What Happened to the Bioresorbable Scaffold Concept
Black Tide or Chernobyl?

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Since Tamai were the first to launch the fascinating bioresorbable scaffold in 1999, Abbott took the leadership of the proof of concept in human with Absorb bioresorbable vascular scaffold (BVS; Abbott Vascular, Santa Clara), a 100% poly-L-lactic acid everolimus-eluting bioresorbable scaffold.[1,2] Despite encouraging noninferiority randomized trials during the first 2-year follow-up, these studies showed an increase in-scaffold thrombosis compared with the drug-eluting stent (DES; Xience; Abbott). Unfortunately, the 3-year outcome of ABSORB II (A Clinical Evaluation to Compare the Safety, Efficacy and Performance of ABSORB Everolimus Eluting Bioresorbable Vascular Scaffold System Against XIENCE Everolimus Eluting Coronary Stent System in the Treatment of Subjects With Ischemic Heart Disease Caused by de Novo Native Coronary Artery Lesions) confirmed by meta-analyses resulted in the end of Absorb BVS use in Europe and the United States.[3,4] In September 2017, Absorb BVS was withdrawn from the market, although higher rates of scaffold thrombosis did not result in increased mortality.[5] Moreover, 4 other scaffolds with European Conformity mark, and several other scaffold projects in the pipeline, could not stop the sinking of the Absorb platform, which resulted in a black tide on the bioresorbable concept itself.[6]

See Article by Capodanno et al

Capodanno et al[7] publish in the current issue of *Circulation: Cardiovascular Interventions* a fascinating predictive model whose message is simple: we need to wait at least 19 years to anticipate a putative superiority of Absorb over Xience, 10 years if we hypothesize a better future device with more adequate deployment protocol, and 28 years if Absorb BVS does not disappear in 3 years but 5 years. Their statistical tool is impressive, and their message is transforming a transient black tide in a permanent Chernobyl disaster. Their objective has to be acknowledged, that is, not only in adding another meta-analysis, but compelling physicians, companies, and stakeholders to face the reality, recognizing how far we are from asking ourselves the right questions to get out of this nightmare. We are not statisticians to argue on their magisterial demonstration, except perhaps in one point. In-device thrombosis is clearly the cornerstone of this drama, although the increased in-scaffold thrombosis did not result in increased scaffold death, and their model does not apparently take into account this aspect. The strong message of their study can lead to either the funerals of the bioresorbable scaffold concept or a drastic positive criticism of the state of the art: we have to conceive a new generation scaffold that would prevent early, late, and very late thrombosis.

To decrease the late events, it seems obvious that the scaffold time life should be reduced. Capodanno et al[7] demonstrated that by increasing the Absorb BVS persistency by 2 years in the coronary artery, 10 years more was needed to reach DES benefit. On the other hand, we can speculate that by decreasing 1 or 2 years, the scaffold presence might close its gap versus DES. Scaffolds should disappear faster: <3 years, 2 years being feasible, and may be <2 years, as shown with corrodible metals or polymers.[8,9] Reducing the time life of a foreign body in the artery wall should reduce the occurrence of late events such as in-device thrombosis or neoatherosclerosis that generate late events.

Concerning the early events, we should focus on an optimal deployment technique and enhanced scaffold able to be overexpanded as safely as a standard DES.[10] As mentioned by other authors, physicians should accept to avoid treating vessels with reference diameters <3 mm, which still represent more than half of the stented vessels. Moreover, the optimal scaffold should have better hemocompatibility (choice of the platform), thinner, ellipsoid rather than rectangular struts that can be competitively performed with corrodible metals or polymers and should lead to less turbulent flow.[11,12] Efforts should be made to limit as much as possible acute and chronic recoil, that is, offering a sustainable optimal radial force during the healing process. Then, we should use the lessons from the first-generation versus second-generation DES: the 2006 Barcelona coup de grâce has not killed the concept of DES, but resulted in a successful evolution. This means that the drug use should be fine-tuned to allow a fast endothelial coverage of the scaffold struts. It is important to state that the amount of everolimus eluted by Absorb BVS was 2-fold higher than those eluted by Xience DES. A scaffold dismantling should then allow an early positive remodeling after a natural increased flow after the healing process, that is, 3 months.[13] If we choose to defend the concept, we need to accept objectively that these issues are not overwhelming and that appropriate solutions can be found. The conclusions of the study of Capodanno et al[7] are simple: they force us to completely revise our strategy if we want to let this revolutionary concept survive.

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Disclosures

Dr Lafont is cofounder of Arterial Remodeling Technologies (Paris, France). The other author reports no conflicts.

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