Heavily Calcified Coronary Lesions: *How Do We Treat Well?*

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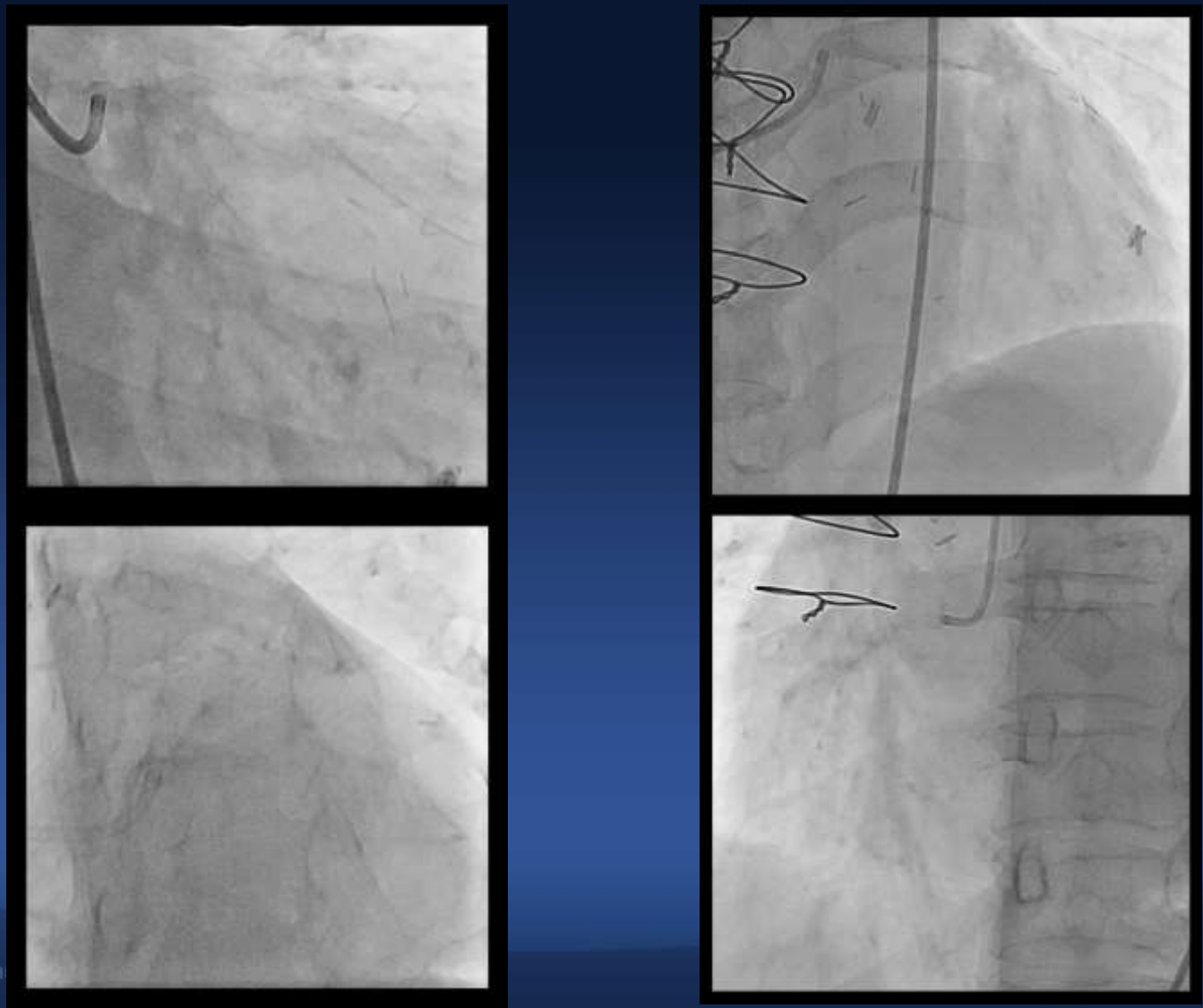
Disclosure Statement of Financial Interest

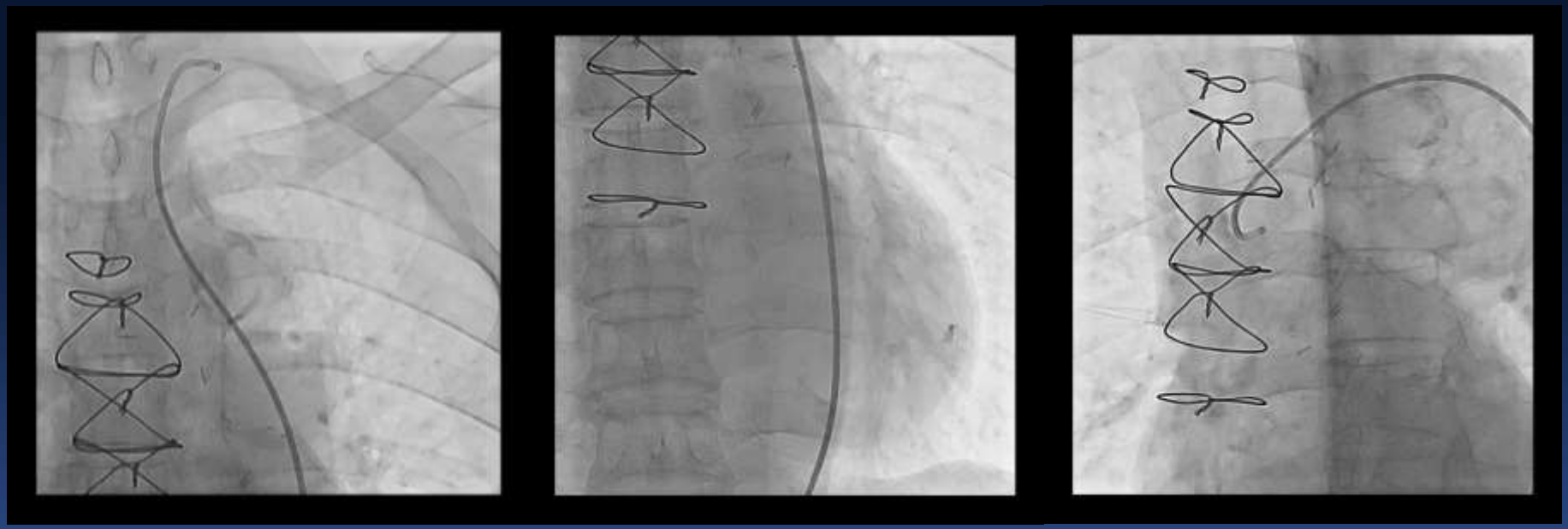
I, (Duk-Woo Park) DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

An Illustrative Case:

68 years, female with PMH of DM,
s/p CABG 2 month ago, recurrent chest pain



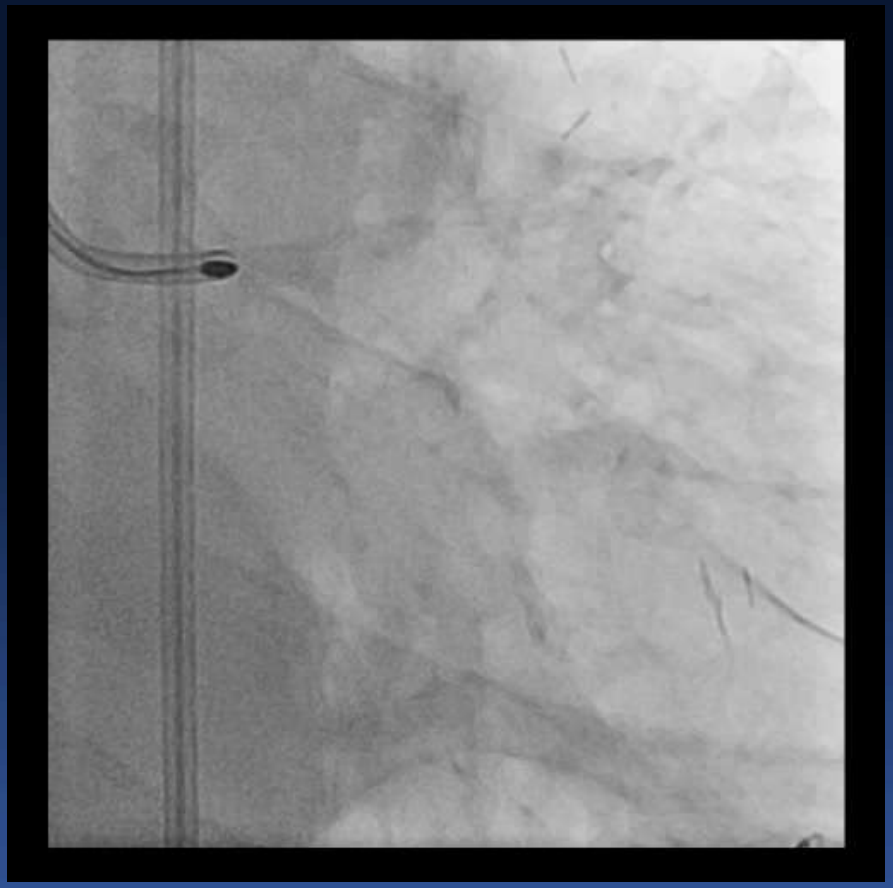
Failed CABG Grafts



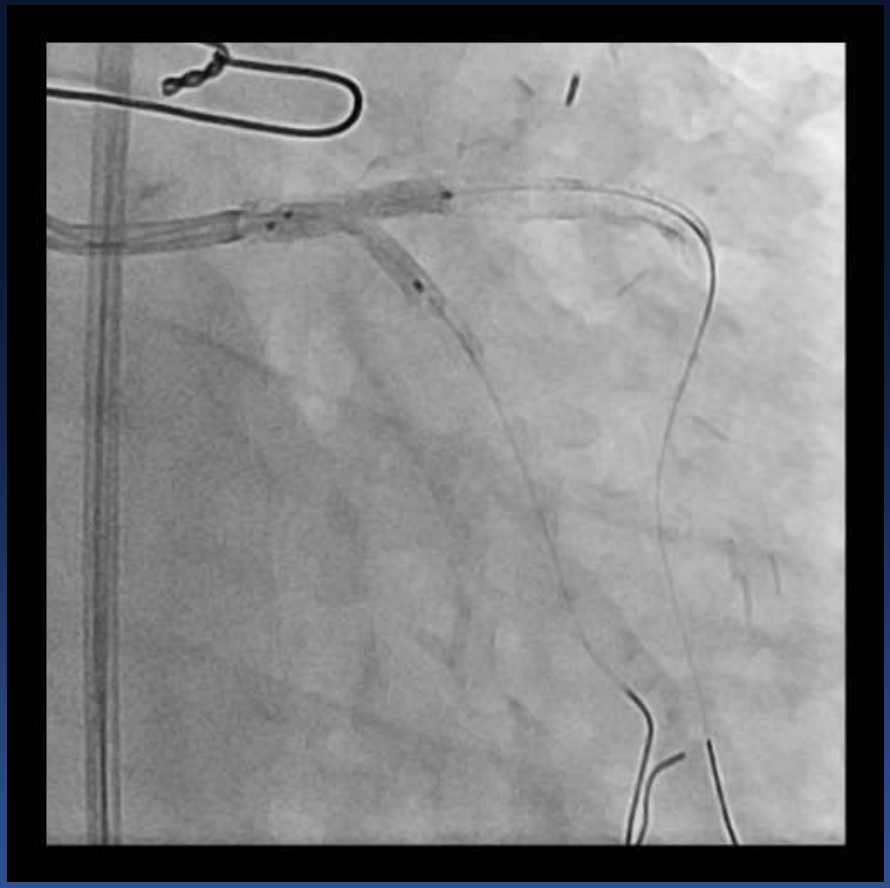
LIMA-LAD

SVG-OM

PCI

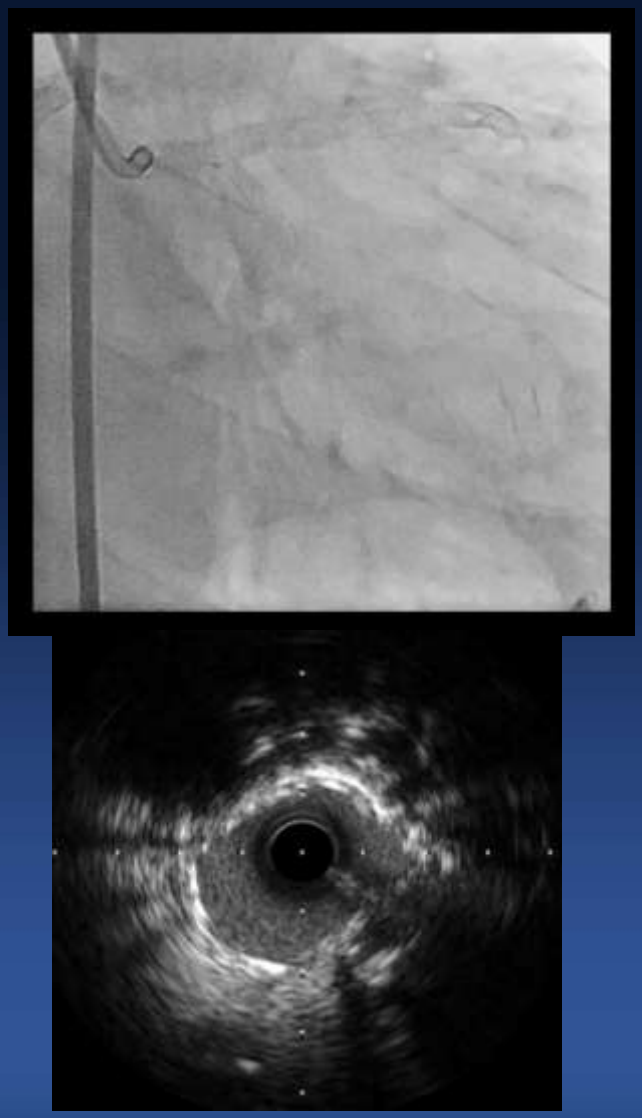


LCX Rotablator 1.5 mm burr
➔ BP drop, urgent situation

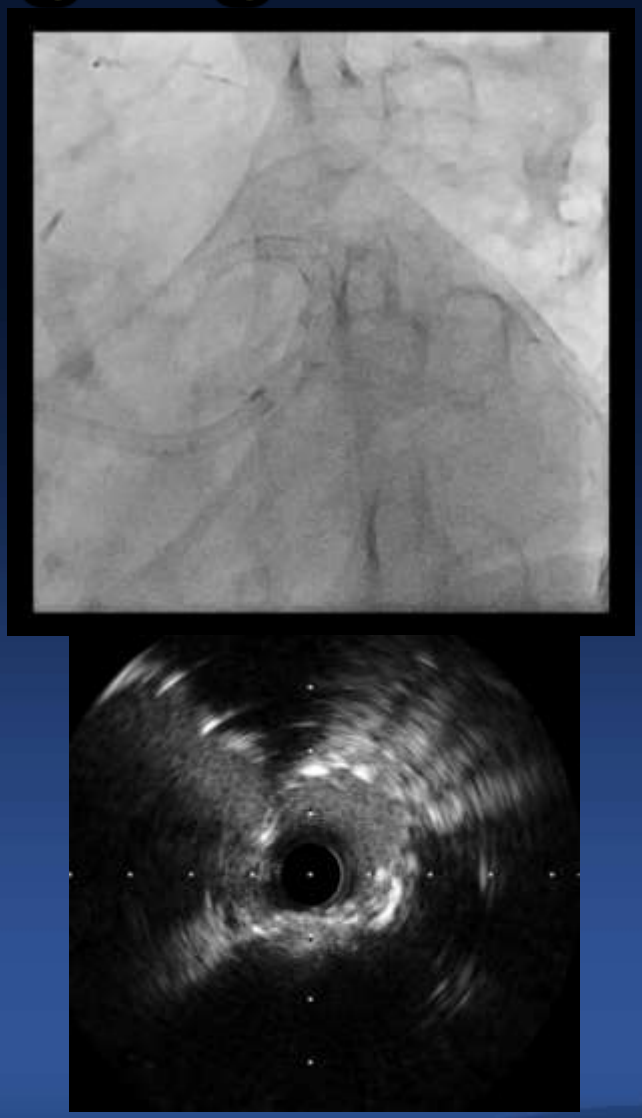


Crush and
Kissing balloon

Post-PCI Angiogram

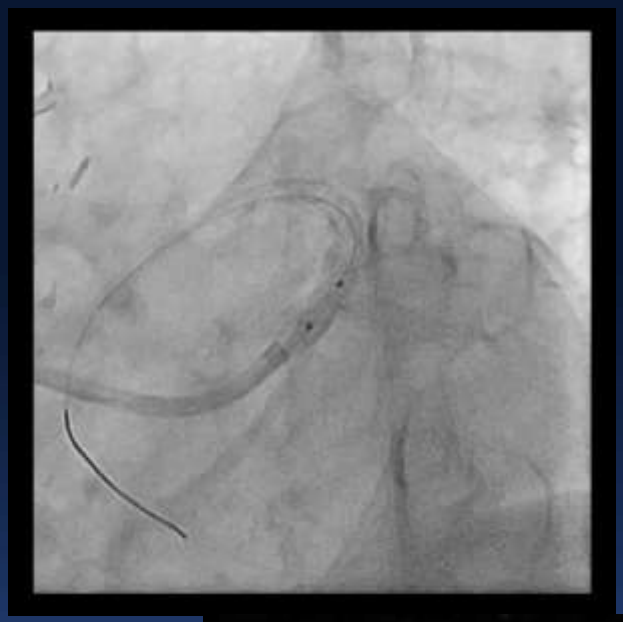


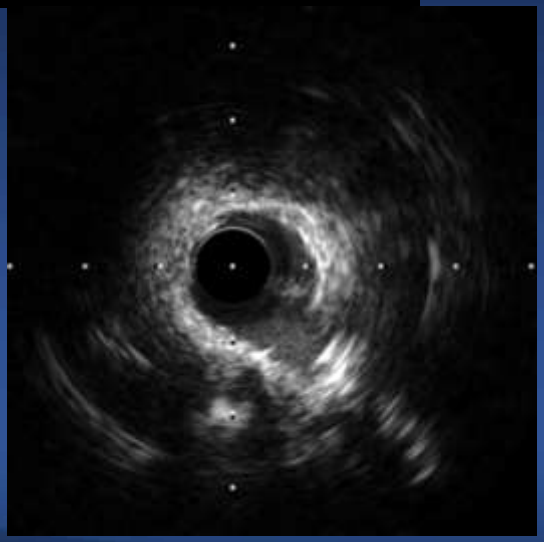
LAD OS MLA 7.0 ㎟

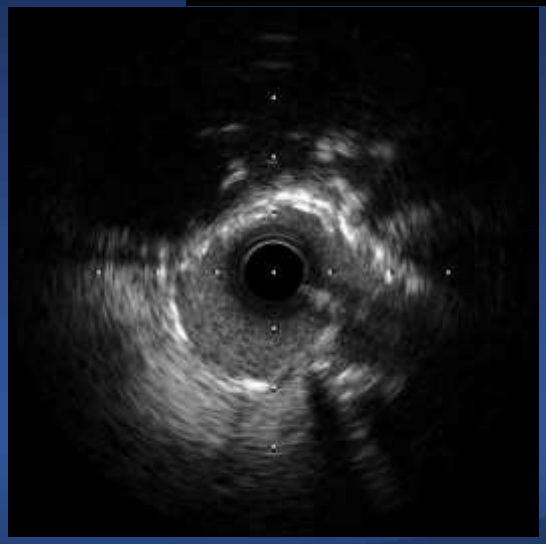


LCX OS MLA 4.3 ㎟

POT and Final







POC MLA 3.2 ㎟

How Do We Treat Well?

