Review Article

The ABSORB Bioresorbable Vascular Scaffold: An Evolution or Revolution in Interventional Cardiology?

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The advent of plain-old balloon angioplasty (POBA), first introduced by Andreas Grüntzig in 1977, revolutionised the treatment of coronary artery disease. Significant coronary lesions were shown to be potentially treatable with balloon dilatation, leading to restoration of lumen patency and vascular flow. Although this mode of treatment was undoubtedly a significant technological breakthrough, multiple weaknesses became evident. These either occurred post-procedurally, leading to acute vessel closure necessitating emergency revascularisation as a consequence of acute vessel recoil aggravated by local intimal and media dissections, or longer term, secondary to neointimal proliferation and constrictive remodelling as a consequence of vascular barotrauma.[1]

Several of the weaknesses associated with POBA were eliminated with the introduction of bare metal stents (BMS), namely the resolution of the acute and chronic recoil by caging the vessel wall with a permanent metallic prosthesis. The landmark BENESTENT trial[2,3] first established the feasibility of this therapeutic approach. Although initial studies were promising, a new entity became evident, namely neointimal hyperplasia (NIH), to which restenosis rates of 16-44% were attributed.

Drug-eluting stents (DES) were thus conceived as the next evolutionary step in improving the limitations of BMS. Initial studies were highly promising, with large-scale reductions in restenosis rates that were reported at 0% in highly selective lesions[4] and up to 16% in a broader range of patients and lesions.[5,6] A potential complication subsequently became evident with first-generation DES, namely that of subacute and late stent thrombosis as a consequence of delayed healing of the permanent metallic struts. Furthermore, late acquired malapposition of the struts implanted in a thrombotic rich milieu were also demonstrated to be a potential issue.[7-9]

The prospect of a temporary vascular stent, termed "scaffold" due to its being based on a temporary bioresorbable platform, has been always a goal of the interventional community. Such a device could offer transient radial strength to resist acute vessel recoil, and at a later stage would be fully resorbed, leading to restoration of the vessel's biological properties.

The purpose of this review is to demonstrate the progress in the development of the ABSORB bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara CA, USA) from the bench to clinical application. The potential advantages of this emerging technology, recently

termed "vascular reparative therapy", over the permanent caging of vessels with conventional metallic DES are discussed.

The ABSORB BVS design, material and the bioresorption process

The ABSORB everolimus-eluting scaffolds include the first generation device evaluated in the ABSORB Cohort A clinical trial (ABSORB 1.0)[10,11] (Figure 1A), the second generation (ABSORB Revision 1.1) (Figure 1B), investigated in the ABSORB Cohort B trial,[12] and the third generation currently under development. The first generation had a crossing profile of 1.4 mm, strut thickness of 150 μm and consisted of out-of-phase zigzag hoops linked together by thin and straight bridges (Figure 1A). This device had to be kept refrigerated at -20˚C to prevent physical ageing of the polymer and ensure device integrity. The second generation (ABSORB Revision 1.1) uses the same polymer as the previous one, with modifications of both the polymer processing and the scaffold design to give the device more prolonged radial support (Figure 1B). Both devices share similar characteristics:

1. A platform made of poly (L-lactide) (PLLA) (PLLA is used in numerous clinical items, such as resorbable sutures, soft tissue implants, orthopaedic implants, and dialysis media). PLLA is a semi crystalline polymer consisting of crystal lamellae interconnected with random polymer chains forming an amorphous segment (Figure 2).
2. A 1:1 mixture of an amorphous matrix of poly-D, L-lactide (PDLLA) and 8.2 μg/mm of the antiproliferative drug everolimus.
3. A pair of radiopaque platinum markers at the proximal and distal ends of the scaffold to allow

