

# Magnesium-based Bioresorbable Scaffold

Metal vs. Plastic  
Best of Both Worlds?

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# The original rationale and goal of a BVS platform

## Vessel scaffolding from a stent is only needed transiently

- Perform the functions of a DES, then be naturally absorbed and metabolized by the body
- Leave no permanent metallic implant
  - No chronic inflammation → potentially reducing the need for long-term dual antiplatelet therapy
  - No Late Stent thrombosis
  - No permanent scaffold – perhaps permitting return of normal vasomotion and late expansive remodeling
  - Facilitating re-intervention (PCI and CABG)
- Provide compatibility with non-invasive diagnostic imaging (CT/MR), allowing non-invasive follow-up

# Disappointing RDC results

- ABSORB II and ABSORB III long term data failed to meet the non-inferiority end-points with regards to TLR, ST, LST, VLST, angina score and vasomotor tone return when compared with Xience.
- Is Xience too strong to beat?
- But late events are 'real'
- The Cypher/Taxus deja vu?



A signal that we should not ignore

With careful **case selection** and **good implantation technique** (PSP), we can still get excellent long-term results...



M/45 yrs ; 4 years after ABSORB at proximal LAD

# BRS: current indication?

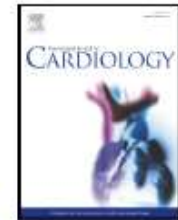
Who and what lesion subset should or should not be treated with BRS?



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## Current practices of Asia-Pacific cardiologists in the utilization of bioresorbable scaffolds



B.B. Chanana<sup>a</sup>, Praveen Chandra<sup>b</sup>, Jack Jun Cheng<sup>c</sup>, Ron Dick<sup>d</sup>, Hyeon-Cheol Gwon<sup>e</sup>, M.S. Hiremath<sup>f</sup>, Do Quang Huan<sup>g</sup>, Anuruck Jeamanukoolkit<sup>h</sup>, Tiemin Jiang<sup>i</sup>, On-Hing Kwok<sup>j</sup>, Michael C.L. Lim<sup>k</sup>, Adrian F. Low<sup>l</sup>, Rony Mathew<sup>m</sup>, Samuel K. Mathew<sup>n</sup>, Dougal McClean<sup>o</sup>, Sunao Nakamura<sup>p</sup>, Michael Nguyen<sup>q</sup>, Shubin Qiao<sup>r</sup>, Teguh Santoso<sup>s</sup>, Sudheer Saxena<sup>t</sup>, Carl Schultz<sup>u</sup>, G. Sengottuvelu<sup>v</sup>, Ashok Seth<sup>w</sup>, Charles A. Simonton<sup>x</sup>, Chee Siong Soo<sup>y</sup>, Krishnankutty Sudhir<sup>x,\*</sup>, Cheng-Ting Tsai<sup>z</sup>, Udayachalerm Wasan<sup>aa</sup>, Alan Whelan<sup>q</sup>, Chris Wong<sup>j</sup>, Yee Guan Yap<sup>ab</sup>

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Application of BVS in real world:

- Patient selection
- Technical consideration
- Deployment practices
- Patient management



# Technical considerations and practical guidance on the use of bioresorbable vascular scaffolds in the Asia-Pacific region: recommendations from an Asia

Gunasekaran Sengottuvelu<sup>1</sup>, MD; C Teguh Santoso<sup>4</sup>, MD; Dougal McClea Jun-Jack Cheng<sup>8</sup>, MD; Hyeon-Cheol Do Quang Huan<sup>11</sup>, MD; Anuruck Jean On-Hing Kwok<sup>14</sup>, MD; Michael C.L. Samuel K. Mathew<sup>18</sup>, MD; Sunao Nak Shubin Qiao<sup>22</sup>, MD; Sudheer Saxena<sup>23</sup>, MD; Chee Si Udayachalerm Wasan<sup>26</sup>, MD; Alan Whelan<sup>20</sup>, MD; Charles A. Simonton<sup>28</sup>, MD; Krishnankutty Sudhir<sup>28</sup>

Table 3. General guidelines for BVS implantation.

The 28 authors surveyed listed their personal experience and learning from the use of the A-BVS in their own patients to create a set of general guidelines for new users of the device.

General guidelines for BVS implantation	
Lesions to begin with	Simple
	Focal
	A/B1
	Not heavily calcified
Lesions to progress to	Long, diffuse lesions
	STEMI/ACS
	Simple bifurcations
	CTOs
Lesions or cases to avoid	Heavily calcified
	Long vein grafts
	True ostial lesions
	Larger than 4 mm
	Smaller than 2.25 mm
Tools & techniques to use	Imaging (IVUS, OCT) when necessary/available
	Plaque modification (with cutting balloons, Rotablator™)

<2.5mm

## Magmaris preliminary recommendation upon commercial launch: a consensus from the expert panel on 14 April 2016



**Jean Fajadet**<sup>1</sup>, MD; Michael Haude<sup>2</sup>, MD, FESC; Michael Joner<sup>3</sup>, MD; Jacques Koolen<sup>4</sup>, MD; Michael Lee<sup>5</sup>, MD; Ralph Tölg<sup>6</sup>, MD; Ron Waksman<sup>7\*</sup>, MD

*1. Department of Interventional Cardiology, Clinique Pasteur, Toulouse, France; 2. Medical Clinic I, Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany; 3. Deutsches Herzzentrum Muenchen und Deutsches Zentrum fuer Herz-Kreislaufforschung e.V., Munich, Germany; 4. Cardiologie, Catharina Ziekenhuis, Eindhoven, The Netherlands; 5. Division of Cardiology, Queen Elizabeth Hospital, Kowloon, Hong Kong, China; 6. Herzzentrum Segeberger Kliniken GmbH, Bad Segeberg, Germany; 7. Interventional Cardiology, MedStar Washington Hospital Center, Washington, DC, USA*



# Lesions recommended for treatment with mBRS

**Table 4. Patient and lesion characteristics recommended for treatment with a bioresorbable scaffold.**

Patient characteristics	Recommendation	Lesion characteristics	Recommendation
Patients with long life expectancy	***	<i>De novo</i> lesions	***
Diabetic patients	**	Tortuous vessels	–
STEMI	–	Severe calcification	–
Cardiogenic shock	–	In-stent restenosis	–
Stable angina	***	Reference vessel diameter less or larger than the available device sizes	–
NSTEMI/unstable angina	**	Diffuse long lesions	–
Contraindications for DAPT	–	Chronic total occlusions	**
Target lesion located in an SVG	–	Ostial lesions	–
Patients with poor medical compliance	–	Bifurcations	**
No adequate lesion preparation	–	Presence of thrombus	–
		Left main lesions	–

– not recommended; \*\* evaluation pending; \*\*\* recommended

# Companies developing bioresorbable scaffolds (cvpipeline)

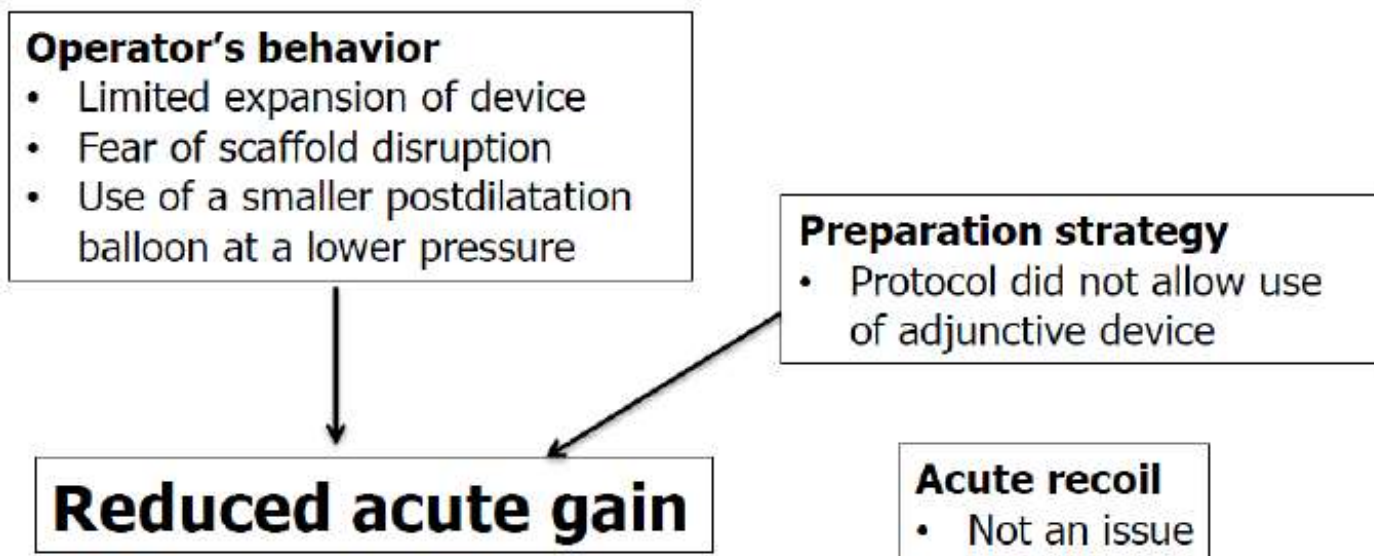
Company	Product	Material	Development	Preclinical	Clinical	Post clinical
Abbott	ABSORB	PLLA/ PDLLA	✓	✓	✓	1 FDA 4 CE
Elixir	DESolve	PLLA / PDLLA	✓	✓	✓	
Meril	MeRes	PLLA	✓	✓	✓	
Amaranth Medical	FORTITUDE	PLLA	✓	✓	✓	
ART	ART18Z	PDLLA	✓	✓	✓	7 clinical
BIOTRONIK	Magmaris	Magnesium+PLLA	✓	✓	✓	
Huaan	XINSORB	PLA/PCL/PGA	✓	✓	✓	
Kyoto Medical	IGAKI-TAMAI	PLLA	✓	✓	✓	
Xenogenics	Ideal BioStent	Polyanhydride (ASA/Adipic acid anhydride)	✓	✓	✓	
Arterius	ReBioStent	Bioresorbable polymer	✓	✓		
Cardionovum	ReNATURAL	metal	✓	✓		
Medtronic	Mg Spiral	Magnesium	✓	✓		8 Pre clinical
OrbusNeich	On-AVS	PLLA/PDLA/TMC/eCAP	✓	✓		
REVA	Fantom	Tyrosine polycarbonate	✓	✓		
S3V	Avatar	?	✓	✓		
Zorion Medical	ZMED	Magnesium+Polymer	✓	✓		
LifeTech	Lifetech Iron Stent	Iron	✓	✓		Total 22 companies (cvpipeline)
Boston Scientific	BSC BRS	?	✓			
Sahajanand	Sahajanand BRS	PLLA?	✓			
Terumo Corporation	Terumo BRS	Bioresorbable polymer	✓			
QualiMed	QualiMed	Magnesium	✓			
ManLi	Cardiology	MIRAGE microfiber scaffold	✓			

# Insights From Absorb II

**#Fact 2. Acute gain was reduced on QCA (ABSORB: 1.15mm vs. Xience: 1.46mm) and Q-IVUS (ABSORB: 2.9mm<sup>2</sup> vs. Xience: 3.6mm<sup>2</sup>).**

## **#Comment:**

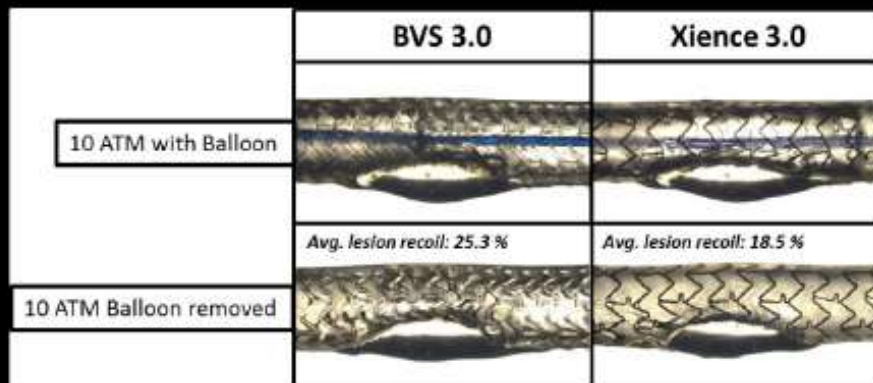
- **Guidance on angiography for sizing and expansion.**
- **Angiography underestimate the luminal dimension**
- **Intravascular imaging for sizing and expansion might have implication for FDA labeling.**





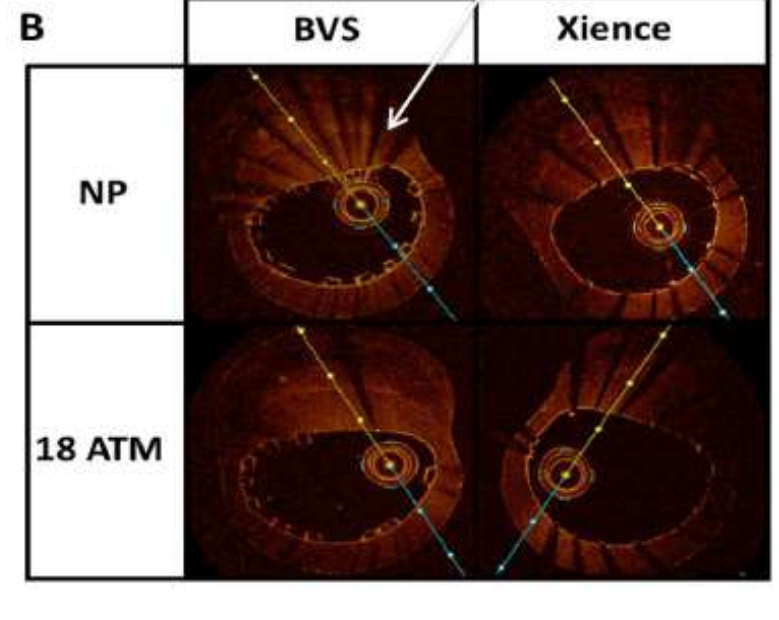
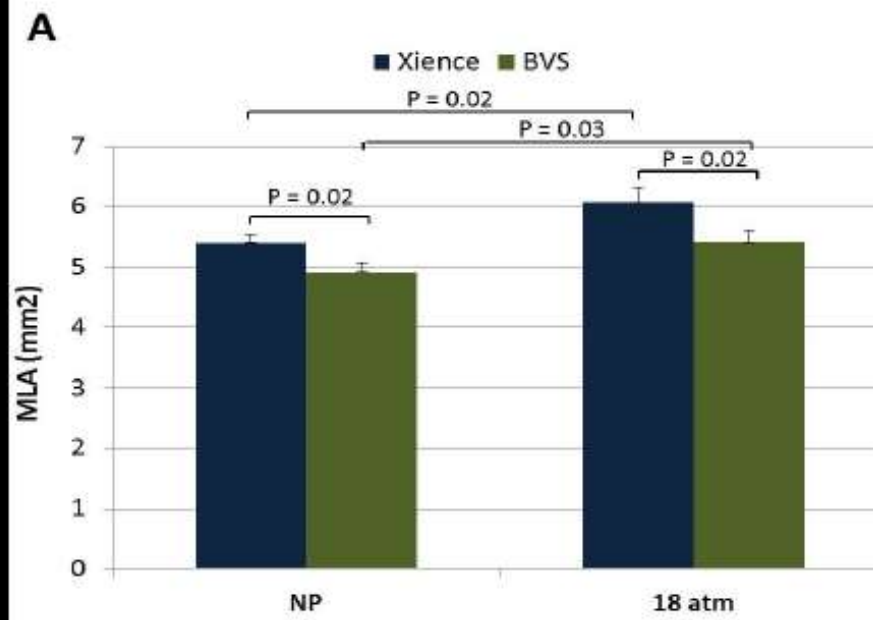
# Bioabsorbable Vascular Scaffold Radial Expansion and Conformation Compared to a Metallic platform

