Early Collapse of a Magnesium Bioresorbable Scaffold with STEMI Presentation

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Abstract

Magmaris is a drug-eluting bioresorbable scaffold (BRS) designed to provide temporary mechanical support to blood vessels in the early phase, whereby scaffold degradation over time allows vascular healing and growth, followed by restoration of vasomotion. It offers an alternative to bare metal stents (BMS) and drug-eluting stents (DES) through its potential to reduce complications in permanent metallic stents. The BIOSOLVE II, III and IV clinical trials showed promising results with low complication rates comparable to DES. There is now renewed interest in Magmaris following case reports and single center studies revealing early collapse of the BRS. Here, we present a case with anterior ST segment elevation myocardial infarction due to early Magmaris collapse at 140 days post implantation on a simple left anterior descending (LAD) lesion. Literature on all currently available case reports and studies written in English has been reviewed. We speculate that the mechanism of early BRS collapse and under-expansion may be rooted in scaffold discontinuity in the early stage, followed by intraluminal hyperplasia. Exposure of intravascular collagen via strut injury leads to thrombus formation.

Keywords: early collapse, magnesium bioresorbable scaffol, acute myocardial infarction

Case

A 52-year-old non-smoking male with type 2 diabetes mellitus (T2DM) and hypertension (HTN) presented with chest pain. There was no significant ST-T segment change on the electrocardiogram (ECG). Computed tomography angiography (CTA) revealed noncalcified plaque with > 69% lumen stenosis of the proximal left anterior descending (LAD) artery (Figure 1). He was started on aspirin 100 mg QD, and atorvastatin 10 mg QD one month prior to angiography, with addition of prasugrel 3.75 mg QD on the day of the angiography. The lesion on the LAD was pre-dilated with a 3.5 mm * 12 mm and 3.0 mm * 15 mm compliant balloon, followed by deployment of 3.5 mm * 15 mm Magmaris, a sirolimus-eluting bioresorbable coronary magnesium scaffold (Figure 2). Optical coherence tomography (OCT) revealed optimal expansion of the magnesium scaffold (Figure 3). Neither under-expansion nor mal-apposition were noted. The patient was

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discharged uneventfully the next day.

One hundred and forty days after discharge, the patient presented again after three hours of chest tightness. ECG revealed ST-elevation on V2-V4 (Figure 4). This finding was compatible with anterior ST-elevation myocardial infarction (STEMI). Emergency percutaneous coronary intervention revealed the collapse of the Magmaris magnesium scaffold with in-stent tissue formation (Figure 5). After the lesion was successfully penetrated with a SION 0.014" guidewire, a drug-eluting stent, Resolute Onyx 3.0 mm * 30 mm, was implanted and post-dilated with non-compliant balloon (3.0 mm * 15 mm and 3.5 mm * 15 mm). Final angiography showed thrombolysis in myocardial infarction (TIMI) grade 3 flow. Intravascular ultrasound (IVUS) further showed good expansion of the stent. The patient was

