Role of Imaging in Calcified Lesion Treatment

Takashi Akasaka, MD, PhD, FESC, FAPSC, FJCA, FJCC, FJCS, FJACHD
Emeritus Professor, Wakayama Medical University
Senior Consultant, Nishinomiya Watanabe Cardiovascular Center
Medical Advisor, Terumo Corporation

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Disclosure Statement of Financial Interest

Takashi Akasaka, MD, PhD, FAPSC, FESC, FJCA, FJACHD, FJCC, FJCS

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- **Grant/Research Support:** Abbott Medical Japan
Daiichi-Sankyo Pharmaceutical Corp.
Nipro Corp.
Terumo Corp.
- **Consulting Fees/Honoraria:** Abbott Medical Japan
Nipro Corp.
Terumo Corp.
- **Medical Advisor (Employed):** Terumo Corp.

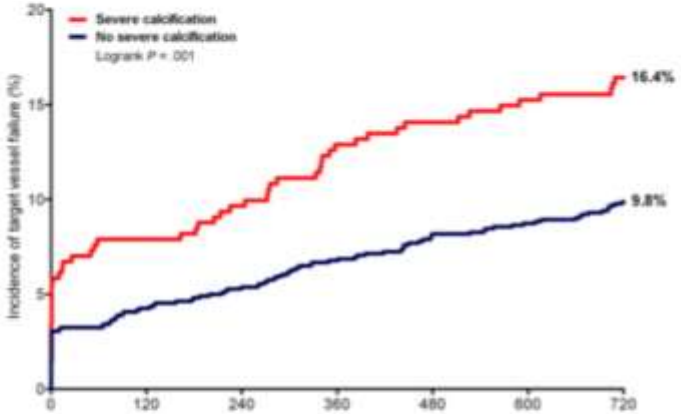
TWENTE and DUTCH PEERS trials

Am Heart J. 2016;175:121-129

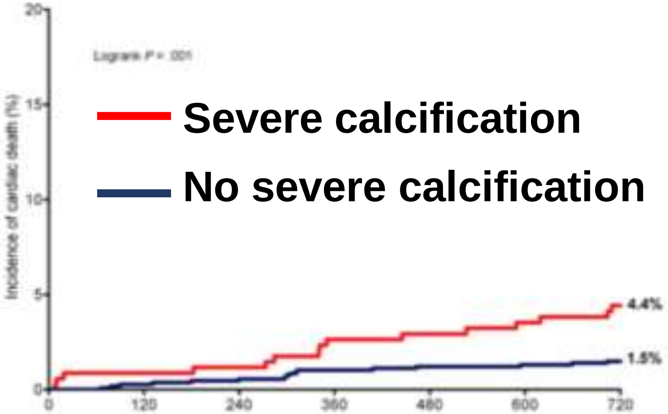
MACE-Trial 1-year results

Catheter Cardiovasc Interv. 2019;94(2):187-194

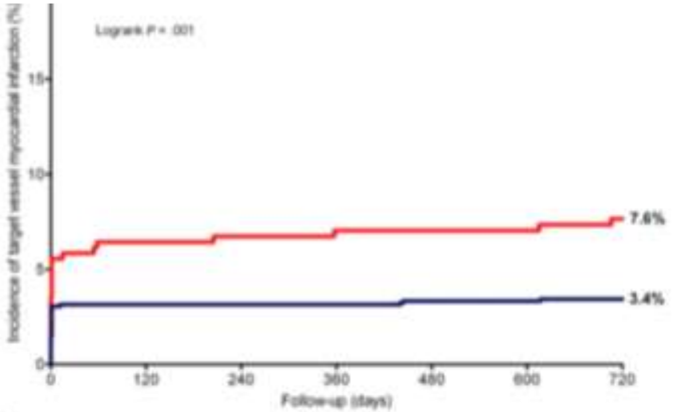
Target vessel failure



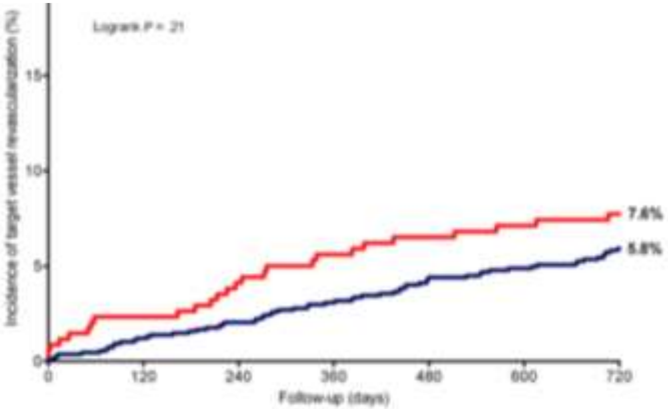
Cardiac death

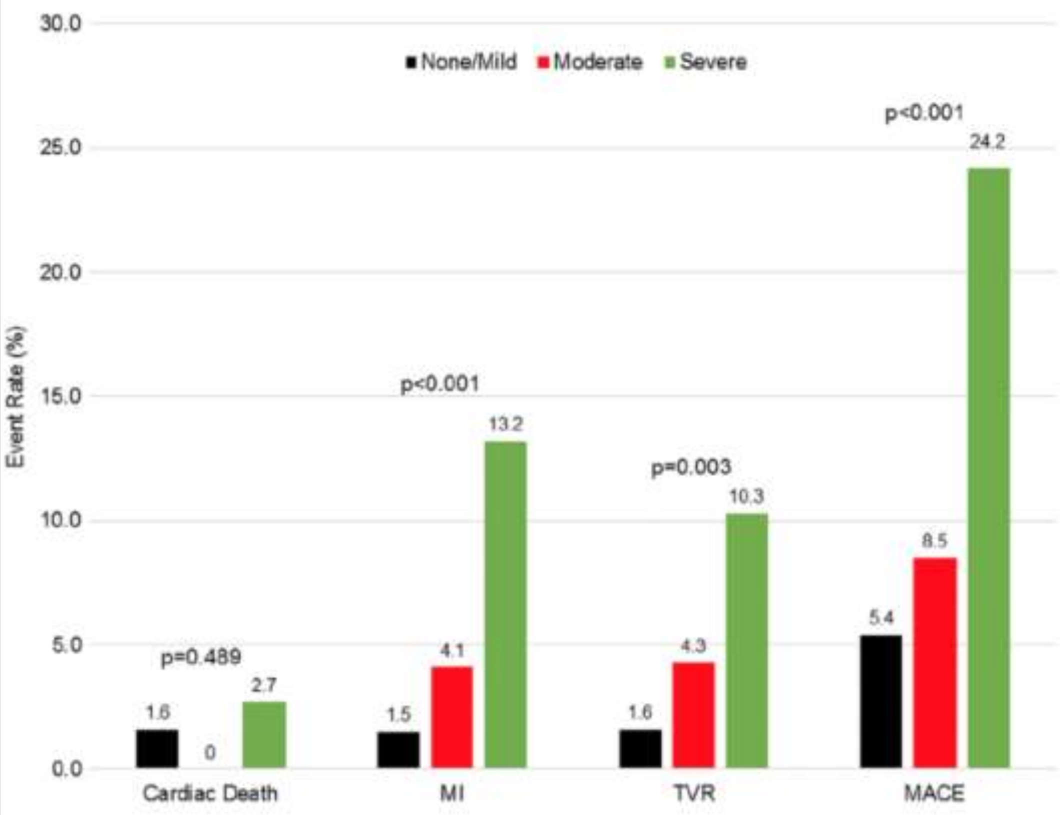


Target vessel MI



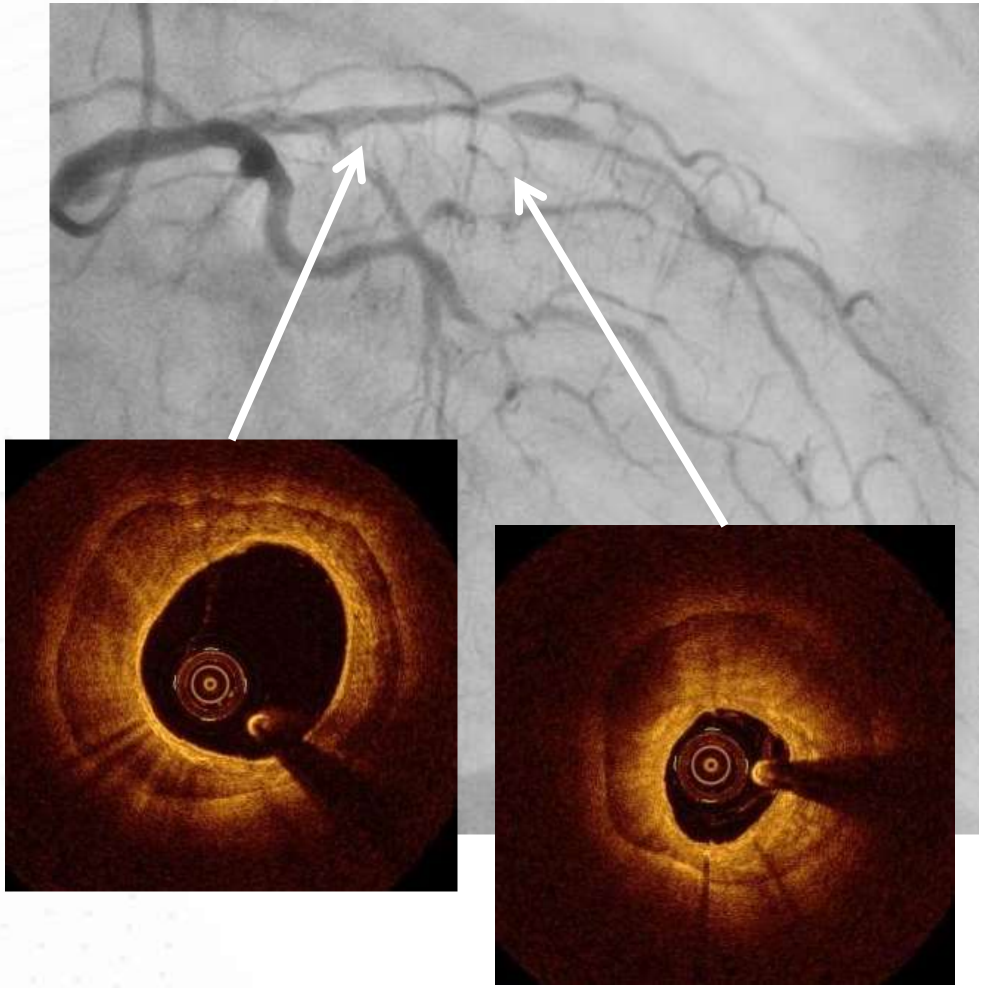
Clinically indicated TVR

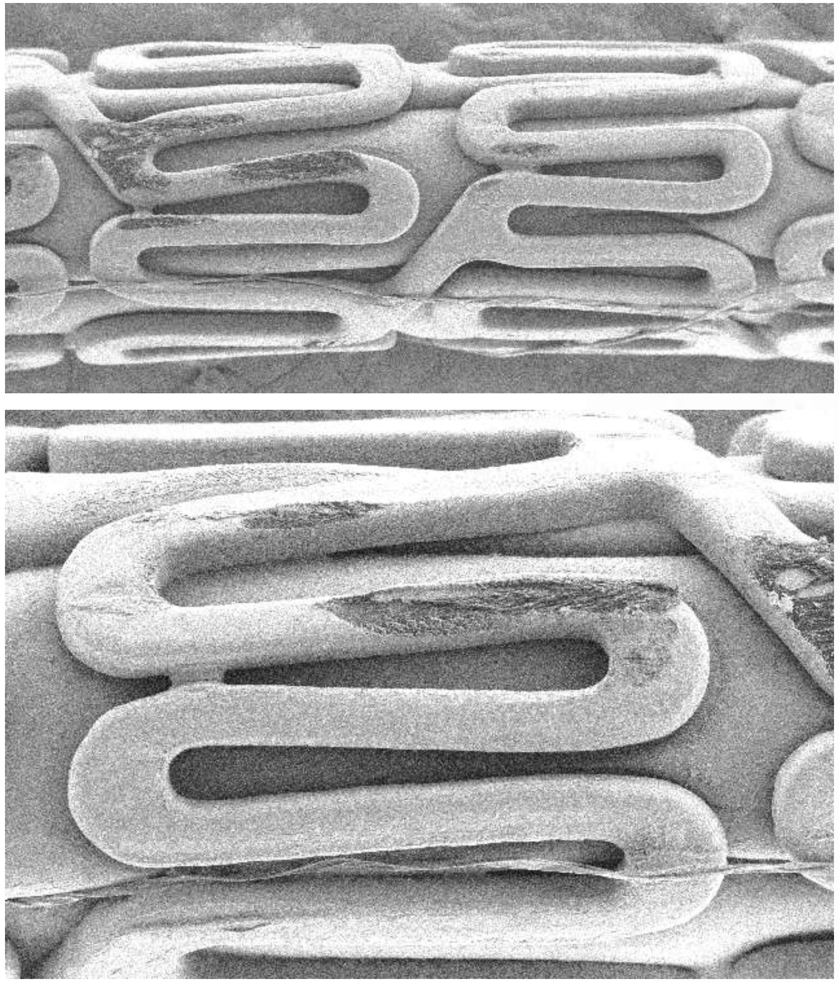




- **Why coronary calcium is so important?⇒Patients with severe calcification had significantly worse outcomes compared to those without.**

Polymer damage of DES during PCI in OCT-derived severe calcified lesion without lesion modification



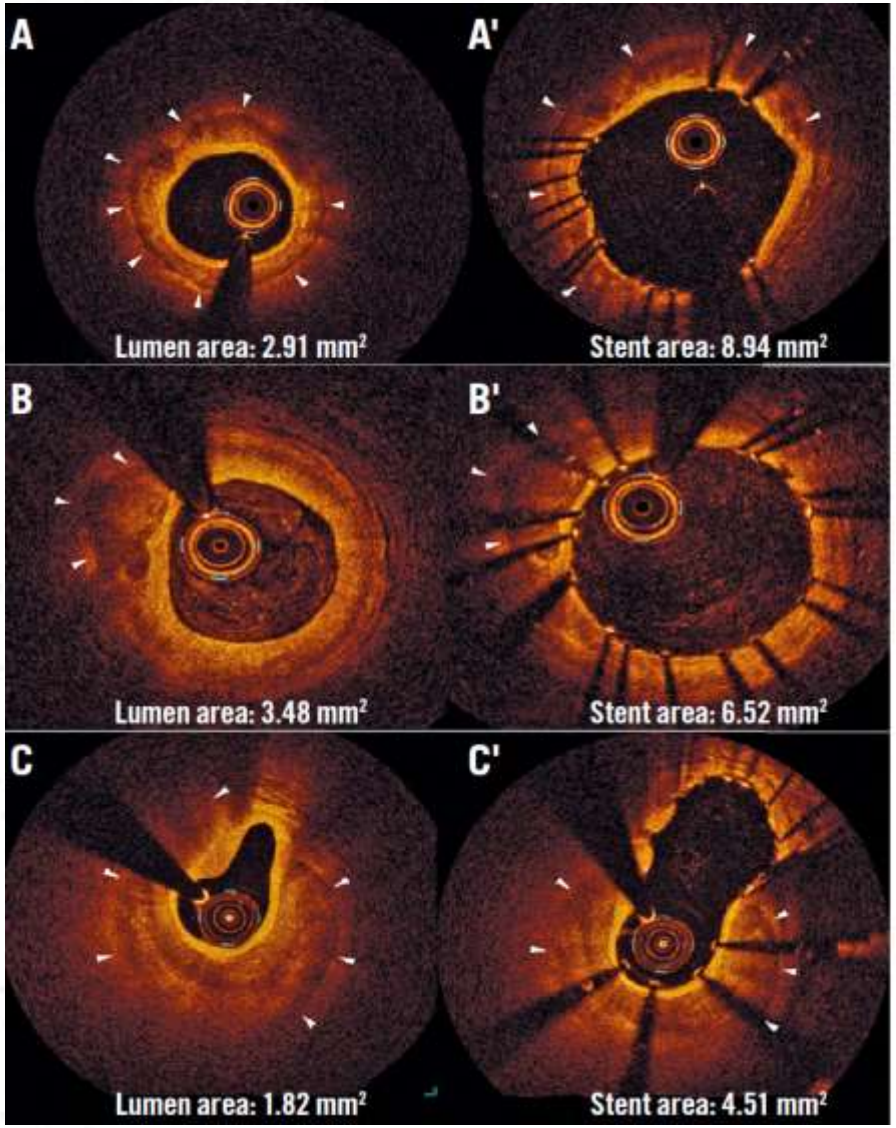


Promus element

Shimokado, Kubo, Akasaka et al. Int J Cardiov Imag. 2013;29:1909-1913

Calcium eccentricity, thickness & length and stent expansion

Baseline | Final



Angle: 360°
Thickness: 0.48 mm
Length: 3.8 mm
Calcium score: 2 points

Expansion: 99%

Enough stent expansion could be expected if the calcium thickness is thin even if it is circumferential.

Angle: 75°
Thickness: 1.1 mm
Length: 4.3 mm
Calcium score: 1 point

Expansion: 97%

Enough stent expansion could be expected in cases with thick calcium if it is localized.

Angle: 312°
Thickness: 1.4 mm
Length: 11.0 mm
Calcium score: 4 points

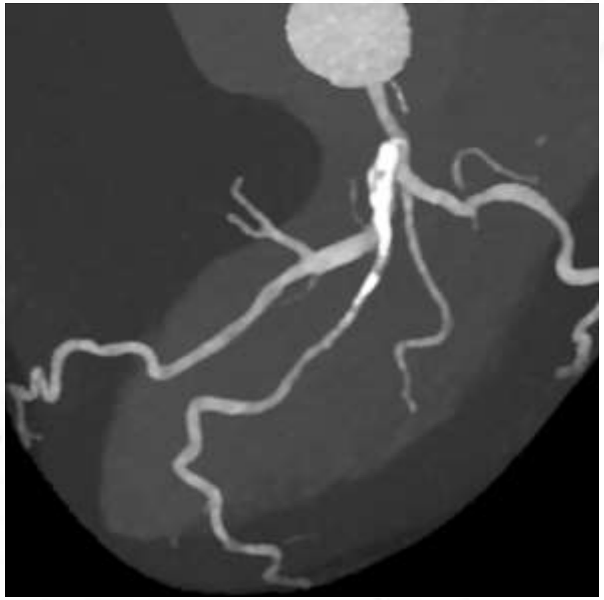
Expansion: 68%

Severe thick calcium more than 180 degree may cause stent under-expansion.

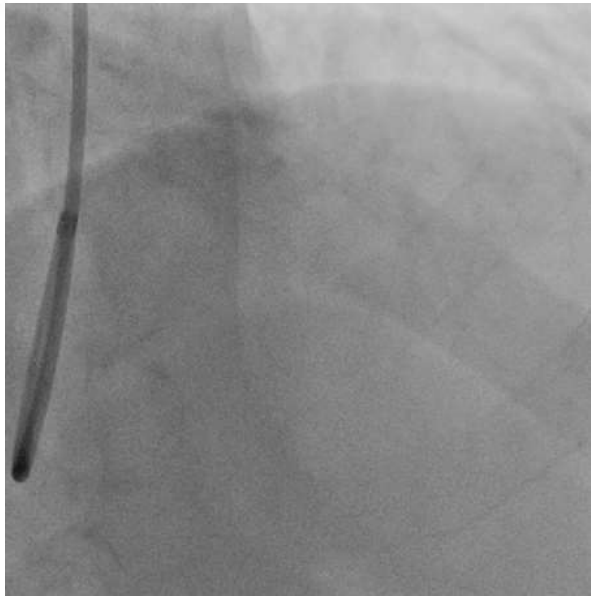
Fusiono A, et al. EuroInterv 2018;13:e2182-e2189

Detection of calcified lesion

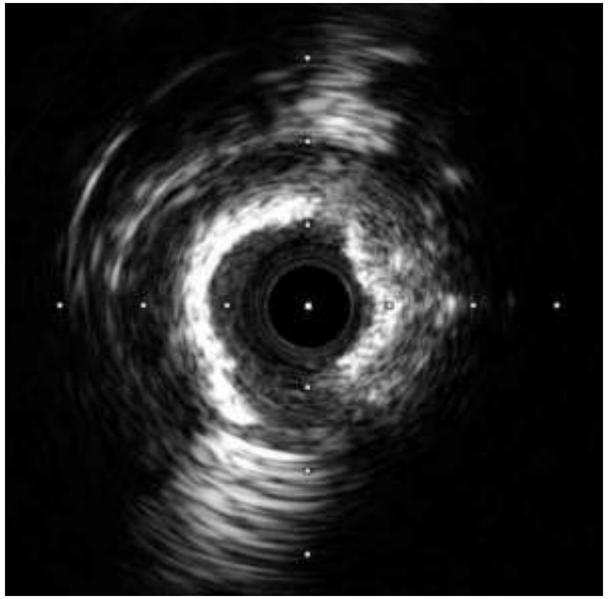
Coronary CTA



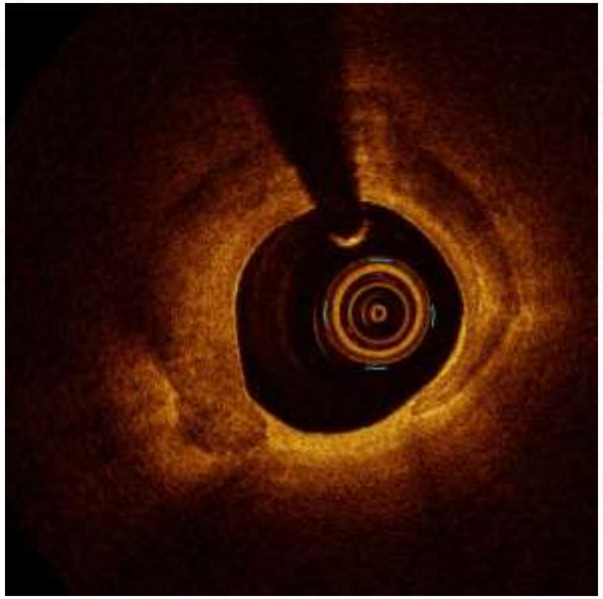
Angiography



IVUS



OCT



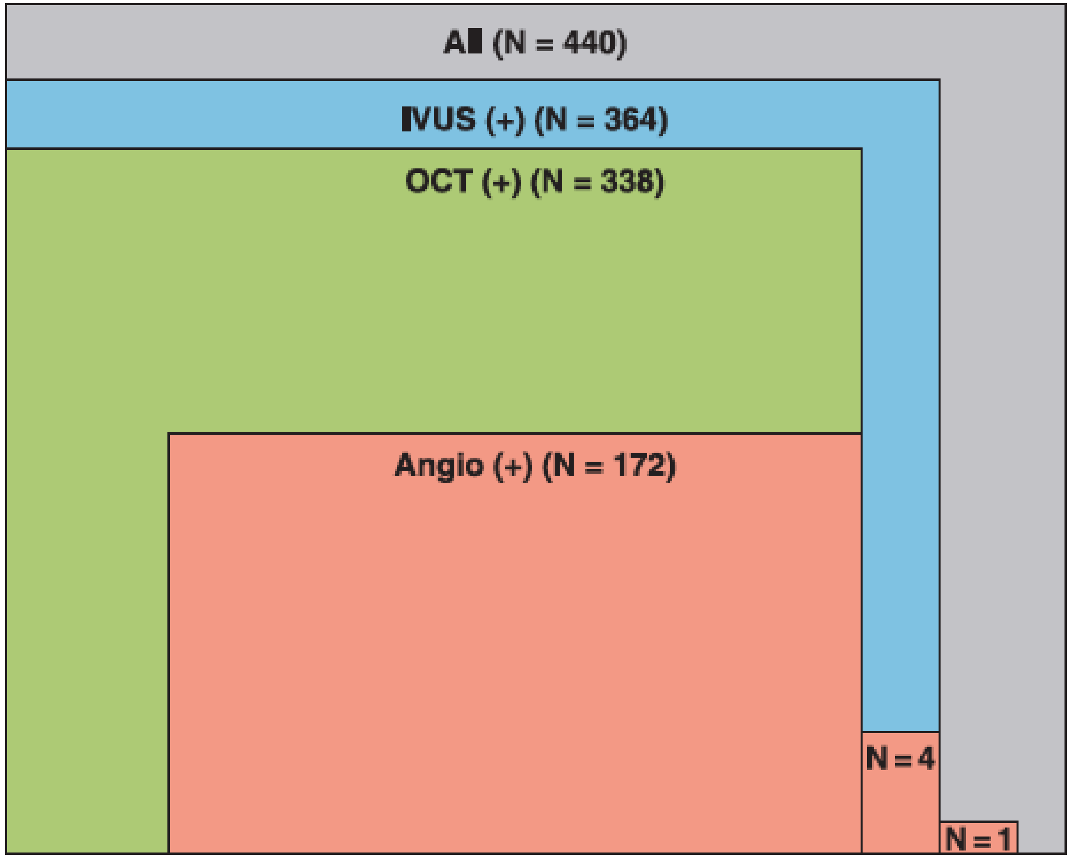
There are several imaging modalities to identify calcium.
Compared with IVUS, OCT can evaluate the thickness of calcium.