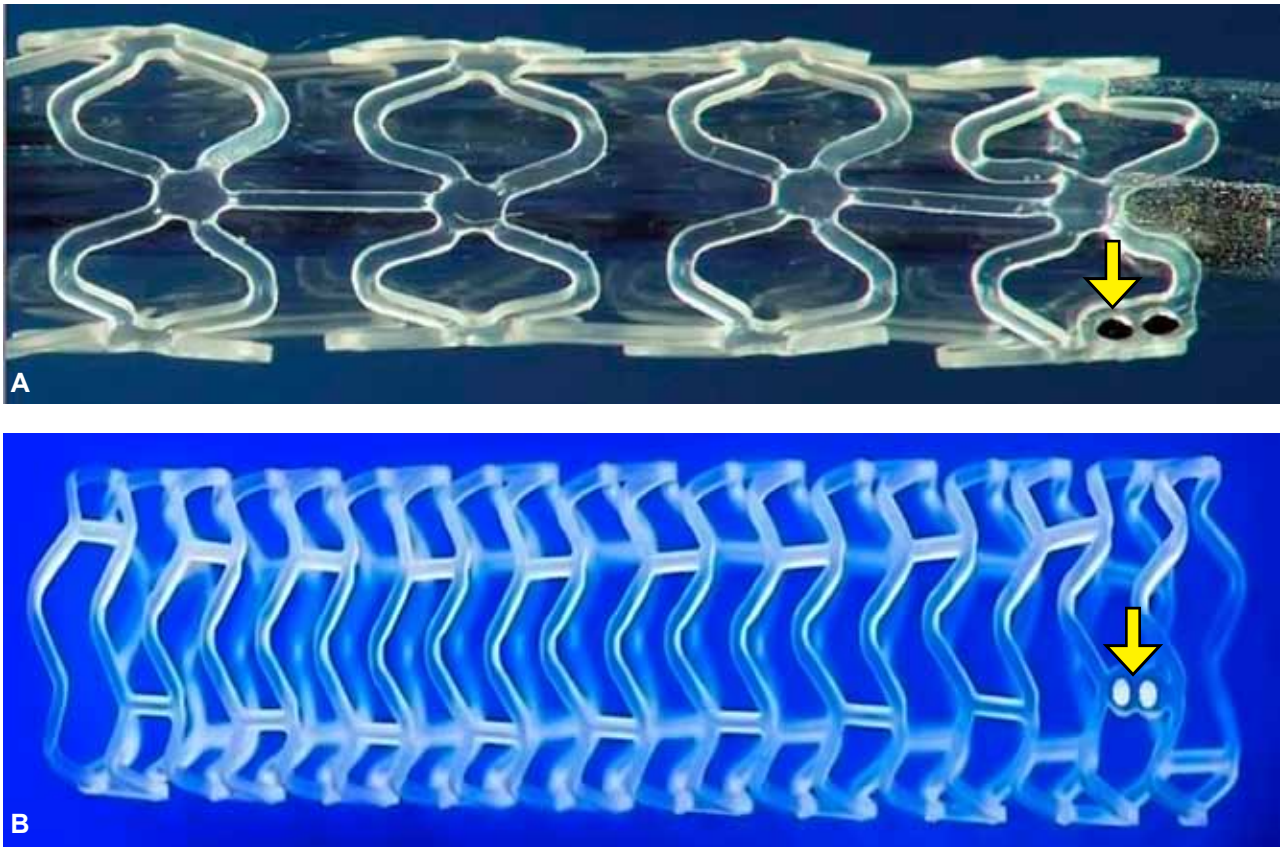


Figure 1. The first and second generations of the ABSORB bioresorbable vascular scaffold (BVS). A: The 1st generation ABSORB BVS had a strut thickness of 150 μm, a crossing profile of 1.4 mm, and consisted of circumferential out-of-phase zigzag hoops linked by thin and straight bridges. The device had one pair of radiopaque platinum markers at each proximal and distal edge (yellow arrow). B: The 2nd generation ABSORB BVS (revision 1.1) has a strut thickness of 150 μm, consisting of in-phase zigzag hoops linked by bridges. The device is radiolucent but has two radiopaque platinum markers at each proximal and distal edge that allow easy visualisation with angiography and other imaging modalities (yellow arrow).

