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Target lesion revascularisation of bioresorbable metal scaffolds: a case series study and literature review

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Introduction

Bioresorbable scaffolds (BRS) were introduced into clinical practice to overcome long-term limitations of drug-eluting stents (DES), but they were instead associated with a high rate of target lesion revascularisation (TLR) and thrombosis. Whereas scaffold discontinuity was the most frequent mechanism for polymeric BRS TLR[1], there are no studies on the causes of second-generation drug-eluting absorbable metal scaffold (MgBRS) TLR (Magmaris; Biotronik, Bülach, Switzerland). We sought to determine the optical coherence tomography (OCT) findings in patients who experienced an MgBRS TLR. Moreover, we performed a systematic review of the reported cases.

Methods

A retrospective screening was conducted to identify all the patients with an MgBRS TLR documented by OCT at six tertiary hospitals in Spain. Clinical data were anonymously collected with the approval of the local ethics committees. The patient selection process is shown in **Supplementary Appendix 1**. OCT and quantitative coronary angiography data were analysed offline in a core lab (BARCICORE-lab, Barcelona, Spain) using dedicated software (LightLab Imaging, Mountain View, CA, USA, and CAAS; Pie Medical Imaging, Maastricht, the Netherlands). A qualitative assessment of the entire OCT pullback was performed by two investigators (L. Ortega-Paz and S. Brugaletta) to determine the main OCT findings associated with TLR. These were predefined as scaffold discontinuity, malapposition, evagination, uncovered struts, neoatherosclerosis, restenosis without neoatherosclerosis, scaffold underexpansion/device collapse, edge dissection, or edge-related disease progression[1]. In case of disagreement, a third analyst (J. Gomez-Lara) was asked in order to reach a consensus. The complete OCT definitions are detailed in **Supplementary Appendix 2**.

CASE REPORTS FROM THE LITERATURE

Two independent reviewers (L. Ortega-Paz and S. Brugaletta) performed a systematic review of the literature applying the methodology detailed in **Supplementary Appendix 3** and **Supplementary Figure 1**.

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Results

Between December 2016 and October 2018, 100 patients received MgBRS at the participating institutions. No deaths were reported, and 12 cases of TLR (12%) were found **(Table 1)**. OCT data were available in all the TLR cases. The patients were mainly male (92%) with a median age of 56 (49-61) years. At the index procedure, all patients received one scaffold with a median diameter of 3.5 (3.0-3.5) mm and length of 20 (15-25) mm. In 10 out of 12 patients the device was implanted in an off-label scenario, mainly ST-segment elevation myocardial infarction (STEMI). Regarding the predilation, sizing, and post-dilation (PSP) technique, in one patient predilation was not performed; post-dilation was carried out in eight patients but in seven of them with a maximal balloon-to-scaffold ratio of 1:1. The complete patient and procedural characteristics are shown in **Supplementary Table 1**. There were no significant differences between the included and not included patients.

At the time of the TLR, six (50%) patients experienced an acute coronary syndrome (ACS), with one case of subacute definite scaffold thrombosis, due to abrupt interruption of dual antiplatelet treatment (DAPT), four days after the index procedure. The median occurrence of TLR was 164 days (IQR 63-242).

The main OCT findings were device underexpansion/collapse (n=7; 58%), scaffold discontinuity (n=4; 33%), and distal edge dissection (n=1; 9%) **(Figure 1, Supplementary Figure 2, Supplementary Figure 3, Moving image 1-Moving image 3)**. Two cases of underexpansion (#5 and #7 in **Table 1**) also had OCT data at the index PCI, showing a well apposed and expanded scaffold, therefore confirming the occurrence of a device collapse. No other baseline OCT data were available. The scaffold discontinuity phenomenon was identified at an earlier stage than underexpansion/collapse (70 days [32-111] vs 224 days [190-366]), p=0.022).

CASE REPORTS FROM THE LITERATURE

In the literature review, up to April 2019, we found six cases of MgBRS TLR with intravascular imaging assessment **(Supplementary Table 2)**[2-7]. The data relating to these cases are shown in **Supplementary Appendix 4**.

Discussion

The main findings of this case series study are the following. 1) The most frequent OCT findings were device underexpansion/collapse and scaffold discontinuity. 2) Scaffold discontinuity was found at an earlier stage than underexpansion/collapse. 3) The majority of the cases were off-label indications with a suboptimal PSP technique. 4) Only one case of scaffold thrombosis was observed.

In this retrospective analysis of patients treated with MgBRS who experienced TLR, the clinical characteristics and OCT

Table 1. Patient data at the index procedure, at the time of TLR and OCT analysis.

