Essentials of Calcium Management

TCTAP 2023

Classification of Coronary Calcification

ACC/AHA Type A Lesion

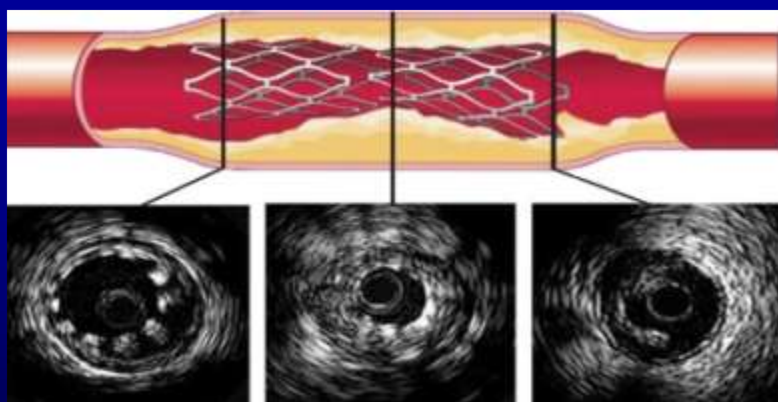
- **None:** No radiopacity
- **Mild:** Faint radiopacities noted during cardiac cycles

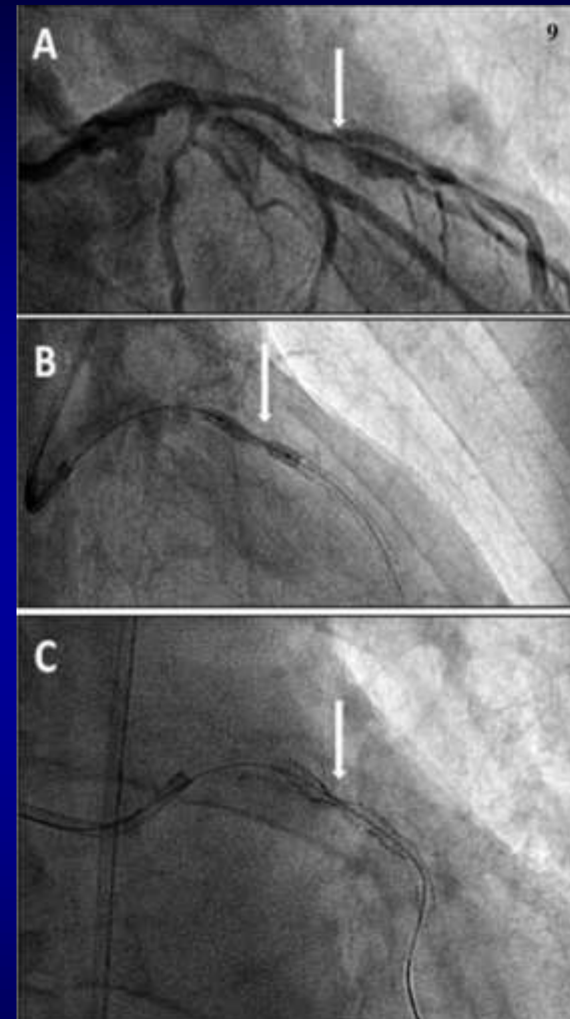
ACC/AHA Type B Lesion

- **Moderate:** Dense radiopacities noted during cardiac cycle before contrast injection.
- **Severe:** Dense radiopacities noted on both sides of the arterial wall ("tram-track") without cardiac motion before contrast injection.

Issues of the Calcified Coronary Lesions

- Angiography underestimates coronary calcification
- Respond poorly to angioplasty
- Difficult to completely dilate
- Prone to dissection during PTCA or predilatation
- Preclude stent delivery to the desired location
- May prevent adequate stent expansion ⟶ ST / ISR
- May result in stent malapposition
- Uneven drug distribution associated with restenosis

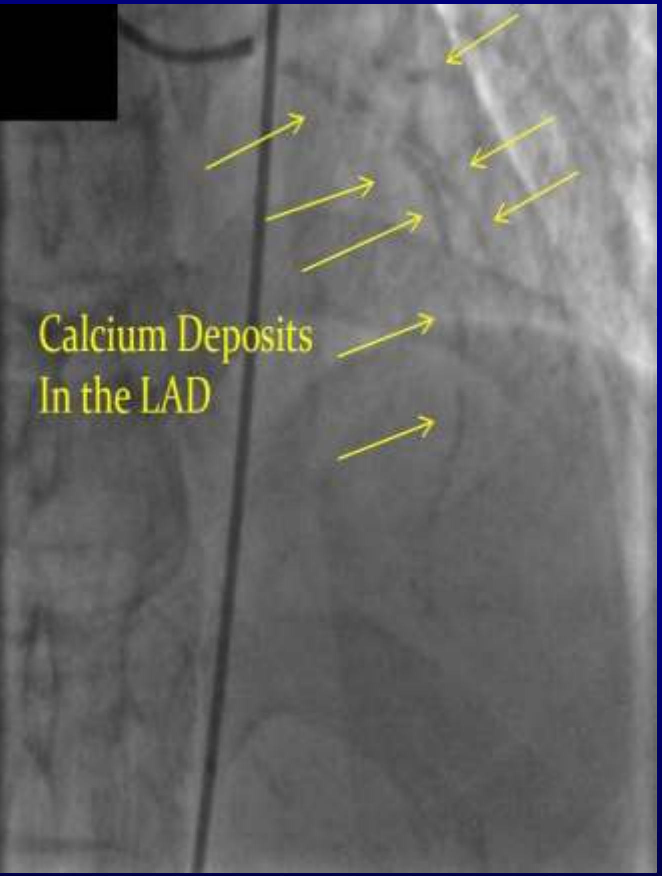




1. Mintz et al., Circulation 1995;91:1959
2. Fitzgerald et al., Circulation 1992;86:64
3. Cavusoglu et al., Catheter Cardiovasc Intervent 2004;62:485
4. Gilutz et al., Catheter Cardiovasc Intervent 2000;50:212
5. Moussa et al., Circulation 1997;96:128
6. Mosseri et al., Cardiovasc Revasc Med 2006;6:147
7. Nakano et al., Eur Heart J 2013;34:3304
8. Buckley CJ Vascular Disease Management 2011;8:87

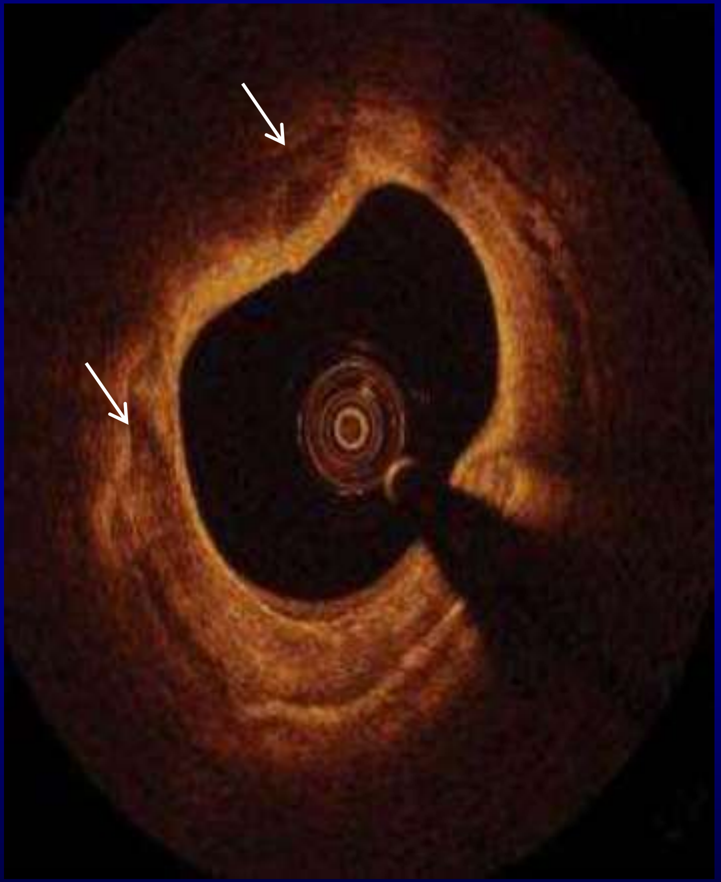
Angio, IVUS and OCT of Severe Coronary Calcium

“Tram-track” sign on Angio X-ray

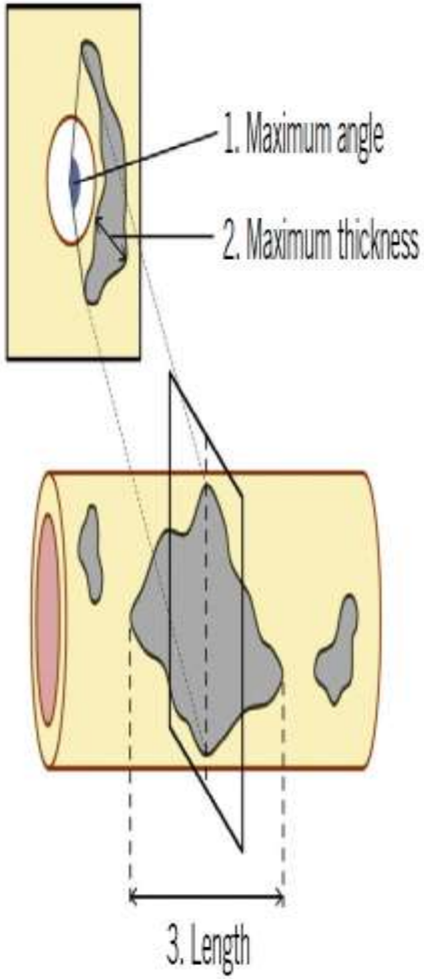


IVUS showing a highly calcified lesion (>2Q)

