

TCT ASLA 2009, Imaging Summit

Current and Future Role of  
IVUS, VH-IVUS and OCT In PCI patients

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TCT ASIA 2009, Imaging Summit

## **Financial Disclosure**



Consulting Fees, Honoraria / Speaker

**Boston Scientific, Volcano / LightLab**

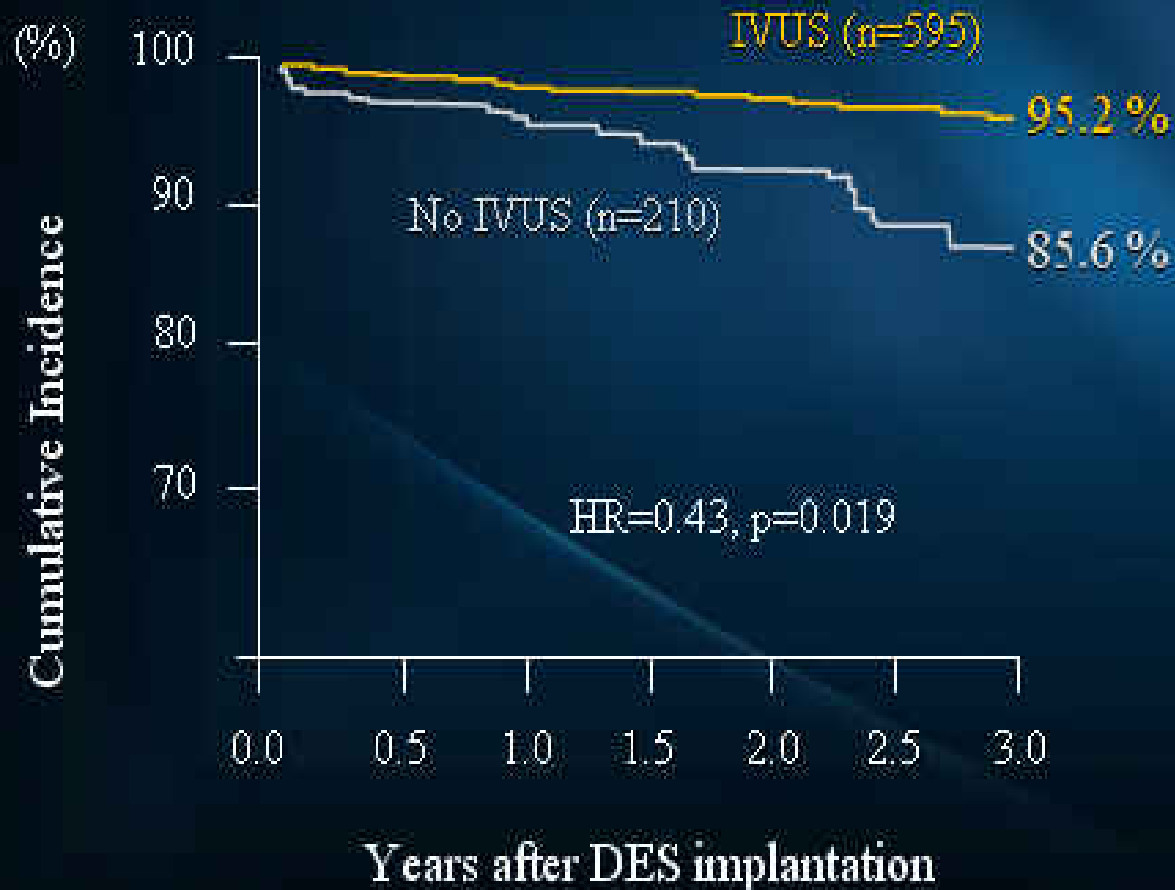
Grant/Research Support

**Abbott Vascular, Boston Scientific, Labcoat, LightLab, Medtronic Vascular**

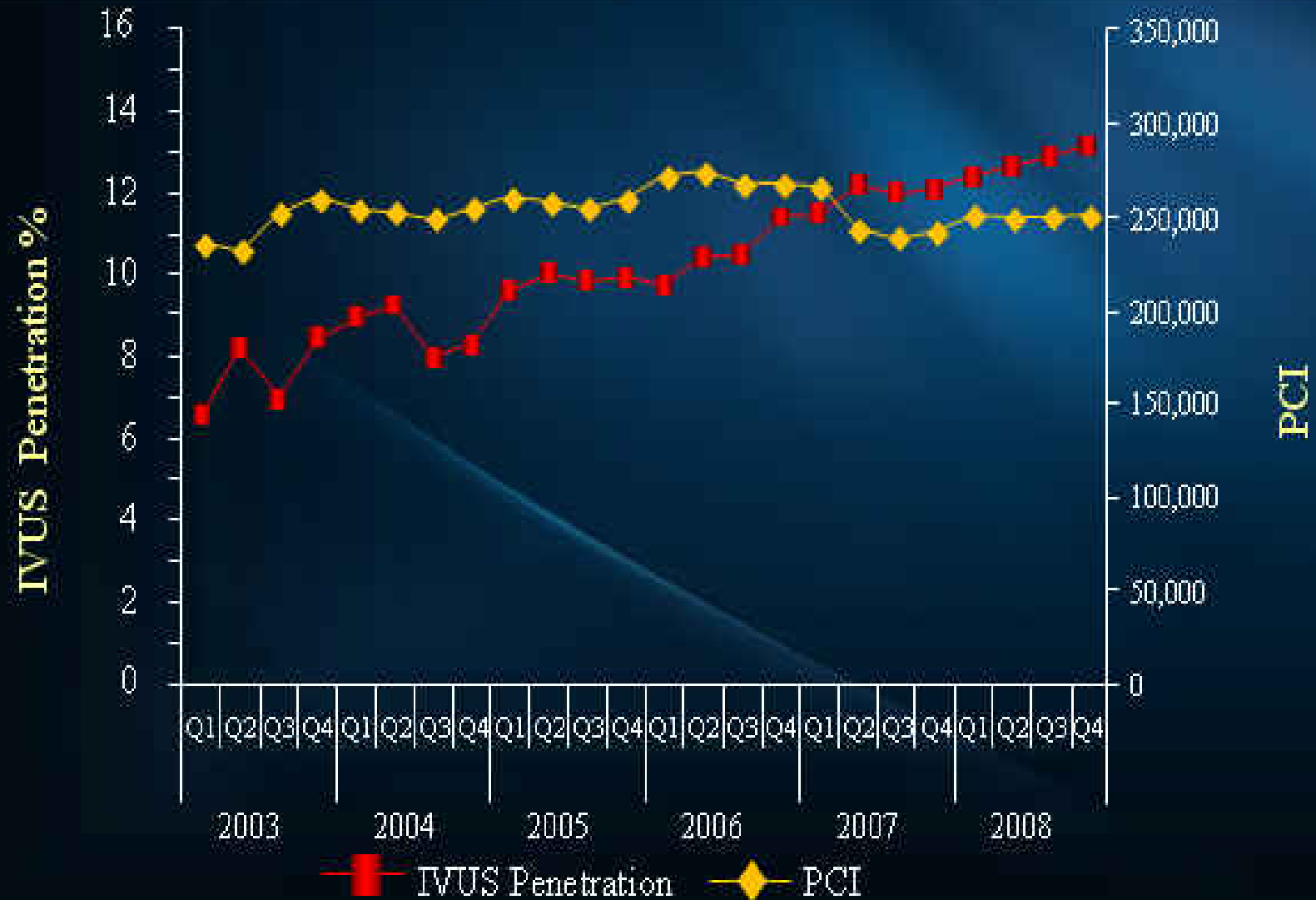
*Giulio Guagliumi, MD*

- High risk patient subsets
  - Renal failure<sup>SAT</sup>
  - Limitations to dual antiplatelet therapy use<sup>SAT</sup>
  - Diabetes mellitus<sup>ISR,SAT</sup>
- High risk lesion subsets
  - Bifurcations<sup>ISR,SAT</sup>
  - Ostial lesions<sup>ISR</sup>
  - Small vessels<sup>ISR</sup>
  - Long lesions<sup>ISR</sup>
  - Treatment of ISR<sup>ISR</sup>
  - Left main disease (given the inconsistent results and risks involved)

## All-Cause Mortality After LMCA DES Implantation: Impact of IVUS Guidance



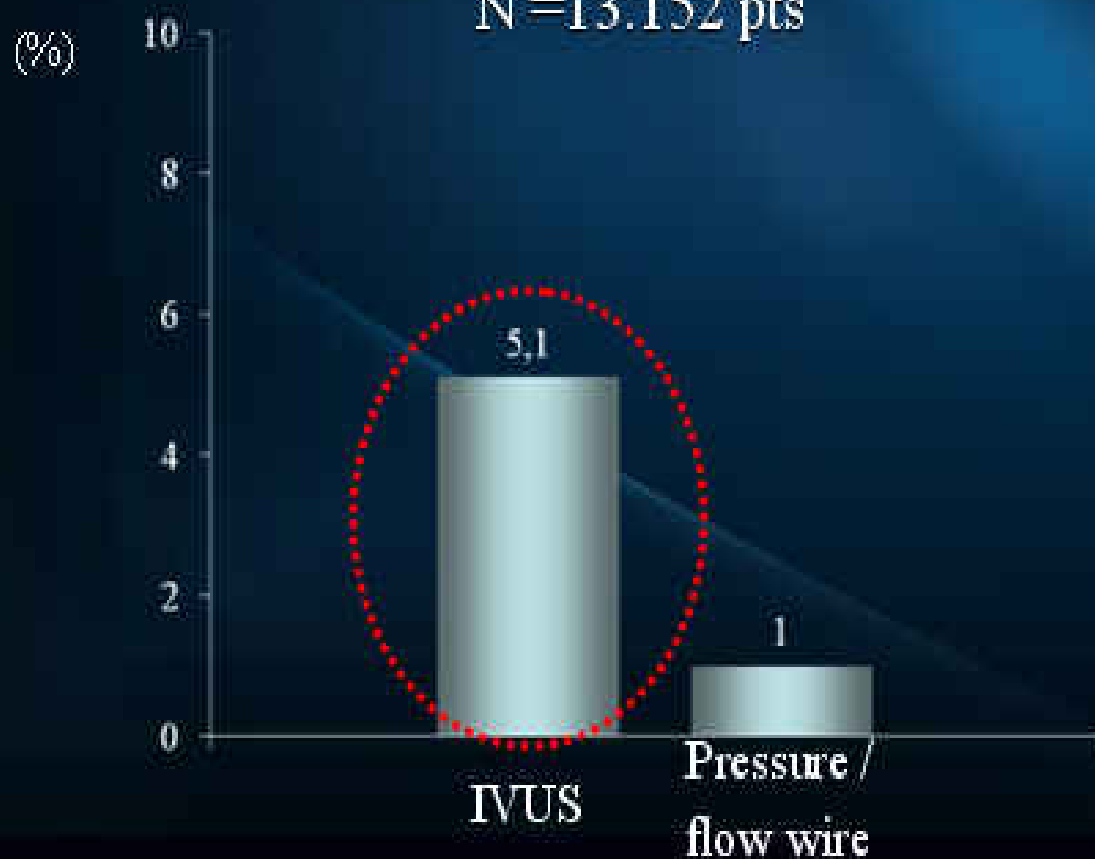
## % U.S. of IVUS Procedure Penetration and # of PCI



# Euro Heart Survey on PCI: June 2005-January 2006

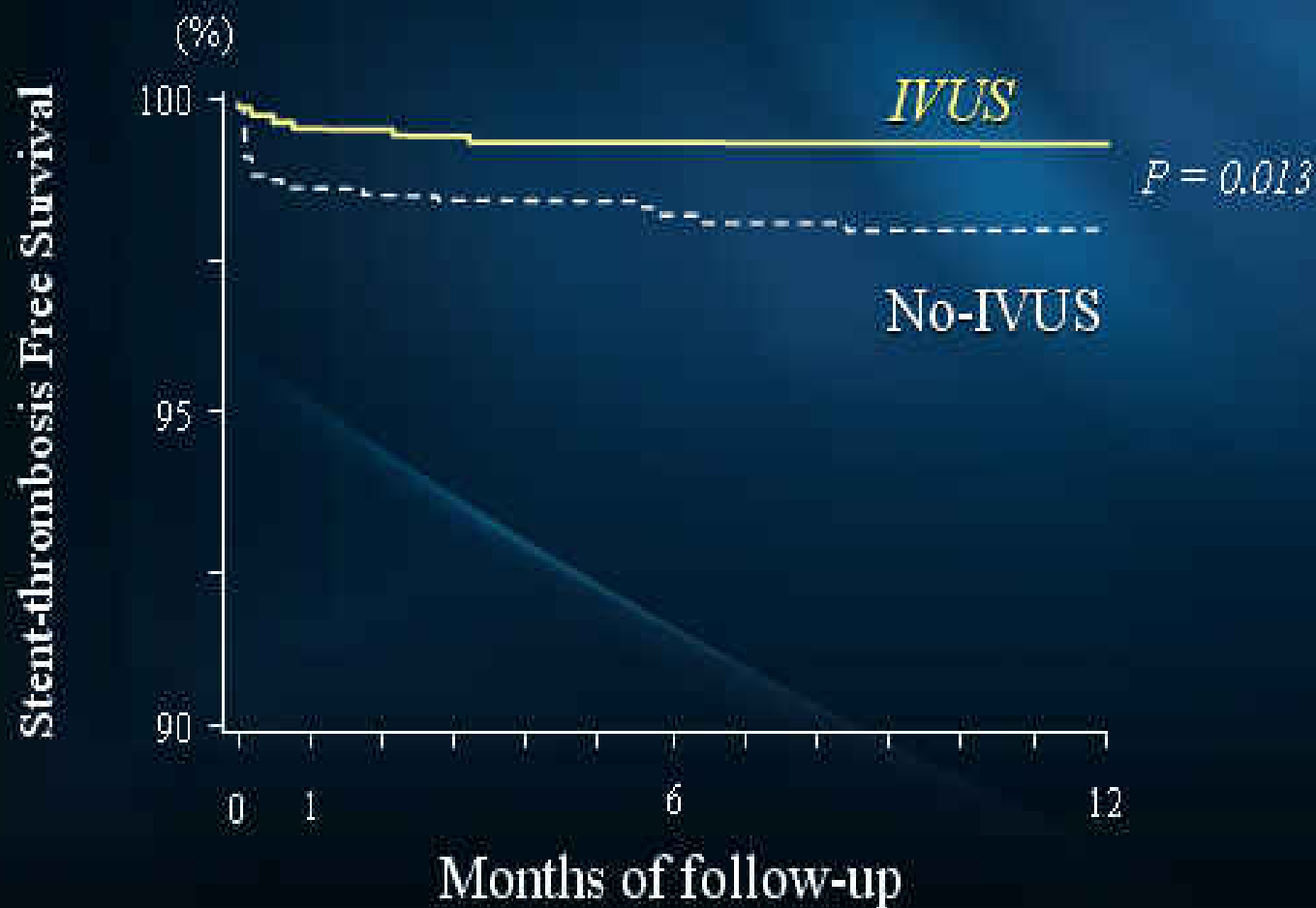
134 Centres, 39 ESC member countries

N=13.152 pts



## Potential Clinical Utility of IVUS guidance PCI

*1296 IVUS-guided, DES-treated lesions in 884 pts vs 1312 matched, angio-guided alone*



