MT1

Coronary Physiology & Imaging Summit 2007

OCT Experience in Real World: Toyohashi Heart Center

Mitsuyasu Terashima, MD

Toyohashi Heart Center

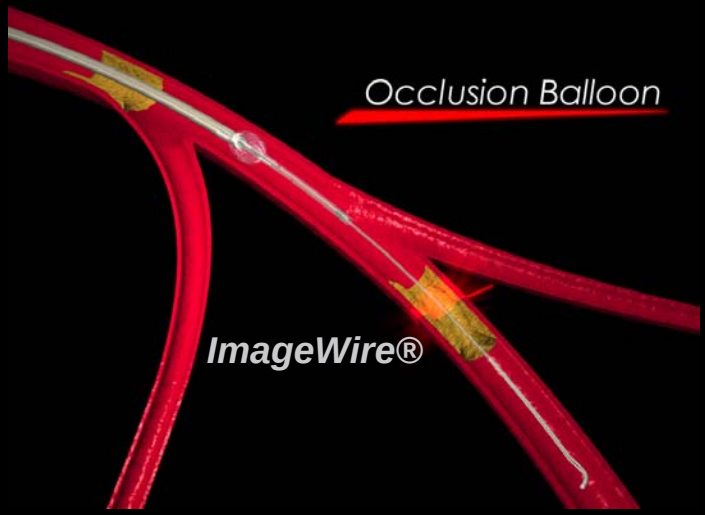
슬라이드 1

MT1 Mitsu, 2005-11-19

Lightlab OCT Imaging System

Console

Probe interface unit
motor drive unit
&
motorized pullback unit
(1.0mm/sec)



OCT image wire (ImageWire®)

- ✓1310 nm broadband light source
- ✓0.014 inch at the tip, 0.016 inch at the lens
- ✓resolution: 10 ~ 15μm
- ✓frame rate: 15fps

Balloon occlusion-flushing catheter

- ✓4Fr. catheter with high compliance balloon
- ✓balloon size: 3.8mm @ 0.3 atm

Toyohashi Heart Center

Safety and Feasibility Trial of OCT Image Wire System -Japanese Multi-center Study-

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[6]Kawasaki Social Insurance Hospital, [7]Toho University Ohashi Medical Center
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Nakamura S, et al, 2006 ACC

Investigators

Primary Investigators:

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Investigators:

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Core lab:

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Nakamura S, et al, 2006 ACC ***OCT Japanese Multi-center Study***

OCT Japanese Multi-center Study

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

Enrolled Patients

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)

Procedural Success Rate

	OCT	IVUS
➢ Over all (110 procedures / 76 Pts)	107 (97.3%)	104 (94.5%)
➢ 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%)

*1: OCT wire could not cross the lesion in one case.
OCT was not performed in two cases due to transient ST elevation during advancing a balloon occlusion-flushing catheter.
*2: IVUS catheter could not cross the lesion in 6 cases.

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OCT Japanese Multi-center Study

Conditions of Vessel Occlusion and Ringer's Solution Flushing

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

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OCT Japanese Multi-center Study

Adverse Events

	n=76
Death	0
Q-wave MI	0
Fatal arrhythmia (VT,VF)	0
Dissection	0
Distal embolism	0
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)

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OCT Japanese Multi-center Study

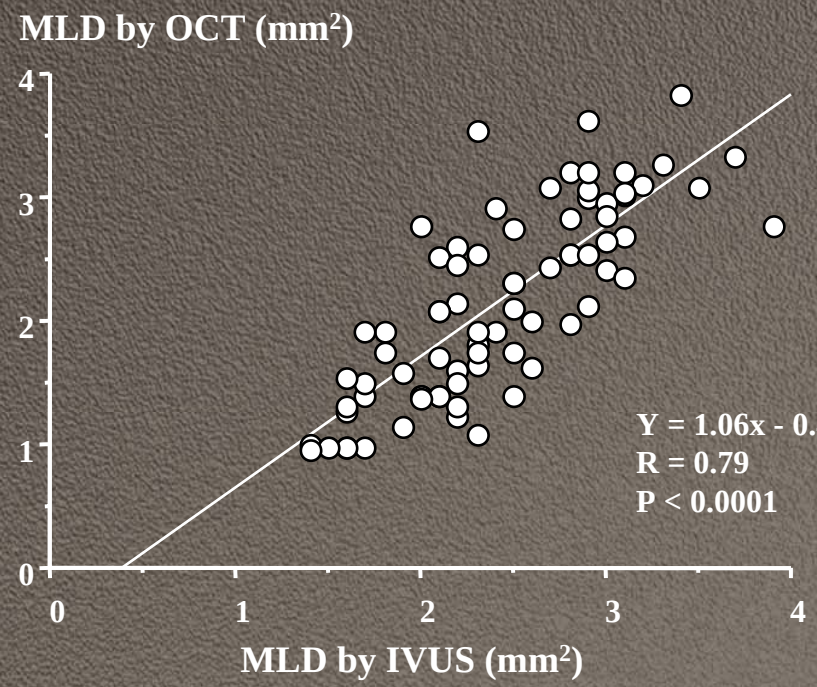
Comparison of Visibility Between OCT and IVUS

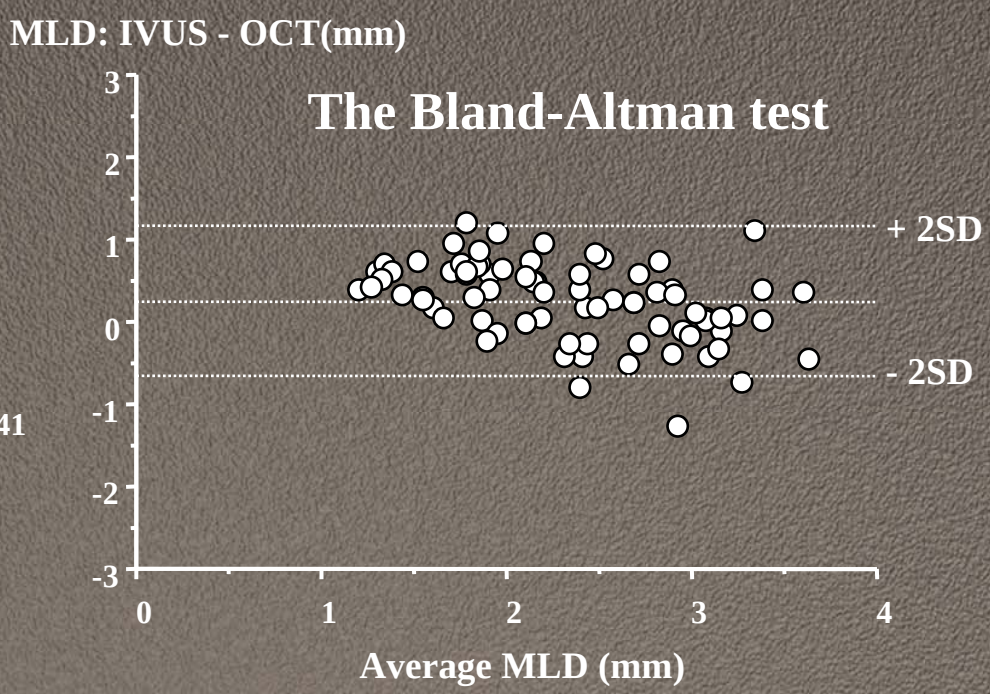
	Lumen border		Vessel border	
	OCT n = 98*	IVUS n = 98*	OCT n = 98*	IVUS n = 98*
Good	88	81	5	55
Fair	4	0	7	7
Poor	6	17 (wedged)	86	36
p value	< 0.05		< 0.0001	

*: Images were obtained by both OCT and IVUS in 98 procedures.

Nakamura S, et al, 2006 ACC *OCT Japanese Multi-center Study*

Comparison of the Minimal Lumen Diameter evaluated by OCT and IVUS





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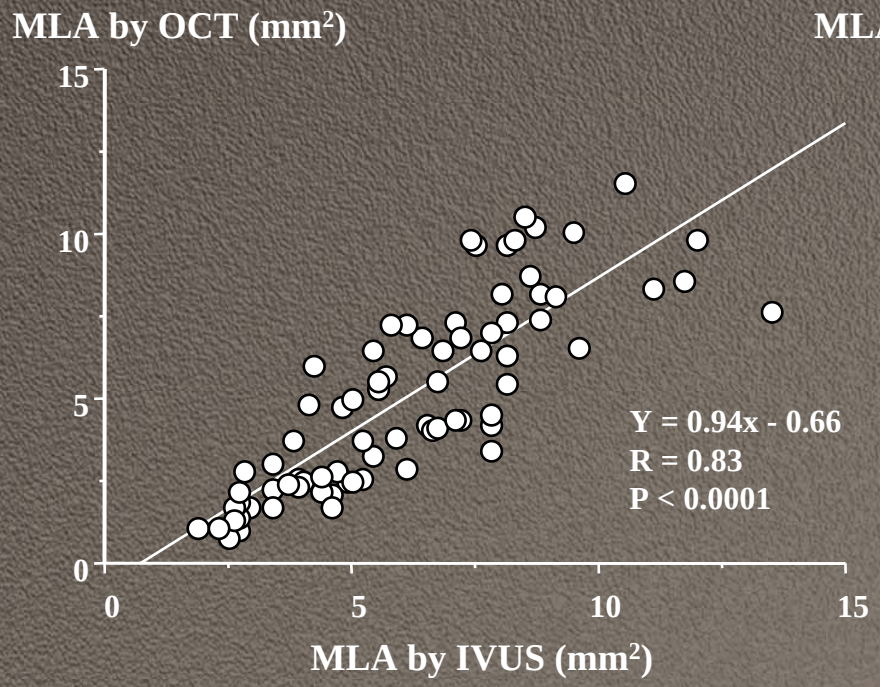
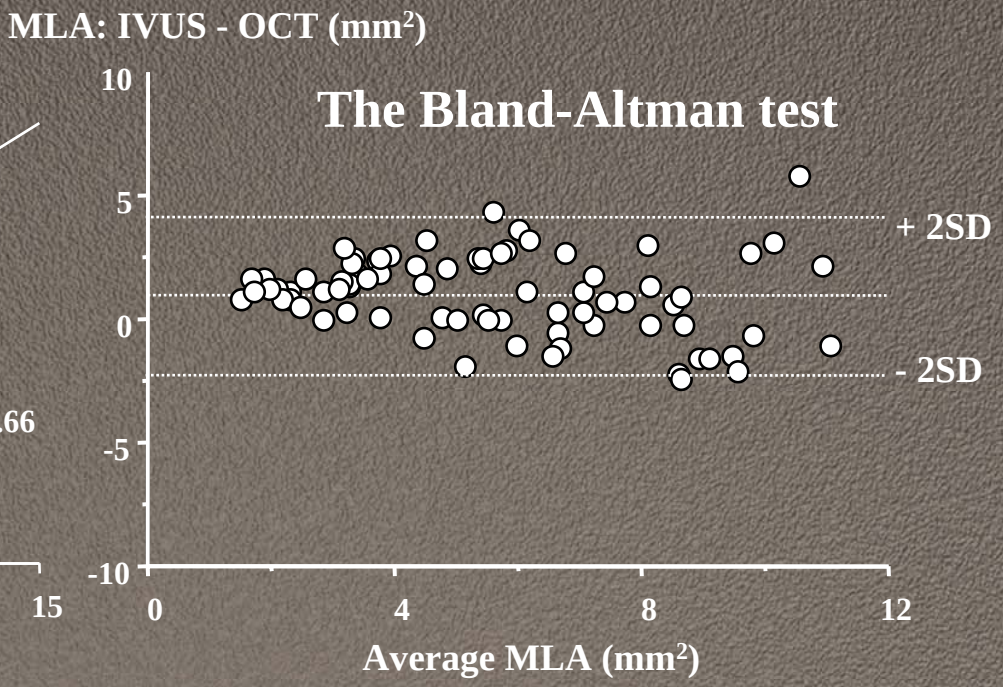
OCT Japanese Multi-center Study

Comparison of the Minimal Lumen Area evaluated by OCT and IVUS





Nakamura S, et al, 2006 ACC

OCT Japanese Multi-center Study

Conclusion

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

Purpose of OCT imaging in THC

- ✓ **Analysis of coronary plaque characteristic**
  ACS etc
- ✓ **Analysis of vascular responses to PCI**

OCT in PCI

Intracoronary Imaging with Optical Coherence Tomography after Cutting Balloon Angioplasty for In-stent Restenosis

Shigenori Ito, MD, *Makoto Itoh, MD, §Takahiko Suzuki, MD

Optical coherence tomography (OCT) represents a promising new technology[1-2] for imaging the vascular microstructure at a level of 10–20 μm,[3-6] which has not yet been achieved with the use of other imaging modalities.[7-9] It may permit the determination of small structural details such as intimal flap width and the presence of fissures, as well as the width of intimal caps[10-12] or malapposition of a stent.[13]

Case Report. *Cutting Balloon® (Interventional Technologies, San Diego, California)[14] angioplasty was performed for in-stent restenosis of an Easy Wallstent™ (Boston Scientific, Maple Grove, Minnesota) 6.0 mm x 100 mm implanted in the left superficial femoral artery in a 63-year-old Japanese male with a history of hypertension. The Fontaine class was IIa. An angiogram showed diffuse and tandem stenosis (Figure A). Since the Easy Wallstent™ was well-dilated by intravascular ultrasound (IVUS), we selected a 5.5 mm x 10 mm Cutting Balloon. It was inflated multiple times to cover the entire stent at 6–10 atms. The balloon was inflated several times for the same stenosis at increasing inflation pressures. Comparison of the IVUS image with that of OCT (Image Wire™, LightLab Imaging, Inc., Westford, Massachusetts) yielded the following results: at baseline, the stent lumen was filled with a hypoechoic mass. Each stent strut could be detected, although the strut edge was ambiguous by IVUS (Figure B). OCT (Figure C) revealed that the plaque was signal-rich and homogenous. The deep segment was signal-poor, most likely due to attenuation. Each stent strut could be well-delineated and they were detected to be as thin as the expected thickness. This plaque was classified as fibrous according to the classification of Yabushita, et al.[15] After the cutting balloon procedure, OCT detected many fine flaps floating in the lumen (Figure E), while IVUS (Figure D) was unable to detect them separately. The contrast between the vessel surface and blood was excellent in OCT, but poor in IVUS.*

Discussion. To the best of our knowledge, this is the first report showing the OCT images after cutting balloon angioplasty. Cutting balloon angioplasty is thought to be less invasive than plain-old balloon angioplasty based on its dilatation mechanism,[14] and intimal flaps can be incised without over-dilatation of the vessel and at a lower inflation pressure due to the action of three or four blades on the cutting balloon.[14] After cutting balloon angioplasty, the lumen surface of the stenosed artery has been shown to be smooth, with cut incisions formed by microcatheters. Adamian, et al.[16] reported good late results with a cutting balloon for in-stent restenosis. The angiographic results are often very excellent, with stent-like results showing a very smooth lumen border. However, we sometimes experience restenosis with cutting balloon use, even in cases that produce optimal initial results according to angiograms and IVUS. According to the OCT images, the lumen surface was not smooth, but rather very irregular with fine floating flaps, despite the fact that the IVUS images showed acceptable results in this case. This may partially contribute to the formation of thrombosis or inflammation, causing intimal hyperplasia and, finally, restenosis. This technology may offer a new approach for interventional cardiologists.[17,18]

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Manuscript submitted August 11, 2004, manuscript accepted November 1, 2004.

