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Article

Significant Late Loss of Magmaris Scaffold at 13-months follow up

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Abstract: A 45-year-old male patient was admitted for stable angina and coronary angiography identified a 95% diameter stenosis in the middle right coronary artery. Optical Coherence Tomography (OCT) imaging revealed a lesion with luminal area of only 1.8mm^2. The lesion was treated 3.5x25 mm Magmaris. The final result is considered to be minimally acceptable. However, 13 months later, the patient felt recurrent chest tightness at rest and received repeat angiography. The angiogram showed a significant in- scaffold restenosis and OCT finding identified a luminal area of only 1.6mm^2 with heterogeneous neo-intimal growth over the remaining poorly defined scaffold struts. This lesion was then successfully treated by a 3.5x30 mm Orsiro stent implantation with angiographically excellent results. In this case, we suggest in-scaffold final luminal area should be greater than 4.5mm^2 and OCT criteria for Magmaris optimization need to be further investigated.

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Keywords: Magmaris, in-scaffold restenosis, optical coherence tomography (OCT)

1. Introduction

Absorbable metal scaffold like Magmaris (Biotronik AG, Buelach, Switzerlabd) constitute an attractive alternative to polymeric BRS, as the magnesium material can potentially provide higher radial strength and hence greater acute lumen gain as compared to the polymeric Absorb. Recently, 12 months' outcomes of the BISOLVE-II were also published and there was no definite or probable scaffold thrombosis up to 12 months and no TLF beyond 6 months. OCT finding in the BISOLVE-II showed 95% of the magnesium scaffold is absorbed within 12 months. Today we reported a case with significant late loss of Magmaris at 13-months follow up.

2. Case report

A 45-year-old male patient, without a history of hypertension, diabetes, hyperlipidemia, and a coronary artery disease (CAD) history of family, was admitted for stable angina (Canadian Cardiovascular Society (CCS) grading II). Coronary angiography identified a 95% diameter stenosis in the middle right coronary artery (Figure. 1A) and Optical Coherence Tomography (OCT) imaging revealed a lesion with luminal area of only 1.8 mm^2 (Figure. 1B), which is an eccentric, mild

calcified, type B1 lesion (American Heart Association/American College of Cardiology (AHA/ACC) classification). In the consideration of the patient's relatively young age, coronary intervention is proceeded with a 3.5x25 mm Magmaris BRSs (Biotronik, Berlin, Germany), followed by 3.5x15mm non compliance (NC) balloon (Pantera LEO, Biotronik, Berlin, Germany) post-dilatation with high pressure 22 atm (rated boost pressure (RBP)=20 atm). Even though, angiography showed satisfactory result (TIMI III), OCT imaging showed lumen area of only 4.2mm^2. Thus, a 4.0X12 mm NC balloon (Pantera LEO, Biotronik, Berlin, Germany) was used for further post-dilatation with high pressure 18 atm (RBP=20 atm). Afterwards, despite the OCT results showed the scaffold expansion is still suboptimal with a luminal area of only 5.8mm^2 at the distal end, but which is considered to be minimally acceptable, (Figure. 1C and D) so no interventional procedure was further proceeded.

However, 13 months later, the patient felt recurrent chest tightness at rest and received repeat angiography. Angiogram showed a significant in-scaffold restenosis (Figure. 2A) and OCT (Figure. 2B) findings identified a luminal area of only 1.6mm^2 with heterogeneous neo-intimal growth over the remaining poorly defined scaffold struts. The lesion was then successfully treated by a 3.5x30 mm cobalt-chromium sirolimus-eluting stent (Orsiro, Biotronik, Berlin, Germany) implantation with angiographically excellent results, and the OCT results showed optimal stent expansion with good apposition, no edge dissection, nor visible thrombus (Figure. 2C and D).

