OCT-guided calcium lesion intervention Rota-Tripsy

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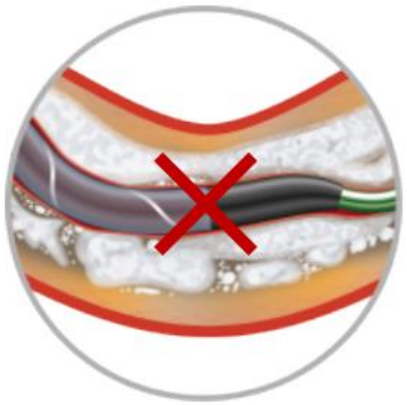
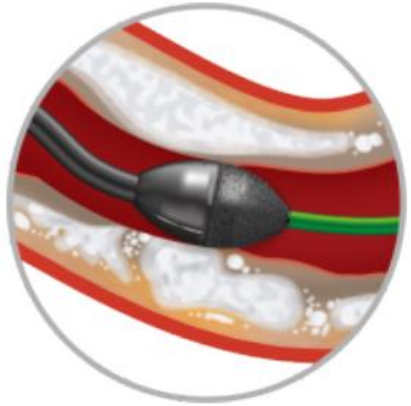
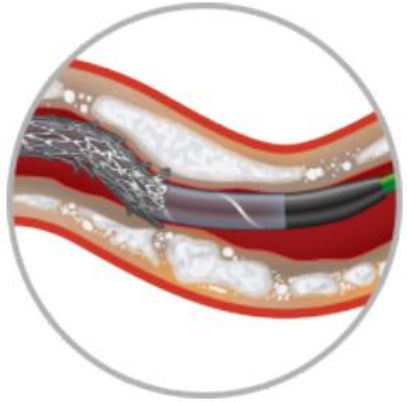
Challenges in calcified lesions



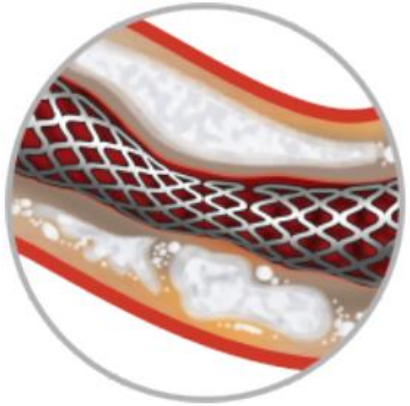
Impairs / prevents delivery of secondary equipment



Requirement for high pressure inflations / specialized equipment



Strut / polymer damage and impaired drug delivery



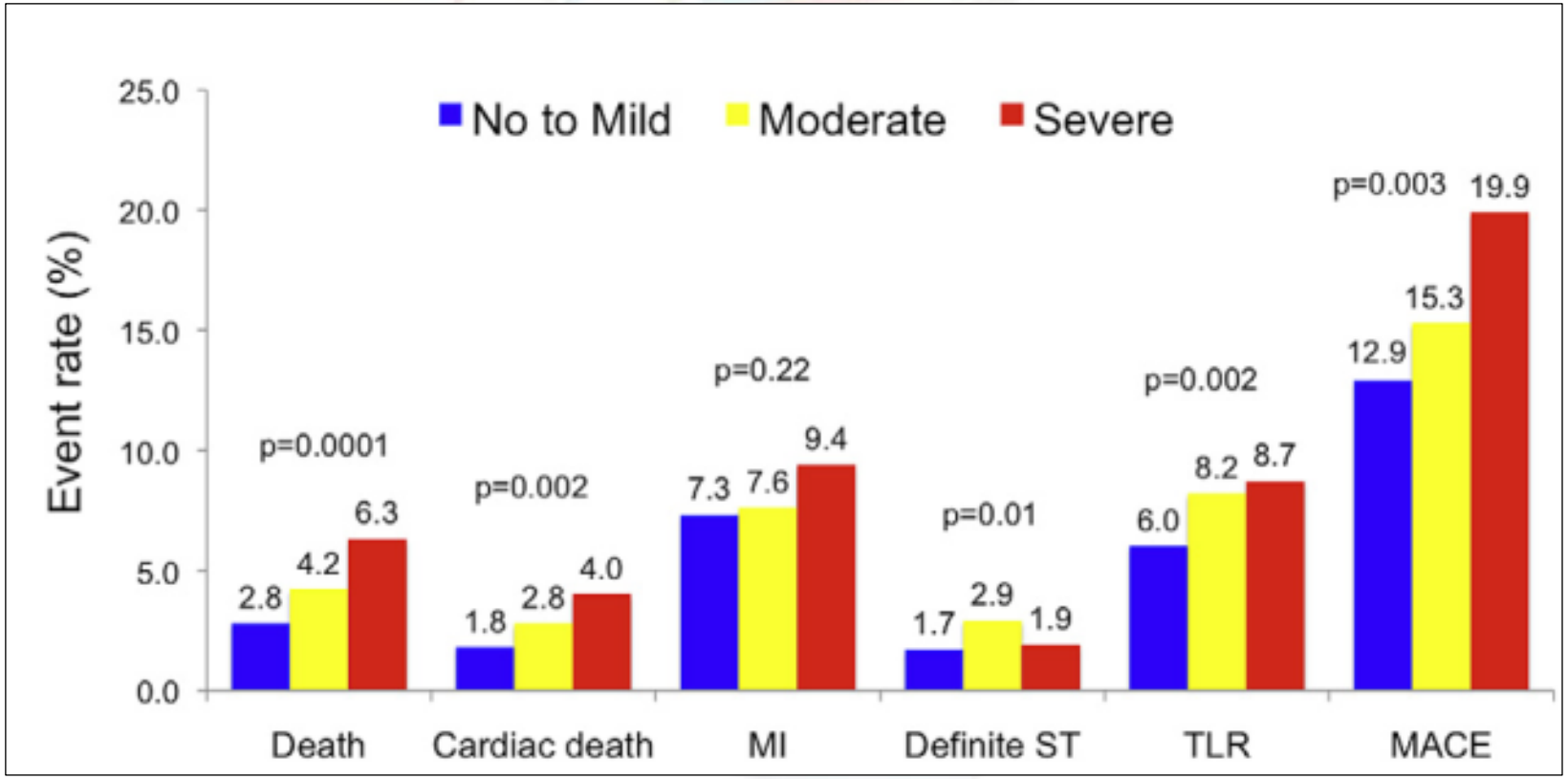
Sub-optimal stent deployment

Procedural failure

Procedural complications

TLF / MACE

Adverse Outcomes Through 1 Year According to Severity of Target Lesion Calcification

