

Debulk or Regret!

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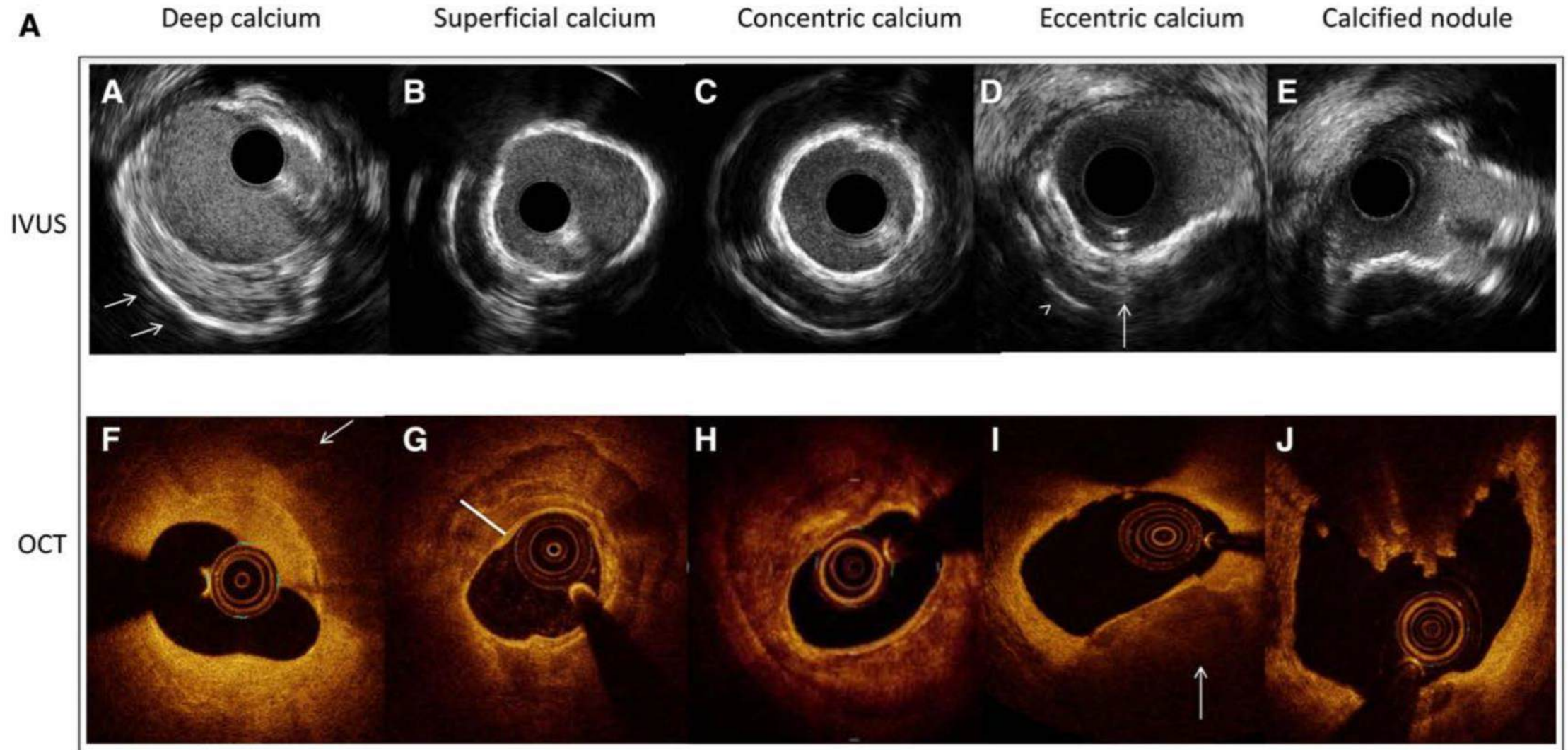
Conflict of interest

- *Honoraria, proctorship, speaker's fee*

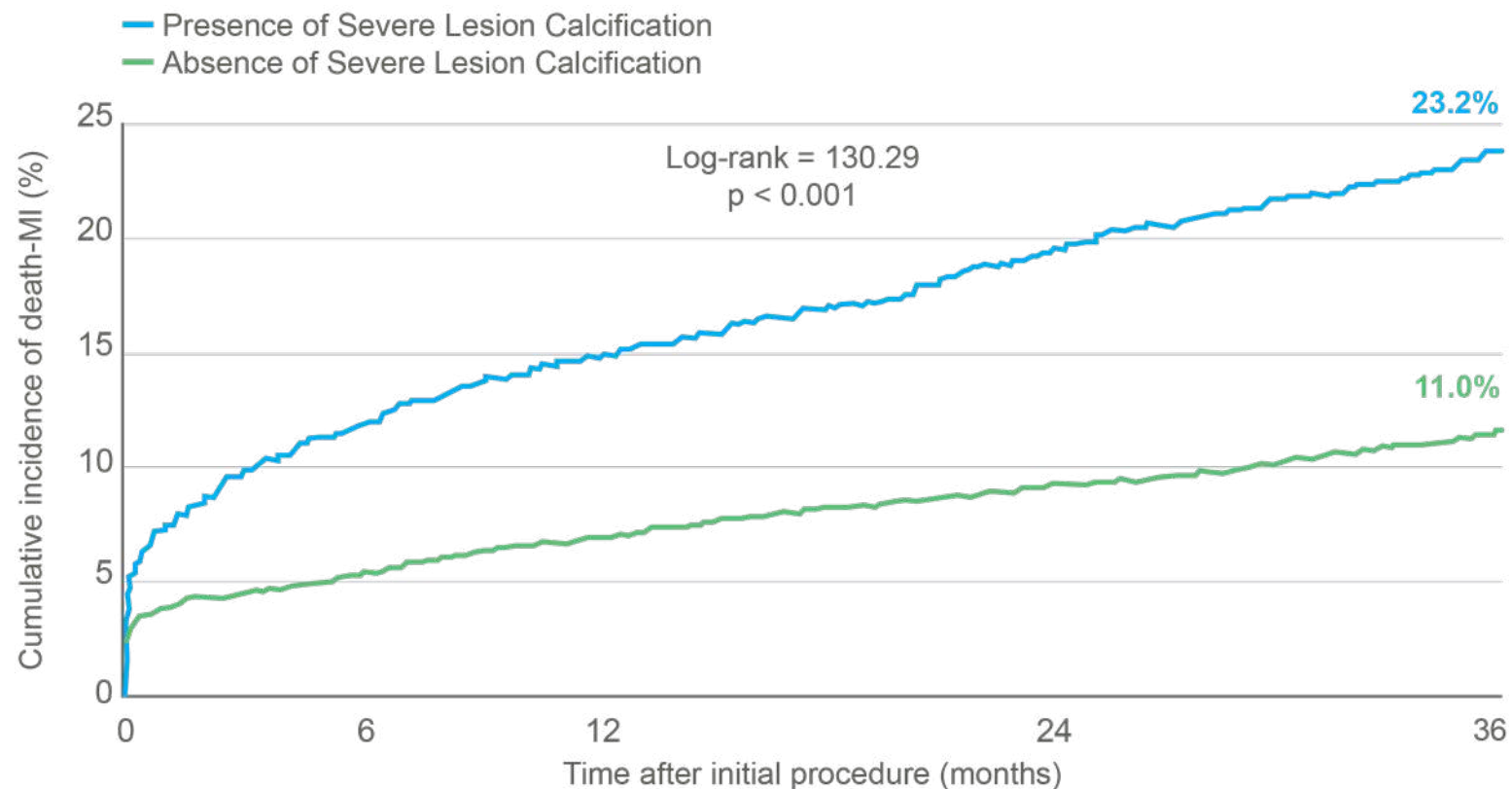
- Abbott Vascular
- Boston Scientific
- Philips
- Spectranetics
- Volcano
- Vascular Perspective
- Merrill
- Svelte
- EPS Medical
- Astra Zeneca
- Abiomed
- Translumina
- Elixir Medical

- Coronary calcium is becoming more and more prevalent in the modern day cath lab / CHIP era
 - Aging population
 - Comorbidities
 - “Downstream” presentations
- Calcified lesions are among the highest risk lesions we treat
 - Short term pain/suffering + risk
 - Long term outcomes

Not all Calcium is the same



What are the real-world impacts of coronary calcium?



Patients with Type 2 Diabetes

- Prospective cohort (n=735)
- Mean age 63±5 years
- ≥1 additional risk factor
- No history or symptoms of CAD
- Recruited & performed CT for coronary artery calcium scoring (CACS) during the years 2006-2008

Median follow-up 17.3 years

Outcome: 1st event of MACE
[MI, stroke or all-cause death]

Main findings

- The predictive value of CACS in asymptomatic diabetics is retained over 17 years of follow-up, particularly for MI.
- CACS increases the discriminatory capacity of MESA 10-year CHD risk score for CV events.
- The distribution of calcifications across multiple coronary arteries provides additional prognostic information.



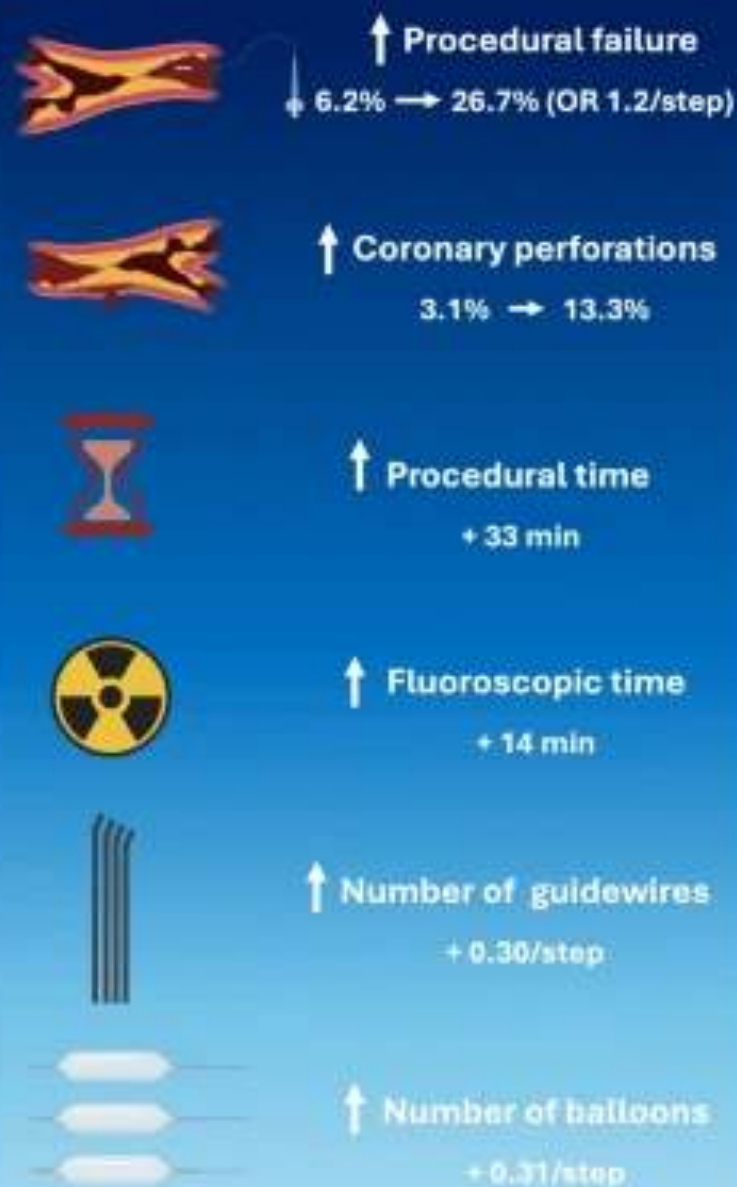
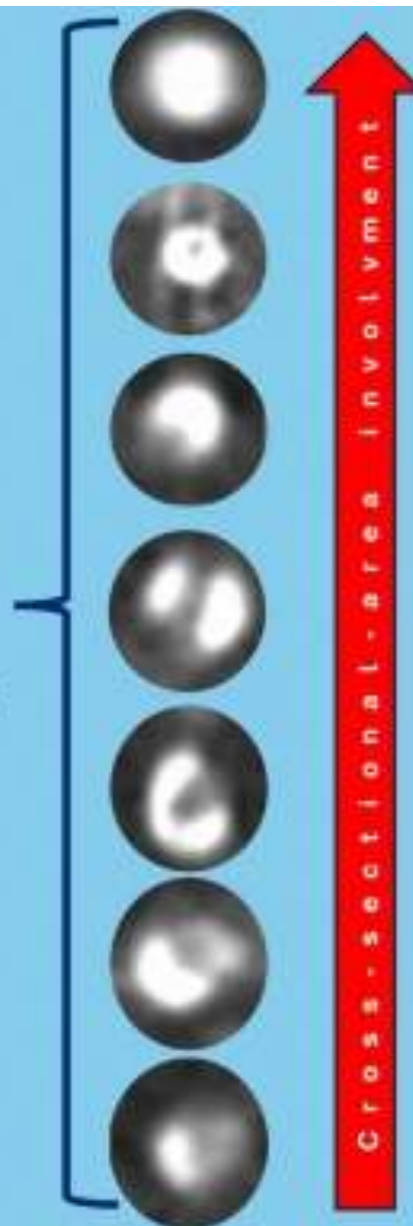
167 patients from two
high volume CTO
centers



CCTA before CTO-PCI



A novel
CCTA
calcification
pattern
classification

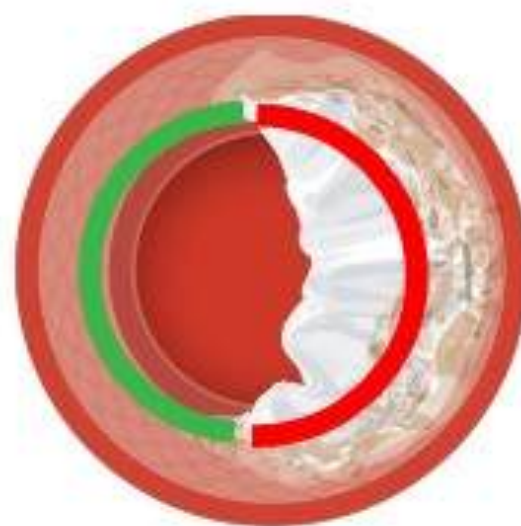


WHY IS CALCIUM TYPE RELEVANT?

