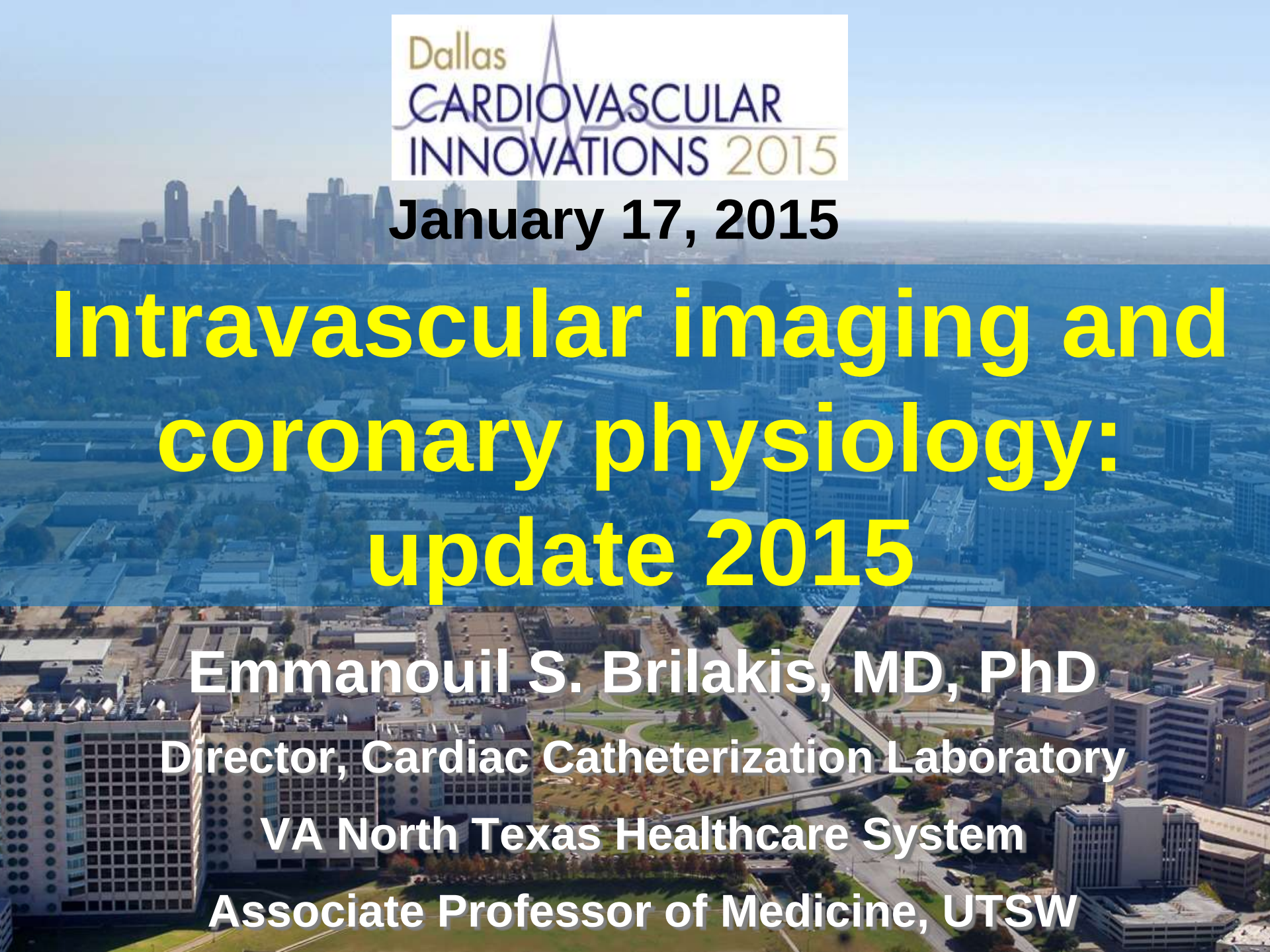

January 17, 2015

Intravascular imaging and coronary physiology: update 2015

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ES Brilakis: Disclosures

Consulting/speaker honoraria: Abbott Vascular, Asahi, Boston Scientific, Elsevier, Somahlution, St Jude Medical, Terumo

Employment (spouse): Medtronic

Grants: NIH –1R01HL102442

VA - I01-CX000787-01

VA CSP#571 – DIVA

Guerbet, InfraRedx

Why?

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Cor physiology and imaging – why?

Lesion significance
Hemodynamic lesion assessment
Plaque assessment
Evaluate plaque composition
Determine culprit lesion in ACS
Pre-PCI
Plan PCI
Determine distal embolization risk
Post-PCI
Stent expansion
Stent malapposition
Thrombus – Dissection

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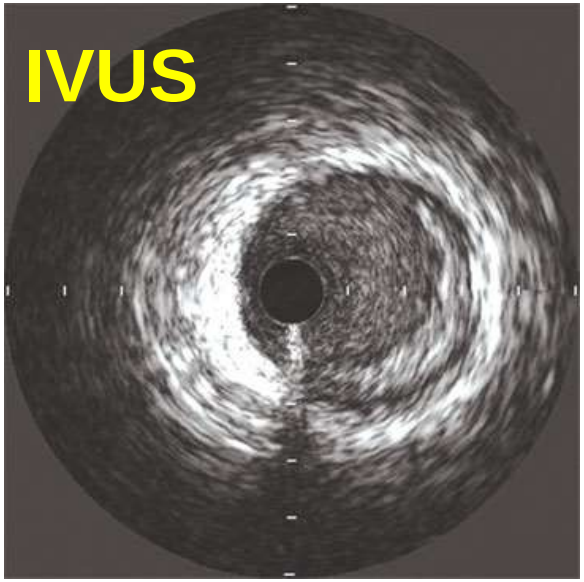
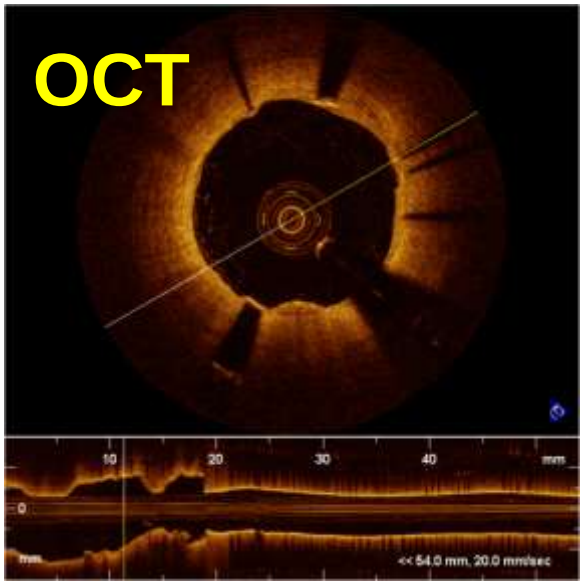
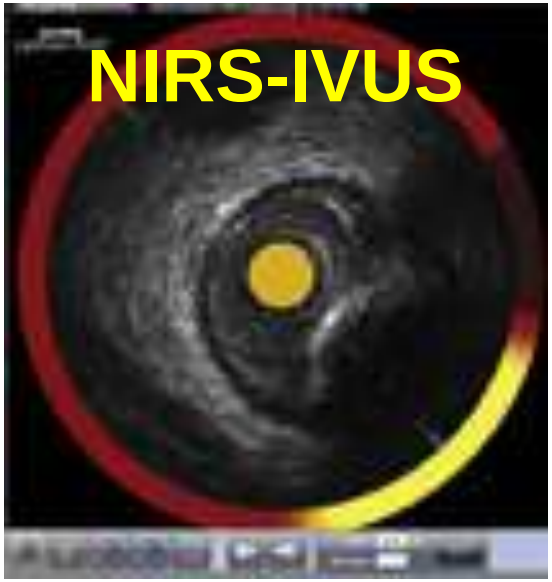
Invasive Coronary Evaluation - 2015

Structure

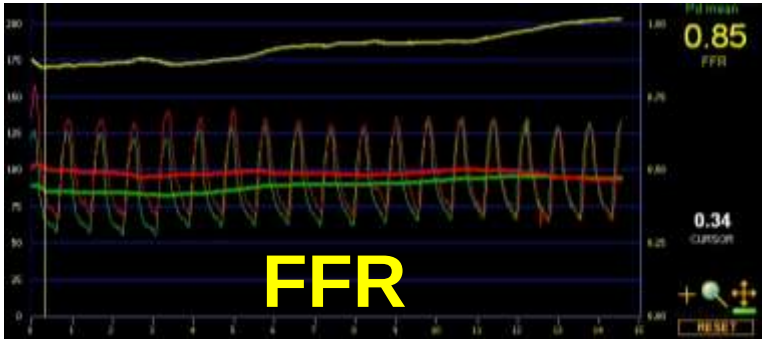




Composition



Hemodynamics



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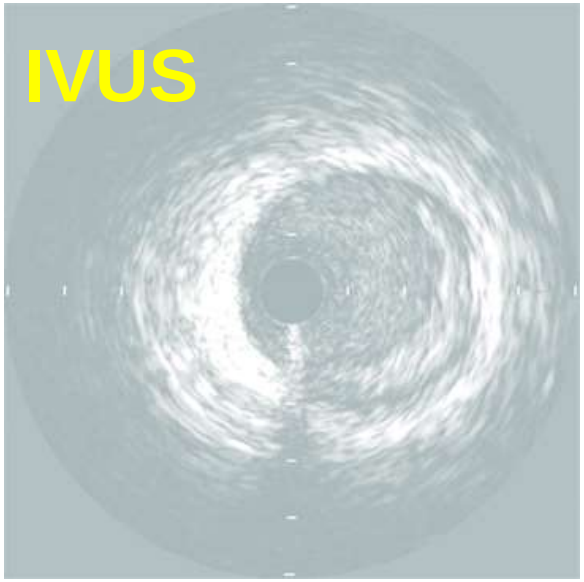
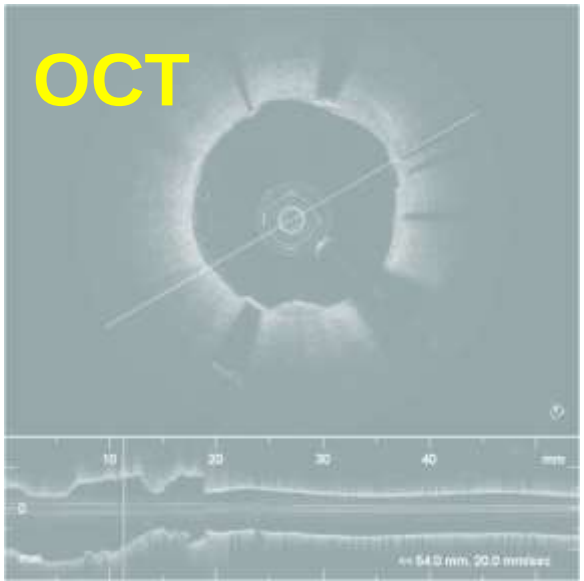
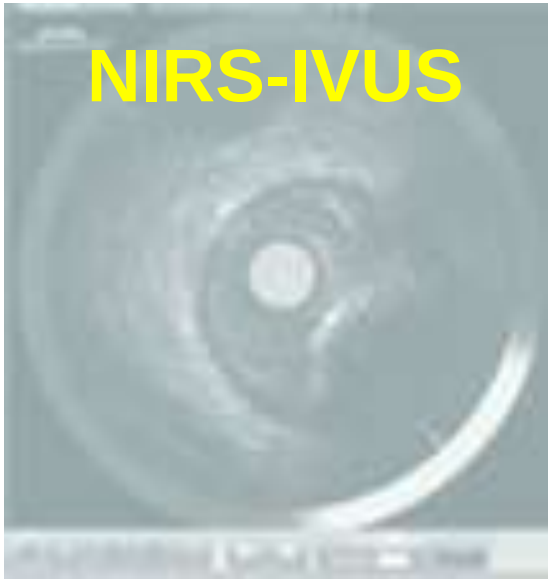
Invasive Coronary Evaluation - 2015

Structure

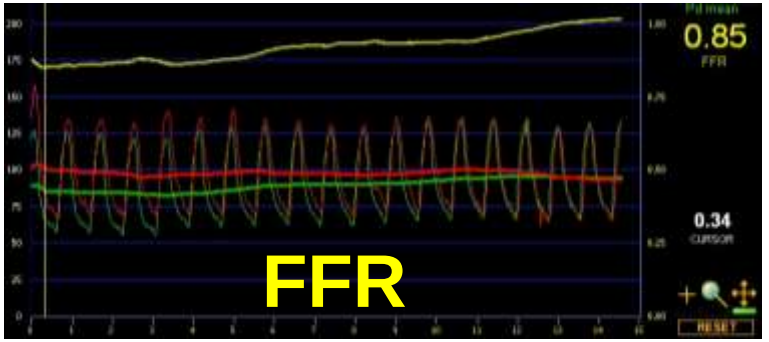




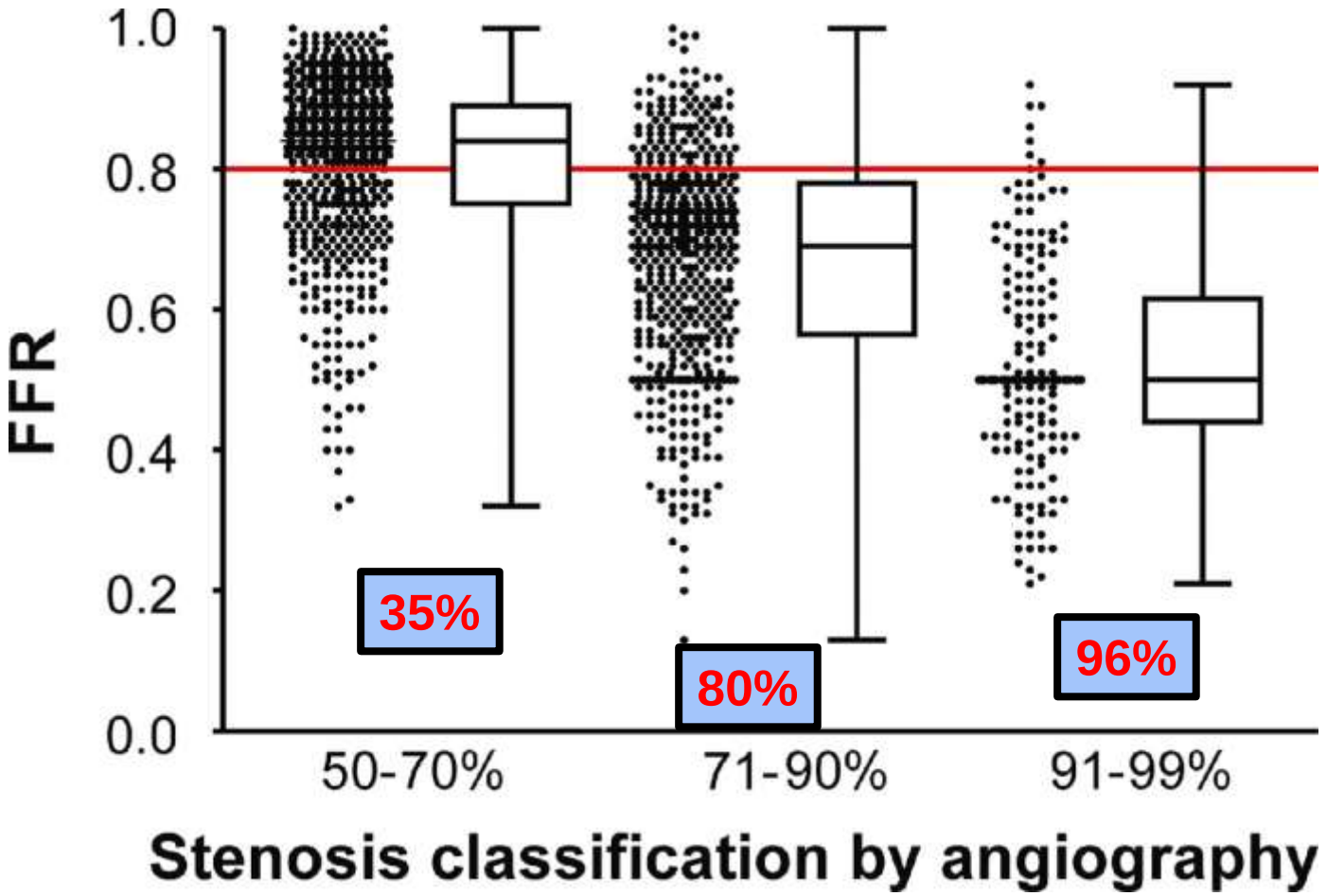
Composition



Hemodynamics

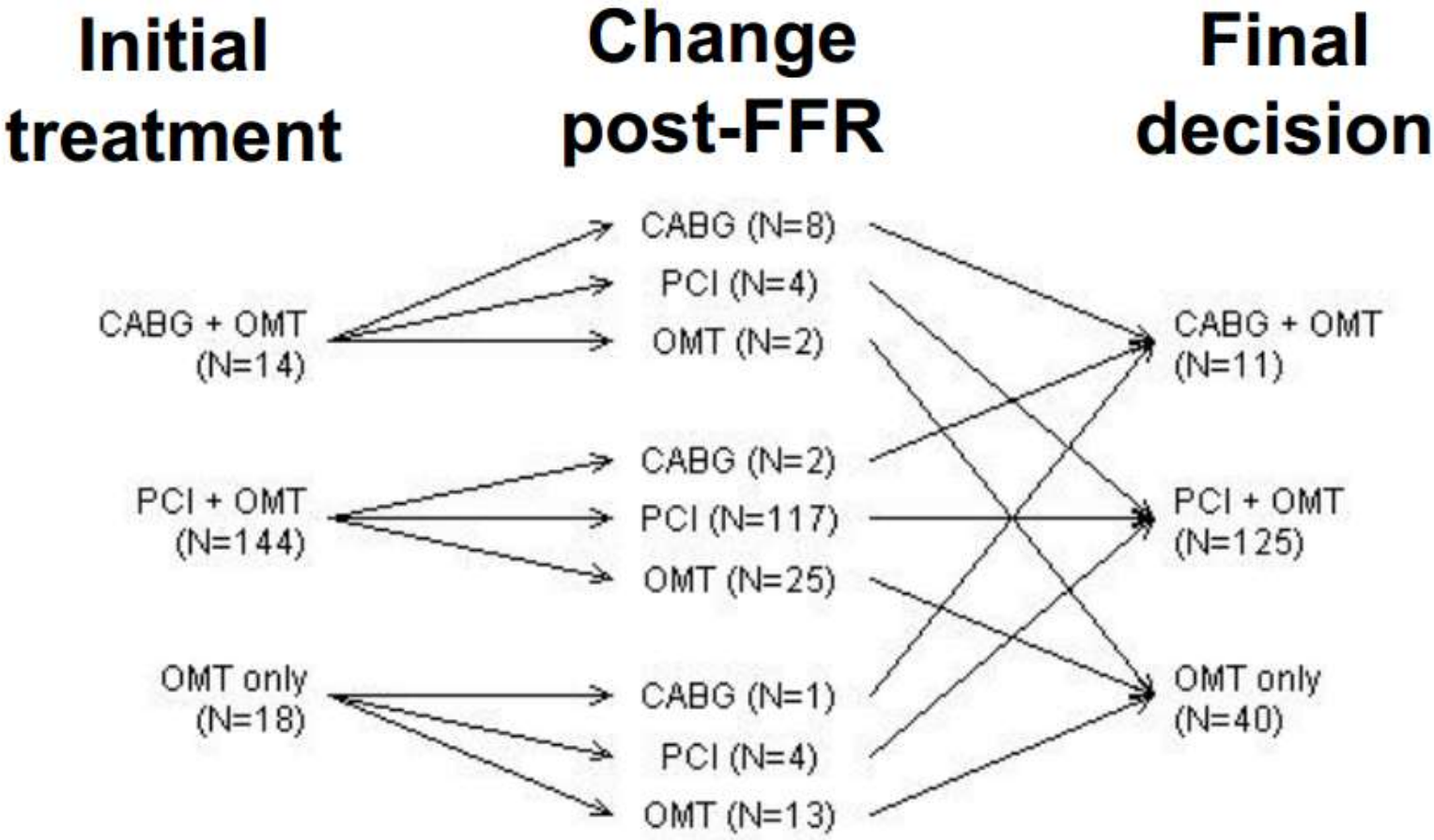


Angiographic vs. Functional Severity of Coronary Artery Stenoses



Tonino, P. A. L. et al. J Am Coll Cardiol 2010;55:2816-2821

FAMOUS-NSTEMI *Eur Heart J 2014*
FFR vs. Stenosis Severity



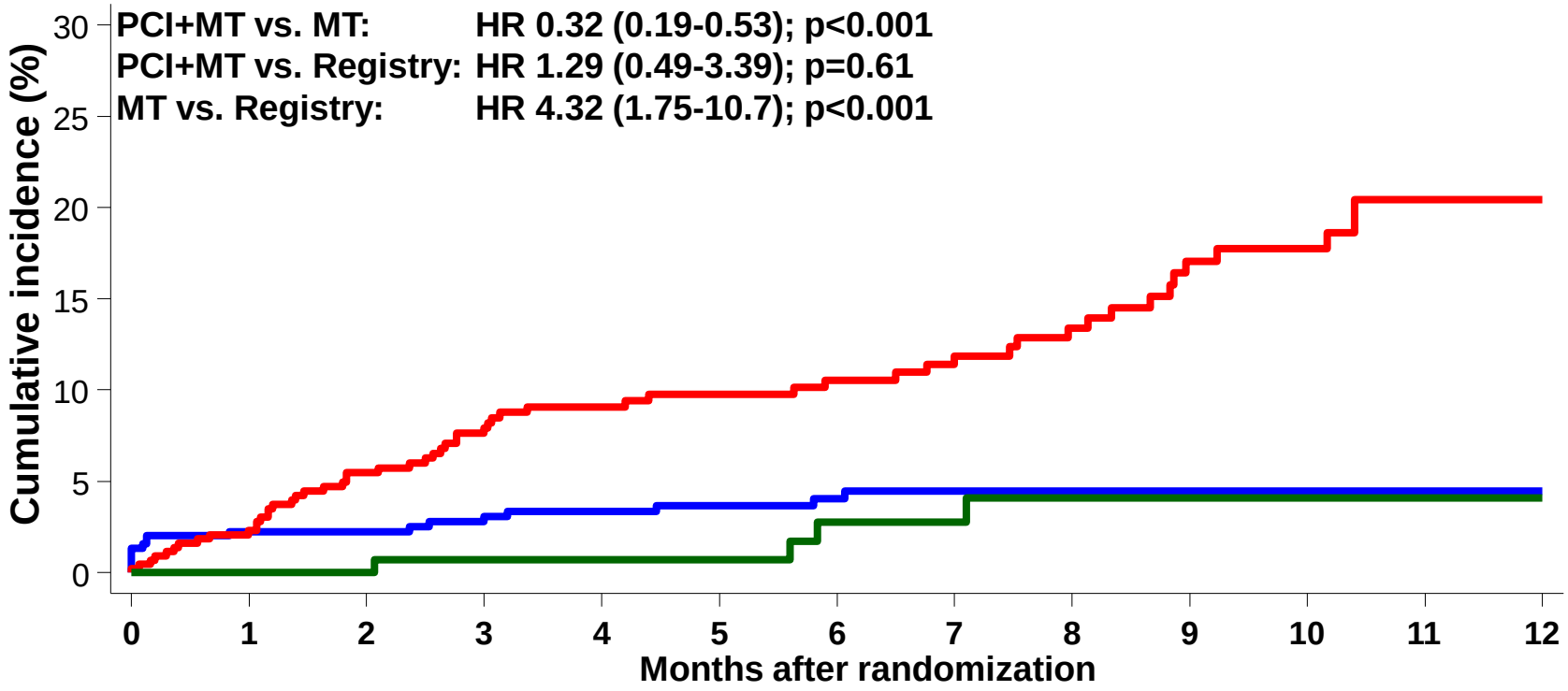
FFR treatment change ~ 22% of patients

FAME study: Adverse Events at 1 year

	ANGIO-group N=496	FFR-group N=509	P-value
Events at 1 year, No (%)			
Death, MI, CABG, or repeat-PCI	91 (18.4)	67 (13.2)	0.02
Death	15 (3.0)	9 (1.8)	0.19
Death or myocardial infarction	55 (11.1)	37 (7.3)	0.04
CABG or repeat PCI	47 (9.5)	33 (6.5)	0.08
Total no. of MACE	113	76	0.02
Myocardial infarction, specified			
All myocardial infarctions	43 (8.7)	29 (5.7)	0.07
Small periprocedural CK-MB 3-5 x N	16	12	
Other infarctions (“late or large”)	27	17	

Tonino et al. N Engl J Med 2009; 360:213-224

FAME 2: Death, MI, unplanned hospitalization with urgent revascularization



No. at risk

MT	441	414	370	322	283	253	220	192	162	127	100	70	37
PCI+MT	447	414	388	351	308	277	243	212	175	155	117	92	53
Registry	166	156	145	133	117	106	93	74	64	52	41	25	13

De Bruyne et al. N Engl J Med 2012; 367:991-1001

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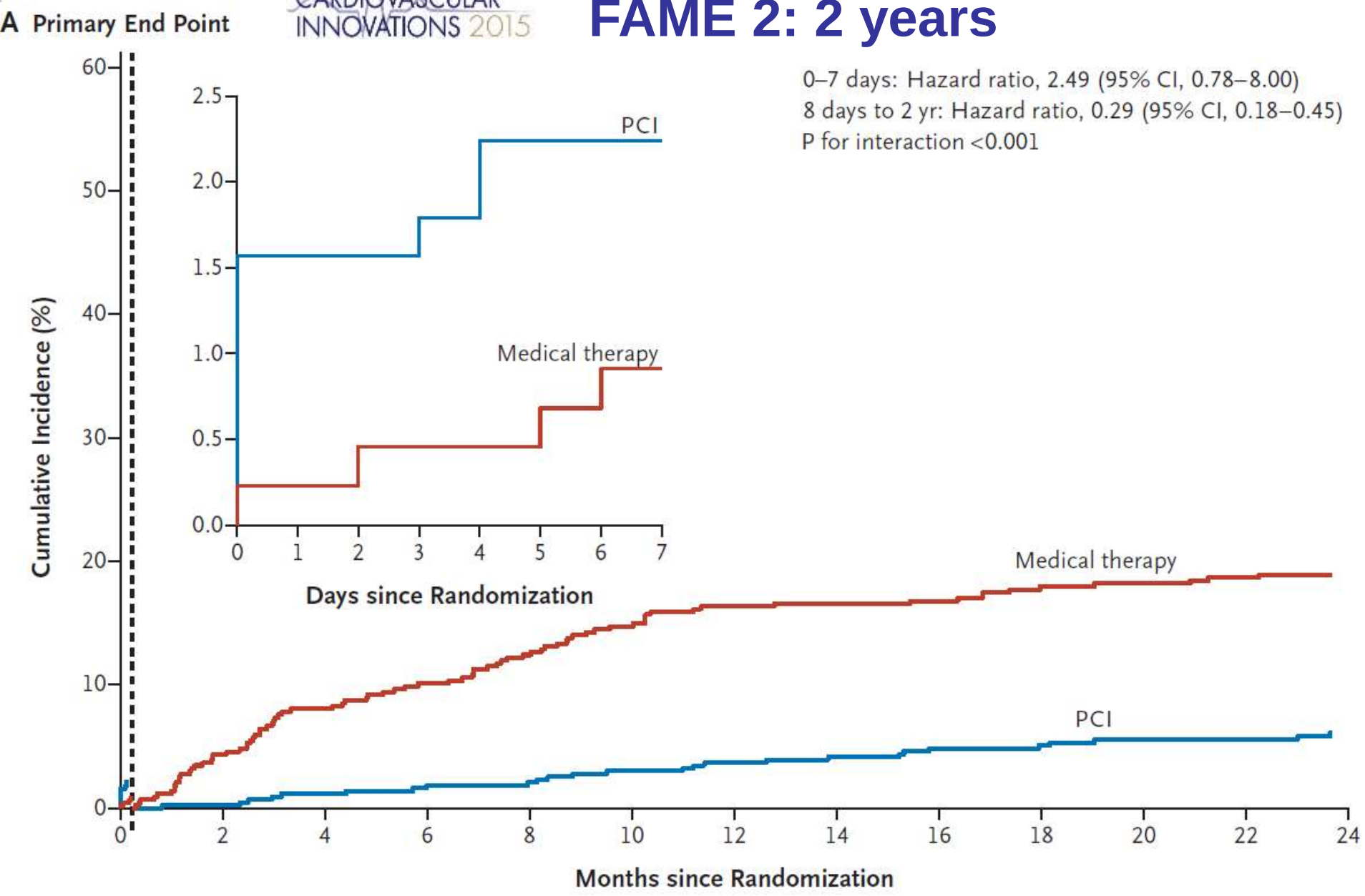
FAME 2: 2 years



De Bruyne et al. Engl J Med 2014; 371:1208-1217

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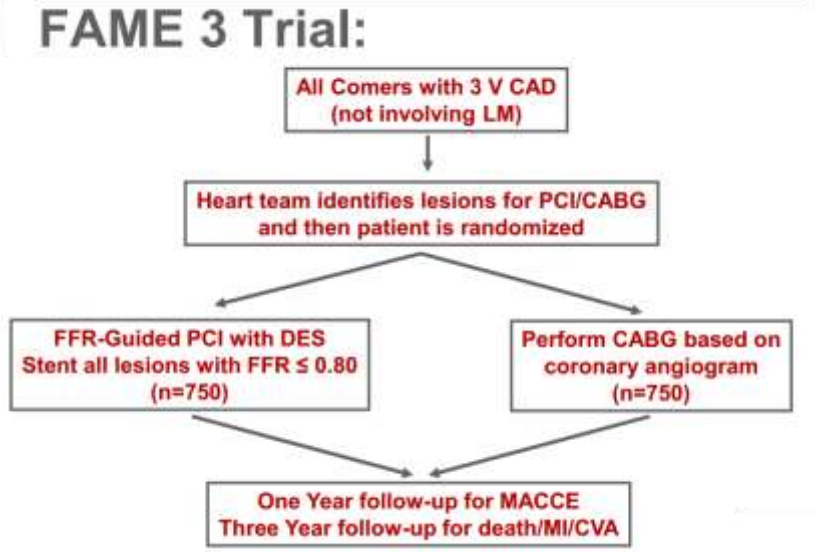
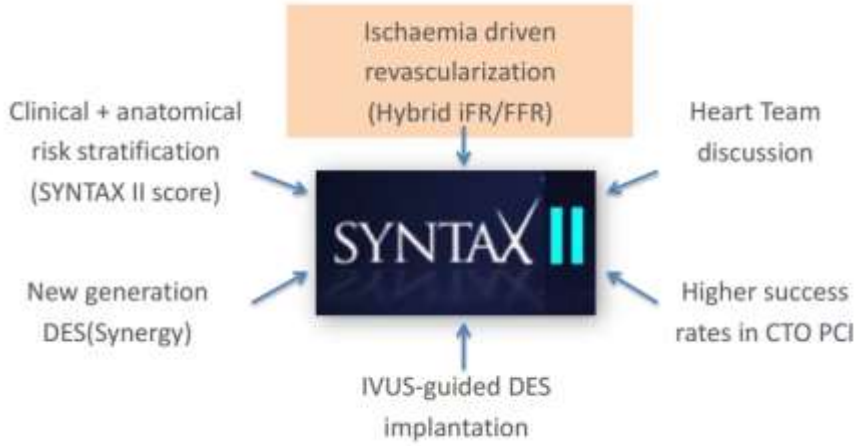
Will FFR-guided PCI replace CABG?