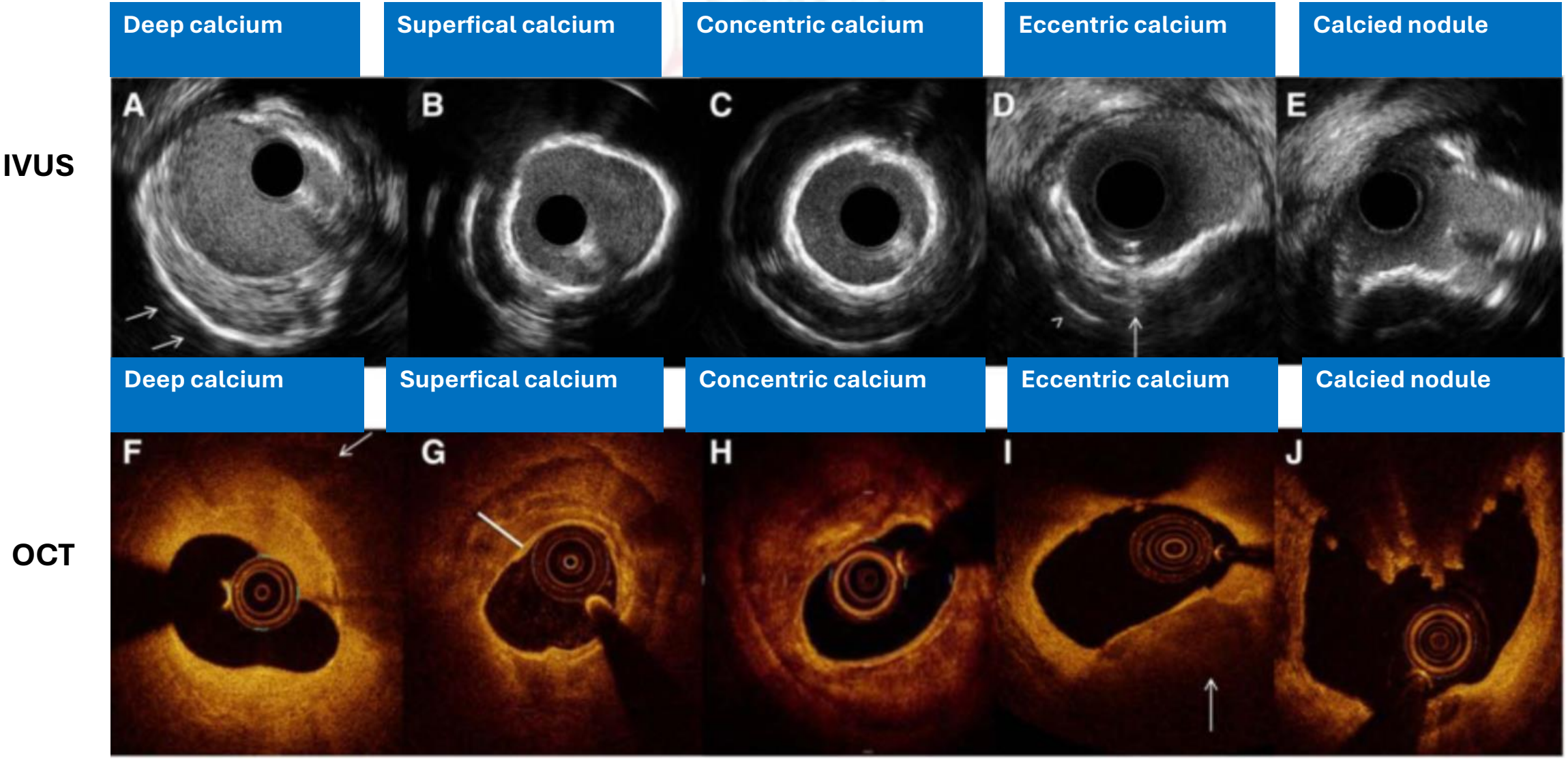


J Am Coll Cardiol 2014;63:1845–54

Comparison of clinically available coronary imaging tools

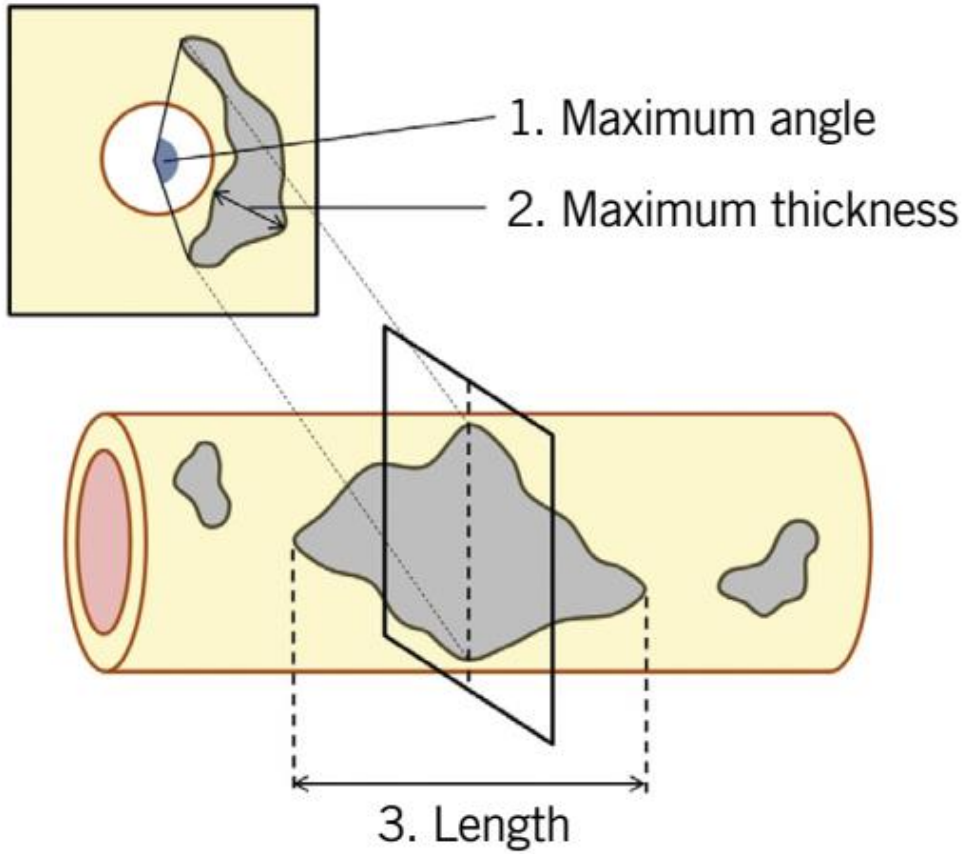
	Non-invasive imaging prior to the catheterization laboratory		ICA	Intravascular imaging in the catheterization laboratory	
	CCTA	CS		OCT	IVUS
Spatial resolution	0.2–0.5 mm	1.25 mm	0.5–0.6 mm	15–20 μ	50–200 μ
Contrast needed	Yes	No	Yes	Yes	No
Time of data acquisition	1–5 min	1 min	15 min[a]	<5–10 s	2–4 min
Availability	+++	+++	+++	+	++
Additional cost	+	+	+	+++	+++
Tissue penetration (non-calcified)	+++	+++	+++	+	++
Global assessment of calcification	+++	+++	+	-	-
Calcium volume quantification	+	-	-	++	-
Calcium arc	++	-	-	+++	+++
Calcium thickness	+	-	-	+++	-
Longitudinal calcium length	+	-	-	+++	+++

Not all calcium is the same



Shlofmitz E, et al. Circ Cardiovasc Interv. 2020

Optical coherence tomography-based calcium scoring system



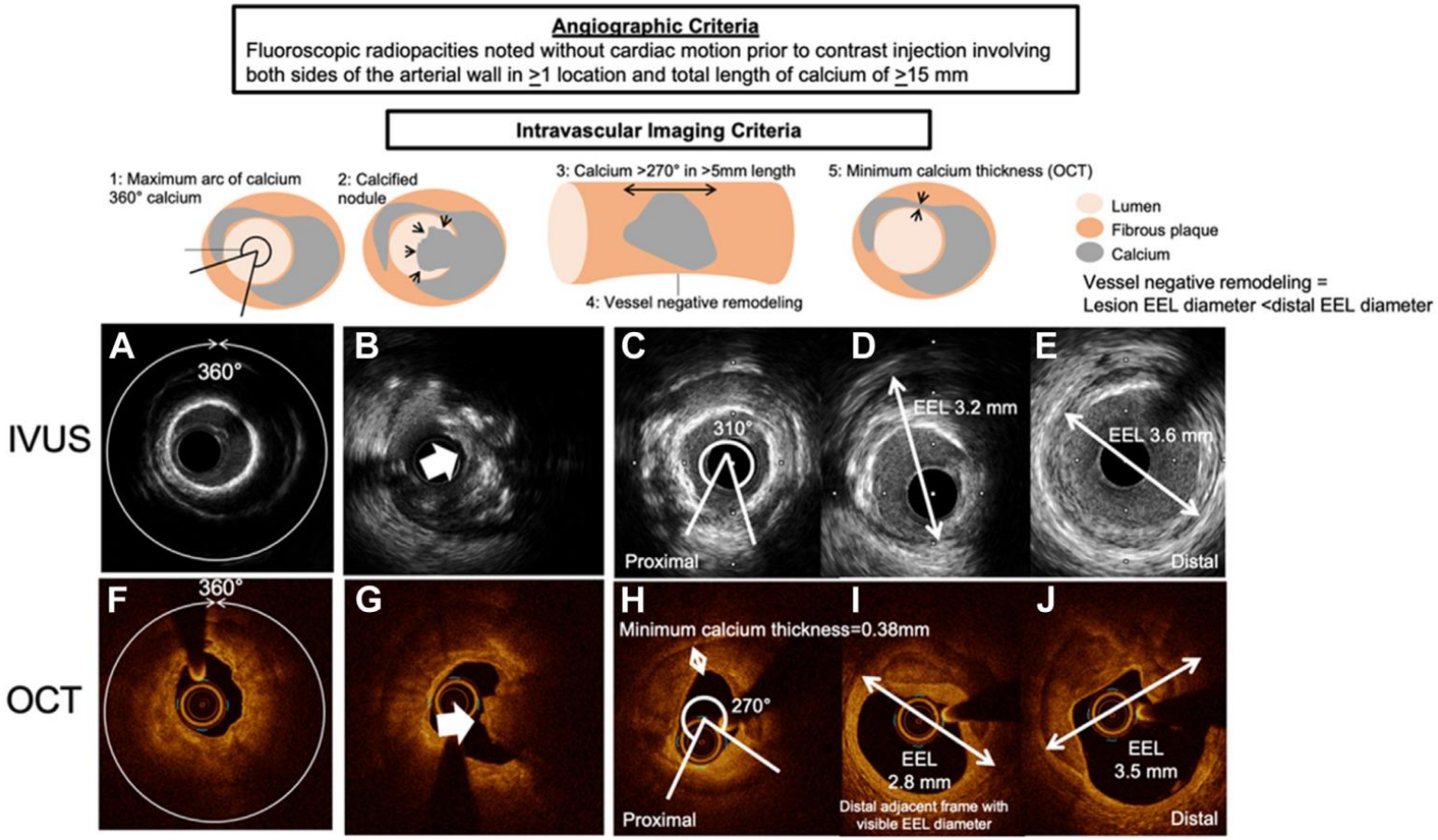
OCT-based calcium score	
1. Maximum calcium angle (°)	≤180° ➡ 0 point >180° ➡ 2 points
2. Maximum calcium thickness (mm)	≤0.5 mm ➡ 0 point >0.5 mm ➡ 1 point
3. Calcium length (mm)	≤5.0 mm ➡ 0 point >5.0 mm ➡ 1 point
Total score	**0 to 4 points**

Euro**Intervention** 2018;13:e**2182**-e**2189**

JSCAI
The official journal of the Society for Cardiovascular Angiography & Interventions

Standards and Guidelines

SCAI Expert Consensus Statement on the Management of Calcified Coronary Lesions



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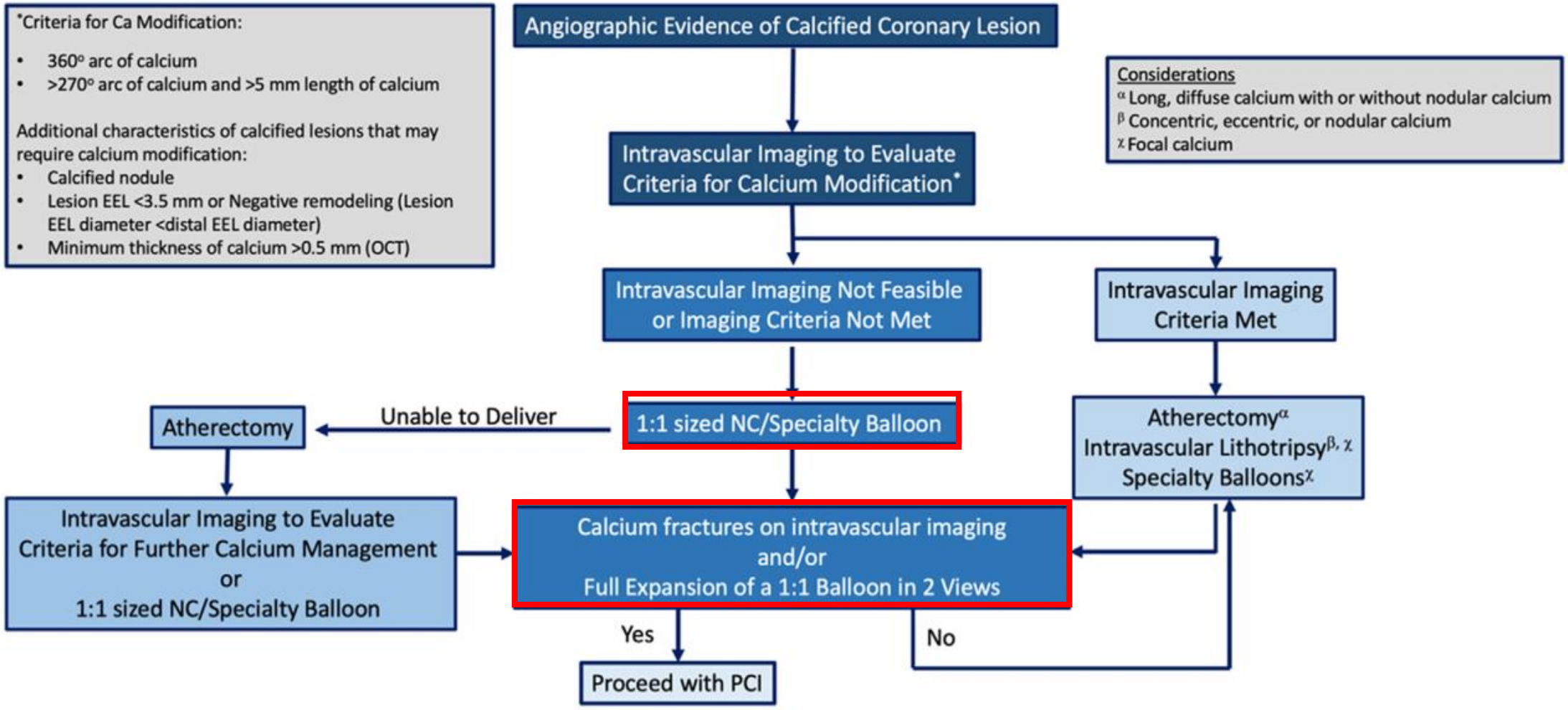
Standards and Guidelines

