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Updated BRS imaging: Lessons from Brand-New data

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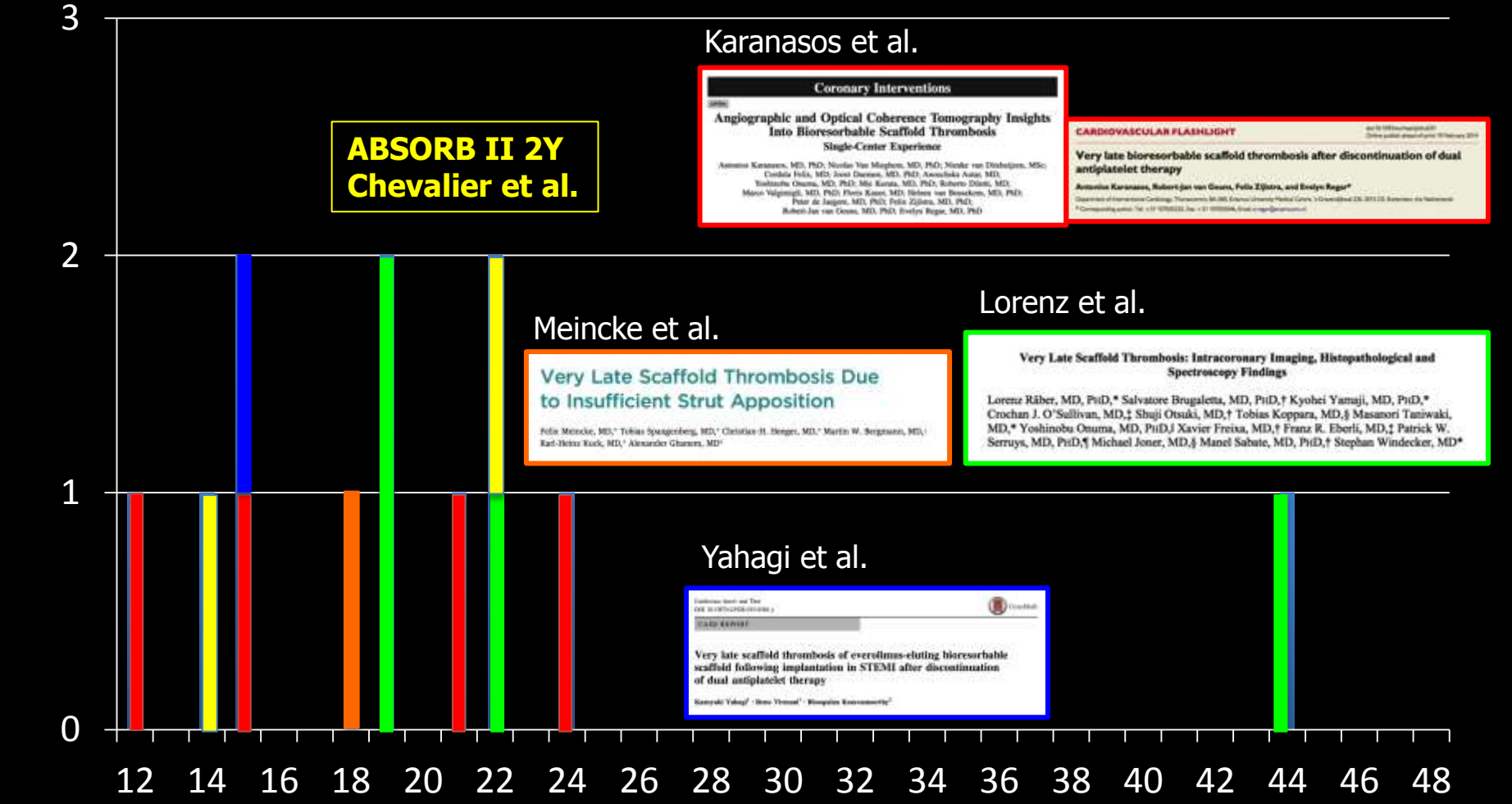
Updated BRS imaging: Lessons from Brand-New data

- **Lessons from Case reports**
  Late discontinuities and late scaffold thrombosis
- **Lessons learned from Absorb Japan**
  QCA and OCT
- **Lessons learned from Absorb II**
  Sizing, Asymmetry
- **Lessons from Absorb TROFI II**
  Healing after STEMI
- **Lessons learned from Absorb B**
  Long-term IVUS/OCT

What is the reported incidence of very late thrombosis? (n=12 – denominator unknown)

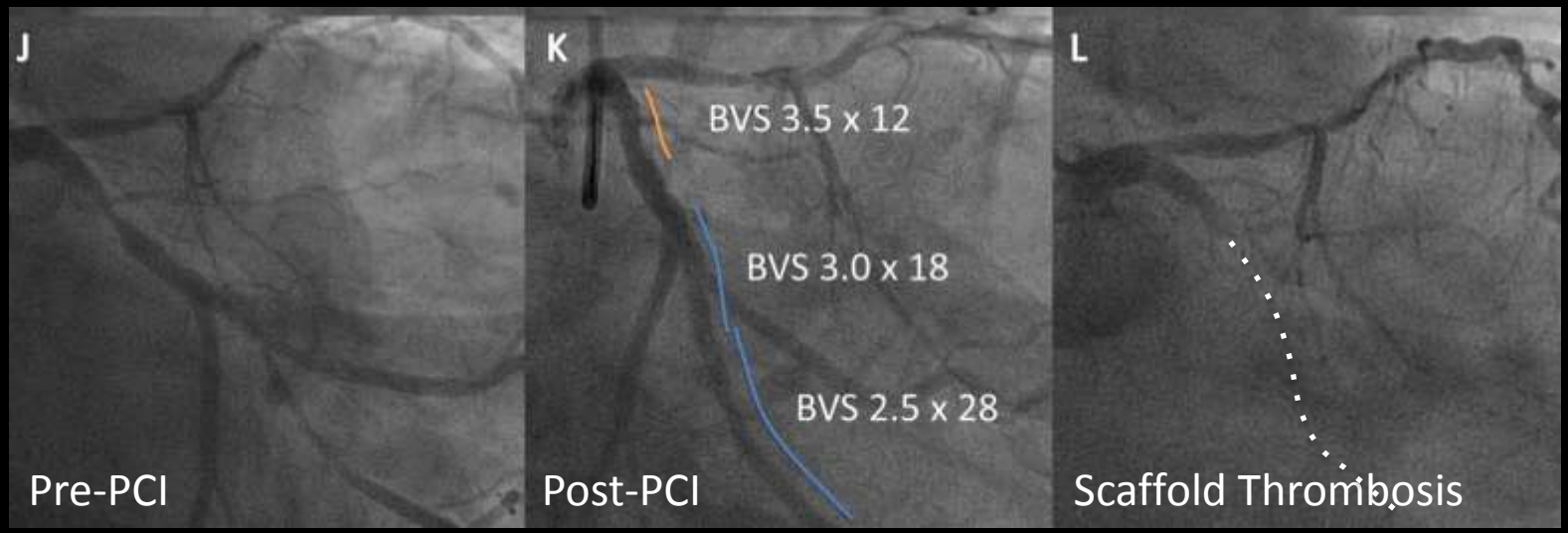


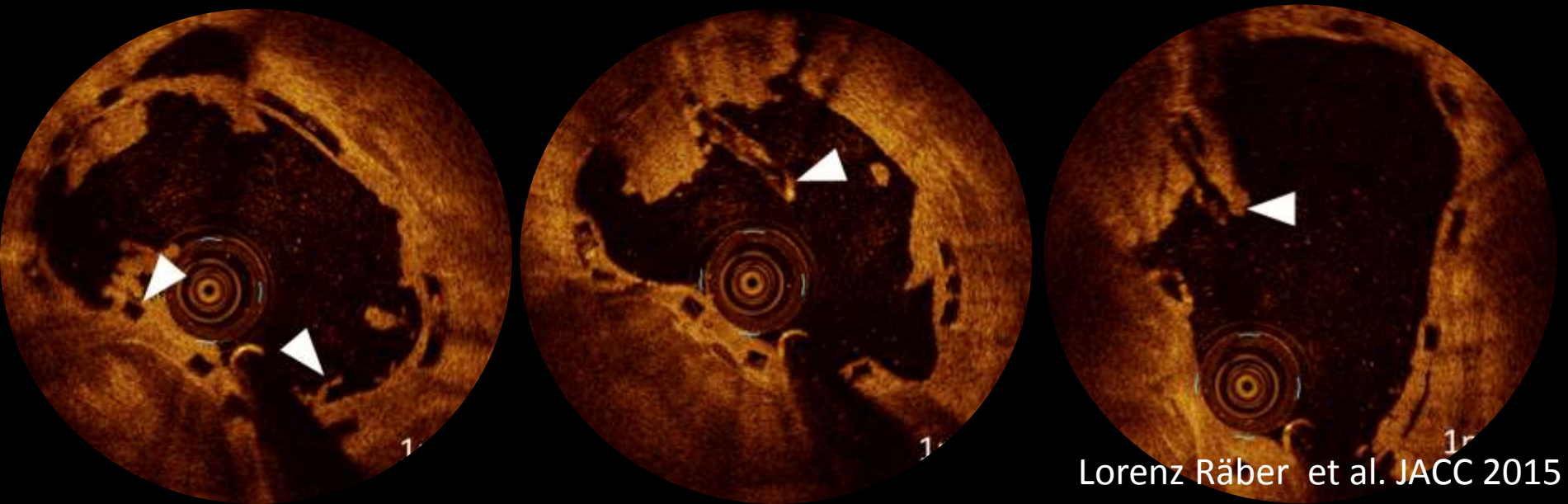
Follow-up duration (months)

#1 VLST with Late discontinuity and Uncovered struts

VLST at 19 months

The cause for thrombus formation was late scaffold strut discontinuity with the particular finding of a long scaffold strut freely floating in the lumen. Uncovered struts were frequently observed (10%) and the majority of struts were covered by thrombus.



