

Bioresorbable Vascular Scaffold Use for Chronic Total Occlusion

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Disclosures

Speaker's name: Dace Sondore

- I have the following** potential conflicts of interest to report:
 - Research contracts
 - Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)

- I do not have any potential conflict of interest**

Evolution of PCI

- 1977: Balloon Angioplasty (POBA)
- 1986: Bare Metal Stent (BMS)
- 2001: Drug Eluting Stent (DES)
- 2006: Drug Eluting Balloon (DEB)
- 2009: DES with b/a Polymer
- 2011: Bioresorbable Scaffold

Our P.Stradins Hospital Data

2016 - total number of PCI- **3982**

PCI of CTO- **394**

- Bioresorbable scaffolds usage since 2013 Janv

CTO's Characteristics

- Long lesions
- Fibrocalcified lesions with high plaque burden¹
- Proximal and distal fibrous cap containing densely packed collagen²
- Usually requires longer segment stenting
(all dissection/re-entry techniques)

1.- Rubartelli A , et al. Eur Heart J 2010

2.- Srivatsa SS et al. J Am Coll Cardiol 1997;29:955-63

Reocclusion after PCI of CTO's

Associated with:

- Stented segment length¹
 - MLD after stent implantation²
 - Residual diameter stenosis³
 - Stent Type⁴
- More often after STAR technique⁴
- More often in retrograde approach³

1.- Sallam M,et al. *J Invasive Cardiol* 2001;13:511-5

2.- Choi SW,et al. *Clin Cardiol* 2003;26:265-8

3.- Isaaq K. *J Inv Card* 2013 Jul;25(7):323-9

4.- Valenti R et al. *JACC* 2013 Feb;60(5)

Alster-OCT-CTO Study

Analysis by OCT	CTO group	Control group	<i>p</i>
Total number of analysed struts, n	9,219	10,724	
Number of analysed struts/lesion, n	461±230.2	383±178.3	0.255
Number of analysed struts/cross-section, n	8.9±2.1	9.3±4.1	0.577
Covered struts/patient, %	68.9±21.9	89.6±10.4	<0.001 (*)
Uncovered struts/patient, %	31.1±21.9	10.4±10.4	<0.001 (*)
Apposed uncovered struts/patient, %	20.2±16.2	7.5±8.7	0.001 (*)
Malapposed uncovered struts/patient, %	10.9±10.3	2.9±2.6	<0.001 (*)
Neointimal thickness of covered struts, µm	92.0±61.2	109.3±39.2	0.033 (*)

Analysis of DES implanted after CTO-PCI vs. DES implanted in non-CTO lesions (control). Values are mean±SD or n (%) as appropriate. The data are presenting evidence for delayed DES coverage after CTO-PCI compared to control.

Why Bioresorbable Scaffold?

- Decrease late adverse events
 - Late thrombosis
 - Hypersensitivity reactions (chronic inflammation)
 - Stent fractures
- Restoration of vasomotion
- Does not restrict positive arterial remodeling
- Permits non-invasive imaging of artery
- Permits bypass surgery in future

Bioresorbable Scaffolds

Igaki-Tamai



PLLA

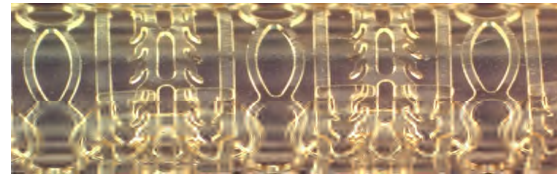
BVS:

