# When and How to Apply Atherectomy Devices

**Ajay J. Kirtane, MD, SM**

*Center for Interventional Vascular Therapy*
*Columbia University Irving Medical Center*
*NewYork-Presbyterian Hospital*

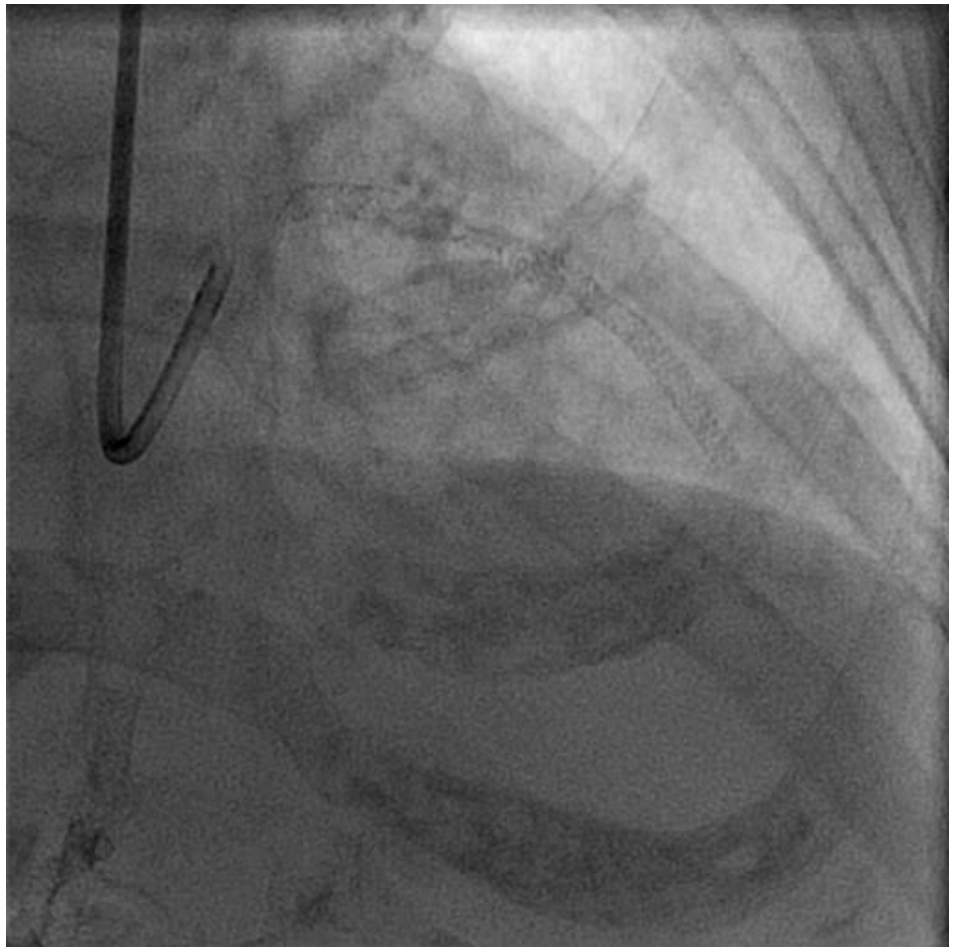
*@ajaykirtane*

# Financial Conflict of Interest Disclosure

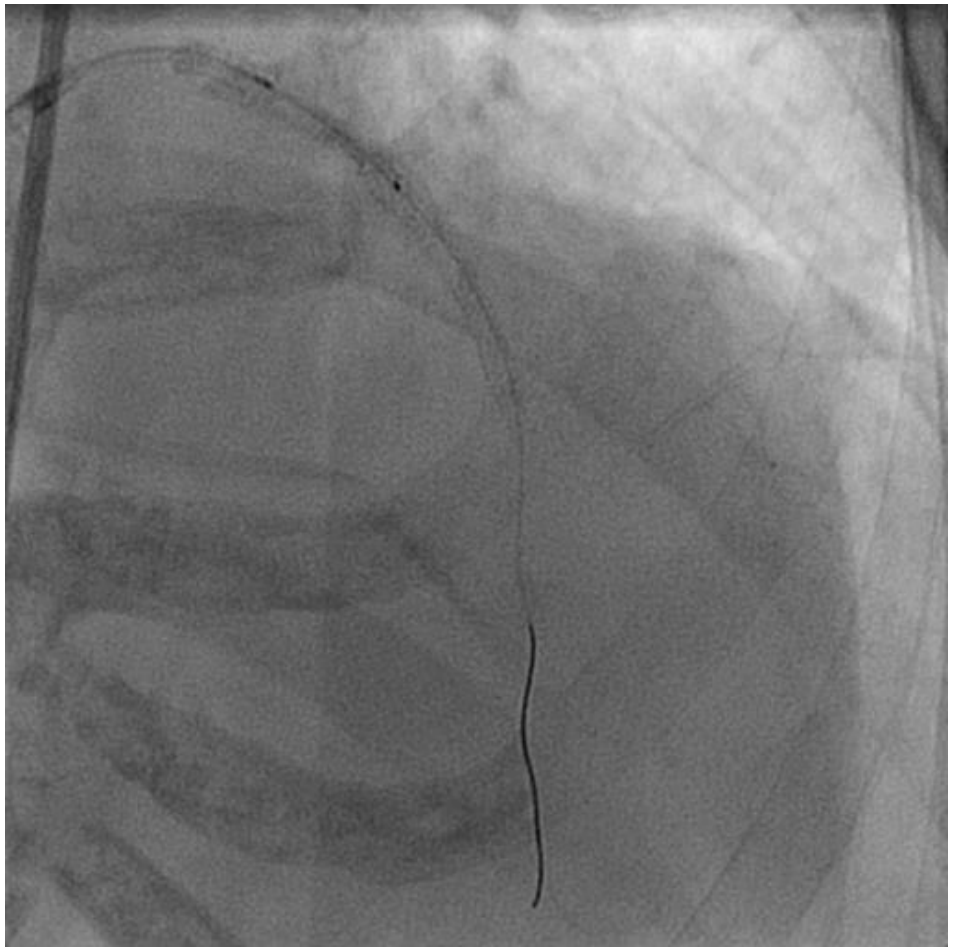
- Dr Kirtane reports Institutional funding to Columbia University and/or Cardiovascular Research Foundation from Medtronic, Boston Scientific, Abbott Vascular, Amgen, CSI, Siemens, Philips, ReCor Medical, Neurotronic, Biotronik. In addition to research grants, institutional funding includes fees paid to Columbia University and/or Cardiovascular Research Foundation for consulting and/or speaking engagements in which Dr. Kirtane controlled the content. Personal: Consulting from IMDS; Travel Expenses/Meals from Medtronic, Boston Scientific, Abbott Vascular, Abiomed, CSI, Siemens, Philips, ReCor Medical, Chiesi, OpSens, Zoll, and Regeneron.

# An Illustrative Case…

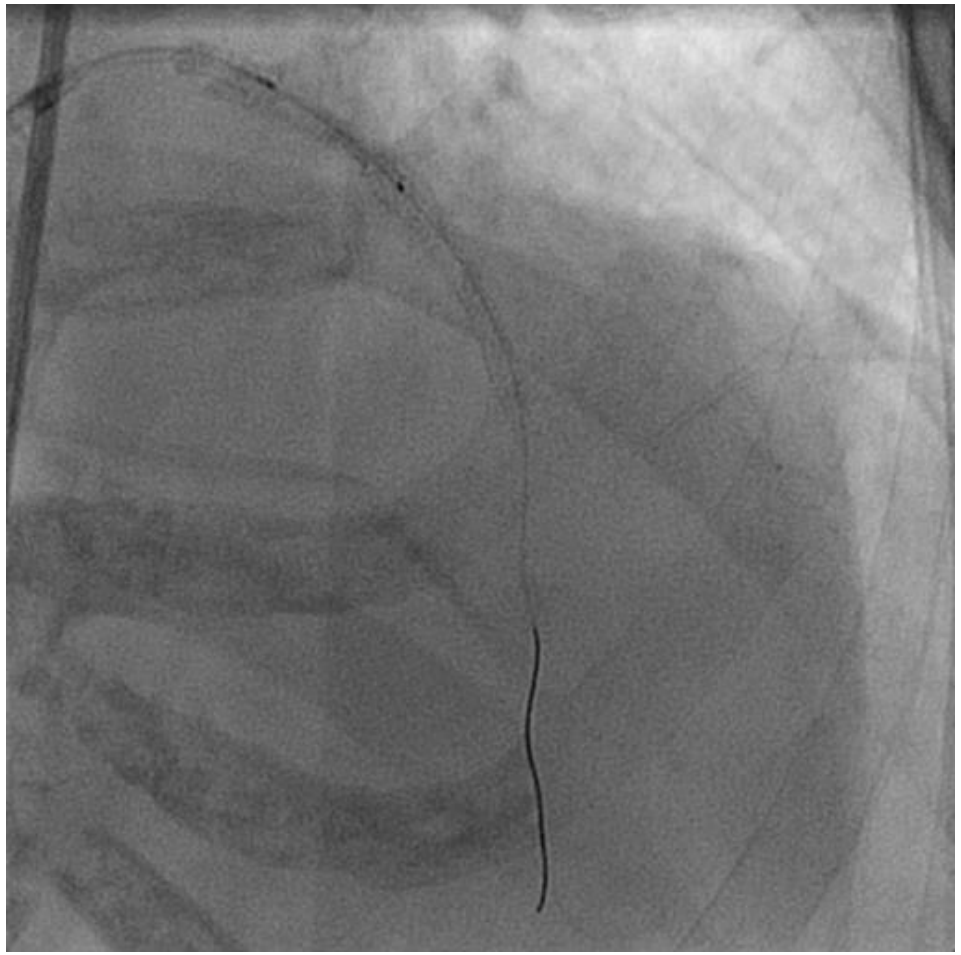
- 70 yo F with PMH of HTN, HLD, DM2, CLL and CAD/PAD with progressive angina
- 2/3/2017 Stents deployed in proximal/mid LAD with noted underexpansion
  - Progressive exertional angina
- 07/14/2017 Rotational atherectomy (stent ablation) with PTCA
  - Still unable to expand stent
  - Continued exertional angina



