



CUORE
E NON SOLO
INTERVENTIONAL
CARDIOLOGY

14/15.04.23
GENOVA

CORONARY IMAGING & PHYSIOLOGY
INNOVATION IN TRANSCATHETER
INTERVENTIONS

“Come usare l’imaging per guidare l’impianto e l’ottimizzazione dello stent?”



Dott. Massimo Fineschi
Cardiologia Interventistica
Azienda Ospedaliero-Universitaria Senese
Siena

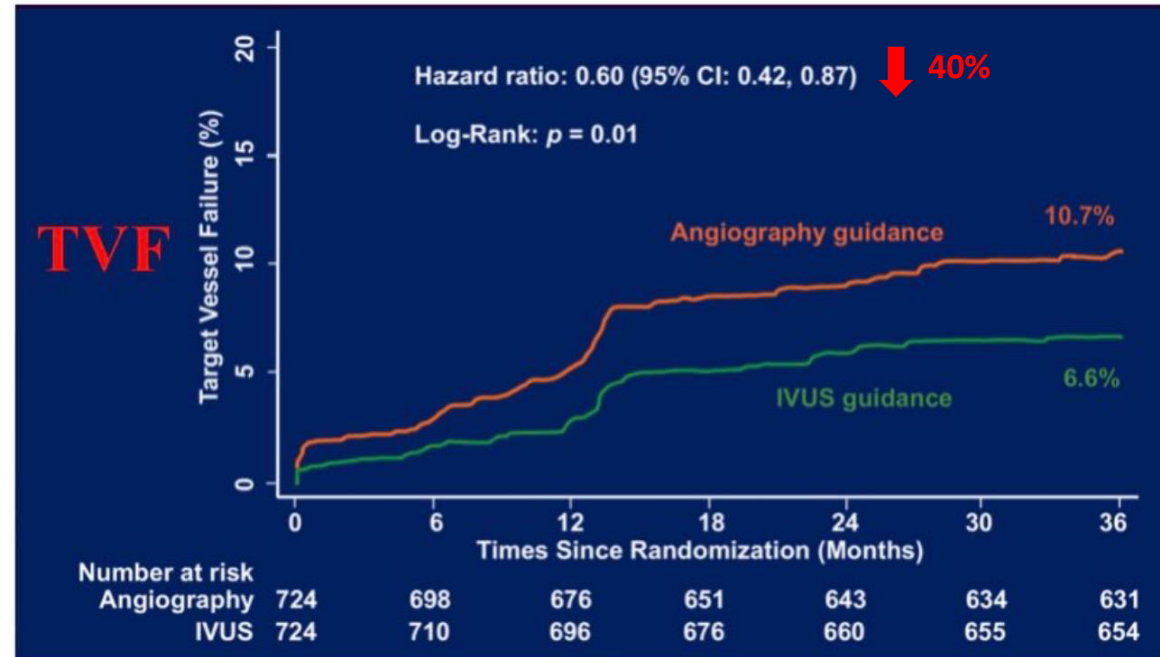


Clinical use of intracoronary imaging

- Randomized controlled trials and registries consistently support procedural and long-term benefit with the use of intravascular imaging (IVI) for percutaneous coronary intervention (PCI) guidance
- The benefits of intracoronary imaging depend largely on the interpretation and the operator's reaction to these findings. Imaging acquisition alone will not be sufficient to impact on outcome !

ULTIMATE

3-year Clinical FU



Intravascular Imaging–Guided or Angiography-Guided Complex PCI

Joo Myung Lee, M.D., Ph.D., M.P.H., Ki Hong Choi, M.D., Ph.D., Young Bin Song, M.D., Ph.D., Jong-Young Lee, M.D., Ph.D., Seung-Jae Lee, M.D., Ph.D., Sang Yeub Lee, M.D., Ph.D., Sang Min Kim, M.D., Ph.D., Kyeong Ho Yun, M.D., Ph.D., Jae Young Cho, M.D., Ph.D., Chan Joon Kim, M.D., Ph.D., Hyo-Suk Ahn, M.D., Ph.D., Chang-Wook Nam, M.D., Ph.D., et al., for the RENOVATE-COMPLEX-PCI Investigators*

Objective: to investigate whether intravascular imaging PCI using IVUS or OCT would improve clinical outcomes compared with angiography guided PCI in patients with complex artery lesions

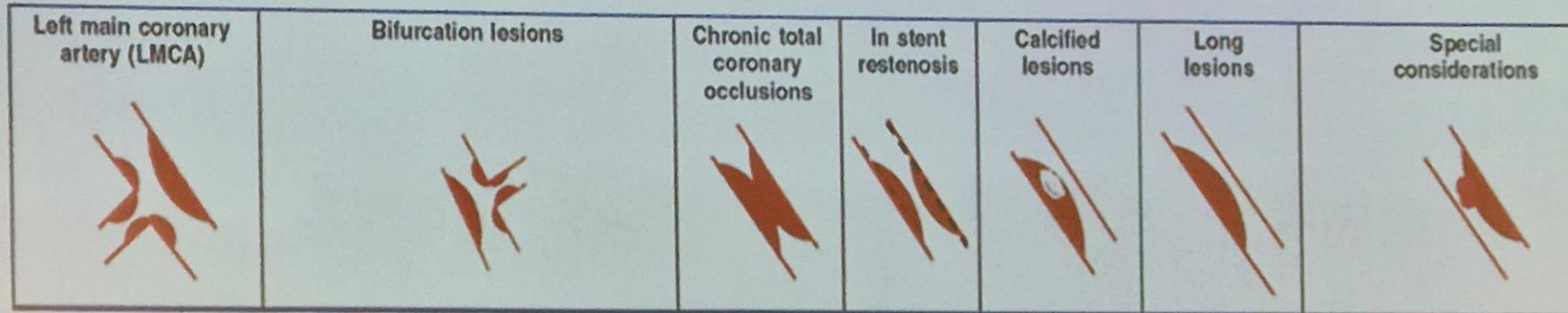
Primary Hypothesis

Intravascular imaging-guided PCI would reduce TVF compared with angiography-guided PCI
In treatment of patients with **complex coronary artery lesions**

Study design

RENOVATE-COMPLEX-PCI Trial (NCT03381872)

1,620 Patients with Complex Coronary Artery Lesions Undergoing PCI



Randomization (2:1) for Treatment Strategy of Target Lesions
(Stratified by acute coronary syndrome and participating centers)

Imaging-Guided Strategy
N = 1,080

Angiography-Guided Strategy
N = 540

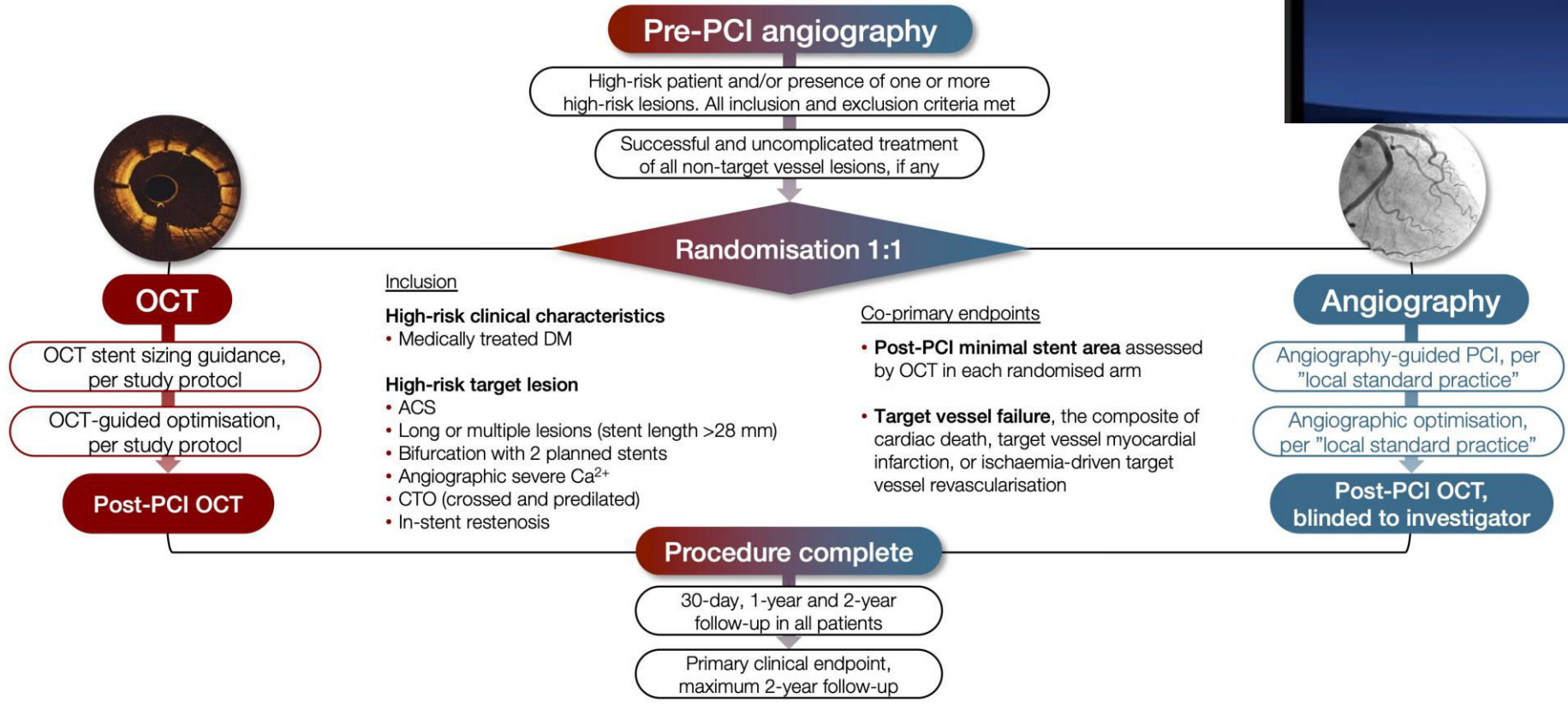
All patients were followed until 1 year after last patient enrollment.