Bioresorbable Vascular Scaffold



PLLA

REVA



**Tyrosine-
Polycarbonate**

BIT



PAE-Salicylate

Biotronik

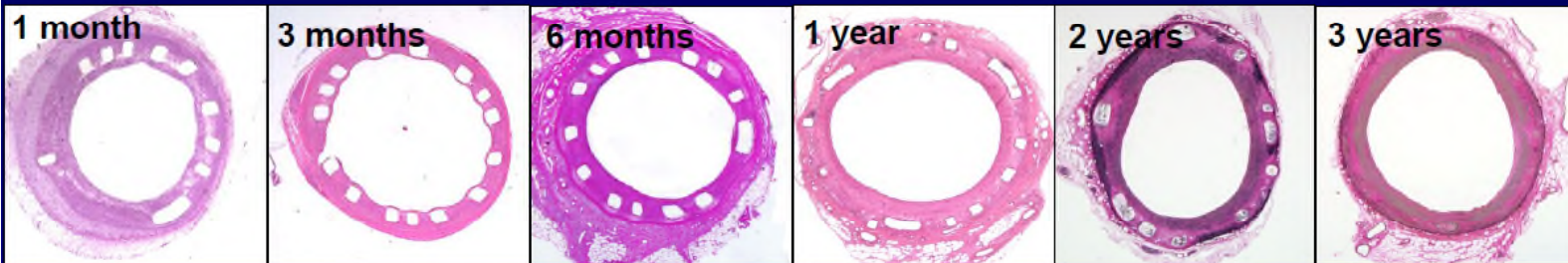


Magnesium

BVS Vascular Response to 3 Years: SMC Rich Neointima Incorporating All Struts

Porcine Coronary Artery Model

BVS



CYPHER



Representative photomicrographs 2X.

Data on file at Abbott Vascular.

Photos taken by and on file at Abbott Vascular.

BVS in CTO's

- Is one of the most challenging scenarios to test, due to long fibrocalcified lesions with high plaque burden ^{1, 2}
- In this setting vessel pretreatment is most needed
- Adequate BVS optimisation with NC is necessary

1.- Rubartelli A , et al. Eur Heart J 2010

2.- Galassi AR, et al. EuroIntervention 2011

Our Hospital Approach

P. Stradins Hospital Approach:

- Aim- ***avoid "full metal jacket"*** by covering total CTO segment with DES
- Method- after CTO crossing with guidewire, predilatation with SC balloon, then pretreatment with cutting balloon
 - DES implantation in ostial/proximal segment
 - BVS implantation in CTO body
 - postdilatation with NC balloon
- Follow-up- at 12 month angio and OCT control

Case Example

Male 73 y.o.

Clinical presentation:

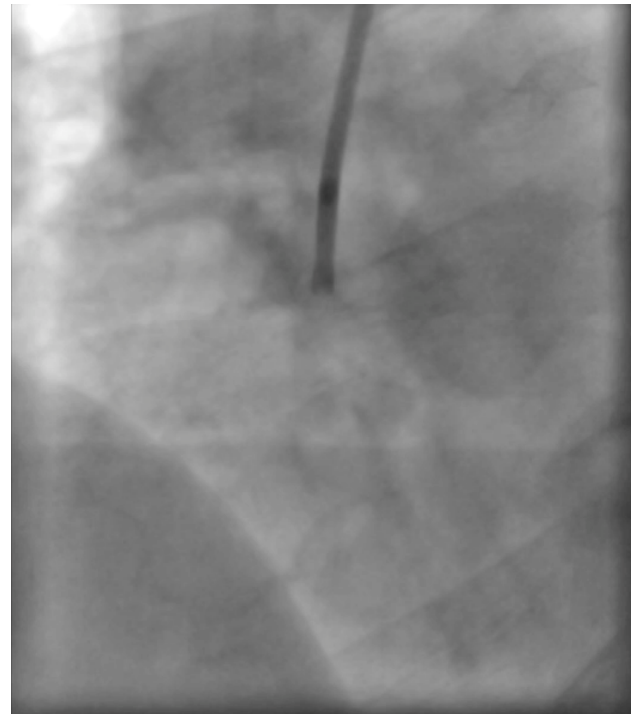
Stable angina III.

