# ECLIPSE: A Large-scale, Randomized Trial of Orbital Atherectomy vs. Conventional Balloon Angioplasty in Severely Calcified Coronary Arteries Prior to DES Implantation

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For the ECLIPSE Investigators

ECLIPSE Clinical Trial

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# Background and Objectives

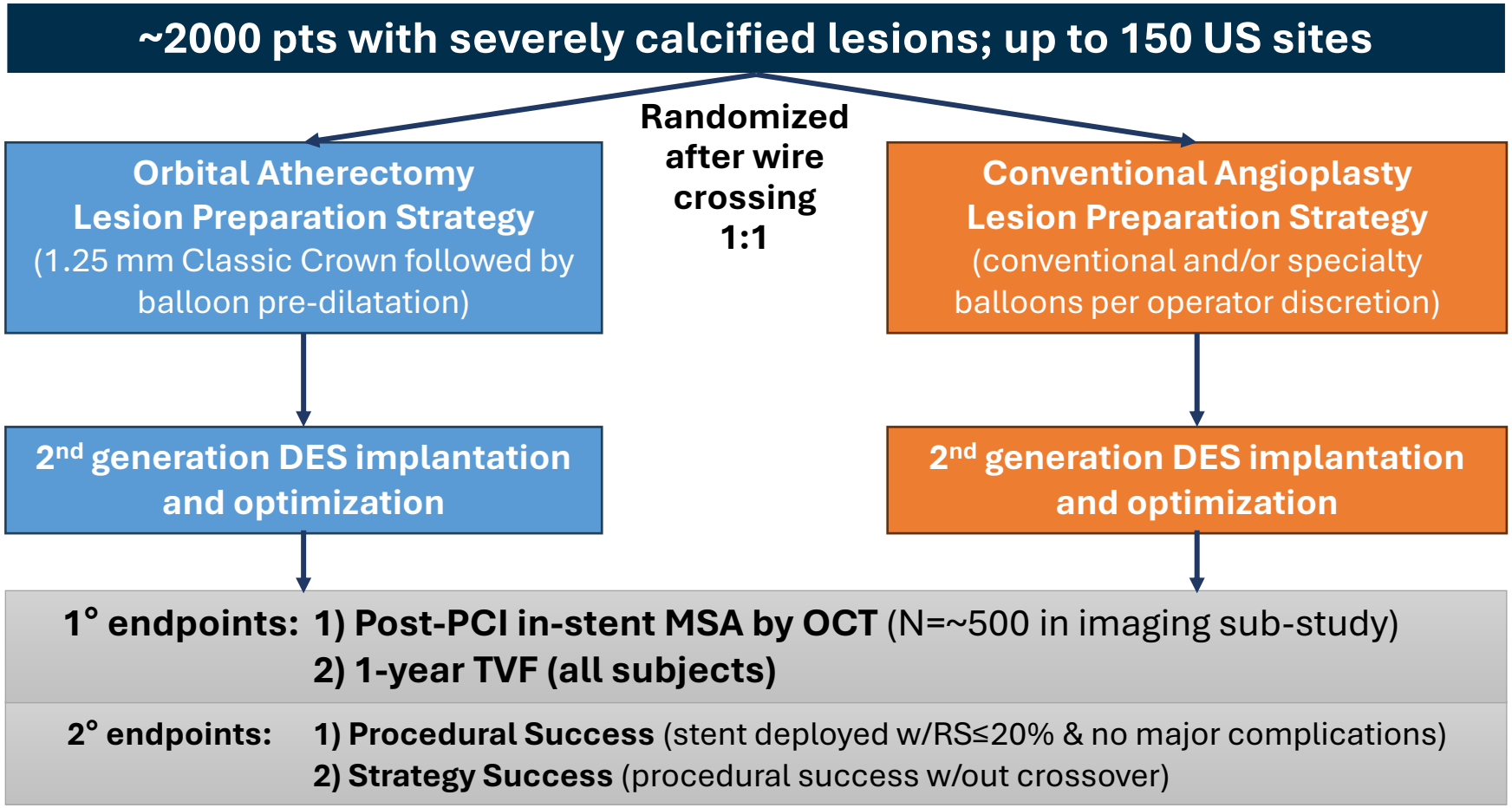
- Coronary lesion calcification is associated with greater PCI complexity, stent under-expansion, and increased rates of early/late adverse events
- Coronary atherectomy can ablate and fracture calcium – improving lesion compliance and facilitating stent delivery and expansion – and is an essential tool to treat balloon-uncrossable or non-dilatable calcified lesions
- *Whether advanced calcium modification strategies improve clinical outcomes compared with conventional balloon angioplasty is unknown*

**We conducted a large-scale randomized trial comparing orbital atherectomy with conventional balloon angioplasty for treatment of severely calcified coronary lesions prior to DES implantation**

# Study Design

**Key Entry Criteria:**

- CCS, NSTEACS or stabilized post-STEMI
- *De novo* lesion with severe calcium
  - Via angiogram: opacities w/o cardiac motion involving both sides of wall w/total $Ca^{++}$ ≥15 mm and extending into the target lesion, or
  - Via IVUS/OCT: ≥270° $Ca^{++}$ in ≥1 cross section
- Equipoise regarding strategies (i.e. either no absolute requirement for or contraindication to atherectomy)




Patients with severely calcified lesions were enrolled by physician determination according to a pre-specified definition, with post-procedure calcium severity confirmed by an independent Core Lab

Funded by Abbott; ECLIPSE ClinicalTrials.gov number NCT03108456

Genereux P, et al. *Am Heart J*. 2022:249:1-11.

# Study Interventions

- **Orbital Atherectomy Arm**
  - Balloon pre-dilatation prior to orbital atherectomy was allowed if necessary
  - Mandatory balloon dilation after atherectomy prior to DES implantation
  - Mandatory post-dilatation with NC balloon sized 1:1 at ≥18 atm

- **Conventional Balloon Angioplasty Arm**
  - Conventional balloon catheters (including cutting and scoring balloons but excluding intravascular lithotripsy) were allowed for lesion preparation prior to DES implantation

- **Crossovers were strongly discouraged**
  - Pre-specified criteria for acceptable vs. unacceptable crossover were adjudicated by an independent committee

# Study Endpoints and Sample Size Calculations

## Primary Imaging Endpoint:

## Post-PCI Minimal Stent Area (MSA) at site of maximum calcification

**Assumed 5.5 $mm^2$ in OAS vs. 4.5 $mm^2$ in balloon w/SD 2.5 $mm^2$**

*Sample size of 414 provides 90% power at alpha 0.01 assuming 10% not evaluable*

## Primary Clinical Endpoint:

## TVF during 1-year clinical follow-up

**Assumed 9% in OAS vs. 14% in balloon**

*Sample size of 1989 provides 90% power at alpha 0.04 assuming 10% attrition*



Genereux P, et al. *Am Heart J.* 2022:249:1-11.