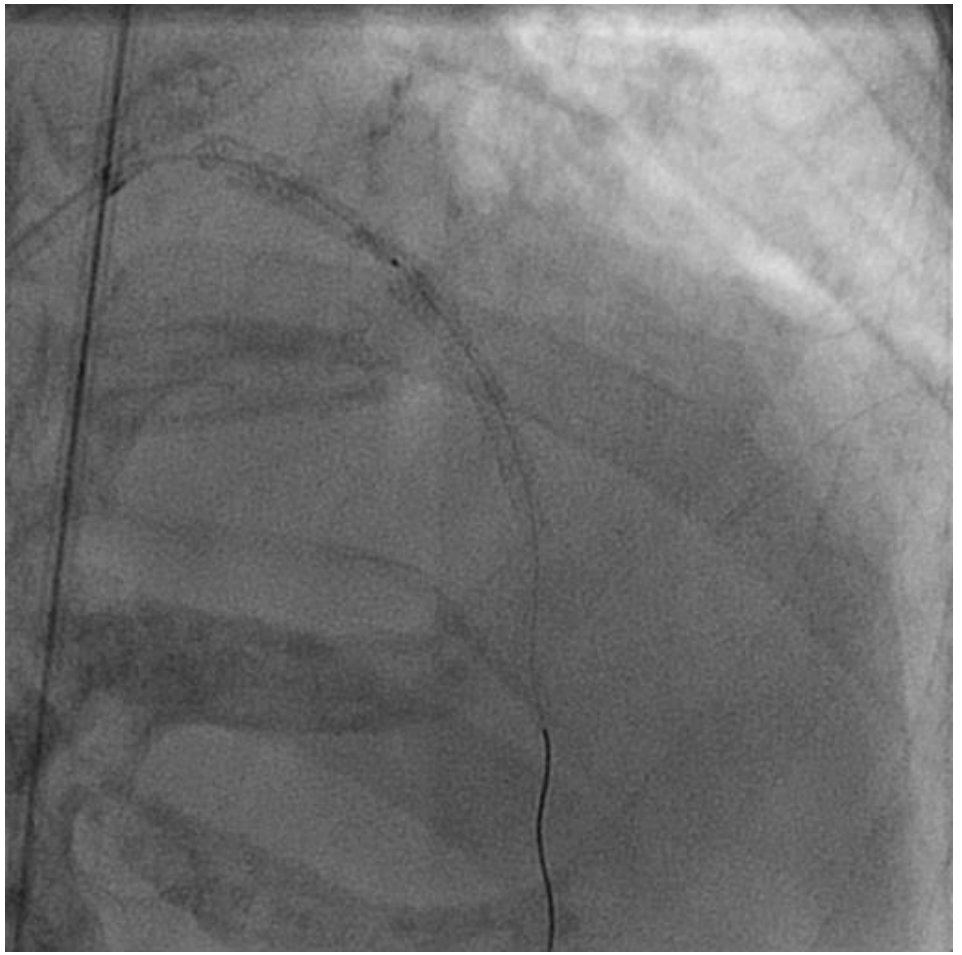
7F EBU 3.5



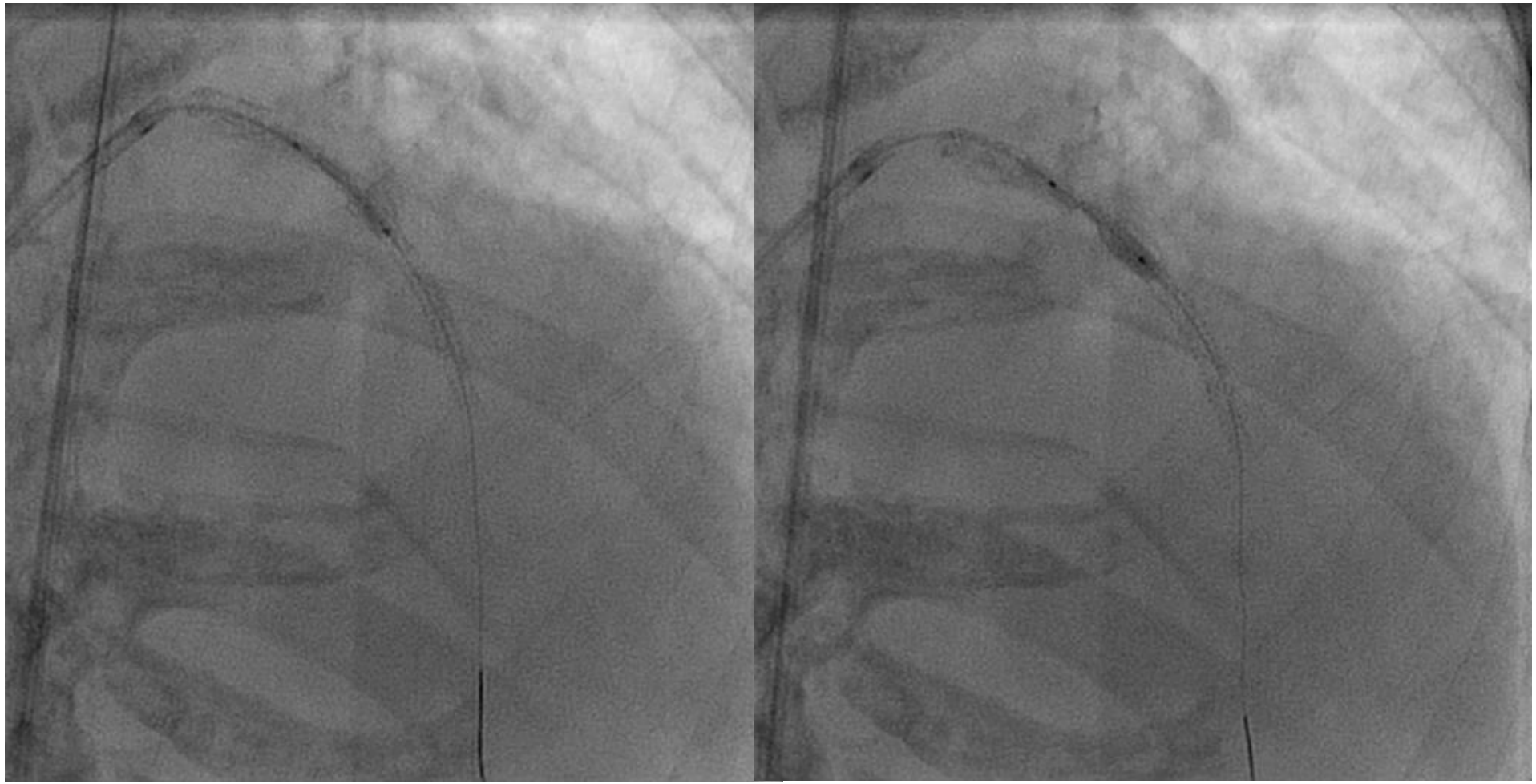
IVUS – Wouldn’t cross



2.0 x 15 balloon: would not cross



1.25 x 6 followed by 1.5 mm balloon



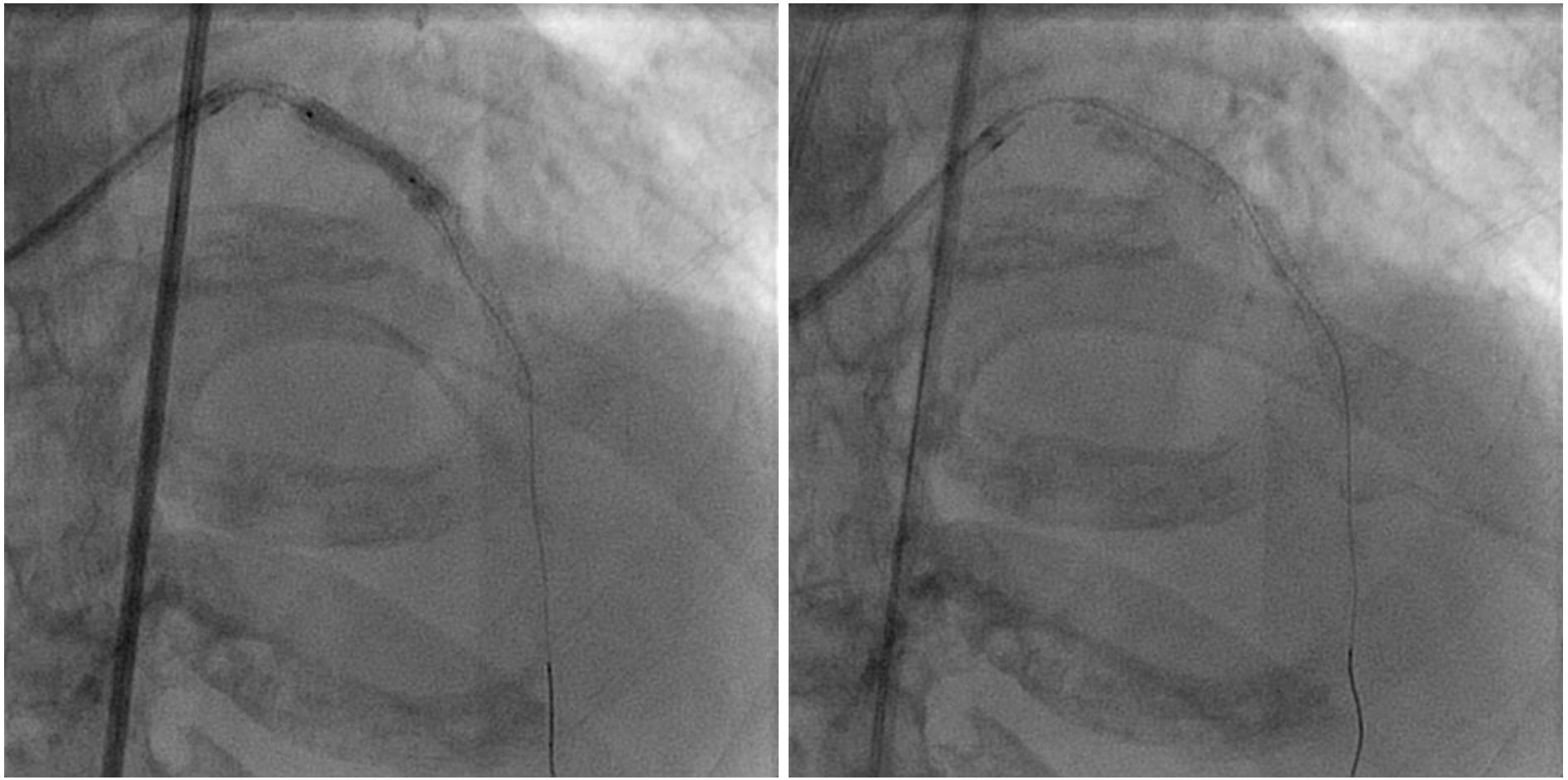
NC Quantum 3.0 x 15 @ 30 (x4 times)

NC Euphora  3.0 x 15 @ 30 (x2 times)

Unable to advance 3.0 balloon past pLAD stent

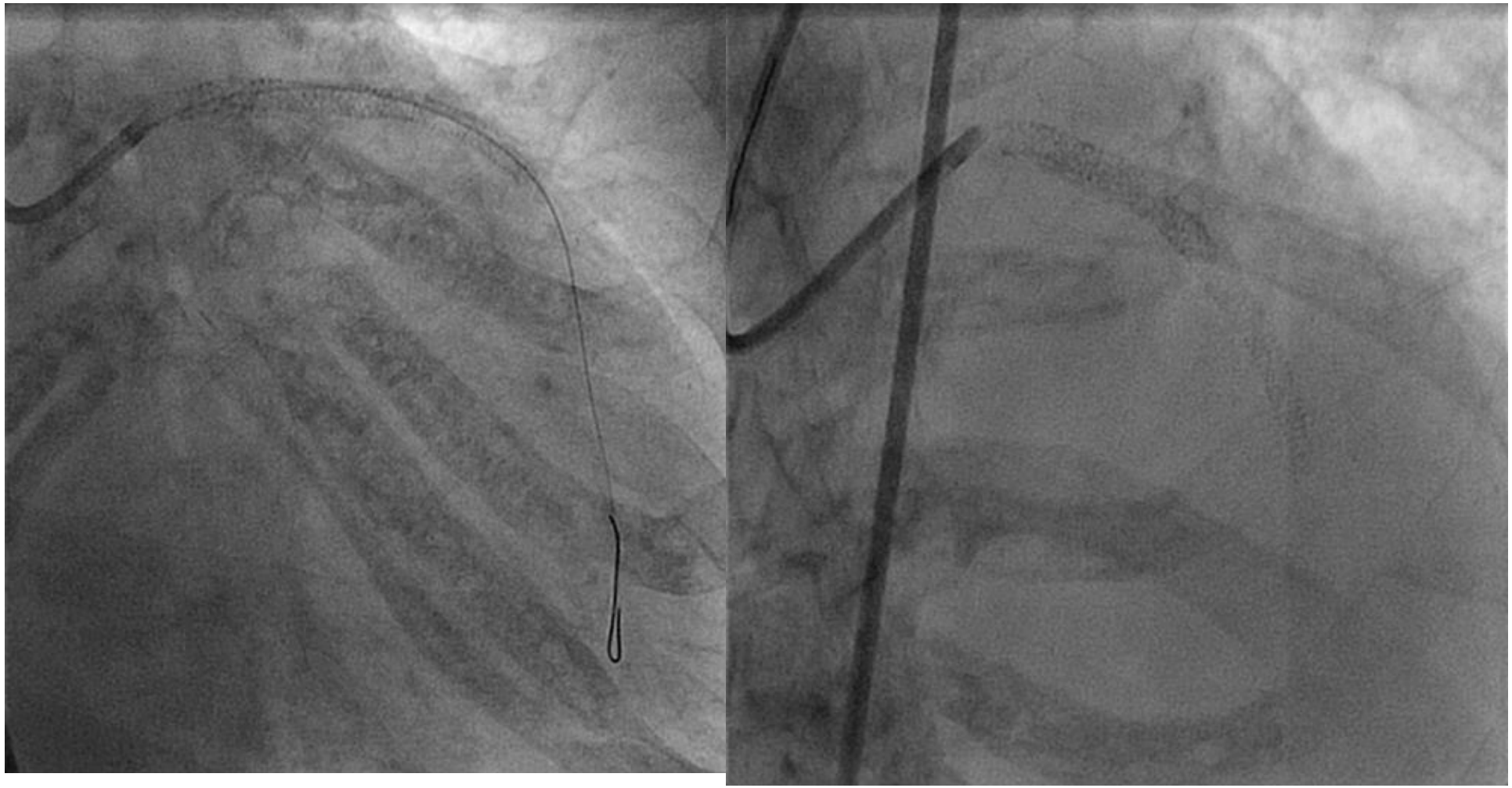
***What Next?***

# After Laser Atherectomy (Contrast)



NC 3.0 x 15 @ 26

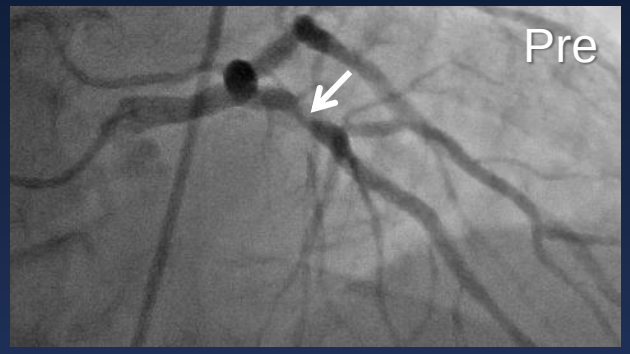
# Final Result

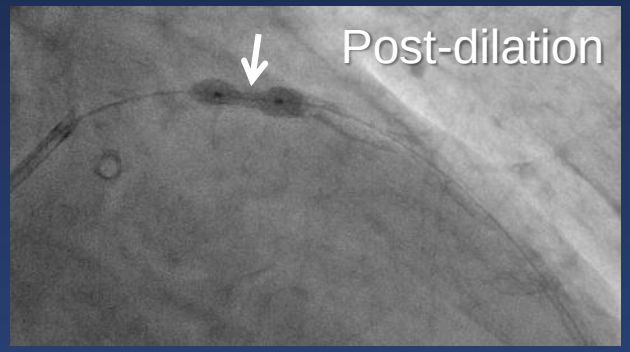


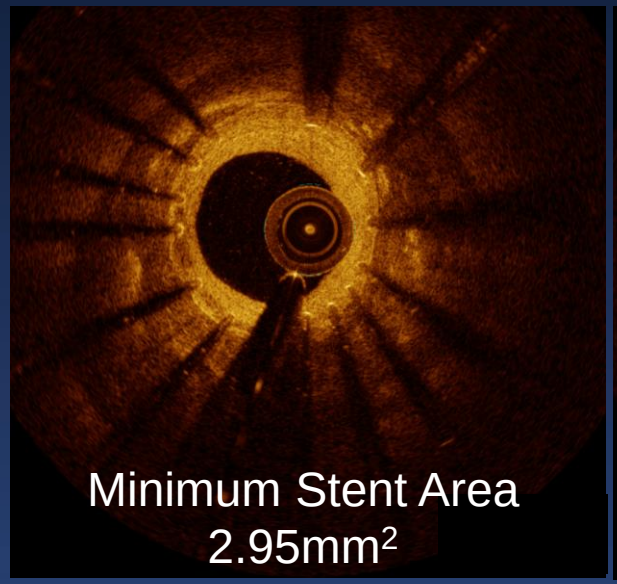
# Is this case more broadly generalizable?

