CLINICA SAN CARLO

Sistema Sanitario

OCT-basic concepts, tips and tricks, and its adjuvance for LM stenting

Bernardo Cortese, MD, FESC

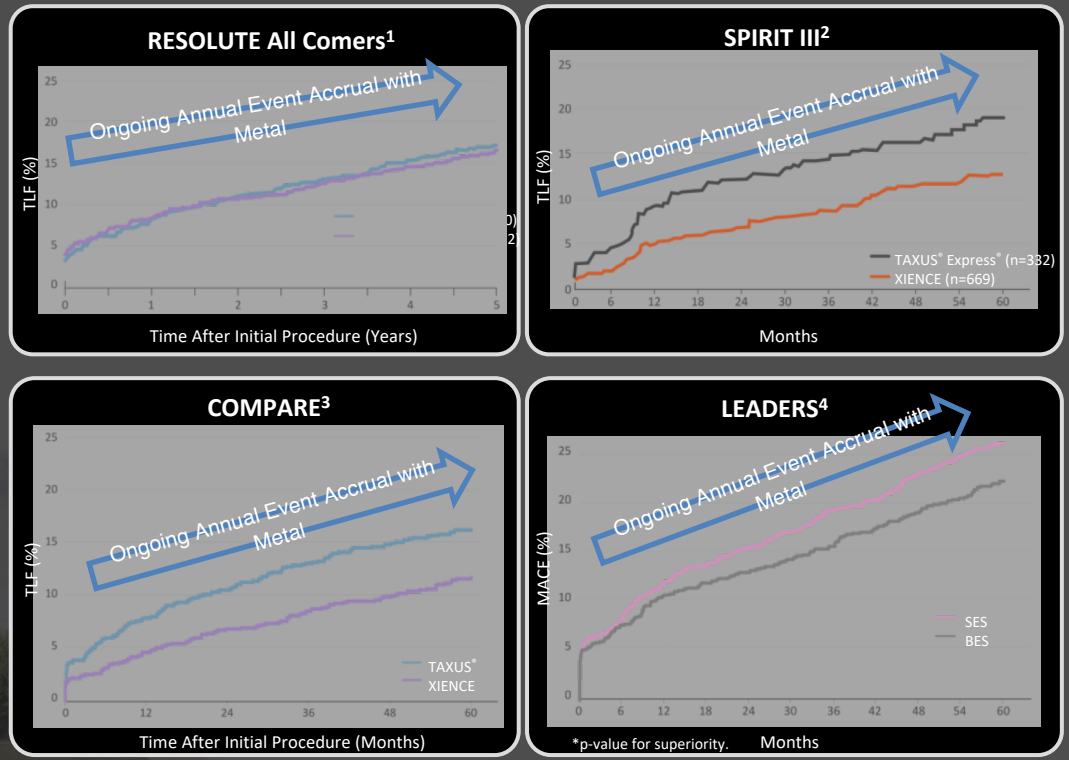
Director of Cardiology, San Carlo Clinic

CNR-Fondazione Monasterio-Regione Toscana

bcortese@gmail.com

bernardocortese.com

By five years, TLF in 2nd generation DES occurs in almost 1 in 6 patients



1. Windecker S. RESOLUTE All Comers 5-Year. EuroPCR 2014. 2. Gada H et al. SPIRIT III 5-year. JACC Cardiovasc Interv. 2013;6:1263-1266. 3. Smits P. COMPARE 5-Year. TCT 2013. 4. Serruys PW. LEADERS 5-Year. TCT 2012. 5. von Birgelen C, van der Heijden LC, Kok MM, et al. TCT-572 Final 5-Year Outcome After Implantation of Zotarolimus-Eluting Resolute Stents Versus Everolimus-Eluting Xience V Stents in the Broad Patient Population of the Randomized TWENTE Trial. J Am Coll Cardiol.2015;66(15_S):. doi:10.1016/j.jacc.2015.08.1042.

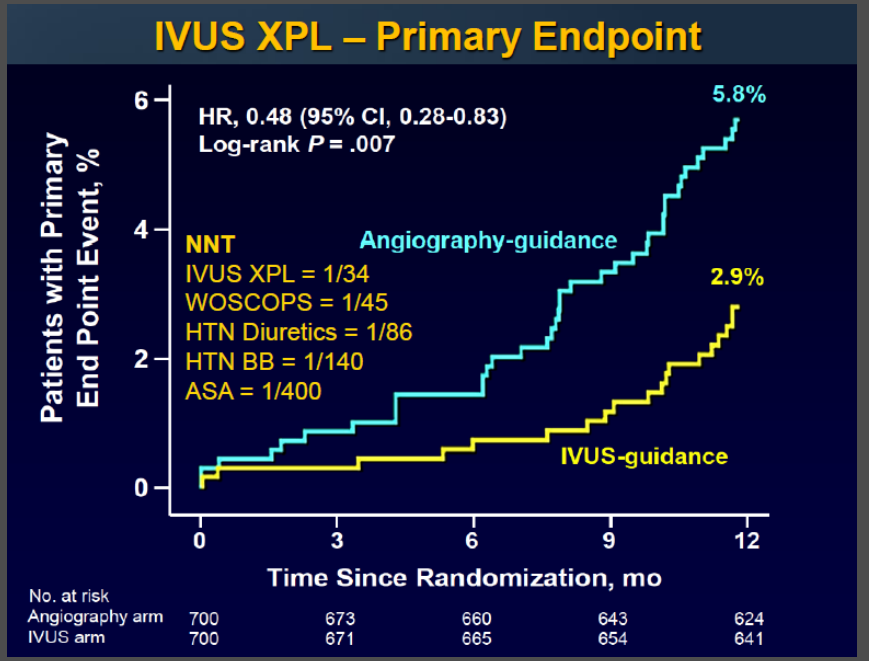
IVUS-guided PCI had a significantly lower MACE rate (48% relative risk reduction) compared to angiographic-guided PCI in IVUS XPL[1]

Expansion was the criteria for stent optimization

- IVUS-guidance arm
  - Minimal lumen area > lumen area of distal reference

Angiography-guidance arm

- Angiographic residual diameter stenosis < 30% with absence of angiographically detected dissection



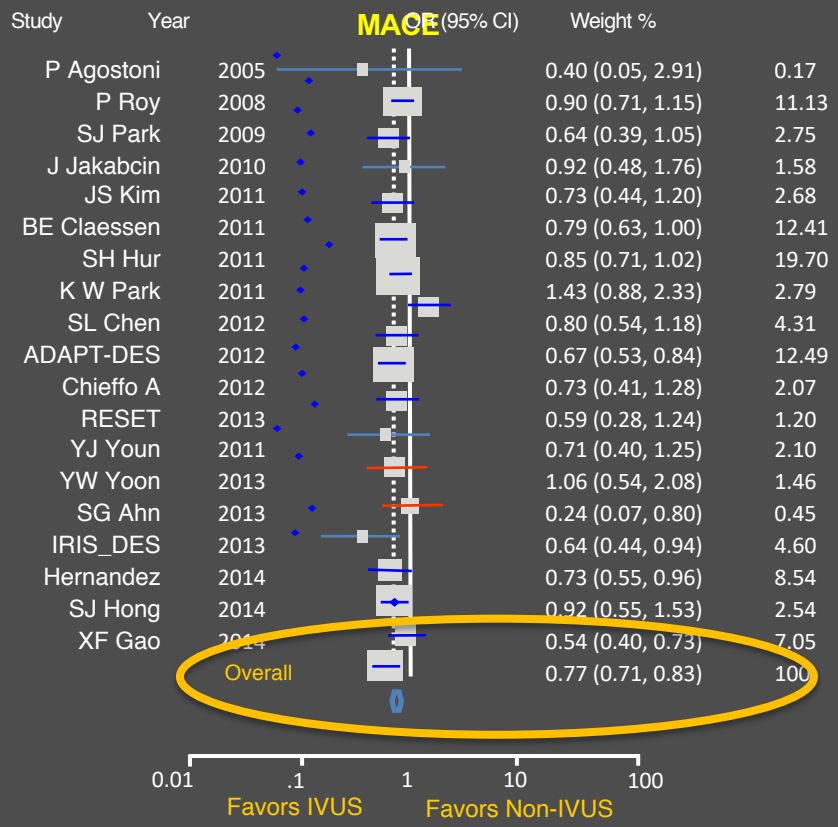
The NNT of Image Guided PCI is less than that for statins for prevention of cardiovascular events.

1. Hong, S. J., Kim, B. K., Shin, D. H., Nam, C. M., Kim, J. S., Ko, Y. G., . . . IVUS-XPL Investigators. (2015). Effect of intravascular ultrasound–guided vs angiography-guided everolimus-eluting stent implantation: the IVUS-XPL randomized clinical trial. *Journal of the American Medical Association, 314*(20), 2155-2163.

Meta-analysis of 29,068 patients show reduced rates of death, MACE and ST with image-guided PCI[1]

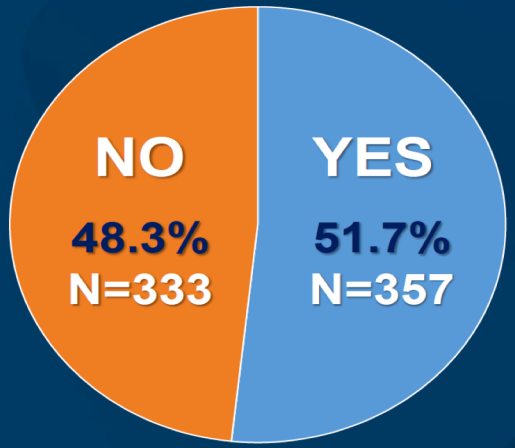
Compared with angiographic guidance, IVUS-guided DES implantation was associated with reduced rates of:

- Death: HR 0.62 (0.54-0.71), p < 0.001
- MACE: HR 0.77 (0.71-0.83), p < 0.001
- TVR: HR 0.86 (0.77-0.97), p = 0.012
- Stent thrombosis: HR 0.59 (0.47-0.73), p < 0.001



Adapted from Zhang, (2015) *BMC Cardiovascular Disorders, 15*, 153

Change in LMCAD stenting by IVUS



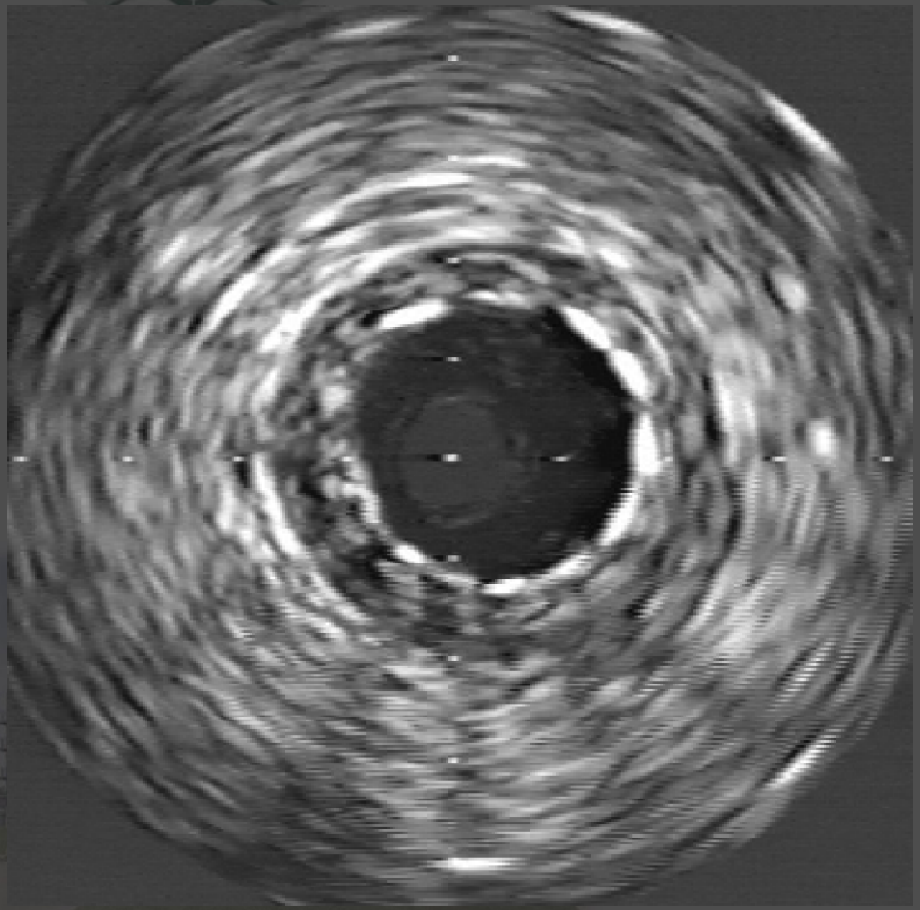
- Used larger balloon: 30% (107)
- Post-dilated: 29% (102)
- Used higher pressure: 17% (62)
- Treated stent under-expansion: 16% (57)
- Led to provisional 1 stent strategy rather than planned 2 stents: 11% (41)
- Led to planned 2 stent strategy rather than provisional 1 stent: 9% (33)

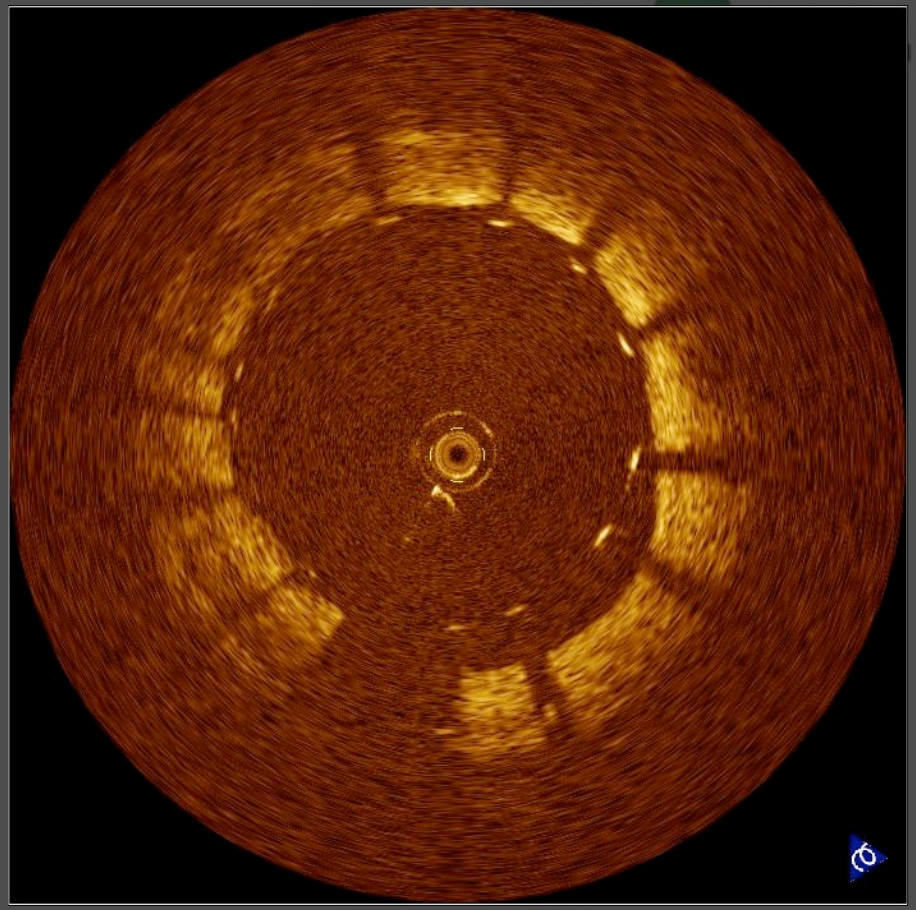
Mehara, IVUS guidance for LM PCI, from the EXCEL trial, in press

3-Year Outcomes

IVUS MSA tertiles (range)	Low: 4.4-8.7 (n=172)	Inter: 8.8-10.9 (n=169)	High: 11.0-17.8 (n=163)	P L vs I	P L vs H
Death/MI/stroke	19.4% (32)	16.1% (26)	9.6% (15)	0.45	0.01
Death/MI/stroke/IDR*	26.6% (44)	23.8% (39)	18.3% (29)	0.66	0.08
All cause death	13.8% (22)	10.0% (16)	5.2% (8)	0.34	0.01
Cardiovascular death	7.4% (12)	4.8% (8)	4.0% (6)	0.39	0.16
MI	10.5% (17)	8.2% (13)	3.7% (6)	0.49	0.02
Stroke	1.8% (3)	1.2% (2)	2.1% (3)	0.66	0.98
Stent thrombosis (D/P)	3.1% (5)	1.2% (2)	0.0% (0)	0.26	0.03
Left main IDR	12.0% (19)	8.3% (13)	8.8% (14)	0.30	0.41
Non-TV IDR	1.9% (3)	3.3% (5)	1.3% (2)	0.48	0.65

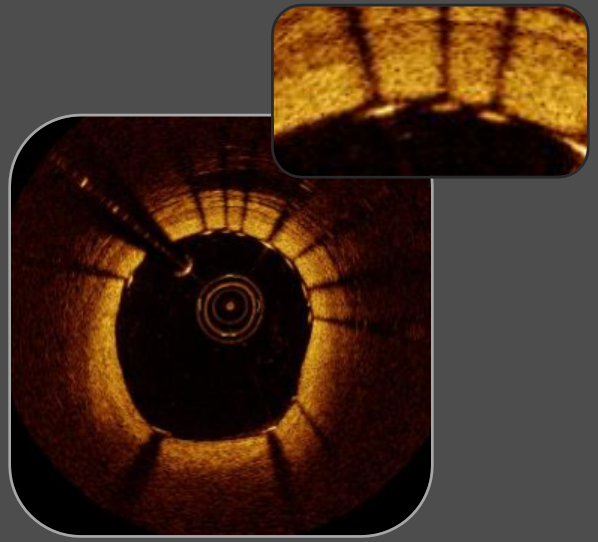
Mehara, IVUS guidance for LM PCI, from the EXCEL trial, in press





What is OCT?

An optical imaging modality that uses near-infrared light for high-resolution imaging of vessel anatomy, tissue microstructure and stents.

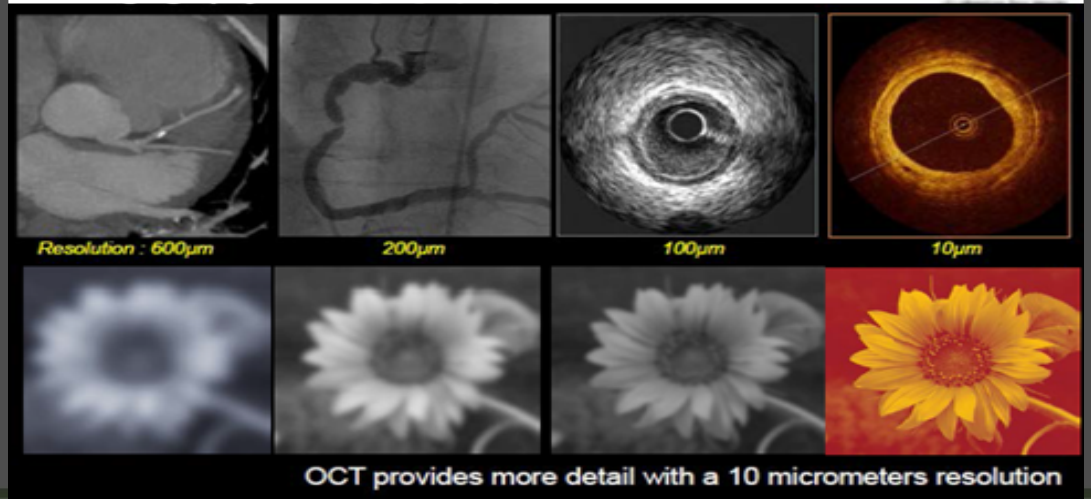


Key Features:

- Uses light, not sound
- Does not use X-ray
- Image acquisition is rapid
- Images acquired are high resolution

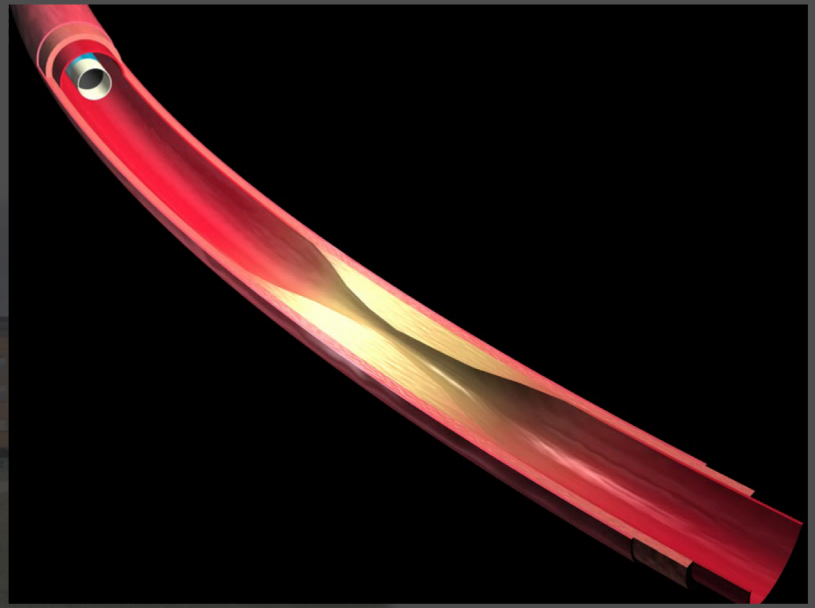
OCT = Improved Resolution

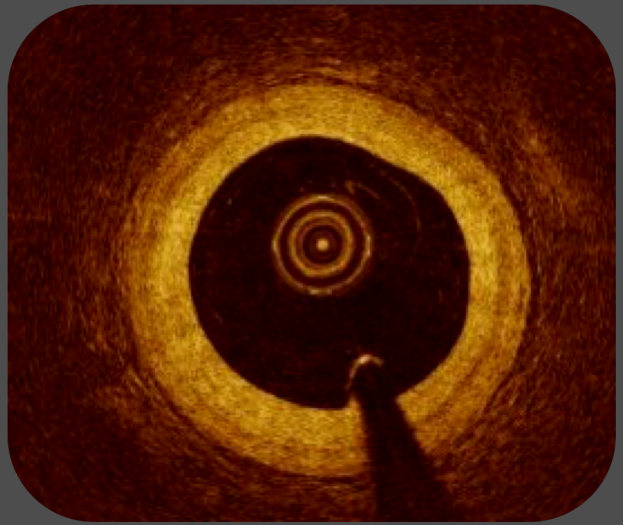
OCT has 10 times the resolution of IVUS



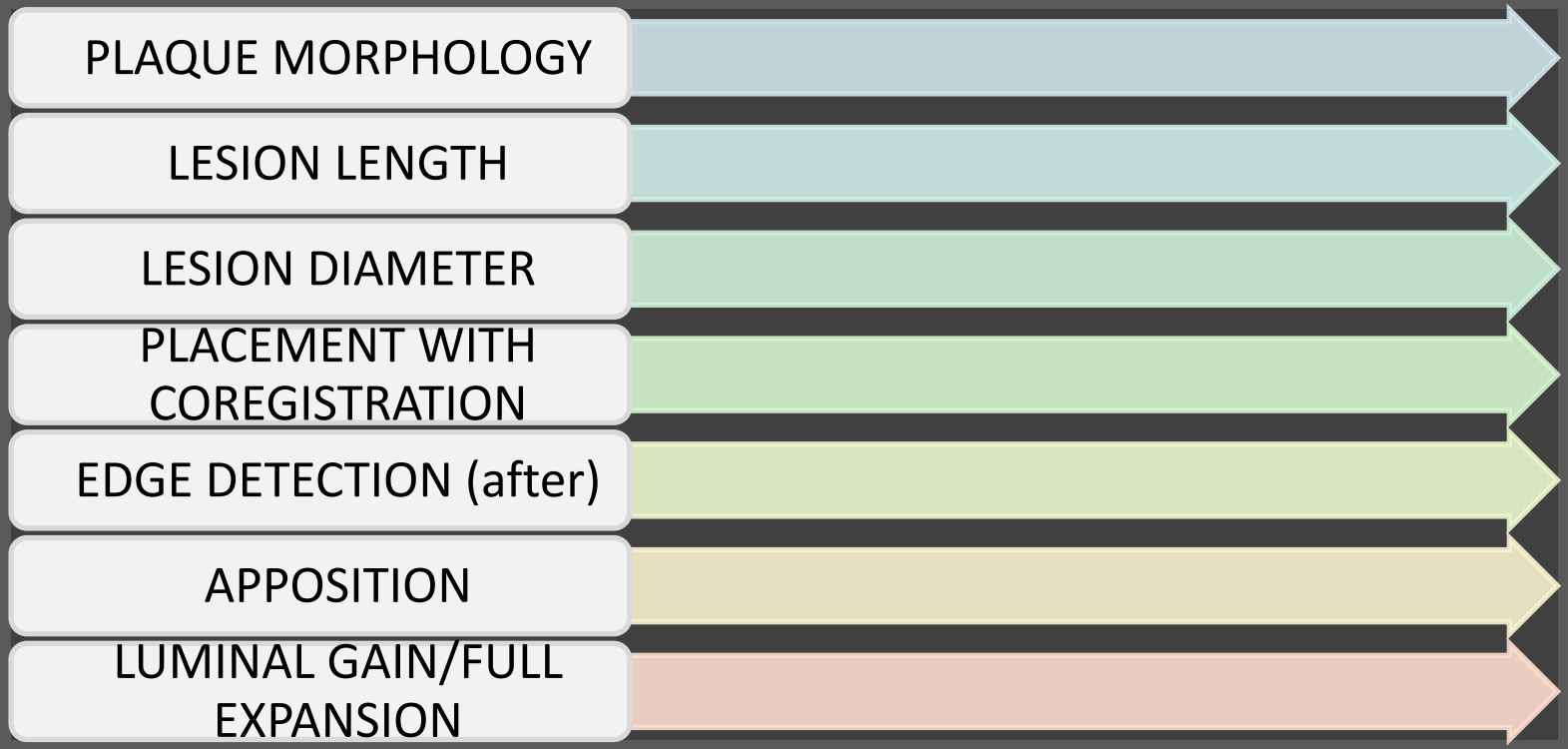
How does OCT work?