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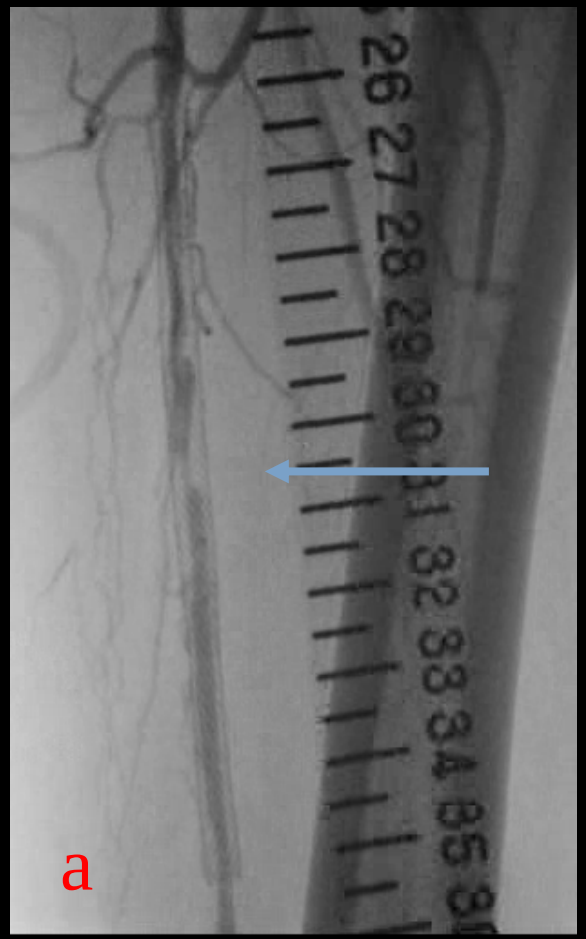
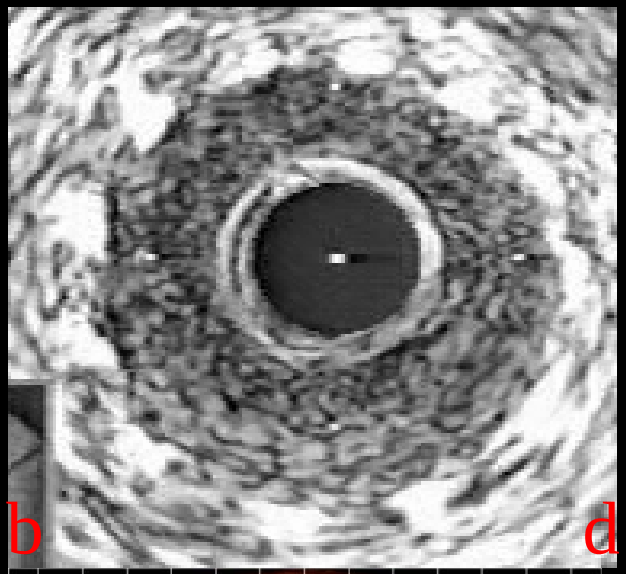
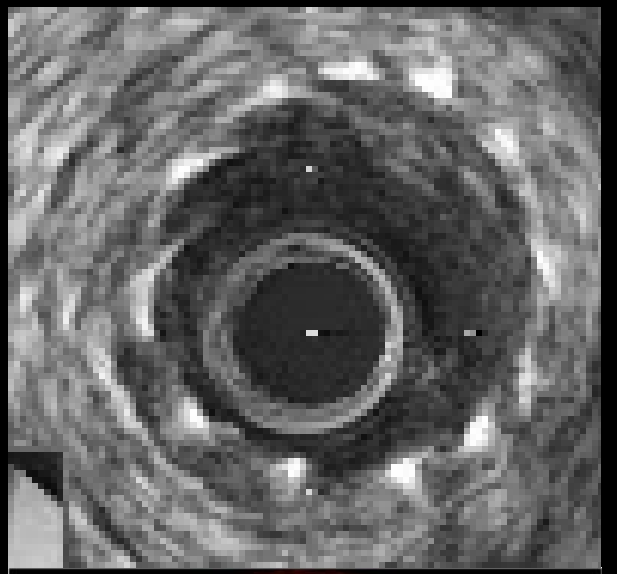
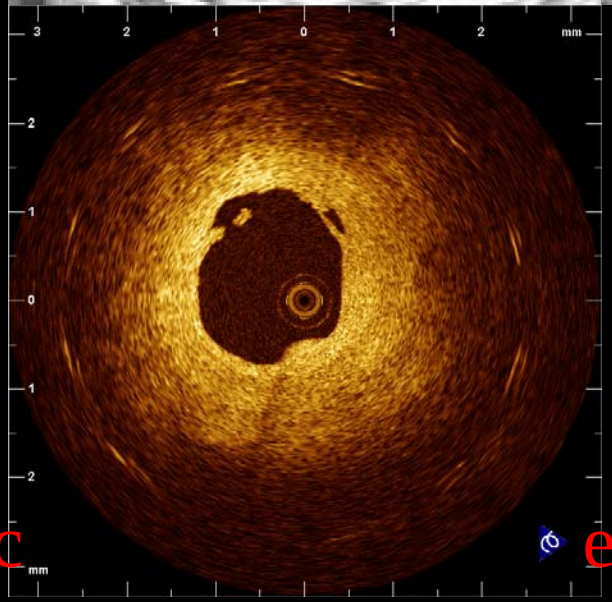
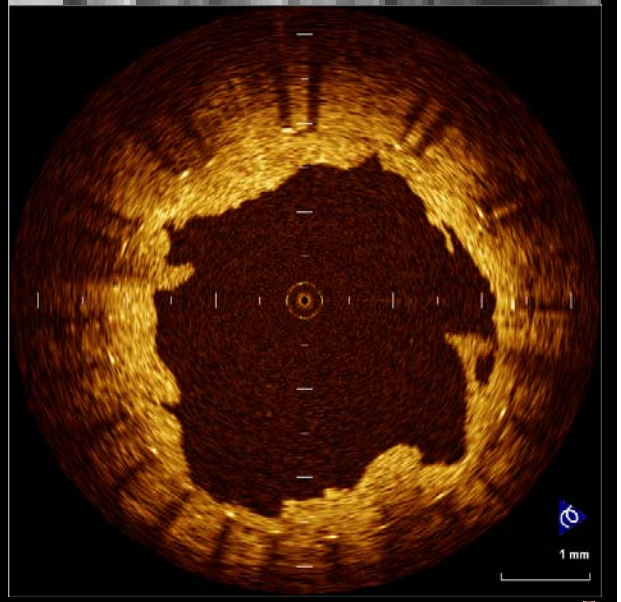
Before After Cutting Balloon











S. Ito, et al, J Inv Cardiol 2005, 17, 369

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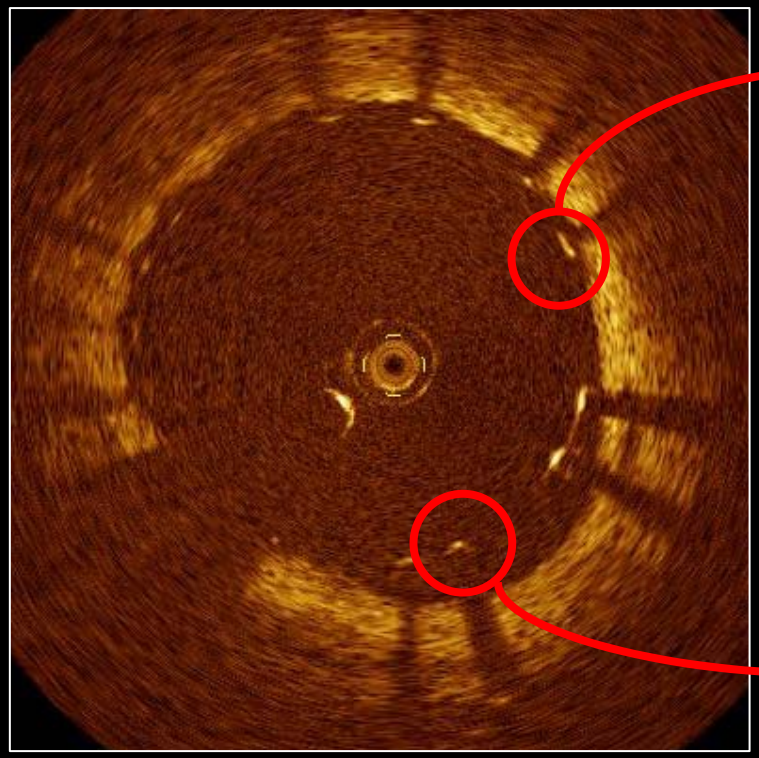
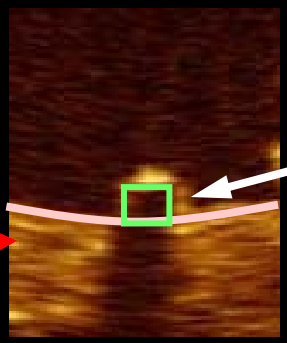
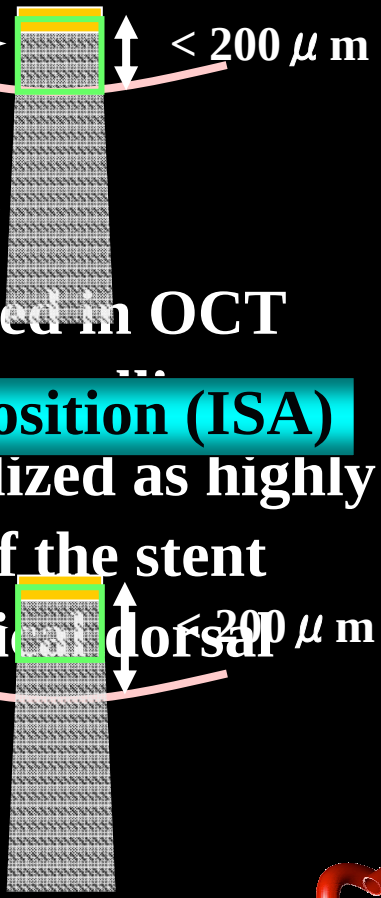
OCT Image of Implanted stent Just after Deployment



Complete stent apposition (CSA)





Near infrared light used in OCT

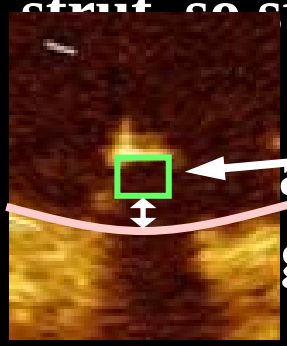
Incomplete stent apposition (ISA)

tent is visualized as highly

structures of the stent

ace with typical dorsal

g in OCT.



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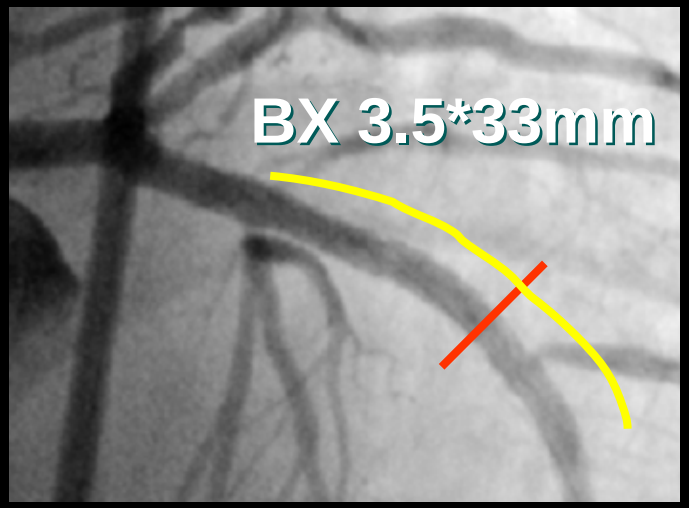
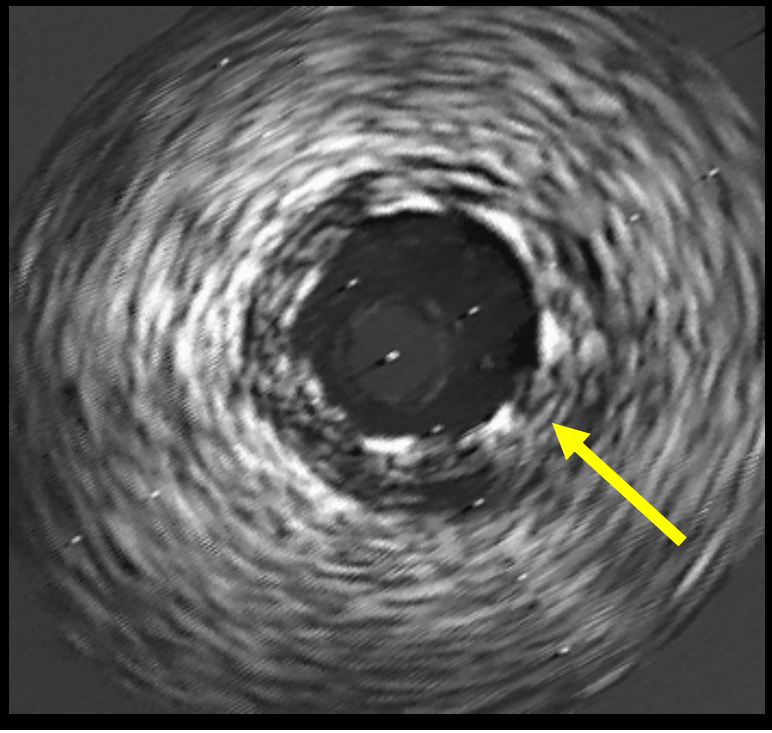
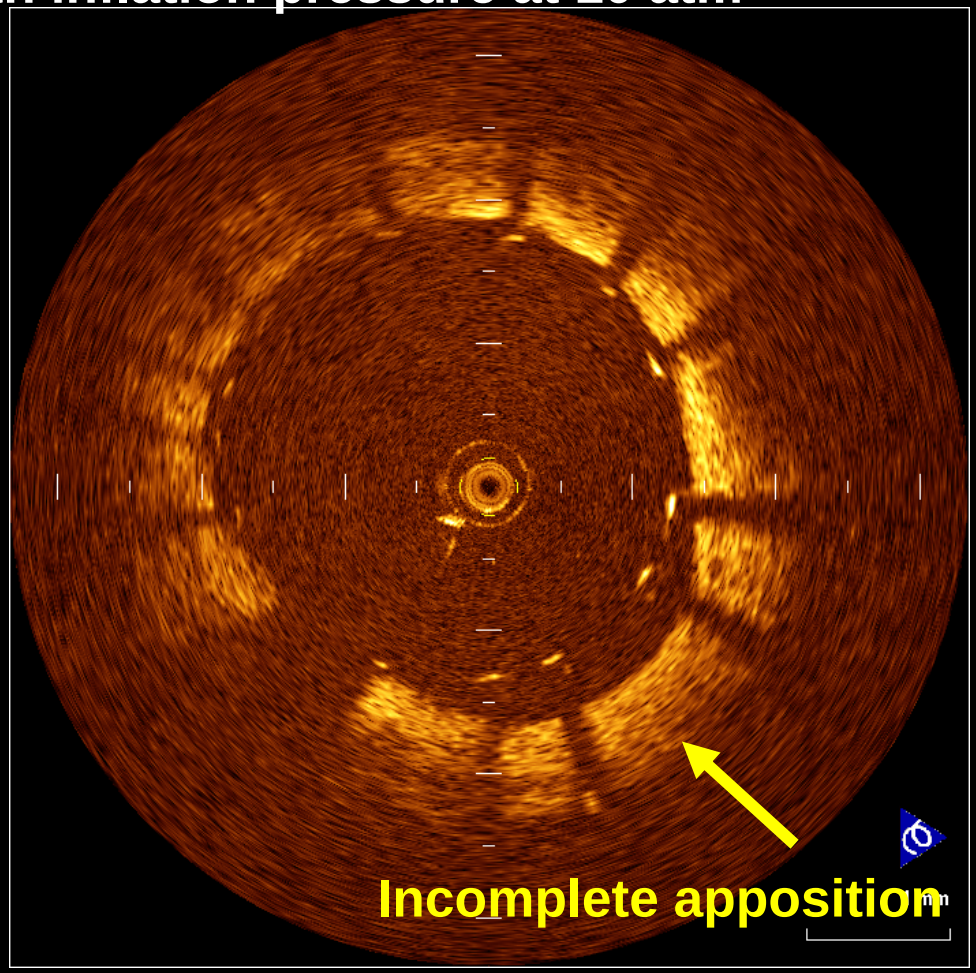
Incomplete apposition





