

# Updated BRS imaging: Lessons from Brand-New data

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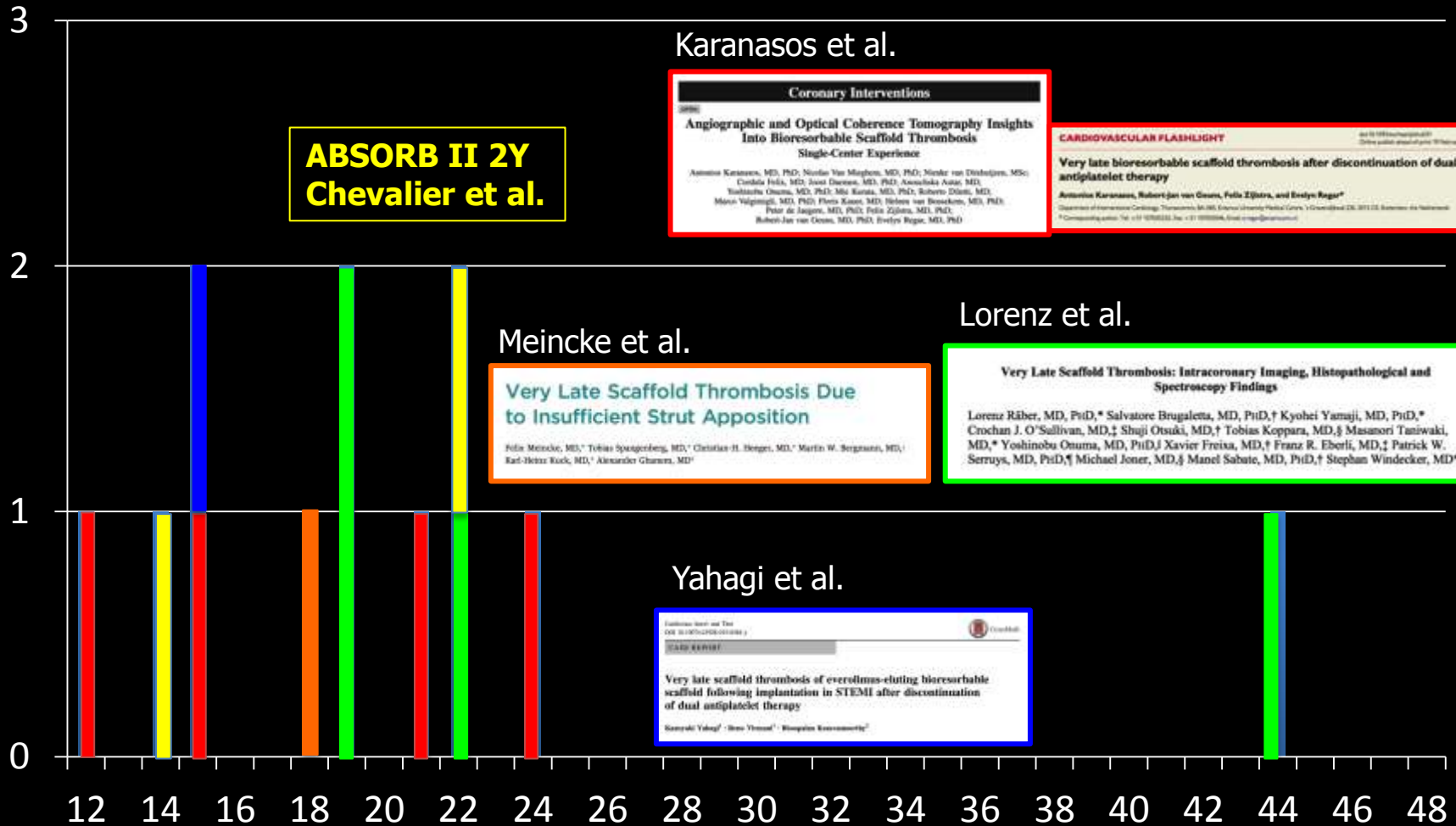
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- **Lessons from Case reports**  
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**Long-term IVUS/OCT**

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

Number

(n=12 – denominator unknown)



**ABSORB II 2Y  
Chevalier et al.**

Karanasos et al.

**Coronary Interventions**  
**Angiographic and Optical Coherence Tomography Insights Into Bioreabsorbable Scaffold Thrombosis: Single-Center Experience**  
 Antonios Karanasos, MD, PhD; Nicolas Van Mieghem, MD, PhD; Mieke van Diekesteijn, MSc; Cordula Fedt, MD; Jozsef Durancs, MD, PhD; Anouk de Azevedo, MD; Bastiaan Ouwens, MD, PhD; Mike Karata, MD, PhD; Roberto Elliott, MD; Marco Valgimigli, MD, PhD; Pietro Kastrup, MD; Tahereh van Boven-Aerts, MD, PhD; Peter de Jaegere, MD, PhD; Felix Zijlstra, MD, PhD; Robert-Jan van Geuns, MD, PhD; Evelyn Regue, MD, PhD

**CARDIOVASCULAR FLASHLIGHT**  
**Very late bioreabsorbable scaffold thrombosis after discontinuation of dual antiplatelet therapy**  
 Antonios Karanasos, Robert-Jan van Geuns, Felix Zijlstra, and Evelyn Regue\*

Meinke et al.

**Very Late Scaffold Thrombosis Due to Insufficient Strut Apposition**  
 Felix Meinke, MD,\* Tobias Spangenberg, MD,\* Christian-H. Heeger, MD,\* Martin W. Bergmann, MD,\* Karl-Heinz Kuck, MD,\* Alexander Ghanem, MD\*

Lorenz et al.

**Very Late Scaffold Thrombosis: Intracoronary Imaging, Histopathological and Spectroscopy Findings**  
 Lorenz Rieber, MD, PhD,\* Salvatore Brugaletta, MD, PhD,† Kyohci Yamaji, MD, PhD,\* Crochan J. O'Sullivan, MD,‡ Shuji Otsuka, MD,† Tobias Koppa, MD,§ Masanori Taniwaki, MD,\* Yoshinobu Ozuma, MD, PhD,‡ Xavier Freixa, MD,† Franz R. Eberli, MD,‡ Patrick W. Serruys, MD, PhD,‡ Michael Joner, MD,§ Manel Sabate, MD, PhD,‡ Stephan Windecker, MD\*

Yahagi et al.

