

# Coronary Intra-Vascular Lithotripsy Across the Calcium Spectrum

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FAsCC; FACC; FSCAI, FESC

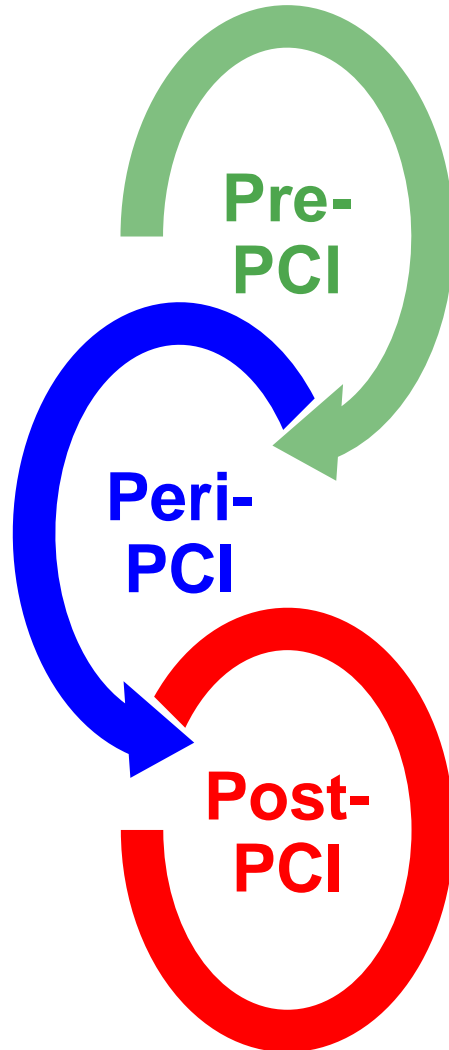
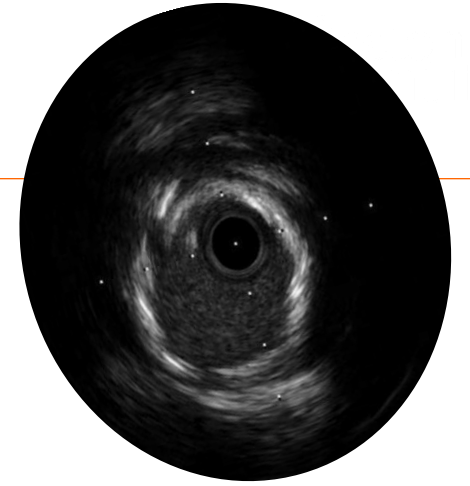


# Disclosure

- No conflicts pertaining to this lecture



# Complications Due to Calcium

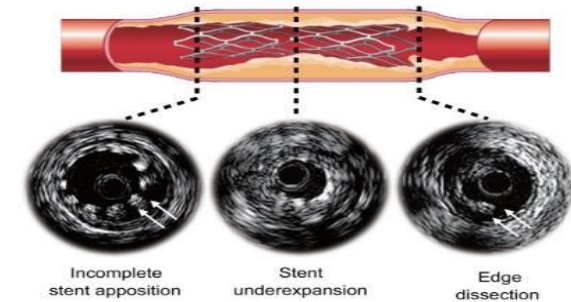


- Dissection during balloon angioplasty or pre-dilatation<sup>1</sup>
- Difficulty with complete dilation<sup>2</sup>

- Inhibition of adequate stent expansion<sup>3</sup>
- Prevention of stent delivery to the desired location<sup>4</sup>
- Stent underexpansion or malapposition<sup>5</sup>
- Stent loss

- Insufficient drug penetration and subsequent restenosis<sup>6</sup>

## Failure to expand



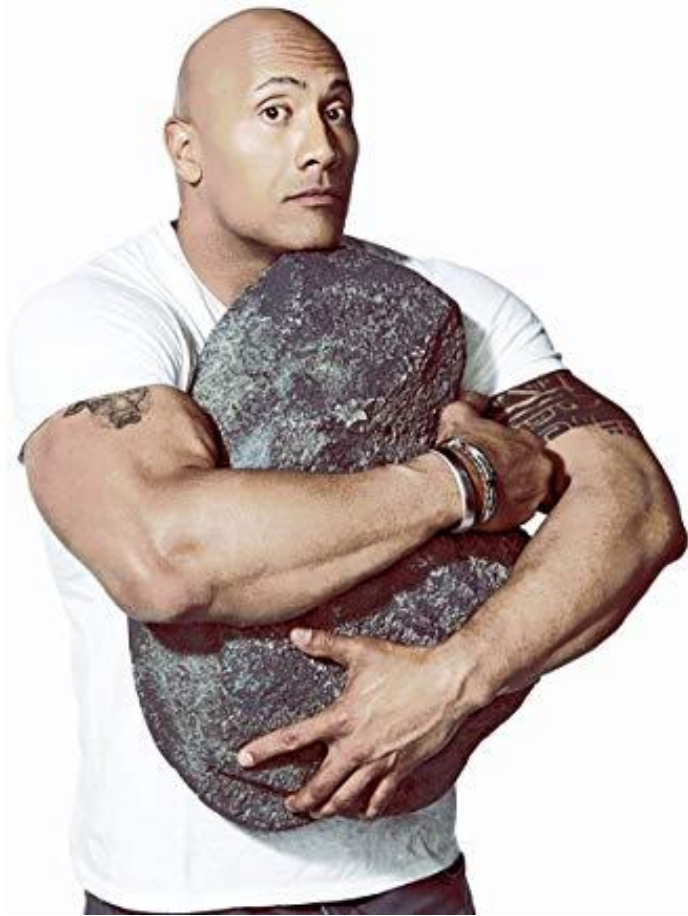
Malapposition

Dissection

Underexpansion

→ *stent thrombosis/restenosis*  
*perforation*

# The Big Question is : How do you deal with the Calcium aka 'The Rock'?



# Tools to Manage the 'ROCK'

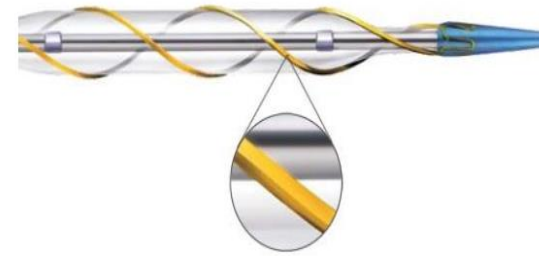
NC Balloons



Wolverine Cutting Balloon



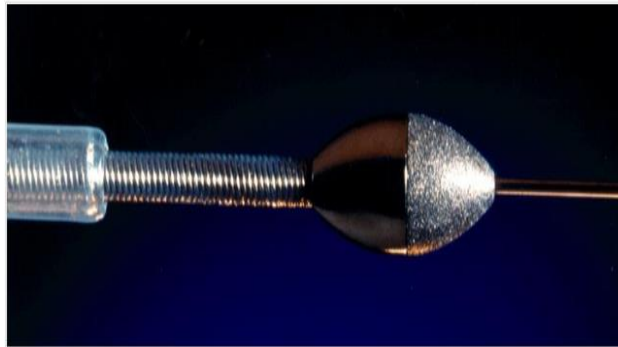
Angiosculpt



Laser



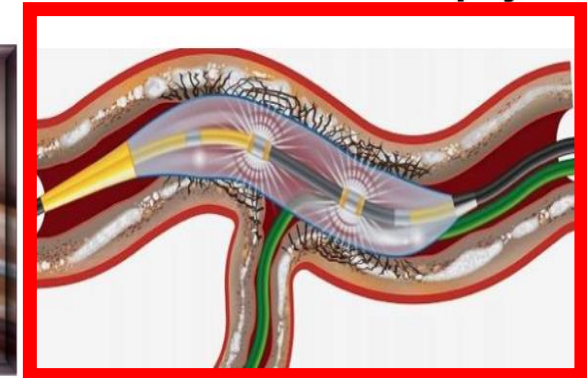
Rotational Atherectomy



Orbital Atherectomy



Intravascular Lithotripsy





# Lithotripsy for Cardiovascular Applications

## Extracorporeal Lithotripsy

30 years of safety data in kidney stone treatment

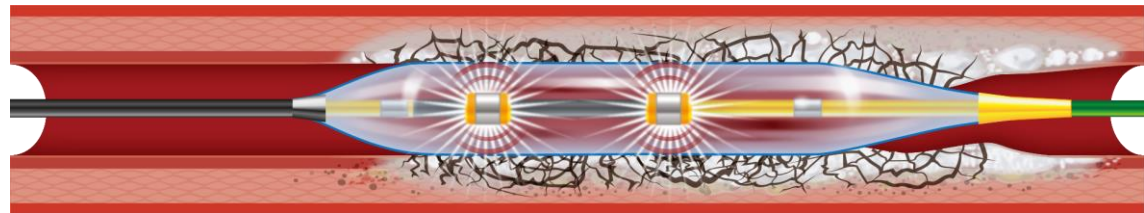
**Sonic Pressure Waves** preferentially impact hard tissue, disrupt calcium, leave soft tissue undisturbed



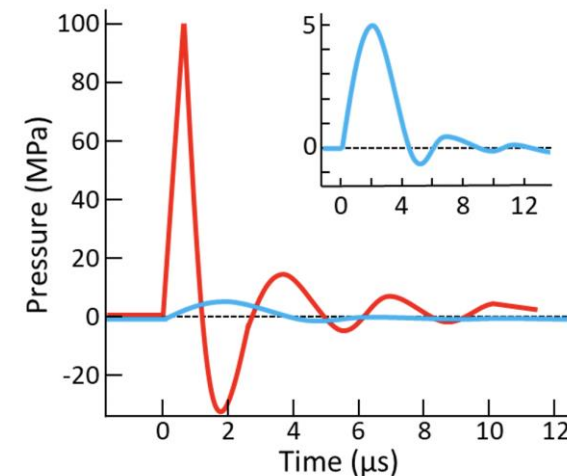
- Designed in Partnership with Optima Education Ltd & VP Education

## Intravascular Lithotripsy (IVL)

Miniaturized and arrayed lithotripsy emitters for localized lithotripsy at lesion location



Energy profile optimized for the treatment of vascular calcium



Superimposed IVL (blue) and extracorporeal lithotripsy (red) waveforms.

# How IVL Cracks Calcium In Situ



Expanding and collapsing vapor bubble creates a short burst of **sonic pressure waves**.

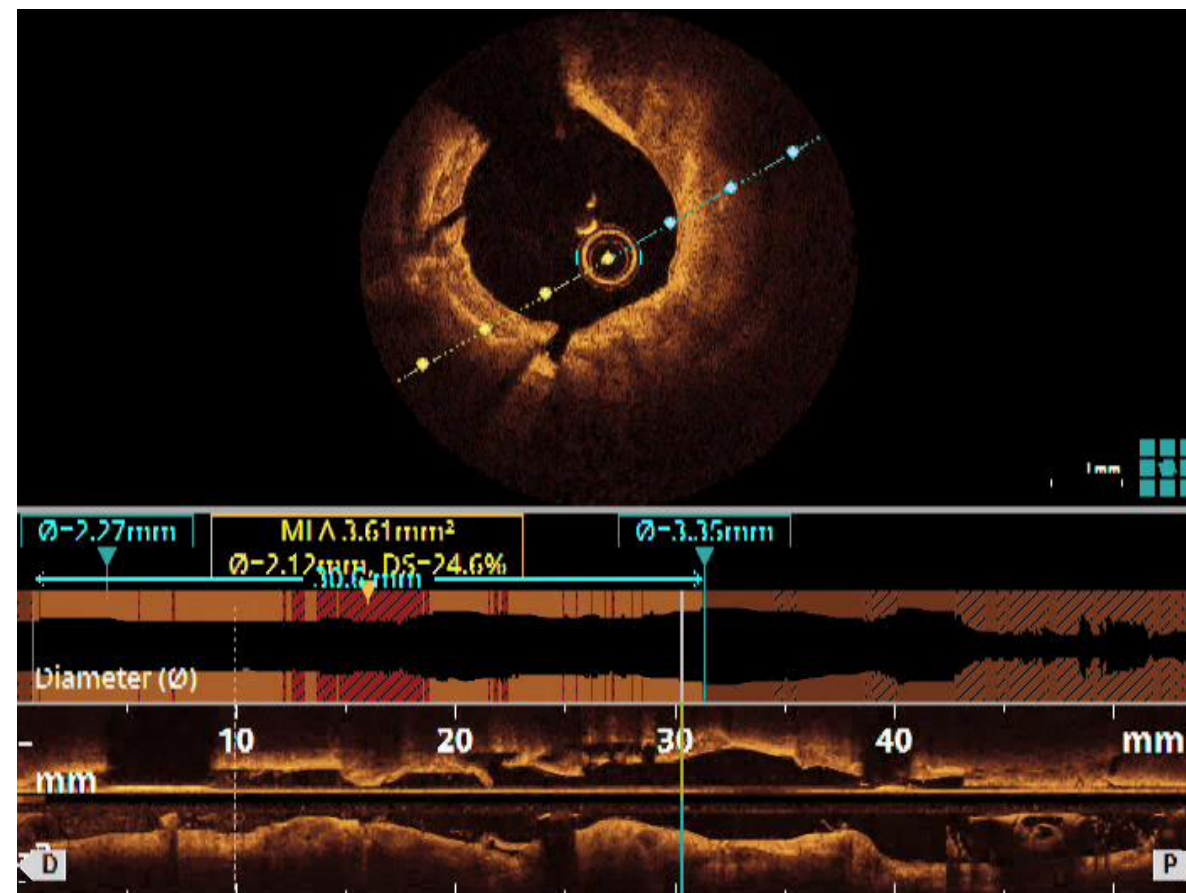
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Sonic pressure waves travel through the vessel with an effective pressure of **~50 atm**.

