Absorb bioresorbable vascular scaffold: What have we learned after 5 years of clinical experience?

Gianluca Caiazzo [a,b], Ismail Dogu Kilic [b], Enrico Fabris [b,e], Roberta Serdoz [b], Alessio Mattesini [c], Nicolas Foin [d], Salvatore De Rosa [a], Ciro Indolfi [a], Carlo Di Mario [b,*]

[a] Division of Cardiology, Department of Medical and Surgical Sciences, "Magna Graecia" University, Catanzaro, Italy
[b] Cardiovascular National Institute of Health Research Biomedical Research Unit, Royal Brompton & Harefield NHS Foundation Trust, London, United Kingdom
[c] Department of Heart and Vessels, AOUC Careggi, Florence, Italy
[d] National Heart Centre Singapore, Singapore
[e] Cardiovascular Department, "Ospedali Riuniti" & University of Trieste, Trieste, Italy

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ABSTRACT

Bioresorbable scaffolds have the potential to introduce a paradigm shift in interventional cardiology, a true anatomical and functional "vascular restoration" instead of an artificial stiff tube encased by persistent metallic foreign body. Early clinical studies using the first commercially available drug-eluting bioresorbable vascular scaffold (BVS) reported very promising safety and efficacy outcomes, comparable to best-in-class second-generation drug-eluting metal stent. To date, more than 60,000 Absorb BVSs have been implanted with only the interim analysis of one randomized trial (ABSORB II RCT) available. Recent registries have challenged the initial claim that BVS is immune from Scaffold Thrombosis (ST). However, suboptimal device expansion and insufficient intracoronary imaging guidance can explain higher than expected ST, especially in complex lesions. The aim of this review article is to critically evaluate the results of the available Absorb BVS studies and discuss the lessons learned to optimize lesion selection and implantation technique of such devices.

1. Introduction

Several bioresorbable scaffolds have been proposed and have now reached clinical testing but only for the Absorb (Abbott Vascular, Santa Clara, CA, USA) bioresorbable vascular scaffold (BVS) a considerable amount of clinical data is available to date [1,2]. First-in-man studies on small and highly selected cohorts, using multimodality intracoronary imaging, have confirmed the timing of the reabsorption process and suggested good safety and efficacy [3,4]. These initial favorable results have been challenged by "real world" registries showing high Scaffold Thrombosis (ST) rates [5–8]. With the fast approaching milestone of 100.000 implanted Absorb BVS and the prediction that more than 50% stents will be BVS by 2017, it is essential to learn from critically reviewing the many studies and registries and the only one randomized trial available to possibly correct current pitfalls in the implantation technique of such devices [9].

Abbreviations: ACS, acute coronary syndrome; BVS, bioresorbable vascular scaffold; DES, drug eluting stent; MACE, major adverse cardiovascular events; MI, myocardial infarction; ST, stent/Scaffold Thrombosis; TLF, target lesion failure; TLR, target lesion revascularization; TVF, target vessel failure; TVR, target vessel revascularization.

* Corresponding author at: NIHR Cardiovascular BRU, Royal Brompton Hospital, Sydney Street, London SW3 6NP, United Kingdom.
E-mail address: c.dimario@rbht.nhs.uk (C. Di Mario).

2. ABSORB bioresorbable vascular scaffold

2.1. The device

The ABSORB BVS is constituted by a poly-L-lactide (PLLA) backbone covered by a 1:1 mixture of an amorphous matrix of poly-D,L-lactide (PDLLA) and the anti-proliferative drug everolimus (100 μl/cm^2) [2]. The first proof of concept study (ABSORB cohort A) used a prototype soon replaced by the 1.1 version, storable at room temperature, with the same high strut thickness of 150 μm but greater resistance to acute and early recoil [10–12] and greater conformability and flexibility provided by in-phase zigzag hoops linked by bridges [13] (Fig. 1). The longer hydrolysis rate translates in a slower mass loss; the actual duration of resorption of the second generation scaffold in vivo is approximately 18 months longer than the first generation, and its mass loss takes approximately 36 months [14]. Reabsorption time is critical for the device performance, with mechanical integrity required over a period of 6 months to avoid recoil [15]. Loss of structural integrity and radial support depends on initial focal degradation within the more amorphous regions, while significant mass loss requires much longer, with the polymer replaced by a provisional matrix of proteoglycan followed by collagen fibers [16]. The reabsorption process has also been studied with Optical Coherence Tomography (OCT) showing progressive strut degradation [17].