*Roy P et al Eur H J 2008; 29:1851*

## What technique do you use to optimise stent deployment?

*Audit of BCIS members: 120 responders*

“ No evidence for anything other than stent balloon and angiography ”



## What technique do you use to optimise stent deployment?

*Audit of BCIS members: 120 responders*

- ✓ *Angiography: 95%*
- ✓ *“Stent boost”: “whats that?”*
- ✓ *FFR: “only if I start with FFR”*
- ✓ *IVUS: <5%*
- ✓ *OCT: “whats that?”*
- ✓ *Other: its OK because I always use HP (14+ATM!!!)*

# Publications on Intravascular OCT

All publications

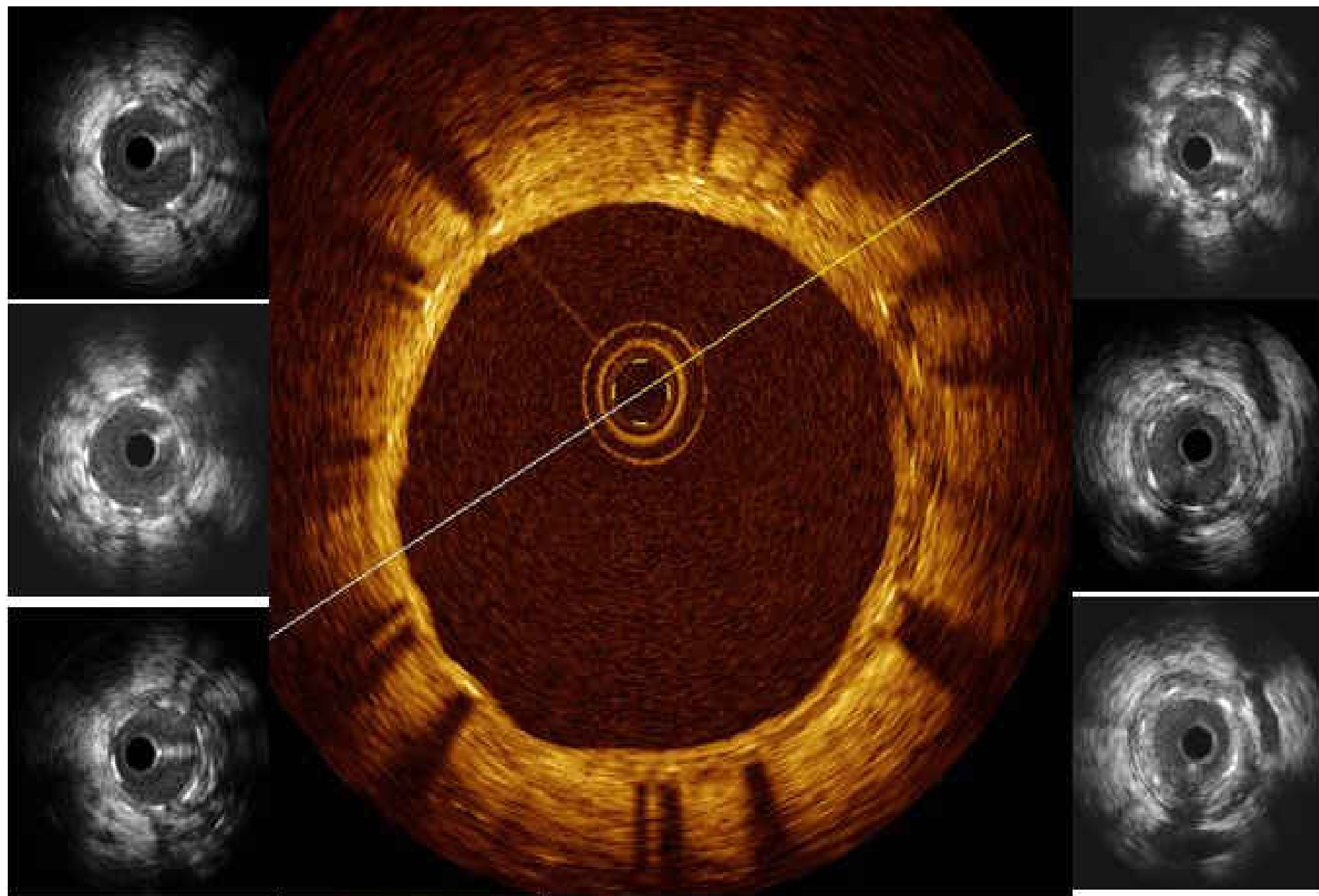
All in-vivo human publications

In-vivo human clinical studies



GC ODESSA TRIAL CYPHER 3.0/33+3.0/8mm

6 MOS FU

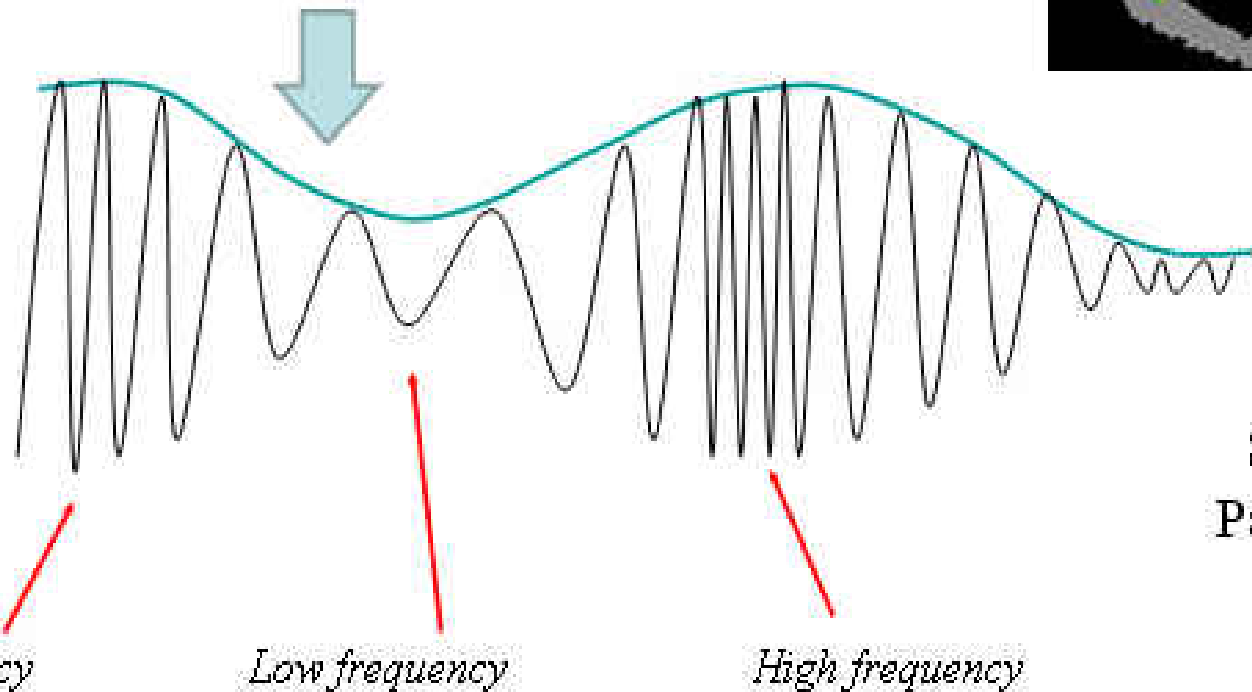
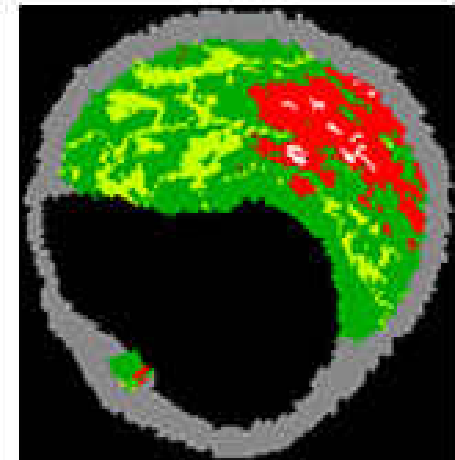


*G. Guagliumi MD, Late Staking Trials TCT 2008*

# VH IVUS <sup>TM</sup>

Analysis is based on Frequency + Amplitude

Only the envelope amplitude (echo intensity) is used to form the grayscale IVUS image

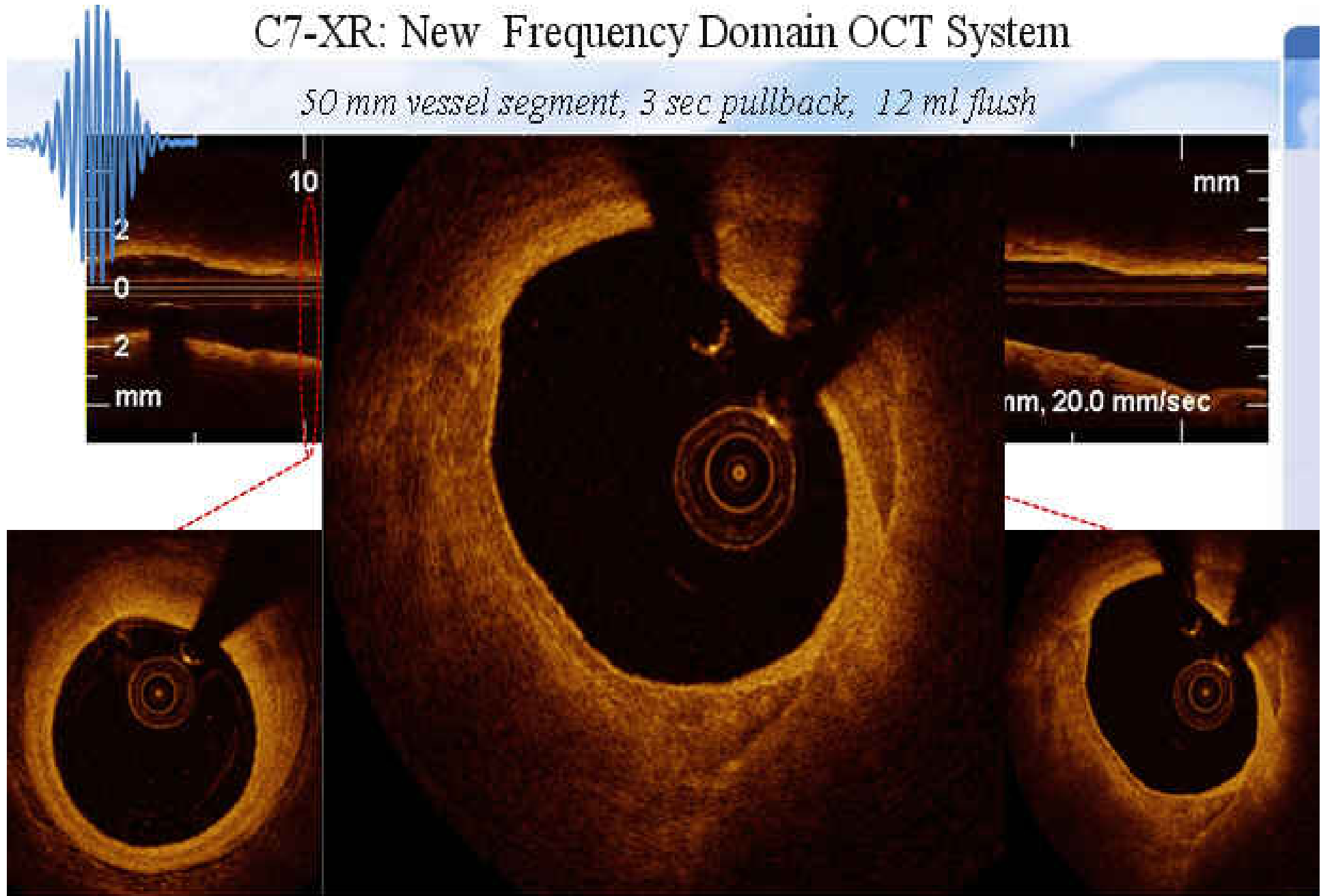


Spectral  
Parameters

Among reflected ultrasound signals of the same intensity,  
frequency can also vary depending on the tissue

# C7-XR: New Frequency Domain OCT System

*50 mm vessel segment, 3 sec pullback, 12 ml flush*



G. Guagliumi, Ospedali Riuniti di Bergamo 2009


## What limited use of IVUS?

- Concerns on use in difficult lesions
- Time
- Expertise in imaging interpretation
- Artifacts and complexity of data handling
- Cost

# Safety and Feasibility of OCT in the Clinical Setting

*Japanese Multicenter Study : 8 medical centers*

*IVUS and OCT  
Independent Core Lab*



<i>Procedural success rates</i>	<i>OCT</i>	<i>IVUS</i>	<i>p</i>
Before PCI <i>n</i> = 40	92.5%	85.0%	0.284
After PCI <i>n</i> = 34	100%	100%	1



<i>MLA</i>	<i>r</i>	<i>% error</i>
Intraobserver correlation	0.999	2.5 ± 2.4%
Interobserver correlation	0.998	4.6 ± 6.8%

## “Does not reach the difficult lesions”

- The manufacturers are making progress



Boston Scientific Corporation

- OCT Dragonfly™ Rx, 2.7 F tip, hydrophilic coating, torque-wire based fiber rotation

