Break the Rock: The Selection of Devices for Calcified Disease

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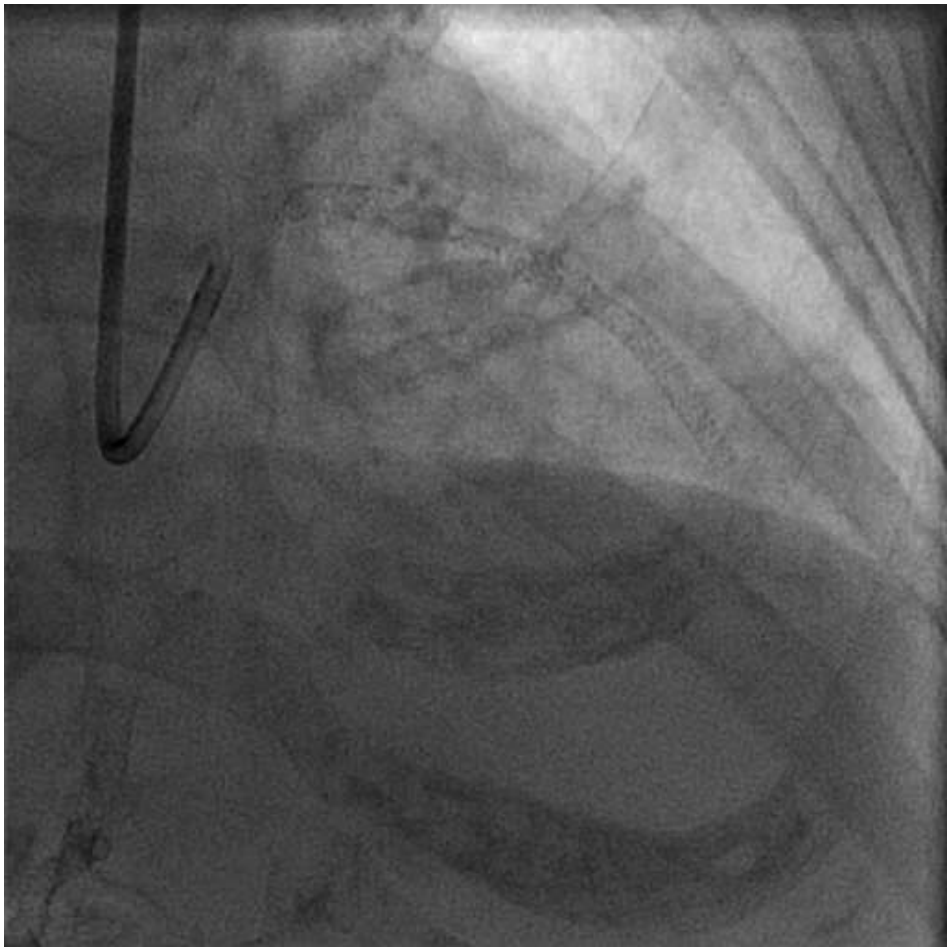
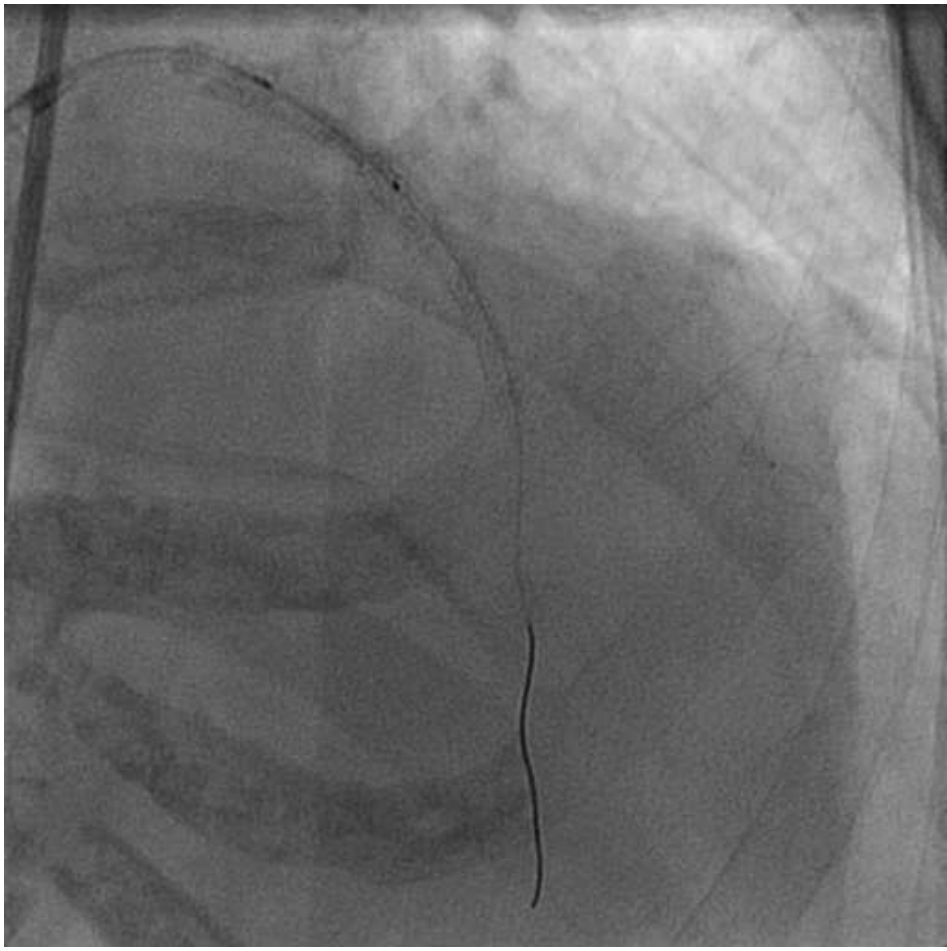
An Illustrative Case…

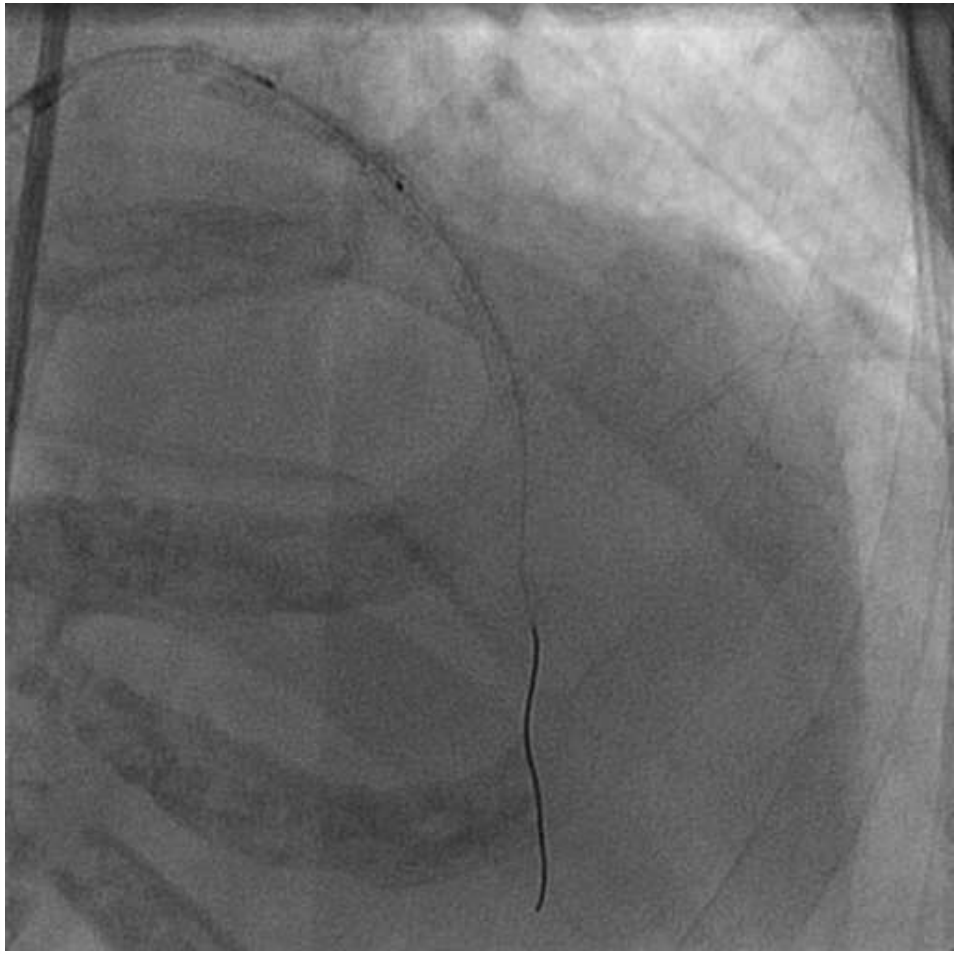
- 70 yo F with PMH of HTN, HLD, DM2, CLL and CAD/PAD with progressive angina
- 2/3/2017 Stents deployed in proximal/mid LAD with noted underexpansion
  - Progressive exertional angina
- 07/14/2017 Rotational atherectomy (stent ablation) with PTCA
  - Still unable to expand stent
  - Continued exertional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



