well as multicenter randomized trials would offer the chance to develop new definitions of AF and better selection criteria for choosing the optimal ablation approach tailored for the individual patient. However, such a registry requires standardization of risk factors and especially of ablation protocols, but it offers the opportunity of a more rapid evaluation of new ablation techniques. Therefore, as of today, it is sometimes challenging to discern apples from oranges in the first place since our understanding of AF pathophysiology remains incomplete.

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Intraluminal Scaffold Dismantling

The Downside of Positive Remodeling?

We read with interest the publication by Räber et al. (1), in which 4 cases of very late scaffold thrombosis (VLScT) were reported. A novel mechanism of VLScT that was not seen with metallic drug-eluting stents (DES), namely that of intraluminal scaffold dismantling (ILSD), was suggested in 3 cases. These cases highlight the concerns that are surfacing following the increasing use of biodegradable vascular scaffolds (BVS) in complex coronary disease.

Pre-clinical and imaging-based clinical investigations have shown favorable BVS healing characteristics because of luminal enlargement due to positive vessel remodeling once bioresorbed (2). However, recent data suggest that this process is associated with higher rates of adverse events, including subacute stent thrombosis, compared with contemporary metallic DES (3). Furthermore, delayed bioresorption and variability in healing have been observed following BVS implantation in diseased human coronary arteries. In 1 case presented by Räber et al., VLScT occurred as late as 44 months after implantation, with optical coherence tomography (OCT)-defined “preserved boxes” suggesting an unfulfilled bioresorption process. Thus, the implantation of BVS, like DES, does not eliminate very late adverse events.

Careful lesion preparation, appropriate sizing, optimal scaffold expansion, and image-guided intervention have been heralded as prerequisites to ensure favorable outcomes. We report a case where, despite these measures, there was evidence of acquired late malapposition and extensive ILSD at 24 months following BVS implantation.

An 81-year-old women underwent stenting of a left main (LM) bifurcation lesion that involved the left anterior descending (LAD) and circumflex (Cx) coronary arteries (Figure 1A1). Following lesion preparation, a 3.5- × 11-mm Axxess biolimus-eluting, self-expanding bifurcation stent (Biosensors International, Morges, Switzerland) was deployed at the LM bifurcation, after which a 3.0- × 12-mm and 2.5- × 18-mm Absorb BVS (Abbott Vascular, Santa Clara, California) were positioned in the proximal LAD and Cx arteries, respectively. Proximal optimization, sequential post-dilation (3.25- and 2.75-mm noncompliant balloons in the LAD and Cx at 20 atm, respectively), and kissing balloon post-dilation (at 10 atm) were performed. The angiographic result was excellent (Figure 1A2), with OCT confirming full bifurcation coverage and excellent strut apposition of the Axxess device and BVS in the LAD and Cx arteries (Figure 1B1 to B6). At 2 years follow-up, the patient remained asymptomatic, and planned control angiography with OCT assessment was performed. Angiographically, the proximal Cx was ectatic with focal haziness (Figure 1A3). OCT (Figure 1C1 to C6) revealed free-floating unapposed and uncovered struts protruding into the lumen (Figure 1C1, C3, and C4, white arrows) in the mid-scaffold region, suggesting ILSD. Struts were absent (Figure 1C4, white dotted line) where intraluminal struts should have been. Uncovered malapposed struts (Figure 1C5, red arrows) and covered malapposed scaffold struts (Figure 1C6) overlapping with the Axxess stent proximally (Figure 1B6 and C6; white asterisk, Axxess marker in proximal Cx) were noted. Many unapposed struts had a preserved box appearance. Acquired malapposition caused by important positive vessel wall remodeling (minimal...
luminal area at baseline 5.00 mm² vs. 7.85 mm² at follow-up), and coronary evaginations (Figure 1C4, arrowhead) were detected in the areas of scaffold disruption. This remodeling was absent in the LAD and distal part of the Cx BVS (Figure 1B1), where struts were adequately covered and embedded.

This case illustrates ILSD that possibly resulted from positive remodeling before bioresorption, where the malapposed and uncovered scaffold dismantled and protruded into the lumen. Although no resistance was noticed, it is conceivable that passing the OCT catheter aggravated scaffold disruption. There was no initial undersizing or overexpansion of the scaffold implanted in the Cx, with baseline OCT revealing an excellent result immediately after scaffold implantation.

We believe there are several important implications arising from these recent observations: 1) the indication for and implantation of current-generation BVS should be considered carefully, and while awaiting further safety data, the use in complex lesions should be confined to a clinical trial setting; and 2) when performing invasive assessment, care must be taken if devices (imaging catheters, etc.) are passed through the BVS within several years after implantation. Moreover, several important questions need to be addressed. In view of the possibility of delayed healing, should dual antiplatelet therapy (DAPT) be advocated for a longer period? What is the appropriate management of ILSD detected in asymptomatic individuals? Should a metallic stent be deployed, or does it suffice for DAPT to be restarted and/or prolonged?

In conclusion, vessel uncaging, restoration of vasmotion, and positive remodeling are considered beneficial effects of BVS technology. However, unexplained ILSD, which is possibly influenced by early positive remodeling, may represent a worrisome consequence of the healing process, tempering the enthusiasm for the technology in its current stage.

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REPLY: Intraluminal Scaffold Dismantling
The Downside of Positive Remodeling?

We appreciate Dr. Bennett and colleagues’ interest in our paper, which addresses the imaging and histopathological findings of patients with very late scaffold thrombosis (1). In their letter, the authors present outcomes of a patient with complex left main bifurcation intervention treated with a hybrid approach, including a dedicated metallic self-expanding, drug-eluting stent (DES) bifurcation device in combination with 2 ABSORB bioresorbable vascular scaffolds (BVS) (Abbott Vascular, Santa Clara, California). Despite a presumably adequate result with full lesion expansion and apposition as assessed by optical coherence tomography, the patient developed considerable positive vessel wall remodeling and late scaffold strut disintegration, which are findings that have been previously associated with stent thrombosis.

Positive remodeling may ensue as consequence of an inflammatory response to scaffold drugs and polymers (2). If the outward remodeling of the vessel wall outpaces the loss of the scaffold’s structural integrity, late acquired malapposition may occur, imposing an important risk for very late stent thrombosis. Although positive remodeling was strongly associated with use of early generation DES (particularly sirolimus-eluting stents) (2), and to a lesser degree with newer generation DES (3), the frequency and clinical sequelae following bioresorbable scaffold implantation are not well established to date. Late scaffold strut disintegration with subsequent malapposition represents a resorption-specific phenomenon. In the absence of full neointimal scaffold integration, struts may protrude into the lumen after loss of structural integrity and potentially trigger thrombosis, as shown by our group (1).

Bioresorbable scaffolds entail promising features to advance the field of coronary revascularization. Although meta-analyses of pivotal clinical trials comparing ABSORB BVS with everolimus-eluting metallic stents attest to a similar efficacy, stent thrombosis occurred more frequently in ABSORB BVS–treated patients (4). This difference occurring within the first year after implantation may be overcome by meticulous implantation techniques as well as guidance by intracoronary imaging, although the benefit of such a strategy has to be confirmed in carefully designed studies and may be dependent on patient and lesion characteristics. Progress in scaffold technology using lower scaffold strut thickness and novel polymeric or metallic bioresorbable materials is expected to further improve results compared with the progress observed with metallic DES.

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