From ABSORB III to the Future

BRS in STEMI and Vulnerable Plaque

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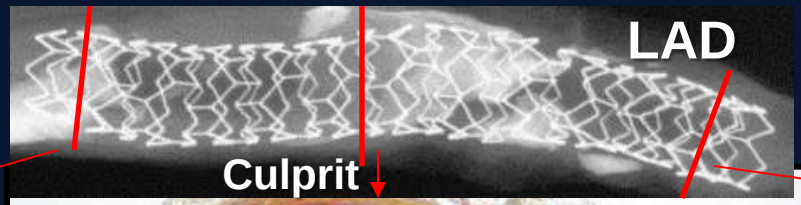
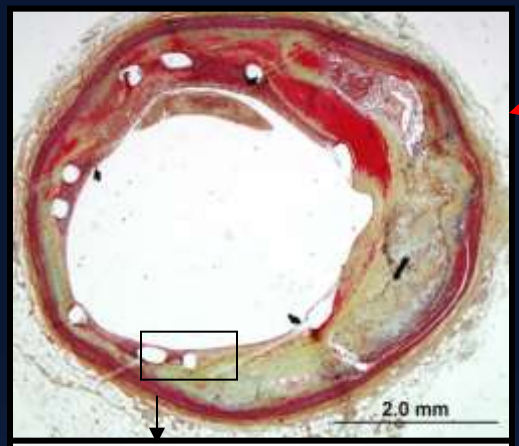
Disclosure Statement of Financial Interest

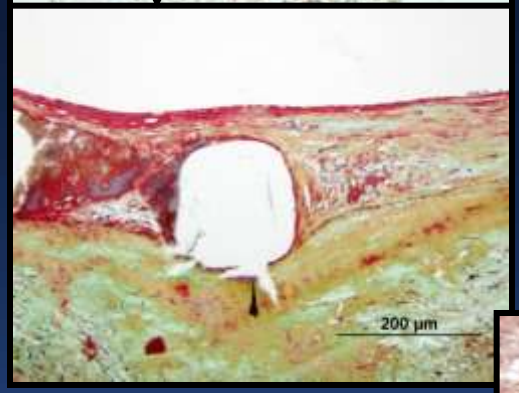
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• ABSORB clinical trial program study chairman (uncompensated)	• Abbott Vascular
• Consultant	• Reva Corp.

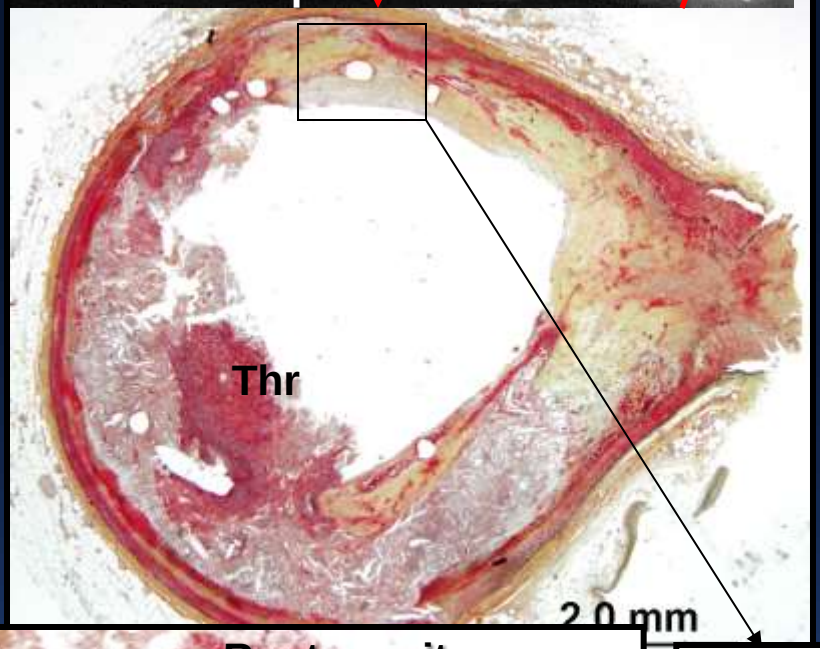
65 yo man w/ACS ⇒ TAXUS in LAD and LCX, died 9 mos later







Non-culprit



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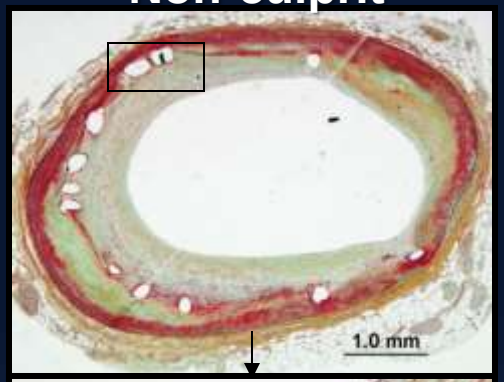

