appropriately apposed to the vessel wall. C, Electron microscopic image of a generation 1.1 ABSORB BVS demonstrating the design features of in-phase sinusoidal hoops linked by straight bridges.
Figure 2. A, Apparently good angiographic result after postdilatation with a compliant 3.5-mm balloon at 16 atm. However, an optical coherence tomography (OCT) cross section in the lower panel (1) shows appearances consistent with strut breakage. The strut luminal and abluminal surfaces are no longer orientated perpendicular to the light source. The struts extend further into the lumen and are overlapped, which can only happen if there is strut fracture. B, Angiographic frame and an OCT cross section (2) at 1 month when there is more extensive strut disarray, not apparent on angiography (B). The angiographic appearance after metallic stenting is depicted in C. To assist in understanding imaging appearances, D is a scanning electron microscopic image of a revision 1.0 bioresorbable vascular scaffold that has been deliberately damaged on the bench showing strut fracture (open arrow) and overlap (yellow arrow).
Figure 3. A, Intravascular ultrasonic image of from the distal end of the bioresorbable vascular scaffold (BVS) scaffold in this patient. Struts appear as parallel lines without acoustic shadowing because ultrasonic waves pass through the struts with a small reflection from the luminal and abluminal surfaces. The struts are well apposed to the vessel wall here. D, Optical coherence tomographic (OCT) cross-section from this same patient displaying the struts as box-like without shadowing. The struts are well apposed. B, Intravascular ultrasound (IVUS), and E, OCT, show that struts lie deeply within the vessel lumen, are overlapped, and appear disorientated because the reflective surfaces are no longer perpendicular to the examining beam (ultrasound or light). Microcomputed tomographic images of a BVS rev 1.0 scaffold that has been deliberately damaged on the bench are displayed in cross section (C) and longitudinal section (F) to aid in understanding of the IVUS and OCT appearances. With loss of integrity of the BVS hoops, the struts protrude into the vessel lumen and can no longer support a vessel wall. The appearance of ruptured struts and their displacement into the vessel lumen with overlap are shown in longitudinal section in F.
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