Understanding the Technical Aspects of Bioresorbable Stent Implantation

The new Absorb polymer-based scaffold requires optimal implantation technique for best results.

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The bioresorbable stent (BRS), or *scaffold* (as it is termed to emphasize its temporary nature and differentiate it from its permanent metallic counterpart), is now a therapeutic reality in the interventional management of coronary artery disease. Although there are a variety of BRS under various stages of development or early clinical trials, the most widely approved and used BRS with the largest amount of clinical data is the Absorb bioresorbable vascular scaffold (A-BVS) from Abbott Vascular. The A-BVS is now available in more than 100 countries with more than 100,000 implantations and is often labelled as the fourth revolution in interventional cardiology.[1] A temporary implant that treats the coronary stenosis, delivers the drug, props open the artery, prevents restenosis, and gradually disappears to uncage the vessel when it has stabilized and healed, the BRS is not just a technological marvel but also physiologically appropriate, psychologically reassuring, and intuitively logical. After all, sutures are removed once a wound has healed, and a plaster cast is removed once a fracture has healed. So, why do we easily accept the idea of potentially harmful metal implants remaining in the coronary arteries for the rest of the patient's life once the artery has healed?

Metallic drug-eluting stents (DES) have been associated with small but definite fresh target lesion failure rates year after year related to late stent malapposition and thrombosis, neoatherosclerosis, and other adverse sequelae related to permanent metallic splinting and caging of the vessels. Other disadvantages are the inability to withdraw antiplatelet therapy at will, the inability to put grafts on the stented vessels, and the inability to get useful information on CT angiography, if the need arises. Also, there could be other physiological and psychological adverse effects of multiple metallic implants left in situ over many years in a young patient. BRS technology has the potential long-term advantage of overcoming the limitations of a DES. However, these benefits remain to be proven in large studies of 5-year (or longer) follow-up, and such studies are already underway (ABSORB III, ABSORB IV).[2,3]

On the other hand, equivalence of the A-BVS in terms of safety and efficacy in the short and intermediate term compared to the best-in-class metallic DES has been addressed and affirmed in large, multicenter, multinational registries and more recently in pivotal larger randomized trials (ABSORB China,[4] ABSORB Japan,[5] ABSORB III[2]), which were powered for both angiographic or clinical endpoints in noncomplex lesion subsets.[2] Despite these data, widespread uptake of BRS by the interventional community has been slow and cautious. While some fence sitters and skeptics have been awaiting the results of the large pivotal randomized studies rather than the multicenter registry data,

TABLE 1. CROSSING PROFILE OF A-BVS AND XIENCE ALPINE		
Size Diameter	**A-BVS Crossing Profile**	**Xience Alpine Crossing Profile**
3 mm	0.056 inch (1.42 mm)	0.042 inch (1.07 mm)

TABLE 2. EXPANSION CHARACTERISTICS OF A-BVS		
BVS Nominal Size	**Maximal Expansion Size**	**Recommended Noncompliant Balloon Size for High-Pressure Postdilatation**
2.5 mm	3 mm	3 mm
3 mm	3.5 mm	3.5 mm
3.5 mm	4 mm	4 mm

there has also been concern about the reports of higher rates of early scaffold thrombosis in some of the earlier registries.[6,7] Recently, the ABSORB III study also demonstrated numerically (but nonsignificantly) higher rates of A-BVS thrombosis at 1 year compared to Xience (Abbott Vascular) (1.5% vs 0.7%, respectively) in a moderately complex lesion subset.[2] On the other hand, data from numerous experienced operator-driven registries and trials consistently demonstrate high success rates and extremely low scaffold thrombosis rates that are no different from results with present-generation DES, even in complex real-world patients.[8-10] Perhaps the real differentiator in achieving best outcomes and safety with the A-BVS is the implantation technique, which has become the prime emphasis for ensuring its appropriate and extended use in real-world interventional practice.