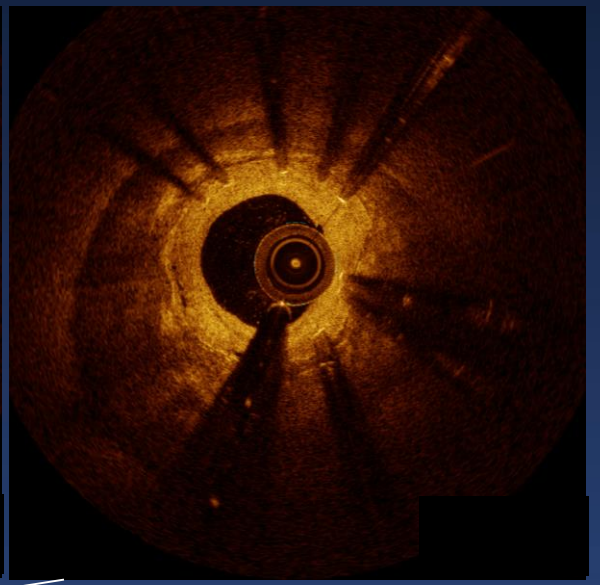
*YES!!*

# 79 yo, Recurrent ISR



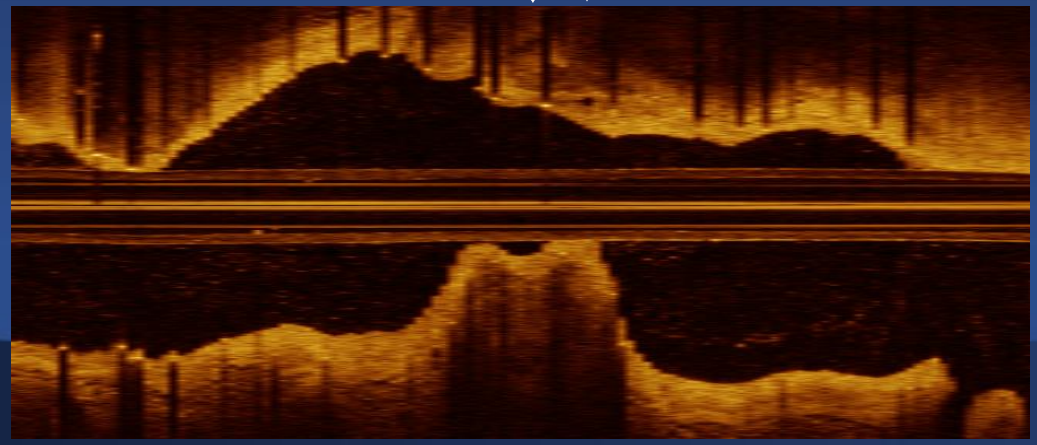



Distal

Proximal



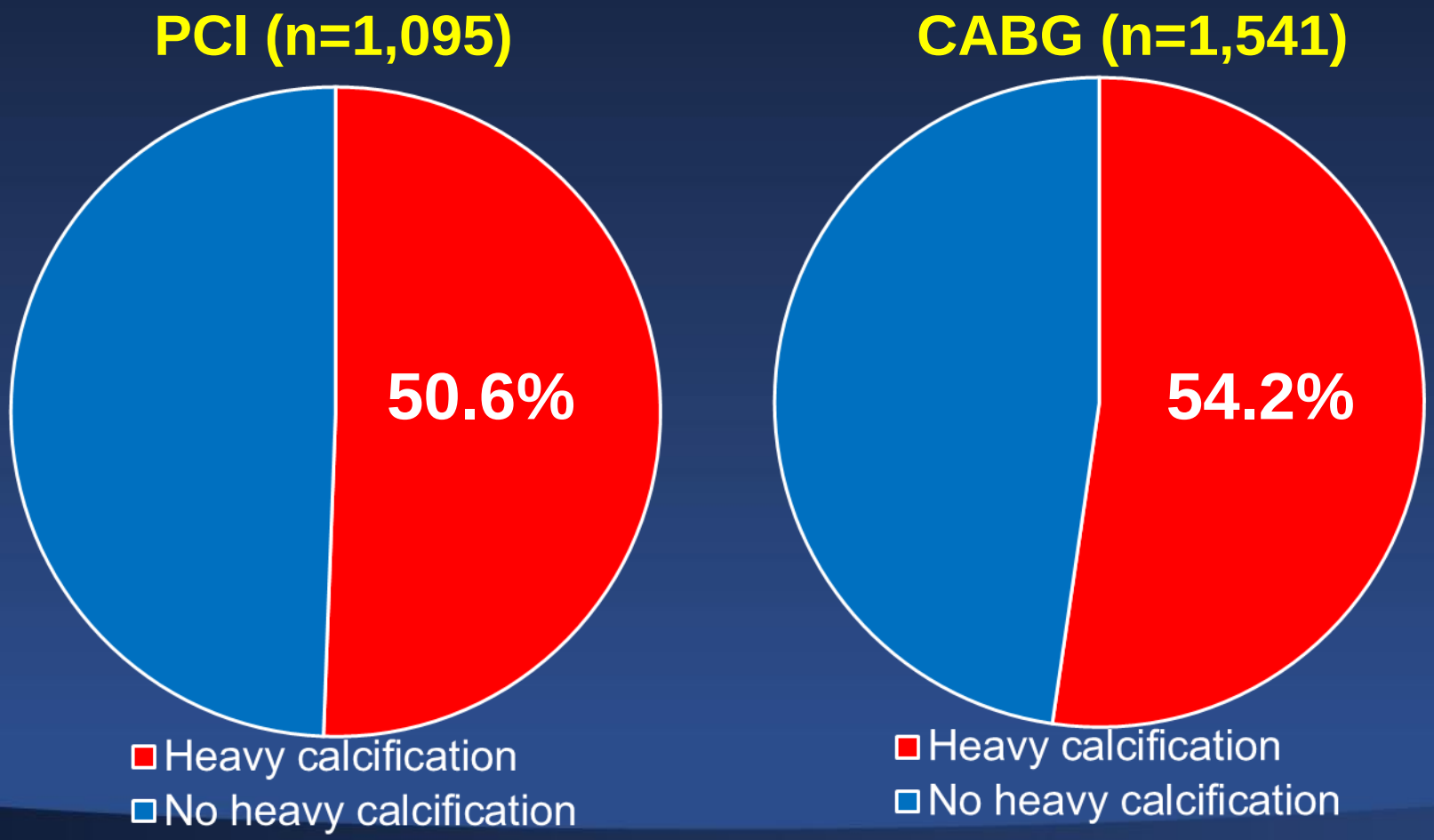
# Frequency of angio core lab moderate-severe calcification in 13 DES studies

(despite being an exclusion criterion in most studies)

| | |
|---|---|
| RAVEL | 23.3% (27/116) |
| SIRIUS | 17.1% (91/531) |
| E-SIRIUS | 16.1% (28/174) |
| C-SIRIUS | 12.0% (6/50) |
| TAXUS IV | 18.3% (121/660) |
| TAXUS V | 32.5% (185/570) |
| TAXUS VI | 29.7% (65/219) |
| ENDEAVOR II | 23.7% (140/590) |
| ENDEAVOR III | 17.9% (78/436) |
| ENDEAVOR IV | 33.2% (513/1546) |
| SPIRIT II | 31.4% (91/290) |
| SPIRIT III | 27.8% (277/997) |
| COMPARE | 38.5% (693/1799) |
| **Pooled** | **29.0% (2,315/7,978)** |

# Frequency of "heavy" calcification in the SYNTAX trial: Randomized + Registry

N=2,636 pts with LM or 3VD

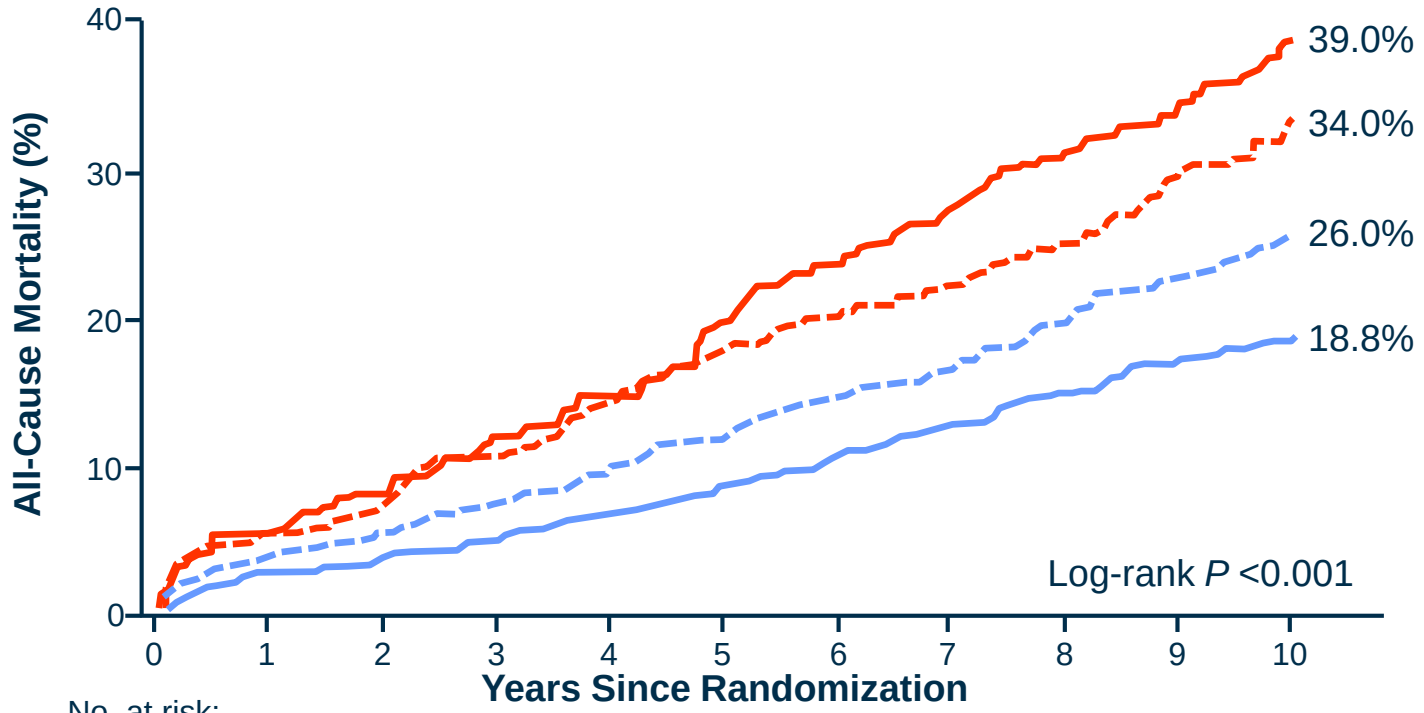



Farooq et al. J Am Coll Cardiol 2013;61:282–94

# Implications of coronary calcification

- ***Coronary calcification results in:***
  - Impaired stent delivery, decreased stent expansion, increased malapposition and stent asymmetry
  - Increased procedural complications (edge dissections and perforations)
  - Increased rates of stent thrombosis and restenosis

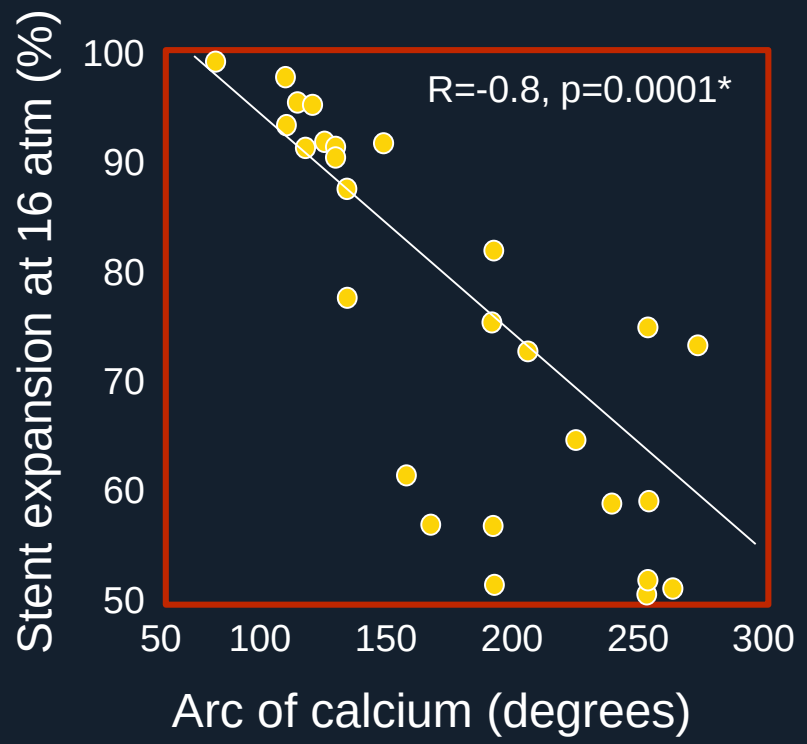
# Heavily Calcified Lesions Are Associated with Late Mortality after PCI or CABG: The SYNTAX Trial (N =1,800)



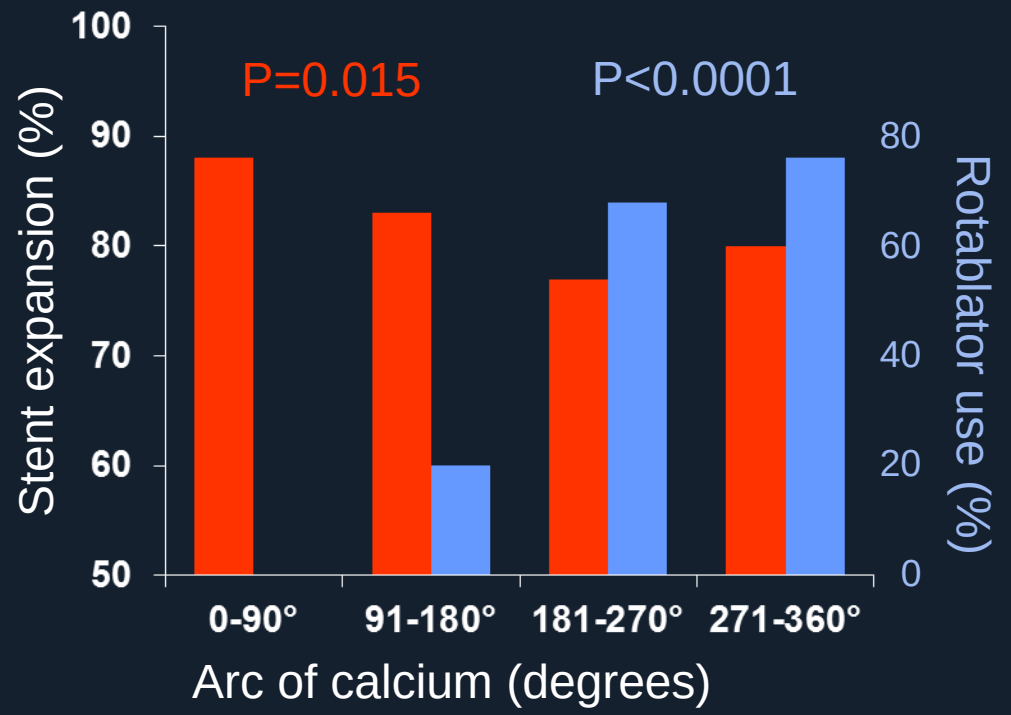

No. at risk:

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Patients Without Heavily Calcified Lesions Undergoing PCI | 627 | 602 | 591 | 578 | 563 | 536 | 503 | 488 | 468 | 449 | 422 |
| Patients Without Heavily Calcified Lesions Undergoing CABG | 641 | 618 | 606 | 598 | 586 | 566 | 543 | 526 | 514 | 500 | 488 |
| Patients With Heavily Calcified Lesions Undergoing PCI | 276 | 258 | 253 | 244 | 232 | 221 | 208 | 202 | 194 | 181 | 170 |
| Patients With Heavily Calcified Lesions Undergoing CABG | 256 | 238 | 232 | 222 | 214 | 198 | 184 | 174 | 165 | 157 | 145 |

# Stent Expansion in Calcified Lesions



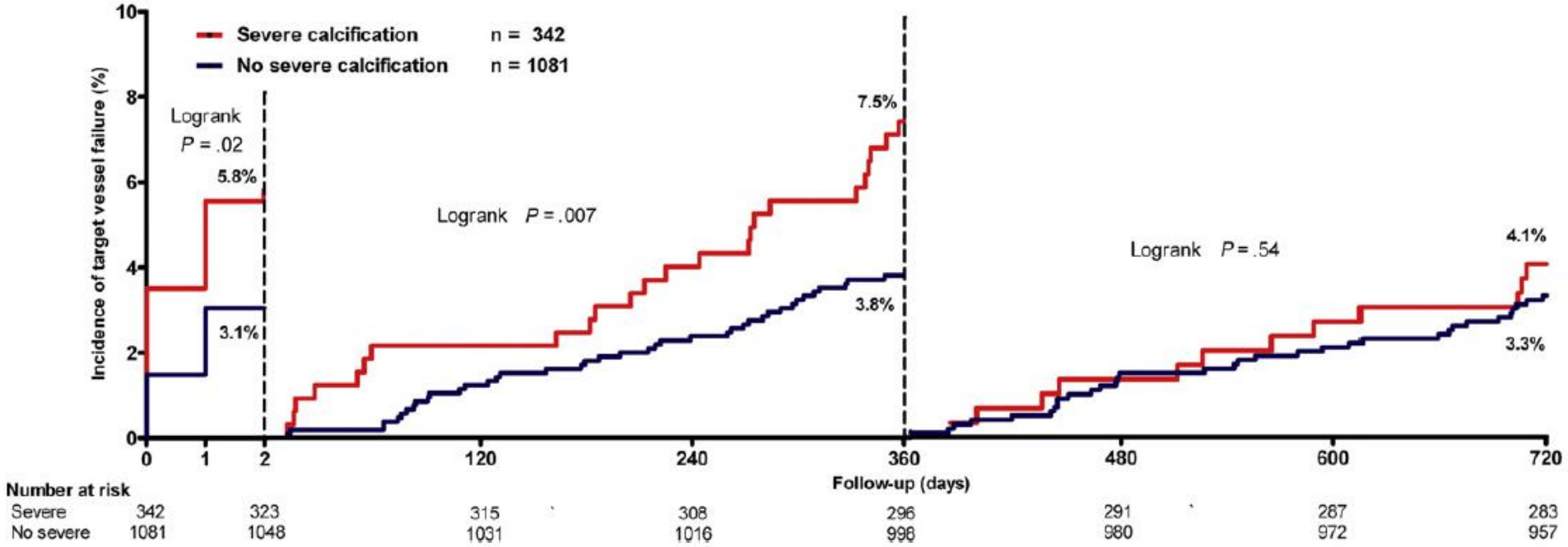

*There was a similar, albeit less strong, correlation after 20 atm inflation (r=-0.58, p=0.0007)




Vavarunakis et al. Catheter Cardiovasc Interv 2001;52:164-172
Hoffmann et al. Eur Heart J 1998;19:1224-31

# TWENTE and DUTCH PEERS (TWENTE II): Impact of Severe Calcification with 2nd Generation DES

1,423 pts with stable angina; 342 with severe calcification (24%)




At 2 years, TVF was 16.4% vs. 9.8%, p=0.001
predominantly driven by events in the first 48 hours and up to 1 year

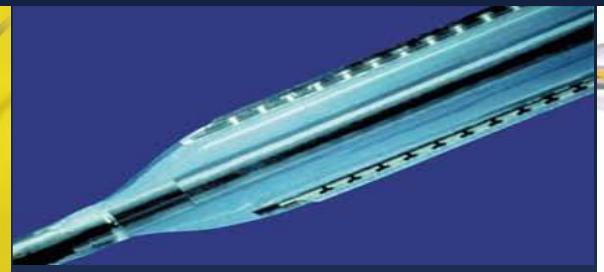
Of note, 2 year definite ST was 1.8% vs. 0.4%, p=0.02

Huisman et al, Am Heart J 2016

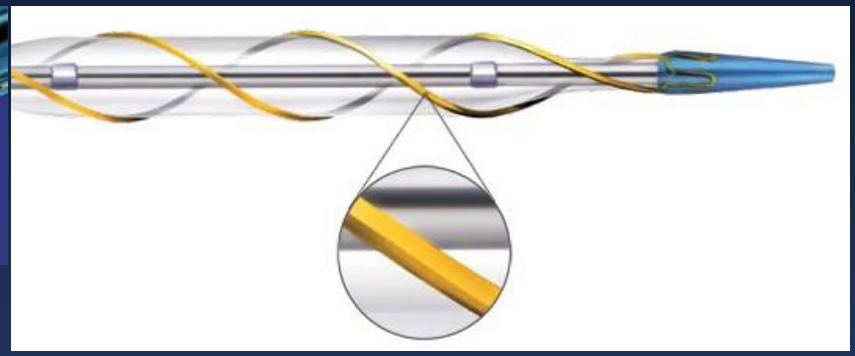
# Treatment of Calcified Lesions: Options

NC Balloons

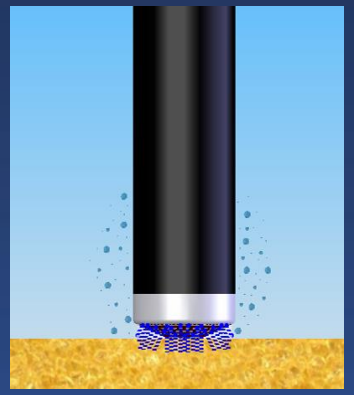
Cutting Balloon



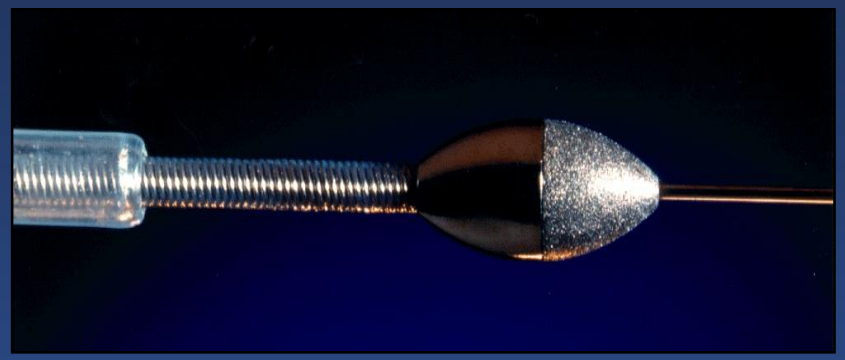
Angiosculpt



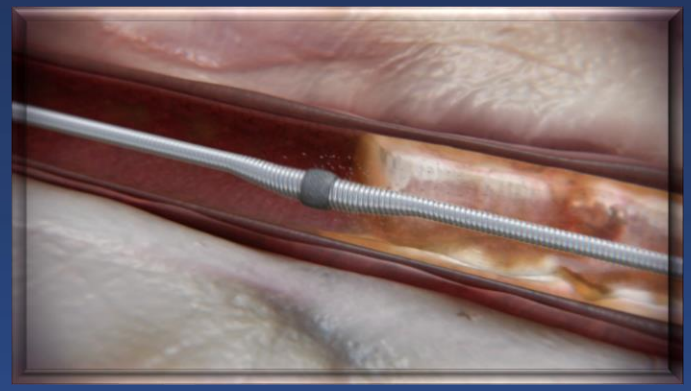
Laser



Rotational Atherectomy



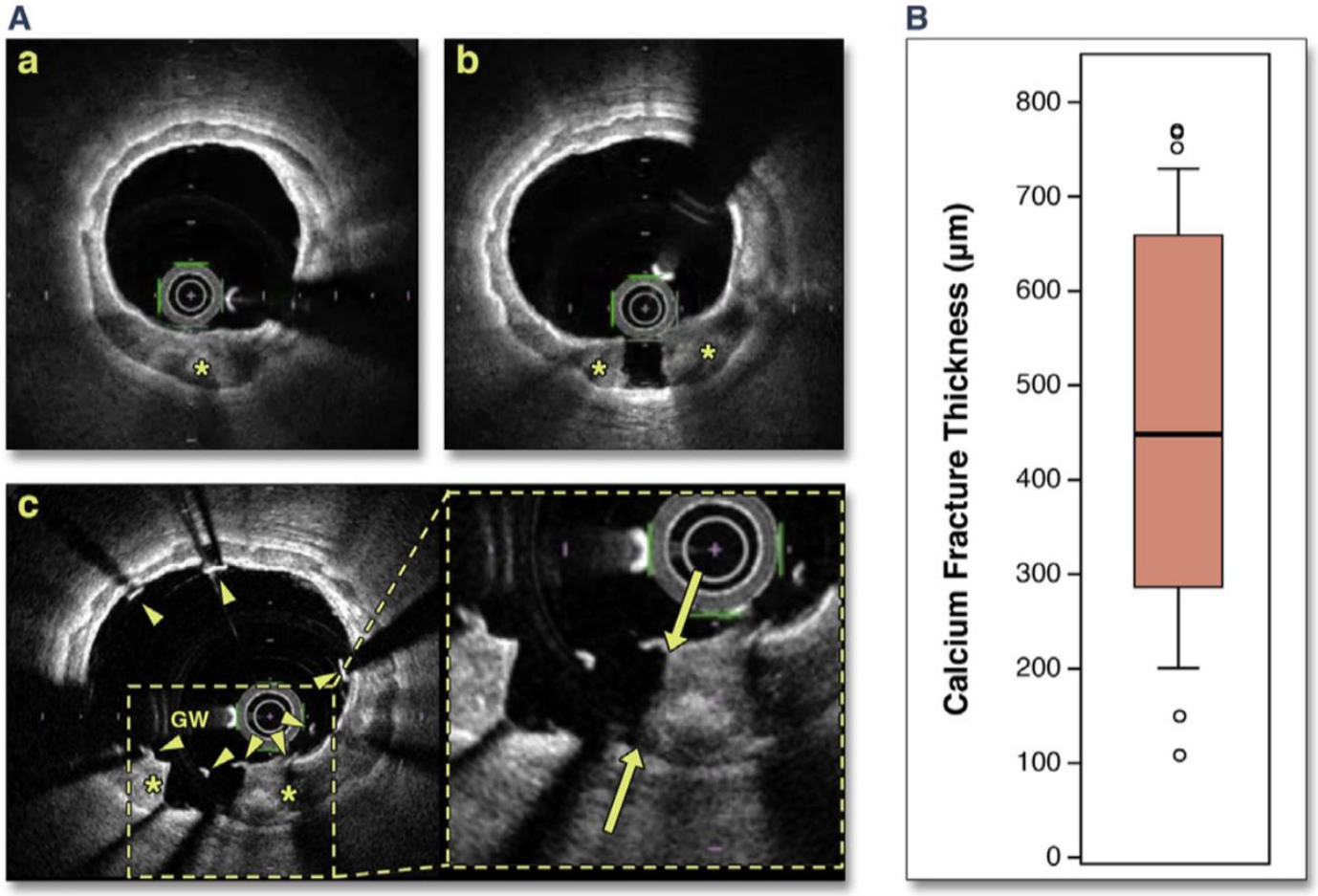
Orbital Atherectomy




Intravascular Lithotripsy

# Calcium Fracture and Relation to Outcomes

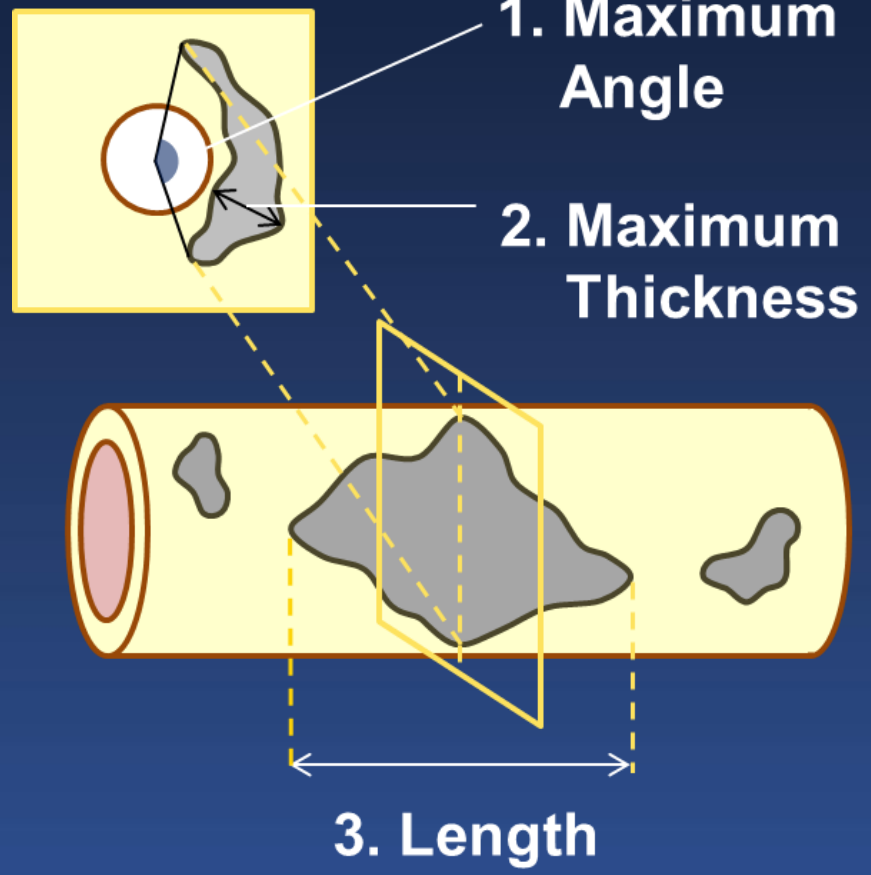
61 pts with heavily calcified lesions studied serially with OCT
Fracture was seen in 48% (more frequently with CB or atherectomy)




