

ABSORB in STEMI TROFI II

April 26 2016 7:05-7:15 PM

Patrick W. Serruys, MD, PhD

Emeritus Professor of Medicine

Erasmus University, Rotterdam, The Netherlands

Professor of Cardiology

Imperial college, London, UK

Yohei Sotomi, MD

Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands

Yoshinobu Onuma, MD, PhD

Erasmus MC, Rotterdam, The Netherlands

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.

Trial organization

Study Investigator:

P.W. Serruys (Chair)
M.Sabate (PI, SP)
S. Windecker (PI, CH)
A. Iñiguez (SP)
L.O. Jensen (DK)
A.Cequier (SP)
S. Brugaletta (SP)
S.H. Hofma (NL)
L. Räber (CH)
E.H.Christiansen (DK)
M.Suttorp (NL)

Clinical Event Committee (CEC):

P. Vranckx (NL)
E. McFadden(UK)
J.P. Herrman (NL)

Data and Safety Monitoring Board (DSMB):

G.Ducrocq(FR)
T.Cuisset(FR)
J.G.P Tijssen(NL)

Core lab:Y. Onuma. Cardialysis,
Rotterdam (NL)

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?

$$\text{Healing score} = [\% \text{ILD} \times 4] + [\% \text{MU} \times 3] + [\% \text{U} \times 2] + [\% \text{M}]$$

