



CASE REPORT

Feasibility of use of magnesium reabsorbable scaffolds in complex coronary artery disease: True bifurcation, multiple overlapping scaffolds and chronic total occlusion treatment



Jeremías Bayón*, Melisa Santá-Álvarez, Raymundo Ocaranza-Sánchez, Carlos González-Juanatey

Hospital Universitario Lucus Augusti, Lugo, Galicia, Spain

Received 8 June 2017; accepted 24 August 2017

KEYWORDS

Bioabsorbable magnesium scaffolds; Nickel allergy; Complex percutaneous coronary intervention

PALAVRAS-CHAVE

Suportes bioabsorbíveis de magnésio; Alergia ao níquel; Intervenção coronária percutânea complexa

Abstract We present first-in-human treatment with bioabsorbable magnesium scaffolds for percutaneous coronary intervention in a patient with nickel allergy. We present images from angiography and optical coherence tomography at three months. We also review the current status of these novel devices.

© 2018 Sociedade Portuguesa de Cardiologia. Published by Elsevier España, S.L.U.

This is an open access article under CC BY-NC-ND license.

(<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

Exequibilidade de *stents* bioabsorbíveis de magnésio na doença coronária complexa: bifurcação verdadeira, *stents* sobrepostos múltiplos e tratamento da oclusão crônica total

Resumo Apresentamos pela primeira vez o tratamento com suportes bioabsorbíveis de magnésio na intervenção coronária percutânea complexa de doentes com alergia ao níquel. Incluímos a angiografia e as imagens da tomografia de coerência óptica efetuadas durante um período de três meses. Analisamos também o estado atual deste equipamento inovador.

© 2018 Sociedade Portuguesa de Cardiologia. Publicado por Elsevier España, S.L.U. Este é um artigo Open Access sob a licença de CC BY-NC-SA (<http://creativecommons.org/licenses/by-nc-sa/4.0/>).

* Corresponding author.

E-mail address: jerebayon@gmail.com (J. Bayón).

Introduction

The Magmaris bioabsorbable sirolimus-releasing magnesium scaffold (Biotronik) is the first device of its kind that is clinically tested and with proven safety data. It features a metallic magnesium backbone with corrugated ring design, six crowns and strut thickness of $150 \times 150 \mu\text{m}$. In vitro tests have demonstrated greater radial strength, 20% less recoil and 80% more flexibility than the Absorb bioabsorbable sirolimus-releasing poly(lactide acid) (PLLA) scaffold (Abbott).¹

The magnesium backbone is coated with a compound called BIOLute, a resorbable PLLA polymer which delivers controlled release of the sirolimus drug for up to 90 days and which is metabolized in the body to carbon dioxide and water. The absorption process is rapid, with 95% of the magnesium being reabsorbed within twelve months.²

A safety study, BIOSOLVE I, enrolled 46 patients with 47 de novo lesions. Three-year follow-up results were obtained from 44 patients, which showed target lesion failure in three cases (6.6%), and no cardiac death or device thrombosis. Seven patients had additional angiographic follow-up at 28 ± 4 months: in-scaffold late luminal loss had improved from 0.51 ± 0.46 mm (median 0.28 mm) at 12 months to 0.32 ± 0.32 mm (median 0.20 mm).³

The 12-month results of BIOSOLVE-II have recently been published, enrolling 123 patients with de novo lesions with a reference diameter between 2.2 mm and 3.7 mm. Quantitative coronary angiography parameters were stable from 6 to 12 months (paired data of 42 patients: in-segment late lumen loss 0.20 ± 0.21 mm vs. 0.25 ± 0.22 mm, $p=0.117$; in-scaffold late lumen loss 0.37 ± 0.25 mm vs. 0.39 ± 0.27 mm, $p=0.446$, respectively. Intravascular ultrasound demonstrated preserved minimal luminal area at six months (6.24 ± 1.15 mm² after percutaneous coronary intervention [PCI] vs. 6.21 ± 1.22 mm² at six months), with a

small neointimal area (0.08 ± 0.09 mm²). Optical coherence tomography (OCT) detected no intraluminal masses. Target lesion failure was observed in 3.4%, with no definite or probable scaffold thrombosis.⁴

Current recommendations for the Magmaris implant are de novo coronary lesions with a vessel diameter near the nominal size of the scaffold and a length shorter than the device. Among lesions not recommended or those in which special care has to be taken are total chronic occlusion, excessive tortuosity and side branches (bifurcations) greater than 2 mm in diameter.⁵

Case report

We present the case of a 65-year-old male with nickel allergy who was admitted to the hospital with non-ST-elevation acute coronary syndrome. Coronary angiography showed significant two-vessel coronary disease not suitable for surgical revascularization because of small caliber and diffuse disease. There were multiple tandem lesions from the proximal to the distal left anterior descending (LAD) artery, bifurcated (Medina 1,1,1) with a diagonal branch, and a chronic total occlusion (CTO) in the mid circumflex (CX) (Figure 1).

