

Unrestricted Adoption in Real World Patients Is Possible.

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Erasmus University, Rotterdam, The Netherlands
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Imperial college, London, UK

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Erasmus University, Rotterdam, The Netherlands


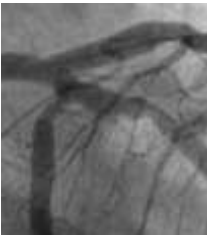
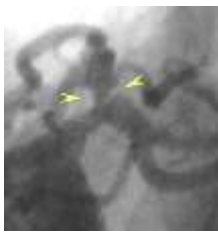
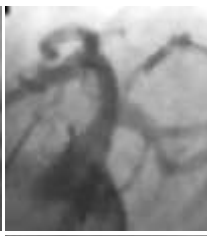


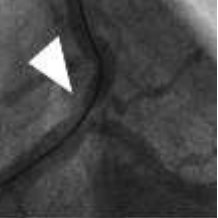
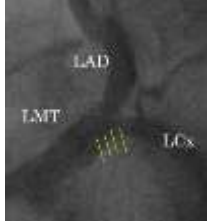
7:30-40 April 29, 2015

In all-comers, you have... Do we have data?

- **Left main**
- **Bifurcation**
- **3 Vessel disease**
- **Small vessels**
- **Chronic total occlusion**
- **Calcified lesions**
- **STEMI**
- **Saphenous vein graft**
- **Diabetes**
- **ISR**

Case reports (5)
Phantom/ Cases
No reports
Some data
Registry data
Anecdotes(Absorb2)
Propensity analysis
Case report
Registry data
Short series

Bioresorbable vascular scaffold for treatment of Left main lesions

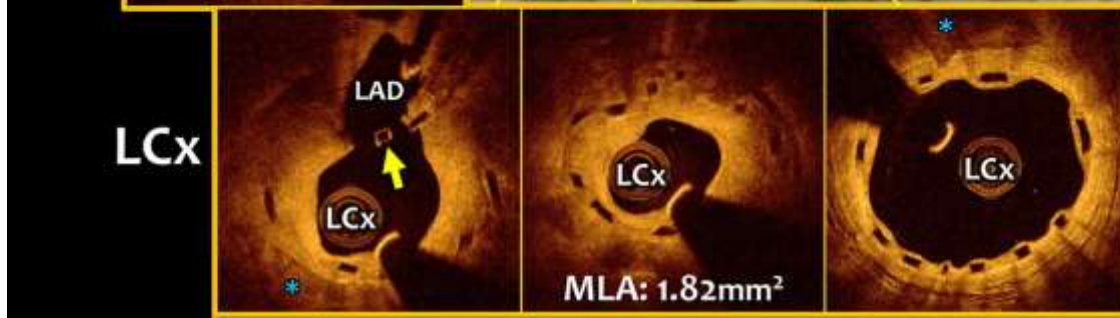
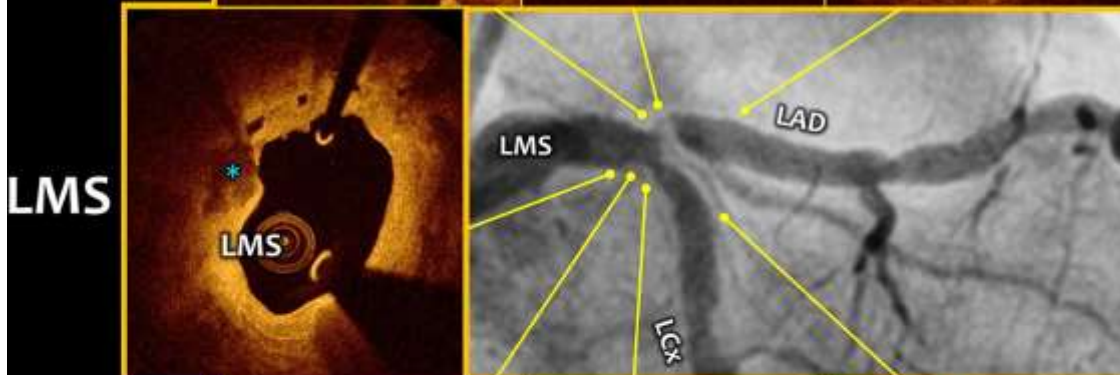
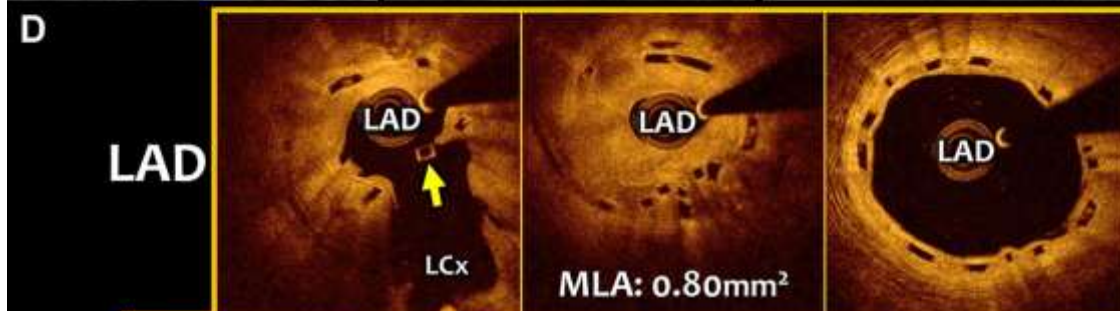
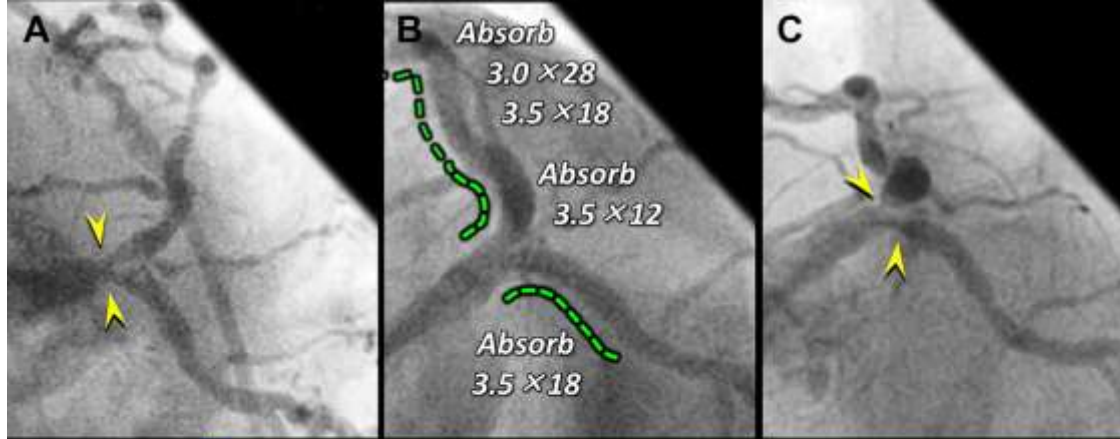
Age	Lesion involve distal LM	Medina classification	Device	Technique/ imaging	SB Post dilate	Pre	Post
52 years ¹	Yes	1,0,0	3.5x18 mm ABSORB BVS (12 atm)	Single stent Cross over LM to LAD OCT	2.0x20 mm (8 atm) and 2.5x15 mm (8 atm) because some plaque shift in the ostium of intermediate branch		
51 years ²	No	0,1,0 Ostial LAD	3.5x28 mm ABSORB BVS	Single stent Cross over LM to LAD IVUS guided	Not performed		
56 years ³	Yes	1,0,0	3.5x18 mm ABSORB BVS (14 atm)	Single stent	Not performed		
66 years ⁴	No	0,1,1	3.5x12 mm (LMCA-LAD) 3.5x18 mm (LMCA-LCX)	V-stenting OCT and IVUS	final kissing-balloon inflation		

1.Grundeken MJ et al, Int J Cardiol. 2013 ;168(3):e107-8

2.Miyazaki T et al, Int J Cardiol. 2014;175(1):e11-3

3.Fernández D et al, Int J Cardiol. 2013 ;168(2):1566-8.

4.Sato K et al, JACC Cardiovasc Interv. 2014;7(8):e103-4



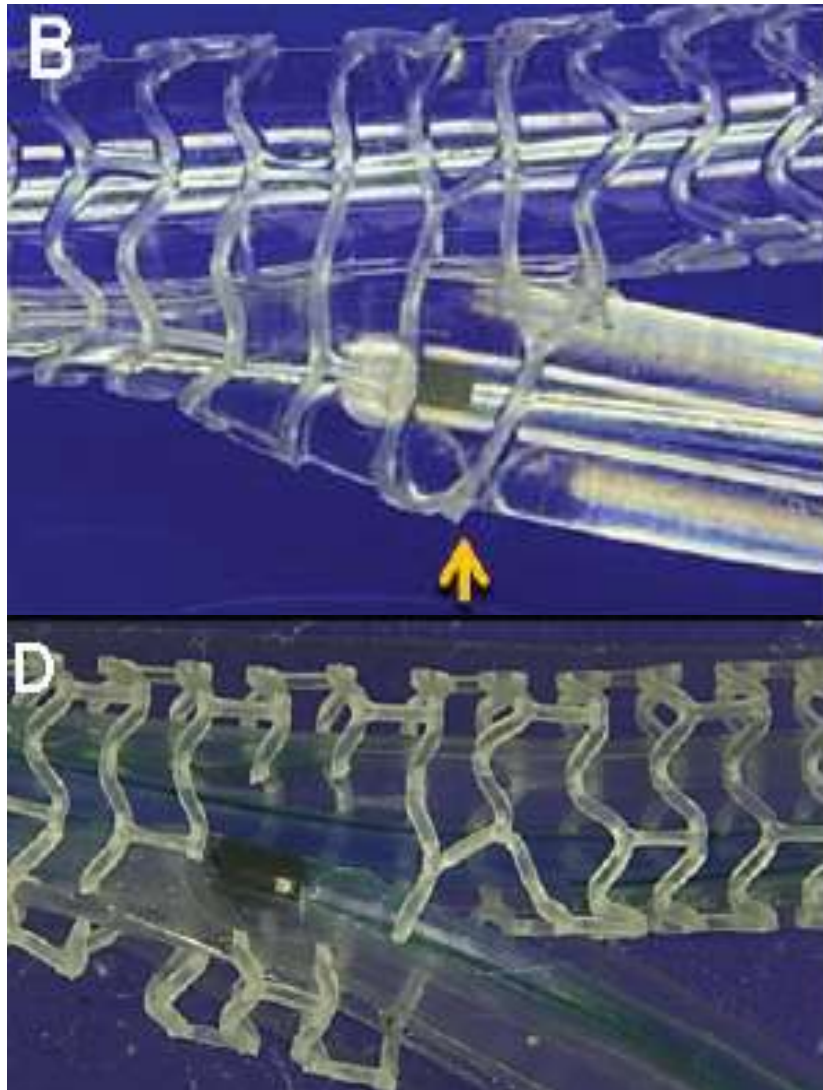
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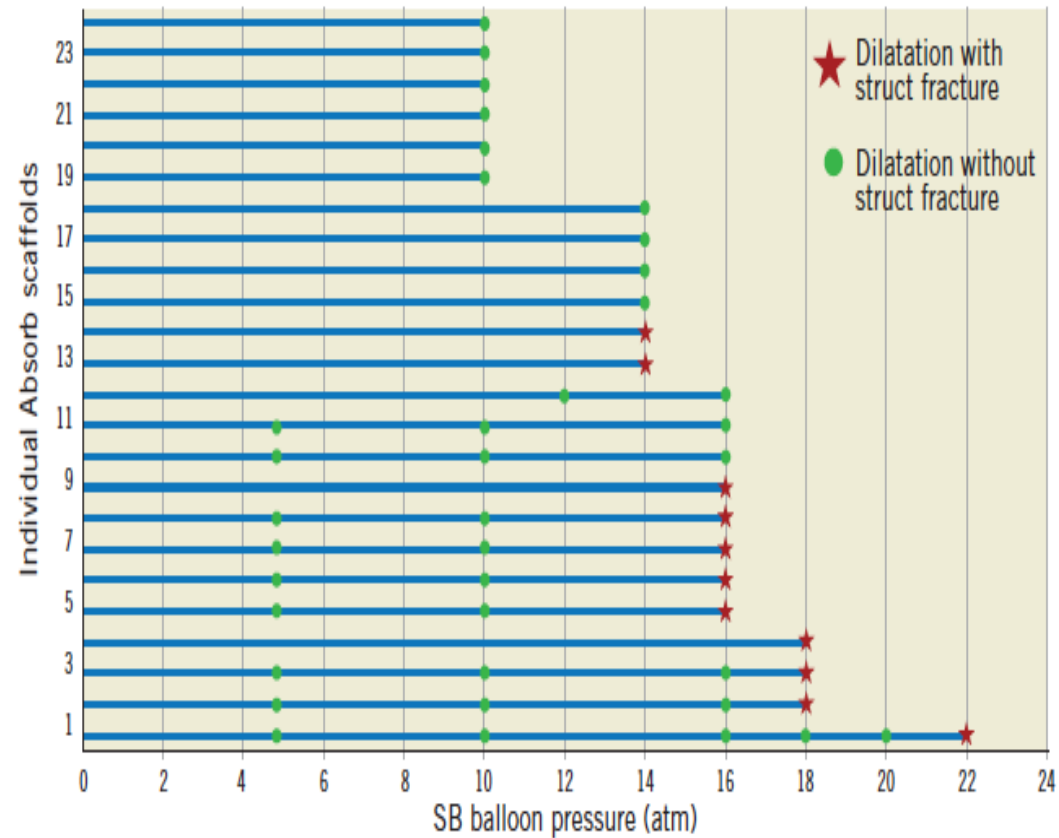
Bench test of sidebranch dilatation with ABSORB scaffolds

