

Optical coherence tomography guidance during bioresorbable vascular scaffold implantation

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Abstract: Bioresorbable vascular scaffold (BRS) represent a revolutionary concept in interventional cardiology. After initial enthusiasm, recent real world registries, including patients with increasing lesion complexity, reported not trivial rates of scaffold thrombosis (ScT). The importance of correct patients selection as well as technical aspects during BRS implantation procedures has been highlighted in several studies suggesting that the high rate of ScT might be related to uncorrected patients/lesions selection together with underutilization of intracoronary imaging guidance leading to suboptimal BRS implantation. The high-resolution power together with the lack of shadowing observed beyond polymer struts makes optical coherence tomography (OCT) the optimal imaging technique to guide BRS implantation and identifies eventually scaffolds failures.

Keywords: Optical coherence tomography (OCT); bioresorbable vascular scaffold (BRS)

Submitted Jun 02, 2017. Accepted for publication Jul 25, 2017.

doi: 10.21037/jtd.2017.07.111

View this article at: <http://dx.doi.org/10.21037/jtd.2017.07.111>

In the last decades angiography has been the keystone to assess coronary anatomy, leading to a rapid development of percutaneous revascularisation techniques. Despite the widespread dissemination and high reproducibility, angiography provides a limited analysis of arterial lumen profile without the possibility to disclose vessel wall characteristics and composition of coronary plaques. Intracoronary imaging techniques have been developed to overcome these limitations. Intravascular ultrasound (IVUS) was the first technique introduced in interventional cardiology in the early 90ies (1), followed more than a decade after by optical coherence tomography (OCT). OCT is a light-based technology that similar to IVUS provides information about intravascular anatomy that far exceeds the level of detail obtained from conventional

angiography (2). The use of near-infrared light rather than ultrasound reflectance allows OCT to have greater resolution at the price of lower penetration power. Moreover, near-infrared light is scattered by red blood cells, and therefore OCT use for guidance of intervention is limited by the need of prolonged crystalloid infusion during imaging (3,4). In so forth, the penetrance of OCT in daily clinical practice was limited and the technology was mainly employed as a research tool to investigate plaque morphology and strut endothelialisation (5). The frequency domain OCT system (FD-OCT) has the advantage of a more rapid image acquisition due to the fast-scanning laser systems minimising the contrast use and increasing imaging speed while delivering an improved image quality than with the earlier time domain systems (TD-OCT) (6). This

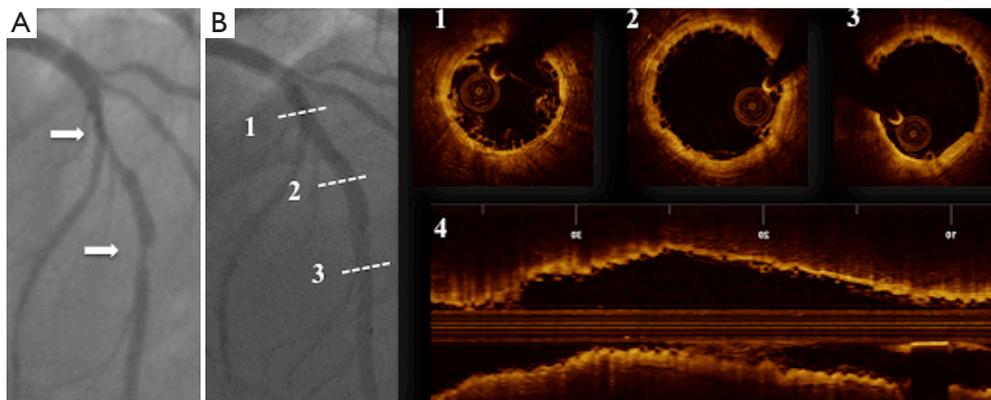


Figure 1 Shows the angiographic view of two sequential stenosis in the mid LAD (A) successfully treated with a 3.0×28 and 2.5×18 mm Absorb BVS (B). OCT cross-sections [1, 2, 3] and the OCT longitudinal view [4] show the optimal scaffold expansion.

allows multiple acquisitions of the entire vascular segment of interest with an amount of contrast only slightly higher than the amount required for the control angiogram (7). Another potential advantage of the FD-OCT over the old TD-OCT is that imaging acquisition does not require arterial balloon occlusion during the pullback, reducing the risk of ischemia and vascular injuries (8). However, despite the safety and high-resolution power, the use of FD-OCT during PCI is less than 5% worldwide and its real role during daily practice still have to be defined. Surely, a potential field of application of OCT is for guidance of bioresorbable vascular scaffold (BRS) implantation.