After stenting of the mid-LAD
with inflation pressure at 10 atm



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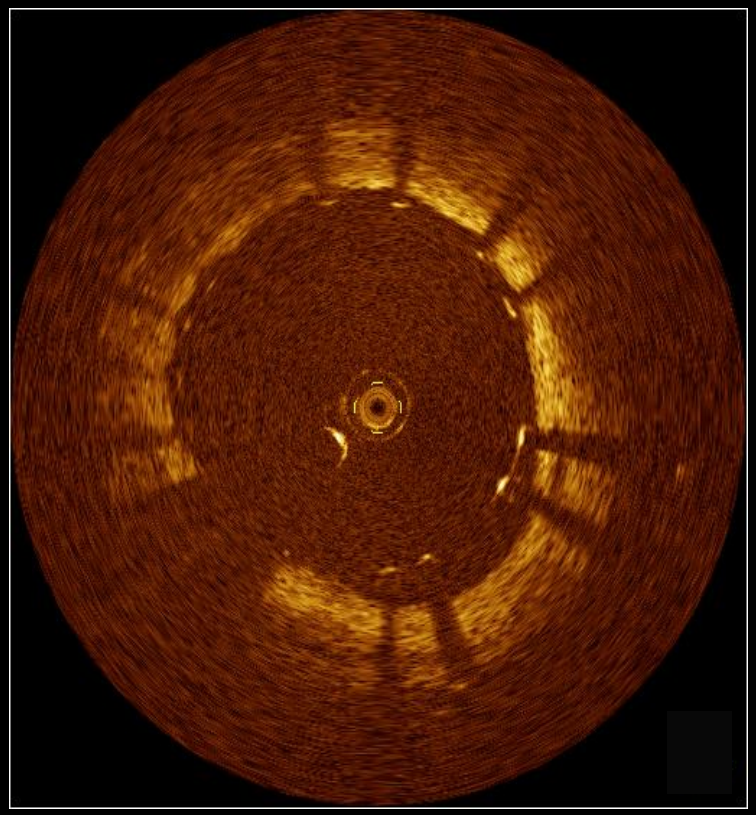
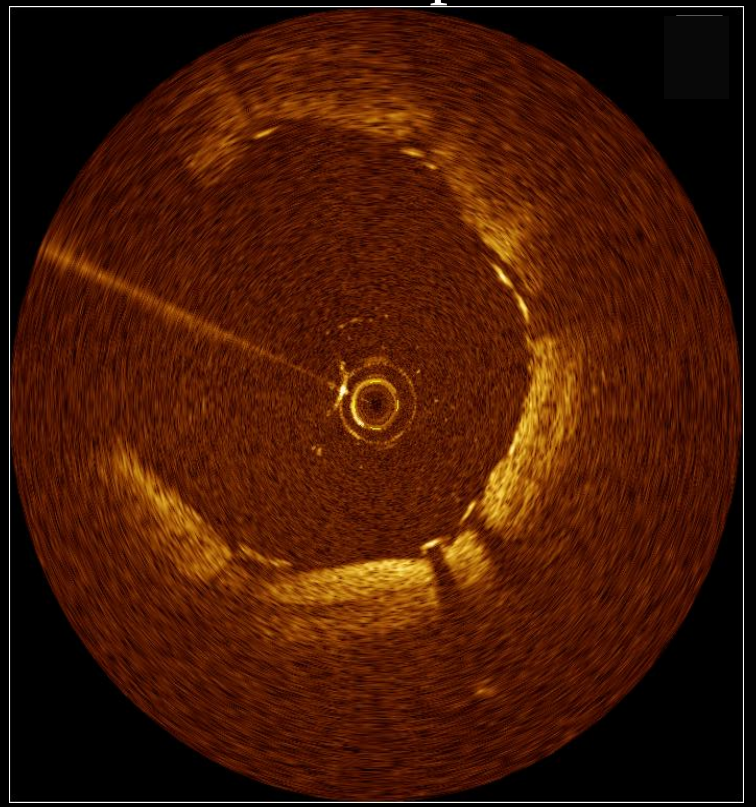
Post Dilatation of Incompletely Apposed Stent

10 atmosphere



Adjunctive ballooning at
20 atmosphere



Incomplete apposition

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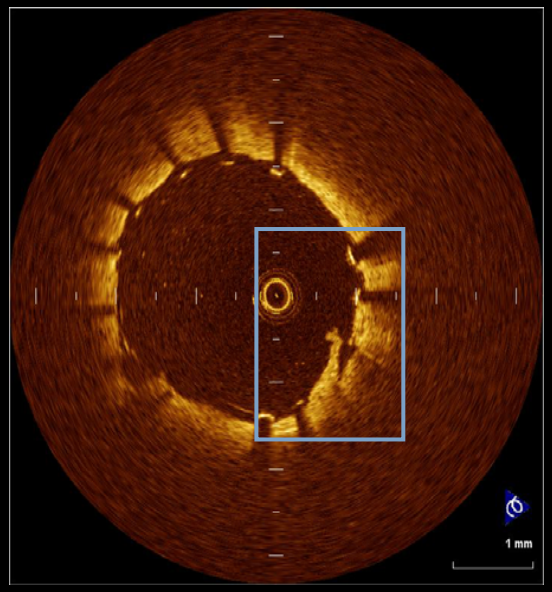
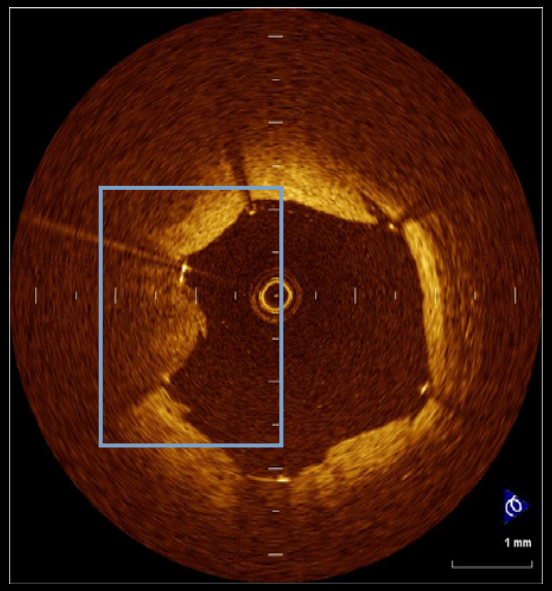
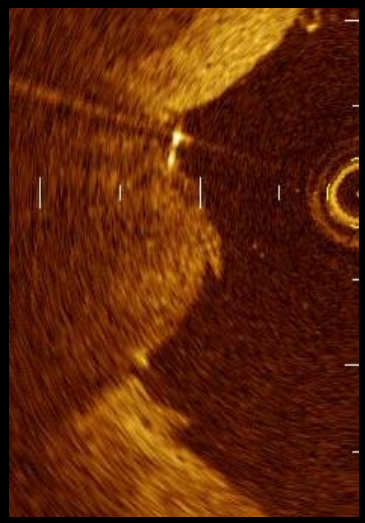
Findings after Stent Implantation

Dissection

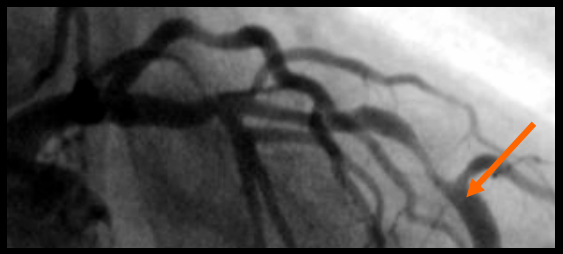


Tissue prolapse

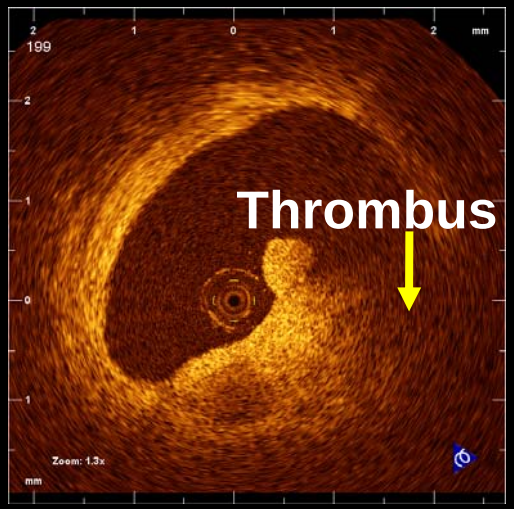


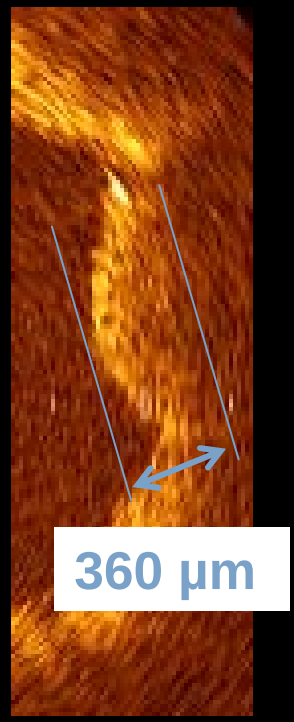


Prolapse

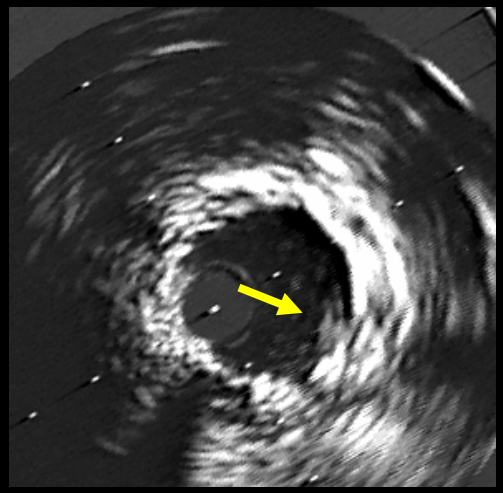


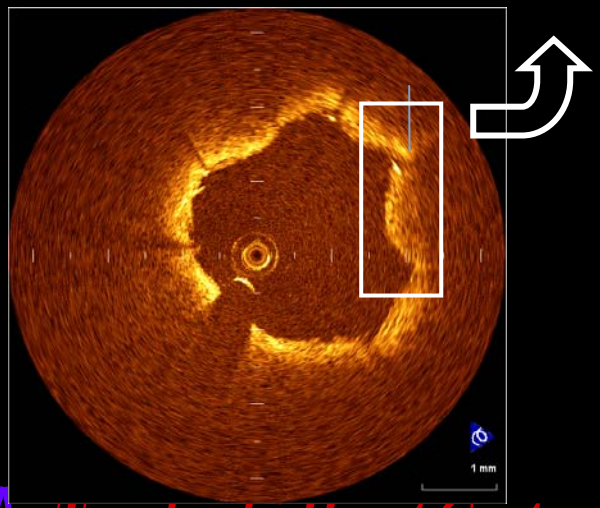
Before intervention





After intervention





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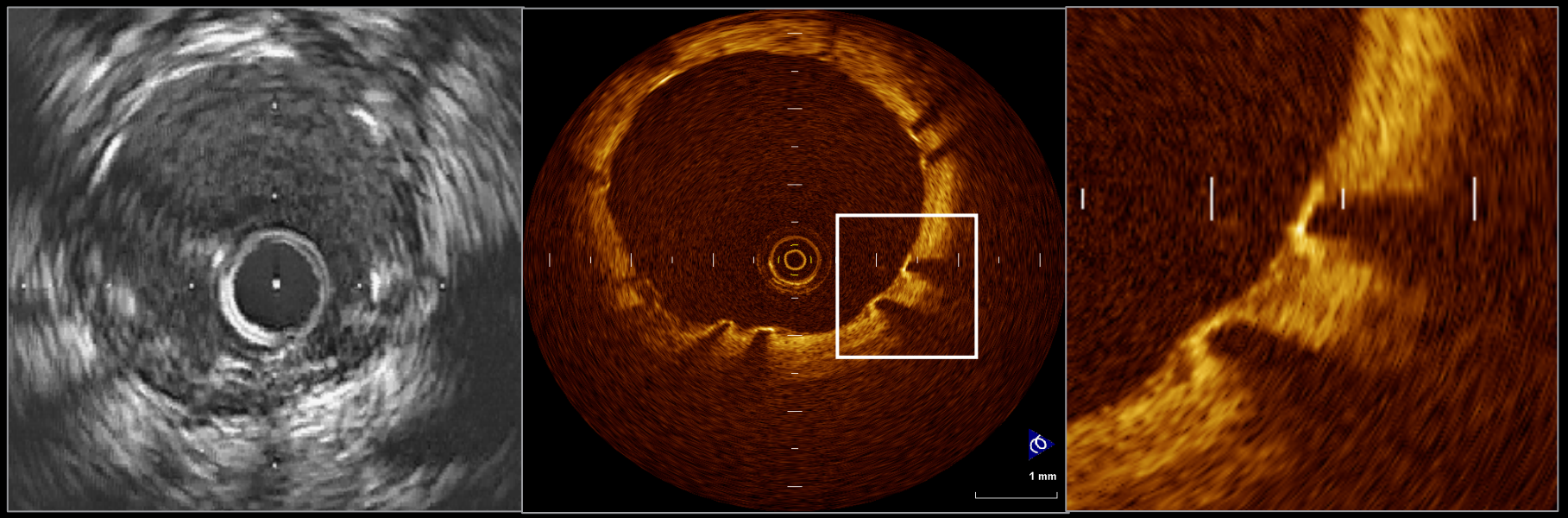
OCT in DES era

Neointimal Coverage of SES

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



✓ **OCT provides detailed visualization of the individual stent struts and neointimal proliferation that is missed by IVUS.**

Neointimal Coverage of SES

Male 87 y.o.

