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OCT-guided BRS implantation

Yoshinobu Onuma, MD, PhD
Erasmus MC/ Cardialysis, Rotterdam , The Netherlands
Yohei Sotomi, MD
Academic Medical Center, University of Amsterdam, the Netherlands
Pannipa Suwannasom
Evelyn Regar
Erasmus MC, Rotterdam , The Netherlands
Patrick W. Serruys, MD, PhD
Imperial college, London, UK

OCT (Imaging) Guidance for BRS

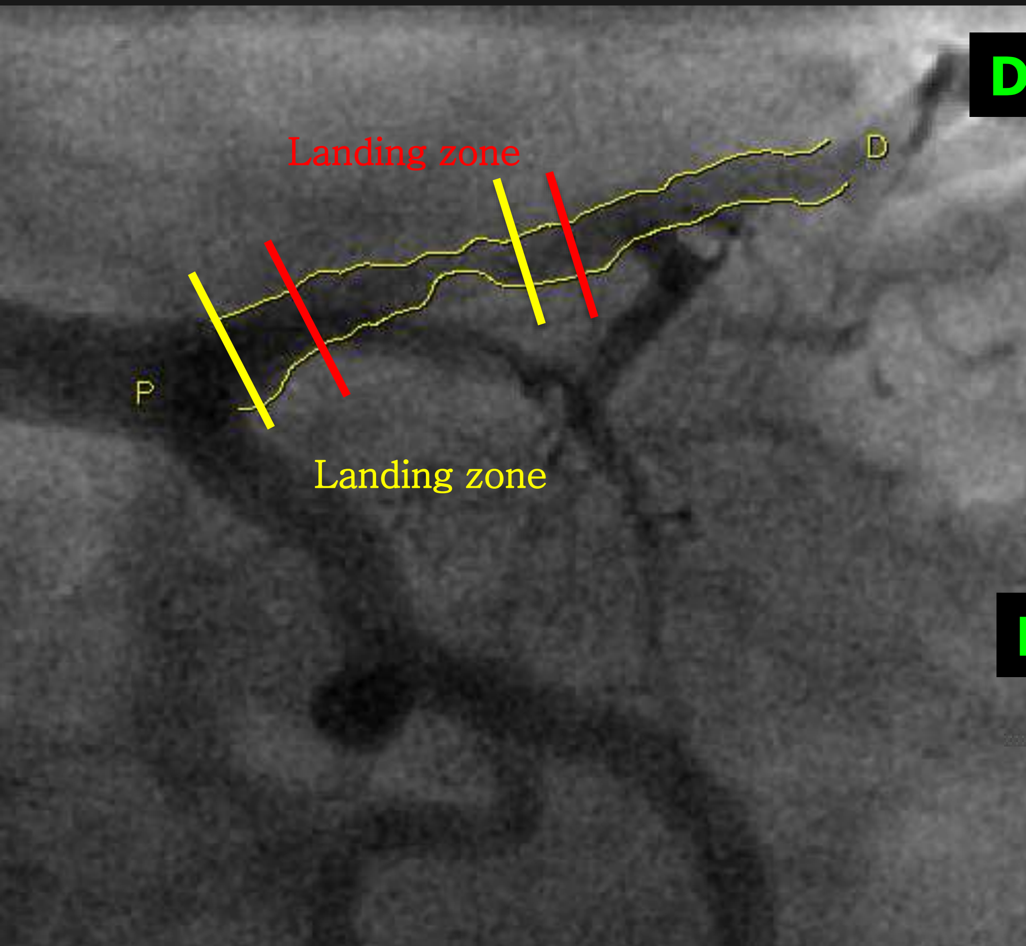
Preprocedure:

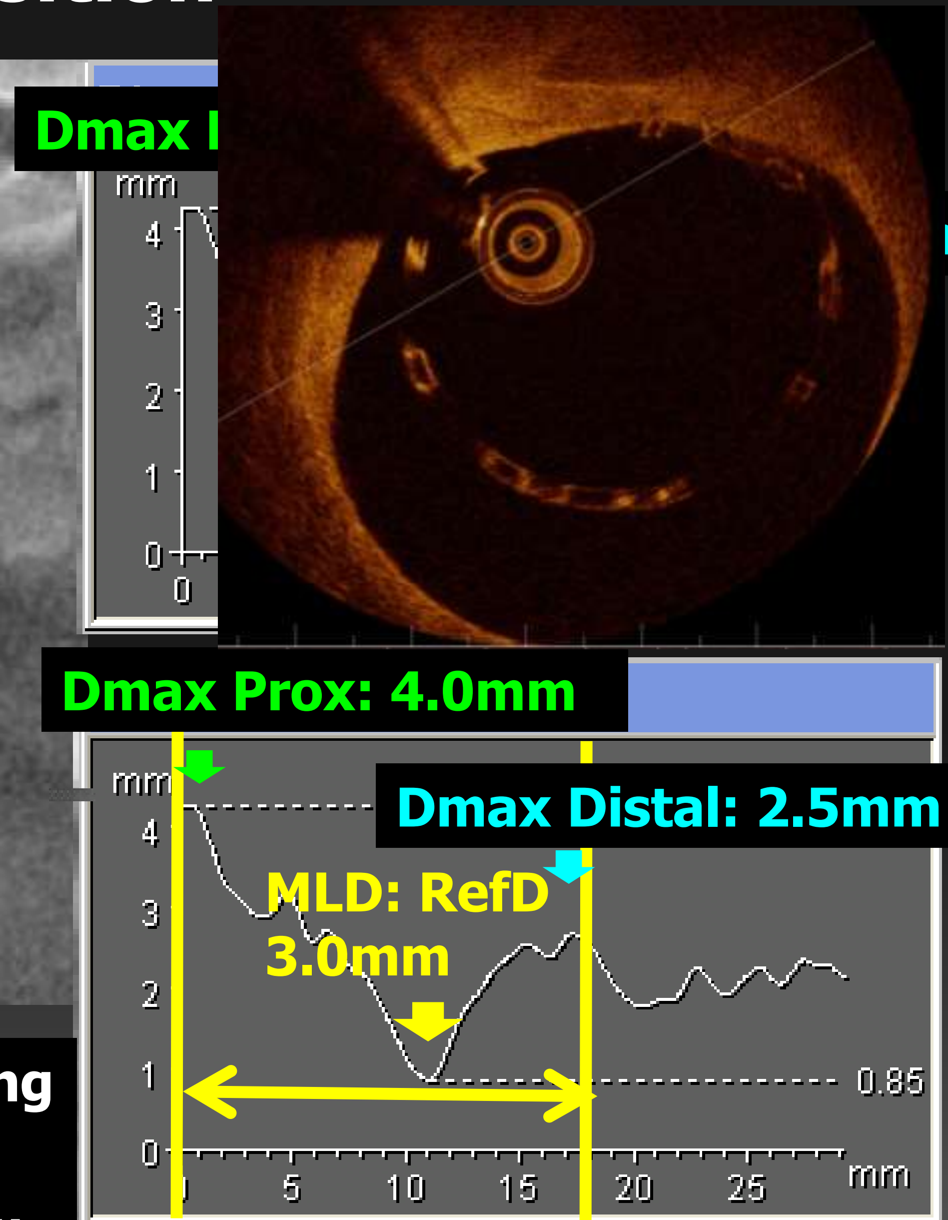
- Sizing
- Landing zone
- Preparation

Post implantation:

- Scaffold expansion
- Eccentricity/ Symmetry
- Malapposition

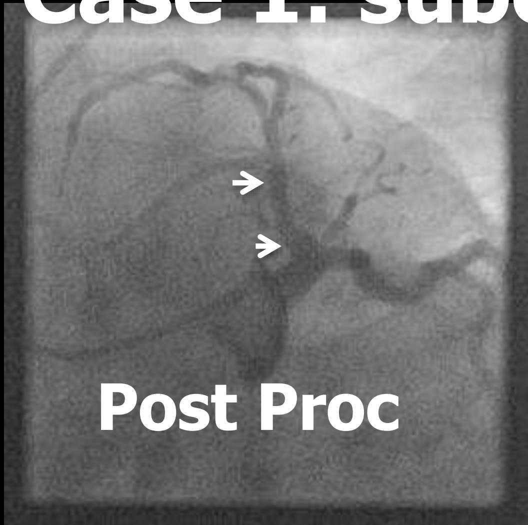
Case 1: suboptimal positioning resulting in uncorrectable malapposition

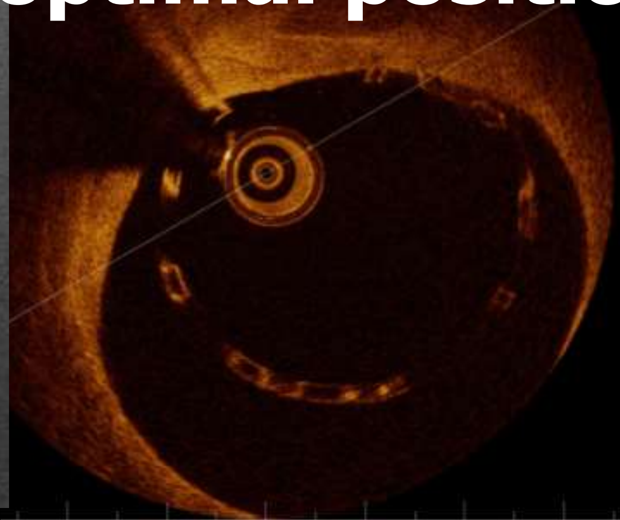


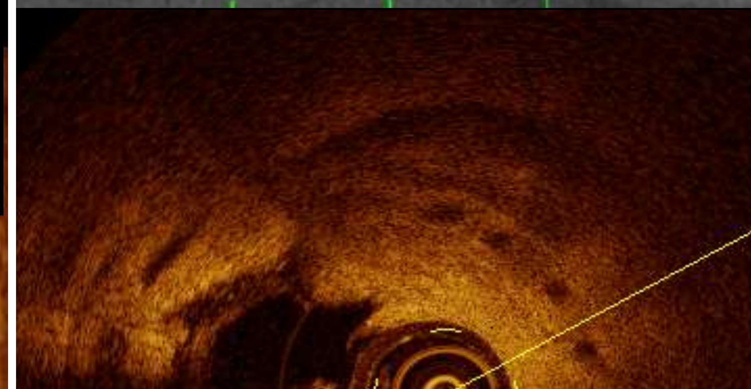


Depending on the position of landing zone Dmax changes, while interpolatedref diameter does not…

Case 1: suboptimal positioning

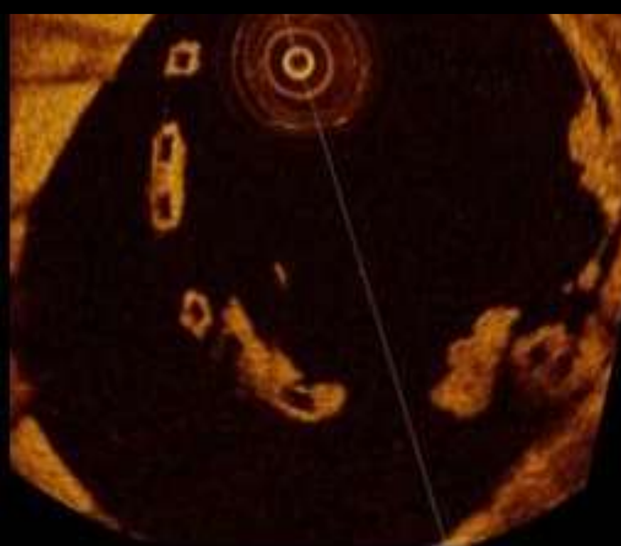






Dilemma: The vessel size is >4.0mm, while the device size is 3.0mm…The operator is aware of ISA, but considering the expansion limit of 3.5mm, the operator cannot correct malapposition by postdilatation.