SCAI Expert Consensus Statement on the Management of Calcified Coronary Lesions

Treatment algorithm for calcified CAD

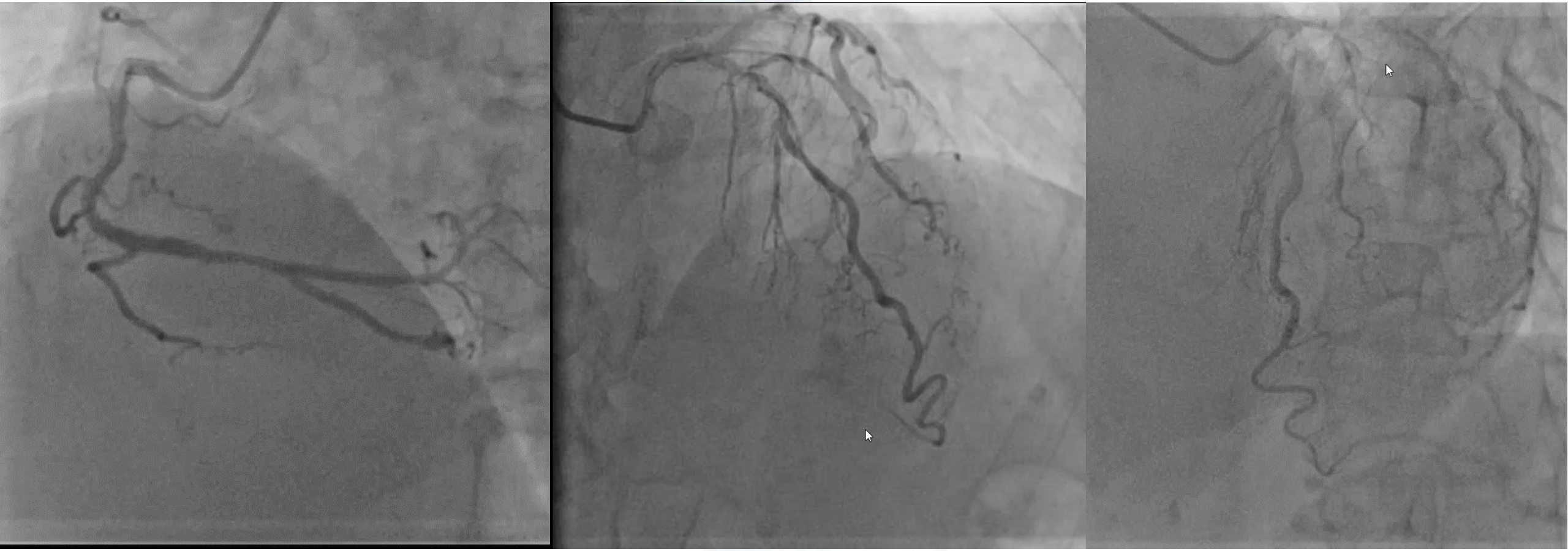


R.F. Riley et al. / Journal of the Society for Cardiovascular Angiography & Interventions 3 (2023) 101259

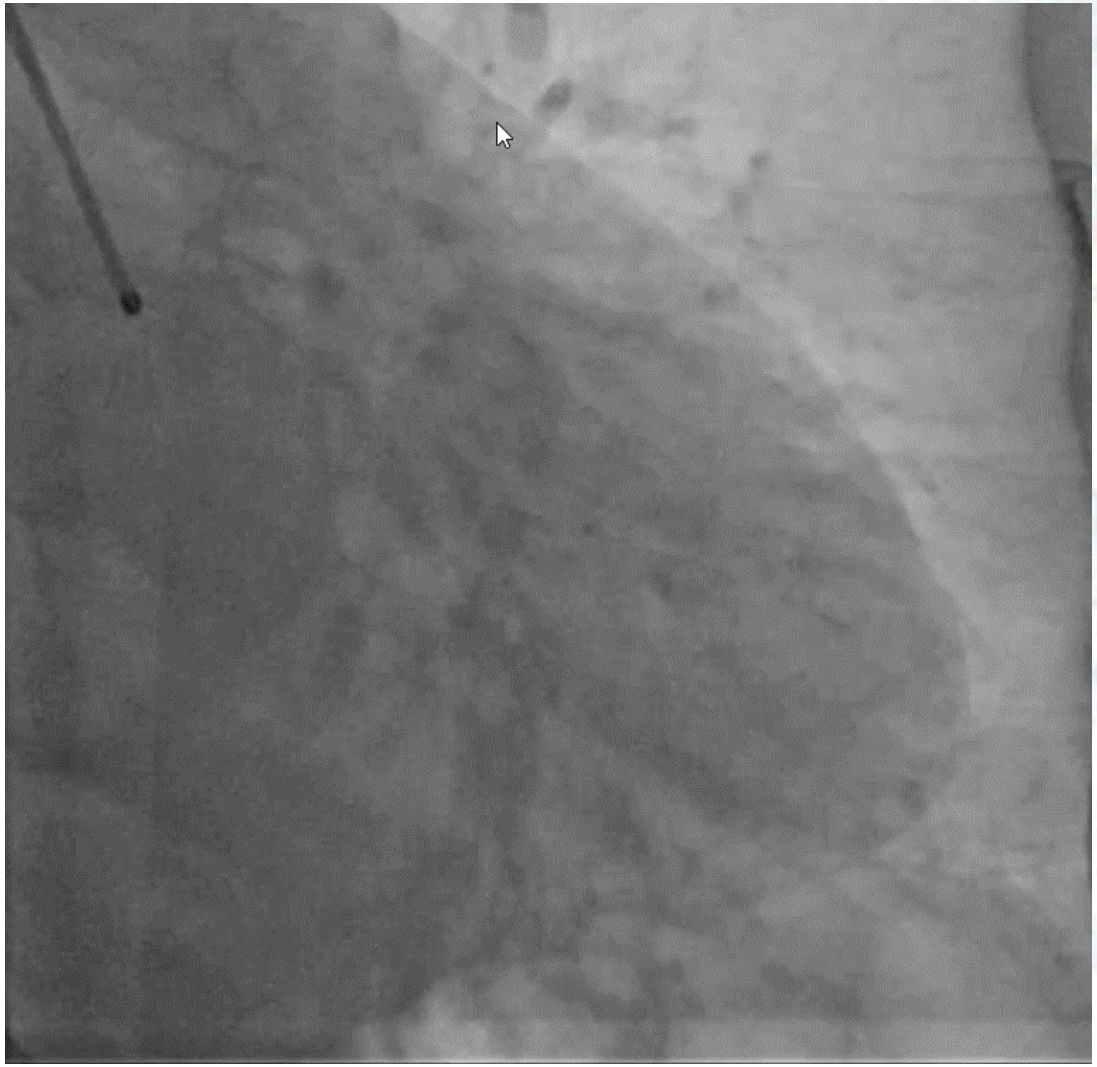
Case briefing

- **A 71 years old femal, she was admitted to the hospital for exertional chest pain. She underwent CAG. The LCx was deployed a DES. While the LAD showed approximately 80% of stenosis with severe calcification.**
- **Past medical history**
  - **Family history: Y**
  - **Hypertension : Y**
  - **Diabetes: N**
  - **Lipidemia: N**
  - **Smoking: N**