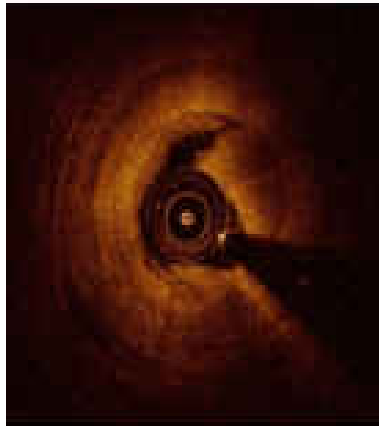
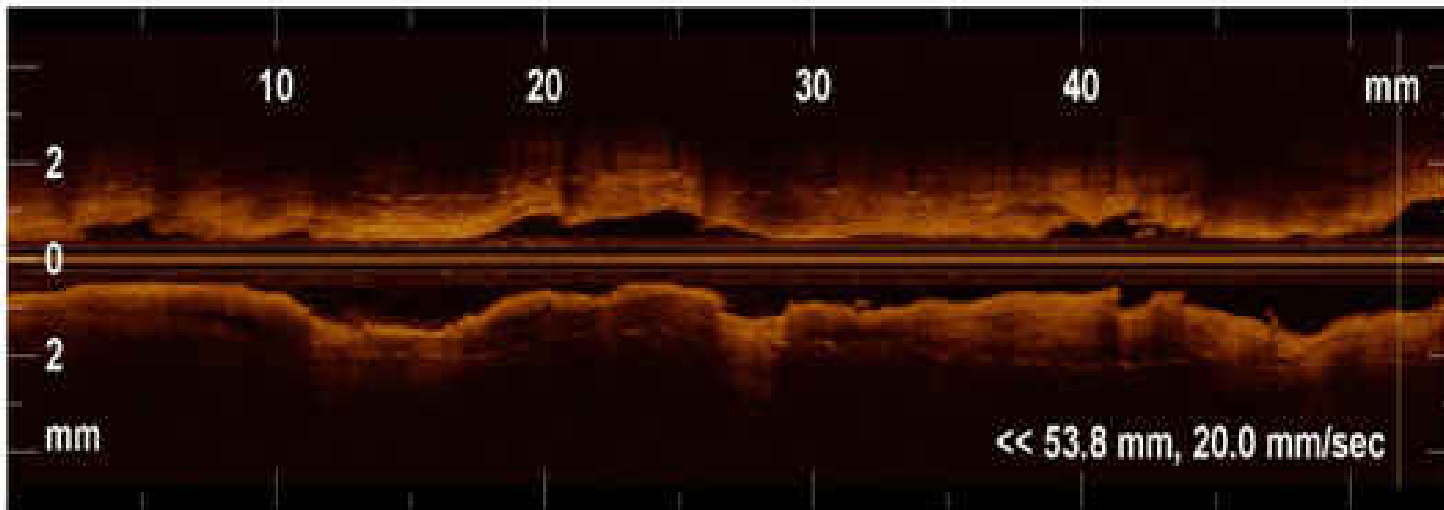
*Time and efficiency also factor into cost*



## BMS Occlusive recurrent-restenosis

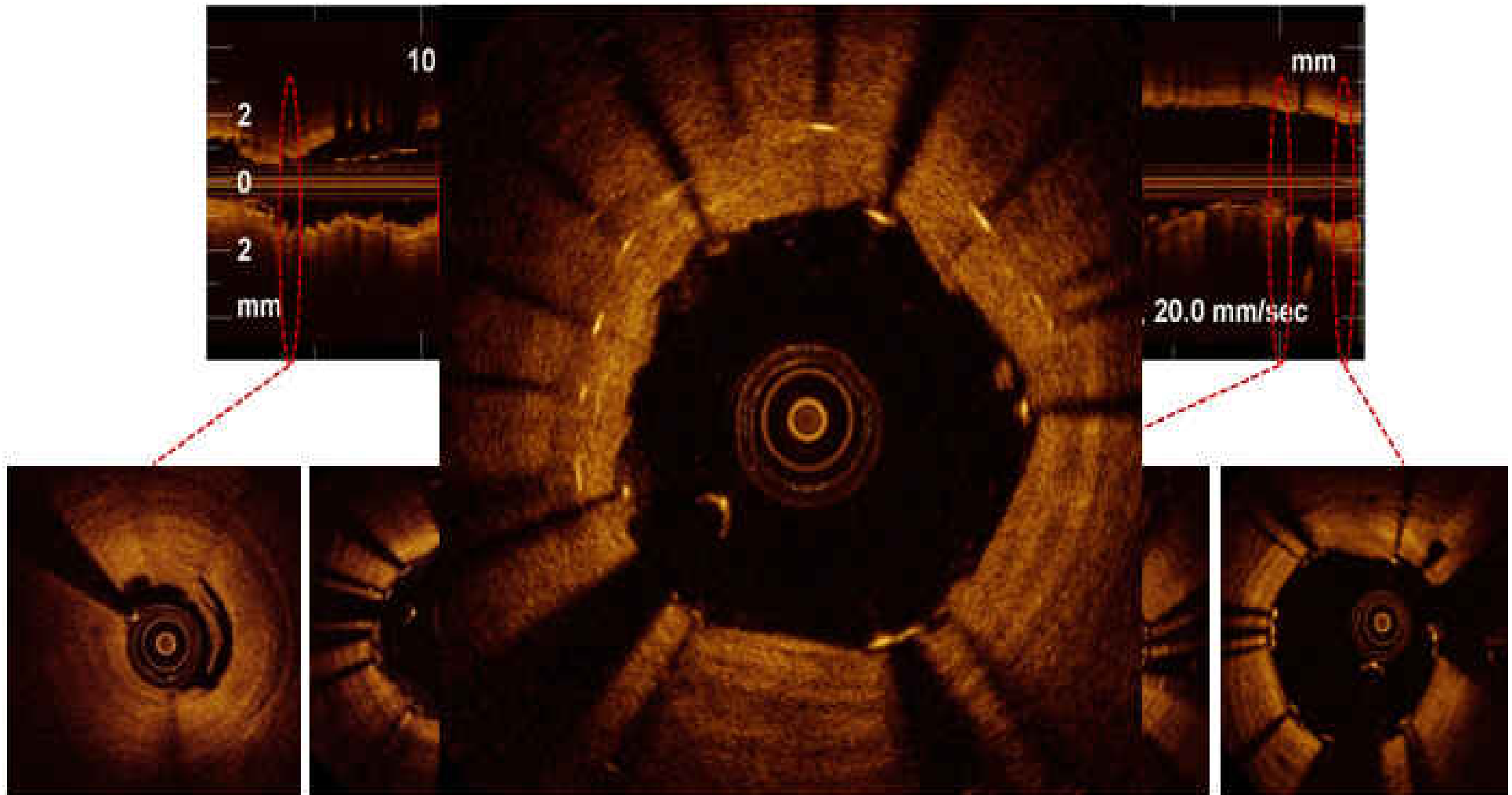


*Ospedali Riuniti di Bergamo, G. Guagliumi 2009*



Frame 236 of RCA:  
man-PB .jpg

# Post Cypher™ 2.5/23+3.0/28 mm

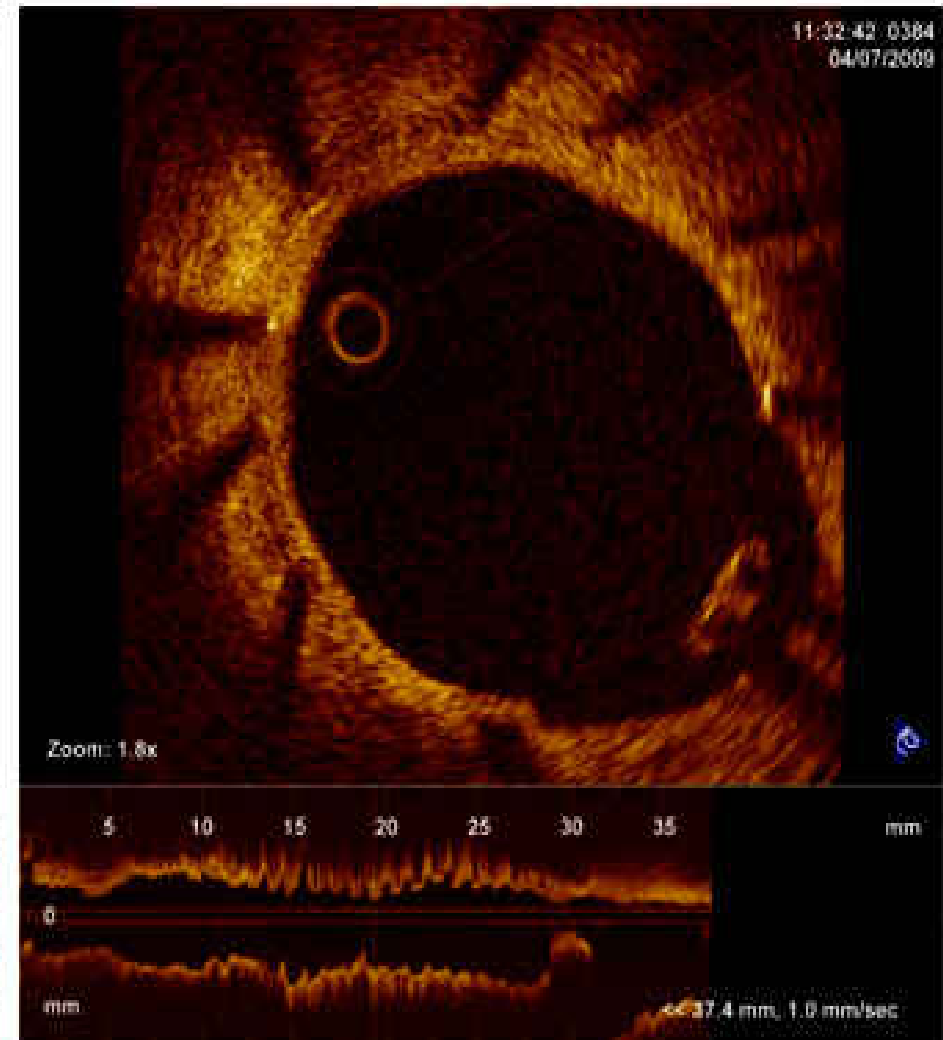
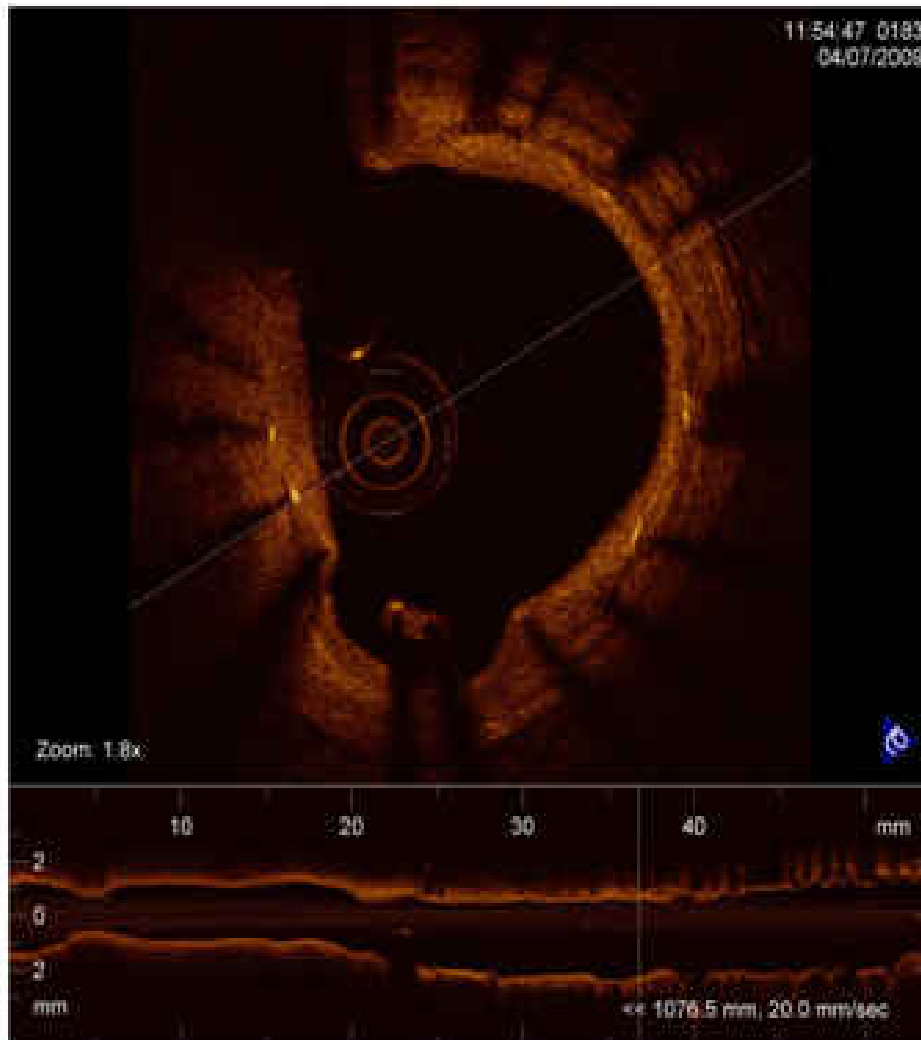