- LCX rotablation.
- Vital status compromised.
- No enough time to do additional rotablation for LAD and left main.
- Unable to expand POC area of LM stent with high-pressure NC balloon.
- **How to do ??**

Final & Signature Live Case in 2nd Complex PCI Meeting

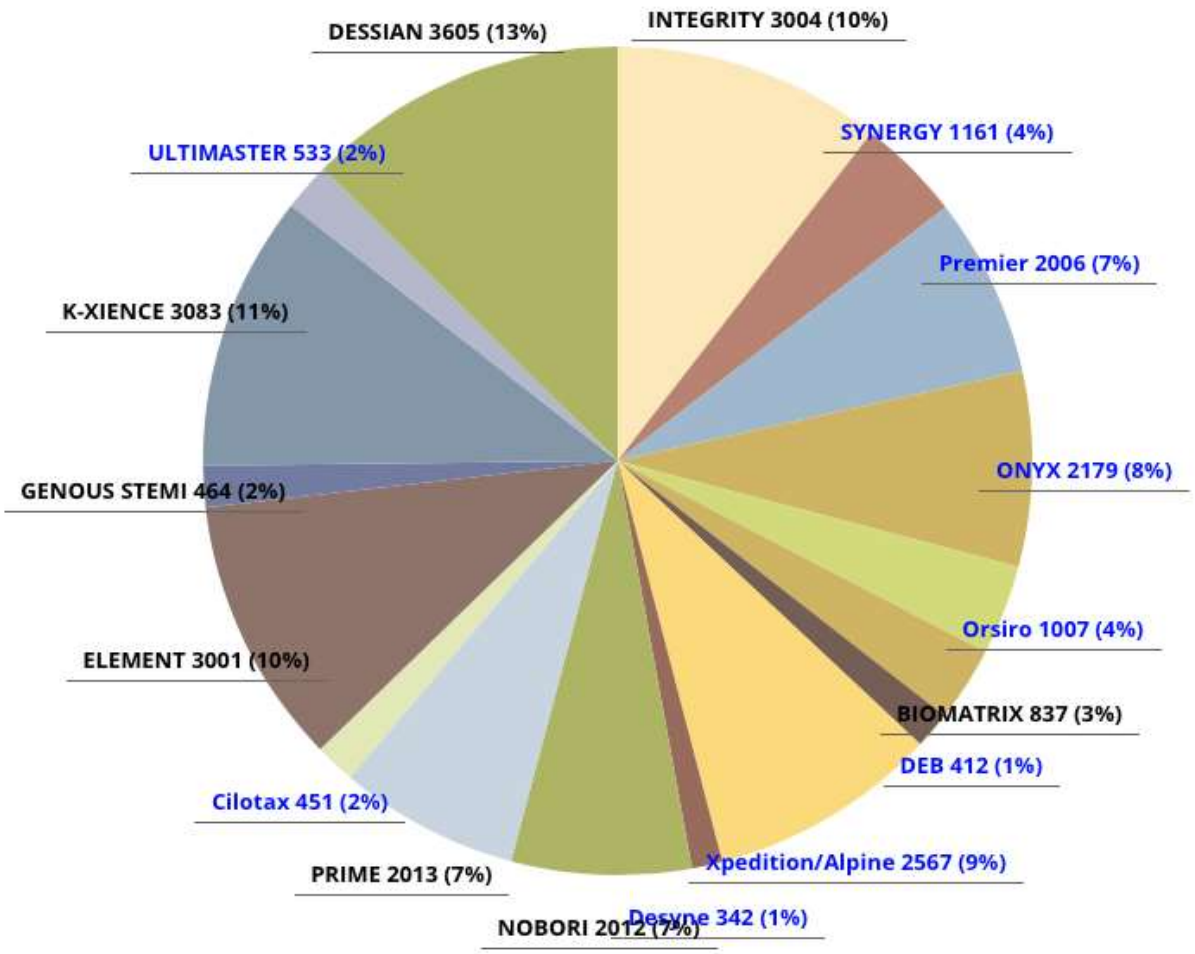
➔ Stent Ablation

How Much Prevalent Is Such Coronary Calcium in Real-World PCI with Contemporary DES?

