Clinical Impact of OCT-Guided PCI

2015. 12. 4
Eun-Seok Shin MD,PhD
Division of Cardiology,
Department of Internal Medicine
Ulsan University Hospital
University of Ulsan College of Medicine

울산대학교병원
ULSAN UNIVERSITY HOSPITAL

Predictors of Stent Failure: early thrombosis, restenosis

Minimum lumen area

Stent underexpansion

Edge dissection

Residual stenosis

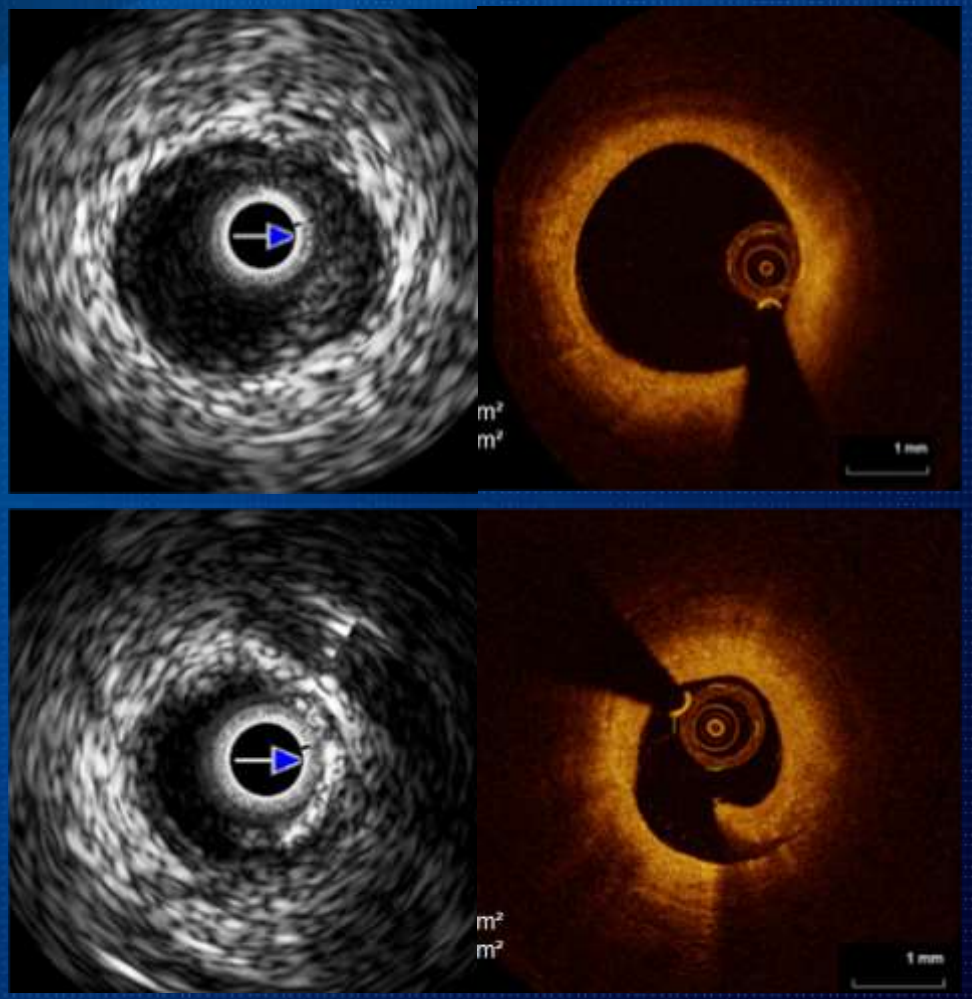
Tissue protrusion

Large plaque burden

Geographic miss etc…

IVUS data!

IVUS & OCT

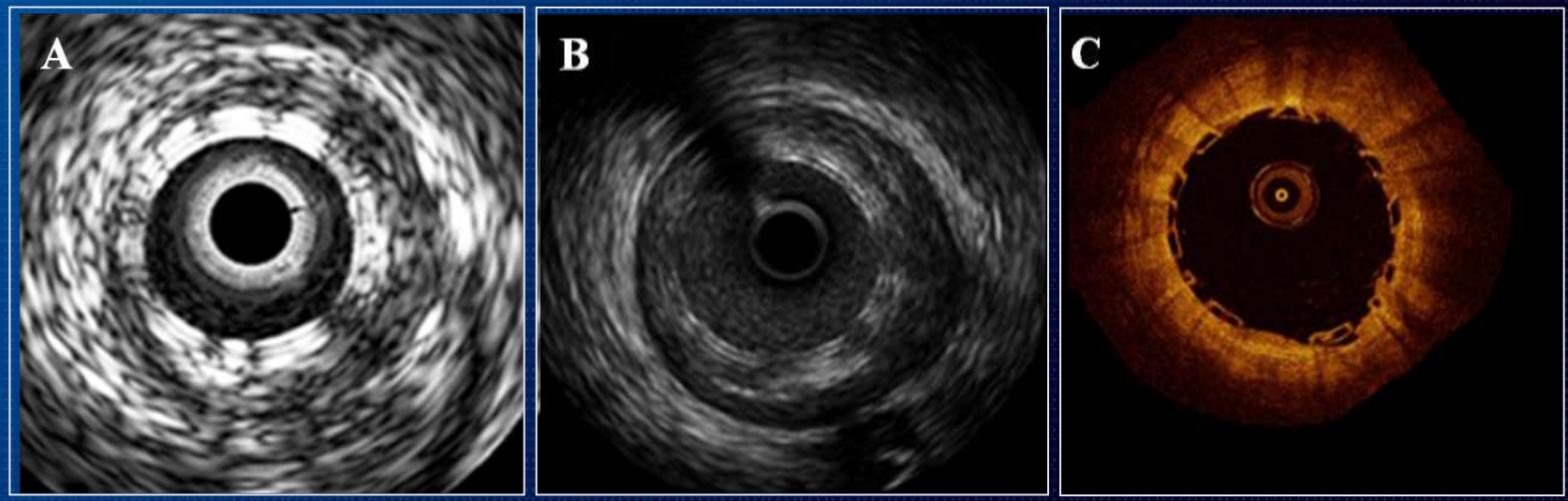


High-definition visualization

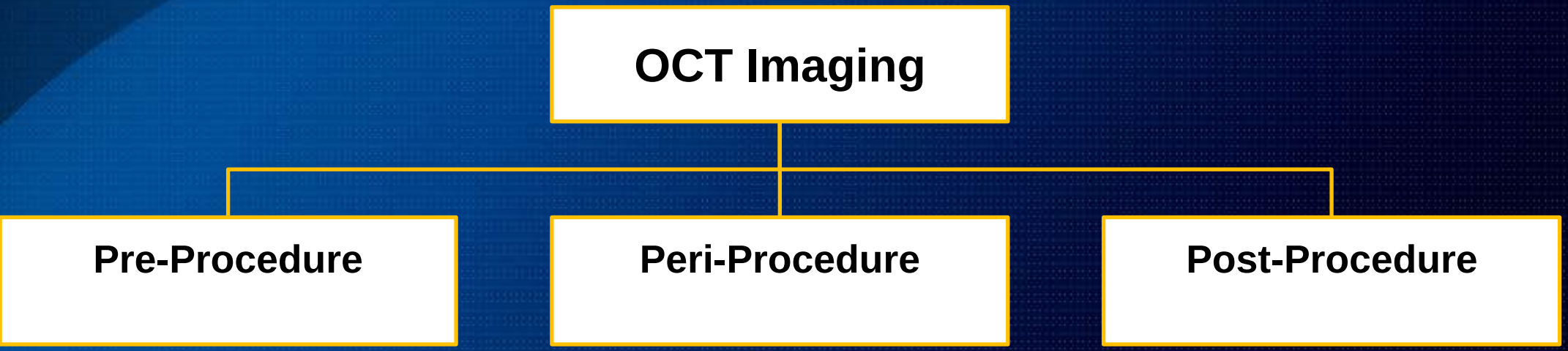
IVUS & OCT

Reducing death, MI, TLR stent thrombosis after PCI

So What?