Fracture was associated with greater MSA and less restenosis/ID-TLR

Kubo et al, JACC CV Imaging 2015

# Calcium Volume Index (CVI) Scoring System



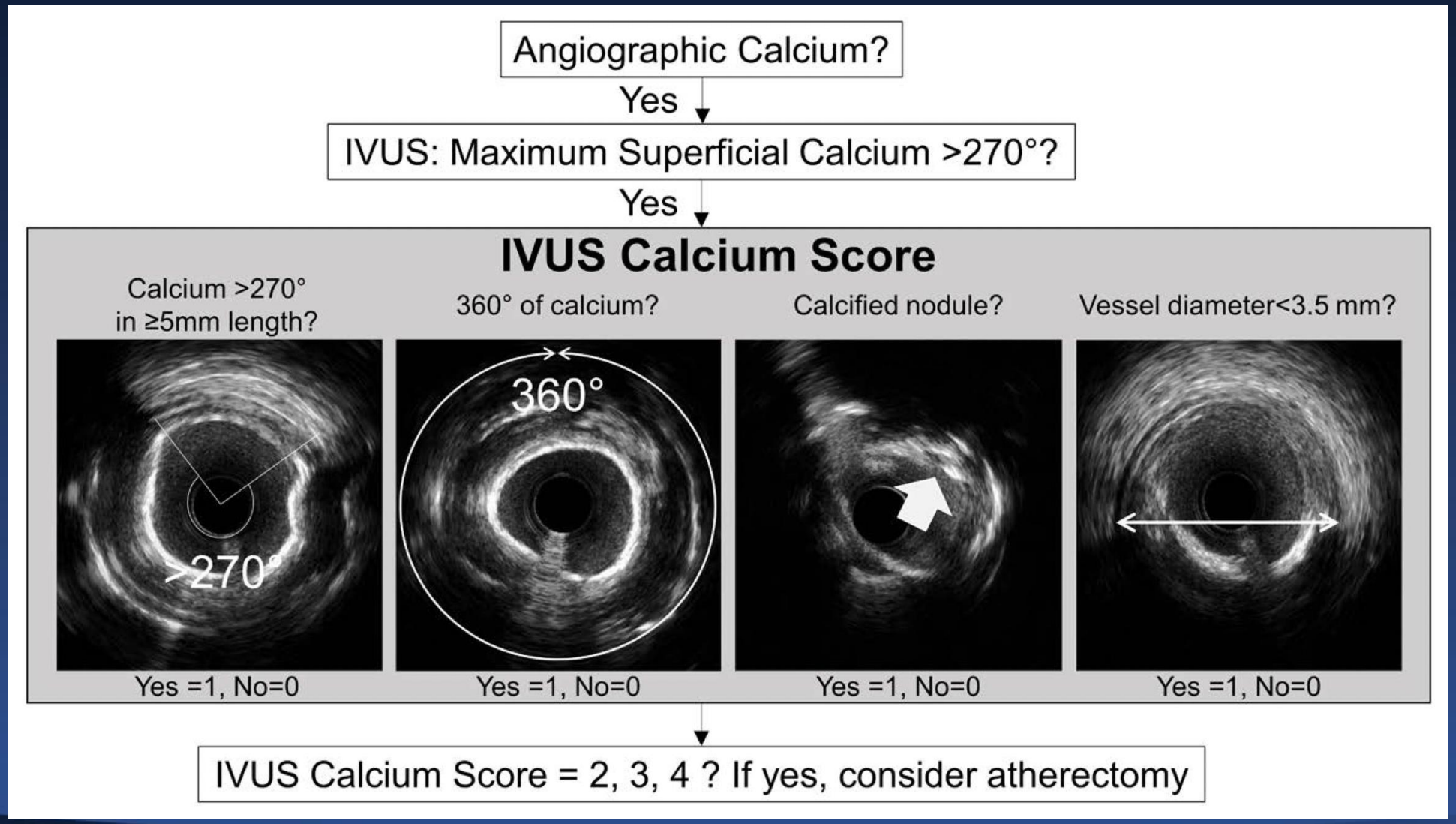

| OCT-based CVI Score | |
|---|---|
| Angle | ≤ 180° ➡ 0 point<br>> 180° ➡ 2 points |
| Thickness | ≤ 0.5 mm ➡ 0 point<br>> 0.5 mm ➡ 1 point |
| Length | ≤ 5.0 mm ➡ 0 point<br>> 5.0 mm ➡ 1 point |
| Total score: 0 to 4 points | |

Cardiovascular Research Foundation®

Columbia University Medical Center
NewYork-Presbyterian

Fujino et al, Eurointervention 2018

# IVUS-Based Calcium Scoring System



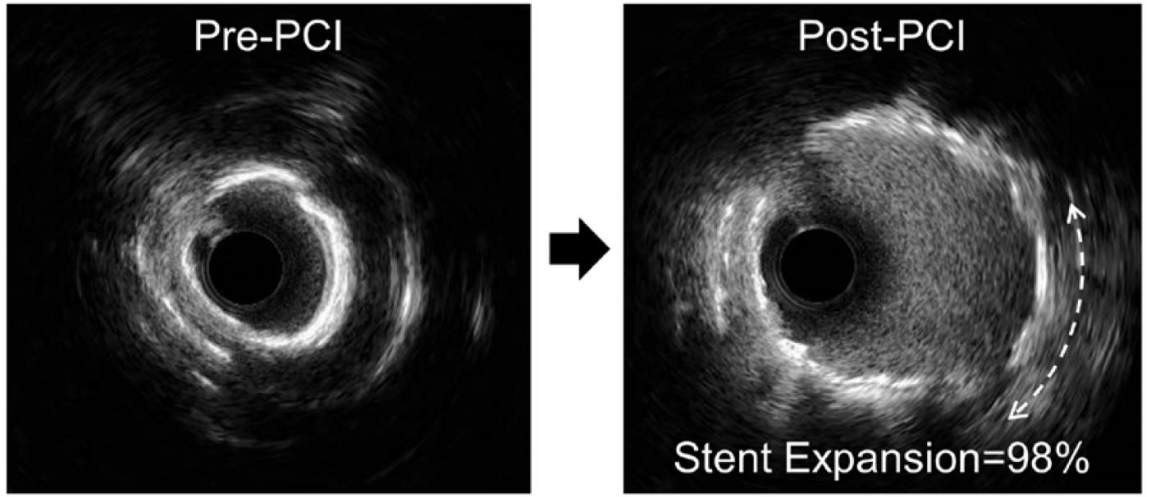

Zhang et al, Circ CV Intv 2021

# Calcium Scoring System (examples)

## Case 1

- Length of Ca >270° = 4.1 mm = 0
- 360° of Calcium (+) = 1
- Calcified nodule (-) = 0
- Vessel diameter = 4.4 mm = 0

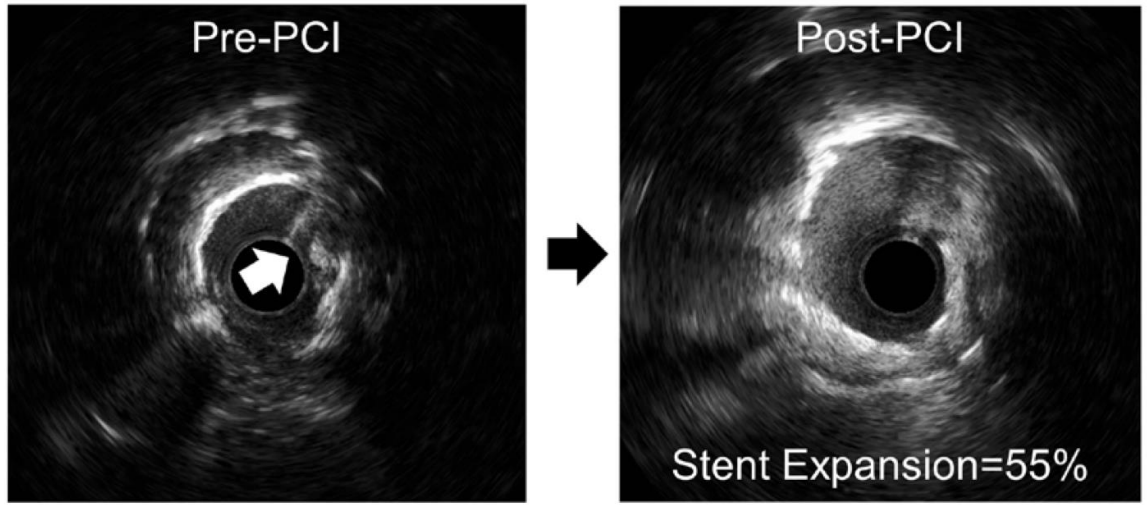
**Calcium Score = 1**




## Case 2

- Length of Ca >270° = 8.9 mm = 1
- 360° of Calcium (-) = 0
- Calcified nodule (+) = 1
- Vessel diameter = 2.9 mm = 1

**Calcium Score = 3**






Zhang et al, Circ CV Intv 2021

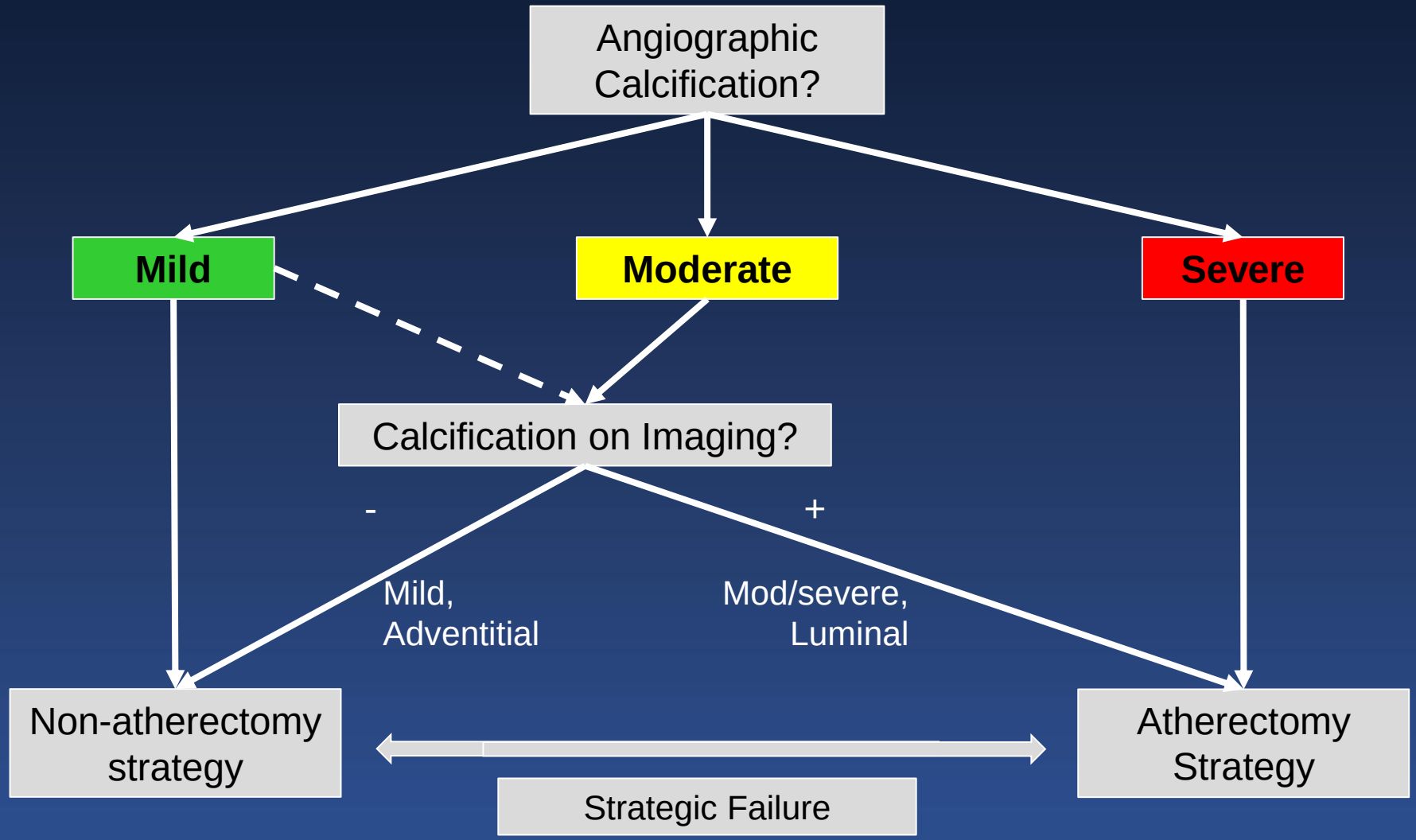
# Treatment of Calcified Lesions: PCI guidelines

| Device | ACCF/AHA/SCAI 2011 | ESC/EAPCI 2014 |
|---|---|---|
| **Cutting/scoring balloon angioplasty** | • Might be considered to avoid slippage induced coronary artery trauma during PCI for in-stent restenosis or ostial lesions in side branches (**Class IIb-C**)<br>• Should not be performed routinely during PCI (**Class III-A**) | May be useful in highly calcified, rigid ostial lesions (also applies to scoring). |
| **Rotational atherectomy** | • Reasonable for fibrotic or ***heavily calcified lesions*** that might not be crossed by a balloon catheter or adequately dilated before stent implantation (**Class IIa-C**)<br>• Should not be performed routinely for de novo lesions or in-stent restenosis (**Class III-A**) | Might technically be required in cases of tight and calcified lesions, to allow subsequent passage of balloons and stents. |
| **Laser angioplasty** | • Might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty (**Class IIb-C**)<br>• Should not be used routinely during PCI (**Class III-A**) | (Laser not mentioned for calcification) |