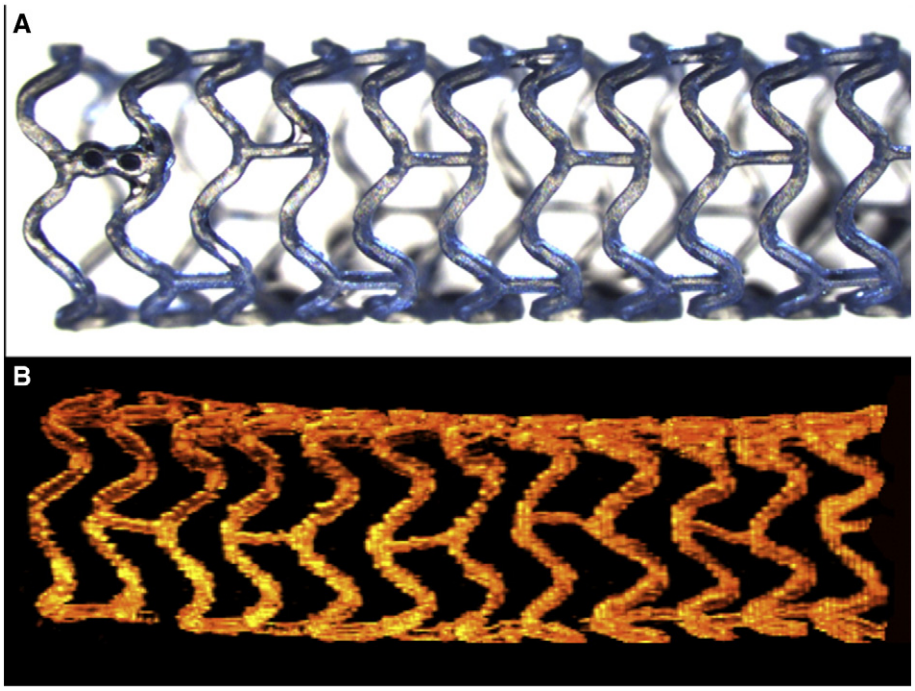

Fig. 1. Absorb BVS structure and design. High-resolution microscope image of a 3.0 mm BVS inflated at nominal pressure (panel A); BVS structure at OCT 3D reconstruction (panel B).

2.2. Landmark studies — the ABSORB program

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 3.0–3.5 mm vessels [2] and showed good clinical outcomes but evidence of early scaffold recoil at 6 months. Of note, the invasive imaging (IVUS and OCT) analysis at 2 years demonstrated late lumen enlargement with restoration of vasoreactivity [2,3]; recently, excellent 5-year clinical outcomes (3.4% MACE) have been reported [18]. The improved BVS 1.1 version 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) [10,14]. In order 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 [19]. The one-year results were reassuring with a 4.3% MACE, 2.9% MI and 0.8% ST. To date, the three-year follow-up data of 250 patients implanted with BVS in the ABSORB EXTEND study showed 9.3% cumulative MACE, with 6.0% TLR and 1.2% definite/probable ST rate (see Table 1). Similar lesions have been treated in the ABSORB II trial, the first randomized study comparing Absorb BVS with the equivalent metallic drug-eluting stent (DES) in 501 patients [9]. The primary endpoint was nitrate induced vasomotion and in-stent late loss at 3 years. At 1-year no significant difference in the prespecified composite secondary clinical outcomes was observed, while a lower cumulative rate of recurrent or worsening angina was reported for the Absorb. However, final in-stent minimum lumen diameter and IVUS minimum lumen cross-sectional area were significantly smaller in the Absorb group than in the Xience group. Also, a trend towards a higher rate of MI and ST was observed in the Absorb-treated arm (4.5% vs 1.2% MI p = 0.06 and 0.9% vs 0.0% ST p = 0.55). Since the study included simple lesions with an average length of 20 mm, a 0.9% difference in the ST rate might represent a worrisome signal, given the catastrophic clinical consequences of ST. The B-SEARCH registry included 88 patients from the ABSORB cohorts A and B and EXTEND with a reassuringly low event rate (only one non-TVR at 1-month follow-up) [20]. New studies included in the ABSORB program (ABSORB III [NCT01751906], ABSORB FIRST [NCT01759290], etc.) are currently

Table 1
The ABSORB program — manufacturer-sponsored studies.