OCT showing a highly calcified lesion

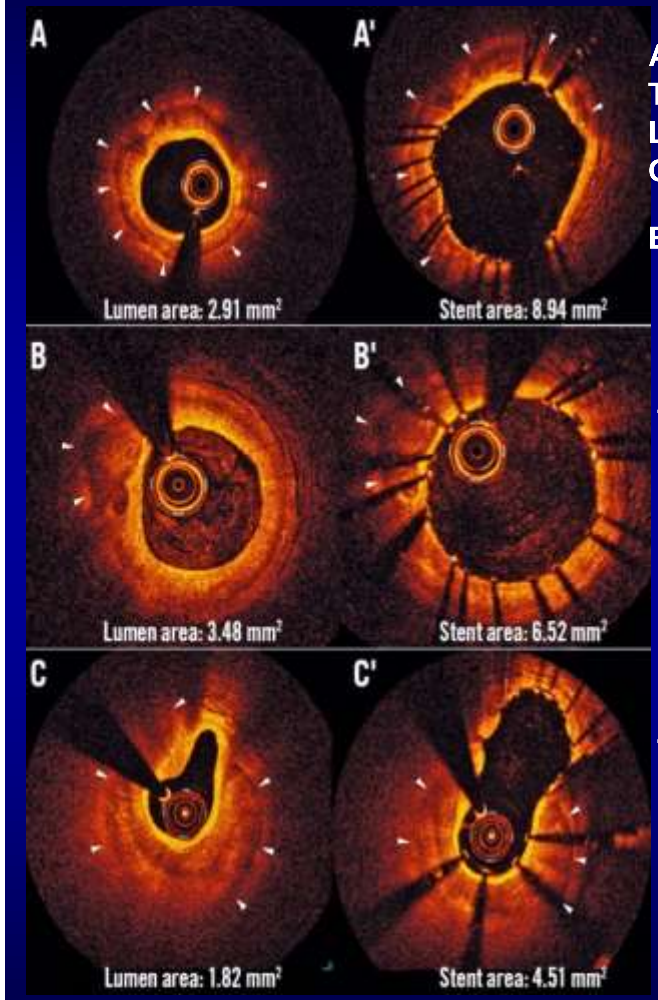


OCT based Calcium Score and Stent Expansion



OCT-based calcium score	
1. Maximum calcium angle (°)	≤180° ➡ 0 point >180° ➡ 2 points
2. Maximum calcium thickness (mm)	≤0.5 mm ➡ 0 point >0.5 mm ➡ 1 point
3. Calcium length (mm)	≤5.0 mm ➡ 0 point >5.0 mm ➡ 1 point
Total score	0 to 4 points

Baseline **Final**



Angle: 360º
Thickness: 0.48 mm
Length: 3.8 mm
Calcium Score: 2 points

Expansion: 99%

Angle: 75º
Thickness: 1.1 mm
Length: 4.3 mm
Calcium Score: 1 point

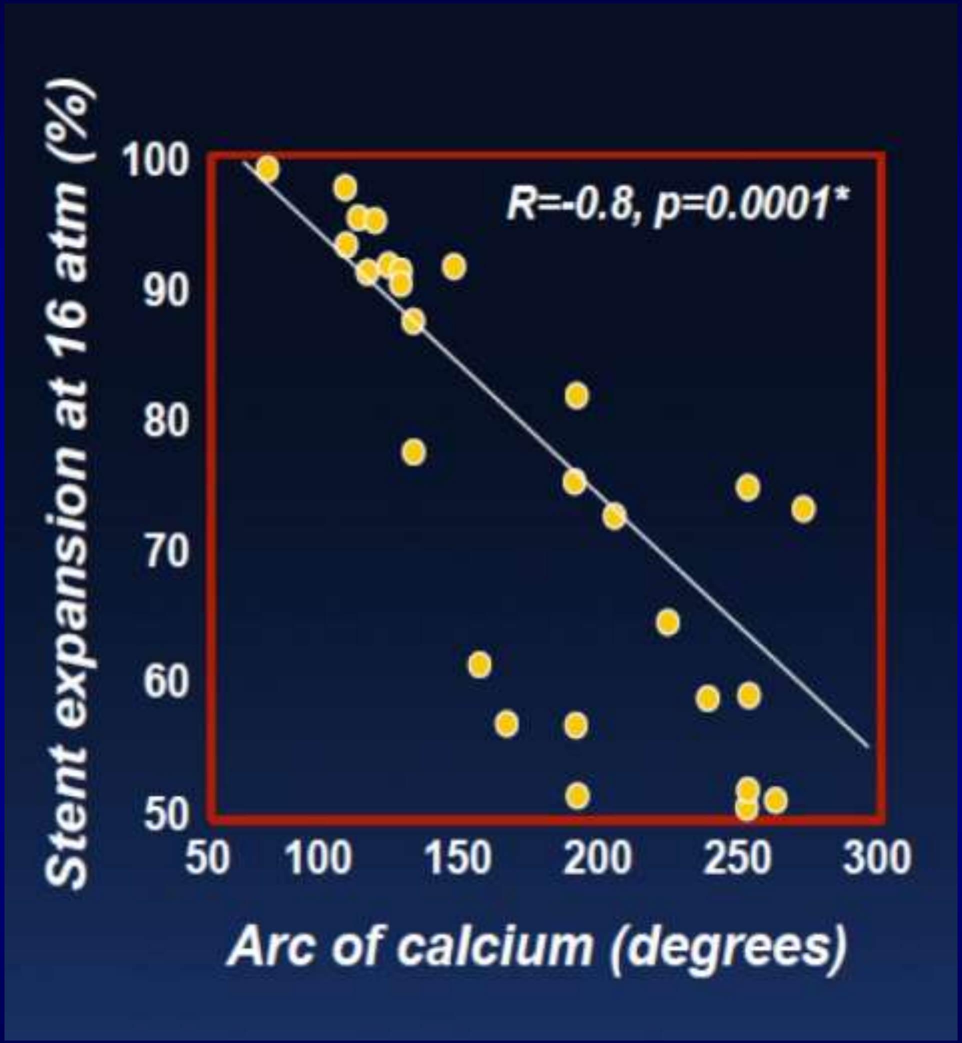
Expansion: 97%

Angle: 312º
Thickness: 1.4 mm
Length: 11.0 mm
Calcium Score: 4 points

Expansion: 68%

Fujino et al., EuroIntervention 2018;13:e2182

Stent Expansion in Calcified Lesions



↑ Arc of Ca++

↓ Stent Expansion

OSTI Trial

	12 atm	18 atm	24 atm
Ca^{++} (n=15)	66%	69%	71%
Non Ca^{++} (n=25)	82%	93%	100%

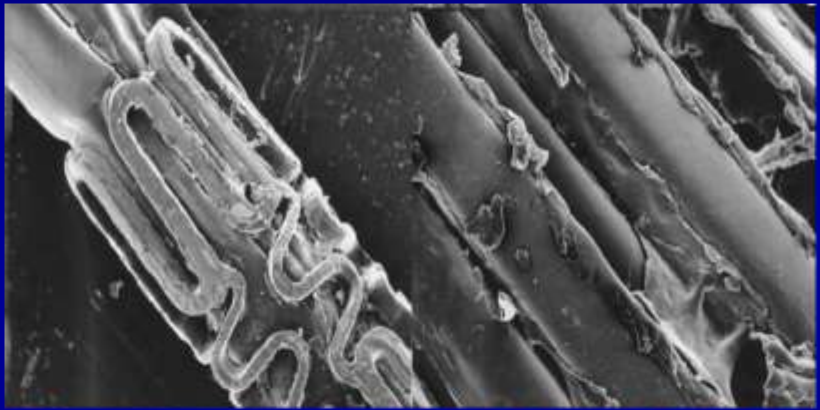
Vavarunakis et al., Catheter Cardiovasc Interv 2001;52:164