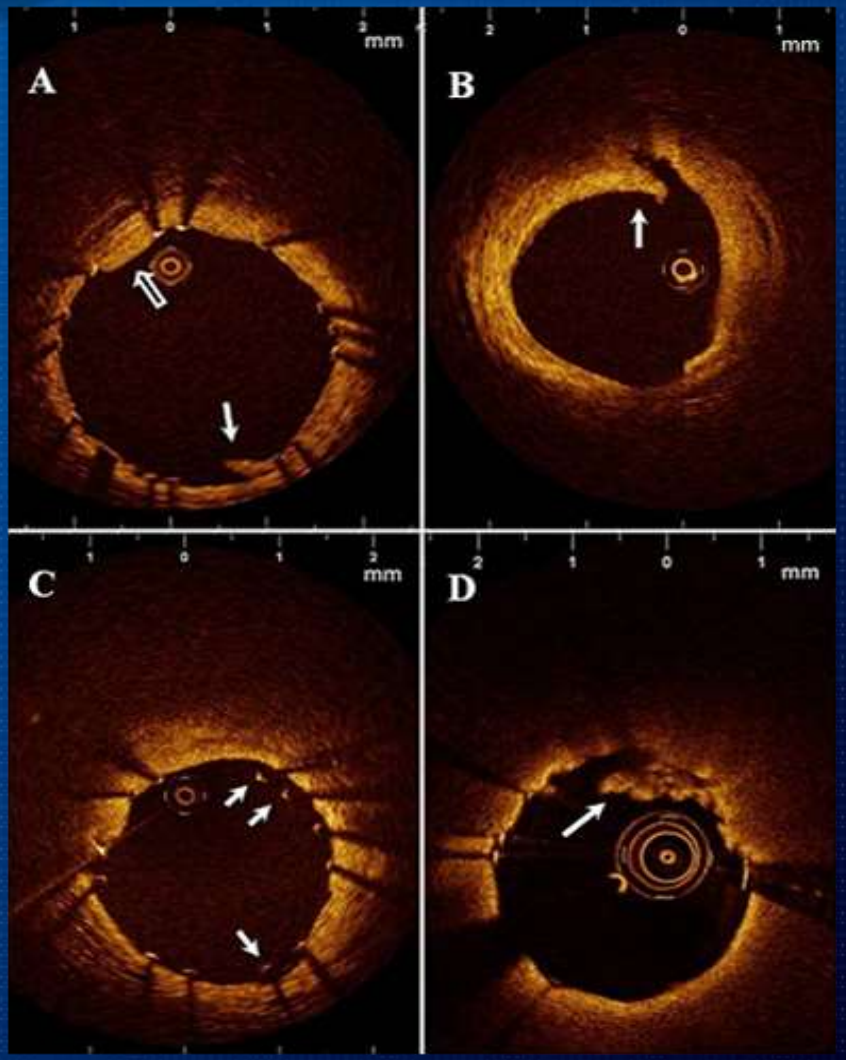


OCT-guided PCI



Lesion assessment **Stent assessment** **Complication assessment**

Acute vessel wall injury after stenting



Tissue prolapse: 100%
Intrastent dissection: 92%
Edge dissection: 28%
ISA: 64%
Thrombus: 44%

→ No associated with clinical outcome

J Invasive Cardiol. 2010 Sep;22(9):435-9.

울산대학교병원 ULSAN UNIVERSITY HOSPITAL

ILUMIEN I

Observational Study of Optical Coherence Tomography (OCT) in Patients Undergoing Fractional Flow Reserve (FFR) and Percutaneous Coronary Intervention – Stage I

418 pts prospectively enrolled

35 sites in North America, EU, Asia and Australia

Patients with stable angina, unstable angina or NSTEMI plus at least 1 angiographically significant stenosis (>50% by visual estimation) in ≥1 native coronary artery

Mandatory use of FFR and OCT pre and post PCI; PCI strongly recommended for FFR ≤0.80

↓

Clinical FU at 30 days, 1 year

Stone G et al. TCT 2014

Rates and types of abnormal findings by post-PCI OCT

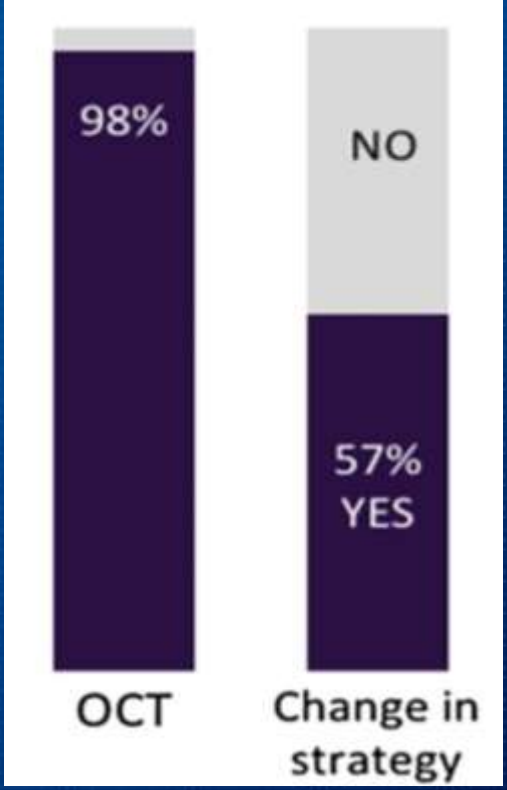
OCT variables	All abnormalities by core Laboratory, *n/N*	Rate (%)	Abnormalities deemed unsatisfactory by operator, *n/N*	Rate (%)
Edge dissection	107/388	27.6	11/408	2.7
Malapposition	126/392	32.1	59/408	14.5
Under-expansion	159/385	41.3	31/408	7.6
Edge dissection and malapposition	34/388	8.8	2/408	0.5
Edge dissection and under-expansion	35/385	9.1	2/408	0.5
Malapposition and tissue protrusion	44/392	11.2	2/408	0.5
Edge dissection, malapposition, and under-expansion	14/385	3.6	0/408	0
Thrombus or tissue protrusion[a]	100/392	25.5	4/408	1.0

*Edge dissection >180° in more than five frames
*Significant malapposition defined as >200 micron in at least five consecutive frames
*Thrombus and/or tissue protrusion on OCT causing flow reduction
(i.e. TIMI < 3 and/or obstruction visible by angiography).
*Under-expansion ≥30% by OCT compared with reference distal lumen area and
when quantitative coronary angiogram (QCA) shows >20% in-stent residual diameter stenosis.

ILUMIEN I. EHJ 2015 Aug 4

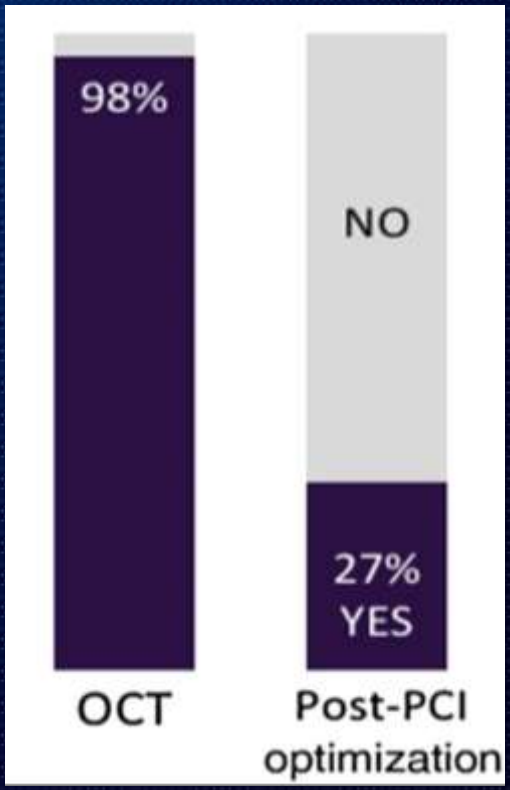
Impact of OCT on PCI

Pre-PCI (n=467 lesions)



Selecting different stent lengths (shorter in 25%, longer in 43%).

Post-PCI (n=467 lesions)



Additional in-stent post-dilatation (81%)

Placement of new stents (12%)

ILUMIEN I. EHJ 2015 Aug 4

Post hoc analysis

MACE at 30 days: death 0.25%, MI 7.7%, repeat PCI 1.7%, and stent thrombosis 0.25%.

Pre-PCI/ Post-PCI	No/No	Yes/No	No/Yes	Yes/Yes	*P* Value
Mean Number of Stents	1.17	1.2	1.33	1.5	.001
Mean Post-PCI FFR	0.89	0.89	0.89	0.86	.003
Mean Procedure Duration, mins	88	90	94	106	.0043
Mean Post-PCI MLA, mm^2	6.1	5.2	5.3	5.0	.004
30-Day Events					
MACE	10.9%	9.8%	12.5%	0	.077
MI[a]	10.2%	8.6%	12.5%	0	.017

ILUMIEN I. EHJ 2015 Aug 4

울산대학교병원 ULSAN UNIVERSITY HOSPITAL

Incidence and Clinical Significance of Poststent OCT Findings: 900 lesions (786 patients)