Diagnosis :

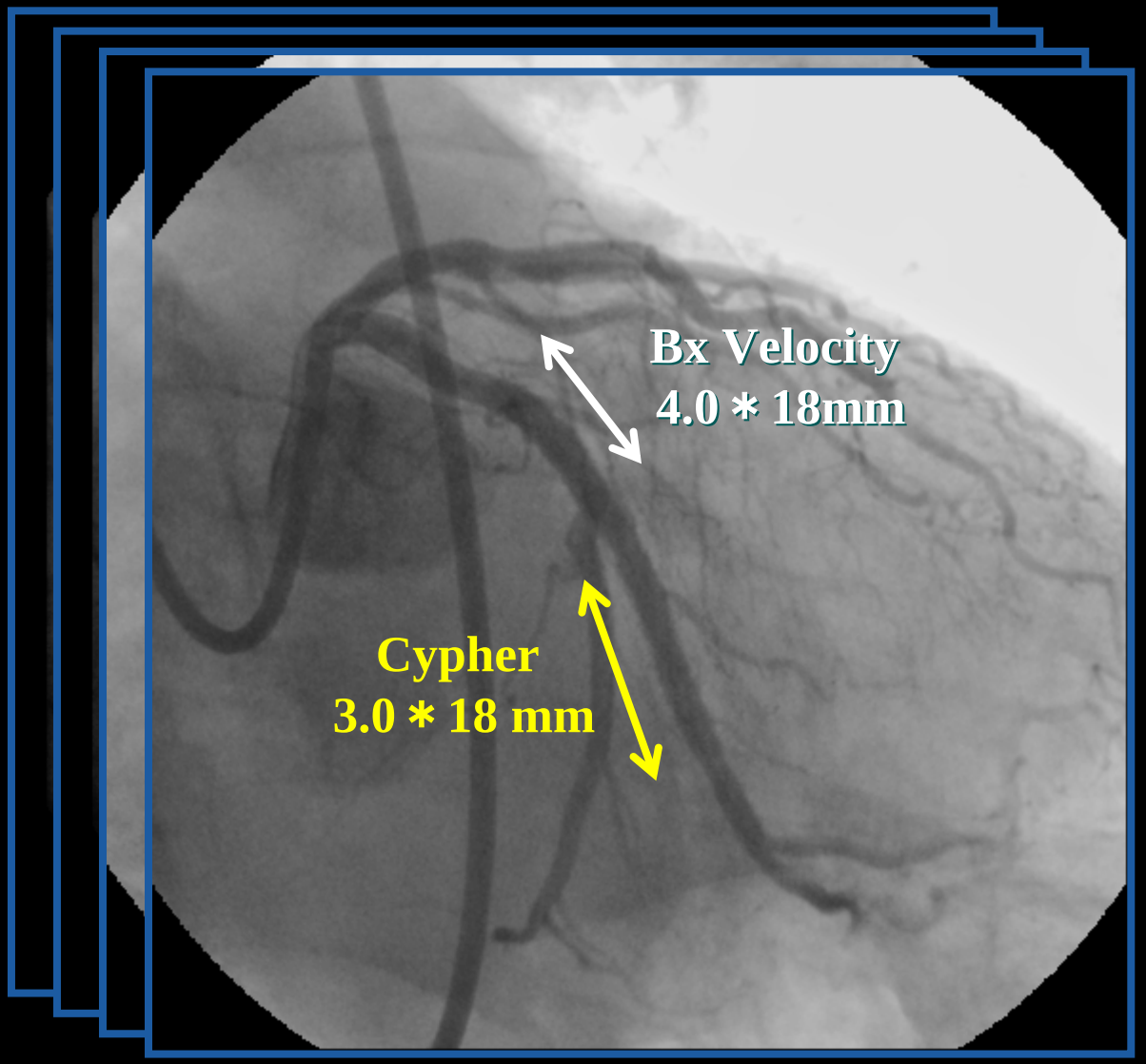
Stable AP

Risk Factor :

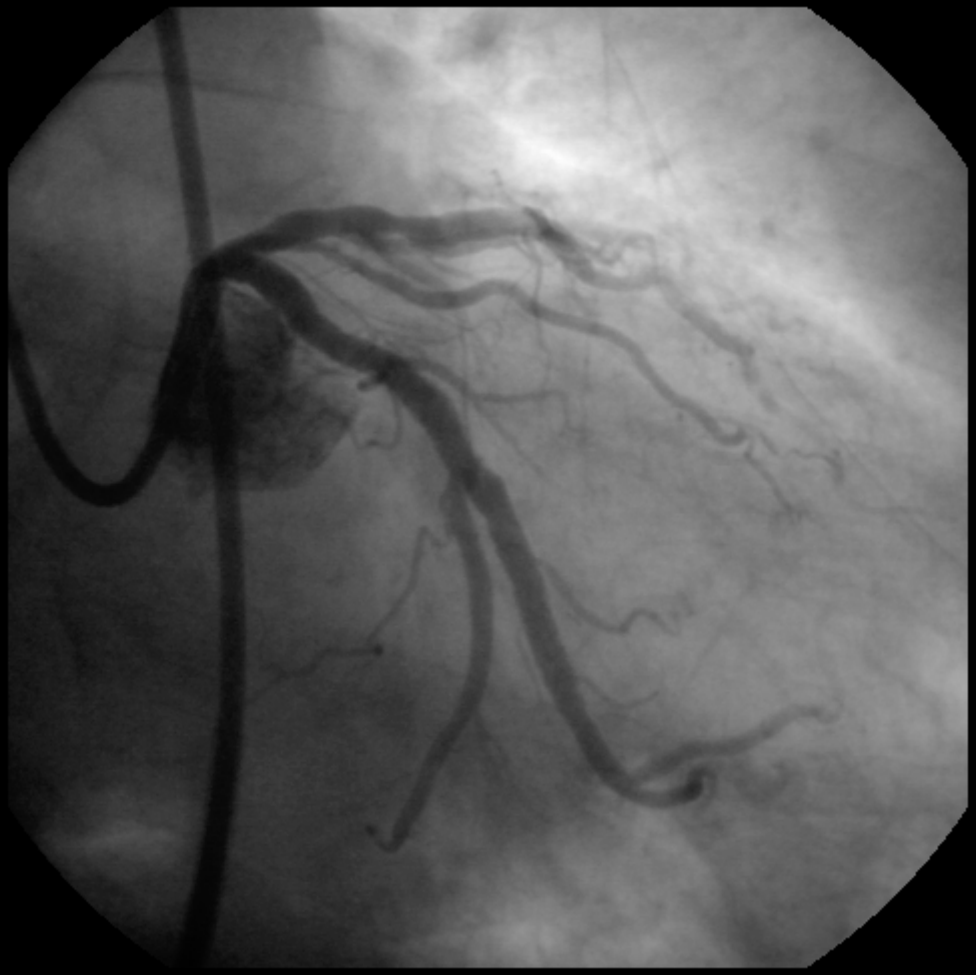
HT

Target Lesions:

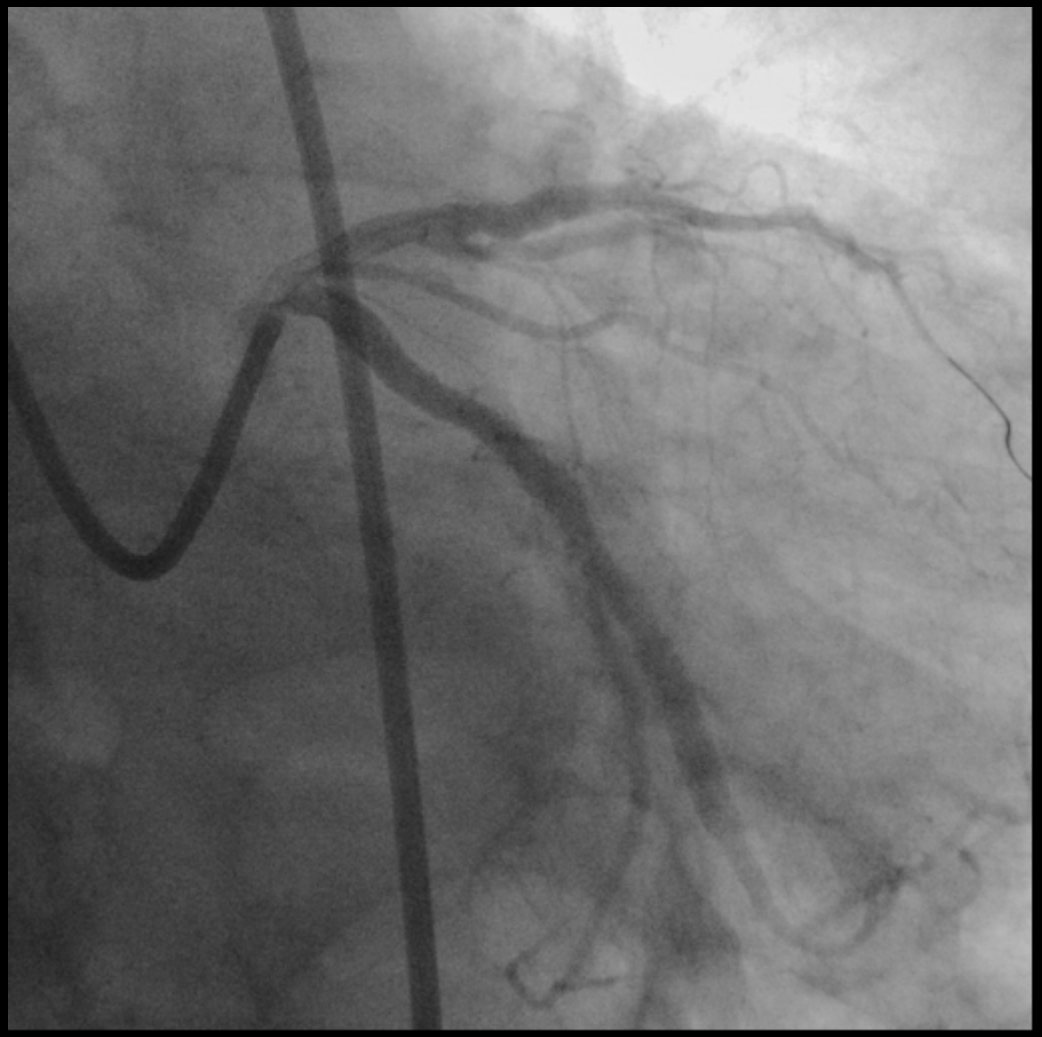
LCX seg.11 75%
seg.13 90%



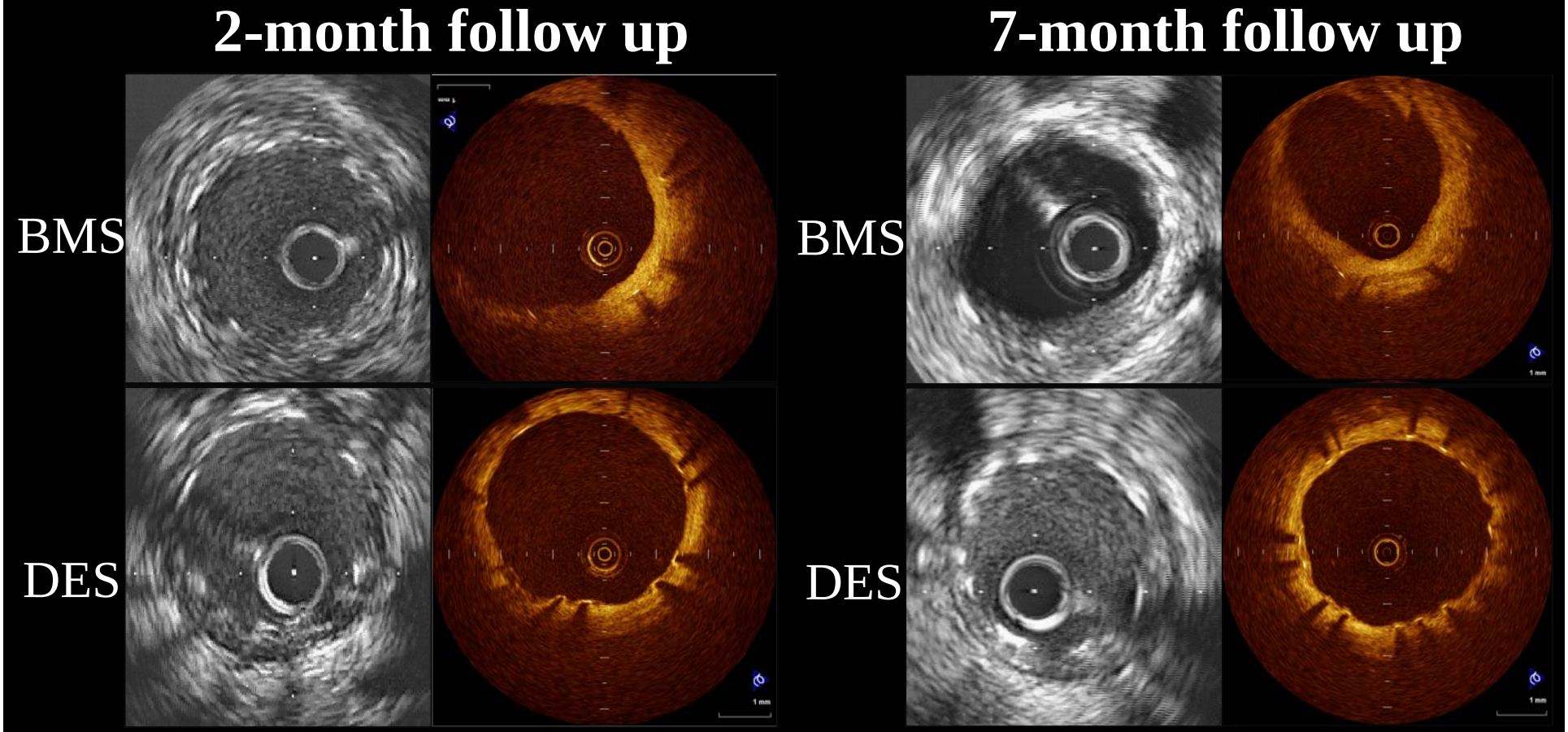
2-Month Follow up



7-Month Follow up



Comparison of IVUS and OCT images between BMS and SES



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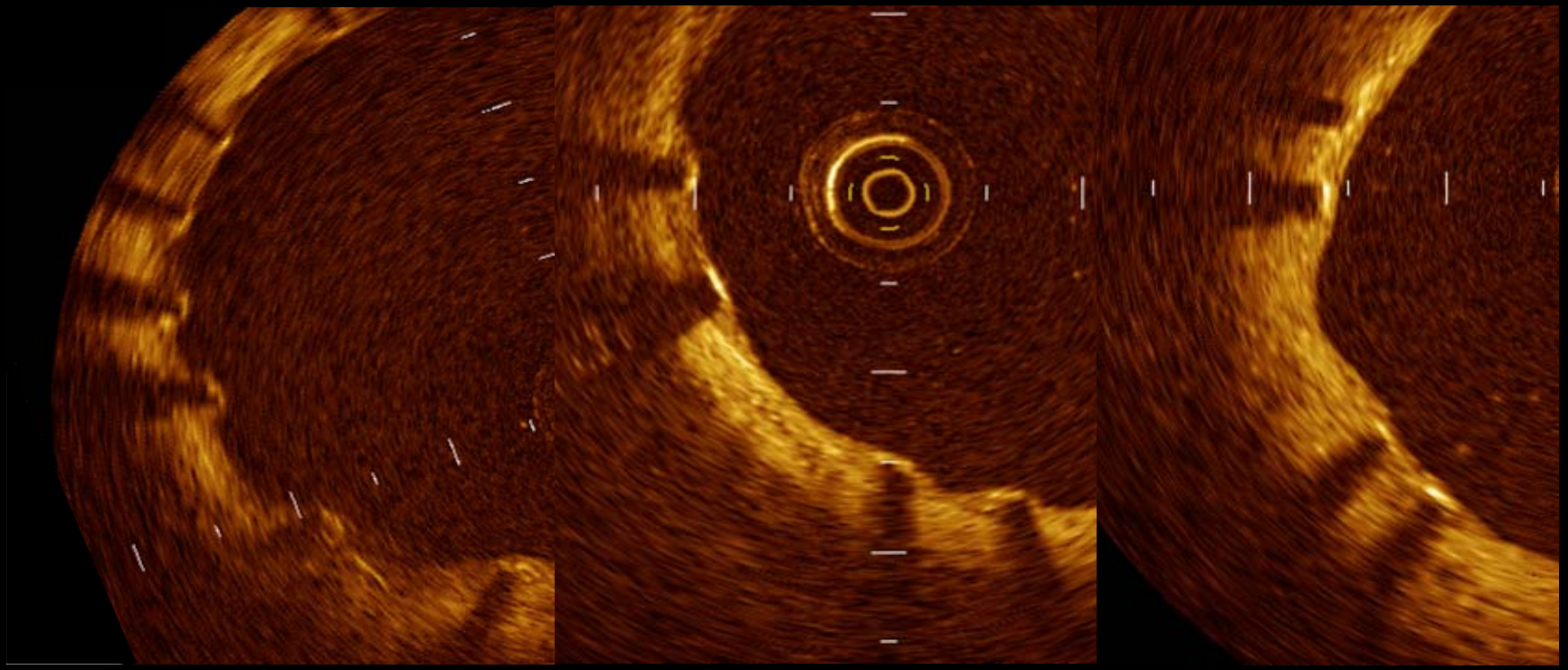
DES: 2-month follow up

Variability of Neointimal Stent Coverage within a stent



Proximal area　　Middle area　　Distal area

Optical Coherence Tomographic Analysis of Neointimal Stent Coverage in Sirolimus-eluting Stent, Compared with Bare Metal Stent

Toyohashi Heart Center, Toyohashi, Japan

Tatsuya Ito, Mitsuyasu Terashima, Yoshihiro Takeda, Osamu Katoh, Tetsuo Matsubara, Etsuo Tsuchikane, Mariko Ehara, Yoshihisa Kinoshita, Kenya Nasu, Jean-François Surmely, Nobuyoshi Tanaka, Akira Murata, Hiroshi Fujita, Koyo Sato, Takahiko Suzuki

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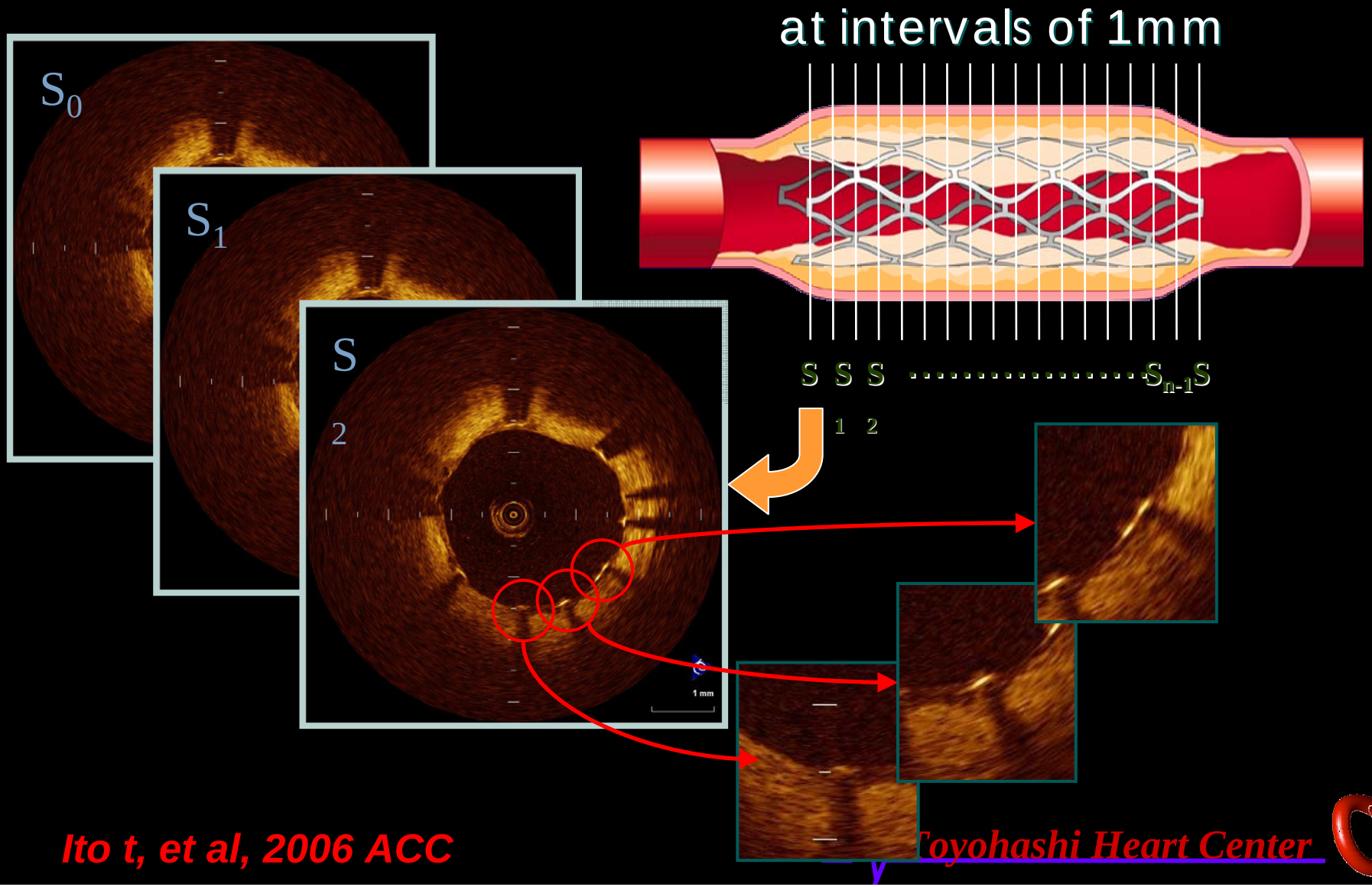
OCT Analysis of Stented segment



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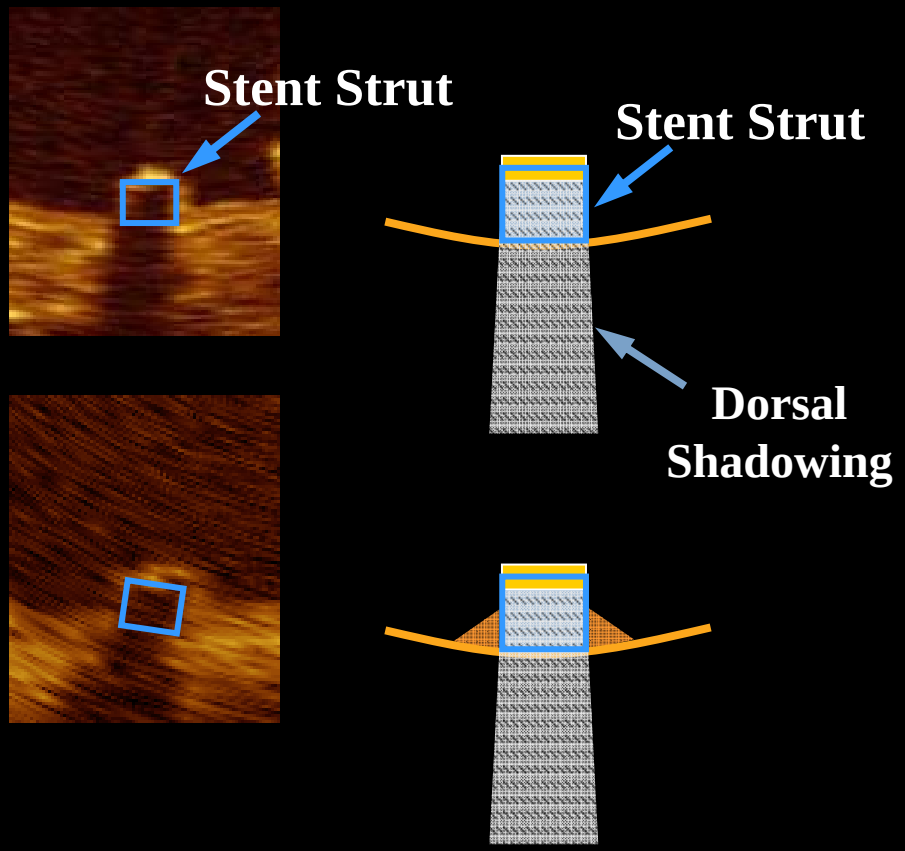
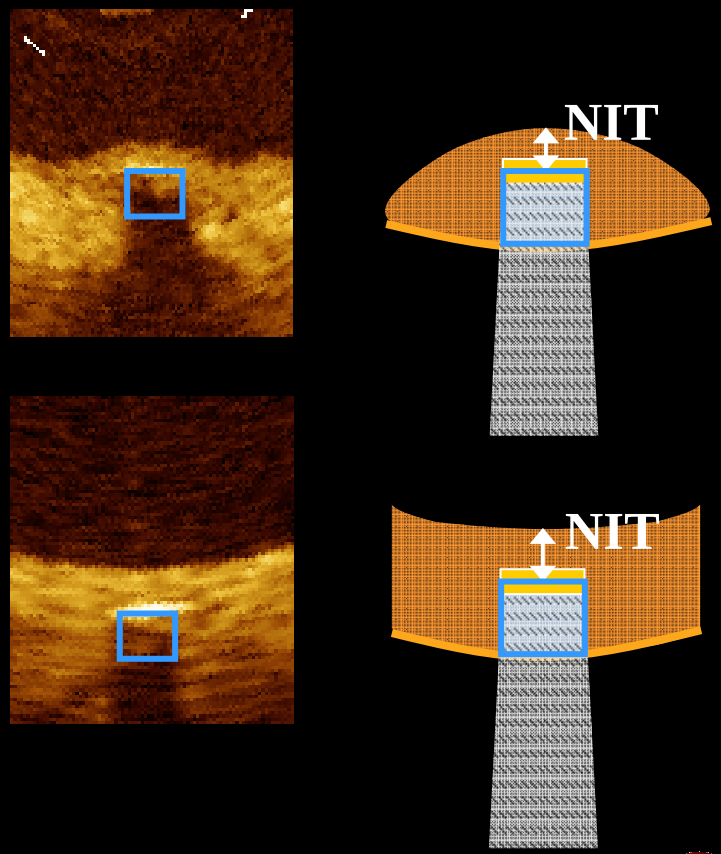
Pattern of “Intimal Stent Strut Coverage”

Uncovered Struts



Covered Struts



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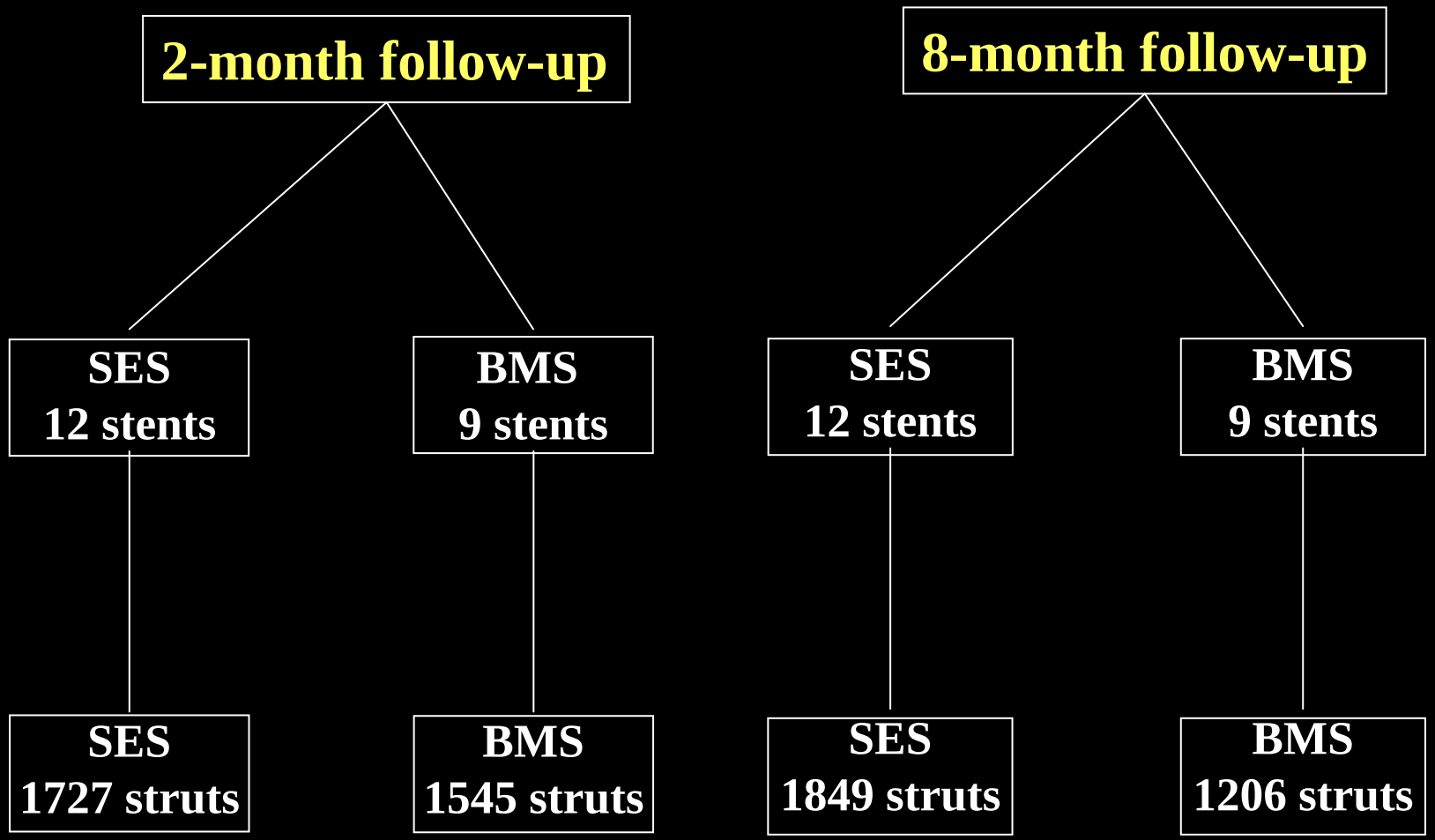
Subjects