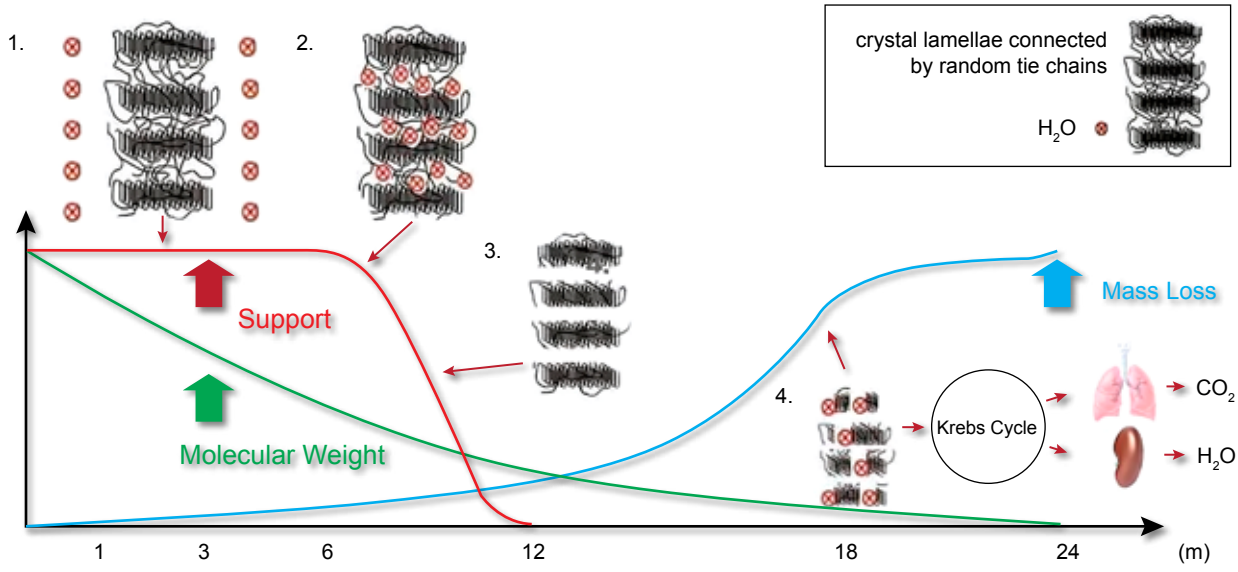


Figure 2. The ABSORB bioresorbable vascular scaffold (BVS) poly-L-lactide bioresorption process up to 24 months, when the polymeric device is expected to be fully resorbed. 1. Polymer hydration (crystalline polylactide) following implantation. Polylactides are hydrophilic, thus water (H_2O) can penetrate the implant. 2. Depolymerisation by hydrolysis, observed as a reduction in molecular weight (green line). 3. Polymer fragmentation into segments of low-weight polymer, resulting in the scission of amorphous tie chains linking the crystalline regions with subsequent gradual loss of the radial strength (red line). 4. Assimilation or dissolution of the monomer. The soluble monomer (e.g. L-lactate) is changed into pyruvate, which eventually enters the Krebs cycle and is further converted into carbon dioxide and water, eliminated by the lungs and kidneys, respectively. From Onuma Y, Serruys PW: Bioresorbable scaffold: the advent of a new era in percutaneous coronary and peripheral revascularization? Circulation. 2011; 123: 779-797. Adapted by permission of Wolters Kluwer Health.

visualisation during coronary angiography (Figure 1 A & B).
4. The balloon delivery system.

Bioresorption process

The bioresorption process of the ABSORB BVS PLLA undergoes four stages (Figure 2):

1. Polymer hydration (crystalline polylactide) following implantation. Polylactides are hydrophilic; thus water can penetrate inside the implant.
2. Depolymerisation by hydrolysis, observed as a reduction in molecular weight.
3. Polymer fragmentation into segments of low-weight polymer, resulting in scission of the amorphous tie chains linking the crystalline regions.
4. Assimilation or dissolution of the monomer. Phagocytes can assimilate small particles and lead to soluble monomeric anions. The soluble monomer (e.g. L-lactate) is changed into pyruvate, which eventually enters the Krebs cycle and is further converted into carbon dioxide and water. These final products are eliminated by the lungs and kidneys, respectively.

