

# Identification of Vascular Responses to Coronary Stenting by Optical Coherence Tomography - A Sub-analysis From The Japanese Multi-center Safety Trial -

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# Safety and Feasibility of a Novel Intravascular Optical Coherence Tomography (OCT) Image Wire System in a Clinical Setting -Japanese Multi-center Study-

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# Safety and Feasibility of an Intravascular Optical Coherence Tomography Image Wire System in the Clinical Setting

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Optical coherence tomography (OCT) is a fiber-optic technology that enables high-resolution intracoronary imaging. The aim of this study was to evaluate the safety and feasibility of intracoronary imaging with OCT in the clinical setting; 76 patients with coronary artery disease from 8 centers were enrolled. The OCT imaging system (ImageWire, Light Imaging Inc., Westford, Massachusetts) consists of a 0.006 inch fiber-optic core that rotates within a 0.016 inch transparent sheath. OCT imaging was performed during occlusion of the artery with a compliant balloon and continuous flushing. Intravascular ultrasound (IVUS) imaging was performed in the same segments. We assessed the safety and feasibility of the OCT imaging, compared with IVUS. Vessel occlusion time was  $48.3 \pm 13.5$  seconds and occlusion-balloon pressure was  $0.4 \pm 0.1$  atmospheres. Flushing with lactated Ringer's solution was performed at a rate of  $0.6 \pm 0.4$  ml/s. No significant adverse events, including vessel dissection or fatal arrhythmia, were observed. Procedural success rates were 97.3% by OCT and 94.5% by IVUS. The OCT image wire was able to cross 5 of 6 tight lesions that the IVUS catheter was unable to cross. Of the 98 lesions in which both OCT and IVUS were successfully performed, OCT imaging had an advantage over IVUS for visualization of the lumen border. Minimum lumen diameter and area measurements were significantly correlated between OCT and IVUS imaging ( $r = 0.91$ ,  $p < 0.0001$  and  $r = 0.95$ ,  $p < 0.0001$ , respectively). In conclusion, this multicenter study demonstrates the safety and feasibility of OCT imaging in the clinical setting. © 2008 Elsevier Inc. All rights reserved. (Am J Cardiol 2008;101:xxx)

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# OCT Japanese Multi-center Study

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**This OCT Japanese multi-center study was designed to evaluate the safety and feasibility of a novel intravascular OCT imaging system in a clinical setting, compared with IVUS**

# Investigators

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## Primary Investigators:

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Takahiko Suzuki M.D.

*Toranomon Hospital  
Toyohashi Heart Center*

## Investigators:

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Takahiro Hayashi M.D.  
Kyoichi Mizuno M.D.  
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## Core lab:

Mitsuyasu Terashima M.D.

*Cardiovascular Imaging Center (CVIC)*

# Enrolled Patients

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**76 cases from 8 centers**

**December 2004 ~ May 2005**

**Target: native coronary artery**

**stenosis < 99%**

**lesion length < 20mm**

**36 cases: Diagnostic coronary angiogram (CAG)**

**40 cases: Coronary intervention (PCI)**

# Objective & Methods

- Safety & Procedure Success Rate (vs. IVUS)
- Qualitative Analysis (vs. IVUS)

