Calcified lesions

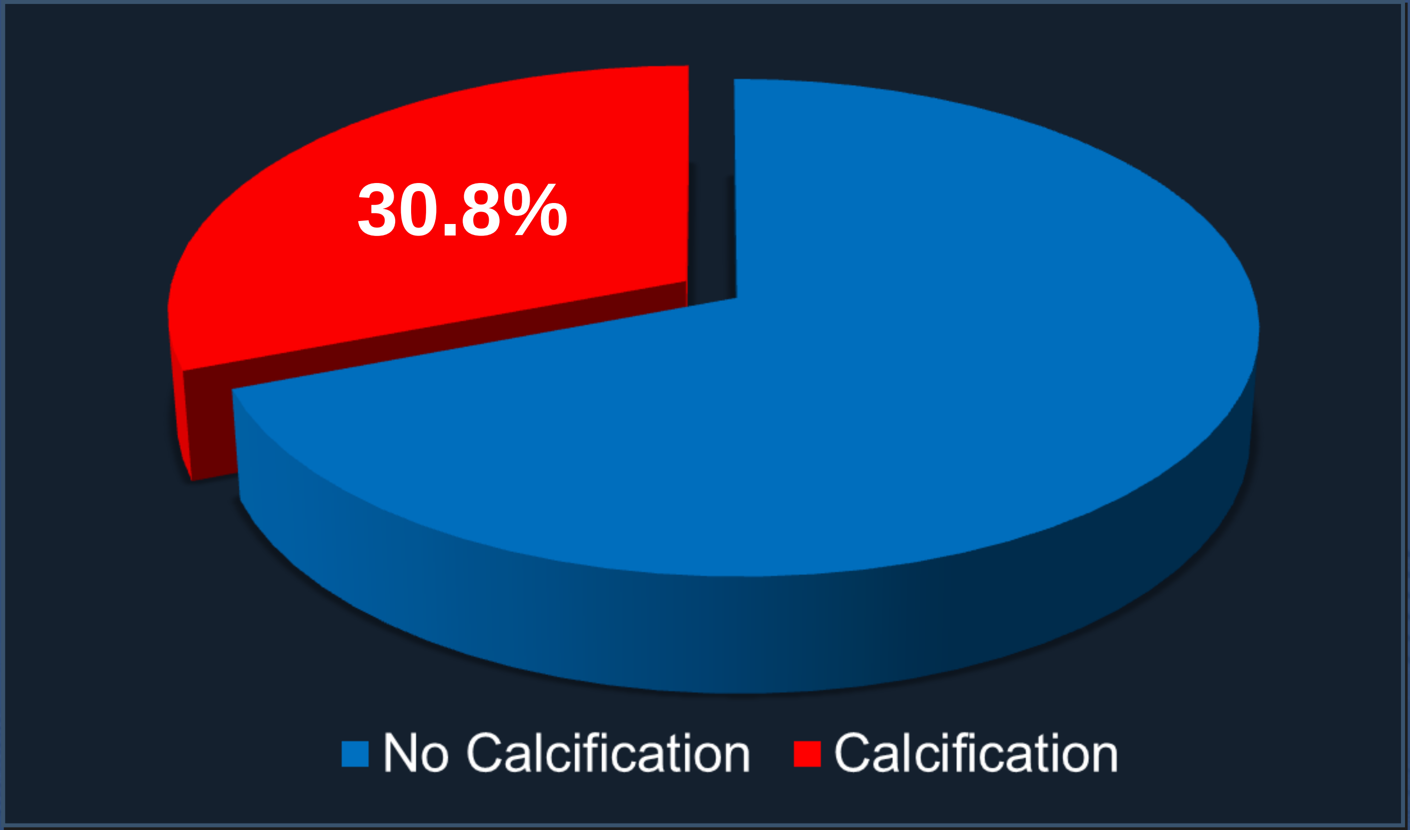
Prevalence of calcified coronary lesions

Moderate-severe calcification in 13 DES 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)
Total	**29.0% (2,315/7,978)**

