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BRS failure: Type, risk and Management

Alaide Chieffo, MD
Interventional Cardiology Unit,
San Raffaele Scientific Institute, Milan, Italy

Disclosure Statement of Financial Interest

I, Alaide Chieffo DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Risks of Target lesion failure

Diabetes present	1·56 (1·19–2·04)	0·002
Previous cardiac intervention	1·36 (1·03–1·78)	0·03
Any lesion with minimum luminal diameter <median (0·93 mm)*	1·37 (1·03–1·82)	0·03
Any lesion with reference vessel diameter <median (2·65 mm)*	1·52 (1·14–2·03)	0·005
Any ACC/AHA class B2 or C lesion (*vs* class A or B1)*	1·65 (1·19–2·28)	0·002
BVS (*vs* CoCr-EES)	1·23 (0·92–1·64)	0·14

Meta-analysis: 6 RCT

Causes of TLF may be similar with DES, however…..

Current BRS specific issues

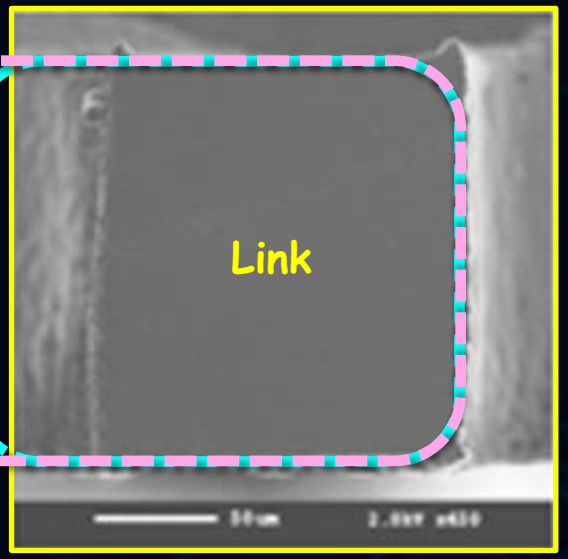
When compared with current DES…

- Thicker struts
- Increased vessel coverage due to wider struts
- Limited expansion capabilities of BRS

Strut width and Vessel coverage

2.5, 3.0mm BRS Hoop

3.5mm BRS Hoop



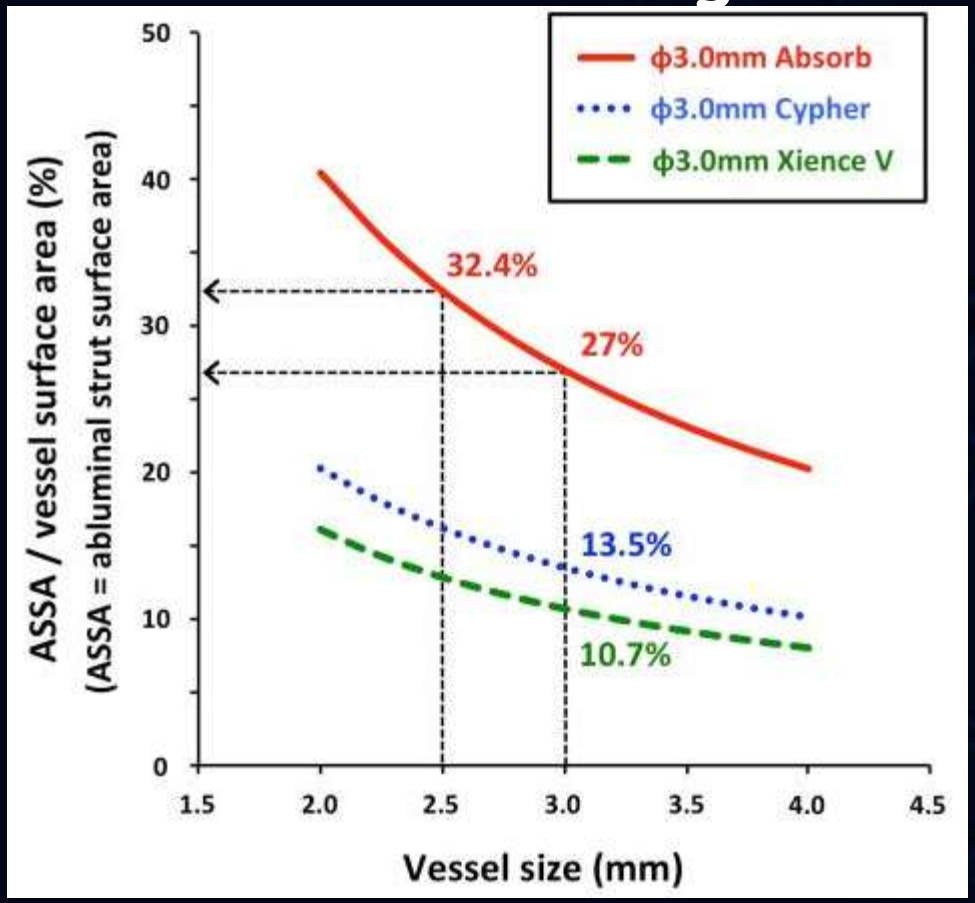
	Absorb	Cypher	Xience V
Strut thickness	157μm	152.6μm	81.3μm
Strut width (link)	140μm	60μm	81.3μm
Strut width (hoop)	2.5, 3.0mm; 190.5μm 3.5mm; 215.9μm	130μm	81.3μm
ASSA/vessel surface area (%)	2.5mm; 32% 3.0mm; 27% 3.5mm; 26%	2.5–3.0mm (6 cells); 12-15% 3.5–4.0mm (7 cells); 12-15%	10.7%

ASSA = abluminal strut surface area

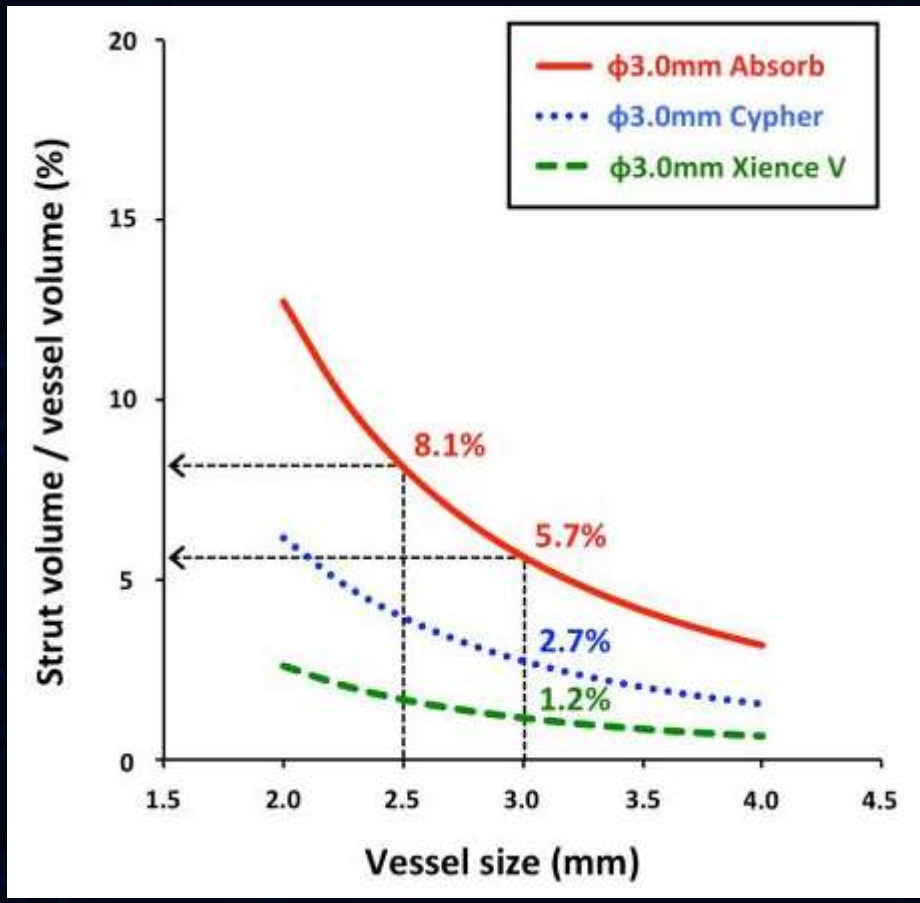
Macroscopic pictures; Absorb (Muramatsu et al. JACC intv 2013),
Cypher and Xience V (Doostzadeh et al. Coronary Artery Disease 2010)