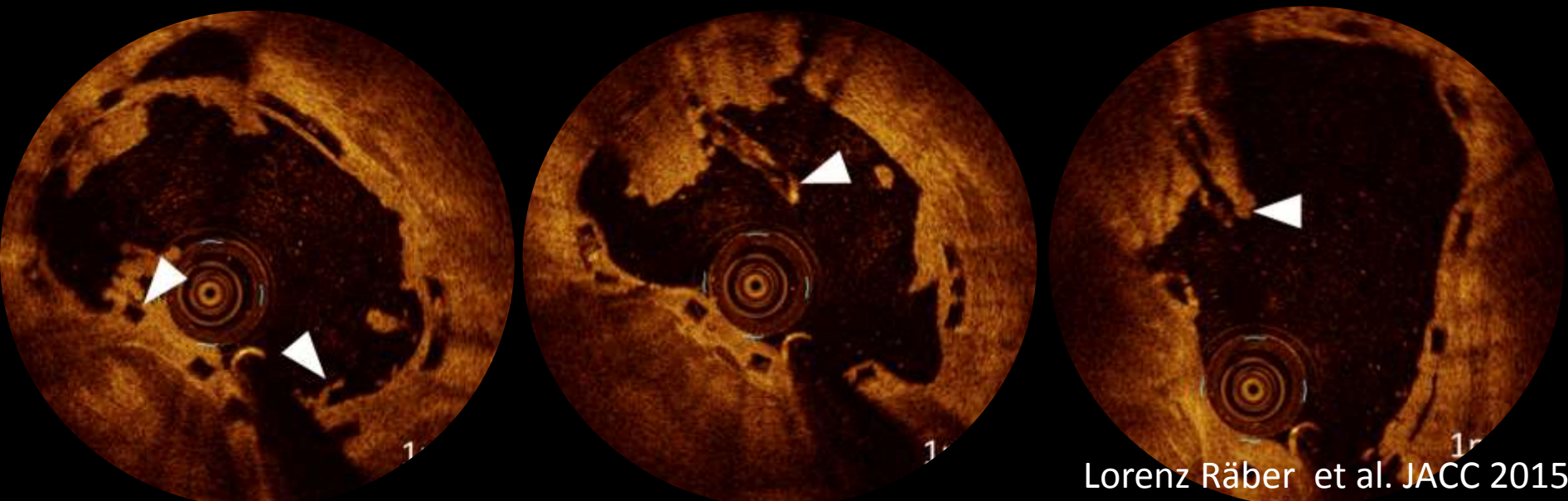
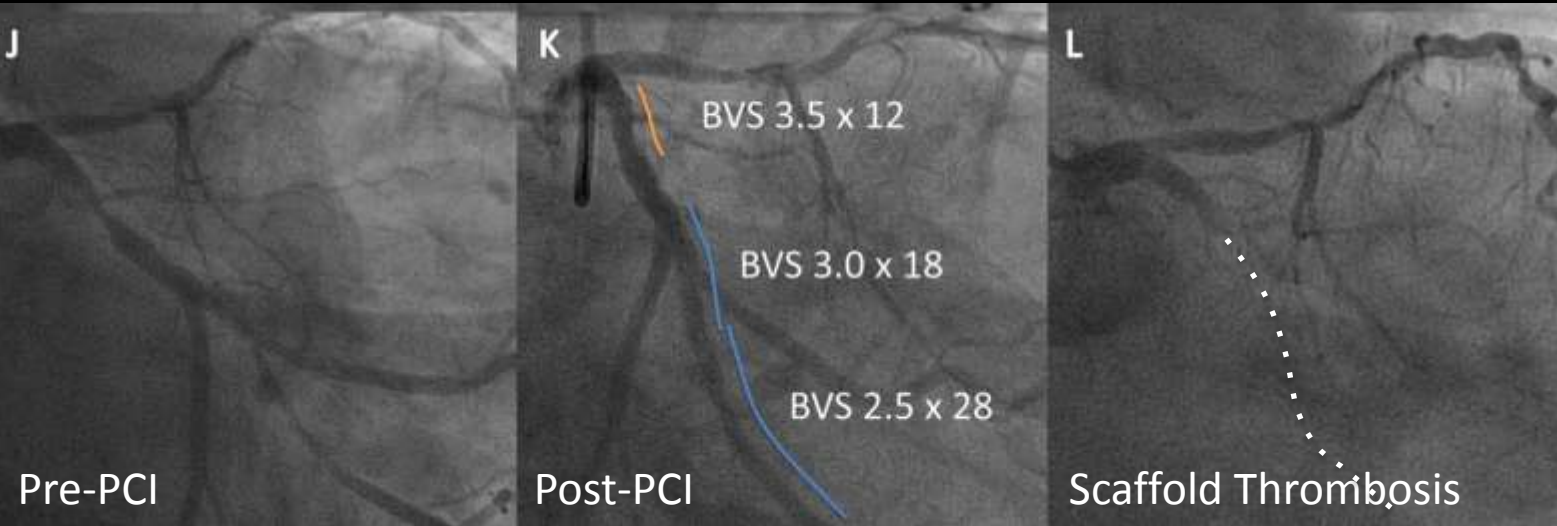
**Very late scaffold thrombosis of everolimus-eluting bioreabsorbable scaffold following implantation in STEMI after discontinuation of dual antiplatelet therapy**  
 Kenyuki Yahagi\*, Ikuo Yamada†, Hisayuki Kawasumi\*

**Follow-up duration (months)**

# #1 VLST with Late discontinuity and Uncovered struts

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.

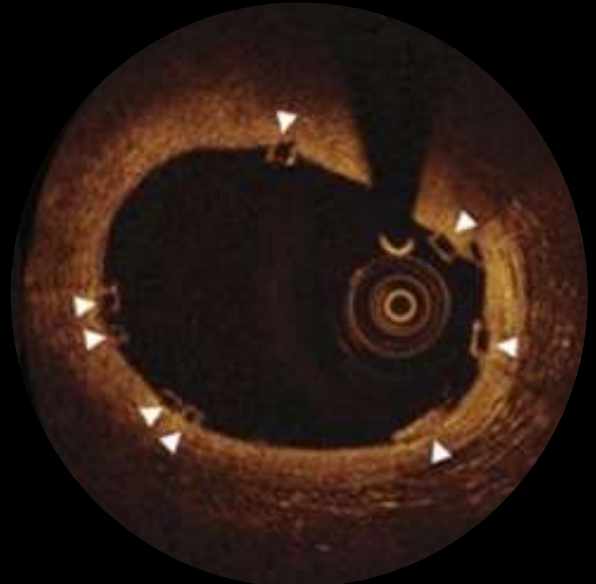
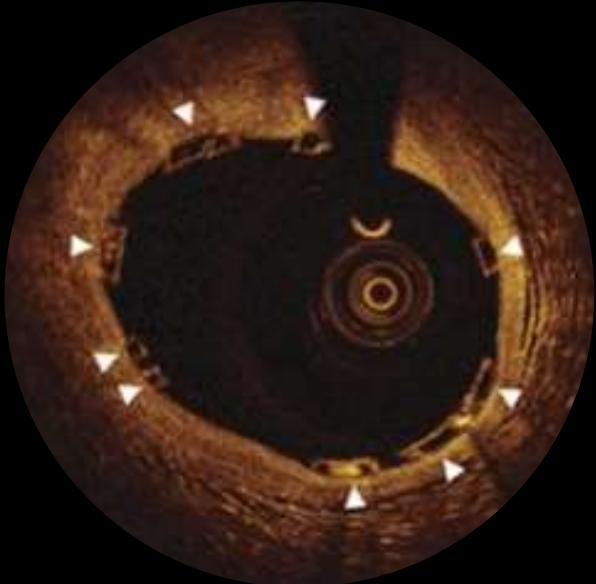
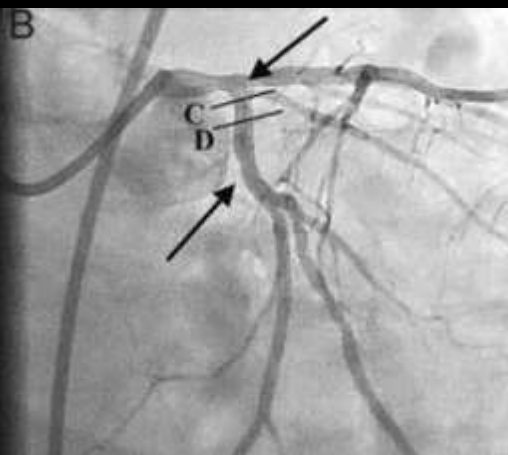
**VLST at 19 months**



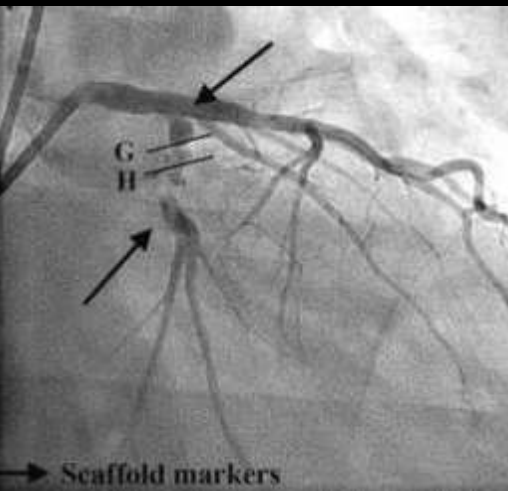
# #2 VLST at 2 years with late discontinuities

