Imaging for BVS

BioResorbable Vascular Scaffold

Roh Jin Seok, RT

Asan Medical Center

Bioabsorbable Coatings in Perspective
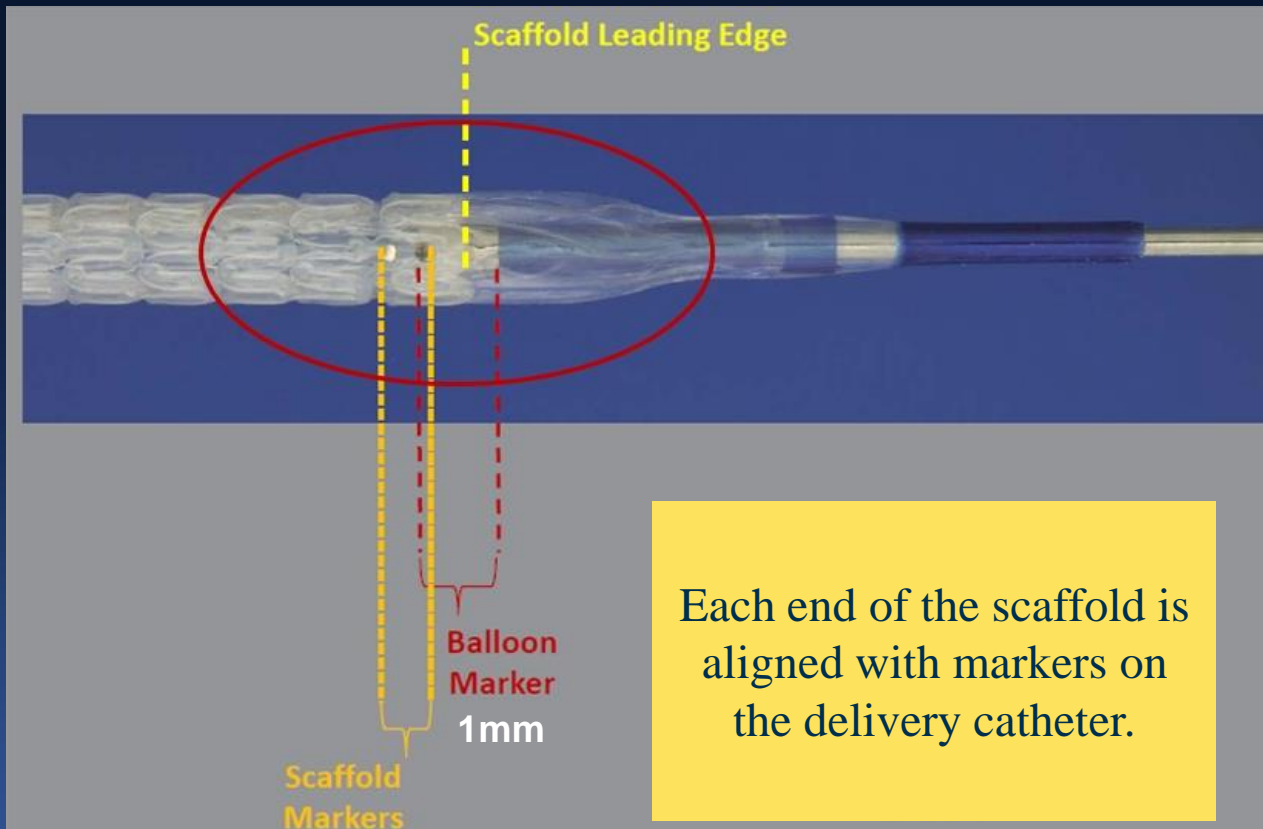## *Relative CoatingThickness*

Scaffold mounted on the balloon

	SYNERGY™ Stent[1]	Xience™ Stent[2]	BioMatrix Flex™ Stent[3]	Absorb™ BVS[4]
Strut Thickness	74 μm (0.0029")	81 μm (0.0032")	120 μm (0.0047")	150 μm (0.0059")
Polymer Coating Type & Thickness	Bioabsorbable Abluminal 4μm	Conformal Durable 8μm	Bioabsorbable Abluminal 10μm	Bioabsorbable Conformal 3μm / side
Total Coated Strut Thickness	78μm	97μm	130μm	156μm

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Scaffold mounted on the balloon

Scaffold Leading Edge

Balloon Marker

1mm

Scaffold Markers

Each end of the scaffold is aligned with markers on the delivery catheter.

Use balloon markers to position scaffold

Locating Scaffold Marker Beads
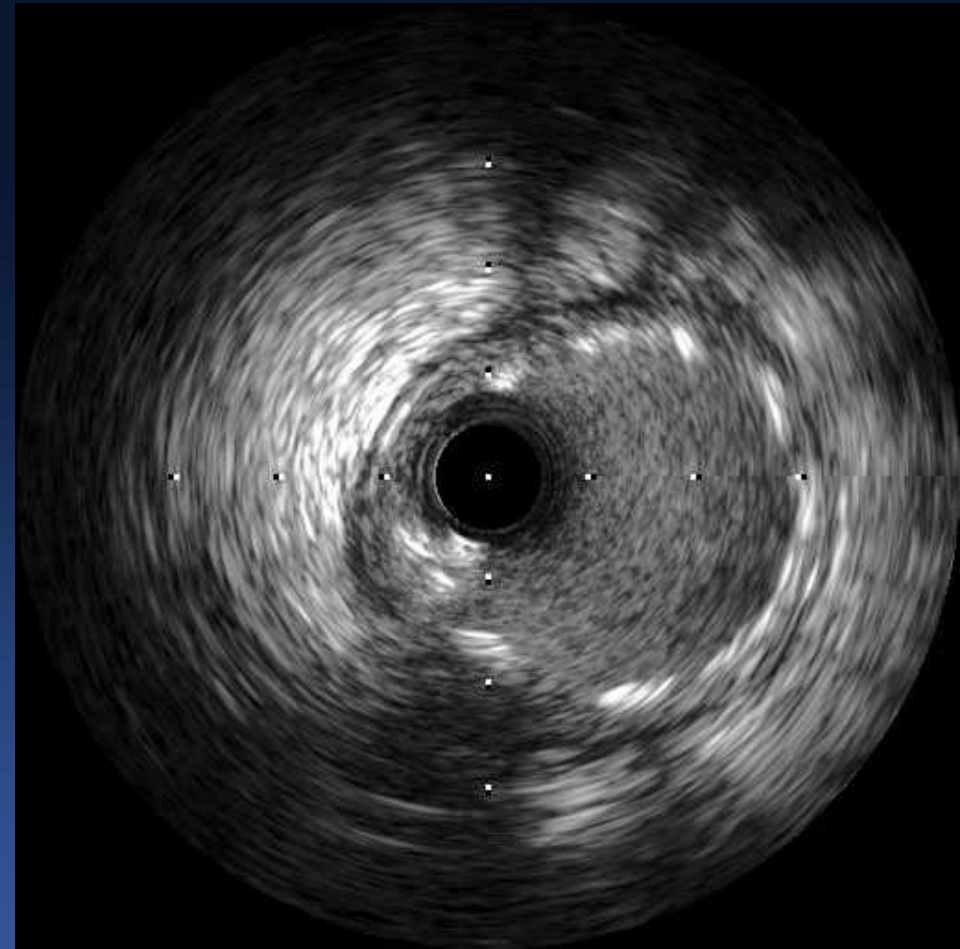

Only balloon catheter markers are visible

During delivery (scaffold crimped on balloon)

Scaffold markers

Balloon catheter marker
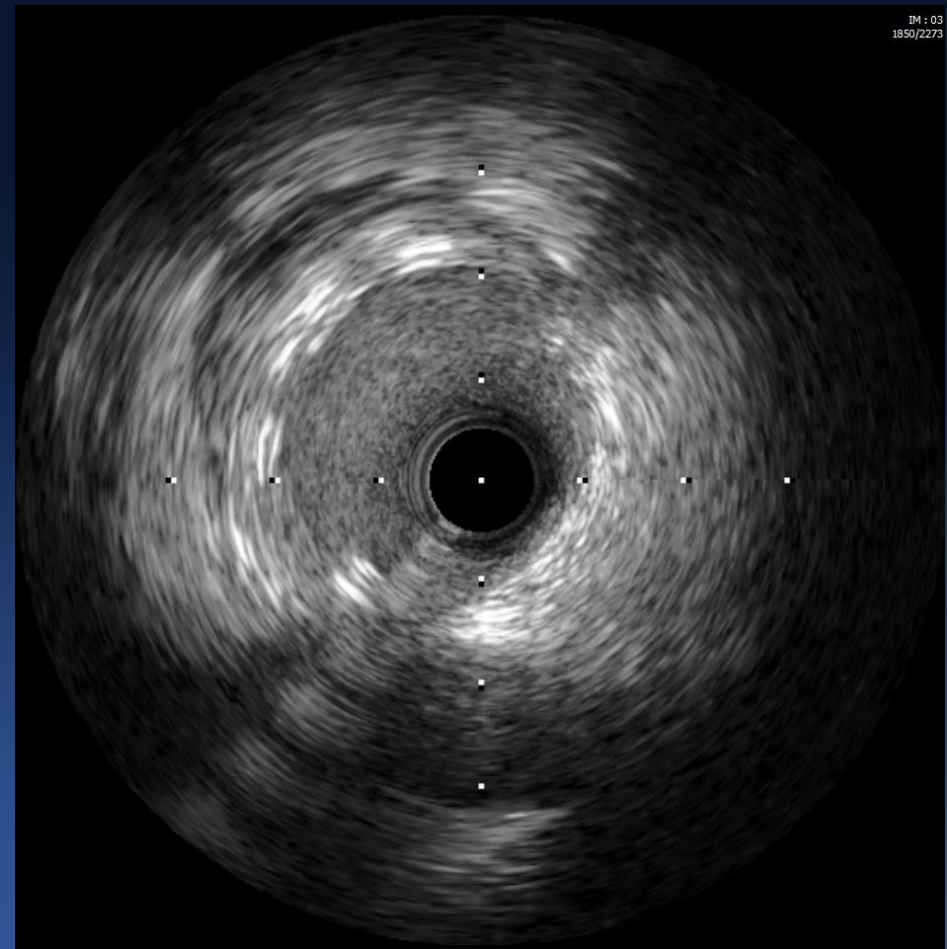
Balloon catheter marker