# Baseline Characteristics

| | Orbital Atherectomy (n=1008) | Balloon Angioplasty (n=997) |
|---|---|---|
| Age | 69.9 ± 8.6 | 69.9 ± 9.1 |
| Male sex | 73.6% | 72.4% |
| Hypercholesterolemia | 88.0% | 87.2% |
| Hypertension | 90.3% | 90.3% |
| Diabetes mellitus | 43.1% | 44.8% |
| Treated with insulin | 18.4% | 18.0% |
| History of CKD | 23.2% | 24.6% |
| On hemodialysis | 6.0% | 5.2% |
| LVEF (%) | 55.1 ± 10.6 | 55.8 ± 9.9 |
| History of PVD | 13.7% | 14.6% |
| History of prior PCI | 43.7% | 46.7% |
| History of prior CABG | 9.1% | 10.9% |

# Baseline Angiographic Characteristics (Core Lab)

| | Orbital Atherectomy (n=1008, 1121 lesions) | Balloon Angioplasty (n=997, 1101 lesions) |
|---|---|---|
| Target lesion vessel | | |
| LMCA | 0.7% | 1.2% |
| LAD | 60.1% | 61.3% |
| LCX | 12.8% | 11.0% |
| RCA | 26.3% | 26.5% |
| Calcification | | |
| None / Mild | 1.0% | 1.2% |
| Moderate | 1.9% | 1.8% |
| Severe | **97.1%** | **97.0%** |
| Bifurcation/trifurcation | 30.3% | 32.2% |
| QCA | | |
| Reference vessel diameter (mm) | 3.0 ± 0.5 | 2.9 ± 0.4 |
| Minimal lumen diameter (mm) | 0.96 ± 0.35 | 0.95 ± 0.34 |
| Percent diameter stenosis | 67.6 ± 10.7 | 67.4 ± 10.9 |
| Lesion length (mm) | 28.9 ± 14.9 | 28.5 ± 15.3 |
| Calcification length (mm) | 42.1 ± 20.2 | 41.5 ± 19.6 |

Note: Calcification length may be longer than lesion length due to extension of calcium beyond the stenotic lesion

Kirtane et al, Lancet 2025

# Procedural Characteristics

| | Orbital Atherectomy (n=1008) | Balloon Angioplasty (n=997) | *p* |
|---|---|---|---|
| Number of target lesions treated | 1.2 ± 0.5 | 1.2 ± 0.5 | 0.44 |
| Femoral access site (any)# | 47.6% | 46.6% | 0.66 |
| Hemodynamic support | 0.8% | 0.7% | 0.81 |
| Temporary pacemaker* | 4.5% | 1.9% | 0.001 |
| Guide extension catheter used | 21.4% | 22.3% | 0.65 |
| Number of guide wires used | 2.7 ± 1.4 | 2.2 ± 1.4 | <0.001 |
| Microcatheter or OTW balloon used | 42.1% | 16.5% | <0.001 |
| Number of balloon catheters used | 3.6 ± 2.3 | 4.0 ± 2.8 | 0.02 |
| OA attempted | 98.9% | 3.7% | <0.001 |
| OA performed | 98.2% | 3.7% | <0.001 |
| Any intravascular imaging performed** | 62.1% | 62.0% | 0.96 |
| OCT | 40.3% | 41.1% | 0.70 |
| IVUS | 25.6% | 25.6% | 0.99 |
| Total contrast volume (mL) | 179.4 ± 94.4 | 160.0 ± 86.9 | <0.001 |
| Total procedure time (minutes) | 73.2 ± 33.8 | 60.1 ± 36.5 | <0.001 |

#Any femoral includes access with multiple sites including at least one femoral access.
*43 pacemakers in the OA group and 18 pacemakers in the BA group were placed prophylactically (pre-PCI).
**Both OCT and IVUS were used in some patients.

Kirtane et al, Lancet 2025

# Procedural Device Usage (Lesion-level)

| | Orbital Atherectomy (n=1008, 1250 lesions) | Balloon Angioplasty (n=1008, 1242 lesions) | *p* |
|---|---|---|---|
| Balloon type, all* | | | |
| Standard | 98.6% | 98.4% | 0.76 |
| Scoring | 2.0% | 11.0% | <0.001 |
| Cutting | 1.7% | 10.1% | <0.001 |
| Other specialty | 1.9% | 3.9% | 0.007 |
| Balloon compliance, all* | | | |
| Compliant | 19.6% | 21.0% | 0.47 |
| Semi-compliant | 37.4% | 43.2% | 0.008 |
| Non-compliant | 90.9% | 87.1% | 0.007 |
| Maximum balloon pressure (atm) | 19.0 ± 3.8 | 18.9 ± 4.1 | 0.46 |
| Orbital atherectomy performed | 93.1% | 3.8% | <0.001 |
| Number of passes | 3.8 ± 2.1 | 4.5 ± 2.8 | 0.01 |
| Total pass time (seconds) | 88.4 ± 59.9 | 112.3 ± 86.6 | 0.01 |
| Orbital atherectomy speed | | | |
| Low only | 71.9% | 63.8% | 0.28 |
| Low and high | 25.4% | 34.0% | 0.23 |
| High only | 2.8% | 2.1% | 0.81 |
| Rotational or laser atherectomy | 0.3% | 0.6% | 0.52 |
| Intravascular lithotripsy | 0.2% | 0.6% | 0.14 |

p-values are based on repeated measures modeling to account for clustering in subjects with multiple lesions
*Total is >100% because more than one balloon catheter type was used in some lesions