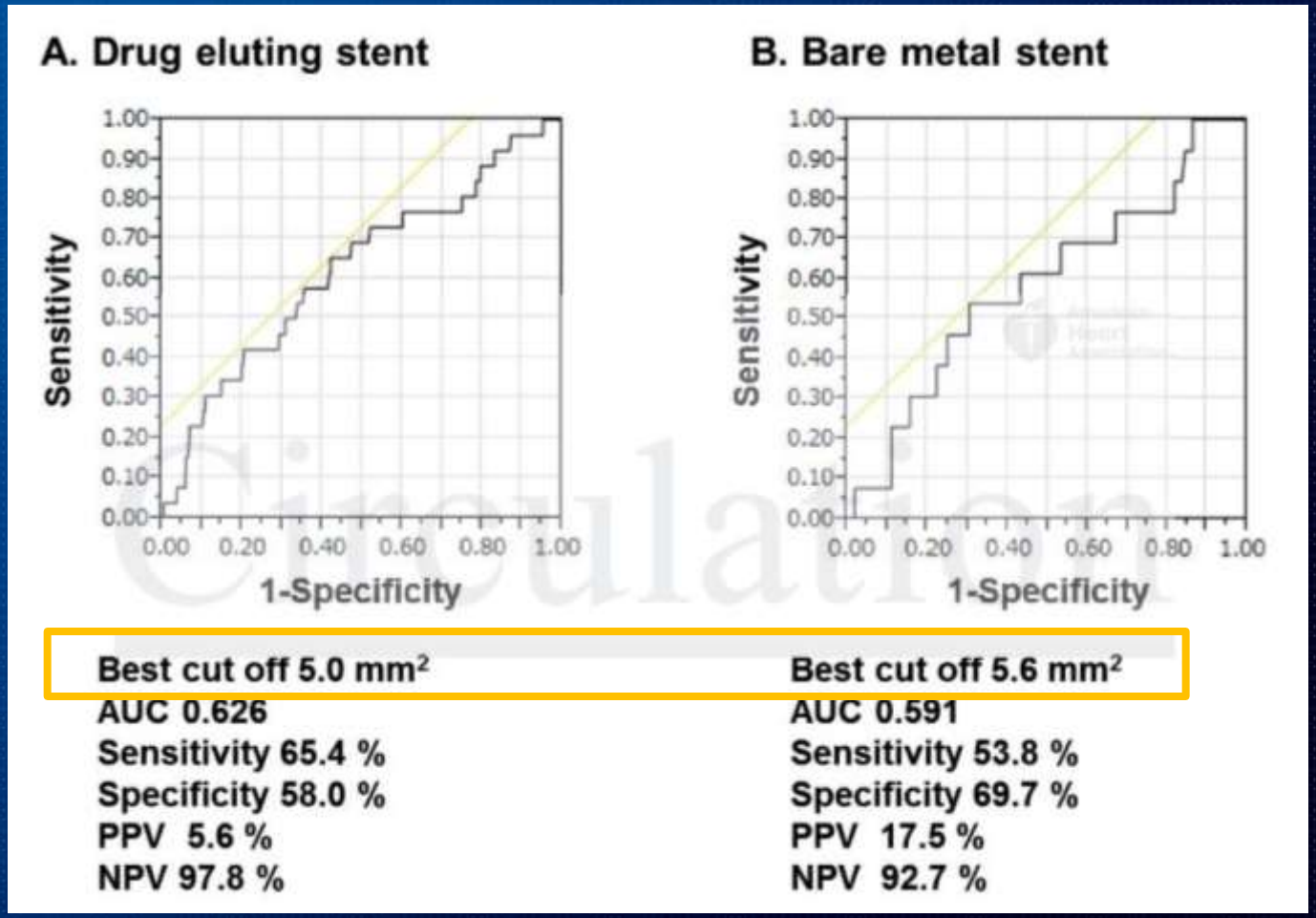
	No-DoCE (795 lesions)	DoCE (39 lesions)	*P* Value
Stent edge dissection	230 (28.9)	12 (30.8)	0.789
Proximal stent edge dissection	125 (15.7)	9 (23.1)	0.202
Distal stent edge dissection	126 (15.8)	8 (20.5)	0.430
Instent dissection	535 (67.3)	24 (61.5)	0.488
Incomplete stent apposition	305 (38.4)	14 (35.9)	0.765
Instent tissue protrusion	767 (96.5)	39 (100)	0.636
Smooth protrusion	735 (92.5)	37 (94.9)	0.688
Disrupted fibrous tissue protrusion	490 (61.6)	21 (53.8)	0.330
Irregular protrusion	416 (52.3)	29 (74.4)	0.003
Thrombus	302 (38.0)	20 (51.3)	0.132
Stent underexpansion	296 (37.2)	13 (33.3)	0.656
Small MSA	321 (40.4)	23 (59.0)	0.039
Minimal stent area, mm^2	5.8±2.0	5.4±2.0	0.264
Minimal lumen area, mm^2	5.9±2.0	5.4±2.0	0.224
Proximal reference area, mm^2	7.8±3.0	7.2±3.2	0.392
Distal reference area, mm^2	6.3±2.7	5.9±2.9	0.429

Device-oriented clinical endpoints (DOCE):

Cardiac death,
Target vessel-related MI,
TLR,
Stent thrombosis.

Circulation. 2015;132:1020-1029

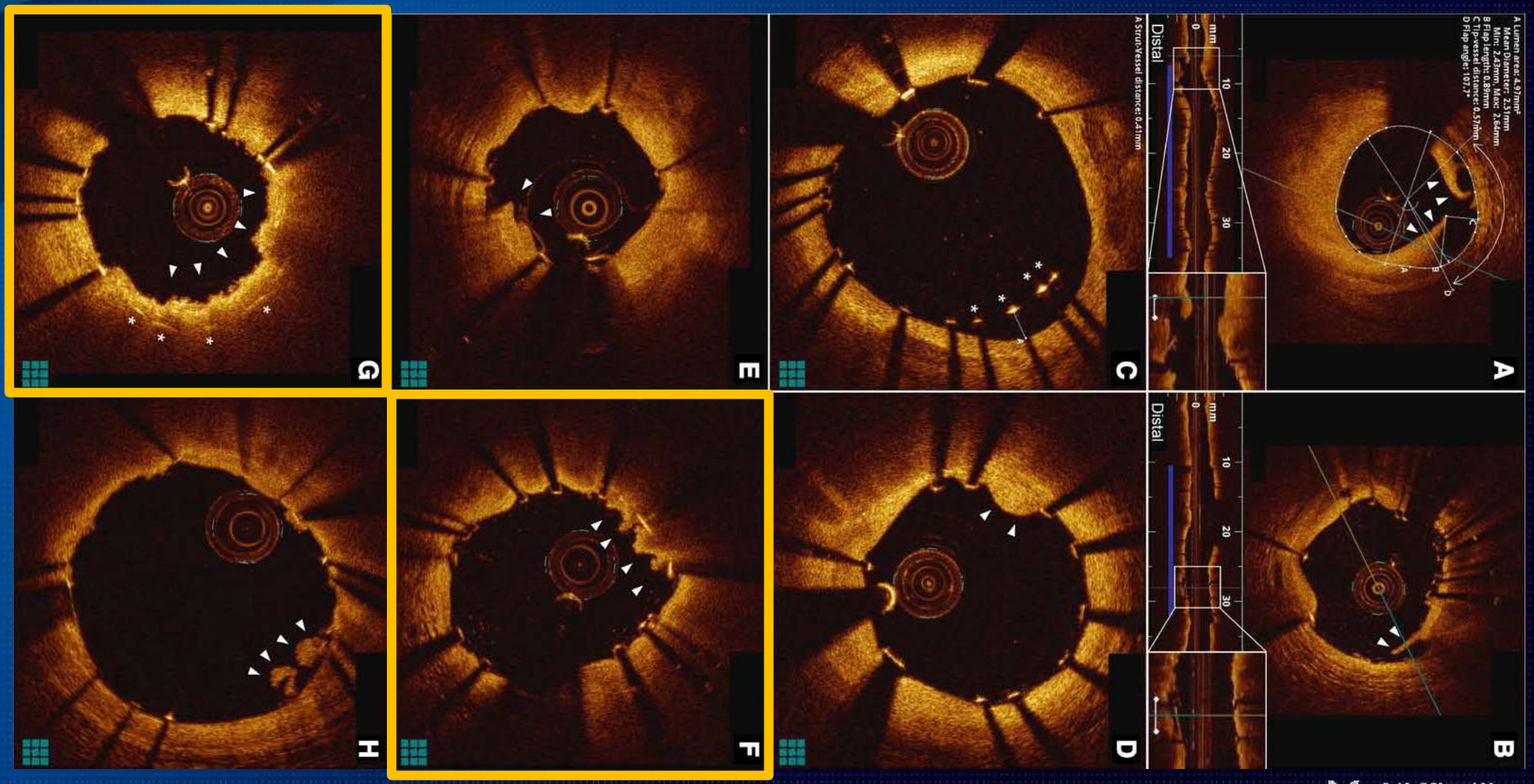
Minimal stent area associated with outcome