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

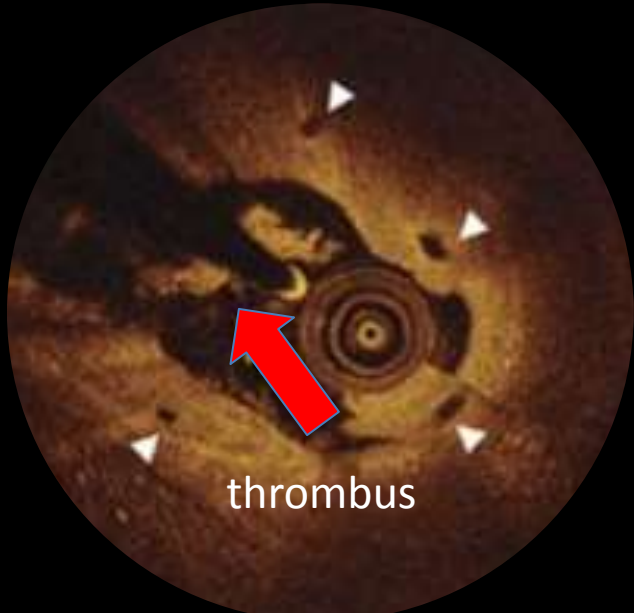
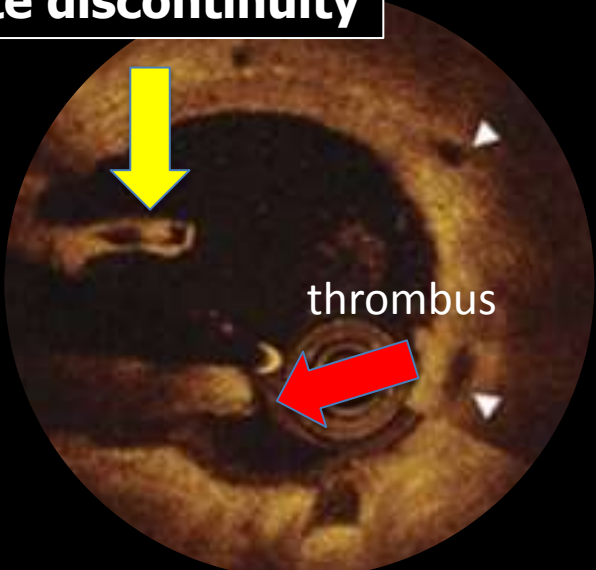
Post-procedure



Scaffold thrombosis



late discontinuity

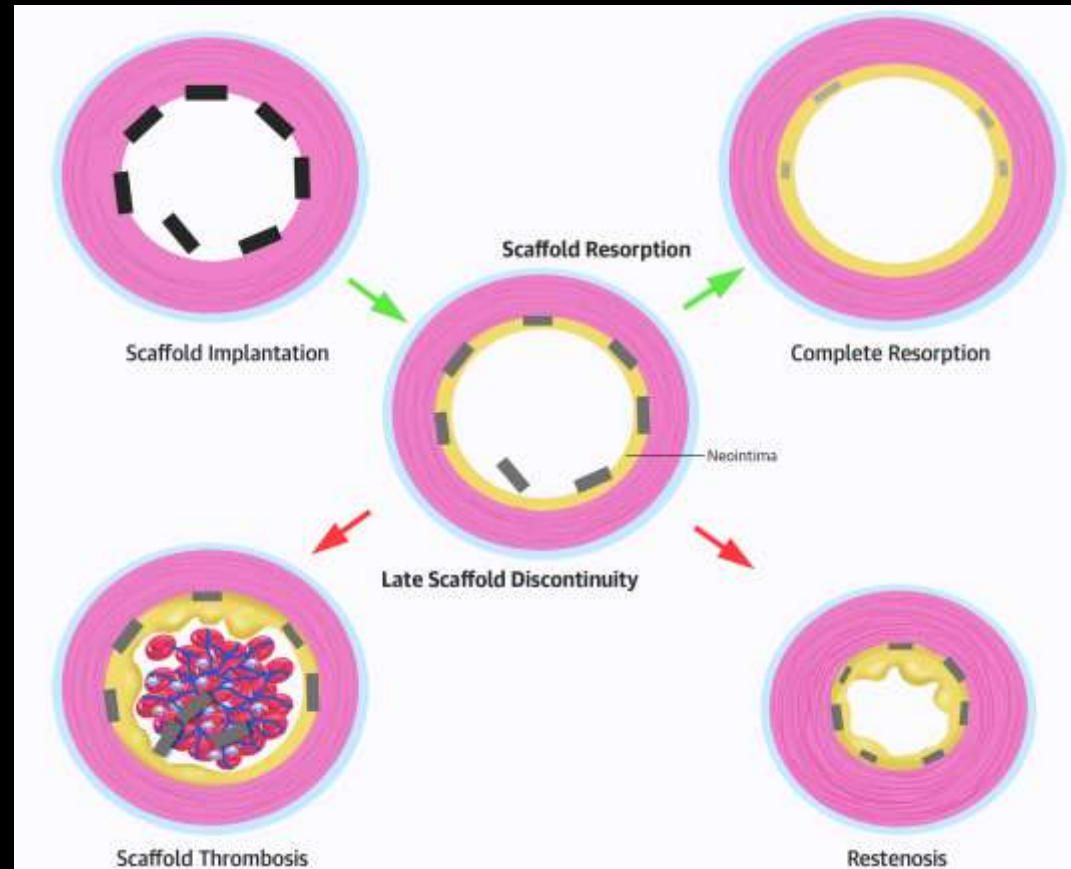




# Late discontinuities: Culprit of late scaffold thrombosis or innocent bystander??

## 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

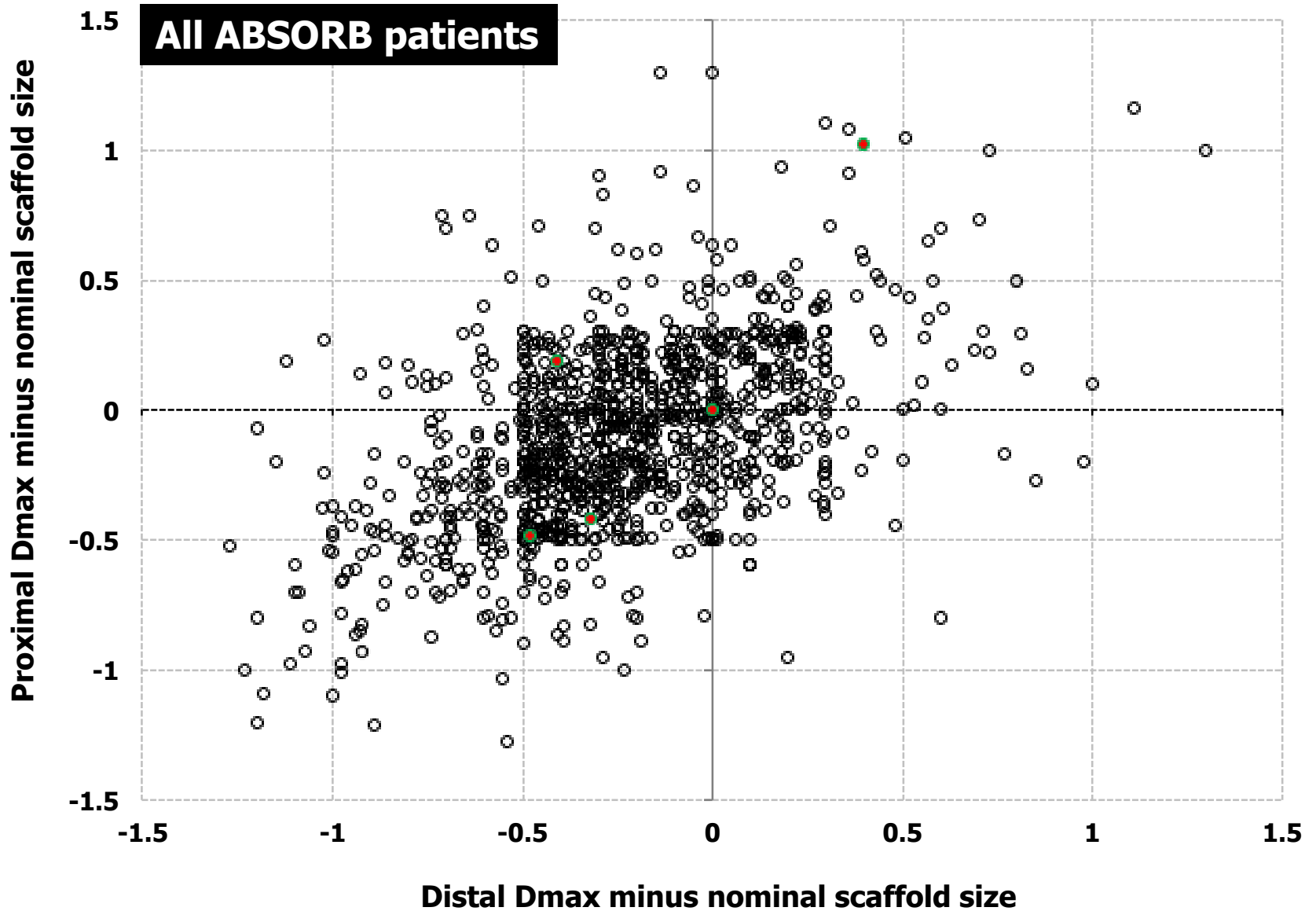
<b>Data present in mean±SD</b>	<b>Absorb</b>	<b>EES</b>	<b>P-value</b>
<b>ABSORB II</b>	<b>1.15±0.4</b>	<b>&lt; 1.46 ± 0.4</b>	<b>&lt;0.001</b>
<b>ABSORB III</b>	<b>1.45±0.45</b>	<b>&lt; 1.59±0.44</b>	<b>&lt;0.001</b>
<b>ABSORB Japan</b>	<b>1.46±0.40</b>	<b>&lt; 1.65±0.40</b>	<b>&lt;0.0001</b>
<b>ABSORB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



