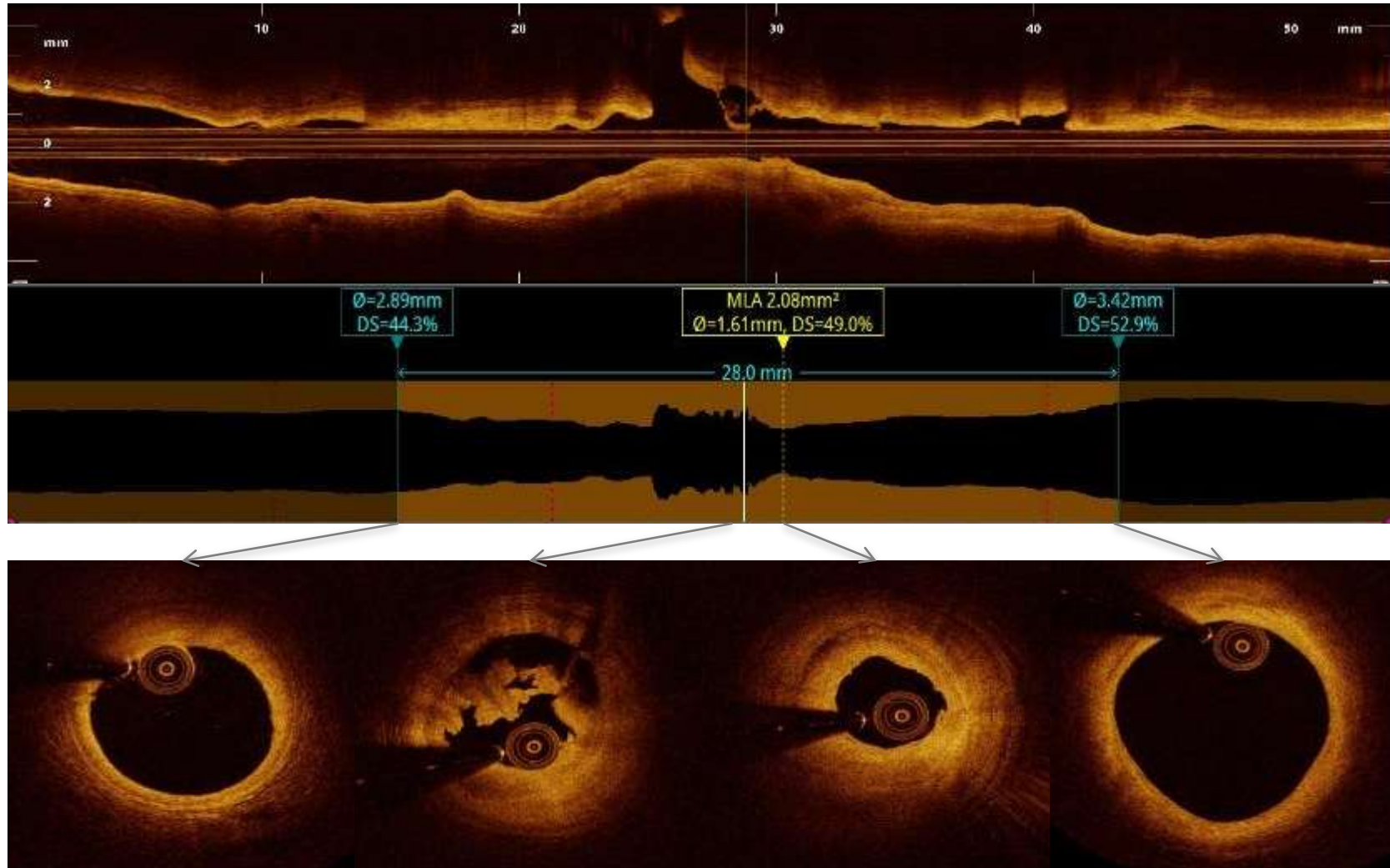


OCT Procedure Guidance in the CathLab Today and Tomorrow

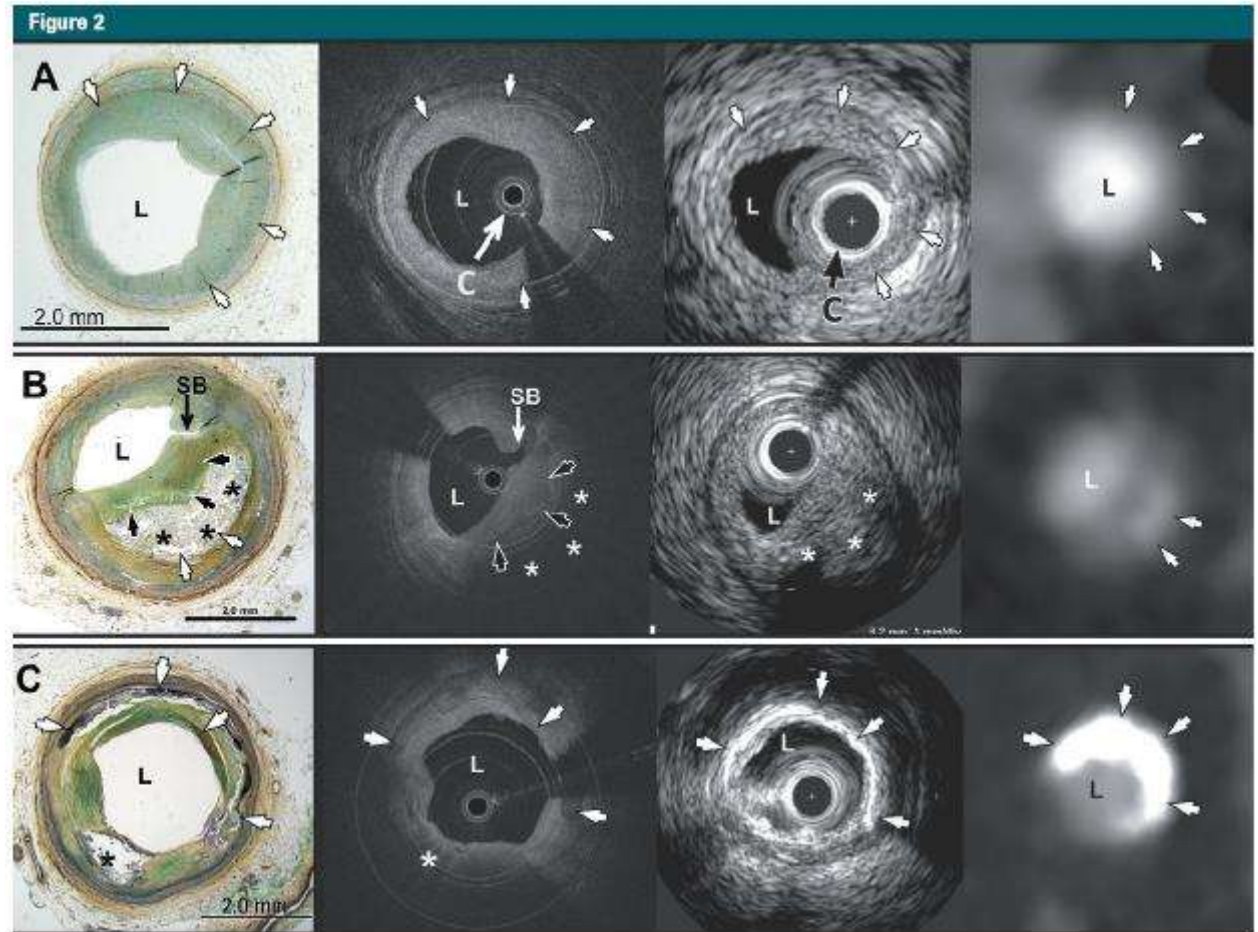
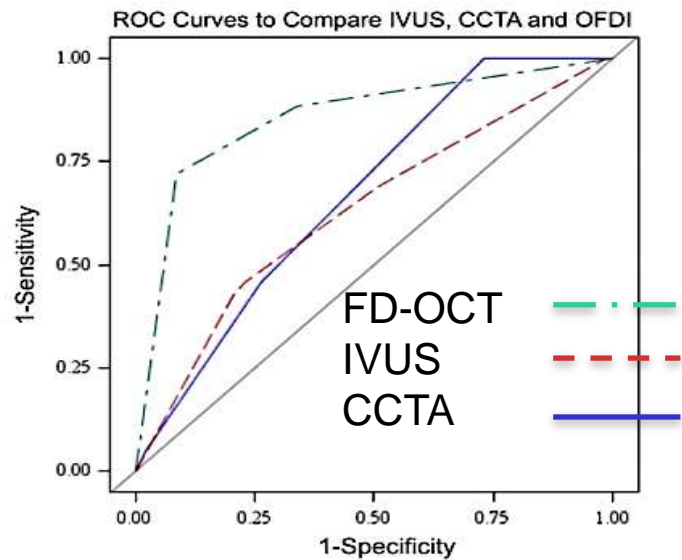


Differentiation of Early from Advanced Coronary Atherosclerotic Lesions

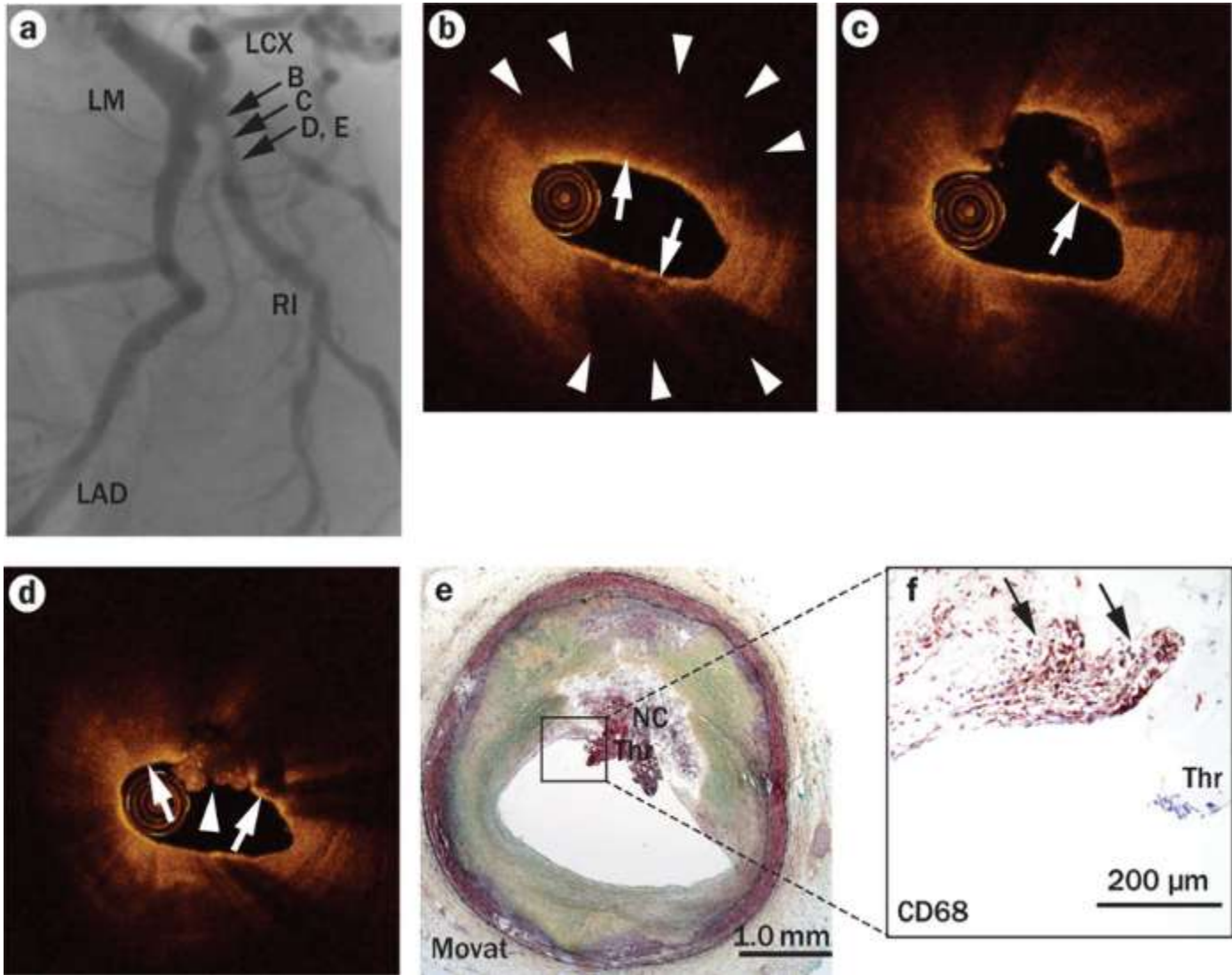
Ex-vivo Comparison of CT, IVUS and OCT

Implications for Patient Care:

The diagnostic performance of OCT for differentiating early from advanced coronary atherosclerotic lesions is significantly better.