*Ospedali Riuniti di Bergamo, Guaghumi, 2009*

“ Takes to much time “

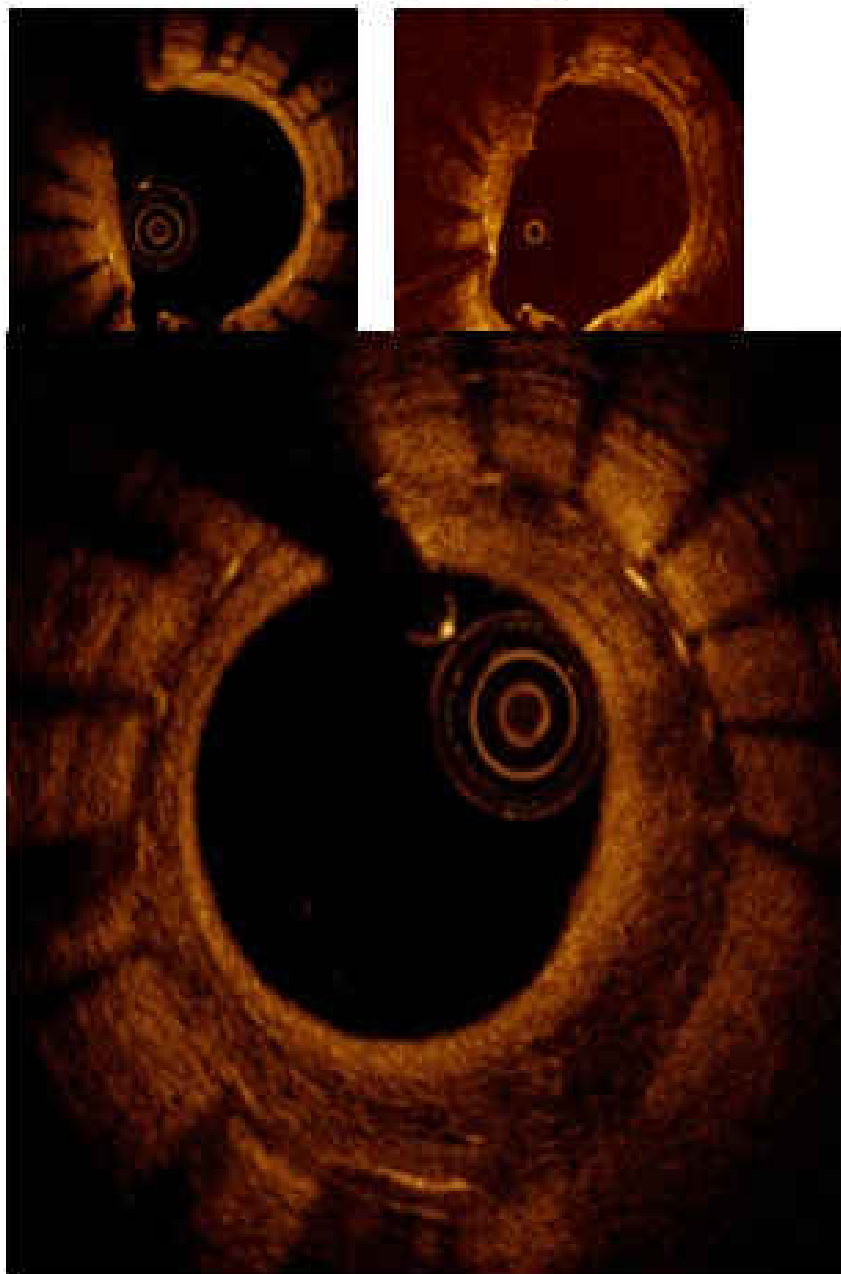
C7-XR FD-OCT (20.0 mm/sec)-55 mm=3 sec

M3 TD-OCT (1mm/sec)-40 mm=40 sec

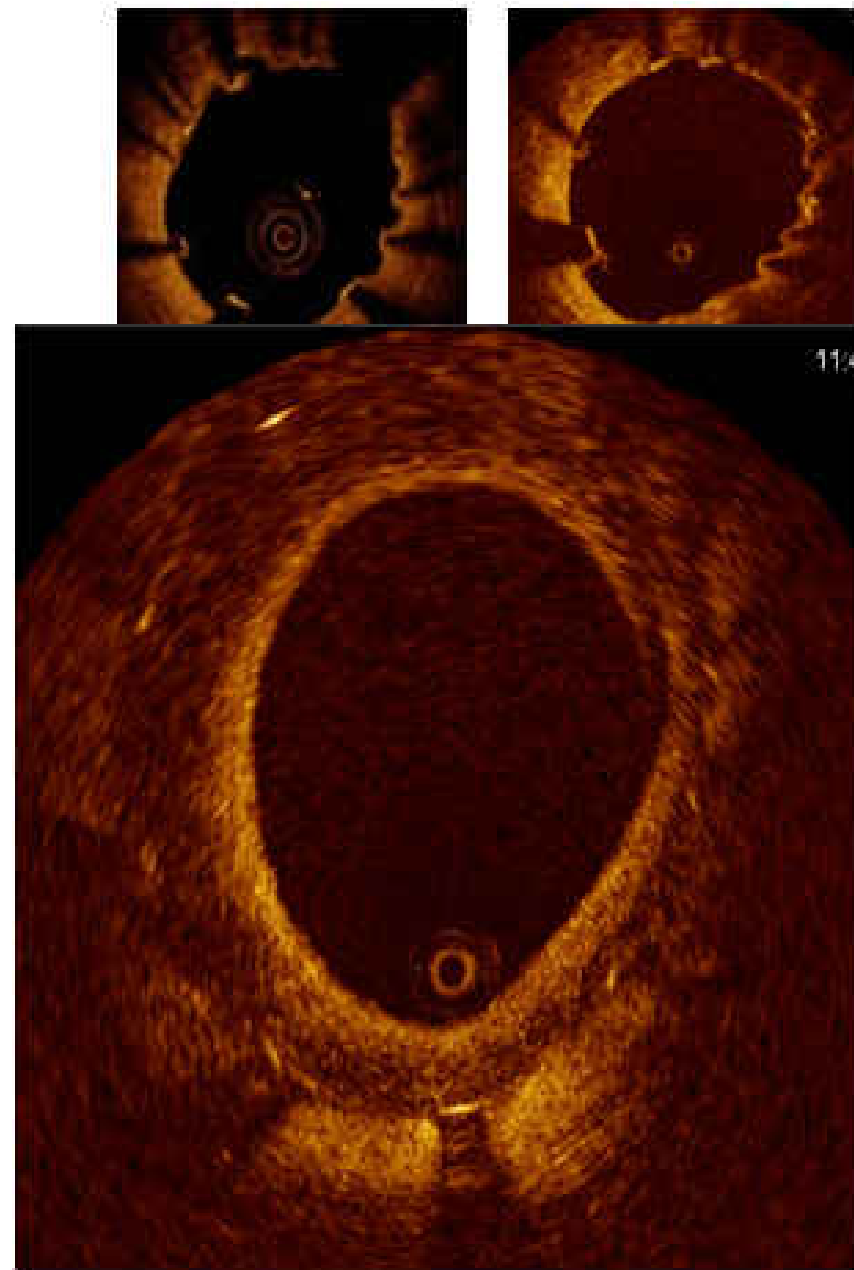


*Ospedali Riuniti di Bergamo, March, 2009*

“Difficult image interpretation” ?



*C7-XR vs M3 pair assessment*

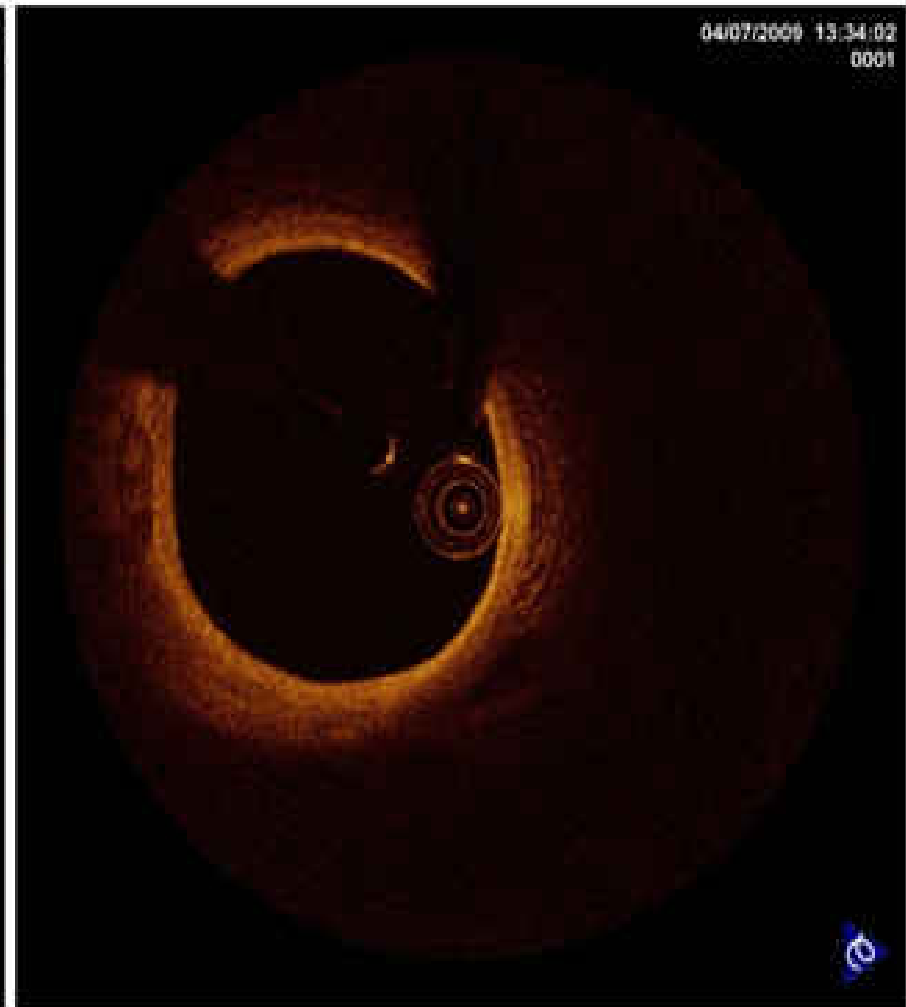
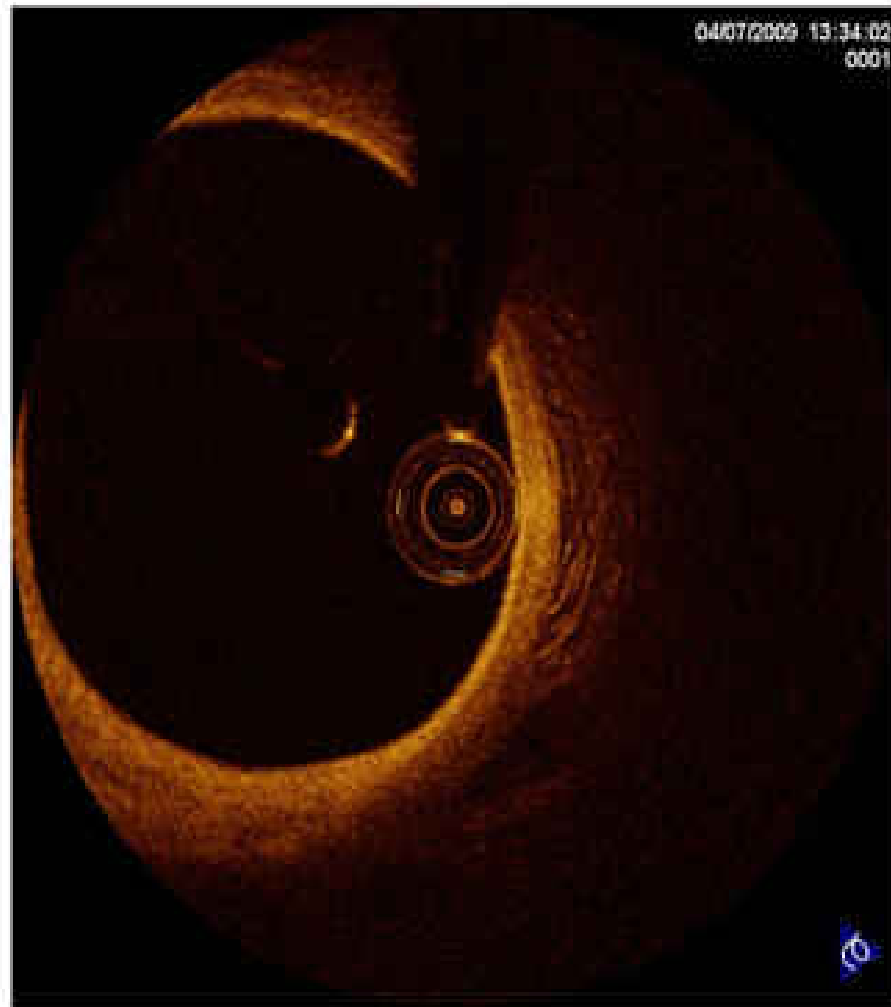


