

# **Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease: The Disrupt CAD III OCT Sub-study**

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## Disclosure Statement of Financial Interest

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

Consulting Fees/Honoraria  
Speaker /No Fee  
Speaker/No Fee

### Company

Shockwave Medical  
Abbott  
CSI

Faculty disclosure information can be found on the app

# Intravascular Lithotripsy

DISRUPT  
CAD III

- Expanding and collapsing vapor bubble creates a short burst of **acoustic pressure waves**
- Acoustic pressure waves travel through the vessel tissue with an effective pressure of **~50 atm**
- A **localized field effect** within the vessel fractures both **superficial and deep calcium**



[Animation placeholder]

# Disrupt CAD III: OCT Sub-study



## Objective

Further understand the mechanism of action of IVL for the treatment of *de novo*, heavily calcified coronary lesions prior to stent placement using optical coherence tomography (OCT)

## OCT Imaging\*



\*Analyzed by OCT core laboratory at MLA, MSA & Maximum Ca<sup>++</sup> sites

Heavily calcified<sup>†</sup>, *de novo* coronary lesions  
RVD 2.5-4.0 mm, stenosis  $\geq 50\%$ ,  
lesion length  $\leq 40$ mm

Patients enrolled from  
January 2019 to March 2020  
N=431 (Safety Population)

Roll-in Population  
(N=47)

ITT Population  
(N=384)

OCT Sub-study  
(N=100)

<sup>†</sup>Radiopacities on both sides of the vessel with a calcified length  $\geq 15$  mm in the vessel by angiography or calcium angle  $\geq 270^\circ$  by OCT

# Procedural Characteristics



	OCT N=100	Non-OCT N=331	P Value
Total procedure time, min	58 ± 24	60 ± 30	0.61
IVL catheters	1.3 ± 0.5	1.2 ± 0.5	0.50
IVL pulses	77 ± 31	67 ± 35	0.01
Max IVL inflation pressure, atm	6.0 ± 0.4	5.8 ± 1.0	0.02
Pre-dilatation	26%	55%	<0.001
Post-IVL dilatation	20%	22%	0.78
Number of stents	1.4 ± 0.5	1.3 ± 0.5	0.15
Post-stent dilatation	99%	99%	1.00



# Case Summary



Patient with history of DM, HTN, HLD presenting with unstable angina

## March 4, 2019

- Diagnostic angiography revealed heavily calcified lesions in LAD (80%) and RCA (75%)
- Underwent PCI w/ atherectomy in pLAD - mLAD
- 3.5 x 33 Xience Sierra stent was placed and RCA staged for PCI using IVL

## March 11, 2019

Staged PCI in mid RCA with pre, post-IVL and post-stenting OCT assessments

### **Pre OCT**

- Assess IVL balloon size and preliminary stent sizing
- Mid-RCA lesion with 334° calcium arc and MLA of 2.87 mm
- 4.0 x 12 Shockwave IVL was used for 8 cycles of treatment

