Magmaris

Presentación

Caso Magmaris

SOTOGRANDE

Viernes 8 de julio de 2016

Innovando el Intervencionismo Coronario

Problems with polymeric scaffold
Bioresorbable vascular scaffold collapse causes subacute thrombosis

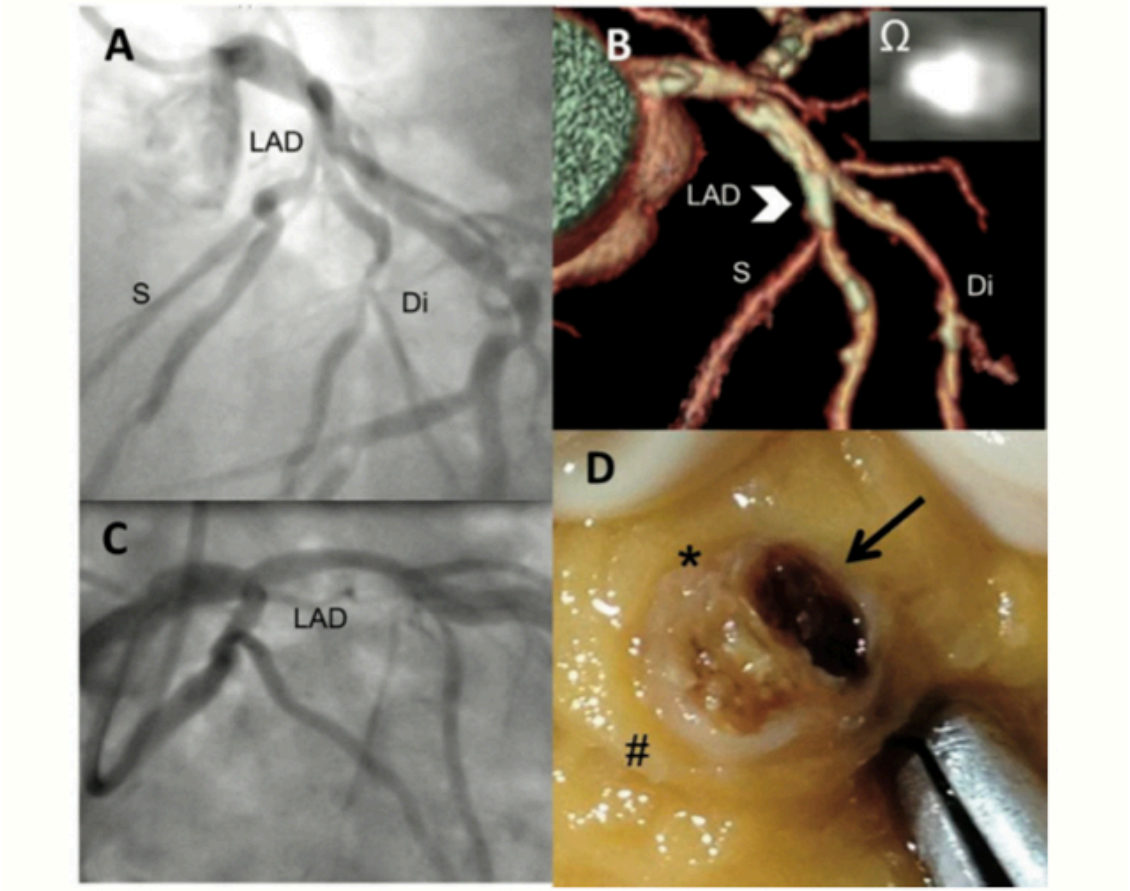


Figure 1. (A) *Left anterior descending (LAD) coronary artery angiography shows a diffuse proximal plaque extending distal to the bifurcation with the first diagonal.* **(B)** *Coronary computed tomography angiography, with volume-rendering reconstruction and cross-sectional view, exhibits huge calcification along proximal LAD (head arrow), protruding into the lumen (Ω).* **(C)** *After plaque preparation, a 3.0 x 28 bioresorbable vascular scaffold (BVS) was implanted with angiographic good result.* **(D)** *Histopathological cross-section of the LAD, viewed from the end of the segment covered by the BVS: fibrocalcific plaque takes up two-thirds of vessel area (#), with heavy calcification impinging upon the arterial lumen (*); the crescent-shaped LAD lumen shows crushed scaffold, completely obstructed by thrombus (arrow). S = septal branch; Di = first diagonal branch.*

Ruiz Salmerón RJ, Pereira S, de Araujo D.
Journal of Invasive Cardiology, 2014 Jul; 26(7): E98-9

Problems with polymeric scaffold

Immediate, Acute, and Subacute Thrombosis Due to Incomplete Expansion of Bioresorbable Scaffolds

