Hot Topics
DES, BRS and DCB

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Theater 1, Level 1

Lessons from ABSORB: How to Improve the Scaffold Outcomes with Imaging

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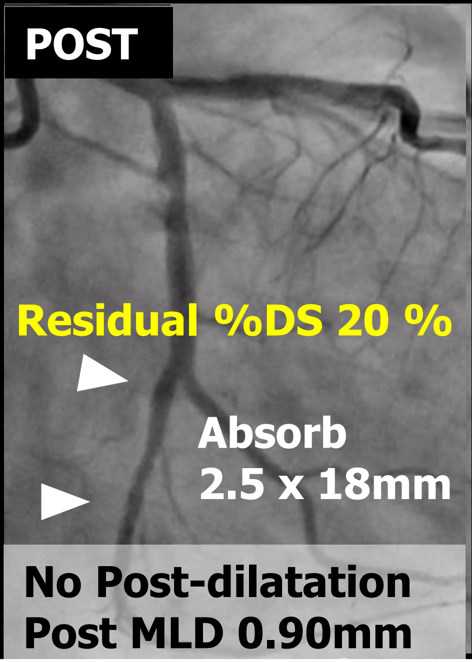
CARDIαLYSIS
Clinical Trial Management - Core Laboratories

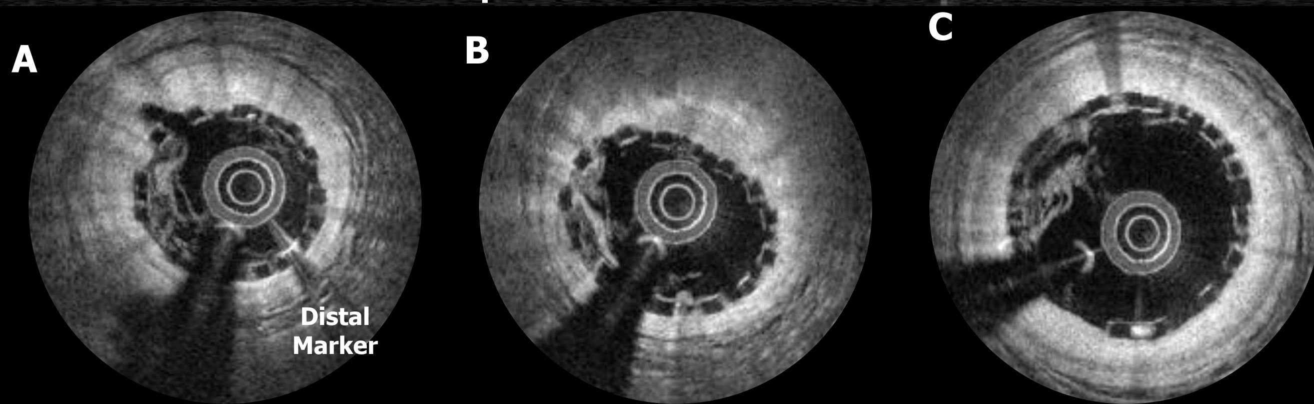
THE UNIVERSITY OF MELBOURNE

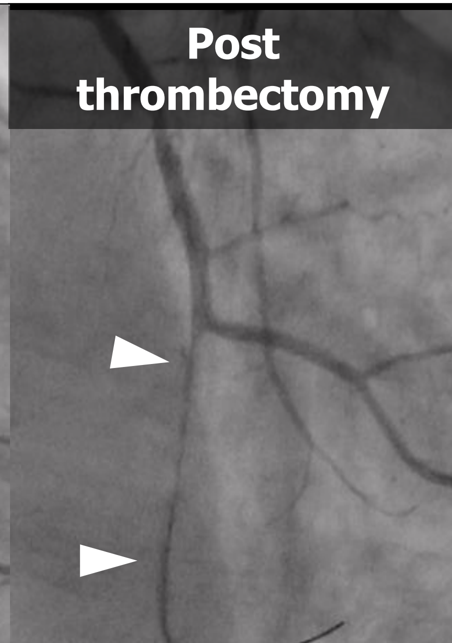
How to Improve the Scaffold Outcomes with Imaging

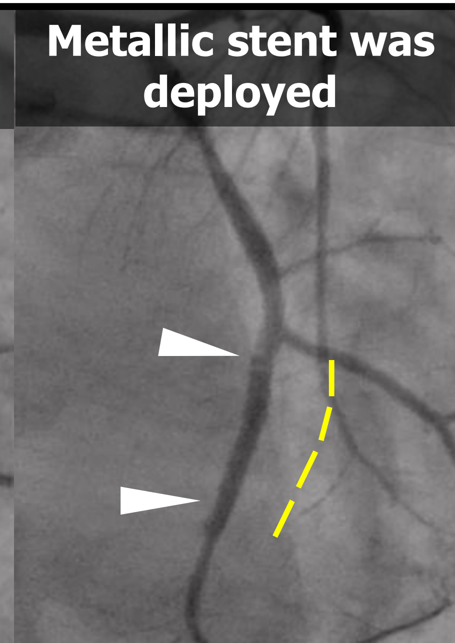
- **What are the imaging parameters associated with acute and late complications?**
  - Size mismatch
  - Asymmetry and Eccentricity
  - Malapposition
  - Embedment
- **What are the potential causes of very late ScT?**

Case example: Absorb Japan (Onuma et al. Eurointervention 2016)









Status of antiplatelet therapy
ASA: on going
Clopidogrel: on going

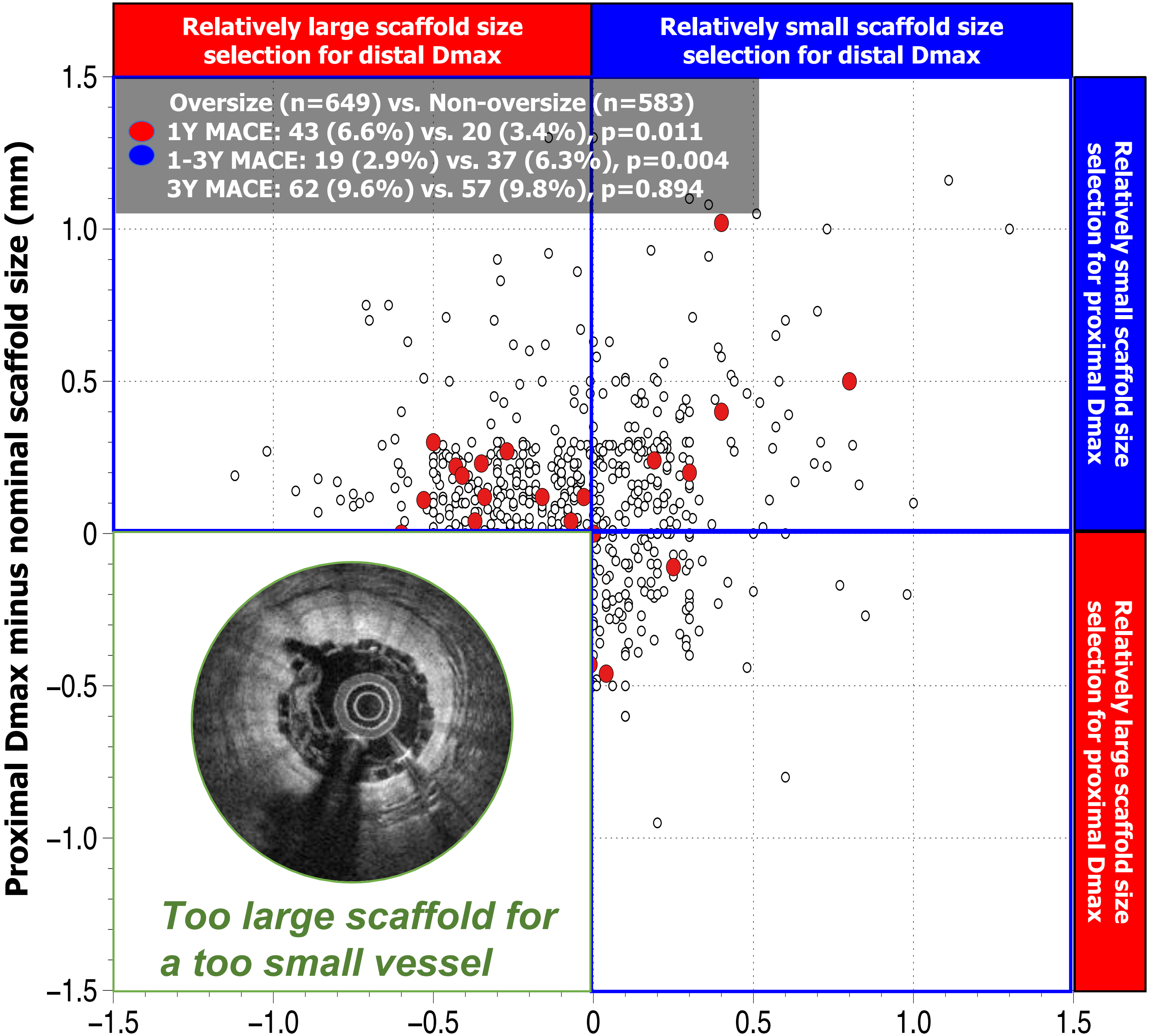
Possible mechanical cause: **Underexpansion** due to Device/vessel size mismatch

Event and scaffold-vessel size mismatch

MACE
(at 1 year)

ABSORB B
n=101
ABSORB Extend
n=799
ABSORB II
n=332

Total N=1232
(same core lab)



Non-oversize group
Oversize group

Ishibashi, Serruys et al.
JACC Cardiovasc Interv. 2015;8:1715-26.

Event and scaffold-vessel size mismatch

ScT
definite/ probable
(at 1 year)

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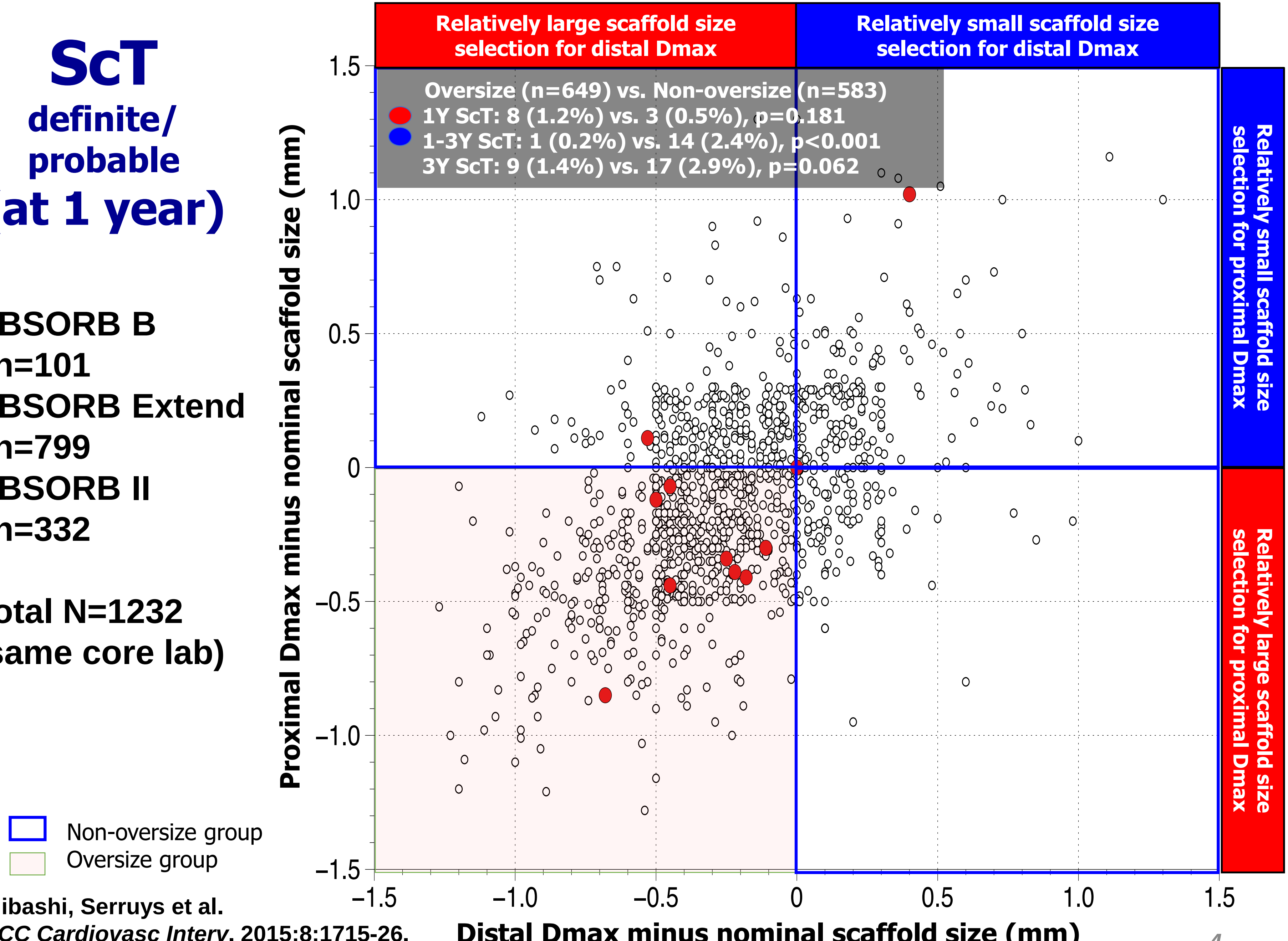
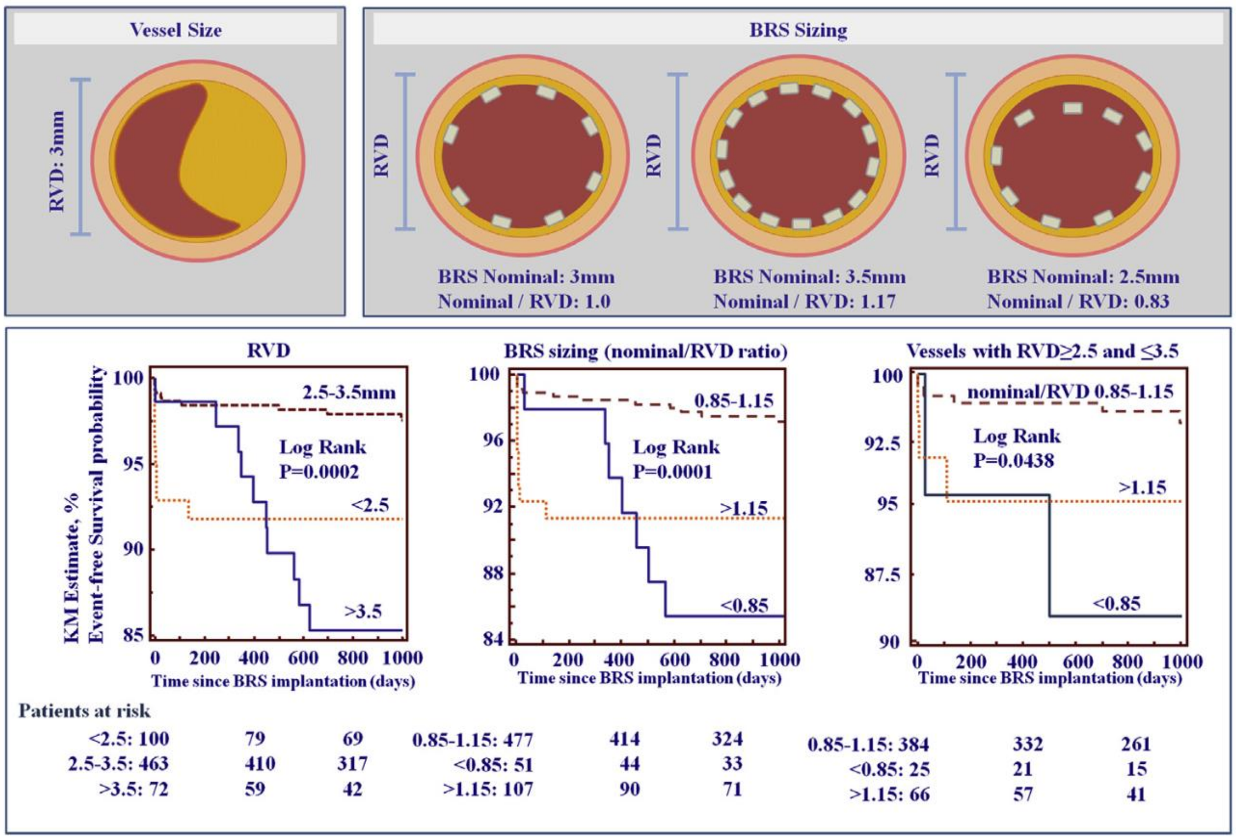


Ishibashi, Serruys et al.
JACC Cardiovasc Interv. 2015;8:1715-26.