Strut width and Vessel coverage

Vessel coverage



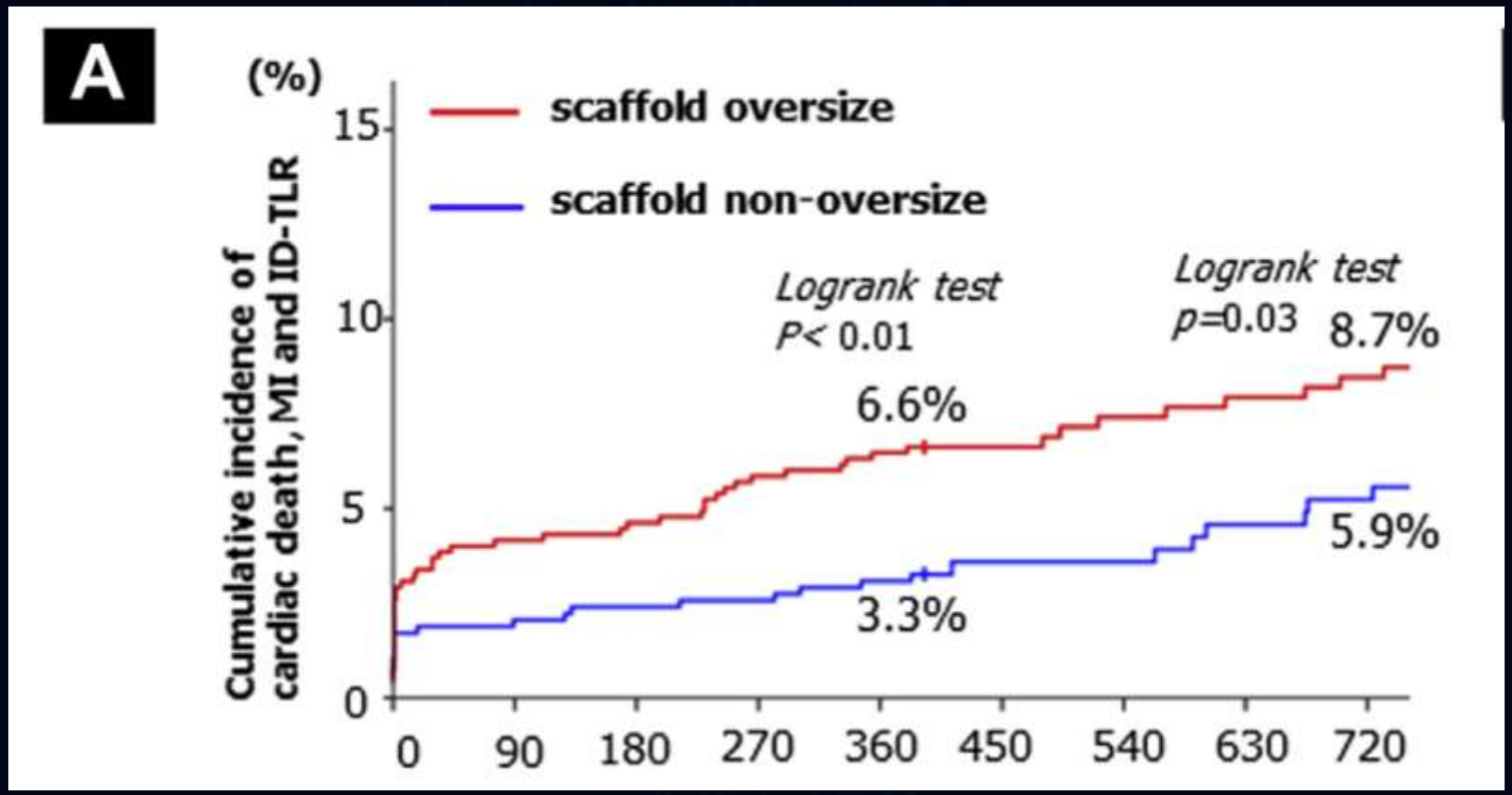
Strut volume



Oversized BRS increases vessel coverage and strut volume..

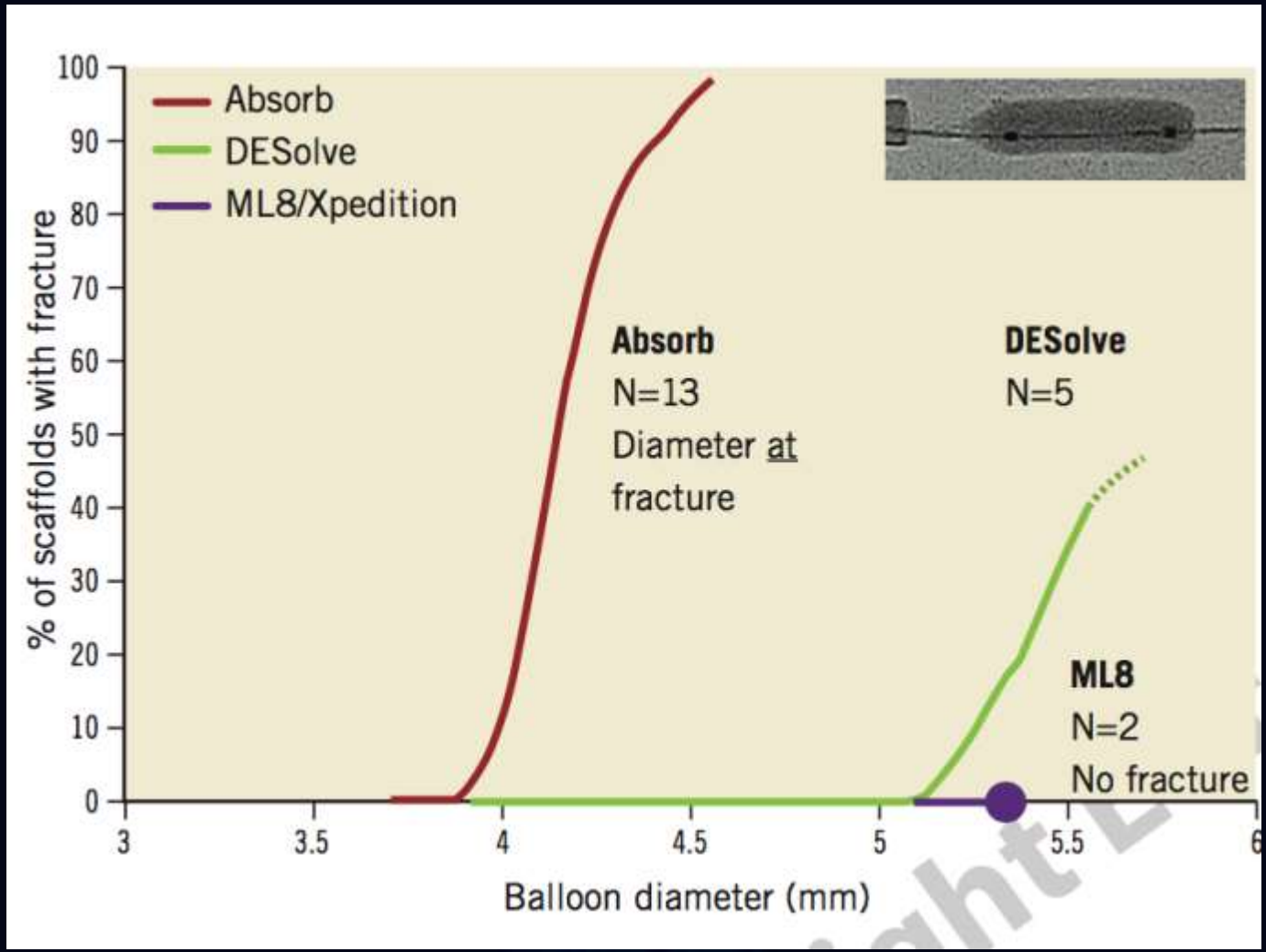
Oversizing may have higher risk..