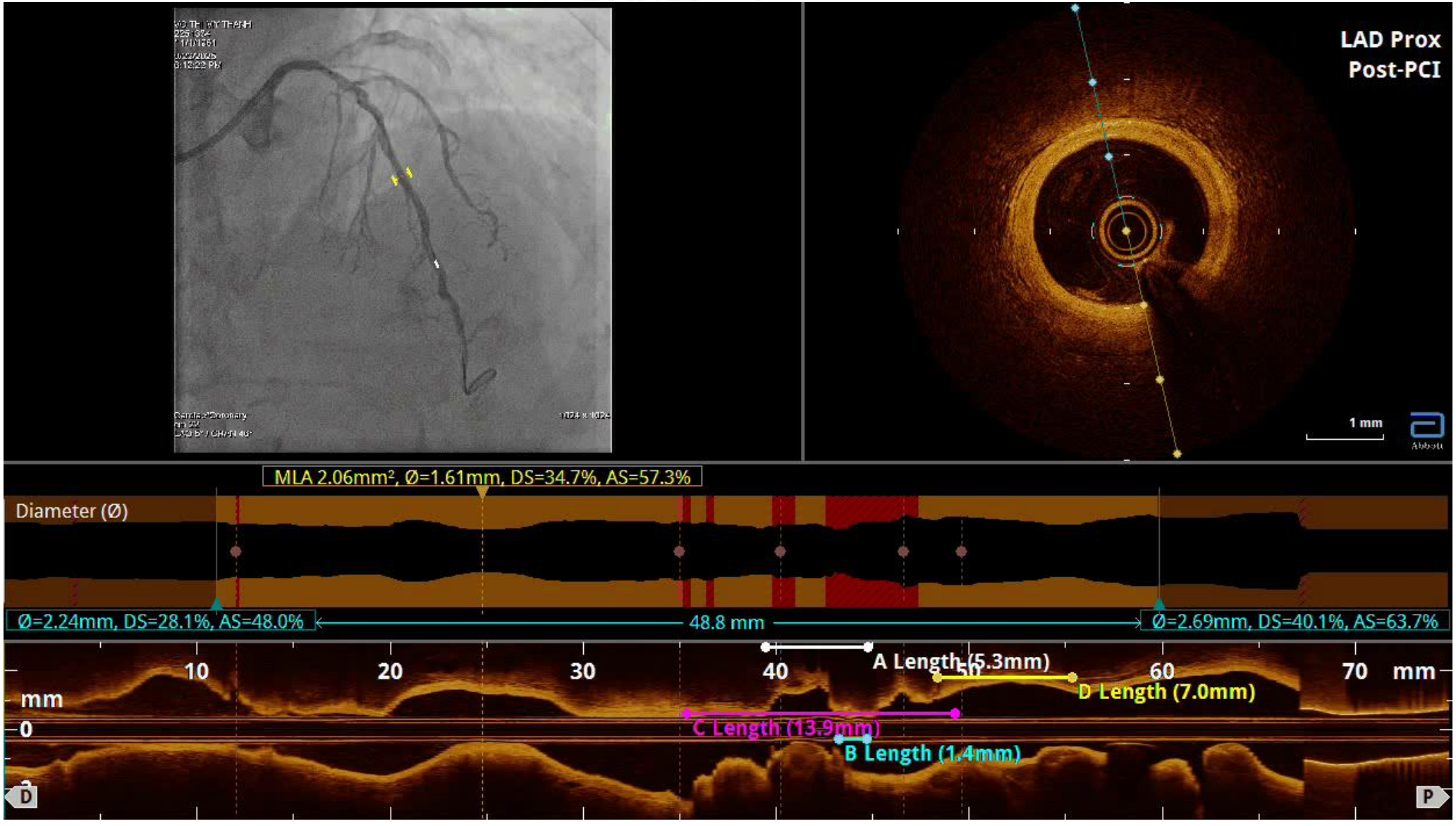
Basis coronary angiography



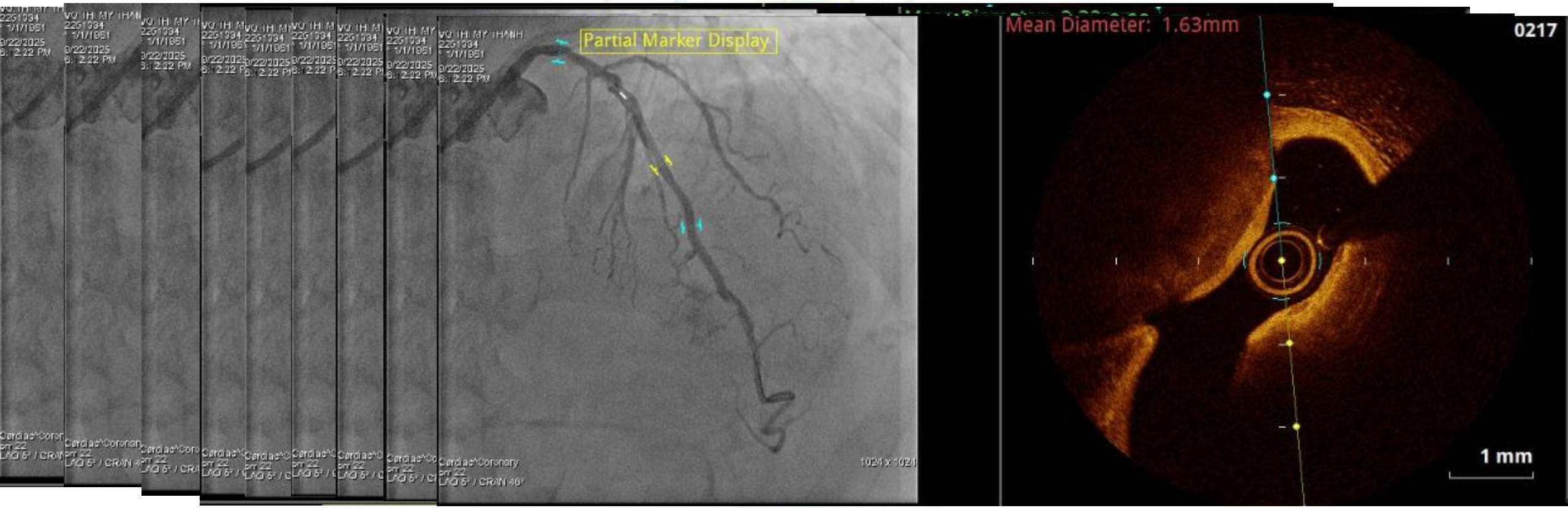
Basis coronary angiography



OCT imaging

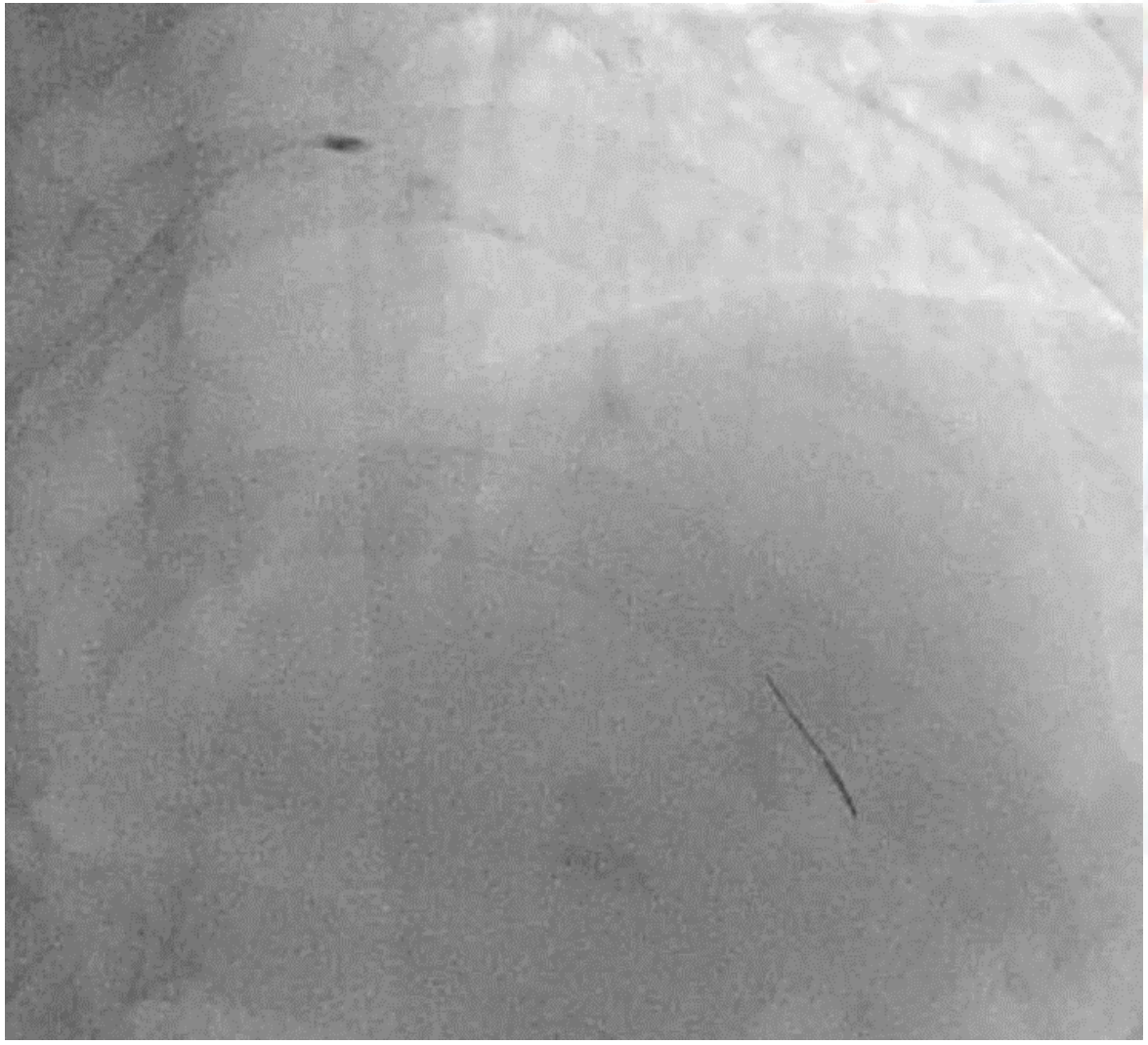

LAD Prox
Post-PCI
1 mm
MLA 2.06mm², Ø=1.61mm, DS=34.7%, AS=57.3%
Diameter (Ø)
Ø=2.24mm, DS=28.1%, AS=48.0%
48.8 mm
Ø=2.69mm, DS=40.1%, AS=63.7%
A Length (5.3mm)
D Length (7.0mm)
C Length (13.9mm)
B Length (1.4mm)
10
20
30
40
50
60
70
mm
mm
0
D
P