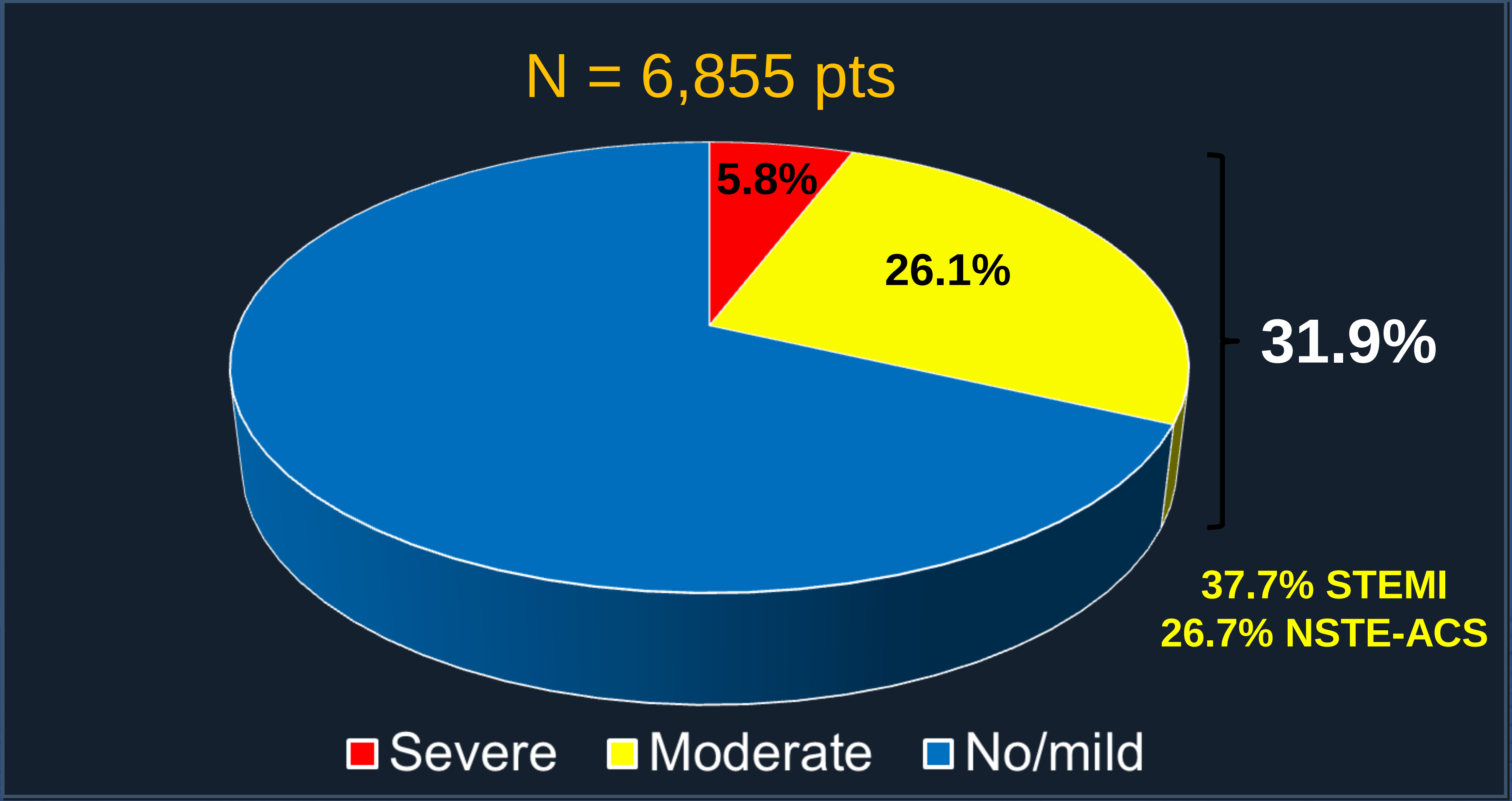
ADAPT-DES (11 center all-comers registry): Mod-Sev Calcification

N = 8,582 pts



Généreux et al, Int J Cardiol 2017

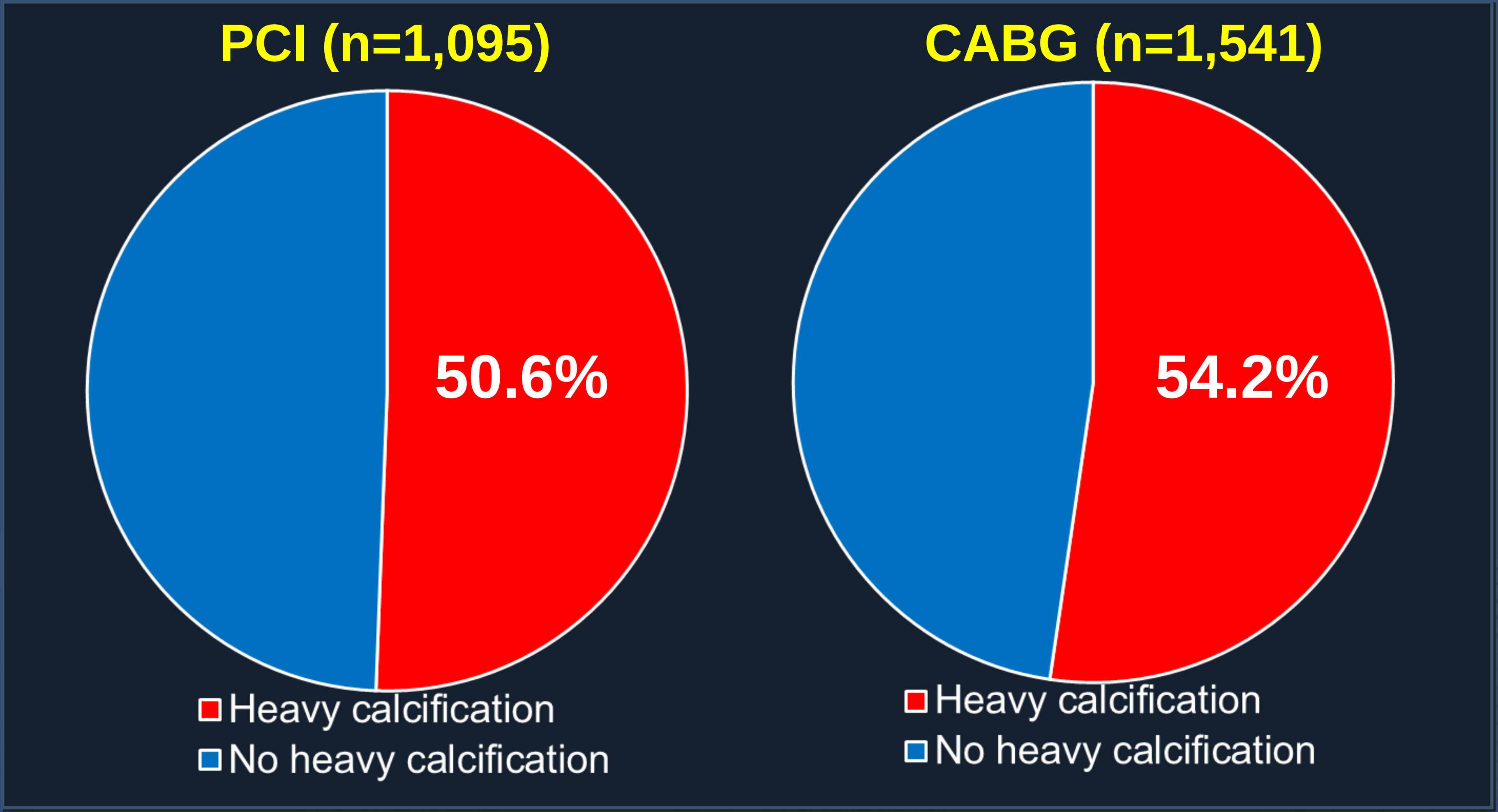
Frequency of Mod-Sev Calcification in NSTE-ACS and STEMI PCI population:
(ACUITY and HORIZONS-AMI)