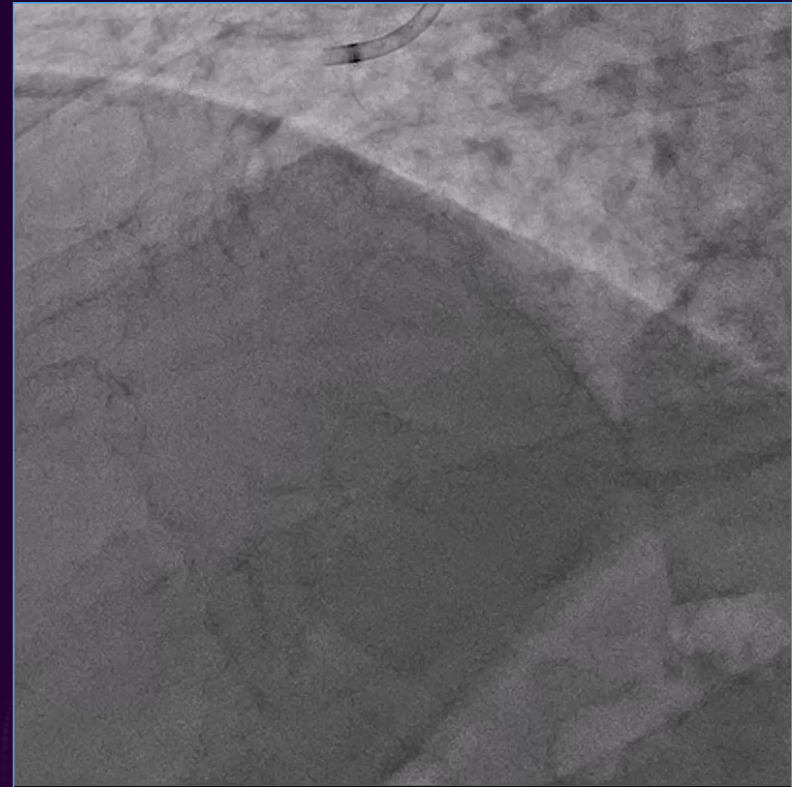
### **Post - IVL OCT**

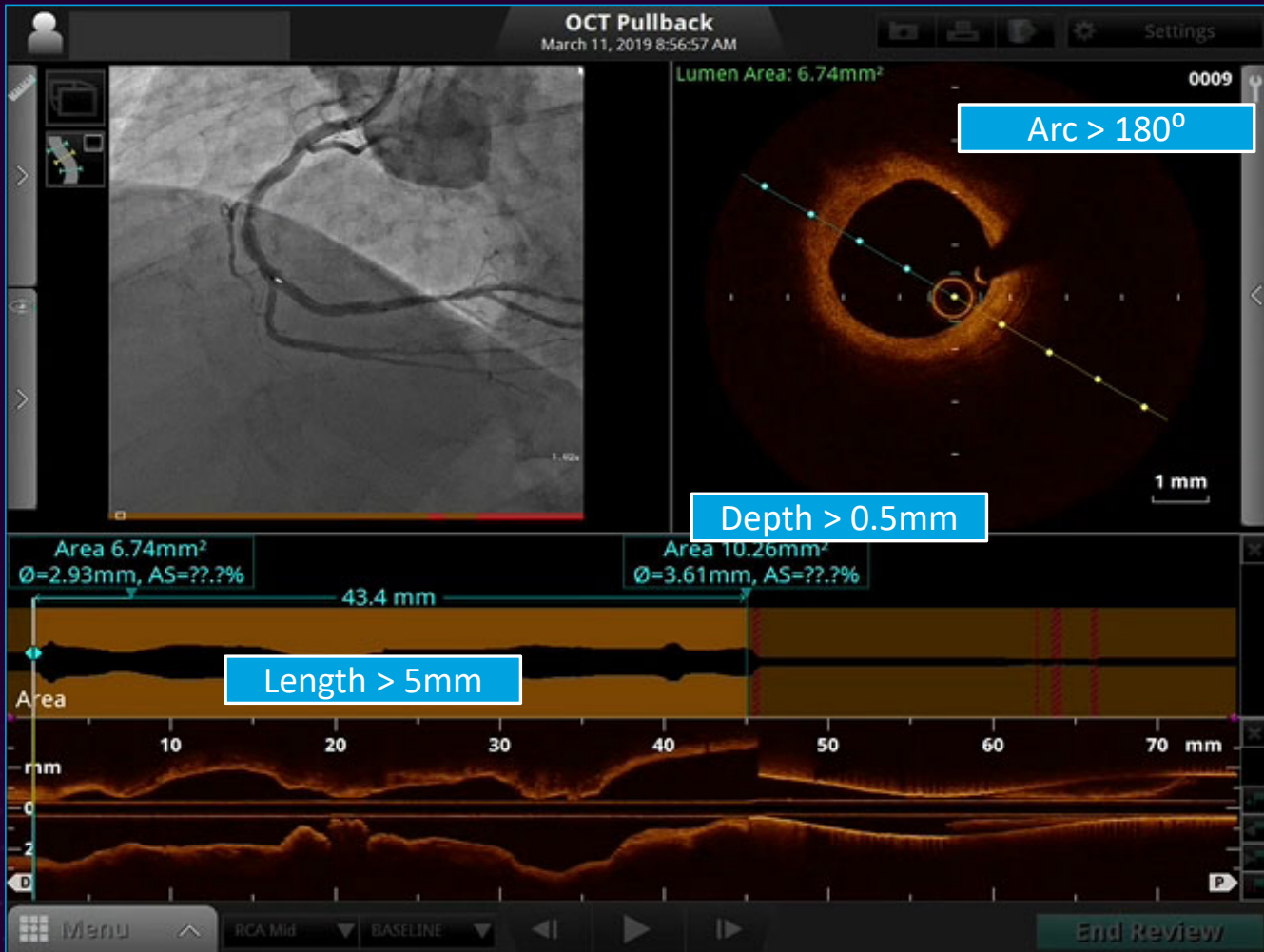
- Assess calcium fractures and confirm stent sizing
- 4.0 x 23 Xience Sierra was used to stent the target area and post dilated with a 4.5 x 12 NC Trek