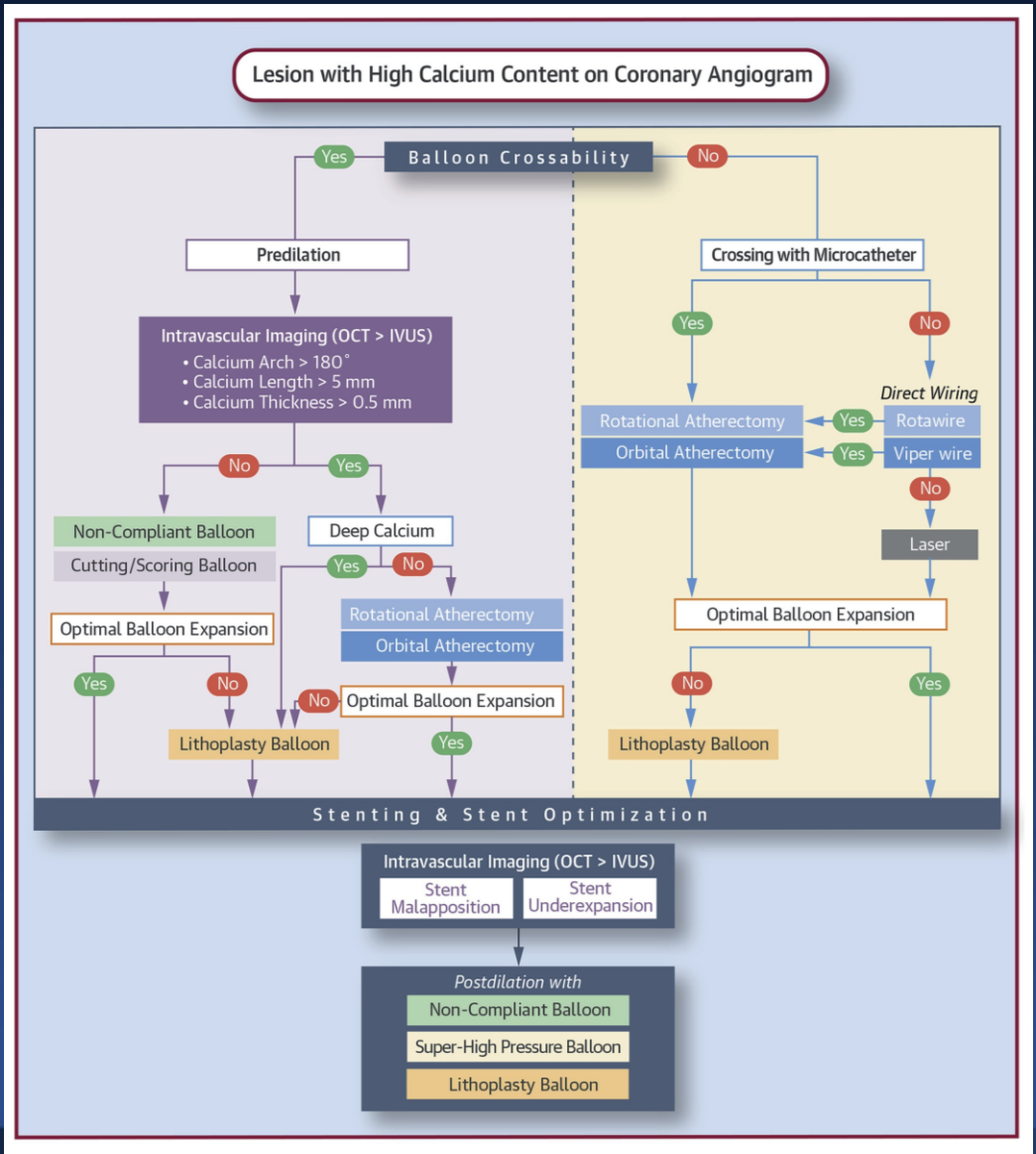
Levine GN et al. JACC 2011;58:e44-122
Windecker S et al. EHJ 2014;35:3541-619

# Strategy for Approaching Calcified Lesions




Adapted from Tomey et al, JACC CV Intv 2014

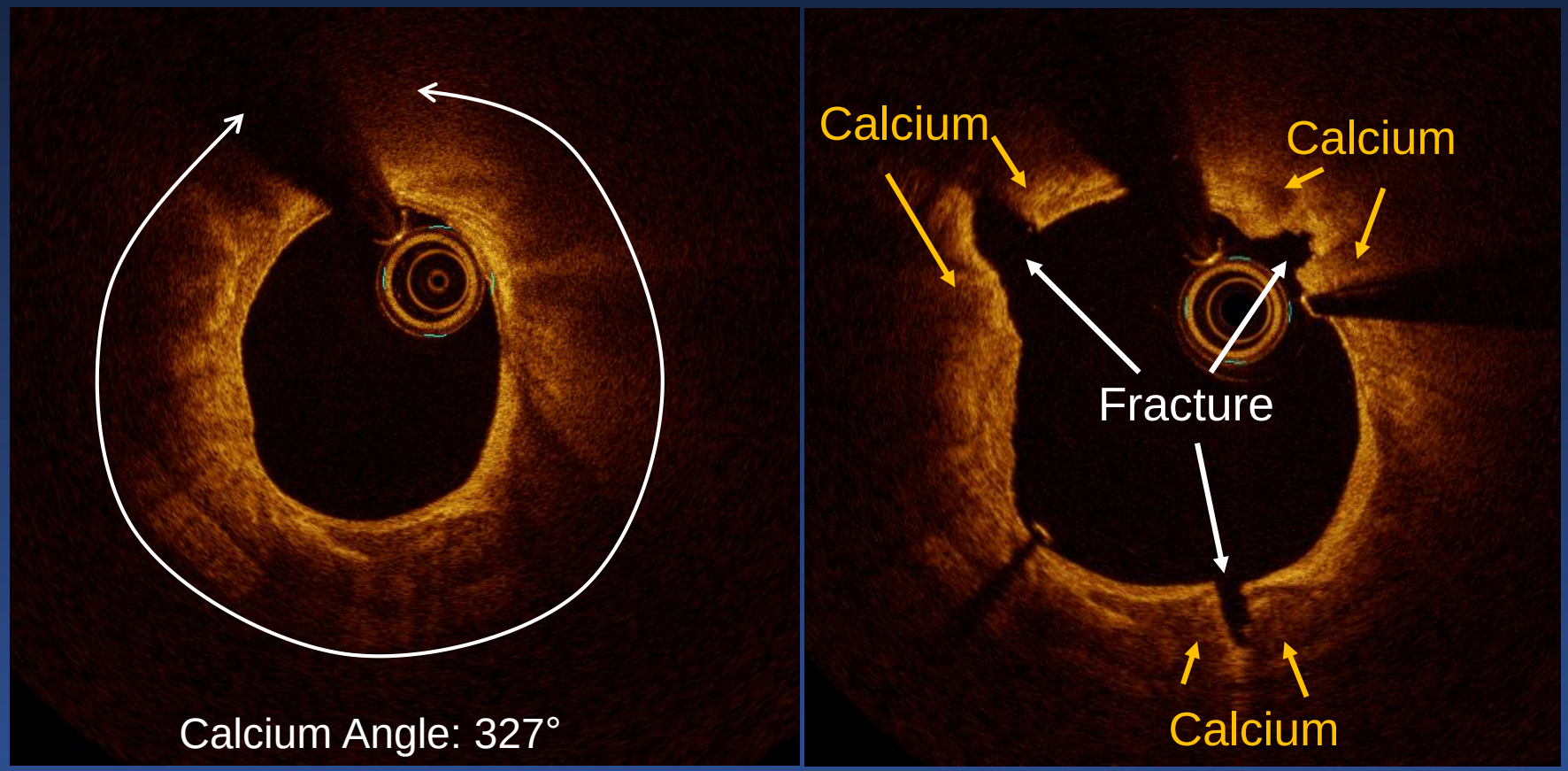
# Algorithm for Approaching Calcified Lesions




