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Long-term follow-up of spontaneous coronary artery dissection treated with bioresorbable scaffolds

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Introduction

Patients with acute spontaneous coronary artery dissection (SCAD) are preferably managed conservatively given the good overall results shown with this approach[1]. In some cases, however, SCAD leads to compromised coronary flow, causing ongoing myocardial ischaemia and requiring revascularisation, generally by percutaneous coronary intervention (PCI)[1]. Bioresorbable vascular scaffolds (BVS) have emerged as an attractive option to avoid a permanent prosthesis and to allow vessel functional recovery in SCAD patients, who are generally young and have non-atherosclerotic arteries that tend to heal spontaneously[1]. However, first-generation BVS showed worse performance than benchmark drug-eluting stents[2]. Despite this, newer-generation BVS are expected to show improved outcomes in atherosclerotic patients and perhaps in SCAD patients[2]. We evaluated the long-term clinical outcomes of SCAD patients treated with first-generation BVS and provide data in this article to inform future decisions about platform choice.

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Methods

Details regarding data collection and variable definitions are available in **Supplementary Appendix 1** and **Supplementary Figure 1**.

Results

From July 2013 to July 2016, 22 SCAD cases treated with BVS were included **(Figure 1)**. Patient demographics **(Table 1)** reflect a characteristic SCAD population with a high-risk profile.

Procedural characteristics can be found in **Supplementary Table 1** and further results can be found in **Supplementary Appendix 2** and **Supplementary Figure 2**.

Clinical outcomes are shown in **Table 2**. The long-term median follow-up time was 3.46 years (IQR: 2.87-3.96; min-max: 1.78-4.82). Bleeding episodes were all minor, and predominantly related to menorrhagia that did not require transfusion or discontinuation of dual antiplatelet therapy (DAPT). Two patients underwent clinically driven repeat revascularisation after discharge: one patient underwent target vessel revascularisation (TVR) one year later for persistent typical angina and persistent dissection flap distal to the previously implanted scaffold, with subsequent resolution of symptoms; the other patient received target lesion revascularisation (TLR) at 13 months due to scaffold shrinkage **(Supplementary Figure 3)**. No recurrent myocardial infarctions, SCAD, or deaths were seen. None of the patients scheduled for surveillance angiography showed findings leading to further intervention.

Discussion

In this multicentre registry comprising 22 high-risk SCAD patients treated with BVS, two patients required repeat revascularisation in the long term, only one being attributable to device failure.

A number of published case reports or mini-series have already reported successful experiences with BVS in SCAD[3-5]. Ielasi et al reported no clinical events in 18 patients with an interquartile follow-up range of 6 to 28.5 months[3]. Our study shows the longest

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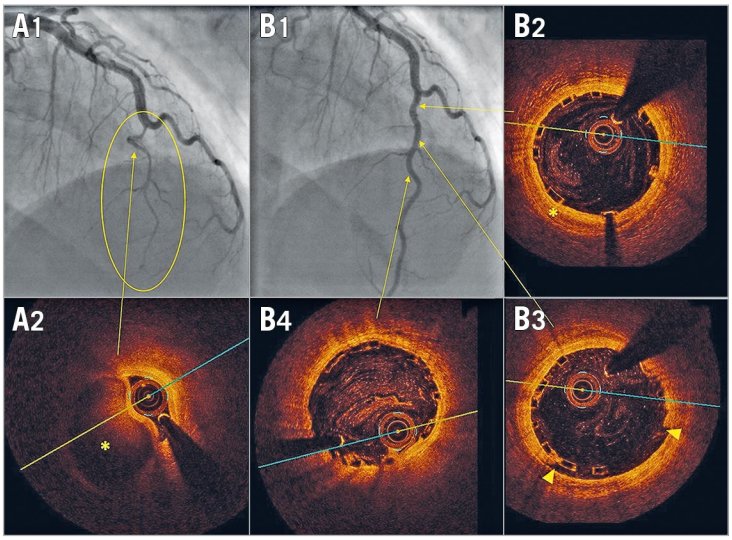

Figure 1. *BVS implantation in a mid-LAD type 2 spontaneous dissection. A1) & A2) Angiography at presentation with a severely narrowed lumen (oval) due to the presence of a compressive haematoma confirmed with OCT (asterisk). B1) Angiographic outcome after implantation of two BVS at 10 atmospheres in which vessel straightening and distal calibre recovery are seen. B2) - B4) OCT cross-sectional views: well-deployed scaffold, intimomedial lamina rupture (B3: arrowheads) and residual intramural haematoma (B2: asterisk).*

Table 1. Clinical and angiographic features.