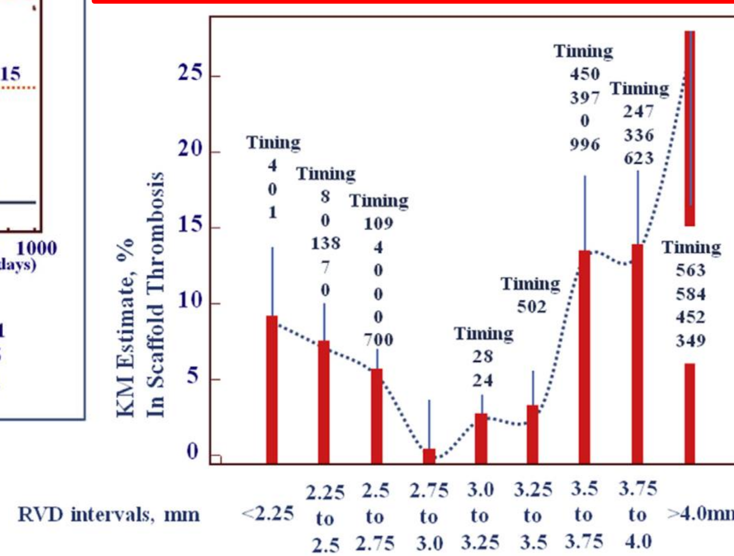
BRS sizing and ScT in Mainzer IntraCoronAry database (MICAT)

- A total of 657 consecutive patients who received 925 Absorb BRS in a single center between May 2012 and January 2015 were analyzed.
- Smaller RVD and oversizing were associated with a higher incidence of early ScT, whereas larger RVD and undersizing were associated with late or very late ScT.



Cox regression analysis

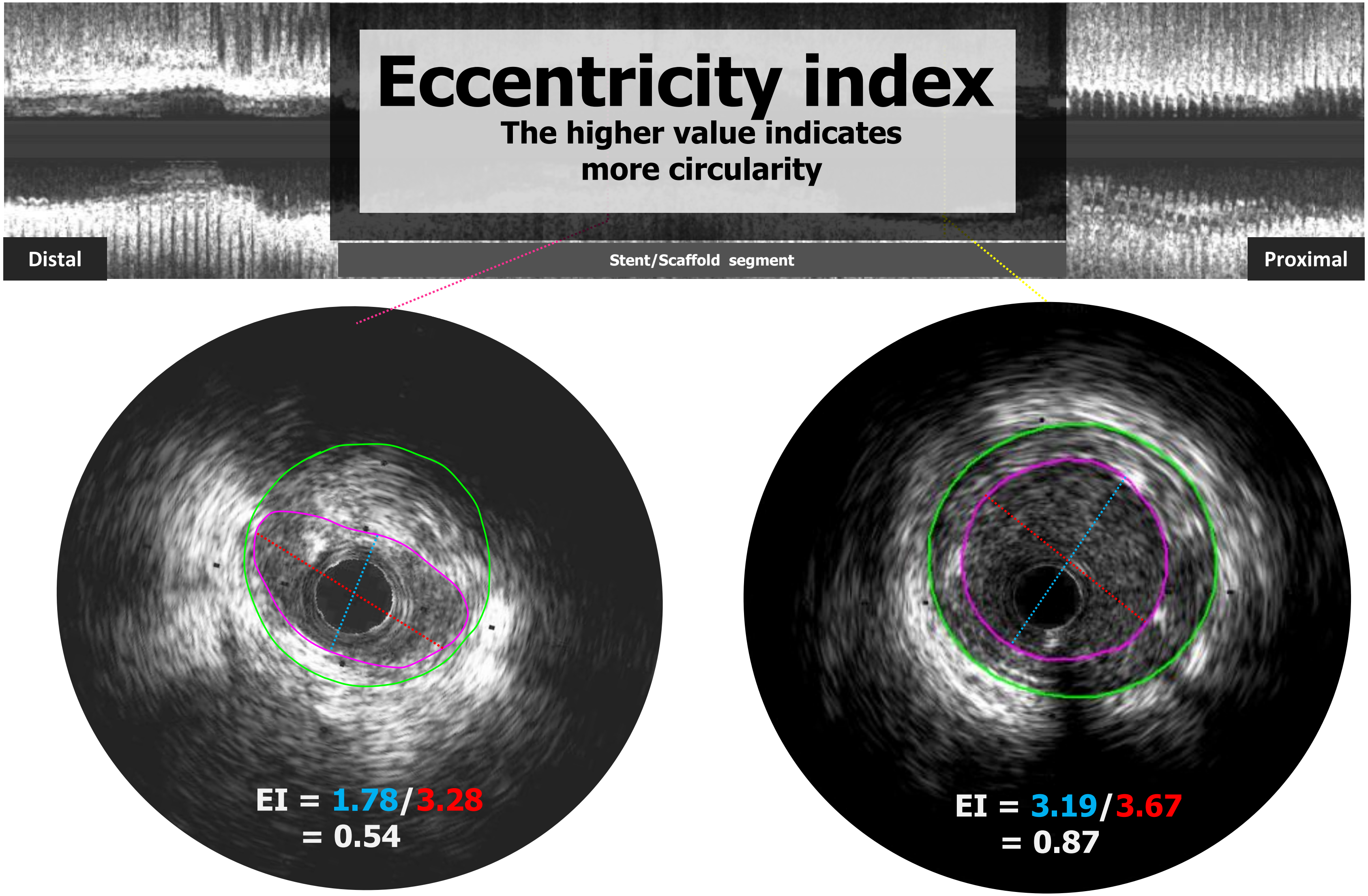
	p Value	HR (95% CI)
Multivariable analysis		
Acute or subacute ScT		
Post-procedural RVD	0.135	0.3700 (0.1010-1.3530)
Scaled stenosis	0.001	1.0670 (1.0260-1.1090)
Late or very late ScT		
Post-procedural RVD	0.000	11.1760 (4.5140-27.6730)
Scaled stenosis	0.199	1.0270 (0.9860-1.0700)



Unveiling the Mechanisms of Device Failure: In Vivo Imaging from Human Studies

- **What are the imaging parameters associated with acute and late complications?**
  - Size mismatch
  - **Asymmetry and Eccentricity**
  - Malapposition
  - Embedment
- **What are the potential causes of very late ScT?**

How was the eccentricity index calculated in the ABSORB II trial?



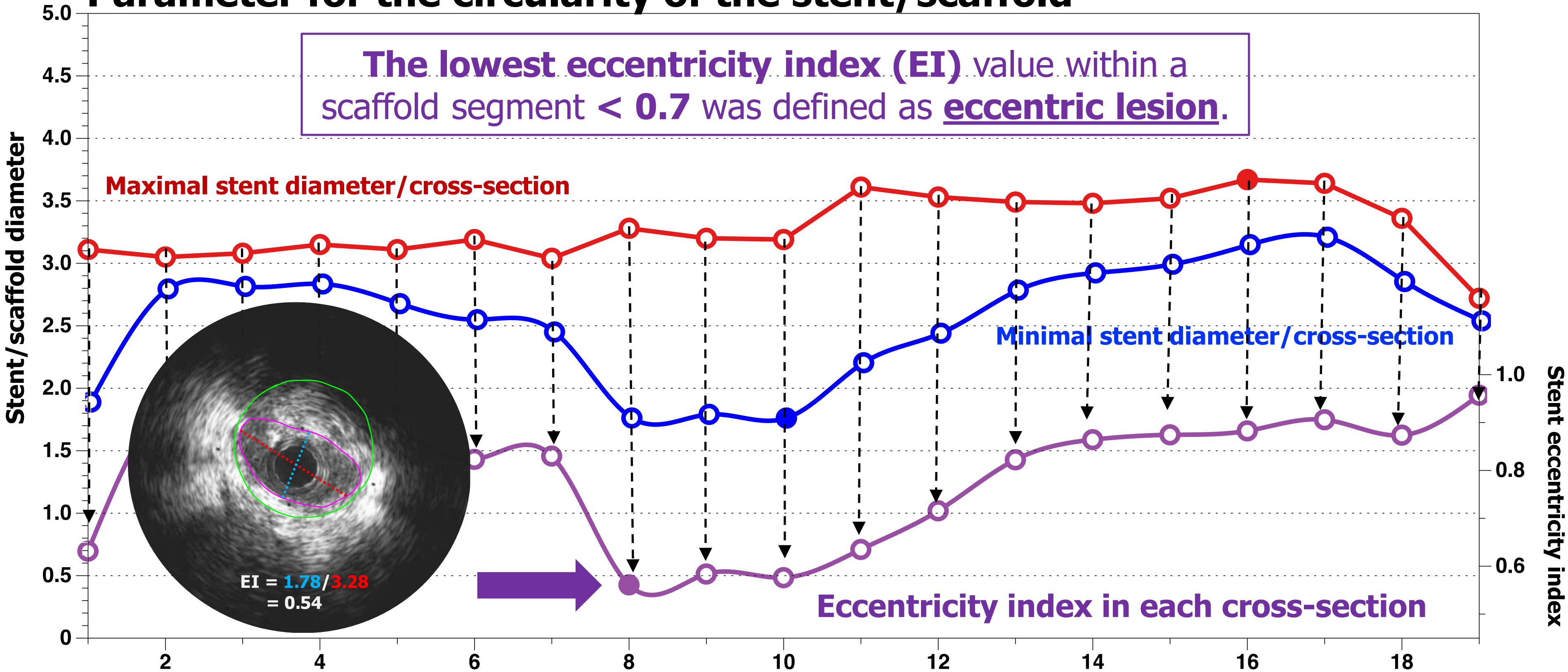
Minimum stent diameter = 1.78 mm
Maximal stent diameter = 3.28 mm

Minimum stent diameter = 3.19 mm
Maximal stent diameter = 3.67 mm

Suwannasom P, et al. JACC Cardiovasc Interv (in press)

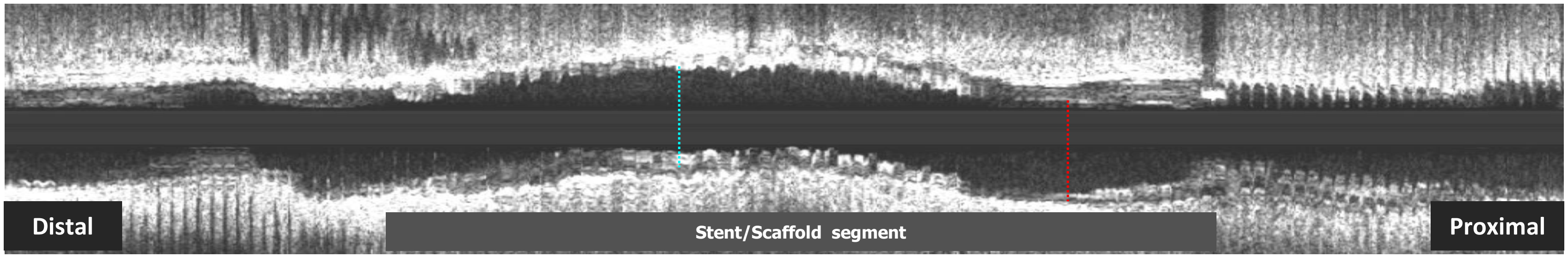
How was the eccentricity index calculated in the ABSORB II trial?

Parameter for the circularity of the stent/scaffold

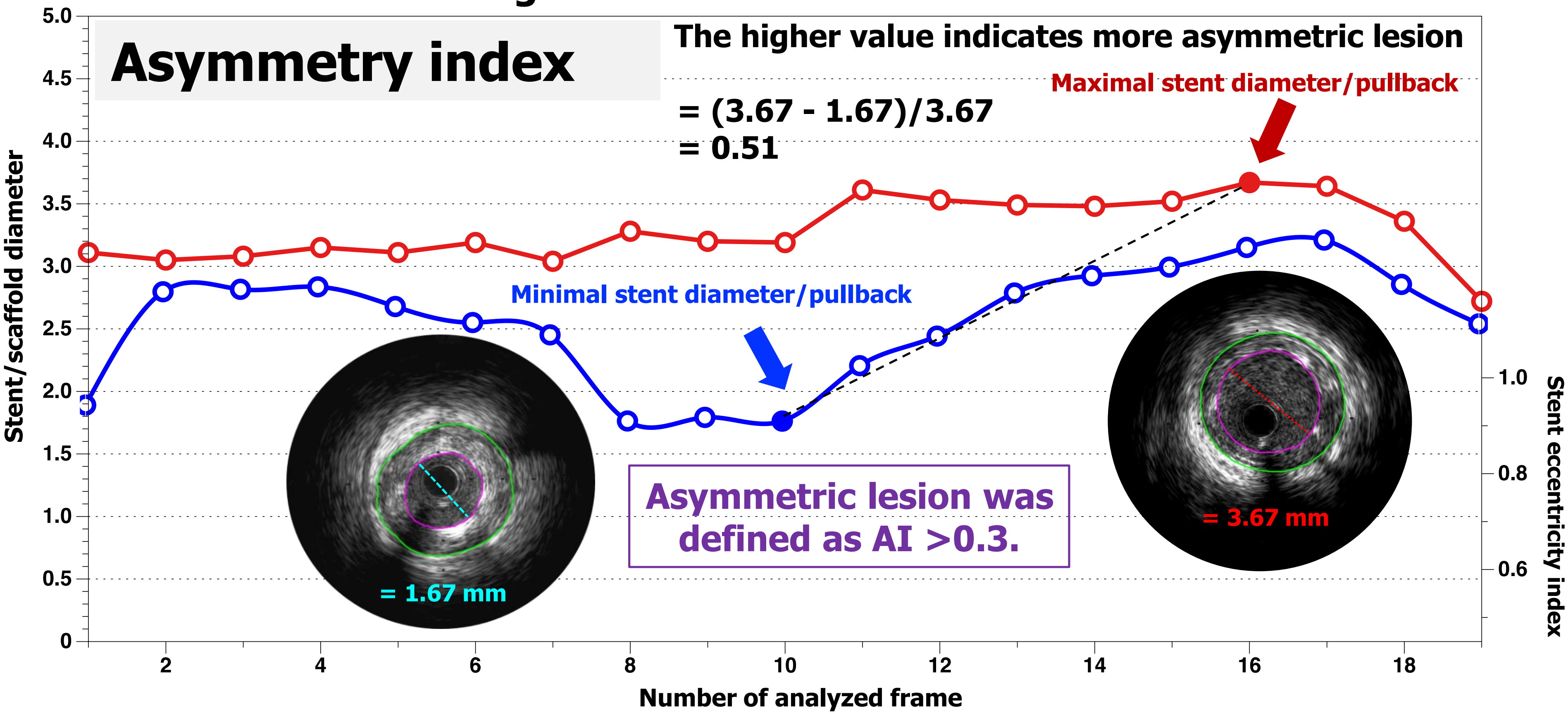


Suwannasom P, et al. JACC Cardiovasc Interv (in press)

How was the asymmetry index calculated in the ABSORB II trial?