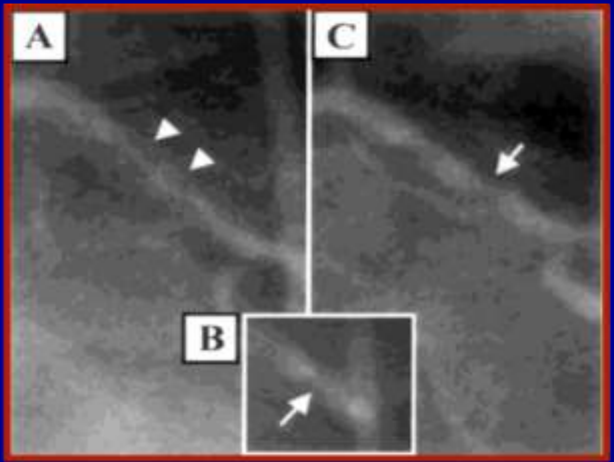
Stone et al. AJC 1999;83:1397

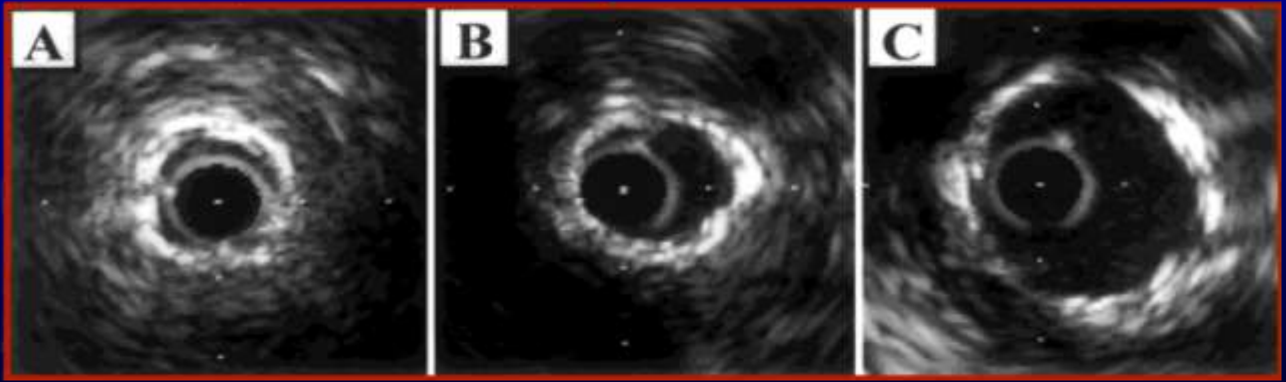
Why is Appropriate Lesion Preparation for Coronary Calcification Important?

Lesion calcification:

- May impair stent delivery or expansion
- May abrade polymers off DES







Therapeutic Tactics/Rationale for Complex Calcified Native Coronary Lesions in the DES Era

Mount Sinai Heart

Plaque modification and imaging: A^3

FFR guided PCI: 32% in NCDR

Pre-Assessment by Angio & IVUS/OCT/FFR

Treatment decision for stent delivery, succ

Calcified, CTO, Bifurcation, Native lesion with graft TO

Simple Lesions	Alteration	Complex Lesions
Stand-alone treatment		Pre-treat: plaque modify
DES	Post-assessment	DES

70-80%

20-30%

Angio & IVUS/OCT

Apposition / Expansion

Final results:
- High Success
- Low TLR
- Lower Bleed

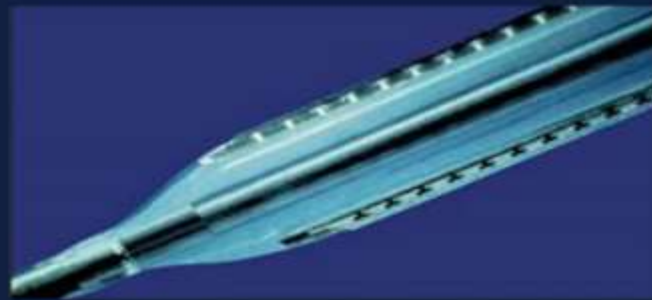
IABP/PTVA/IMPELLA in High risk cases with low EF <30-35%

Final results:
- Procedural complication
- Lower Bleed
- TLR?

Treatment of Calcified Lesions: Options

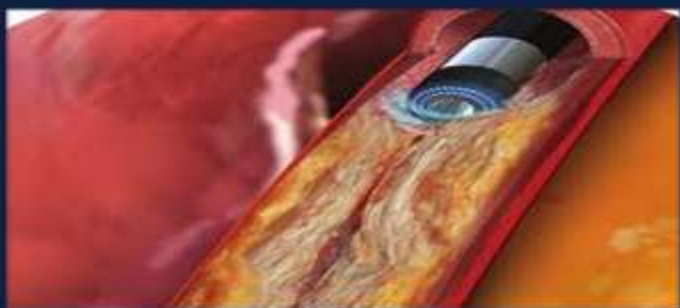
NC Balloon

Cutting Balloon

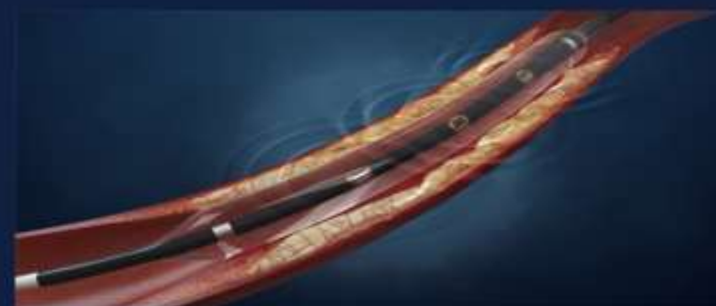


Angiosculpt

Laser



Intravascular Lithotripsy



Rotational Athrectomy

Orbital Atherectomy

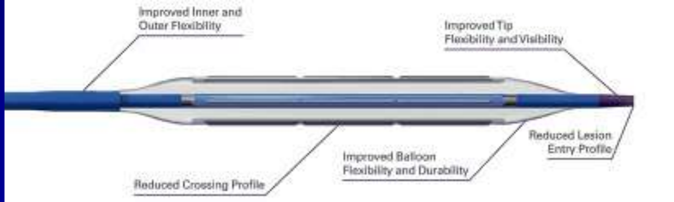
Management of Heavily Calcified Lesions

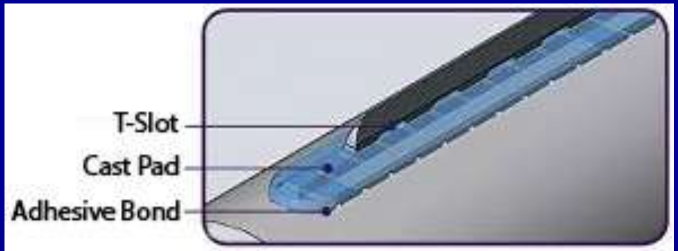
- **High pressure non-compliant balloon dilatation (OPN NC)**
- **Atherotomy (Wolverine Cutting balloon, AngioSculpt, Chocolate balloon, Scoreflex)??**
- **Excimer laser coronary atherectomy (ELCA)?**
- **Rotational atherectomy (RA, PRCA)**
- **Orbital atherectomy (OA)**
- **Shock-wave intravascular lithoplasty (IVL)**

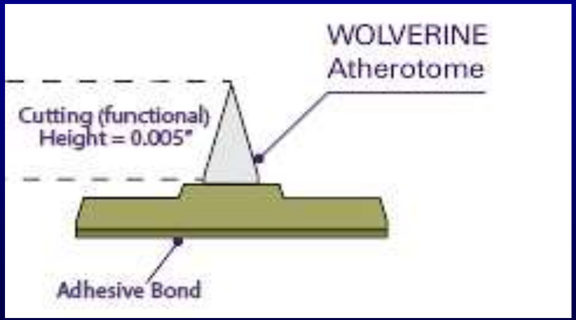
Severe Ca++

Balloon Angioplasty: New Devices

Cutting Balloon/Wolverine







- **Longitudinal microtomes (Atherotomes) are five times sharper than surgical blades**
- **Exclusive Atherotome T-notches enhances mounting surface area & maximize flexibility**
- **Atherotome height is approximately the same as a coronary stent strut (0.125mm)**
- **Mounting pad secures Atherotomes to non-compliant balloon**
- **Proprietary folding mechanism shields the Atherotomes**