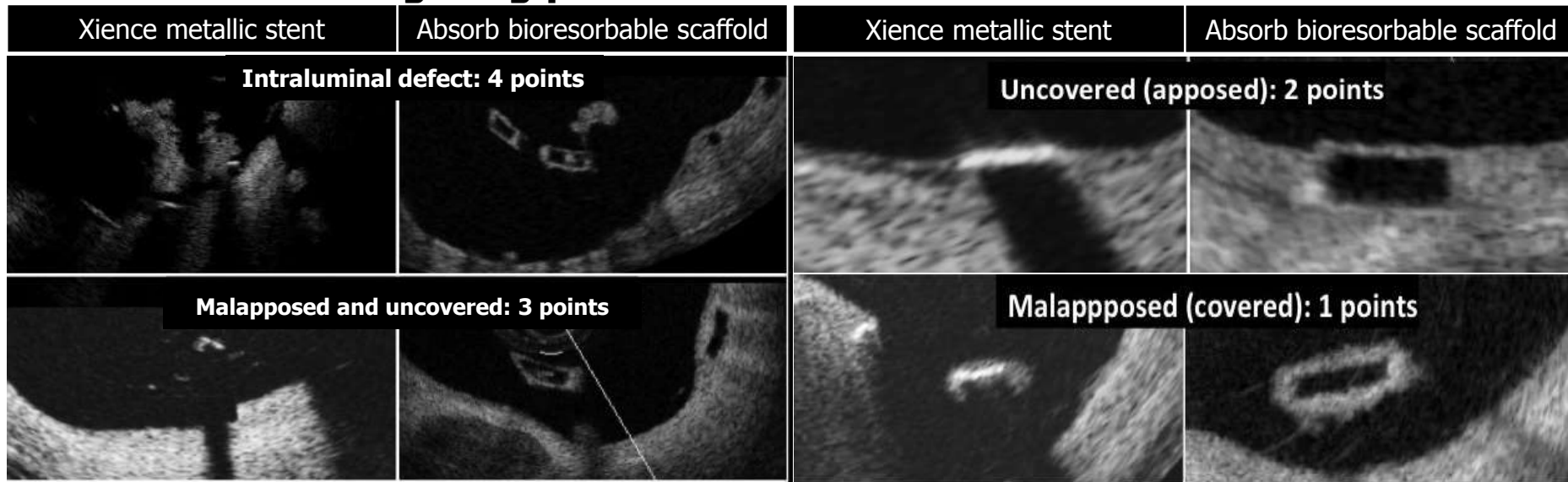
ILD: intraluminal defect

MU: malapposed and uncovered

and their weighting points in the formula

U: uncovered

M: malapposed



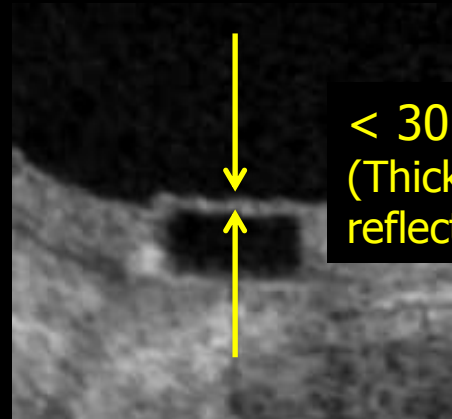
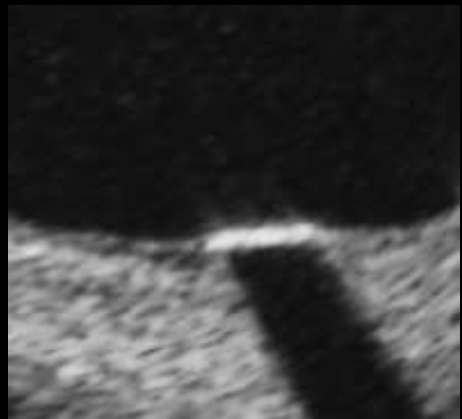
Reference: TROFI trial *Eur Heart J.*2013;34:1050-1060; *Eur Heart J Cardiovasc Imaging.*.. 2014;15:987-995
Leaders trial *Eur Heart J.* 2010;31:165-176; **Resolute all comers trial** *Eur Heart J.* 2011;32:2454-63
Absorb cohort B *EuroIntervention* 2015;10:1299-306; **NANO Plus** *AsiaIntervention*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

OCT Methodology: Strut Coverage at Follow-up

Metallic strut

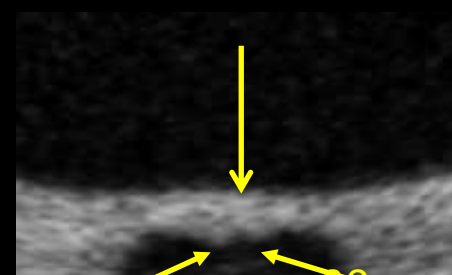
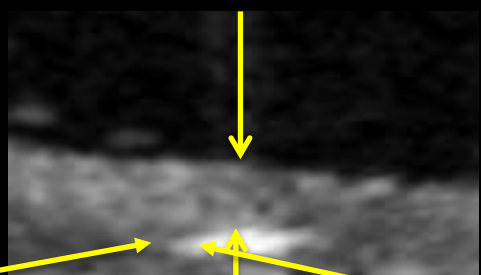
Polymeric strut (Absorb)

Uncovered



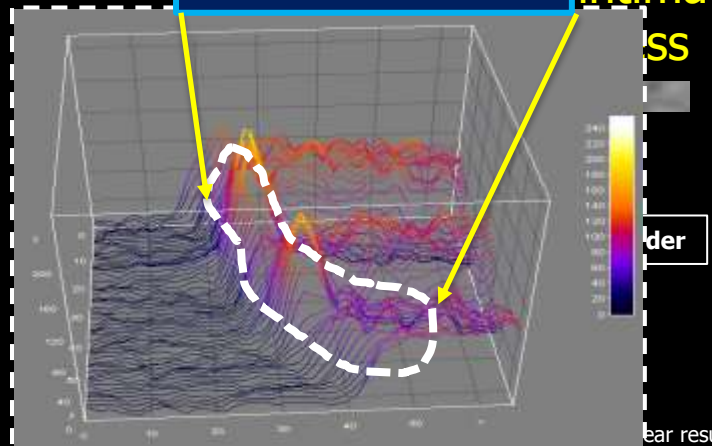
< 30µm
(Thickness of reflective border)