Généreux, P. et al. J Am Coll Cardiol 2014 13;63 (18):1845-54

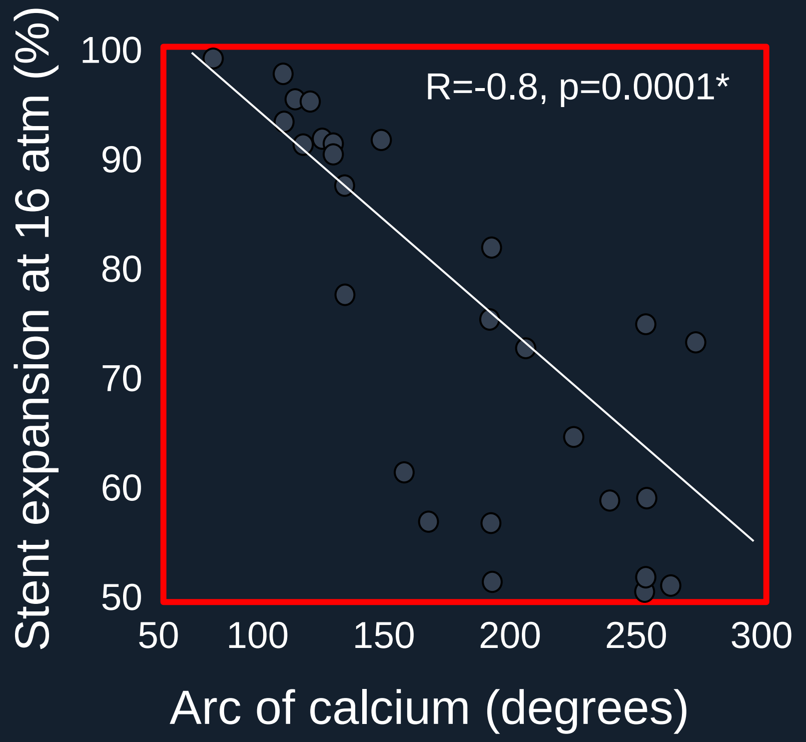
Frequency of "heavy" calcification in the SYNTAX trial: Randomized + Registry