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A **localized field effect** within the vessel fractures both **intimal and medial** calcium.

# OCT Showing Large Multi-plane & Longitudinal Calcium Fractures

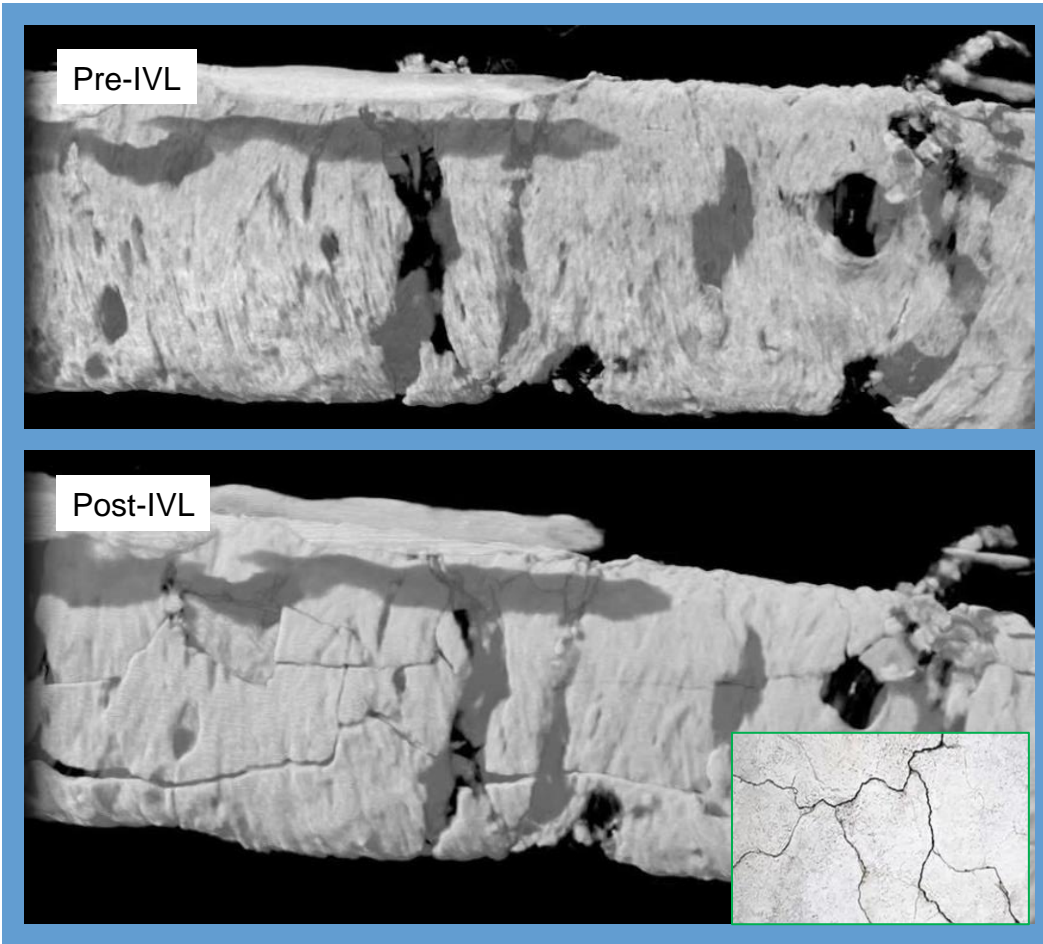


1 DISRUPT CAD III Case Example

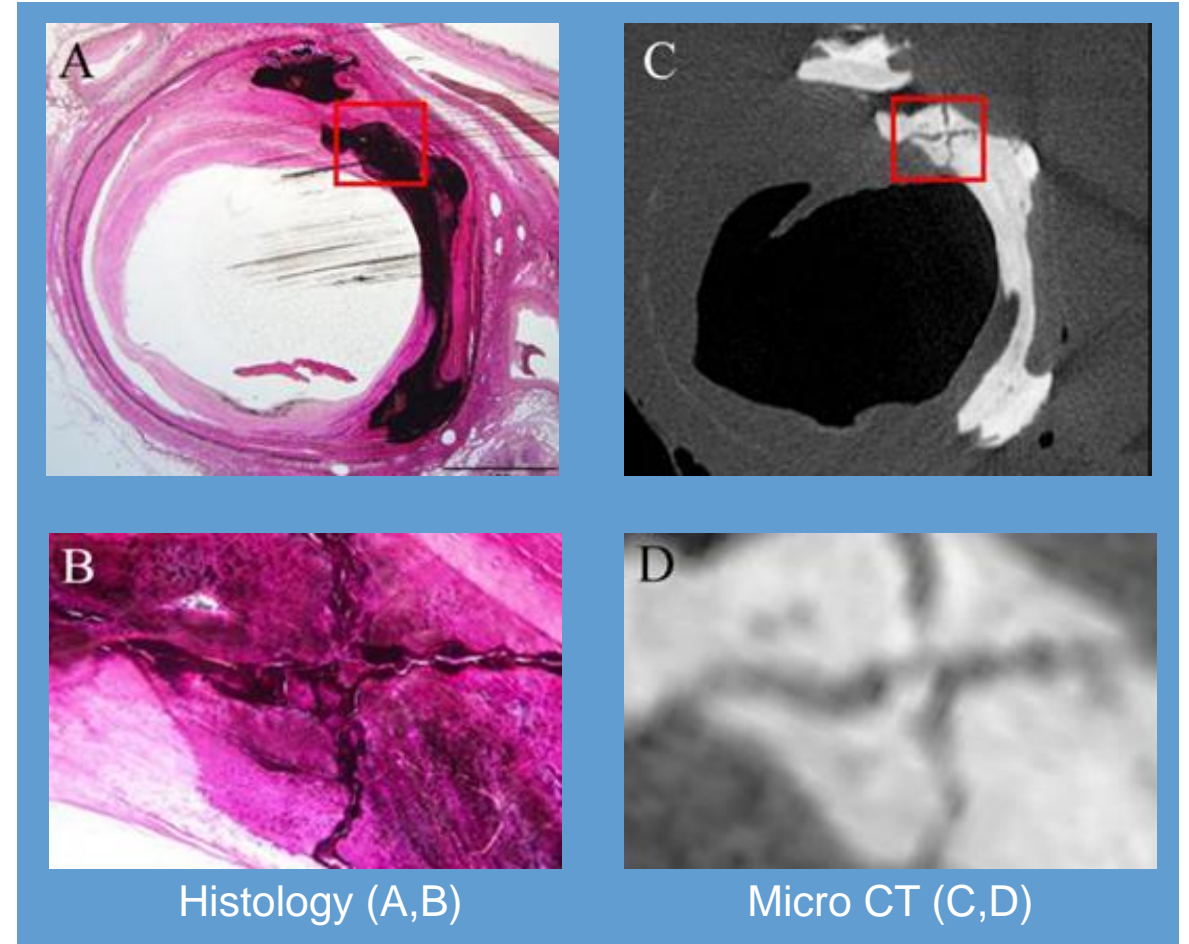


# Microfractures Occur Beyond Resolution of IVUS & OCT

## Cadaveric Superficial Femoral Artery (Micro CT)



## Histologic & Micro CT after IVL Treatment (SFA)



# Coronary IVL DISRUPT CAD Clinical Program

## Excellent Outcomes in Core Lab Adjudicated Studies

	DISRUPT CAD I	DISRUPT CAD II	DISRUPT CAD III	DISRUPT CAD IV	DISRUPT CAD POOLED
Status	Circ	Circ Intrv	JACC	Circ Journal	JACC
Study design	Single arm, safety and feasibility	Single arm, post-market, safety and effectiveness	Single arm, IDE, safety and effectiveness	Single arm, pre-market safety and effectiveness	Individual patient-data (IPD) pooled analysis of the Disrupt CAD I- IV studies
# of patients	60	120	384	64	628
# of sites	7	15	47	8	72
Regions	AU, EU	EU	U.S., EU	Japan	U.S.,EU
OCT Sub-study	N=31	N=47	N=100	N=71	NA