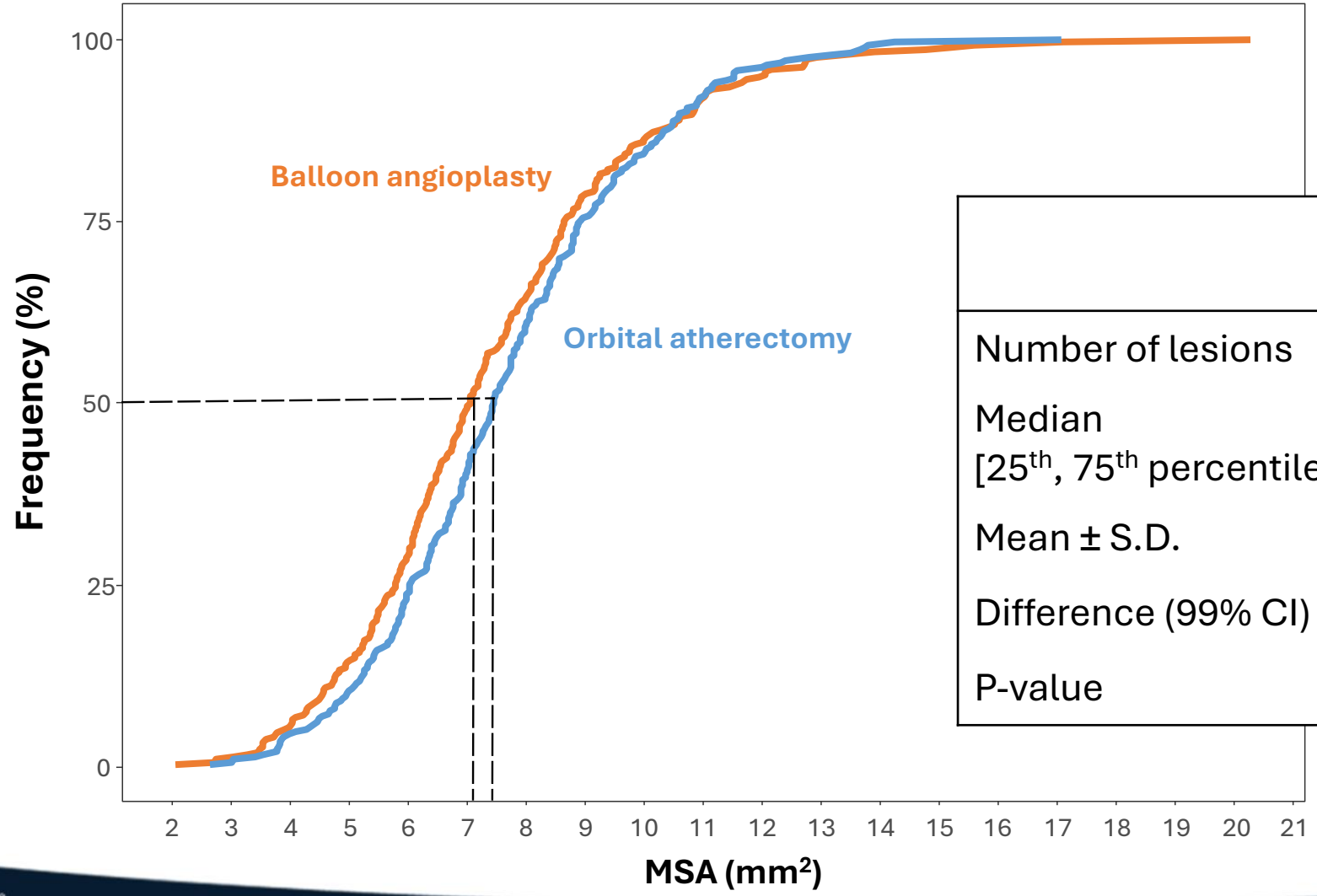
Kirtane et al, Lancet 2025

# Procedural Complications

| | Orbital Atherectomy (n=1008) | Balloon Angioplasty (n=997) | *p* |
|---|---|---|---|
| Thrombus | 5 (0.5%) | 3 (0.3%) | 0.73 |
| Spasm | 30 (3.0%) | 21 (2.1%) | 0.22 |
| Abrupt closure | 6 (0.6%) | 2 (0.2%) | 0.29 |
| No reflow | 3 (0.3%) | 1 (0.1%) | 0.62 |
| Slow flow | 14 (1.4%) | 4 (0.4%) | 0.03 |
| Type C-F dissection | 70 (6.9%) | 63 (6.3%) | 0.57 |
| Distal embolization | 2 (0.2%) | 2 (0.2%) | 1.0 |
| Perforation | 18 (1.8%) | 10 (1.0%) | 0.14 |
| Ellis I | 5 (0.5%) | 1 (0.1%) | 0.30 |
| Ellis II | 4 (0.4%) | 4 (0.4%) | |
| Ellis III | 9 (0.9%) | 5 (0.5%) | |

# Primary Imaging Endpoint (OCT Cohort)

## Minimal stent area at maximum calcium site

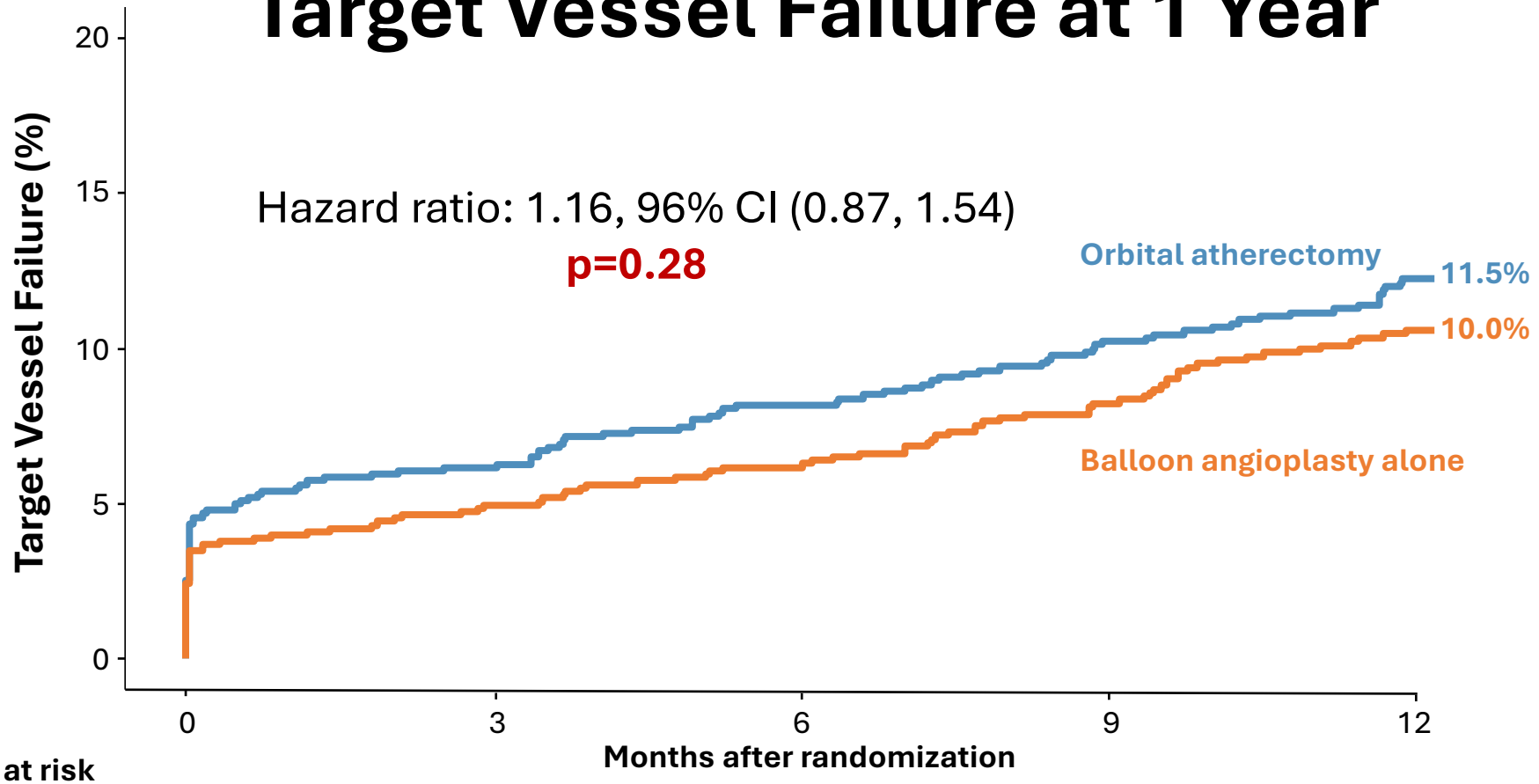



| | Orbital atherectomy | Balloon angioplasty |
|---|---|---|
| Number of lesions | 286 | 292 |
| Median [25th, 75th percentiles] | **7.44** [6.03, 8.94] | **7.05** [5.78, 8.66] |
| Mean ± S.D. | **7.67** ± 2.27 | **7.42** ± 2.54 |
| Difference (99% CI) | **0.26** (-0.31, 0.82) mm² | |
| P-value | **0.08** | |

Kirtane et al, Lancet 2025

**Overall MSA: 6.13 ± 2.01 with Orbital Atherectomy vs. 5.87 ± 2.04 with Balloon Angioplasty; p=0.10**

# Primary Clinical Endpoint
# Target Vessel Failure at 1 Year




**Number at risk**

| | | | | | |
|---|---|---|---|---|---|
| Orbital Atherectomy | 1008 | 927 | 883 | 860 | 838 |
| Balloon Angioplasty | 997 | 928 | 891 | 862 | 834 |