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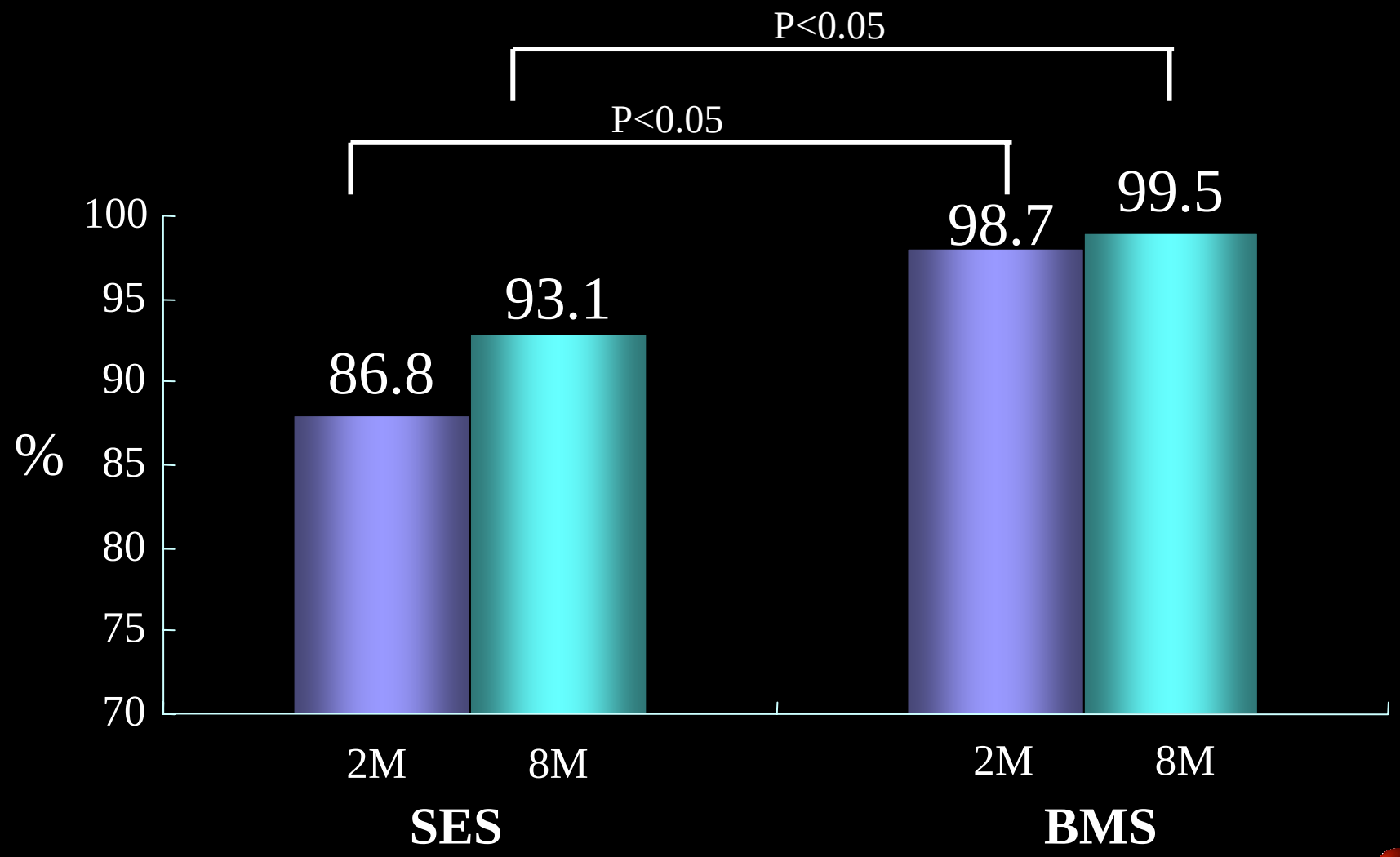
Neointimal Stent Coverage (%)



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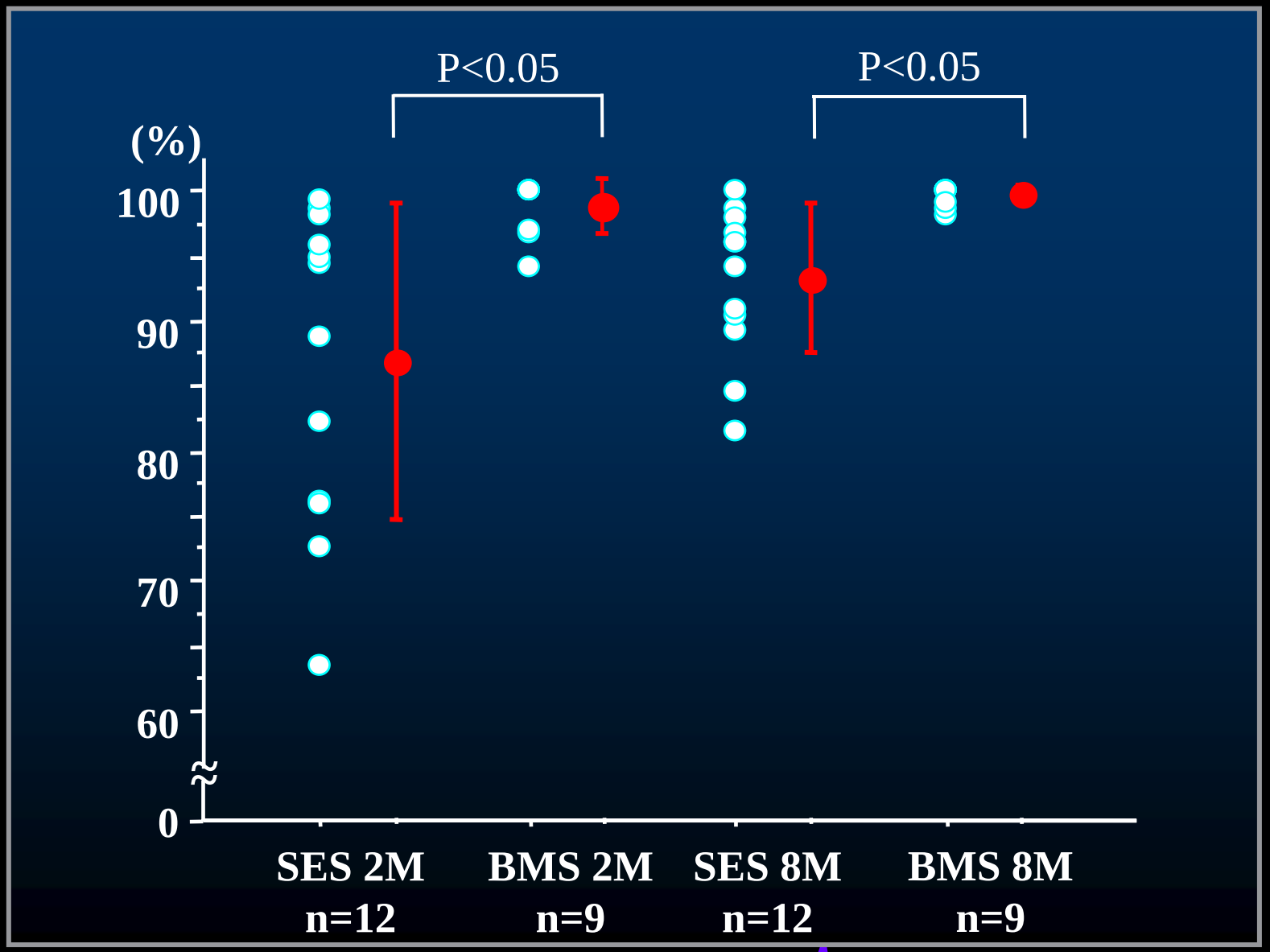
Neointimal Stent Coverage (%)



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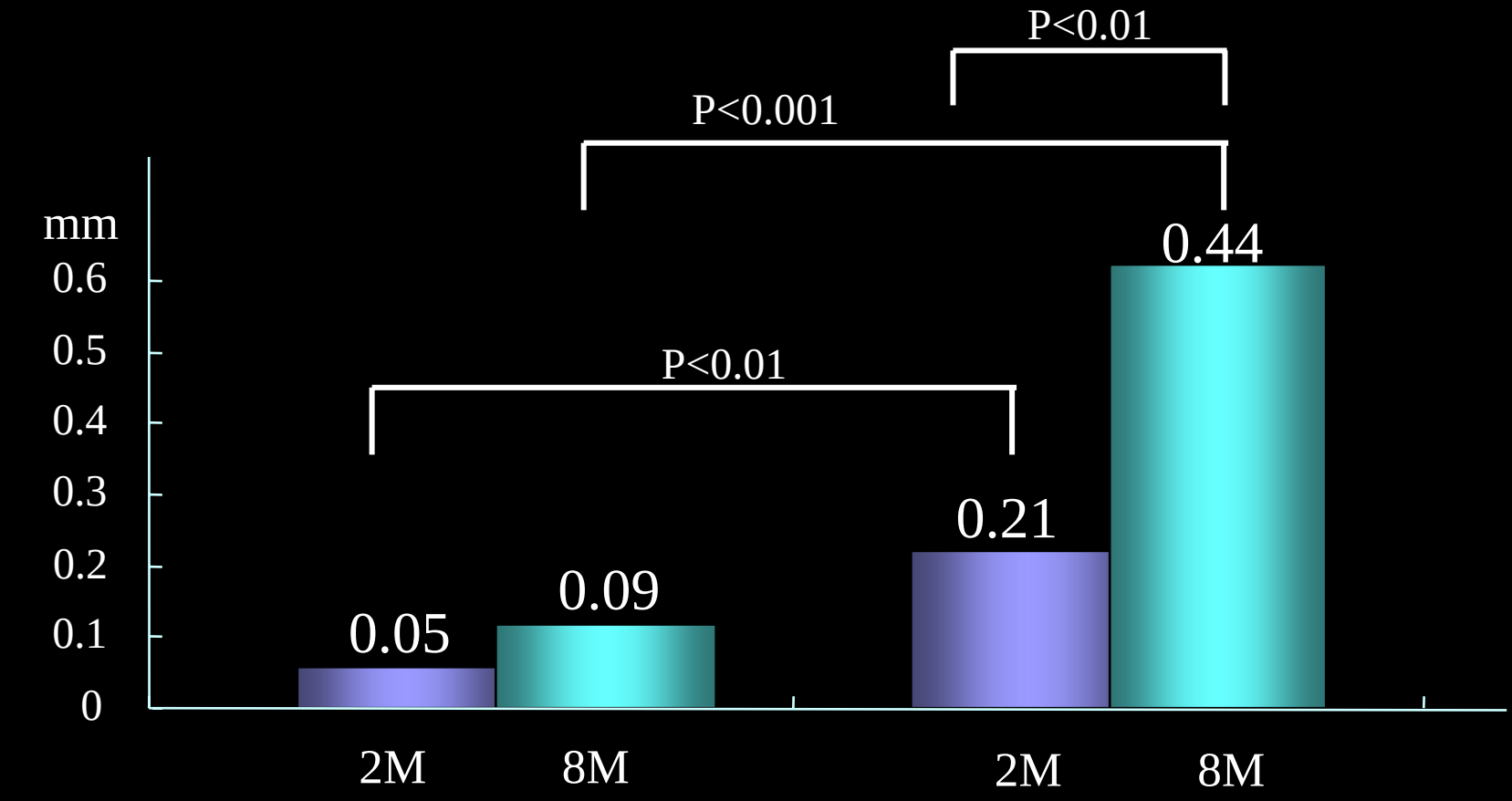
Neointimal Thickness (NIT)

Mean NIT (mm)



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EXPEDITED REVIEW

Incomplete Neointimal Coverage of Sirolimus-Eluting Stents

Angioscopic Findings

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Amagasaki, Japan; and New York, New York

OBJECTIVES The goal of this study was to use angioscopy to investigate the amount of neointimal coverage after sirolimus-eluting stent (SES) implantation.

BACKGROUND Sirolimus-eluting stents reduce intimal hyperplasia.

METHODS We used angioscopy to evaluate 37 consecutive stented coronary artery lesions (15 SES and 22 bare-metal stents [BMS]) in 25 patients (18 men, 7 women) at 3 to 6 months after stent implantation. Angioscopic evaluation focused on: 1) neointimal coverage of stent struts, and 2) the existence of thrombi. The degree of neointimal coverage was classified as grade 0 when there was no neointimal coverage (similar to immediately after the implantation); grade 1 when stent struts bulged into the lumen, but were covered and still translucently visible; grade 2 when stent struts were visible but not clearly seen (not translucent); and grade 3 when stent struts were not visible because they were embedded in the neointima.

RESULTS Thrombi were identified in eight stented segments, tended to be more common with SES ($p = 0.14$), but were not seen on angiography. Three of the 15 SES (20%) had grade 0 neointimal coverage, and only 2 SES (13.3%) had complete coverage (grades 2/3). In contrast, all 22 BMS showed complete intimal coverage (grades 2/3). Thrombi were more common in stents with incomplete neointimal coverage ($p = 0.09$).

CONCLUSIONS The SES had incomplete neointimal coverage three to six months after implantation, and this was associated with subclinical thrombus formation. (J Am Coll Cardiol 2006;47:2108–11)

Why is there difference in the rate of neointimal coverage of stent struts between Kotani's data and our data?

