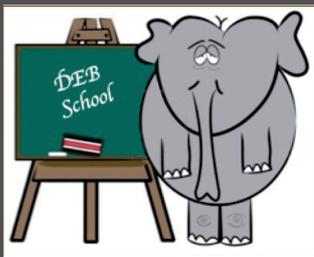


a drug-coated scoring balloon for coronary use



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Potential conflicts of interest

Speaker's name: Bernardo Cortese

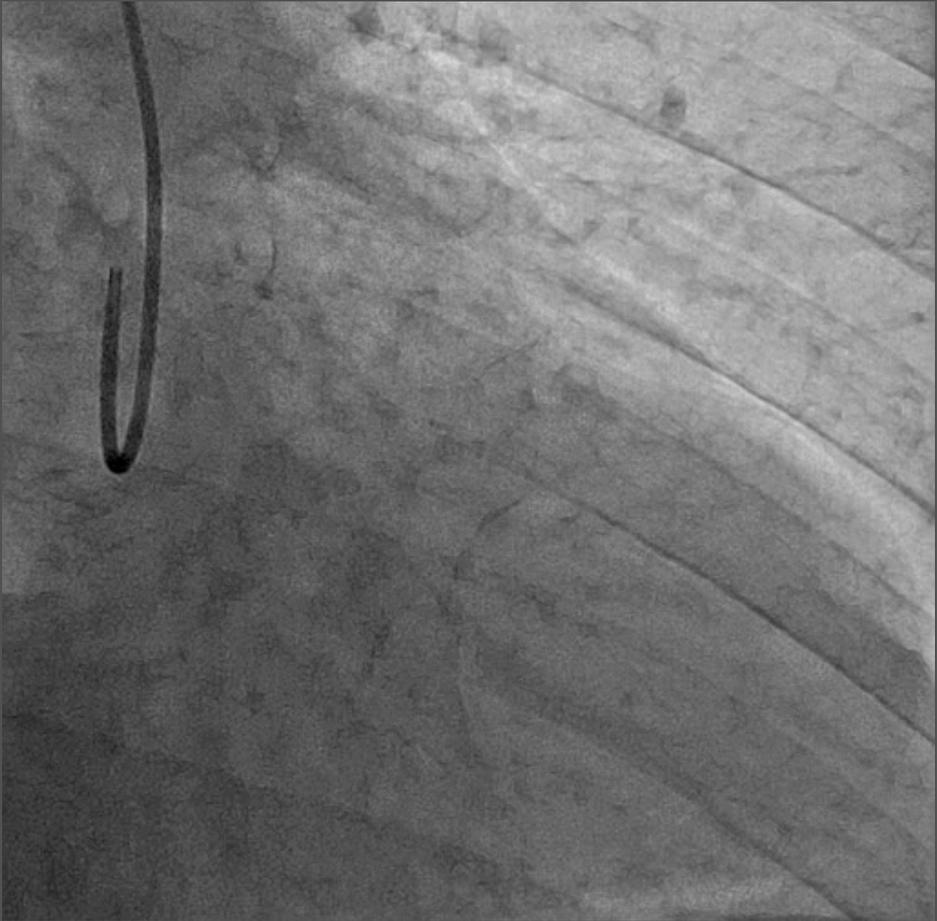
I have the following potential conflicts of interest to report (last 2 years):

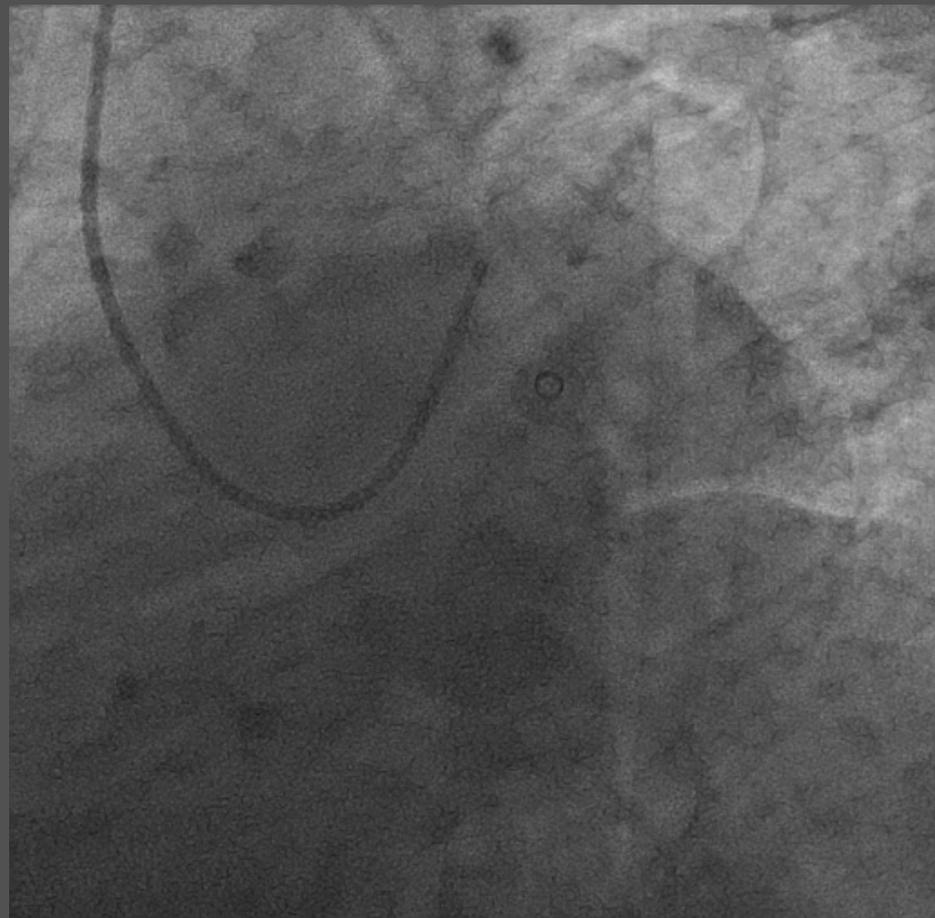
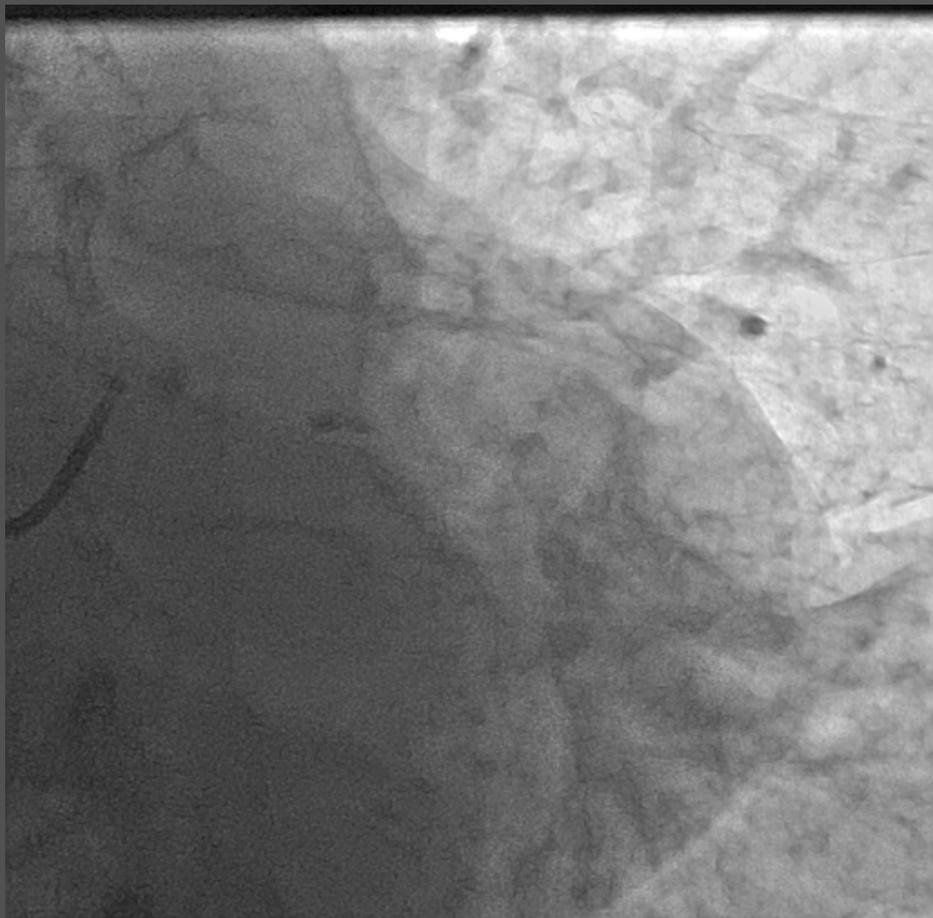
Consultant: Aachen Resonance, Abbott Vascular, Astra Zeneca, Kardia, Innova, Stentys, Daiiki-Sankyo.