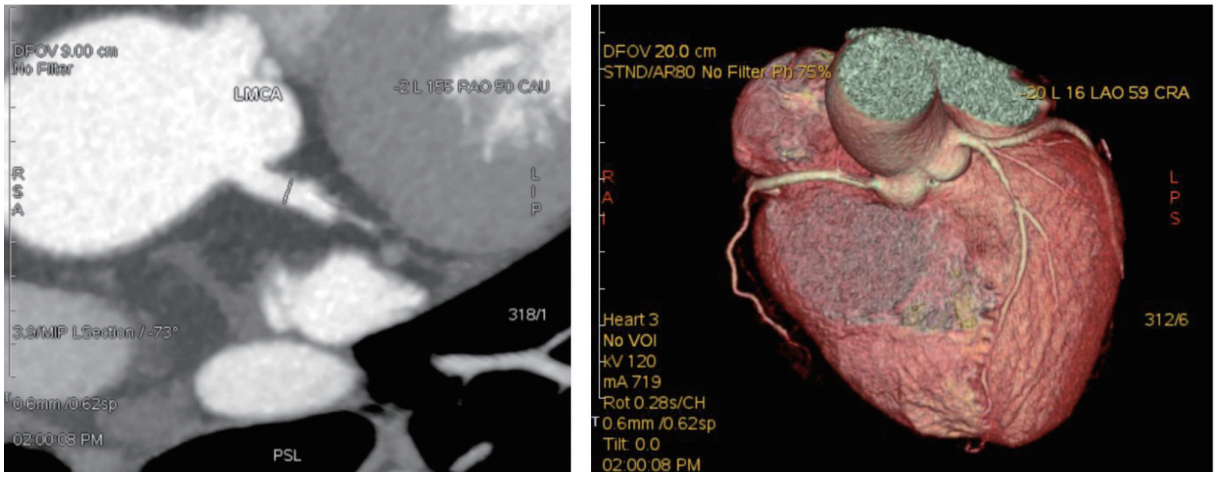

Figure 1. Computed tomography angiography with aorta and left main coronary artery (LMCA) (left) and 3-dimensional rendered image of the coronary arteries (right).

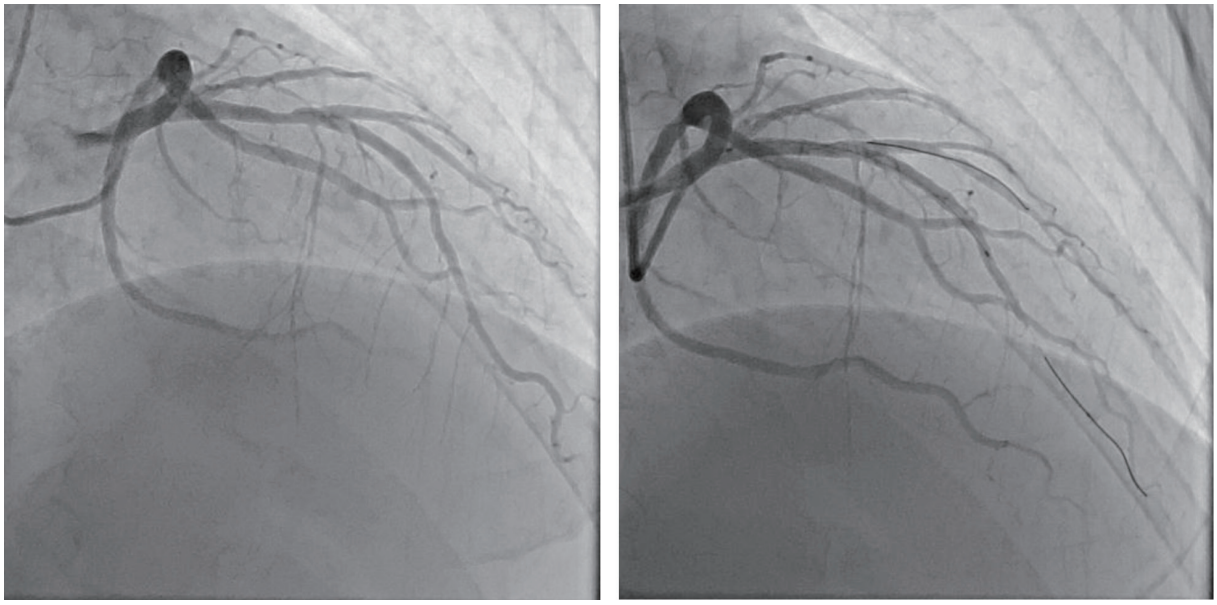

Figure 2. Initial angiography (left) and final angiography after magnesium bioresorbable scaffold implantation (right).

