RESEARCH CORRESPONDENCE

The Long-Term Impact of Post-Procedural Asymmetry and Eccentricity of Bioresorbable Everolimus-Eluting Scaffold and Metallic Everolimus-Eluting Stent on Clinical Outcomes in the ABSORB II Trial

Previously, Suwannasom et al. (1) reported that the bioresorbable scaffold (BRS) exhibits more lumen eccentricity and asymmetry than metallic everolimus-eluting stents (EES) as assessed by intravascular ultrasound (IVUS) post-implantation and that lesion asymmetry was an independent predictor of the device-oriented composite endpoint (DOCE) following percutaneous coronary intervention.

As the BRS struts gradually disappear over time, the initial eccentricity and asymmetry of the lumen may change according to the full resorption of the struts and the remodeling of the vessel wall (2). However, the long-term lumen adaptation after BRS implantation has never been explored in the context of a randomized trial. In this correspondence, we report the impact of post-procedural scaffold/stent asymmetry and eccentricity on 3-year outcome, updating the previous report (1) in the ABSORB II, prospective randomized trial.

The study including 501 patients with de novo coronary lesions, randomized in a 2:1 ratio to receive either treatment with an everolimus-eluting BRS (Absorb, Abbott Vascular, Santa Clara, California) or with a metallic EES (Xience, Abbott Vascular). IVUS pre- and post-procedure, and at 3 years were mandated. The details of the study and the definition of asymmetry index (AI) and eccentricity index (EI) were reported elsewhere (1,3).

Among patients with post-procedural IVUS available (n = 308 in Absorb, n = 162 in Xience), DOCE (cardiac death, target-vessel myocardial infarction, or ischemia-driven target lesion revascularization) was observed in 16 (5.2%) and 5 (3.1%) patients up to 1 year; 18 (5.8%) and 3 (1.9%) patients between 1 to 3 years; and 34 (11.0%) and 8 (4.9%) patients through 3 years in the Absorb arm and the Xience arm, respectively. DOCE distribution as a function of baseline asymmetry and eccentricity index is plotted in Figure 1A. During the first year of follow-up, DOCE was observed significantly more in the asymmetric group or in the eccentric group than in the symmetric group or in the concentric group. However, from 1 to 3 years, DOCE occurred in 10 of 246 patients (4.1%) in the asymmetry group and 11 of 224 patients (4.9%) in symmetry group ($p = 0.658$); 4 of 97 patients (4.1%) in the eccentric group and 17 of 373 patients (4.6%) in the concentric group ($p = 0.854$).

Changes in lumen asymmetry and eccentricity were analyzed in lesions with paired post-procedure and 3-year IVUS (247 and 136 lesions in the Absorb and Xience arms, respectively). In Absorb, the lumen became more asymmetric and eccentric in 3 years, with AI increasing from 0.34 ± 0.08 to 0.42 ± 0.09 ($p < 0.001$) and EI decreasing from 0.74 ± 0.07 to 0.71 ± 0.09 ($p < 0.001$). (Figure 1B) On the other hand, in Xience, the lumen became more asymmetric, with AI increasing from 0.28 ± 0.07 to 0.30 ± 0.08 ($p = 0.002$), whereas lumen eccentricity remained unchanged (0.80 ± 0.06 post-procedure and 0.79 ± 0.06 at 3-year [$p = 0.124$]) (Figure 1C).

At 1 year, clustering of DOCE in asymmetric and eccentric lesions was observed; however, at 3 years, cases with DOCE became scattered irrespective of asymmetry or eccentricity (Figure 1A). In 3 years, lesions treated with Absorb became more asymmetric and eccentric.

The different clustering of event cases in this scatter plot of asymmetry and eccentricity at 1 and 3 years suggests that the mechanical causes of long-term events are at variance with those of early events. In the short term, post-procedural asymmetry and eccentricity of the device may cause an inhomogeneous strut distribution, which theoretically may decrease local drug concentration and alter shear stress, thereby promoting scaffold failure. Possible causes of late scaffold failure such as very late scaffold thrombosis include late discontinuity of the scaffold associated with thrombogenicity (4), which is presumably not directly related to asymmetry and eccentricity of the lumen.

The lumen shape of the scaffold segment became more circular at 5-year follow-up as compared with post-procedure results in an optical coherence tomography substudy of ABSORB Cohort B (5). Taking into account the result of the current analysis, such change may occur later than 3 years, after complete