Scaffold markers

Balloon catheter markers

After Deployment

IVUS Image

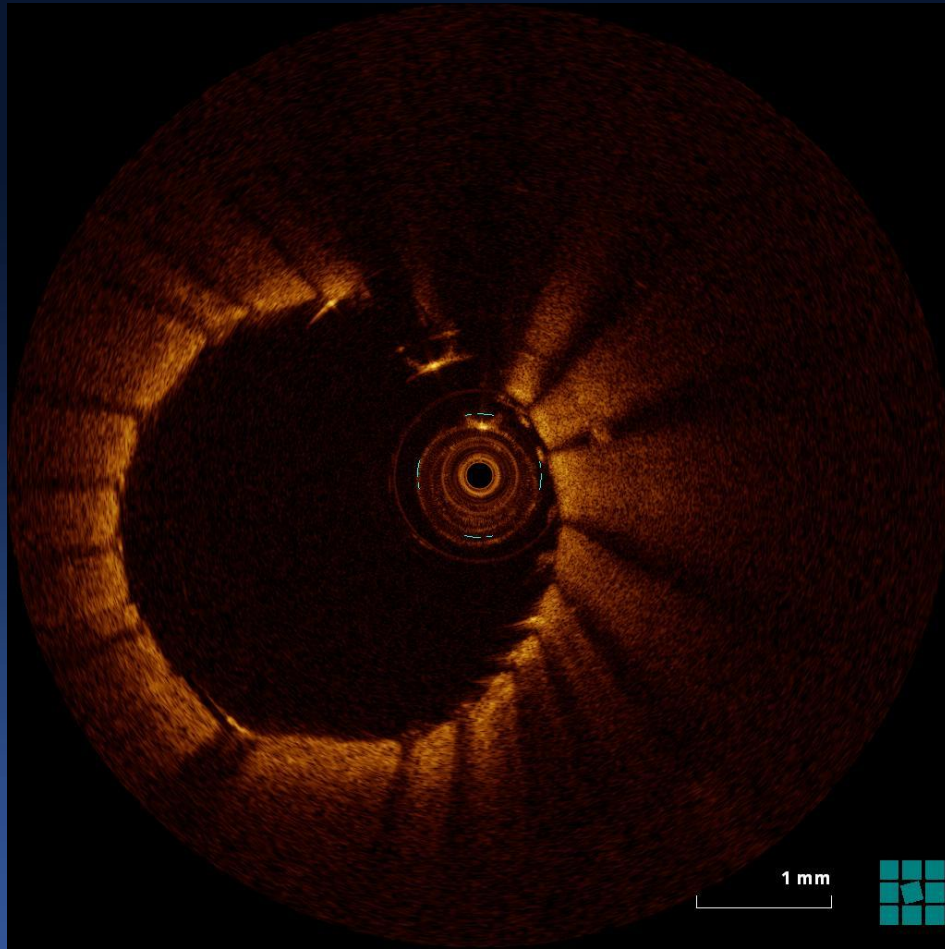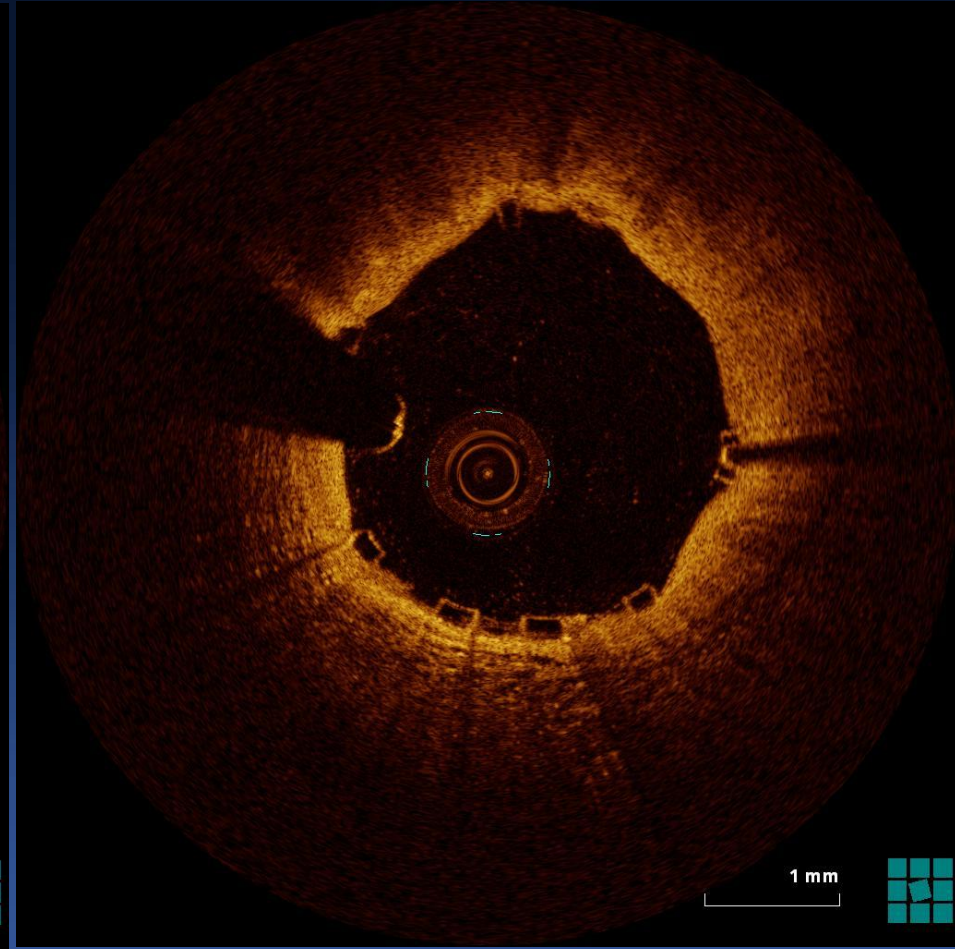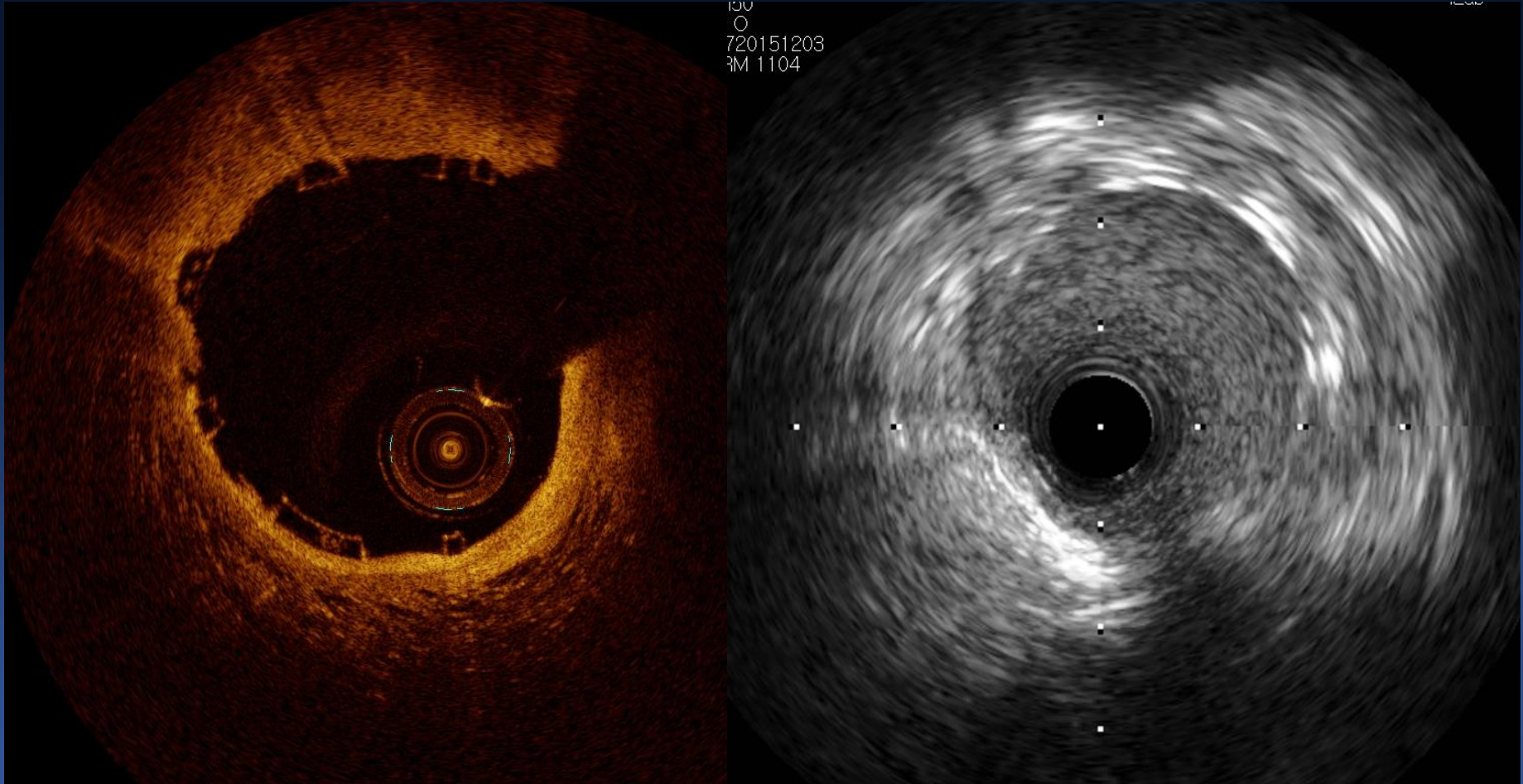DES   BVS

OCT Image

DES

BVS

BVS - IVUS OCT Image

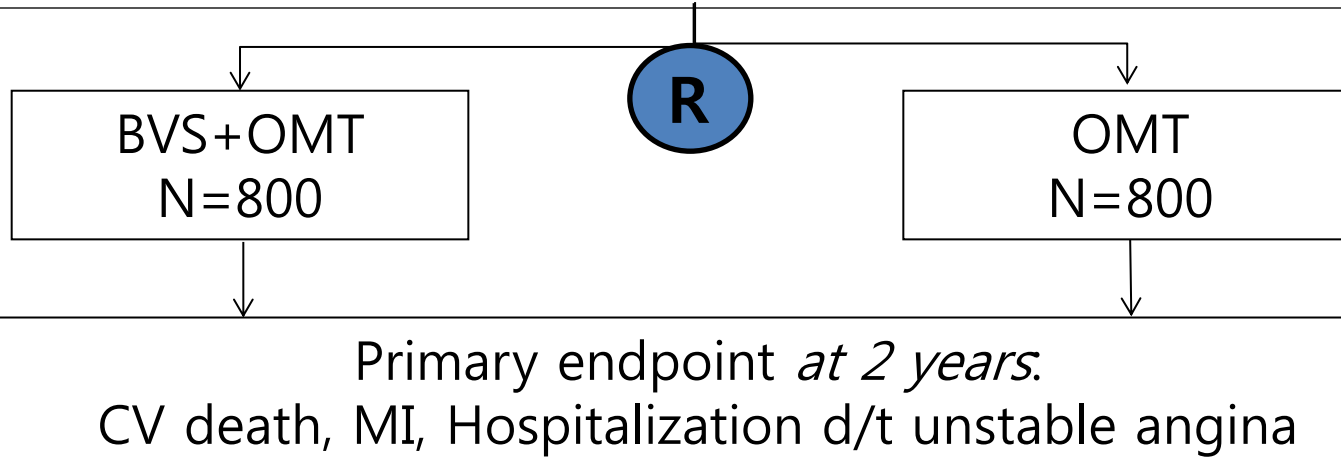BVS - OCT   BVS - IVUS

The *PREVENT*ive Implantation of Bioresorbable Vascular Scaffold on Stenosis With Functionally Insignificant Vulnerable Plaque

PREVENT Trial

Any Significant Epicardial Coronary Stenosis (DS>50%)
with *FFR >0.80* and with *Two* of the following

1. MLA <4.0mm^2
2. Plaque Burden at MLA site >70%
3. Lipid-Rich Plaque on NIRS ($_{max}$LCBI$_{4mm}$>315)
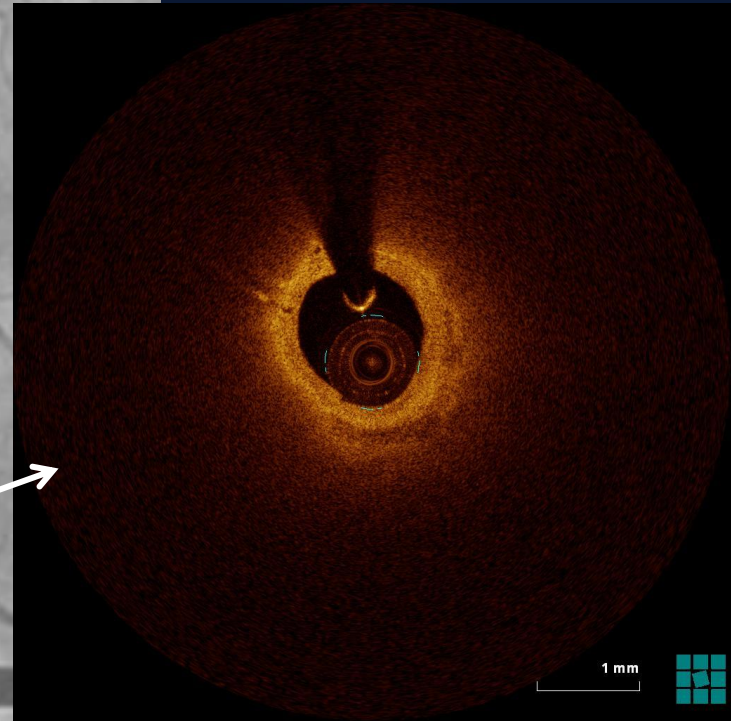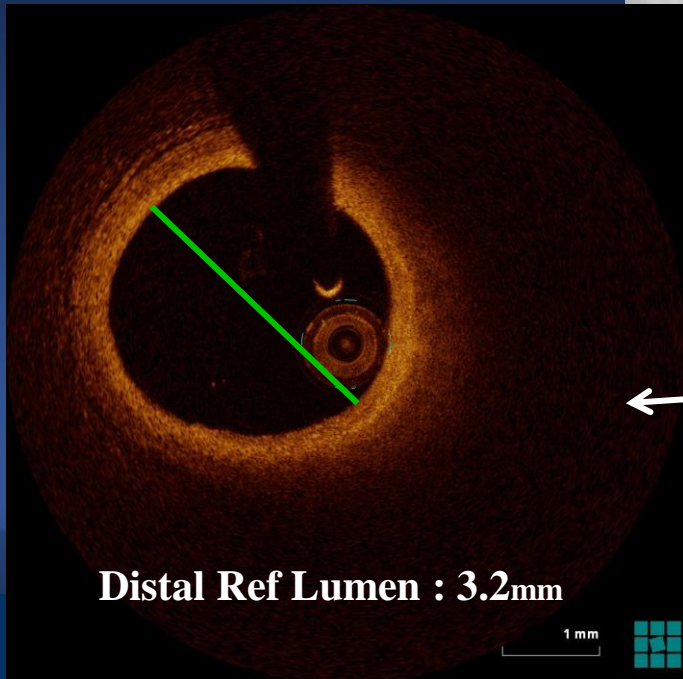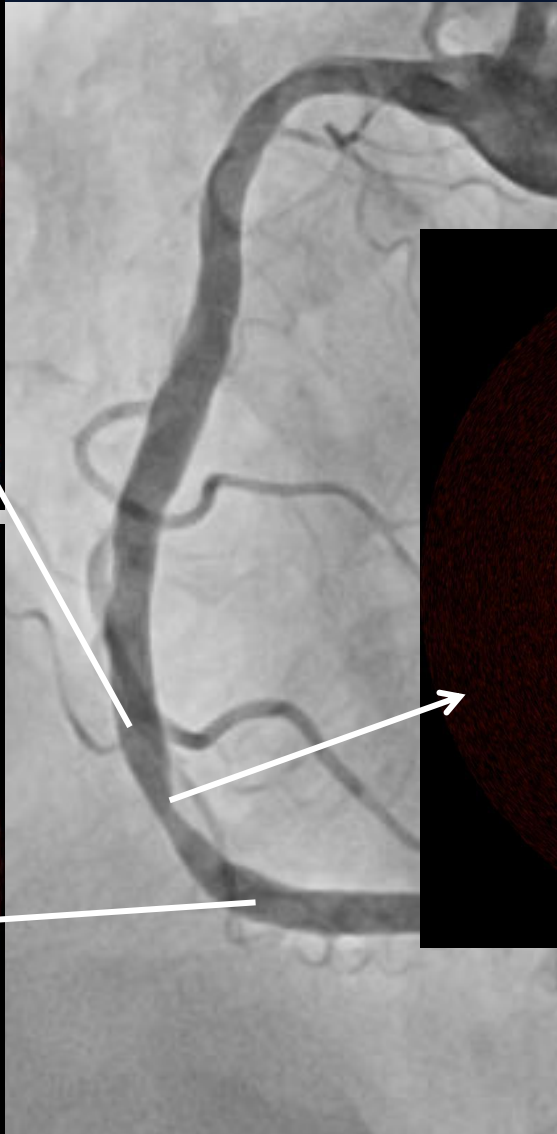4. TCFA defined by OCT or VH-IVUS