# Artifacts and out of screen imaging

*Scan diameter (in saline) 10.5 mm C7-XR vs 6.8 mm M3*

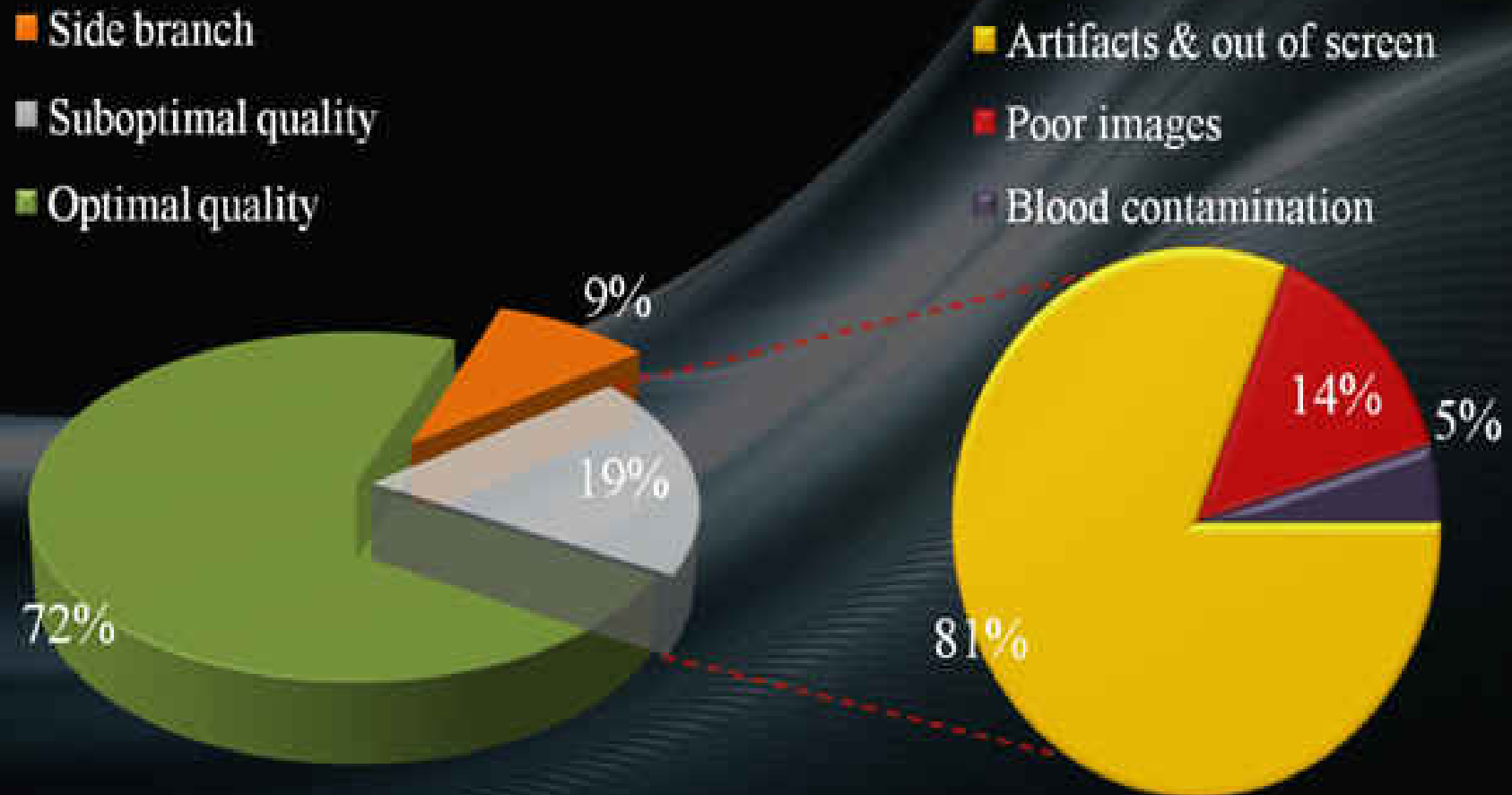
Zoom in

Zoom out



# HORIZONS OCT Analysis Status

*10,749 frames: Independent Core Laboratory Analysis*

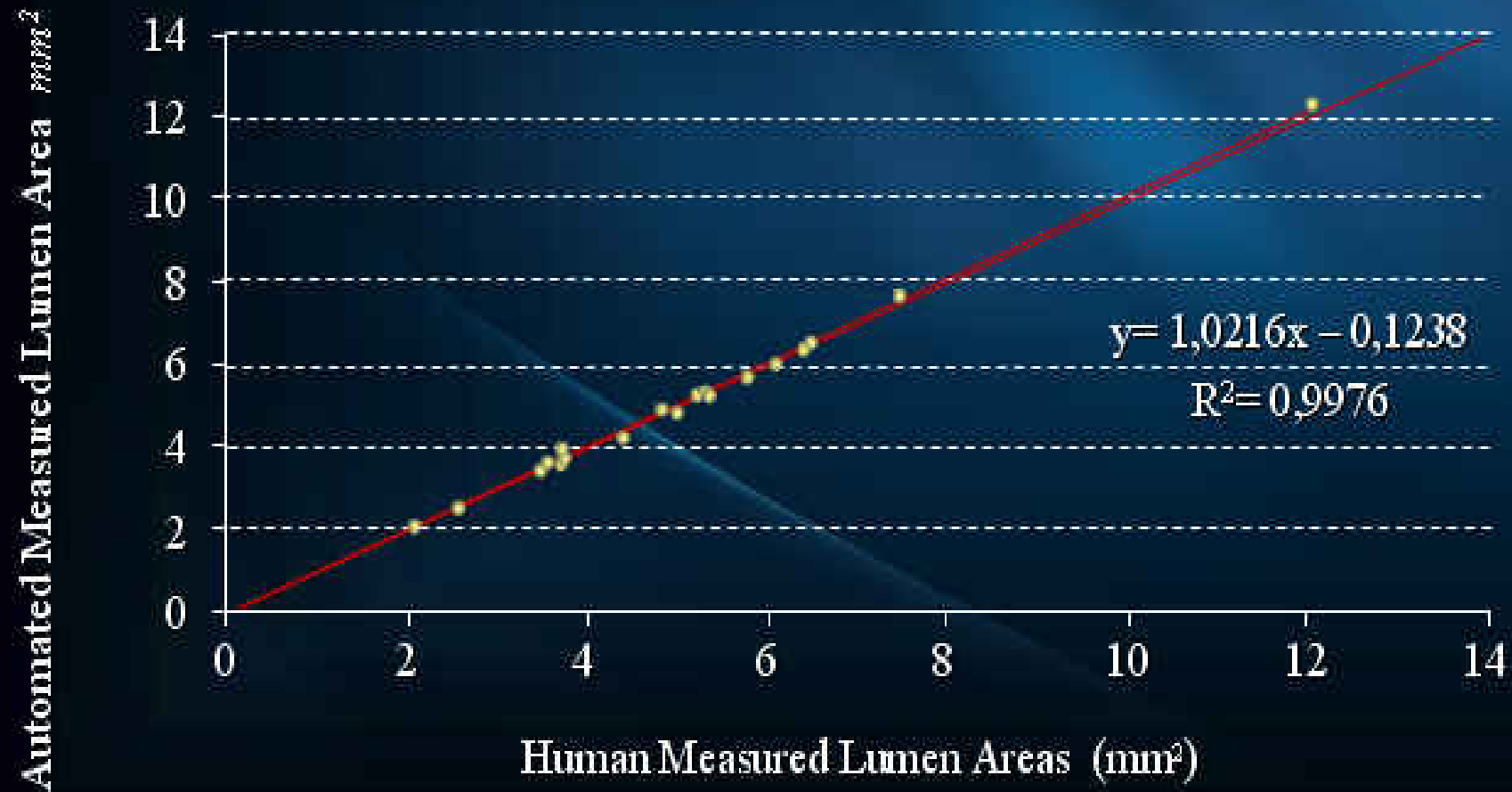


*G. Guagliumi AHA 2008, Late Breaking Clinical Trials*

# Full Automated vs Human OCT Lumen Area Measurements

## Regression Analysis

2-5 sec/frame, only 3% of contour data correction





# OCT vs IVUS: Technical Characteristics

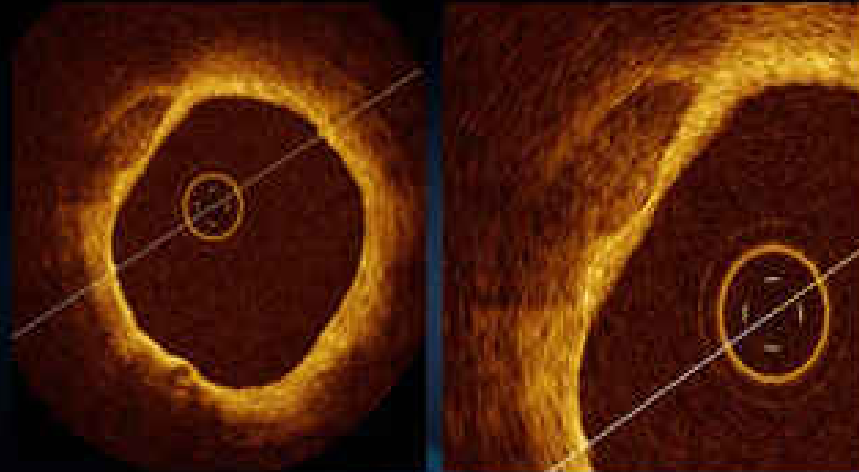
Specifications are projections/approximations

	<b>Current FD-OCT</b>	<b>Current IVUS*</b>	<b>Future IVUS**</b>
Resolution (axial x lateral)	12 x 19 $\mu\text{m}$	120 x 540 $\mu\text{m}$	70 x 140 $\mu\text{m}$
Max. frame rate	100 fps	30 fps	90 fps
Lines per frame	500	100	200
Pullback speed	20 mm/sec	0.5-1.0 mm/sec	10 mm/sec
Profile	2.7 Fr	3.2 Fr	2.4 Fr
Depth penetration (into tissue)	2 mm	4-8mm <sup>†</sup>	4-7mm
Guide catheter compatibility	6 Fr	6 Fr	5 Fr
Ability to image through blood	No	Yes	Yes

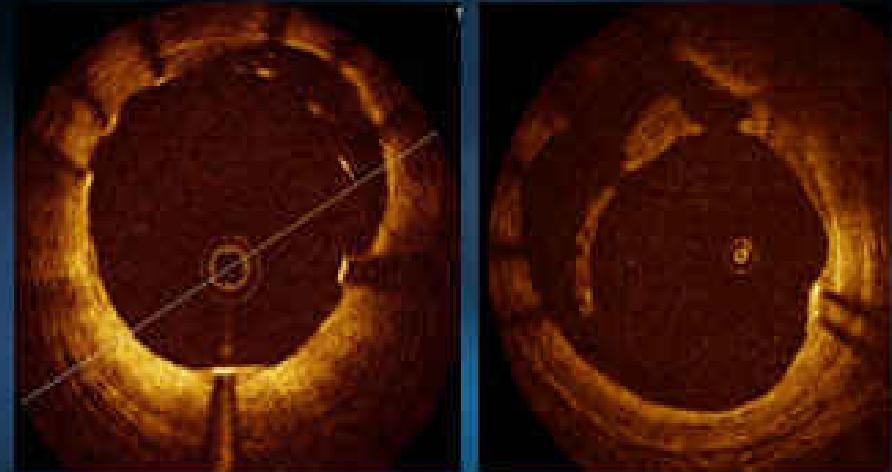
*\*Source: Provided by Boston Scientific unless otherwise noted.*

*\*\*Source: Internal estimates provided by Boston Scientific unless otherwise noted.*

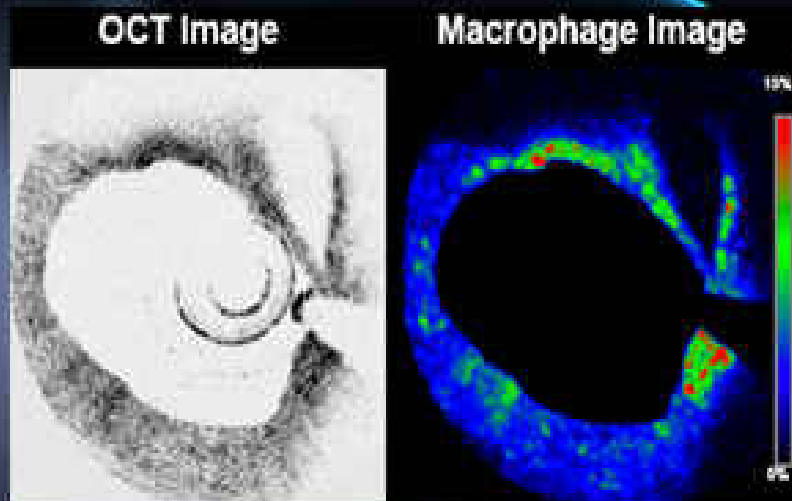
## TCFA Characterisation



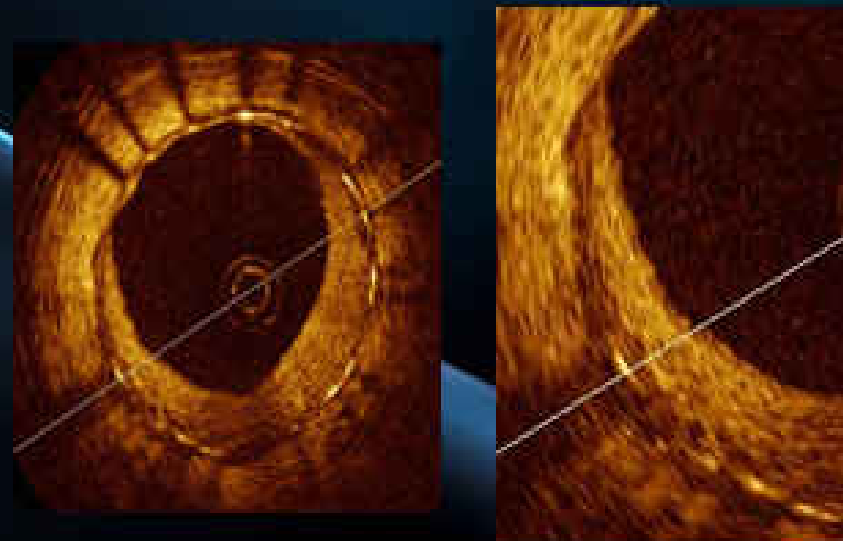
## Stents



## Macrophages



## Coverage/neointima/healing



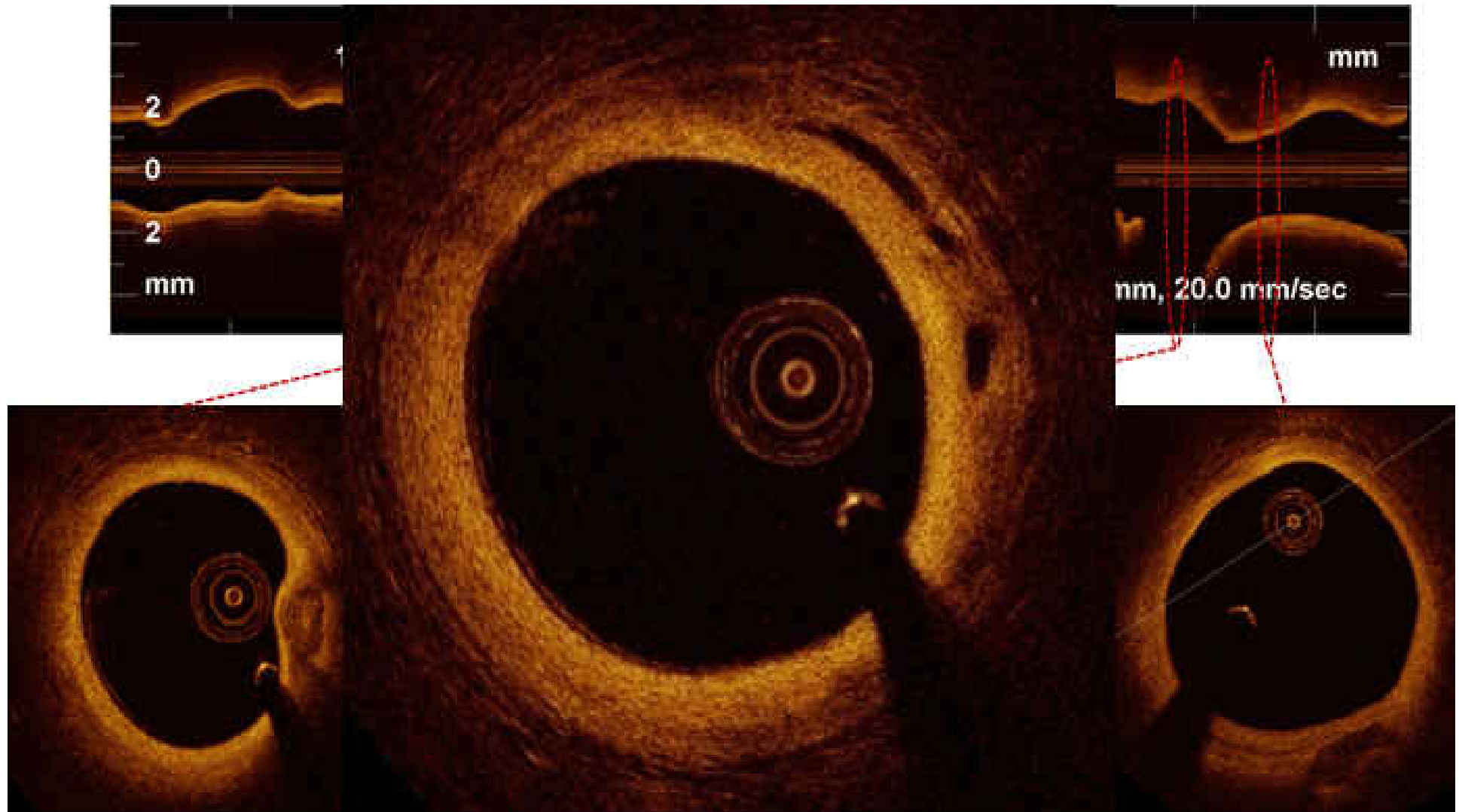
## Comparison of Lumen Border and Vessel Visibility

### OCT vs IVUS imaging

	Lumen Border		Vessel Border	
	OCT (n=98)	IVUS (n=98)	OCT (n=98)	IVUS (n=98)
Good	88	81	5	55
Fair	4	0	7	7
Poor	6	17 <sup>†</sup>	86	36
<i>p</i>	0.037		< 0.0001	