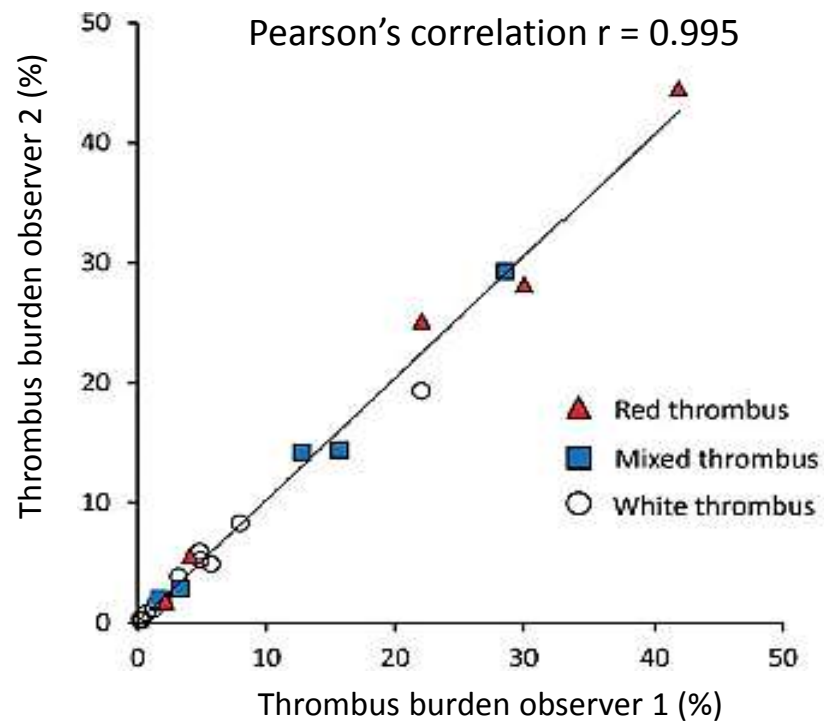
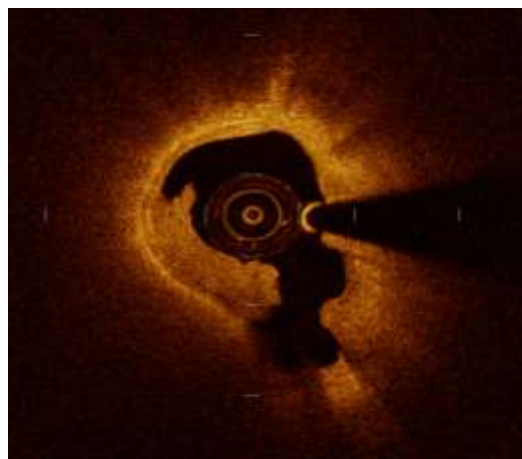
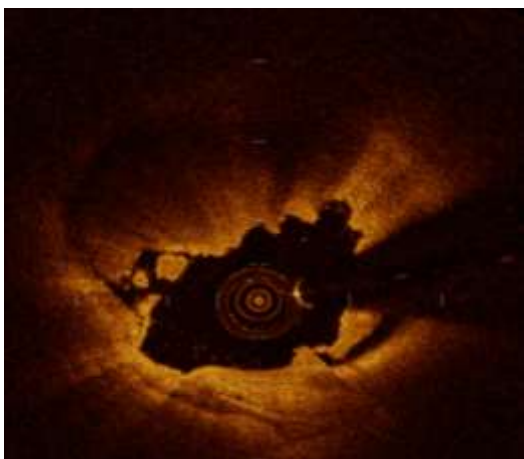


Pathologically Distinct Types of Advanced Coronary Plaques



Feasibility and repeatability of optical coherence tomography measurements of pre-stent thrombus burden in patients with STEMI treated with primary PCI

Olli A. Kajander^{1*}, Laura S. Koistinen¹, Markku Eskola¹, Heini Huhtala²,
Ravinay Bhindi³, Kari Niemelä¹, Sanjit S. Jolly⁴, and Tej Sheth⁴, for the TOTAL-OCT
Substudy Investigators[†]



$r = 0.993$ for red thrombi $r = 0.993$ for white thrombi $r = 0.997$ for mixed thrombi

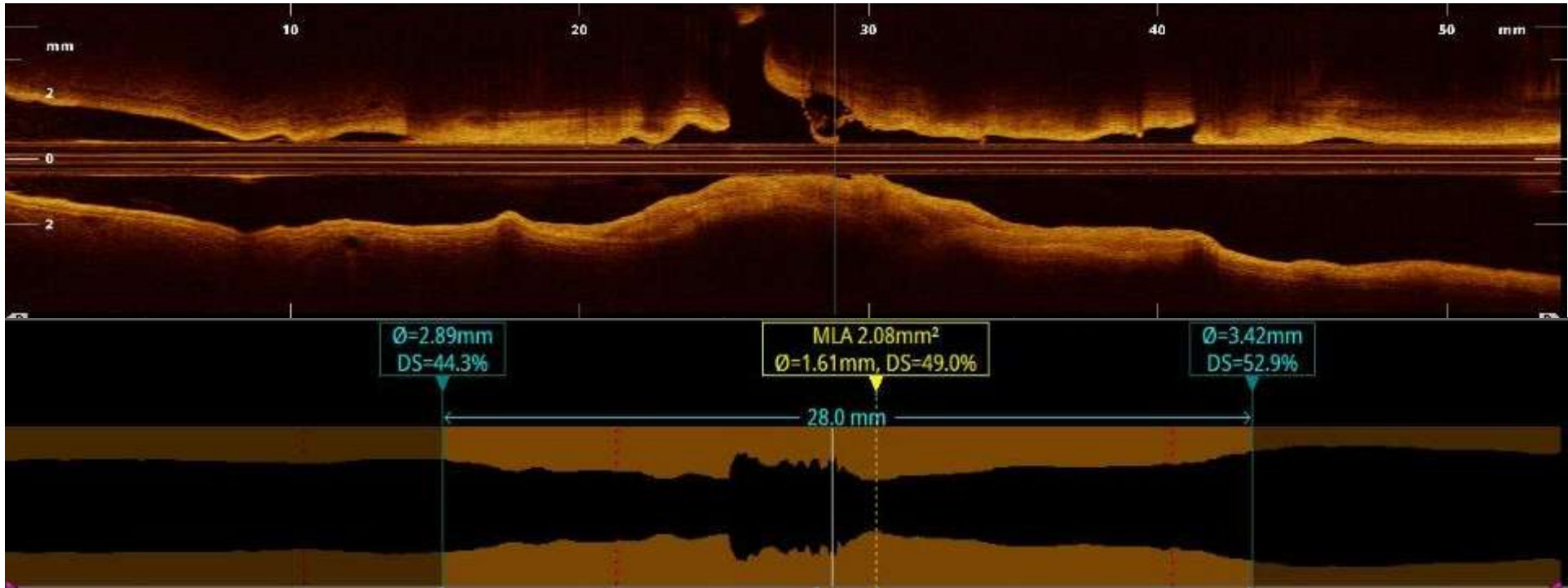
2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

TABLE I. 2011 PCI Guideline Recommendations

5.4.3 Optical Coherence Tomography

The appropriate role for OCT in routine clinical-decision making has not been established

STEMI culprit vessel: 75 mm in 2 sec, prompt automatic lumen measures





Reproducibility for Lumen Area and

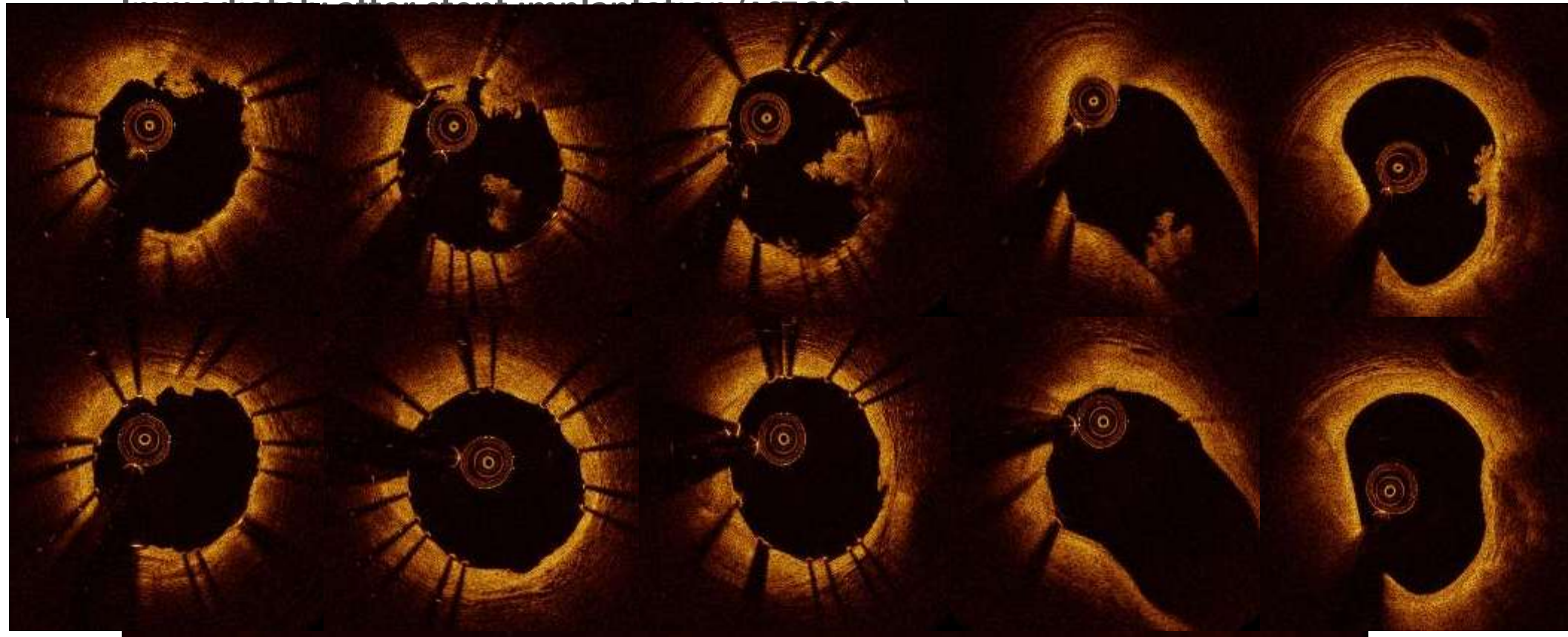
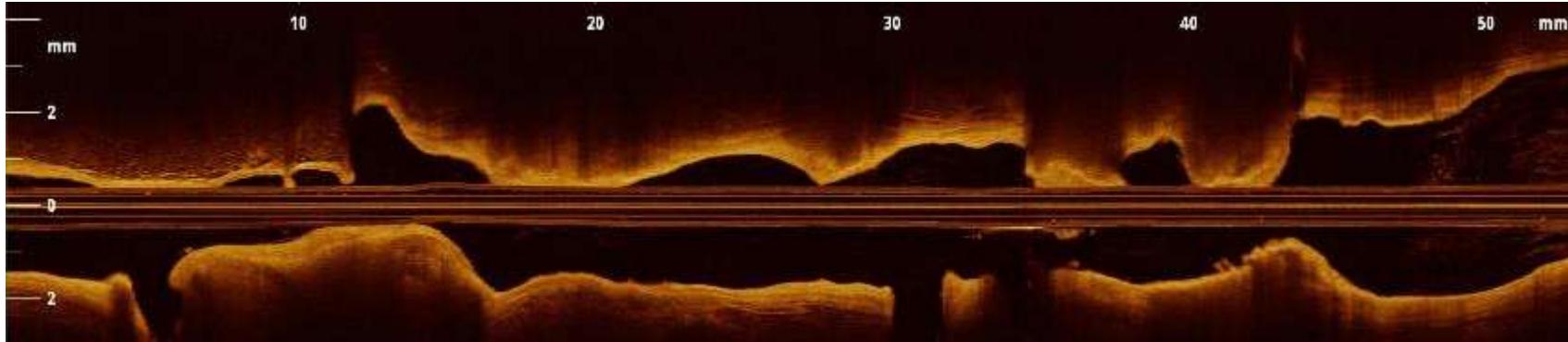
Length Measurements