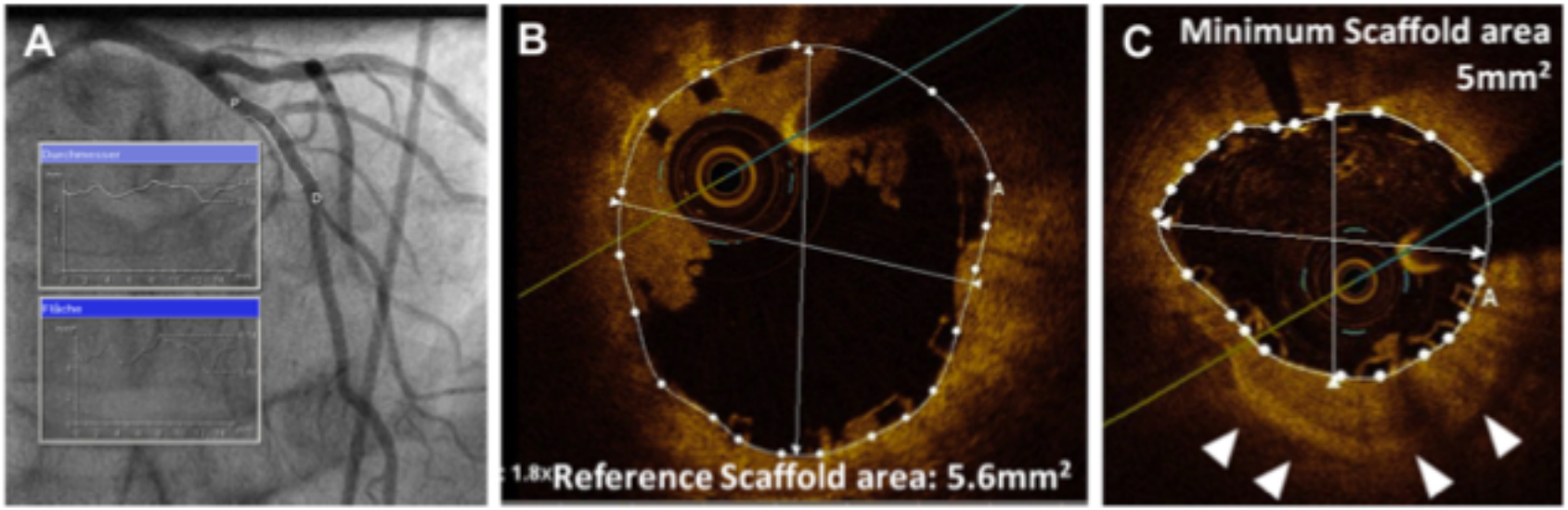


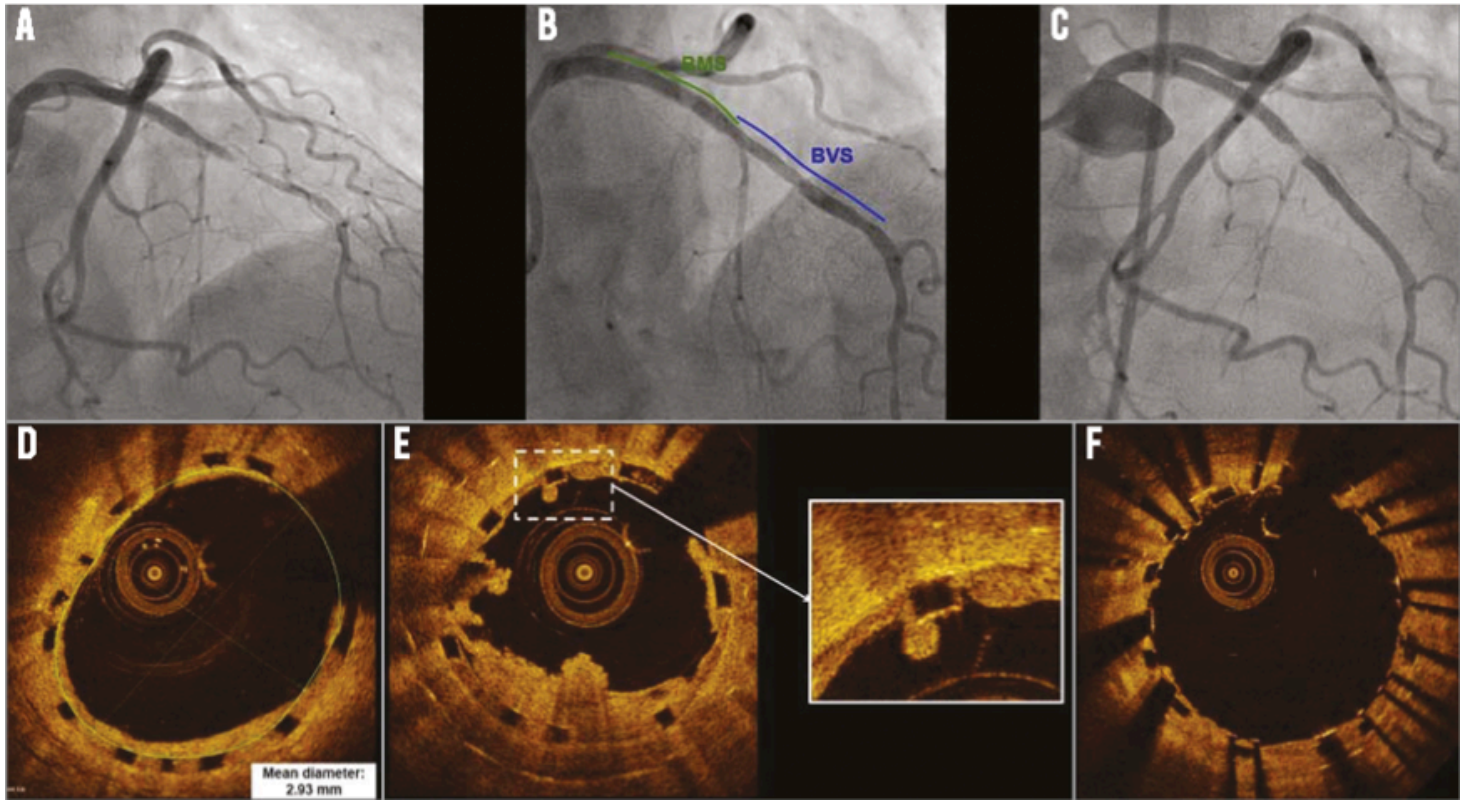
FIGURE 1 **Bioresorbable Coronary Scaffold in the Proximal LAD**

A bioresorbable coronary scaffold implanted in the proximal left anterior descending artery (LAD) **(A)**. Optical coherence tomography shows in-scaffold, red blood cell-rich thrombus, a highly calcific plaque, and mild scaffold underexpansion **(B and C)**

Gori T, Schulz E, Münzel T. JACC: CARDIOVASCULAR INTERVENTIONS 2014. VOL. 7, NO. 10: 1194-1195.