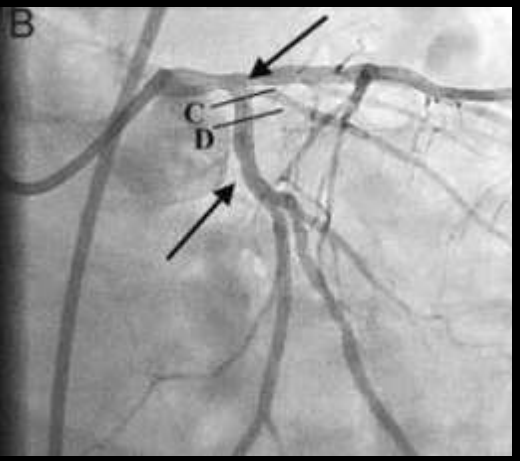


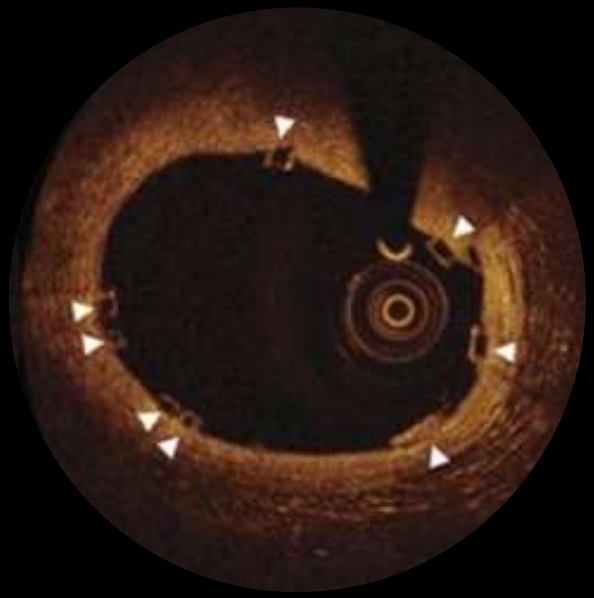
Lorenz Räber et al. JACC 2015

#2 VLST at 2 years with late discontinuities

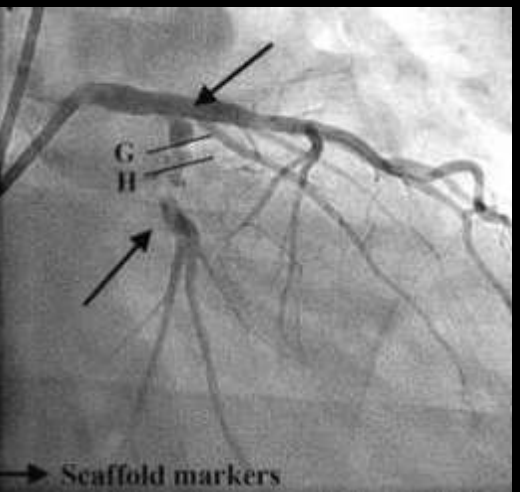
Karanasos A et al. Eur Heart J 2014;35:1781.

Post-procedure

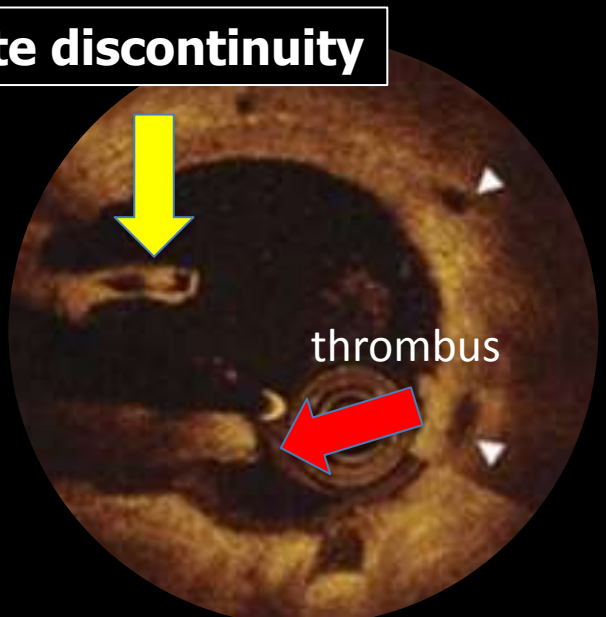


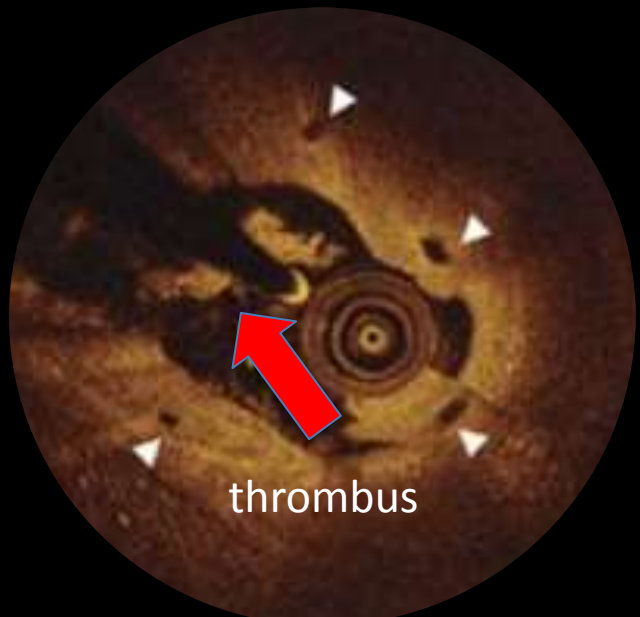


Scaffold thrombosis



late discontinuity

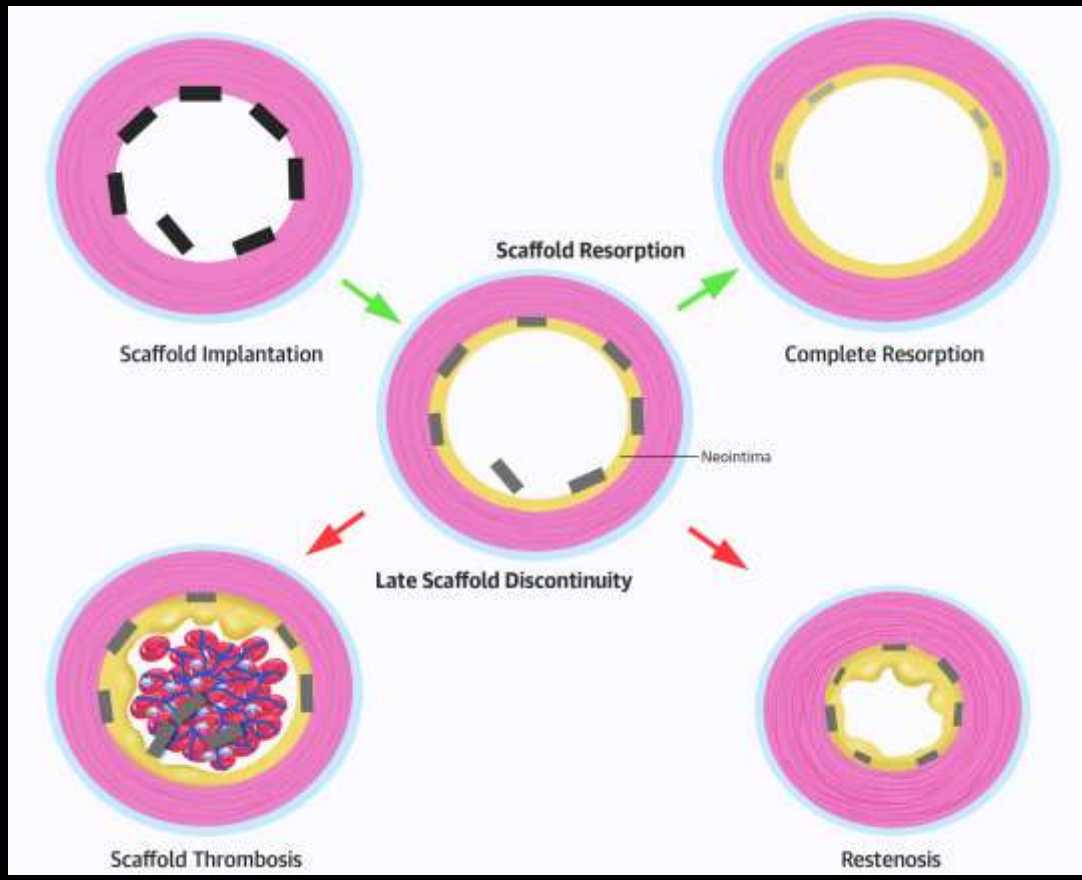




Late discontinuities: Culprit of late scaffold thrombosis or innocent bystander??