De Maria et al, JACC CV Intv 2019

# Mechanism of IVL

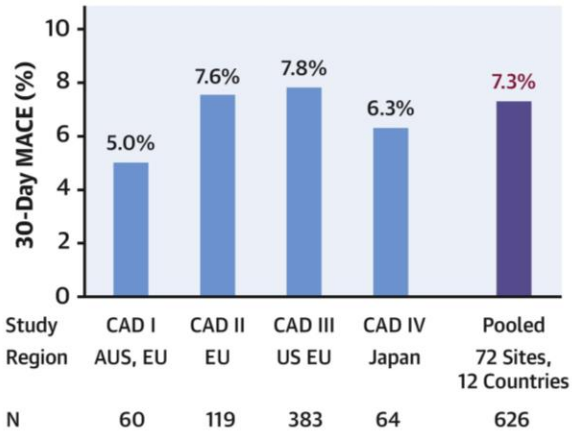
## *Circumferential Calcium Fracture*

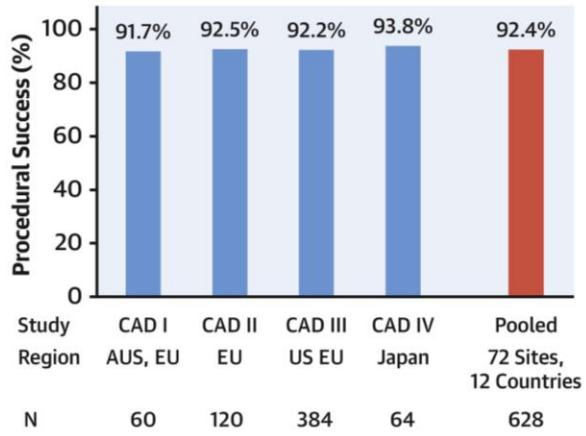


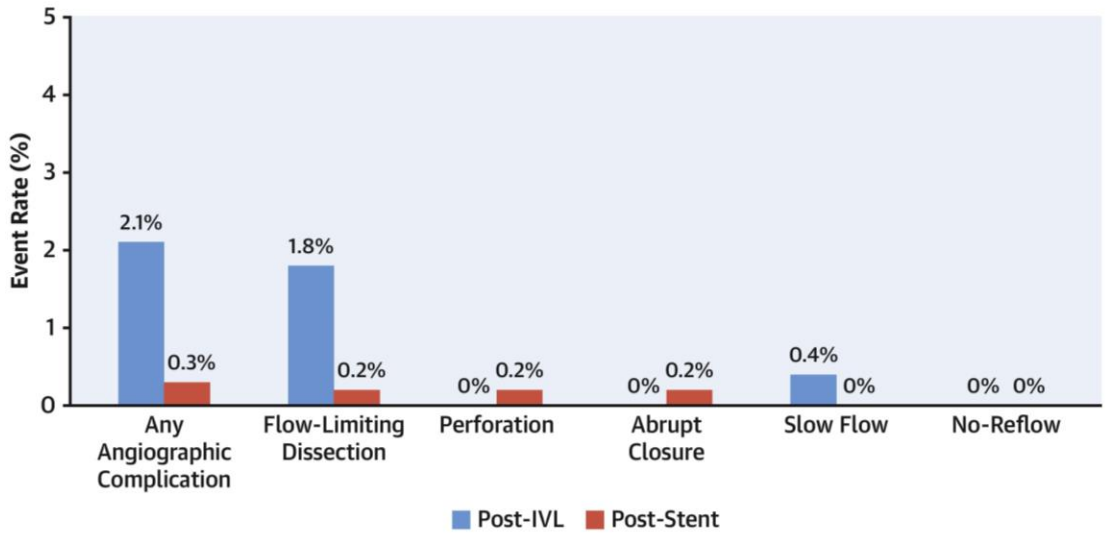

**Pre-Procedure** **Final**

Brinton T, Ali Z, Hill J et al. TCT 2016. Disrupt CAD

# Pooled Analysis of DISRUPT CAD Studies




628 patient pooled analysis of IVL

97% severe calcium

Mean 63.7% diameter stenosis

Predilation used in 47.6% of cases

IVL success in 98.7% of cases

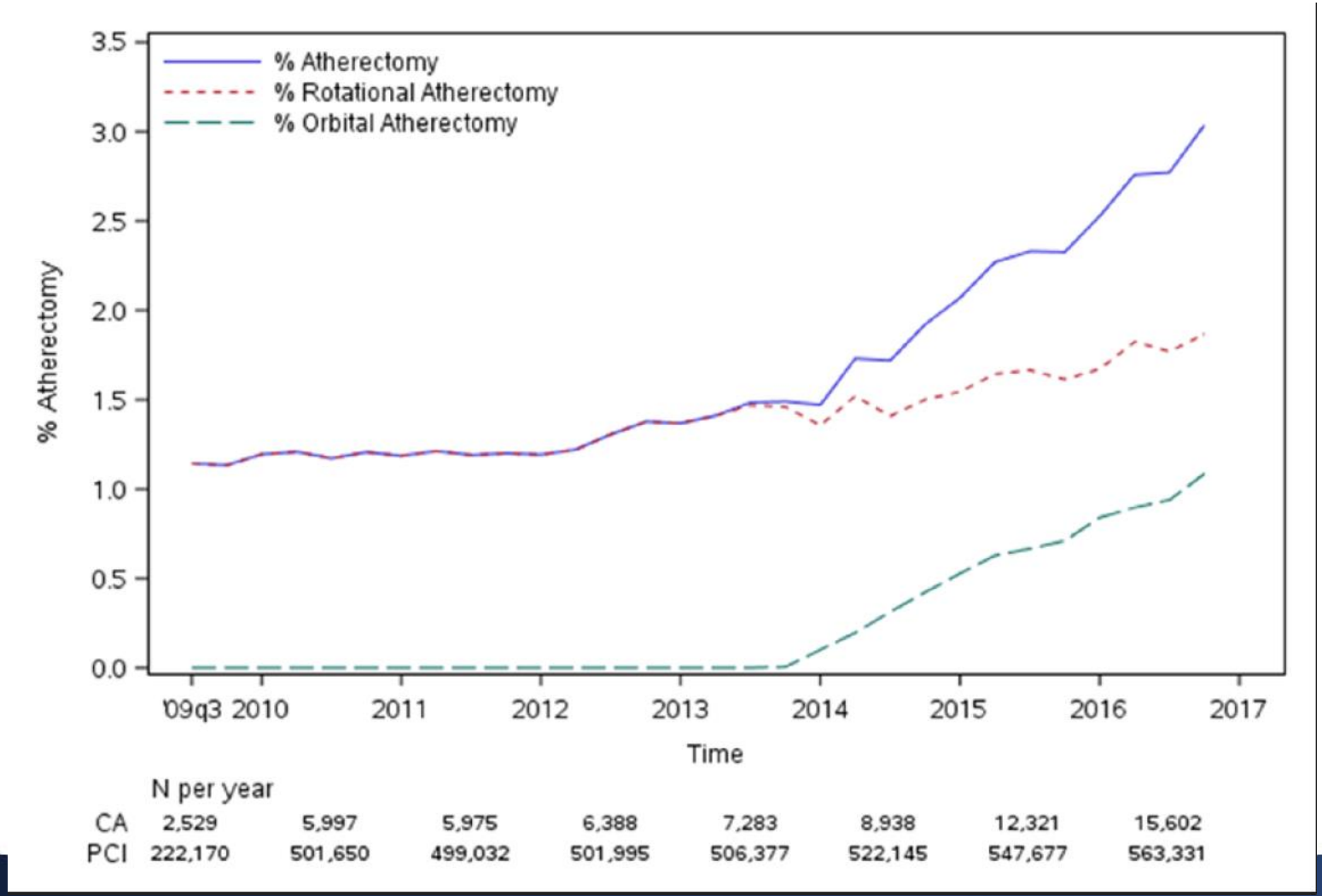
Cardiovascular Research Foundation®

Columbia University Medical Center
NewYork-Presbyterian

Kereiakes et al, JACC CV Inv 2021

# NCDR: Quarterly Trends in Atherectomy Usage

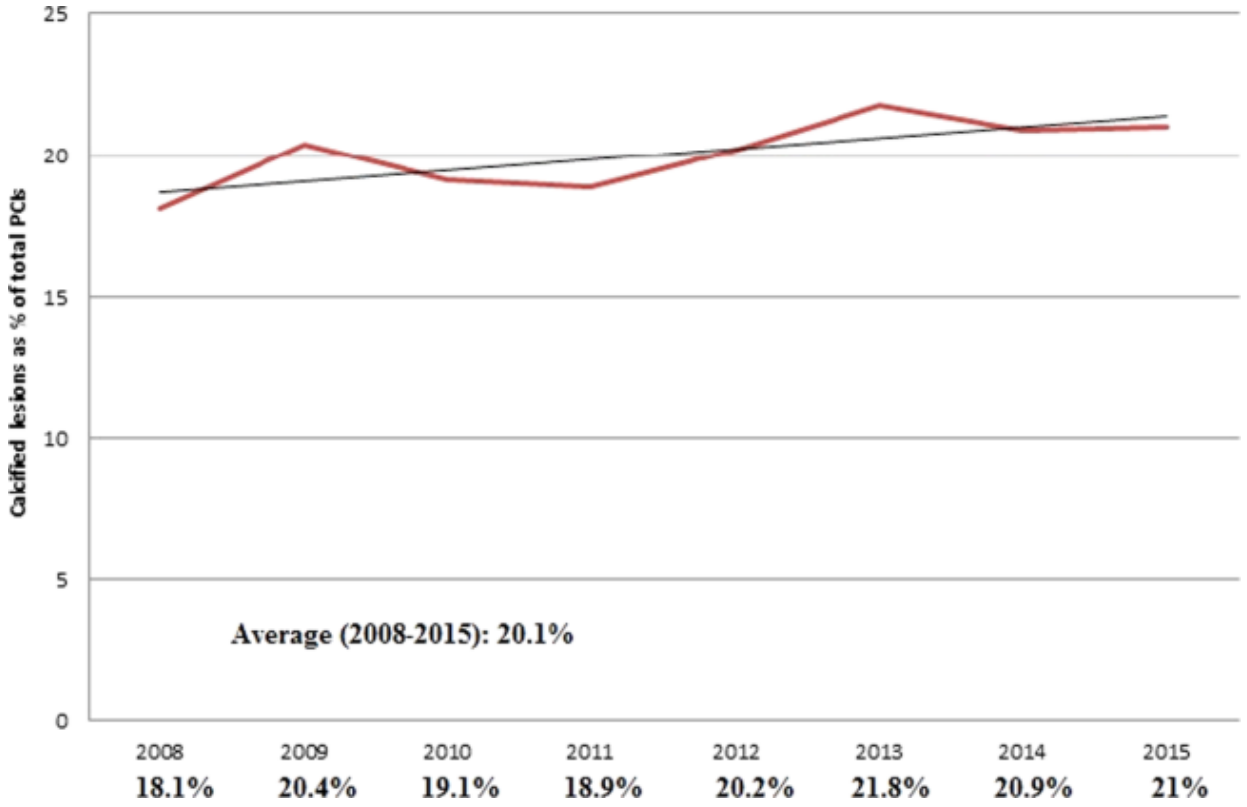
Among hospitals performing PCI, 34.5% performed no atherectomy
Increased hospital atherectomy volume was associated with lower mortality




N. Beohar et al, Circ CV Interventions 2020

# Calcium in the VA-CART Registry

Series of 9,719 patients with 11,595 calcified lesions within the VA system
Prevalence of calcium in native single vessel (not STEMI) lesions increased over time



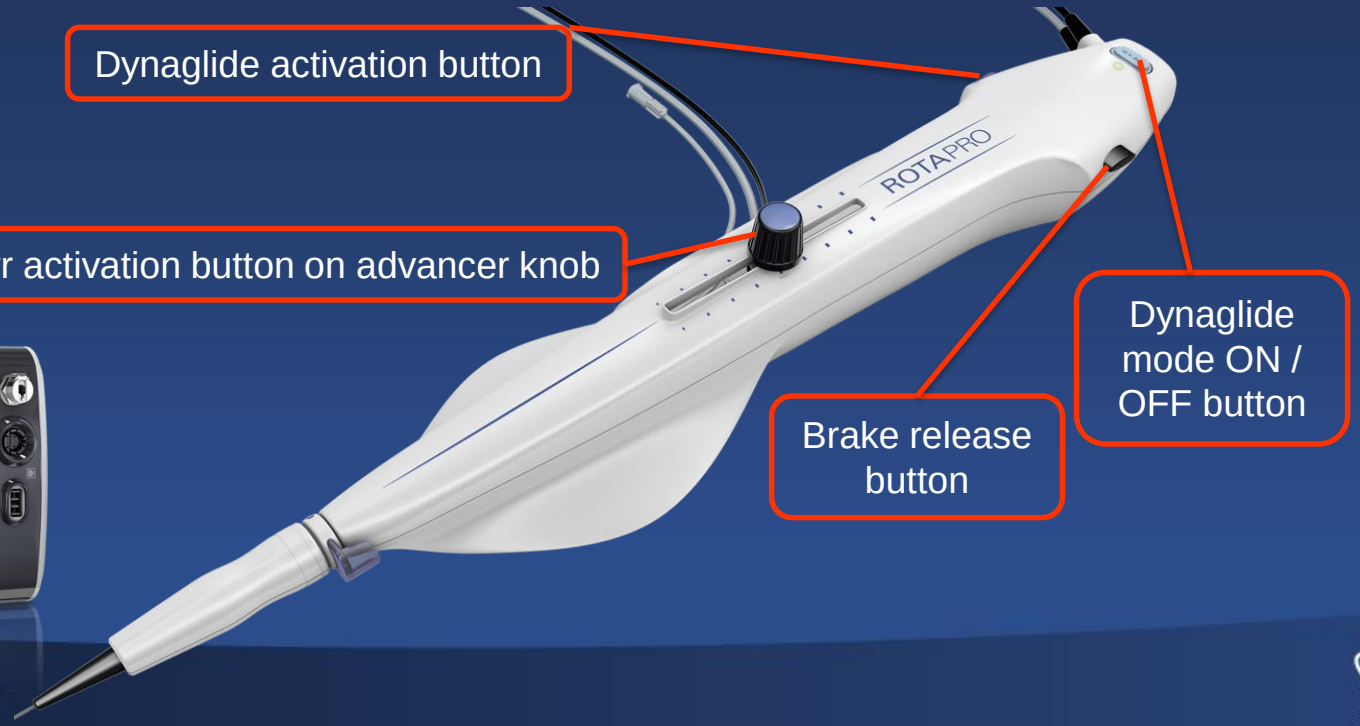

Atherectomy was used in 18% of single-vessel PCI cases of native calcific coronary artery lesions and was associated with a decrease in procedural/clinicial complications

Armstrong et al, CCI 2017

# RotaPRO Rotational Atherectomy System


## *Design Goals:*

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


Cardiovascular Research Foundation®

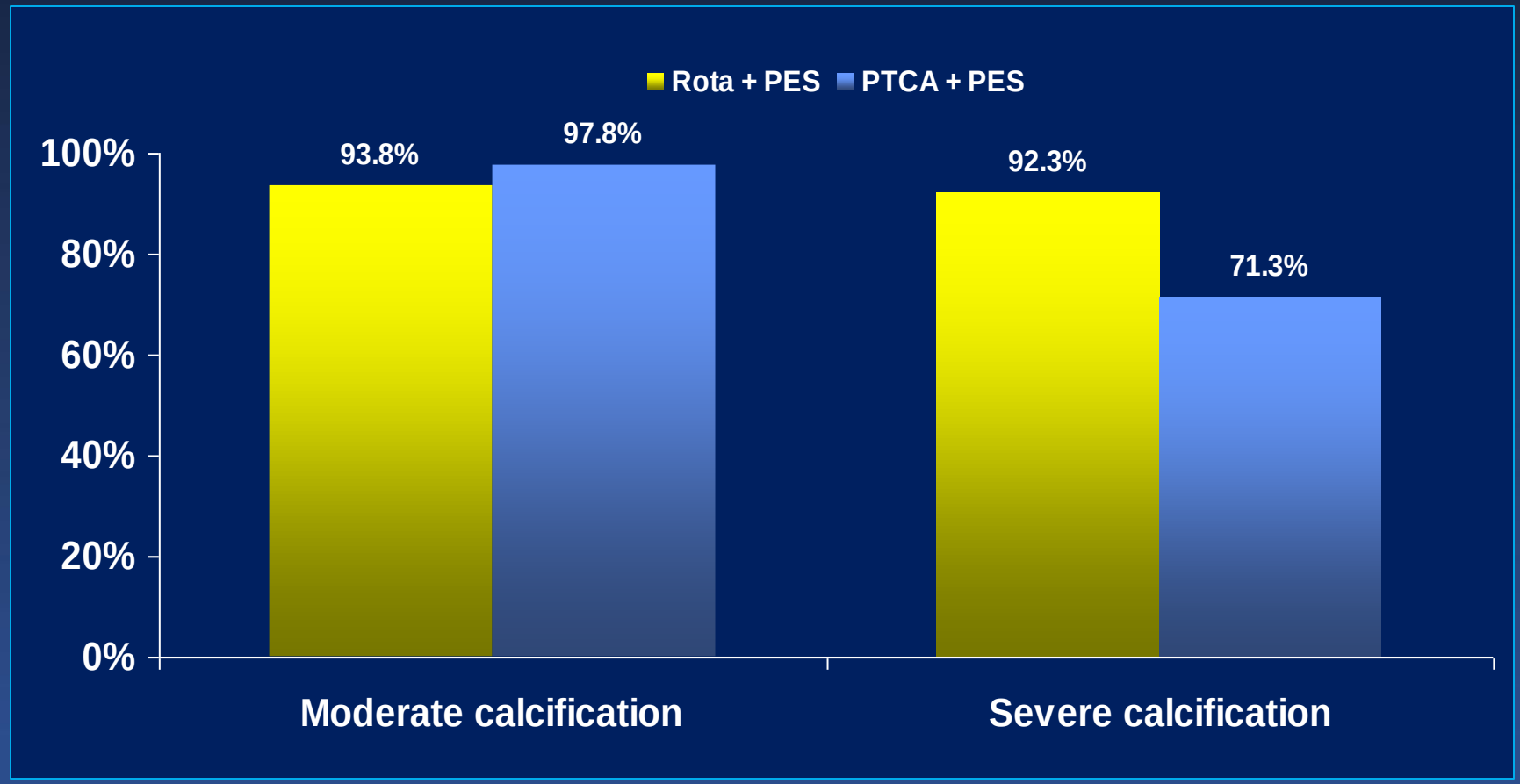
Columbia University Medical Center
NewYork-Presbyterian