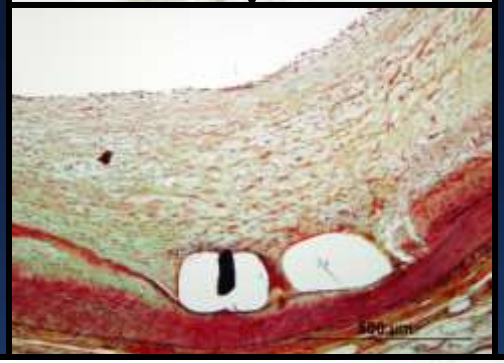

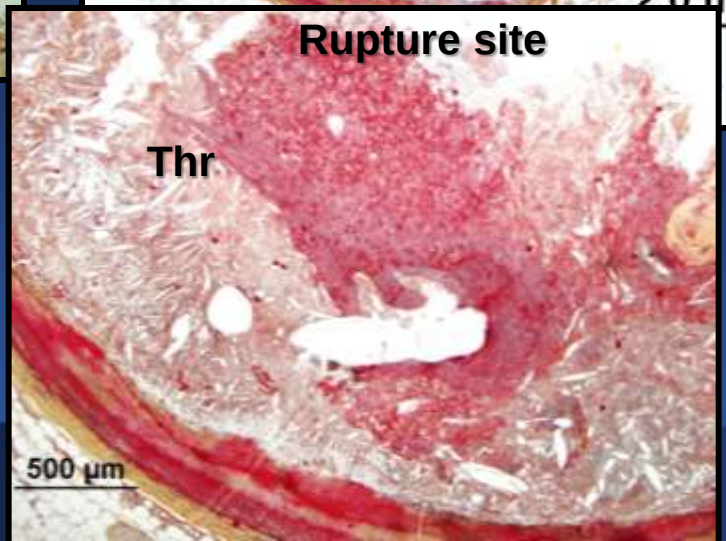

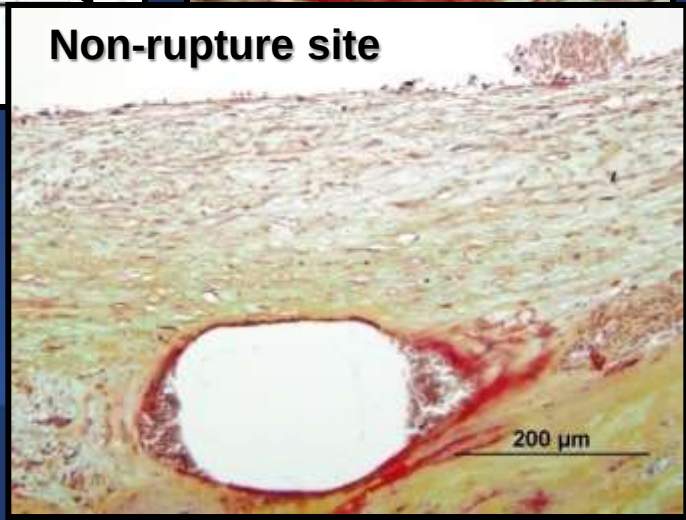

C/O
Renu Virmani

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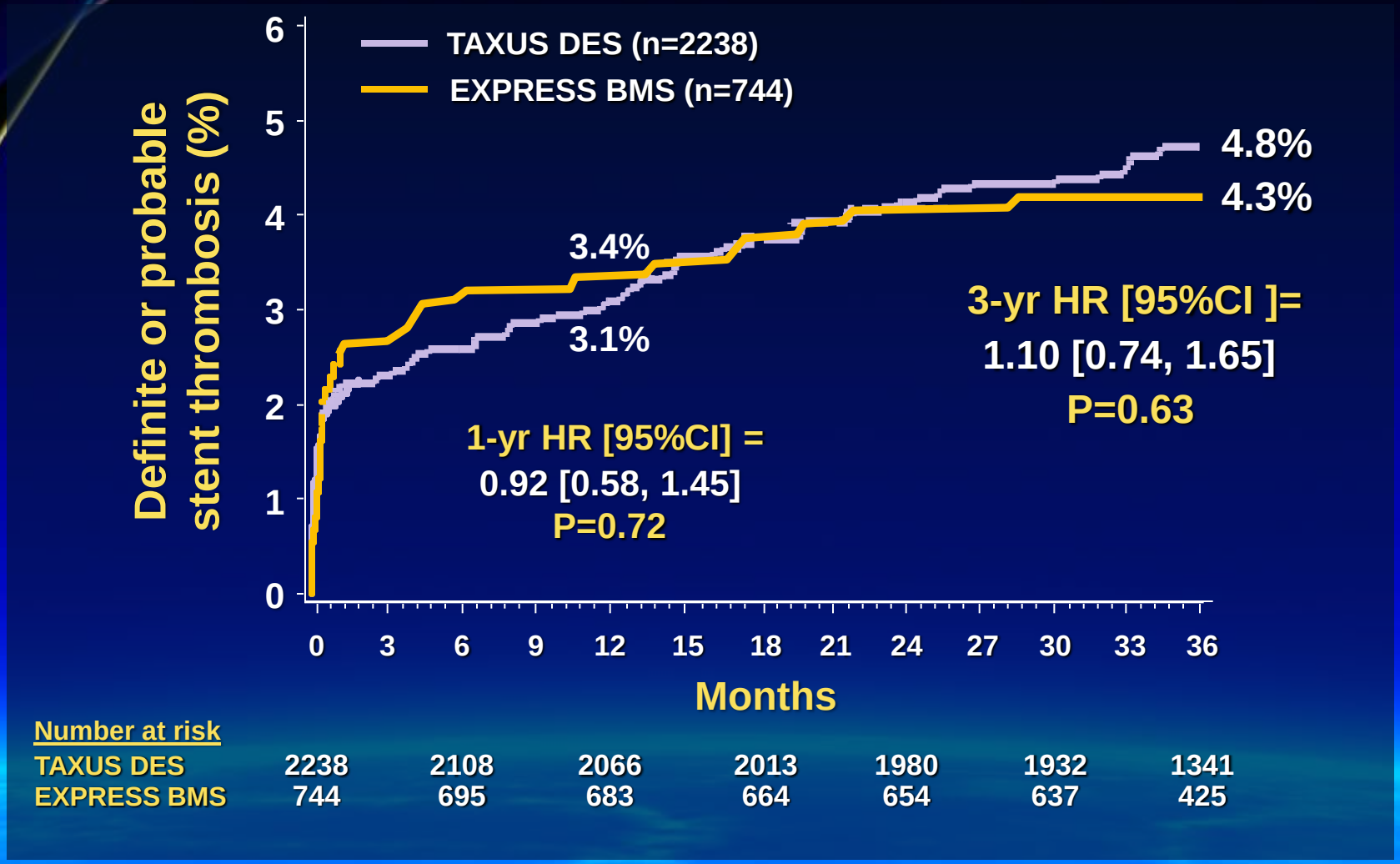
HORIZONS-AMI: 3-Year Stent Thrombosis

Stent randomization



Stone GW et al. Lancet 2011;377:2193-204

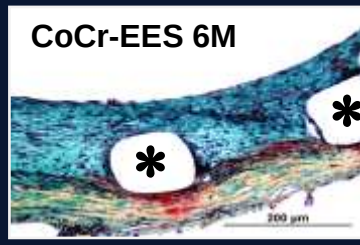
HORIZONS-AMI

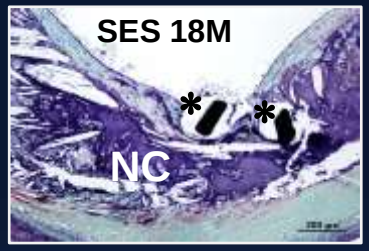
204 lesions (SES=73; PES=85; CoCr-EES=46) from 149 autopsy cases with implant duration >30 days and ≤3 years

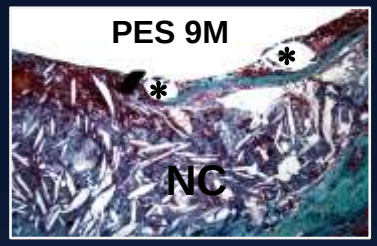
Greater strut coverage with less inflammation, less fibrin deposition, and less late and very late stent thrombosis – but similar rates of neoatherosclerosis and fracture-related adverse pathological events.