Fedele S *et al.* Am J Cardiol 2012, 110(8): 1106-12

Variable	Bland-Altman Bias	Regression Analysis (R Value, P Value)
Lumen Area (mm²)		
<i>Per-segment analysis</i>		
Interobserver	0.001(-0.012,0.009)	1.0, <0.001
Intraobserver	0.003 (-0.002,0.009)	1.0, <0.001
Interpullback	0.150 (-0,371,0.086)	0.982, <0.001
<i>Per-frame analysis</i>		
Interobserver	0.001 (-0.001,0.002)	1.0 <0.001
Intraobserver	0.002 (0.001,0.003)	1.0 <0.001
Interpullback	-0.091 (-0.139, -0.040)	0.959, <0.001
Length (mm)		
Per-segment analysis		
Interpullback	-0,200 (-3.00,2.00)	0.990, <0.001

High sensitivity to thrombus formation

Baseline

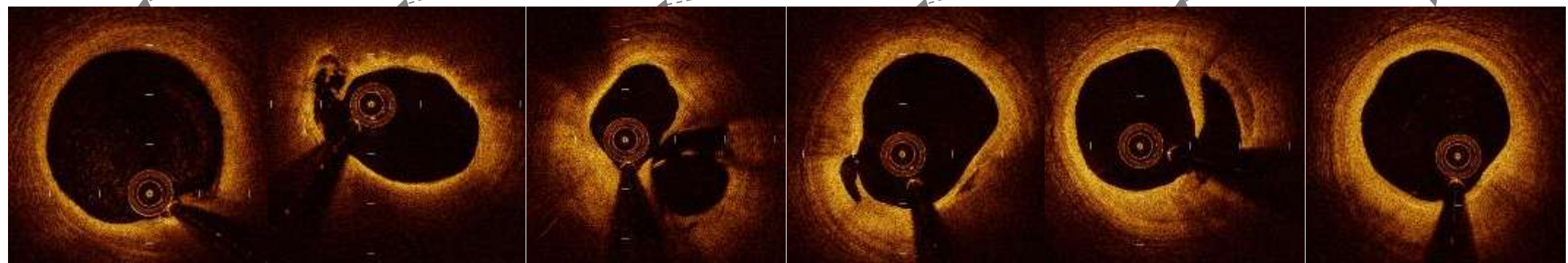
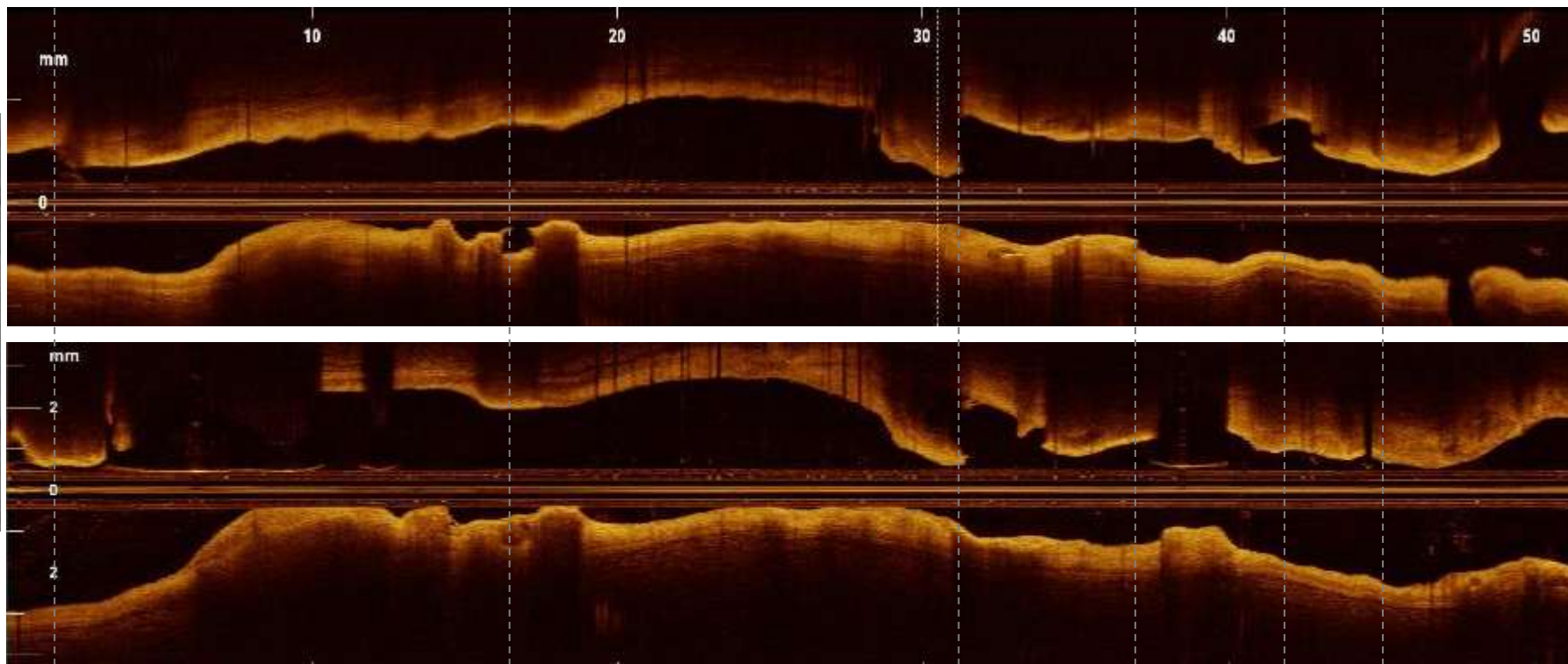


2014 SCAI Expert Consensus Statement on the Use of Fractional Flow Reserve, Intravascular Ultrasound and OCT

Recommendations for Optical Coherence Tomography

- Probably Beneficial. Determination of optimal stent deployment (sizing, apposition, and lack of edge dissection), with improved resolution compared with IVUS.
- Possibly Beneficial. OCT can be useful for the assessment of plaque morphology.
- No Proven Value/Should be Discouraged. OCT should not be performed to determine stenosis functional significance.

Possible beneficial: not only lesion severity but plaque types



Integrated Angio-OCT Co-Registration

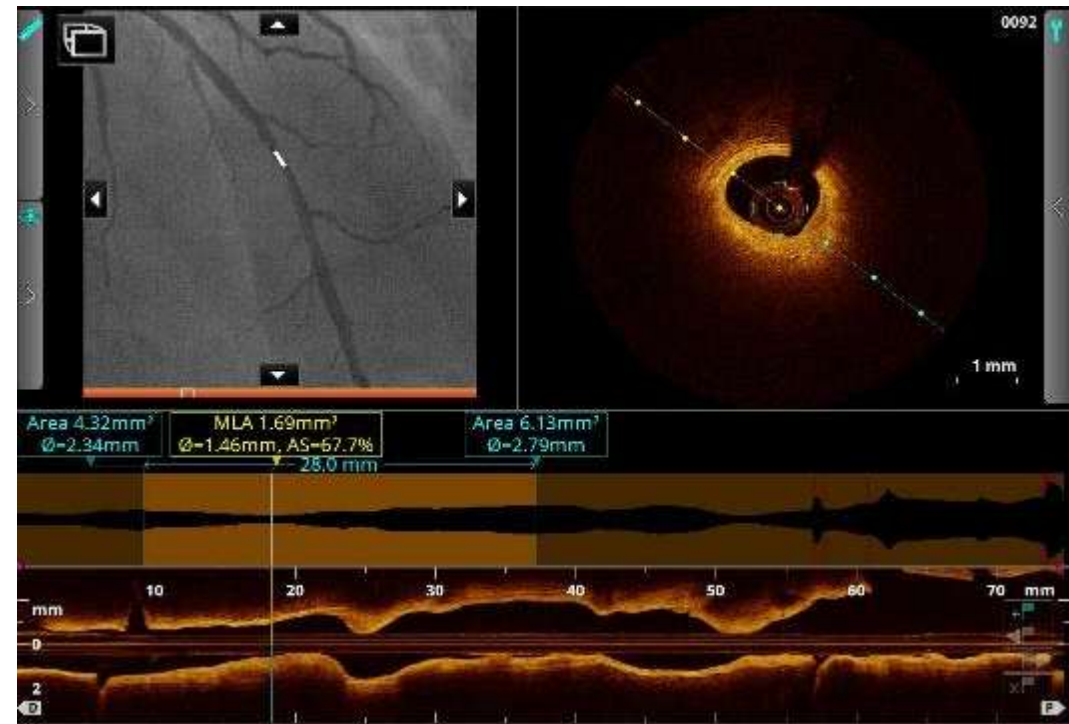


Basic rules

Angio Co-Registration (ACR) works by tracking the radiopaque (RO) lens marker on the Dragonfly™ OPTIS™ or Dragonfly™ DUO catheter on a cine acquired during an OCT pullback.

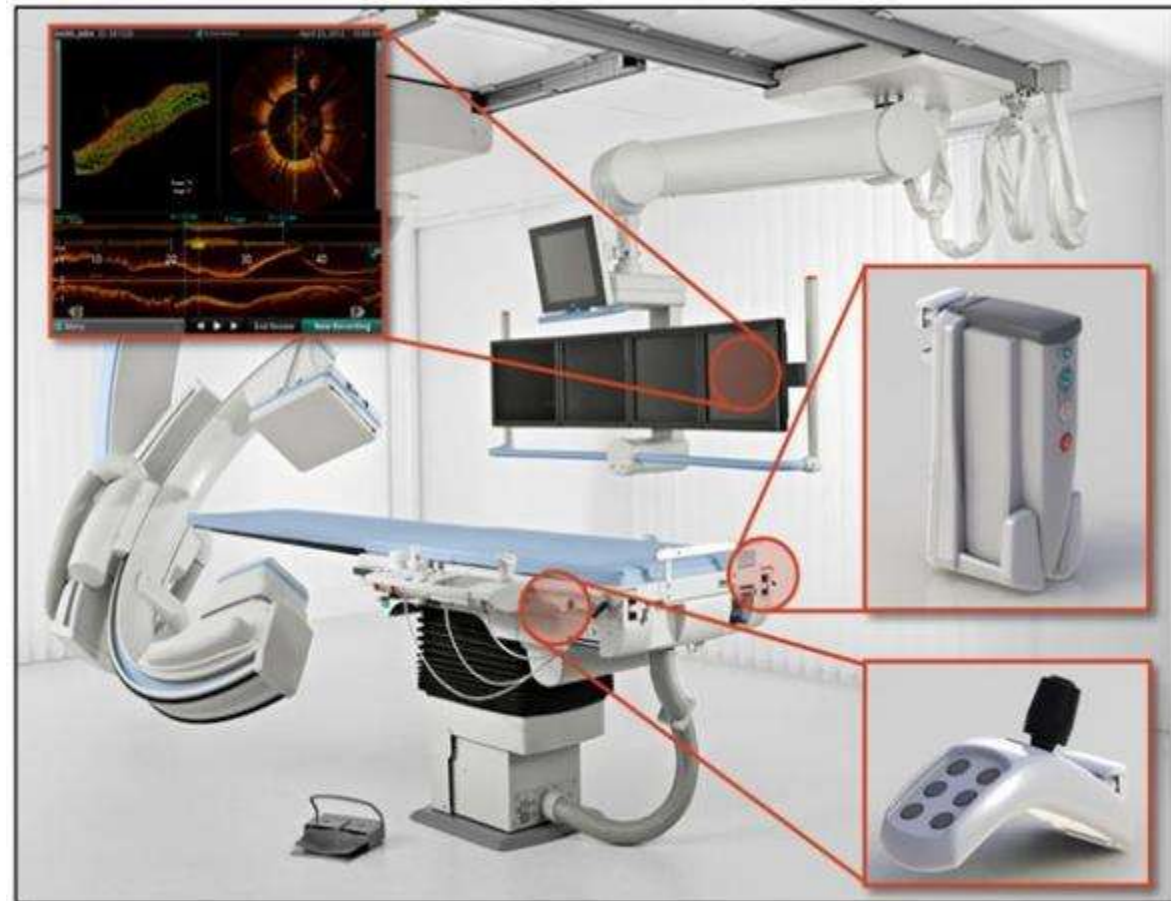
- **Clinical Benefits**

- Quick overview of pullback
- Highlight of areas of interest
- Display of key stent planning metrics
- Improved stent planning workflow



Integrated System Co-Registration

- Enable better integration of OCT in PCI workflow
 - Immediate availability during PCI procedure
 - Direct tableside control of acquisition and analysis by physician (no needs of additional experts!)
 - Enables real-time angio co-registration with OCT for planning and optimizing stent implantation