*Insights from expansion in a Coronary Artery Lesion Model*

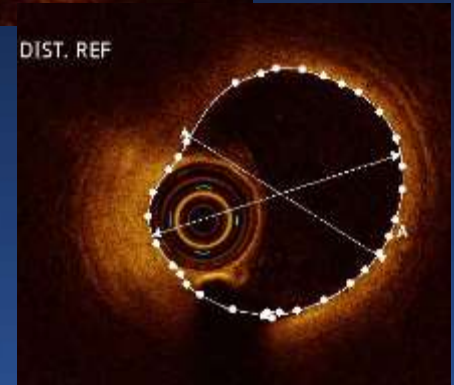
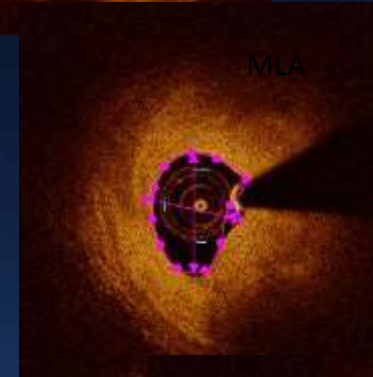
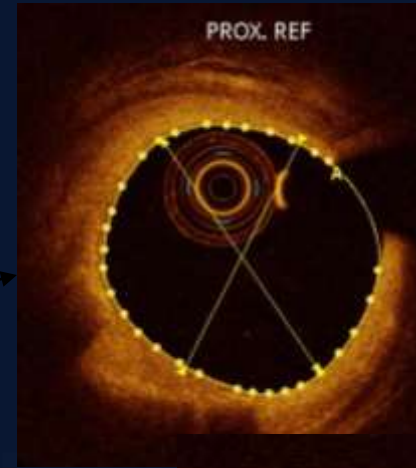


*In a model fibrotic lesion:*

- Higher Eccentricity with BVS
- Smaller MLD compared with Metal
- Residual stenosis hard to correct after BVS implantation
- “what you prep is what you get”

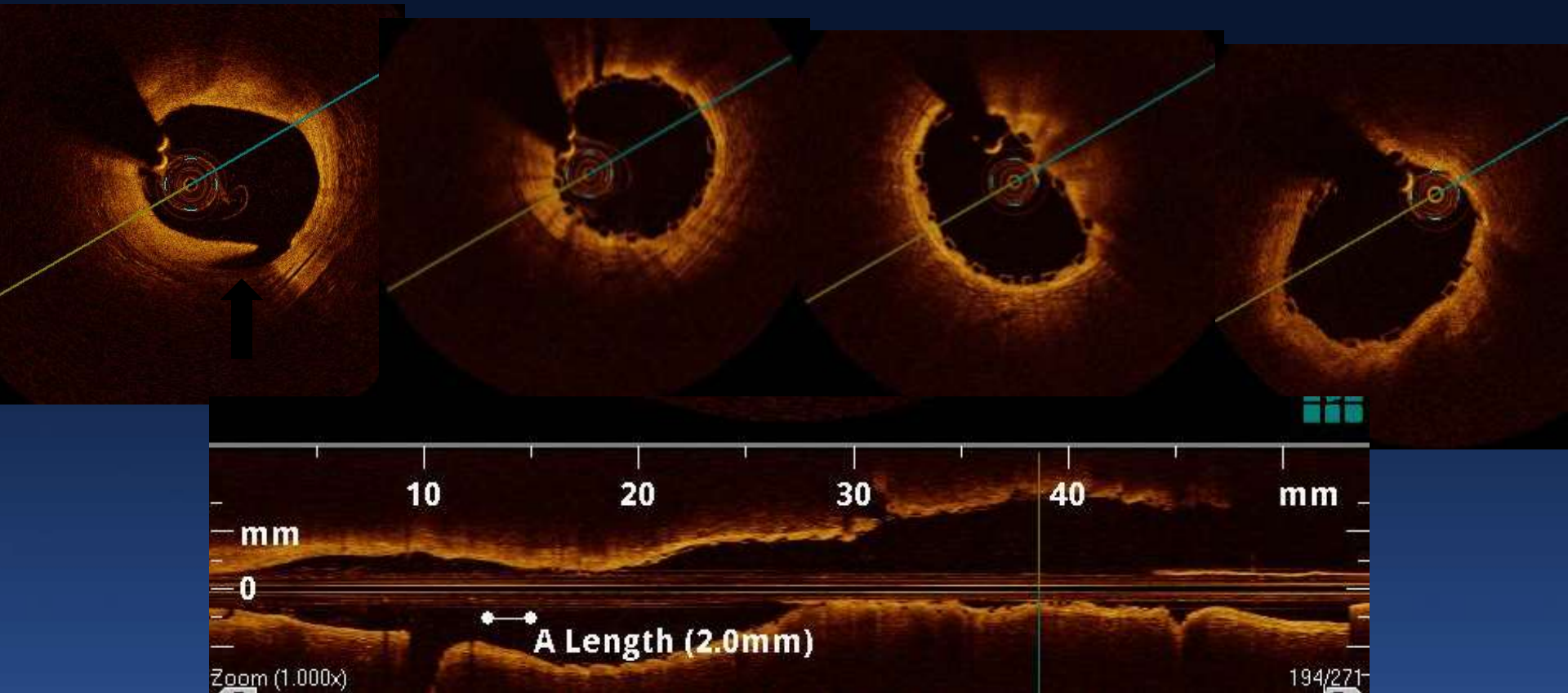


# LAD angiogram

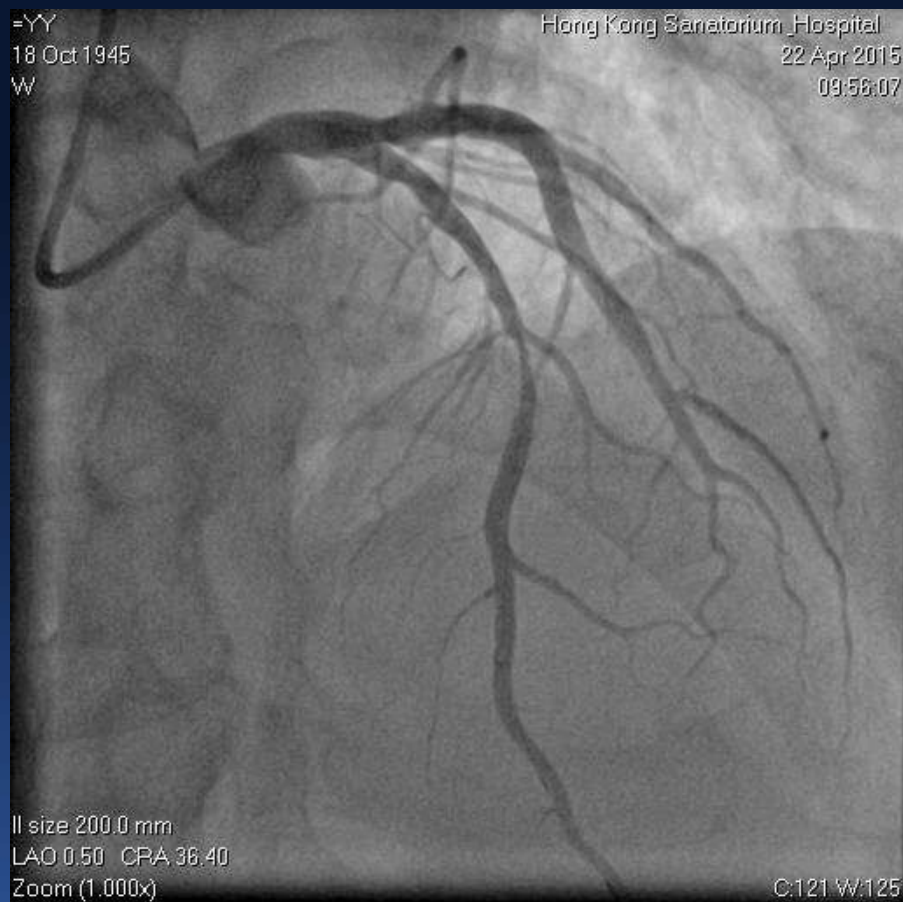




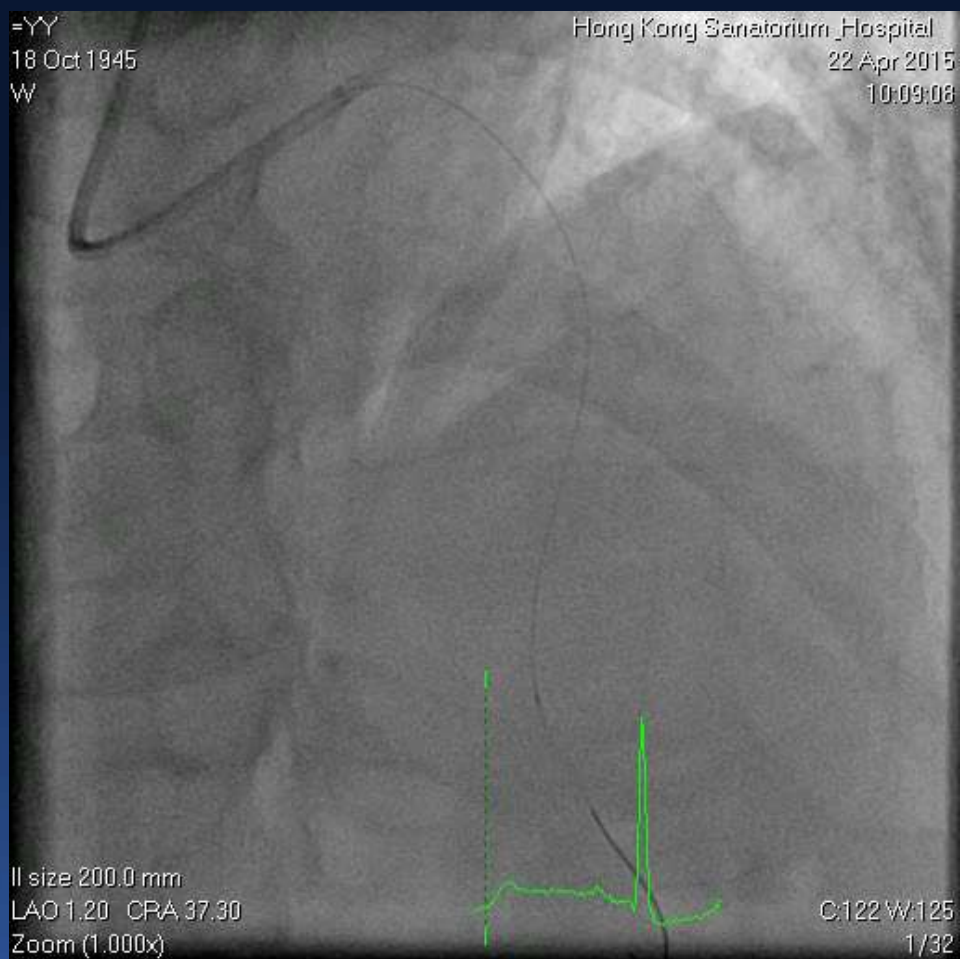
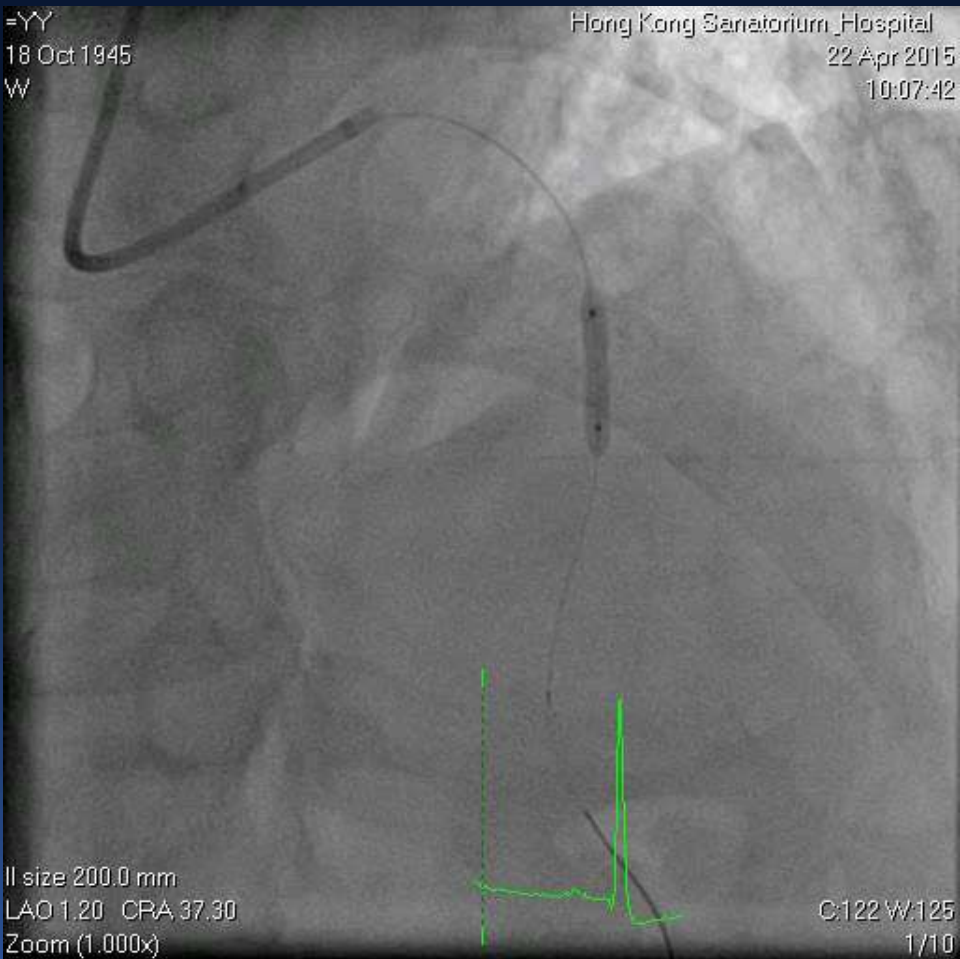
# OCT after Absorb implantation