Clinical characteristics		n=22
Female, n (%)		21 (95)
Age, years (min-max)		49.6±11.2 (30-75)
≥1 cardiovascular risk factor, n (%)		9 (41)
ST-elevation myocardial infarction, n (%)		11 (50)
Non-ST-elevation myocardial infarction, n (%)		11 (50)
Cardiogenic shock, n (%)		1 (5)
Left ventricular dysfunction, n (%)		4 (18)
Initial conservative approach, n (%)		5 (23)
Angiographic characteristics		
Main dissected vessel, n (%)	Left main stem	2 (9)
	Left anterior descending	16 (73)
	Right coronary artery	3 (14)
	Left circumflex	1 (5)
Multivessel, n (%)		1 (5)
Proximal segment involved, n (%)		8 (36)
SCAD angiotype, n (%)	1	5 (23)
	2	14 (64)
	3	3 (14)
Baseline TIMI flow, n (%)	0	2 (9)
	1	4 (18)
	2	9 (41)
	3	7 (32)
Quantitative analyses, mm		
Ostium-to-dissection length		36.7±28
Dissection length		47.8±24
Reference vessel diameter		2.87±0.41
Minimum luminal diameter		0.72±0.6
% diameter stenosis		63.5±30
Procedural characteristics and complications are shown in Supplementary Table 1 and Supplementary Figure 2.		

Table 2. Clinical outcomes.

		n=22
Second antiplatelet agent, n (%)	Ticagrelor	12 (55)
	Prasugrel	4 (18)
	Clopidogrel	6 (27)
Median of months of DAPT duration		12 (IQR:12-18, min:12)
Minor bleeding, n (%)		5 (23)
Residual/recurrent chest pain, n (%)		9 (41)
atypical characteristics		8 (36)
Clinically driven repeat angiography, n (%)		5 (23)
in-hospital		3 (14)
delayed propagation		2 (9)
Scheduled surveillance angiography, n (%)		12 (55)
TVR, n (%)		2 (9)
TLR, n (%)		1 (5)
Device thrombosis		0
Device restenosis		0
Myocardial infarction		0
Death		0

follow-up of a true high-risk SCAD population undergoing PCI with BVS. The proportion of ST-elevation myocardial infarction (55%), impaired Thrombolysis In Myocardial Infarction (TIMI) flow (68%), left anterior descending (LAD) or left main stem (LMS) (81%) and proximal segment involvement (39%) is similar if not greater than those observed in the previously published revascularisation series[1,3,6].

Procedural complications (three propagations requiring extended stenting) and early events (two in-hospital revascularisations due to late propagation [**Supplementary Figure 2**]) were common in this series, in keeping with those observed in other published SCAD revascularisation series. We previously reported 19% procedural propagation in a large multicentre series of SCAD patients receiving

PCI with stents (n=108)[6], while Nakashima et al reported a rate of 24% of this same event within the PCI subgroup (n=34) of their multicentre series[7]. Moreover, early events during hospitalisation of SCAD patients treated with PCI are also commonly reported[1,6].

The predilation, sizing, and post-dilation criteria for scaffold implantation, central to improving outcomes of BVS in an atherosclerotic population[2], can be challenging in SCAD cases because of the risk of dissection propagation. In this regard, intracoronary imaging guidance is of paramount importance for a correct BVS deployment[1]. The use of intracoronary imaging was reasonably high in our series (86%), higher than in the series by Ielasi et al (50%)[3]. Finally, although a 12-month DAPT regimen was generally used here, a prolonged regimen may be beneficial for SCAD patients undergoing PCI, especially for those receiving BVS.

Limitations

Owing to the rare nature of this condition, this is a small retrospective study lacking power to generalise its findings. Each case was selected at the operator's discretion, and thus at risk of bias. However, baseline characteristics reflect the true high-risk profile of the overall cohort. Finally, the studied device is no longer available for clinical use. However, this experience might be regarded as a benchmark for newly developed BVS entering the market[2].

Conclusions

Bioresorbable devices represent an attractive option for patients with SCAD who require revascularisation. In this series of high-risk SCAD patients treated with BVS, the long-term favourable outcome brings hope for the future use of new-generation bioresorbable devices in this population.