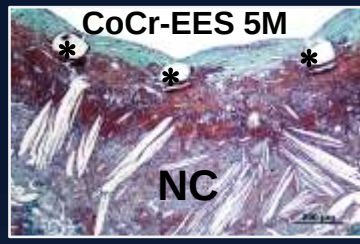
DES for Stable CAD

DES for ACS





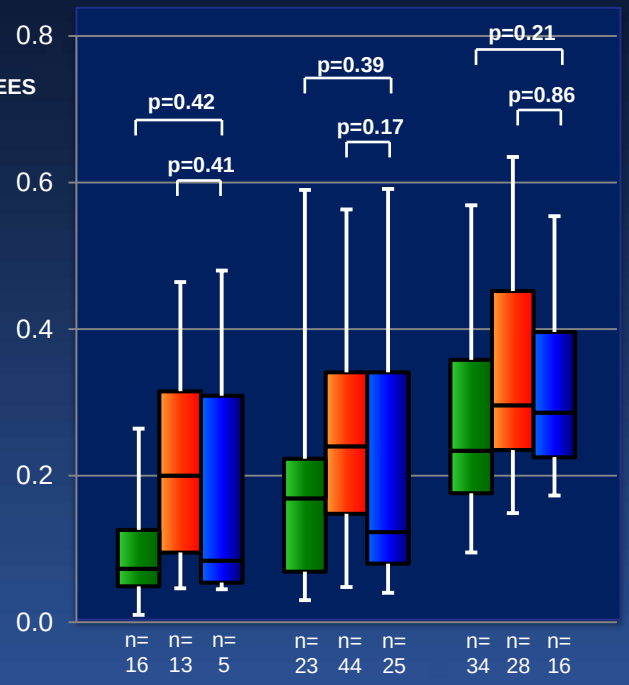


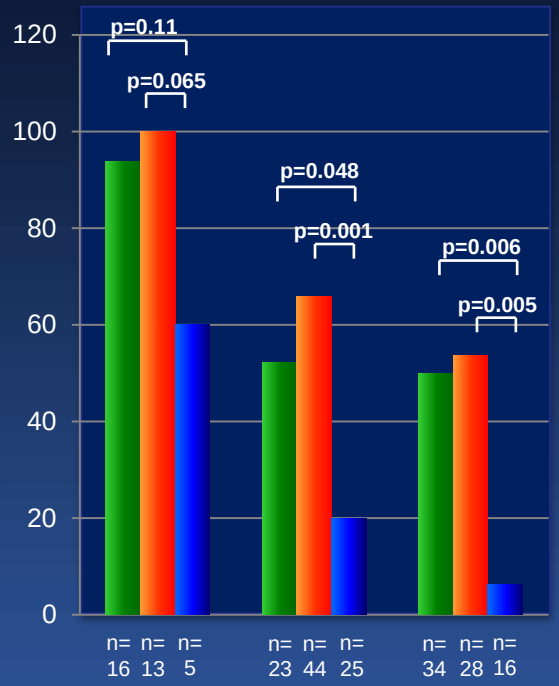


SES PES CoCr-EES

Maximum Neointimal Thickness (mm)

Equivalent efficacy in reducing neointima compared to 1st gen DES





SES PES CoCr-EES

Prevalence of DES with >30% Uncovered Struts (%)

Increased safety with regards to strut coverage compared to 1st gen DES.

Otsuka et al. Circulation 2014;129:211-23

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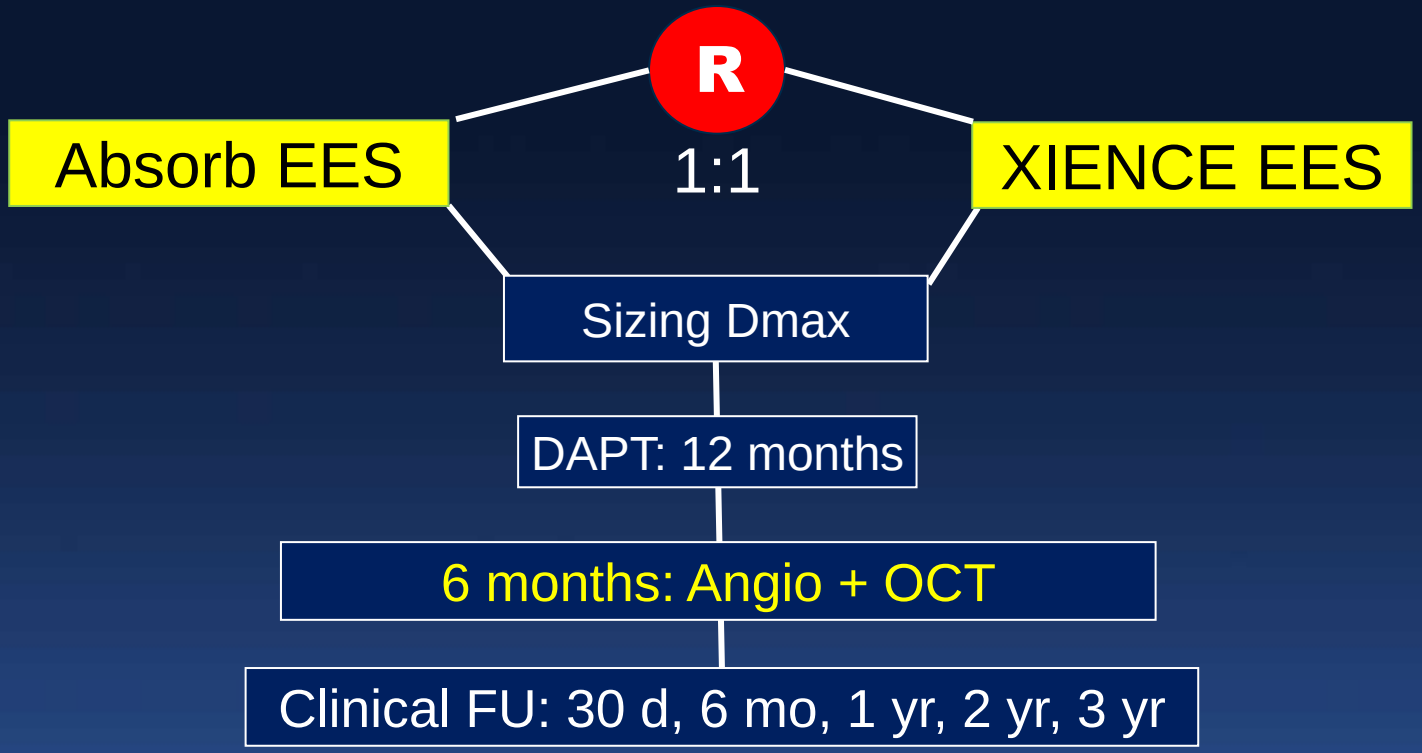
ABSORB in STEMI: TROFI II