- Multicenter, worldwide, prospective, randomized trial
- Non-inferiority design
- 1500 patients from 50 sites
- Plan for 2 years enrollment and up to 5 year follow-up

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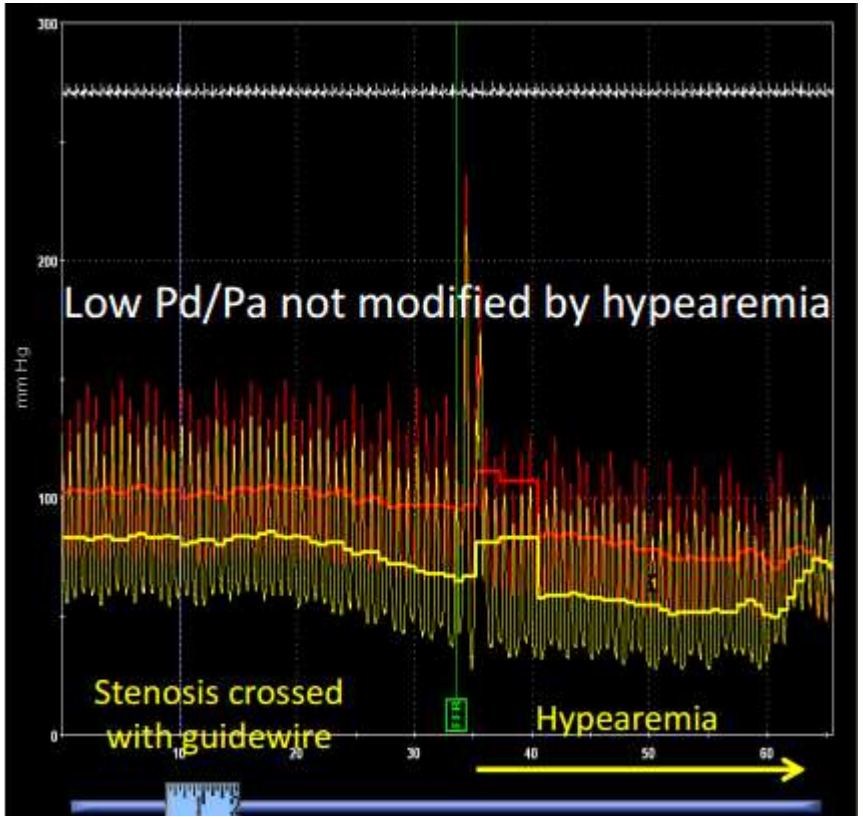
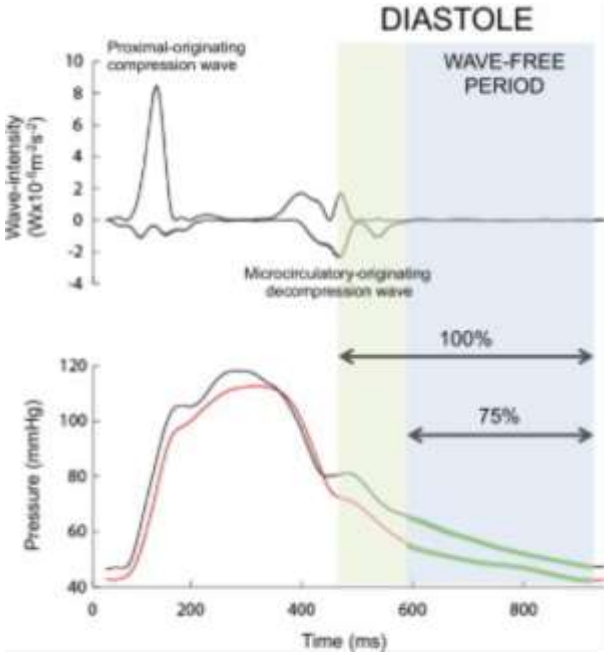
Skip the adenosine?

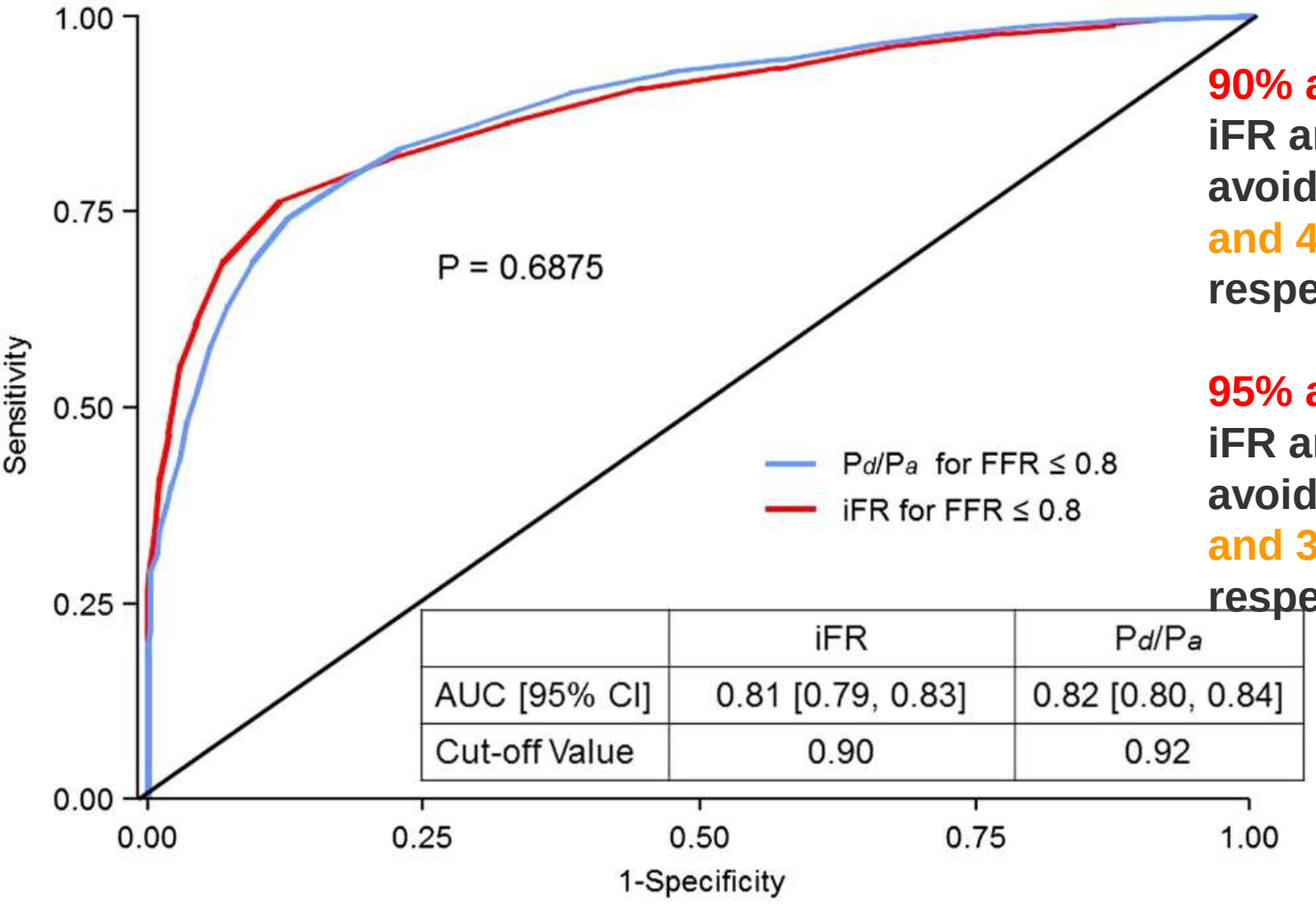
Pd/Pa



iFR



Multicenter Core Laboratory Comparison of the Instantaneous Wave-Free Ratio and Resting P_d/P_a With Fractional Flow Reserve: The RESOLVE Study



	iFR	Pd/Pa
AUC [95% CI]	0.81 [0.79, 0.83]	0.82 [0.80, 0.84]
Cut-off Value	0.90	0.92

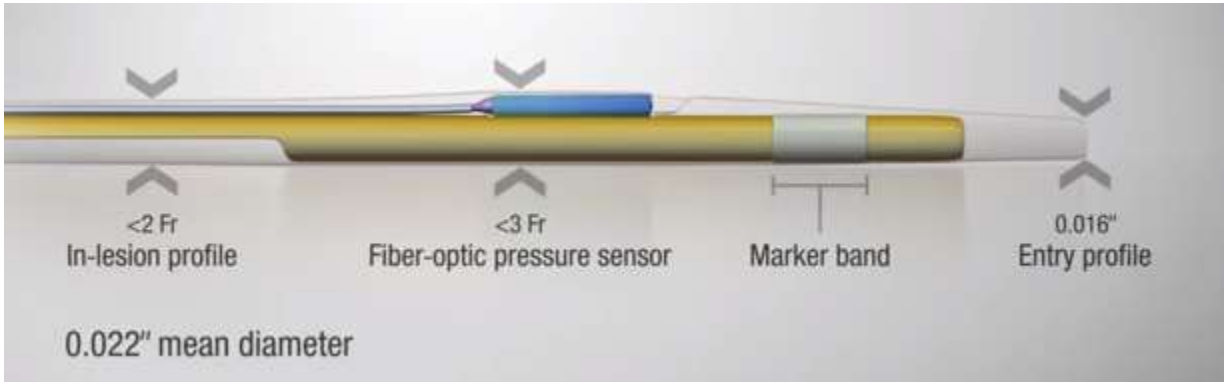
90% accuracy: use of iFR and P_d/P_a might avoid hyperemia in **65% and 48%** of lesions, respectively.

95% accuracy: use of iFR and P_d/P_a might avoid hyperemia in **29% and 36%** of lesions, respectively.

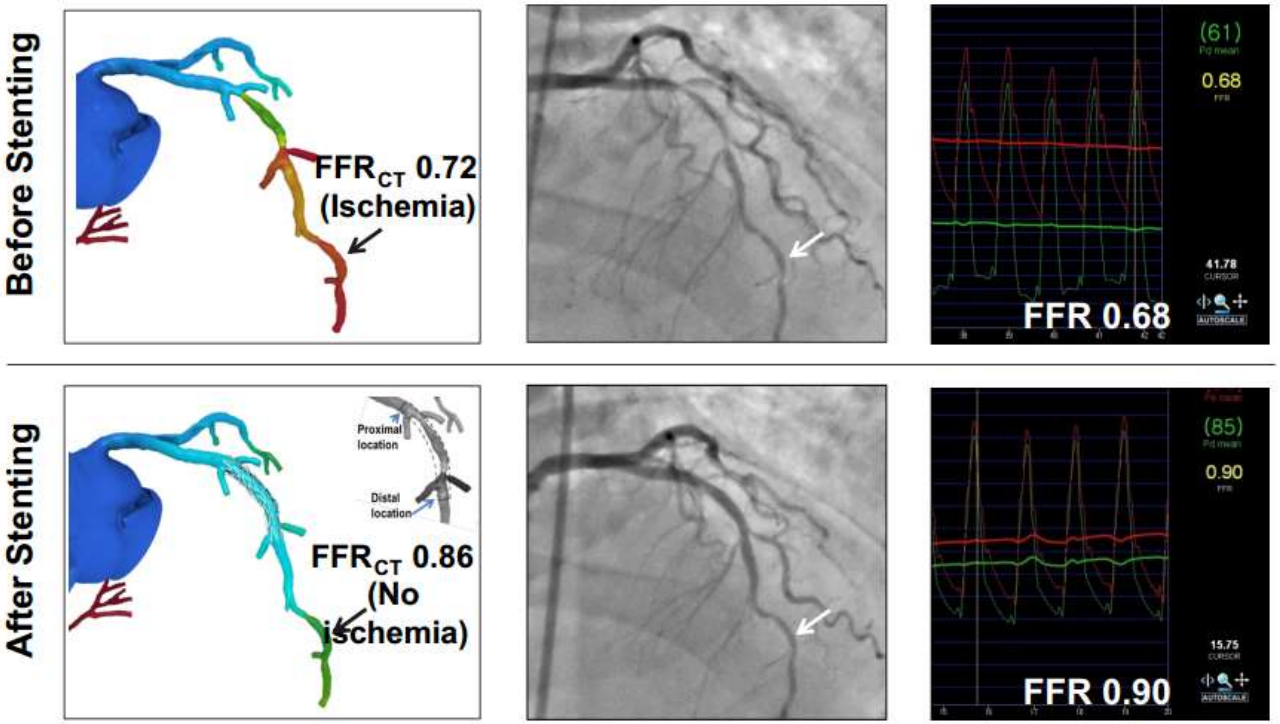
DEFINE-FLAIR
iFR - Swedeheart

Jeremias et al. J Am Coll Cardiol. 2014;63:1253-1261

Microcatheter-based FFR



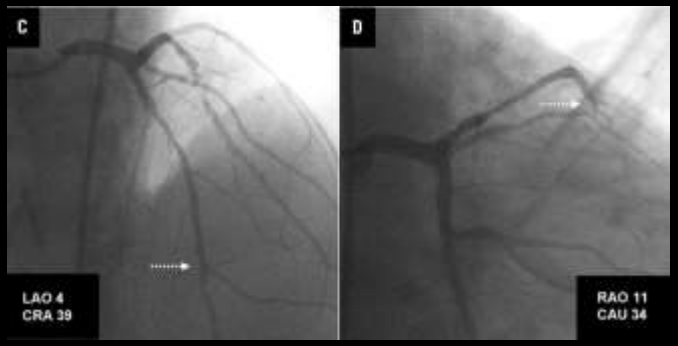
CT and angio-based FFR



Functional Assessment Using Routine Angiography: 3DQCA and Computational Fluid Dynamics

What is needed?

Two angiographic views for ***3D QCA***



+

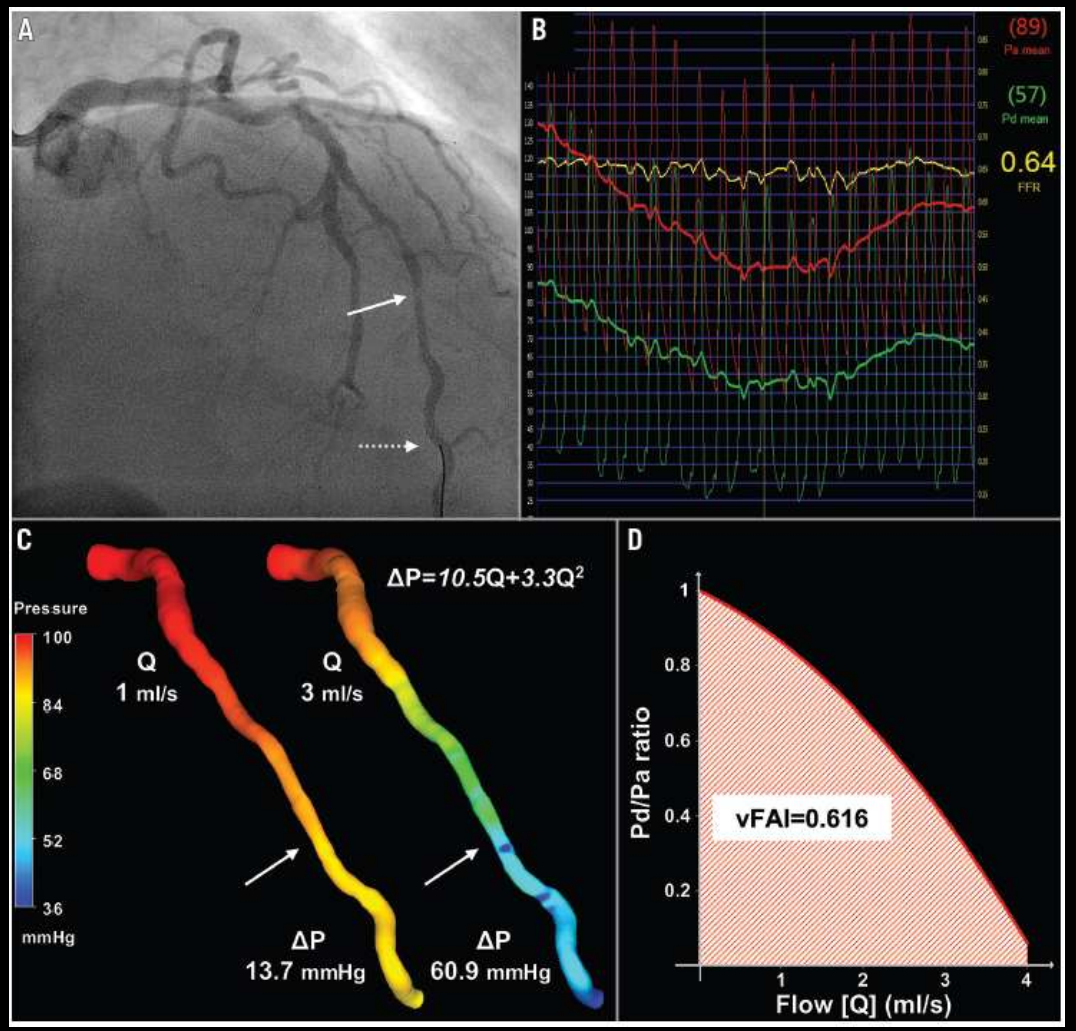
Computational Fluid Dynamics
(Blood Flow Simulation)
for **Pressure Distribution**

+

Use of the artery-specific
pressure-flow relationship

$$\Delta P = 0 + f_v\ Q + f_s\ Q^2$$

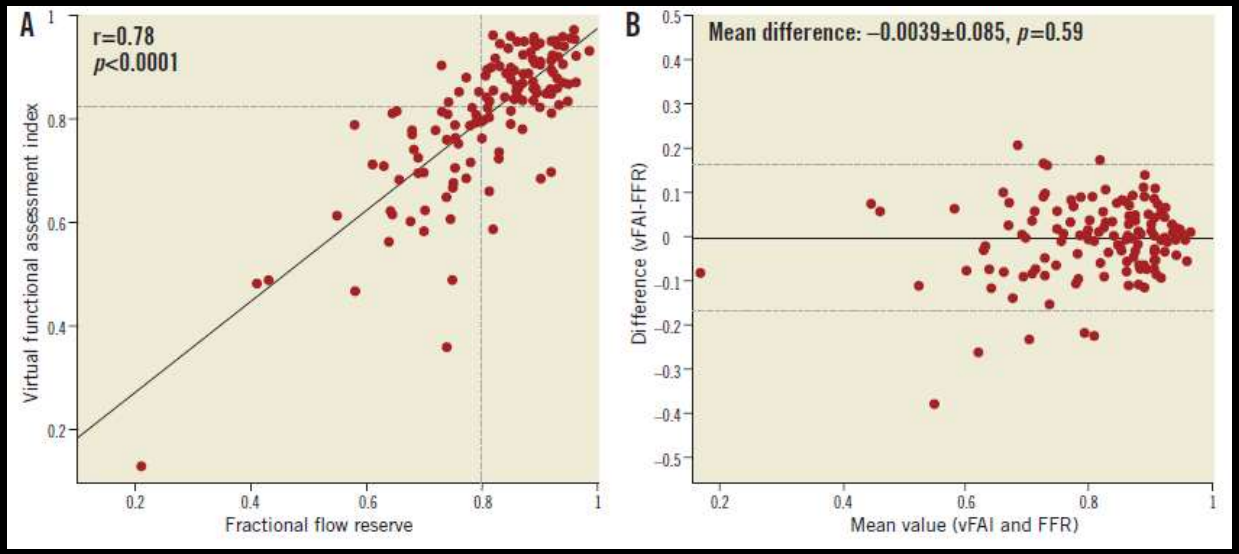
virtual Functional Assessment Index

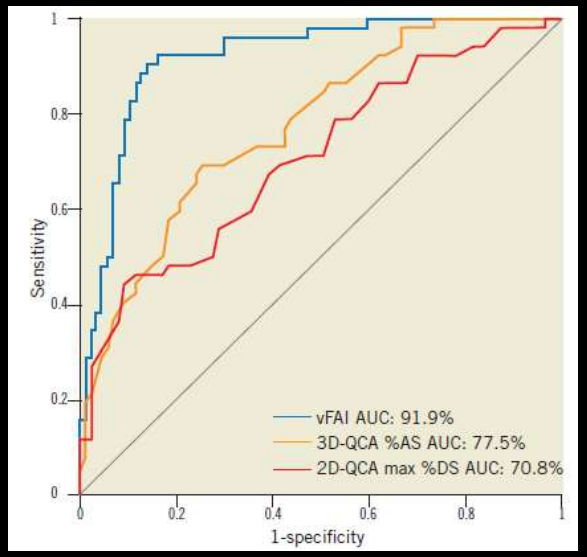


Papafaklis MI, et al. *EuroIntervention* 2014;10:574-583

Functional Assessment Using Routine Angiography: Correlation / Accuracy vs wire-FFR

Tested in 139 vessels (120 patients): *High correlation and agreement vs wire-FFR*





Improved diagnostic accuracy vs 2D/3D-QCA for predicting wire-FFR

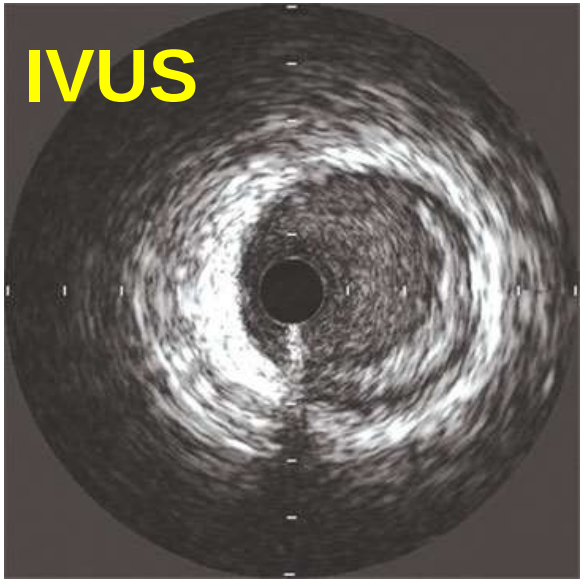
Diagnostic measure	vFAI ≤0.82	3D-QCA %AS >64%	3D-QCA MLA ≤1.66 mm²	3D-QCA %DS >41%	2D-QCA max %DS >51%
Diagnostic accuracy	87.8% (81.1-92.7%)	72.7% (64.5-79.9%)	79.1% (71.4-85.6%)	74.1% (66-81.2%)	73.4% (65.2-80.5%)
Sensitivity	90.4% (79-96.8%)	69.2% (54.9-81.3%)	80.8% (67.5-90.4%)	65.4% (50.9-78%)	44.2% (30.5-58.7%)
Specificity	86.2% (77.2-92.7%)	74.7% (64.3-83.4%)	78.2% (68-86.3%)	79.3% (69.3-87.3%)	90.8% (82.7-96%)
Positive predictive value	79.7% (67.2-89%)	62.1% (48.4-74.5%)	68.9% (55.7-80.1%)	65.4% (50.9-78%)	25.8% (11.9-44.6%)
Negative predictive value	93.8% (86.01-97.9%)	80.3% (69.9-88.3%)	87.2% (77.7-93.7%)	79.3% (69.3-87.3%)	73.2% (63.8-81.2%)

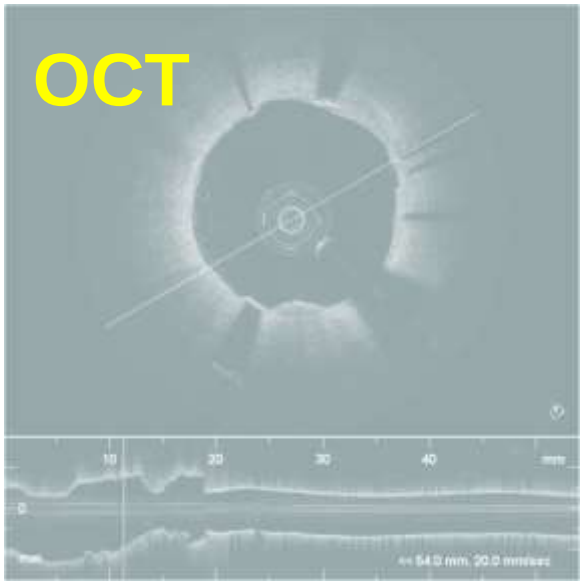
Values are presented as estimates (95% CI); %AS: percent area stenosis; %DS: percent diameter stenosis; MLA: minimum lumen area

Papafaklis MI, et al. *EuroIntervention* 2014;10:574-583

Invasive Coronary Evaluation - 2015

Structure





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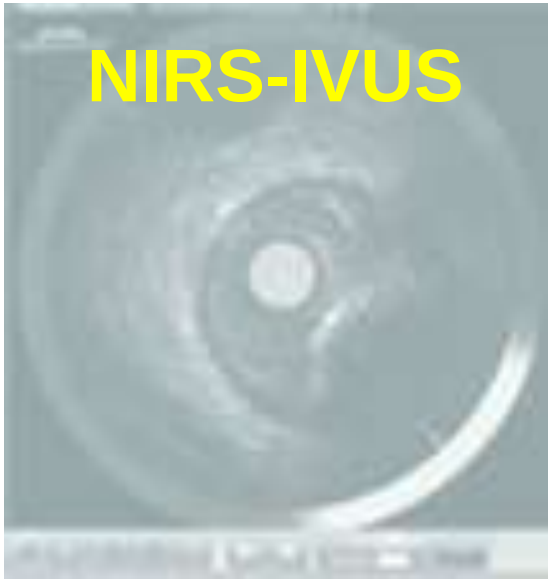
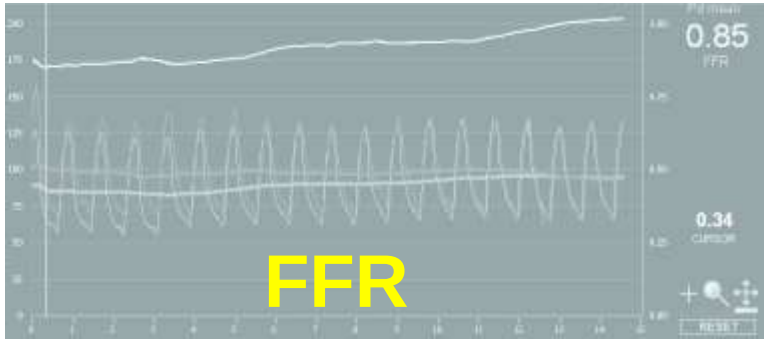


Hemodynamics



LMCA

MLA = 6 mm²

Prospective Application of Pre-Defined Intravascular Ultrasound Criteria for Assessment of Intermediate Left Main Coronary Artery Lesions

Results From the Multicenter LITRO Study

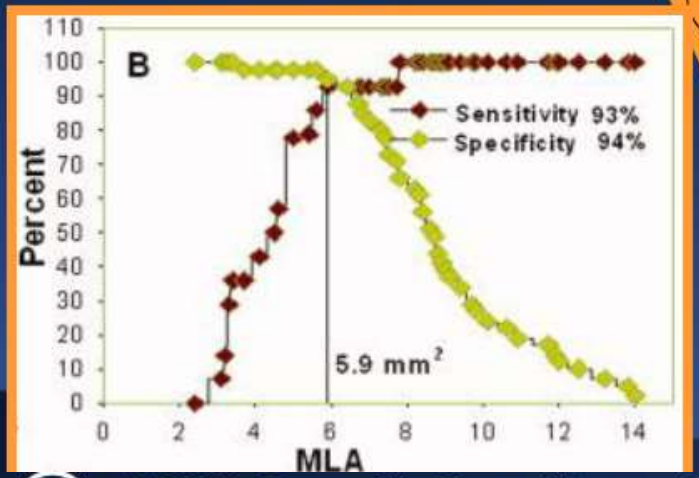
De la Torre Hernandez, et al. J Am Coll Cardiol 2011; 58:351-8

Proximal LAD

MLA = 3 mm²

Proximal LCx

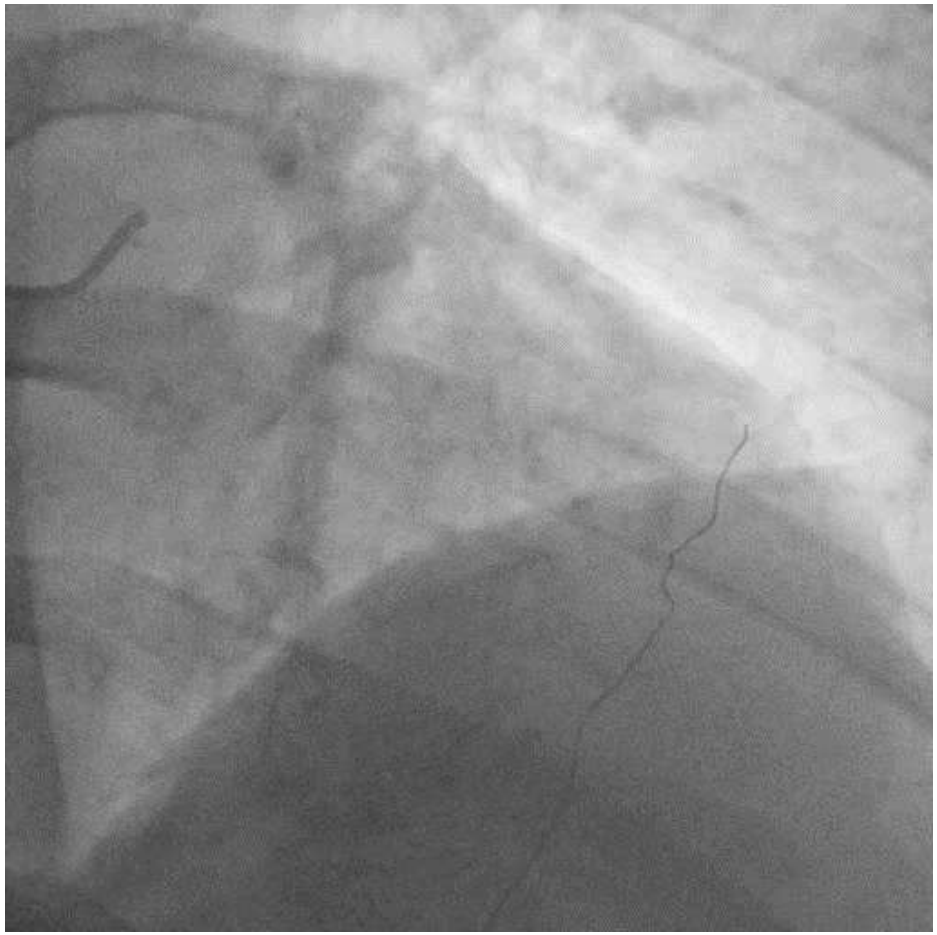
MLA = 3 mm²

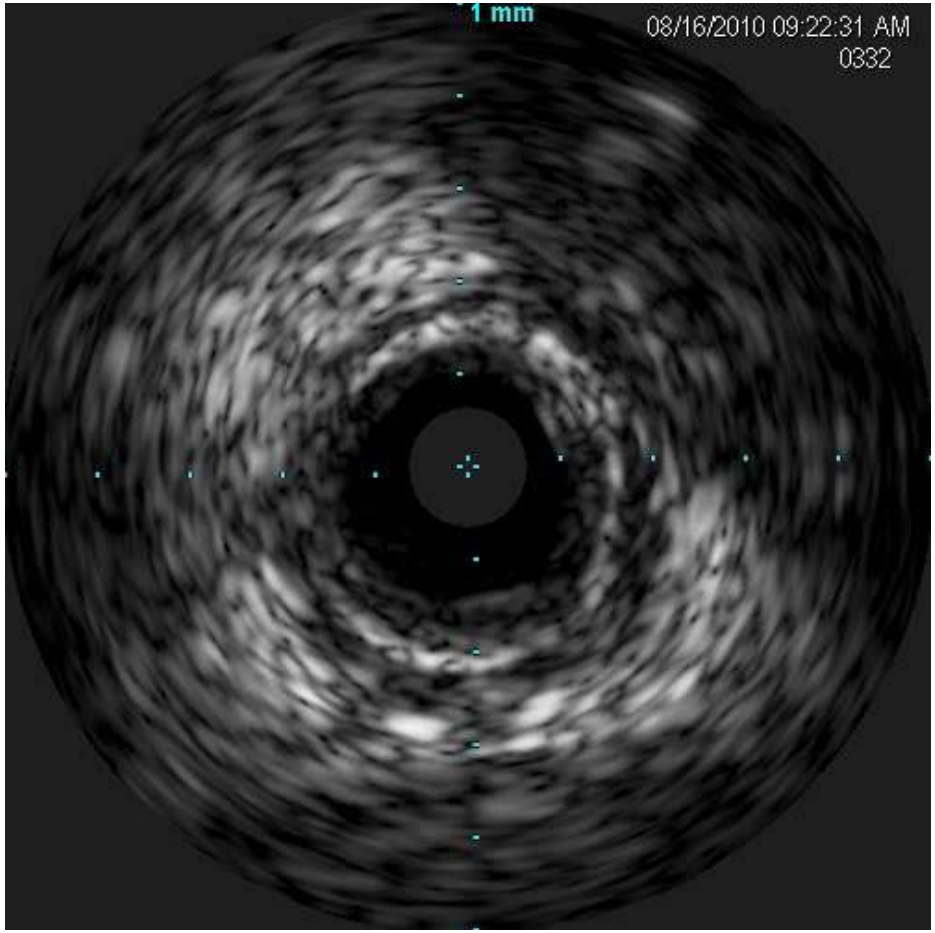


Linear law (epicardial coronary artery)
Do = 0.678*(D1+D2)