OCT imaging



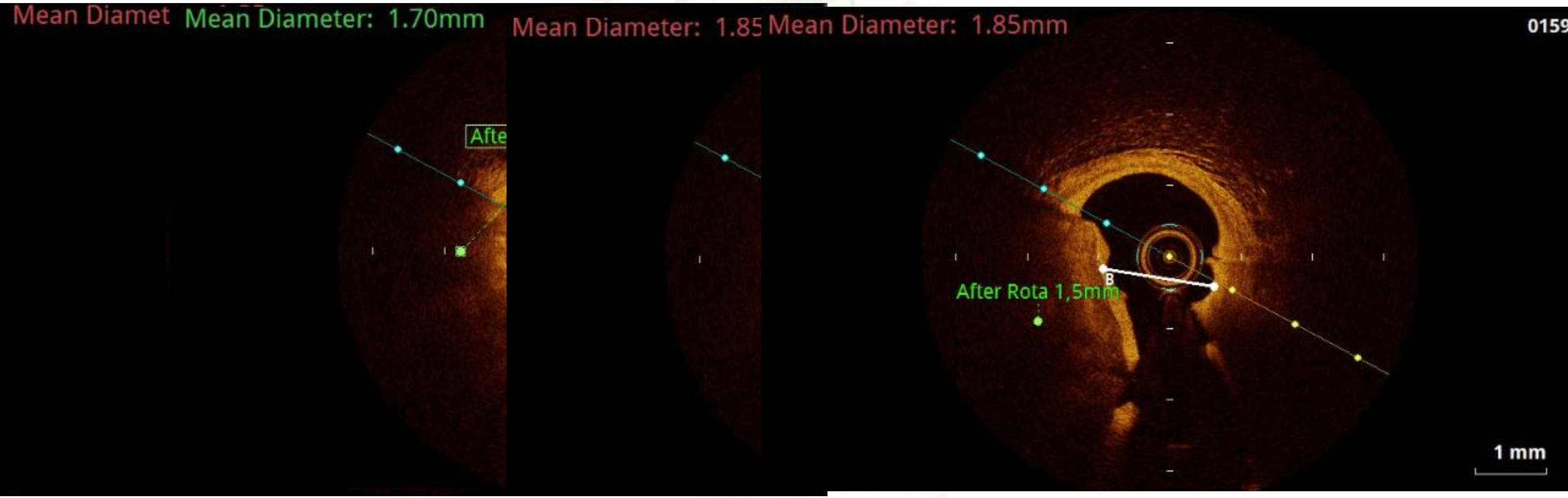
Rotational Atherectomy
burr 1.5 mm

First times

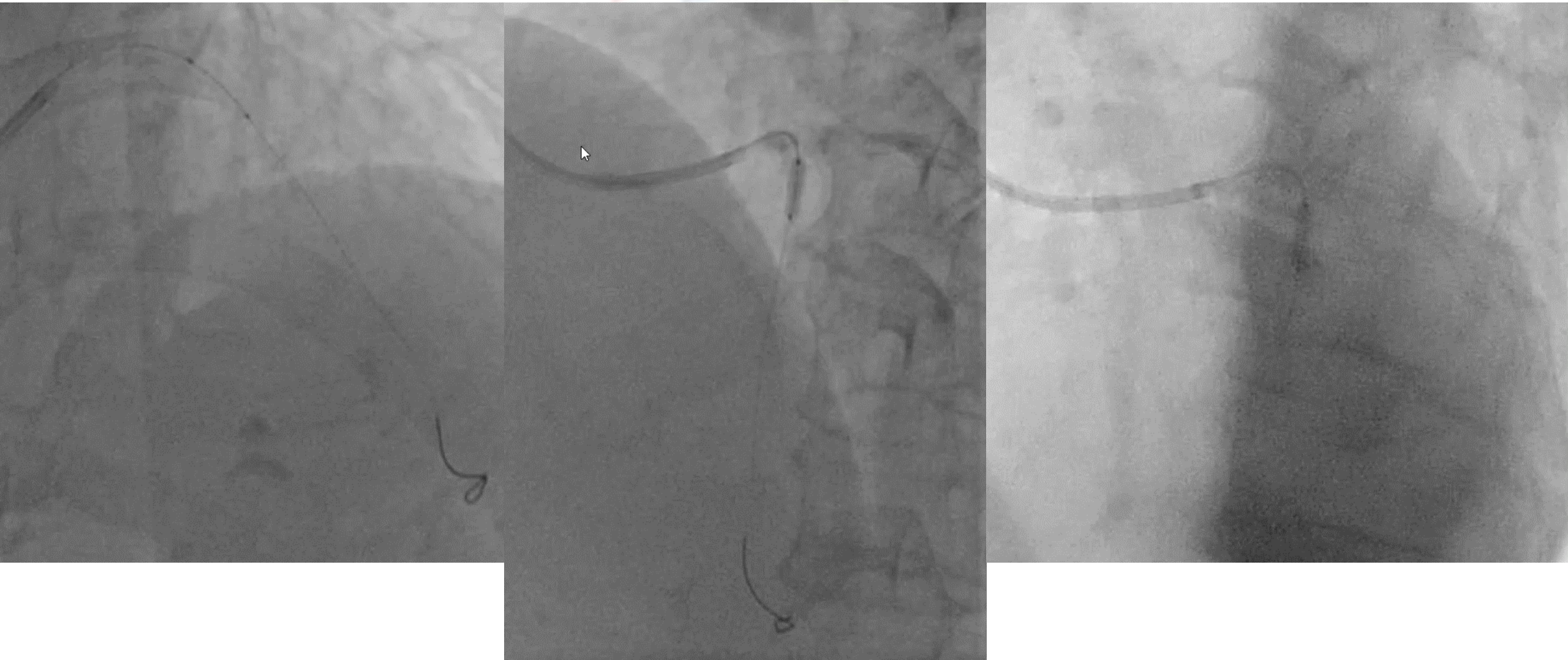


Third times

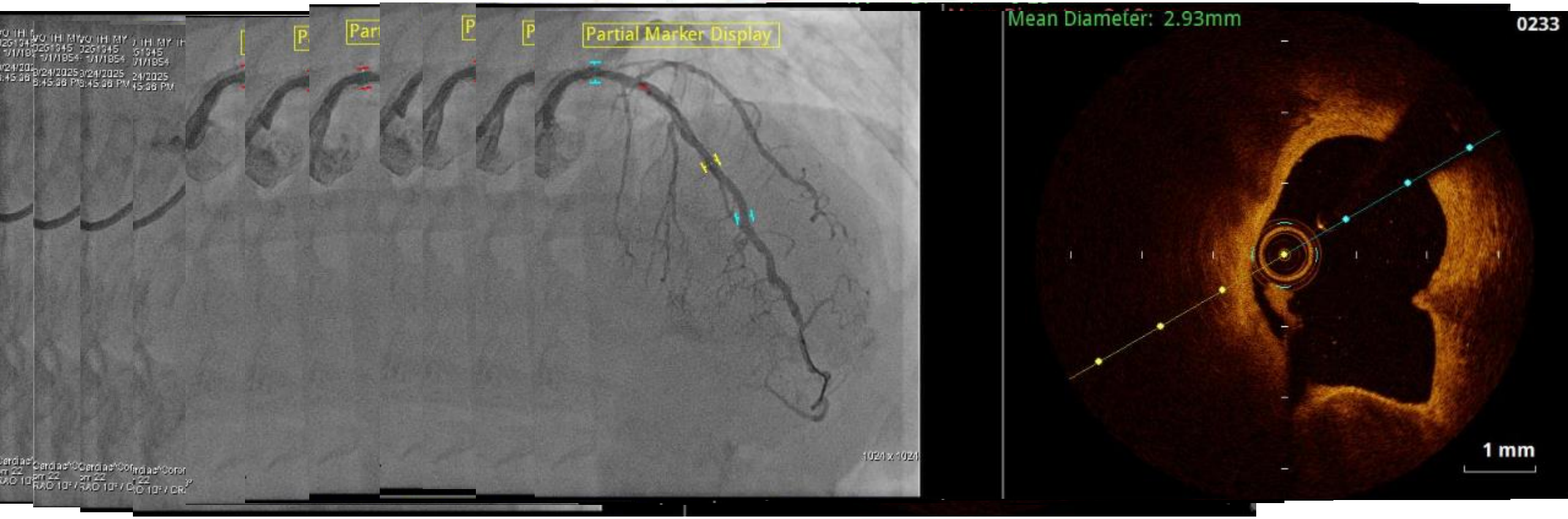
OCT imaging after Rotational Atherectomy



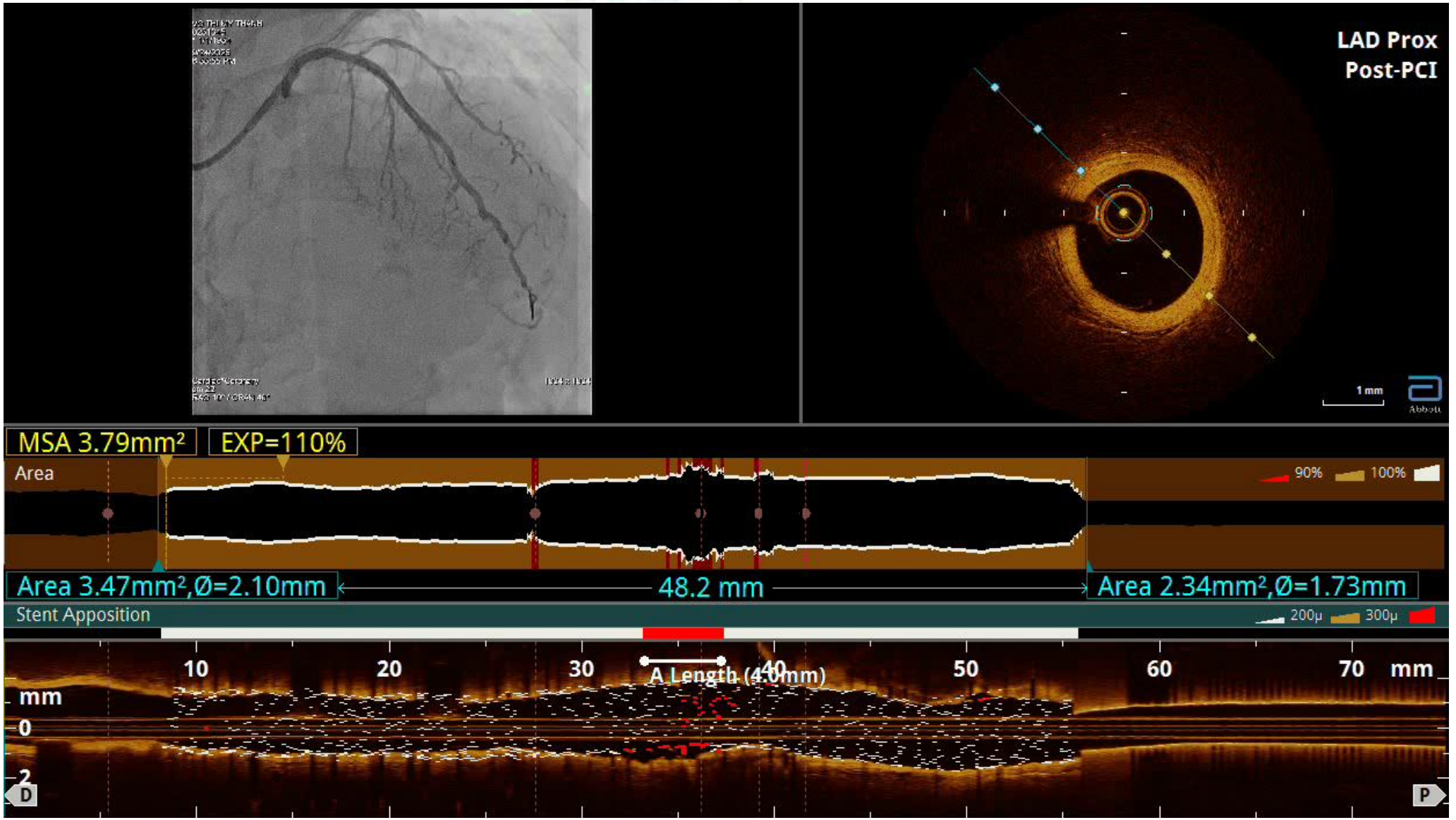
Lithotripsy procedure
IVL balloon 3.0x12 mm