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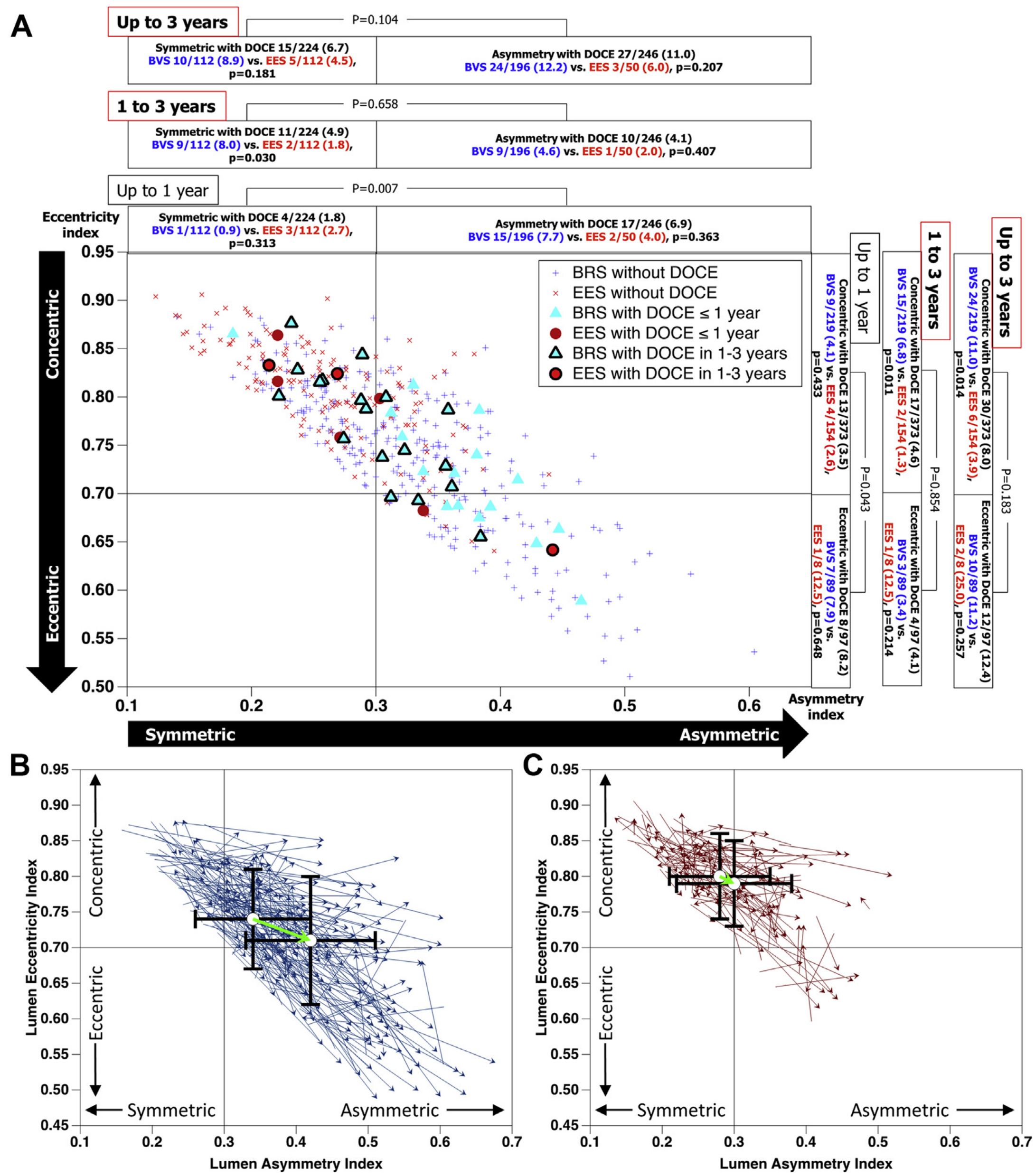
FIGURE 1 **Distribution of Geometrical Morphology According to Type of Device in the ABSORB II Trial and the Incidence of DOCE Over 3-Year Follow-Up**



(A) DOCE distribution as a function of baseline asymmetry and eccentricity index was plotted. **(B)** Changes in AI and EI observed in individual lesions in BRS. The **green line** indicates a mean change of lumen asymmetry index and eccentricity index. **(C)** Changes in AI and EI observed in individual lesions in EES. The **green line** indicates a mean change of lumen asymmetry index and eccentricity index. Data are counts (percentage). AI = asymmetry index; BRS = bioresorbable scaffold; DOCE = device-oriented composite endpoint; EES = everolimus-eluting stent(s); EI = eccentricity index.

bioresorption of the device. These observations suggest that longer-term follow-up (≥5 years) is essential to understand the effect of bioresorbable scaffold in coronary artery disease.

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RESEARCH CORRESPONDENCE

Predictors of Calcium Fracture Derived From Balloon Angioplasty and its Effect on Stent Expansion Assessed by Optical Coherence Tomography

Calcium fracture during percutaneous coronary intervention (PCI) is associated with better stent expansion (1,2). Optical coherence tomography (OCT) can penetrate calcium, evaluate calcium thickness, and identify the severity and pattern of calcium requiring additional lesion modification. Maejima et al. (2) reported OCT thresholds for predicting calcium fracture in lesions treated with rotational atherectomy as a maximum calcium angle of 227° and a minimum calcium thickness of 0.67 mm; however, there are no data regarding the thresholds for predicting calcium fracture using only pre-dilation followed by stent implantation and, therefore, the threshold for plaque modification pre-stenting.

We studied 261 calcified, de novo, native coronary artery lesions in 261 patients treated at St. Francis Hospital (Roslyn, New York) (n = 128) or Tsuchiura Kyodo General Hospital (Ibaraki, Japan) (n = 133) in which pre- and post-PCI OCT evaluations were performed and a stent was implanted using only balloon pre-dilation (i.e., no rotational, orbital, or laser atherectomy). OCT images were acquired with the ILUMIEN OPTIS system with the Dragonfly Duo or Dragonfly OPTIS imaging catheter (Abbott Vascular, Santa Clara, California) with a frame interval of 0.2 mm.

Each target lesion calcium deposit was evaluated by pre-PCI OCT including maximum calcium angle, maximum and minimum calcium thickness, and calcium length. The analysis was performed on a per-calcium deposit basis as well as on a per-target lesion basis; if there was more than 1 calcium deposit, the one with the largest maximum calcium angle was chosen to represent target lesion calcium. Individual calcium deposits within a single target lesion were separated by at least 1 mm of noncalcified plaque. Calcium fracture was defined as a slit or complete break in the calcium plate that was identified in the post-PCI OCT (**Figure 1A**). Stent