# Requiem for a Scaffold

On 8 September 2017, the medical device manufacturer Abbott announced that it would halt the sale of its Absorb GT1 bioresorbable vascular scaffold (BVS), citing low sales and unsustainable margins (1). At the time of the announcement, Absorb accounted for less than 1% of the overall market for coronary stents, and the company's move came on the heels of a series of setbacks for the BVS program. In March 2017, Abbott, working with European authorities, imposed restrictions on BVS use outside clinical trials and registries. In that same month, the U.S. Food and Drug Administration (FDA) issued a letter to health care providers about potential safety concerns (2).

In light of these developments, the medical community's initial optimism regarding the BVS concept is hard to recall. However, the reasons investigators were so excited about the BVS are worth revisiting. In the United States, approximately 650 000 percutaneous coronary interventions are performed annually (3). Metallic stents are implanted in more than 90% of these procedures (4), but they have important drawbacks: they inhibit remodeling (5), may preclude future coronary artery bypass grafting, and put patients at risk for stent thrombosis. The BVS theoretically addressed these concerns. Because BVSs are completely resorbed, arteries in which a BVS is implanted would retain the ability to positively remodel. Furthermore, the absence of metallic stent struts would preserve future access as a bypass graft anastomosis and reduce the risk for vessel thrombosis and the need for long-term dual antiplatelet therapy.

With these advantages in mind, device manufacturers invested millions of dollars in BVS programs, with Abbott enjoying a considerable competitive market advantage. The Absorb BVS became available commercially in Europe in 2011 (5), and the FDA approved it for commercial use in the United States in July 2016 (6). Approval in the United States was based largely on the ABSORB III single-blind noninferiority trial, in which 2008 patients were randomly assigned 2:1 to receive a first-generation BVS or an everolimus-eluting stent. This study demonstrated noninferiority of the Absorb BVS to the drug-eluting stent for a composite end point of cardiac death, target vessel myocardial infarction, or ischemia-driven target lesion revascularization at 1 year (7).

The BVS, however, was intended to provide an alternative to metallic stents that was safe and effective for both the short and long term, and it was never clear that the Absorb BVS met this goal. With their current *Annals* report, Zhang and colleagues (8) add to a growing body of literature highlighting safety concerns regarding these devices. The authors performed a systematic review and meta-analysis of 7 randomized trials and 38 observational studies to characterize the mid- and long-term follow-up of patients receiving a BVS or an everolimus-eluting stent. The authors scoured the medical literature for relevant information, including abstracts, presentations, and published manuscripts with at least 6 months and 100 patient-years of follow-up. They found that the rate of definite or probable scaffold thrombosis after BVS implantation was 1.8% at a median follow-up of 1 year and 0.8% beyond 1 year. Compared with patients who received an everolimus-eluting stent, those who received a BVS had 3.40 (95% CI, 2.01 to 5.76) times greater odds of definite or probable scaffold thrombosis at a median follow-up of 25 months. Consistent with this increased risk, patients with a BVS were at higher risk for myocardial infarction and target lesion revascularization than those with a drug-eluting stent.

If the findings seem familiar to *Annals* readers, it is no mistake. The article represents an update of a 2016 study published in *Annals* by many of the same investigators. That study focused on outcomes at a median follow-up of 10.5 months after BVS implantation. That the updated study has been published in *Annals* is a credit to both the authors and editorial staff. It would have been easy to discount the study as merely representing a marginal incremental advance and relegate it to a lower-tier journal. Instead, decision makers recognized that despite superficial similarities, the updated study addresses key knowledge gaps regarding clinically meaningful differences in longer-term outcomes associated with BVSs and provides the quantitative estimates physicians and patients need to have informed discussions about scaffold selection. Their findings demonstrate that many of the purported benefits of BVS resorption have not been realized, and it seems increasingly unlikely that any BVS platform will put a dent in the dominance of metallic stents.

Nevertheless, the timing of the article's publication, on the heels of Abbott's announcement, exposes the limitations of using the peer-reviewed literature to disseminate research findings. Although publishers are actively working to reduce review times, months and sometimes years pass between manuscript submission and publication. As important as the findings of Zhang and colleagues are to defining the role of the Absorb BVS in clinical practice, the authors missed an opportunity to truly affect the BVS debate. Peer-reviewed publication remains a priority for researchers, particularly those associated with academic institutions, but we need mechanisms to get the preliminary findings into circulation before publication. Many disciplines have accepted that early versions of articles will be publicly available through "preprinting," and perhaps it is time for medical research to follow suit.

The larger portfolio of BVS-related research demonstrates a role for a robust device surveillance pro-

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gram. The FDA's approval was based largely on 1-year follow-up, and ideally the FDA would have prespecified plans for frequent reassessments of BVS data to incorporate findings, such as those of Zhang and colleagues in their meta-analysis, into its regulatory decision making. The goal of providing patients with access to beneficial new technologies means that long-term follow-up will not always be available at approval, but such data must be obtained, monitored, and acted on rapidly to ensure that patients are receiving safe and effective devices. The creation of the National Evaluation System for Health Technology is an important step toward meeting this need (9), but its success will require stakeholders to set aside self-interest for the greater good of public safety.

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**Disclosures:** Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M17-2522.

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