Circulation. 2015;132:1020-1029

울산대학교병원 ULSAN UNIVERSITY HOSPITAL

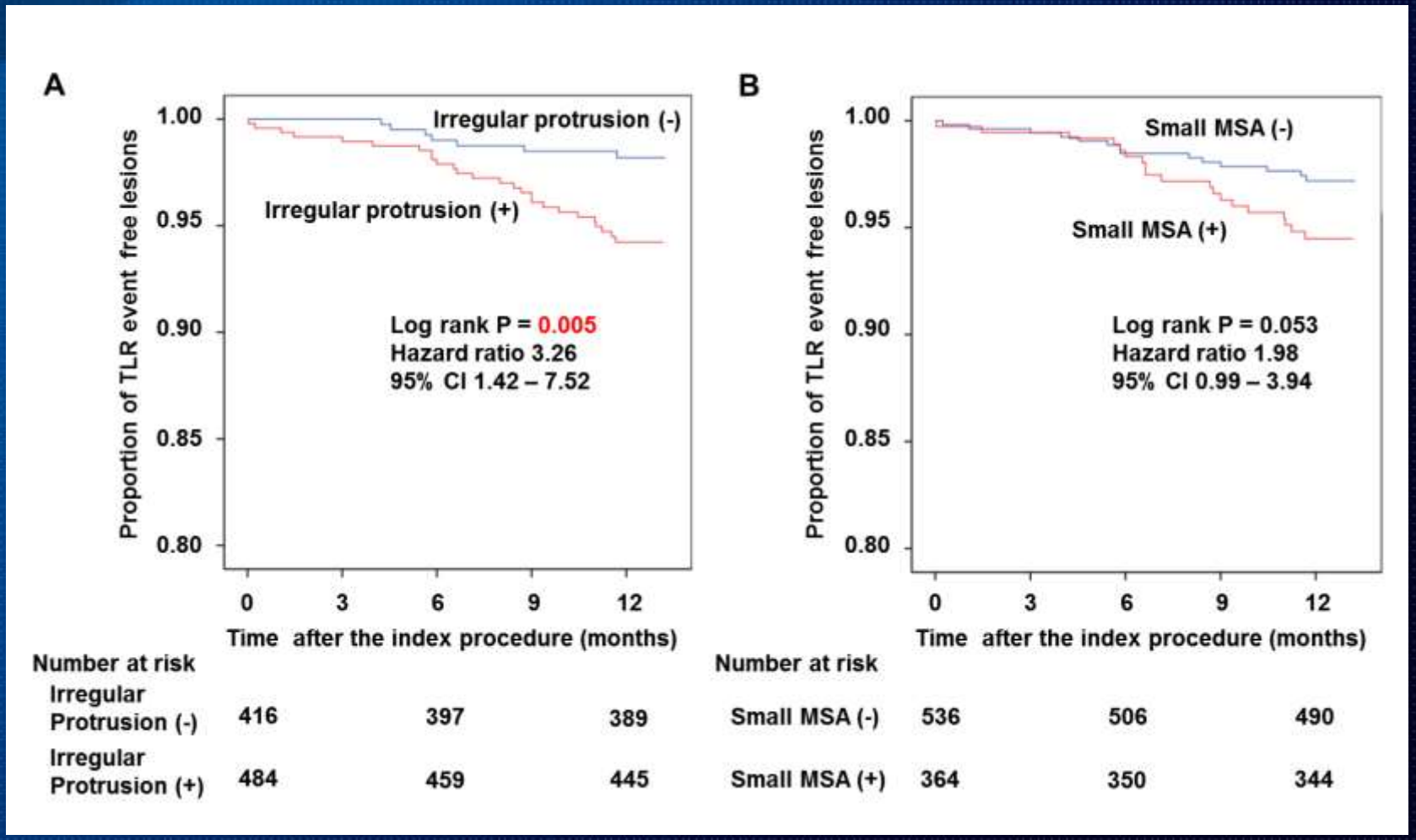
Poststent OCT findings



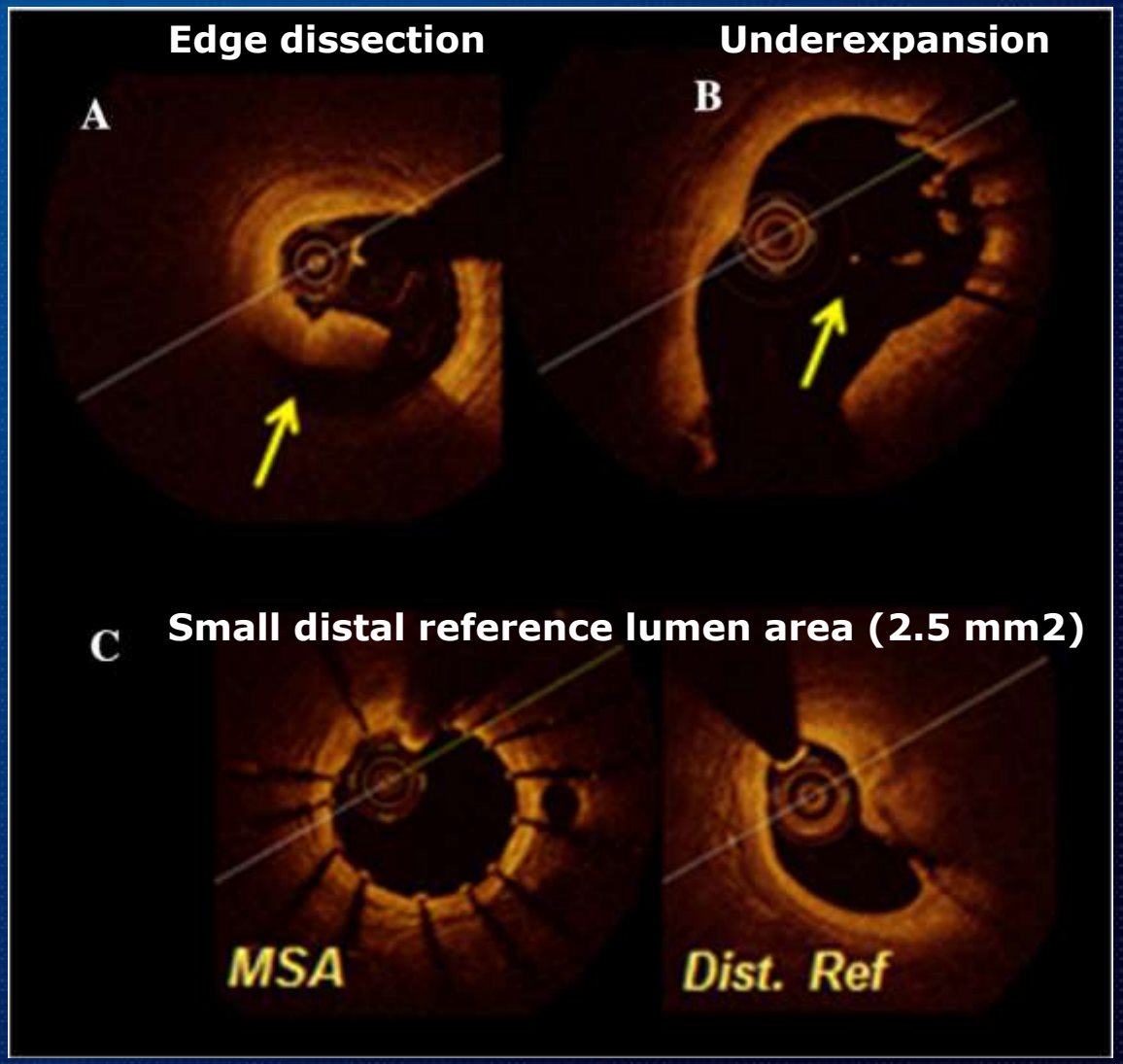
Circulation. 2015;132:1020-1029

울산대학교병원 ULSAN UNIVERSITY HOSPITAL

TLR event free survival distributions of lesions



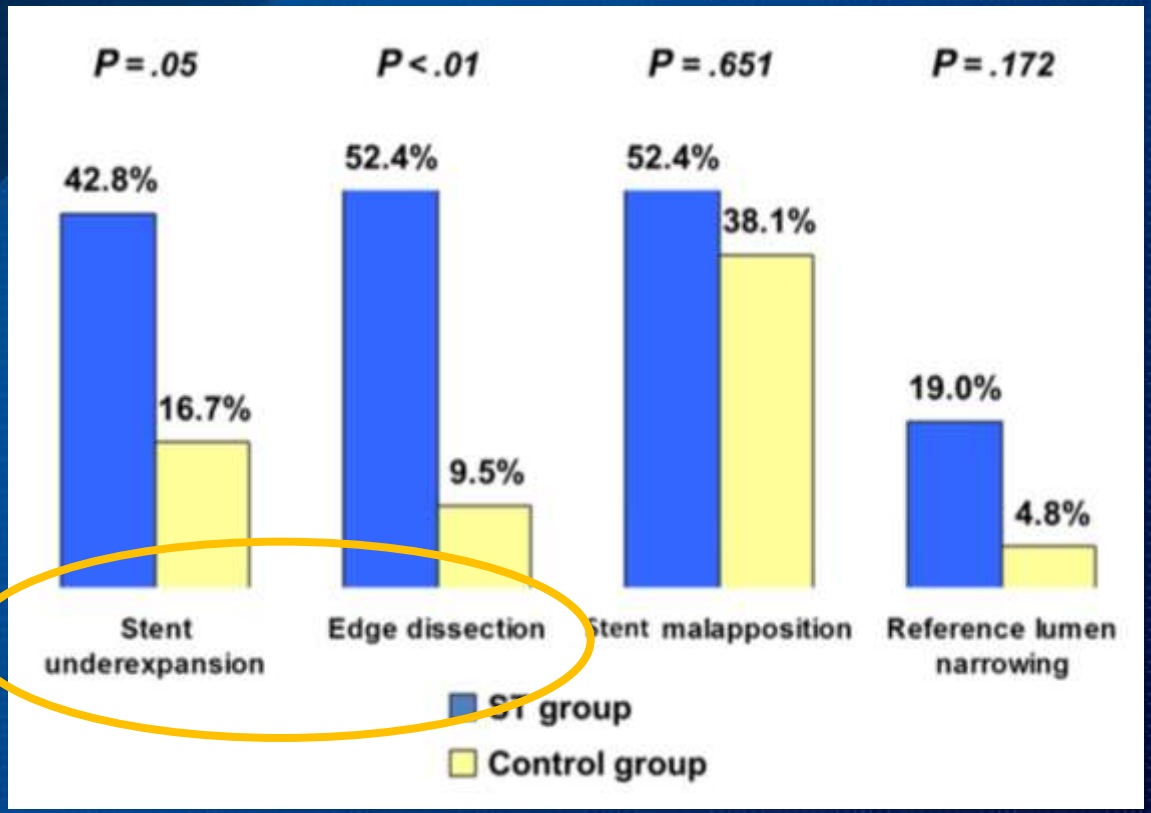
OCT results for subacute thrombosis

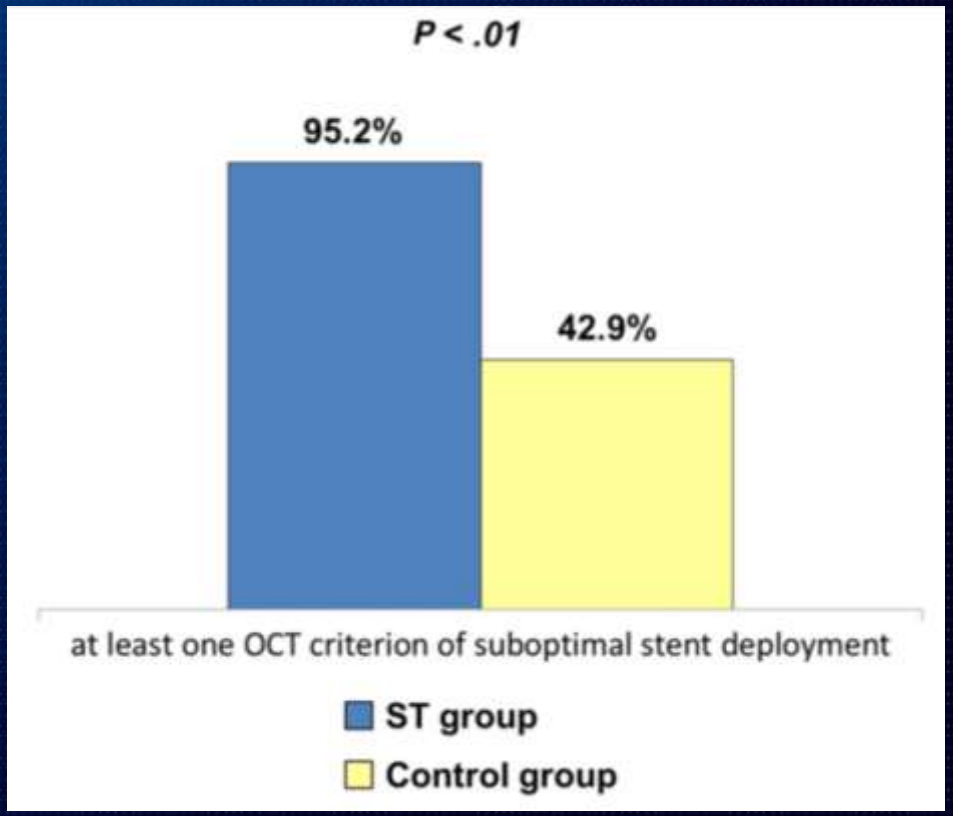


21 definite subacute ST

Am Heart J 2015;169:249-256

OCT results in subacute thrombosis & control





Am Heart J 2015;169:249-256

Clinical events of stent malapposition

Acute stent malapposition: 62%
Late-persistent stent malapposition: 31%
Late-acquired stent malapposition: 15%.

	Overall Patients (N=351)	Both Late-Persistent and Late-Acquired Stent Malapposition (n=23)	Late-Acquired Stent Malapposition Alone (n=31)	Late-Persistent Stent Malapposition Alone (n=45)	No Stent Malapposition (n=252)	*P* Value
Follow-up duration after PCI, mo	28.6±10.3	24.3±4.3	27.7±10.0	28.4±9.2	29.1±10.8	0.175
Follow-up duration after follow-up OCT, mo	22.8±10.4	18.4±4.4	22.0±10.4	22.6±8.9	23.3±10.9	0.180
Composite of clinical events	10 (2.9%)	0 (0%)	1 (3.2%)	1 (2.2%)	8 (3.2%)	1.0
Cardiovascular death	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)	1 (0.4%)	1.0
Nonfatal myocardial infarction	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)	1 (0.4%)	1.0
Stent thrombosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1.0
Target lesion revascularization	8 (2.3%)	0 (0%)	1 (3.2%)	1 (2.2%)	6 (2.4%)	0.900

Circ Cardiovasc Interv. 2014;7:88-96

Post-procedure OCT & clinical outcome