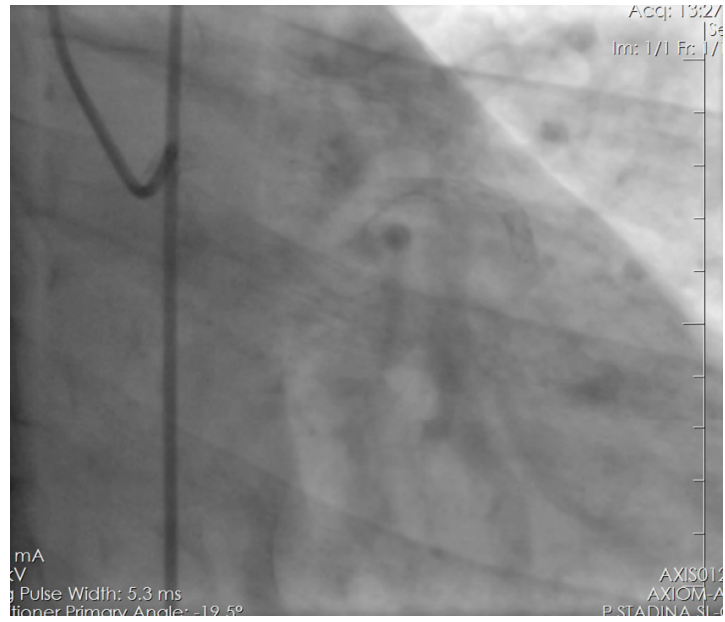
Previous PCI with DES LAD 2 month ago.

Hypertension I.

Dyslipidemia.

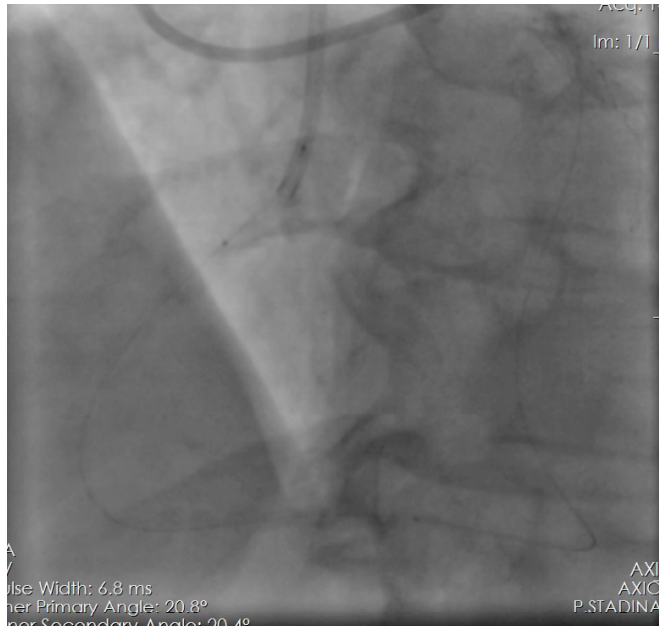
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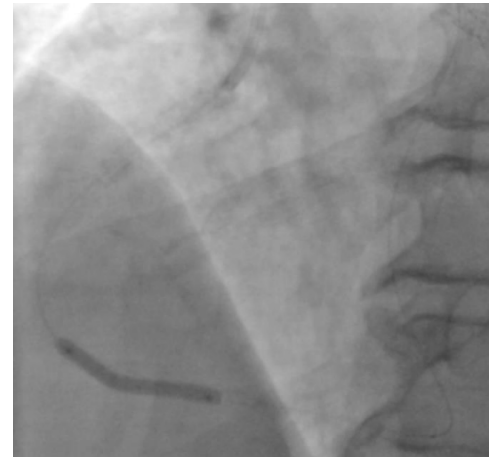


Intended Equipment (retrograde approach)

- Both femoral approach – 7 F JR4SH, 6F EBU 3,75
- Microcatheter FineCross 150 cm, Choice floppy and Sion Black, Gaia2
- Predilatation - with Regular balloon 2,0-20 mm, 3,0-30 mm,
Cutting balloon 3,25-10 mm
- Stents: DES 3.5-24 mm (RCA ostial)
Bioresorbable scaffold(Absorb) 3.5-23 mm (RCA mid)
- Postdilatation - NC balloon 3.75- 15 mm
- Femoral closure: AngioSeal



