

# Implantation Technique for Bioresorbable Scaffolds

Device description and patient/lesion selection with the Absorb BVS.

BY JIANG MING FAM, MD, MBBS, AND ROBERT-JAN VAN GEUNS, MD, PhD, FESC, FACC

The need for mechanical support for dilated vessels is temporary; beyond the first few months, there are potential disadvantages to the use of a permanent metallic prosthesis.<sup>1,2</sup> Bioresorbable scaffolds (BRSs) were recently developed as an alternative to metallic stents. BRSs demonstrated complete bioresorption after approximately 3 years, accomplished by vessel lumen enlargement, a reduction of the plaque-to-media ratio, and restoration of vasomotion,<sup>3,4</sup> essentially overcoming the limitations of metallic drug-eluting stents (DESs). The Absorb bioresorbable vascular scaffold (BVS; Abbott Vascular) is the most widely available commercial BRS and has demonstrated in early studies to be safe and efficacious when implanted in simple coronary lesions.<sup>5</sup> Early studies have also suggested that implantation of the Absorb BVS is noninferior to second-generation DESs in terms of clinical outcomes, although these outcomes vary.<sup>6-8</sup>

These varying clinical outcomes have also been attributed to the lack of a standardized protocol in the implantation of a BRS-specific protocol, especially in light of a new device that is structurally different from the newer-generation DESs currently used. The Absorb BVS is constructed of a poly-L-lactide (PLLA) polymer backbone in a semicrystalline composition. To achieve sufficient radial strength, the current strut thickness is 156  $\mu\text{m}$ , almost twice that of current metallic DESs. Even more, overexpansion of these semicrystalline scaffolds is limited to 0.5 mm to avoid rupture of the device during implantation.

Recently, there have been concerns regarding the risk of scaffold thrombosis (ST).<sup>9</sup> Main pathomechanisms include factors pertaining to incomplete lesion coverage, underexpansion of the scaffold, and malapposition. The reported findings of a slightly higher thrombosis rate—

early ST in particular—seem to be related to procedural factors such as the implantation technique necessary to compensate for the relative thick struts, similar to first-generation metallic bare-metal stents and DESs, and are therefore potentially preventable.<sup>10,11</sup> The importance of a dedicated implantation protocol for BRSs, including preimplantation plaque modification, routine high-pressure scaffold postdilatation with noncompliant balloons, and the liberal use of intracoronary imaging, such as optical coherence tomography (OCT) to evaluate scaffold apposition and coverage, was highlighted in a recent study that showed that BRS thrombotic rates can be reduced by approximately 70% using a specific implantation technique.<sup>11</sup> In this article, we discuss the standard implantation technique of the Absorb BVS and its potential use in more complex and challenging lesions.

## DEVICE DESCRIPTION

The Absorb BVS is composed of a bioresorbable PLLA polymer backbone coated with a thin bioabsorbable poly-D,L-lactide, which allows everolimus to be eluted in a manner identical to that of the Xience V stent (Abbott Vascular). The scaffold is balloon-expandable, and other than two platinum radiopaque markers at each end of the scaffold, the rest of the scaffold is radiolucent, facilitating clear visualization on angiography and other imaging modalities such as cardiac CT. The scaffold edges on each end start within 1 mm of the balloon markers. The radiopaque scaffold markers are not located at the edges of the scaffold, but are placed approximately 1 mm from the proximal edge and 0.3 mm from the distal edge of the scaffold, which is worth noting, especially when implanting overlapping scaffolds.