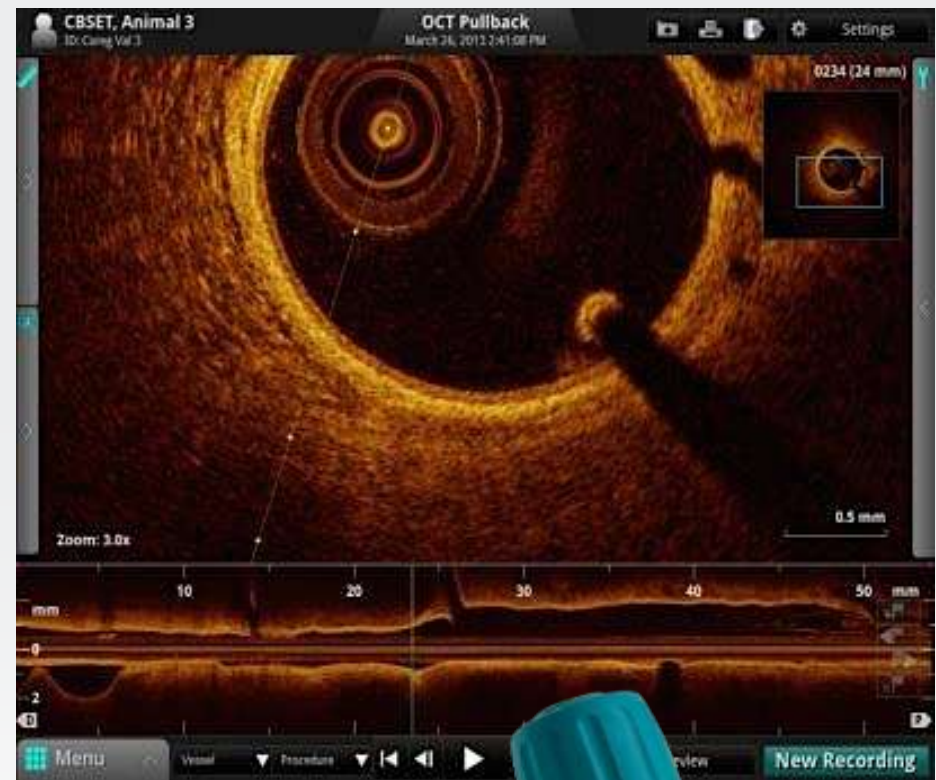


INTERACTIVE FEATURES

Cut Plane Rotation Hot Spot



Single Click Zoom



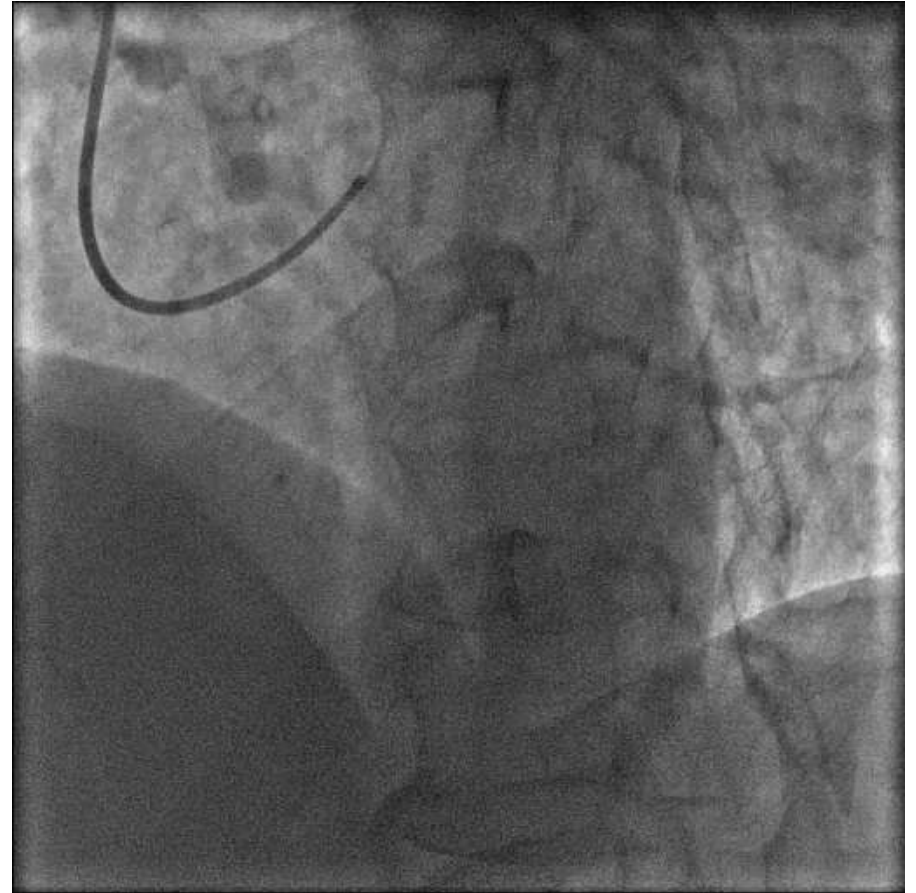
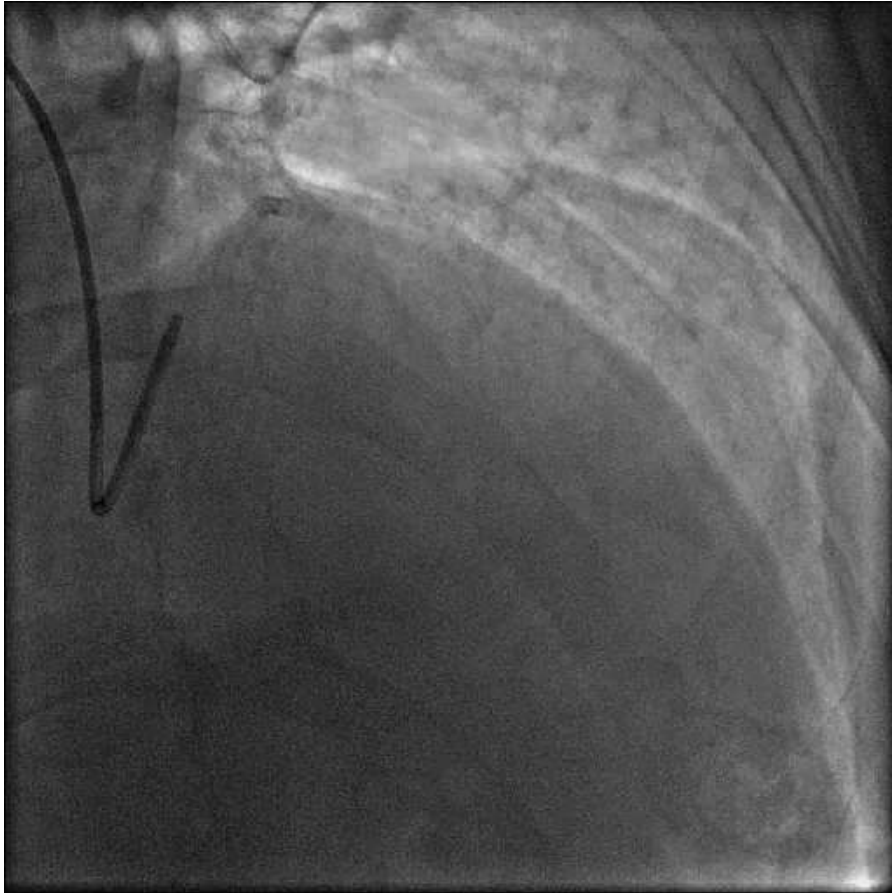
Navigation Controller



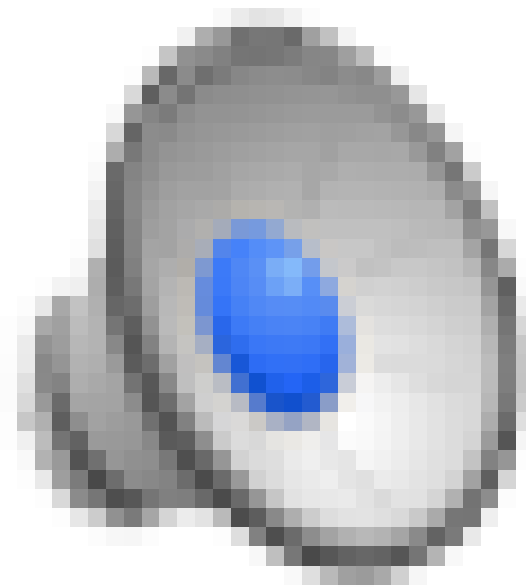
- The Tableside Controller may be used to position the mouse cursor by tilting the Navigation Controller to the left, right, up, down or variations thereof.