Similarities & differences between OCT & IVUS

Maehara A, et al. J Am Coll Cardiol Img 2017;10:1487-1503

OCT				IVUS		
Very good	Good	Feasible	**Pre-PCI**	Feasible	Good	Very good
●	●	●	Severity of calcium	●	●	
		●	Prediction of slow flow	●		
	●	●	Stent sizing by vessel wall	●	●	●
●	●	●	Stent length to cover normal to normal	●	●	●
			Post-PCI			
●	●	●	Stent expansion	●	●	●
●	●	●	Tissue protrusion through strut	●	●	
●	●	●	Stent malapposition	●	●	
	●	●	Stent deformation (frequently at aorto-ostium)	●	●	
●	●	●	Stent edge dissection	●	●	
●	●	●	Residual disease at stent edge	●	●	●
			Follow-up			
●	●	●	Old stent expansion	●	●	●
	●	●	Tissue coverage	●		
●	●	●	Neointimal hyperplasia	●	●	●
	●	●	Stent fracture	●	●	
●	●	●	Stent malapposition	●	●	
		●	Positive remodeling of vessel wall	●	●	●
●	●	●	Neoatherosclerosis	●	●	

Assessment of angiographically visible calcium

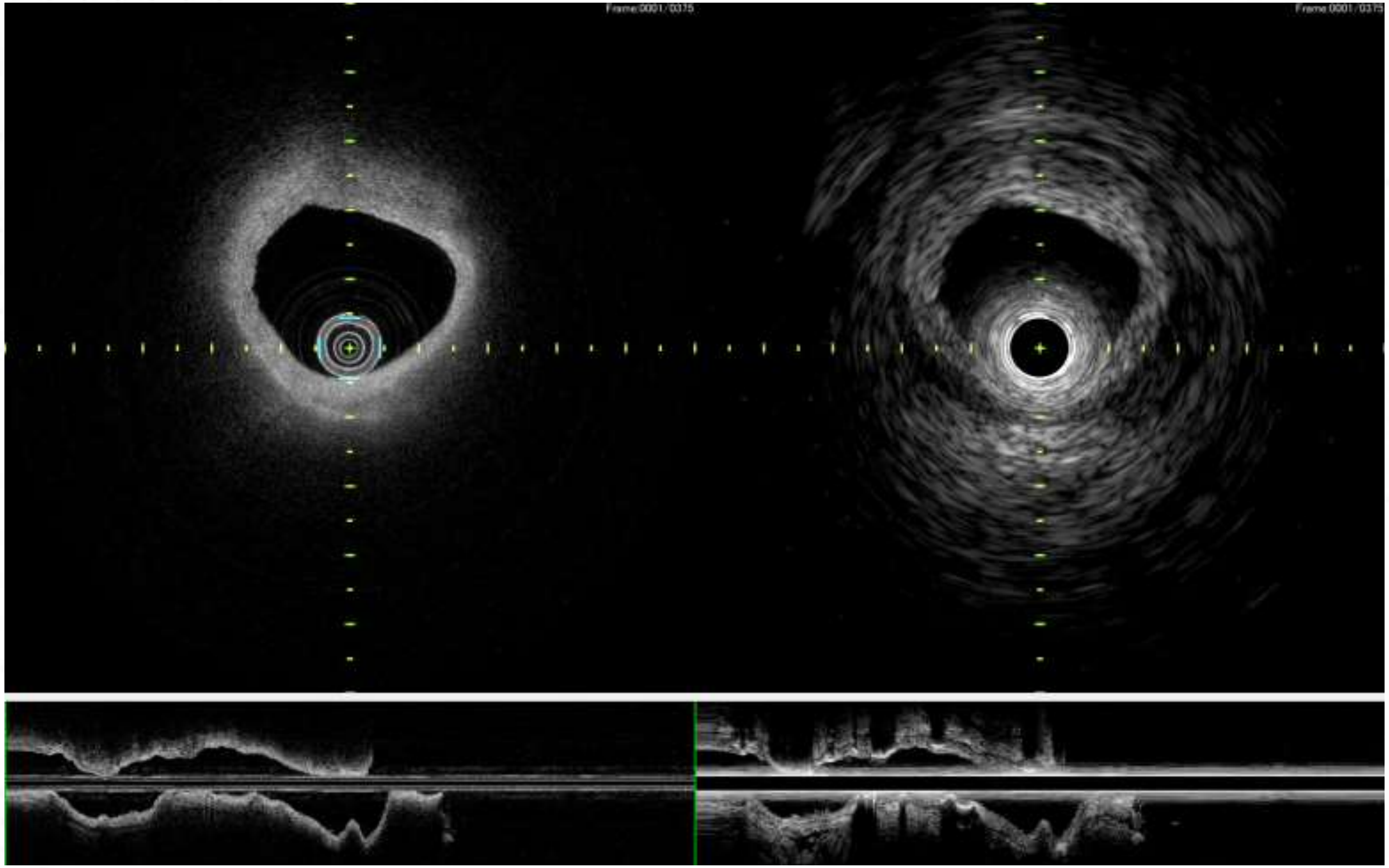


	Angiographically Visible Calcium		
	No (n = 16)	Yes (n = 58)	p Value
Pre-PCI intravascular ultrasound findings			
Maximum calcium angle,°	228 (190,286)	259 (230,322)	0.03
Pre-PCI optical coherence tomography findings			
Presence of any calcium	100 (16)	98.3 (57)	0.99
Maximum calcium angle,°	190 (146,300)	250 (174,320)	0.15
Angle of calcium <0.5 mm thickness,°	160 (69,249)	56 (0,131)	0.002
Angle of calcium ≥0.5 mm thickness,°	61 (10,92)	171 (98,242)	<0.001
Mean calcium angle*,°	44 (33,90)	68 (43,105)	0.047
Maximum calcium thickness, mm	0.71 (0.52,0.89)	0.95 (0.75,1.15)	0.004
Calcium length, mm	11.0 (6.0,18.0)	16.0 (11.0,23.0)	0.01
Post-PCI optical coherence tomography findings			
Minimum stent area, mm^2	8.1 (6.6,9.3)	5.9 (4.6,7.3)	0.001
Reference lumen area†, mm^2	9.4 (7.6,11.4)	6.6 (5.4,8.2)	0.001
Stent expansion, %	80.8 (74.5,107.0)	91.7 (77.6,101.1)	0.88

- **Angiographically visible calcium (thick calcium) seemed to be a marker to predict stent underexpansion.**
- **In 13.2% of IVUS-detected calcium, calcium was either not visible (n=26) or underestimated (>90 smaller) (n=22) by OCT mostly due to superficial OCT plaque attenuation and penetration depth of images.**

JACC Cardiovasc Imaging . 2017;10(8):869-879

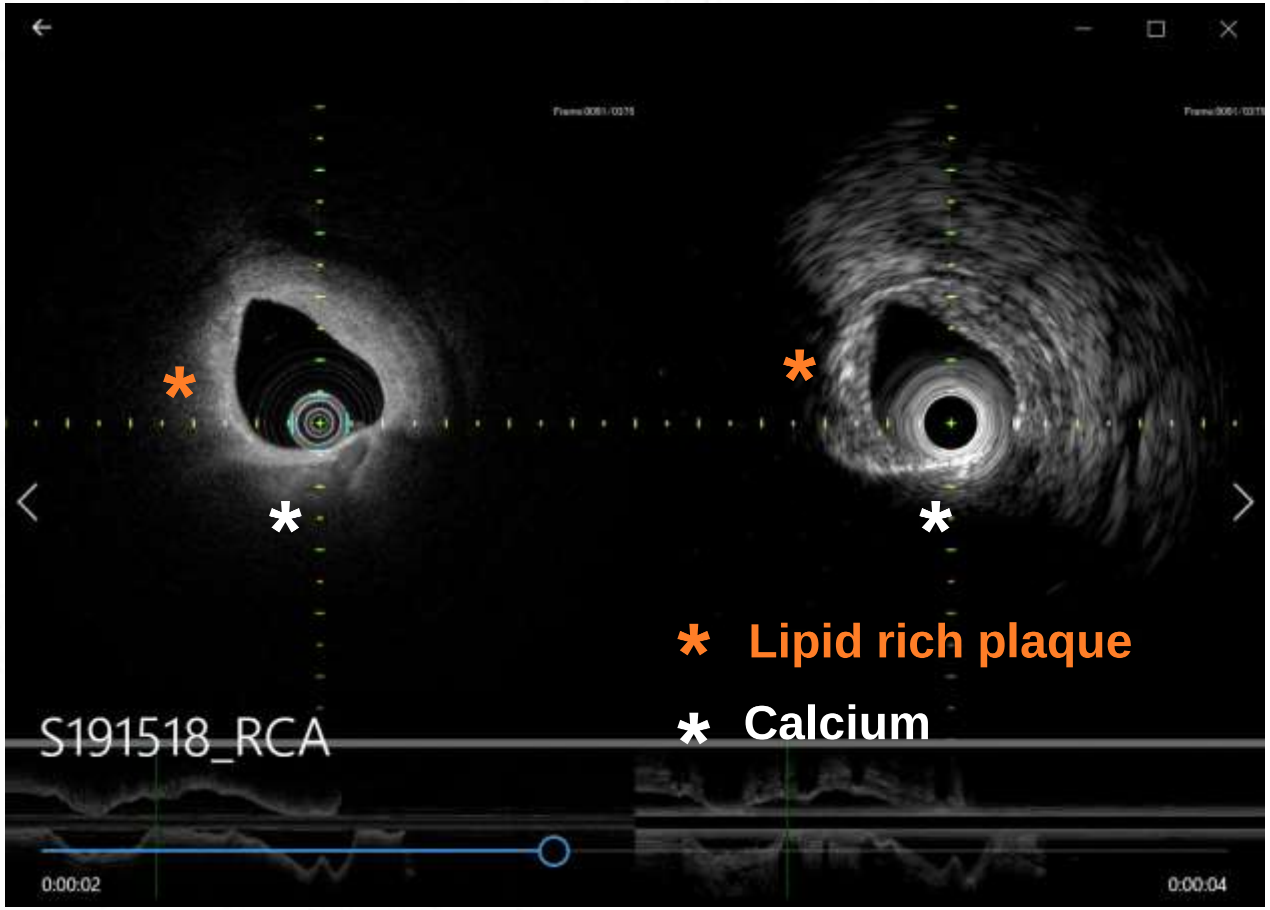
Dual sensor images with FD-OCT & IVUS



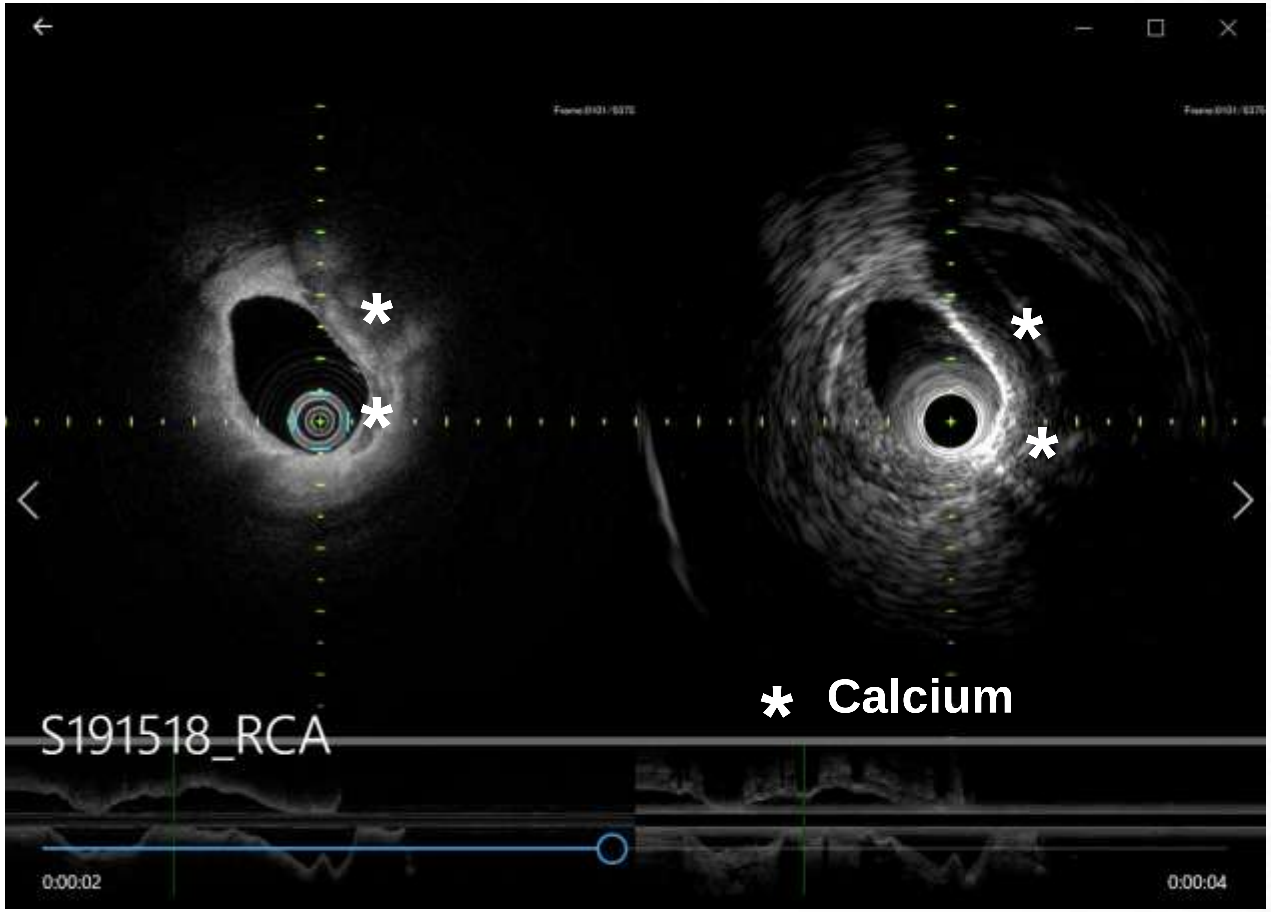
Because each modality may have advantages & disadvantages, dual sensor images may resolve these disadvantages in each modality.

Representative images using dual sensor images

FD-OCT IVUS



FD-OCT IVUS



Using dual sensor images with FD-OCT & IVUS, not only identification of calcium with accurate measurement of its' thickness but also differentiation among attenuation plaques by IVUS could be easy by OCT.

Case 1.   60's y.o. Female

Clinical Diagnosis: Effort AP

Colon cancer (before operation)

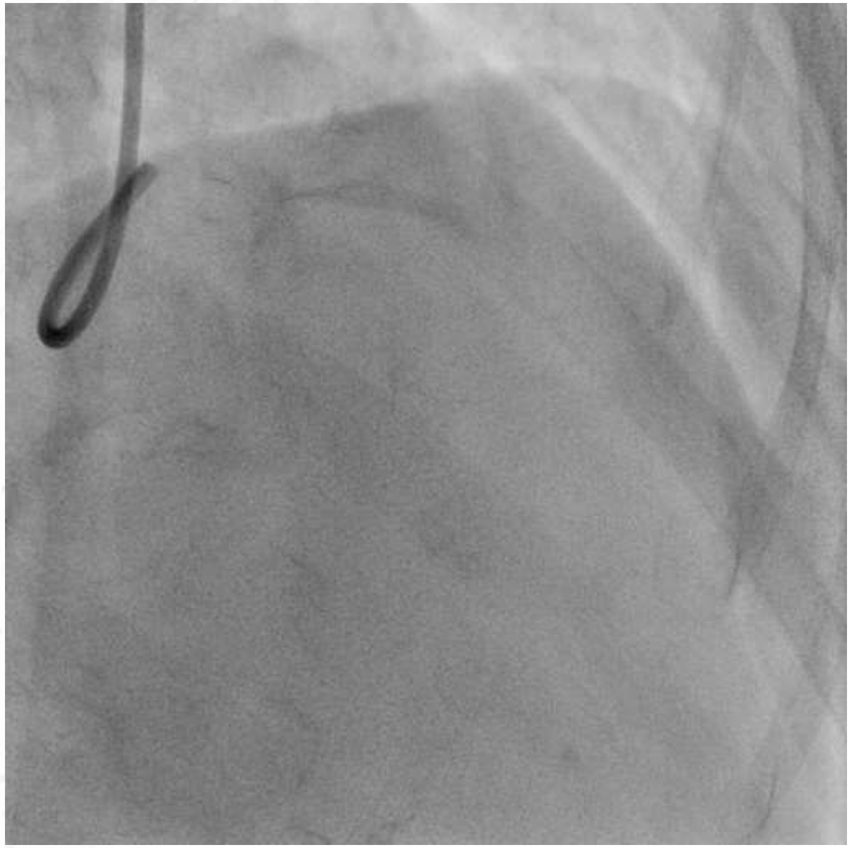
Coronary risk factor: HT, DM

Renal Function: Cr 0.88mg/dl, eGFR 56.3ml/min/1.73m^2

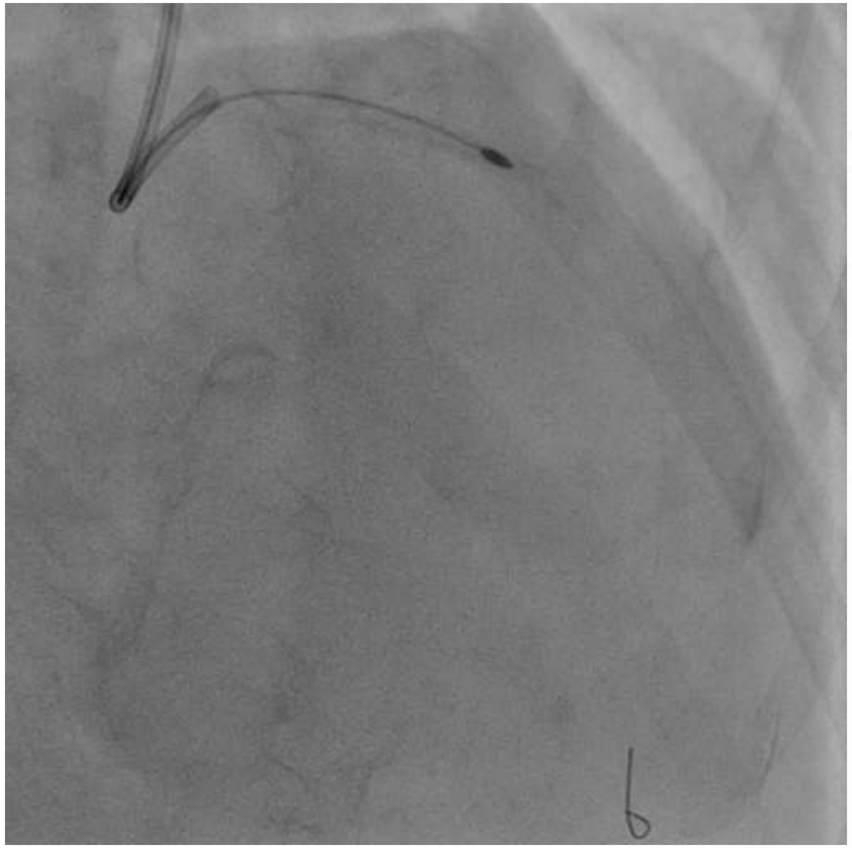
Cardiac Function: EF 63%, asynergy(-)

