Coronary Bioresorbable Vascular Scaffold Use in the Treatment of Coronary Artery Disease

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Abstract—Bioresorbable vascular scaffolds (BVS) represent a promising novel approach for the treatment of coronary artery disease. BVS promise to address some of the well-known limitations of current drug-eluting stents, while providing a transient scaffolding of the vessel to prevent acute vessel closure/recoil. Drug elution by BVS prevents neointimal proliferation in a similar fashion to drug-eluting stents, and complete bioresorption is associated with late vessel lumen enlargement, plaque regression, and restoration of vasomotion. Based on the pathophysiological reasons and on the results derived from clinical studies, BVS are increasingly being used in clinical practice. The aim of this review is to provide an overview of the current evidence supporting the use of BVS in clinical practice. In particular, we will discuss the randomized controlled trials and registries evaluating the clinical outcome of these devices, with a special focus on their application in patients with acute coronary syndrome and in specific lesion subsets (bifurcations, chronic total occlusions, and in-stent restenosis). **(*Circ Cardiovasc Interv*. 2016;9: e003978. DOI: 10.1161/CIRCINTERVENTIONS.116.003978.)**

Key Words: biodegradable polymers ■ bioresorbable vascular scaffold ■ coronary artery disease

Bioresorbable vascular scaffolds (BVS) represent a promising novel approach for the treatment of coronary artery disease. Current-generation drug-eluting stents (DES) have improved outcomes of percutaneous coronary interventions (PCI) compared with previous-generation DES and bare metal stents, by substantially reducing rates of in-stent restenosis, stent thrombosis, and need for repeat revascularization.[1,2] However, potential limitations of DES include the permanent presence of both a metallic foreign body within the artery and often a durable polymer, either of which may cause vascular inflammation, neoatherosclerosis, and restenosis or perpetuate the risk of very late stent thrombosis.[3] Moreover, permanent metallic stents indefinitely impair physiological vasomotor function of the vessel and hamper the occurrence of late luminal enlargement and the potential for grafting within the stented segment. BVS promise to address some of these issues. Indeed, they aim to provide a transient scaffolding of the vessel, preventing acute vessel closure/recoil and subsequently disappear. Drug elution by BVS prevents neointimal proliferation in a similar fashion to DES, and complete bioresorption is associated with late vessel lumen enlargement, plaque regression, and restoration of vasomotion. Thus, BVS hold the potential to achieve the paradigm of vascular restoration therapy, restoring both vessel lumen and vascular function.[4–7] The aim of this review is to provide an overview of the current evidence supporting the use of BVS in clinical practice. In

particular, we will discuss about randomized controlled trials and registries evaluating the clinical outcome of these devices, with a special focus on their application in patients with acute coronary syndrome and in specific lesion subsets (bifurcations, chronic total occlusions [CTO], and in-stent restenosis).

Overview of Bioresorbable Vascular Scaffold Devices

Current-generation BVS are composed of either a polymer or a metallic alloy (Table 1 and Figure), and several different platforms are under development or at different stages of evaluation,[5–12] but only 3 have the Conformité Européenne mark for clinical use in coronary artery disease: the Absorb bioresorbable vascular scaffold (BVS; Abbott Vascular) in 2011, the DESolve scaffold (Elixir Medical Corporation) in 2013, and the Magmaris (Biotronik) in 2016.[5,6] The Igaki-Tamai stent (Kyoto Medical Planning, Co, Ltd) also has the Conformité Européenne mark, but only for peripheral use. The Absorb BVS (Abbott Vascular) recently received the US Food and Drug Administration approval.

The Absorb BVS is constituted by a poly-L-lactide backbone covered by a 1:1 mixture of an amorphous matrix of poly-D,L-lactide and the antiproliferative drug everolimus (100 μL/cm^2).[5] The first study, ABSORB cohort A, used a prototype soon replaced by the 1.1 version because of a high rate of early scaffold recoil at 6 months. BVS 1.1 has the same high strut