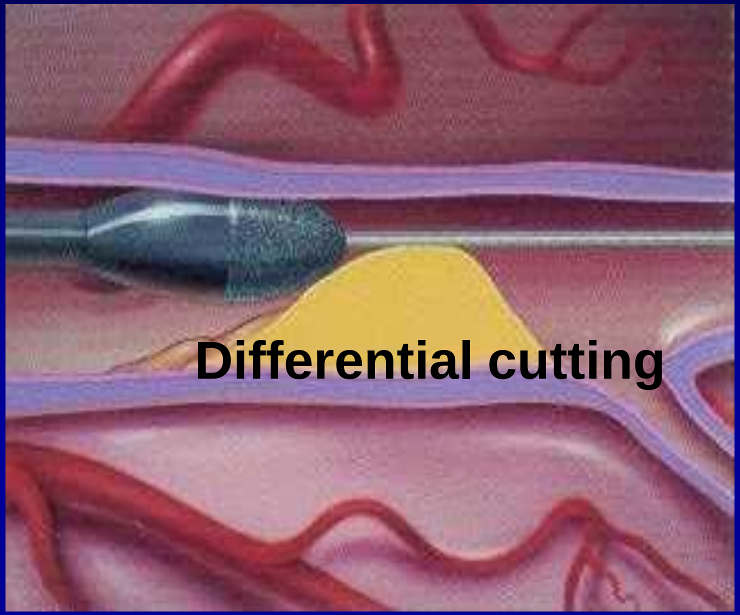
Atherotomy: Cutting Balloon/Wolverine

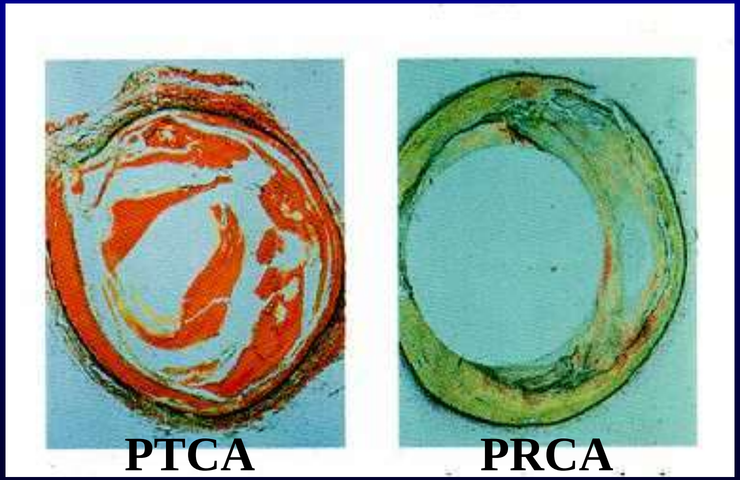
Lesion Indications

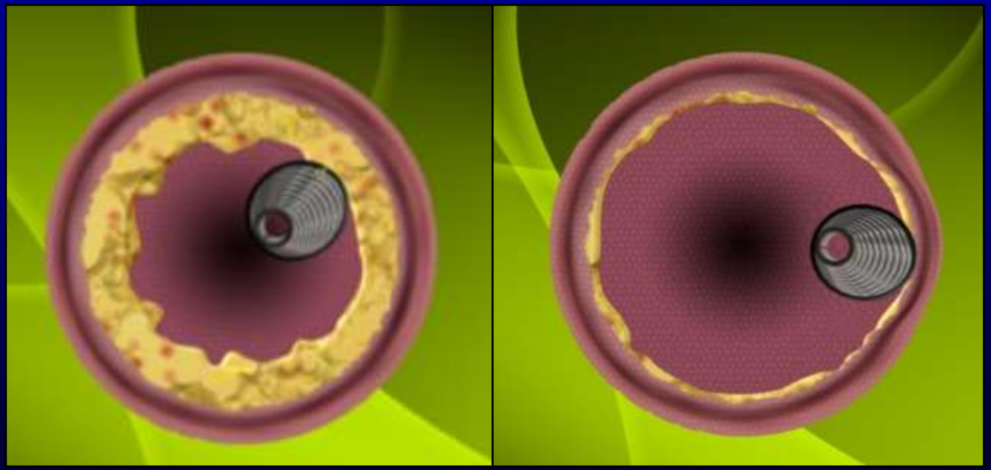
- **Small vessels**
- **Bifurcations / Ostial side branches**
- **Fibrotic lesions**
- **Mild-moderate calcified lesions**
- **In-stent restenosis**

Rotational Atherectomy (RA): Rotablator

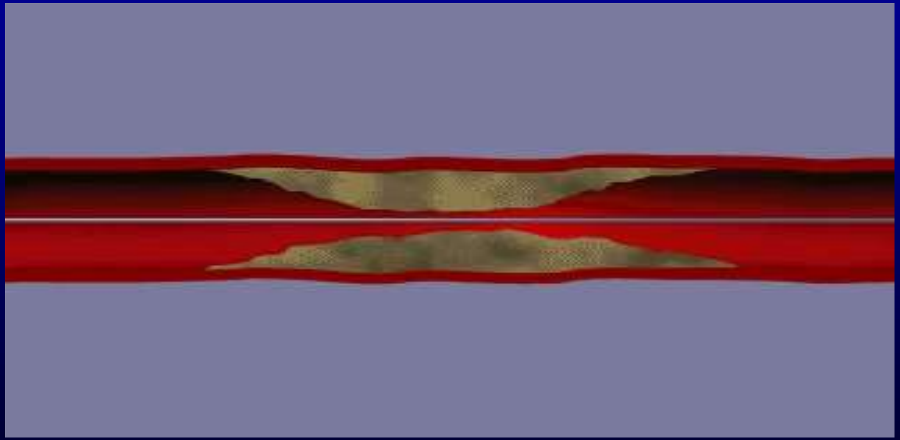
Orbital Atherectomy (OA): Diamondback







ORBITAL ATHERECTOMY	ROTATIONAL ATHERECTOMY
Eccentrically mounted diamond coated crown	Diamond-tipped burr that spins *concentrically* on the wire
Bi-directional treatment	*Front*-cutting, *mono*directional burr
One burr size, 1,25 mm classic crown	*Multiple* bur sizes (1.25 – 2.5 mm)
0.012” ViperWire Advance with 0.014” tip	*0.009”* RotaWire with 0.014” tip
Power source: *Electric*	Power source: *Pneumatic*
Controlled *entirely* with hand controller	Controlled with hand controller *and* foot pedal
2 speeds: 80,000 rpm and 120,000 rpm	Speeds from 140,000 to 180,000 rpm
Technique: *Slow* forward/backward motion 1-3 mm/sec	Technique: Pecking forward/backward motion

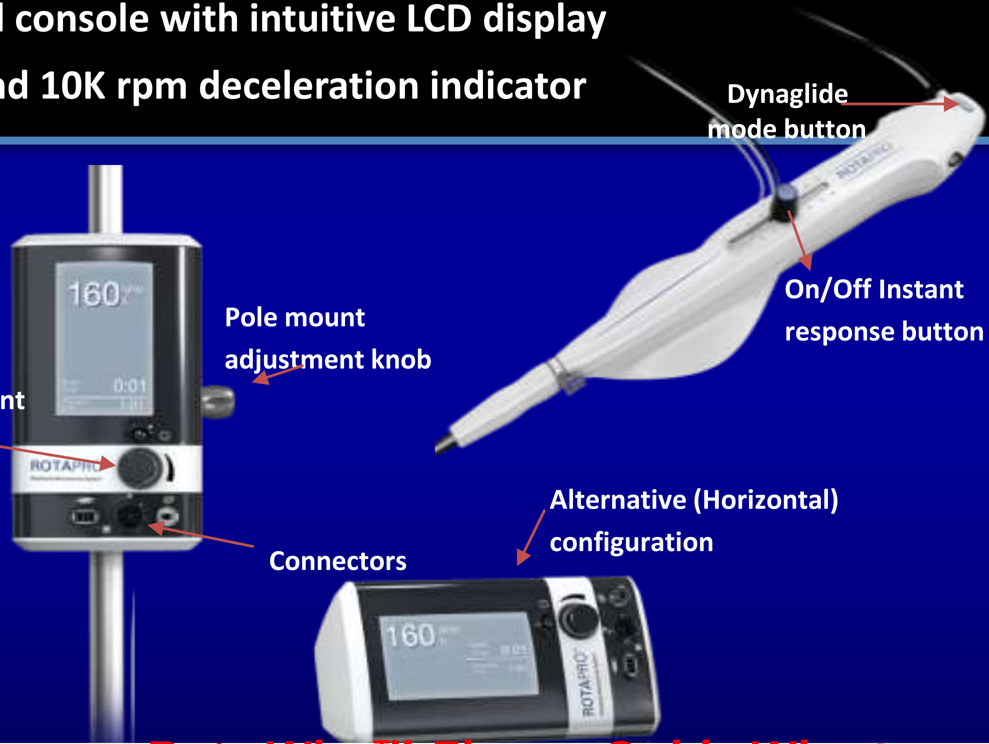


ROTAPRO™ Rotational Atherectomy System

Gold Standard Rotablator Therapy on an Enhanced, Easy-to-Use Platform

- Advancer with on/off and Dynaglide controls
- Small console with intuitive LCD display
- 5K and 10K rpm deceleration indicator

Mobile cart with small gas tank allows for quick set-up and easy portability



Rota Wire™ Floppy Guide Wire (>90%)

Newer Rota wires; Rota Wire Drive Floppy and Extra support

Atherectomy, Burr Motion, and Ablation Speed

Preparatory Steps for RA

Confirm optimal antiplatelet and anticoagulant therapy
Confirm appropriate position of RotaWire across lesion
Open and prepare noncompliant balloon sized 1:1 with reference vessel diameter
After assembly and connection of device, verify free flow of flush solution
Ensure proper gas pressure (500 psi in tank and 80–110 psi in console)
Verify free movement of the advancer knob
Backload the burr onto the RotaWire and apply WireClip torquer to back end
Check and optimize speed outside the body
Lock advancer knob
Ensure hemostatic valve is not closed too tightly
Advance burr via guide as associate withdraws wire to maintain stable wire position
Three steps to remove system tension
1. Unlock and gently advance and retract advancer knob
2. Disengage hemostatic valve and gently advance and retract drive shaft
3. Tap on foot pedal while on Dynaglide (low rotational speed) mode