BRS represent a revolutionary concept in interventional cardiology. This technology has the potential to induce a true anatomical and functional “vascular restoration” after coronary revascularization, with the scaffold losing mechanical integrity after 6–12 months and completely reabsorbed in 3–5 years (9,10). After initial enthusiasm, justified by the positive results reported in initial small studies and by the ABSORB III randomized trial that showed a non-inferiority for target lesion failure (TLF) at 1 year between Absorb BVS (Abbot Vascular, Santa Clara, California, USA) and the Xience everolimus eluting stent (EES) (11,12), the AIDA trial and the three years follow up of the ABSORB II trial reported not trivial rates of scaffold thrombosis (ScT), requiring further investigations (13,14). These negative findings affected so much the credibility of bioresorbable therapy that the ABSORB BVS has been recently retired unless if used in controlled study protocols. Surely, the uncorrected patients and plaques selection together with suboptimal scaffold implantation might be partially related to the BRS negative results.

One of the potential pitfalls of bioresorbable scaffold is the low radial strength. While new generation metallic drug eluting stents (DES) presents a high radial strength able to counteract plaque recoil, the BRS structure is further weakened during the reabsorption process. Moreover, the presence of calcium or fibrosis that impairs distensibility of the vessel wall behind the scaffold might represent major limitations to an optimal scaffold opening. In so forth, tissue characterization and lesion preparation before BRS implantation is one of the crucial step for optimal BRS response.

OCT can accurately assess plaque characteristics such as calcifications, fibrous and lipid-rich plaque components, as well as the presence of dense macrophage infiltration, neovascularization and mural/luminal thrombi (15-19). Unfortunately, because of its limited tissue penetration, OCT is not suitable to properly visualise the external elastic membrane (EEM) in heavily diseased segments so that IVUS remains the gold standard to study vessel remodelling (19,20).

Once correct plaques characterization has been performed, the next step for optimal BRS response sees a proper lesion preparation followed by optimal scaffold apposition (*Figure 1*) (21-23). In fact the mechanical properties of BRS substantially differ from those of metal stents and the relatively less radial strength may results in insufficient scaffold expansion that might not be corrected by an aggressive post-dilatation because of the awareness that it might results in scaffold fracture. The lack of shadowing observed beyond polymer struts makes OCT the optimal imaging technique to optimize BRS implantation and identify eventually scaffolds failures such as malapposition, edge dissection, tissue protrusion, thrombus and fractures (24).

Role of OCT guidance for BRS in clinical trial and registries: apposition, coverage and reabsorption

OCT has been largely applied in dedicated cohorts of patients from major clinical BRS-trials for the assessment of acute post-procedural and long-term outcome (Table 1).

The ABSORB trial has provided the first description of the OCT appearance of the scaffolds. In the ABSORB cohort B study, enrolling 101 patients treated with the ABSORB everolimus-eluting scaffold (Abbott Vascular, Santa Clara, California), OCT was performed in 2 groups of patients, respectively at 6 and 24 months (B1, n=45) and 12 and 36 months (B2, n=56). Baseline imaging was optionally performed in 51 patients. The results showed the maintenance of the scaffold area at distance, with a slight decrease in luminal area, as a consequence on neointimal proliferation inside the BRS. In fact, 97% of the struts were covered at 1 year, with the scaffold displaying initial signs or resorption, but still largely visible (25). In addition, the comparison of post-procedural and late imaging allowed the discrimination between the acute scaffold disruption, which has been associated to an increased risk of TLF and thrombosis, and late discontinuities, representing the natural consequence of the reabsorption process (26).

In the subsequent ABSORB Japan trial, 400 patients were randomized to receive either the ABSORB BVS or cobalt-chromium EES. One-hundred twenty-five patients were randomly assigned to the OCT cohort, undergoing an imaging assessment at baseline and 2 years of follow-up. The OCT findings showed a complete vascular healing at 2 years, almost full struts coverage and minimal scaffold malapposition both in BRS and DES groups. Larger tissue growth was observed inside the BRS, resulting in a smaller flow area. The authors reported a 1.6% of very late ScT rate certainly superior to the <1% reported with newer generations of DES. OCT imaging of this subgroup of patients showed struts malapposition and discontinuities, but whether this was a late acquired “physiological” phenomenon or an acute post-implantation rupture could not be discriminated for the lack of immediate post-implantation data because OCT evaluation was performed only after the event (27).

