

# Final shape of biovascular scaffolds and clinical outcome. Results from a multicenter all-comers study with intravascular imaging

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## ABSTRACT

**Aims:** Radial strength of bioresorbable vascular scaffolds (BVS) implanted in coronary arteries is still under debate. Moreover, their final shape patterns, when implanted in an all-comer, unselected population, have not yet been completely correlated with clinical outcome and should be better investigated.

**Methods and results:** A multicenter collaborative analysis was performed on all consecutive patients with native coronary artery disease undergoing PCI with intravascular imaging-guided BVS implantation. The BVS was arbitrarily categorized as having a final “oval shape” through intravascular imaging, if maximal lumen diameter was longer than 150% of minimal lumen diameter at the target lesion. Primary study-endpoint was device-oriented major adverse events (DOCE) at mid-term follow-up. Sixty-seven consecutive patients were evaluated at 6 European centers. Mean patient age was  $58 \pm 11$  years, and 12 patients (18%) had diabetes. Mean percent diameter stenosis was  $79 \pm 12.5\%$ . Average lesion length was  $24.4 \pm 13.8$  mm and 66% of lesions were AHA/ACC type B2/C. Postdilation rate was 91% and all BVS resulted well apposed to the vessel wall. Procedural success was achieved in all patients and 10 (14.9%) had an “oval shape” at intravascular imaging. This occurrence was not associated with an increase in periprocedural myocardial infarction ( $p = 0.37$ ) or DOCE during hospitalization ( $p = 0.65$ ). Seven-month DOCE occurred in 3 patients (5.6%) of the oval shape group, they were target-vessel revascularization and did not differ significantly between patients with vs. without final “oval shape” ( $p = 0.34$ ). We did not register episodes of scaffold thromboses.

**Conclusions:** In an all-comer population with complex coronary lesions treated with BVS, a final oval shape after postdilation was not rare and not associated with immediate and medium term adverse events.

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## 1. Introduction

Intravascular imaging guidance for percutaneous coronary intervention (PCI) with metallic stents or bioresorbable vascular scaffolds (BVS), performed either with ultrasounds (IVUS) or optical coherence tomography (OCT), has shown how an optimal angiographic result does not always correspond to a correct device deployment. Therefore, intravascular guidance is useful in optimizing device implantation, at least in selected cases [1–3]. Moreover, IVUS has been shown to improve the clinical and angiographic outcome of PCI [1,2]. In addition to standard IVUS or OCT evaluations (e.g., stent apposition to the vessel wall or in-

stent area/diameter), several geometrical parameters related to clinical outcomes have been previously identified [1].

With the advent of BVS, because of their structural peculiarities compared to metallic stents, a new evaluation of geometrical parameters after implantation seems particularly intriguing. However, still little is known on the influence of geometrical parameters of BVS immediately after implantation – namely eccentricity and symmetry – on clinical follow-up. In this study we investigated the role of a not infrequent behavior of BVS just after implantation, that we defined “oval shape”.

## 2. Methods

### 2.1. Study description and population

This was a multicenter, international study, with prospective data entry of consecutive patients treated with BVS for de novo lesions at 6 European Hospitals, with mandatory intravascular imaging during index procedure.

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Indication to percutaneous myocardial revascularization was any clinical indication including stable angina or acute coronary syndrome (ACS). Exclusion criteria were common contraindications to BVS use: severe coronary calcification (judged at operator's discretion), unavailable scaffold sizes and contraindication for prolonged double antiplatelet therapy (DAPT).

All patients were treated according to international guidelines but following local practice. Specifically, all patients were pretreated with aspirin (chronically or with endovenous bolus of 250–500 mg) plus clopidogrel or ticagrelor or prasugrel. During the procedure the anticoagulant of choice was unfractionated heparin given with a bolus of 70–100 IU/Kg at the beginning of the procedure, with additional boluses given according to the activated clotting time. Procedural success was defined as a final stenosis <30% with TIMI 3 flow distally, and the absence of device-related major adverse cardiac events (DOCE) during hospitalization, a composite of cardiac death, myocardial infarction or target lesion revascularization (TLR). After discharge, all patients underwent clinical visits after 1 and 6 months.

## 2.2. Study device

The device investigated in this study was the Absorb BVS version 1.1 (Abbott Vascular, Santa Clara CA, USA). This is a reabsorbable scaffold whose structure is made of poly-L-lactide (PLLA) with two radiopaque platinum markers at the proximal and distal ends to allow visualization during coronary angiography. PLLA is a semi crystalline polymer consisting of crystal lamellae interconnected with random polymer chains forming an amorphous segment. This device elutes a 1:1 mixture of poly-D,L-lactic acid and the antiproliferative drug everolimus. Full hydrolytic degradation takes as long as 3 years [4]. PLLA is completely degraded via hydrolysis and bioresorbed via the Krebs cycle [5,6]. Physically, the scaffold has struts with an approximate thickness of 150 µm.

## 2.3. Intravascular imaging analysis

Intravascular imaging was performed with IVUS or OCT depending on operator's preference after BVS implantation. The IVUS manufacturer was Volcano Corp. (San Diego, CA, USA), and the OCT manufacturer was St. Jude Medical (St. Paul, MN, USA). Before inserting the probe, the patient was given an intracoronary bolus injection of nitroglycerin 0.25 mg. Automatic pull-back at a speed of 0.5 mm/s was performed from a distinct landmark, through the entire stented lesion, back to the guiding catheter. OCT images were acquired using a non-occlusive technique with injection of contrast medium to limit blood-derived artifacts.