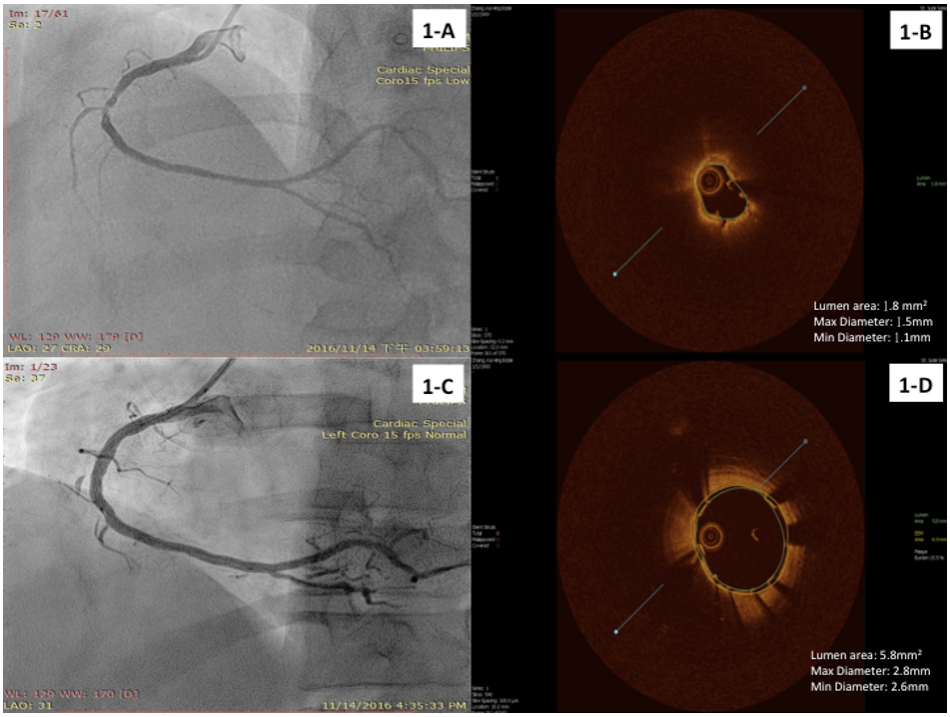

Figure 1. (A) Baseline angiogram, showed a severe focal lesion. (B) OCT findings showed a calcified, lipid-rich eccentric lesion with minimal lumen area of 1.8 mm^2, maximal luminal diameter of 1.5 mm and minimal luminal diameter of 1.1 mm. (C) Final angiogram after implantation of a 3.5x25mm Magmaris bioresorbable scaffold showed satisfactory result. (D) OCT findings after Magmaris implantation and post-dilated with a high pressure NC balloon showed under-expansion at the distal end of the scaffold with a minimal lumen area of 5.8 mm^2, maximal luminal diameter of 2.8 mm and minimal luminal diameter of 2.6 mm.

3. Discussion

Bioresorbable scaffold (BRS) have been designed to overcome problems related to long-term persistence of metallic stents implanted in coronary arteries [1,2]. Even though, several randomized controlled trials (RCTs) comparing polymeric BRS with new-generation drug-eluting stents (DES)

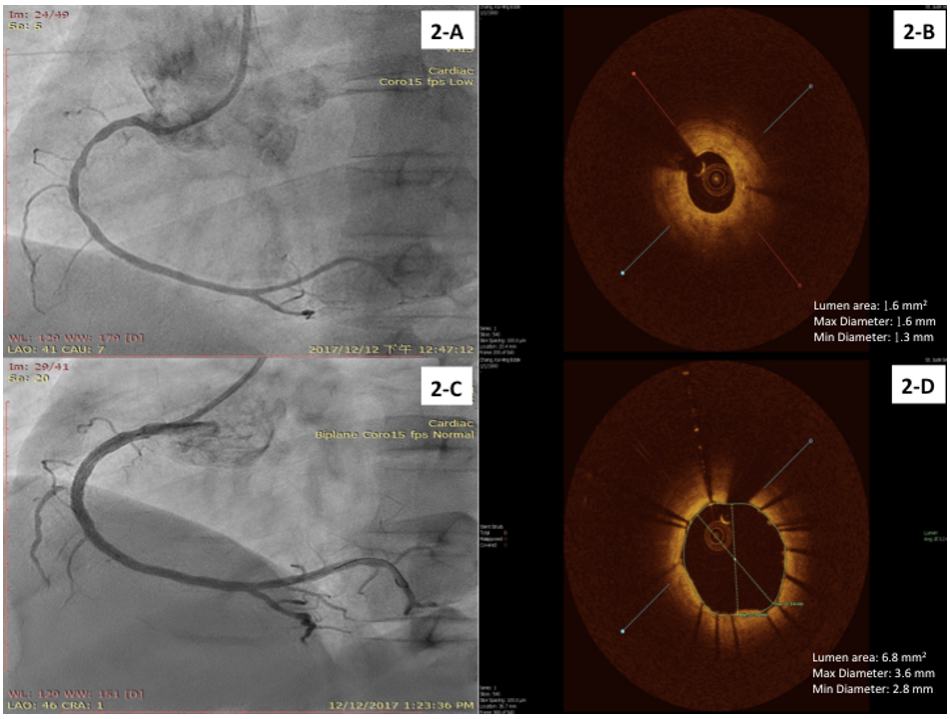

Figure 2. (A) At 13 months follow-up, angiography showed severe in-scaffold restenosis. (B) OCT results showed a luminal area of only 1.6mm^2 with heterogeneous neo-intimal growth over the remaining poorly defined scaffold struts at the follow-up. (C) Final angiogram after implantation of a 3.5x30 mm cobalt-chromium sirolimus-eluting stent (Orsiro, Biotronik, Berlin, Germany) showed satisfactory result. (D) OCT results showed good stent expansion and good apposition with minimal lumen area of 6.8 mm^2, maximal luminal diameter of 3.6 mm and minimal luminal of diameter 2.8 mm.

found similar clinical outcomes at 1 year [3–5]. Recent studies showed the BRS was associated with a higher incidence of device related thrombosis than the metallic stent [6,7] and as a result, the importance of PSP technique (the use of pre-dilation, proper sizing, and post-dilation) is emphasized, and has been shown to be associated with better scaffold expansion and a lower risk of thrombotic events [8]. Besides, newer generation of BRS with thinner struts, increased radial strength, different composition, and faster resorption is urgently needed.