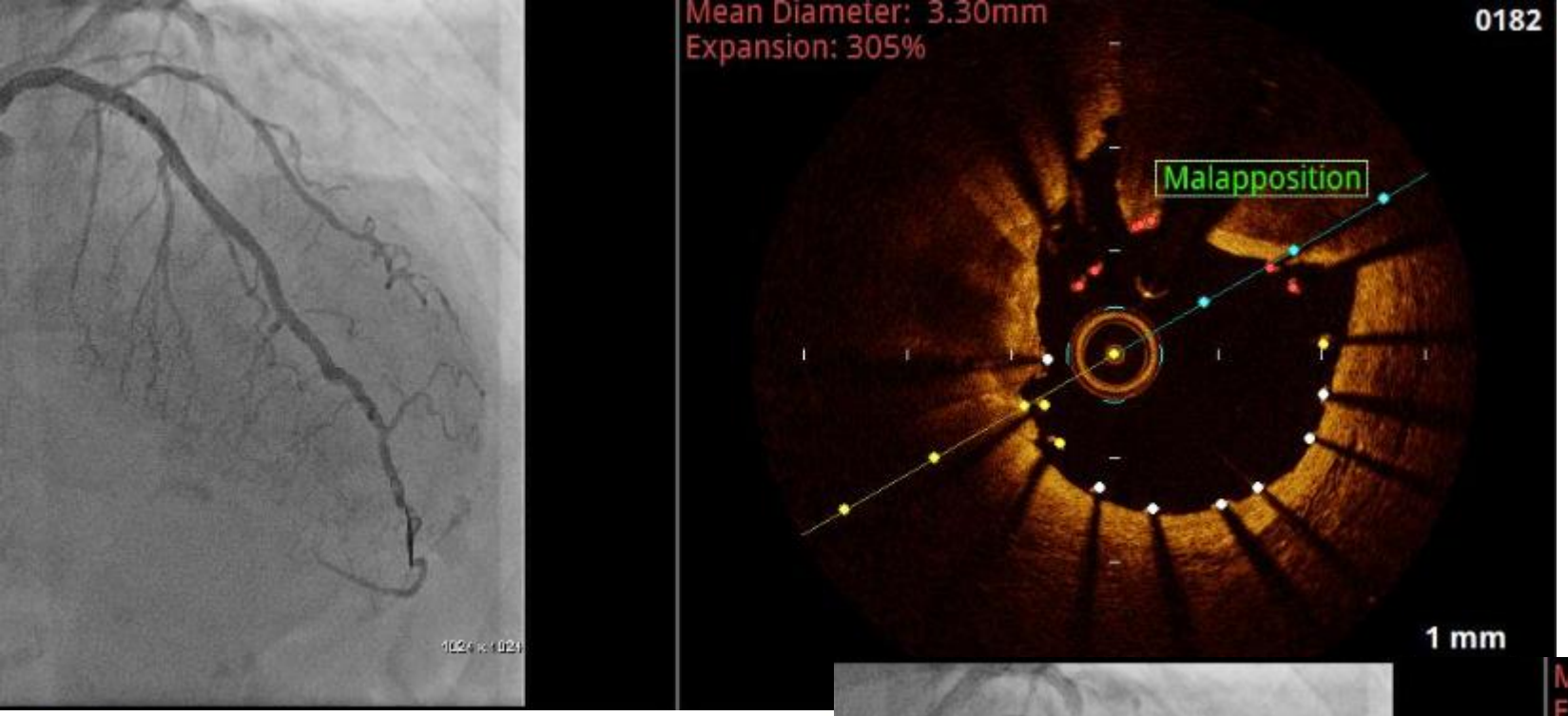


After IVL

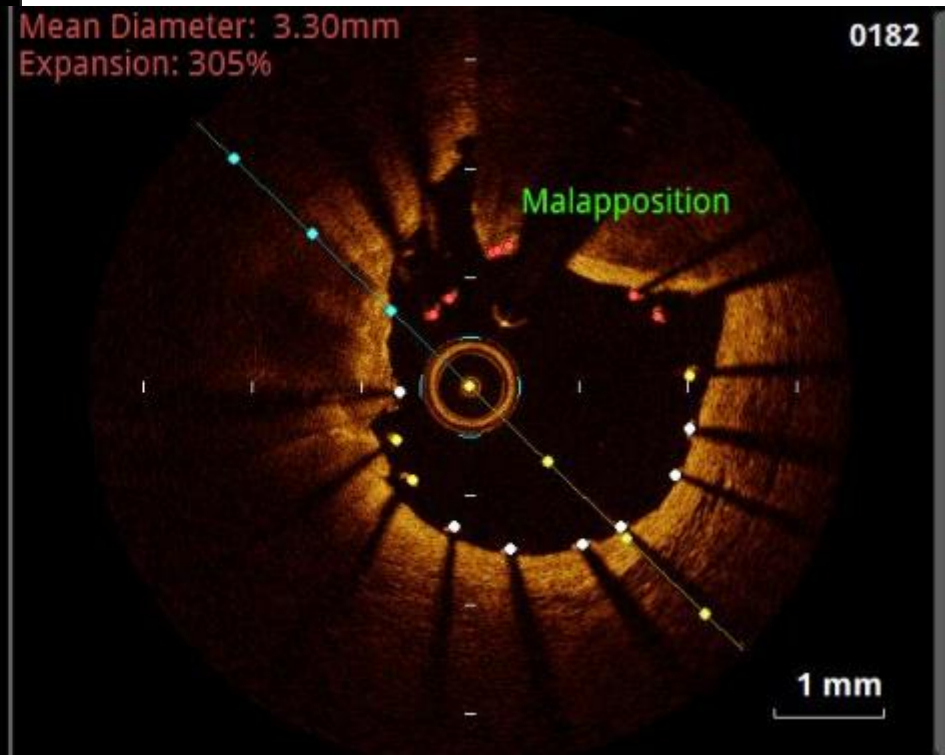


After stenting
DES 3.0x48 mm

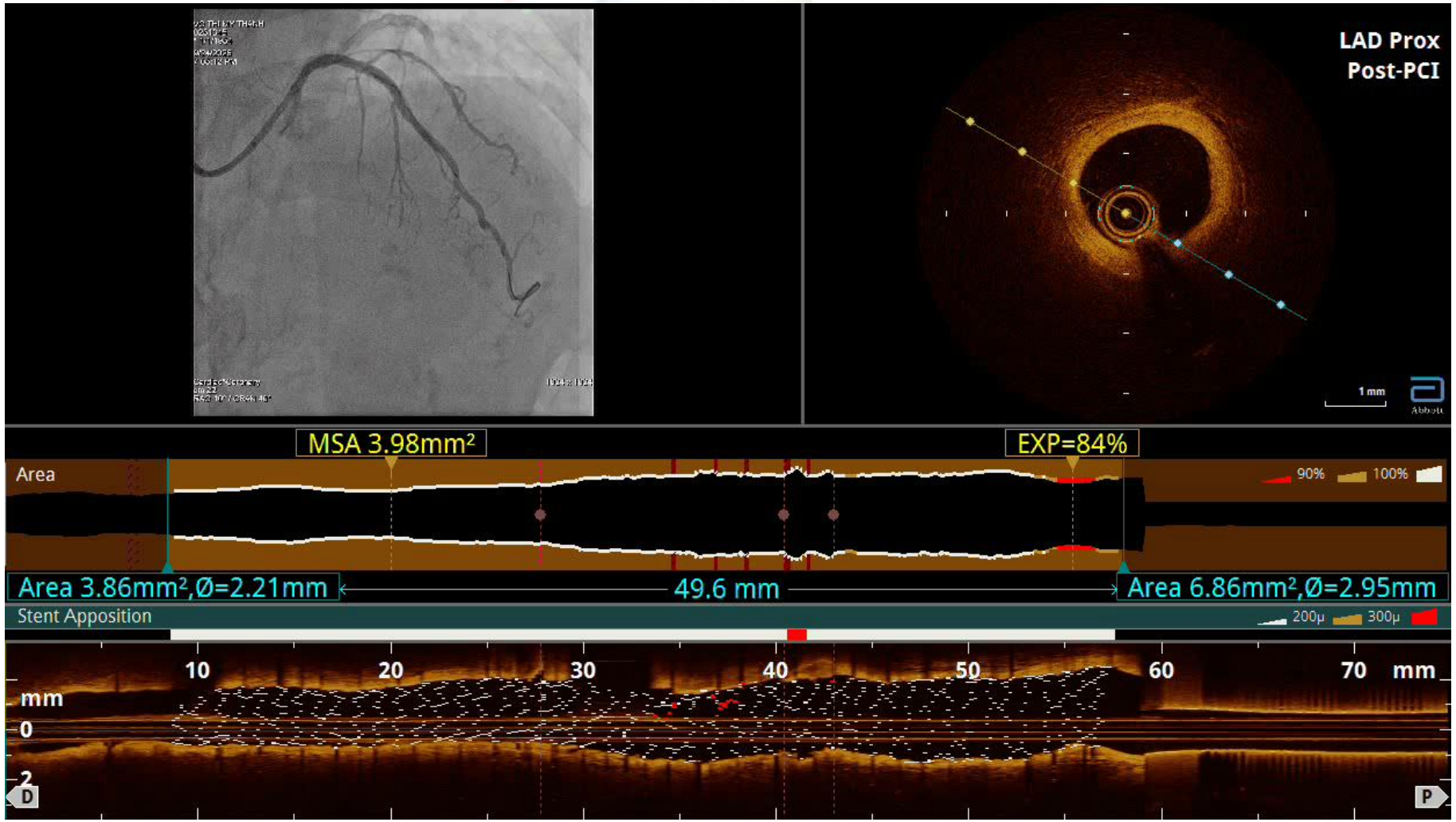




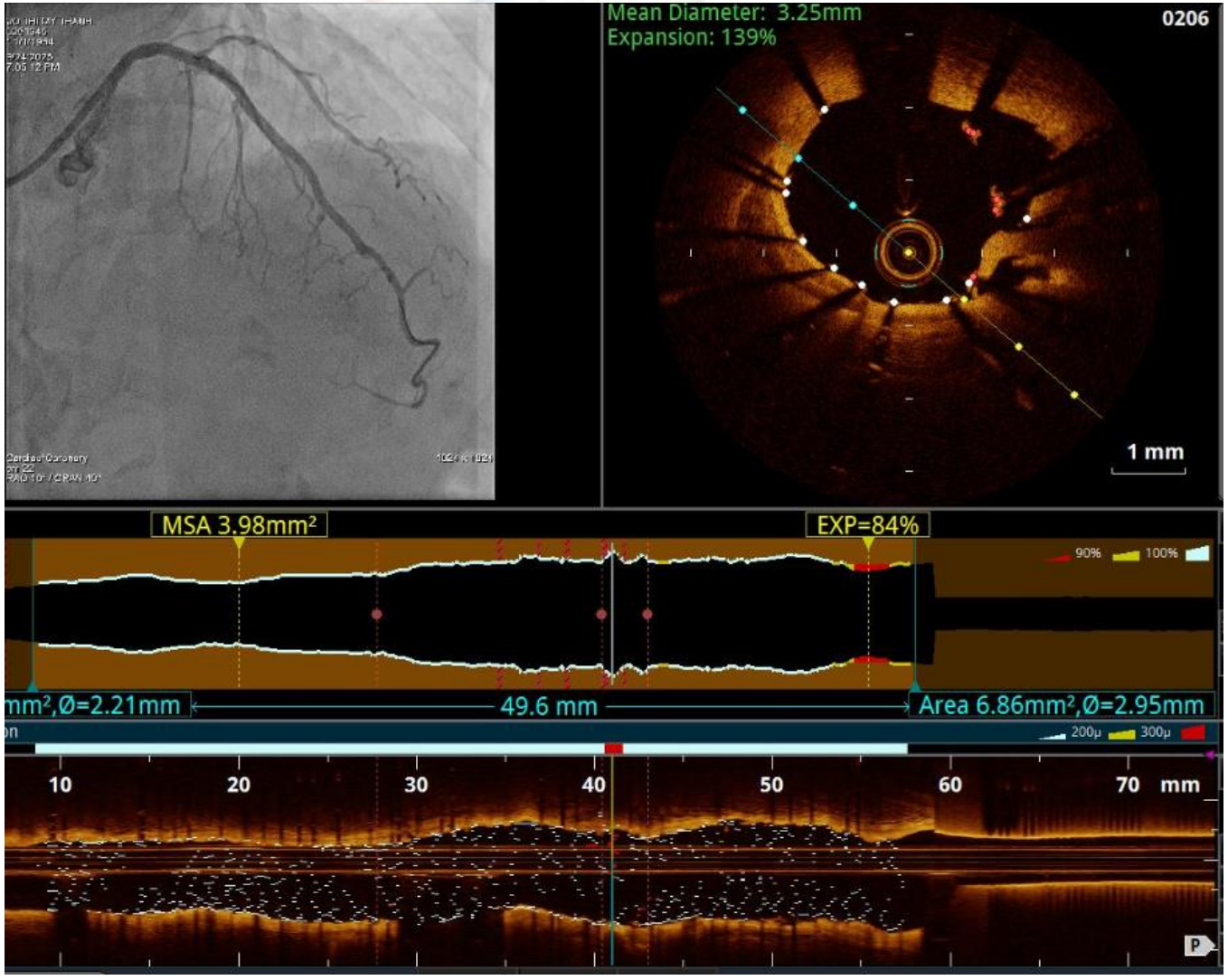
Malapposition



Final OCT – finding
After Postdilatation NC 3.25 x 15 mm

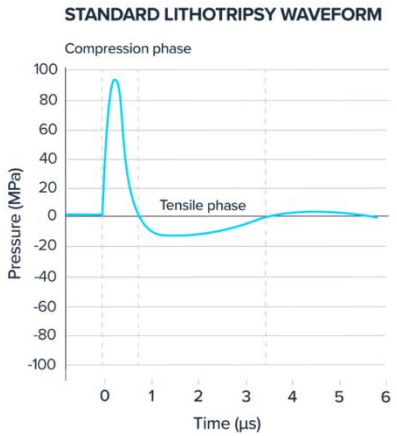


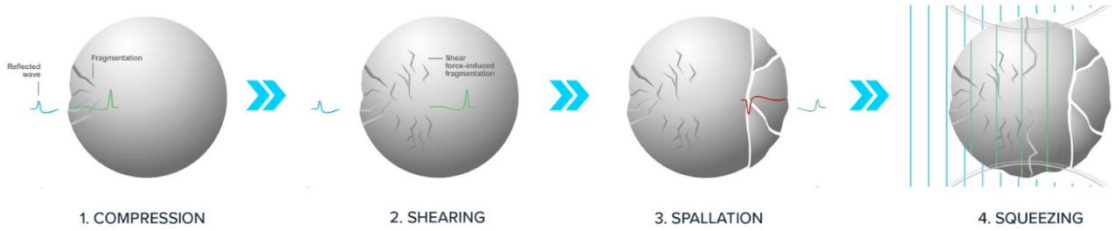
Final OCT – finding
After Postdilatation NC 3.25 x 15 mm