Target lesion failure



Ishibashi et al. JACC intervent. 2015

Limited expansion capabilities



Ormiston et al. Eurointervention 2015

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More careful sizing is important

Because…

- Oversizing --- vessel coverage ↑ event ↑
- Undersizing/ Large vessels

--- Malapposition event risk ↑

- ✓ It is difficult to correct after deployment due to expansion capabilities
- ✓ Overexpansion might cause fracture: event risk↑

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BVS thrombosis

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Causes of Stent thrombosis

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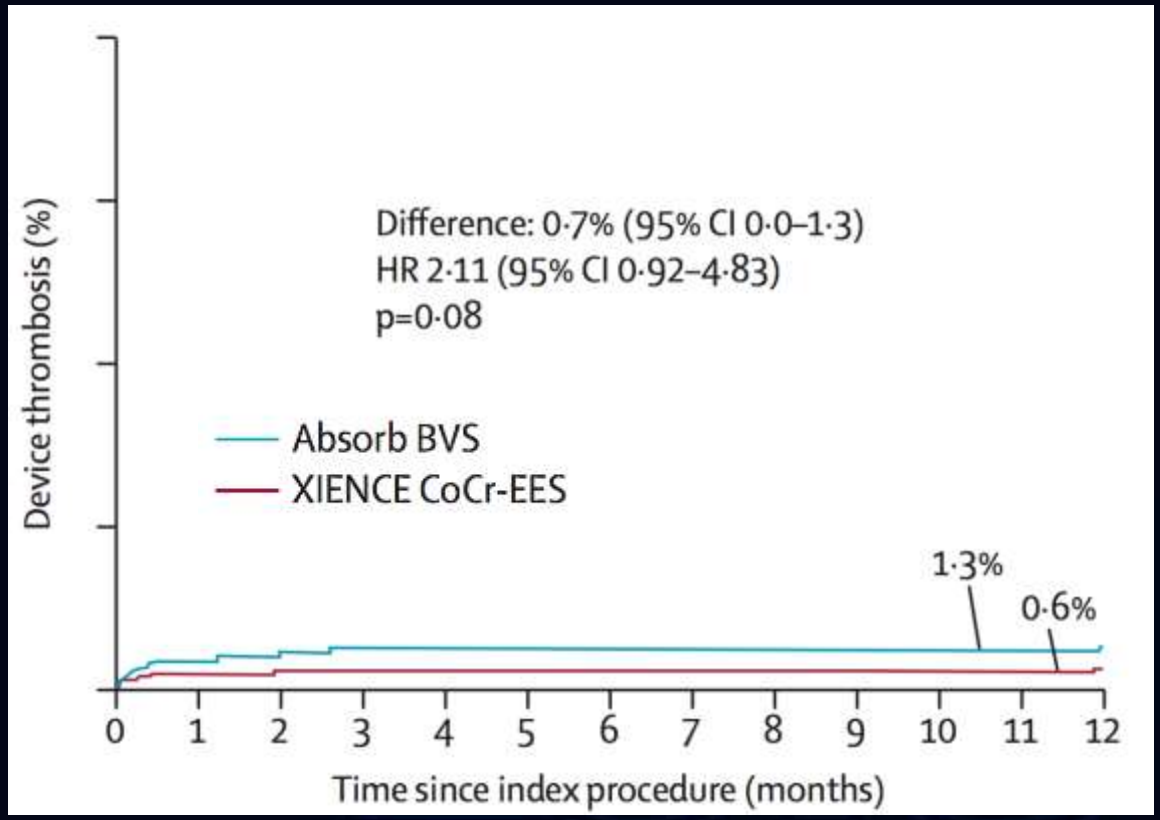
Stent factors	Hypersensitivity to drug coating or polymer Incomplete endothelialization Stent design Covered stents (64,65)
Patient factors	PCI for acute coronary syndrome/ST-segment elevation MI Diabetes mellitus Renal failure Impaired left ventricular function Premature cessation of dual antiplatelet therapy Aspirin nonresponsiveness Clopidogrel nonresponsiveness Glycoprotein IIb/IIIa inhibitors Prior brachytherapy Malignancy Saphenous vein graft disease
Lesion characteristics	Lesion/stent length Vessel/stent diameter Complex lesions (bifurcation lesions, chronic total occlusions) Saphenous vein graft target lesion Stasis
Procedural factors	Inadequate stent expansion/sizing Incomplete stent apposition Stent deployment in necrotic core Residual edge dissection

Causes of Scaffold thrombosis may be similar, however…..

BVS might have higher risk of ST…



Meta-analysis: 6 RCT

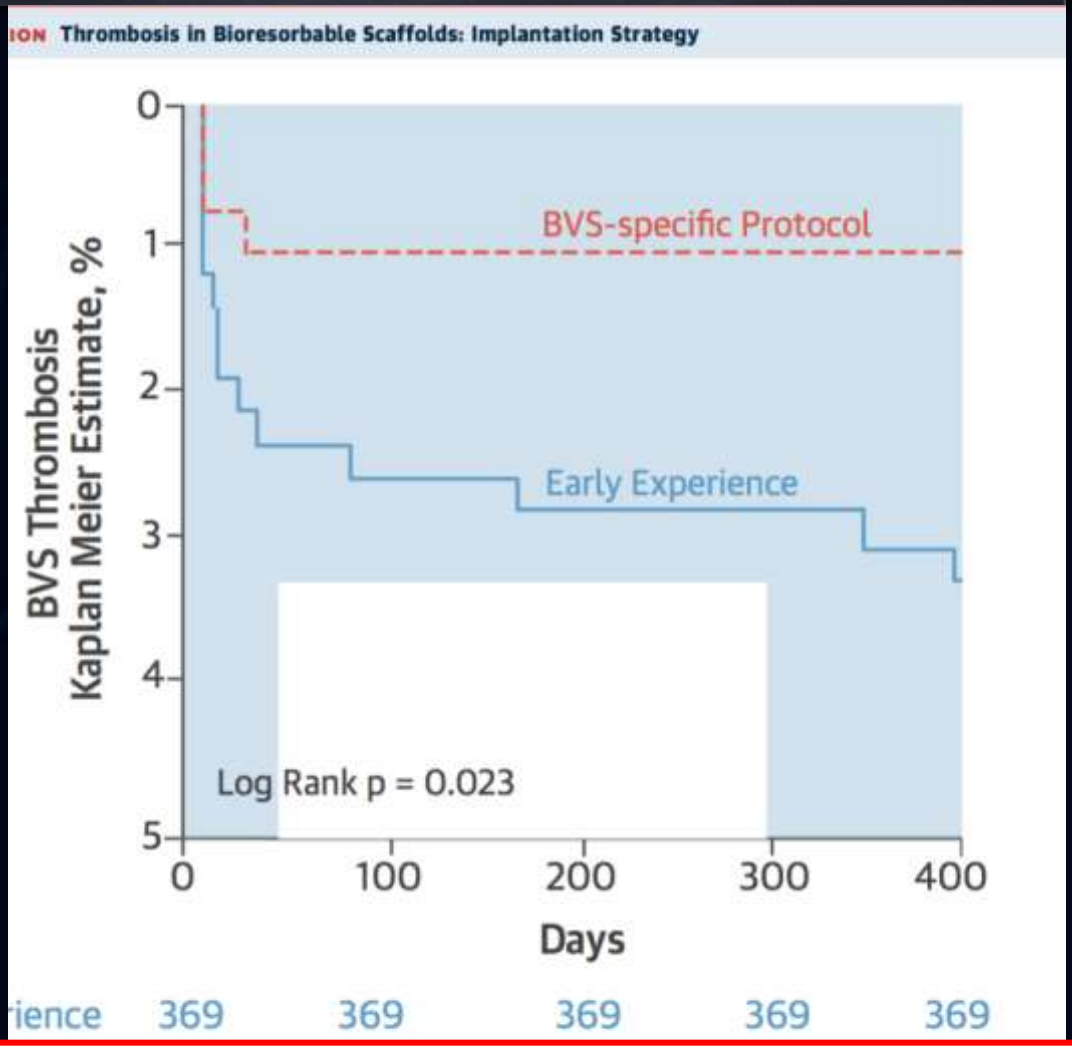
(ABSORB II, ABSORB china, ABSORB Japan, ABSORB III , EVERVIO II, TROFI II)