Key Elements of Optimal RA Technique

Maximum burr-to-artery ratio of 0.4 to 0.6
Rotational speed of 140 000 to 150 000 rpm, with higher speeds reserved for cases in which burr cannot cross lesion despite optimal technique
Gradual burr advancement using pecking motion
Short ablation runs up to 20 s in duration
Avoidance of decelerations exceeding 5000 rpm
Final polishing run at completion of atherectomy

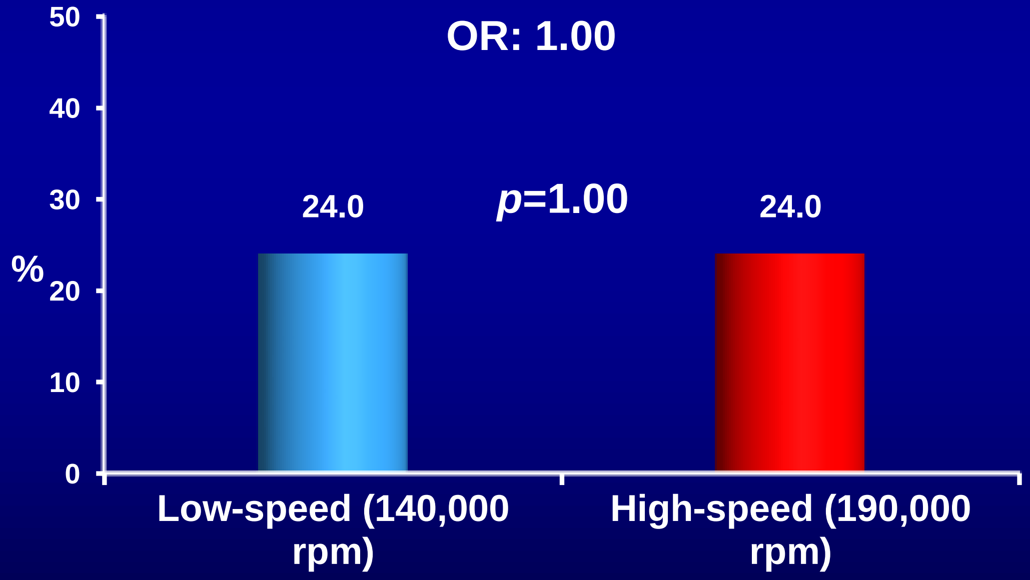
Sharma, Tommey, Kini et al., Circ Cardiovasc Interv 2019;12:e007448

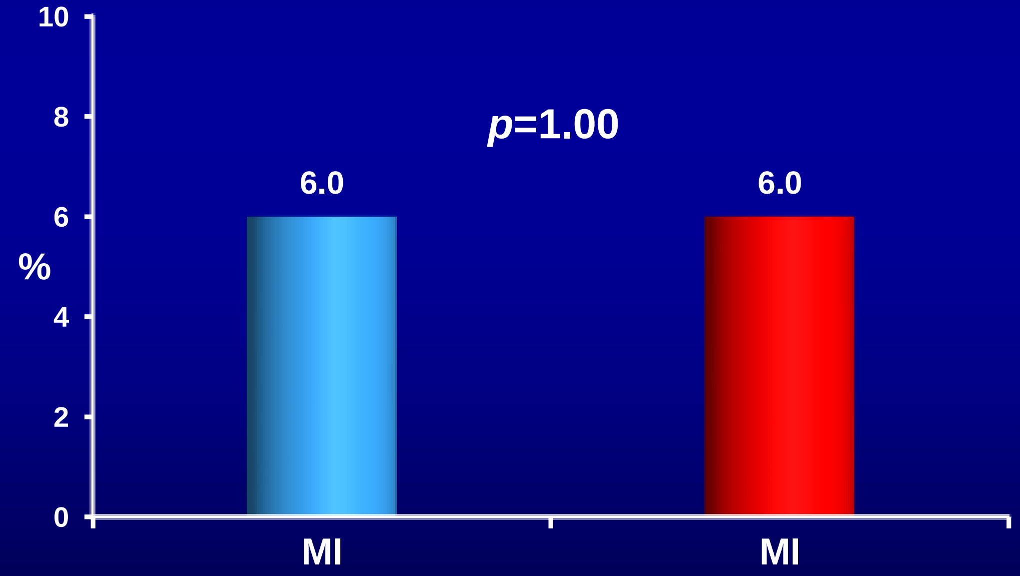
Randomized Trial of Low-Speed vs High-Speed Rotational Atherectomy

Incidence of Slow Flow Following RA (Primary Endpoint)

Incidence of MI Event

Low-speed (140,000 rpm) (n=50) High-speed (190,000 rpm) (n=50)





Sakakura et al., Catheter Cardiovasc Interv 2017;89:832

Rotational Atherectomy (RA, PRCA, PTRCA)

Indications

- Calcified lesion
- Undilatable/chronic lesion
- Diffuse long lesion
- Small vessels (<2.5 mm)
- In-stent restenosis- segmental
- Unexpanded stents
- Bifurcation lesion
- Ostial lesion
- RotaStent (SPORT, ROTAXUS trials)

Limitations

- Slow flow / No flow
- Perforation
- CK-MB release
- Wire bias and dissection
- Technically challenging

Rotational Atherectomy: Complications

Slow-flow

Settings

- Long calcified lesions
- Total occlusion and right coronary artery
- Poor LV function & hemodynamic instability
- Thrombotic lesions (also post MI)
- ? on β-blockers

Technical modifications

- Small initial burr size and small upsizing
- Short ablation runs and avoid RPM drops ?Slow-speed
- Avoid hypotension and bradycardia
- Rota flush & platelet inhibitors
- Treatment: verapamil, nitro, adenosine, SNP, IABP

Best treatment to prevent slow flow is to avoid it from happening.

Management of Transient Clinical Events

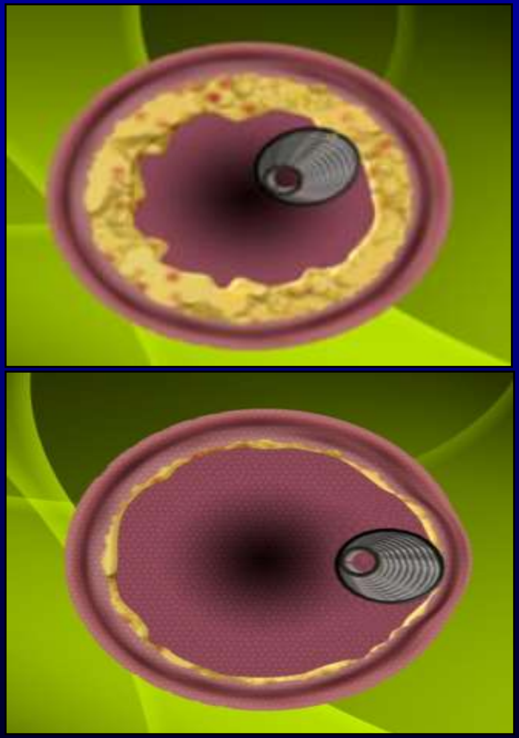
- Bradycardia
- ST segment changes
- Residual chest pain

Potential Mechanical Failures

- Burr stalling
- Guide wire fracture
- Burr detachment

Orbital Atherectomy for Severely Calcified Coronary Lesions

- Easy setup and use
- Control of device in operating field
- 0.012” OAS guide wire with 0.014” tip (1.4 grams force at 10mm)
- Compatible with 6 French guiding catheters
- Fast learning curve
- Less slow flow
- ? Lower TLR



Rotational vs. Orbital Atherectomy for Heavily Calcified Lesions: Preferred Device?

Majority of Heavily Calcified Lesions are suitable for one's preferred device (OA or RA) based on the experience and comfort level and Cath Lab setup. Following is the suggested preference for RA vs. OA.