Honorarium: Hexacath, Amgen

Institutional grant/research support: AB Medica, St Jude

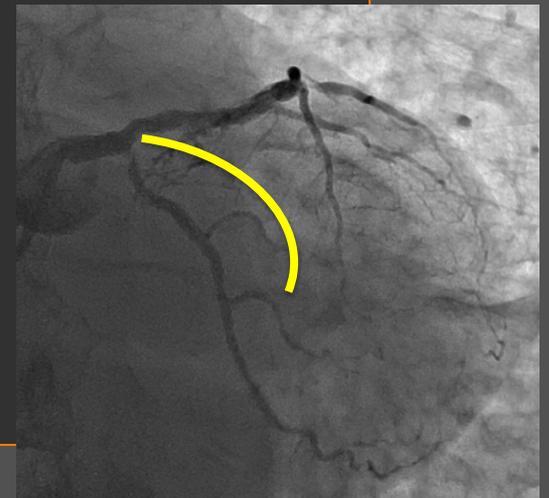
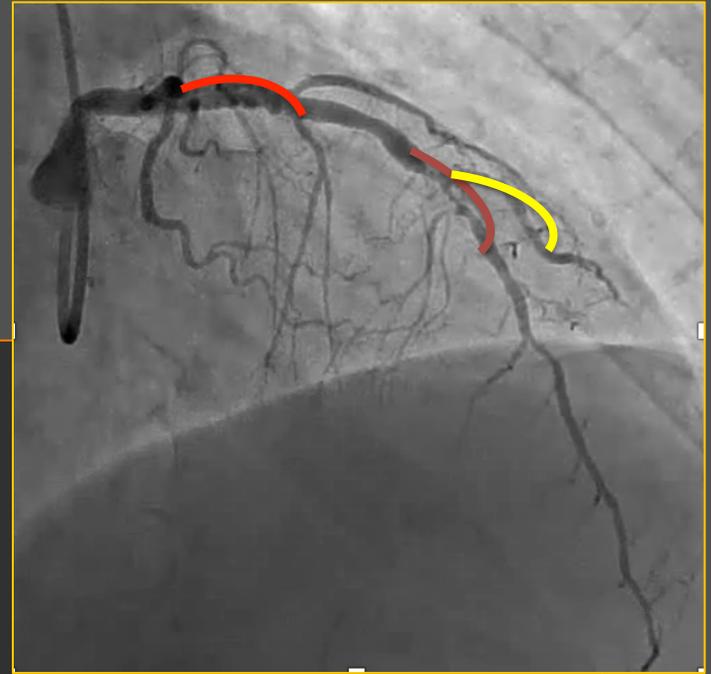
- Male, 71 y.o.
- fam + CAD
- dyslipidemia
- effort angina
- LV EF 65%

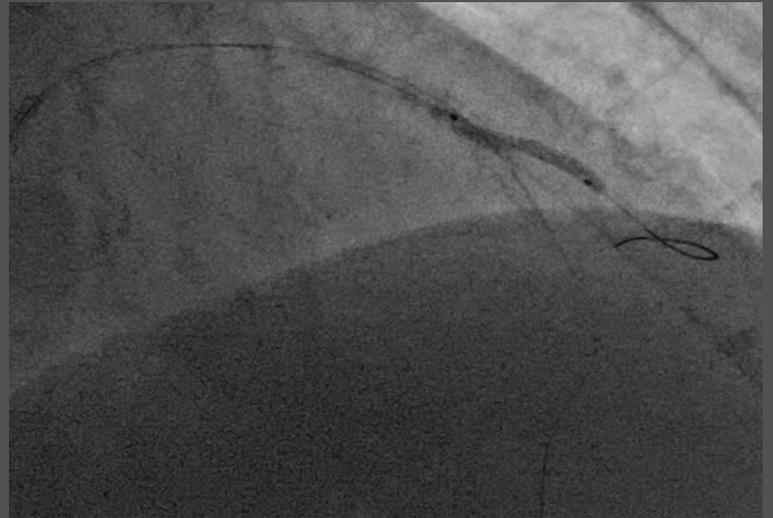
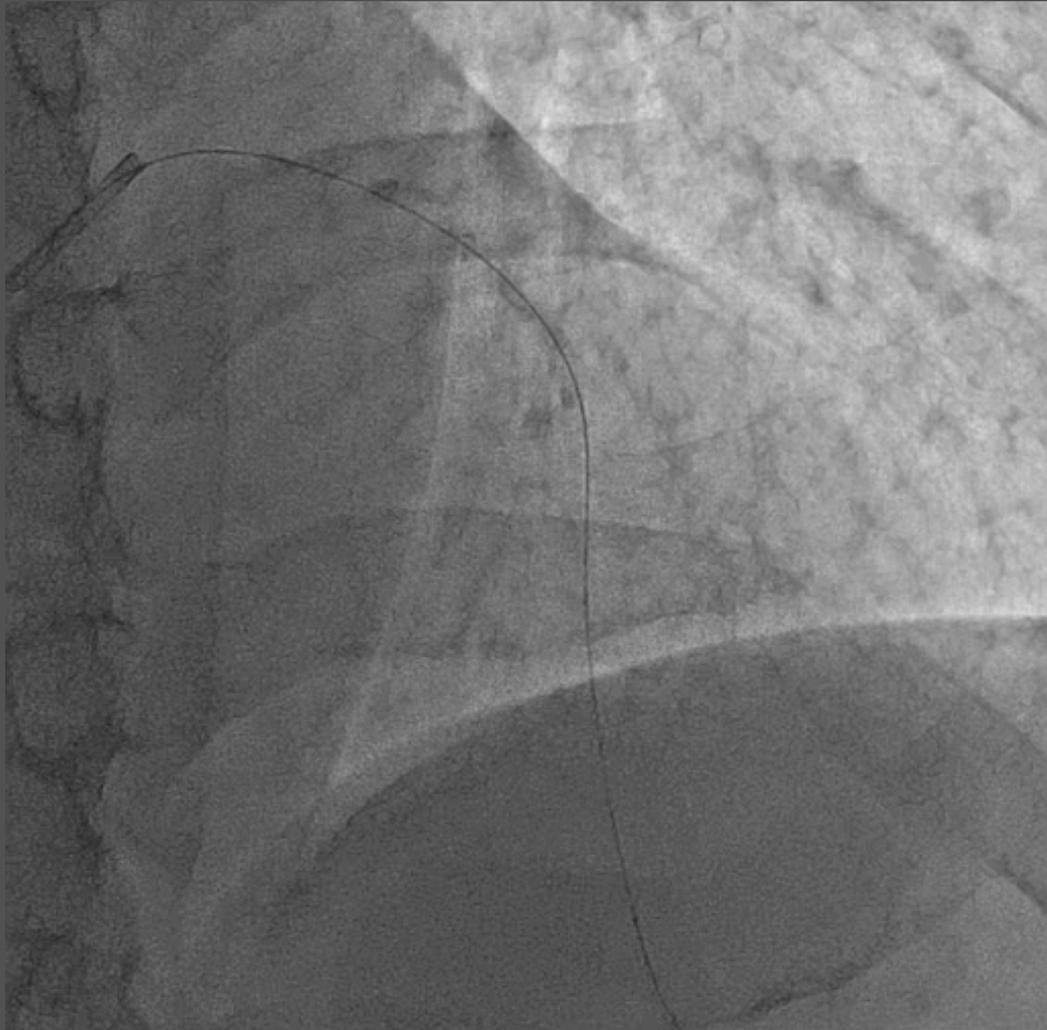