Ormiston et al. EI 2014

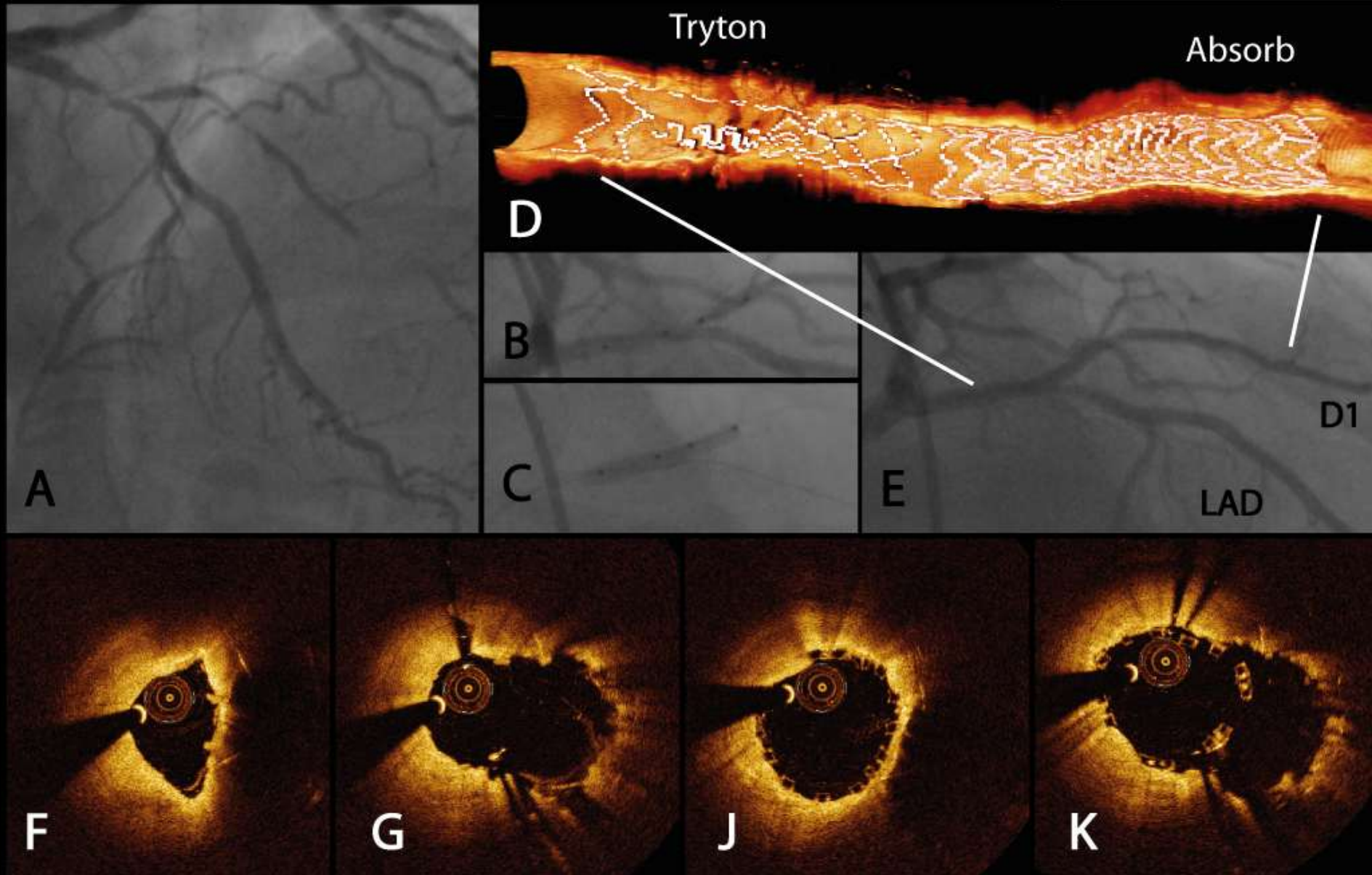


A

Individual Absorb 3.0 mm scaffolds (n=24), 3.0 mm balloon side branch dilatation pressure (atm) and fracture

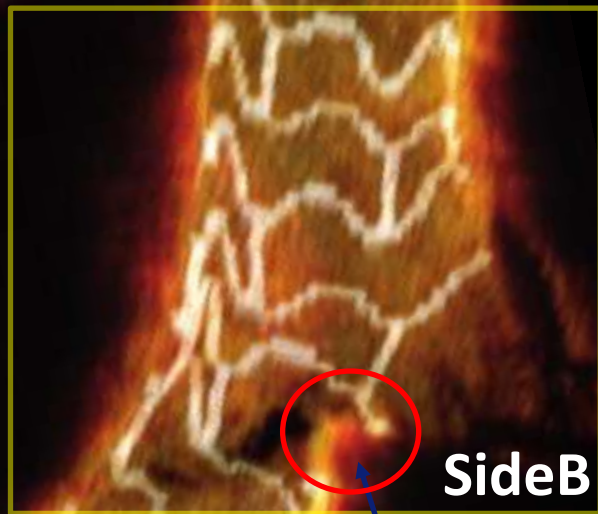


Bifurcation -hybrid



Bifurcation -hybrid

PMV



Side B

→ Shadow of metallic stent

Carina

BVS strut was partially migrated into the side branch without damaging strut continuities

DMV

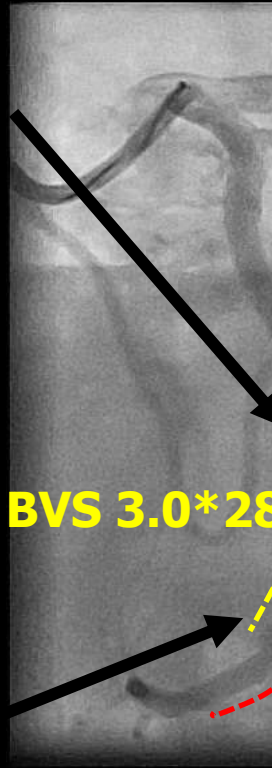
OCT after culotte stenting with bioabsorbable everolimus



Proximal edge

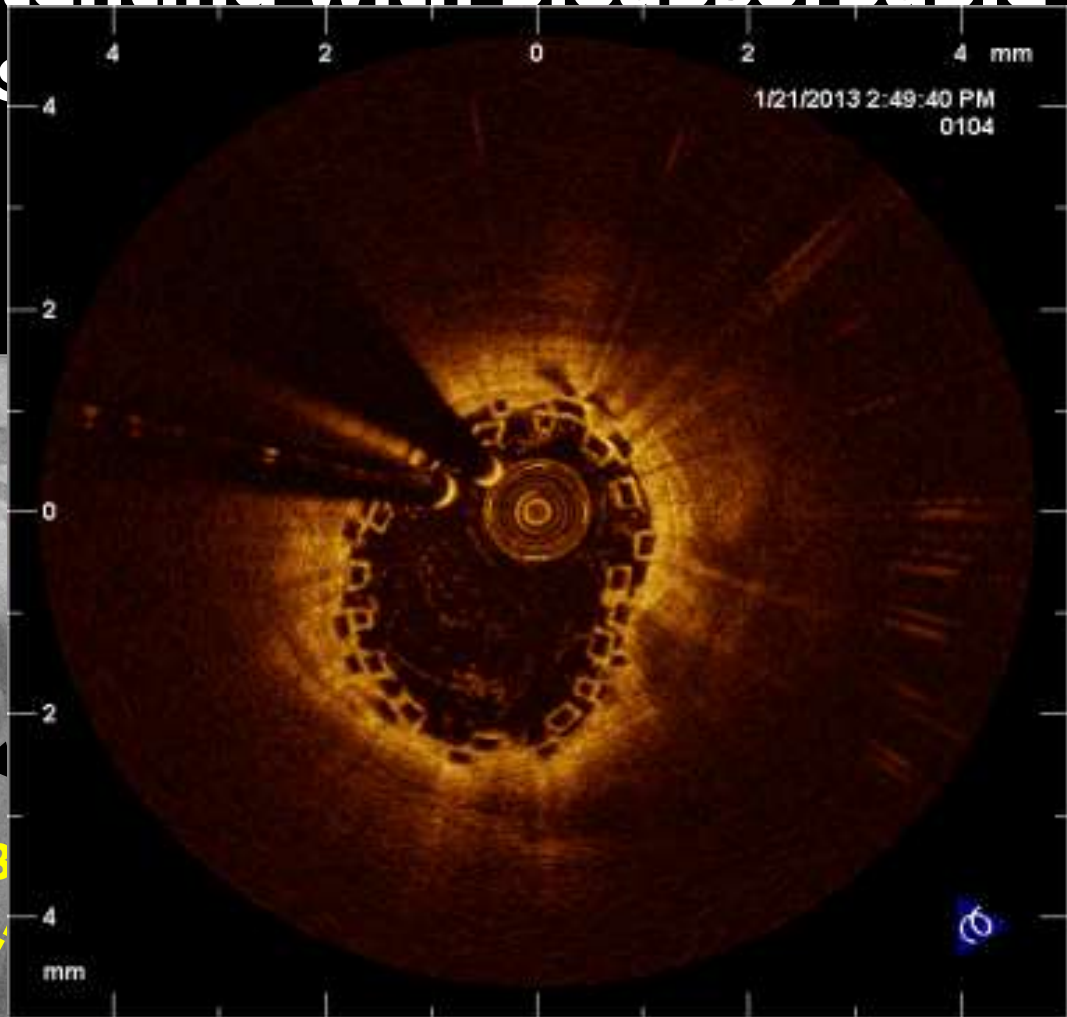


Distal edge



BVS 3.0*28

BVS 2.5*18



OM

(C7 Dragonfly®, St. Jude Medical Lightlab Inc. Westford, MA, USA)