Coronary angiography & rotational atherectomy

Pre PCI

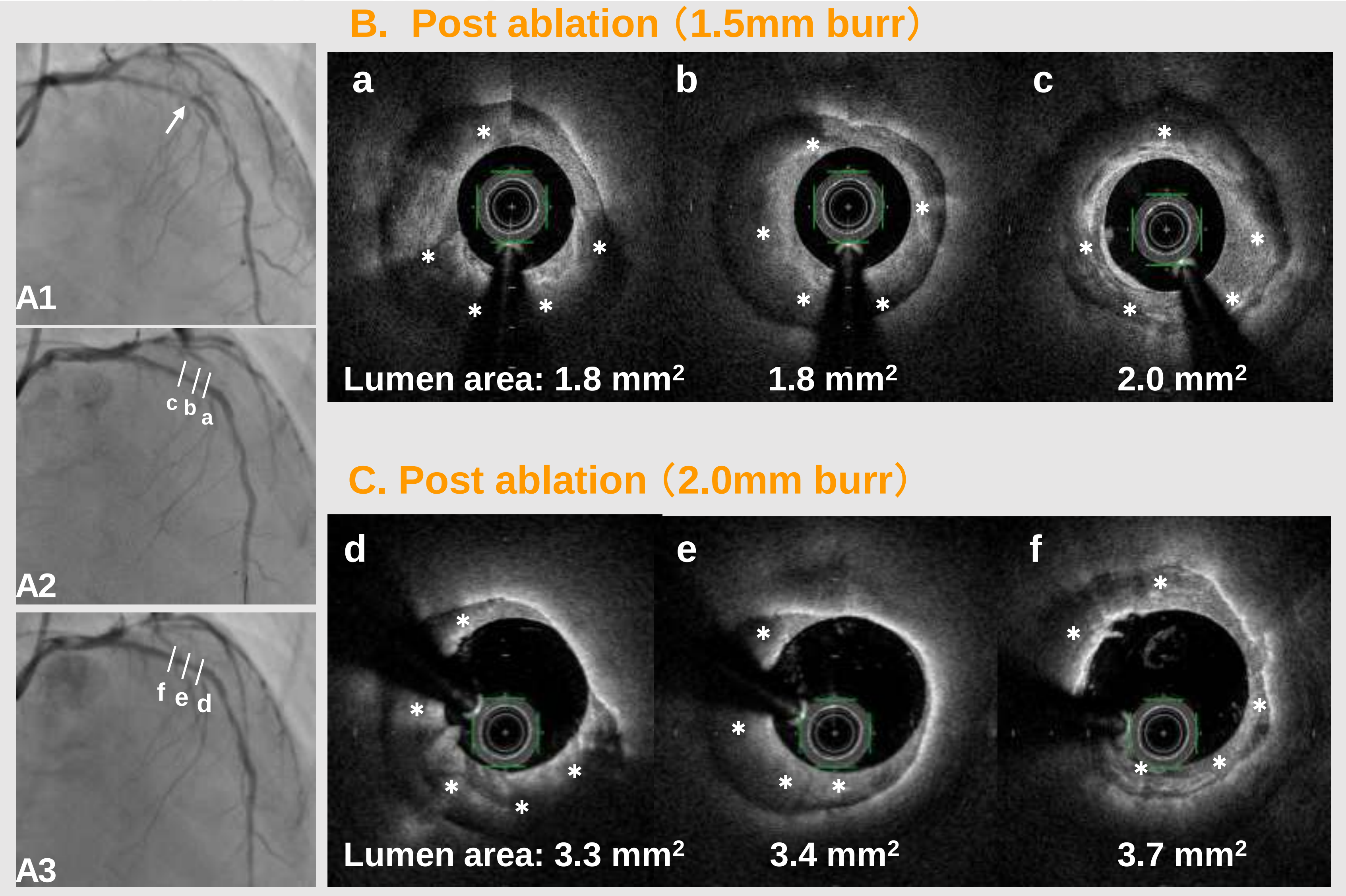


Rota 1.5 mm



Because of heavy calcification, it was difficult to pass any PCI devices & imaging modalities through the MLA site, and rotational atherectomy with 1.5mm burr was selected for lesion modification.

Comparison of OCT findings after rotational atherectomy



Burr size-up could be safely decided, and non-stent strategy was selected because of colon cancer operation.

Case 2. 70's y.o., Male

Clinical diagnosis

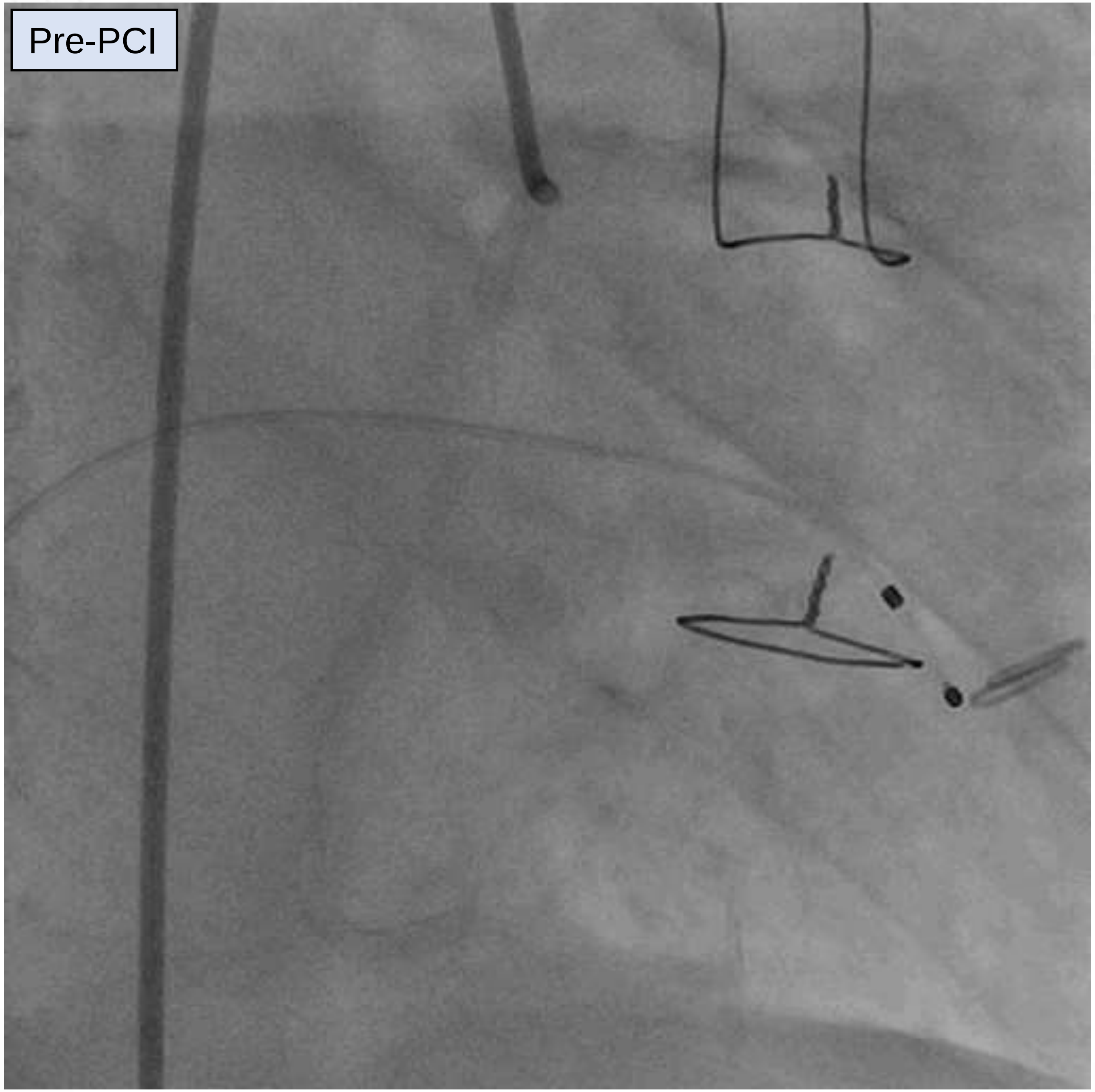
Stable AP, AF

Clinical history

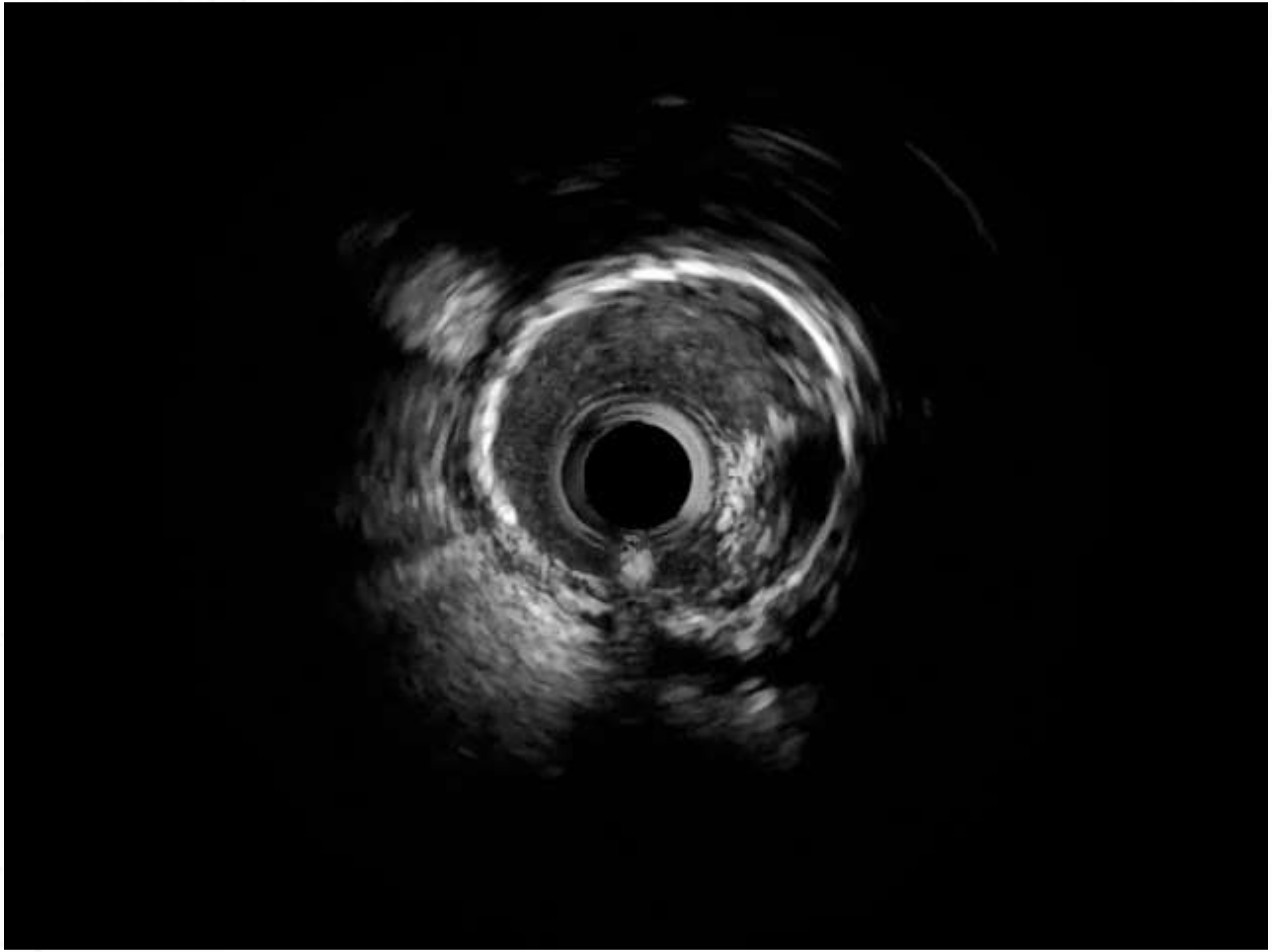
1978. CKD (Glomerular nephritis) ⇒ Hemodialysis
2003. Effort AP, LAD prox. lesion, CABG (LITA to LAD)
2013. Tl Scintigraphy: LV inferior ischemia

Coronary risk factors

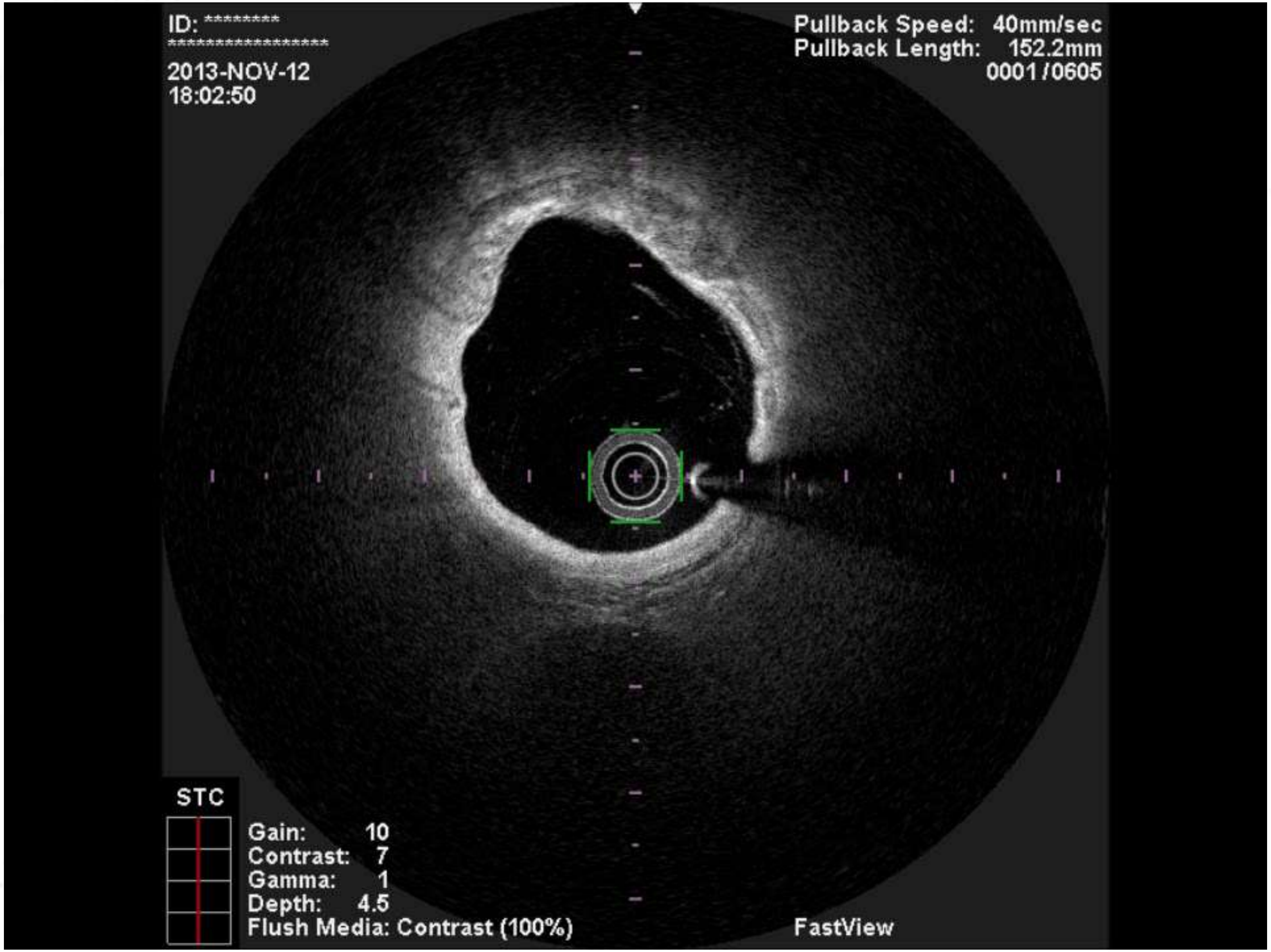
HT (-), DLP (-), DM (-), Obesity (-), Smoker (+)