When it comes to high pressure balloon post-dilation, there is always a concern that too high pressure may lead to fracture of the scaffold, however, Fabris [9] and coworkers demonstrated with OCT that high-pressure post dilation of BRS using up to 30 atm does not lead to strut fracture and with a lesser degree of strut malapposition if the BRS is properly sized. They performed post-dilation with maximal balloon inflation pressure of 28.0±3.8 atm and the subsequent OCT finding showed small percentage of residual area stenosis (RAS)(16±9.6%) and very low percentage of ISA (1.8 ±2.4%) with no scaffold edge dissection or scaffold fractures.

Absorbable metal scaffold like Magmaris (Biotronik AG, Buelach, Switzerlabd) constitute an attractive alternative to polymeric BRS, as the magnesium material can potentially provide higher radial strength and hence greater acute lumen gain as compared to the polymeric Absorb. The Magmaris, formerly known as DREAMS 2G, is the first metal-basal absorbable scaffold to be introduced into clinical practice. It is made of a proprietary magnesium alloy coated with a poly-L-lactic acid (PLLA) biodegradable polymer eluting sirolimus, with both strut thickness and width of 150 μm [1].

Six-months outcomes of the BISOLVE-II [10] showed favorable angiographic and clinical outcomes with low rate of target lesion failure (TLF) and no definite or probable scaffold thrombosis. Recently, 12 months' outcomes of the BISOLVE-II [11] were also published and there was no definite or probable

scaffold thrombosis up to 12 months and no TLF beyond 6 months. OCT finding in the BISOLVE-II showed 95% of the magnesium scaffold is absorbed within 12 months.

In the present case report, we showed that even after 13 months of implantation, the magnesium material struts still in the progress of resorption. Besides, despite angiographically satisfactory result together with the OCT minimally acceptable scaffold luminal area, late luminal loss is still high. Stent under-expansion has been established as a major predictor of DES failure. In principle, a better stent expansion will lead to better clinical outcomes and a lower risk of stent failure. OCT data from the CLI-OPC II study [12] demonstrated that in-stent minimum lumen area of 4.5 mm^2 (hazards ratio (HR): 1.64, p=0.040) best discriminates subsequent events in non-left main lesion implanted with DES. Although, post procedure minimal scaffold area (MSA) achieved 5.8mm^2 in the present case, greater than the previously proposed DES threshold for discriminating patients with MACEs, the late luminal lose is still very high. We hypothesized that the OCT criteria for stent optimization in DES could be not applied for Magmaris. In general, by the rule of Kepler Circular area formula, stenting with a 3.5mm Magmaris has an ideal area of 9.6mm^2 (Area=3.14x1.752), however, the minimal scaffold luminal area at the distal end of our patient has only achieved 5.8mm^2. Therefore, we suspected the reason why in the present case the patient has a recurrent angina and has such a high luminal lose at the 13-month follow-up is mainly due to scaffold under-expansion together with neo-intimal growth.

The Magmaris scaffold design consists of six in-phase sinusoidal hoop/ring linked by two straight mid-strut connectors, with both strut thickness and width of 150 μm, which is thicker than DES. Therefore, when it comes to Magmaris scaffold implantation, lesion preparation, post-dilatation with high pressure ballooning under OCT guidance is needed to ensure well Magmaris scaffold expansion. The impact of OCT findings on clinical outcome was well defined in DES, but remains undefined in Drug-eluting metal scaffold. High pressure NC balloon post-dilatation is very important, besides, luminal area achieving OCT criteria in DES (4.5mm^2) is not enough to be a predictor of clinical outcome for Drug-eluting metal scaffold like Magmaris. We suggest in-scaffold final luminal area should be greater than 4.5mm^2 and OCT criteria for Magmaris optimization need to be further investigated. Absorbable metal scaffold like Magmaris constitute an attractive alternative to polymeric BRS. OCT guidance and high pressure NC balloon post-dilatation is also needed in Magmaris implantation. Besides, luminal area achieving OCT criteria in DES (4.5mm^2) is not enough to be a predictor of clinical outcome for Drug-eluting metal scaffold like Magmaris. We suggest in-scaffold final luminal area should be greater than 4.5mm^2 and OCT criteria for Magmaris optimization need to be further investigated.

Conflicts of Interest:
The authors declare no conflict of interest.

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