VISUAL ILLUSTRATION. Optical Coherence Tomography-guided Coronary Stenting Compared to Angiography: Design and Rationale of ILUMIEN IV: OPTIMAL P

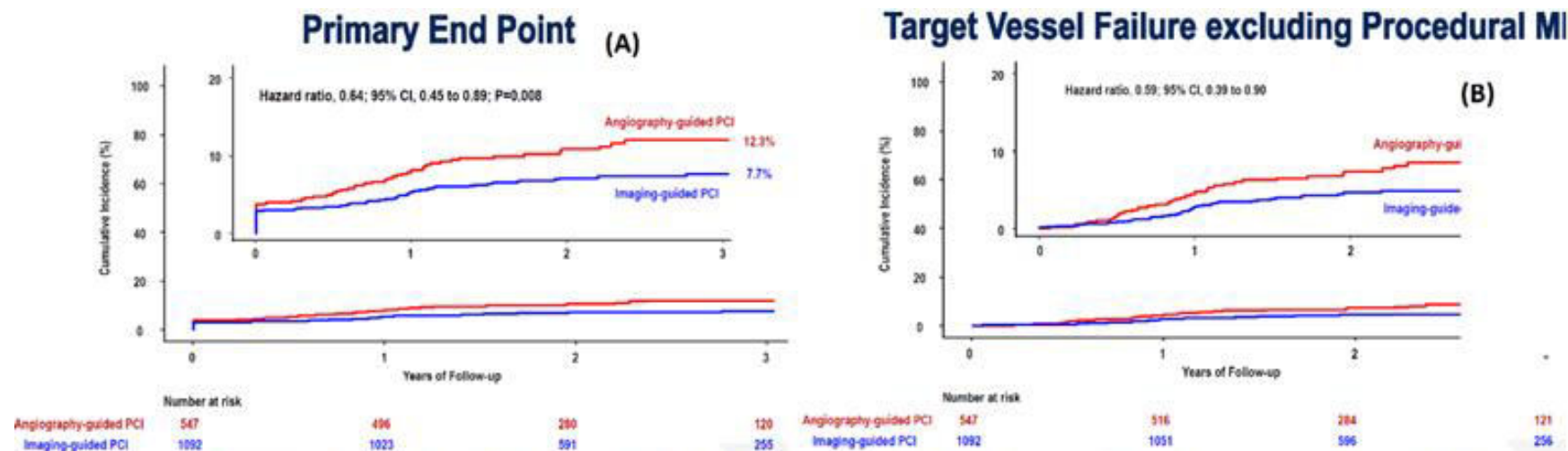
ILUMIEN IV: HYPOTHESIS

In high-risk patients and complex lesions, OCT-guided PCI compared to angiography-guided PCI will reduce TVF.

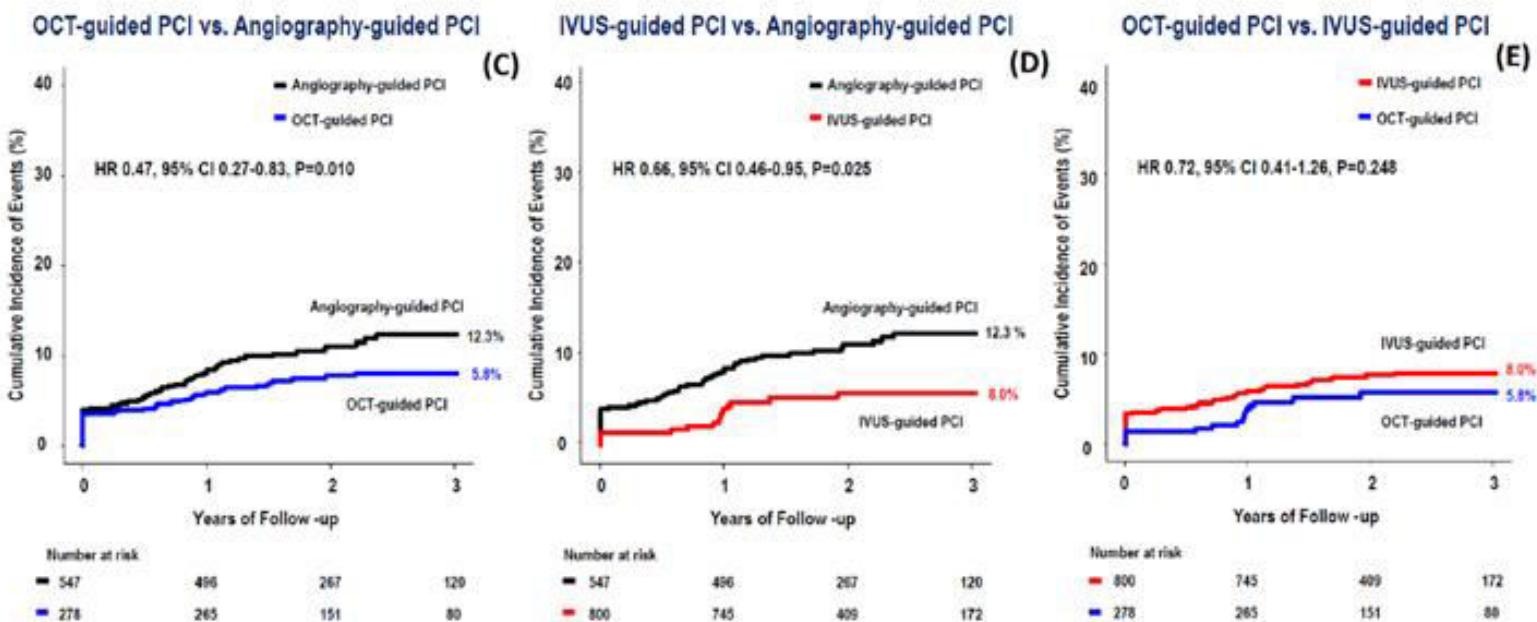


Abbreviations: ACS, acute coronary syndrome; CTO, chronic total occlusion; DM, diabetes mellitus; OCT, optical coherence tomography; PCI, percutaneous coronary intervention.

Use of intravascular optical coherence tomography or intravascular ultrasound to guide stent implantation. The choice is yours!



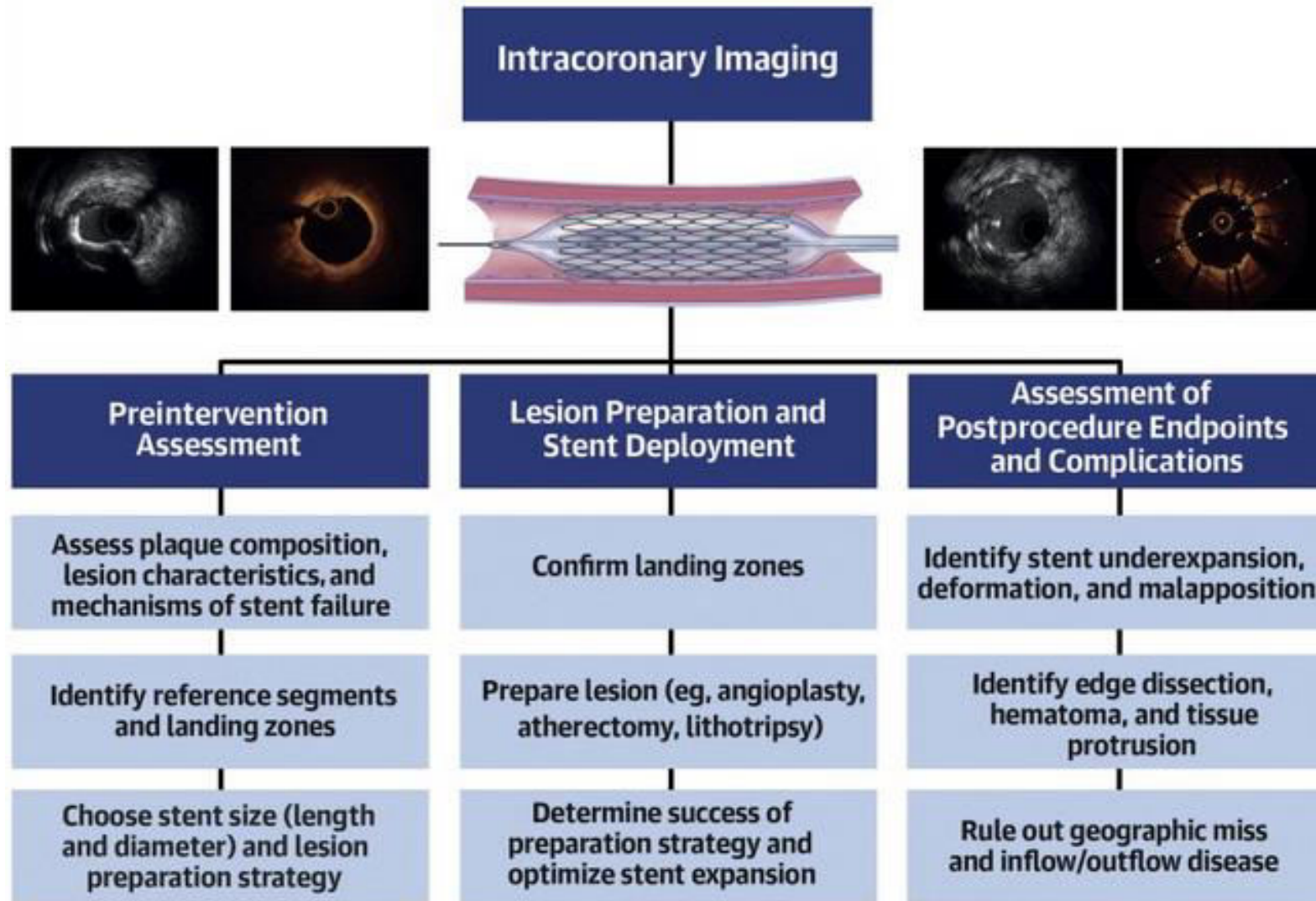
OCT-guided PCI vs. IVUS-guided PCI vs. Angiography-PCI



CENTRAL ILLUSTRATION IVUS and OCT: Similarities and Differences

OCT				IVUS		
Very good	Good	Feasible	Pre-PCI	Feasible	Good	Very good
●	●	●	Severity of calcium	●	●	
		●	Prediction of slow flow	●		
	●	●	Stent sizing by vessel wall	●	●	●
●	●	●	Stent length to cover normal to normal	●	●	●
			Post-PCI			
●	●	●	Stent expansion	●	●	●
●	●	●	Tissue protrusion through strut	●	●	
●	●	●	Stent malapposition	●	●	
	●	●	Stent deformation (frequently at aorto-ostium)	●	●	
●	●	●	Stent edge dissection	●	●	
●	●	●	Residual disease at stent edge	●	●	●
			Follow-up			
●	●	●	Old stent expansion	●	●	●
	●	●	Tissue coverage	●		
●	●	●	Neointimal hyperplasia	●	●	●
	●	●	Stent fracture	●	●	
●	●	●	Stent malapposition	●	●	
		●	Positive remodeling of vessel wall	●	●	●
●	●	●	Neoatherosclerosis	●	●	

CENTRAL ILLUSTRATION: Best Practice Summary for Use of Intracoronary Imaging



Modern OCT Guided PCI Workflow | MLD MAX

Each OCT run serves a separate purpose. The pre-PCI run helps determine the PCI strategy, and the post-PCI run allows for optimization of the stent as needed.