THE A-BVS

To put this into perspective, the A-BVS is a 156-µm-thick strut, poly (L-lactide) (PLLA) stent that is twice as thick as the present-generation DES; hence, it takes longer to endothelialize completely. Furthermore, it possesses less radial strength in vivo when treating large bulky and hard plaques, which may result in underexpansion. All of these factors could predispose to unfavorable short- and long-term outcomes, most importantly early scaffold thrombosis, myocardial infarction, and target lesion failure. In essence, the A-BVS is less forgiving than the present-generation, thin-strut DES. The A-BVS also has a unique set of delivery performance characteristics, deployment features, and expansion parameters. The A-BVS is a new device and, like all new devices in interventional cardiology during the last 30 years, the optimal technique of implantation and result optimization, as well as the tips and tricks for its use in real-world complex lesions, have evolved over the last 2 to 3 years since its commercial availability. Meticulous attention to the optimal implantation technique results in the A-BVS being as safe and effective as the best-in-class metallic DES.[11]

IMPORTANT TECHNICAL FEATURES

The following technical features play an important role in influencing successful A-BVS implantation:

- The struts are 156 µm thick (twice the size of present-generation DES)
  - –It has poor trackability through calcified tortuous arteries
  - –It has poor crossability through high-grade, calcified, or underdilated lesions
- It is available in only three sizes: 2.5 mm, 3 mm, and 3.5 mm
- It is available in limited lengths: 8 mm, 12 mm, 18 mm, 23 mm, and 28 mm
- It is a larger-profile device (Table 1)
- It requires graded and gradual deployment going up 2 atm every 5 seconds; the total deployment time ranges from 40 to 60 seconds
- It has limited expansion characteristics: the A-BVS can only be expanded to 0.5 mm beyond the nominal size, beyond which there is an increasing risk of device disruption (Table 2)
- It is an "invisible device": its presence can only be detected by the two platinum markers at each end of the device (placed at approximately 0.7 mm from the edge of the scaffold) seen either on high-intensity fluoroscopy, cine, or best seen in stent enhancement programs (Figure 1)

Thus, the basic principles of optimal A-BVS implantation are similar to the basics of optimal stent deployment that we learned 20 years ago with first-generation, thick-strut metal stents and should still be considered the optimal way to deploy all stents to achieve best outcomes. These are relatively easy to put into practice: (1) prepare the lesion adequately; (2) properly size the vessel; and (3) postdilate at high pressure with a noncompliant balloon.

SEVEN MANTRAS FOR SUCCESS

In our experience of more than 1,500 A-BVS implantations, we have evolved the following seven mantras which encapsulate the steps necessary to achieve best results with the A-BVS.

1. Good Guide Catheter Support

Six-French guides can be used for simple lesions and nontortuous coronary anatomy, while 7-F guides are preferred for complex lesions, tortuous anatomy, calcification, bifurcations, and long diffuse segments with diffuse disease. Use of mother-and-child catheters, such as GuideLiner (Vascular Solutions) may be needed to deliver the A-BVS across proximal calcified tortuousities.[12]

2. Adequate Guidewire Support

Workhorse wires are for simple lesions and anatomy. Heavy-weight wires, extra support, or buddy wires are for complex tortuous anatomies or moderate calcified arteries or when using 6-F guides through radial routes.

TIP: During difficulty in tracking across a tortuousity or calcification, use of sustained pressure rather than Dottering will make the A-BVS gradually slip through the curves.