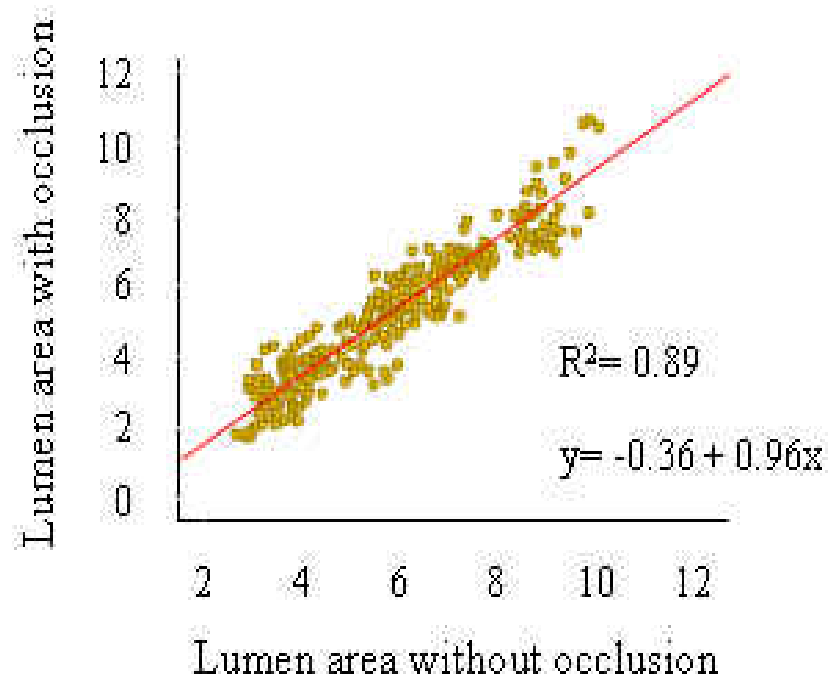
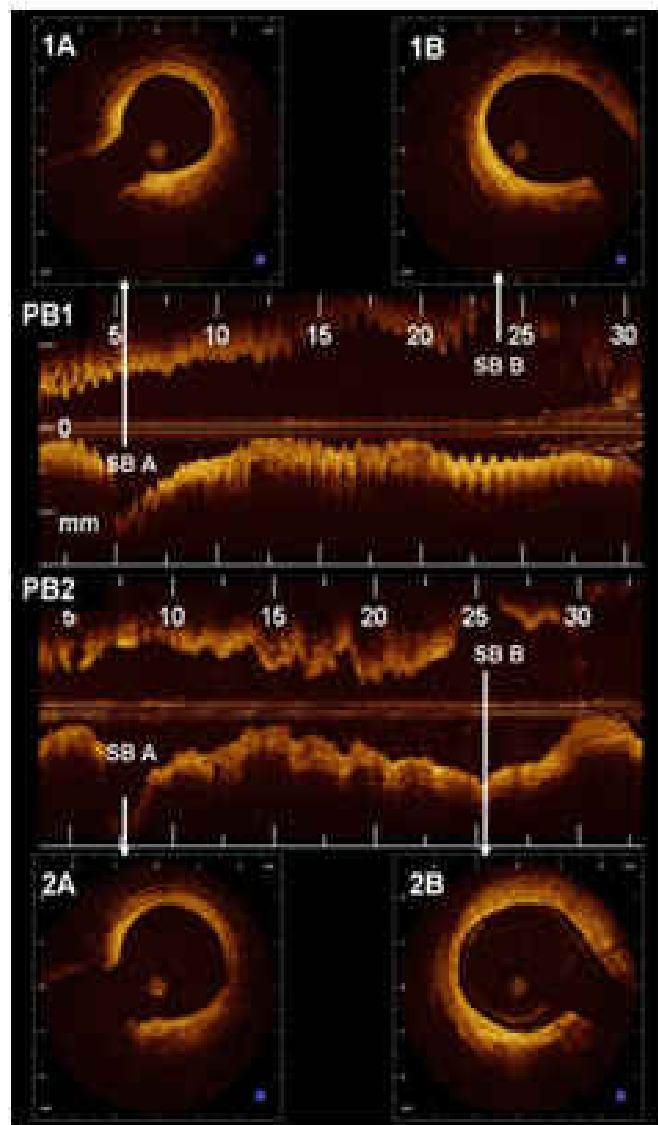
\*IVUS catheter was wedged

# “ The Race to Break the Gold Standard “

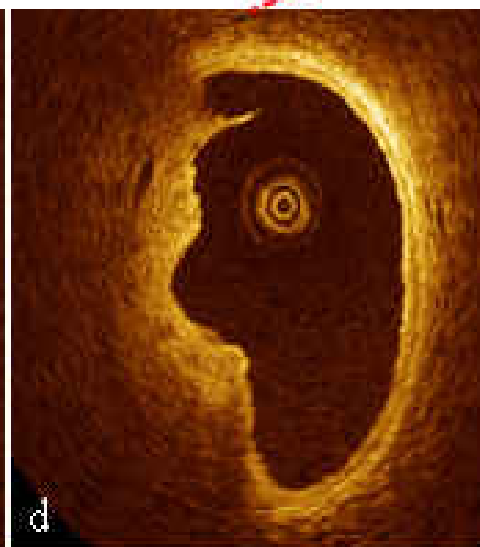
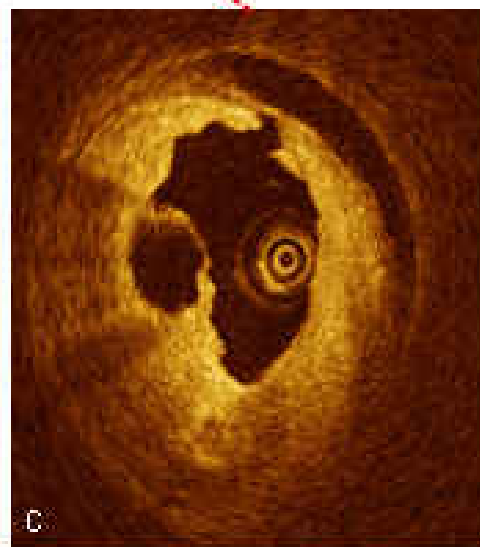
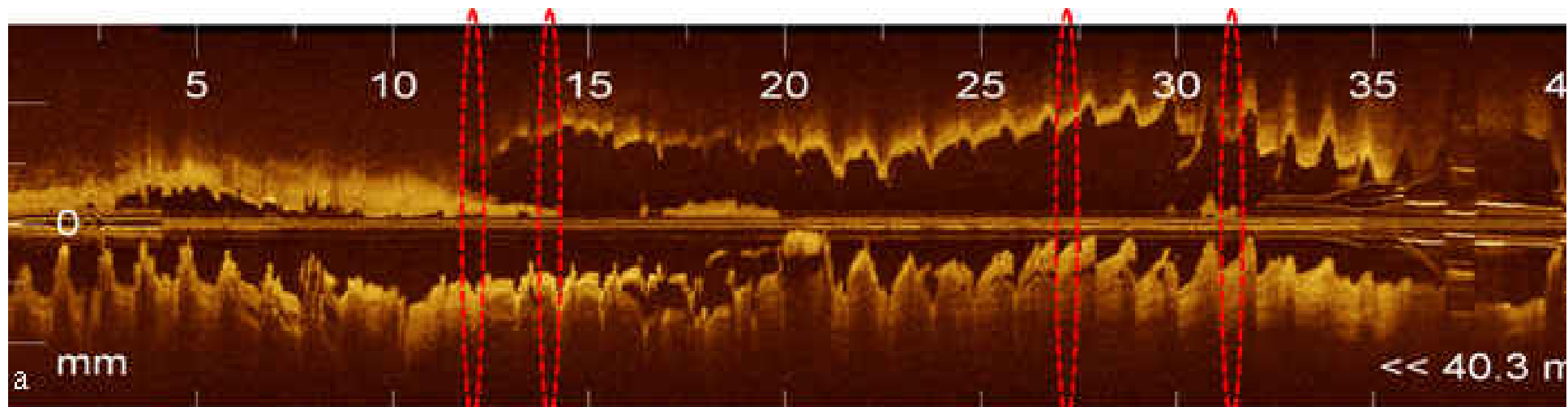


G. Guagliumi and R. Virmani *EDITORIAL COMMENT* Revista Española de Cardiología 2009, in press

# Quantitative *Ex-vivo* and *In-vivo* Comparison of Lumen Dimensions Measured by OCT and IVUS in Human Coronary Arteries

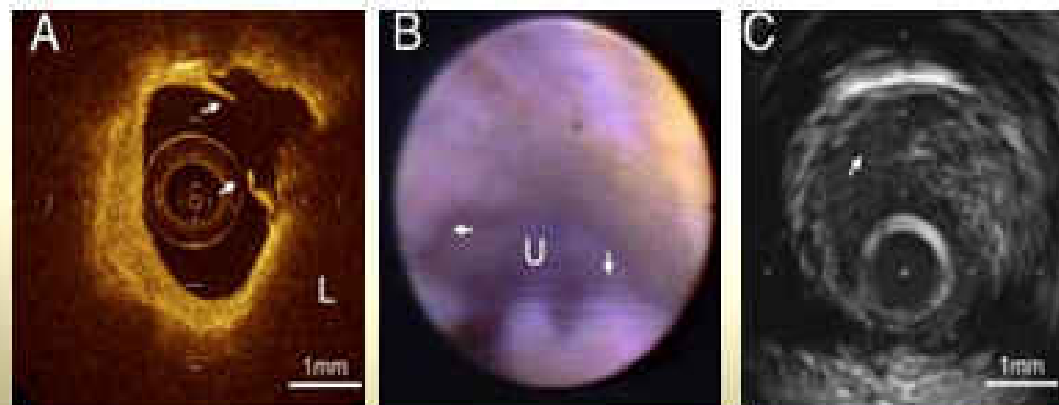


# Plaque Morphology



# OCT identifies plaque rupture, cap erosion and TCFA

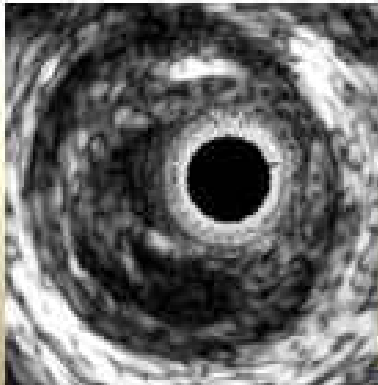
OCT vs AS vs IVUS: 30 AMI pts



<i>Finding</i>	OCT (n=30)	AS (n=30)	IVUS (n=30)	P
Fibrous cap disruption	73% *†	47%	40%	0.021
Fibrous cap erosion	23% *†	3%	0%	0.003
Thrombus	100% †	100% ‡	33%	< 0.001

\* OCT vs AS,  $p < 0.05$ . † OCT vs IVUS,  $p < 0.01$ . ‡ AS vs IVUS,  $p < 0.01$ .

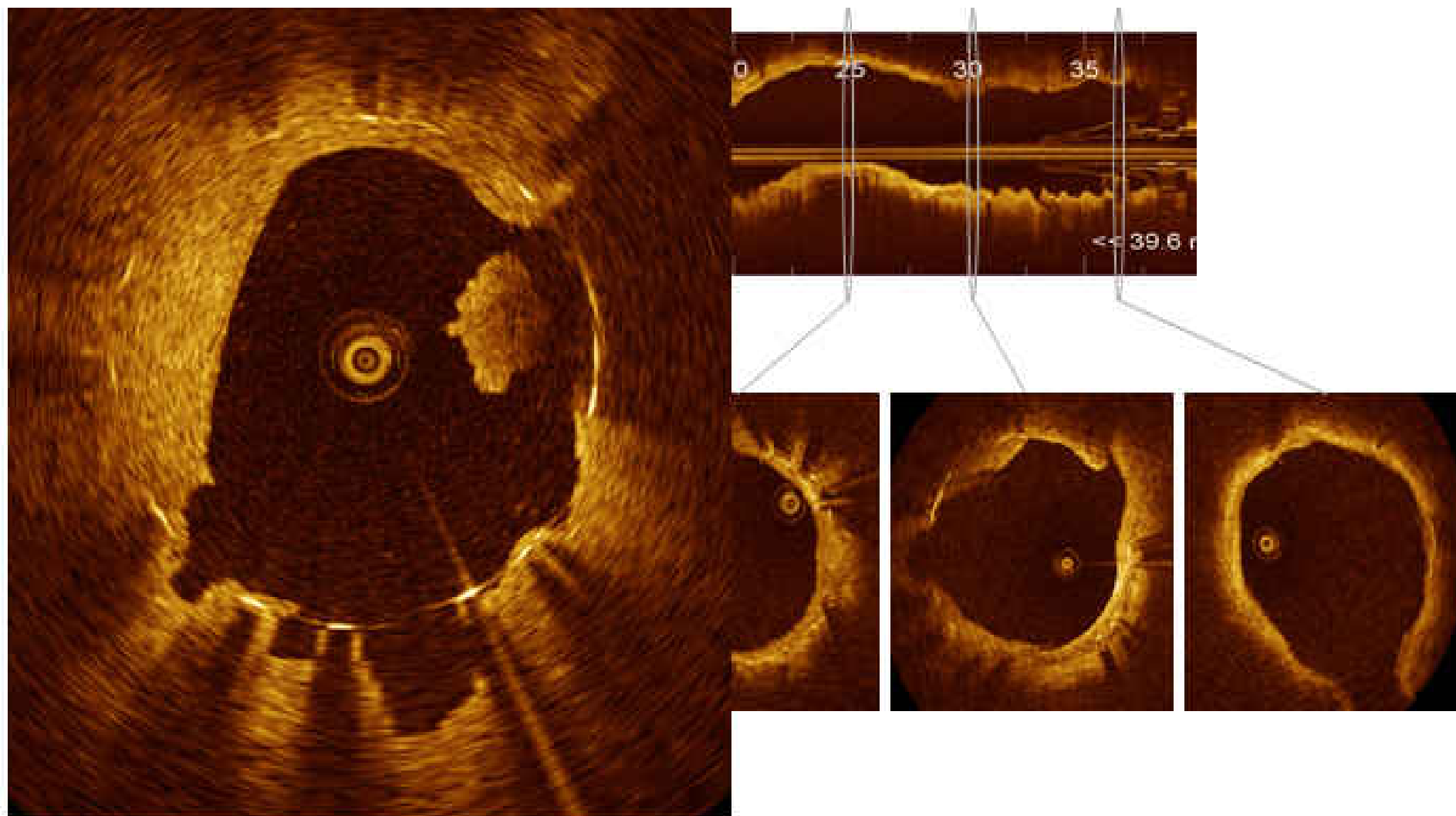
## Impact of Intramural Thrombus on the Accuracy of Tissues Characterization by VH-IVUS