Problems with polymeric scaffold

Very late bioresorbable vascular scaffold thrombosis: a new clinical entity



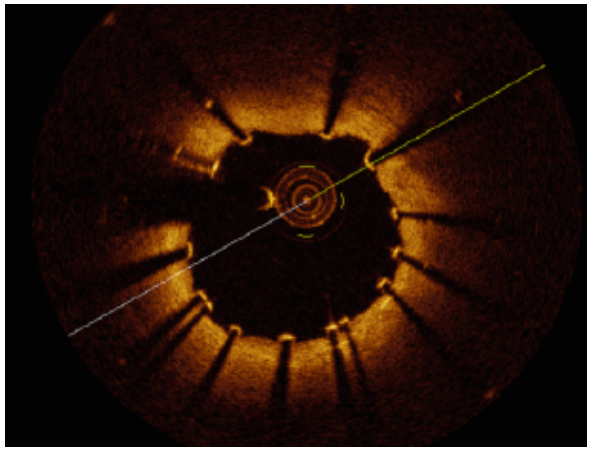
Bioresorbable vascular scaffold implantation and very late thrombosis. A) Pre-treatment angiogram. Final result was optimal (B). Fourteen months later, the patient presented with anterior STEMI. After thrombectomy (C), OCT was performed (D). Thrombotic material was found at the BVS-BMS junction (E), where incomplete tissue coverage was also observed (zoom). (F) Final result.

Azzalini L, Al-Hawwas M, MD; L'Allier PL. EuroIntervention 2015 May 19;11(1):e1-2.

Magmaris resorption in OCT imaging

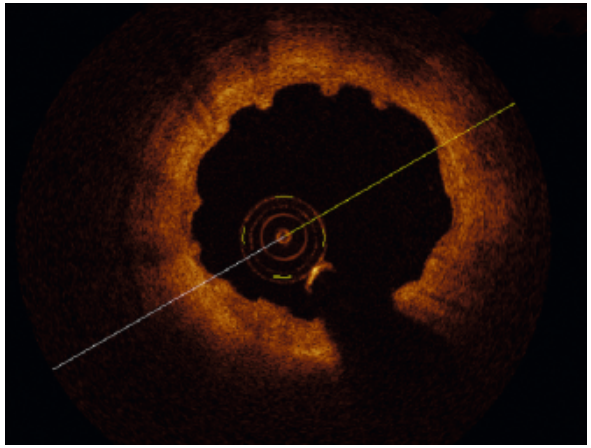
BIOSOLVE-II

Post-Implantation



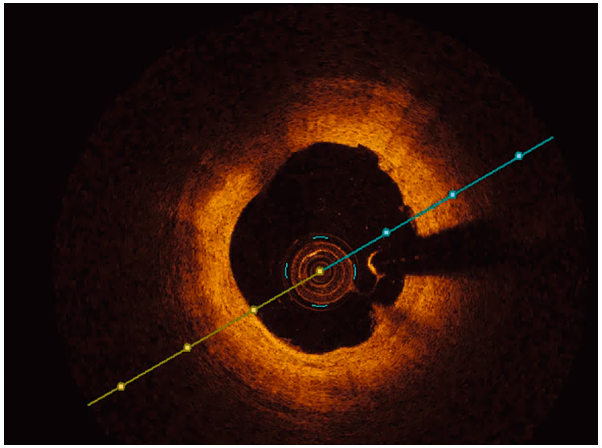
Immediately after implantation, struts are well apposed to the vessel wall.

6 month



While the Magnesium resorption process continues, endothelialization progresses.

12 month



At 12 months after implantation, the Magnesium resorption is almost completed.

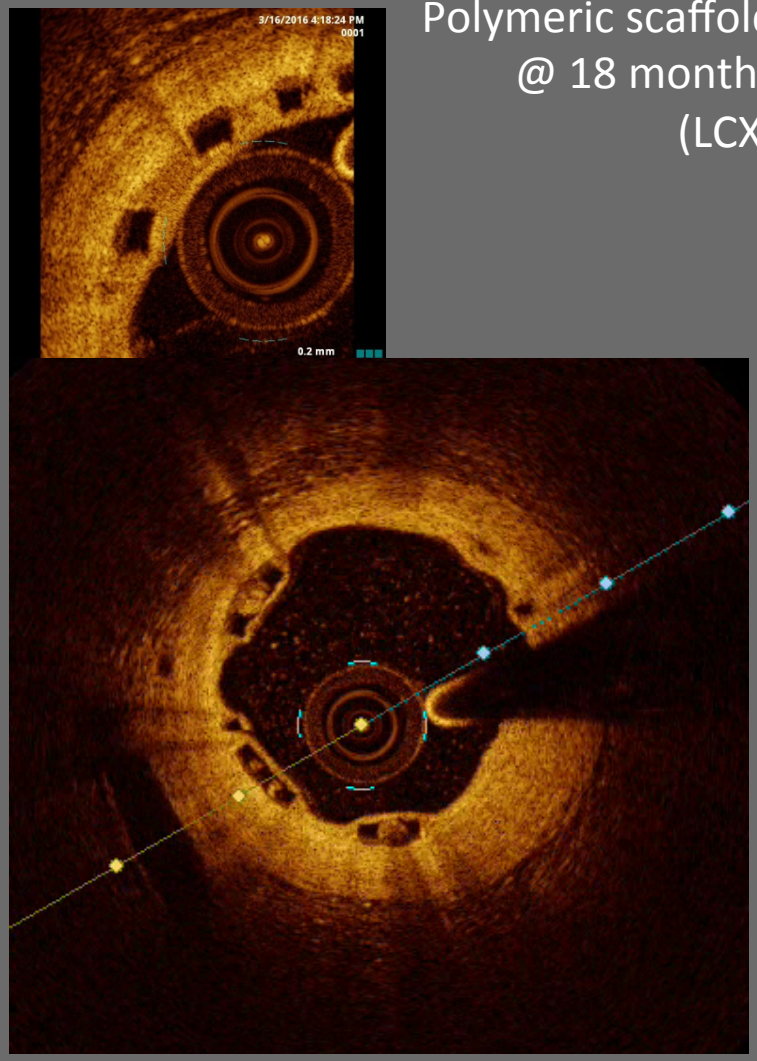
BIOSOLVE-II case, GER443-001. Courtesy of M. Haude, Lukaskrankenhaus Neuss, Germany 2015.