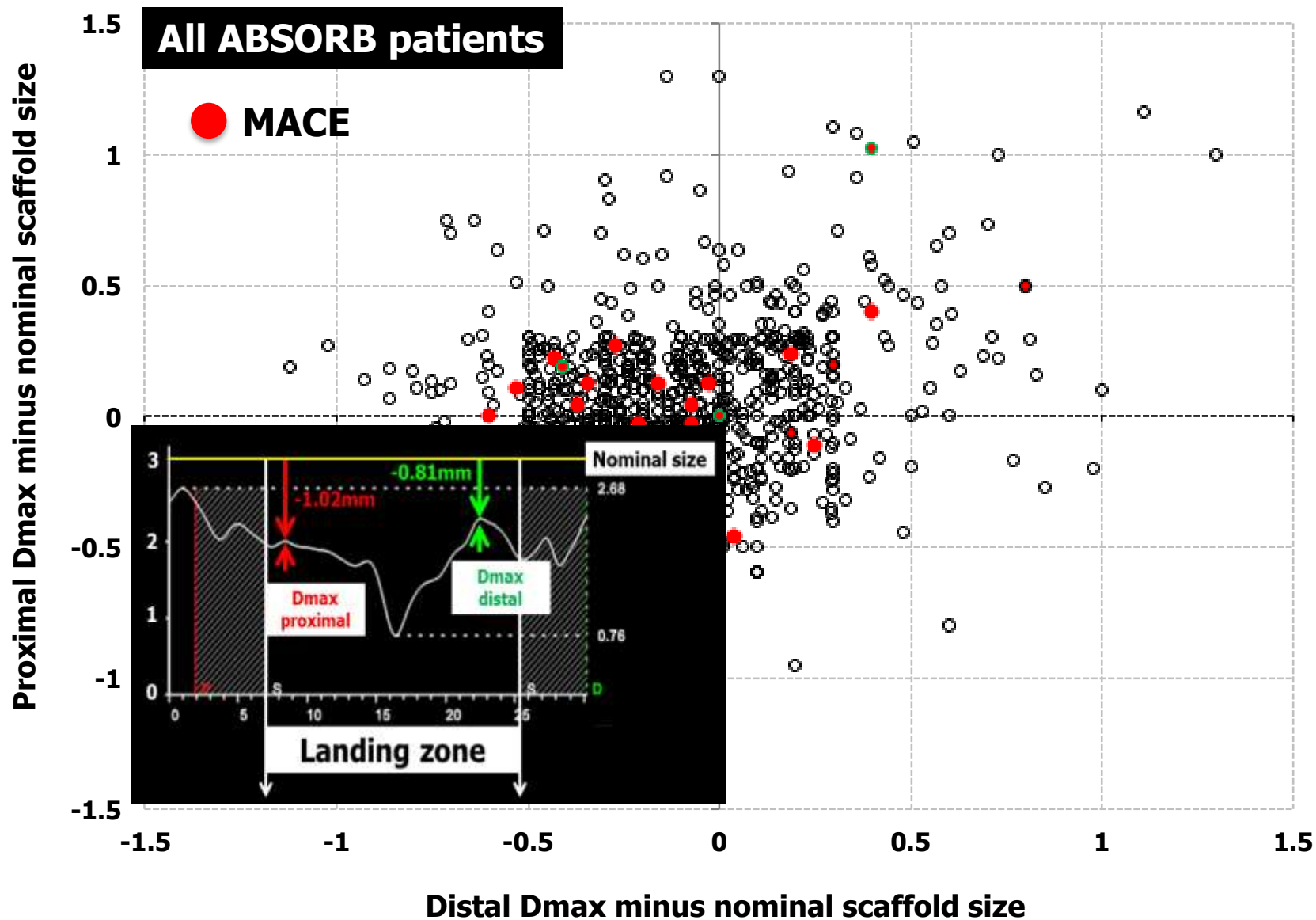
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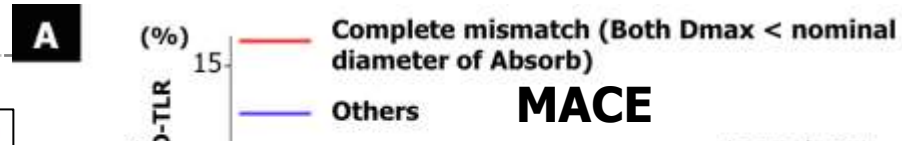
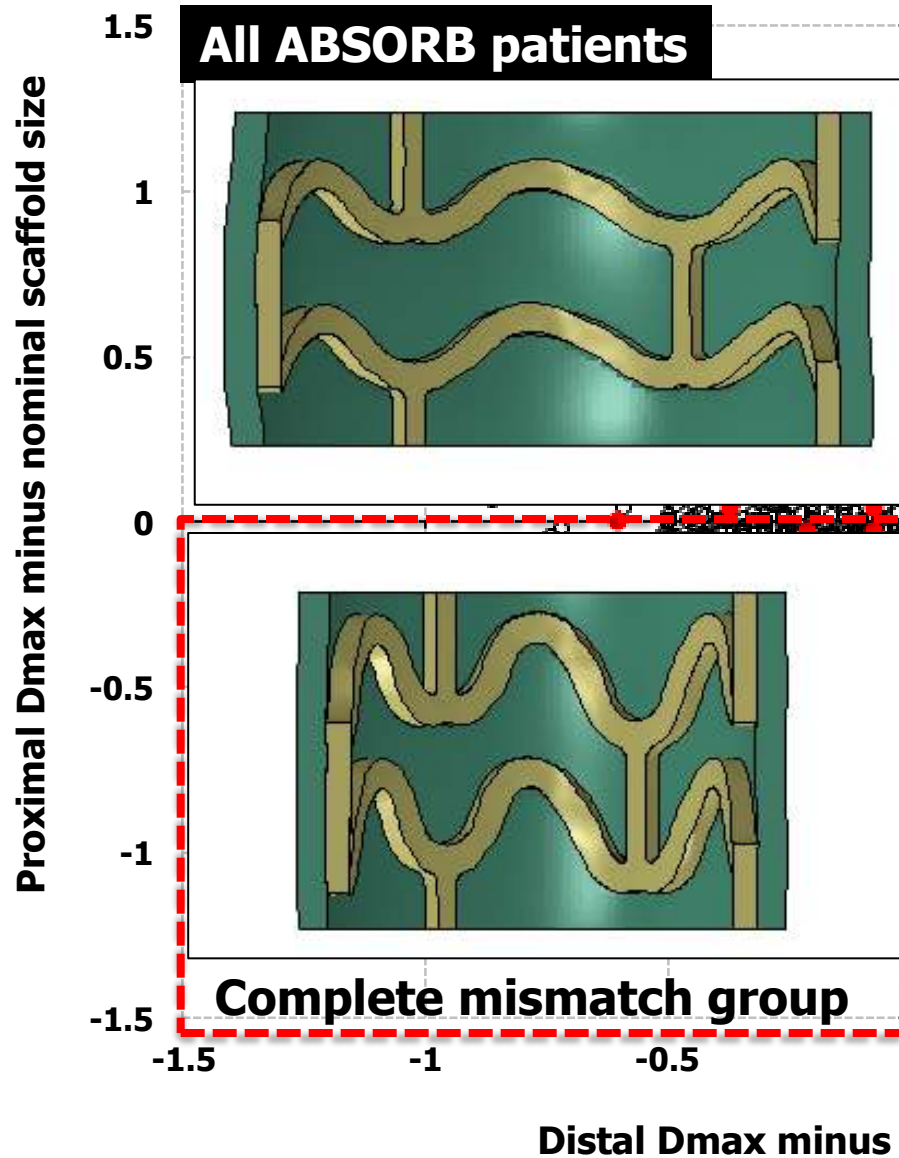
# Distribution of Dmax Prox and Dmax Distal related to the nominal device size in the **ABSORB II, Extend and B (n=1248)**