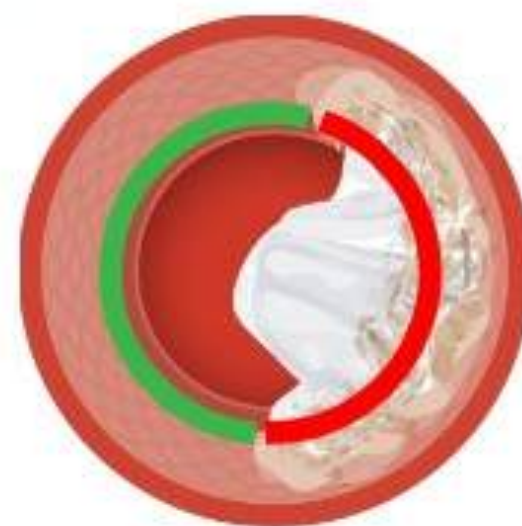
Compliance pattern



Concentric



Eccentric



Nodular

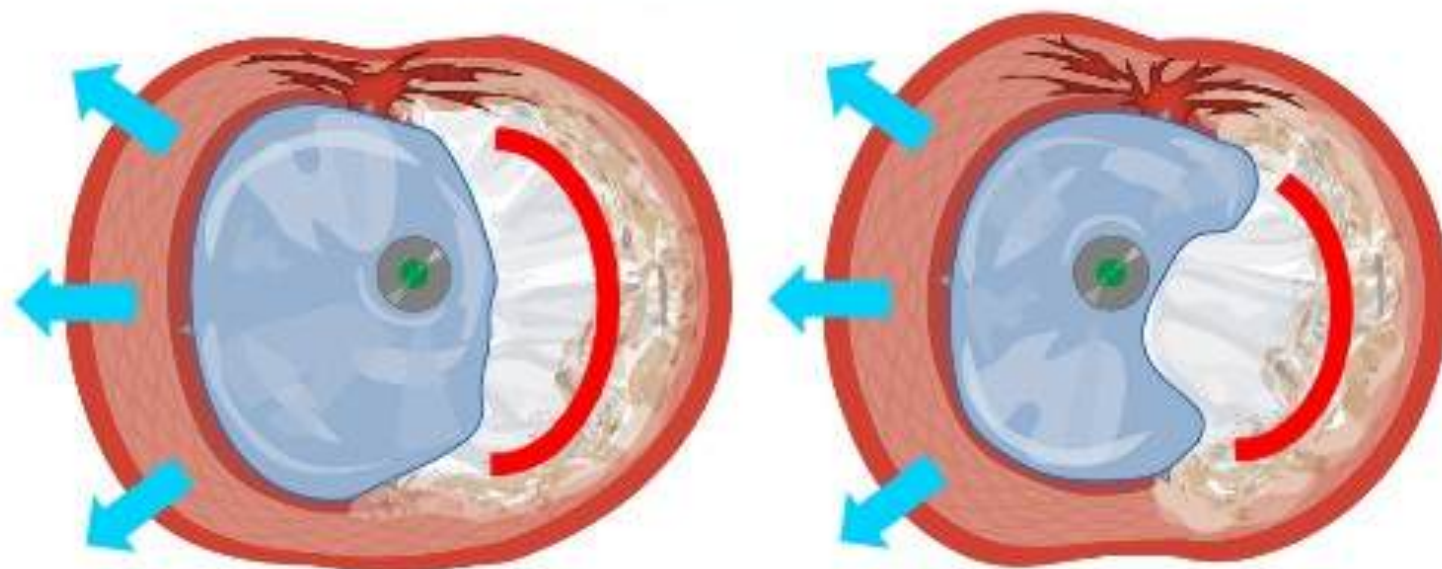
 Low compliance

 High compliance

Alfonso F et al, JACC 1994.

WHY IS CALCIUM TYPE RELEVANT?

Balloon-based devices



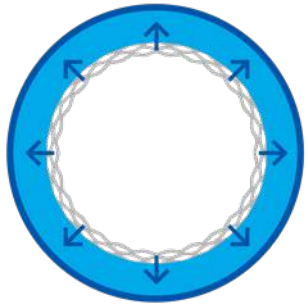
Eccentric

Nodular

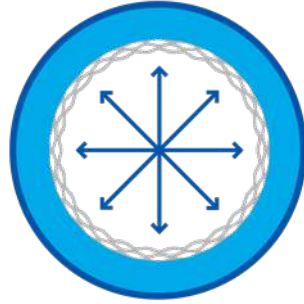
 Low compliance

 High compliance

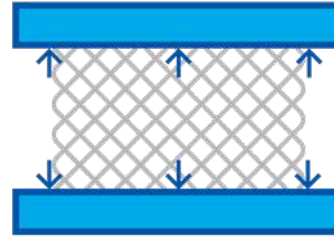
Fundamentals of stent use



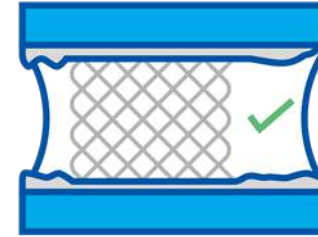
**Well sized
for vessel**



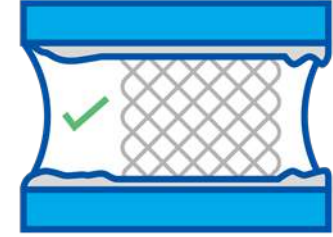
**Symmetrical
Expansion**



**Apposed
throughout length**

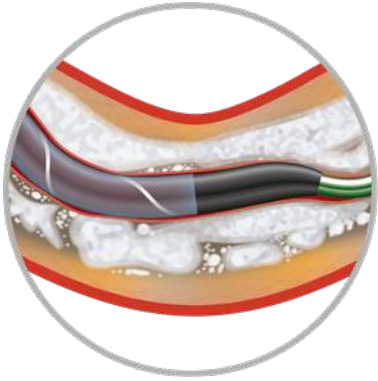


**No distal edge
dissection**

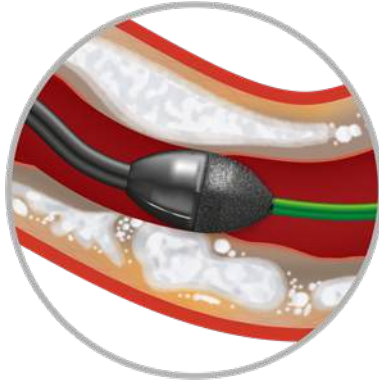


**No proximal
edge dissection**

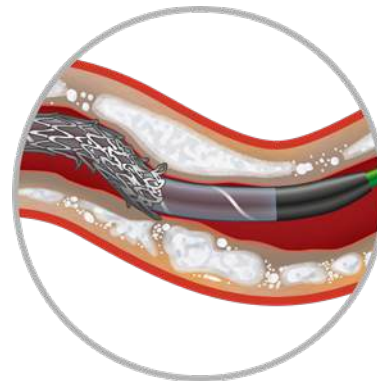
Effect of calcium



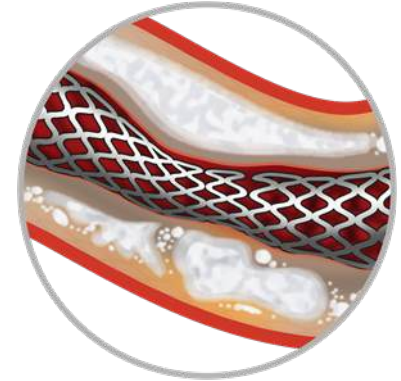
Impairs equipment delivery



Requirement for specialized equipment



Strut / polymer damage and impaired drug delivery

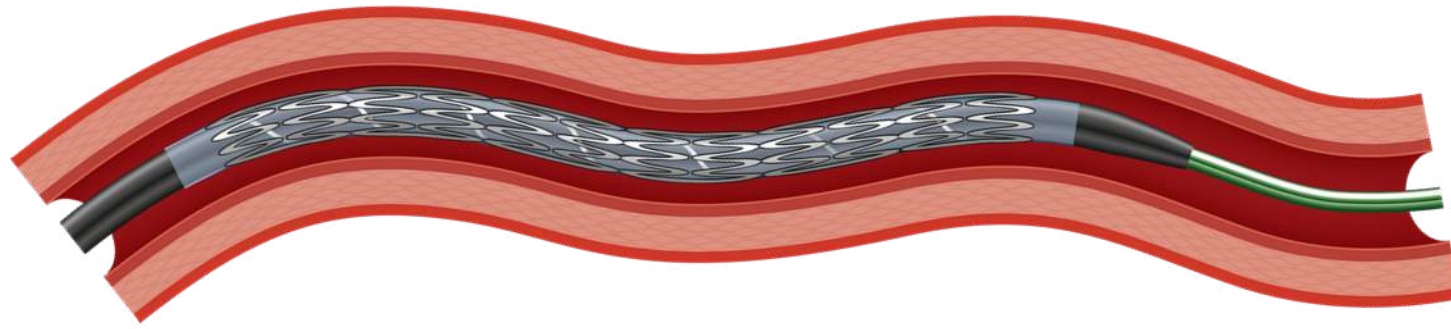


Sub-optimal stent deployment

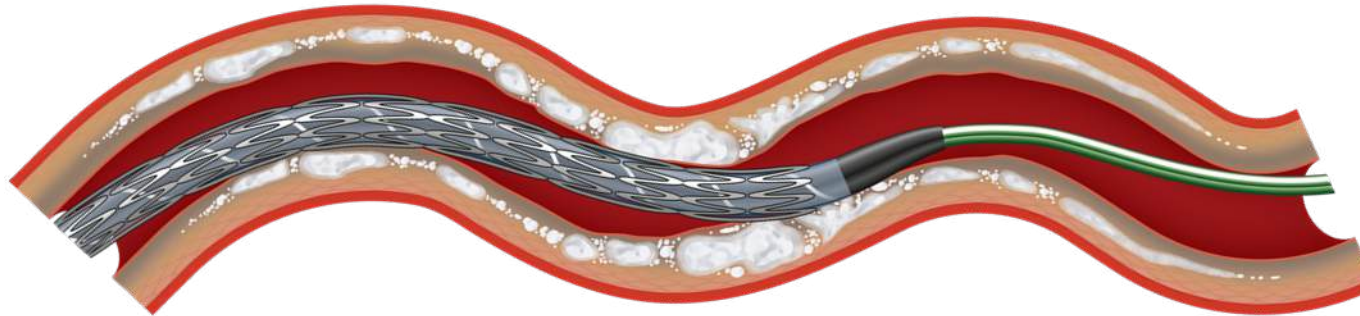


PCI of heavily calcified lesions is associated with procedural complications and/or late adverse events

How does decreasing compliance affect coronary angioplasty?



Elastic vessels deform,
(i.e., following wire passage)
facilitating device delivery

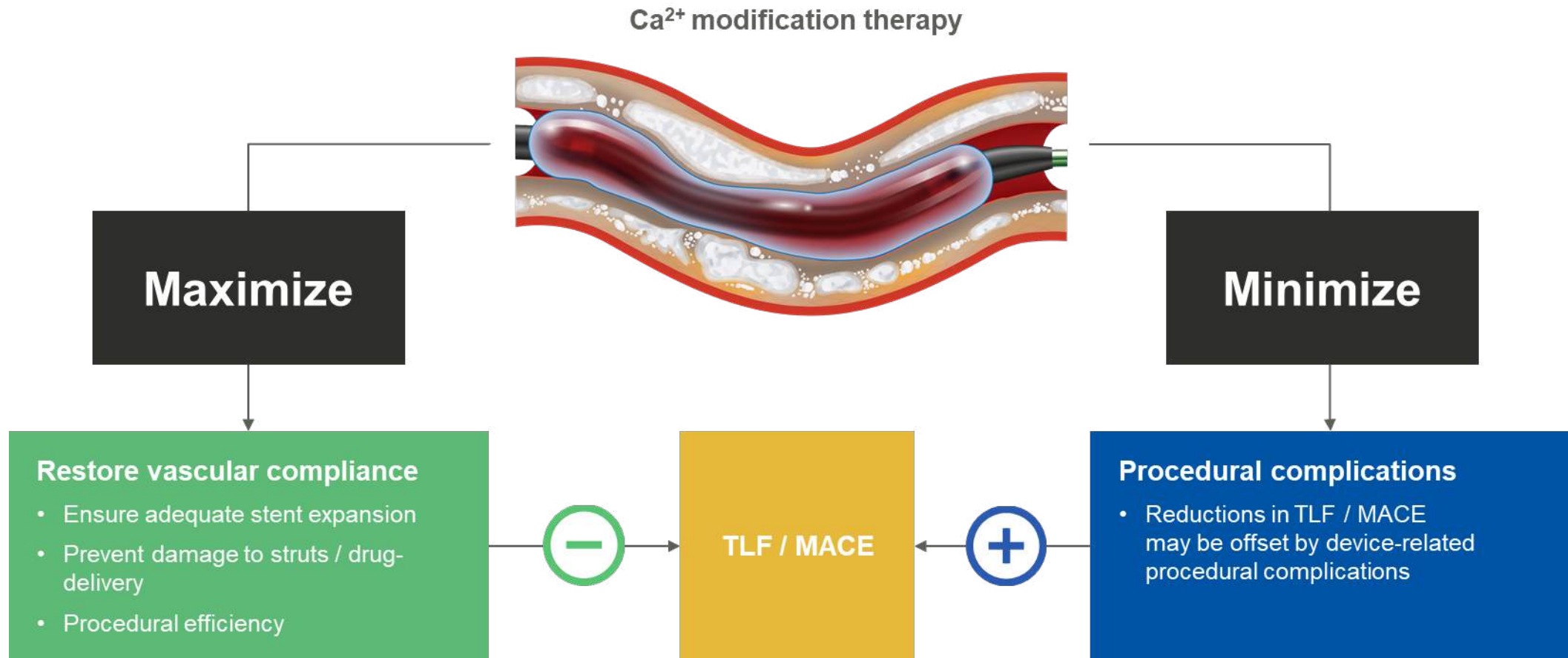


Inelastic (calcific) vessels
remain rigid, thereby resisting
device passage

Why Modify

- Facilitates Procedural Success when treating complex lesions
 - *Enabling lesion access*
- Plaque Modification: Making the complex simple
 - *Changes lesion compliance*
 - *Minimizes vessel trauma*
 - *Creates larger MLD's*

Impact of calcium modification on PCI outcomes



Goals of therapy

- Cross the lesion
- Modify the lesion
 - **Volume reduction of CA++**
 - **Only debulking RA, OA**
 - Fracture CA++



**Maximal
Luminal
Gain**

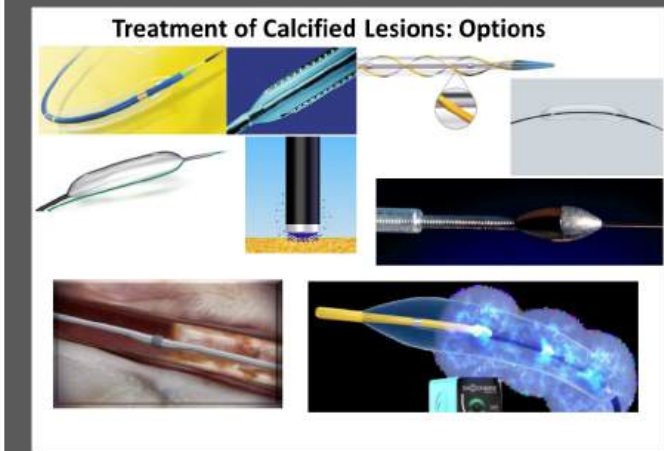
AVAILABLE DEVICES.... WHEN TO USE WHAT?