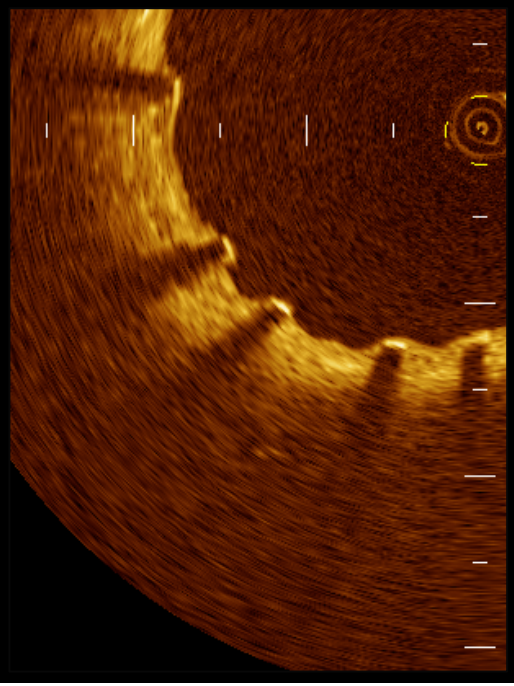
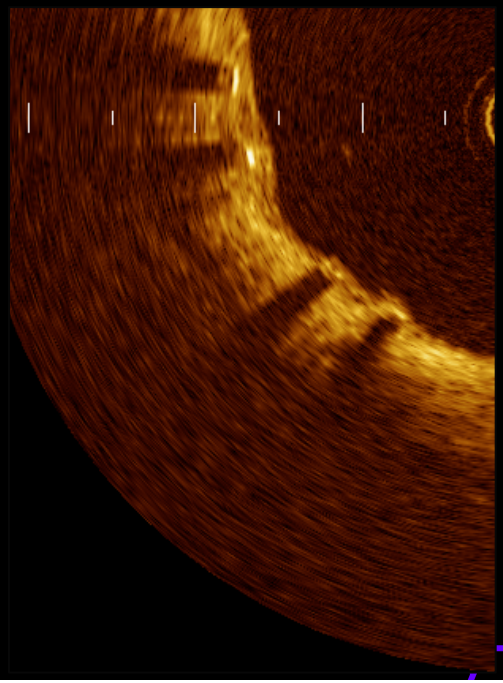
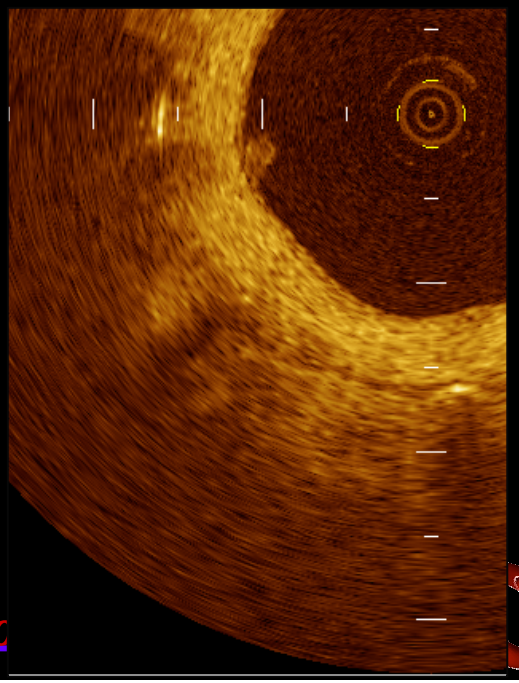
Differences in Follow-up Perios

	Kotani's data	Our data	
		2-month FU	8-month FU
SES	116±47	60 ± 17	241 ± 31
BMS	132±48	55 ± 13	268 ± 66

Differences between Angioscopy and OCT

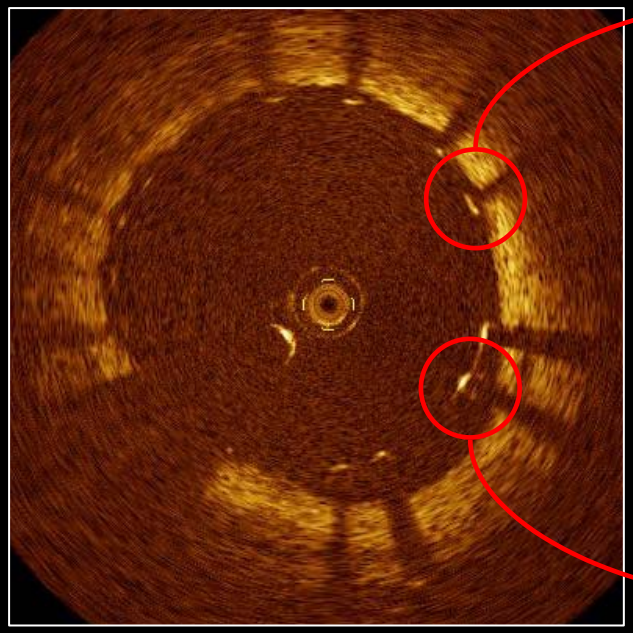
Grade 0 **Grade 1** **Grade 2**



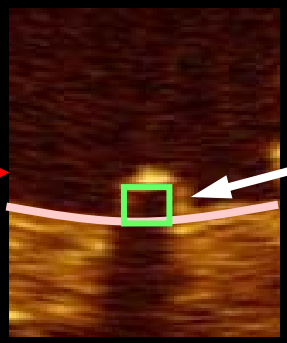





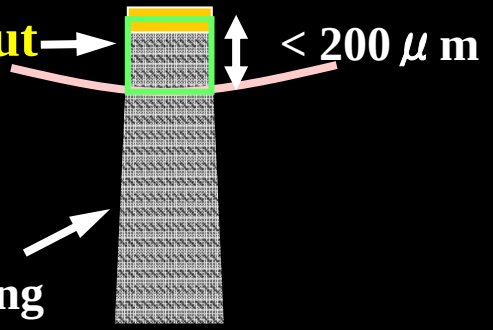
Stent Incomplete Apposition

Stent Apposition

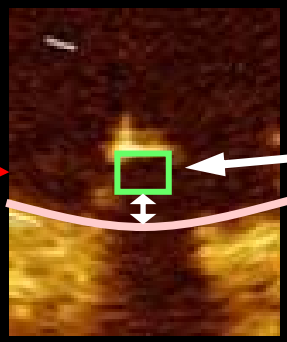


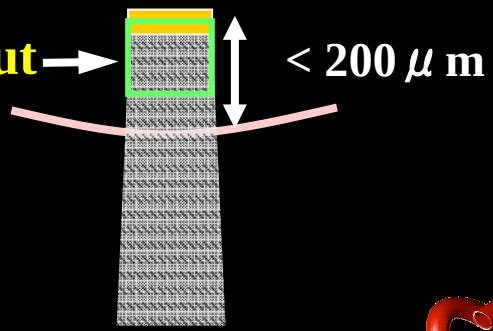
Complete stent apposition (CSA)





Incomplete stent apposition (ISA)





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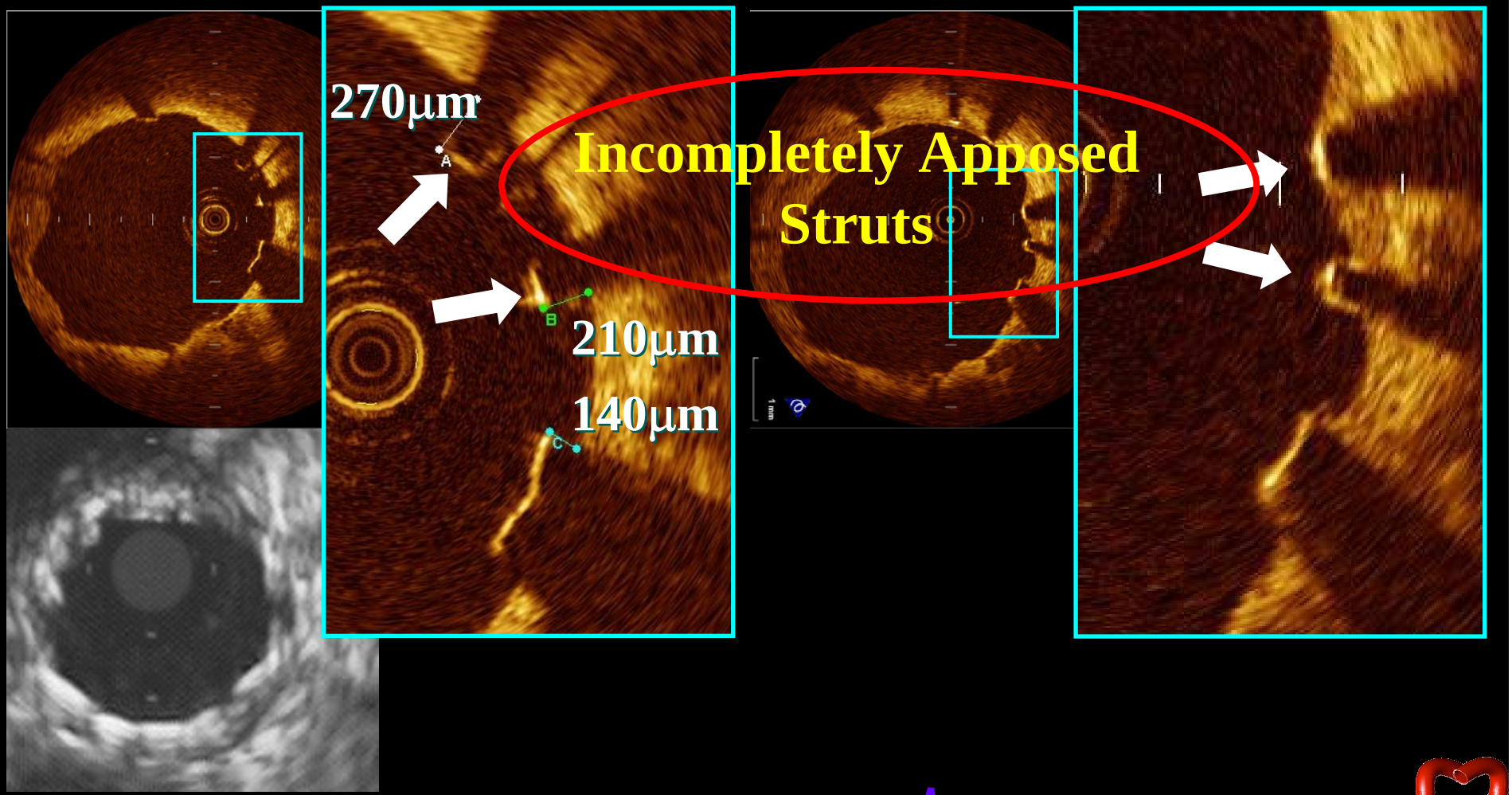
Follow-up of Struts with Incomplete apposition

Post PCI

2Mo. FU



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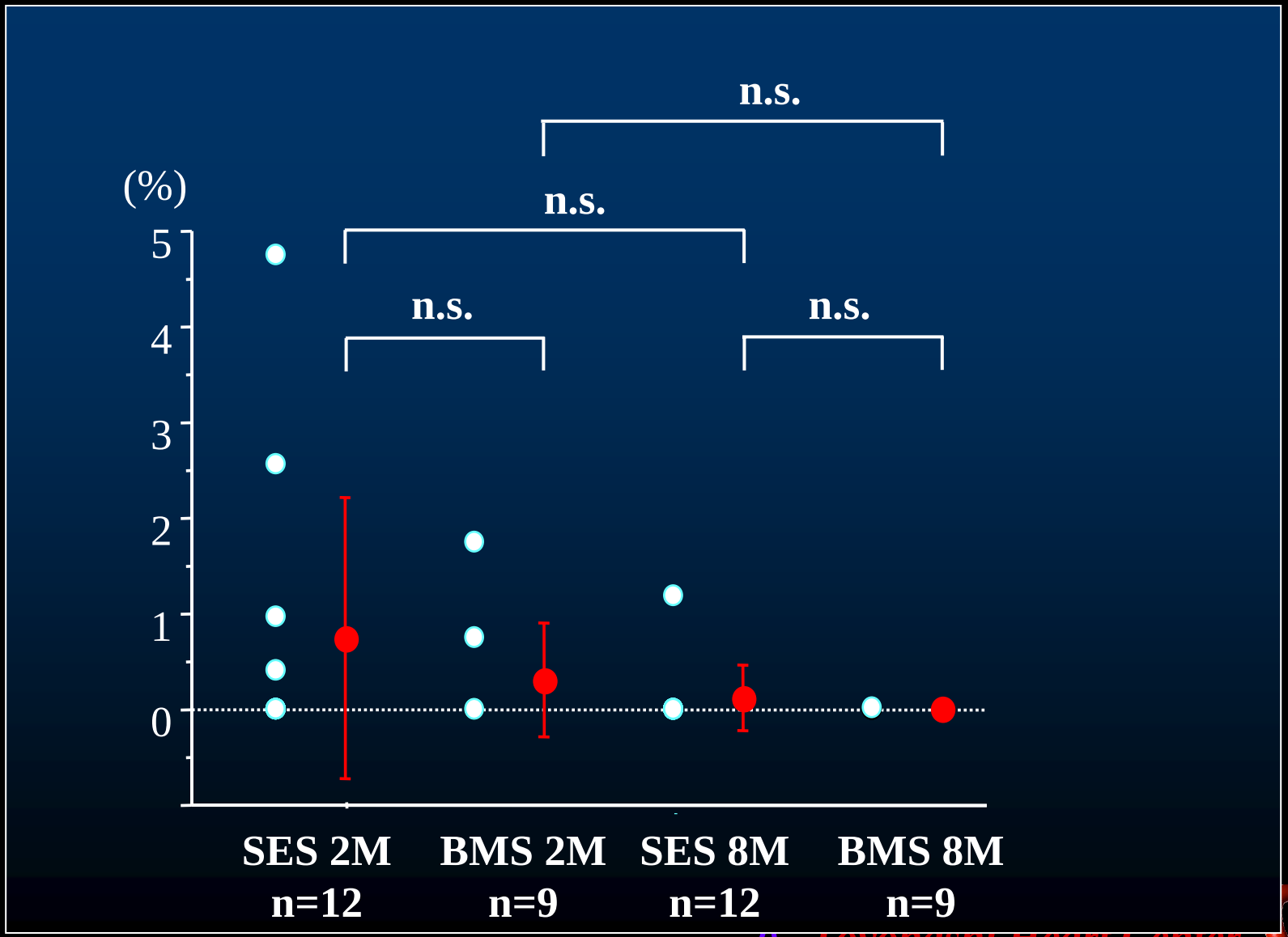
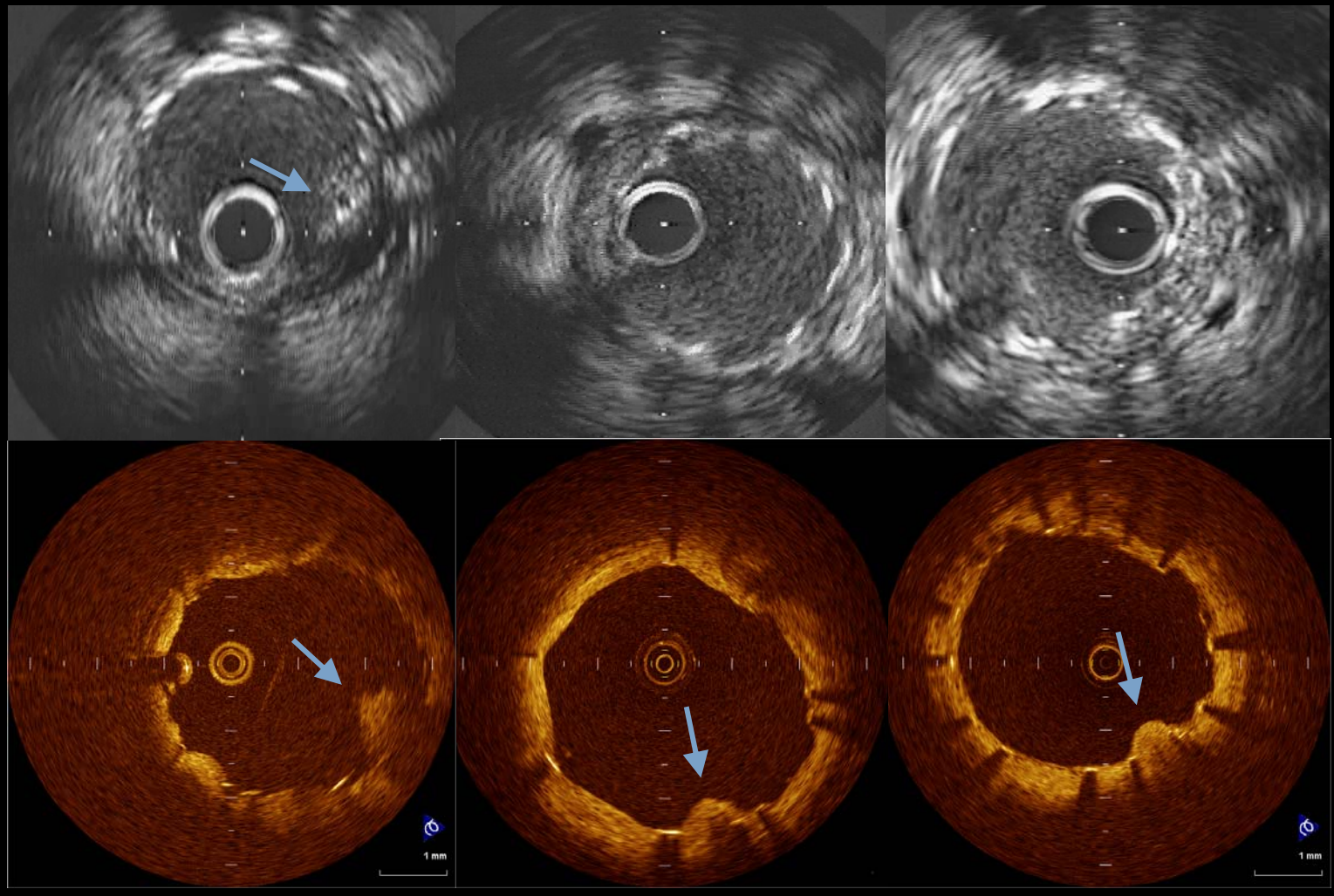
Frequency of Incomplete Stent Apposition / Stent