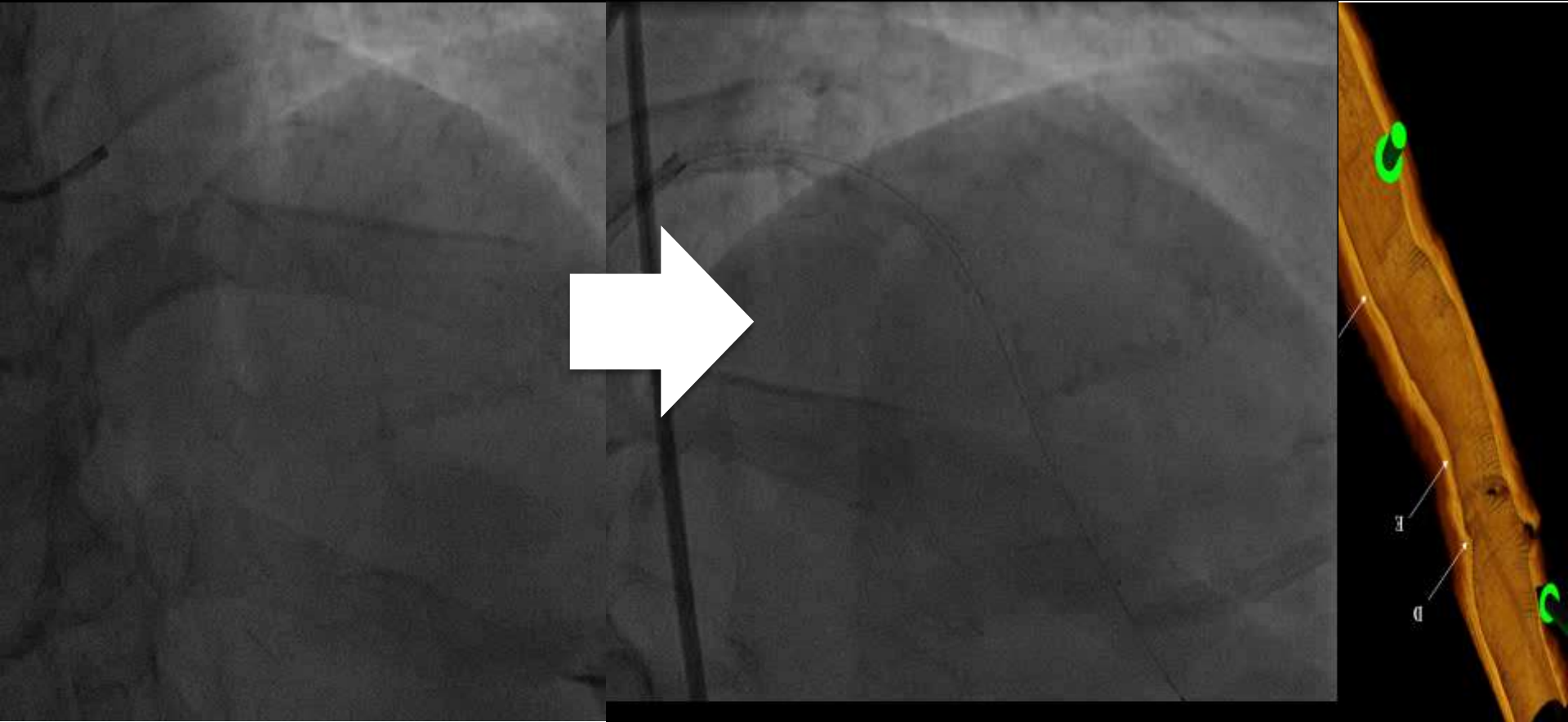
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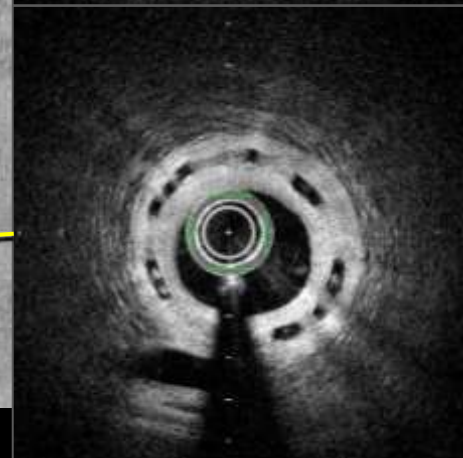
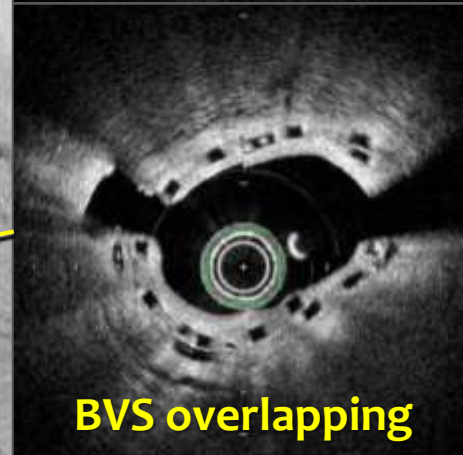
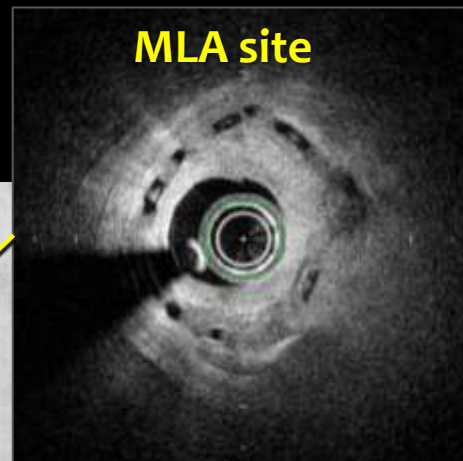
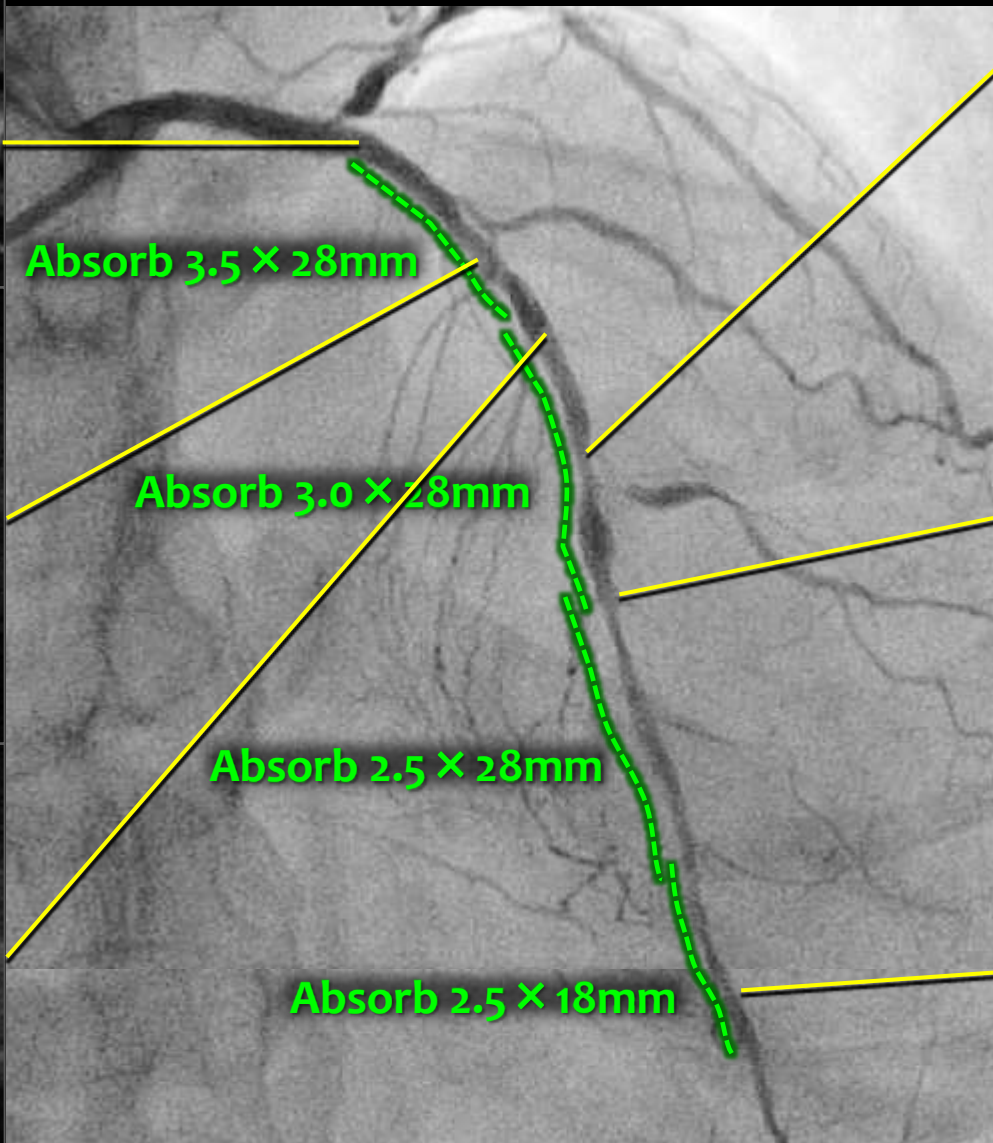
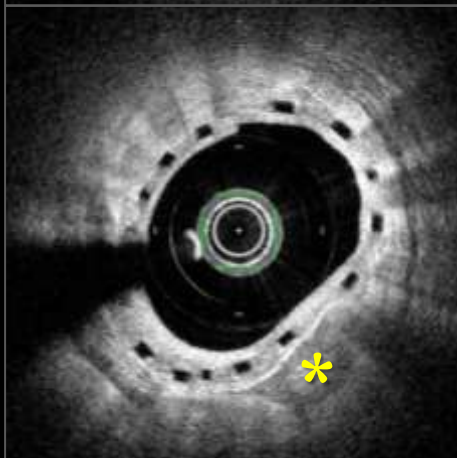
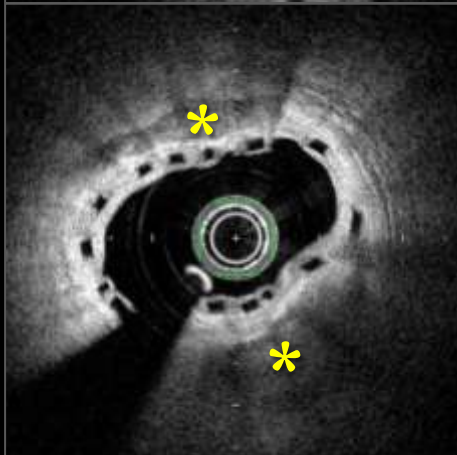
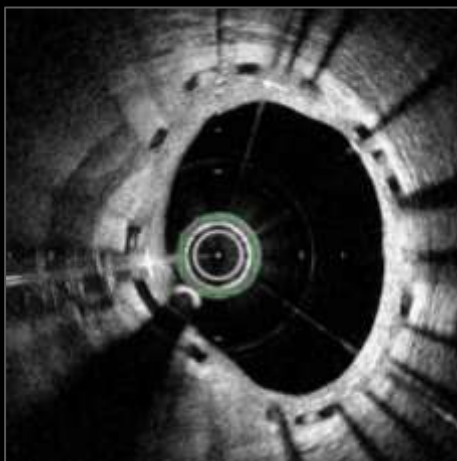
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Endoluminal bypass by the bioresorbable scaffolds

Courtesy of Dr. Colombo



130mm of endoluminal bypass



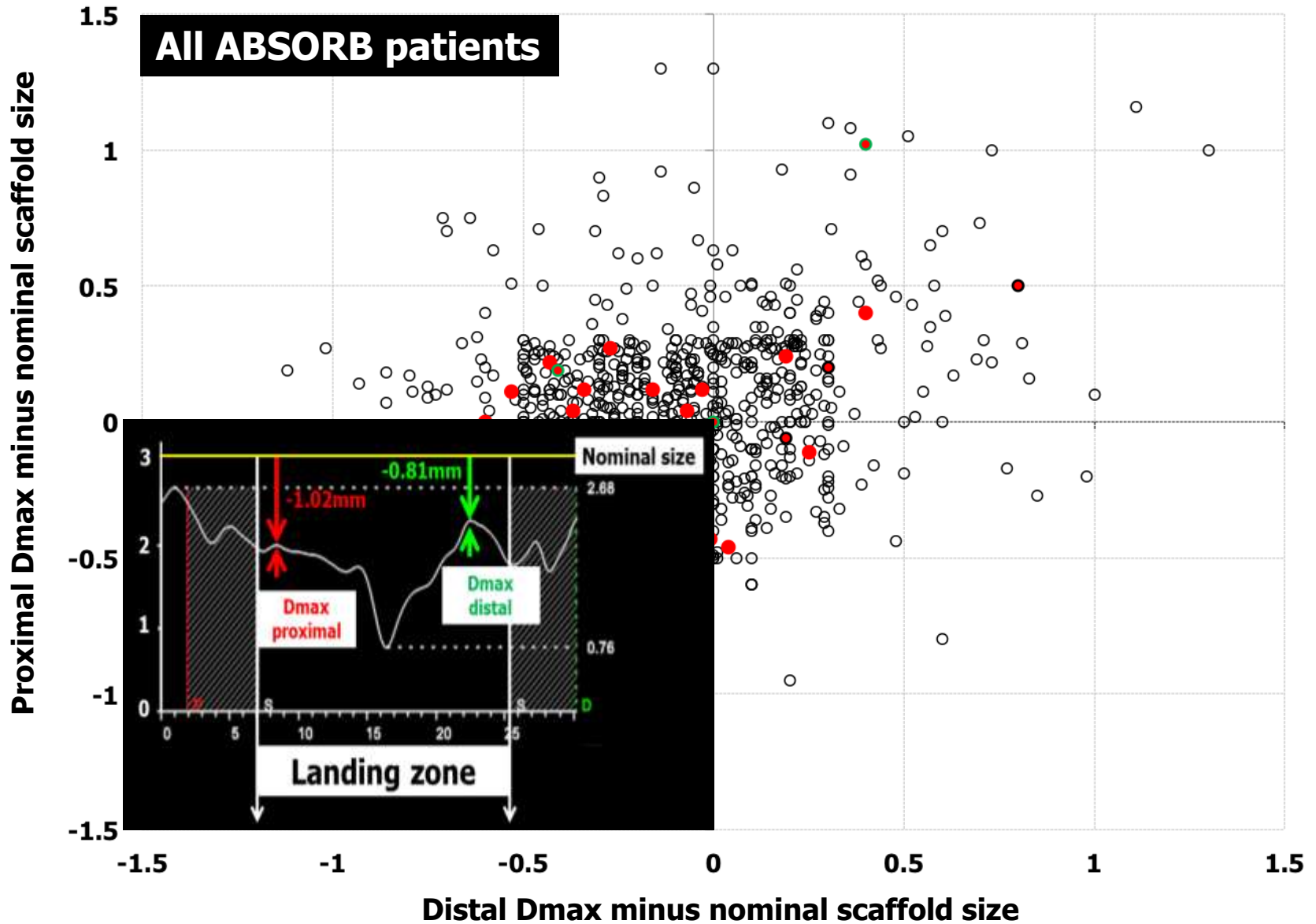
Calcium *

In all-comers, you have... Do we have data?