3. Size the Vessel Accurately

Accurate vessel sizing is important because the A-BVS only comes in three sizes (2.5 mm, 3 mm, 3.5 mm) and can only be expanded to 0.5 mm more than its actual size. An undersized scaffold with limited expansion may lead to incomplete apposition and subsequent risk of acute scaffold thrombosis or restenosis. On the other hand, a larger scaffold in a smaller vessel could also lead to the crowding of multiple thick struts, decreasing the lumen of the vessel further and again risking early scaffold thrombosis and restenosis. Vessel sizing should be done after administration of intracoronary nitroglycerine. Sizing may be done by visual estimation comparing the vessel to the predilatation balloon or by intravascular imaging using quantitative coronary analysis (QCA), intravascular ultrasound (IVUS), or optical coherence tomography (OCT). It should be kept in mind that visual estimation and QCA usually underestimate vessel size, whereas IVUS usually overestimates vessel size, and OCT is closest to the actual vessel size. Use of an A-BVS in vessels < 2.5 mm has a greater risk of scaffold thrombosis and acute myocardial infarction (as seen in a subanalysis of ABSORB III data).[13]

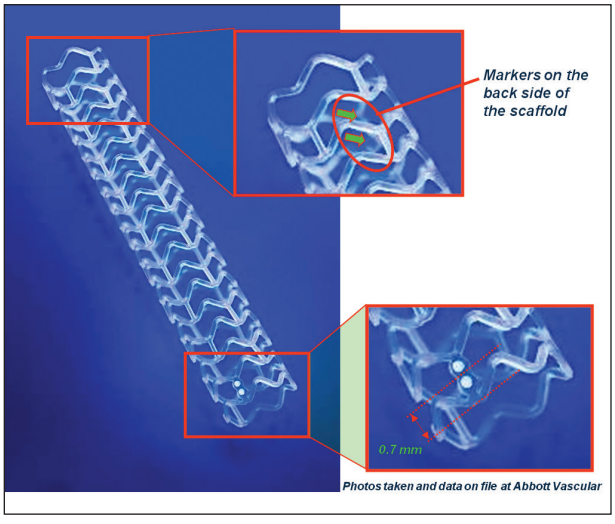
TIP: Vessel sizing may best done by intravascular imaging, such as IVUS or OCT, especially during the learning curve or when in doubt. However, as operator experience grows, intravascular imaging is not essential and can be used selectively for highly complex cases or in smaller vessels to optimize results.

4. Prepare the Lesion Well

Adequate lesion preparation is important to achieve full expansion of the device and maximal luminal gain. It also enables delivery of this high-profile device across the lesion. Predilate the lesion fully with a shorter "near-optimally" sized noncompliant balloon to high pressure in order to open the lesion completely and leave minimal or no residual stenosis. For mild to moderately calcified lesions and fibrotic lesions, use of scoring or cutting balloons is recommended. For severe calcified lesions, it is advisable to use rotational atherectomy to achieve adequate lesion modification and dilatation.

5. Appropriate Deployment of the A-BVS

The A-BVS should be appropriately sized to the vessel after the administration of intracoronary nitroglycerine. When in doubt, it is better to upsize than undersize the A-BVS because the scaffold cannot be expanded to more than 0.5 mm larger than its nominal size. If a vessel by visual assessment or QCA appears to be between 3 and 3.5 mm, it is better to use a 3.5-mm A-BVS because it has the ability to go up to 3.75 to 4 mm and gives greater safety margin for error than it is to use a 3-mm A-BVS, which can only be expanded up to 3.5 mm. This becomes even more important when using long scaffolds in tapering vessels where a smaller scaffold may become undersized at its proxi-



Courtesy of Abbott Vascular.

Figure 1. A-BVS is a polymer "plastic-like" stent with two platinum markers at each end.

TIPS AND TRICKS FOR SPECIFIC LESION SUBSETS

LONG LESION AND OVERLAPPING SCAFFOLDS

Long lesions and diffuse disease require coverage with multiple overlapping scaffolds (Figure 2; page 47). The inability to expand the scaffold beyond 0.5 mm of its nominal size necessitates choosing a scaffold size that, in a tapering vessel, is matched to the proximal vessel diameter rather than the distal vessel diameter.

The overlap between two scaffolds needs to be minimal because the overlapping struts occupy nearly 0.6 mm (150 µm X 4) of the lumen diameter and undergo delayed endothelization. Minimal overlap is achieved by placing the distal marker of the proximal scaffold just next to the proximal marker of the distal scaffold, resulting in < 1 mm of overlap in many cases (Figure 3; page 47). In vessels ≤ 3 mm in diameter, we prefer side-by-side implantation with practically no overlap.