Table 1. Characteristics of BVS

Basic Material	Poly-Lactid Acid					Magnesium			Other
Scaffold Name	Igaki-Tamai	Absorb BVS 1.0	Absorb BVS 1.1	DESolve	Amaranth	AMS	DREAMS 1.0	DREAMS 2.0	Reva ReZolve
Manufacturer	Kyoto Medical Planning Co, Ltd, Kyoto, Japan	Abbott Vascular, Santa Monica, CA	Abbott Vascular, Santa Monica CA	Elixir Medical Corp, Sunnyvale CA	Amaranth Medical Inc, CA	Biotronik, Berlin, Germany	Biotronik, Berlin, Germany	Biotronik, Berlin, Germany	Reva Medical Inc, San Diego, CA
Composition	PLLA	PLLA	PLLA	PLLA	PLLA	Magnesium and rare earth metals	Magnesium and rare earth metals	Magnesium and rare earth metals	Desaminotyrosine polycarbonate
Design	Zigzag helical coil	Out-of-phase sinusoidal hoops with inks	In-phase zigzag hoops, cross-linked by bridges	Tubularly arranged hoops, linked by bridges	Zigzag hoops, linked by bridges	4-crown design	6-crown design	6-crown design	Slide-and-lock (ratchet)
Strut thickness	170	150	150	150	…	165	120	150	122
Antiproliferative drug	No	Everolimus	Everolimus	Novolimus	No	No	Paclitaxel	Sirolimus	Sirolimus
Resorption time	3 y	≤3 y	≤3 y	1 y	1–2 y	2 mo	9–12 mo	…	2–3 y

BVS indicates bioresorbable vascular scaffolds; and PLLA, poly-L-lactic-acid.

thickness of 150 μm but greater resistance to acute and early recoil and greater conformability and flexibility provided by in-phase zigzag hoops linked by bridges.[5,6] The longer hydrolysis rate translates in a slower mass loss. Indeed, the actual duration of resorption of the second-generation scaffold in vivo is ≈18 months longer than the first generation, and its mass loss takes ≈36 months.[13,14] Reabsorption time is critical for the device performance, with mechanical integrity required for a period of 6 months to avoid vessel recoil.[15] Loss of structural integrity and radial support depends on initial focal degradation within the more amorphous regions, whereas significant mass loss requires much longer, with the polymer replaced by a provisional matrix of proteoglycan followed by collagen fibers.[15]

The DESolve scaffold (Elixir Medical Corporation) is constituted by poly-L-lactide and eluting anti-inflammatory novolimus. Strut thickness is 150 μm, and >95% of the device is resorbed after 1 year. Its advantage, compared with other BVS, is a wider range of expansion, with consequently reduced strut fracture risk and self-correction of minor malapposition.[16] However, DESolve has rather rapid drug release (85% during 4 weeks). Therefore, there are some concerns about its long-term efficacy. Metallic BVS are intuitively attractive because they have potential to perform similar to the conventional metallic stents with respect to profile, deliverability, radial strength in the initial phase, and the advantage of bioresorption subsequently. In particular, magnesium-based metallic BVS such as the Magmaris (Biotronik AG) have been tested as an alternative to polymeric ones.[5,6]

The Absorb BVS is the most widely implanted in the world. Consequently, the largest available amount of evidence for BVS use in clinical practice derives from Absorb trials and registries.
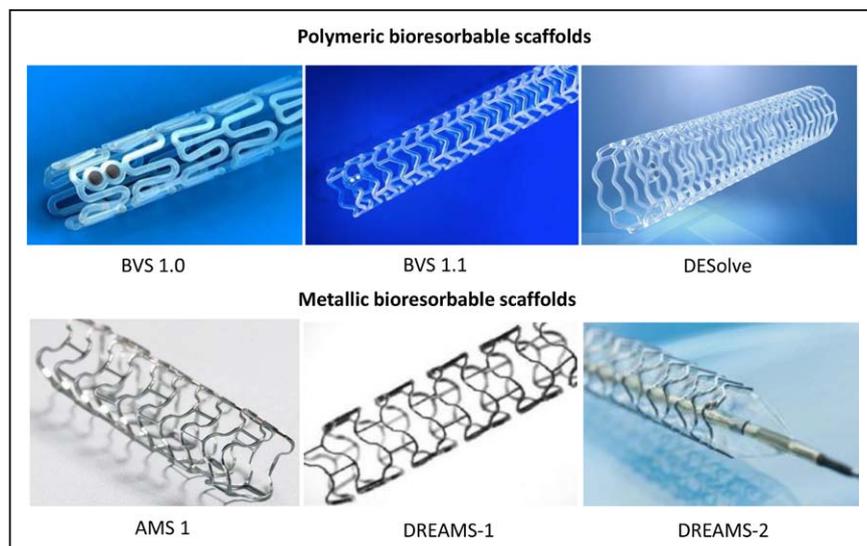

Figure. Current generation of BVS. BVS indicates bioresorbable vascular scaffolds.