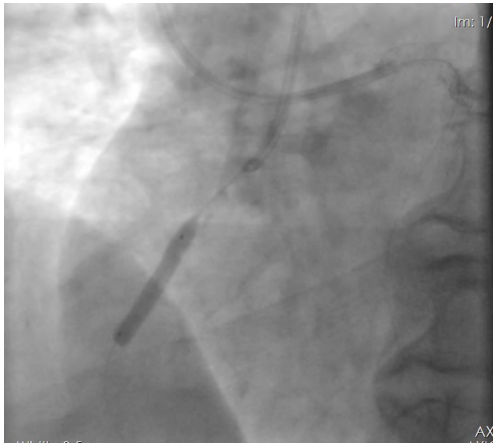
Predilatation with 3,0-30 mm SC balloon



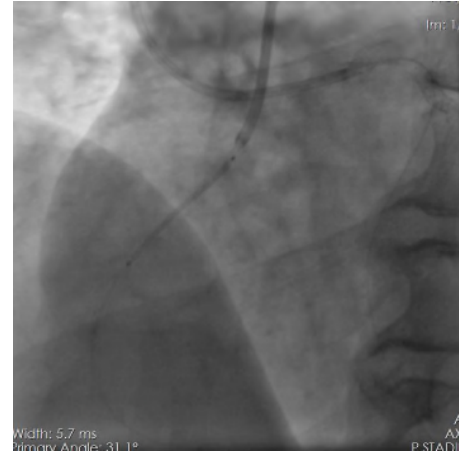
Pretreatment with 3,25-10 mm Cutting balloon



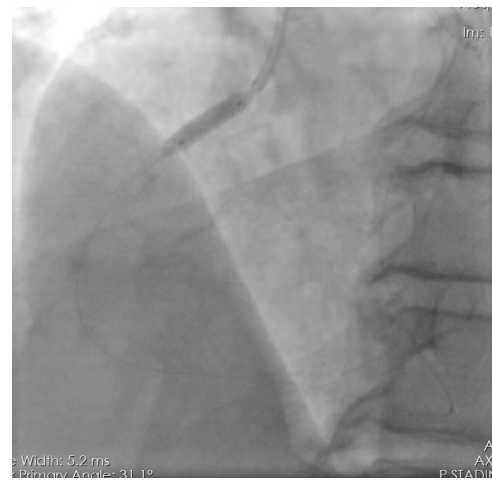
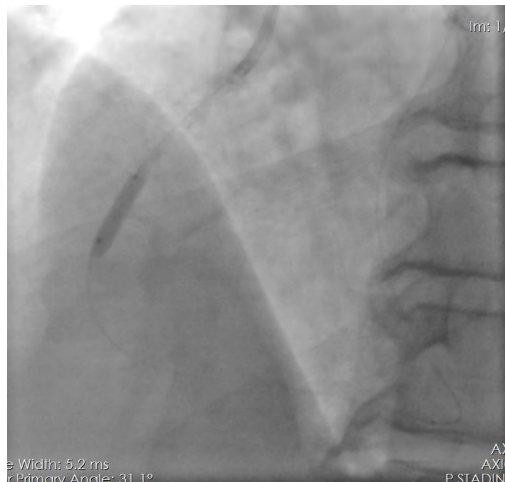
Absorb Implantation