R

BVS+OMT
N=800

OMT
N=800

Primary endpoint *at 2 years*:
CV death, MI, Hospitalization d/t unstable angina
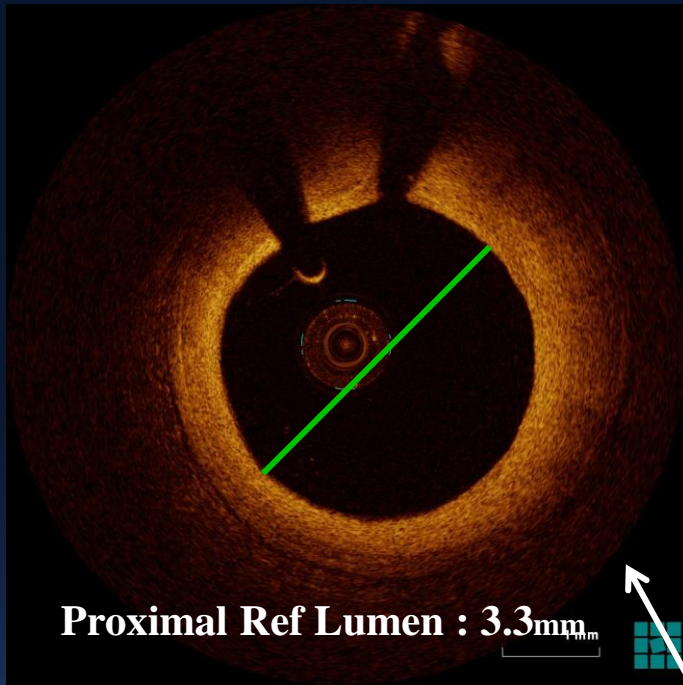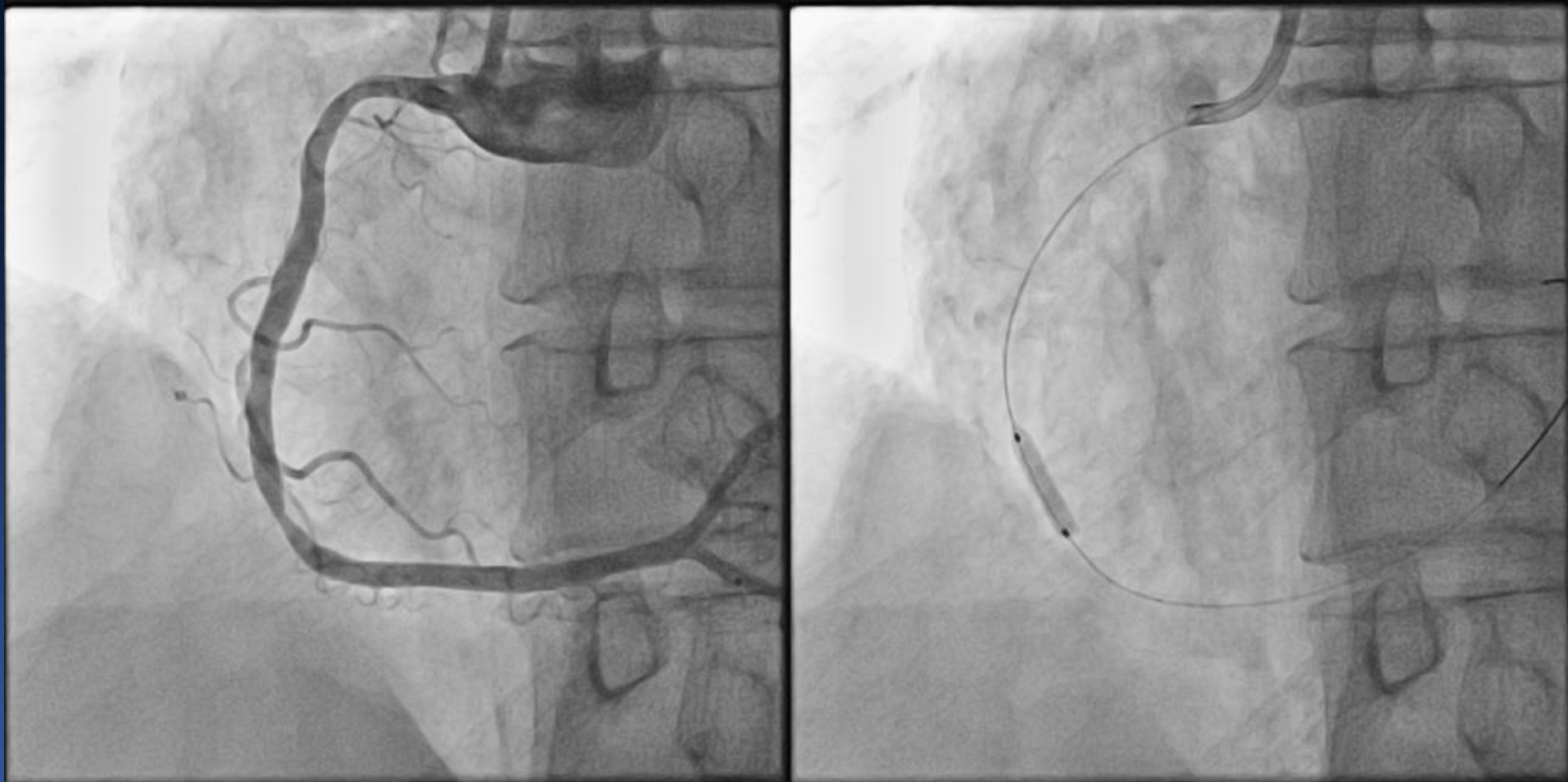
TCFA
- OCT definition: fibrous cap thickness<65 μm and arc>90°
- VH-IVUS definition: ≥10% confluent NC with >30° abutting to the lumen in 3 consecutive slices
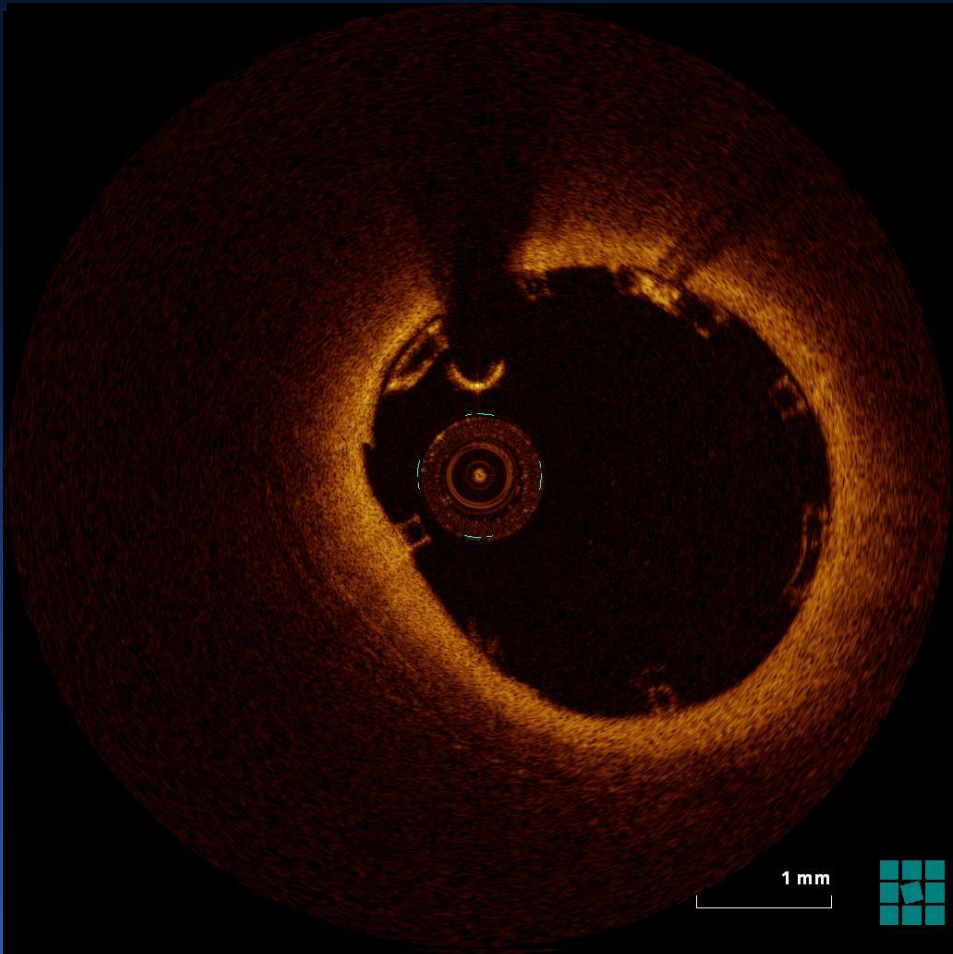
CASE - I

Proximal Ref Lumen : 3.3mm

Distal Ref Lumen : 3.2mm

CASE - I

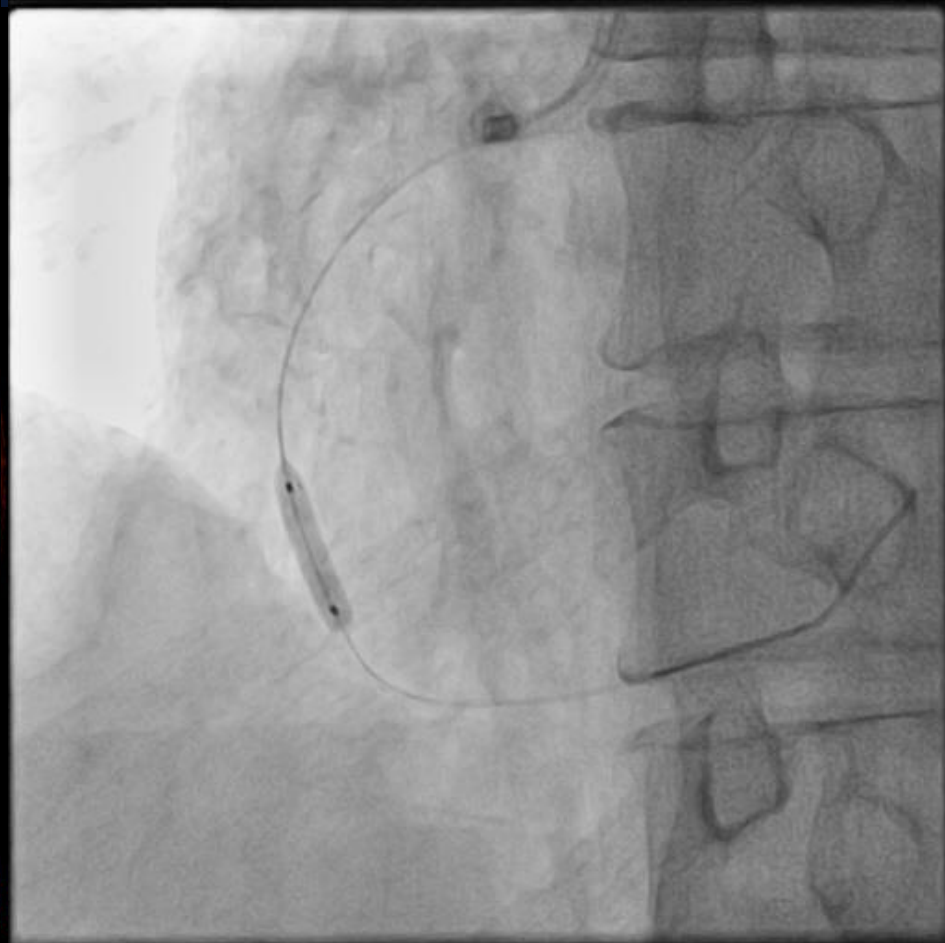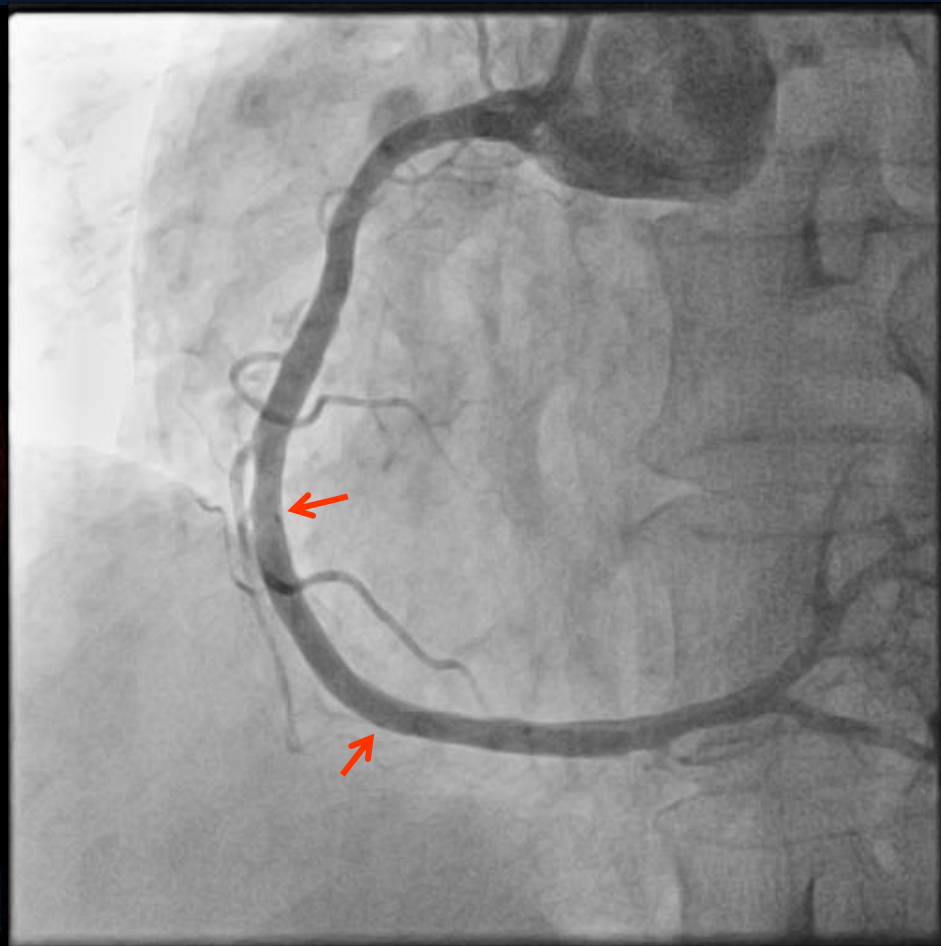
NC Balloon 3.0mm

CASE - I

BVS 3.0 / 23mm
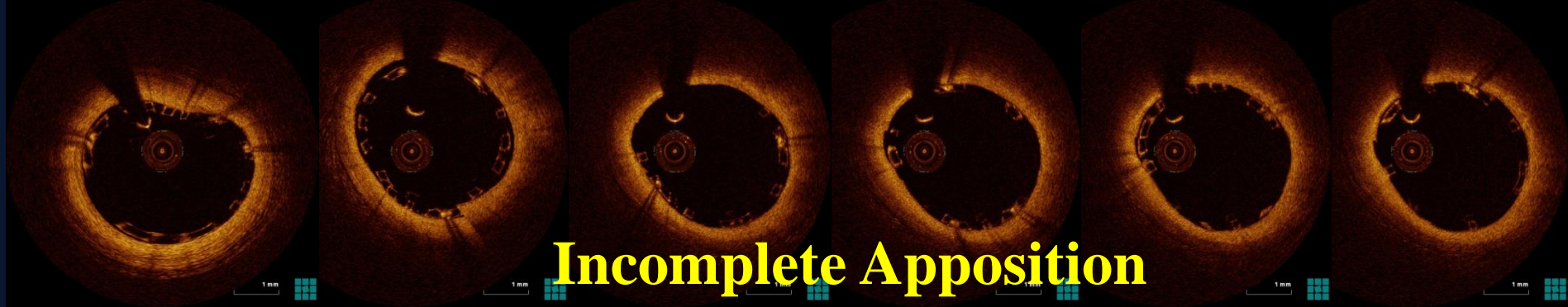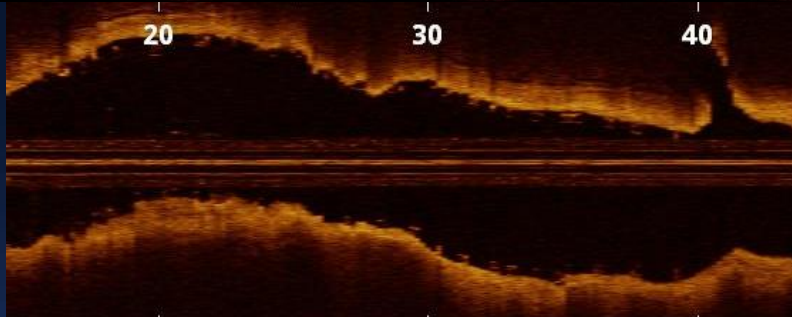
NC Balloon 3.0mm