Bioresorbable Vascular Scaffold Use in the Clinical Arena: Evidence From the Absorb Trials and Registries

Absorb Trials

The first-in-man study, the ABSORB cohort A study, enrolled 30 patients undergoing implantation of the first-generation (Absorb BVS 1.0) scaffold for the treatment of lesions shorter than 14 mm in 3.0 to 3.5 mm vessels, showing good clinical outcomes but evidence of early scaffold recoil at 6 months,[17] and with excellent 5-year clinical outcomes (3.4% major adverse cardiac event [MACE]).[18] The second-generation BVS 1.1 achieved a greater lumen area at 6 months in the larger ABSORB cohort B (n= 101) with persistently good late clinical outcomes (10.1% MACE and no ST at 3 years).[19,20] To build a body of evidence to support a broader utilization of the Absorb BVS, a prospective, single-arm, open-label clinical study (the ABSORB EXTEND) was designed.[20] The 1-year results were reassuring with a 4.3% MACE, 2.9% myocardial infarction (MI), and 0.8% ST. Similar lesions have been treated in the ABSORB II trial, the first randomized study comparing Absorb BVS with the equivalent metallic DES in 501 patients.[21] The primary end point was nitrate-induced vasomotion and in-stent late loss at 3 years. At 1 year, no significant difference was observed in the prespecified composite secondary clinical outcomes, whereas a lower cumulative rate of recurrent or worsening angina was reported for the BVS. However, final in-stent minimum lumen diameter and intravascular ultrasound minimum lumen cross-sectional area were significantly smaller in the BVS group than that in the Xience group. Also, a trend toward a higher rate of MI and ST was observed in the BVS-treated arm (4.5% versus 1.2% MI; P=0.06 and 0.9% versus 0.0% ST; P=0.55). Because the study included simple lesions with an average length of 20 mm, a 0.9% difference in the ST rate might represent a warning signal, The B-SEARCH registry included 88 patients from the ABSORB cohorts A and B and EXTEND with a reassuringly low event rate (only 1 non–target-vessel revascularization at 1-month follow-up).[22] The recently published ABSORB III,[23] a large, multicenter, randomized clinical trial designed to generate data that could lead to device approval for the Absorb scaffold in the United States, enrolled 2008 patients with stable or unstable angina randomly assigned in a 2:1 ratio to receive an everolimus-eluting Absorb BVS (1322 patients) or an everolimus-eluting cobalt–chromium (Xience) stent (686 patients). This trial demonstrated in the intention-to-treat analysis that target-lesion failure at 1 year occurred in 7.8% of patients in the BVS group and in 6.1% of patients in the Xience group (difference, 1.7%; 95% confidence interval, −0.5 to 3.9; P=0.007 for noninferiority and P=0.16 for superiority). There was no significant difference between the BVS group and the Xience group in rates of cardiac death (0.6% and 0.1%, respectively; P=0.29), target vessel myocardial infarction (6.0% and 4.6%, respectively; P=0.18), or ischemia-driven target-lesion revascularization (3.0% and 2.5%, respectively; P=0.50). Device thrombosis within 1 year occurred in 1.5% of patients in the BVS group and in 0.7% of patients in the Xience group (P=0.13). However, several concerns have been raised about the results of this study.[24] Indeed, in the as-treated analysis, the difference in target-lesion failure (TLF) between the devices was slightly more pronounced (8.0% versus 6.0%). Moreover, the noninferiority margin is large at 4.5% against a background rate of the primary outcome of 6.0% with the metallic stent. Finally, although not statistically different, rate of device thrombosis was double in the BVS group compared with metallic stent group.[24] Of note, a recently published meta-analysis[25] with 6 randomized controlled trials comparing BVS and metallic everolimus-eluting stent (EES; 3738 patients randomized and 2337 patients implanted with BVS) demonstrated that BVS had a higher incidence of subacute definite or probable scaffold thrombosis (odds ratio 1.99 [95% confidence interval, 1.00–3.98]; P=0.05).