Finet G et al.
Eurointervention 2007;3:10-17

Myocardial bridging





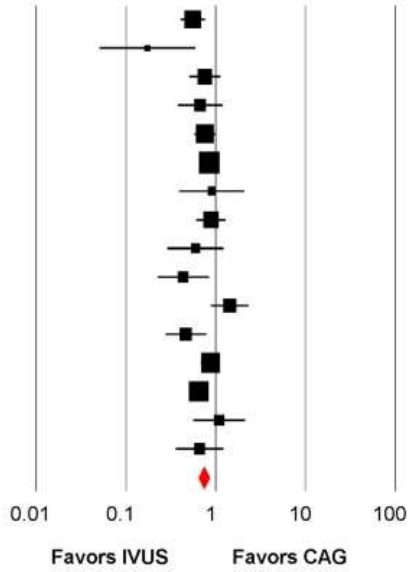
A

Major Adverse Cardiovascular Events

Author Name (Year)	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Ahn JM et al. (2013)	0.555	0.400	0.772	-3.499	0.000
Ahn SG et al. (2013)	0.174	0.050	0.604	-2.755	0.006
Chen SL et al. (2012)	0.759	0.503	1.146	-1.312	0.190
Chieffo A et al. (2013)	0.673	0.374	1.211	-1.321	0.186
Claessen BE et al. (2011)	0.755	0.566	1.009	-1.900	0.057
Hur SH et al. (2012)	0.851	0.706	1.026	-1.689	0.091
Jakabcin J et al. (2010)	0.906	0.388	2.118	-0.227	0.820
Kim JS et al. (2011)	0.889	0.599	1.318	-0.587	0.557
Kim JS et al. (2013)	0.598	0.287	1.247	-1.370	0.171
Kim SH et al. (2010)	0.436	0.223	0.852	-2.430	0.015
Park KW et al. (2012)	1.434	0.872	2.358	1.421	0.155
Park SJ et al. (2009)	0.466	0.271	0.802	-2.755	0.006
Roy P et al. (2008)	0.877	0.677	1.137	-0.991	0.322
Witzenbichler B et al. (2013)	0.649	0.514	0.819	-3.631	0.000
Yoon YW et al. (2013)	1.097	0.556	2.167	0.268	0.789
Youn YJ et al. (2011)	0.664	0.354	1.246	-1.276	0.202
Random Effect Model	**0.735**	**0.637**	**0.849**	**-4.197**	**<0.001**
Test for Heterogeneity	**Q=27.9, df=15, p=0.02, I^2=46.2**				

Statistics for Each Study

Odds Ratio and 95% CI



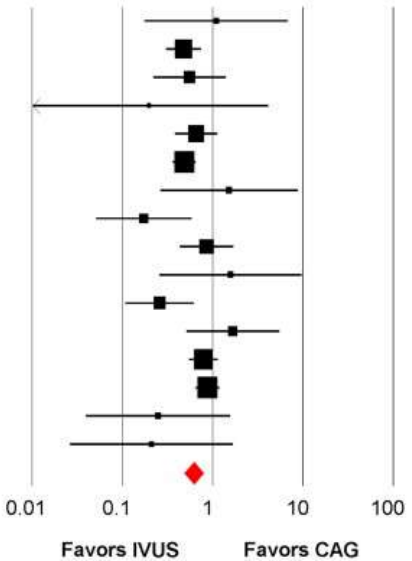
B

Death

Author Name (Year)	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Ahn SG et al. (2013)	1.095	0.174	6.898	0.097	0.923
Ahn JM et al. (2013)	0.477	0.301	0.756	-3.152	0.002
Chen SL et al. (2012)	0.554	0.216	1.422	-1.227	0.220
Chieffo A et al. (2013)	0.198	0.009	4.170	-1.041	0.298
Claessen BE et al. (2011)	0.656	0.376	1.147	-1.478	0.139
Hur SH et al. (2012)	0.486	0.358	0.661	-4.604	0.000
Jakabcin J et al. (2010)	1.515	0.259	8.874	0.461	0.645
Kim SH et al. (2010)	0.172	0.050	0.590	-2.802	0.005
Kim JS et al. (2011)	0.857	0.425	1.725	-0.433	0.665
Kim JS et al. (2013)	1.578	0.254	9.784	0.490	0.624
Park SJ et al. (2009)	0.259	0.107	0.629	-2.982	0.003
Park KW et al. (2012)	1.673	0.506	5.533	0.844	0.399
Roy P et al. (2008)	0.791	0.539	1.160	-1.200	0.230
Witzenbichler B et al. (2013)	0.875	0.636	1.204	-0.818	0.413
Yoon YW et al. (2013)	0.248	0.039	1.587	-1.472	0.141
Youn YJ et al. (2011)	0.210	0.026	1.698	-1.463	0.143
Random Effect Model	**0.613**	**0.478**	**0.786**	**-3.861**	**<0.001**
Test for Heterogeneity	**Q=25.9, df=15, p=0.039, I^2=42.2**				

Statistics for Each Study

Odds Ratio and 95% CI



IVUS improves outcomes!

Anh et al. Am J Cardiol;113:1338-1347

Clinical Data

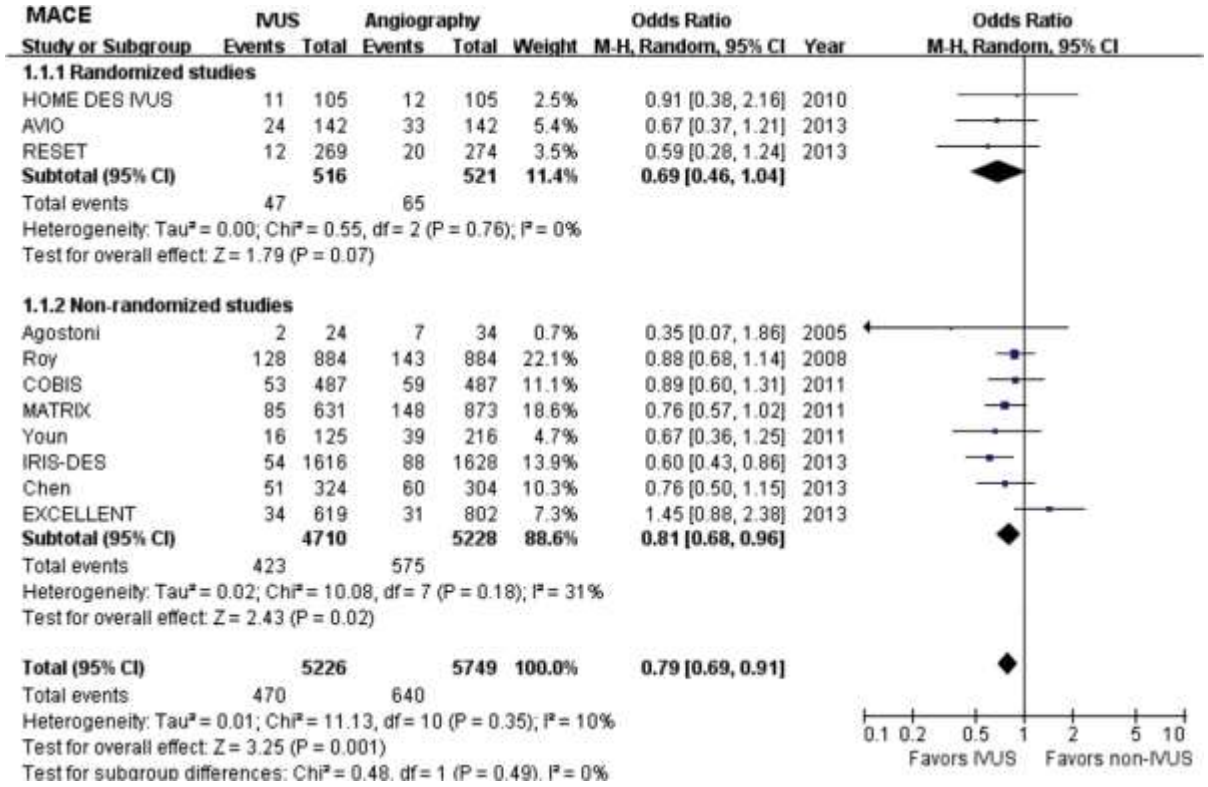
Meta-Analysis of IVUS-Guided Implantation of DES to Improve Outcome

MACE

3 RCTs
12 observational studies

24,849 pts

21%↓ MACE
43%↓ MI
35%↓ Death
19%↓ TVR



MACE	IVUS		Angiography			Odds Ratio		Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	Year	M-H, Random, 95% CI
1.1.1 Randomized studies								
HOME DES IVUS	11	105	12	105	2.5%	0.91 [0.38, 2.16]	2010	
AVIO	24	142	33	142	5.4%	0.67 [0.37, 1.21]	2013	
RESET	12	269	20	274	3.5%	0.59 [0.28, 1.24]	2013	
Subtotal (95% CI)		**516**		**521**	**11.4%**	**0.69 [0.46, 1.04]**		
Total events	47		65					
Heterogeneity: Tau² = 0.00; Chi² = 0.55, df = 2 (P = 0.76); I² = 0%								
Test for overall effect: Z = 1.79 (P = 0.07)								
1.1.2 Non-randomized studies								
Agostoni	2	24	7	34	0.7%	0.35 [0.07, 1.86]	2005	
Roy	128	884	143	884	22.1%	0.88 [0.68, 1.14]	2008	
COBIS	53	487	59	487	11.1%	0.89 [0.60, 1.31]	2011	
MATRIX	85	631	148	873	18.6%	0.76 [0.57, 1.02]	2011	
Youn	16	125	39	216	4.7%	0.67 [0.36, 1.25]	2011	
IRIS-DES	54	1616	88	1628	13.9%	0.60 [0.43, 0.86]	2013	
Chen	51	324	60	304	10.3%	0.76 [0.50, 1.15]	2013	
EXCELLENT	34	619	31	802	7.3%	1.45 [0.88, 2.38]	2013	
Subtotal (95% CI)		**4710**		**5228**	**88.6%**	**0.81 [0.68, 0.96]**		
Total events	423		575					
Heterogeneity: Tau² = 0.02; Chi² = 10.08, df = 7 (P = 0.18); I² = 31%								
Test for overall effect: Z = 2.43 (P = 0.02)								
Total (95% CI)		**5226**		**5749**	**100.0%**	**0.79 [0.69, 0.91]**		
Total events	470		640					
Heterogeneity: Tau² = 0.01; Chi² = 11.13, df = 10 (P = 0.35); I² = 10%								
Test for overall effect: Z = 3.25 (P = 0.001)								
Test for subgroup differences: Chi² = 0.48, df = 1 (P = 0.49), I² = 0%								

Jang et al. J Am Coll Cardiol Intv. 2014

ADAPT-DES - Current Cohort -

Assessment of Dual AntiPlatelet Therapy with Drug-Eluting Stents

8582 pts prospectively enrolled

No clinical or anatomic exclusion criteria

11 sites in US and Germany

↓

PCI with ≥1 non-investigational DES

Successful and uncomplicated

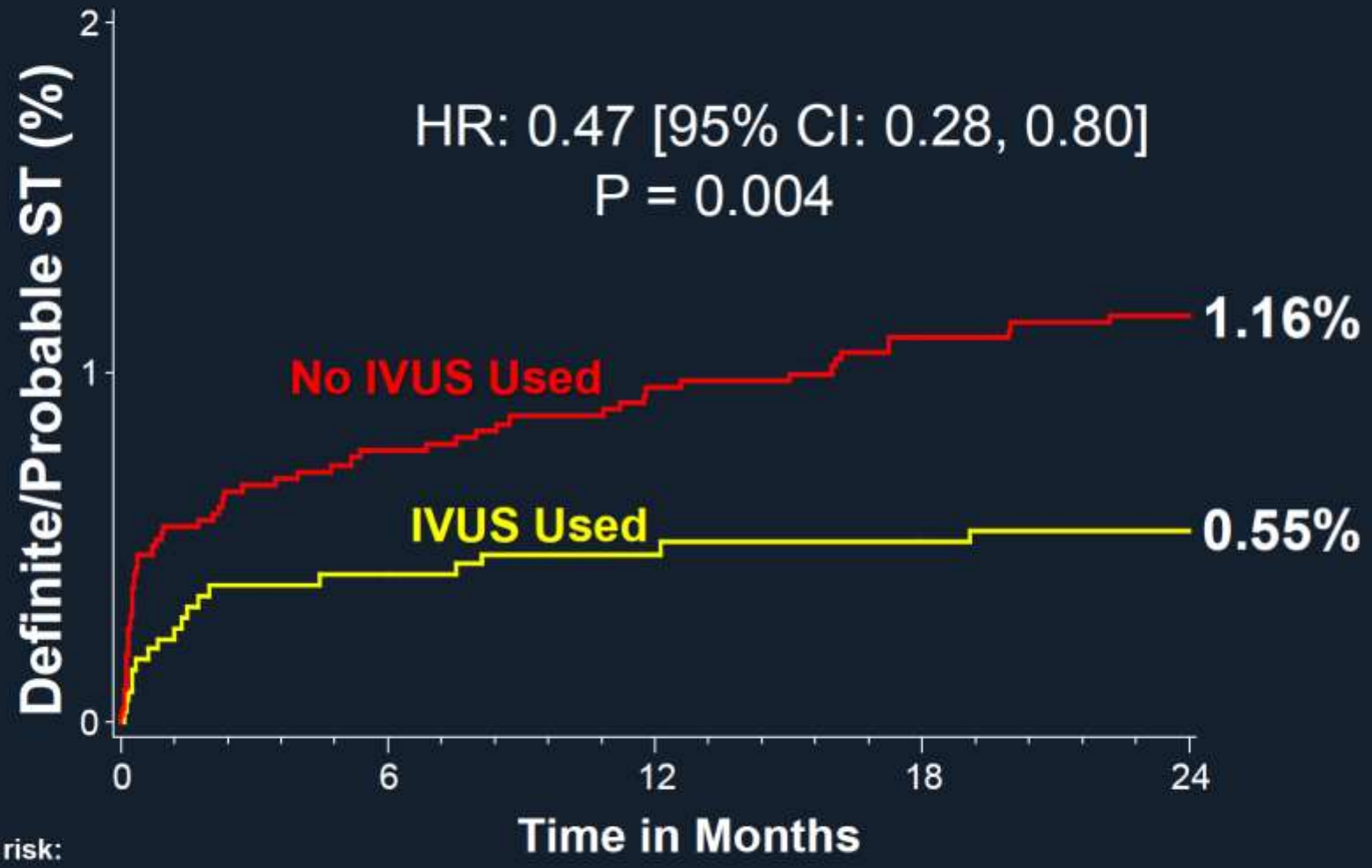
↙ ↘

IVUS Use: 3361 pts | **No IVUS: 5221 pts**

↓ ↓

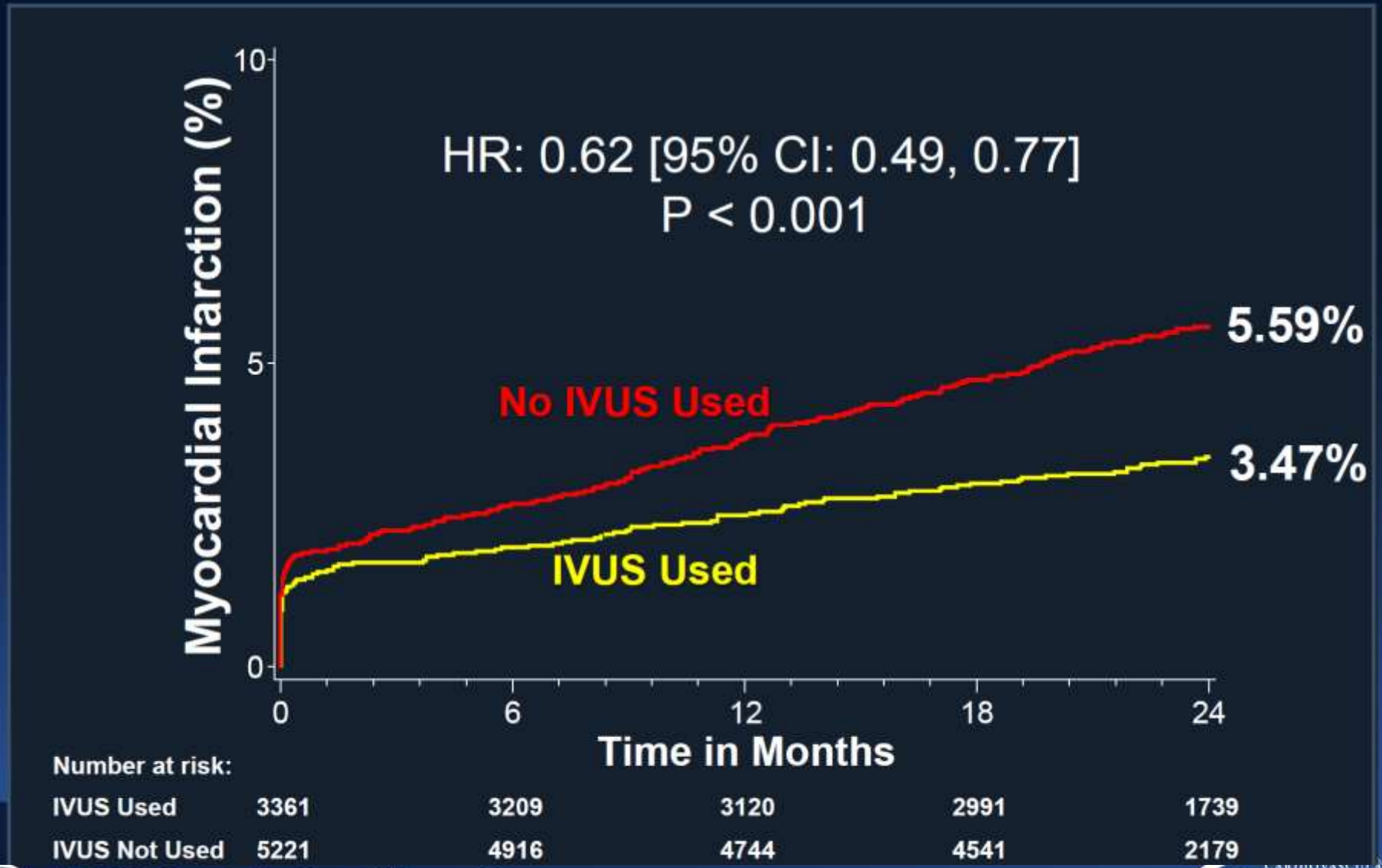
Clinical FU at 30 days, 1 year, 2 years

Relationship Between IVUS Use and Definite/Probable Stent Thrombosis Within 2 Years



Number at risk:					
IVUS Used	3361	3260	3182	3065	1791
IVUS Not Used	5221	5019	4886	4713	2279

Relationship Between IVUS Use and MI Within 2 Years

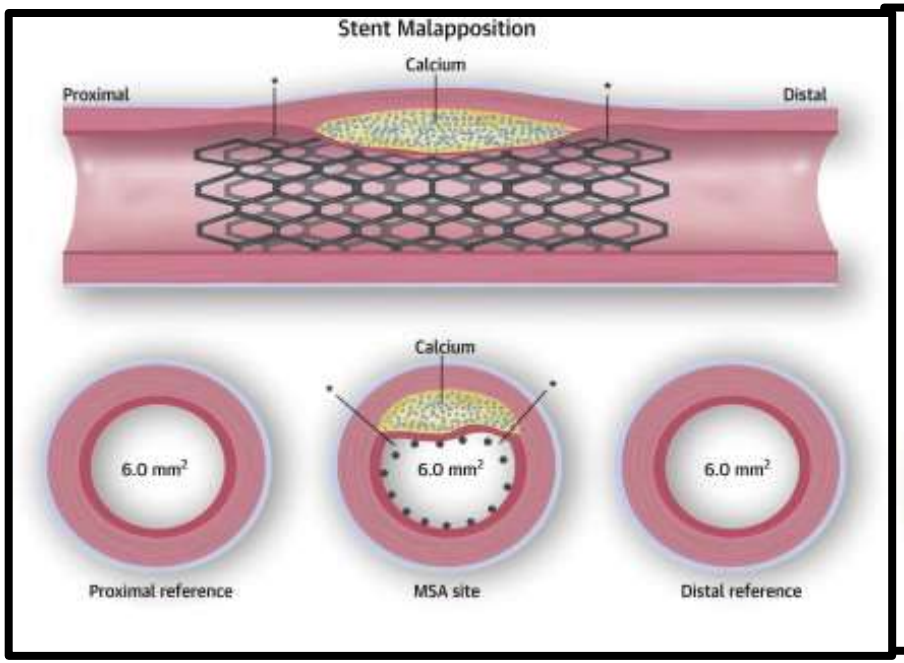


Number at risk:

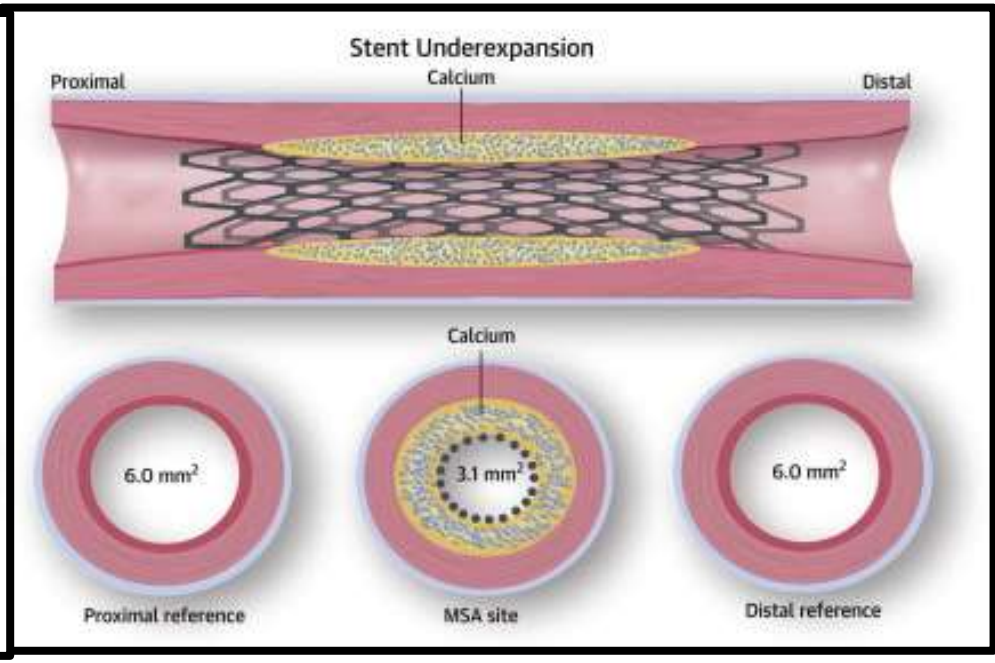
IVUS Used	3361	3209	3120	2991	1739
IVUS Not Used	5221	4916	4744	4541	2179

Expand the stent!

Malapposition



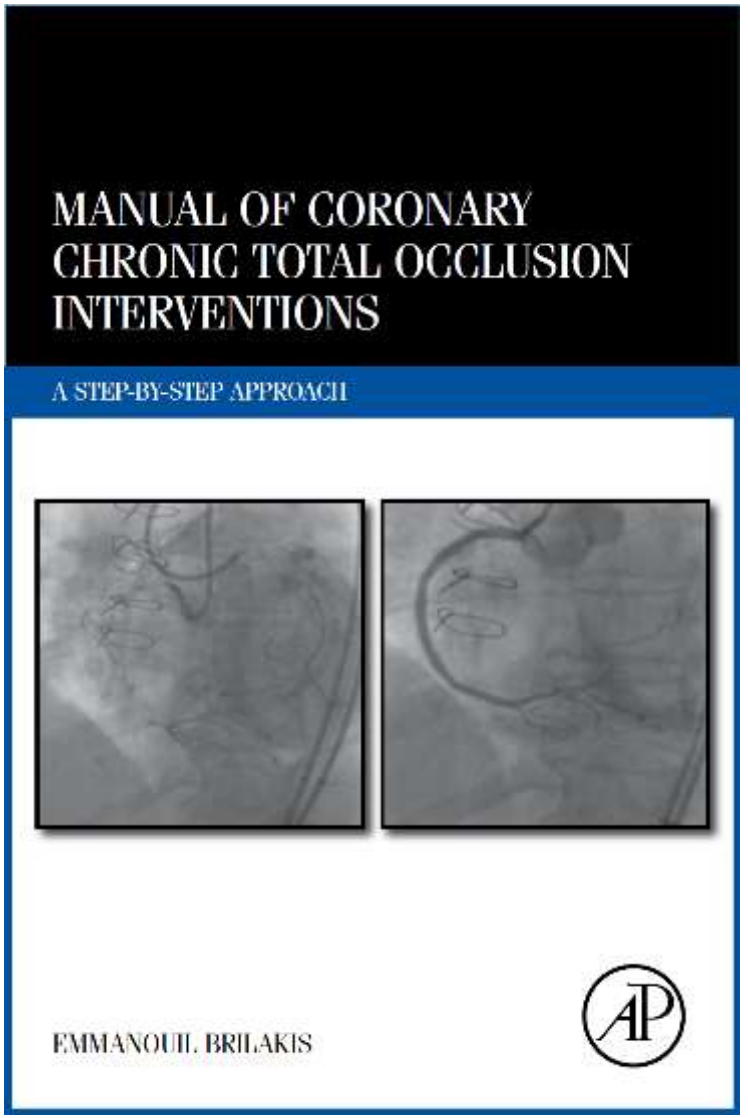
Underexpansion



Mintz et al. J Am Coll Cardiol. 2014;64:207-222

IVUS for CTO PCI

1. Resolve proximal cap ambiguity
2. Guide wiring
3. Facilitate reverse CART
4. Stent sizing
5. Stent optimization
6. Assess complications