Follow-up of Protrusion within SES

Post PCI　　2Mo. FU　　7Mo. FU



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Restenosis Rate of Cypher Stent in Toyohashi Heart Center

- 1701 lesions (May 2004 – Jan 2006)

6-9 months Follow up	706 lesions (Follow up rate 41.5%)
Restenosis Rate	8.4% (60/706)

Stent Fracture Rate of Restenosis Lesions

13.3% (8/60)

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Restenosis in SES

Case 1
2004.9.7
K.C Female
Age:73
ACC/AHA
Type B2
CCS Class2

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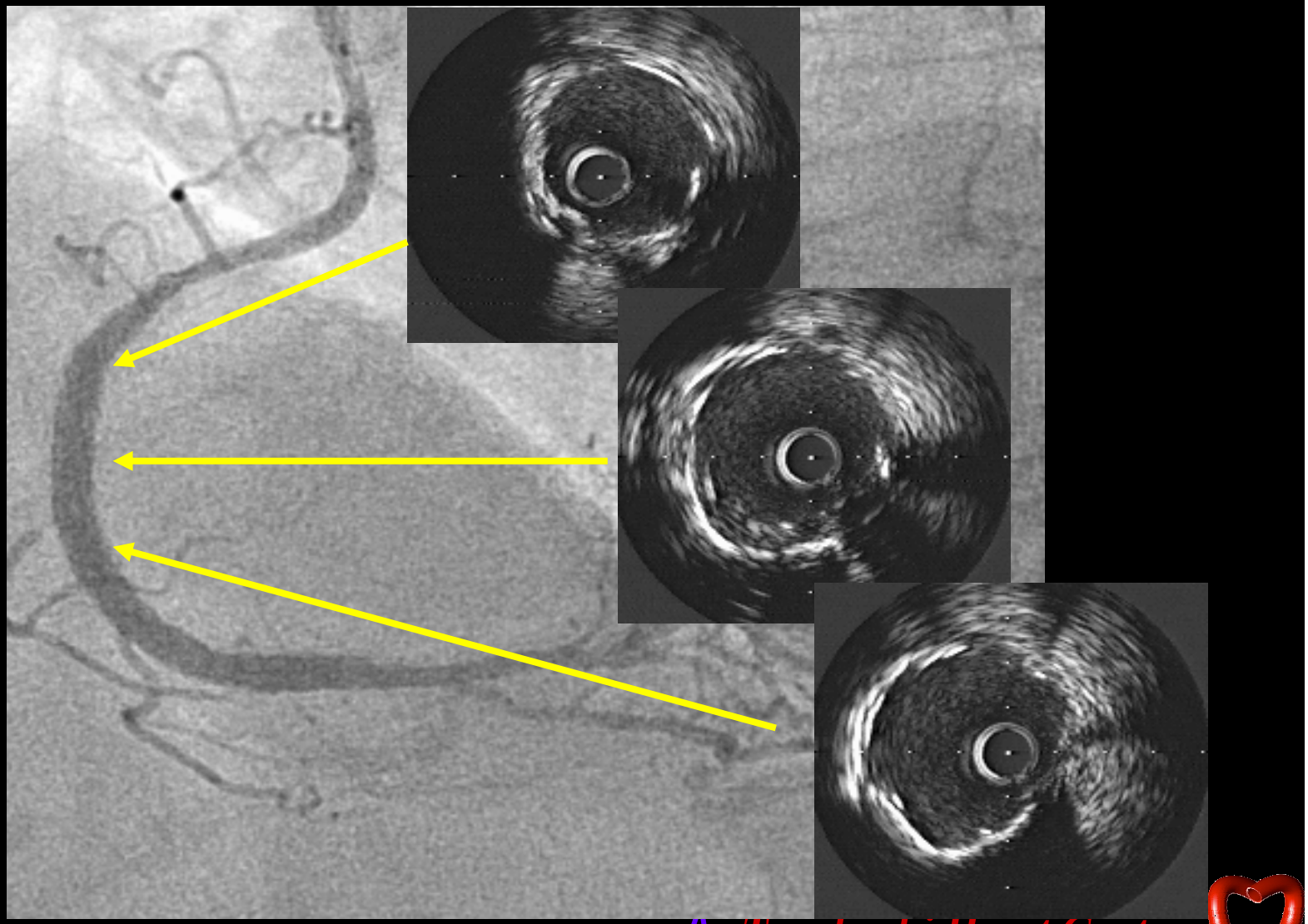
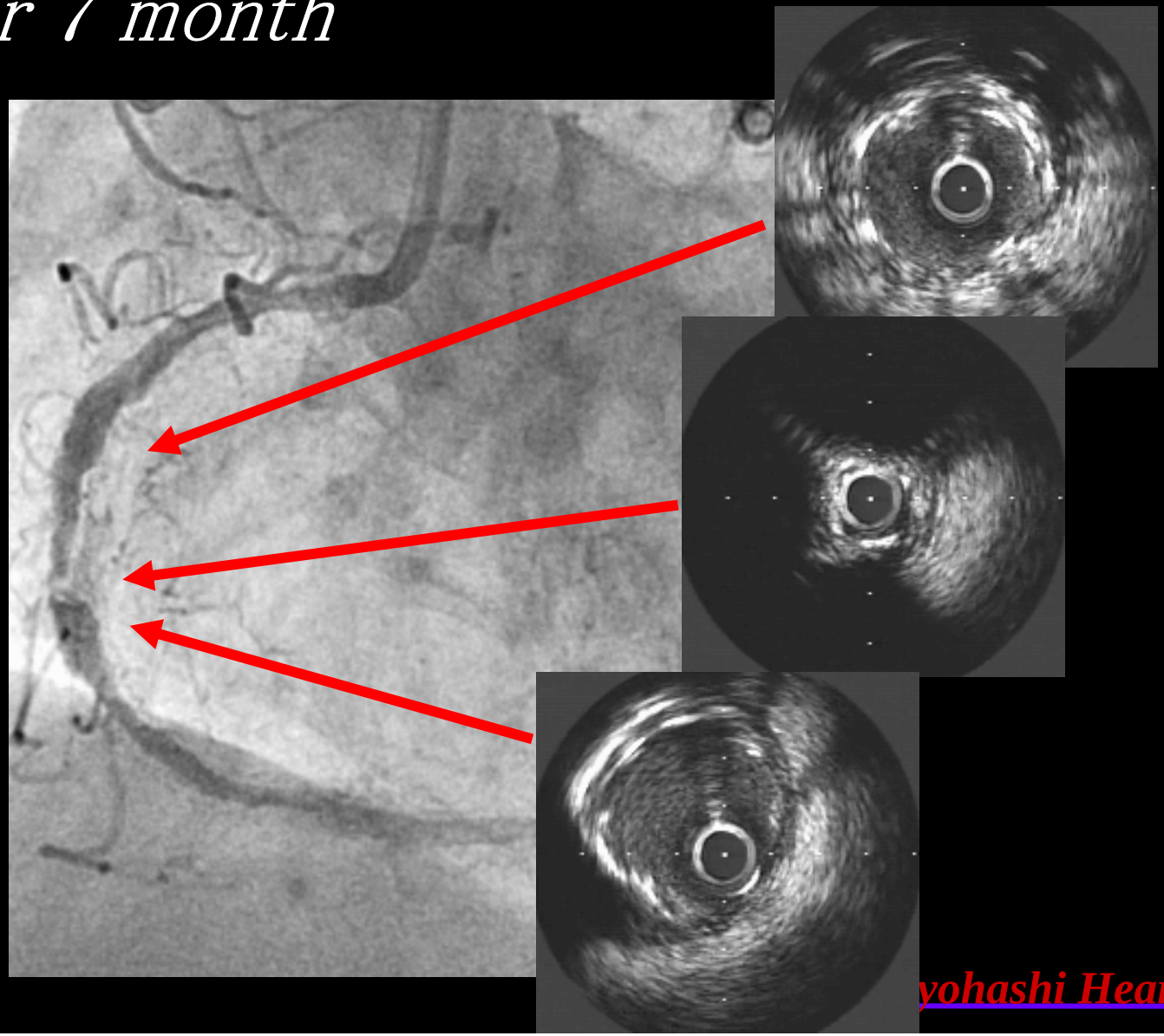
Restenosis in SES

Final



Restenosis in SES

After 7 month



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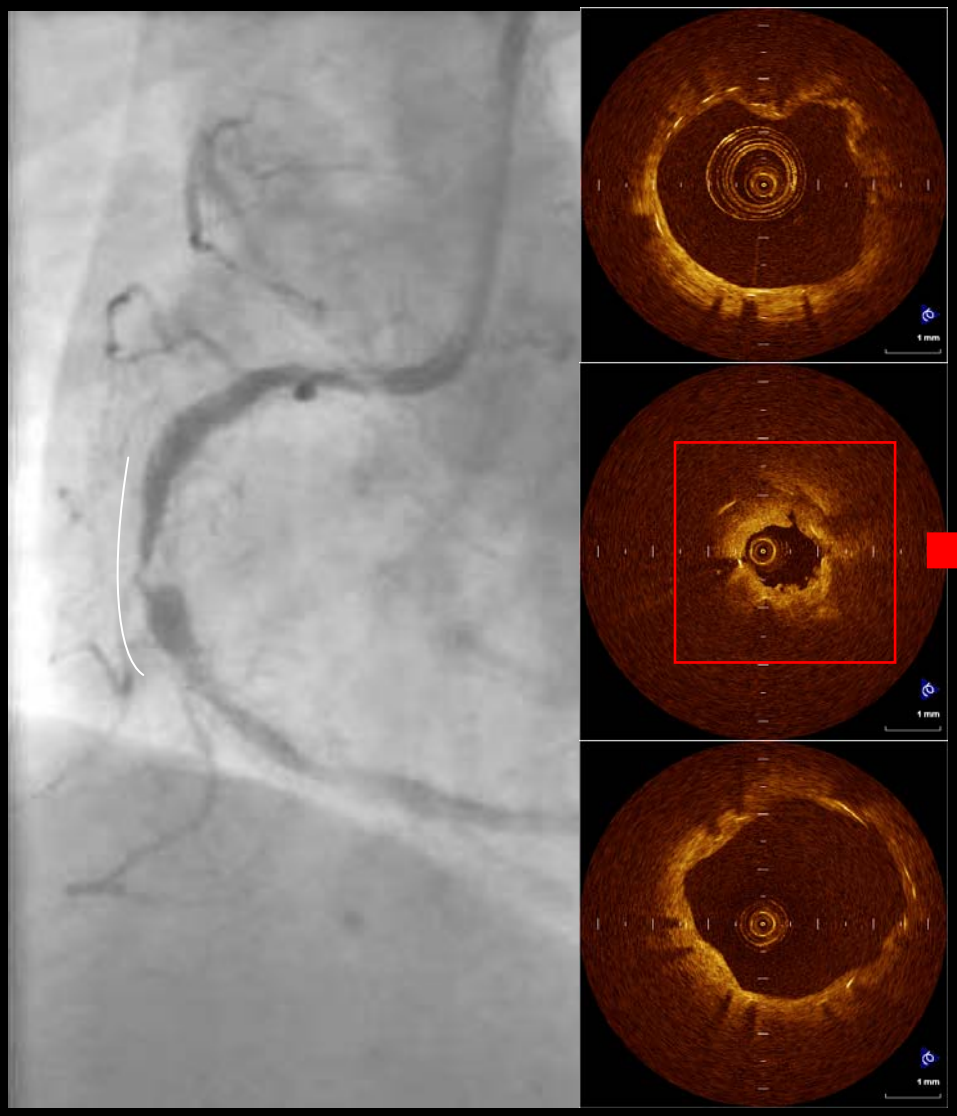
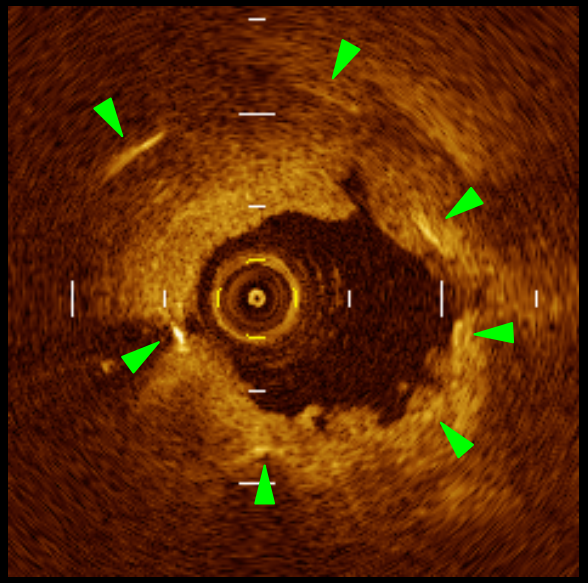
Case with Restenosis of SES



Stent collapse

Stent diameter 1.44 x 1.96mm



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