Study	Study design	Phase	N	Reported FU
ABSORB cohort A	Observational, prospective	Completed	30	5 years
ABSORB cohort B	Non-randomized, open label	Completed	101	3 years
ABSORB EXTEND	Observational, prospective	Active, not recruiting	1000	3 years[a]
ABSORB II	Randomized, single blind	Active, not recruiting	330	1 year
ABSORB physiology[b]	Randomized, single blind	Terminated	35	N/A
ABSORB FIRST	Observational, prospective	Recruiting	1800	1 month
ABSORB III	Randomized, single blind	Recruiting	1502	N/A
ABSORB IV	Randomized, single blind	Recruiting	3000	N/A
ABSORB Japan	Randomized, single blind	Active, not recruiting	265	N/A
ABSORB China	Randomized, open label	Active, not recruiting	200	N/A
ABSORB UK	Observational, prospective registry	Recruiting	1000	N/A

[a] Smits PC. ABSORB EXTEND: An Interim Report on the 36-month Clinical Outcomes from the First 250 Patients Enrolled. Presented at: TCT Congress; September 13, 2014; San Francisco, USA.

[b] Only 1 patient recruited; Eeckhout E. ABSORB FIRST: An interim report on baseline characteristics and acute performance on the first 1200 patients from a prospective, multi-center, global registry. Presented at: TCT 2014, San Francisco, USA. N = number of patients; FU = Follow-Up; N/A = not available.

ongoing to evaluate the Absorb BVS in different populations and lesion subsets (Table 1).

2.3. Registries

Data from registries should always be interpreted with caution, especially when evaluating newly introduced devices, since they are prone to several biases. However, very recent results on Absorb BVS come from registries that, although not having "all comers" design of other DES registries, are of interest since they include patients and lesion subsets of greater complexity including ST-segment elevation myocardial infarction, very long and/or calcific lesions, chronic total occlusions (CTO) and bifurcations (Tables 2 and 3, see also Electronic Appendix). Interestingly, findings from BVS registries showed greater than 2% rates of ST within the first year after BVS implantation (Tables 2 and 3) [5–8], higher than the 1-year ST rate reported for second-generation DES [21].

The GHOST-EU registry involved 10 European centers, enrolling 1189 patients with over 50% of ACC/AHA type B2-C lesions treated and using 1731 Absorb BVS (17.3% overlapping stents) [6]. The primary outcome, TLF defined as the combination of cardiac death, target vessel MI, or clinically driven TLR, reached a cumulative incidence of 2.2% at 30 days and 4.4% at six months. Six-months and 1 year ST were 1.5% and 2.1%, respectively (Table 3). The Amsterdam Medical Center registry [5] reported a high 6-month ST of 3.0%. All the four ST events were definite: two patients had prematurely interrupted dual antiplatelet therapy (DAPT), while in the remaining two cases scaffold-induced dissection and scaffold under-expansion were observed. Other groups [22, 23] reported no ST events after BVS implantation despite the inclusion of complex lesion subsets (over 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 [22,23] and a similar final lumen area and low percentage of

Table 2
Procedural characteristics and definite/probable ST among early studies and registries.*.