- Optical fiber inside catheter spins around to create a radar-style image
- 74 mm OCT image acquired in < 3 seconds



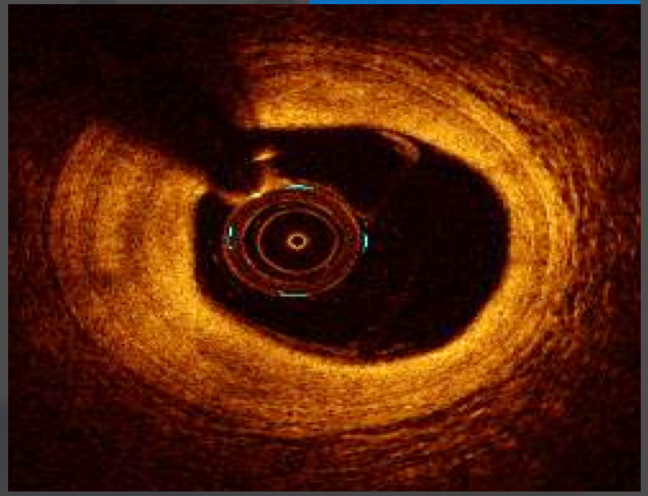


Possible OCT applications?

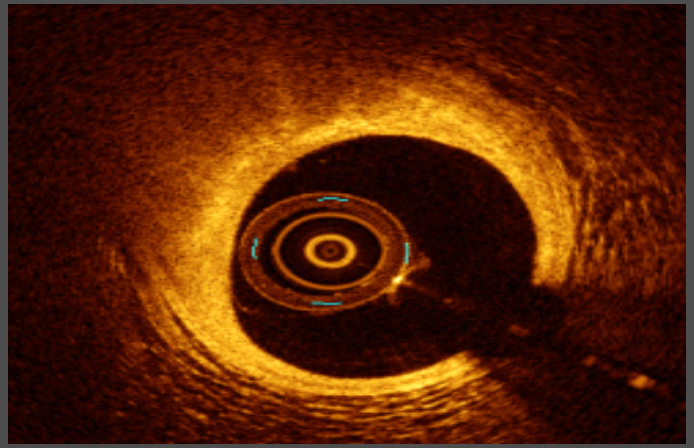


Understanding the composition of the plaque

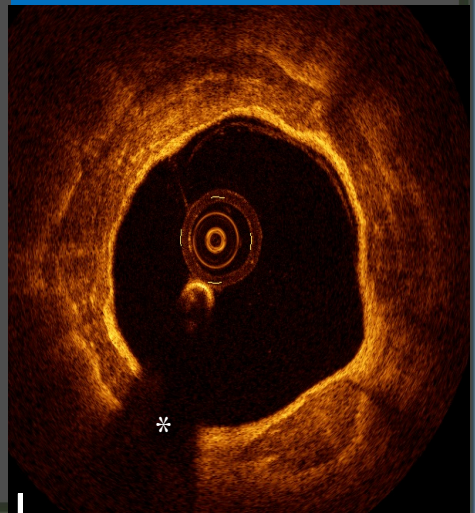
- **Fibrous**



- **Fibro-Fatty**

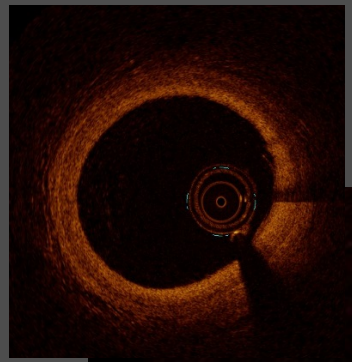


- **Calcific**



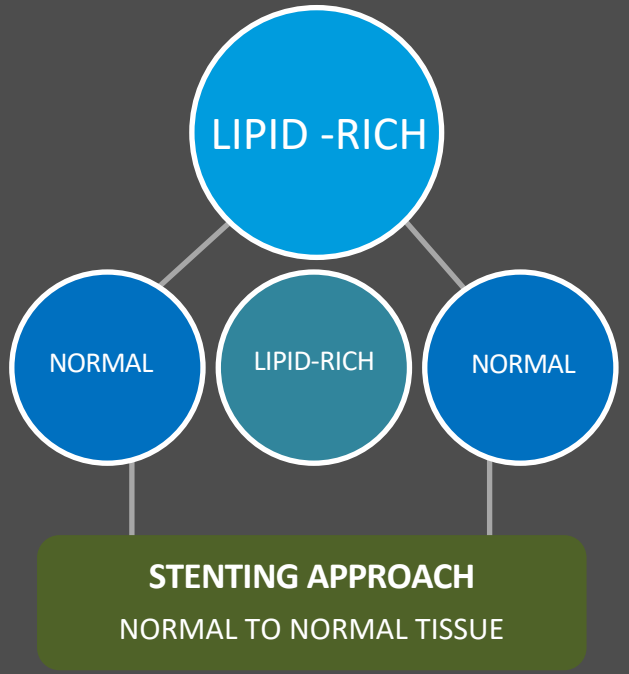
Lipid-rich plaque:

Stenting from normal to normal tissue for complete lesion coverage

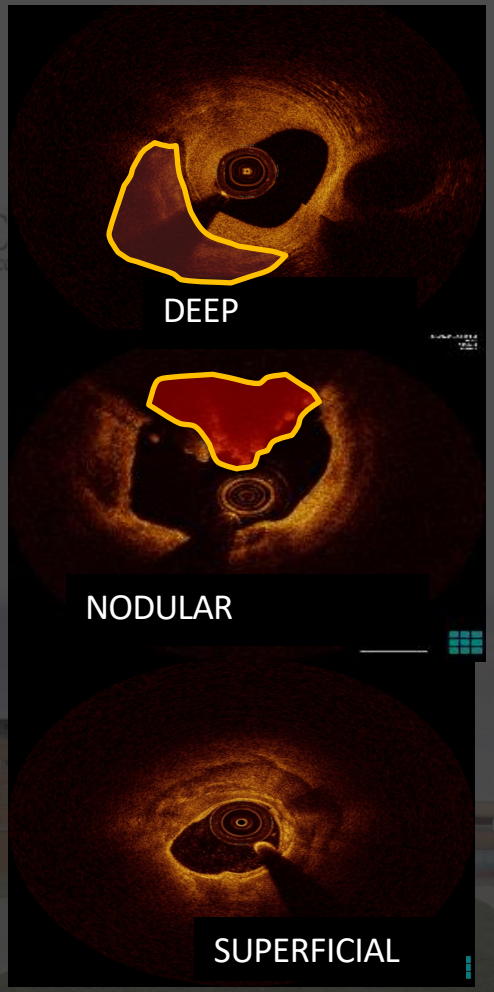


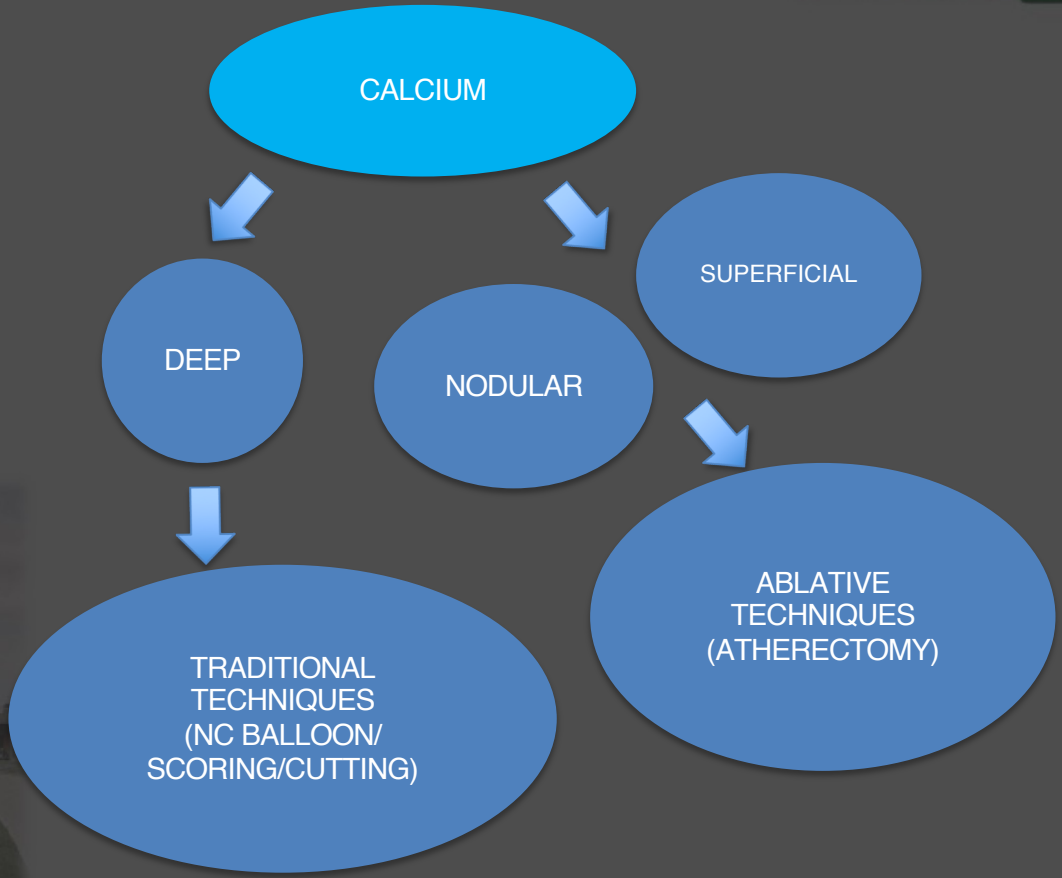
Normal

Lipidic

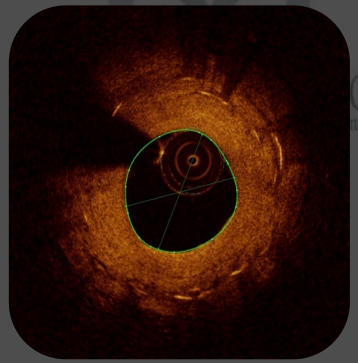


Types of calcific plaques

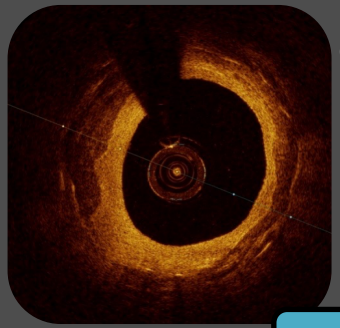




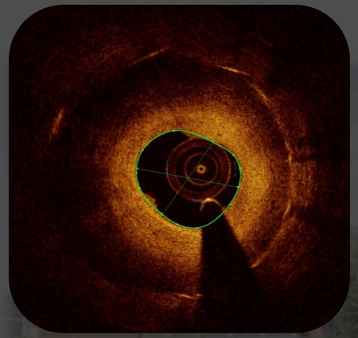
mechanism of ISR to guide treatment



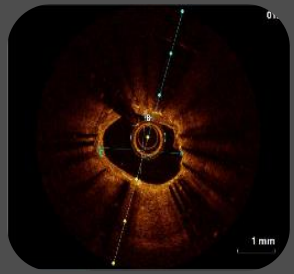
FIBROTIC ISR



CALCIFIC ISR



LIPIDIC ISR



UNDEREXPANSION

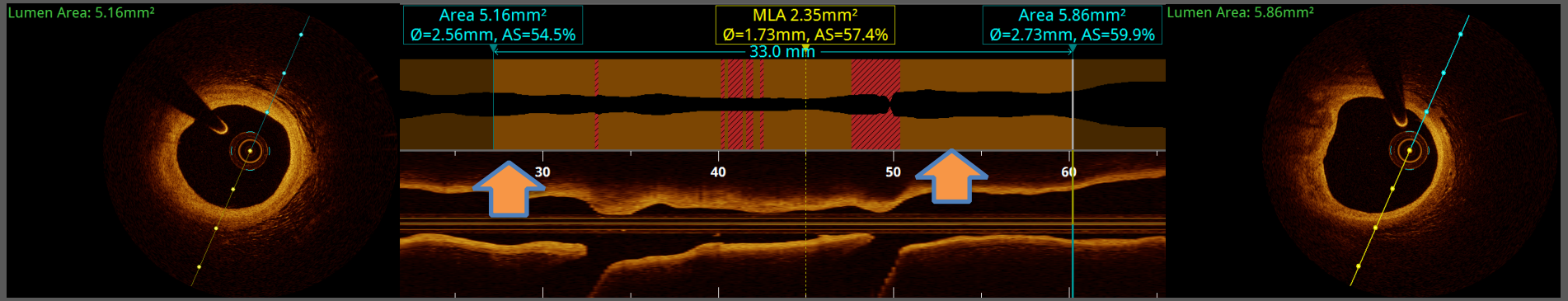
Identify reference segments: Choose length

May avoid edge problems by stenting from normal to normal tissue

L-mode makes it easy to see and measure lesions to choose landing zone

STRATEGIC TREATMENT ASSESSMENT

- **Vessel Size and Lesion Length Assessment**

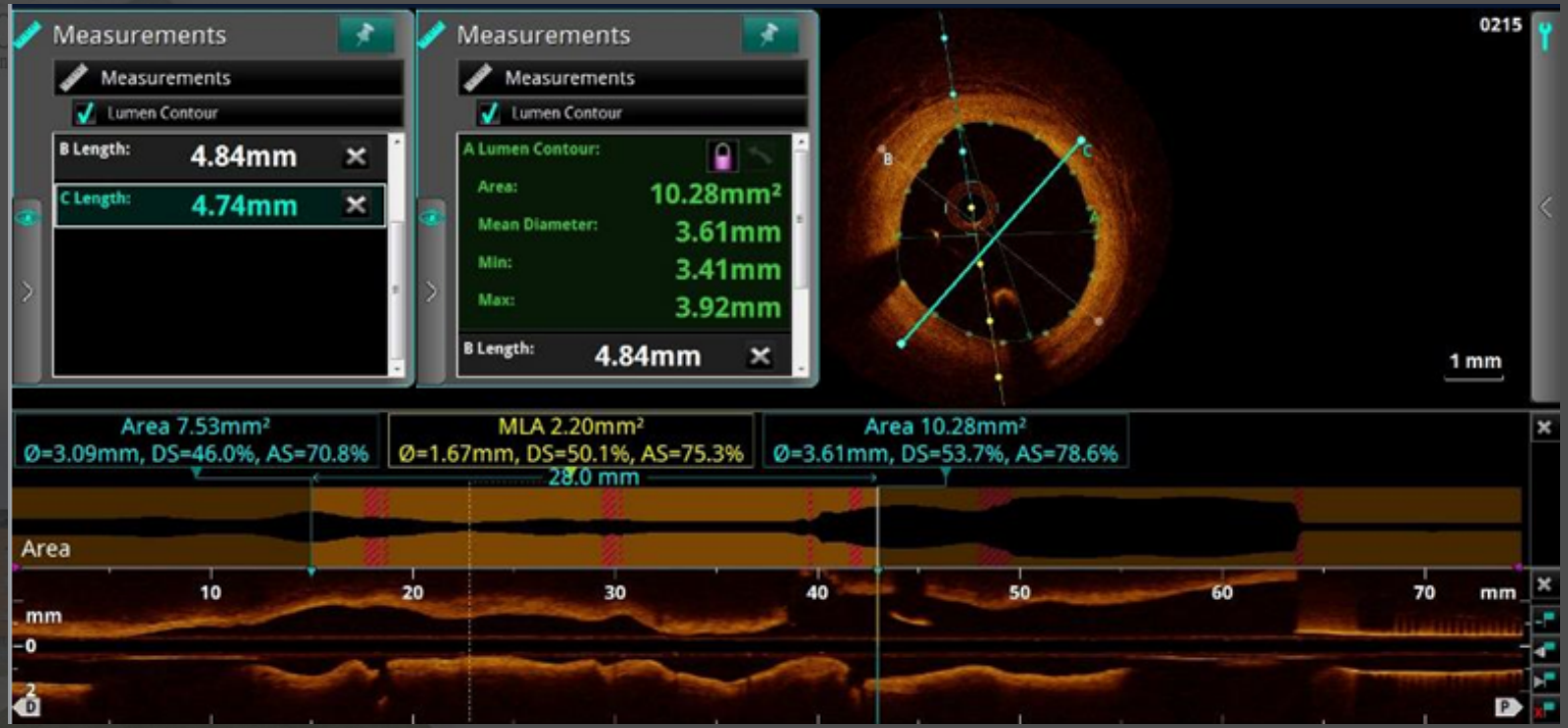


DISTAL REFERENCE

PROXIMAL REFERENCE

- Drag and drop each reference marker to normal tissue
- Automatically get exact stent length

OCT can accurately size vessel diameter
Fast, automatic measurements of lumen, length, area

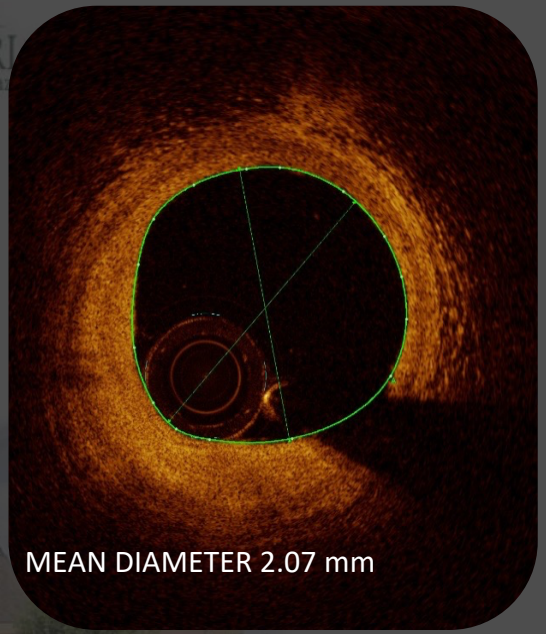


Akiko Maehara, Gary S. Mintz, Gregg W. Stone OCT Versus IVUS: Accuracy Versus Clinical Utility JACC: Cardiovascular Imaging Oct 2013, 6 (10) 1105-1107; DOI: 10.1016/j.jcmg.2013.05.016

