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.

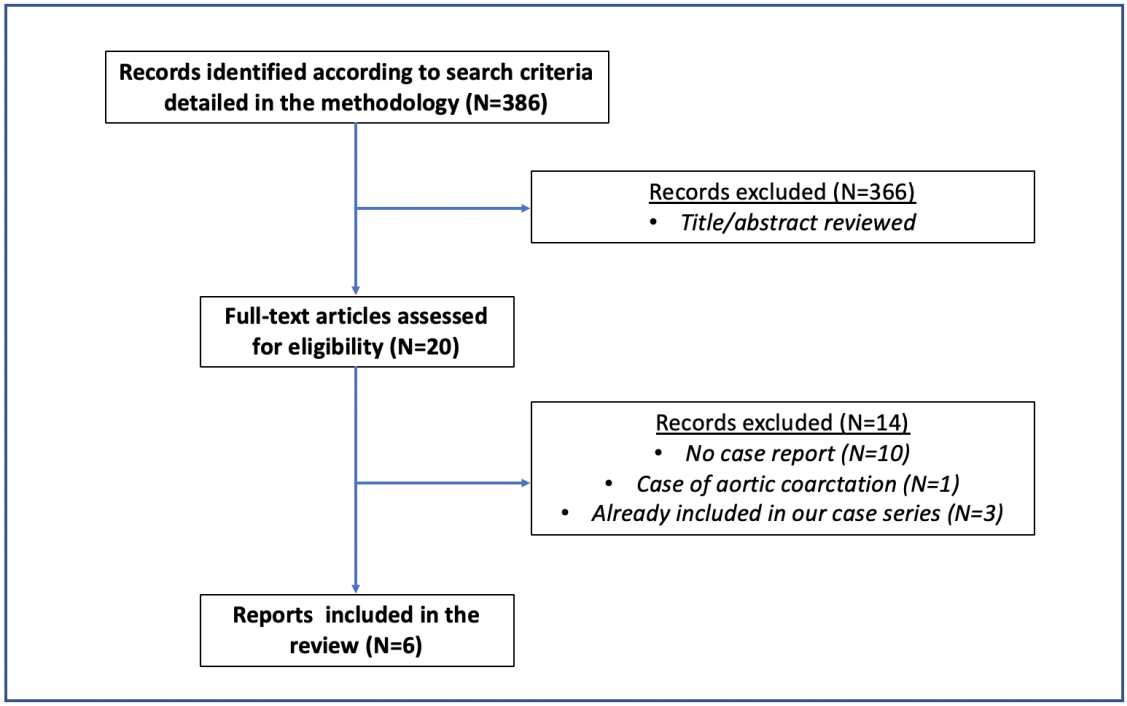
Supplementary Appendix 4. Systematic literature review results

Case reports from the literature

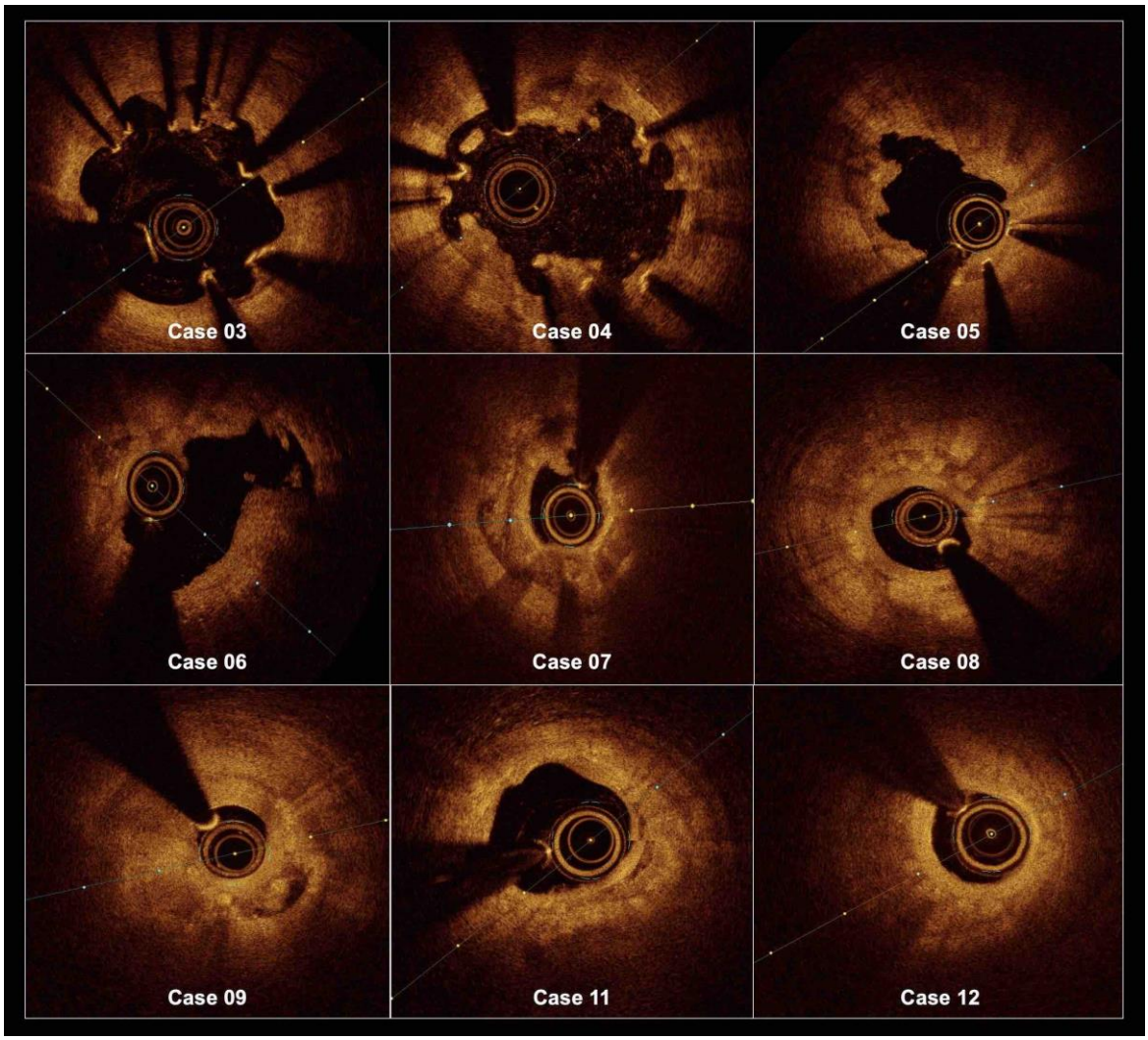
In the literature review, up to April 2019, we found six cases of MgBRS TLR with intravascular imaging assessment **(Supplementary Table 2)** [2-7]. All patients were male, with a median age of 51 (44-58) years. At the index procedure, four patients received one scaffold, and two were treated with two 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.