To overcome this less forgiving device, Optimal implantation should be important

Optimal implantation and ST risk

BVS-specific protocol

1.Pre-dilatation
2.BVS implantation
only in full expansion
3.BVS implantation
(size=RVD) 10-12atm
4.Post-dilatation
with NC14-16atm



ST risk can be reduced by implantation technique

Puricel et al. J Am Coll Cardiol 2016 67:921-931

Incidence of ST

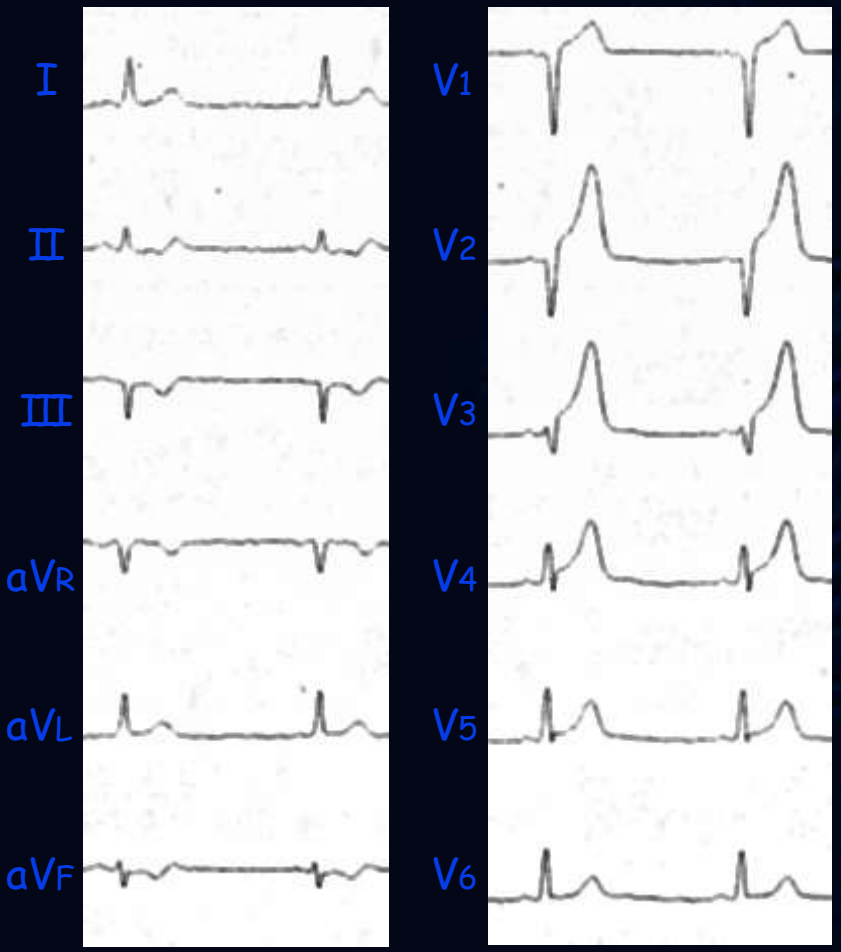
	Milan 400 Lesion, 264 Pt	ABSORB III 1322 Lesion, Pt	Ghost EU 1440 Lesion, 1189 Pt
Definite/Probable ST	1.2% at 1y	1.5% at 1y	2.1% at 6m
ACC/AHA class B2/C	74.8%	68.7%	53.5%
Bifurcation	46.8%	Excluded	23.1%
Total BVS length per Pt	53.2±32.5mm	20.5±7.2mm	32.6±23.0mm
Pre-dilatation	97.3%	Mandatory	98%
Post-dilatation	99.8%	65.5%	49%
Post-dilatation pressure	20.8±4.5atm	15.4±3.0 atm	-
Intravascular imaging	85.8%	11.2%	14.4%

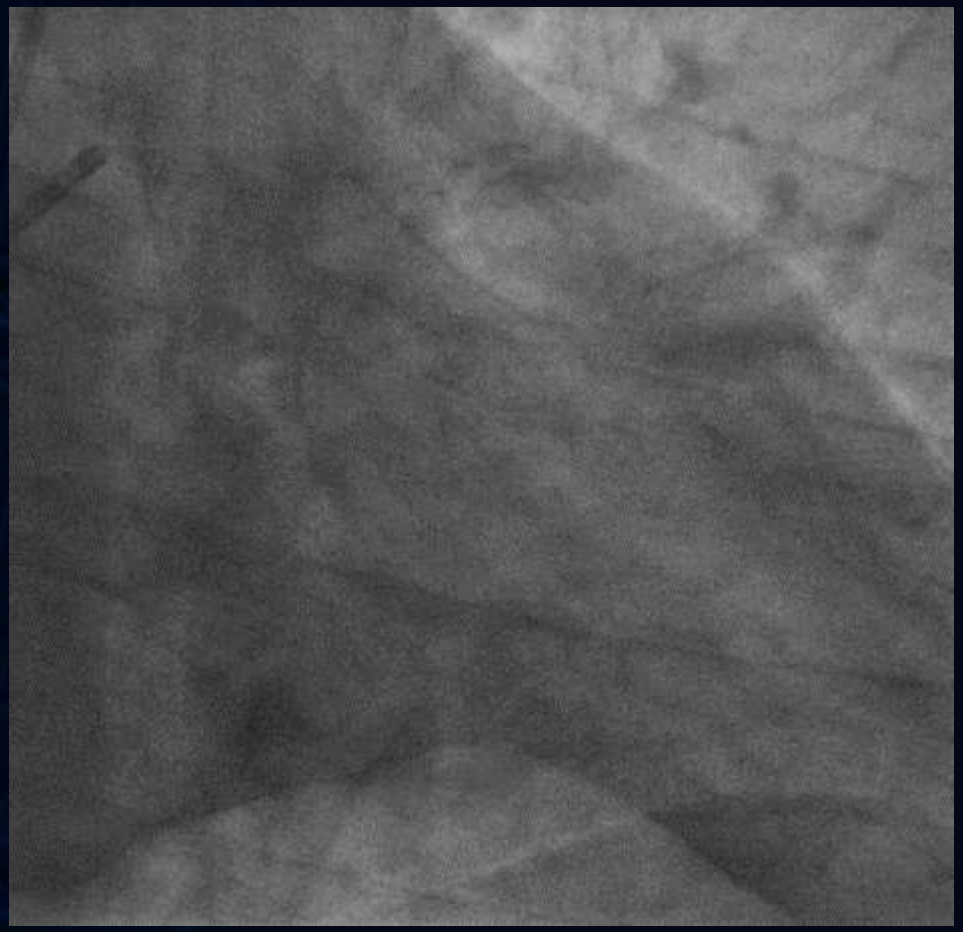
Capodanno et al. EuroIntervention 2014 *Ellis et al. N Engl J Med 2015*