## 1. Visibility of Lumen Border at the Lesion

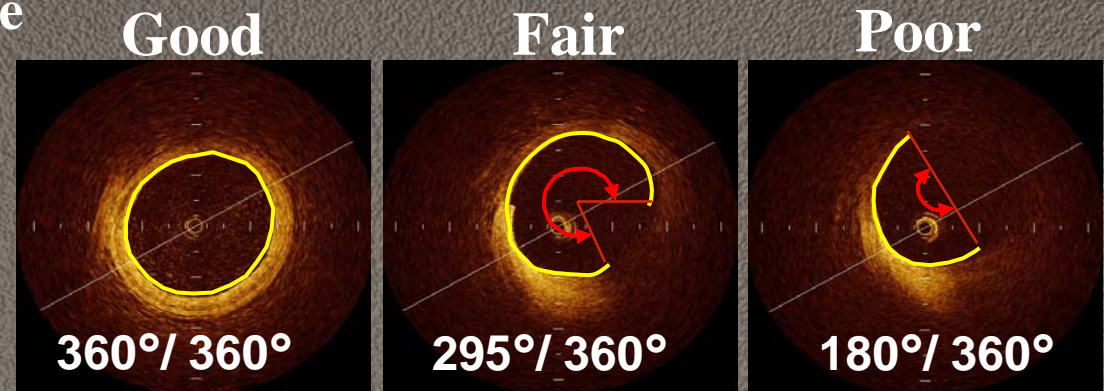
Good: Visible on entire circumference

Fair:  $\geq 75\%$  of circumference

Poor:  $< 75\%$  of circumference

## 2. Visibility of Vessel Border at the Lesion

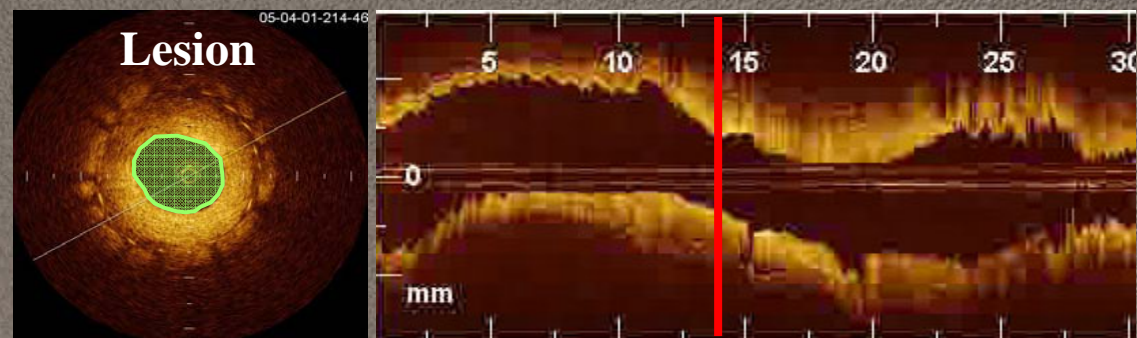
Good, Fair, Poor (as described above)



- Quantitative Analysis (vs. IVUS)

## 1. Minimal Lumen Diameter

## 2. Minimal Lumen Area



- IVUS: 40-MHz, Boston Scientific

# Procedural Success Rate

	OCT	IVUS
▪ Diagnostic Angiogram (n = 36)	36 (100%)	36 (100%)
▪ PCI		
Pre PCI (n = 40)	37 (92.5%) *1	34 (85%) *2
Post PCI (n = 34)	34 (100%)	34 (100%)
▪ Over all (110 procedures / 76 Pts )	107 (97.3%)	104 (94.5%)

\*1: OCT wire could not cross the lesion in one case.

OCT was not performed in 2 cases due to transient ST elevation during advancing a balloon occlusion-flushing catheter.

\*2: IVUS catheter could not cross the lesion in 6 cases.



# Conditions of Vessel Occlusion and Ringer's Solution Flushing

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Occlusion Time (sec)	$48.3 \pm 14.7$ (23 ~ 120 )
Occlusion Pressure (atm)	$0.4 \pm 0.1$ (0.2 ~ 1.0 )
Flush Volume (ml/sec)	$0.6 \pm 0.4$ (0.3 ~ 3.0 )
Flush Volume (ml/Pull Back)	$28.6 \pm 14.0$ (12 ~ 96 )
Injector Pressure (psi)	$108.9 \pm 24.7$ (94 ~ 200 )

# Adverse Events

n=76

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**Death**

**0**

**Q-wave MI**

**0**

**Fatal arrhythmia (VT,VF)**

**0**

**Dissection**

**0**

**Distal embolism**

**0**

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**Pre procedural CK-MB (%/ng/dl)**

**8.3 ± 4.7 (1.0 ~ 28.0)**

**Post procedural CK-MB (%/ng/dl)**

**9.5 ± 6.2 (1.0 ~ 35.0)**

# Conclusion

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- **This multi-center study demonstrates the safety and feasibility of the OCT image wire system for visualizing coronary lesions in a clinical setting.**
- **This OCT system also allows visualization of structures of coronary arteries with tight lesions.**

# Identification of Vascular Responses to Coronary Stenting by Optical Coherence Tomography - A Sub-analysis From The Japanese Multi-center Safety Trial -

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# Aim

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This study, which is a sub-analysis from the Japanese multi-center safety trial for the OCT imaging system, was conducted to evaluate potential advantages of OCT over intravascular ultrasound (IVUS) for identification of vascular response to coronary stenting.