Covered

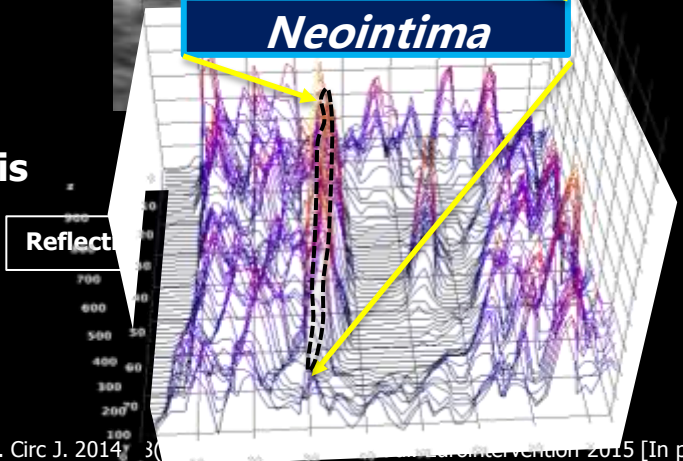


Neointima

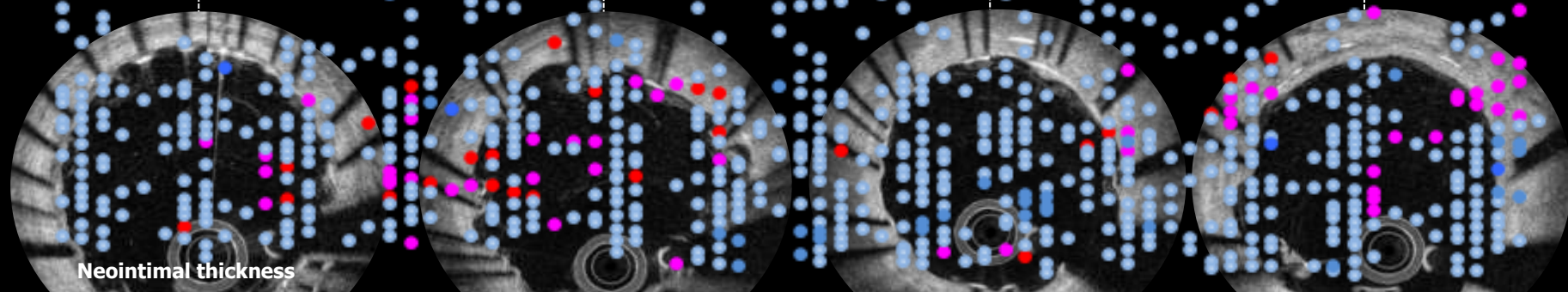
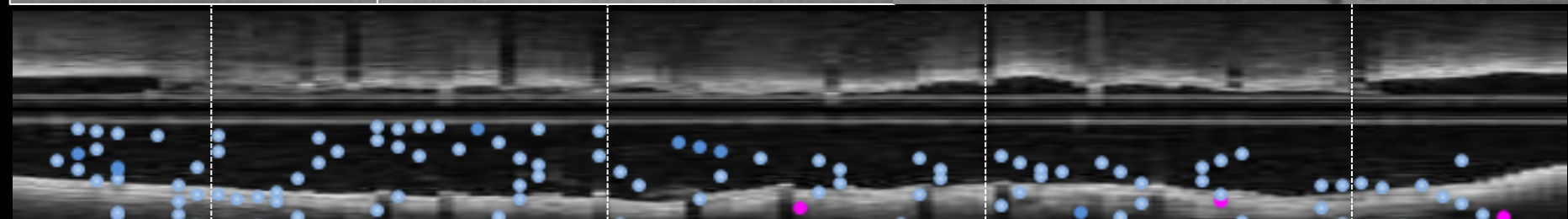
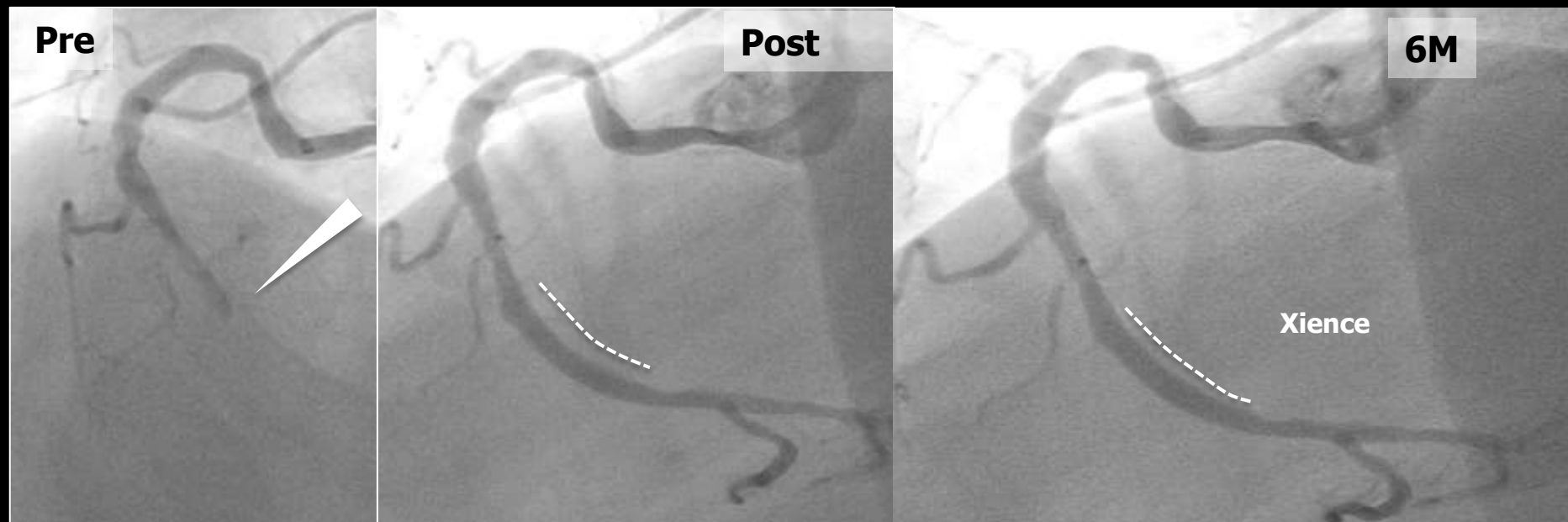
Neointima



