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ABSORB in STEMI
TROFI II

April 26 2016 7:05-7:15 PM

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Disclosure Statement of Financial Interest

- PW Serruys is a member of the international advisory board of Abbott Vascular.
- Stephan Windecker receives research grants to the institution from Biotronik and St. Jude.
- All other PIs have no potential conflict of interest.

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Trial organization

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Sponsor: European Cardiovascular Research Institute (ECRI)
Grant givers: Abbott vascular, Terumo Corporation.

Background and study objective

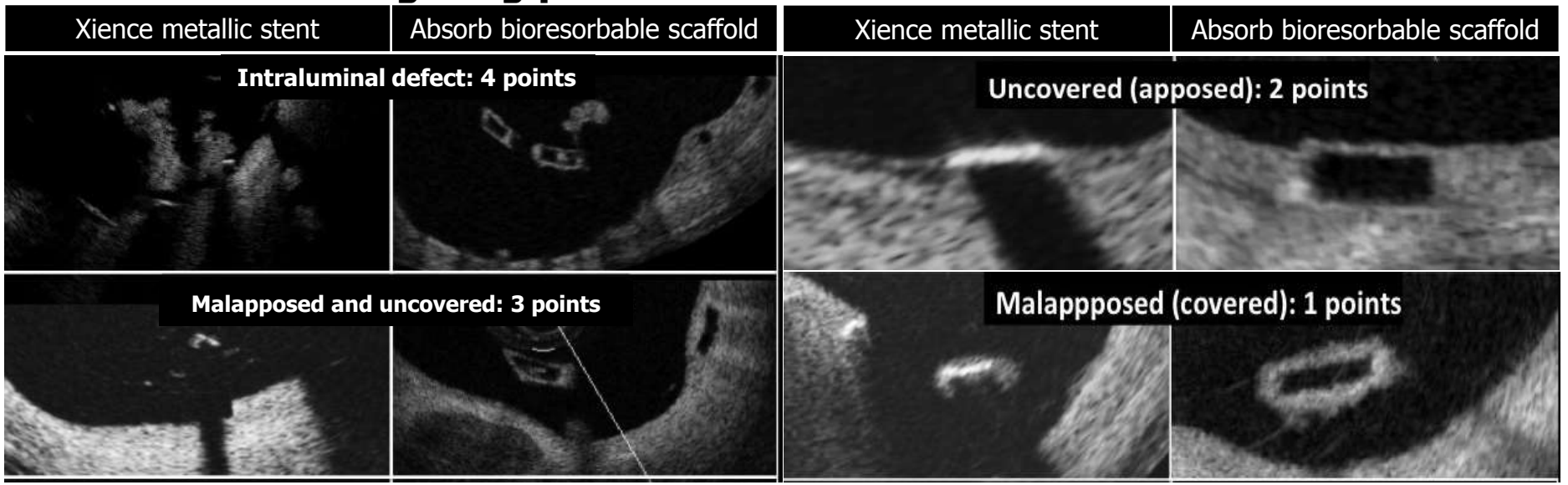
- No head-to-head comparison to assess the early phase of the arterial healing response to a bioresorbable scaffold (Absorb) implantation in patients with STEMI relative to the healing of Everolimus metallic DES (Xience).
- To compare the arterial healing response of these two technologies by optical frequency domain imaging (OFDI).

How to evaluate vessel healing after device implantation?

Healing score = [% ILDx4] + [% MUx3]+ [% Ux2]+ [% M]

ILD: intraluminal defect
MU: malapposed and uncovered
U: uncovered
M: malapposed

and their weighting points in the formula



Reference: TROFI trial *Eur Heart J.*2013;34:1050-1060; *Eur Heart J Cardiovasc Imaging.*. 2014;15:987-995
Leaders trial *Eur Heart J.* 2010;31:165-176; **Resolute all comers trial** *Eur Heart J*. 2011;32:2454-63
Absorb cohort B EuroIntervention 2015;10:1299-306; **NANO Plus** *AsiaIntervention* 2015; 1:57-70.