192 pts with STEMI <24hrs

Thrombectomy ± pre-dilatation
(based on angiographic guidance)



Primary Endpoint: Healing Score at 6 months (NI)

Sabaté M et al. Eur Heart J 2016;37:229-40

absorb stemi
The Trofi II Study

Healing Score

Healing score = [% ILDx4] + [% MUx3]+ [% Ux2]+ [% M]

ILD: intraluminal defect
MU: malapposed and uncovered
U: uncovered
M: malapposed

Weighting points in the formula

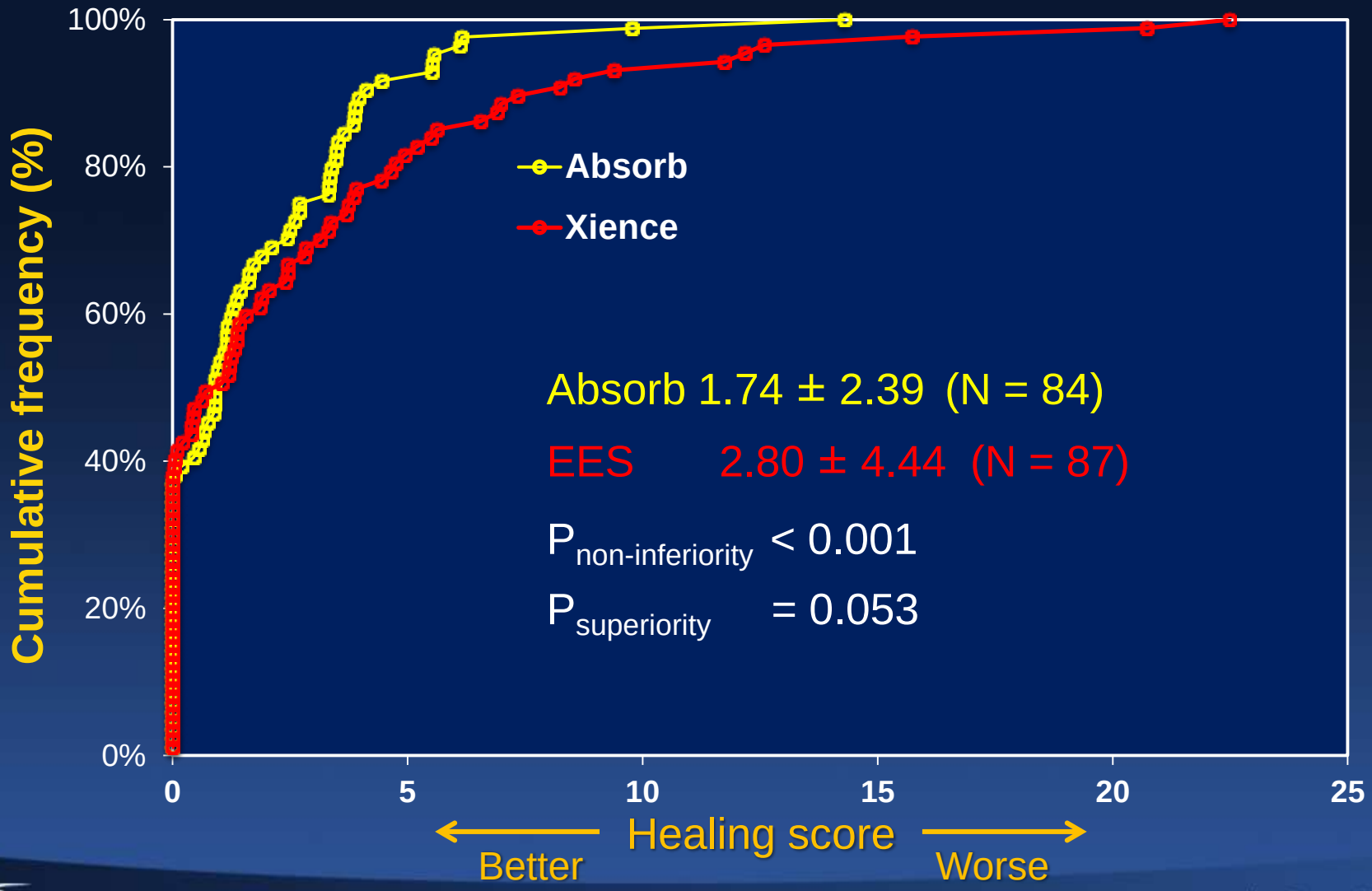
Xience metallic stent	Absorb BVS	Xience metallic stent	Absorb BVS
Intraluminal defect: 4 points		Uncovered (apposed): 2 points	
Malapposed and uncovered: 3 points		Malappposed (covered): 1 points	

References: TROFI trial *Eur Heart J.*2013;34:1050-1060; *Eur Heart J Cardiovasc Imaging.*. 2014;15:987-995
Leaders trial *Eur Heart J.* 2010;31:165-176; Resolute all comers trial *Eur Heart J*. 2011;32:2454-63
Absorb cohort B EuroIntervention 2015;10:1299-306; NANO Plus *AsiaIntervention* 2015; 1:57-70.

absorb stemi
The Trofi II Study

Cumulative Healing Score

Primary endpoint for non-inferiority was met



Sabaté M et al. Eur Heart J 2016;37:229-40

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absorb stemi
The Trofi II Study