Light Intensity analysis



Xience: Healing Score 12.2



Neointimal thickness

- > 0.0 - 100.0 μm
- 100.1 - 200.0 μm
- 200.1 - 300.0 μm
- ≥ 300.1 μm
- Apposed Uncovered
- Malapposed Uncovered
- Malapposed Covered

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

191 patients with STEMI < 24h
1:1 randomisation

Thrombectomy
+/- predilatation



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.

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

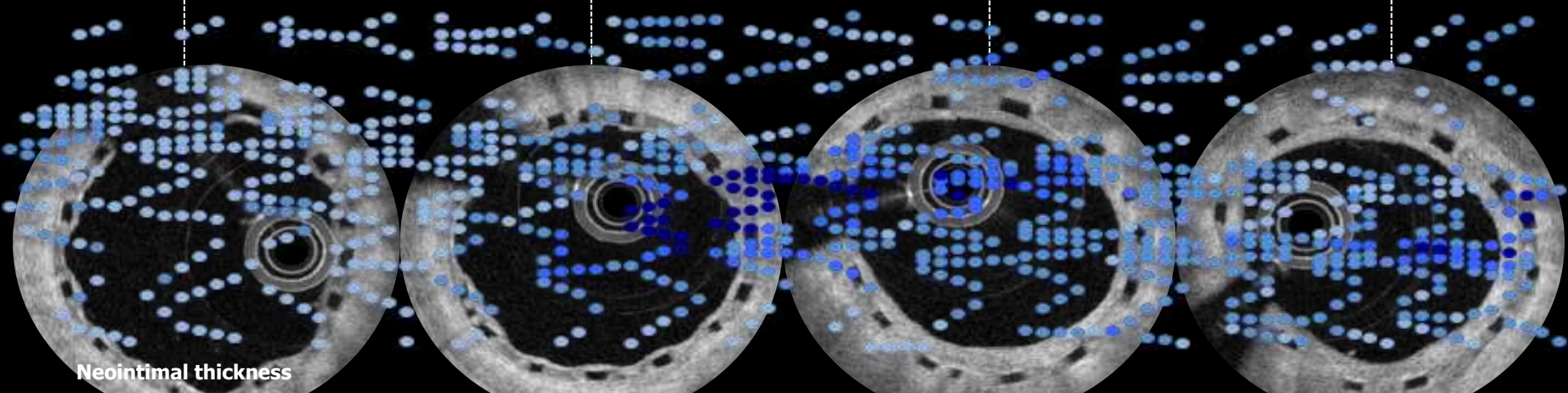
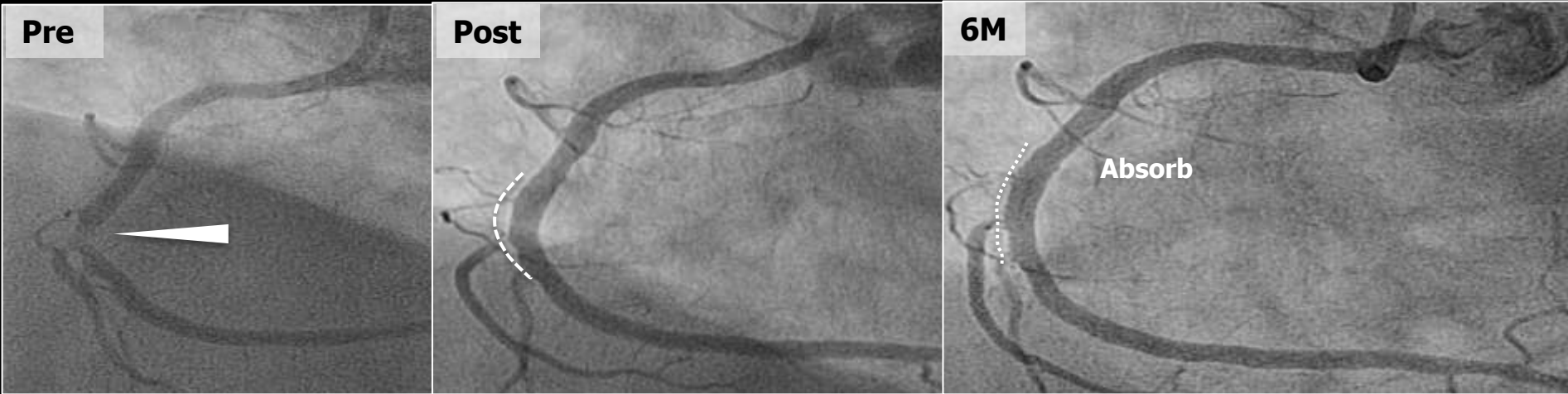
Quantitative coronary angiography