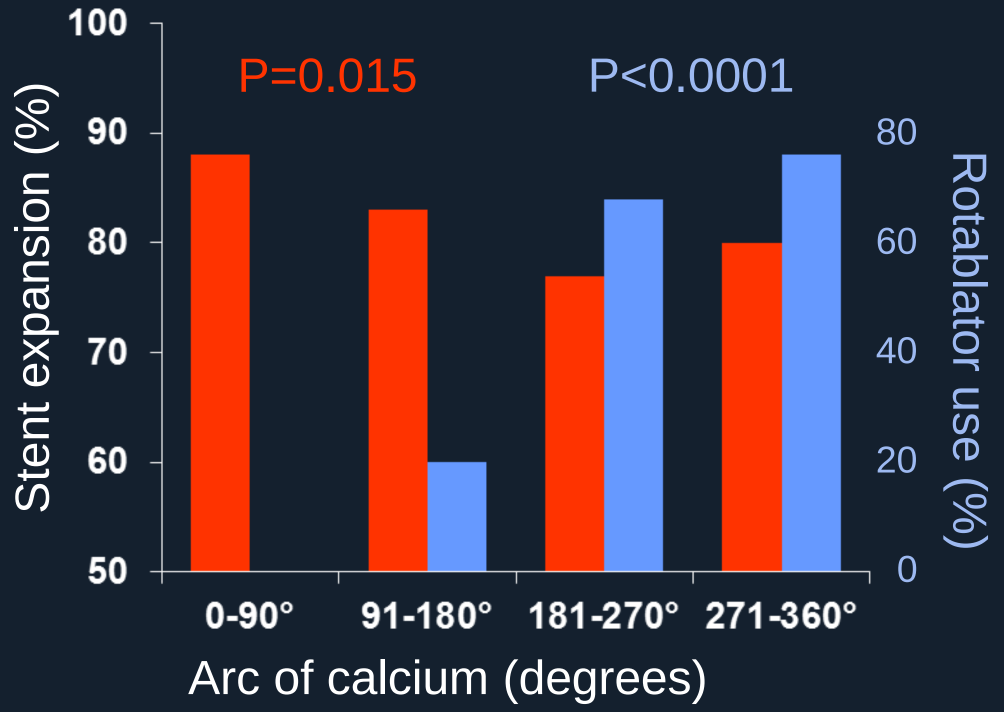
N=2,636 pts with LM or 3VD



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

Stent Expansion in Calcified Lesions

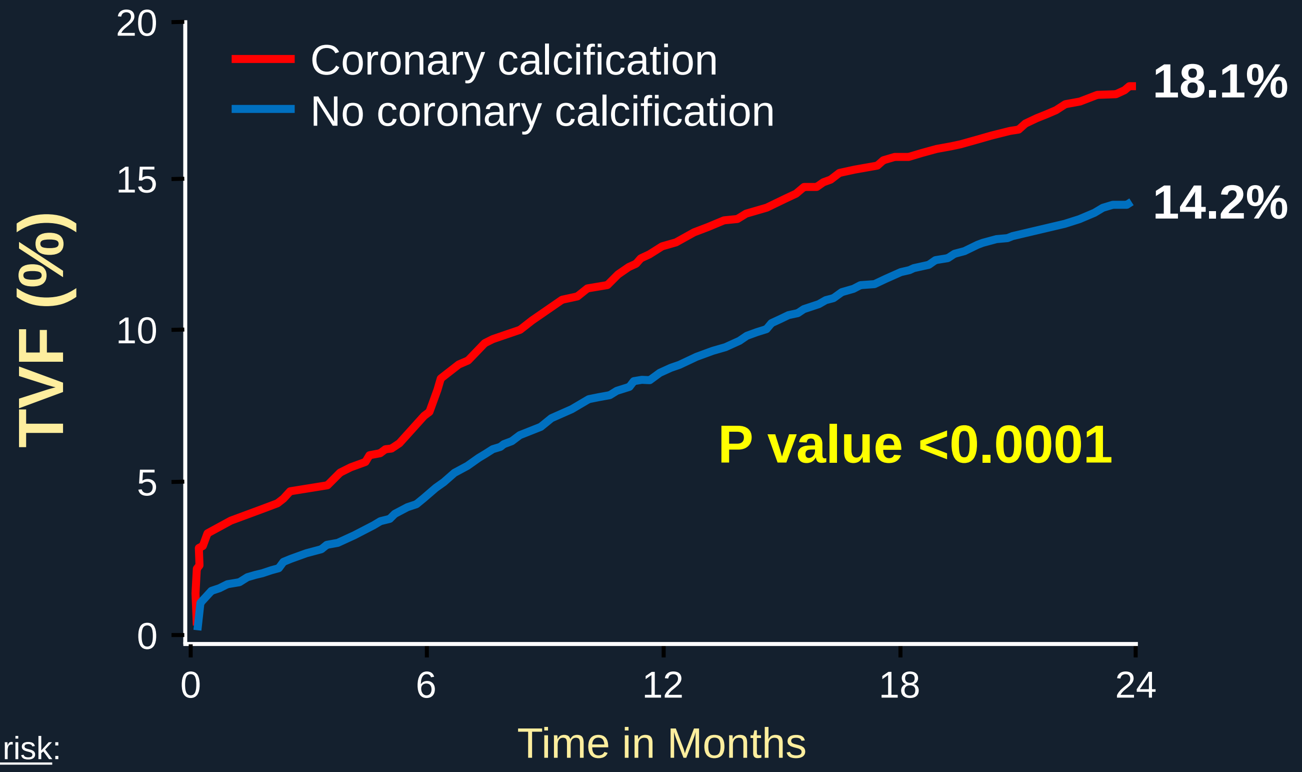




*There was a similar, albeit less strong, correlation after 20 atm inflation (r=-0.58, p=0.0007)

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

ADAPT-DES (N=8,582)
Target vessel failure at 2 years



No at risk:					
CCA	2,644	2,426	2,277	2,178	1,198
No CCA	5,938	5,505	5,177	4,849	2,392

