

Orbital and Laser Atherectomy in Complex PCI

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Disclosure Statement of Financial Interest

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

Financial Relationship

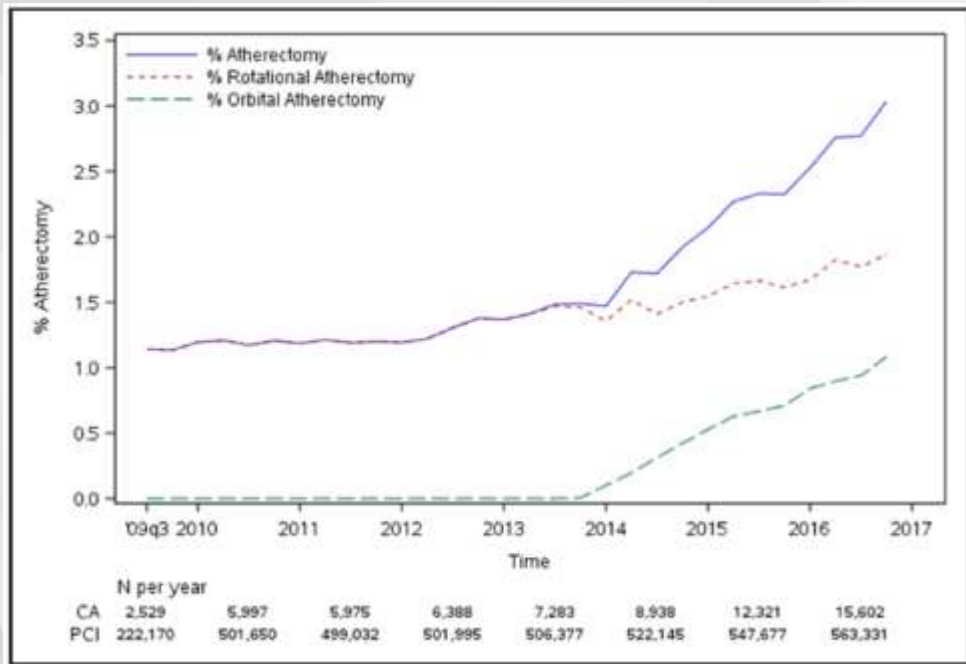
- Grant/Research Support
- Proctor/ Consulting Fees/Honoraria/ Advisory Board

Company

- Takeda, Abbott, Teleflex, Boston Scientific
- Abbott, Boston Scientific, Philips, Abiomed, Cordis, CSI, Takeda,

Calcium is Under Recognized and Worsens PCI Outcomes -Despite Increasing PCI Complexity-

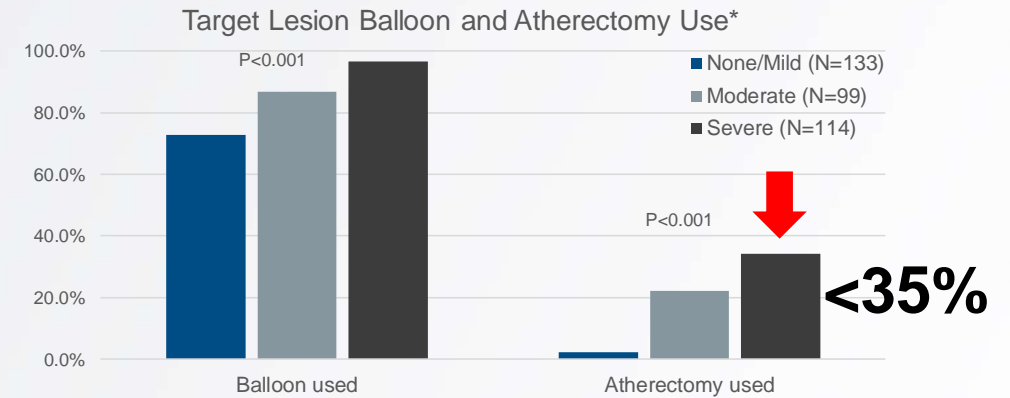
**NCDR = Low atherectomy utilization
34.5% of hospitals – no atherectomy**



Circ Cardiovasc Interv. 2020;13:e008239.

Low Atherectomy Use in Severely Calcified Lesions

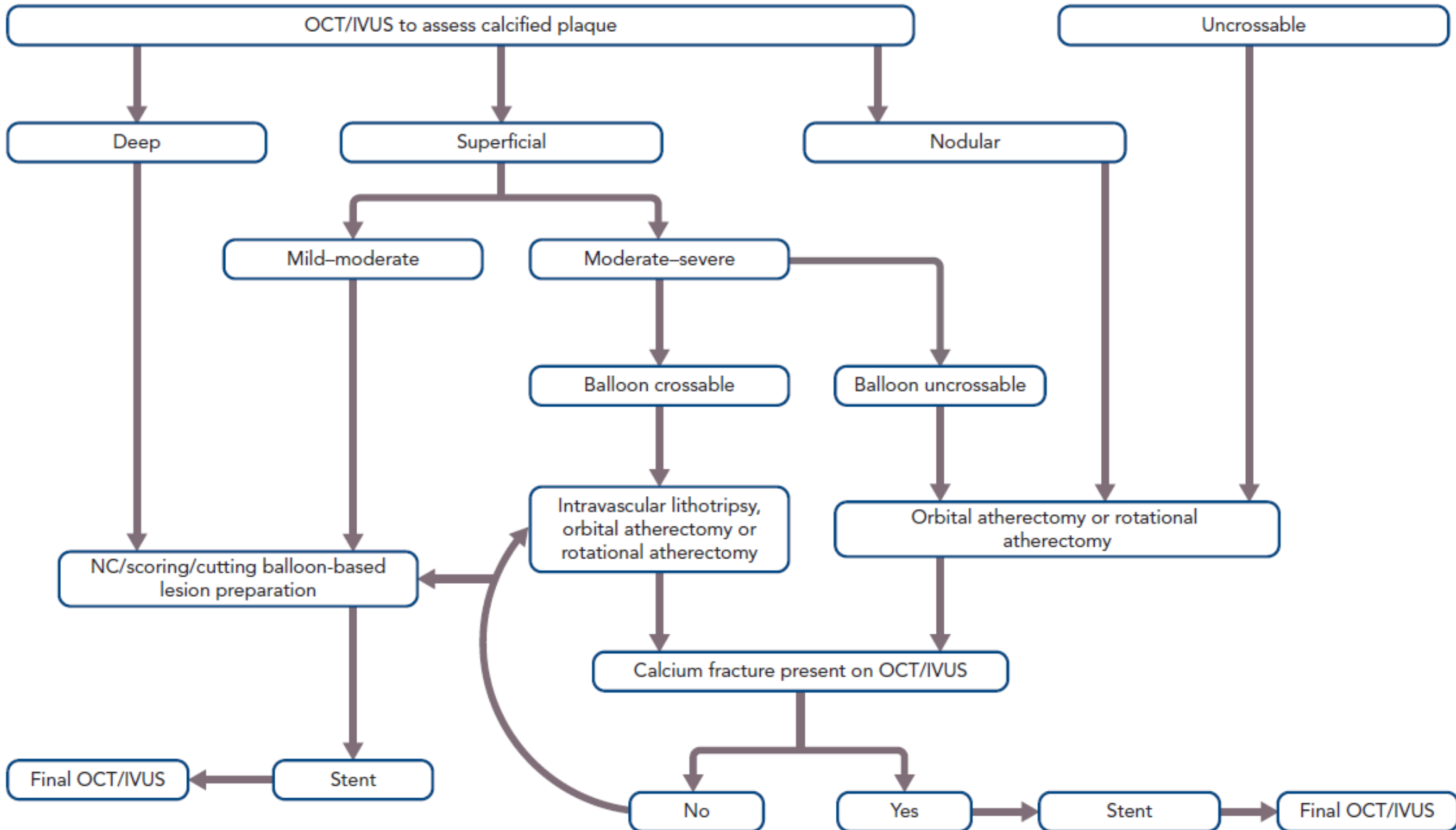
MACE: Prospective, multi-center, non-randomized PCI study evaluating cardiovascular outcomes of patients with and without coronary calcification; PCI strategy was at the discretion of the study physician.



Less Than 35% of Severely Calcified Lesions Were Treated With Atherectomy

MACE was sponsored by Cardiovascular Systems, Inc. (ClinicalTrials.gov/NCT01930214) Sharma SK, et al. Catheter Cardiovasc Interv. 2019;94(2):187-194.
*In overall study population:
Of balloons used: 98.3% Conventional Balloon, 11.6% Cutting Balloon, 0.7% Focal Force Balloon
Of atherectomy devices used: 93.8% Rotablator, 3.1% Turbo Elite, 3.1% OAS [Use of OAS was not permitted in the MACE study; however, the initial protocol allowed any FDA approved device for treatment. Due to the timing of device approval, there were 2 subjects treated with OAS prior to a protocol revision explicitly excluding OAS. Both subjects had severely calcified lesions as reported by the Investigator.]

New Paradigm: Contemporary Image Guided Atherectomy PCI



Intravascular imaging permits identification of calcified plaque characteristics and morphology to guide optimal lesion preparation. Following lesion preparation, intravascular imaging facilitates identification of the adequacy of calcium fracture and plaque modification, and guides appropriate stent sizing. Final postintervention imaging is recommended to ensure adequate stent expansion. IVUS = intravascular ultrasound; NC = non-compliant; OCT = optical coherence tomography.

Imaging Guides Decision for Atherectomy

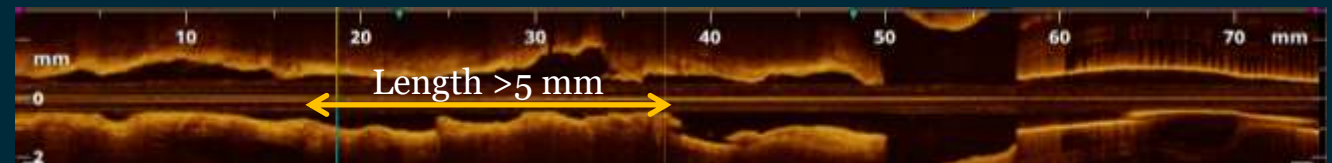
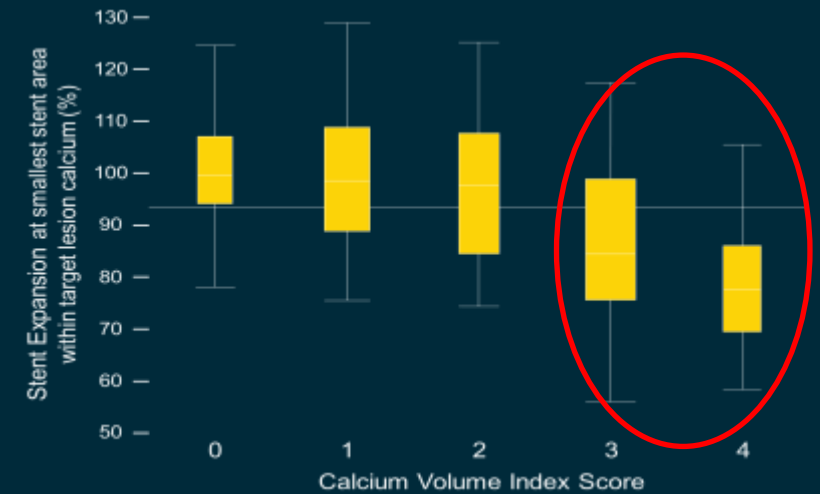
Influence of Ca²⁺ on Stent Expansion by OCT

OCT-Based Calcium Volume Index Score¹

1. Maximum Calcium Angle (°)	<p>≤ 90° ▶ 0 point</p> <p>90° < Angle ≤ 180° ▶ 1 point</p> <p>> 180° ▶ 2 points</p>
2. Maximum Calcium Thickness (mm)	<p>≤ 0.5 mm ▶ 0 point</p> <p>> 0.5 mm ▶ 1 point</p>
3. Calcium Length (mm)	<p>≤ 5.0 mm ▶ 0 point</p> <p>> 5.0 mm ▶ 1 point</p>
Total score	0 to 4 points

Rule of 5's

- 0.5 mm thickness
- 5.0 mm long
- 50% vessel arc



1. Fujino, A. et al. A new optical coherence tomography-based calcium scoring system to predict stent under expansion. *EuroIntervention*, April 2018; 13(18):e2182-e2189.