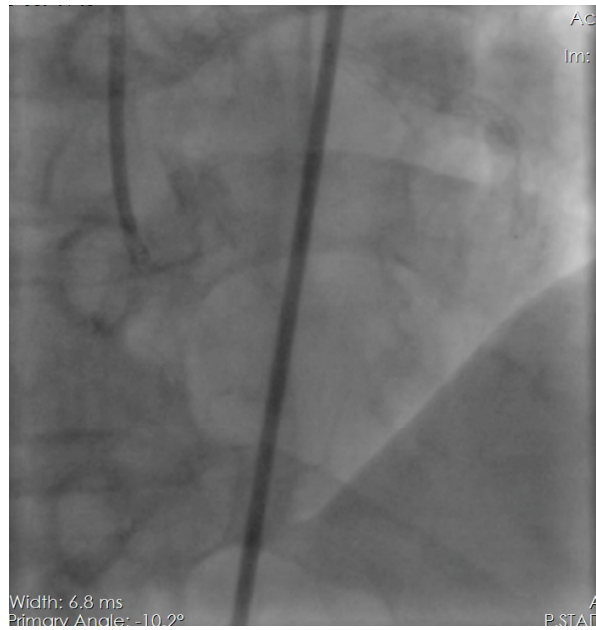


DES Implantation

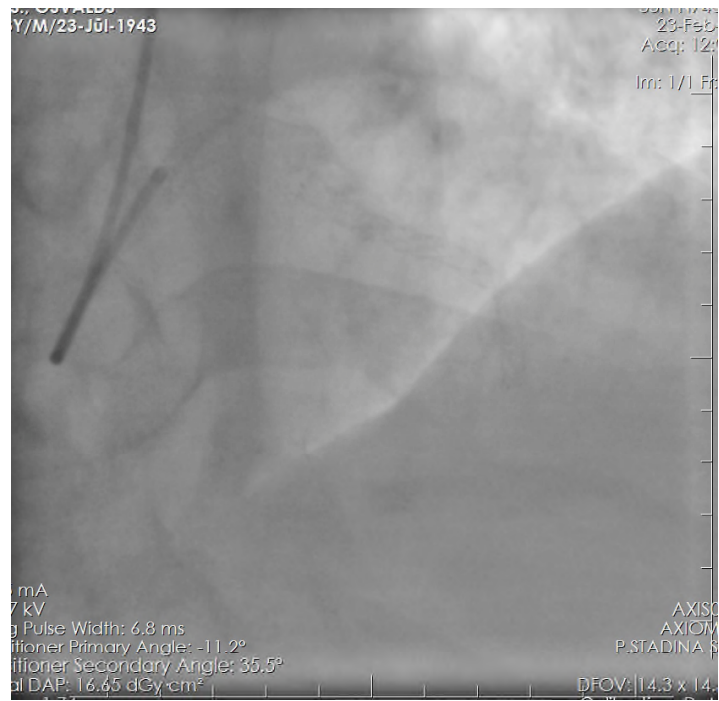


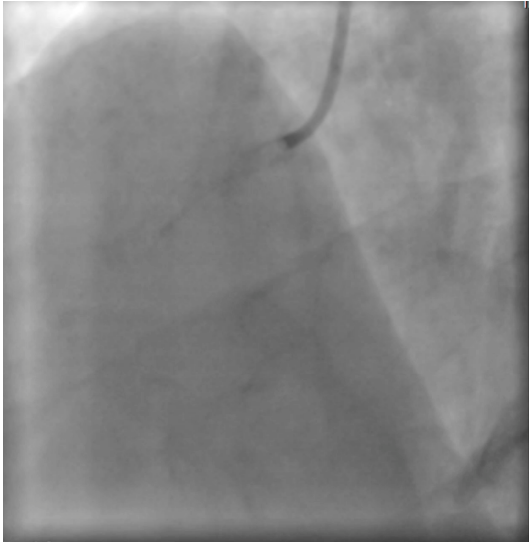
Postdilatation with NC 3,75-15 mm