# Subjects & Methods

## Subjects

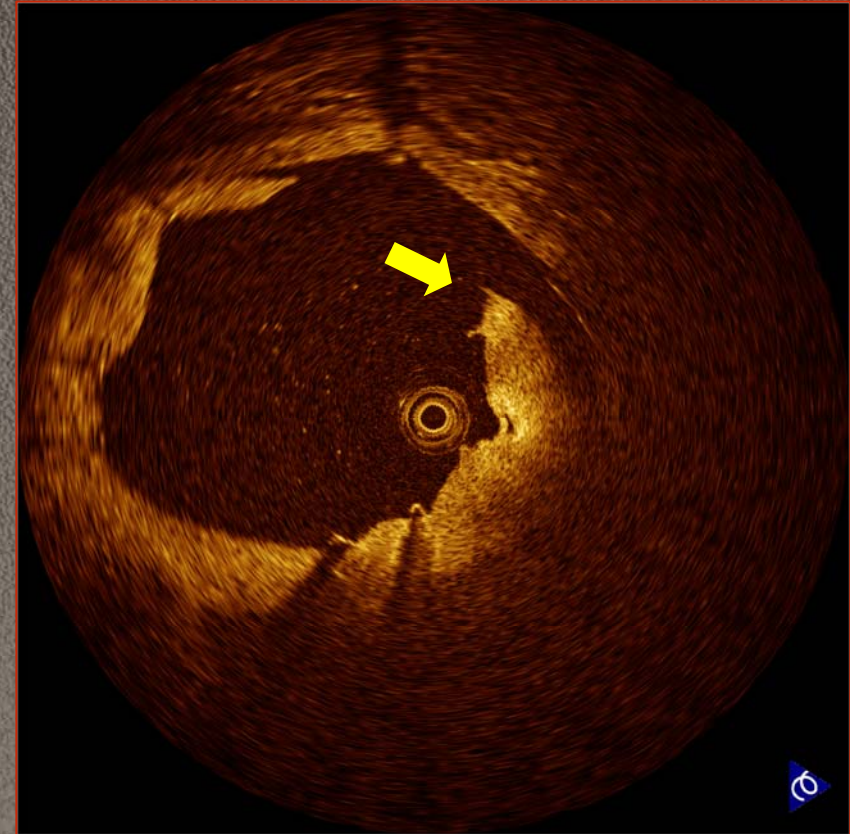
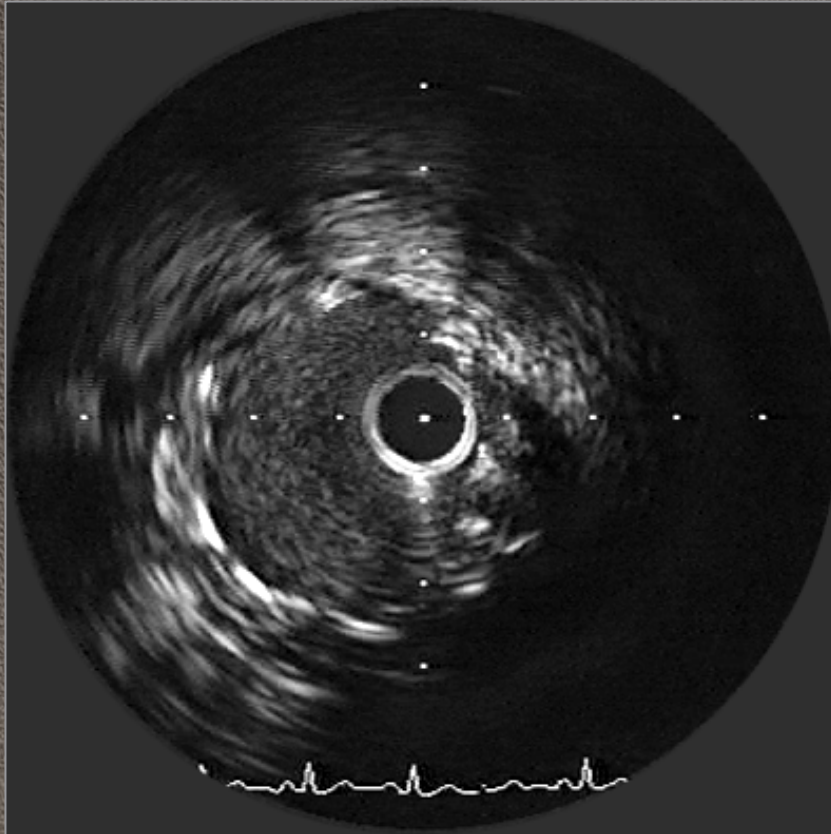
27 cases, in which both OCT and IVUS were performed following successful coronary stenting, were enrolled from the Japanese multi-center safety trial.