OCT Methodology: Strut Coverage at Follow-up

Metallic strut

Polymeric strut (Absorb)

Uncovered

< 30μm
(Thickness of reflective border)

Covered

Neointima

Neointima

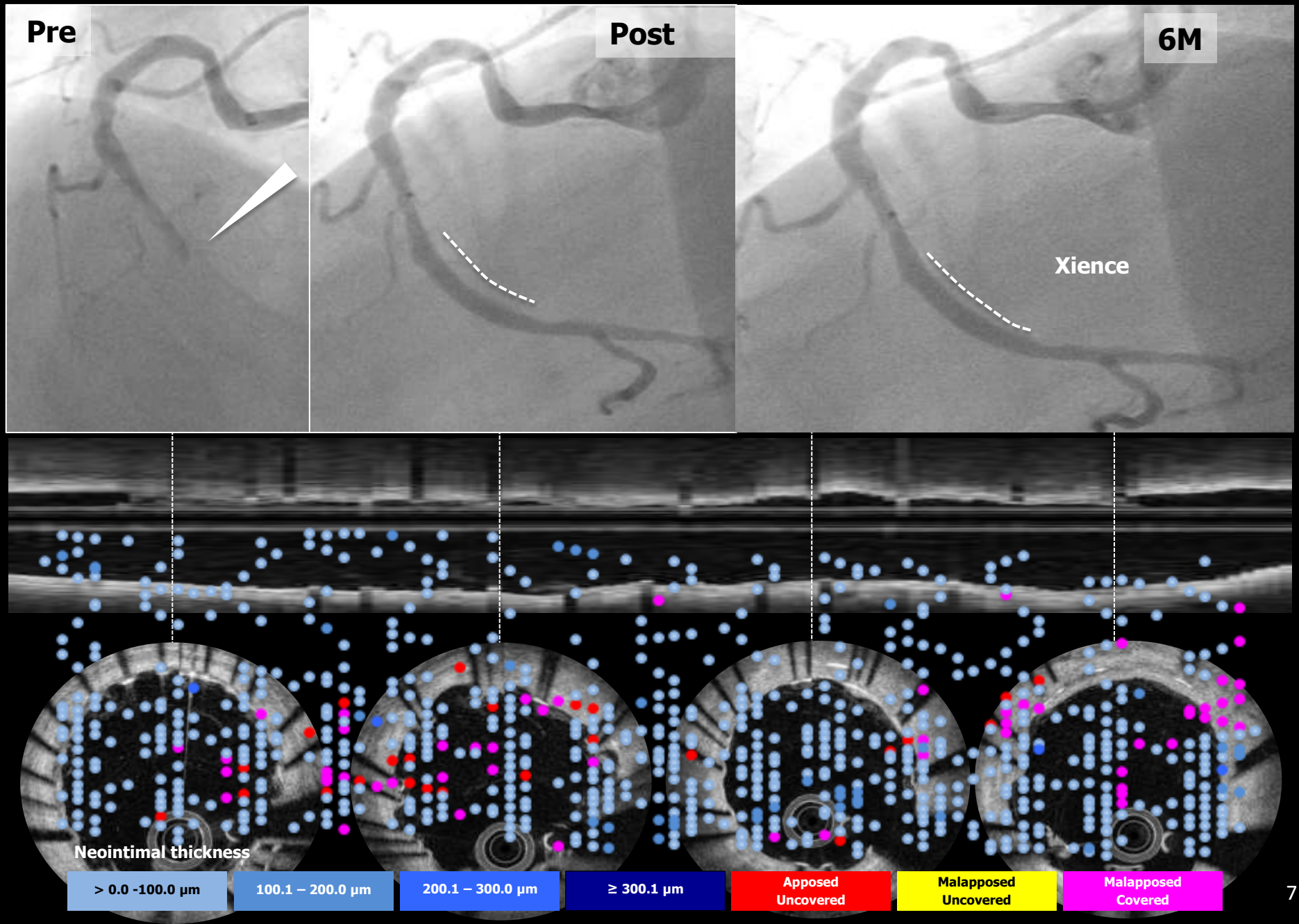
>30μm

Light Intensity analysis

Reflect

ear results of the ABSORB cohort B; Nakatani et al. Circ J. 2014; 3(...rventional 2015 [In press]

Xience: Healing Score 12.2



Study design

- A prospective, randomised study(1:1), active control, single-blind, non-inferiority trial, using web based software for randomisation in 8 European sites.