RA+  0.009"wire	OA+  0.012"wire
• Aorto-ostial lesion	• Ease of setup
• Angulated lesion >90°	• Fast learning curve
• Subtotal or total Ca+ occlusion	• Hemodynamic instability
• Large vessel (>3.5m) requiring 2.00mm+ burr	• Vascular access issues (1.25mm crown via 6 Fr Sheath)
• ISR/unexpanded stent	• Distal/multiple lesions

ECLIPSE Trial

Evaluation of Treatment Strategies for Severe CaLcifIc Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty Prior to Implantation of Drug Eluting StEnts

~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)

Conventional Angioplasty Strategy

(conventional and/or specialty balloons per operator discretion)

2nd generation DES implantation and optimization

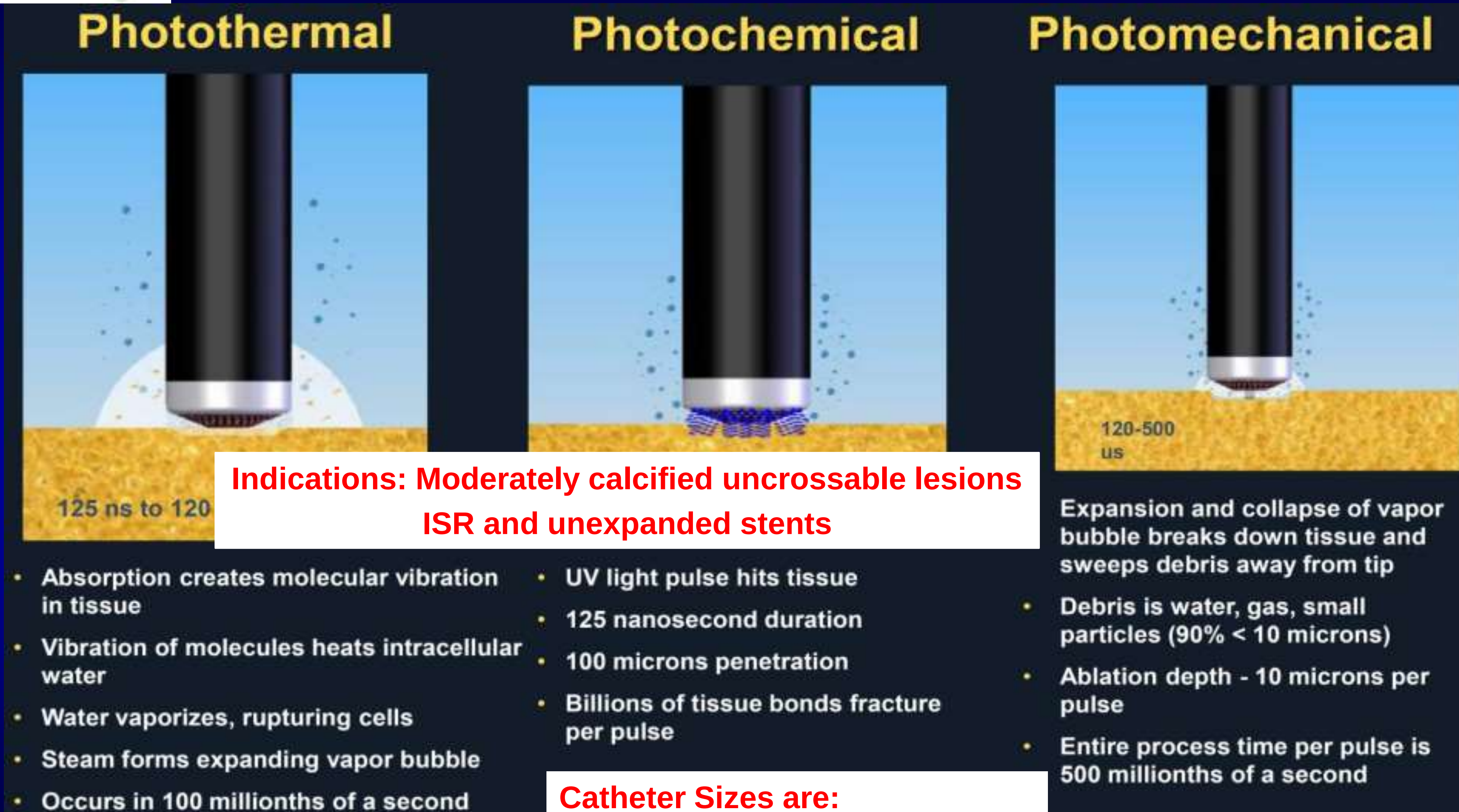
2nd generation DES implantation and optimization

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

Secondary endpoint: Procedural Success (stent deployed w/RS<20% & no major complications)

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

Excimer Laser Coronary Angioplasty (ELCA) Mechanism of Action: Photoablation



Indications: Moderately calcified uncrossable lesions ISR and unexpanded stents

Catheter Sizes are:

- **0.9mm and 1.4 mm**

Catheter Energy:

- **40-80 mJ/mm^2/40-80Hz**

LEONARDO Study (N=100)

Lesion Characteristics (n=100)

	n	%
Calcification	57	57
Percutaneous transluminal coronary angioplasty failure	32	32
Chronic total occlusion	11	11
Target vessel distribution		
Left anterior descending coronary artery	48	48
Right coronary artery	35	35
Left circumflex coronary artery	10	10
Left main artery	4	4
Saphenous vein graft	3	3
ACC/AHA classification		
A	0	0
B1	5	5
B2	67	67
C	28	28

Procedural Results

	%
Laser success	93.7*
Procedural success	91.7
Clinical success (1 major complication)	90.6

*6 lesions could not be crossed with the laser even at high energy

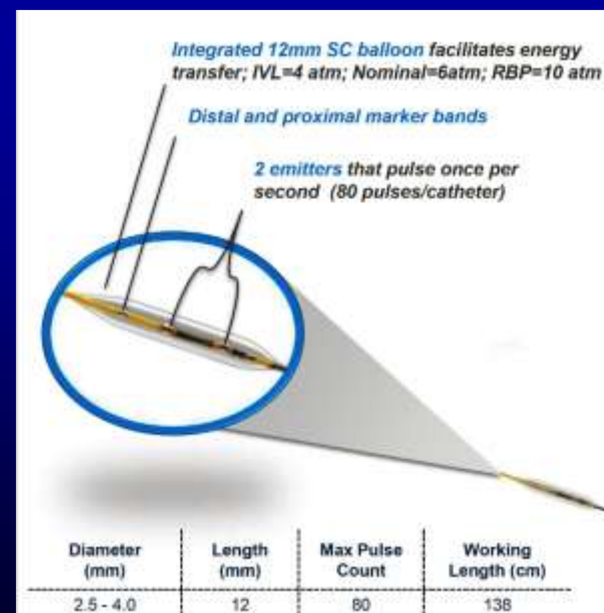
Ambrosini et al., Cardiovasc Revasc Med 2015;16:141

Lithoplasty™: Shockwave Therapy for Calcified Lesions

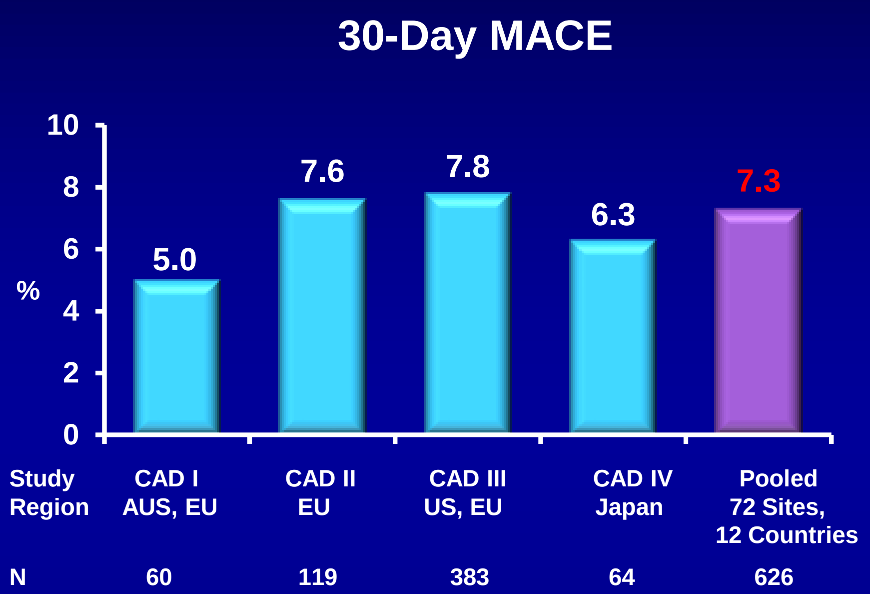
Intravascular Lithotripsy (IVL)

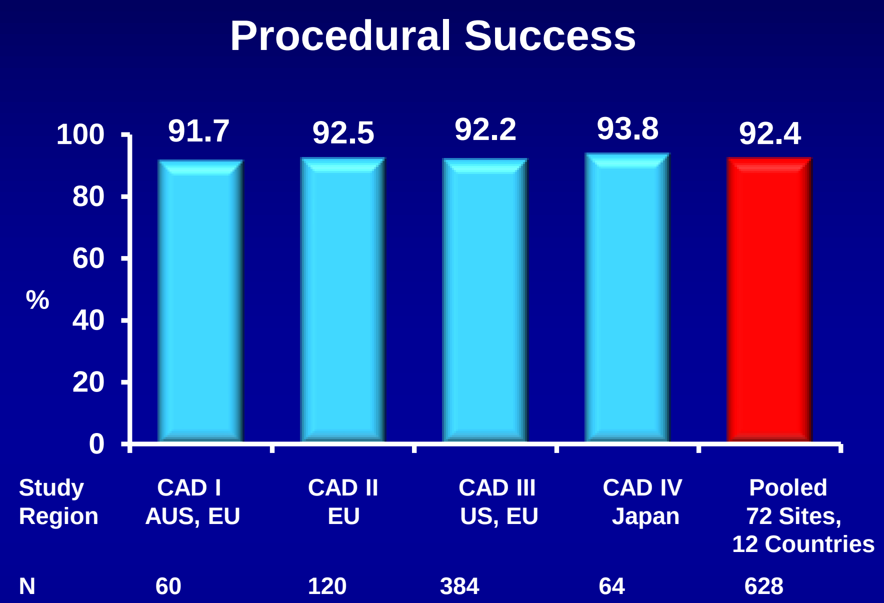
Lithotripsy waves travel outside low pressure balloon, disrupt deep, superficial calcium <u>pre-dilation</u>