Orbital Technology for Calcified Coronary Lesions

Electric OAS



Eccentric Crown

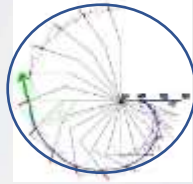


ViperWire™



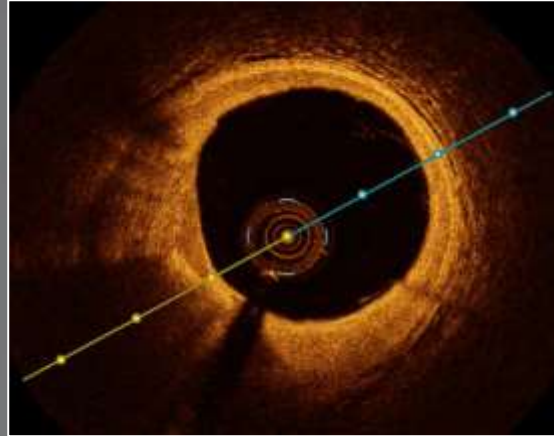
Orbital vs. Rotational Mechanism

Orbital atherectomy is designed to rotate in an orbit, treating 360° of lumen



Will orbital mechanism of action produce a uniform lumen shape?

Post OAS,
Pre Stent¹



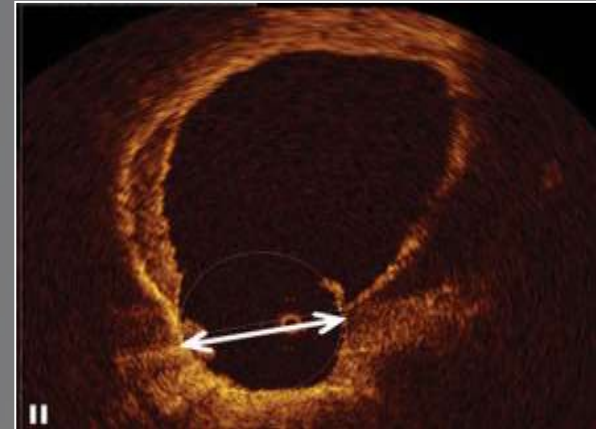
- Smooth concentric uniform lumen.
- Resistant calcified plaque reduced to modify compliance.
- Due to centrifugal force healthy vessel tissue flexes away.

Rotational atherectomy is designed to rotate in a straight drill line



Will a single size burr be able to treat entire lumen and precisely true lumen?

Post RA,
Pre Stent²



- Drill Follows path of least resistance.
- Entire lumen treated?
- Uniformity and concentricity achieved, but true lumen?

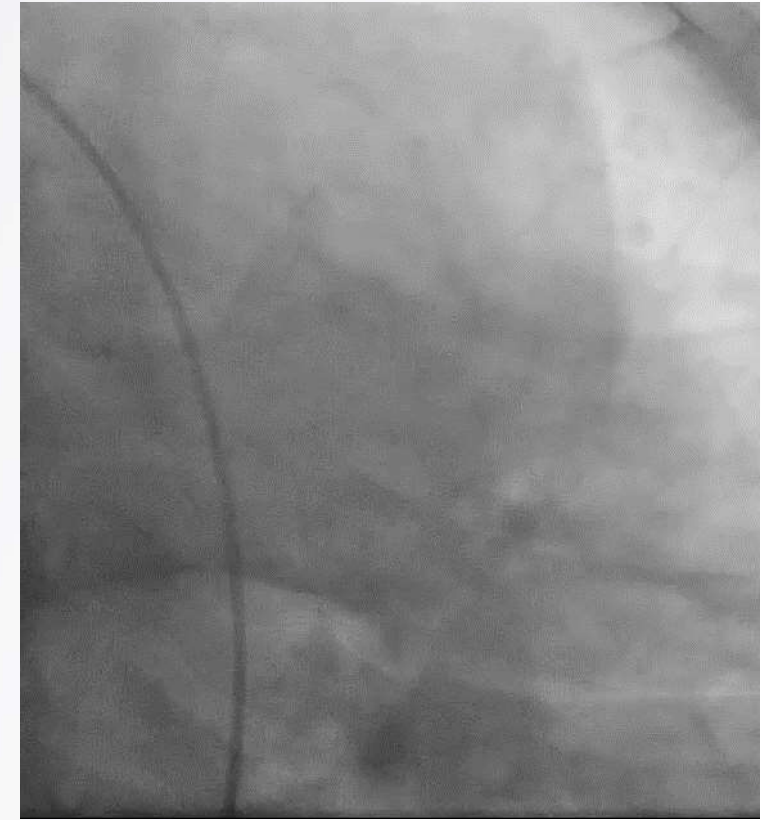
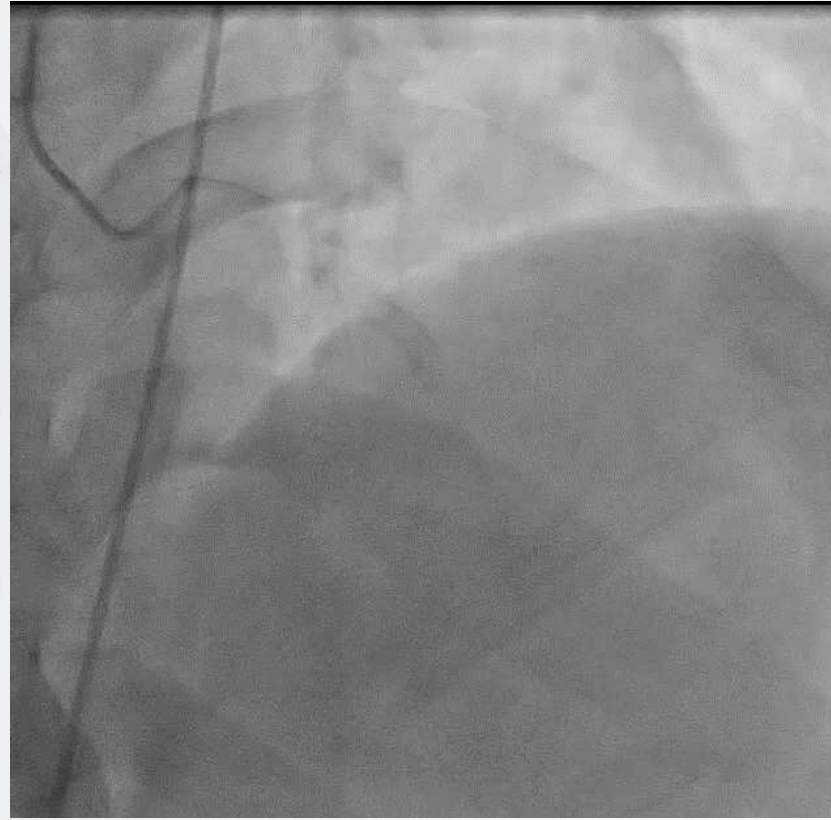
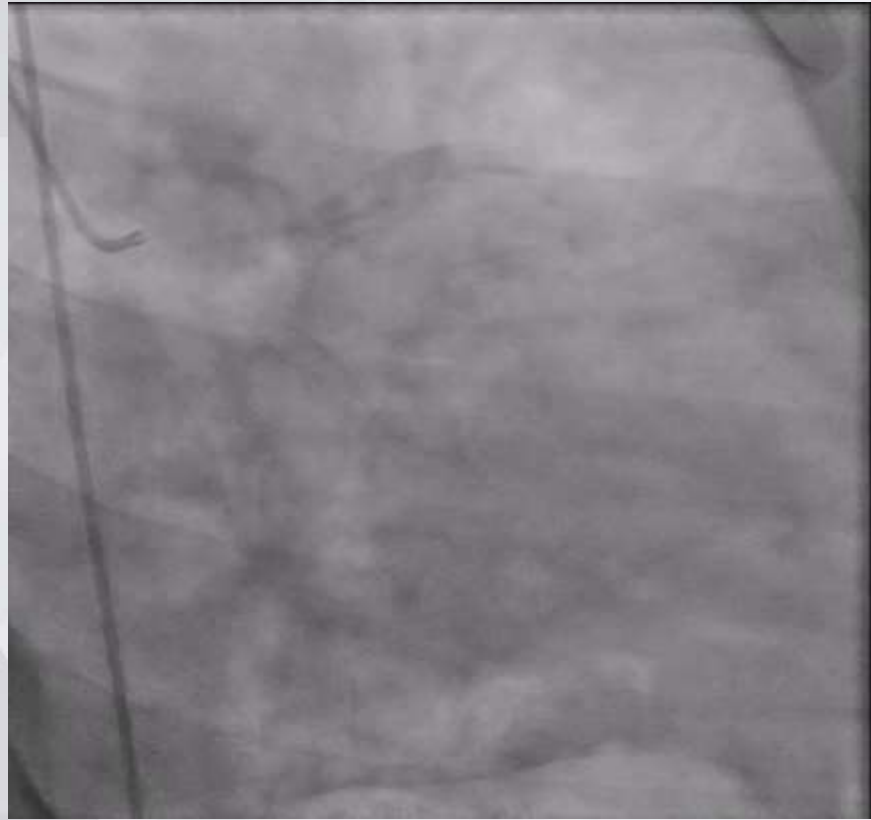
1. Courtesy of Dr. Lee

2. Attizzani, Guilherme. OCT Assessment of Calcified Plaque modification after RA

* OCT results may vary images based on different physician's, patients, atherectomy technique for treatment

Image Guided LAD Orbital Atherectomy Case

- 68m ESRD on RRT with peritoneal dialysis
- Chest pain, positive stress test



RCA = no obstructive disease

Modern Image Guided PCI Workflow | MLD MAX

Each OCT run serves a separate purpose.

Pre-PCI OCT | Strategize

MMORPHOLOGY

LENGTH

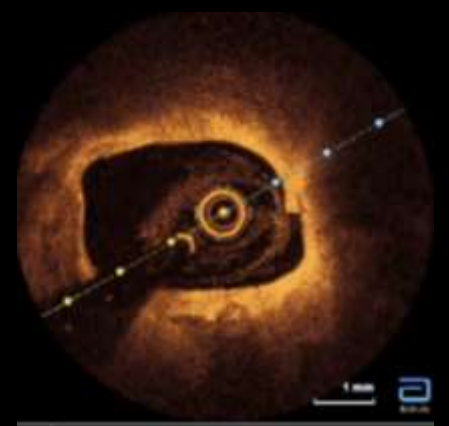
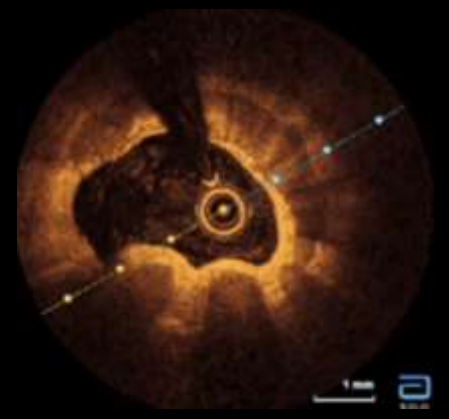
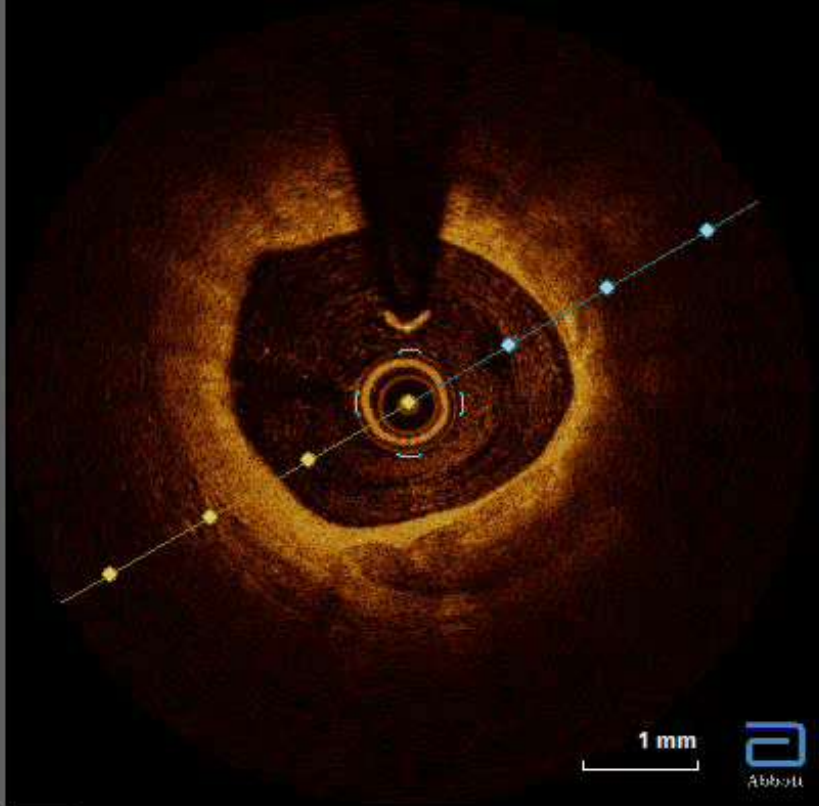
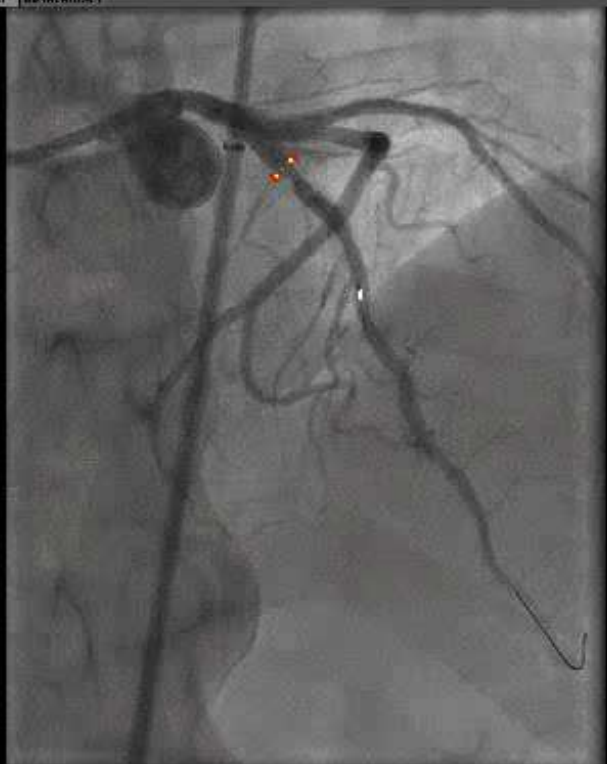
DIAMETER