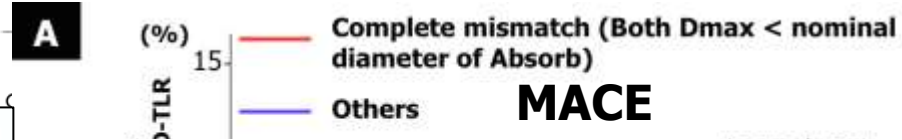
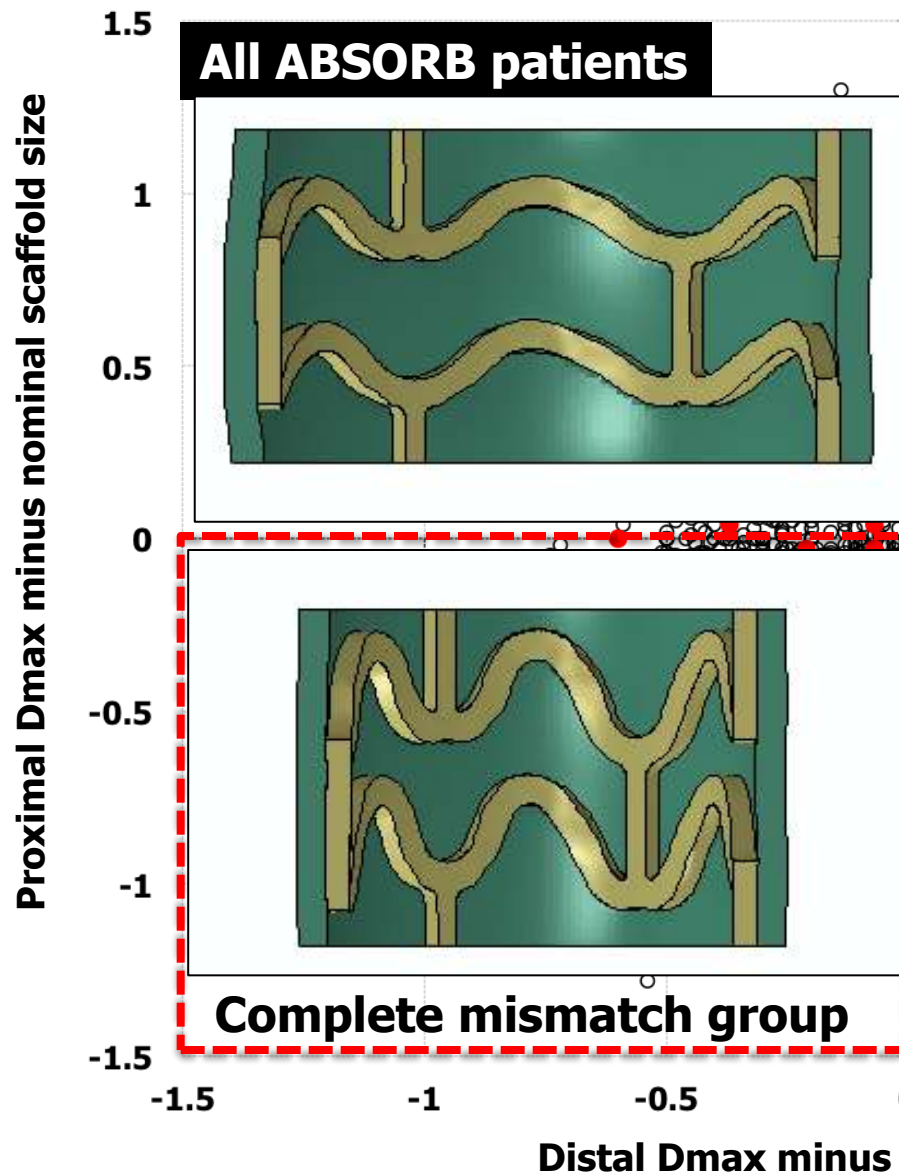
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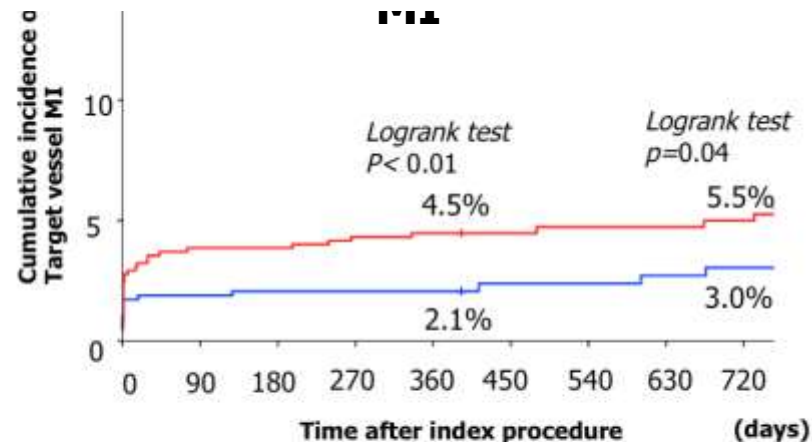
Distribution of Dmax Prox and Dmax Distal related to the nominal device size in the ABSORB II, Extend and B (n=1248)



Distribution of Dmax Prox and Dmax Distal related to the nominal device size in the ABSORB II, Extend and B (n=1248)



The implantation of a "large" Absorb scaffold in a relatively small vessel had a higher risk of MACE at 1 year. The selection of nominal scaffold size below the diameter of both proximal and distal Dmax might lead to a denser polymer surface pattern, which could be associated with MI after procedure.



Number at risk (days)	0	37	194	393	758
Group A	649	626	624	620	613
Group B	583	572	571	571	566

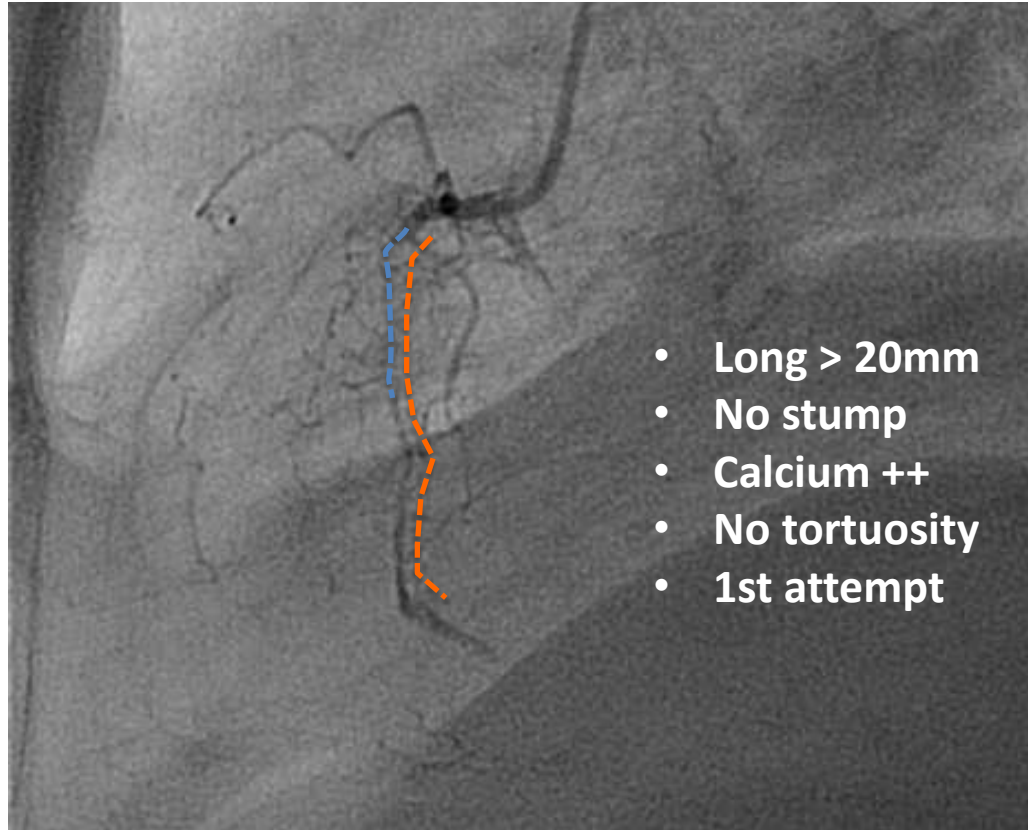
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CTO angiographic characteristics

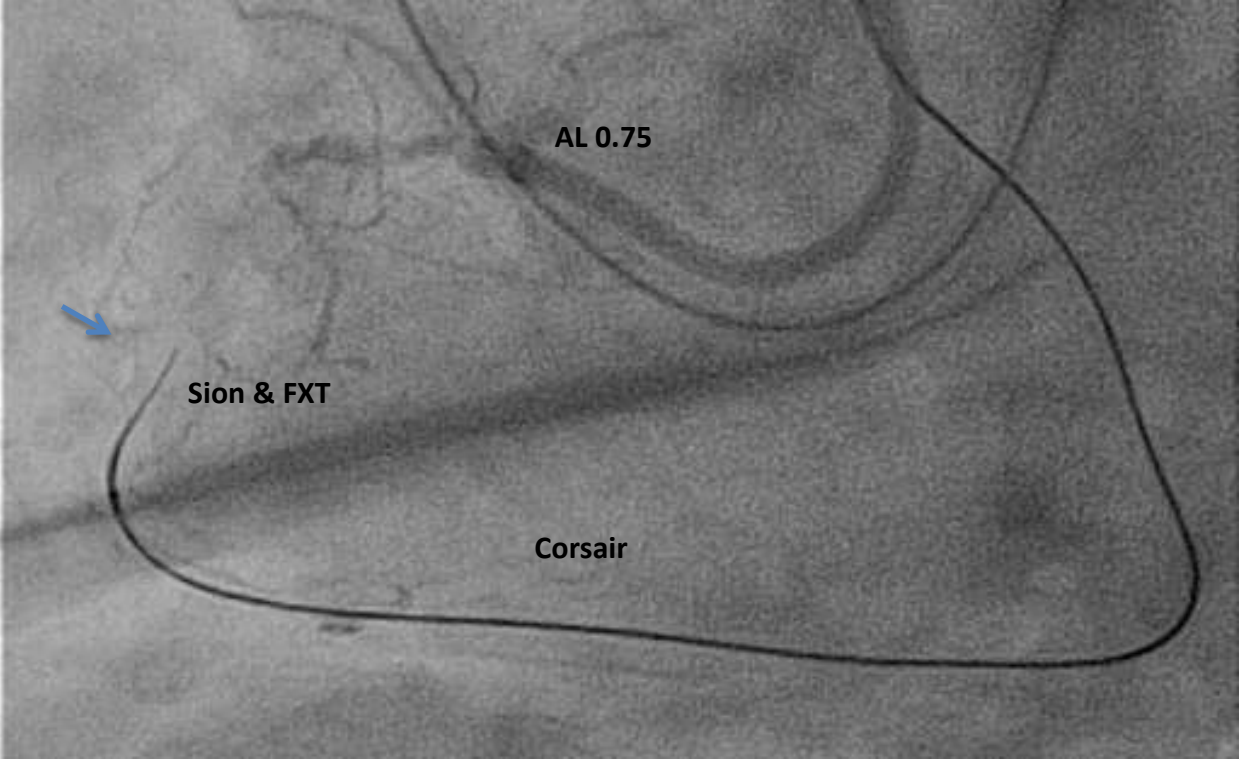
✓ Occlusion duration: Probable; 18 months



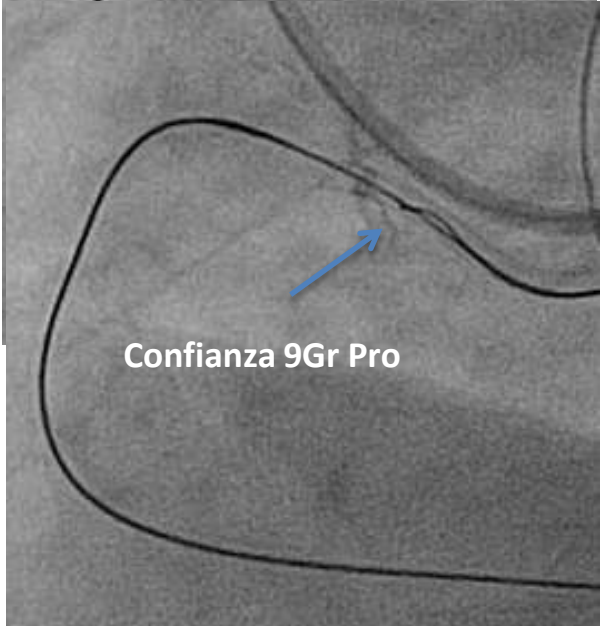
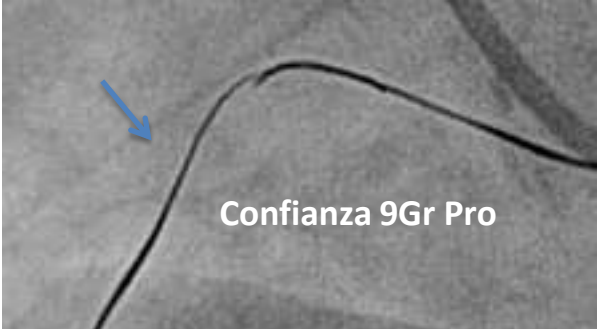
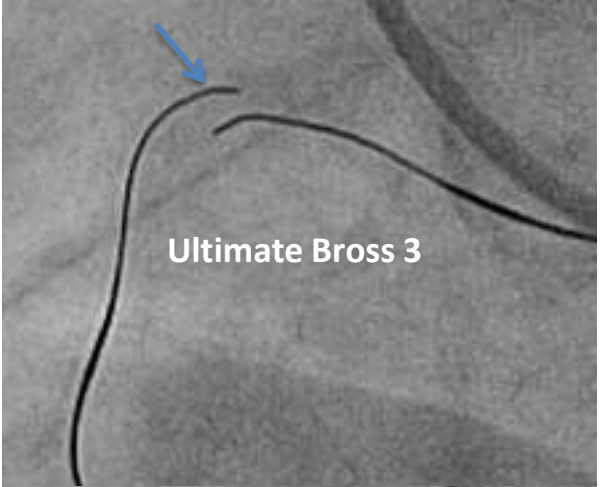
✓ CTO Length: > 20 mm ✓ Lesion length: NA mm ✓ No Clear stump
J- CTO score*: 3, Very difficult