>60

Peer-reviewed  
Journal Publications

>1,200

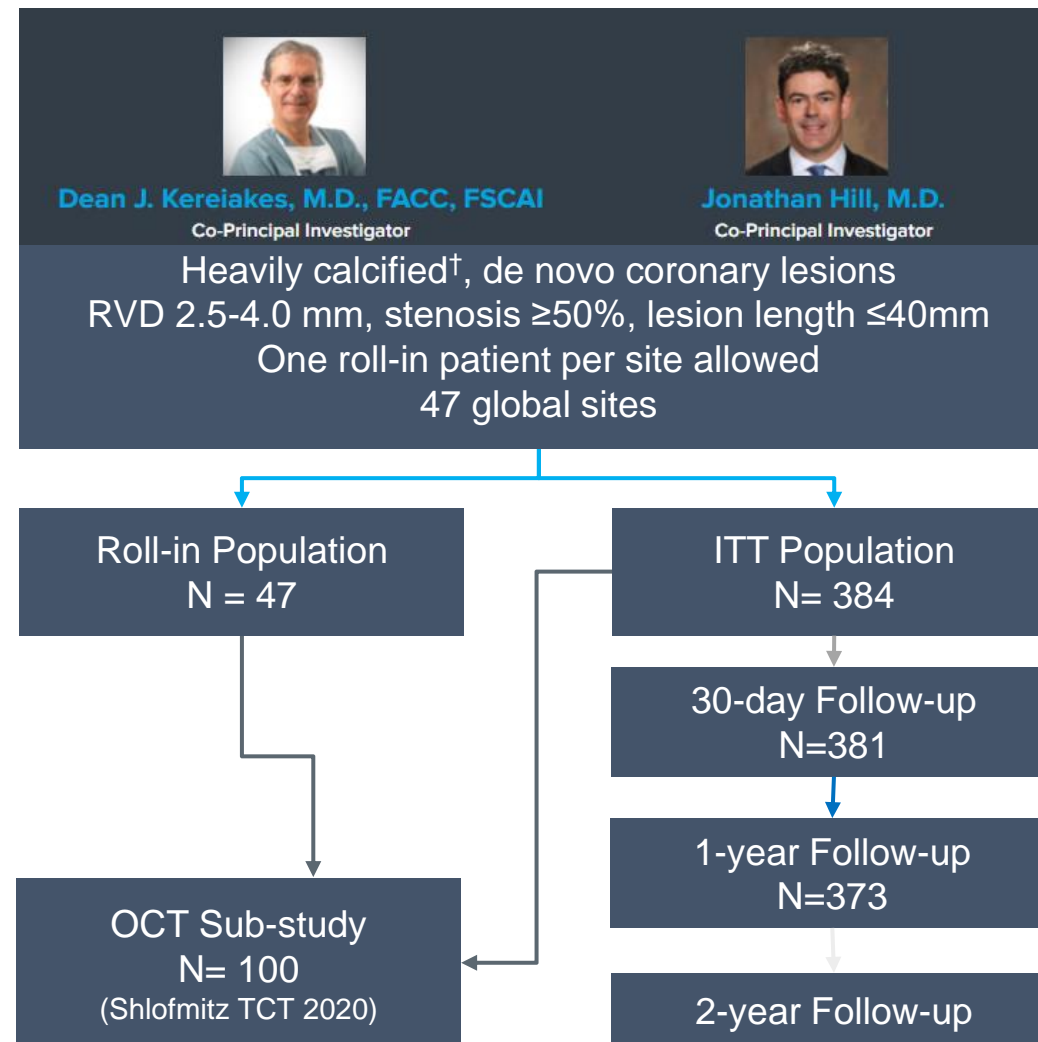
Published Patient  
Outcomes



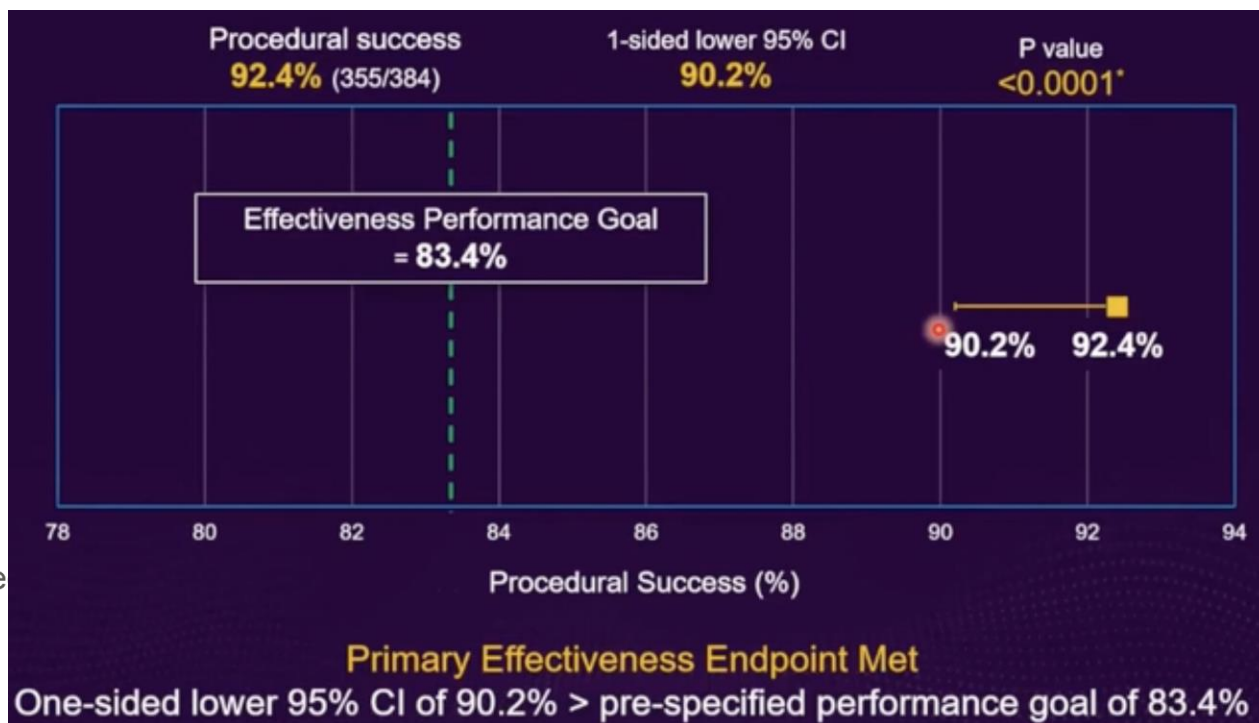
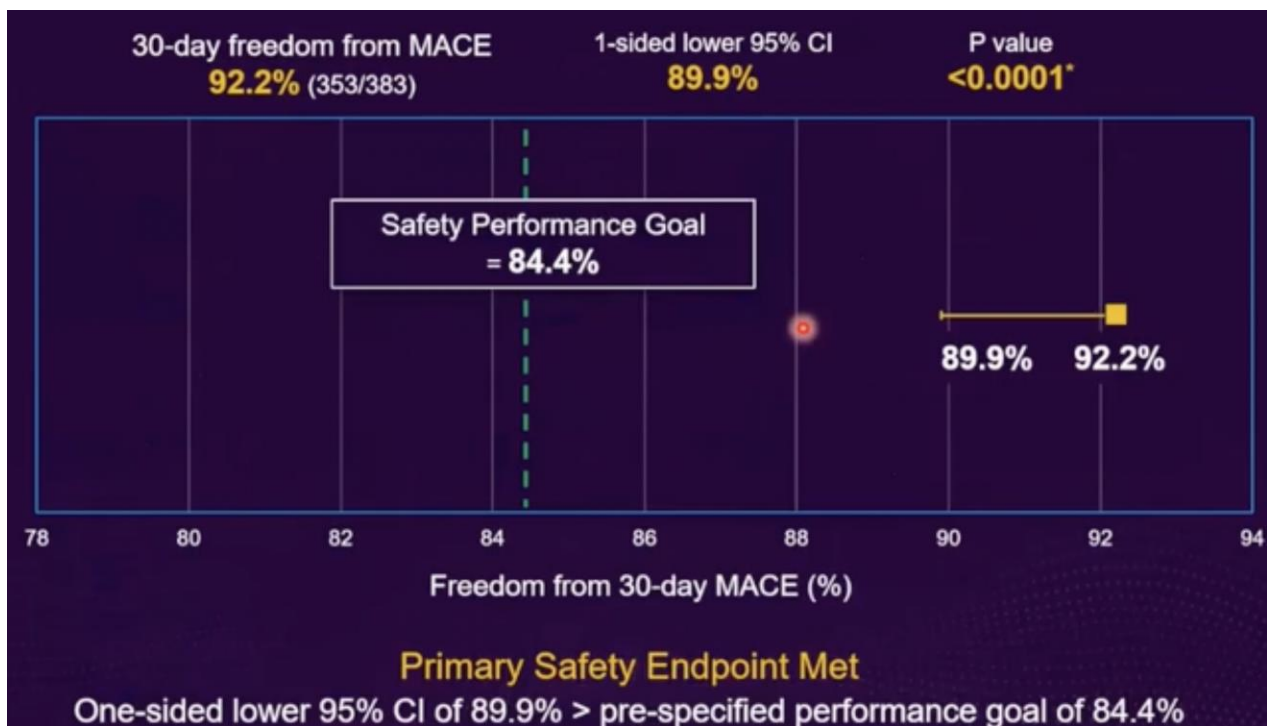
# Disrupt CAD III: Study Design\*

- **Prospective, multicenter, single-arm global IDE**

- **Objective:** Designed to assess safety and effectiveness of the Shockwave Medical Coronary Intravascular Lithotripsy (IVL) System
- **Performance Goal:** Based on ORBIT II
  - Primary safety endpoint: 30d MACE rate
  - Primary effectiveness endpoint: <50% residual and no in-hospital MACE
- **Enrollment:** 431 subjects, across 47 sites
- **Sub-Studies:** OCT, PPM/ICD and Hemodynamics
- **Follow-Up:** Procedural, 30d, 6, 12 & 24mo



# Primary Safety & Effectiveness Endpoints Met



- \*One-sided asymptotic Wald test for binomial proportion
- Hill J., Kereiakes D., et al. IVL for Severely Calcified Coronary Artery Disease. J Am Coll Cardiol. 2020 Dec, 76 (22) 2635–2646. <https://www.jacc.org/doi/full/10.1016/j.jacc.2020.09.603>



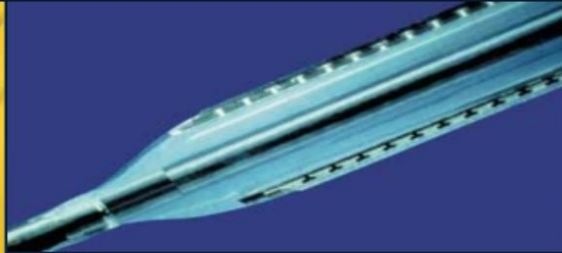
# There Are Many Options to Modify Calcium ?

Blow It / Cut It

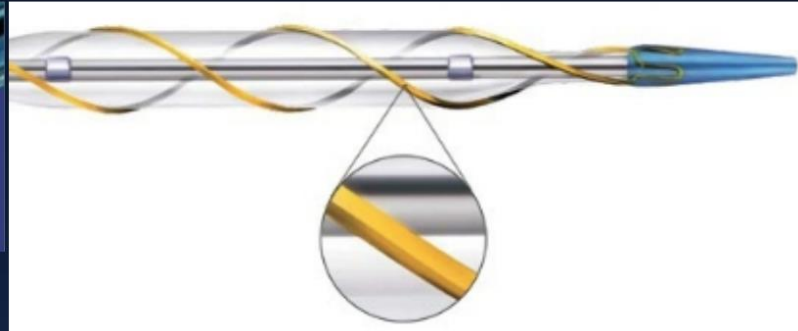
NC balloons



Cutting balloon



Angiosculpt



Laser It

Laser



Drill It

Ro



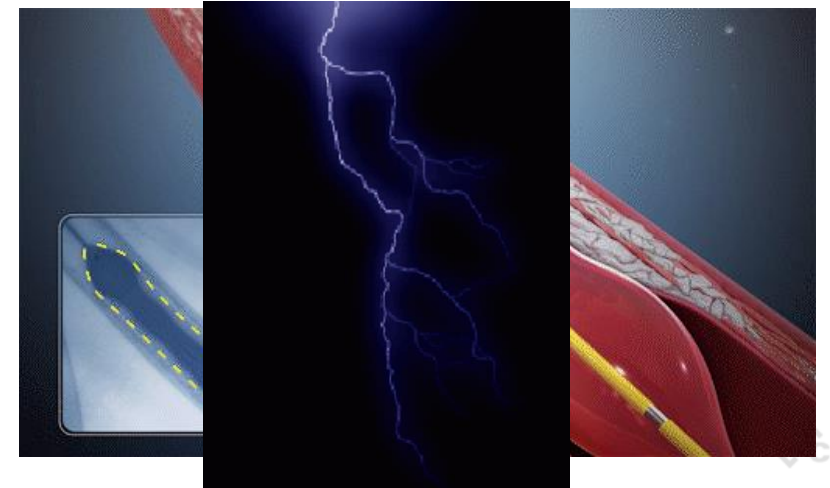
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Sand It



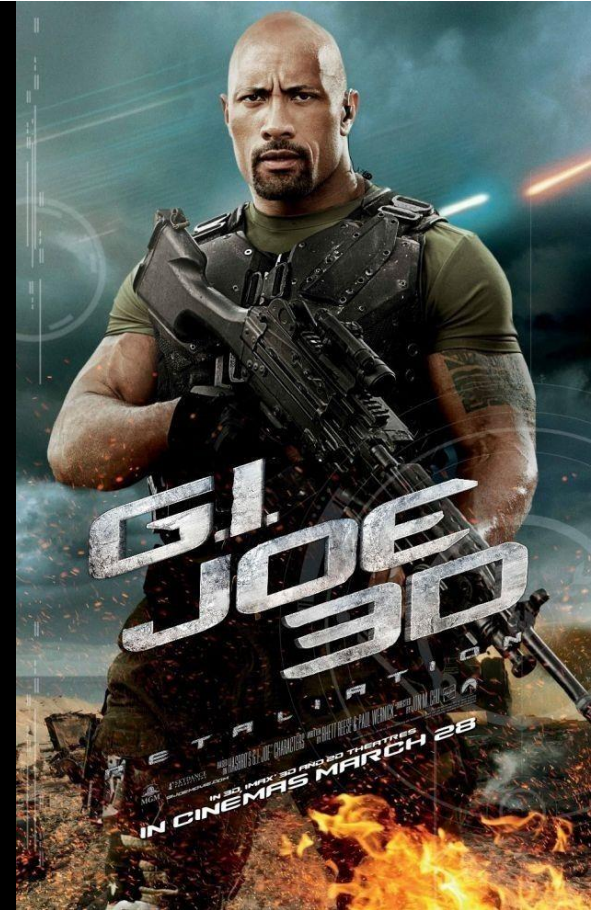
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Shock It