The patient was on aspirin so a loading dose of 180 mg ticagrelor was added. For the coronary angiography 8000 U heparin (weight-adjusted) and 300 μg intracoronary nitroglycerine were administered, in order to obtain a better assessment of the actual size of the coronary arteries. No imaging techniques were performed because of difficulty in crossing the lesion.

The LAD was treated, first with predilatation with a 3.0 mm \times 20 mm non-complaint balloon in the distal LAD and the diagonal branch, and a 3.5 mm \times 20 mm balloon in the proximal LAD (balloon-scaffold ratio 1:1). Sequential

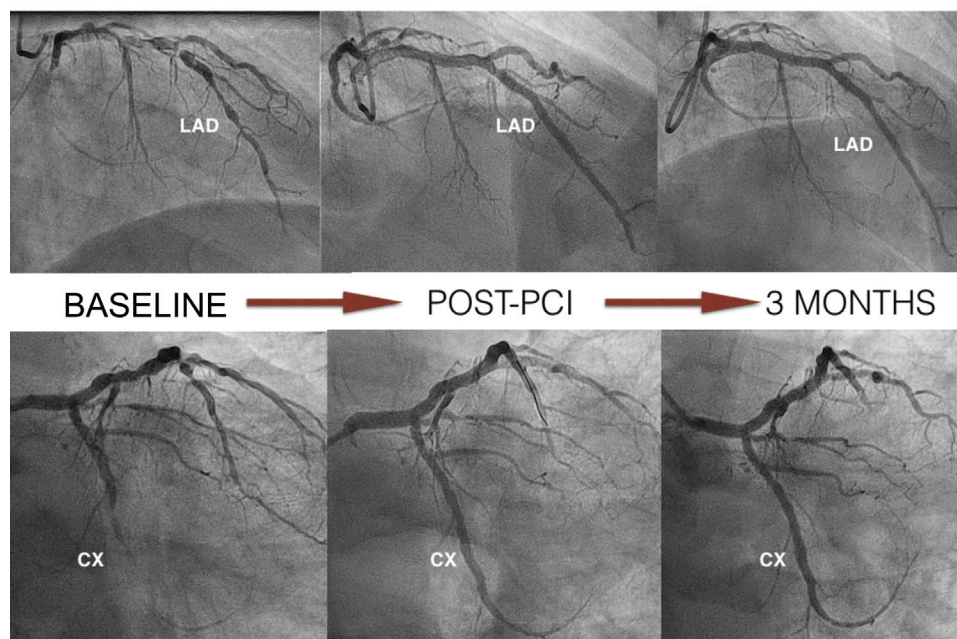


Figure 1 Coronary angiography at baseline, post-percutaneous intervention with implantation of Magmaris devices, and follow-up at three months. CX: circumflex; LAD: left anterior descending.