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

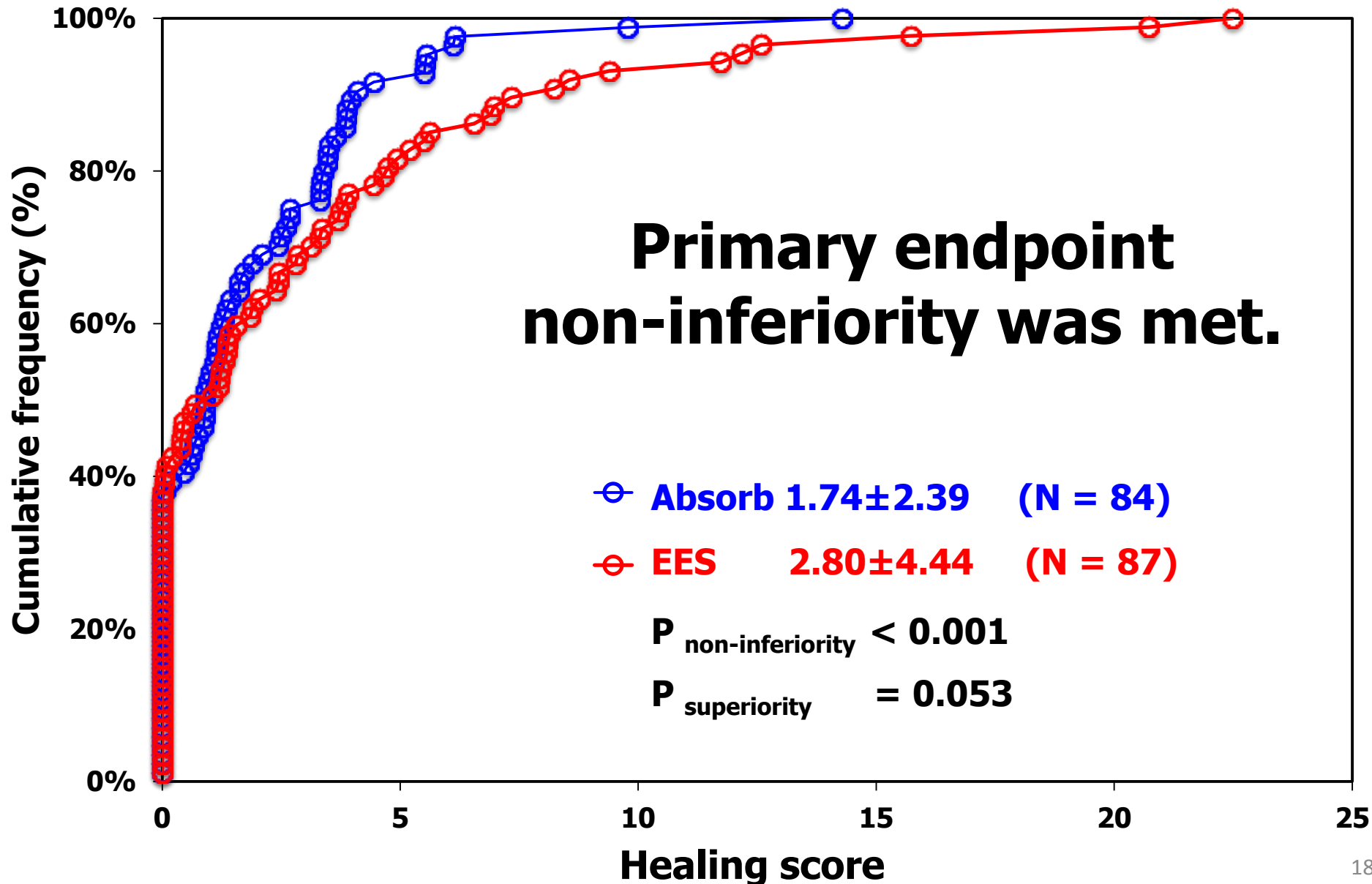
Absorb: Healing Score 0



Neointimal thickness



Cumulative curve of Healing Score



Optical coherence tomography analysis(2)

Data present in mean±SD	Absorb N=95	EES N=98	P-value
Abluminal scaffold/stent area, mm²	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, mm²	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, mm²,	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, mm²	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

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.

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 Sabaté¹, Stephan Windecker², Andres Iñiguez³, Lisette Okkels-Jensen⁴, Angel Cequier⁵, Salvatore Brugaletta¹, Sjoerd H. Hofma⁶, Lorenz Räber², Evald Høi Christiansen⁷, Maarten Suttorp⁸, Thomas Pilgrim², Gerrit Anne van Es^{9,10}, Yohei Sotomi¹¹, Hector M. García-García⁹, Yoshinobu Onuma^{9,12}, and Patrick W. Serruys^{10,13*}

¹Thorax Institute, University Hospital Clinic, Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), University of Barcelona, Barcelona, Spain; ²Bern University Hospital, Bern, Switzerland; ³Meixoeiro Hospital, Vigo, Spain; ⁴Odense University Hospital, Odense, Denmark; ⁵Bellvitge University Hospital, Barcelona, Spain; ⁶Medical Center Leeuwarden, The Netherlands; ⁷Aarhus University Hospital, Skejby, Denmark; ⁸St Antonius Hospital, Nieuwegein, The Netherlands; ⁹Cardialysis B.V., Rotterdam, The Netherlands; ¹⁰European Cardiovascular Research Institute (ECRI), Rotterdam, The Netherlands; ¹¹The Heart Center, Academic Medical Center, Amsterdam, The Netherlands; ¹²Thorax Centre, Erasmus MC, PO Box 2125, 3000 CC Rotterdam, The Netherlands; and ¹³International Center for Circulatory Health, NHLI, Imperial College, London, UK