Magmaris clinical program

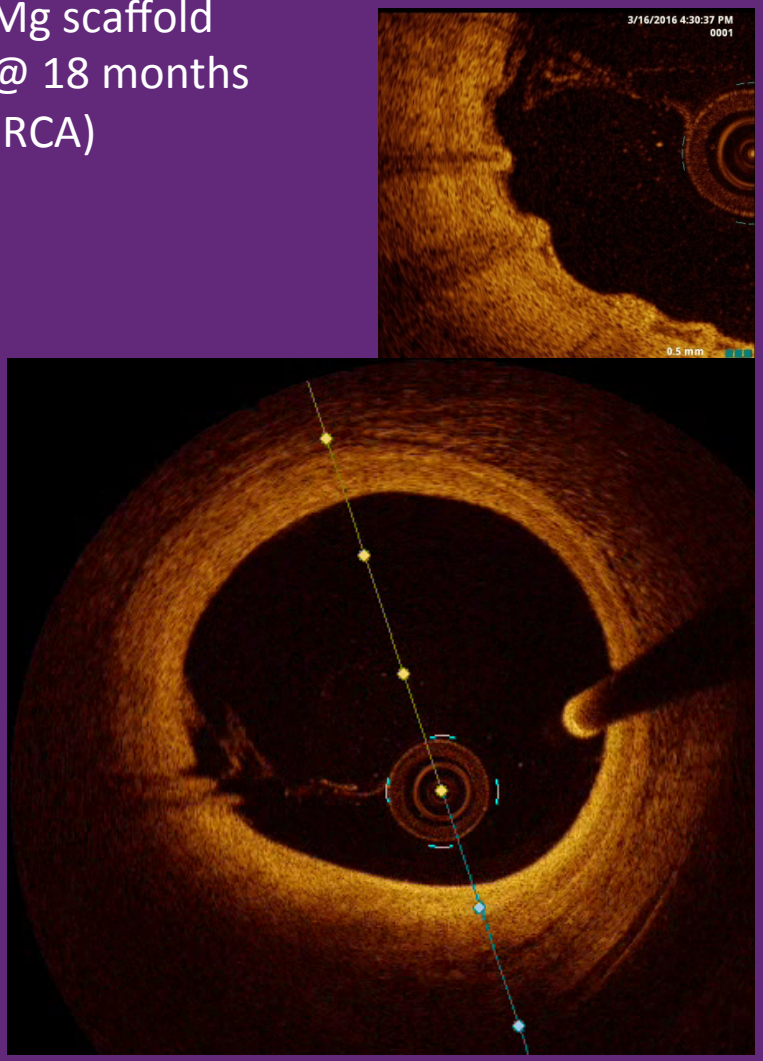
Study	Design	Status
BIOSOLVE-I **PI: J. Koolen**	**First-in-man trial** aimed at investigating the first generation of drug eluting magnesium scaffold in **46 patients with de novo lesions**. The primary endpoint was **target lesion failure** defined as a composite of cardiac death, target-vessel MI and clinically driven TLR at **6 and 12 months**.	Study completed. 3-year FU available Primary endpoint published in The Lancet
BIOSOLVE-II **PI: M. Haude**	**First-in-man trial** aimed at investigating the second generation of drug-eluting magnesium scaffold in **123 patients with a maximum of 2 de novo lesions**. The primary endpoint was **in-segment late lumen loss at 6 months**.	Primary endpoint published in The Lancet 12-month presented at EuroPCR 2016
BIOSOLVE-III **PI: M. Haude**	**Prospective, multicenter trial** aimed at investigating the seocond generation of drug-eluting magnesium scaffold with improved delivery system in **61 patients with de novo lesions**. The primary endpoint is **procedural success during hospital stay** defined as a final diameter stenosis of < 30% measured by QCA without any deaths, MIs or TLRs.	Enrolling
BIOSOLVE-IV **Europe PI: S. Verheye** **APAC PI: Michael Lee**	**Post-market registry** aimed at investigating the first available magnesium scaffold in **1065 real-world patients**. The primary endpoint is **TLF at 12 months** defined as a composite of cardiac death, target-vessel MI and TLR.	First patient planned Dec 2016
BIOSOLVE-V **To be determined**	**Randomized clinical trial** testing the first magnesium resorbable scaffold in a real-world setting.	First patient planned Jan 2017

Polymeric and Mg scaffolds in the same patient

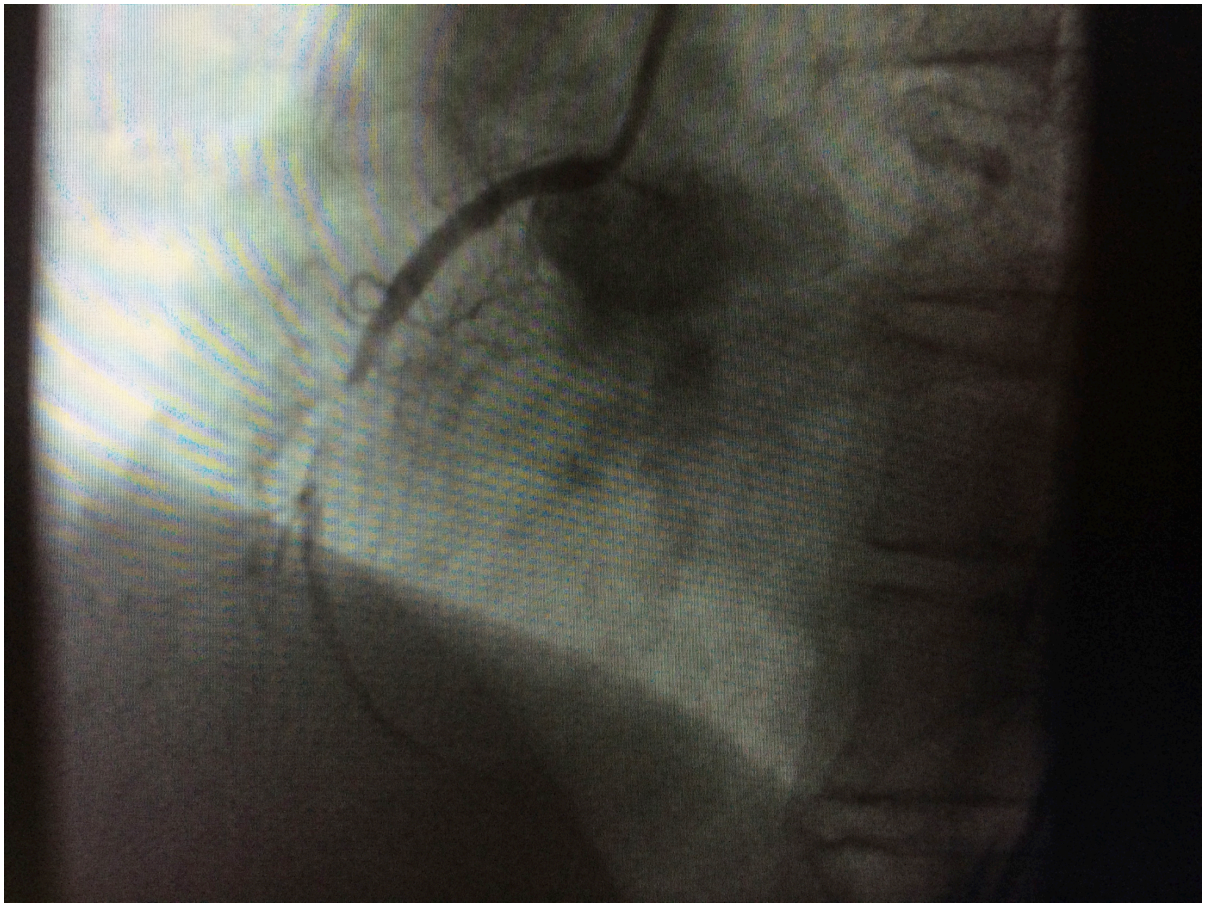
Polymeric scaffold
@ 18 months
(LCX)