# 'The Rock' Also Comes in Many Forms



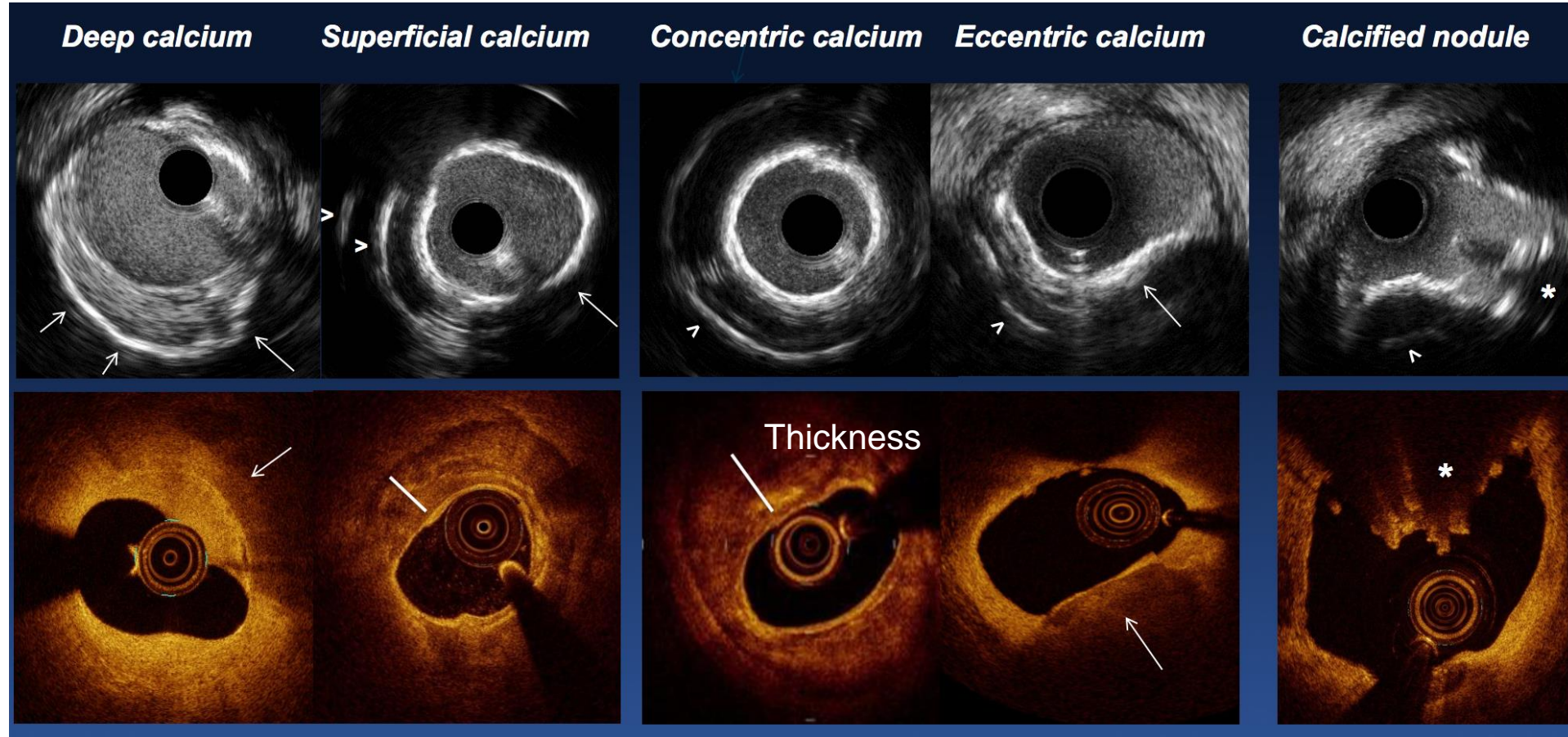


# Who Do You Choose to Fight 'The Rock' ?





# Various Forms of Coronary Calcium on Intravascular Imaging

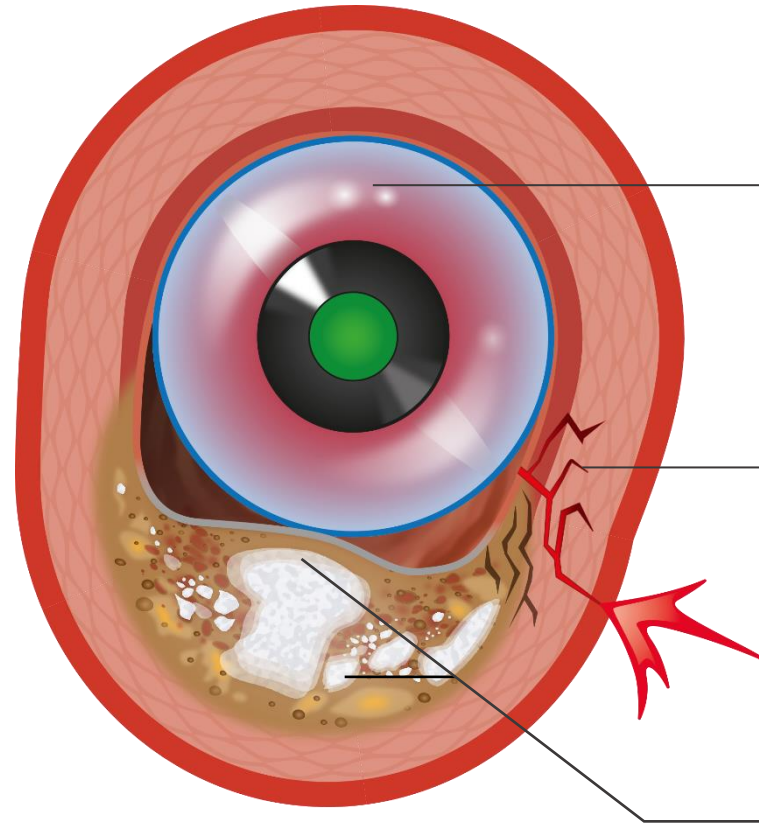


A Jeremias et al. Circ Cardiovasc Interv. 2020;13:e008686

# **Calcium & Lesion Characteristics May Determine Your Choice of Calcium Modifying Tools**

# 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.<sup>1</sup>

High pressure inflations are predisposed to major dissection and perforation - often at the interface between calcium and healthy tissue.<sup>1</sup>

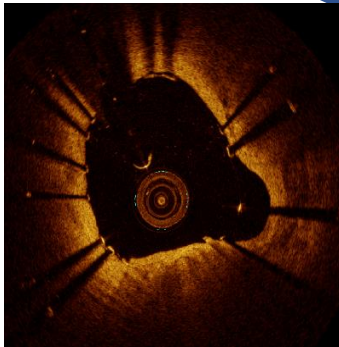
Balloons are typically unable to modify deep or very thick calcium.<sup>1</sup>

<sup>1</sup> Madhavan MV, Tarigopula M, Mintz GS, Maehara A, Stone GW, Généreux P. Coronary artery calcification: pathogenesis and prognostic implications.

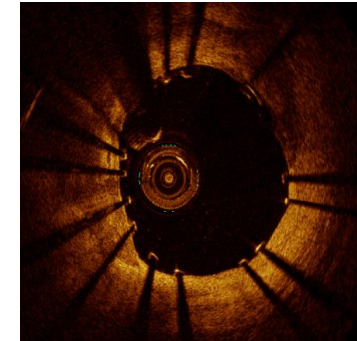
J Am Coll Cardiol 2014;63:1703.



# ATHERECTOMY OPTIONS :



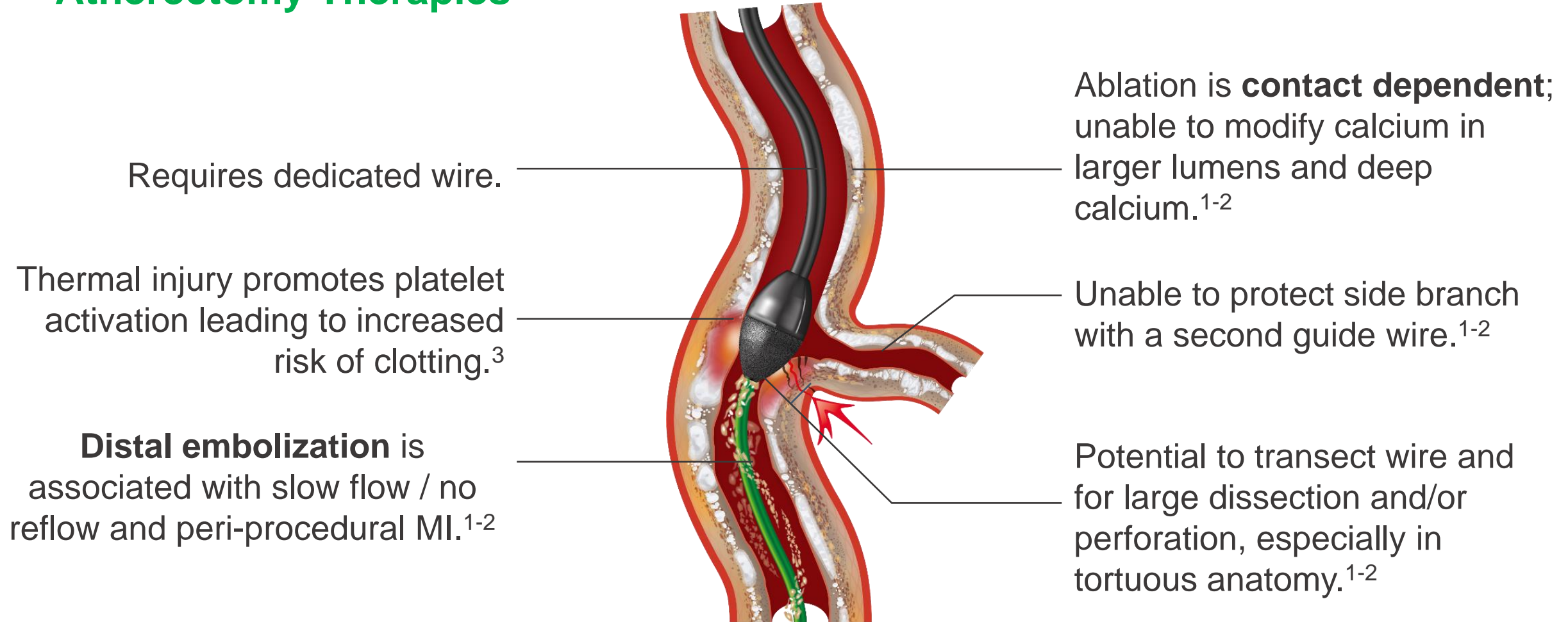
Rotational Atherectomy  
Fixed burr



Orbital Atherectomy  
360 degree vessel preparation

# Limitations of Conventional Tools in Calcium

## Atherectomy Therapies



1 Tomey et al, J Am Coll Cardiol Interv. 2014

2 Okamoto et al, Eurointervention. 2019.

3 Reisman et al. Analysis of heat generation during rotational atherectomy using different operational techniques. Catheterization and Cardiovascular Diagnosis. 1998 Aug;44(4):453-5.