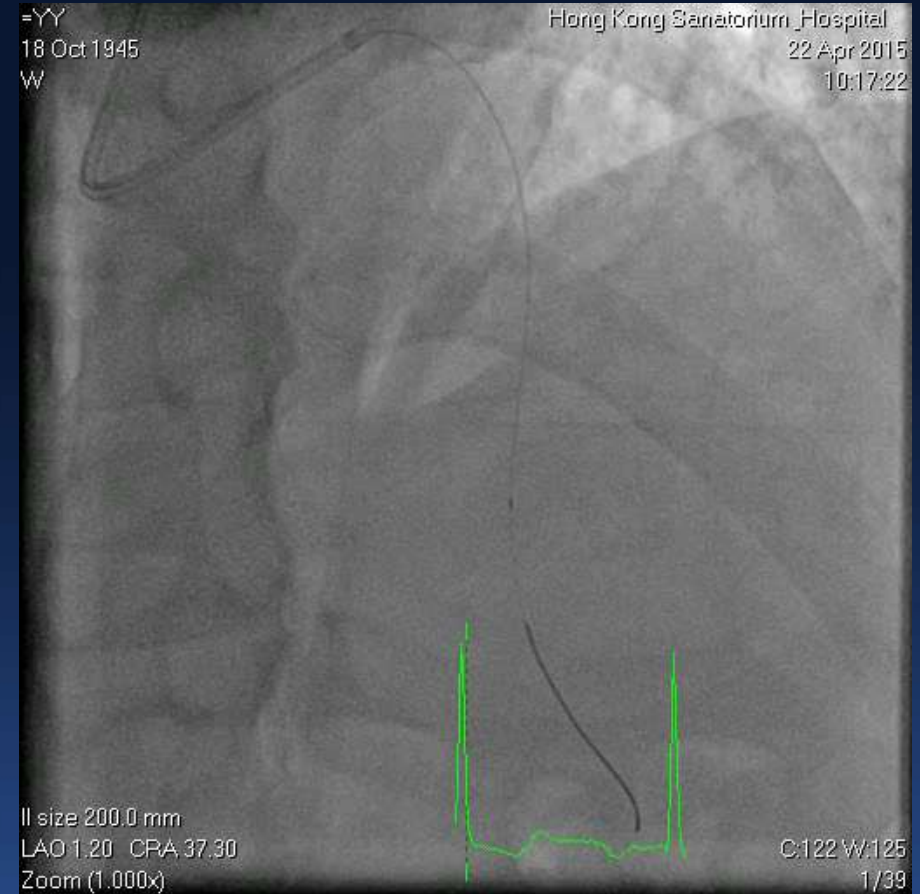
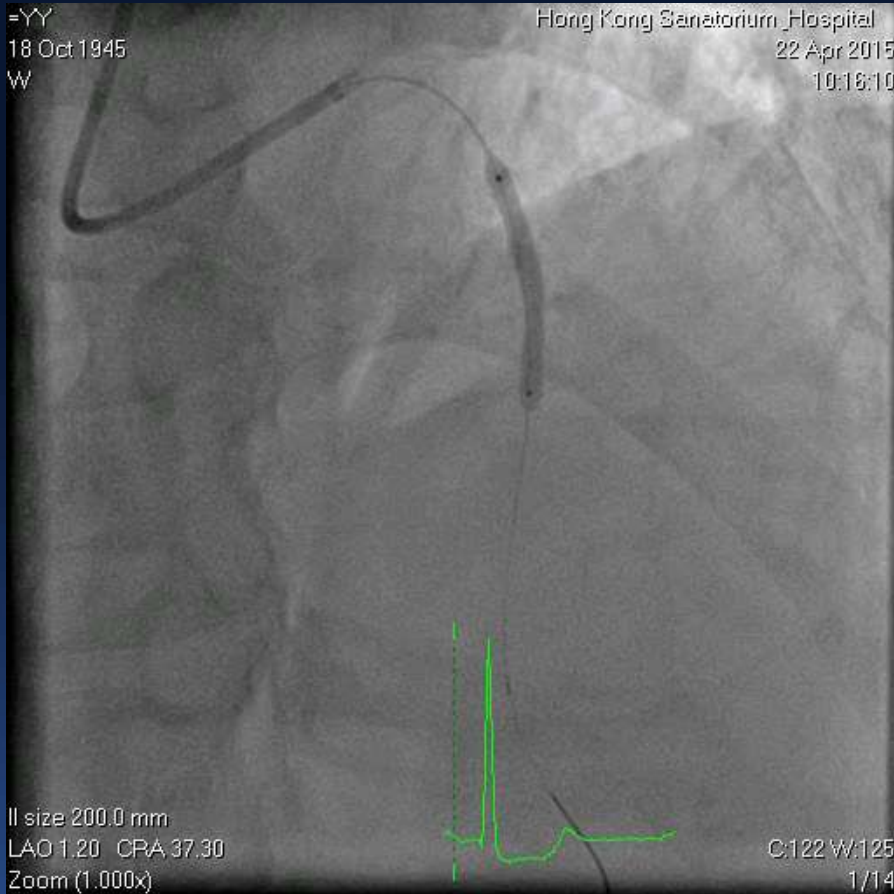
# Real-World experience with Elixir DESolve



# Predilated with 3.0 Angioscrupt and 3.0 NC balloon



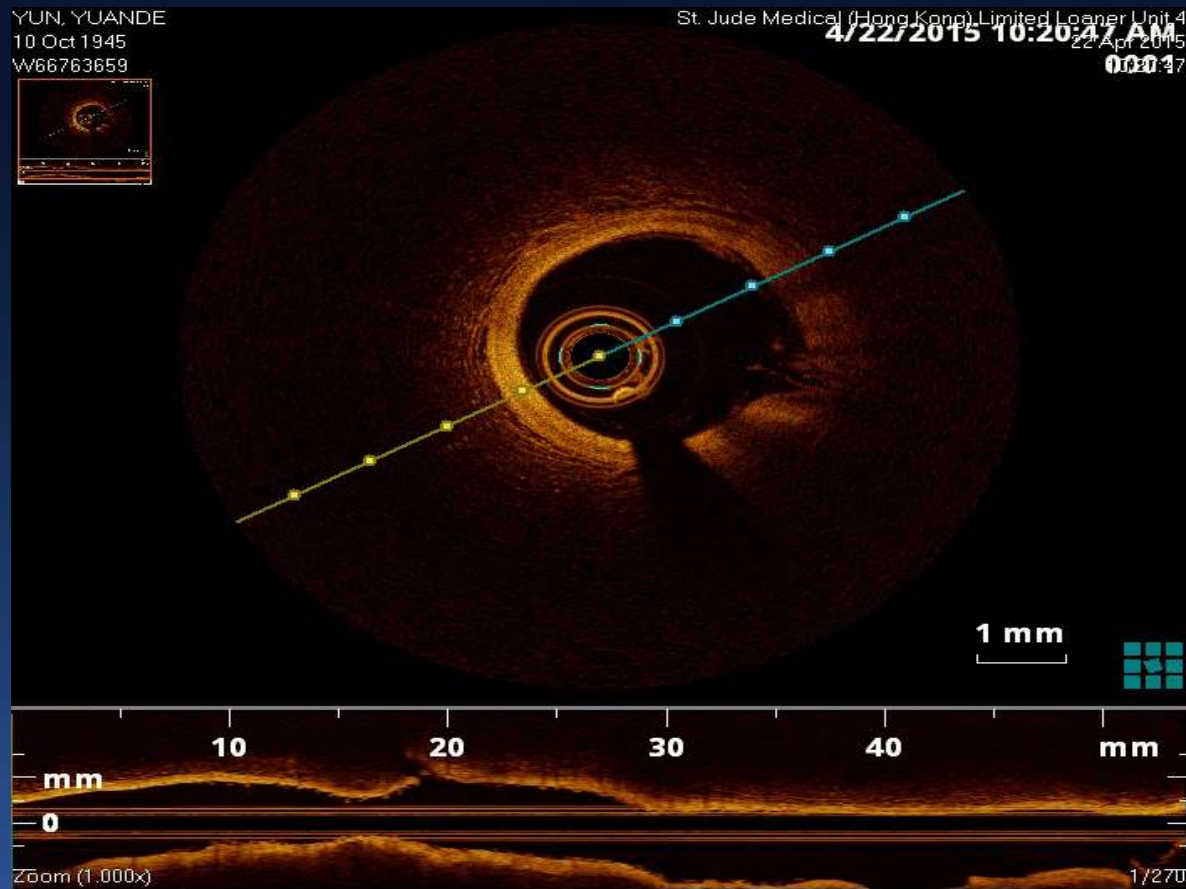
# 3.0x28mm Elixir DESolve BRS



Significant acute Recoil  
Poor radial strength!  
Inadequate predilatation

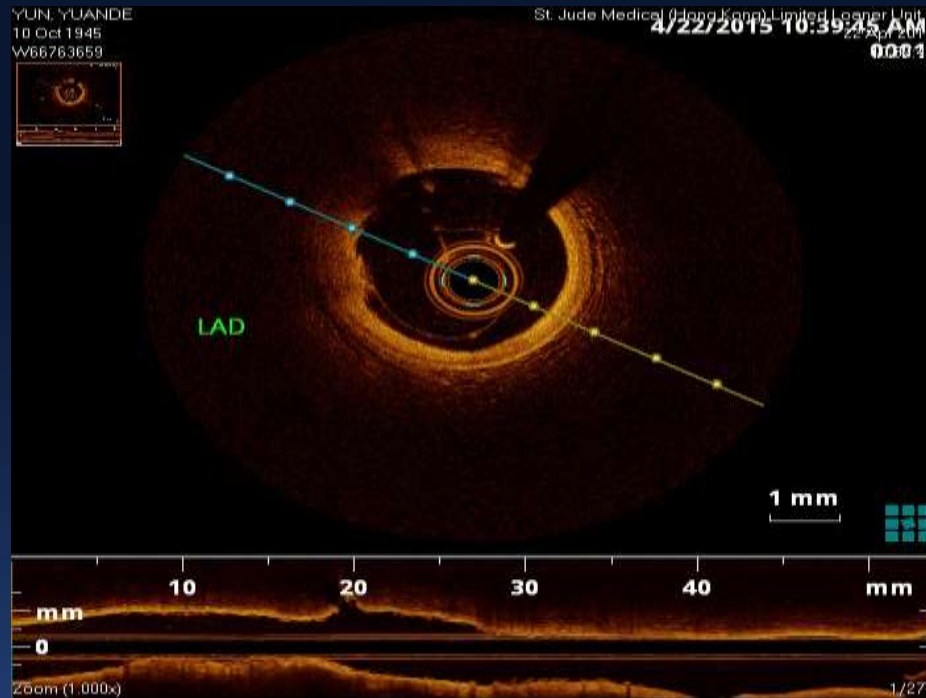


# OCT after post-dilation with 3.5mm NC balloons at up to 22ATM repeatedly





# Final OCT after 3.75mm NC balloon up to 24 ATM



- What you prep is what you get with the PLLA platform
- Residual stenosis is hard to correct after 1<sup>st</sup> gen BVS implant