6-Month OCT and QCA

OCT (median)	Absorb (n=95)	EES (n=98)	P-value
Healing score	0.90 [0.00, 0.30]	1.04 [0.00, 3.85]	0.053
Uncovered and malapposed struts	0.0 [0.0, 0.0] (min 0.00; max 0.75)	0.0 [0.0, 0.0] (min 0.00; max 2.47)	0.036
Covered and malapposed struts	0.0 [0.0, 0.9] (min 0.00; max 6.77)	0.02 [0.0, 2.3] (min 0.00; max 20.51)	0.01
Covered and apposed struts	99.9 [99.2, 100]	100 [99.1, 100]	0.27
Uncovered and apposed struts	0.0 [0.0, 0.8]	0.0 [0.0, 0.3]	0.96
Strut coverage, mm	0.10 [0.09, 0.13]	0.07 [0.05, 0.10]	<0.001
Neointimal hyperplasia, mm^3	29.0 [23.2, 41.5]	25.8 [17.2, 40.0]	0.24
QCA	**Absorb (n=94)**	**EES (n=98)**	**P-value**
Late loss, in-stent (mm)	0.17 ± 0.24	0.08 ± 0.28	0.02
Late loss, in-segment (mm)	0.14 ± 0.28	0.06 ± 0.29	0.09
Binary restenosis, %	0%	1.1%	1.0

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Sabaté M et al. Eur Heart J 2016;37:229-40

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HORIZONS-ABSORB AMI

Harmonizing Outcomes with Revascularization, Stents and ABSORB in AMI

6,969 pts with STEMI undergoing primary PCI

IV cangrelor bolus + infusion

(+ oral P2Y12 inhibitor and aspirin)

Randomize 1:1:1

- Bivalirudin + 4 hr post-PCI infusion (n=2,323)
- Bivalirudin, short infusion (n=2,323)
- Heparin, no infusion (n=2,323)