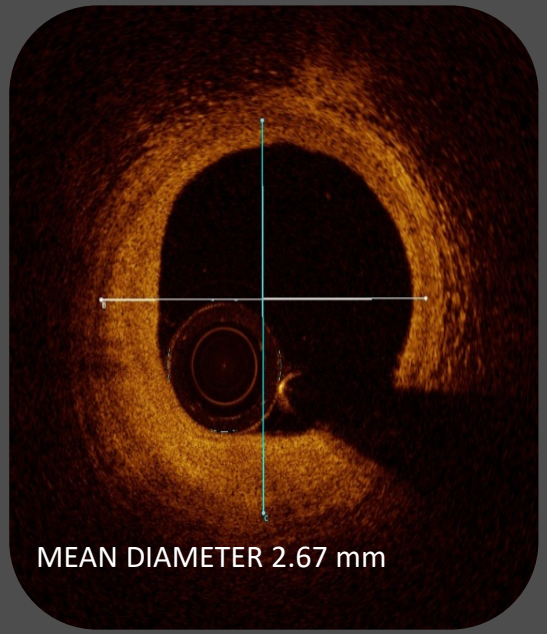
Stent sizing: lumen to lamina

Regione Lombardia

LUMINAL MEASUREMENTS



MEDIAL MEASUREMENTS

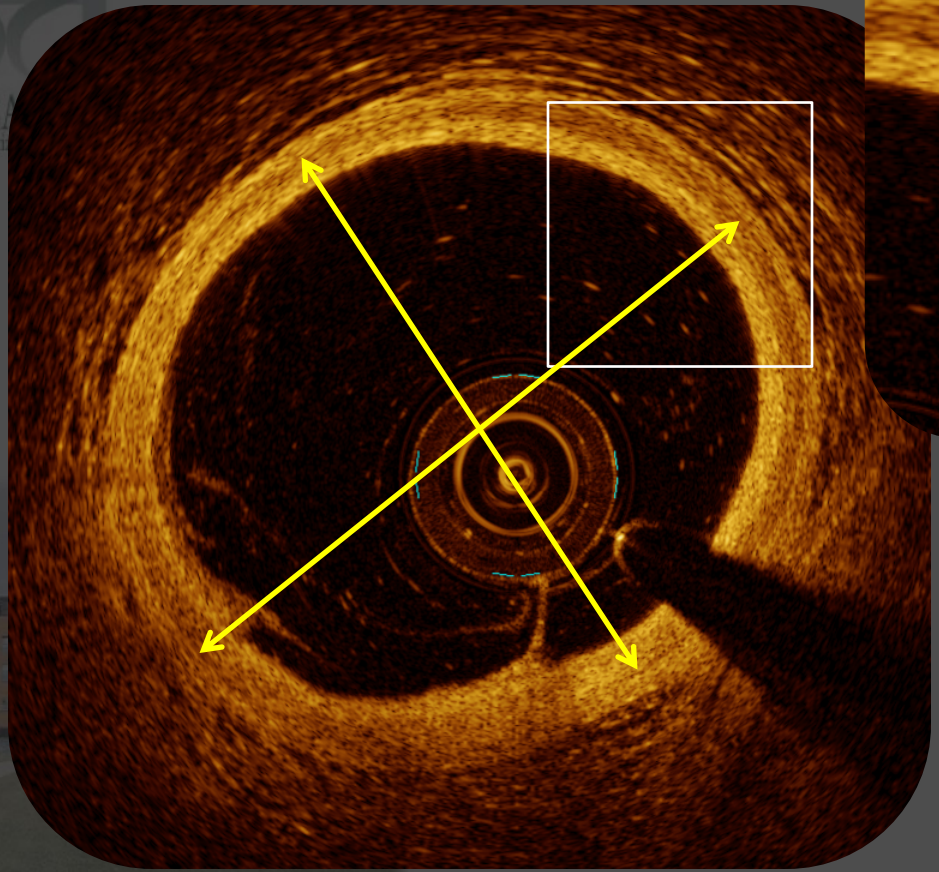


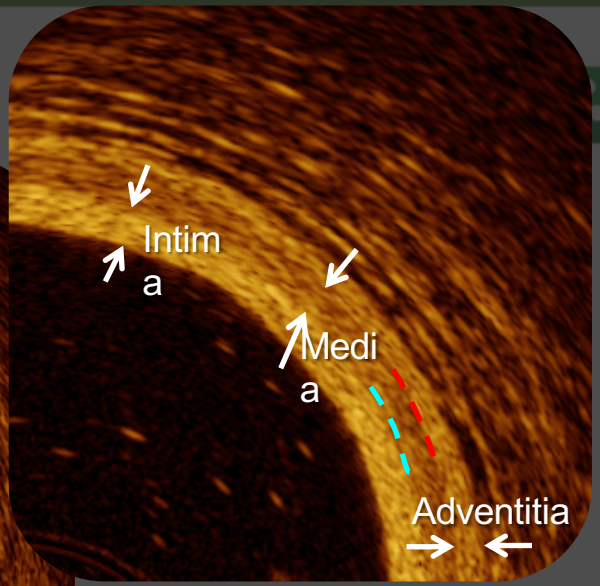
Lamina based stenting leads to significantly larger stent sizes, safely[1]

Ali, Ziad A et al. Optical coherence tomography compared with intravascular ultrasound and with angiography to guide coronary stent implantation (ILUMIEN III: OPTIMIZE PCI): a randomised controlled trial The Lancet , Volume 388 , Issue 10060 , 2618 - 2628

External Elastic Lamina (EEL)

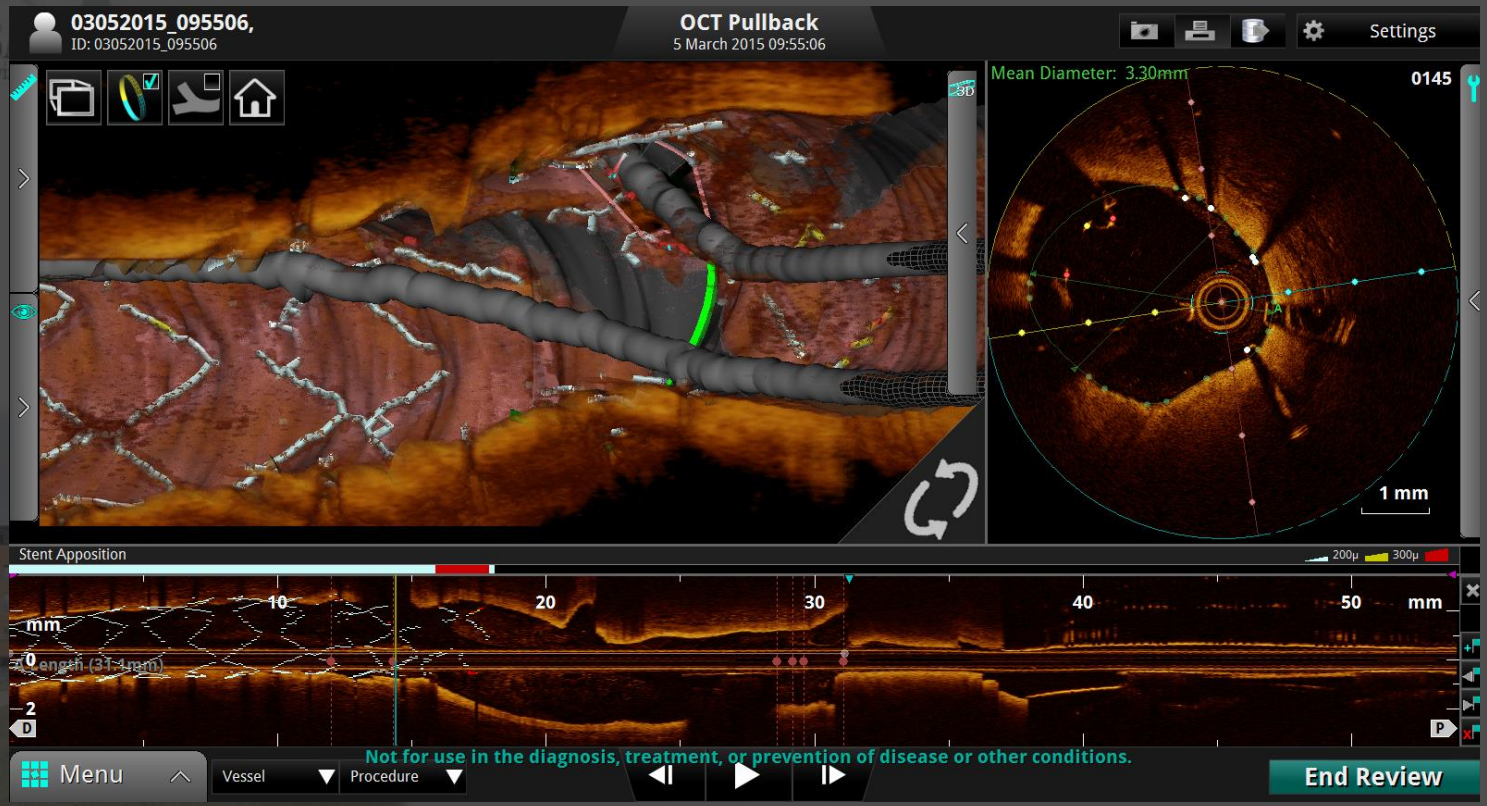
Internal Elastic Lamina (IEL)



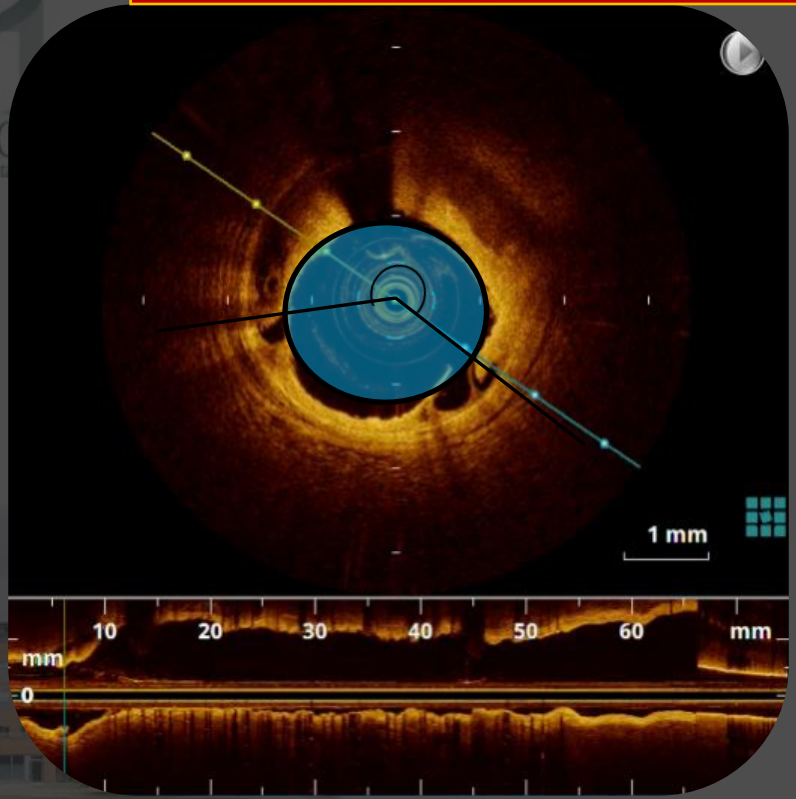


EEL is the outer layer of media shown by the dotted red line.

3D Guidewire/ bifurcation mode with side branch detection

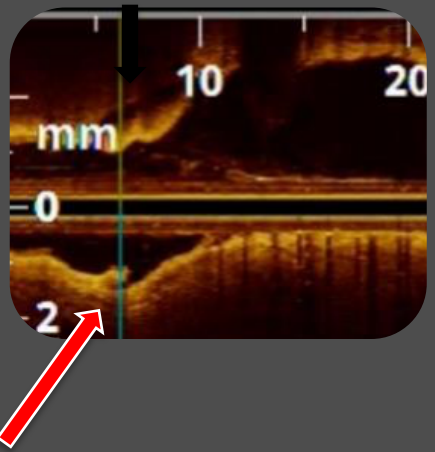


Identify stent edge dissections



Major Edge Dissection Category

1) >60°
2) >3 mm length
3) Flow limiting (TIMI)
4) Inadequate MLA



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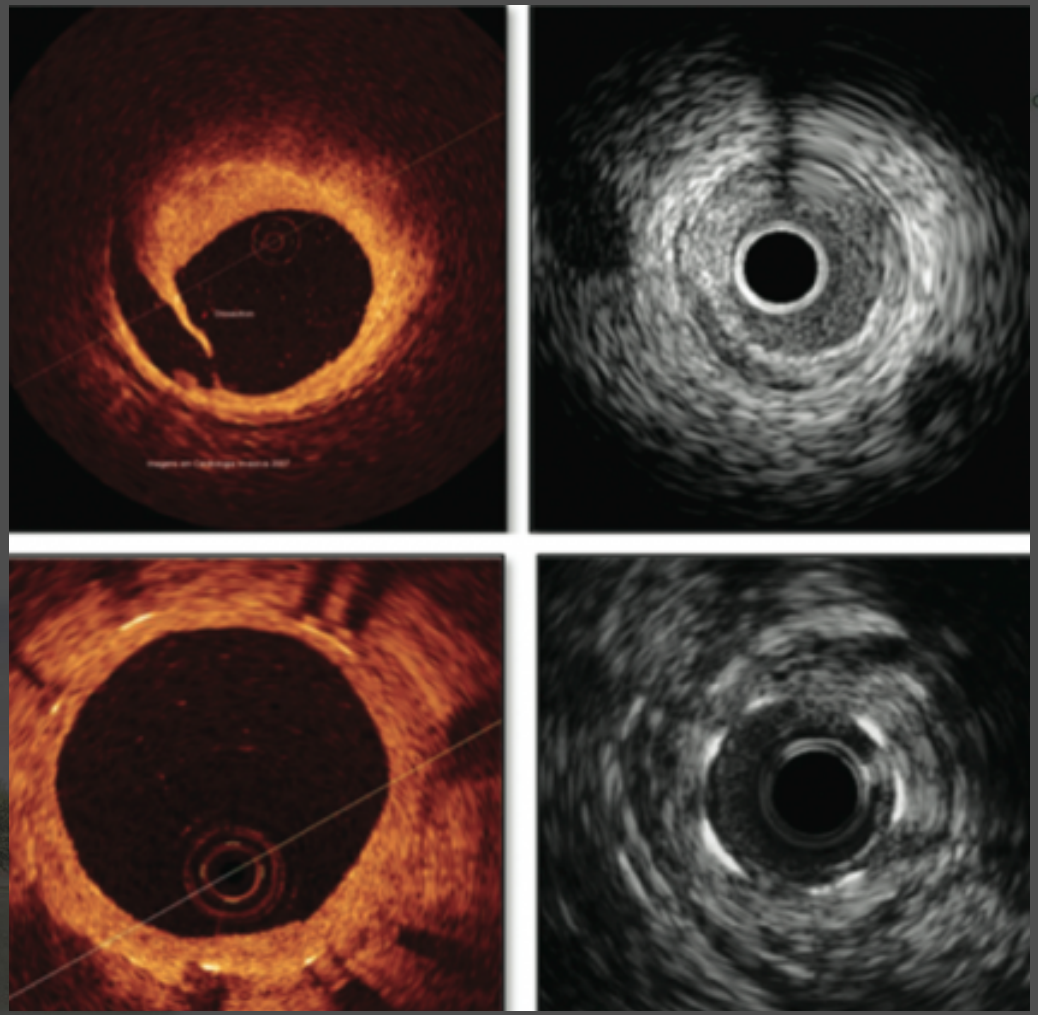
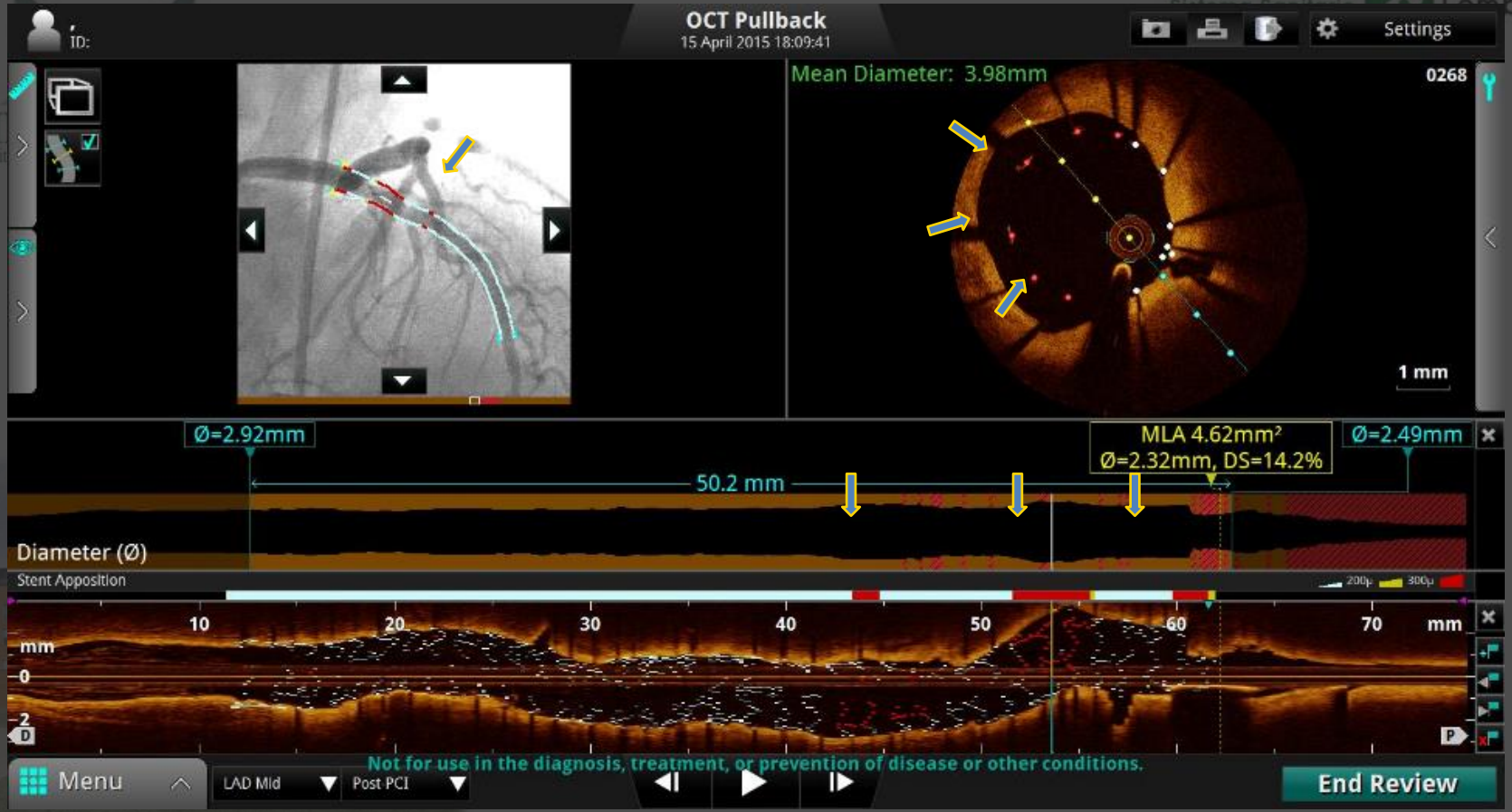
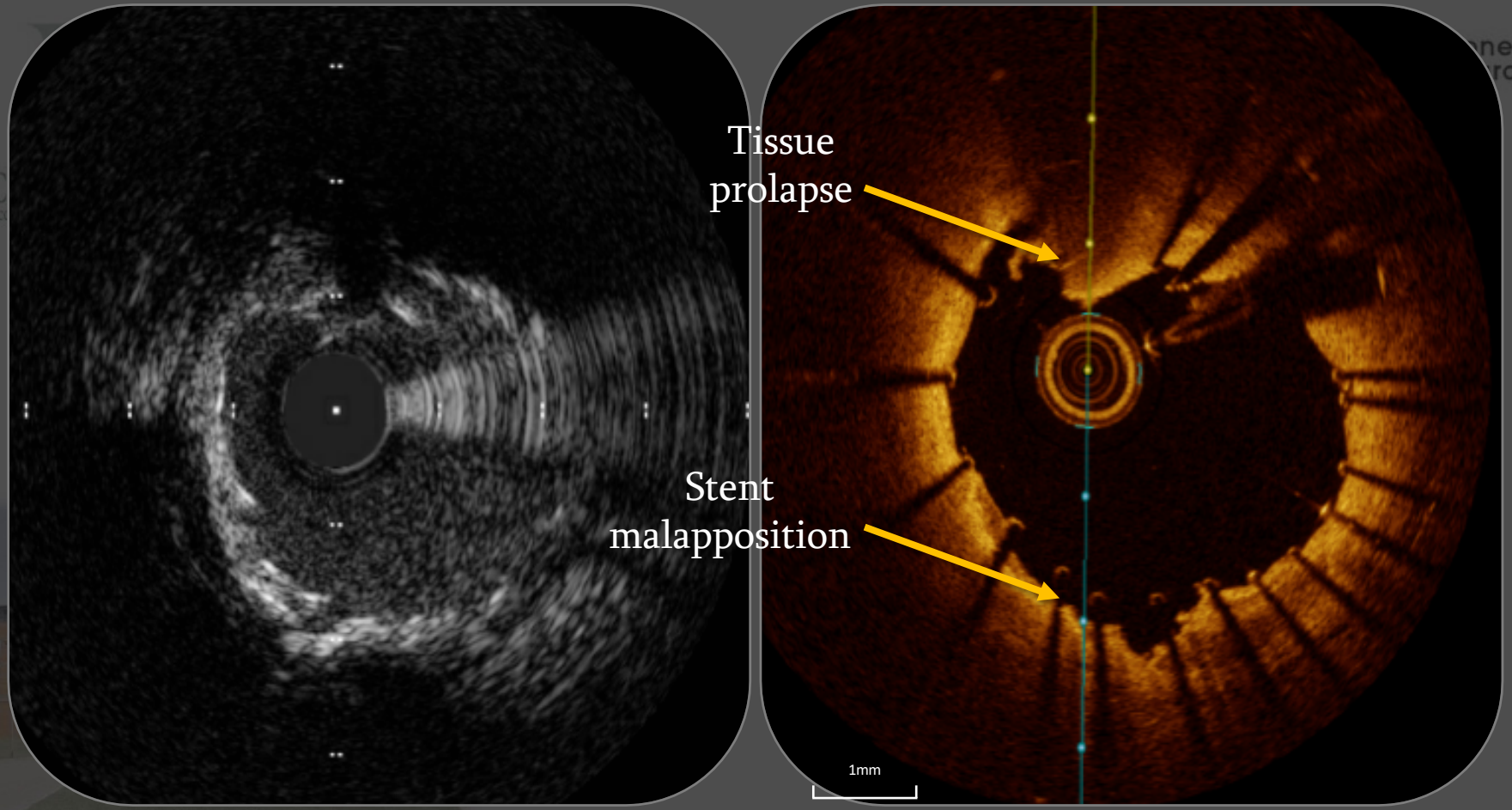


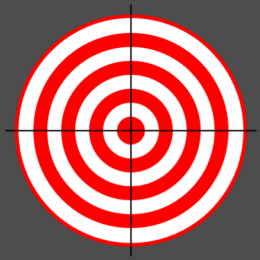
Stent apposition



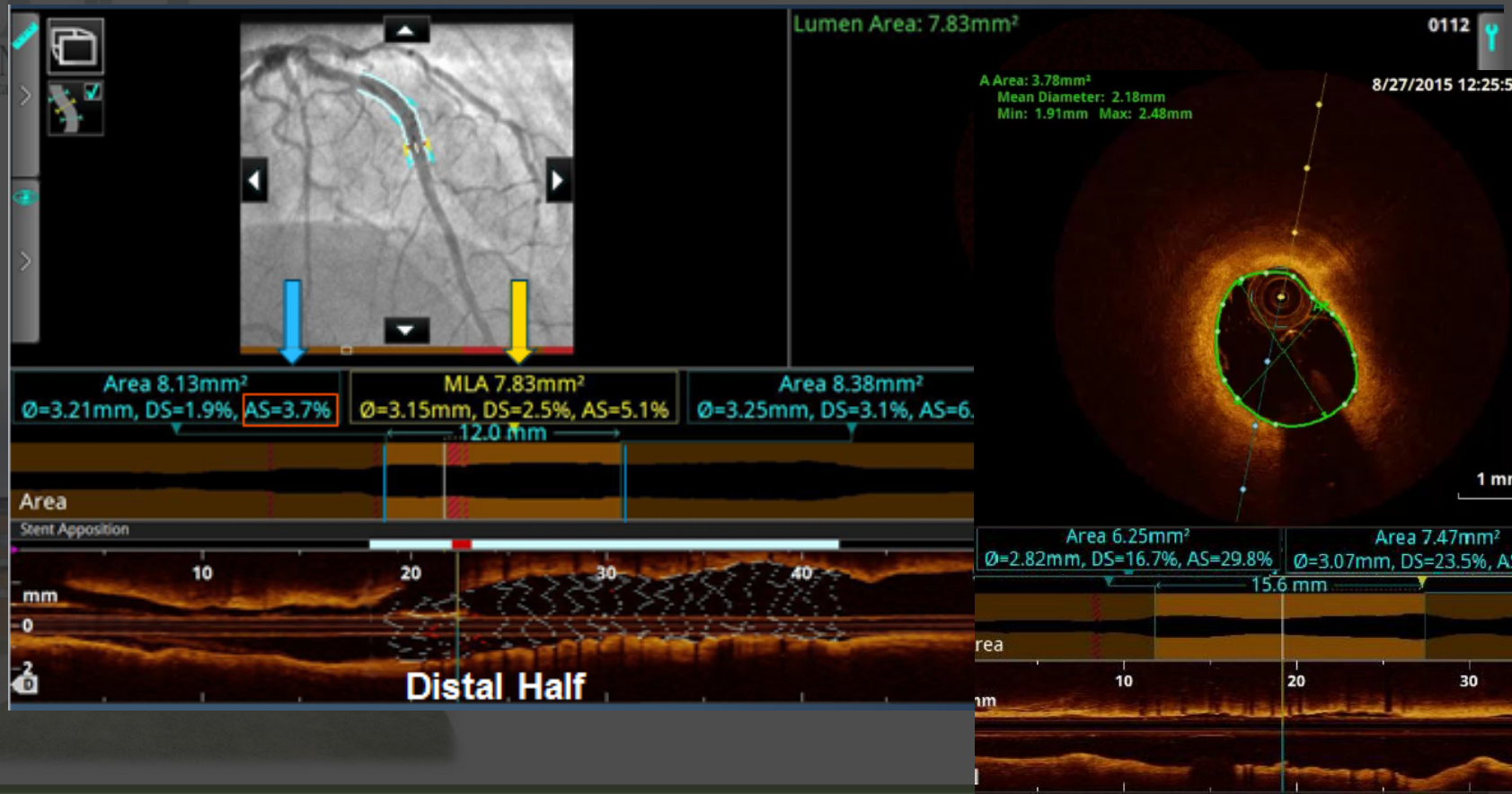

Tissue
prolapse
Stent
malapposition
1mm

How can I define a stent correctly expanded?