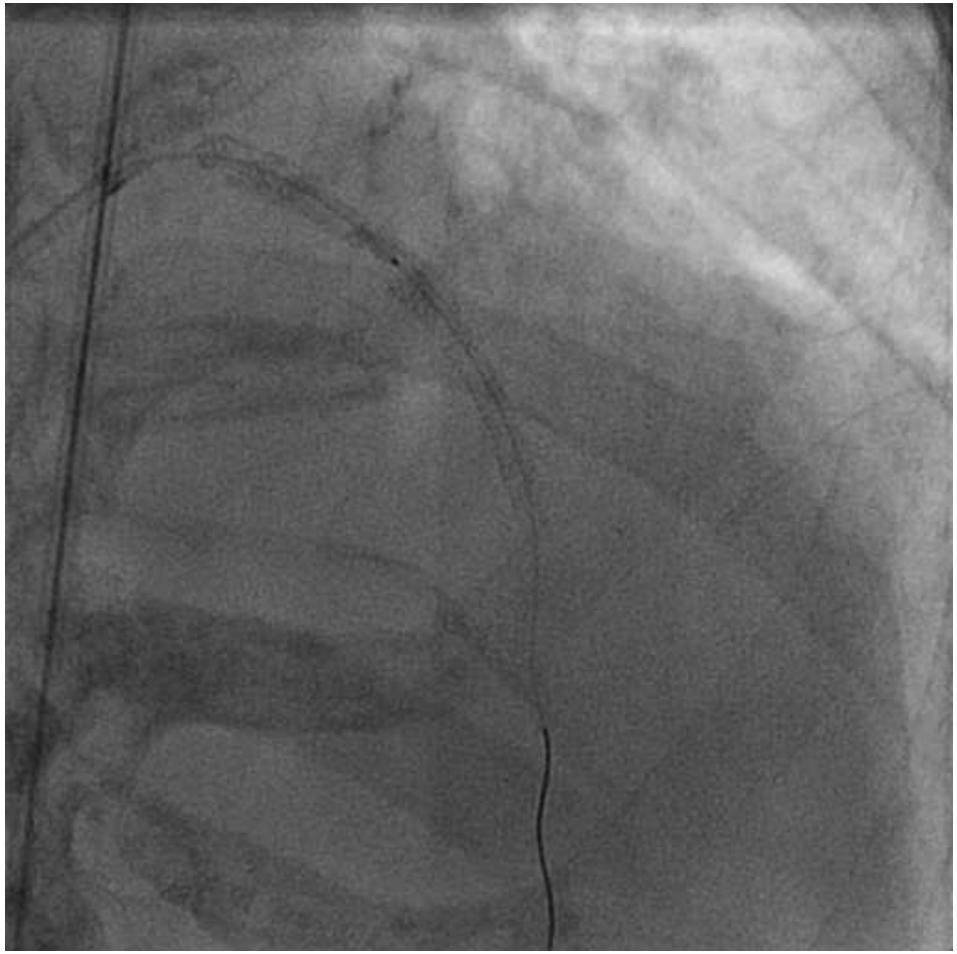
7F EBU 3.5



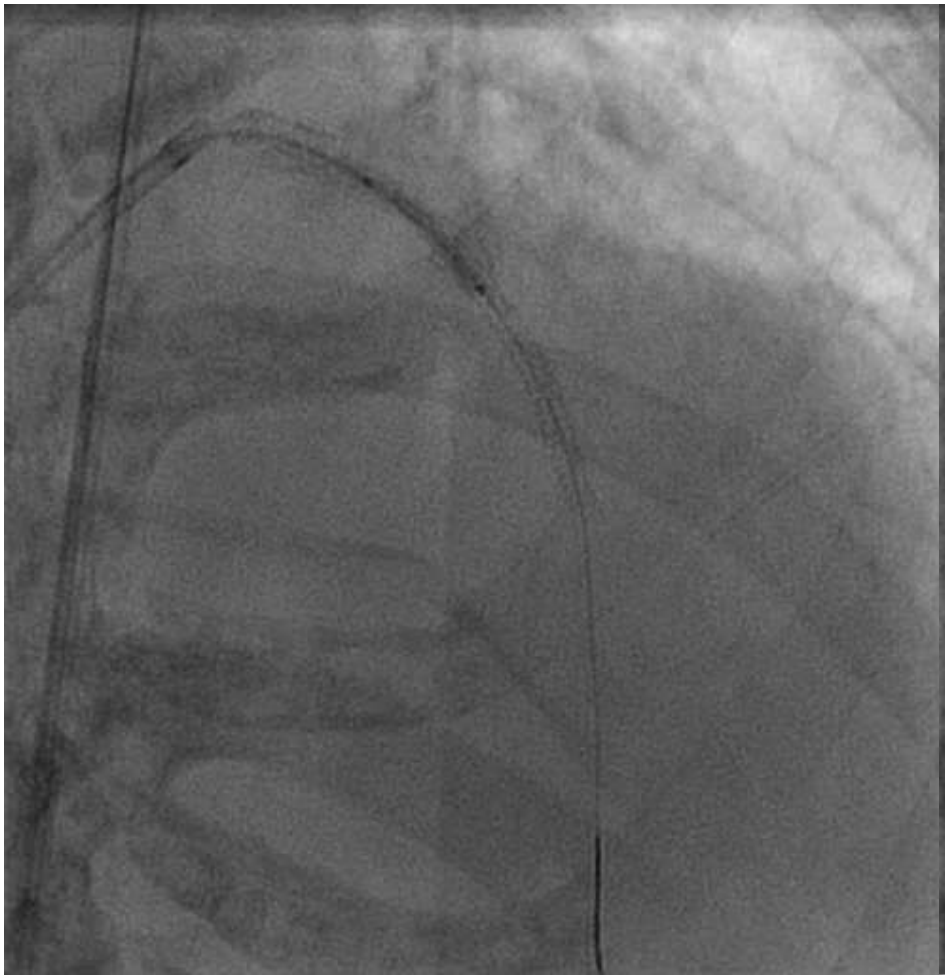
IVUS – Wouldn’t cross



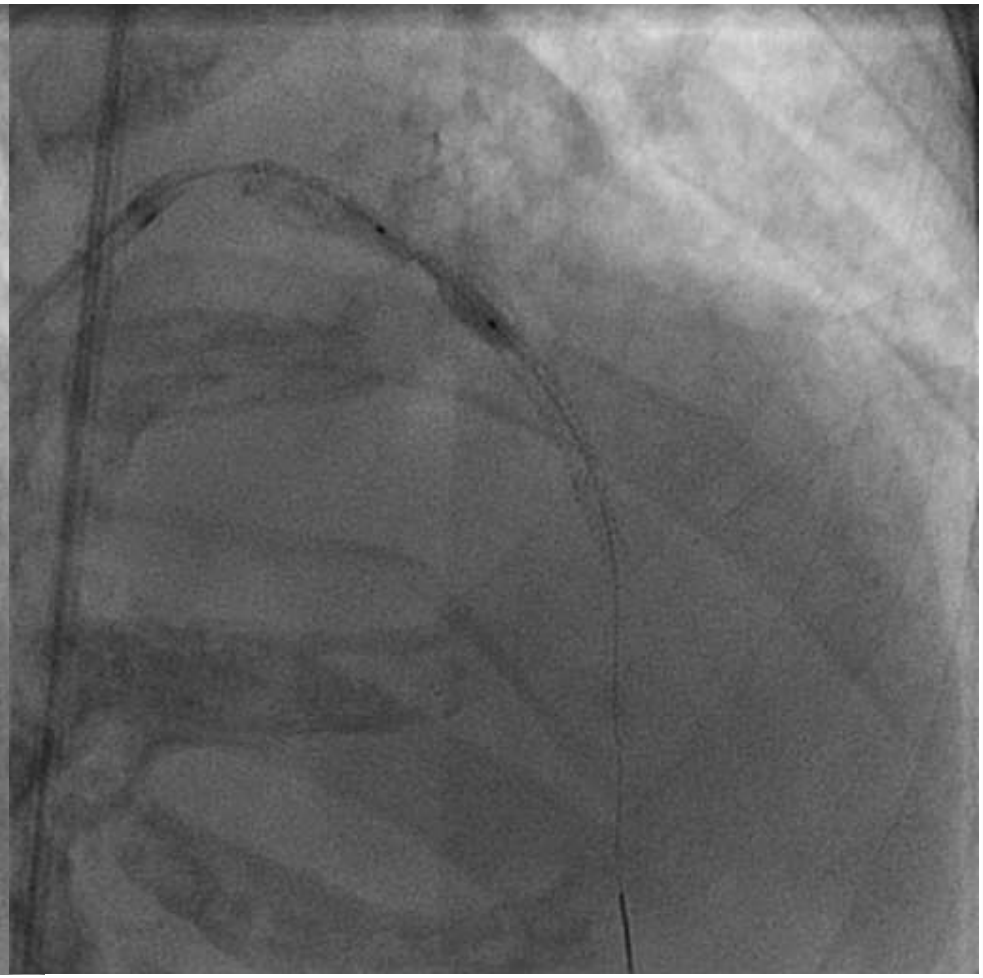
2.0 x 15 balloon: would not cross



1.25 x 6 followed by 1.5 mm balloon



NC Quantum 3.0 x 15 @ 30 (x4 times)

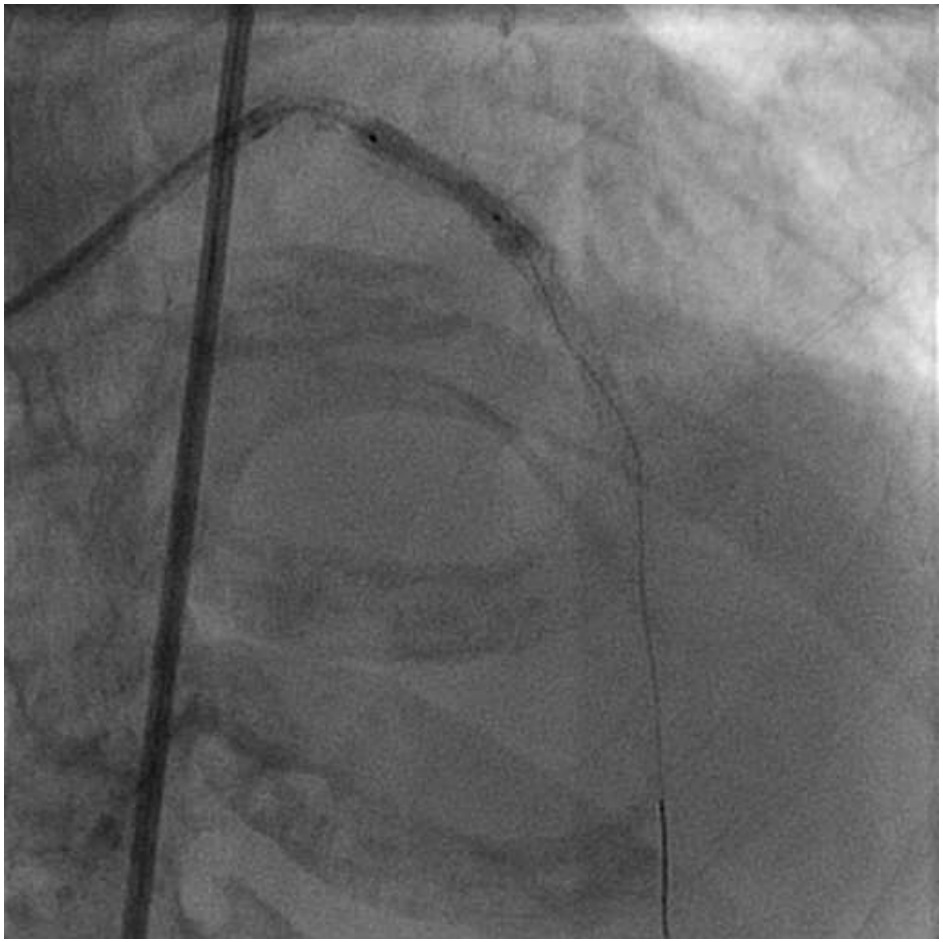


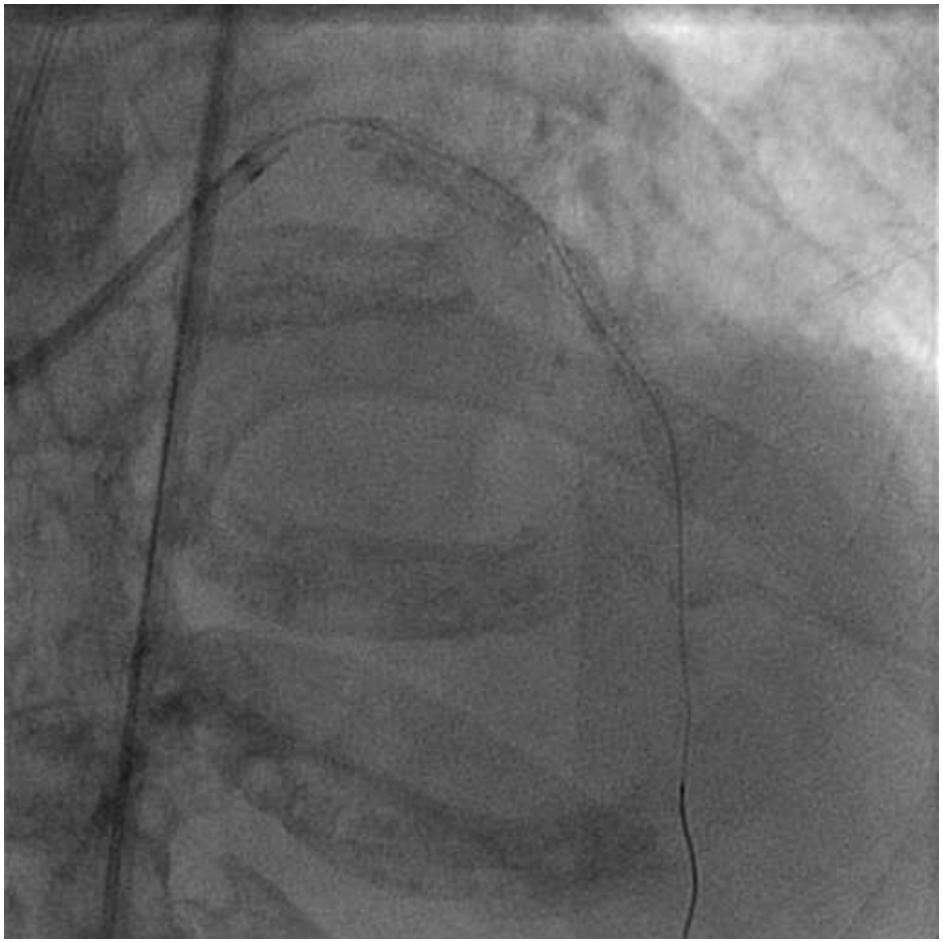
NC Euphora 3.0 x 15 @ 30 (x2 times)

Unable to advance 3.0 balloon past pLAD stent

What Next?