Impact on daily practice

With the advent of newer and improved bioresorbable platforms, interventional cardiologists dealing with high-risk SCAD patients will have an available reference for the safety and effectiveness of BVS in this setting.

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Conflict of interest statement

J. Escaned and N. Gonzalo report consultancies and speaker fees at educational events for Abbott. D. Adlam has received research funding from St. Jude Medical for OCT research. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Appendix 1. Methods.

Supplementary Appendix 2. Results.

Supplementary Figure 1. 3D quantitative coronary analysis of post-stenting plus delayed propagation of a haematoma to a proximal coronary segment.

Supplementary Figure 2. The two cases presenting with delayed propagation.

Supplementary Figure 3. Optical coherence tomography of late BVS failure.

Supplementary Table 1. Procedural characteristics.

The supplementary data are published online at: http://www.pcronline.com/eurointervention/146th_issue/253

Supplementary data

Supplementary Appendix 1. Methods

We conducted a retrospective multicentre registry of SCAD patients receiving BVS (Absorb™; Abbott Vascular, Santa Clara, CA, USA) in tertiary hospitals in Spain and the United Kingdom. SCAD was defined as an acute non-iatrogenic and non-atherosclerosis-related dissection causing myocardial ischaemia. Published specific angiographic diagnostic criteria and classification were used [1]. Six Spanish centres (total sample of 111 SCAD cases, 32% PCI) and the UK SCAD Registry (317 cases, 50% PCI) provided 15 and 7 BVS cases, respectively.

