Evolution of bioresorbable vascular scaffolds and their role in everyday practice

Evolución de los dispositivos vasculares biorreabsorbibles y su papel en la práctica cotidiana

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Abstract

Bioresorbable vascular scaffolds offer several potential advantages over conventional metallic stents for the percutaneous treatment of coronary artery disease. The absence of a permanent metallic cage and polymer in the treated coronary artery can theoretically reduce the long-term risk of stent (scaffold) thrombosis allowing positive remodeling with an increase in lumen area after scaffold absorption. In this review, we summarize information regarding currently available bioresorbable scaffolds concentrating on their pre-clinical and clinical studies. We also discuss the potential advantages and challenges associated with these novel devices in routine clinical practice.

Key words: *bioresorbable vascular scaffold.*

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INTRODUCTION

The permanent existence of a metallic cage, that remains beyond its intended function of preventing recoil and providing sufficient radial support, can interfere with positive remodeling and vessel geometry.[1] It can also be a source of inflammation predisposing to neoatherosclerosis, in-stent restenosis (ISR) and stent thrombosis (ST).[2,3] It also results in artifacts in cardiac magnetic resonance and computer tomography (CT) imaging, thus limiting the possibilities of non-invasive coronary imaging for post-percutaneous coronary intervention (PCI) follow-up. Bioresorbable vascular scaffolds (BVS) can address these issues whilst maintaining access for future coronary artery bypass grafting and repeat percutaneous revascularization of a previously treated arterial segment. The use of most BVS is currently limited to clinical trials with the ABSORB BVS (Abbott Vascular, Santa Clara, CA, USA) being available for use in 'real-world' patients. The use of this device is expanding from simple to complex lesions such as calcified lesions, chronic total occlusions, unstable lesions and those at bifurcation sites. The purpose of this review is to summarize available data regarding the use of these devices providing insights regarding their use in routine clinical practice.

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DRUG-ELUTING BIORESORBABLE SCAFFOLDS

ABSORB Bioresorbable Vascular Scaffold

The Abbott Vascular BVS (Abbott Vascular, Santa Clara, CA, USA) is made from semicrystalline poly-L-lactic acid (PLLA) coated with amorphous poly-D, L-lactide polymer eluting everolimus. Degradation of the scaffold is mainly through hydrolysis, fol-