- 191 patients randomised in a 1 to 1 ratio.
  (ABSORB Arm: 95, XIENCE Arm: 96)

- Randomisation performed after establishment of at least TIMI 2 flow after thrombus aspiration and/or pre-dilatation.

- DAPT at least for 1 year after PCI

Sample size calculation

Non-inferiority Design for Primary Endpoint

- Assuming a mean neointimal healing score of 9.0 in the ABSORB BVS scaffold group (Cohort B1, stable patients)
- The healing score of the EES is anticipated to be similar as the one observed with the ABSORB BVS (cohort B1)
- A non-inferiority margin : 4.5 points
- A one-sided type I error rate : 0.05
- Power : 90%
- Attrition rate: 20%
- Assumed sample size: 190 patients

Inclusion & Exclusion criteria

- **Inclusion**

  -STEMI patients within the first 24 hours of symptoms and with the following ECG criteria:

  at least 1 mm in ≥ 2 standard leads or at least 2 mm in ≥ 2 contiguous precordial leads or a new LBBB

  -a vessel size ranging between 2.25 and 3.8 mm

- **Exclusion**

  - cardiogenic shock
  - severe tortuosity or calcification

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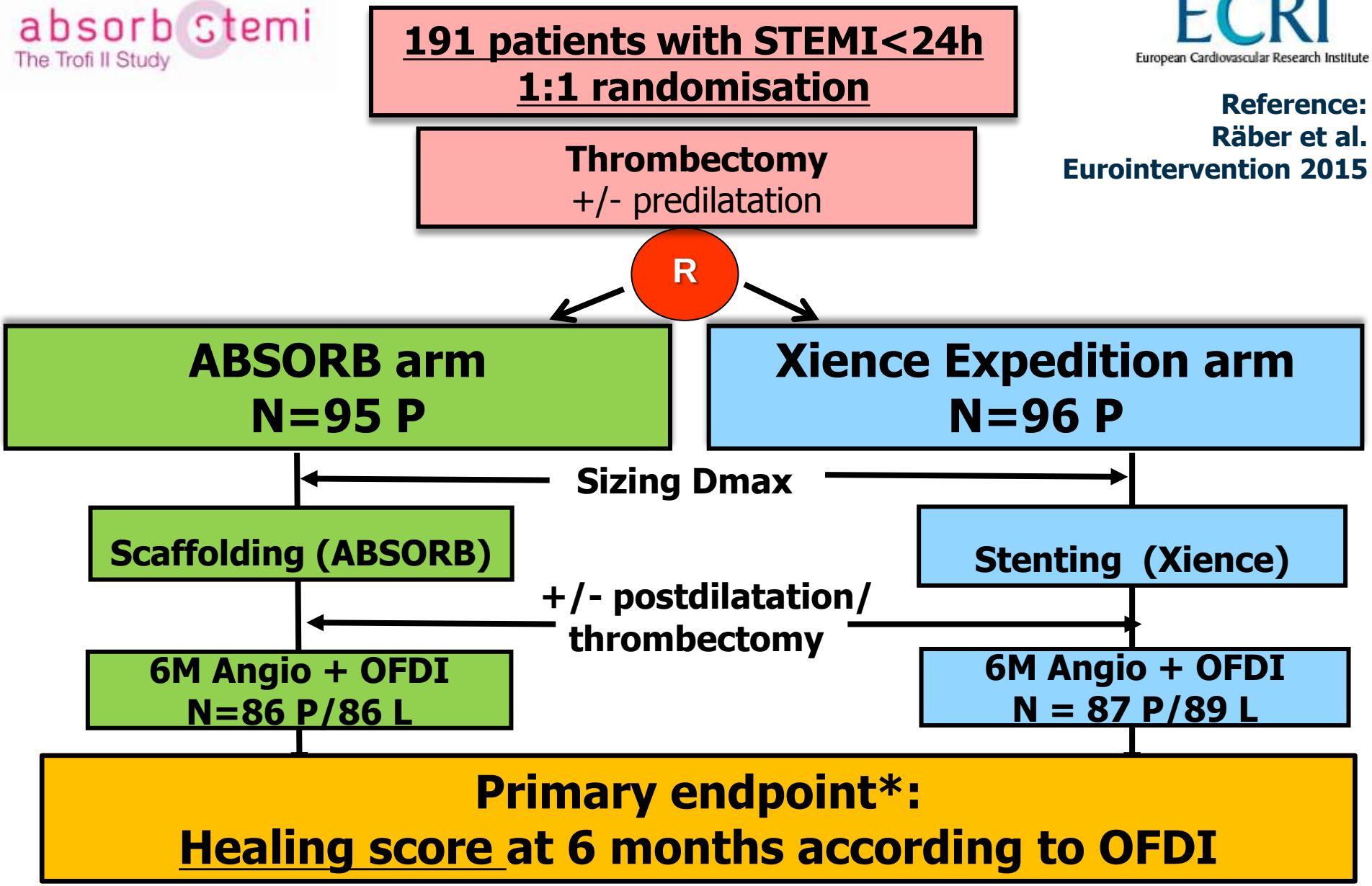
Reference:
Räber et al.
Eurointervention 2015