NON-ROLE

- NON-COMPLIANT BALLOONS
- CUTTING BALLOONS
- SCORING BALLOONS
- HI PRESSURE OPN BALLOONS

ROLE

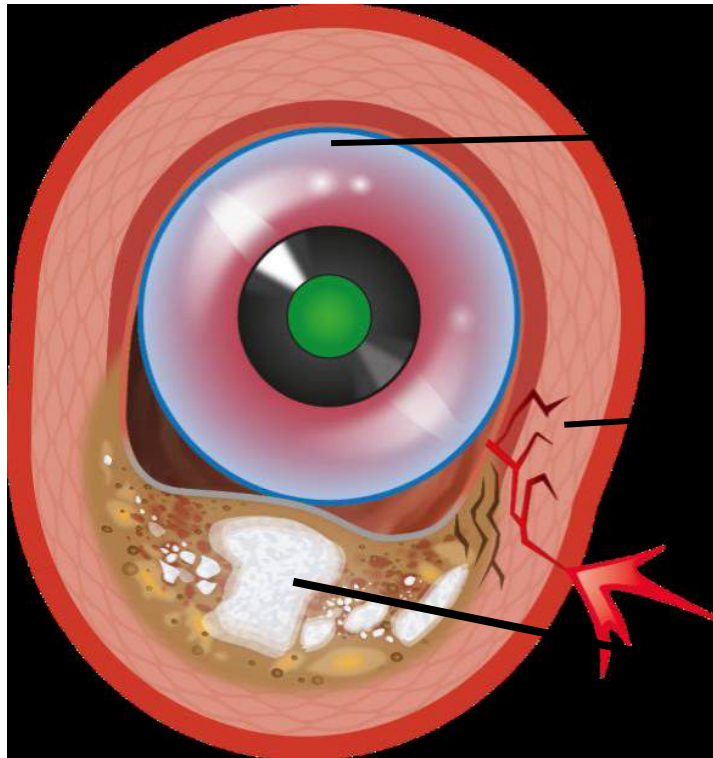
- **R**OTATIONAL ATHERECTOMY
- **O**RBITAL ATHERECTOMY
- **L**ITHOTRIPSY: IVL, LITHIX
- **E**XCIMER LASER ATHERECTOMY



- ***No one device offers all that is required***
- *They are just tools , and one should always select the right tool for the right job.*
- Need to know the mechanism and properties
- RA & OA require special wire 0.009, 0.012, **NO WIRE NO RA or OA**
- Personal and departmental experience are crucial

Limitations of Conventional Tools in Calcium

Balloon-based Therapies



Cross sectional view

High pressure balloons preferentially expand away from calcium, having limited effect on eccentric calcium.

High pressure inflations are predisposed to major dissection and perforation -often at the interface between calcium and healthy tissue.

Balloons are typically unable to modify deep or very thick calcium.

Atherectomy: Two Approaches

Illustrative examples, results may vary.



Image: Boston Scientific website¹



ROTATIONAL ATHERECTOMY	ORBITAL ATHERECTOMY
Uni-directional, front cutting, risk burr entrapment ²	Bi-directional differential sanding and pulsatile forces ⁴
Concentrically mounted burr rotates to create a lumen same size as the burr, larger vessels may require multiple burrs.	Eccentrically mounted crown creates centrifugal force: - Designed to treat 360° of the vessel for improved compliance - Treat 2.5 mm to 4 mm vessel with a single crown
May not allow blood and micro-debris to flow past the engaged burr ³	Allows for continuous flow of blood and saline during orbit ⁴

1. Boston Scientific website: <https://www.bostonscientific.com/en-US/products/atherectomy-systems/rotational-atherectomy-systems/rotablator.html> Accessed 23 Mar 2020.

2. Gupta, T. et al. Interv Cardiol. 2019;14(3):182-189.

3. Solom, Y. et al. IntervCardiol. 2016;11(1):33-38.

4. Shlomm, E. et al. Exp Rev Med Dev. 2017;14(11):867-879.

Rotational atherectomy

First application **1989**

Lille, France (Bertrand)

Essen, Germany (Erbel)



Rotablator : Catheter Components

Forward Pressure defines depth of diamonds
“digging” into vessel



Continuous movement keeps device from becoming
Warm especially in angled/tortuous vessels

Differential Cutting

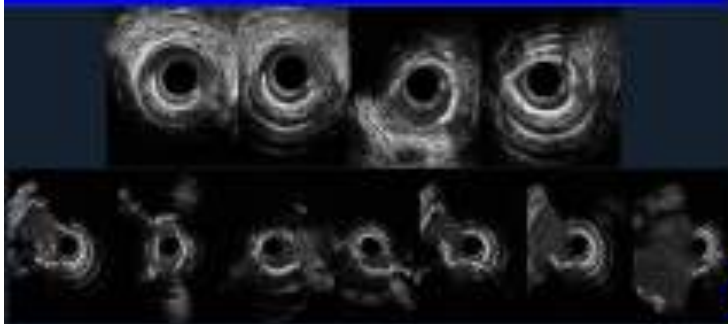
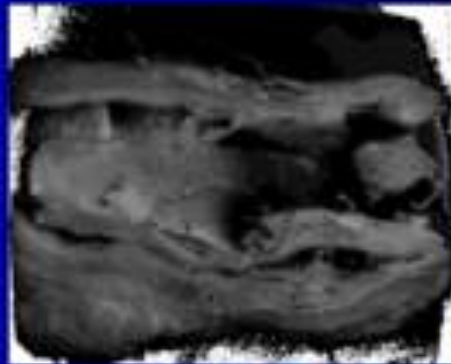
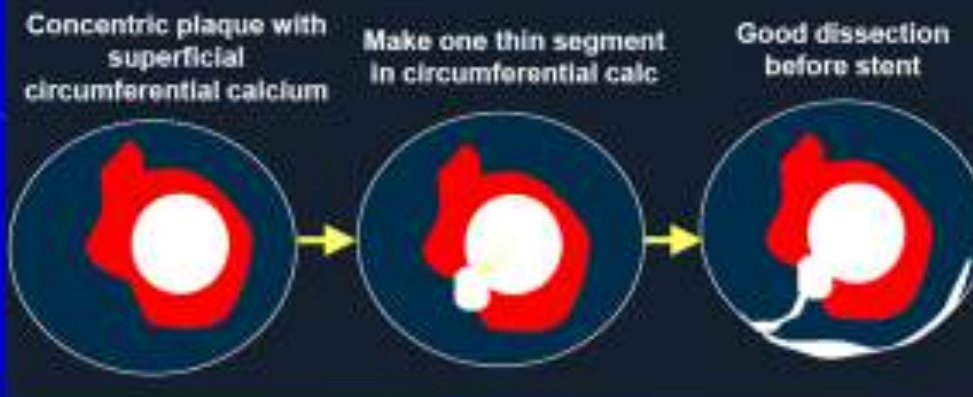


Orthogonal Displacement of Friction



Rotablation properly utilized

- Minimizes vessel wall stretch and elastic recoil
- Eliminates vessel barotrauma
- Removes all plaque morphologies; Soft, fibrotic, calcified
- Produces a smooth lumen channel for improved hemodynamic flow



post-PTCA procedure

post-Rotablator® procedure

Prototype next generation rotablator advancer

Design Goals:

- Easier to learn & use (no foot pedal)
- Easier to set up (consolidated cables)
- Allows single operator use



RotaWire "Elite"

1:1 Torqueability

Enhanced stainless steel
core wire technology



Same wire dimensions and tip design

Diamondback 360™ Coronary OAS Coronary OAS Components



All components are sold separately

Diamondback 360™ Coronary OAS Classic Crown 1.25 mm

The Classic Crown 1.25 mm features:

- Saline Sheath: PEBAX with Stainless Braid and Atraumatic Tip
- Driveshaft: 3-Filar 304V Stainless Steel
- Crown: Diamond-coated 304 Stainless Steel



Diamondback 360™ Coronary OAS *ViperWire Advance™* with Flex Tip Coronary Guide Wire

	Core Wire	Support Coil	Tip	Coating	Spring Tip Load	Dimensions
<i>ViperWire Advance™</i> with Flex Tip First and only Nitinol-core coronary atherectomy wire Designed for reduced wire bias and link resistance	Nitinol	Stainless Steel	Platinum/Tungsten	Silicone	1.0 gf	Diagram illustrating the dimensions of the ViperWire Advance with Flex Tip coronary guide wire: - Handle diameter: .014" - Support coil diameter: .008" - Tip diameter: .010" - Flex tip diameter: .012" - Handle length: 2.5 cm - Support coil length: 3.2 cm - Tip length: 3.5 cm - Flex tip length: 1 cm - Wire length: 6.8 cm - Tip length: 2 cm - Total length: 30.6 cm - Total length: 32.5 cm

Diamondback 360™ Coronary Orbital Atherectomy Dual Mechanism of Action



Atherectomy:

Bi-directional Differential Sanding

Reduces superficial calcium^{1,2}

Calcium Modification:

Pulsatile Forces

May contribute to compliance change²

The *Diamondback 360™* orbital atherectomy system sands intimal lesions and facilitates fracture of medial calcium to optimize stent delivery, expansion and apposition.³⁻⁶

1. Shofrit E, et al. *Exp Rev Med Dev*. 2017;14(11):867-879.

2. CSI Data on File, based on cadaver atherosclerotic lesions, porcine coronary lesions, and graphite block test models.

3. Yamamoto M, et al. *Catheter Cardiovasc Interv*. 2019;93(7):1211-1218.

4. Kim A, et al. *Catheter Cardiovasc Interv*. 2015;86(6):1024-1032.

5. Shofrit E, et al. *Interv Cardiol*. 2019;14(3):169-173.

6. Yamamoto M, et al. *JACC Cardiovasc Interv*. 2017;10(24):2584-2586.

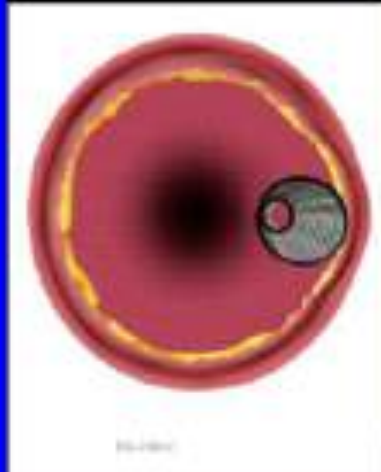
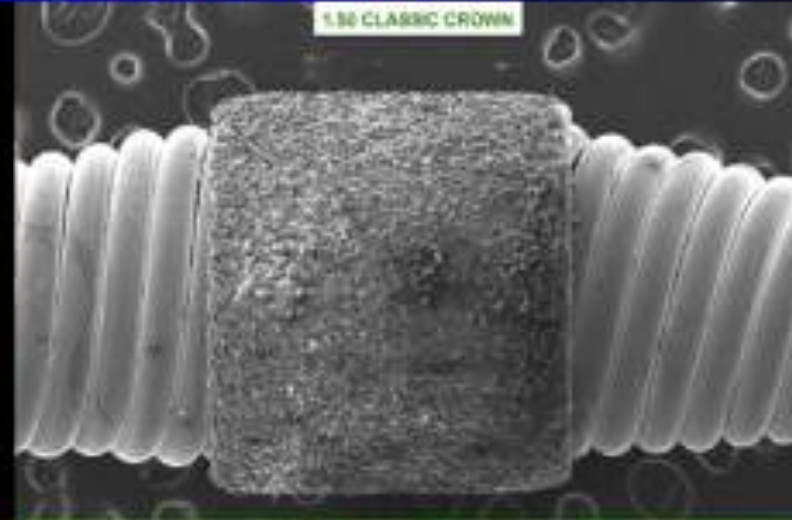
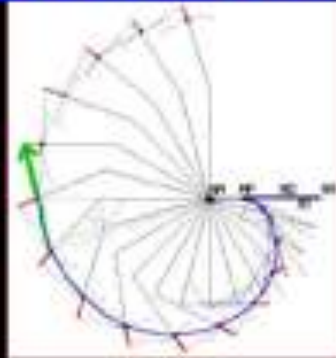
Diamondback 360™ Coronary Orbital Atherectomy Mechanism of Action

- Orbiting 6Fr, 1.25 mm diamond-coated crown.
- Treats vessels 2.5 mm to 4.0 mm.¹
- Provides bi-directional treatment.²
- Reduces plaque while potentially minimizing damage to the medial layer of the vessel.²
- Average particulate size smaller than a capillary vessel.^{2,3}

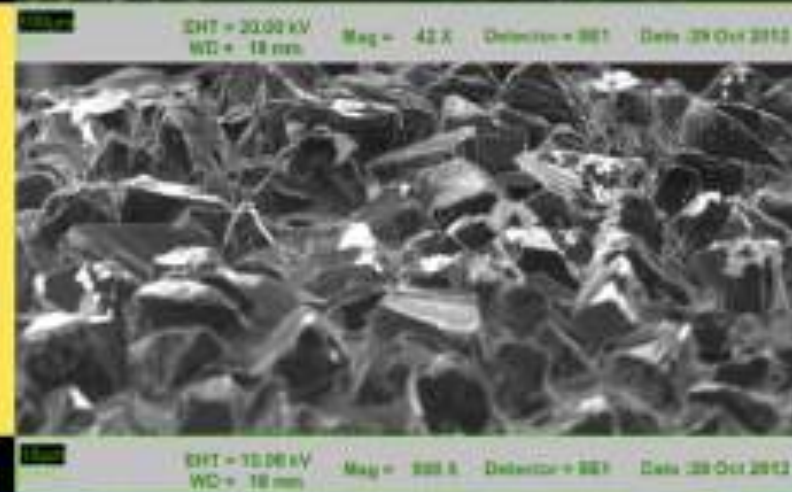


1. Chambers JW et al. JACC Cardiovasc Interv. 2014 May;7(5):510-8.
2. Shlitz, E. et al. Exp Rev Med Dev. 2017;14(11):867-875.
3. CSI Data on File, based on cadaver atherosclerotic lesions, porcine coronary lesions, and graphite block test models.