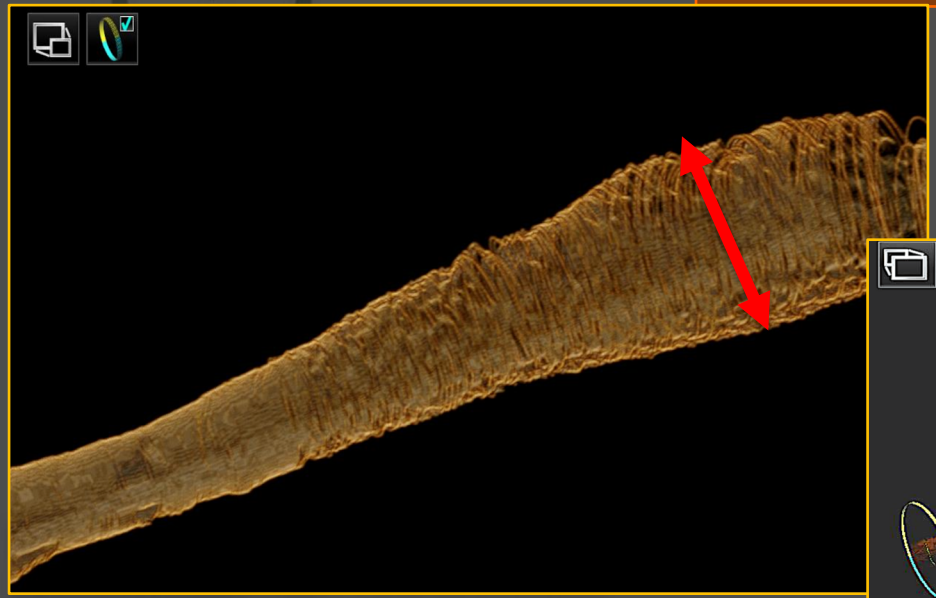
- >90% of the mean of the proximal and distal reference areas (MUSIC Criteria)
- >100% of the distal reference area (IVUS XPL Criteria)
- >90% of the distal reference area in the distal half of the stent and >90% of the proximal reference area in the proximal half of the stent (OPTIMIZE PCI Criteria)

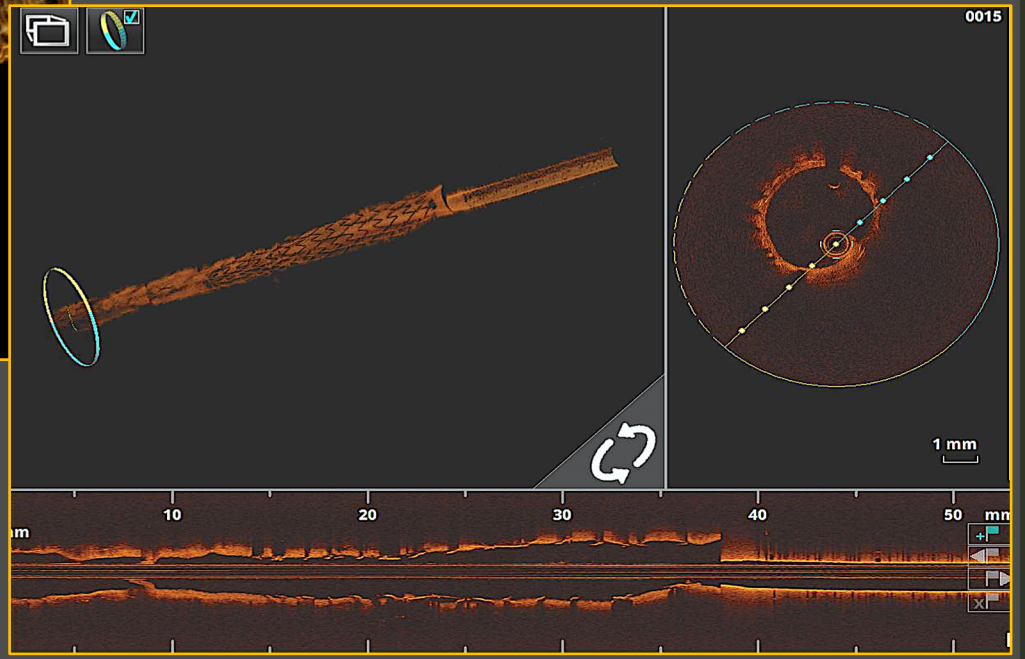


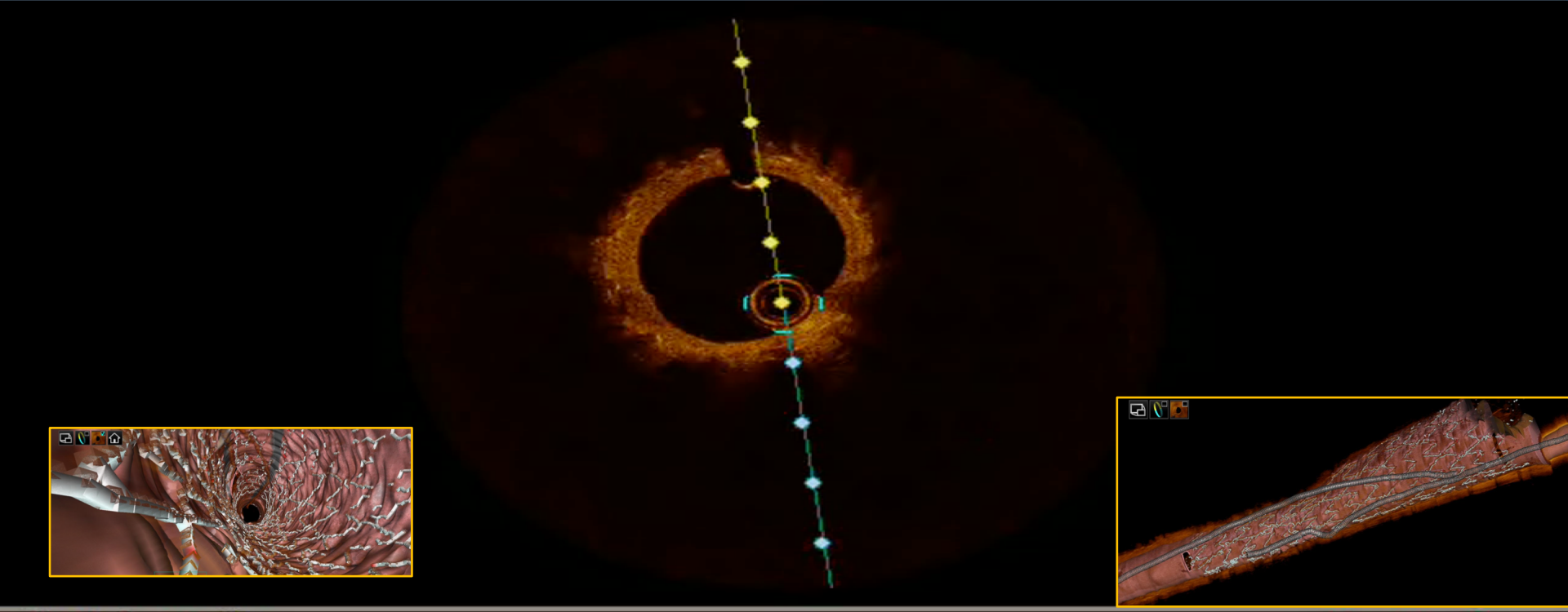
The MLA (minimal lumen area) or MSA (minimal stent area) after implantation, marker is designed to make it easier & faster to treat underexpansion



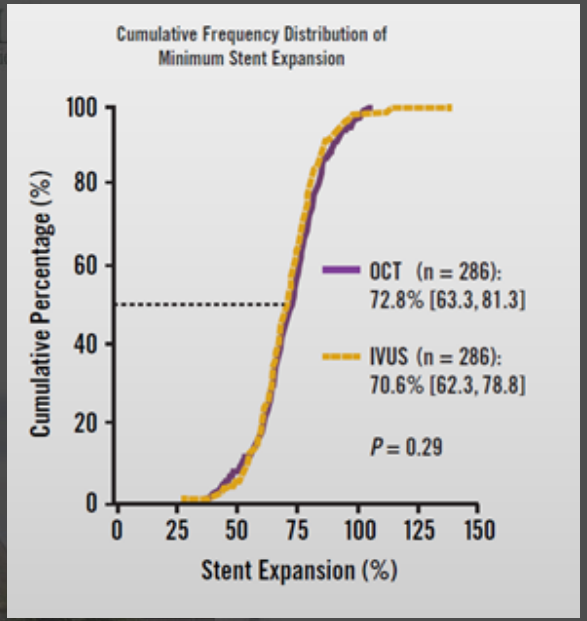
final result OCT






Stent Apposition
300µ
10
20
30
40
mm
mm
2
D
P

ILUMIEN II: Similar stent expansion was achieved using IVUS- and OCT-guided PCI



- Post-PCI OCT recognized malapposition, tissue protrusion and edge dissection significantly more frequently than post-PCI IVUS, a result of its superior resolution
- Multivariable analysis confirmed that stent expansion was not different between OCT- and IVUS-guidance

Maehara A, Ben-Yehuda O, Ali Z, et al. Comparison of Stent Expansion Guided by Optical Coherence Tomography Versus Intravascular Ultrasound: The ILUMIEN II Study JACC Cardiovasc Interv. 2015;8(13):1704-14.

CLI-OPCI I study provided guidance on clinical outcomes when OCT is used vs. angiography alone

CLI-OPCI I INCLUDED CONSECUTIVE PATIENTS UNDERGOING PCI WITH ANGIO ALONE (N=335) VS. PCI WITH OCT (N=335)[2]

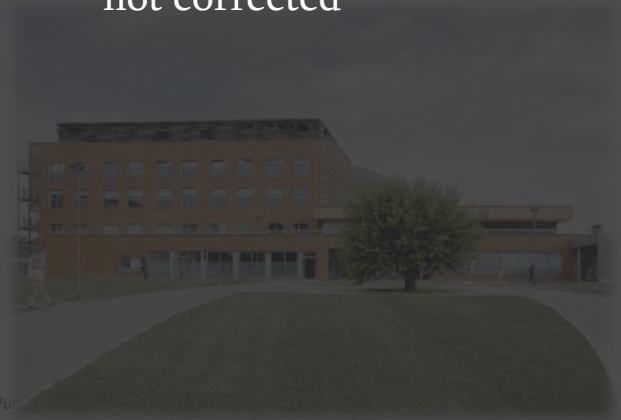
- OCT-guided PCI vs. Angio guided-PCI identified
  - additional procedural issues not recognized by angiography
  - adverse features requiring further intervention in 34.7% of subjects
- OCT-guided PCI may improve clinical outcomes, reducing the 1-year rate of cardiac death or MI

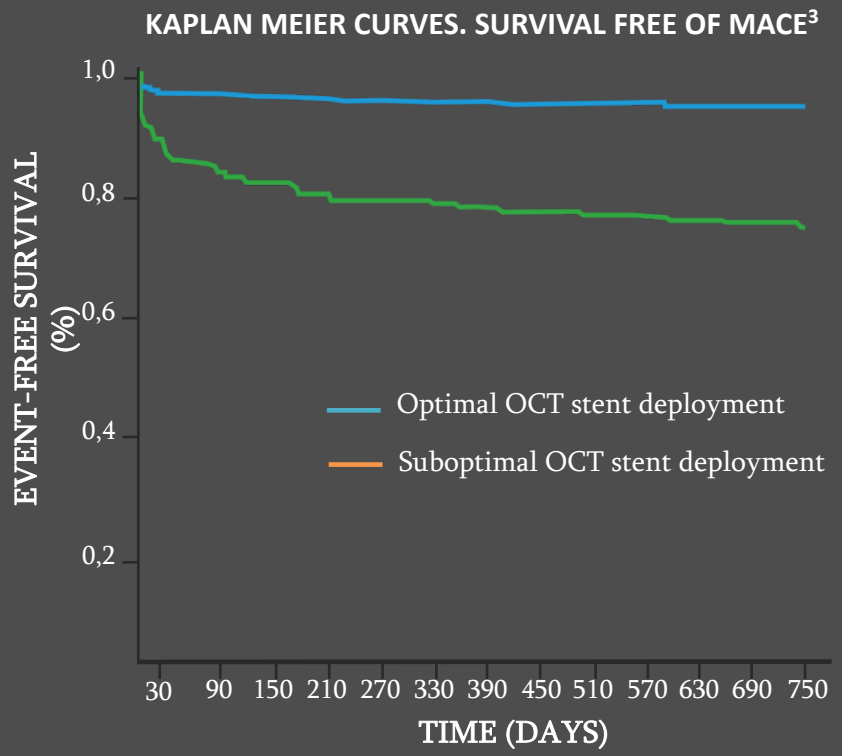
EVENTS AT 1-YEAR FOLLOW-UP	ANGIOGRAPHIC GROUP (n=335)	OCT + ANGIOGRAPHIC GROUP (n=335)	P VALUE
Death	23 (6.9%)	11 (3.3%)	0.035
Cardiac death	15 (4.5%)	4 (1.2%)	0.010
Myocardial infarction	29 (8.7%)	18 (5.4%)	0.096

CLI-OPCI II study provided guidance on clinical outcomes when OCT is used vs. angiography alone

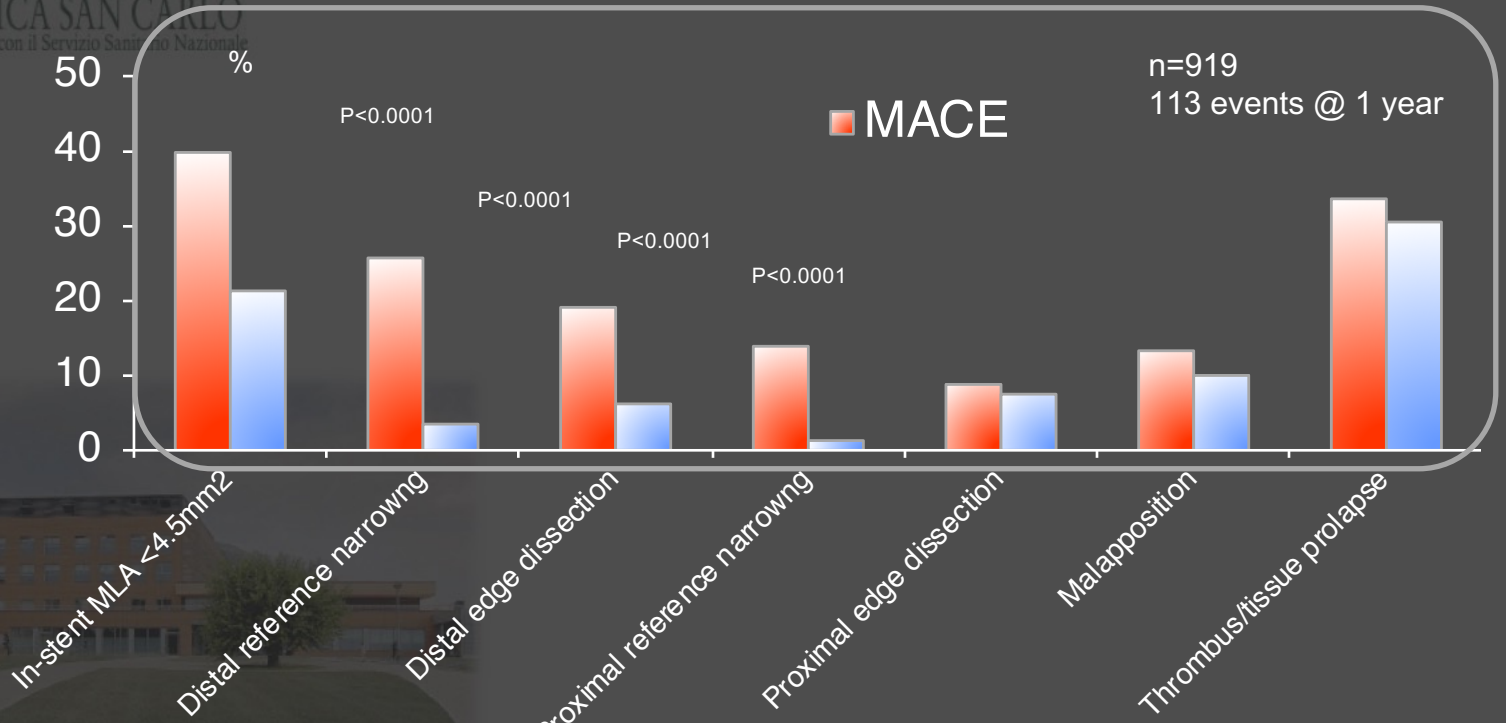
CLI-OPCI II STUDY VALIDATES THAT THE USE OF OCT SHOULD BE ENCOURAGED

Patients with MACE* have a significantly higher incidence of procedural issues that are not corrected





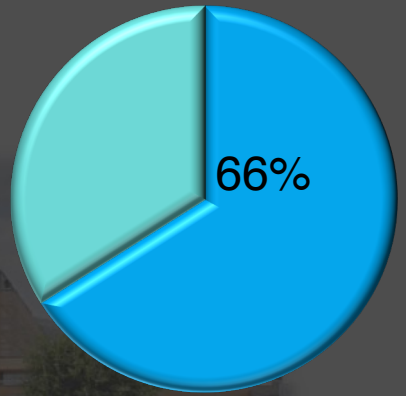
CLI-OPCI II: Independent predictors of MACE were in-stent MLA <4.5mm2, distal edge dissection, distal reference narrowing, and proximal reference narrowing[1]



1. Prati et al Clinical Impact of OCT-Guided PCI, JACC: Cardiovascular Imaging, Vol. 8, No. 11, 2015, November 2015:1297-305

ILUMIEN I: OCT influenced physician decision making in 66% of patients

OCT imaging influenced decisions in 66% of patients



Pre-PCI OCT altered treatment planning in 57% of lesions and led to changes in decisions related to stent length and diameter.

Post-PCI OCT resulted in further stent optimization in 27% of lesions to correct abnormalities such as malapposition, underexpansion and edge dissection.

Wijns W, Shite J, Jones MR, et al. Optical coherence tomography imaging during percutaneous coronary intervention impacts physician decisionmaking: ILUMIEN I study. Eur Heart J 2015;36:3346-55.

METHODS This was a cohort study based on the Pan-London (United Kingdom) PCI registry, which includes 123,764 patients who underwent PCI in National Health Service hospitals in London between 2005 and 2015. Patients undergoing primary PCI or pressure wire use were excluded leaving 87,166 patients in the study. The primary endpoint was all-cause mortality at a median of 4.8 years.