Study	B2+C[a] (%)	Pre-dilatation (%)	Post-dilatation (%)	Post-dilatation (max atm)	IVUS (%)	OCT (%)	ST (1-12 months) (%)
ABSORB cohort A	35	100	N/A	N/A	83.3	23.3	0
ABSORB cohort B	43.6	100	N/A	N/A	90.1	45.8	0
ABSORB EXTEND 1y	43.4	100	68.4	N/A	N/A	6.25[x]	0.8
ABSORB II RCT	45.5	100	60.7	14.2	100	0	0.9
B-SEARCH registry	32.6	100	55	N/A	34	0	0
AMC registry	67.2	98	55	14.4	5	20	3.0
ASSURE registry	64.7	99	12.6	17.3	0	0	0
Costopoulos et al.	83.9	97.8	99.3	20.9	82.5	21.2	0
GHOST-EU registry	51.2	98	49	N/A	14.4	13.8	2.1
Mattesini et al.	100	100	100	21.3	0	100	0

ACS studies and studies reporting in-hospital outcomes only are not included; [a]B2 + C = B2 and C type lesions; cohorts B1 + B2; [x]Planned OCT subgroup (50 out of 800 pts). IVUS = intravascular ultrasound; OCT = Optical Coherence Tomography; ST = Scaffold Thrombosis; N/A = not available. Orange = "ideal world" studies; BLU = "real world" studies.

Table 3
Clinical outcomes among early studies and registries within 12-months follow-up.*.

Study	N	FU	Cardiac death (%)	MI (%)	TLR (%)	ST (%)	MACE[â] (%)
ABSORB Cohort A	29	12	0	3.4	3.4	0	3.4
ABSORB Cohort B	101	12	0	3.0	4.0	0	7.1
ABSORB EXTEND 1y	512	12	0.4	2.9	1.8	0.8	4.3
ABSORB II RCT	335	12	0	4.5	1.2	0.9	5.1
B-SEARCH registry	88	1	0	0	0	0	0
AMC registry	134	6	0.8	3.0	6.3	3.0	N/A
ASSURE registry	183	6	0.5	1.7	2.8	0	5.0
Costopoulos et al.	92	6	0	0	3.3	0	3.3
GHOST-EU registry	1731	6	1.0	2.7	2.5	2.1	N/A
Mattesini et al.	50	8.5	0	2.8	0	0	N/A
RAI registry	74	6	0	2.7	4.1	1.3	N/A
BVS STEMI	49	1	0	2.6	0	0	2.6
POLAR ACS	100	12	0	3.0	2.0	1.0	N/A
PRAGUE 19	41	9	0	2.4	2.4	2.4	N/A
Gori et al.	150	6	1.4	4.0	N/A	2.7	10.7
Kajiya et al.	11	1	9.1	0	N/A	0	9.1
Wiebe et al.	24	4.4	4.2	4.2	0	0	8.3

*1–12-month results are listed since only few studies with reported longer follow-ups were available; Studies reporting in-hospital outcomes only are not included; [â]Ischaemia-driven adverse events; Unstable angina only. N = number of patients; FU = follow-up; MI = myocardial infarction; TLR = target lesion revascularization; ST = definite/probable ST; MACE = major adverse cardiovascular event(s); N/A = not available. Orange = "ideal world" studies; BLU = "real world" studies; GREEN = ACS studies.

malapposed struts in both arms (BVS 2.1% vs DES 2.4%) at the OCT analysis [23]. Such encouraging 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 (Fig. 2). Similarly, the very recently published 1-year results of the ASSURE registry [24] 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 [25].

2.4. ACS registries

Thick BVS struts could potentially facilitate the entrapment of stratified thrombotic material, a phenomenon known as the "snow racket" concept [26,27]. Initial experiences by Kajiya et al. and Wiebe et al. reported satisfactory short-term results (11 and 25 patients, respectively) [28,29]. The "Prague 19" study [7], comparing Absorb to metal stents in STEMI patients, reported only 2 adverse events in the BVS arm, with only one sub-acute ST documented at OCT. Similar good clinical outcomes were observed in the BVS STEMI study (n = 49) [26] where the OCT analysis also revealed a low malapposition rate. The same

