Different vascular healing process between bioabsorbable polymer-coated everolimus-eluting stents versus bioresorbable vascular scaffolds via optical coherence tomography and coronary angiography (the ENHANCE study: ENdothelial Healing Assessment with Novel Coronary tEchnology)

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Abstract
Recent clinical trials have raised concerns about the safety and efficacy of ABSORB™ bioresorbable vascular scaffolds (BVS). The difference in the vascular healing process between SYNERGY™ bioabsorbable polymer-coated everolimus-eluting stents (BP-EES) and BVS remains unclear. The aim of the ENHANCE study was to compare vascular healing on BP-EES versus BVS by optical coherence tomography (OCT) and coronary angiography (CAS) at 4- and 12-month follow-ups. This is a prospective, non-randomized, single center clinical trial. Thirteen eligible patients with multivessel disease were enrolled. BP-EES and BVS were simultaneously implanted in the same patients, but in different coronary vessels. Imaging follow-up with both OCT and CAS was completed in 11 patients at 12 months. Neointimal coverage rates were similar between the two groups based on OCT measurements. The neointimal thickness of BP-EES was significantly thicker at the 12th month than at the 4th month, whereas the neointimal thickness of BVS did not change between the measurements taken at the 4th and 12th month. Existence of intra-stent thrombus was significantly higher in the BVS group, compared to the BP-EES group. On the other hand, CAS revealed that red-thrombi and yellow-plaque were more frequently observed in BVS at 4 months and up to 12-month follow-ups than in BP-EES. These findings suggested that the evidence of instability remained up to 12 months in the vascular healing with BVS, compared to that with BP-EES. Vascular healing of the stented wall was recognized at the very early phase after BP-EES implantation. However, vascular healing with BVS was still incomplete after 12 months.

Keywords Vascular healing · Optical coherence tomography · Coronary angiography · Bioabsorbable polymer-coated everolimus-eluting stents · Bioresorbable vascular scaffolds

Introduction
The drug eluting stent (DES) made it possible to drastically reduce restenosis, but some concerns regarding very late stent thrombosis have not yet been overcome. The delayed healing with incomplete neointimal coverage, persistent of inflammation, hypersensitivity and neothrombosis at the stent implanted site may be involved in stent thrombosis [1–3].

The bioabsorbable polymer-coated everolimus-eluting Stent (BP-EES: SYNERGY™, Boston Scientific, Marlborough, MA, USA) was designed to enhance stent healing by incorporating thin P Cr struts with abluminal bioabsorbable polymer, which is reabsorbed within 4 months. These