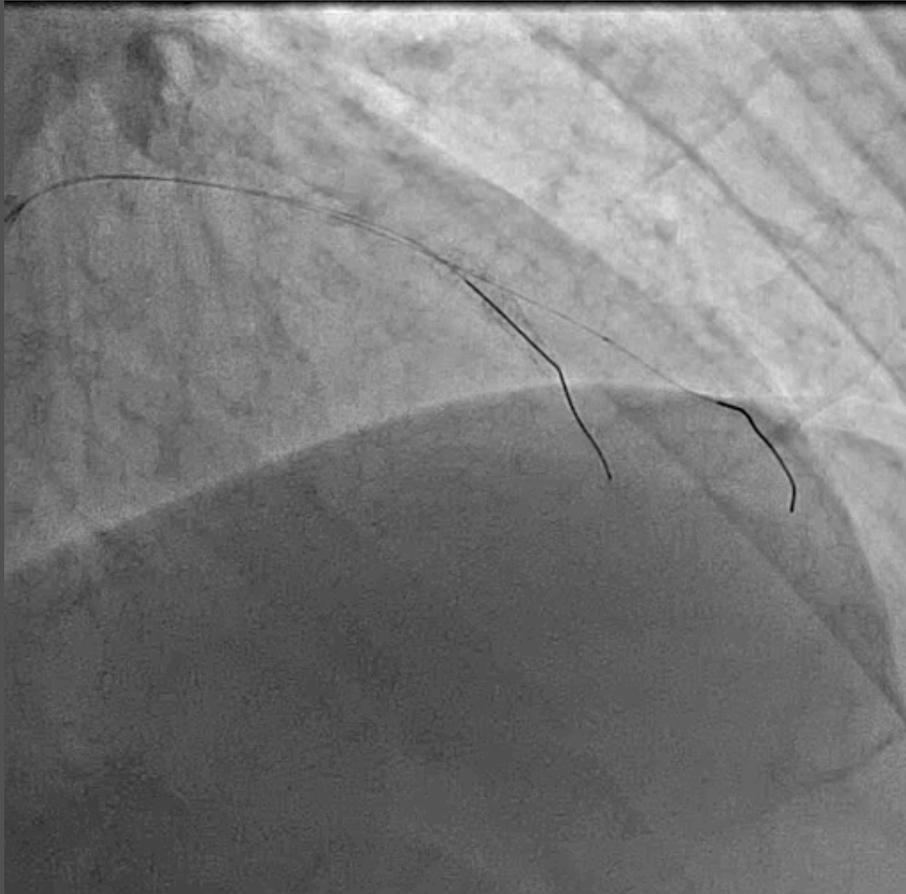
Planning:

- DES mid-LAD
- auto-expandable DES prox-LAD
- DCB ostial DIA1
- DES/DCB IR



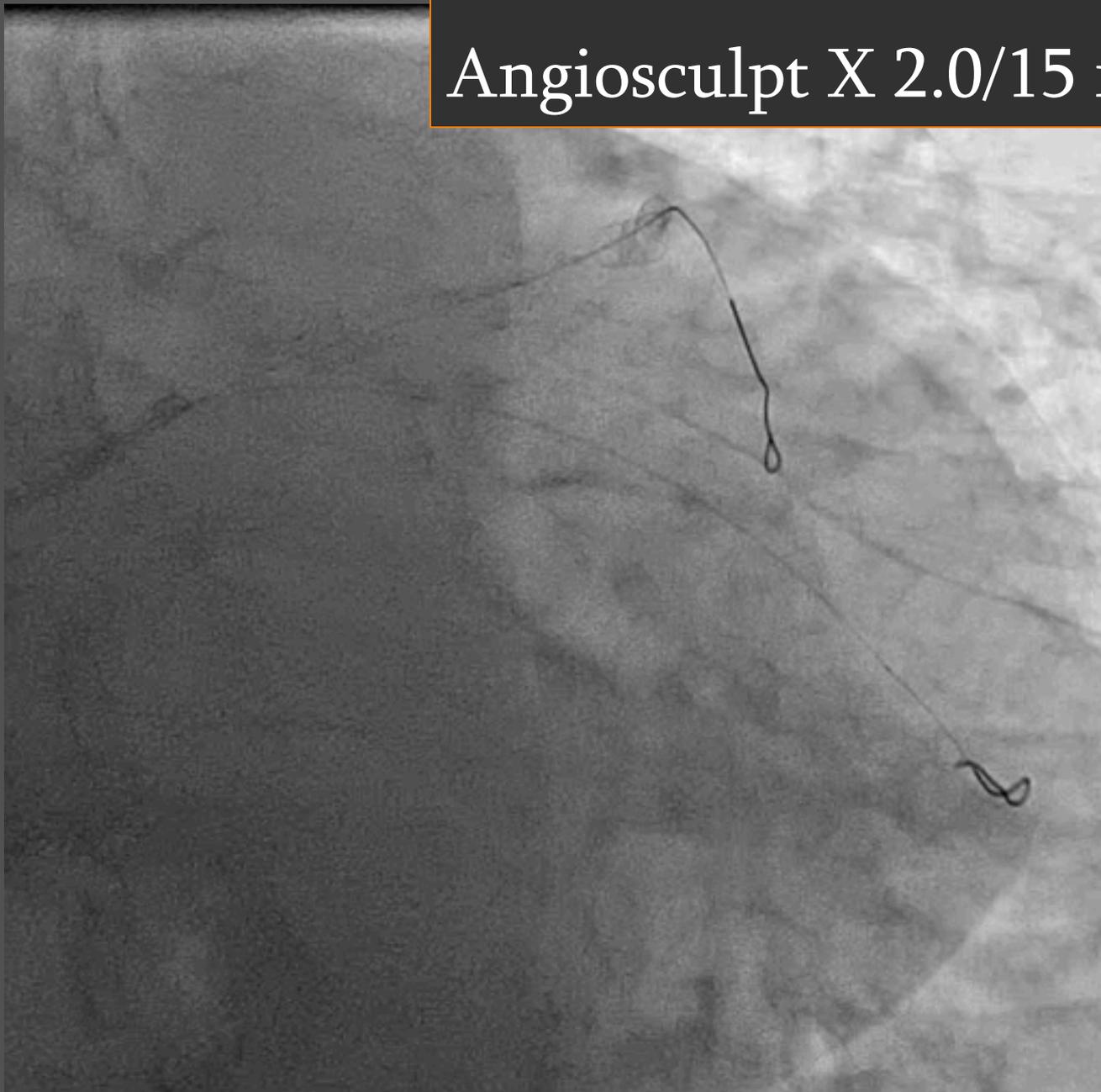


Angiosculpt X 2.0/20



Persisting dissection (A),
final stenosis 50%

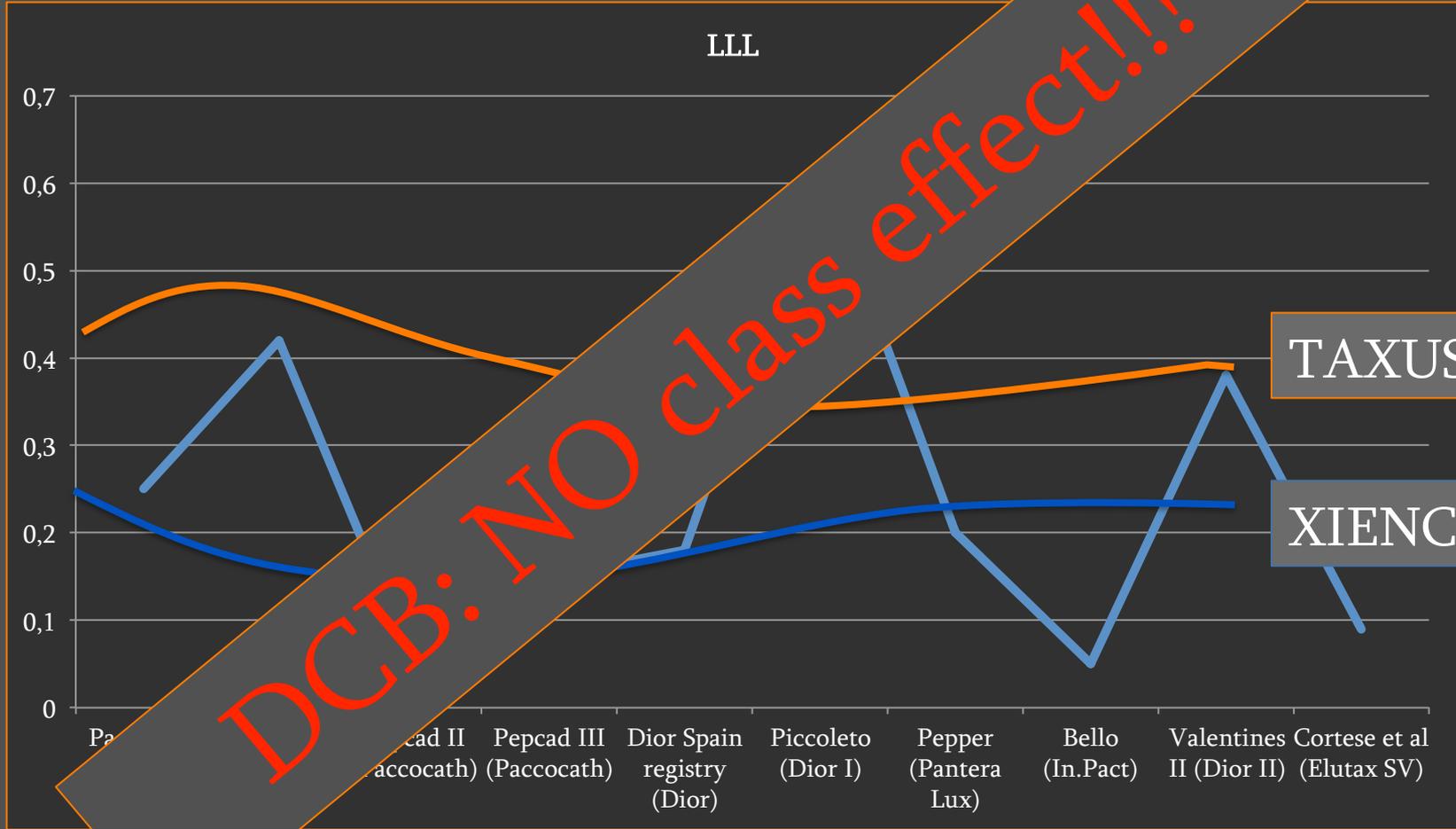
Angiosculpt X 2.0/15 x2



DCB goals

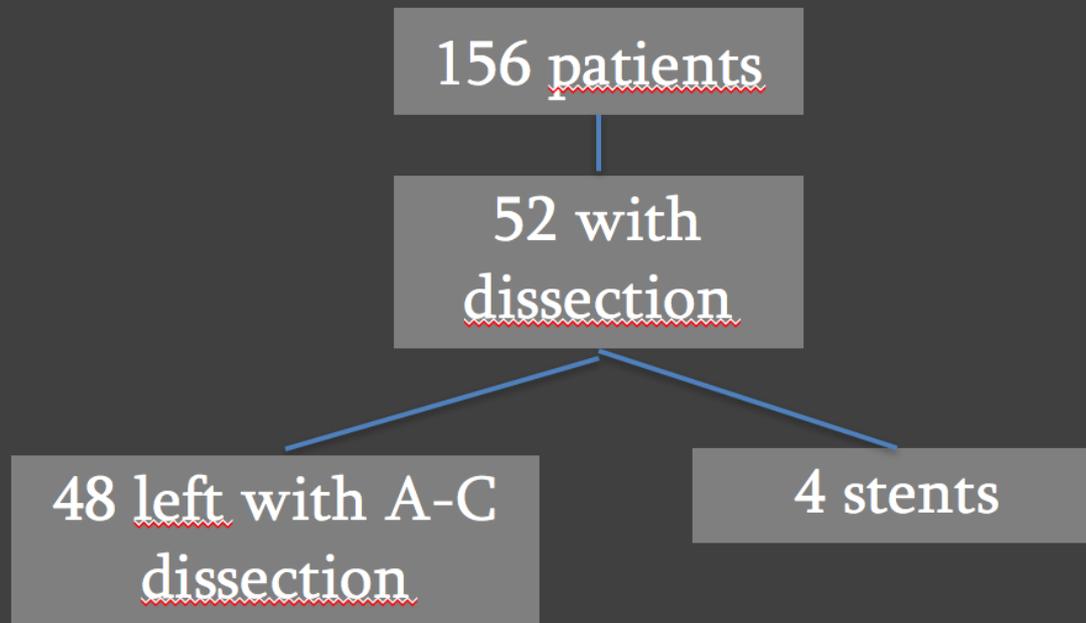
- antiproliferative effect,
- single shot, efficacious drug delivery,
- diffuse drug delivery,
- prolonged uptake and sustained effect,
- no permanent implants and their consequences.