Mapping Coronary Intervention with OCT and ACR

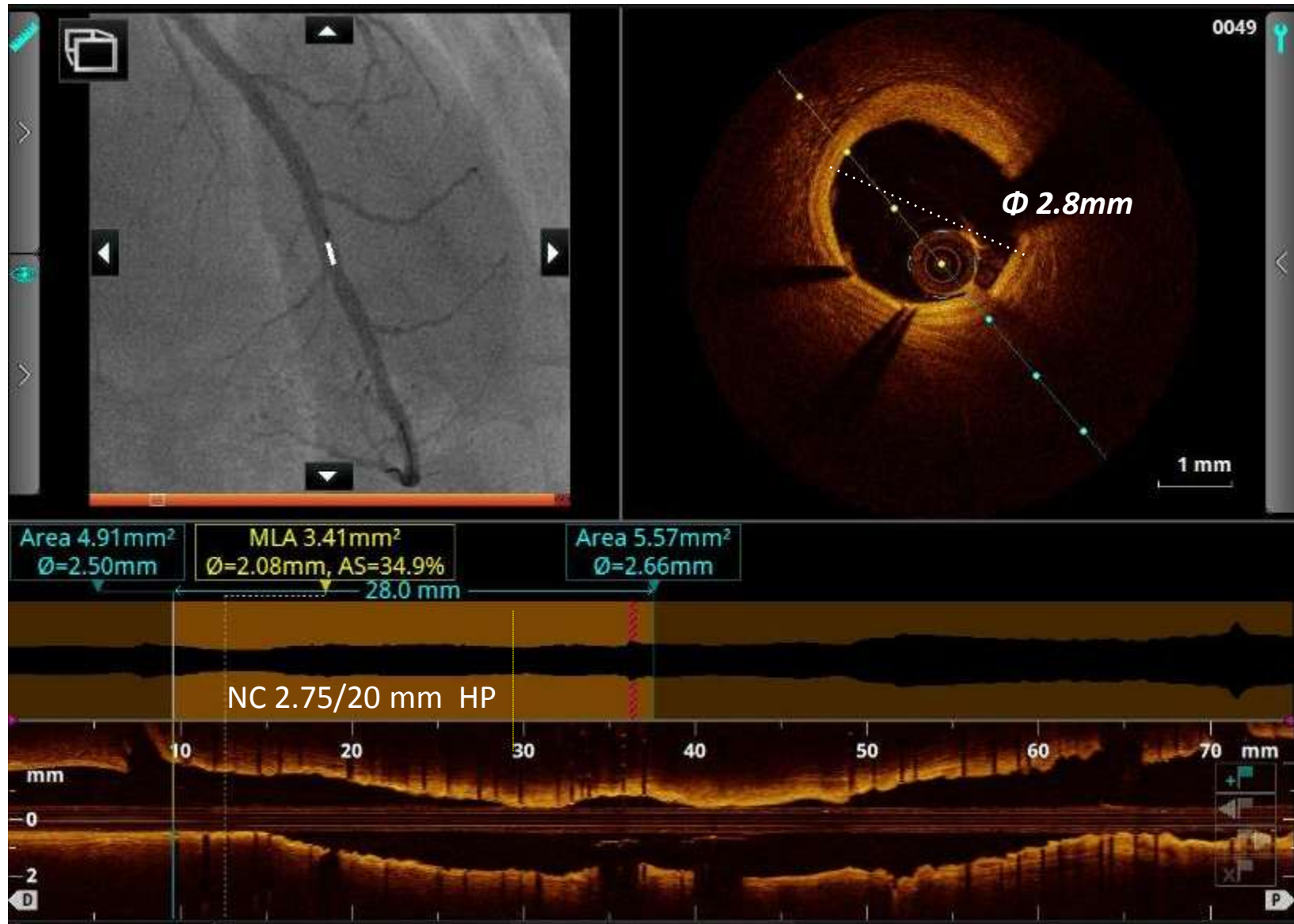
Multiple lesions



ACR- PCI Procedural Mapping



Distal stent: underexpansion



Position at MSA

Distal MSA

Proximal MSA

Distal MSA

Proximal MSA

MLA 4.55mm²
 $\Phi = 2.50\text{mm}$, AS=9.1%

MLA 6.59mm²
 $\Phi = 2.88\text{mm}$, AS=9.9%

10 20 30 40 50 60 70 mm

mm

0

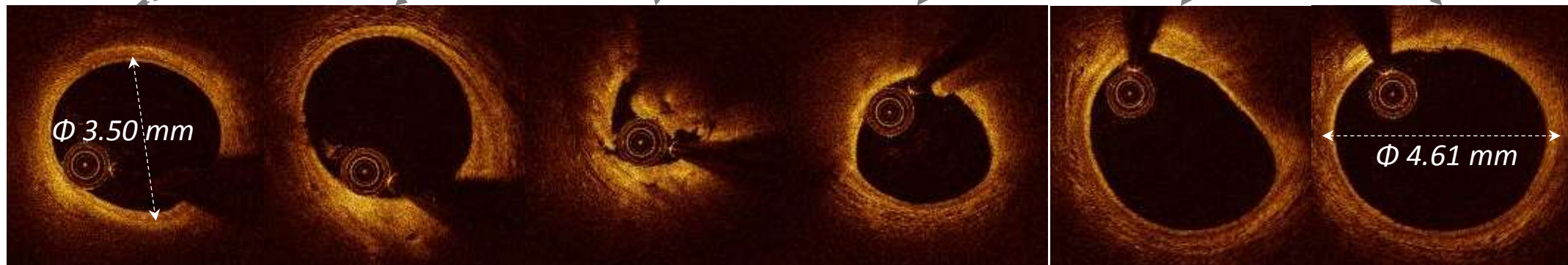
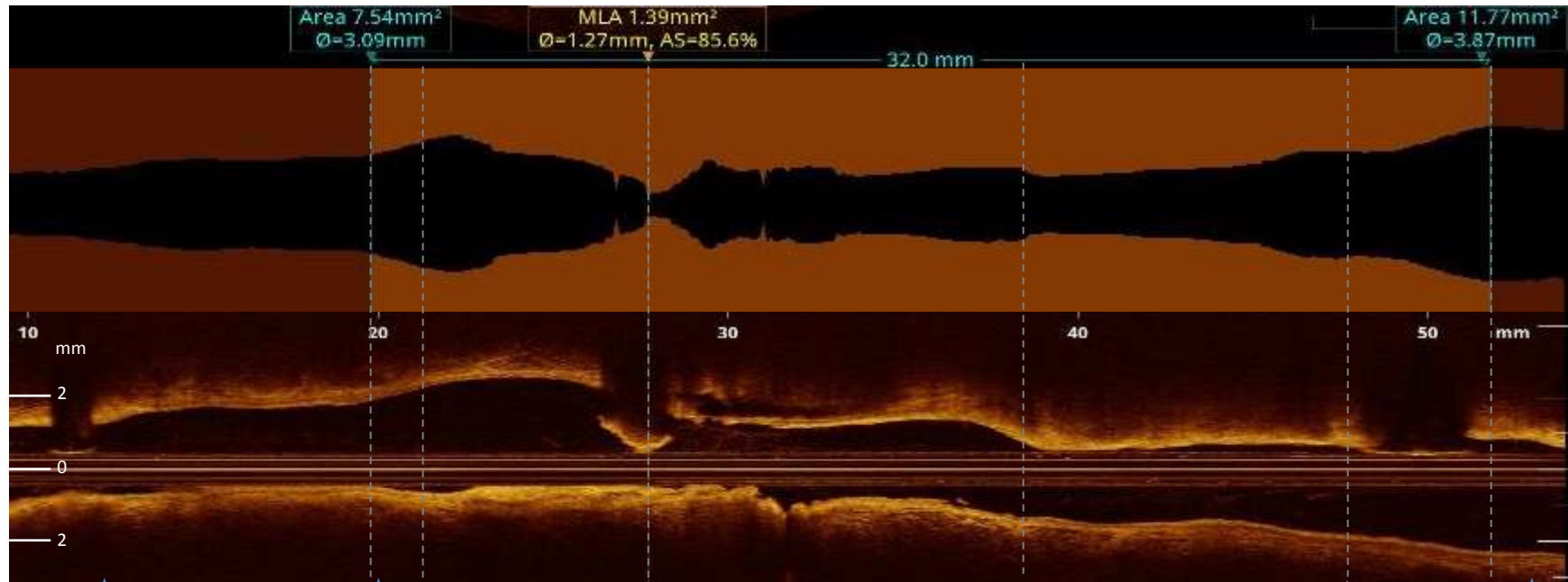
2

mm

0

2

How to select stent size and length?



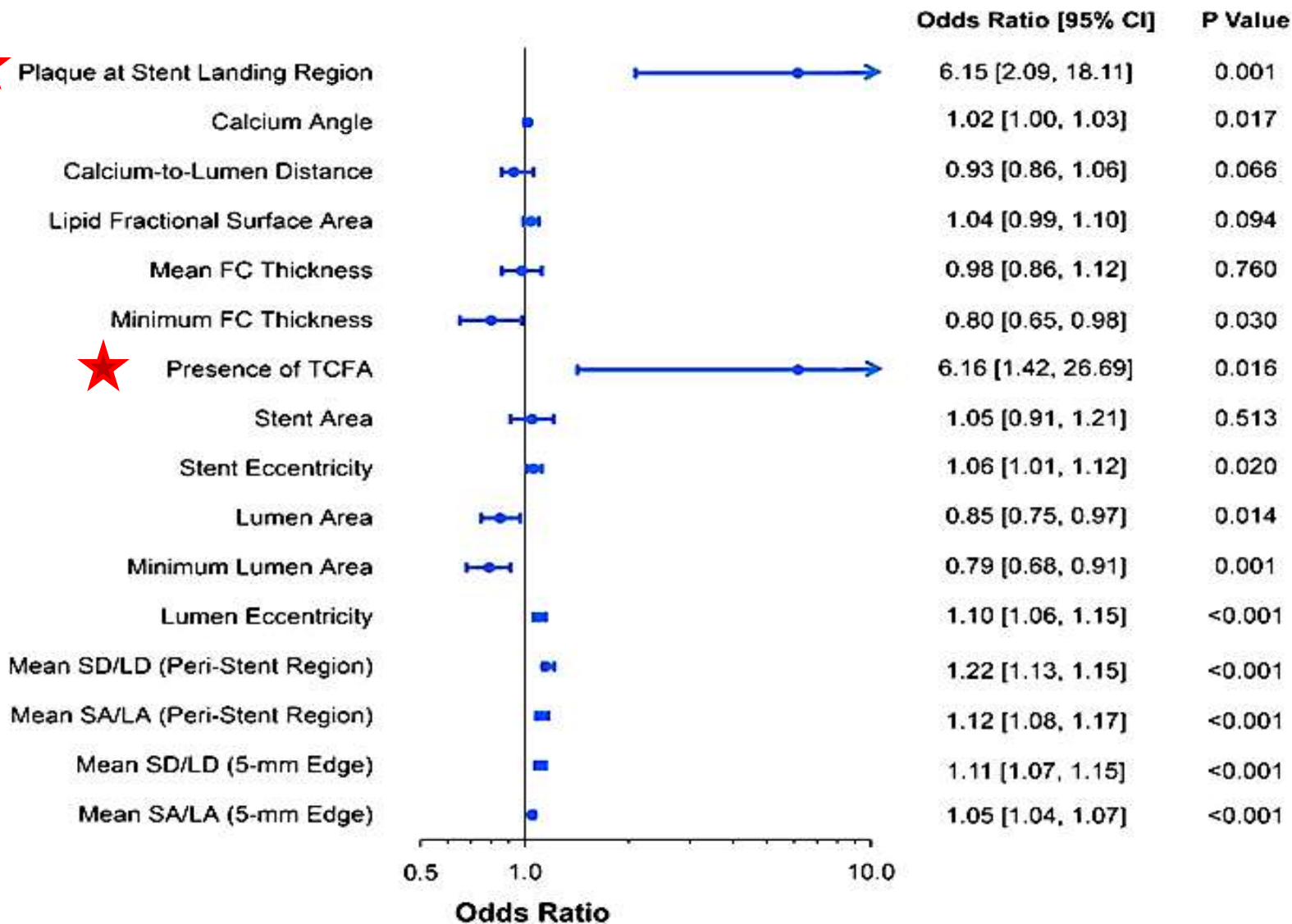
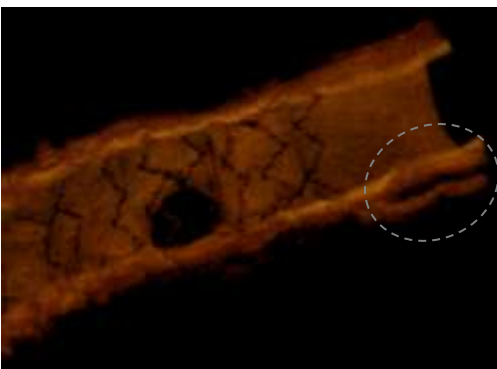
Independent Predictors of OCT-Detected Stent Edge Dissections



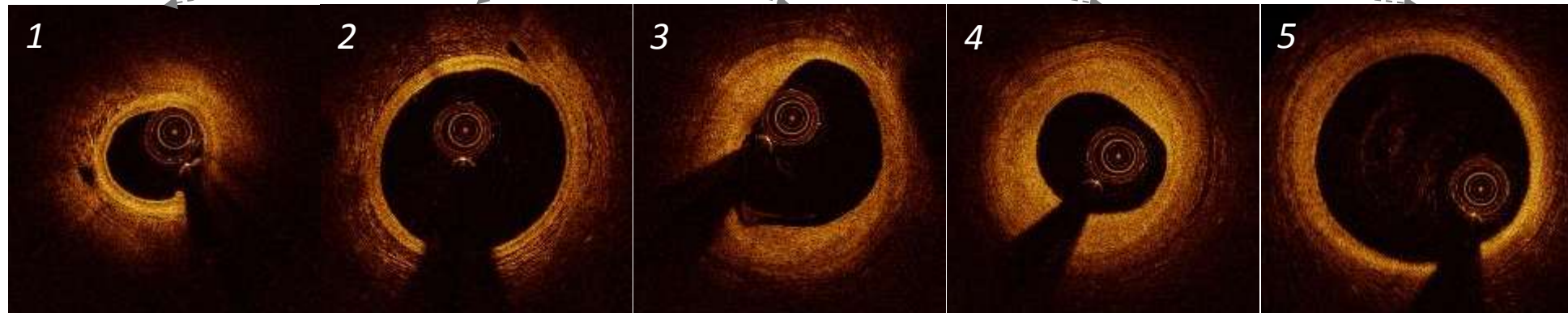
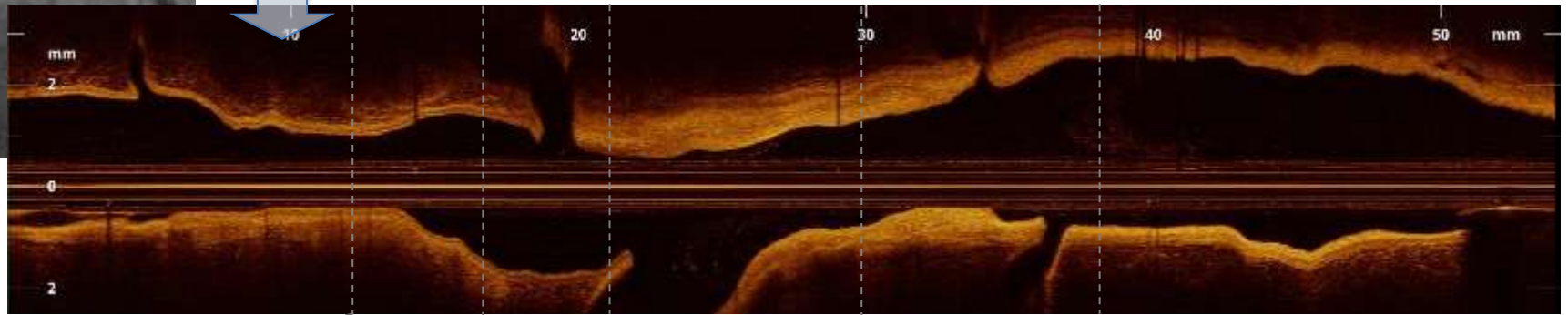
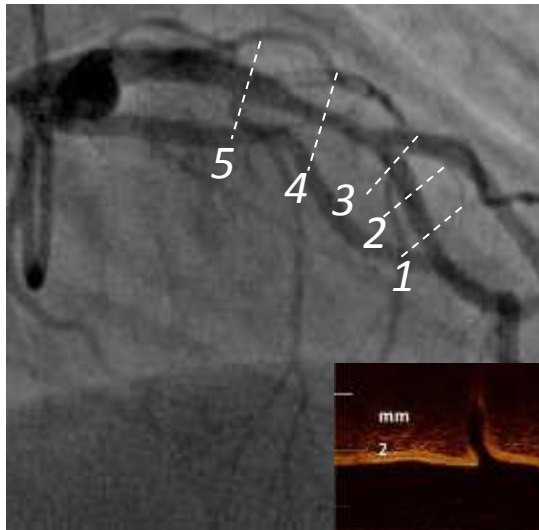
Plaque at Stent Landing Region



Presence of TCFA



Planning the procedure: what to avoid and how to choose



ILUMIEN III: OPTIMIZE PCI*

Principal Investigator: Ziad Ali', Columbia University.