**Final (Post-Stent) OCT** was acquired with final MSA of 9.57 mm

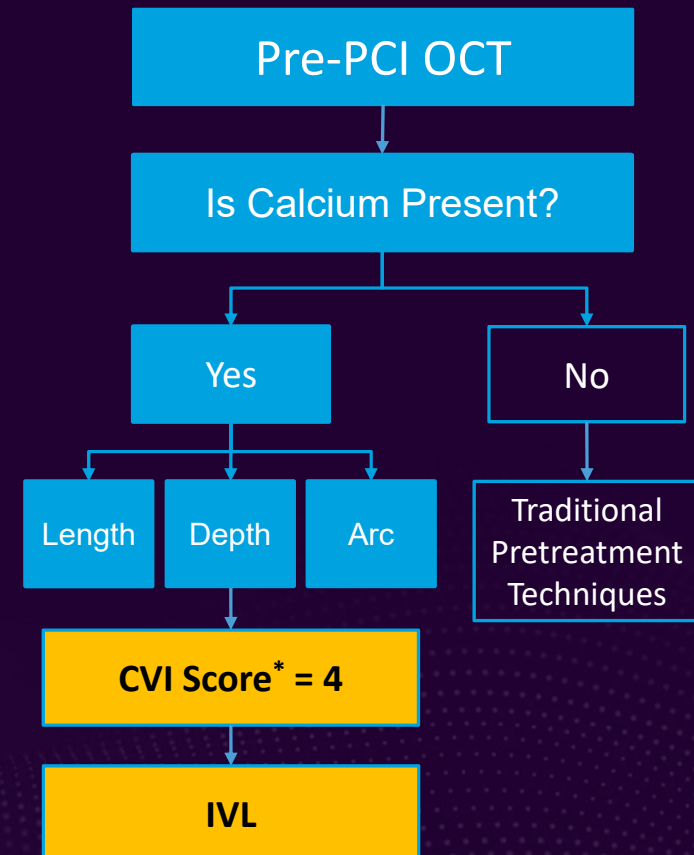
# Baseline

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**CAD<sup>III</sup>**





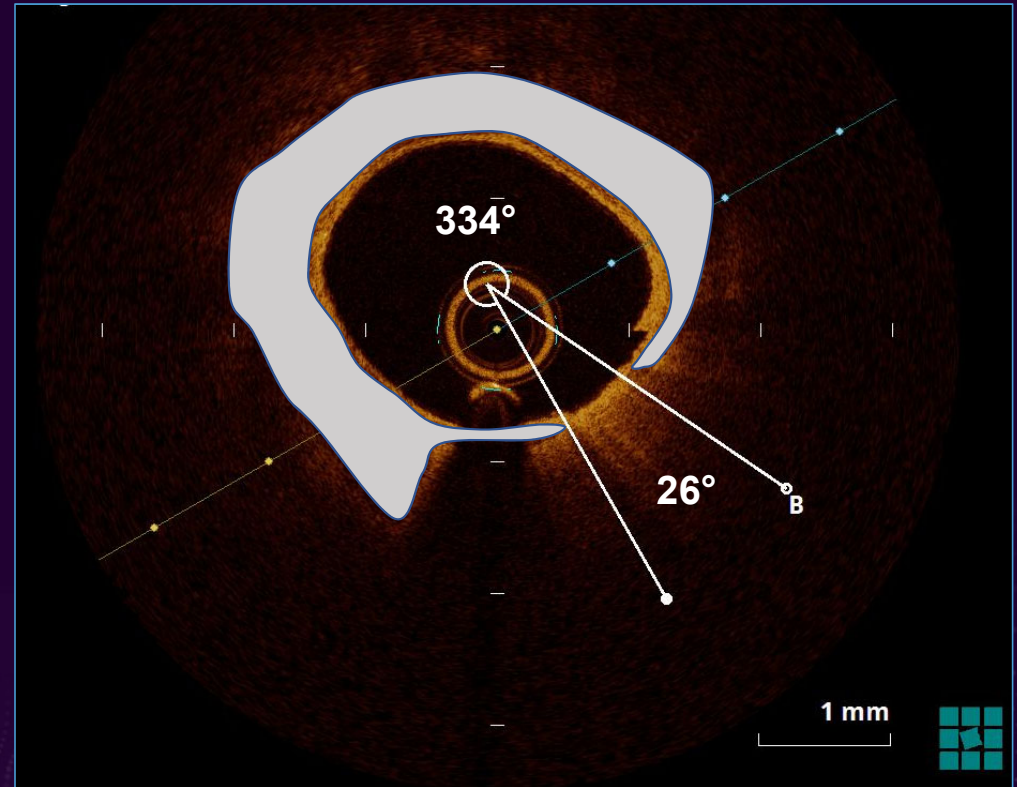
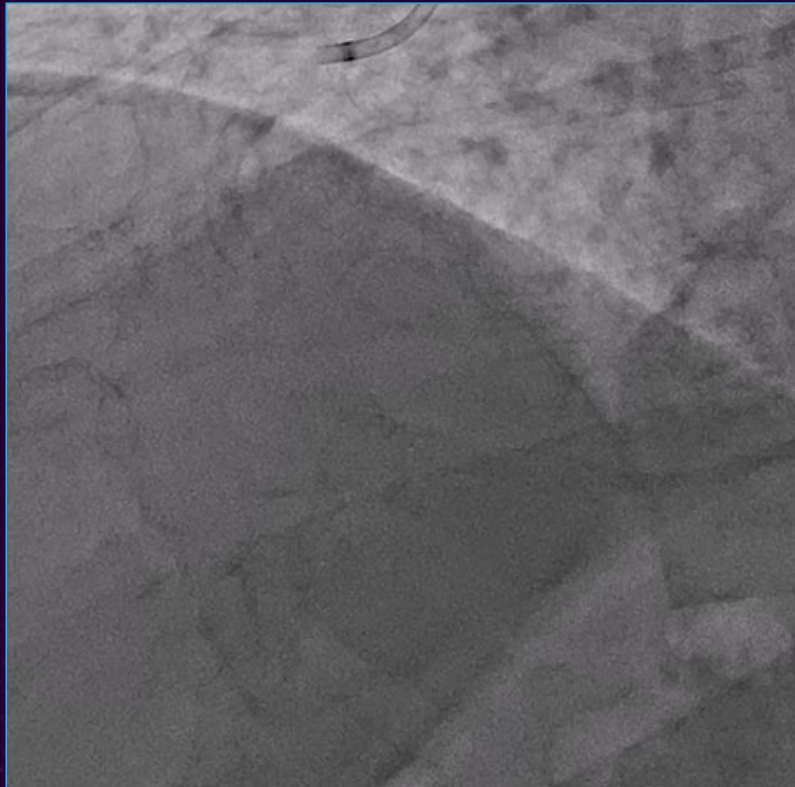
**DISRUPT  
CAD III**