No dissection
Good Apposition
Well Expansion > 80%

Intravascular LithotripsyMechanism of Action





- Electrical impulses
- Evaporation
- Rapid expansion & contraction of microbubbles
- Acoustic shockwaves
- Disruption of calcified plaques

Crack The Code For Calcium

New Treatment Option for Coronary Calcified Lesions - SoniCracker™

Soni Cracker ™ | CL

Coronary intravascular lithotripsy catheter

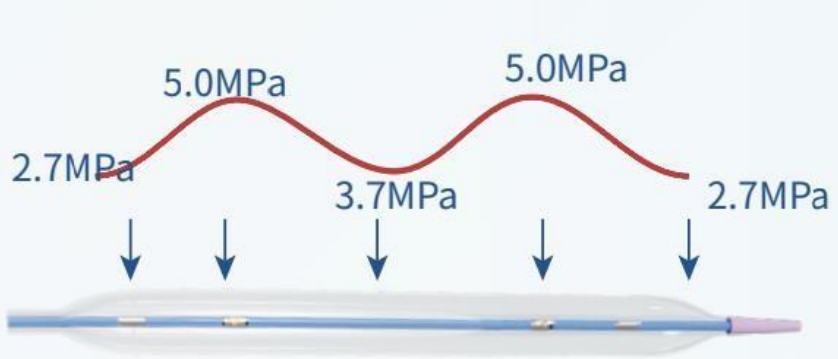
+

Soni Cracker ™

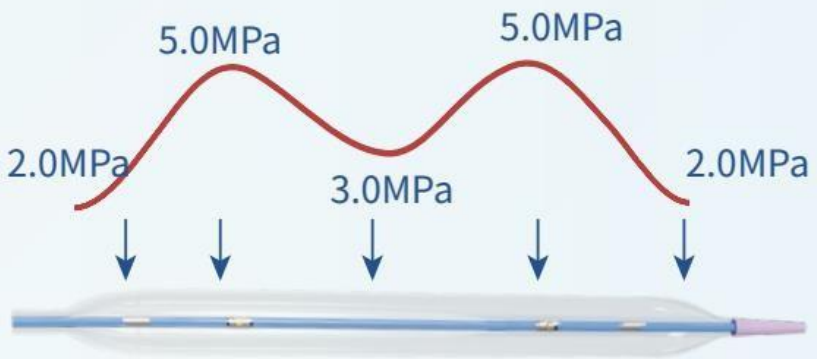
Coronary intravascular lithotripsy therapy device

Excellent treatment outcomes for calcified lesions
— uniform acoustic pressure distribution

Exclusive patented electrode design, capable of achieving **higher acoustic pressure intensity** and **more uniform** shockwave distribution



12mm balloon sound pressure distribution



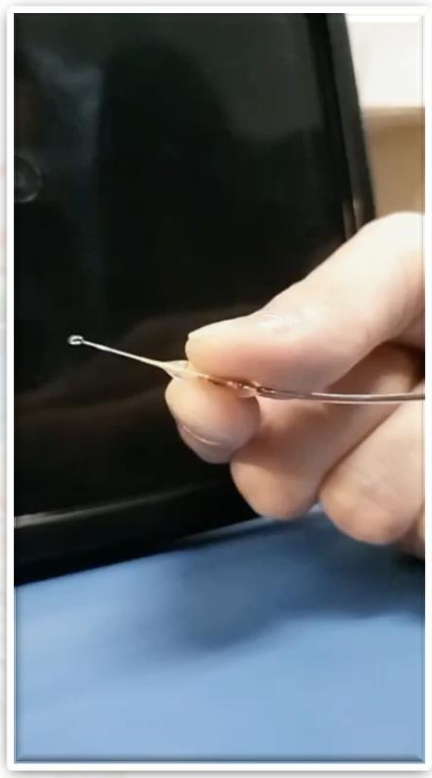
15mm balloon sound pressure distribution

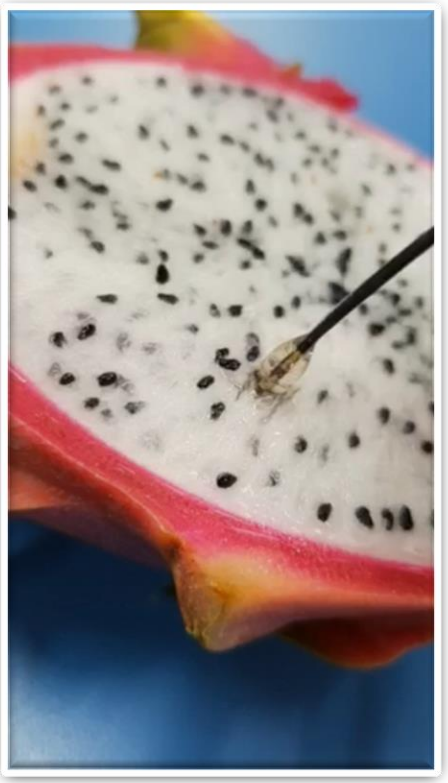
✓ The central region between the two electrodes distributes sufficient acoustic energy ≥ 3MPa, enabling the design of **a 15mm length balloon**, thus enhancing treatment efficiency.

Image for illustration purposes only

Effects of SoniCracker™ (IVL) at different media

Fracturing solid substances



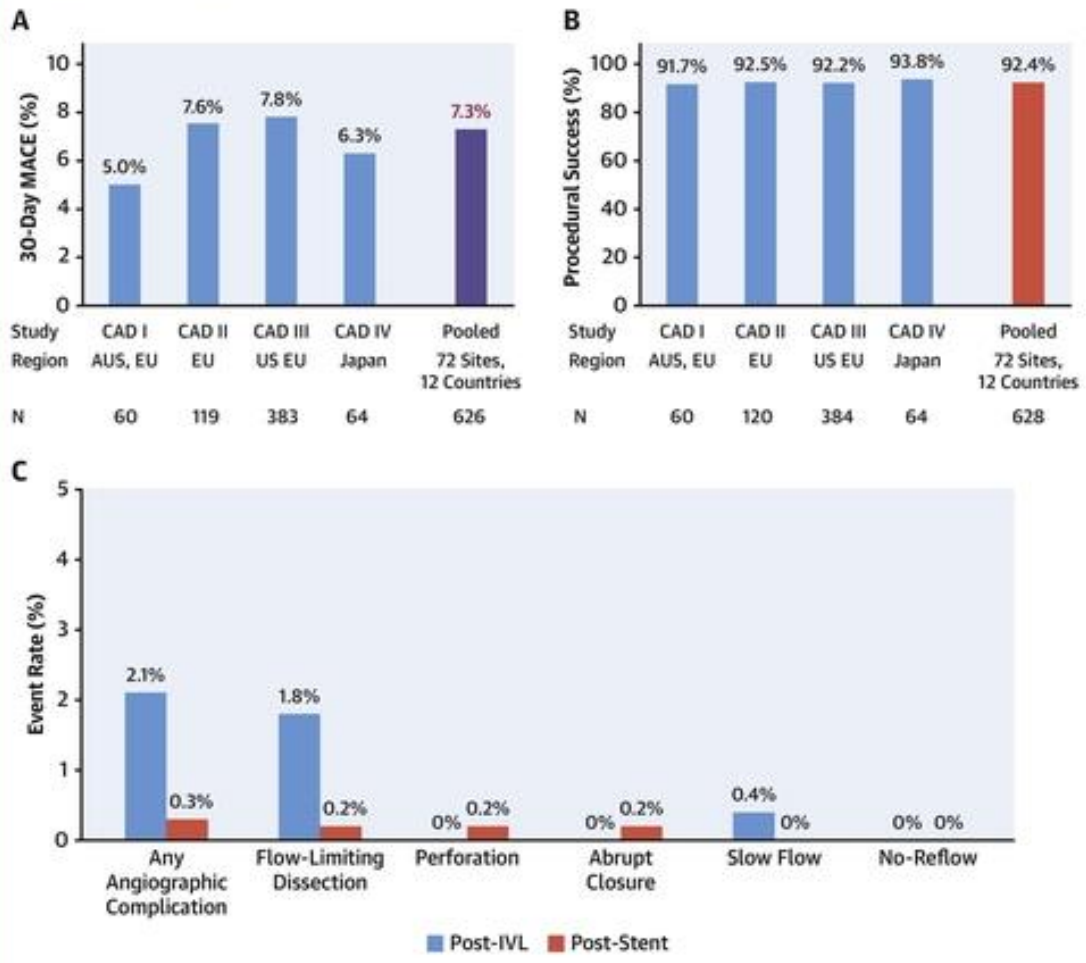


***without causing damage** to soft tissues*

*Internal Bench Test

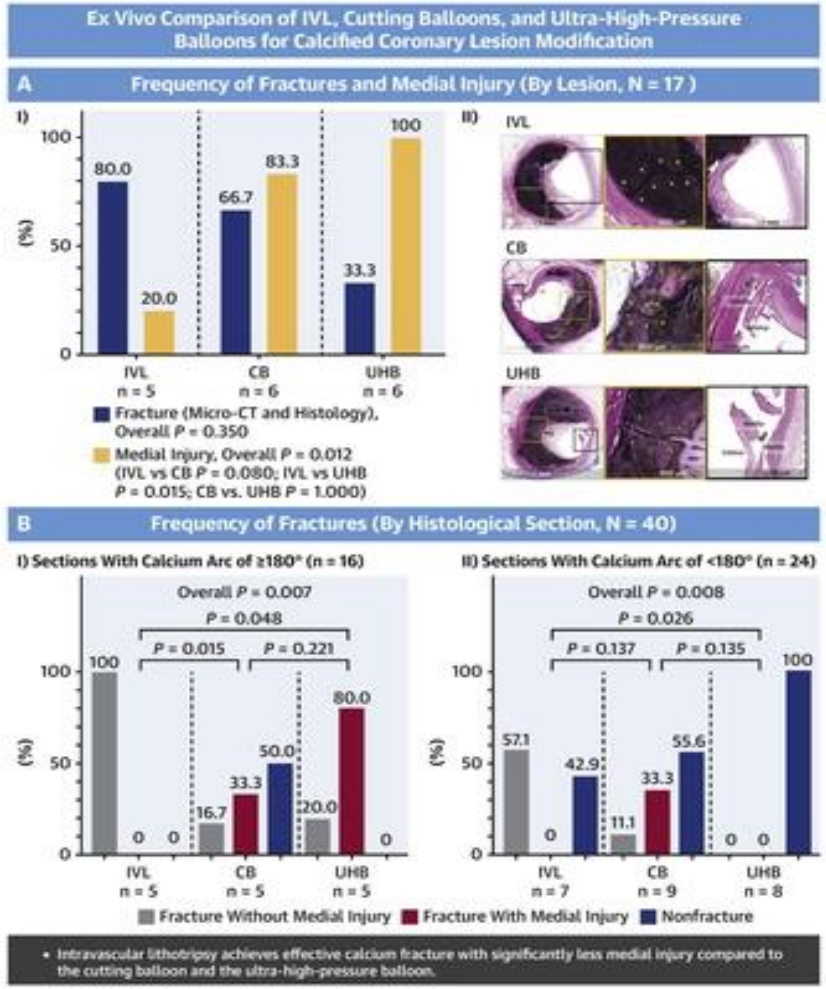
Safety and Effectiveness of IVL

CENTRAL ILLUSTRATION: Safety and Effectiveness of Intravascular Lithotripsy Across the Disrupt CAD Studies



Kereiakes, D.J. et al. J Am Coll Cardiol Intv. 2021;14(12):1337-48.