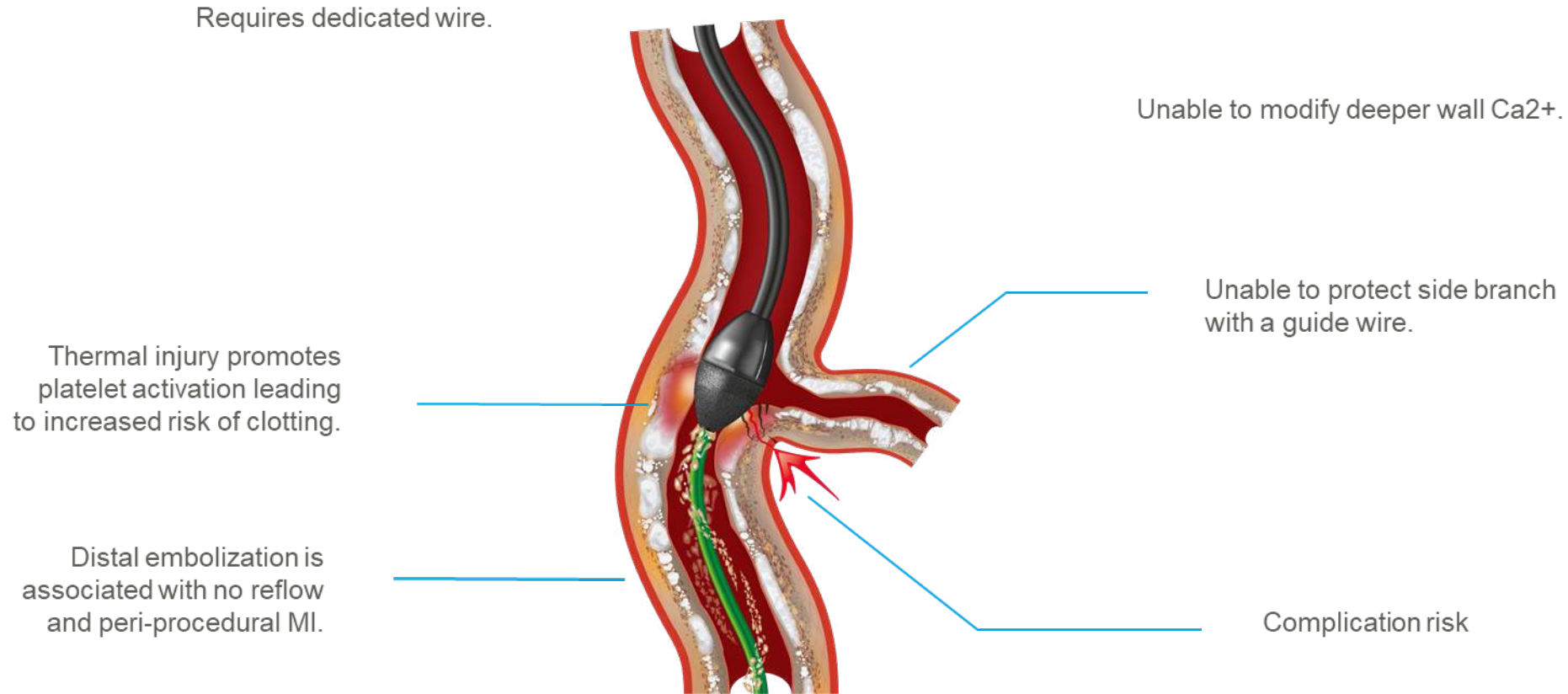
Orbital Atherectomy: Crown Surface Features, differential sanding



10 microns
of exposed cutting
surface,
healthy elastic
tissue flexes away
minimizing damage
to the vessel.



Limitations of atherectomy devices?



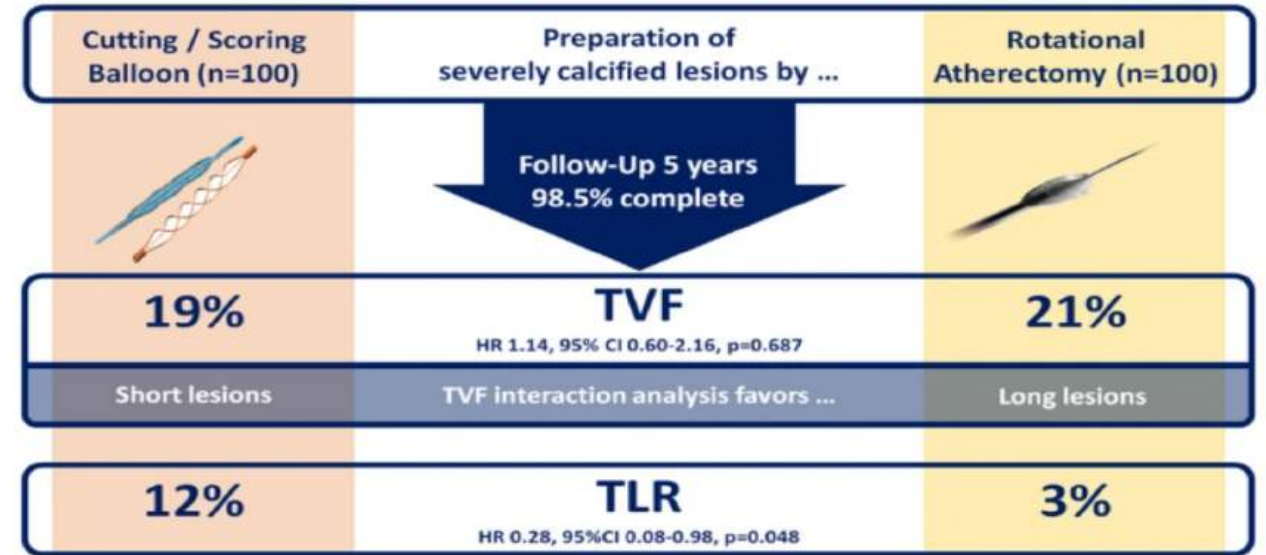
Primary Endpoint – Strategy Success

	Modified balloon (n = 100 pts.)	Rotational atherectomy (n = 100 pts.)	p-value
Strategy success	81 (81%)	98 (98%)	0.0001
Final TIMI flow < III	0 (0%)	1 (1%)	0.99
Residual stenosis >20%	2 (2%)	0 (0%)	0.49
Stent failure	4 (4%)	1 (1%)	0.36
Crossover	16 (16%)	0 (0%)	<0.0001

Significantly higher rate of successful procedure without increase in complications with a up-front rotational atherectomy approach in PREPARE-CALC study.

Abdel-Wahab M et al, High-Speed Rotational Atherectomy Versus Modified Balloons Prior to Drug-Eluting Stent Implantation in Severely Calcified Coronary Lesions. Circ Cardiovasc Interv 2018

Lower Revascularization Rates after High-Speed Rotational Atherectomy Compared to Modified Balloons in Calcified Coronary Lesions: Five Year Outcomes of the Randomized PREPARE-CALC Trial.

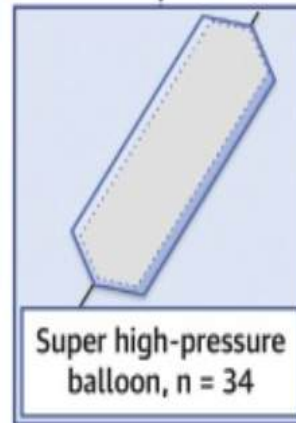
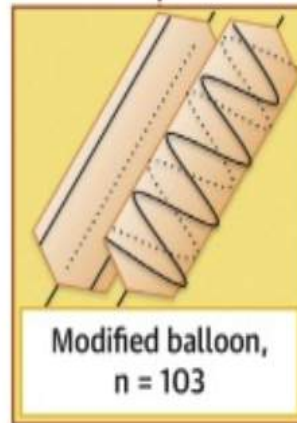
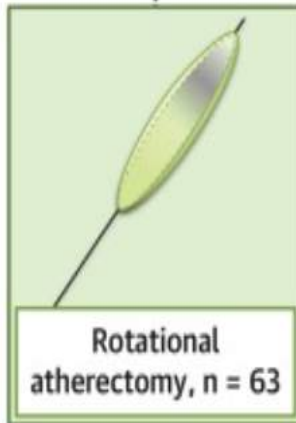


5-year follow-up of PREPARE-CALC study showed a trend towards lower rates of TLR with up-front rotational atherectomy

Mankarious, N., Richardt, G., Allali, A. et al. Lower revascularization rates after high-speed rotational atherectomy compared to modified balloons in calcified coronary lesions: 5-year outcomes of the randomized PREPARE-CALC trial. Clin Res Cardiol

Patients With Severely Calcified Coronary Artery Lesions Amenable to Drug-Eluting Stent Implantation and Enrolled in the Randomized PREPARE-CALC and ISAR-CALC Trials (N = 274)

Patients with available OCT imaging after stenting included in the pooled analysis (n = 200)



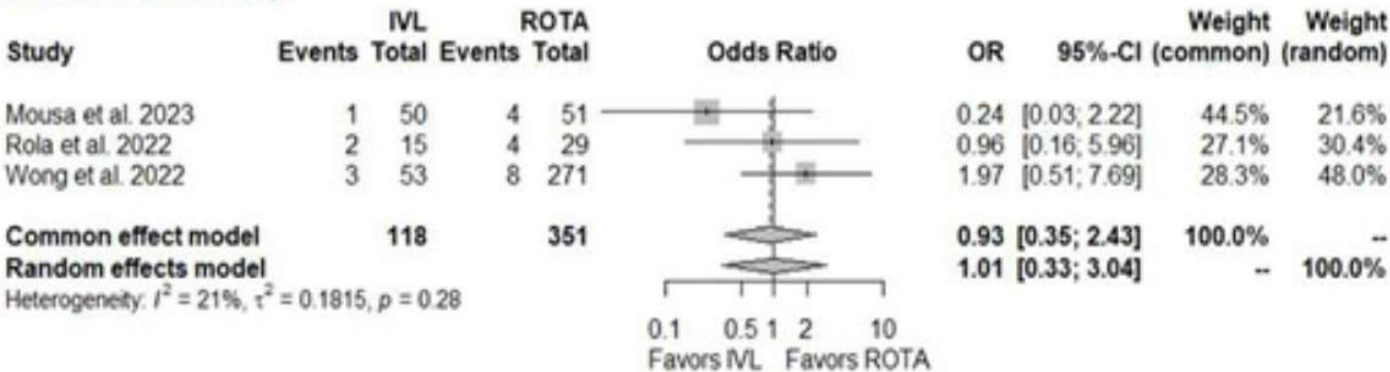
Main outcomes

Main findings

Stent expansion, %	73.2 ± 11.6	70.8 ± 13.6	71.8 ± 12.2	No significant difference
Maximal stent eccentricity	0.70 ± 0.06	0.70 ± 0.08	0.74 ± 0.09	Super high-pressure balloon better
Strategy success, %	100	86.4	91.2	Rotational atherectomy better

Substantially greater success with rotational atherectomy compared to balloon-based strategies

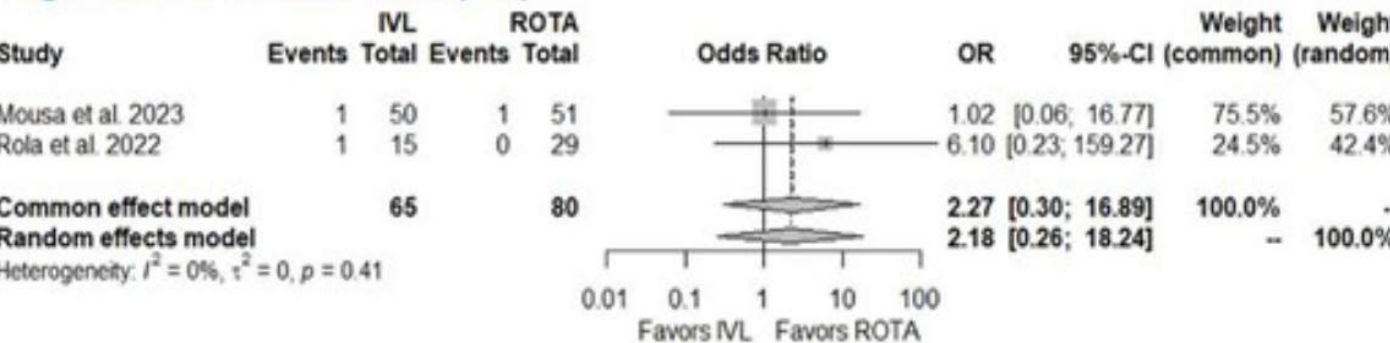
All-cause mortality



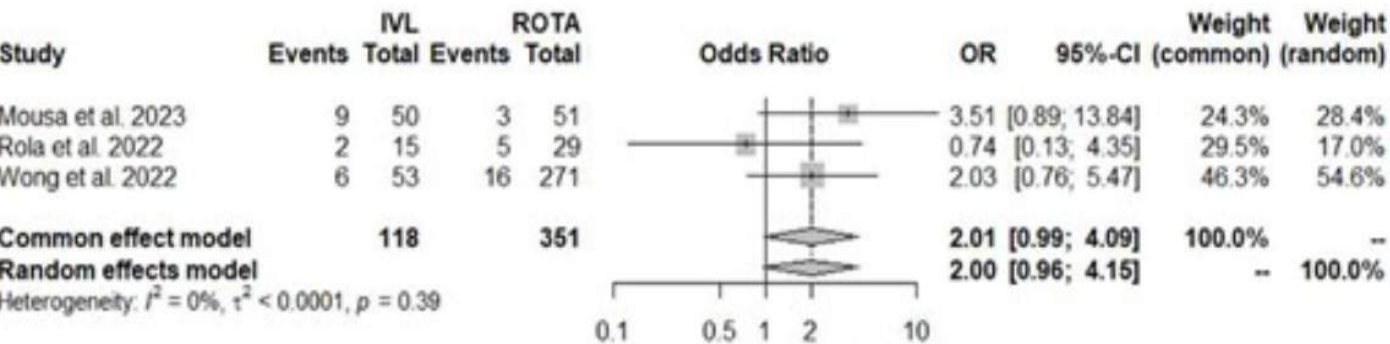
Meta analysis shows a trend towards more favourable outcomes with rotational atherectomy but small numbers.

M A Shabbir, M Hamza, U Naseer, M Ehtesham, J Basit, M H Arshad, S Malik, To shock or to drill: comparison of intravascular lithotripsy and rotational atherectomy - a meta-analysis, European Heart Journal, 2024

Target lesion revascularization (TLR)



Major adverse cardiovascular events (MACE)



The data supports early debulking as safe, with a signal of better long-term results

Calcium debulking improves vessel compliance facilitates PCI

If you think you need it, then do it.
Don't try and cut corners, you may well regret that

History

- Male 67 Y/O
- PMH: IHD, PCI to RCA, LCx, LAD-CTO, AF, TIA, HTN, DM II, UC, Celiac Dx.
- Good LVFx with angina symptoms
- Previous failed attempt of heavily calcified LAD-CTO,
- Referred for LAD/CTO PCI, plan for RA