Received 3 August 2015; revised 26 August 2015; accepted 28 August 2015

Thank You!



Volume 11 - Number 13 - April 2016 - ISSN: 1774-024X

EuroIntervention

CORONARY INTERVENTIONS

- 1457** Complex coronary Bifurcation lesions: RANdOmized comparison of a strategy using a dedicated self-expanding biolimus-eluting stent versus a culotte strategy using everolimus-eluting stents: primary results of the COBRA trial
C. Dubois, T. Adriaenssens, et al
- 1468** Significance of prior percutaneous revascularisation in patients with acute coronary syndromes: insights from the prospective PROSPECT registry
A. Itiguez, G.W. Stone, et al
- 1475** Clinical outcomes following "off-label" versus "established" indications of bioresorbable scaffolds for the treatment of coronary artery disease in a real-world population
T. Miyazaki, A. Colombo, et al
- 1479** A novel approach to treat in-stent stenosis: 6- and 12-month results using the everolimus-eluting bioresorbable vascular scaffold
P. Janshidi, F. Cuculi, et al
- 1487** Patient preference regarding assessment of clinical follow-up after percutaneous coronary intervention: the PAPAAYA study
M.M. Kok, M.J. Uerman, et al
- 1495** Does access to invasive examination and treatment influence socioeconomic differences in case fatality for patients admitted for the first time with non-ST-elevation myocardial infarction or unstable angina?
S. Mårtensson, M. Osler, et al
- 1503** Virtual reality training in coronary angiography and its transfer effect to real-life catheterisation lab
U.J. Jensen, P. Tornvall, et al