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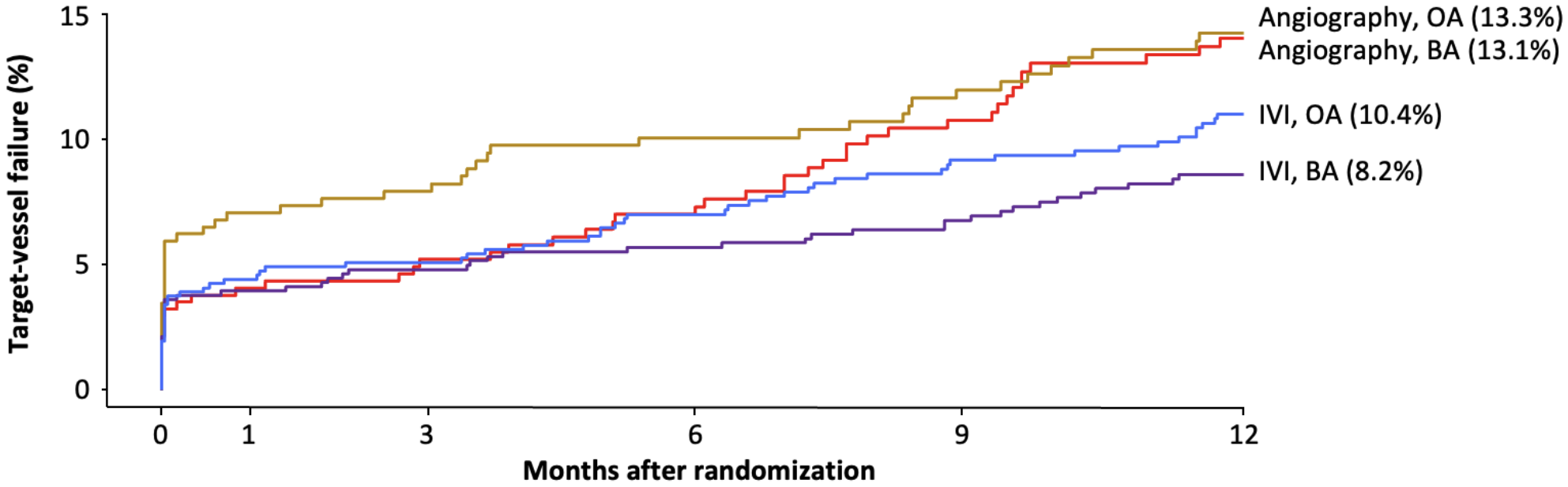
# 1-Year Clinical Outcomes

| | Orbital Atherectomy (n=1008) | Balloon Angioplasty (n=997) | *p* |
|---|---|---|---|
| All-cause death | 61 (6.2%) | 53 (5.5%) | 0.48 |
| Cardiac | 39 (4.0%) | 26 (2.7%) | 0.12 |
| Vascular | 4 (0.4%) | 2 (0.2%) | 0.43 |
| Non-cardiovascular | 18 (1.9%) | 25 (2.6%) | 0.28 |
| All MI | 80 (8.1%) | 74 (7.6%) | 0.65 |
| Procedural | 41 (4.1%) | 34 (3.4%) | 0.45 |
| Non-procedural | 41 (4.3%) | 40 (4.2%) | 0.94 |
| Target-vessel related | 55 (5.6%) | 43 (4.4%) | 0.24 |
| Non-target-vessel related | 27 (2.8%) | 32 (3.4%) | 0.49 |
| Ischemia-driven revasc | 81 (8.5%) | 76 (8.1%) | 0.70 |
| Ischemia-driven TVR | 40 (4.2%) | 41 (4.4%) | 0.88 |
| Ischemia-driven TLR | 32 (3.4%) | 32 (3.4%) | 0.98 |
| Stent thrombosis | 11 (1.1%) | 4 (0.4%) | 0.08 |
| Definite | 8 (0.8%) | 4 (0.4%) | 0.26 |
| Probable | 3 (0.3%) | 0 (0.0%) | 1.00 |

# Target Vessel Failure at 1-Year

OA: IVI guidance vs. angiography guidance alone - HR, 0.76, 95% CI, 0.53 to 1.11
CBA: IVI guidance vs. angiography guidance alone - HR, 0.62, 95% CI, 0.42 to 0.93
IVI guidance: OA vs. BA - HR, 1.27, 95% CI, 0.88 to 1.84
Angiography guidance alone: OA vs. BA - HR, 1.04, 95% CI, 0.70 to 1.56

$P_{interaction} = 0.48$



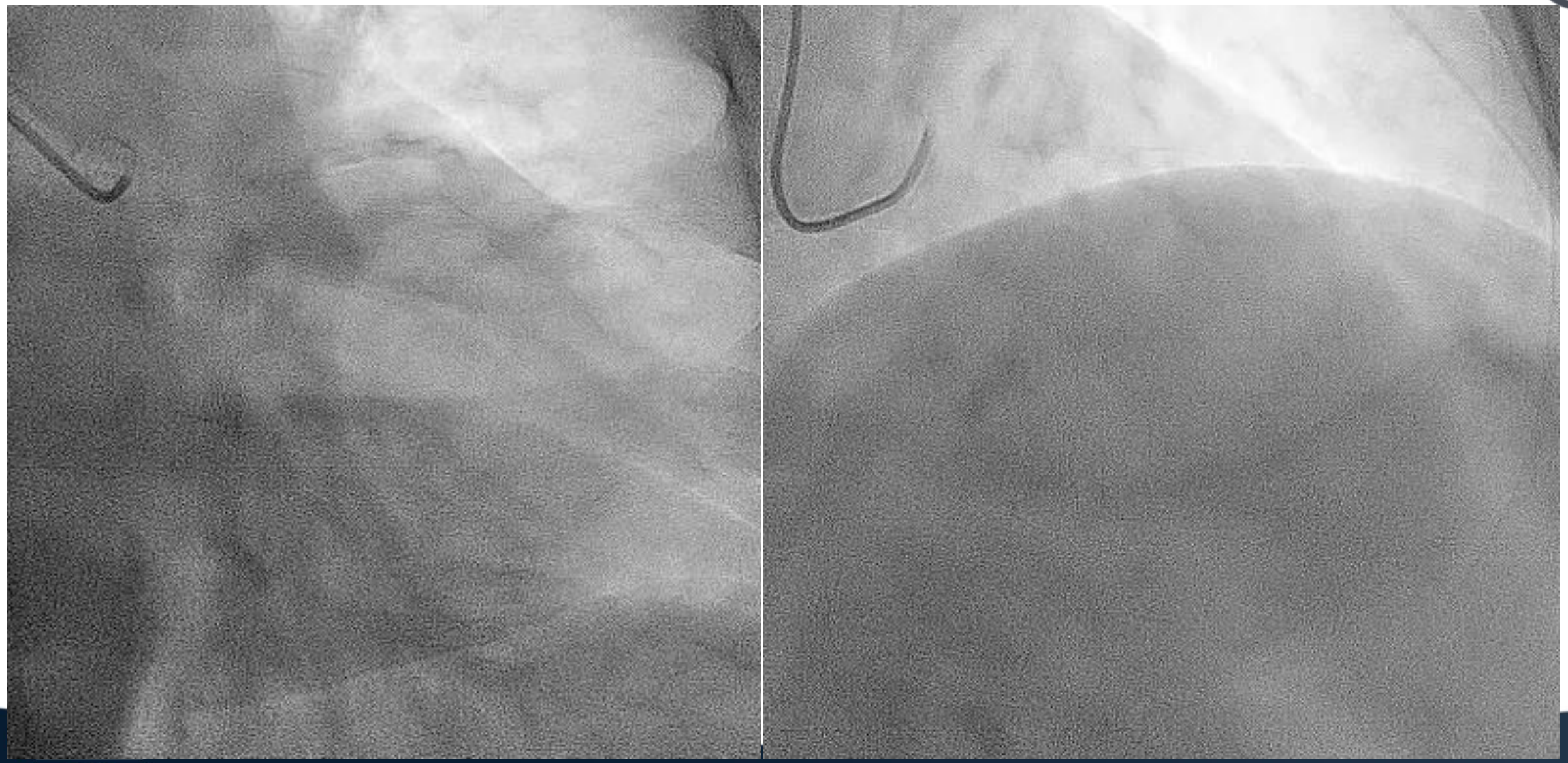

| Number at risk | | | | | | |
|---|---|---|---|---|---|---|
| Angiography guidance, BA | 378 | 355 | 347 | 327 | 311 | 296 |
| Angiography guidance, OA | 381 | 350 | 343 | 319 | 311 | 301 |
| IVI guidance, BA | 619 | 593 | 581 | 564 | 551 | 538 |
| IVI guidance, OA | 627 | 594 | 584 | 564 | 549 | 537 |