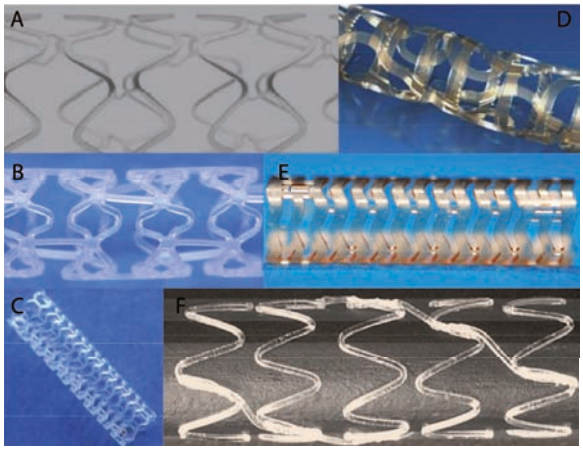

Figure 1. *Different bioresorbables (BVS) stents designs.*

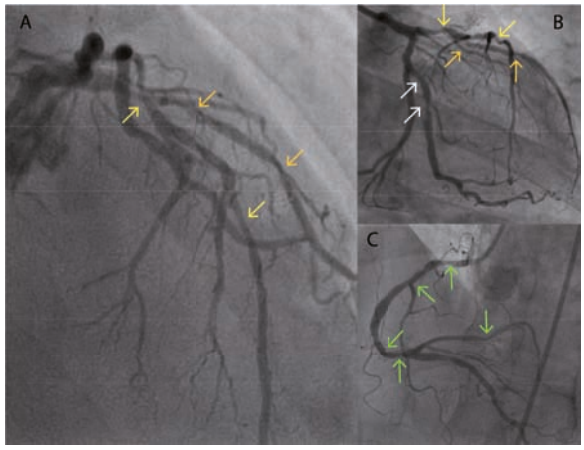

Figure 2. *Patients with severe three vessel disease treated with BVS.*

lowed by macrophage phagocytosis of the resulting degradation products, a process that takes 2-3 years to complete. The open label prospective first-in-man (FIM) ABSORB trial: A Bioresorbable Everolimus Eluting Coronary Stent System for Patients With Single De-Novo Coronary Artery Lesions tested the safety and feasibility of the first generation BVS (1.0).[4] In this study, follow-up analyses using multi-modality imaging such as multi-slice CT, angiography, intravascular ultrasound (IVUS) and optical coherence tomography (OCT) were performed. At 6-months, the angiographic in-stent late lumen loss (LLL) was 0.44 mm and mainly due to a reduction of the scaffold area (-11.8%) as measured by IVUS. This appeared to be more prominent in lipid-laden and fibrofatty plaques [5]. However, vasomotion appeared to be restored with vasoconstriction induced by methyl ergonovine maleate and vasodilatation induced by nitroglycerin possible in the treated segment.[6] The second generation BVS device (Revision 1.1) was developed in order to address the issues regarding scaffold area loss in the aforementioned lesions, although the polymer used and total absorption time remained similar. Moreover, the new version did not require to be stored at -20° C and had a shelf life >8 weeks which were important practical limitations of the previous version and would have limited the commercial success of the device. This device was assessed in the ABSORB Cohort B trial which recruited 101 patients with single- or two-vessel de novo disease. Patients who underwent a 3 x 18 mm BVS implantation were divided into 2 groups; group 1 was assessed at 6-months and 2-years and group 2 at 1- and 3-years, respectively. CT coronary angiography was performed in all patients at 18-months. At 6-month follow-up in group 1, there was only 1 target lesion revascularization (TLR) and LLL was 0.19 ± 0.18 mm. At 2-years, LLL was 0.27 ± 0.20 mm. Similar results were reported for group 2 at 12-months. Scaffold area progressively increased during follow-up although at 6-months there was significant reduction in minimal lumen area on IVUS as compared to baseline (6.60 ± 1.22 mm2 to 6.37 ± 1.12 mm2 vs. p <0.005) [7]. In the whole cohort, there were 3 non-ST elevation myocardial infarction (MI) and 4 ischemia-driven TLR at 18-months [8]. Furthermore, follow-up angiography at 2-years showed no differences in LLL (0.29 ± 0.16 mm vs. 0.25 ± 0.22 mm, p = 0.439) between small vessels [reference vessel diameter (RVD) <2.5 mm] and large vessels (RVD ≥2.5 mm). At 2-year clinical follow-up, no differences in ischemia-driven major adverse cardiac events (MACE) (7.3% vs. 10.2%, p = 0.733) were noted between the small vessel and large vessel groups with no observed cases of ST.[9] Data regarding the use of ABSORB in everyday practice is becoming available. In the prospective, single-center, BVS Expand registry examining the use of ABSORB in routine clinical practice, with the exception of patients with ST-elevation MI (STEMI) and restenotic lesions, the use of BVS was associated with 1 MI and 1 repeat intervention [non target vascular revascularization (TVR)] at 30-day follow-up in a cohort of 131 patients.[10] The POLish Absorb Registry (POLAR) specifically evaluated ABSORB in 88 acute coronary syndrome patients reported 100% procedural success with 1 case of in-hospital repeat PCI (non-TVR).[11] The Prague-19 registry on the other hand is enrolling only STEMI cases. The hypothesis is that STEMI with low Killip class may be an ideal setting for BVS (young and less calcium). The use of ABSORB in a small cohort of 22 patients was associated with good procedural results with only 1 case where ABSORB delivery could not be achieved.[12] Reported early clinical outcomes were acceptable with 1 case of ST, 3 days after the procedure following cessation of ticagrelor. The longer-term data from these 'real-world' registries will shed further light regarding the use of BVS in routine clinical practice.