Mg scaffold
@ 18 months
(RCA)

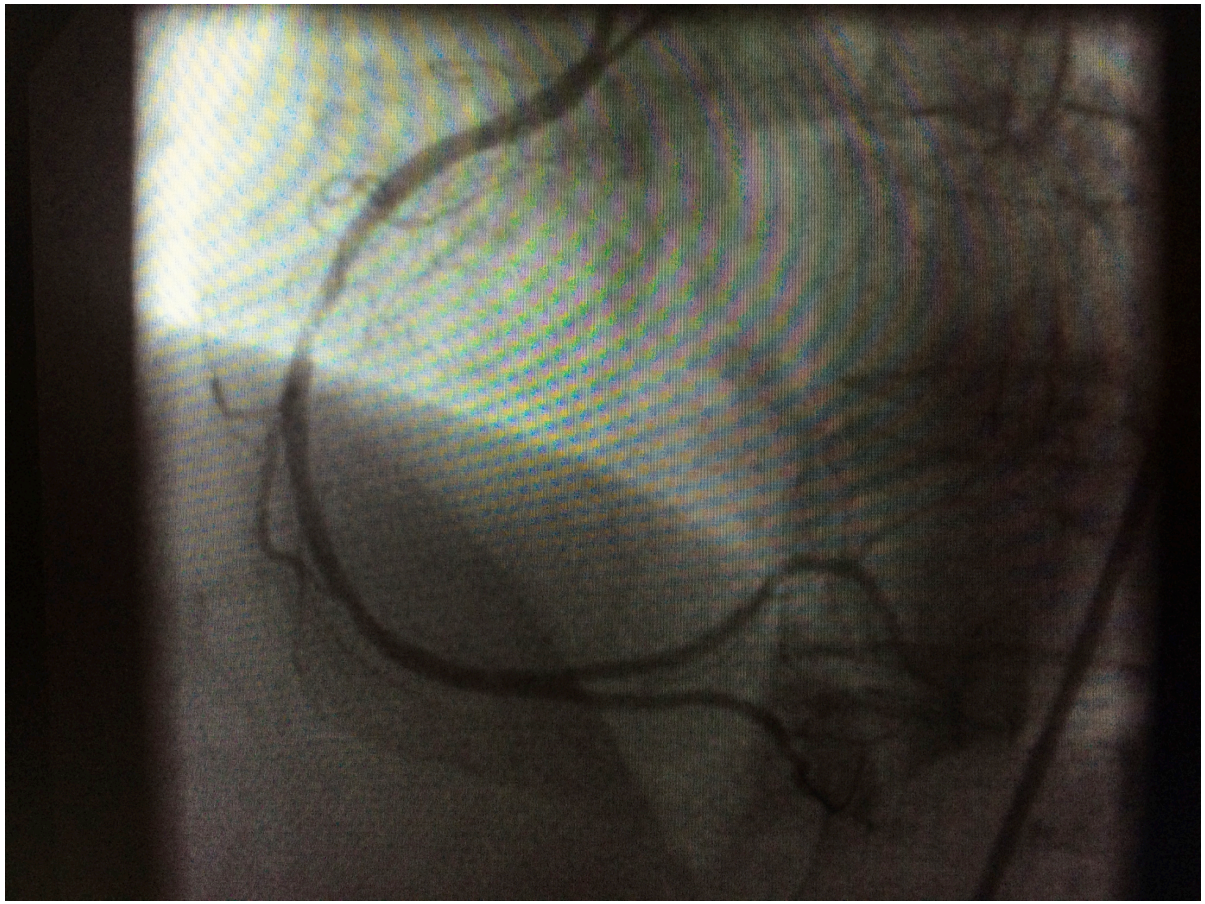


Primer caso con stent Magmaris



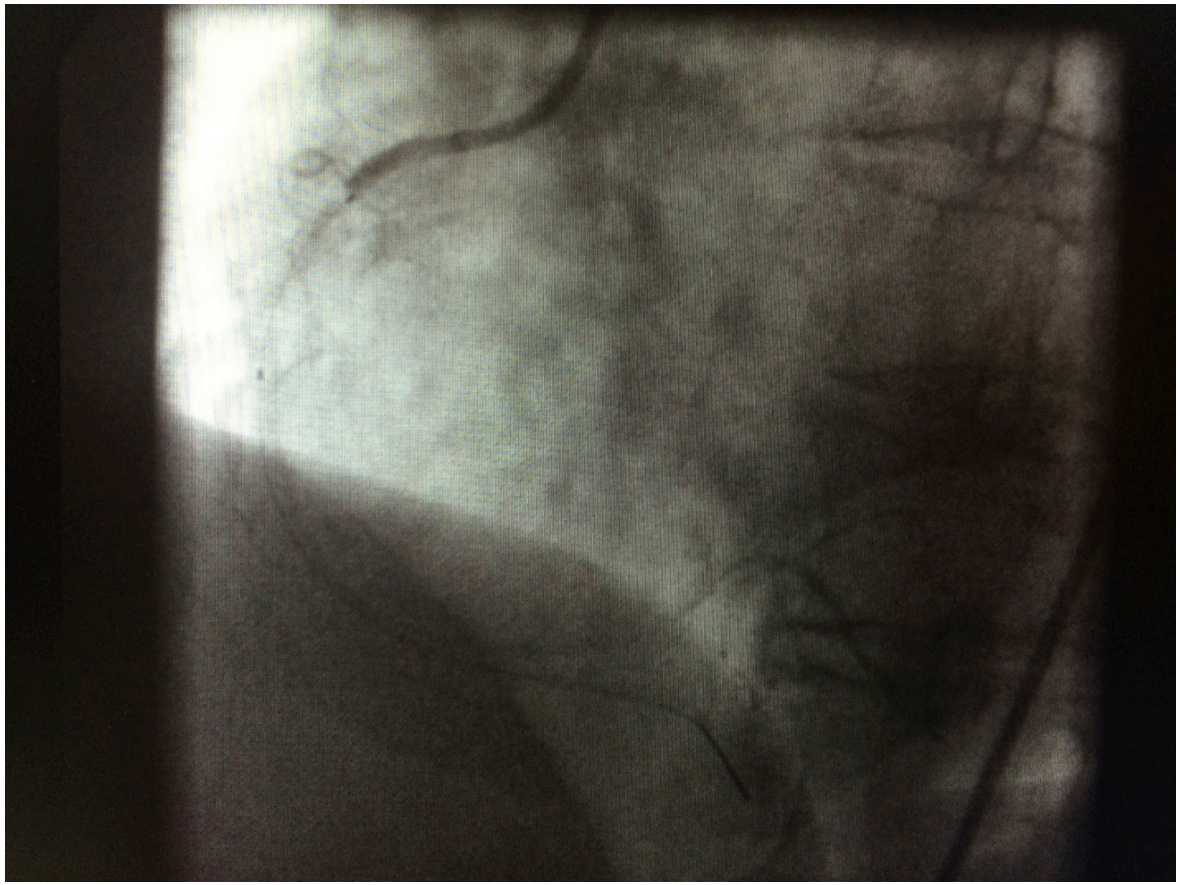
MUJER
59 AÑOS
SCACEST INFERIOR
HTA Y TABAQUISMO