Pre-PCI

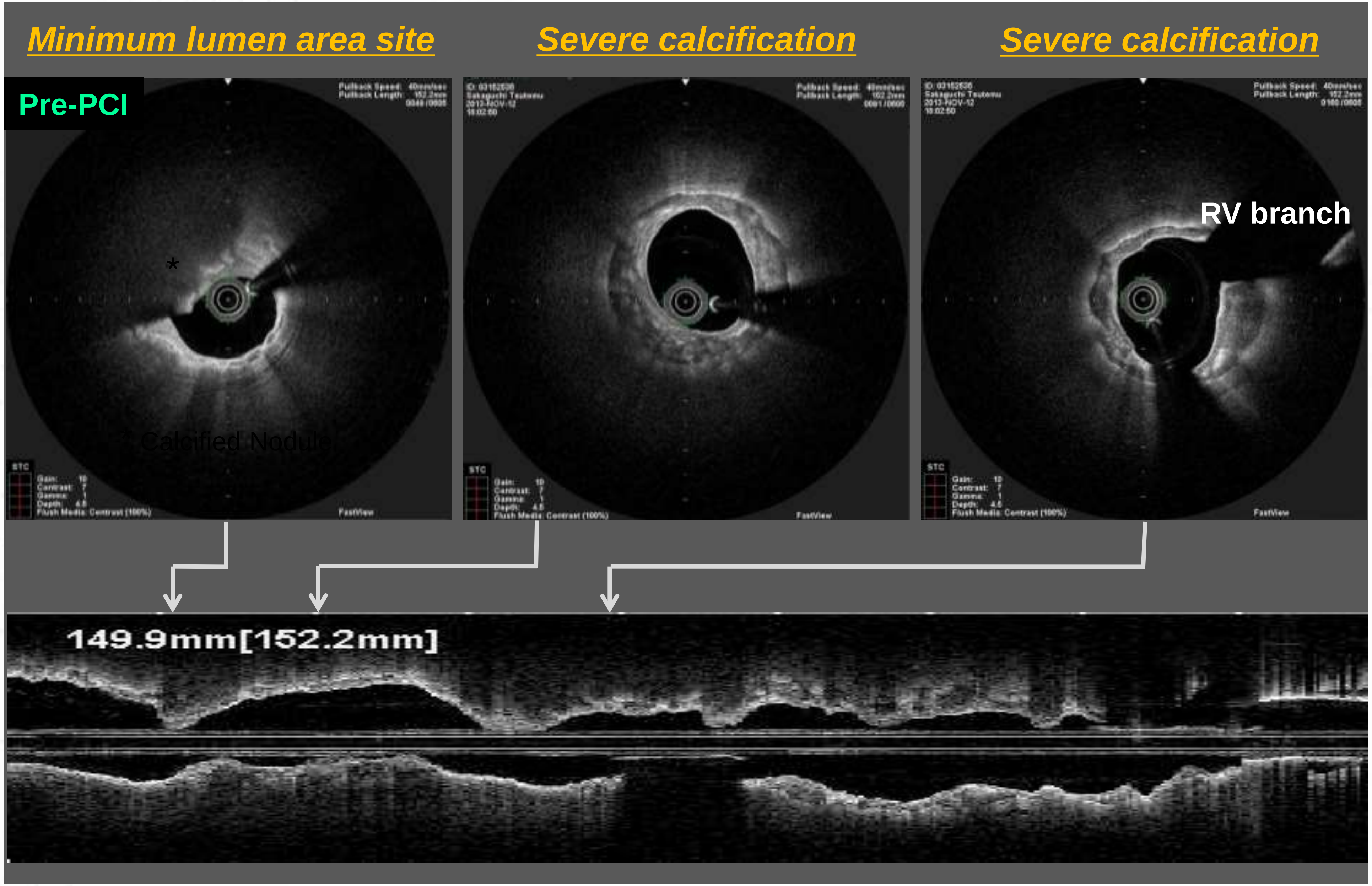
Pre-PCI IVUS



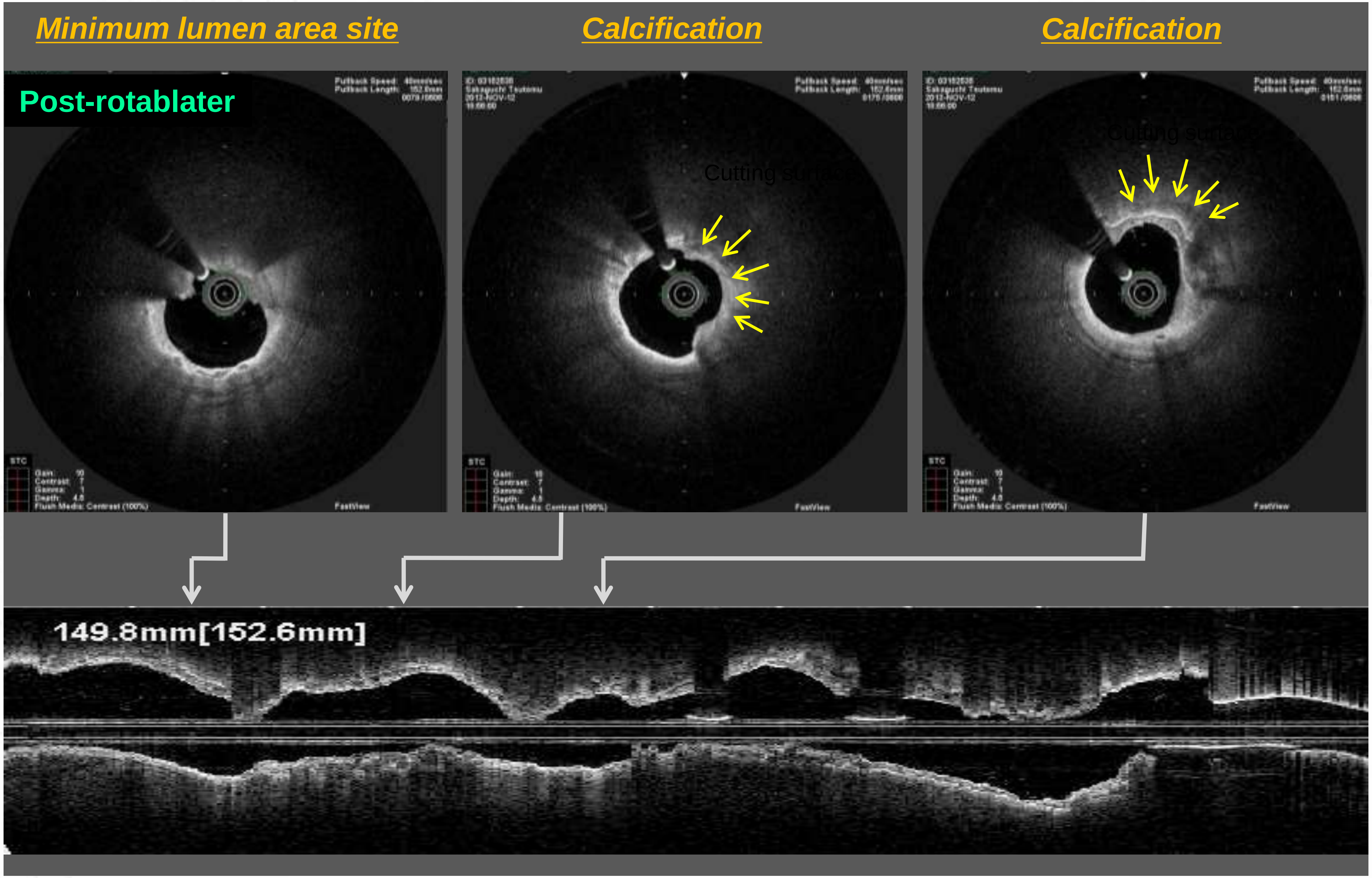
Pre-PCI FD-OCT



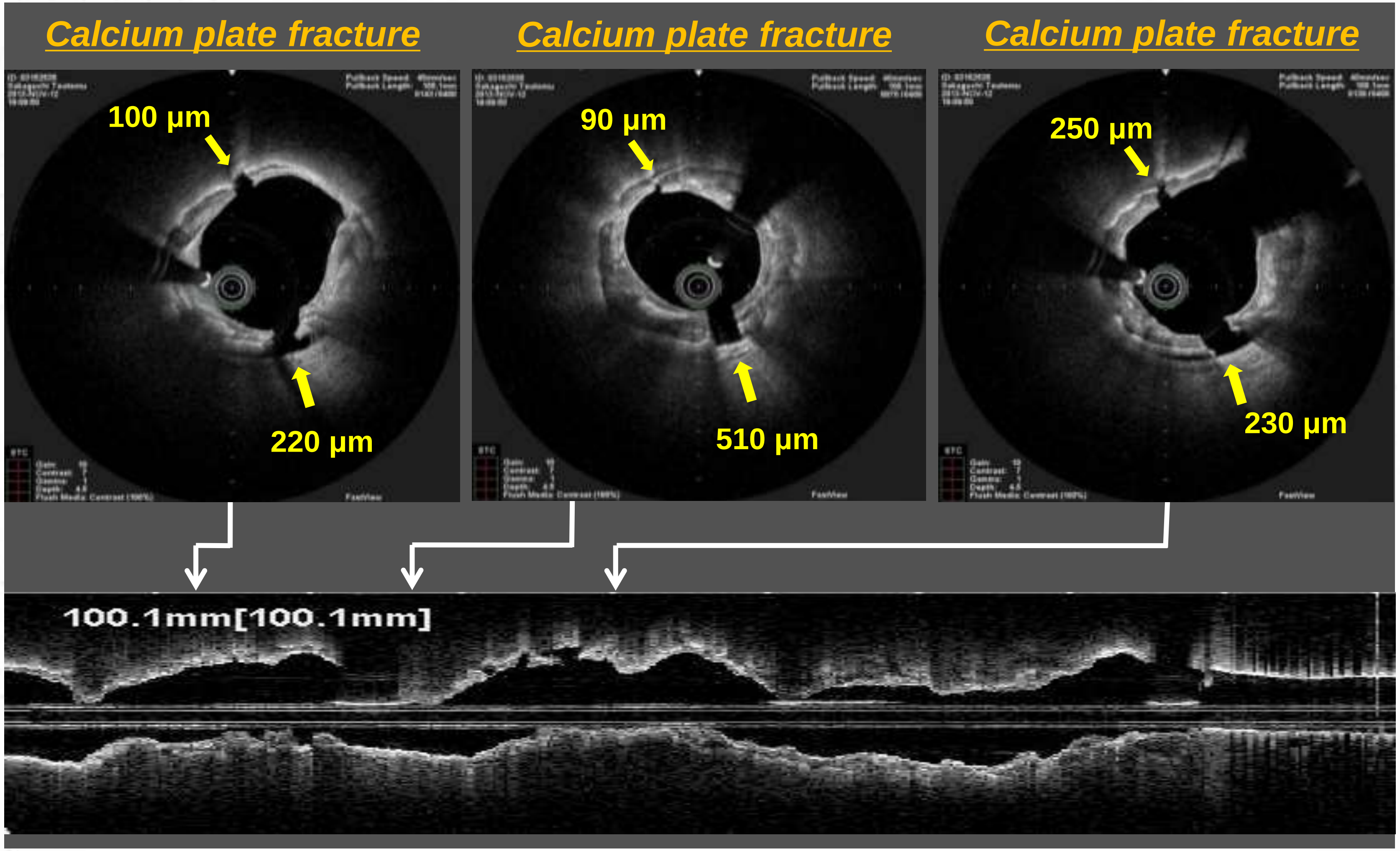
Pre-PCI FD-OCT



Post-Rotablator FD-OCT

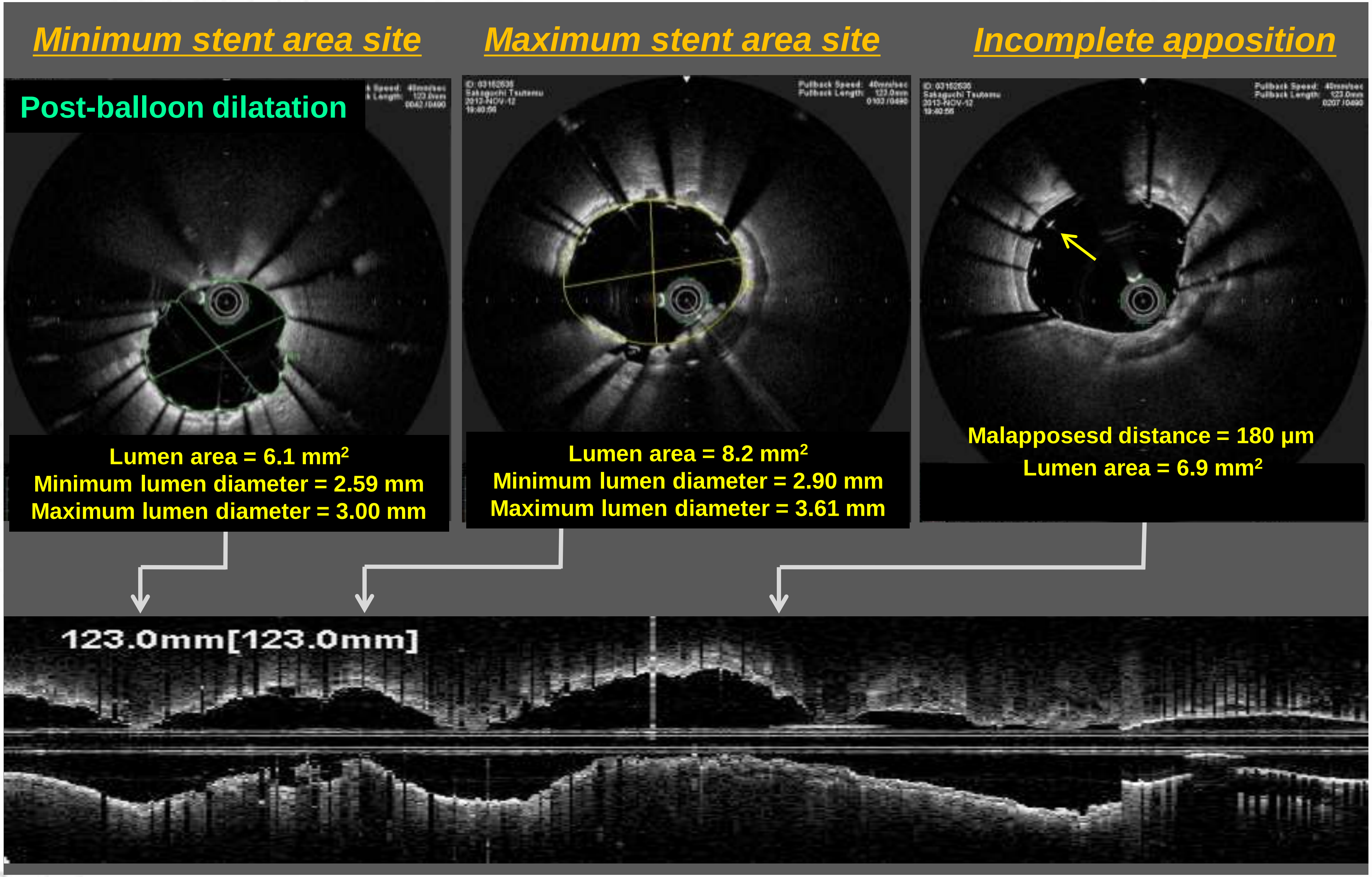


Post-high pressure ballooning



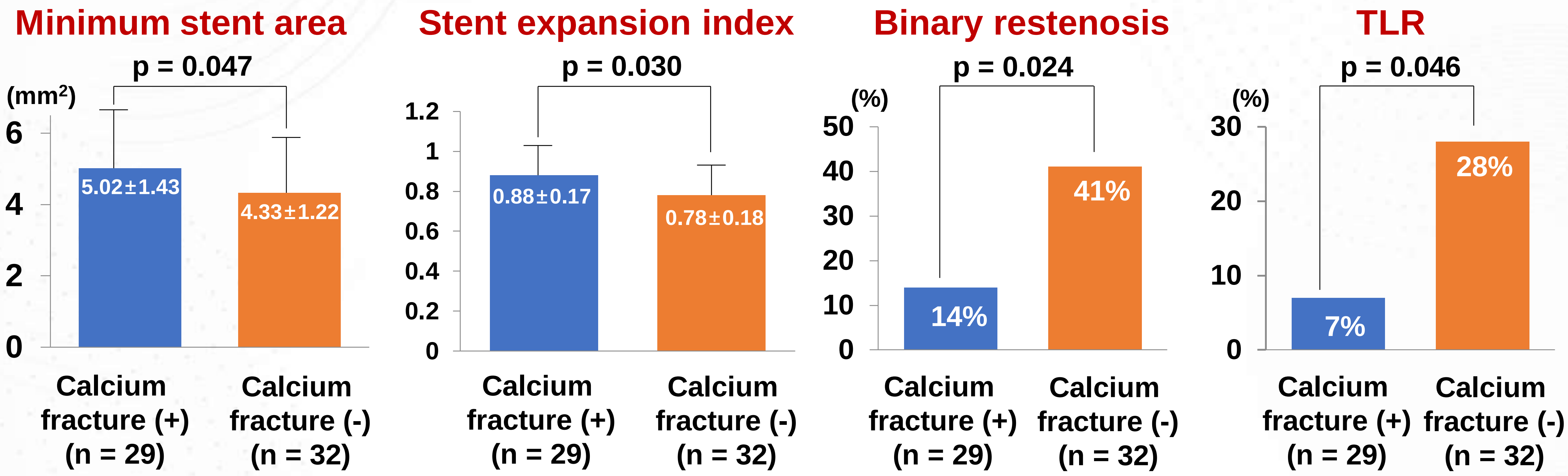
Calcium plate fracture can be made by high pressure ballooning if the thickness of it becomes <500 μm, and confirmation of it by imaging should be important before stenting.

Post-high pressure ballooning after stenting



Stent expansion at post-PCI

Restenosis and TLR at 10 months follow-up



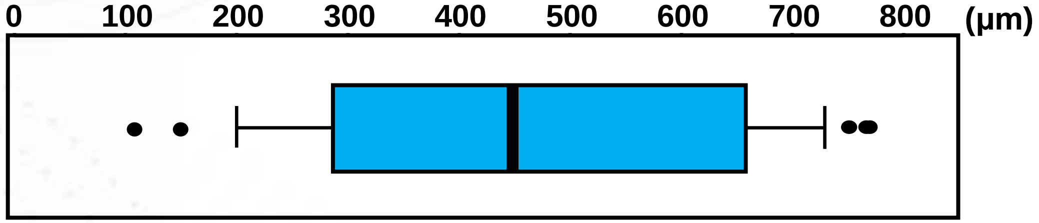
Minimum stent area and stent expansion index were significantly greater, the rate of binary restenosis and TLR was significantly lower in the group with calcium fracture compared with those in the group without calcium fracture.

Kubo, Akasaka et al. JACC Imag 2015;8:1228-1229

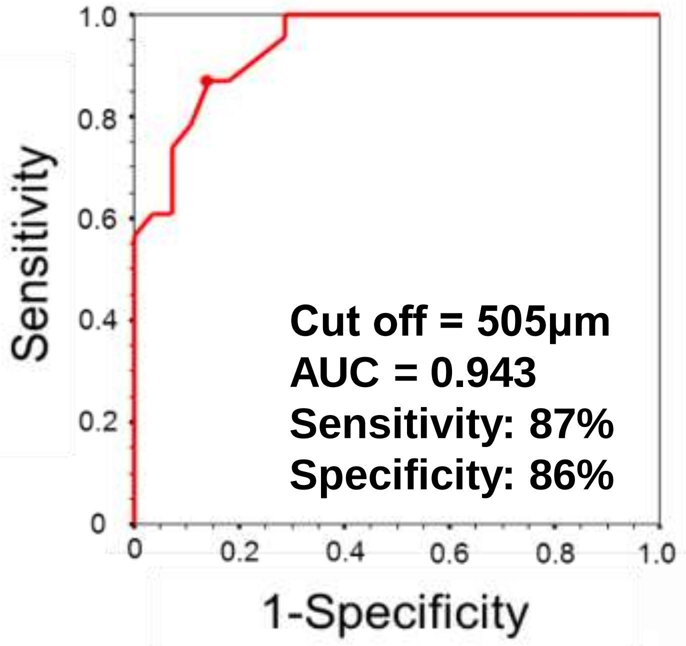
Prediction of calcium plate fracture by ballooning

FD-OCT was performed to assess vascular response immediately after high pressure ballooning in 61 patients with severe calcified coronary lesion.

Thickness distribution of calcium fracture



Median = 450μm; Lower quartile = 300μm; Upper quartile = 660μm; Minimum = 110μm; and Maximum = 770μm.



Conclusion: A calcium plate thickness < 505 μm was the corresponding cut-off value for predicting calcium plate fracture by high pressure ballooning.

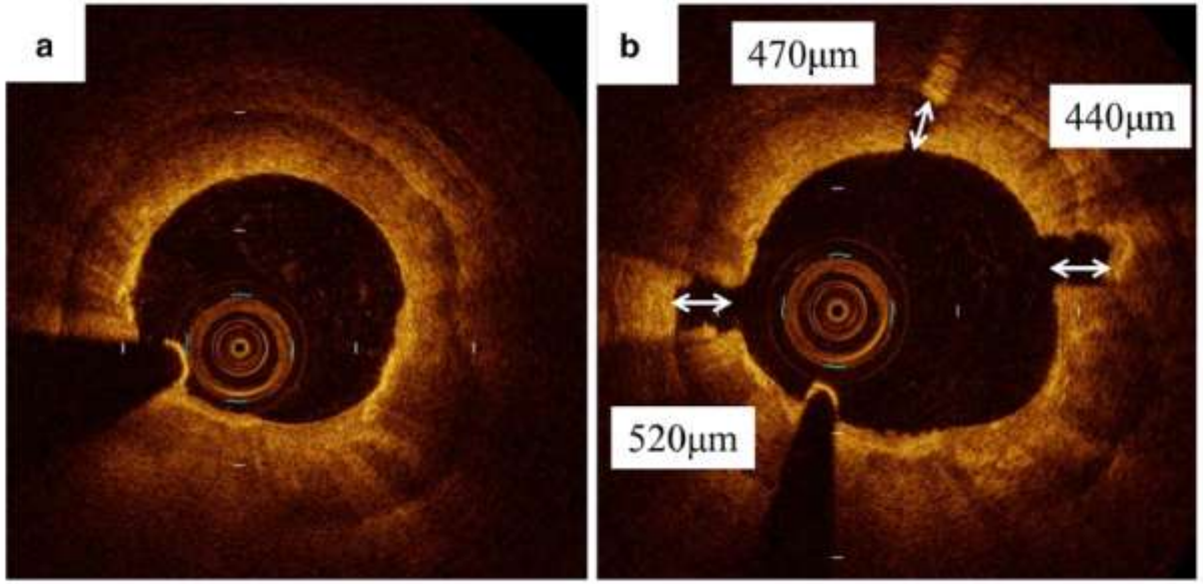
Kubo, Akasaka et al. JACC Imag 2015;8:1228-9

Cardiovascular Intervention and Therapeutics (2019) 34:242–248
https://doi.org/10.1007/s12928-018-0553-6

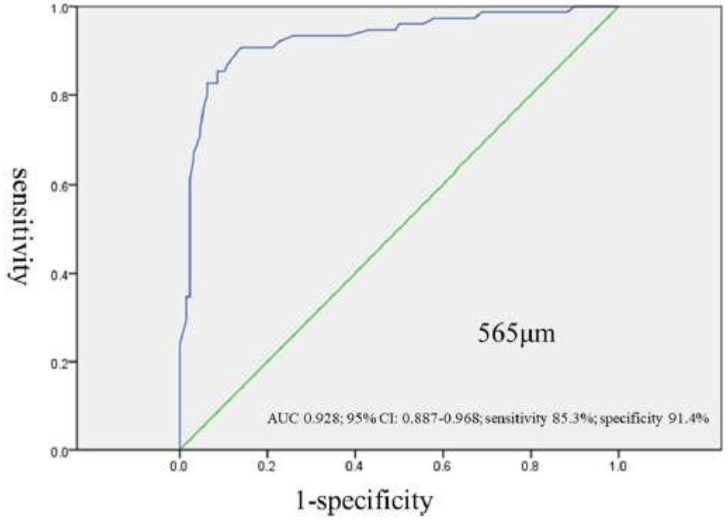
ORIGINAL ARTICLE

Plaque modification of severely calcified coronary lesions by scoring balloon angioplasty using Lacrosse non-slip element: insights from an optical coherence tomography evaluation

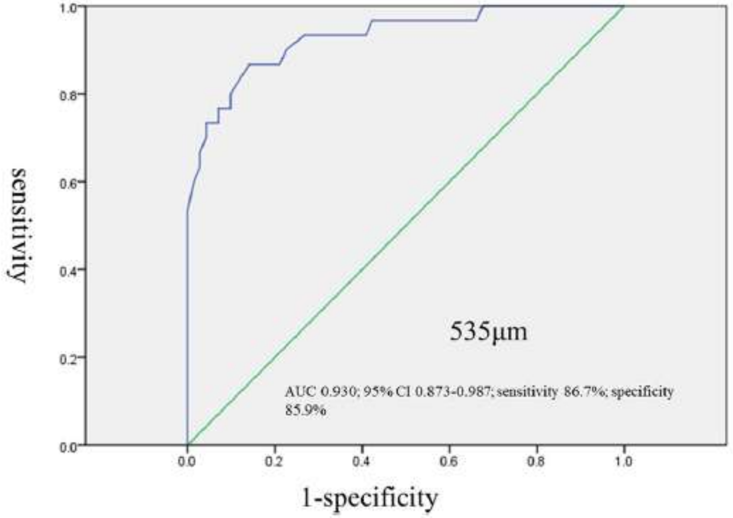
Yu Sugawara[1] · Tomoya Ueda[1] · Tsunenari Soeda[1] · Makoto Watanabe[1] · Hiroyuki Okura[1] · Yoshihiko Saito[1]