Post-PCI OCT | Optimize

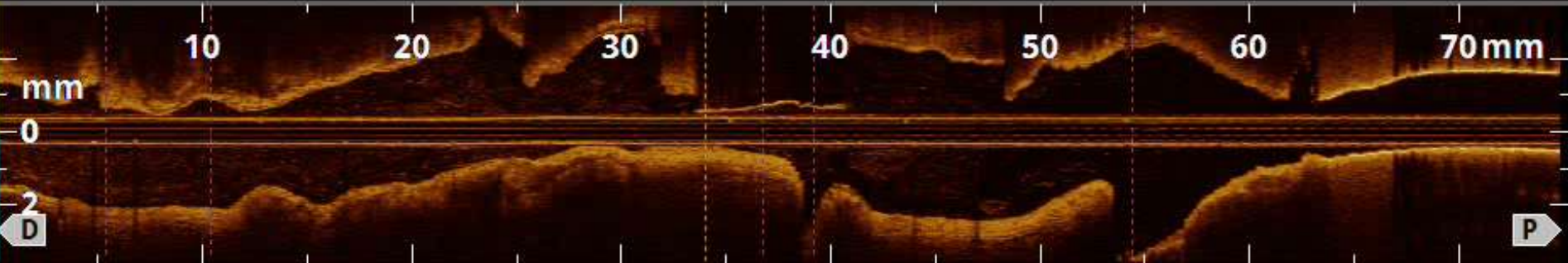
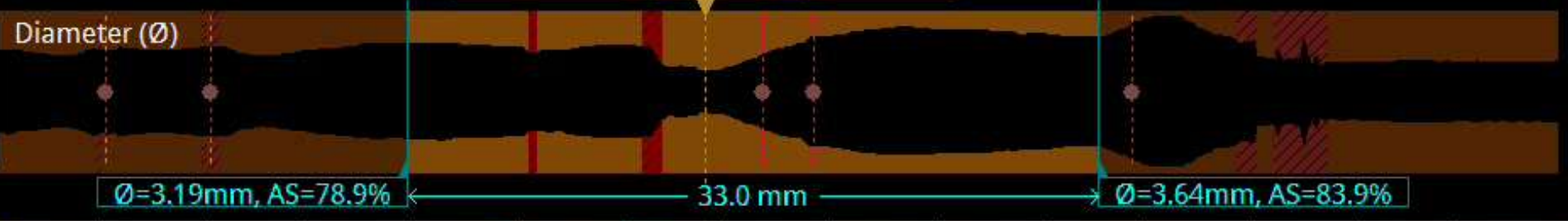
MEDIAL DISSECTION

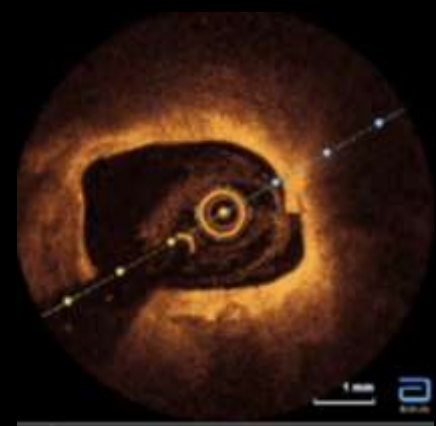
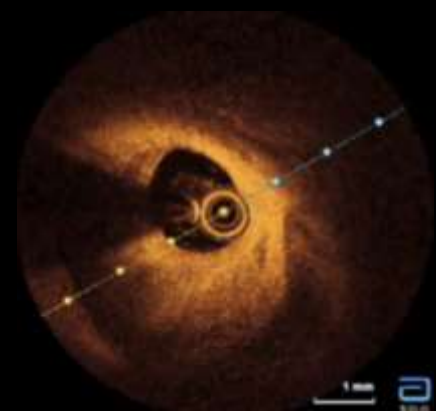
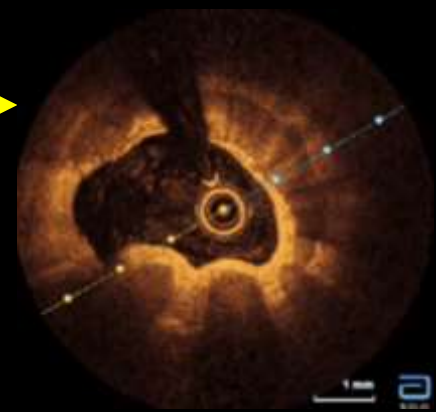
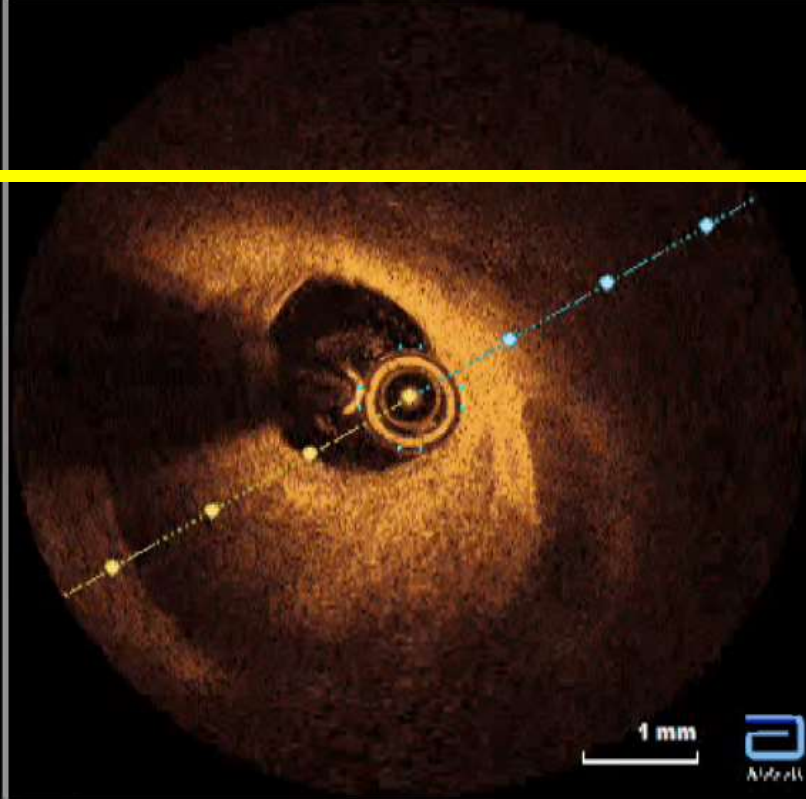
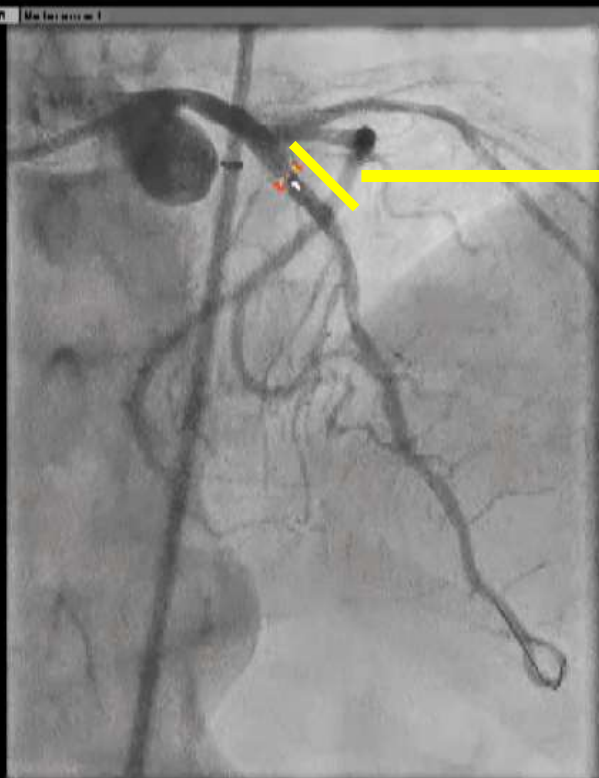
APPOSITION

EXPANSION

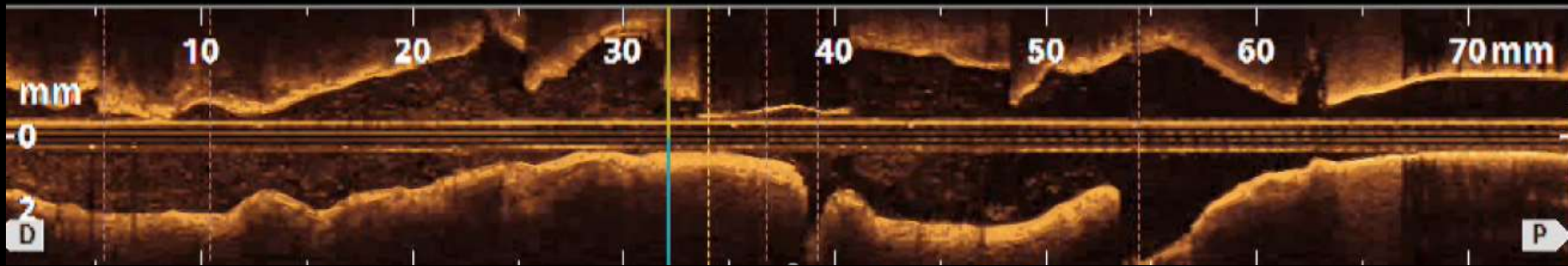
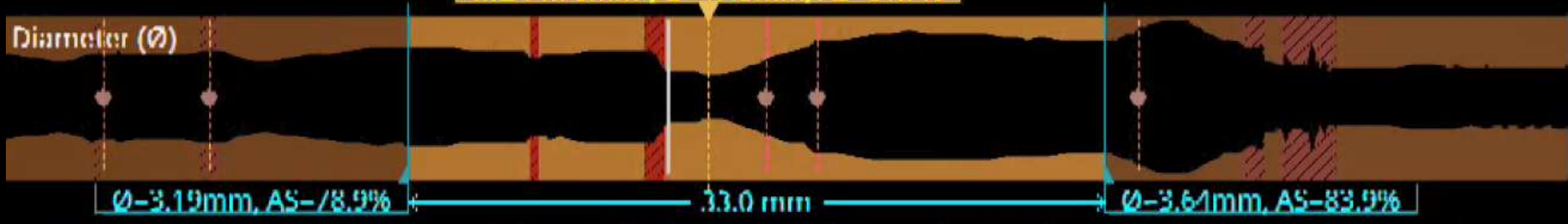