~5,000 pts eligible for device randomization — **1,840 pts not randomized**

Randomize 1:1

- Xience CoCr-EES
- Absorb BVS

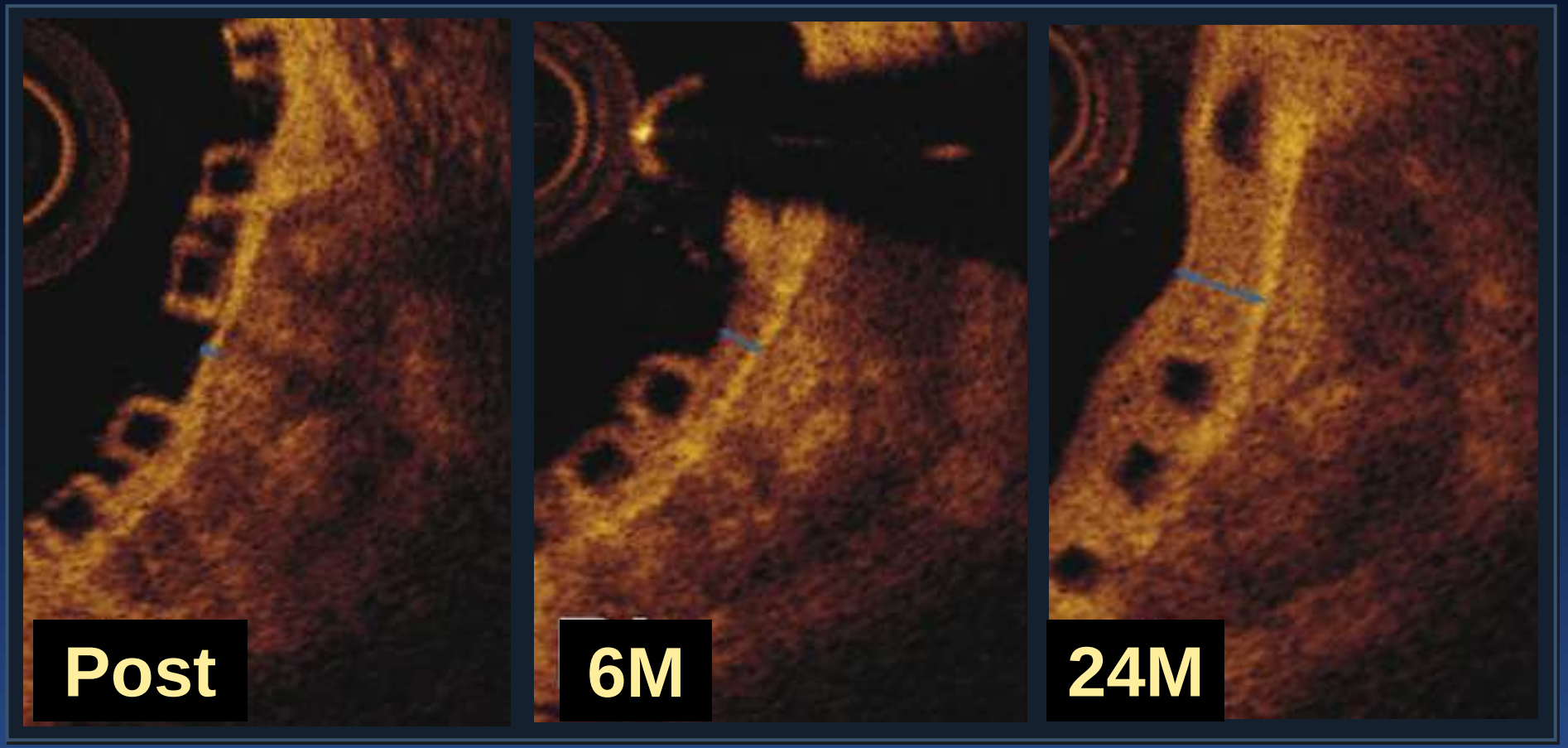
Xience CoCr-EES

Clinical FU: 30 days, 1 year, yearly through 5 years

HORIZONS AMI

Sponsors: The Medicines Company and Abbott Vascular

Sealing and Shielding of Plaques After Scaffold Implantation



Example of capping a calcified plaque

Brugaletta S et al. Atherosclerosis 2012

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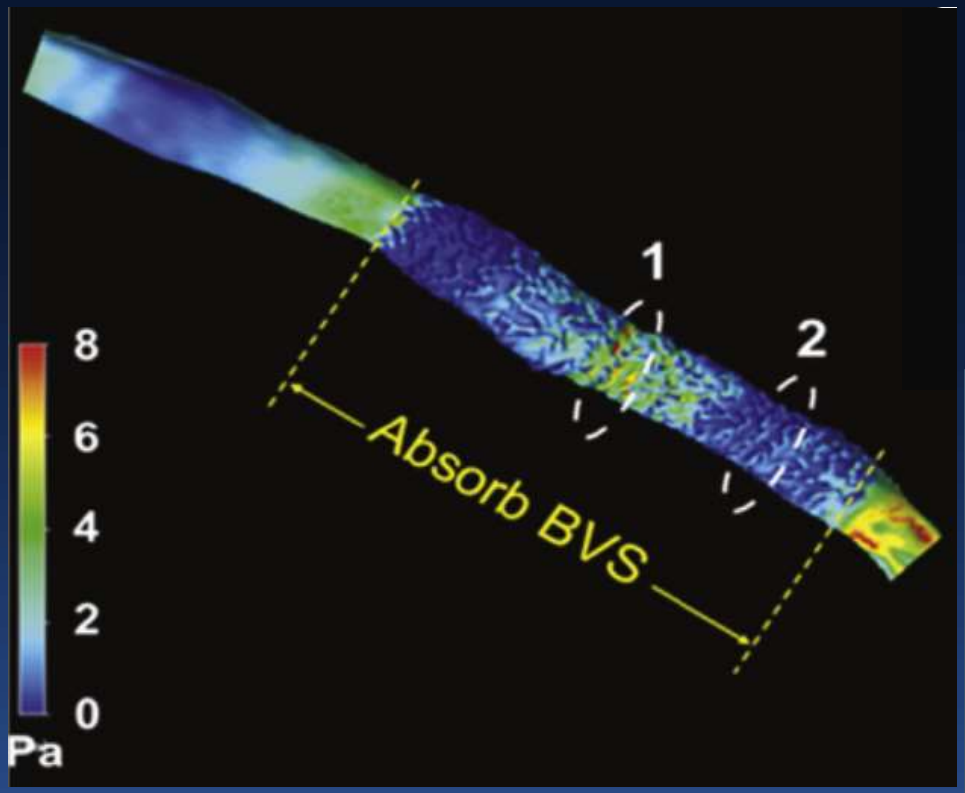
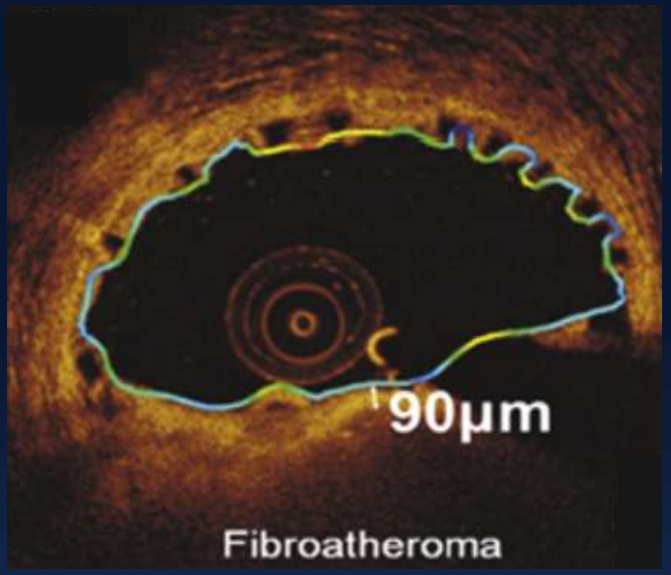
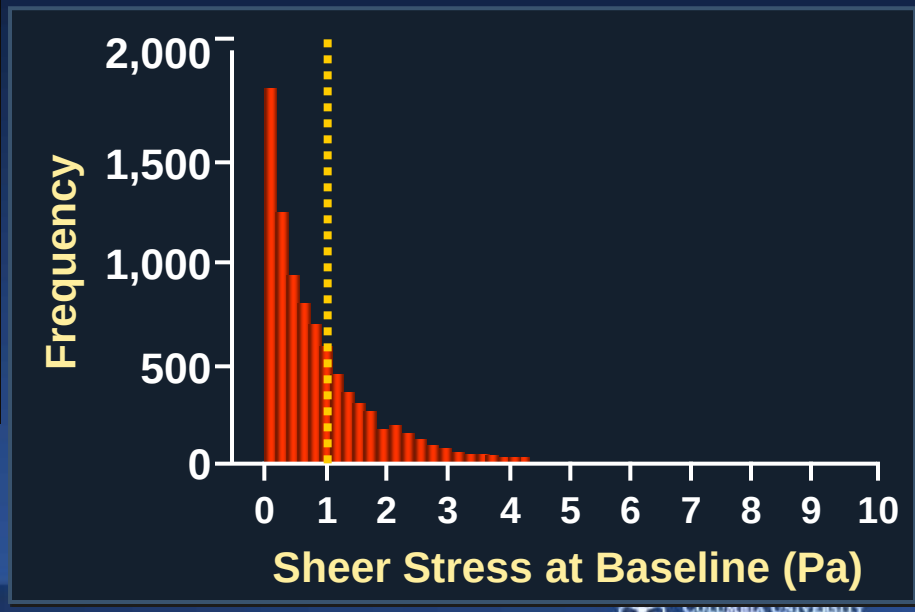
BVS Implantation Over a Fibroatheroma