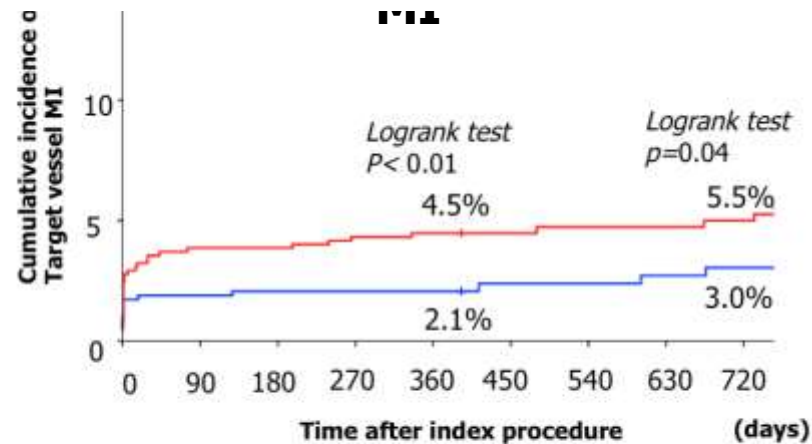
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# Distribution of Dmax Prox and Dmax Distal related to the nominal device size in the ABSORB II, Extend and B (n=1248)



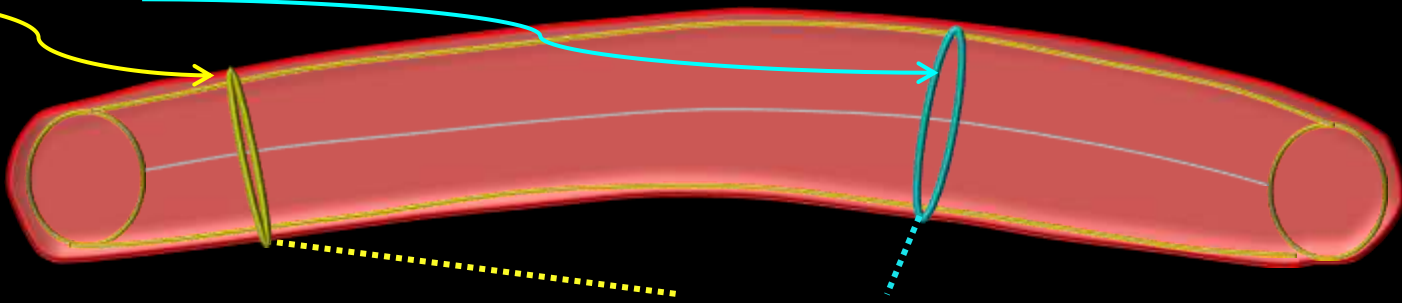
The implantation of a "large" Absorb scaffold in a relatively small vessel had a higher risk of MACE at 1 year. The selection of nominal scaffold size below the diameter of both proximal and distal Dmax might lead to a denser polymer surface pattern, which could be associated with MI after procedure.



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

# 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

**Max diameter**

Projected max SD = 3.37 mm

**Min diameter**

Projected min SD = 2.52 mm

### Eccentricity index (cross-section)

Projected max stent diameter = 2.64

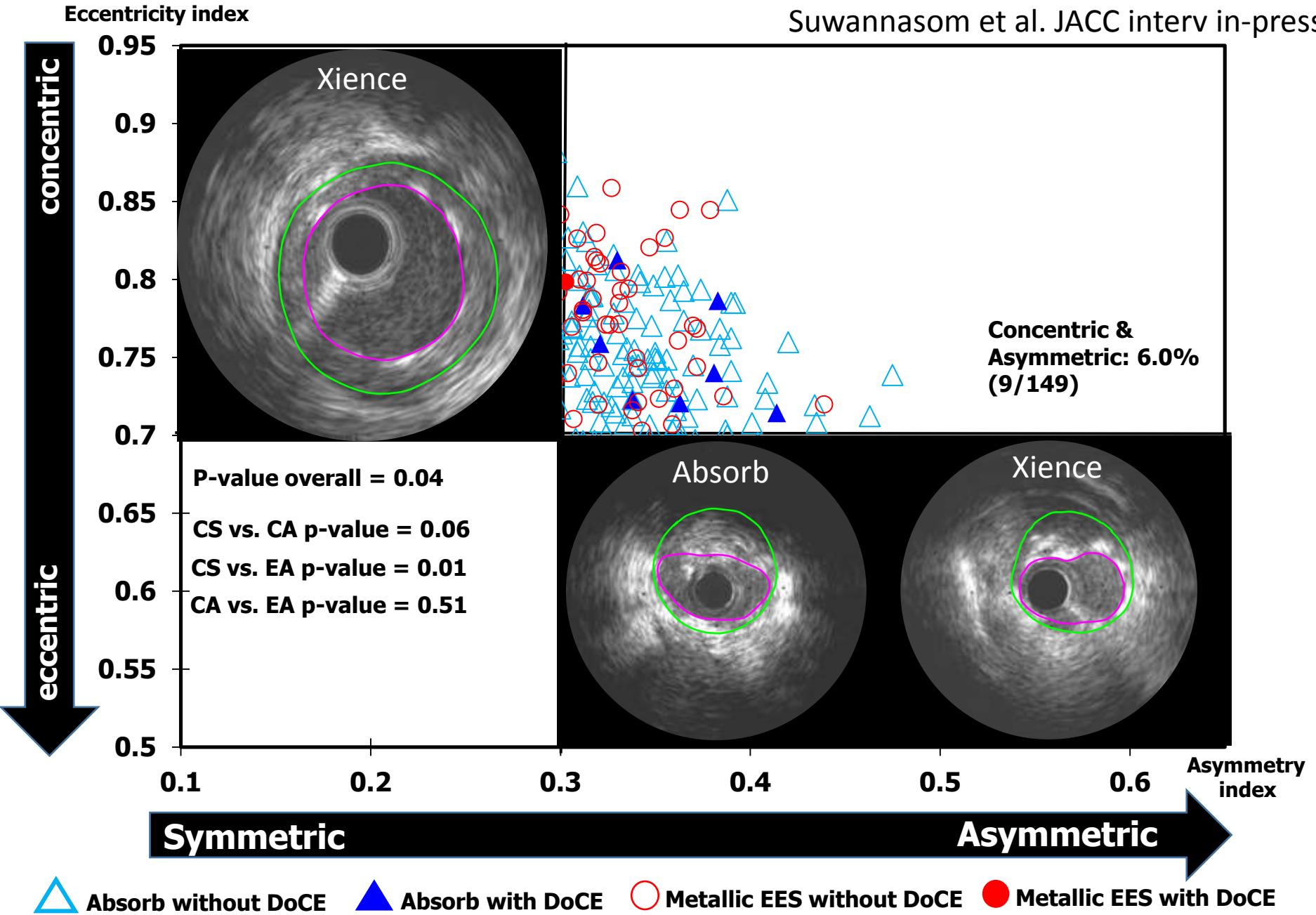
Projected min stent diameter = 2.46

**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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**191 patients with STEMI < 24h**  
**1:1 randomisation**