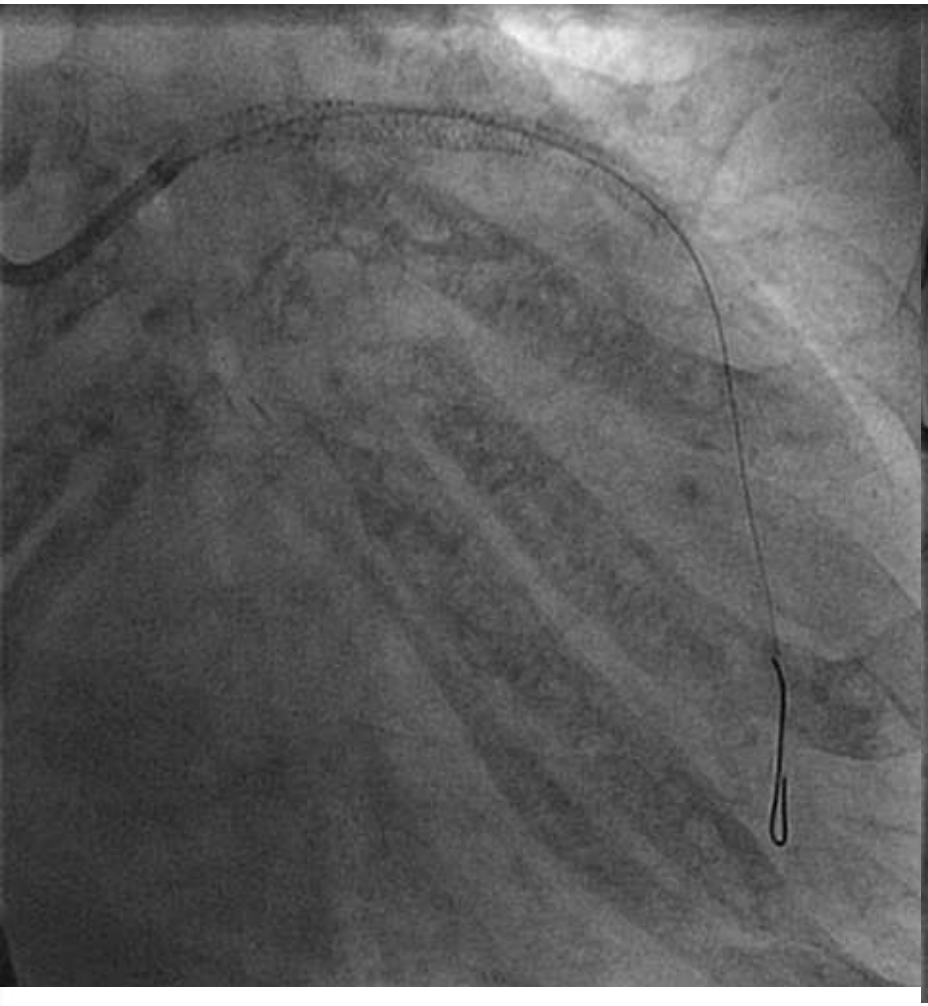
After Laser Atherectomy (Contrast)

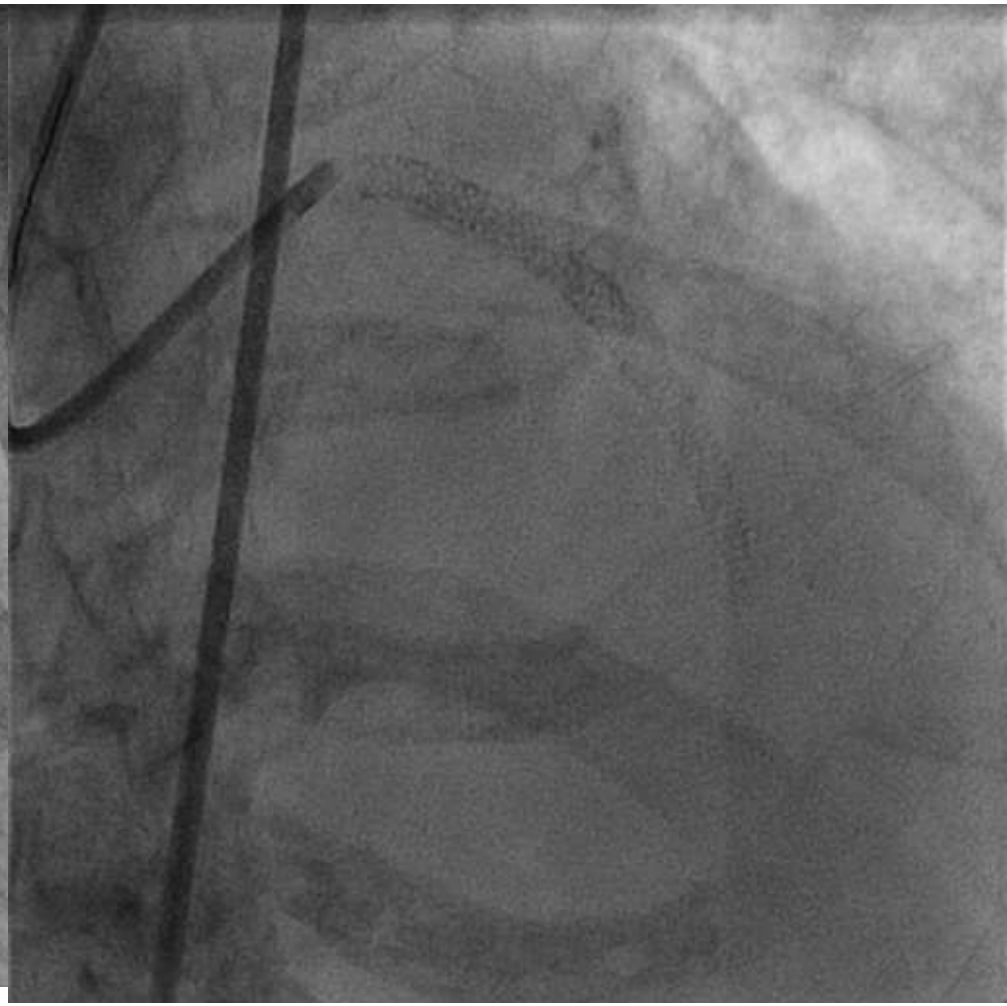




NC 3.0 x 15 @ 26

Final Result

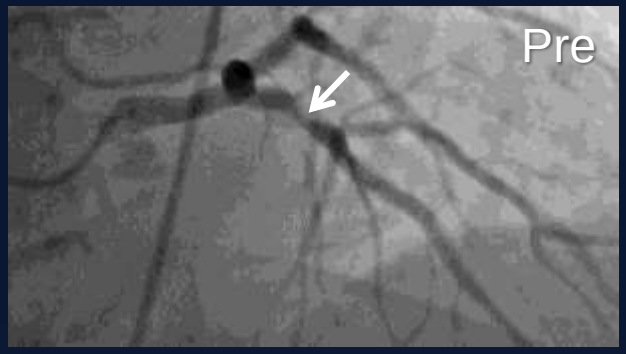


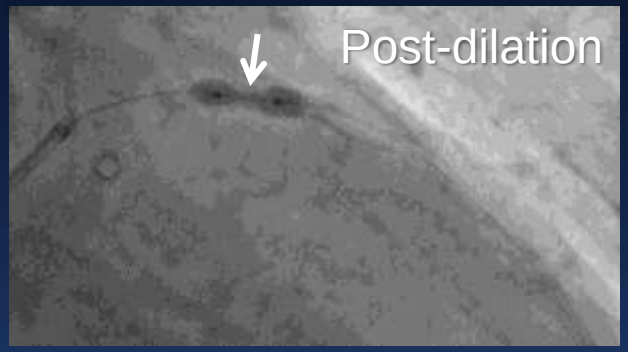


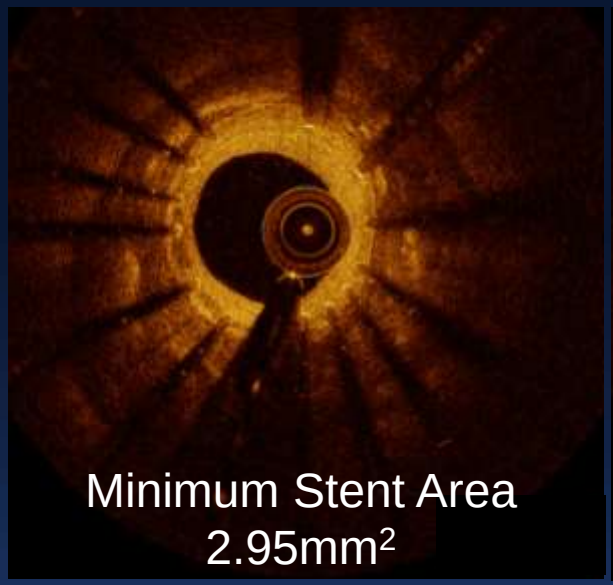
Is this case more broadly generalizable?

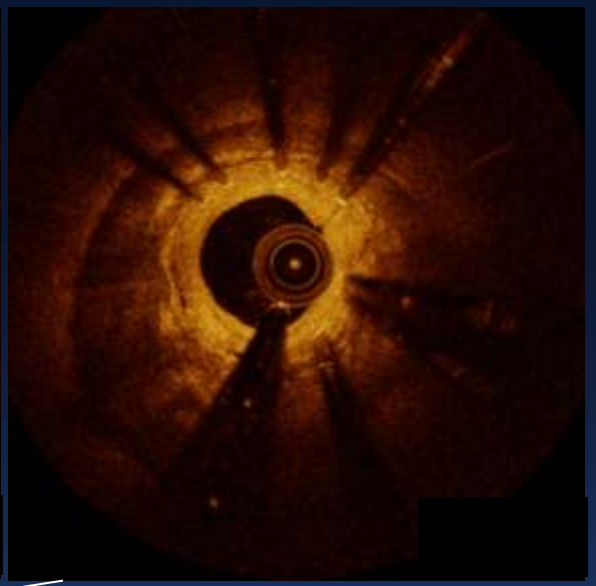
YES!!