Pre-PCI OCT | Strategize

MMORPHOLOGY

LLENGTH

DDIAMETER

Post-PCI OCT | Optimize

MMEDIAL DISSECTION

AAPPOSITION

EXPANSION

1. Morphology

Assess Plaque Composition

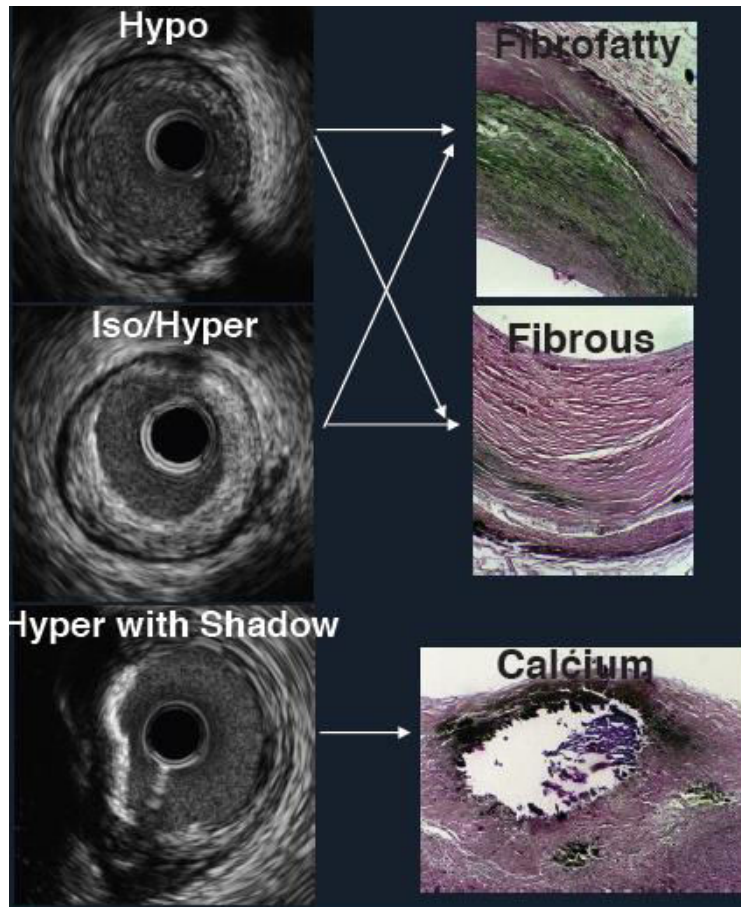
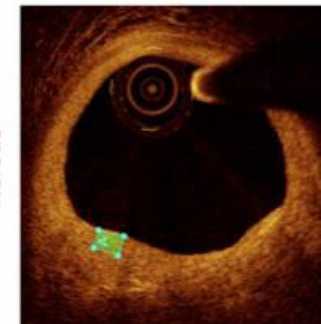
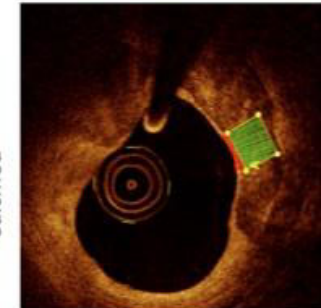
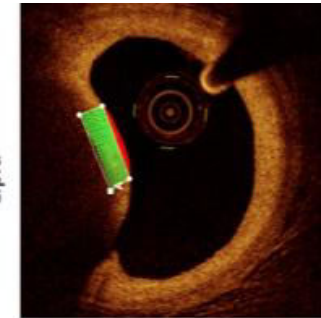


Table 2 Image characteristics of optical coherence tomography vs. IVUS

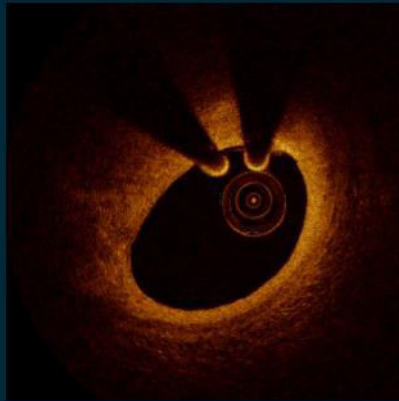
Tissue type	Image characteristics	
	OCT	IVUS
Fibre	Homogeneous High reflectivity Low attenuation	Homogeneous High reflectivity
Calcium	Sharp edges Low reflectivity Low attenuation	Very high reflectivity Shadowing
Lipid	Diffuse edges High reflectivity High attenuation	Low backscatter
Red thrombus	Medium reflectivity High attenuation	Medium-high reflectivity
White thrombus	Medium reflectivity Low attenuation	

OCT, optical coherence tomography.

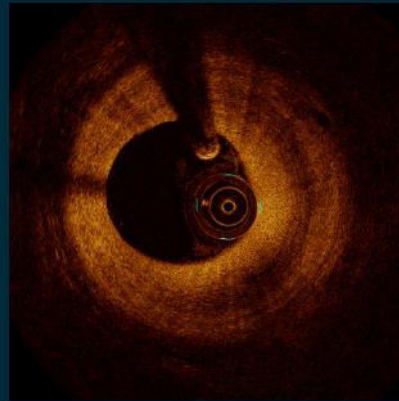


OCT **penetration** is due to plaque composition: penetration maximal for fibrotic tissue and progressively less for lipid and thrombus.