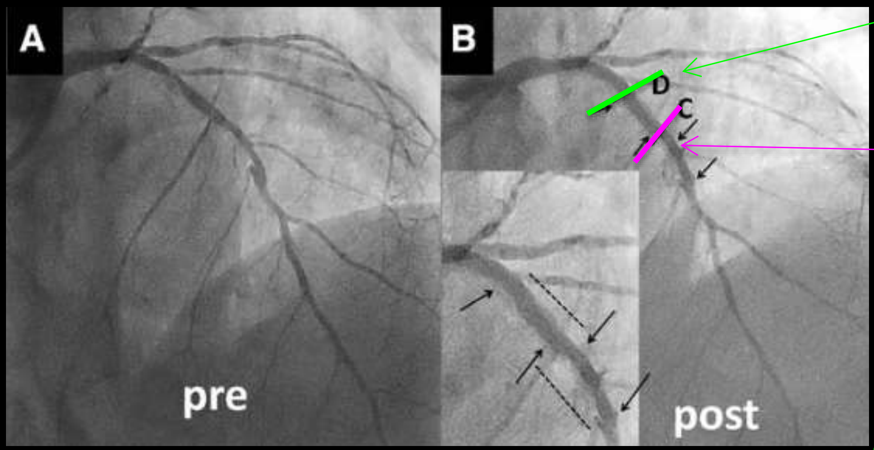
1Y

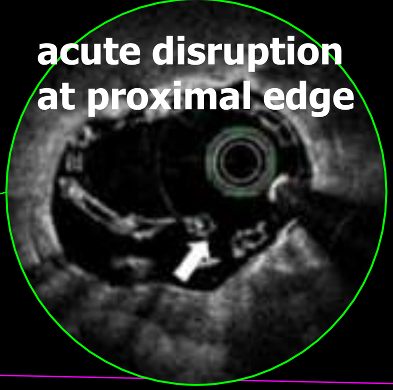


Preprocedural sizing and accurate positioning is important!

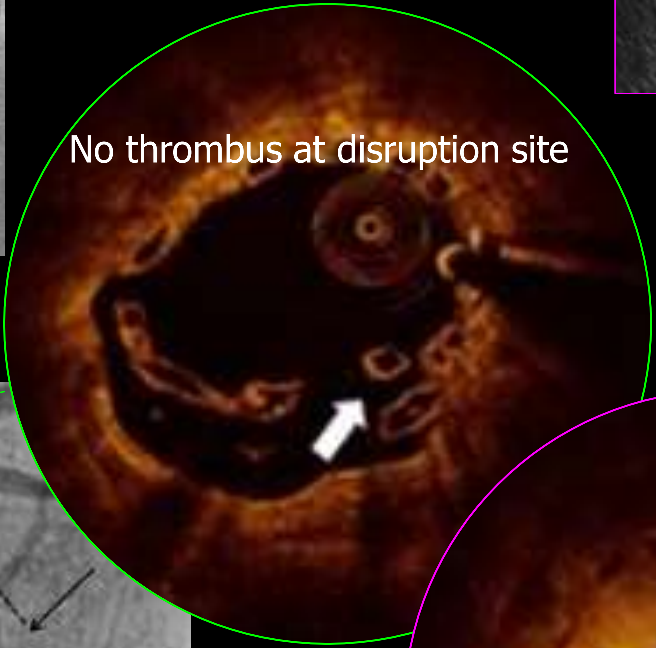
#2. Underexpansion and Late Thrombosis -161 days after implantation, 2 days after cessation of DAPT

Pre-procedure Post-procedure

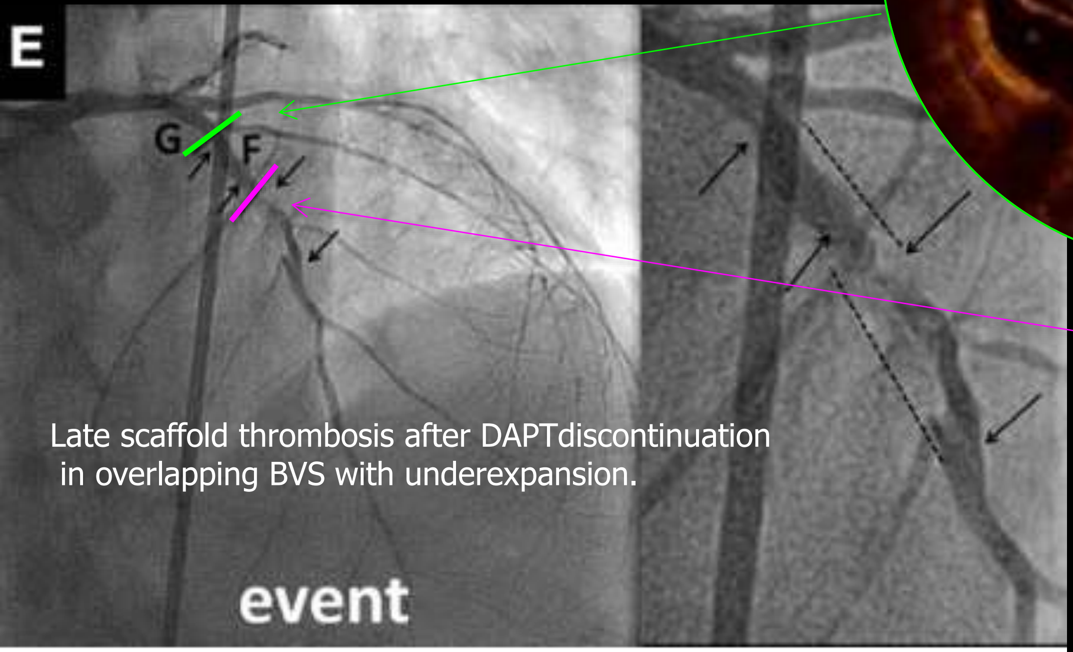




<u>underexpansion</u>
at mid scaffolded part (overlap)

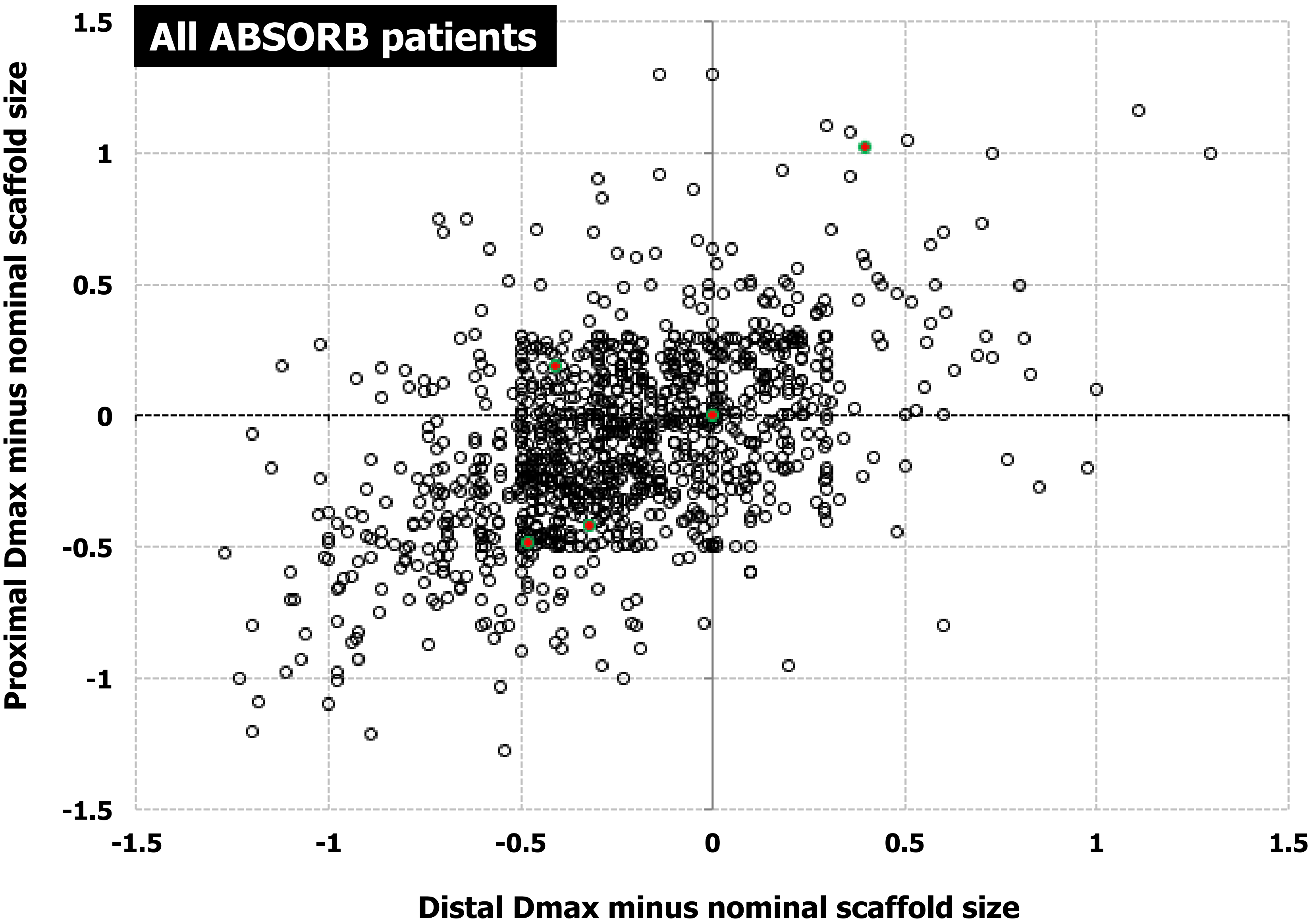


Scaffold thrombosis on 161 days



Karanasos A et al. Circ Cardiovasc Interv 2015;8.

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 in press

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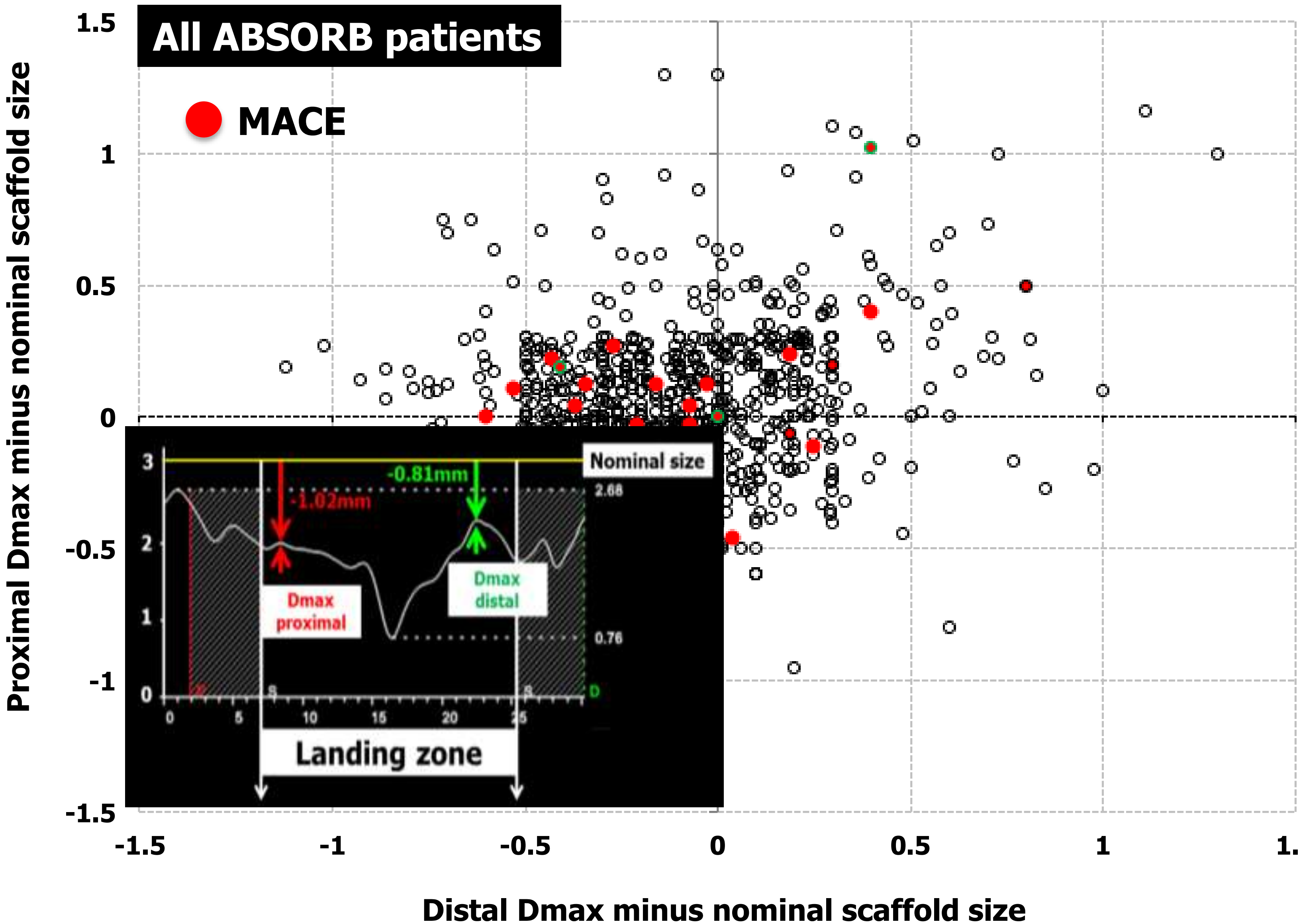