Set up
angio

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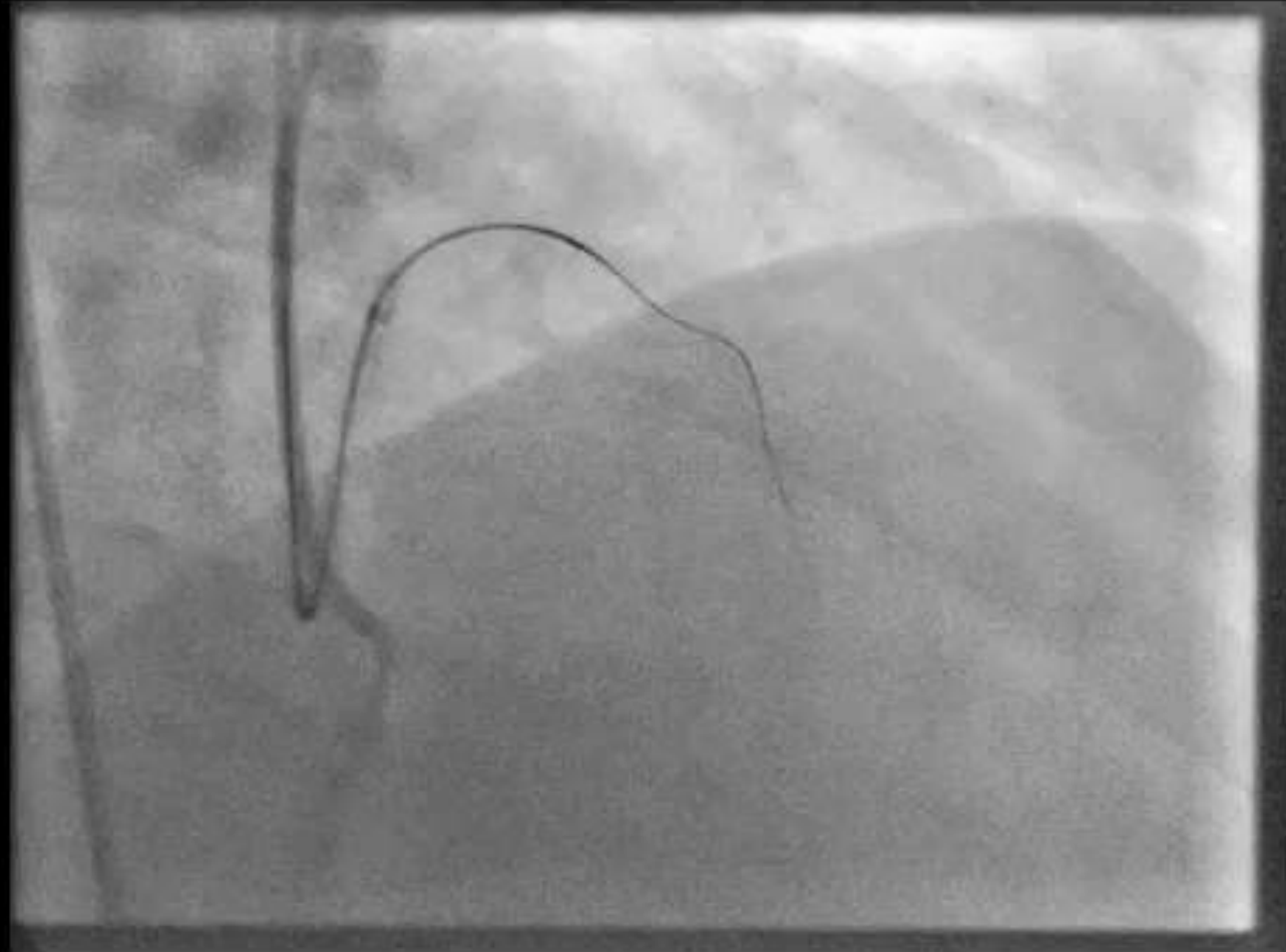


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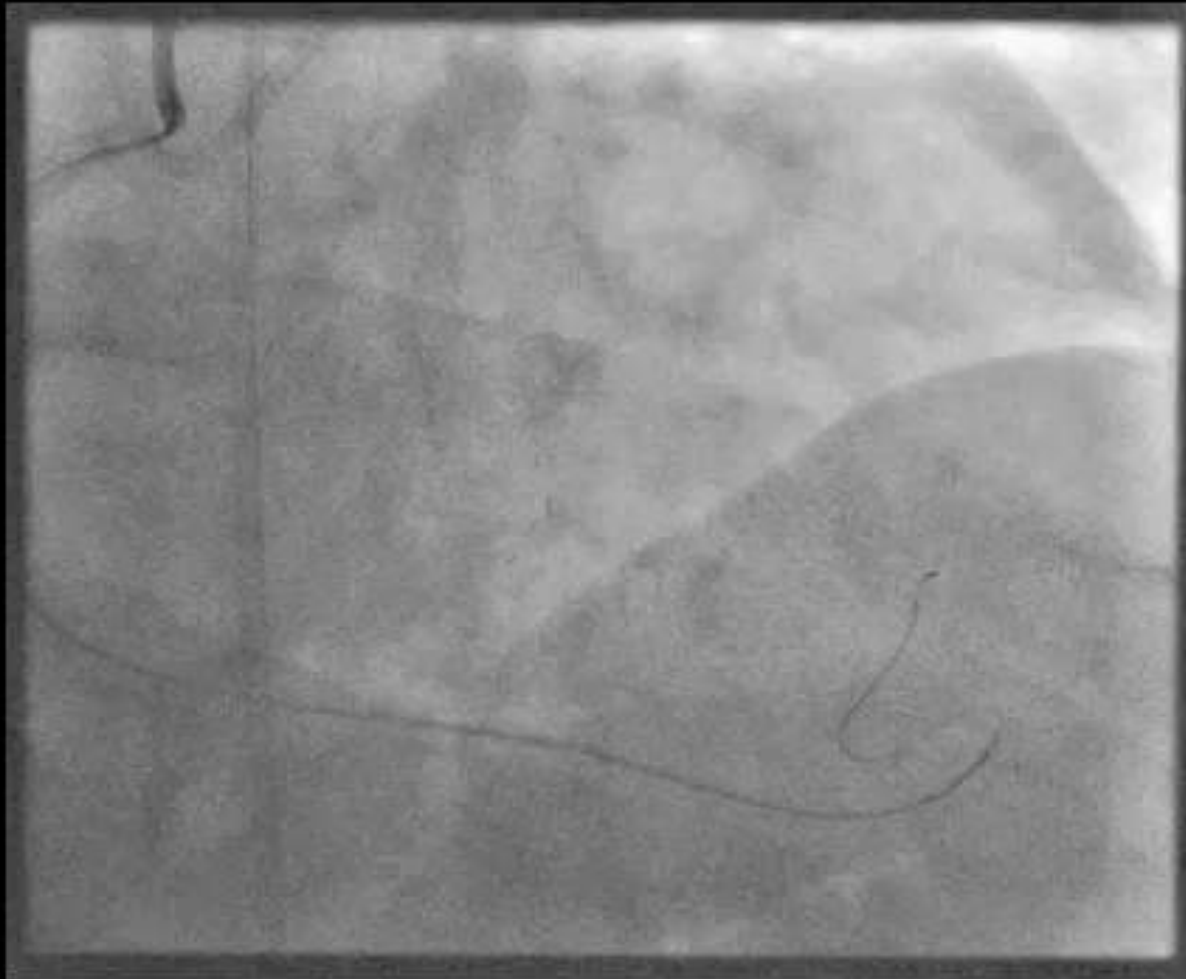
AWE,
subintim
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Retrograde
epicardial

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Externalised
RG3 &
predilatatio
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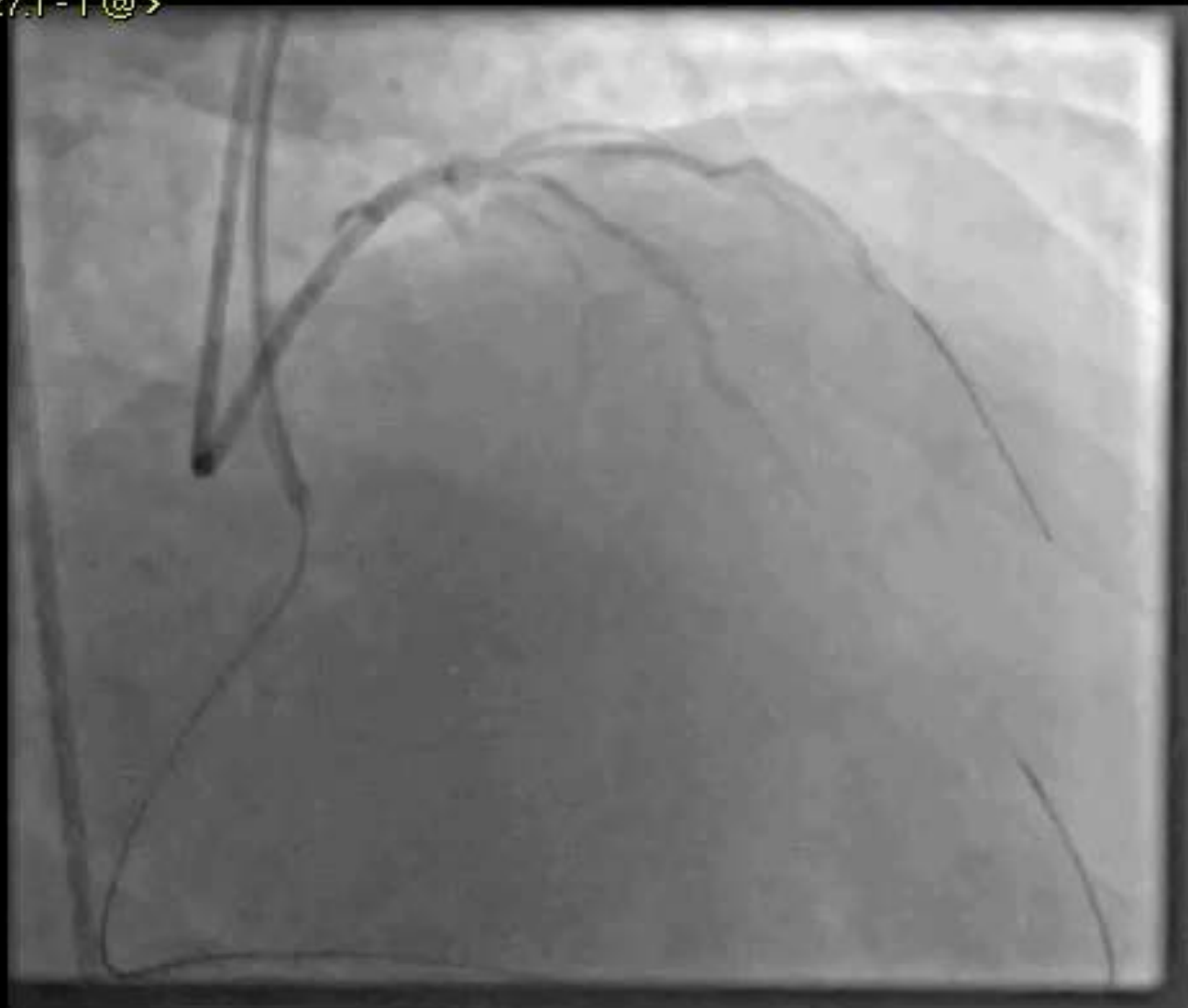
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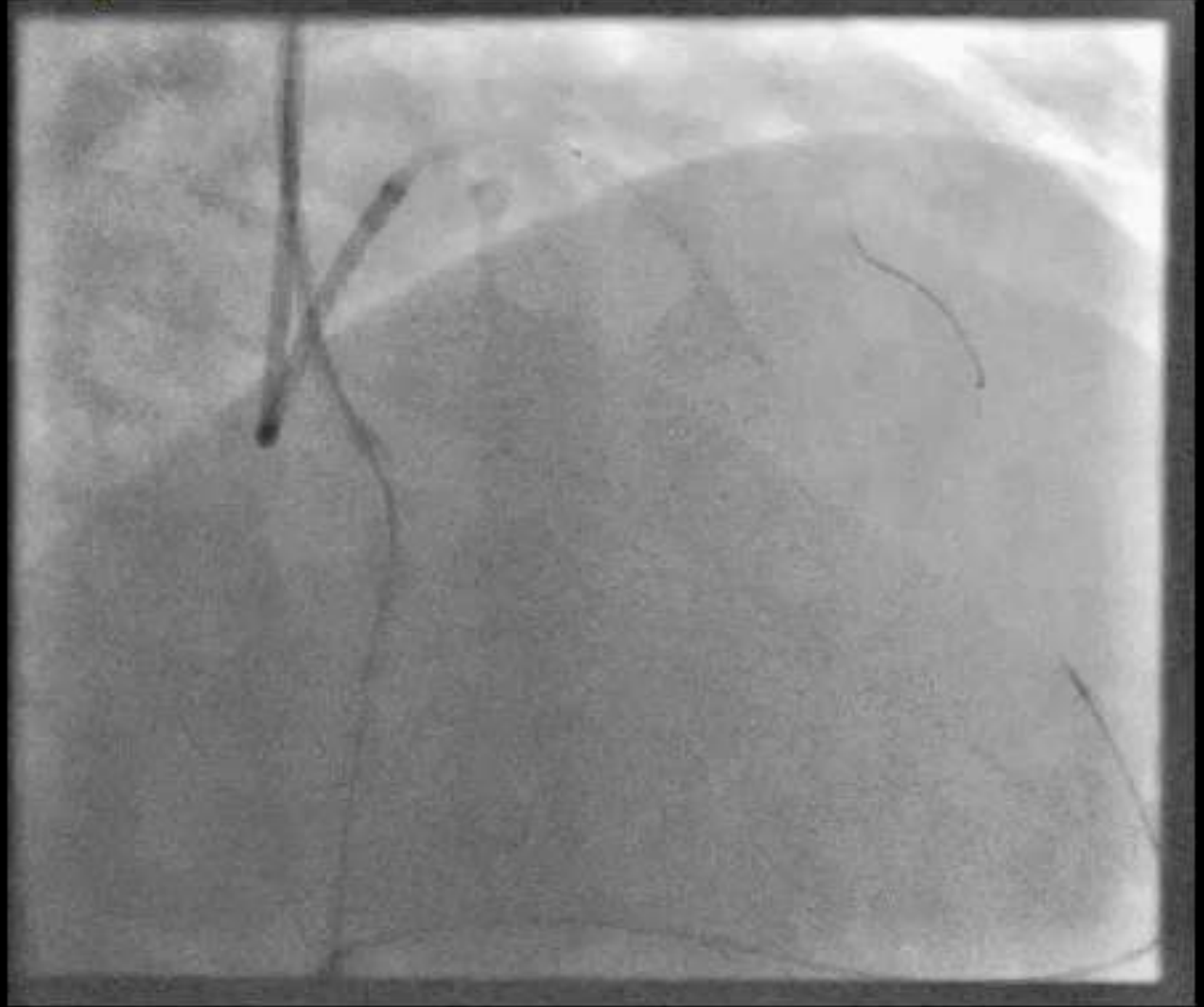