79 yo, Recurrent ISR



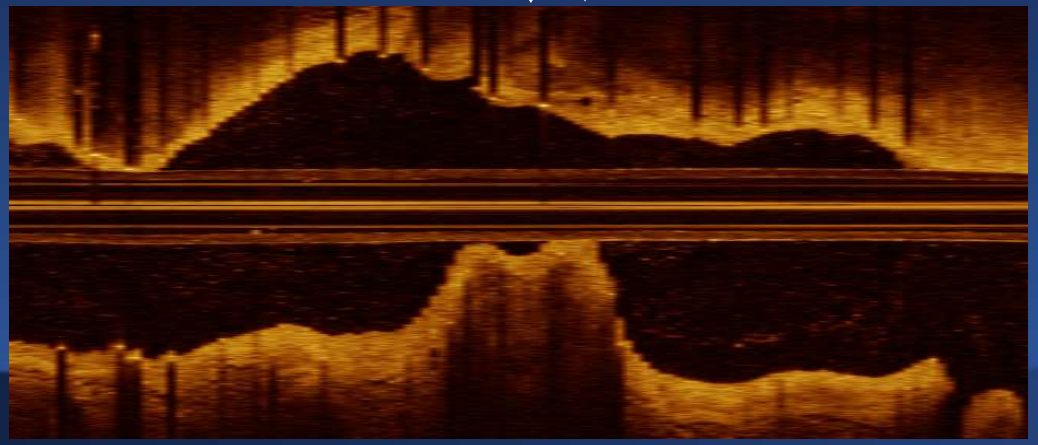






Distal

Proximal



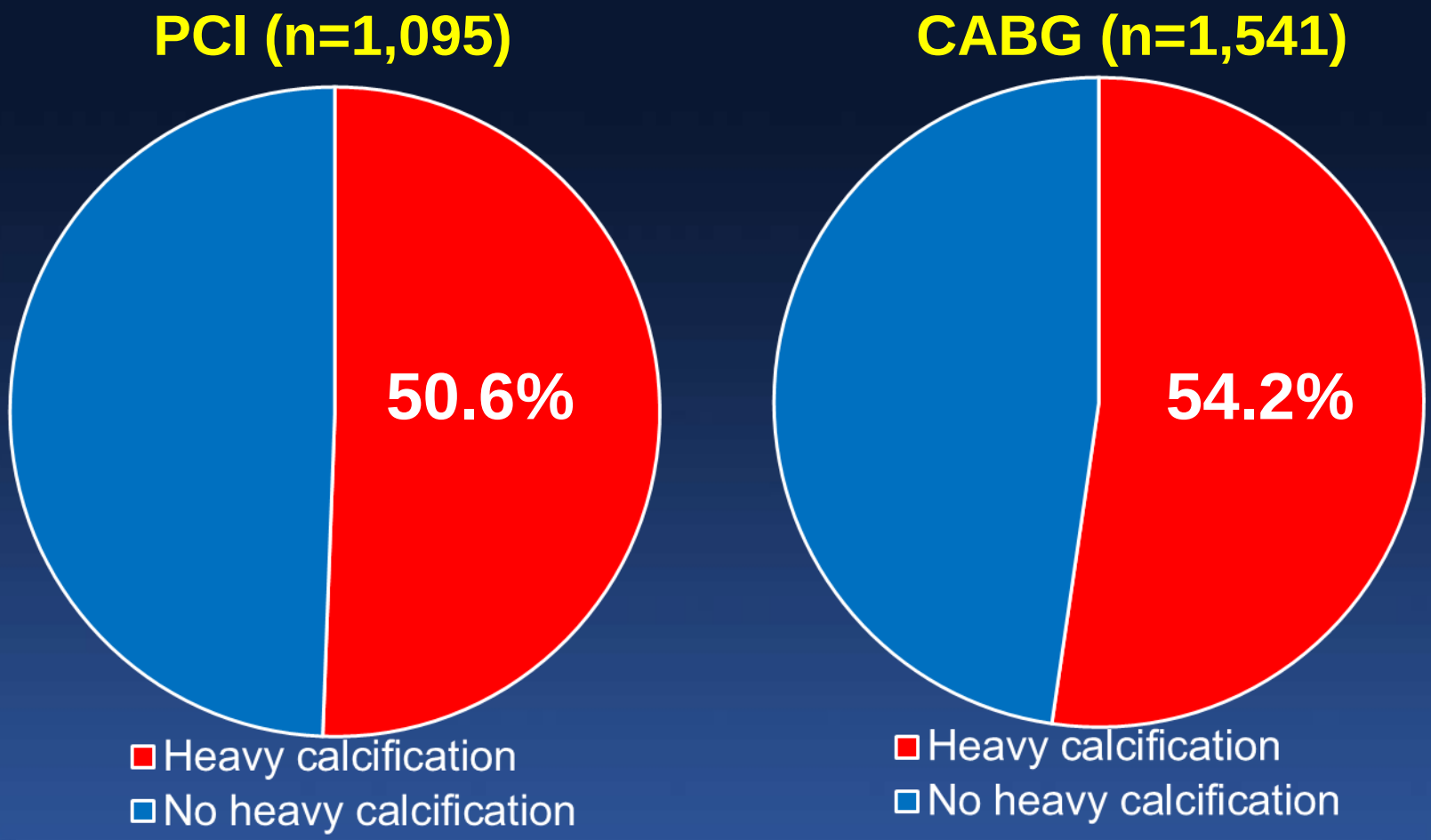
Frequency of angio core lab moderate-severe calcification in 13 DES studies

(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

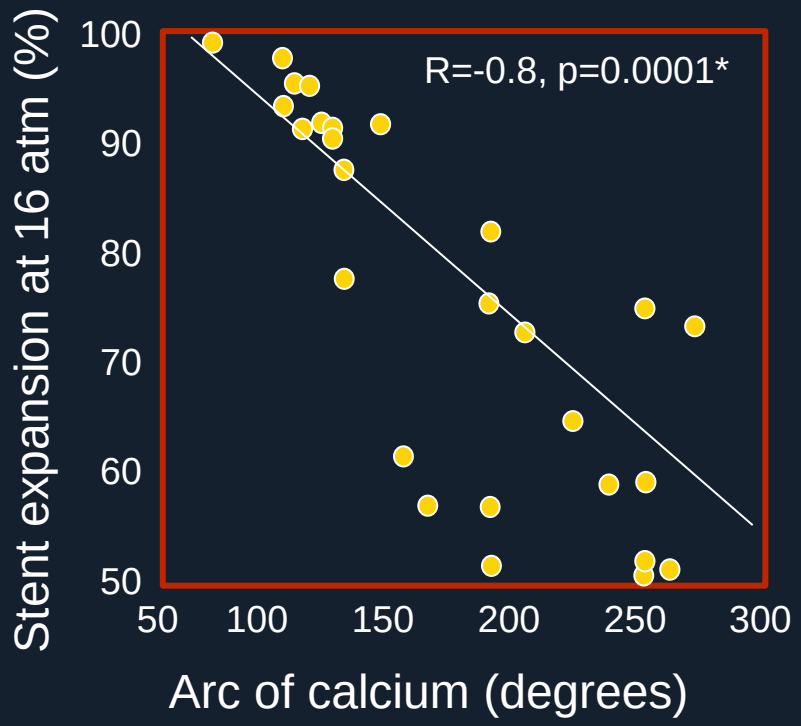


Farooq et al. J Am Coll Cardiol 2013;61:282–94

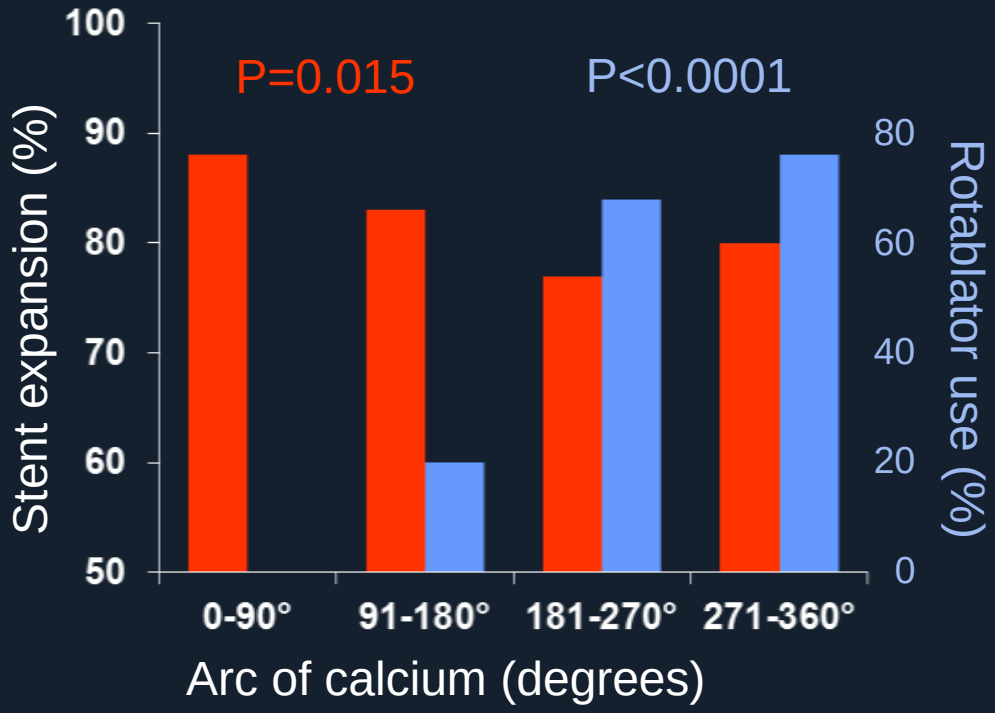
Implications of coronary calcification

- ***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

Stent Expansion in Calcified Lesions



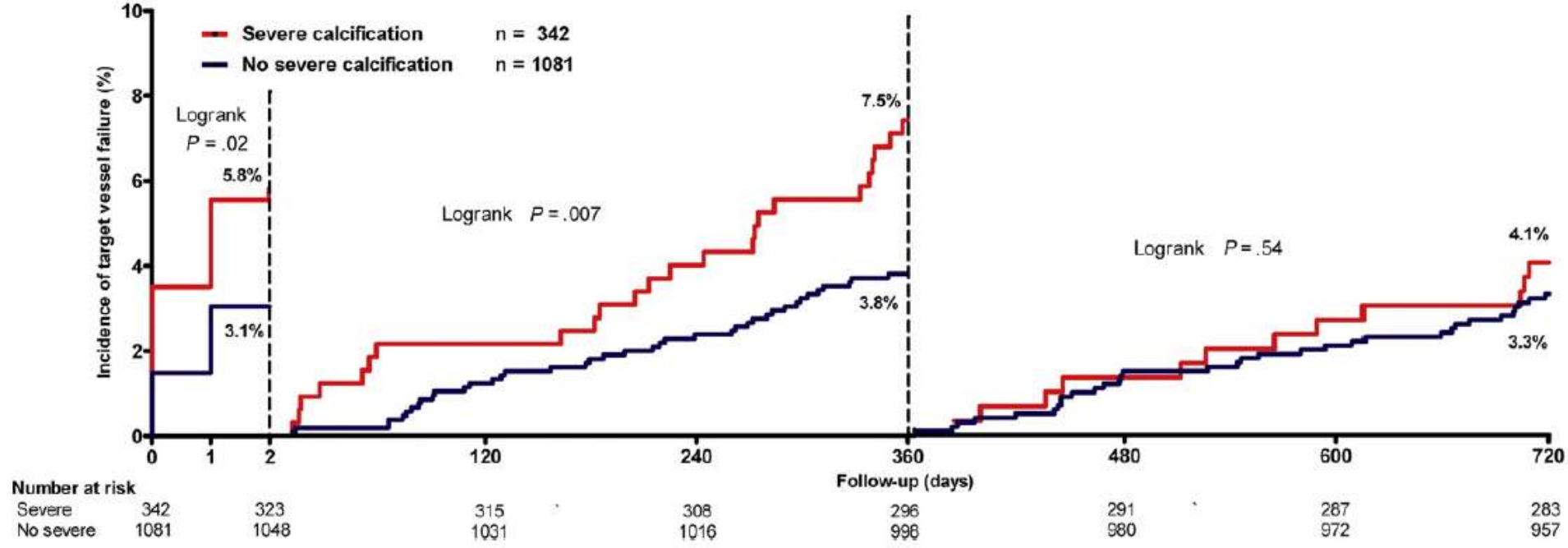
*There was a similar, albeit less strong, correlation after 20 atm inflation (r=-0.58, p=0.0007)



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%)



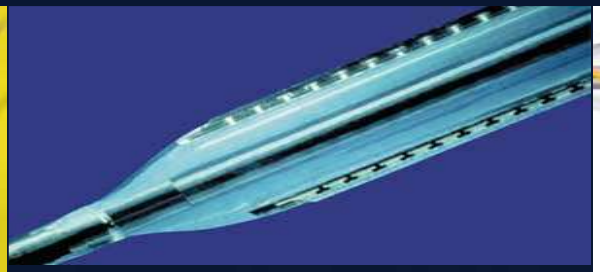
At 2 years, TVF was 16.4% vs. 9.8%, p=0.001
predominantly driven by events in the first 48 hours and up to 1 year