More studies are currently underway evaluating the BVS 1.1. The ABSORB Extend study is recruiting 1000 patients worldwide with de novo single- or two-vessel disease. It allows recruitment of patients with disease in smaller vessels (>2.0 mm) as well as

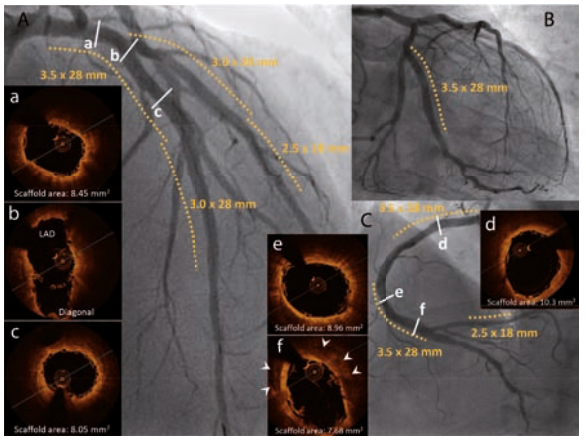

Figure 3. *Optical coherence tomography (OCT) during follow up in long coronary artery segments treated with BVS.*

those with long lesions. Ischemia-driven TLR rate and MACE rates at 12-months in a cohort of 450 patients were 1.8% and 4.2%, respectively. The definite or probable ST rate was 0.9%.[13] The ABSORB Physiology study will examine the acute and long-term effects of BVS 1.1 on coronary physiology as compared to currently used metallic drug-eluting stents (DES). Vascular compliance, distensibility, endothelial responsiveness and changes in the shear stress distribution will be analyzed after BVS or DES implantation and at 2-year follow-up. On the other hand, the prospective, randomized ABSORB II study will compare BVS 1.1 to the Xience Prime everolimus-eluting stent (Abbott Vascular, Santa Clara, CA, USA). This study will recruit 501 patients with stable angina and single- or two-vessel disease and randomize them on a 2:1 basis to BVS 1.1 and Xience Prime stent implantation thereby allowing evaluation of both the efficacy and safety of ABSORB. The trial is expected to be completed in 2015. The multi-center US pivotal study ABSORB III trial is aiming to recruit over 2000 patients with up to 2 de novo lesions in different epicardial vessels (vessel diameter 2.5-3.75 mm, length ≤24 mm) randomizing these patients to BVS 1.1 and Xience Prime at a 2:1 ratio. This trial has commenced enrollment earlier this year. The primary endpoint will be target lesion failure (TLF) at 1-year. Finally, the ABSORB IV study will aim to add another 4000 patients to ABSORB III in order assess for BVS 1.1 superiority over Xience Prime with regards to TLF between 1- and 5-years.

Absorbable Metallic Stent (AMS)

Biotronik (Biotronik, Berlin, Germany) has developed a balloon expandable AMS composed of magnesium alloy. The first generation AMS (without drug elution) degraded to inert products within 4 months without causing significant inflammation. Interestingly, pre-clinical studies had suggested that its resorption was associated with an antithrombotic effect.[14] The first generation scaffold (AMS-1) was assessed in the non-randomized, prospective, multi-center PROGRESS AMS trial that recruited 63 patients with single de novo lesions.[15] In this study, 71 scaffolds with length 10-15 mm and diameter 3.0-3.5 mm were used with an immediate angiographic effect similar to that seen with other metallic stents. IVUS at 4-months showed only small remnants of the original struts, although there was a significant increase in diameter stenosis from 12.6% to 48.4%. TLR at 1-year follow-up was high at 45%. This was attributed both to the early and rapid scaffold degradation, resulting in the loss of radial force, as well as to the absence of an antiproliferative drug. Second-generation devices, AMS-2 and AMS-3, have since been designed with different magnesium alloys and slower degradation times. The AMS-3 DREAMS (DRug Eluting AMS) includes a biodegradable matrix that elutes the antiproliferative drug, paclitaxel. The FIM study, BIOSOLVE-I, enrolled 46 patients with de novo lesions ≤12 mm and RVD: 3.0-3.5 mm. At 12-month follow-up, TLF rate was 7.0% and TLR rate was 4.7%. LLL was 0.52 ± 0.39 mm, and greater than that seen with currently used permanent metallic DES. However, vascular vasomotion was shown to be restored by 6-months with no changes at 1-year. At 2-years, TLF and clinically-driven TLR were both 10.0%.[16] DREAMS has since been modified to DREAMS 2, which possesses tantalum radiopaque end-markers and elutes sirolimus instead of paclitaxel. Animal studies suggested that this newer version is associated with improved endothelization and reduced inflammation.[17]