The assessment of bioresorption was recently evaluated by our group in a porcine coronary artery model at 28-days, 2, 3 and 4 years (Figure 3). Thirty-five ABSORB BVS 3.0 × 12 mm were implanted in the main coronary arteries of 17 pigs evaluated with optical coherence tomography (OCT) and histology following euthanasia: immediately (n=2), at 28 days (n=2), 2 years (n=3), 3 years (n=5) or 4 years (n=5). Immediately after implantation, all struts had a preserved box appearance. At 28 days, OCT showed 82% of the struts as preserved box, and 18% as an open box appearance. At 2 years four fifths of the struts showed a preserved box appearance and only a few struts (2.4%) demonstrated open box appearance. Histological analysis at this time point showed the polymeric strut voids to be replaced by proteoglycan-rich matrix, with polylactide residues at low levels, as quantified by chromatography (Figure 3A & B). At 4 years, OCT showed 51.2% of the struts classified as dissolved bright box and 48.8% as dissolved black box. The strut remnants were hardly detectable by histology, appearing as foci of low-cellular-density connective tissue (Figure 3C & D).[13,14]

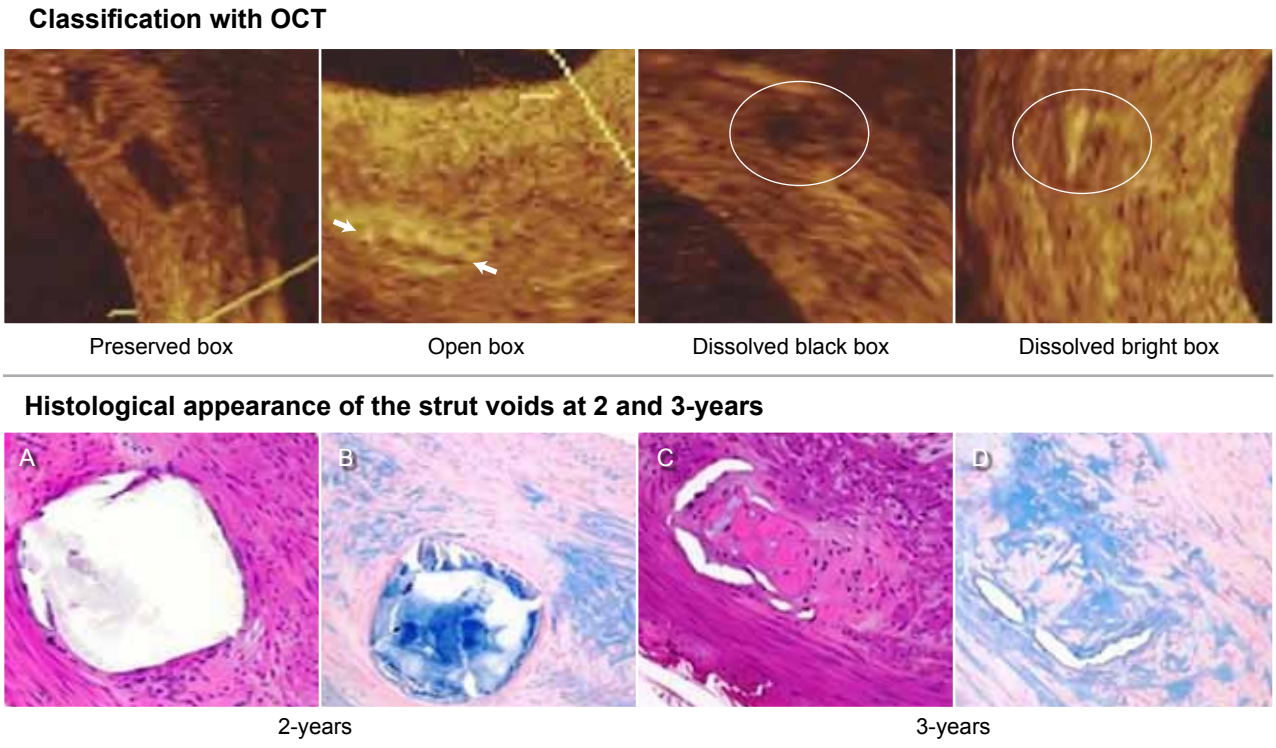


Figure 3. Classification with optical coherence tomography of the bioresorption process (4 sequential stages) and histological appearance of the remnants of the polymeric struts (strut voids) at 2 years (Panels A & B) and 3 years (Panels C & D), following implantation in a porcine coronary artery model. From Onuma Y, Serruys PW, Perkins LE, et al: Intracoronary optical coherence tomography and histology at 1 month and 2, 3, and 4 years after implantation of everolimus-eluting bioresorbable vascular scaffolds in a porcine coronary artery model: an attempt to decipher the human optical coherence tomography images in the ABSORB trial. Circulation. 2010; 122: 2288-2300. Reproduced by permission of Wolters Kluwer Health.

Lessons from the ABSORB BVS in clinical trials

The family of bioresorbable devices that have undergone clinical evaluation are illustrated in Figure 4. The feasibility and clinical safety of the first generation ABSORB BVS (1.0) has been proven with the ABSORB Cohort A trial [NCT00300131] in 30 low risk patients with coronary artery disease (CAD). A reported incidence of a major adverse cardiac event (MACE) rate of 3.4% at 4-year follow up was shown, with no episodes of device thrombosis.