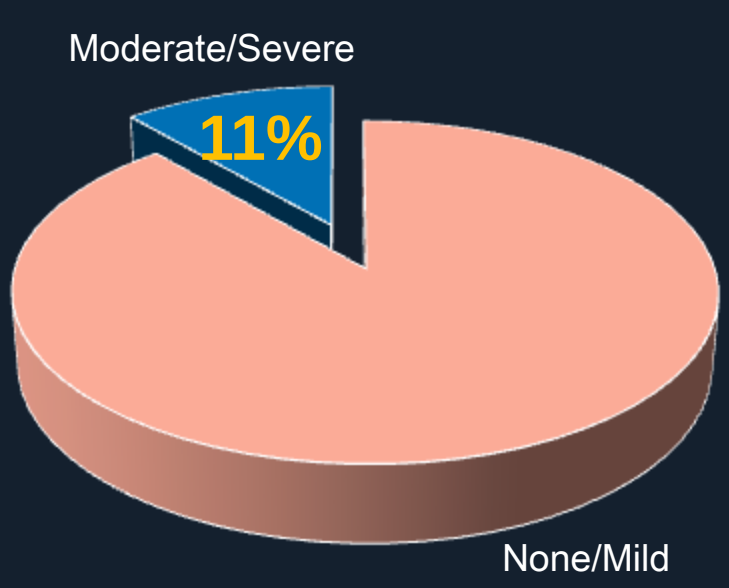
Insights from the IRIS-DES registry

IRIS-DES,Total 28,677

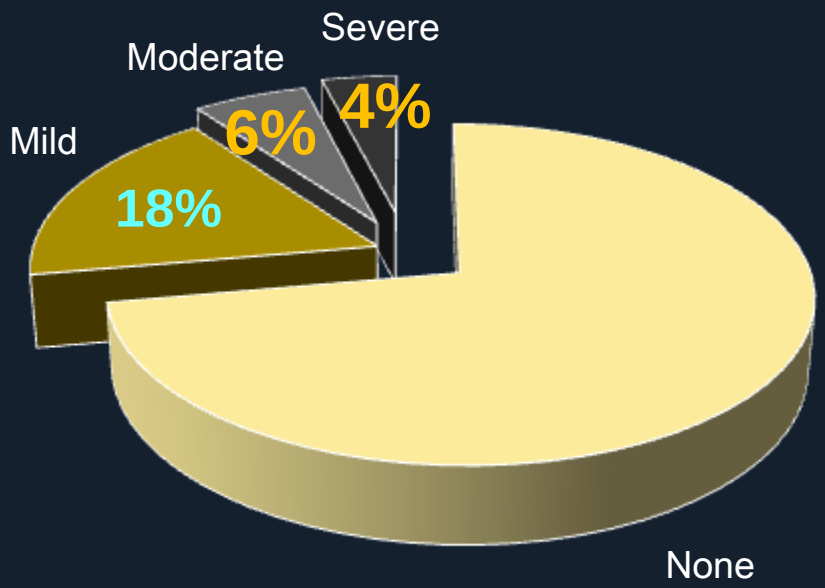
연구별 등록현황



Prevalence of calcium according to severity



Number of Patient

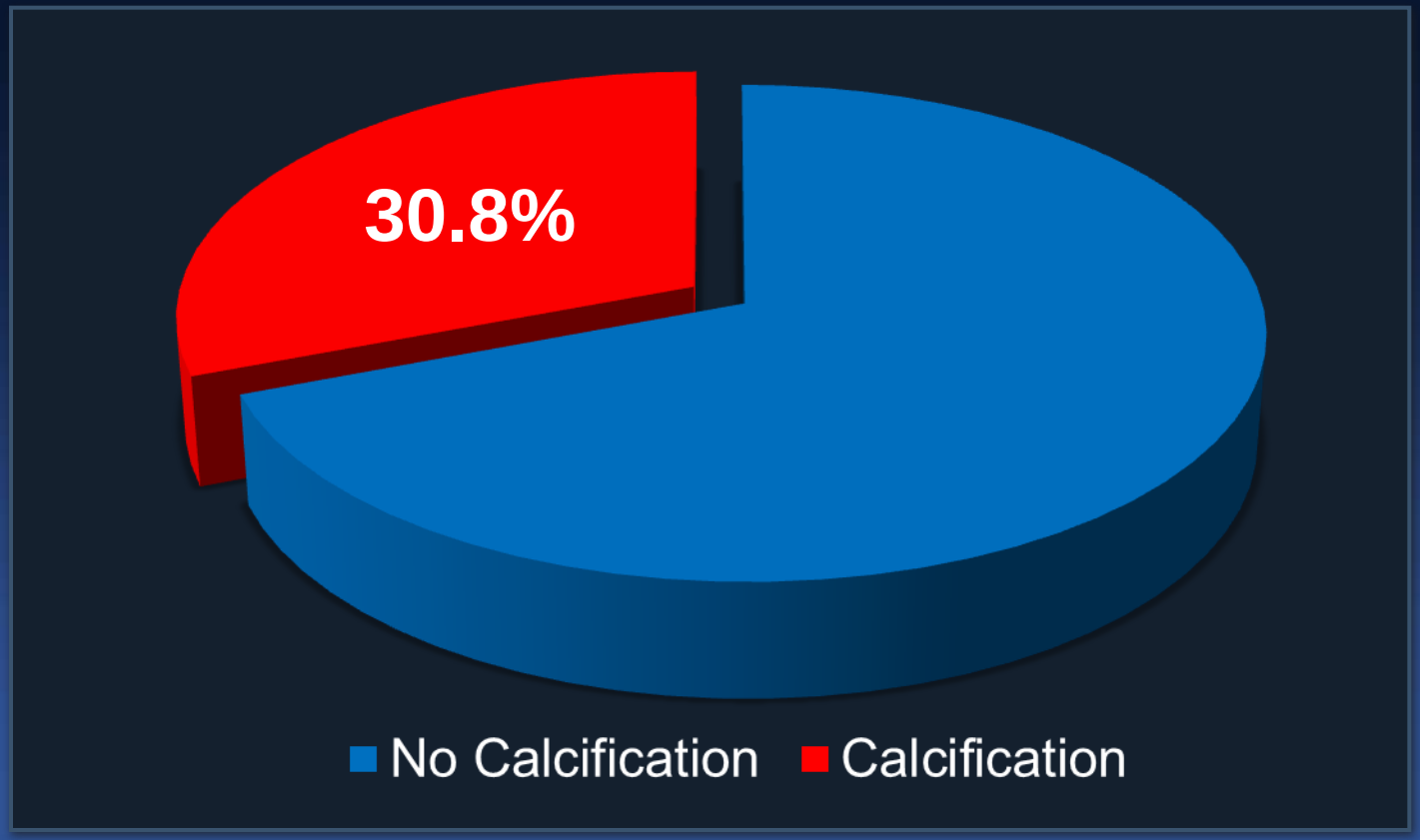


Number of Lesion

From IRIS-DES Registry

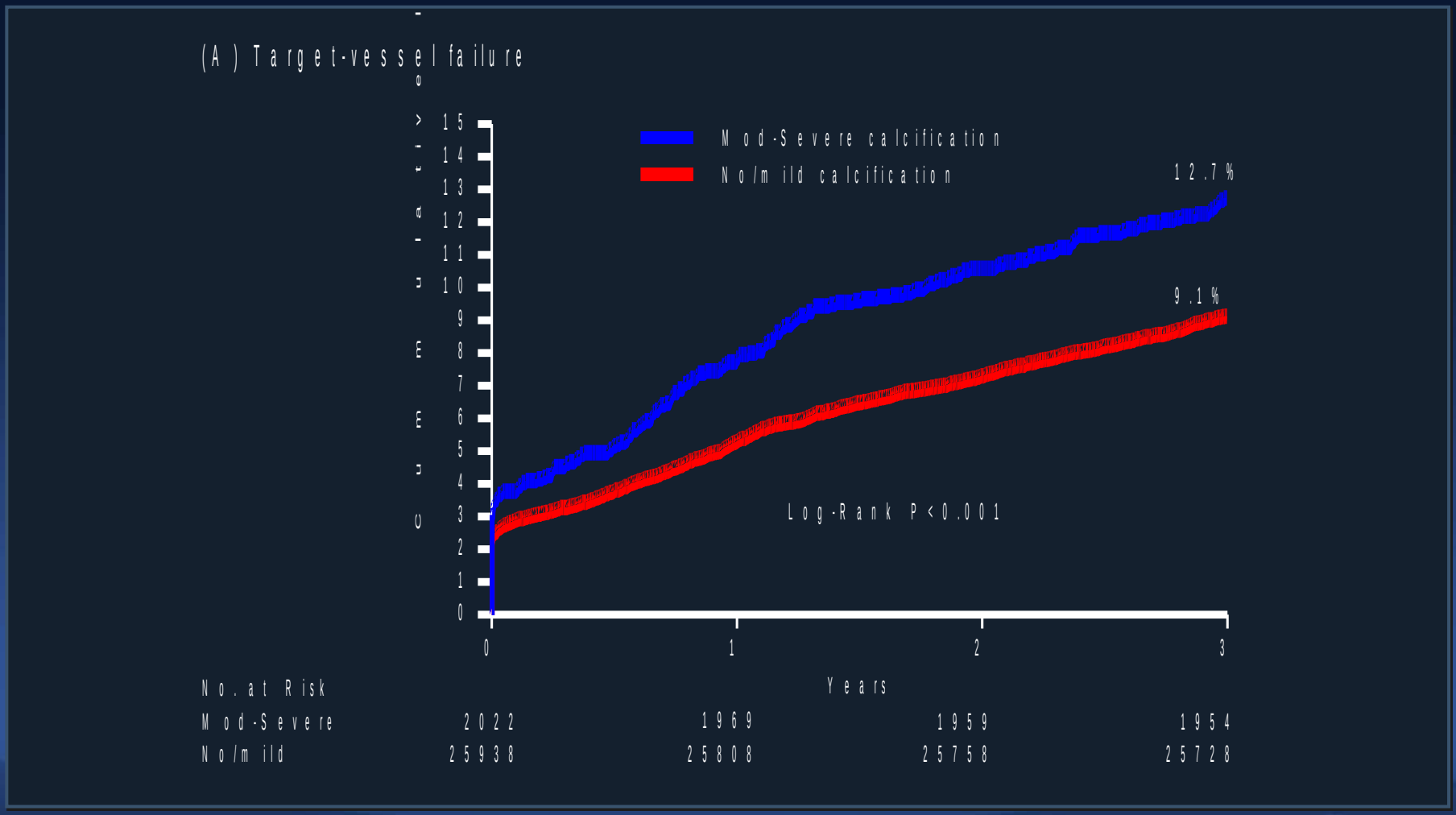
ADAPT-DES (11 center all-comers registry):
Site-reported Mod/Sev Calcification

N = 8,582 pts

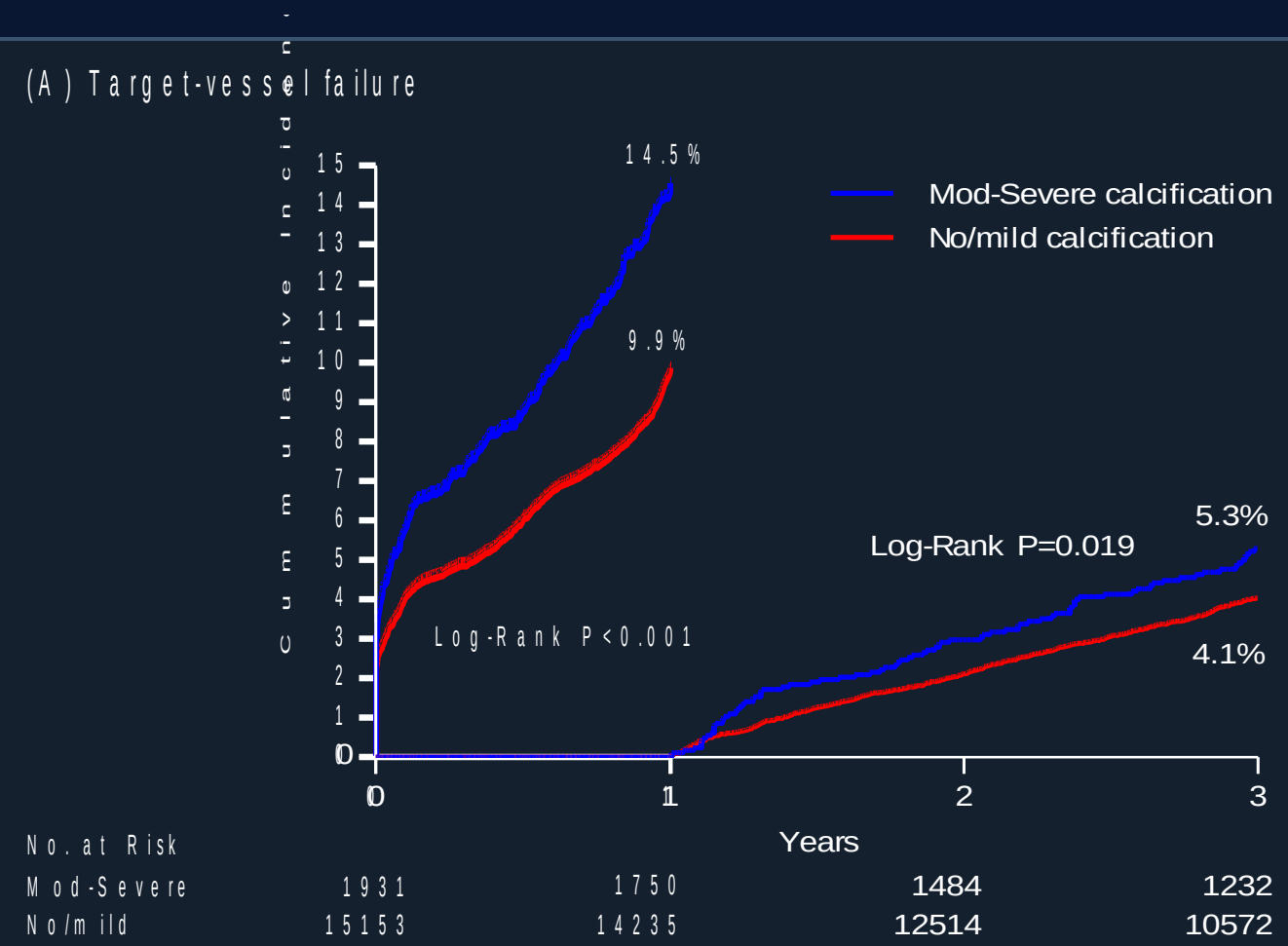


Généreux et al, Int J Cardiol 2017

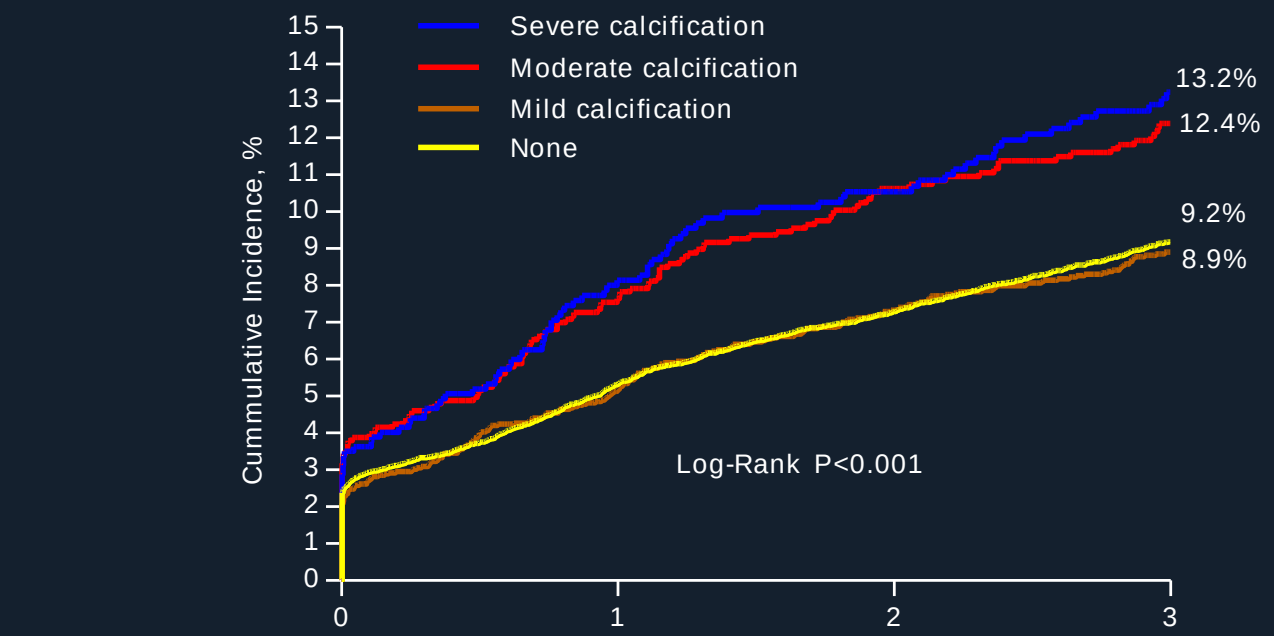
IRIS-DES, 3-year
Target-vessel failure (cardiac death, target vessel MI, ischemic driven TVR)