CASE - I

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0228

1 mm

NC Balloon 3.5mm

Incomplete Apposition

NC Balloon 3.0mm

Full Strut Apposition & Complete Scaffold Expansion
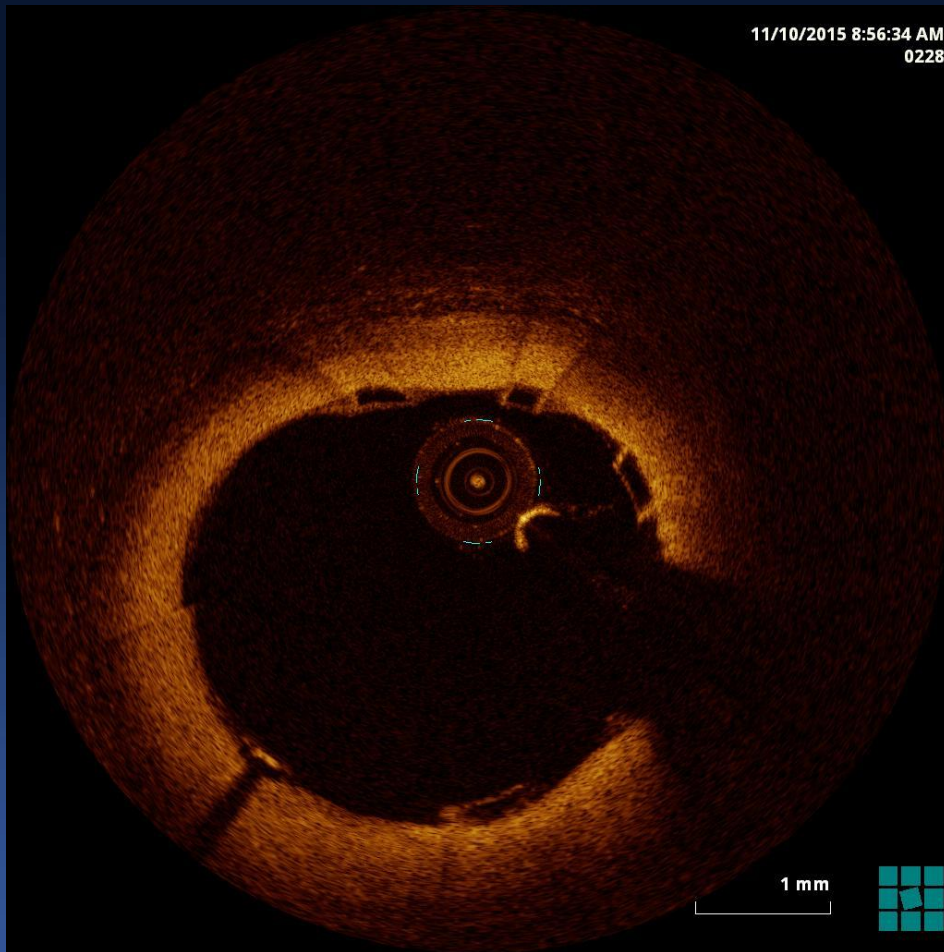
NC Balloon 3.5mm
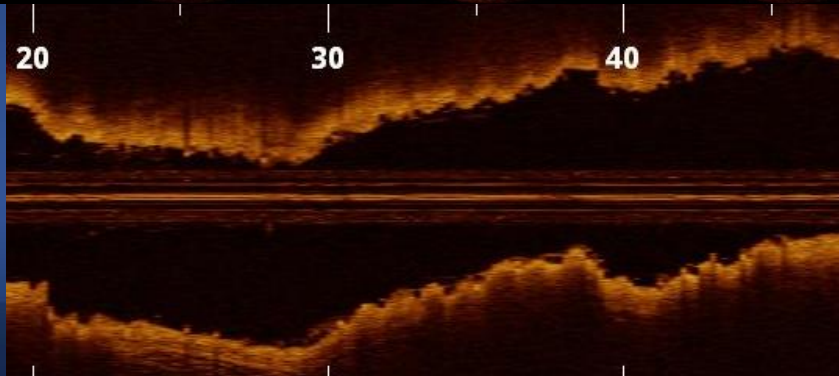
Operating Protocol of BVS

Figure 1. *Practical operating protocol for new users of BVS.*

Flowchart steps:

- Administer intracoronary nitrates
- Use intravascular imaging or the predilatation balloon for sizing
- Predilate the lesion with whatever it takes until a balloon of nominal scaffold size is fully expanded at 10 atm within the lesion
- Implant the scaffold stepwise 2 atm every 5 seconds until at least 10 atm and up to the maximum desired pressure (no more than the rated burst pressure), keeping the scaffold balloon inflated for at least 30 seconds
- Post-dilate with short non-compliant balloons, to at least of the nominal scaffold size and a maximum of nominal scaffold size +0.5 mm, making sure that full expansion is achieved.
- Non-compliant balloon post dilatation may be dropped if intracoronary imaging shows full strut apposition and complete scaffold expansion.
- Prescribe dual antiplatelet therapy for no less than 6 months and preferably for 12 months

Tamburino C. EuroIntervention 2015 May;11(1):45-52

For lesion preparation, it is generally advisable to use semi- or non-compliant balloons with a diameter equal to or only minimally undersized compared to the diameter of the selected BVS delivery system. Short (6 to 10 mm long) high-pressure balloons should be used after predilation of the segments when lesions show focal residual underexpansion due to the presence of highly calcific atherosclerotic plaques. Although no supporting data are available, the use of plaque modification devices (i.e., cutting/scoring balloons, rotational atherectomy) is encouraged when necessary to enable the BVS to cross and better expand calcified stenoses, but in the authors' experience this is rarely required. In the event that one cannot achieve full opening of the (last) predilatation balloon with no indentation, it is advisable not to implant a BVS.
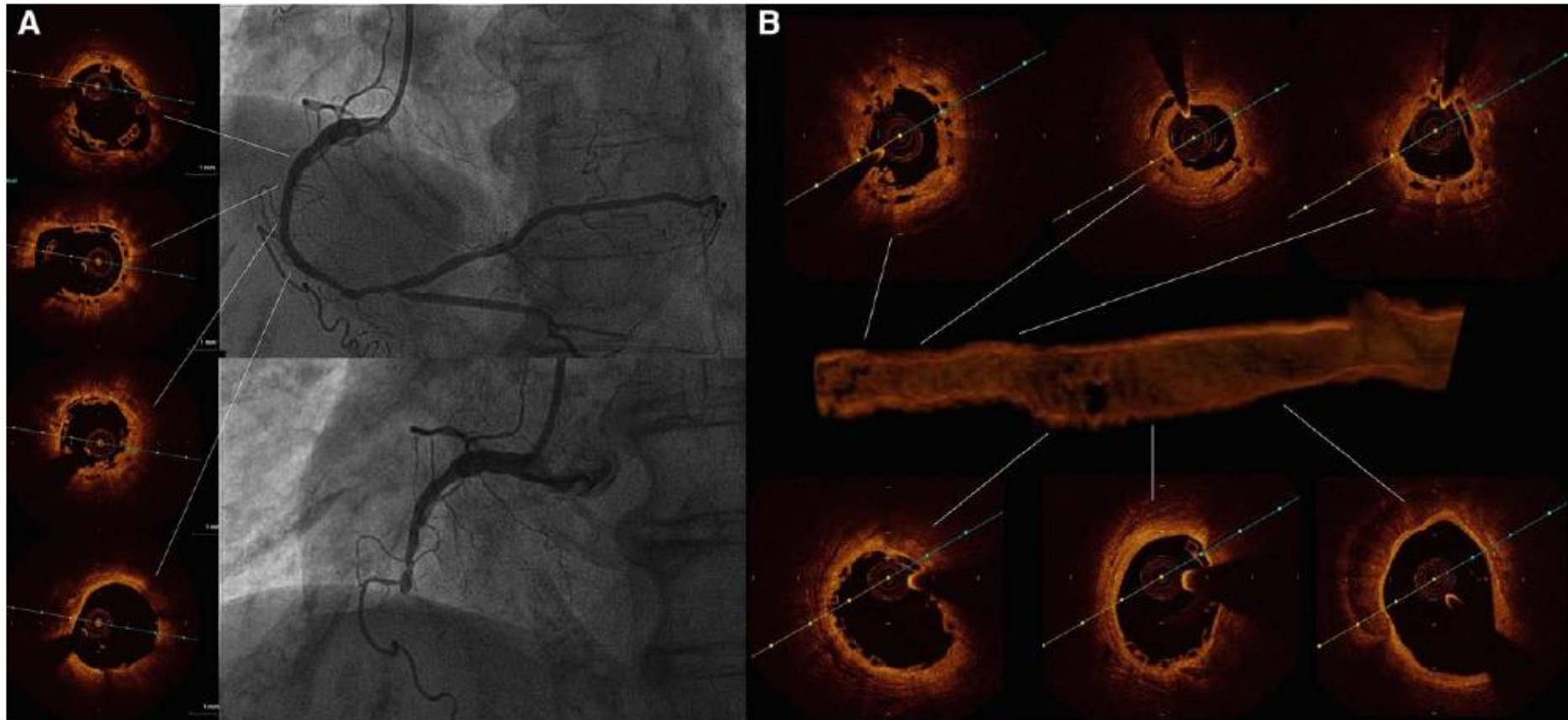
onds. Due to the polymeric material, the BVS has a maximum scaffold expansion limit of 0.5 mm above its nominal diameter, which should be respected strictly during implantation. Upon scaffold deployment, one should aim to obtain <10% residual stenosis, full scaffold expansion and optimal wall apposition. Therefore, routine post-dilatation for 10-30 seconds using a high-pressure non-compliant balloon is advisable unless intracoronary imaging confirms full expansion and apposition.
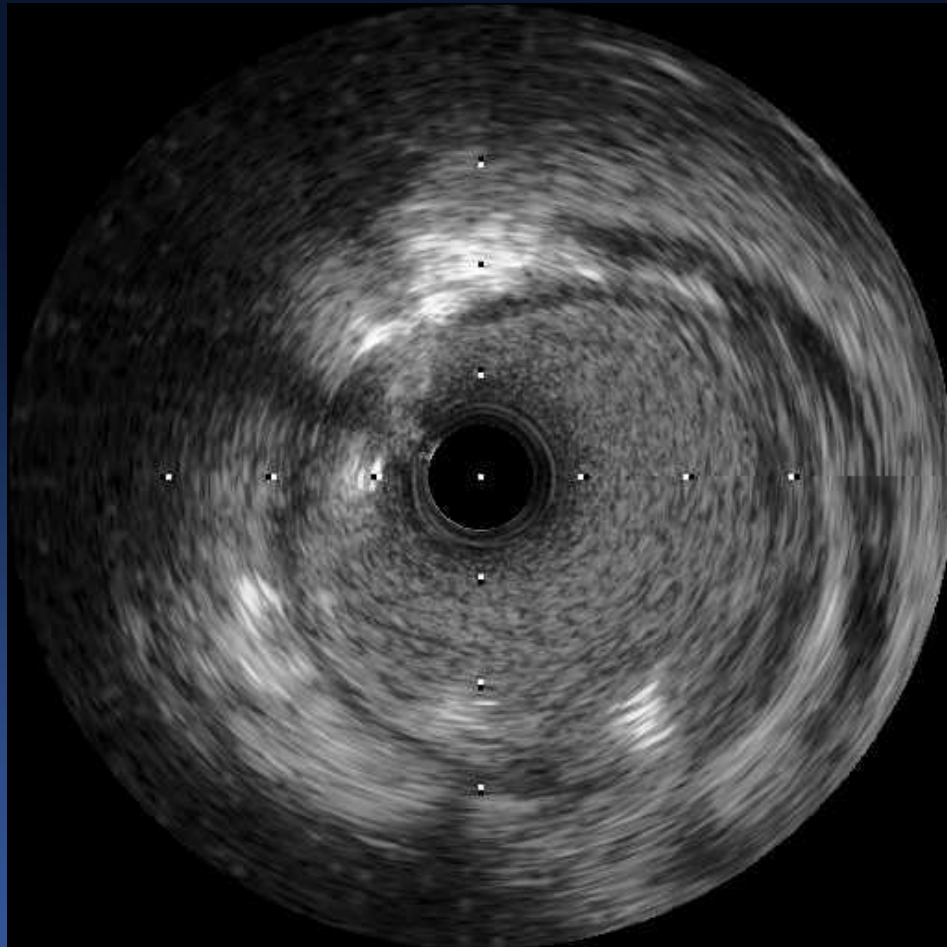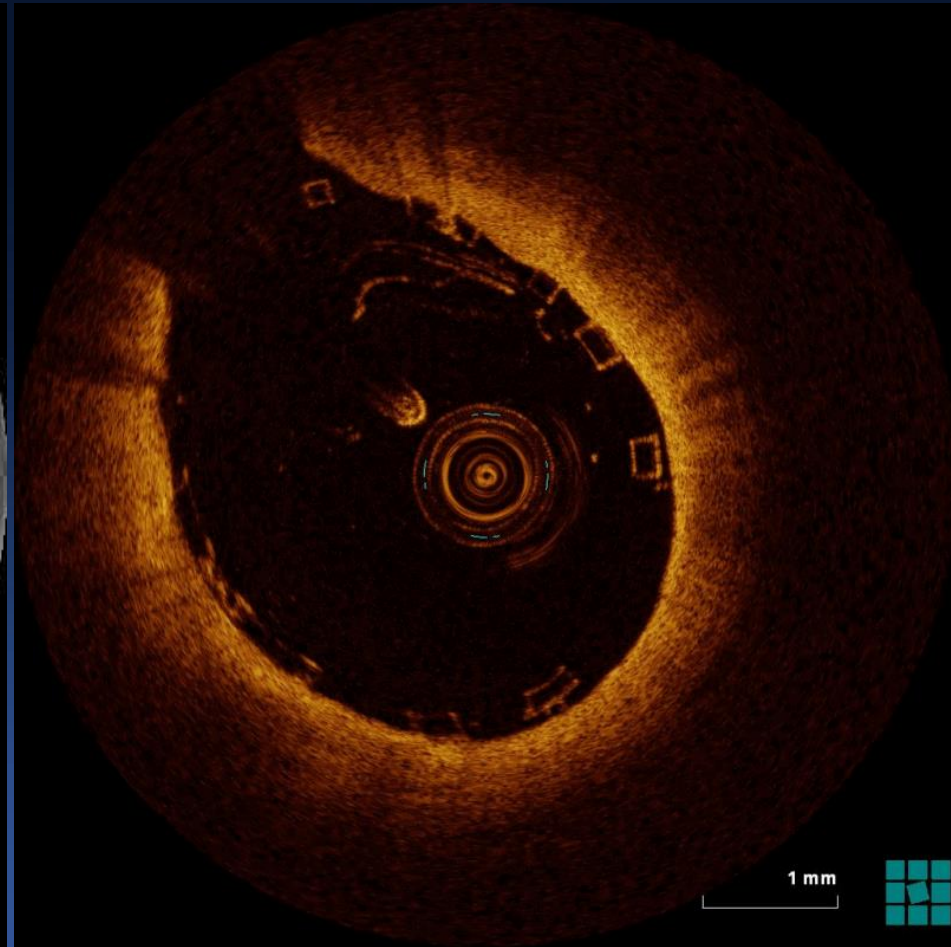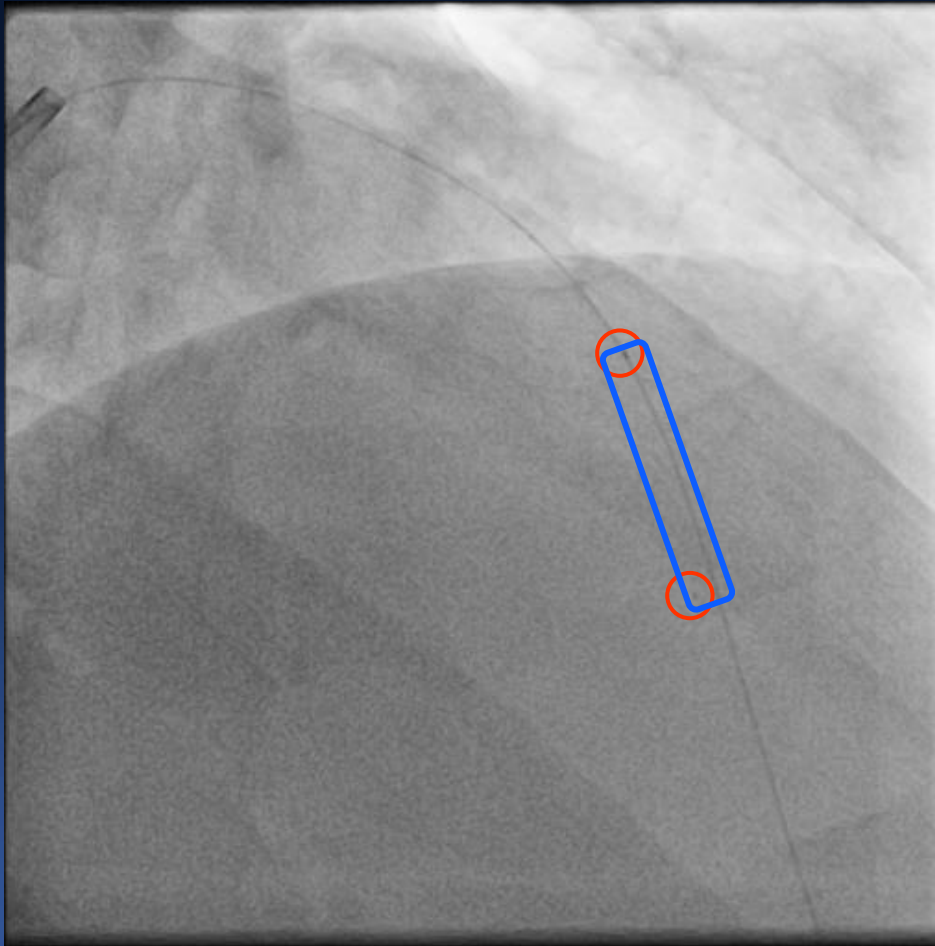
ScT – Scaffold thrombosis