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

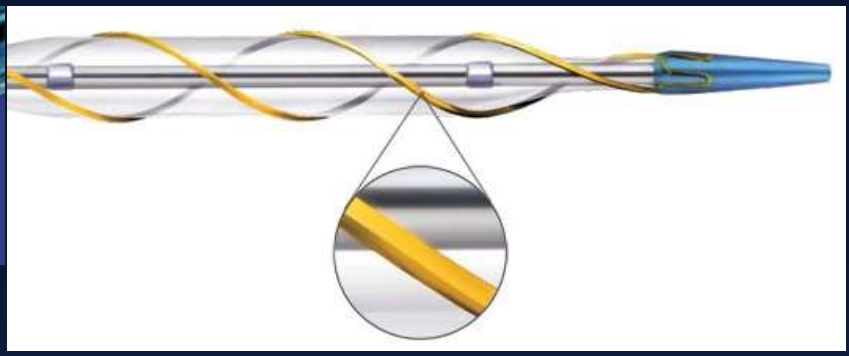
Treatment of Calcified Lesions: Options

NC Balloons

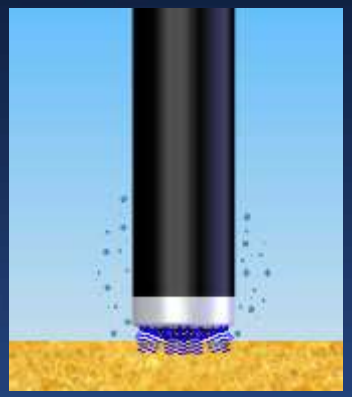
Cutting Balloon



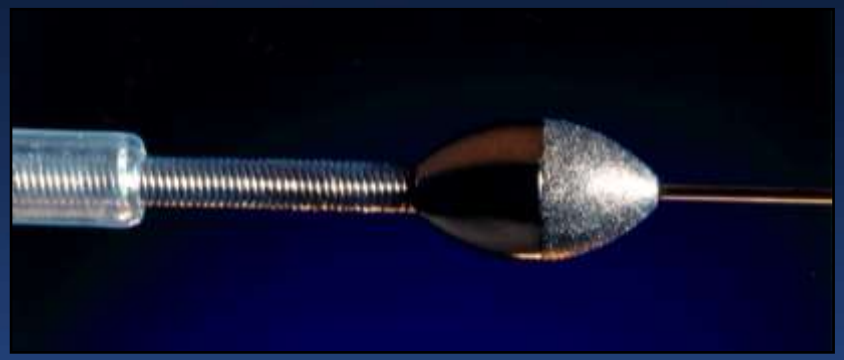
Angiosculpt



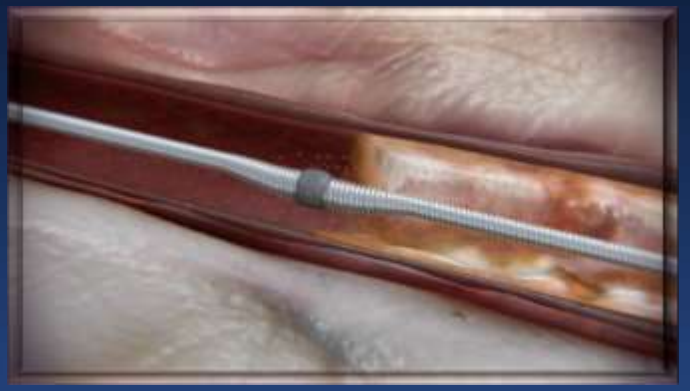
Laser



Rotational Atherectomy



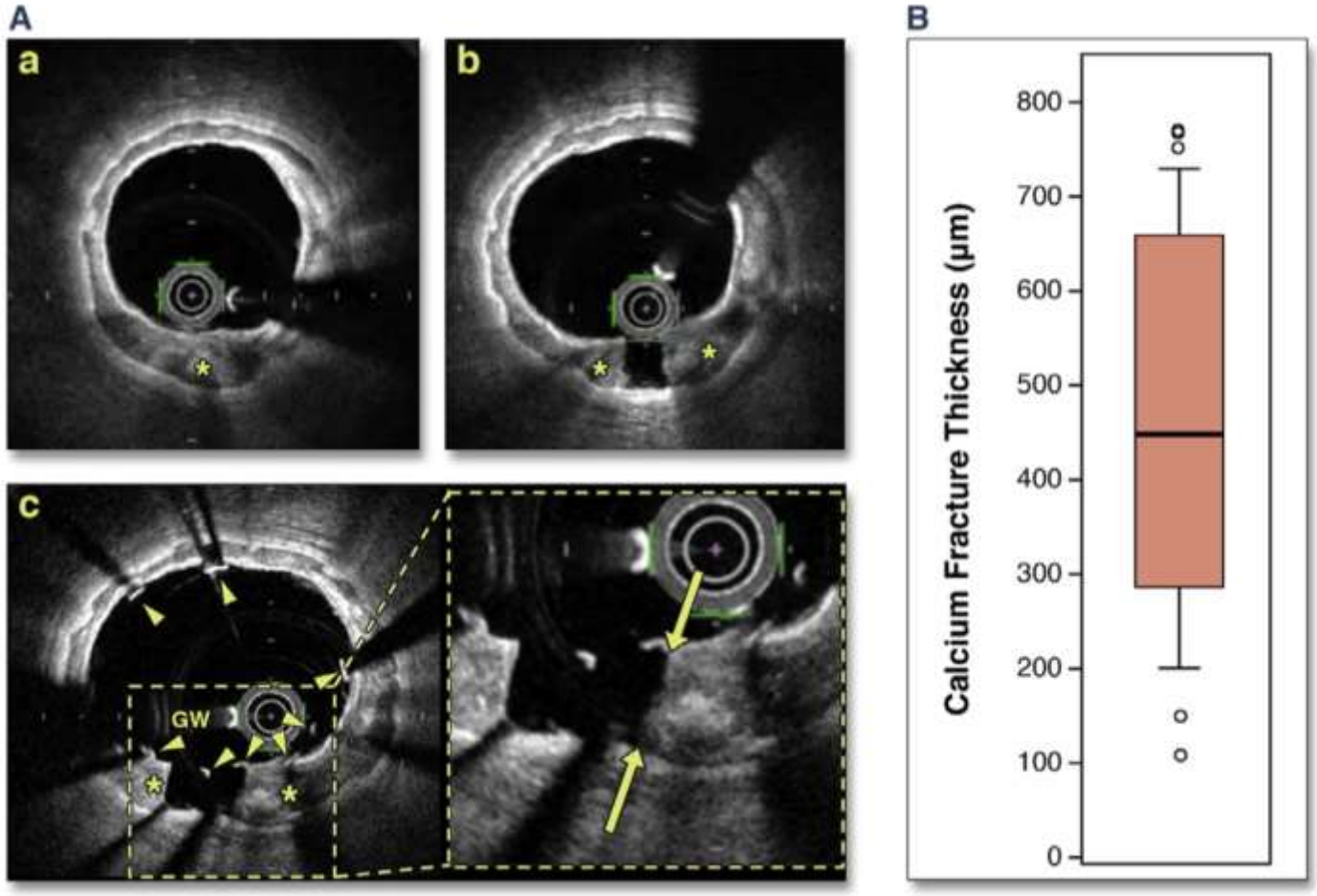
Orbital Atherectomy



Intravascular Lithotripsy

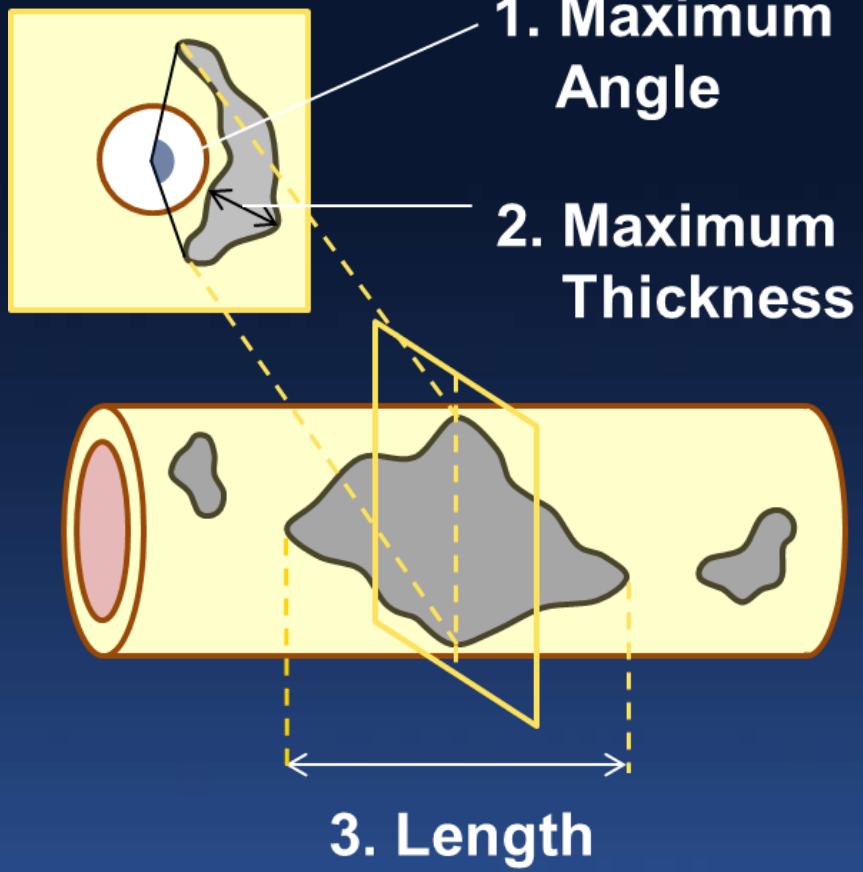
Calcium Fracture and Relation to Outcomes

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

Calcium Volume Index (CVI) Scoring System



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

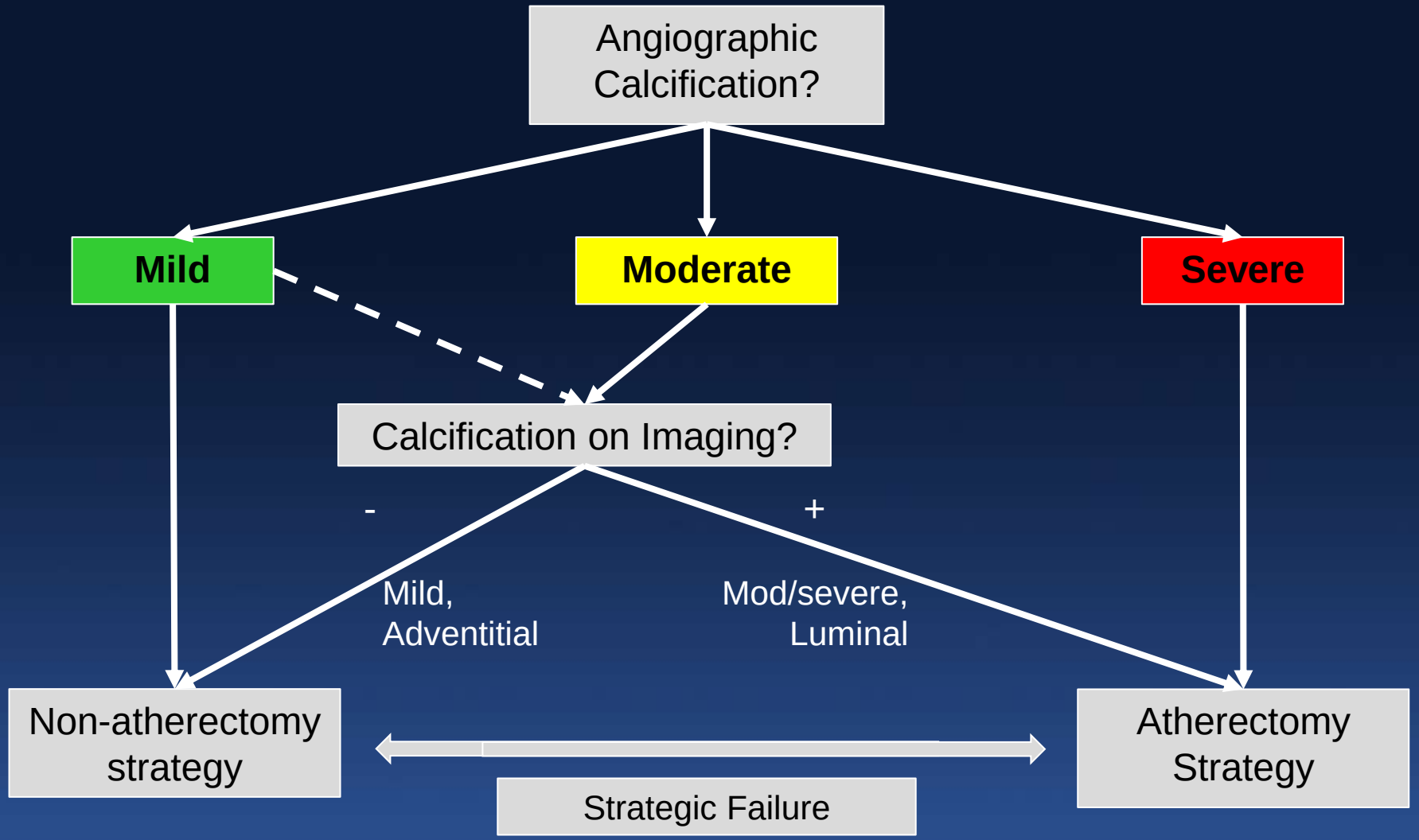
Fujino et al, Eurointervention 2018

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**) • 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**) • 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**) • Should not be used routinely during PCI (**Class III-A**)	(Laser not mentioned for calcification)