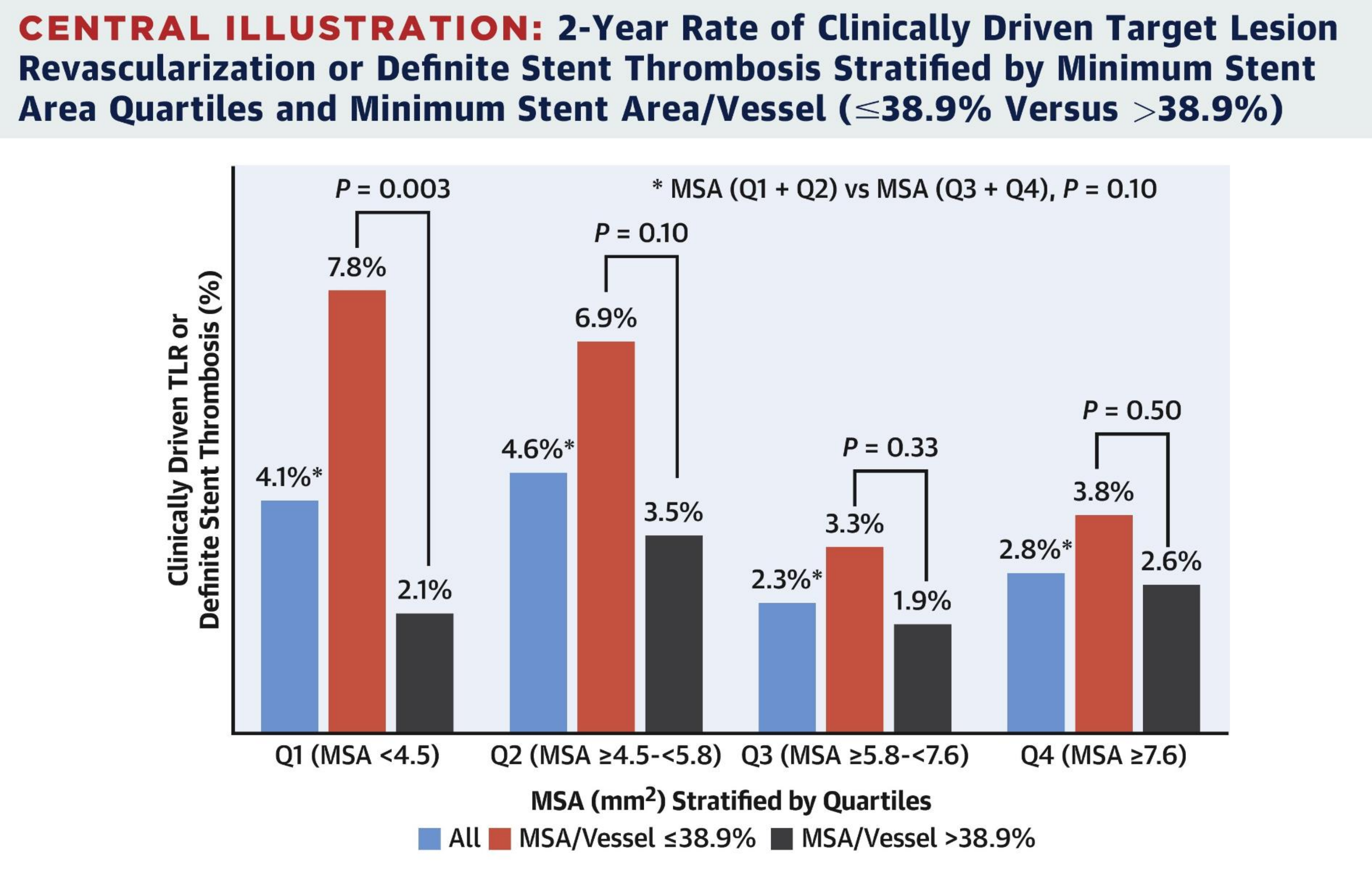
Généreux et al, Int. J. Cardiol 2017

ADAPT-DES (N=8,582): Calcification and 2-year Events

	Calcification		Unadjusted *p*	Adjusted HR [95% CI]	Adjusted *p*
	No (n=5,938)	Yes (n=2,644)			
TVF	14.2%	18.1%	<0.0001	1.23 [1.09, 1.39]	0.0008
MACE	5.6%	8.3%	<0.0001	1.47 [1.22, 1.76]	<0.0001
Death	3.5%	4.8%	0.003	1.15 [0.90, 1.46]	0.26
CV death	2.3%	2.8%	0.09	1.09 [0.80, 1.48]	0.60
MI	4.0%	6.4%	<0.0001	1.61 [1.30, 1.99]	<0.0001
Clinically-driven TVR	9.5%	10.4%	0.16	1.10 [0.94, 1.29]	0.24
Stent thrombosis	0.9%	1.1%	0.32	1.49 [0.92, 2.43]	0.11

Généreux et al, Int. J. Cardiol 2017

Stent Expansion Indexes to Predict Clinical Outcomes: An IVUS Substudy From ADAPT-DES

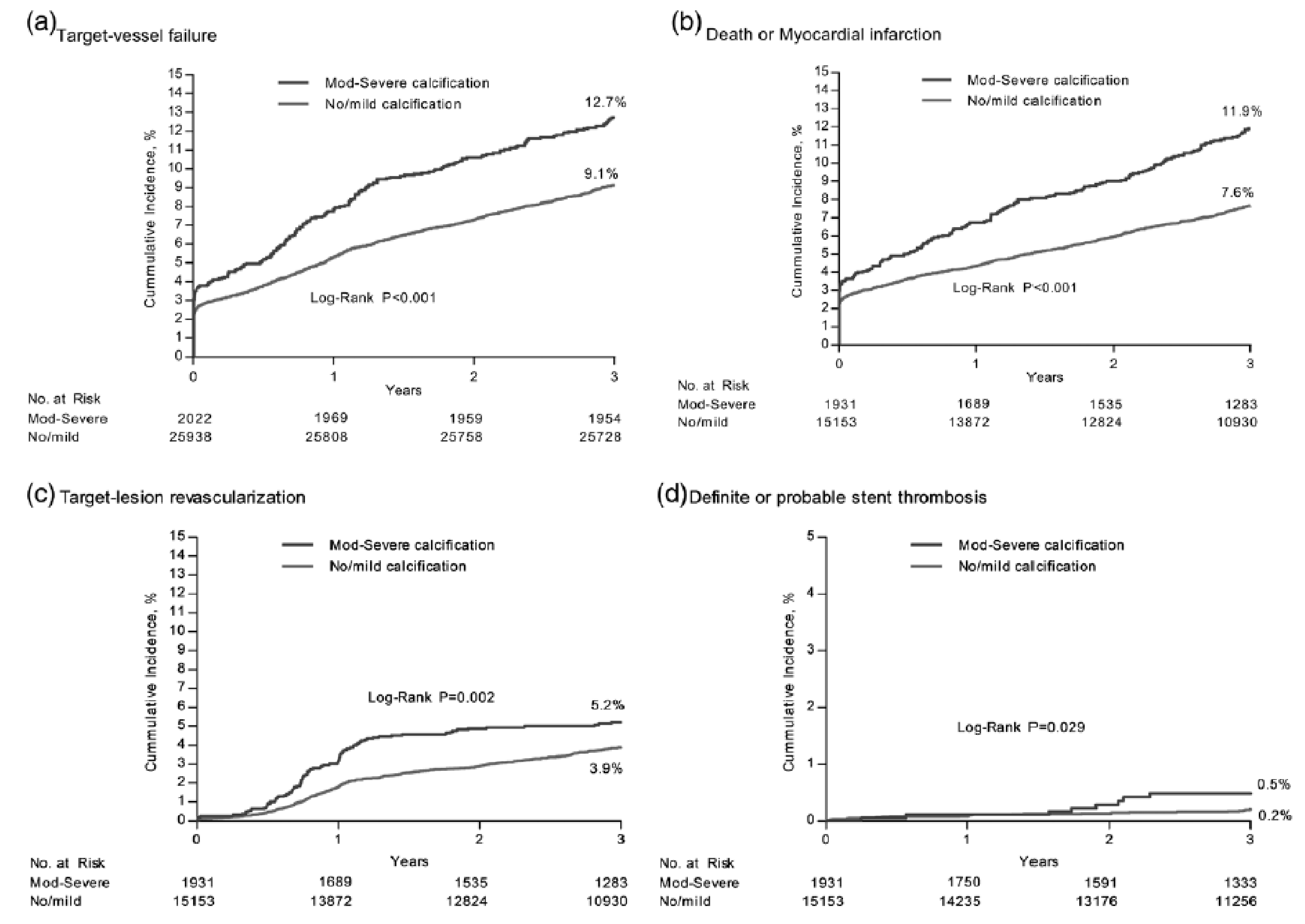


Stent/vessel area at the MSA site, an index of relative stent expansion, was superior to absolute MSA and other expansion indexes in predicting 2-year clinically driven TLR or definite stent thrombosis