**Thrombectomy**  
+/- predilatation

R

**ABSORB arm**  
**N=95 P**

**Xience Expedition arm**  
**N=96 P**

Sizing Dmax

**Scaffolding (ABSORB)**

**Stenting (Xience)**

+/- postdilatation/  
thrombectomy

**6M Angio + OFDI**  
**N=86 P/86 L**

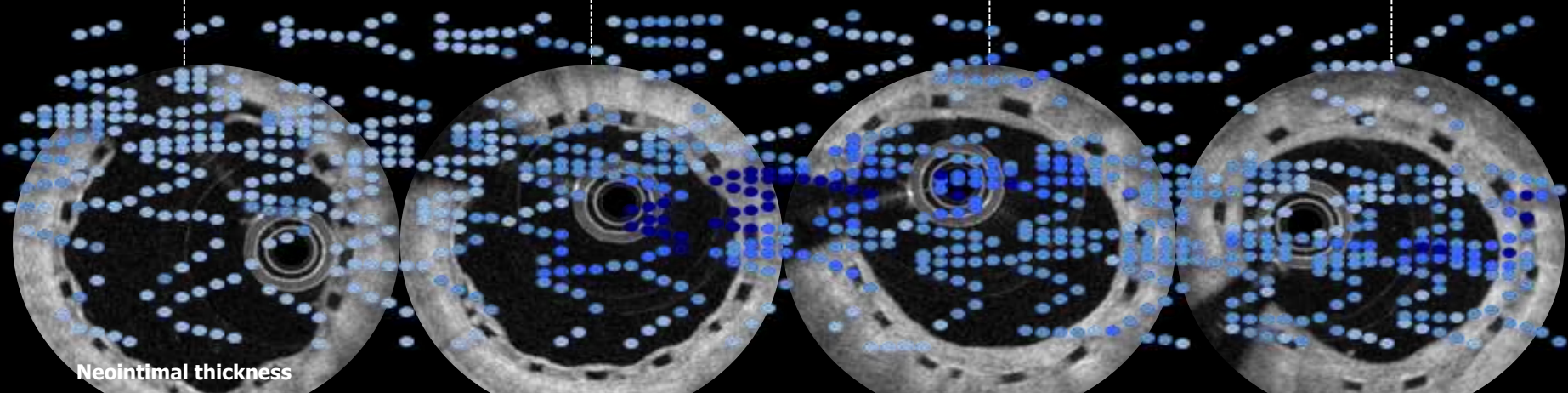
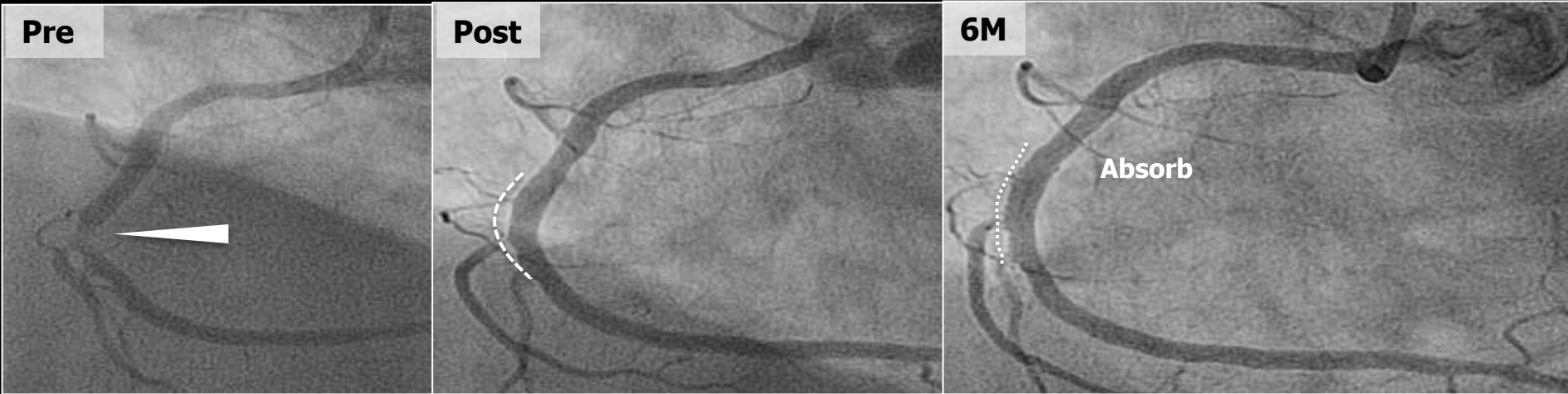
**6M Angio + OFDI**  
**N = 87 P/89 L**

**Primary endpoint\*:**  
**Healing score at 6 months according to OFDI**

\*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.