CASE	Time to failure (days)	INDEX PCI						TLR		OCT ANALYSIS		
		Baseline presentation	Target vessel	BRS size (mm)	Predilation (mm)	RVD (mm) (RVD/BRS)	Post-dilation (mm) @atm	Clinical presentation	$P2Y_{12}$ on top of ASA	Main finding	Neointimal pattern	Thrombus
1	6	NSTEMI (off-label)	LCX	3.0×20	2.5×15	2.23 (0.74)	No	STEMI (definite scaffold thrombosis)	None	Distal dissection	Homogeneous	Yes
2	8	NSTEMI (off-label)	RCA	3.5×15	2.5×10	2.58 (0.74)	No	NSTEMI	Ticagrelor	Discontinuity	Homogeneous	Yes
3	57	sCAD (on-label)	LAD	3.5×15	No	3.25 (0.93)	3.5×12; @16	sCAD	Clopidogrel	Discontinuity	Homogeneous	Yes
4	84	NSTEMI (off-label)	LAD	3.5×20	3.5×15	3.13 (0.89)	3.5×10; @20	UA	Ticagrelor	Discontinuity	Heterogeneous layered	Yes
5	85	NSTEMI (off-label)	LAD	3.5×25	3.5×15	2.95 (0.84)	No	NSTEMI	Clopidogrel	Collapse	Heterogeneous	No
6	139	STEMI (off-label)	LAD	3.0×20	2.5×15	2.86 (0.95)	3.0×15; @26	sCAD	Prasugrel	Discontinuity	Heterogeneous layered	Yes
7	190	STEMI (off-label)	RCA	3.5×20	2.5×10	3.49 (0.99)	3.5×15; @20	sCAD	Prasugrel	Collapse	Heterogeneous layered	No
8	203	UA (on-label)	RCA	3.0×15	3.0×10	2.82 (0.94)	3.5×10; @20	sCAD	Ticagrelor	Underexpansion/collapse	Heterogeneous layered	No
9	224	STEMI (off-label)	LAD	3.0×15	2.5×8	2.77 (0.92)	3.0×12; @18	UA	Ticagrelor	Underexpansion/collapse	Heterogeneous layered	No
10	248	NSTEMI (off-label)	LAD	3.5×15	2.5×10	3.16 (0.90)	No	NSTEMI	Ticagrelor	Underexpansion/collapse	Heterogeneous layered	No
11	366	STEMI (off-label)	LAD	3.5×25	2.5×15	2.23 (0.64)	3.5×15; @20	sCAD	Ticagrelor	Underexpansion/collapse	Heterogeneous layered	No
12	388	STEMI (off-label)	RCA	3.0×20	2.5×6	2.63 (0.87)	3.0×15; @18	sCAD	Ticagrelor	Underexpansion/collapse	Heterogeneous layered hyperplasia	No

ASA: aspirin; atm: atmospheres; BRS: bioresorbable scaffold; LAD: left anterior descending artery; LCX: left circumflex artery; NSTEMI: non-ST-segment elevation myocardial infarction; OCT: optical coherence tomography; RCA: right coronary artery; RVD: reference vessel diameter; sCAD: stable coronary artery disease; STEMI: ST-elevation myocardial infarction; TLR: target lesion revascularisation; UA: unstable angina