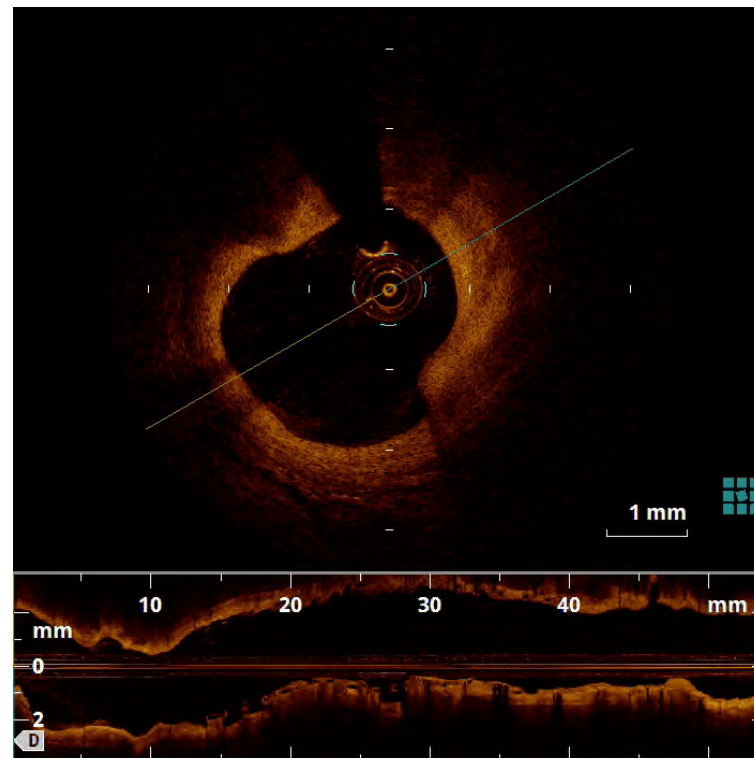


9 Month Follow-up





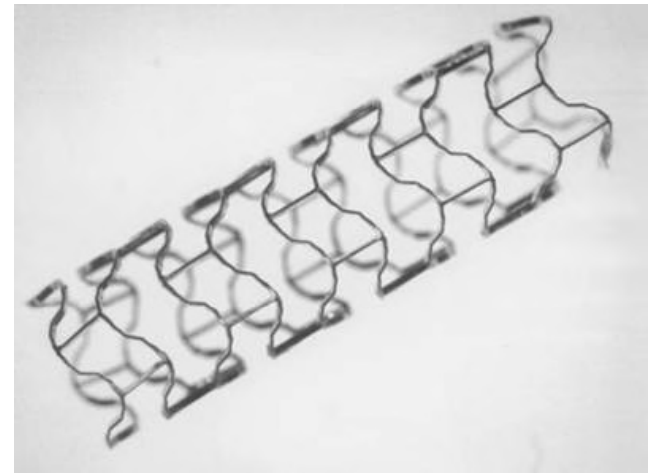
9 Month Follow-up OCT



Magnesium Alloy Biodegradable Stent (AMS, Biotronik, Inc.)