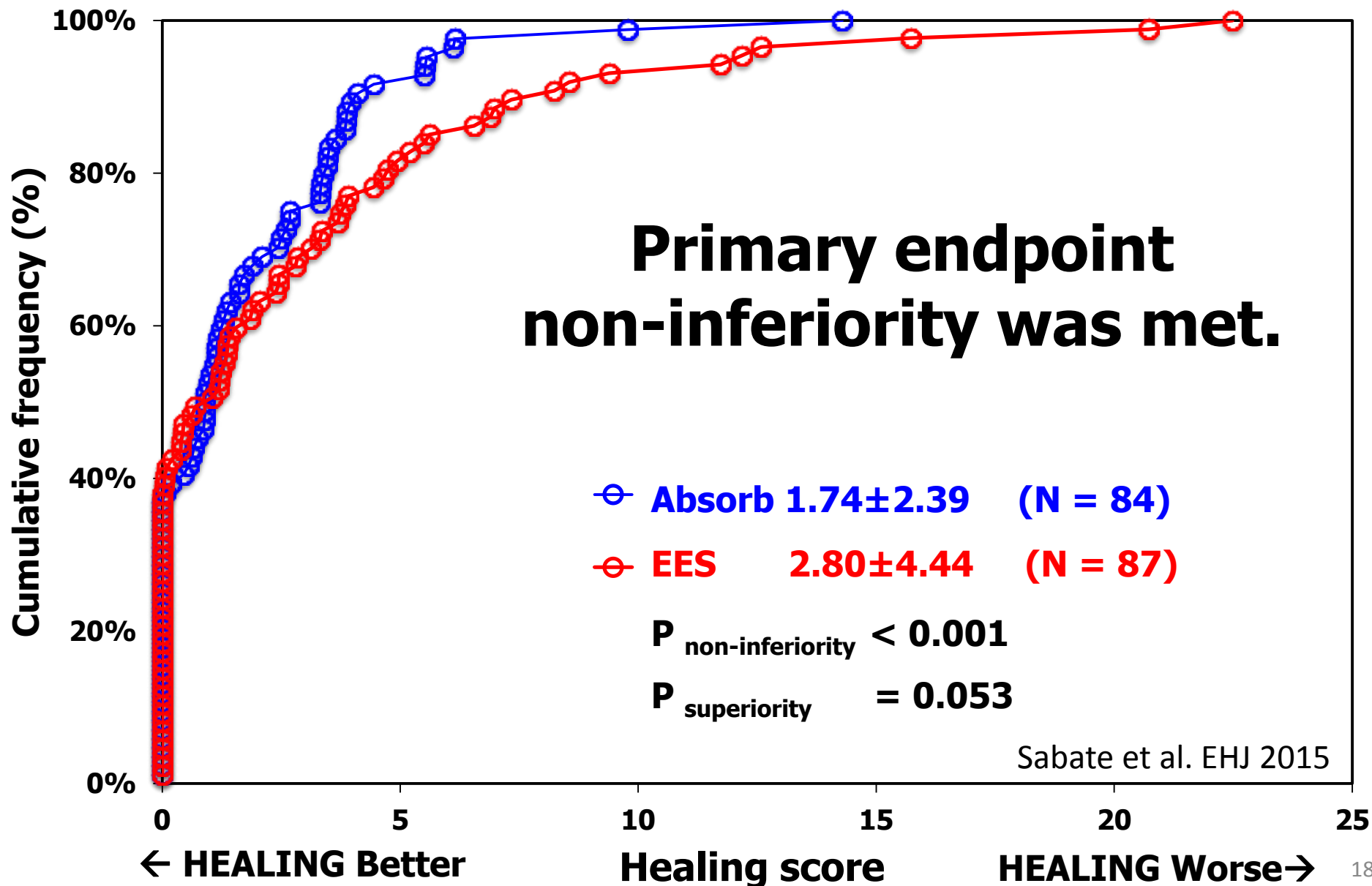
# Absorb: Healing Score 0



Neointimal thickness



# Cumulative curve of Healing Score

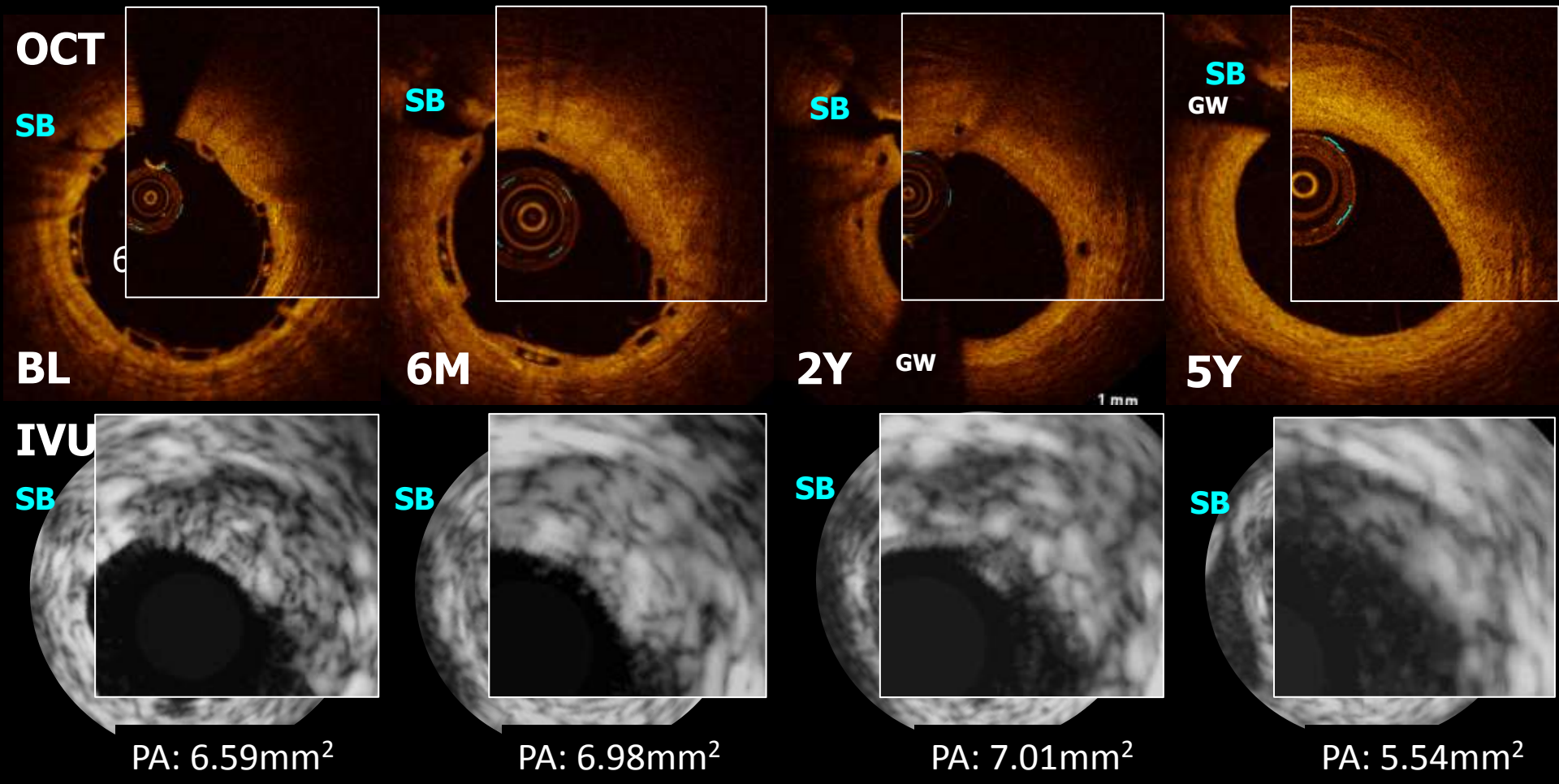




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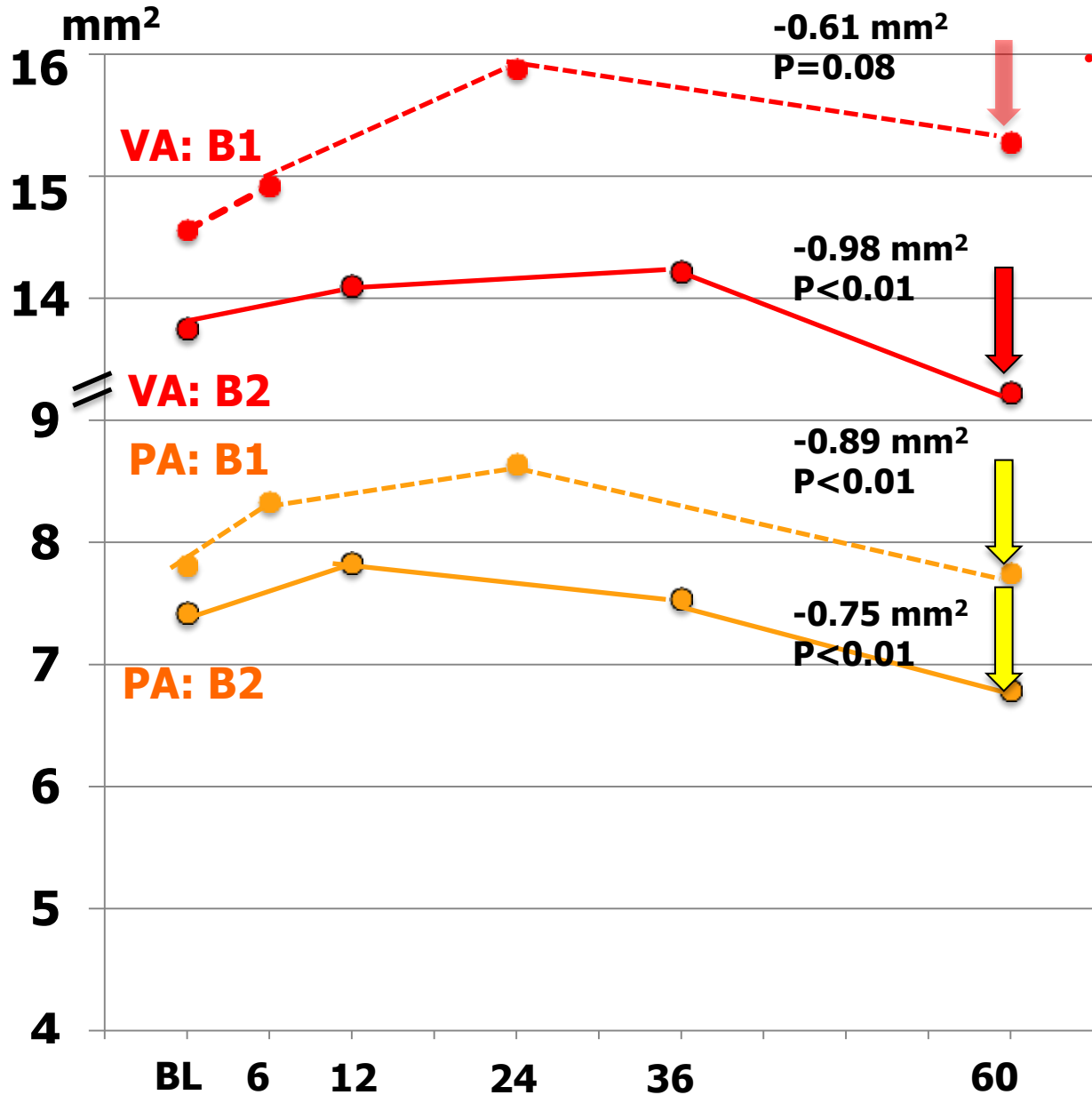
# Plaque reduction with the change of plaque morphology