DCB: the LLL dispersion

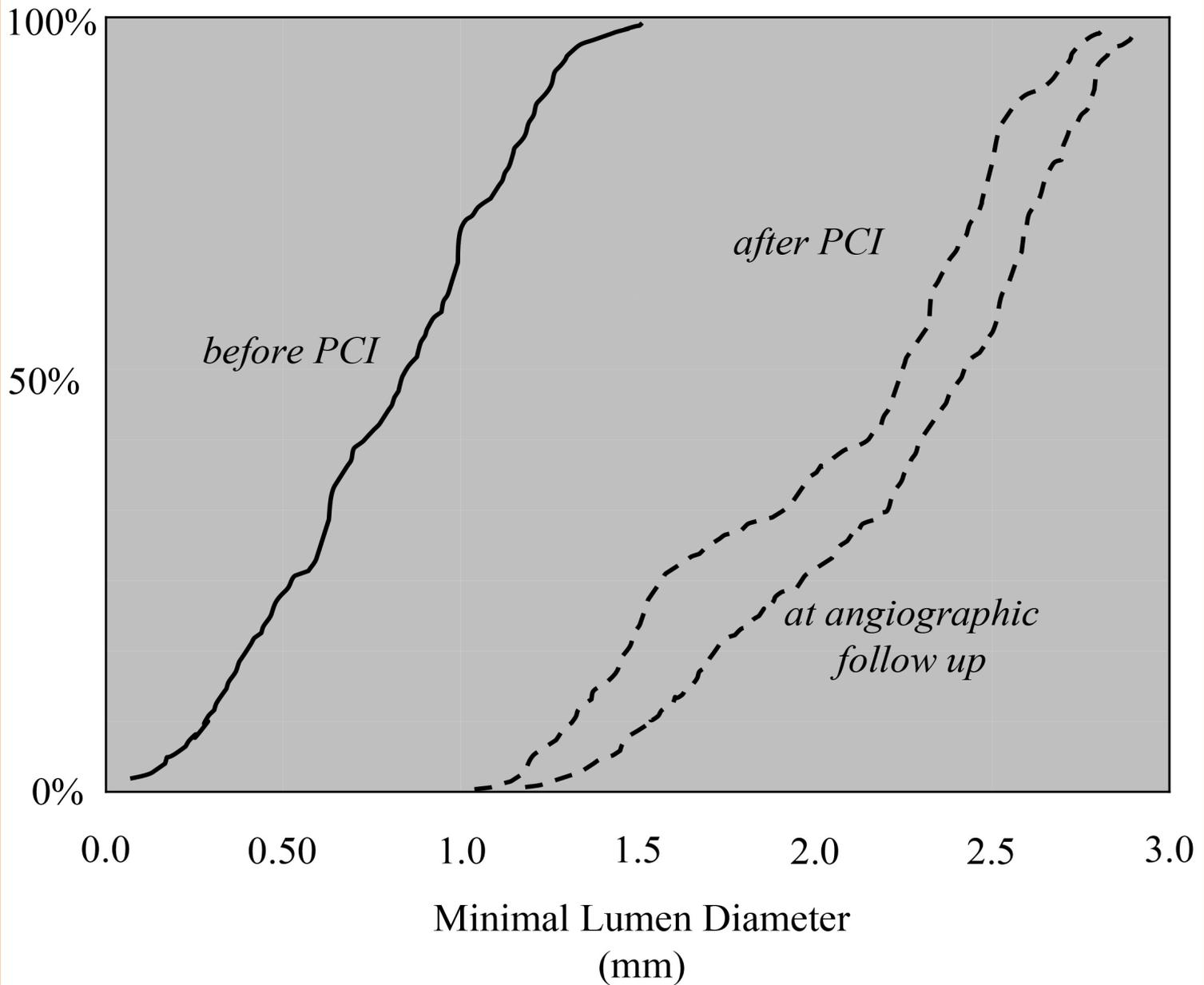


Coronary dissection healing with DCB

July 2012-July 2014: DCB in native coronary vessels



6-month angio follow up



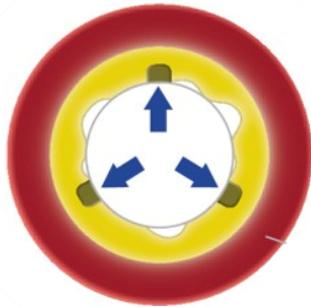
Coronary dissection healing with DCB

Reference vessel diameter (mm) *	2.87 (2.11-2.98)
Minimal lumen diameter (mm) *	2.42 (2.22-2.66)
Diameter stenosis %*	12 (8-20)
LLL (mm) *	0.14 (-0.14-0.42)
Complete vessel healing (%)	45 (93.8)
Binary restenosis (%)	3 (6.2)

ANGIOSCULPT-X Device Specifications:



Plaque Scoring



Controlled Dissections

- ✓ Higher Stability and Dilation Power
- ✓ Better acute Luminal Gain and ↓ Recoil
- ✓ Lower Major Dissection Rate
- ✓ Enhance drug delivery/retention
- ✓ Improve stent expansion

- AngioSculpt PTCA platform
- Rapid exchange
- 4 diameters: 2.0, 2.5, 3.0, 3.5 mm
- 3 lengths: 10, 15, 20 mm
- Compliance range: 8-20 atm

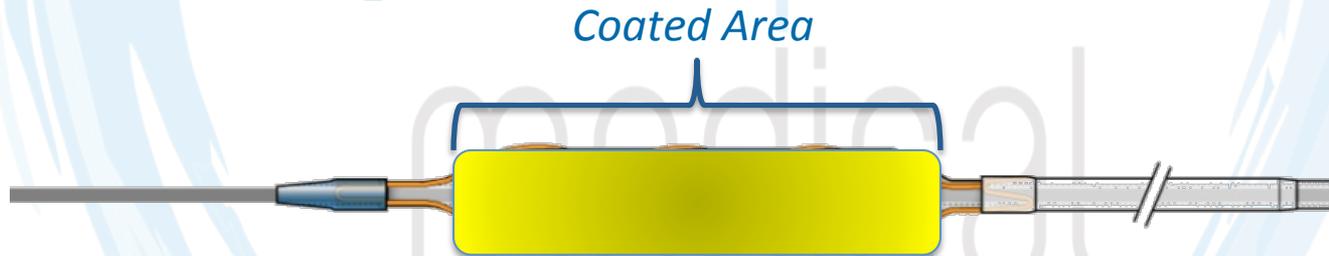
ANGIOSCULPT-X coating

- Non-polymer based formulation of drug + excipient

Paclitaxel
Surface concentration = 3 $\mu\text{g}/\text{mm}^2$

NDGA Excipient
Minimizes drug release until balloon inflation
Designed for homogeneous drug distribution
to target vessel wall