Intravascular imaging for CTO crossing

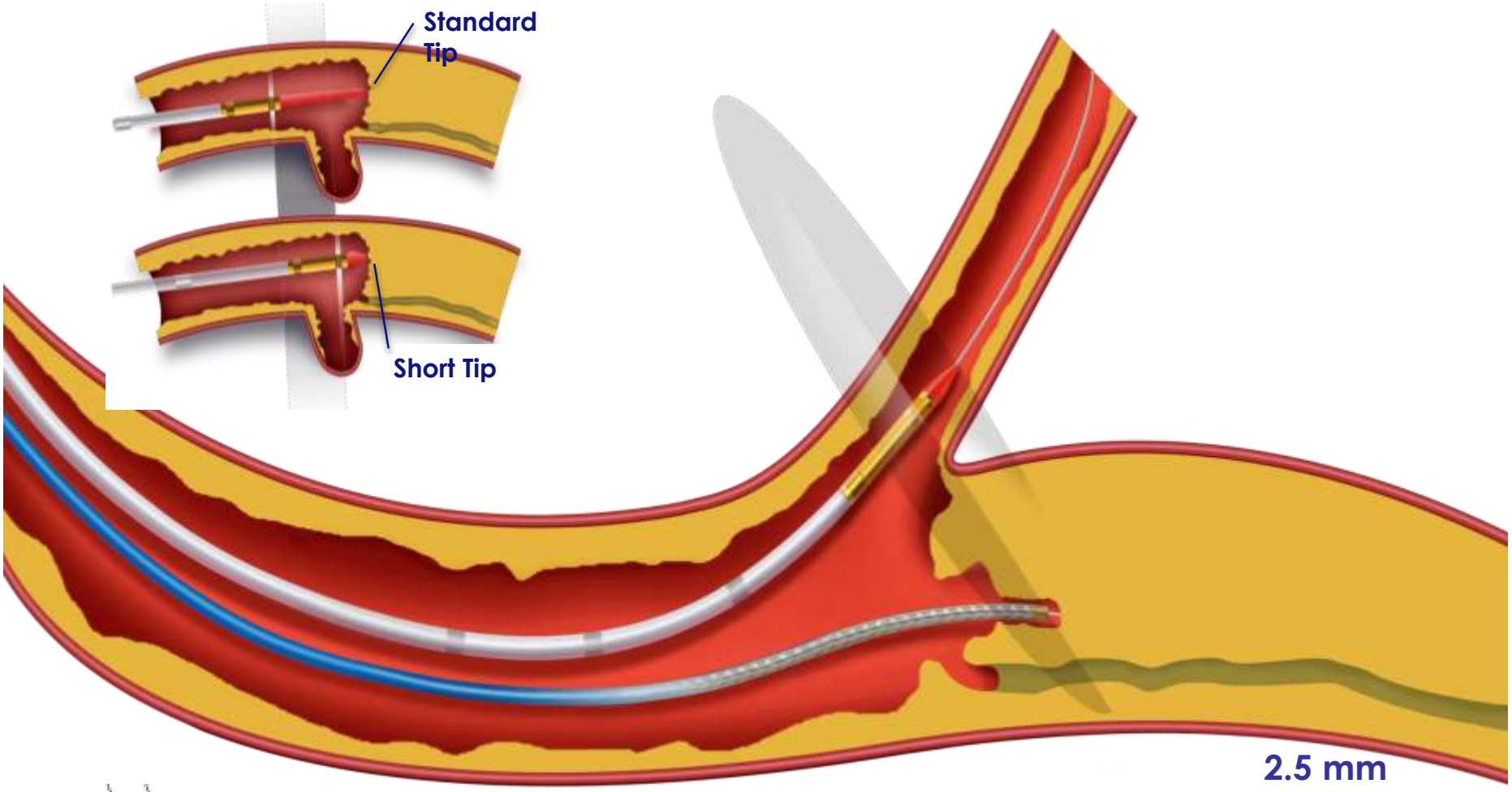
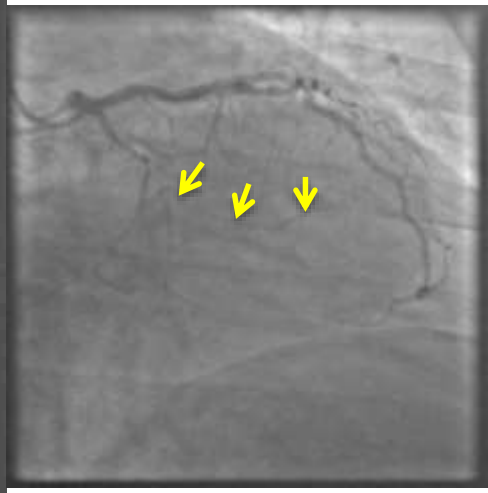
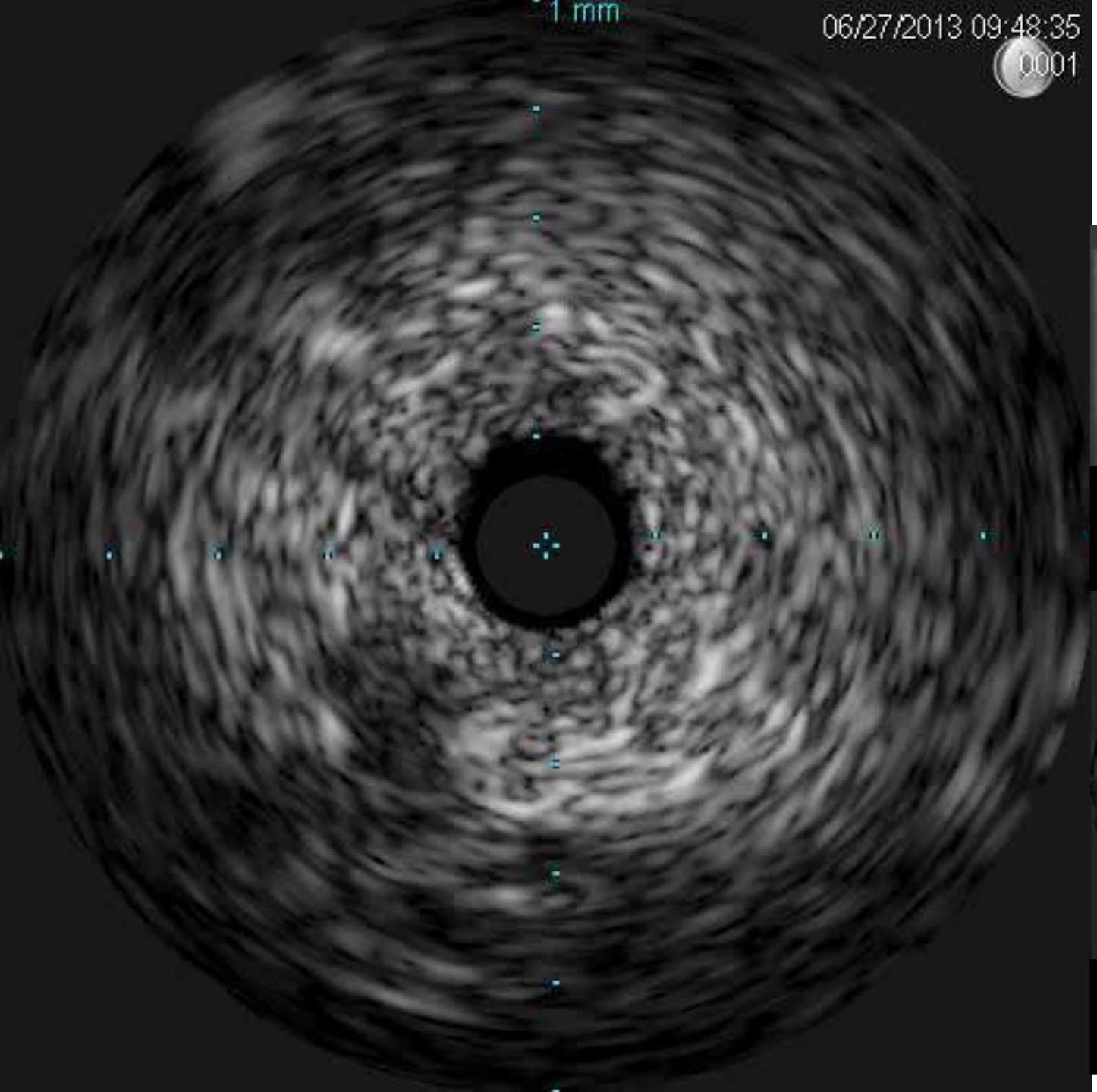


Image courtesy of Volcano

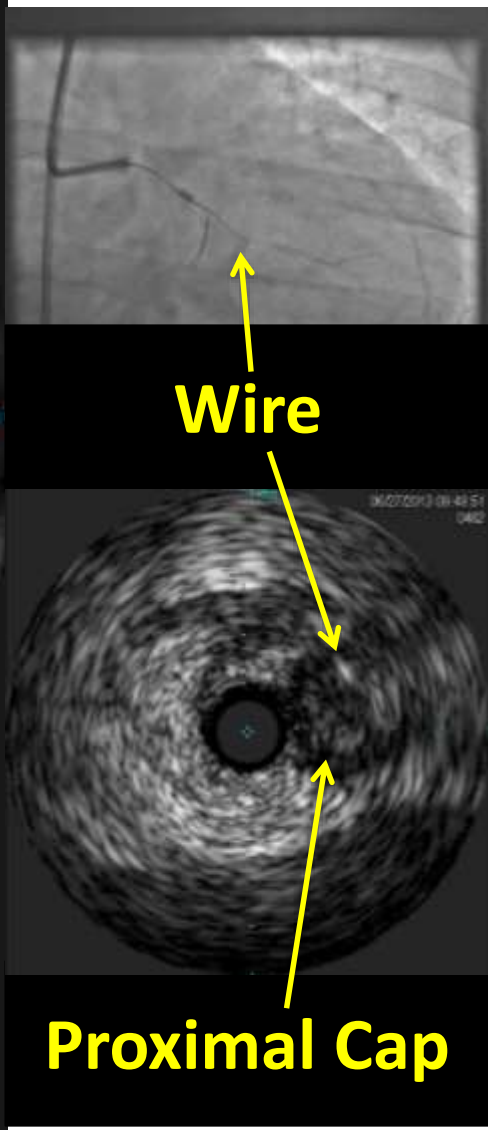
RAO Caudal



OM fills late by collaterals but the proximal cap is ambiguous



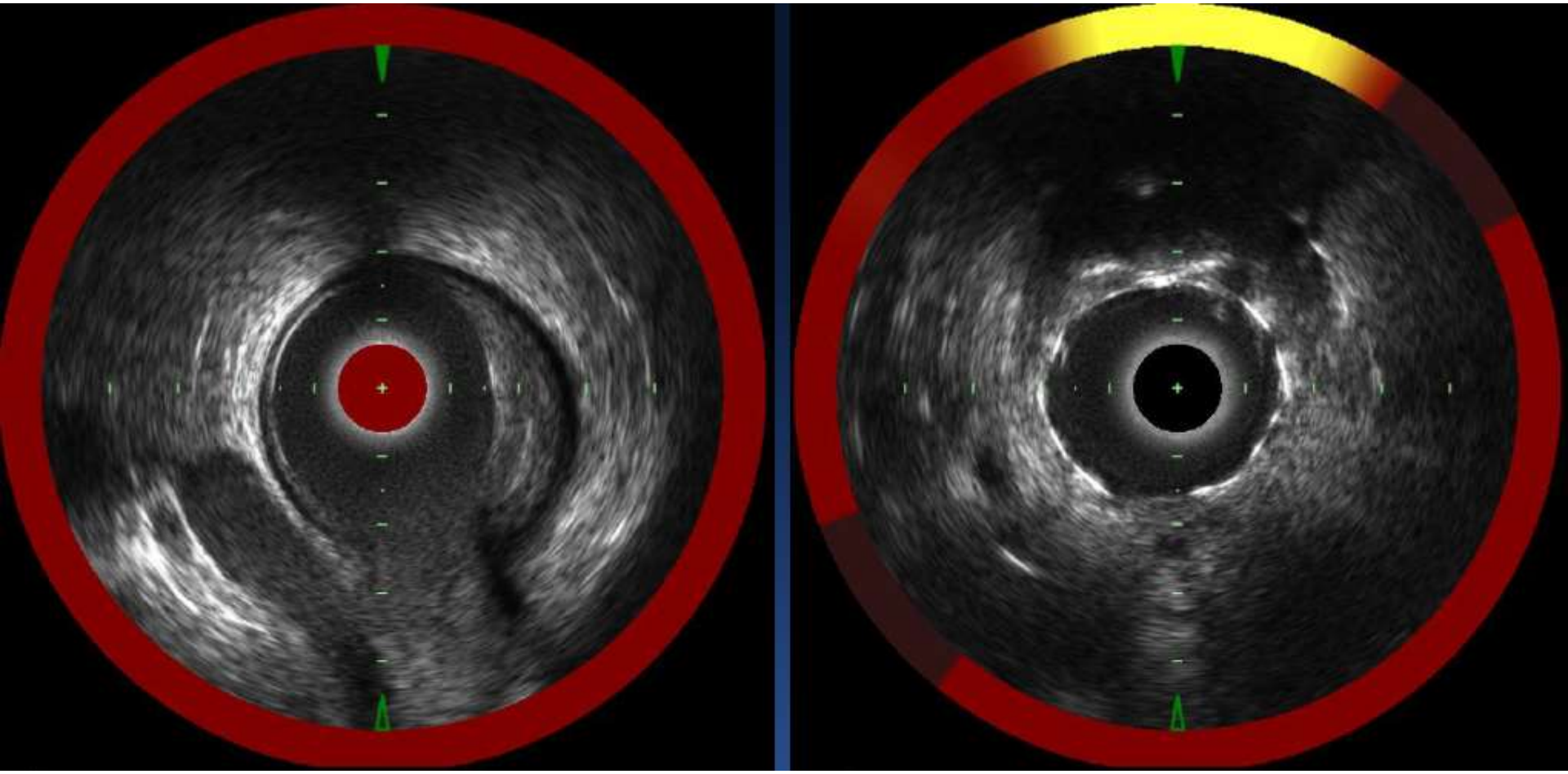
IVUS shows wire correctly enters proximal cap



High Definition IVUS

Feature	ACIST HDi / Kodama	Boston Scientific	Volcano FACT	InfraReDx	St Jude Medical OCT
Frequency or Wavelength	60 MHz	55 MHz	NA	50 MHz	1.3 µm
Nature of the Energy	Ultrasound				Optical
Axial Resolution	40 µm	22 µm	<50 µm	20 µm	15 µm
Lateral Resolution	90 µm	50-140 µm	100-200 µm	<200 µm	40 µm
Soft Tissue Penetration	> 2.5 mm	>3.5 mm			0.8-1.2 mm*
Blood Penetration	> 3.4 mm	>4.0 mm			≤ 1.2 mm
Pullback Speed (mm/s)	0.5, 1.0, 2.5, 5.0, 10	0.5,1.0		0.5	20
Pullback Length (mm)	130	100		150	75

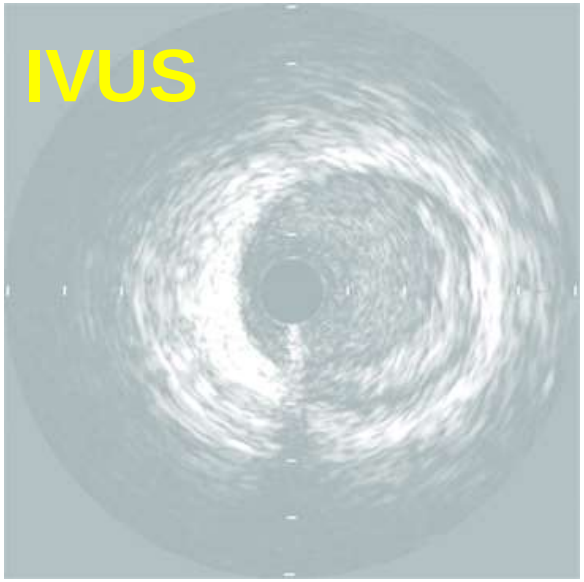
High Definition IVUS

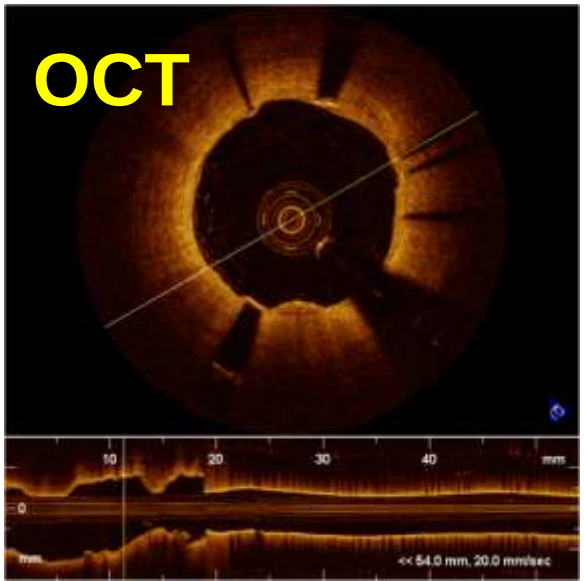


Dallas CARDIOVASCULAR INNOVATIONS 2015

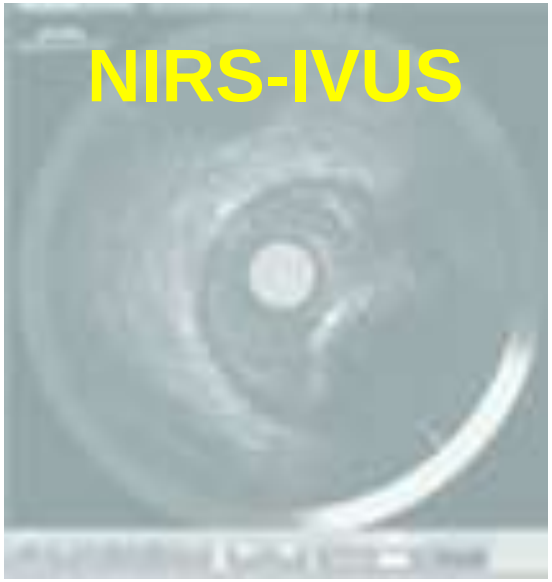
Invasive Coronary Evaluation - 2015

Structure

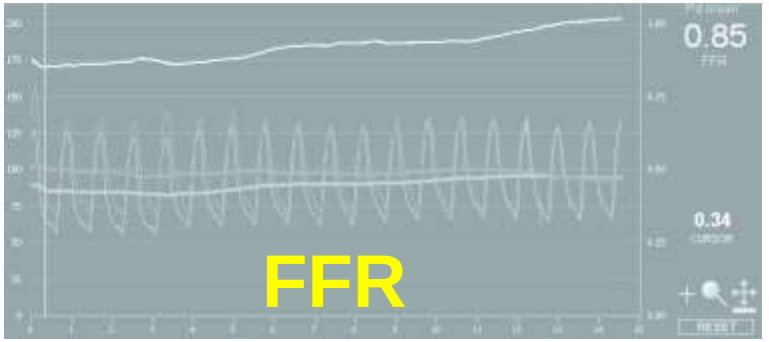




Composition



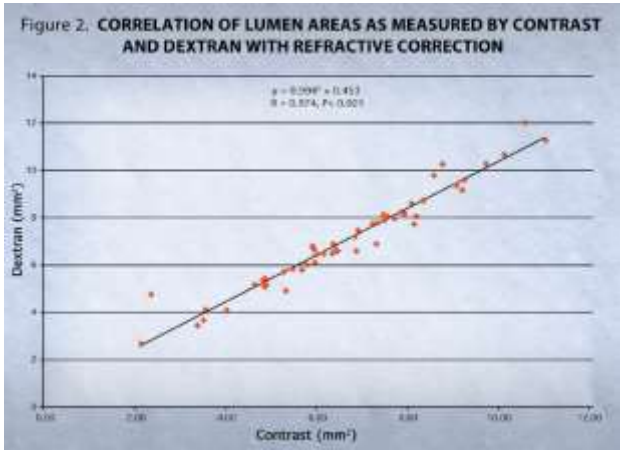
Hemodynamics



OCT vs. IVUS

	OCT	IVUS
Energy source	Near-infrared	Ultrasound (20-45MHz)
Wave-length, *mm*	1.3	35-80
Resolution, *μm*	15-20	100-200
Frame rate, *frames/sec*	100	30
Blood clearing	Required	Not required
*Maximum penetration, *mm*	~2	10
Imaging through calcium	Yes	No

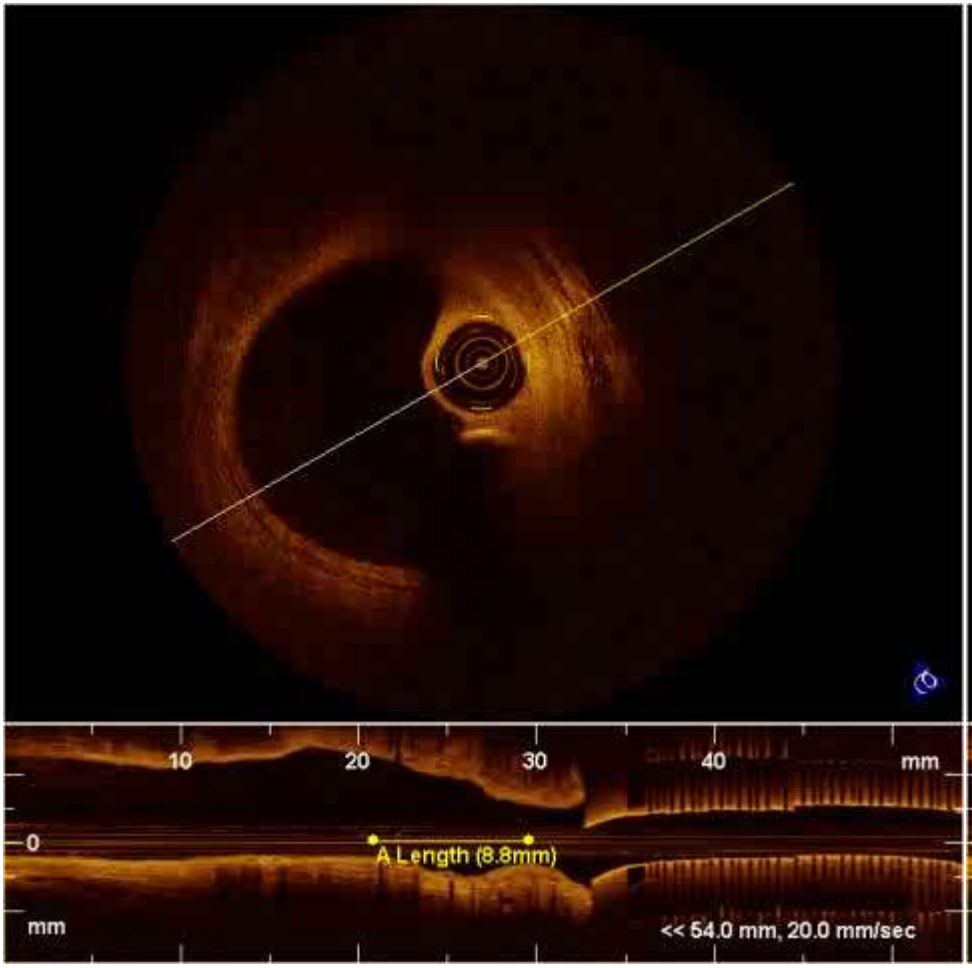
Dallas CARDIOVASCULAR INNOVATIONS 2015

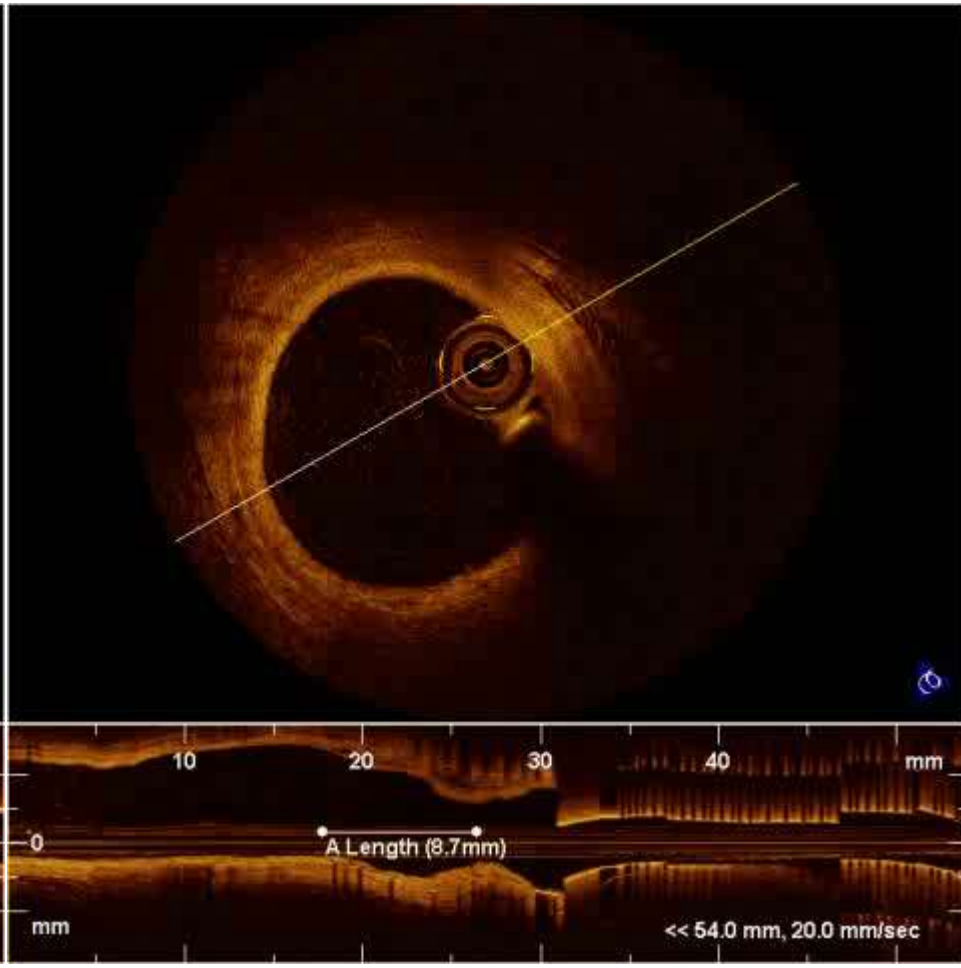


Frick et al. CCI 2013

CONTRAST

DEXTRAN





Dallas CARDIOVASCULAR INNOVATIONS 2015

How can OCT help?

Pre-PCI - Assess plaque

1. Lesion severity
2. Facilitate stent sizing – need to prepare lesion
3. PCI risk: Lipid Core Plaque, Thrombus, Calcium

Post PCI

1. Dissections - thrombus
2. Malapposition
3. Stent expansion

long-term

4. Stent strut coverage-apposition

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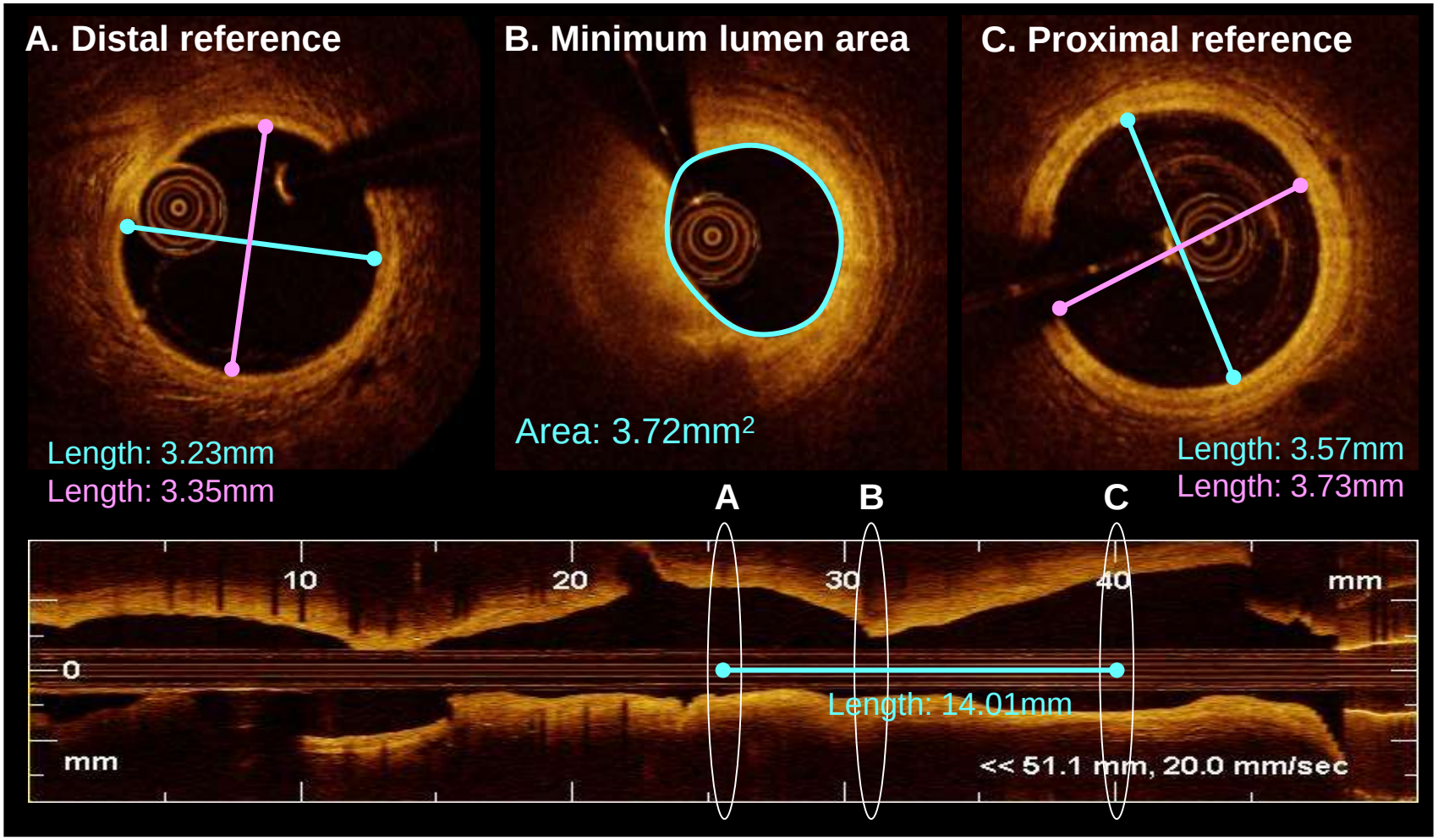
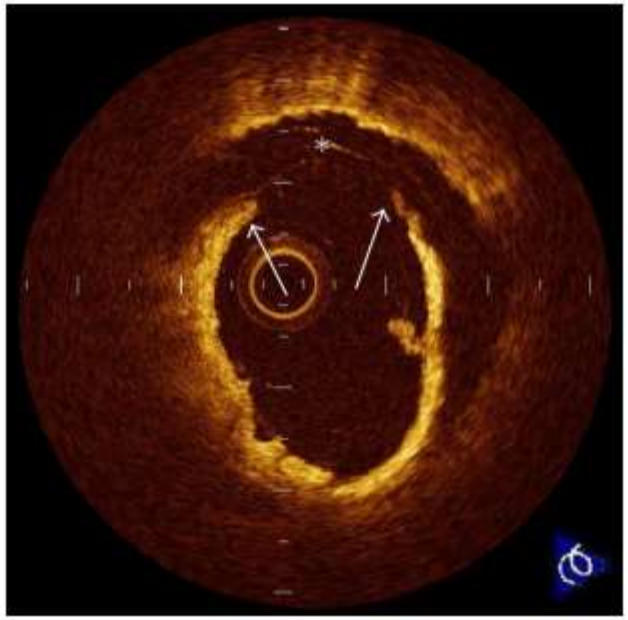
Pre-PCI OCT measurements