The first generation of the Absorb BVS (revision 1.0; average strut thickness, 150  $\mu\text{m}$ ; crossing profile, 1.4 mm; circumferential out-of-phase zigzag hoops linked together by three longitudinal struts between each hoop) was tested in ABSORB Cohort A.<sup>5</sup> This version unfortunately showed significant angiographic late loss and strut area reduction at 6 months, suggesting loss of radial support before vascular healing was completed.<sup>5</sup> At 2-year follow-up, the concept of bioresorbable technology was finally demonstrated with resorption of the device, late lumen enlargement, restoration of vasomotion, and endothelial function.<sup>12,13</sup> The second-generation Absorb BVS (revision 1.1) underwent modification in the strut design (in-phase zigzag hoops linked by bridges) and polymer manufacturing process. The metabolic process is slower in the second version, thus it provided more lasting mechanical support with reduced recoil. The polymeric scaffold maintains its radial strength for approximately 6 months after implantation and then undergoes a gradual metabolic process through the Krebs cycle into  $\text{CO}_2$  and  $\text{H}_2\text{O}$  over the course of 2 to 4 years.<sup>14,15</sup>

## GENERAL TECHNICAL CONSIDERATIONS

Technical considerations behind the successful implantation of the Absorb BVS are largely related to mechanical and structural properties of the polymeric scaffold structure. The current scaffold has relatively thick struts (156  $\mu\text{m}$ ) to maintain its radial strength. After the crimping process, the crossing profile (1.4 mm) is significantly larger than a contemporary metallic DES.<sup>16</sup> This has implications on device delivery and trackability, creation of flow disturbances, and delays in scaffold re-endothelialization, possibly accounting for the differences seen in procedure duration, device success rates, and event rates in myocardial infarction (MI) and ST at 12 months.<sup>17-19</sup> Table 1 summarizes the limitations and their impact on percutaneous coronary intervention (PCI).<sup>20</sup> The situation is exacerbated by operators' varying experience with Absorb BVS implantation, inconsistencies in device sizing, lesion preparation, routine high-pressure postdilation, and guidance with intracoronary imaging. Only 66.2% of patients treated with Absorb in four randomized trials had postdilation, and 23.9% underwent intracoronary imaging.<sup>21</sup>

A BRS-specific implantation protocol is based on following the five simple rules:

- Prepare the lesion
- Properly size the vessel
- Pay attention to the expansion limits of the scaffold
- Postdilate the BRS with a properly sized noncompliant balloon
- Pay attention to dual antiplatelet therapy and patient compliance

## PATIENT AND LESION SELECTION

In general, patients who may benefit from BRS implantation are younger and have longer lesions, as long metallic stents are associated with an increased risk of stent failure.<sup>22</sup> Lesions that cannot be adequately predilated, such as when the predilation balloon cannot fully expand or when residual stenosis exceeds 40%, may not be considered for a BRS because the BRS with relatively thick struts would be underexpanded, increasing the potential risk of ST.<sup>11</sup> Other factors to be considered include lesions that may pose potential deliverability issues, such as vessel tortuosity (vessels with extreme angulation of the segment proximal to the lesion) or heavily calcified lesions, and should be avoided. In such lesions, the thick polymeric struts of the scaffold with a large crossing profile may cause a buildup of friction between the device and lesion/catheter, increasing the risk of scaffold dislodgement during forceful movement in delivering the scaffold,

**TABLE 1. LIMITATIONS AND ASSOCIATED IMPACT OF ABSORB BVS ON PCI**

| Technical Considerations                                                                              | Effect on Procedural Technique and Outcomes                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Thicker struts                                                                                        | <ul style="list-style-type: none"> <li>• Higher crossing profile leading to reduced deliverability, particularly in calcified lesions</li> <li>• Predisposed to increased turbulence</li> <li>• Increased risk of malapposition or scaffold underexpansion</li> <li>• Potential increased risk of coronary dissections, side branch occlusion, and periprocedural myocardial infarct</li> </ul> |
| Strongly recommended lesion preparation such as 1:1 predilation                                       | <ul style="list-style-type: none"> <li>• Particularly in lesions that are calcified</li> <li>• Potentially requires more elaborate lesion debulking techniques such as the use of cutting balloons or rotational atherectomy</li> </ul>                                                                                                                                                         |
| Limited scaffold lengths and diameters                                                                | <ul style="list-style-type: none"> <li>• Need for longer or overlapping stents</li> </ul>                                                                                                                                                                                                                                                                                                       |
| Limited compatibility with guide extension catheter                                                   | <ul style="list-style-type: none"> <li>• Limited</li> </ul>                                                                                                                                                                                                                                                                                                                                     |
| Expansion limits restricts "upsizing" due to risk of scaffold fracture associated with overdilatation | <ul style="list-style-type: none"> <li>• Require accurate preprocedural sizing</li> <li>• Increased use of intravascular imaging or assessment leading to longer procedure times</li> </ul>                                                                                                                                                                                                     |

especially when used by relatively inexperienced operators.<sup>21</sup> Ideally, new operators of BRSs should start with stable, simpler lesions in stable patients and build up their expertise gradually before attempting implantation of the BRS in more complex lesions.