Fujimura T. et al. J Am Coll Cardiol Intv. 2021;14(15);1639-50.

Data from IRIS-DES Registries

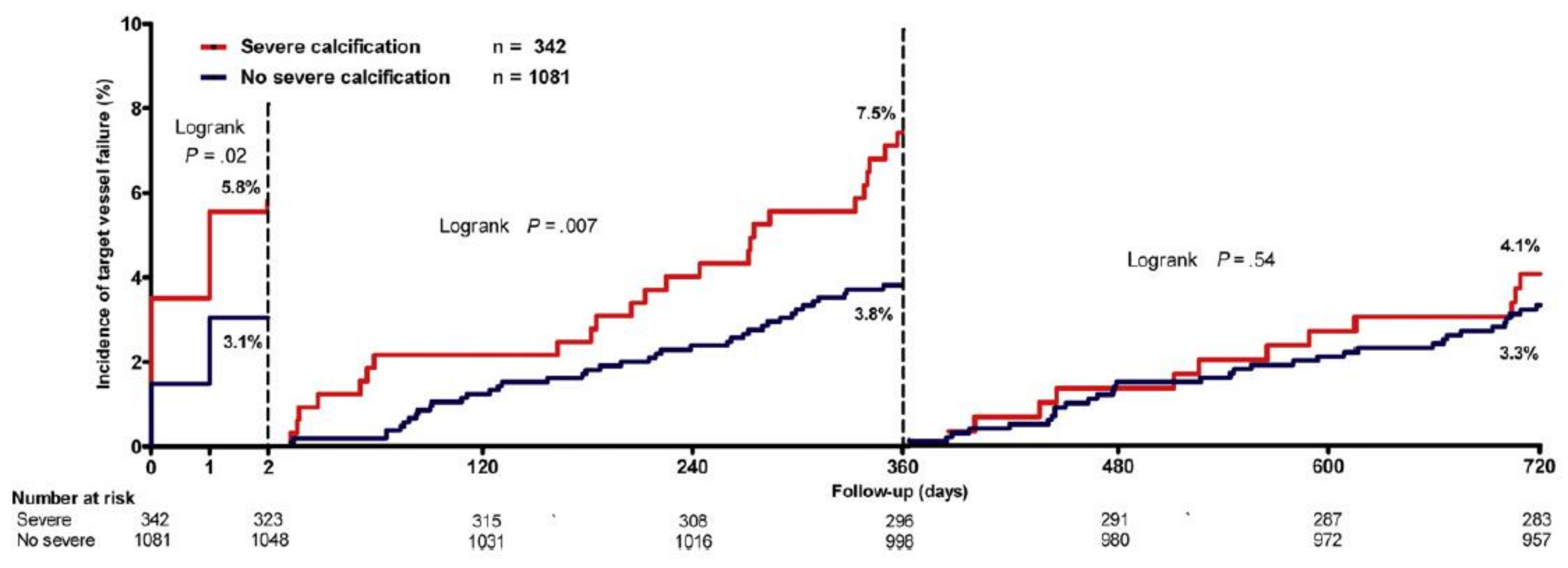
17,084 patients who underwent PCI with DES