G. Stone, ACC 2025

# ECLIPSE Data Summary

- **The routine use of orbital atherectomy did not improve MSA or reduce TVF** at 1 yr compared w/conventional balloon angioplasty for preparation of severely calcified coronary lesions prior to DES implantation
  - *It's NOT that atherectomy didn't work… it's that balloons worked FAR better than anticipated!*
- Extremely calcified lesions that would be balloon-uncrossable or -undilatable (i.e. would require atherectomy) were excluded
  - ➢ Only 4.9% of lesions randomized to balloon crossed over
- Most lesions were qualified based upon angio, but use of intravascular imaging was high (62%), with better outcomes in both groups

# Case Example: Calcified LAD, randomized to balloon



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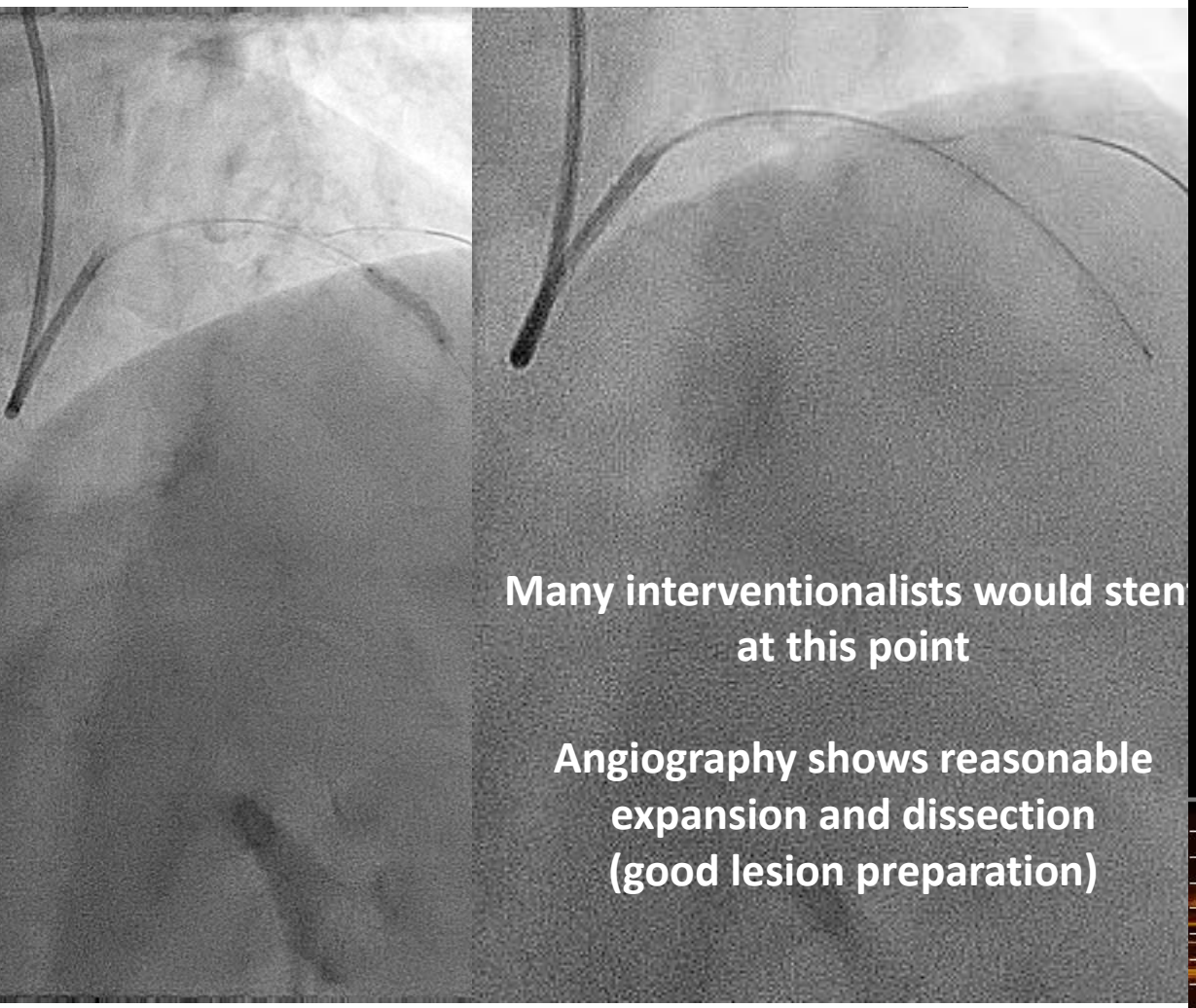
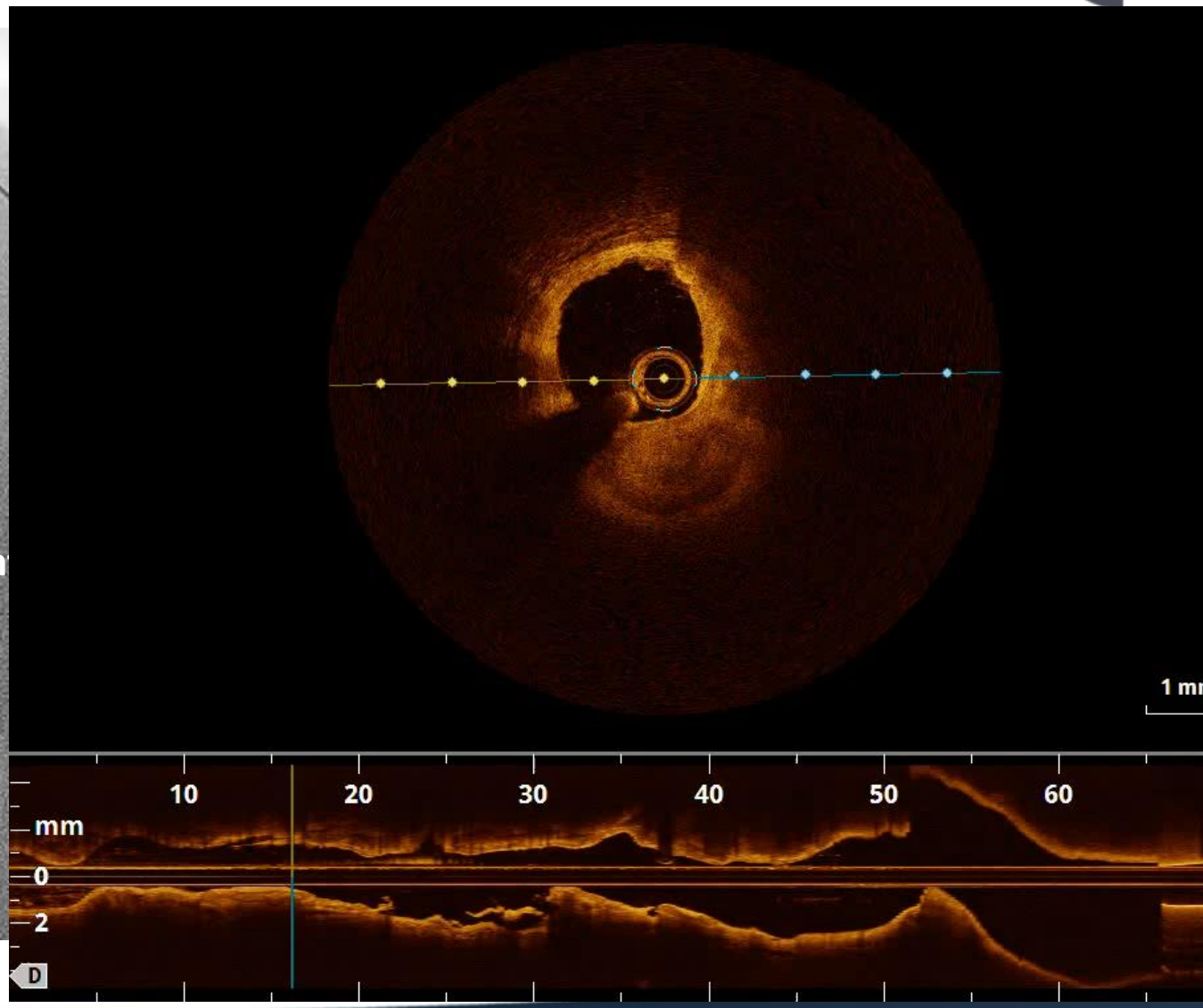
# Predilation: 3.0 mm NC balloon at 20 atm