FIGURE 1 Number of OCT and IVUS Procedures Performed Over Time

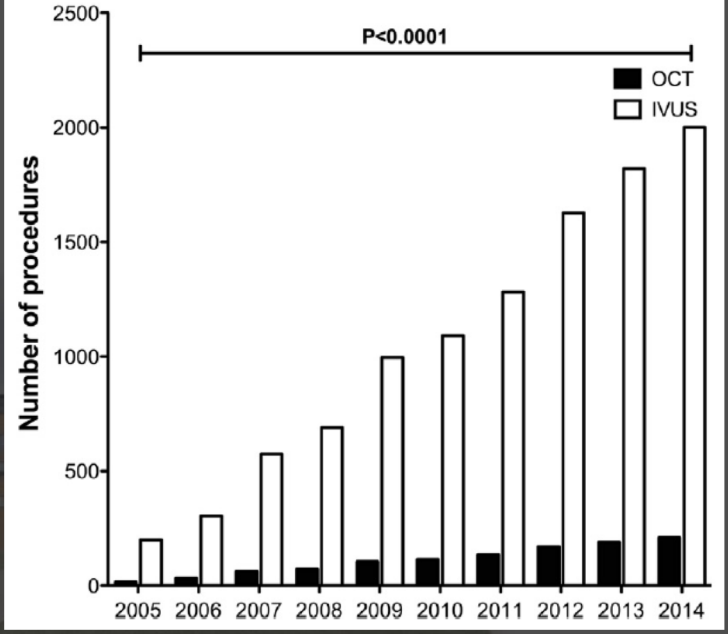
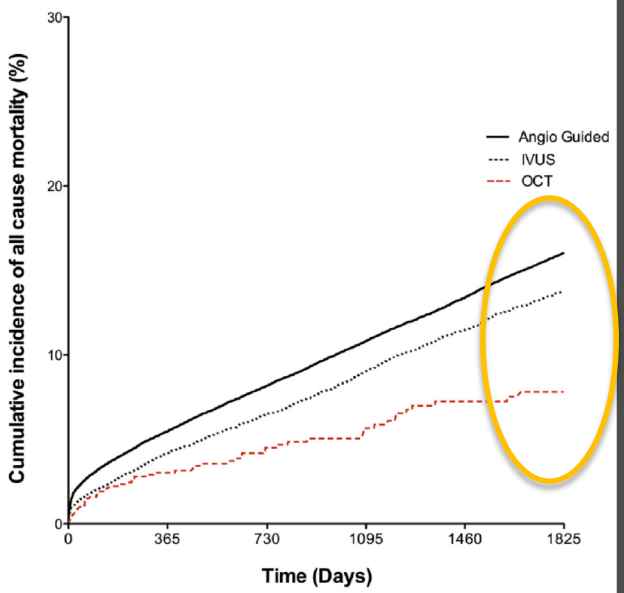


FIGURE 2 Kaplan-Meier Curve Comparing All-Cause Mortality Between OCT-Guided, IVUS-Guided, and Angiography-Alone Procedures



Numbers at risk

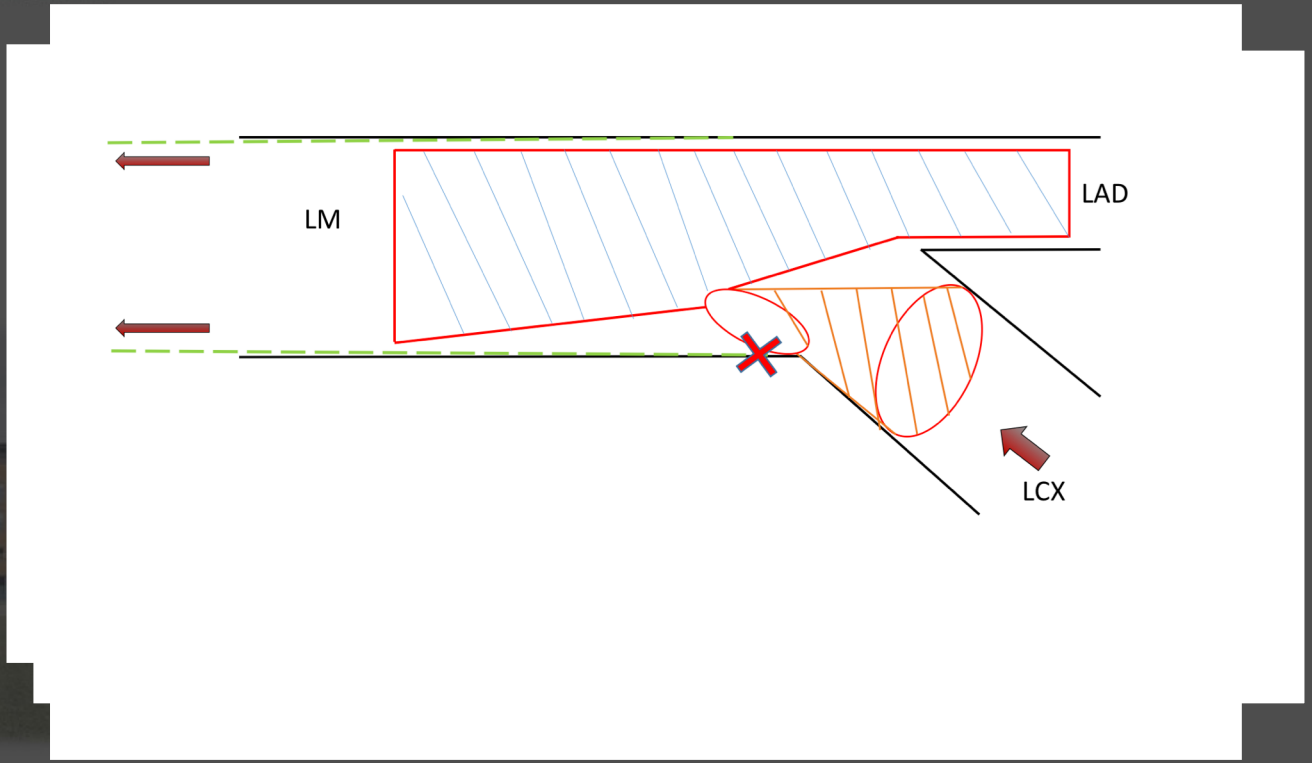
Angio Only	75046	66033	56182	51030	40053	28765
IVUS	10971	8954	7838	6632	5431	4242
OCT	1149	901	789	654	561	410

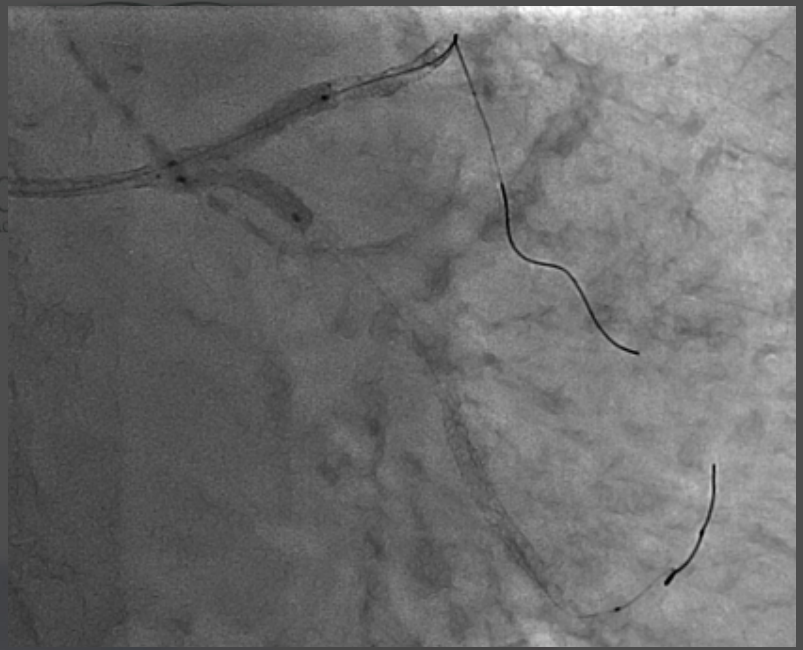
D Jones, JACC Int '18

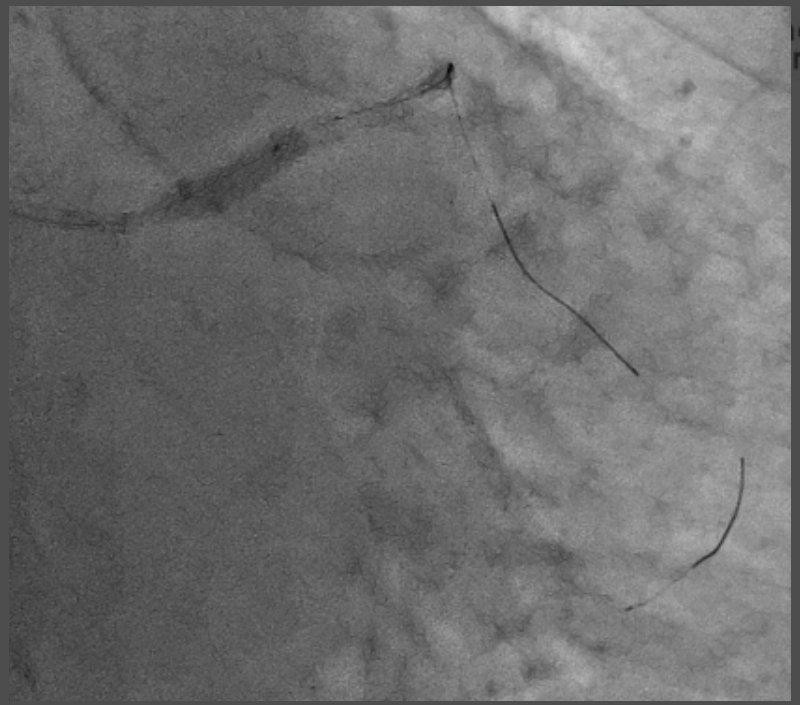
- 62-year-old woman.
- Diabetes mellitus, hypertension, hypercholesterolemia.
- Previous PTCA+DES on mid-LAD, Cx-OM.
- Jan 2017 stable angina

What happened?

During Stentys sheath retrieval, there was the “catch” of the Xience in CX, that was retrieved in the LM.







KB pre-dilation with 2 NC balloons 3/20 on LM-LAD, 3/15 on Cx

PTCA on LM with NC balloon 4.5/12 in order to crush the protruded struts of the Cx DES

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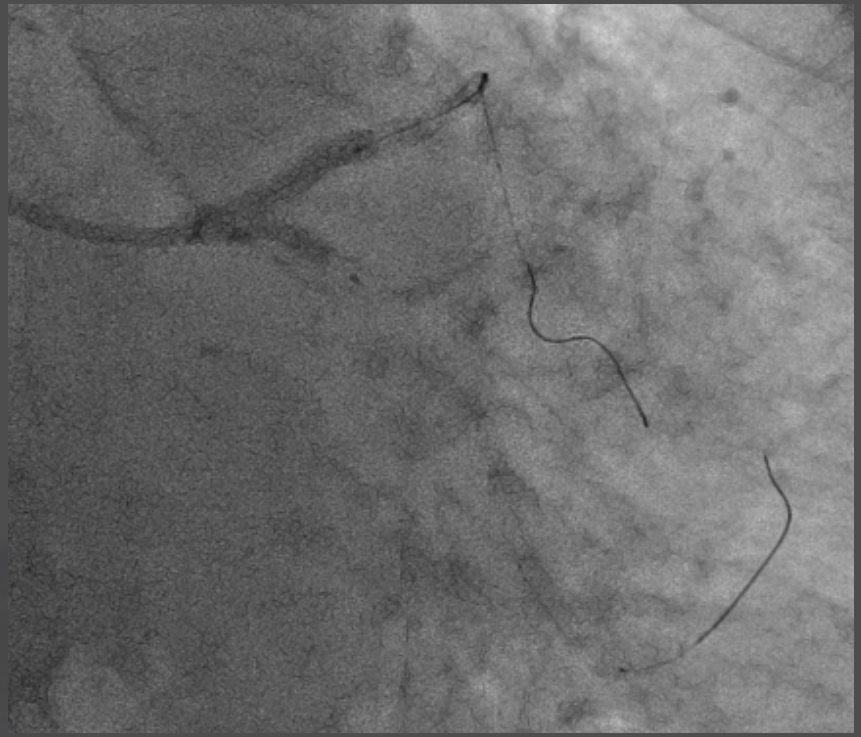
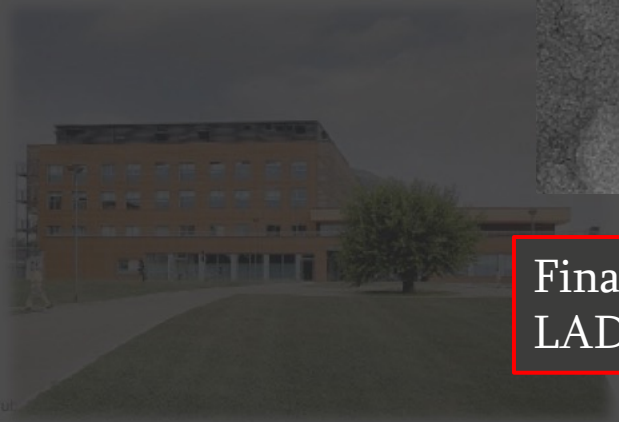
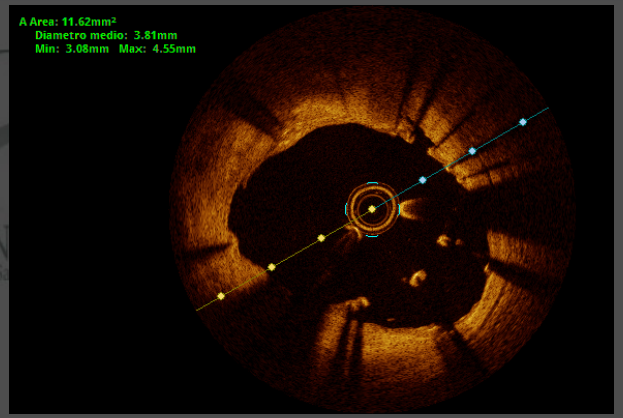
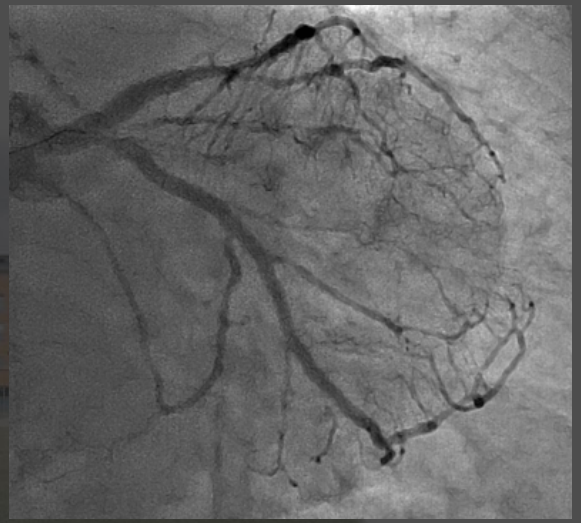


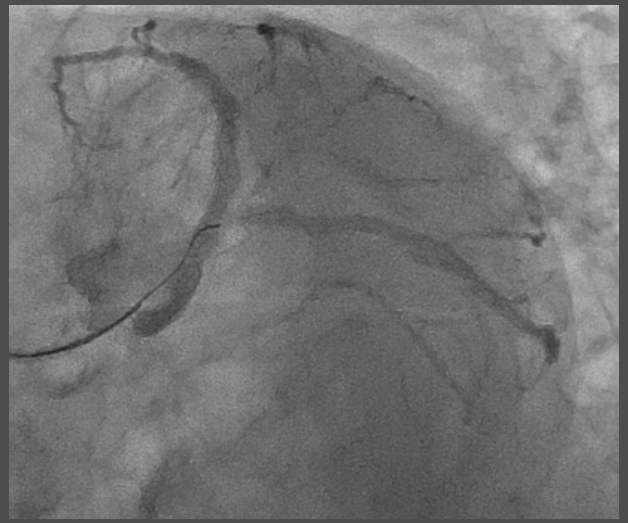


Final KB with NC balloon 3.5/20 on LM-LAD and DCB 3/20 on Cx.



Final OCT shows mild malapposition of few struts, with a good angiographic result and a 30% residual stenosi on ostial Cx



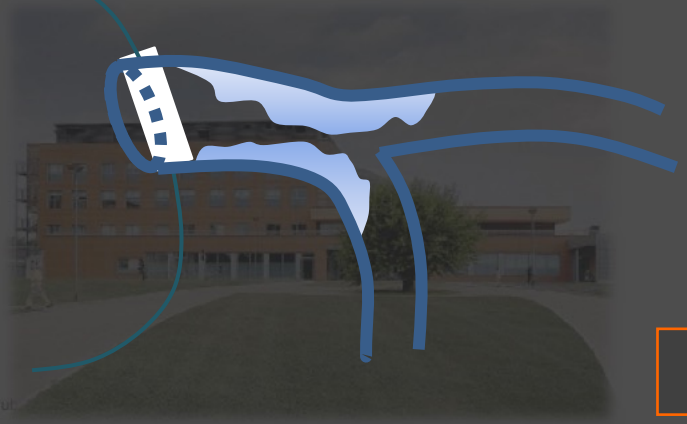


Guidelines-intravascular adjuvance for LM stenting

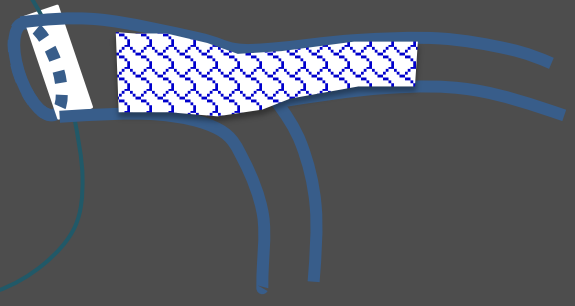
ESC European Society of Cardiology
European Heart Journal (2018) 00, 1–96
doi:10.1093/eurheartj/ehy394
ESC/EACTS GUIDELINES

2018 ESC/EACTS Guidelines on myocardial revascularization

IIa B
IVUS to assess severity and optimize treatment of unprotected left main lesions.



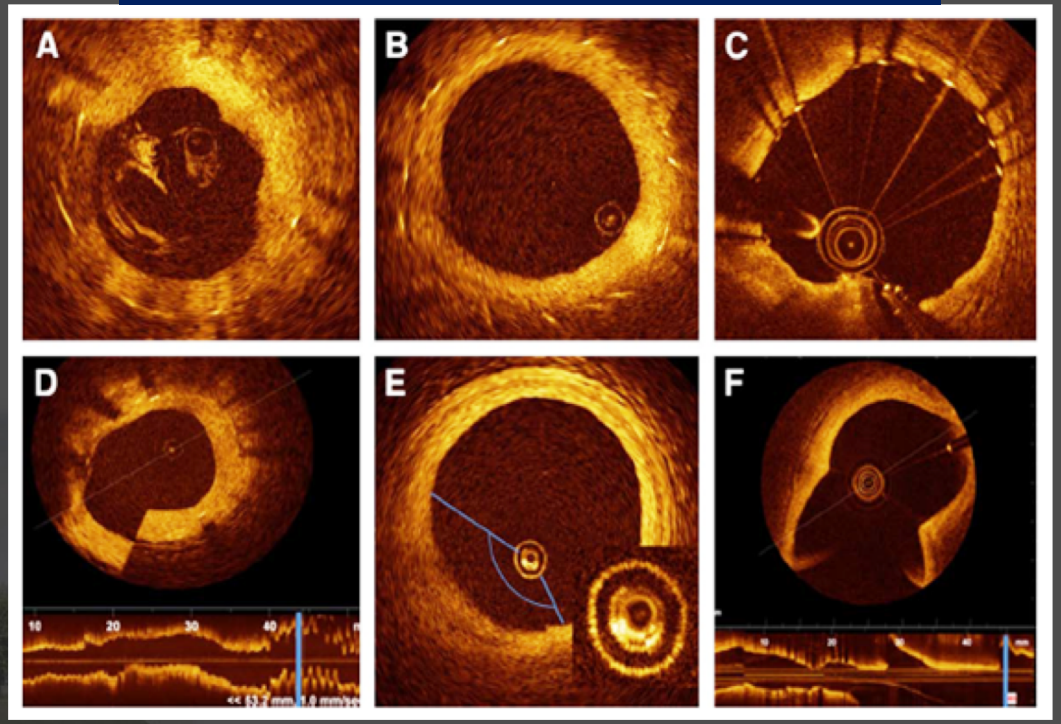
IIa B
IVUS should be considered to assess the severity of unprotected left main lesions.
IVUS should be considered to optimize treatment of unprotected left main lesions.



OCT: not arrived

SHOULD WE BE CONCERNED ABOUT OCT IN LM ?

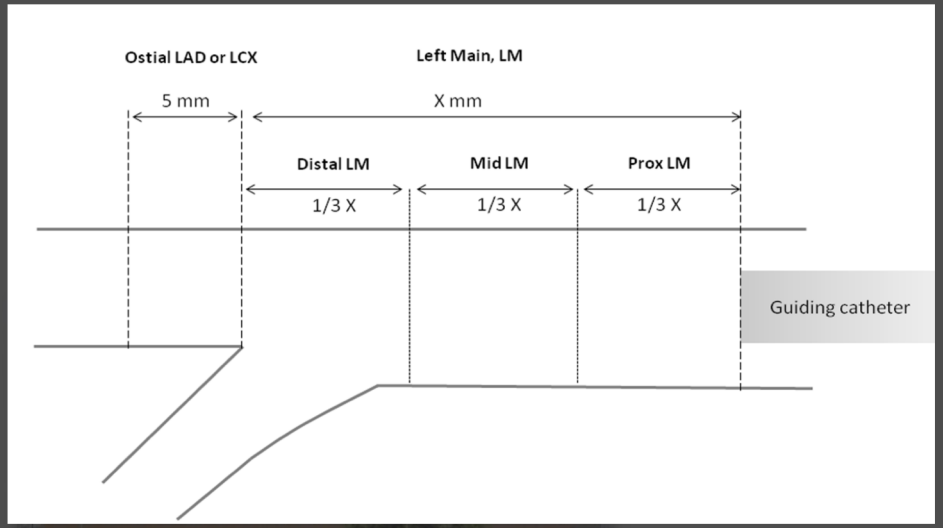
Common OCT artifacts



Bezerra HG et al. J Am Coll Cardiol Intv 2009

OCT QUALITY IN LEFT MAIN

STUDY END-POINT:
Nr of artifacted frames (failure of MLA automatic calculation)

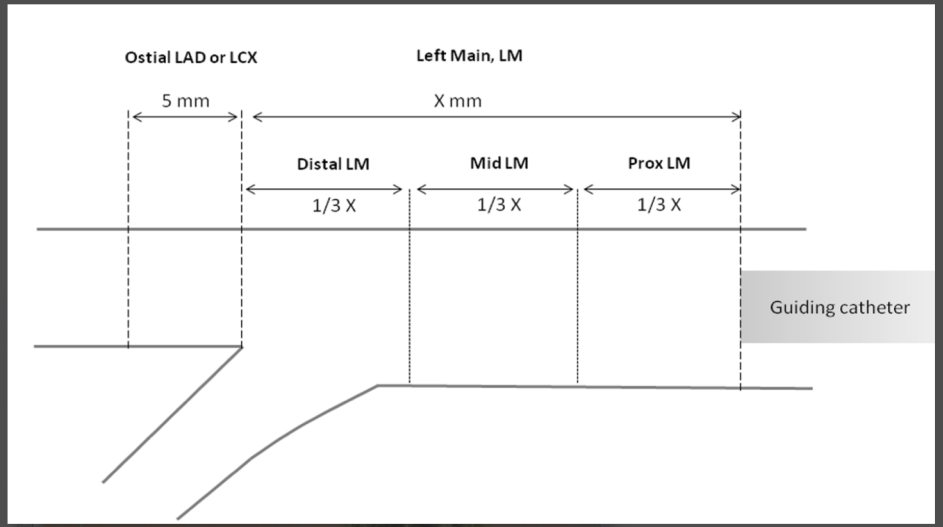


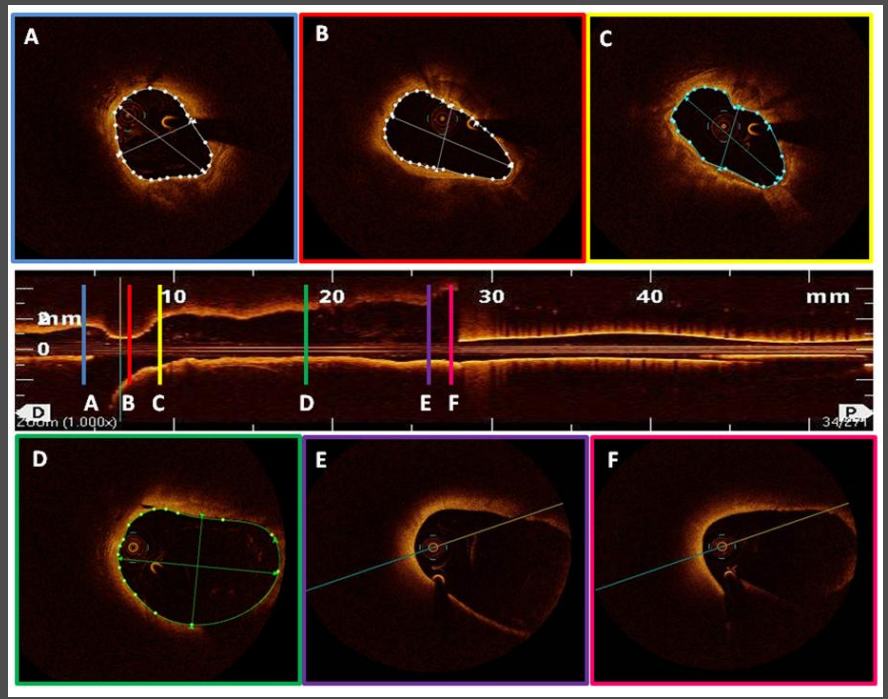
Artifacted frames where present in 19% of the total number of LM frames analysed