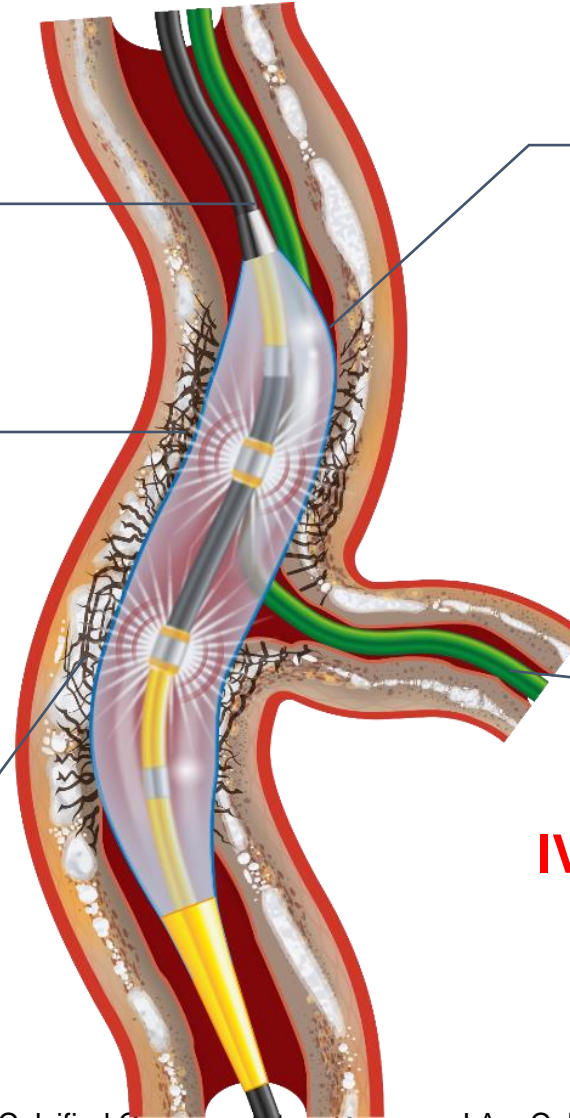
# Opportunities for Coronary Intravascular Lithotripsy

## Potential Advantages

No requirement for a specialized wire.<sup>1</sup>

Shockwaves pass through the plaque/vessel wall enabling modification of **deep calcium**.<sup>1</sup>

Disrupted calcium remains in vessel wall thereby reducing the risk of distal embolization.<sup>1</sup>



Lithotripsy allows calcium modification to be performed at **low balloon pressure** thereby avoiding the risk associated with high pressure inflations.<sup>1</sup>

Able to protect side branch with second wire.<sup>1</sup>

**IVL is easy to learn compared to other forms of calcium modification.<sup>1</sup>**

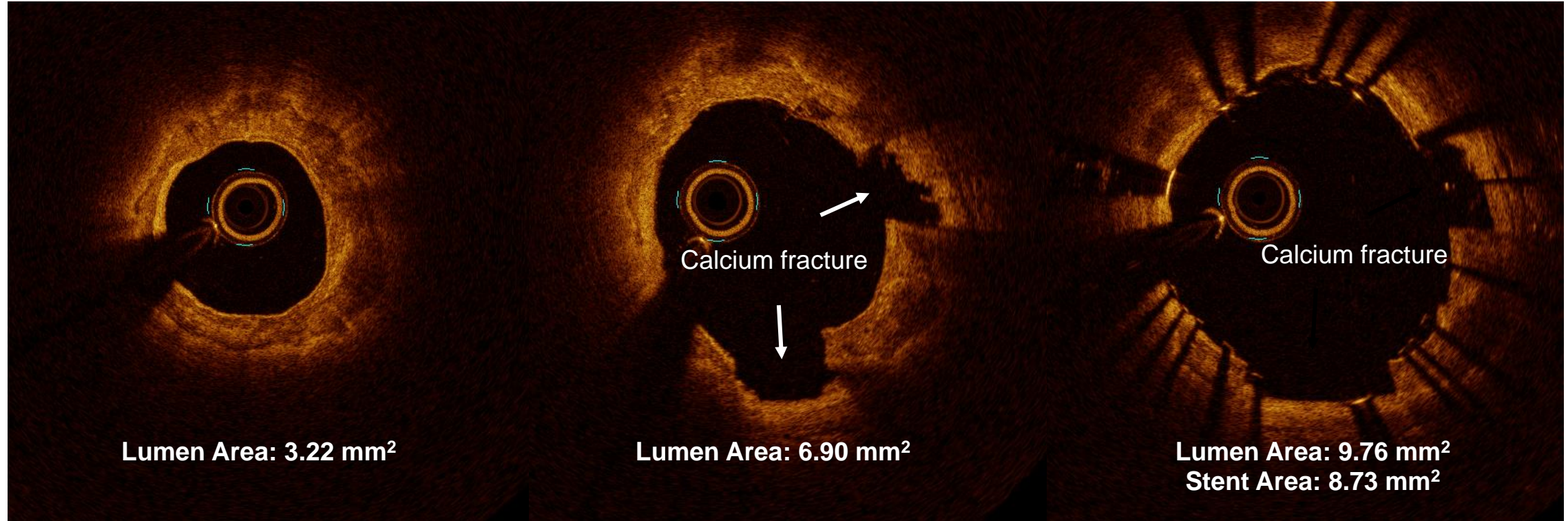


# Impact of IVL Treatment in 360° Coronary Calcification

Pre-IVL

Post-IVL

Post-Stent

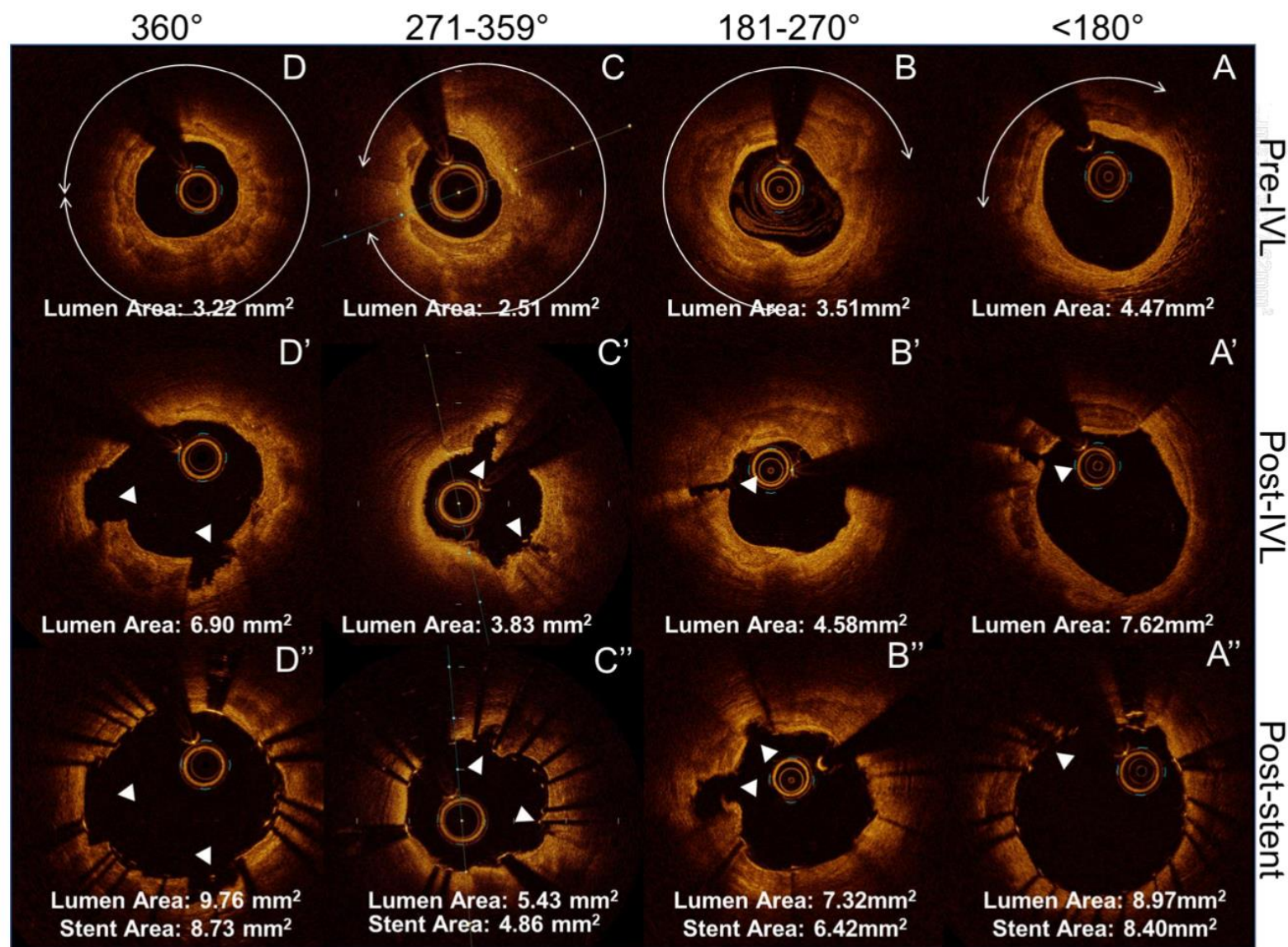


Good luminal gain following IVL treatment (continuous calcium angle: 360°)

Moderated Poster, TCT 163: OCT Characterization of Eccentric Versus Concentric Calcium Treated With Shockwave IVL:

Patient-level Pooled Analysis of the Disrupt CAD OCT Sub-studies. Ziad A. Ali, TCT 2021