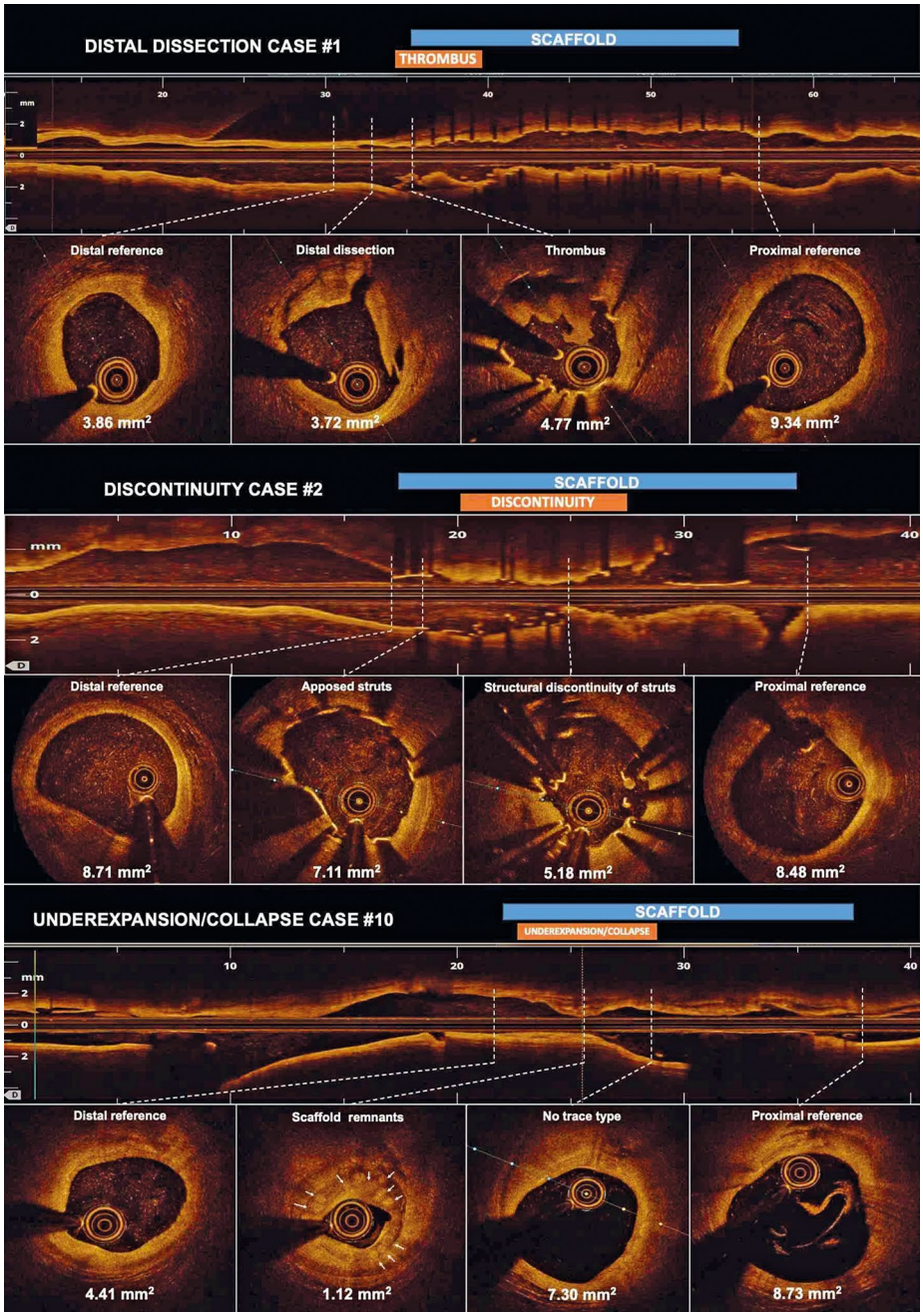

Figure 1. *Second-generation drug-eluting absorbable metal scaffold target lesion revascularisation OCT findings. Minimum lumen area is shown per each cross-section. In case #2, predilation was performed before OCT assessment. Therefore, it cannot be ruled out that the scaffold structure was iatrogenically altered. A three-dimensional reconstruction of case #2 is shown in Supplementary Figure 3.*

findings resembled very closely those of the cases reported in the literature. Although both populations are very selected, the TLRs analysed may be related either to scaffold use in an off-label scenario or to a suboptimal PSP implantation technique[8,9]. Nevertheless, a recent study showed that the procedural characteristics do not impact on the MgBRS healing process[10]. It is worth mentioning that in first-in-man studies MgBRS were used in a very selected population, including only simple lesions and excluding ACS patients[9]. Notably, the off-label implantation in STEMI patients may be related to the high TLR rate because of the difficulties of accurate device sizing and worse clinical outcomes.

Of note is that, irrespective of adverse OCT findings, only one patient had definite scaffold thrombosis, in the context of early DAPT interruption, which is in line with previous studies showing a lower acute MgBRS thrombogenicity as compared to polymeric BRS[11].

Eventually, prolongation of the scaffolding time and increasing the radial force could reduce the incidence of scaffold discontinuity

or device collapse during follow-up. These hypotheses need to be confirmed in larger studies and should be taken into consideration for further improvements in the technology.

Limitations

This study has limitations that should be acknowledged. First, this is a retrospective study without a control group. However, to date, this is the largest cohort of MgBRS TLR analysed at a core lab facility. Second, only two cases had baseline and TLR OCT data. Third, for the assessment of MgBRS, the use of intravascular ultrasound (IVUS) and virtual histology may be better than OCT[9], although the spatial resolution of OCT is higher than that of IVUS. Fourth, as the magnesium scaffold shadow disappears by six months, the struts can be ambiguously identified, making the discrimination of the OCT findings challenging. Fifth, the OCT definitions applied were derived from polymeric BRS studies. However, currently there are no standardised definitions for MgBRS failure assessment.

Conclusion

In patients who experienced an MgBRS TLR, the most frequent OCT finding was device underexpansion/collapse followed by scaffold discontinuity.

Impact on daily practice

The most common OCT findings in patients who experienced an MgBRS TLR were device underexpansion/collapse and scaffold discontinuity. The discontinuity cases occurred at an earlier stage compared to device underexpansion/collapse. However, a scaffold thrombosis conditioning a myocardial infarction was unusual. All these data should be considered for the clinical decision-making process and further improvements in the technology.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Appendix 1. Patient selection criteria.

Supplementary Appendix 2. Optical coherence tomography definitions.