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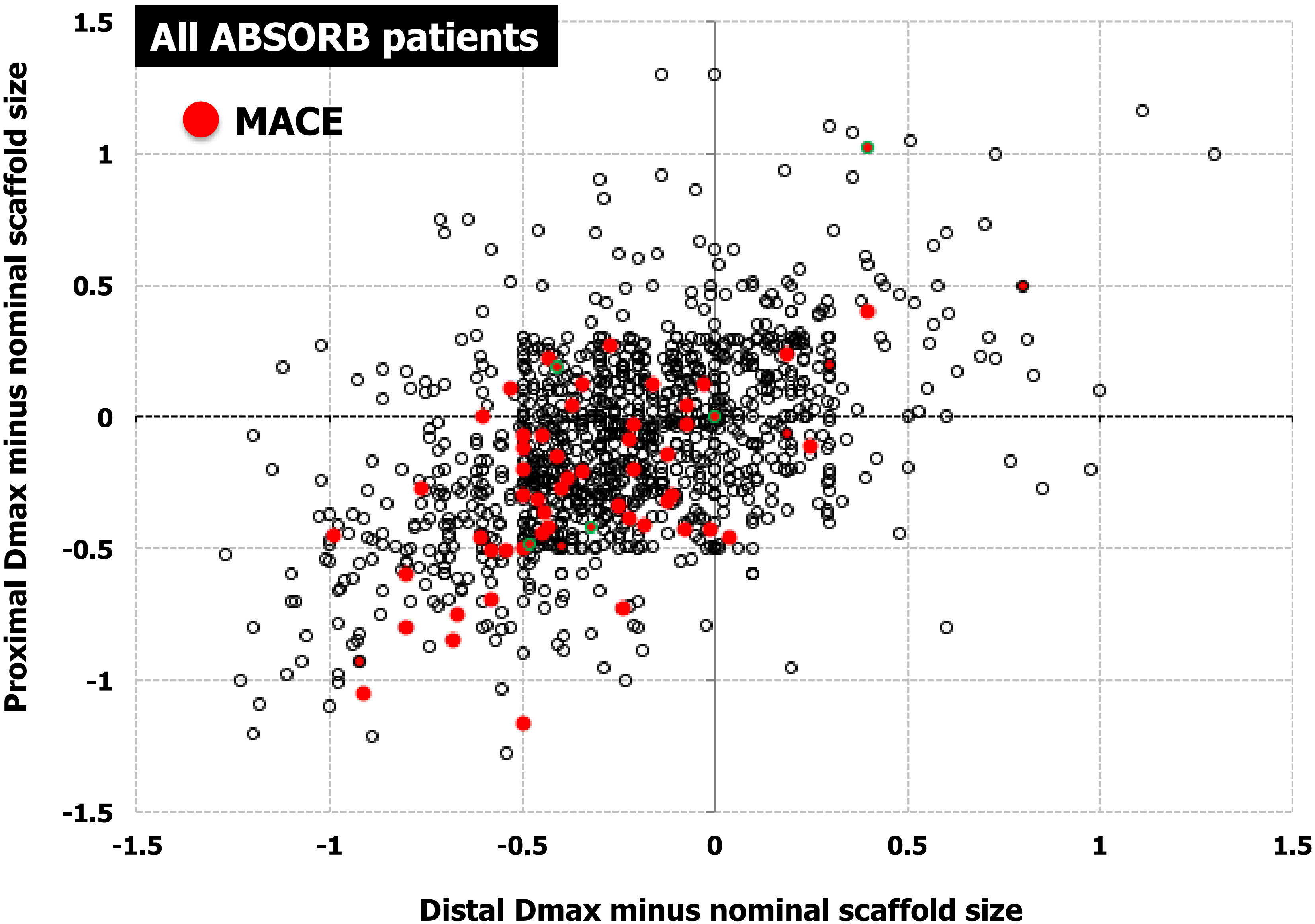

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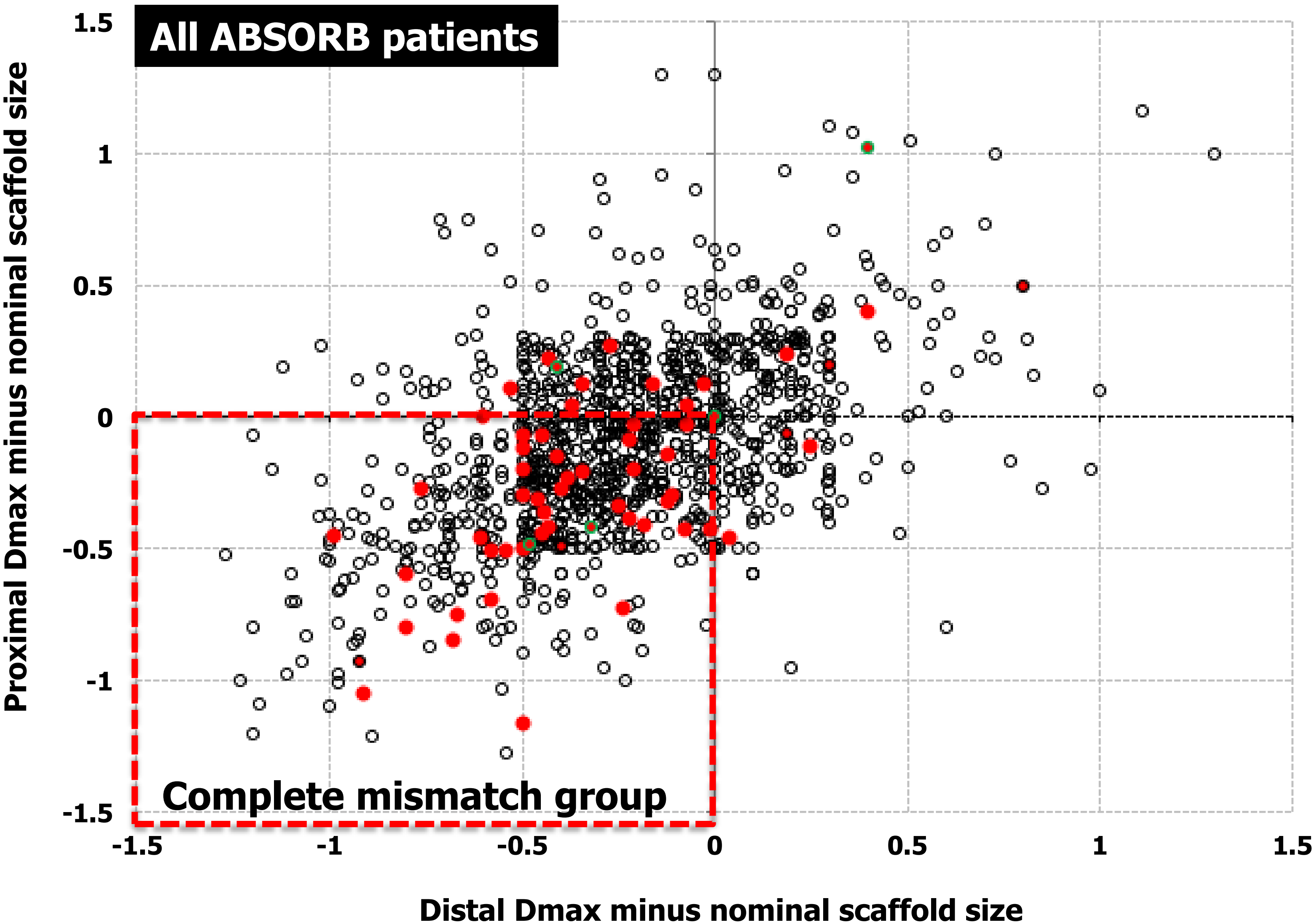

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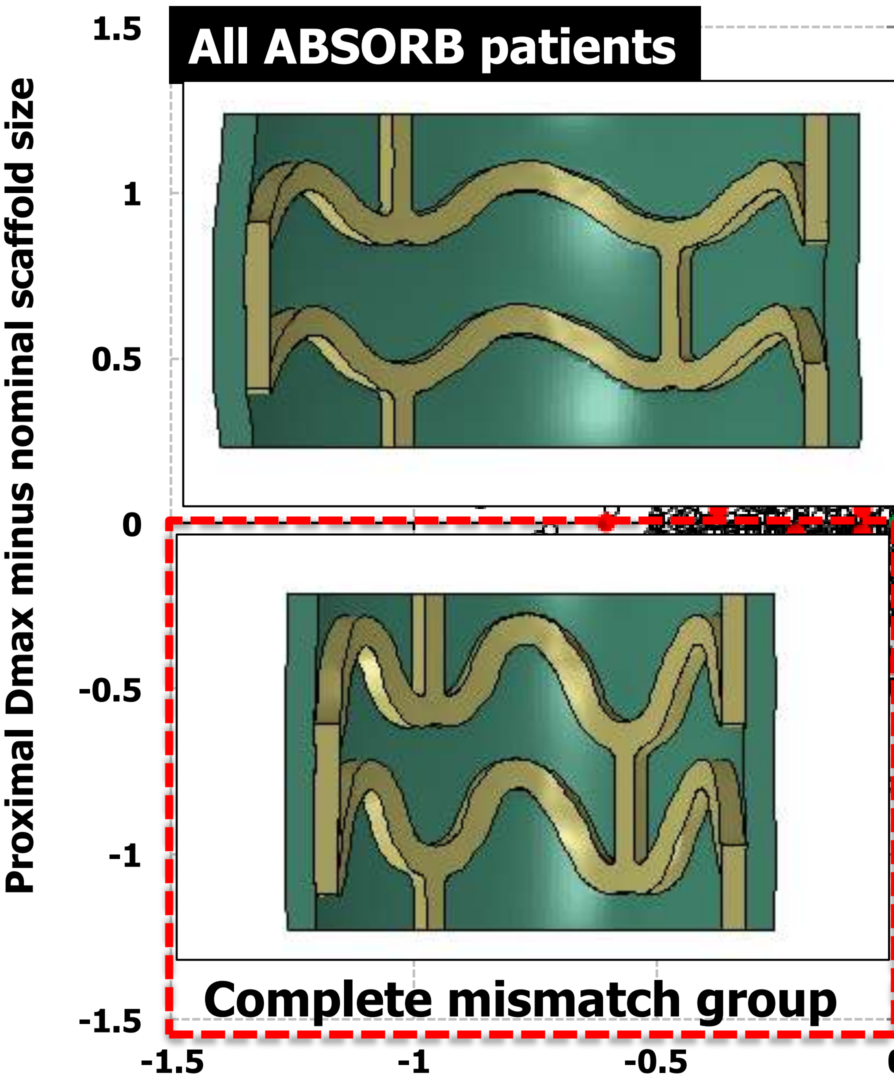
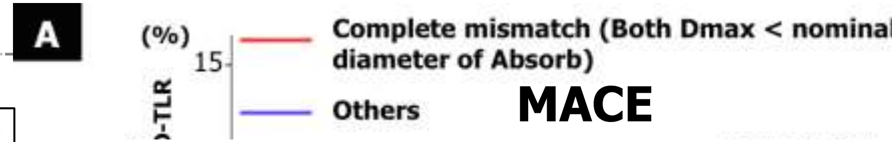
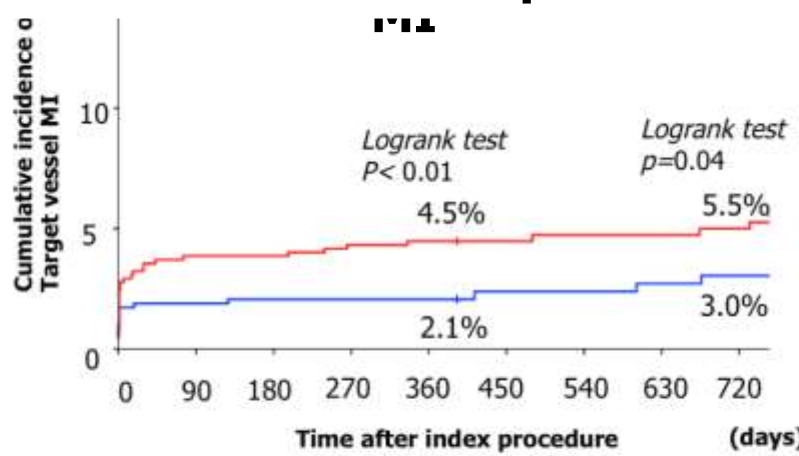




The implantation of a "large" Absorb scaffold in a relatively small vessel had a higher risk of MACE at 1year. The selection of nominal scaffold size below the diameter of both proximal and distal Dmax might lead to a denser polymer surface pattern, which could be associated with MI after procedure.