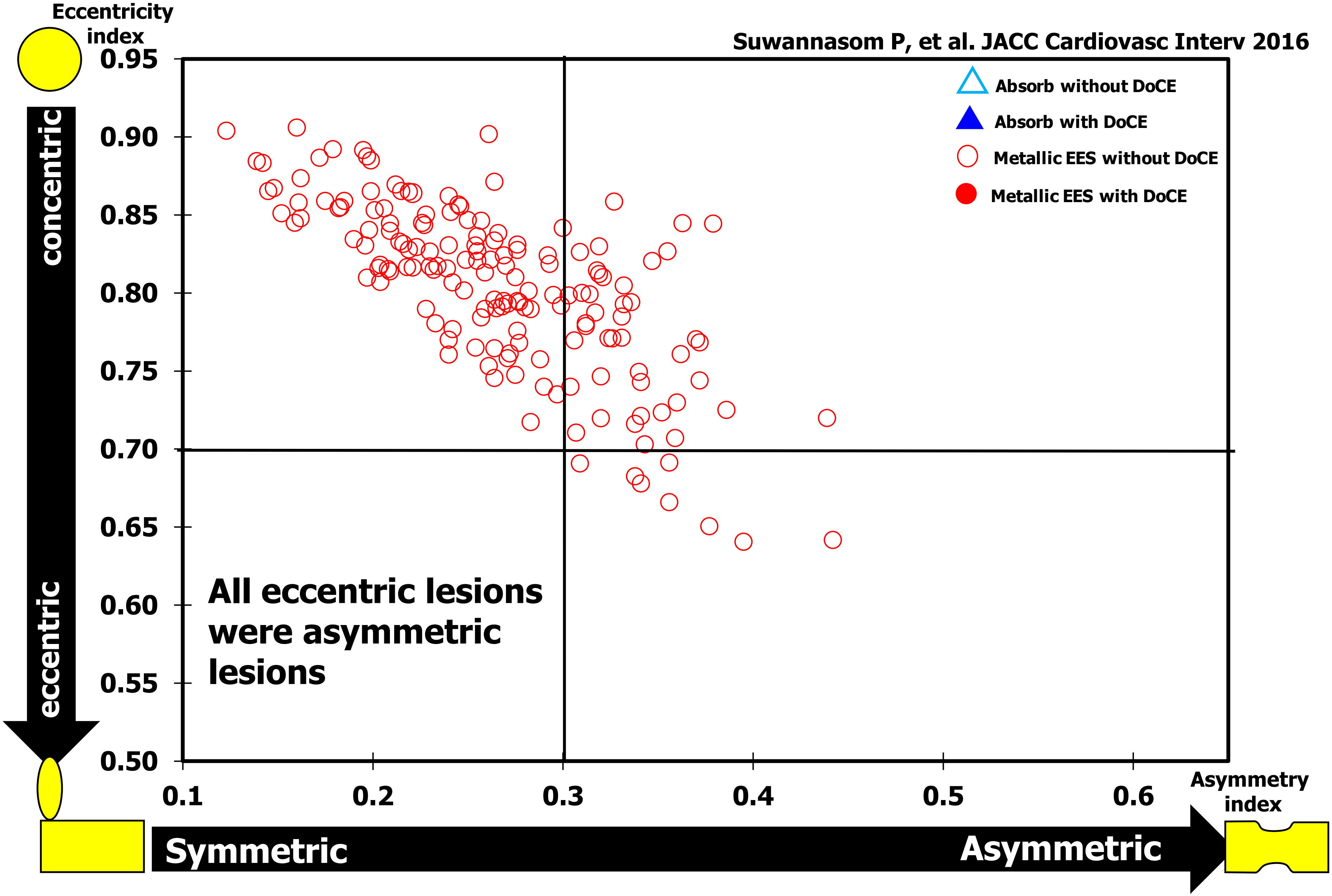
Parameter for the longitudinal variance in stent diameter



Suwannasom P, et al. JACC Cardiovasc Interv (in press)

Acute performance in ABSORB II

Distribution of geometrical morphology



Acute performance in ABSORB II

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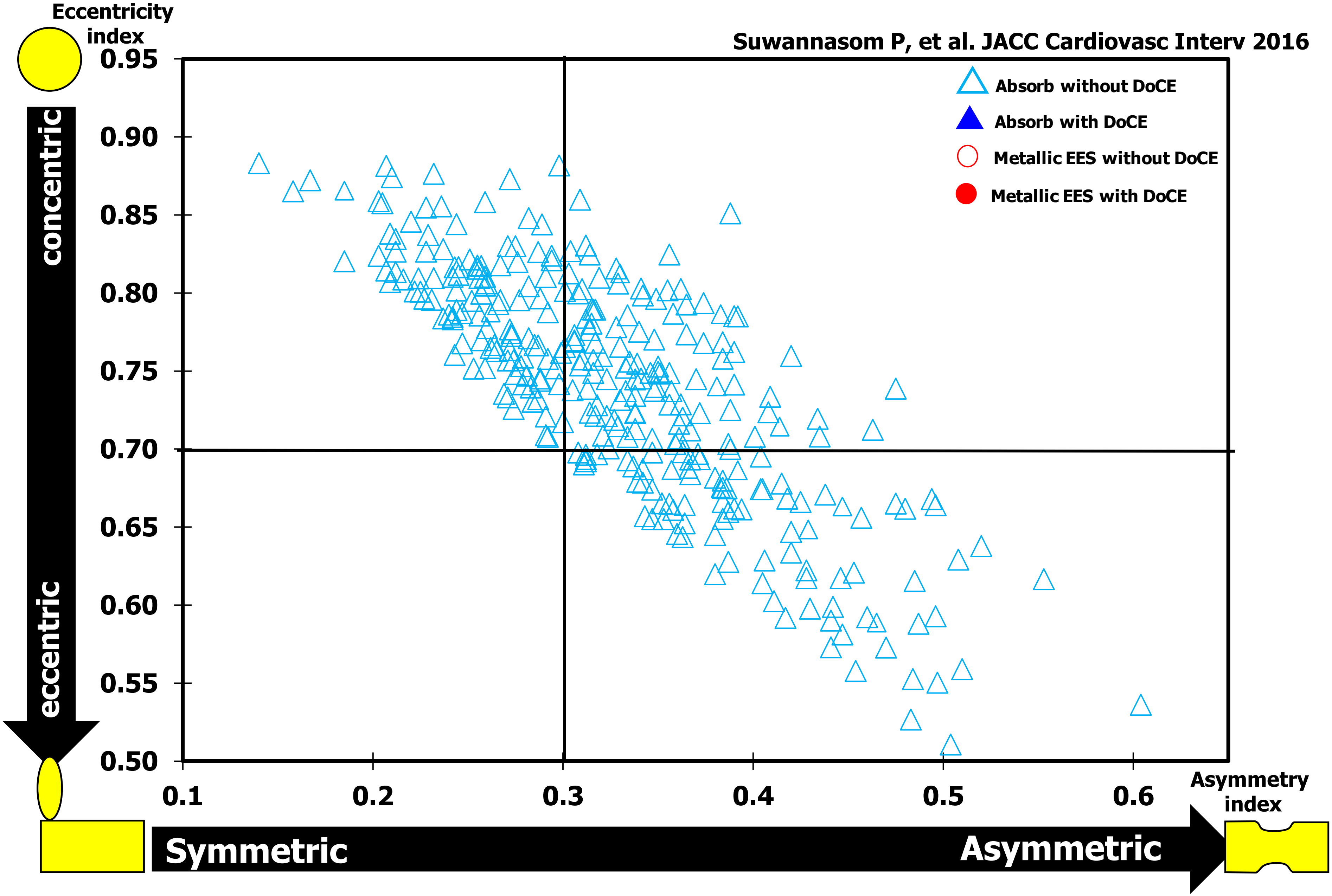
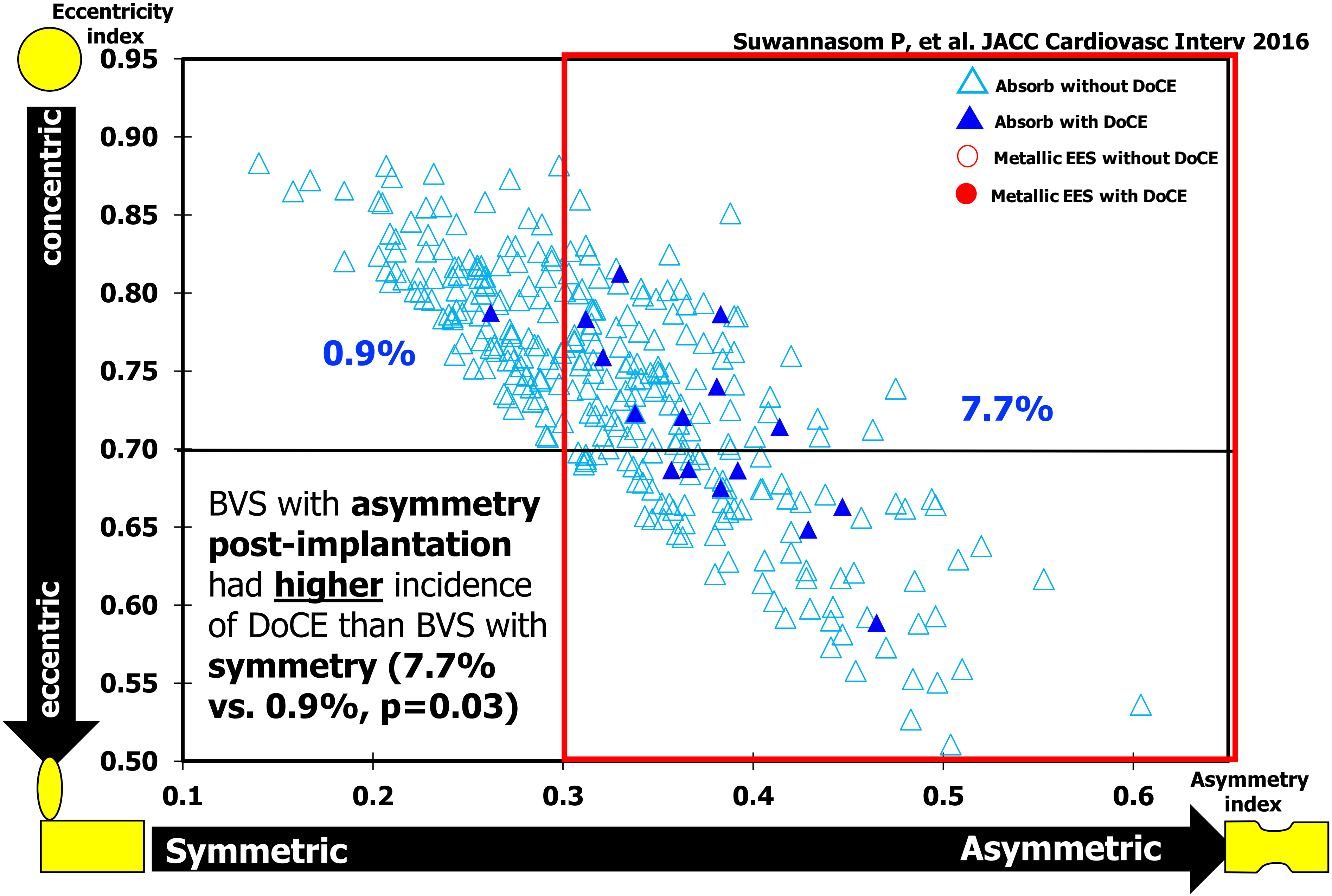


Acute performance in ABSORB II

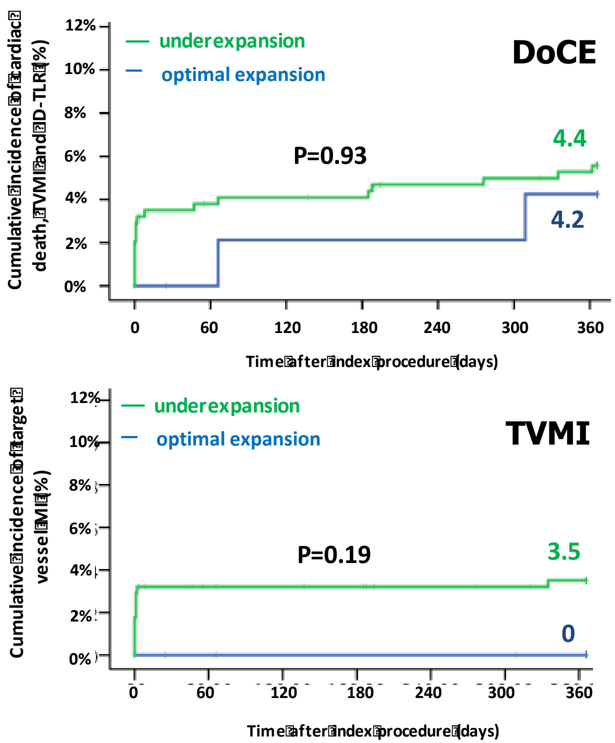
the incidence of DoCE over 1 year follow-up



BVS with **asymmetry post-implantation** had **higher** incidence of DoCE than BVS with **symmetry (7.7% vs. 0.9%, p=0.03)**