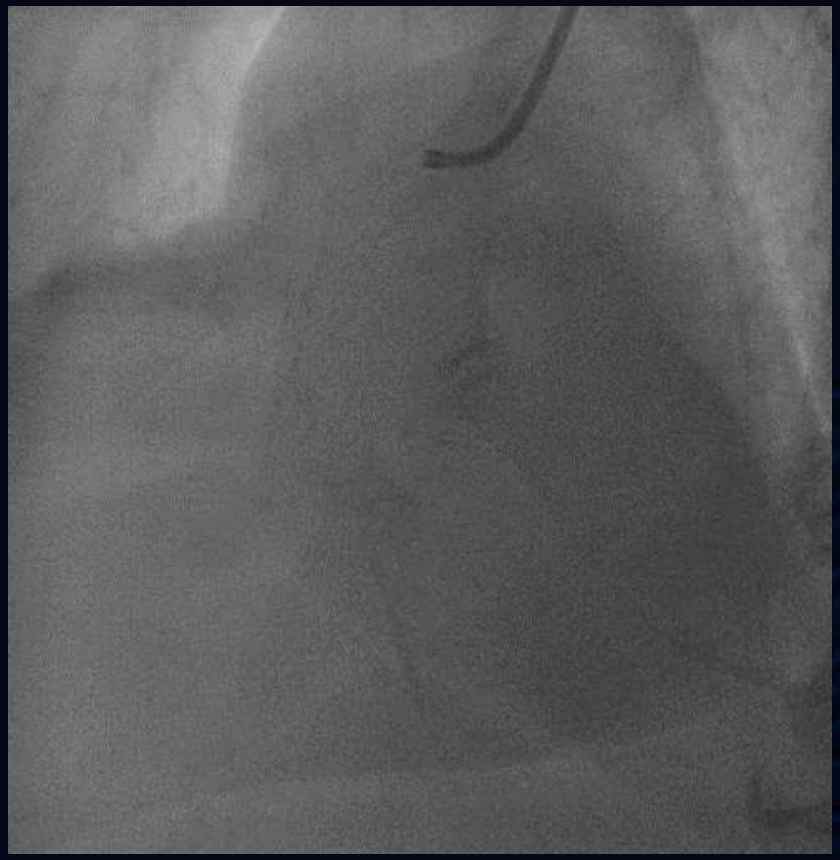
ST risk can be overcome by optimal implantation techniques even in complex lesion subset

65 y.o Male STEMI

Baseline angiogram







CTO of RCA mid segment, collaterals to LAD branches

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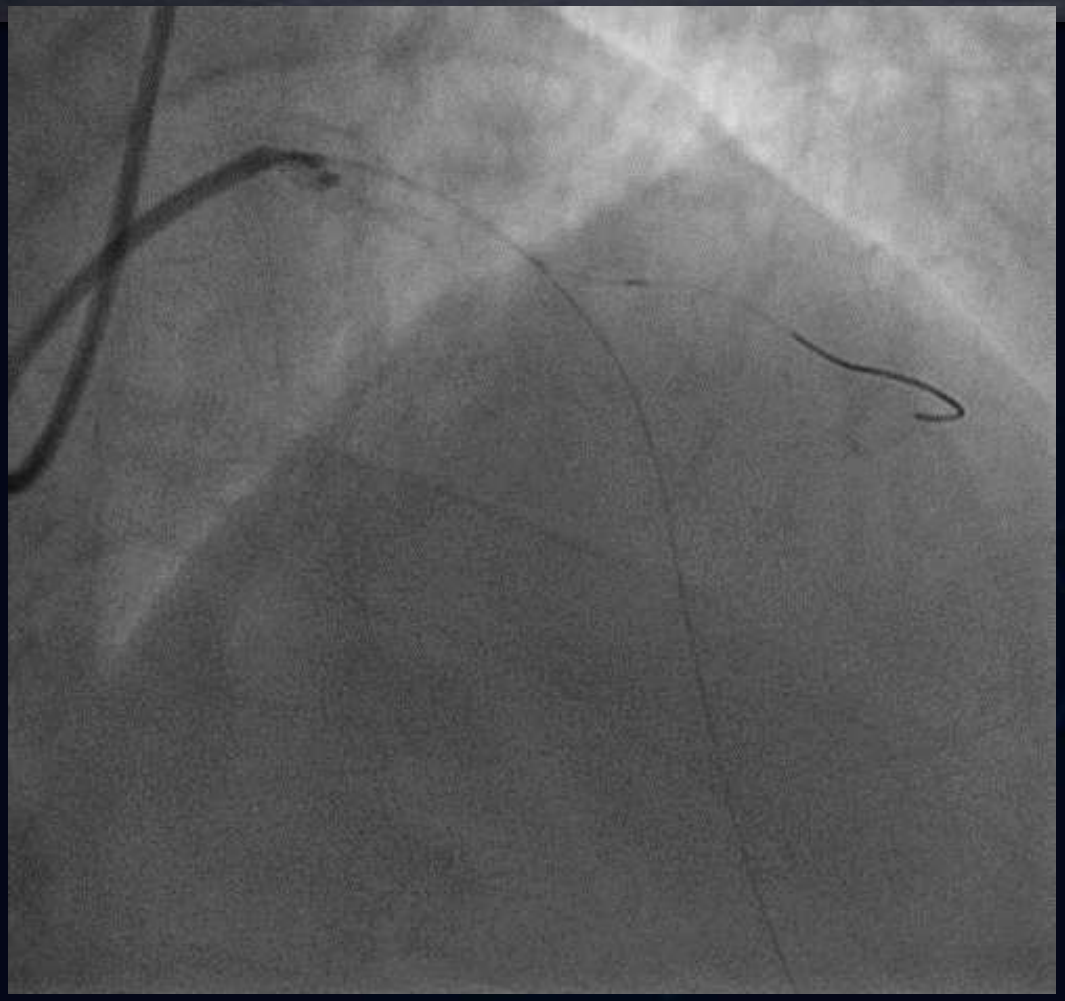
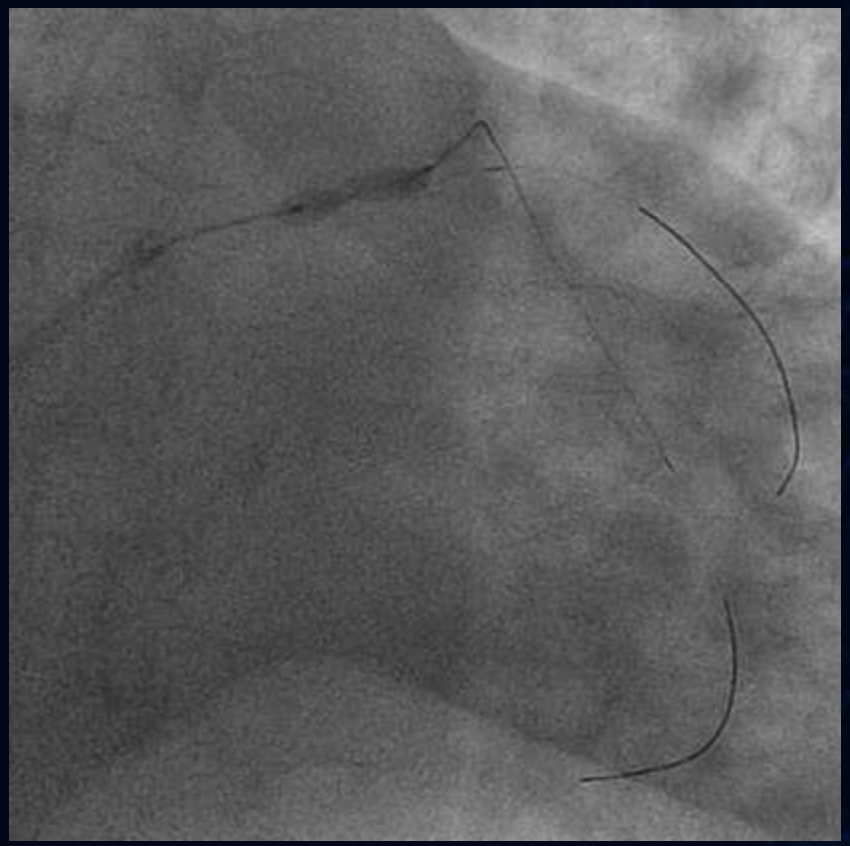
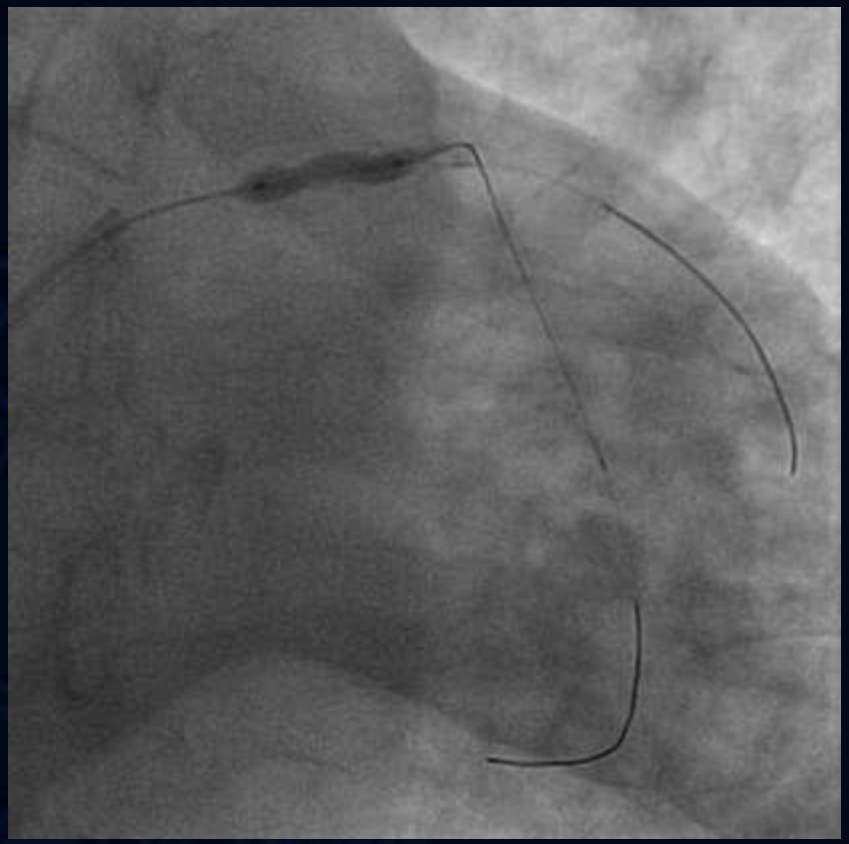
After administration of Ticagrelor + Bivalirudin- wire crossing and thrombus aspiration -