Supplementary Appendix 3. Systematic literature review methodology.

Supplementary Appendix 4. Systematic literature review results.

Supplementary Figure 1. Search strategy flow chart.

Supplementary Figure 2. Second-generation drug-eluting absorbable metal scaffold target lesion revascularisation OCT findings.

Supplementary Figure 3. OCT three-dimensional reconstruction of the scaffold discontinuity case number two.

Supplementary Table 1. Patient and procedural characteristics.

Supplementary Table 2. Case reports of magnesium-based bioresorbable scaffold TLR found in the systematic literature review.

Moving image 1. Distal dissection case #1.

Moving image 2. Discontinuity case #2.

Moving image 3. Underexpansion case #10.

The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-19-00421

Supplementary data

Supplementary Appendix 1. Patient selection criteria

The patient selection and implantation technique were left to operator discretion. However, the application of the manufacturer's Instructions For Use (IFU; Biotronik, Bülach, Switzerland) was recommended. Eventually, four of the participating centres were enrolling patients in the BIOLSOLVE-IV study (Safety and Performance in de NOvo Lesion of NatiVE Coronary Arteries With Magmaris- Registry: BIOSOLVE-IV, NCT02817802) and the MAGSTEMI trial (MAGnesium-based Bioresorbable Scaffold in ST Segment Elevation Myocardial Infarction, NCT03234348). For this reason, off-label indications such as ST-segment elevation myocardial infarction and patients with evidence of myocardial infarction within 72 hours before index procedure were also included.

Supplementary Appendix 2. Optical coherence tomography definitions

In this case series study, we applied the definitions of OCT findings previously reported in the INVEST registry (Independent OCT Registry on Very Late Bioresorbable Scaffold Thrombosis, NCT03180931) [1].

- Scaffold discontinuity: struts are overhanging each other at the same angular sector, with or without malapposition, or isolated struts at the luminal centre without an obvious connection to other surrounding struts.
- Malapposition: the absence of contact of the scaffold strut with the vessel wall. This definition does not include struts in front of side branches or their ostium (polygon of confluence), which are defined as side branch-related struts.
- Evagination: outward bulging of the vessel wall between scaffold struts more than one fourth of lumen diameter.
- Uncovered struts: the absence of a homogenous regular tissue coverage over the entire strut.
- Neoatherosclerosis: the presence of either a fibro-calcific plaque (signal-poor regions with sharply delineated upper and lower borders) or lipid-rich plaques (diffusely bordered, signal-poor regions) on the luminal side of scaffold struts.

- Restenosis without neoatherosclerosis: neointimal hyperplasia >70% by visual estimate.
- Scaffold underexpansion/device collapse: minimal scaffold area <50%.
- Edge dissection: disruptions of the arterial lumen surface (circumferentially >60°) in both the 5 mm distal and proximal stent edges.
- Edge-related disease progression: the presence of plaque tissue (fibro-calcific or lipid-rich plaques) by visual estimate, in the scaffold edge segments (5 millimetres proximal and distal).

Supplementary Appendix 3. Systematic literature review methodology

For the systematic review of the literature the following methodology and criteria were applied.

- **Investigators**: Luis Ortega-Paz and Salvatore Brugaletta (individual searches).
- **Date**: 19th April 2019.
- **Exposure of interest**:
  - *Device*: Magmaris; Biotronik, Bülach, Switzerland.
  - *Outcome:* target lesion revascularisation.
  - *Assessment*: intravascular imaging optical coherence tomography or intravascular ultrasound.
- **Geographic locations**: without restriction.
- **Language:** without restriction.
- **Databases**: MEDLINE/PubMed, EMBASE, Web of Knowledge, and SCOPUS.
- **Participants:** without restriction.
- **Peer review**: only peer-reviewed reports were included.
- **Type of publication:** without restriction.
- **Search strings**:
  - ("magmaris"[tiab] OR "Magnesium scaffold"[tiab] OR "Resorbable scaffold"[tiab] OR "Metal scaffold"[tiab] OR "Magnesium based"[tiab] OR "magnesium stent"[tiab]).
  - (resorbable[All Fields] AND ("magnesium"[MeSH Terms] OR "magnesium"[All Fields]) AND scaffolds[All Fields]).