CH Lee et al. Coronary Artery Disease 2021, 32:42–50

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

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



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

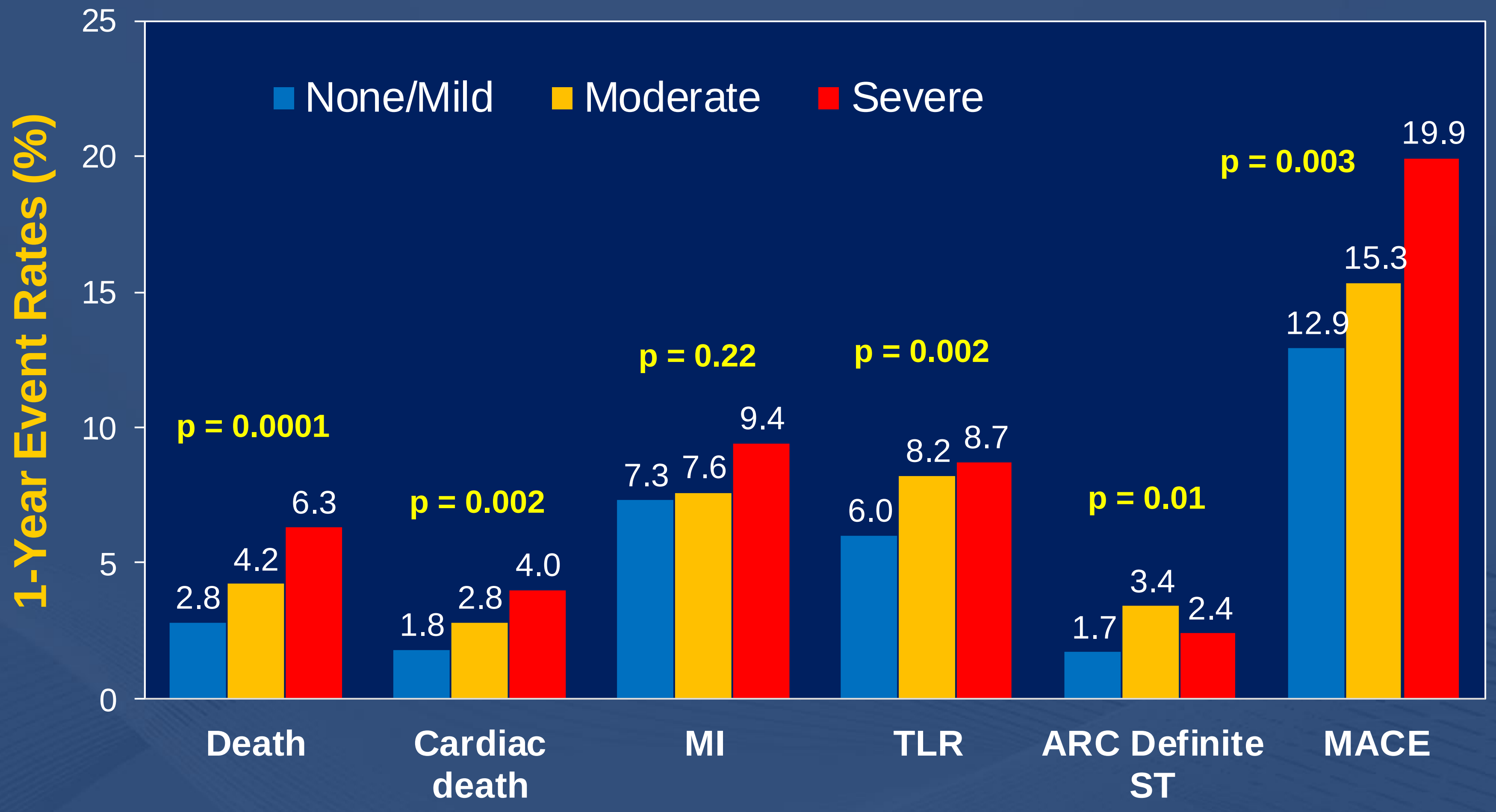
Huisman et al, Am Heart J 2016

ACUITY/HORIZONS-AMI: Implications of Calcified Lesions on PCI in ACS

Post-PCI	Moderate/Severe (n=2,958)	None/Mild (n=5,783)	P value
TIMI flow 0/1	2.6%	1.6%	0.001
TIMI flow 2	6.8%	5.2%	0.004
TIMI flow 3	90.6%	93.1%	<0.0001
No reflow	0.4%	0.1%	0.02
Perforation	0.1%	0.1%	0.41
Spasm	1.1%	0.6%	0.02
Dissection	2.9%	1.2%	<0.0001
Abrupt closure	0.5%	0.1%	0.001

Généreux P et al. J Am Coll Cardiol 2014 13;63:1845-54

ACUITY/HORIZONS-AMI: Implications of Calcified Lesions on PCI in ACS



Généreux P et al. J Am Coll Cardiol 2014 13;63:1845-54

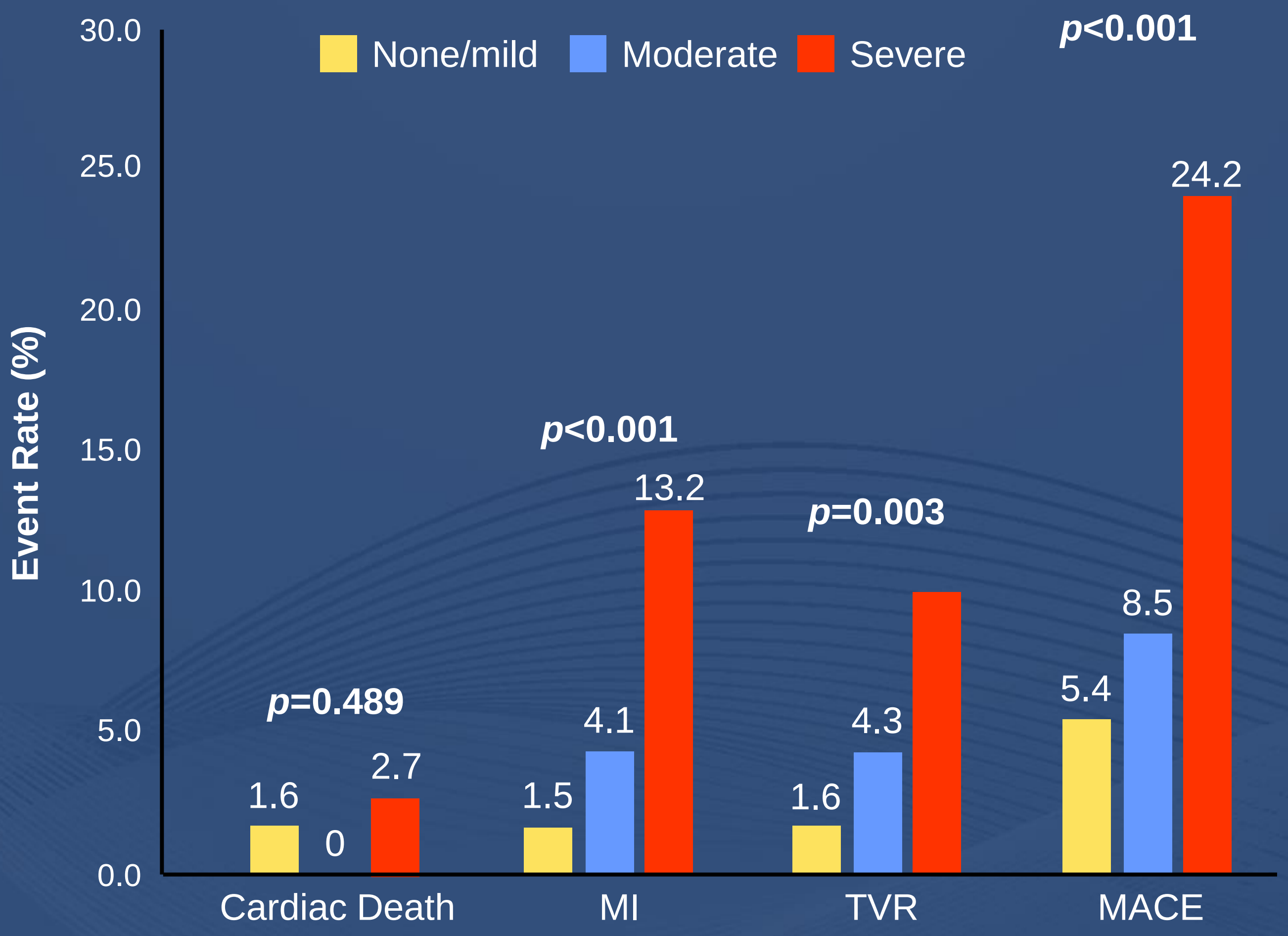
ACUITY/HORIZONS-AMI: Implications of Calcified Lesions on PCI in ACS