Burzotta et al. Eurointervention 2015

OCT QUALITY IN LEFT MAIN

STUDY END-POINT:
Nr of artifacted frames (failure of MLA automatic calculation)





Burzotta et al. Eurointervention 2015

OCT QUALITY IN LEFT MAIN

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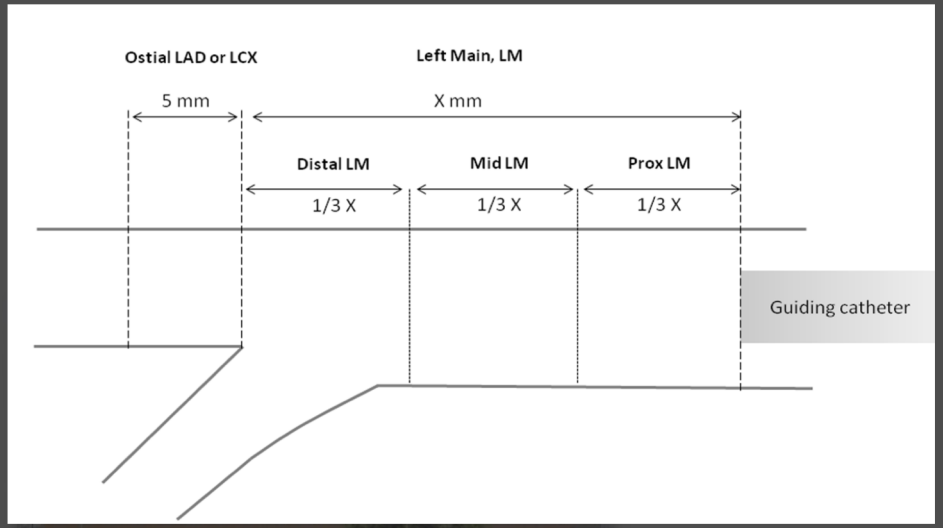
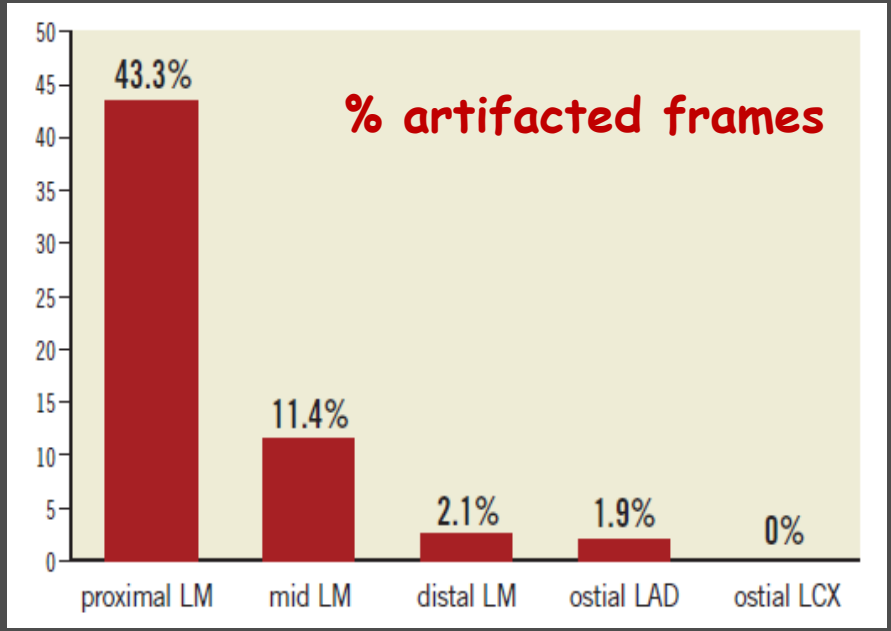
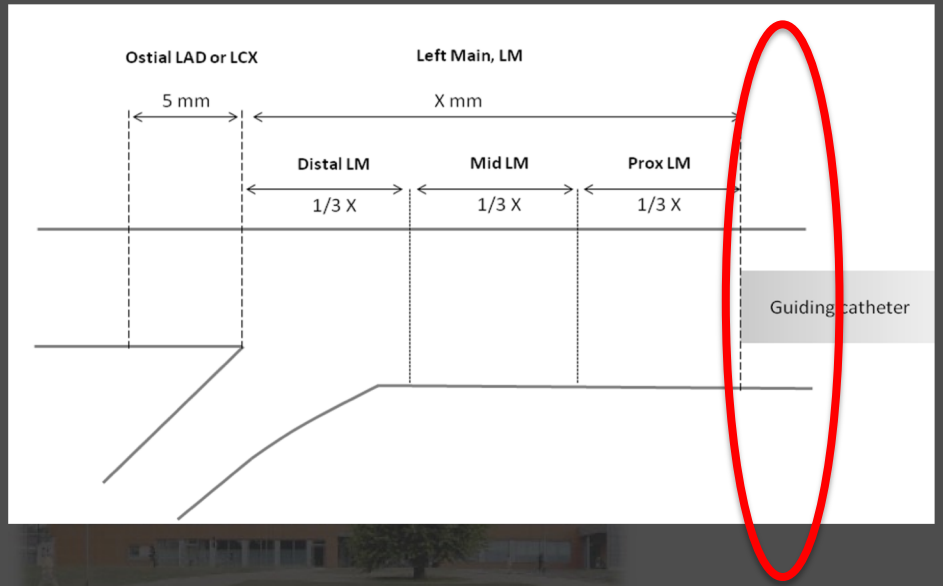




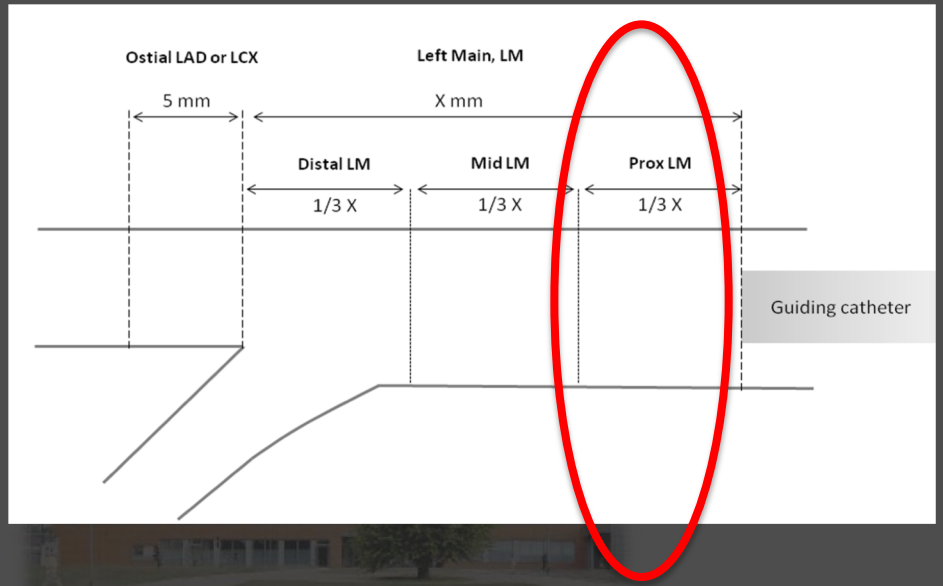
Burzotta et al. Eurointervention 2015

OCT QUALITY IN LEFT MAIN



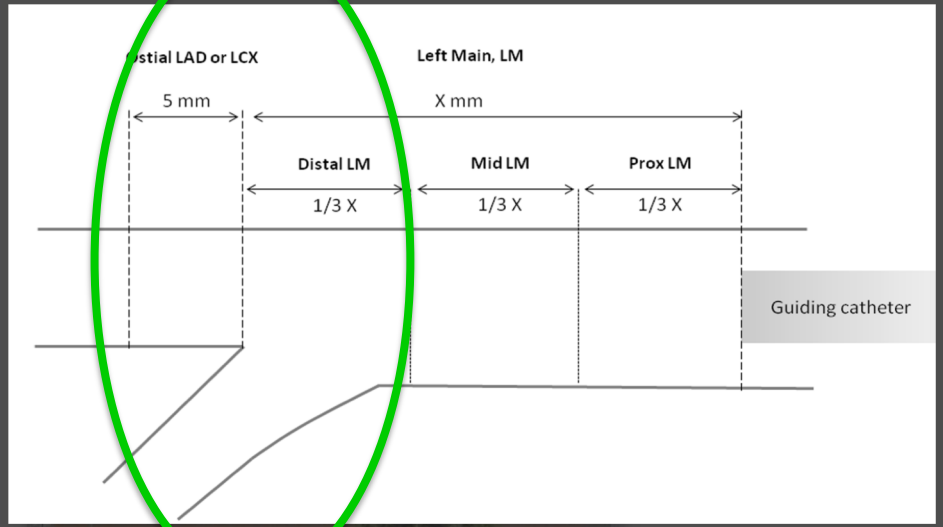
OCT systematically misses the first LM segments

OCT QUALITY IN LEFT MAIN



OCT has often artifacts in the proximal part of LM

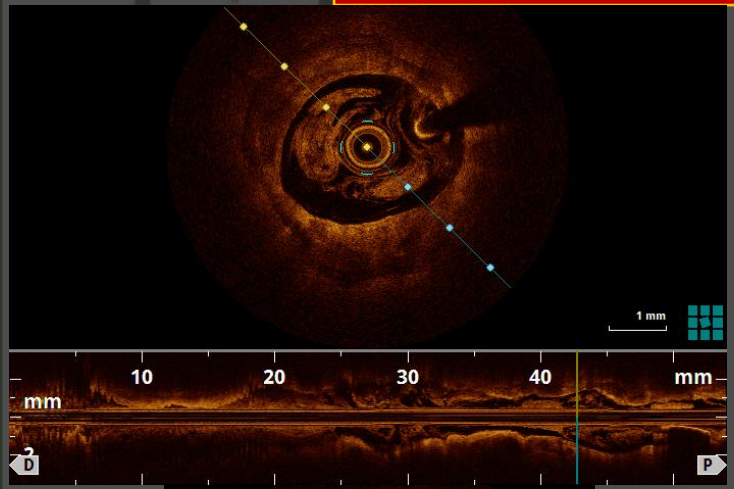
OCT QUALITY IN LEFT MAIN

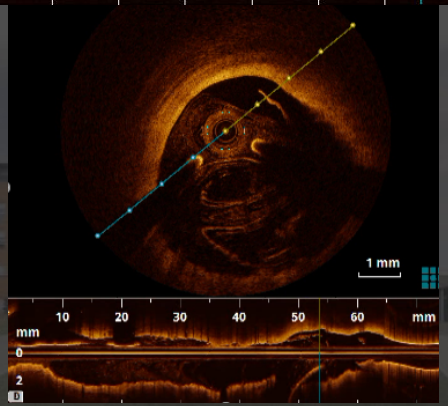


OCT may allow optimal imaging for distal LM (and ostial LAD/LCX)

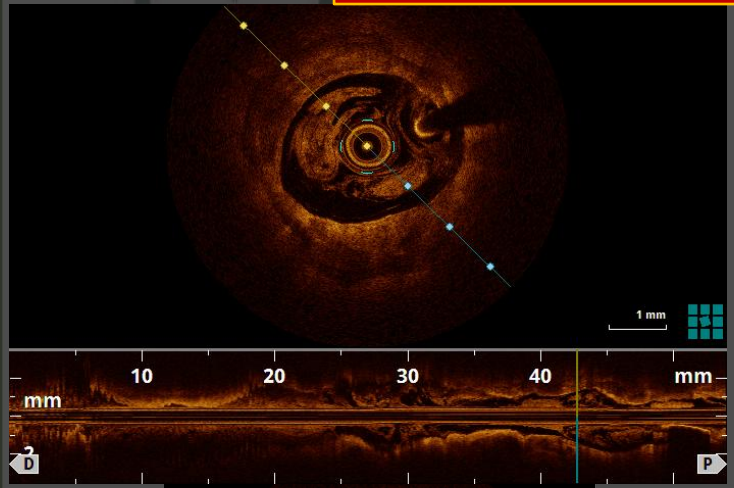
…which accounts for 70-80% of LM PCIs

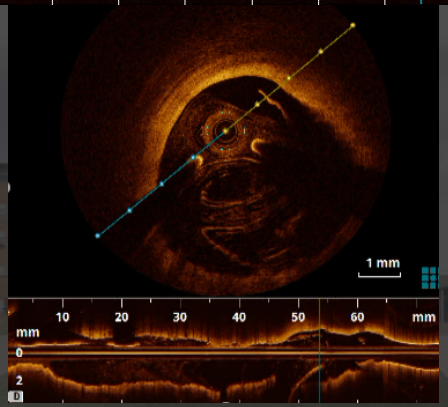
HOW TO IMPROVE OCT QUALITY IN LM ?

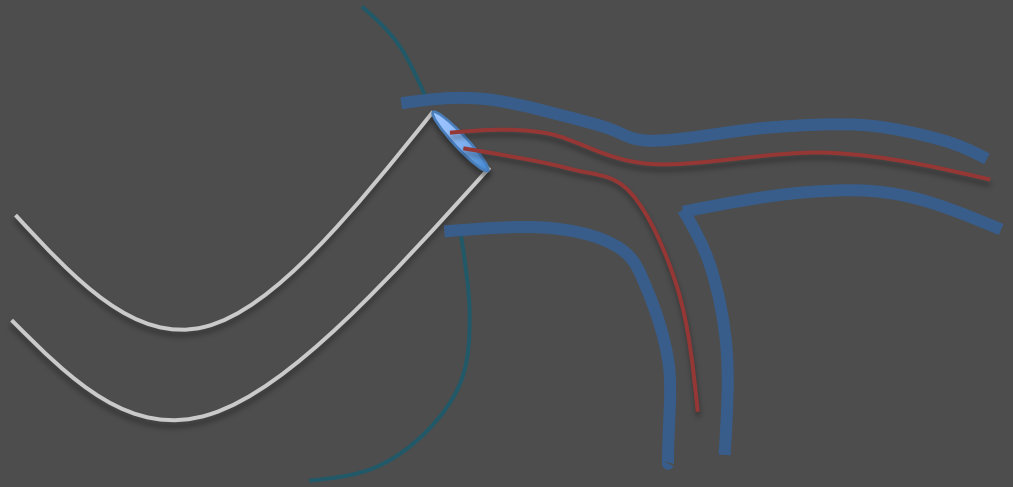




HOW TO IMPROVE OCT QUALITY IN LM ?

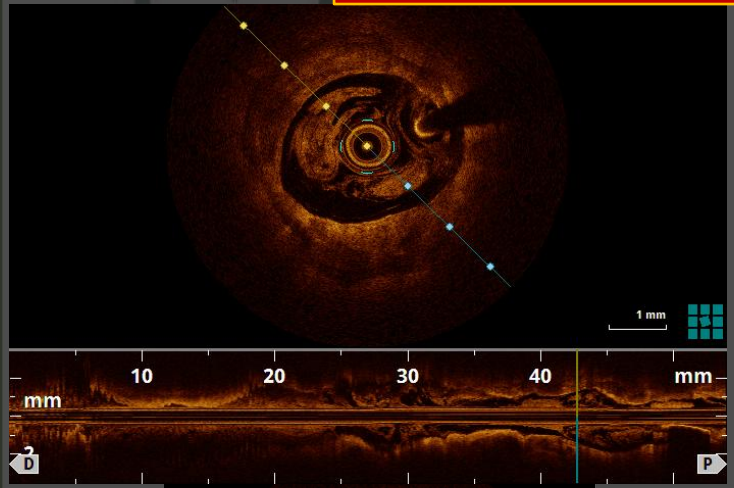


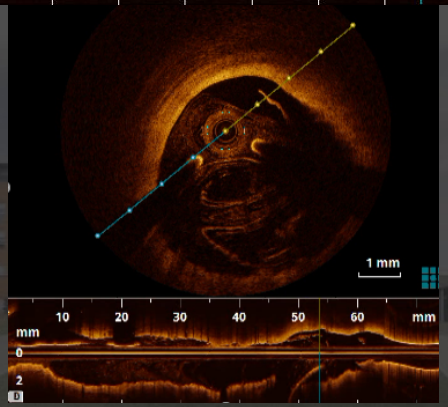


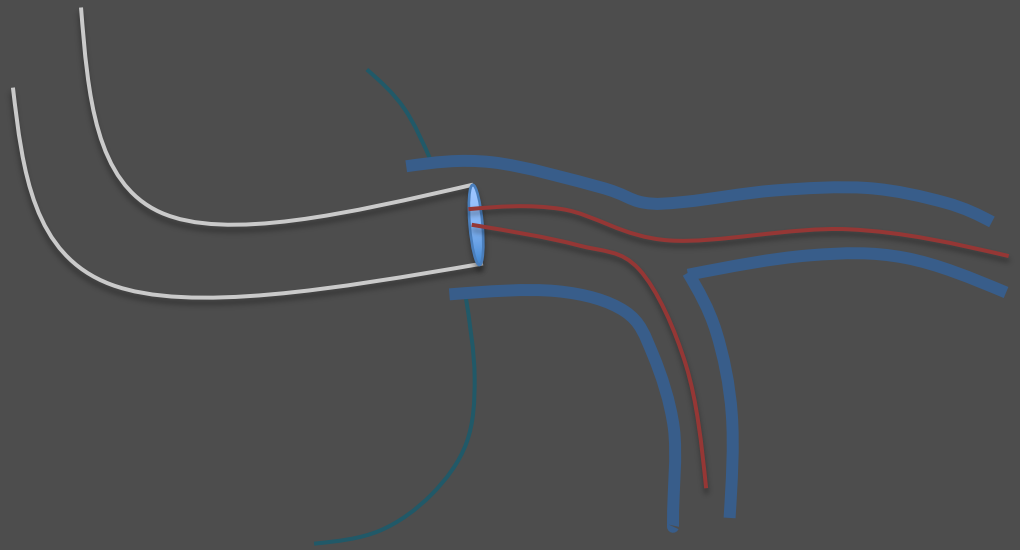


Acquisition technique may be pivotal

HOW TO IMPROVE OCT QUALITY IN LM ?

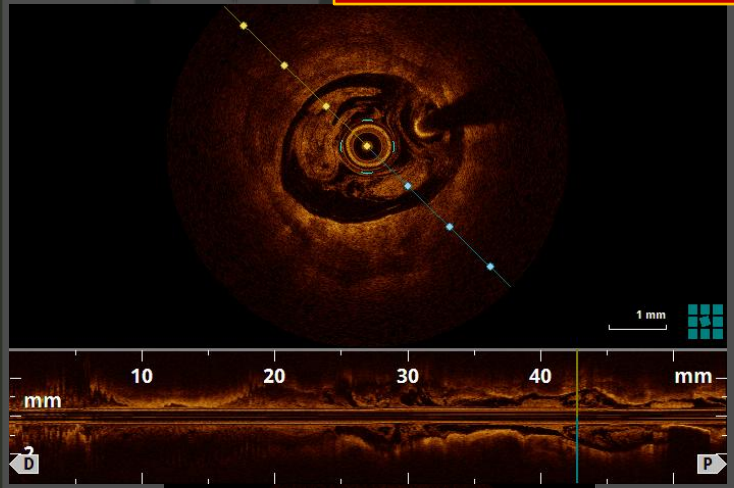


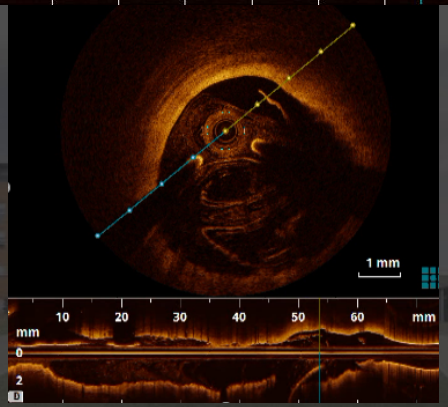


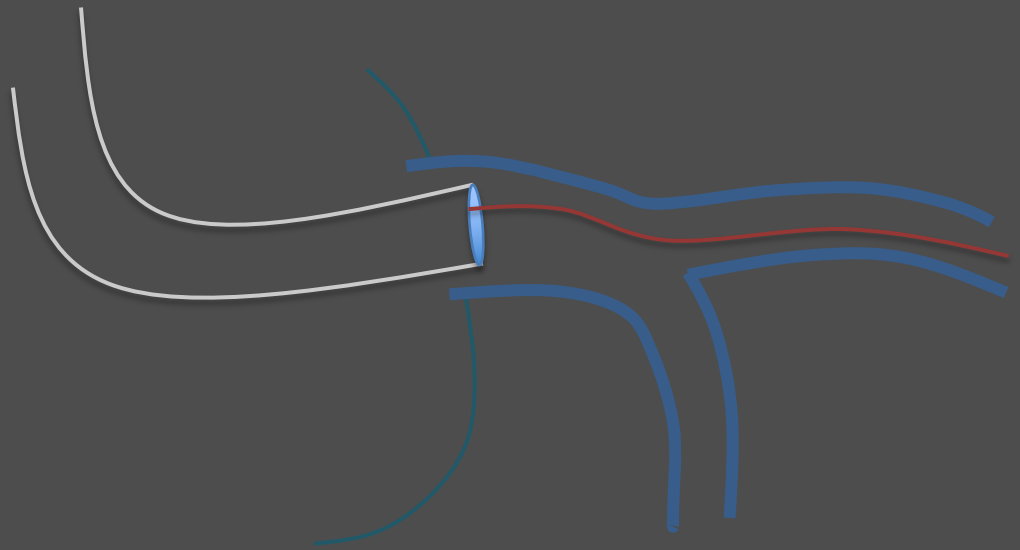


Look for a better guiding catheter alignment (and check with a test injection before acquisition)

HOW TO IMPROVE OCT QUALITY IN LM ?