### Rule 1: Prepare the Lesion

It is highly recommended to achieve adequate lesion preparation by using semi- or noncompliant balloons with a diameter equal or just undersized compared to the reference diameter of the BRS device selected (1:1 predilation). Sometimes, short, high-pressure balloons may be used to treat isolated segments of underexpansion.

### Rule 2: Properly Size the Vessel

Exact vessel sizing and compliance to manufacturers' guidelines on scaffold matching of lumen dimension are crucial. An analysis of the nominal BVS scaffold size to quantitative coronary angiography (QCA) maximum reference vessel diameter and to clinical outcomes was reported in a pooled patient-level analysis involving > 1,200 patients from three ABSORB studies.<sup>23</sup> Subjects in the "scaffold oversize" group (defined as subjects with both proximal and distal maximum reference vessel diameters smaller than nominal scaffold size) experienced higher rates of major cardiovascular events and target vessel MI than those in the "scaffold non-oversize" group (defined as those in whom the proximal or distal maximum reference vessel diameter was larger than that of the scaffold). In ABSORB III, if vessels < 2.25 mm were excluded from the analysis, the incidence of ST was equivalent to the Xience EES.<sup>6</sup> Compliance to vessel sizing guidelines may further improve target lesion failure by reducing the incidence of MI and ST. Thus, implanting BRSs in vessel sizes that are too small (mean reference vessel external elastic lamina diameter < 2.5 mm, which corresponds to a reference vessel diameter of 2.25 mm on QCA) should be avoided.

Because the Absorb BVSs have thicker struts, preferably, long regions of scaffold overlap should be avoided because it increases the risk of ST and side branch occlusion. In addition, polymers are invisible under x-ray, with the exception of two radiopaque edge markers. Therefore, placement of the scaffold can be difficult, especially in regions of significant overlap or foreshortening.

### Rule 3: Pay Attention to the Expansion Limits of the Scaffold

Compared to DESs, BRSs have a limited range of expansion (ie, 0.5 mm more than the reference diameter) due to their polymeric composition, limiting their use in cases of vessel tapering (Table 2). Huge malapposition

**TABLE 2. SIZING RECOMMENDATION FOR ABSORB BVS**

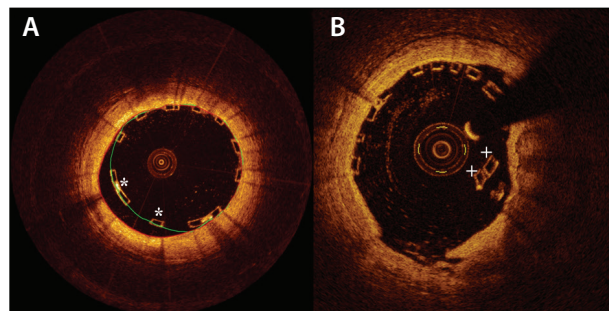
| Proximal and Distal Reference Diameters of Target Vessels (mm) | Recommended Diameter of the Absorb BVS Scaffold (mm) |
|----------------------------------------------------------------|------------------------------------------------------|
| > 2.5, < 2.75                                                  | 2.5                                                  |
| > 2.75, < 3.25                                                 | 3                                                    |
| > 3.25, < 3.75                                                 | 3.5                                                  |

can be uncorrectable and persist at follow-up until resorption occurs, and attempts to correct large malapposition by overexpansion with a large balloon can lead to scaffold disruption (Figure 1).