# ROTATE: Procedural outcomes

| | Planned ROTA n = 358 (433 lesions) | Provisional ROTA n = 309 (349 lesions) | p value |
|---|---|---|---|
| Total No. of pre-balloon | | | |
| Mean | 1.17 ± 0.60 | 1.47 ± 0.76 | < 0.001 |
| 0 (No pre-dilation) | 27 (7.6) | 7 (2.1) | < 0.001 |
| 1 | 251 (70.7) | 211 (62.6) | |
| 2 | 65 (18.3) | 74 (22.0) | |
| >3 | 12 (3.4) | 45 (13.4) | |
| Maximum pre-balloon size | 2.66 ± 0.48 | 2.60 ± 0.43 | 0.09 |
| Total No. of post-balloon | | | |
| Mean | 1.12 ± 0.43 | 1.10 ± 0.44 | 0.65 |
| 0 (No post-dilation) | 12 (2.8) | 12 (3.5) | 0.73 |
| 1 | 355 (83.9) | 292 (84.6) | |
| 2 | 51 (12.1) | 35 (10.1) | |
| >3 | 5 (1.2) | 6 (1.7) | |
| Maximum post-balloon size | 3.27 ± 0.62 | 3.12 ± 0.52 | < 0.001 |
| Final TIMI flow 3 | 430 (99.8) | 345 (99.1) | 0.33 |
| Procedure time, min | 65.2 ± 36.8 | 84.4 ± 43.1 | < 0.001 |
| Fluoroscopy time, min | 33.1 ± 22.9 | 51.2 ± 29.6 | < 0.001 |
| Contrast volume, ml | 232.9 ± 141.6 | 302.9 ± 150.3 | < 0.001 |

Kawamoto et al, CCI 2016

# ROTAXUS: Strategy Success according to calcification




Abdel-Wahab M et al. JACC CV Interv 2013;6:10-19

# 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** |

**200 patients, elective PCI, native coronaries, severe calcification**

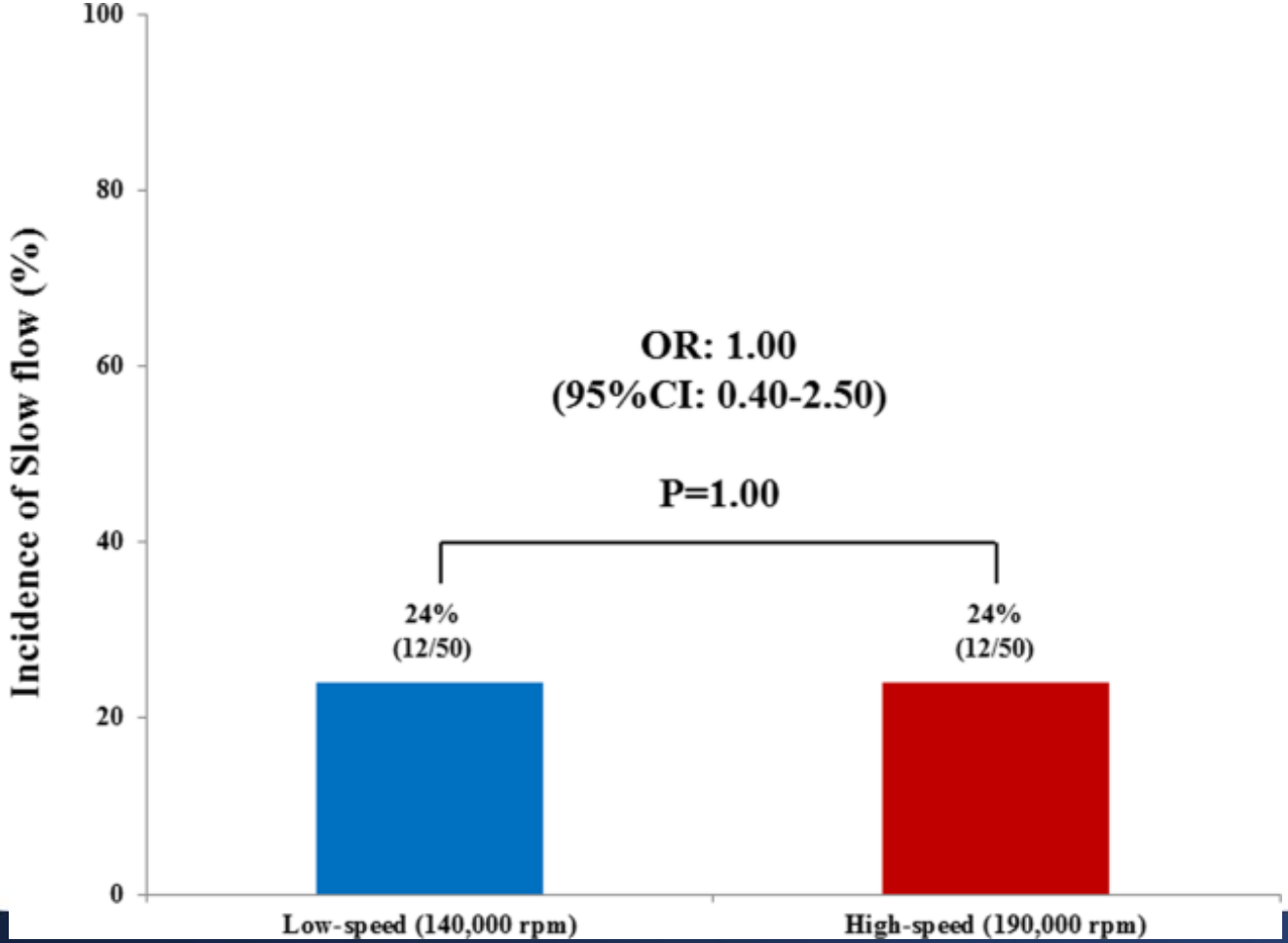
**2 German centers (Bad Segeberg, Munich)**



Abdel-Wahab et al, Circ CV Intv 2018

# Low vs. High Speed for Rotational Atherectomy

100 patient RCT of 140,000 rpm vs. 190,000 rpm, mostly 1.25 mm single burrs
Total run time of 120 seconds; mean run time of ~20 seconds
Only 6% of patients needed higher burr speed than assigned




Cardiovascular Research Foundation®

Columbia University Medical Center
NewYork-Presbyterian

Sakakura et al, CCI 2016

# DIAMONDBACK 360: Coronary Orbital Atherectomy System

**Device Features**
- Simple device setup
- Microsecond feedback to changes in loading
- 135cm usable length

**On-handle speed control**
- Low (80K) and High Speed (120K)

**Power on/off switch**
- 8 cm axial travel

**Electric motor powered handle**

**Eccentric diamond coated crown**




**0.012" Viper Wire**

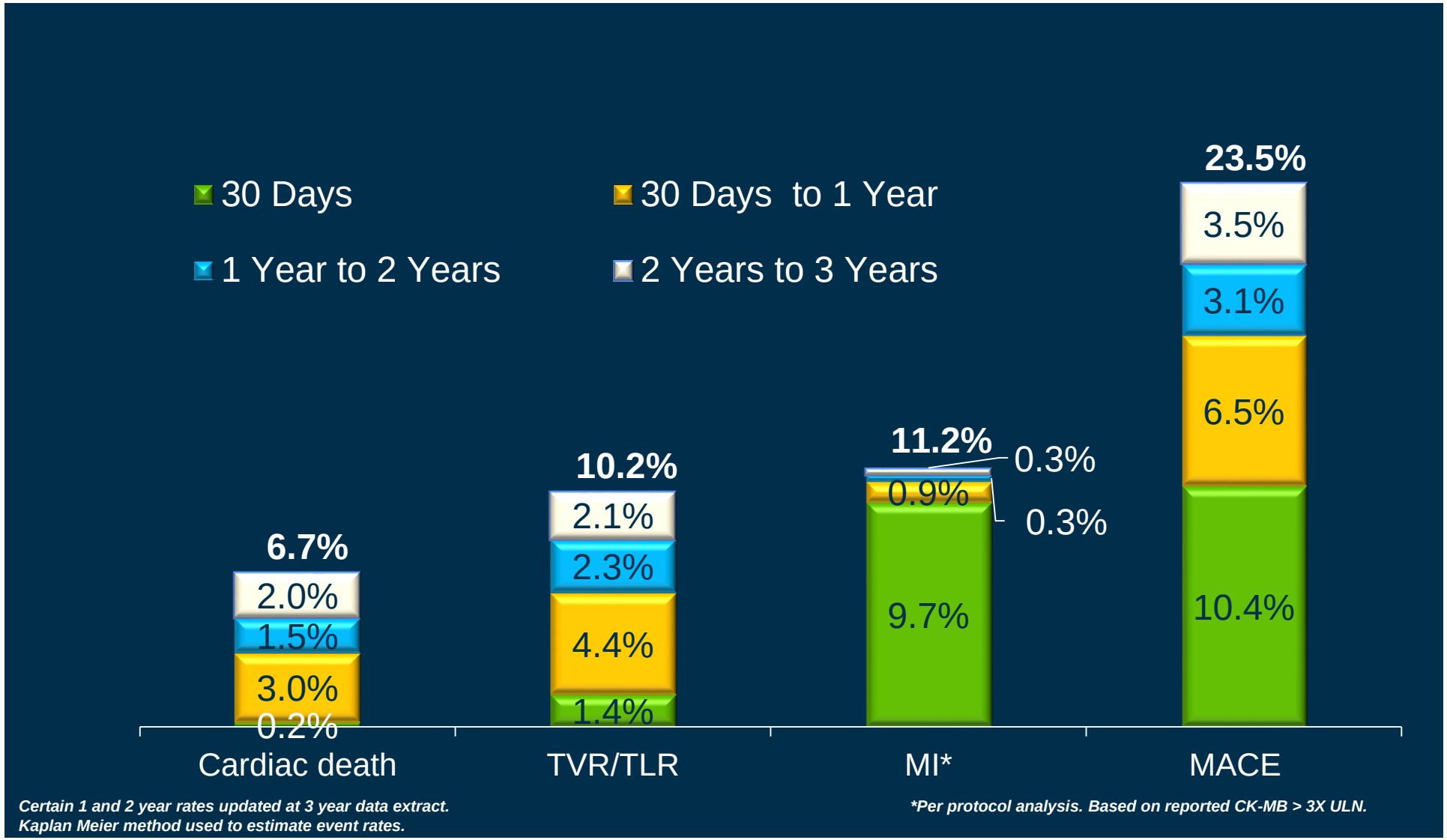
**6Fr Guide Compatible**




**Saline Infusion Pump**
- Mounts directly on to an IV pole
- Provides power
- Delivers fluid
- Includes saline sensor

**ViperSlide® Lubricant**
- ViperSlide reduces friction during operation
- 20ml ViperSlide per liter of saline

# ORBIT II: Late Outcomes




*Certain 1 and 2 year rates updated at 3 year data extract. Kaplan Meier method used to estimate event rates.*

**Per protocol analysis. Based on reported CK-MB > 3X ULN.*

# Mt. Sinai Miami Observational Registry

519 patient retrospective, single arm study

| Lesion Characteristics | | | |
|---|---|---|---|
| AHA/ACC Type C lesions | 53.8% | | |
| Mean treated length | 22.6 mm | | |
| Mean diameter stenosis | 86.9% | | |
| **Safety** | | | |
| **Angiographic complications:** | | | |
| Severe dissection (C-F) | 0.4%[1] | | |
| Perforation | 0.8% | | |
| Persistent slow-flow/ no-reflow post-procedure | 0.0% | | |
| In-Hospital MI | 0.8%[1] | | |
| **Results by Treatment Tertile** | | | |
| | 1st | 2nd | 3rd |
| MACE (p=1.0) | 1.2% | 1.7% | 1.2% |
| Cardiac Death (p=1.0) | 0.6% | 1.1% | 0.6% |
| MI (p=0.33) | 0.6% | 1.7% | 0.0% |

# Relative Advantages of OAS and RA

| OAS (0.012” wire, 2 choices) | RA (0.009” wire, 2 choices) |
|---|---|
| • Hardware/set-up<br>• Faster learning curve<br>• Single device for all lesions/ vessel diameters<br>• Full 6 Fr compatibility (including guide extension)<br>• Hemodynamic stability (less slow flow/pacer?)<br>• +/- distal/multiple lesions using low speed glide assist | • Aorto-ostial lesions<br>• Severe angulation/bias<br>• Subintimal crossing<br>• Front cutting for uncrossable lesions<br>• ISR/underexpansion for stent ablation<br>• Specific scenarios with need for 2.0+ mm burr<br>• Lower cost of single device |

**Either can be used in most cases of severe calcium!**

# ECLIPSE

*E*valuation of Treatment Strategies for Severe *C*a*L*cif*I*c Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty *P*rior to Implantation of Drug Eluting *S*t*E*nts

**~2000 pts with severely calcified lesions; ~150 US sites**

Randomize 1:1

**Orbital Atherectomy Strategy**

(1.25 mm Classic Crown followed by balloon pre-dilation)

2nd generation DES implantation and optimization

**Conventional Angioplasty Strategy**

(Conventional and/or specialty balloons per operator discretion)

2nd generation DES implantation and optimization

**1° endpoints:** 1) Post-PCI in-stent MSA by OCT (N~500 in imaging sub-study)
2) 1-year TVF (all subjects)

**2° endpoints:** 1) Procedural Success (Stent deployed w/RS<20% & no maj complications)
2) Strategy Success (Procedural success w/out crossover)

**Patients are enrolled at physician discretion with post-procedure calcium confirmation by the Core Lab**

**Principal investigators:** Ajay J. Kirtane, Philippe Généreux; **Study chairman:** Gregg W. Stone
**Sponsor:** Cardiovascular Systems Inc.

Cardiovascular Research Foundation®

Columbia University Medical Center
NewYork-Presbyterian

# Conclusions

- 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
  - Longer-term outcomes

# Conclusions

- Imaging is a MUST
  - Diagnosis of calcium
  - Treatment algorithms (based upon length, arc, thickness)
  - After initial lesion preparation / prior to stent implantation
  - Stent optimization

- The field of adjunctive therapies for calcific lesions is heating up with more and more data emerging soon…