Absorb Registries

Data from registries should always be interpreted with caution, especially when evaluating newly introduced devices because they are prone to several biases. However, recent results on Absorb BVS come from registries that, although not having all comers design of other DES registries, are of interest because they include patients and lesion subsets of greater complexity including ST-segment–elevation myocardial infarction, long and/or calcified lesions, CTO, and bifurcations. Interestingly, findings from BVS registries showed ST rates of >2% within the first year after BVS implantation,[26,27] higher than the 1-year ST rate reported for second-generation DES.[1] The GHOST-EU registry involved 10 European centers, enrolling 1189 patients with >50% of American College of Cardiology (ACC)/American Heart Association (AHA) type B2-C lesions treated and using 1731 Absorb BVS (17.3% overlapping stents).[26] The primary outcome, TLF, defined as the combination of cardiac death, target vessel MI, or clinically driven target-lesion revascularization (TLR), reached a cumulative incidence of 2.2% at 30 days and 4.4% at 6 months. Six-months and 1-year ST were 1.5% and 2.1%, respectively. The Amsterdam Medical Center registry[27] reported a high 6-month ST of 3.0%. All the 4 ST events were definite: 2 patients had prematurely interrupted dual antiplatelet therapy (DAPT), whereas in the remaining 2 cases scaffold-induced dissection and scaffold underexpansion were observed. Other studies[28,29] reported no ST events after BVS implantation despite the inclusion of complex lesion subsets (>80% ACC/AHA type B2-C lesions in both studies). These studies compared the performance of BVS with the equivalent metallic DES, reporting a similar and low clinical event rate[28,29] and a similar final lumen area and low percentage of malapposed struts in both arms (BVS 2.1% versus DES 2.4%) at the optical coherence tomography (OCT) analysis.[29] Such positive results in terms of ST were attributed to the aggressive lesion preparation with frequent use of cutting/scoring balloons and routine use of high-pressure postdilation and intracoronary imaging in both studies. Similarly, the recently published 1-year results of the ASSURE registry[30] showed a similar safety profile on a larger population of 183 patients after BVS implantation, with 5% MACE and no ST. Of note, slight BVS oversizing and high-pressure postdilation were key features of this study. Finally, the retrospective analysis of 591 patients in the Polish National registry also reported good short-term results.[31]

Evidence for Other Bioresorbable Devices Deriving From Clinical Trials

At the moment, the DESolve Nx is the only published trial evaluating the DESolve BVS.[16] This trial enrolled 126 patients

showing an acceptable in scaffold late lumen loss (0.21+0.34 mm) at 6 months. An intravascular ultrasound evaluation at 6-month in a subset of 40 patients demonstrated a significant increase in vessel area (17%), mean scaffold area (16%), and mean lumen area (9%). MACE rate was 3.35%, including 1 cardiac death, 1 non–Q-wave MI, and 2 cases of TLR.

The first metallic bioresorbable scaffold implanted in humans is the magnesium alloy scaffold studied in PROGRESS-AMS (Clinical Performance and Angiographic Results of Coronary Stenting with Absorbable Metal Stents) trial. PROGRESS-AMS was a prospective, nonrandomized study where 71 magnesium scaffolds were implanted in 63 patients with de novo native coronary artery lesions.[32] The immediate angiographic results were similar to those of other metallic stents. However, with this first-generation bare metal device, radial support was lost too early, within only a few weeks. Consequently, the restenosis rate at 4 months was high with 47.5%. The target vessel revascularization rate reached 23.8%.

The drug-eluting bioresorbable metal scaffold-1 that eluted paclitaxel (0.07 mg/mm^2) for the first 3 months was tested in the BIOSOLVE-1 study, showing good safety (1 case of MI, no death, and no stent thrombosis) and efficacy at 12 months.[33] The second-generation device, drug-eluting bioresorbable metal scaffold-2, has been further optimized, with a 6-crown, 2-link design, 150-mm strut thickness, radiopaque marker at both ends, and a thin poly-L-lactide–based carrier to deliver a more potent antiproliferative drug (sirolimus) and tested in the BIOSOLVE-II trial[34] in patients with stable or unstable angina or documented silent ischemia. Routine angiographic surveillance at 6 months revealed a mean in-segment late lumen loss of 0.27+0.37 mm and discernible vasomotion in 80% of 25 tested patients. Intravascular ultrasound and OCT showed preservation of the scaffold area, a low mean neointimal area, and no intraluminal masses. Overall, TLF occurred in 4 patients (3%) with no definite or probable scaffold thrombosis observed.

Evidence for BVS Use in Patients With Acute Coronary Syndromes

Thick BVS struts could potentially facilitate the entrapment of stratified thrombotic material, a phenomenon known as the snow racket.[35,36] Kajiya et al[37] first reported results from 11 acute coronary syndromes (ACS) patients undergoing primary PCI; only 1 patient died (presented with cardiogenic shock) and no other MACE occurred up to the 1-month follow-up. A slightly longer follow-up (median 137 days) was performed in 25 ACS patients.[38] Total MACE was 8.3%, with 1 case of stent thrombosis. The authors reported that during the index procedure, a dissection distal to the implanted scaffold was successfully treated by balloon angioplasty. The thrombotic event occurred 2 days later at the site of the previously treated dissection. Recently, an investigator-initiated, prospective, single-arm, single-center study[35] aimed at assessing the second-generation everolimus-eluting BVS for the treatment of 49 ST-segment–elevation myocardial infarction (STEMI) patients has been reported. The procedural success was 97.9% and preprocedural Thrombolysis in Myocardial Infarction (TIMI) flow was 0 in 50% of the patients. After BVS implantation, TIMI 3 flow was achieved in 91.7% of patients and the postprocedural percentage diameter stenosis was 14.7±8.2. No patients had angiographically visible residual thrombus at the end of the procedure. At the 30-day follow-up, the TLF rate was 0%. Non–target-vessel revascularization, target-vessel MI, and non–target-vessel non–Q-wave MI were not reported nor any case of cardiac death or scaffold thrombosis. The Prague 19 Registry,[39] a prospective multicenter open-label study, analyzed the feasibility and safety of BVS implanted during primary PCI. Of note, the study also focused on the practical question of what proportion of consecutive STEMI patients are suitable candidates for Absorb BVS implantation. Forty-one of 142 patients (28.9%) treated with primary PCI fulfilled the inclusion–exclusion criteria for BVS implantation. The BVS device success rate was 98%, TIMI 3 flow was restored in 95% of patients, and acute scaffold recoil was 9.7%. Clinical outcomes were comparable with those of a control group formed by patients who had implanted metallic stents and were in Killip class I or II. Event-free survival was also similar in both groups: 95% for the BVS group and 93% for the control group (P=0.674).