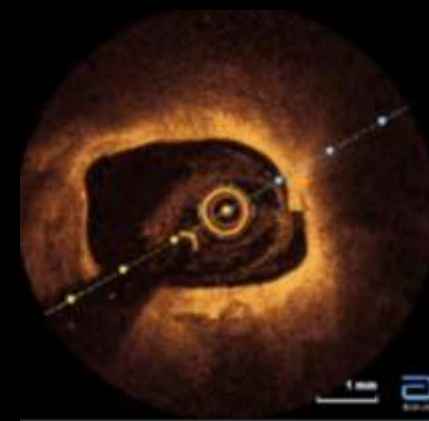
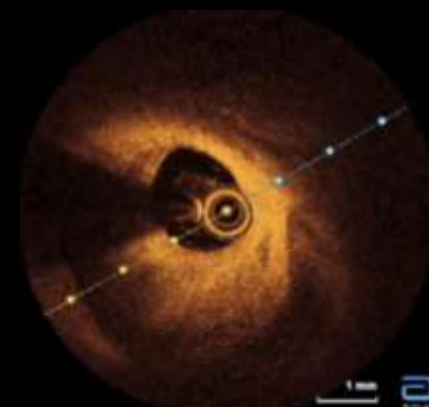
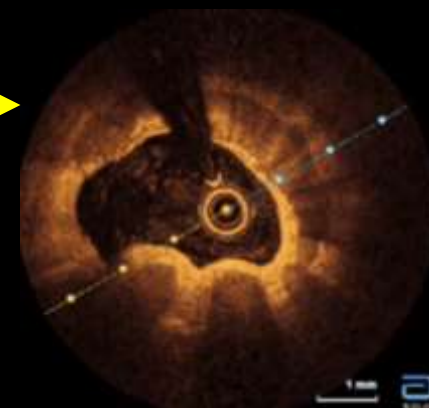
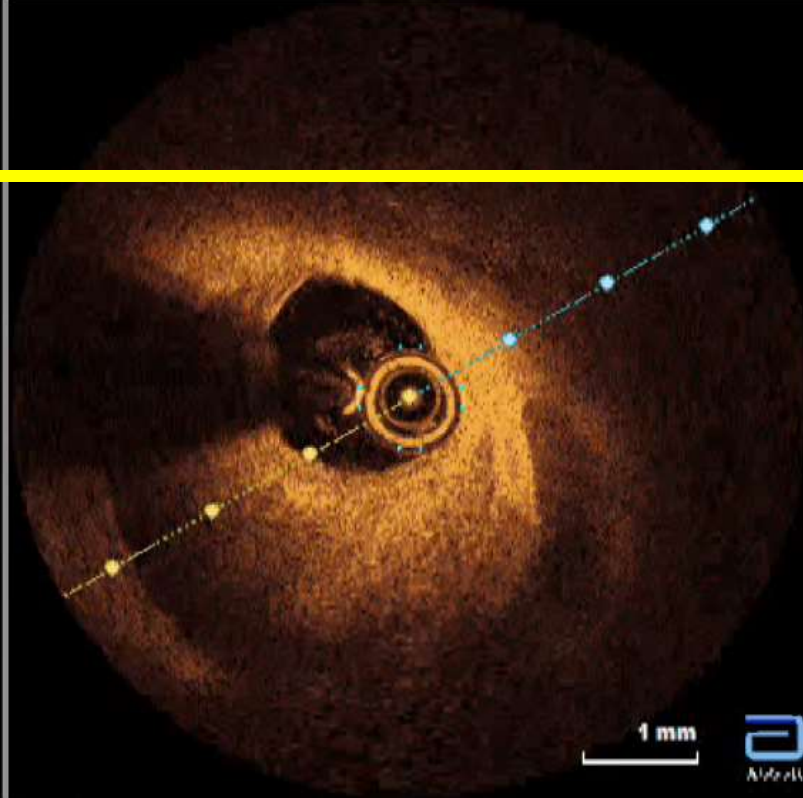
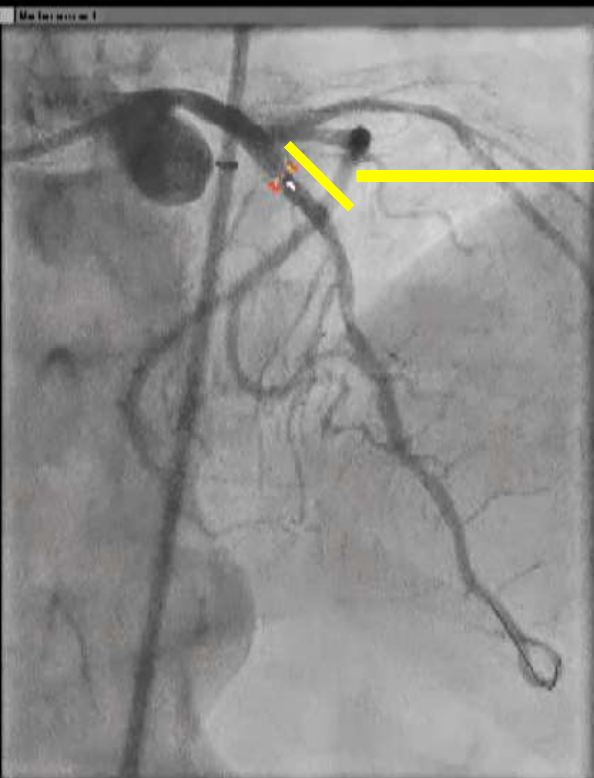
MLA 1.70mm², \varnothing =1.45mm, AS=81.7%





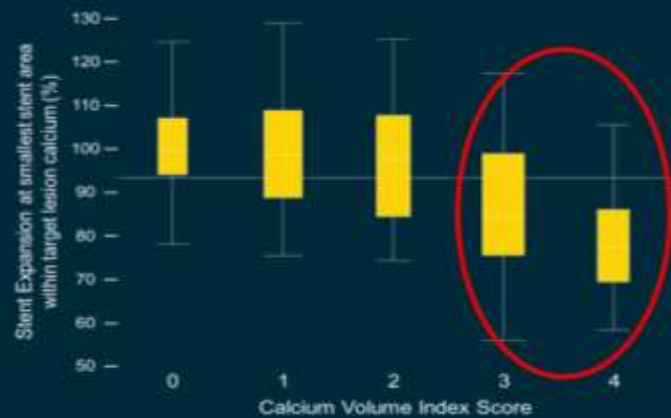
MLA 1.70mm², ϕ -1.45mm, AS-81.7%





Rule of 5's

- 0.5 mm thickness
- 5.0 mm long
- 50% vessel arc



CVI Score = 4

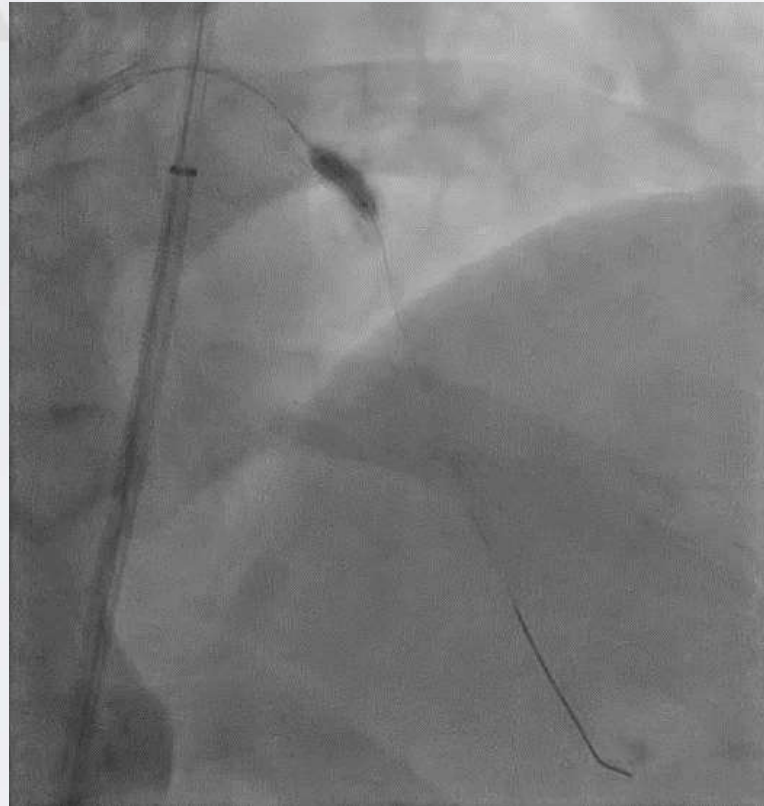
MLDMAX OCT Guided PCI Plan

- Orbital atherectomy
- 4.0x33mm Stent
- 4.0mm distal post dilation
- 4.75mm proximal post dilation

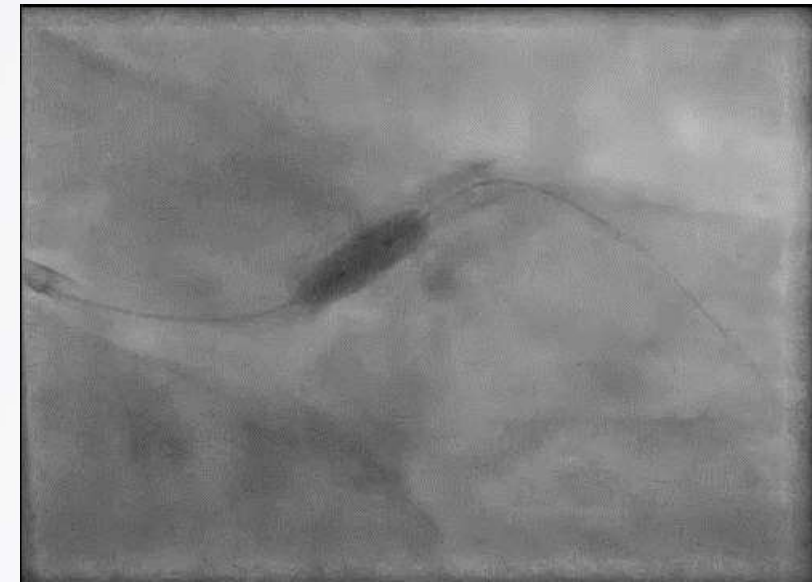
Orbital 8 runs (3 on high speed)

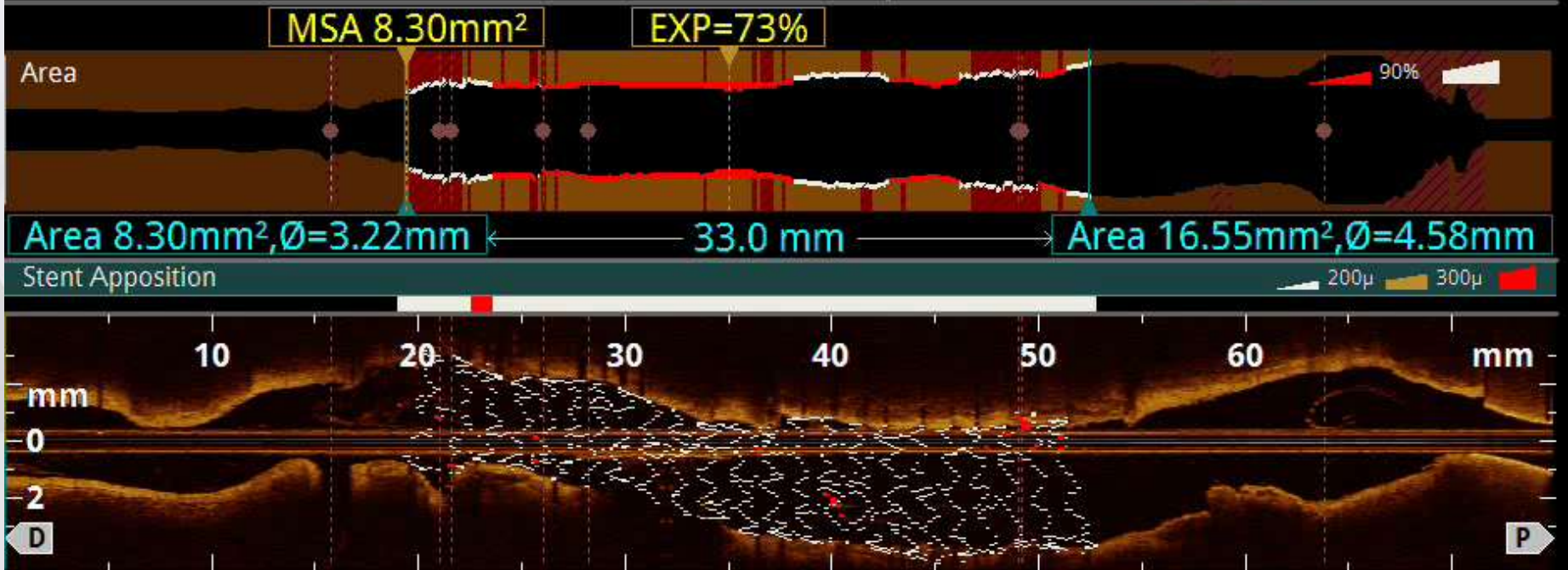
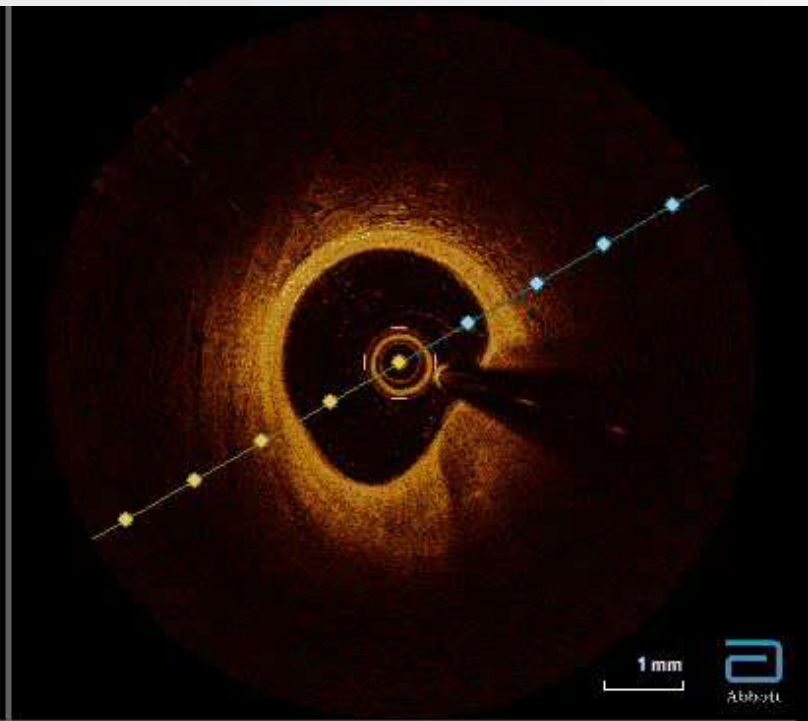
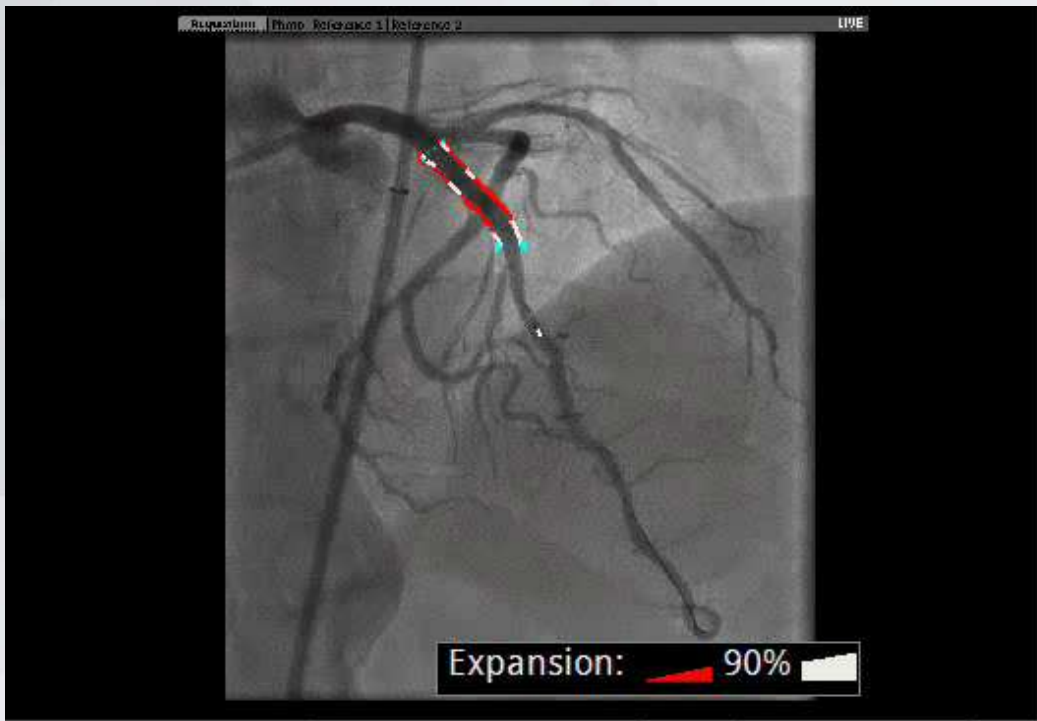