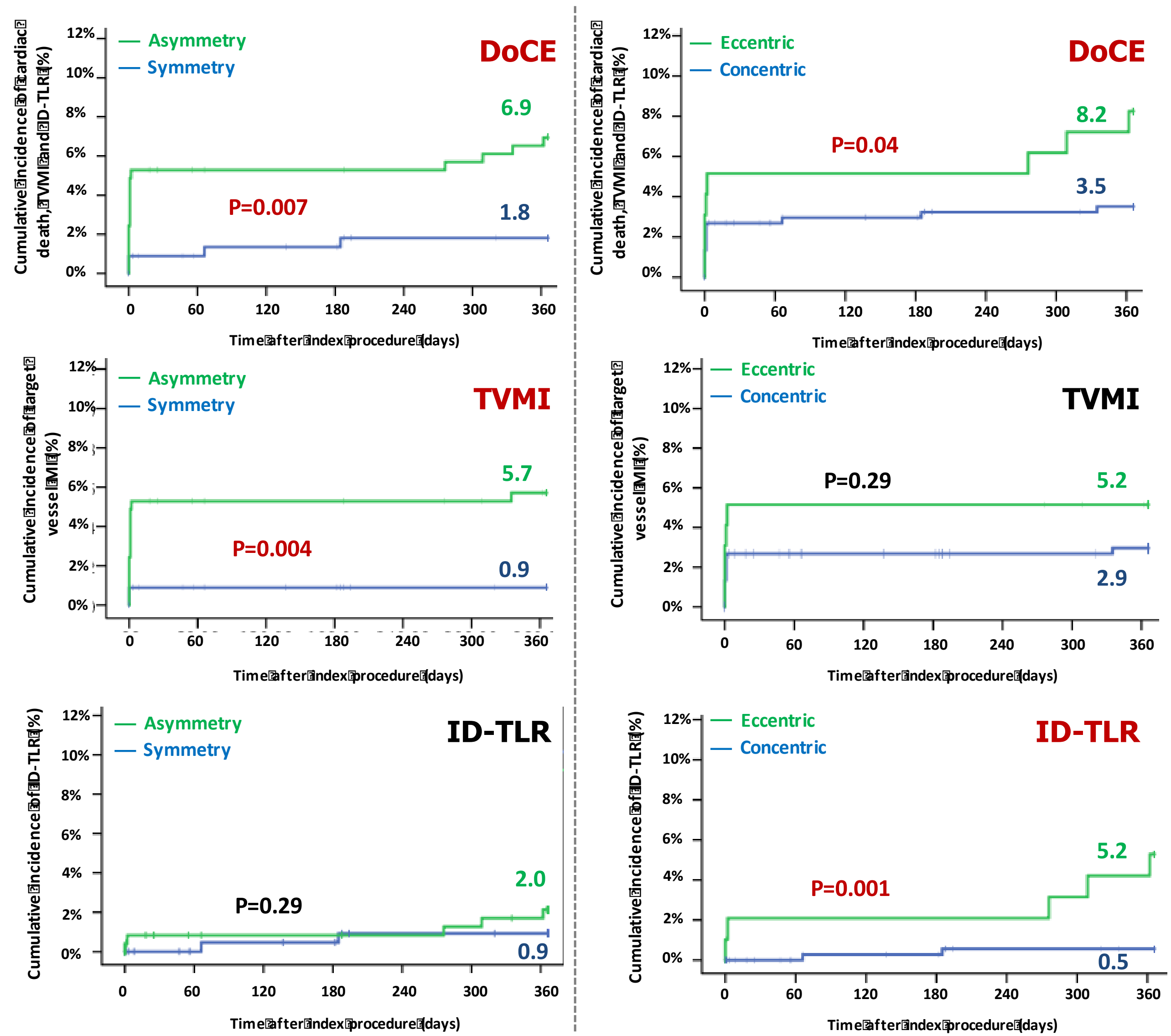
Incidence of DoCE at 1-year follow-up according to acute device performance post-implantation

Expansion



Asymmetry

Eccentricity



Post-procedural AI >0.30 is an independent predictor of DoCE (hazard ratio: 3.43; 95% confidence interval: 1.08 to 10.92; p=0.037)

Suwannasom P, et al. JACC Cardiovasc Interv 2016

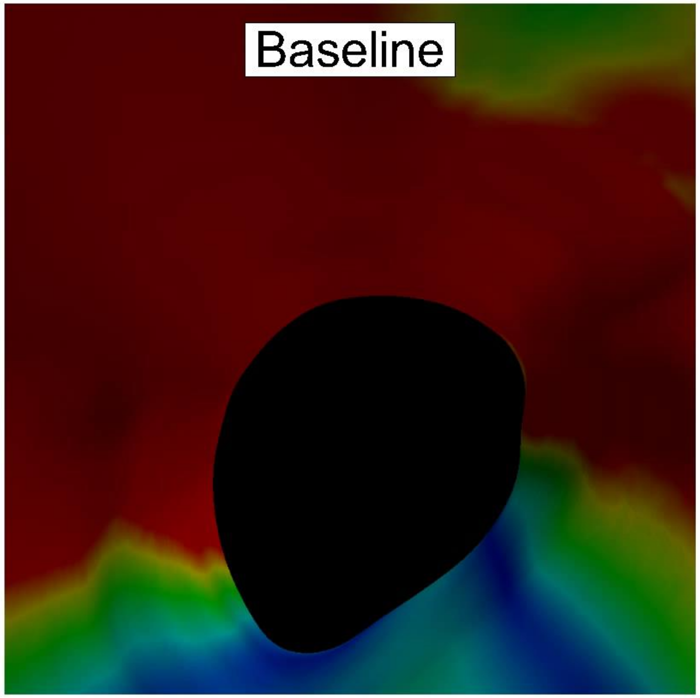
How to Improve the Scaffold Outcomes with Imaging

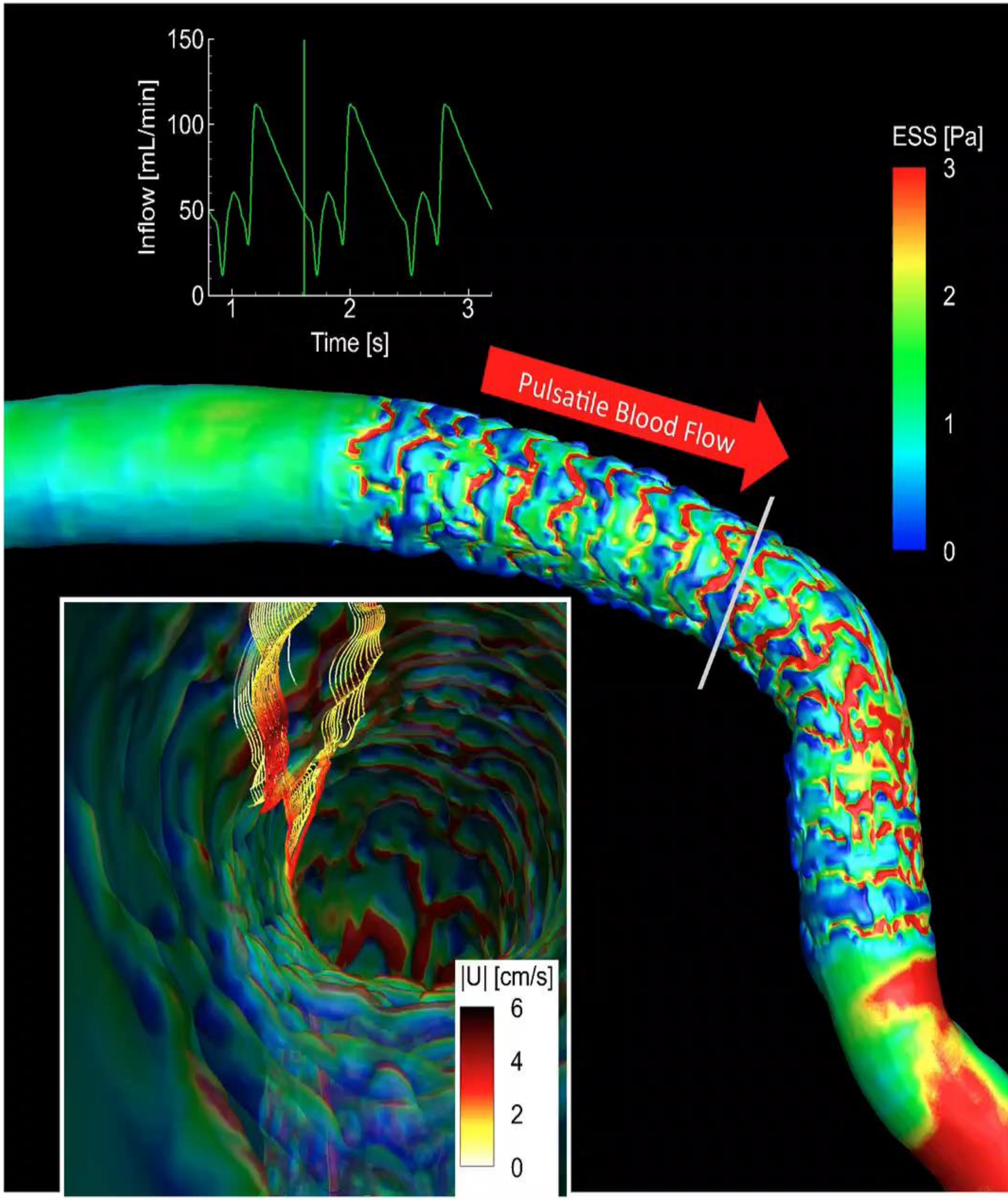
- **What are the imaging parameters associated with acute and late complications?**
  - Size mismatch
  - Asymmetry and Eccentricity
  - **Malapposition**
  - **Embedment**
- **What are the potential causes of very late ScT?**

The Nidus for Possible Thrombus Formation

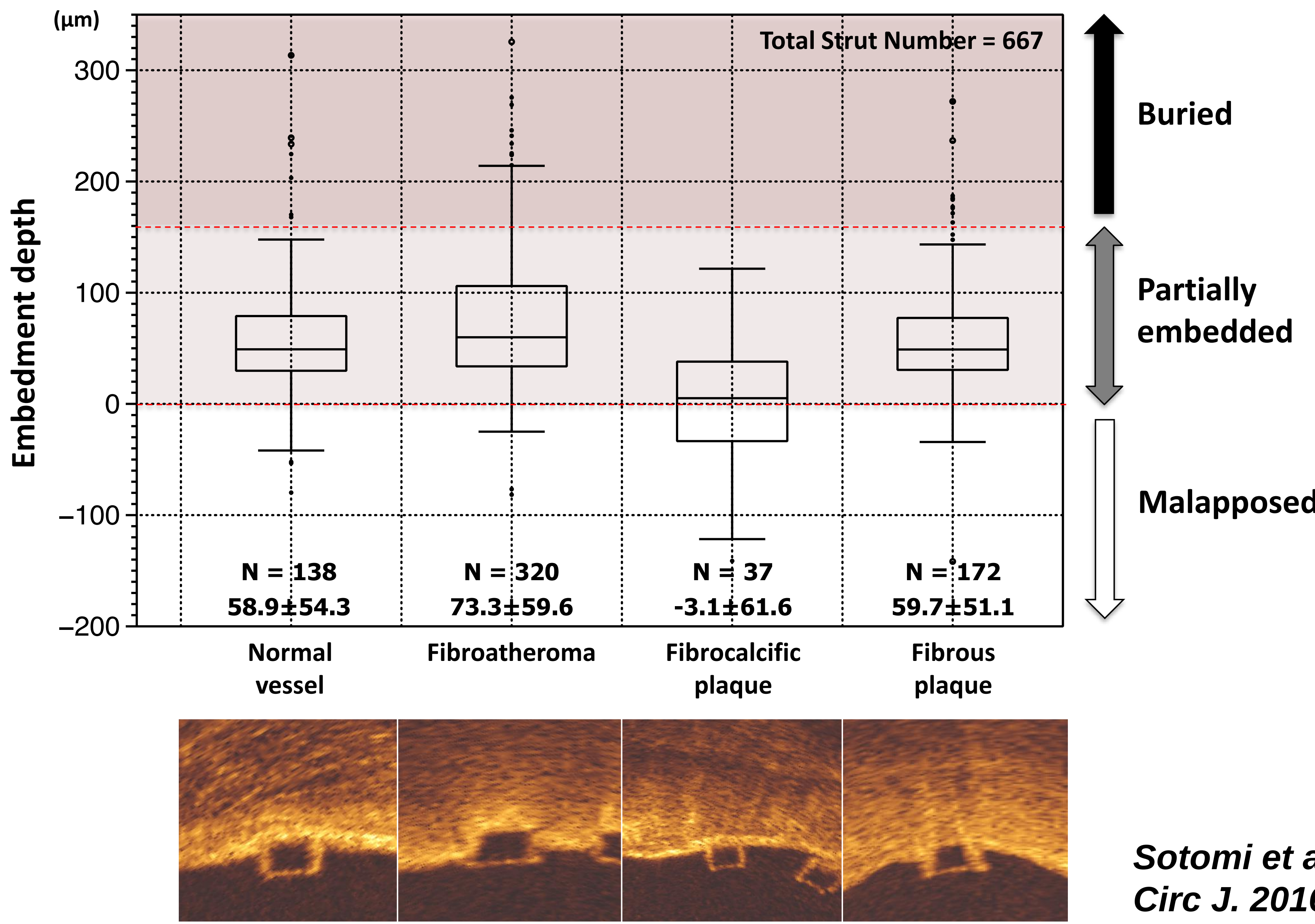
Insight From the Microenvironment of Bioresorbable Vascular Scaffold

JACC interv 2016:2167-8
Tenekecioglu et al.