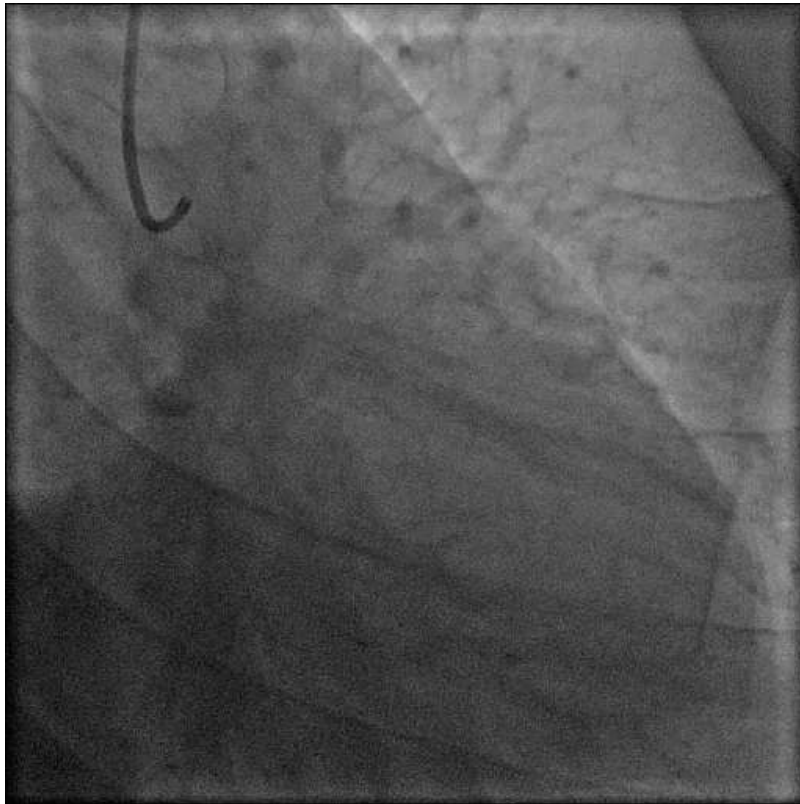
Title	ILUMIEN III: OPTIMIZE PCI: Optical Coherence Tomography (OCT) Compared to Intravascular Ultrasound (IVUS) and Angiography to Guide Coronary Stent Implantation: a <u>Multicenter Randomized Trial</u> in PCI.
Primary Objective	To demonstrate the safety and efficacy of an OCT guided strategy for stent implantation.
Trial Hypothesis	OCT-guided stent placement with application of a <u>novel algorithm</u> is non-inferior to IVUS-guided stent placement and <u>superior to Angiography</u> , all as measured by post-PCI minimum stent area (MSA)

** Protocol Approved at my Hospital Friday April 24 2015*



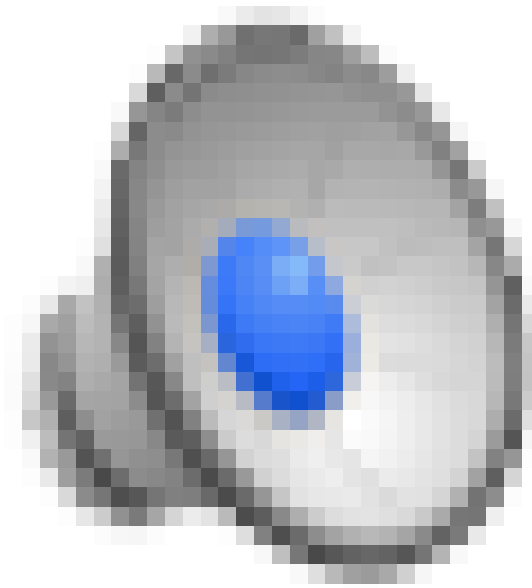
39 yrs

Crescendo angina:radiotherapy for lymphoma in 2008

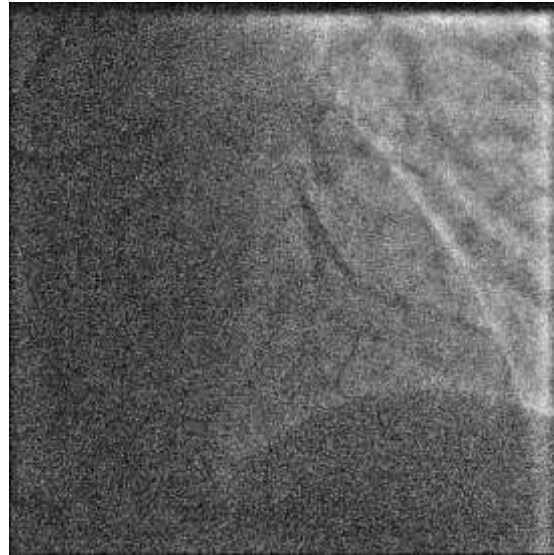
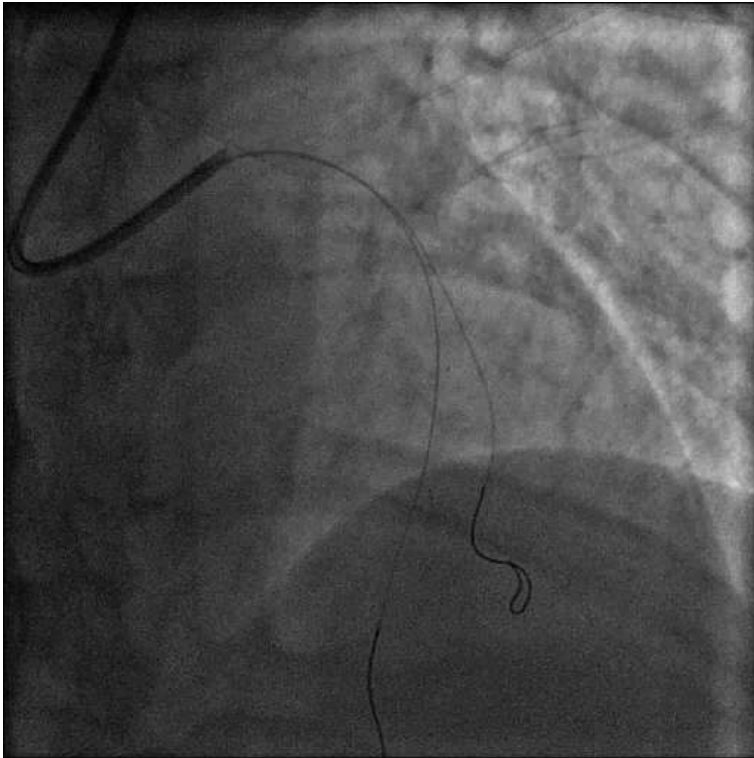


March 5 2015

- How to size BVS
- How to deal with major bifurcation

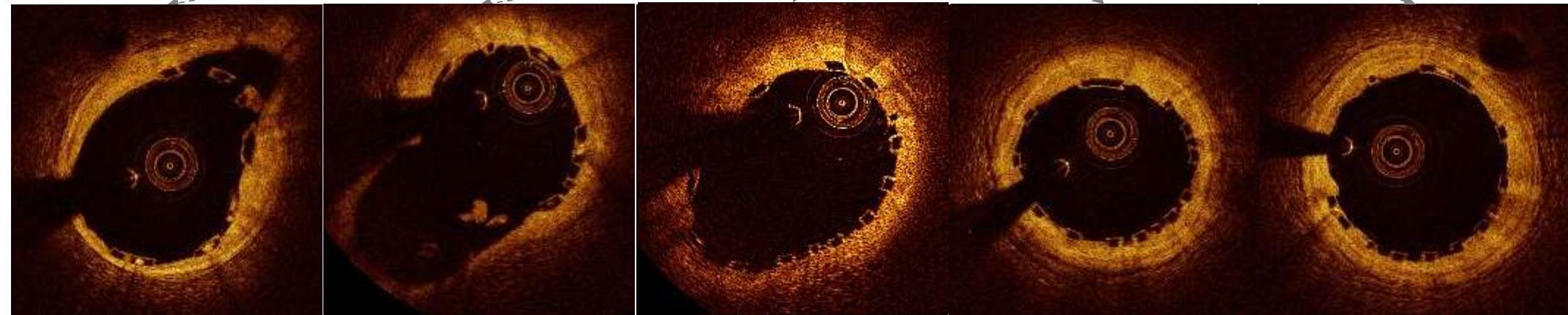
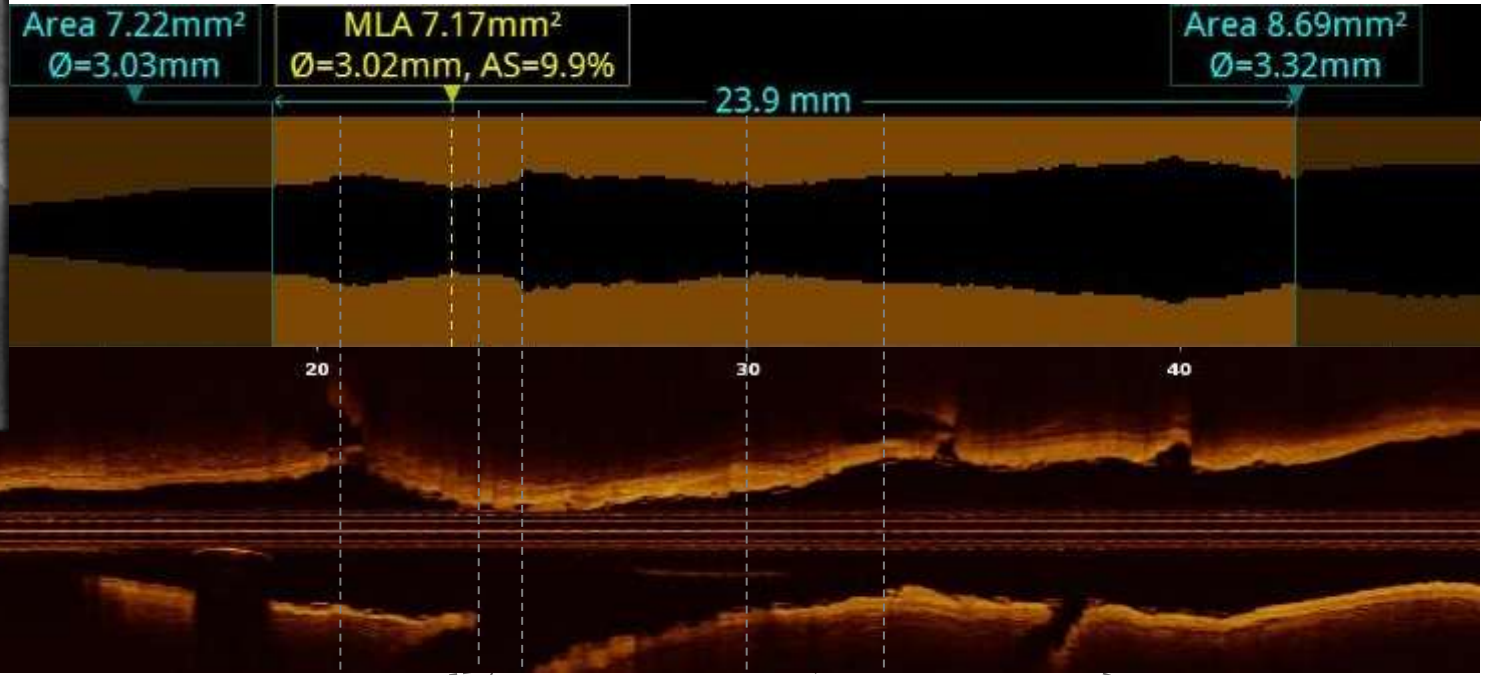


BVS 3.5/23mm in LAD with mini-KBPD (ϕ 2.0mm in D1, 5 atm)