Figure 1. Early scaffold thrombosis (ScT). **A,** ScT 6 days after scaffold implantation for inferior ST-elevation myocardial infarction. Optical coherence tomography revealed undersizing in the proximal part of the scaffold as the key mechanism for ScT. **B,** ScT 8 days after scaffold implantation for non–ST-elevation myocardial infarction. Optical coherence tomography revealed underexpansion as the key mechanism for ScT: 3D reconstruction demonstrates an underexpanded distal segment with good expansion in the proximal segment of the scaffold.

BVS Incomplete apposition

BVS - IVUS

BVS - OCT

CASE - II

BVS 3.5 / 28 mm

CASE - II

Distal BVS proximal markers

Proximal BVS distal markers
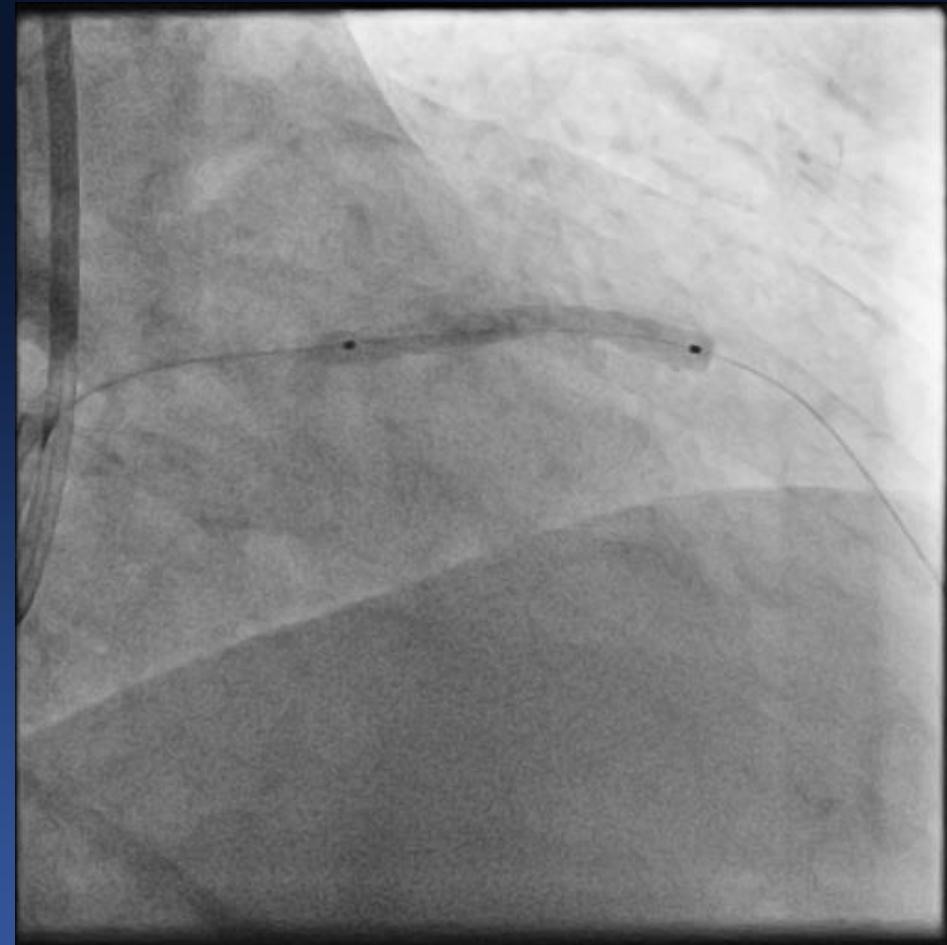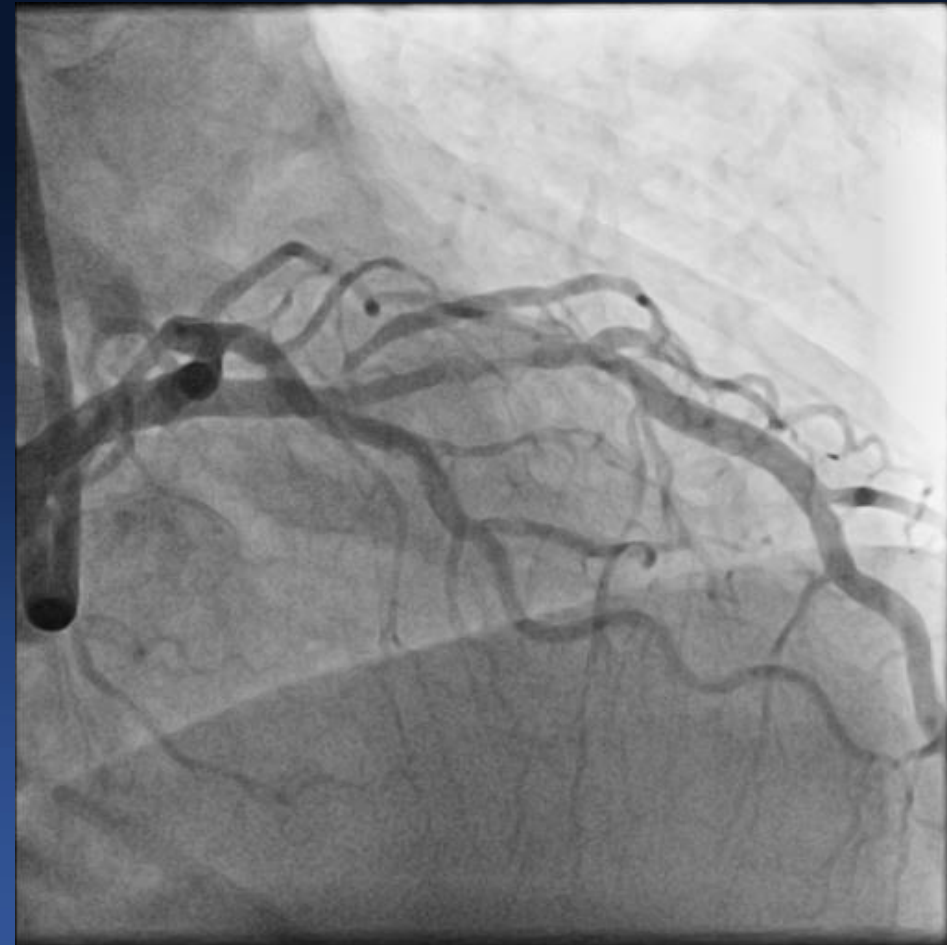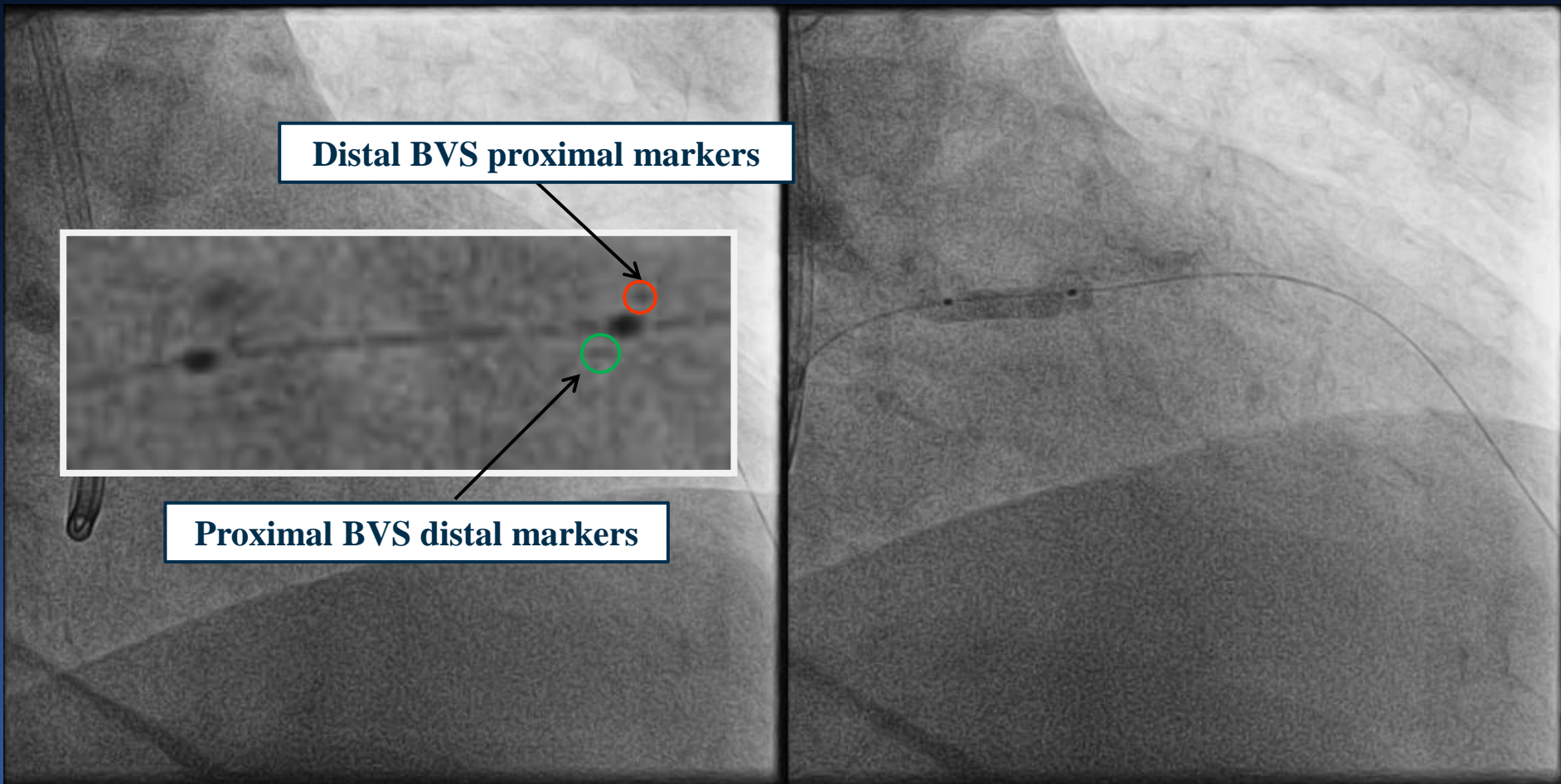
BVS 3.5 / 12 mm