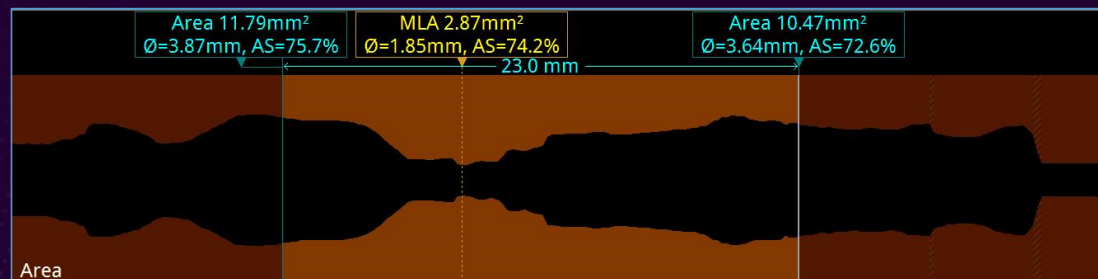
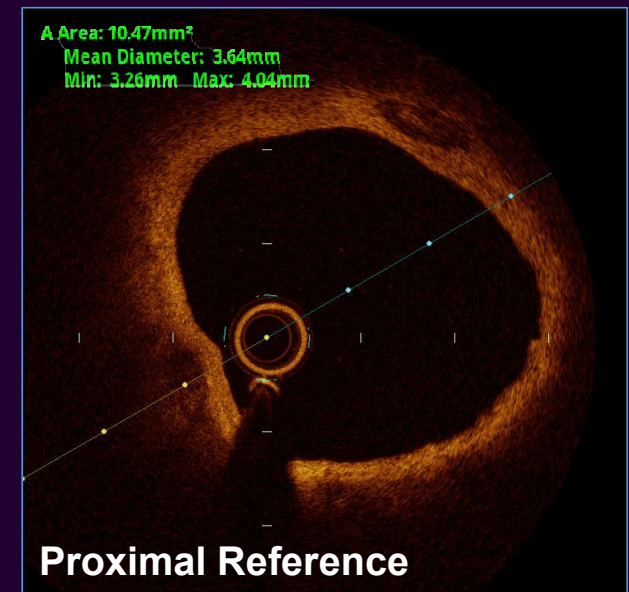
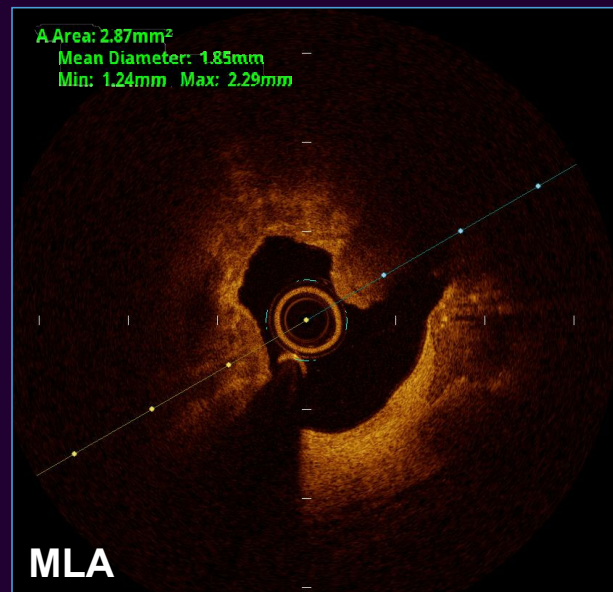
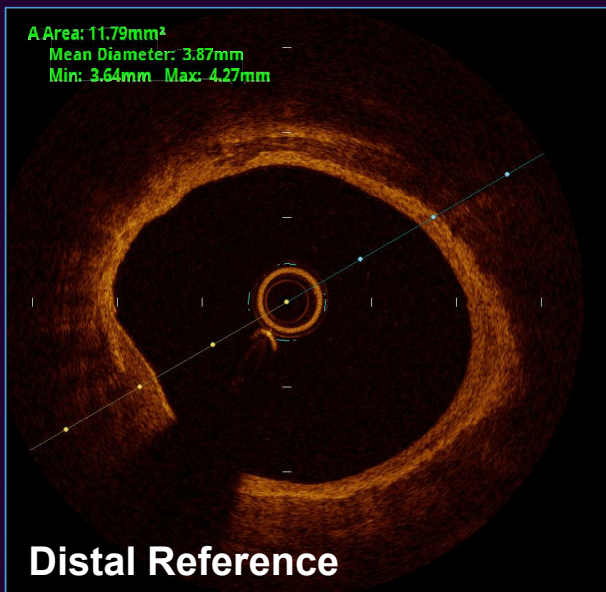
# Calcium Arc Assessment: Angio vs OCT