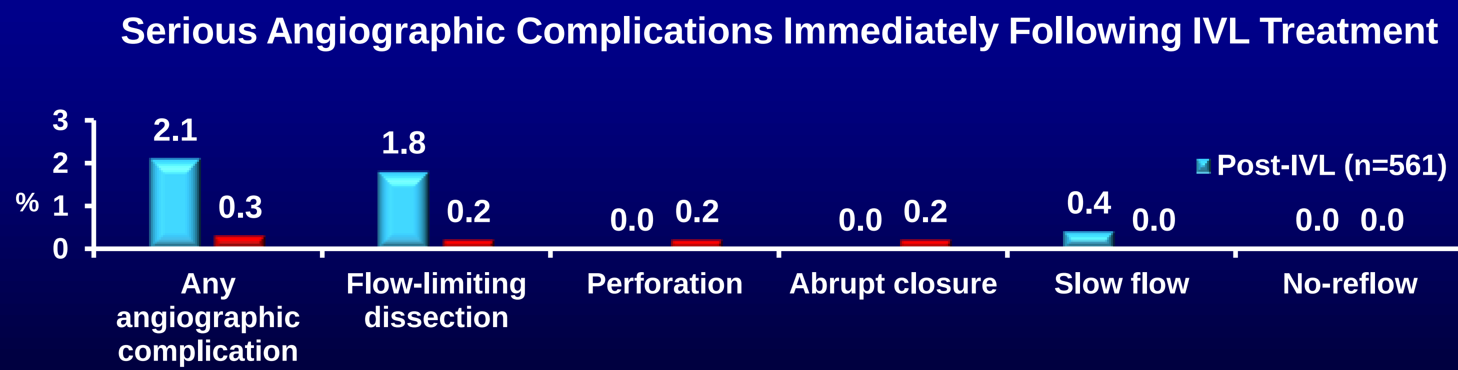
- **Familiar Balloon-based endovascular technique**
- **“Front-line” balloon strategy (0.014” compatible)**
- **Disrupts both deep and superficial calcium pre-dilation**
- **Normalizes vessel wall compliance**
- **Ultra-low pressure**
- **Minimized effect on healthy tissue**



Safety and Effectiveness of IVL Across the DISRUPT CAD Studies

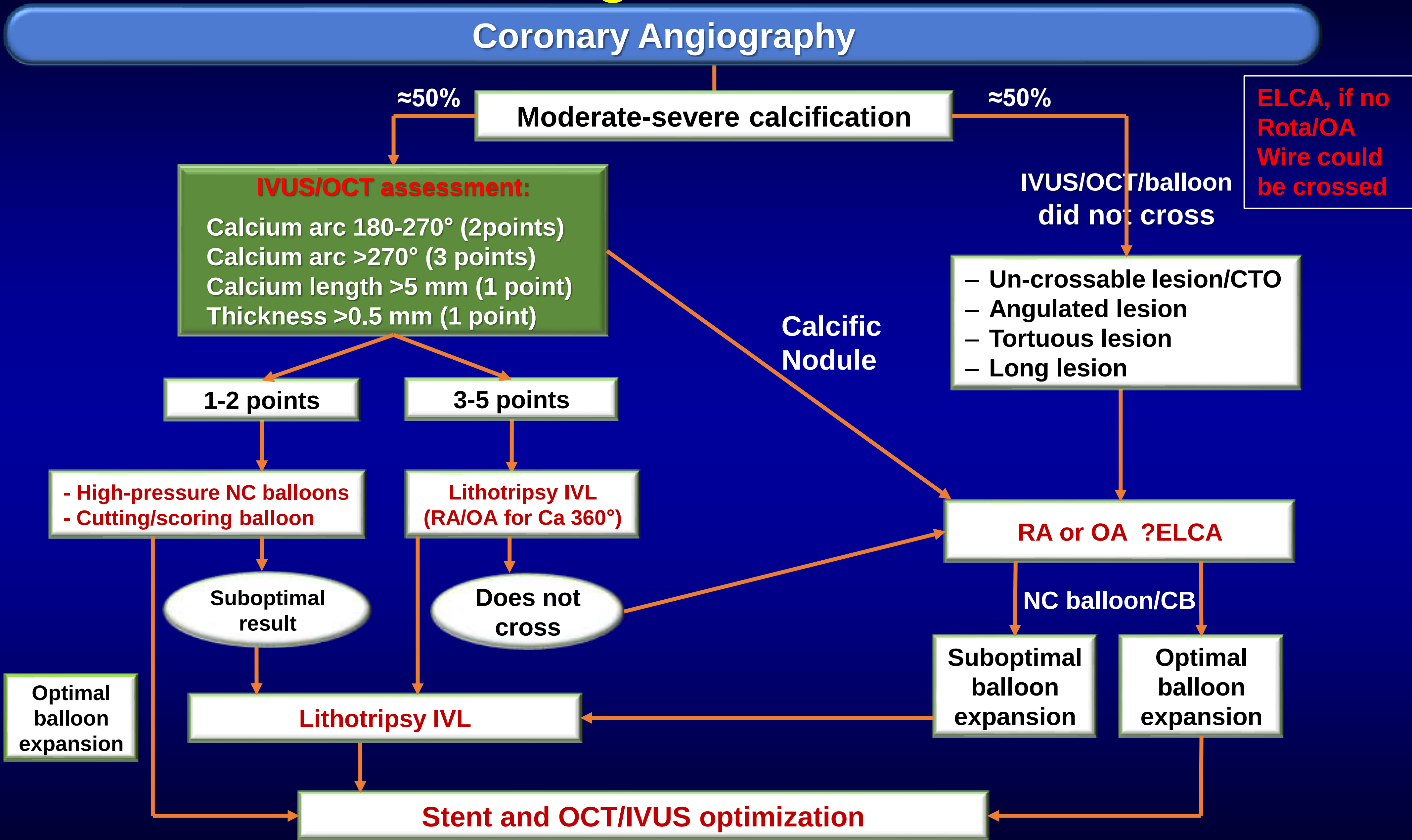






Kereiakes et al., J Am Coll Cardiol Intv 2021;14:1337

Protocol for Management of Calcific Lesions



Heavily Calcified Lesions

Mount Sinai practical approach in current era

- Severe angiographic calcium
- Diffuse lesion or Very tight calcified lesion

IVL: Vessel >3.5mm/ <80% lesion

Rotablator
0.4-0.5 burr/artery ratio

- Effects of RA
- Arc of calcium at MLD
- Nodular calcium
- Wire bias
- Length of calcified lesion
- Vessel size at landing zones