Morino et al. JACC Intv 2011; 4:213-21

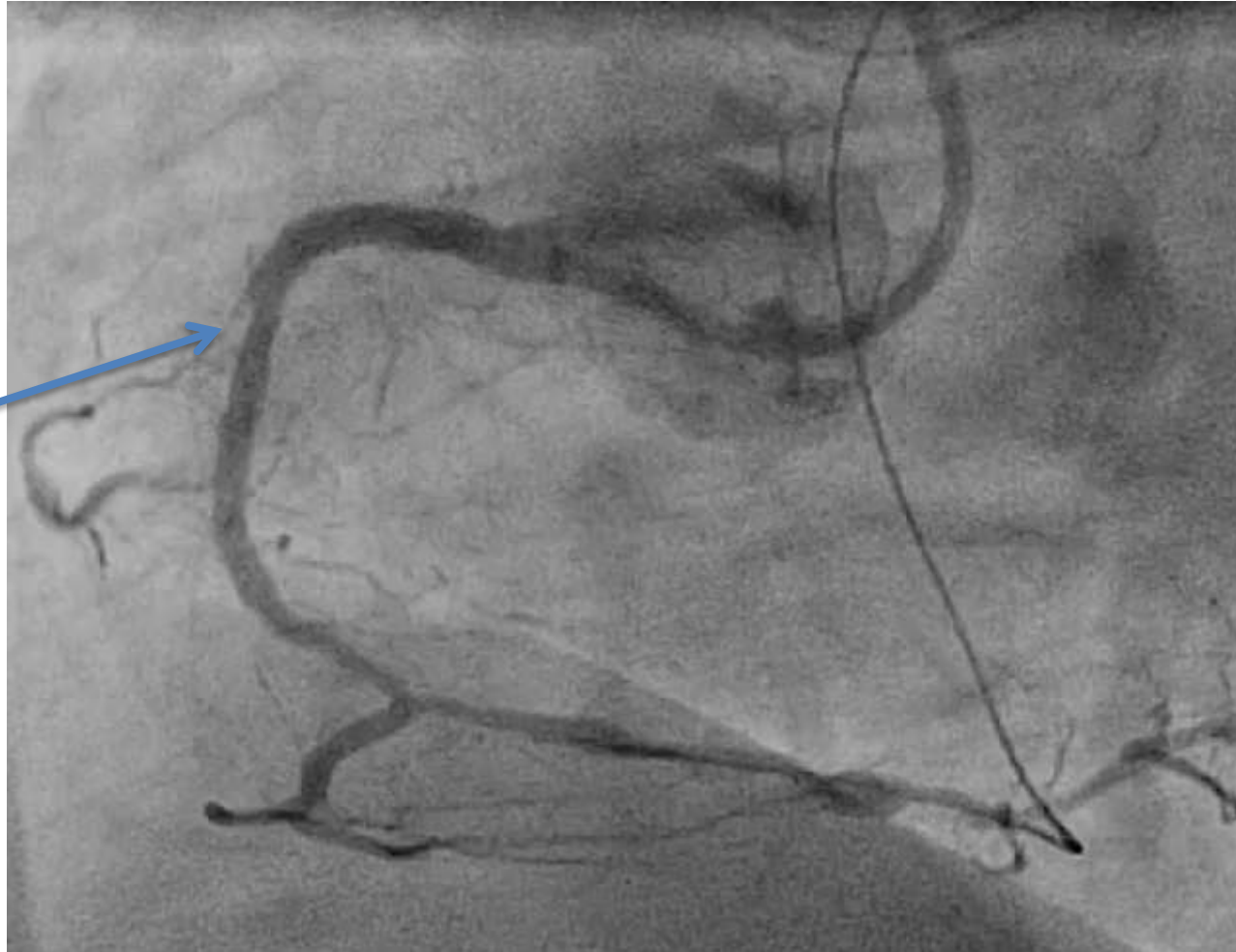
Retrograde approach



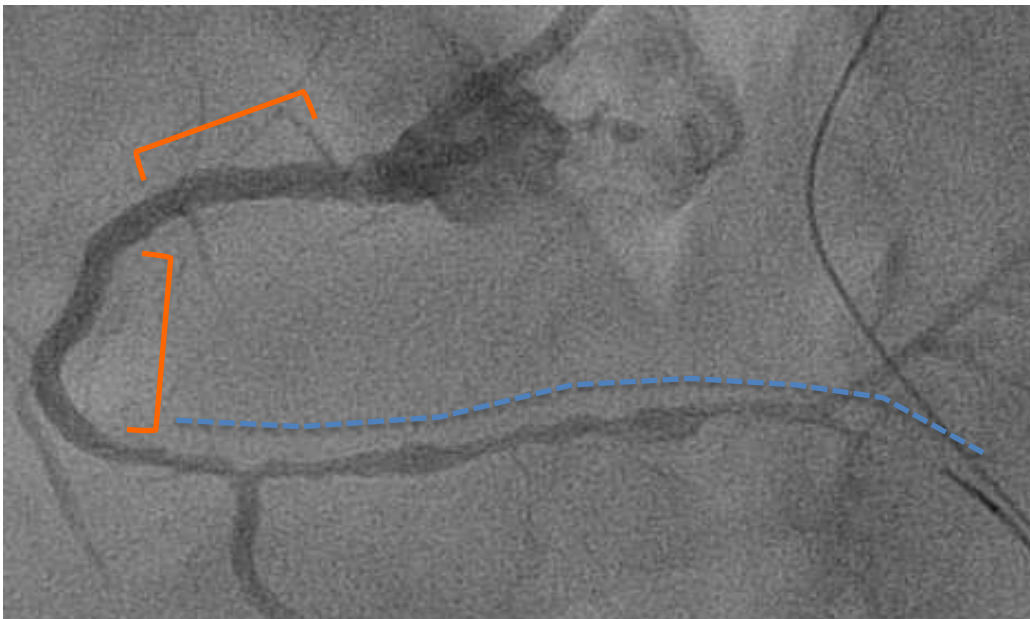
Wire escalation to cross the CTO by retrograde approach



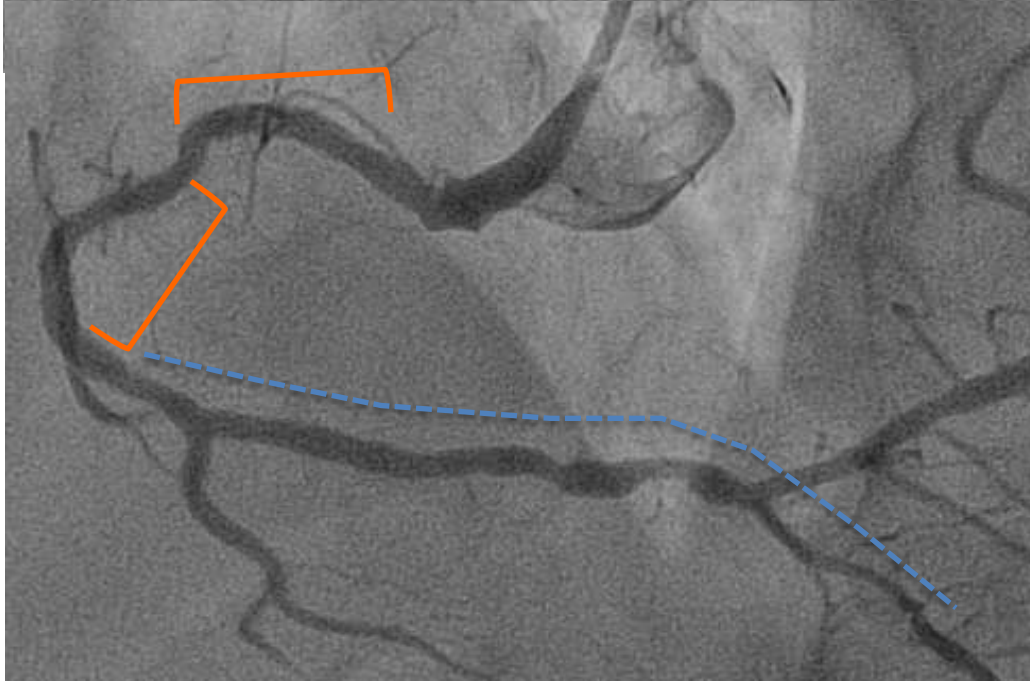
BVS Absorb 3.0 x 28mm & 3.0 x 18mm



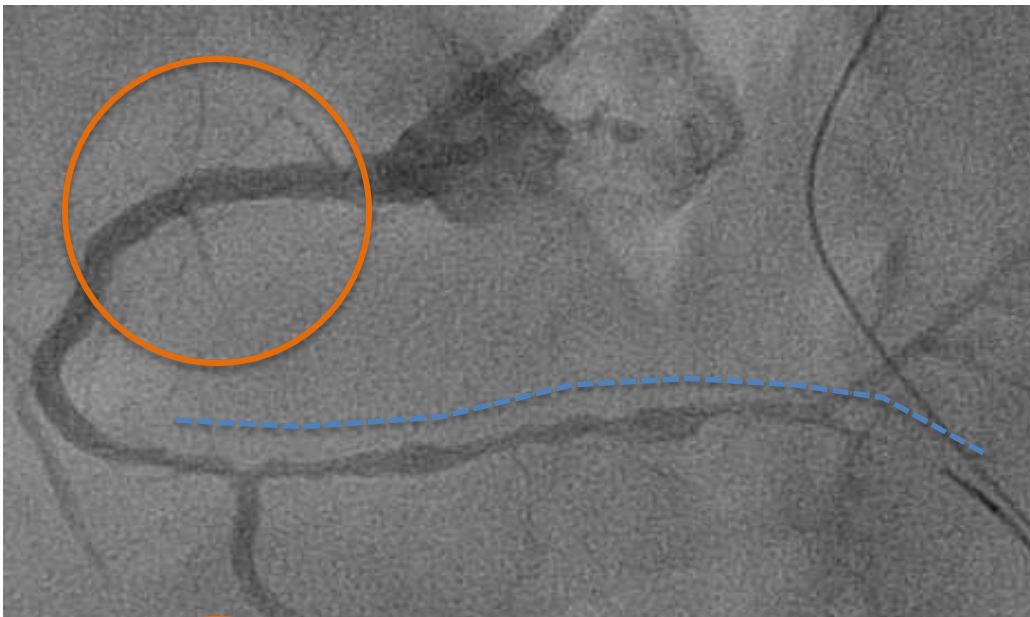
**3.5 x 12mm
NC post-
dilatation**



Immediate result



12m follow-up



Immediate result



12m follow-up

Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study

Beatriz Vaquerizo^{1*}, MD; Antonio Barros¹, MD; Sandra Pujadas¹, MD; Ester Bajo¹, NP; Darlene Estrada¹, MD; F. Miranda-Guardiola², MD; Juan Rigla³, MD, PhD; Marcelo Jiménez¹, MD; Juan Cinca¹, MD; Antonio Serra¹, MD

1. Cardiology Department, Hospital Sant Pau, Barcelona, Spain; 2. Interventional Cardiology Unit, Hospital del Mar, Barcelona, Spain; 3. Perceptual Computing Lab, Faculty of Mathematics, University of Barcelona, Barcelona, Spain

Table 6. Short and midterm outcomes.

	In-hospital	6-month follow-up
Overall death	0 (0)	0 (0)
Cardiac death	0 (0)	0 (0)
Q- or non-Q-wave MI	0 (0)/0 (0)	0 (0)/0 (0)
Target lesion revascularisation	0 (0)	0 (0)
MACE	0 (0)	0 (0)
Scaffold thrombosis	0 (0)	0 (0)
In-scaffold reocclusion*	0 (0)	2 (5.7)
Values are number (%) of patients. *6 months of multislice computed tomography follow-up (100% completed). MACE: major adverse cardiac events; MI: myocardial infarction		

35 Absorb CTO cases assessed at 6 to 8 months

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Registry data
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Propensity analysis
Case report
Registry data
Short series

A Severely Calcified lesion treated with a Mirage scaffold

Pre Procedure

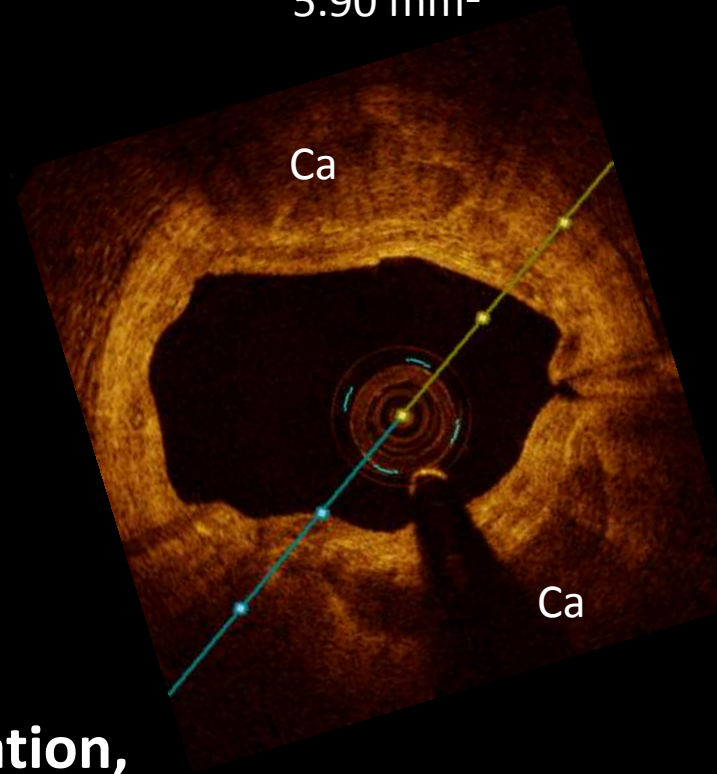
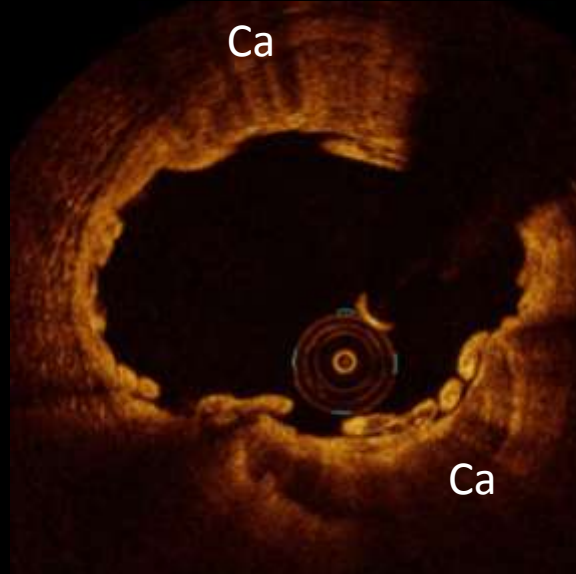
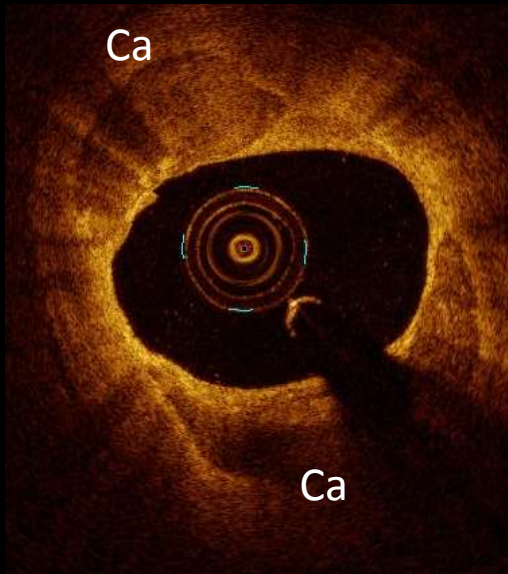
Lumen Area:
3.33 mm²