- ("magmaris"[tiab]) AND ("collapse"[tiab] OR "restenosis"[tiab] OR "failure"[tiab] OR "thrombosis"[mh] OR "revascularisation"[tiab] OR "thrombosis"[tiab]).
- (“resorbable magnesium scaffold”[tiab]) AND ("collapse"[tiab] OR "restenosis"[tiab] OR "failure"[tiab] OR "thrombosis"[mh] OR "revascularisation"[tiab] OR "thrombosis"[tiab]).
- (“magnesium bioresorbable scaffold”[tiab]) AND ("collapse"[tiab] OR "restenosis"[tiab] OR "failure"[tiab] OR "thrombosis"[mh] OR "revascularisation"[tiab] OR "thrombosis"[tiab]).
- (“second-generation drug-eluting absorbable metal scaffold”[tiab]) AND ("collapse"[tiab] OR "restenosis"[tiab] OR "failure"[tiab] OR "thrombosis"[mh] OR "revascularisation"[tiab] OR "thrombosis"[tiab]).
- (magnesium based BRS”[tiab]) AND ("collapse"[tiab] OR "restenosis"[tiab] OR "failure"[tiab] OR "thrombosis"[mh] OR "revascularisation"[tiab] OR "thrombosis"[tiab]).
- (“bioresorbable magnesium scaffold”[tiab]) AND ("collapse"[tiab] OR "restenosis"[tiab] OR "failure"[tiab] OR "thrombosis"[mh] OR "revascularisation"[tiab] OR "thrombosis"[tiab]).

The identified case reports of MgBRS TLR with intravascular imaging assessment were collected for analysis. The investigators extracted the clinical, procedural and intravascular imaging data as reported by the authors and pooled them in a database for further analysis.

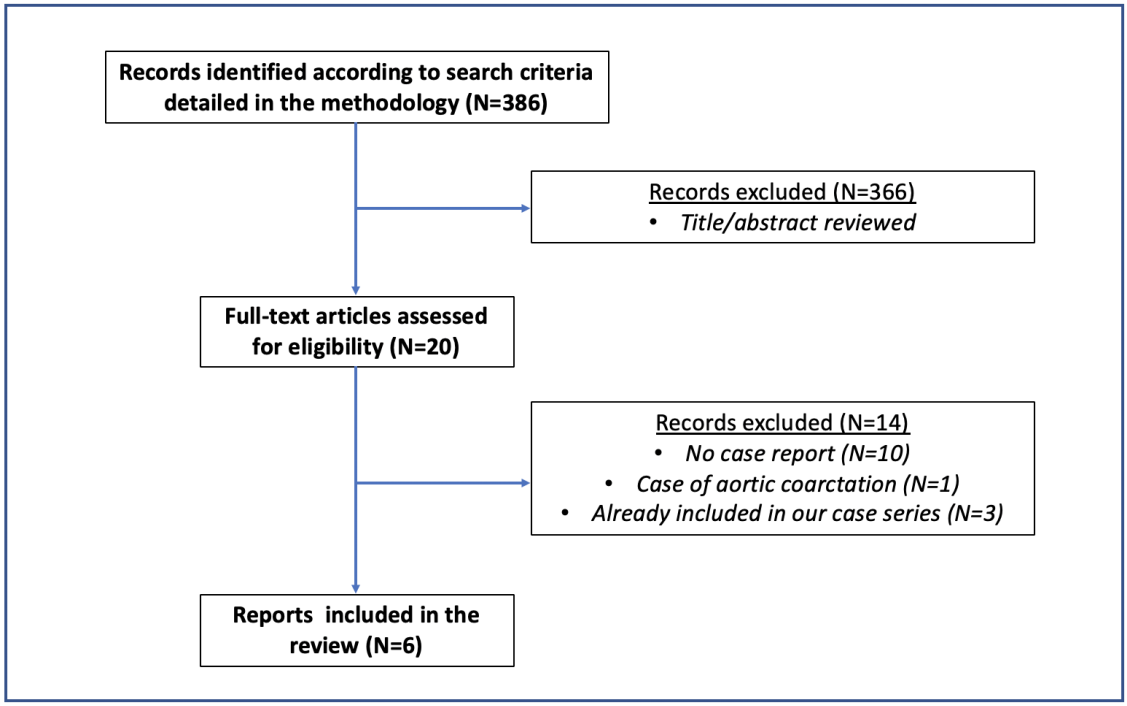
Supplementary Appendix 4. Systematic literature review results