- 1511** A disaster never comes alone: total ostial occlusion of the left main coronary artery with an anomalous origin
P. Rodrigues, S. Torres, et al

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

- 1512** Left atrial appendage occlusion with the AMPLATZER Amulet device: an expert consensus step-by-step approach
A. Tzikas, H. Omran, et al
- 1522** The prognostic value of acute and chronic troponin elevation after transcatheter aortic valve implantation
J.M. Sinning, N. Werner, et al
- 1530** Emergency transcatheter aortic valve replacement in patients with cardiogenic shock due to acutely decompensated aortic stenosis
C. Frerker, K.H. Kuck, et al
- 1537** First-in-man report of residual "intra-clip" regurgitation between two MitraClips treated by AMPLATZER Vascular Plug II
M. Taramasso, F. Maisano, et al
- 1541** First transfemoral percutaneous edge-to-edge repair of the tricuspid valve using the MitraClip system
T. Wengenmayer, S. Grundmann, et al
- 1545** First Lotus aortic valve-in-valve implantation to treat degenerated Mitroflow bioprostheses
F. Castriota, A. Cremonesi, et al
- 1549** Direct Flow valve-in-valve implantation in a degenerated mitral bioprosthesis
G. Bruschi, F. De Marco, et al

AsiaIntervention

www.asiaintervention.org

Volume 2 - Number 1 - January 2016 - ISSN: 2426-3958

CORONARY INTERVENTIONS

- 19** Late angiographic and clinical outcomes of the novel BioMime™ sirolimus-eluting coronary stent with ultra-thin cobalt-chromium platform and biodegradable polymer for the treatment of diseased coronary vessels: results from the prospective, multicentre meriT-2 clinical trial
- 28** Impact of chronic lung disease after percutaneous coronary intervention in Japanese patients with acute coronary syndrome
- 36** Distribution characteristics of coronary calcification and its substantial impact on stent expansion: an optical coherence tomography study
- 44** Smooth arterial healing after paclitaxel-coated balloon angioplasty for in-stent stenosis assessed by optical frequency domain imaging
- 48** Mediastinal haematoma complicating percutaneous coronary intervention via the radial artery

INTERVENTIONS FOR STRUCTURAL HEART DISEASE AND HEART FAILURE

- 49** Comparison of aortic annulus dimensions between Japanese and European patients undergoing transcatheter aortic valve implantation as determined by multi-detector computed tomography: results from the OCEAN-TAVI and a European single-centre cohort
- 57** Combined percutaneous transvenous mitral commissurotomy and left atrial appendage closure as an alternative to anticoagulation for rheumatic atrial fibrillation

EDITORIAL

- 7** Evolution and current status of interventional cardiology in India
- 10** Tailoring TAVI in Asia: insights from MSCT
- 13** Opening the shell for better stent results

ASIA-PACIFIC HOTLINES AT TCT 2015

- 16** Asia-Pacific Hotlines at TCT 2015: a prospective randomised trial of paclitaxel-eluting vs. everolimus-eluting stents in diabetic patients with coronary artery disease (TUXEDO)
- 17** Asia-Pacific Hotlines at TCT 2015: bioresorbable vascular scaffolds versus metallic stents in patients with coronary artery disease (ABSORB China Trial)
- 18** Asia-Pacific Hotlines at TCT 2015: evaluation of initial surgical versus conservative strategies in patients with asymptomatic severe aortic stenosis (The CURRENT AS registry)

HOW SHOULD I TREAT?

- 58** How should I treat a patient with critical stenosis of a bifurcation of the left main coronary artery with an acute angulation between the left main artery and the left circumflex artery?
- 65** How should I treat a percutaneous posteromedial mitral periprosthetic paravalvular leak closure in a bioprosthesis with no radiopaque ring?