Challenges in interpretation:

- **Malapposition/ Disruption exists at BL? (Persistent or late acquired?)**
- **Artefacts created by wiring, predilatation or thrombectomy before OCT at the time of scaffold thrombosis?**
- **Late discontinuities exists in 40% cases up to 3 year FUP.**
- **What is a differential factor to determine the fate of Late discontinuities?**



Lorenz Räber et al. JACC 2015, Onuma et al. JACC interv 2014, Sotomi et al. Submitted

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Radio-opacity of metallic struts and Protruded radio-lucent polymeric struts influence QCA

Sotomi et al. Submitted

In-device acute gain in randomized trials

Data present in mean±SD	Absorb		EES	P-value
ABSORB II	1.15±0.4	<	1.46 ± 0.4	<0.001
ABSORB III	1.45±0.45	<	1.59±0.44	<0.001
ABSORB Japan	1.46±0.40	<	1.65±0.40	<0.0001
ABSORB China	1.51±0.03	<	1.59±0.03	0.04
ABSORB STEMI TROFI II	2.16±0.52		2.21±0.56	0.57

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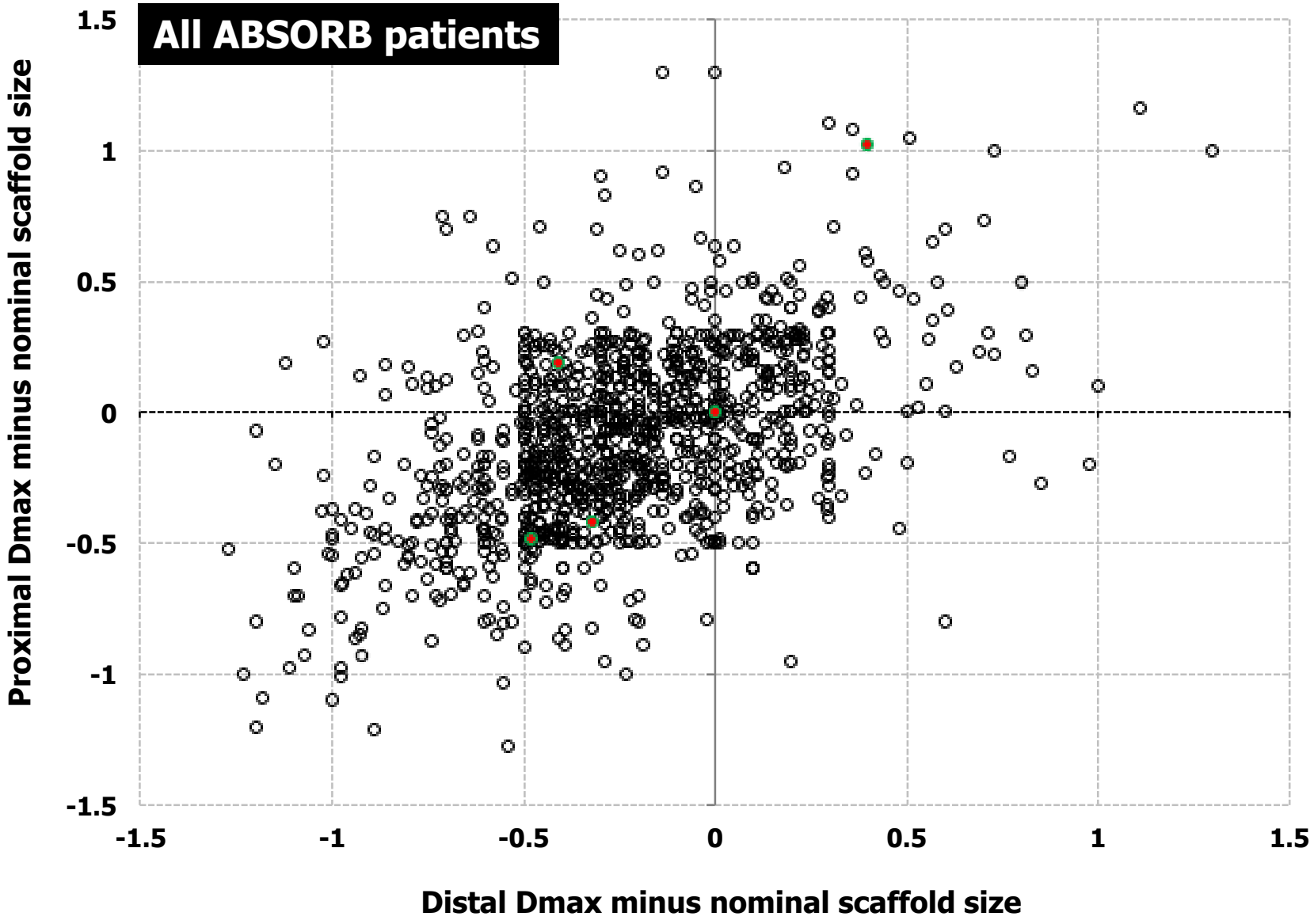
Distribution of Dmax Prox and Dmax Distal related to the nominal device size in the ABSORB II, Extend and B (n=1248)



Ishibashi et al. JACC CI 2015

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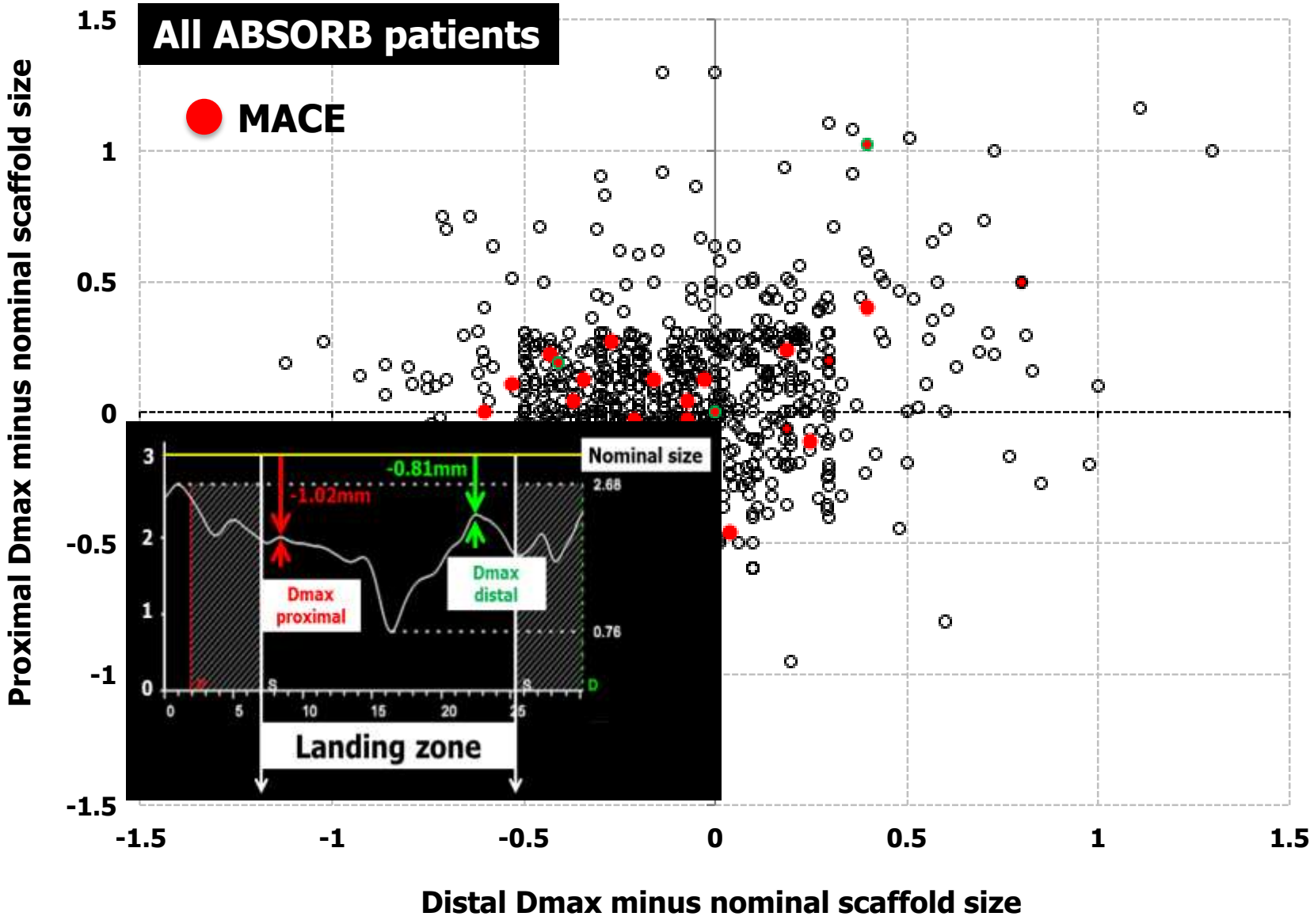