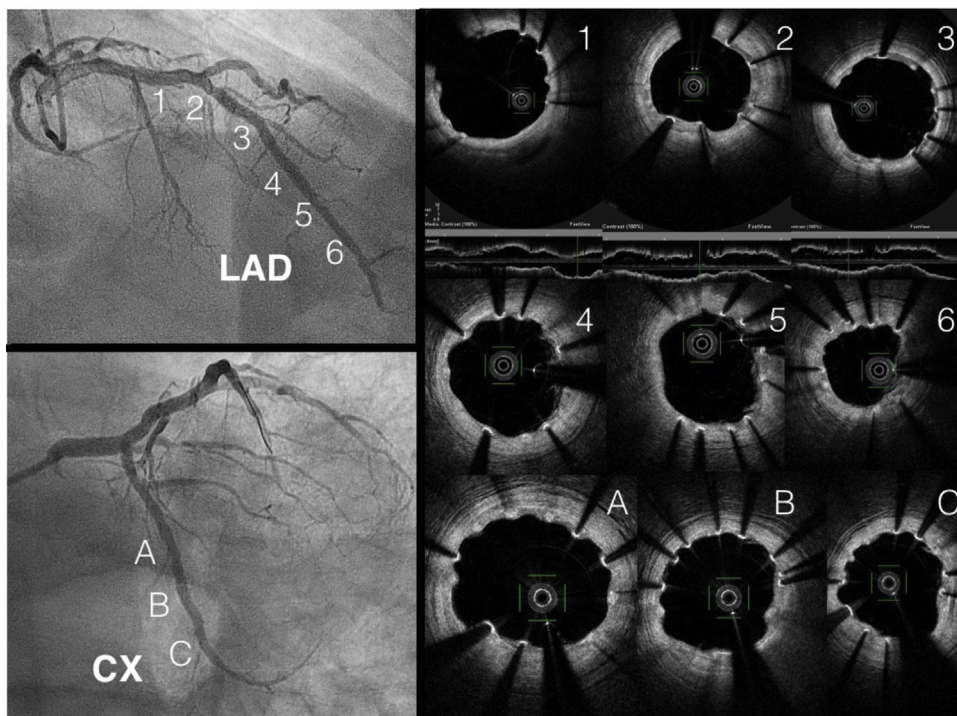


Figure 2 Optical coherence tomography images of the left anterior descending (LAD) and circumflex (CX) arteries, showing adequate apposition with partial covering of the struts. PCI: percutaneous coronary intervention.

and overlapping Magmaris scaffolds were then implanted (leaving 1 mm between the devices) from the distal LAD (one 3 mm×15 mm and two 3.5 mm×25 mm) to the bifurcation with the diagonal. StentBoost image enhancement (Philips) was used to adjust the overlap. Two more Magmaris scaffolds were then implanted in the median LAD (3.5 mm×25 mm) and the diagonal (3 mm×15 mm) by the reverse T and protrusion technique. The CTO of the CX was treated with a 3 mm×25 mm Magmaris. The scaffolds were implanted according to the manufacturer's recommendations to adequately predilate the lesion, select a device diameter very similar to vessel size, and postdilate without exceeding 0.6 mm above the nominal size of the device (Figure 1). In this case, we used non-compliant balloons with a 1:1 ratio except for the scaffold in the proximal LAD, which was postdilated with a 4.0 mm×20 mm non-compliant balloon. The final result was confirmed by OCT.

The patient was discharged with recommendation for 12 months dual antiplatelet therapy with aspirin 100 mg daily and ticagrelor 90 mg twice daily.

At three months, with no symptoms and with the patient's consent, coronary angiography was repeated (Figure 1). Three-month OCT showed appropriate strut apposition and partial covering of the majority of the struts (Figure 2).

Conclusion

We present first-in-human complex PCI in a patient with nickel allergy treated with Magmaris bioabsorbable sirolimus-releasing magnesium scaffolds (Biotronik). We highlight the good apposition in the CTO lesion and the true

bifurcation and overlapping in the LAD, with good results on OCT. This novel device is becoming a real option in these patients.

Conflicts of interest

The authors have no conflicts of interest to declare.

References

- Schmidt W, Behrens P, Brandt-Wunderlich C, et al. In vitro performance investigation of bioresorbable scaffolds – standard tests for vascular stents and beyond. *Cardiovasc Revasc Med.* 2016;17:375–83.
- Waksman R, Zumstein P, Pritsch M, et al. Second-generation magnesium scaffold Magmaris, device design, and preclinical evaluation in a porcine coronary artery model. *EuroIntervention.* 2017;13:440–9.
- Haude M, Erbel R, Erne P, et al. Safety and performance of the DRug-Eluting Absorbable Metal Scaffold (DREAMS) in patients with de novo coronary lesions: 3-year results of the prospective, multicentre, first-in-man BIOSOLVE-I trial. *EuroIntervention.* 2016;12:e160–6.
- Haude M, Ince H, Abizaid A, et al. Sustained safety and performance of the second-generation drug-eluting absorbable metal scaffold in patients with de novo coronary lesions: 12-month clinical results and angiographic findings of the BIOSOLVE-II first-in-man trial. *Eur Heart J.* 2016;37:2701–9.
- Fajadet J, Haude M, Joner M, et al. Magmaris preliminary recommendation upon commercial launch: a consensus from the expert panel on 14 April 2016. *EuroIntervention.* 2016;12: 828–33.