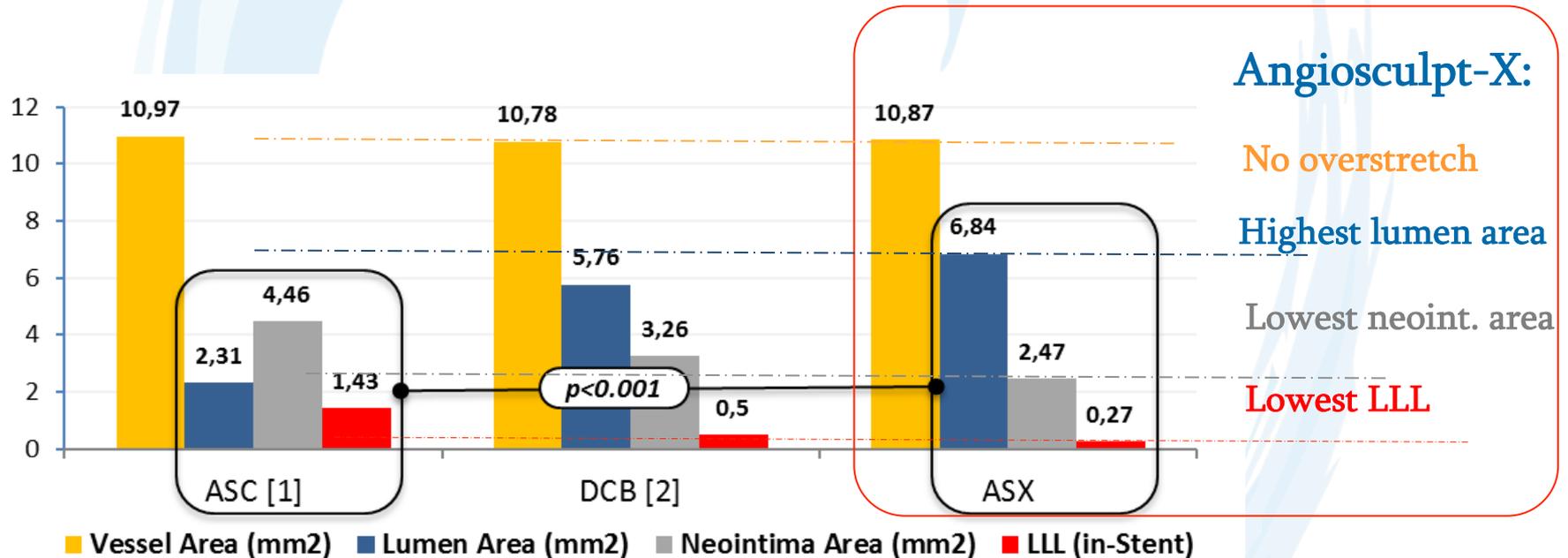
- Coating applied to working balloon surface, scoring element, and part of balloon cones



- Drug transfer from balloon to vessel wall requires **minimum of 30 seconds** inflation

Pre-Clinical data:

Porcine model with 3 treatments



*Porcine stent-overstretched model of 18 swines randomized to 3 treatments: 1) ASX, 2) plain ASC, 3) DCB
[1] ASC: plain / uncoated Angiosculpt; [2] Paccocath DCB

ISAR-DESIRE 4: Study Design

- ◆ *ANGIOSCULPT + PTX-DCB vs. PTX-DCB*
- ◆ *LIMUS-ES Restenosis*

Scoring balloon
pre-dilation

Vs.

Standard balloon
pre-dilation

Study Design

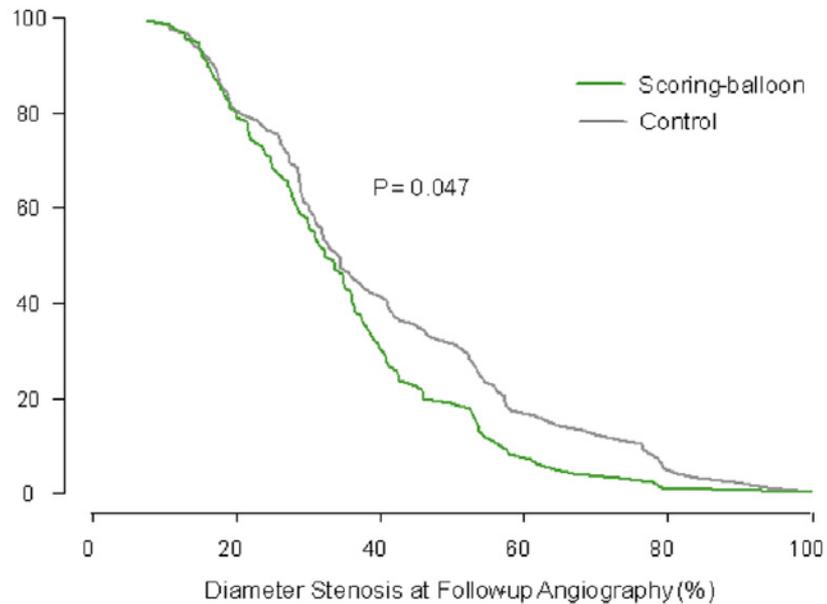
- Prospective RCT
- Multi-Centric: 4
- PI: Dr. R. A. Byrne
- Angiographic follow-up at 6-8 months in 80.4% (N=203)
- Clinical follow-up at 12 months

Key Baseline Characteristics

N = 252	Key Baseline Characteristics		p
	ASC+ DCB (n=125)	PTCA + DCB (n=127)	
Age	69.4 y	69.4	0.5
Females	20%	12.6%	NS
Diabetes	40.8%	43.3%	NS
ISR morph. Foc/diff/prol/ occl.	76.8/18.4/ 1.6/3.2 %	75.6/22.1/ 0.8/1.6 %	NS
Stenosis pre	65.7%	67.2%	NS

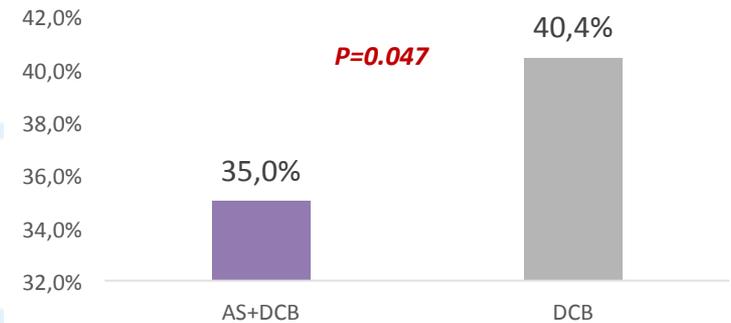
ISAR-DESIRE 4: main results

FIGURE 1 Cumulative Frequency Distribution Curves for Primary Endpoint According to Treatment Group



Percentage diameter stenosis on 6- to 8-month follow-up angiography; data shown for scoring balloon group (**green**) and control group (**gray**).