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CAD III



# Assessment of Length: Normal to Normal Lumen

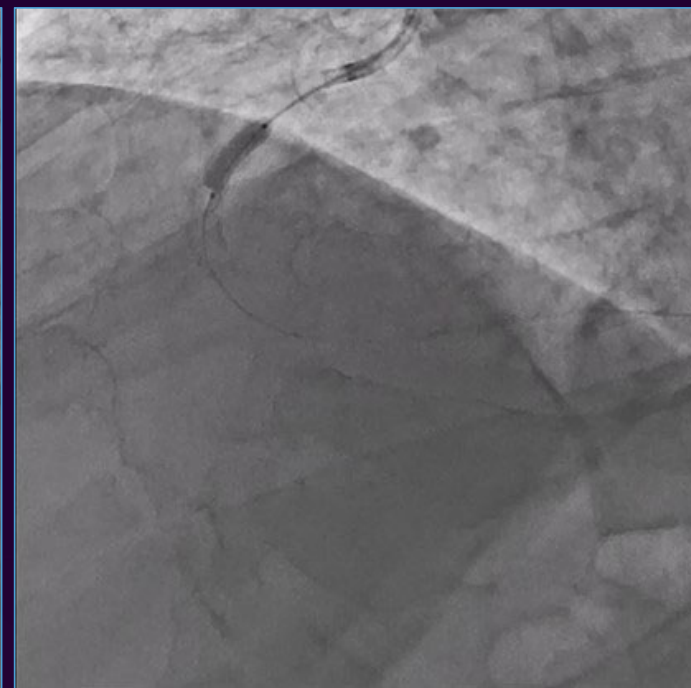
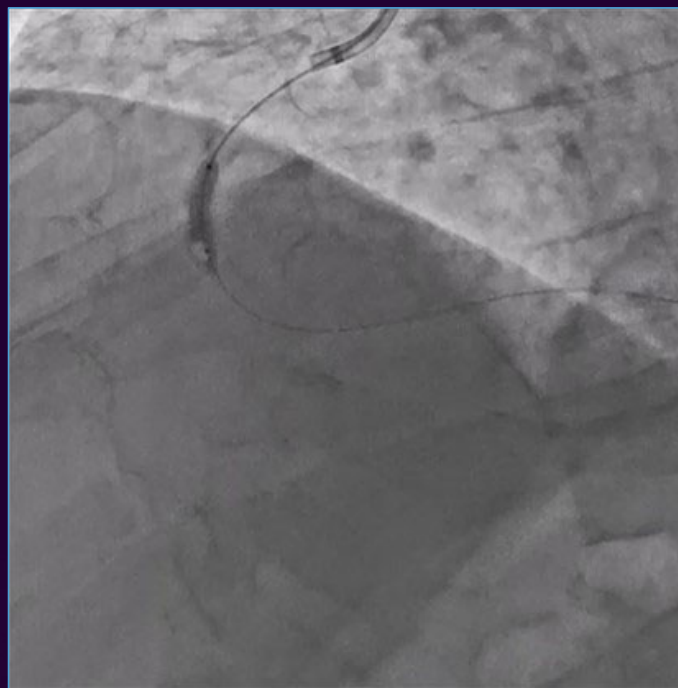
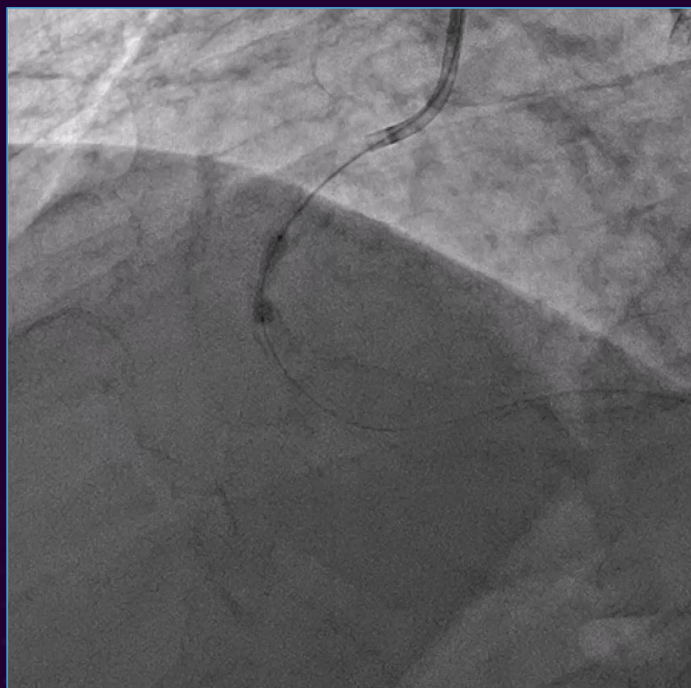
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CAD III