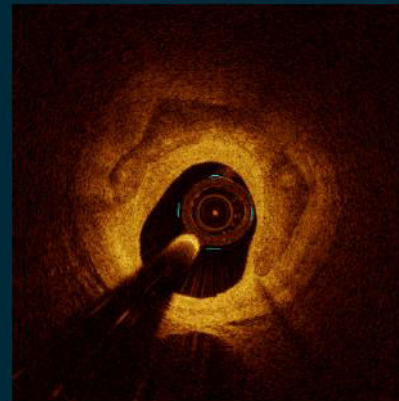
Morphology Guided Lesion Preparation



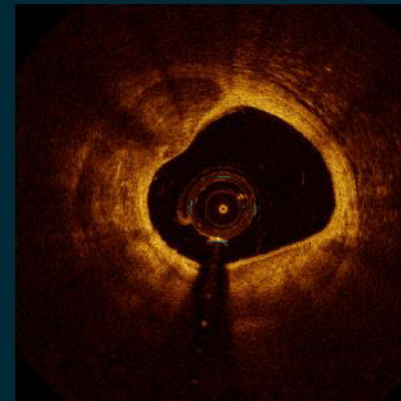
Lipidic



Fibrotic



Mild/Moderate Ca²⁺



Severe Ca²⁺

DIRECT STENTING¹

COMPLIANT BALLOON²

NON-COMPLIANT BALLOON³

ATHERECTOMY OR IVL⁴

THE CALCIUM PROBLEM



**ABSENCE OF
INTRAVASCULAR IMAGING**



UNDERESTIMATION OF CALCIUM



**INCREASED LIKELIHOOD OF IMPROPER
VESSEL PREP**



**STENT
UNDEREXPANSION**

**MORE
STENTS**

**INCREASE RISK OF
COMPLICATIONS**

**LONGER
PROCEDURES**

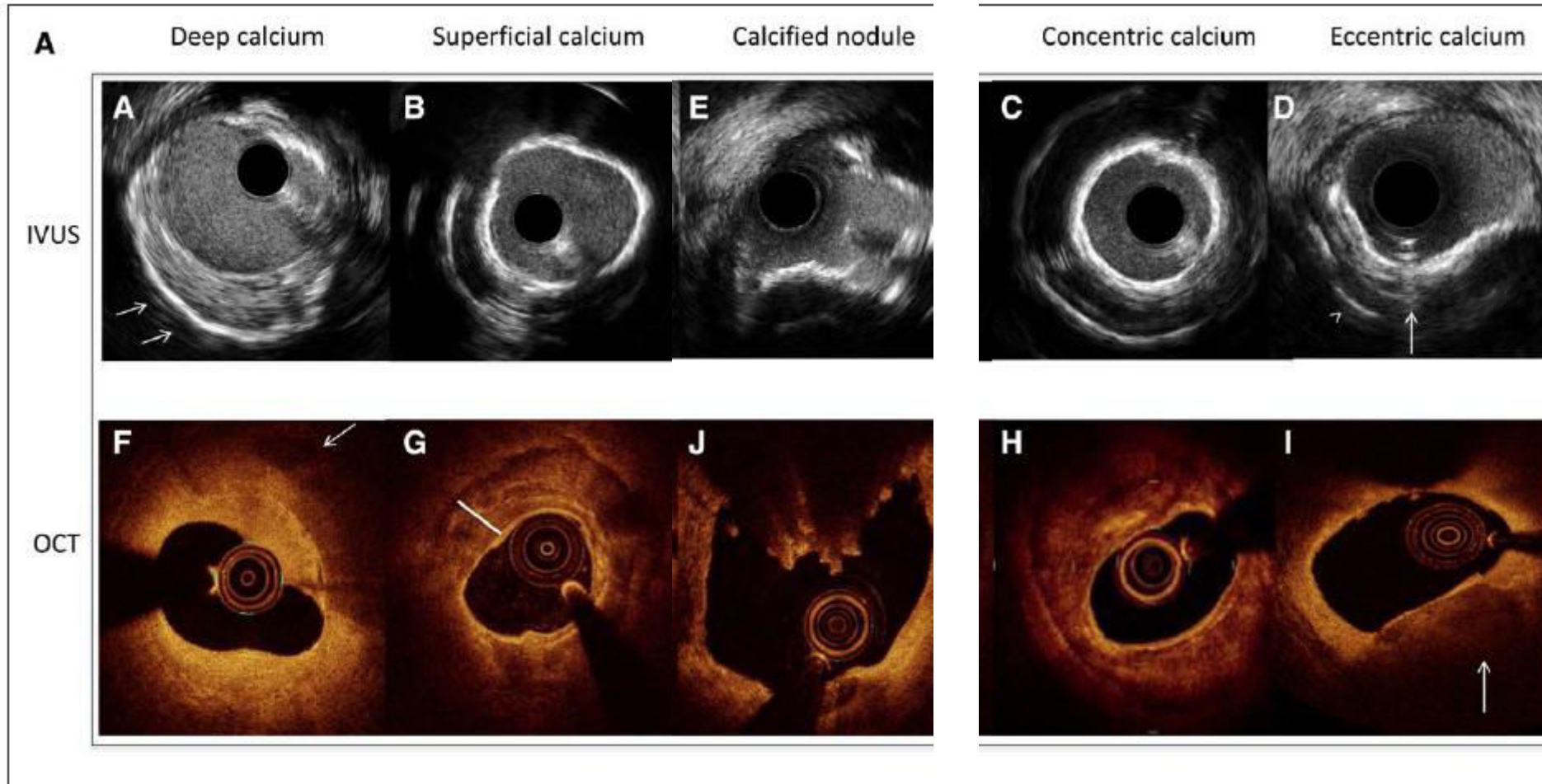


**STENT
MALAPPOSITION**



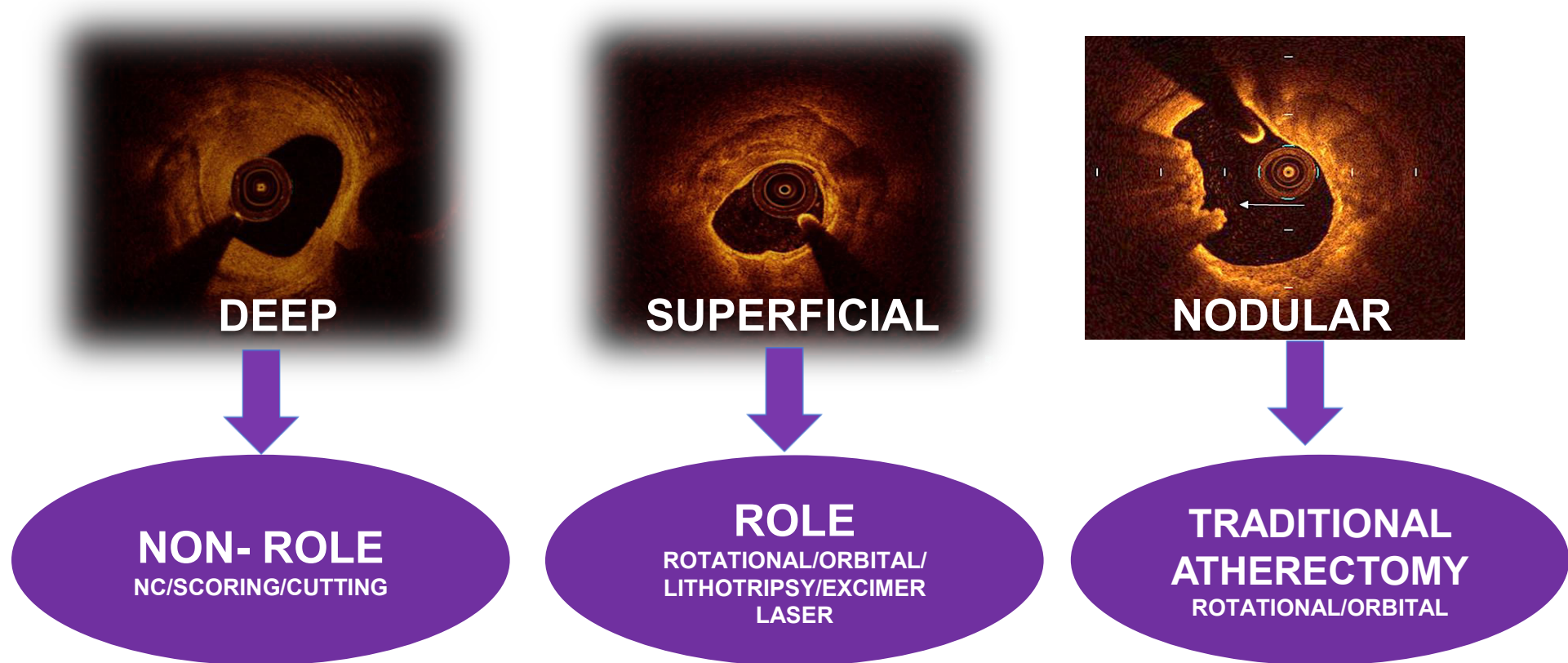
PRE-PCI detection of calcium

DEFINE TYPE CALCIUM...



DEFINE TYPE CALCIUM...

ROLE FOR CALCIUM MODIFICATION



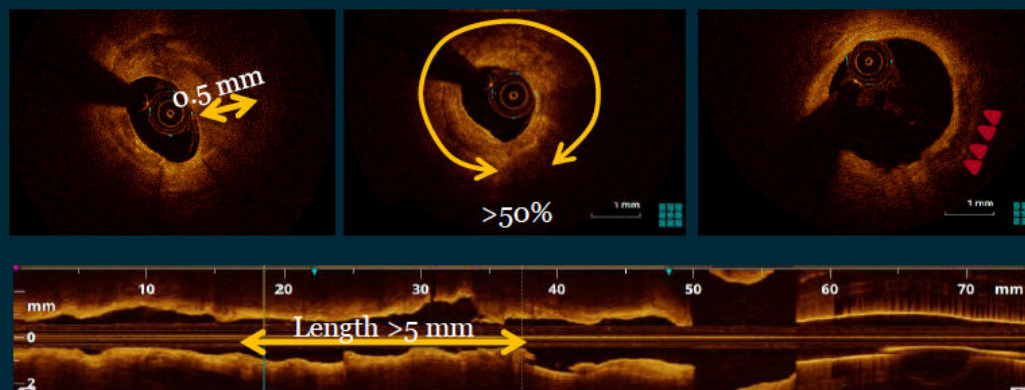
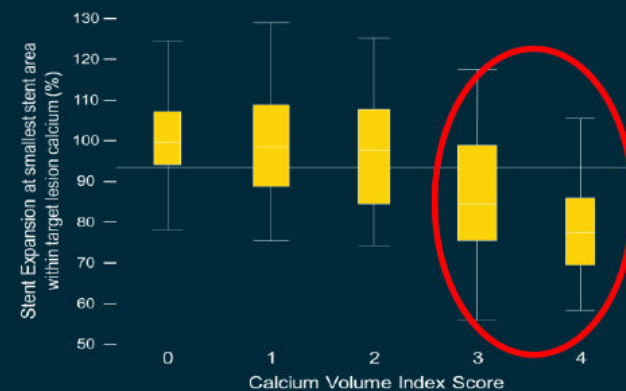
Influence of Ca²⁺ on Stent Expansion by OCT

OCT-Based Calcium Volume Index Score¹

1. Maximum Calcium Angle (°)	<ul style="list-style-type: none"> ≤ 90° ▶ 0 point 90° < Angle ≤ 180° ▶ 1 point > 180° ▶ 2 points
2. Maximum Calcium Thickness (mm)	<ul style="list-style-type: none"> ≤ 0.5 mm ▶ 0 point > 0.5 mm ▶ 1 point
3. Calcium Length (mm)	<ul style="list-style-type: none"> ≤ 5.0 mm ▶ 0 point > 5.0 mm ▶ 1 point
Total score	0 to 4 points

Rule of 5's

- 0.5 mm thickness
- 5.0 mm long
- 50% vessel arc



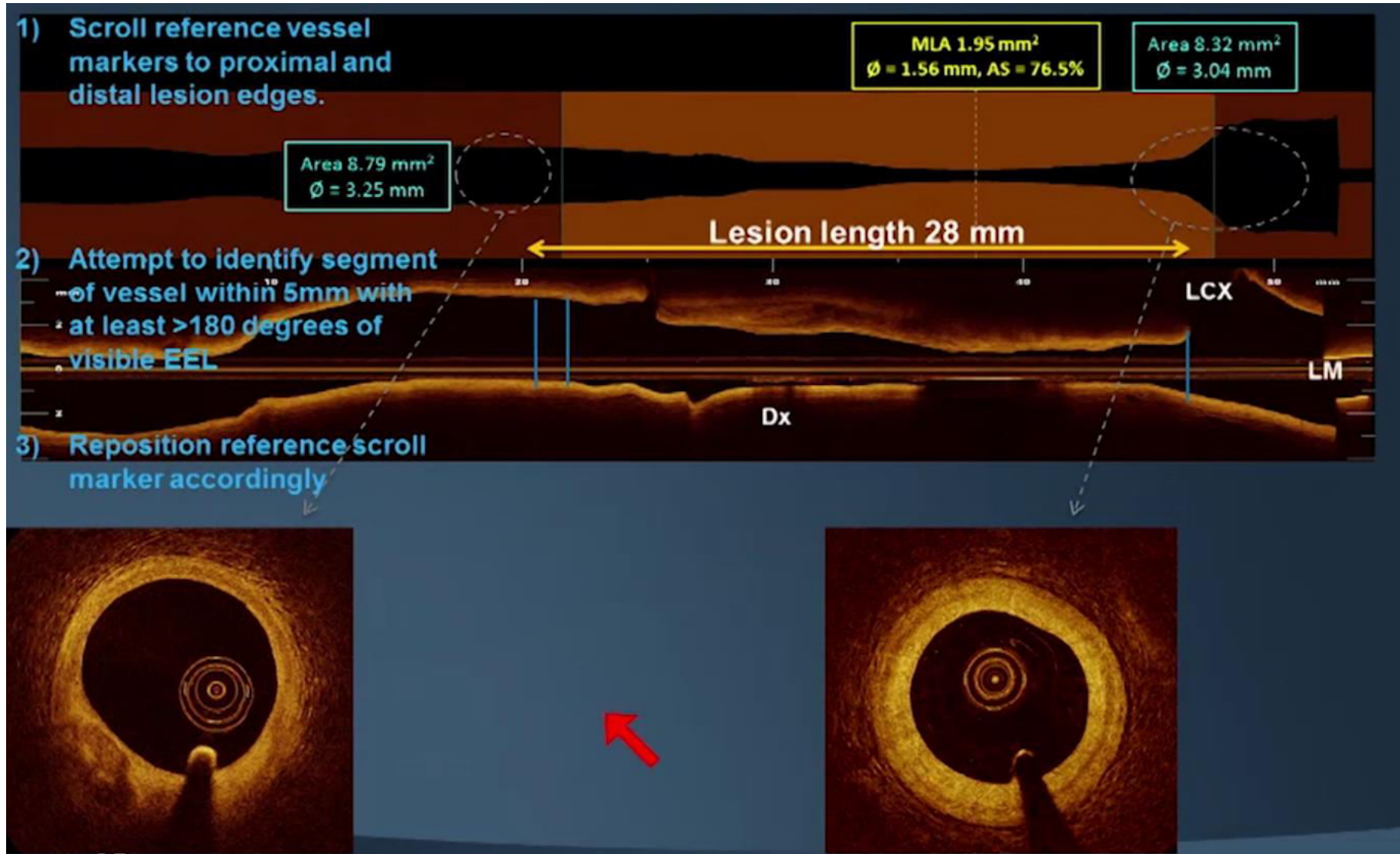
1. Fujino, A. et al. A new optical coherence tomography-based calcium scoring system to predict stent under expansion. *EuroIntervention*, April 2018; 13(18):e2182-e2189.