DESolve Bioresorbable Vascular Scaffold

The DESolve bioresorbable scaffold (Elixir Medical, Sunnyvale, CA, USA) is made from a PLLA-based polymer eluting novolimus, a major metabolite of sirolimus. The DESolve scaffold is designed to be fully reabsorbed within 2 years. In the FIM, 15 patients with lesion length <10 mm and RVD: 2.75-3.00 mm underwent DESolve implantation with 14 patients completing 6-month angiography follow-up. Quantitative coronary angiography (QCA) analysis at 6-months showed a reasonable in-scaffold LLL (0.19 ± 0.19 mm) with OCT showing low neointimal hyperplasia.[18] At 1-year follow-up, 1 cardiac death, 1 target vessel MI and 1 TLR for proximal edge restenosis occurred with no ST. Multi-slice CT at 12-months showed continued neointimal suppression and vessel patency (minimal lumen diameter: 2.4 ± 0.4 mm and minimal diameter stenosis: 15.9 ± 10.9%).[19] The multi-center, prospective DESolve Nx trial having enrolled 123 patients worldwide is assessing this device further. At 6-month follow-up, the MACE rate has been reported to be 3.3% with 2 cases of TLR and no cases of ST.

IDEAL Bioresorbable Vascular Scaffold

The IDEAL BVS (Xenogenics Corp, Canton, MA, USA) is the only scaffold incorporating salicylate directly into the polymer chain. As the polymer de-

TABLE 1. Bioresorbable vascular scaffolds available for clinical use or under development.

Scaffolds	Strut material	Strut thickness (μm)	Drug (concentration)	Duration of radial support	Bioresorption period (months)
BVS 1.1 (Abbot Vascular)	Poly-L-Lactic acid	150	Everolimus (8.2 μg/mm)	3 months	24
DREAMS 2 (Biotronik SE)	Magnesium alloy	150	Sirolimus (NA)	Weeks	>4
DESolve (Elixir)	Poly-L-Lactic acid	150	Novolimus (5 μg/mm)	3-6 months	24
IDEAL Generation II (Bioabsorbable therapeutics)	Polyanhydride ester with salicylate	175	Sirolimus (higher dose than 8.3 μg/mm that was present in 1st generation), salicylate	3 months	6
REVA ReZolve2 (REVA medical)	Tyrosine-derived polycarbonate	114-228	Sirolimus (80 μg)	3-6 months	24-48
ON-AVS (OrbusNeich)	Poly-L-Lactic acid, poly (D, L-lactide), poly (L-lactide-co-ε-carprolactone)	150	Sirolimus/CD34+ (NA)	6 months	>6
Igaki-Tamai (Kyoto Medical Planning)	Poly-L-Lactic acid	170	Nil	6 months	24
Amaranth (Amaranth Medical Inc.)	Poly-L-Lactic acid	150-200	Nil	3-6 months	24
ART (Arterial Remodeling Technologies)	Poly-L-Lactic acid	170	Nil	5-7 months	18

grades, salicylate and sirolimus are released, thereby reducing inflammation and platelet aggregation. In a small human study with the first generation IDEAL BVS, a larger than expected reduction in lumen area was seen, believed to be due to insufficient neointimal suppression.[20] This was attributed to inadequate drug dosing and rapid drug release. The second generation IDEAL BVS addressed these issues by incorporating a higher drug dose and a slower release rate. In addition, as opposed to the first generation version this can be delivered through a 6F catheter. The device is currently undergoing pre-clinical evaluation.[21]