## Methods

Concerning the following vascular responses to coronary stenting, OCT and IVUS (40-MHz, Boston Scientific) records were independently evaluated, and frequencies of each response were compared.

- ✓ Intimal Flap
- ✓ Stent Incomplete Apposition
- ✓ Tissue Prolapse
- ✓ Thrombus

# Intimal Flap (Dissection)



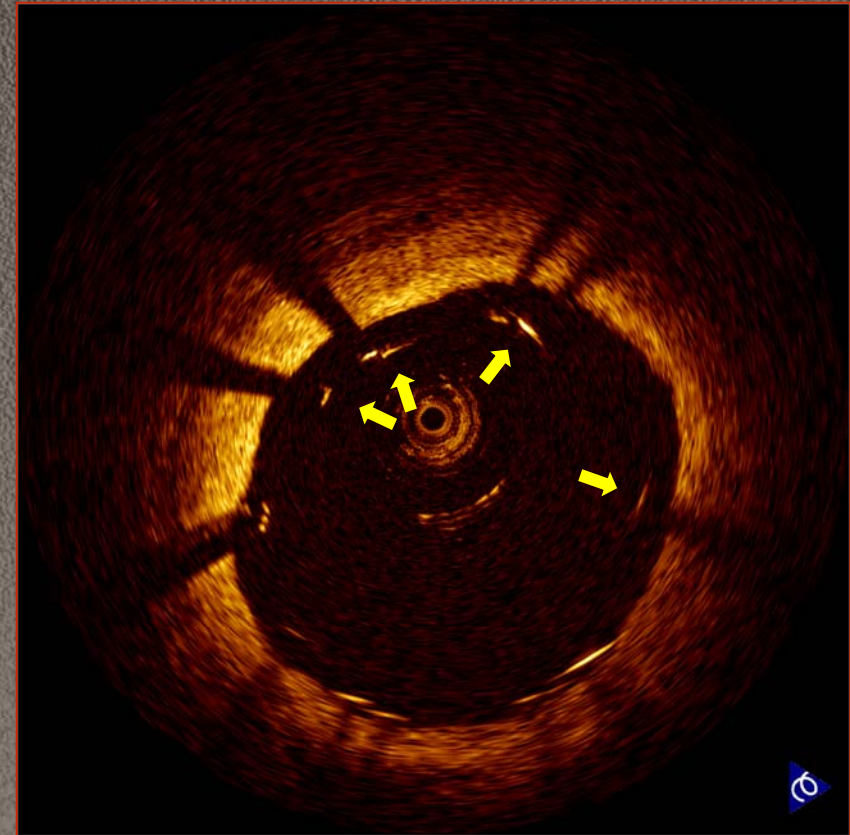
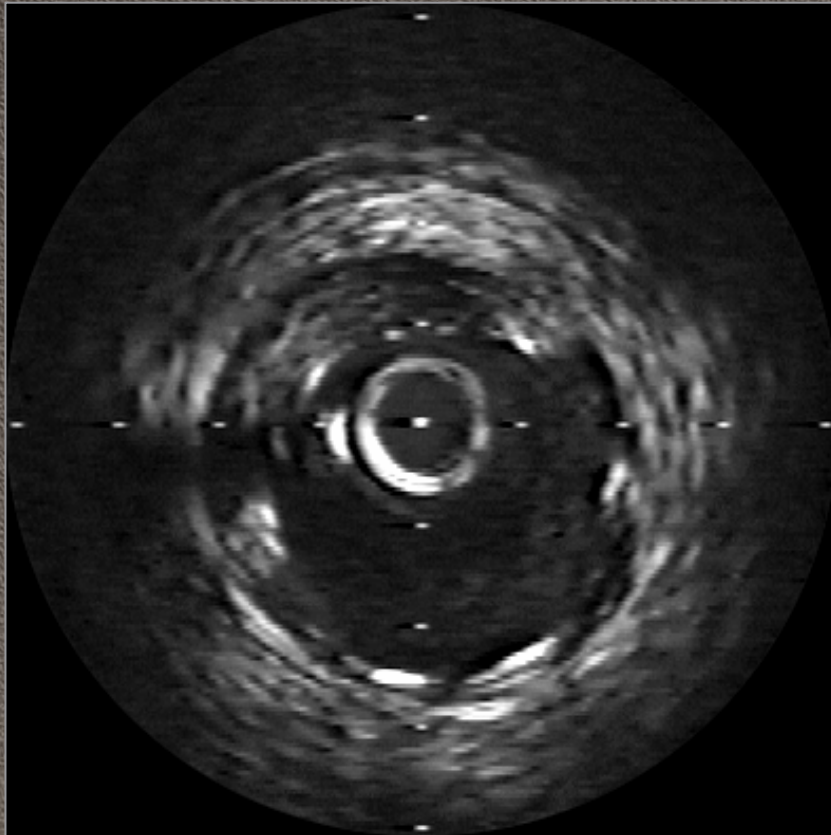
	OCT	IVUS
Exist	8	1
Absent	19	26

