Primary percutaneous coronary intervention (PCI) currently represents the first choice of treatment in experienced centers for patients presenting with ST-segment elevation myocardial infarction (STEMI) with limited time delay. In this context, first-generation drug-eluting stents (DES) have reduced the need for repeat revascularization compared with bare metal stents (BMS). However, the 1st-generation DES have been associated with late complications, such as neo-atherosclerosis, late restenosis, and stent thrombosis. In particular, in the acute thrombotic setting, the antiproliferative drug elution used in DES has been shown to interfere with vascular healing processes, creating the background for delayed strut coverage, and persistent or acquired malapposition. Possible explanations for this phenomenon are thrombus sequestration behind the struts, which subsequently resolves with acquired malapposition, and vasoconstriction during the acute phase. The newer-generation DES with improved biocompatibility of polymers have also shown a lower rate of clinical events in acute patients as compared with either 1st-generation DES or BMS. The clinical introduction of biodegradable stents resulted in a revolutionary change among local coronary therapies. Indeed, these devices have the unique ability to provide a temporary scaffold that is necessary to maintain the patency of the vessel after intervention, releasing antiproliferative drugs while the Bioresorbable vascular scaffolds (BVS) gradually degrades, liberating the vessel from its cage and permitting restoration of vascular physiology and integrity. More specifically, the potential benefits of BVS as compared with metallic platform DES may include: decrease in late adverse events through complete biodegradation of stent struts preventing the risk of thrombus formation at the site of impaired endothelialization; normalization of vasomotion and compensatory remodeling during follow-up, thus suggesting restoration of normal vessel physiology after complete biodegradation of the stent struts; no interference with diagnostic or therapeutic measures (eg, coronary artery bypass graft) in case of disease progression; improved vascular healing; and discontinuation of long-term antiplatelet therapy in patients with single-vessel coronary artery disease. In particular, some crucial points in STEMI patients have to be emphasized. First of all, culprit lesions are frequently localized in the proximal segments of the coronary artery tree; restoration of physiological vasomotion may therefore have a greater effect in patients with STEMI as compared with patients with stable coronary artery disease. Secondly, vulnerable plaque of STEMI lesions, often characterized by necrotic core, interferes with vascular healing after metallic stent implantation, thus leading to coronary evagination or late acquired malapposition, both of which have been correlated with adverse ischemic outcomes. Recent study suggests that BVS may eventually decrease the incidence of angina during follow-up, by reducing fixed and dynamic restenoses and by improving vasomotor responses. Finally, the potential advantages of implanting BVS (vs. other DES) in STEMI may be mostly related to the young age of these patients. Indeed, they usually have less extensive coronary artery disease (compared with non-ST-
Vascular Response to BVS: Vascular Restoration Therapy and “Plaque Sealing”

BVS represent a breakthrough technology for STEMI management. Principal advantages of these transient devices are mostly related to “vascular restoration therapy” and the process of “plaque sealing”. This unique vascular response mainly consists of late lumen enlargement with wall thinning, restoration of vasomotion and return of pulsatility. These features are important in effecting optimal repair of the vessel wall, potentially reducing adverse events such as late/very late neo-atherosclerosis and stent/scaffold thrombosis. Moreover, in preclinical studies, biodegradable stent coatings showed less inflammation than permanent polymeric stent coatings. A recent study reported that, compared with polymeric metal DES, BVS in a rabbit iliac artery model demonstrated ongoing vascular healing at 3 and 6 months, and complete vessel restoration, re-endothelialization and no minimal vascular inflammation at 86 months. In particular, inflammation scores were comparable between arteries implanted with BVS and DES at 3 months (1.1 vs. 1.1, P=0.99), which decreased over time in the BVS-implanted arteries (36 month: 0.0 vs. 0.2, P<0.05).

The current-generation BVS are constructed of either a polymer or a metallic alloy. Among the various polymers tested in the preclinical and/or clinical stages of investigation, the most frequently used is poly-L-lactide acid (PLLA). After implantation of a PLLA scaffold in vivo, the polymeric struts are progressively hydrolyzed and replaced by a provisional matrix; as it is released, the mononuclear component, lactic acid, is metabolized via the Krebs cycle into carbon dioxide and water, with complete resorption occurring within approximately 24–36 months. The duration of bioresorption is influenced by the individual molecular weight of the main component and the presence of oligomer, monomer and/or solvents. After completion of bioresorption, the provisional matrix becomes cellularized with connective tissue and the struts eventually become fully integrated into the surrounding vessel wall.