CD MEDIA OCLUIDA
EN TERCIO MEDIO

Primer caso con stent Magmaris



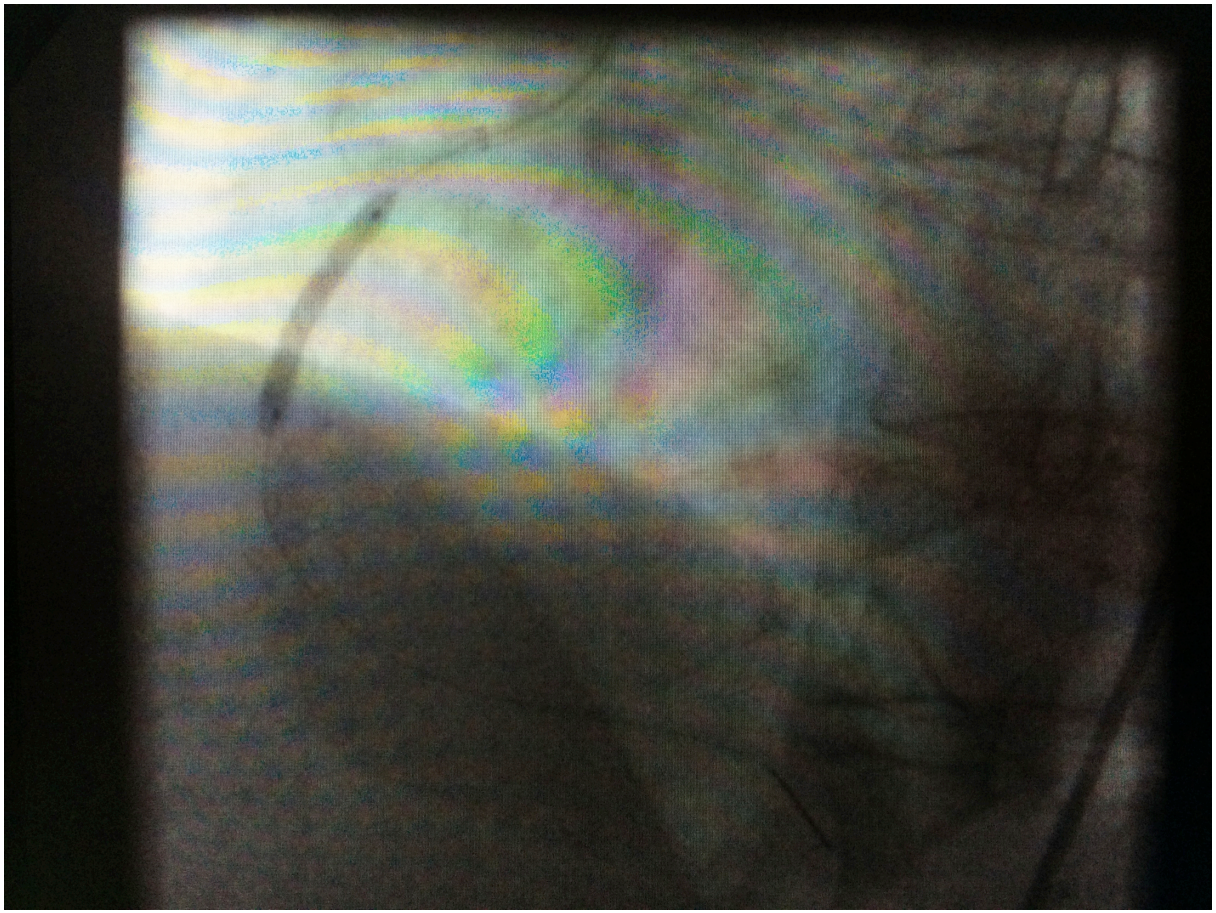
Tras aspirar trombo con 3Flow® de Biotronik, se consigue la apertura de la arteria

