Bioresorbable Scaffolds
Clinical Outcomes and Considerations

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KEYWORDS

• Bioresorbable scaffolds • Biodegradable stents • Scaffold • Absorb • BRS • BVS

KEY POINTS

- Second-generation drug-eluting stents (DESs), because of their permanent metallic nature, may represent a long-lasting trigger for late coronary events (ie, restenosis, thrombosis, neoatherosclerosis).
- Bioresorbable scaffolds (BRSs) eliminate this theoretic stimulus by a process of engineered resorption after the scaffold has fulfilled its purpose of stabilizing the coronary vessel for several months.
- Recently, large studies of the Absorb scaffold, with a primary or secondary focus on clinical end points, have been made available.
- Current evidence with the Absorb device supports noninferiority to everolimus-eluting stents in selected and relatively simple lesions; however, meta-analyses have recently raised concerns about a higher rate of device thrombosis compared with second-generation DESs.
- Ongoing studies with long-term follow-up will clarify the role of BRSs in daily practice. Technical ameliorations are expected to improve the outcomes of current-generation BRSs.

INTRODUCTION

Second-generation drug-eluting stents (DESs) are the current standard of choice for patients undergoing percutaneous coronary intervention (PCI) in the elective and emergent setting.[1] These devices have significantly tempered some of the traditional concerns attributed to the use of bare-metal stents and first-generation DESs. However, even second-generation DESs, because of their permanent metallic nature, represent a long-lasting trigger for late coronary events (ie, restenosis, thrombosis, neoatherosclerosis).

The principle behind the clinical development of an emerging new generation of devices for PCI, namely "bioresorbable scaffolds" (BRSs), is that of eliminating this theoretic stimulus by a process of engineered bioresorption after the scaffold has fulfilled its purpose of stabilizing the coronary vessel for several months. Although the concept of "a stent that does it job and then disappears" is intrinsically intriguing, this may come at the price of some steps back in user-friendliness and early safety compared with second-generation DESs. In fact, most BRS are made of a more fragile platform compared with metallic DESs, which limit their application and use in some PCI scenarios (ie, calcified lesions, complex bifurcations). To counteract the lower radial strength ascribable to the nature of their manufactured BRS, some companies have designed their product with thicker struts than most second-generation DESs available in the market, resulting in technical shortcomings and higher rates of early thrombosis.[2]

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However, the landscape of BRS devices is rapidly evolving and many manufacturers are now experimenting new concepts and prototypes to address the limitations of the first-generation devices. The Absorb BVS (bioabsorbable vascular scaffold [BVS], Abbott Vascular, Temecula, CA) acts as a front-runner in this challenging arena, because most of the clinical data of BRSs so far have been obtained with this particular device. For years, most of the theoretic considerations surrounding the topic of BRSs for PCI have been adapted from long-term imaging studies of the Absorb BVS version 1.0 (ABSORB Cohort A) and 1.1 (ABSORB Cohort B).[3] Although interesting and pivotal in describing the potential of BRSs at long-term (Box 1), the clinical information vehicled by these early studies has been limited. More recently, larger studies of the Absorb BVS with a primary or secondary focus on clinical end points have been made available. In parallel, several manufacturers are at the beginning of their line of clinical development of competing BRSs. This article reviews the contemporary clinical outcomes of the Absorb BVS, and provides an updated state of the art on the other players in the BRS field.

CLINICAL DEVELOPMENT OF CURRENT-GENERATION BIORESORBABLE SCAFFOLDS

Three polymeric BRS have currently obtained the CE mark for use in Europe: Absorb, DESolve (Elixir, Sunnyvale, CA), and ART (Arterial Resorbable Technologies, Noisy le Roi, France and Terumo, Tokyo, Japan). Absorb is so far the only BRS that has been approved by the US Food and Drug Administration. Other BRSs in the early stages of clinical development include the polymeric Fortitude (Amaranth Medical, Mountain View, CA), NeoVas (Lepu Medical Technology, Beijing, China), Mirage (Manli, Singapore, Singapore), MeRes (Meril Life Sciences, Gujarat, India), Xinsorb (Huaan Biotechnology, Laiwu, China), Fantom (REVA Medical, San Diego, CA), and the metallic DREAMS (Biotronik AG, Aarau, Switzerland) (Table 1). Other BRS are still in preclinical testing and have not launched an official clinical development program, such as ON-AVS (OrbusNeich Medical, Ft. Lauderdale, FL), ZMED (Zorion Medical, Zionsville, IN), Sahajanand BRS (Sahajanand Medical Technologies, Gujarat, India), Avatar BRS (S3V, Karnataka, India), Stanza BRS (480 Biomedical, Watertown, MA), Biolute (Envision Scientific, Gujarat, India), and ArterioSorb (Arterius, Bradford, United Kingdom).

Absorb

Absorb is the BRS with the most extensive clinical evaluation so far, and several randomized studies versus everolimus-eluting stents (EESs) have been published recently:

- A small investigator-driven trial named EVERBIO II concluded that second-generation metallic DESs (EESs or biolimus-eluting stents) were not superior to the Absorb BVS in terms of

Box 1
Predicated advantages of bioresorbable scaffolds

Superior conformability and flexibility
- Improved distribution of tissue biomechanics
- Preserved vessel geometry

Liberation of vessel from a metallic cage
- Restoration of physiologic vasomotion, adaptive shear stress, late luminal gain, and late expansive remodeling

Absence of any residual foreign material and restoration of functional endothelial coverage
- Reduced risk of late thrombosis
- Reduced need for long-term dual antiplatelet therapy

Additional technical benefits
- No "jailing" of the side branches
- No overhang at ostial lesions
- No inability to graft the stented segment
- No artifacts on computed tomography

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