Many interventionalists would sten
at this point

Angiography shows reasonable
expansion and dissection
(good lesion preparation)



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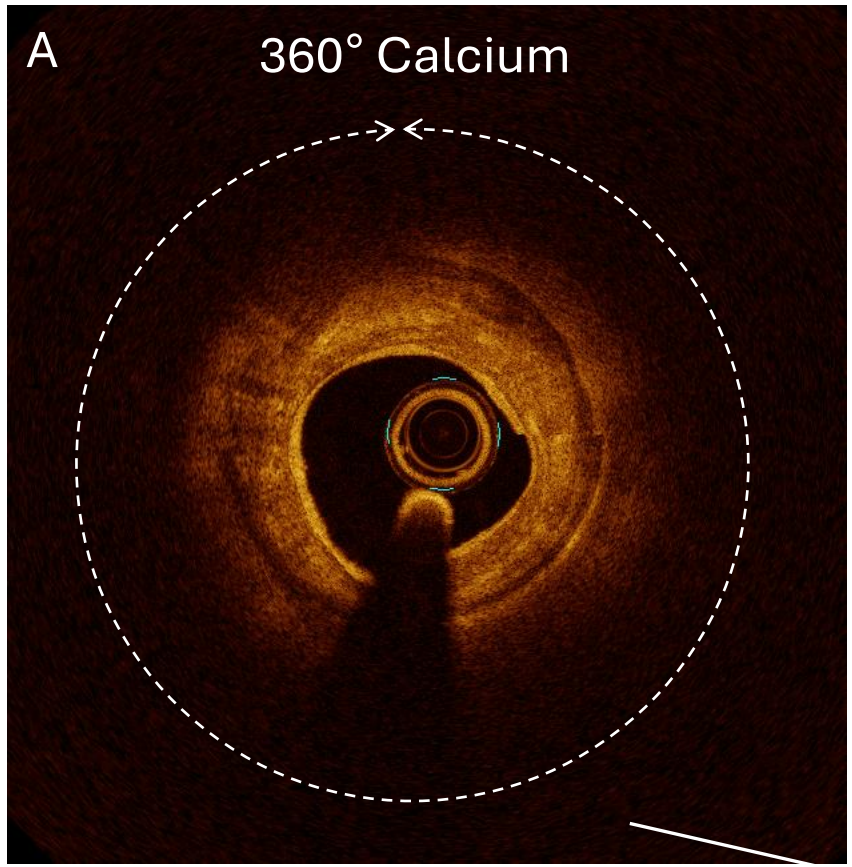
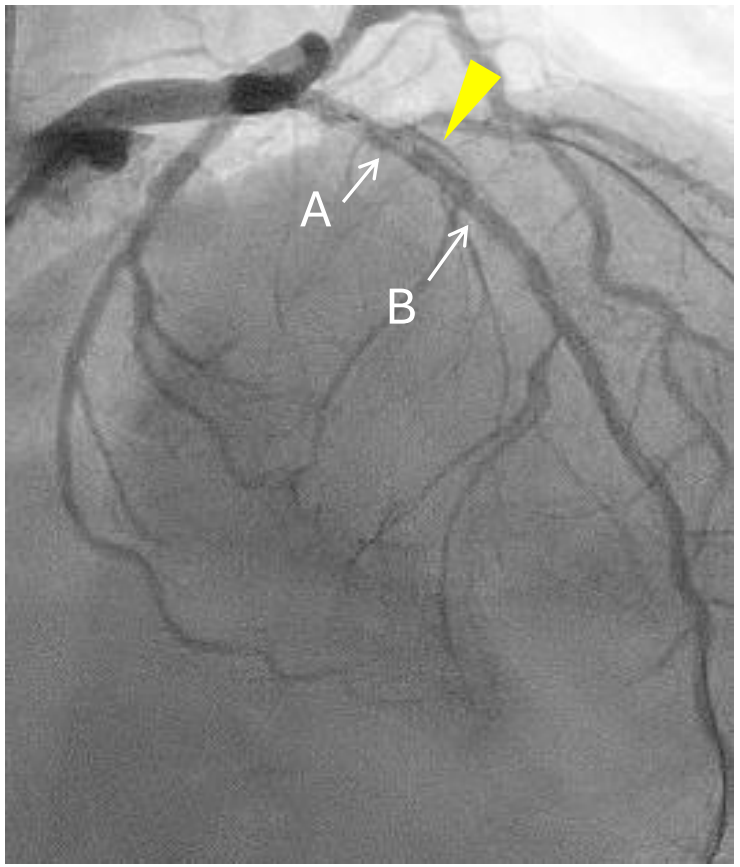
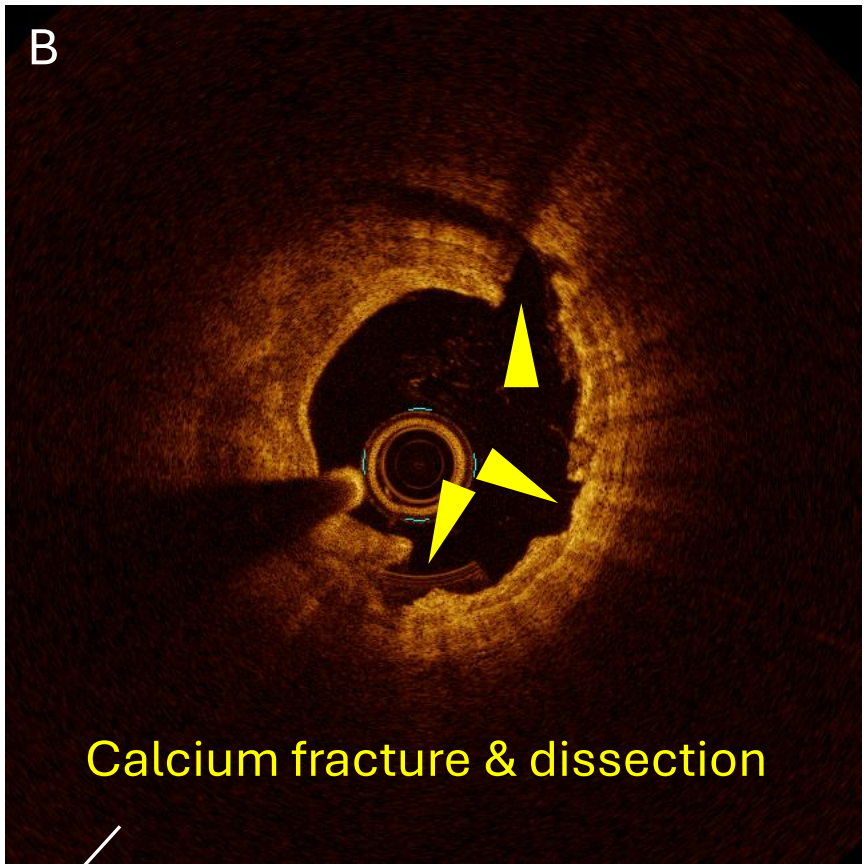
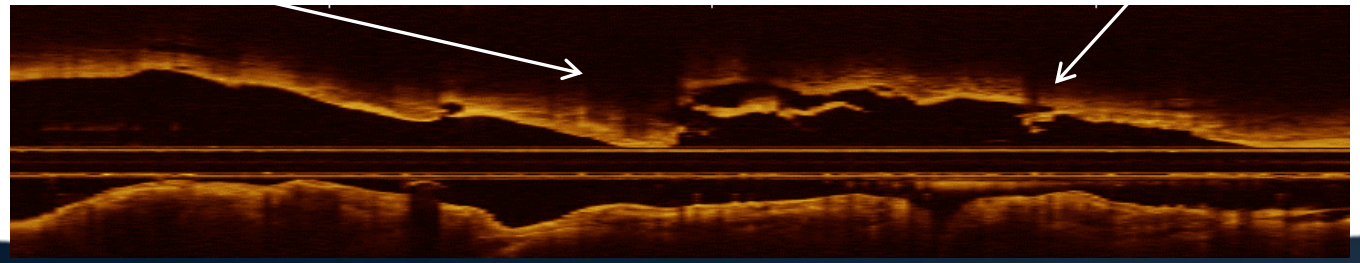