In this context, previous studies demonstrated that the ability of a coronary segment scaffolded by an Absorb BVS device to react to vasoactive drugs is related to the bioresorption of the polymeric struts. The ABSORB Cohort A trial was the first study demonstrating some degree of recovery of vasoreactivity in a coronary segment scaffolded by a polyactide device, after administration of acetylcholine (Ach), methylergonovine, and nitrates at 2-year follow-up. Later, the ABSORB Cohort B trial showed that the scaffolded segments exhibit a vasoactive response to Ach and methylergonovine as early as 12 months, because of partial subsidence of the radial force of the scaffolded vessel. Moreover, previous reports have monitored the degradation of the scaffold as a reduction in hyper-echogenic tissue over time, associated with a normal vasodilatory response to Ach. Furthermore, the recovery of normal endothelial function appears to be associated with a low plaque burden and absence of necrotic core on virtual histology, which represents a proven site of active inflammation and oxidative stress. Of note, the vasoreactive behavior of the distal edge of the scaffold does not differ substantially from the physiological reaction observed in scaffolded segments. Clinical data support the hypothesis that drug impregnation distal but not proximal to the device contributes to a lower restenosis rate at the distal compared with the proximal edge.

In this context, the coronary segment distal to a 1st-generation DES classically exhibits a paradoxical response to Ach, especially when compared with BMS. The introduction of the 2nd-generation DES has been shown to reduce this endothelial dysfunction. Brugala et al demonstrated that, with the Absorb BVS, the segment distal to the implanted scaffold did not have a significant vasoconstrictive response to Ach administration, thus suggesting a more ‘endothelium friendly impact’ of the drug-eluting BVS in the coronary segment distal to the device. Taken together, these findings also suggest recovery of normal physiological reactivity to vasoactive drugs in the treated coronary segments once the mechanical integrity of the device has disappeared. Of note, previous studies revealed that, once the device becomes integrated into the tissue, there is a gradual increase of neointimal tissue, which, however, is accommodated by the expanding scaffold and does not appear to affect luminal dimensions. Moreover, previous studies demonstrated asymmetric distribution of neointimal tissue around the circumference of the vessel wall, indicating that local factors (ie, vessel wall trauma, increased plaque inflammation, and local hemodynamics) are likely to be involved and regulate this process. A recent study, using serial optical coherence tomography (OCT) data and computational fluid dynamics techniques, showed that low endothelial shear stress may contribute to neointimal formation and that thick, protruding struts of the implanted scaffold create a rough surface that causes flow disturbance and recirculation zones resulting in low endothelial shear stress. Hence, the current design (in-phase zigzag hoops linked with bridges; strut thickness of 156 mm) and composition (poly-L-lactic struts, covered by a thin layer of an amorphous matrix of poly-D,L-lactide that controls the release of the antiproliferative drug everolimus) of the Absorb BVS seems to provide a template for the formation of a potentially protective thin layer of neointimal tissue without altering the dimensions of the vessel lumen over the underlying plaque or of the scaffold’s struts, thus minimizing the risk of late scaffold thrombosis. Furthermore, the neointima tissue that develops in the areas between the struts appears to smooth the luminal morphology, creating in the long term an atheroprotective environment. Recent studies suggest that the same process of cellularization and contracture observed by preclinical investigations and studies combining OCT and histology, also occurs clinically and may correspond to vessel wall thinning, which could contribute to luminal enlargement with/without adaptive remodeling. In this context, Bourantas et al examined the implications of the Absorb BVS on the phenotype of the plaque and compared the changes in plaque morphology with those occurring after BMS implantation. At short-term follow-up, a significant reduction in luminal area with the BMS was noted, which was higher than that reported by the Absorb BVS group (−2.1±1.97 mm² vs. −1.34±0.99 mm², P=0.026). Of note, with the Absorb BVS, neointimal tissue continued to develop at mid-term follow-up (2.17±0.48 mm² vs. 1.38±0.52 mm², P<0.0001) and covered the underlying tissues without compromising the luminal dimensions (5.93±1.49 mm² vs. 6.14±1.49 mm², P=0.571) because it was compensated by the increase in scaffold area (8.28±1.74 mm² vs. 7.67±1.28 mm², P<0.0001). Finally, at 6–12-month follow-up, only 8% of the thin cap fibroatheroma detected at baseline was still present in the Absorb BVS and 27% in the BMS implantation segment. Along the same line, Karanasos et al demonstrated a favorable vascular healing response with late lumen enlargement with simultaneous increase in luminal symmetry, side branch patency, complete
strut resorption, and formation of a potentially protective tissue layer at 5 years from BVS implantation.\textsuperscript{28} Taken together, these findings are consistent with the hypothetical concept of “plaque sealing”. Of note, the complete integration of the BVS scaffold into the vascular wall has shaped a neoplaque phenotype that results from the complex interaction of pre-existing plaque, morphological changes of the pre-existing plaque subject to dynamic local rheological factors, strut resorption, and neointimal formation. However, although the vascular response seems to be favorable and in line with large-scale clinical reports, different biological reactions could eventually occur, leading to recurrent plaque rupture after BVS implantation. Further larger clinical studies are required to properly investigate this issue.