# IVL Delivery

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CAD<sup>III</sup>

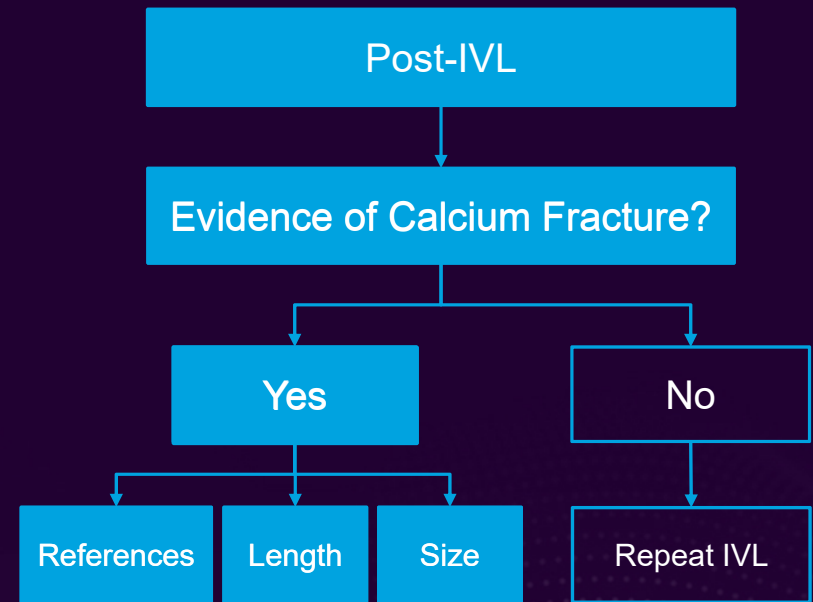
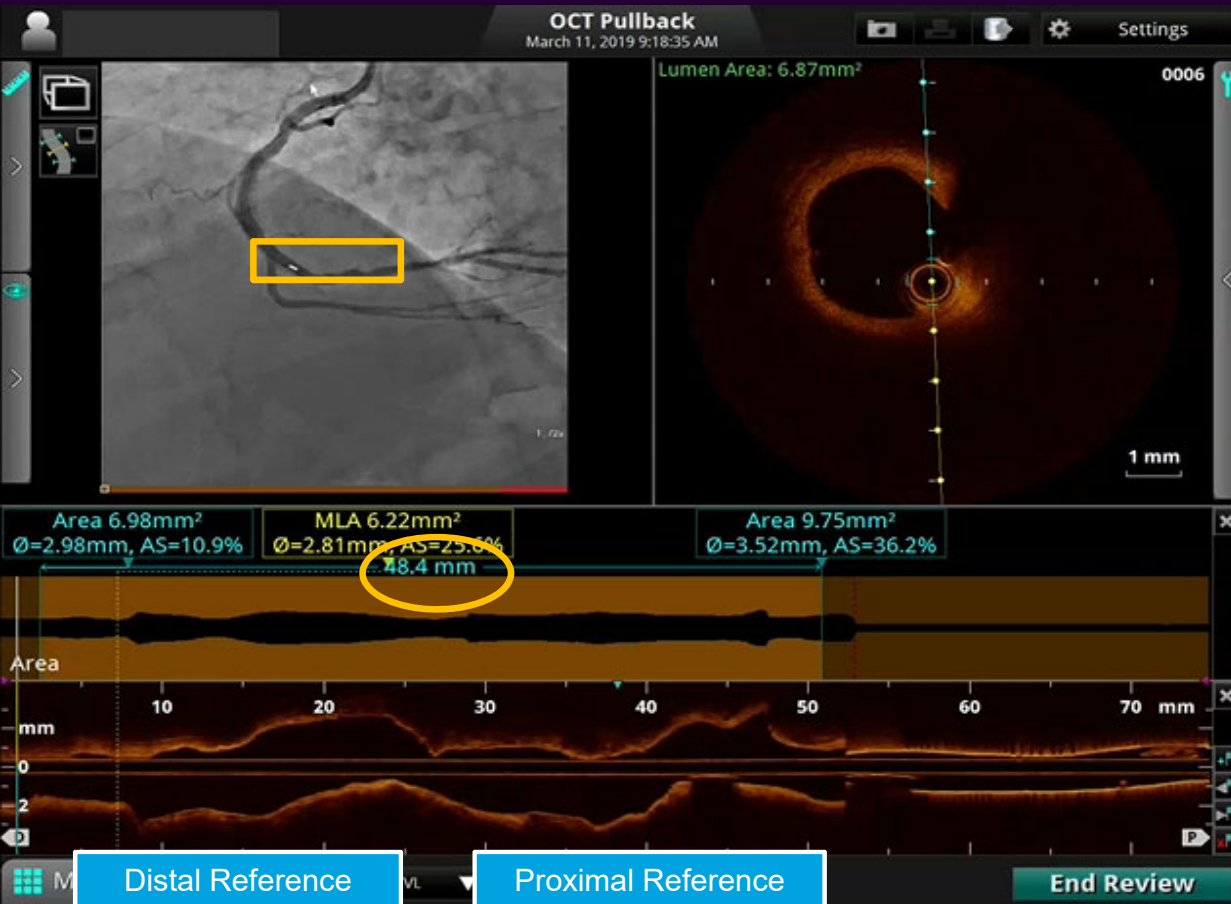


Treatment area 1  
*Balloon expansion at 8 pulses*

Treatment area 2

Treatment area 3

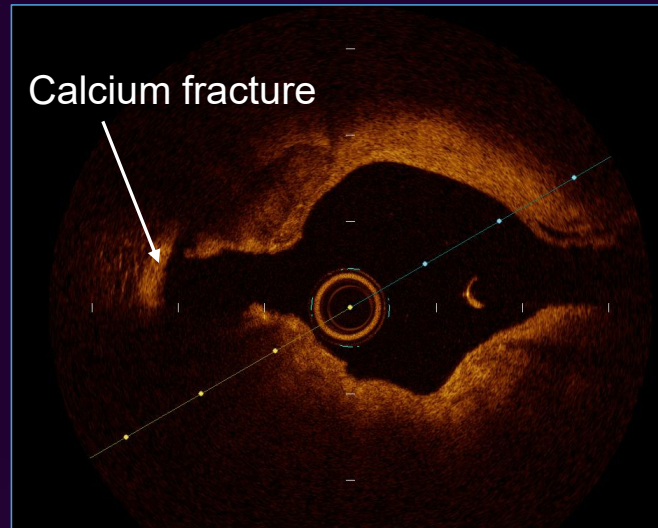
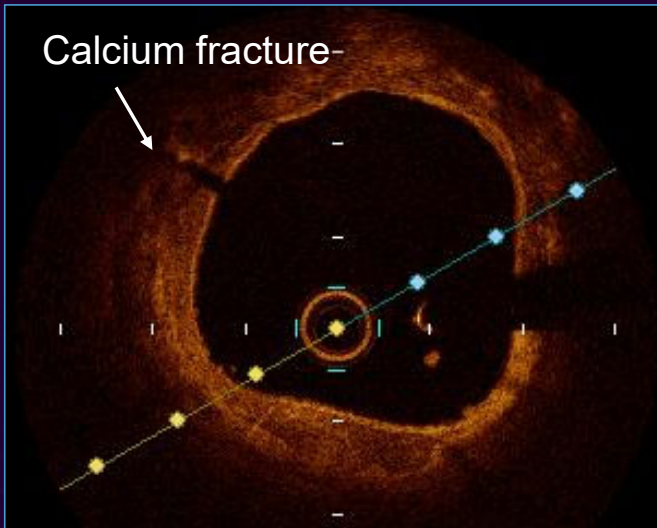
# Post-IVL Assessment