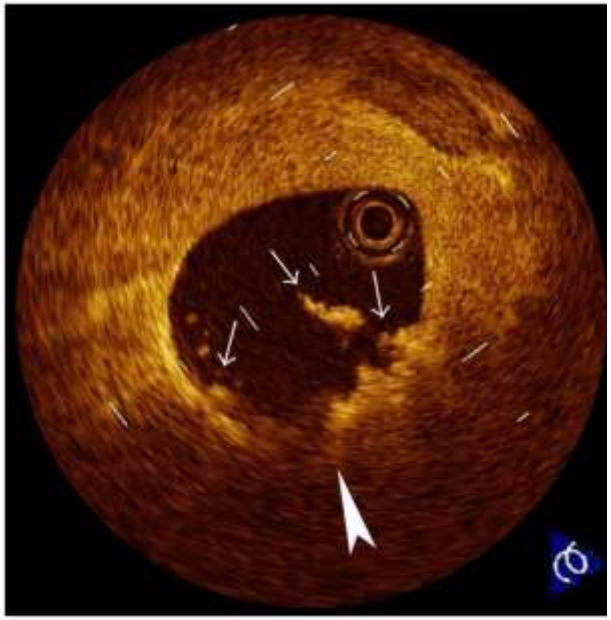
Kubo, Akasaka et al, CVIT 2010;25:2-10

Detecting the culprit lesion

Plaque Rupture



Plaque Erosion

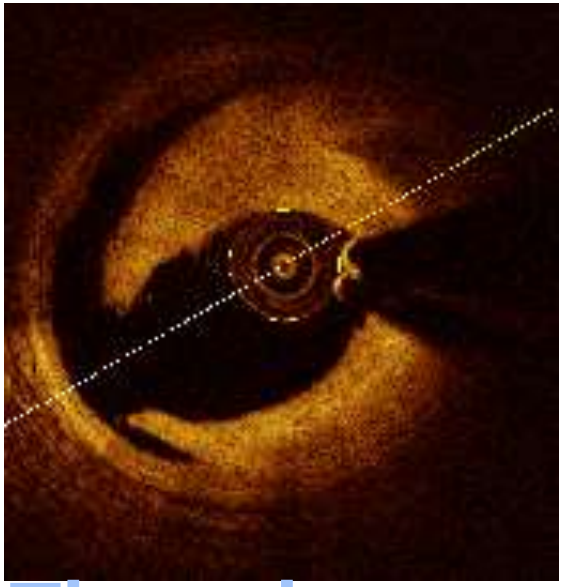


Thrombus

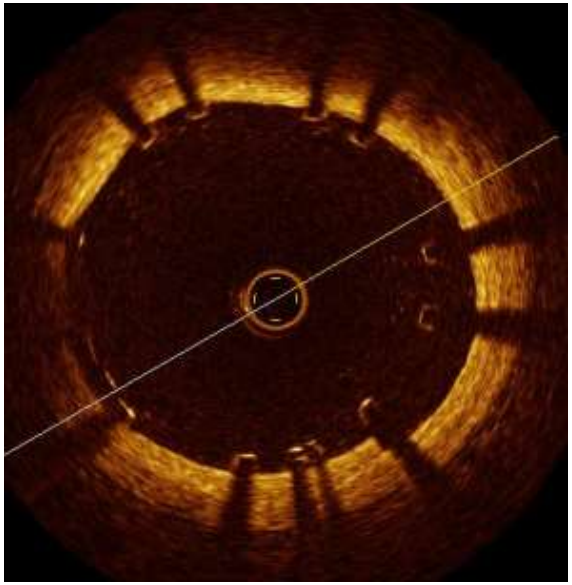
Dallas CARDIOVASCULAR INNOVATIONS 2015

OCT optimization post stenting

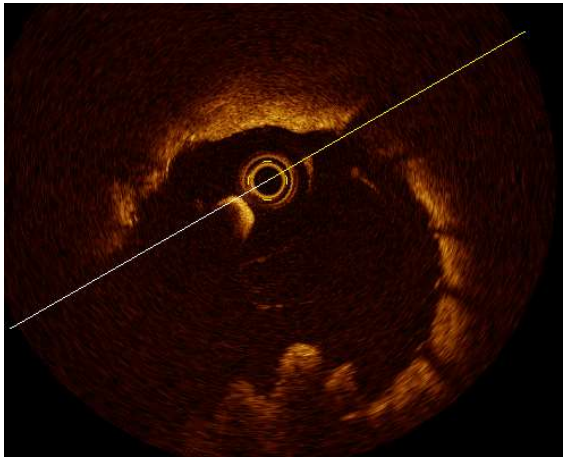
Edge dissection



Stent malapposition



Thrombus



Stent under-expansion

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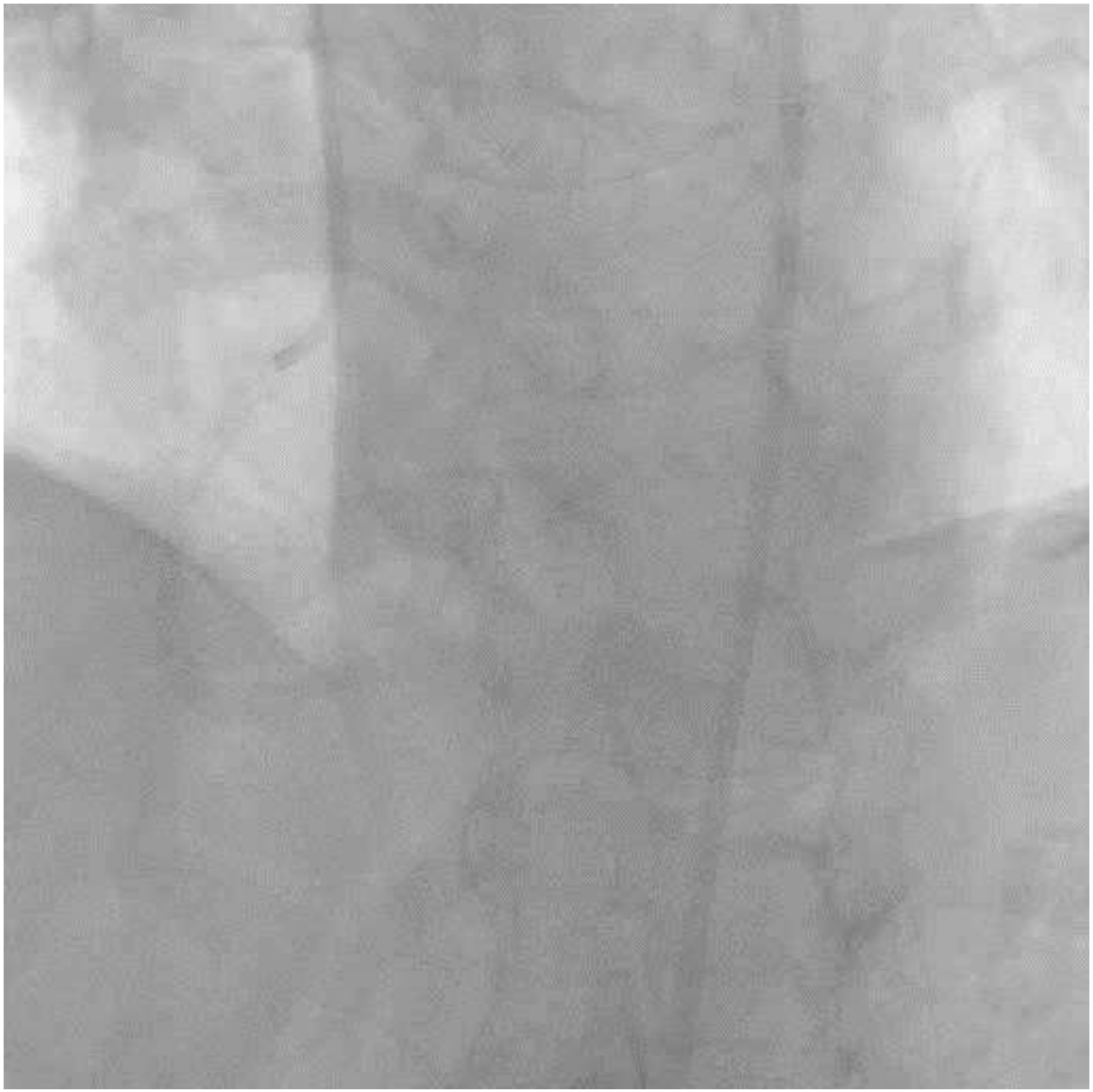
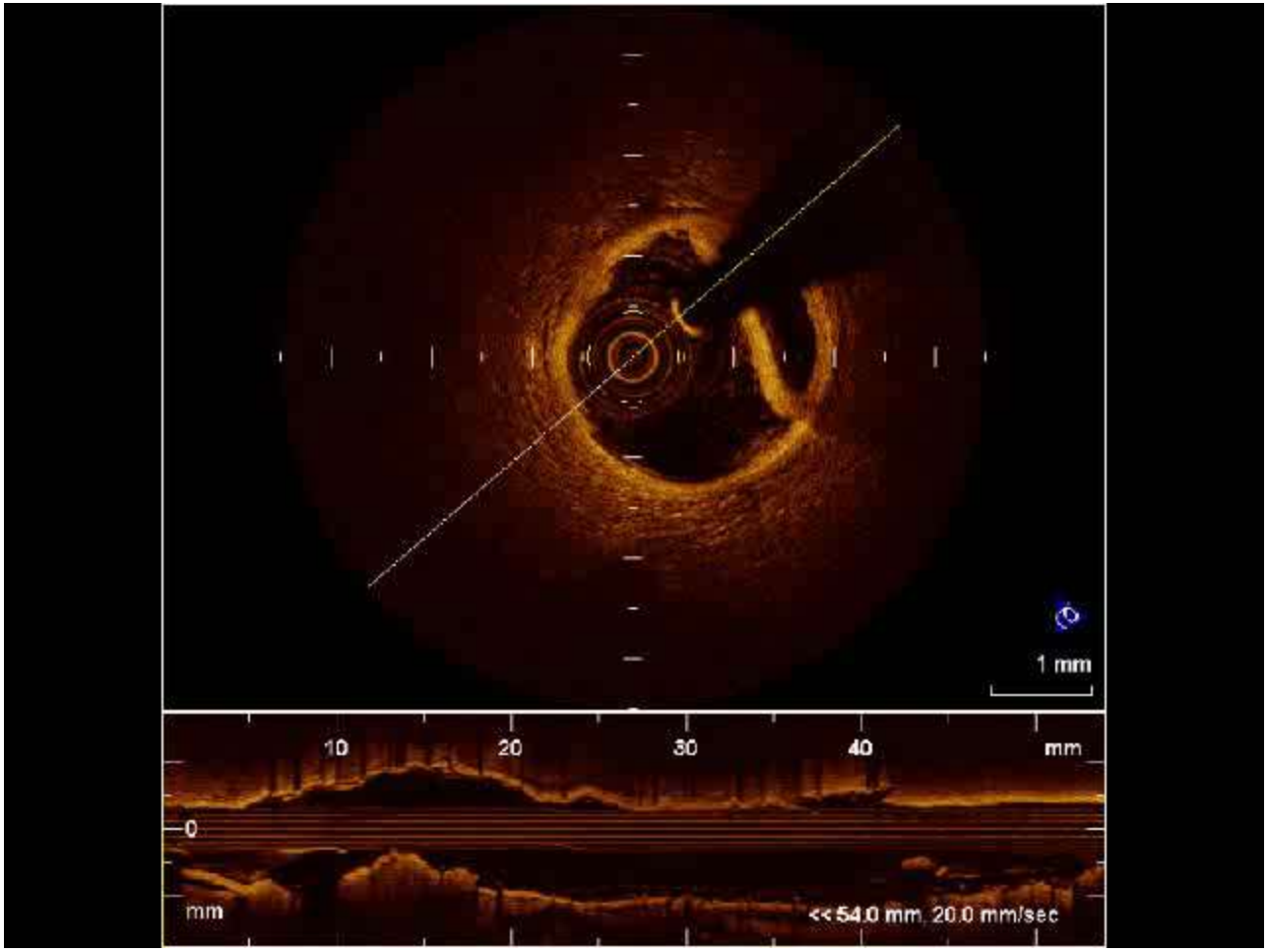
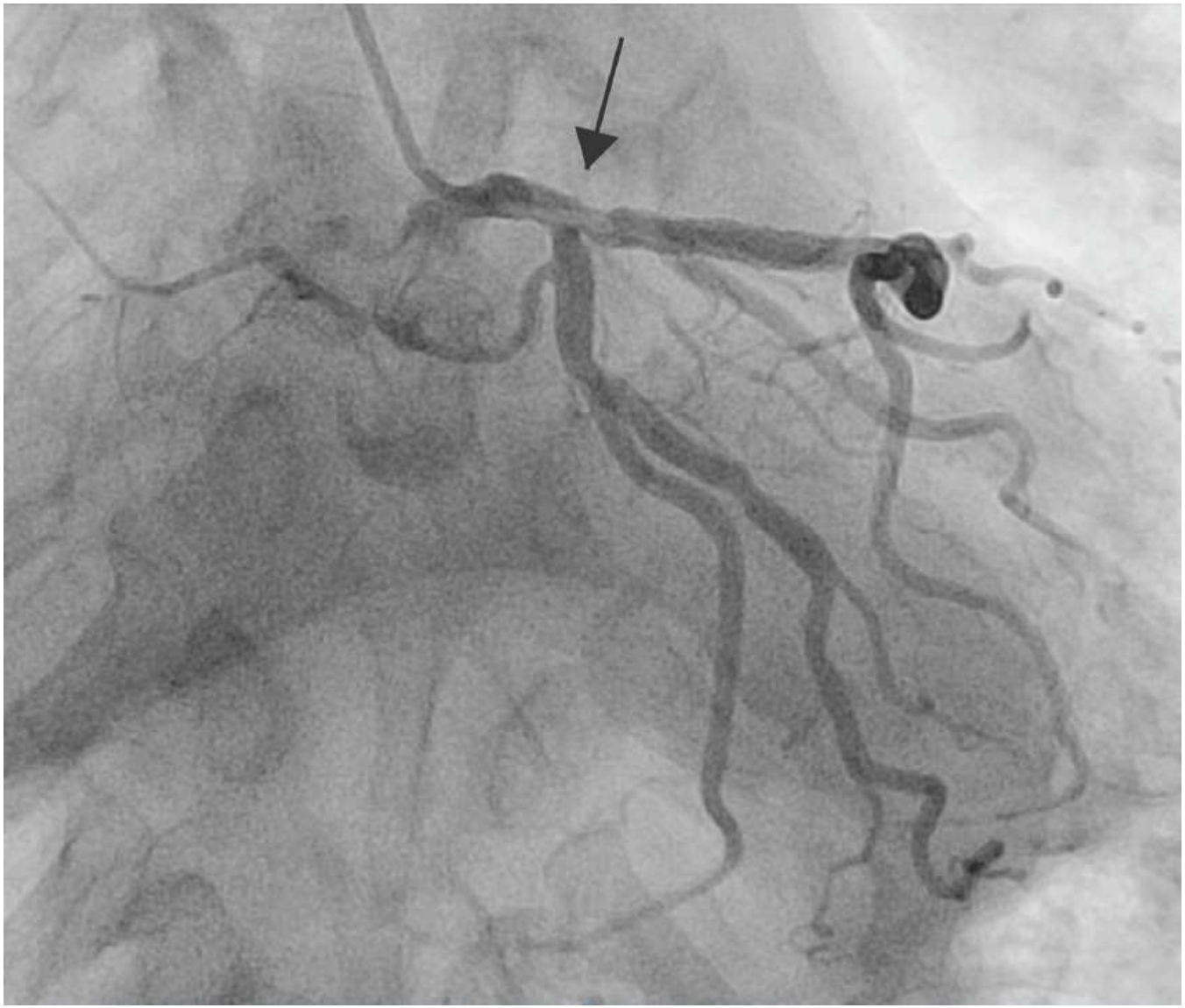
After stenting



OCT - distal to stent

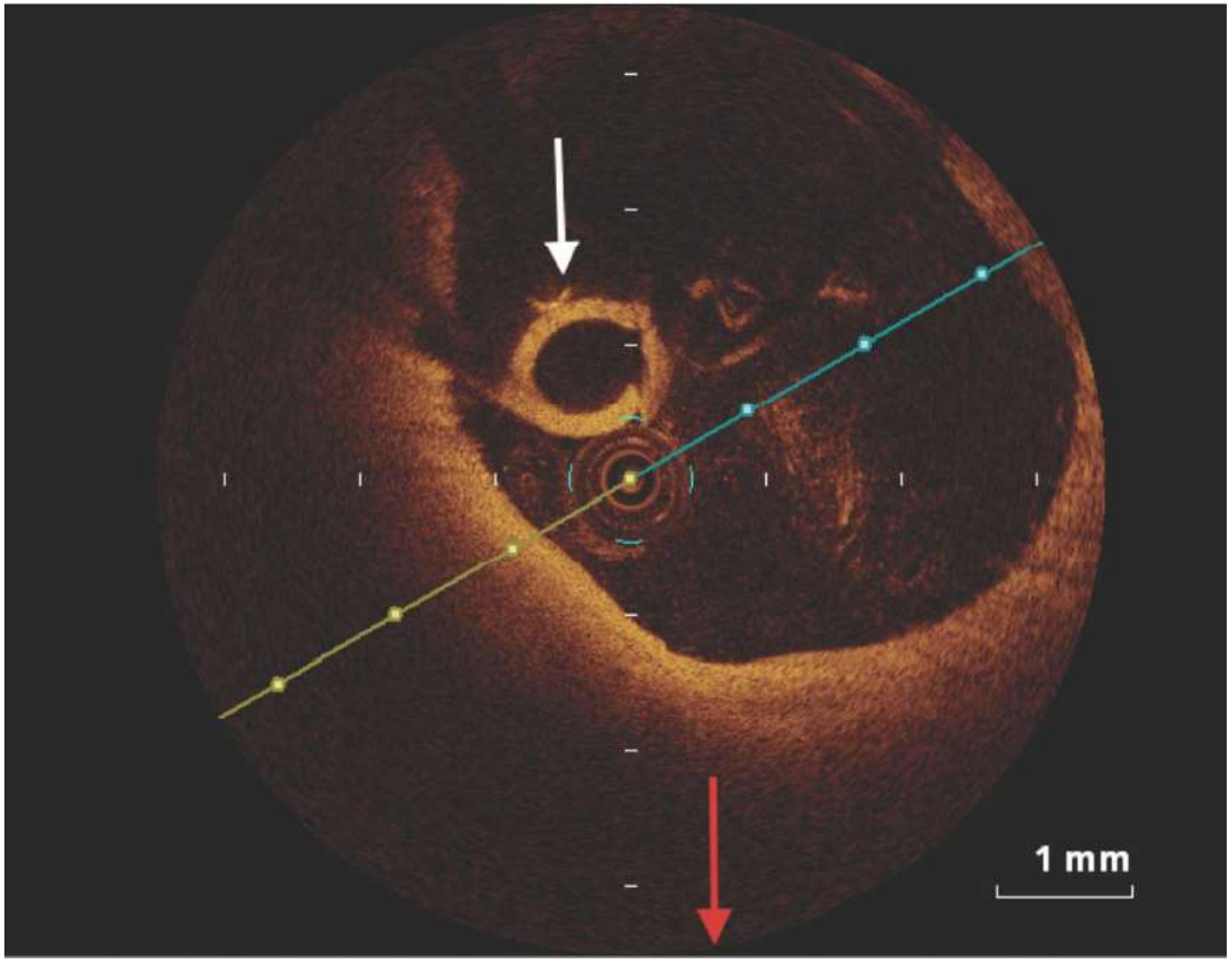


Foreign body in the LAD



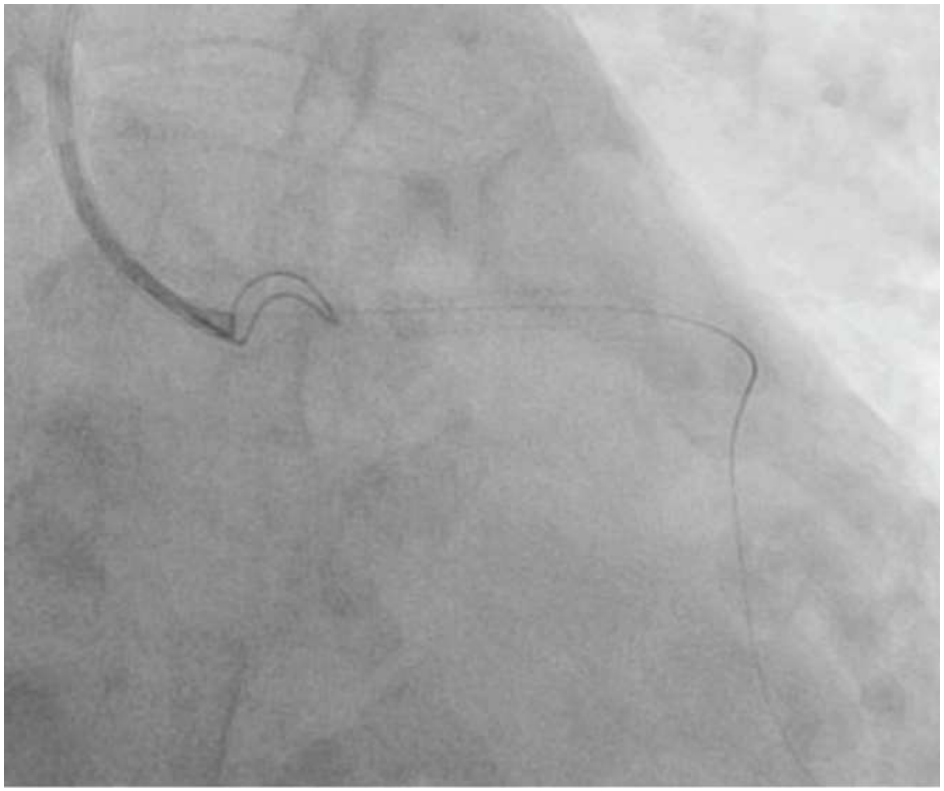
Ertel, Shroff, Vidovich. Cath Cardiovasc Interv 2014;84:677-81