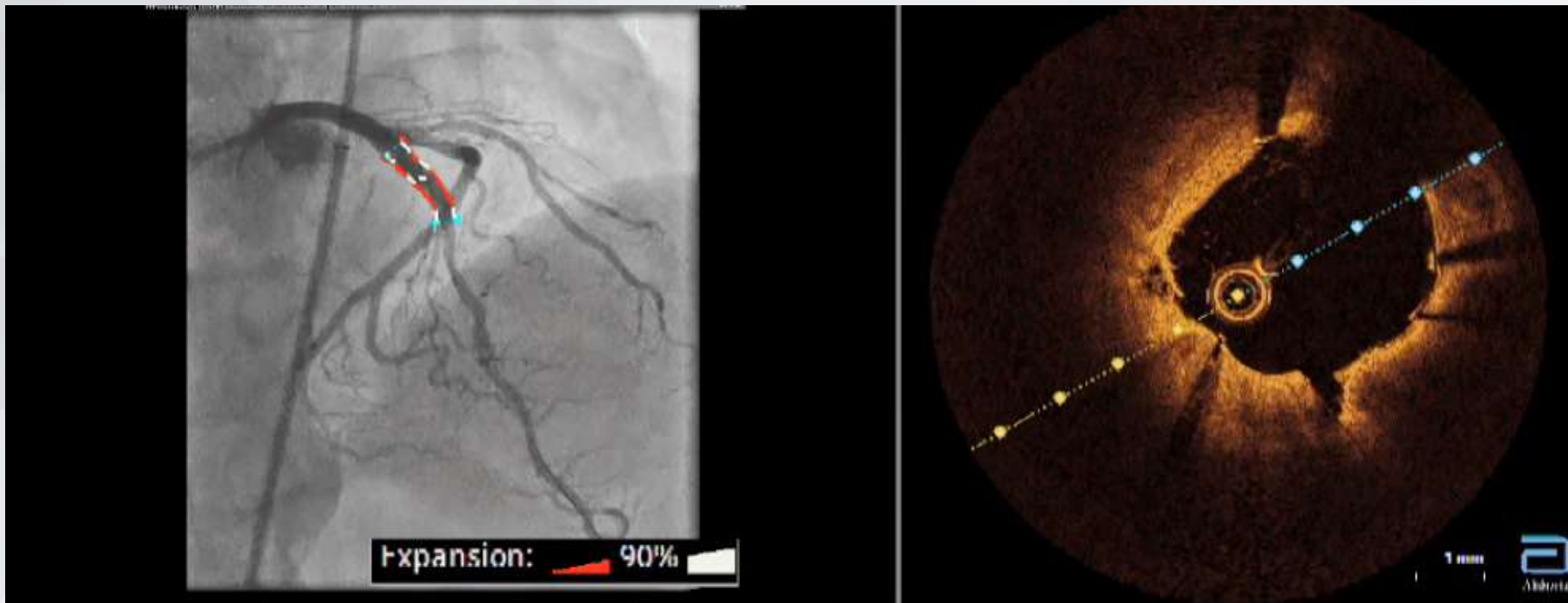
4.0mm Pre dilation



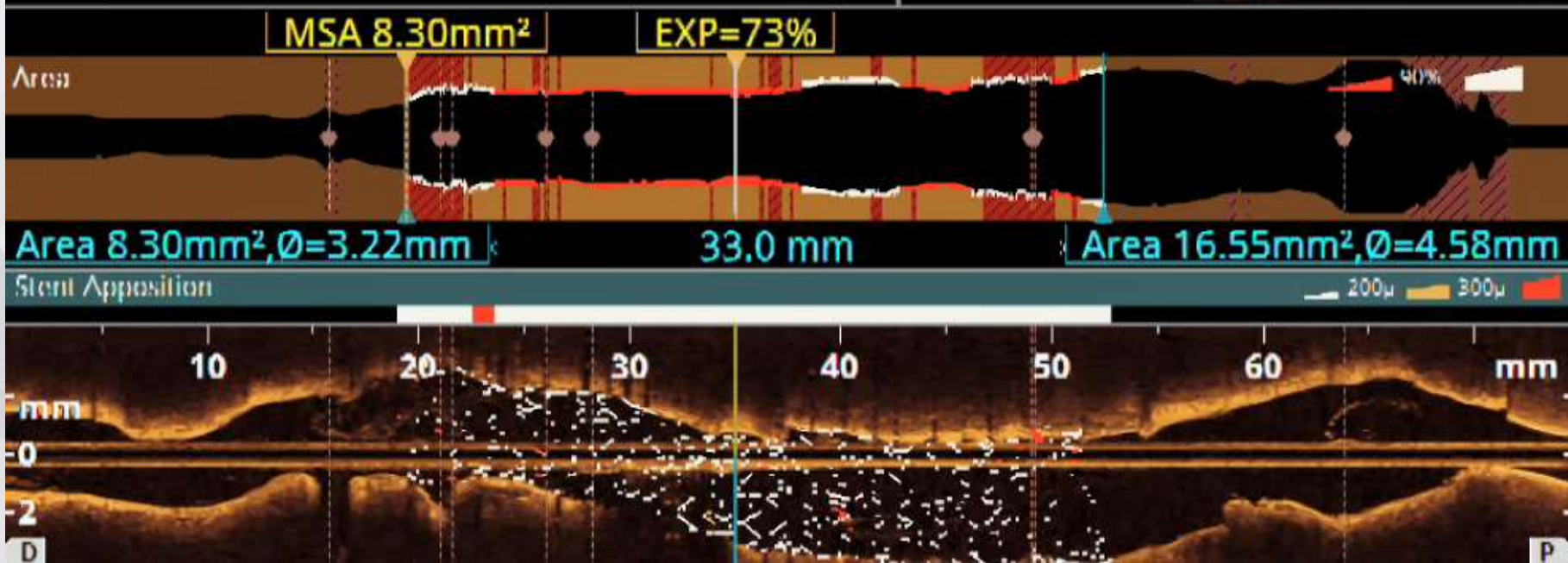
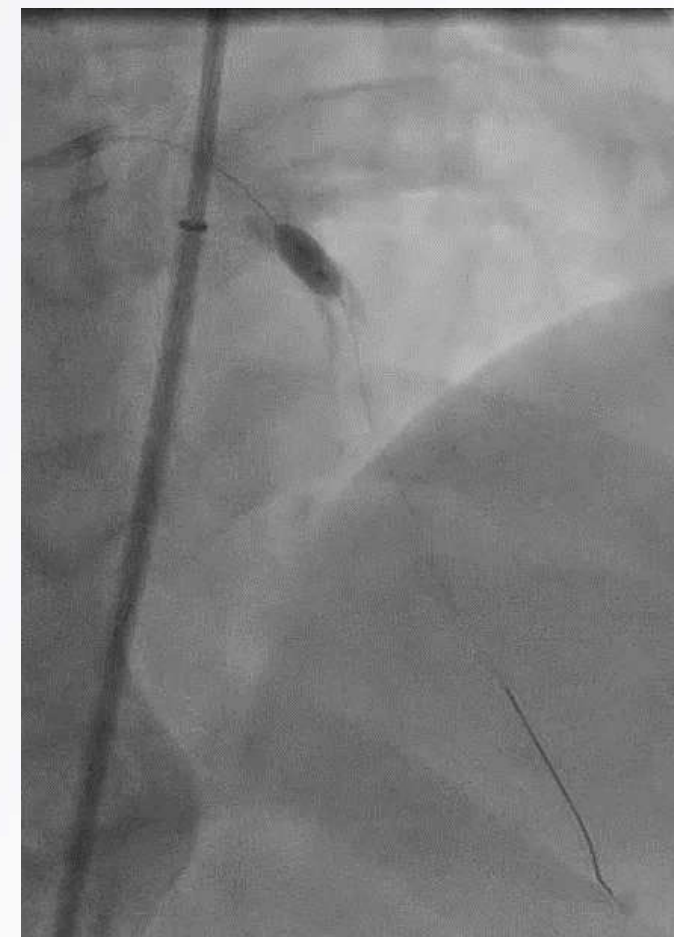
4.75mm and 4.0mm Post dilation