Cardiogenic shock was defined as the need for inotropes for maintaining systolic blood pressure above 90 mmHg. Left ventricular dysfunction (dichotomic) was defined as an ejection fraction below 50% obtained during the convalescence phase. "Initial conservative approach" meant that such management was adopted first but the subsequent ischaemic relapse ultimately led to performing rescue (secondary) PCI. Post-stenting propagation (haematoma longitudinal migration or flap extension) was defined as an increase in dissection length or % stenosis in a contiguous segment after stent implantation, whereas delayed propagation was defined as clinically significant ischaemia combined with angiographic progression occurring within two weeks after the index PCI **(Supplementary Figure 1)**.

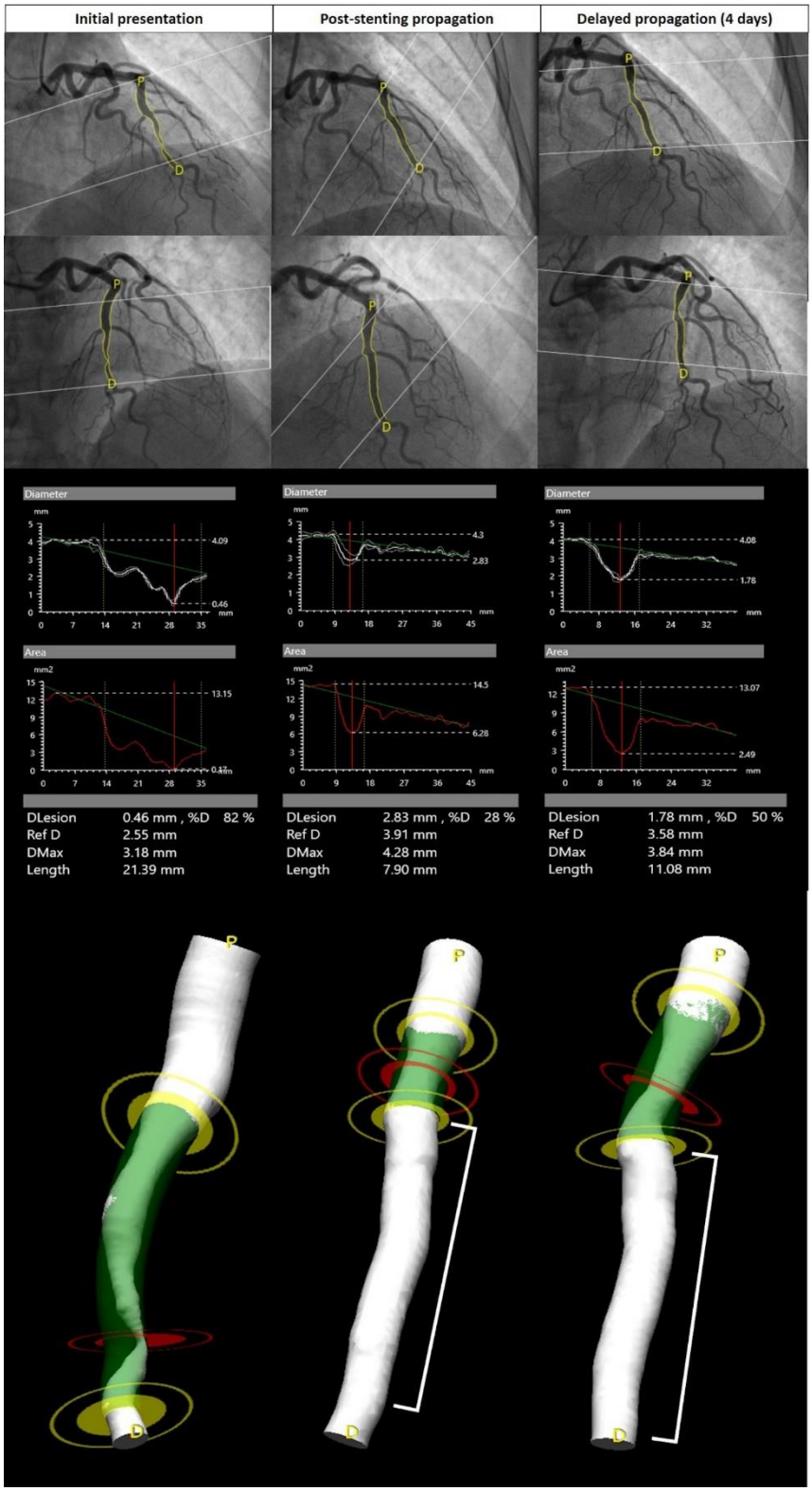
Clinical outcomes were obtained by telephone or at an outpatient clinic. Follow-up angiographies were differentiated between clinically and non-clinically indicated (scheduled surveillance). TLR was defined as any revascularisation in the stented segment. TVR referred to revascularisation in any part of the treated vessel. Stent thrombosis (definite) and restenosis were defined according to Academic Research Consortium criteria.