JACC: CARDIOVASCULAR IMAGING
VOL. 8, NO. 11, 2015

PUBLISHED BY ELSEVIER INC.
ISSN 1936-878X/$36.00
http://dx.doi.org/10.1016/j.jcmg.2015.08.013

Clinical Impact of OCT Findings During PCI

The CLI-OPCI II Study

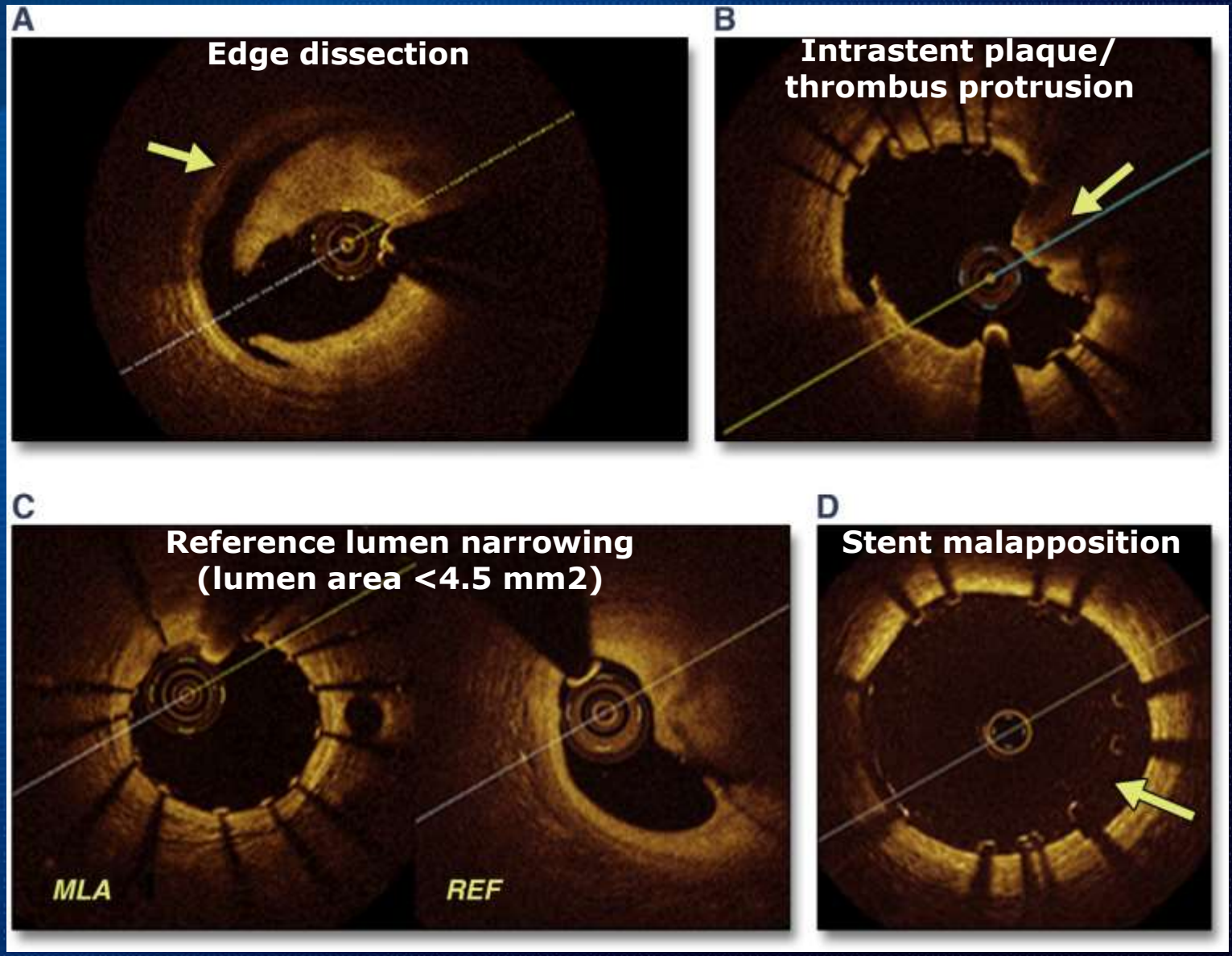
Francesco Prati, MD, PhD,*† Enrico Romagnoli, MD, PhD,† Francesco Burzotta, MD, PhD,‡ Ugo Limbruno, MD,§ Laura Gatto, MD,*† Alessio La Manna, MD,‖ Francesco Versaci, MD,¶ Valeria Marco, RN,† Luca Di Vito, MD, PhD,* Fabrizio Imola, MD,* Giulia Paoletti, RN,† Carlo Trani, MD,‡ Corrado Tamburino, MD,‖ Luigi Tavazzi, MD,# Gary S. Mintz, MD**

1,002 lesions (832 patients)

J Am Coll Cardiol Img 2015;8:1297–305

울산대학교병원 ULSAN UNIVERSITY HOSPITAL

OCT criteria of suboptimal stent implantation



J Am Coll Cardiol Img 2015;8:1297–305

Suboptimal OCT findings

	All Lesions (N = 984)	Lesion With MACE (n = 125)	Lesion Without MACE (n = 859)	p Value
Suboptimal OCT criteria				
Minimum in-stent lumen area <4.5 mm^2	230 (23.4)	51 (40.8)	179 (20.8)	<0.001
In-stent lumen underexpansion†	233 (23.7)	38 (30.4)	195 (22.7)	0.07
Malapposition >200 μm	485 (49.3)	63 (50.4)	422 (49.1)	0.85
Intrastent plaque/thrombus protrusion >500 μm	289 (29.4)	38 (30.4)	251 (29.2)	0.83
Edge dissection >200 μm	125 (12.7)	25 (20.0)	100 (11.6)	0.013
Distal dissection	69 (7.0)	20 (16.0)	49 (5.7)	<0.001
Proximal dissection	65 (6.6)	8 (6.4)	57 (6.6)	0.92
Reference narrowing‡	74 (7.5)	38 (30.4)	36 (4.2)	<0.001
Distal narrowing	57 (5.8)	28 (22.4)	29 (3.4)	<0.001
Proximal narrowing	24 (2.4)	14 (11.2)	10 (1.2)	<0.001
At least 1 predictive OCT criterion§	305 (31.0)	74 (59.2)	231 (26.9)	<0.001