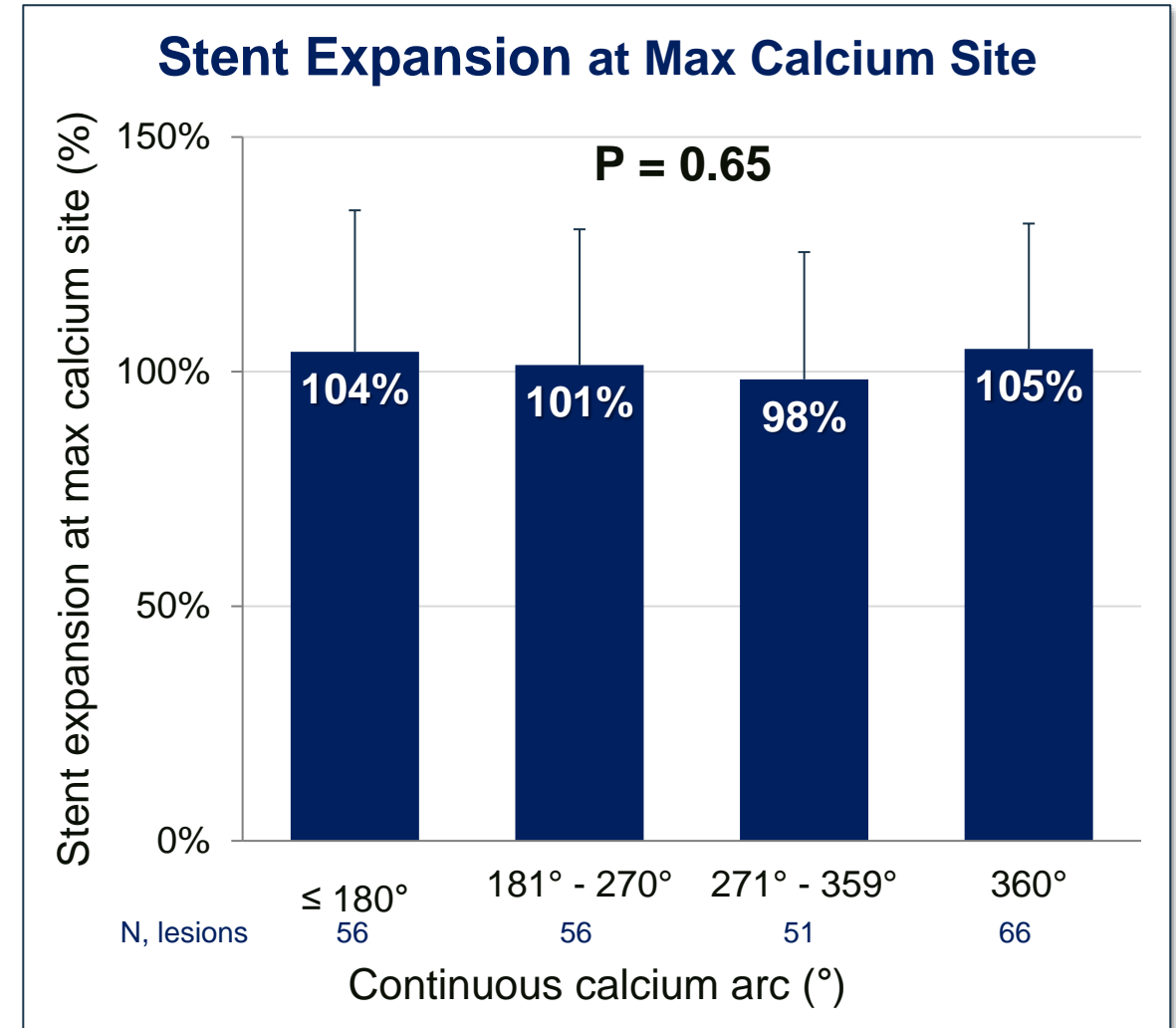
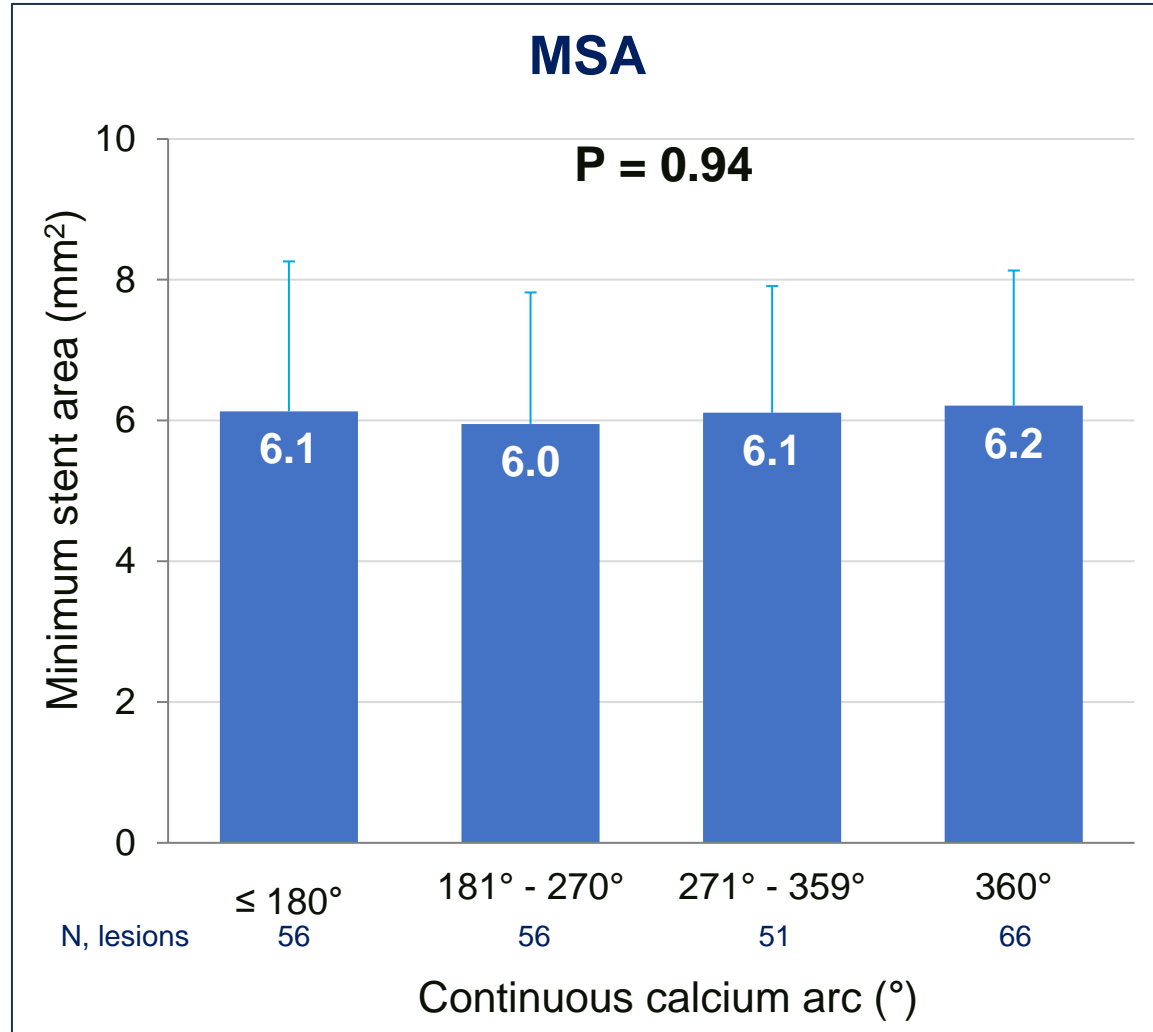
# Clinical Impact of eccentric calcium treated with IVL



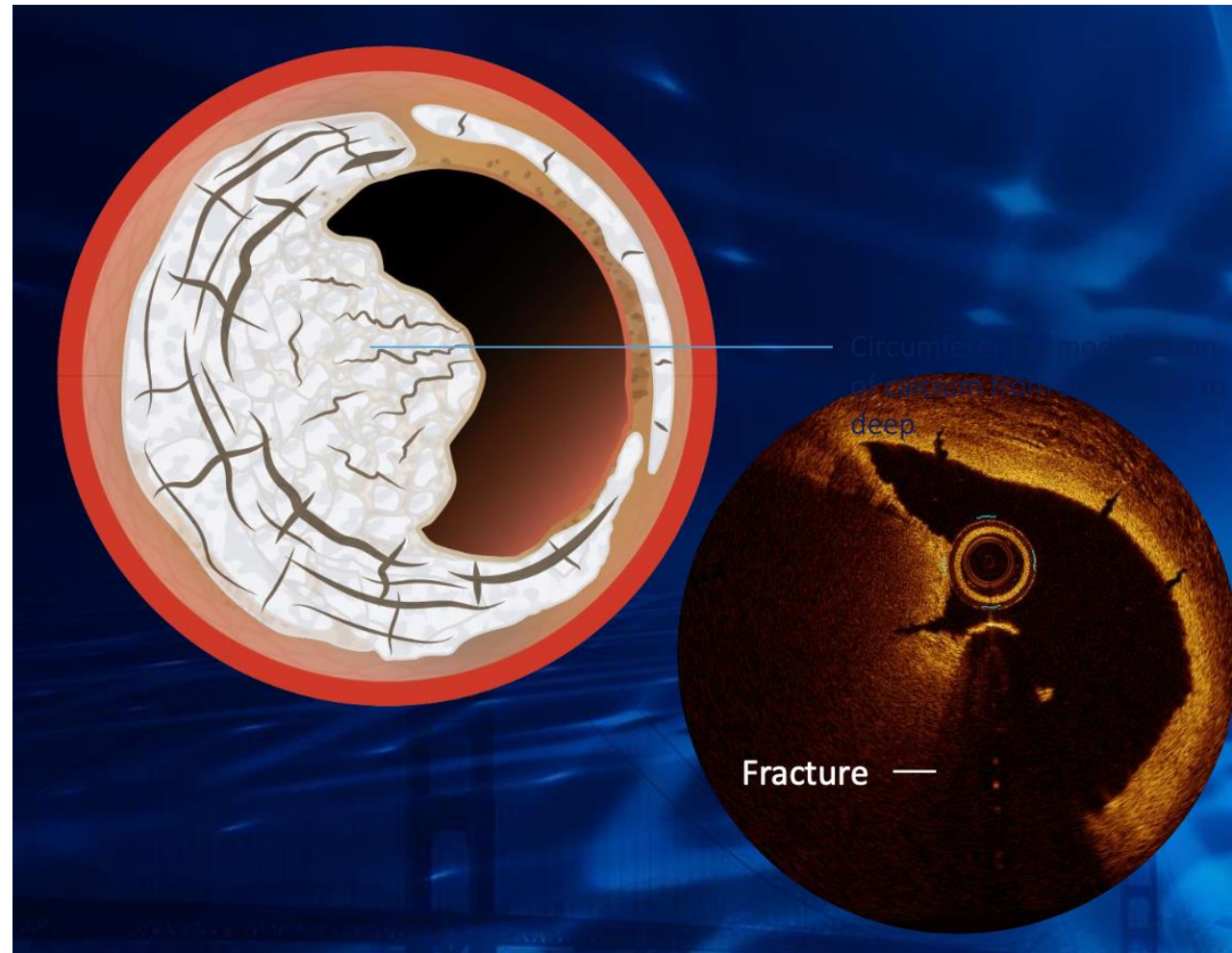
Ali Z, et al. Pooled data from DISRUPT CAD I-IV OCT sub-studies Circ Cardiovasc Interv. 2023



# Consistent Outcomes in Eccentric and Concentric Calcium



# Does IVL work with Nodular Calcium ?

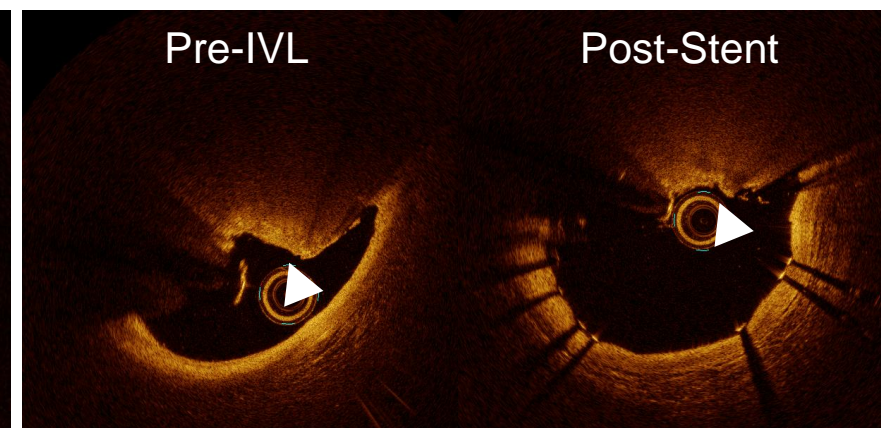
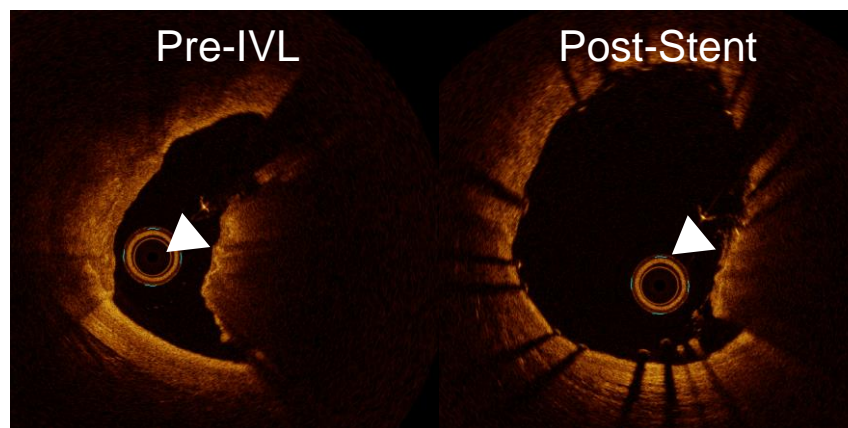
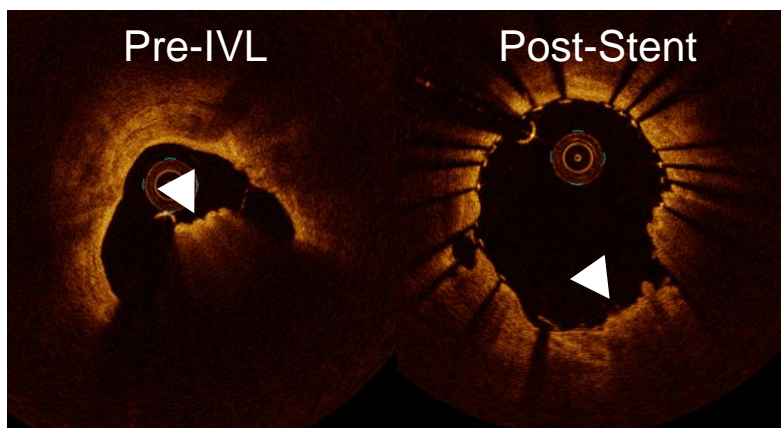