### BVS in STEMI: Evidence From Clinical Trials

However, despite STEMI representing the ideal scenario for BVS implantation, and up to 57% of physicians declaring they use this technology in this setting,\textsuperscript{29} very limited data are currently available. Table summarizes the major trials evaluating the use of BVS in STEMI patients. Kajiya et al first reported results from 11 ACS patients undergoing primary PCI; only 1 patient died (presented with cardiogenic shock) and any other major adverse cardiac event (MACE) occurred up to the 1-month follow-up.\textsuperscript{30} A slightly longer follow-up (median 137 days) was performed in 25 ACS patients.\textsuperscript{31} 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,\textsuperscript{32} aimed at assessing the 2nd-generation everolimus-eluting BVS for the treatment of 49 STEMI patients, has been reported. The procedural success was 97.9% and preprocedural 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\%\textpm\,8.2. No patients had angiographically visible residual thrombus at the end of the procedure. At the 30-day follow-up, the target lesion failure (TLF) rate was 0%. Non-target-vessel revascularization (TVR), target-vessel myocardial infarction (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,\textsuperscript{33} 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. A total of 41 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)\textsuperscript{34} is a multicenter registry of 100 patients presenting with ACS (STEMI=16) and treated with Absorb scaffold im-

<table>
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<tr>
<th>Study</th>
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ACS, acute coronary syndrome; BVS, biodegradable vascular scaffold; DOCE, device-oriented endpoint; DS, diameter stenosis; EES, everolimus-eluting stent; MACE, major adverse cardiac event; MI, myocardial infarction; STEMI, ST-segment elevation myocardial infarction; TLF, target lesion failure; TLR, target lesion revascularization; TVF, target vessel failure; TVR, target vessel revascularization.
planted. The aim of this registry was to evaluate the safety, clinical device and procedural success in this setting of patients. PCI BVS resulted in a decrease in the mean corrected TIMI frame count (cTFC) and improvement in final TIMI flow (TIMI 3 in 99%). The clinical device success rate was 100%. Clinical procedure success rate was 98%, whereas in-hospital MACE rate was 3%. At 1 year, there were no deaths, 3.2% MI (periprocedural at index PCI and 1 during 30-day follow-up), 1.1% TVR, 1.1% hospitalization for heart failure and 1 case of stent thrombosis (1.1%), caused by discontinuation of dual antiplatelet therapy (DAPT).

Gori et al. 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. Procedural success was obtained in all but 2 patients in the BVS group. 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 utilization did not influence the incidence of MACE (P>0.9).