Foreign body in the LAD - OCT



Ertel, Shroff, Vidovich. Cath Cardiovasc Interv 2014;84:677-81

Foreign body in the LAD - snaring

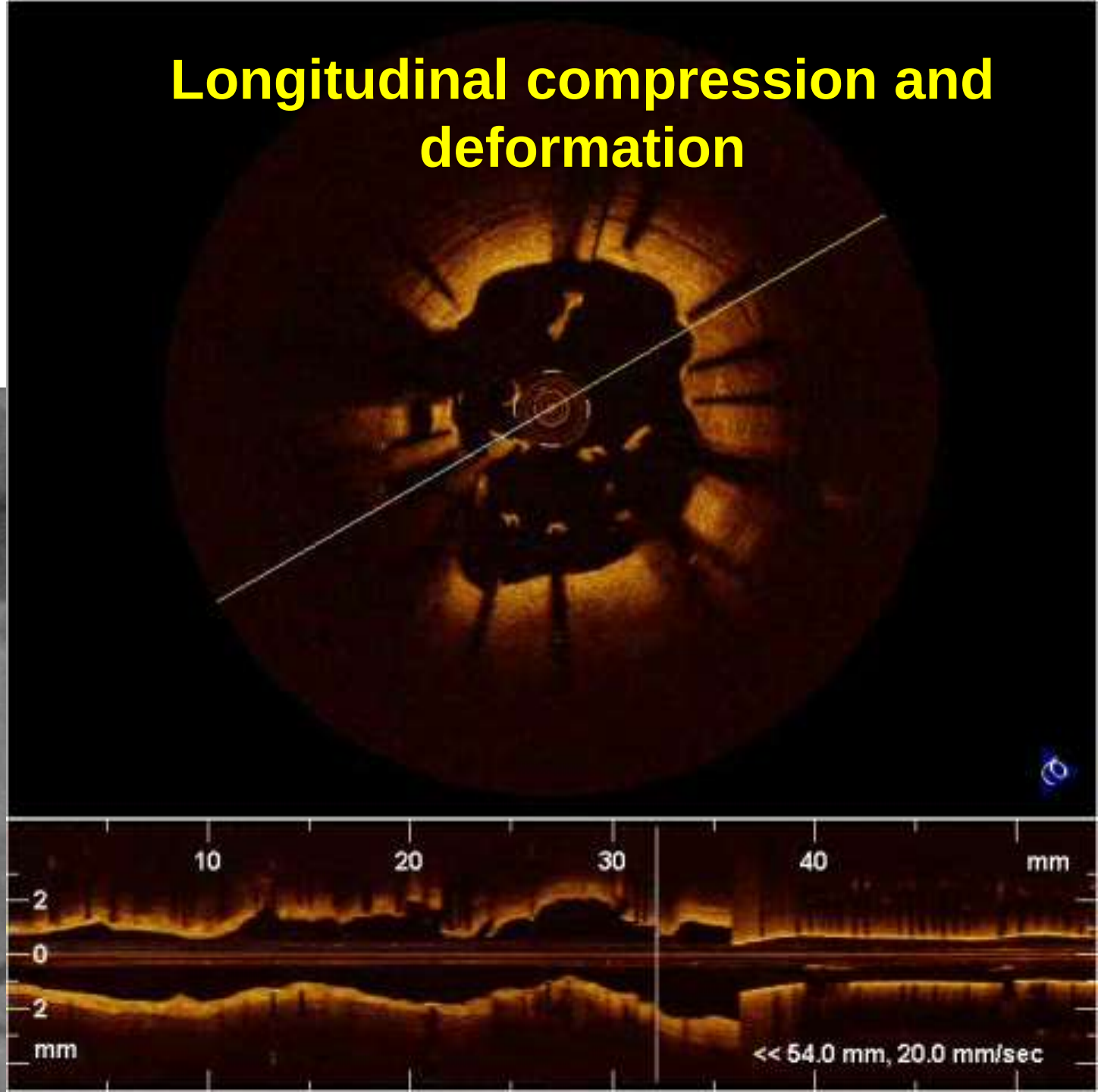


Ertel, Shroff, Vidovich. Cath Cardiovasc Interv 2014;84:677-81

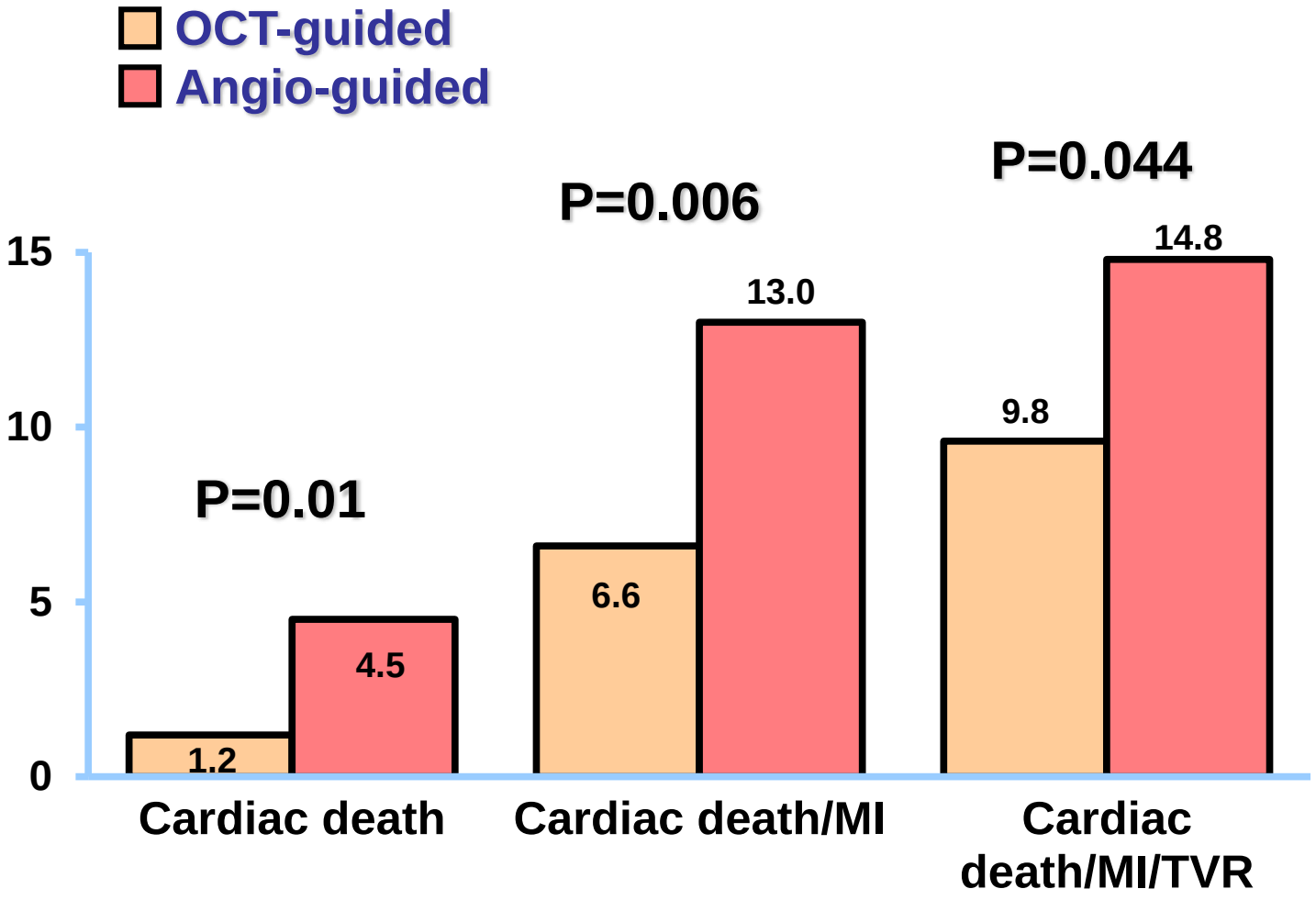
Safety

Difficulty advancing IVUS catheter

Longitudinal compression and deformation



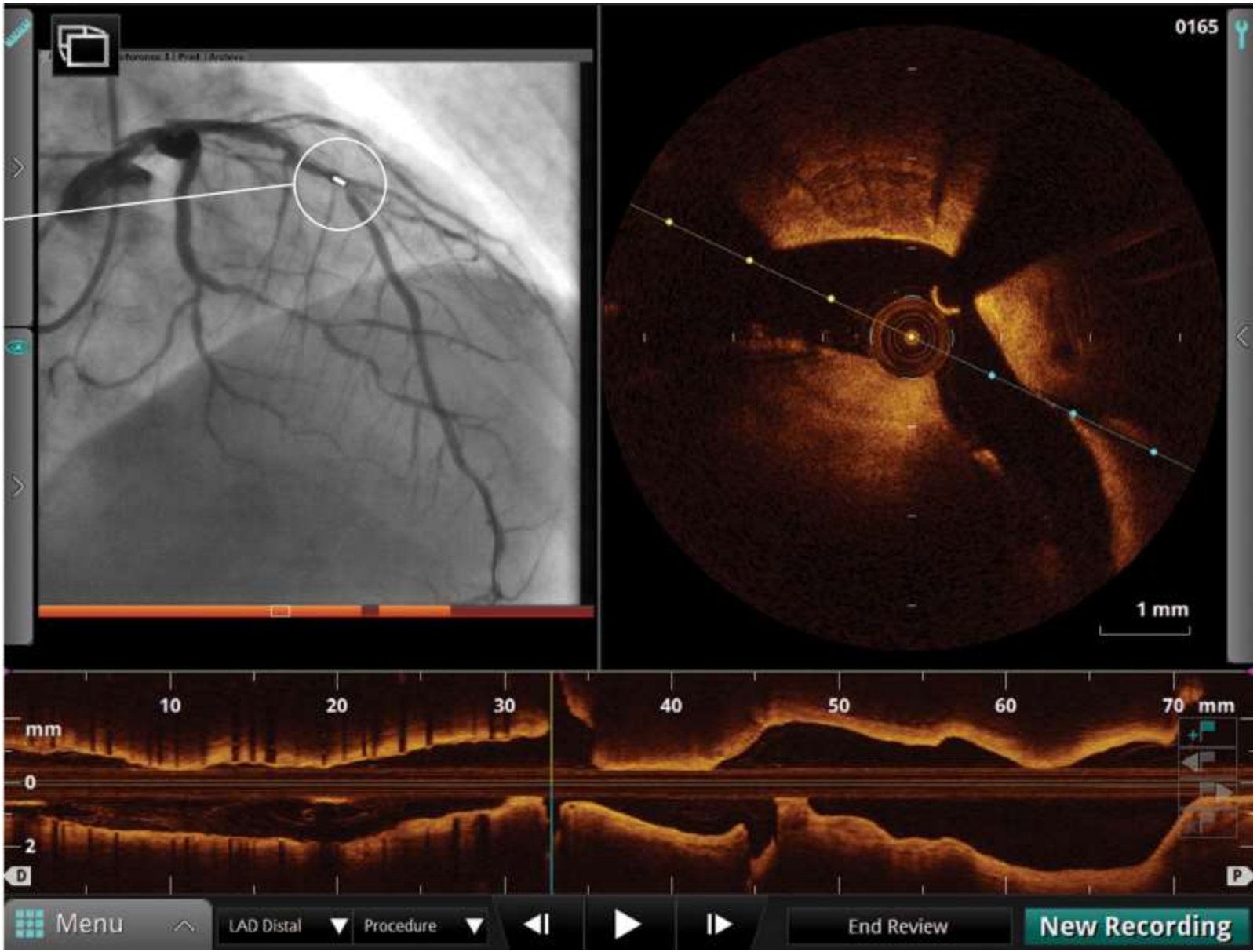
CLI-OPCI: 1-year outcomes



Prati et al. Eurointervention 2012

Dallas CARDIOVASCULAR INNOVATIONS 2015

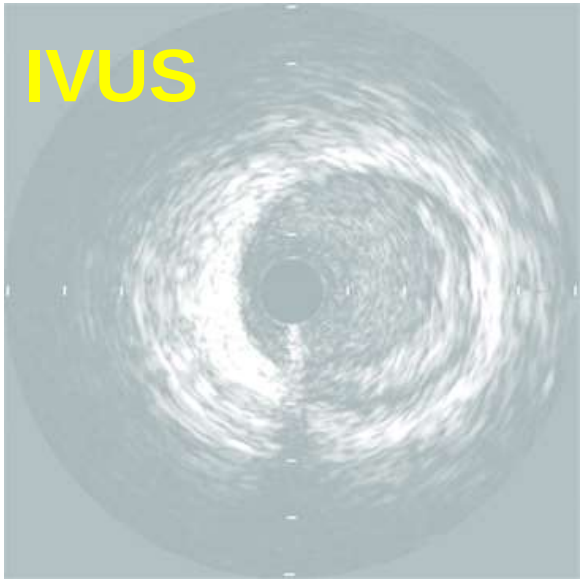
OCT-angio coregistration

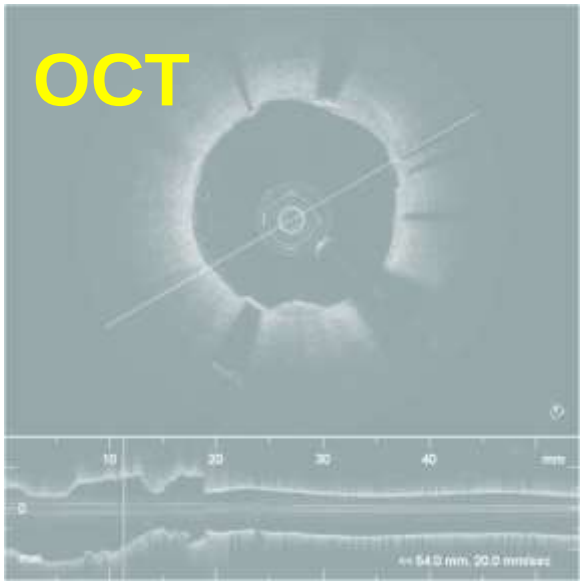


Dallas CARDIOVASCULAR INNOVATIONS 2015

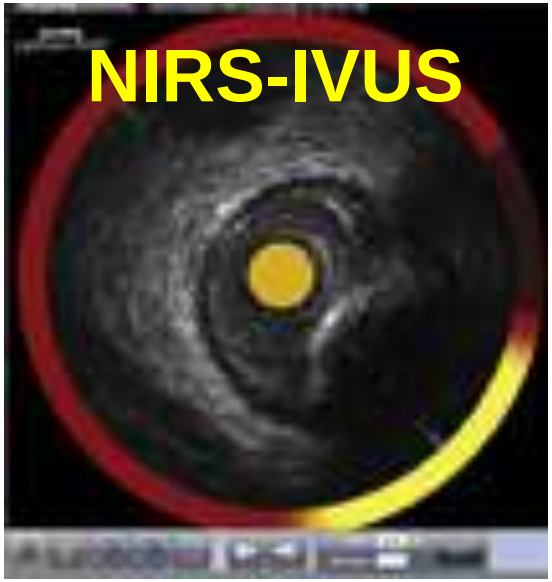
Invasive Coronary Evaluation - 2015

Structure

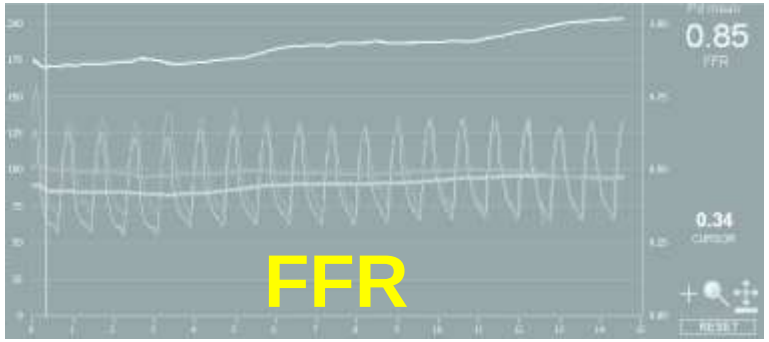




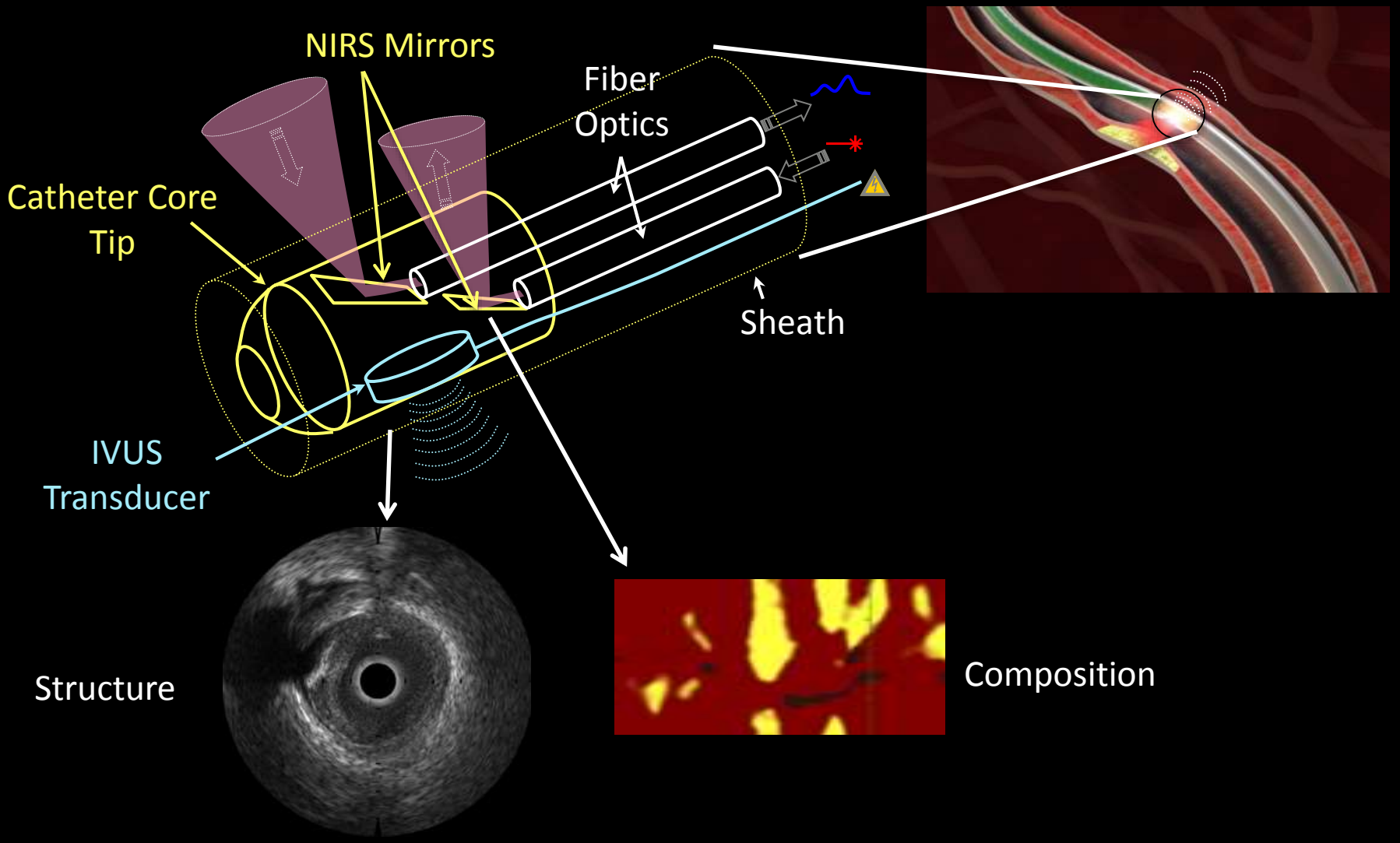
Composition



Hemodynamics



NIRS and IVUS Combined Catheter



NIRS clinical applications

1. **All applications of IVUS**
2. **Optimizing acute PCI outcomes**
3. **Evaluating anti-atherosclerotic therapies**
4. **Understanding natural history of CABG**

NIRS clinical applications

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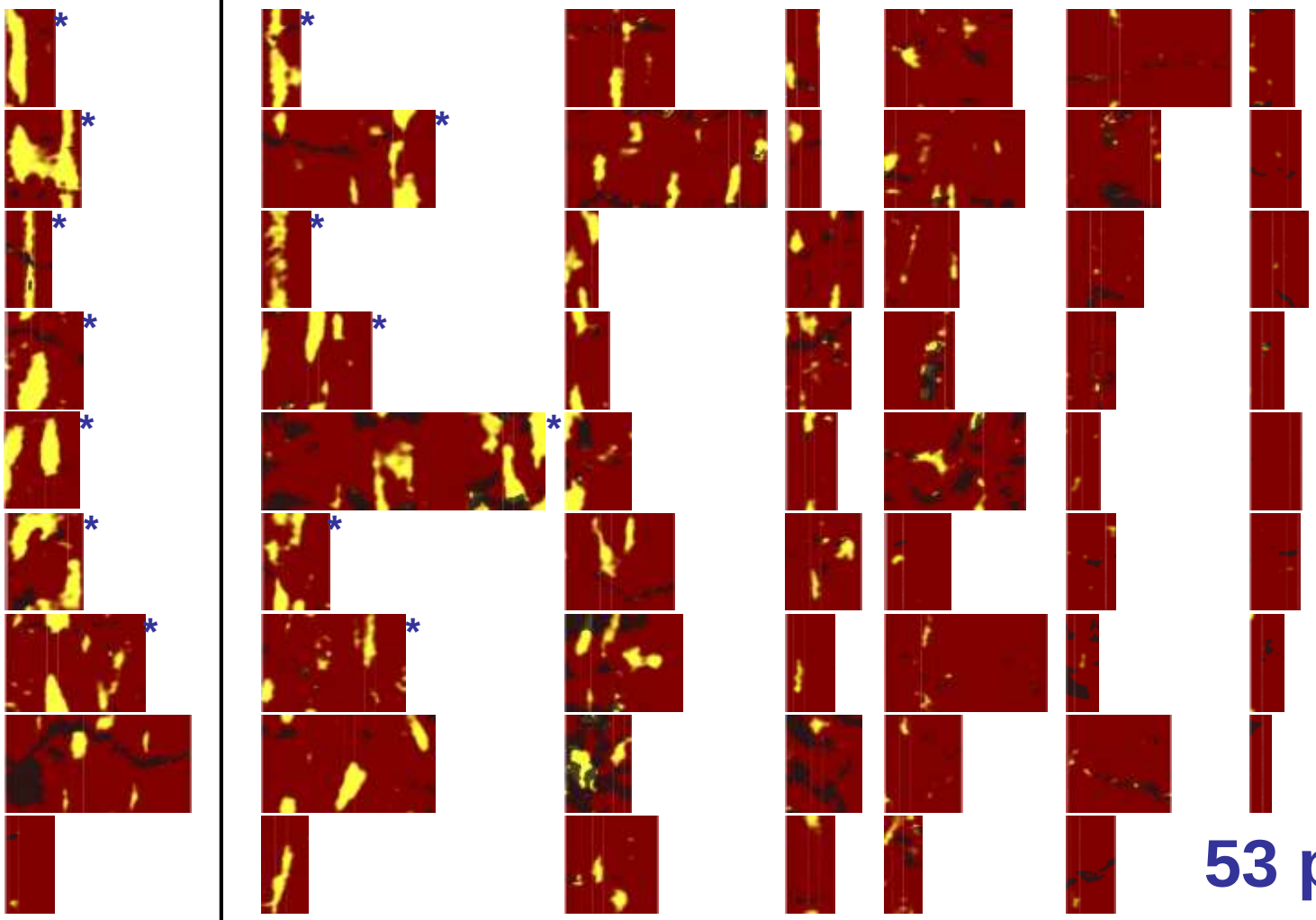
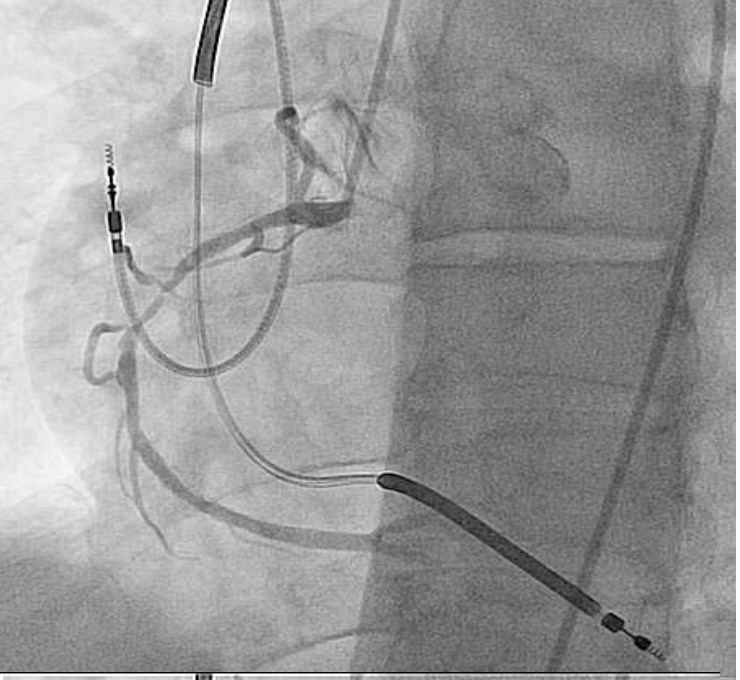
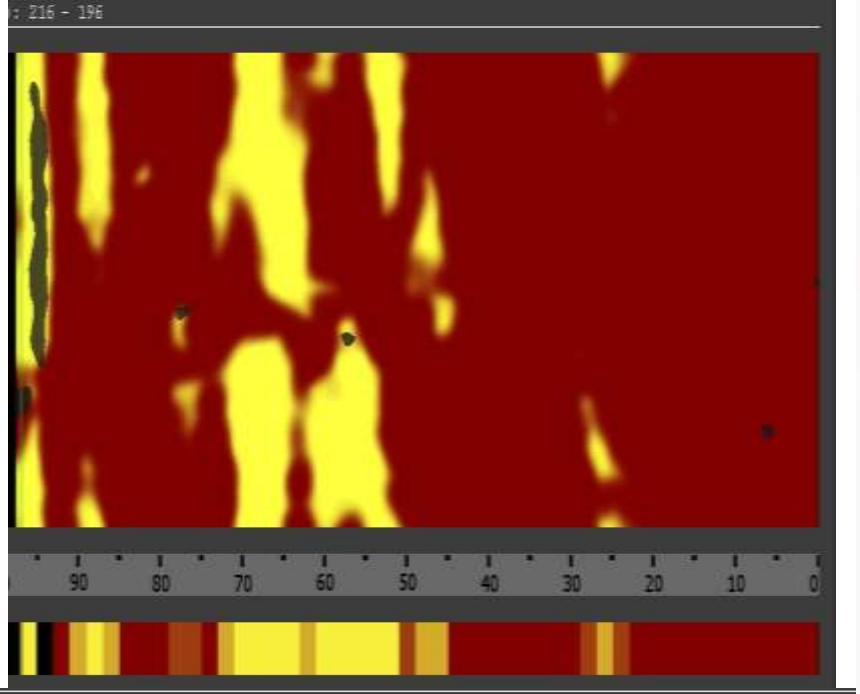
Dallas CARDIOVASCULAR INNOVATIONS 2015

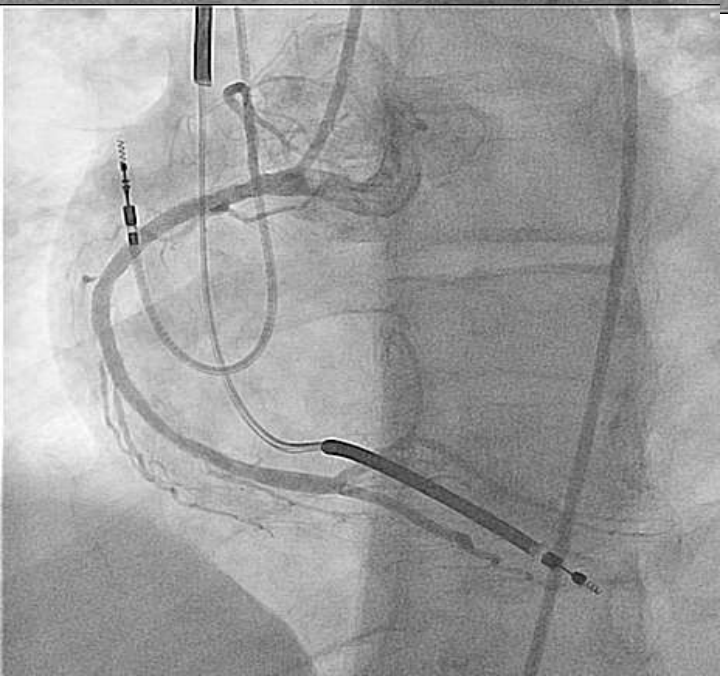
NIRS and post-PCI MI

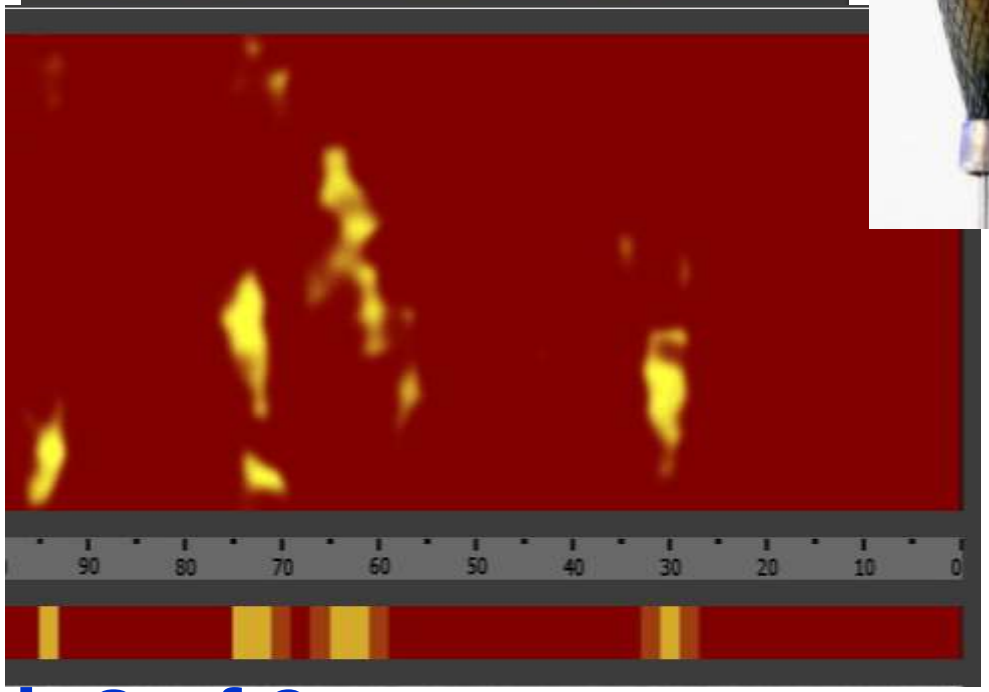


Goldstein et al. Circ Intv 2011

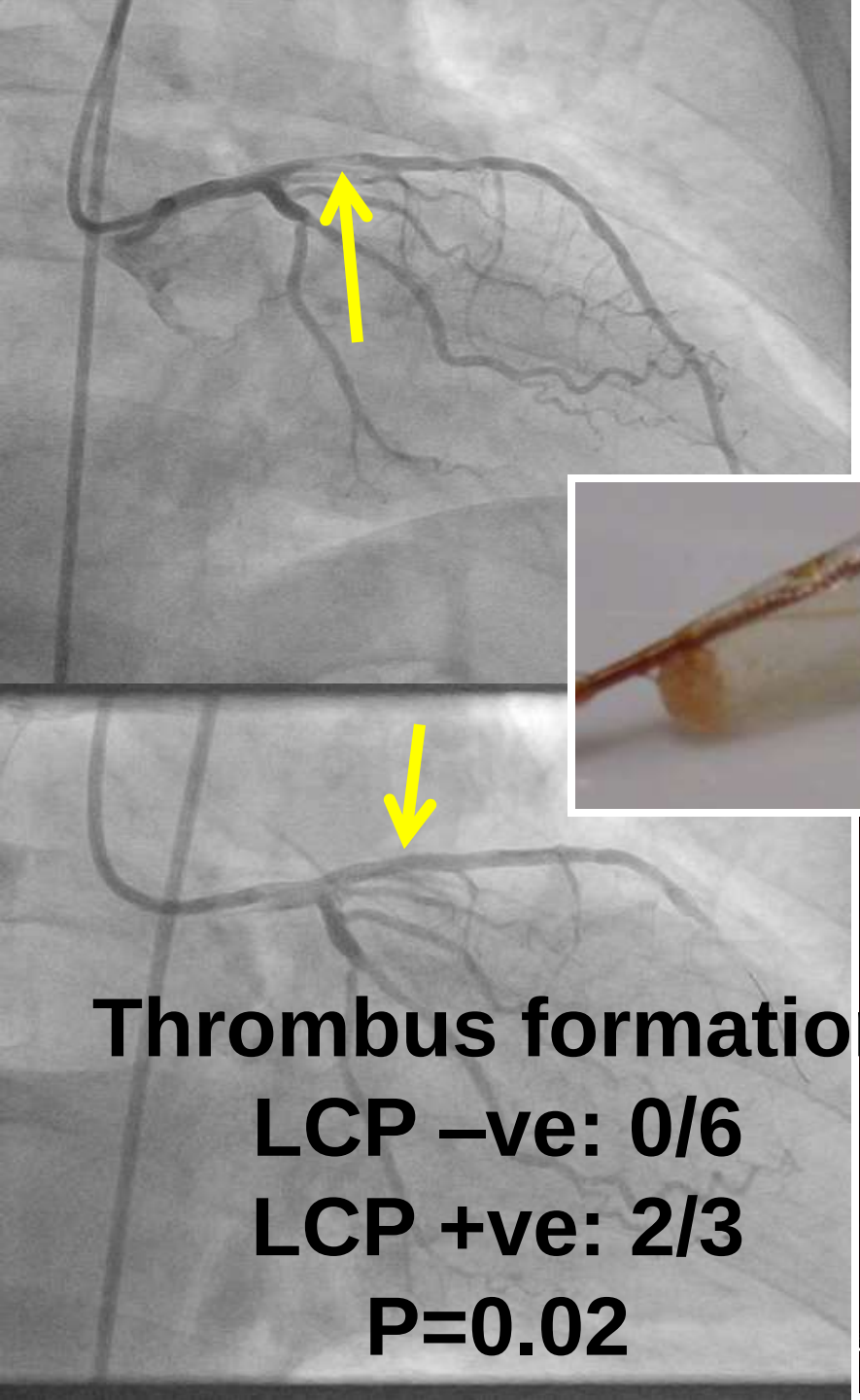


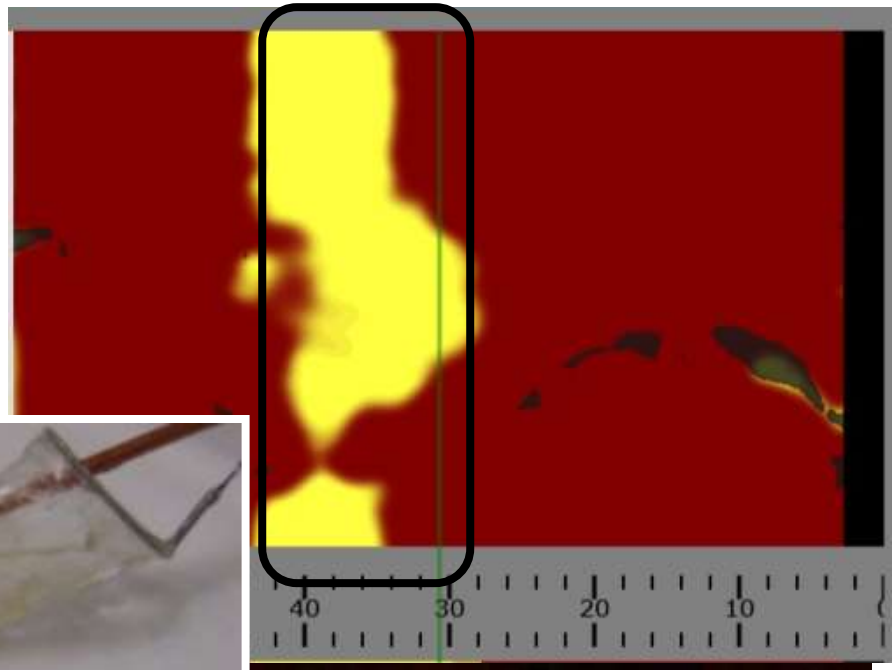


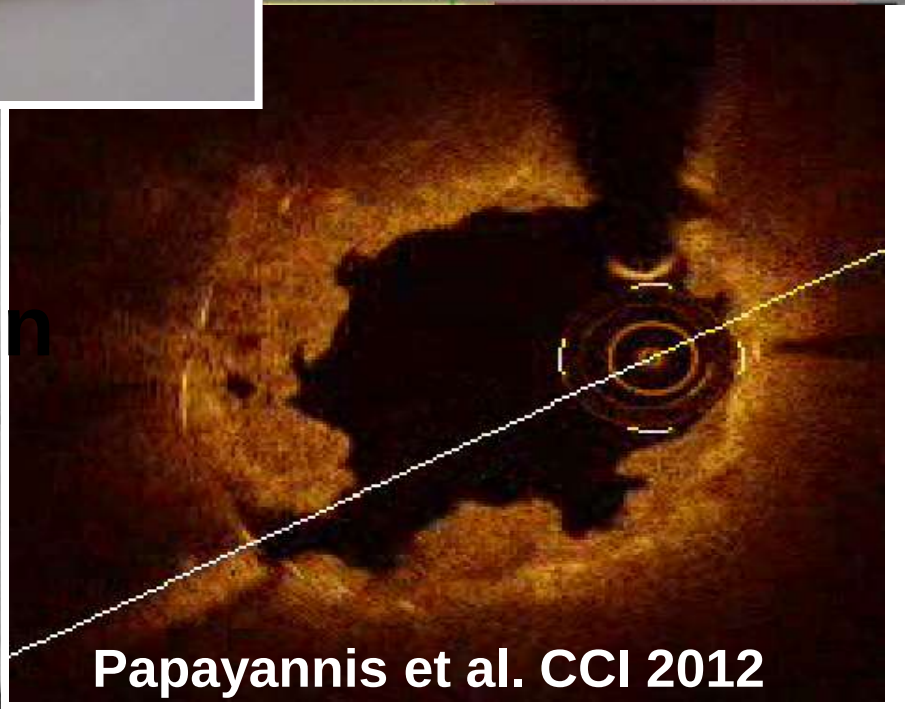




Debris retrieved: 8 of 9 pts Brilakis et al. CCI 2012







Thrombus formation

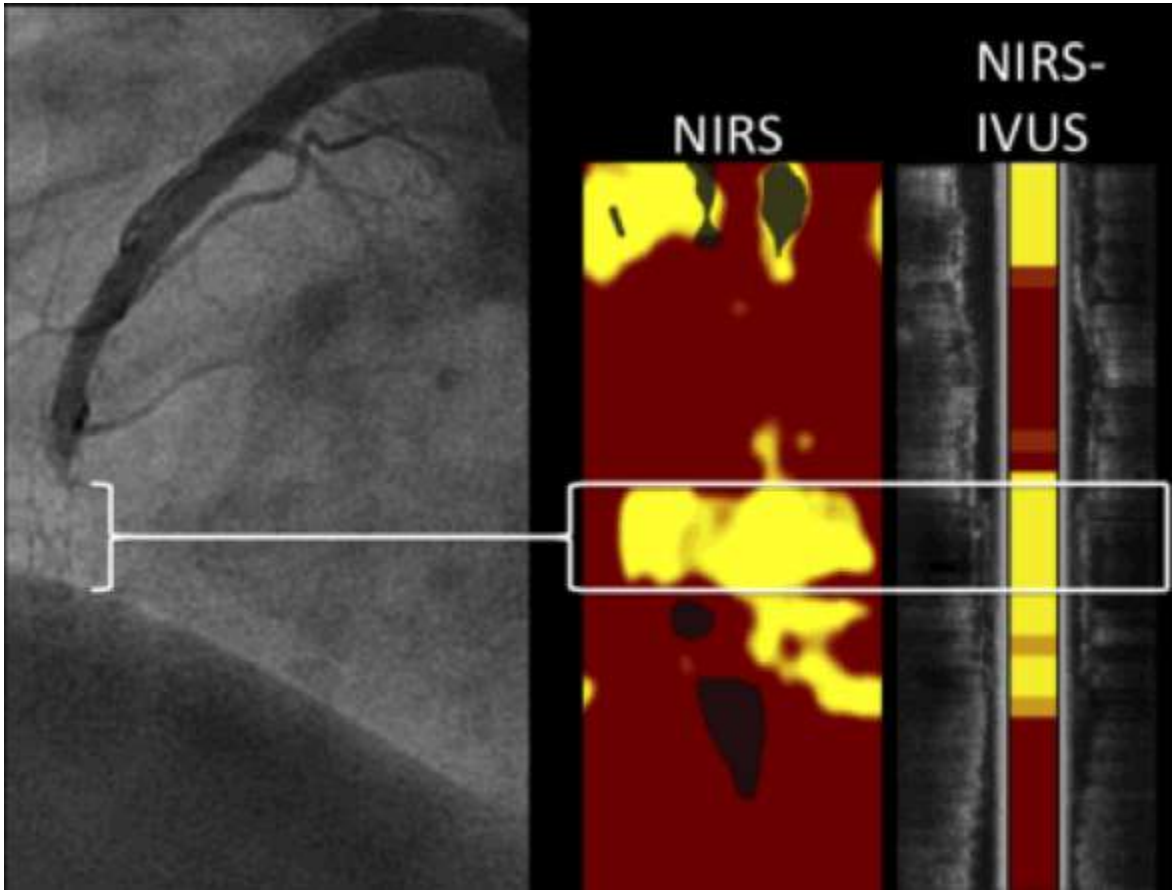
LCP –ve: 0/6

LCP +ve: 2/3

P=0.02

Detection by Intracoronary Near-infrared Spectroscopy of Lipid-rich Plaques within Remotely Implanted Stents

Chemogram recorded at the site of stent thrombosis occurring several years post-implantation.