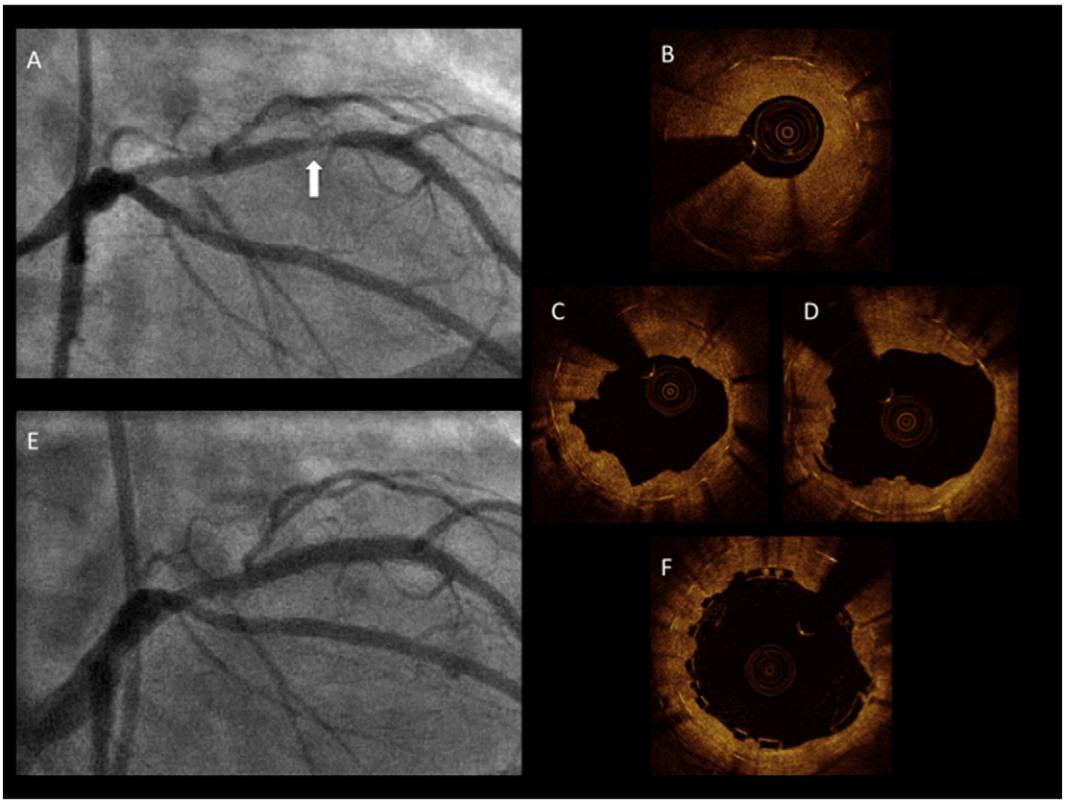

Fig. 2. Absorb BVS in a complex lesion. Angiographic (panel A) and OCT (panel B) views of an in-stent restenosis (see the arrow in panel A) twenty-seven months after drug-eluting stent implantation. The OCT shows the sub-optimal results after dilatation of the lesion with a cutting balloon and then with a drug-eluting balloon (panels C and D). Panels E and F show a good final result after Absorb BVS deployment at both angiographic and OCT assessment.

comparison was performed in the largest study to date involving ACS patients (n = 253) [8]. The six-month MACE rate was similar in both arms (all p > 0.5). However, a similarly a high definite/probable ST rate was reported: 2.7% in the BVS group vs 2.9% in the DES group. Two out of the three thrombotic events had incomplete expansion of the BVS at OCT analysis as a possible explanation. Some registries have been designed in order to address specific issues related to the Absorb. In-stent late lumen loss (LLL) measured at QCA was the primary endpoint in the EVERBIO II (NCT01711931), a single-center, randomized study comparing three different typologies of DES in a broader setting of lesions [30]. The 9-months interim analysis results couldn't find any significant difference in LLL, but in-segment LLL was significantly higher in the Absorb BVS compared to EES/BES group (Cook S. Comparison of EES and BES with BVS — the randomized controlled EVERBIO II trial. Presented at: TCT 2014; September 16, 2014; San Francisco, USA). The transitory constrictive effect found by Gogas et al. [31] as well as an increase in neo-intimal proliferation at the scaffold proximal edge have been proposed as possible explanations [32]. BVS overlapping has been investigated in the RAI registry which recently reported a low TLR of 4,1% and a ST of 1,3% at six-months follow-up in a population of 74 STEMI patients [33]. Finally, the 1-year results of the POLAR ACS study (n = 100) disclosed no "no-reflow" phenomenon and one case of ST [34]. Clinical outcomes from all the mentioned registries are reported in greater detail in Table 3 (see also Electronic Appendix). Several prospective investigator-initiated studies using Absorb BVS are currently ongoing. Thus, in the next few years, a large amount of data will be available, including long-term endpoint studies, on the safety and efficacy of the Absorb. In Tables 4 and 5 a comprehensive list of the upcoming randomized studies and registries is shown.