LAD reconstruction showing low shear stress throughout the BVS







Bourantas CV et al. *Am Heart J* 2013;165:869-81

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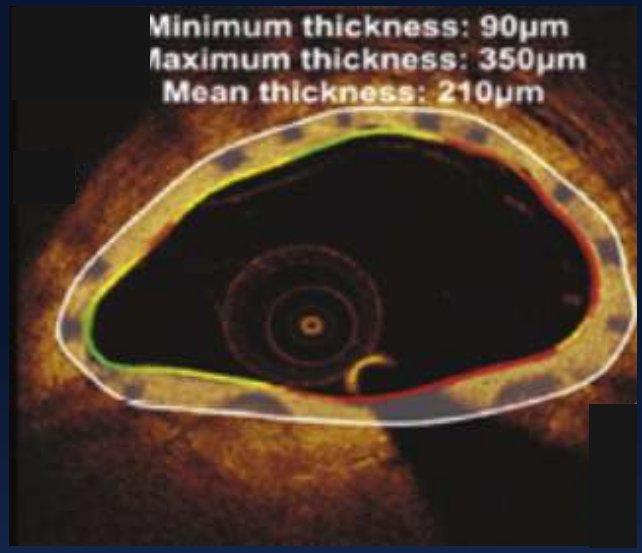
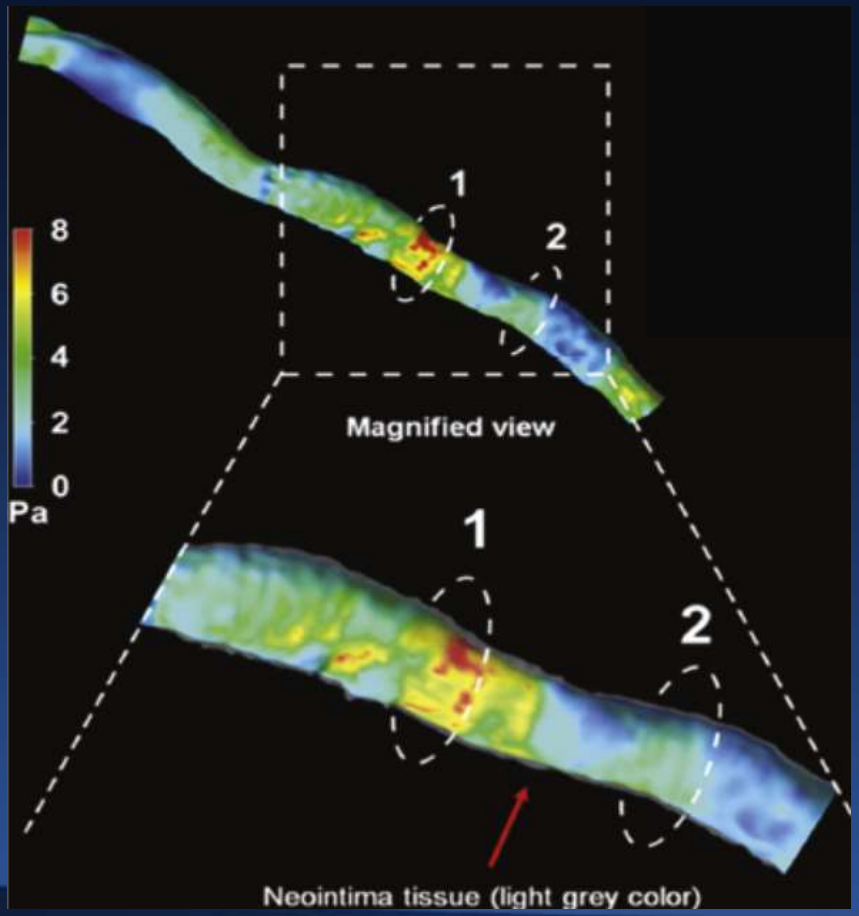
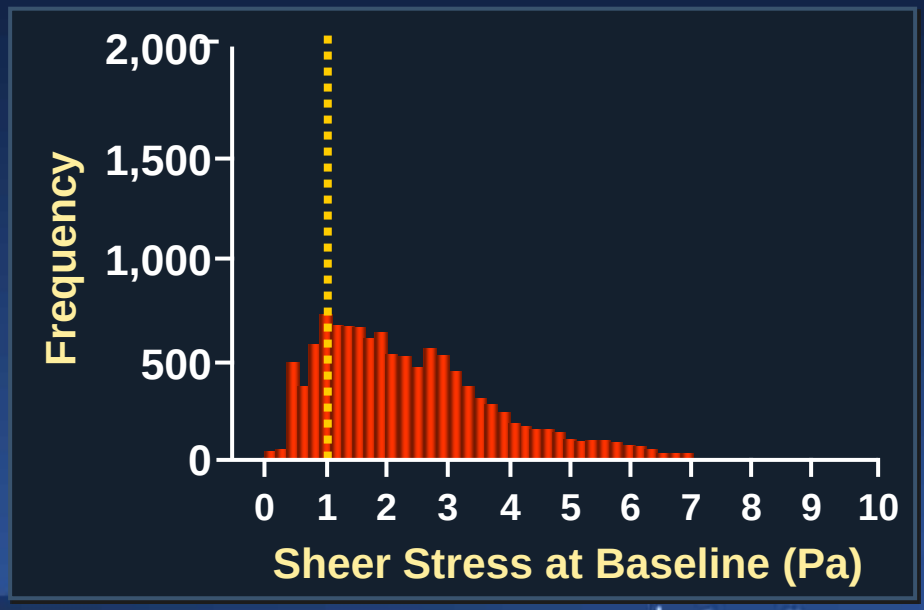
BVS Implantation Over a Fibroatheroma

2 years later: ESS has normalized over the scaffold, and a 210 um layer of neointima has developed







Bourantas CV et al. *Am Heart J* 2013;165:869-81

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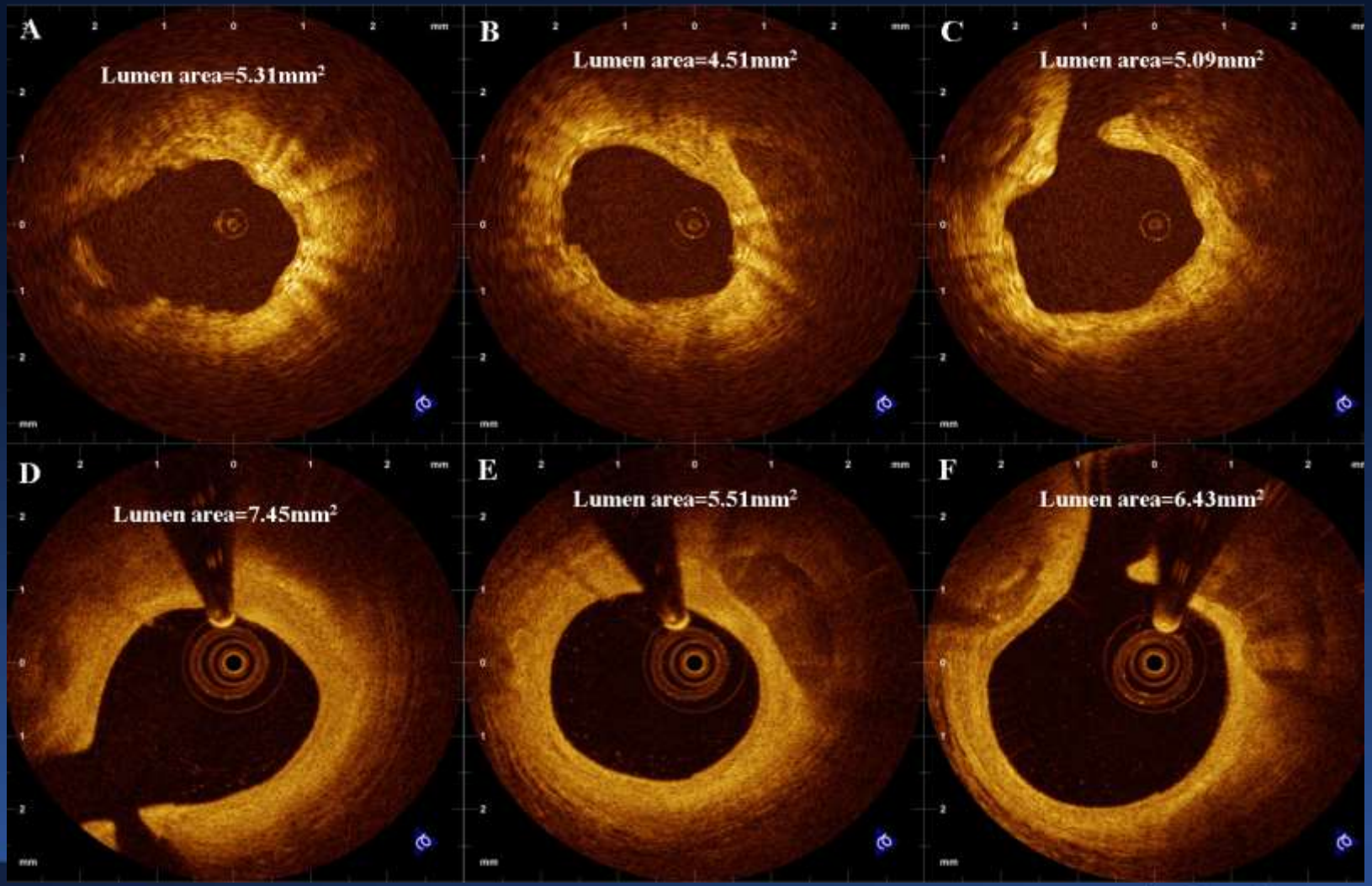
Treatment of a TCFA with BVS: Substantial lumen enlargement due to plaque regression with adaptive remodeling (cohort A pt)