Primer caso con stent Magmaris



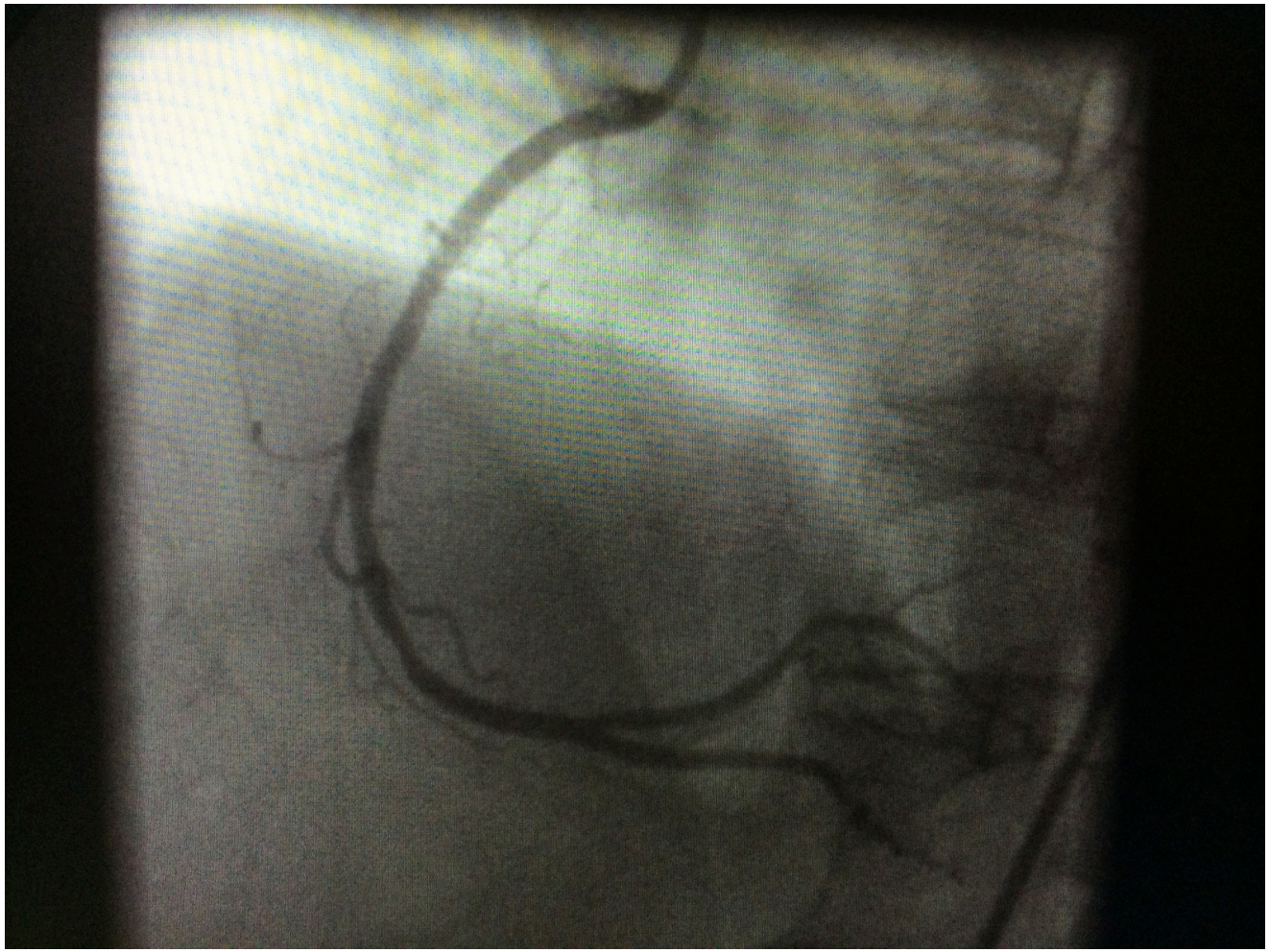
Posicionamiento del stent Magmaris®
3.0x20 mm

Primer caso con stent Magmaris



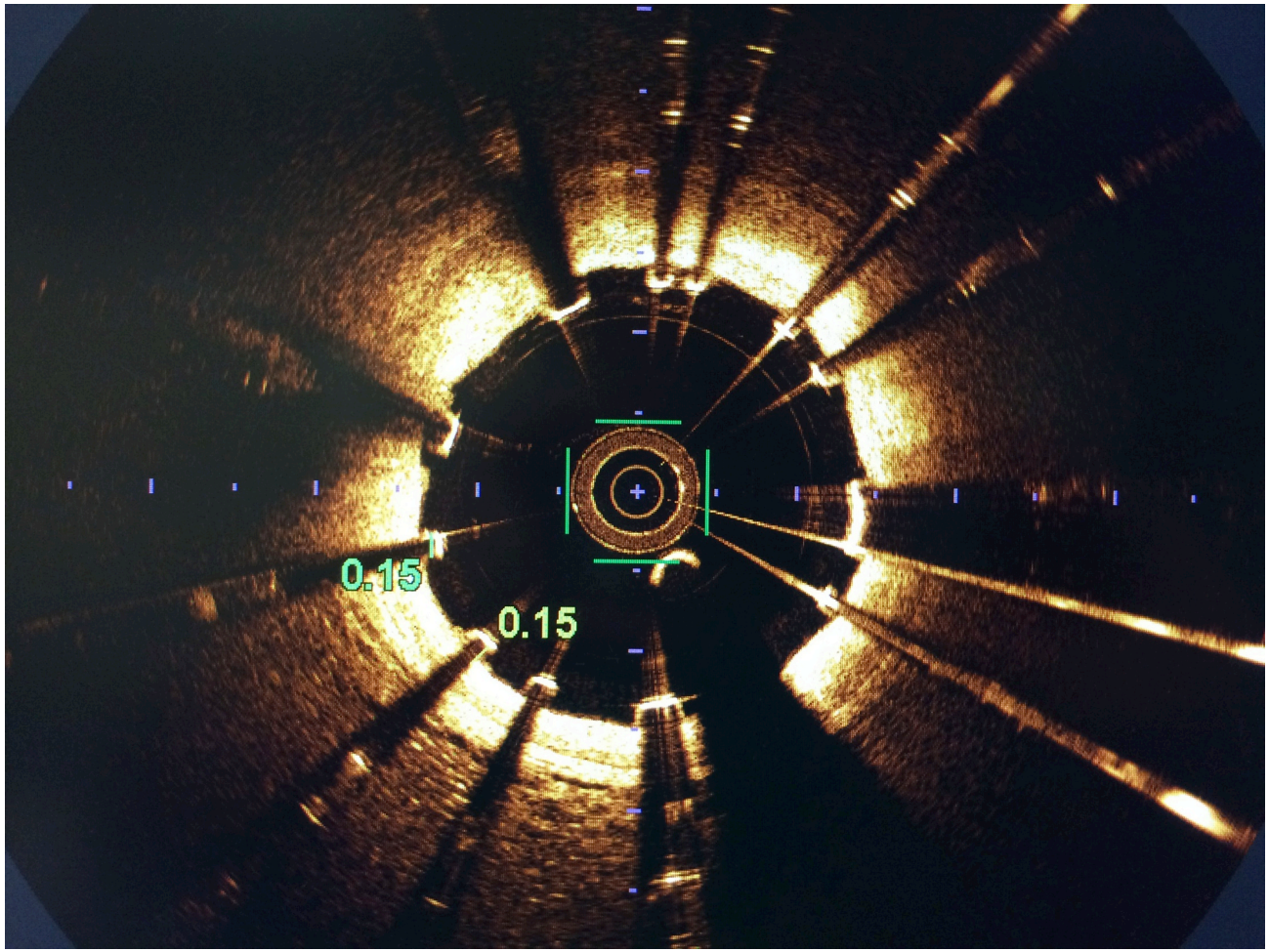
Liberación del stent a nivel de la oclusión aguda en CD media