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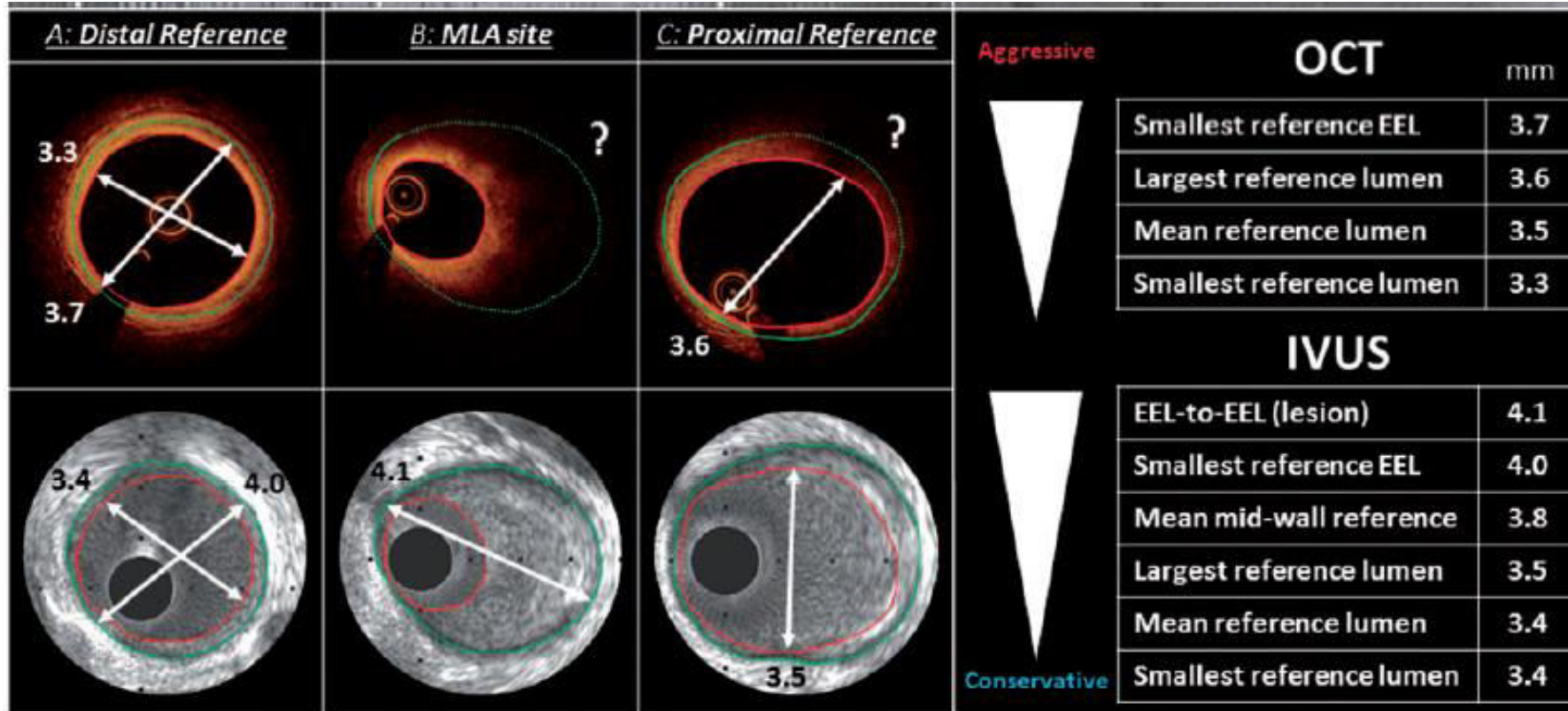
2. Identify Reference Segments (Prox & Dist)

Choose Stent Length: avoidance the landing zone within an area of residual plaque burden >50% and particularly lipid-rich plaque

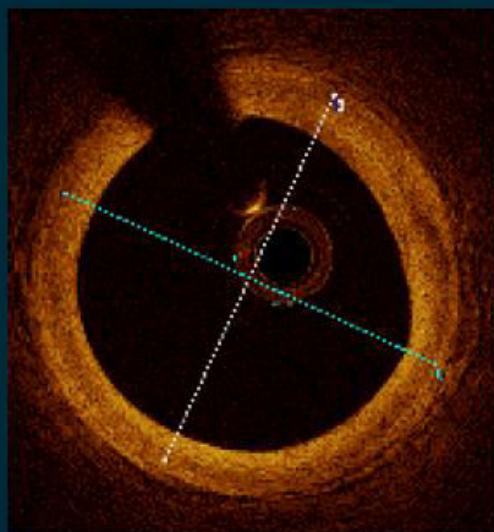


3. Diameter

Choose Stent Size (vessel size assessment)



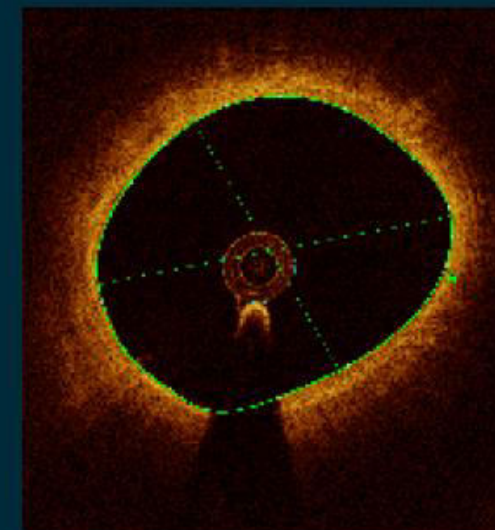
OCT Stent Sizing Algorithm



PRE-PCI OCT



Can the EEL be identified at the distal reference segment to allow vessel diameter measurement?



YES

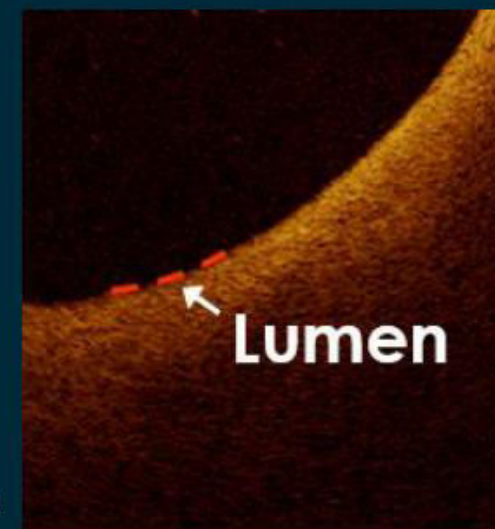
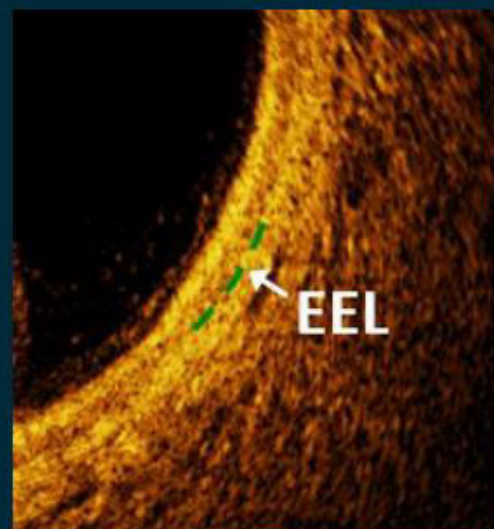


NO



Stent diameter decided by OCT measurement of mean EEL to EEL diameter rounded down to nearest stent size¹

Stent diameter decided by OCT measurement of mean lumen diameter rounded up to nearest stent size²



1. Ali, Z., et al., ILUMIEN III Study, Lancet Journal, 2016; 1-11. 2. Shlofmitz, E. et al. Algorithmic Approach for OCT Guided Stent Implantation During PCI. Intervent Cardiol Clin 7 (2018) 329-344.

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Modern OCT Guided PCI Workflow | MLD MAX

Each OCT run serves a separate purpose. The pre-PCI run helps determine the PCI strategy, and the post-PCI run allows for optimization of the stent as needed.