[10,11,15] In this study, multimodality imaging was performed using intravascular ultrasound (IVUS), virtual histology-IVUS (VH-IVUS), palpography and OCT at 6 months and 2 years following implantation of the device. The angiographic follow up at 6 months revealed a late loss (LL) of 0.44 mm, lower than that reported with BMS (>0.8 mm) but significantly higher than the Xience V everolimus-eluting stent (LL=0.11 mm). A combination of neointimal hyperplasia (+5.5%) and a reduction of the device area (-11.8%) as a consequence of early bioresorption and early recoil of the device leading to "scaffold shrinkage", were the main reasons for these reported findings.

The second generation ABSORB BVS (Revision 1.1) was designed to overcome the limitations seen with the first generation, with design modifications and a different polymer manufacturing process to give it more prolonged radial support. The device was tested in 101 patients in the ABSORB Cohort B trial [NCT00856856]. This cohort was split in two subgroups: Cohort B_1 (n=45), evaluated with invasive imaging by quantitative coronary angiography (QCA), IVUS, VH-IVUS and OCT, and Cohort B_2 (n=56), evaluated with the same invasive imaging at 1 year and 3 years (Figure 5).

Current data from the 6-month follow up of Cohort B_1 are available: the reported LL was 0.19 ± 0.18 mm, with a relative decrease in minimal luminal area of 5.4% on IVUS. Furthermore, the late "scaffold shrinkage" reported with the first generation ABSORB BVS was almost eliminated, with a reduction in scaffold area of 2.9% and 1.9% with IVUS and OCT, respectively.[12] Recent data from the 1-year follow up of Cohort B_2 demonstrated a sustained preservation of the scaffold area, as assessed with IVUS and

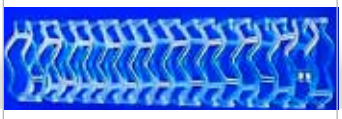
Company / Device	Design of the biorsorbable device	Strut thickness, (μ m)	Polymer / Drug	Absorption time	Late loss, (mm)
Kyoto Medical/ Igaki-Tamai		170	PLLA	2 years (y)	0.48 (6m)
Biotronik / DREAMS		125	Mg alloy (AMS-4) / sirolimus	4 to 6 months (m)	0.68 (6m)*
Abbott / ABSORB BVS		150	PLLA / everolimus	2y	0.19 (6m)
Reva Medical / ReSolve		200	Tyrosine poly carbonate with iodine / sirolimus abluminal	2y	1.81 (6m)
-/ BTI		200	Salicylic acid into polymer (PLA or adipic acid) / sirolimus	6m	NA
Elixir / DESolve		150	PLLA / novolimus	1 to 2y	NA

Figure 4. The family of bioresorbable devices that have undergone clinical evaluation. The platform design, strut thickness, polymer/drug formulation, absorption time and late lumen loss are illustrated. PLLA – poly-L-Lactide. BVS – bioresorbable vascular scaffold; AMS – absorbable magnesium stent. *Evaluated with the AMS-3 device.