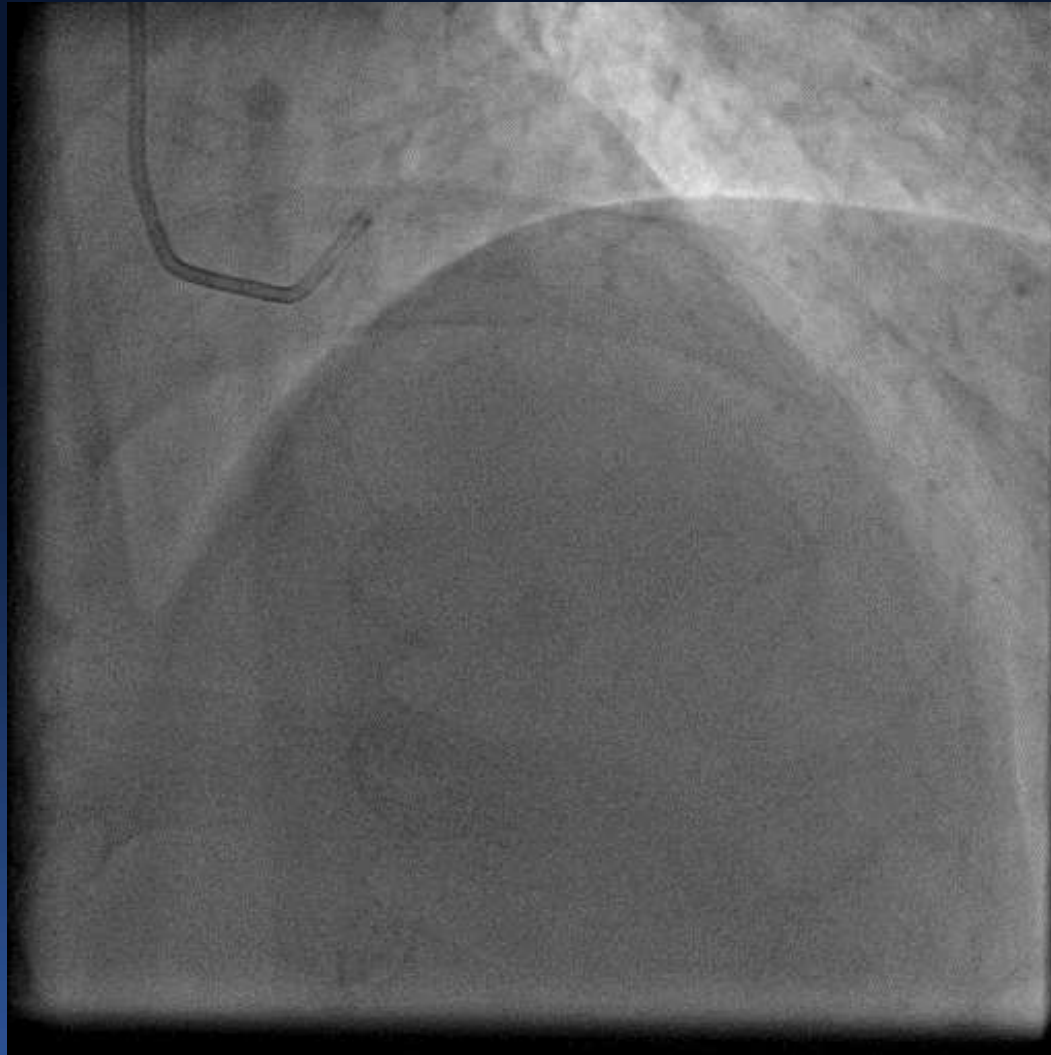
# Unmet need for faster resorption

- Neointimal hyperplasia and plaque rupture within BVS has been reported.
- *Late & Very late scaffold thrombosis rate (Absorb) is higher than DES after 2-3 years*
- ? Residual PLLA may be pro-inflammatory  
(in fact, it takes 2-4 years for complete resorption of Absorb BVS)

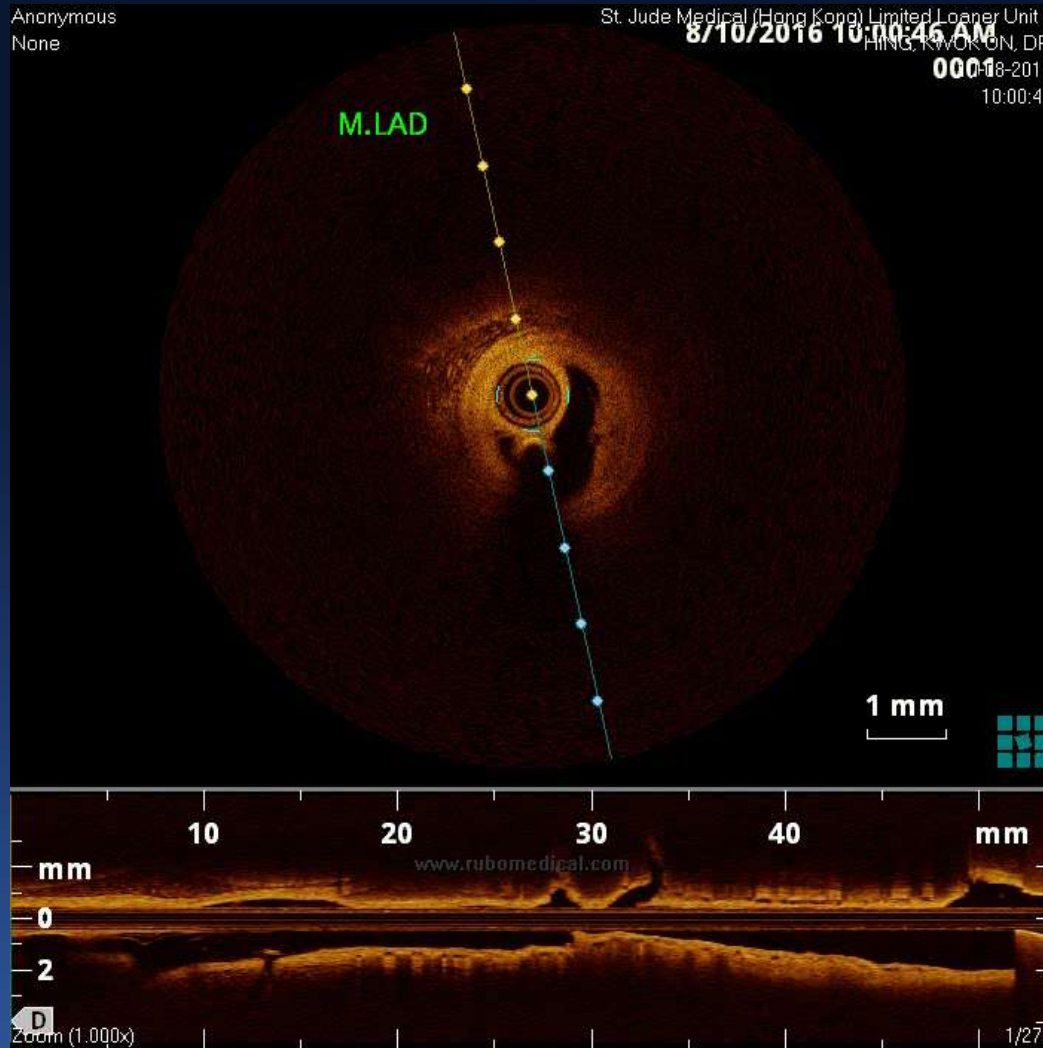
# Case Study

- M/59 yrs
- High cholesterol
- PCI mid LAD with Absorb BVS in Beijing in 2014  
(**ABSORB CHINA clinical trial patient**)
- One-year restudy angiogram: Patent BVS, no restenosis
- Self-stop all medications
- Recent exertional angina
- CTA: suspected high grade BVS ISR
- Request BVS...

# Diffuse BVS ISR

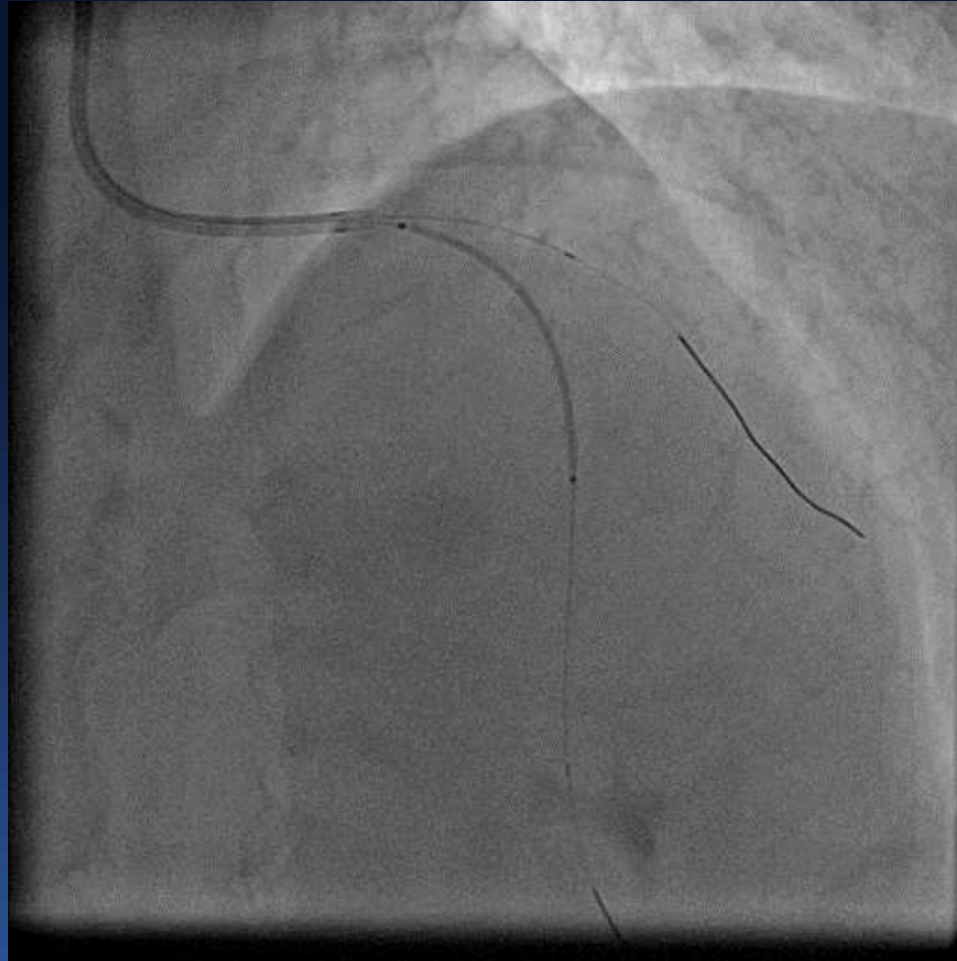


# OCT study: Evidence of neo-atherosclerosis and plaque rupture

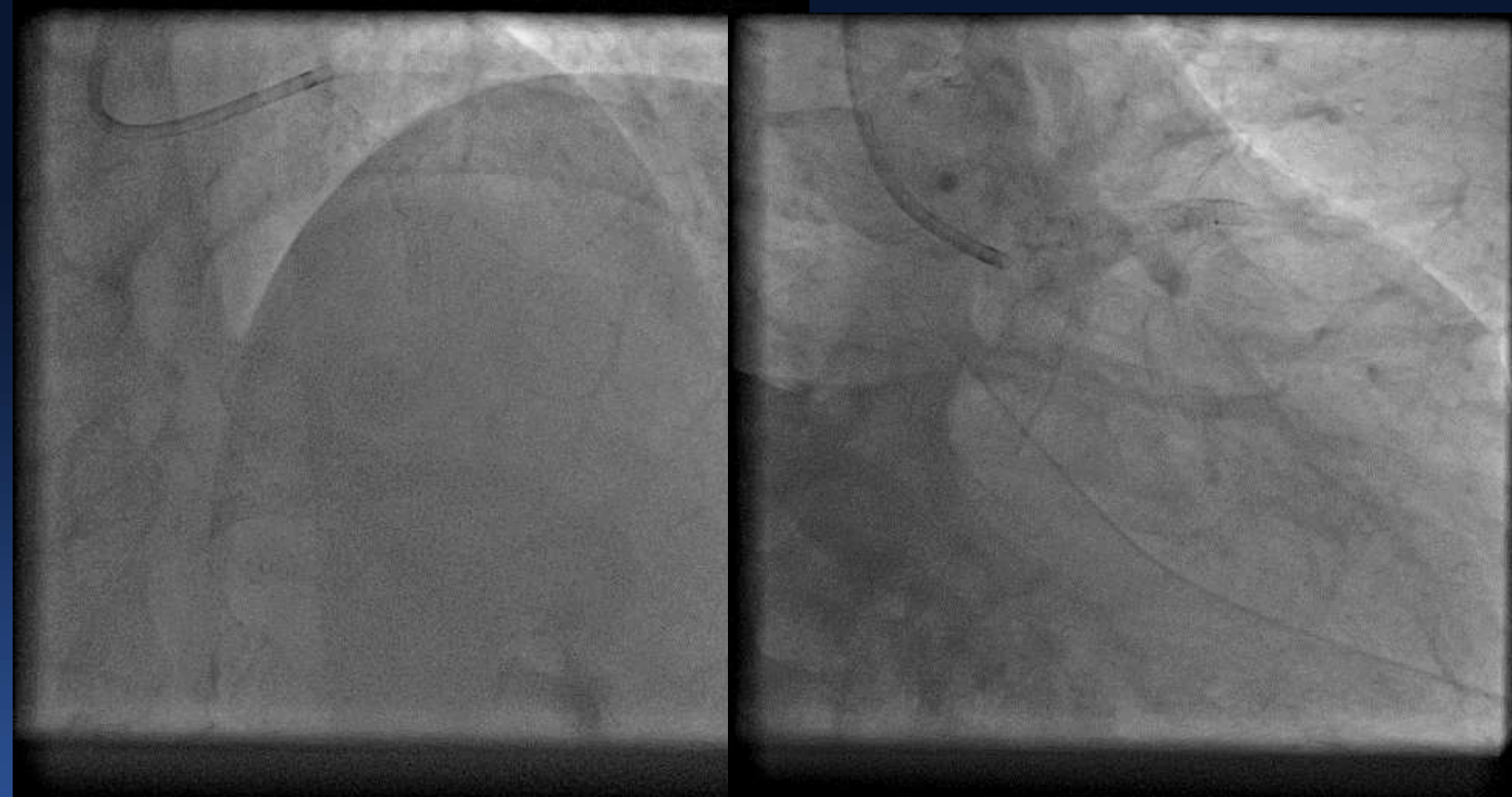




2.75x38mm BSC Synergy BP stent was deployed, and further post-dilated up to 3.75/3.0mm with NC balloons (after a long negotiation with the patient and his relatives)



# Final angiogram



# Final OCT

Anonymous  
None

St. Jude Medical (Hong Kong) Limited Loaner Unit - Anonymous  
8/10/2016 11:12:55 AM  
HMG, KWOK GN, DFN  
00018-2016  
11:12:55

St. Jude Medical (Hong Kong) Limited Loaner Unit 4  
8/10/2016 11:13:32 AM  
HMG, KWOK GN, DR  
00018-2016  
11:13:32