P = 0.0106

Case 08 - 06

*OCT Japanese Multi-center Study*

# Stent Incomplete Apposition



	OCT	IVUS
Exist	10	3
Absent	17	24

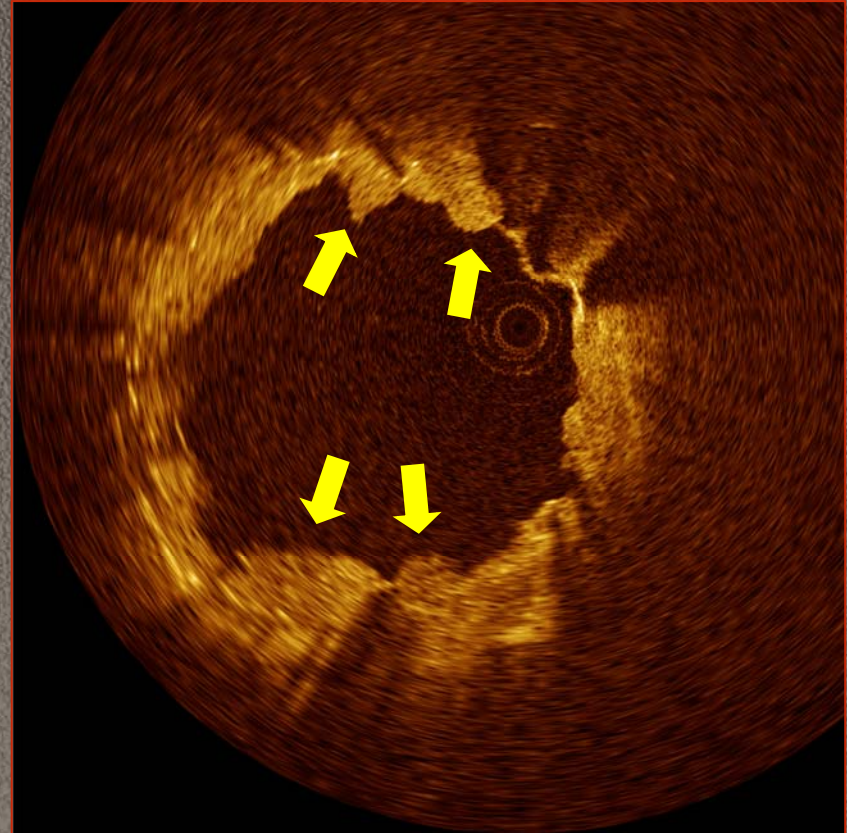
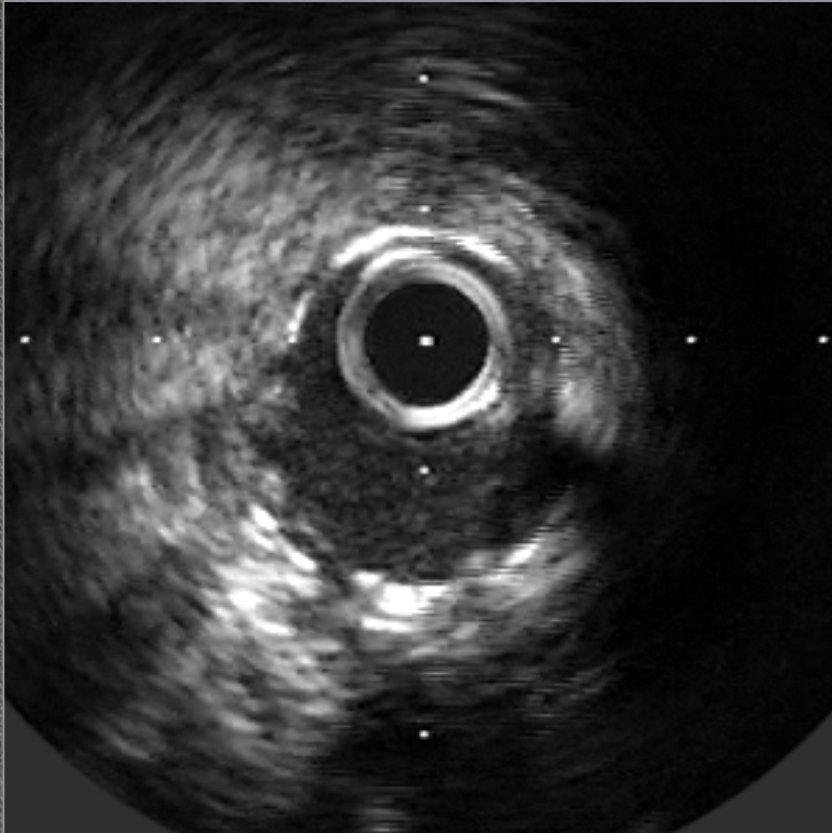
P = 0.0259