All cross sectional OCT images



Calcium angle >270°



Case 3 – 60’s y.o. Female

Clinical diagnosis

Effort AP

Clinical history

Chest pain on effort

No history of prior intervention

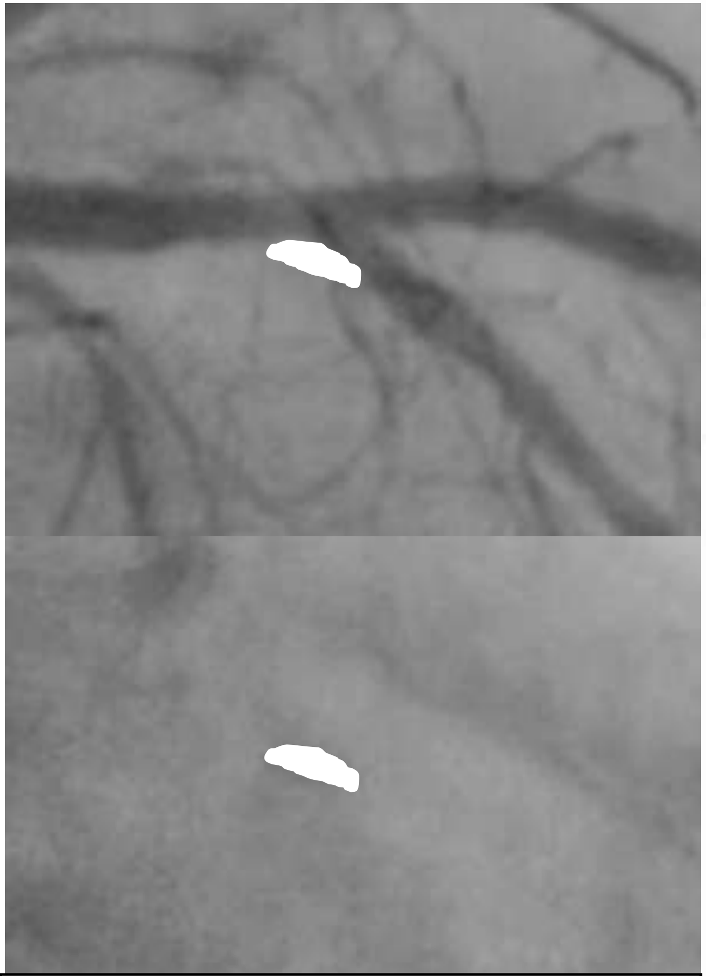
LVEF: 55%

Cr: 1.0, eGFR: 40

Coronary risk factors

HT, DLP, DM

Coronary angiography – Target lesion: LAD seg 7:50-75%

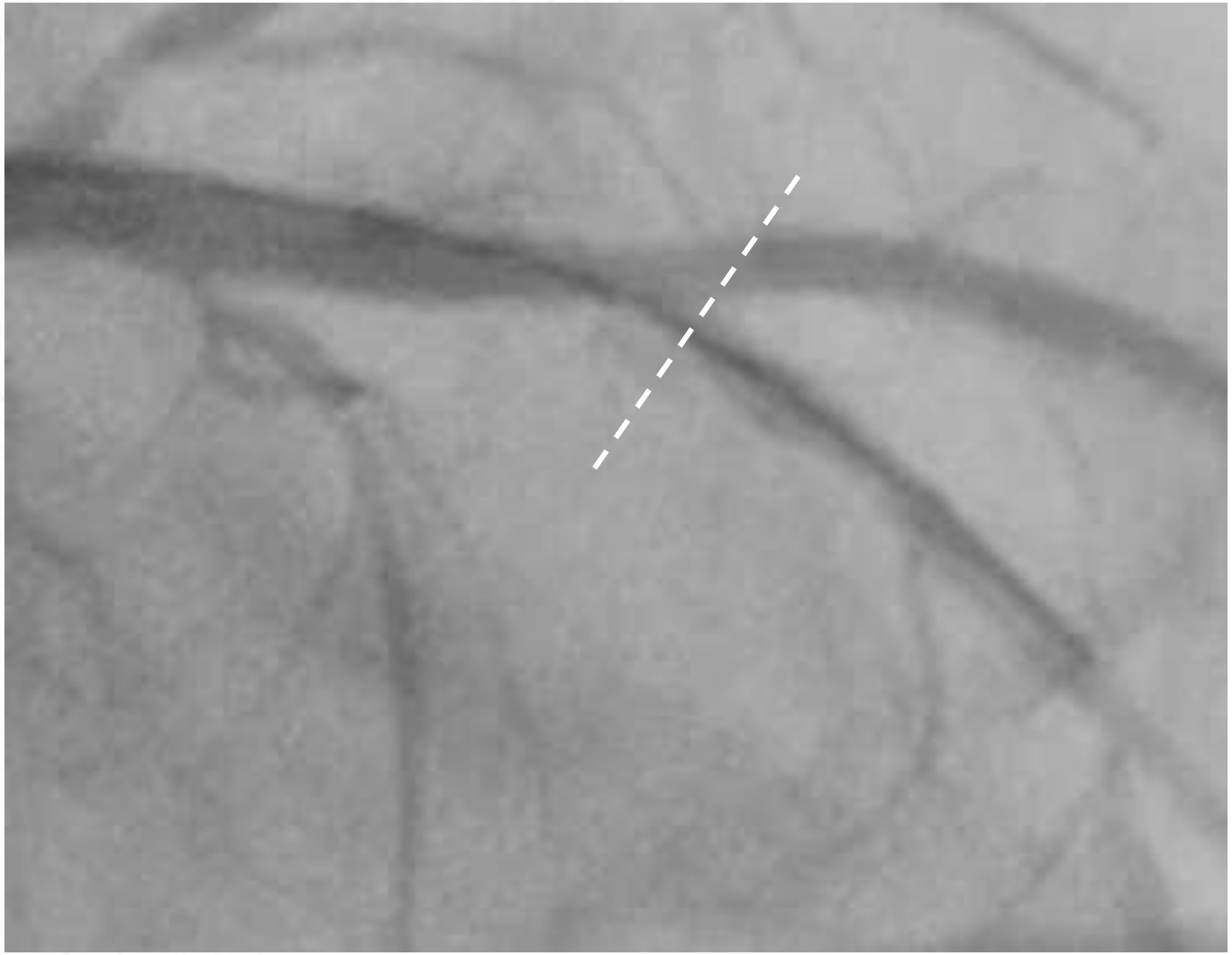


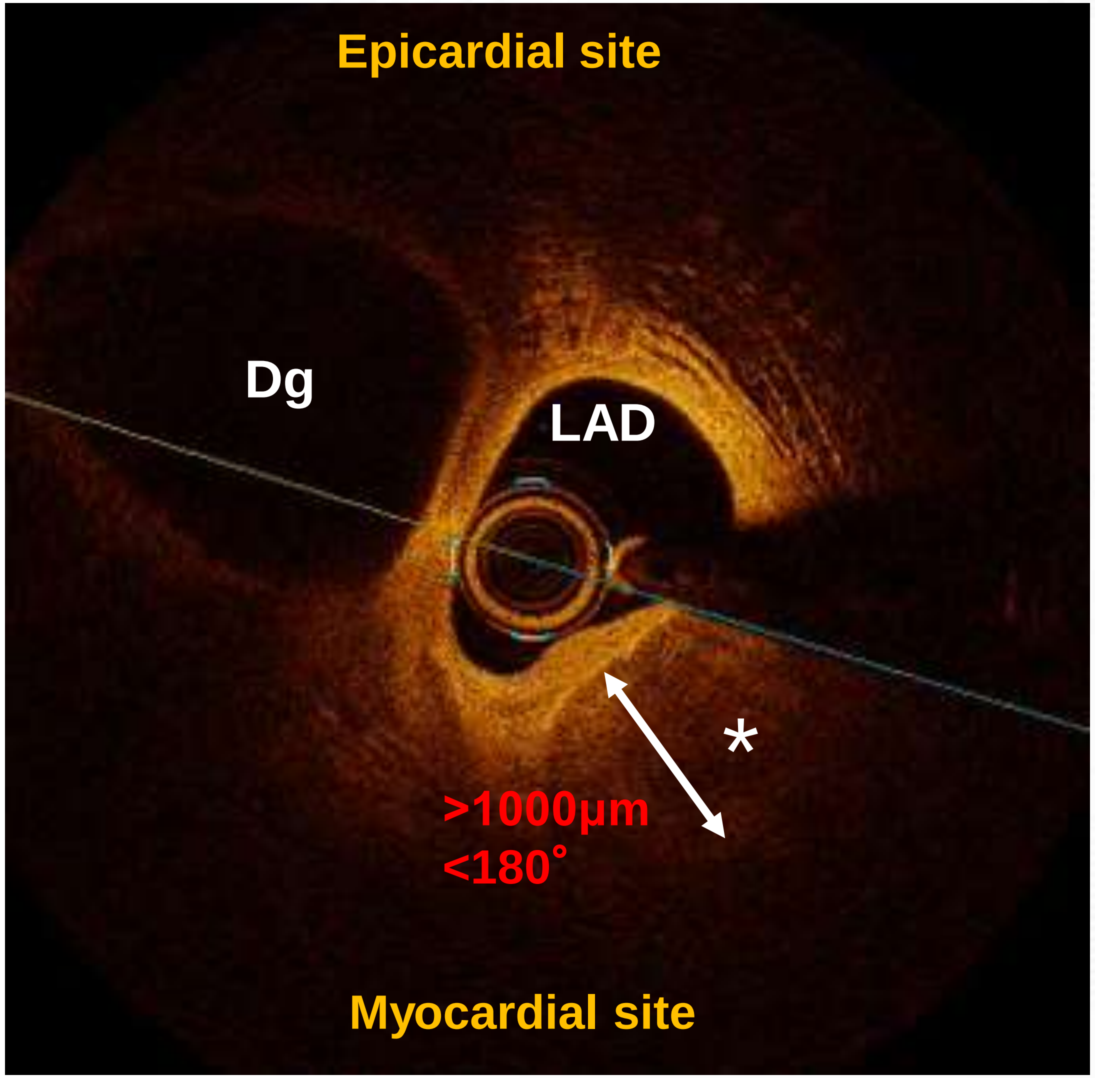
angiographically visible calcium

FFR_{LAD}=0.72,
seg 7:75% & ΔFFR=0.23.

Eccentric heavily thick calcium

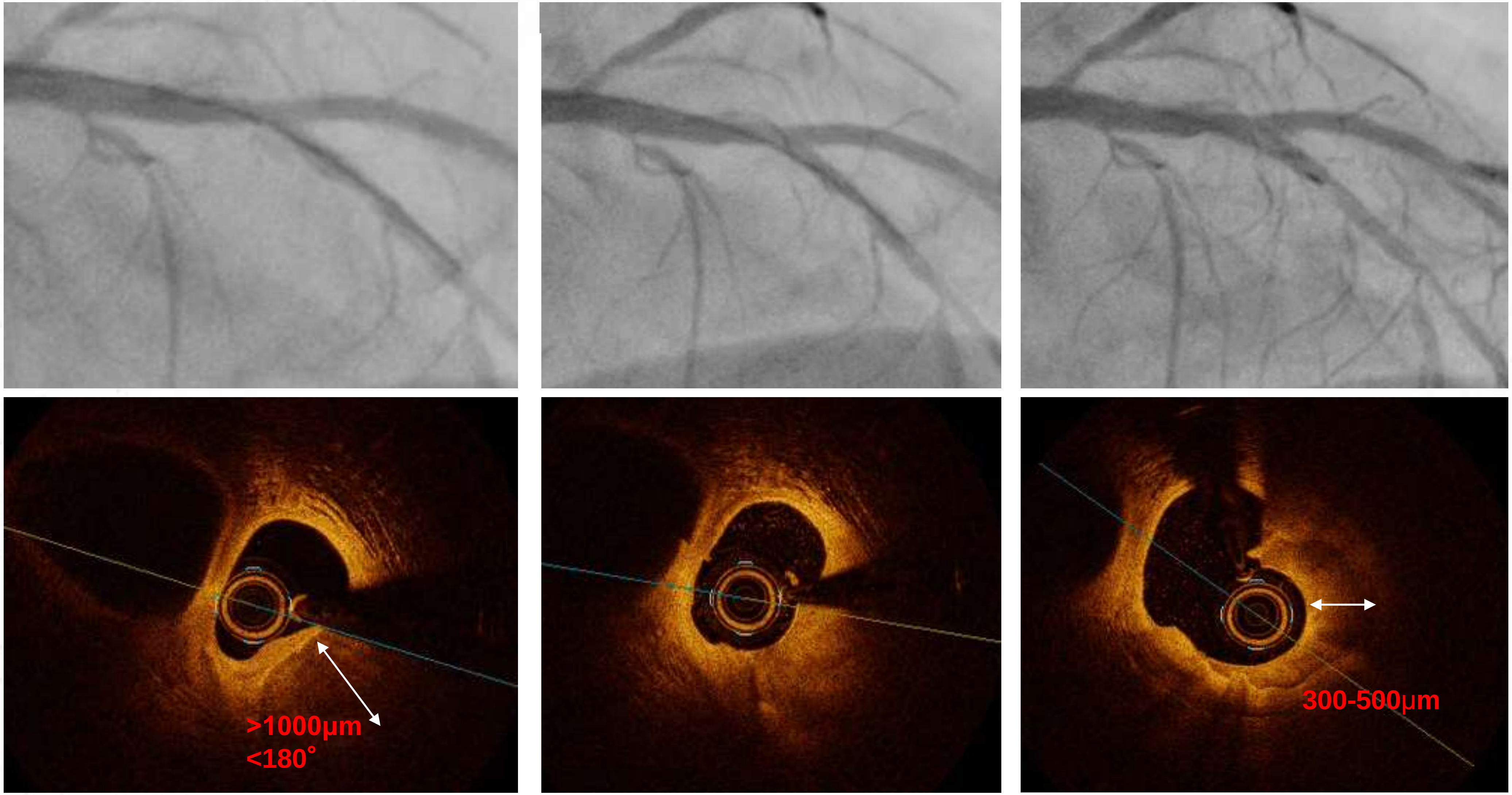
LAD seg.7:50-75%, FFR_{LAD}=0.72, ΔFFR=0.23





OCT findings of the lesion before and after OAS

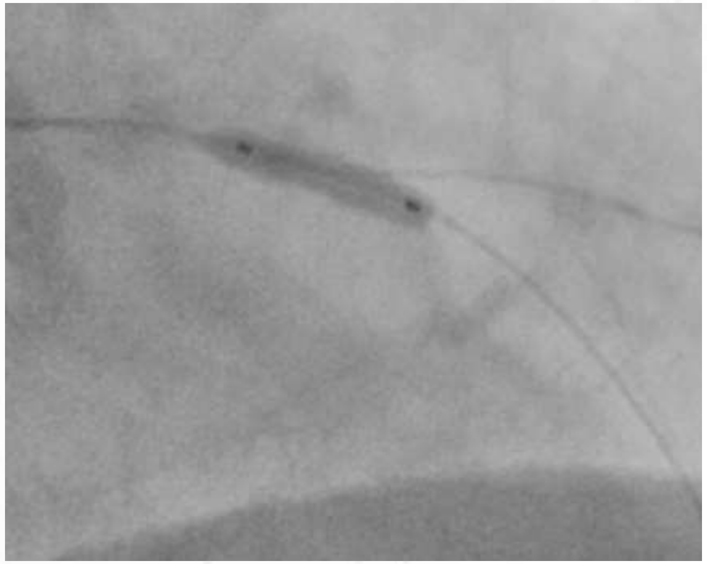
Before OAS **After low speed OAS** **After high speed OAS**

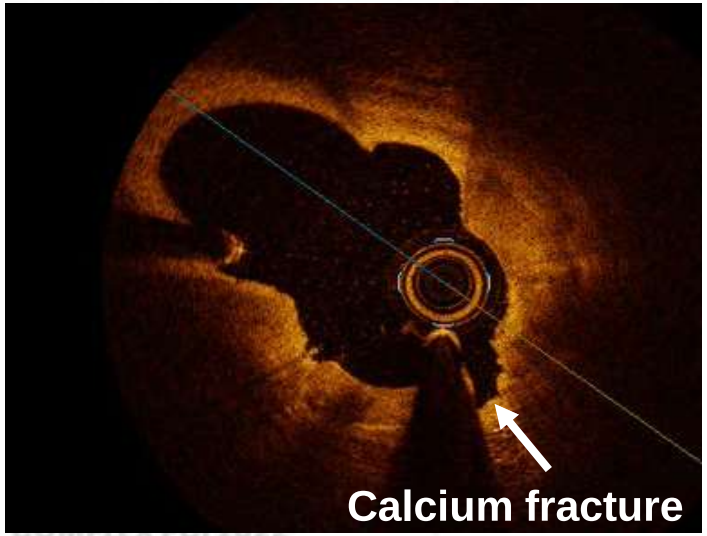


After confirming the effect of OAS with low speed using Viper wire bias, additional OAS with high speed was repeated 4 times as a pull back way.

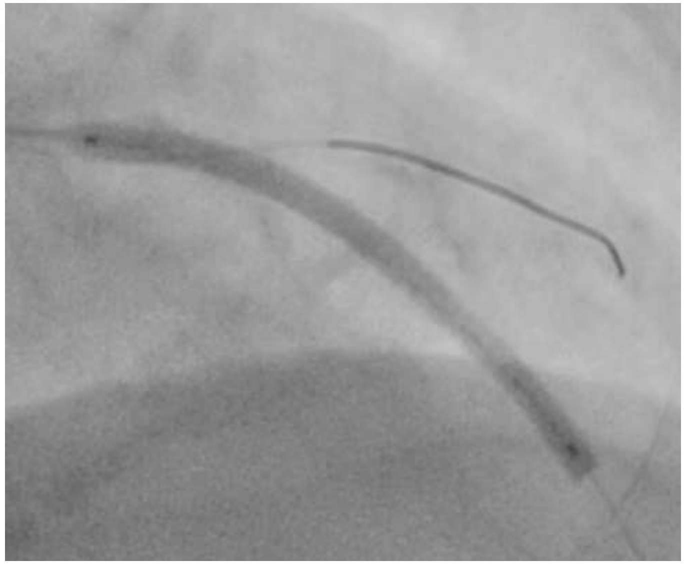
POBA & Stenting

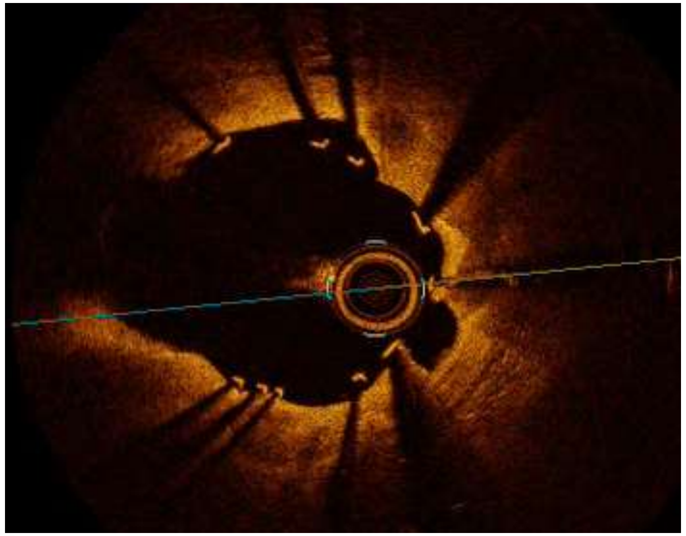
POBA
Wolverine 2.75*10mm





DES
3.0*38mm





Final Angiography
After stenting

Case 4 – 70's y.o. Female

Clinical diagnosis

NSTEMI (Culprit: LCX seg11os:99%)

Clinical history

Chest pain at rest

Prior CABG:

LITA-LAD, SVG-LCx seg14(failure), SVG-seg 4PD

LVEF: 40%

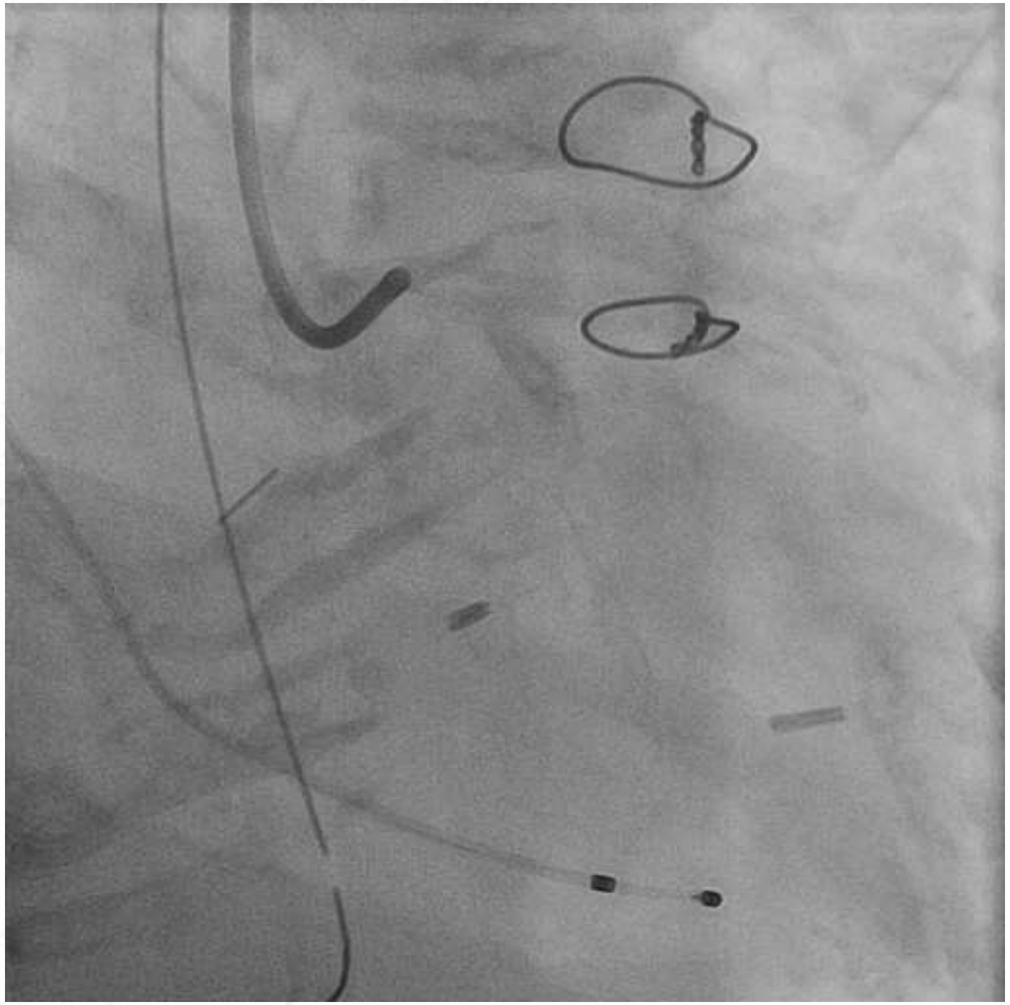
Cr: 2.3, eGFR: 28

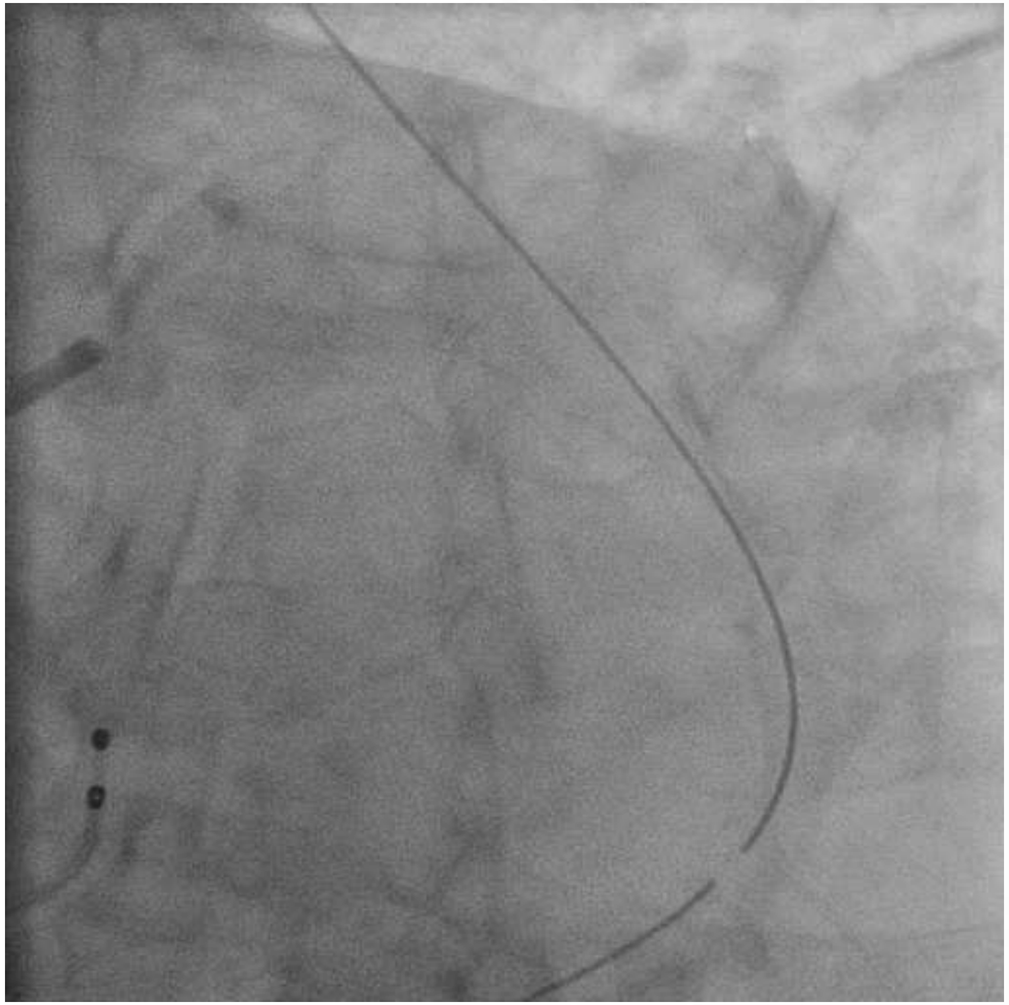
Coronary risk factors

HT, DLP, DM, CKD

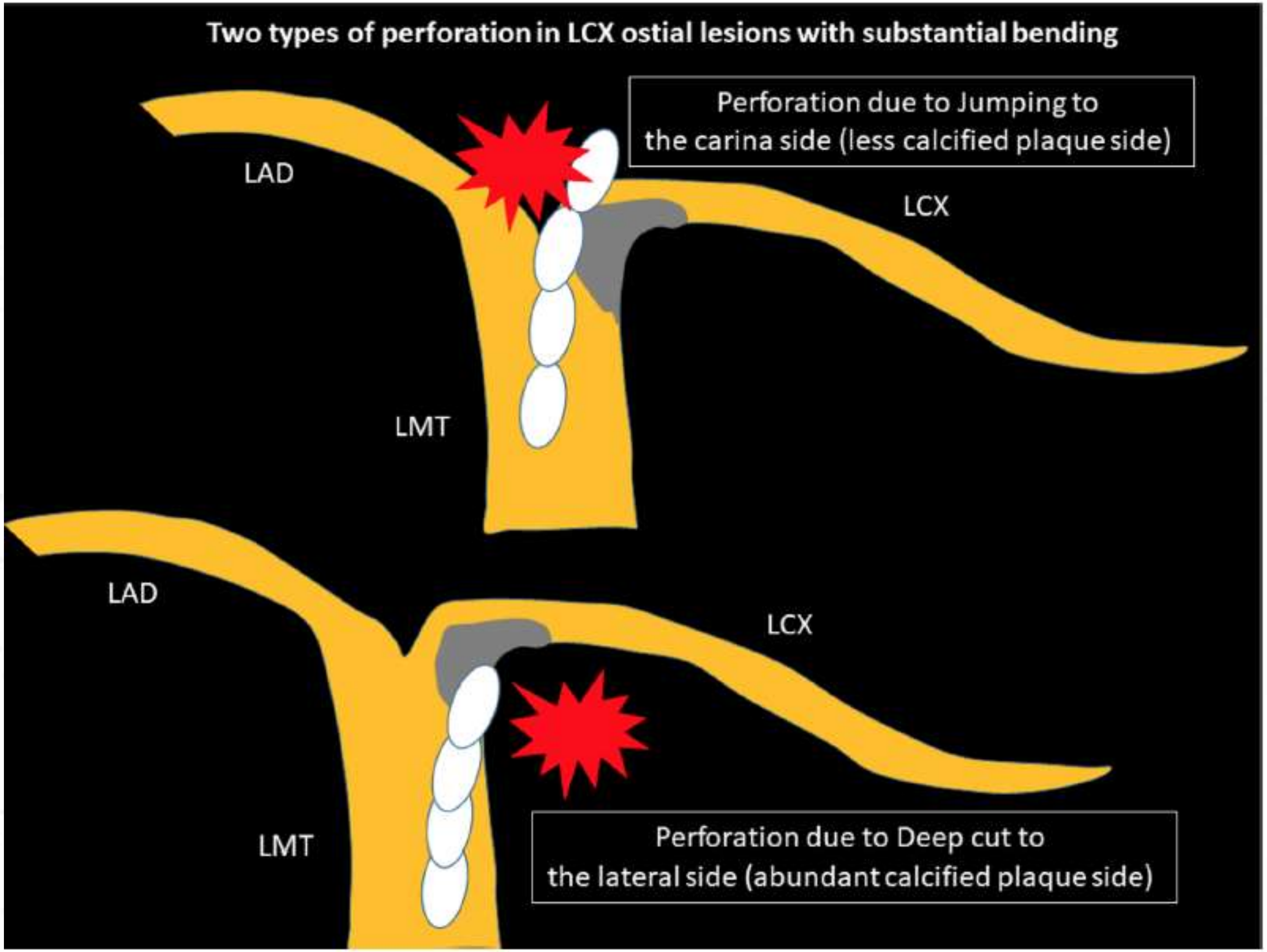
Coronary angiography

LCX seg11os:99%, SVG to seg14:occluded



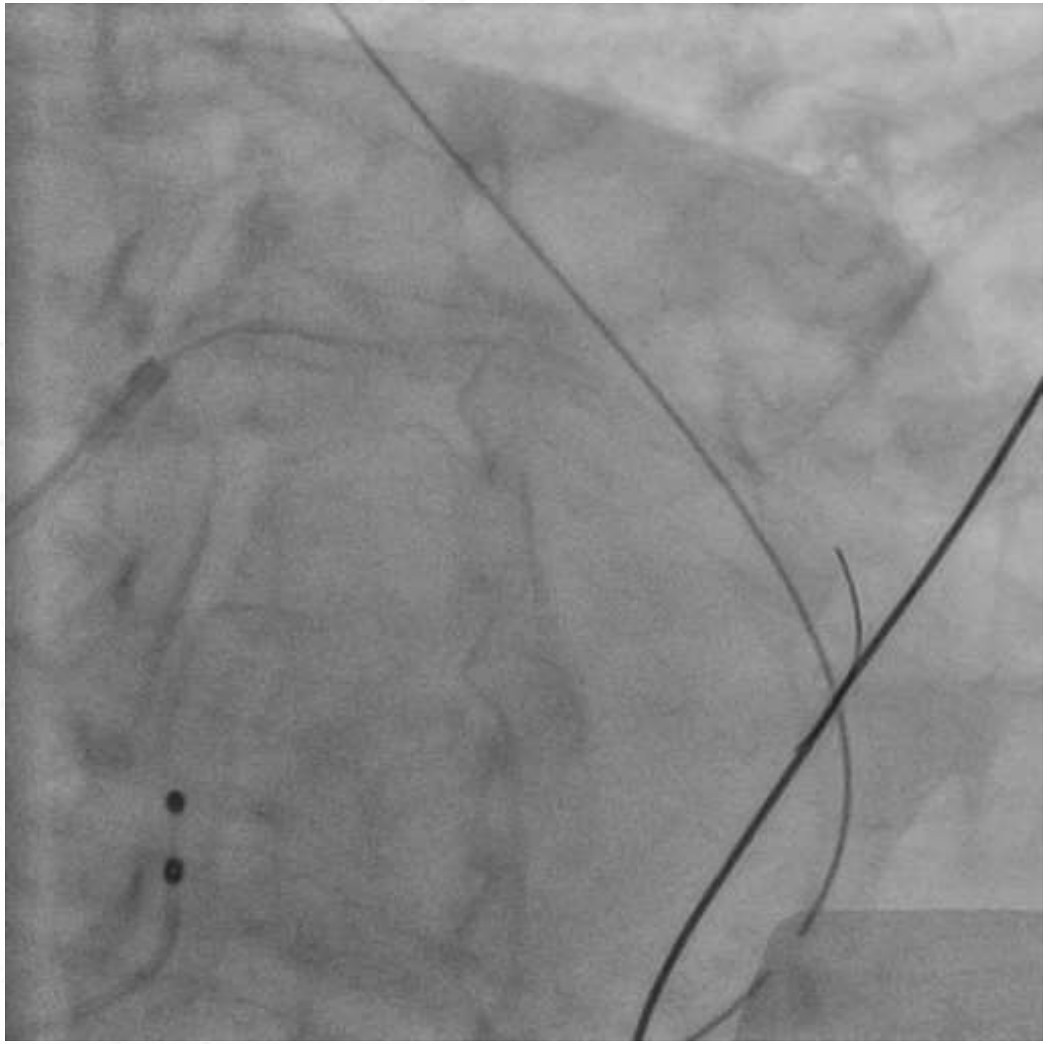


LCx ostial lesion – 2 types of coronary perforation by rota.

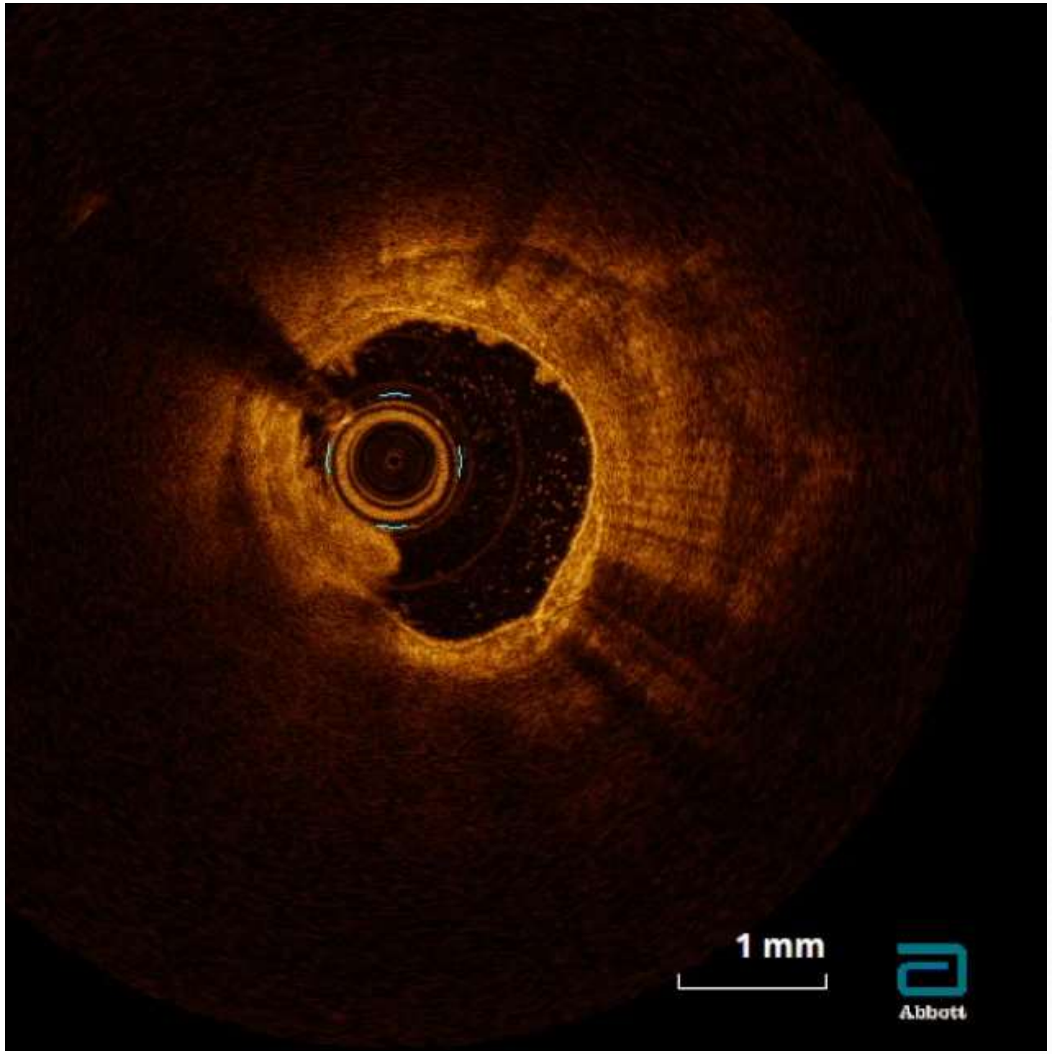


OAS - high speed・pullback manner・4 times -

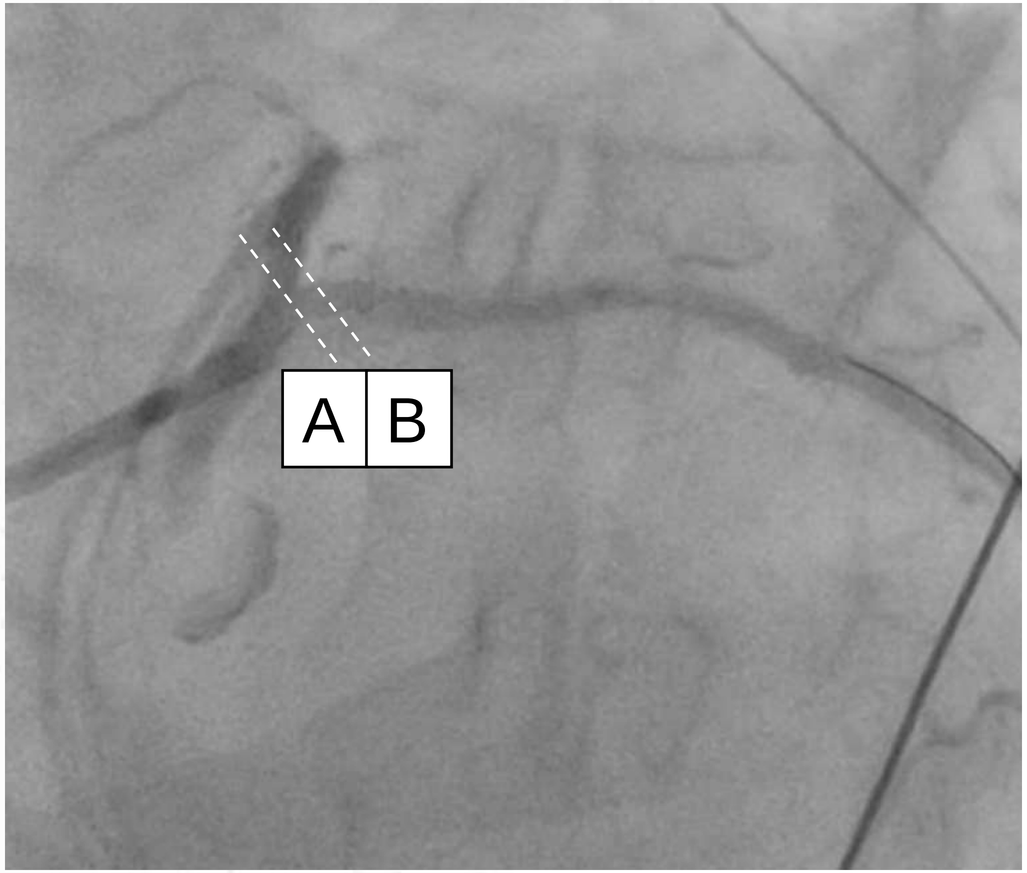
Angiography during OAS

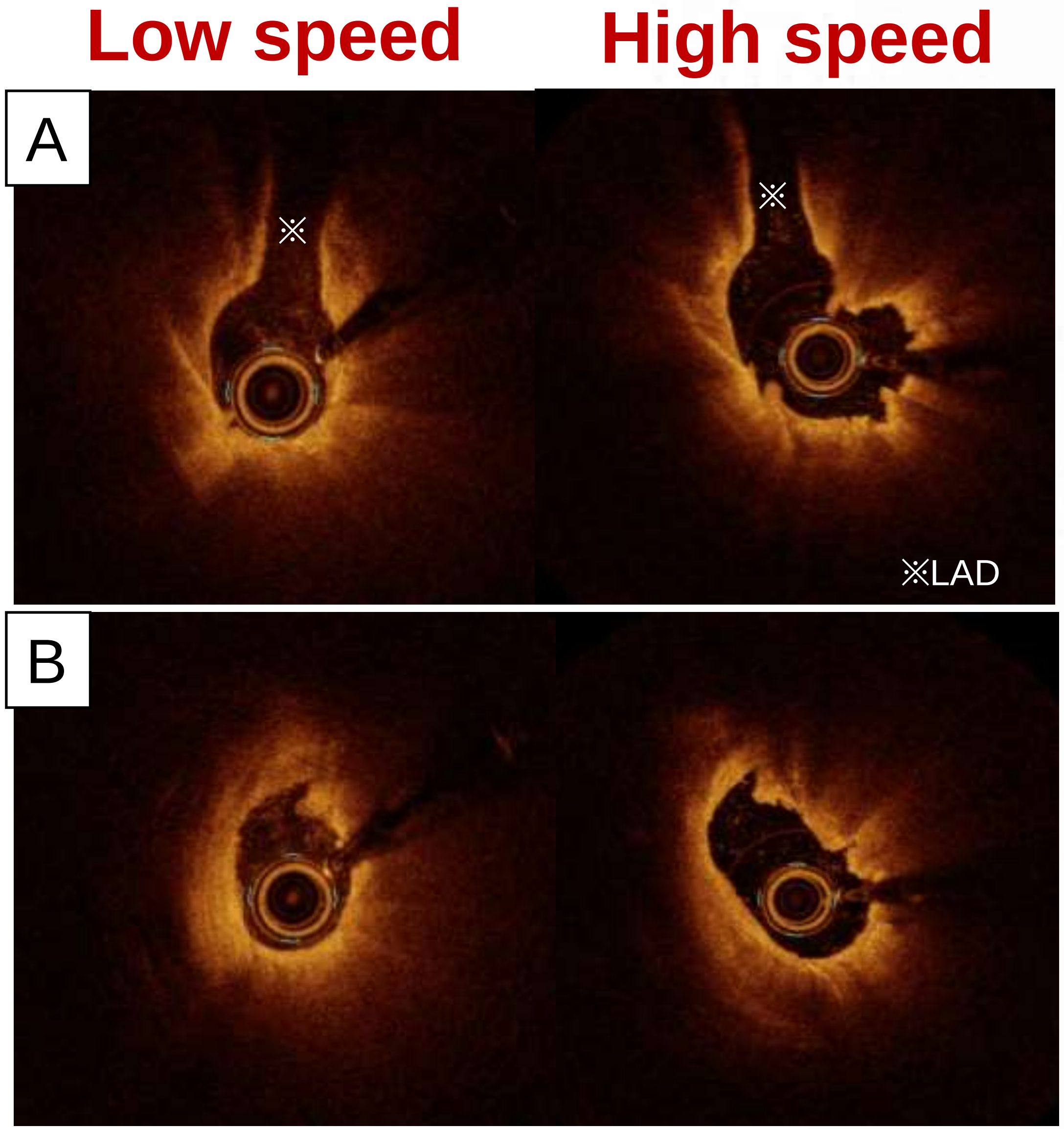


OCT after high speed OAS



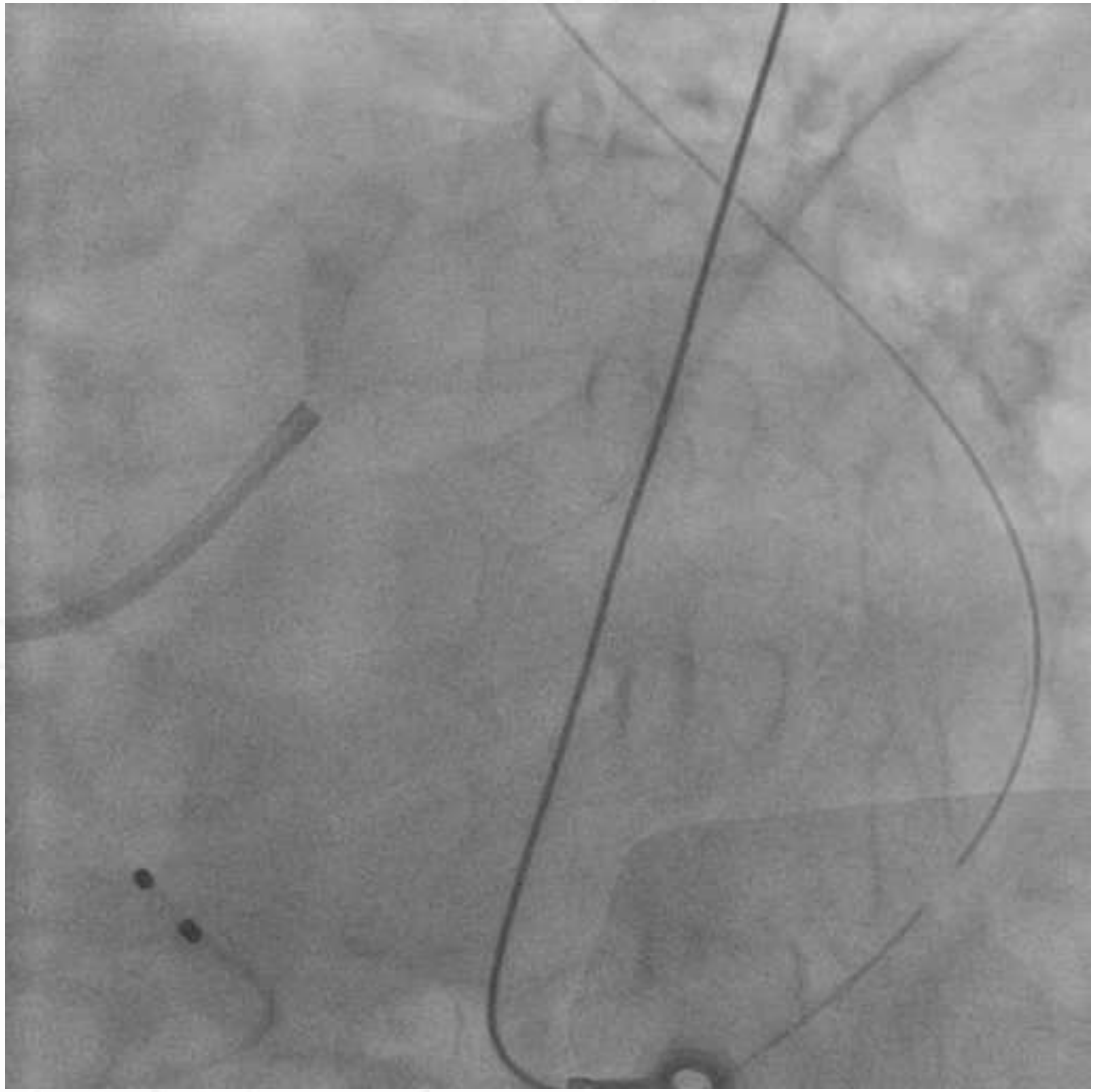
OCT findings after low and high speed OAS