BIFURCATION LESIONS

In real-world practice, bifurcation lesions with large-size branches are commonly encountered and often pose a procedural challenge even with DES. The limited expansion capabilities of the thick plastic struts of the BVS and the limited access into side branches increases the challenge. In vitro testing in bifurcation phantoms and clinical experience has helped to evolve tips and strategies to treat most bifurcation lesions safely and effectively. While using the A-BVS, the guiding principles of dealing with bifurcation lesions are similar to those using DES.[15]

- A single A-BVS in the main branch with provisional stenting of the side branch is the preferred strategy.
- The side branch can be wire protected, and the A-BVS can be implanted in the main branch at high pressures. If the side branch remains patent, the jailed wire can be removed easily.
- If the side branch has a threatened closure, a proximal optimization technique with a 0.25-mm to 0.5-mm larger balloon is performed in the proximal part of the main branch stent, while remaining within the expansion limits of main branch scaffold. The struts of the main branch A-BVS are recrossed with a wire into the side branch, and the struts can be dilated through gradual inflations (using up to a 2.75-mm balloon for a 3-mm main branch scaffold and up to 8-10 atm) without causing device disruption. Using larger balloons in the side branch or higher pressures may cause device disruption and breakage of links or connectors, fragmentation, or device recoil.[16]
- A final simultaneous snuggle balloon dilatation (and not a kissing-balloon dilatation) in which there is minimal protrusion of the side branch balloon into the main branch is performed using a noncompliant balloon at low pressures (up to 7–8 atm).[15]
- If the side branch needs provisional stenting, an A-BVS or DES can be passed through the dilated struts of the main branch scaffold into the side branch and micro T and protrusion performed with final simultaneous snuggle balloon dilatation (Figures 4 and 5; pages 47 and 48).
- In cases in which an upfront two-scaffold strategy is considered: the choice of techniques could be (1) T-stenting (side branch scaffold first and main branch after), (2) T and protrusion technique, or (3) V-stenting. Coullotte and Crush techniques are not advisable because they lead to extensive device disruption, as well as a greater volume of intravascular thick struts that run the risk of developing acute thrombosis.

mal end and compared to the vessel size. Deploy the A-BVS slowly going up 2 atm every 5 seconds until 8 to 10 atm is achieved, and then hold for another 20 seconds. Hence, the overall implantation process may take approximately 40 to 60 seconds. The A-BVS is mounted on a compliant balloon, hence going to high pressures during deployment increases the risk of dog boning and overexpansion of the balloon at the edges, leading to edge dissections.

6. Postdilate With a Noncompliant Balloon to High Pressures

High-pressure postdilatation with a noncompliant balloon not only achieves maximal apposition and expansion with a larger minimum luminal area but also embeds the thick struts into the intima. These factors help to decrease the risk of early scaffold thrombosis and improve outcomes in the short and long term.[14] Routine use of high-pressure postdilatation may obviate the need for intravascular imaging in most cases. Postdilatation is performed with a noncompliant balloon at high pressures ≥ 18 to 20 atm (using a 0.25- to 0.5-mm larger balloon than vessel size as assessed visually) but staying with the expansion limits of the scaffold.