# Patterns of Stent Expansion in Calcific Nodules

Concentric expansion  
Deformed Eruptive Nodule  
**34%**

Concentric expansion  
Deformed Nodular Calcification  
**43%**

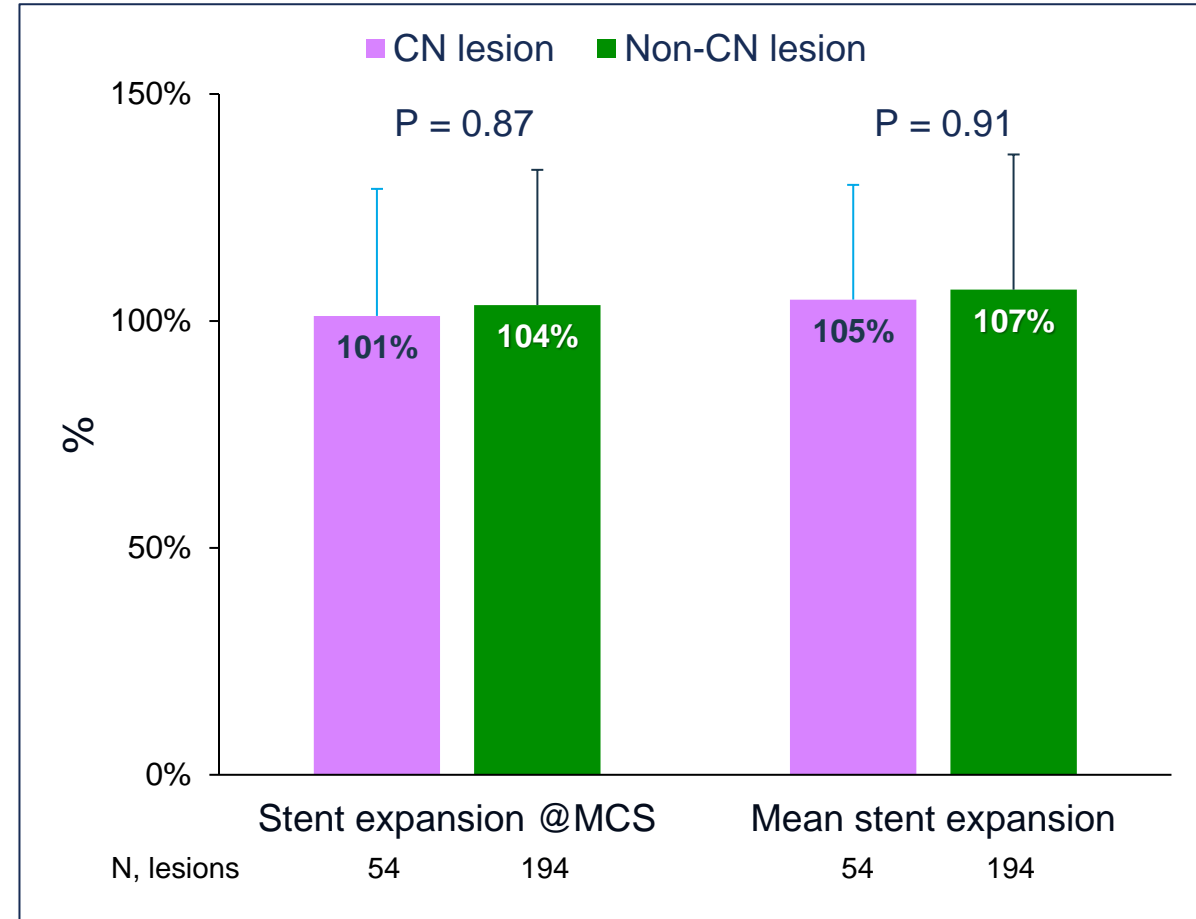
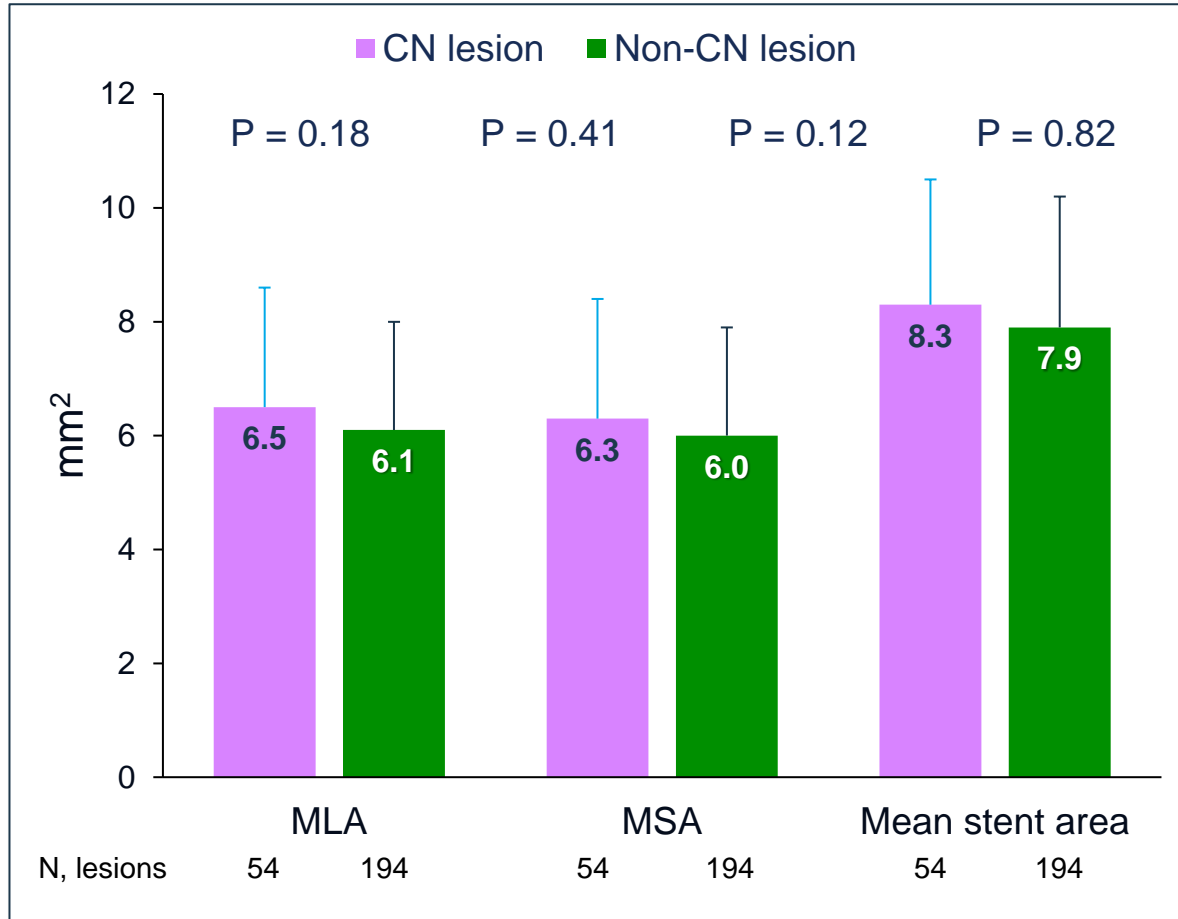
Eccentric expansion  
Non-deformed Nodular Calcification  
**23%**



Ali Z, et al. Pooled data from DISRUPT CAD I-IV OCT sub-studies Circ Cardiovasc Interv. 2023

# Post-stent Outcomes : Calcified Nodule

Consistent MSA and stent expansion in both CN and non-CN lesions



# Angiographic Complications

## Minimal Safety Complications Post-IVL & Post-Stent

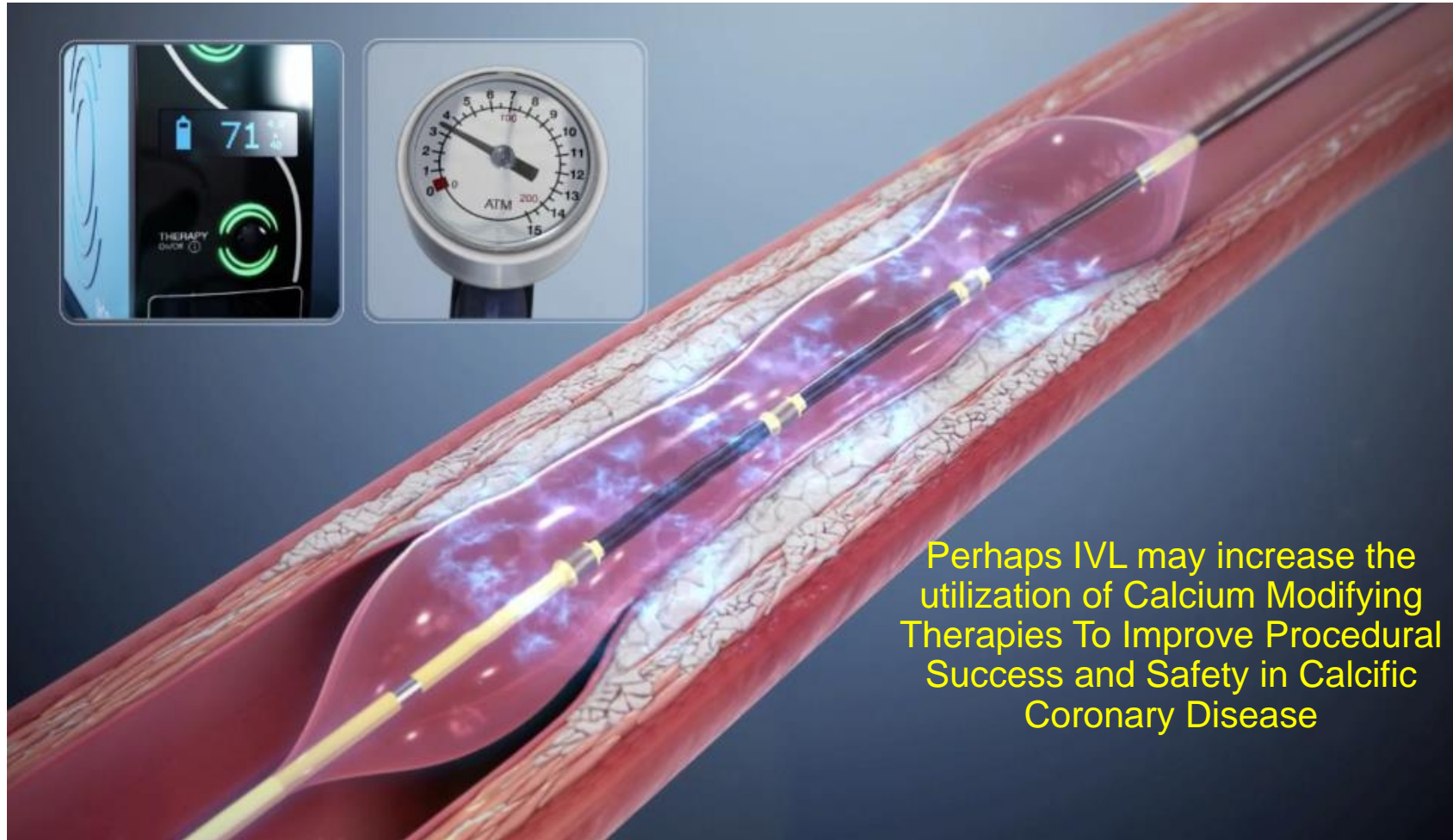
Core Lab Analysis	Immediately Post-IVL	Final
Any serious angiographic complication	2.6%	0.5%
Severe dissection (Type D-F)	2.1%	0.3%
Perforation	0.0%	0.3%
Abrupt closure	0.0%	0.3%
Slow flow	0.6%	0.0%
No-reflow	0.0%	0.0%

Hill J., Kereiakes D., et al. IVL for Severely Calcified Coronary Artery Disease.