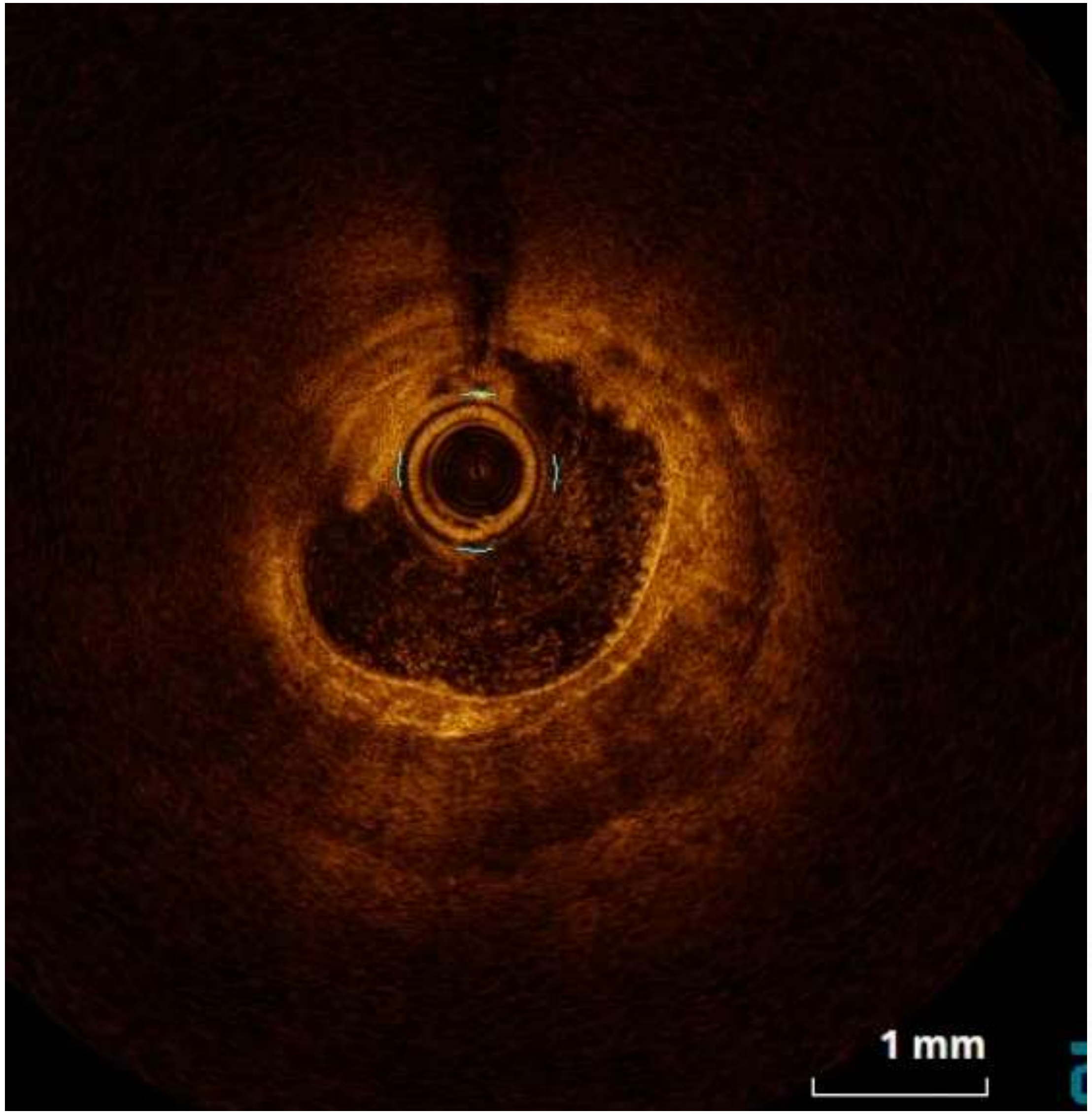




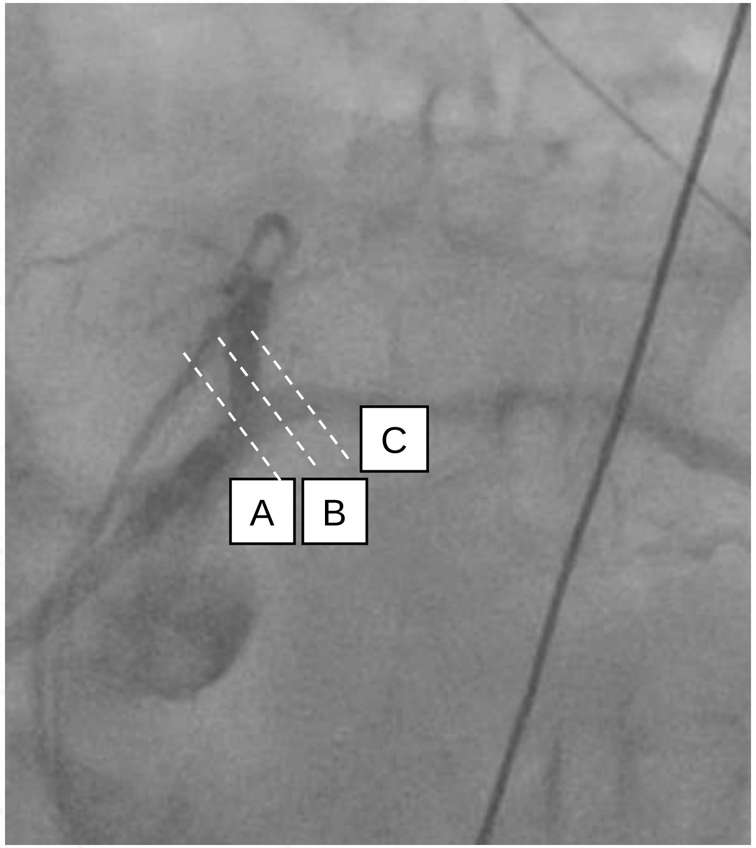
Rotational atherectomy – Burr size2.0mm.

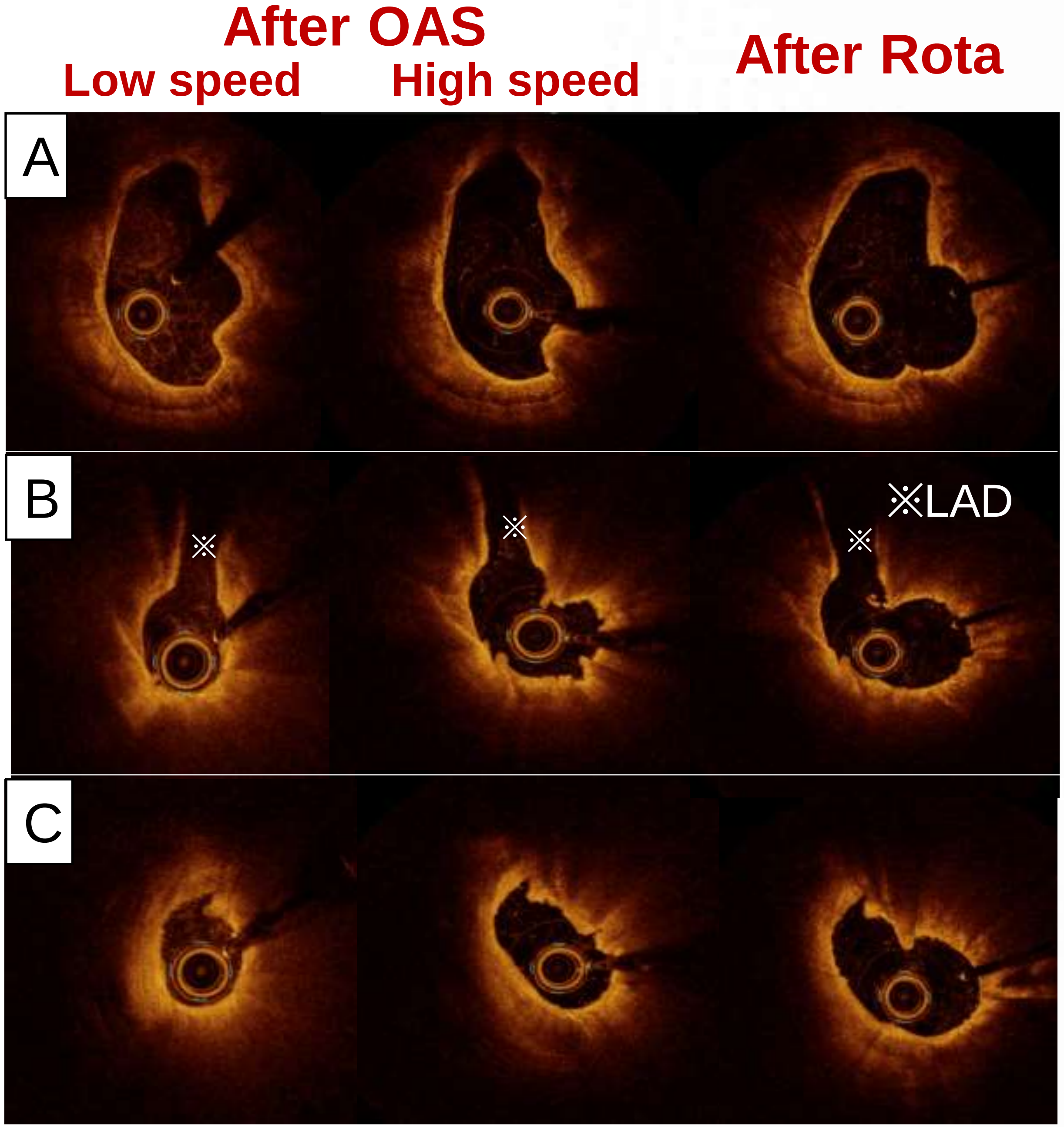
Final angiography and OCT



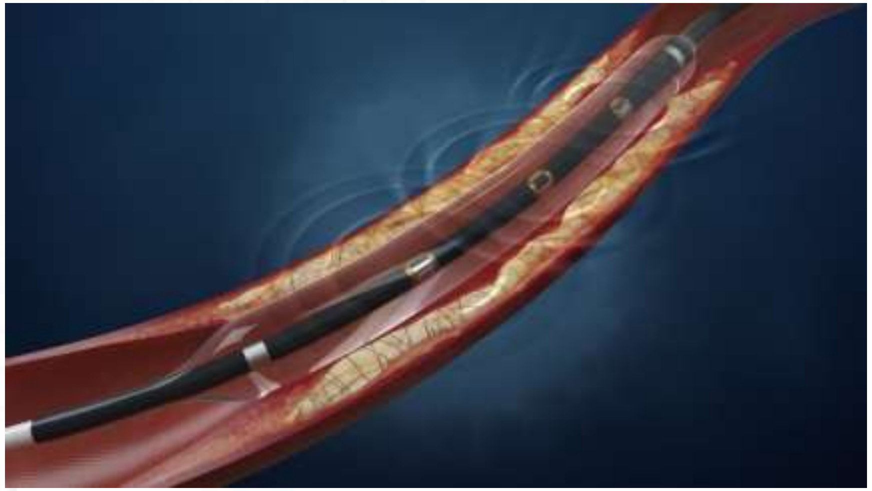


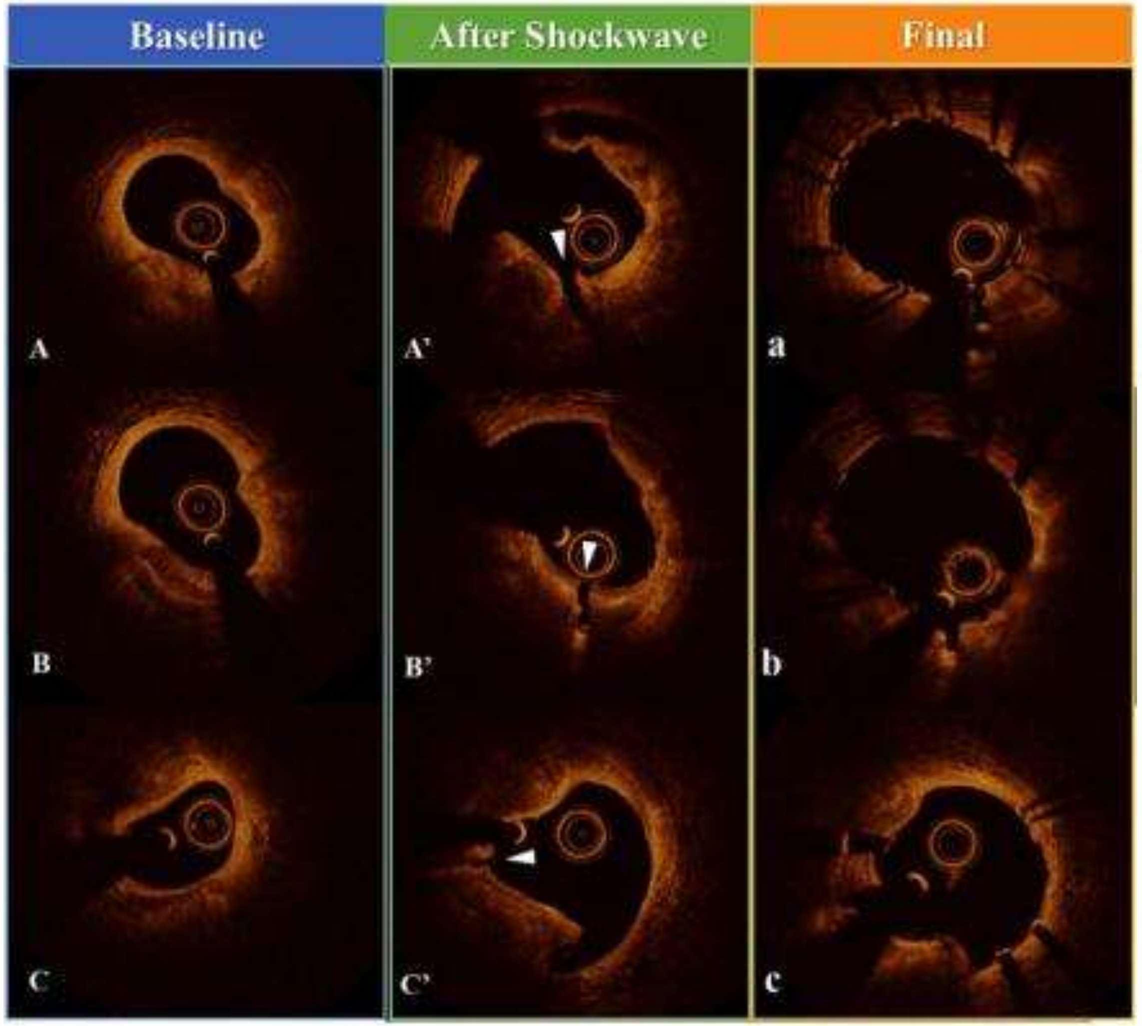
OCT findings after OAS and Rotablator





Shockwave Intravascular Lithotripsy





ORIGINAL ARTICLE

Safety and Effectiveness of Coronary Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Stenoses

The Disrupt CAD II Study

BACKGROUND: The feasibility of intrava
for modification of severe coronary arter
demonstrated in the Disrupt CAD I study
Disease). We next sought to confirm the
for these lesions.

METHODS: The Disrupt CAD II study wa
single-arm post-approval study conducte
Patients with severe CAC with a clinical i
underwent vessel preparation for stent in
primary end point was in-hospital major a
death, myocardial infarction, or target ve
optical coherence tomography substudy
mechanism of action of IVL, quantifying
plaque fracture. Independent core labora
and optical coherence tomography, and a
committee adjudicated major adverse ca

RESULTS: Between May 2018 and March
enrolled. Severe CAC was present in 94.2
and use of the IVL catheter was achieved
angiographic acute luminal gain was 0.8
was 32.7±10.4%, which further decrease
eluting stent implantation. The primary e
patients, consisting of 7 non–Q-wave my
no procedural abrupt closure, slow or no
patients with post-percutaneous coronar
tomography, calcium fracture was identi
3.4±2.6 fractures per lesion, measuring 5

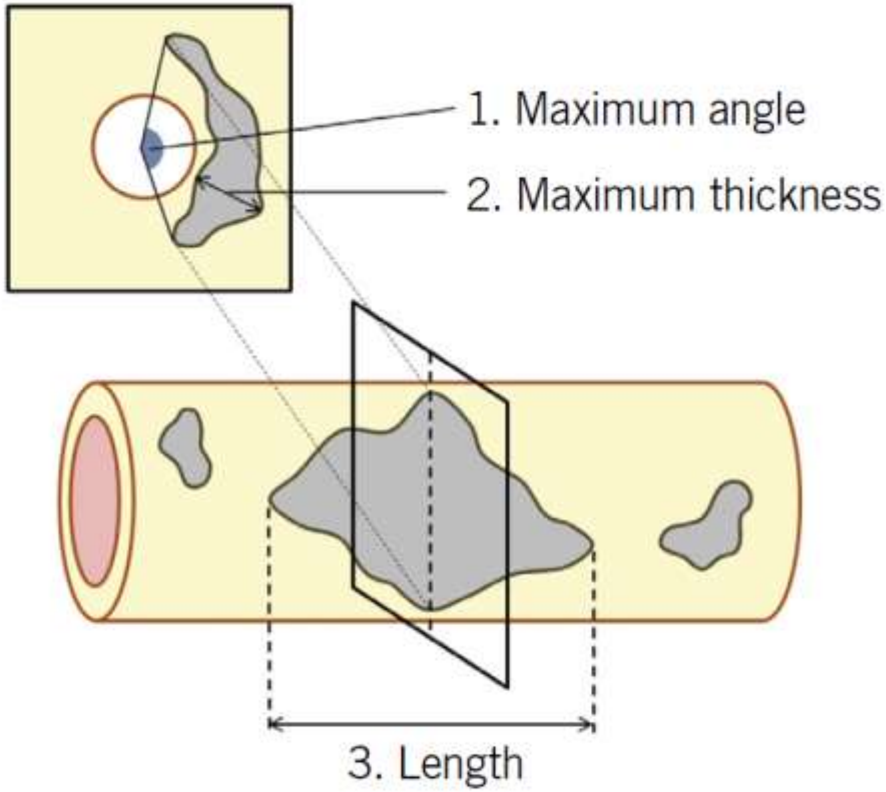
CONCLUSIONS: In patients with severe
revascularization, IVL was safely performe
and minimal complications and resulted i
fracture in most lesions.

	Pre-IVL	Post-Stent	*P* Value
At Pre-IVL MLA site, n	48	47	
Lumen area, mm²	2.33±1.35	6.10±2.17	<0.0001
Calcium angle, °	175.8±96.9	127.1±97.6 [28]	0.055
Maximum calcium thickness, mm	0.9±0.3	0.8±0.3 [28]	0.45
Calcium fracture		17.9% (5/28)	
Stent area, mm²		6.06±2.20	
Stent expansion, %		79.1±21.0 [44]	
Acute area gain, mm²		3.99±1.72 [38]	
At pre-IVL maximum calcium site, n	48	38	
Lumen area, mm²	3.64±1.78	8.47±3.04 [38]	<0.0001
Calcium angle, °	266.3±77.1	215.1±69.4	<0.0001
Maximum calcium thickness, mm	0.93±0.2	0.89±0.2	0.004
Calcium fracture		50% (19/38)	
Stent area, mm²		7.77±2.65 [38]	
Stent expansion, %		102.8±30.6 [35]	
Acute area gain, mm²		4.79±2.45	
At final MSA site, n	48	47	
Lumen area, mm²	4.26±2.86	6.25±2.25	<0.0001
Calcium angle, °	176.6±100.4 [23]	149.4±94.8 [30]	0.0004
Maximum calcium thickness, mm	1.0±0.3 [23]	0.9±0.3 [30]	0.055
Calcium fracture		23.3% (7/30)	
Stent area, mm²		5.92±2.14	
Stent expansion, %		77.6±20.5 [44]	
Acute area gain, mm²		2.52±2.03 [35]	

By using IVL, fracture of calcium plate at the sites of pre-IVL MLA and maximum calcium, and final MLA site could be observed only 18 to 50%.