LAD was restored its flow and appeared to be diffusely diseased

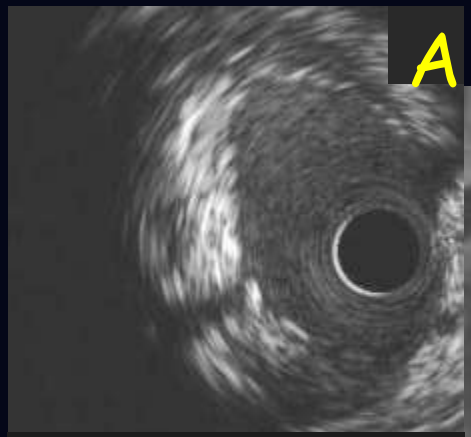
BVS implantation



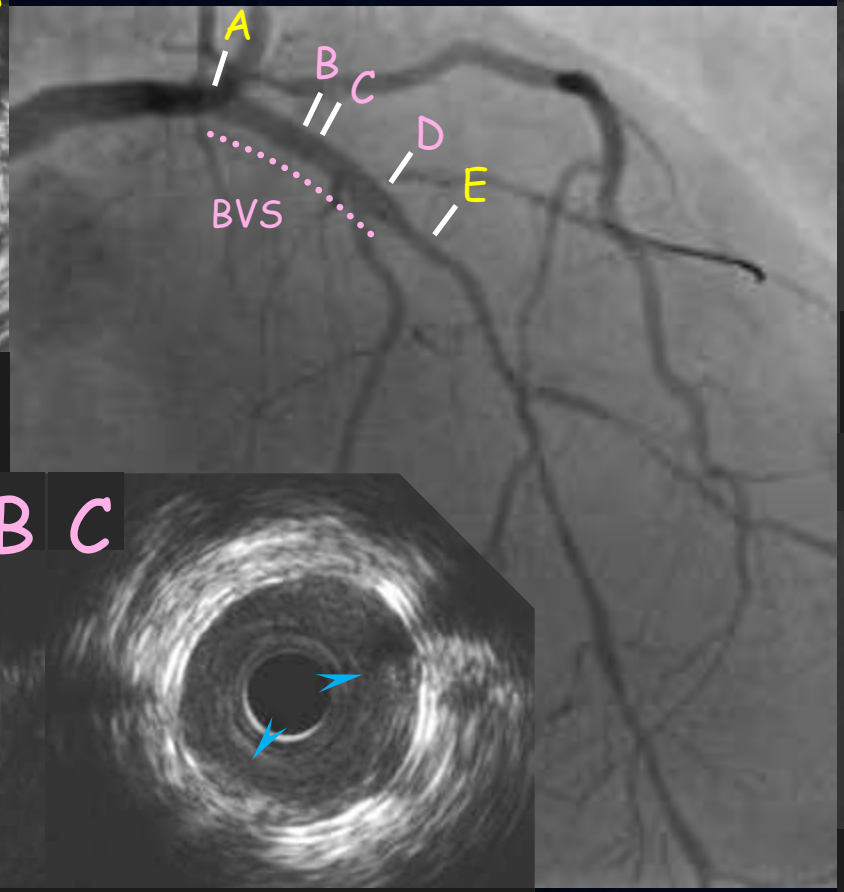


ABSORB 3.0/18mm (7atm) followed by Post-dilatation NC3.0mm

Final IVUS



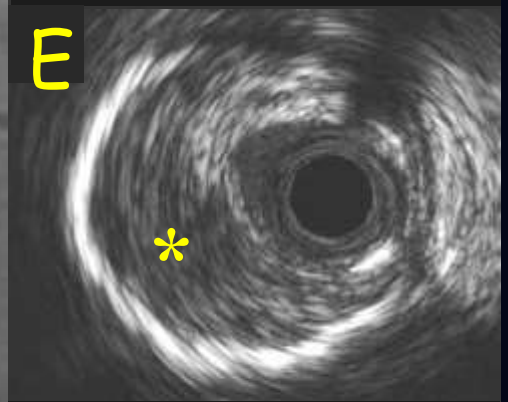
Lumen area 6.67mm^2
(3.85*2.22mm)



Lumen area 6.3mm^2 (3.00*2.72mm)

: Materials protruded into the lumen through the scaffolds

Lumen area 5.06mm^2
(2.83*2.29mm)



Lumen area 2.64mm^2
(2.08*1.58mm)