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

Ishibashi et al. JACC CI in press

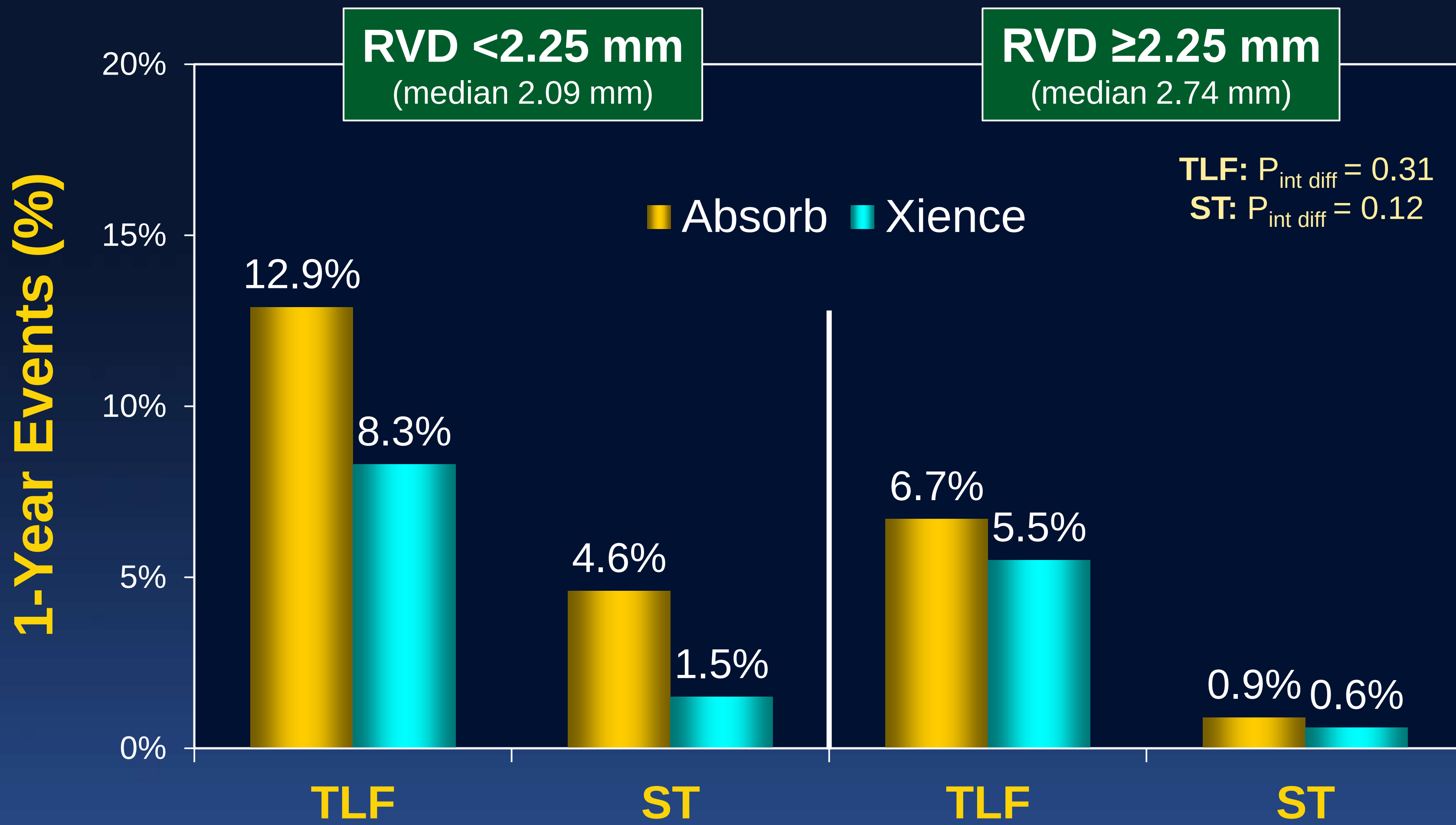
2.5 mm Device Only*

Target Lesion Failure

	Absorb N=285	**Xience** N=164	**Relative Risk** [95% CI]	**p-value**
TLF	8.5%	9.3%	0.91 [0.49, 1.69]	0.77
- Cardiac death	0.4%	0.6%	0.57 [0.04, 9.06]	1.00
- TV-MI	7.0%	6.8%	1.04 [0.51, 2.11]	0.92
- ID-TLR	4.2%	4.3%	0.98 [0.39, 2.43]	0.96

*As treated analysis

Outcomes by QCA RVD 2.25 mm



	TLF		ST		TLF		ST	
# Events:	31	11	11	2	71	30	9	3
# Risk:	241	133	238	133	1067	542	1058	540

Median based on pooled Absorb and Xience

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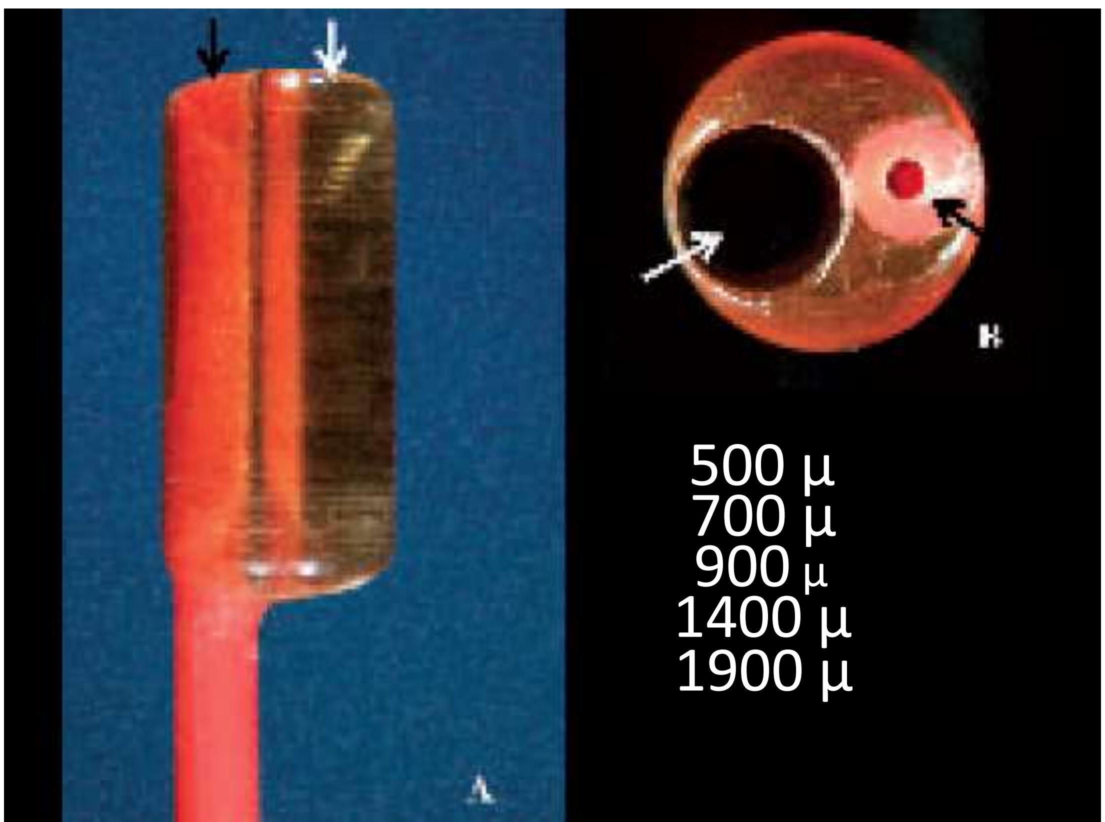
EuroIntervention

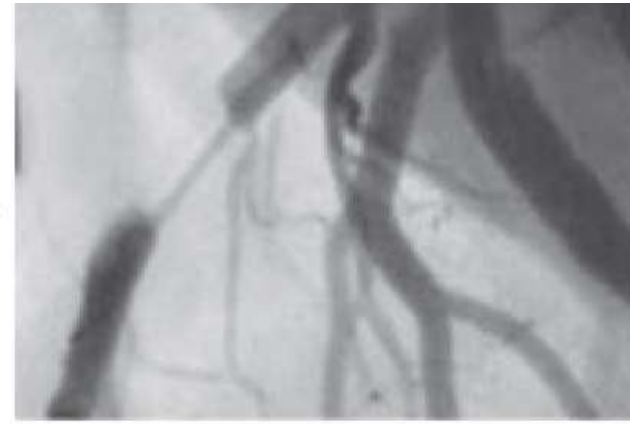
Pre implantation
In-vivo QCA vs. calibrated phantom vs. OCT ex vivo

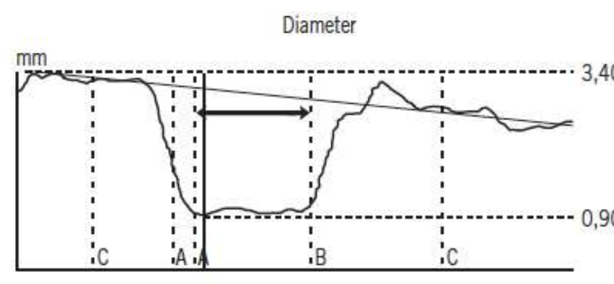
In vivo validation of a novel three-dimensional quantitative coronary angiography system (CardiOp-B™): comparison with a conventional two-dimensional system (CAAS II™) and with special reference to optical coherence tomography

Keiichi Tsuchida, MD, PhD; Willem J. van der Giessen, MD, PhD; Mark Patterson, MRCP; Shuzou Tanimoto, MD; Héctor M. García-García, MD, MSc; Evelyn Regar, MD, PhD; Jurgen M. R. Ligthart, BSc; Anne-Marie Maugenest; Gio Maatrijk; Jolanda J. Wentzel, PhD; Patrick W. Serruys*, MD, PhD, FACC, FESC

Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands







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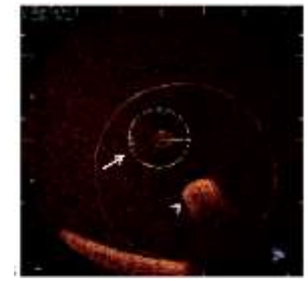
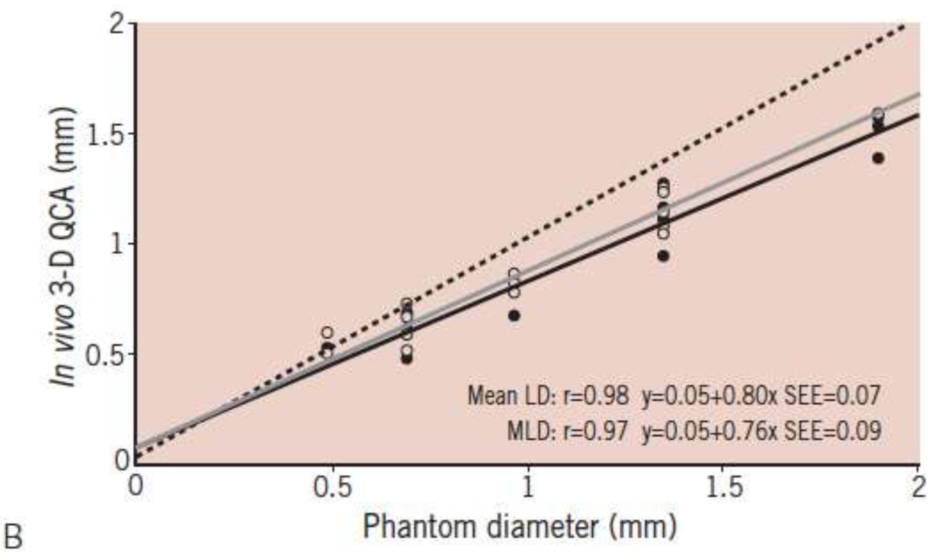
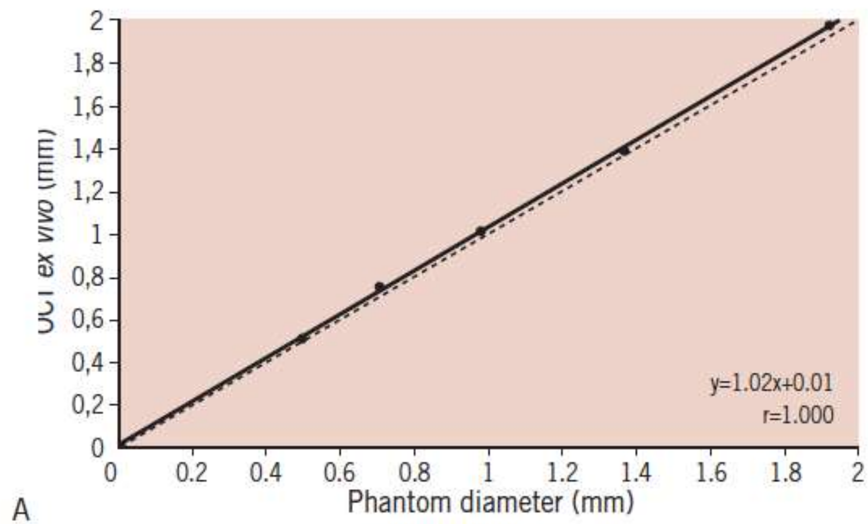
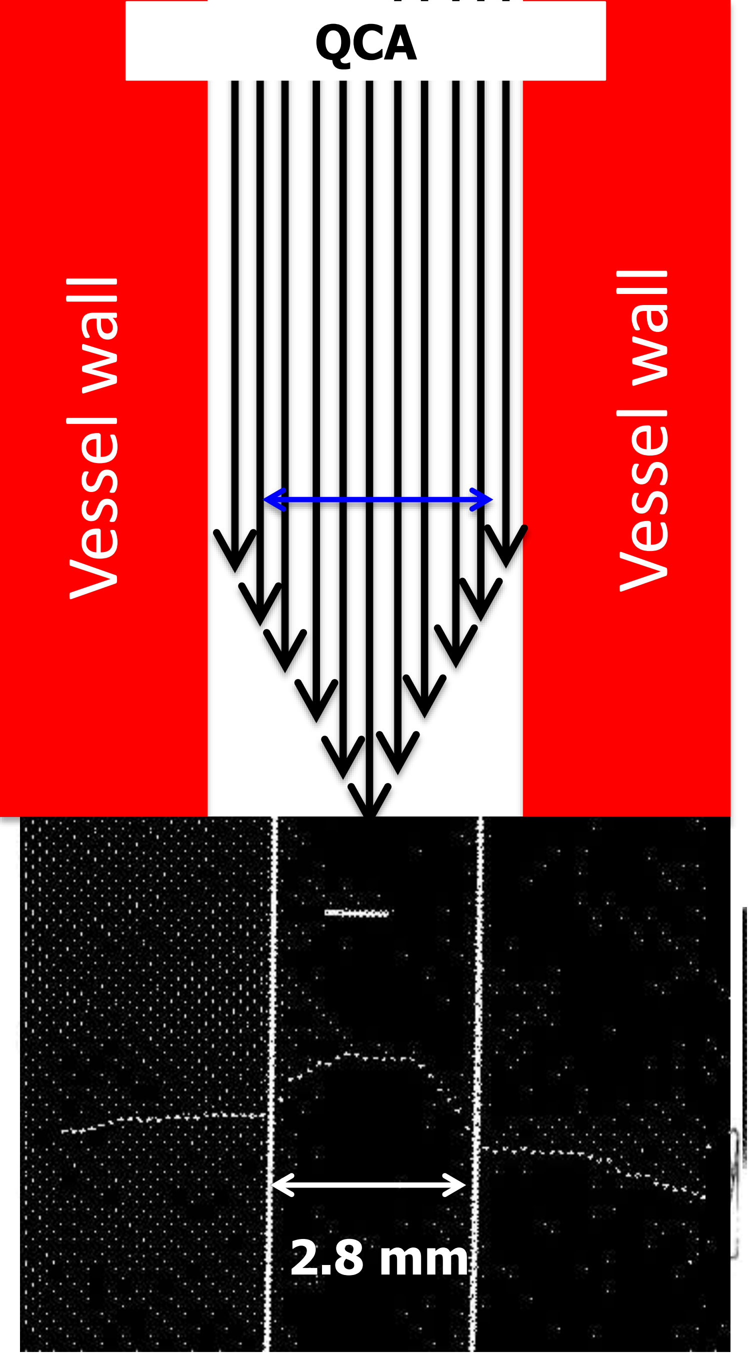


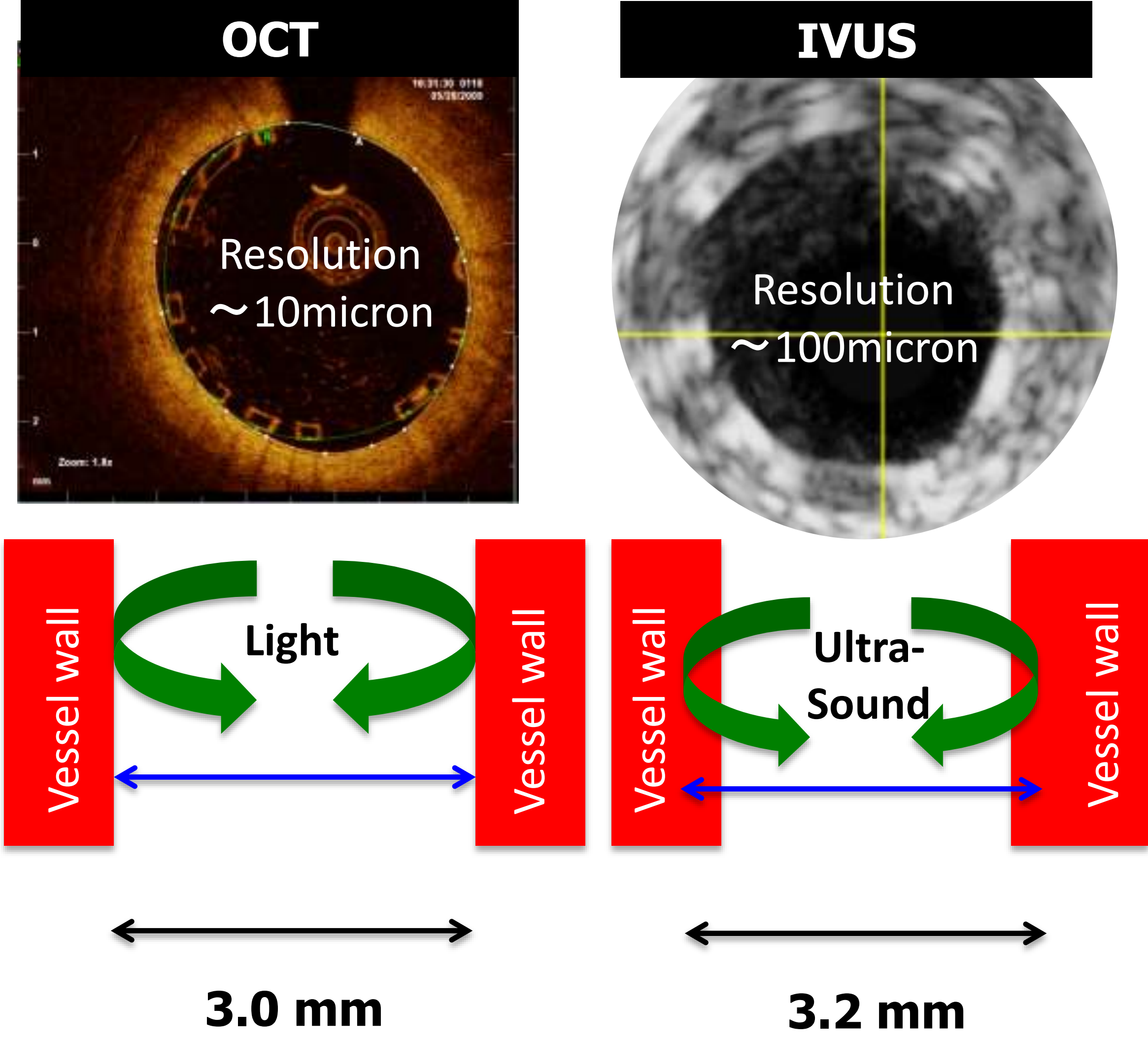
QCA underestimates the lumen dimension.



OCT provides the correct lumen dimension.