***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.

Baseline characteristics

Data present in mean±SD or percentage	Absorb N=95	EES N=96
Male	**76.8%**	**87.5**
Age, years	**59.1±10.7**	**58.2±9.6**
Current smoking	**48.4%**	**49.5%**
Previous smoking	**23.2%**	**23.2%**
Diabetes mellitus	**18.9%**	**14.7%**
Hypertension	**44.1%**	**36.5%**
Hypercholesterolemia	**63.8%**	**57.3%**
Previous MI	**2.1%**	**3.1%**
Previous PCI	**4.2%**	**3.1%**
COPD	**3.2%**	**3.1%**
Killip Class I	**94.7%**	**96.9%**

Lesions characteristics

Data present in percentage	Absorb N=95	EES N=98
Infarct related target lesions:		
RCA	46.3%	44.9%
LAD	35.8%	41.8%
LCX	17.9%	13.3%
Grade of perfusion (TIMI):		
TIMI 0	63.2%	62.9%
TIMI 1	3.2%	3.1%
TIMI 2	8.4%	13.4%
TIMI 3	25.3%	20.6%

Medication

Data present in percentage	Absorb N=95	EES N=98
Medication before procedure		
ASA loading	100%	100%
Ticagrelor	44.2%	42.7%
Clopidogrel	37.9%	30.2%
Prasugrel	18.9%	27.1%
Medication during procedure		
Heparin and GP IIb/IIIa	38.9%	36.5%
Heparin only	32.6%	38.5%
Heparin and Bivalirudin	18.9%	13.5%
Bivalirudin only	7.4%	9.4%
GP IIb/IIIa only	1.1%	2.1%

No statistical differences between the two arms.

Procedural details

Data present in mean±SD or (%)	Absorb N=95	EES N=98	P-value
Successful thrombectomy	81.1%	73.5%	0.19
Direct stenting	44.2%	49.0%	0.51
Number of study devices	1.2±0.4	1.1±0.4	0.54
Devices maximum pressure, atm	14.1±3.8	13.3±3.0	0.27
Nominal length of scaffold/stent	20.6±5.8	20.7±6.7	0.86
Nominal diameter of scaffold/stent	**3.25±0.30**	**3.12±0.37**	**0.005**
Post-dilatation performed	**50.5%**	**25.5%**	**<0.001**
Diameter of postdilatation balloon, mm	3.51±0.34	3.29±0.62	0.11
Postdilatation max pressure, atm	**15.8±3.4**	**18.6±3.9**	**0.002**
Post-procedural TIMI 3 flow	98.0%	100.0%	0.50
Device success (%DS ≤ 30%, QCA core lab)	95.8%	100.0%	0.057