Case reports from the literature

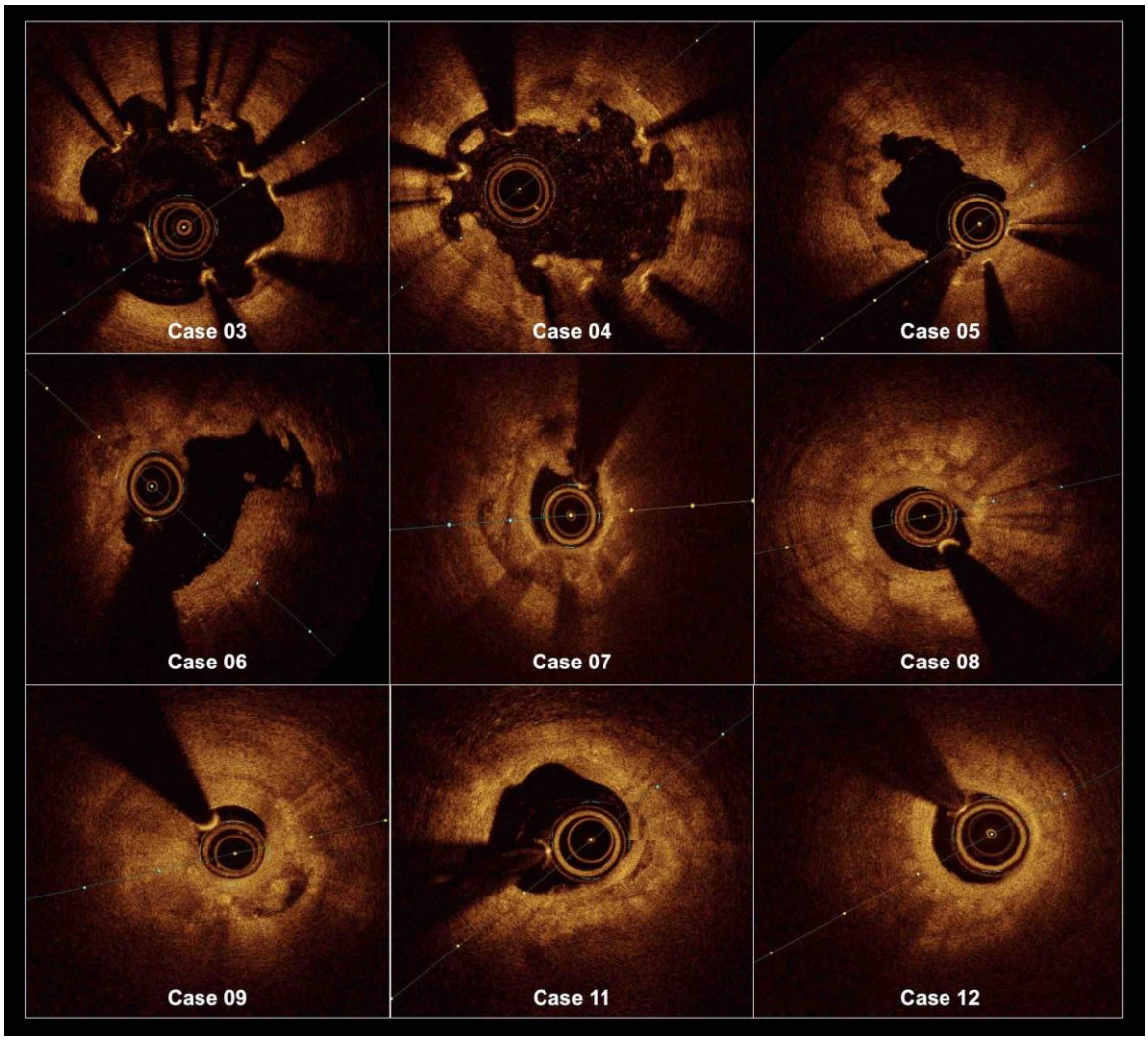
In the literature review, up to April 2019, we found six cases of MgBRS TLR with intravascular imaging assessment **(Supplementary Table 2)** [2-7]. All patients were male, with a median age of 51 (44-58) years. At the index procedure, four patients received one scaffold, and two were treated with two overlapping scaffolds. The median diameter of the scaffold was 3.0 (3.0-3.5) mm and length of 15 (15-40) mm. In half of the patients, the device was implanted in an off-label indication (overlap and STEMI). Furthermore, in one patient no predilation or post-dilation was performed. At the TLR

procedure, all patients suffered from stable or unstable angina with no evidence of device thrombosis. The median time to failure was 165 days (IQR 71-315).
The OCT findings reported by the authors were in 3 cases (50%) a device collapse, 2 (33%) neointimal hyperplasia, and 1 (17%) scaffold discontinuity. The discontinuity case was reported at 60 days, while the rest were reported at a median time of 210 days (IQR 97-360).

Supplementary Figure 1. Search strategy flow chart.