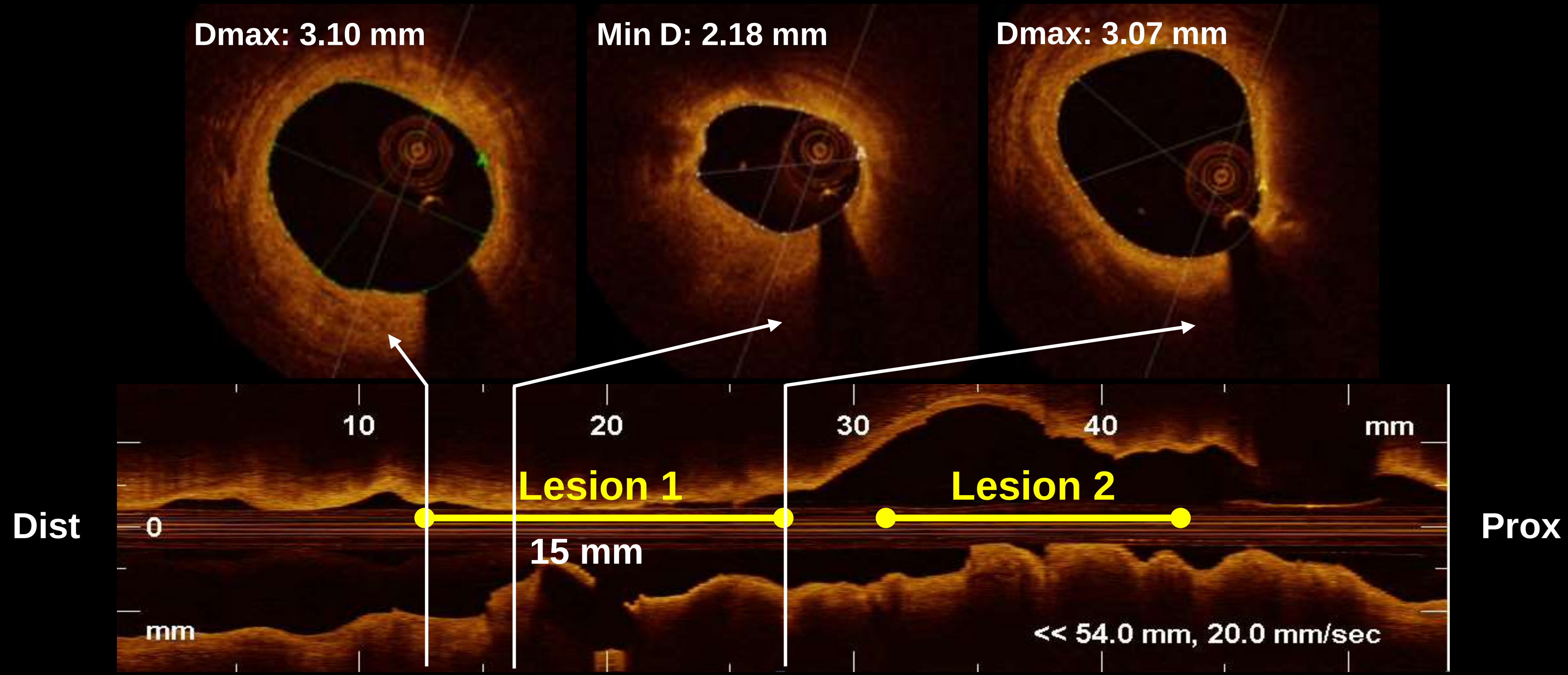
Pre-procedure

Area assessment

IVUS > OCT = real value > QCA

Preprocedural sizing: which modality to use

OCT-guided PCI



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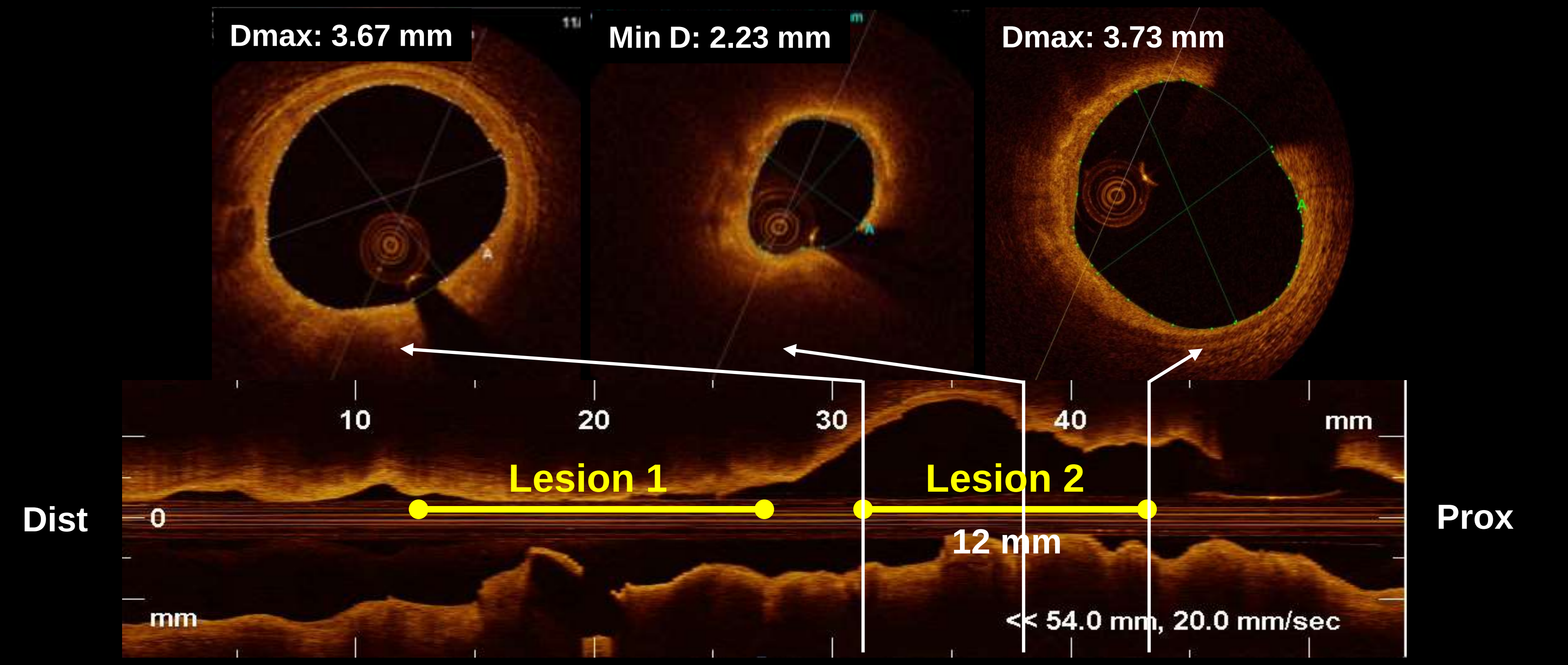

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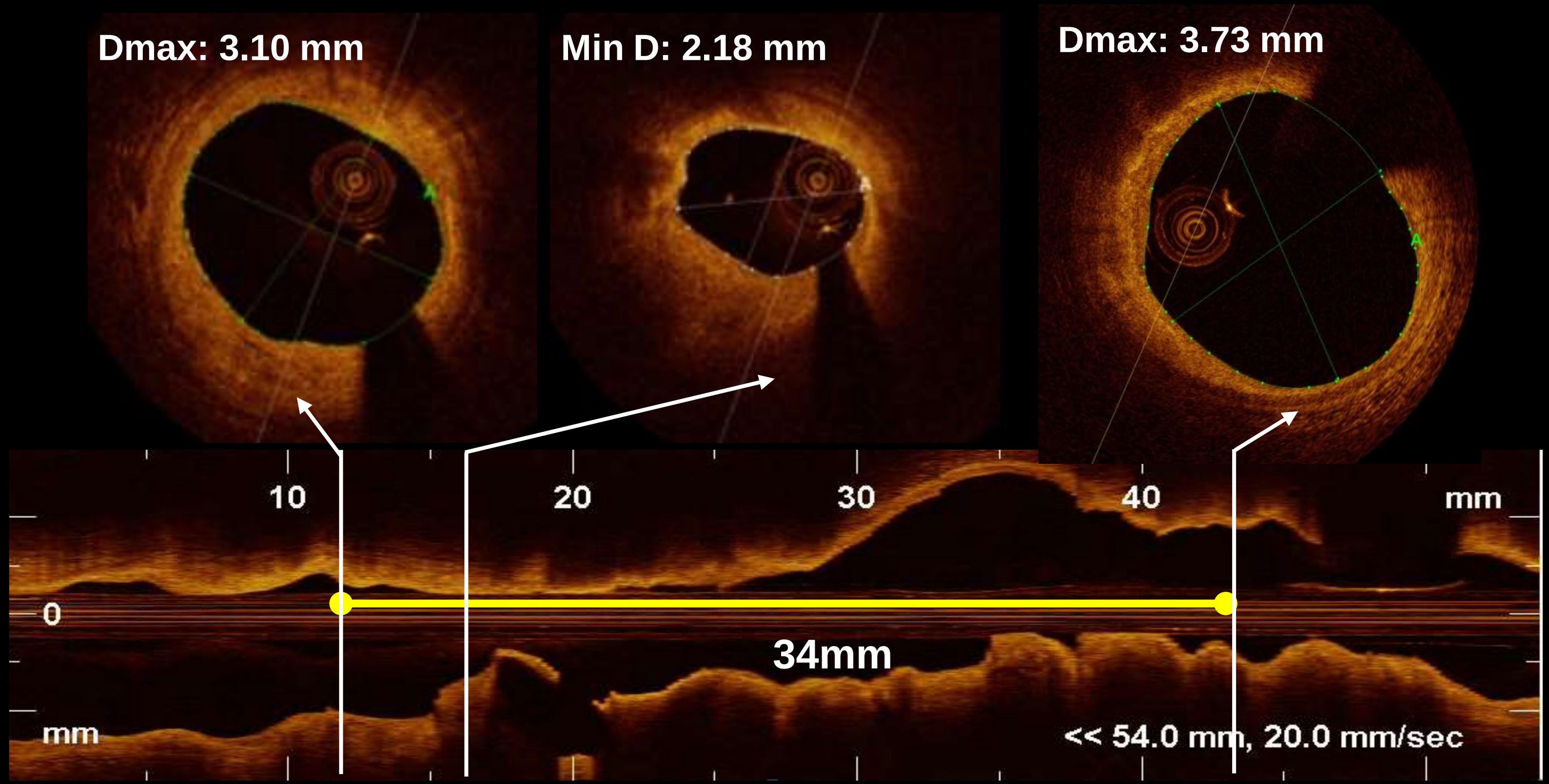
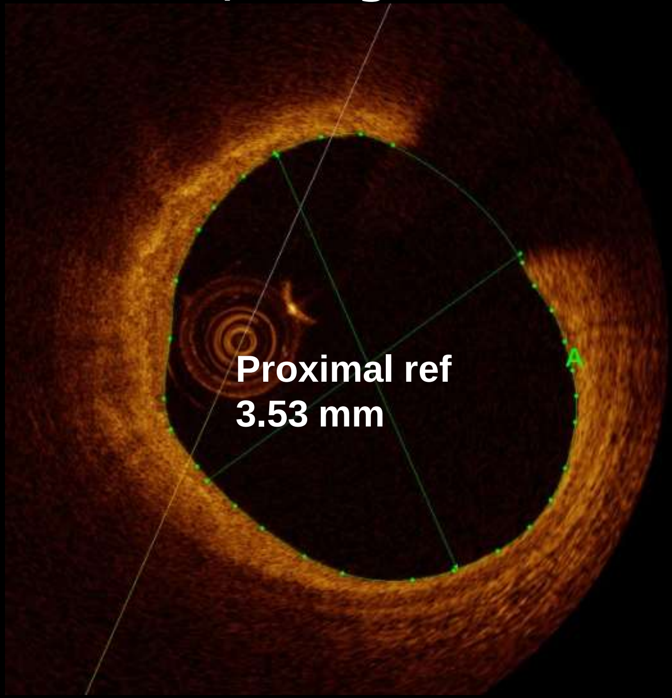