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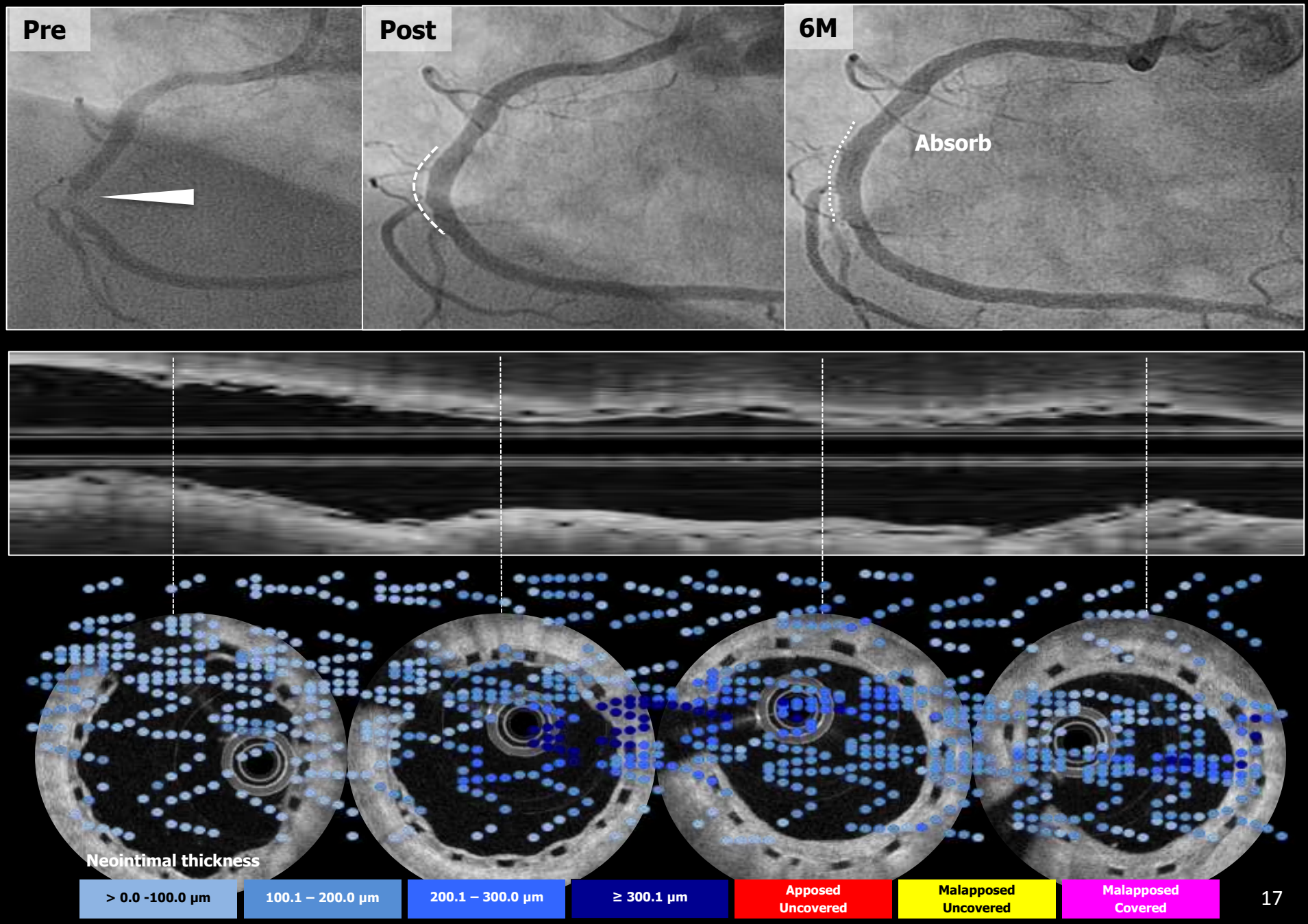
Quantitative coronary angiography

Data present in mean±SD	Absorb N=94*	EES N=98	P-value
Preprocedure			
Lesion length, mm	12.88±6.94	13.41±7.40	0.53
Reference diameter, mm	2.86±0.48	2.76±0.51	0.91
MLD, mm	0.29±0.43	0.28±0.43	0.84
%DS	89.5±15.1	89.9±15.4	0.86
Postprocedure			
Device length, mm	21.41±9.86	21.16±9.77	0.86
In-device reference diameter, mm	2.88±0.40	2.85±0.47	0.73
In-device MLD, mm	**2.46±0.33**	**2.46±0.40**	**0.94**
In-device %DS	**14.1±6.8**	**13.4±5.5**	**0.43**
In-device acute gain, mm	**2.16±0.52**	**2.21±0.56**	**0.57**