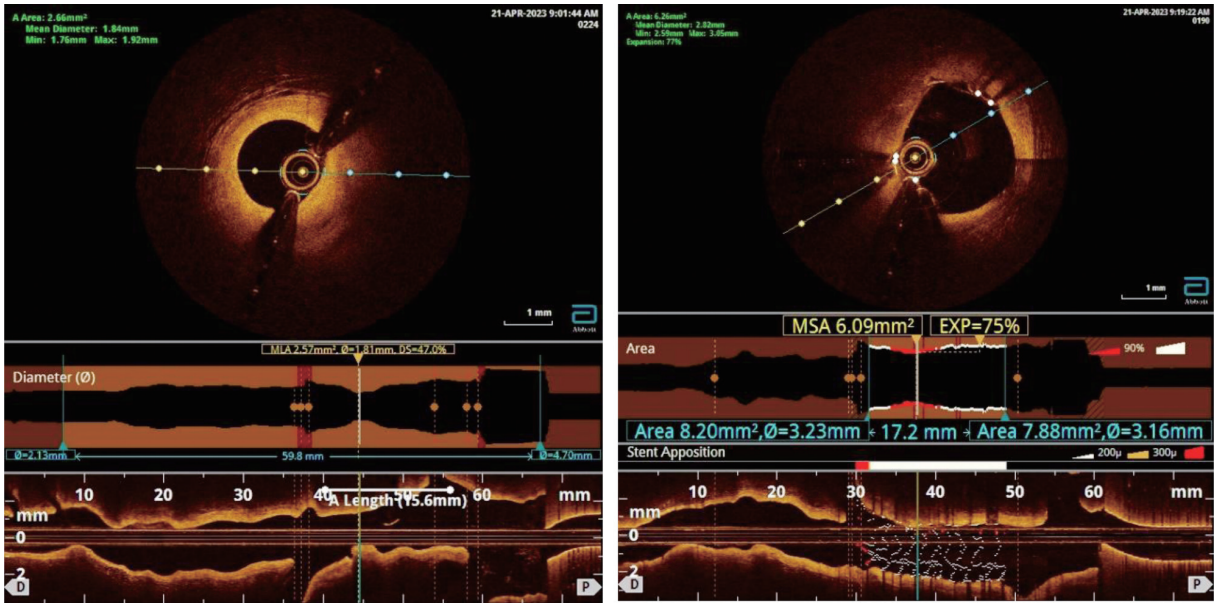

Figure 3. Optical coherence tomography of the LAD before (left) and after (right) magnesium bioresorbable scaffold implantation.