Post Procedure

Lumen Area:
8.49 mm²

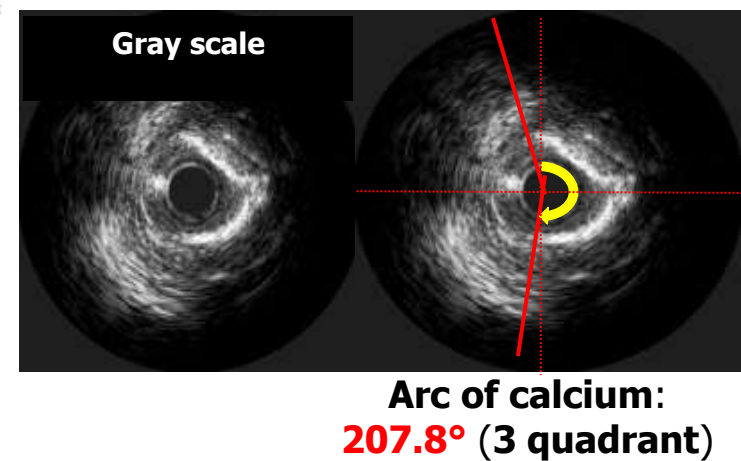
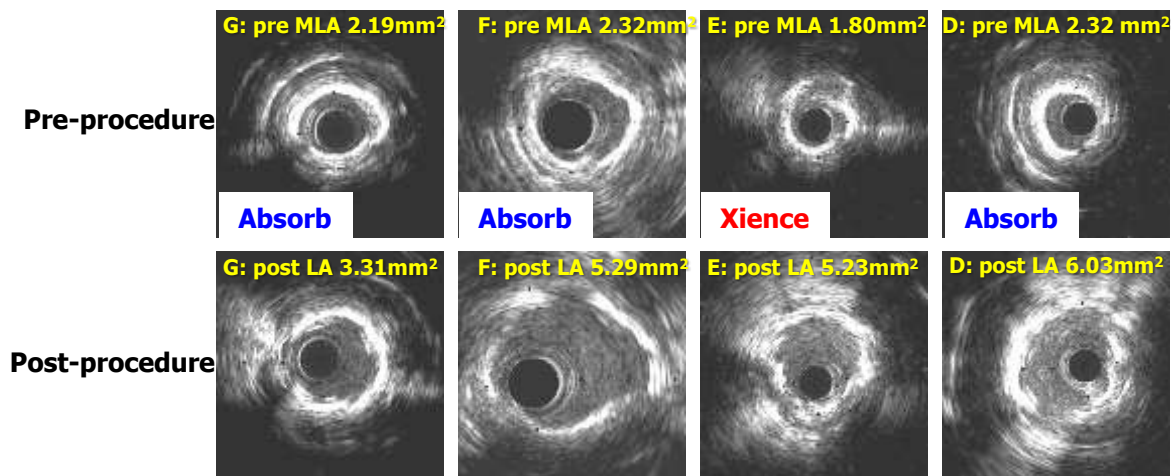
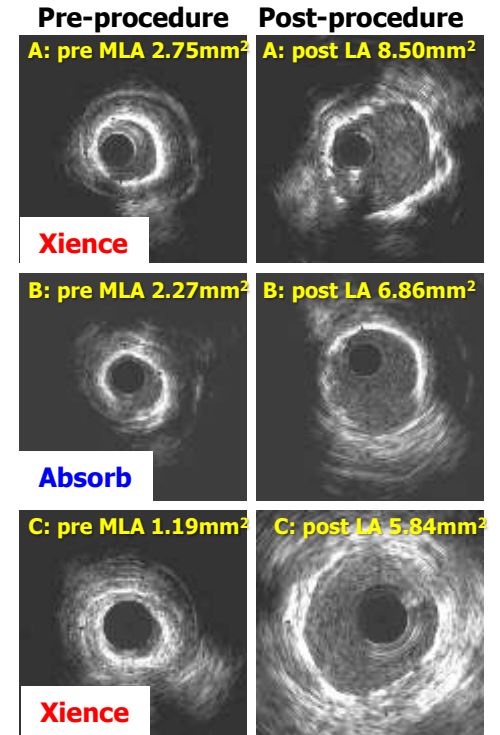
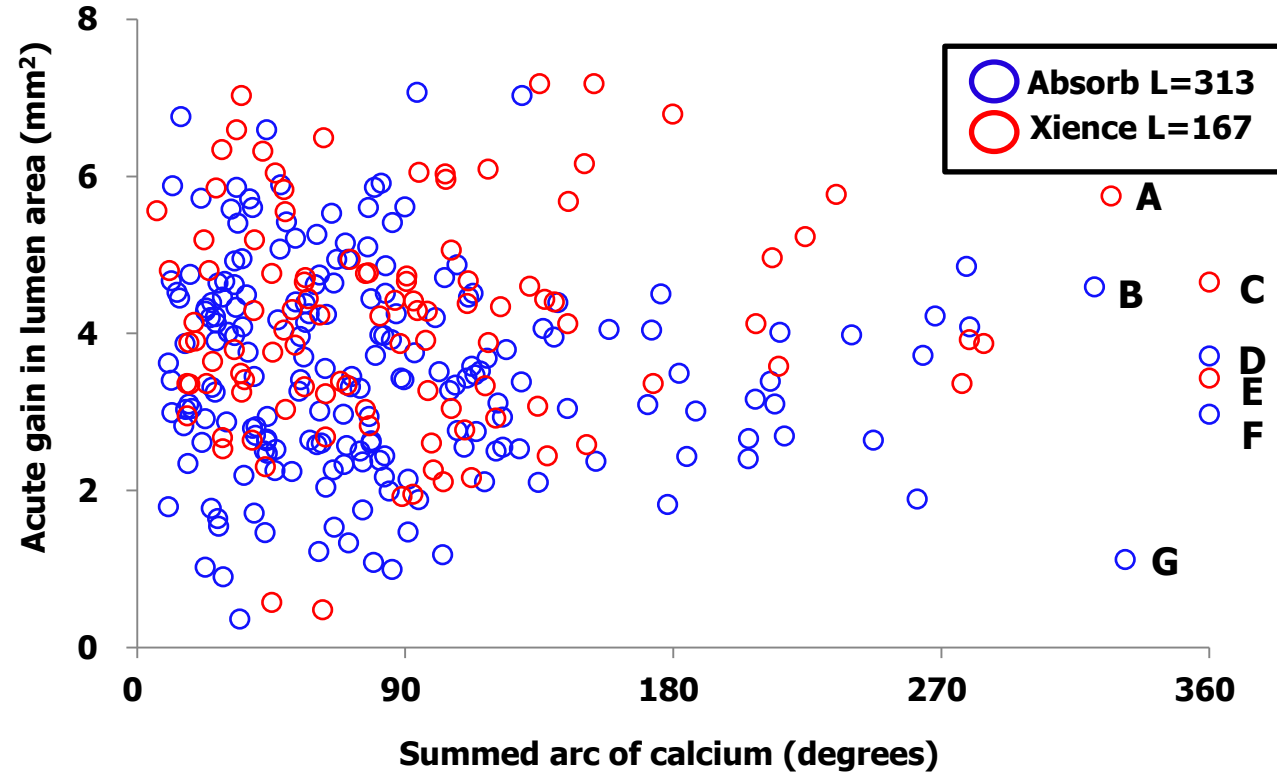
6M follow-up

Lumen Area:
5.90 mm²

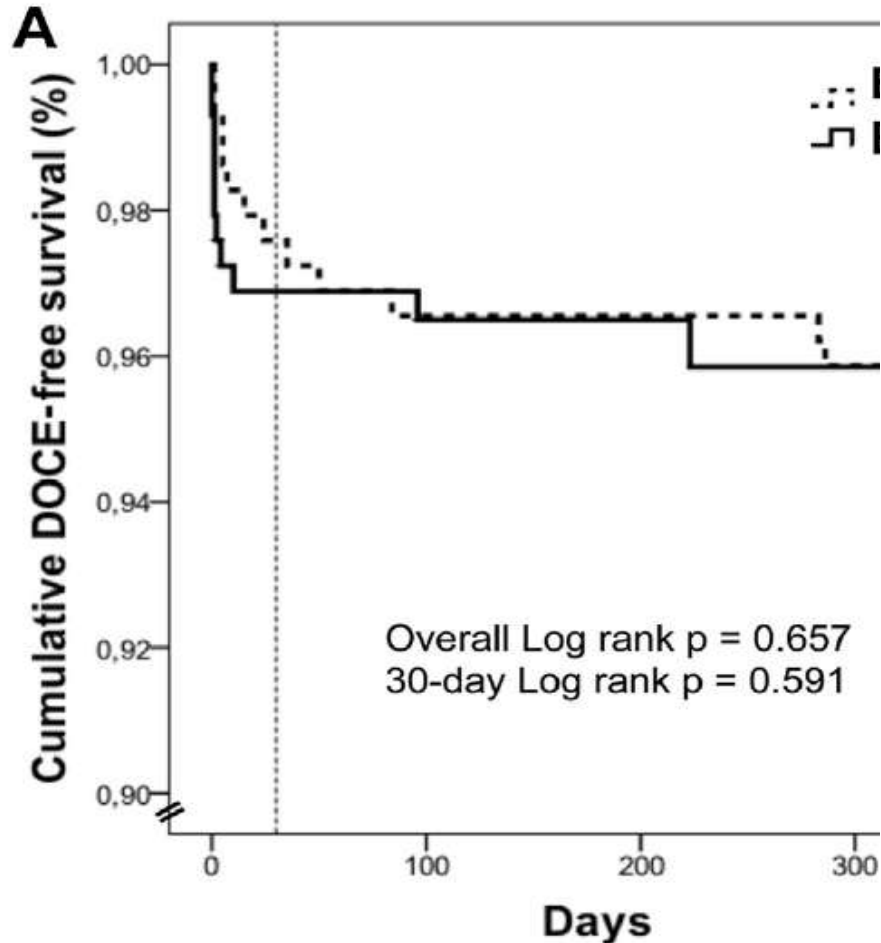


**Despite severe calcification,
the scaffold/lumen expanded quite well.**

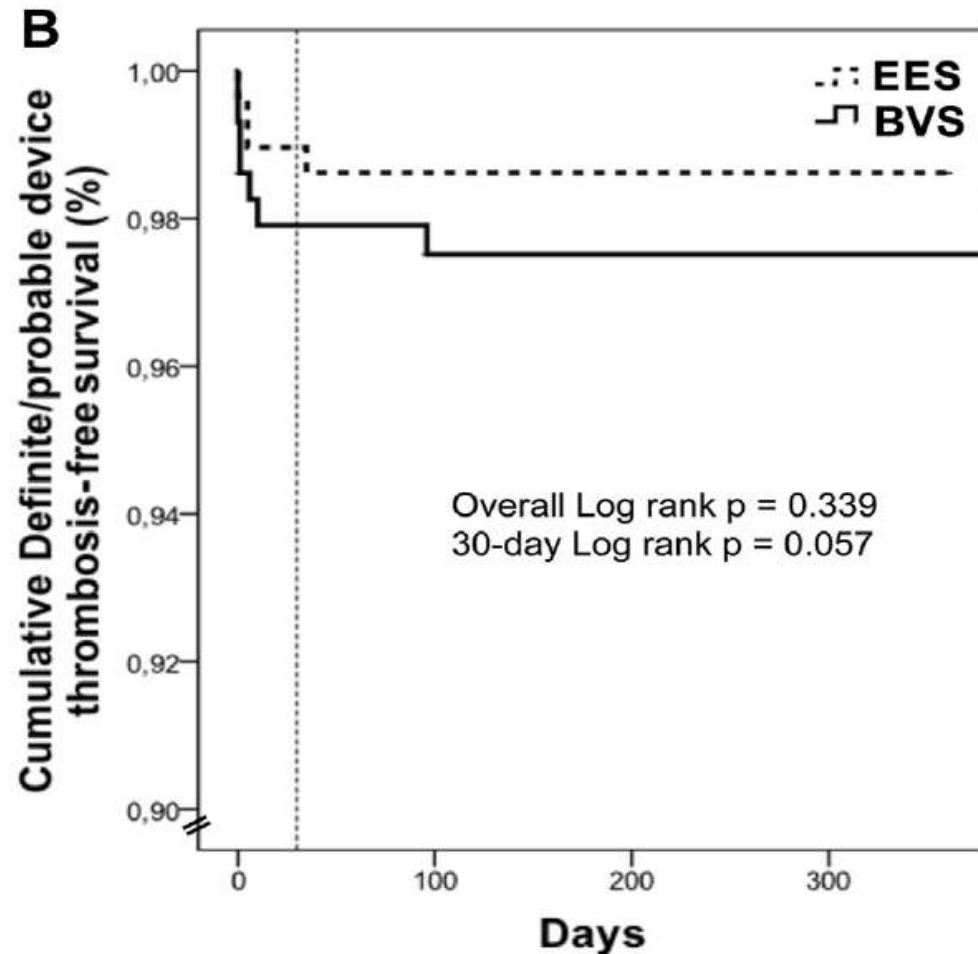
#1. Acute performance: What is the impact of calcification on Acute gain on IVUS?