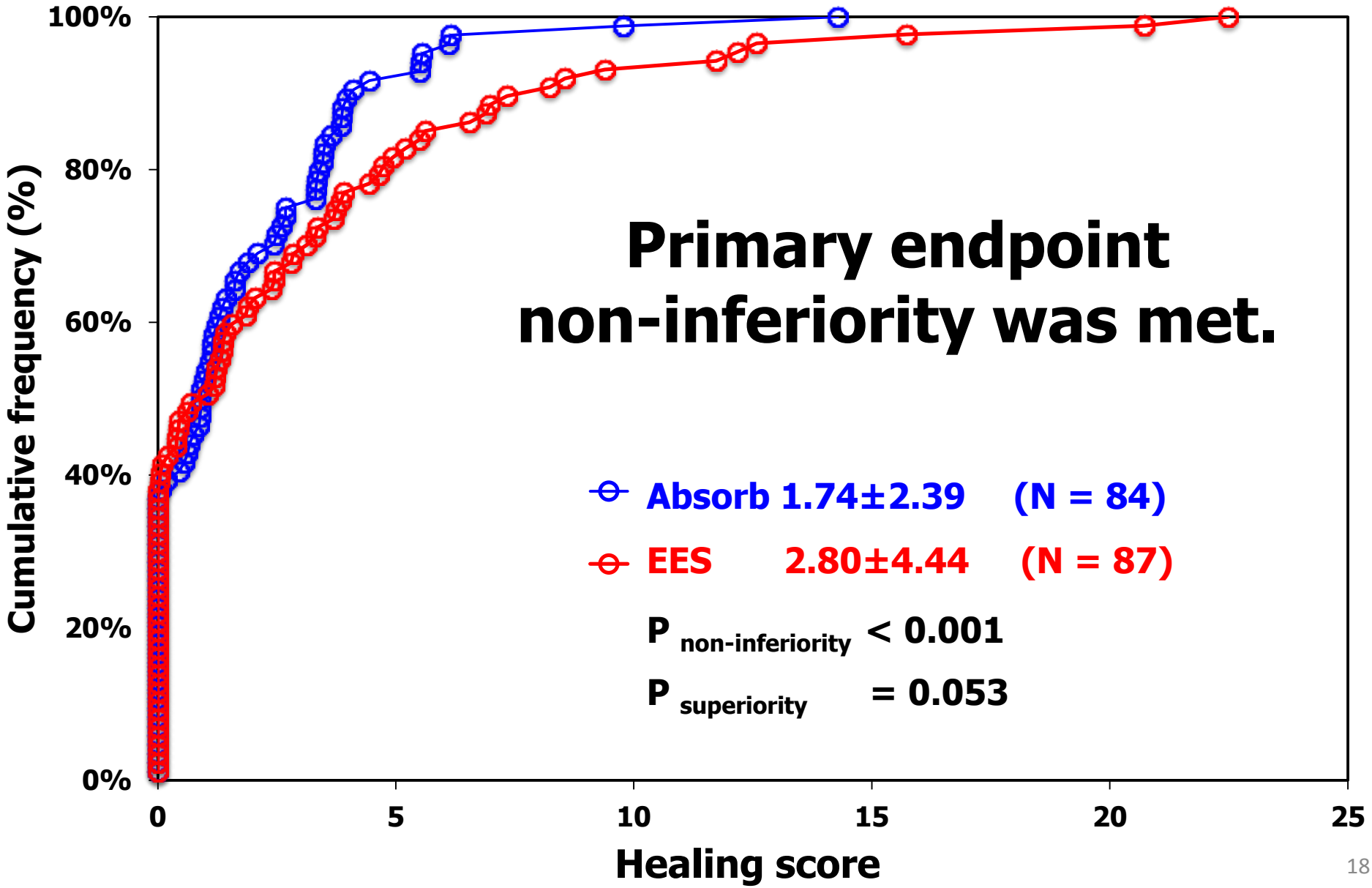
***One patient in Absorb arm did not receive Absorb scaffold but received Xience**