Pre-PCI OCT | Strategize

MMORPHOLOGY

LLENGTH

DDIAMETER

Post-PCI OCT | Optimize

MMEDIAL DISSECTION

AAPPOSITION

EXPANSION

SECTION 4

Medial Dissection

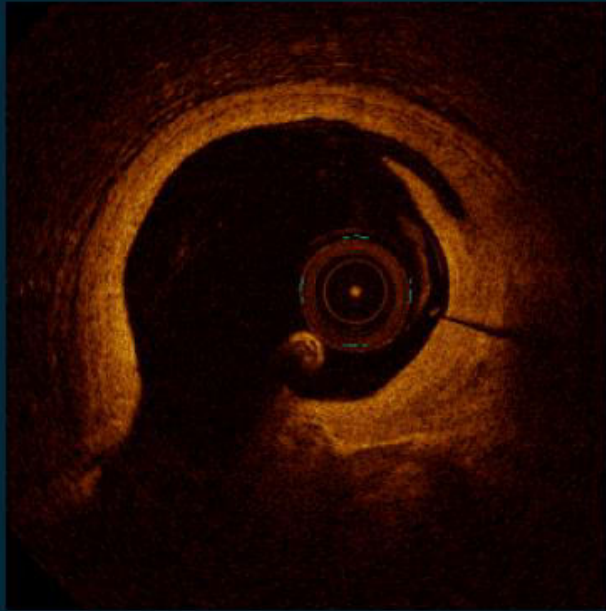
Dissections

Address Significant Dissection¹

Dissection penetrates medial layer, and is greater than 1 quadrant arc

Common Practice^{1,2}

Place additional stent (particularly for distal dissections)



Intimal



Medial



Intramural Hematoma

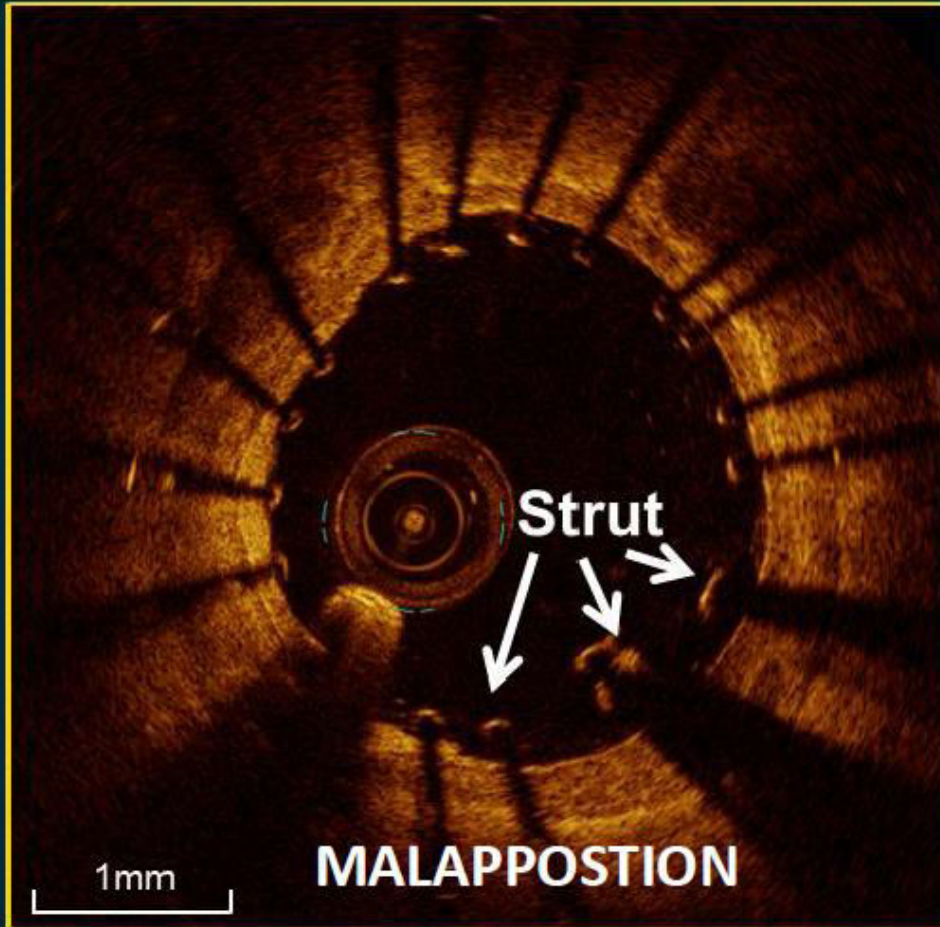
Edge Dissection: no major edge dissection in the proximal or distal reference segments defined as a location that is 5 mm from the edge of the stent, extends to the medial layer with potential to provide flow disturbance (defined as $\geq 60^\circ$ of the circumference of the vessel at site of dissection and/or ≥ 3 mm in length of the dissection flap)

SECTION 5

Apposition

Apposition

If the stent struts are in contact with the artery wall, the stent is apposed



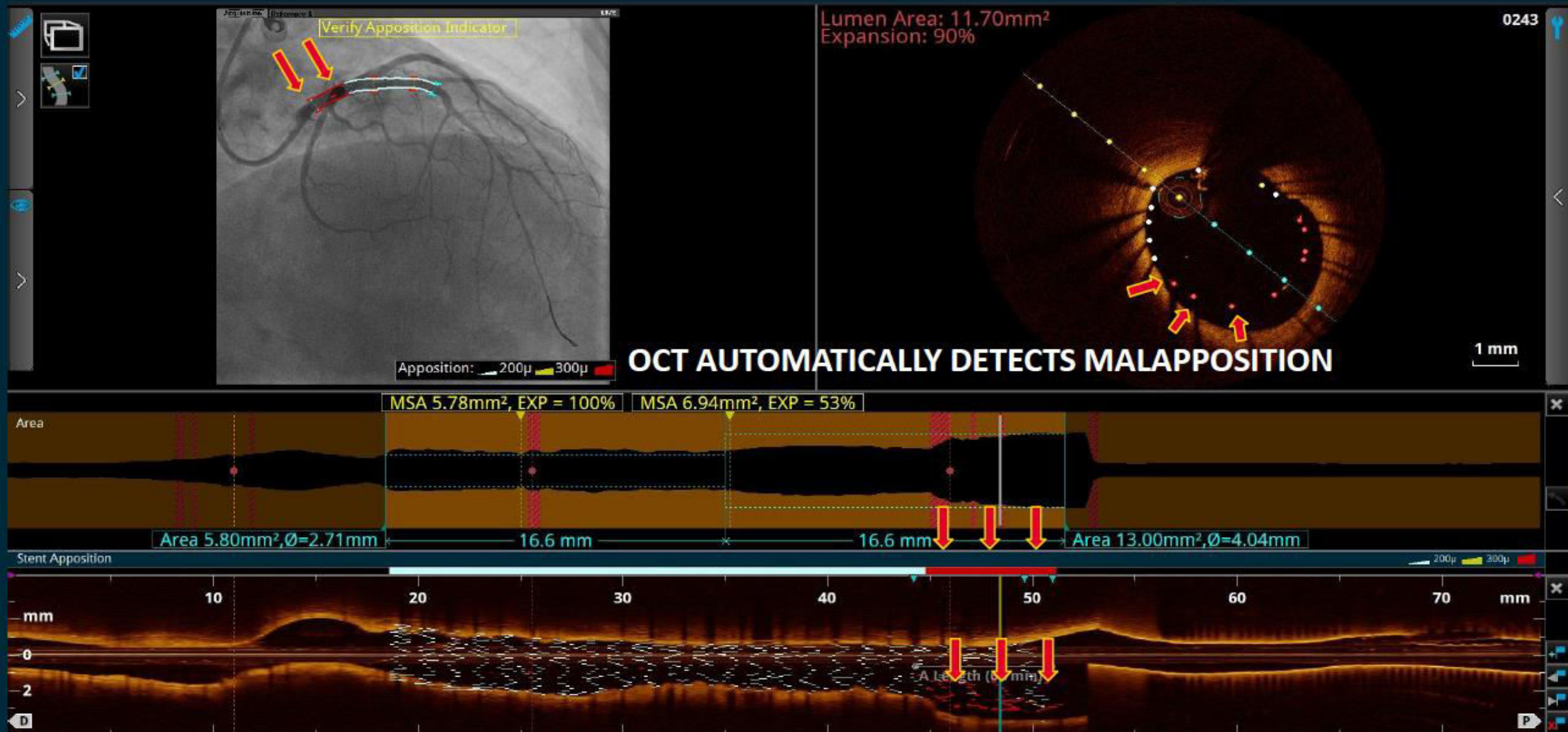
Address Gross Malapposition

- Longer than 3 mm,¹ and ≥ 0.3 mm from wall²

Common Practice³

- Dilate with semi-compliant balloon at low pressure

Apposition Indicator



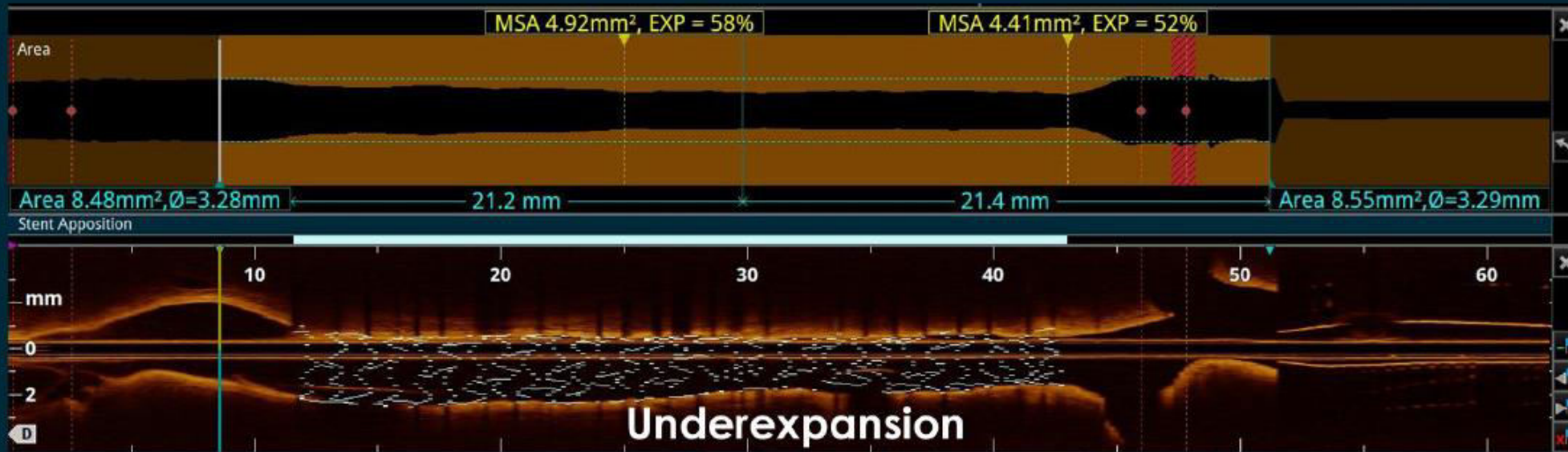
SECTION 6

eXpansion

Stent underexpansion is established as a major predictor of stent failure (restenosis/thrombosis)
Stent expansion describes the minimum stent CSA either as an absolute measure (**absolute expansion**) or compared with the predefined reference area (**relative expansion**: prox-dist-average)

eXpansion

If the stent is **expanding** the lumen, holding the lesion close to, or greater than, the normal reference segment, the stent is expanded.