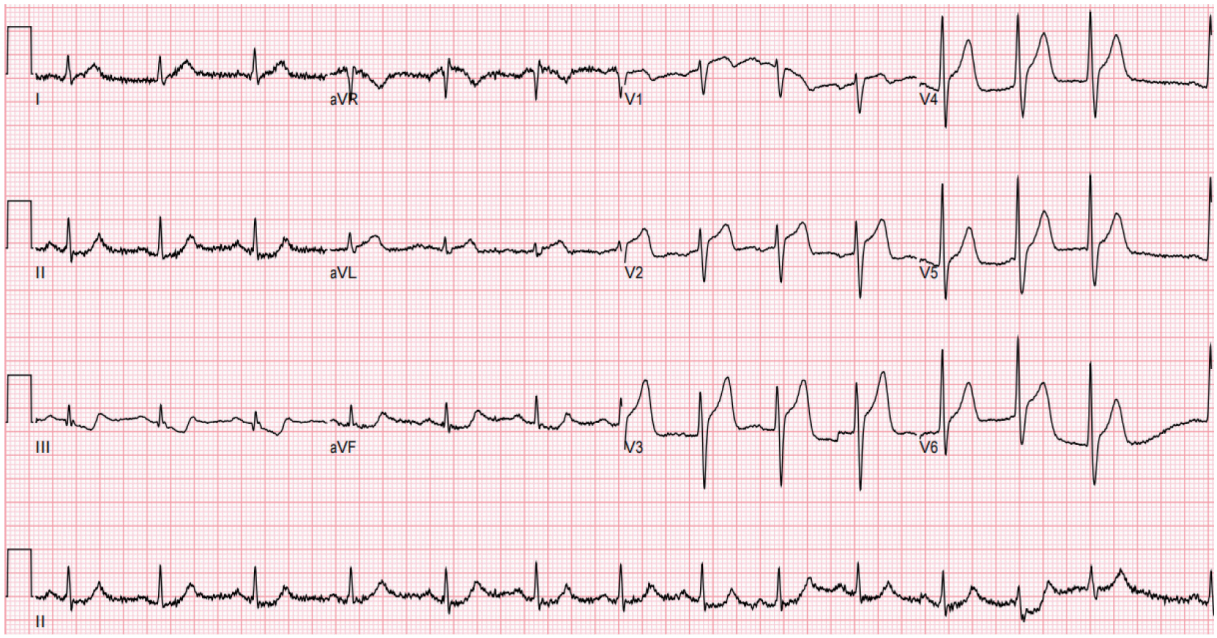

Figure 4. ECG.

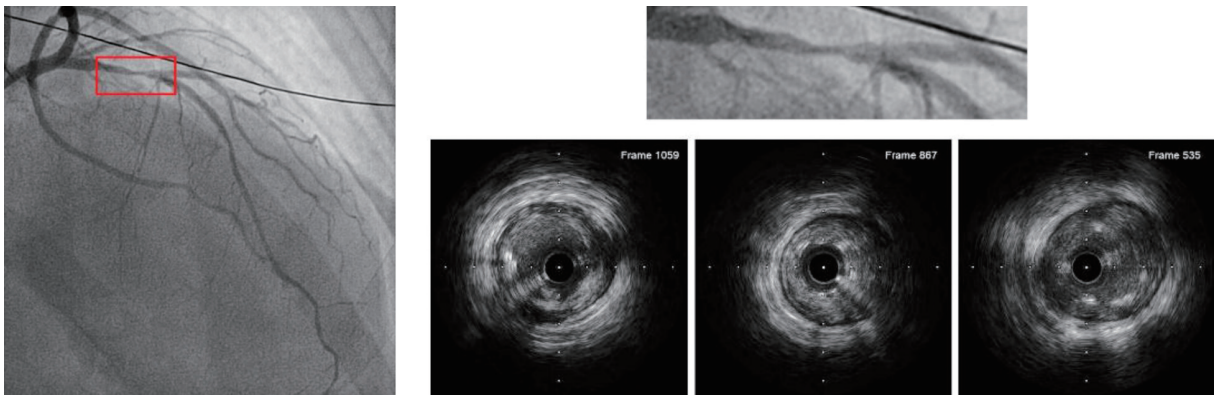

Figure 5. Initial angiography (left). Intravascular ultrasound of the proximal, middle and distal region of the LAD lesion (right).