% Diameter Stenosis at 6 months (PE)



% Binary Restenosis at 6-months



Angiosculpt X

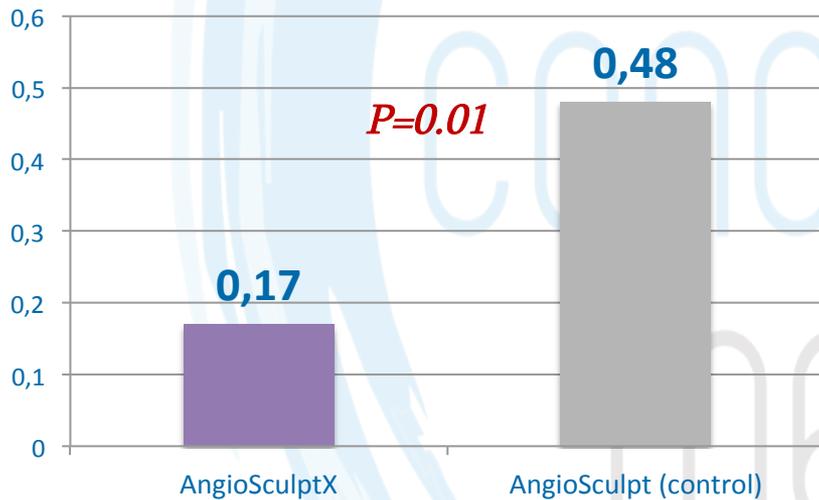
PATENT-C Trial: Study Design

- MULTICENTER, RCT
ANGIOSCULPT vs.
ANGIOSCULPT-X in BMS-ISR.
- PI: B. Scheller
- Independent QCA corelab
- Primary endpoint: 6-month
angiographic in-segment Late
Lumen Loss (LLL)

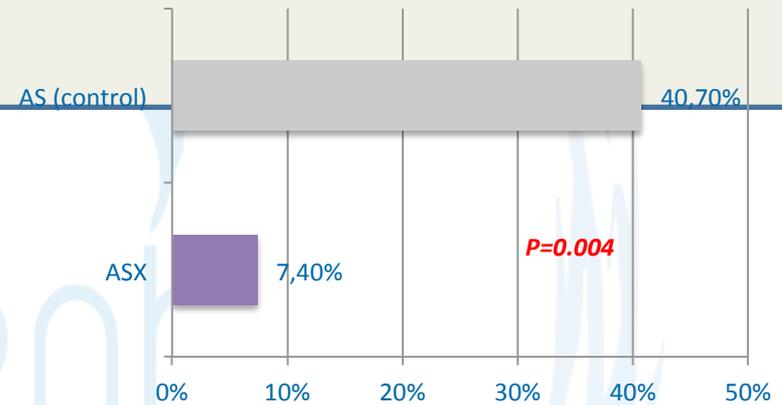
N = 61	Key Baseline Characteristics		
	ASX	ASC	p
Age	65 y	64 y	NS
Females	30.3%	25.0%	NS
Diabetes	42.4%	35.7%	NS
Mehran I/II/ III/IV	63.7/21.2/ 9.1/6.1%	66.6/33.3/ 0/0%	NS
Lesion Length	16.5 mm	13.8 mm	NS
% DS (in-segm.)	66.8%	72.0%	NS

PATENT-C Trial: angiographic results

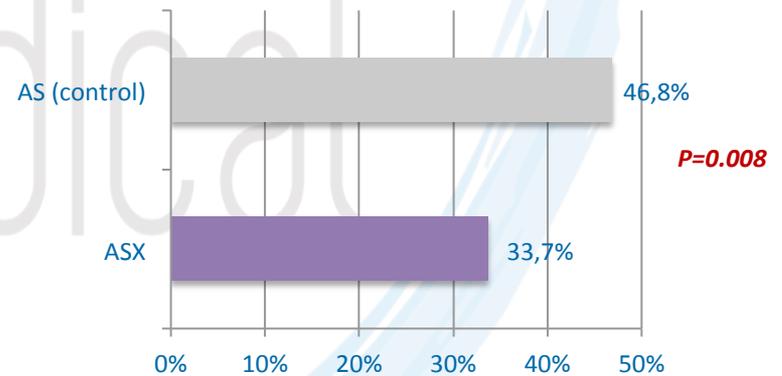
6-Month In-Segment LLL¹ (Primary EP)



Binary Restenosis



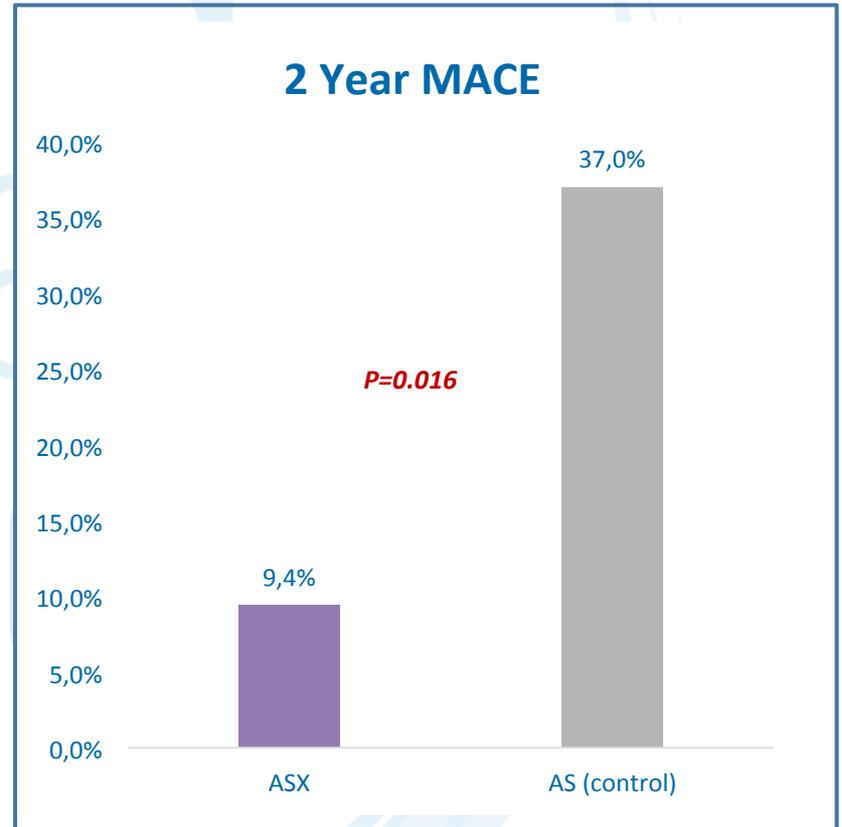
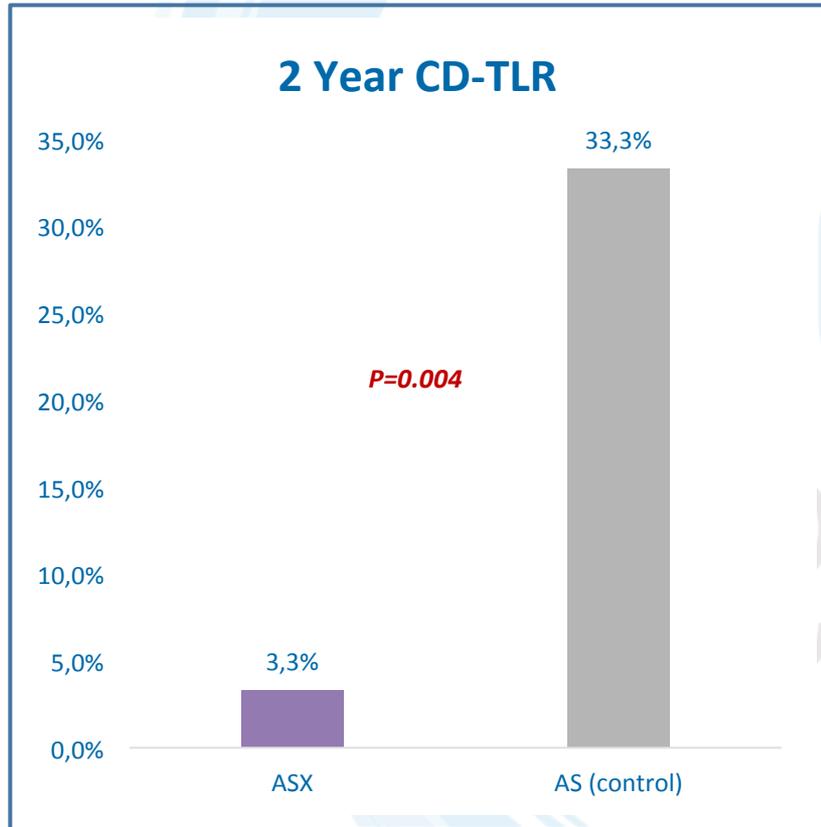
In-Segment % Diameter Stenosis