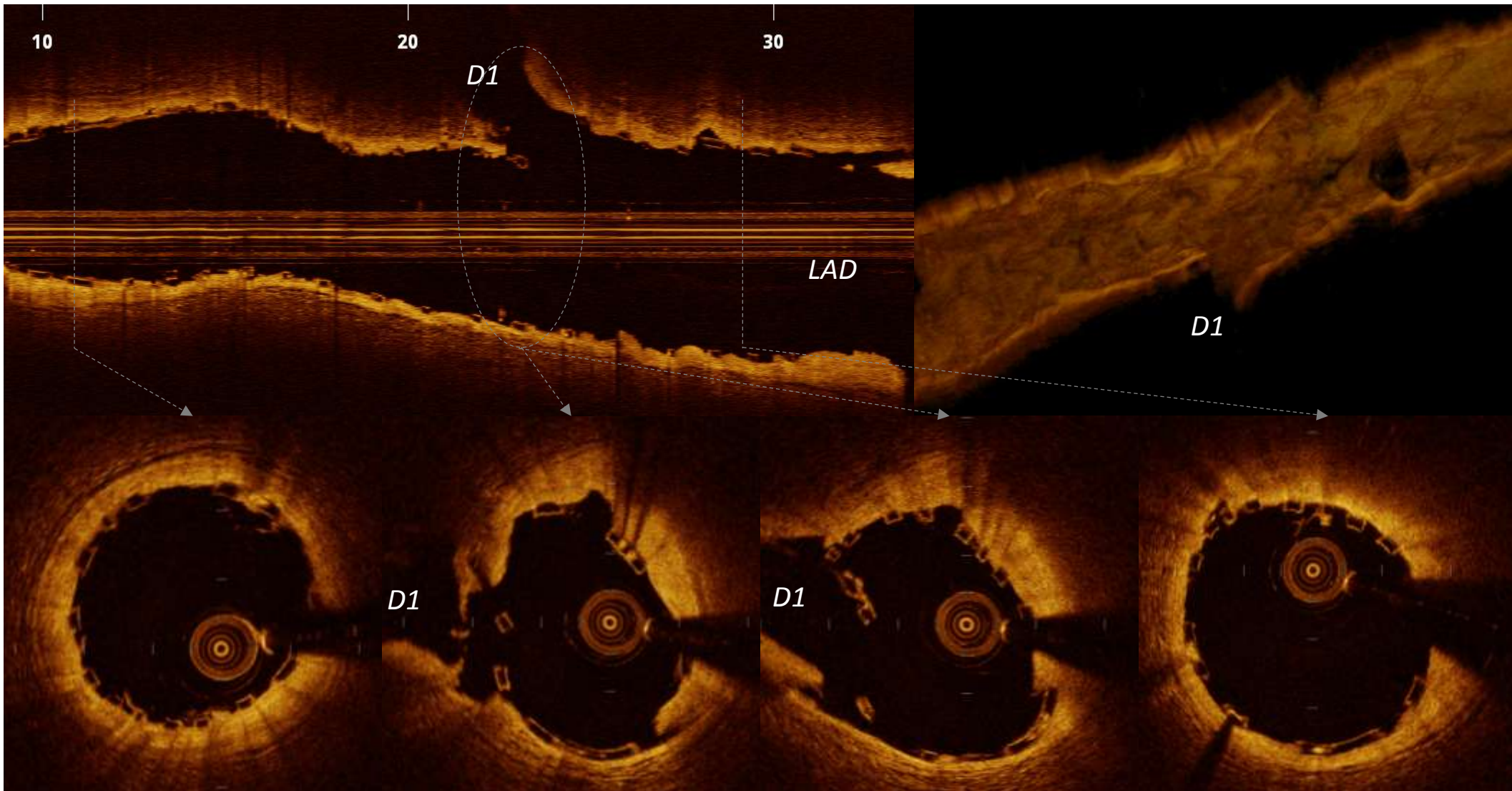
* Not approved for sale in United States, nor recommended as indication for use

Final BVS result



Complex Lesions

apposition, distortion, fracture, overlap, plaque/thrombus protrusion





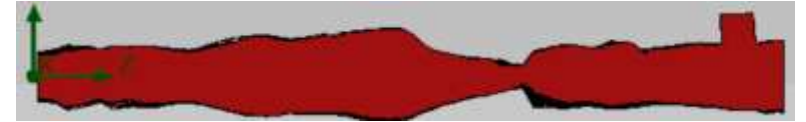
1.7 F = Improved Clearing Distal to Lesions

Smaller profile, better crossing, less hemodynamic impact, less contrast

Dragonfly DUO – Clears in 5.0 seconds

Dragonfly NG – Clears in 0.75 seconds

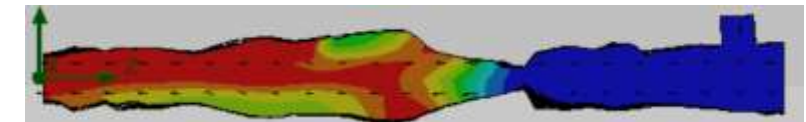
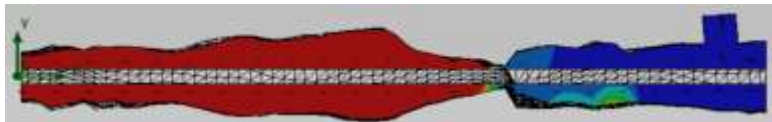
T = 0



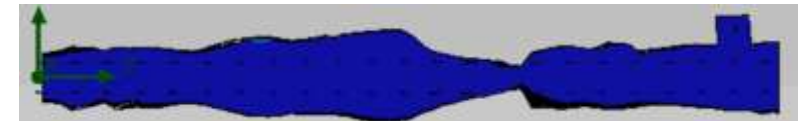
T = 0.25 sec



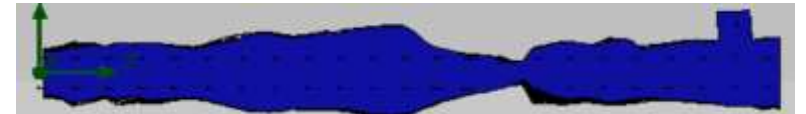
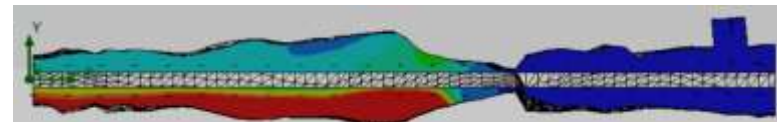
T = 0.50 sec



T = 0.75 sec



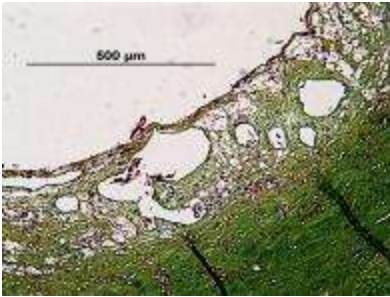
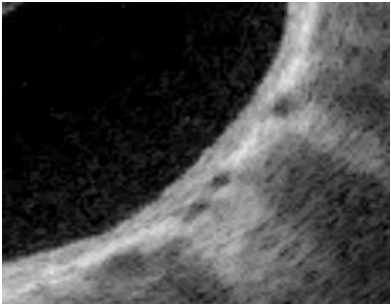
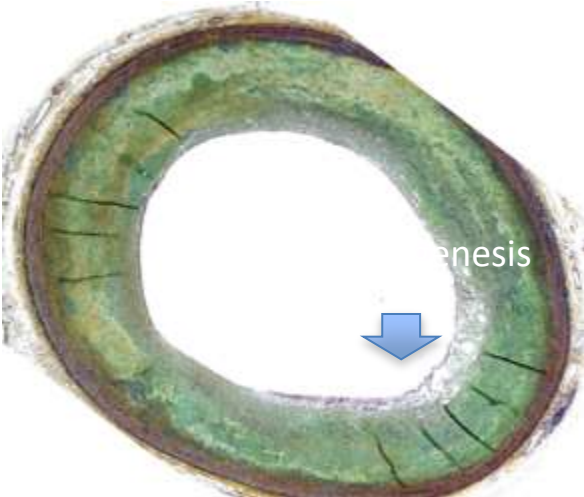
T = 1.00 sec



ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

Association of OCT-based Plaque Characteristics and Subsequent Progression



Univariate Analysis

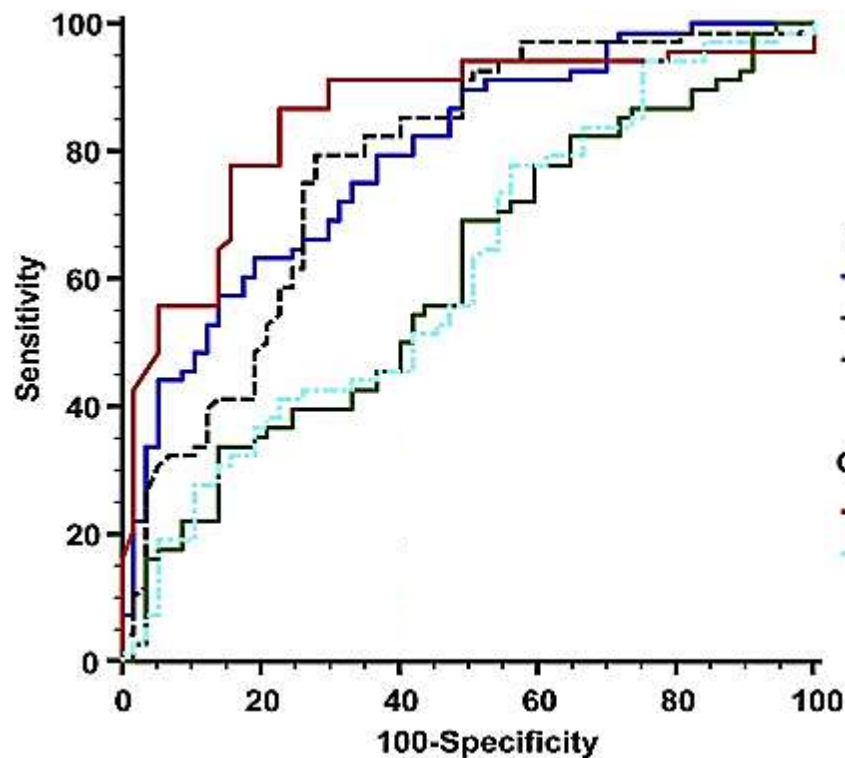
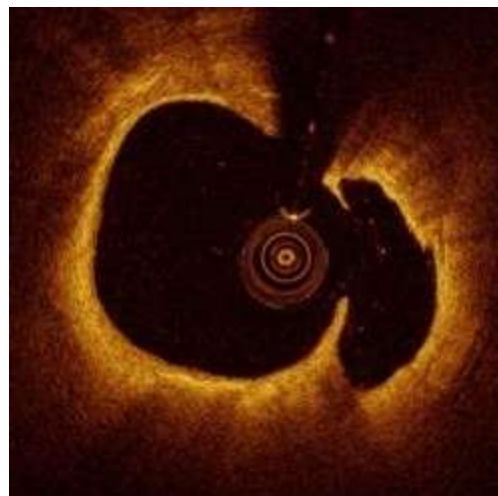
	OR (95% CI)	P
Eccentric	3.3 (0.7-14.4)	0.230
◆ Microchannel	20 (4.8-83.0)	<0.001
◆ TCFA	20 (4.8-83.0)	<0.001
◆ Macrophage	9.6 (2.6-35.6)	0.001
Calcium	1.3 (0.4-4.3)	0.890
◆ Thrombus	12 (2.2-64.3)	0.002

Uemura S. Eur. Heart J 2012, 33: 78-85

Distinct Morphological Features of Ruptured Culprit Plaque for Acute Coronary Events Compared to Those With Silent Rupture and Thin-Cap Fibroatheroma

A Combined Optical Coherence Tomography and Intravascular Ultrasound Study

Jinwei Tian, MD, PhD,*† Xuefeng Ren, MD,* Rocco Vergallo, MD,† Lei Xing, MD,* Huai Yu, MD,*