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DES

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DES

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AG wire

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Post
dilatatio
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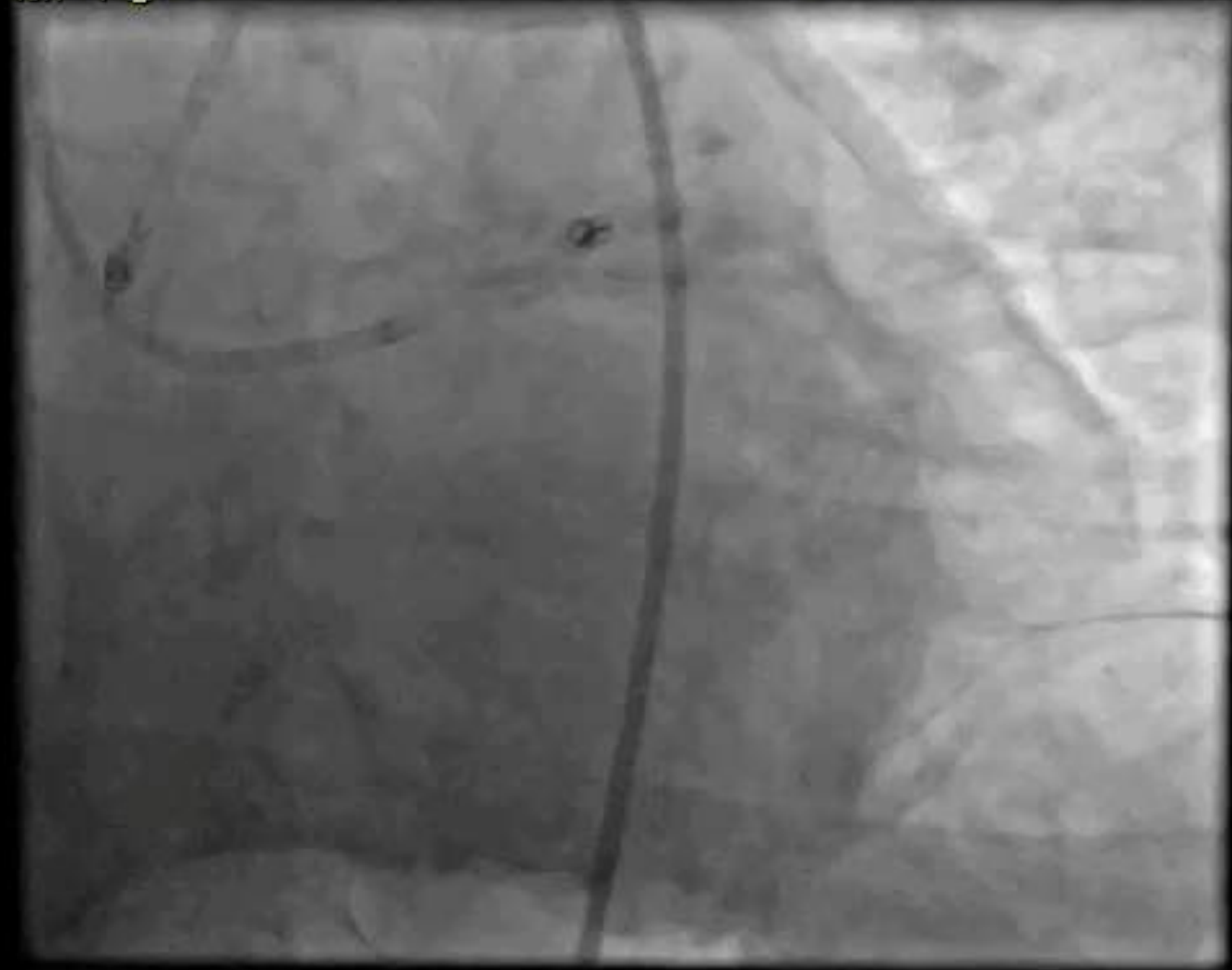


Final
image

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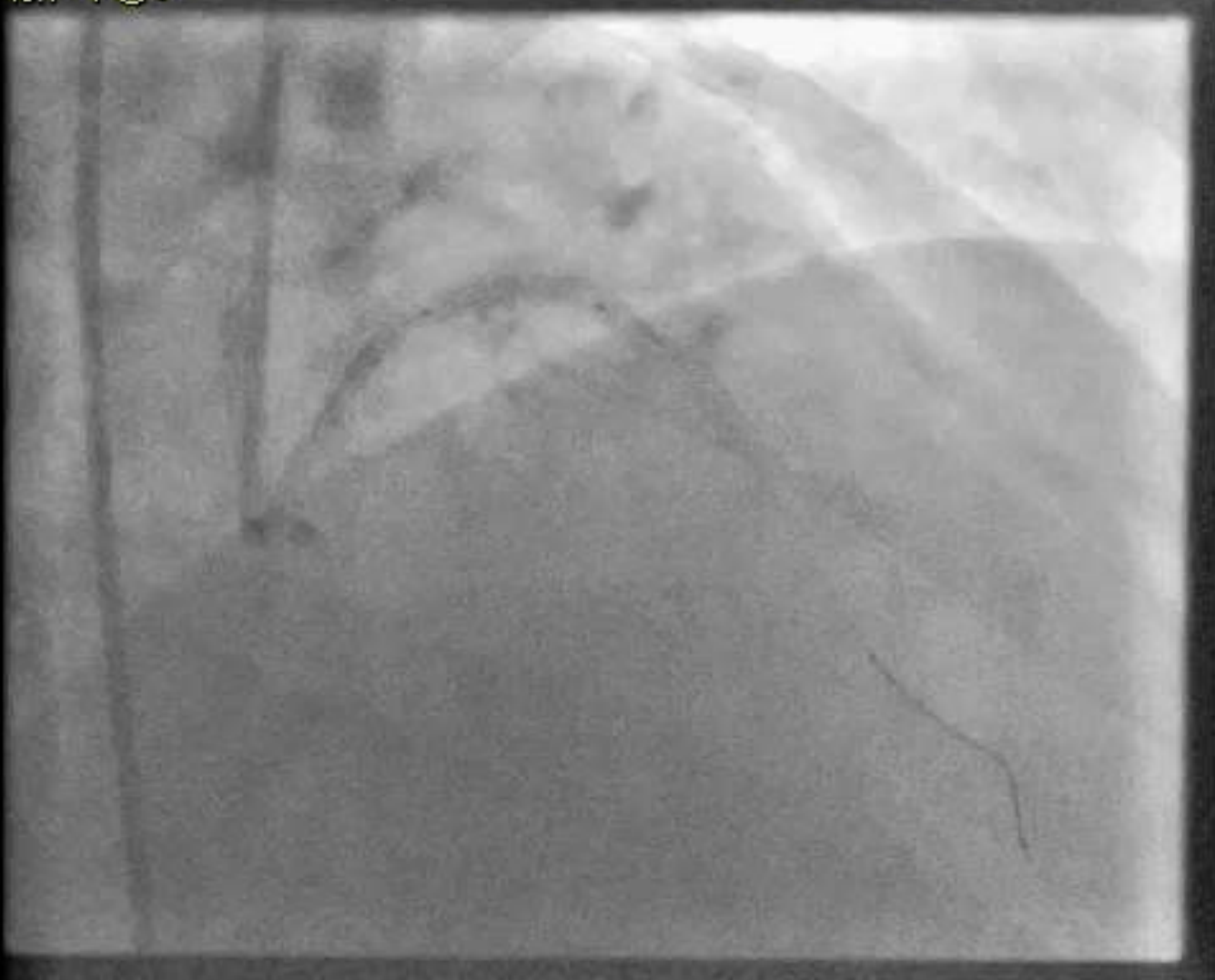


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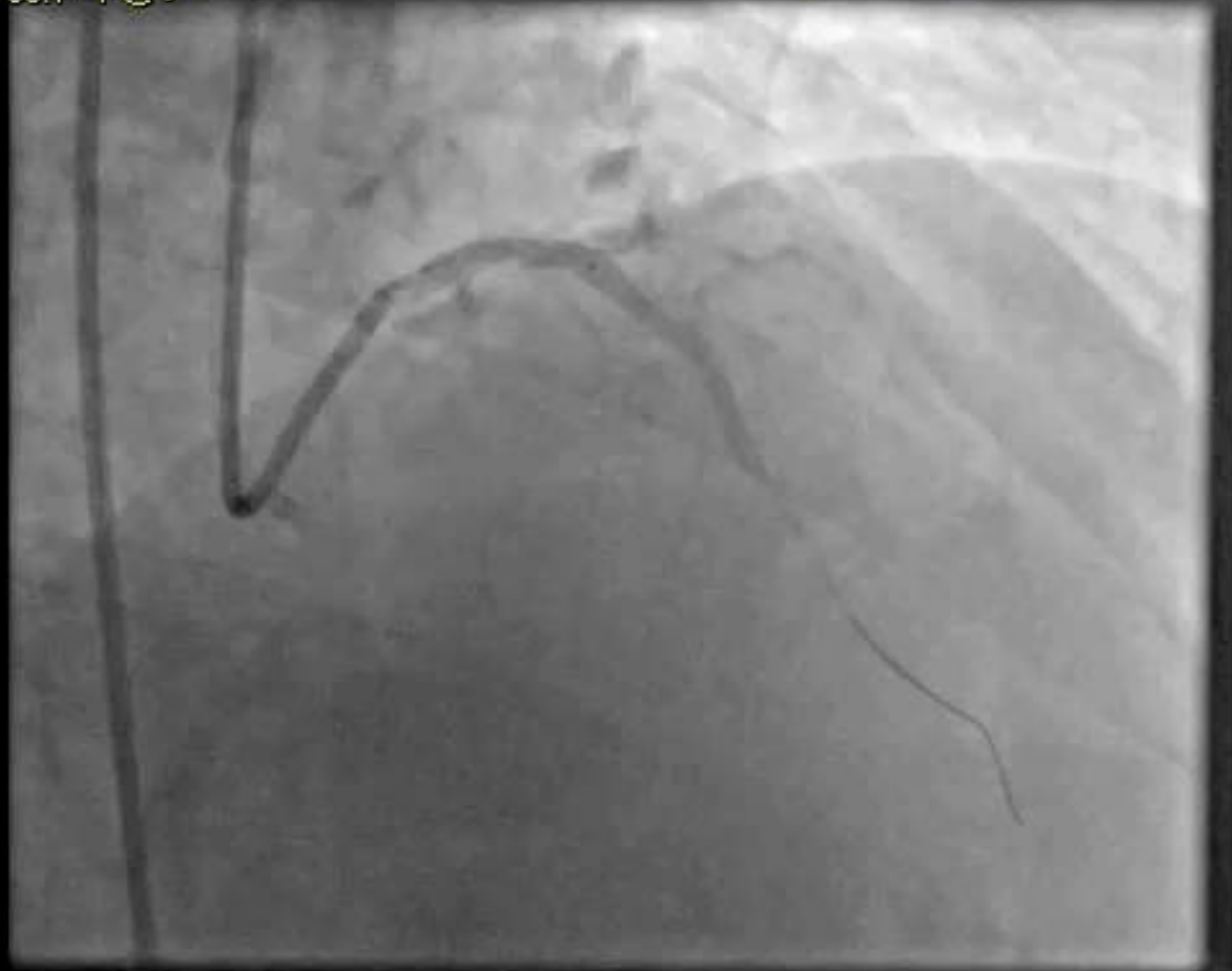


Balloon
tamponad
e

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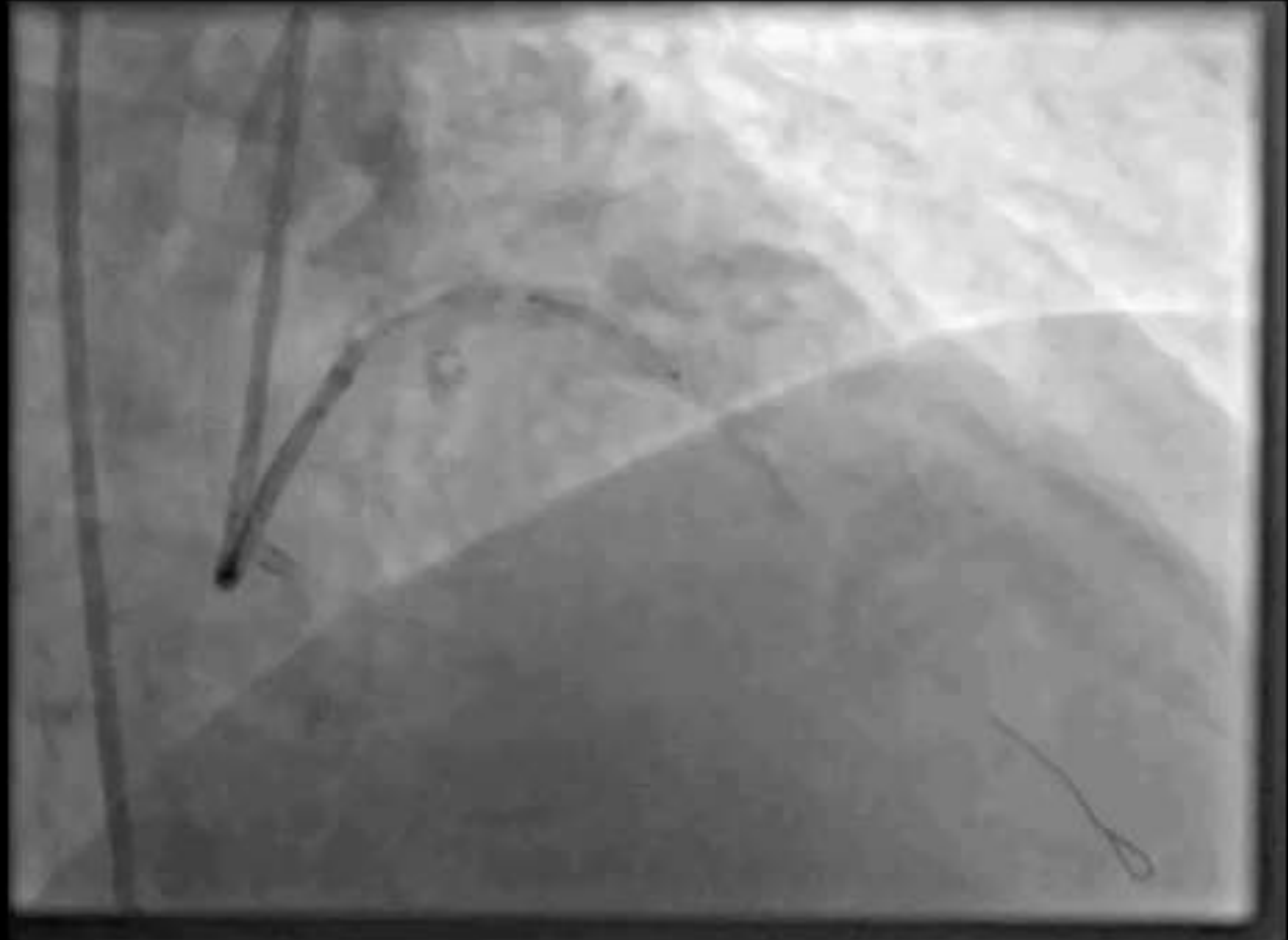