More recently, Kochman et al. performed an OCT assessment of acute procedural results of BVS implantation in 23 STEMI patients, also evaluating mid-term 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±7.9%) were well apposed. The final minimum lumen diameter was 2.6±0.35 mm, minimum scaffold area was 6.98±1.54 mm² and final residual stenosis was 8.8±24.3%. In a median follow-up period of 229 (R 199–248) days, 1 MI, caused by subacute stent thrombosis, occurred in a patient who discontinued pharmacotherapy. In addition, the multicenter prospective RAI Registry has recently been published, reporting compelling data from a population of 74 STEMI patients. A very high procedural success rate has been observed (97.3%), as well as low rates of target lesion revascularization (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, a study from our group compared 290 STEMI patients treated by BVS with either 290 STEMI patients treated with everolimus-eluting stent (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 endpoint (DOCE), 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% vs. 2.4%, vs. 2.8%, respectively) or 1 year (4.1% vs. 4.1%, vs. 5.9%, respectively). Definite/probable BVS-thrombosis rate was numerically higher either at 30 days (2.1% vs. 0.3%, vs. 1.0%, respectively) or 1 year (2.4% vs. 1.4%, vs. 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 post-dilation in the BVS than in the other groups. Of note, whereas preprocedural TIMI flow was lower in the BVS than in the EES group, postproce-

Safety and Procedural Concerns of BVS: Scaffold Thrombosis, Technical Challenges, Intracoronary Imaging Guidance and Acute Recoil

Although the potential advantages of transient devices in STEMI patients are attractive, the outcomes of BVS remain to be determined with respect to safety and efficacy in routine clinical practice of primary PCI. Early clinical testing has been limited by patient selection, follow-up restriction or small sample size, the latter precluding a clear understanding of the true magnitude of low-frequency events (ie, scaffold thrombosis). In particular, the vast majority of “real world” studies report quite high BVS-thrombosis rates, mainly occurring within the first 30 days after device implantation and even higher than those reported for the 1st-generation DES. Discontinuation of DAPT is thought to have a central role in this context, but we still do not know to what extent in the case of BVS. Nevertheless, in the GHOST-EU Registry (the largest BVS registry to date, with 16% of STEMI enrolled), 20 of the 23 cases of stent thrombosis occurred in patients on DAPT. Hence, other factors have to be examined to explain the higher-than-expected BVS acute and subacute thrombosis rates. Periprocedural features such as device-related structural aspects (ie, strut thickness: 150 μm for BVS, similar to that of 1st-generation DES), implantation technique (ie, scaffold expansion optimization, intracoronary imaging guidance etc) or patient/lesion characteristics might represent important adjunctive factors.

The importance of predilatation before BVS implantation is widely recognized, especially given the lower radial strength and higher propensity to scaffold recoil. Brown et al. recently reported excellent acute results after OCT-guided BVS implantation, showing that 1:1 balloon/vessel predilatation improved scaffold expansion. It is interesting to note in this study that post-dilatation was performed in approximately half of cases (59.3%), therefore not enabling definitive assessment of the net benefit given by predilatation. However, the importance of post-dilatation in achieving better stent expansion is well known, of note, it has been extensively demonstrated that the final minimal lumen area is a strong predictor of both restenosis and stent thrombosis. Given the high strut thickness and low conformability, correct BVS implantation might need more accurate final optimization than for metal stents, especially when used for the treatment of complex lesions. Newseworthy, the studies with the lowest BVS-thrombosis rates were also those with the highest post-dilatation rates (99.3% and 100%) and the highest...
The use of intra-coronary (IC) imaging modalities is becoming an essential tool for optimizing BVS implantation. balloon predilatation) and optimization of the final result could lead to better outcomes after BVS implantation, similar to those for 2nd-generation DES.\textsuperscript{54}

The use of intra-coronary (IC) imaging modalities is becoming an essential tool for optimizing BVS implantation.

**Figure 1.** Angiographic result (A) of BVS Absorb implantation (3.5×18 mm at 12 atm, red arrow) at 6-month follow-up and (B) corresponding OCT cross-sectional views. BVS, bioresorbable vascular scaffold; OCT, optical coherence tomography.