**Scaffold implantation.** Delivery of the BRS requires the application of gentle constant pressure to the lesion through a 6 F or larger guiding system. The main difference from the metallic stents is that balloon inflation for scaffold deployment should be gradual (2 atm every 5 seconds), with a minimum inflation duration of 30 seconds. When difficulties are encountered during delivery of the BRS, active support with the guiding catheter in the form of deep-vessel intubation may alleviate this problem, but there is a risk of coronary dissection with potentially disastrous consequences. Other methods to overcome this problem include vessel straightening with a second buddy wire<sup>24</sup> or buddy balloon,<sup>25</sup> the use of an anchor balloon,<sup>26</sup> and the use of an extra back-up support guiding catheter or a guide extension.<sup>27</sup>

### Rule 4: Postdilate the BVS With a Properly Sized Noncompliant Balloon

Operators should aim to achieve to cover  $\geq 2$  mm of the healthy vessel at either edge of the treated lesion using the BRS, with a result of < 10% residual stenosis



**Figure 1.** Malapposed struts (indicated by \*) (A). Attempts to correct large malapposition by overexpansion with a large balloon can lead to acute disruption of the scaffold (disrupted struts indicated by +) (B).

after deployment of the BRS with optimal scaffold expansion and apposition.<sup>1</sup> Performing postdilation using high-pressure balloons (> 16 atm) for 10 to 30 seconds is frequently required, and an optimal result is confirmed using intravascular imaging.

**Role of intravascular imaging.** The application of IVUS and OCT, a light-based intravascular imaging technology,<sup>28</sup> has enabled us to address the challenges facing the use of BRSs and overcome the limitations of angiography in assessing the significance of coronary stenosis and the results of PCI in a clinical setting.<sup>29</sup> The advantages of using intracoronary imaging include the capability to provide accurate luminal measurements and optimal detection of scaffold malapposition and fracture, which cannot be reliably detected on a simple angiogram. One main advantage of IVUS is the high depth of penetration that allows direct and easy visualization of total vessel diameter and area, allowing operators to optimize scaffold size without increasing the risk of disruption with oversized balloons.<sup>30</sup>

There are also advantages to using OCT in the deployment of BRSs. OCT was one of the most useful techniques for the early evaluation of the Absorb BVS and its resorption process. New OCT probes are low-profile

(2.6–2.7 F), flexible, coated with a hydrophilic layer, and the acquisition speed is at least 10 times higher when compared to IVUS. OCT catheters have a low delivery profile and can pass almost every lesion with few anatomical or patient exclusion criteria. The OCT imaging procedure is safe<sup>30</sup> and fast, providing all necessary information in just seconds (Figure 2).<sup>31</sup> The latest European Society of Cardiology guidelines on myocardial revascularization has already recommended OCT as a tool in selected patients to optimize stent implantation (level of evidence class II B, level C).<sup>29</sup>

An improvement in clinical and angiographic outcomes with intracoronary imaging-guided PCI was first shown in the use of IVUS.<sup>32</sup> In a meta-analysis, IVUS-guided DES deployment compared with standard angiographic guidance was associated with a reduced incidence of major adverse cardiac events.<sup>33</sup> The advantages of imaging guidance observed by IVUS may also apply to OCT, which was supported by findings of an observational study in which angiographic plus OCT guidance was associated with a significantly lower risk of cardiac mortality or MI, even after multivariate adjustment or propensity score-adjusted analyses.<sup>34</sup> Preliminary observations support a potentially beneficial role of OCT during BVS implantation in improving outcomes.<sup>9</sup>