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



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

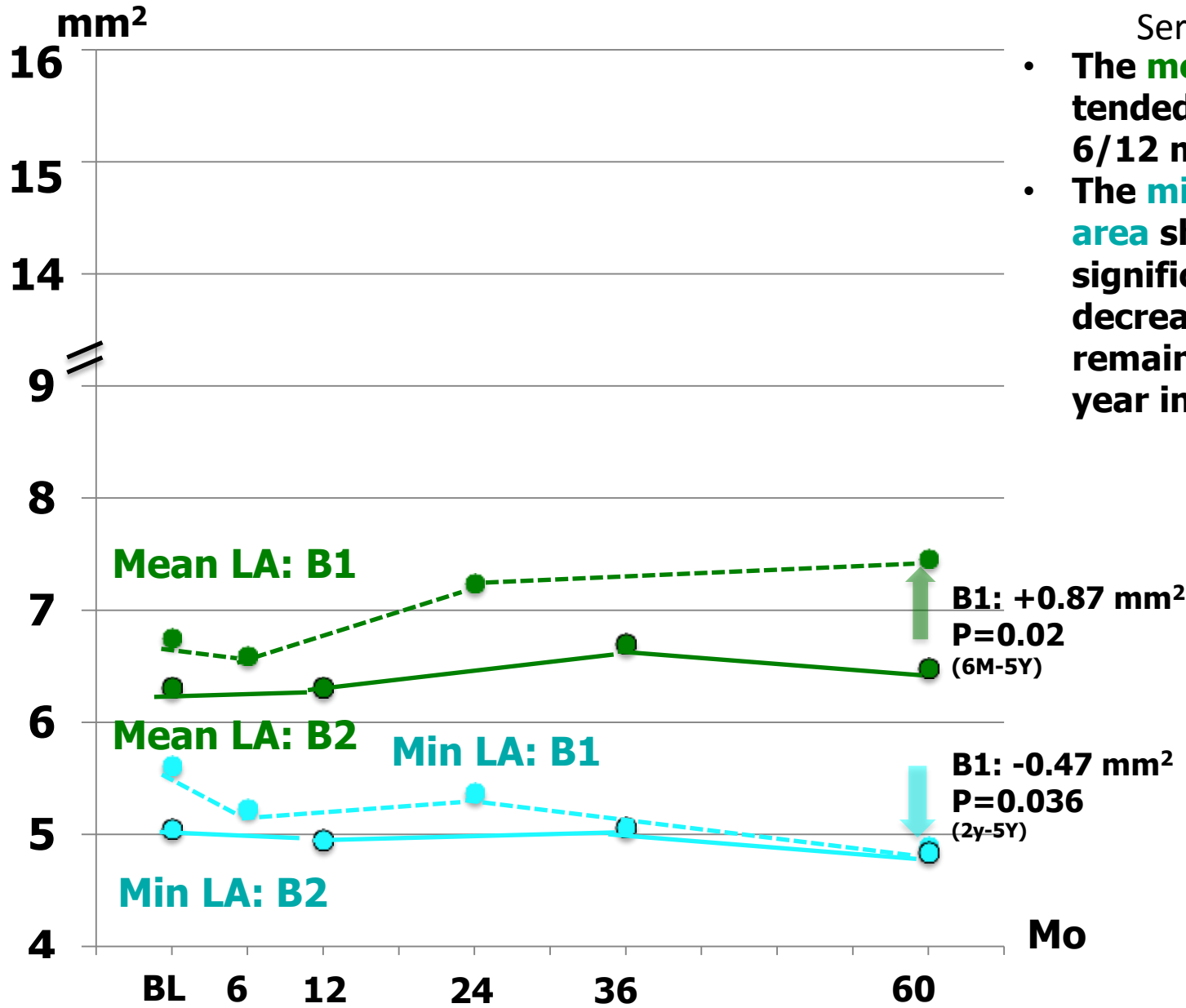


The Vessel area and total plaque area show a biphasic change with an increase between the first and second year. A significant plaque reduction occurs in B1 and B2 between the second and fifth year follow-up accompanied by an adaptive and constrictive remodeling of the vessel area.

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

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.

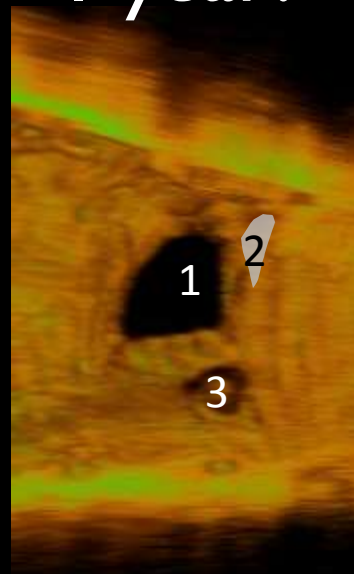




3 compartments

Ostial area:  $0.91 \text{ mm}^2$

1 year:



2 compartments

Ostium area:  $0.81 \text{ mm}^2$

Cell nr 2 covered

3 years:

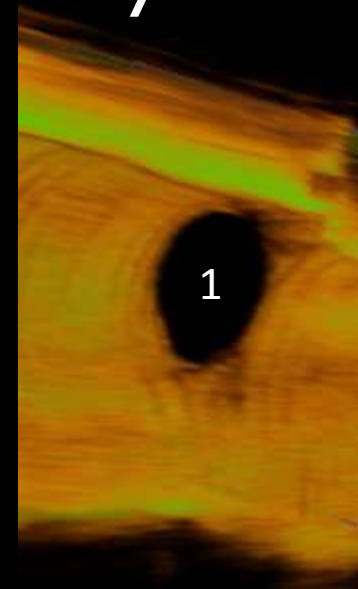


1 compartment

Ostial Area:  $0.77 \text{ mm}^2$

Cell nr 3 covered

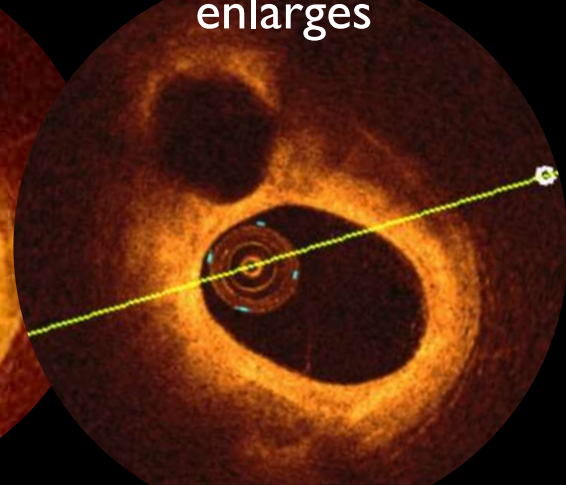
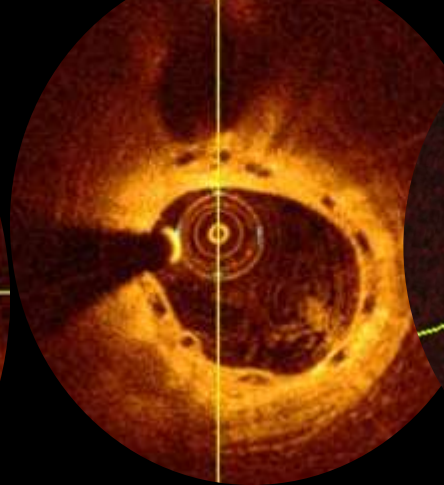
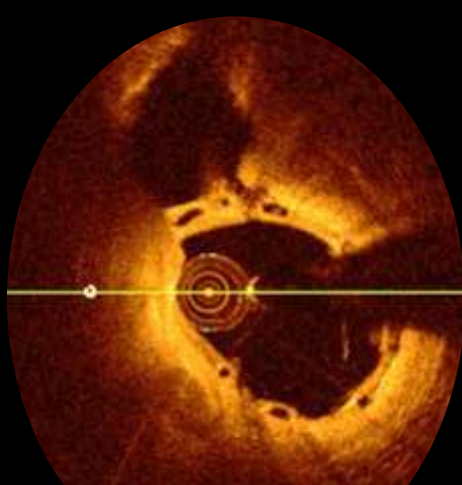
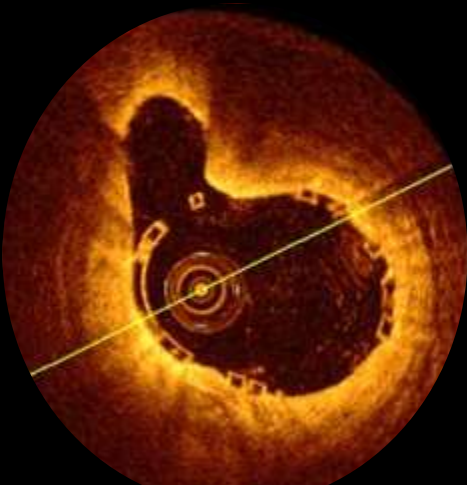
5 years:



1 compartment

Ostial area:  $1.11 \text{ mm}^2$

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.**