Case 05 - 09

*OCT Japanese Multi-center Study*



# Tissue Prolapse



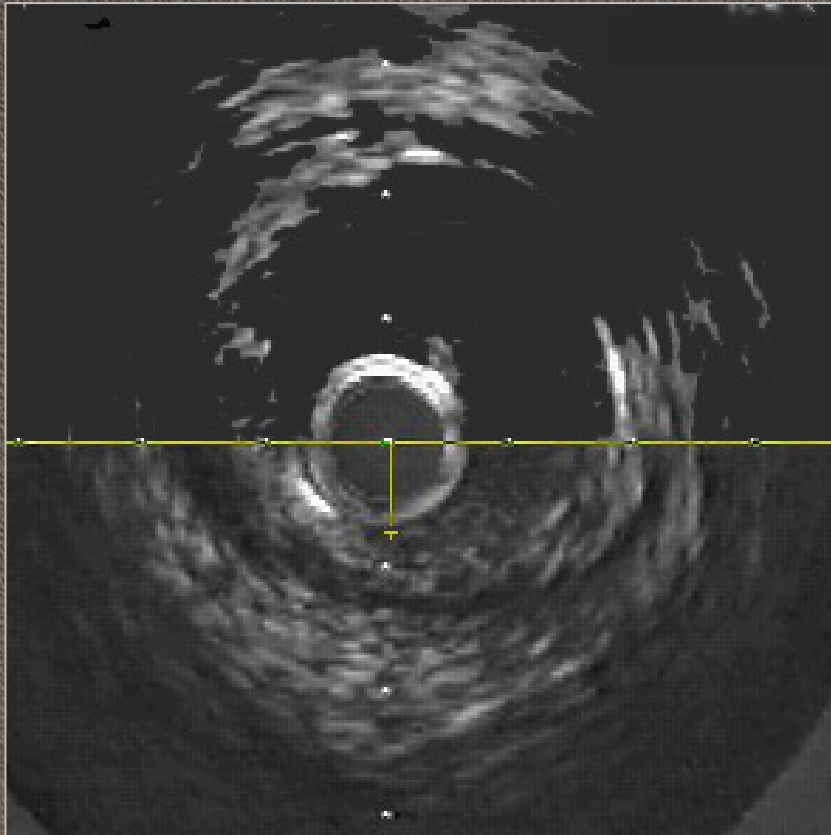
	OCT	IVUS
Exist	24	9
Absent	3	18

$P < 0.0001$

Case 03 - 08

*OCT Japanese Multi-center Study*

# Thrombus1



	OCT	IVUS
Exist	6	0
Absent	21	27

P = 0.0094

Case 05 - 09

*OCT Japanese Multi-center Study*

# Results

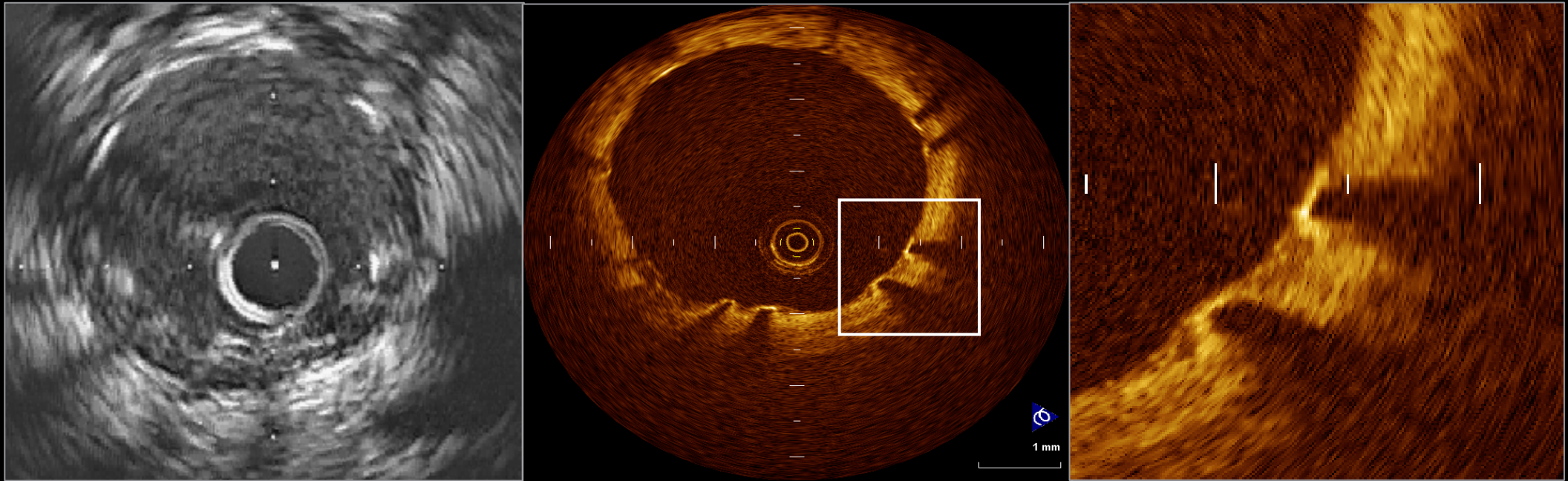
	OCT n = 27 (%)	IVUS n = 27 (%)	p value
Intimal Flap	8 (29.6)	1 (3.7)	0.0106
Stent Incomplete Apposition	10 (37.0)	3 (11.1)	0.0259
Tissue Prolapse	24 (88.9)	9 (33.3)	< 0.0001
Thrombus	6 (22.2)	0 (0)	0.0094
Overall	25	12	0.0001

# Conclusion

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- **This study demonstrates potential advantages of OCT over IVUS for identification of vascular responses to coronary stenting because of its higher resolution.**
- **These precise findings obtained by OCT might be related to chronic vascular responses after stenting.**

# *IVUS and OCT image of SES at 3-month follow-up*



- ✓ OCT also provides detailed information of chronic vascular responses following DES implantation.
- ✓ OCT visualized thin neointimal layer over DES struts that IVUS can not detect.