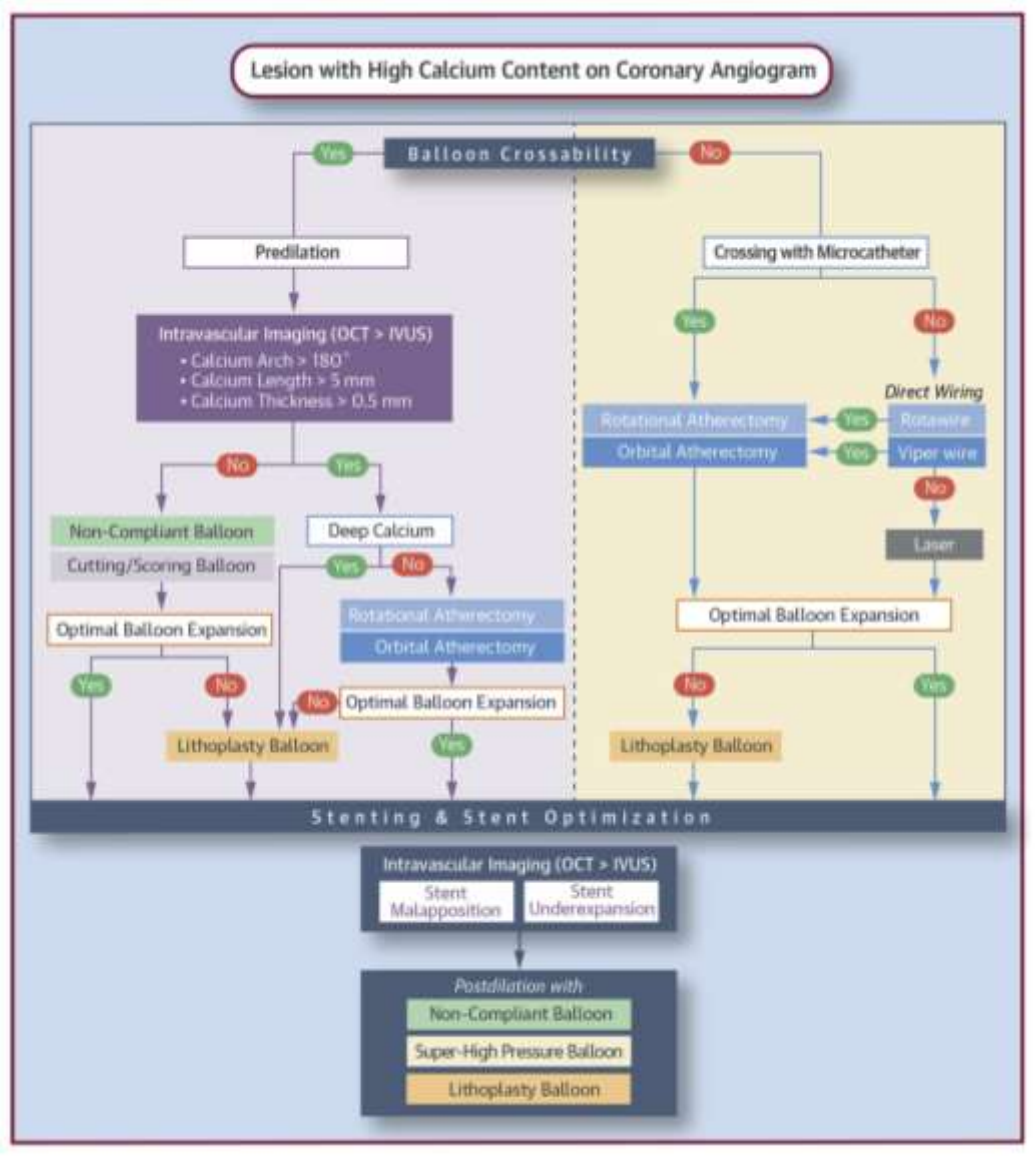
Levine GN et al. JACC 2011;58:e44-122
Windecker S et al. EHJ 2014;35:3541-619

Strategy for Approaching Calcified Lesions



Adapted from Tomey et al, JACC CV Intv 2014

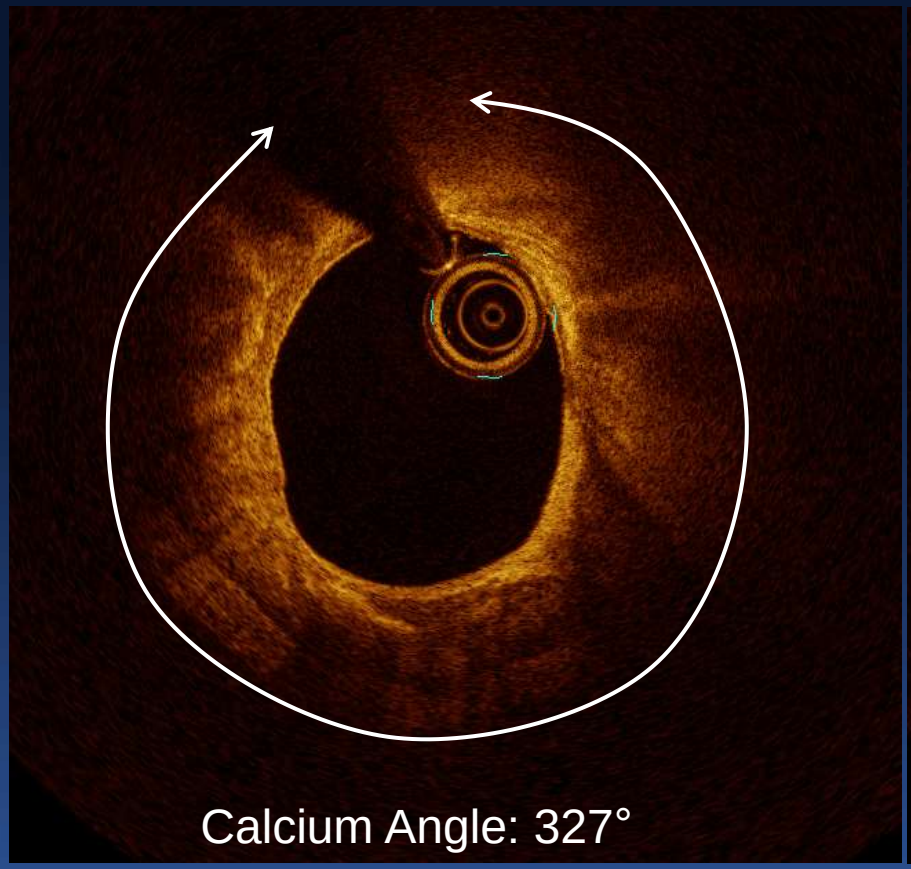
Algorithm for Approaching Calcified Lesions