**Figure 2.** Preprocedural angiography of a STEMI patient, with proximal occlusion of the left anterior descending coronary artery, before (A) and after thrombo-aspiration (B), during (C) and after BVS Absorb implantation (3×28 mm at 14 atm) (D), and at 6-month follow-up (E).
Indeed, this scaffold technology requires new imaging methodologies for its assessment because of the design, degradation rate, loss of mechanical property, and drug deliverability. Already in the past decade, several large studies have been published showing that IC imaging guidance may be important for achieving optimal DES expansion, lower malapposition rates and, consequently, better clinical outcomes, especially in complex PCI. For instance, OCT enables better visualization of the struts and the vessel wall, with a 10-fold higher axial resolution (14 μm) than intravascular ultrasound. For these reasons, OCT represents an effective imaging modality to identify stent failures (eg, stent malapposition, dissection, tissue protrusion, and thrombus) and it is currently considered the “gold standard” imaging technique for BVS (Figure 1). As a matter of fact, the BVS enables assessment of the vessel wall behind the struts without the usual shadowing of metallic struts during OCT analysis. In particular, OCT guidance could be useful in understanding the pitfalls responsible for the disappointing results from some of the recent “real world” studies. Interestingly, the evidence of a higher rate of stent thrombosis in the studies with less utilization of IC imaging seemingly support this hypothesis. Of note, in a recent study, Allahwalla et al reported that, despite achieving angiographic success in all BVS implantations, further optimization was required in more than one-quarter of patients on the basis of OCT findings.

Consistently, a recent study comparing acute BVS expansion with compliance chart information and longitudinal integrity in 32 lesions by OCT, showed scaffold under-expansion in 97% of OCT cross-sections, with only 8.3% revealing BVS area <5 mm. Moreover, 54.8% of scaffolds were elongated during implantation, but no signs of scaffold fracture were revealed. Again, IC imaging modalities could be useful also for analyzing the characteristics of the plaque, thus providing prognostic information. In this regard, Brown et al demonstrated that in BVS implantation an increased rate of malapposition was associated with fibrocalcific plaques.

Another concern related to acute BVS implantation is acute recoil. Although “late recoil” has been used frequently in interventional cardiology to describe constructive remodeling of the external elastic membrane area, here it relates more specifically to reduction in the area of the scaffolded segment, a phenomenon not previously observed with metallic stents. Attributed to early alteration of the mechanical integrity of the scaffold, this phenomenon can be controlled by polymer processing. In particular, the ABSORB cohort A trial, using BVS revision 1.0, demonstrated a slightly higher acute recoil with BVS than with metallic stents. More recently, Onuma et al showed that, among 88 patients enrolled in the ABSORB cohort B trial, absolute recoil of BVS 1.1 was numerically high—yet this phenomenon can be controlled by polymer processing. In particular, the ABSORB cohort A trial, using BVS revision 1.0, demonstrated a slightly higher acute recoil with BVS than with metallic stents. More recently, Onuma et al showed that, among 88 patients enrolled in the ABSORB cohort B trial, absolute recoil of BVS 1.1 was numerically higher than that of metallic SES and similar to that of BVS 1.0, but the differences did not reach statistical significance. In their multivariable regression model, high absolute recoil was predicted by high balloon/artery ratio. Of note, the stent/scaffold type was not a predictor of acute recoil.

Finally, a recent study analyzing clinical data from the first 450 patients enrolled in ABSORB EXTEND has demonstrated low rates of ischemia-driven MACE (4.2%) and target vessel failure (4.7%) at 12 months. Of note, the cases of device failure were principally caused by dislodgement (0.67%) and to late scaffold thrombosis (0.89%).

In STEMI, predilation is sometimes perceived as being more risky than in stable lesions, and accurate evaluation of lumen diameter is hampered by vasospasm and the thrombotic nature of the lesion. In this setting, thrombectomy and intracoronary nitrate administration may be 2 important steps before deciding whether a BVS can be implanted. The use of thrombectomy devices prior to scaffold implantation may also help to foresee passage of the lesion by the device and potential difficulties to be encountered during implantation (Figure 2).

Conclusions

BVS represent a breakthrough technology for PCI. The unique properties of the BVS, together with the concepts of “vascular restoration therapy” and “plaque sealing”, make STEMI the ideal scenario for BVS implantation. Consistently, 57% of physicians state they use this device in this context in their clinical practice. However, to date, we have only few data from registries and trials, characterized by small sample size and short-term follow-up. The concerns raised by a possible increase in-stent thrombosis need to be dispelled by data from sufficiently large observational studies with long-term follow-up.

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References


**BVS in STEMI**


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