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Covered
stent

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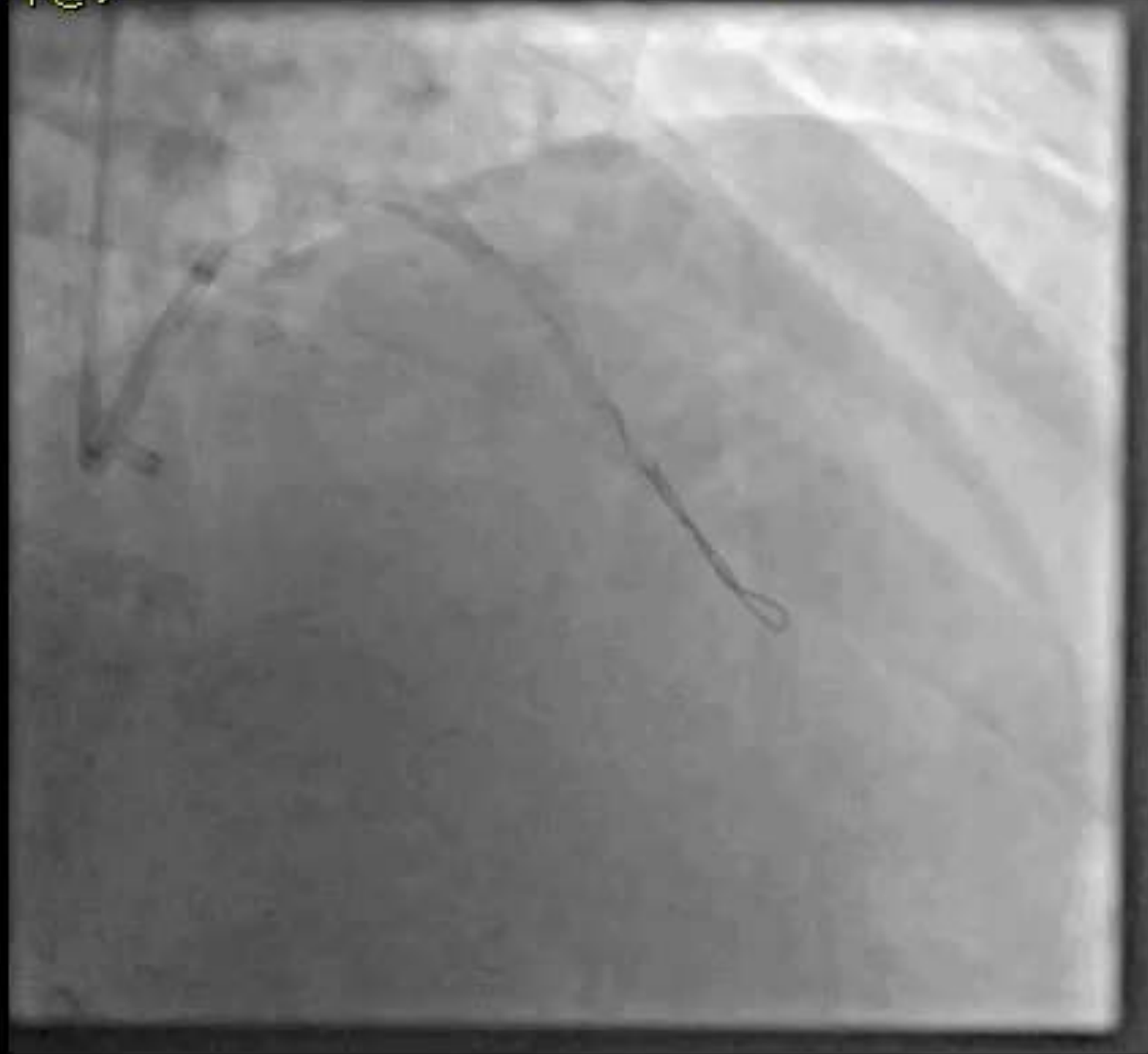


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Now its
over

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Case

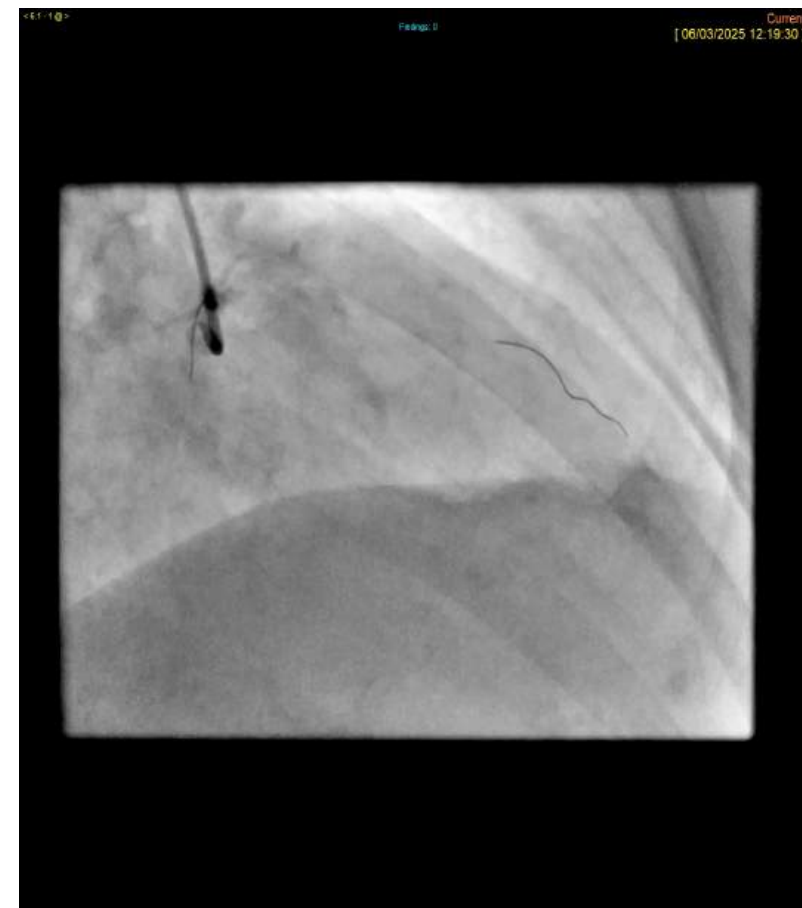
74-year-old lady referred with stable angina

PMH: Hypertension, hyperlipidemia, peripheral vascular disease, previous NSTEMI with PCI to RCA.

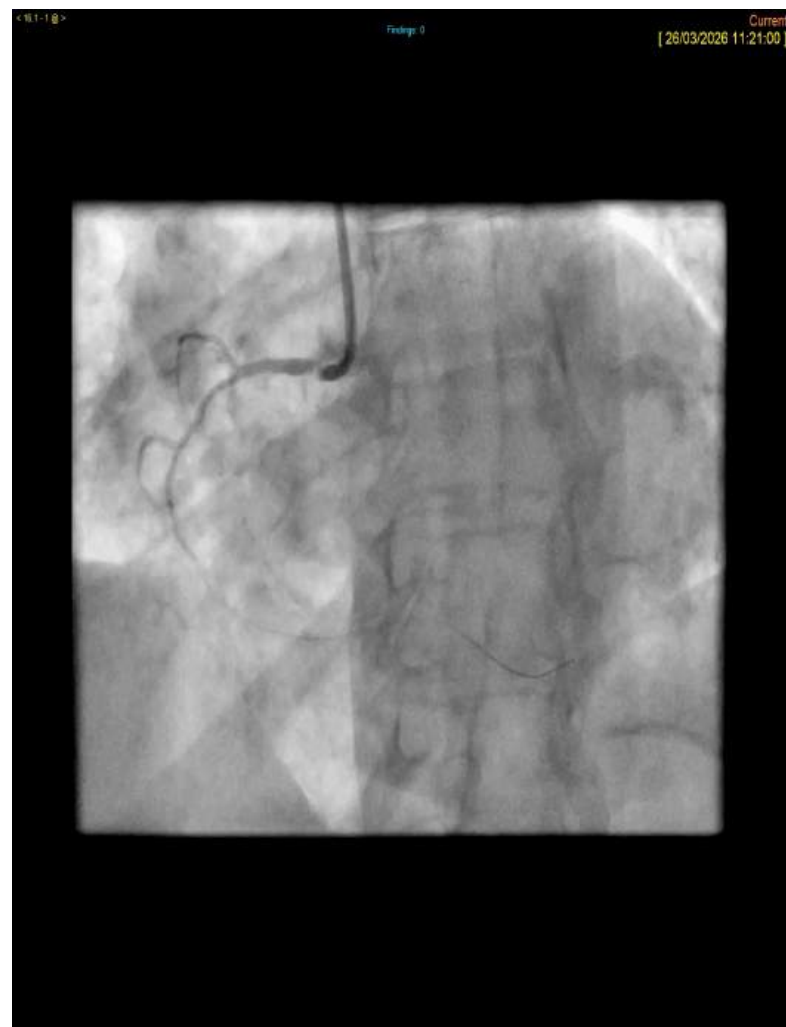
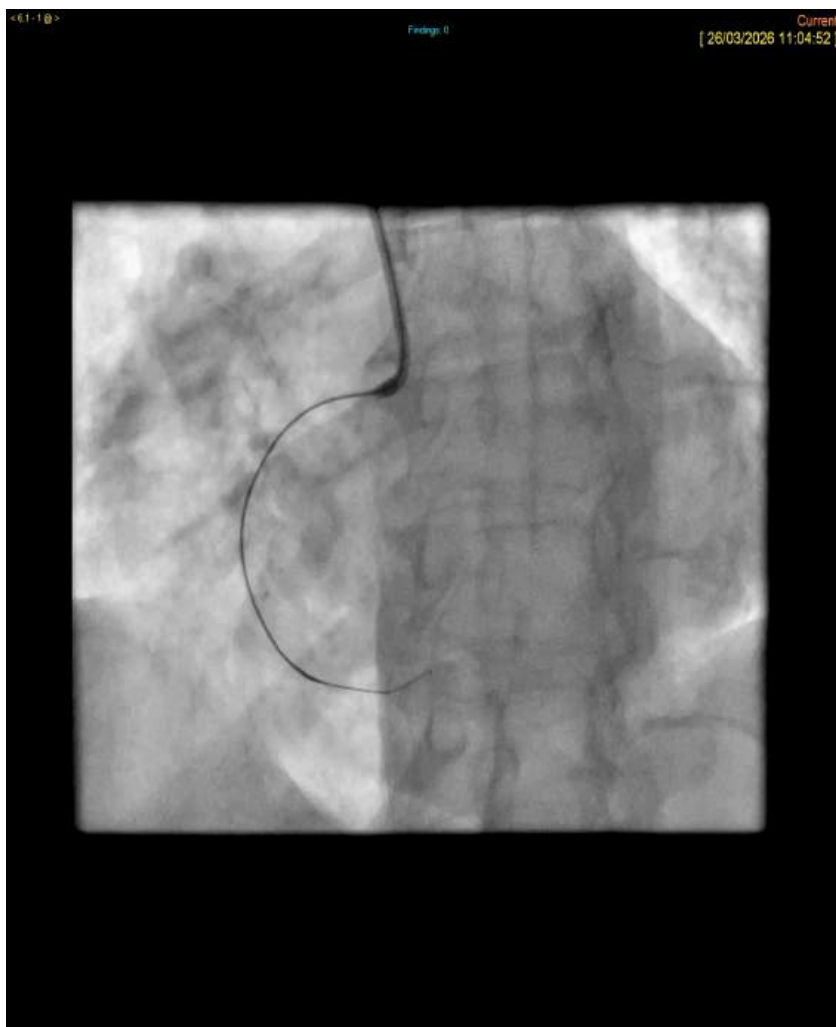
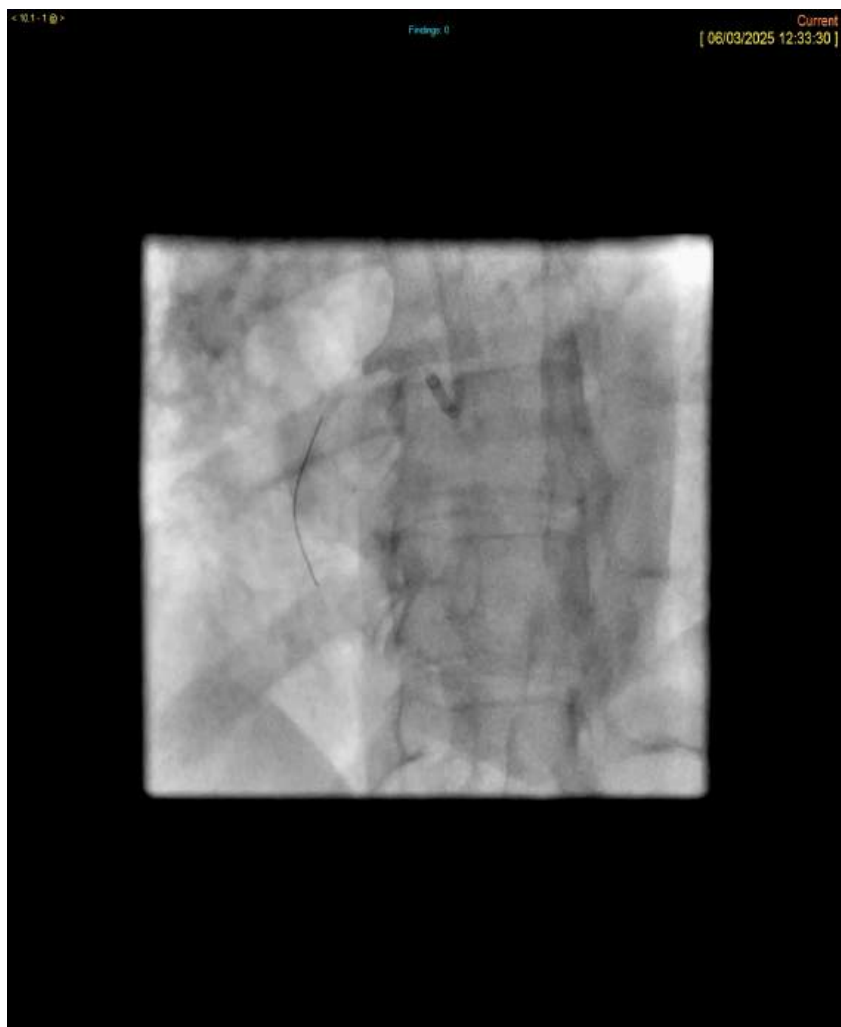
Initial angiogram done showed sub-total occlusion of RCA and severe left main stem stenosis