The fact that over 60,000 Absorb BVS have been implanted worldwide in the face of one single randomized control trial, that included around 500 patients, should signal caution. The large number of registries published comes with the weakness and limitations of this study design. The primary endpoints of the Absorb II RCT are arguably not clinically relevant, and the secondary endpoints that are arguably more important (death, myocardial infarction, target lesion revascularization) could not

Table 4
Investigator-sponsored up-coming randomized studies using Absorb BVS.

Study	Study design	N	Primary endpoint	Phase	FU
AIDA	Randomized, all-comers	2690	2-Year TVF	Recruiting	5 years
BVS in STEMI	Randomized, open label	120	Coronary stent healing index	Recruiting	1 year
EVERBIO II	Randomized (EES vs BES vs BVS)	240	In-stent LLL at 9 months	Active, not recruiting	5 years
ISAR-ABSORB MI	Randomized, open label	260	% diameter stenosis at 6–8 months	Recruiting	1 year
PROSPECT ABSORB	Randomized, open label (BVS vs GDMT in vulnerable plaque)	900	2-Year IVUS MLA	Recruiting	3 years
PROACTIVE	Randomized (BVS vs Xience)	20	Peri-procedural platelet reactivity	Recruiting	1 year
TROFI II	Randomized (BVS vs Xience in STEMI)	190	Healing Score at 6 months	Follow-up	3 years
VANISH	Randomized (BVS vs Xience)	60	Myocardial blood flow over time	Recruiting	3 years

N = number of patients; FU = follow-up; TVF = target vessel failure; EES = everolimus-eluting stent; BES = biolimus-eluting stent; LLL = late lumen loss; BVS = bioresorbable vascular scaffold; GDMT = guideline directed medical treatment; IVUS = intravascular ultrasound; MLA = minimal lumen area; STEMI = ST-segment elevation myocardial infarction.

Table 5
Investigator-sponsored up-coming registries using Absorb BVS.

Study	Study design	N	Primary endpoint	Phase	FU
ABSORB-ACS	Observational, prospective	300	MACE	Recruiting	2 years
ASSURE	All comers, observational, prospective	183	MACE	Recruiting	3 years
ABSORB CTO	Prospective registry (CTO)	20	MACE	Active, not recruiting	2 years
BVS expand	All-comers (excl. STEMI), observational, prospective	300	1-Year MACE	Recruiting	5 years
FRANCE-ABSORB	De novo lesions, observational, prospective	2000	1-Year MACE	Recruiting	1 year
GABI-R	All-comers, observational, prospective	5000	MACE	Recruiting	5 years
GHOST-EU registry	All-comers registry	2000	TVF	Recruiting	1 year
IT-DISAPPEAR	Prospective, open label (MVD, long lesions)	1000	MACE	Recruiting	5 years
PABLOS	Bifurcations	30	Device, procedural success	Recruiting	2 years
PREVENT	Vulnerable plaque at IVUS and/or NIRS*	2000	2-Year MACE	Not recruiting	2 years
REPARA	All comers, observational, prospective	1500	1-Year MACE	Recruiting	1 year
TIGER-BVS	Randomized, open label	100	CBF after CTO in ticagrelor vs clopidogrel	Not yet recruiting	3 years

N = number of patients; FU = follow-up; MACE = major adverse cardiovascular event(s); CTO = chronic total occlusion; STEMI = ST-segment elevation myocardial infarction; TVF = target vessel failure; MVD = multivessel disease; IVUS = intravascular ultrasound; NIRS = intracoronary near-infrared spectroscopy; CBF = coronary blood flow.

be fully tested because the study was significantly underpowered to detect these differences. Having said that, all the trends were in favor of the metal stent, underlining the reasons why the cardiology community should proceed with caution. While results of the large experience with the current BVS offer an undeniable proof of concept that this technology is undoubtedly here to stay and likely to be important in the future, the current iterations do not meet the required clinical standards to support widespread use as an alternative to the well tested and highly successful second generation metallic DES.