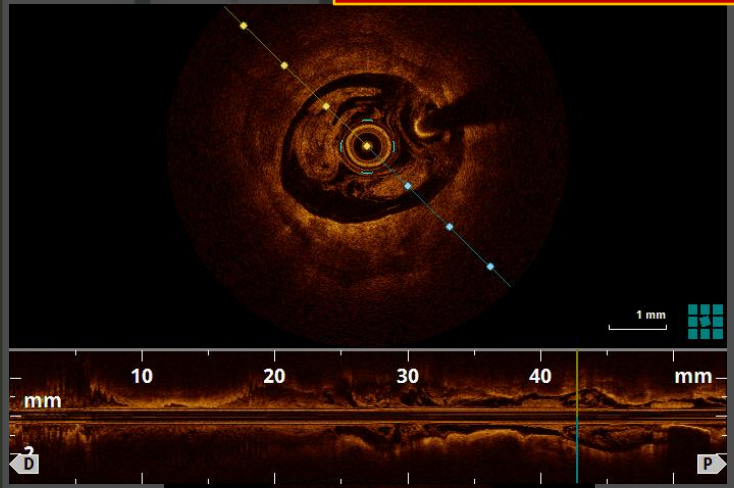


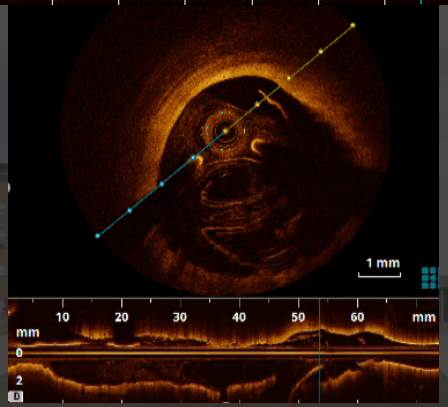


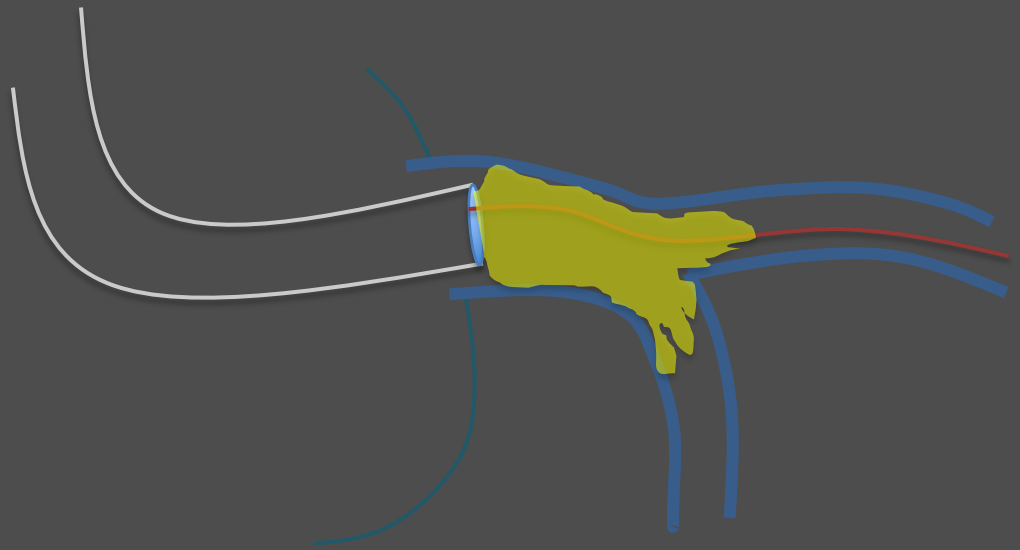
Consider using one wire only

(systematically feasible for baseline LM scanning and often feasible for post-PCI check)

HOW TO IMPROVE OCT QUALITY IN LM ?

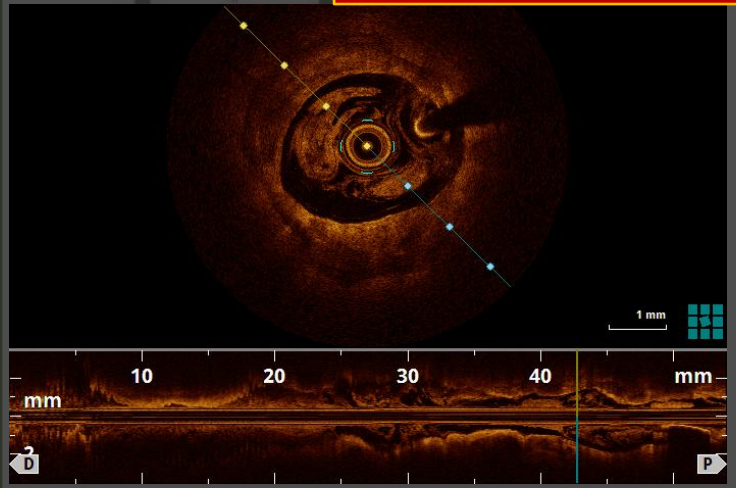




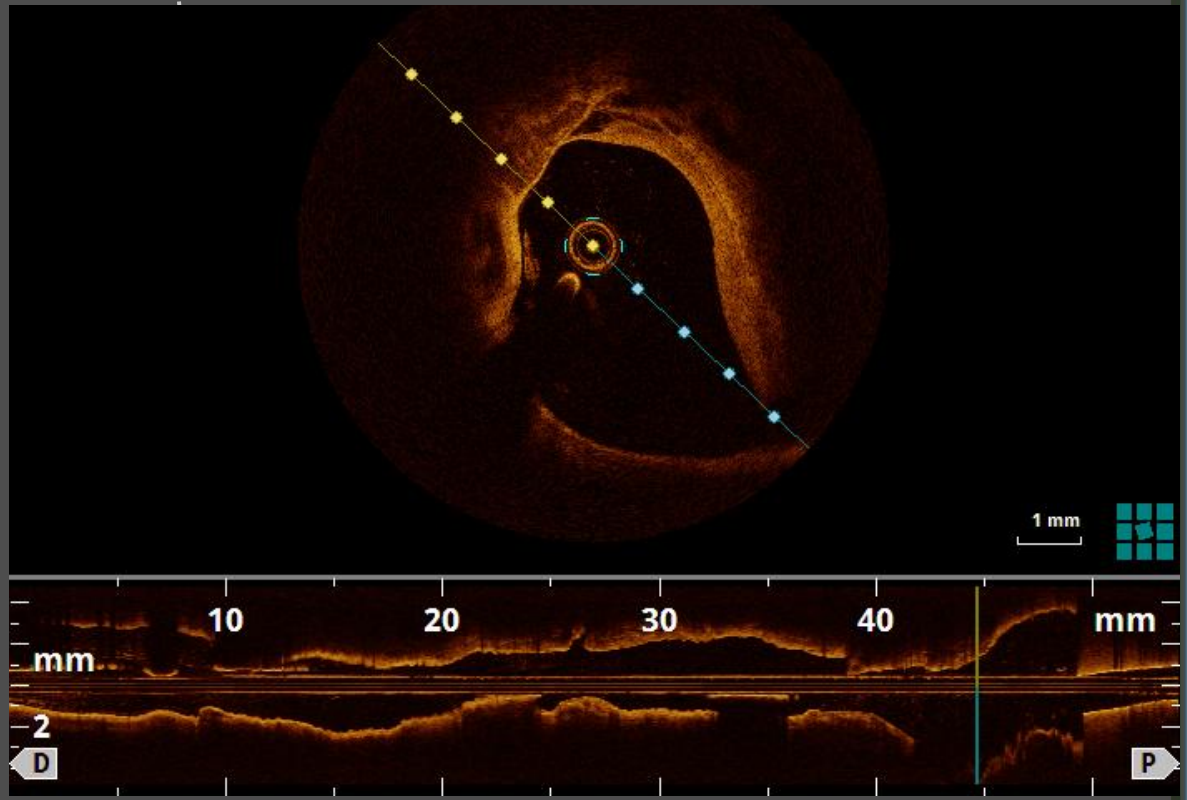


Use enhanced contrast injection protocol (6 ml/s*) in case of large LM

HOW TO IMPROVE OCT QUALITY IN LM ?



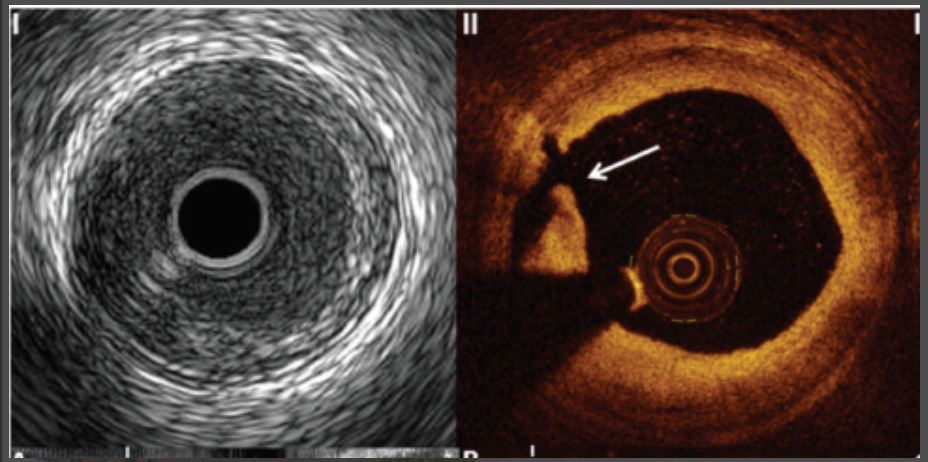
Later, in the same patient……

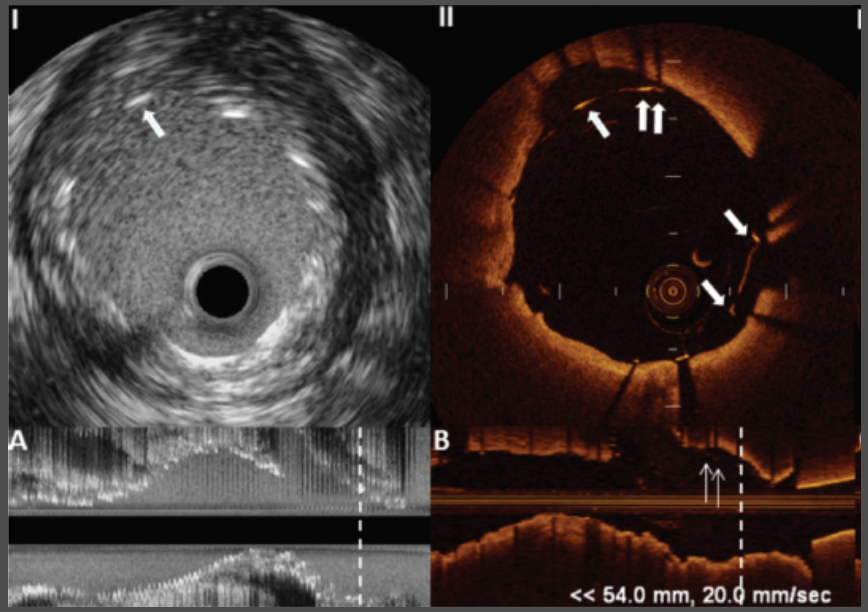


OCT / IVUS COMPARISON IN LEFT MAIN

Regione Lombardia

Frequency-Domain Optical Coherence Tomography Assessment of Unprotected Left Main Coronary Artery Disease—A Comparison With Intravascular Ultrasound





WE SEE MUCH BETTER WITH OCT !!!

Fujino et al. CCI 2013

OCT / IVUS COMPARISON IN LEFT MAIN

TABLE IV. IVUS and FD-OCT Imaging Analysis[a]

	IVUS	FD-OCT	*P*-value
Pre-PCI			
Lesion completeness			
Proximal completeness, *n* (%)			
Distal completeness, *n* (%)			
Total length (mm)			
ULM body length (mm)			
Lumen area (mm²)			
Mean			
Min			
Intraluminal thrombus, *n* (%) PRE			
Vessel out of screen, n (%)			
Post-PCT			
Stent completeness			
ULM body stent length (mm)	8.26 ± 3.52	7.13 ± 3.60	0.014

TABLE V. Post-PCI and Follow-up FD-OCT Imaging Analysis[a]

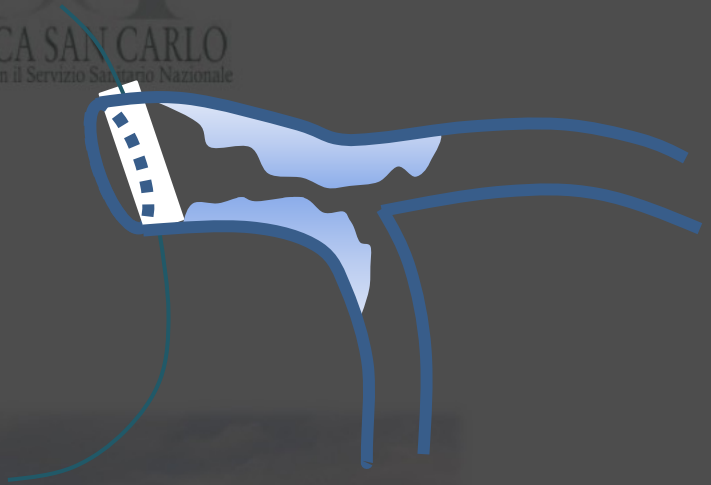
N = 21	FD-OCT (post-PCI)	FD-OCT (follow-up)	*P*-value
		9.83 ± 2.18	0.002
		5.89 ± 2.03	0.001
		10.43 ± 1.92	0.299
		6.57 ± 2.04	0.317
		–	NA
		0.85 ± 0.55	NA
		0.13 ± 0.14	0.002
		3.07 ± 3.85	0.027
Intraluminal thrombus, *n* (%)	0 (0.00)	0 (0.00)	NA

MLA measured by OCT is significantly smaller than by IVUS
(FD-OCT MLA being 10-15% lower than IVUS MLA)

WE CANNOT USE THE SAME CUT-OFFS VALIDATED IN IVUS STUDIES !!!

Fujino et al. CCI 2013

WHICH CLINICAL DATA SO FAR ?



TO UNDERSTAND DISEASE
SEVERITY AND
MORPHOLOGY

LEFT MAIN MANAGEMENT DECISION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Optical coherence tomography guidance for the management of angiographically intermediate left main bifurcation lesions: Early clinical experience

Ilaria Dato, Francesco Burzotta *, Carlo Trani, Andrea Romano, Lazzaro Paraggio, Cristina Aurigemma, Italo Porto, Antonio Maria Leone, Giampaolo Niccoli, Filippo Crea

Institute of Cardiology, Catholic University of Sacred Heart, Rome, Italy

122 patients
with **angiographically-intermediate** LM bifurcation

↓

OCT assessment

- LM area stenosis ≥75% *or*
- LM plaque with MLA<4 mm2 and/or ulceration *or*
- Critical lesion in ostial LAD or ostial LCX

↓ YES

Myocardial Revascularization
64 pts (52%, 48 PCI, 16 CABG)

↓ NO

Conservative management
58 pts (48%)

Dato et al. Int J Cardiol 2017

LEFT MAIN MANAGEMENT DECISION

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Institute of Cardiology, Catholic University of Sacred Heart, I

Table 3
Clinical outcomes observed at mean follow-up time of 18 months.

MACE	Revascularized group (n = 64)	Deferred group (n = 58)
TVF	6 (9)	2 (3.5)
CV death	2 (3)	0
AMI	1 (1.5)	0
TVR	3 (4.5)[a]	2 (3.5)

Myocardial Revascularization
64 pts (52%, 48 PCI, 16 CABG)

Conservative management
58 pts (48%)

Dato et al. Int J Cardiol 2017

WHICH CLINICAL DATA SO FAR ?

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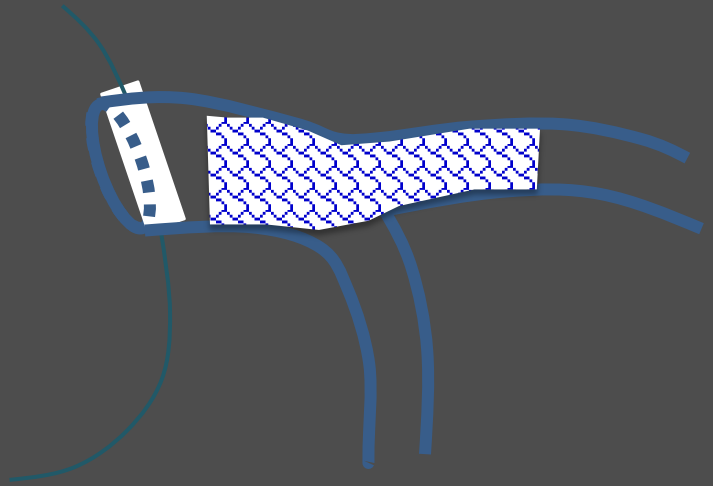
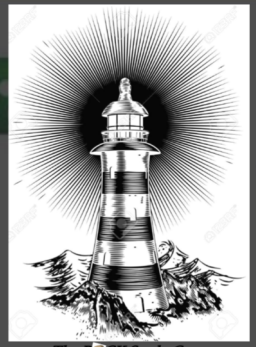


TO ACHIEVE THE BEST RESULT DURING STENTING (PCI OPTIMIZATION)

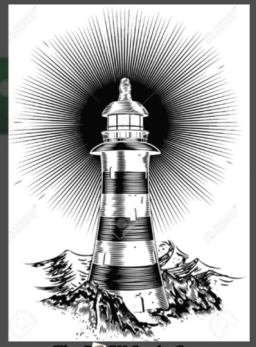
The ROCK I study

- Retrospective, multicenter, spontaneous clinical registry.
- to observe and evaluate the diagnostic performance of OCT for left main trunk angioplasty, as compared with the gold standard imaging technique, including IVUS.
- Investigators: B. Cortese, F. Alfonso, F. Burzotta, F. Prati, C. Aurigemma, P. Silva, C. Trani.
- Centralized core lab



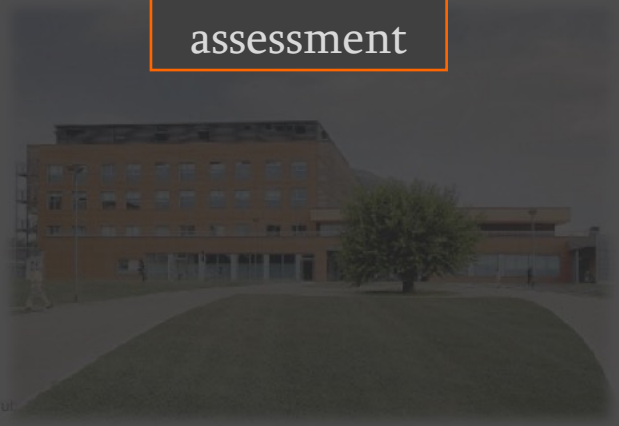
Inclusion criterion: any previous distal LM revascularization with II-gen DES AND available 6-12 mo. scheduled angiographic follow up

The ROCK I study



Reasons for using OCT:

- Vessel/lesion assessment
- Actual lumen area
- Stent deployment assessment



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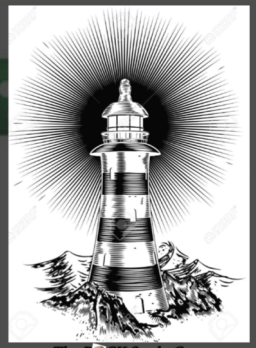
Study endpoints



Primary endpoint

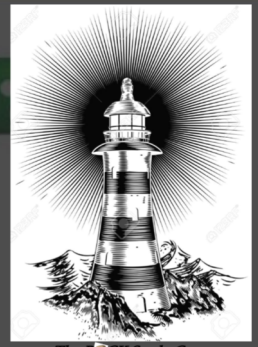
In-segment late lumen loss (LLL) of LM and SB at 6-12 month control angiography.

Statistical assumptions

We expected a LLL of 0.13 +/- 0.20 mm. We expect the noninferiority of the OCT vs standard of care. Power 90%, alpha level 5%. To confirm the hypothesis we needed to enroll 55 patients per group.

