Table 1
Baseline Characteristics of Study Population With Initial Risk of CHD Between 10% and 20%

Variable	Men (n = 329)	Women (n = 247)
Age (y)	70 (66-73)	74 (71-78)
Body mass index (kg/m^2)	26.5 (24.8-28.7)	28 (25-31)
Systolic blood pressure (mm Hg)	144 (131-155)	149 (135-161)
Diastolic blood pressure (mm Hg)	78 (70-85)	76 (69-82)
Total cholesterol (mg/dL) (mmol/L)	222 (201-240) (5.7 [5.2-6.2])	240 (217-232) (6.2 [5.6-6.8])
HDL cholesterol (mg/dL) (mmol/L)	46 (33-63) (1.2 [1.1-1.4])	50 (39-54) (1.3 [1.1-1.4])
LDL cholesterol (mg/dL) (mmol/L)	146 (124-165) (3.75 [2.42-5.1])	158 (135-178) (4.1 [2.63-5.62])
Cholesterol-lowering medication (%)	52 (15.8)	44 (17.8)
Antihypertensive medication (%)	87 (26.4)	117 (47.4)
Antithrombotic agents	97 (29.5)	43 (17.4)
Smokers		
Never (%)	29 (9)	124 (50)
Current (%)	70 (21)	33 (13)
Former (%)	230 (70)	90 (36)
Diabetes mellitus (%)	19 (5.8)	42 (17)
Calcium score (%)		
0 (%)	11 (3)	16 (7)
1-100 (%)	122 (37)	104 (42)
101-400 (%)	79 (24)	65 (26)
401-1000 (%)	64 (20)	37 (15)
> 1000 (%)	63 (16)	25 (10)

Values are mean (interquartile range) or n (%).
CHD, coronary heart disease; HDL, high-density lipoprotein; LDL, low-density lipoprotein.
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Drug-Eluting Stents

Evaluation of Second-Generation Drug-Eluting Stents

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Evaluation of the Second Generation of a Bioresorbable Everolimus-Eluting Vascular Scaffold for the Treatment of De Novo Coronary Artery Stenosis: 12-Month Clinical and Imaging Outcomes

Serruys PW, Onuma Y, Dudek D, et al.

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The development of bioresorbable stents is driven by the possibility of reducing the risk of late thrombosis by having eventual and complete absorption of the drug delivery scaffolding and normalization of vasomotor function. The desire to reduce thrombotic potential and normalize vascular function has to be weighed against a potential increase in angiographic late loss and with that

restenosis due to the loss of stent scaffolding. The investigators report on 12-month outcomes of the ABSORB™ Bioresorbable Vascular Scaffold (BVS) (Abbott Vascular, Abbott Park, IL) by assessing quantitative coronary angiography, IVUS, and optical coherence tomography (OCT). The ABSORB BVS system consists of a polymer backbone of poly(L-lactide) coated with a layer of a 1:1 mixture of poly(D,L-lactide) polymer and everolimus. The device and its polymer coating have been found to be fully absorbed by 2 years after implantation.

The ABSORB (A Clinical Evaluation of the Bioabsorbable Everolimus-Eluting Coronary Stent System in the Treatment of Patients With de Novo Native Coronary Artery Lesions) Cohort B trial is a multicenter, single-arm trial assessing the safety and performance of the ABSORB BVS (Rev 1.1) in the treatment of patients with de novo coronary artery lesions with a maximum diameter of 3.0 mm and a length ≤ 14 mm.

In cohort B1, 56 patients received a total of 57 ABSORB BVS Rev 1.1 stents. IVUS and OCT images at baseline and 12 months after implantation showed that the average scaffold area remained unchanged, whereas the radiofrequency backscattering and the echogenicity of the struts decreased by 16.8% ($P < .001$) and 20% ($P < .001$) as the struts were resorbed into the vessel wall. OCT showed the area covered by the strut cores decreased by 11.4% ($P = .003$) (Figure 2).

The angiographic late lumen loss shown on IVUS was 0.27 mm. Normal vasomotion within the scaffolded segments was demonstrated with an intravenous bolus of 0.3 mg of methylergonovine and intracoronary acetylcholine. The major adverse cardiac event rate, including myocardial infarction and revascularizations, was 7.1%. The positive results of this trial will lead to a pivotal trial to compare the ABSORB stent with an everolimus-eluting metallic stent (Xience Prime™; Abbott Vascular). Because stent thrombosis is a rare event in the setting of antiplatelet therapy, any trial will have difficulty demonstrating differences in this outcome according to stent type. ■

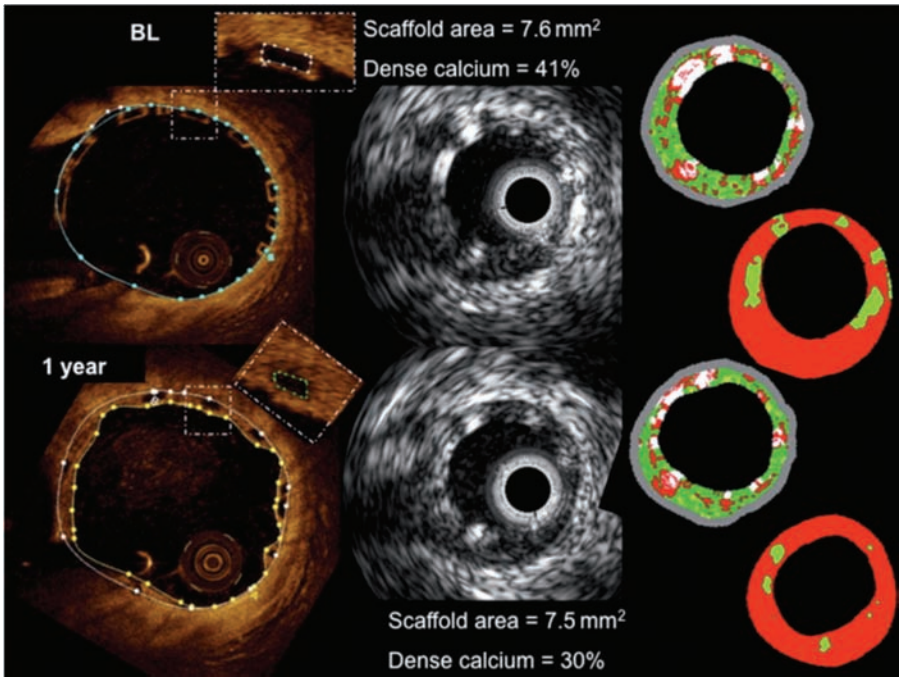

Figure 2. *OCT, IVUS gray scale, and IVUS-VH at baseline and 12 months. Baseline postprocedure (*left top panel*) and 1-year (*left bottom panel*) OCT assessment of corresponding cross-sectional images with a sidebranch selected as an anatomical landmark. Postprocedure, light backscattering strut frames, well-apposed to the vessel wall (*left lower panel*). At 1 year, all struts appeared covered but are still visible; neointima partially filled gaps between struts (*right lower panel*). Illustrated is reduction in strut core area, whereas the scaffold area remains unchanged. Corresponding grayscale and VH cross-sections at follow-up show reduction of the echogenic backscattering. IVUS, intravascular ultrasound; OCT, optical coherence tomography; VH, virtual histology. Reprinted from Serruys PW et al.* J Am Coll Cardiol. *2011;58:1578-1588; with permission from Cardiosource.*