OCT, and an angiographic LL of 0.27 ± 0.32 mm, similar to that reported with the Xience V everolimus eluting stent (LL: 0.23 ± 0.29 mm, as demonstrated in the SPIRIT I trial) at the same time point. Additionally, the hierarchical MACE rate of the 101 patients (Cohort B_1 and B_2 trials) at 1 year (7.1%) was comparable to that observed in the historical series of the Xience V metallic EES.[16,17]

The ongoing ABSORB EXTEND study, a multicentre single-arm study that aims to recruit approximately 1000 patients from 50 centres worldwide, will further investigate the ABSORB BVS. Additionally in the pipeline for the near future is the pivotal non-inferiority trial of the ABSORB BVS vs. the metallic EES (Xience Prime) in approximately 500 patients in 2:1 fashion.

The potential benefits of transient bioresorbable vascular scaffolds vs. permanent metallic stents

The advent of the bioresorbable technology in clinical practice has several advantages compared to permanent metallic devices, such as:

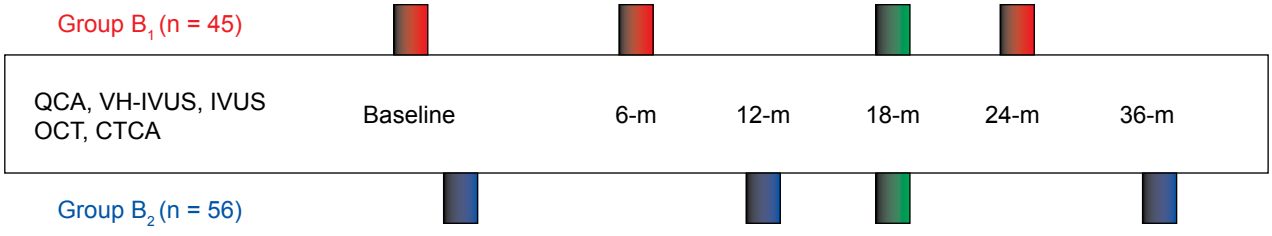


Figure 5. The ABSORB Cohort B study design. The ABSORB Cohort B trial enrolled a total of 101 patients who were split into two groups. Group B_1 underwent invasive imaging post-procedure, at 6 months and 2 years; Group B_2 underwent invasive imaging post-procedure at 1 year and will undergo another imaging follow up at 3 years. At 18 months all patients underwent non-invasive imaging assessment with coronary computed tomography angiography (CCTA).

1. The "liberation" of the treated vessel from its "metallic cage" and the subsequent reactivation of the physiological processes of vasomotion, vascular remodelling and late lumen enlargement.
2. The potential elimination/integration into the vessel wall of the polymeric struts from jailed side-branches after the completion of the bioresorption process.
3. The superior conformability and flexibility compared to conventional metallic stents, thereby leading to a less altered distribution of the tissue biomechanics and preservation of the vessel geometry.
4. The potential long-term beneficial edge vascular response.
5. The elimination of the late acquired or persistent malapposition, which has been implicated in causing thrombotic events with conventional metallic devices.