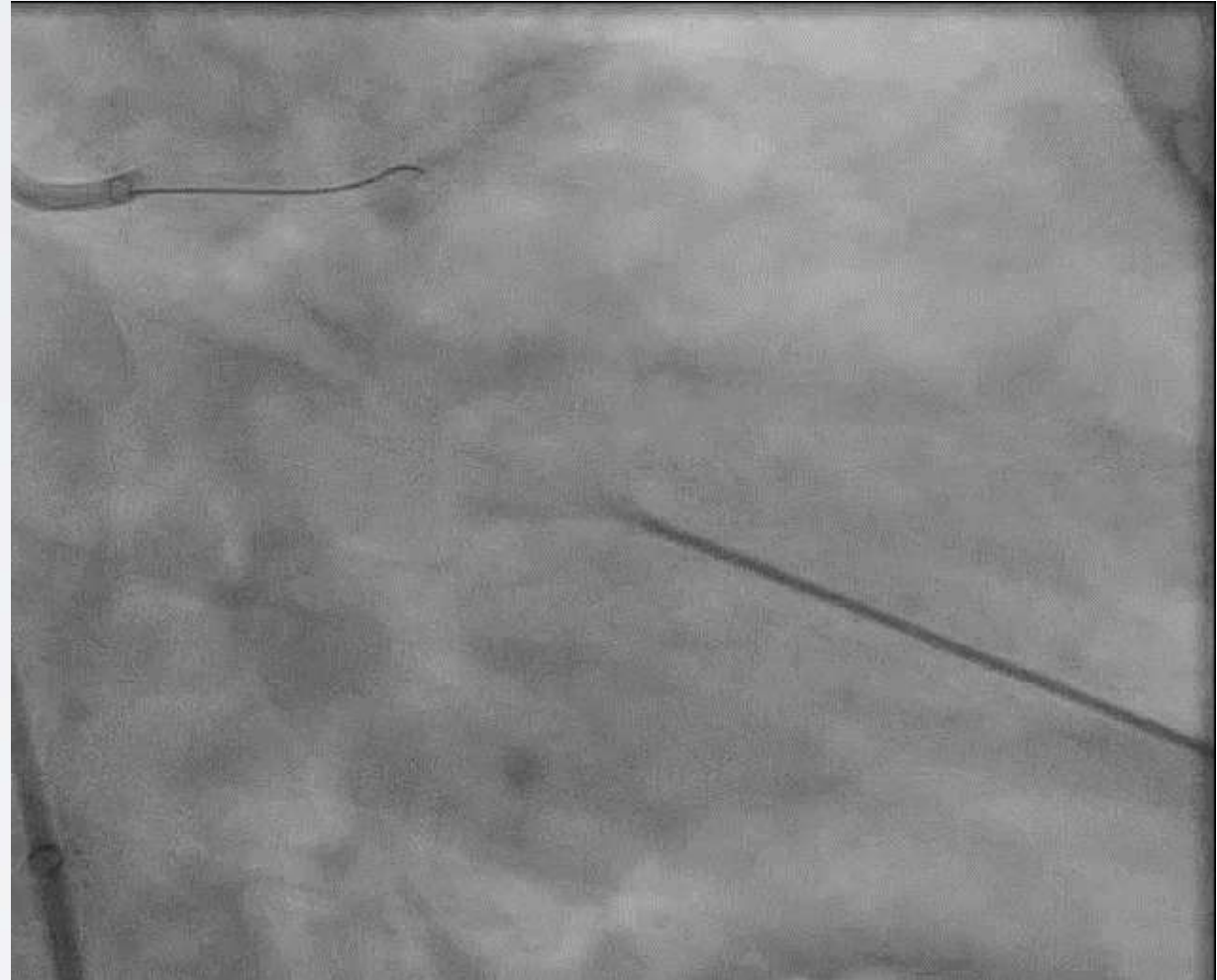
Further optimization
 5.0 x8 MM NC @ 18ATM
 > 80% expansion



Final



Final



Laser Atherectomy Indications

Clinical situation	Philips ELCA	CSI-Diamondback	BSC- Rotablator
Coronary	✓		No coronary indication
Total occlusions – traversable by guidewire	Indicated		
In-stent restenosis (316L stents prior to brachytherapy)	Indicated	Contraindicated	Warning
Saphenous vein grafts	Indicated		
Moderately calcified	Indicated		
Severely calcified		Indicated	
Failed balloon	Indicated		
Ostial lesions	Indicated		
Long lesions	Indicated		
Thrombus	Labeled (1.4/1.7/2.0)	Contraindicated	Contraindicated



Laser sizes:

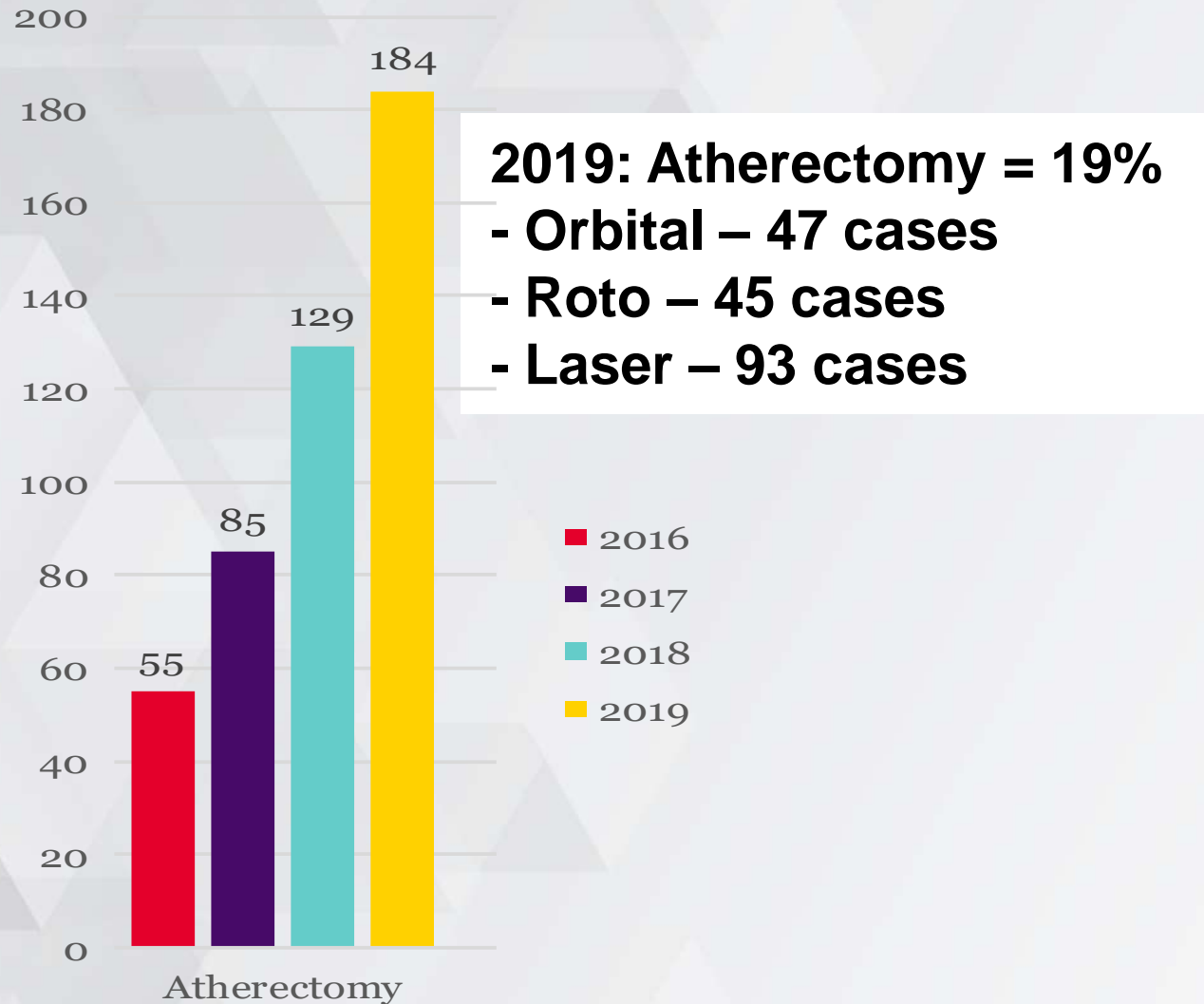
- 0.9mm
- 1.4mm
- 1.7mm
- 2.0mm

Comparing Indications for Use

<http://www.bostonscientific.com/en-US/products/atherectomy-systems/rotablator-rotational-atherectomy-system/rotablator-indications-safety-and-warnings.html>

<https://csi360.com/products/diamondback-360-coronary-orbital-atherectomy-system/>

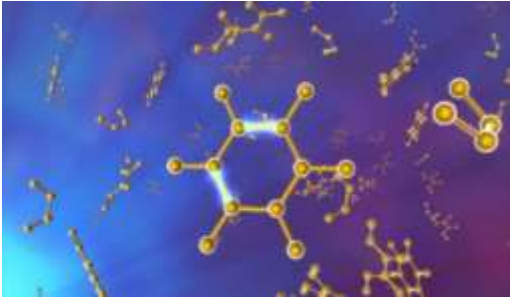


Atherectomy and Laser in Our Practice



LASER:

- In stent restenosis - 78%
- Wire across gear won't go- 9%
- Tissue ablation (thrombus, plaque debulking) - 6%
- CTO impenetrable proximal cap - 7%

Laser Use in Complex PCI: Understand Mechanisms of Action

① Light Pulse	② Acoustic Wave	③ Cavitation Bubble
Ablates mixed morphologies at molecular level by breaking molecular bonds	Impacts rigid materials and changes vessel compliance	Debulks mixed morphologies and breaks down materials
 A 3D molecular model showing a central ring of atoms with various bonds and side chains, representing the molecular level of laser ablation.	 A cross-sectional view of a blood vessel with a catheter tip inside, emitting a blue, circular wave representing an acoustic wave.	 A close-up photograph of a catheter tip with a thin wire extending from it, illustrating the mechanism of cavitation bubbles used for debulking.
Safe and effective in variety of lesion types	Treats both luminal and medial disease	Debulking for luminal gain

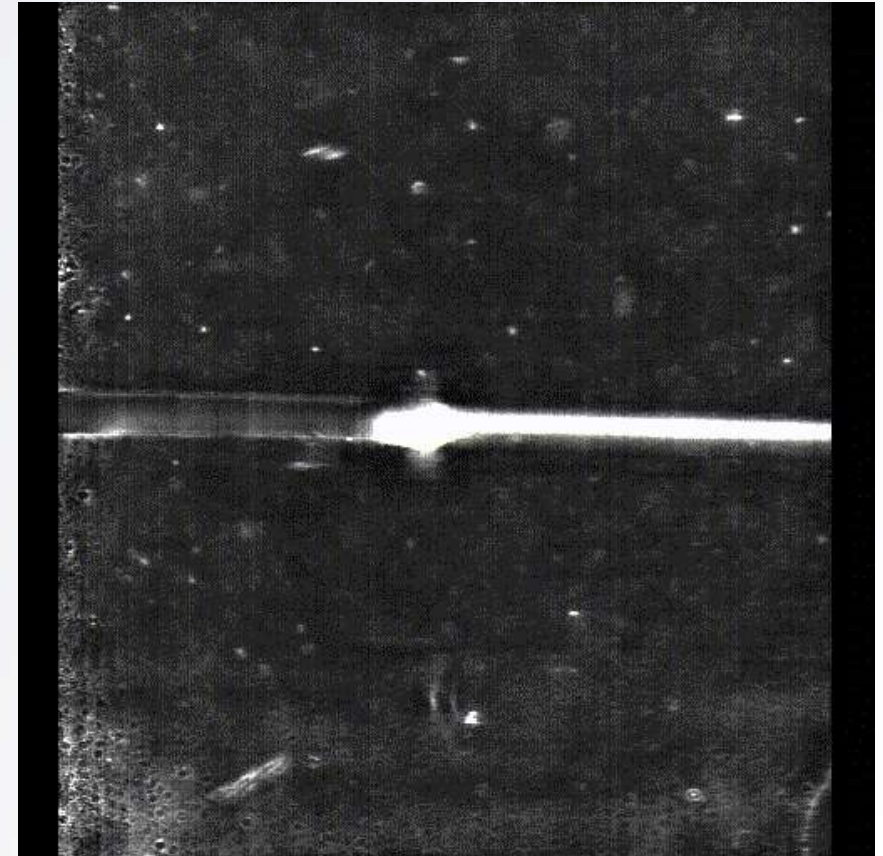
Laser Mechanisms of Action

Light Pulse



Ablate forward

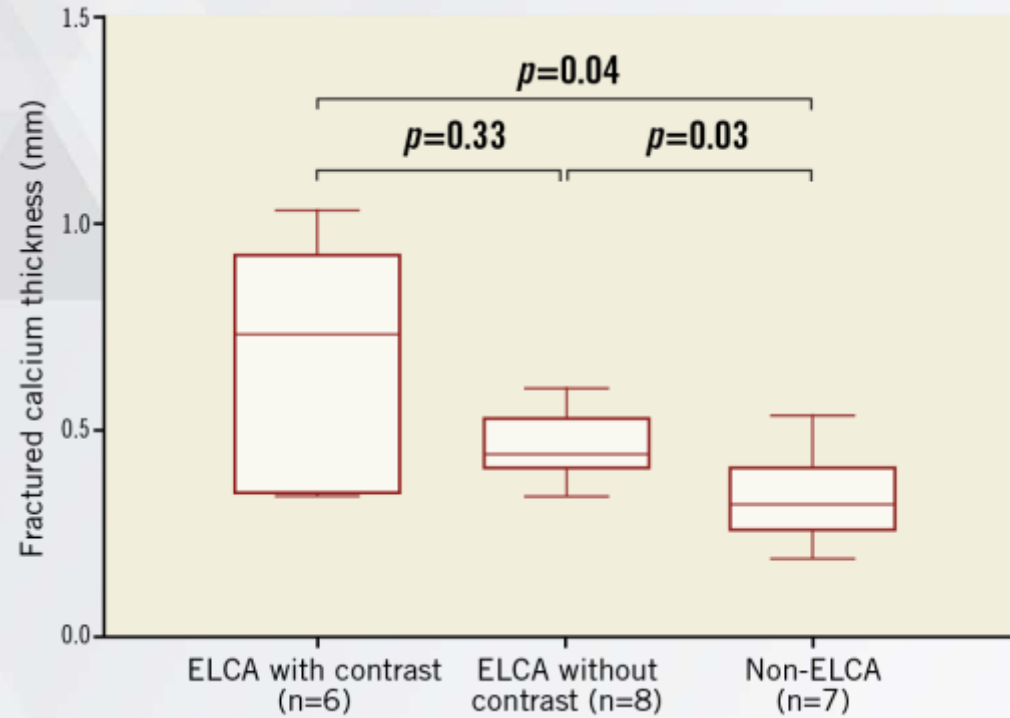
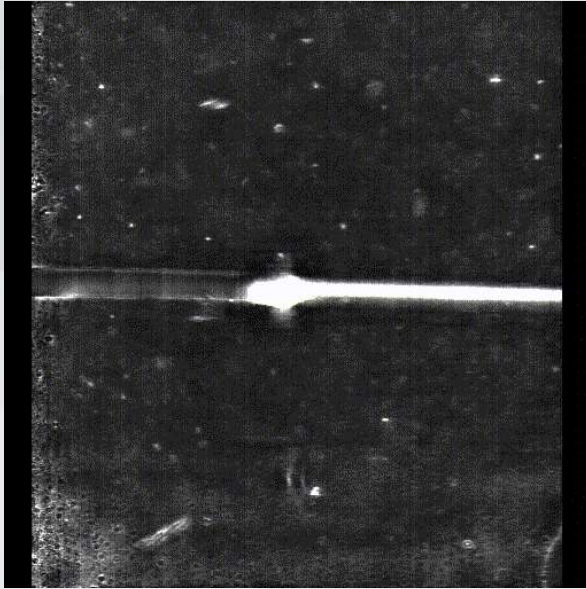
Acoustic Wave