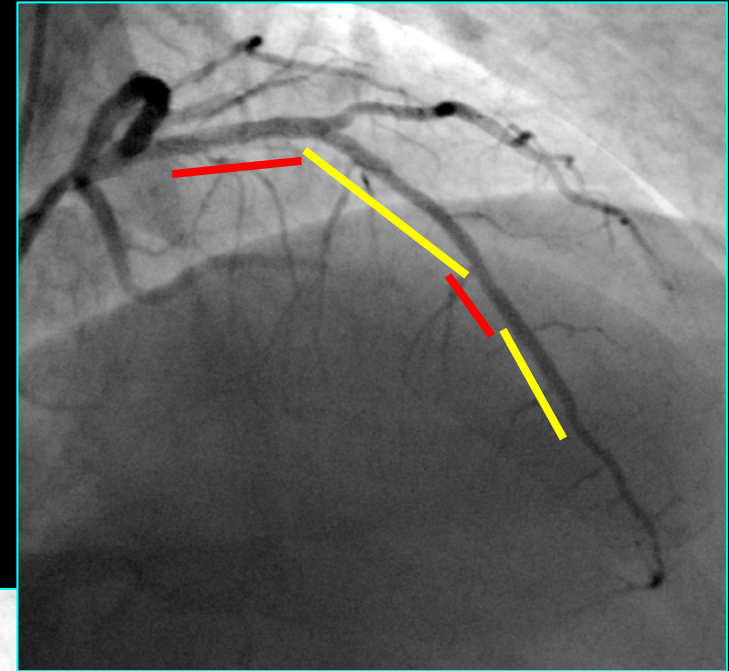


# CASE: BMS, SES and PES

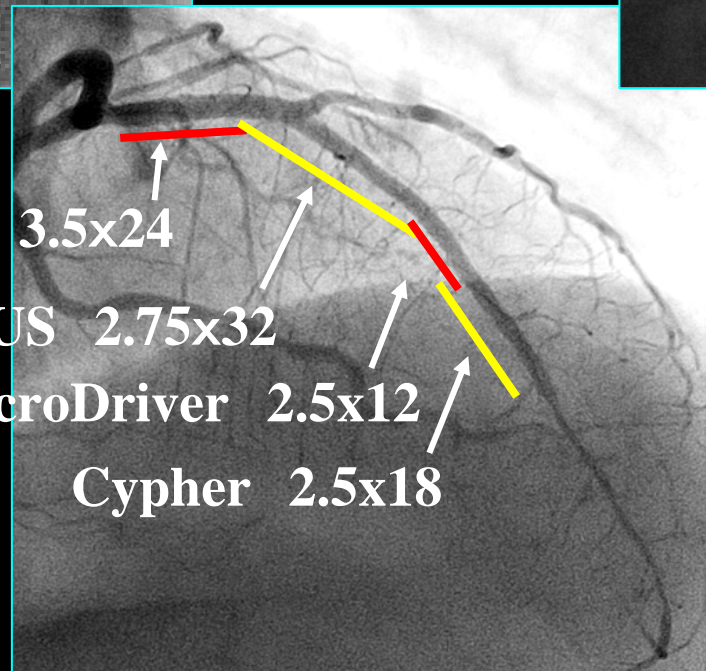
Pre



9-M Fu



Post



TAXUS 3.5x24

TAXUS 2.75x32

MicroDriver 2.5x12

Cypher 2.5x18



# *Conclusion*

- ✓ **OCT provides various information of acute and chronic vascular response to PCI.**
- ✓ **OCT might be a powerful imaging tool in DES era.**