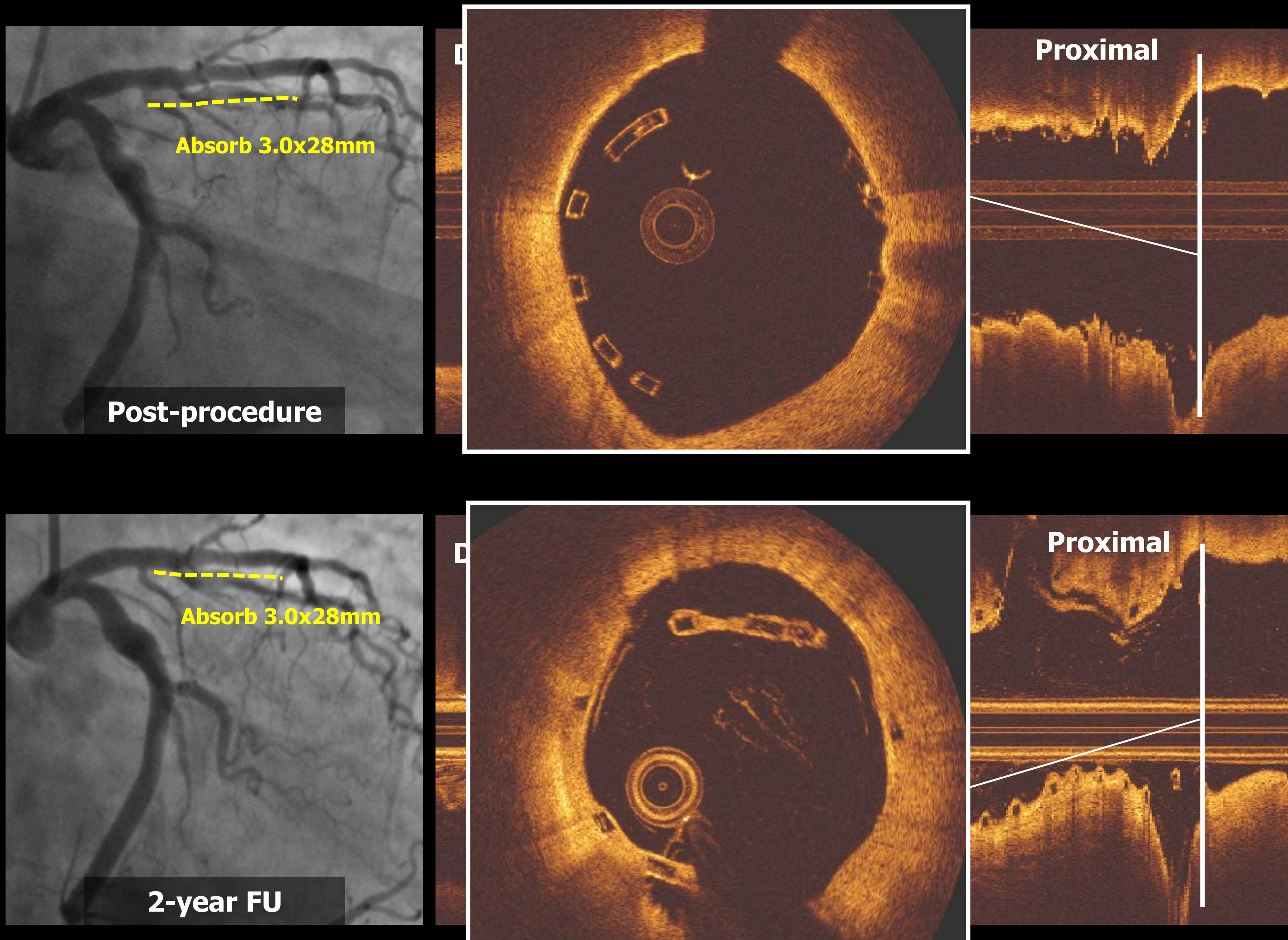


Influence of underlying plaque morphology

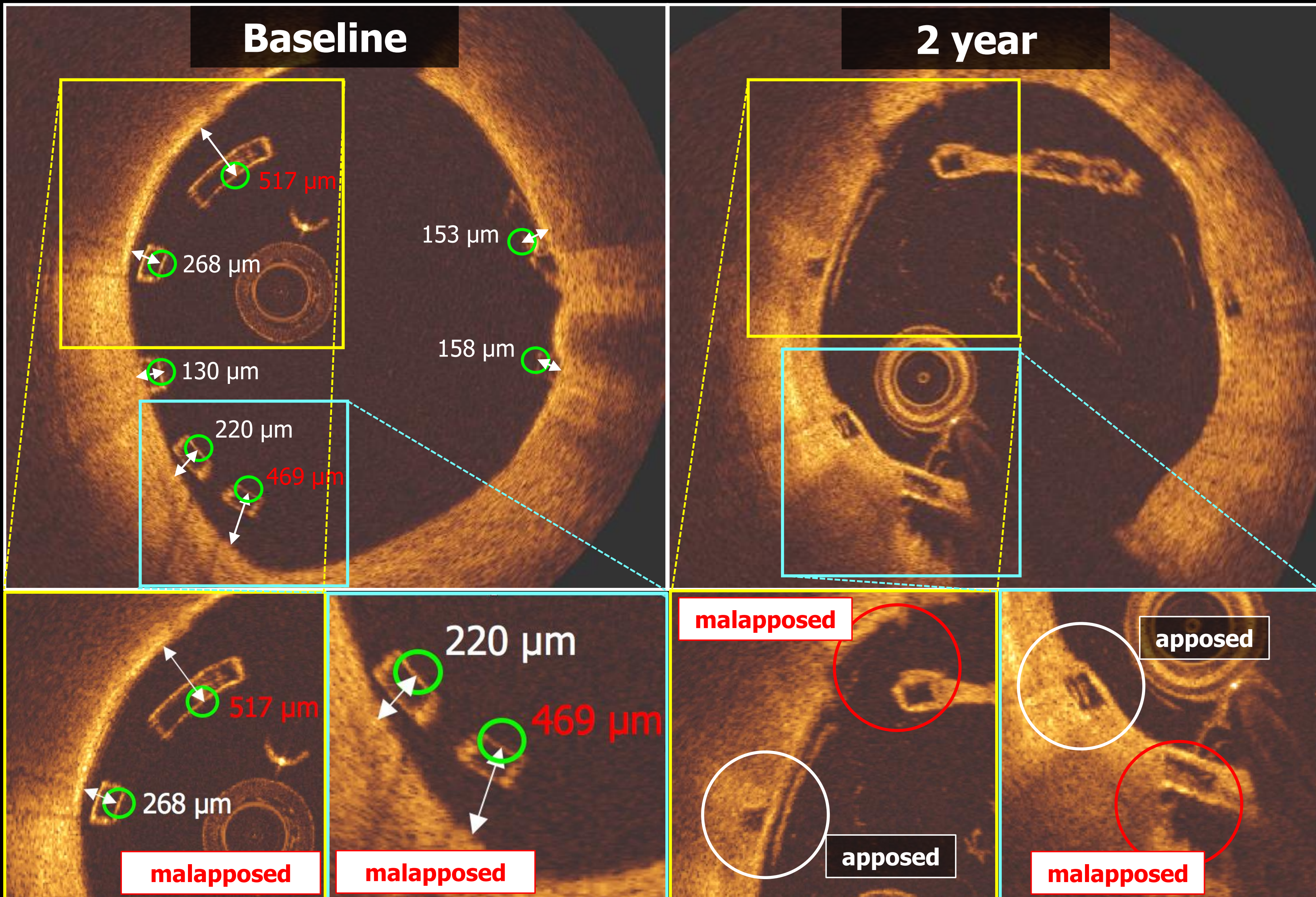


Sotomi et al. Circ J. 2016

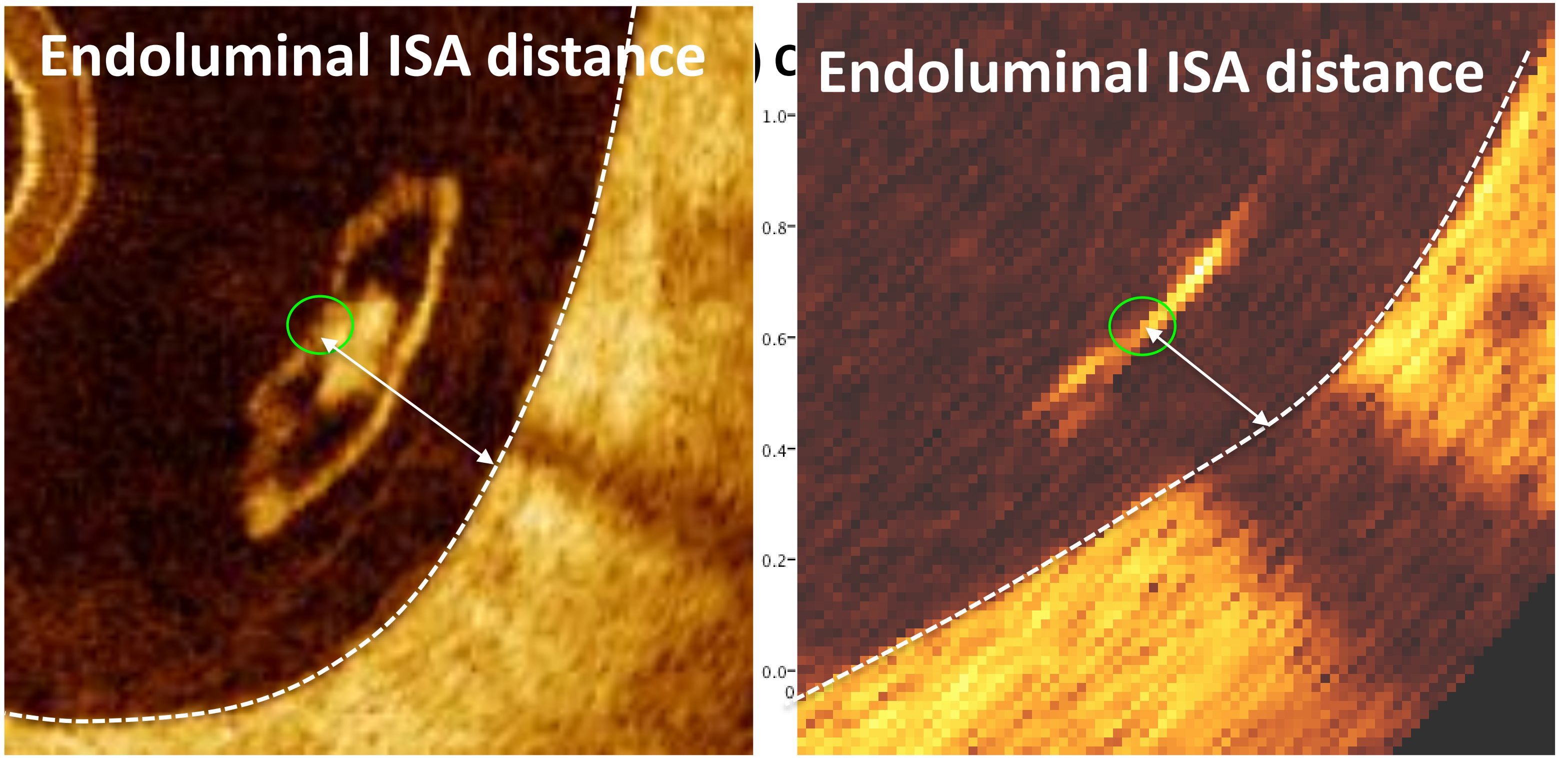
Persistent malapposed strut at 2 year (Absorb)



Persistent malapposed strut at 2 year (Absorb)



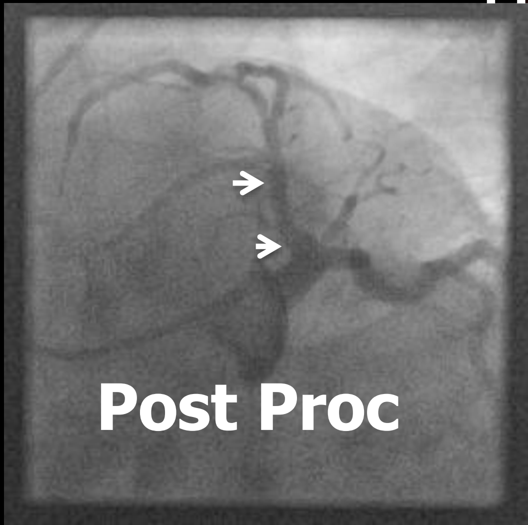
Receiver-operating curve analysis for predicting **persistent ISA** at 2-year follow-up

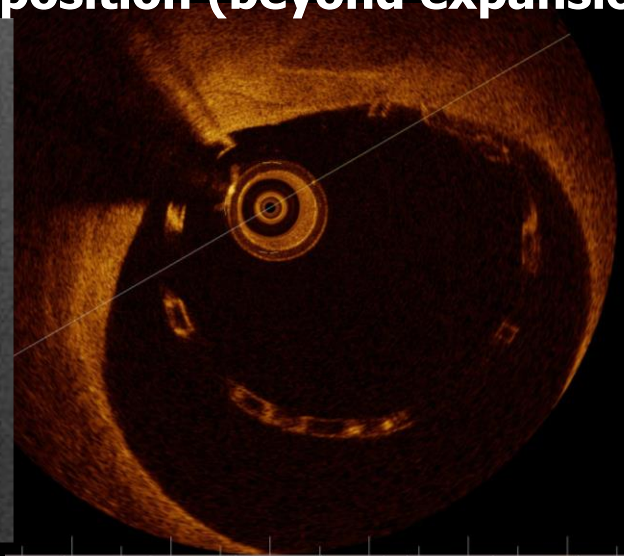


Stent	**BVS**	**CoCr-EES**
Cutoff value ISA distance	**≥ 396 µm**	**≥ 359 µm**
Sensitivity	0.875	0.778
Specificity	0.851	0.881

Sotomi et al. Eur Heart J Cardiovasc Imaging. 2017

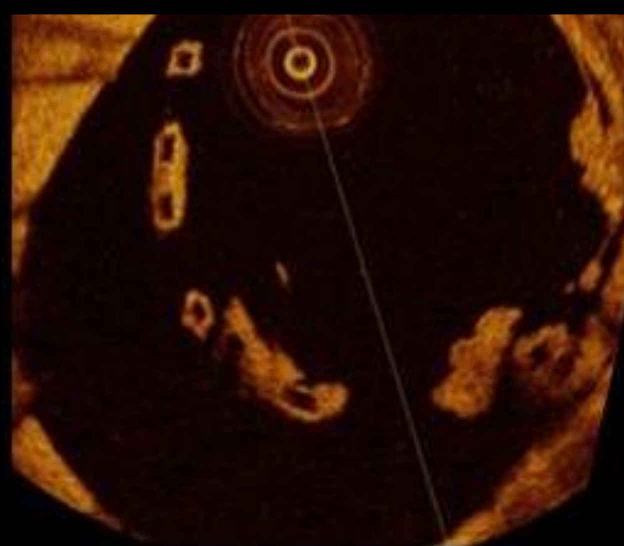
Uncorrectable Malapposition (beyond expansion limit)

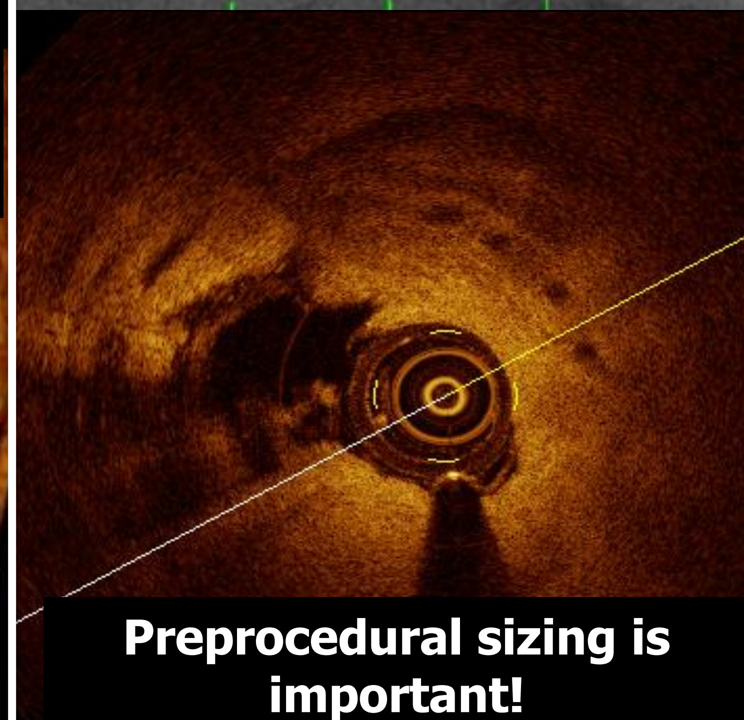




Dilemma: The vessel size is >4.0mm, while the device size is 3.0mm…The operator is aware of ISA, but considering the expansion limit of 3.5mm, the operator cannot correct malapposition by postdilatation.

1Y





Preprocedural sizing is important!