GOAL

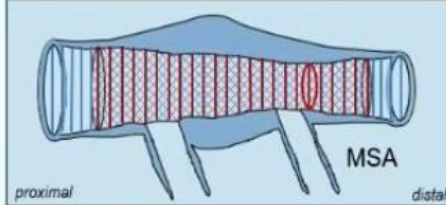
ACCEPTABLE = MSA ≥ 80% OF MEAN REFERENCE LUMEN AREA¹

OPTIMAL = MSA ≥ 90% OF MEAN REFERENCE LUMEN AREA¹

Definitions of 10 stent expansion indexes

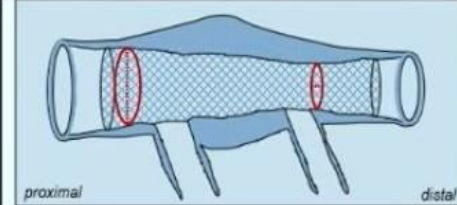
MSA

Minimum stent area
in the entire stent



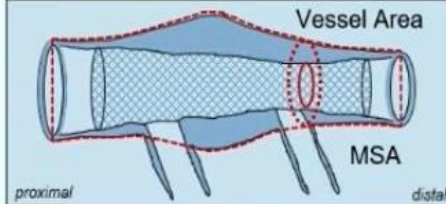
Stent Asymmetry

Minimum Stent Diameter in the entire stent
Maximum Stent Diameter in the entire stent



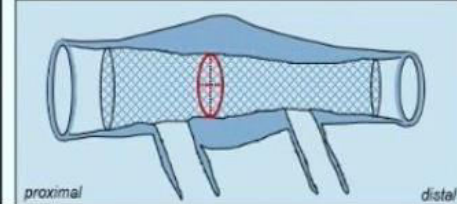
MSA/Vessel Area Stent Exp

$$\frac{\text{MSA}}{\text{Vessel Area at MSA}} \times 100$$



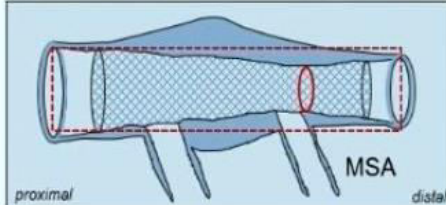
Stent Eccentricity

Minimum of $\frac{\text{Minimum Stent Diameter}}{\text{Maximum Stent Diameter}}$



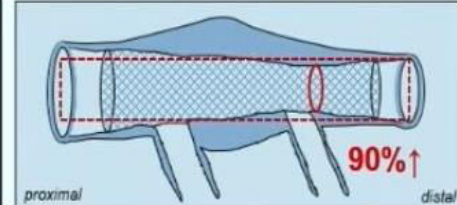
Conventional Stent Exp

$$\frac{\text{MSA}}{\text{Average of Proxi and Dist RLA}} \times 100$$



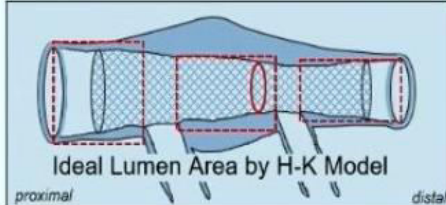
IVUS-XPL Criteria

Minimum Lumen Area
>90% of distal reference lumen area



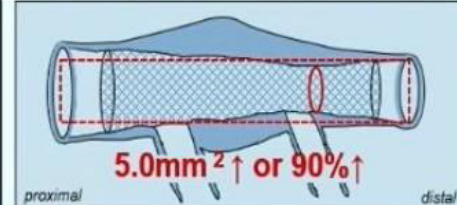
Minimum Stent Exp by H-K Model

$$\text{Minimum of } \frac{\text{Stent Area}}{\text{Ideal Lumen Area}} \times 100$$



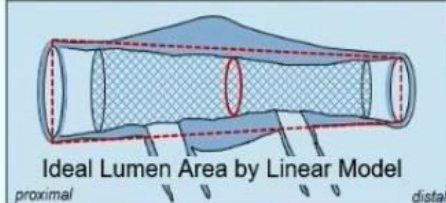
ULTIMATE Criteria

minimum lumen area
>5.0mm² or
>90% of distal reference lumen area



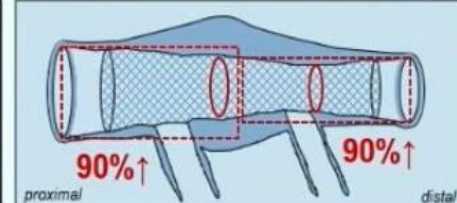
Minimum Stent Exp by Linear Model

$$\text{Minimum of } \frac{\text{Stent Area}}{\text{Ideal Lumen Area}} \times 100$$

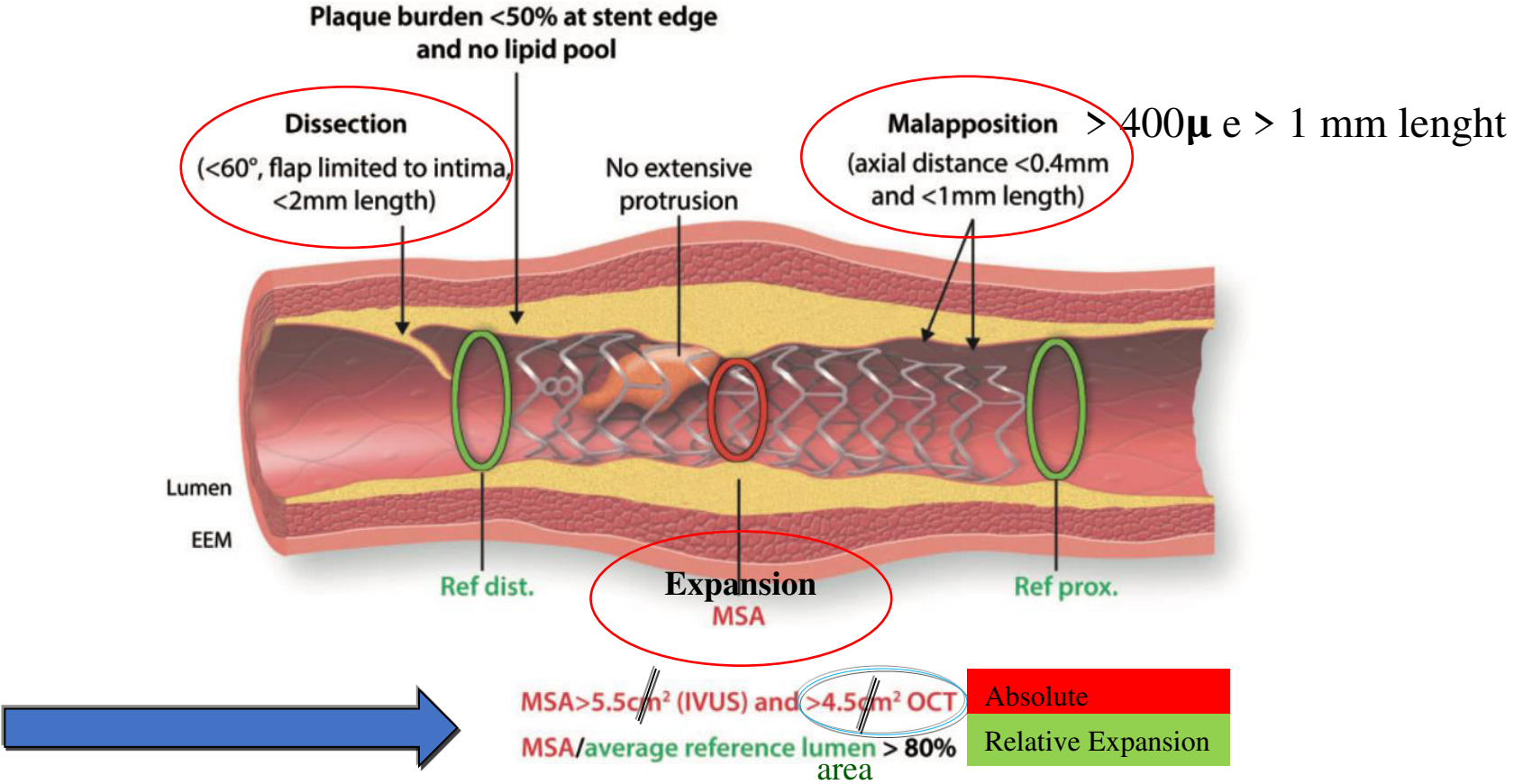


ILUMIEN IV Criteria

$\frac{\text{Proximal MSA}}{\text{Proximal Reference Lumen Area}} \times 100$ (≥90%)
And
 $\frac{\text{Distal MSA}}{\text{Distal Reference Lumen Area}} \times 100$ (≥90%)



Post-Procedural Assessment and Complication



Take home figure Summary of post-percutaneous coronary intervention optimization targets. The most relevant targets to be achieved following stent implantation in non-LM lesions are shown. These include optimal stent expansion (absolute as well as relative to reference lumen diameter); avoidance of landing zone in plaque burden >50% or lipid rich tissue; avoidance of large malapposition regions, irregular tissue protrusion, and dissections. Thresholds provided reflect the consensus of this group. Some are based on consistent and robust prospective data (e.g. stent expansion, landing zone) and others are less established (e.g. malapposition).

Conclusion

- The interventional community is moving towards comprehensive approaches in PCI, integrating anatomical information with imaging and function
- Integration of routine IVI for PCI has the potential to improve procedural safety and clinical outcomes.

No excuse for not using !