ReZolve Bioresorbable Vascular Scaffold

The ReZolve scaffold (Reva Medical Inc., San Diego, CA, USA) consists of a tyrosine-based polymer, resorption of which takes 18-24 months to complete. The first generation scaffold was assessed in the FIM RESORB study which recruited 27 patients. The high rate of adverse clinical outcomes in this study (18 TLR and 3 MI) at 1-year led to the redesign of the device.[22] The current scaffold consists of a more resilient polymer that incorporates sirolimus. It also has a unique slide and spiral lock mechanism, which reduces acute recoil and provides better radial support. The ReZolve BVS is undergoing clinical evaluation in the RESTORE trial: ReZolve Sirolimus-Eluting Bioresorbable Coronary Scaffold, which aims to recruit 50 patients with de novo coronary artery disease. Of the 26 patients enrolled as of July 2012, technical success was achieved in 85% (n = 22).[23] At 6-month follow-up, 2 TLR were observed. A further CE Mark study with ReZolve2 (a sheathless, lower profile device with enhanced polymer formulation that can be delivered through a 6 Fr sheath), the RESTORE-II study, is underway that will recruit 125 patients across 30 worldwide sites.

Bioresorbable drug-eluting scaffolds under pre-clinical investigation

The ON-AVS (OrbusNeich Medical, Fort Lauderdale, FL, USA) differs from other drug-eluting BVS as it incorporates CD34+ antibodies for endothelial progenitor cell capture.[24] This aims to promote and achieve faster endothelialization. The device also has sirolimus elution. Angiographic and intravascular imaging results from animal models showed optimal device implantation without evidence of fracture. The Xinsorb BRS (Huaan Biotechnology Group, Laiwu, China) is made of PLLA and elutes sirolimus. Results from porcine arteries comparing this scaffold with a metallic DES also eluting sirolimus have been promising with regards to percentage area stenosis and degree of inflammation.[25] Other BVS under evaluation include the Avatar BVS (S3V; Vascular Technologies Pvt Ltd, Bangalore, Karnataka, India India) and the MeRes BVS (Meril Life Science, Vapi, Gujarat, India). Results of the MeRes in porcine arteries were reported in EuroPCR 2013.

NON-DRUG-ELUTING BIORESORBABLE SCAFFOLDS

Igaki-Tamai stent

The Igaki-Tamai stent (Kyoto Medical Planning Co., Ltd, Kyoto, Japan) is a non-drug-eluting scaffold made of PLLA and was the first fully bioabsorbable scaffold successfully implanted in man. It has a zigzag helical design with the proximal and distal ends of the scaffold 'marked' with radiopaque markers. The initial version of this pioneering stent required a balloon expandable covered sheath system and balloon inflation using heated dye at 80° C. In the FIM study, 15 patients and 19 lesions were treated with RVD: 2.85 ± 0.34 mm on the basis of QCA [26]. Re-

TABLE 2. Guidance for BVS use.

Favour BVS	Use BVS with caution	Avoid BVS
Young patient	STEMI	Lesions in vessel with diameter <2.5 mm and >4.0 mm
Any lesion in vessels with diameter ≥2.5 mm and ≤4.0mm	Patient where DAPT <6 months is preferred	
Long diffuse disease especially in LAD		
Long occlusion requiring vessel reconstruction		
Multivessel disease		

BVS = bioresorbable vascular scaffolds. DAPT = dual antiplatelet therapy. LAD = left anterior descending artery. STEMI = ST-elevation myocardial infarction.

peat angiography the day following the procedure in conjunction with IVUS did not show any evidence of acute recoil. Angiographic and IVUS follow-up at 3-months demonstrated some lumen loss (7.42 ± 1.51 mm2 to 5.67 ± 2.42 mm2), although this did not worsen significantly when re-assessed at 6-months. At 6-month follow-up there was 1 TLR. The long-term (>10-year) results of a cohort of 50 patients and 63 lesions treated with this scaffold have recently been published [27]. Over the 10-year follow-up period there were 7 deaths, 1 of unknown cause and 6 secondary to non-cardiac causes, and 3 MI of which only 1 was lesion related. There was 1 case of subacute ST attributed to cessation of dual antiplatelet therapy as a result of a bleeding gastric ulcer. TLR was relatively high at 28%. Importantly however, in a group of 18 patients in whom IVUS was performed at 3-year follow-up, lumen area increased from 4.23 ± 1.82 mm2 at 6-months to 4.95 ± 1.79 mm2 at 3-years, supporting the notion that lumen area following implantation of a bioresorbable scaffold can increase as a result of positive remodeling. Despite the theoretical advantages of the Igaki-Tamai stent, the need for an 8F guide catheter and heated contrast prevented its widespread use. A newer generation of this scaffold, compatible with a 6F guide catheter and without the requisite of heated contrast is currently undergoing pre-clinical evaluation. Currently, the Igaki-Tamai stent has CE Mark for only lower limb peripheral application (femoral artery).