How to Improve the Scaffold Outcomes with Imaging

- **What are the imaging parameters associated with acute and late complications?**
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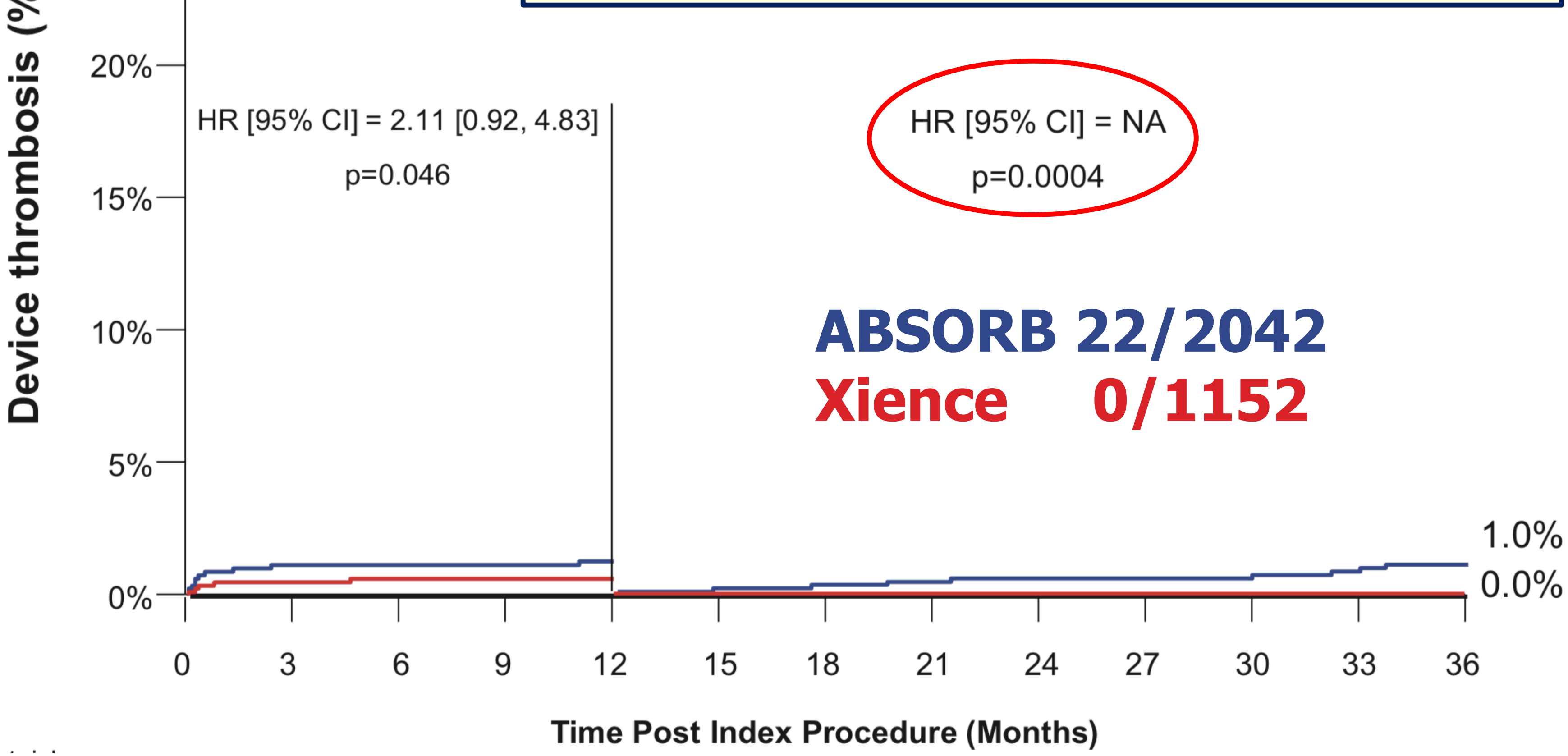
- **What are the potential causes of very late ScT?**

High incidence of very late scaffold thrombosis at 3 years

- Four RCT (ABSORB II, China, Japan, III) with **3,389** patients
- ABSORB (2,164) vs Xience (1,255)
- Median follow-up **3 years**



Predictors for VLScT: Univariate Cox regression analysis

Variable	Odds ratio [95% confidence interval]	p value
Procedure		
Post-dilatation performed	0.55 [0.11-2.78]	0.471
Post-dilatation maximal pressure (atm)	0.76 [0.51-1.13]	0.176
QCA		
In-device % diameter stenosis (%)	1.07 [0.96-1.19]	0.218
In-device minimum lumen diameter (mm)	2.58 [0.25-26.08]	0.422
Lesion coverage ratio per 0.1 increase	**0.74 [0.56-0.98]**	**0.032**
IVUS		
Minimum lumen diameter (mm)	1.80 [0.18-17.74]	0.613
Asymmetry index per 0.1 increase	0.34 [0.10-1.18]	0.088
Expansion index per 0.1 increase	0.58 [0.32-1.04]	0.066
Minimum eccentricity index per 0.1 increase	2.29 [0.63-8.35]	0.208
Deployment index per 0.1 increase	1.78 [0.75-4.22]	0.188
Expansion index <0.6	**6.93 [1.24-38.82]**	**0.028**

Serruys et al. 2017 CRT

Event and scaffold-vessel size mismatch

ScT
definite/ probable
(at 3 year)

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ABSORB Extend
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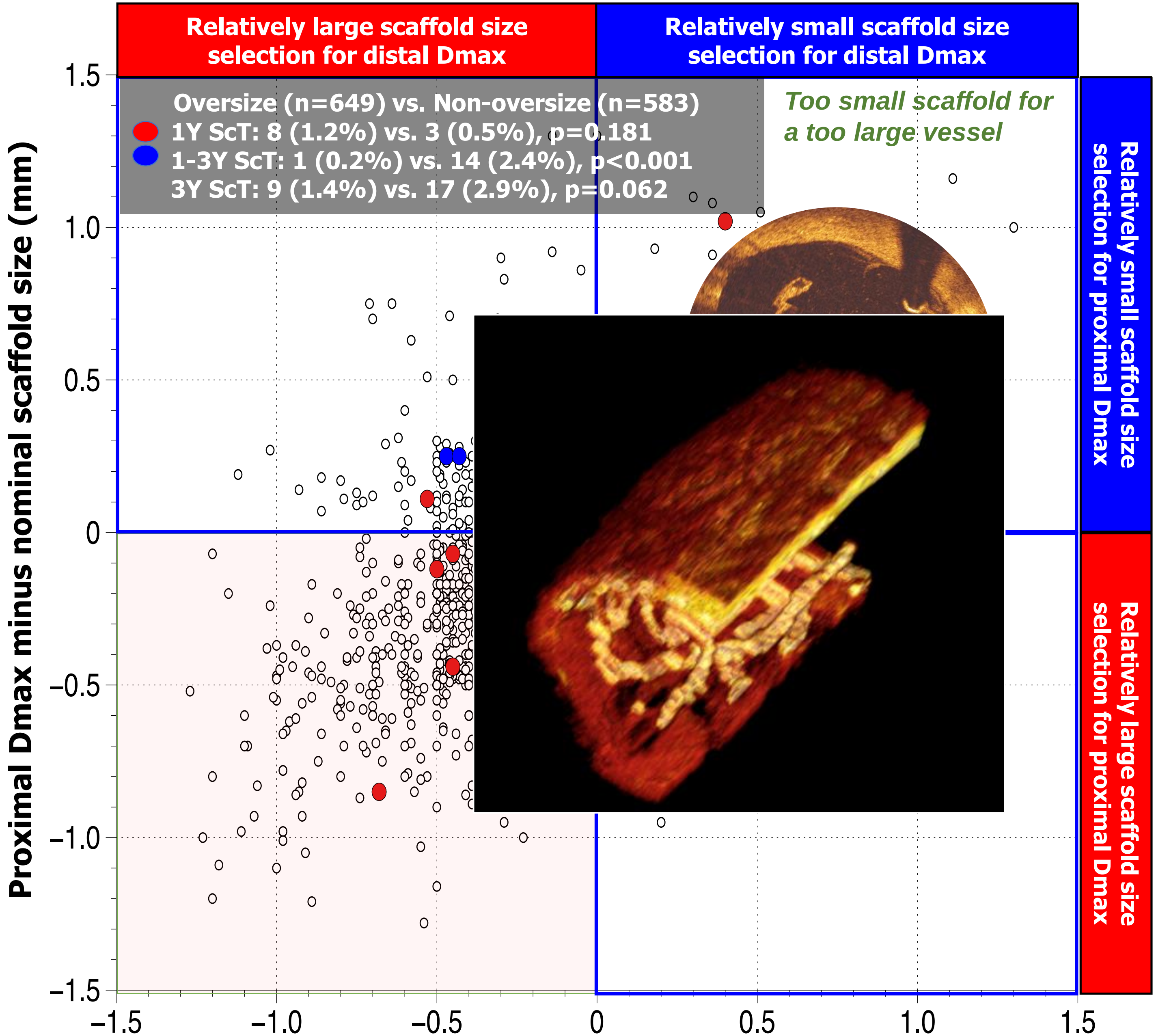
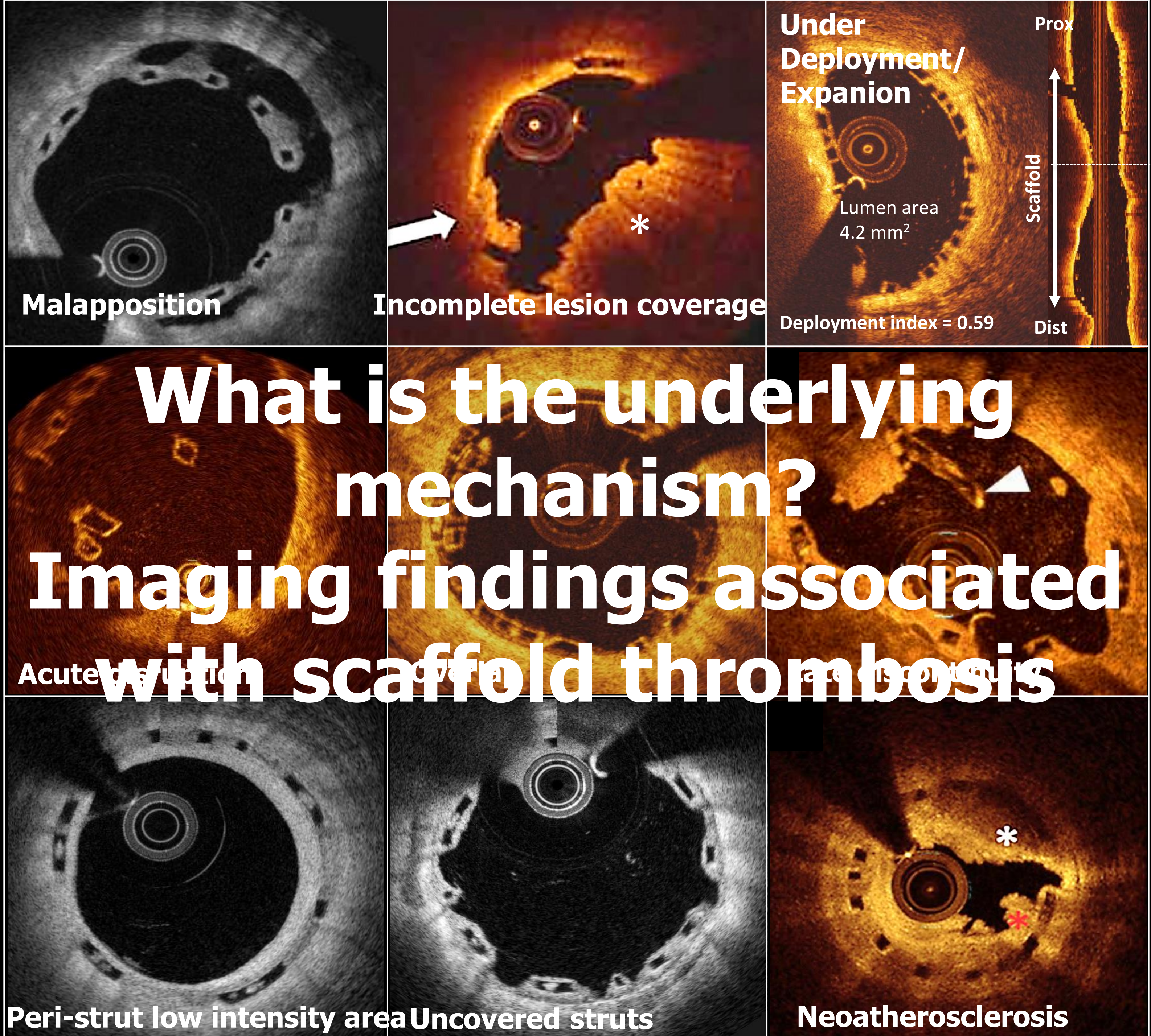


Ishibashi, Serruys et al.
JACC Cardiovasc Interv. 2015;8:1715-26.

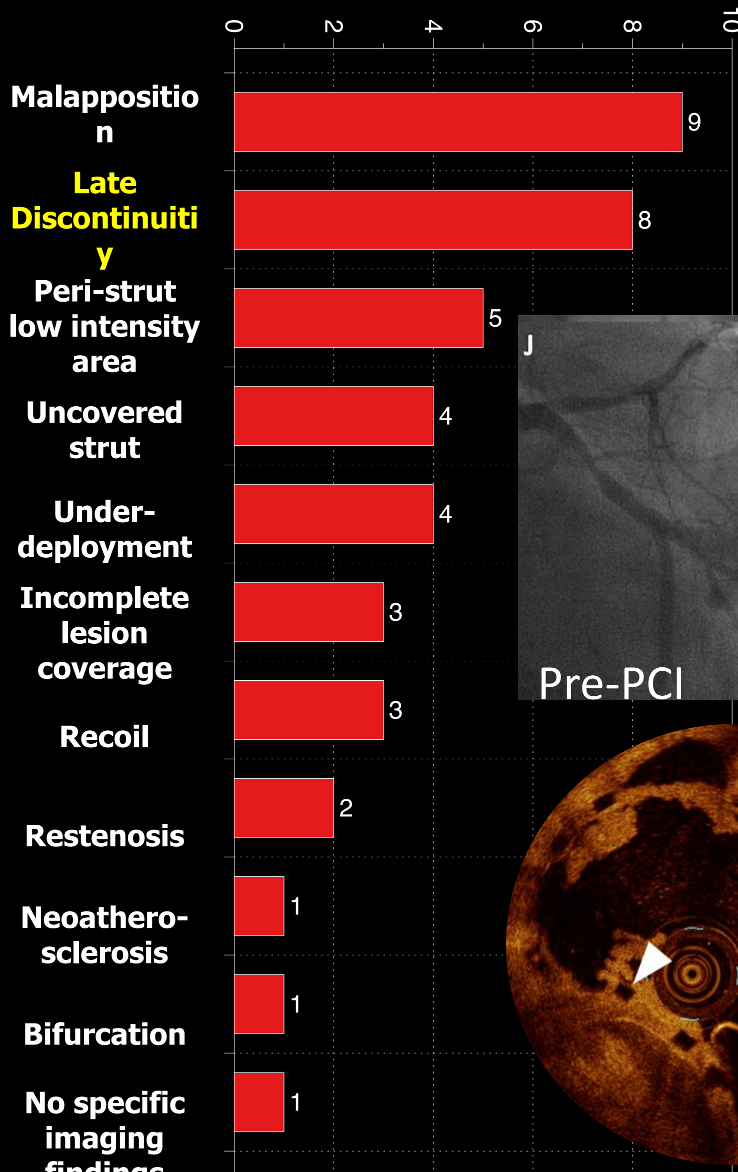
What is the underlying mechanism?