CASE - II

CASE - II

1 mm
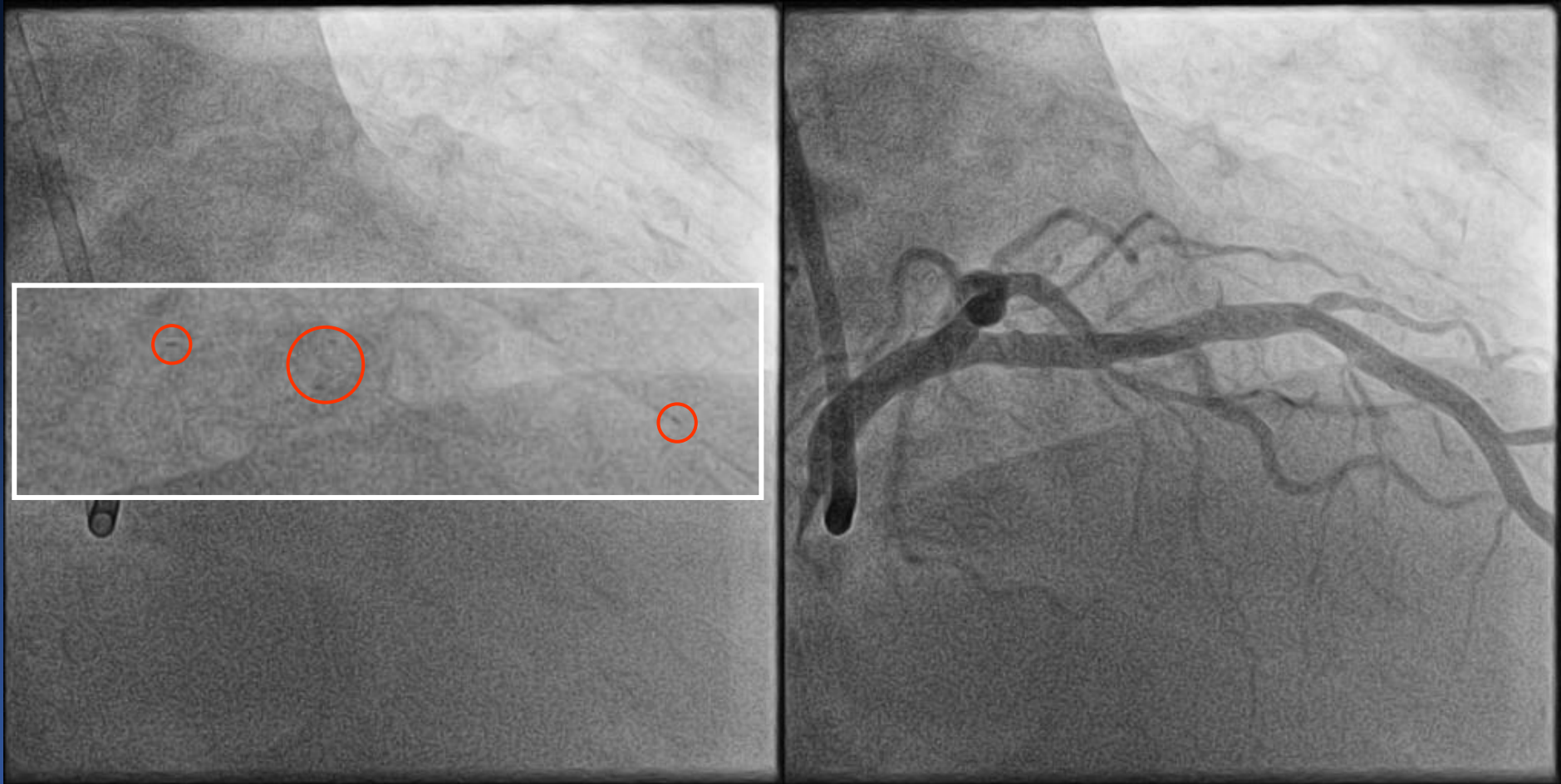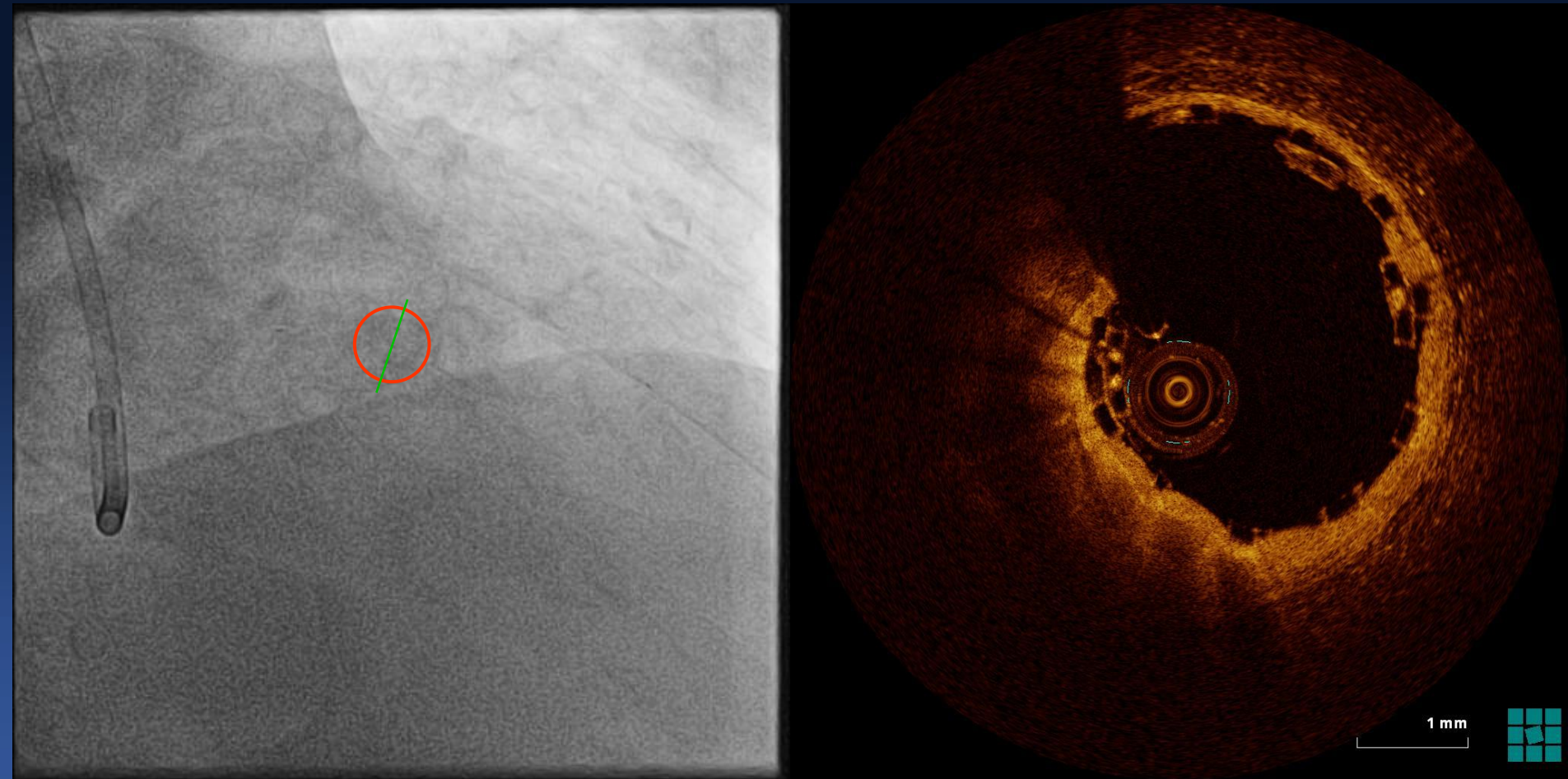
BVS Overlap
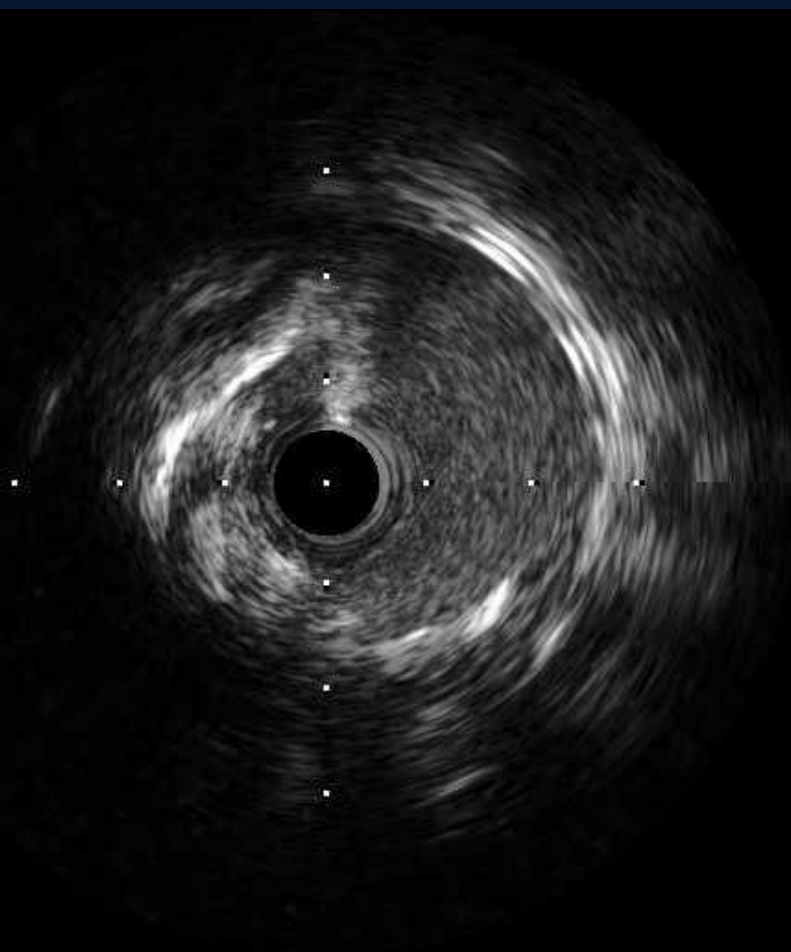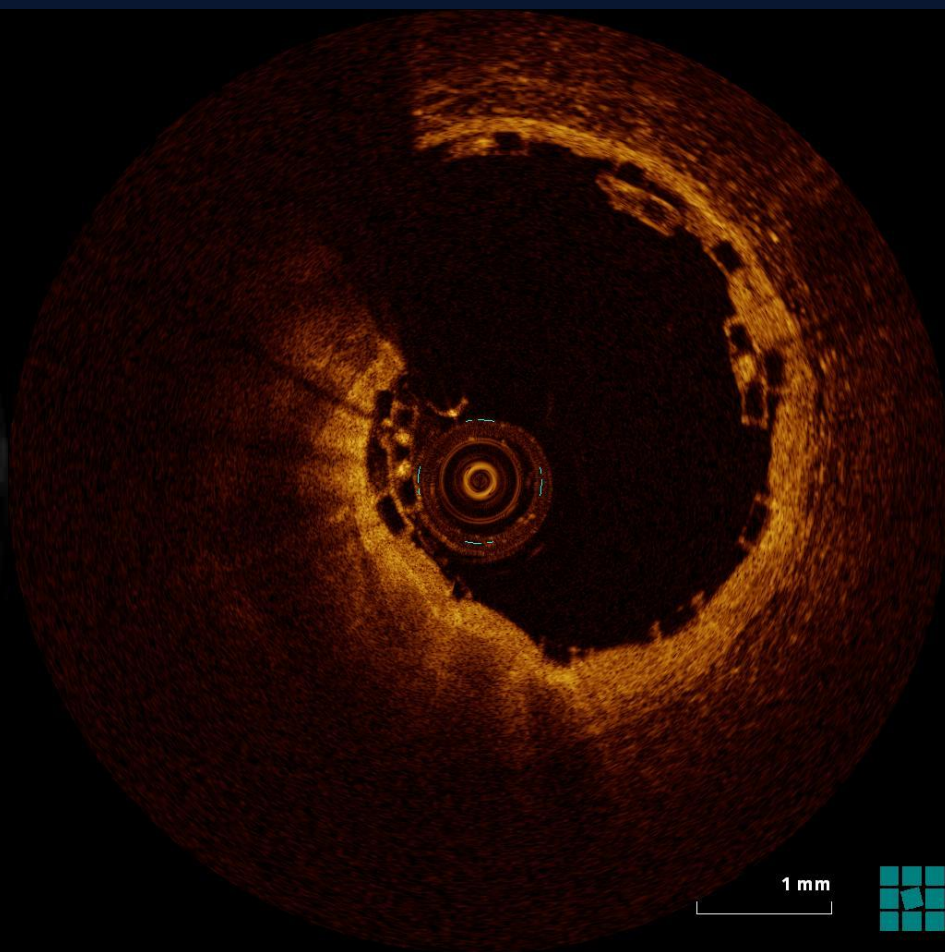
BVS - IVUS   BVS - OCT