ROCK I patient population

Baseline Clinical Characteristics	
Number of patients, N=112	N (%)
Age years, mean	67.9
Males, %	73
Arterial hypertension, %	82.7
Diabetes mellitus, %	45.6
Insulin-dependent diabetes mellitus, %	11.8
Dyslipidemia, %	70
Smoking history, %	55
Previous MI, %	28
LV EF, %	53



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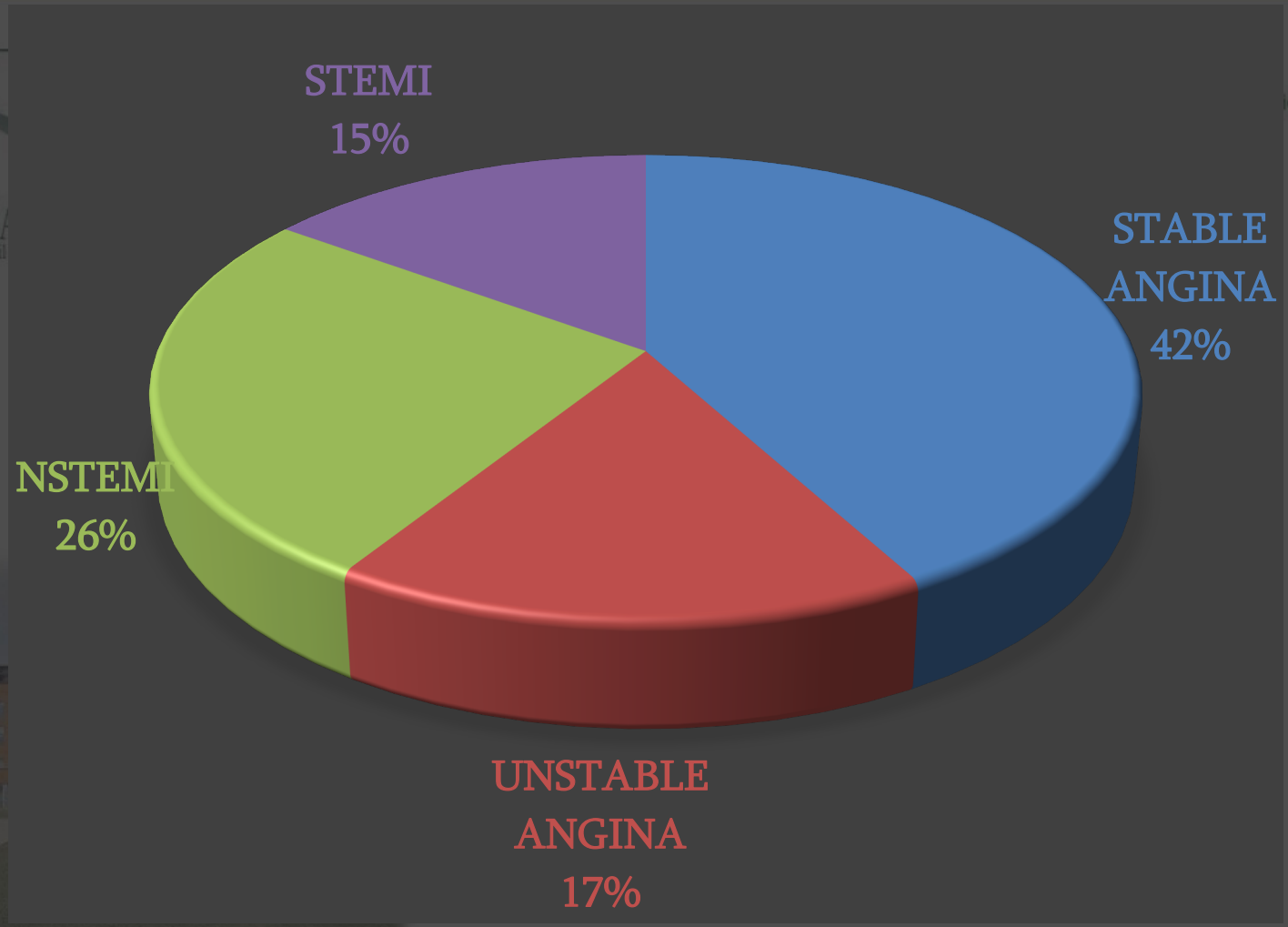
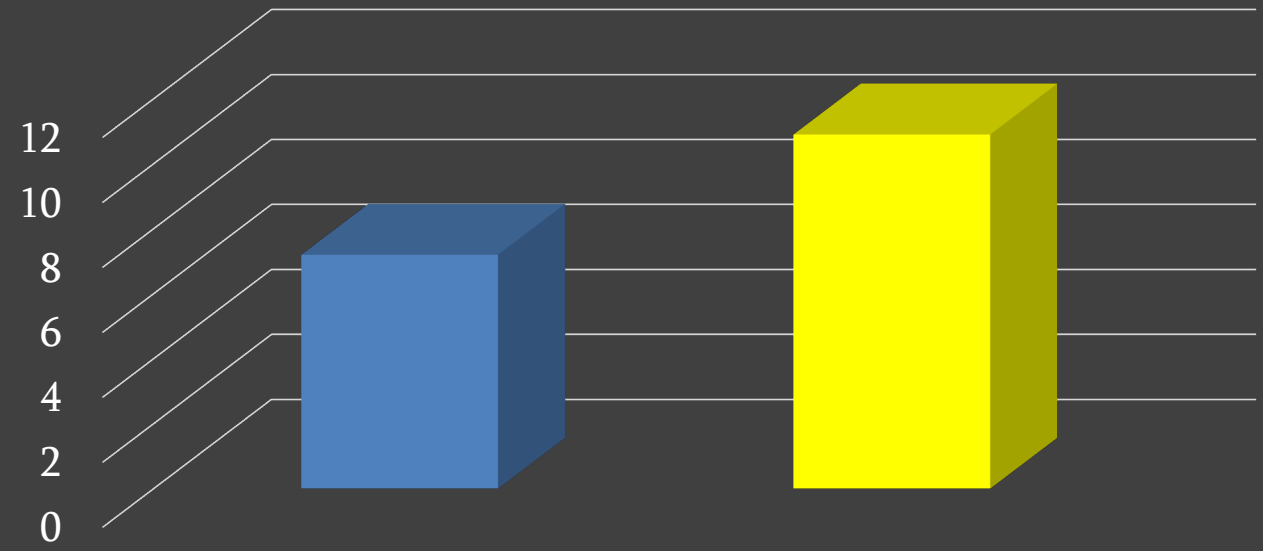

STEMI
15%
STABLE
ANGINA
42%
NSTEMI
26%
UNSTABLE
ANGINA
17%

OCT group= 55

Control group= 57

IVUS= 14 (24.6%)



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ROCK I intervention

LM intervention	
Number of patients, N=112	N (%)
Predilatation, %	71
Stent diameter, mm	3.6
Stent length, mm	21.7
Postdilatation, %	81.5
Postdil balloon size, mm	4.15
LM-LAD stenting, %	85
DCB use for SB, %	17
2-stent technique, %	14
Final KB inflation, %	61
Final LM POT, %	36.7
Angiographic success, %	100
Procedural success, %	97.2

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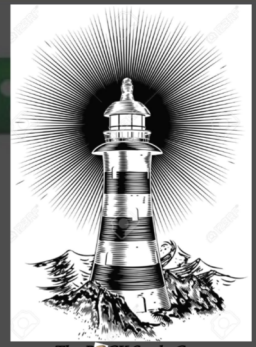
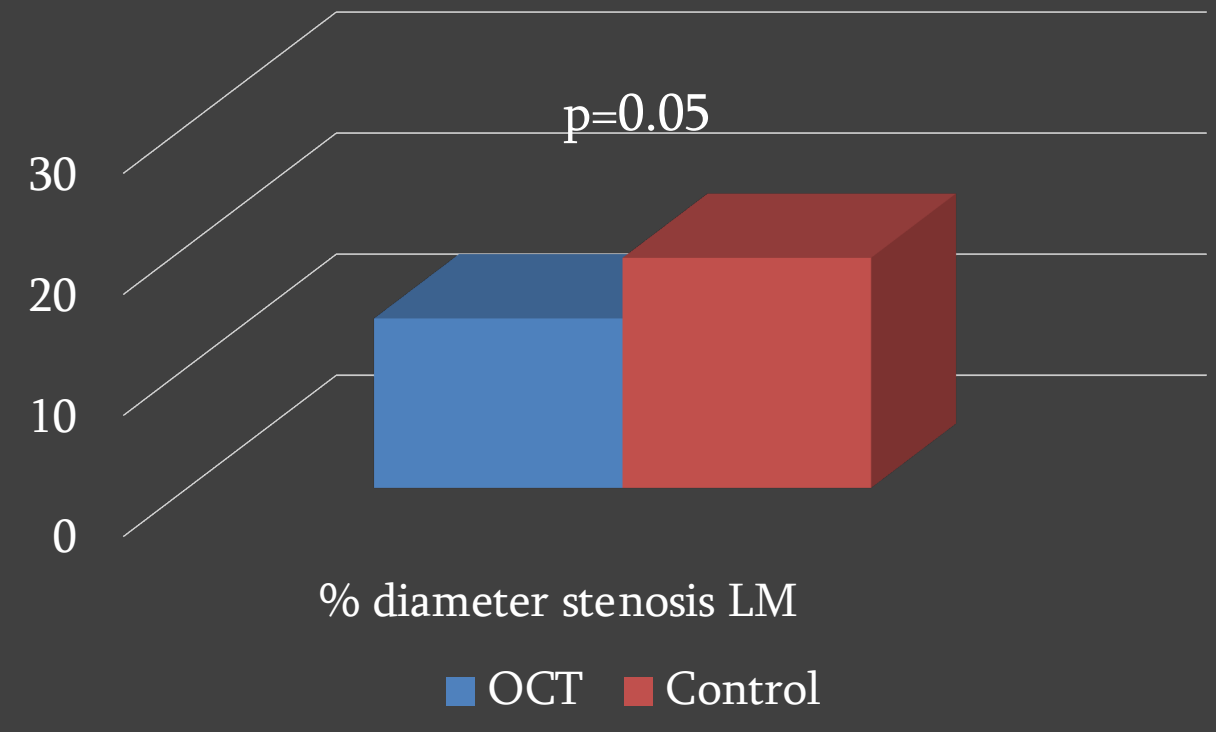


ROCK I study-angiographic follow up (279±67 days)



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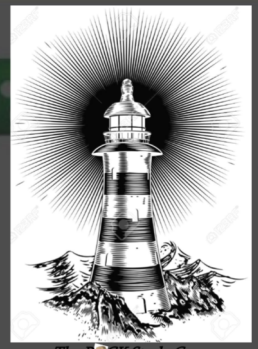
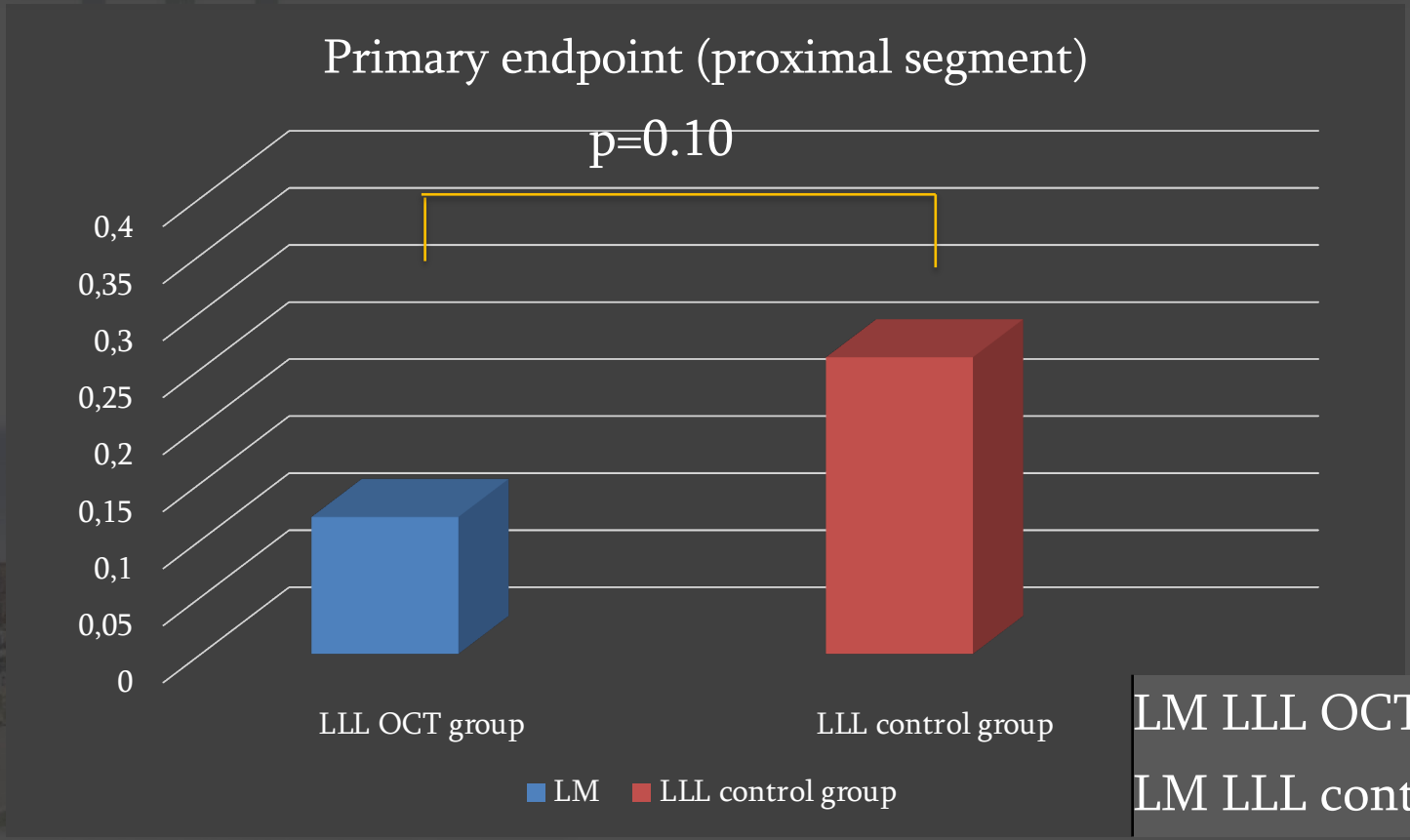
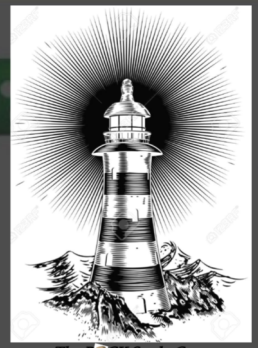


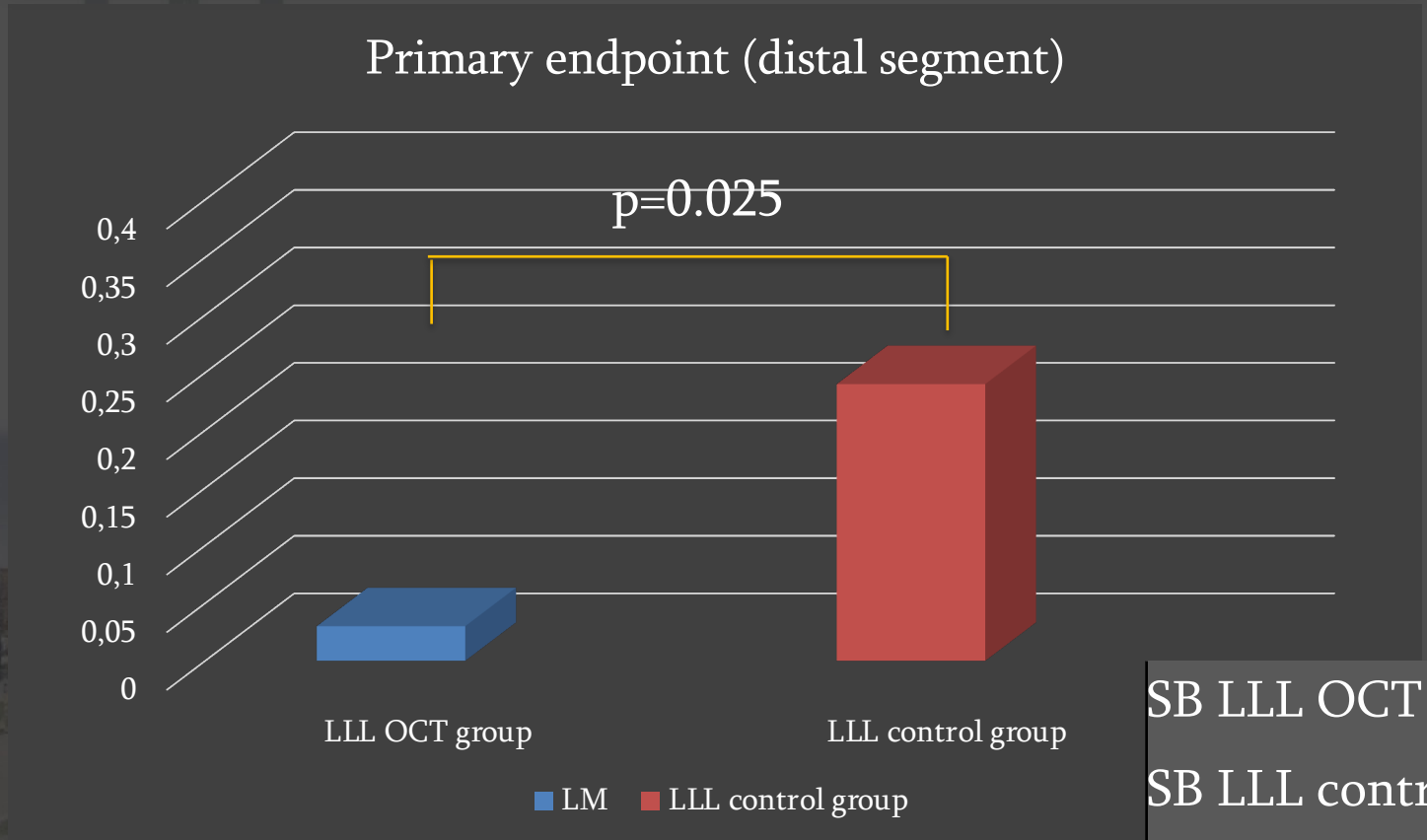
ROCK I study-angiographic follow up (279±67 days)



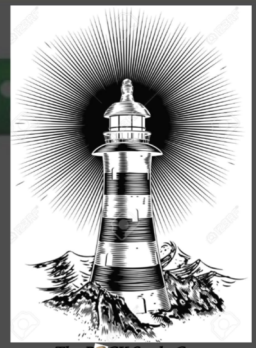
LM LLL OCT	0.12±0.41
LM LLL control	0.26±0.52



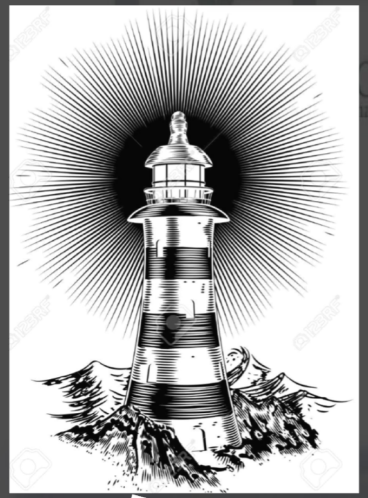
ROCK I study-angiographic follow up (279±67 days)



SB LLL OCT	0.03
SB LLL control	0.24



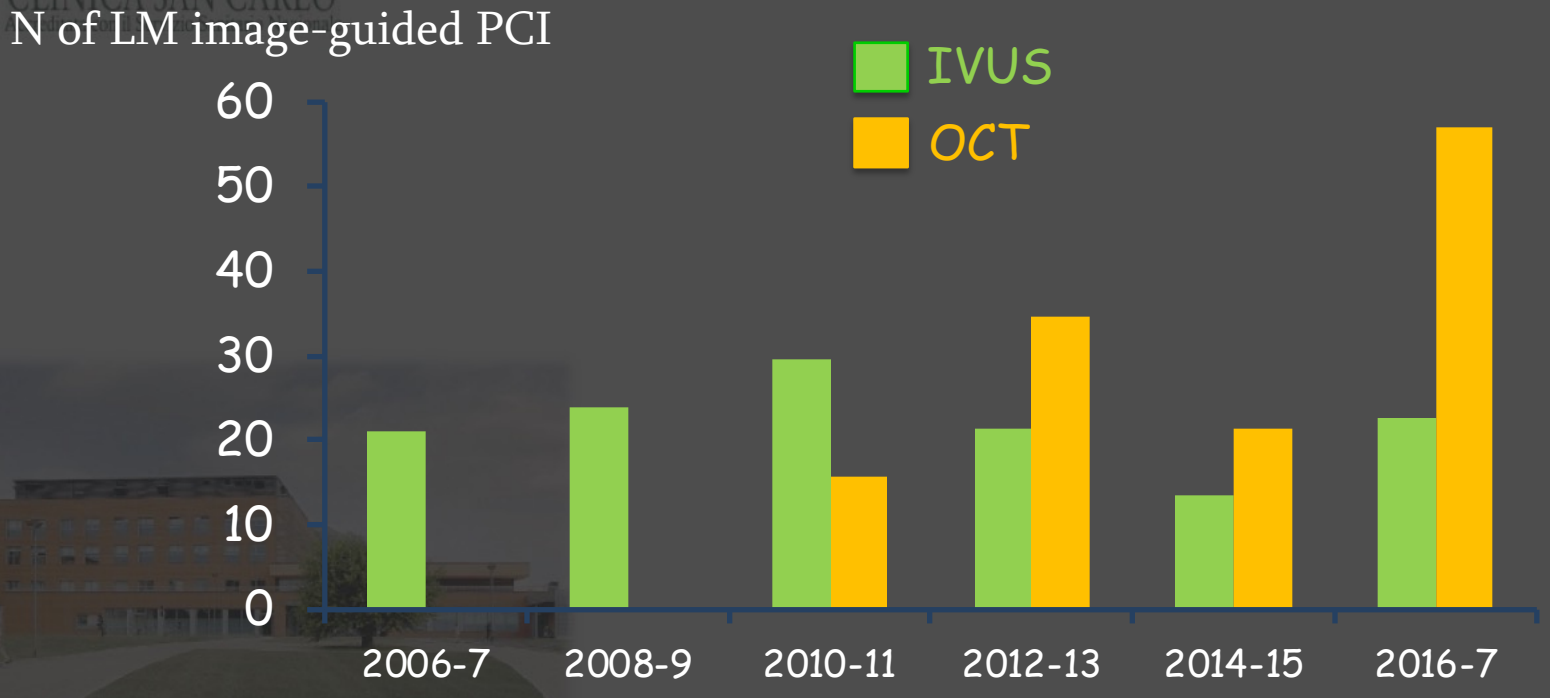
ROCK II study-on the go



- a retrospective, multicenter, spontaneous clinical registry
- grants from Abbott
- patients undergone **distal LM trunk angioplasty**
- **3 groups: OCT, IVUS, angio only**
- **primary EP: TLF at 1 year (noninferiority OCT vs. IVUS)**
- **15-20 European centers**

UNPROTECTED LEFT MAIN IMAGING SELECTION

Imaging selection for LM in 657 elective unprotected LM PCI



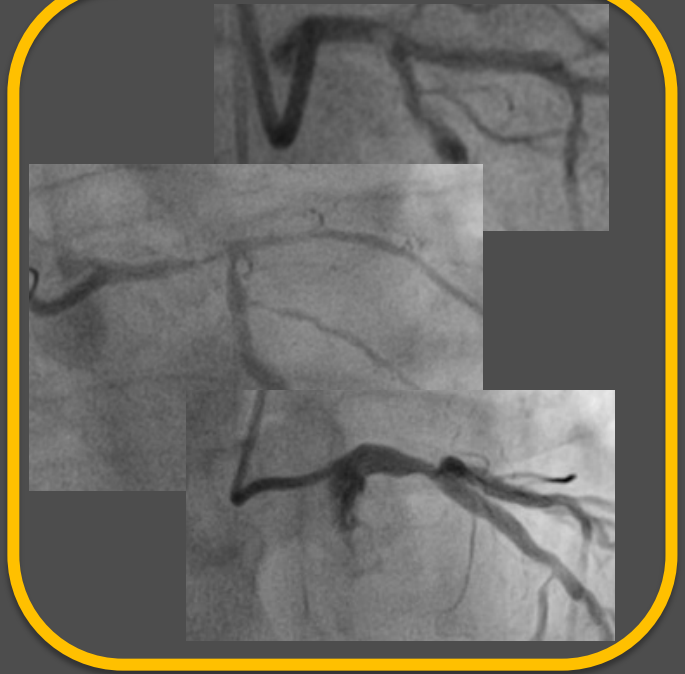
UNPROTECTED LEFT MAIN IMAGING SELECTION

OSTIAL LM

IVUS

OCT

DISTAL LM



conclusions

- OCT guidance during complex angioplasty is safe and associated with improved outcome.
- This imaging modality can be usedboth for lesion assessment and final stent optimization,

conclusions

- OCT guidance during LM angioplasty, both for lesion assessment and final stent optimization, is feasible.
- in the ROCK Cohort I study, the use of OCT allowed to easily detect acute stent underexpansion and malapposition.
- OCT guidance was associated with improved angiographic outcome at mid-term if compared to angiography±IVUS guidance.