Massive plaque with necrotic core (*)
and deep calcification

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Final Angiogram

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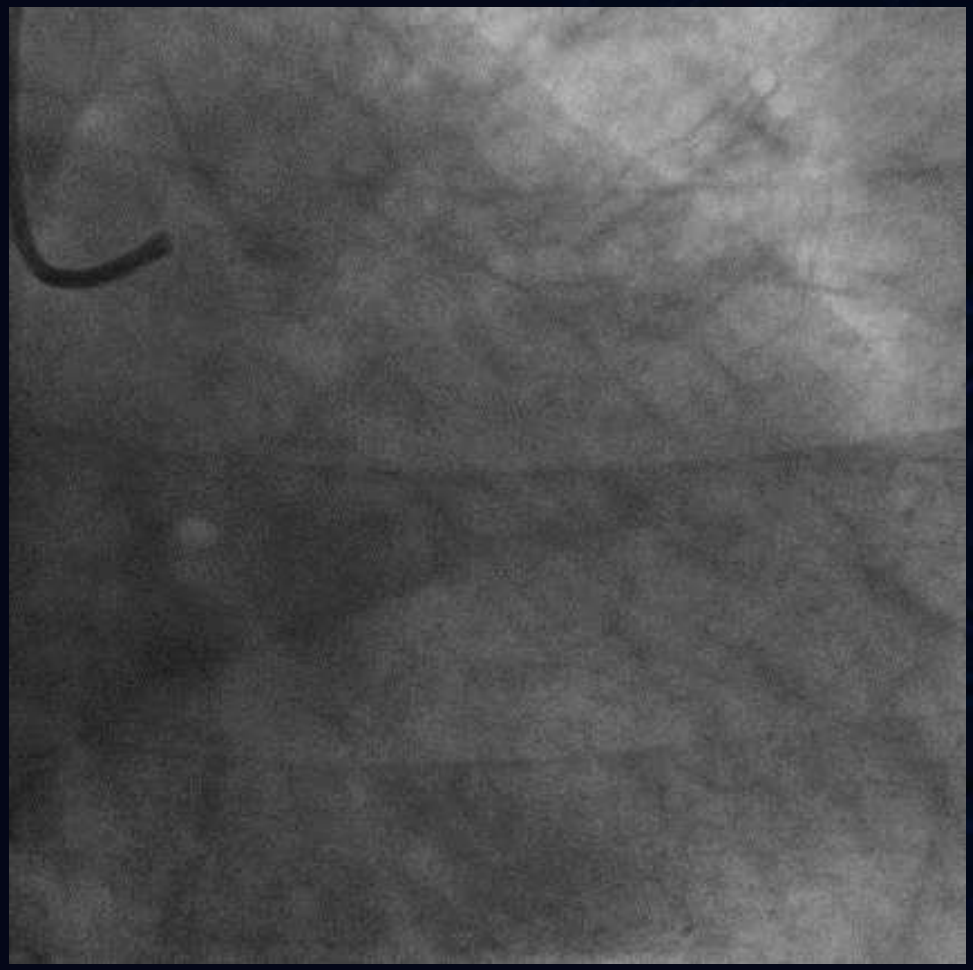
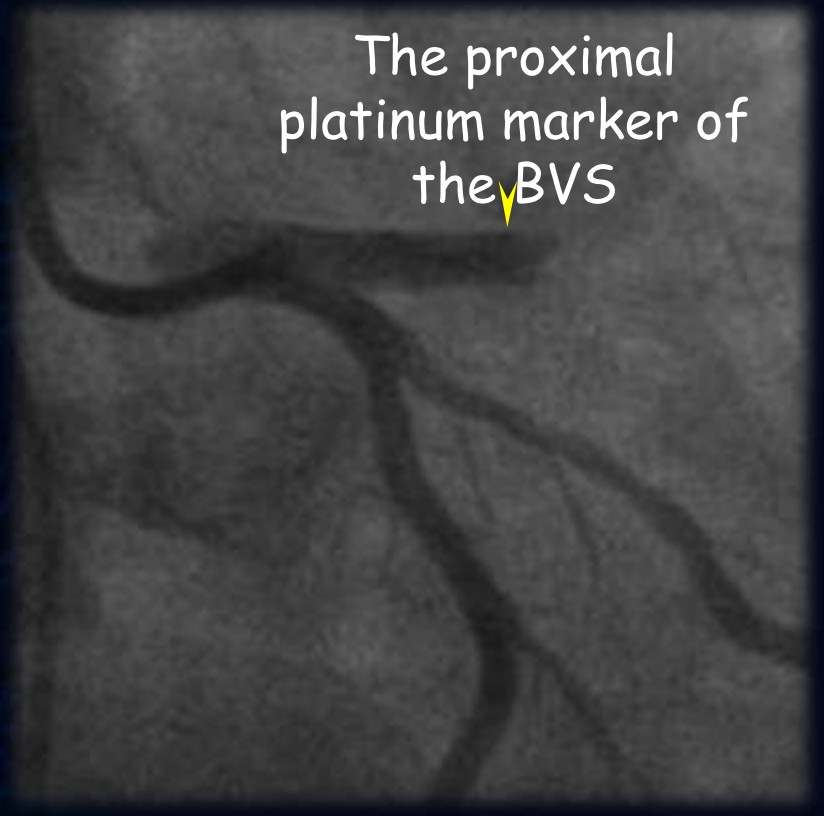
Two hours later… chest pain and ST elevation

Coronary Angiogram





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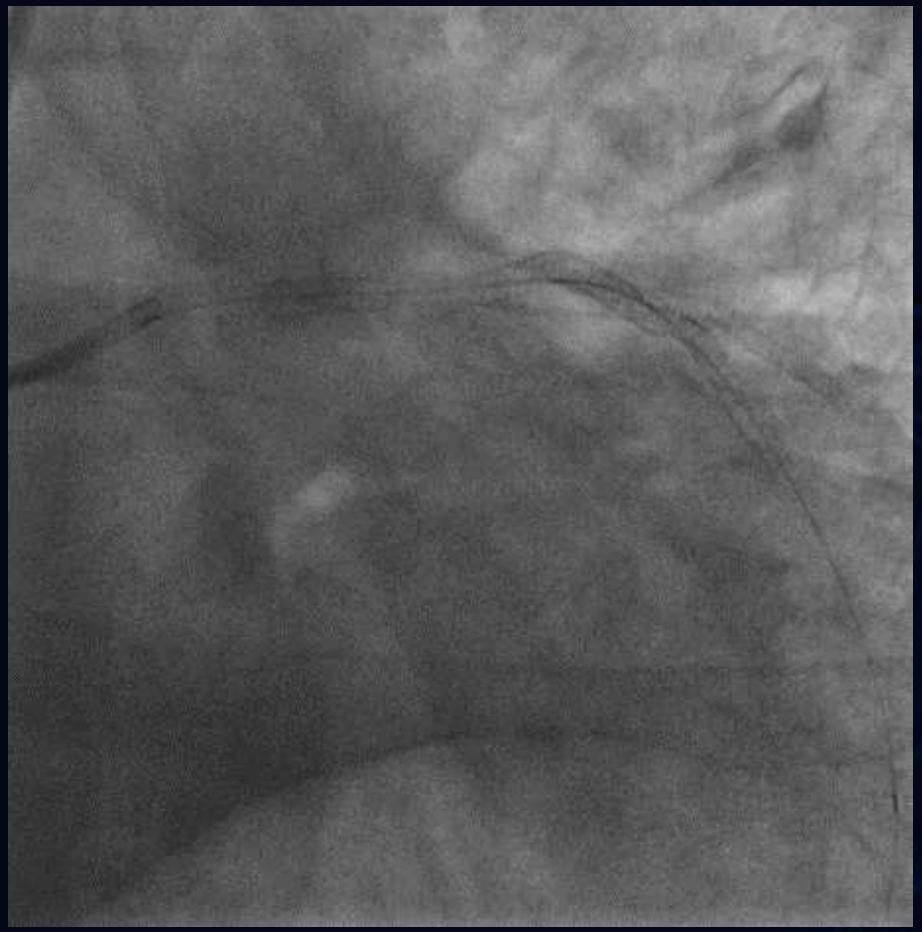
EES implantation and Final Angiogram



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Management of BRS failure
-Follow-up after TLR-

Tanaka et al. Catheter Cardiovasc Interv. 2015 Sept2

Subjects

Among BVS implantation 300 lesions (215 patients) May 2012 – Dec 2014 in 2 centers, Milan

TLR: 20 lesions (18 patients) for BVS failure

Follow-up: median 345 days (292-470 days)

Summary

ISR pattern

Focal Lesion 15 /20

Management at TLR

- DES 11
- Another BRS 4
- DCB 3
- POBA 2

Clinical event after TLR

Event	Time from TLR to Event	Management of repeat TLR
Sudden death	293	–
Repeat TLR	250	DES
Repeat TLR	90	BRS
Repeat TLR	123	CABG