Absorb Bioresorbable Vascular Scaffold Versus Everolimus-Eluting Metallic Stent in ST-Segment Elevation Myocardial Infarction: 1-Year Results of a Propensity Score Matching Comparison



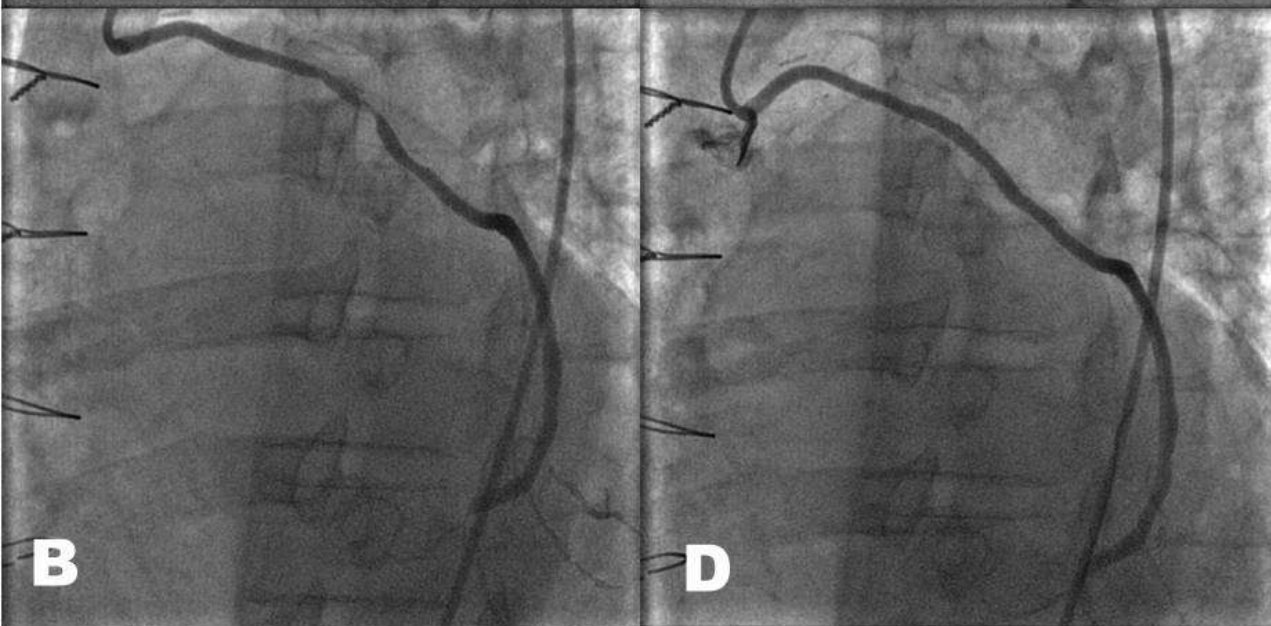
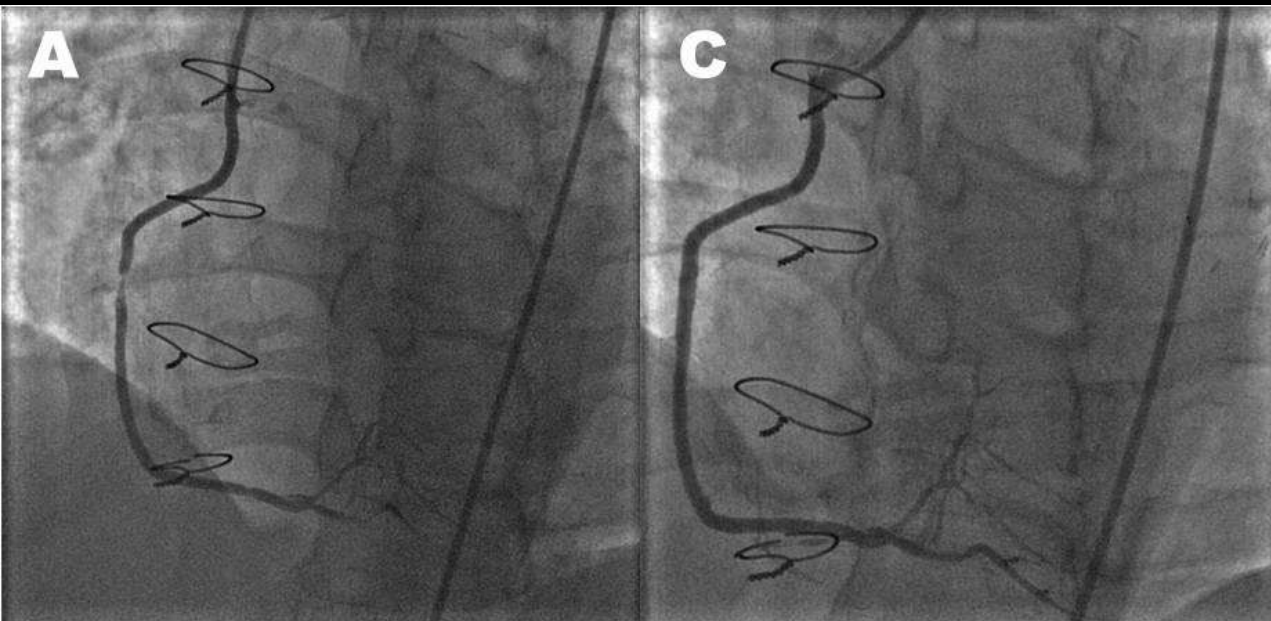
No. at risk				
BVS	290	274	274	272
EES	290	280	280	278



No. at risk				
BVS	290	279	279	279
BMS	290	286	286	286

SVG

By courtesy of Dr. Ong



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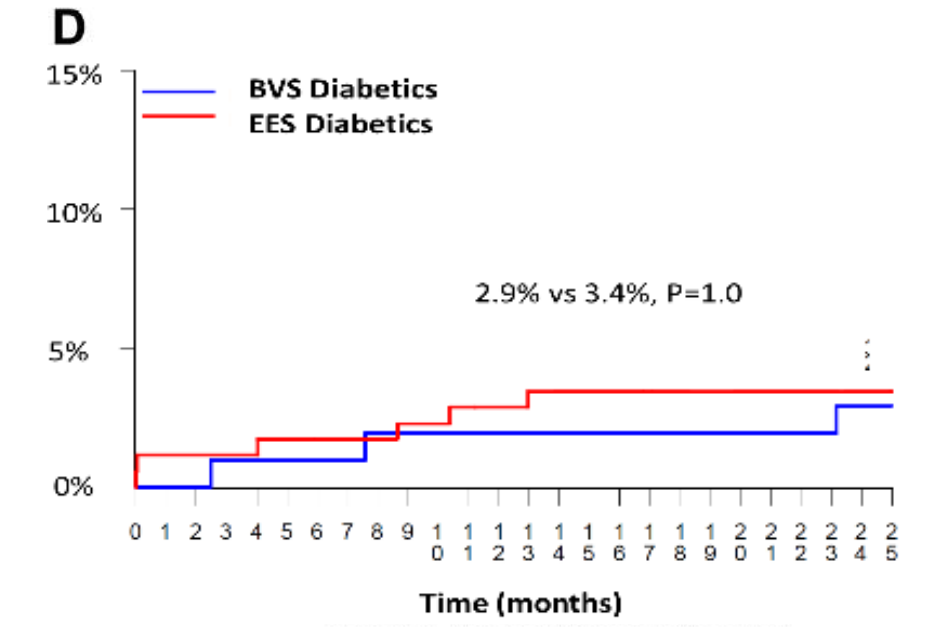
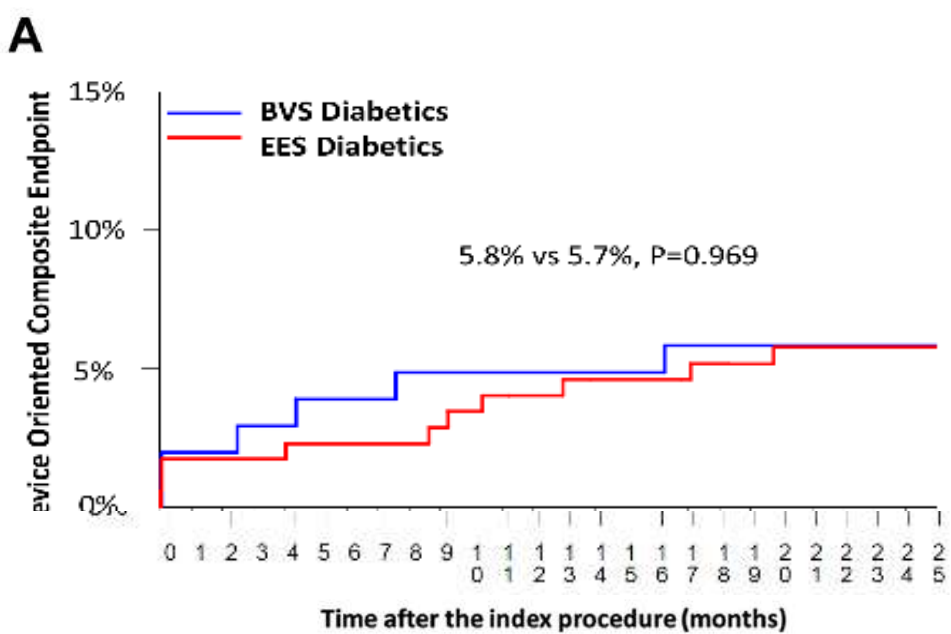
Case report

Registry data

Short series

1-Year Clinical Outcomes of Diabetic Patients Treated With Everolimus-Eluting Bioresorbable Vascular Scaffolds

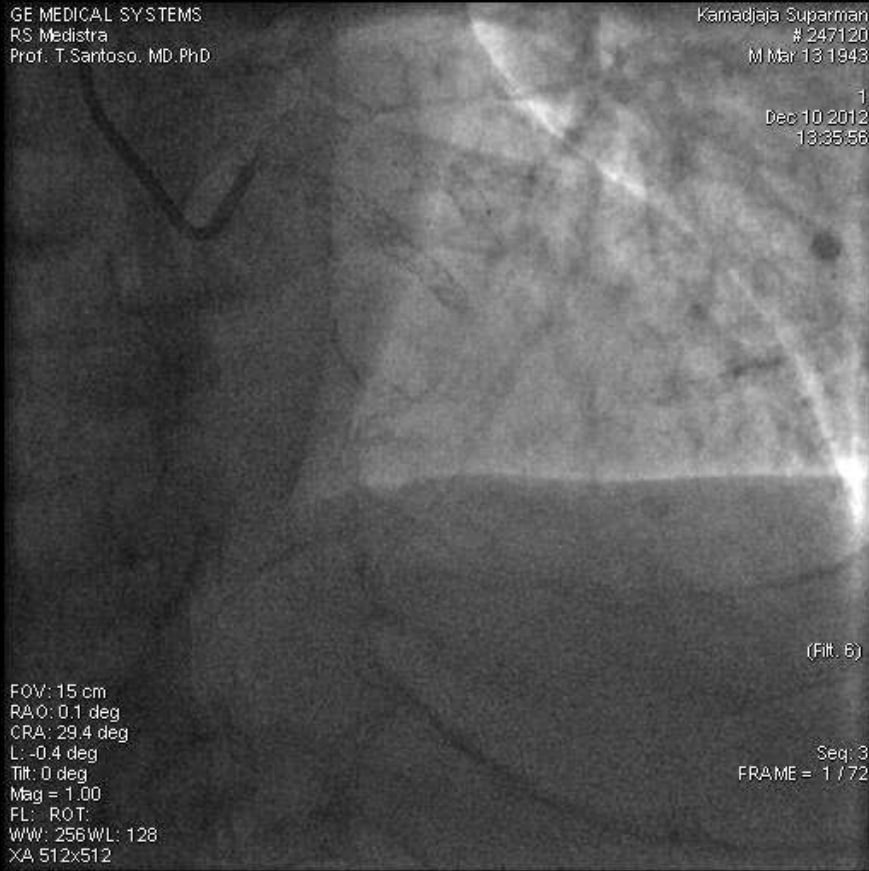
A Pooled Analysis of the ABSORB and the SPIRIT Trials



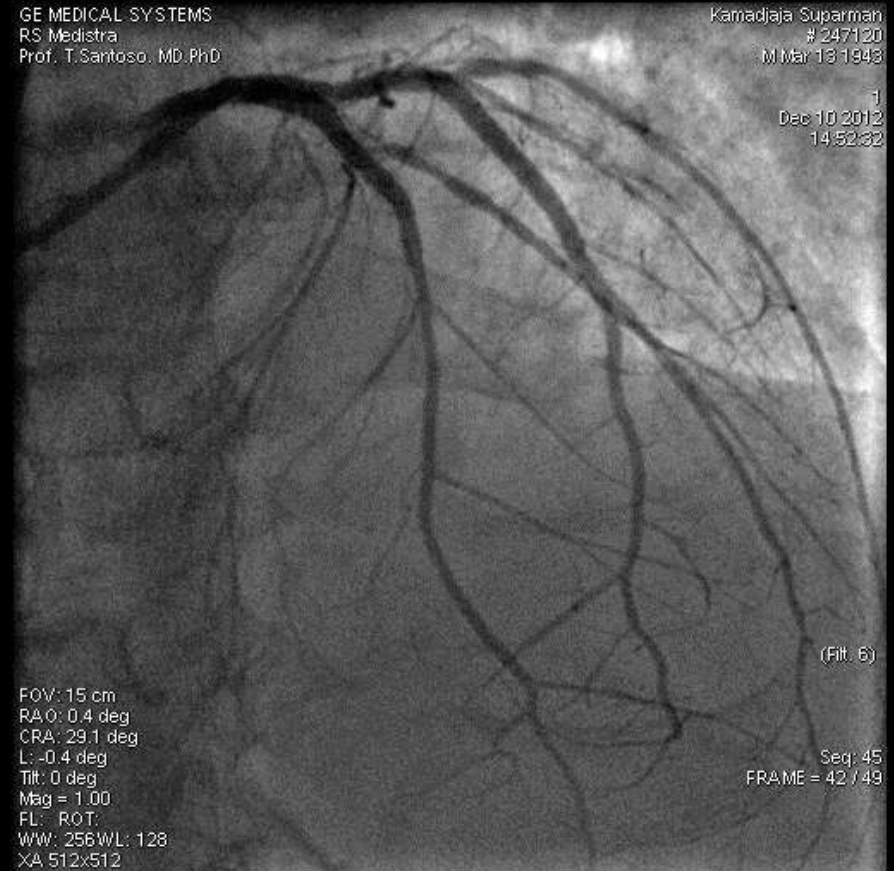
Number at risk (d)	0	37	194	393
BVS Diabetes	102	100	99	98
EES Diabetes	172	169	168	160