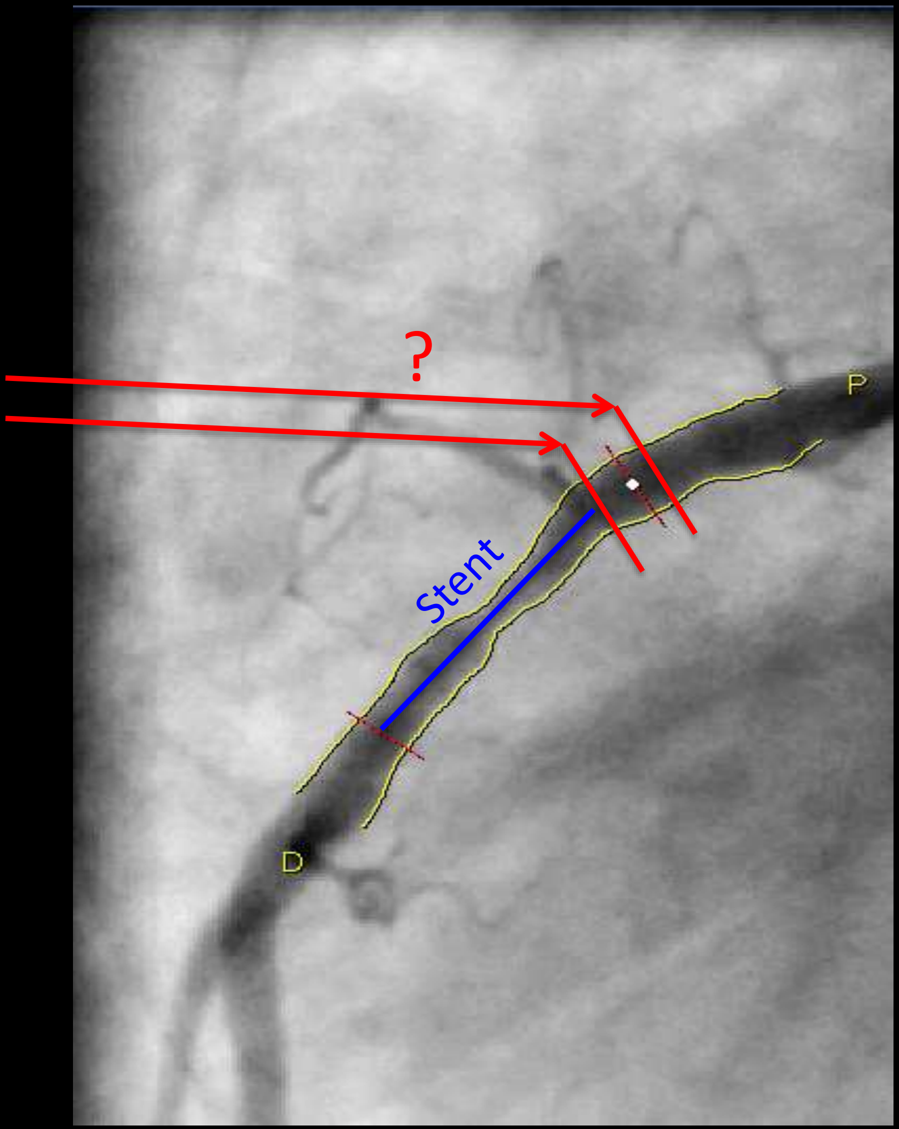
Scaffold/stent: 3.0x18 mm

Scaffold/stent: 3.5x18 mm

Preprocedural sizing: which modality to use

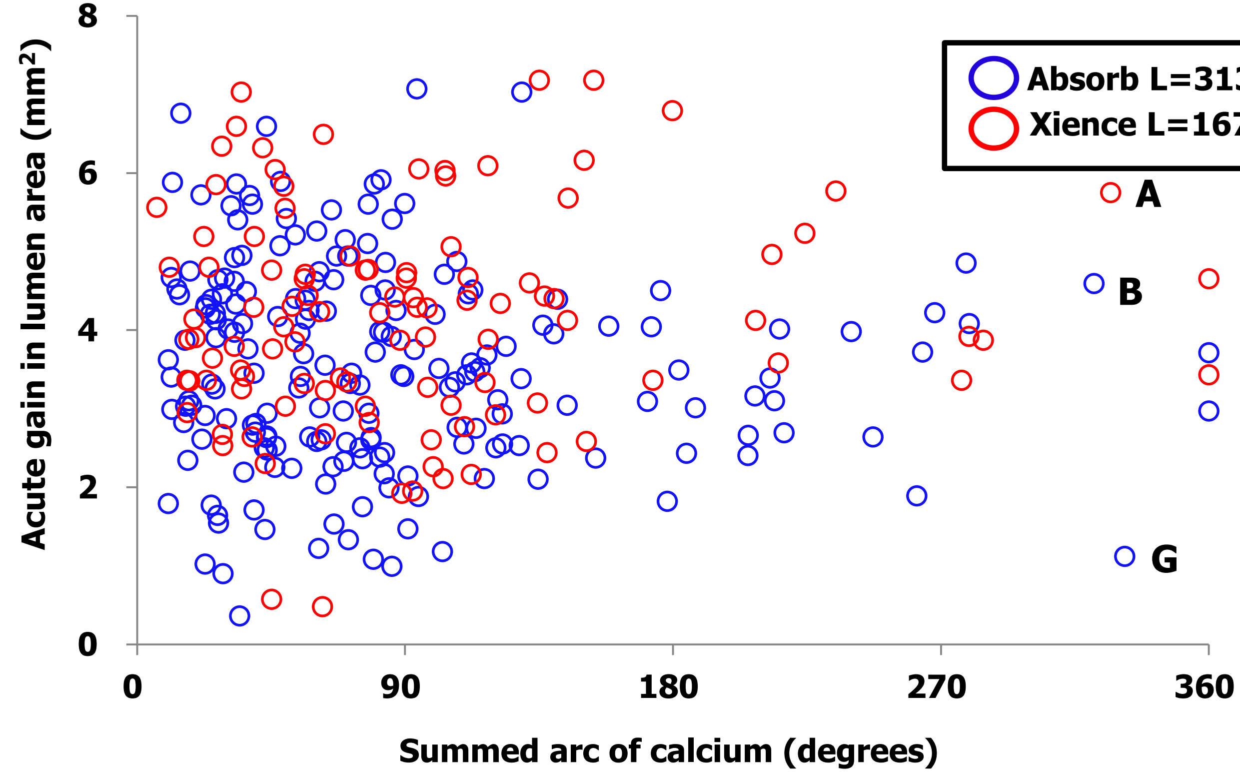
However, coregistration with OCT and Angiogram is necessary…

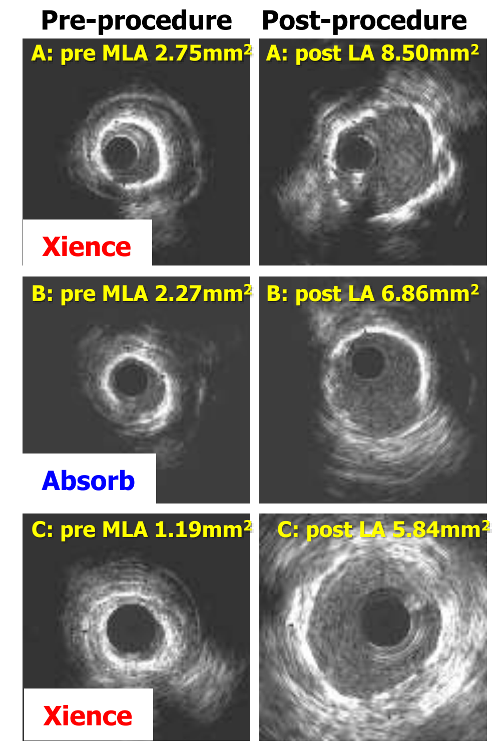


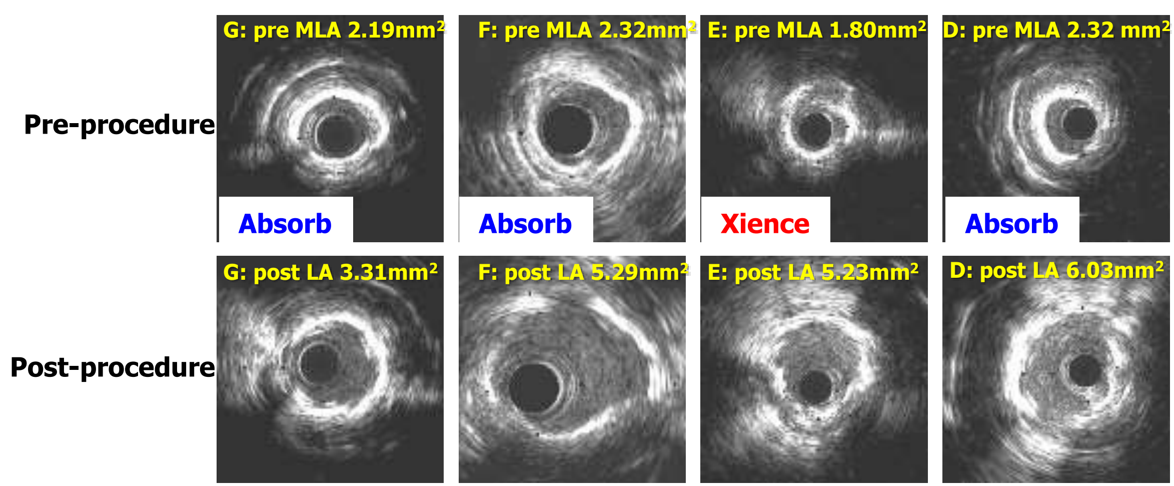


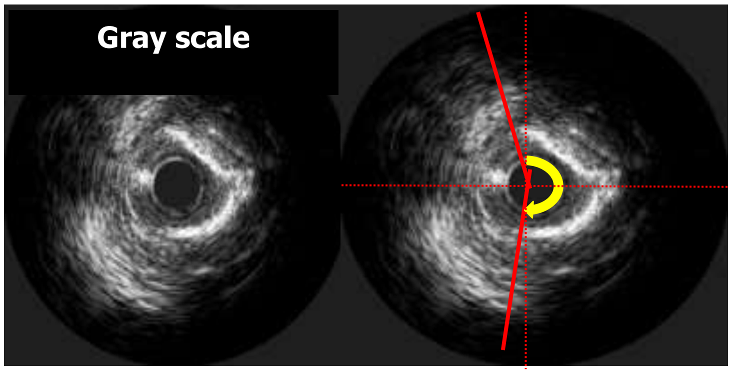
Coregitration is now possible on Console

In both arms acute gain was not affected by the circumferential distribution of calcium









Arc of calcium:
207.8° (3 quadrant)

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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

#1. Acute performance: OCT guidance might improve the performances…

ABSORB Biodegradable Stents Versus Second-Generation Metal Stents

A Comparison Study of 100 Complex Lesions Treated Under OCT Guidance

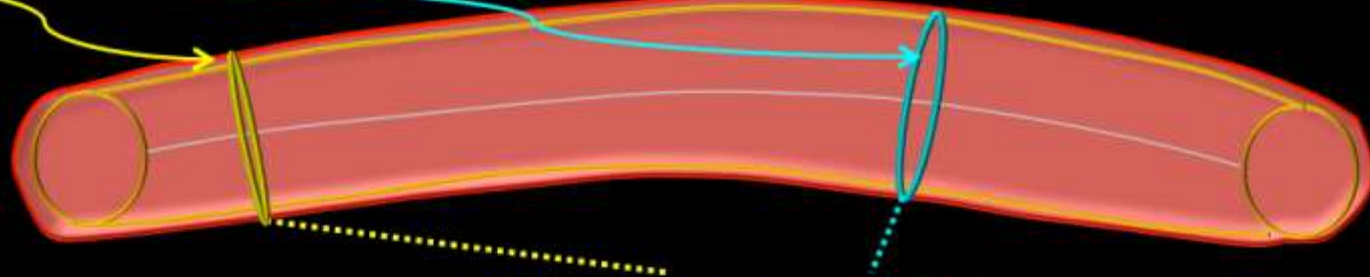
Mattesini et al. JACC 2014

Table 4. Optical Coherence Tomography Findings (N = 124)

	BVS (n = 63)		DES (n = 61)	p Value
Mean stent area, mm^2	7.3 (2.3)		7.5 (1.6)	0.51
Minimal stent area, mm^2	5.9 (1.9)	=	5.8 (1.5)	0.67
Mean lumen area, mm^2	7.2 (2.2)	=	7.4 (1.6)	0.40
Minimal lumen area, mm^2*	5.8 (1.9)		5.8 (1.5)	0.97
Median stent diameter, mm	2.9 (0.5)		3.1 (0.3)	0.33
Minimal stent diameter, mm	2.7 (0.4)		2.8 (0.5)	0.46
Maximal stent diameter, mm	3.2 (0.5)		3.3 (0.4)	0.52
Percentage RAS	20.2 (7.5)	=	21.7 (9.9)	0.32

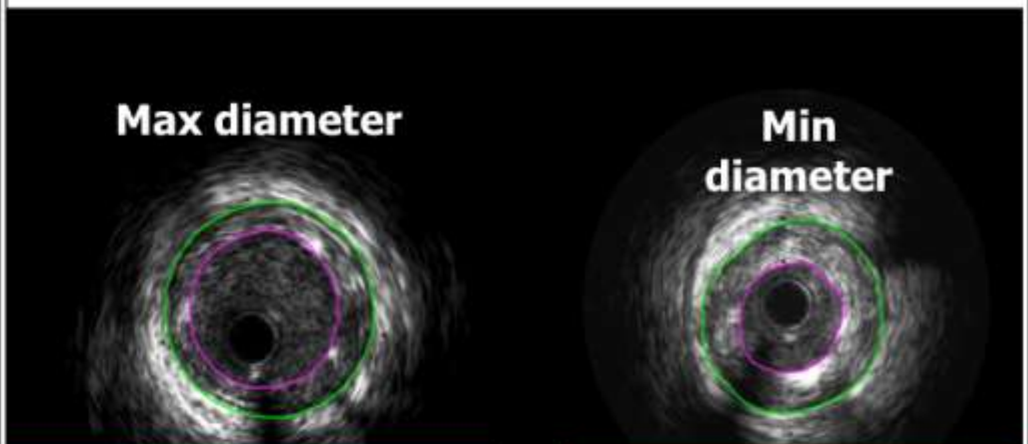
IVUS assessment for asymmetry/eccentricity

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

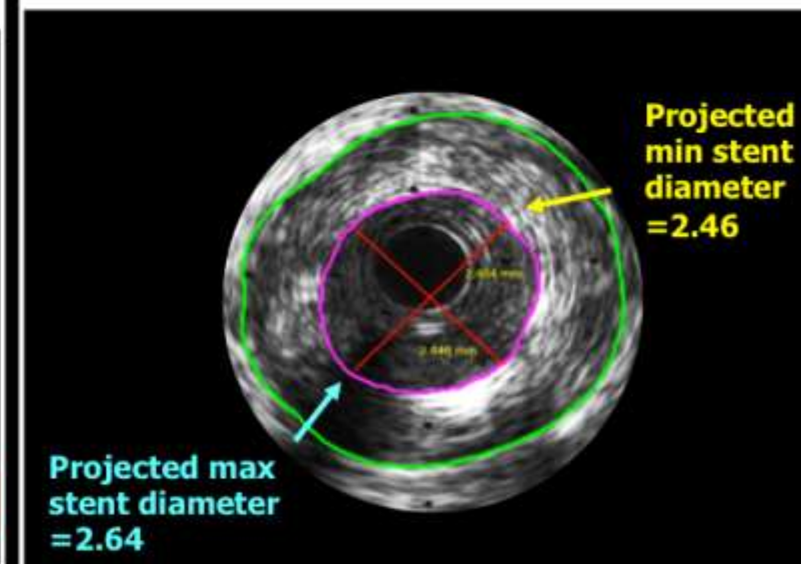


Cross sections of the device with the minimum and maximum diameter through the gravitational center of the lumen, showing different eccentricity indexes.