The Polish Absorb Registry for ACS Patients (POLAR ACS)[40] is a multicenter registry of 100 patients presenting with ACS (STEMI=16) and treated with BVS. BVS resulted in a decrease in the mean corrected TIMI frame count and improvement in final TIMI flow (TIMI 3 in 99%). The in-hospital MACE rate was 3%. At 1 year, there were no deaths, 3.2% MI, 1.1% non–target-vessel revascularization, 1.1% hospitalization for heart failure, and 1 case of stent thrombosis (1.1%), caused by discontinuation of DAPT. Gori et al[41] compared 150 consecutive patients with ACS (194 lesions) (STEMI 44%) treated with BVS with a control group composed of 103 consecutive patients (129 lesions) who underwent DES implantation in the same time period. In-hospital, 30-day and 6-month MACE rates were similar in both groups (all P>0.5), with most complications occurring during the first 10 days. Definite or probable in-stent/scaffold thrombosis was 1.4% in the BVS group and 1% in the DES group during the index admission, and 2% and 1.9%, respectively, in the first month after BVS/DES implantation. Of note, in the multivariate analysis, BVS was not associated with the incidence of MACE (P>0.9). More recently, Kochman et al[42] performed an OCT assessment of acute procedural results of BVS implantation in 23 STEMI patients, also evaluating midterm clinical outcomes. Procedural and clinical success rates were 95.7%, whereas the device success rate was 100%. In a post-PCI OCT evaluation, most of the struts (95.4±7.96%) were well apposed. The final minimum lumen diameter was 2.6±0.35 mm, minimum scaffold area was 6.98±1.54 mm^2 and final residual stenosis was 8.8±24.37%. In a median follow-up period of 229 (range 199–248) days, 1 MI, caused by subacute stent thrombosis, occurred in a patient who discontinued DAPT. In addition, the multicenter prospective RAI Registry[43] has recently been published, reporting compelling data from a population of 74 STEMI patients. A high procedural success rate has been observed (97.3%) and low rates of TLR and stent thrombosis (4.1% and 1.3%, respectively) at 6-month follow-up. Interestingly, the investigators could not find any significant difference in outcomes comparing the patients with multiple overlapping BVS during primary PCI to those with single BVS implantation. Recently, the BVS-EXAMINATION study[44]

Table 2. Main Clinical Data of Current-Generation BVS

Scaffold	Clinical Study	Number of Patients	TLR	Lumen Late Loss, mm	Scaffold Thrombosis (Definite/Probable)	MACE
Polymeric						
Igaki-Tamai	Igaki-Tamai study[7]	15	6.7% at 6 mo	0.48 at 6 mo	13.3% at 10 y	50% at 10 y
			16% at 12 mo			
			28% at 10 y			
BVS 1.0	ABSORB Cohort-A[18]	30	0% at 6 mo	0.44 at 6 mo	0.0% at 5 y	3.4% at 5 y
BVS 1.1	ABSORB Cohort-B[19,20]	101	3.6% at 12 mo	0.19 at 6 mo 0.27 at 12 mo	…	9.0% at 2 y 10.0% at 3 y
	ABSORB II[21]	335	1% at 12 mo	…	0.9% at 12 mo	5% at 12 mo
	ABSORB III[23]	1322	7.8% at 12 mo	…	1.5% at 12 mo	…
	ABSORB China[8]	238	2.9% at 12 mo	0.24 at 12 mo	0.4% at 12 mo	3.8% at 12 mo
	ABSORB Japan[9]	266	4.2% at 12 mo	0.19 at 13 mo	1.5% at 12 mo	9.8% at 12 mo
	EVERBIO II[10]	80	10% at 9 mo	0.28 at 9 mo	0.0% at 9 mo	27% at 9 mo
	TROFI II[45]	95	1.1% at 6 mo	0.17 at 6 mo	1.1% at 6 mo	1.1% at 6 mo
DeSolve	DESolve Nx[16]	15	0% at 12 mo	0.19 at 6 mo	0% at 12 mo	0% at 12 mo
Reva	RESORB[11]	27	66.7% at 6 mo	1.81 at 6 mo	…	…
ReZolve	RESTORE[12]	50	2 out of 12 at 6 mo	0.20 at 12 mo (only 8 patients)	…	2 out of 12 at 6 mo
Metallic						
AMS-1	PROGRESS-AMS[32]	63	38% at 4 mo 45% at 12 mo	1.08 at 4 mo	0% at 12 mo	…
DREAMS-1	BIOSOLVE-I[33]	46	4.3% at 6 mo 6.8% at 24 mo	0.64 at 6 mo 0.52 at 12 mo	0.0% at 36 mo	6.8% at 24 mo
DREAMS-2	BIOSOLVE-II[34]	123	3% at 6 mo	0.27 at 6 mo	0% at 6 mo	…