### In-vitro histologic correlation analysis obtained by DCA

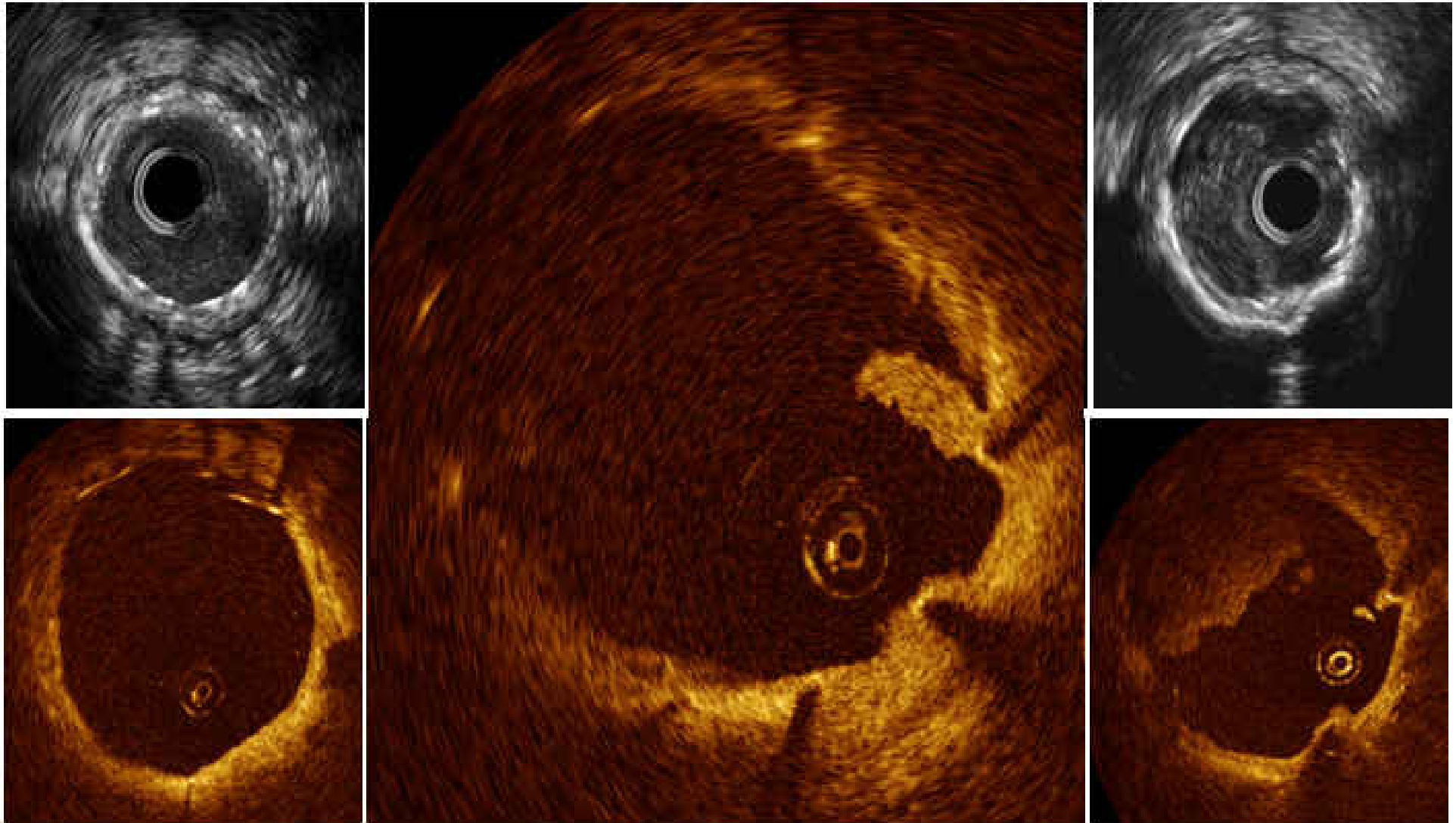
	<i>Sensitivity</i>		<i>Specificity</i>		<i>Predictive Accuracy</i>	
	<b>Th (+)</b> (N = 81)	<b>Th (-)</b> (N = 173)	<b>Th (+)</b> (N = 81)	<b>Th (-)</b> (N = 173)	<b>Th (+)</b>	<b>Th (-)</b>
Fibrous tissue	100%	100%	<b>36%</b>	<b>94%</b>	<b>78%</b>	<b>99%</b>
Fibrofatty plaque	100 %	100 %	<b>9%</b>	<b>60%</b>	<b>68%</b>	<b>83%</b>
Necrotic core	100 %	89%	77%	84%	88%	85%
Dense calcium	100 %	100%	94%	99%	94%	99%





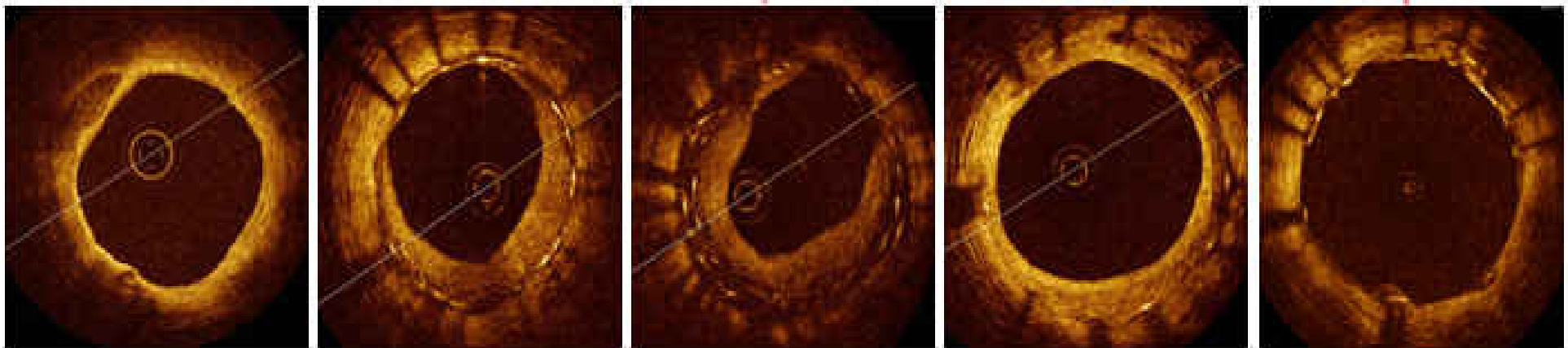
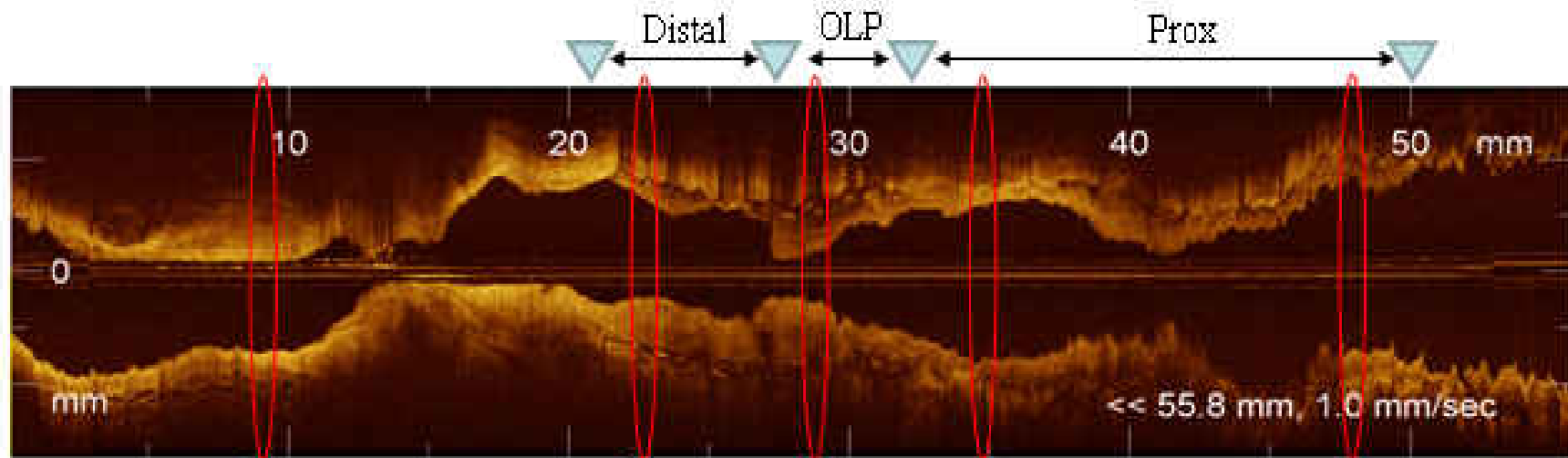
## In-vivo mechanisms of DES late and very late stent thrombosis

*Mean time 729 days (485-1836 days after implant)*



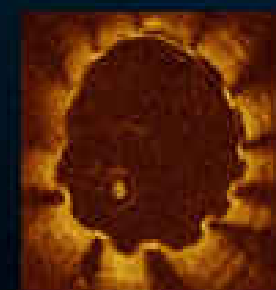
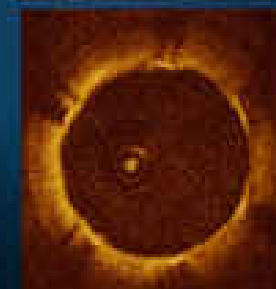
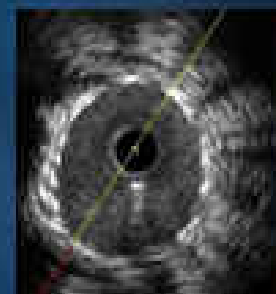
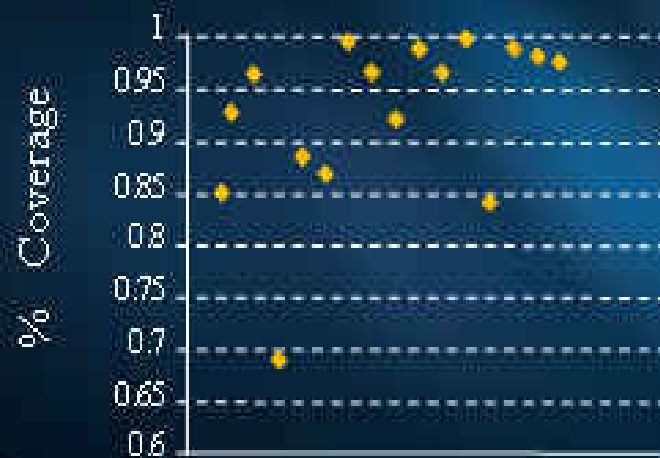
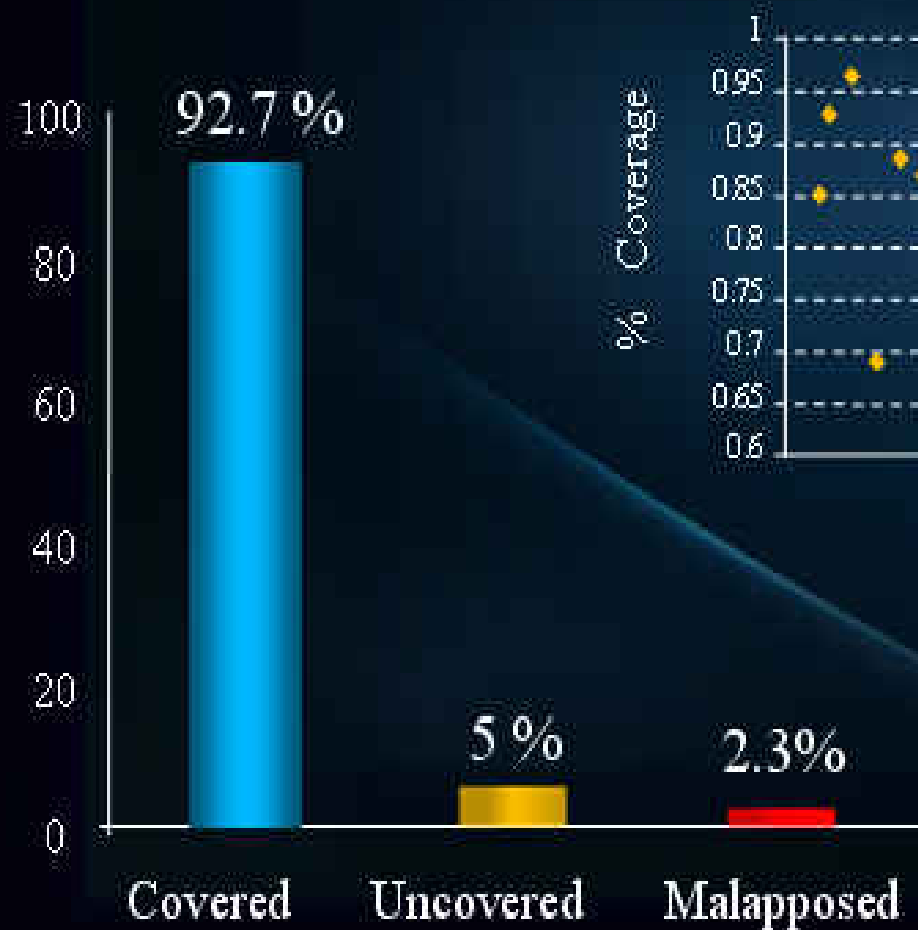
## ODESSA -long lesions requiring overlap-