**Pressure wave - forward
and backward**

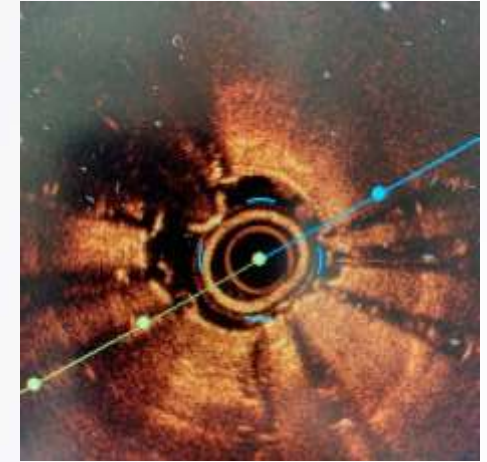
Laser Facilitates Stent Expansion

Acoustic Wave

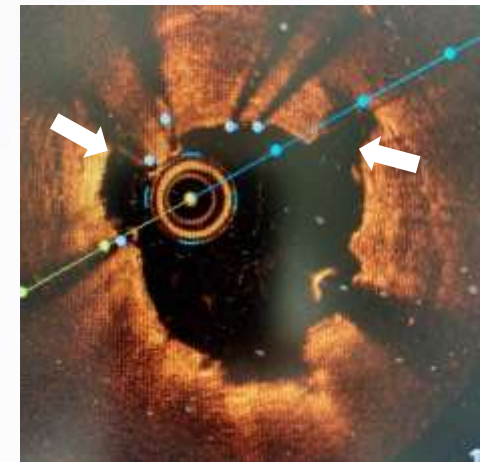


LAD Acute Stent Regret

Pre



Post



EuroIntervention 2019;15:e279-e288. DOI:
10.4244/EIJ-D-18-00139

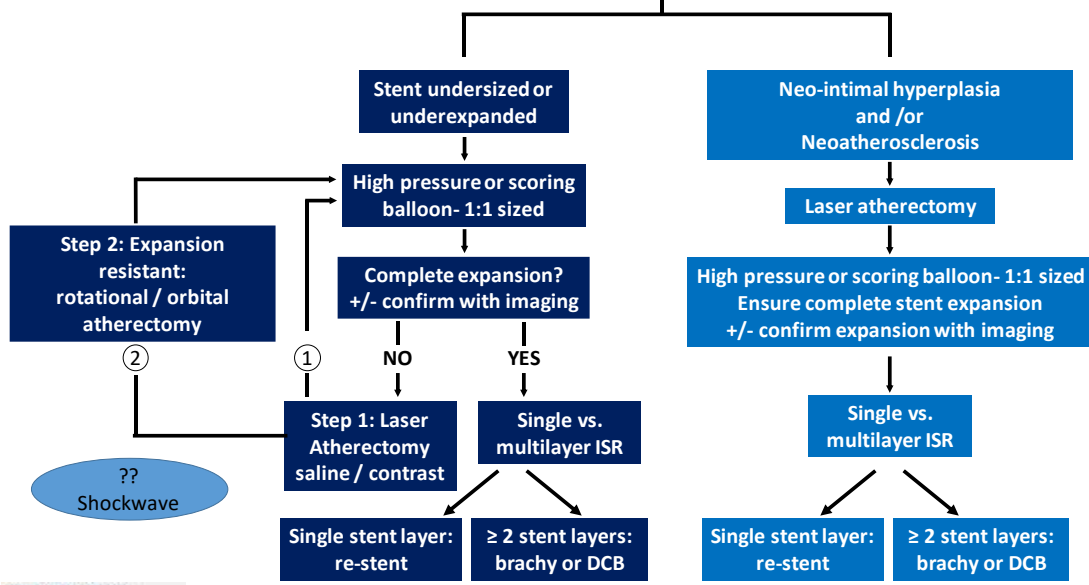


Laser in Contrast

ISR: Laser Facilitates Stent Expansion

ISR Treatment Algorithm

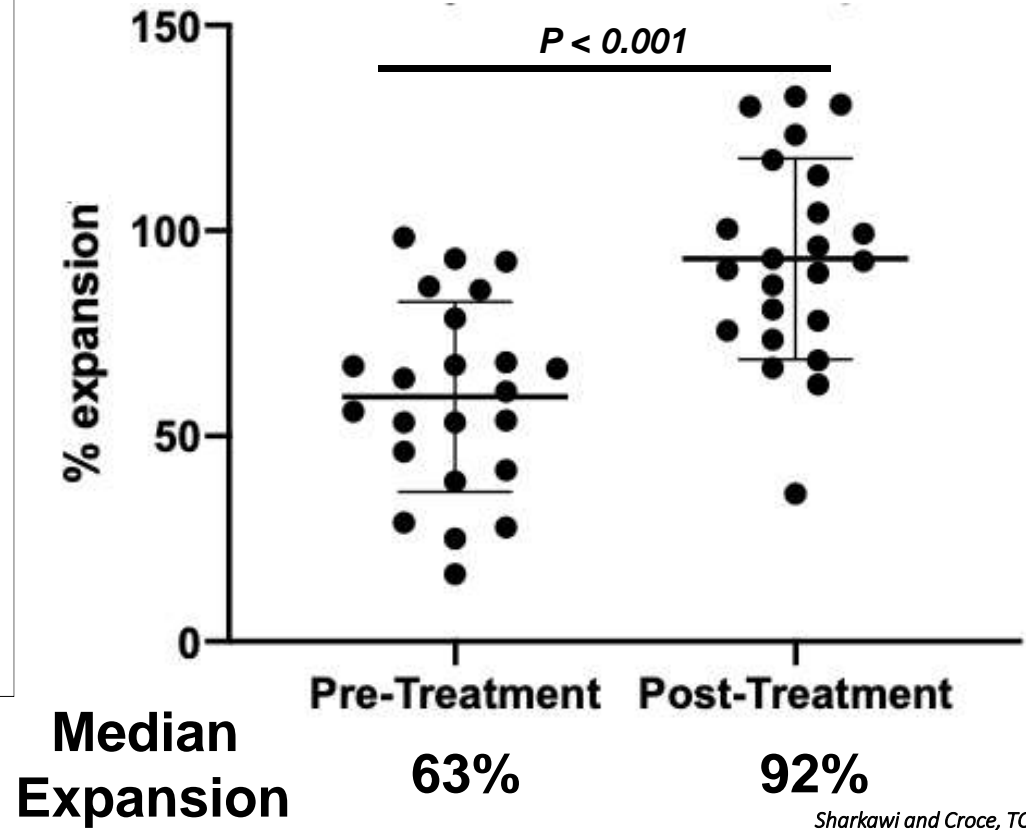
- 1) Obligate initial intravascular imaging: diagnose cause of stent failure
- 2) Treatment goal: maximize stent expansion and lumen size



Kevin J. Croce MD, PhD



Resistant Multilayer ISR Stent Expansion after Laser Atherectomy



Sharkawi and Croce, TCT 2020

Laser Atherectomy – Multilayer ISR Brachy Case

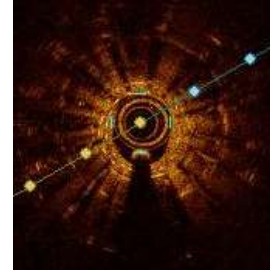
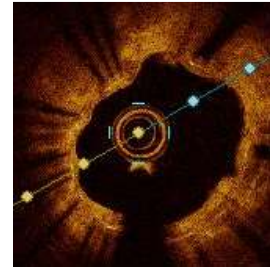
Recurrent angina - Recurrent recalcitrant ISR
3 layers of underexpanded DES