As treated

Absorb: Healing Score 0



Cumulative curve of Healing Score



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Optical coherence tomography analysis(2)

Data present in mean±SD	Absorb N=95	EES N=98	P-value
Abluminal scaffold/stent area, mm^2	**8.73±1.73**	**8.19±2.04**	**0.07**
Abluminal Minimal scaffold/stent area; mm^2	7.30±1.69	7.04±1.88	0.34
Mean Flow area, mm^2	**7.05±1.78**	**7.01±2.00**	**0.89**
Minimal flow area, mm^2	5.40±1.75	5.53±1.87	0.65
Mean Lumen area, mm^2,	**7.06±1.79**	**7.02±2.01**	**0.89**
Minimal Lumen area, mm^2,	5.40±1.75	5.53±1.87	0.65
Mean Neointimal area, mm^2	**1.52±0.38**	**1.35±0.54**	**0.018**
% volume obstruction	17.9±4.8	16.9±6.2	0.27
Mean neointimal thickness of the strut coverage, µm	**110±30**	**90±50**	**<0.001**

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Quantitative coronary angiography 6-month follow-up

Data present in mean±SD or (%)	Absorb N=85	EES N=89	P-value
In-device MLD, mm	2.26±0.44	2.38±0.41	0.07
In-device reference diameter, mm	2.76±0.37	2.79±0.44	0.68
In-device %DS	**18.3±11.6**	**14.5±9.3**	**0.02**
In-device late loss, mm	**0.20±0.31**	**0.08±0.28**	**0.01**
In-segment late loss, mm	**0.16±0.34**	**0.06±0.29**	**0.049**
In-segment binary restenosis	**1 (1.2 %)**	**1 (1.1%)**	**1.00**

The OCT and QCA measurement of the patient (n=1 Absorb) who presented with a subacute thrombosis in the Absorb group are excluded from the 6 months result.

Clinical follow-up

- Clinical event rates were low (Absorb 1.1% vs. Xience 0.0%) at 6 months

- There was only one patient suffering subacute definite scaffold thrombosis leading to MI and clinically-driven TLR in the Absorb group†.

- At follow-up, angina-free patients were 91.4% vs. 91.7% in the Absorb and EES group, respectively (p=0.94).

† Stent thrombosis caused from an inadequate matching of the vessel and device size; vessel size 1.92 mm, scaffold size 2.5mm.

Conclusion

- Scaffolding of culprit lesions with **Absorb in the setting of STEMI resulted in nearly complete arterial healing**, which was comparable to that of metallic EES at six months.

- Frequency of **malapposed, and both malapposed and uncovered struts were lower in the Absorb arm**, while there was no presence of intraluminal mass in both groups.

- QCA revealed similar acute gain and MLD postprocedure. At 6 months, late lumen loss was lower in the EES arm, but binary restenosis rate was comparably low between groups.

Limitation

- The observed event rate was exceedingly low due to a substantial selection process (191 included/2055 admitted STEMI pts)
- The HS was assessed at 6 month which is an intermediate time point in the healing process otherwise only completed at 5 years.
- **These findings cannot be extrapolated to other bioresorbable devices with different materials or strut thickness.**
- Sample size does not allow us to draw any meaningful conclusion regarding the impact of the healing score on clinical outcomes.

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Acute coronary syndromes

Everolimus-eluting bioresorbable stent vs. durable polymer everolimus-eluting metallic stent in patients with ST-segment elevation myocardial infarction: results of the randomized ABSORB ST-segment elevation myocardial infarction—TROFI II trial

Manel Sabaté[1], Stephan Windecker[2], Andres Iñiguez[3], Lisette Okkels-Jensen[4], Angel Cequier[5], Salvatore Brugaletta[1], Sjoerd H. Hofma[6], Lorenz Räber[2], Evald Høi Christiansen[7], Maarten Suttorp[8], Thomas Pilgrim[2], Gerrit Anne van Es[9,10], Yohei Sotomi[11], Hector M. García-García[9], Yoshinobu Onuma[9,12], and Patrick W. Serruys[10,13]*

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Thank You!

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EDITORIAL

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