IRIS-DES, KM landmark curve 0,1,3-year
Target-vessel failure

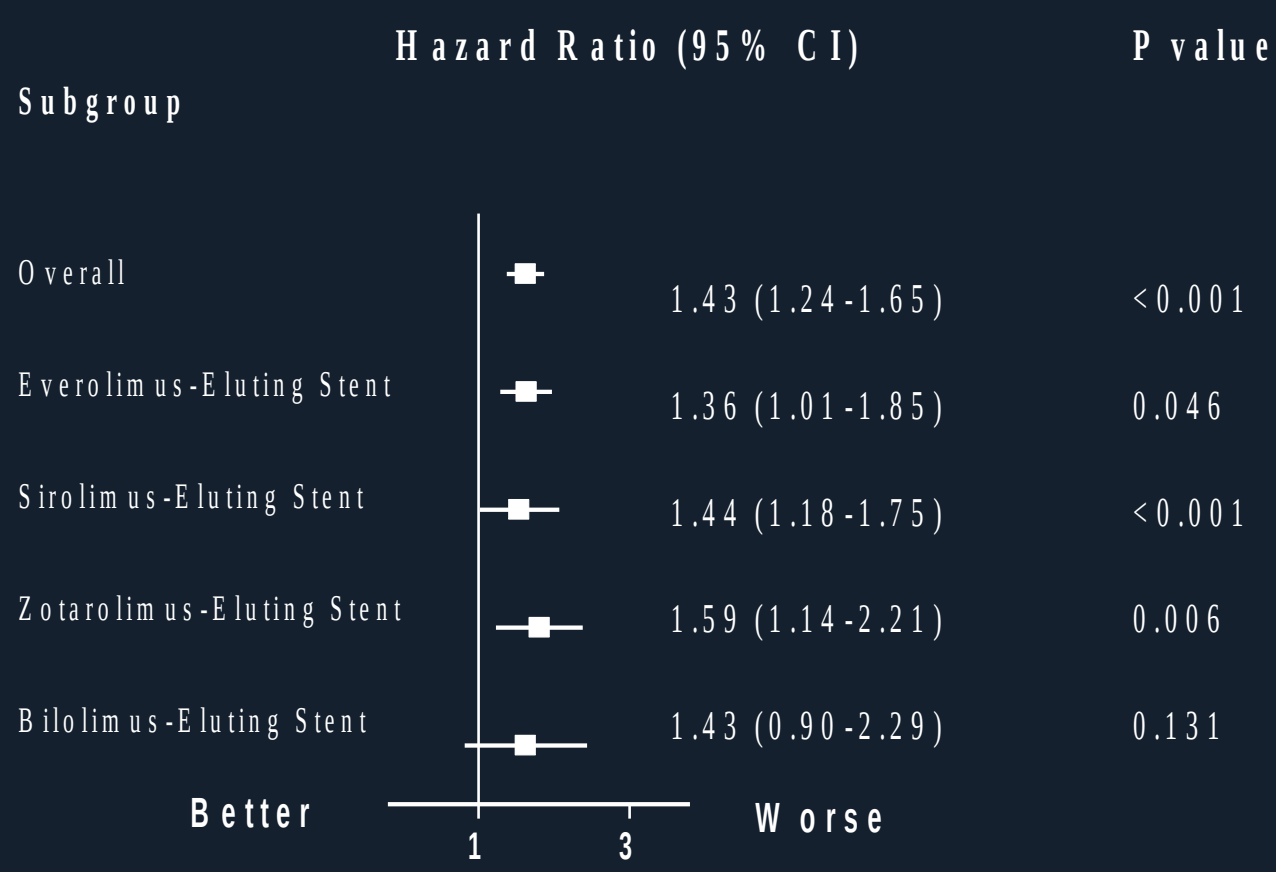


IRIS-DES, 3-year
Target-vessel failure



No. at Risk				
Severe	798	664	604	497
Moderate	1133	986	885	735
Mild	3016	2733	2502	2197
None	12137	10925	10024	8375

Hazard ratio for TVF
Subgroup Analysis by Stent-Types

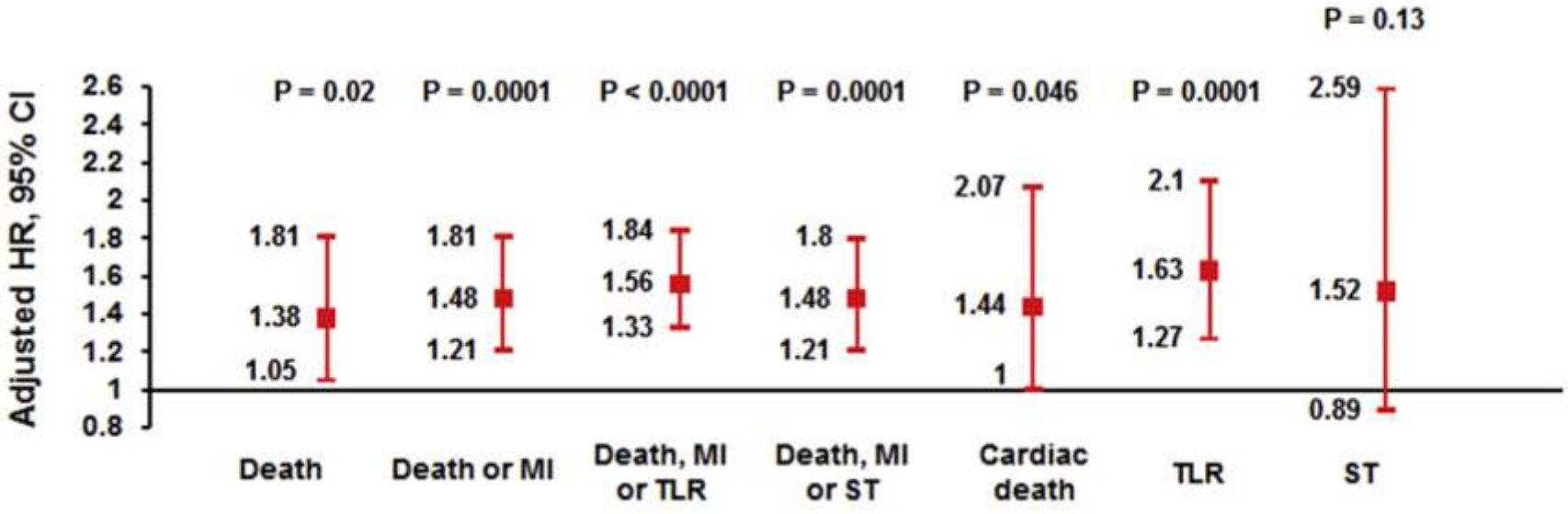


Women with coronary artery calcifications (CAC) requiring PCI

Clinical Correlates

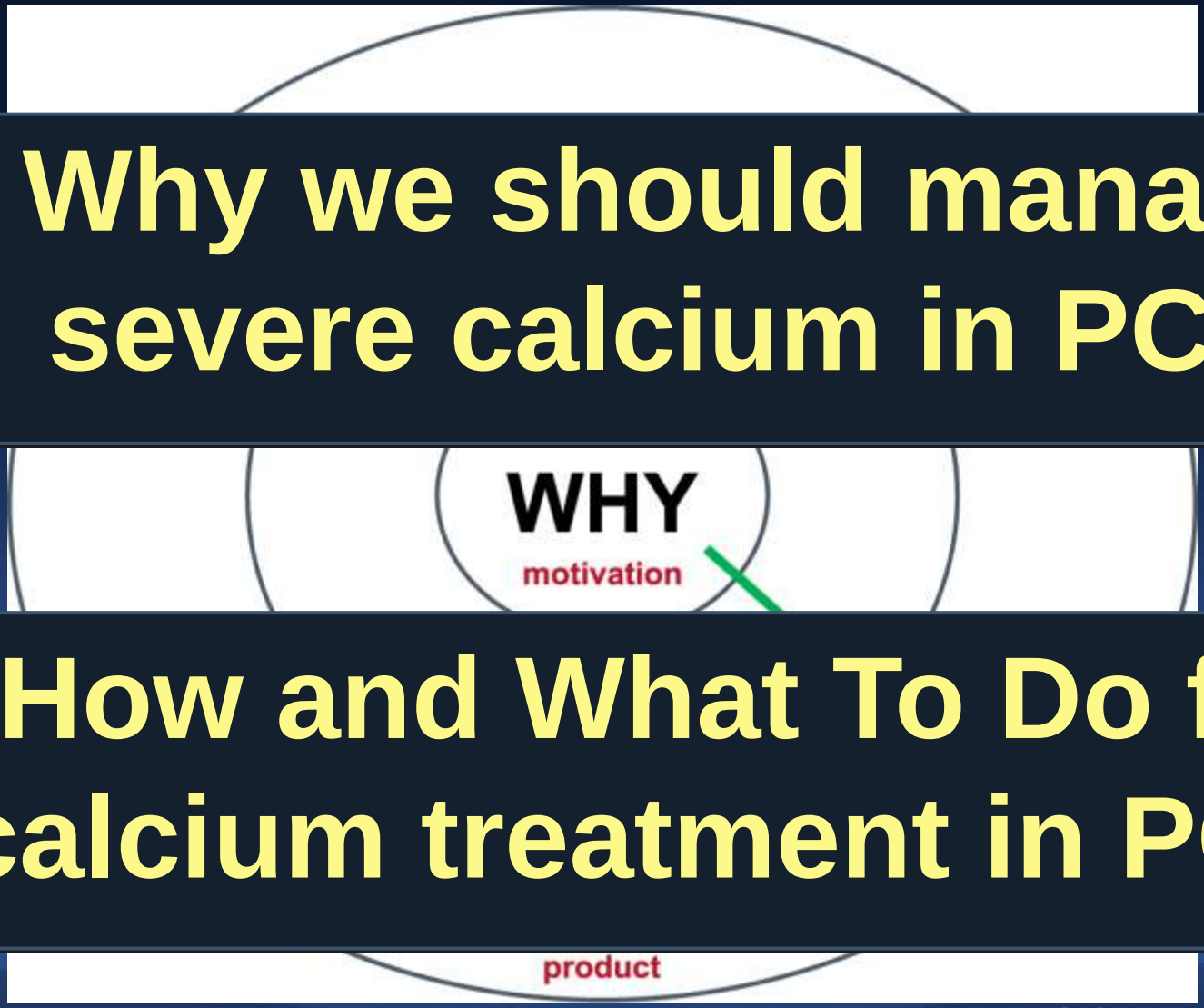
- Older age
- Arterial hypertension
- Smoking
- Previous CABG
- Stable clinical presentation
- Lower left ventricular function
- Impaired renal function

3-year outcomes for moderate or severe CAC (N = 1,622) versus mild or none CAC (N = 4,749)



Giustino, G et al. J Am Coll Cardiol Intv 2016;9:1890-901

The Golden Circle…



Why we should manage severe calcium in PCI?

How and What To Do for calcium treatment in PCI?

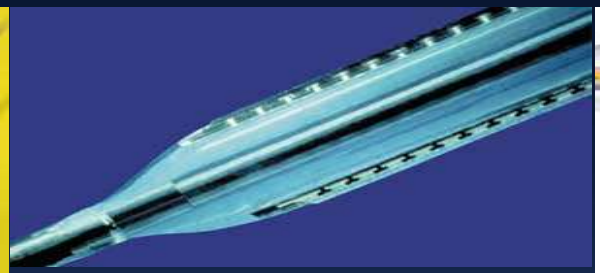
Why Calcium Lesion Preparation?