Table. OCT Definitions of ACS Culprit Lesions

Lesion type	Description
Plaque erosion	Intact fibrous cap; with or without luminal thrombosis; underlying plaque can be lipid, fibrous, or intimal thickening; calcification rare
Definite OCT-erosion	Luminal thrombus; intact fibrous cap; underlying plaque visible
Probable OCT-erosion	(a) Absence of luminal thrombus; irregular luminal surface (b) Luminal thrombus; attenuation of underlying plaque by thrombus; no superficial lipid or calcification immediately proximal or distal to the site of thrombus
Plaque rupture	Lipid plaque with cap disruption; with or without luminal thrombus; cavity may exist
Calcified nodule	Disrupted fibrous cap; protruding nodular calcification with underlying fibrocalcific plaque; luminal thrombus; superficial calcium; substantive calcium proximal and/or distal to lesion

ACS, acute coronary syndrome; OCT, optical coherence tomography.

- The presence of a large amount of thrombus doesn't allow to detect the underlying structure. Plaque morphology is defined unclassifiable when OCT is unable to visualize clearly the lesion type because of an excess of thrombus obscuring the underlying structure.
- The inability to classify with OCT the culprit plaque has been reported in one quarter of the case, sometimes manual thrombectomy before OCT could allow a better visualization
- **In this case we can only speculate the presence of erosion because normal vessel wall architecture was preserved proximal and distal to the lesion**

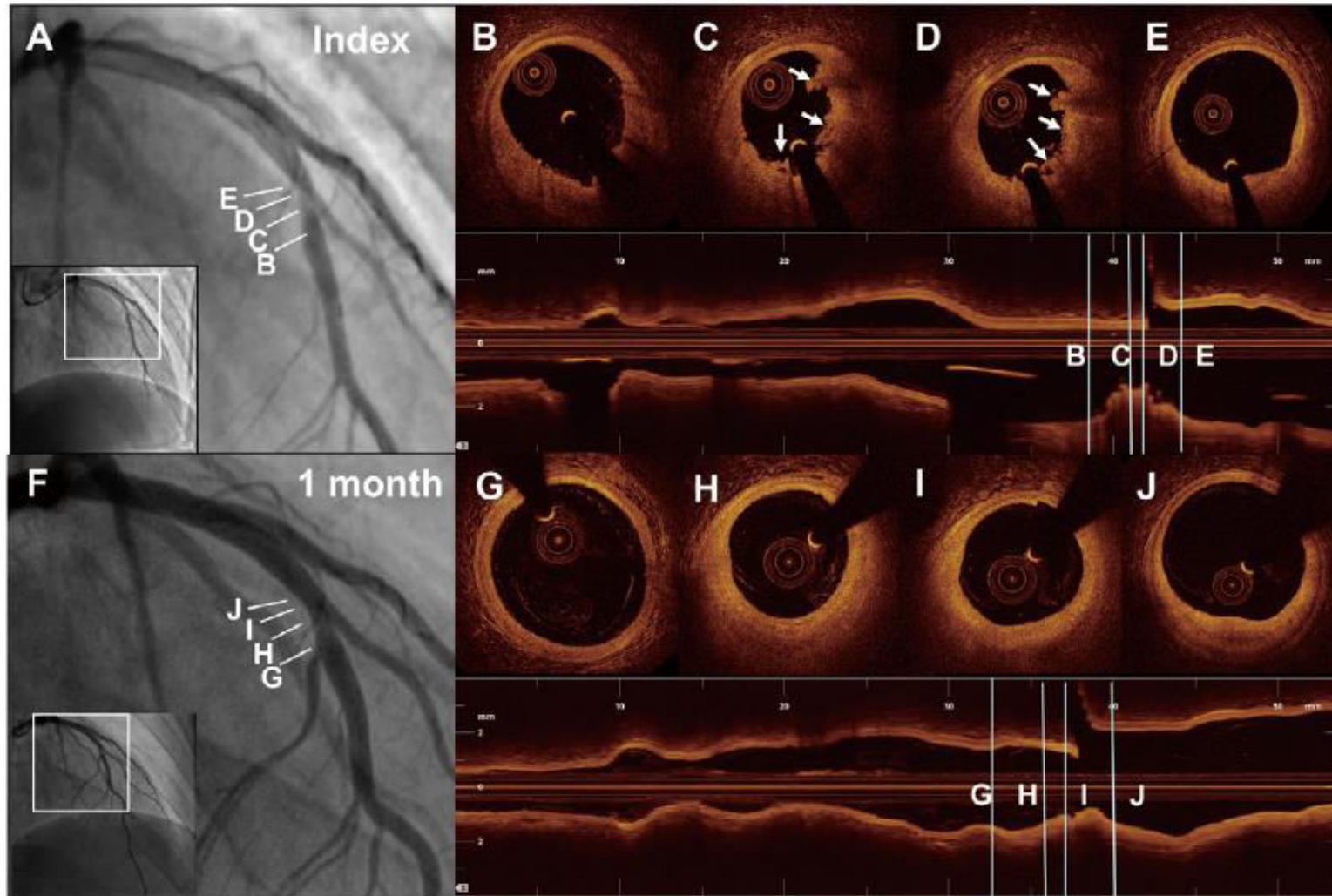


Figure 3. Representative case of ST-segment elevation myocardial infarction (STEMI) caused by plaque erosion in a 27-year-old man. Baseline angiogram (A) shows a total occluded lesion in the mid left anterior descending artery (LAD). After thrombus aspiration, residual stenosis on the angiogram (A) at the culprit site was mild (40%). Serial optical coherence tomography (OCT) cross-sectional images from distal to proximal (B–E) of the culprit lesion indicate plaque erosion with white thrombus (arrows). After 1 month of treatment with antithrombotic agents, angiogram (F) shows a 30% stenosis, and OCT images (G–J) show no visible thrombus overlying a fibrous plaque.

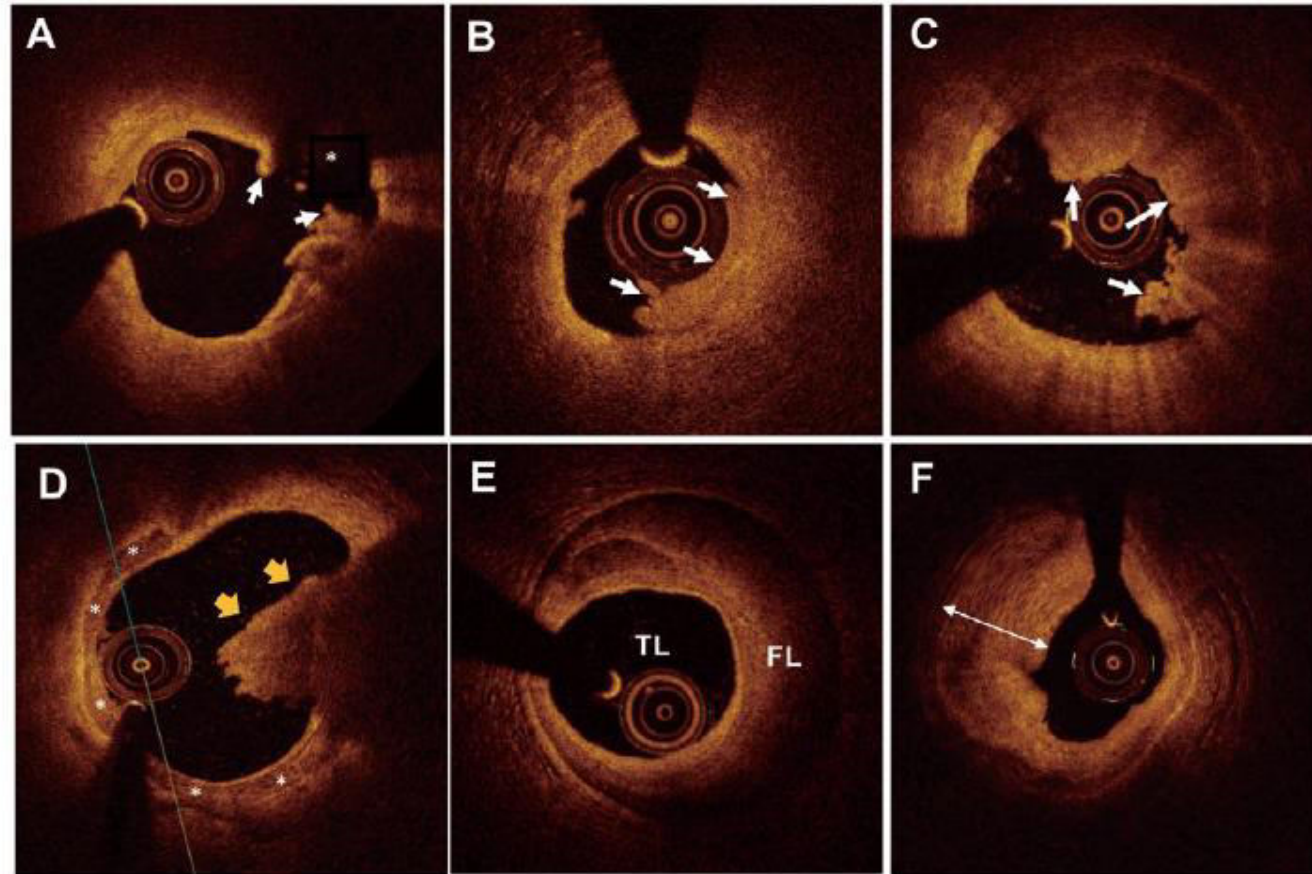


Figure 2. Representative images of culprit lesions by optical coherence tomography (OCT). **(A)** Plaque rupture: disrupted fibrous cap (white arrows) with presence of a cavity (asterisk). **(B)** Definite plaque erosion: mural thrombosis (white arrows) overlying an intact fibrous cap plaque. **(C)** Probable plaque erosion: presence of massive thrombus (white arrows) without superficial lipid pool and calcification immediately proximal or distal to the thrombus. **(D)** Calcified nodule: presence of thrombus (yellow arrows) overlying a superficial and protruding calcification (asterisk). **(E)** Spontaneous coronary artery dissection with hematoma (TL, true lumen; FL, false lumen). **(F)** Coronary spasm characterized by intimal/medial thickening (double arrow).

ILUMIEN IV

ILUMIEN IV (OCT) criteria

Choice of stent size based on external elastic lamina diameter or (if EEL not visible) the mean lumen diameter

Minimum stent area >90% reference lumen area

Minimum lumen area at stent edges >4.5mm²