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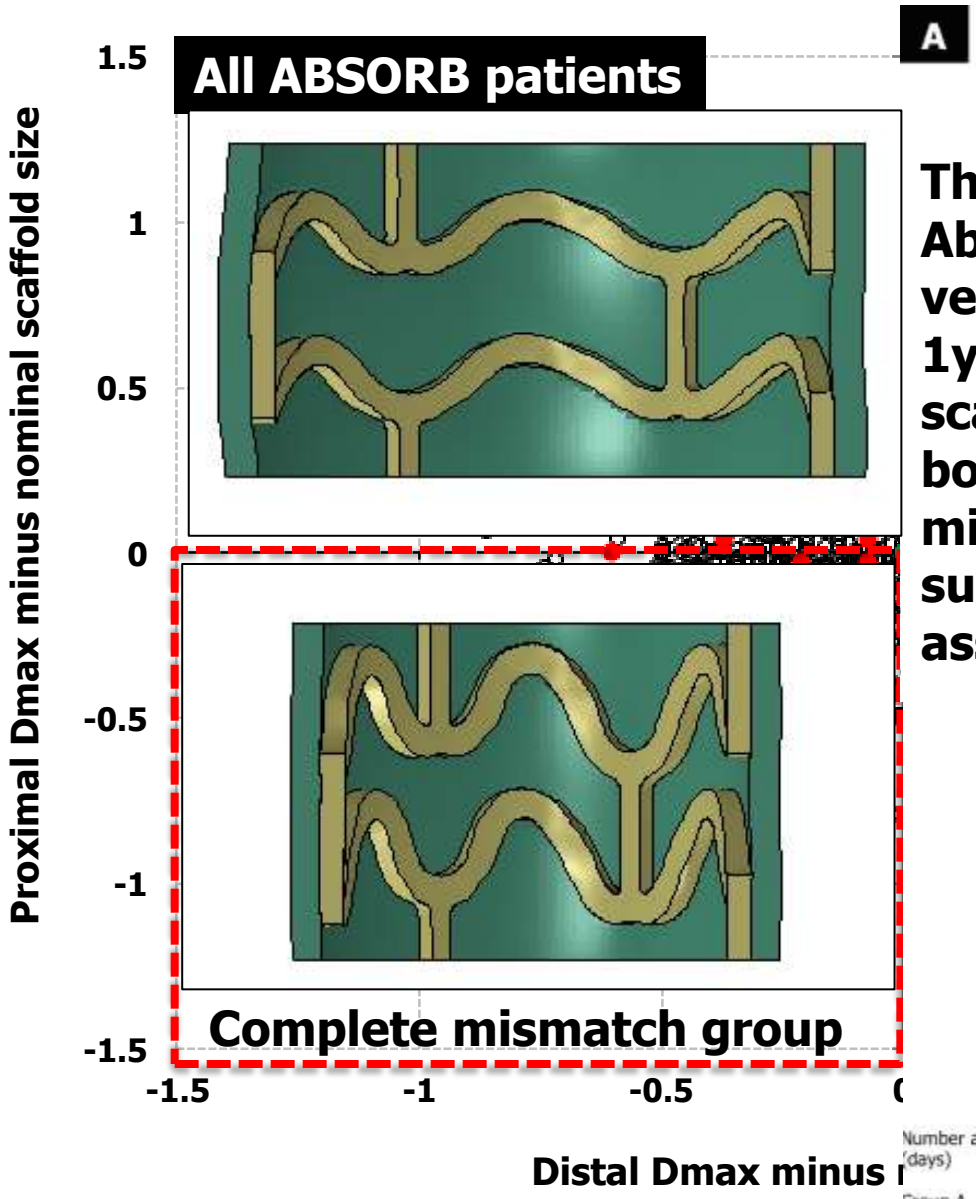
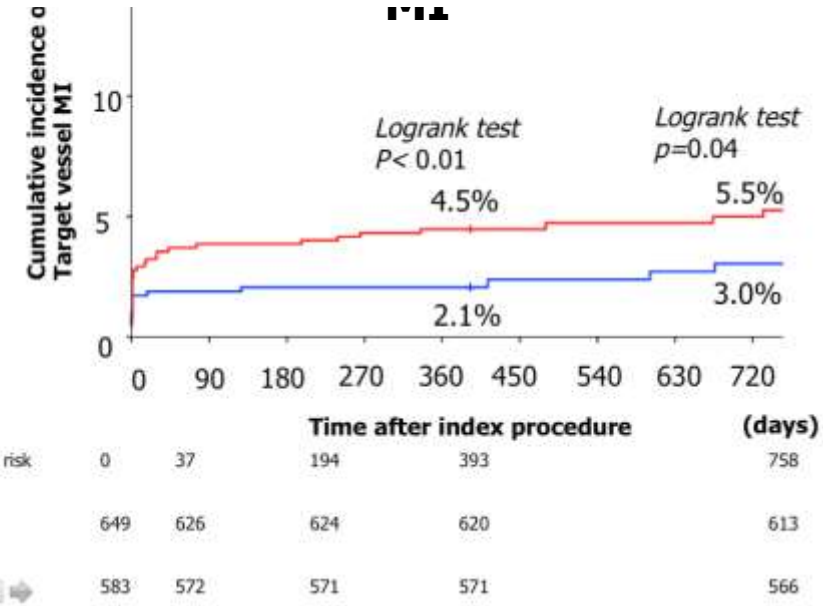


The implantation of a "large" Absorb scaffold in a relatively small vessel had a higher risk of MACE at 1year. The selection of nominal scaffold size below the diameter of both proximal and distal Dmax might lead to a denser polymer surface pattern, which could be associated with MI after procedure.



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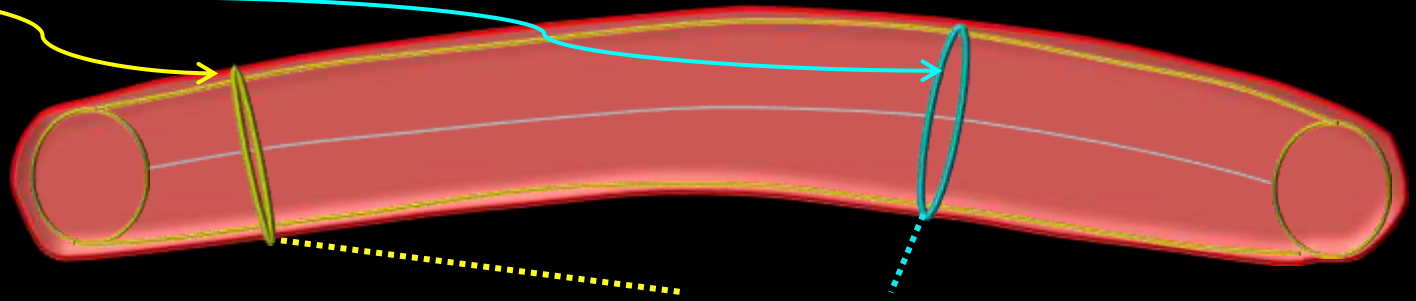
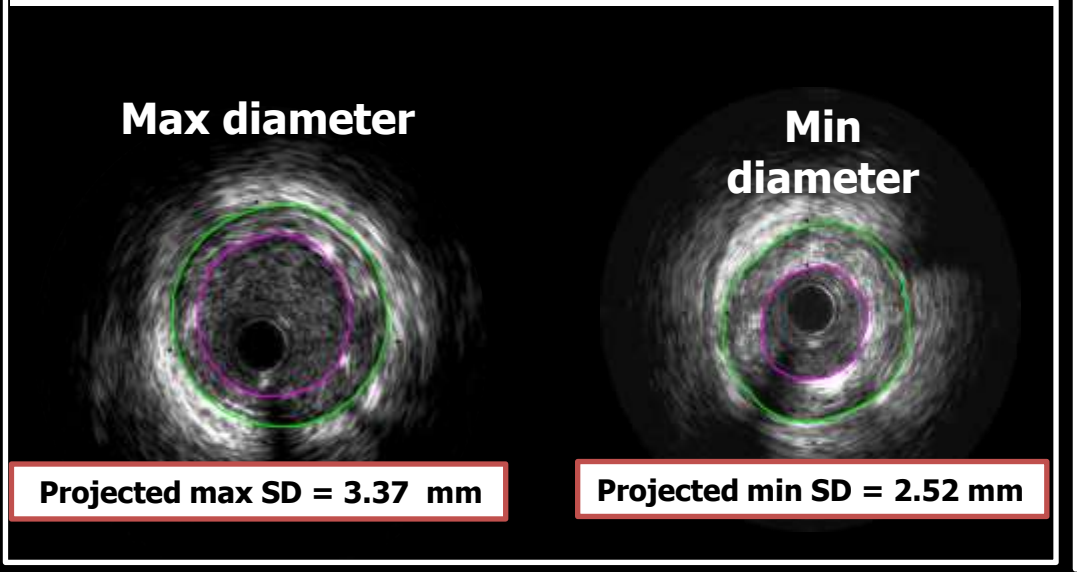
IVUS assessment for asymmetry/eccentricity

Minimum and Maximum diameter per device through the gravitational center of the lumen

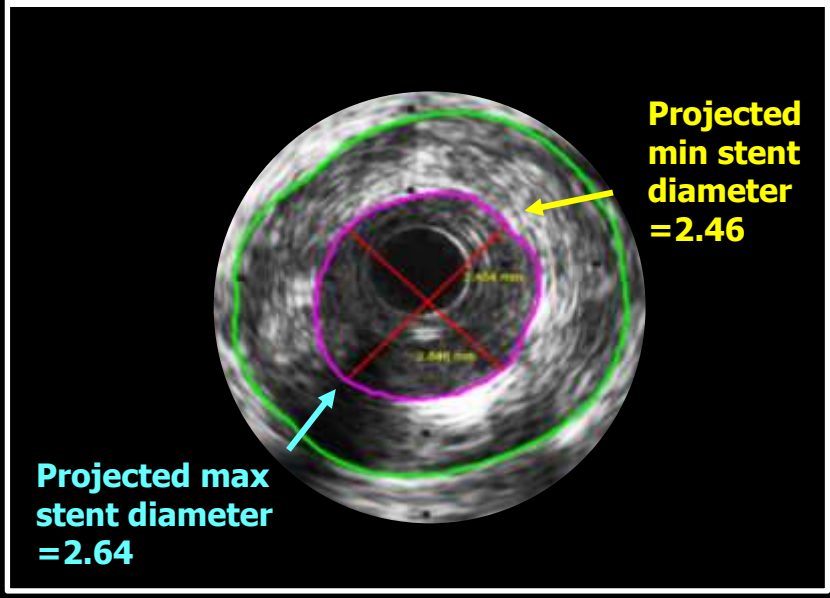


Cross sections of the device with the minimum and maximum diameter through the gravitational center of the lumen, showing different eccentricity indexes.