- ***Facilitates procedural success***
  - lumen expansion
  - enables lesion access for balloons and especially stents
- ***Plaque modification***
  - changing lesion compliance
  - minimizes vessel “trauma” (severe dissections)
  - creates a larger MLD

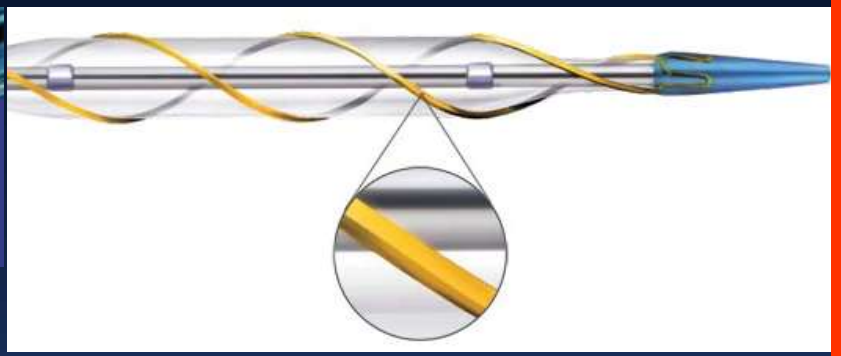
How and What: 6 Options

NC balloons

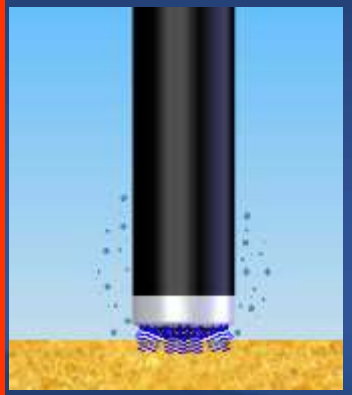
Cutting balloon



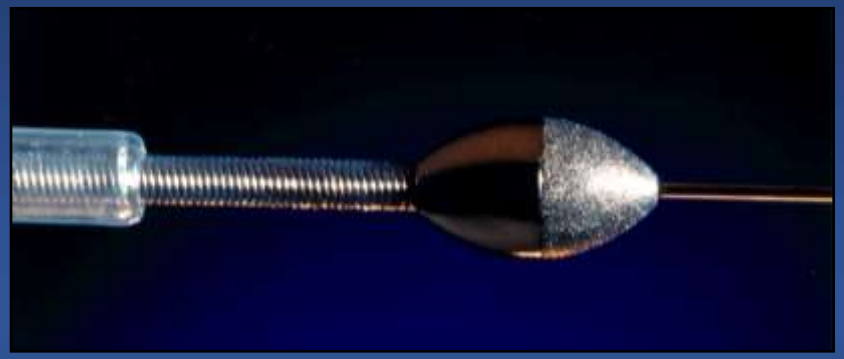
Angiosculpt



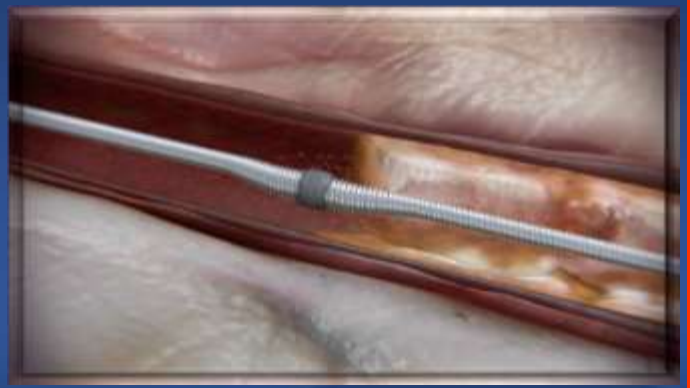
Laser



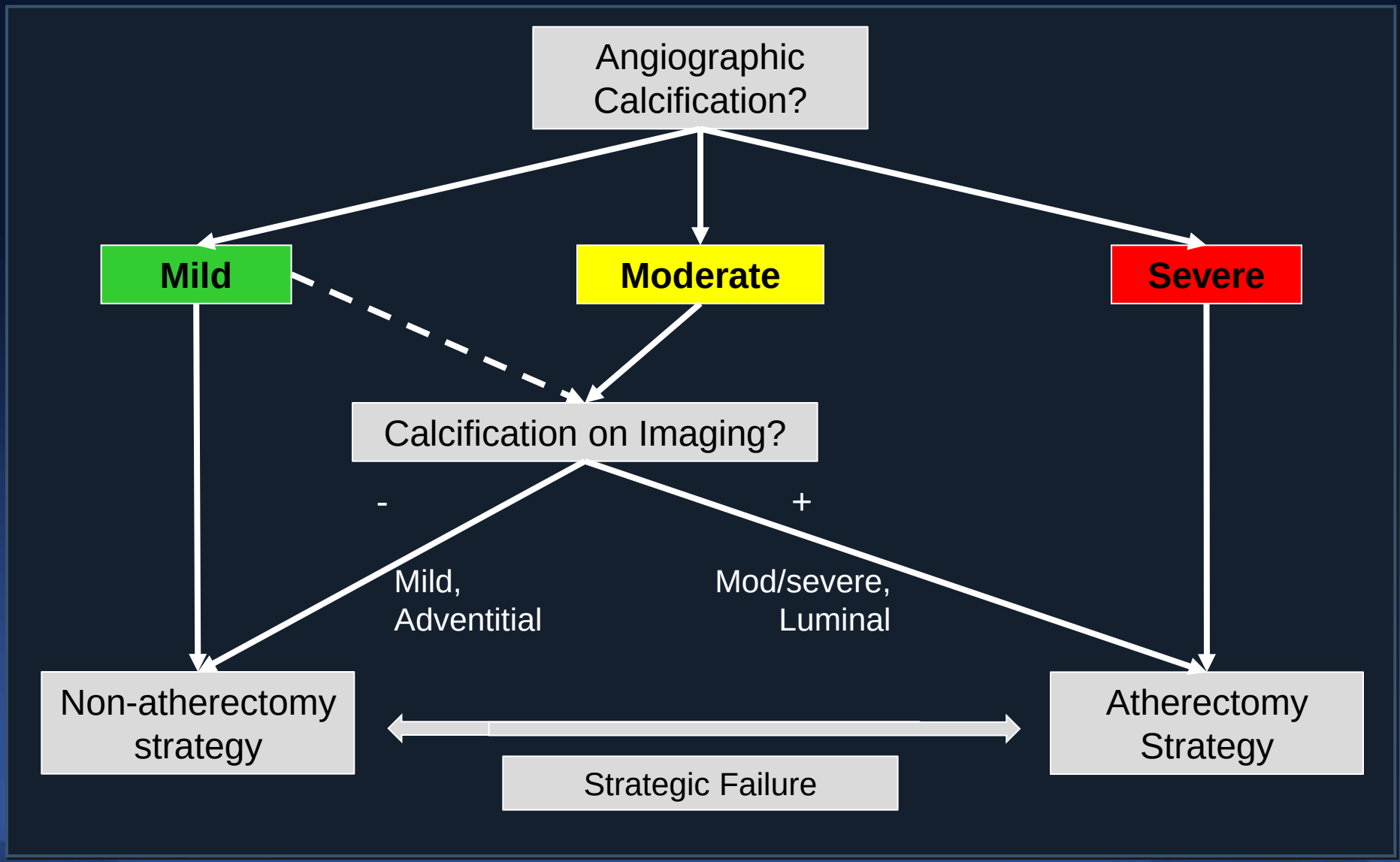
Rotational atherectomy



Orbital atherectomy



Strategy for Approaching Calcified Lesions



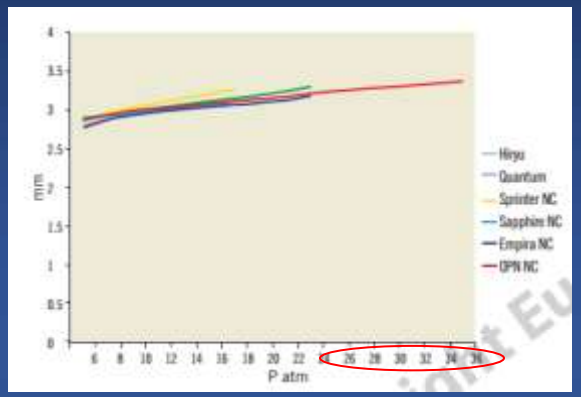
Adapted from Tomey et al, JACC CV Intv 2014

Non Compliant High Pressure Balloon

- Twin layer balloon construction
- Long tapered tip design for a better crossability
- Super high pressure PTCA balloon (RPB 35atm)
- Linear compliance curve up to over 50atm
- Better crossing profile (0.028'' 2.0mm) than scoring and cutting balloons
- Minimum guiding catheter: 5F
- Sizes available from 1.5 to 4.5mm diameter

PRESSURE (atm)	OPN NC 2.0	OPN NC 2.5	OPN NC 3.0	OPN NC 3.5	OPN NC 4.0
10	2.0	2.5	3.0	3.5	4.0
20	2.1	2.6	3.14	3.67	4.19
30	2.18	2.7	3.29	3.85	4.37
35	2.2	2.77	3.36	3.91	4.41

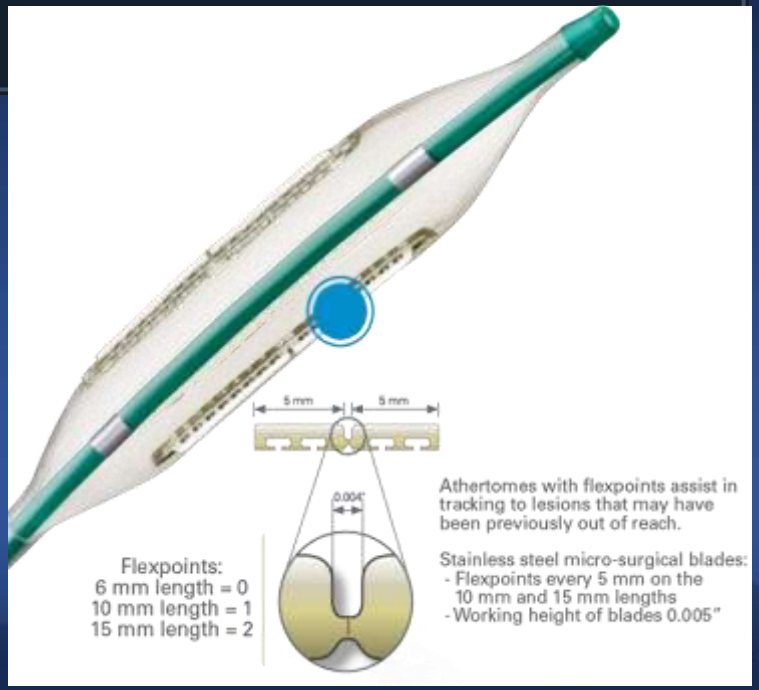
Comparison among different NC balloons' compliance 3.0 mm diameter



Cutting Balloon

- Flexotome has three or four microblades or atherotomes
- Atherotomes are mounted longitudinally on the surface of NC balloon
- During dilation, the device creates endovascular radial incisions through the fibrocalcific tissue → allowing further expansion with conventional balloons.
- The atherotomes anchor into the intima→ preventing balloon slippage,
- Sizes available up to 4.0 mm diameter
- Lenght 6,10 ,15 mm