2.5. Lessons from the clinical experience: scaffold optimization

The importance of pre-dilatation before BVS implantation is widely recognized; Brown et al. recently reported excellent acute results after OCT-guided BVS implantation showing that 1:1 balloon/vessel pre-dilatation improves scaffold expansion [35]. On the other hand, the importance of postdilation to achieve better stent expansion is well known [36,37] and the final minimal lumen area (MLA) is a strong predictor of restenosis and ST [38–40]. Given the higher strut thickness and the higher conformability, proper BVS implantation might need more accurate final optimization than metal stents, especially in complex lesions. Consistently, the studies reporting high postdilation rates (over 90%) and pressures (over 20 Atm) have shown lower rates of ST [22,23]. This suggests that improvements in the implantation technique could significantly impact BVS performance, as it was demonstrated for DES [41]. However, it is worth mentioning here that, in the ABSORB II RCT trial, final in-stent minimal lumen diameter (MLD) and IVUS Minimal Lumen Cross-section Area (MLCSA) were significantly smaller in BVS than in Xience; the latter could help to explain the higher ST rate observed for BVS. Furthermore, the average minimal area of 4.89 mm^2 (vs 5.73 mm^2 in Xience) is close but lower than the cut-off measurements indicated in many IVUS studies as predictive of DES failure [38,40,42]. These results could be partly related to the implantation protocol: the mean diameter of post-dilation balloon was indeed low, with a low final deployment pressure (14.23 atm in Absorb vs 15.03 Atm in Xience, $p = 0.01$). Surprisingly, IVUS was purely performed to assess the implantation results and not intended to guide the procedure. The percentage of BVS post-dilation, together with other key procedural characteristics, is reported in Table 2.

2.6. Intracoronary imaging guidance

2.6.1. IVUS

In the past decade, IVUS has been increasingly recognized as a useful tool to optimize PCI results [43–46]. One advantage of IVUS is the penetration depth, allowing visualization of the entire lumen and the vessel wall. These features are of key importance for BVS implantation, providing useful information on vessel morphology, the need for lesion preparation and the size of the scaffold to be selected. For these reasons, IVUS has also been widely used during BVS implantation procedures. Gomez-Lara et al. [47] recently reported their experience from 45 patients included in the ABSORB trial on the agreement and reproducibility of IVUS and OCT during BVS implantation. IVUS showed a poor reproducibility and ability to assess qualitative measurements like incomplete stent apposition (ISA), protrusions, dissections and number of struts; the agreement with the OCT for such qualitative parameters was also unsatisfactory. However, in that study IVUS showed an excellent reproducibility for the assessment of lumen and scaffold areas, which are critical to guide BVS deployment. Given the wide availability of IVUS-guided PCI clinical data, IVUS remains a widely used tool for intracoronary imaging trials [48].

2.6.2. OCT

OCT is an established tool for the diagnosis and treatment of coronary lesions [49,50]. This technology allows good visualization of the struts and of the surface of vessel lumen, with a 10-fold higher axial resolution (14 μm) compared to IVUS. For these reasons, it is very effective to identify stent malapposition, dissections, tissue protrusion, and thrombus, which could be very useful in guiding BVS implantation. Allahwalla et al. [51] recently reported that despite achieving angiographic success, further optimization was required in over a quarter of lesions on the basis of OCT findings. Although, a comprehensive consensus document has been issued for the acquisition, measurement, and reporting of intravascular optical coherence [52], the limited amount of clinical OCT data and the lack of standardized criteria is still limiting its use in current practice. Accordingly, whether IVUS criteria for optimal stent placement can be translated to OCT-guided stent implantation is still unknown. As a matter of fact, several studies reported that lumen dimensions measured by OCT were smaller than those measured by IVUS, probably due to its higher axial resolution [53,54]. Notwithstanding these pending limitations, OCT is considered a useful breakthrough technology for the evaluation of biodegradable scaffolds; indeed, at OCT analysis, the BVS allows the assessment of the vessel wall behind the struts without the usual shadowing of metallic struts [55]. Thanks to these characteristics, the OCT has been used for BVS deployment in most of the available studies and significantly contributed to the current knowledge of the Absorb BVS characteristics and its interplay with the coronary wall [55,56]. Accordingly, OCT is considered the gold standard for struts coverage evaluation and an important tool for BVS assessment at follow-up [56]. Indeed, OCT made possible the clear identification of the fibrotic de novo cap (a neo-intimal layer covering the scaffold struts) when struts are no more identifiable, as well as the lumen enlargement phenomenon [2,56]. These aspects represent two of the most interesting long-term findings seen with BVS and, only if confirmed on a large scale, could be among the reasons to favor BVS use over metal stents, especially when focusing on the issue of plaque re-progression. Indeed, when the atherosclerotic plaque develops in a vessel still able to accommodate plaque growth with an outward