Asymmetry Index



Eccentricity index (cross-section)

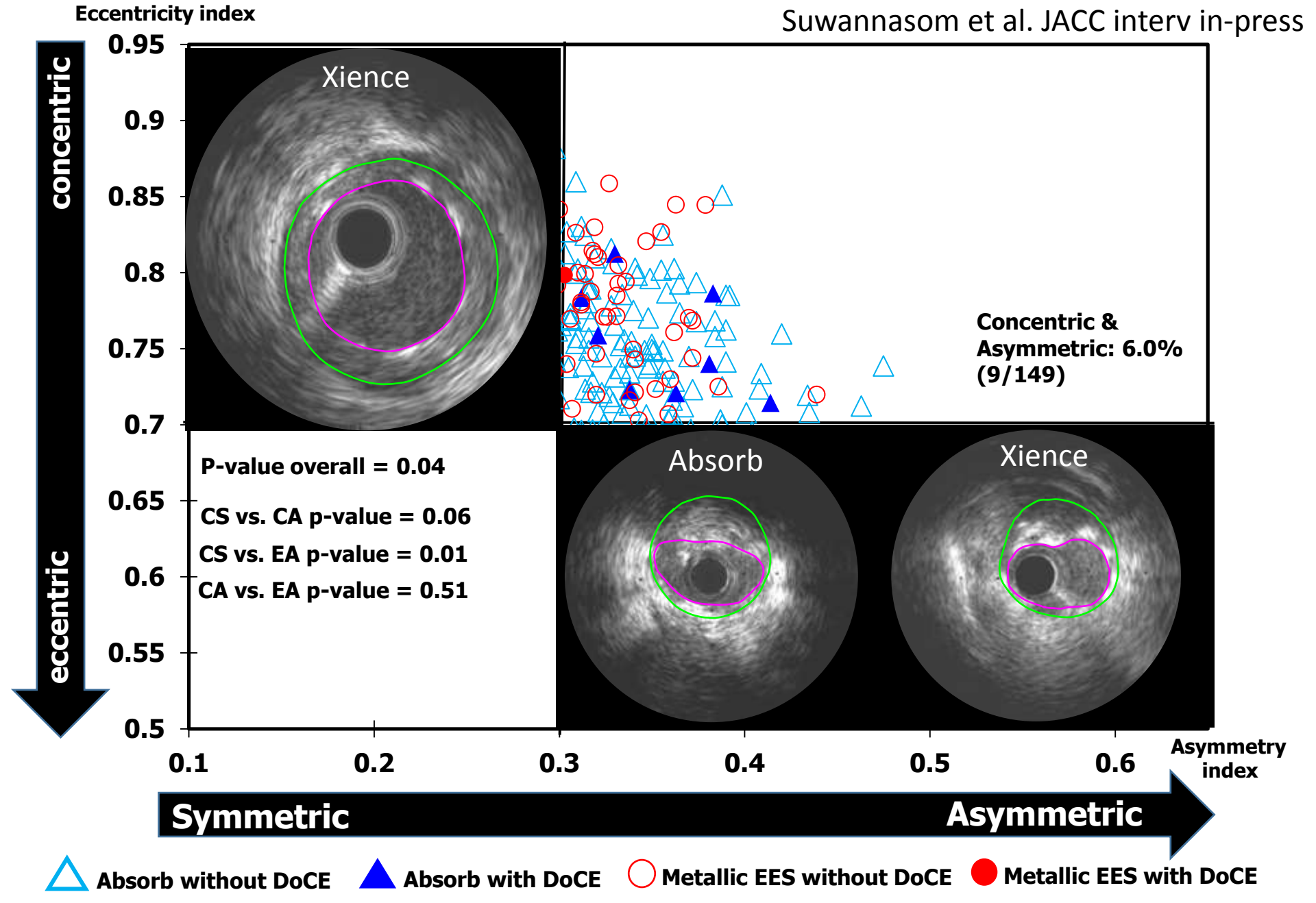


Symmetry index
= (3.37-2.52)/3.37 = 0.25

Eccentricity index
= 2.46/2.64 = 0.93

Distribution geometrical morphology according to type of devices in ABSORB II-trial and the incidence of DoCE over 1 year follow-up.

Suwannasom et al. JACC interv in-press



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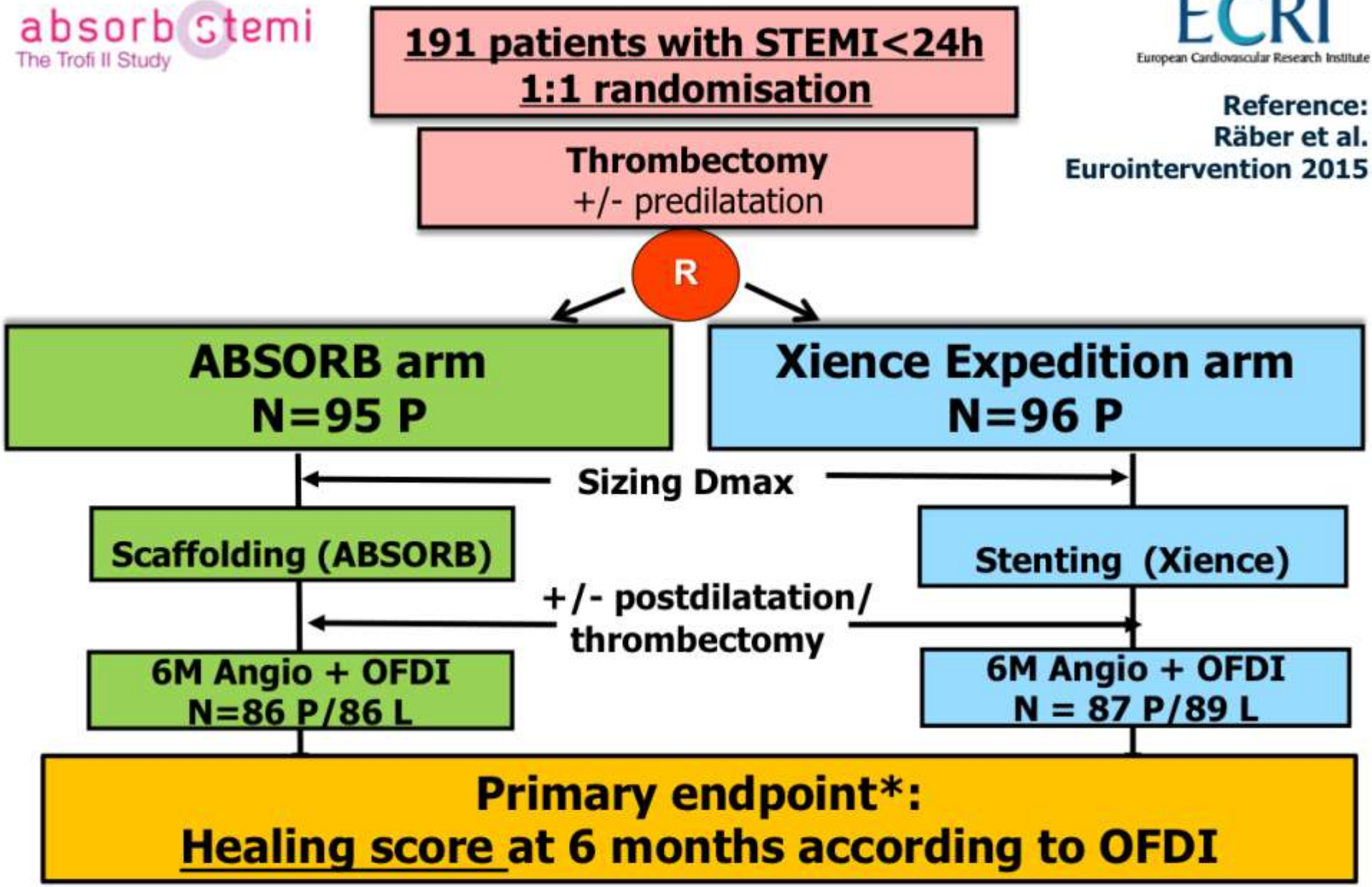
absorb Stemi
The Trofi II Study