Flexotome Cutting Balloon
Boston Scientific



Scoring Balloon: Angiosculpt

- Semicompliant balloon with nitinol spiral cage.
- Three rectangular scoring edges lock the device in place
- Focal concentrations of dilating force and thereby assisting in the luminal expansion of coronary lesions.
- 15–25 times the force of conventional balloons
- Post scoring, low dissection rate: 13.6 %
- Sizes available: from 2.0 mm to 3.5 mm

AngioSculpt RX

Compliance Chart		Balloon diameter x length (mm)			
		ø 2.0 x 10-20	ø 2.5 x 10-20	ø 3.0 x 10-20	ø 3.5 x 10-20
Nominal Pressure	atm*	8	8	8	8
(NP)	ø (mm)	2.01	2.49	3.01	3.51
Rated Burst Pressure	atm*	20	20	18	16
(RBP)	ø (mm)	2.37	2.95	3.50	3.86

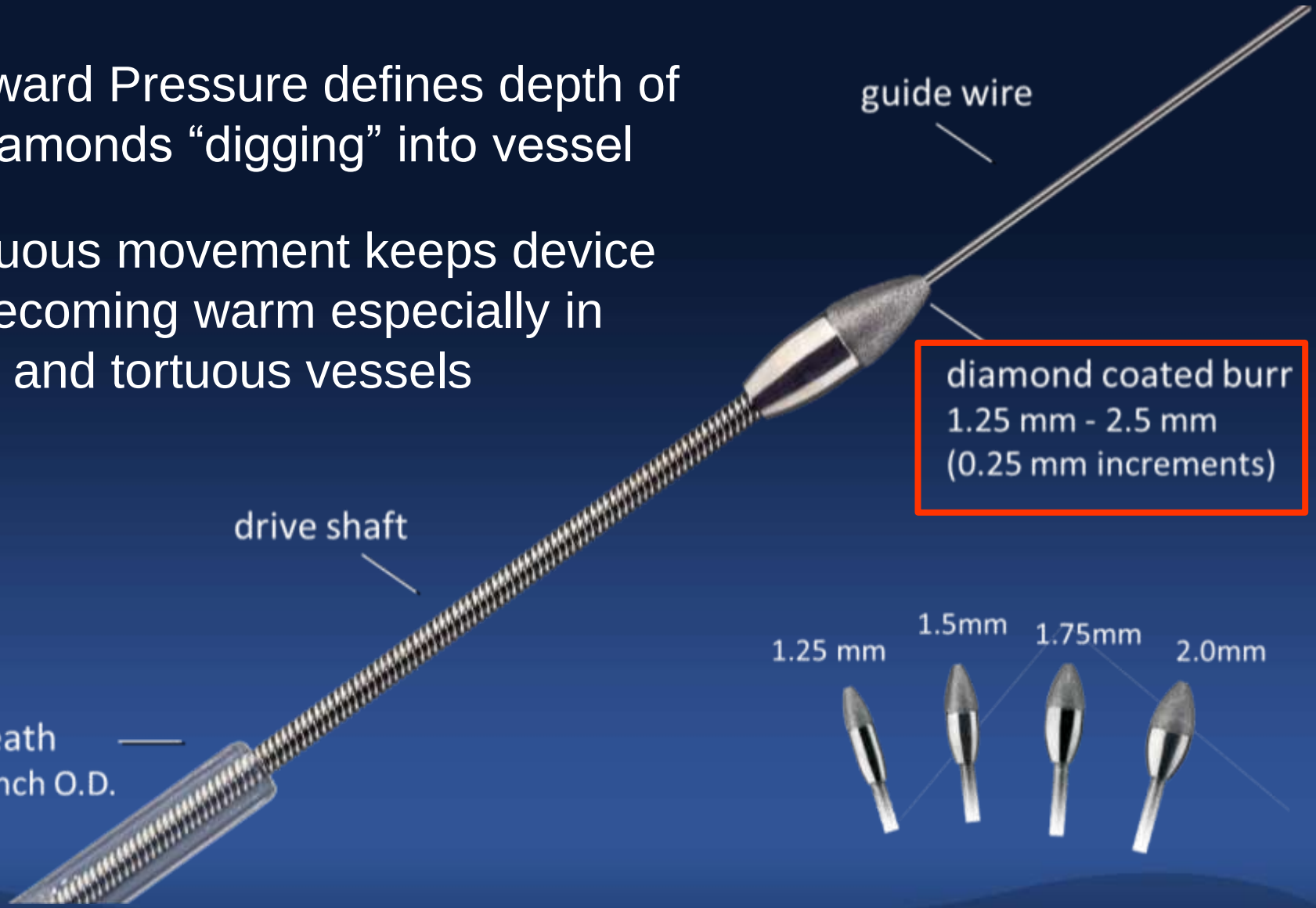
Rectangular scoring edges

Ashida K, Hayase T et al J INVASIVE CARDIOL 2013;25(10):555-564

Rotablator

Forward Pressure defines depth of diamonds “digging” into vessel

Continuous movement keeps device from becoming warm especially in angled and tortuous vessels



Rotablator is a PROVEN choice for Coronary Atherectomy

20+ years of proven clinical safety and efficacy

900+k procedures performed worldwide*

600+ certified operators in the US

1.25 – 2.50 mm Better lumen gain than orbital atherectomy

↓ low rate of complications in a real-world patients

2.5 – 3X Less expensive than orbital atherectomy

***Based Boston Scientific sales estimate**

Next Generation Rotablator System

- Mounted IV pole
- Reduced set-up time
- On screen deceleration alert
- Vertical or horizontal display

- **Foot pedal elimination** (burr activation button on advancer knob)
- **Allows single-operator use**

Orbital Atherectomy

Mechanism of Action

Differential Sanding:

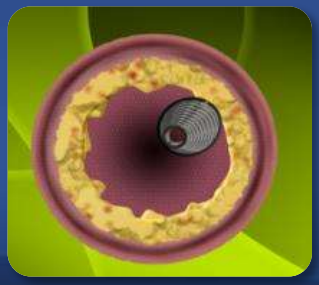
- 30 micron diamond coating
- Bi-directional sanding, eccentric mounted crown
- Healthy elastic tissue flexes away minimizing damage to the vessel

Centrifugal Force: 원심력

- 360° crown contact designed to create a smooth, concentric lumen
- Allows constant blood flow and particulate flushing during orbit
- Increasing speed increases orbital diameter
- Ability to treat multiple vessel diameters with one crown
- Treat large vessels through 6 French

Before OAS

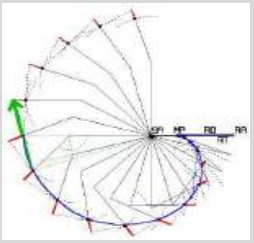
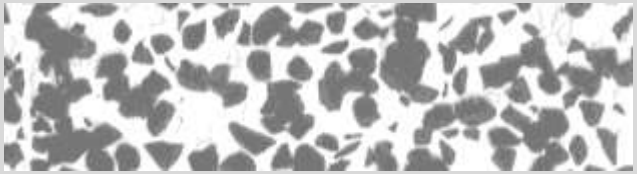
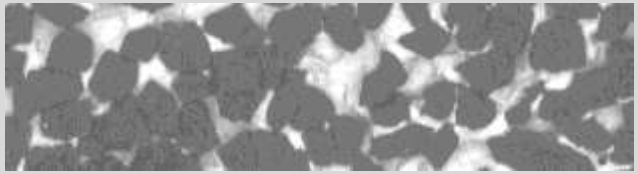
Crown will only sand the hard components of plaque



After OAS

Soft components (plaque/tissue) flex away from crown

Rotational vs. Orbital Atherectomy

	Rotablator	CSI Diamondback
Burr Action	 Burr spins concentrically on wire ***(Front cutting)***	 Crown oscillates in orbital path ***(Circumferential cutting)***
Lumen Sizing	Lumen size = burr size	Lumen size = f (time, speed, passes)
Grit Size	5 µ exposed diamonds 	10 µ exposed cutting surface 

2.5-3X more expensive than Rotablator*

Diamondback 360®
Coronary Orbital Atherectomy System

Device Features
- Only device indicated for severe calcium
- Easy setup and use <2 mins
- Control of device in operating field
- Compatible with 6 Fr approach