M.LAD

P.LAD

1 mm

1 mm

10 20 30 40 mm

10 20 30 40 mm

mm

0

2

www.rubomedical.com

mm

0

2

www.rubomedical.com

1/270

Distal half of DES

Proximal half of DES

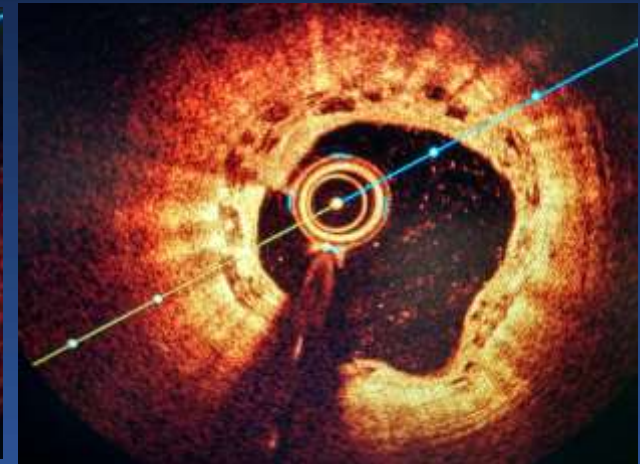
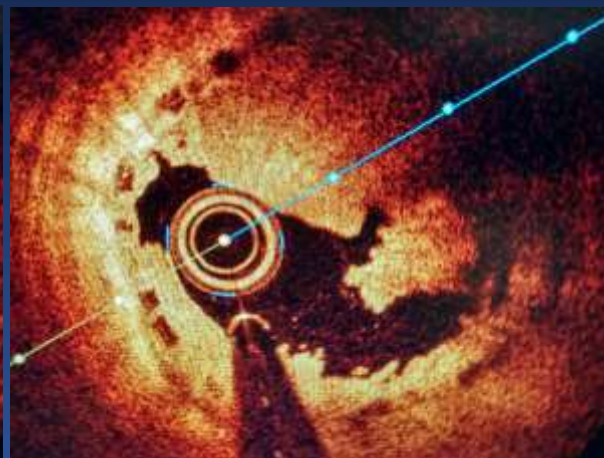
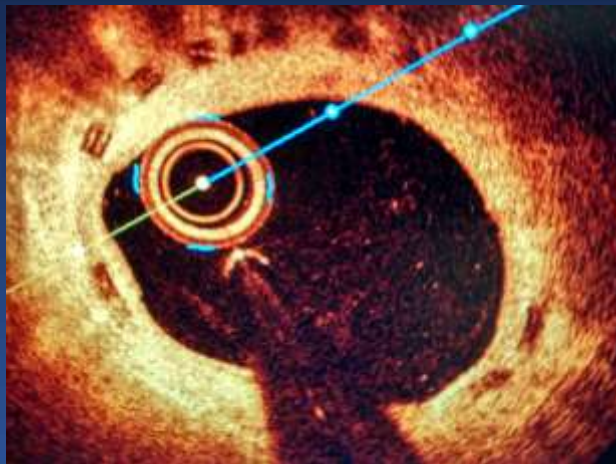
## Real-world Case #2

- M/43 yrs
- High cholesterol, strong Family history of IHD
- March 2013: PCI proximal-mid LAD with 3.5x23mm + 3.0x28mm ABSORB BVS. OCT-guided. Post-dilated with 3.5/3.0mm NC balloons at 20ATM. (PSP)
- After 1.5 years, defaulted follow up and stopped all medications.



# VLST

- 3 years and 3 months after the indexed procedure, developed STEMI (anterior)
- Admitted to a public hospital
- Emergency PCI . Proximal LAD thrombotic occlusion. Thrombus aspiration + DES
- OCT: No mal-apposition. No fracture.





## Alternative BRS option

- Stronger Radial Force
- Faster Resorption Rate
- Easy Handling (Better crossing profile, faster deployment)
- Low thrombosis rate