Madder R et al. JACC 2014

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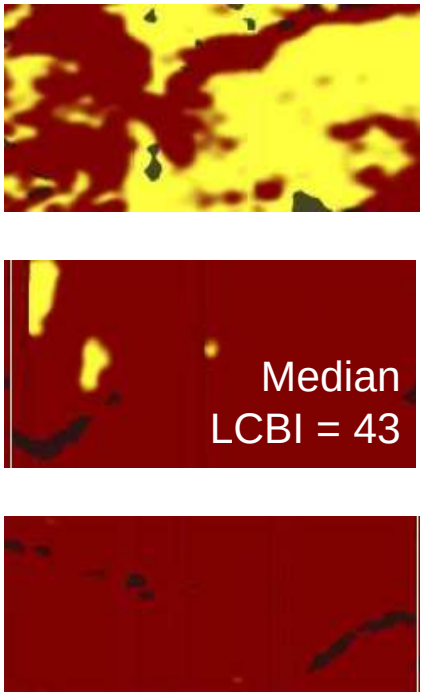
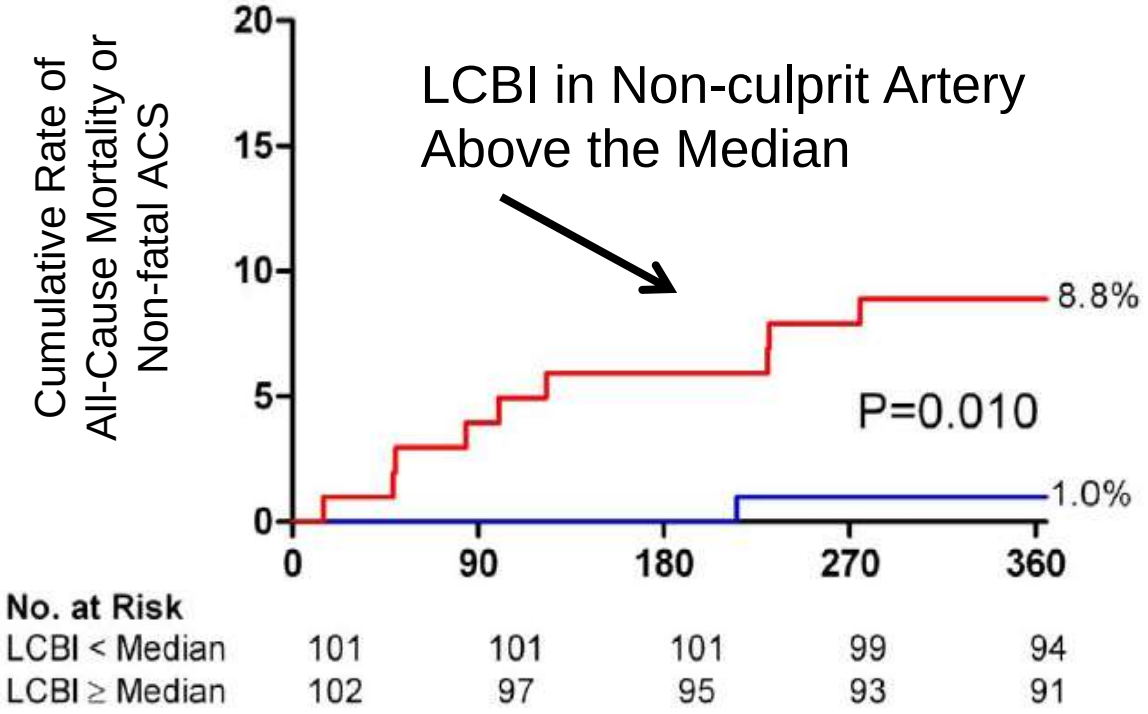
Dallas CARDIOVASCULAR INNOVATIONS 2015

LCBI in Non-culprit Artery Identifies Vulnerable Patients





Oemrawsingh R et al. JACC 2014

- Non-culprit vessel LCBI reflects vascular vulnerability of the larger coronary tree
- LCBI ≥43 predicts vulnerable patients with a 4x risk of event
- Ongoing studies will correlate events to yellow on the chemogram detecting vulnerable plaque and vulnerable patients

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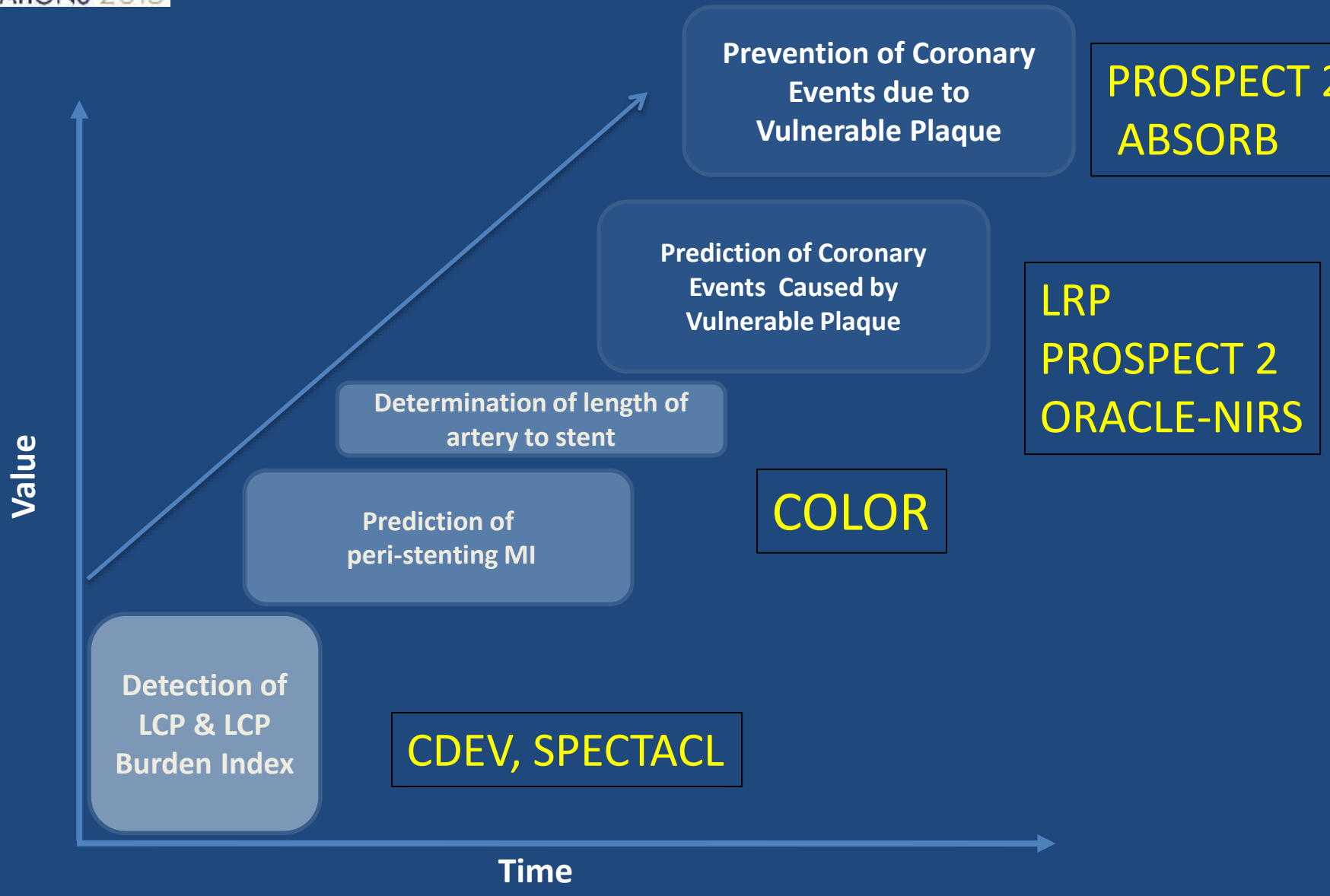
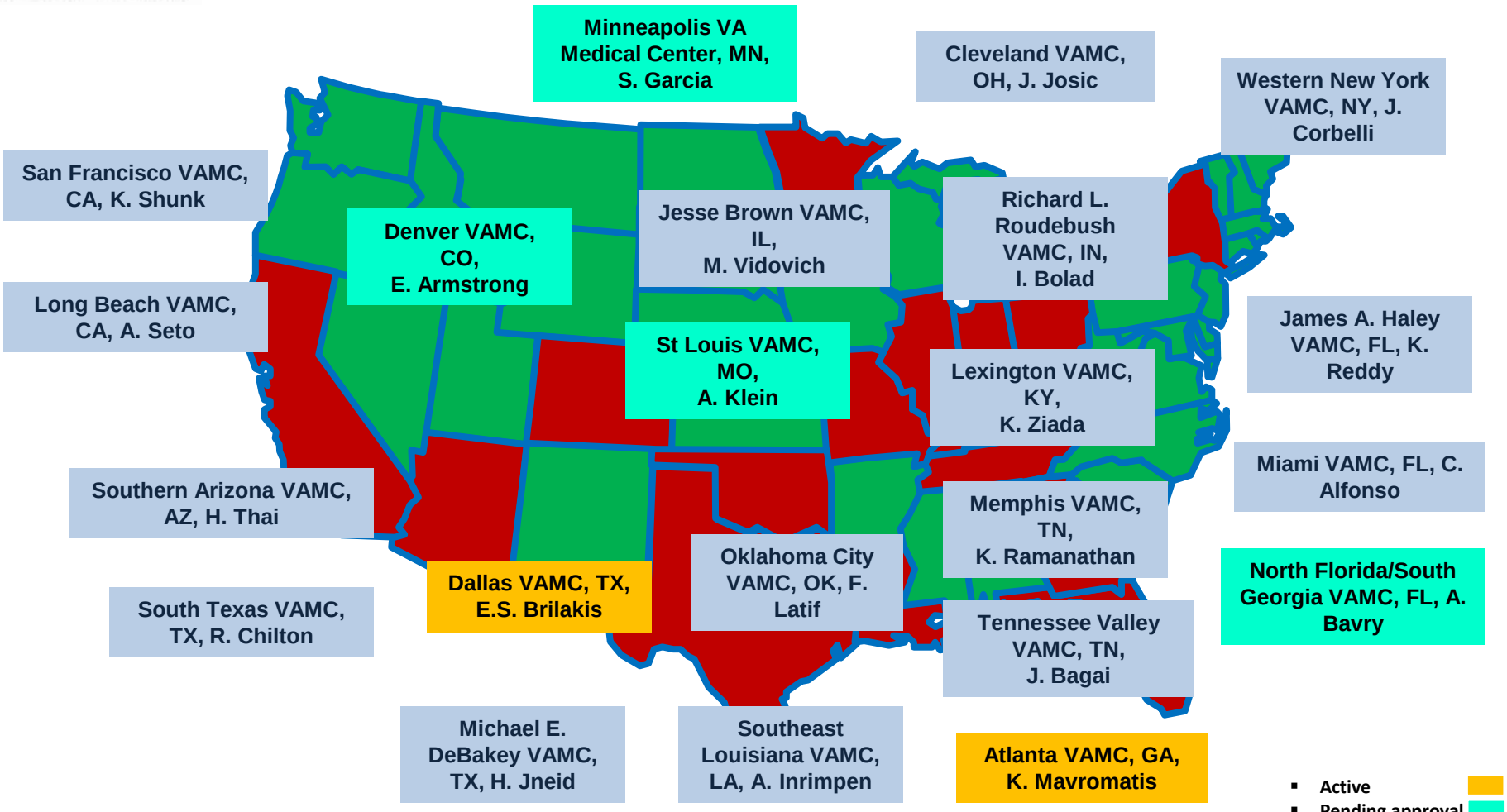
NIRS Clinical Trials



Lipid cORe plaque Association with CLinical Events: a Near-InfraRed Spectroscopy study

ORACLE-NIRS



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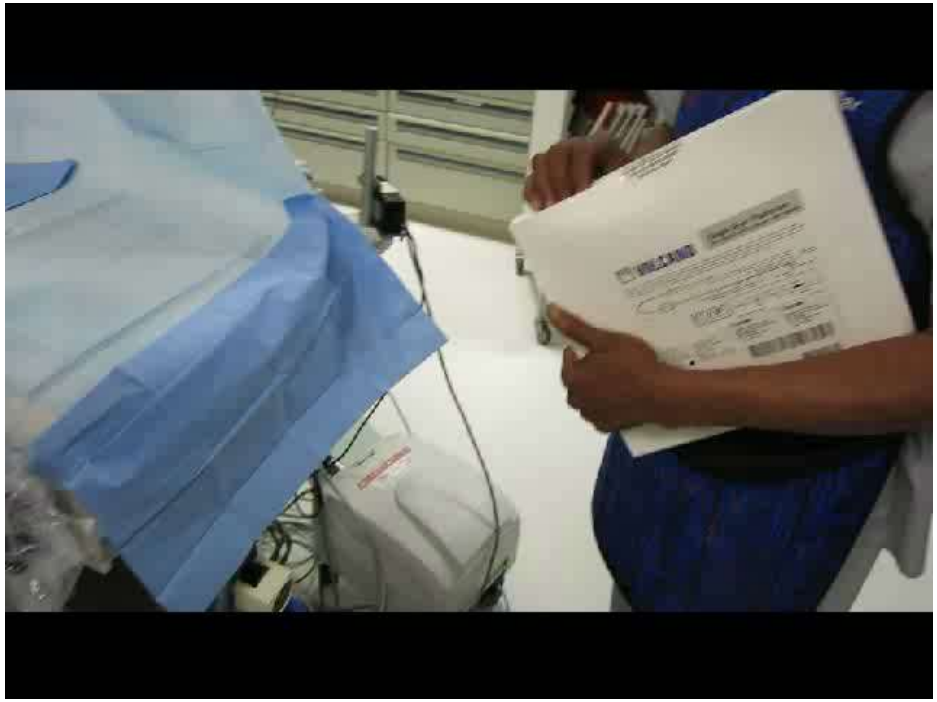
Preparation times

Loren Makke, RCIS

Solid state IVUS



27 seconds

OCT

129 seconds

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Putting it all together

	FFR	IVUS	OCT	NIRS
Lesion significance				
Hemodynamic lesion assessment	++	+	+	+
Plaque assessment				
Evaluate plaque composition	-	+	++	++
Determine culprit lesion in ACS	-	+	++	+
Pre-PCI				
Plan PCI	-	++	++	++
Determine distal embolization risk	-	+	++	++
Post-PCI				
Stent expansion	-	++	++	++
Stent malapposition	-	+	++	+
Thrombus – Dissection	-	+	++	+

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Palo Alto CSPCC
All 25 participating sites

2014 SCAI consensus document

	OCT	IVUS
Definitely beneficial		**Determine size of vessel Optimal stent deployment**
Probably beneficial	**Optimal stent deployment**	**LMCA assessment**
Possibly beneficial	**Plaque morphology**	**Plaque morphology**
No proven value/discouraged	**Non-LMCA lesion severity**	**Determine lesion significance**

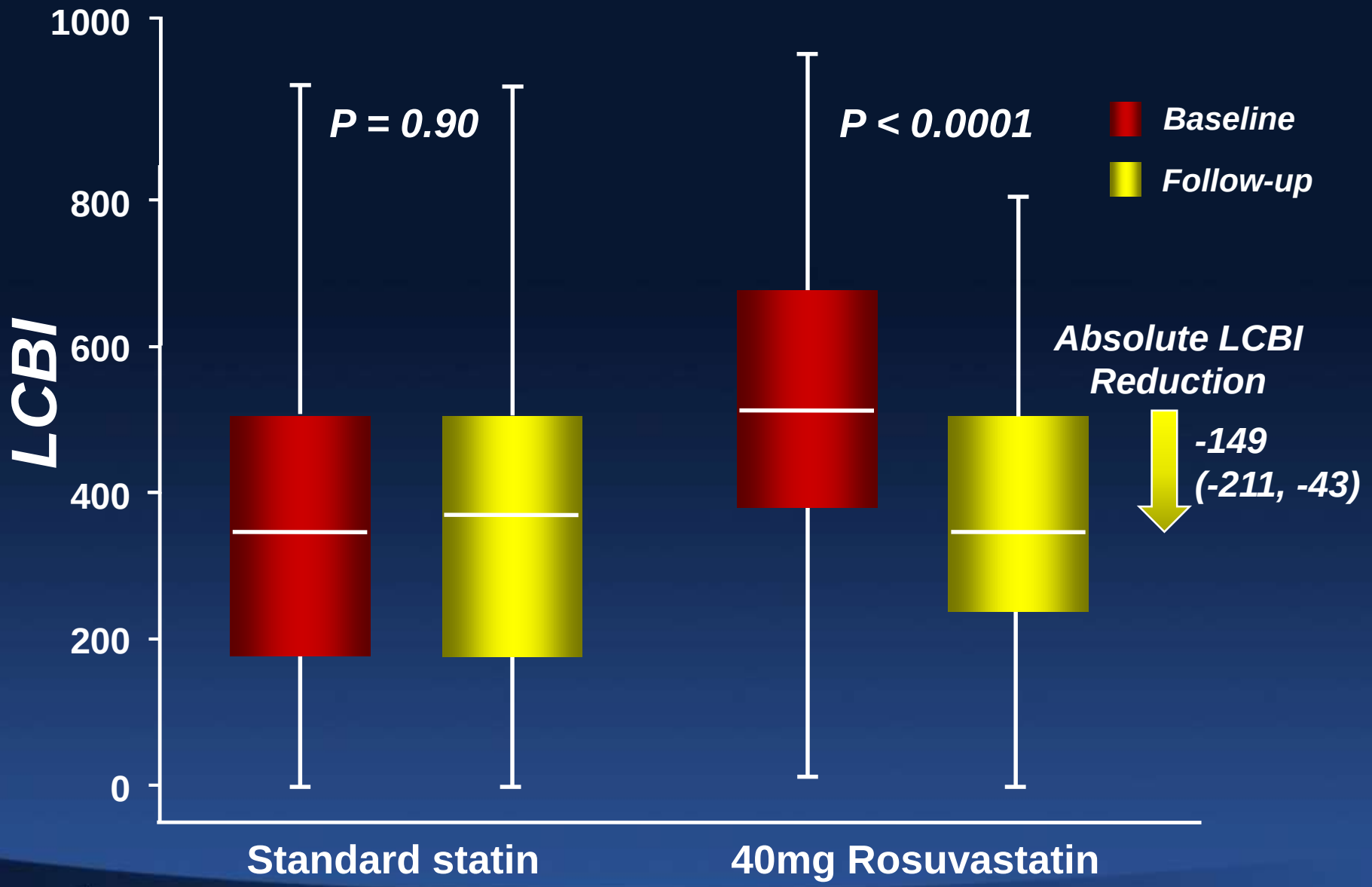
Lotfi A et al. Cath Cardiovasc Interv 2014;83:509-518

2011 ACC/AHA PCI Guidelines

	I	IIa	IIb	III
IVUS		1. Indeterminate LM 2. ISR mechanism 3. Allograph vasculopathy	1. Non-LM intermediate lesions 2. Guide stenting (esp. LM) 3. Stent thrombosis mechanism	1. No plan for revasc
OCT	-	-	-	-

Levine et al J Am Coll Cardiol 2011;58:e44-122

Yellow Trial – MaxLCBI$_{4mm}$

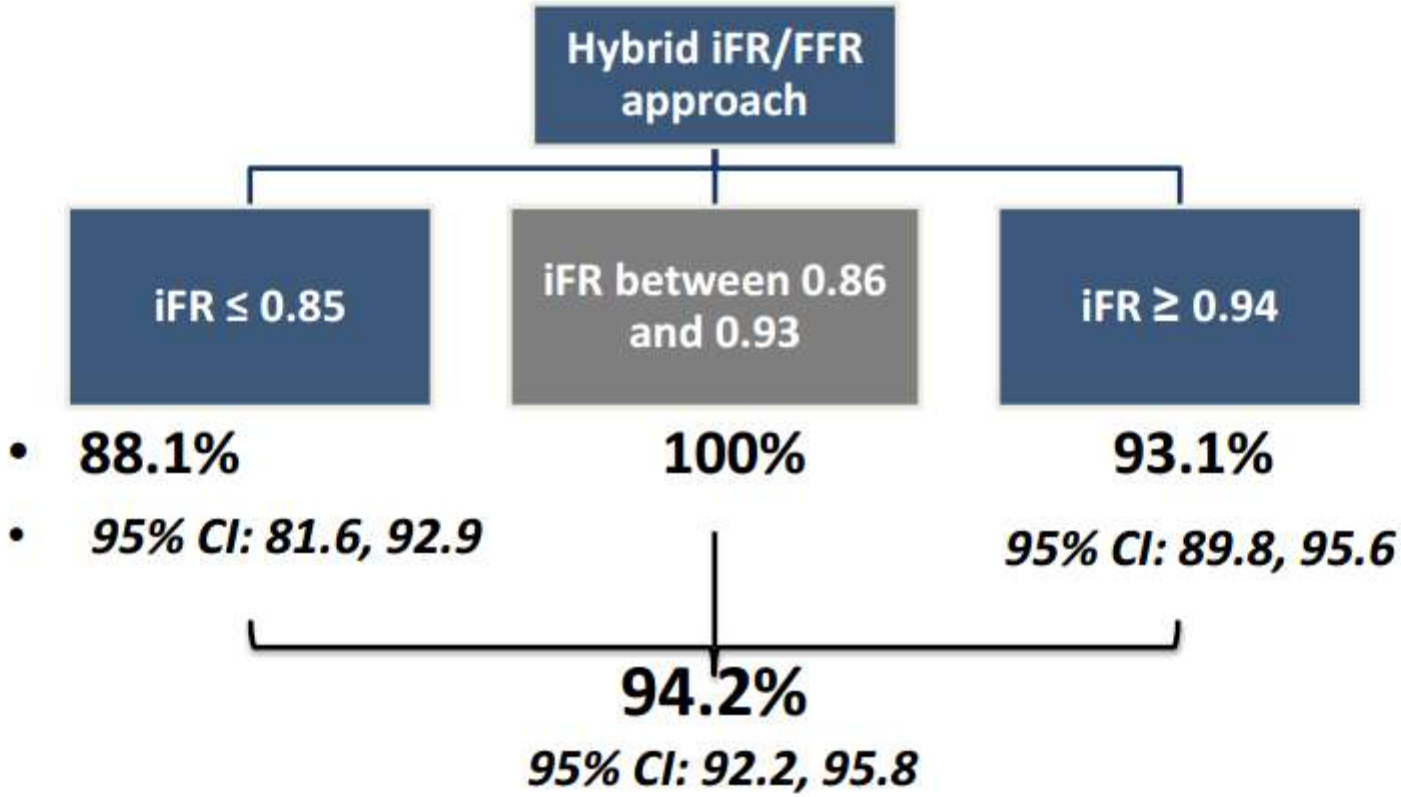


Kini et al. J Am Coll Cardiol 2013;62:21-9

Hybrid iFR/FFR approach

ADVISE II

The percentage of stenoses properly classified by using the hybrid iFR/FFR approach was **94.2%**.



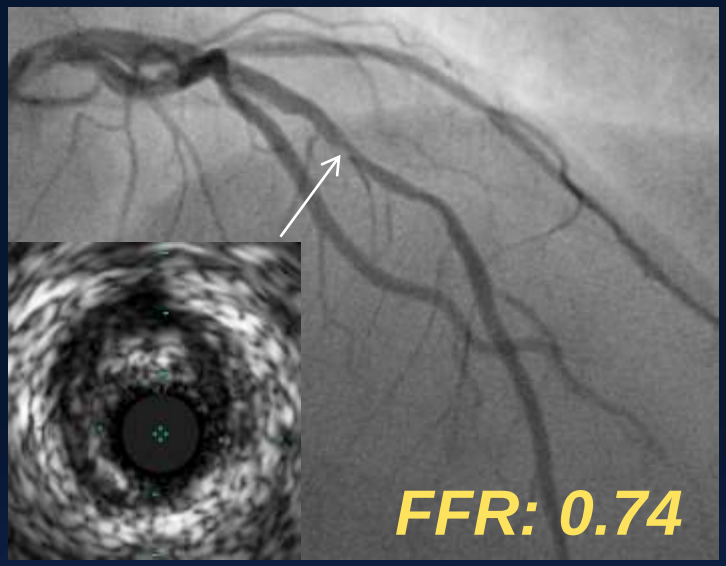
Sensitivity: 90.73%

Specificity: 96.15%

PPV: 92.98%

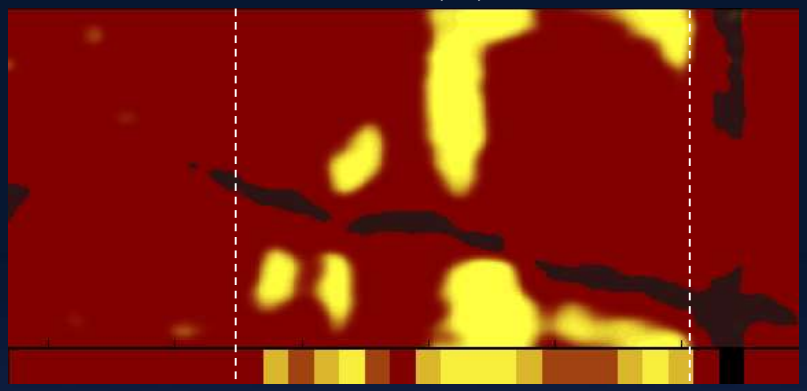
NPV: 94.87%

Baseline

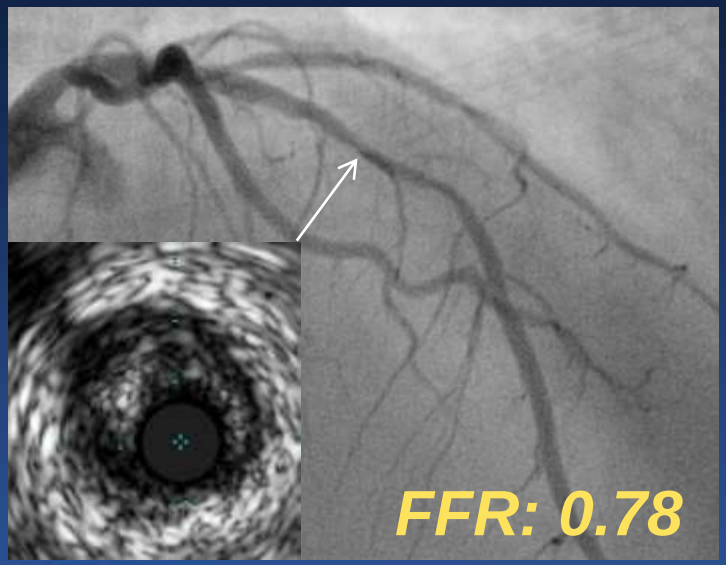


Plaque Area
5.6mm²

MaxLCBI$_{4mm}$: 802

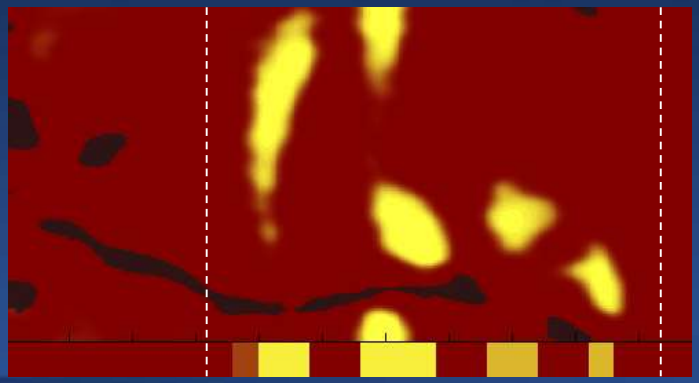


Follow-up



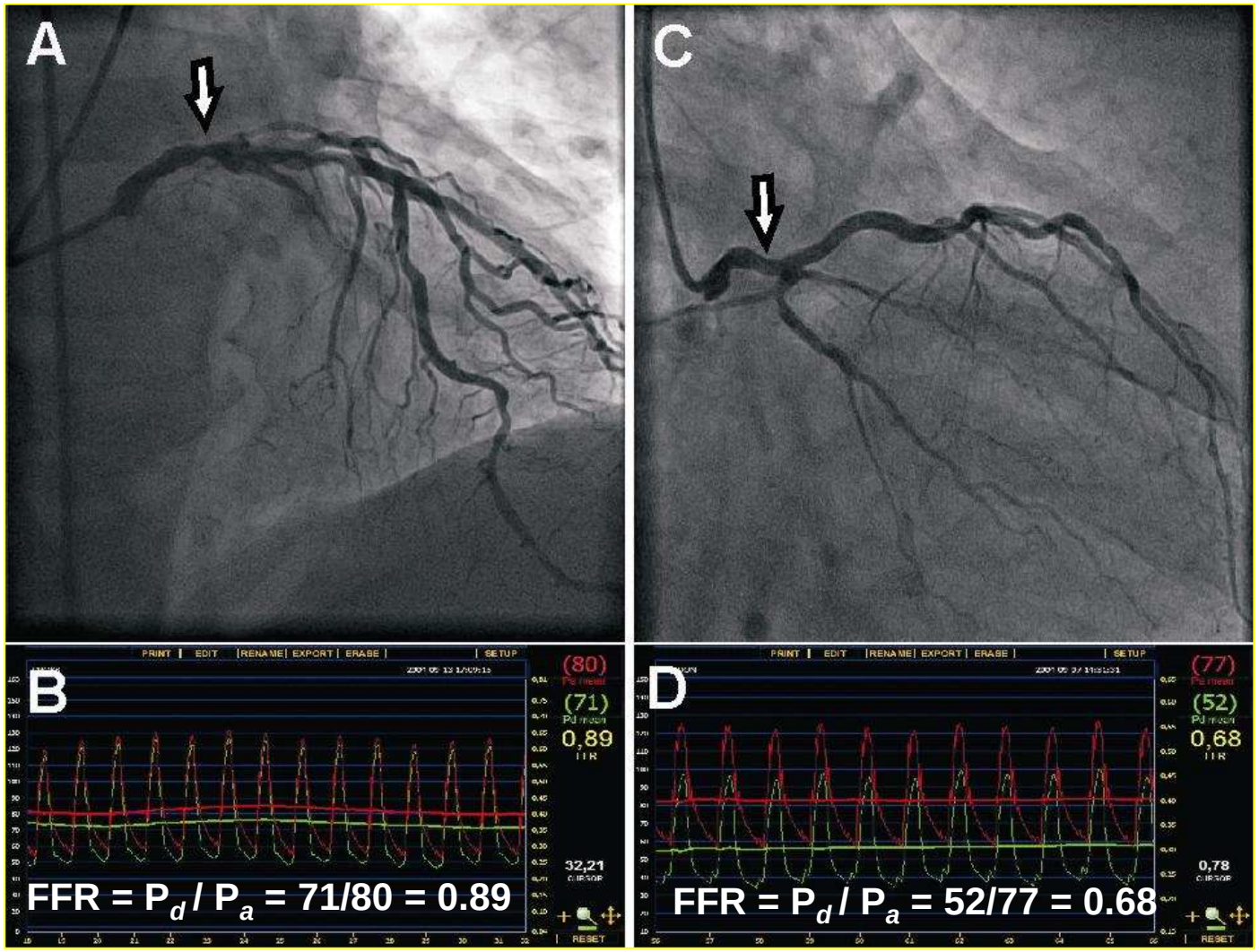
Plaque Area
5.5mm²

MaxLCBI$_{4mm}$: 474

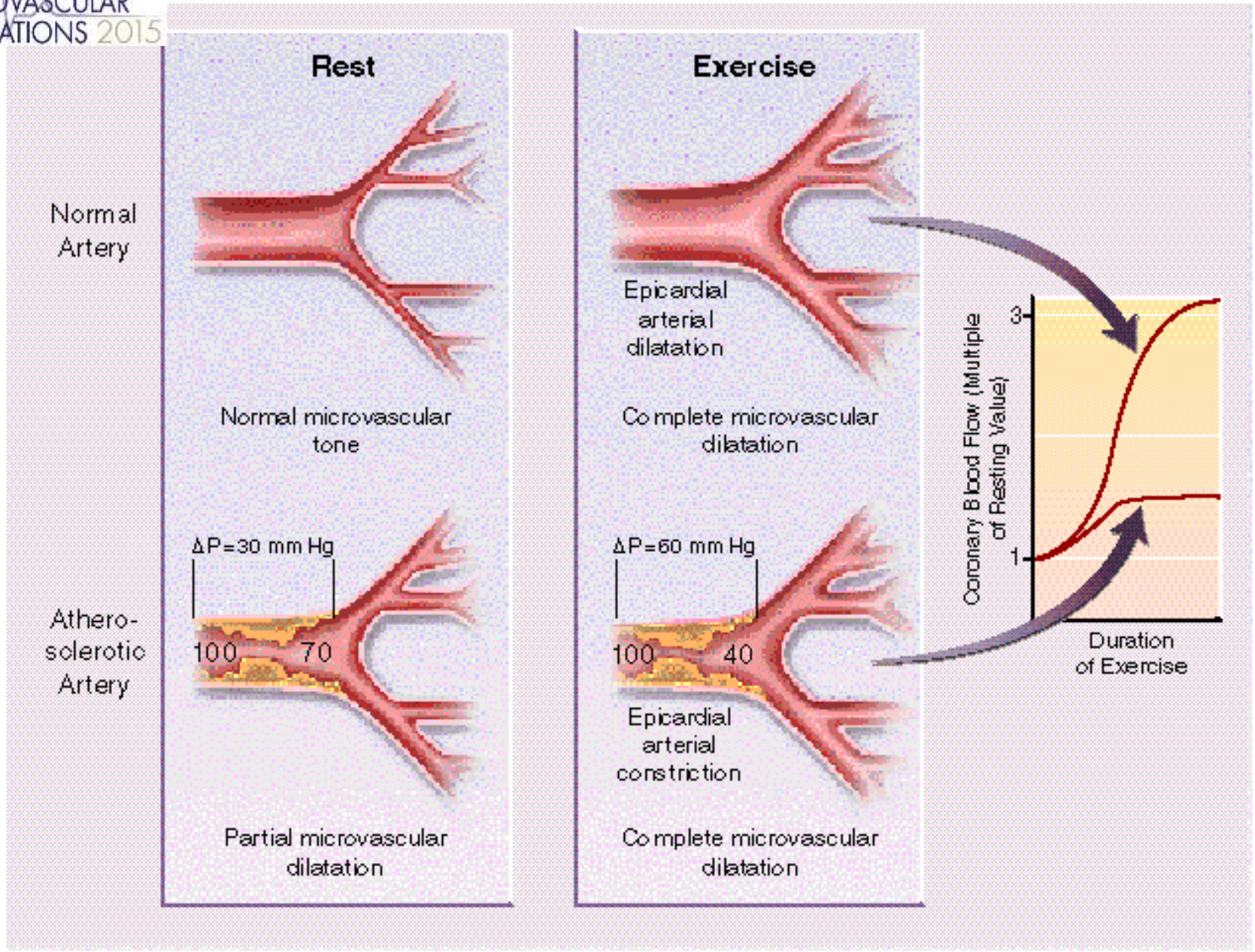


Kini et al. J Am Coll Cardiol 2013;62:21-9

The limitations of visual estimation



Hamilos et al. Circulation 2009


Rest
Exercise
Normal Artery
Normal microvascular tone
Epicardial arterial dilatation
Complete microvascular dilatation
Athero-sclerotic Artery
ΔP=30 mm Hg
100
70
Partial microvascular dilatation
ΔP=60 mm Hg
100
40
Epicardial arterial constriction
Complete microvascular dilatation
Coronary Blood Flow (Multiple of Resting Value)
3
1
Duration of Exercise