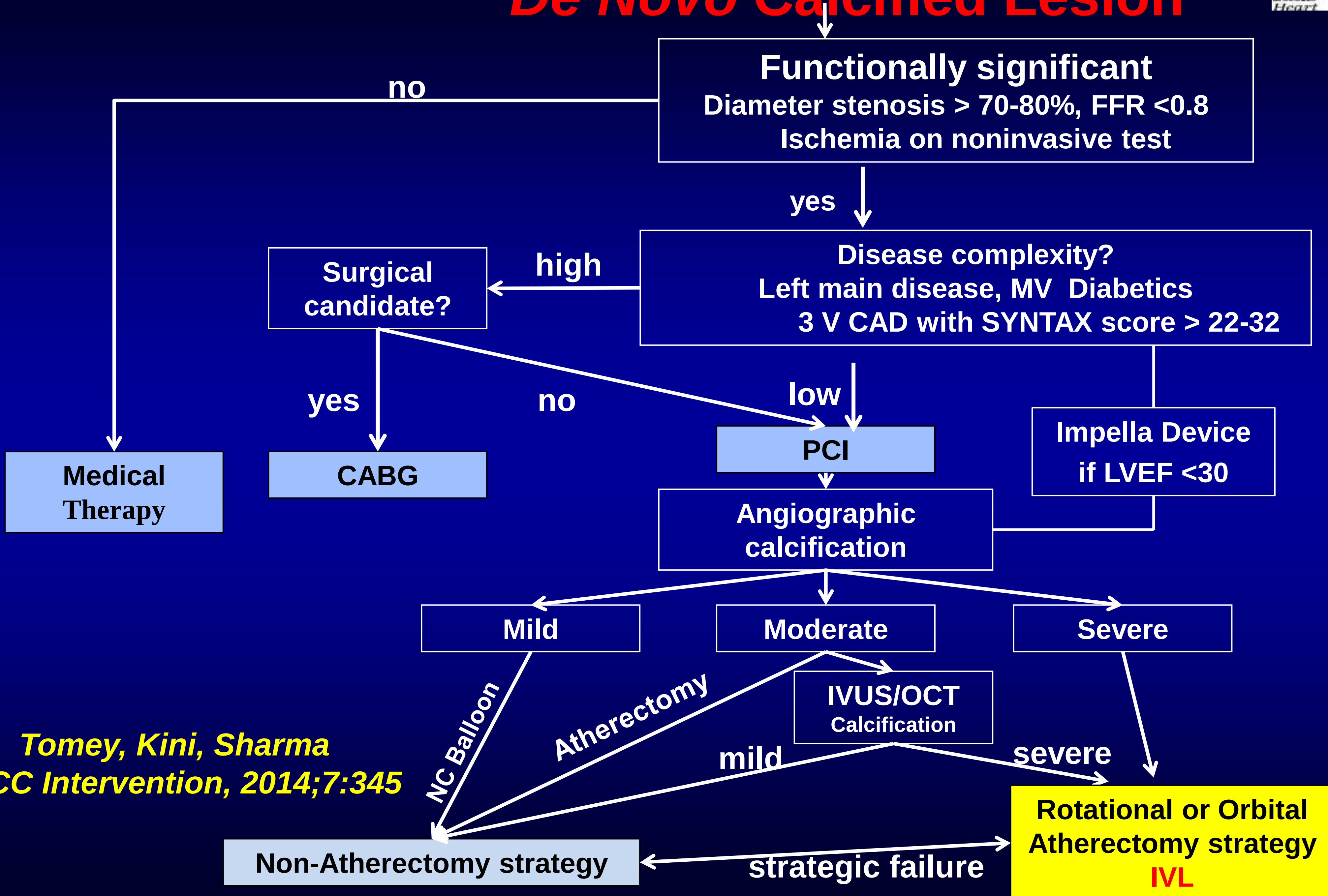
→ **IVUS/OCT**

→ Upsize burr *(Calcific Nodule)*
Balloons NC or cutting *(Based on vessel size)*
IVL *(>3mm vessel, >270 Ca+ arc)*

→ Balloon expand → Stent
If unexpanded
IVL → *Stent*

In complex cases (LM, long Ca+ lesions, bifurcation)
Final Imaging (IVUS/OCT) in the end for
Further stent optimization or dissections

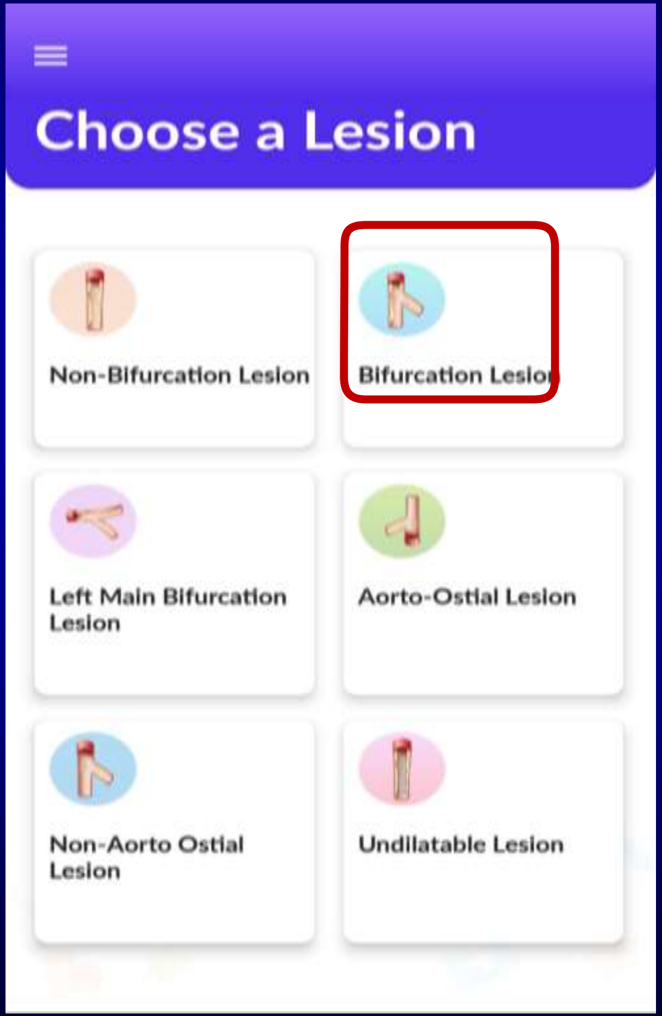
De Novo Calcified Lesion

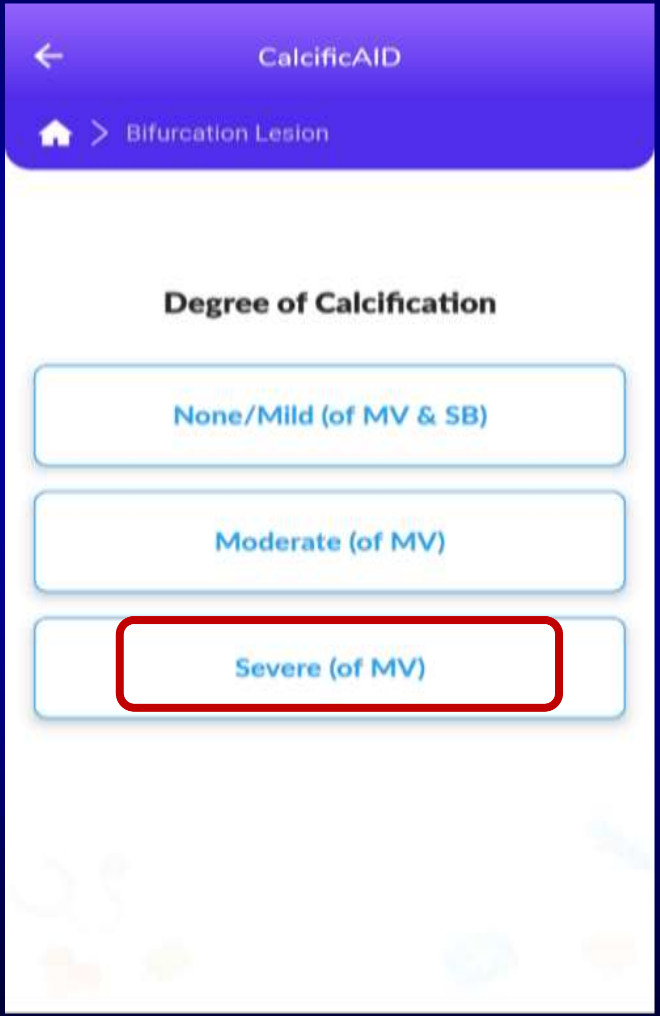


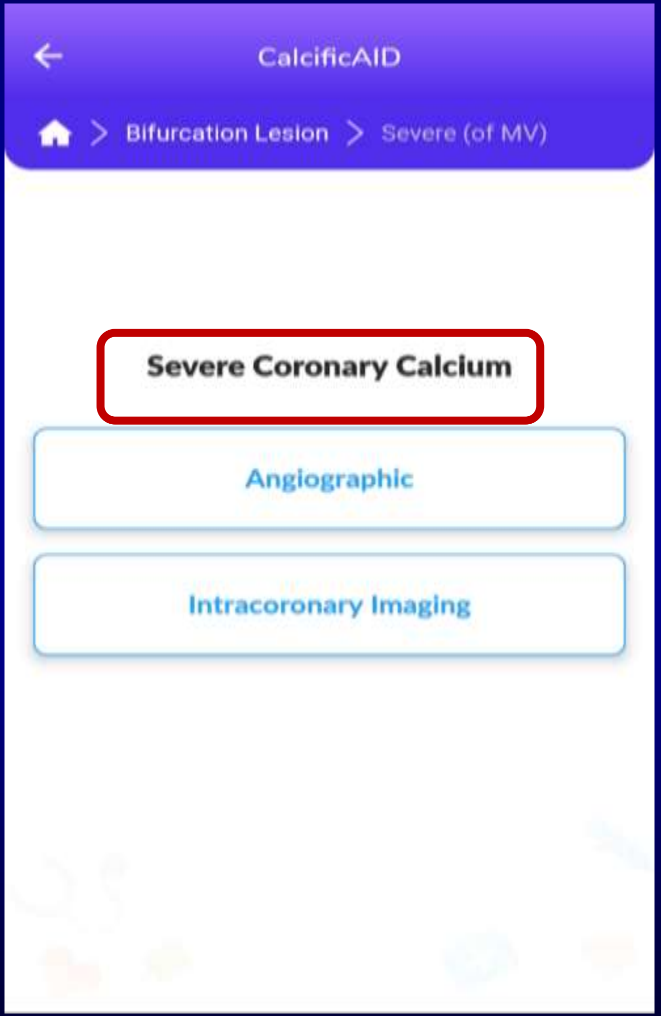
Tomey, Kini, Sharma
JACC Intervention, 2014;7:345

CalcificAID

Future will be frequent device synergy: CalcificAID-2 - RotaShock, - LaserShock, - OrbitalShock







Conclusions

- Calcified coronary lesions are a common especially in high risk pts
- Vessel calcification may cause stent mal-apposition, stent under expansion, stent fracture, and higher restenosis
- In the complex calcified high risk cases, optimal stent procedural techniques are critical to achieve good short and long-term results
- The use of atherectomy/IVL to prepare severely calcified coronary lesions and advanced imaging are essential for optimal stent procedure for best acute and longterm interventional results.