MACE indicates major adverse cardiac events; and TLR, target-lesion failure.

compared 290 STEMI patients treated by BVS with either 290 STEMI patients treated with EES or 290 STEMI patients treated with BMS, by applying propensity score matching. In particular, individual data from 6 different high-volume centers with large experience in BVS implantation in STEMI were collected, allowing us to have the currently largest cohort of STEMI patients treated with BVS. We showed that the cumulative incidence of device-oriented end point, including cardiac death, target-vessel MI, and TLR did not differ between the BVS and EES or BMS groups either at 30 days (3.1% versus 2.4% versus 2.8%, respectively) or 1 year (4.1% versus 4.1% versus 5.9%, respectively). Definite/probable BVS thrombosis rate was numerically higher either at 30 days (2.1% versus 0.3% versus 1.0%, respectively) or 1 year (2.4% versus 1.4% versus 1.7%), as compared with EES or BMS. Moreover, with regard to procedural characteristics, the BVS and metallic device groups differed in device implantation technique, with higher use of pre- and postdilation in the BVS than in the other groups. Of note, whereas preprocedural TIMI flow was lower in the BVS than in the EES group, postprocedural TIMI flow did not differ among the groups. Finally, the recently published ABSORB-TROFI II Study,[45] a multicenter, single-blind, noninferiority, randomized controlled trial enrolled STEMI patients undergoing primary PCI randomly allocated 1:1 to treatment with the BVS or EES (Table 2). The primary end point was the 6-month OCT frequency domain imaging healing score based on the presence of uncovered and/or malapposed stent struts and intraluminal filling defects. Main secondary end point included the device-oriented composite end point according to the Academic Research Consortium definition. At 6 months, healing score was lower in the Absorb arm when compared with EES arm (1.74 [2.39] versus 2.80 [4.44]; difference [90% confidence interval] 21.06 [21.96–20.16]; P for noninferiority=0.001). Device-oriented composite end point was also comparably low between groups (1.1% BVS versus 0% EES). One case of definite subacute stent thrombosis occurred in the BVS arm (1.1% versus 0%; P=ns).

Bioresorbable Vascular Scaffold Use in Different Lesion Subsets

BVS in Bifurcations

Bifurcation lesions are an important part of routine PCI, and the advent of BVS adds new possibilities for the treatment of bifurcation lesions.

Coronary bifurcations that have side branches >2 mm with BVS have been considered off-label and excluded from the pivotal BVS studies. However, bifurcations may still be associated with higher event rates than nonbifurcation lesions, and

concerns remain about implanting 2 stents in the bifurcation and about the risks of excess metal at the carina. Indeed, the absence of a permanent metallic cage as the scaffold reabsorbs and the restoration of normal bifurcation anatomy, flow, and vascular function may result in the unjailing of side branches (SB), less shear stress, and a decreased risk of late complications, in particular scaffold thrombosis.[46,47] Potential limitations in treating bifurcations with BVS are the larger profile, decreased deliverability, increased strut thickness, which limit the performance of certain bifurcation techniques, and limited tolerance to postdilatation (0.5 mm) that affects the performance of bifurcation optimization techniques such as dilatation toward the SB and final kissing balloon inflation because of the risk of strut disruption.[47,48]