Supplementary Appendix 2. Results

Supplementary Table 1 shows the procedural characteristics. Radial access was used in 19/22 and intracoronary imaging guidance in 19/22. Mean number and length of stents were 2.05 and 46 mm, respectively. All cases were direct stenting without predilation or post-dilation. One patient had a coronary perforation after device implantation, which resolved with prolonged balloon inflation. Another patient presented a catheter-induced dissection remote from the SCAD requiring extended PCI. Immediate dissection propagation after device implantation occurred in 8 cases (towards proximal segments in 5) requiring extended PCI in 3. TIMI 3 flow was achieved in 21/22 patients. During the index admission, 3 patients underwent clinically driven repeat angiography with 2 of them showing delayed propagation (ischaemia + angiographic progression) that required further stenting **(Supplementary Figure 2)**.

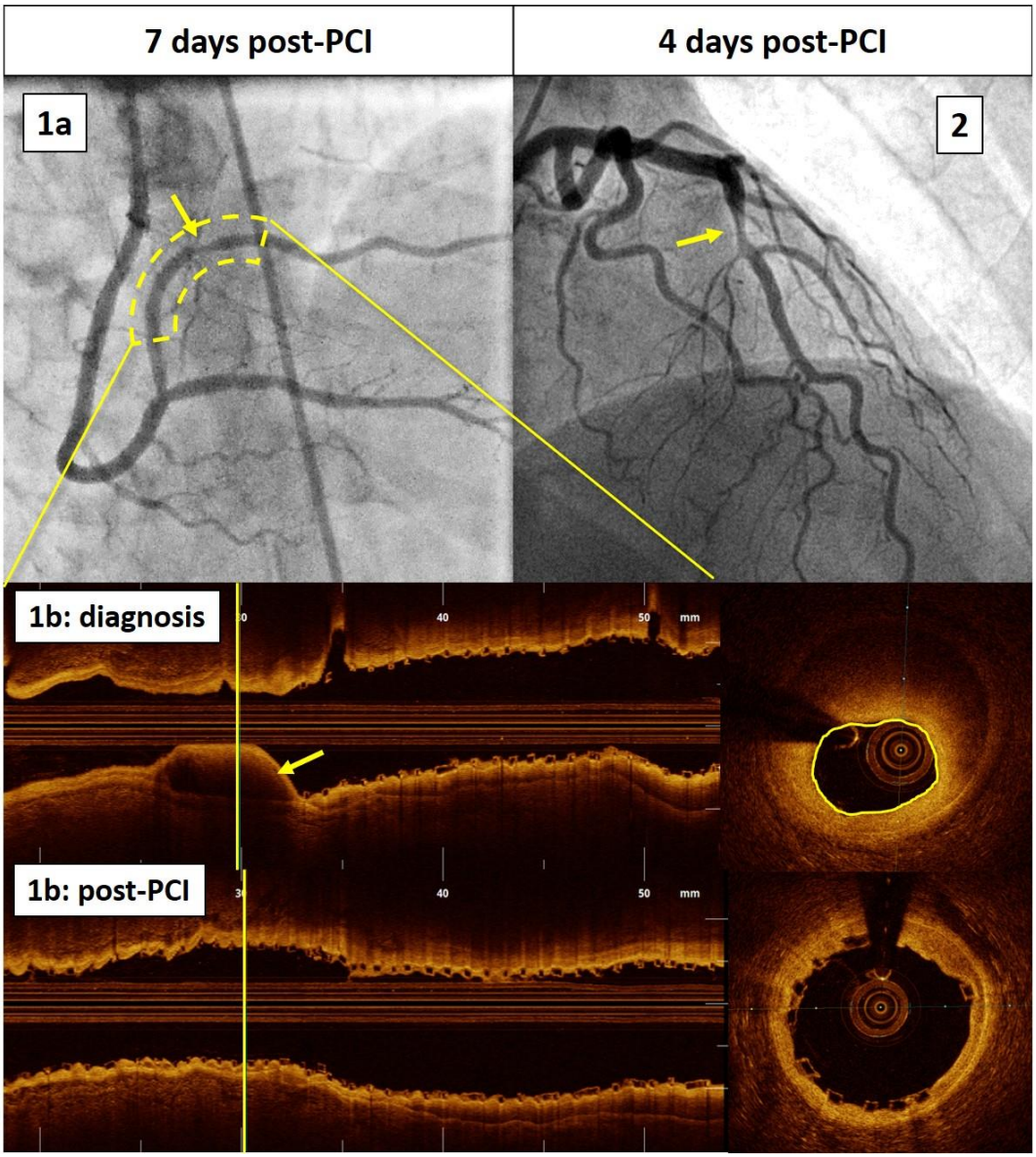
Supplementary Figure 1. 3D quantitative coronary analysis of post-stenting plus delayed propagation of a haematoma to a proximal coronary segment.

First and second columns correspond to pre- and post-stenting of the dissected mid-LAD segment. Third column is the clinically driven repeat angiogram 4 days later showing delayed propagation. White brackets indicate the stented segment.