7. Meticulous Attention to Antiplatelet Therapy

Because of the thicker struts, which occupy a large lumen and may undergo delayed endothelialization,

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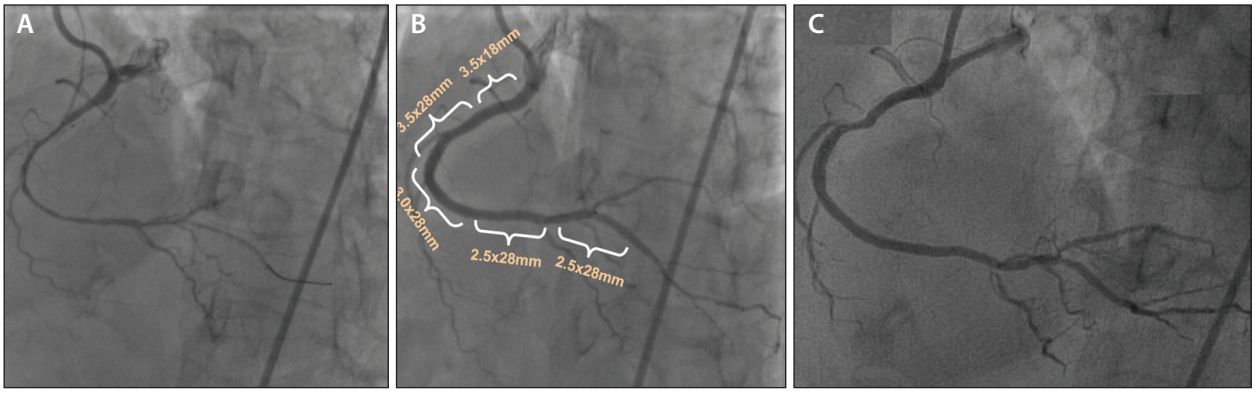
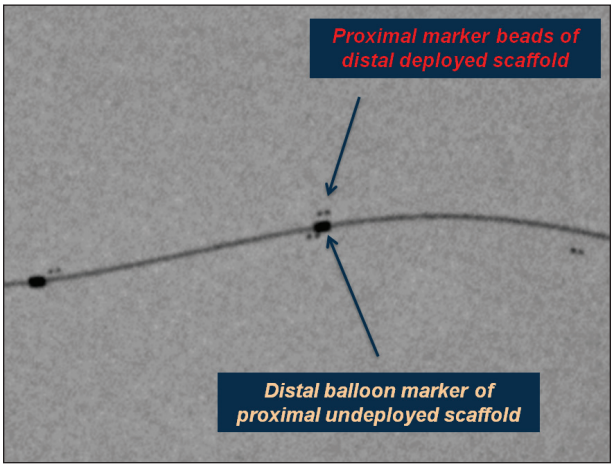


Figure 2. Diffuse right coronary artery disease treated with multiple overlapping scaffolds covering 13 cm of the vessel: diffusely diseased right coronary artery (A); full plastic jacket (five scaffolds) (B); coronary angiography demonstrating the patent right coronary artery at 2-year follow-up (C).

it is imperative to make sure antiplatelet and anticoagulant therapy during the postprocedure period is adequate and well monitored. In clopidogrel-naive patients during ad hoc percutaneous coronary intervention, it is our practice to load them with ticagrelor or prasugrel to initiate a more rapid and predictable onset of platelet inhibitor compared to loading with clopidogrel.

With growing experience across the world, the use of the A-BVS in our practice and other experienced operators has transitioned from stable patients and simpler lesions to the real-world complex patient and lesion subsets; these now regularly include bifurcation lesions, severely calcified lesions, long lesions and diffuse disease, full plastic jackets, chronic total occlusion, ostial lesions, and acute myocardial infarction primary intervention. The application of these man-



Courtesy of Abbott Vascular.

Figure 3. Technique of overlapping the A-BVS to achieve less than 1 mm of overlap.