CENTRAL ILLUSTRATION: Comparison of Calcium Fracture and Medial Injury Following Lesion Modification



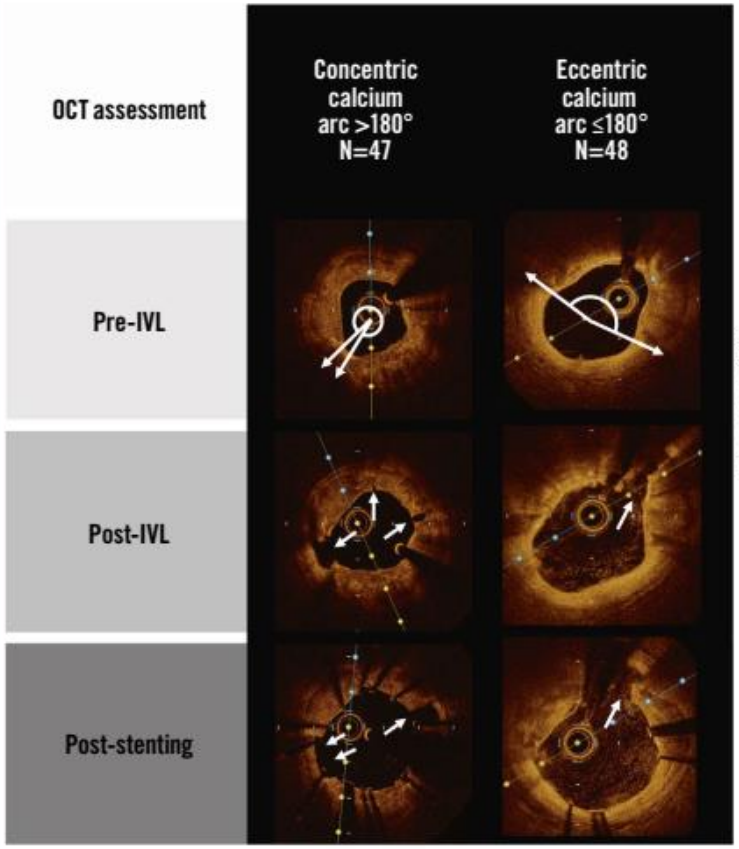
Sekimoto T, et al. JACC Cardiovasc Interv. 2025;18(17):2093-2104.

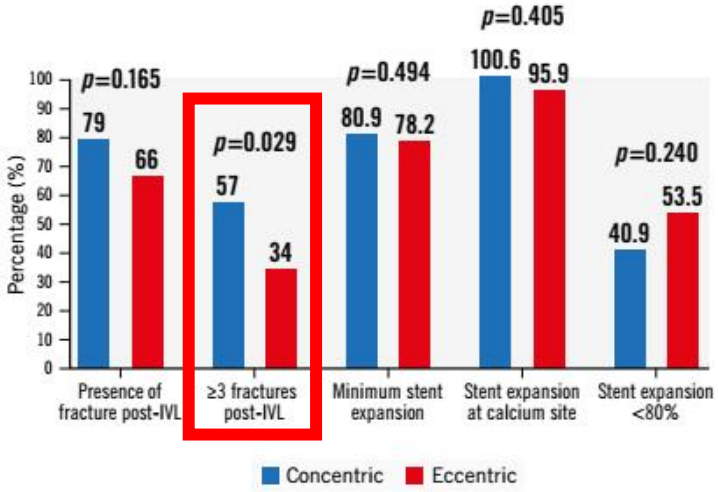
JACC Cardiovascular Interventions

Impact of coronary calcium morphology on IVL

EuroIntervention Central Illustration

Overview of the important study findings.





Angela McInerney *et al.* • *EuroIntervention* 2024;20:e656-e668 • DOI: 10.4244/EIJ-D-23-00605

The OCT images (A) depict typical findings in concentric and eccentric lesions, with white arrows highlighting the fracture within the calcium. B) The chart depicts the main results after IVL and stenting in concentric and eccentric lesions. IVL: intravascular lithotripsy; OCT: optical coherence tomography

CONCENTRIC vs ECCENTRIC

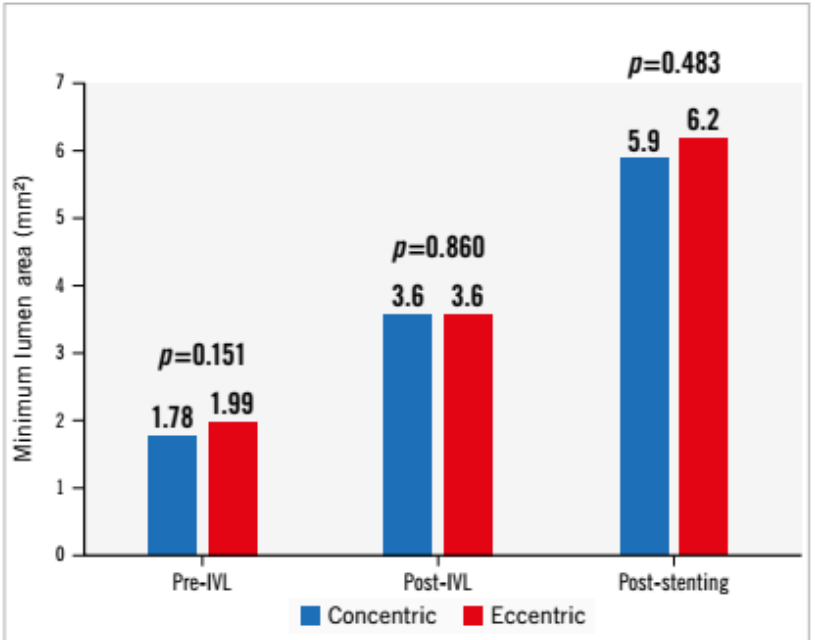


Figure 2. *Changes in minimum lumen area by optical coherence tomography (OCT) from baseline to after IVL, and after stenting. IVL: intravascular lithotripsy*

Device Preparation

1| Power Up

- Press the **POWER** button
- The **POWER** indicator light will turn green, indicating that the device is successfully switched on

* If the **POWER** indicator light is yellow and the battery icon is yellow, the device has a battery capacity of less than 20%. Pay attention to the remaining battery power and evaluate if it is sufficient to successfully carry out the procedure.

** If the **POWER** indicator light is red and the battery icon is red, do not continue to use the device as it has a battery capacity of less than 10% and may automatically shut down without warning.

2| Cable Connection

- Connect either the handheld trigger or foot pedal to the device
- Connect catheter interface cable to the device
- Once connected, press the **THERAPY** button
- The **THERAPY** indicator light will turn yellow, indicating that the handheld trigger or foot pedal is successfully connected

* Note: Align cables of the same colour to corresponding connection ports.

** Do not trigger the pulse in this state. When the balloon catheter is dry or not inflated, pressing the **THERAPY** button may cause damage to the balloon catheter.

3| Put On Sterile Sleeve

- Put on sterile sleeve to cover the distal end of the catheter interface cable and the handheld trigger to prevent contamination of sterile area.

Manufactured by Shanghai Bluesail Boyuan Medical Technology Co., Ltd. Marketed by Biosensors Interventional Technologies Pte Ltd

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Balloon Catheter Preparation

1| Deflate Balloon

- Select a balloon catheter with a 1:1 size ratio to vessel diameter
- Prepare 1:1 ratio of saline to contrast agent mixture for use
- Apply negative pressure for at least 3 times to remove air from delivery system

2| Balloon Catheter Cable Connection

- Connect proximal end of catheter interface cable to the distal end of balloon catheter by aligning the blue marker

Treatment Procedure

1| Inflate Balloon

- Slowly pressurize balloon to treatment pressure of 6 atm

2| Activate Therapy Mode

- Press the **THERAPY** button
- The **THERAPY** indicator light will turn green, indicating that the therapy mode is now activated

3| Deliver Treatment

- Press the button on the handheld trigger (or step on foot pedal) once for single firing, hold for 2 seconds tor continuous firing
- The system automatically pauses after each cycle
- Inflate balloon to nominal pressure of 8 atm and hold for 10 seconds

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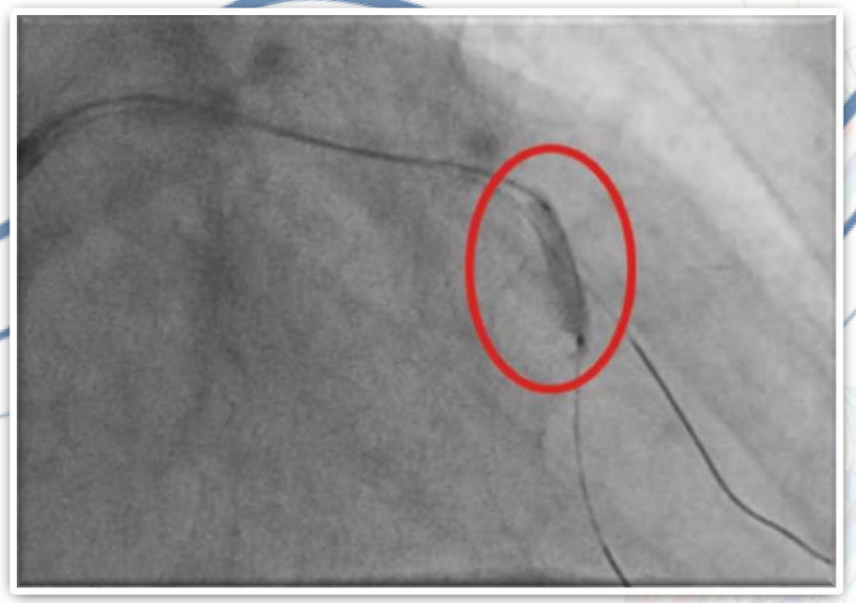
Treatment Procedure



4 | Observe Treatment

- Deflate the balloon with negative pressure and wait for 1 minute before the next treatment cycle
- 2 treatment cycles are recommended per lesion site
- Observe the balloon's expansion morphology to assess treatment effectiveness

*For long lesions, it is recommended to overlap the balloon by at least 2 mm to avoid geographic miss

5 | Switch Off Device

- After treatment, press and hold the **THERAPY** button until the **THERAPY** indicator light goes out.
- Repeat the same step for the **POWER** button.
- Disconnect the balloon catheter cable and catheter interface cable by twisting it towards the direction of the blue arrow

Conclusion

Severe calcium lesions

1. Diagnose morphology of calcium with intravascular imaging (OCT).
2. Employ calcified modification algorithms.
3. Understand mechanisms of calcified modification devices.
4. Selection of optimal device for each type of calcified morphology.

Thank you for your attention