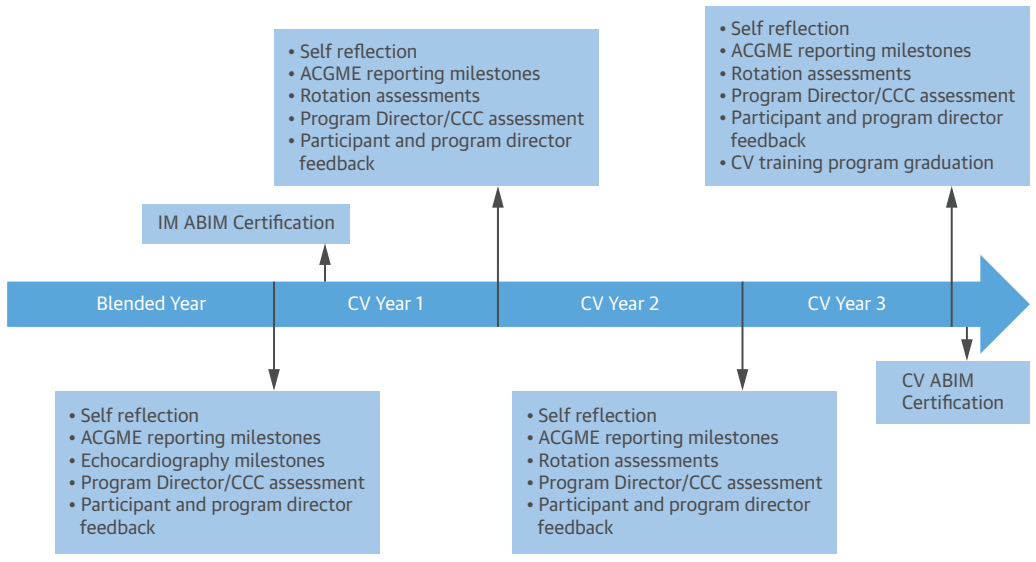
FIGURE 1 ABIM/ACC Pilot Program Evaluation Timeline



Timeline of evaluation of pilot trainees throughout the program. ABIM = American Board of Internal Medicine; ACC = American College of Cardiology; ACGME = Accreditation Council for Graduate Medical Education; CCC = Clinical Competence Committee; CV = cardiovascular.

training innovation and restructure CVM fellowship. As the ability to pay off debt and length of training affect both specialty and long-term career choice (3,4), the importance of achieving competency in a shorter time frame than the traditional training period has become important. This pilot may provide a roadmap for further investigation into how to most effectively use limited training resources in producing subspecialty physicians.

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Bioresorbable Scaffold Thrombosis

A Multifactorial Phenomenon Also Involving Hypersensitivity Inflammation?

In the large scale meta-analysis of individual controlled trials published in the *Journal* (1) that involved 5,583 patients randomized to receive either the Absorb bioresorbable vascular scaffold (BVS) or metallic everolimus-eluting stents, BVSs were associated with both lower efficacy and higher

stent thrombosis over time (2.4% vs. 0.7%). The investigators recommended a prolonged period of dual antiplatelet therapy and suggested further investigation.

However, they should have been referred to the Food and Drug Administration (FDA) safety alert (2) on the Absorb GT1 Bioresorbable Vascular Scaffold System-P150023 (Abbott Vascular, Santa Clara, California), which stated that it is contraindicated for patients who have a known hypersensitivity or allergy to materials used in the device, such as poly L-lactide (PLLA), poly D, L-lactide (PDLLA), everolimus, contrast media, aspirin, or antiplatelet agents.

The Absorb BVS is composed of PLLA backbone, coated PDLLA, and everolimus macrolide immunosuppressant. Both polymers are eventually degraded into lactic acid through metabolism in the Krebs cycle, a process that takes up to 2 years to complete. Acidic degradation products accumulate and decrease the pH of the surrounding tissue, which could trigger inflammatory and foreign body reactions in vivo. Immunohistochemical studies in the coronary arteries of mini-pigs implanted with PLLA scaffolds revealed that positive staining of nuclear factor (NF)-κB was mainly distributed in the nuclei of the vascular endothelium and endangium. NF-κB constitutes a nuclear factor that binds to the enhancer element of the immunoglobulin-κ light-chain of activated B cells and is regarded as a marker of inflammation because it can mediate expression of numerous inflammatory cytokines (3).

Clinically, local foreign body reactions, hypersensitivity reactions, and synovitis, especially in orthopedics, were correlated with the use of PLLA. Systemic hypersensitivity reactions to PLLA acid screws, including rash, facial swelling, packed sinuses, localized alopecia, water retention, and fatigue, were confirmed by positive skin tests and necessitated further removal of the screw (4).

In a recent report (5), eosinophilic thrombus infiltration was absent in 3 patients with Absorb BVSs and late stent thrombosis. However, in 1 patient, foreign material that displayed the bands of the Absorb BVS was demonstrated in thrombus 44 months after scaffold implantation. The investigators admitted that until larger cohort studies are available, including histopathological analysis of thrombus and autopsy studies, hypersensitivity reactions to PLLA polymer cannot be excluded.

Therefore, strict adherence to FDA recommendations and further efforts for discovering inert materials seem to be of paramount importance to avoid such dangerous consequences.

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REPLY: Bioresorbable Scaffold Thrombosis

A Multifactorial Phenomenon Also Involving Hypersensitivity Inflammation?

We thank Dr. Kounis and colleagues for their interest in our meta-analysis of randomized controlled trials (RCTs) that compared the Absorb bioresorbable vascular scaffold (BVS) with everolimus-eluting stent (EES) in patients who underwent percutaneous coronary intervention (1). In our study, BVS were associated with greater risk of device thrombosis (absolute risk difference: +1.67%) compared with EES at a median follow-up of 2 years. This effect appeared to be uniform across the early, late, and very late periods, which may support the use of prolonged dual antiplatelet therapy (DAPT) beyond 1 year to prevent this complication. We agree with Dr. Kounis and colleagues that hypersensitivity to the