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Spreading New (OCT-) Light on Bioresorbable Vascular Scaffolds' Performance. Can the Future of BRS Become Brighter?☆

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With thousands of devices implanted and a consistent body of research developed in the last years, the 4th revolution of bioresorbable vascular scaffolds (BRS) has represented so far only an unfulfilled idea. The ambitious goal of the vascular restoration therapy with fully-resorbable and drug-eluting devices has – with a general disappointment – led to uncertainty and suspicion. Indeed results from the AIDA and the Absorb trials [1,2] have shown an unacceptably high rates of late and very-late scaffold thrombosis (ST), leading to the end of Absorb-BRS (Abbott Vascular, Santa Clara, California) and to a drastic limitation of all BRS adoption in the western countries. More specifically, the randomized trial from Wykrzykowska et al. disclosed an incidence of ST of 3.5% (vs 0.9% in the conventional DES group, $p < 0.001$) and the meta-analysis from the Absorb Trials showed about 2.4% of ST against 0.6% in the control group. These outcomes were associated with a significantly higher incidence of target lesion revascularization (TLR) and, more importantly, with increased rates of myocardial infarction (MIs).

However, many efforts in understanding the mechanisms of failure of BRS have been made – and are still ongoing - to provide additional insights in the pursuit of the guilty gear of this novel therapeutic process. In their elegant draft, Yamaji and colleagues identified three possible levels for assessing the determinants of BRS outcome: the device, the operator and the lesion [3]. While device characteristics - including the large strut-thickness (150 μm), the loss of radial force during the absorption process resulting in late recoil, and loss of structural integrity leading to scaffold discontinuity - are findings that are specific to BRS and difficult to prevent [4], much more can be done regarding the operator choices and lesion assessment.

Not surprisingly, technical choices aiming at optimal scaffold expansion and apposition have been shown to be highly correlated with clinical outcomes and freedom from thrombotic events in retrospective analysis [5]. In their post-hoc analysis, Stone et al. highlighted that only a minor proportion of patients enrolled in the Absorb trials underwent proper pre- (60%) and post-dilatation (12%), and furthermore demonstrated that the lack of these technical precautions was associated with the worst clinical outcome.

With a similar purpose, a number of registries and investigations have focused on providing prospective insights in BRS performance depending on plaque burden and composition. In this issue of Cardiovascular and Revascularization Medicine, Boeder and colleagues reported on optical coherence tomography (OCT) findings after implantation of a recent novolimus-eluting BRS (DESolve®, Elixir Medical Corporation, Sunnyvale, CA, USA) in relation with plaque morphology and composition [6]. Main goal was to detect indices of acute mechanical performance (namely expansion, symmetry and eccentricity) of the BRS in the settings of fibrous and/or calcific plaques. Fifteen patients were included in the present analysis, with high rates of lesion preparation and device optimization (pre-dilatation and post-dilatation with NC balloon in 87% of case). The authors reported that only fibrous plaque burden (namely area, thickness and arc-angle as detected by OCT) was associated with sub-optimal acute mechanical outcome, as expressed by the index of scaffold eccentricity. On the contrary, device eccentricity and expansions were not influenced by the classically adverse plaque features such as calcific plaques burden, calcific plaque area and extension. Of note, overall good parameters of eccentricity and symmetry in scaffold implantation were reported, indicating – in this specific group of patients – a satisfying device performance.

These results are of particular interest when compared with those previously published with the Absorb BRS. In 2015, Shaw et al. investigated with OCT the Absorb BRS expansion-parameters after implantation in the settings of coronary stenosis with a wide spectrum of plaque compositions and morphology [7]. Their findings highlighted how the presence of calcium - and more specifically calcium plaque area, thickness and arc angle –were predictors of worse BRS eccentricity and expansions. In their paper, the authors concluded that these features could be responsible for device suboptimal implantation and require careful evaluation before BRS adoption. These data contributed to an increased scepticism of BRS use when plaque characteristics appear more adverse, including the presence of calcium.

Although limited by the number of patients analyzed, the novel light-based data provided by Boeder et al. in the present issue seem to offer an initial signal of more reliability in BRS performance, even in these adverse settings. The authors underline the value of a meticulous pre-dilation, followed by appropriate post-dilation, when comparing their observed better outcome, but do not exclude possible mechanical benefits from the different devices. As a matter of fact, these results may indicate that there are clear differences among the different BRS and that not all BRS are created equally. Differences in platform, struts design and mechanical characteristics, discriminating Desolve from Absorb may have a relevant role in acute performance as well as in long-term clinical outcome.

In conclusion, a definitive responsible for the unmet goals of the first generation of BRS is still evading our full comprehension. However, encouraging results in those settings where its use appeared not only sub-optimal but also contra-indicated may represent the first signals for a

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new current of reliability on the vascular-restoration therapy. Future efforts in a better understanding of our previous mistakes and in improving the mechanical properties of the devices we are using may convert the – still awaited - 4th revolution of interventional cardiology in a brighter future for our patients.

References

[1] Wykrzykowska JJ, Kraak RP, Hofma SH, et al. Bioresorbable scaffolds versus metallic stents in routine PCI. N Engl J Med 2017;376:2319–28.
[2] Ali ZA, Gao R, Kimura T, et al. Three-year outcomes with the Absorb bioresorbable scaffold: individual-patient-data meta-analysis from the ABSORB randomized trials. Circulation 2018;137:464–79.
[3] Yamaji K, Räber L, Windecker S. What determines long-term outcomes using fully bioresorbable scaffolds - the device, the operator or the lesion? EuroIntervention 2017;12:1684–7.
[4] Räber L, Brugaletta S, Yamaji K. Very late scaffold thrombosis: intracoronary imaging and histopathological and spectroscopic findings. J Am Coll Cardiol 2015;66:1901–14.
[5] Stone GW, Abizaid A, Onuma Y, et al. Effect of technique on outcomes following bioresorbable vascular scaffold implantation: analysis from the ABSORB trials. J Am Coll Cardiol 2017;70:2863–74.
[6] Boeder NF, Dörr O, Bauer T, et al. Effect of plaque composition, morphology, and burden on DESolve novolimus-eluting bioresorbable vascular scaffold expansion and eccentricity — an optical coherence tomography analysis. Cardiovasc Revasc Med 2018. https://doi.org/10.1016/j.carrev.2018.07.030 (pii: S1553-8389(18)30329-4).
[7] Shaw E, Allahwala UK, Cockburn JA, et al. The effect of coronary artery plaque composition, morphology and burden on Absorb bioresorbable vascular scaffold expansion and eccentricity - a detailed analysis with optical coherence tomography. Int J Cardiol 2015;184:230–6.