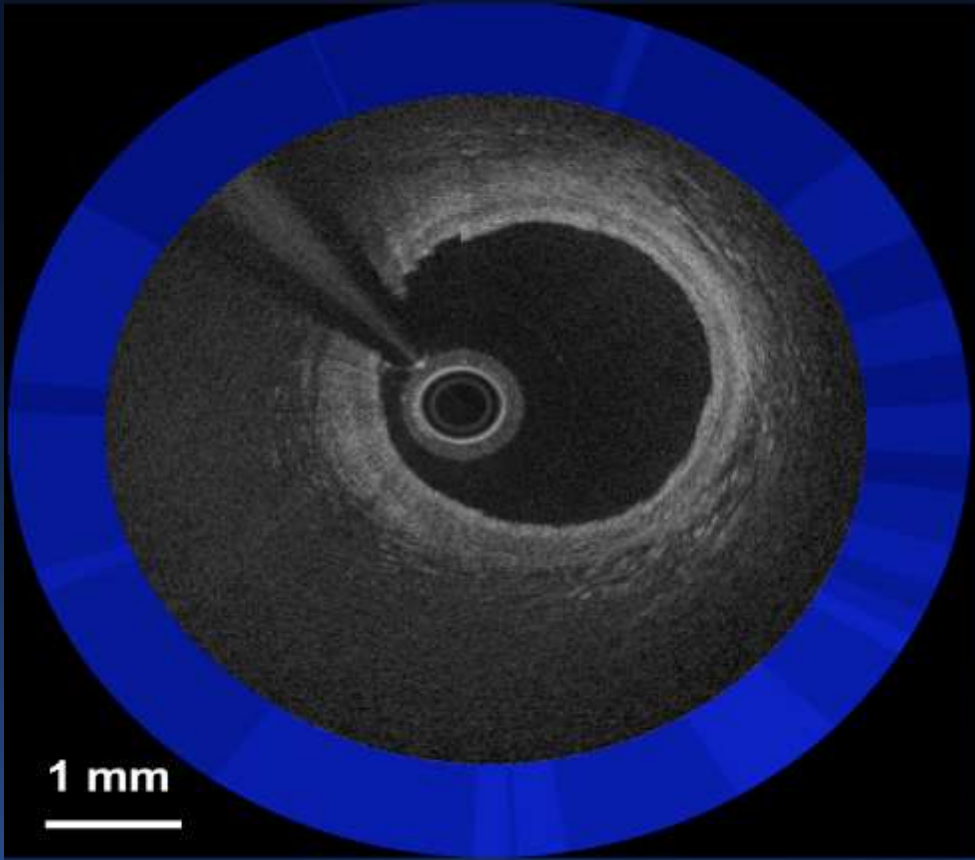


IVUS parameters:
— Plaque burden (AUC=0.791, $P < 0.001$)
--- Lumen CSA (AUC=0.776, $P < 0.001$)
— P+M CSA (AUC=0.608, $P = 0.034$)

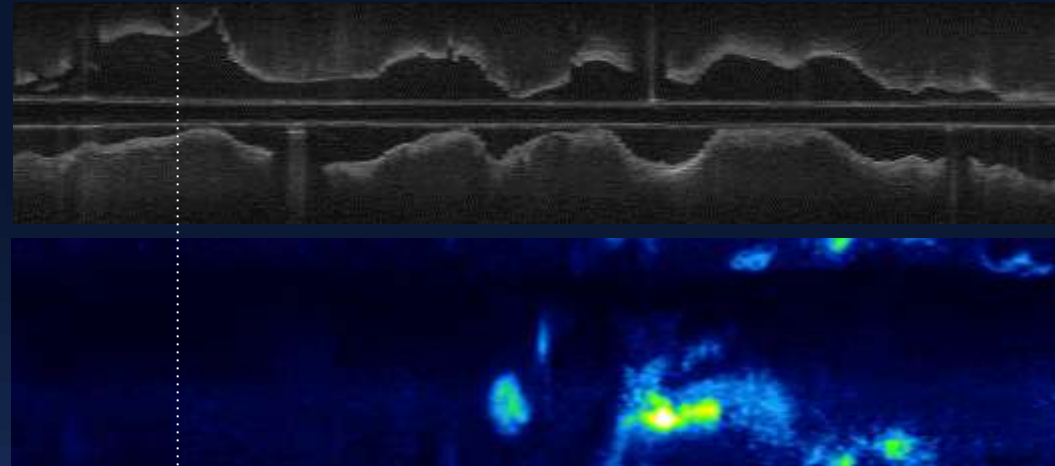
OCT parameters:
— FCT (AUC=0.855, $P < 0.001$)
- - - Lipid arc (AUC=0.611, $P = 0.029$)

IVOCT-NIRAF pullback

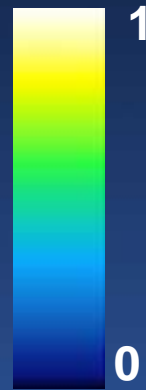
LAD



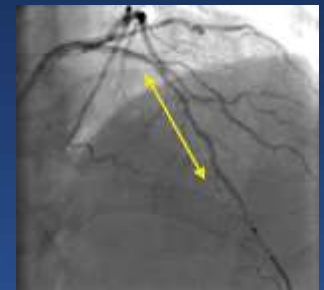
Pullback length \longrightarrow 55 mm



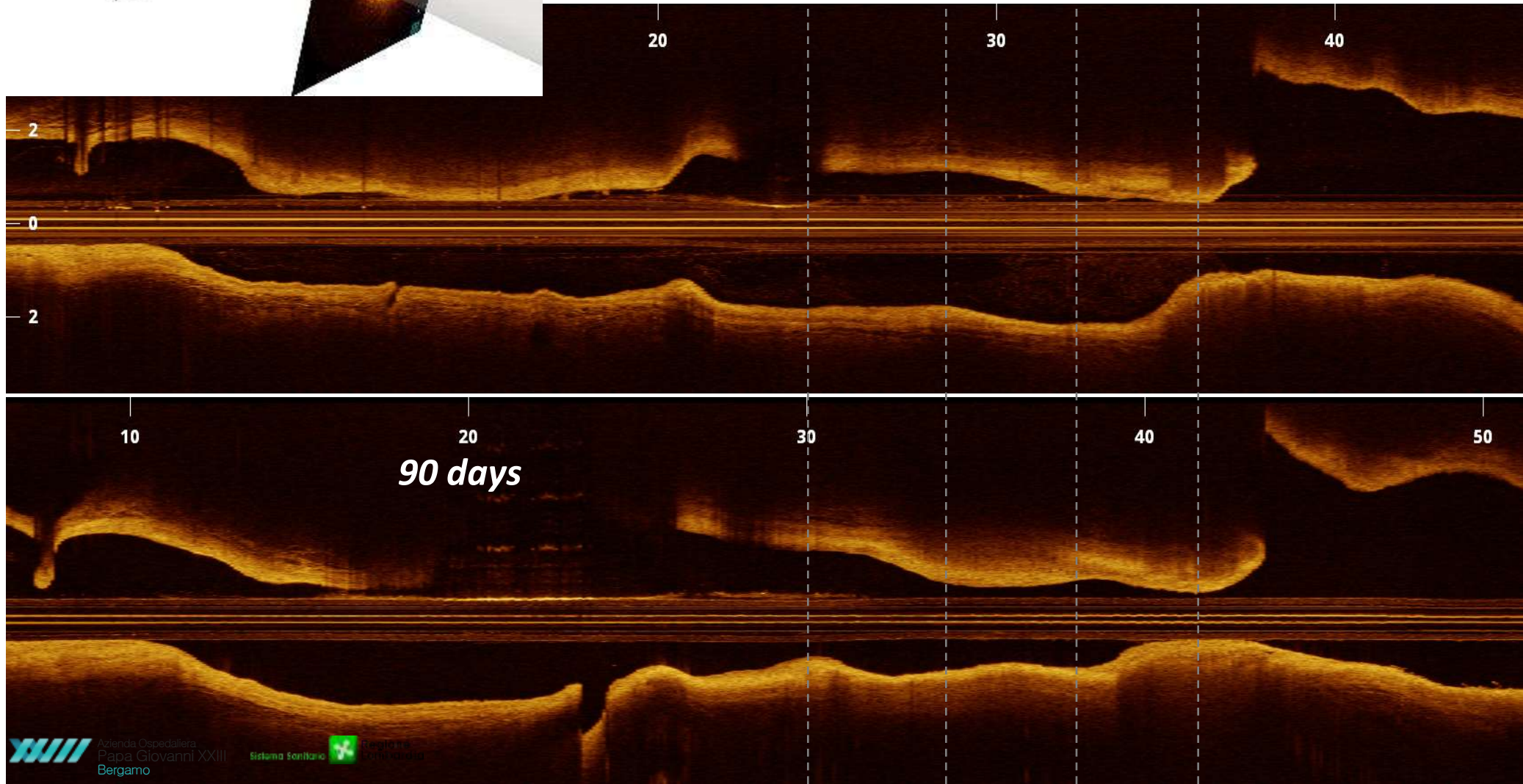
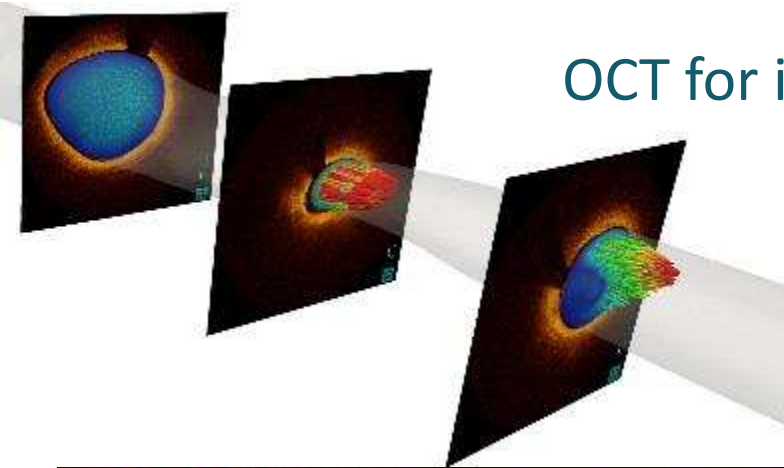
C TCFA C



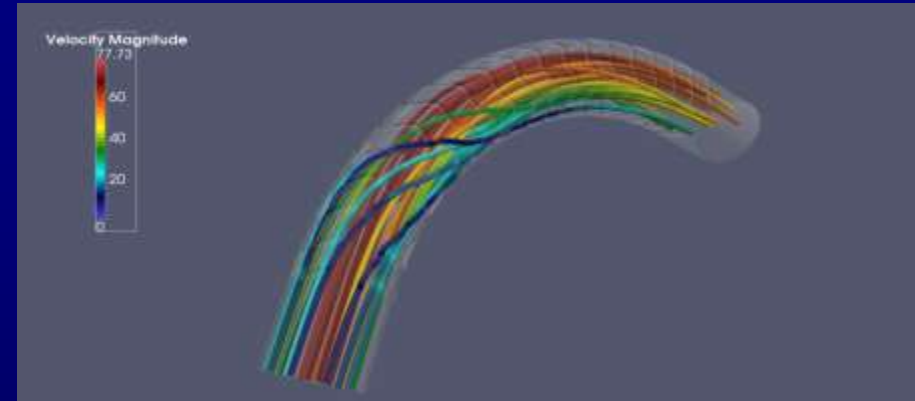
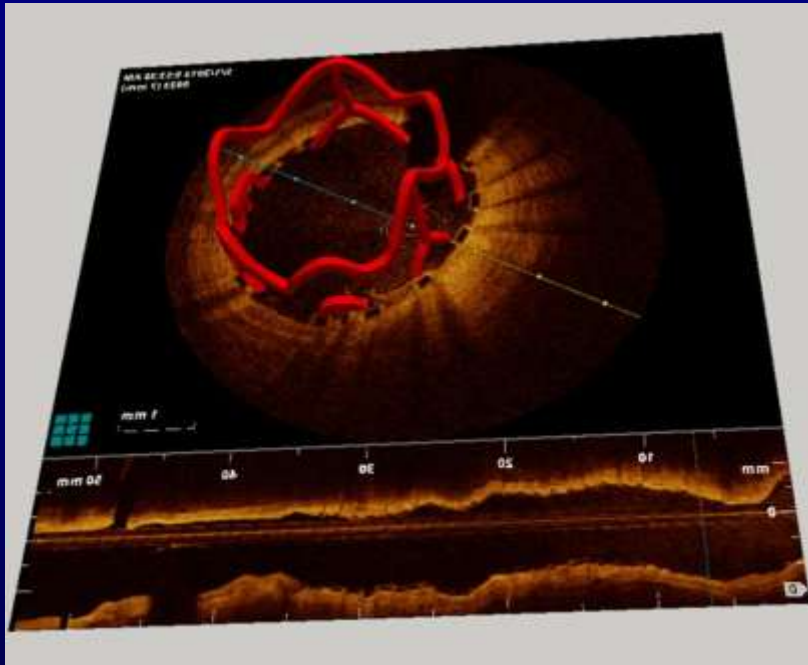
Normalized NIRAF intensity



OCT for informing on risk of progression



Reconstructed stent from OCT , velocity Streamlines, shear stress



Courtesy B. Yang, B. Gogas MD, A. Veneziani Phd, H. Samady MD March 2015



OCT PROCEDURE GUIDANCE IN THE CATHLAB....

- Quick overview of the pullback: full vessel assessment of coronary plaques phenotypes with accurate lumen measures, in only couple of seconds (plus in unstable patients)
- Highly sensitive for thrombus (detection and removal) and high-risk plaques (ACS, LST)
- Display of key stent planning metrics with full tableside control
- Best for mapping, positioning and controlling the planned stent with high quality point-to point longitudinal view (automatic lumen profile) and software capability for daily use (angio co-registration).

The impact of this innovative technology on day-to day treatment strategies and outcome remains to be proved by prospective, RCTs.