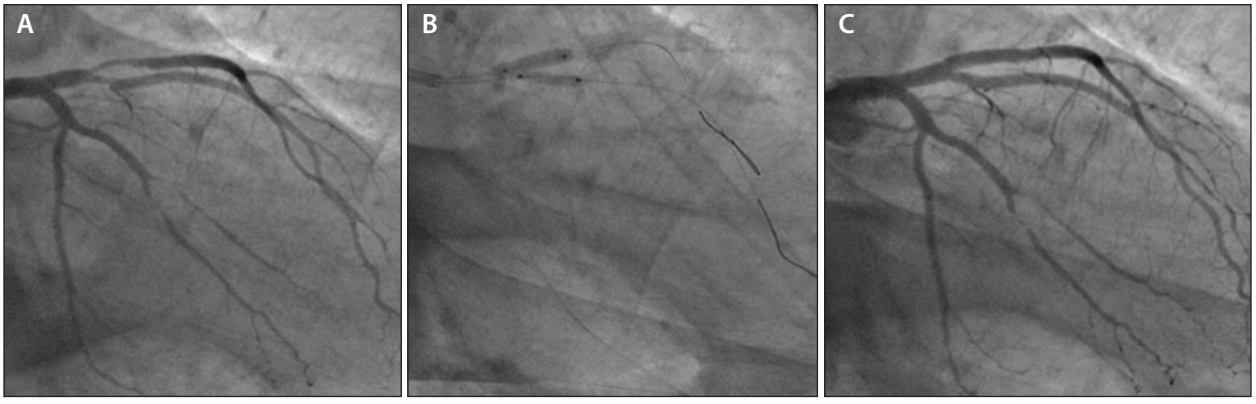


Figure 4. Bifurcation treatment with the A-BVS, two-scaffold strategy: bifurcation lesion of the left anterior descending artery and diagonal artery (Medina classification 1,1,1) (A); A-BVS in the left anterior descending artery main branch and A-BVS in D1 by TAP technique followed by snuggle balloon dilatation of scaffolds in the left anterior descending and diagonal arteries (B); good final result of two-scaffold strategy by TAP technique (C).

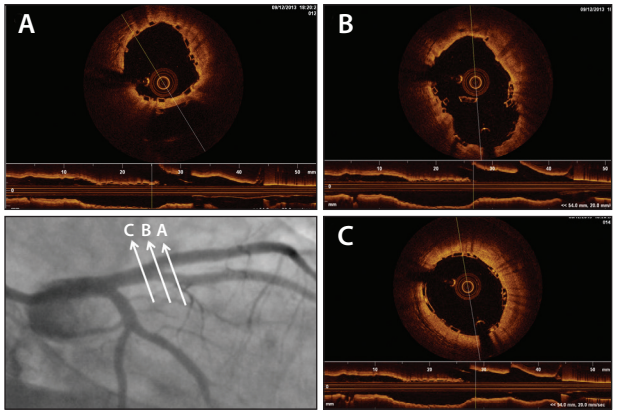


Figure 5. OCT demonstrating microcarina of the left anterior descending/diagonal bifurcation lesion with good optimization of the scaffold at the side branch ostium and the main branch at the level of the distal main branch (A), the microcarina (B), and the proximal main branch (C).

tras has led to extremely low DES-like rates of stent thrombosis and very favorable outcomes.

Although these mantras apply uniformly to all patient subsets and lesion anatomy, specific lesion subsets require their own additional sets of tips and tricks (see *Tips and Tricks for Specific Lesion Subsets* sidebar on page 37) to achieve the best success. It would be fair to say that with increased operator experience and optimal implantation technique, the extended use of the A-BVS even in complex lesion subsets appears to be as safe and effective as with DES, although larger and longer registries in real-world patients are warranted and awaited. Certain complex lesions that are common in interventional practice, such as bifurcations and long diffuse disease segments, stand to gain much benefit from the A-BVS.

SUMMARY

The safety and efficacy of the current-generation A-BVS relies heavily on the optimal technique of implantation in which appropriate sizing and high-pressure postdilatation with noncompliant balloons are essential. Meticulous attention to implantation technique helps to achieve short- and long-term outcomes and stent thrombosis rates that are no different than those associated with present-generation, best-in-class DES.

Thinner strut (100 µm) BRS in a larger variety of diameters and lengths, with greater expansion thresholds, are under development and should be available in 2 to 3 years. This would make the next-generation BRS more user friendly for easier applicability to our complex real-world patients. ■

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