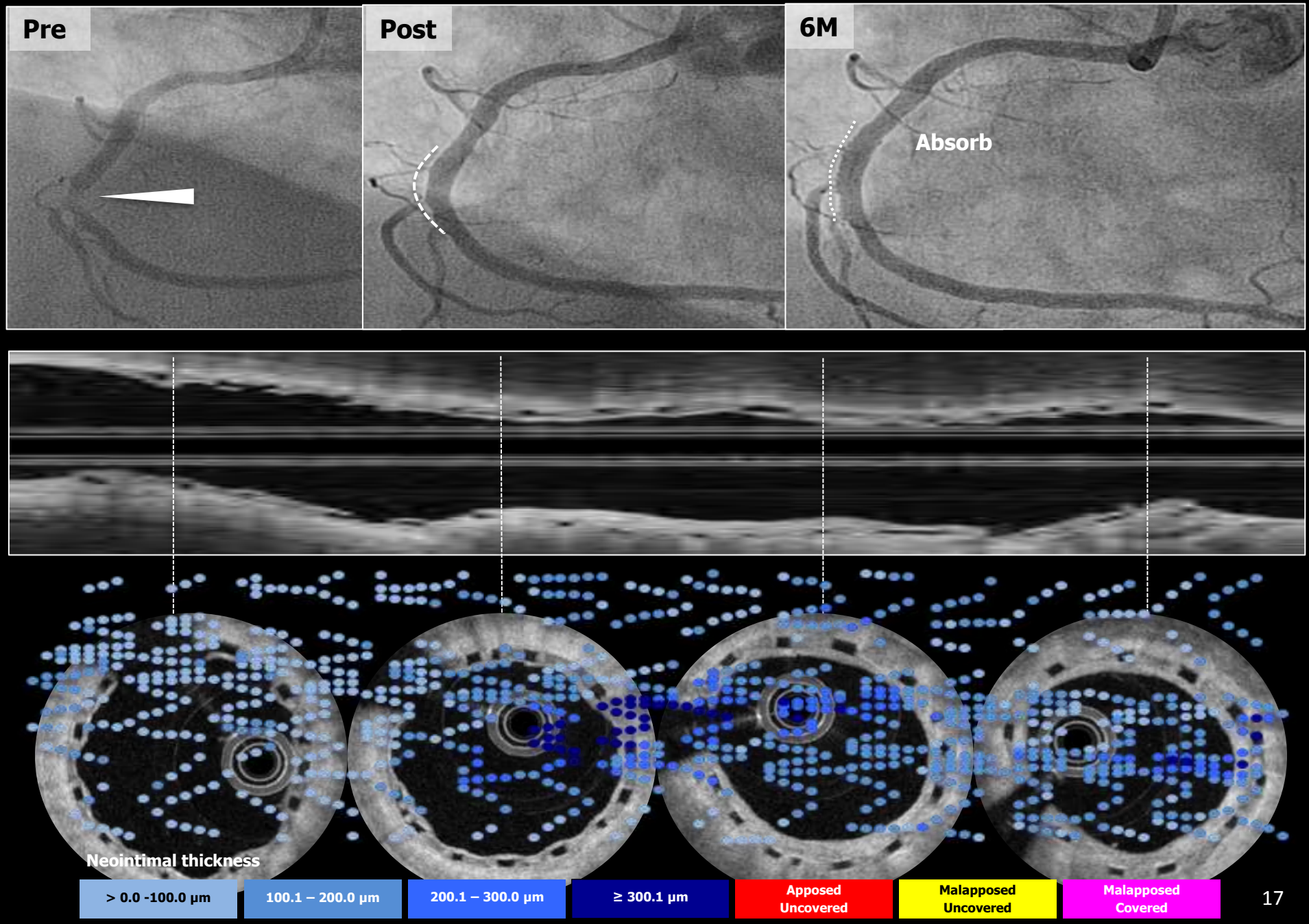
ECRI
European Cardiovascular Research Institute

Reference:
Räber et al.
Eurointervention 2015

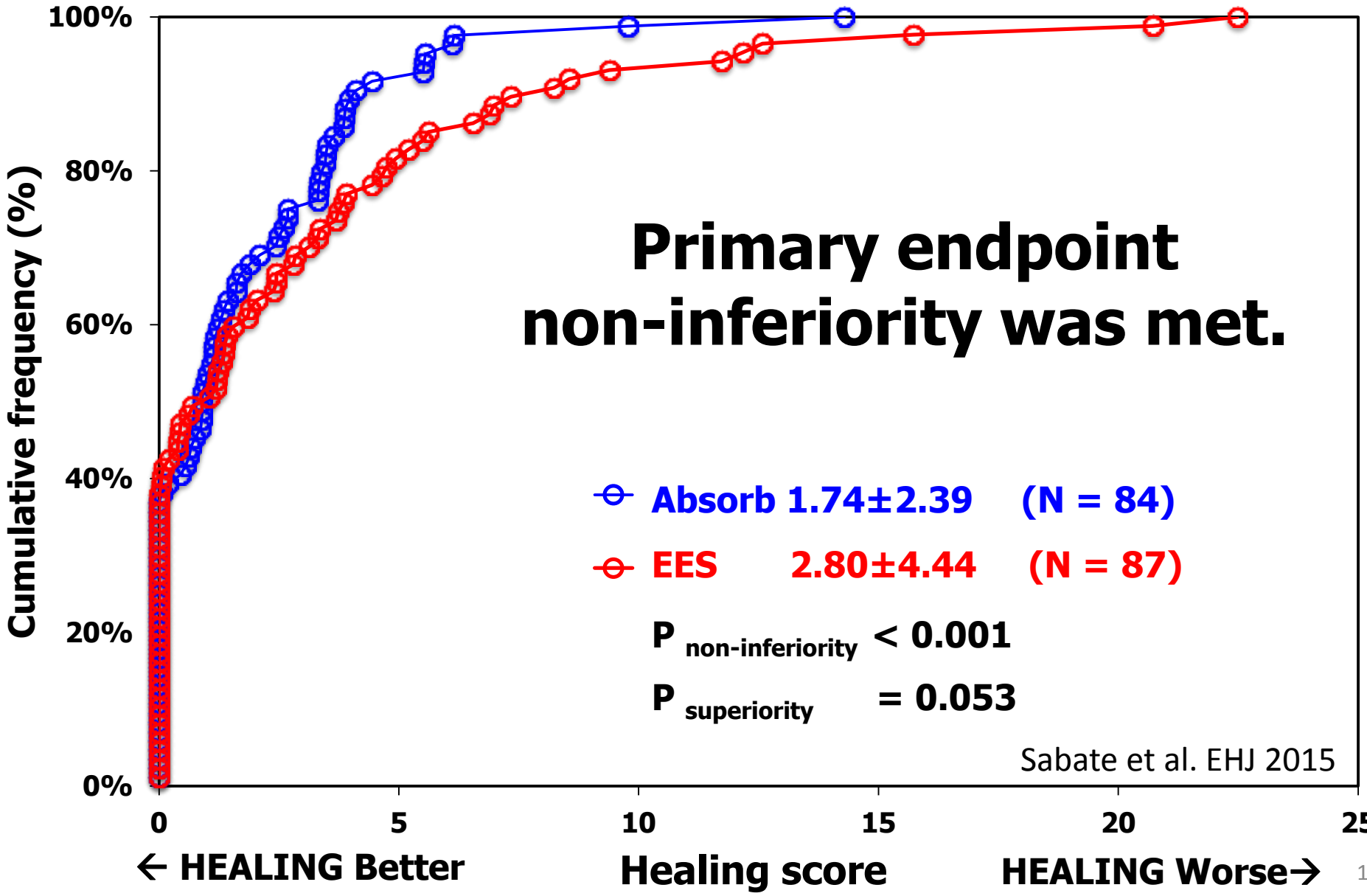


***Primary endpoint and other imaging endpoints** were analyzed in the as-treated population, excluding the patients/lesions who did not receive the assigned treatment (n=1).
Clinical follow-up was based on intention-to-treat population.

Absorb: Healing Score 0



Cumulative curve of Healing Score



Primary endpoint non-inferiority was met.