CASE - III

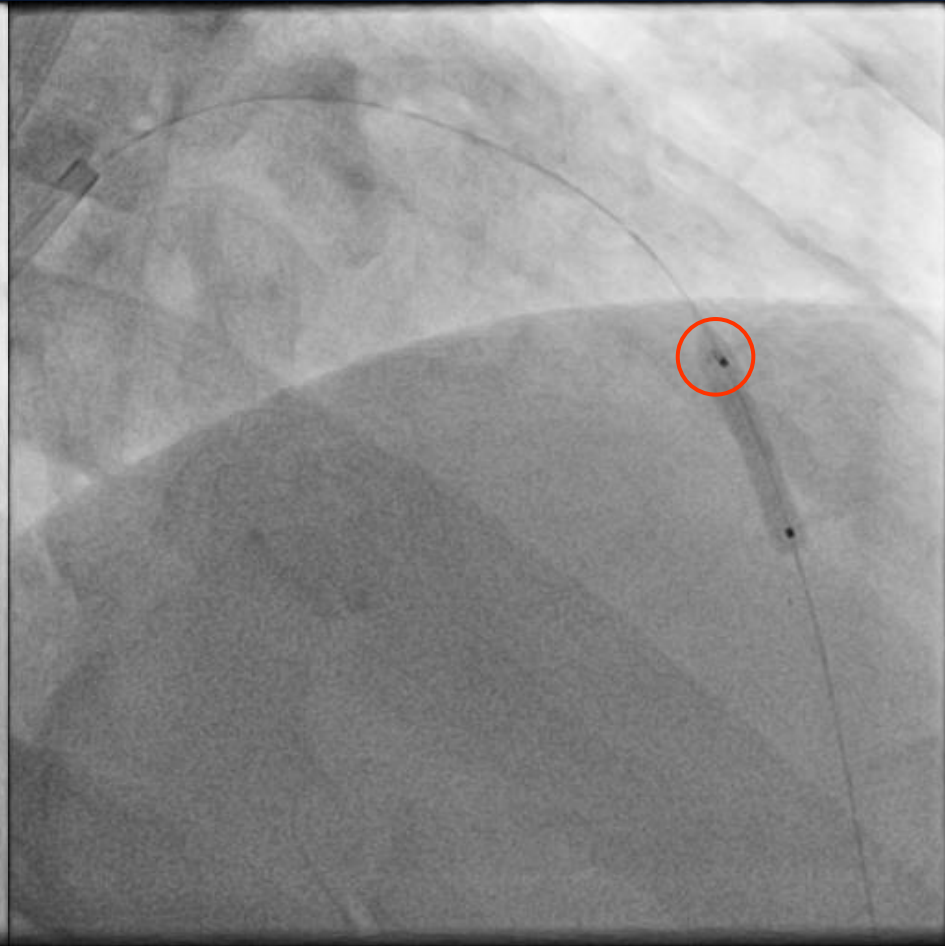
NC Balloon 2.75mm

CASE - III
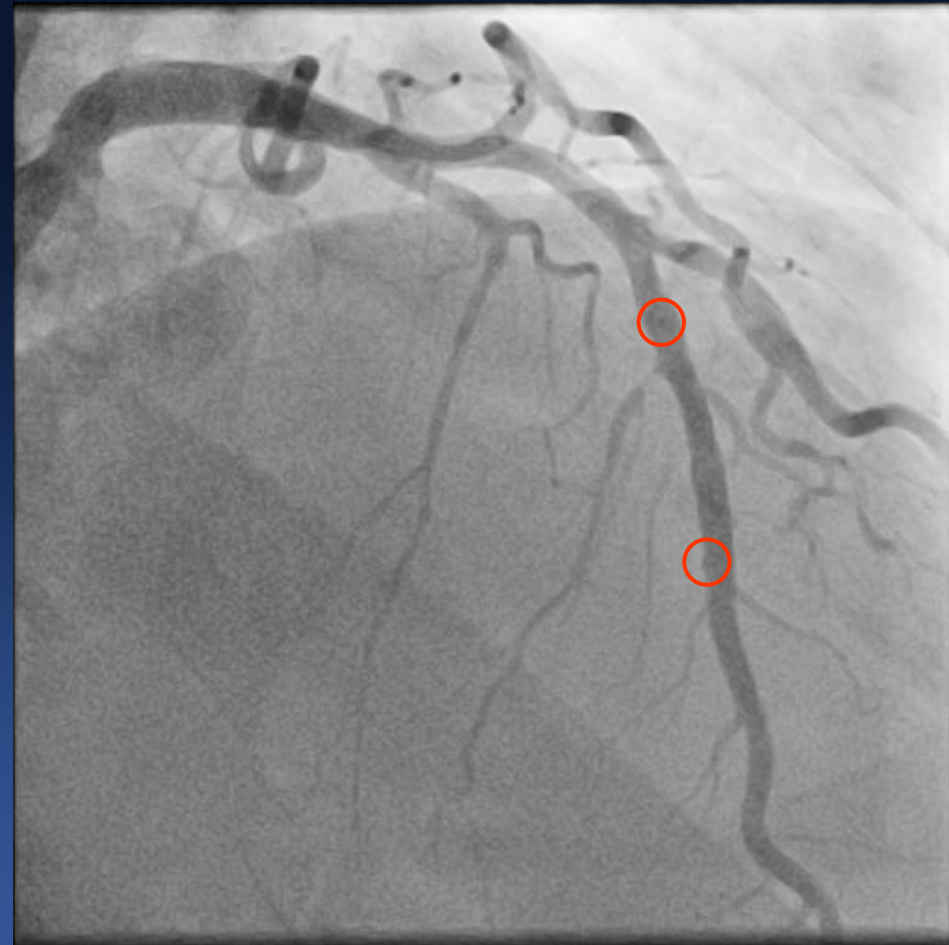

BVS 3.0 / 23mm   NC Balloon 3.5mm
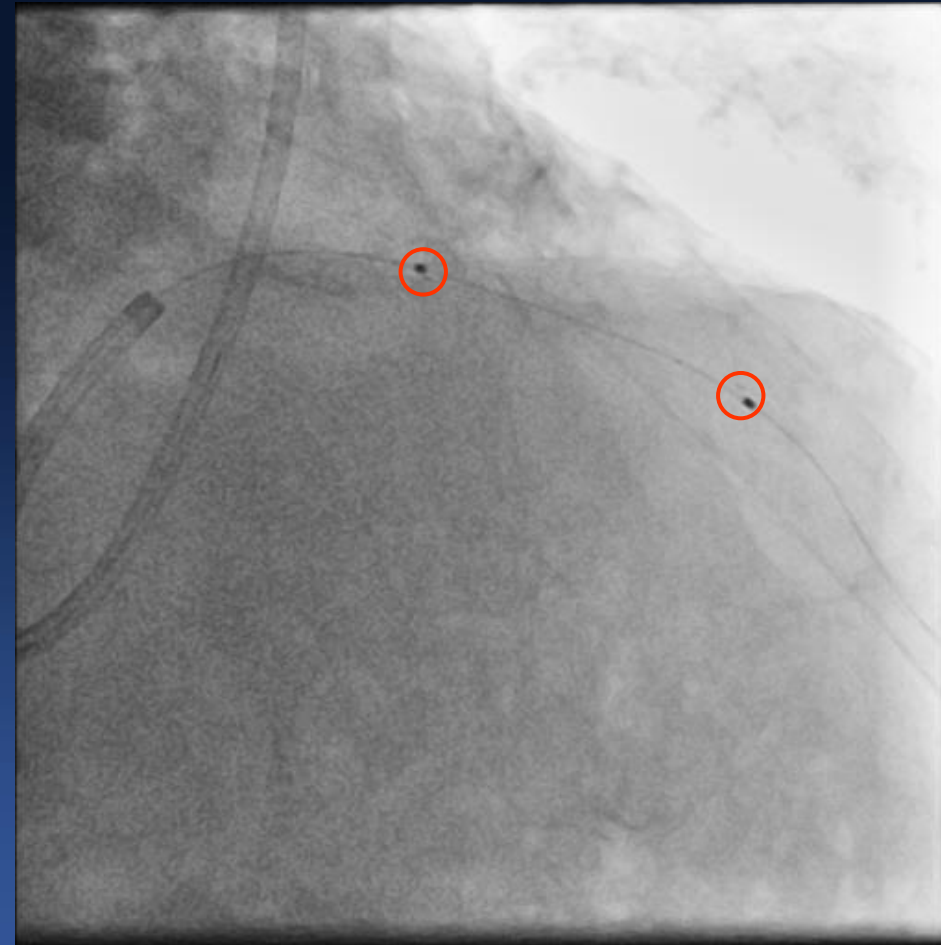
CASE - III
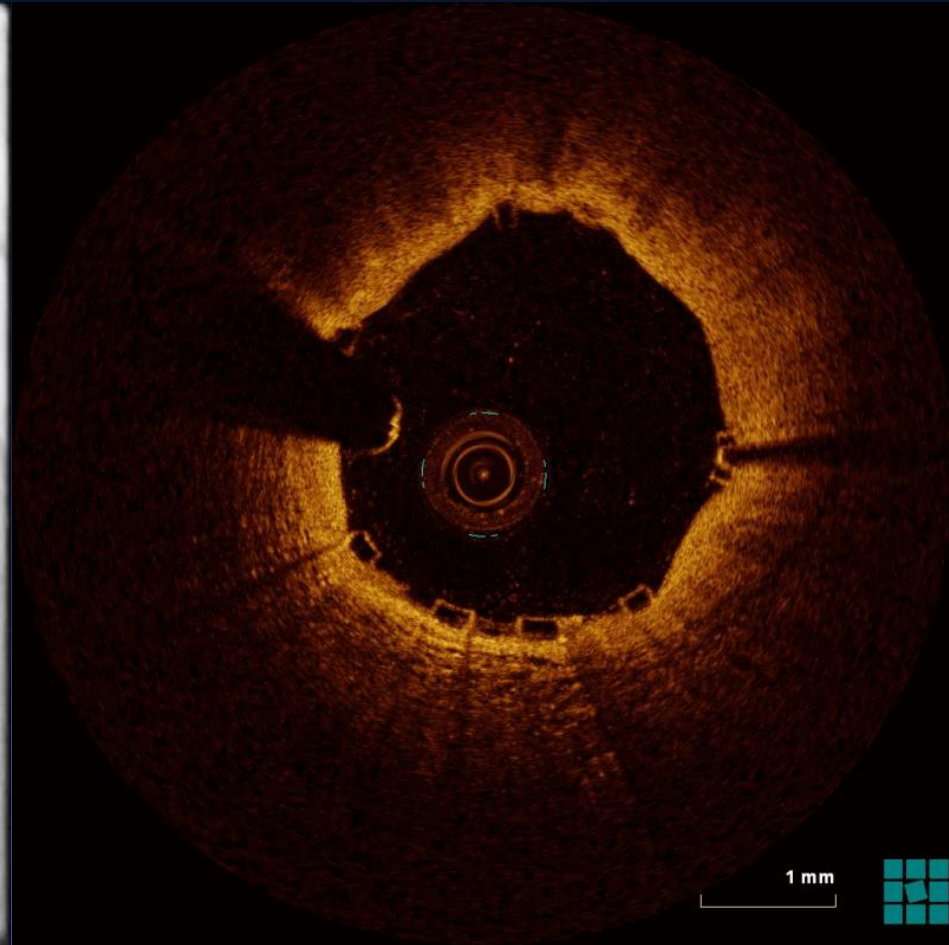
CASE - III
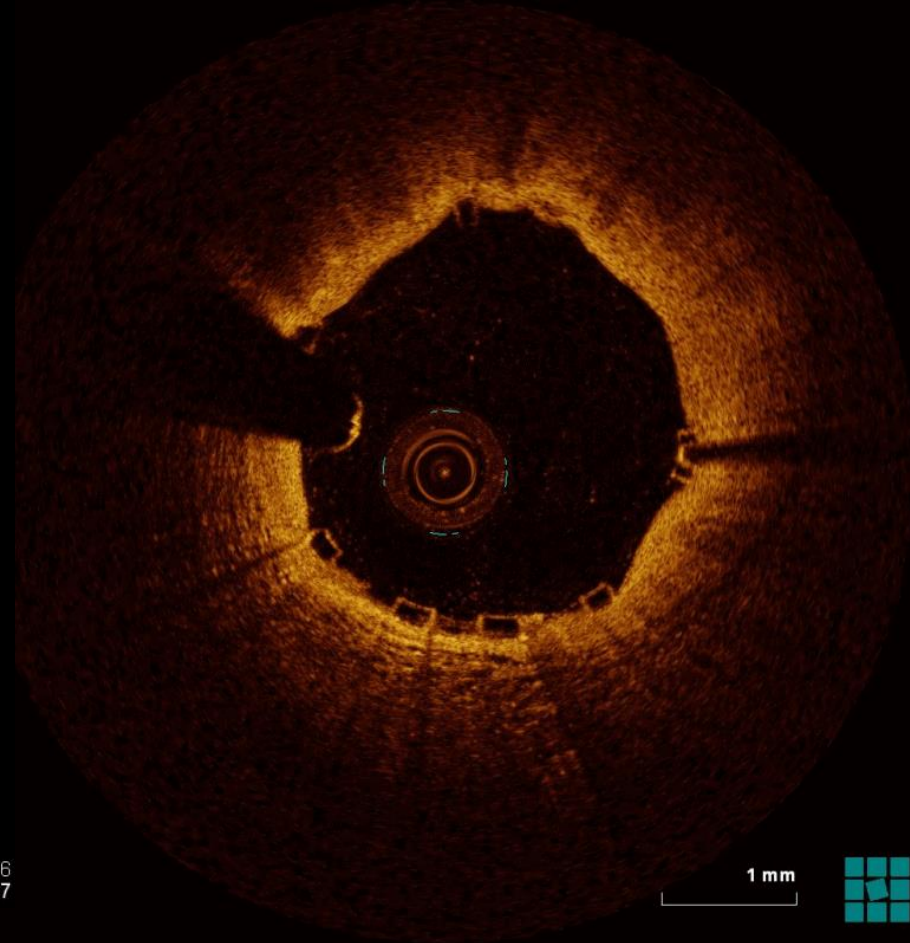
Proximal Edge Dissection
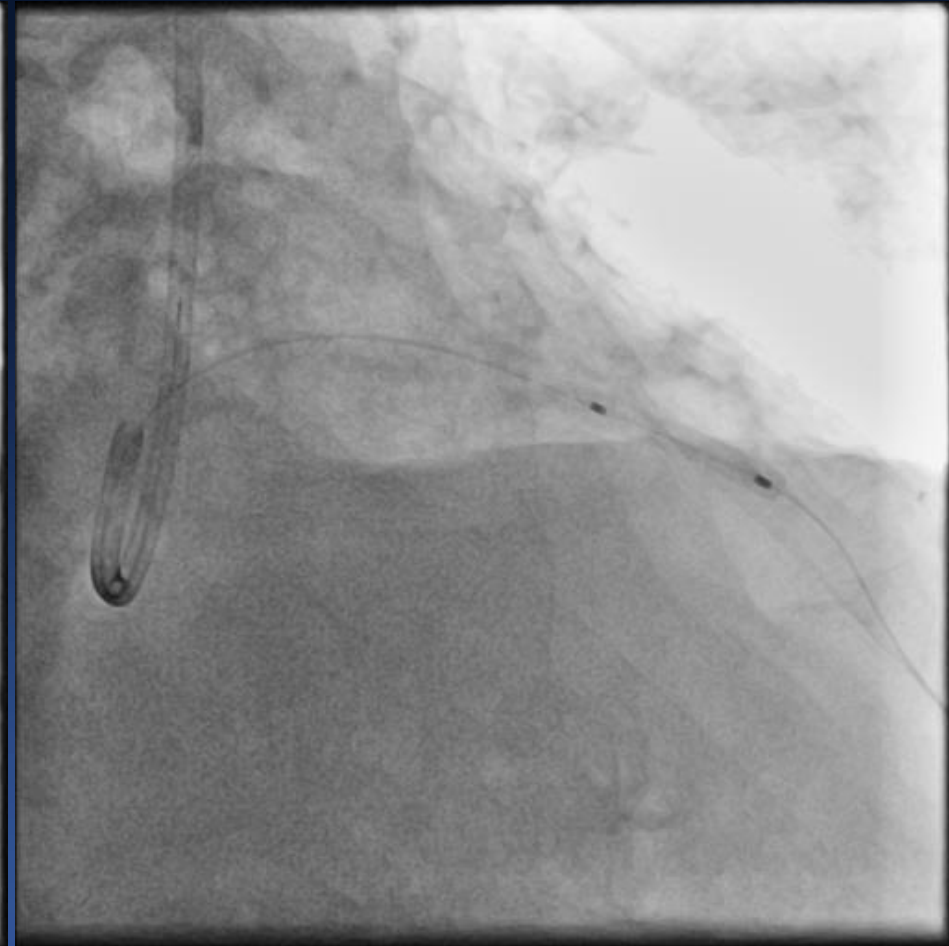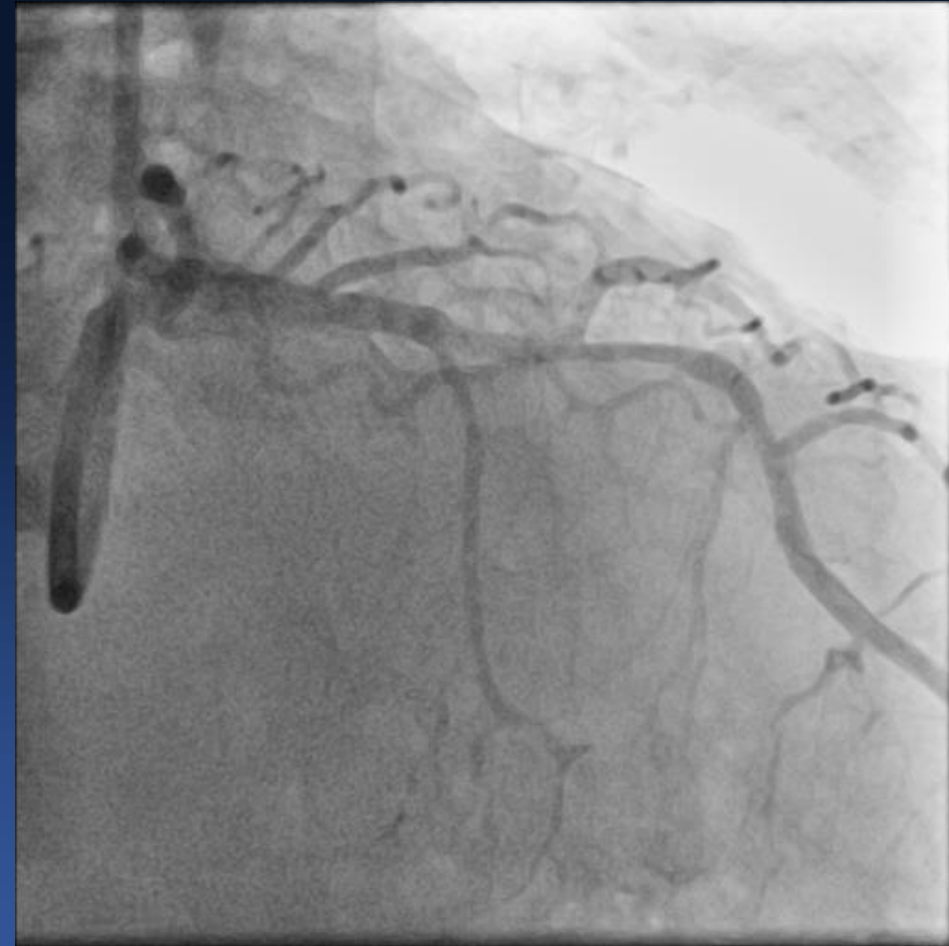
CASE - IV