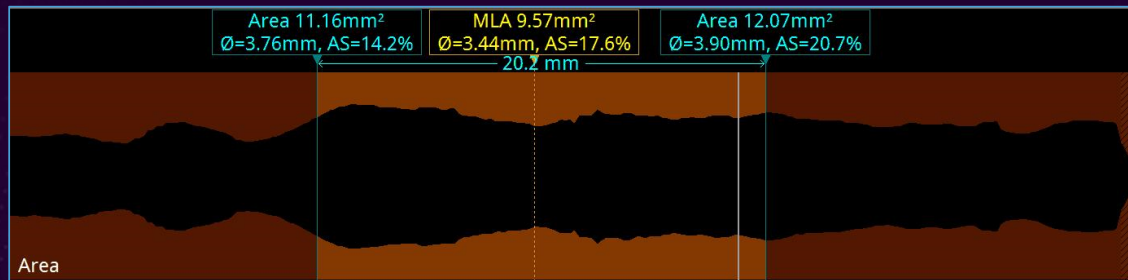
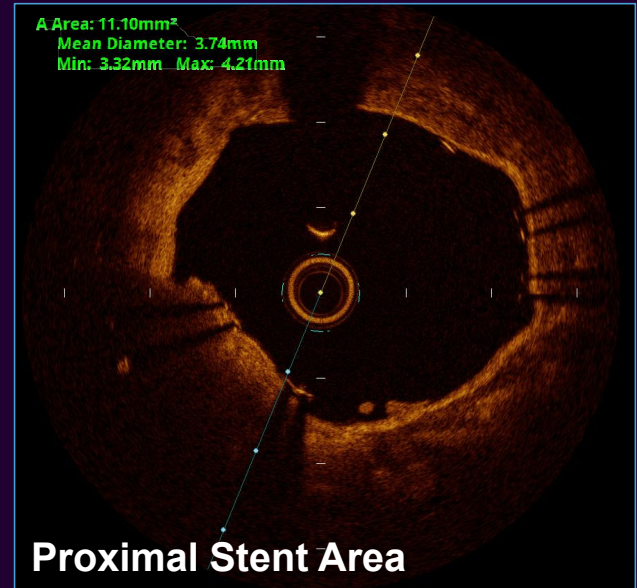
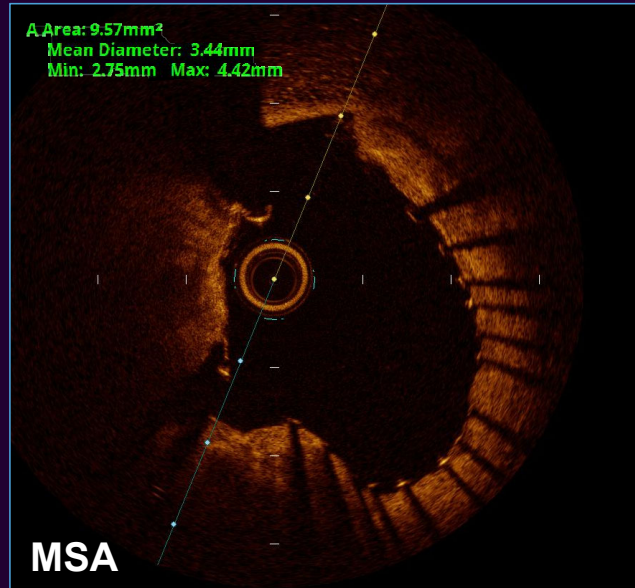
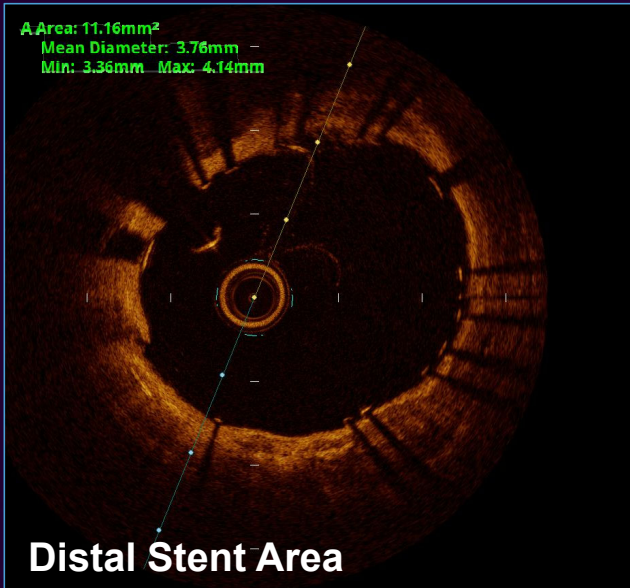
# Post-IVL