J Am Coll Cardiol Img 2015;8:1297–305

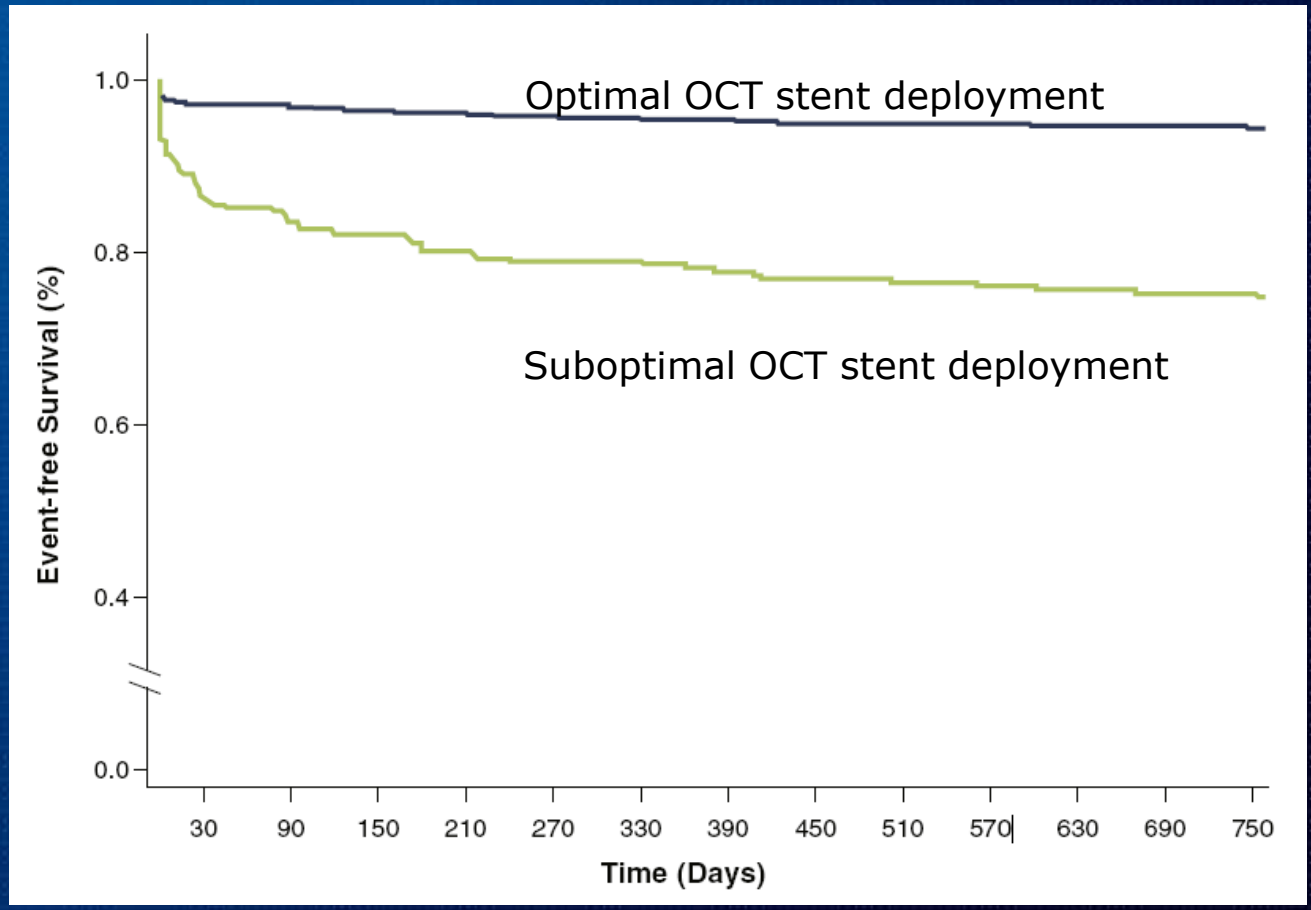
울산대학교병원 ULSAN UNIVERSITY HOSPITAL

Suboptimal OCT deployment & clinical outcome

	All Patients (N = 832)	Patients With Suboptimal OCT Deployment* (n = 254)	Patients With Optimal OCT Deployment (n = 578)	HR (95% CI)	p Value
MACE	105 (12.6)	64 (25.2)	41 (7.1)	4.41 (2.9-6.8)	0.001
Death	24 (2.9)	11 (4.3)	13 (2.2)	1.97 (0.9-4.5)	0.104
Myocardial infarction	64 (7.7)	42 (16.5)	22 (3.8)	5.01 (2.9-8.6)	0.001
Periprocedural	22 (2.6)	11 (4.3)	11 (1.9)	2.33 (1.0-5.5)	0.050
During follow-up	42 (5.1)	31 (12.2)	11 (1.9)	7.17 (3.5-14.5)	0.001
Target lesion revascularization	56 (6.7)	42 (16.5)	14 (2.4)	7.98 (4.3-14.9)	0.001
Stent thrombosis	30 (3.6)	26 (10.2)	4 (0.7)	16.36 (5.6-47.4)	0.001
Days of follow-up	319 (123-576)	312 (118-584)	324 (129-575)	-	0.536

*Either in-stent minimum lumen area <4.5 mm2, dissection >200 mm at the distal stent edge, or distal or proximal reference narrowing

Survival free of MACE according to optimal versus nonoptimal stent

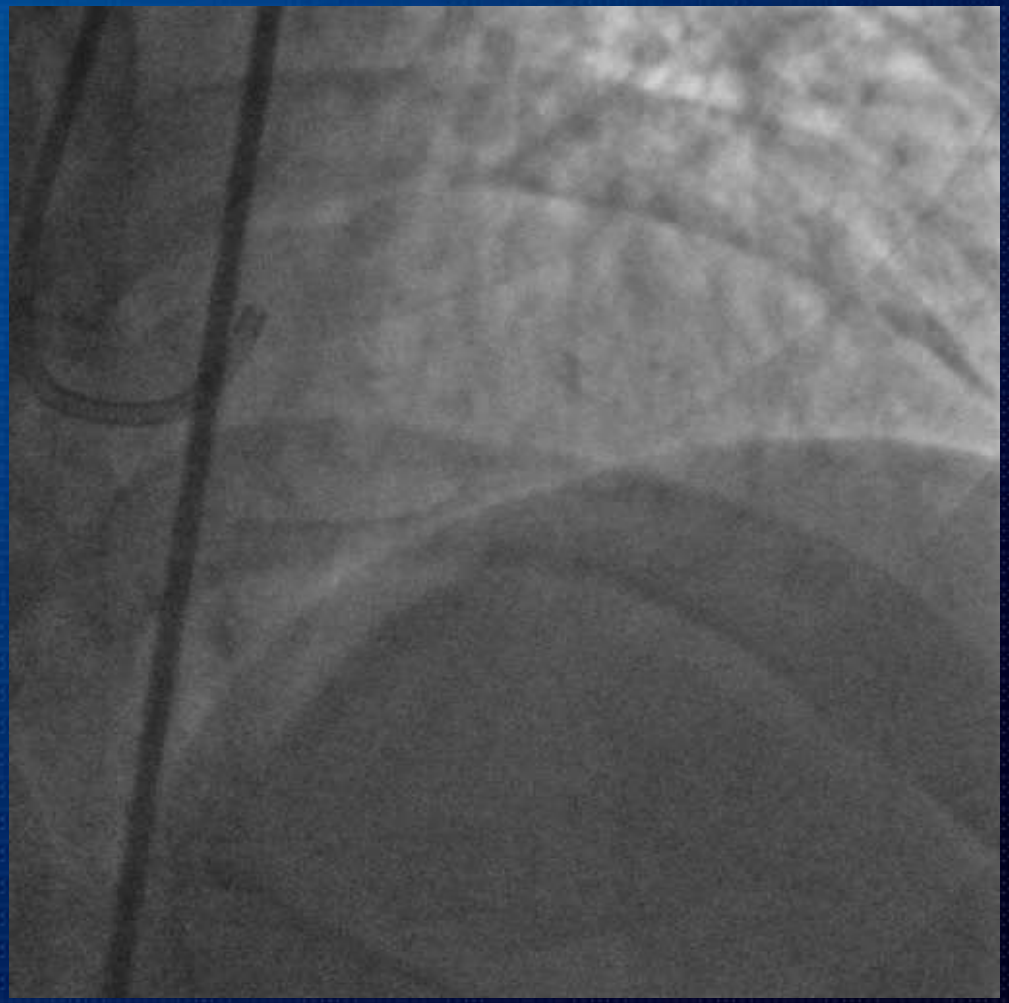


*Either in-stent minimum lumen area <4.5 mm2, dissection >200 mm at the distal stent edge, or distal or proximal reference narrowing

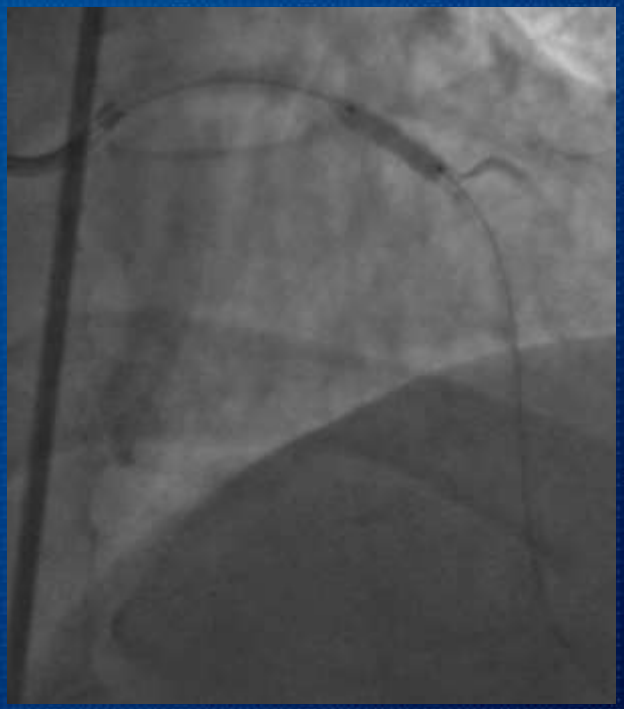
Chest pain at exertion
Aggravation, 1 week ago