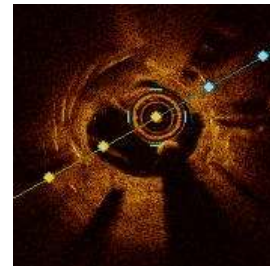
PROX



DISTAL

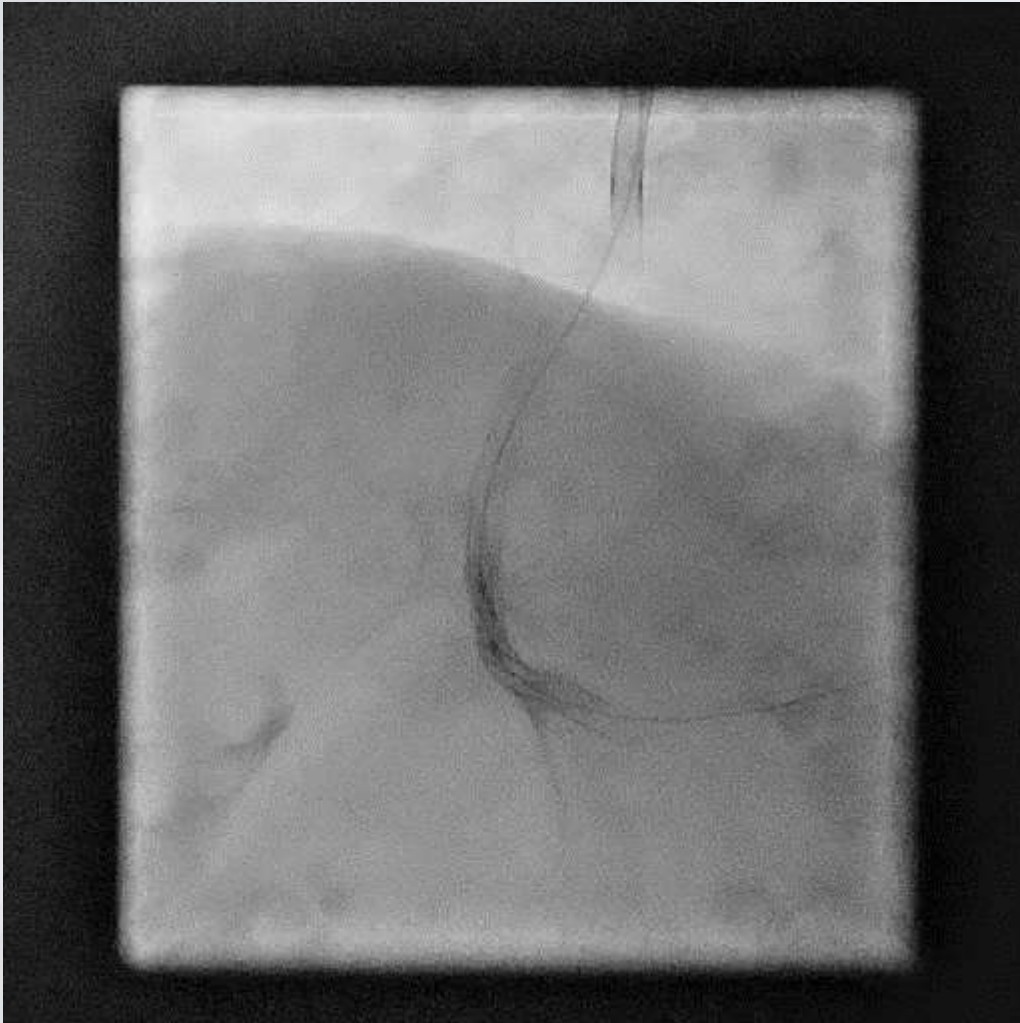


3 layers under-expanded stent



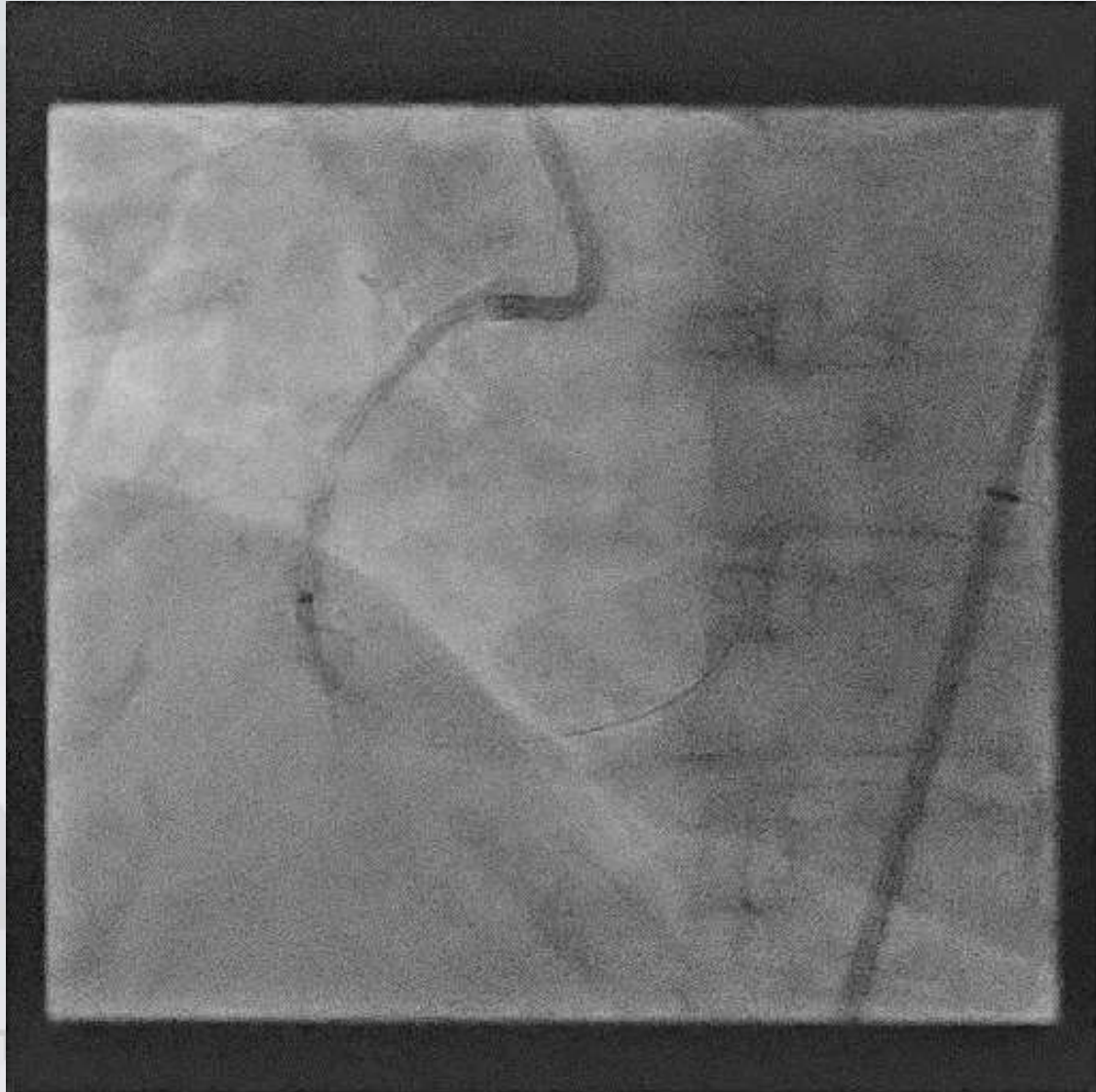
Laser Atherectomy—Brachy Case

- Balloon dilation -Unexpandable
- 3.0x6mm angiosculpt at 30atm



Laser Atherectomy—Brachy Case

Laser atherectomy 1.4mm Laser @ 60/40
on contrast



Balloon dilation post laser

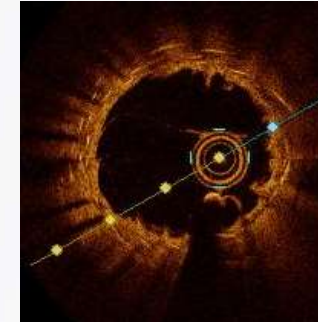
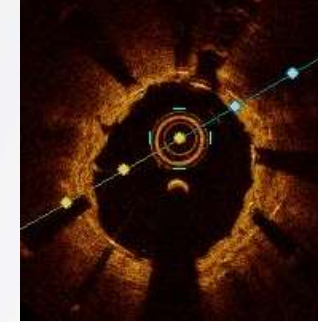


Laser Atherectomy—Brachy Case

Brachy treatment
Angiographic result – no new stents

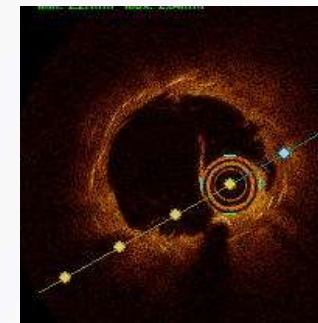


PROX



Final
OCT

DISTAL



Laser Atherectomy – Wire Across Gear Won't Go



LCX and RCA CTO

RCA CTO Long Standing

64M CCS 3 Angina

7F Radial

Laser Atherectomy – Wire Across Gear Won't Go

True Lumen Wiring

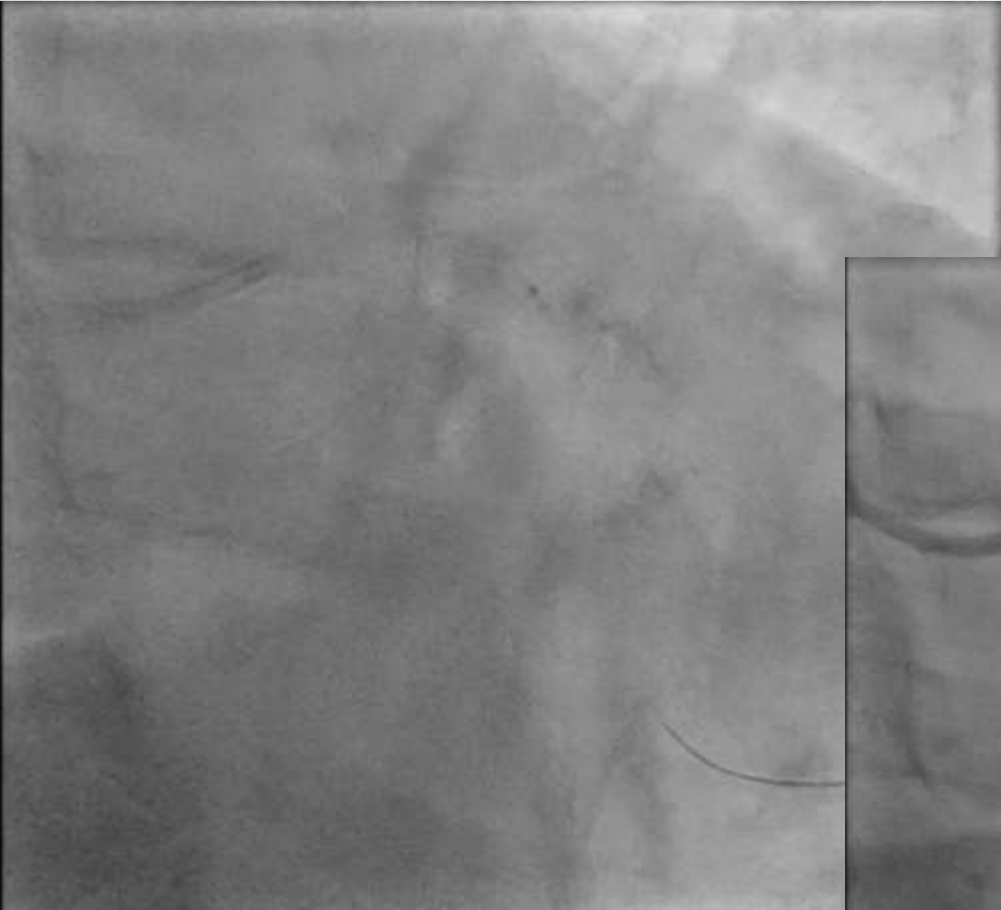
*No cross
-Turnpike LP and
-Turnpike Spiral
-1.5mm x15 mm Takeru*

Wire Across Gear Wont Go Algorithm

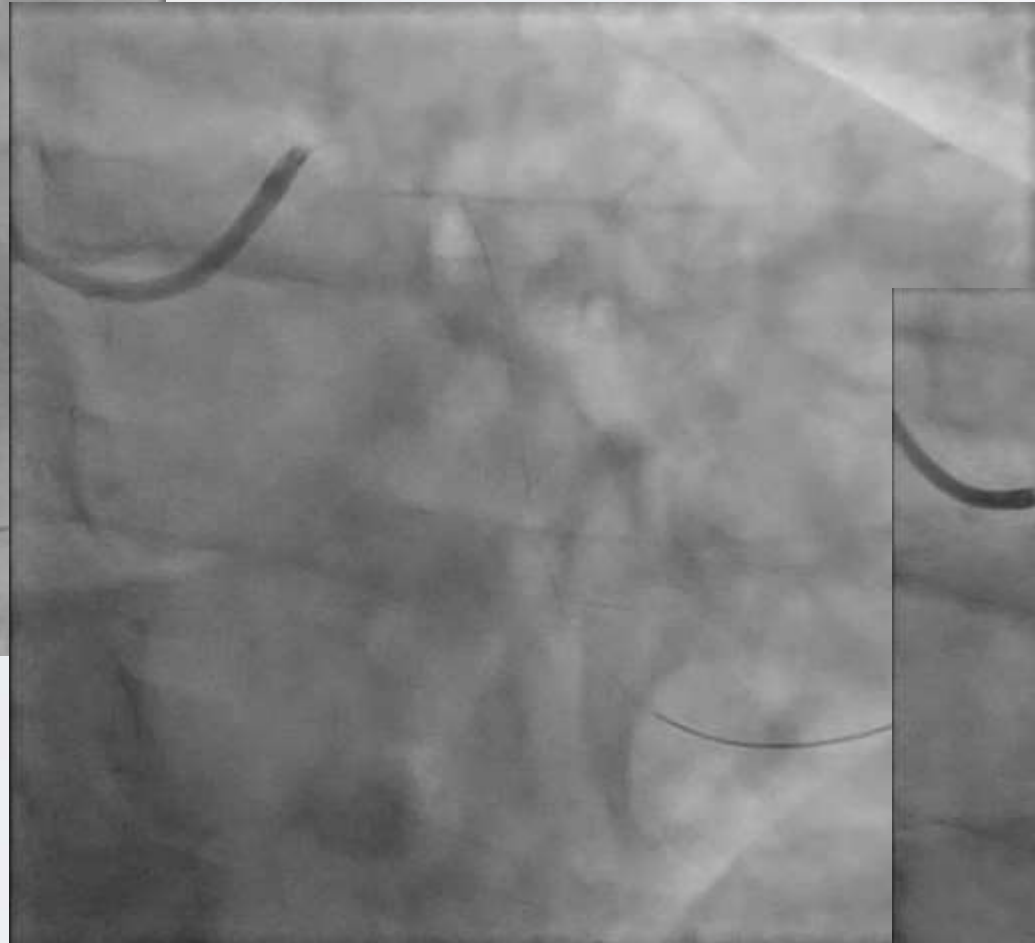
- Increase backup
 - Better guide
 - Guide extender
 - Anchor balloon
- Add a microcatheter
 - Torqueable microcatheter – Teleport Control, Corsair, Corsair Pro
 - Lower profile microcatheter – Teleport, Turnpike LP, Caravel
 - Threaded catheter – Turnpike spiral, Turnpike gold
- Small balloon with progressive inflations
- Balloon-assisted microdissection (BAM) – “Grenadoplasty”
- Laser
- Subintimal plaque modification
- External trap of guide extender in vessel with a second guide/balloon
- Cross with rotawire/RG3/viper and do atherectomy
- Tip injection to hydraulically modify/dissect plaque - “Carlino”

0.9 Laser 60/60

Laser Atherectomy – Wire Across Gear Won't Go



Timi 3 Flow Post Laser



***OCT Guided PCI
Final Result***





Summary:

Orbital and Laser Atherectomy in Complex PCI

- Intravascular imaging should be used to guide complex PCI and calcium modification

Laser Atherectomy:

- ISR and acute stent regret
- Wire across gear won't go
- Debulk – thrombus

Orbital Atherectomy:

- Large vessels calcium
- Calcified nodules
- ISR – after laser (off label)