FAME study: Procedural Results (1)

	ANGIO-group N=496	FFR-group N=509	P-value
# indicated lesions per patient	2.7 ± 0.9	2.8 ± 1.0	**0.34**
FFR results			
Lesions succesfully measured, No (%)	-	1329 (98%)	-
Lesions with FFR ≤ 0.80 ,No (%)	-	874 (63%)	-
Lesions with FFR > 0.80 ,No (%)	-	513 (37%)	-
stents per patient	2.7 ± 1.2	1.9 ± 1.3	**<0.001**
Lesions succesfully stented (%)	92%	94%	-
DES, total, No	1359	980	-

Tonino: NEJM 2009

SOUTHWESTERN

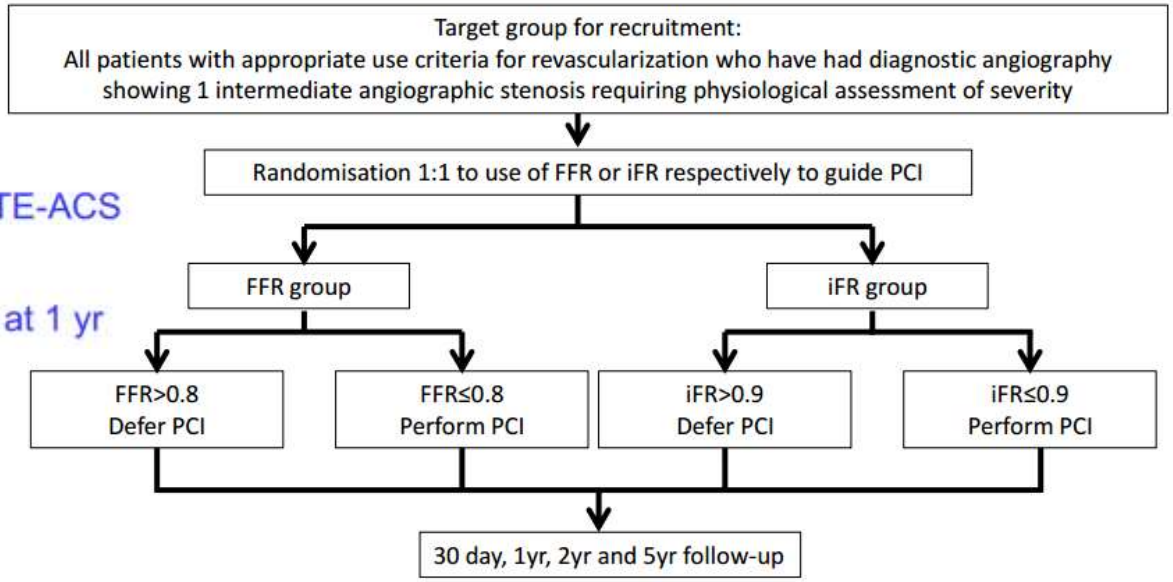
DEFINE FLAIR: Study characteristics

iFR Swedeheart NCT02166736

Registry-based RCT; n=2000, stable / NSTE-ACS

Superiority design

Primary EP = All-cause death, MI, revasc, at 1 yr



Inclusion criteria:

- Single intermediate lesion requiring physiological assessment of severity
- In the case of ACS the lesion must be an intermediate non-culprit lesion

FAME 2 - Fractional Flow Reserve versus Angiography for Multivessel Evaluation 2

Stable CAD patients scheduled for 1, 2 or 3 vessel DES-PCI
N = 1220

Exclusions:
1. Prior CABG
2. LVEF < 30%
3. LM disease

FFR in all target lesions

Randomized Trial

At least 1 stenosis with FFR ≤ 0.80 (n=888)

Randomization 1:1

PCI + MT

MT

73%

Registry

When all FFR > 0.80 (n=332)

MT

27%

50% randomly assigned to FU

Follow-up after 1, 6 months, 1, 2, 3, 4, and 5 years

De Bruyne et al. N Engl J Med 2012; 367:991-1001

FAME study: Procedural Results (2)

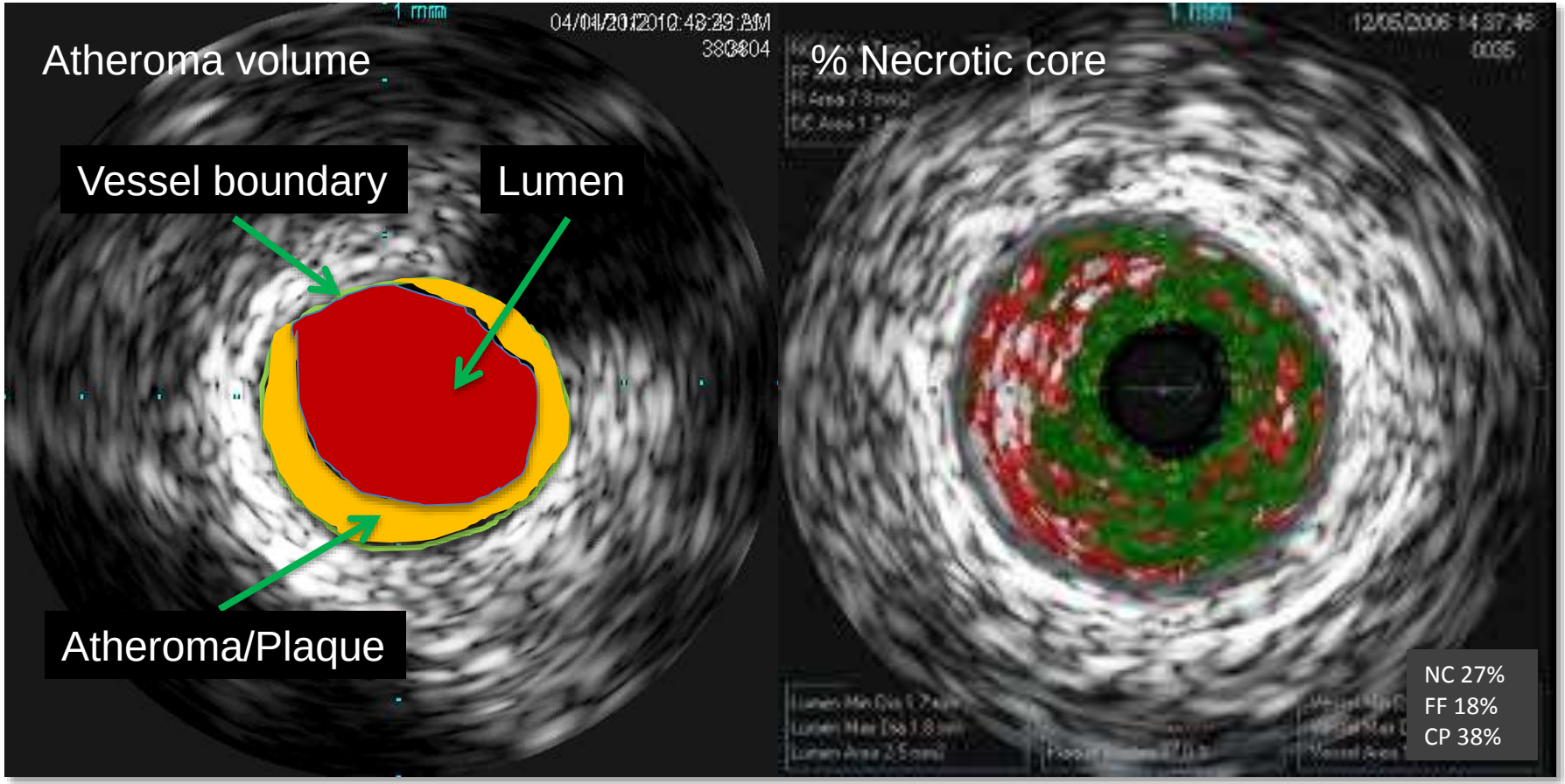
	ANGIO-group N=496	FFR-group N=509	P-value
Procedure time (min)	70 ± 44	71 ± 43	0.51
Contrast agent used (ml)	302 ± 127	272 ± 133	<0.001
Materials used at procedure (US $)	6007	5332	<0.001
Length of hospital stay (days)	3.7 ± 3.5	3.4 ± 3.3	0.05

Tonino: NEJM 2009

Fractional Flow Reserve

FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful in guiding revascularization decisions in patients with SIHD.

PREMIER Trial: IVUS Analysis



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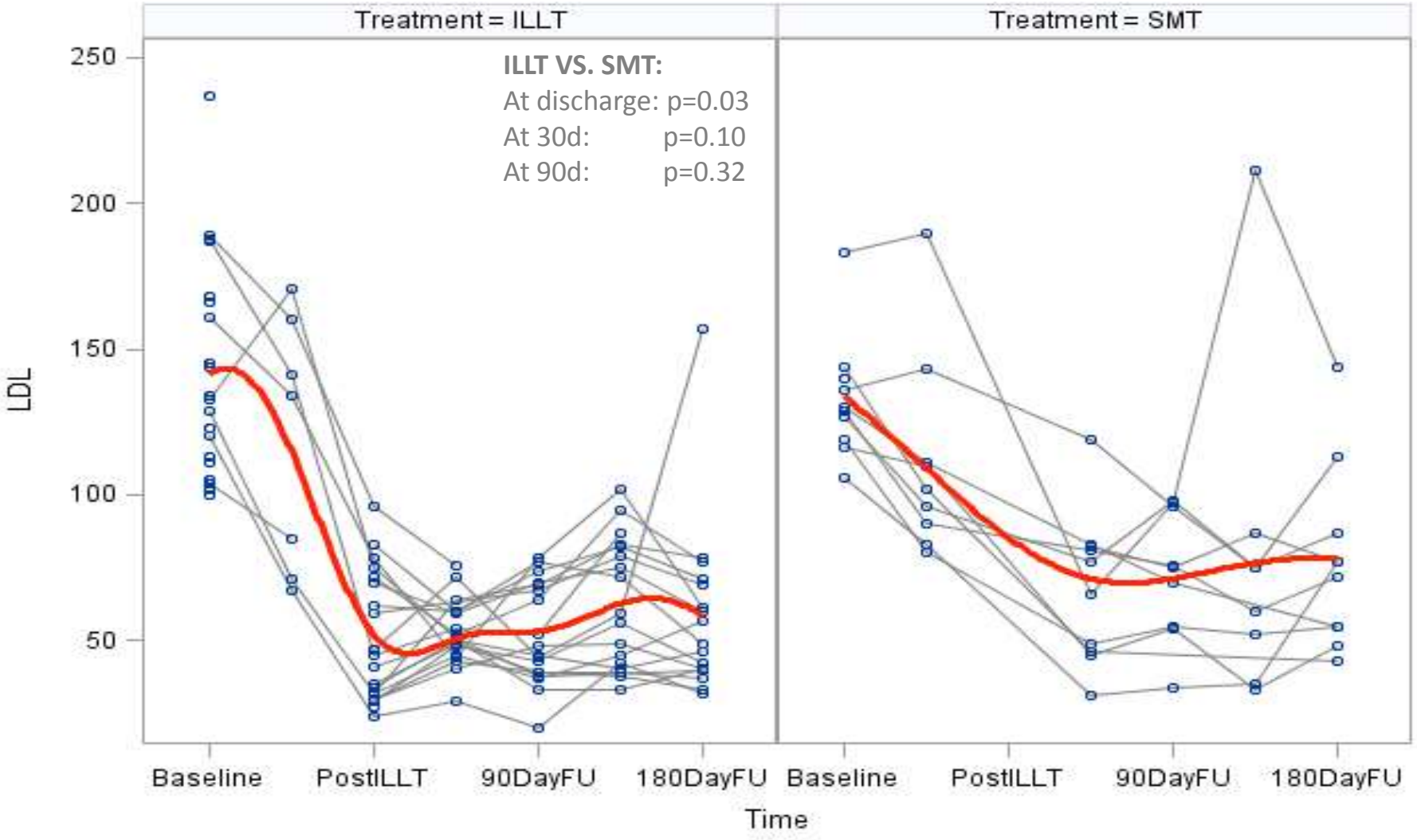
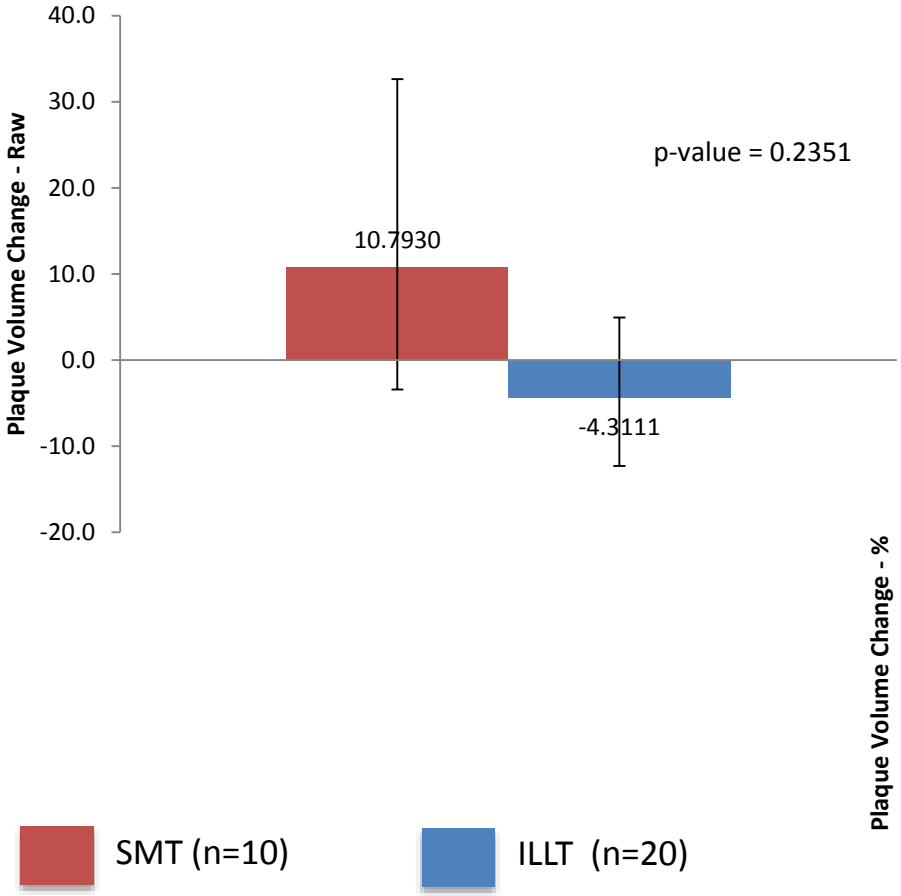
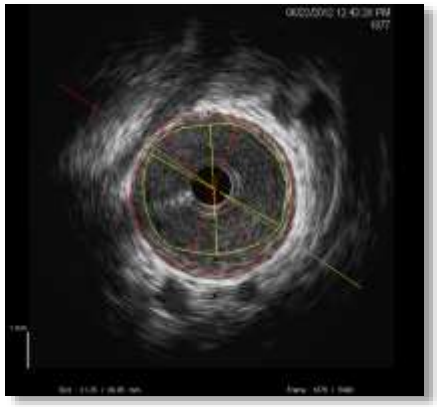
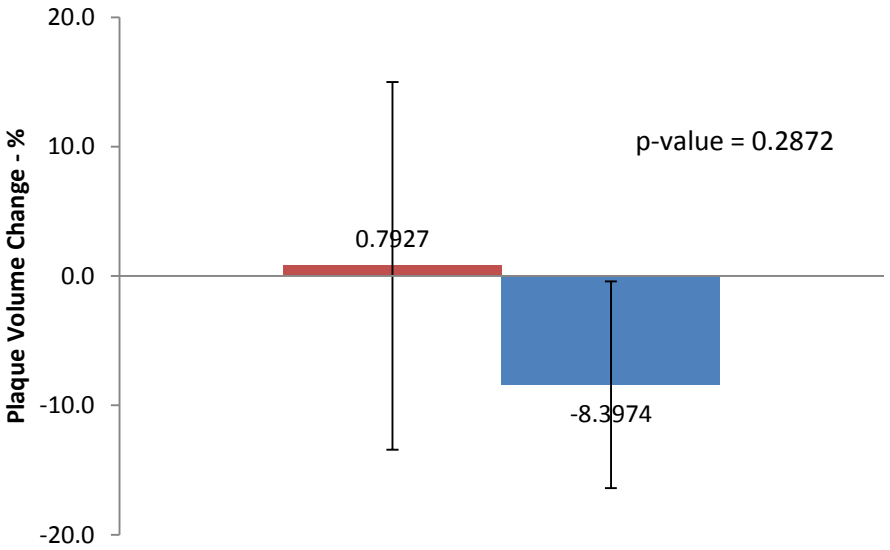
Phase 1 PREMIER Results: LDL



Phase 1 PREMIER Results: IVUS Assessment of Change in Atheroma Volume







LMCA

MLA = 6 mm²

Prospective Application of Pre-Defined Intravascular Ultrasound Criteria for Assessment of Intermediate Left Main Coronary Artery Lesions

Results From the Multicenter LITRO Study

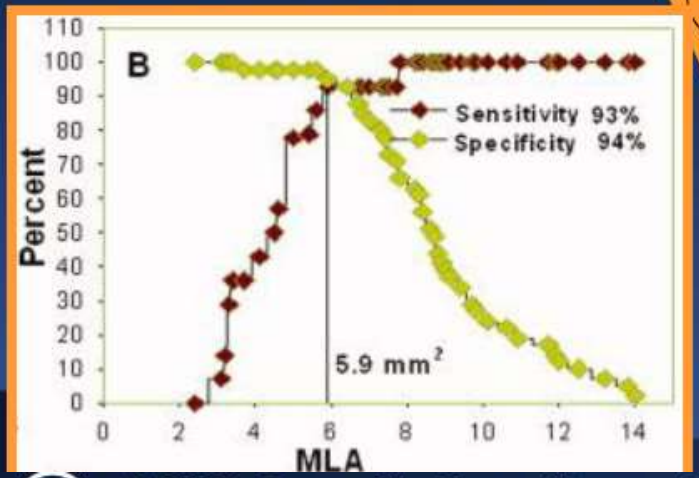
De la Torre Hernandez, et al. J Am Coll Cardiol 2011; 58:351-8

Proximal LAD

MLA = 3 mm²

Proximal LCx

MLA = 3 mm²



Linear law (epicardial coronary artery)
Do = 0.678*(D1+D2)

Finet G et al.
Eurointervention 2007;3:10-17

Relation Between FFR and OCT and IVUS Measurements

61 stenoses

Best OCT MLA cutoff:

1.95 mm²

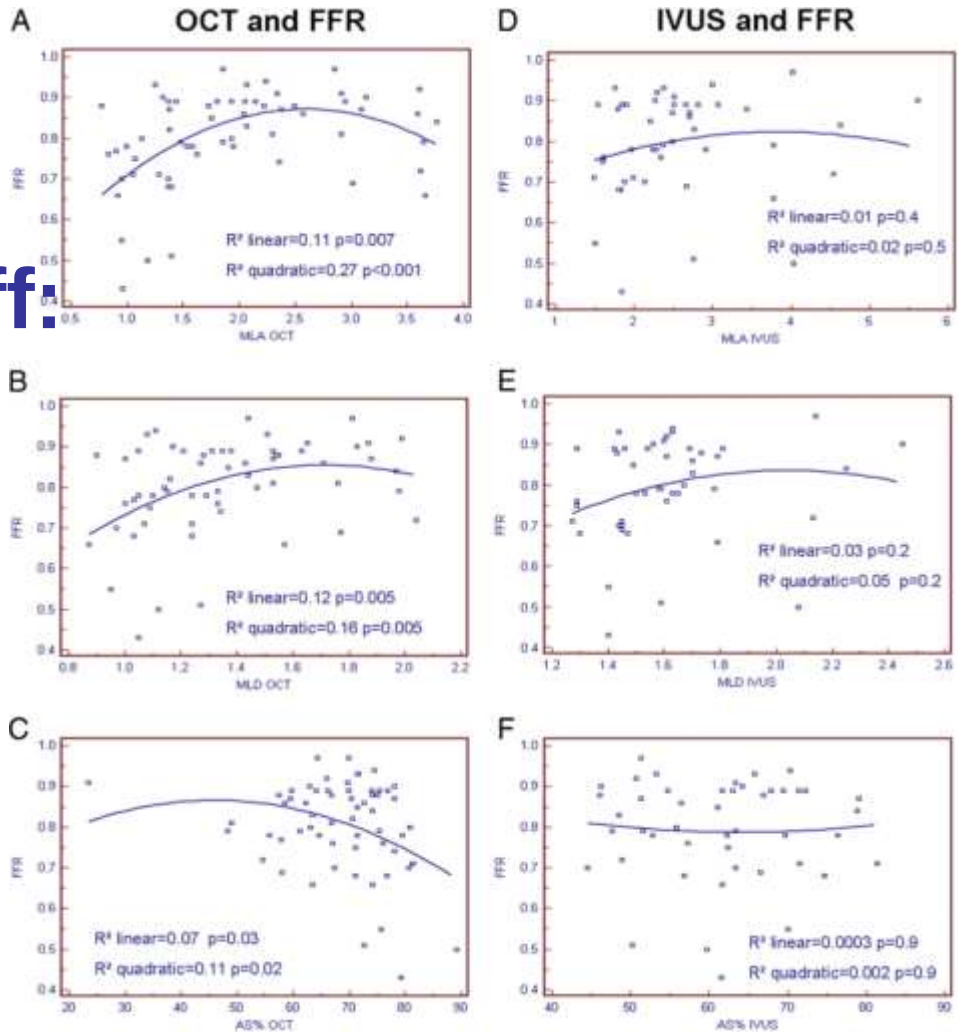
Sensitivity: 82%

Specificity: 63%

PPV: 66%

NPV: 80%

Accuracy: 72%



IVUS:11-22% larger than OCT

IVUS cutoff: 2.36 mm²

5 of 26 patients with MLA >1.95 mm² had an FFR ≤80; all of them in LAD

Gonzalo, N. et al. J Am Coll Cardiol 2012;59:1080-1089

Angiography alone versus angiography plus optical coherence tomography to guide decision-making during percutaneous coronary intervention: the Centro per la Lotta contro l'Infarto-Optimisation of Percutaneous Coronary Intervention (CLI-OPCI) study

Francesco Prati[1,2]*, MD; Luca Di Vito[2], MD, PhD; Giuseppe Biondi-Zoccai[2,3], MD; Michele Occhipinti[2,4], MD; Alessio La Manna[4], MD; Corrado Tamburino[4], MD; Francesco Burzotta[5], MD, PhD; Carlo Trani[5], MD; Italo Porto[5], MD; Vito Ramazzotti[1], MD; Fabrizio Imola[1], MD; Alessandro Manzoli[1], MD; Laura Materia[2], PharmD; Alberto Cremonesi[6], MD; Mario Albertucci[2], MD

1. Department of Interventional Cardiology, San Giovanni-Addolorata Hospital, Rome, Italy; 2. Centro per la Lotta contro l'Infarto - Fondazione Onlus, Rome, Italy; 3. Department of Medico-Surgical Sciences and Biotechnologies, Sapienza University of Rome, Latina, Italy; 4. Division of Cardiology, University of Catania, Catania, Italy; 5. Institute of Cardiology, Catholic University, Rome, Italy; 6. GVM Care and Research, E.S. Health Science Foundation, Cotignola, Italy

EuroIntervention 2012;8:823-829 published online ahead of print October 2012

PCI n=670

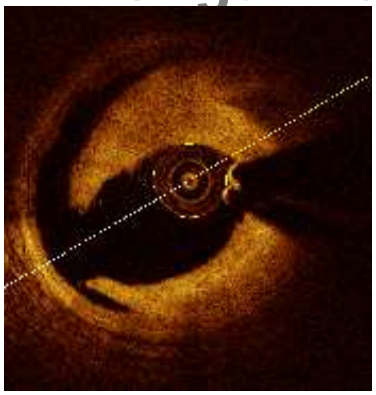
Angio-guided (n=335)

OCT-guided (n=335)

1-year follow up for MACE

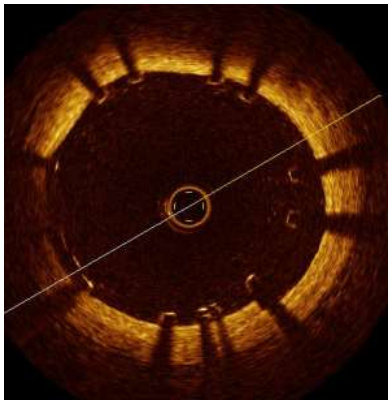
Edge dissection (14.2%)

- >200 µm
- length >600 µm



Stent malapposition (29.7%)

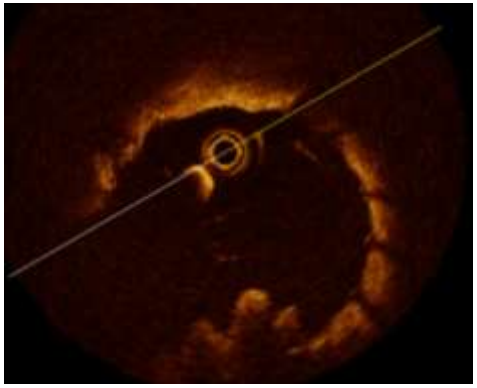
- >200 µm
- length >600 µm



Additional intervention: 34.7%

Thrombus (22%)

- >200 µm
- length >600 µm



Stent under-expansion (11.4%)

MLA ≥90% of the average reference lumen area or ≥100% of lumen area of the reference segment with the lowest lumen area

Prati et al. Eurointervention 2012

4. OCT advantages over IVUS

1. **More deliverable (lower profile)**
    - **Especially in areas of tortuosity**

2. **Faster**
    - **Less time to acquire images**
    - **Faster browsing**
    - **Faster automated measurements**

3. **Easier to interpret**

IVUS preferred for:

- **CTO lesion crossing**
- **Ostial lesions**
- **Longitudinal plaque progression/regression studies**

For everything else….
OCT

Intravascular Imaging and Physiology Why?

1. **Improve procedure flow and outcomes**
   a) **Determine lesion severity**
   b) **Determine culprit lesion**
   c) **Optimize stent sizing**
   d) **Optimize PCI result**
   e) **Assist with complication management**

2. **Safe and easy to use**

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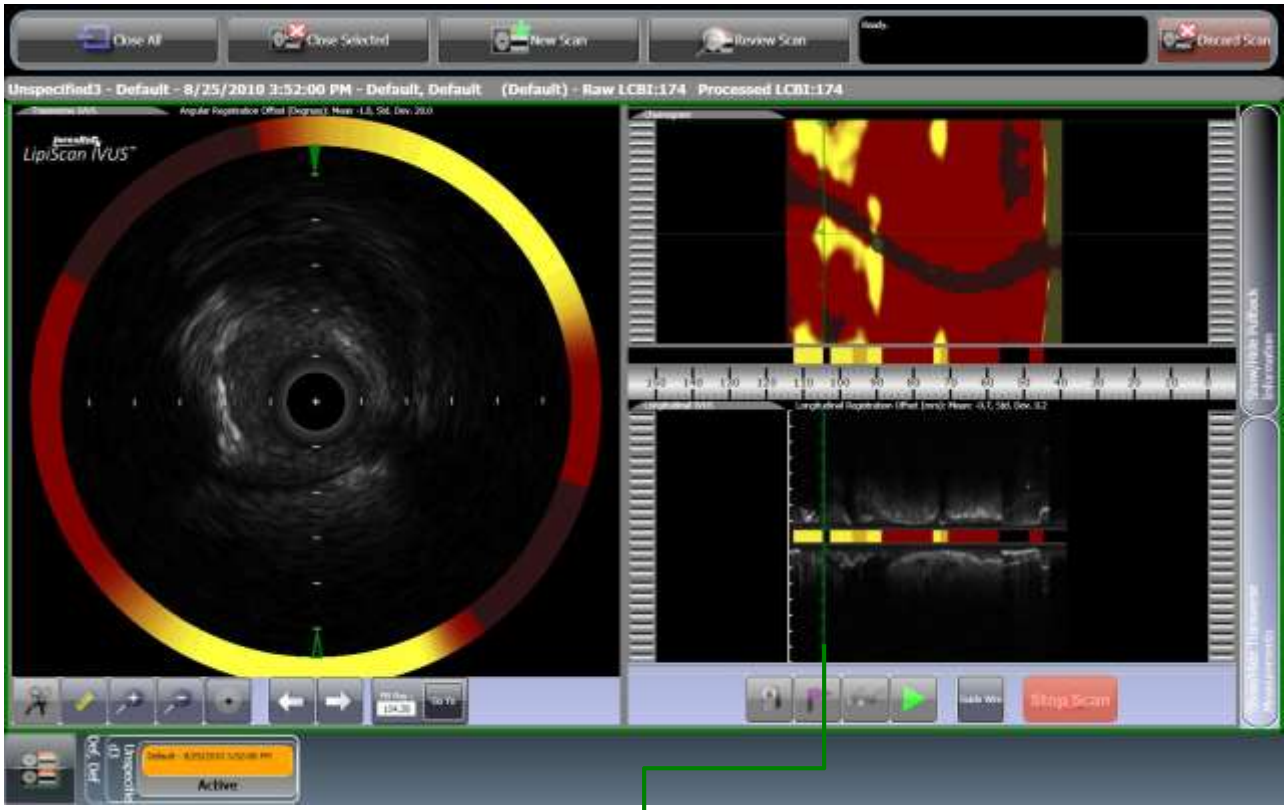
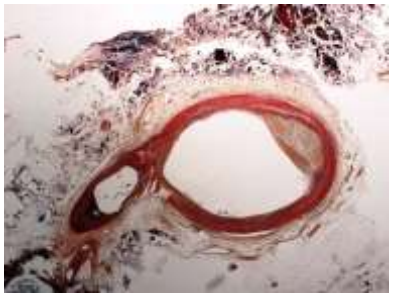
NIRS IVUS





108mm

104mm

102mm