Absorb 1.74±2.39 (N = 84)

EES 2.80±4.44 (N = 87)

$P_{non\text{-}inferiority} < 0.001$

$P_{superiority} = 0.053$

Sabate et al. EHJ 2015

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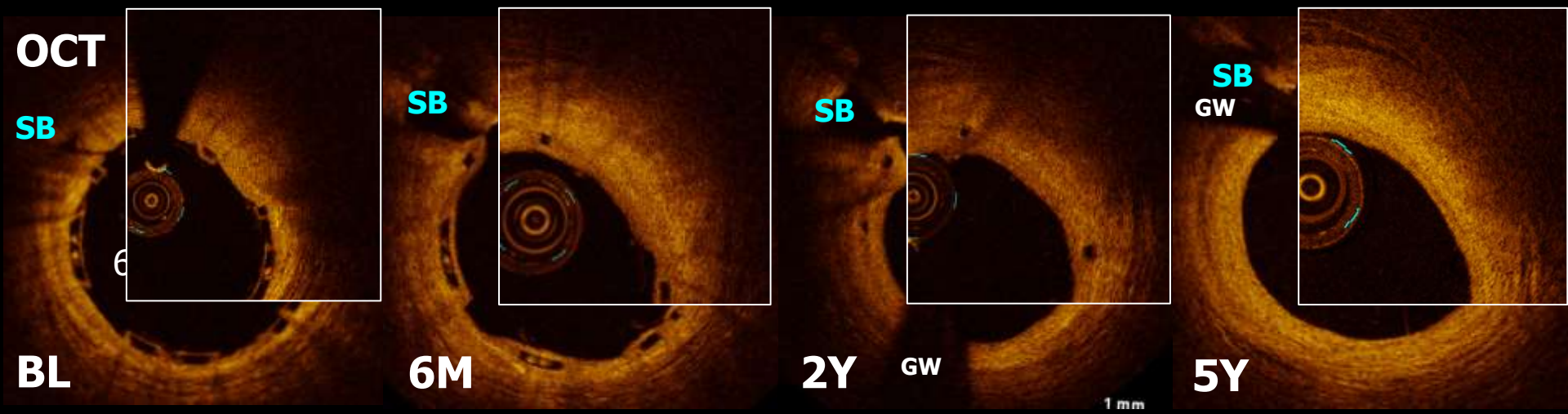
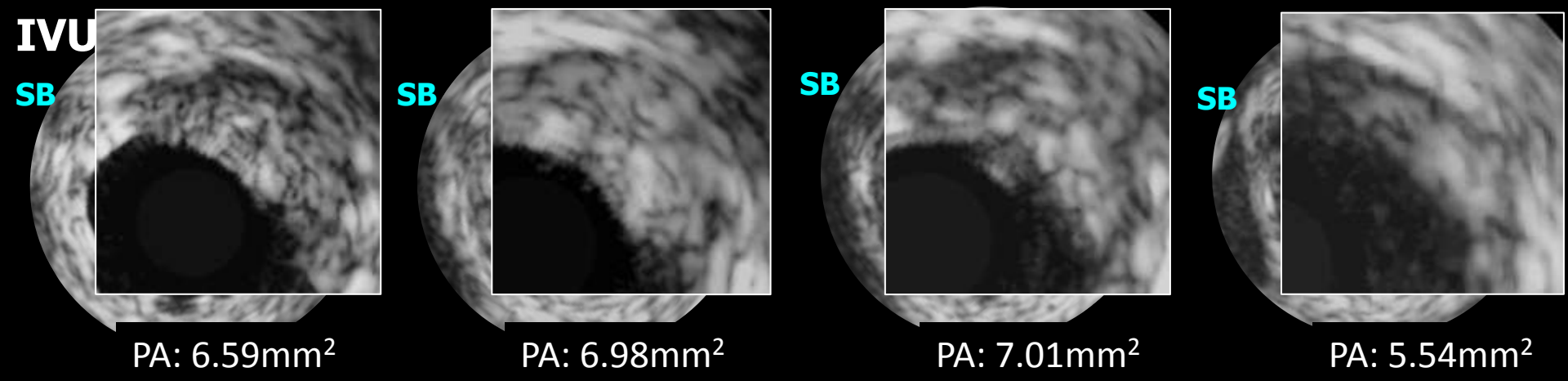
Plaque reduction with the change of plaque morphology

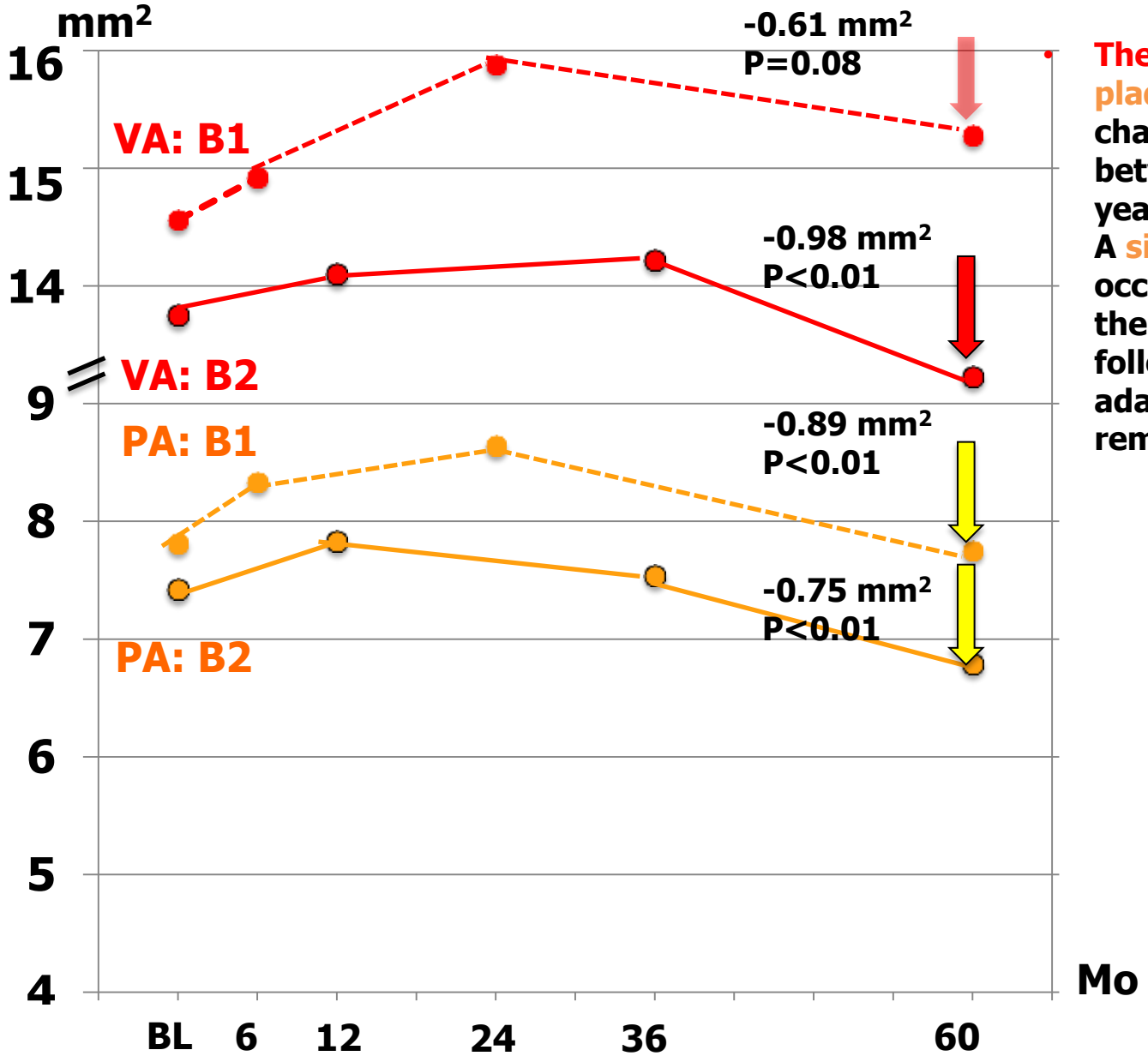




The change of plaque morphology, which makes the media visible at 5 years

100353-002

IVUS follow-up of the First-in-man trial (ABSORB B1/B2) over 5 years (B1: n=21, B2: n=30)



The Vessel area and total plaque area show a biphasic change with an increase between the first and second year.
A significant plaque reduction occurs in B1 and B2 between the second and fifth year follow-up accompanied by an adaptive and constrictive remodeling of the vessel area.