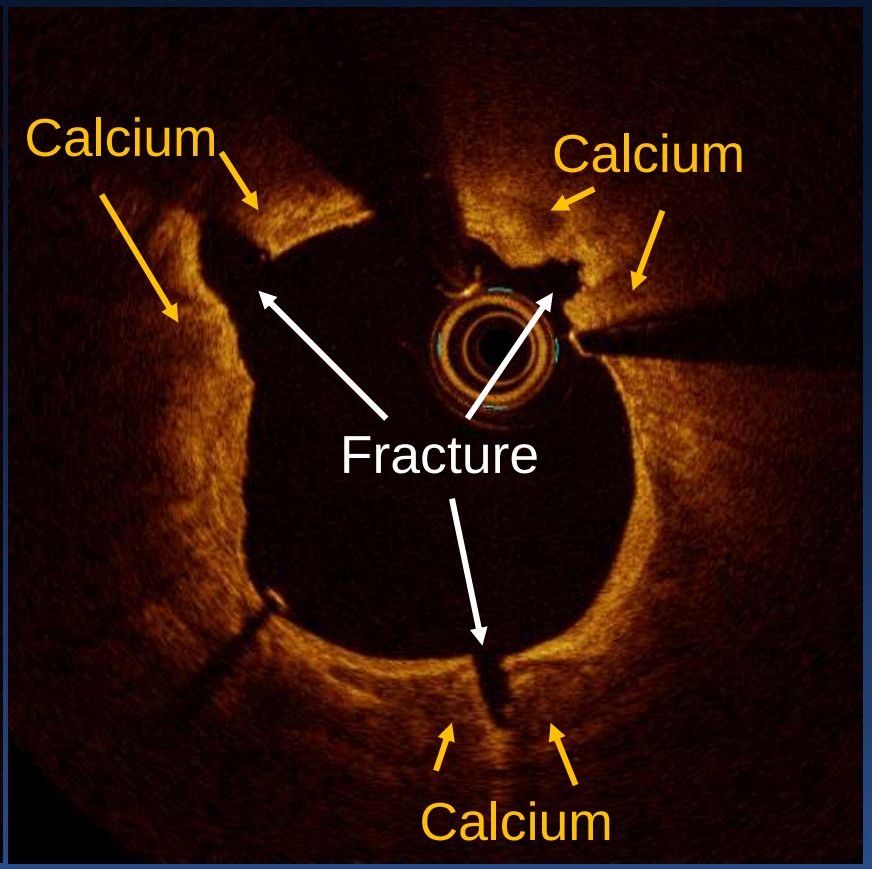
De Maria et al, JACC CV Intv 2019

Mechanism of IVL

Circumferential Calcium Fracture



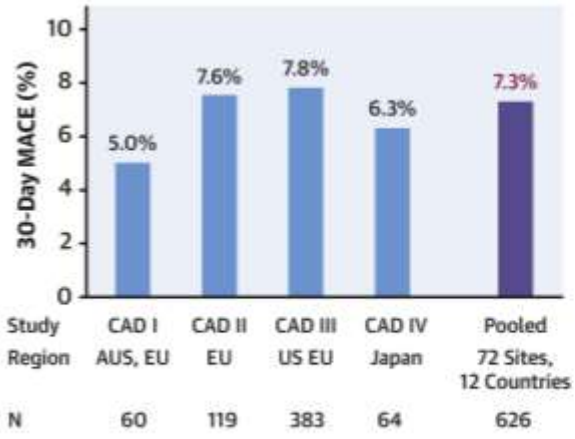
Pre-Procedure

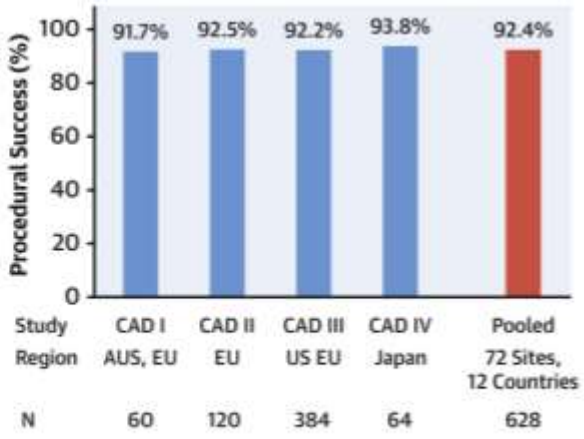


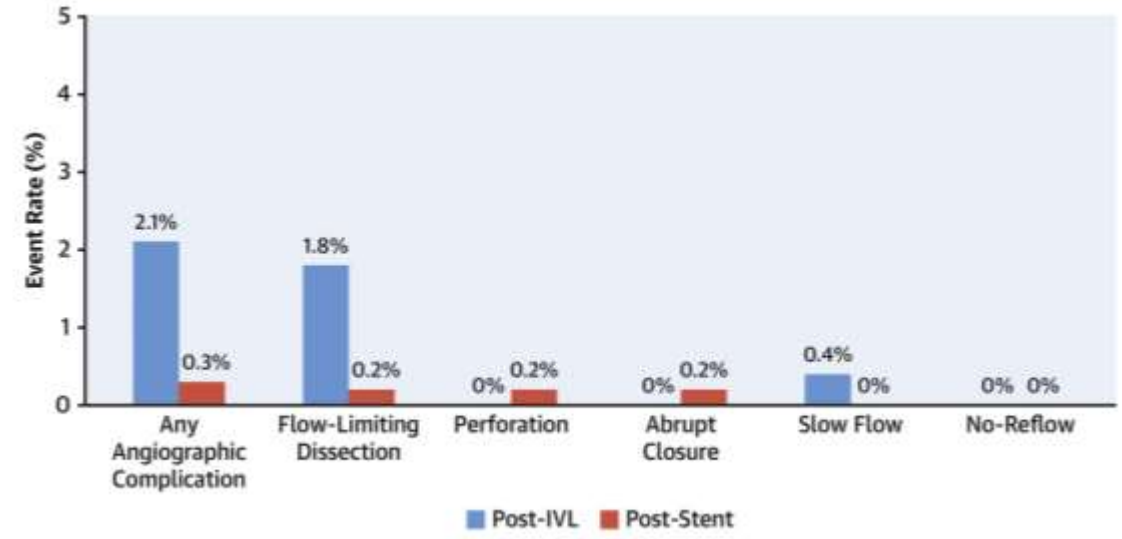
Final

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

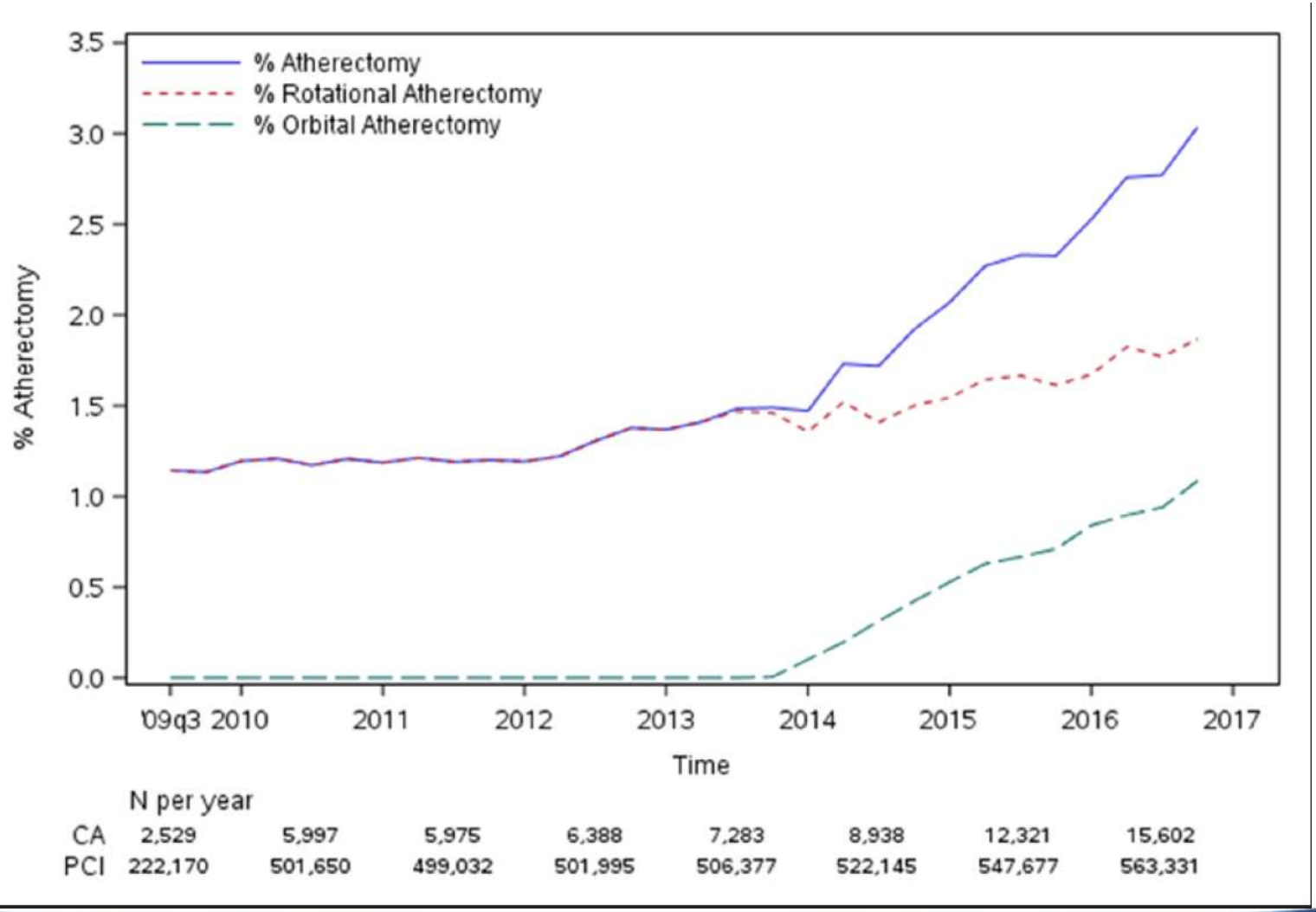
Mean 63.7% diameter stenosis

Predilation used in 47.6% of cases

IVL success in 98.7% of cases

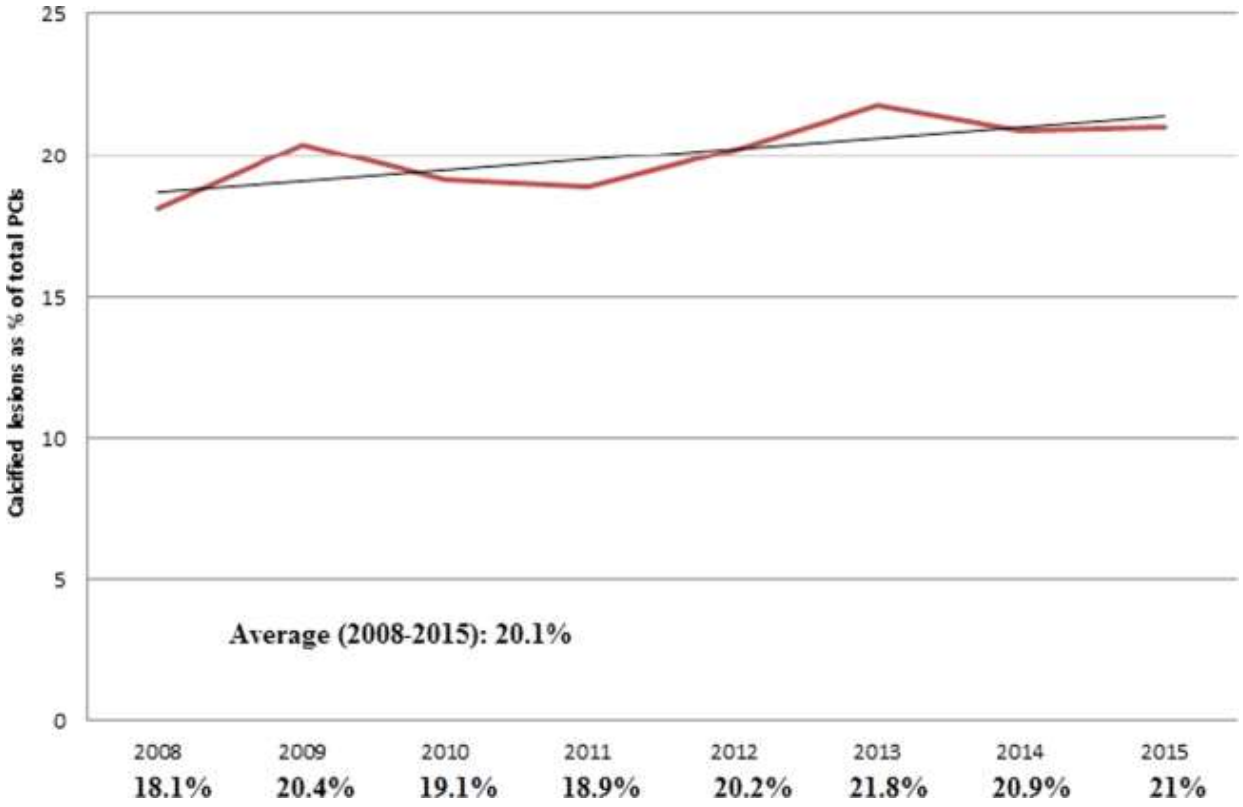
NCDR: Quarterly Trends in Atherectomy Usage

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



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

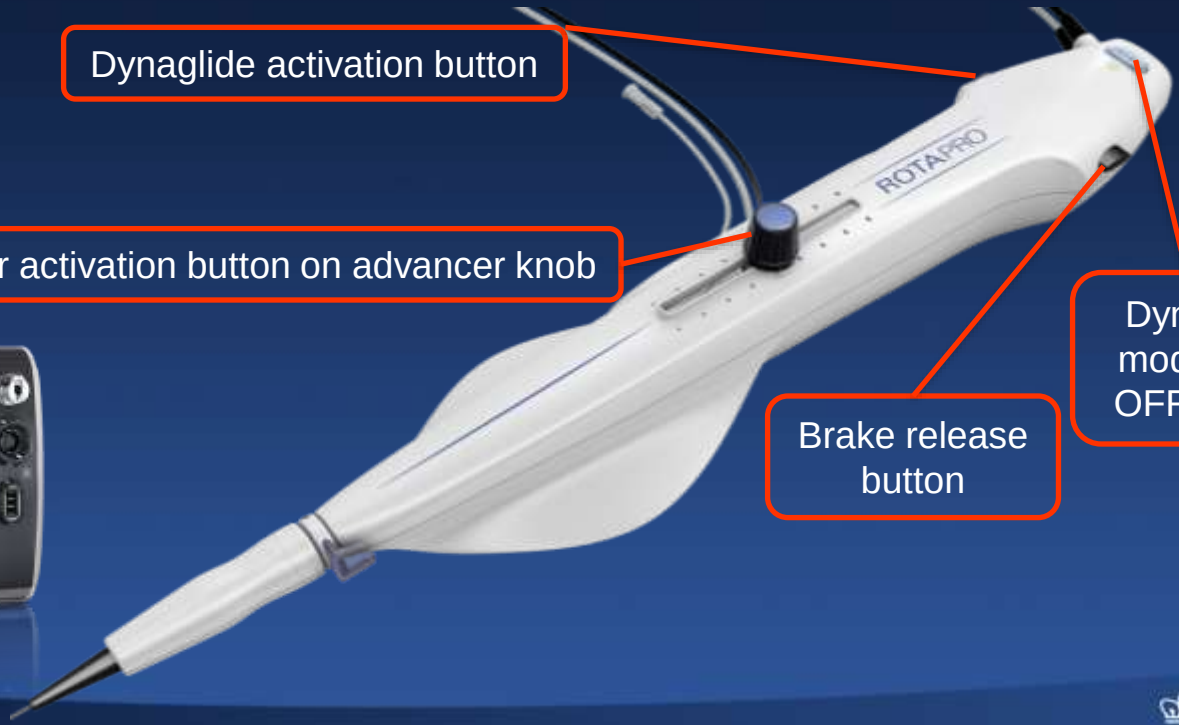


Atherectomy was used in 18% of single-vessel PCI cases of native calcific coronary artery lesions and was associated with a decrease in procedural/clinicial complications

RotaPRO Rotational Atherectomy System

Design Goals:

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



Dynaglide activation button

Burr activation button on advancer knob

Dynaglide mode ON / OFF button

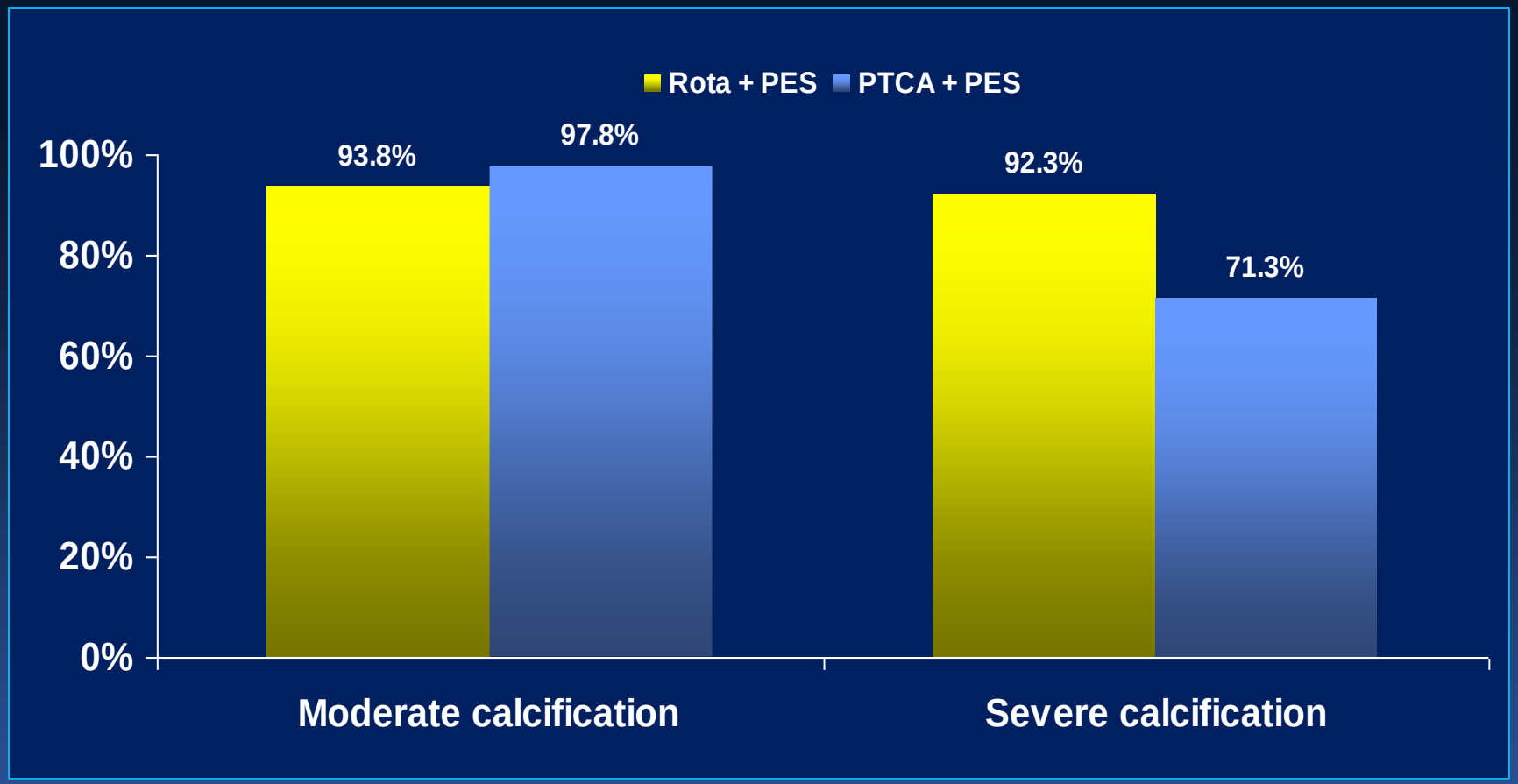
Brake release button

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**

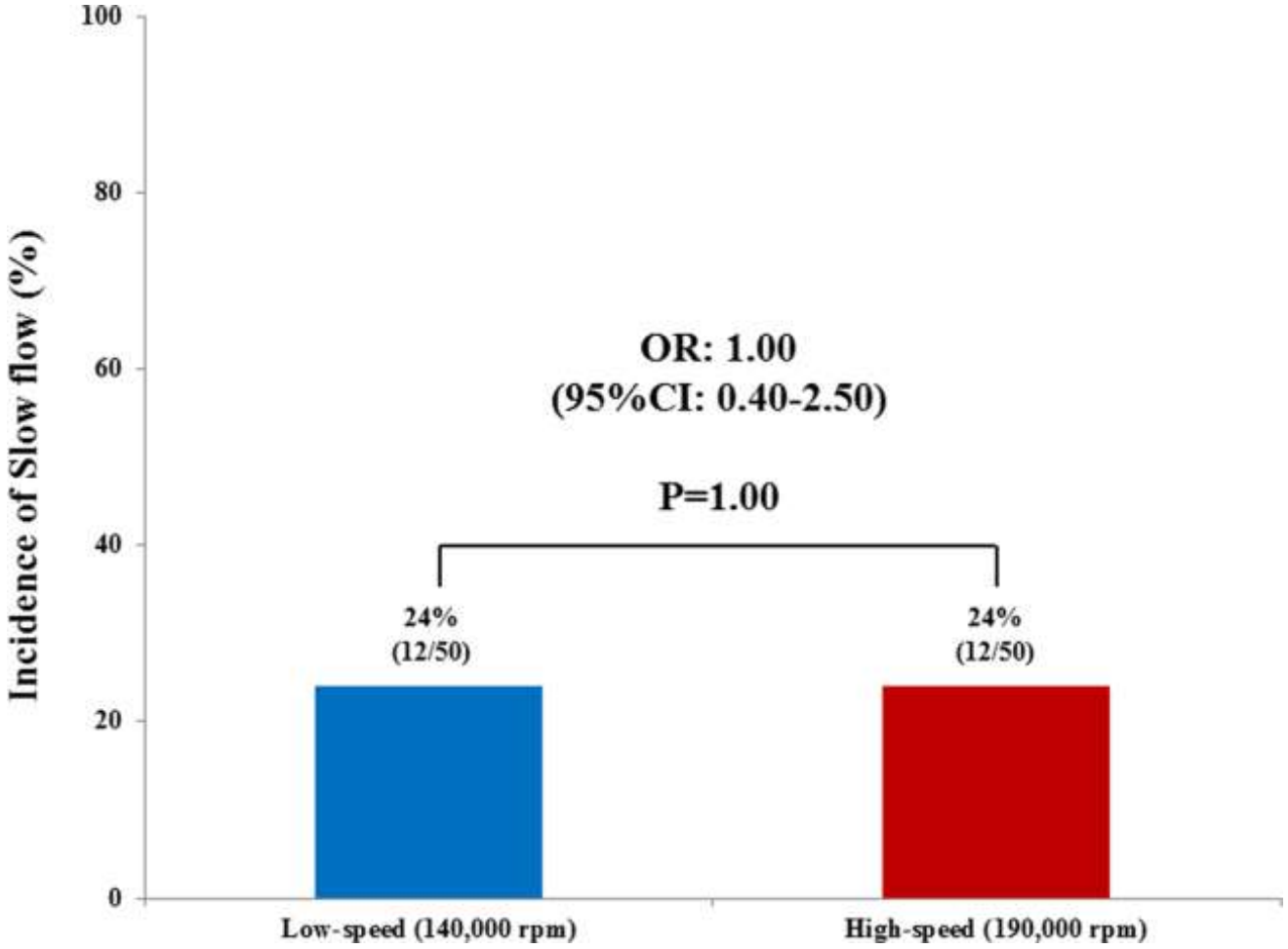
200 patients, elective PCI, native coronaries, severe calcification

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



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

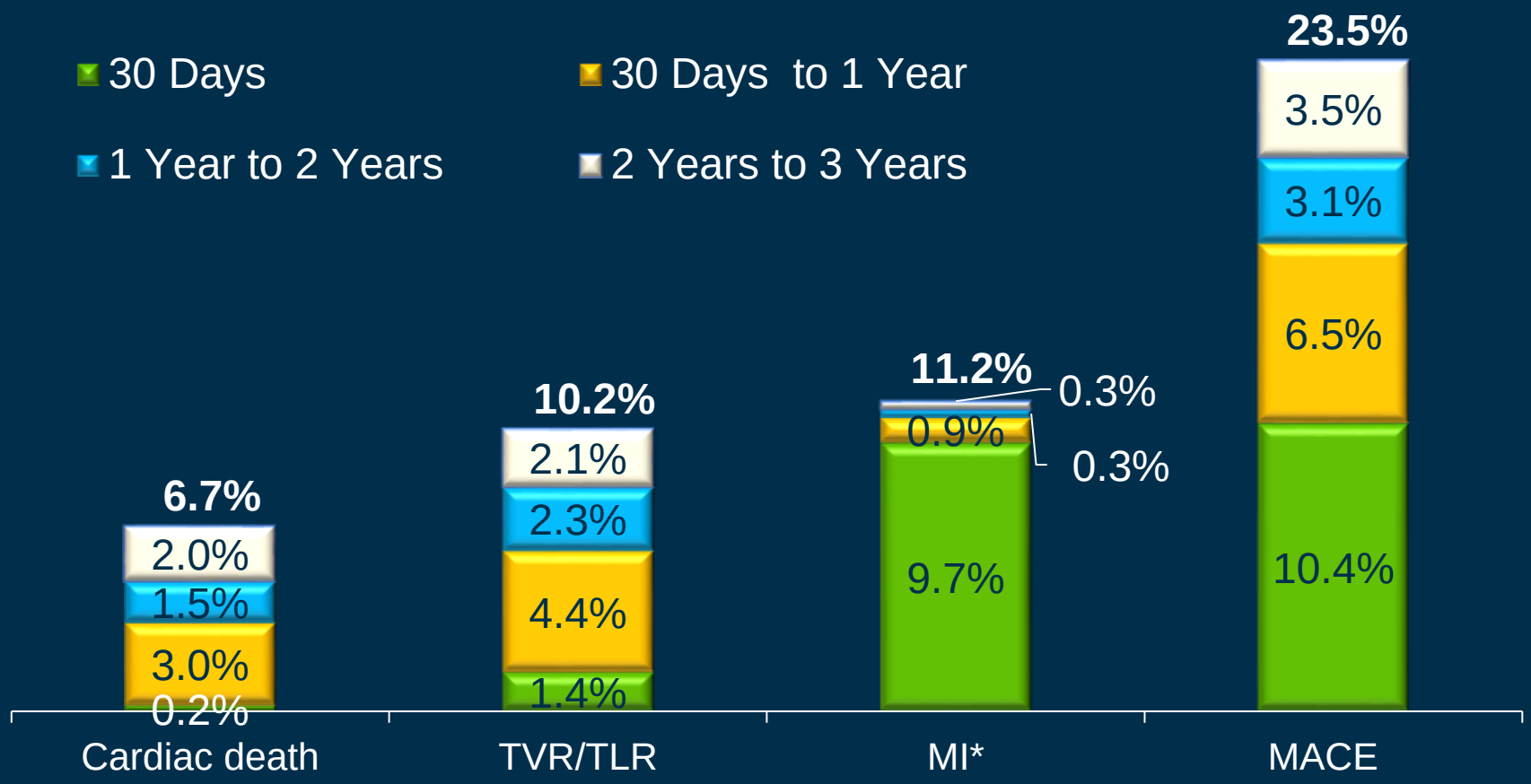
Saline Infusion Pump

- 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.*

1. Chambers JW, et al. J Am Coll Cardiol Intv. 2014;7:510-518.
2. Chambers JW. Presented at CRT 2016.

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	• Aorto-ostial lesions
• Faster learning curve	• Severe angulation/bias
• Single device for all lesions/ vessel diameters	• Subintimal crossing
• Full 6 Fr compatibility (including guide extension)	• Front cutting for uncrossable lesions
• Hemodynamic stability (less slow flow/pacer?)	• ISR/underexpansion for stent ablation
• +/- distal/multiple lesions using low speed glide assist	• Specific scenarios with need for 2.0+ mm burr
	• 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.

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…