In another study our group showed that an extensive use of OCT for guidance of BRS implantations allowed achieving similar acute performance than second generation metallic DES even during treatment of complex coronary lesions (28). We compared fifty complex coronary lesions

(all type ACC/AHA B2-C) treated with BRS under OCT guidance matched to an equal number of lesions treated with second generation DES. We found a similar incidence of residual area stenosis (RAS) and overall percentage of incomplete stent apposition (ISA) between the DES-group and BRS-group. Mean and minimal lumen area were similar in the two groups with also a similar mean and minimum eccentricity as well as symmetry index between the two groups. In the BRS group, there was a trend toward a higher prolapse area but this did not significantly impact on the final lumen area. These results however required a higher balloon diameter/mean reference vessel diameter ratio for predilatation in the BRS group with significantly higher pre and post dilatation inflation pressure together with a more extensive use of NC balloons for lesion preparation in the BRS group. Despite this, our data suggest that a satisfactory scaffold expansion can be achieved also in complex coronary lesions, at least when appropriate lesion preparation and BRS deployment under OCT guidance is performed. Moreover, in a small subgroup of 22 calcified lesions we also showed the safety and feasibility of super high-pressure dilatation (max post dilatation pressure of 28 ± 3 ATM) after BRS deployment without reporting any scaffold fractures (29).

The importance of OCT examination during BRS implantation is also highlighted by another study (30). In this retrospective analysis of more than 200 consecutive BRS implanted in 101 patients, we found that almost half of the OCT examinations led to a change in strategy before and/or after scaffolds implantation. When used before, OCT images suggested additional lesions preparation and allowed fine-tuning of the length and size of BRSs used. When used as a final control, OCT-pullback led to further post-dilatation in almost one third of the cases despite the aggressive systematic angiography-guided optimization technique used in the study. Interestingly, we also found that lesions treated with 2.5-mm overlapping scaffolds, considered at a higher degree of complexity, required more than one OCT pullback in a higher proportion of cases compared with the other lesions; not a trivial finding since the vast majority of ScT reported generally affect BRS improperly used during treatment of small coronary vessels.

Similar results, as compared to the ABSORB BVS, have also been achieved with the DESOLVE novolimus-eluting BRS (Elixir Medical Corporation, Sunnyvale, California, USA). The authors compared the OCT findings from a cohort of patients treated with the ABSORB (n=35) and 37 matched patients receiving the DESOLVE-150 scaffold. There was no difference in minimal and mean lumen area

Table 1 Randomized trials and registries evaluating the role of OCT guidance during BRS implantation

Study	Year	Total patients	Total OCT	Timing of follow-up	Device	Struts thickness (µm)	Study results
ABSORB-cohort B	2011	101	101 (51 at baseline)	6 and 24 months OR 12 and 36 months	ABSORB everolimus-eluting scaffold (Abbott Vascular, Santa Clara, California, USA)	156	No scaffold area reduction, well controlled inhibition of neointima, and almost complete coverage of the struts (97% at 1 year)
ABSORB Japan	2014	400	125	24 months	ABSORB everolimus-eluting scaffold (Abbott Vascular, Santa Clara, California, USA)	156	Vessel healing by two-year OCT was nearly complete in both BVS and CoCr-EES arms with almost fully covered struts, and minimal malapposition. The flow area by two-year OCT was smaller in the BVS arm than in the CoCr-EES arm, mainly due to tissue growth inside the device (BVS: $-1.49 \pm 1.13 \text{ mm}^2$ vs. CoCr-EES: $-0.80 \pm 0.74 \text{ mm}^2$, $P=0.001$)
Mattesini <i>et al.</i>	2014	73	35 patients with ABSORB BVS (50 lesions) matched with 38 patients with 2nd generation DES (50 lesions)	Post-implantation	ABSORB everolimus-eluting scaffold (Abbott Vascular, Santa Clara, California, USA)	156	Incidence of RAS > 20% was not statistically significant different in the BVS and DES ($P=0.85$) and there was no difference in the mean RAS ($P=0.32$). There was a higher incidence of ISA at the proximal edge in the BVS group ($P=0.05$) but no difference in the overall percentage of ISA ($P=0.62$); The mean and minimum eccentricity index and the symmetry index were similar in the two groups; In the BVS group, there was a trend toward a higher prolapse area ($P=0.08$) but this did not significantly impact on the final lumen area, which was similar in both groups
Caiazzo <i>et al.</i>	2016	101	65 patients (147 OCT-pullbacks)	Pre and post implantation	ABSORB everolimus-eluting scaffold (Abbott Vascular, Santa Clara, California, USA)	156	49.0% of OCT pullbacks caused a change in strategy during the BVS implantation procedure; OCT-pullbacks pre BVS insertion suggested: need for further pre-dilatation (10.2%); selection of a different scaffold diameter (4.8%); different scaffold length (11.6%); OCT-pullbacks after BVS insertion suggested: the need for a second post-dilatation for scaffold apposition/expansion optimization (18.4%); need for further BVS/stent implantation for incomplete lesion coverage and/or edge dissection (4.1%)