# Magmaris Case Study

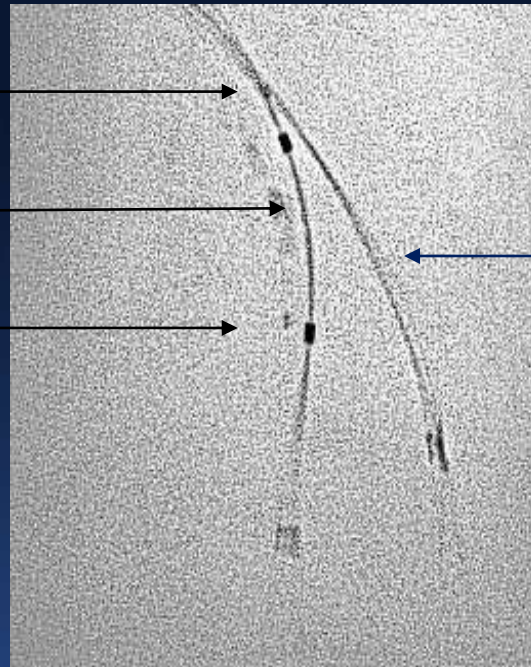


# Now you see me!

Proximal markers

Post-dilation NC  
balloon

Distal markers

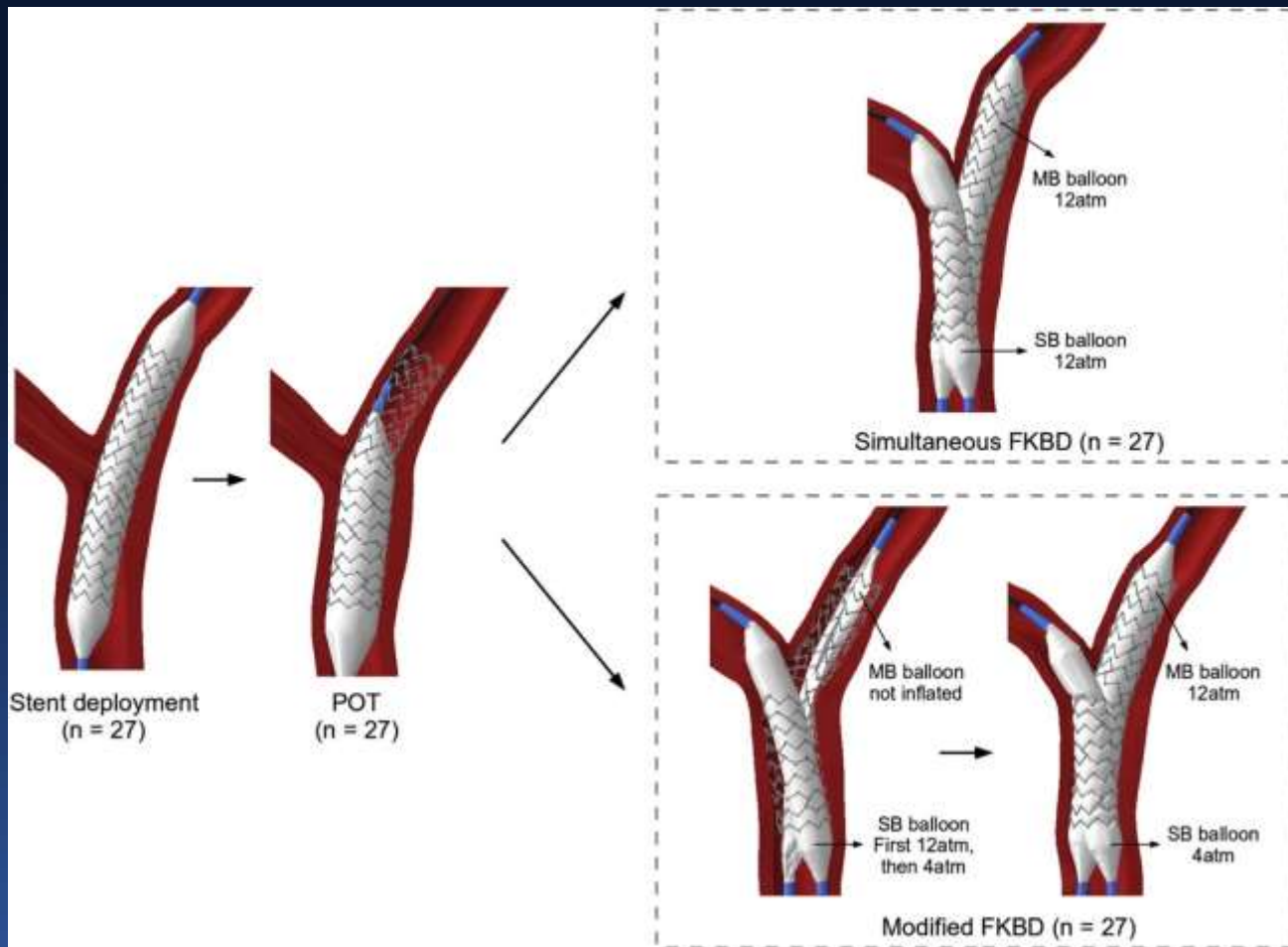


Diagonal guidewire

# Metallic stent-like 3D OCT

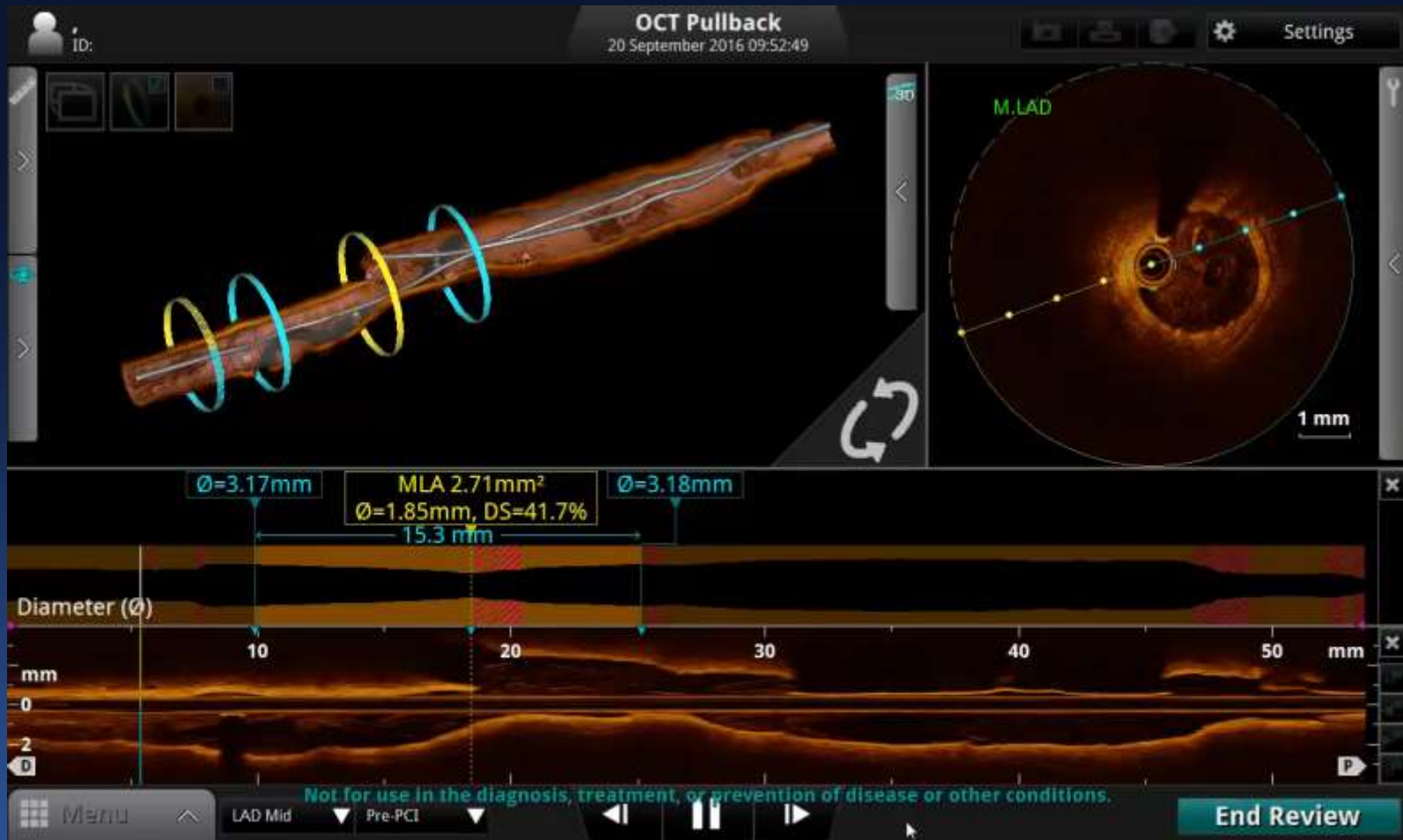


# Proximal Optimization POT

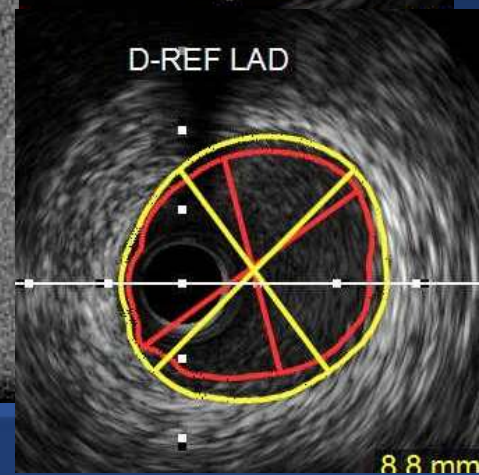
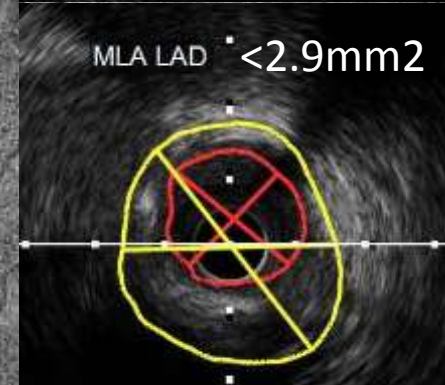
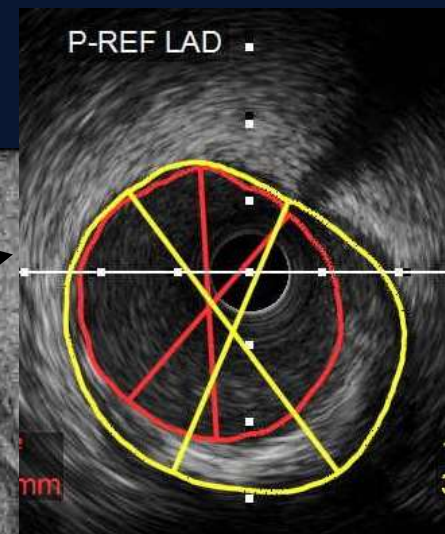
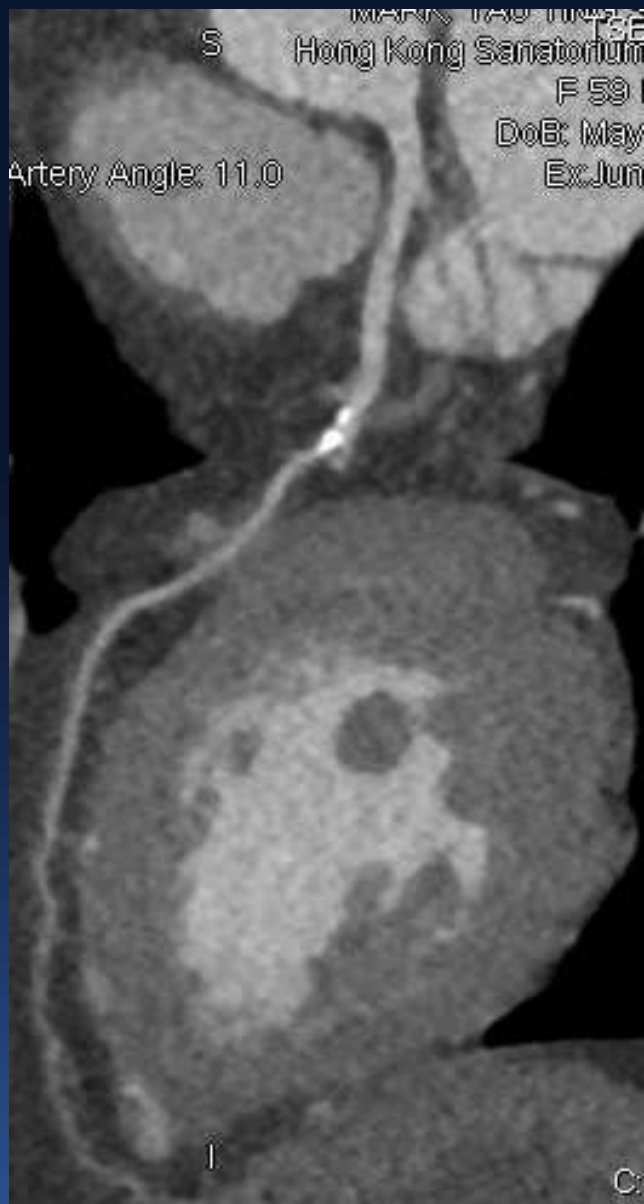




# Pre-procedure OCT







# Case Study

## (1<sup>st</sup> Magmaris Case in Asia-Pacific)

**M/ 39 yrs old Chinese**

Risk Factors:

Hypertension, Hypercholesterolemia

Strong FHx (Father had CABG at age 50)

Indication: exertional angina

CTA:

**Calcium score 216.**

Multiple mixed calcified and non-calcified plaque in coronary arteries. >70% stenosis at distal RCA and proximal LAD. Dense calcified plaque at distal LAD

CAG Findings:

LMCA: normal

LAD: pLAD 75% tubular stenosis. Moderate calcification. mLAD 70% stenosis after D1 take-off

LCX: dLCX 30% stenosis

RCA: Co-dominant RCA. dRCA 80% discrete stenosis. Diffuse proximal-mid RCA 30% stenosis

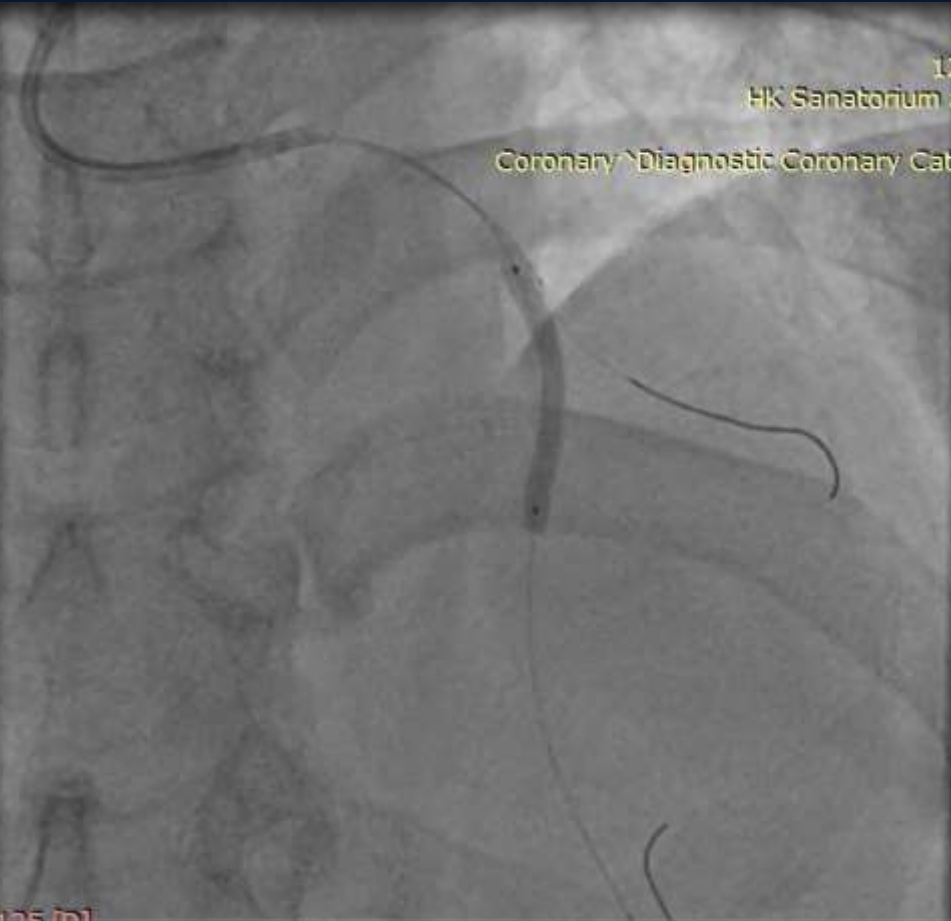
# LAD Angiogram

37

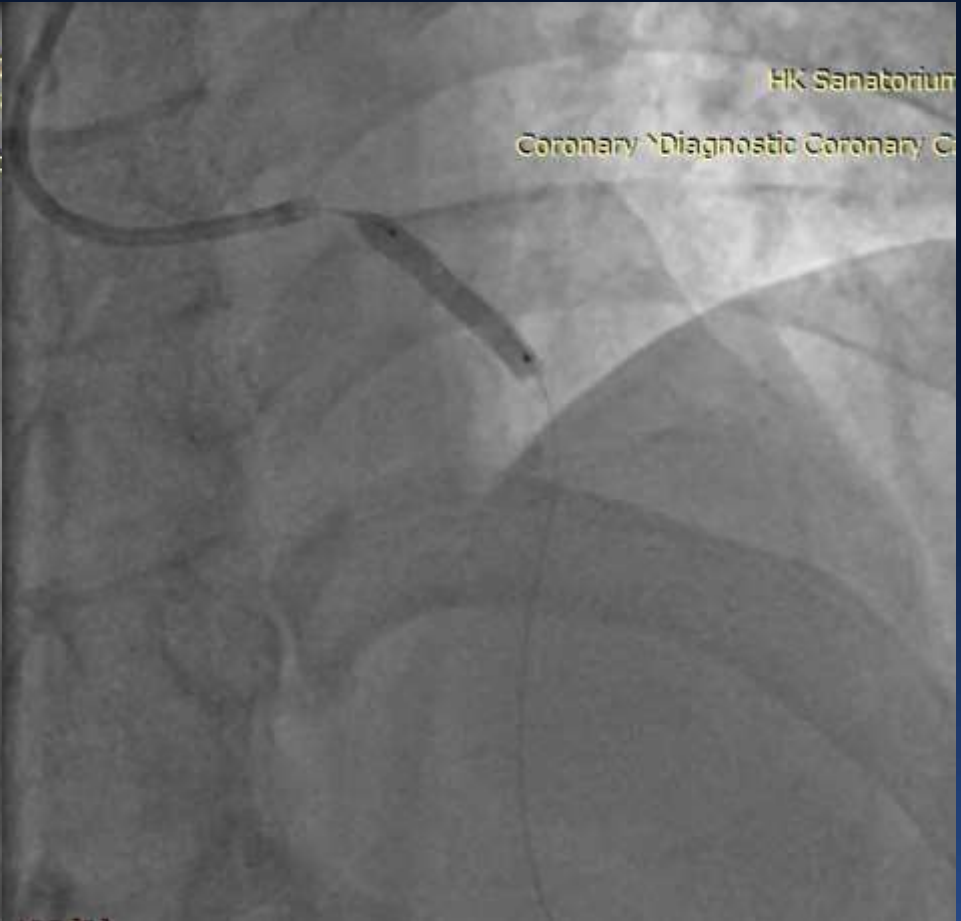




Proximal to mid LAD Tubular Stenosis Treated by Overlapping Absorb  
3.50x23mm & 3.00x28mm ABSORB GT1  
(pre-dilated with 3.0mm cutting balloon and 3.5NC balloon  
Sizing with IVUS)



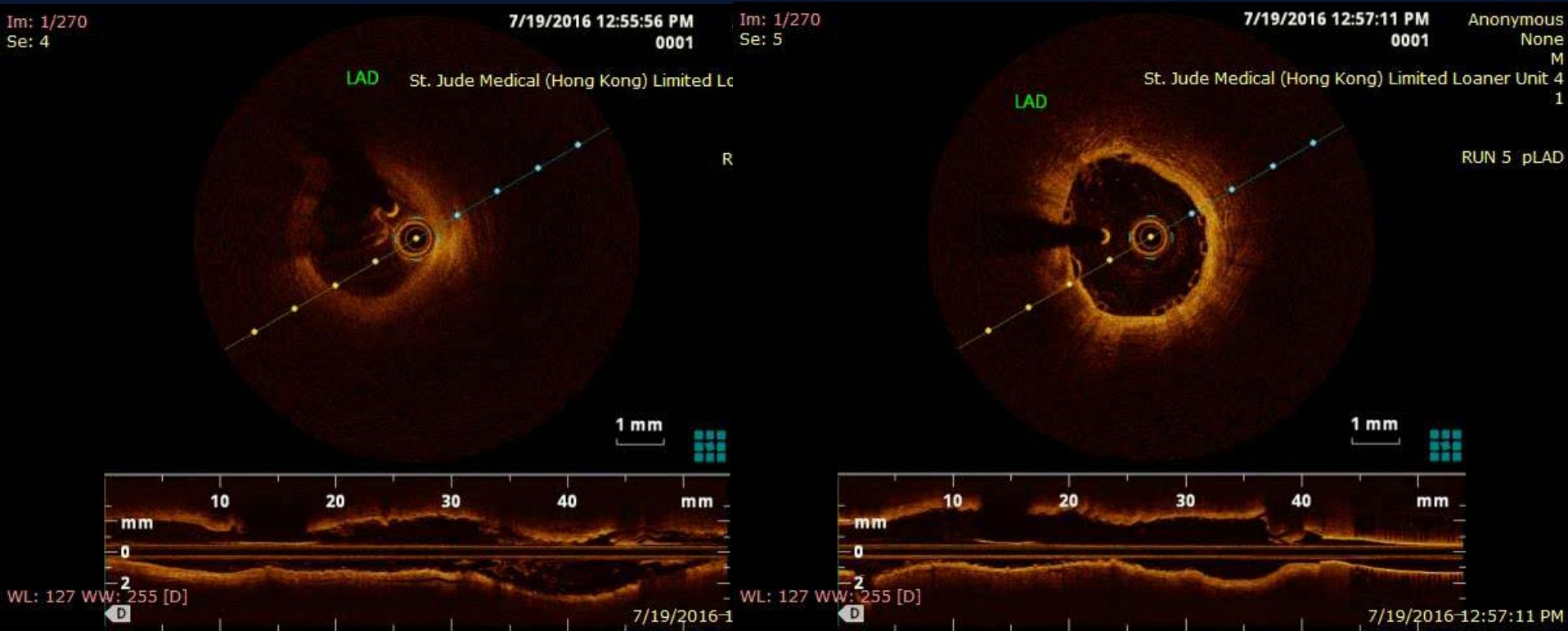
**Absorb GT1 3.00x28mm, dilated up  
to 3.5mm**



**Absorb GT1 3.50x23mm, dilated up  
to 4.0mm  
(Marker-to-Marker)**



# OCT Image



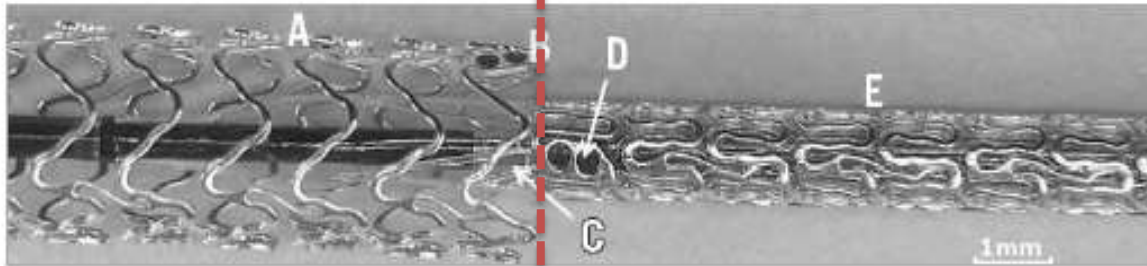
**mLAD**

**pLAD**

# LAD Final Angiogram



# Magmaris “Marker-to-Marker”



**Figure 1.** *Optimal positioning of two adjacent Magmaris scaffolds. A) Expanded Magmaris. B) Tantalum markers of the expanded Magmaris. C) Balloon marker of the Magmaris delivery system. D) Tantalum markers of the unexpanded Magmaris. E) Unexpanded Magmaris on the delivery balloon.*