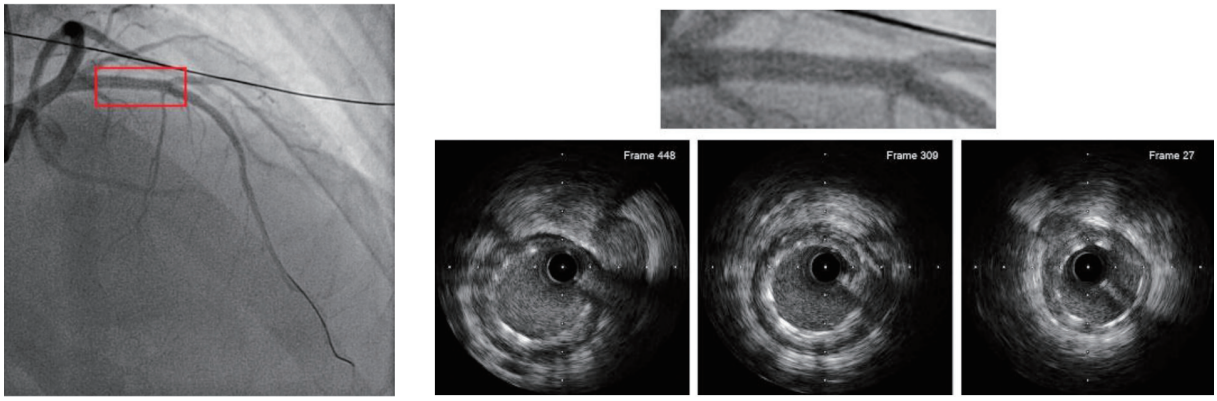

Figure 6. Final angiography (left). Intravascular ultrasound of the proximal, middle and distal region of the stented and post-dilated LAD region.

started on ticagrelor 180mg loading with 90 mg QD in place of prasugrel. He was discharged on aspirin and ticagrelor 4 days later without further complications.

Discussion

Magmaris is a sirolimus-eluting resorbable magnesium scaffold coated with poly-L-lactide acid (PLLA).[1] It is an attractive alternative to bare metal stents (BMS) and drug-eluting stents (DES) because it provides temporary mechanical support to the culprit lesion while allowing vasomotion restoration after complete resorption. Magmaris must be avoided in left main lesions, and in ostial lesions.[2] It is suitable for simple lesions that are not diffuse or long, and are without heavy calcification, bifurcation and challenging tortuosity or angulation.[2] Magmaris first became available on October 8th, 2013, in the BIOTRONIKS - Safety and Performance in de Novo Lesion of Native Coronary Arteries with Magmaris (BIOSOLVE) II trial and received Conformité Européene approval in June 2016. The safety and performance of Magmaris has been confirmed by the BIOSOLVE IV registry with 1075 patients over 12 months,[3] and a full registry of 2066 patients over 24 months (reported in Transcatheter Cardiovascular Therapeutics (TCT) Conference 2022).[4]

Magmaris was an ideal stent for our patient because he was diagnosed with unstable angina

and with a CTA-proven simple lesion in a single vessel. One hundred and forty days after stent implantation, the patient presented again with anterior STEMI due to early Magmaris collapse. IVUS showed maximal lumen stenosis in the middle section of the implantation (Figure 5). In a previously reported case that involved Magmaris implantation in a patient with inferior STEMI, mal-apposition and under-expansion were found to be the main promoters of scaffold restenosis after five months, during a pre-scheduled angiography.[5] In another previously reported case that involved thrombotic lesion in the right coronary artery (RCA), post-dilatation was not performed. Scaffold dismantling was revealed 8 days later during a staged percutaneous intervention (PCI). A 3.5 x 23.0 mm cobalt chromium everolimus-eluting stent was implanted. One month later, the patient was diagnosed with NSTEMI with OCT revealing intraluminal thrombus, uncovered struts, and heterogeneous neointimal tissue.[6] In our case, there was neither thrombus nor under-expansion of the stent. Follow up OCT of our case revealed no sign of stent under-expansion, mal-apposition, or stent damage (Figure 3).

Early Magmaris collapse,[7,8] collapse with neointimal hyperplasia,[9] and collapse with in-stent tissue and thrombus[10] have been previously reported. The cases with early Magmaris collapse presented with unstable angina 2.5 months[7] or recurrent angina 9 months[8] after stent implantation. Magmaris collapse with neointimal hyperplasia was revealed by OCT on a 58-year-old male with progressive effort angina 8 months after Magmaris implantation. A 49-year-old male presented with recurrent angina 2 months after Magmaris implantation.[10] IVUS revealed significantly collapsed struts toward the lumen and mixed echogenic tissue around the struts, suggesting thrombus formation.[10] Although the index IVUS showed the stent fully expanded, the presence of concentric and thick fibrotic plaque was perceived as the cause of early stent recoil and partial collapse. A case series in Spain including 100 patients with Magmaris implantation showed 12 patients with target lesion revascularization (TLR).[11] The main OCT findings were device under-expansion/collapse (n = 7; 58%), scaffold discontinuity (n = 4; 33%), and distal edge dissection (n = 1; 9%).[11] The scaffold discontinuity phenomenon was identified at an earlier stage than under-expansion/collapse (70 days [32-111] vs 224 days [190-366]), p = 0.022).[10] Among the 12 patients with TLR, only one showed a STEMI presentation and evidence of definite scaffold thrombosis associated with early dual anti-platelet therapy (DAPT) interruption.[10]