Case 1: M/61

Hypertension (+)
Dyslipidemia (+)



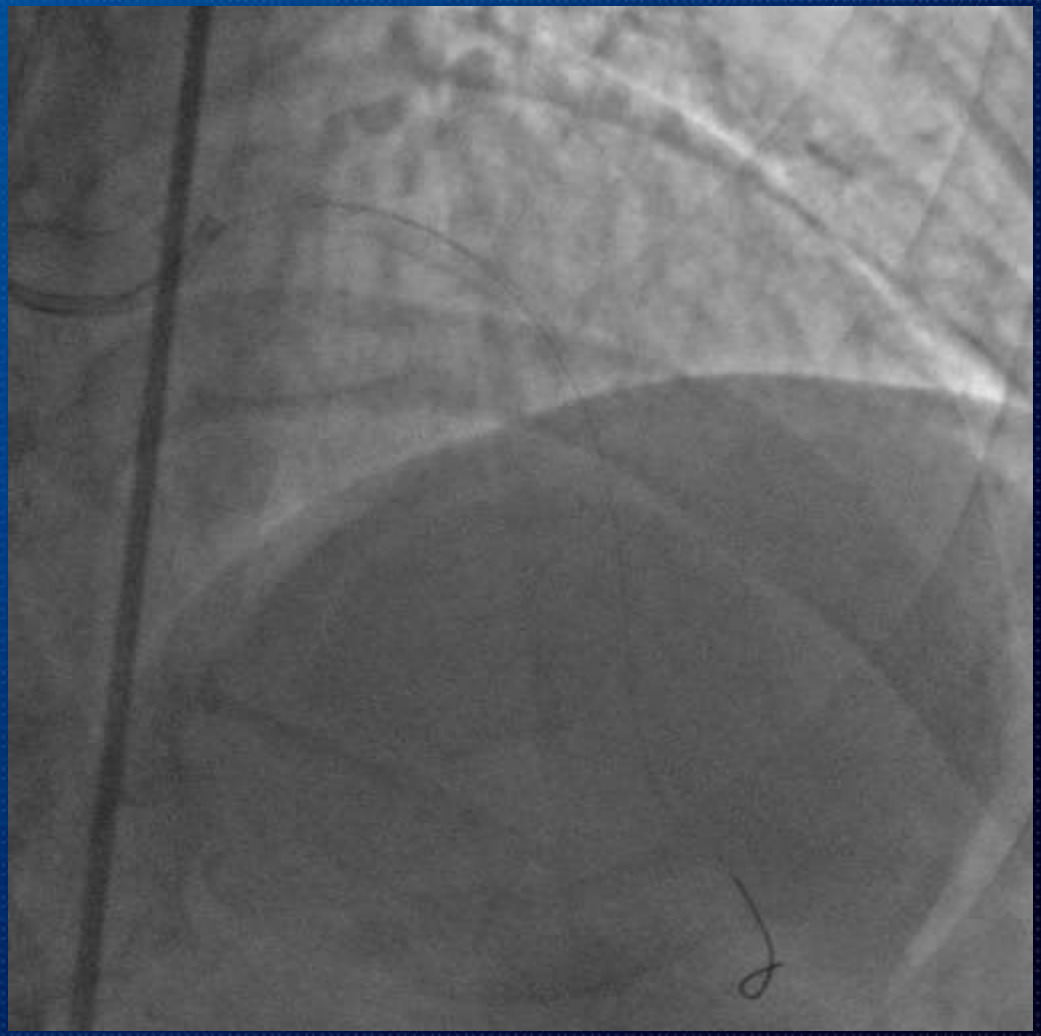
Stenting at pLAD



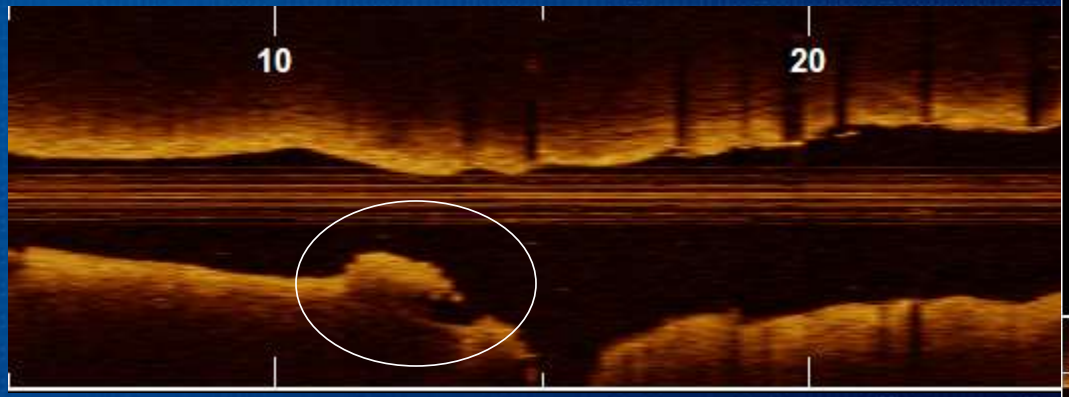
Balloon angioplasty

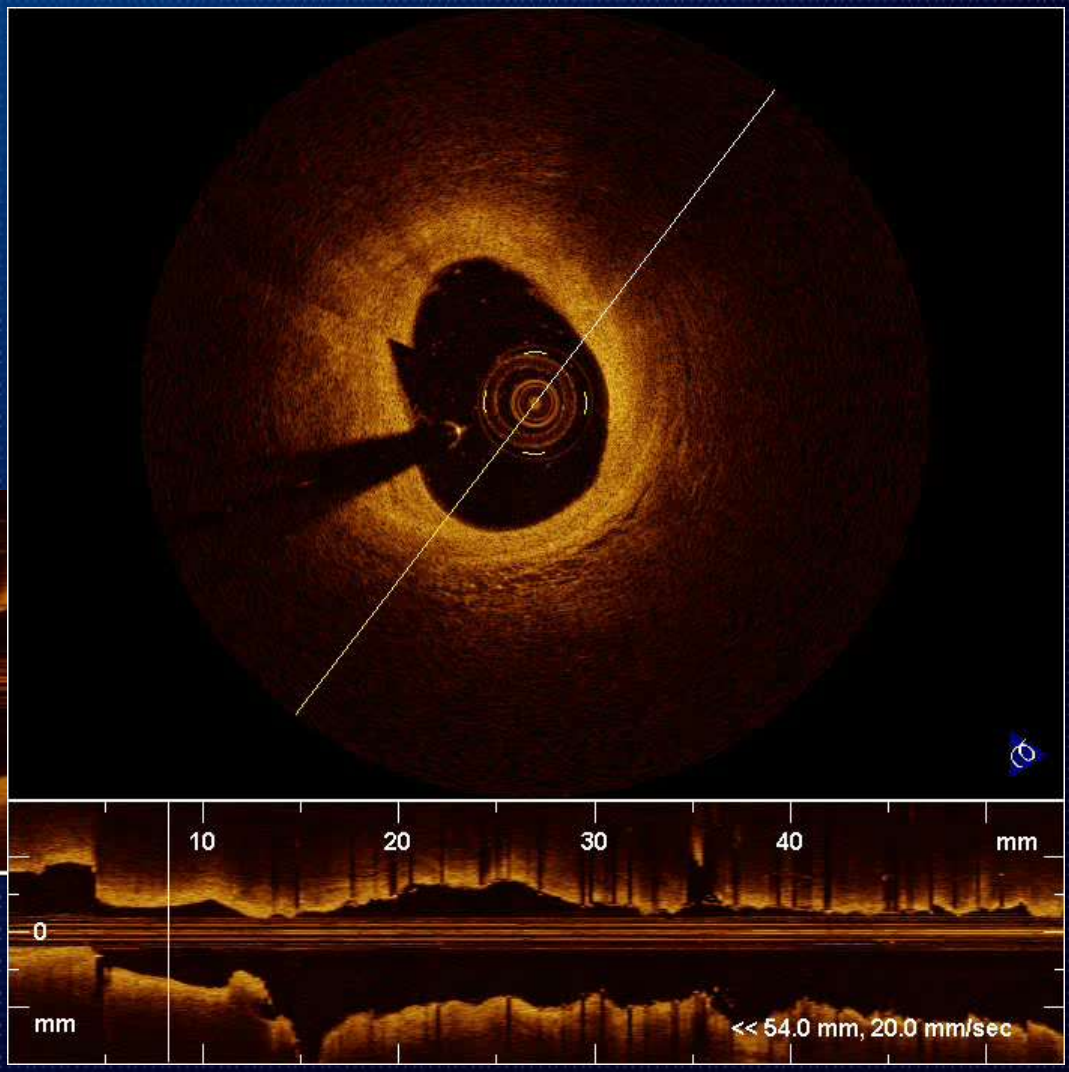
Stenting

Coronary angiography after stenting

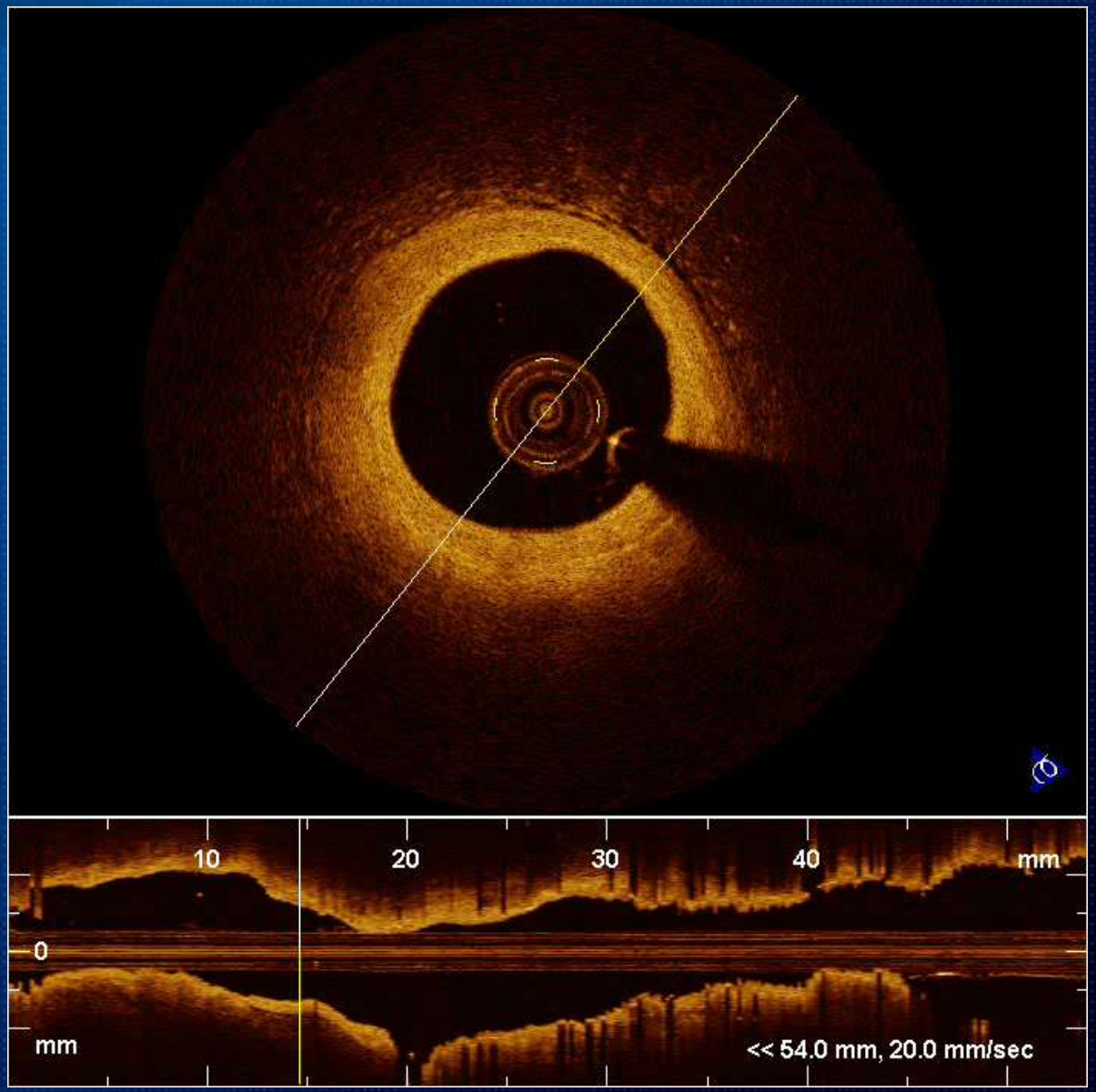


Oops… by final OCT



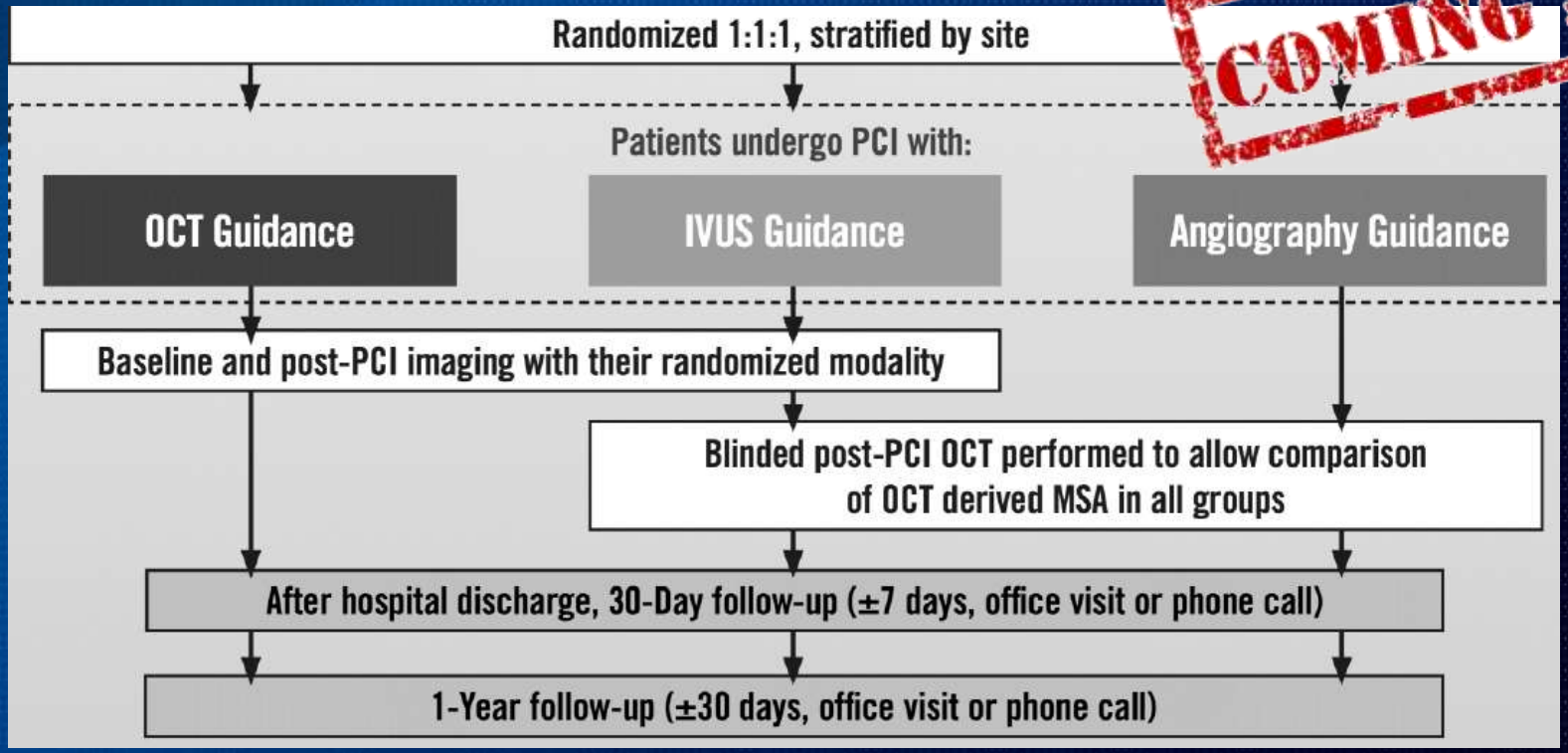


9 months later



ILUMIEN III: Optimize PCI

COMING SOON



Scope: Up to 35 sites (US, EMEA, Japan)

420 randomized subjects

Endpoint: Safety/Efficacy Study

Primary Efficacy Endpoint (powered).

: Post-PCI MSA assessed by OCT in each randomized arm

울산대학교병원 ULSAN UNIVERSITY HOSPITAL

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

COMING SOON

OPtical Frequency Domain Imaging vs. INtravascular Ultrasound in Percutaneous Coronary InterventiON (OPINION)

This study is ongoing, but not recruiting participants.

Sponsor:
Translational Research Informatics Center, Kobe, Hyogo, Japan

Collaborator:
Wakayama Medical University

Information provided by (Responsible Party):
Translational Research Informatics Center, Kobe, Hyogo, Japan

ClinicalTrials.gov Identifier:
NCT01873027

First received: May 26, 2013
Last updated: August 11, 2014
Last verified: August 2014
History of Changes

Primary Outcome Measures:

- Target Vessel Failure (TVF) [Time Frame: 12 months after PCI] [Designated as safety issue: Yes]

  The composite endpoint comprised of cardiac death, target vessel-related myocardial infarction (MI) and clinically-driven target vessel revascularization (TVR)

Enrollment:	829
Study Start Date:	June 2013
Estimated Study Completion Date:	December 2015
Estimated Primary Completion Date:	December 2015 (Final data collection date for primary outcome measure)

Take Home Messages

- OCT allow high-resolution images of pre-, peri- and post-procedure, so we can assess lesion characteristics, stent optimization, and procedure complications with it.
- Abnormal post-stent OCT findings are frequent.
- Procedural strategy has been influenced by OCT findings of both pre-PCI and post-PCI in the majority of patients.
- The potential impact of OCT guidance to optimize PCI outcome seems promising and requires further investigations in large-scale prospective trials.