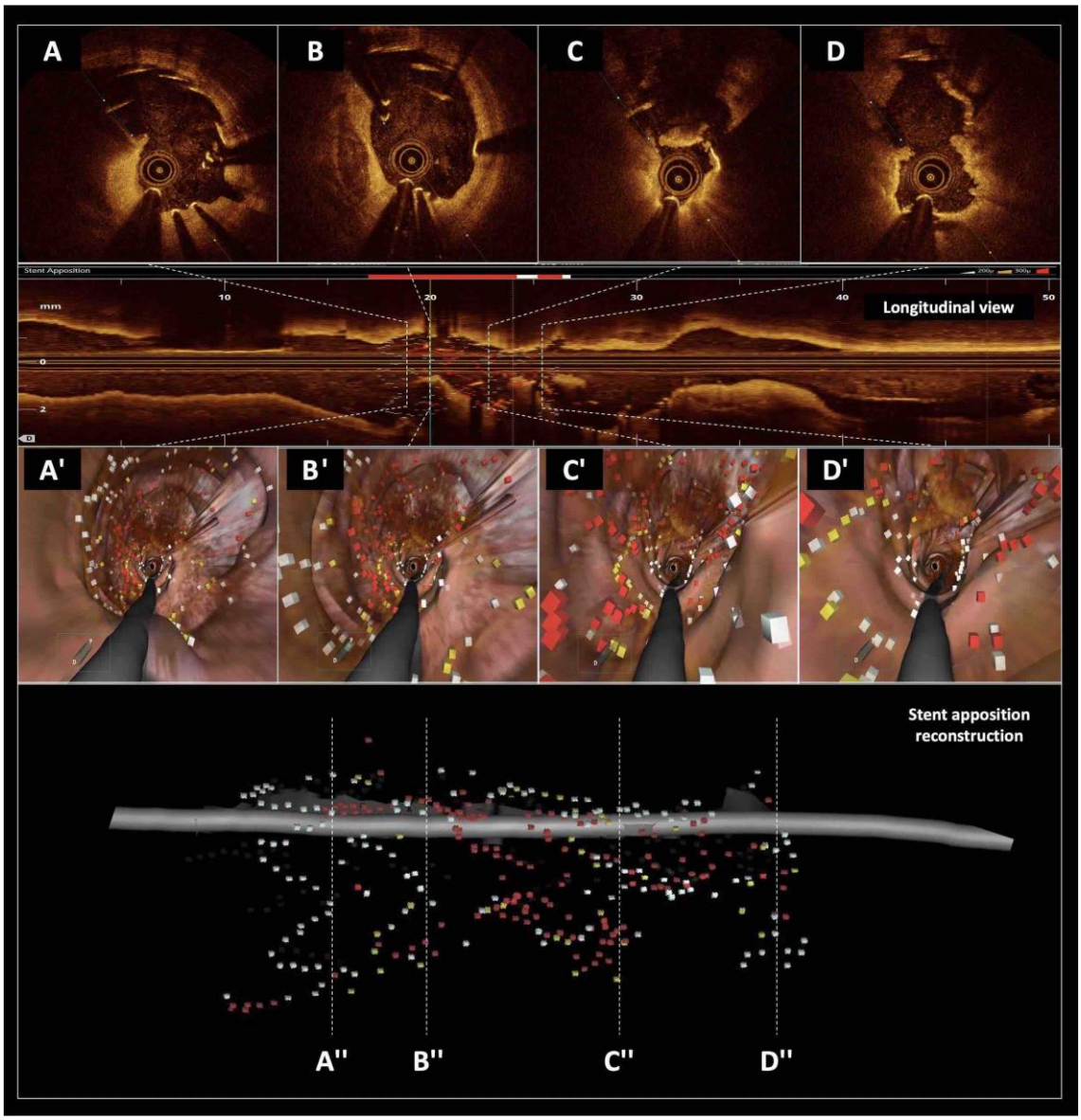


Supplementary Figure 2. Second-generation drug-eluting absorbable metal scaffold target lesion revascularisation OCT findings.



Representative cross-sectional OCT images from patients with MgBRS TLR. The case numbers correspond with those in Table 1. Scaffold underexpansion/collapse was the most frequent OCT finding. OCT: optical coherence tomography

Supplementary Figure 3. OCT three-dimensional reconstruction of the scaffold discontinuity in case number two.



A) – D) OCT cross-sections of the scaffold.
A') – D') Three-dimensional reconstruction in the navigation view. The dotted lines, A"–D", in the stent apposition reconstruction panel, correspond to the locations of the dotted lines in the OCT longitudinal view panel. In the stent apposition reconstruction, white struts represent a distance of <200 µm between the strut and the vessel lumen contour, yellow between 200 and 300 µm, and red >300 µm.
OCT: optical coherence tomography

Supplementary Table 1. Patient and procedural characteristics.