Serruys et al. JACC 2016

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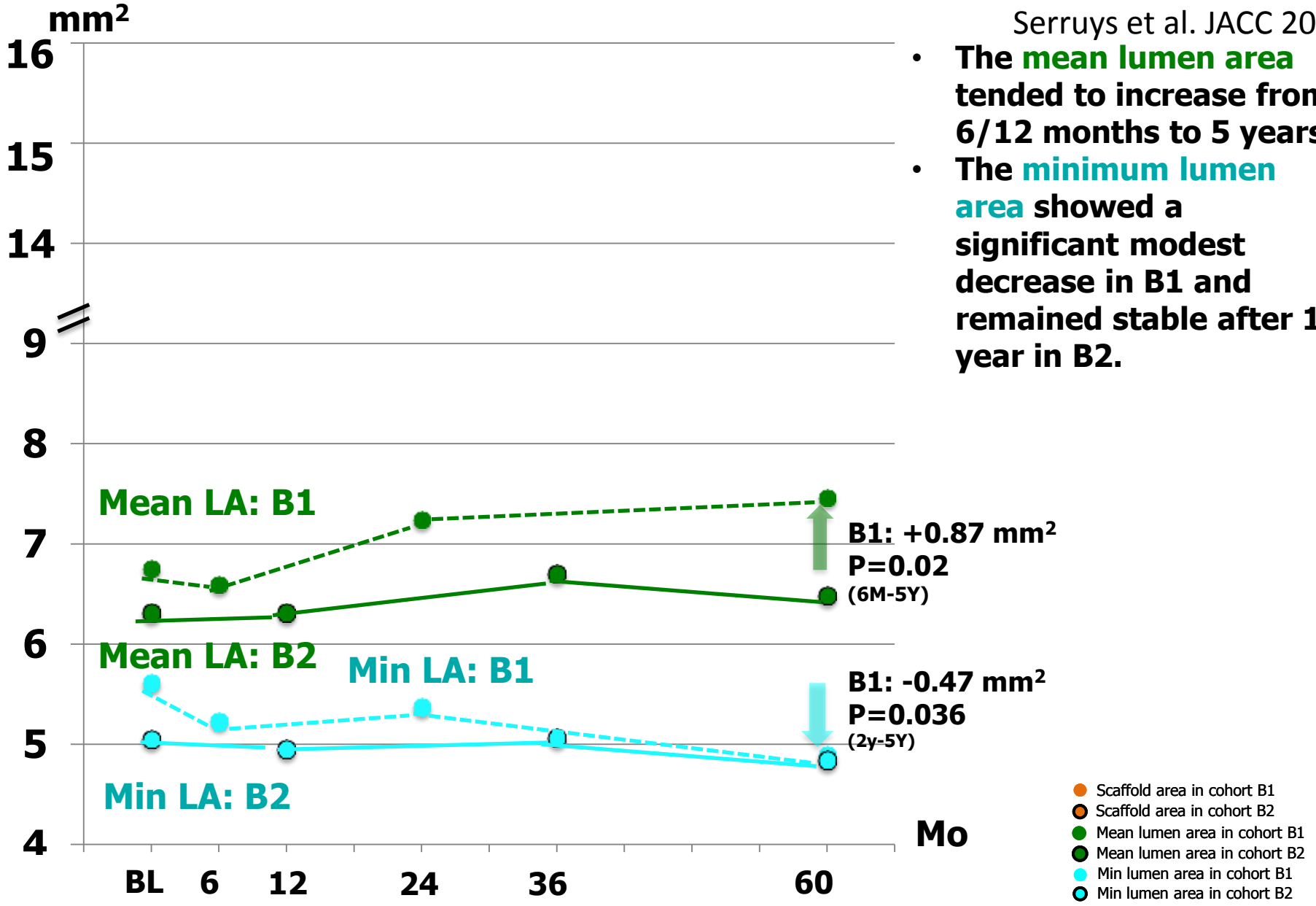
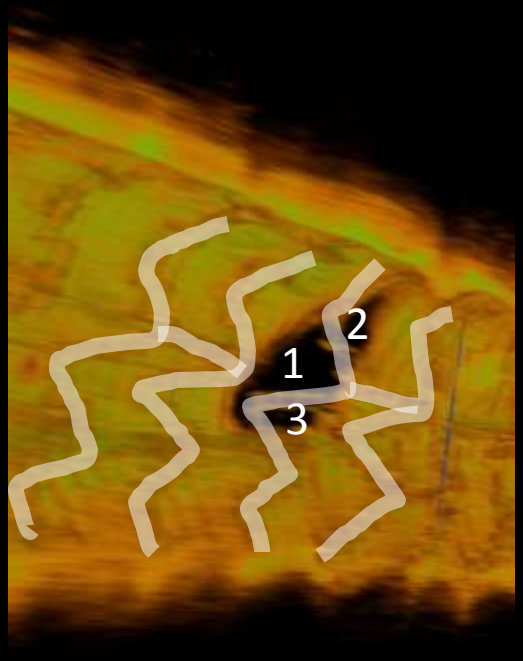
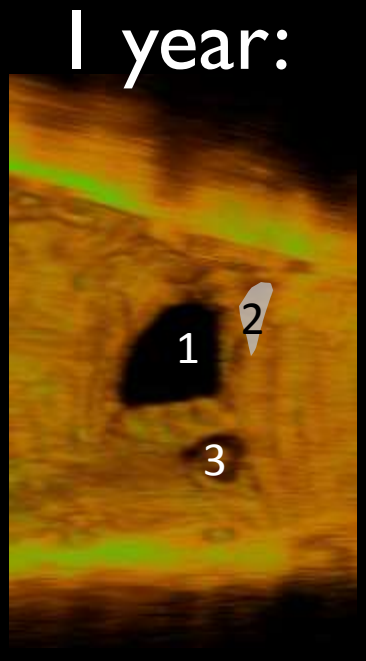
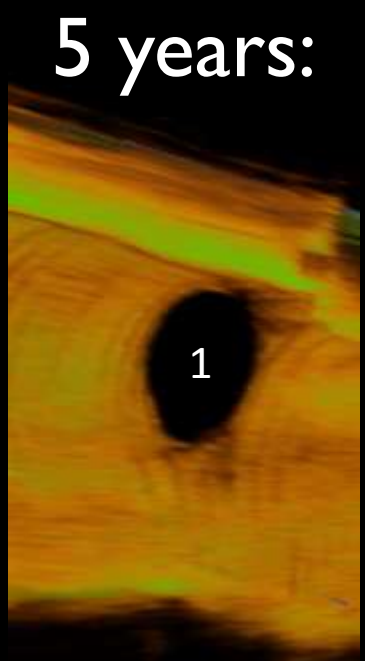
Serruys et al. JACC 2016



- The mean lumen area tended to increase from 6/12 months to 5 years
- The minimum lumen area showed a significant modest decrease in B1 and remained stable after 1 year in B2.







1 year:

3 years:

5 years:

3 compartments

Ostial area: 0.91mm^2

2 compartments

Ostium area: 0.81mm^2

Cell nr 2 covered

1 compartment

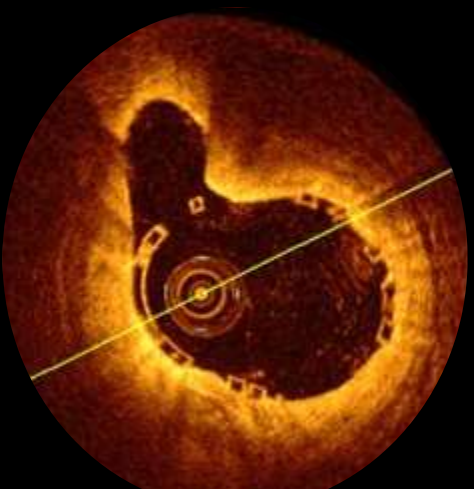
Ostial Area: 0.77mm^2

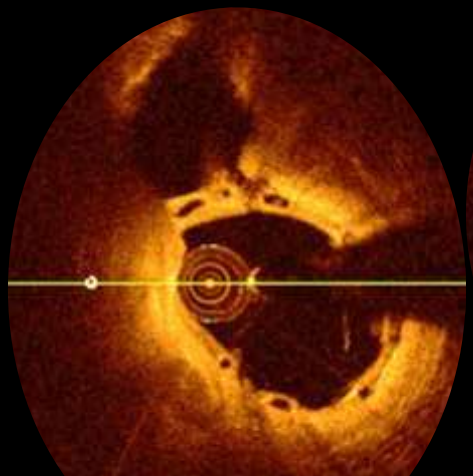
Cell nr 3 covered

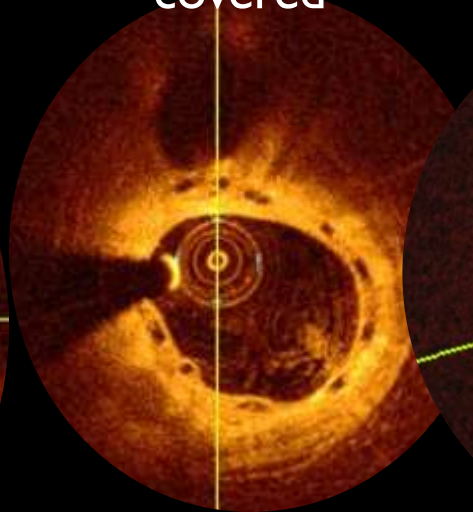
1 compartment

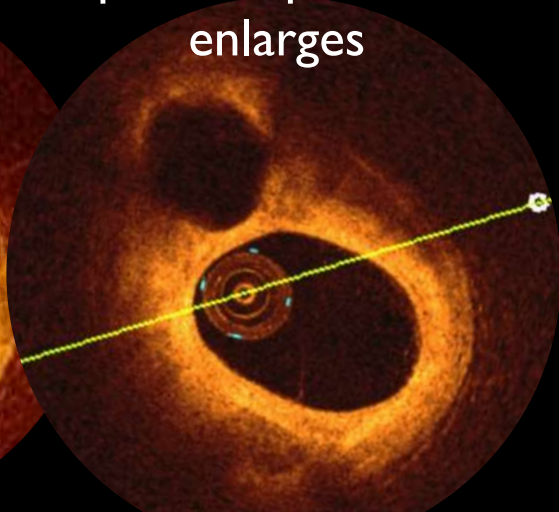
Ostial area: 1.11mm^2

The remaining open compartment enlarges









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- **Late discontinuities are frequently observed in cases of late/very late scaffold thrombosis while in previous serial imaging study late discontinuities are common and benign phenomenon associated with bioresorption (40%). It remains unclear whether it is the definite cause of thrombosis. Further research is needed to investigate what impacts the differential outcomes of late discontinuities.**

- **Absorb Japan showed that radio-opacity of metallic stent and protrusion of radiolucent polymeric struts influence QCA measurement. When OCT is used as a reference, lumen diameter of polymeric scaffolds tends to be more underestimated than metallic stents**

- **ABSORB II showed that oversizing (scaffold-vessel size mismatch) and postprocedural asymmetry are associated with increased MACE events.**

- **TROFI II OCT data showed that the healing after scaffolding in a setting of STEMI is benign.**

- **Long-term imaging (5 year) of Absorb B showed plaque reduction from 3 to 5 years. Remodeling of bifurcation was observed.**