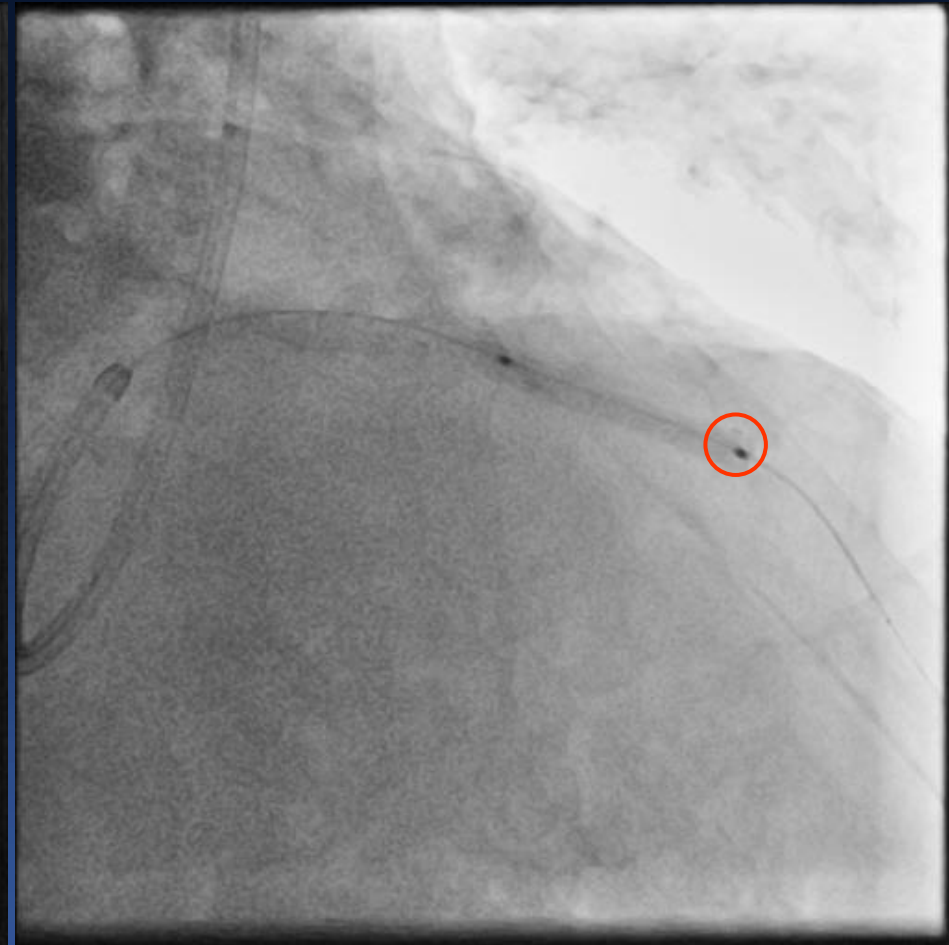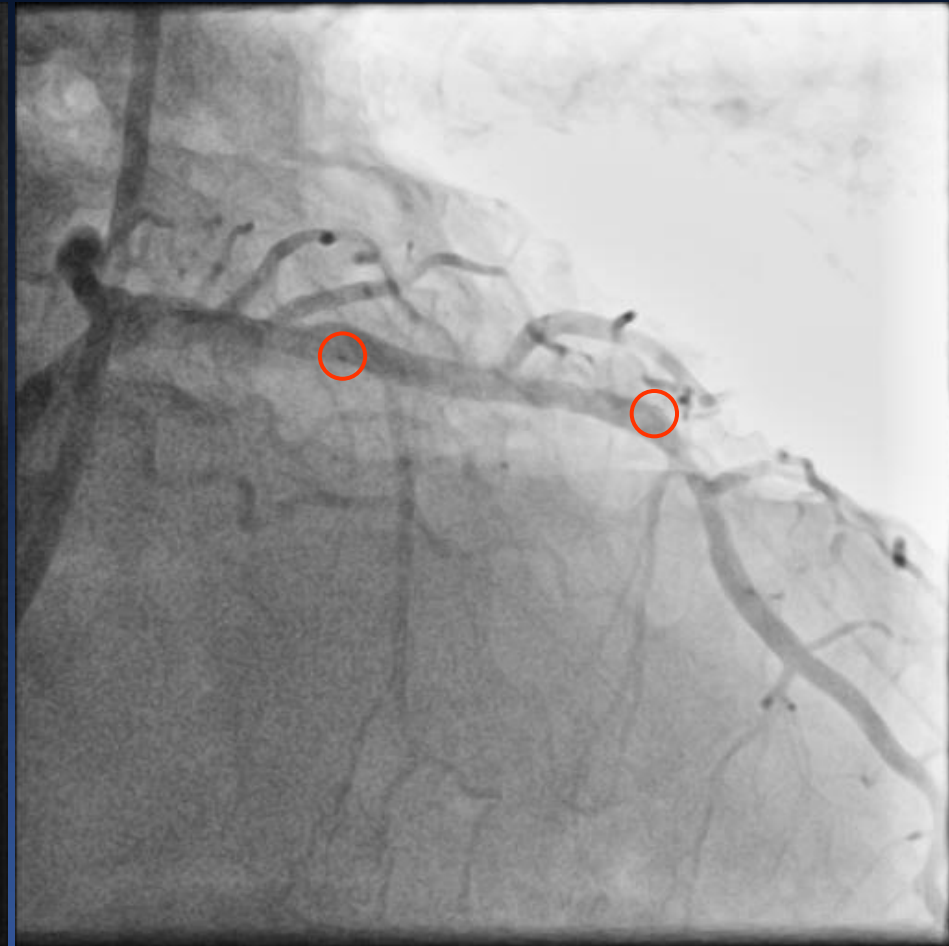
NC Balloon 2.75 mm

CASE - IV

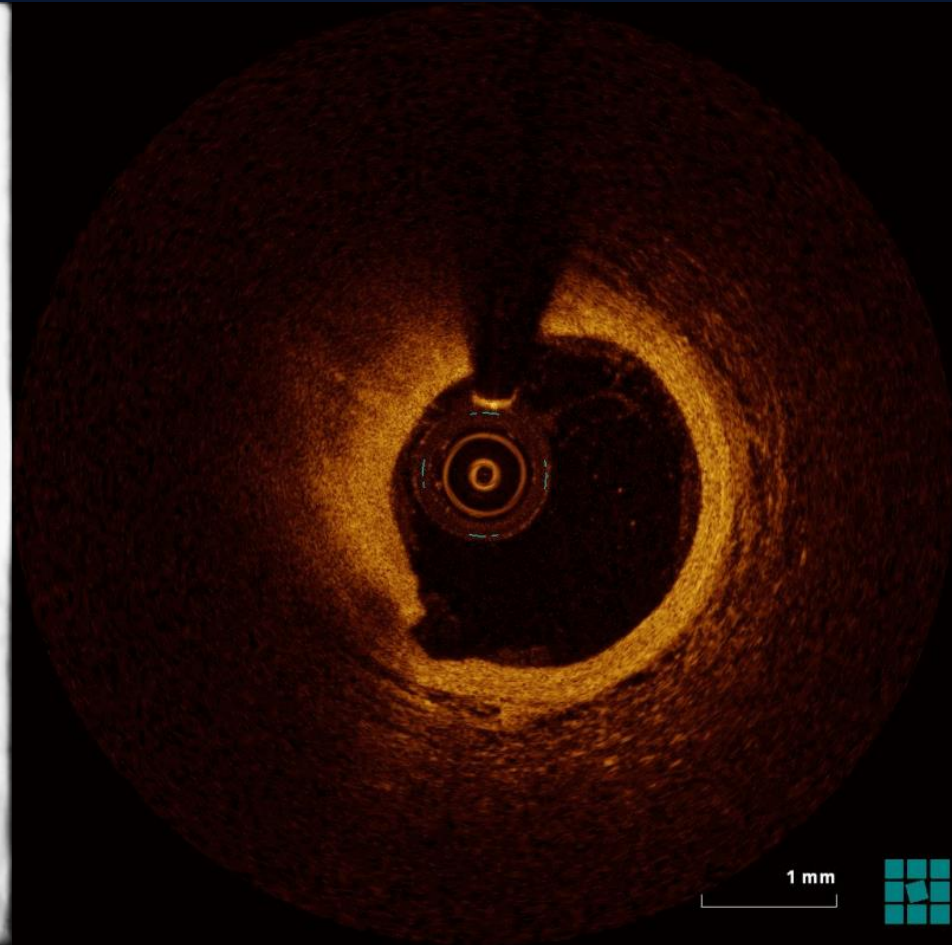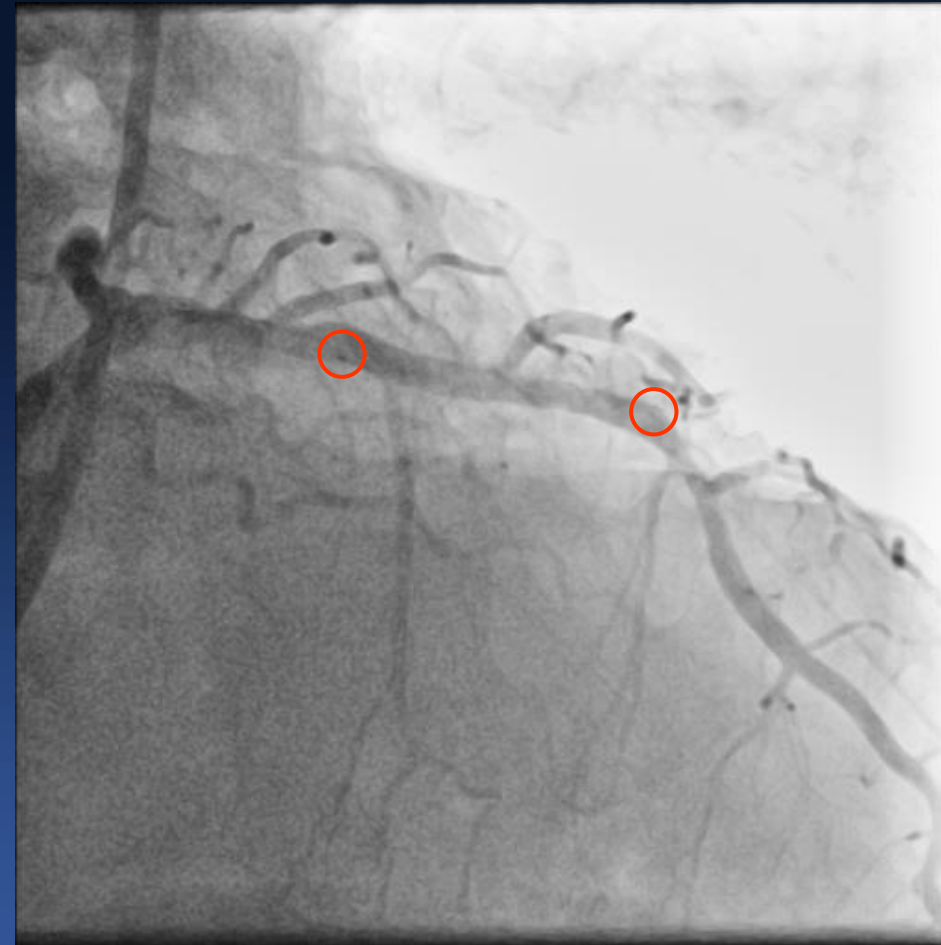BVS 3.0 / 28mm

NC Balloon 3.0mm

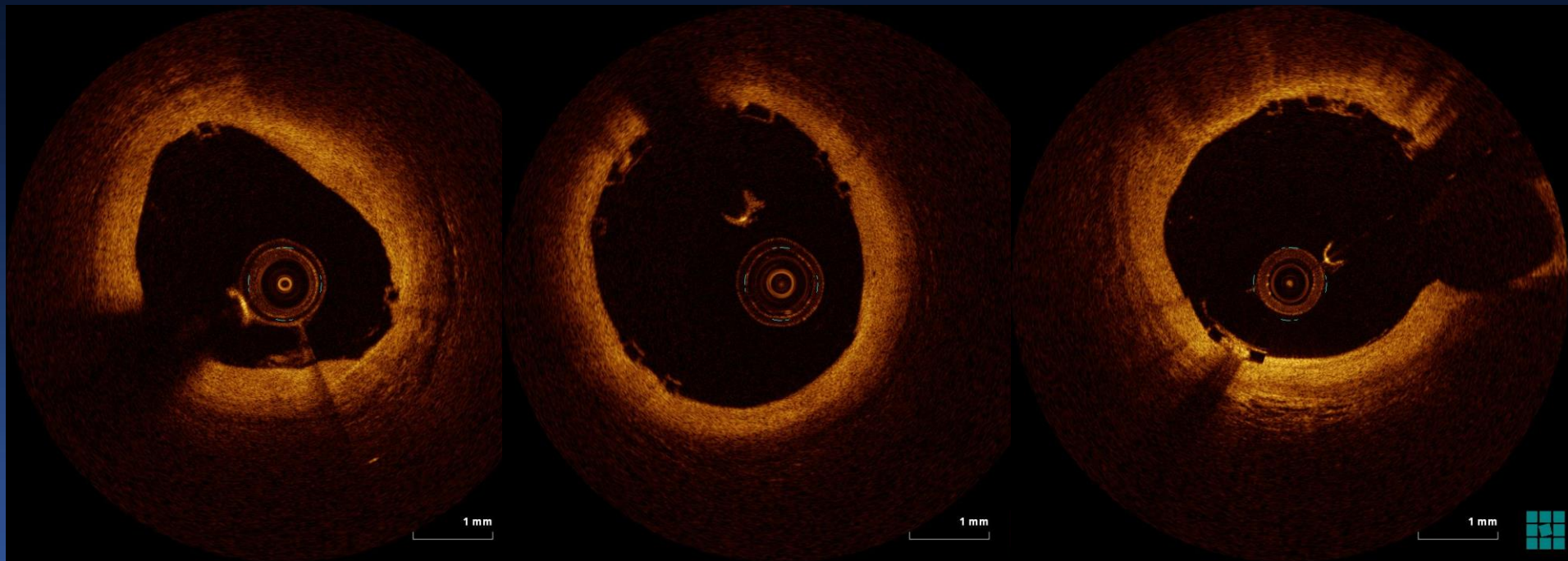# CASE - IV

NC Balloon 3.0mm

CASE - IV

Distal Edge Dissection

Post HP Balloon Inflation

Summary

- **IVUS** has advantage of visualising the total vessel diameter and area, which allows optimization of scaffold size while reducing the risk of disruption with oversized balloons.

- **OCT** has higer resoultion, so that scaffold intergrity, appostion to the underlying wall. Presence of thrombus, edge dissections, and changes in strut characteristics over time can be easily studied.