Non-drug-eluting bioresorbable scaffolds under pre-clinical investigation

The Amaranth BVS (Amaranth Medical Inc., Mountain View, CA, USA) is composed of a PLLA polymer, resorption of which takes 12-24 months. LLL in animal models has been shown to be similar of that of bare metal stents (BMS). The FIM comparing this device against a commercially available BMS is expected to commence soon. The ART BVS (Arterial Remodeling Technologies, Noisy le Roi, France) manufactured from a PLLA amorphous polymer takes 18-months to dissolve, demonstrated good results in terms of LLL in animal models.[28] The FIM "ARTDIVA" (Arterial Remodeling Transient Dismantling Vascular Angioplasty) trial, which has already enrolled a few patients, will recruit 30 patients with the primary endpoint of MACE at 6-months.

BVS in routine clinical practice

The ABSORB BVS is the only scaffold currently commercially available and thus the only one that has been used in 'real-world' patients.[29] In our experience (patient number = 102, lesion number = 144), procedural success with BVS can be high (98%) with clinical results similar to those with conventional DES at early follow-up. Patients treated in our centers had mostly complex disease (Figures 2 and 3) and in theory are those that have the most to gain from BVS implantation. Patients with long segments of diffuse disease and those requiring multivessel revascularization are attractive candidates for BVS as eventual scaffold resorption avoids a 'permanent full metal jacket' that can predispose to ISR and ST. This is particularly important for younger patients since such an approach does not only maintain access for future bypass graft surgery, if required, but also offers the possibility of repeated percutaneous treatment without the addition of further permanent metallic layers. Optimal BVS implantation requires good lesion preparation and accurate assessment of vessel diameter as the distensibility of these devices is limited (0.5 mm tolerance). In that regard, the use of intravascular imaging can be helpful not only in evaluating vessel size but also in providing information regarding scaffold expansion and the need for post-dilatation, which we routinely perform at moderate to high pressures. When treating long diffuse disease, BVS overlap should be kept to a minimum due to the thick struts (150 μm) of these devices. This is especially important in the smaller vessels as the 300 μm strut layer in the area of overlap can lead to significant lumen reductions. Another lesion subset that could particularly benefit from BVS is bifurcation lesions treated with a 1-stent strategy. This is particularly important in cases of small jailed side-branches as these branches will be 'liberated' following scaffold resorption. In our experience, treatment of bifurcation lesions is certainly possible and even final balloon kissing inflation can be performed, ideally at low-moderate atmospheres without balloon overlap in the proximal main branch. In general, we believe that if the operator avoids oversizing in the proximal segment, the possibility of scaffold is slim. If stenting of the side-branch is required after BVS implantation in the main-branch, this is more likely to be possible by using conventional DES as these may be more deliverable due to their thinner struts. If a systematic 2-stent technique with only BVS is preferred, it is best to implant the side-branch scaffold first to avoid crossing the main-branch scaffold with a BVS as this, although

possible, can be challenging. BVS can also be used in heavily calcified lesions, including chronic total occlusions and ISR, once adequate lesion pre-dilation has taken place. The use of scoring balloons and rotational atherectomy, both of which we have used successfully may be required in such cases, prior to BVS implantation. However, it is important to note that BVS should be avoided in certain cases. An example would be vessels requiring >4.0 mm stents should be treated with conventional DES as post-dilatation of BVS beyond its 0.5 mm tolerance may lead to scaffold disruption. Table 2 provides a simple guidance according to our experience regarding the use of ABSORB BVS in the real-world.

CONCLUSIONS

BVS are the single most important innovation in the percutaneous treatment of coronary disease since the introduction of DES as they offer the possibility of reducing future adverse events many of which have been attributed to the permanent presence of stent materials in the vessel wall. Our experience with ABSORB BVS is encouraging as it demonstrates that its use outside the context of clinical trials is feasible with encouraging early clinical outcomes. Longer follow-up and larger studies will provide further insights regarding the role of these devices in routine clinical practice.

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