20 lesions 18 patients

Median 345 days after TLR

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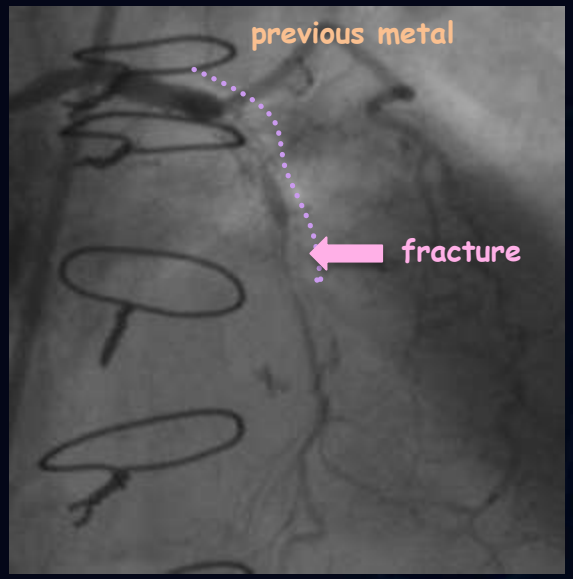
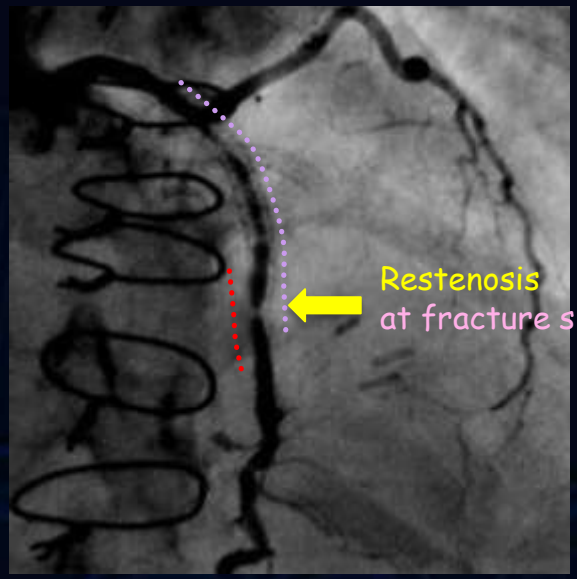
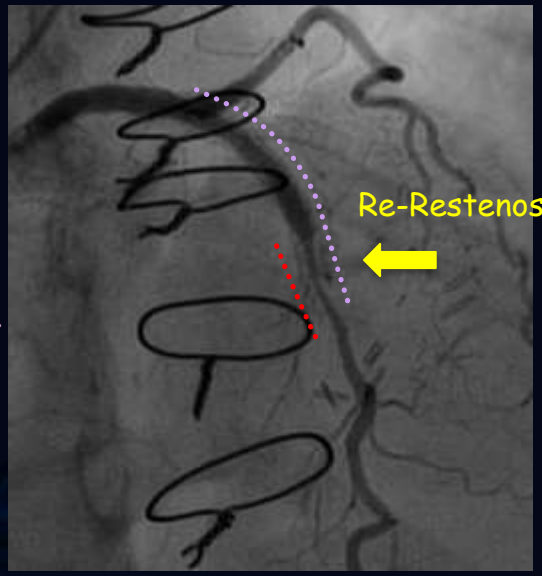
Index procedure — 300 days — **TLR** — 250 days — **Re-TLR**

Pre

Post

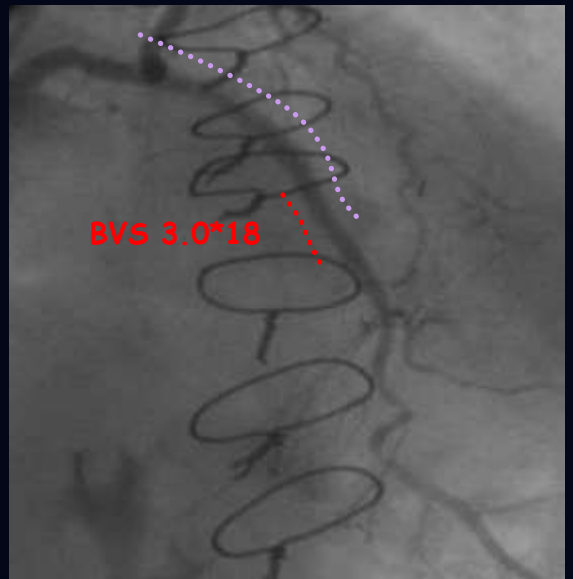


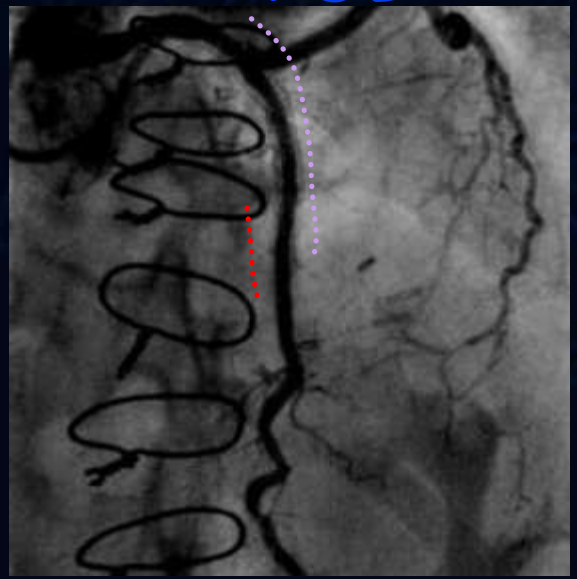


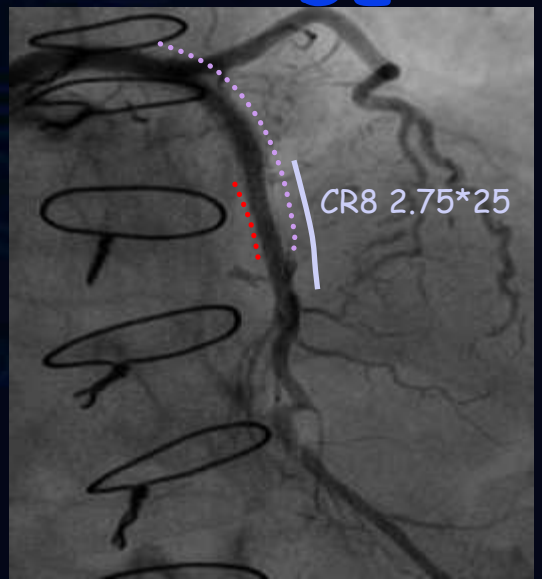


POB

DE







Implantation techniques

-to overcome limitations of current BRS-

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1. Lesion preparation

- *For Scaffold expansion*

  - Less radial force and greater acute recoil
  - Inadequate lesion preparation may correlate with underexpansion

Brown et al. Cather Cardiovasc Interv 2014;84:37-45
Mattesini et al. J Am Coll Cardiol Intev 2014;7:741-750
Danzi et al. Cather Cardiovasc Interv 2015;

1:1 pre-dilatation with NC / Low threshold for debulking devices

2. Post-dilatation

- *Importance of Post-dilatation*
  - Acute lumen gain is lower for current BRS than metallic stents with similar pressures even in simplest lesion subset *Ellis et al. N Eng J Med 2015/Kimura et al. Eur Heart J 2015 Gao et al. J Am Coll Cardiol 2015/Serruys et al. Lancet 2015*
  - High post-dilatation rates (over 90%) and pressures (over 20 atm) were associated with lower rates of ST *Caiazzo et al. Int J Cardiol 2015:201;129-136*
- *Risk with Overexpansion*
  - Overexpansion might cause strut disconnection *Foin et al. Eurointerv2015; Sep, Epub*

- ***Non-oversized NC balloon with high-pressure (over 20 atm)***
- ***Balloon/Scaffold diameter 1:1, maximum +0.5mm***

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3. Intravascular imaging

- *To assist Sizing*
  - BRS requires more careful sizing
    - Undersize → Malapposition → ✓ ST risk
    - Oversize → Increased foot print → ✓ Worse clinical outcomes; ✓ Side branch occlusion
- *End of procedure*

To detect… *-Underexpansion: -Malapposition -Edge injury:*

Lorenz et al. J Am Coll Cardiol 2015;66:1901-14

Low threshold for Intravascular imaging especially at procedure end

Conclusions

- ✓ Currently commercially available BRS are still first generation bulky device with inherent limitations
- ✓ However in order to overcome their limitations in order to minimize BRS failures it is fundamental the use of approppriate implantation techniques such as proper vessel preparation with aggressive predilatation, proper post dilatation and usage of imaging guidance, IVUS and/OCT
- ✓ Awaiting for new generation BRS