VARIABLE	PATIENTS INCLUDED (N=12)	PATIENTS NOT INCLUDED (N=88)	*p*-value
Age, years (IQR)	56 (49–61)	58 (51–62)	0.798
Male, n (%)	11 (92)	79 (90)	0.656
Hypertension, n (%)	8 (67)	41 (47)	0.229
Diabetes mellitus, n (%)	4 (33)	32 (36)	0.758
Smoking, n (%)			
Current	6 (50)	36 (41)	0.527
Former	5 (42)	41 (47)	0.769
Hypercholesterolaemia, n (%)	6 (50)	46 (52)	0.862
Family history, n (%)	2 (17)	18 (20)	0.554
Previous MI, n (%)	2 (17)	22 (25)	0.725
Previous PCI, n (%)	2 (17)	20 (23)	0.732
Previous CABG, n (%)	0	0	-
Number of diseased vessels			
Single-vessel disease, n (%)	12 (100)	81 (92)	0.593
LVEF, % (IQR)	60 (56–60)	62 (57–65)	0.811
Clinical presentation			
sCAD/UA	2 (18)	10 (11)	0.839
NSTEMI	5 (41)	31 (35)	
STEMI	5 (41)	47 (54)	
Target vessel			
LAD	7 (58)	46 (52)	0.932
LCx	1 (8)	9 (10)	
RCA	4 (34)	33 (38)	
Lesion type B2/C[*], n (%)	10 (83)	68 (77)	0.732
Bifurcation, n (%)	0	0	-
Calcified lesion, n (%)	1 (8)	16 (18)	0.515
Intracoronary imaging at index PCI, n (%)	2 (17)	12 (14)	0.528
Number of scaffolds per lesion	1 (1–1)	1 (1–1)	0.313
Overlap, n (%)	0	0	-
Total scaffold length, mm	20 (15–25)	20 (15–20)	0.973
Median scaffold diameter, mm	3.5 (3.0–3.5)	3.5 (3.0–3.5)	0.901
Predilation	11 (92)	85 (95)	0.405
Balloon diameter, mm	2.5 (2.5–3.0)	2.5 (2.5–3.0)	0.738
Implantation pressure, atm	15 (14–18)	14 (12–16)	0.889
Post-dilation	8 (67)	62 (71)	0.689
Maximal balloon diameter, mm	3.5 (3.0–3.5)	3.5 (3.0–3.5)	0.831
Maximal balloon ratio 1:1	7 (58)	53 (60)	0.695
Maximal balloon ratio >1:1 up to 0.5 mm	1 (8)	9 (10)	
Maximal balloon ratio >1:1 over 0.5 mm	0	0	-
Post-dilation balloon pressure, atm	20 (18–20)	20 (18–24)	0.357
≥16, n (%)	8 (67)	61 (70)	0.544
$P2Y_{12}$ inhibitor treatment at discharge			
Clopidogrel	2 (16)	14 (16)	0.990
Prasugrel	2 (16)	16 (18)	
Ticagrelor	8 (68)	58 (66)	
Treatment of device failure, n (%)			
Balloon dilation only	0	-	-
DES stent implantation	11 (92)	-	-
BRS implantation	1 (8)	-	-
TIMI flow grade (pre-PCI), n (%)		-	-
0	3 (25)		
1	2 (17)		
2	0		

3	7 (58)		
TIMI flow grade (post-PCI), n (%)			
3	12 (100)	-	-

*ACC/AHA lesion classification. Values are expressed as number (%) or median (interquartile range [IQR]). atm: atmospheres; BRS: bioresorbable scaffold; CABG: coronary artery bypass grafting; DES: drug-eluting stent; LVEF: left ventricular ejection fraction; MI: myocardial infarction; PCI: percutaneous coronary intervention

Supplementary Table 2. Case reports of magnesium-based bioresorbable scaffold TLR found in the systematic literature review.

	INDEX PCI						TLR		INTRAVASCULAR IMAGING	
Case	**Time to failure (days)**	**Baseline presentation**	**Target vessel**	**BRS size (mm)**	**Predilation (mm)**	**Post-dilation (mm) @atm**	**Clinical presentation**	**$P2Y_{12}$ on top of ASA**	**Intravascular imaging findings described by the authors**	**Ref**
1	60	sCAD (on-label)	LAD	3.0x25 3.5x15 (off-label)	3.5x10	3.5x15; @22	sCAD	Clopidogrel	IVUS Dismantling & collapse Suggestive image of thrombus	[2]
2	75	UA (on-label)	LAD	3.5x15	3.5x12	3.5x10; @16	UA	Clopidogrel	OCT Restenosis in a collapsed segment	[3]
3	120	STEMI (off-label)	LAD	3.0x15	3.0x10	3.0x10; @16	sCAD	NA	OCT Diffuse restenosis Homogenous neointimal pattern of high signal intensity	[4]
4	210	sCAD (on-label)	LAD	3.5x15	3.0x13 *Scoring*	3.75x8	sCAD	Ticagrelor	OCT Restenosis in a collapsed segment	[5]
5	270	UA (on-label)	LAD	3.0x25 3.5x15 (off-label)	No	No	UA	NA	OCT Restenosis in a collapsed segment	[6]
6	450	sCAD (on-label)	LAD	3.0x15	3.0x10	3.25x12; @16	sCAD	NA	OCT Focal neointimal hyperplasia	[7]

ASA: aspirin; atm: atmospheres; BRS: bioresorbable scaffold; IVUS: intravascular ultrasound; LAD: left anterior descending artery; NA: not available; OCT: optical coherence tomography; Ref: reference; sCAD: stable coronary artery disease; TLR: target lesion revascularisation; UA: unstable angina