Table 1 (continued)

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Study	Year	Total patients	Total OCT	Timing of follow-up	Device	Struts thickness (μm)	Study results
Mattesini <i>et al.</i>	2016	72	35 patients with ABSORB BVS and 37 matched patients with DESOLVE-150	Post-implantation	ABSORB everolimus-eluting scaffold (Abbott Vascular, Santa Clara, California, USA) vs. DESOLVE novolimus-eluting BRS (Elixir Medical Corporation, Sunnyvale, California, USA)	156 vs. 150	OCT analysis showed similar MLA (Absorb vs. DESolve: 5.8 ± 1.9 vs. 6.1 ± 2.6 mm^2 , $P=0.43$) and mean luminal area (Absorb vs. DESolve: 7.1 ± 2.2 vs. 7.2 ± 1.9 mm^2 , $P=0.77$). The mean eccentricity index was 0.85 ± 0.05 with Absorb and 0.80 ± 0.05 with DESolve, $P<0.01$. There was no difference in the incidence of overall ISA. A smaller prolapse area was found with Absorb (Absorb vs. DESolve 1.0 ± 1.1 vs. 3.6 ± 6.2 mm^2 , $P<0.01$)
Boeder <i>et al.</i>	2017	60	45 patients with DESOLVE-150 and 15 patients with DESOLVE-100	Post-implantation	DESOLVE novolimus-eluting BRS (Elixir Medical Corporation, Sunnyvale, California, USA)	100 vs. 150	OCT showed similar post-procedural scaffold geometry and outcome indicating that both BRS may be implanted with good acute performance. However, the data suggest a decreased radial strength for the 100 μm BRS (minimal lumen area of 6.1 ± 1.9 vs. 5.2 ± 1.6 mm^2 , $P=0.06$; mean residual area stenosis was 15.3% vs. 21.3, $P=0.22$; mean eccentricity index did not differ significantly (0.8 ± 0.1 vs. 0.6 ± 0.1 , $P=0.61$). Prolapse area was 4.5 ± 8.8 vs. 5.6 ± 9.8 mm^3)
FORTITUDE	2016	62	60	9 months	FORTITUDE sirolimus-eluting scaffold (Amaranth, Mountain View, CA, USA)	150	High levels of strut coverage (96%) and scaffold stability (1.7% late discontinuities)
RENASCENT II	2017	60	59	9 months	APTTITUDE sirolimus-eluting scaffold (Amaranth, Mountain View, CA, USA)	115	High level of strut coverage (97.0%) and low rate of malapposition (0.037%, all covered)
MERES-1	2017	108	108	6 months	MeRes 100 BRS (Meril Life Sciences Pvt. Ltd., Vapi, India) sirolimus-eluting BRS	100	Minimum scaffold area (6.86 ± 1.73 mm^2) and percentage neointimal strut coverage (99.30%)
BIOSOLVE-II and -III	2017	BIOSOLVE-II, 11 N=123; BIOSOLVE-III, N=61	11	12 months	DREAMS 2G scaffold (Magmaris; Biotronik, Büllach, Switzerland) sirolimus-eluting scaffold with magnesium alloy	150	No intraluminal mass was detected by optical coherence tomography in BIOSOLVE-II at 6 and 12 months and no malapposed struts were detected at six months, when scaffold struts were already well embedded into the vessel wall. With its 95% absorption at 12 months, a late acquired malapposition was unlikely