Vasomotion

In the ABSORB Cohort A trial, either the endothelium-dependent vasoconstrictor methylergonovine maleate (methergin) or the endothelium-dependent vasoactive agent acetylcholine was administered at the 2-year follow up for the study of vasomotion. In the methergin group there was significant vasoconstriction in the scaffolded segment (before methergin: 2.64 ± 0.22 mm; after methergin: 2.44 ± 0.33 mm; p=0.03) while in the acetylcholine group five patients exhibited vasodilation in the scaffolded segment.[11] The restoration of vasomotion was also recently shown during the 1-year follow up of the ABSORB Cohort B_2, with changes in the mean lumen diameter as assessed by QCA in the target vessel proximal to the scaffold, distal and within the scaffold, following the administration of either acetylcholine or methylergonovine.[17]

Arterial remodelling and late lumen enlargement

Arterial remodelling is an adaptive process to compensate for plaque expansion in order to preserve lumen dimensions (Glagov phenomenon), where the threshold for the transition of the expansive (increase of the external elastic membrane, EEM) to constrictive remodelling is highly dependent on the underlying plaque burden being >40%. The implantation of permanent metallic devices interrupts this dynamic process. After the completion of the bioresorption process, in vessels treated with the ABSORB BVS, IVUS based imaging has shown late luminal enlargement of 10.9%, with a significant plaque media reduction of -12.7%, and no significant change in the vessel area (EEM). This phenomenon of plaque regression requires further investigation, as the interplay among the tissue composition and the artefactual observation of the polymeric struts as dense calcium structures by the VH-IVUS modality have previously been shown to be an issue.[18]

Side branch jailing

The jailing of the side branch (SB) is a potential area of concern during bifurcation stenting. Higher incidences of MACE have been reported with bifurcation stenting compared to conventional percutaneous intervention of non-SB lesions. In *post hoc* analyses of the original ABSORB studies, the SB jailing during provisional T-stenting with the ABSORB BVS appeared to have a benign behaviour compared to metallic devices. Okamura et al demonstrated, at 2-year follow up post BVS implantation, that the polymeric struts had cleared at the side branch ostium, with evidence of integration into the underlying tissue and, in some cases, causing a membranous neocarina.[19] Our group recently demonstrated the feasibility of crossing the polymeric struts of the ABSORB BVS using three-dimensional OCT and presented the first report of successful post-dilation of the device's polymeric struts in a jailed SB for flow restoration.[20,21] Large scale studies to confirm these encouraging preliminary findings are planned.

Conformability

The ABSORB BVS has been shown to be more conformable compared to metallic stents (Multi-link Vision or Xience V EES), altering vessel angulation and curvature to a lesser degree and consequently having a smaller effect on flow dynamics and shear stress distribution in the scaffolded segment and the scaffold edges.[22]

Edge vascular response

The edge vascular response (EVR) was firstly described during brachytherapy with the use of radioactive stents[23] and later on with metallic platforms: either first generation DES (SES and PES) up to 6 months, or second generation DES (Xience V EES) up to 2 years. It became evident that the EVR is not the result of a single precipitating factor, but rath-

er the interplay among several confounding factors: 1) device related: platform (metal or polymer) and drug (limus-based elution or paclitaxel); 2) iatrogenic: geographical miss (axial, longitudinal or both); and 3) tissue composition at the edge (necrotic core rich plaque at the landing zone of the device) (Figure 6). The advent of bioresorbable devices with transient scaffolding properties prompted the re-evaluation of the EVR, as any potential initial adverse response might potentially regress in parallel with the bioresorption of the implanted device.

The proximal and distal edges following implantation of the second generation ABSORB BVS were investigated with *in vivo* VH-IVUS, non-serially at 6 months (Cohort B_1) and 1 year (Cohort B_2), and serially at 6 months and 2 years (Cohort B_1).

The non-serial evaluation demonstrated a dynamic biologic behaviour with some degree of proximal edge constrictive remodelling: Δ vessel area -1.80% [-3.18; 1.30] ($p<0.05$) at 6 months, which tended to regress at 1 year to Δ vessel area -1.53% [-7.74; 2.48] ($p=0.06$), and distal edge tissue composition changes, mainly with an increase of the fibro-fatty (FF) tissue component, Δ FF + 43.32% [-19.90; 244.28] ($p<0.05$).[24]

The serial evaluation up to 2 years (post-procedure to 2 years) revealed a lumen loss of: Δ -6.68% [-17.33; 2.08], ($p=0.027$) with a trend toward plaque area increase of: Δ +7.55% [-4.68; 27.11], ($p=0.06$) at the proximal edge and distal edge tissue composition changes with a significant increase of the fibro-fatty tissue (FF) tissue component (from 6 months to 2 years) from 0.09 mm^2 [0.04; 0.22] to 0.22 mm^2 [0.14; 0.51] respectively, translated to a percentage increase of: Δ +68.37% [17.82; 171.17], ($p=0.013$).