6 months

5 years



Karanasos A et al. Circulation. 2012;126:e89-e91

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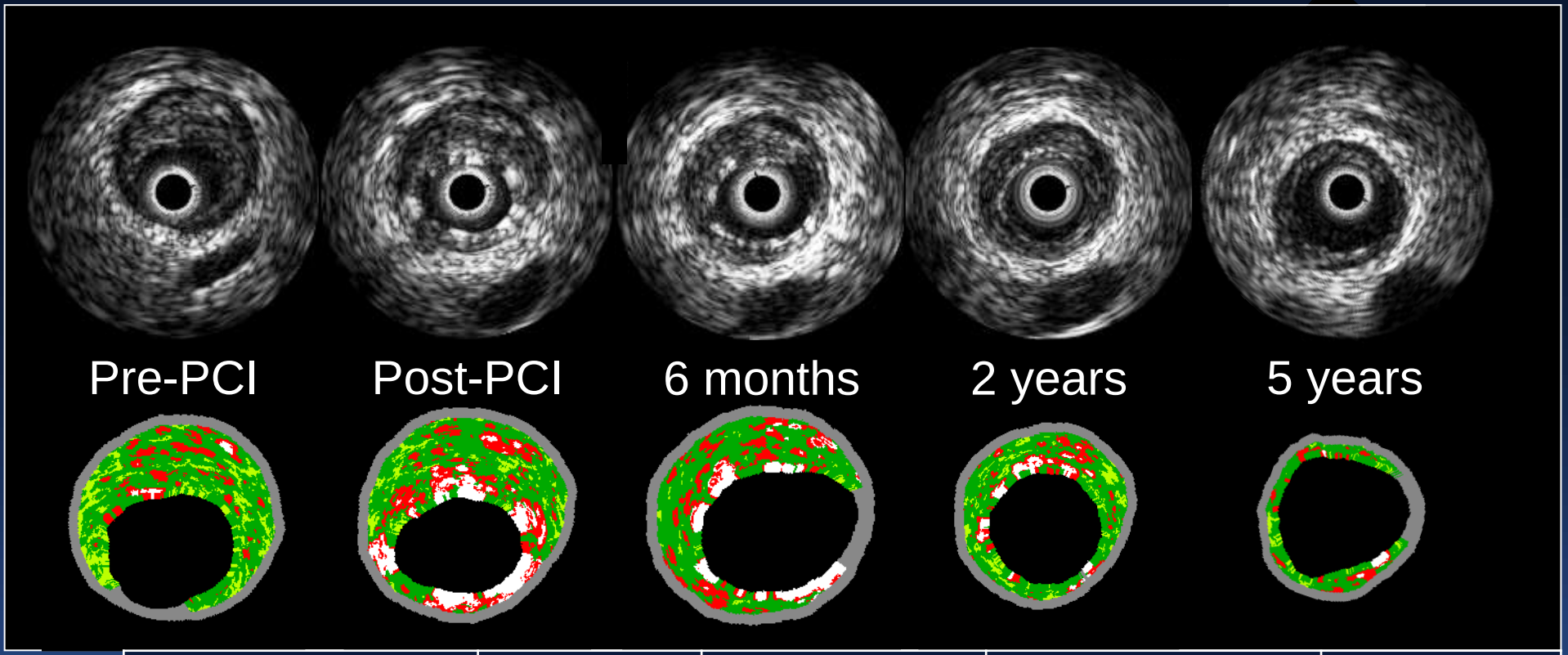
Interventional Plaque Regression by BVS:
Substantial lumen enlargement due to plaque regression with adaptive remodeling (cohort A pt)



All pts

Vessel area (mm^2)	15.72	15.34	14.09	13.76
Mean lumen area (mm^2)	6.95	6.17	6.56	8.09
Plaque area (mm^2)	8.78	9.17	7.54	7.07

PROSPECT II
PROSPECT ABSORB

PROSPECT II Study

PROSPECT ABSORB RCT

900 pts with ACS after successful PCI

3 vessel IVUS + NIRS (blinded)

≥1 IVUS lesion with ≥65% plaque burden present?

Yes (N=300)

No (n=600)

R 1:1

ABSORB BVS + GDMT (N~150)

GDMT (N=150)

Routine angio/3V IVUS-NIRS FU at 2 years

Clinical FU for up to 15 years

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PREVENT Trial

All-comers, with any epicardial coronary stenosis with FFR ≥0.80 and with 2 of the following:

1. TCFA by OCT or VH-IVUS
2. IVUS MLA ≤4.0mm^2
3. IVUS Plaque Burden >70%
4. Lipid-Rich Plaque on NIRS ($_{max}LCBI_{4mm}$>315)

R

BVS+OMT
N=800

OMT
N=800

Primary endpoint at 2 years:

CV death, MI, or hospitalization due to unstable angina

OCT sub-study/ NIRS sub-study (300 pts in each arm at 2 yrs)

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