Asymmetry Index



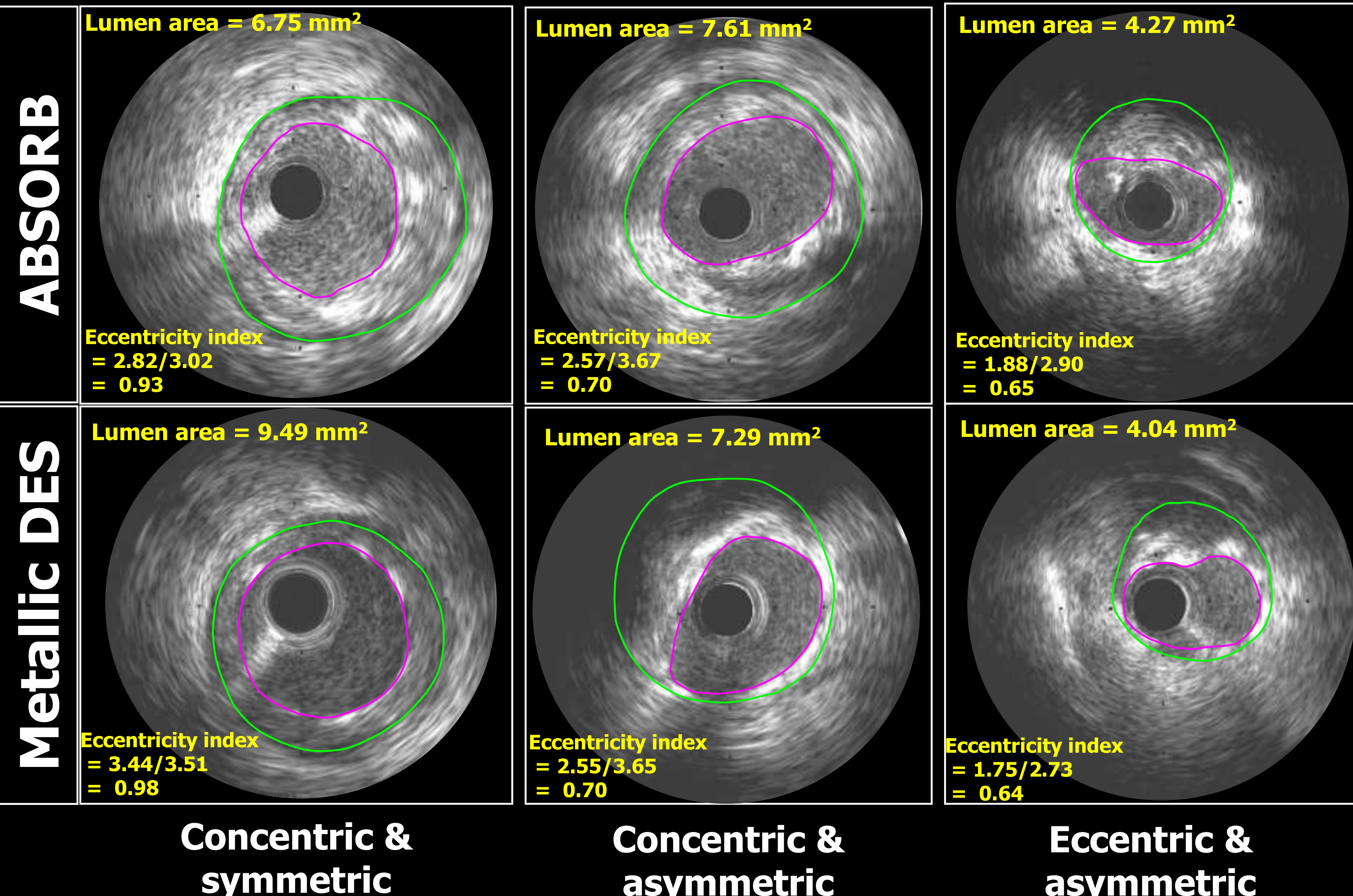
Eccentricity index (cross-section)



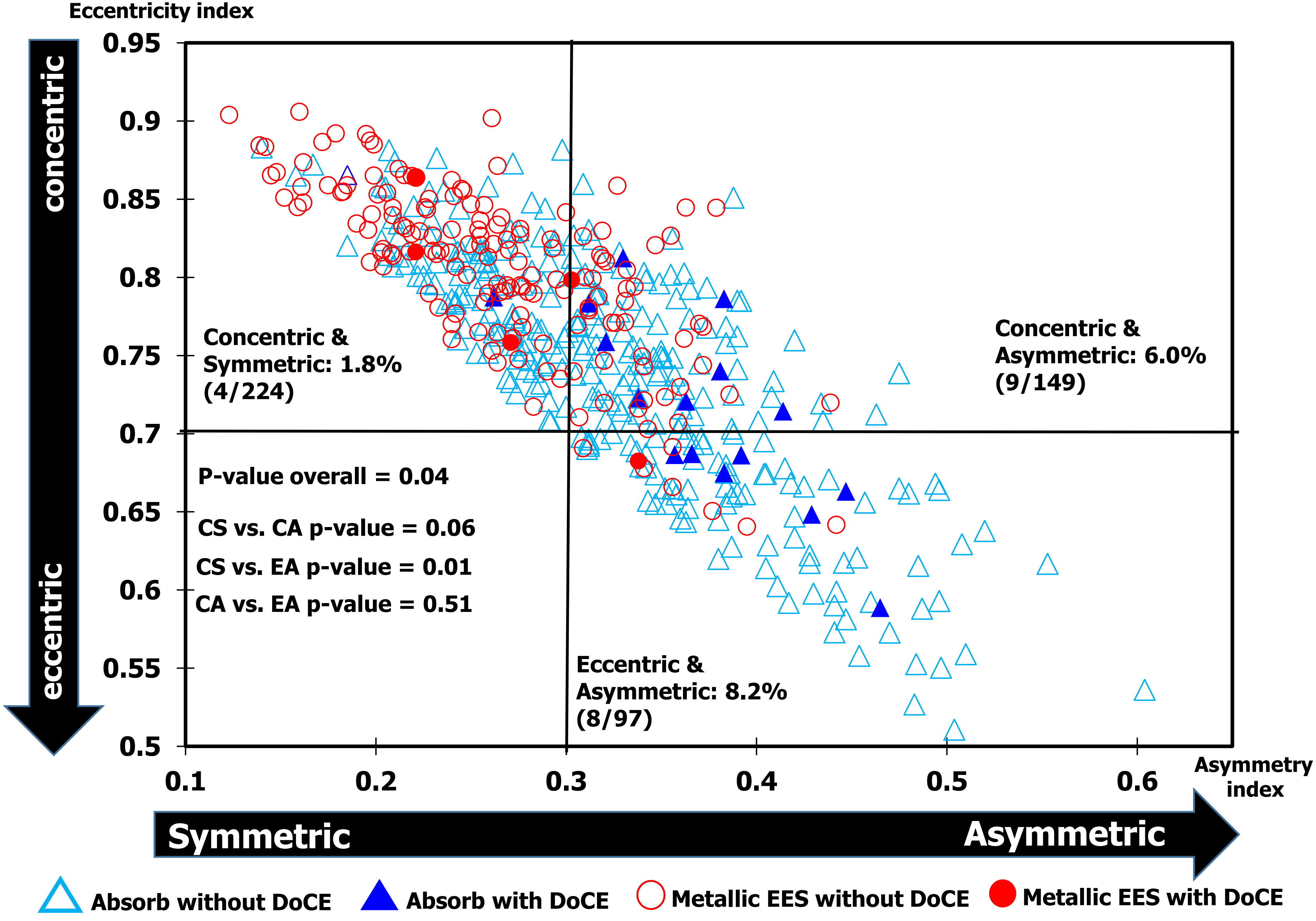
Symmetry index
= (3.37-2.52)/3.37 = 0.25

Eccentricity index
= 2.46/2.64 = 0.93

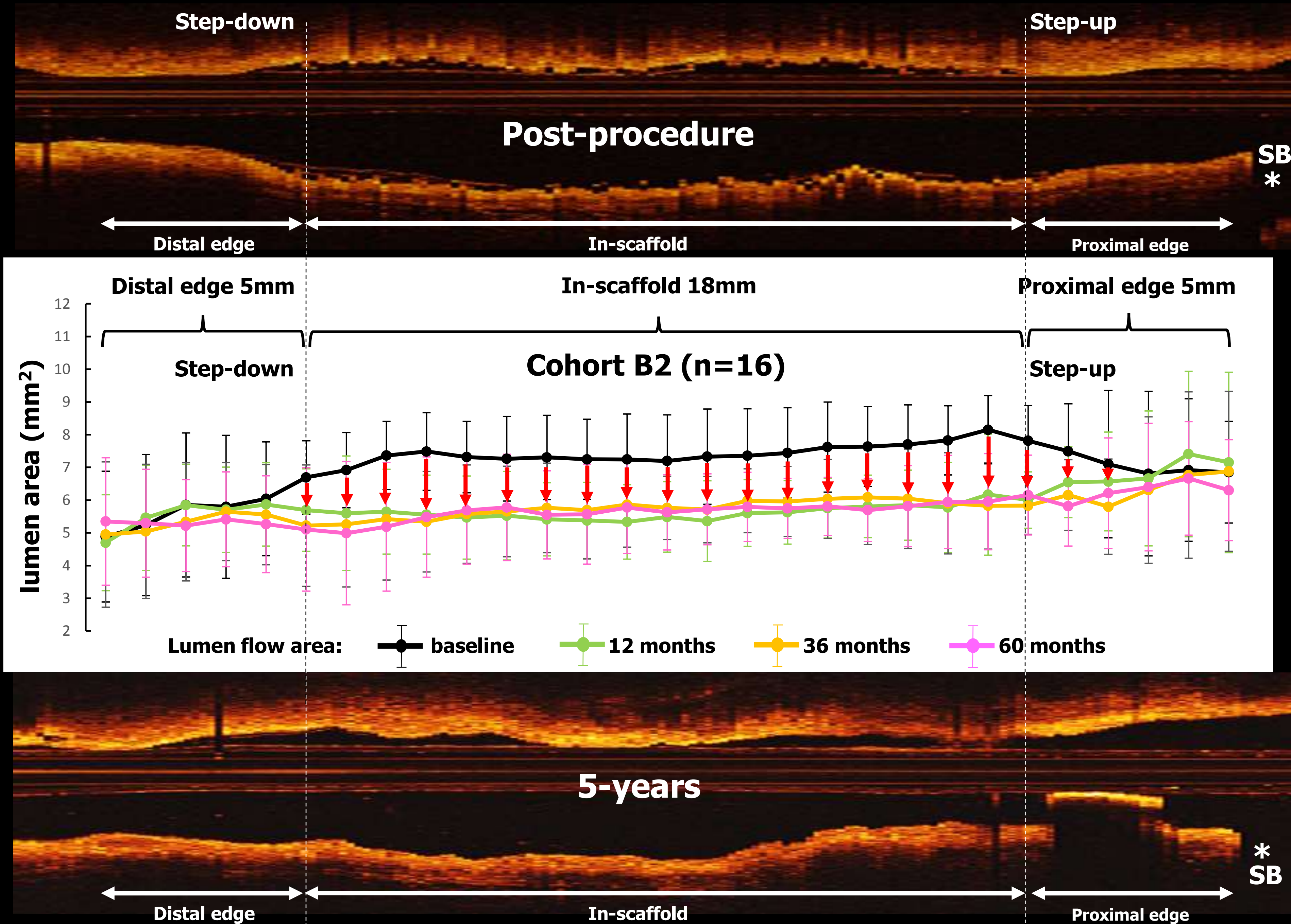
Geometrical morphologies post-implantation



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



Edge vascular response: truly serial (4 times) OCT assessment



Conclusion

- Considering the limited expansion capability of the polymeric scaffold and the risk of underexpansion, preprocedural sizing is of paramount importance.
- Be aware of difference in imaging modality:

  QCA< OCT = reality < IVUS
- Coregistration of intravascular imaging on angiography is useful to guide precise implantation based on IVUS/OCT.
- OCT is useful to optimize the acute expansion of scaffold.2nd postdilatation should be performed if optimal expansion is not achieved. Asymmetric expansion should be avoided.
- Initial step-up/step-down will be resolved in long term as the device resorbs.
- Clinical benefit of OCT guidance should be tested in prospective trial with predefined "criteria" of guidance .