Our patient presented with anterior chest tightness that had commenced three hours prior, and with anterior STEMI. His initial hs-troponin I was 0.0028 ng/mL. An elevated hs-troponin level of 0.0875 ng/mL is deemed abnormal in our center. To our knowledge, this is the first reported case of acute onset of Magmaris collapse with STEMI presentation. Unlike previously reported cases in the literature,[10] there was no evidence of thrombus involvement and the patient's compliance with DAPT was good. He was a relatively young patient with T2DM and hyperlipidemia managed by metformin 500 mg QD and atorvastatin 20 mg QD. The lesion involved was simple without evidence of thick fibrotic plaque or calcification on the initial OCT (Figure 3), and the location of the lesion was not tortuous. OCT also revealed proper sizing of the Magmaris stent. As reported in another case series, scaffold discontinuity is identified earlier than under-expansion/collapse.[10] We speculate that scaffold discontinuity in the early stages might lead to under-expansion/collapse, and hence intraluminal hyperplasia. Vessel injury by the strut may further lead to collagen exposure followed by thrombus formation.

Two single center studies revealed higher rates of early Magmaris stent degradation.[12,13] The original studies (BIOSOLVE II, including 123 patients and BIOSOLVE III, including 61 patients) reported target lesion failure (TLF) occurring in six patients (3.3%), including two cardiac deaths, one target-vessel myocardial

infarction, and three clinically driven target lesion revascularizations. No definite or probable scaffold thrombosis was observed.[14] BIOSOLVE IV was a prospective multicenter study with enrollment of 2,066 patients and 2,154 lesions. The 24-month TLF rate was 6.8%.[4] Among the 84 patients (mean age 62 ± 11 years and 63 (75%) men) treated with Magmaris in Switzerland, 14 (18%) patients experienced a device-oriented composite endpoint, whereas scaffold thrombosis was found in 4 (4.9%) patients (early scaffold thrombosis (<30 days) in three cases and two fatal cases).[12] The BIOSOLVE II trial reported a slight increase in in-segment and in-scaffold late lumen loss and diameter stenosis between 12 and 36 months (by 0.11 +/-0.28 mm and 0.13 +/-0.30 mm for late lumen loss, and by 3.8 +/-10.1% and 4.1 +/-10.2% for diameter stenosis).[1] A prospective single study in the Netherlands found a significant reduction in both minimal lumen area (MLA) and scaffold area at the site of the MLA by 43.44 ± 28.62 and 38.20 ± 25.74%, respectively.[13] A fast and heterogeneous scaffold degradation process was found with a significant reduction of patent struts at 4-5 months.[13] These two studies may not have had as large a sample size as BIOSOLVE II-IV, but their results illustrate the necessity to closely follow and further our understanding of the process of Magmaris degradation.

Conclusion

We present a rare case of anterior STEMI associated with premature degradation and collapse of a Magmaris stent. We speculate that scaffold discontinuity in the early stages might have led to under-expansion and early collapse of the stent, and subsequently to intraluminal hyperplasia. Vessel injury during the process may have led to collagen exposure followed by thrombus formation. The biodegradable scaffold remains an attractive option for the treatment of coronary artery disease. Pending further perfection of the device and our understandings of the process of scaffold degradation, we agree with the 2018 guidelines on myocardial revascularization published by the European Society of Cardiology (ESC), whereby any BRS should not be used outside well-controlled clinical studies.[15] Prolonged-duration DAPT over three years or longer, with close follow-up in the early stages after BRS implantation may be considered in patients treated with BRS.

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