Despite an initial hesitancy, many centers have explored and evaluated the techniques for treating bifurcations with these new devices. The large multicenter GHOST-EU (Gauging coronary Healing with biOresorbable Scaffolding plaTforms in EUrope) registry offers a glimpse of the real-world experience with BVS.[26] In 27% of patients, an Absorb BVS was implanted at a bifurcation lesion. Almost half of the bifurcation lesions treated were true bifurcations, and the left anterior descending diagonal artery bifurcation was the most common bifurcation treated. More than 80% of bifurcations were treated with a provisional approach of only the main branch with crossover to stenting of the SB in about 5% of cases. Final kissing balloons inflation was performed in 18% and sequential SB–main branch dilatation in 5% of bifurcations. However, significant overlapping of the kissing balloons in the main branch scaffold should be avoided and can result in scaffold disruption. Final kissing balloons inflation performed at low pressure with minimal protrusion of the SB balloon is feasible and does not seem to be associated with in vivo scaffold disruption.[49] Ormiston et al[50] have shown that an inflation pressure of 5 atm is a safe threshold for two 3.0-mm noncompliant balloons in a 3.0-mm scaffold. However, it must be noted that some operators prefer sequential SB and main branch dilatation rather than kissing balloon technique, to avoid scaffold disruption and excessive elliptical expansion with kissing balloons. As in the use of metallic stents, the T and protrusion technique has been suggested as the preferred strategy for crossover from provisional when the SB needs to be stented.[50,51] The T and protrusion technique is easy to perform and results in complete coverage of the ostium without excessive overlapping struts. T-stenting techniques are the first choice for planned double BVS implantation while the culotte and crush techniques should be avoided to prevent excessive overlapping of the thick struts and structural deformation of the scaffold. However, T-stenting requires precise SB scaffold placement and a favorable bifurcation angle close to 90°.[49]

BVS in Chronic Total Occlusions

Coronary CTO currently represents the most challenging type of lesion for PCI. Although technological improvements and the development of specific skills by the operators have considerably increased the success rate, it continues to be low compared with non-CTO PCI.[52] In addition, after recanalization, a long coronary segment must usually be stented. It is known that the stented length is a strong predictor of events at follow-up, such as stent thrombosis and need for repeat revascularization.[53,54] Additionally, the permanent caging of the artery inhibits the recovery of the physiological properties of the vessel. In CTO PCI, BVS could have obvious advantages compared with metallic stents by fully avoiding the problems arising from having permanent metal caging in the vessel.[5] When an occluded artery is reopened, it may be difficult to know the true size of the vessel. Moreover, segments distal to a successfully recanalized CTO can show significant lumen and vessel enlargement at follow-up.[55] Both facts can lead to an underestimation of the diameter of the chosen stent with the resulting risk of late stent malapposition and stent thrombosis.[56] The disappearance of the scaffold struts implies the liberation of the vessel, and therefore, this problem can be avoided. Despite the advantages described, the BVS approach in CTO is not exempt from difficulties. The crossing profile is 1.4 mm, and the crossability is worse compared with the new DES. This aspect is especially relevant in this type of lesion where the calcification and tortuosity of the vessel are frequent.

Recently, the ABSORB-CTO registry (35 patients with true CTO lesions)[57] clearly showed that BVS use in this subset is feasible with a good midterm efficacy. Indeed, all scaffolds were successfully delivered and deployed, without any strut malapposition at postprocedural OCT analysis. Moreover, at 6-month follow-up, multislice computed tomography identified only 2 cases of scaffold reocclusion, without any major adverse event. Safety and feasibility of BVS implantation in CTO has been confirmed also in other registries.[58,59]

BVS in In-Stent Restenosis

The use of DES for the treatment of in-stent restenosis (ISR) have raised concerns about the risk of adding additional layers of stents into the arterial wall, thus predisposing patients to an increased risk of stent thrombosis.[60] Drug-eluting balloon has been proposed as a valid alternative to current DES, thanks to the ability to elute the antiproliferative drug without the long-term limitation of adding a further layer of struts. However, drug-eluting balloon are limited by the shorter therapeutic window of the antiproliferative drug, by a greater late lumen loss compared with new-generation DES,[61,62] and the frequent need for bail-out stenting because of the occurrence of flow-limiting vessel dissection. Moreover, as shown by the early results of the RIBS IV trial, the use of drug-eluting balloon is also associated with poorer clinical outcome when compared with EES for the treatment of DES ISR.[63] On the basis of this background, the BVS could represent an attractive treatment option for ISR as it provides transient vessel scaffolding combined with drug delivery capability, avoiding the long-term limitations of permanent metallic stents. On the contrary, the use of this new device in the complex ISR setting might be limited by the actual thickness (150 μm) of the BVS struts, particularly in case of implantation in small restenotic vessels. Furthermore, the presence of the previously implanted metallic struts may partially attenuate the potential benefits associated with the BVS resorption.