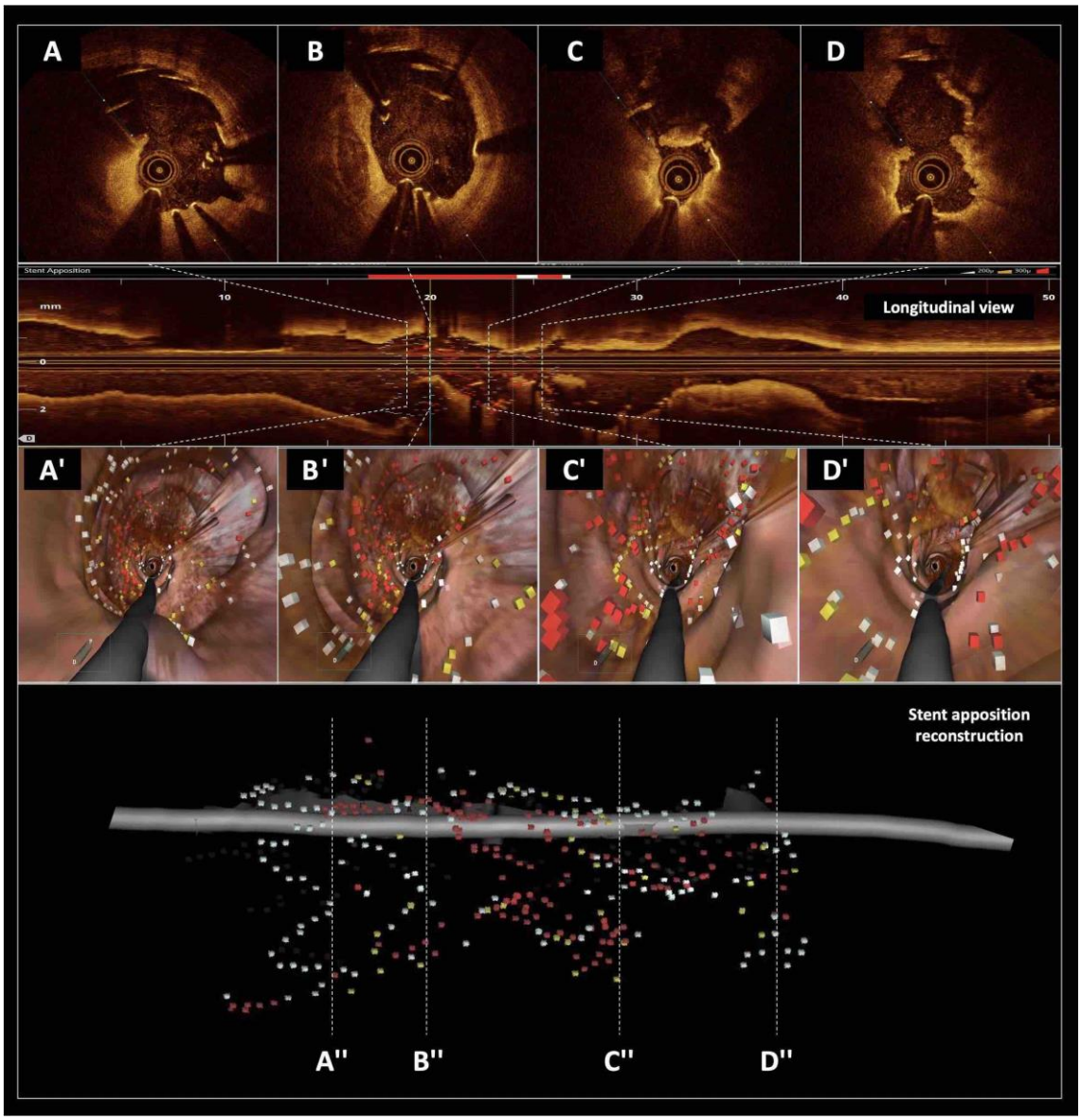


Supplementary Figure 2. Second-generation drug-eluting absorbable metal scaffold target lesion revascularisation OCT findings.



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