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

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

0.012 Viper Wire Advance®

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

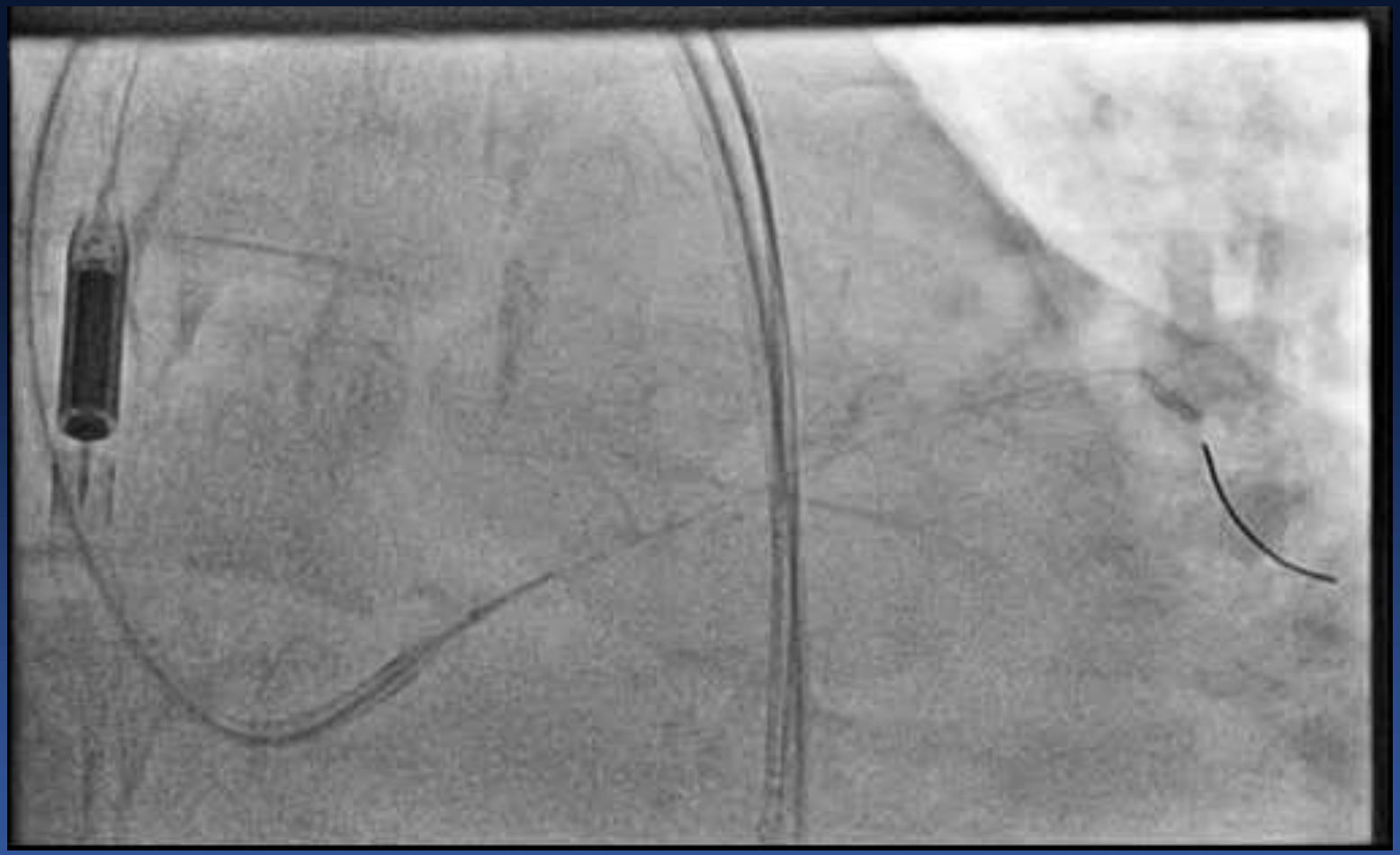
Power on/off switch
- 8cm axial travel

6Fr Guide Compatible Saline Sheath

Electric motor powered handle

Eccentrically mounted diamond-coated 1.25mm classic crown

Orbital Atherectomy Case



1.25mm crown at 80k RPM for 15s

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; ~60 US sites

Randomize 1:1

Orbital Atherectomy Strategy

(1.25 mm Crown followed by non-compliant balloon optimization)

2nd generation DES implantation and optimization

Conventional Angioplasty Strategy

(conventional and/or specialty balloons per operator discretion)

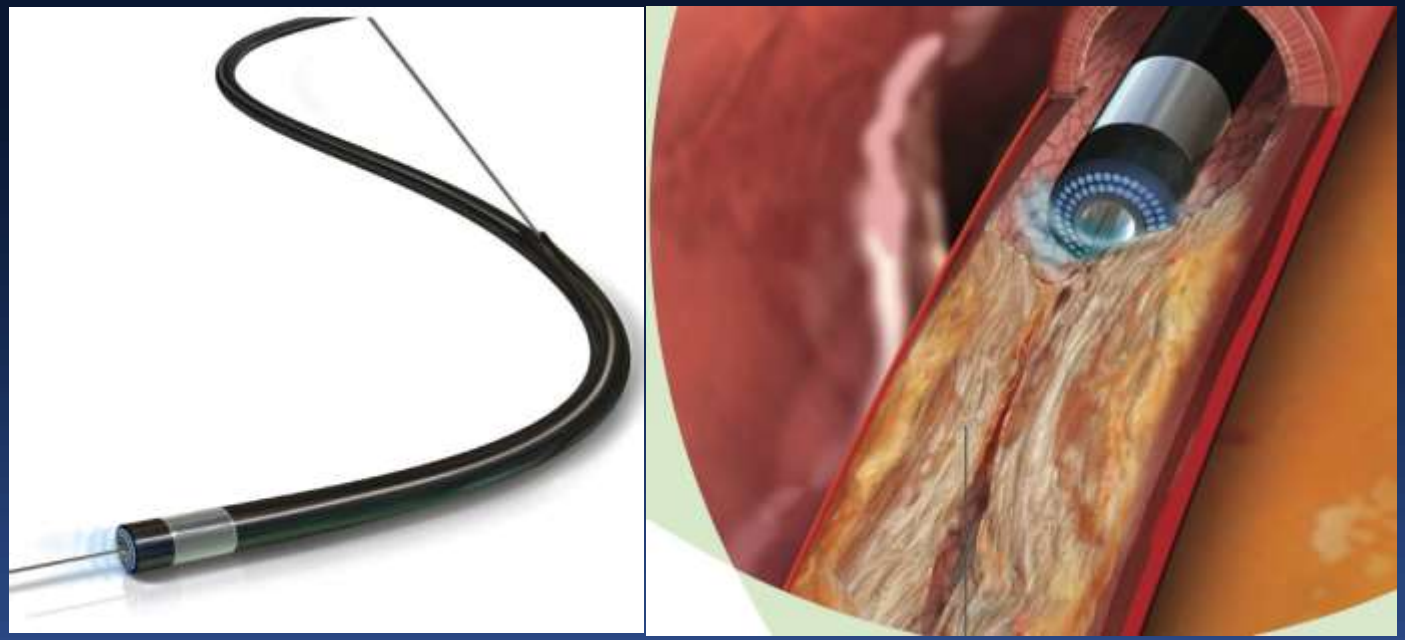
2nd generation DES implantation and optimization

1° endpoints: 1) Post-PCI in-stent MSA (N~400 in imaging study)
2) 1-year TVF (all patients)

2° endpoint: Procedural Success (stent deployed w/RS<20% & no maj complications)

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

Laser Lithotomy (ELCA)



- ELCA transmits pulses of ultraviolet light at 308 nm (low heat).
- ELCA works by vaporization of tissue.

Laser Lithotomy (ELCA)

Mechanisms of Action

- Absorption of the light vibrates the molecular bonds of the plaque
- Vibration of bonds heats intracellular water
- Water vaporizes, molecules break apart, & cells rupture
- Expanding vapor bubble forms in 100 millionths of a second (100 ms)

Balloon Lithoplasty: Shockwave

Lesion modification using lithotripsy in a balloon

Tissue-selective:

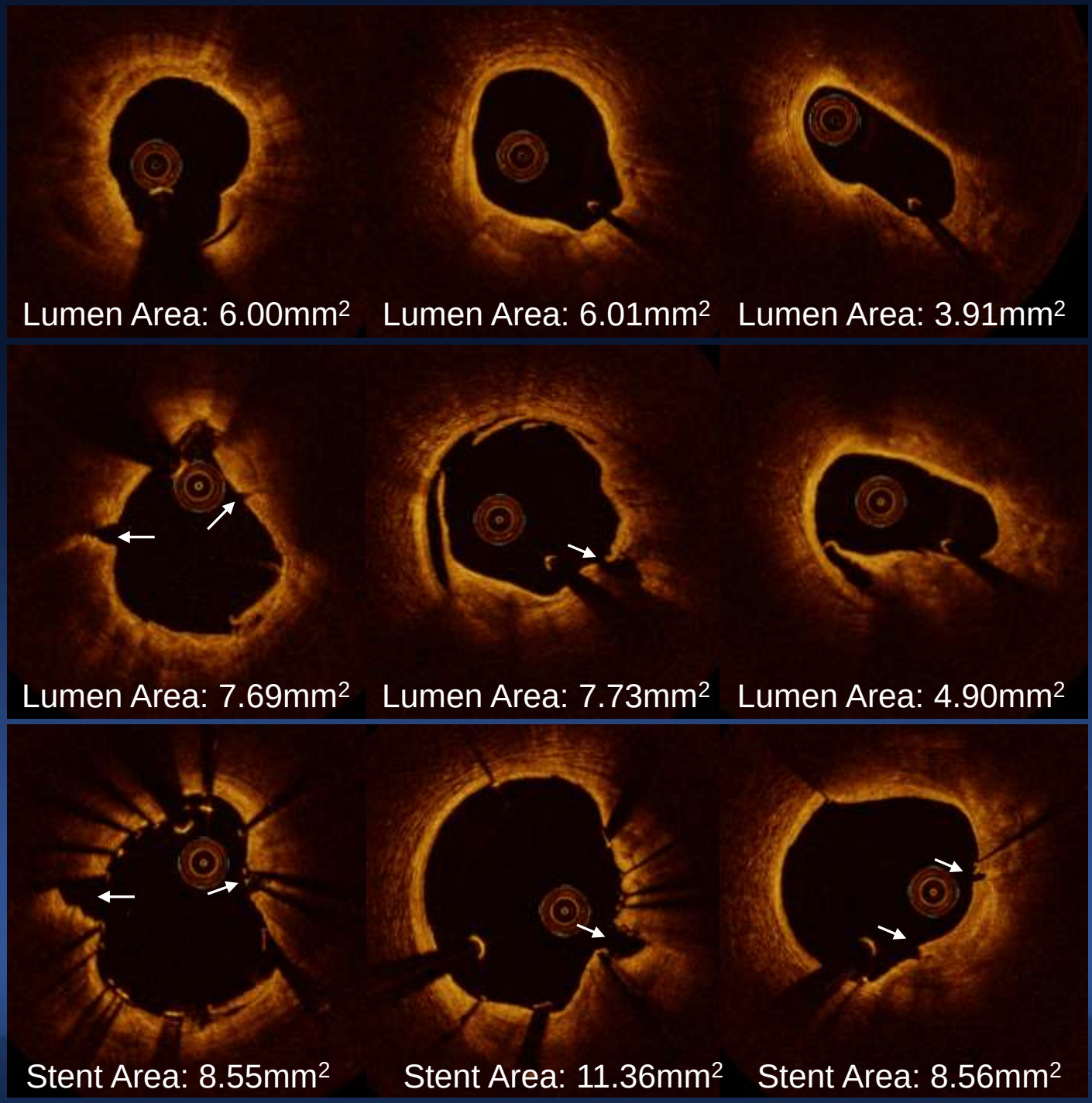
- **Hard on hard tissue, Soft on soft tissue**
- **Lithotripsy waves travel outside balloon**
- **Designed to disrupt both superficial, deep calcium**

- Designed to normalize vessel wall compliance prior to controlled, low pressure dilatation
- Effective lesion expansion with minimized impact to healthy tissue
- “Front-line” balloon-based Rapid Exchange .014 platform

Pre-Procedure

Post-Lithoplasty

Post-Stent



Summary I. Coronary Calcification

- In the contemporary DES ear, approximately 10%-20% of patients had moderate-to-severe CAC.
- Patients with moderate or severe CAC have a higher clinical risk profile and remain at higher risk for short- and long-term adverse clinical events.
- The adverse effect of CAC on outcomes appears to be uniform across clinical and angiographic subsets, including new-generation DES.

Summary II. Coronary Calcification

- During PCI of calcified lesions, IVUS and OCT are useful to determine the extent of calcification and to optimize stent results.
- Scoring and cutting balloons are useful in mild and some moderately calcification to improve vessel compliance, facilitating stent delivery and expansion.
- Atherectomy provides effective lesion “decalcification” and should be used when device delivery and/or adequate stent expansion are unlikely to be achieved by balloon pre-dilatation alone.