6 mos analysis: 53.047 struts in 6968 cross-sections



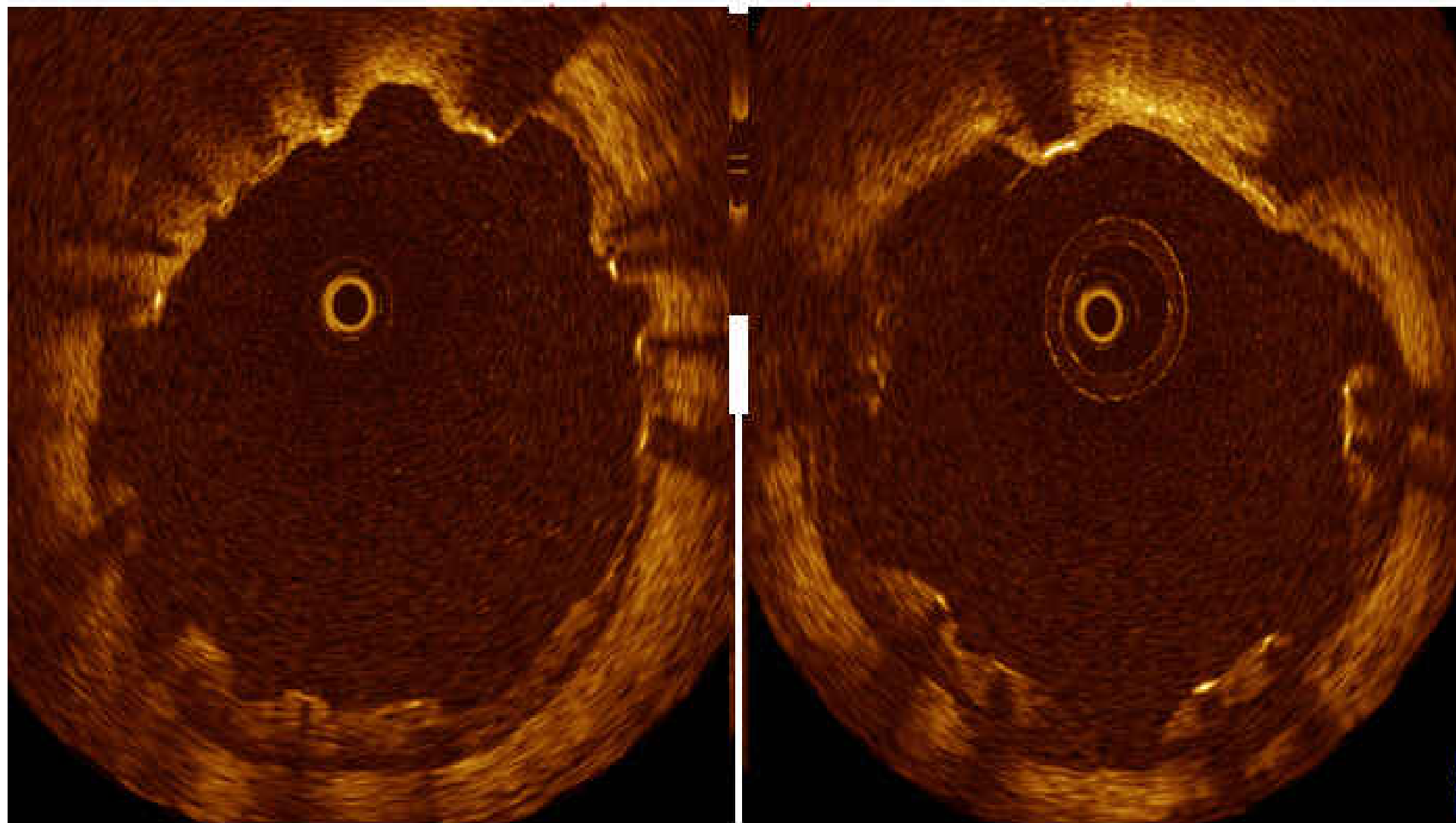
# "Zero" IVUS NIH and no Malapposition interrogated with OCT

*Subanalysis of the ODESSA Trial: 250 stented segments, 6968 cross-sections*



*LAD TAXUS 3.0/20 mm*

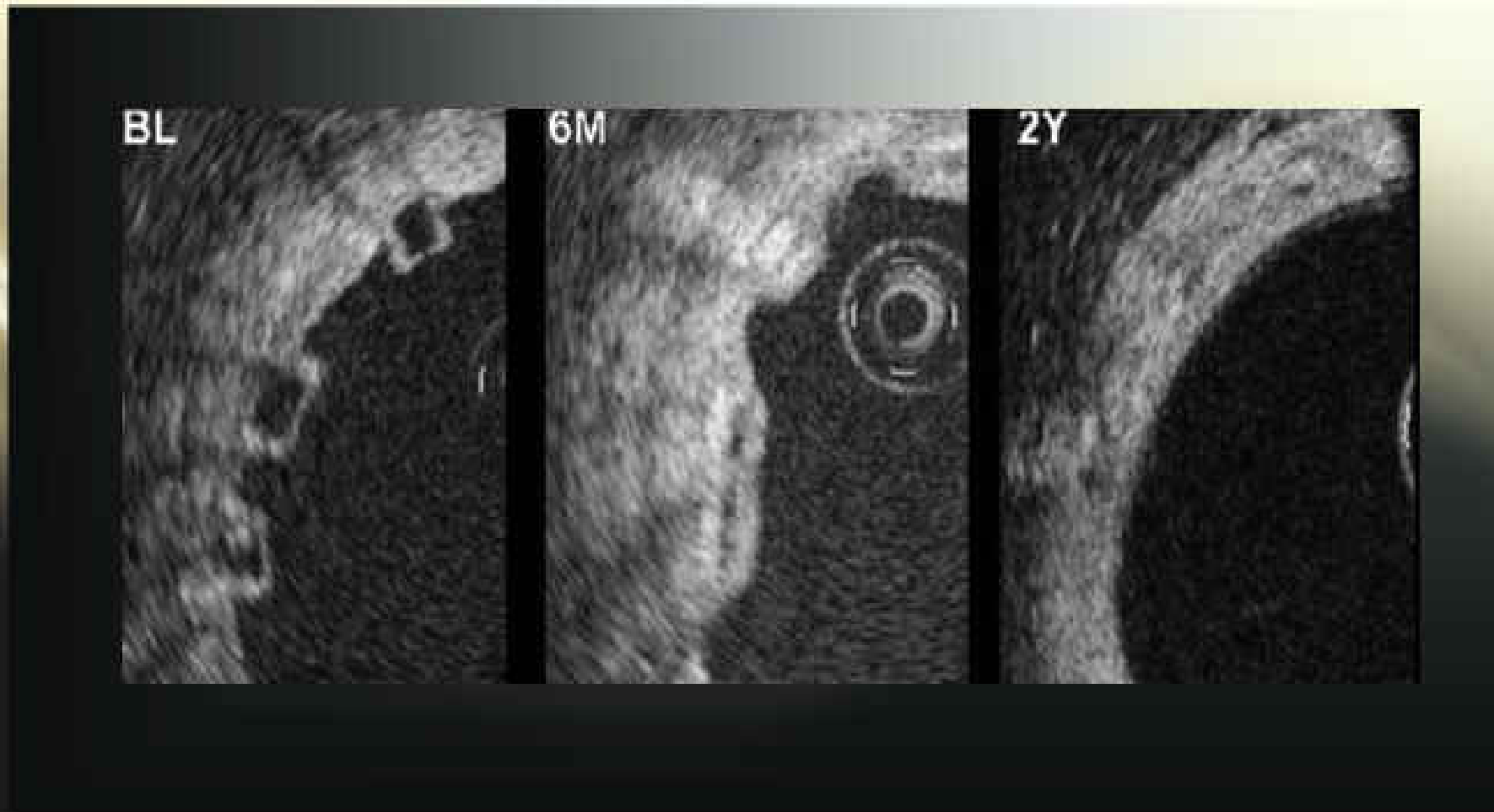
*VLST*



*Ospedali Riuniti di Bergamo, December 2008*

## OCT Findings at 2 Years FU in Fully Biodegradable Everolimus DES

*Majority of stent struts were covered and apposed, without intraluminal thrombi*



*Gonzalo N et al., Circulation 2008;118:S 1043*

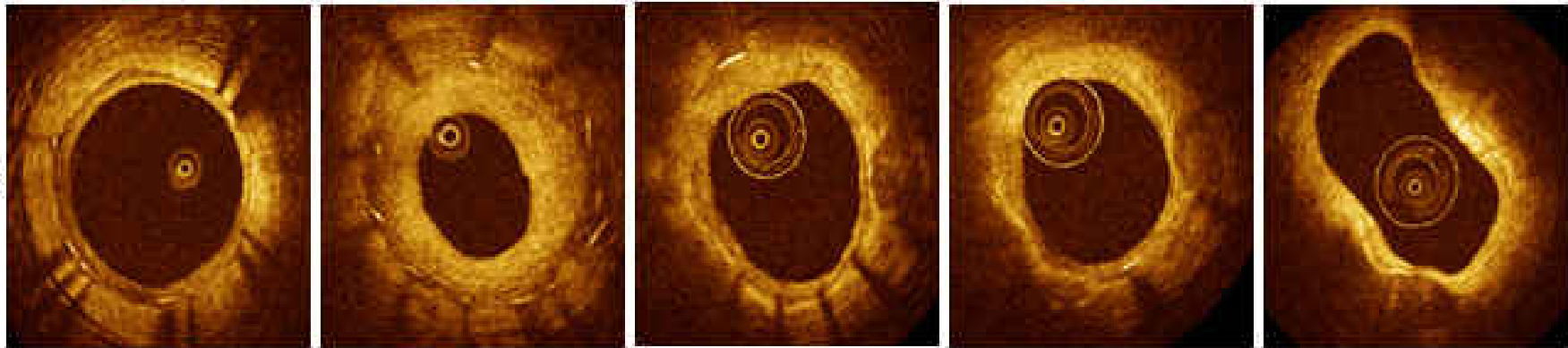
***OCTAXUS TRIAL***

**LAD DES 2.5/24 mm**

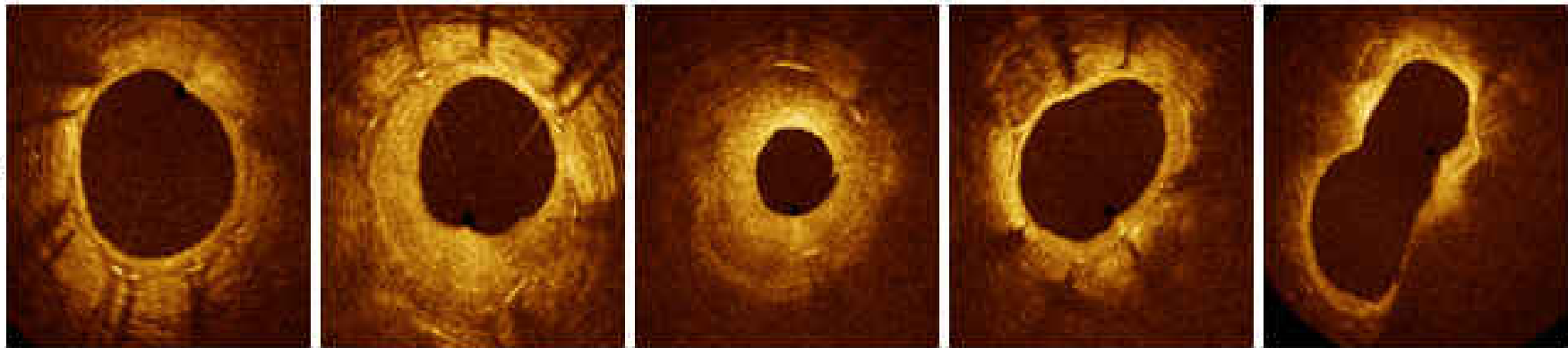
***index***



***3 mos***

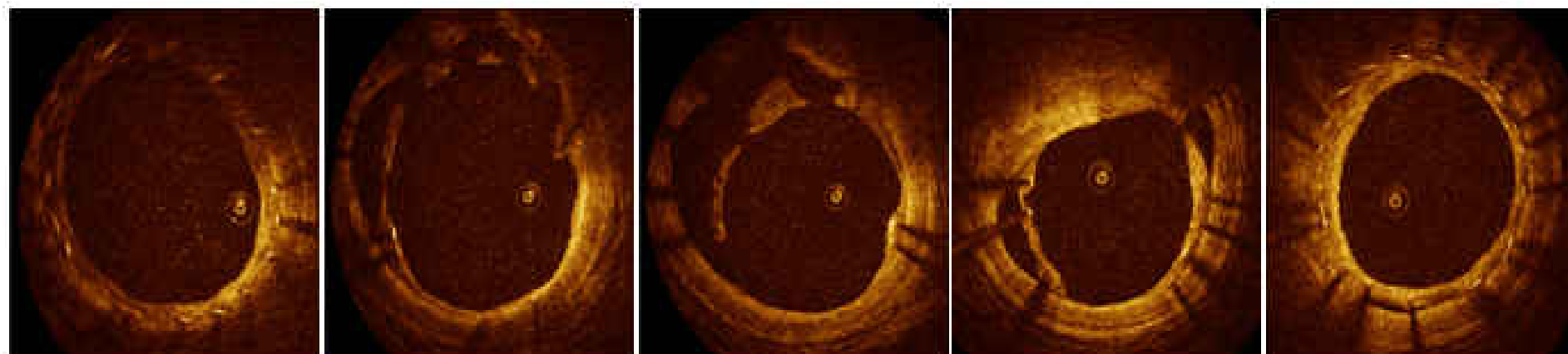
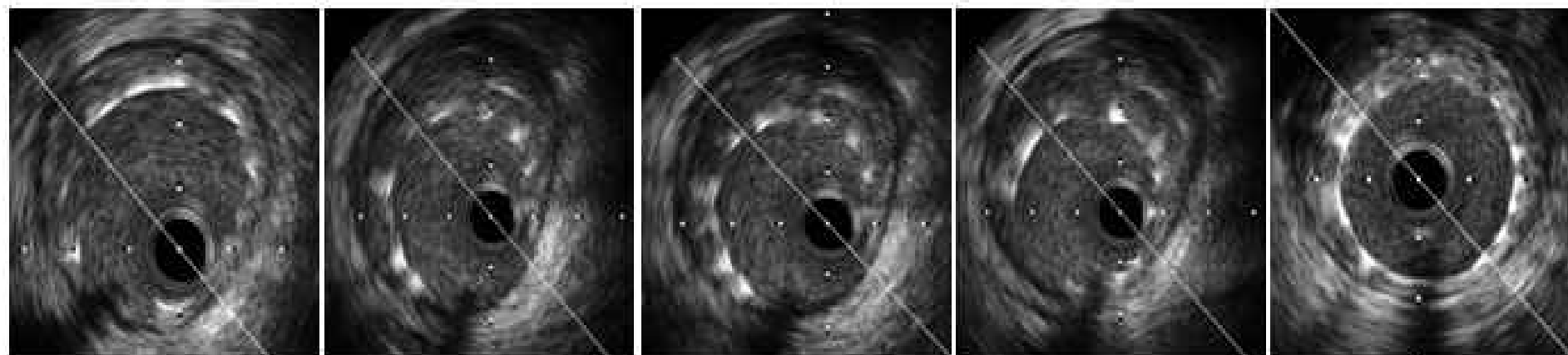


***9 mos***



# 302 OCT-IVUS Procedures in 290 Consecutive pts -556 Stents Analyzed-

*Safety and Feasibility in Real World Stented Patients*



*V. Sirbu et al Am J Cardiol 2008 ; 102 suppl 8 abstract 526*



# Multi-Modality Integration



Tomorrow's *integrated* cath lab will be equipped with:

- OCT
- Phased Array IVUS
- Rotational IVUS
- Peripheral IVUS
- FFR
- ICE
- VH IVUS
- ChromaFlo
- Image Guided Therapy
- Forward Looking IVUS
- Others...

Some items under development and not commercially available at this time

*Courtesy Volcano Corporation, Rancho Cordova*