remodeling it may remain silent for a longer period of time whereas the chronic inflammation induced by the metallic foreign body appears to cause a small but chronic increase in late loss. However, the neoatherosclerosic phenomenon will eventually occur within any stent if sufficiently potent risk factors remain active. In this context, caution is mandatory since few data are available and long-term evidences are not universal.

Finally, OCT guidance for BVS implantation could be even more useful in special conditions such as complex lesions, bifurcations and CTOs [57–59]. In conclusion, intracoronary imaging with IVUS and OCT is a useful tool in guiding BVS implantation, and the two modalities seem to be complementary. While IVUS could be more helpful for the evaluation of the plaque morphology and in the preparation phase, OCT allows better qualitative scaffold analysis and follow-up evaluations. Overall, both technologies ensure reliable lumen and scaffold measurements.

3. Future perspectives

As always for novel technologies, the first device introduced into the market has many aspects that can be improved. The Absorb strut thickness (150 μm, similar to the first-generation metal DES) has been claimed to be potentially responsible for higher rates of adverse events. The next generation scaffolds, as the DESsolve C, the MeRes and the Biolute BRS have a strut thickness of 100 μm, 100 μm and 108 μm, respectively. This will represent a major improvement, if they maintain an adequate radial strength, as it will also allow the reduction of the crossing profile. Moreover, thinner struts could reduce flow disturbances and ultimately the thrombogenicity of such scaffolds as well as the protrusion into the lumen when overlapping. Similar improvements could be seen with the introduction of the Mirage BRS, a microfiber scaffold with a streamlined strut geometry (round struts) that is supposed to reduce flow separation and warrant a high shear peak with consequent reduced platelet activation. The ideal time for resorption together with the progressive reduction of radial strength is another crucial point. Shortening the resorption process would reduce the risk of ST and ISR but could be responsible for higher rate of chronic recoil. In this respect, promising results have been reported with the DESolve scaffold; its biodegradation and bioresorption have been demonstrated to take place within 1 and 2 years, respectively. Whether similar results will be extended to complex lesion settings need to be addressed. The possibility to over-expand the scaffolds without fractures represents one more important point; on this regard, the Fantom (a desaminotyrosine-derived polycarbonate scaffold), the DESsolve and the Amaranth BRS (both PLLA-based polymer scaffolds) showed greater resistance to over-expansion. Based on a completely different structural concept, magnesium-based metallic bioresorbable scaffolds have been developed, to pair the mechanical characteristics of metal DES. After the initial discouraging results [60], the DREAMS-1 (paclitaxiel-eluting) and the DREAMS-2 (sirolimus-eluting) BRS yield a better promise; the latter is currently being tested in the BIOSOLVE-II study (n = 120).

4. Conclusions

Recent registries have challenged the initial claim that BVSs are immune from Scaffold Thrombosis. Although prudence and careful monitoring are essential in the adoption of a potentially revolutionary technique and further large randomized studies are warranted to support the widespread use of BVS in clinical practice, more favorable results have been obtained with the optimization of the implantation technique and wider use of intracoronary imaging tools.

Conflict of interest

The authors report no relationships that could be construed as a conflict of interest.

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