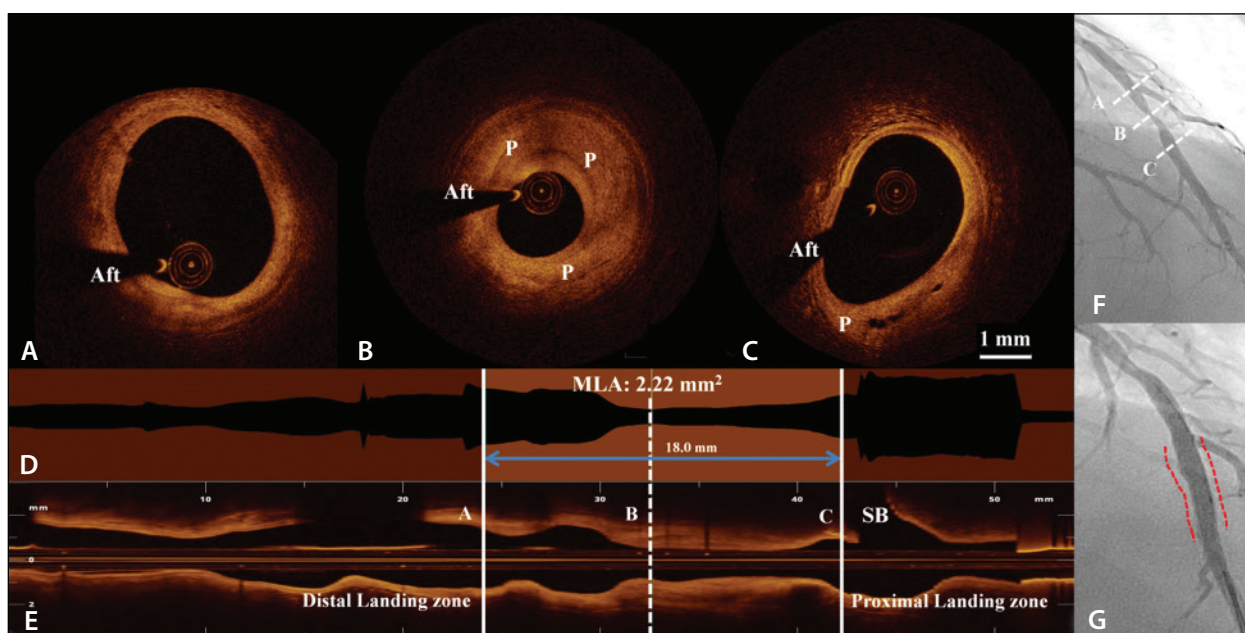


Figure 2. “Virtual PCI” planning. OCT images of the left anterior descending artery before scaffold implantation showing the distal landing zone (A), minimal lumen area (B), and proximal landing zone (C). OCT can assess lumen dimensions accurately, assess underlying plaque composition, and shows the location of the minimal lumen area in relation to the treated vessel on the lumen profile (D). In this way, OCT can guide scaffold implantation strategy by assessing the scaffold length (18 mm, in this example) required for optimal lesion coverage and avoiding SB ostia. The SB is seen on the longitudinal profile (E). The LAD is shown before (F) and after (G) implantation of a 3-X 18-mm Absorb BVS (dashed line). Aft, guidewire artifact.

### Rule 5: Pay Attention to Dual Antiplatelet Therapy and Patient Compliance

A minimum duration of 12 months of dual antiplatelet therapy is suggested in both stable and acute patients treated with a BRS. However, an even longer duration of dual antiplatelet therapy (18–24 months) and/or more potent antiplatelet medications, such as ticagrelor or prasugrel, may be used depending on the risk-benefit balance between thrombotic/ischemic risk and bleeding risk.

### CONCLUSION

Procedure- and lesion-related factors play an important role in acute procedural success, and various technical difficulties can be encountered in the implantation of the Absorb BVS. The impact of these factors may be mitigated by systematically applying the BRS implantation recommendations. The long-term success of BRSs relies on a combination of careful patient and lesion selection with proper implantation technique and optimization of procedural results in the clinical arena. By taking proactive steps to perform accurate patient/lesion selection and implement an optimal implantation technique, risks of adverse outcomes will be minimized, translating into improved clinical outcomes. ■

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### Jiang Ming Fam, MD, MBBS

Consultant

Department of Cardiology

National Heart Centre Singapore

Singapore

*Disclosures: None.*

### Robert-Jan van Geuns, MD, PhD, FESC, FACC

Professor of Interventional Cardiology

Department of Cardiology

Thorax Centre

Erasmus Medical Centre

Rotterdam, The Netherlands

r.vangeuns@erasmusmc.nl

*Disclosures: Research grants and speaker fees from Abbott Vascular.*