This dynamic biological behaviour of the vessel wall architecture is seemingly associated with the transient scaffolding properties of the ABSORB BVS, and warrants further observations of the evolving biologic processes manifesting at 3 years when the connective tissue replacing the bioresorbed polymeric strut begins to shrink, as previously shown in preclinical studies.

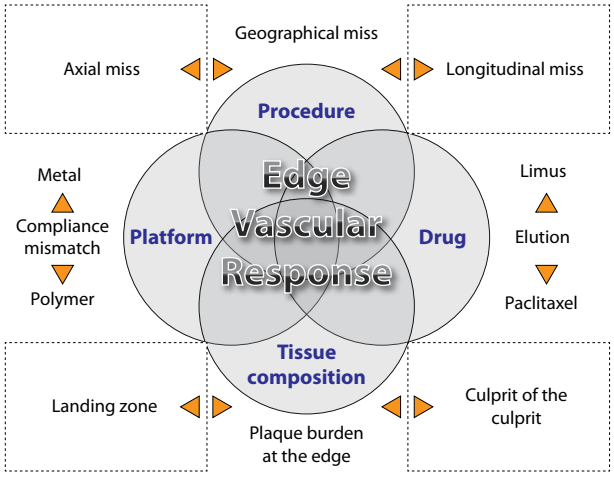


Figure 6. The edge vascular response as a consequence of iatrogenic, device-related and biologic factors.

Incomplete stent apposition

Incomplete stent apposition (ISA) occurring with conventional metallic stents, either immediately post-implantation or as a late acquired phenomenon, has been implicated in late stent thrombosis (LST).[25] Additionally, the vascular healing with first generation DES (SES or PES) remains incomplete up to 5 years following implantation and is a potential mechanism of LST with an annual rate of 0.65%.[9] A potential advantage of the bioresorbable technology over metallic devices is that any visible ISA post-implantation has the potential to resolve after the bioresorption process has been completed; furthermore, the phenomenon of incomplete healing may potentially not be an issue, as the device is expected to have disappeared after the time point of 2 years. Although these are hypothesis-generating concepts, large scale studies to confirm the probable lower incidence of device thrombosis with the use of the bioresorbable devices are eagerly expected and needed.

The challenges faced by the ABSORB BVS

The polymeric material as an implantation medium potentially has numerous advantages compared to metal, as previously discussed. The main challenges faced by the ABSORB BVS are its limited distensibility, and therefore its suitability for implantation in appropriately sized vessels. Consequently, at present QCA guidance is mandatory for implantation of the device.

Although the radial strength of the ABSORB BVS has been reported to be comparable to metallic stents, this is provided the BVS is deployed within the limits of its size. If the BVS is over-stretched beyond its designed limits, it has been shown to lose some of its radial strength and may possibly fracture. Much effort has been invested in improving its supportive properties, with the introduction of a new strut design

in order to enhance the distensibility of the device whilst maintaining its radial strength, features which are expected in the next generation BVS.

In an anecdotal case from the ABSORB cohort A, a 3.0 mm scaffold was over expanded with a 3.5 mm balloon, which resulted in strut fracture as documented by OCT;[26] additionally, Ormiston et al recently illustrated the strut fracture of a post-dilated ABSORB BVS (24 Atm) with a non-compliant balloon (3.25 mm) to correct underlying malapposition. These clinical examples are proofs that although the technology has immense potential, it needs further improvements.

Conclusion

Bioresorbable technology is an alternative and challenging therapeutic approach for the treatment of coronary artery disease. Although the scenario of a dynamic device that "does the job and disappears", leading to the restoration of vascular physiology, is here ("vascular reparative therapy"), this innovative and rapidly progressing technology is still in its infancy.

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