No Overlap

# RCA Angiogram

42

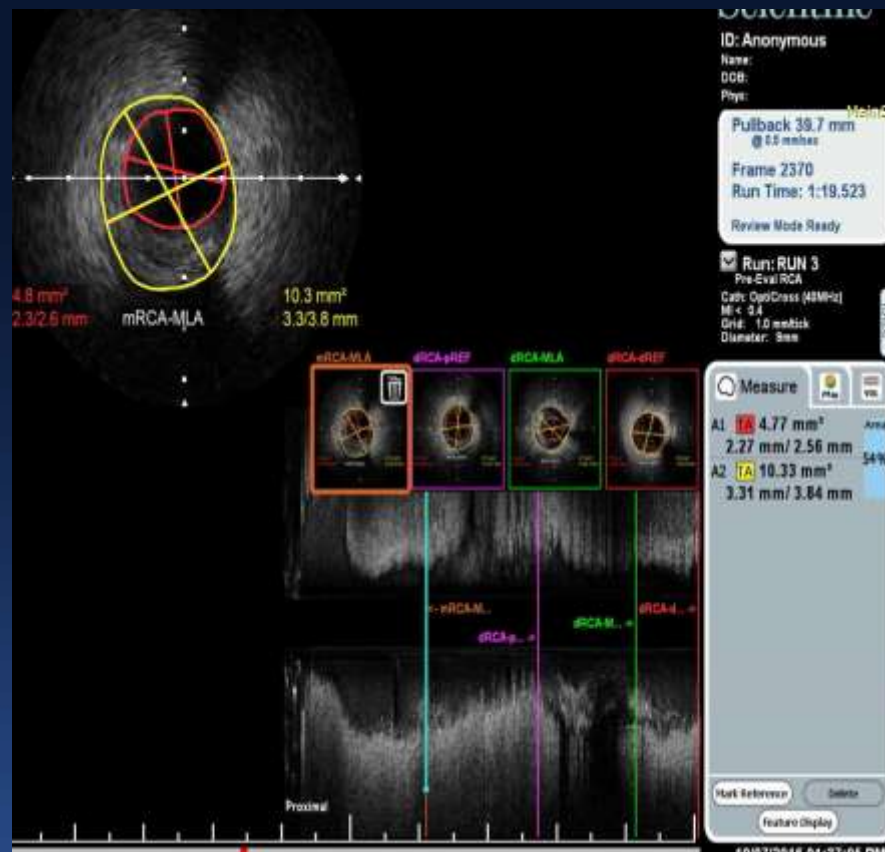




# IVUS



**dRCA: Concentric MLA 2.78mm<sup>2</sup>**

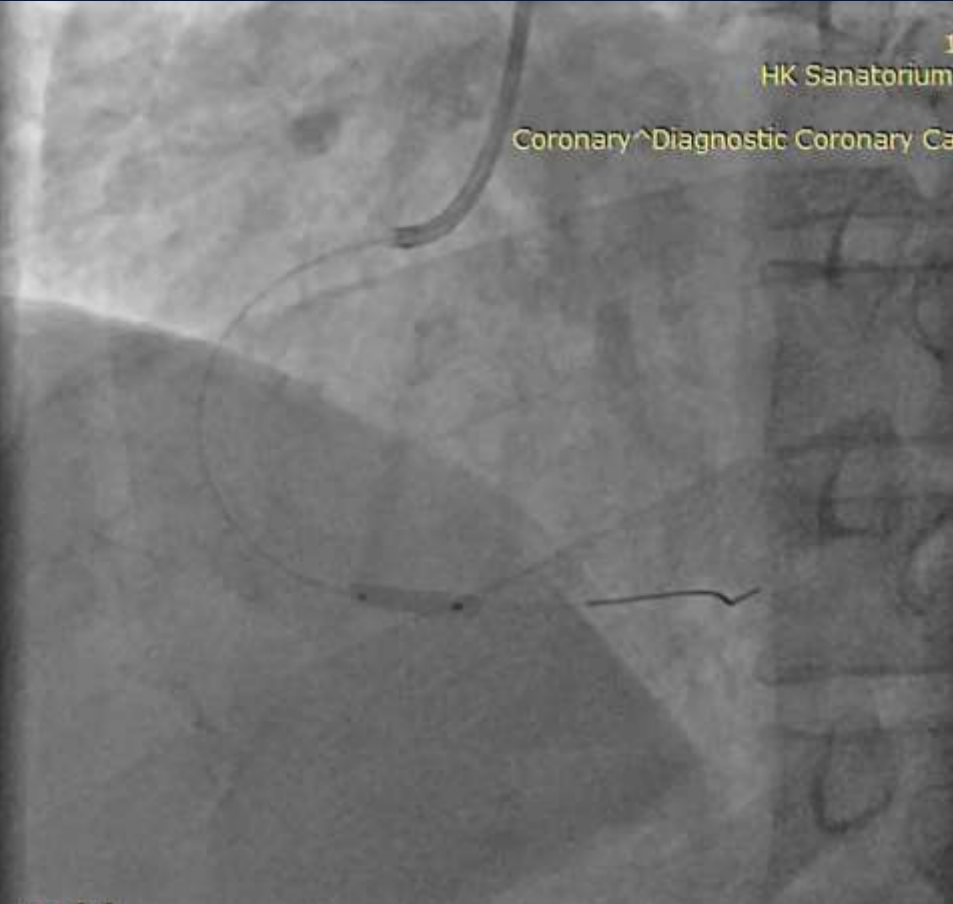


**mRCA: Eccentric MLA 4.77mm<sup>2</sup>**

6Fr MAC 3.0 guiding catheter  
Pre-dilatation by Sapphire NC 2.50x12mm &  
Pantera LEO 3.00x12mm



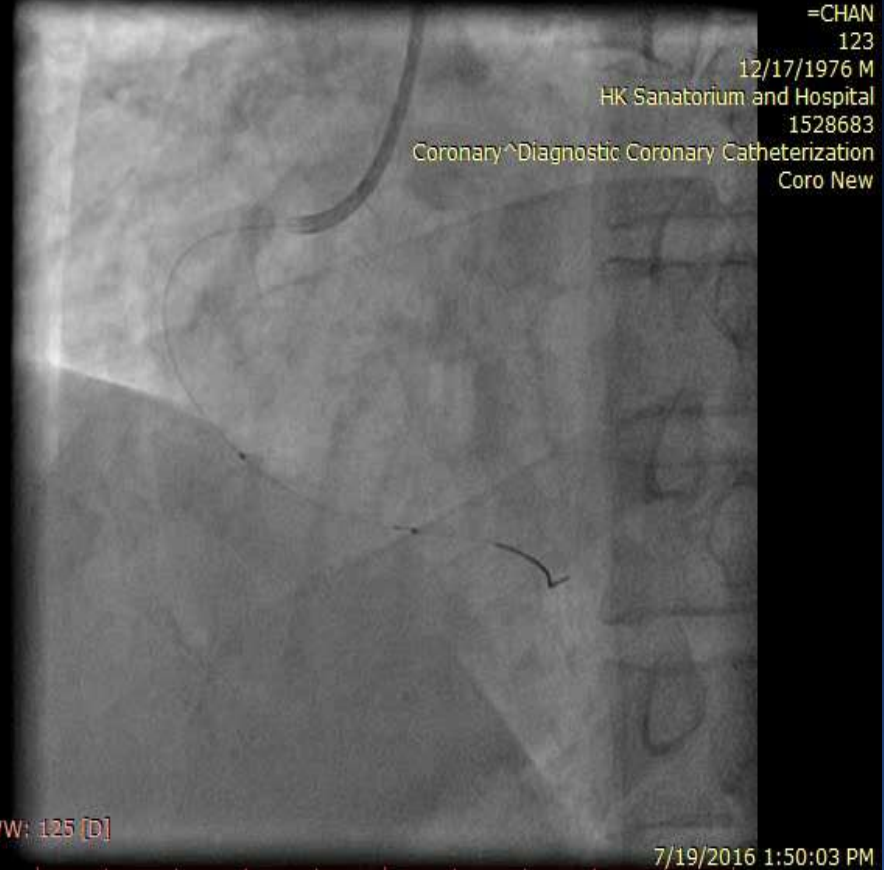
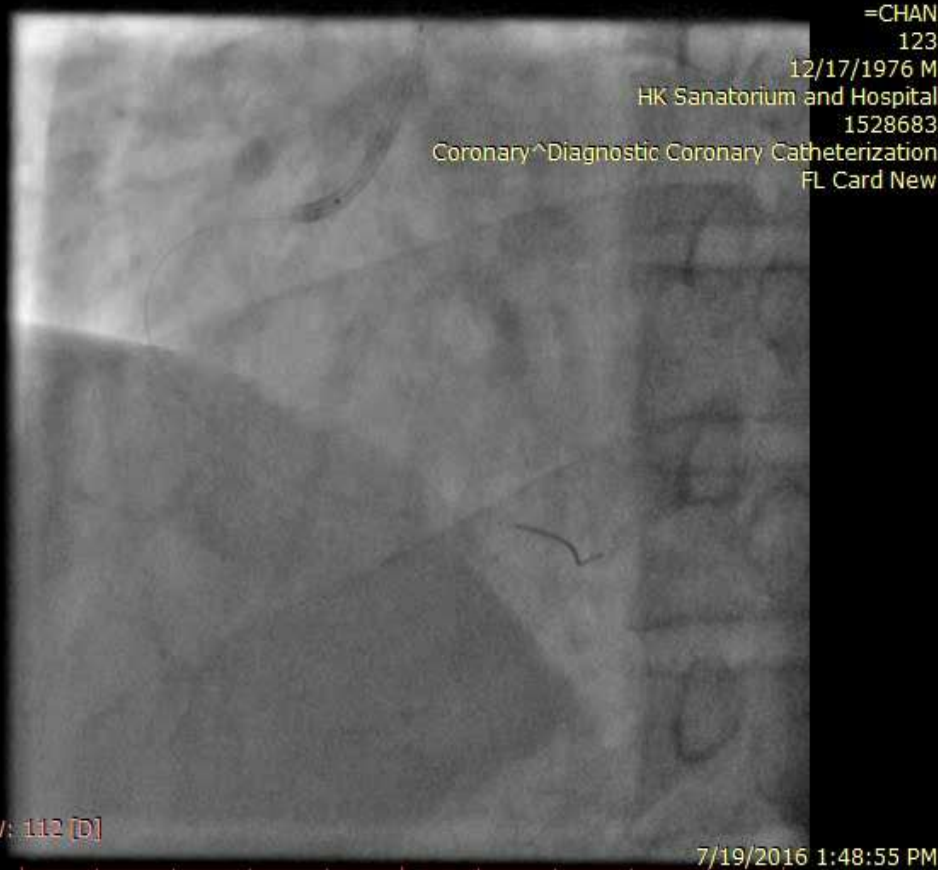
**Sapphire NC 2.50x12mm**