Ali ZA. et al. Circ Cardiovasc interv. 2019; e008434

OCT based calcium scoring system

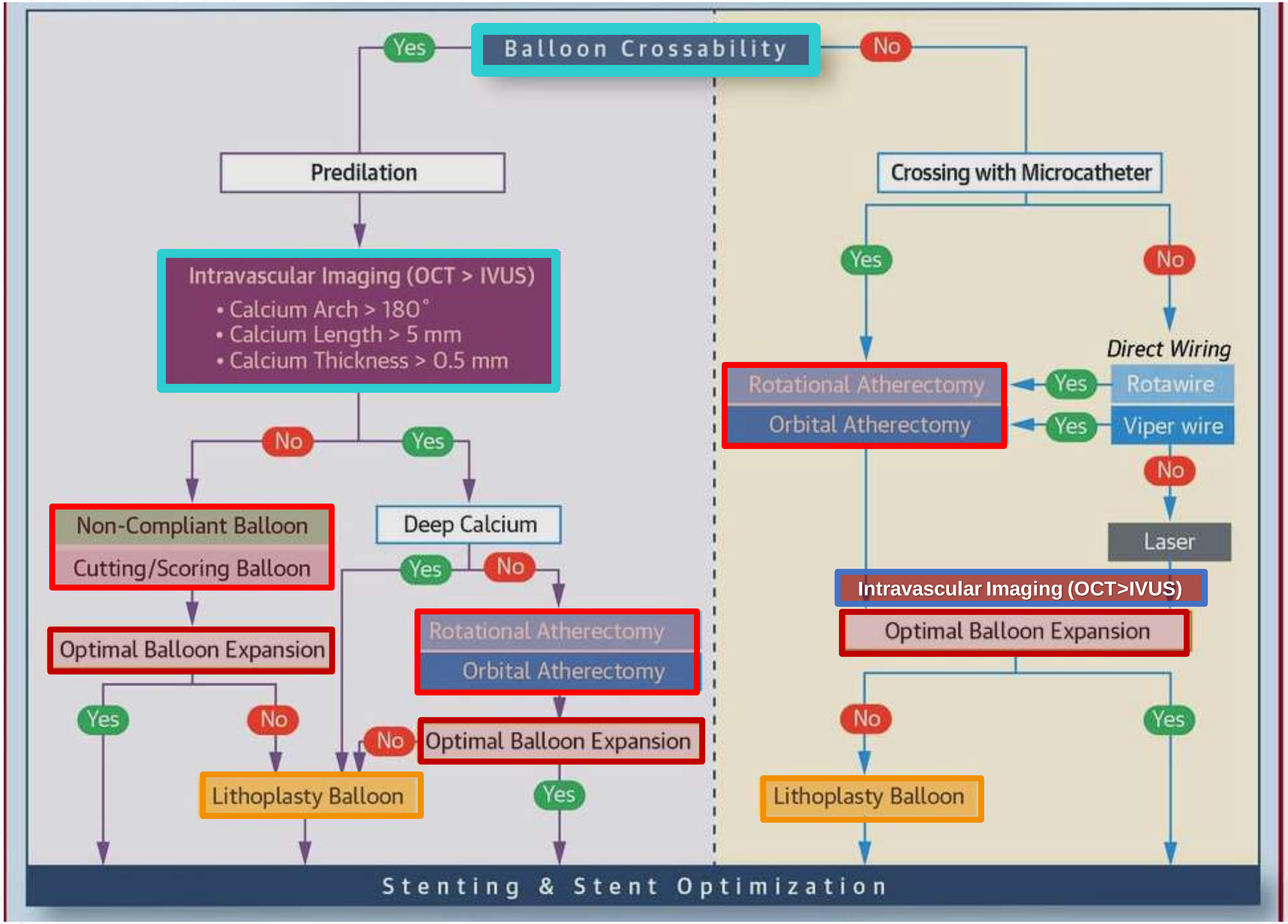


OCT-based calcium score	
1. Maximum calcium angle (°)	≤180° ➡ 0 point >180° ➡ 2 points
2. Maximum calcium thickness (mm)	≤0.5 mm ➡ 0 point >0.5 mm ➡ 1 point
3. Calcium length (mm)	≤5.0 mm ➡ 0 point >5.0 mm ➡ 1 point
Total score	**0 to 4 points**

Fusiono A, et al. EuroInterv 2018;13:e2182-e2189

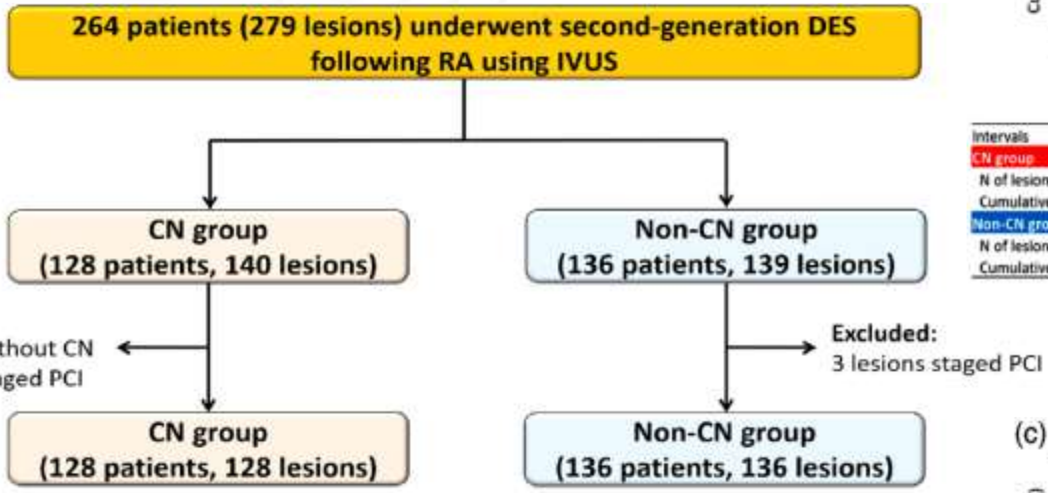
OCT-guided management of calcified lesions

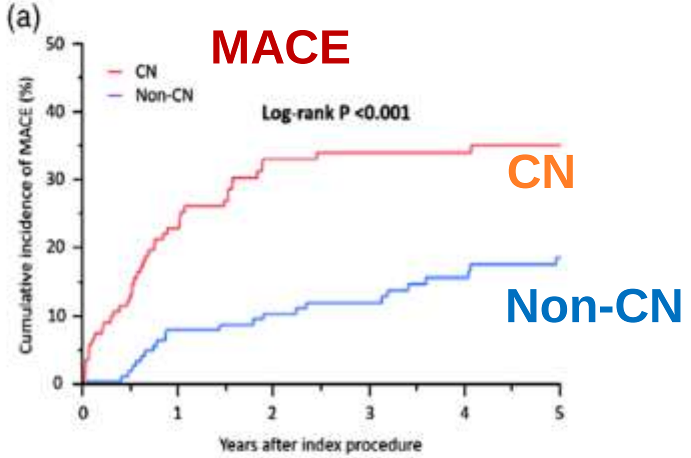
De Maria, G. L. et al. JACC interv. 2019; 12: 1465-1478



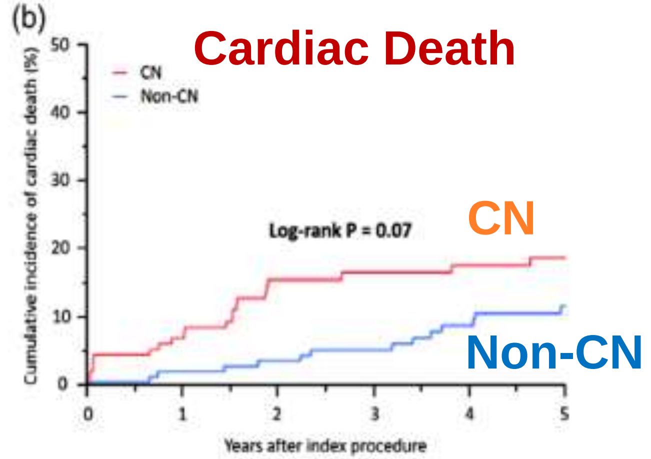
Clinical impact of calcified nodule in patients with heavily calcified lesions requiring rotational atherectomy

Toru Morofuji MD[1] | Shoichi Kuramitsu MD, PhD[1] | Tomohiro Shinozaki PhD[2]
Hiroyuki Jinnouchi MD[1] | Shinjo Sonoda MD, PhD[3] | Takenori Domei MD[1] |
Makoto Hyodo MD[1] | Shinichi Shirai MD[1] | Kenji Ando MD[1]

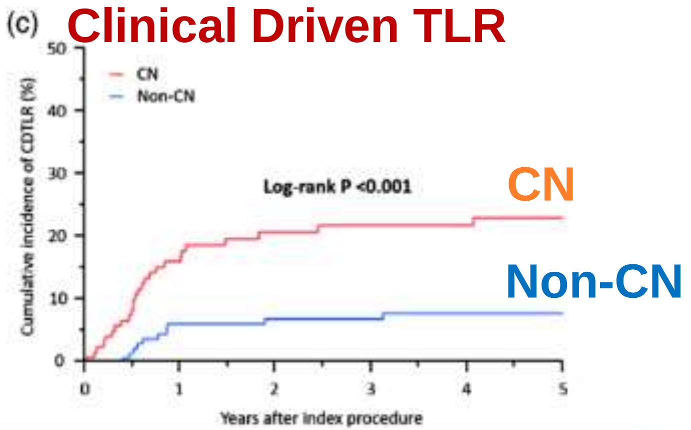




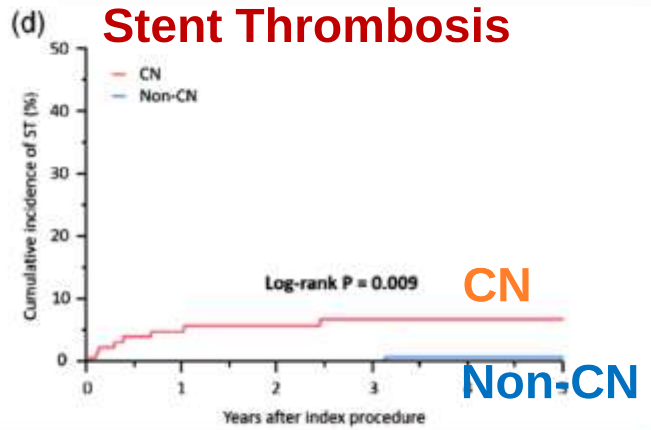
Intervals	0	30 days	1 Year	2 Years	3 Years	4 Years	5 Years
CN group							
N of lesions at risk	128	119	94	73	65	63	56
Cumulative incidence	0.0%	6.3%	24.7%	33.3%	34.3%	34.3%	35.4%
Non-CN group							
N of lesions at risk	136	135	121	111	102	91	81
Cumulative incidence	0.0%	0.74%	8.3%	10.7%	12.3%	15.9%	18.8%



Intervals	0	30 days	1 Year	2 Years	3 Years	4 Years	5 Years
CN group							
N of lesions at risk	128	120	114	94	84	78	70
Cumulative incidence	0.0%	4.7%	8.0%	15.7%	16.7%	17.7%	18.9%
Non-CN group							
N of lesions at risk	136	136	129	120	110	100	90
Cumulative incidence	0.0%	0.0%	2.3%	3.8%	5.5%	9.1%	11.9%



Intervals	0	30 days	1 Year	2 Years	3 Years	4 Years	5 Years
CN group							
N of lesions at risk	128	119	94	74	66	64	57
Cumulative incidence	0.0%	0.79%	17.0%	20.8%	21.9%	21.9%	23.2%
Non-CN group							
N of lesions at risk	136	136	121	111	101	91	81
Cumulative incidence	0.0%	0.0%	6.1%	7.0%	7.0%	7.9%	7.9%



Intervals	0	30 days	1 Year	2 Years	3 Years	4 Years	5 Years
CN group							
N of lesions at risk	128	119	108	89	80	74	66
Cumulative incidence	0.0%	0.79%	5.0%	5.9%	7.0%	7.0%	7.0%
Non-CN group							
N of lesions at risk	136	136	129	120	110	99	89
Cumulative incidence	0.0%	0.0%	0.0%	0.0%	0.0%	0.93%	0.93%

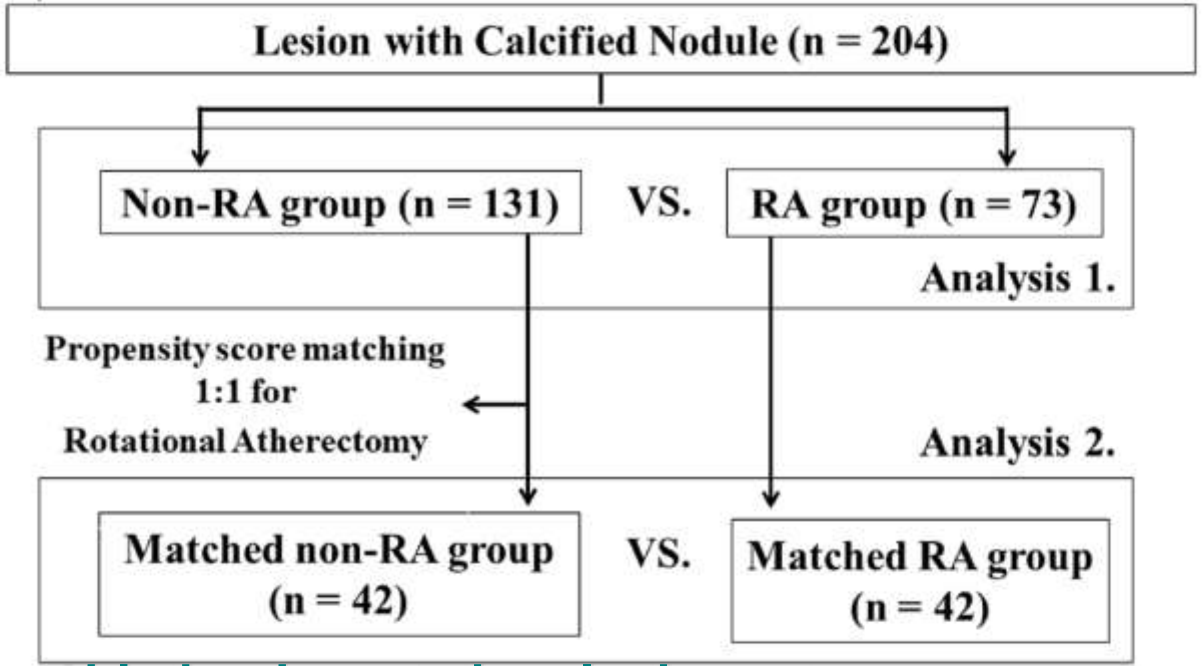
Compared with non-calcified nodule, calcified nodule demonstrates poor prognosis including significantly higher rate of MACE, cardiac death, clinical driven TLR and stent thrombosis.

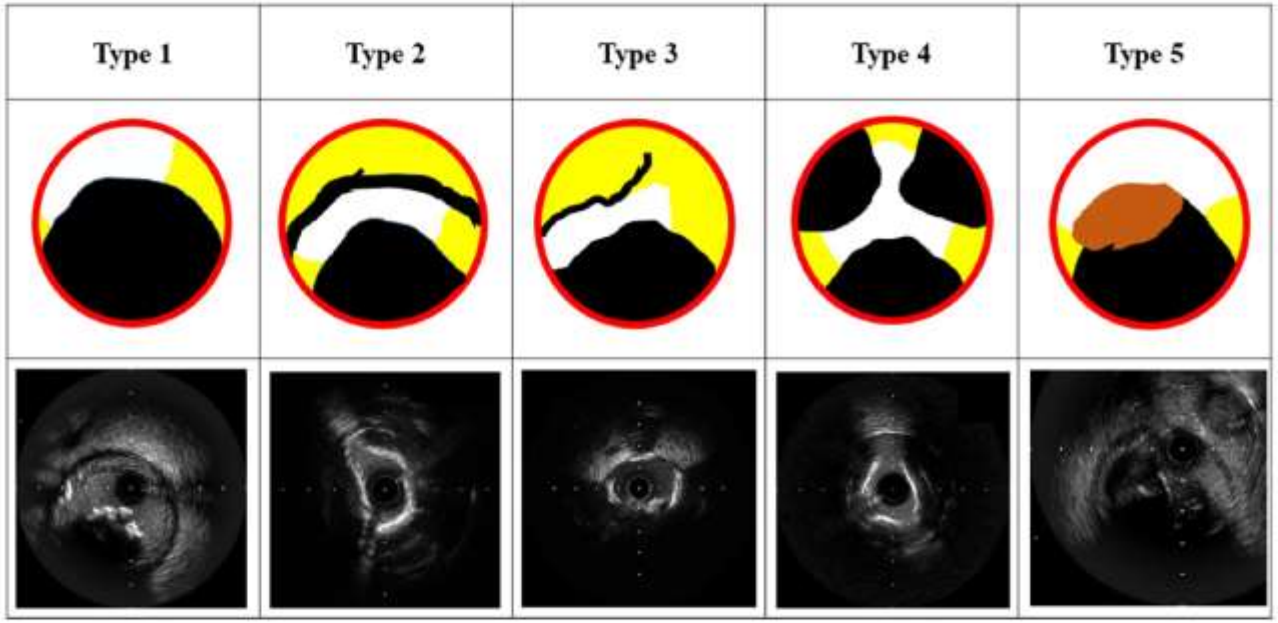
Morofuji T, et al. *Catheter Cardiovasc Interv. 2021;97:10-19*

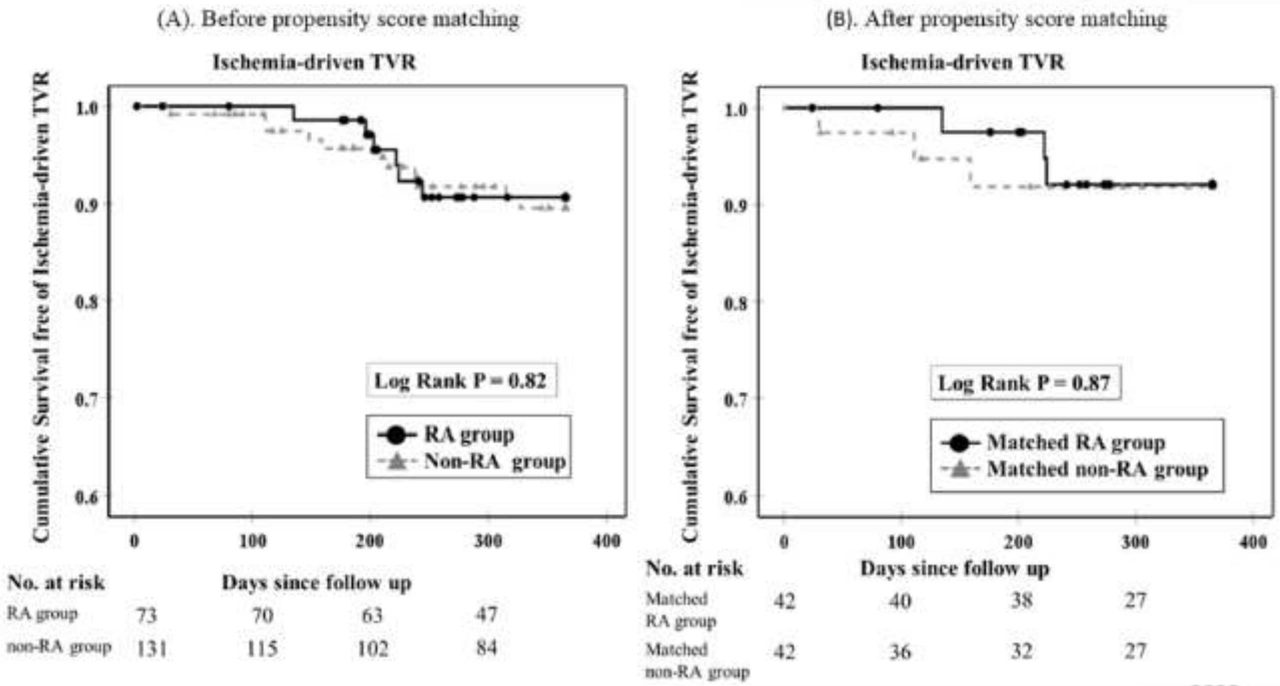
Comparison of clinical outcomes of intravascular ultrasound-calcified nodule between percutaneous coronary intervention with versus without rotational atherectomy in a propensity-score matched analysis

Yusuke Watanabe, Kenichi Sakakura*, Yousuke Taniguchi, Kei Yamamoto, Masaru Seguchi, Takunori Tsukui, Hiroyuki Jinnouchi, Hiroshi Wada, Shin-ichi Momomura, Hideo Fujita

Division of Cardiovascular Medicine, Saitama Medical Center, Jichi Medical University, Shimotsuke, Japan







Ablation by rotational atherectomy may not improve the prognosis of calcified nodule

Watanabe Y, et al. *PLoS ONE* 2020;15:e0241836

Conclusions

Role of Imaging in Calcified Lesion Treatment

- Lesion modification by atherectomy would be recommended if any imaging devices could not be passed through the tight lesion with severe calcification.
- Step by step approach by changing in burr size and/or rotation speed would be recommended for ablating calcium safely using wire bias under imaging-guide.
- OCT may allow us to demonstrate clearly the position, distribution and thickness of calcium, although IVUS might be more sensitive to detect calcium than OCT.
- Confirmation of calcium plate fracture by imaging modalities after high pressure ballooning with noncompliant, scoring or cutting balloon should be mandatory if the thickness of it become less than 500μm.
- Enough stent expansion and less instent restenosis could be expected if calcium plate fracture can be obtained after high pressure ballooning following step by step calcium ablation by atherectomy and/or IVL system.
- Calcified nodule demonstrated poor prognosis compared with non-calcified nodule even after ablation under the guidance of intracoronary imaging.