J Am Coll Cardiol. 2020 Dec, 76 (22) 2635–2646. <https://www.jacc.org/doi/full/10.1016/j.jacc.2020.09.603>



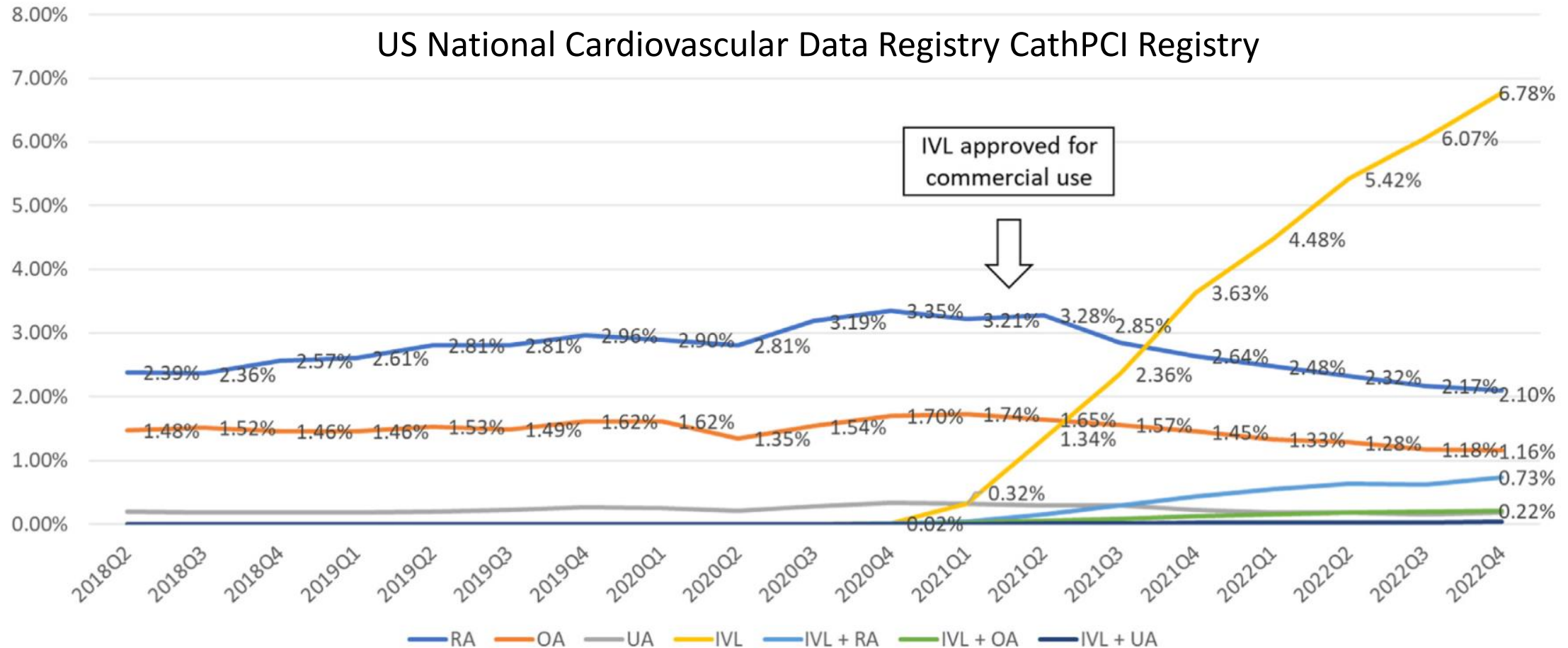
# Low Atherectomy Use Even in Severely Calcified Lesions: MACE Study



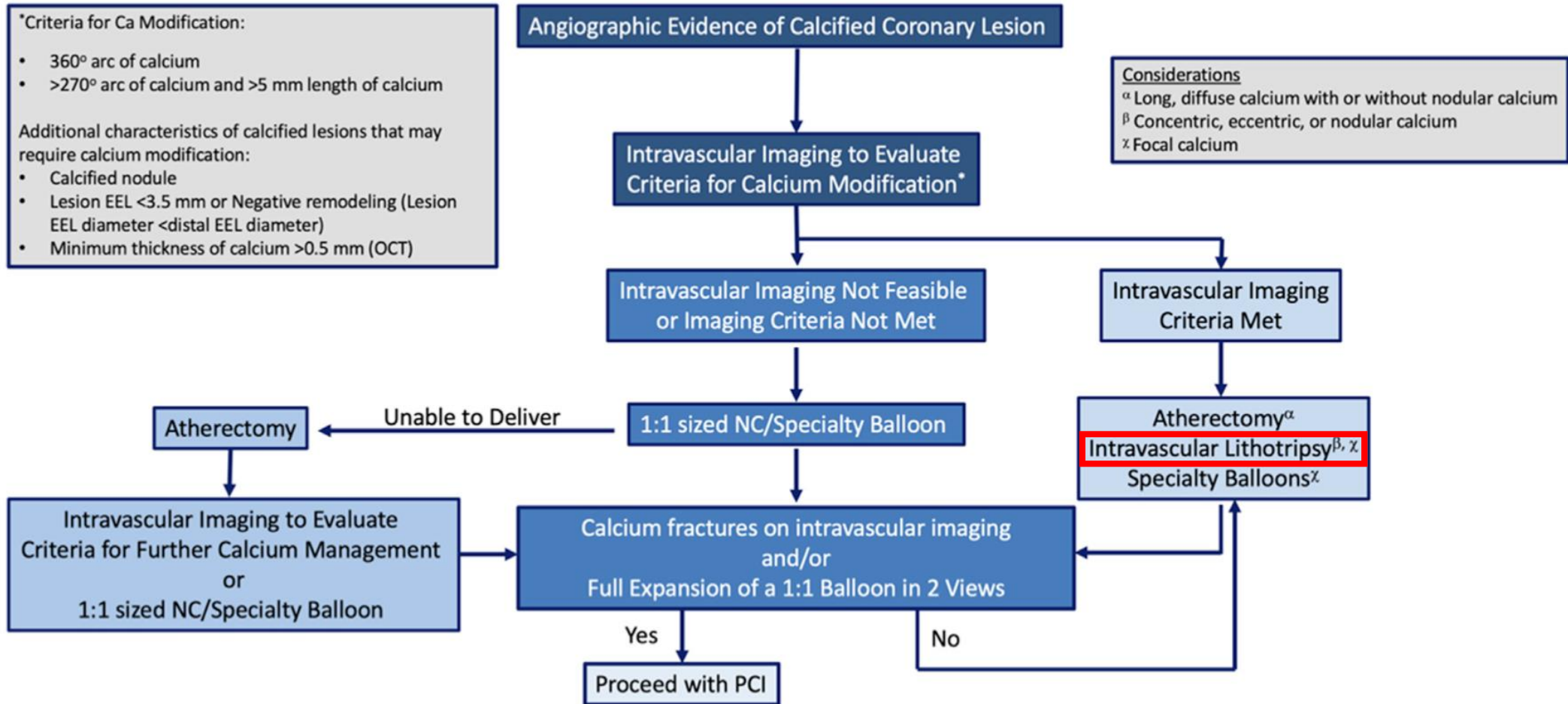
Perhaps IVL may increase the utilization of Calcium Modifying Therapies To Improve Procedural Success and Safety in Calcific Coronary Disease

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

# Trends in use of type of atherectomy and IVL among patients undergoing PCI.



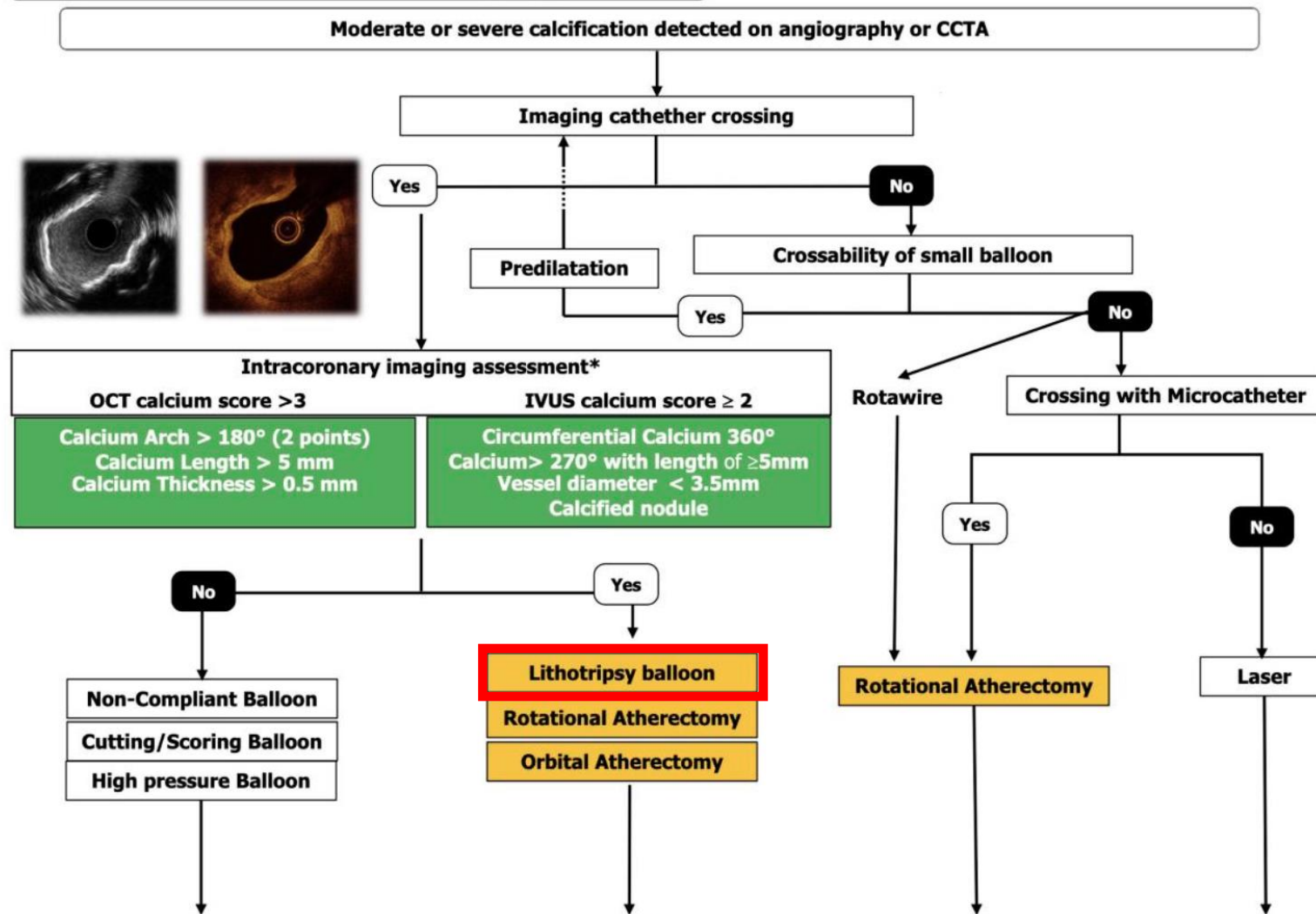
# 2023 SCAI Expert Consensus Statement on the Management of Calcified Coronary Lesions





# EAPCI Clinical Consensus 2023

## Algorithm with intravascular imaging guidance



# Take Home Messages :

- Calcium poses PCI technical challenges and impacts acute procedural success, safety and longer term outcomes
- Intravascular imaging is extremely important in defining the calcific pathology; aids selection of devices and to optimize outcomes
- Intravascular Lithotripsy (IVL) is an effective tool to modify coronary calcium
- Shown to be effective across the whole spectrum of coronary calcium severity and morphologies (regardless of depth, arc, thickness, length). Efficacy extends to calcified nodules and eccentric calcium
- IVL Technology is effective, safe , provides a predictable outcome and easy to learn

**Thank You Very Much !**

**감사합니다 !**