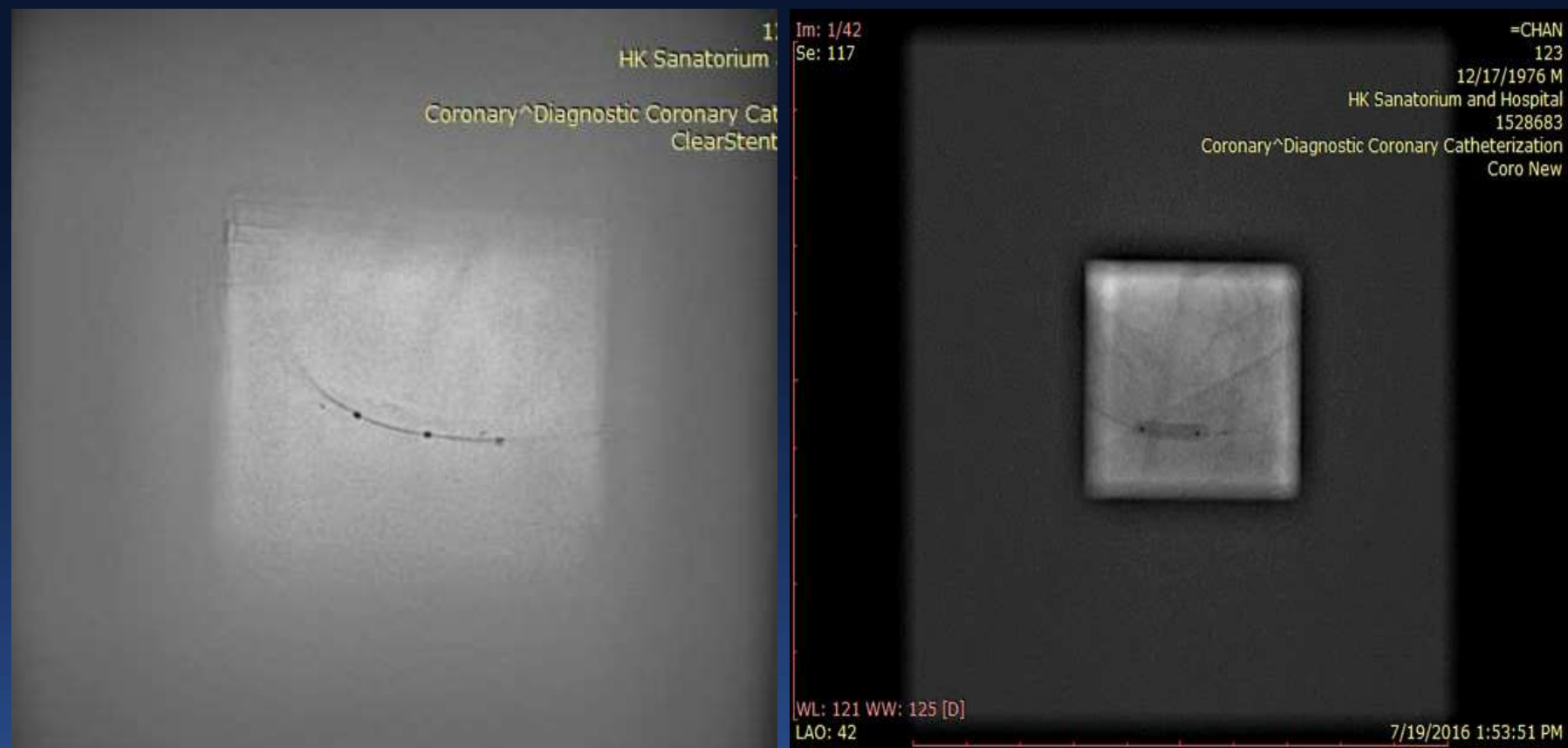
**Pantera LEO 3.00x12mm**

# Magmaris 3.00x25mm was deployed

4



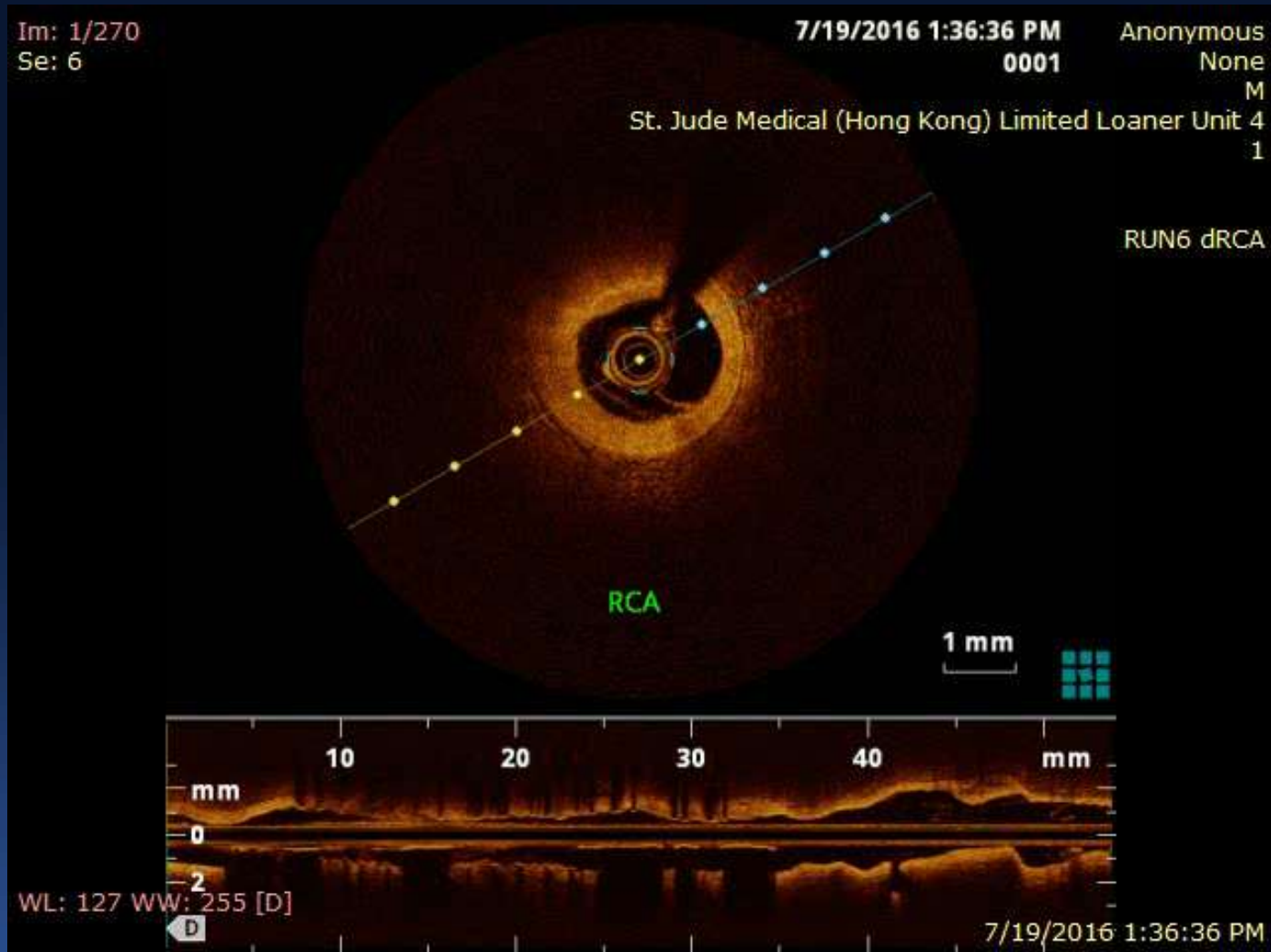
# Post-Dilatation by Sapphire NC 3.25x12mm



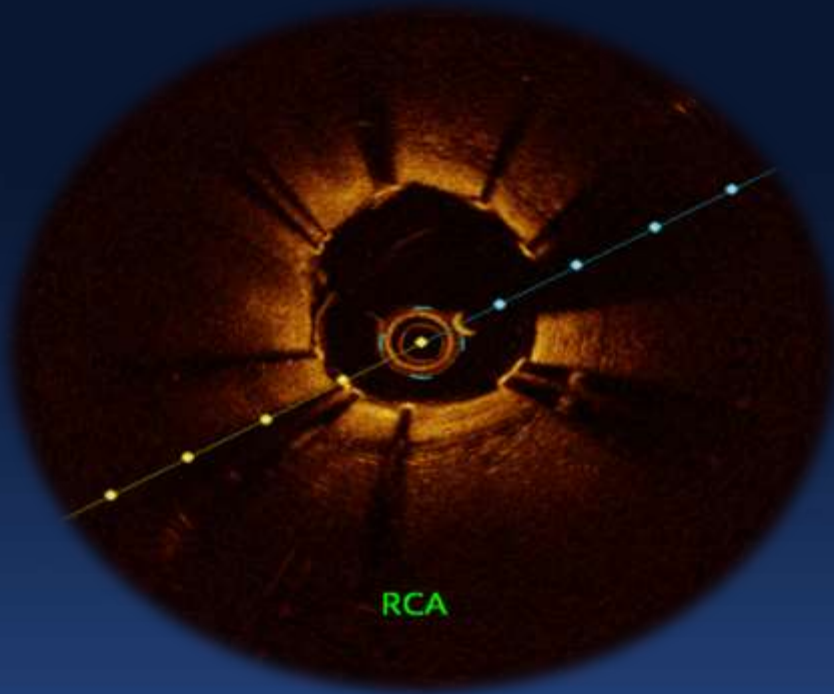
## Stent Boost



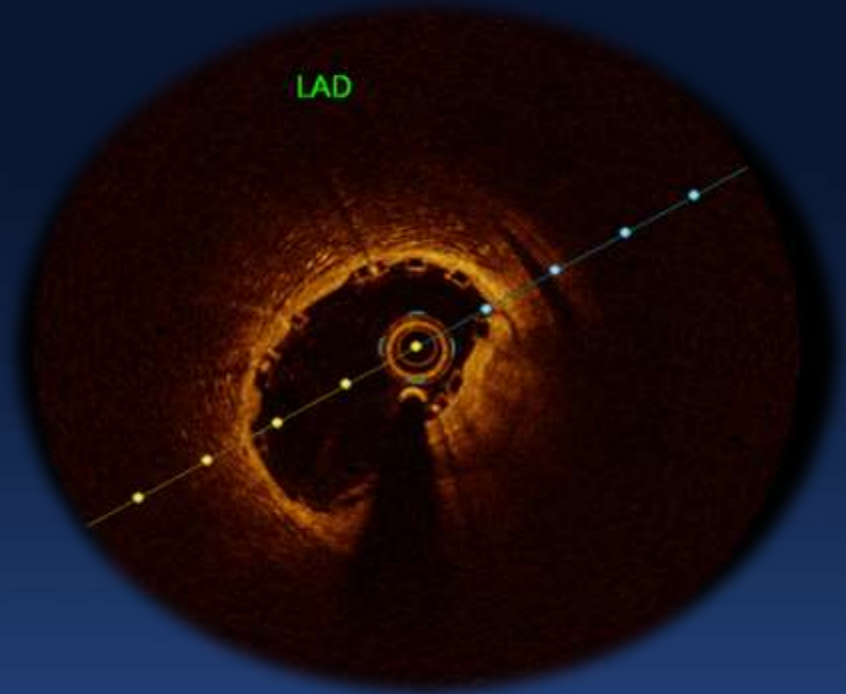
# OCT Image: metallic stent-like appearance



# Metal versus Plastic

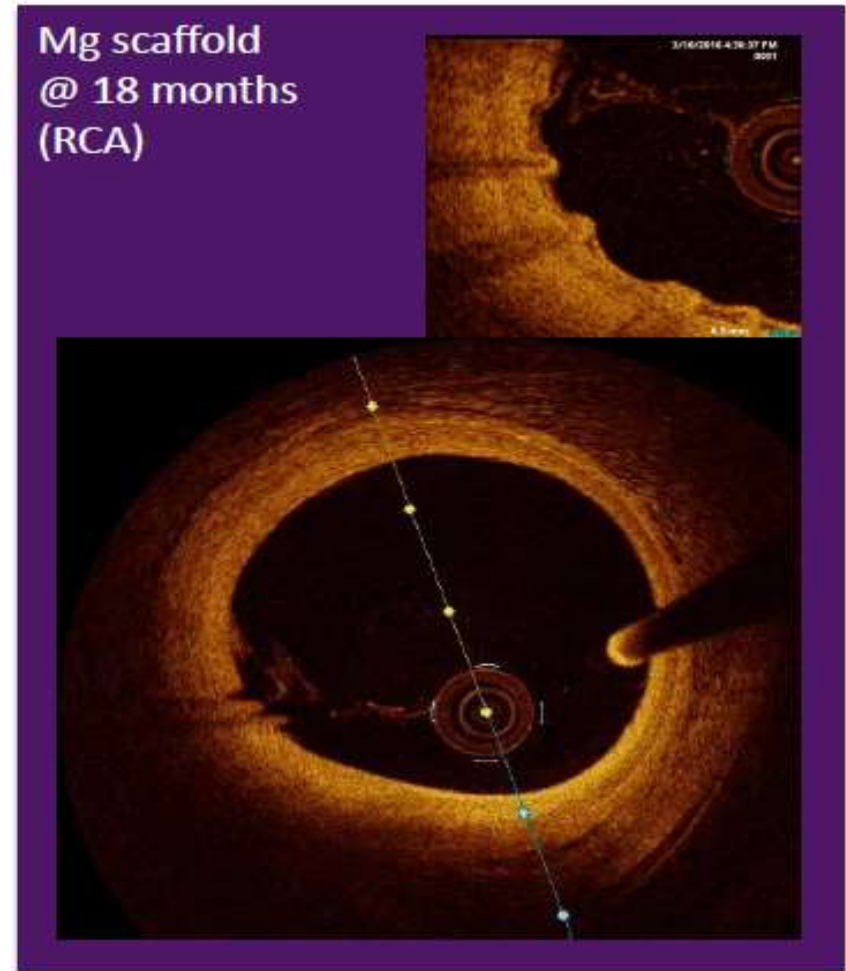
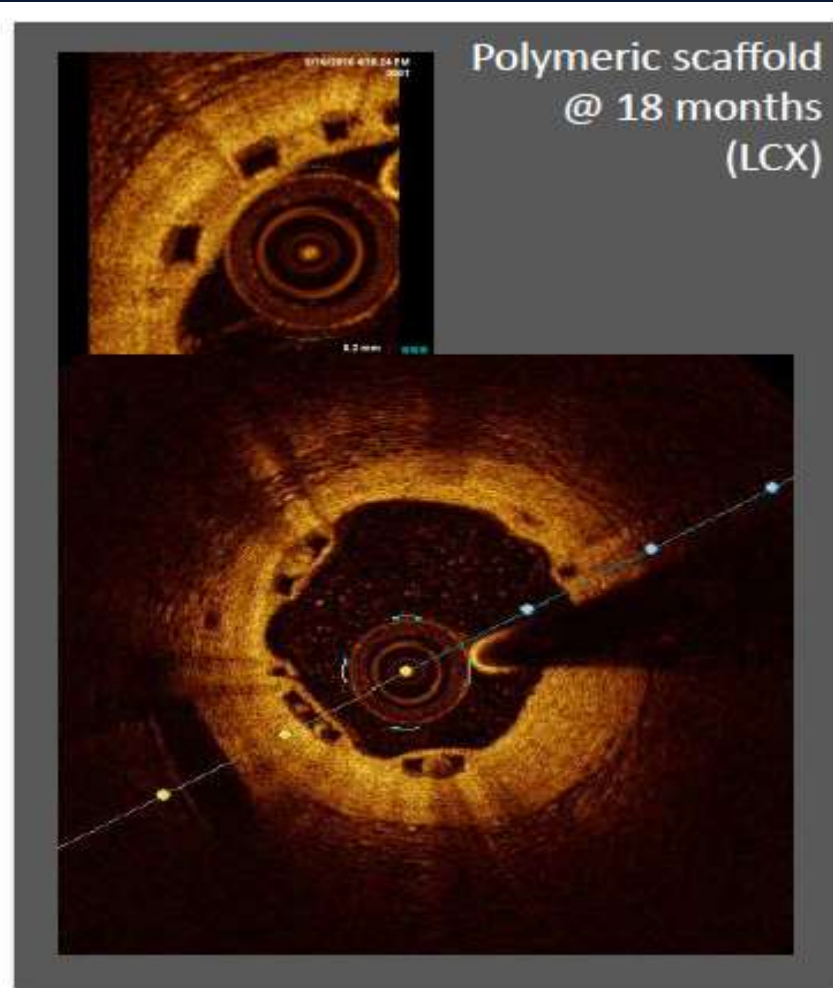


**Magmaris**



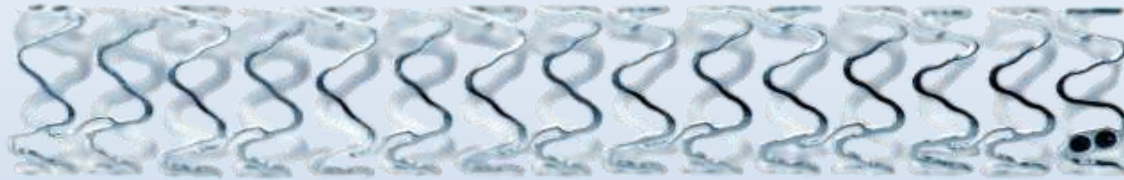
**Absorb**

# Magmaris and polymeric scaffold in the same patient



# Magmaris

## First Proven Magnesium Bioresorbable Scaffold



Novel **design** and **benefits** only available in a Magnesium scaffold:

### 1. Robust Mg backbone

- Delivers **strong radial resistance**
- Delivers **stable recoil**

### 2. Combination of strut design and electropolished scaffold surface

- Facilitates **rapid endothelial coverage**
- Facilitates **fast resorption time**

3. **No scaffold thrombosis** shown in three clinical studies\* with up to 12 months follow-up and n=232 patients.