Imaging findings associated with scaffold thrombosis

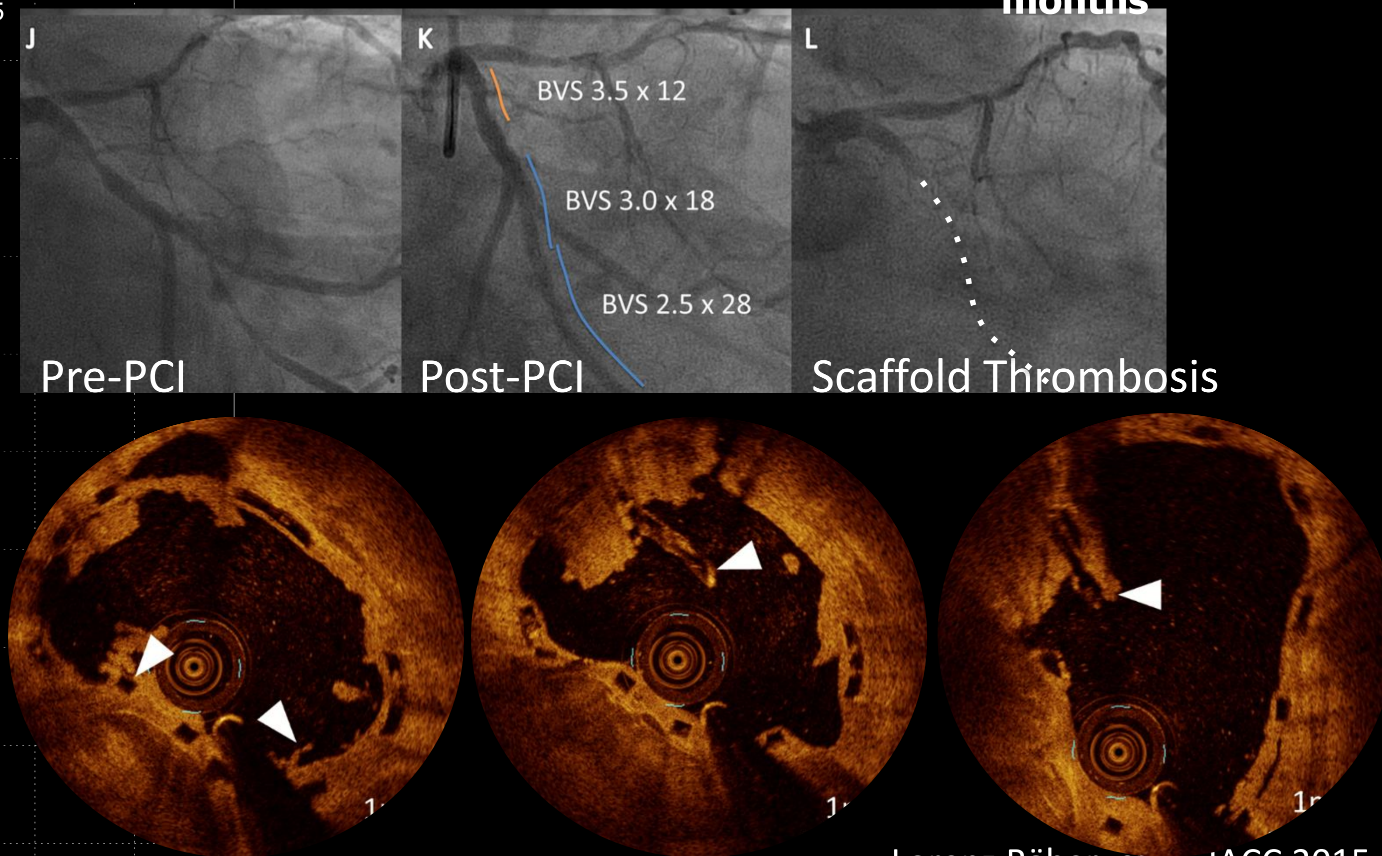


Sotomi et al. EI 2016

Major Imaging findings associated with Late/ Very Late scaffold thrombosis



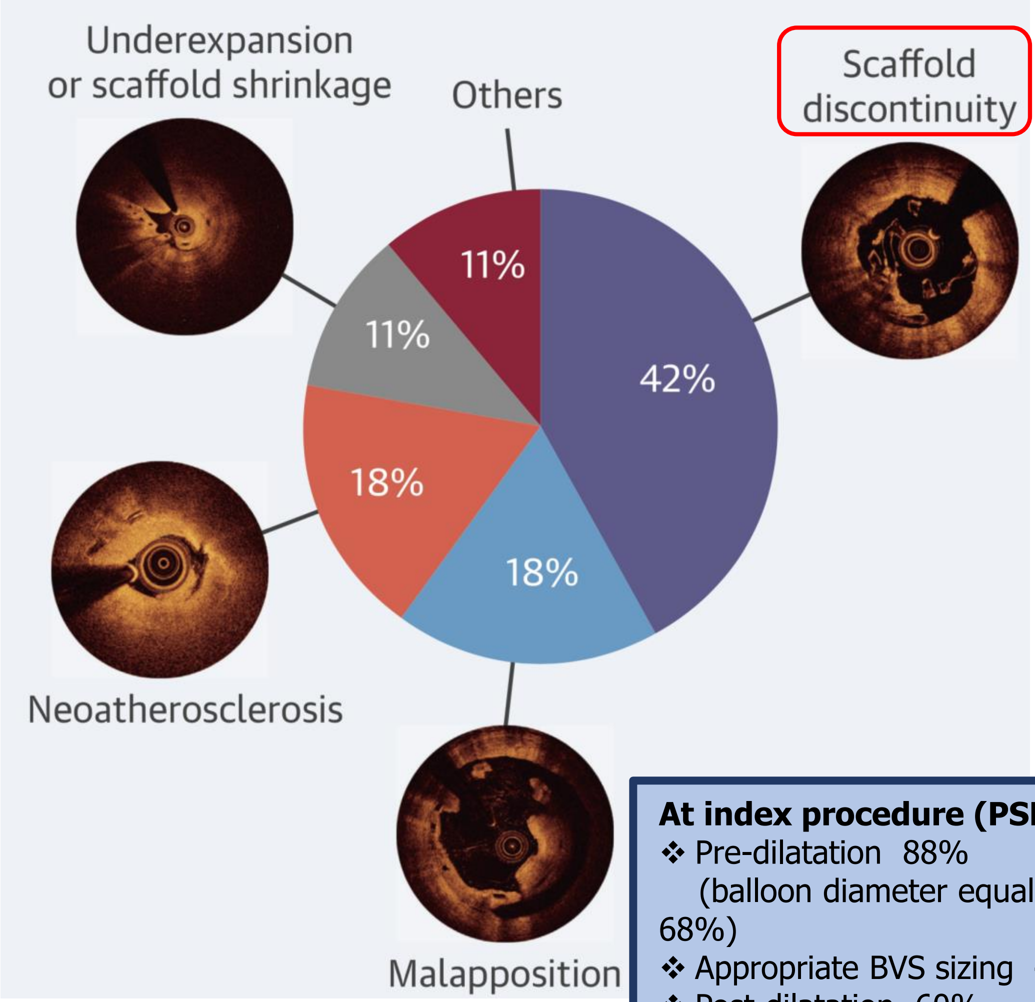
VLST at 19 months



Lorenz Räber et al. JACC 2015

Mechanisms of Very Late Scaffold Thrombosis: The INVEST Registry

- **Multicenter registry**
- **Total 36 patients (38 lesions)** with **VLScT** underwent **OCT**
- VLScT occurred at a median of **20 months**
- At the time of VLScT, **83%** of patients received **aspirin monotherapy**, **17%** received **DAPT**
- The leading mechanism of underlying VLScT was **scaffold discontinuity (42.1 %)**



At index procedure (PSP)
- Pre-dilatation 88%
  (balloon diameter equal to RVD 68%)
- Appropriate BVS sizing 44%
- Post-dilatation 60%
  (high pressure (≥16atm) 34%)
- Post in-segment %DS<30% 84%

Yamaji, K. et al. J Am Coll Cardiol.201

#3. Mechanism of ST/VLST

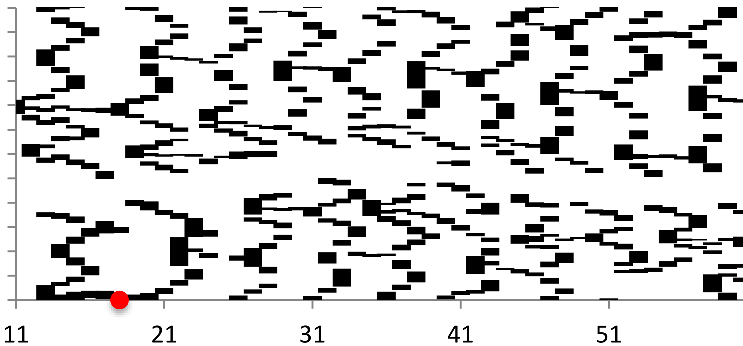
Late discontinuities of a s

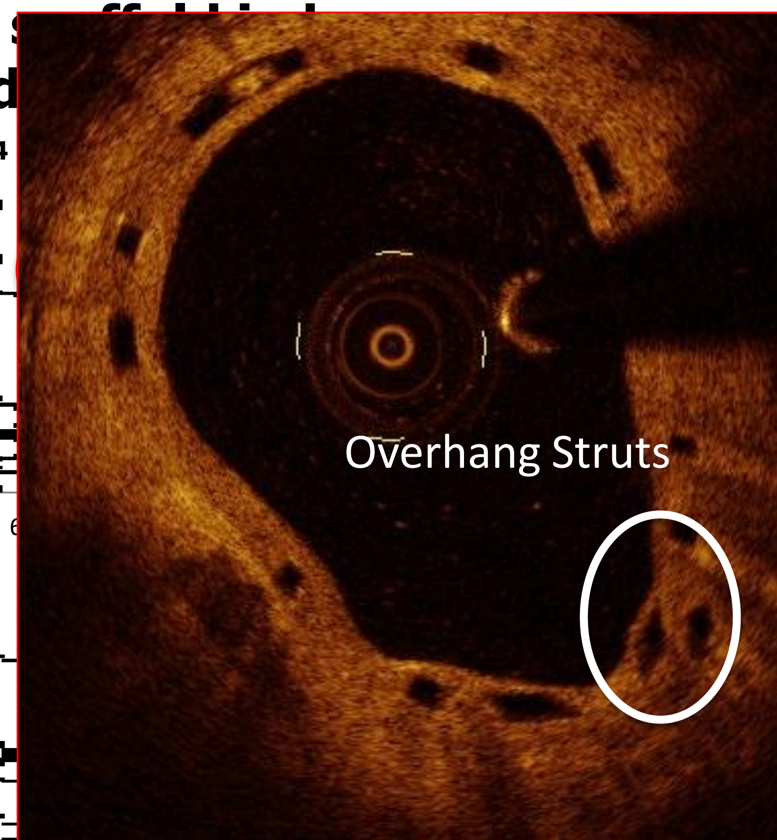
Carpet view of the scaffold

Onuma et al. JACC int 2014

Post Procedure

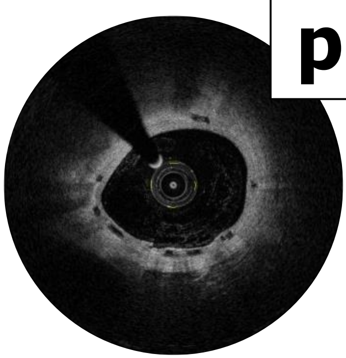
←Distal



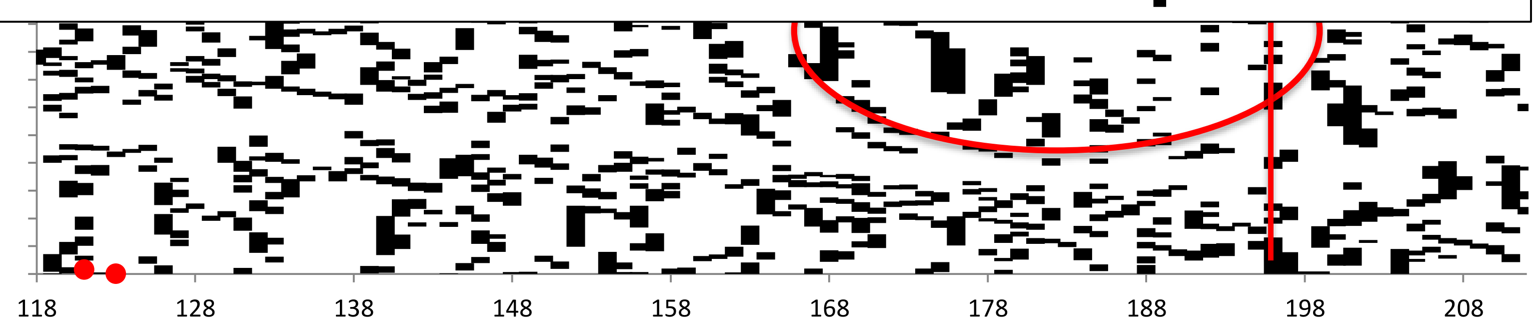


One year

Three yea

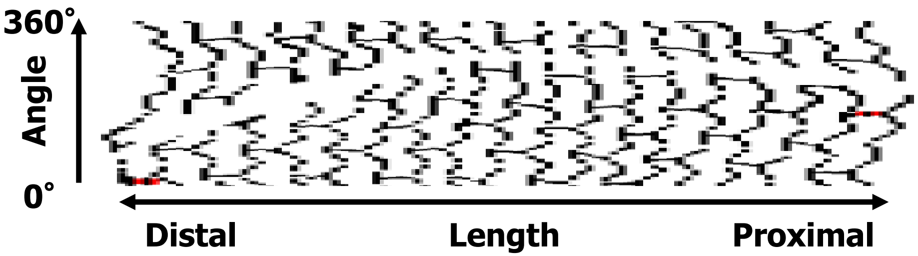


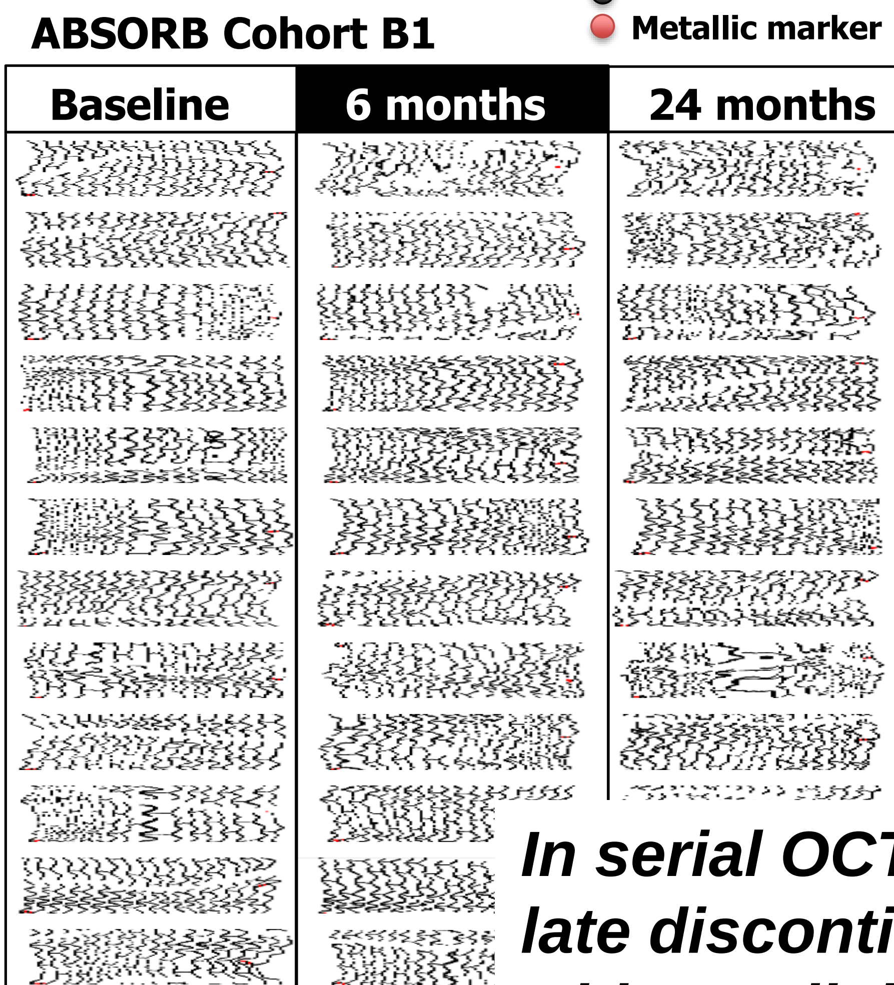
Late discontinuity is expected phenomenon related to bioresorption.