Primer caso con stent Magmaris



Resultado final tras el implante del stent Magmaris®

Primer caso con stent Magmaris

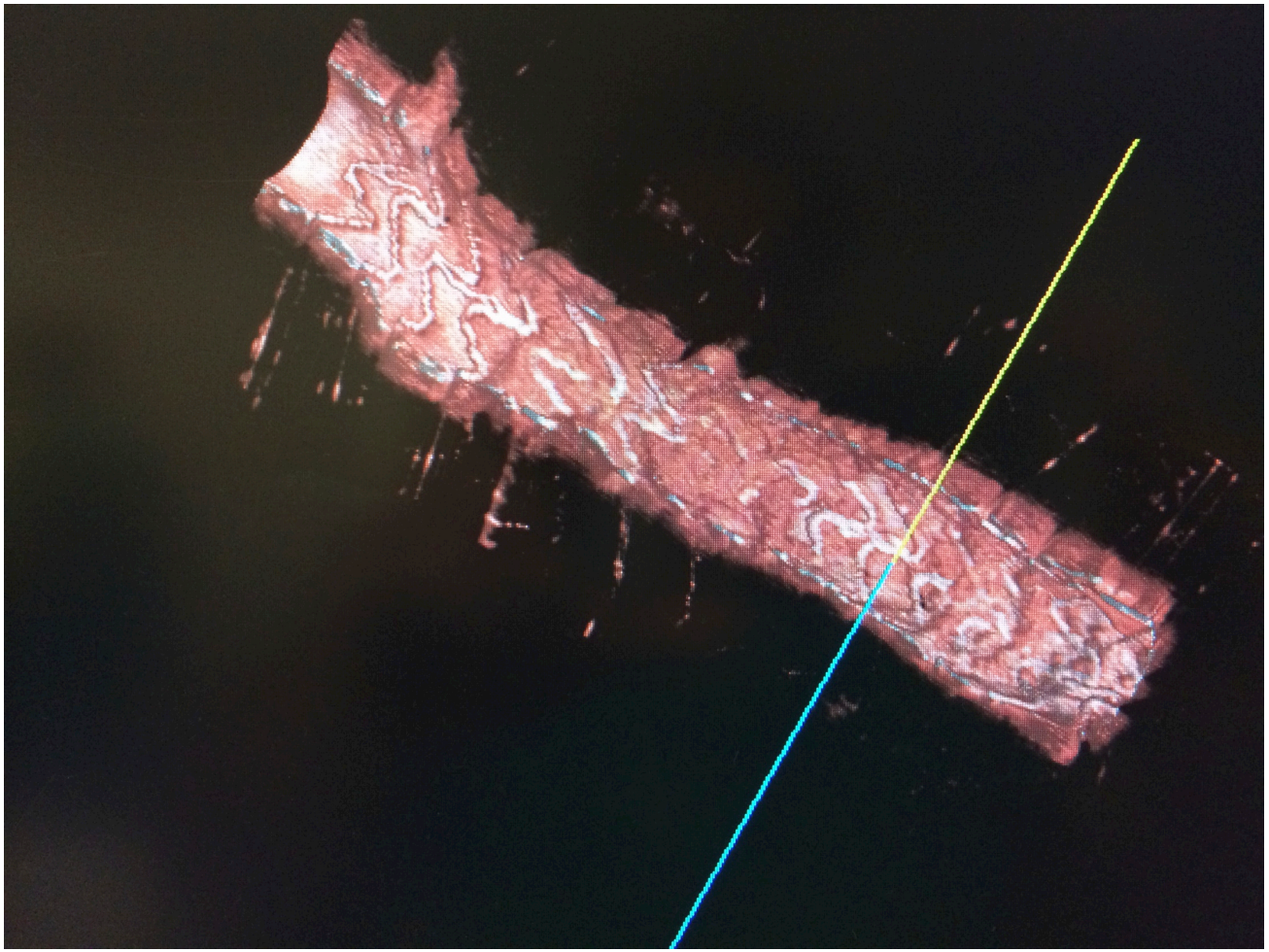


Comprobación mediante OCT del resultado excelente del procedimiento.

En la imagen puede observarse la dimensión del strut del stent: 150 µm en sus 2 longitudes

Luis A. Íñigo
Hospital Costa del Sol

Primer caso con stent Magmaris



Reconstrucción tridimensional mediante OCT del resultado del stent