Number at risk (d)	0	37	194	393
BVS Diabetes	102	102	101	100
EES Diabetes	172	170	169	162

SK, 69, male, stable angina

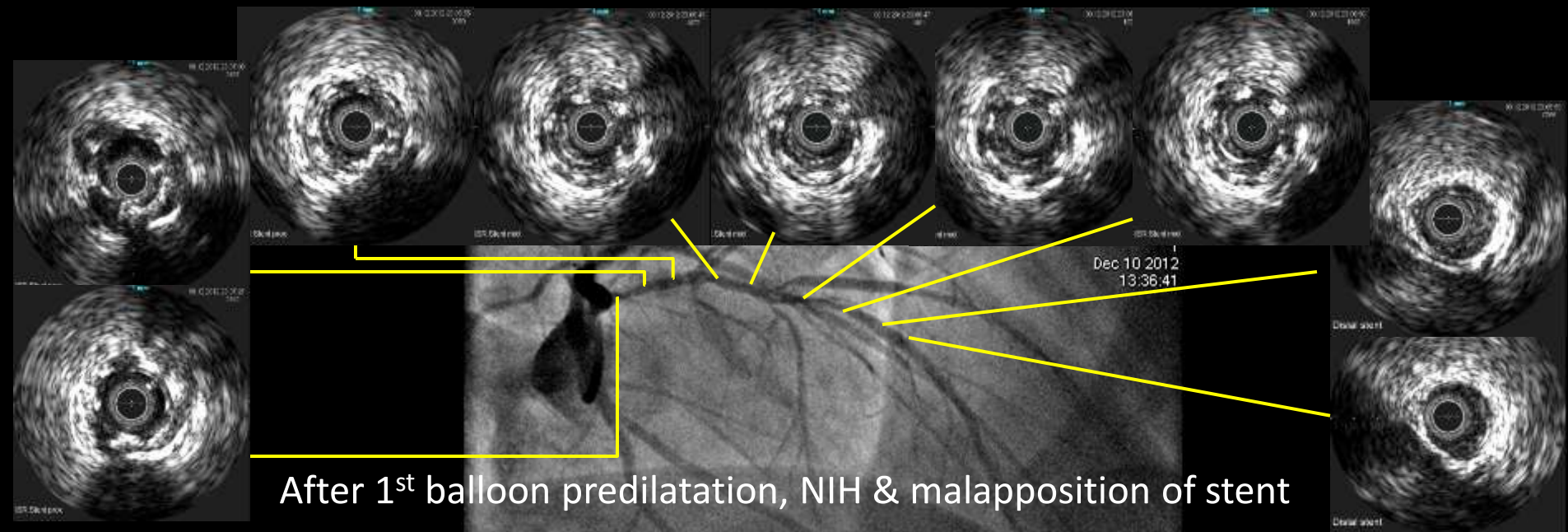


Baseline: proliferative in-stent restenosis in the LADp-m



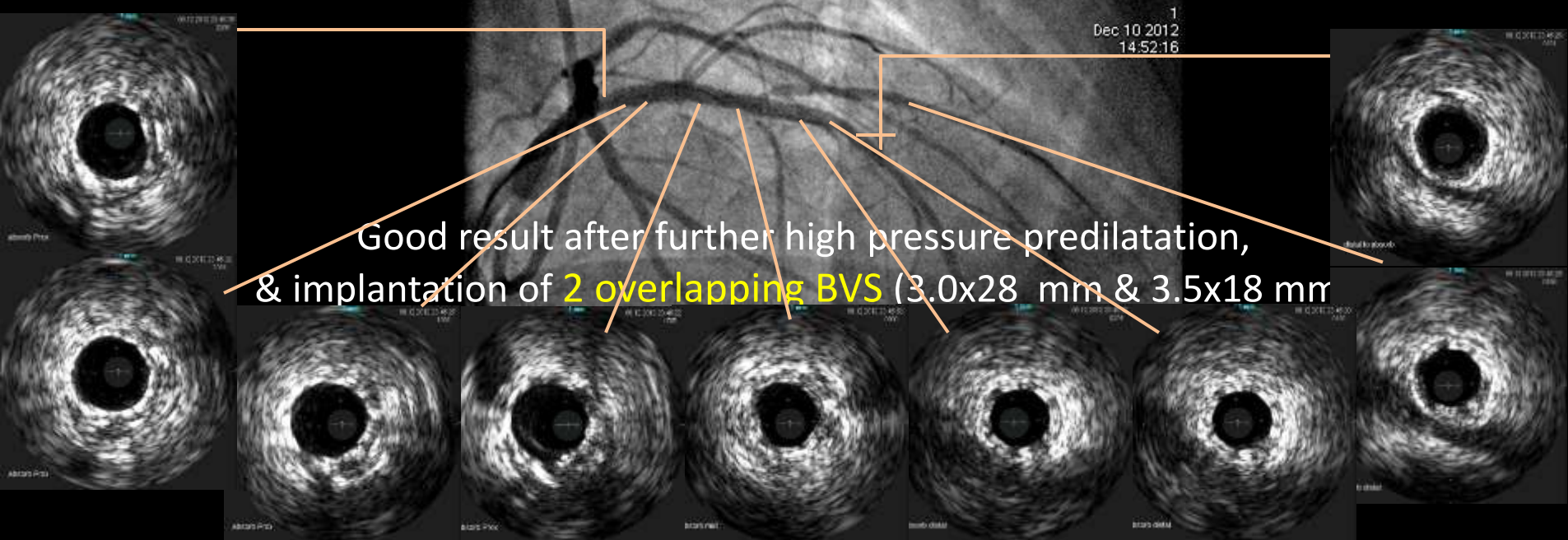
Final: after high pressure dilatation to achieve good lesion preparation & implantation of **2 overlapping BVS** (3.0x28 mm & 3.5x18 mm)

By courtesy of Dr. Santoso



MD, PhD
Prof. T. Santos, MD, PhD

M Mar 13 1943



Early results following everolimus-eluting bioresorbable vascular scaffold implantation for the treatment of in-stent restenosis

Alfonso Ielasi^a, Azeem Latib^{b,d}, Toru Naganuma^{b,d}, Bernardo Cortese^c, Katsumasa Sato^{b,d}, Tadashi Miyazaki^{b,d}, Vasileios F. Panoulas^{b,d}, Maurizio Tespili^a, Antonio Colombo^{b,d,*}

^a Cardiology Department, Bolognini Hospital, Seriate (BG), Italy

^b Interventional Cardiology Unit, EMO-GVM Centro Cuore Columbus, Milan, Italy

^c Catheterization Laboratory, Fatebenefratelli Hospital, Milan, Italy

^d San Raffaele Scientific Institute, Milan, Italy

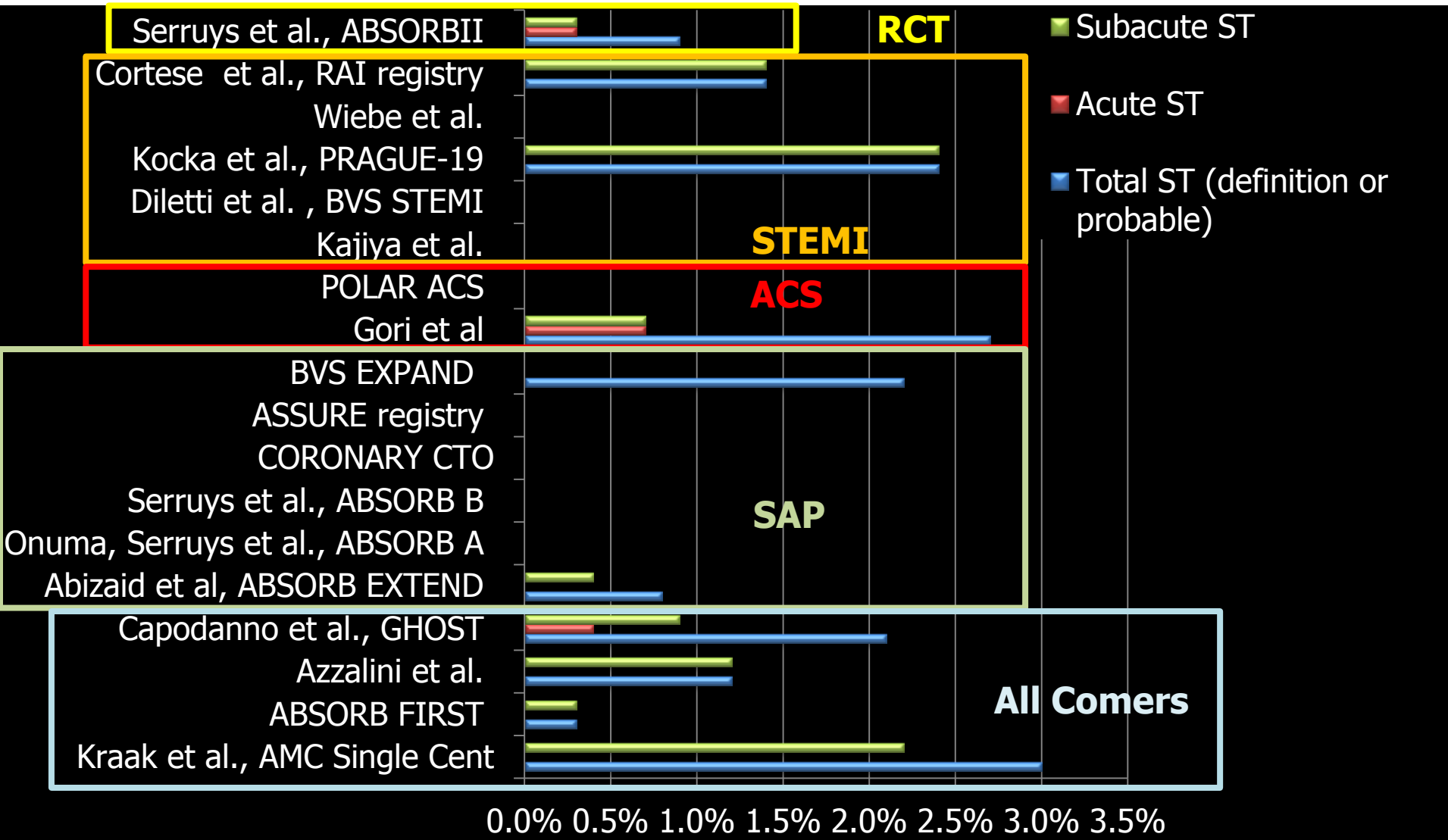
Table 2

In-hospital and early outcomes following BVS implantation for ISR.

Number of patients	25
<i>In-hospital events</i>	
Peri-procedural MI, n (%)	1 (4.0)
Death, n (%)	0
Intraprocedural/acute “BVS-in-stent” thrombosis, n (%)	0
Follow-up period (months), median (IQR)	7 (1–11)
<i>Follow-up events</i>	
Death, n (%)	0
Cardiac death, n (%)	0
MI, n (%)	1 (4.0)
TVR, n (%)	1 (4.0)
TLR per patient, n (%)	2 (8.0)
TLR per lesion, n (%)	2 (6.6)
ARC definite/probable “BVS-in-stent” thrombosis, n (%)	0

MI: non ST-elevation myocardial infarction; IQR: interquartile range; BVS: bioresorbable vascular scaffold; ISR: in-stent restenosis; TVR: target vessel revascularization; TLR: target lesion revascularization; and ARC: Academic Research Consortium.

Definite and probable bioresorbable scaffold thrombosis in stable and ACS patients



The Landscape of BRS Randomized Trial -2

Study /Country	Number	Population	Exclusion	Control	Primary endpoint	Start date
Bioresorbable Vascular Scaffold in Patients With Myocardial Infarction /Italy	100	STEMI		Xience	Procedural and clinical success in the duration of hospital stay	May 2013
AIDA /Netherlands	2690	All-comer		Xience	TVF at 2year	Aug 2013
ISAR-Absorb MI /Germany	260	STEMI		Xience	%DS at 6-8 months	Sep 2013
The TROFI II study /Denmark, Netherlands, Spain, Switzerland	190	STEMI		Xience	Healing score at 6 months	Dec 2013
PROSPECT ABSORB /Sweden, Norway, Denmark	300	ACS		Sham	MLA at 2 years TLF at 2 years	Jun 2014
Performance of Bioresorbable Scaffold in Primary Percutaneous Intervention of ST Elevation Myocardial Infarct /Norway	120	STEMI		Drug eluting stent	<ul style="list-style-type: none"> Minimum flow area with OCT at 1year MSCT at 2years compared with CAG and OCT at 1year 	Mar 2014
COMPARE / Europe	2100	All-comer		Xience	<ul style="list-style-type: none"> Ischemia driven DOCE 	April 2015

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