Note: cardiac deaths were not device or procedure related

1. Scheller B, Fontaine T, Mangner N, et al. A Novel Drug-Coated Scoring Balloon for the Treatment of Coronary In-Stent Restenosis: Results From the Multi-Center Randomized Controlled PATENT-C First in Human Trial. Cath and Cardiovasc Interv. 2016; 88:51-59

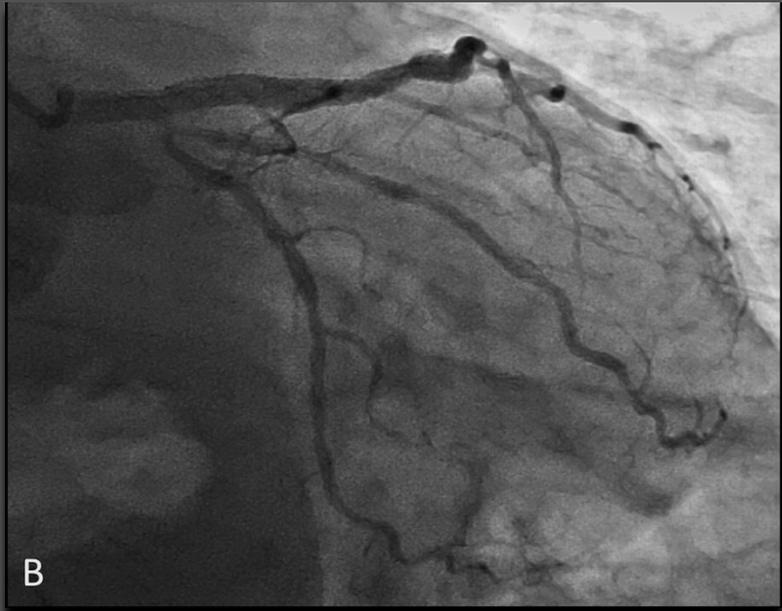
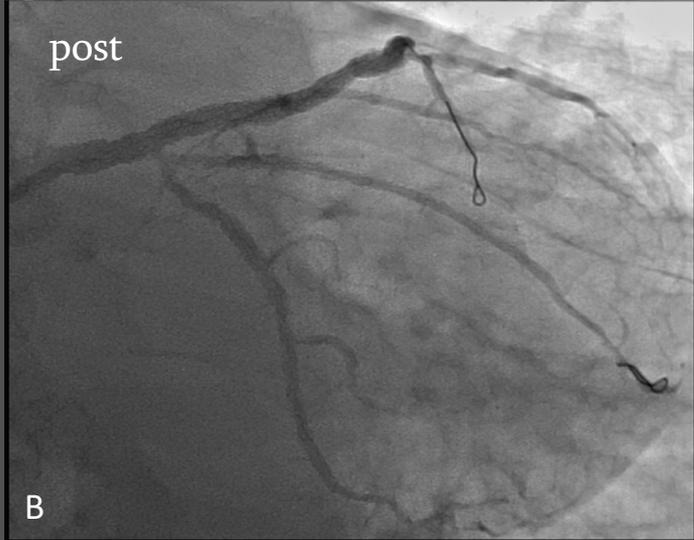
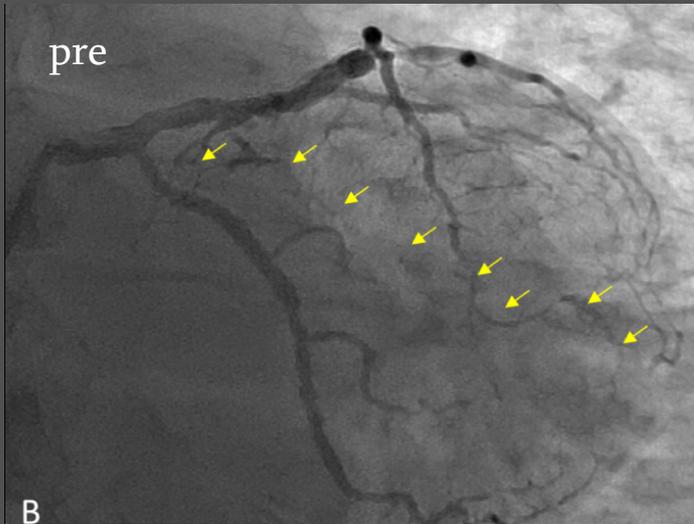
PATENT-C Trial: 24-month results



Follow up angio (DIA1, 6-mo)



I.R, 6-mo.

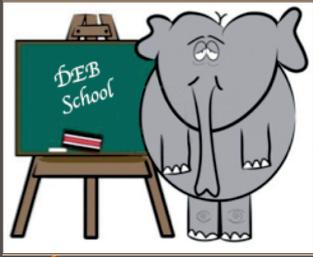




INTERNATIONAL, MULTICENTER, SPONTANEOUS CLINICAL TRIAL

Angiosculpt X drug-coated balloon for complex native coronary artery disease, and its effect on vascular lumen gain

- native coronary vessels <3mm
- moderate-severe calcifications, *or*
- ostial lesions
- @ 4 european sites



Key messages



- A “controlled” dissection left after DCB-PCI does not raise safety issues, and seems effective.
- The possibility of “scoring” the plaque in order to facilitate PTX entrance, and persistence, is charming
- We need clinical data in a broader population, and/or in specific lesions settings.