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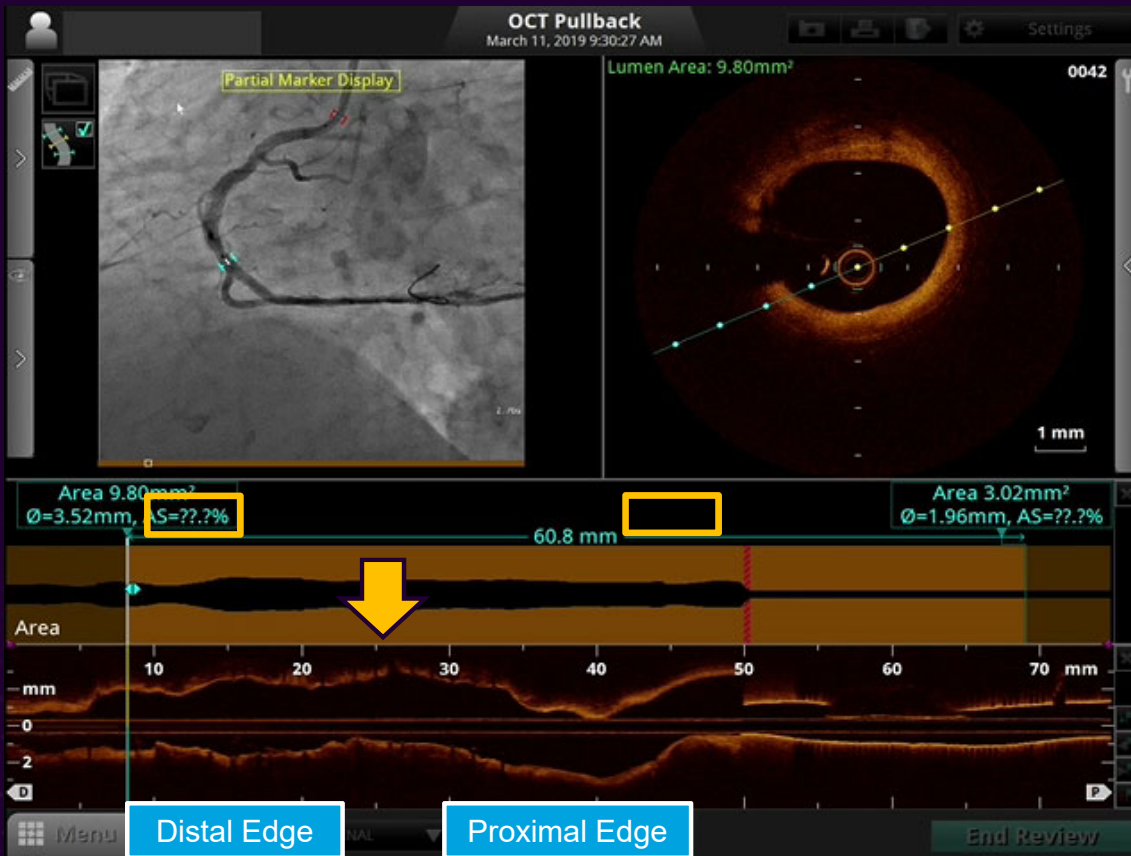


# Final Outcome

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# Final Outcome



OCT Post Assessment

Edge Assessment

Expansion

Apposition

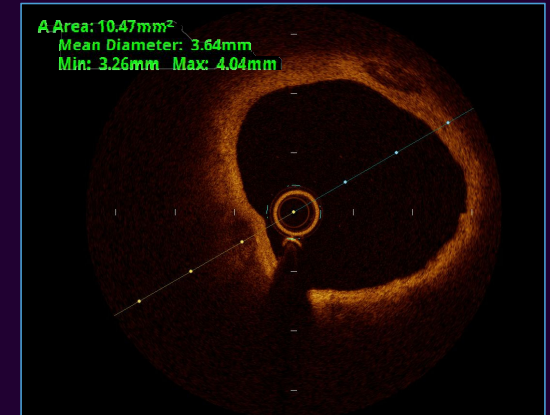
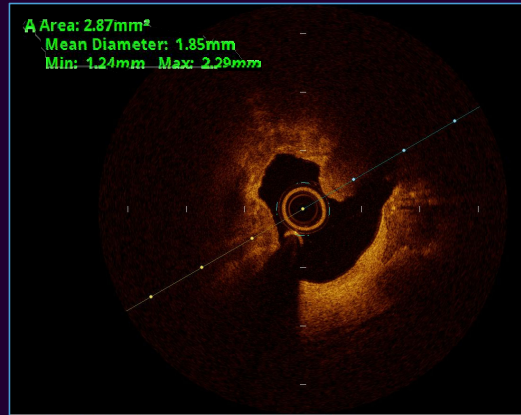
**PRECISION PCI WITH IVL**



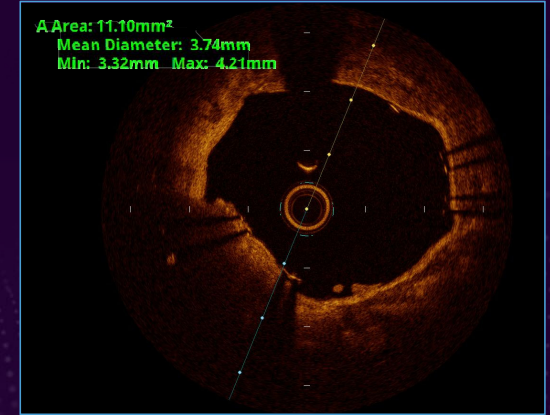
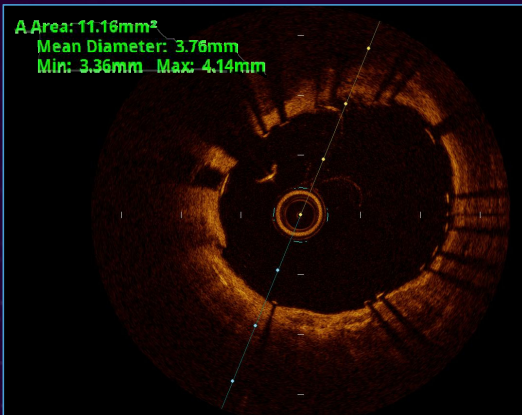
# Final Comparison

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Baseline



Final





# Key Takeaways

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## OCT imaging is useful at every step

### Assess Morphology

- Length calcium

- Arc calcium

- Depth calcium

Assess length of stent –normal to normal

Assess size of stent- 1:1 IVL to EEL

### Co-registration

- IVL pulses

- Stent Placement

Detect distal or proximal edge dissection

Evaluate >90% luminal gain

Evaluate Apposition