Of interest, a recently published multicenter registry[64] evaluating 83 selected patients (90 lesions) undergoing ISR treatment by BVS implantation reported that procedural success was achieved in all patients, and at a median of 7-month

(interquartile range 3–18) follow-up major adverse cardiac and cardiovascular events rate was 12%, TLR 7.7%, whereas only 1 (1.1%) definite BVS in-stent thrombosis occurred. Of note, favorable clinical results were independent from the type of ISR lesion (focal or diffuse, de novo or recurrent, BMS or DES ISR).

Current Status Between Promises and Pitfalls of BVS

Globally, the use of BVS has been relatively hindered by several concomitant issues[65]:

1. The high cost of the device, that is particularly true in countries where the cost of the commercially available DES is particularly low;
2. the lack of an appreciable advantage, on a clinical ground, as compared with current DES;
3. the evidence of an increased risk of stent thrombosis;
4. the unclear duration of DAPT.

The higher cost of the BVS is attributable to the investments made by the manufacturers in the past decade, and it will probably follow the same pattern followed by the DES, that is, the cost is destined to progressively drop once the share of the BVS technology will be high enough and the evidence of benefit robust. However, there are countries in which the cost is not an issue (for example the Middle East Countries) as the implantation of a DES or a BVS does not imply a significant difference in terms of cost.

As for the clinical benefit as compared with DES, there is a general need for change in terms of the time-window we consider to assess the benefit of the restoration therapy. In other words, it is not conceivable to observe, at least with the current generation of BVS, a meaningful clinical benefit against DES at short term. The expected advantage will be measurable only at long term, that is, when the BVS will be resorbed and the risk of device-related long-term events would be nullified.

At short term, it is not a surprise that current DES perform well in comparison with BVS. Current DES are forgiving toward procedural optimization because of their thin struts in combination with drug-delivery systems promoting rapid endothelialization. The specific features of current Absorb BVS with stent struts that are 157 µm thicker and also wider when compared with DES (2.5- and 3.0-mm BVS: 190.5 mm; 3.5-mm BVS: 215.9 mm) results in greater protrusion of struts causing loss of laminar flow, with areas of oscillatory shear stress promoting platelet activation.[66] These physical attributes require the scaffold to be fully postdilated to embed the struts deeply in the wall of the vessel to avoid any malapposition and favoring rapid endothelialization. Additionally, it is of paramount importance to achieve the largest possible lumen cross-sectional area. Many studies (with both metal stents and scaffolds) identify a small final lumen cross-sectional area as a predictor of ST.[67]

The Virchow triad for thrombogenesis can be almost completely controlled by the operator.[65] The doctor can optimize: (1) the lumen with appropriate pre- and postdilation; and (2) the flow by selecting the appropriate vessel (with adequate size, run-off, without myocardial bridging and supplying viable myocardium). The third element of the triad—the optimal modulation of blood thrombogenicity with DAPT—remains uncertain. DAPT after stent implantation is mandatory to reduce the risk of ST; however, despite the recent findings showing a relationship between ST and the degree of platelet inhibition,[68] it is still unclear how to individualize antiplatelet therapy. In other words, although 12 months seems to be the minimum, there are no evidence supporting a prolongation of DAPT.

A possible approach, in patients at low risk of bleeding, is to consider the implantation of BVS as an element supporting a prolonged DAPT.

Conclusions

BVS represent a novel promising approach for the treatment of coronary artery disease, and they are increasingly used in different clinical scenarios based on the promise that complete bioresorption is associated with late vessel lumen enlargement, plaque regression, and restoration of vasomotion.

Recently published meta-analysis showed an increased incidence of subacute scaffold thrombosis with BVS compared with everolimus-eluting metallic stents. However, an optimal implantation technique may overcome this limitation and favor the large-scale implementation of this new technology that intends to be the future mainstream in the treatment of coronary artery disease.

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Disclosures

None.

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Coronary Bioresorbable Vascular Scaffold Use in the Treatment of Coronary Artery Disease

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Correction

In the article by Testa et al (Testa L, Latib A, Montone RA, Colombo A, Bedogni F. Coronary bioresorbable vascular scaffold use in the treatment of coronary artery disease. *Circ Cardiovasc Interv*. 2016;9:e003978. DOI: 10.1161/CIRCINTERVENTIONS.116.003978.), which published online on July 13, 2016, and appeared in the July 2016 issue of the journal, a correction was needed.

On page 5, in Table 2, row DeSolve, column Number of Patients, "120," column TLR, "6.25% at 12 mo," column MACE, "18.75% at 12 mo," has been changed to read "15; 0% at 12 mo; 0% at 12 mo," respectively.

This correction has been made to the article, which is available at http://circinterventions. ahajournals.org/content/9/7/e003978.