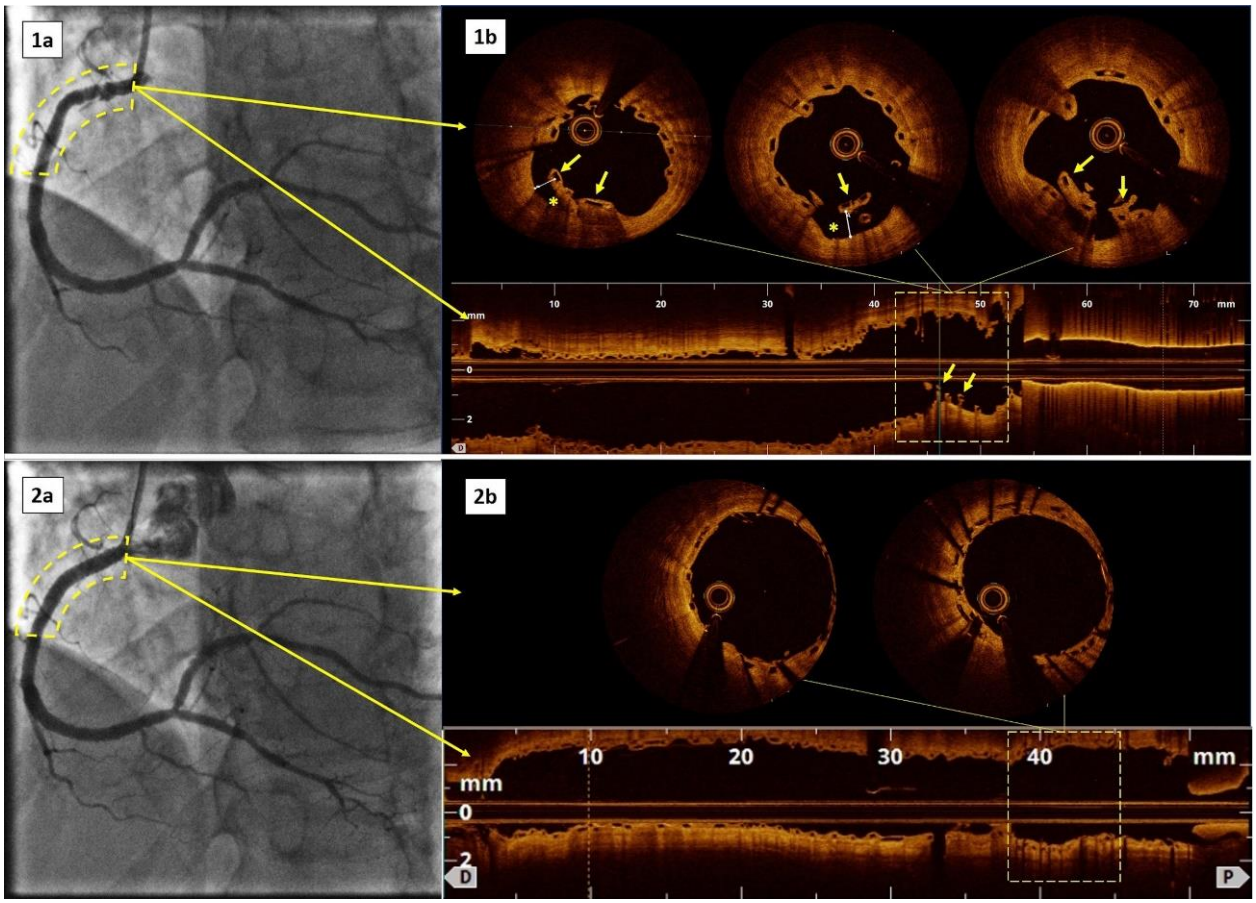
Supplementary Figure 2. The two cases presenting with delayed propagation.

Yellow arrows indicate haematoma propagation. Dashed sector indicates the segment studied with OCT. Case 1 (panels 1a, 1b): a patient with prior PCI to RCA-PL with BVS presented with delayed distal propagation in the PL branch 7 days later that was successfully treated with another BVS with OCT guidance. Panels 1b show OCT aspect before and after implanting this new BVS. Case 2 (panel 2): another patient who received BVS in the mid-LAD presented delayed proximal propagation at 4 days and received further PCI that required covering the LMS due to post-stenting propagation, for which a DES was chosen given the size unsuitability of BVS.



Supplementary Figure 3. Optical coherence tomography of late BVS failure.

Patient initially treated with BVS in the RCA. At 13 months, symptom-driven angiography with OCT showed malapposition and late scaffold discontinuity with overhanging struts in the proximal segment (panels 1a, 1b), presumably due to scaffold resorption and dismantling and/or possibly related to guiding catheter damage. Arrows indicate malapposed struts and asterisks indicate a hollow that might have been generated by scaffold shrinkage +/- possible haematoma late resorption (no initial OCT study available). TLR was performed, implanting one drug-eluting stent deployed in-scaffold (panels 2a, 2b).



Supplementary Table 1. Procedural characteristics.

	BVS (n=22)
Procedural characteristics	
Access site (radial), n (%)	19 (86)
Intracoronary imaging guidance, n (%)	19 (86)
• Intravascular ultrasound	9 (41)
• Optical coherence tomography	10 (45)
Full dissection length stenting, n (%)	13 (59)
Mean number of stents/scaffolds	2.05±1.1
Mean total stent length, mm	45.8±25
Mean stent diameter, mm	2.97±0.3
Mean stent/vessel diameter	1.02±0.2
Perforation	1
Iatrogenic dissections	1
Post-stenting propagation, n (%)	8 (36)
• requiring immediate further stenting	3 (14)
Procedure final result	
TIMI flow 3, n (%)	21 (95)
Non-stented residual lesion (not exclusive), n (%)	
• Proximal to stent	3 (14)
• Distal to stent	11 (52)
Quantitative analyses	
% in-stent residual stenosis	11.7±6.9
% pre-stent residual stenosis*	25.1±2.9
% post-stent residual stenosis*	31.7±19

* only calculated for those presenting angiographic residual dissection.