Serial changes of strut distribution

BRS textbook



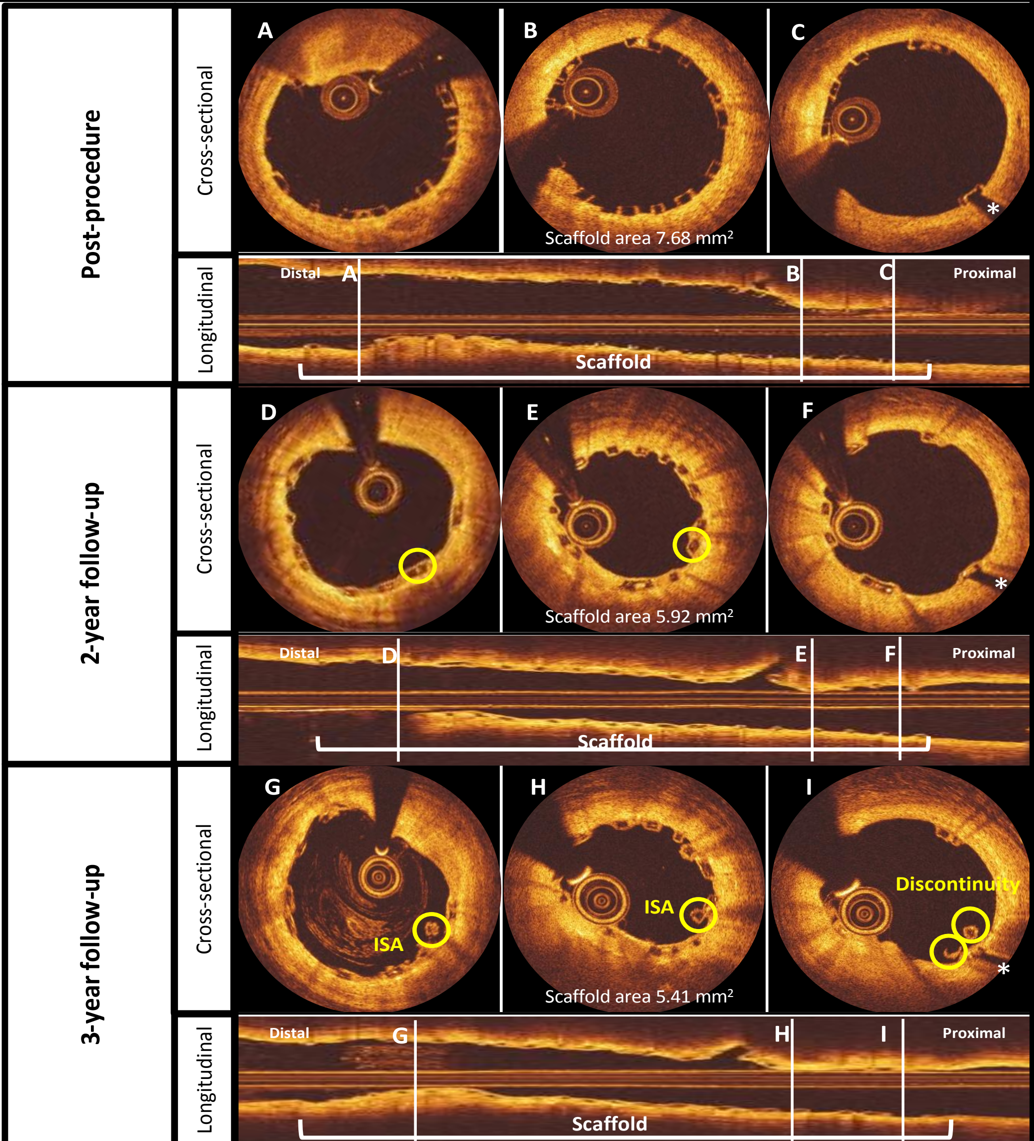


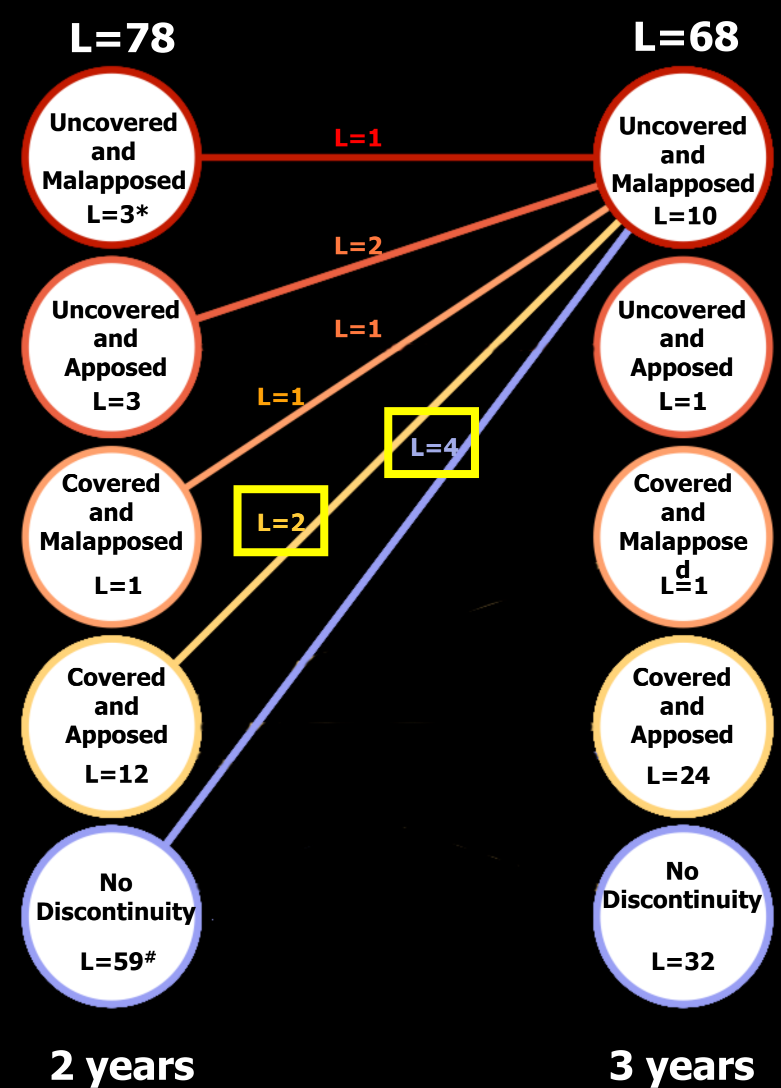
In serial OCT observation up to 36 months, late discontinuities were observed in 43%, without clinical events

Onuma et al. JACC int 201

Frequency of late discontinuities between 2 and 3 years (truly serial analysis at lesion level)

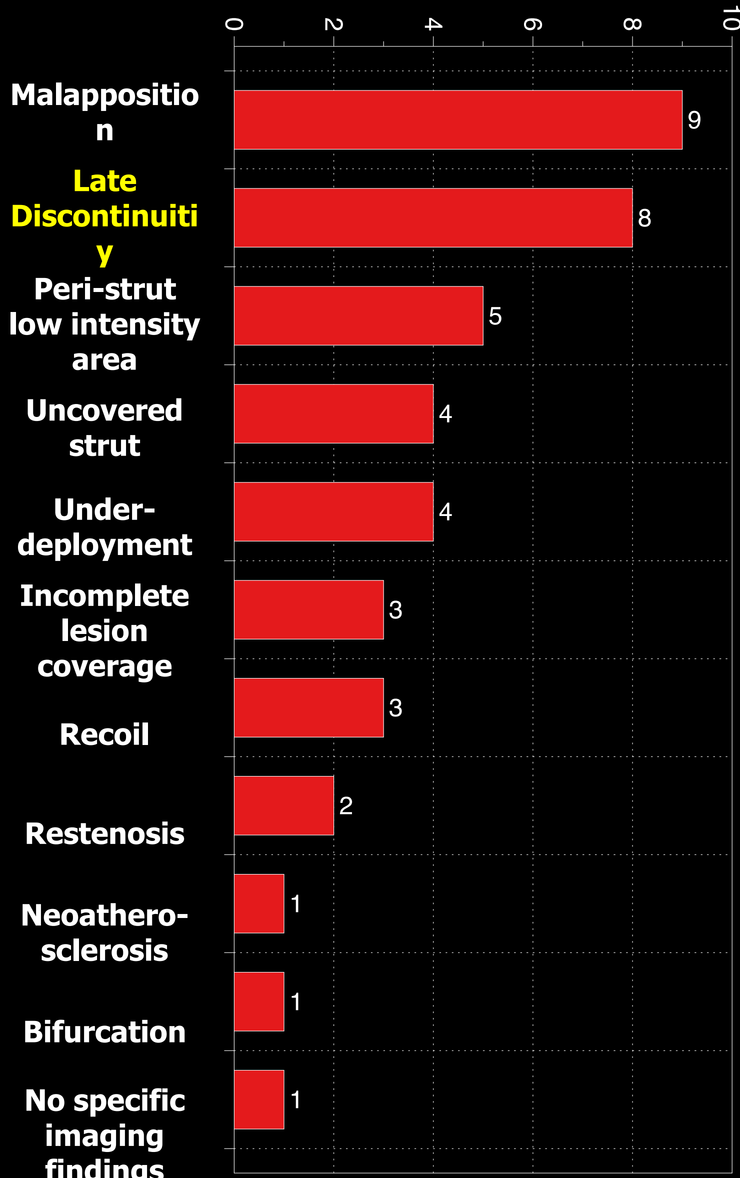
-by courtesy of Prof. Kimura

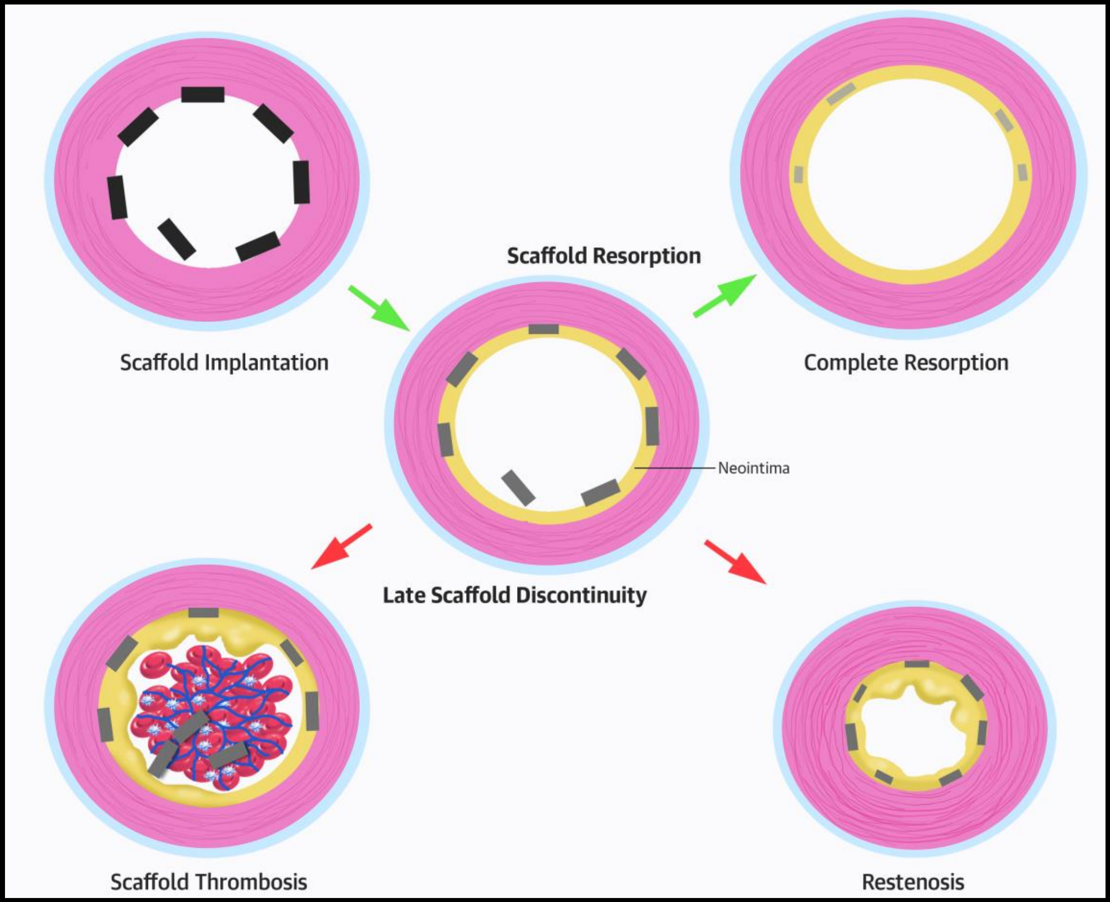




* Two lesions were not analyzable at 3 years. # Eight lesions were not analyzable at 3 years.

Imaging findings associated with Late/ Very Late scaffold thrombosis reported in literature





- ***What is triggering VLST?***

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

How to Improve the Scaffold Outcomes with Imaging

- Correct Sizing
  - Avoid oversizing (early/late ScT)
  - Avoid under-sizing (Very late ScT)
- Avoid post-procedural eccentricity and asymmetry
- Avoid significant malapposition
- Avoid underexpansion

- Late discontinuity likely plays a role in mechanism of VLScT. Late discontinuities is in general a benign change during the bioresorption process. However, in case struts are not covered by neointima, late discontinuity could be a malignant potential cause of ScT.
- **Enhancement of neointimal coverage** would be a key to prevent VLScT associated with late discontinuity.

- These imaging analyses suggested a potential benefit of image guidance of acute/late results if the above mentioned parameters were appropriately corrected at the time of implantation.