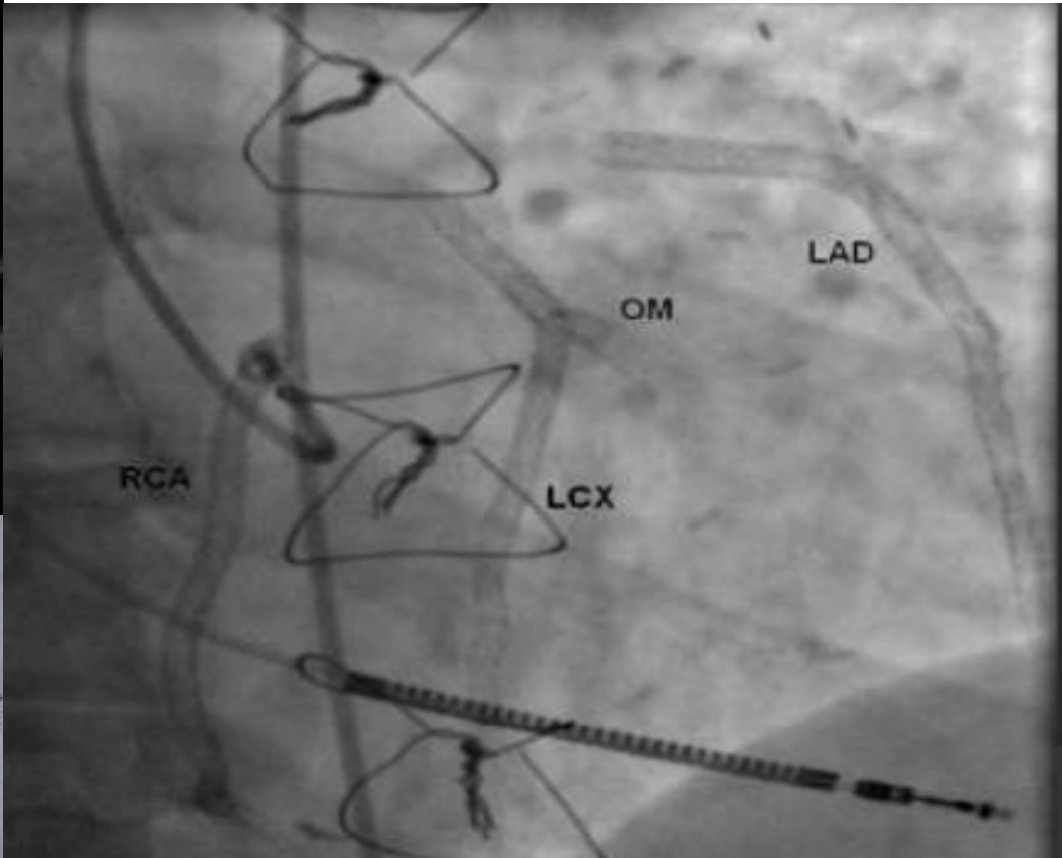
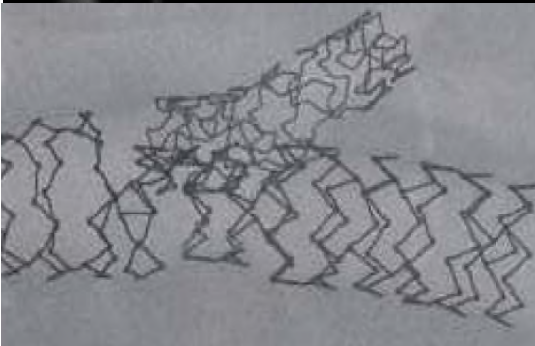
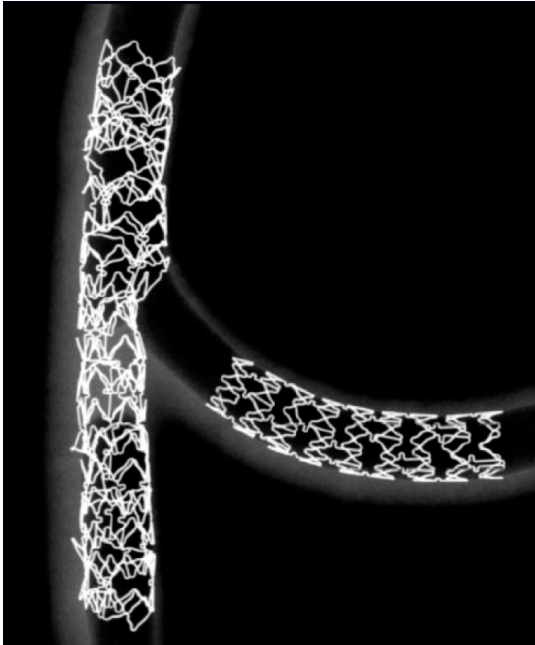
Magnesium and the Human Body

- Essential element for human body involved in the synthesis of more than 300 enzymes (4th most common mineral)
- Quantity in human body: ~ 20 g
- Daily need (adult) : ~ 350 mg
- Quantity in the intracellular space: > 40%
- Degradation by replacement with Calcium and Phosphorous (2 months)



3.0 x 10 mm stent: ~ 3 mg

Is "Full Metal Jacket" a Past?



Summary

- This first generation scaffold(Absorb) requires different techniques than standard stents
- Lesion preparation and adequate postdilatation is demanding
- Scaffold fracture, malapposition, incomplete expansion are the reasons of it's early thrombosis
- Pay attention to DAPT during 1→2 ?? years

Thank you!