Intravascular imaging before BVS implantation was not mandatory and left at operator's discretion, whereas post-implantation analysis was required. All analyses of intravascular imaging were undertaken by a single expert operator in order to reduce possible evaluation bias.

Analyses evaluated BVS adaptability and conformability to vessel wall after implantation, according to eccentricity and symmetry indices [7,8]. In brief, analyzed parameters were:

- ✓ Eccentricity index at the minimum scaffold area (MSA) frame, defined as a ratio between the minimum and maximum diameters in that frame.
- ✓ Eccentricity index, defined as the average of all eccentricity indices of each frame.
- ✓ Symmetry index, defined as [maximum scaffold diameter in a single frame minus minimum scaffold diameter in a single frame] divided by the maximum scaffold diameter (Fig. 1).

MSA was described as the flow-limiting area and has been previously related to angiographic and clinical outcomes [9–10].

In our evaluation, the BVS was arbitrarily categorized as having a final “oval shape” through IVUS or OCT images, if maximal lumen diameter was longer than 150% of minimal lumen diameter as average of three intravascular measurements (in both edges and in the central segment of BVS, Fig. 2).

During intravascular analyses data on scaffold apposition to the vessel wall, scaffold recoil, underexpansion and edge dissections were collected as well [8,11,12].

## 2.4. Study endpoints

Primary study endpoint was the occurrence of DOCE during follow up, comparing the “oval shape” group versus the control group, in a consecutive series of patients at centers expert in BVS-PCI. We hypothesized the noninferiority between the 2 study groups.

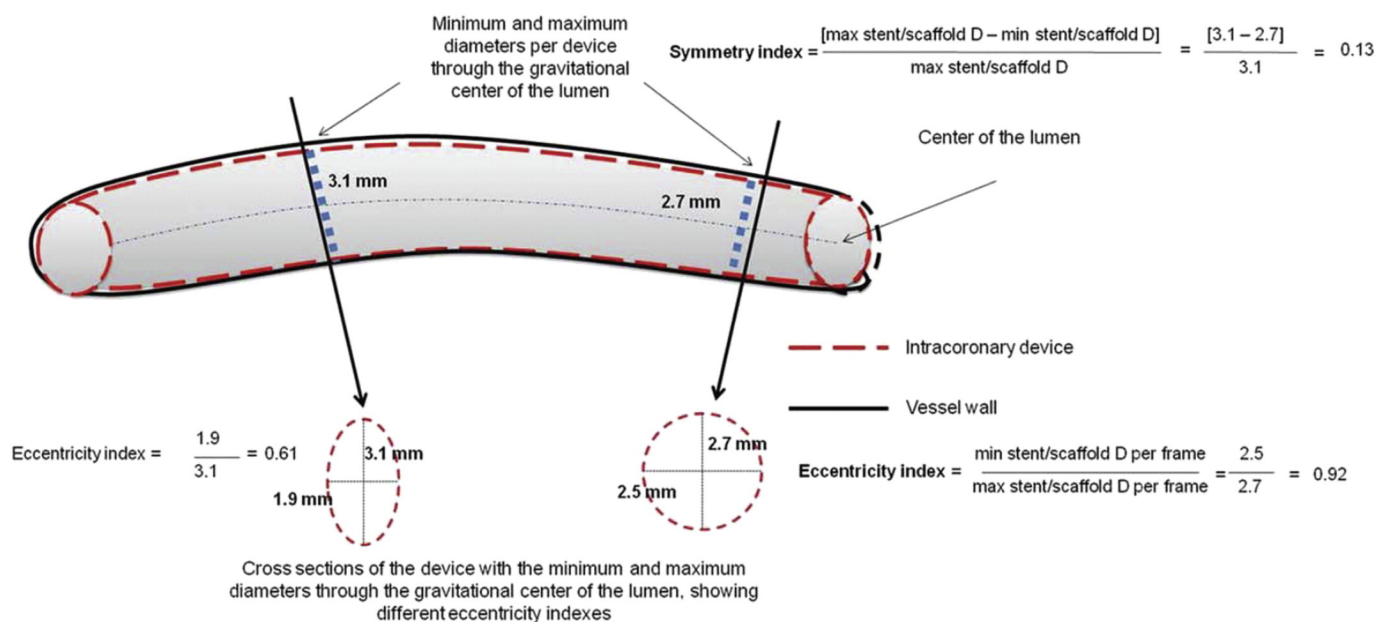
Secondary endpoints were periprocedural myocardial infarction (defined by elevation of cardiac Troponin – cTn – values >5 × 99th percentile of upper reference level in patients with normal baseline values, or a rise of cTn values >20% if the baseline values were elevated, both stable or falling), in-hospital DOCE or DOCE single determinants during hospitalization or at follow up in patients with or without final oval shape.

## 2.5. Statistical analysis

For binary variables, we calculated percentages. Continuous variables are presented as means ± standard deviation. Univariate analysis was employed to compare various clinical and procedural parameters between patients with and without final oval shape after BVS implantation. The Student's t-test was used for continuous normally distributed variables, and the Mann–Whitney U test was used for non-normally distributed variables. Chi-square and Fisher's exact tests were applied for categorical variables, when appropriate.

## 3. Results

We analyzed 67 consecutive patients treated with BVS at 7 different European hospitals with accredited > 1 year experience in this type of



**Fig. 1.** Relationship between the symmetry and eccentricity indices of BVS. Minimum and maximum diameters over the length of the device are shown. Two cross-sections with different eccentricity indexes are also shown. Permissions obtained by Wiley. From Brugaletta et al., Cath Cardiovasc Interv 2012;79:219–228.

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