Patient declined surgery-planned for PCI to RCA/LMS

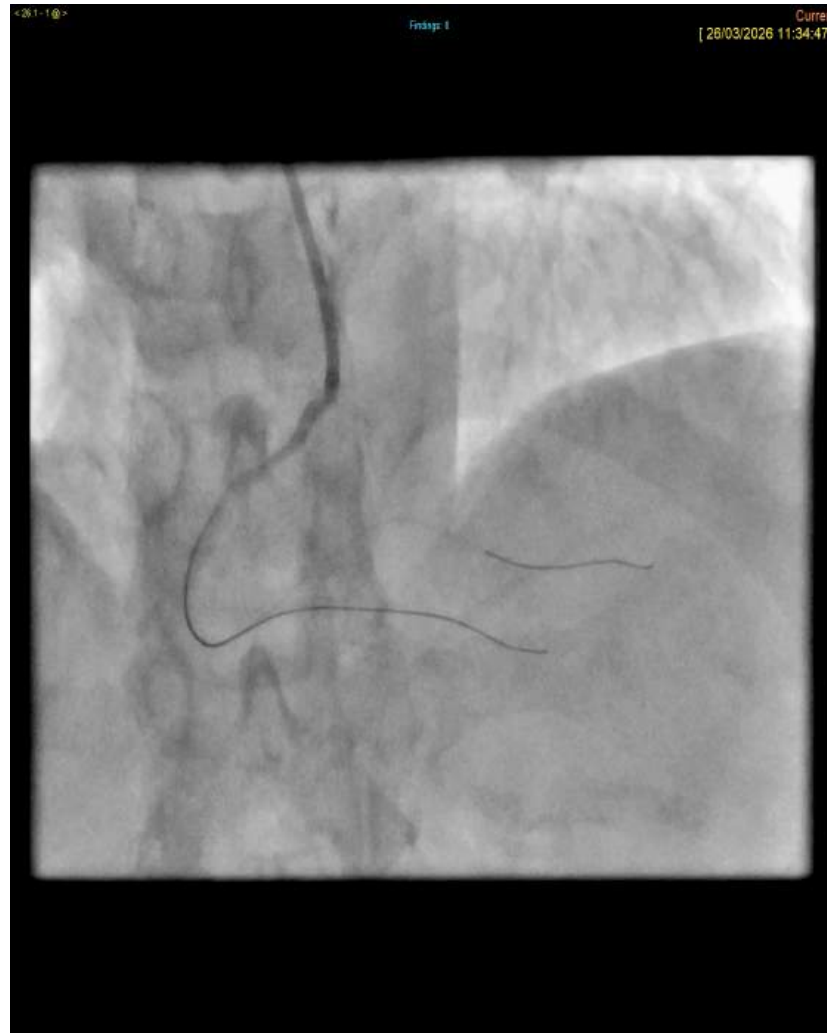
Initial Images



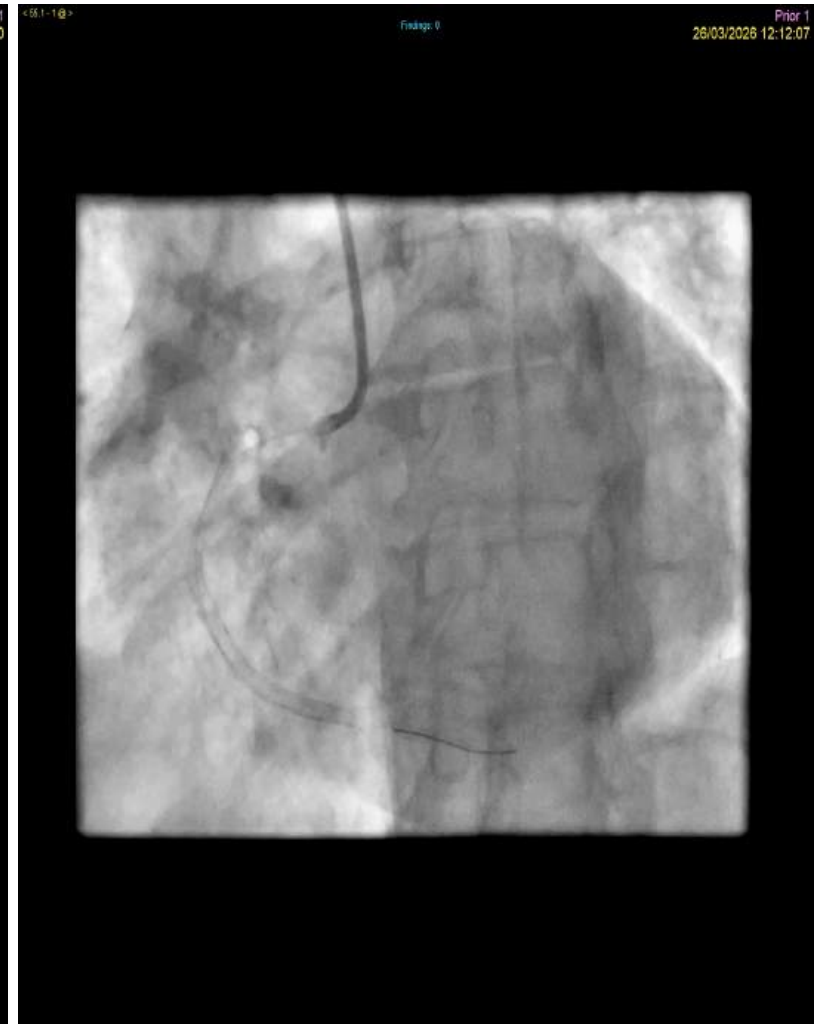
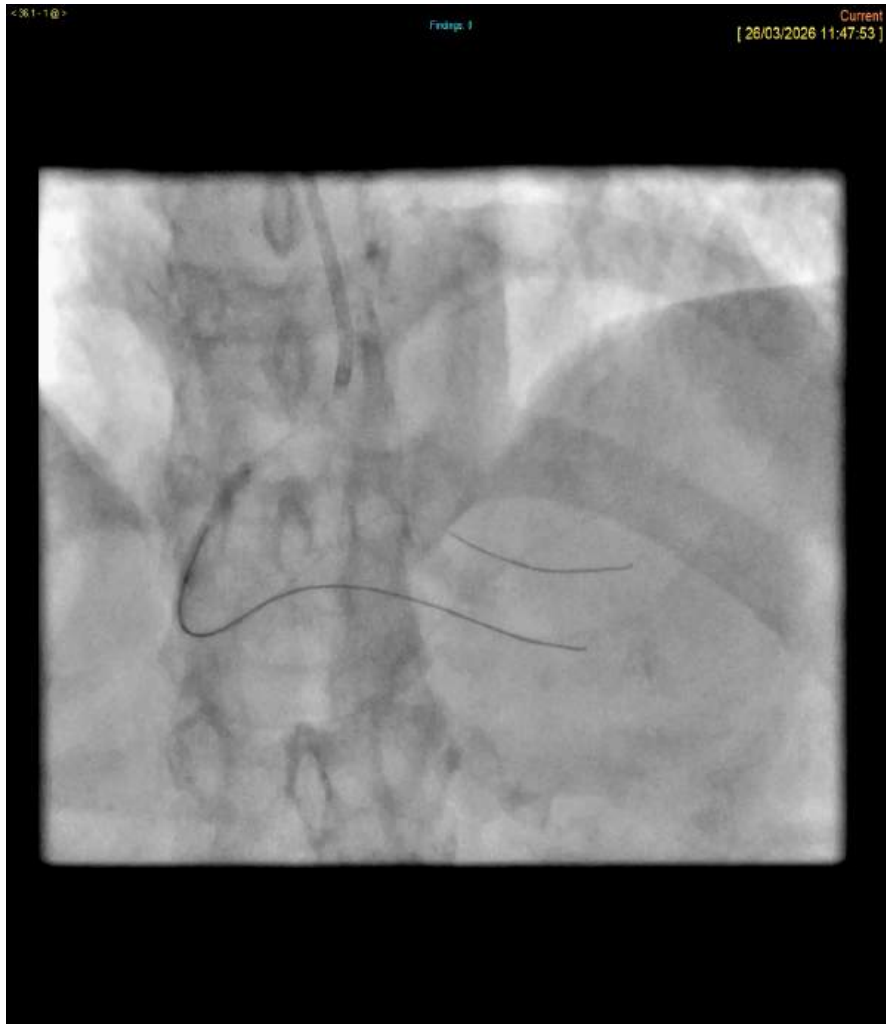
AWE into PLV system



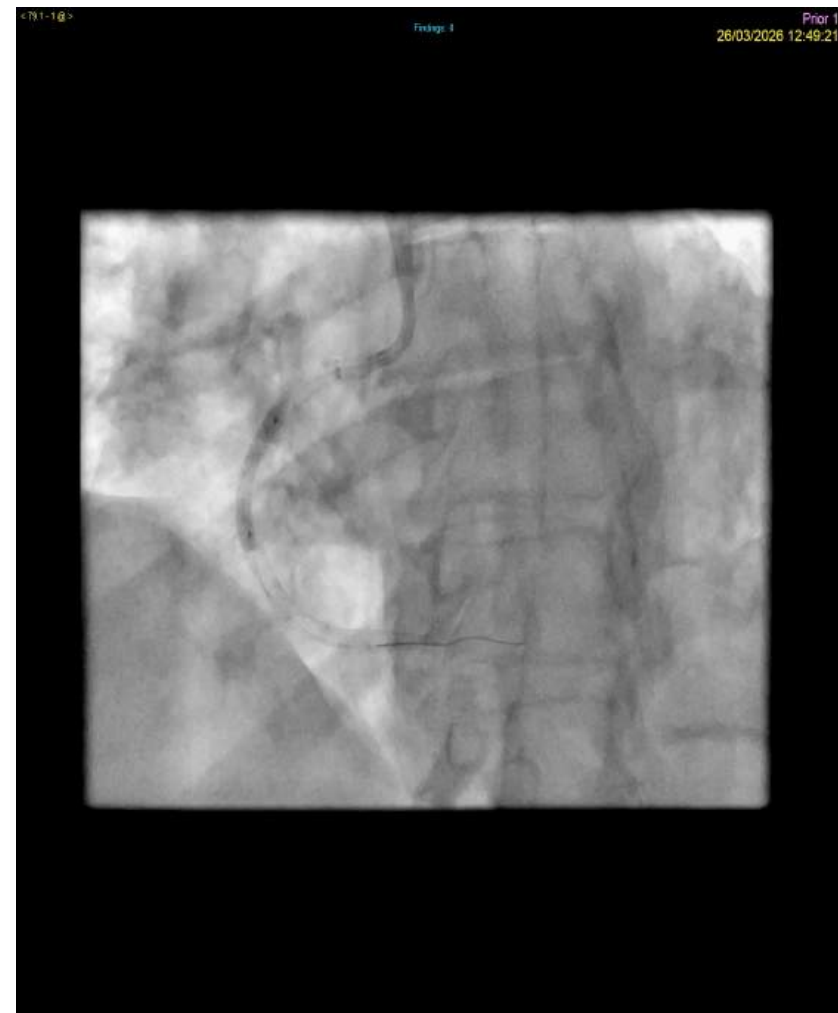
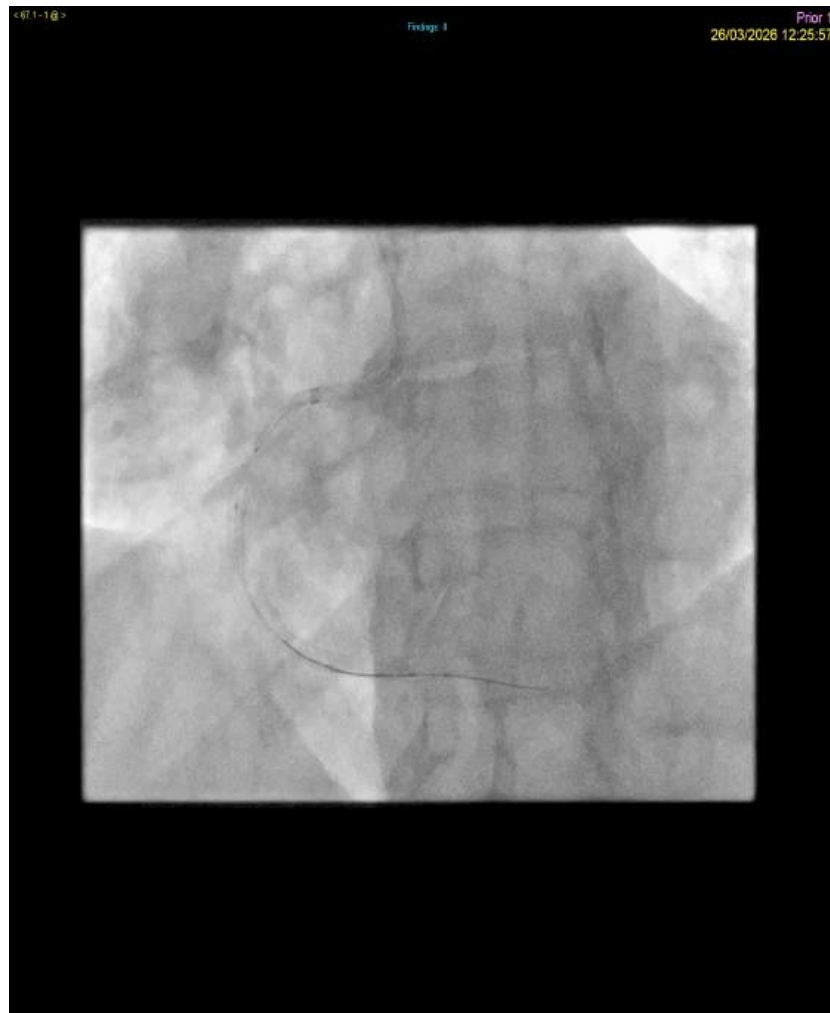
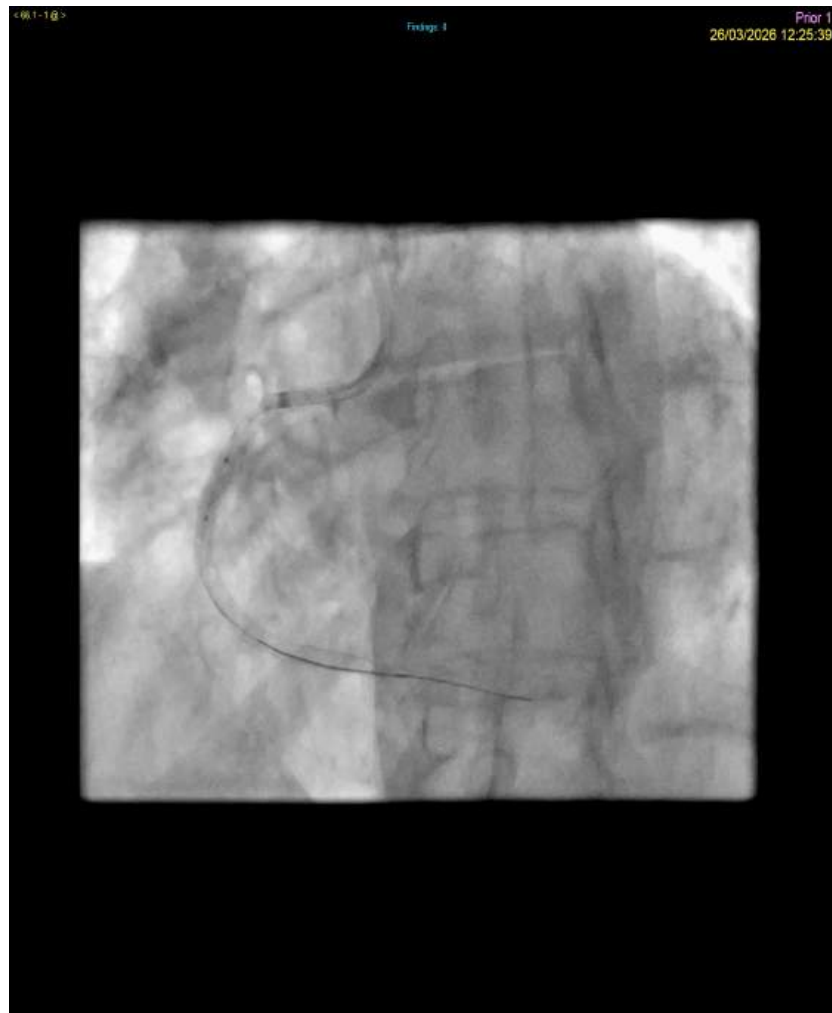
Wired PDA with Miracle Neo 3 and POBA to PLV



Pre-dilatation and stenting of RCA



NC balloon



Final Result



Summary

- Debulking of CA++ is more effective and help complete PCI by changing vessel compliance
- Assess on a case-by-case basis

- If you think you need debulking, do it
 - You get into trouble when trying to get away with a balloon
- Don't have any debulking regret



***THAN
K YOU***

CENTRAL ILLUSTRATION: Summary of Major Global CAC Guidelines