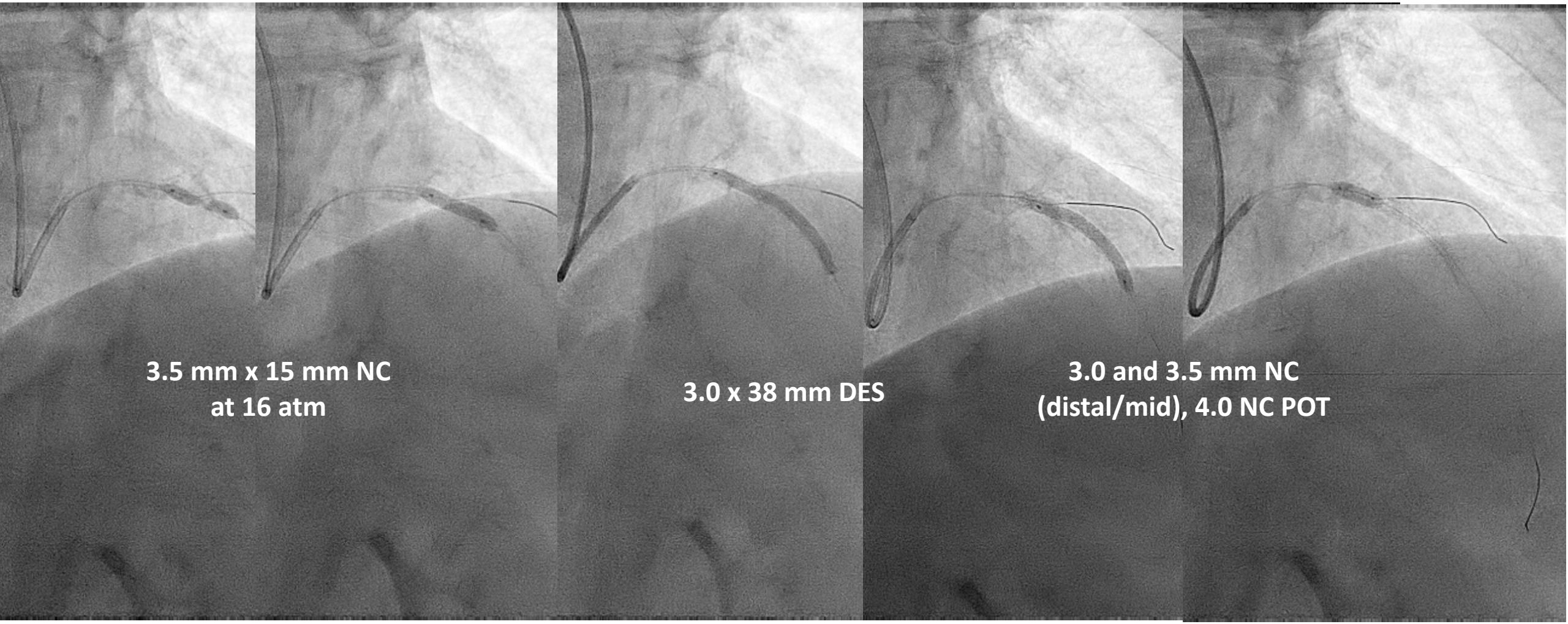




proximal



distal

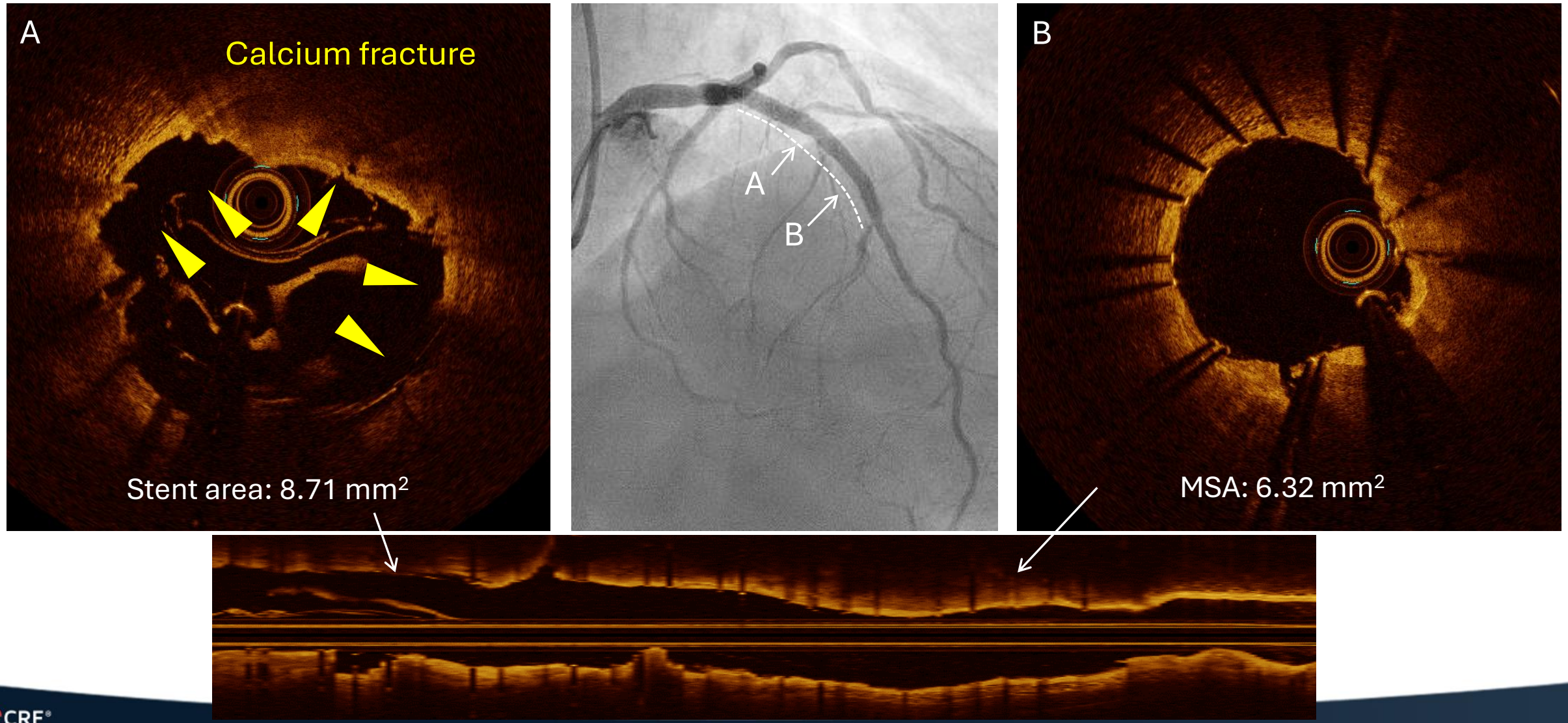
# Further Lesion Prep / Stenting / Optimization



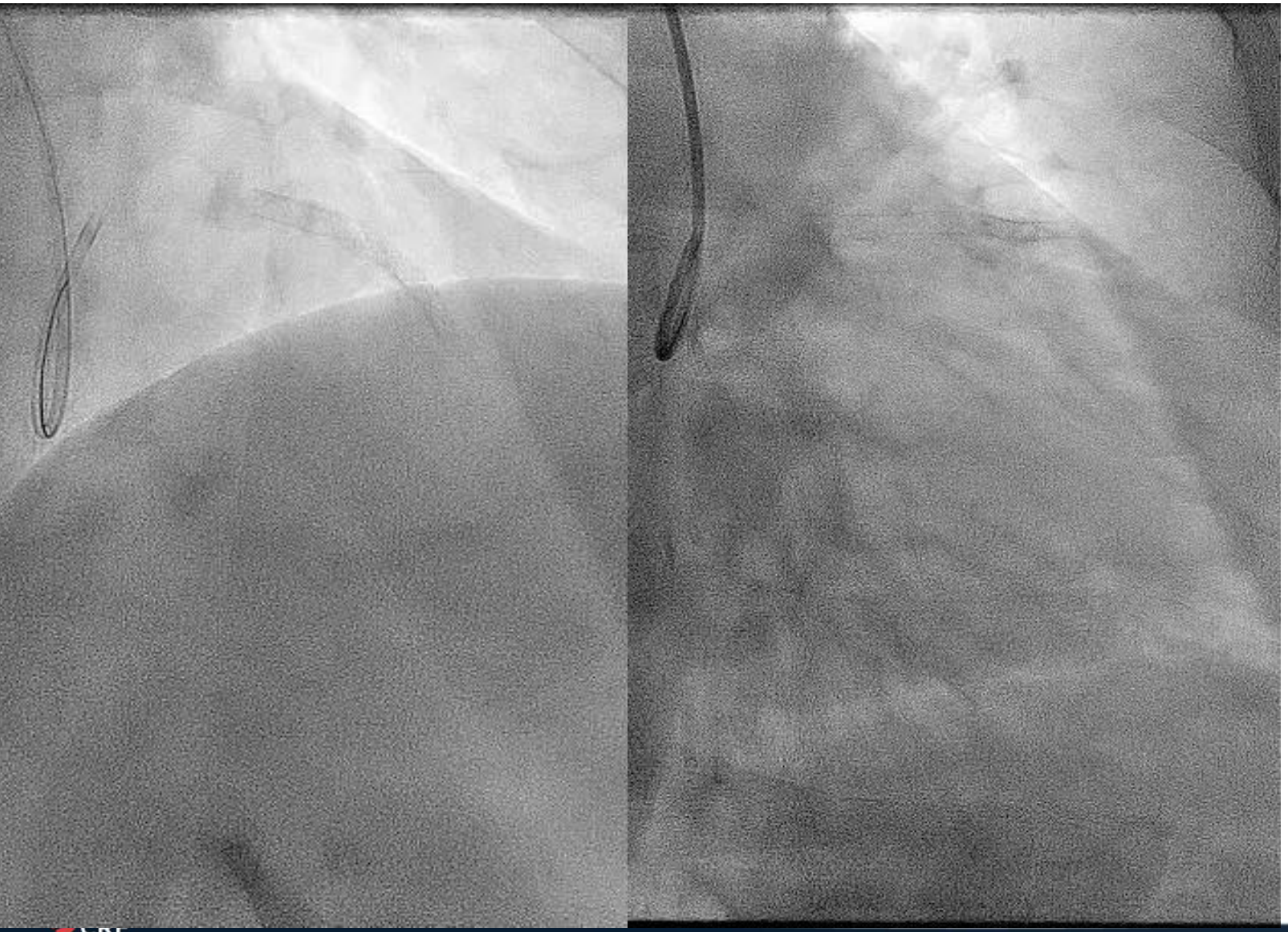
# Final OCT

360° Calcium Site

MSA Site



# Final Angiography and Lessons from ECLIPSE



1. **ECLIPSE shows that for lesions like this, using conventional balloons is a wholly reasonable first approach**
2. The initial angiogram recognized calcium, *but was not sufficient to optimize lesion preparation*
3. The use of intraprocedural imaging allowed me to confirm adequate lesion preparation prior to stent implantation (preventing stenting an unprepped site), and also facilitated safe optimization of my stents

# ECLIPSE: Take Home Messages

***Adequate stent expansion and low rates of adverse outcomes are achievable with conventional balloon angioplasty in a substantial proportion of severely calcified lesions if meticulous attention (including IV-imaging) is paid to lesion preparation***

**RCTs are essential to inform treatment strategies in this space…**

**(Especially with the areas observed in the OCT cohort of patients, *this result could have happened with any technology*)**

ECLIPSE Clinical Trial

THE LANCET

Articles

# Orbital atherectomy versus balloon angioplasty before drug-eluting stent implantation in severely calcified lesions eligible for both treatment strategies (ECLIPSE): a multicentre, open-label, randomised trial

*Ajay J Kirtane, Philippe Généreux, Bruce Lewis, Richard A Shlofmitz, Suhail Dohad, Jithendra Choudary, Thom Dahle, Andres M Pineda, Kendrick Shunk, Akiko Maehara, Alexandra Popma, Bjorn Redfors, Ziad A Ali, Mitchell Krucoff, Ehrin Armstrong, David E Kandzari, William O'Neill, Carlye Kraemer, Krista M Stiefel, Denise E Jones, Jeff Chambers, Gregg W Stone, on behalf of the ECLIPSE Investigators**

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