OCT, optical coherence tomography; BRS, Bioresorbable vascular scaffold; ISA, impaired scaffold apposition.

and in the incidence of struts malapposition between the two scaffolds. However, the DESOLVE-150 showed a non-significantly higher tissue prolapse and asymmetric expansion, potentially conditioned by the slightly inferior thickness of the struts as compared with the ABSORB BVS (150 *vs.* 156 μm). Nevertheless, differences in the characteristics of the treated lesions could also have influenced the results of the study (31).

Indeed, the relevance of the thickness of the BRS struts has emerged after the demonstration that large scaffold platforms present limits in deliverability and favour the disruption of the laminar flow, with increase in thrombogenicity. The DESOLVE-100 μm (Elixir Medical Corporation, Sunnyvale, California, USA), in fact, has been implanted in 15 patients and compared with the results of the larger DESOLVE-150 (n=45 patients). OCT showed a good mechanical acute performance of the thinner platform, with lower rates of edge dissections. However, higher rates of scaffold fractures and reduced radial force emerged with the 100 μm platform, despite larger experiences are certainly needed to draw more definite conclusions (32).

A similar reduction in the thickness of the struts has been observed in the Amaranth research program (Mountain View, CA, USA), although their BRSs still represent investigational products not available on the market. The first FORTITUDE—150 μm sirolimus-eluting scaffold showed 96% struts coverage and scaffold stability at 9-months OCT examinations. The subsequent APTITUDE—115 μm sirolimus-eluting scaffold, in the RENASCENT II study, confirmed at 9-months OCT good struts coverage (97%), with a low rate of malapposition (0.037% of struts, all re-endothelized), whereas the MAGNITUDE—100 μm sirolimus-eluting scaffold is currently evaluated in the ongoing RENASCENT III study.

The MeRes 100 BVS (Meril Life Sciences Pvt. Ltd., Vapi, India) also is an analogous low-profile, sirolimus-eluting BRS, that has been implanted in 166 lesions (108 patients) in the MeRes-1 first-in-man study. The OCT re-assessment showed an early 6-months high rate of neointimal coverage (99.3%), potentially providing an explanation for the good clinical performance (low rate of MACE, 0.93%, with no ScT) at 1-year clinical follow-up (33).

Finally, a different scaffold design, has been developed for the DREAMS 2G (Magmaris; Biotronik, Bülach, Switzerland), a sirolimus-eluting scaffold built in a magnesium alloy. In the BIOSOLVE II and III program, OCT was performed on volunteer basis at 6, 12 and 36 months. No intraluminal mass was detected by OCT in BIOSOLVE-II at 6 and

12 months and no malapposed struts were detected at 6-months, when scaffold struts were already well embedded into the vessel wall, with 95% of absorption at 12-months. Thanks to its laser-polished surface the DREAMS 2G present a smooth surface, and strut cross-sections are rectangular with rounded edges, which may facilitate embedding into the vessel wall (34). Nevertheless, a dedicated Magmaris-OCT study is currently ongoing and will enrol 60 consecutive patients undergoing Magmaris scaffold implantation. The primary end point will be the percentage of uncovered scaffold struts assessed by OCT at the prespecified follow-up up to 12 months (35).

Conclusions

BRS represent a revolutionary concept in interventional cardiology with their unique potentiality to induce a true anatomical and functional “vascular restoration” after coronary revascularization. However, the mechanical properties of these polymer-based scaffolds highly differ from the metallic stents used in our daily practice. The importance of correct patients selection as well as technical aspects during BRS implantation procedures has been highlighted in several studies suggesting that the high ScT reported might be related to the underutilization of intracoronary imaging guidance during BRS implantation. OCT might represent the optimal imaging technique to optimize BRS implantation and identify eventually scaffolds failures.

Acknowledgments

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Cite this article as: Secco GG, Verdoia M, Pistis G, De Luca G, Vercellino M, Audo A, Parisi R, Reale M, Ballestrero G, Marino PN, Di Mario C. Optical coherence tomography guidance during bioresorbable vascular scaffold implantation. *J Thorac Dis* 2017;9(Suppl 9):S986-S993. doi: 10.21037/jtd.2017.07.111