	Adjusted Hazard Ratio [95% CI]	P Value
Death	1.10 [0.81,1.48]	0.55
MI	1.06 [0.86,1.30]	0.58
Ischemic TLR	1.44 [1.17,1.78]	**0.0007**
ARC definite ST	1.62 [1.14,2.30]	**0.007**

Généreux P et al. J Am Coll Cardiol 2014 13;63:1845-54

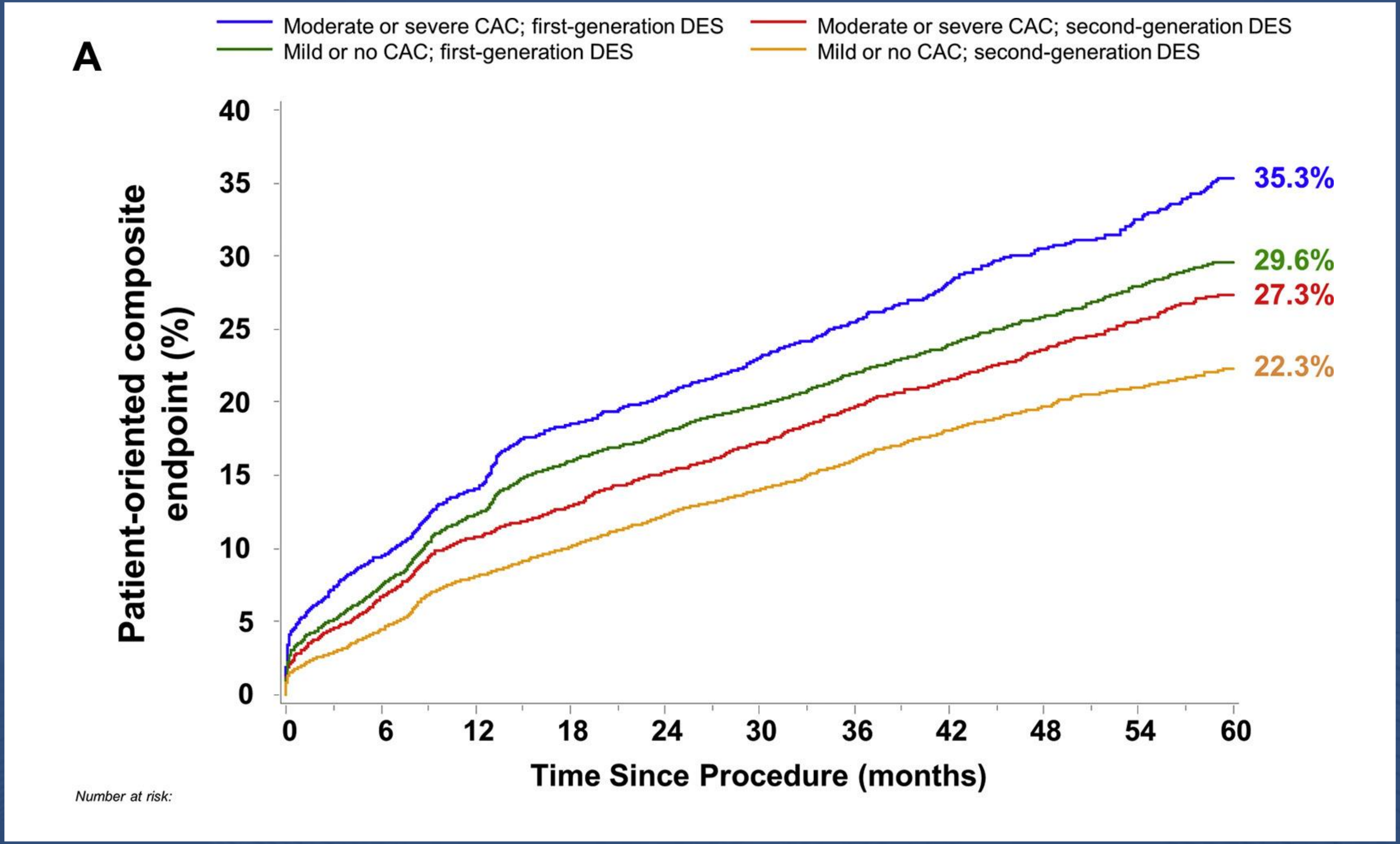
Impact of calcification on percutaneous coronary intervention:

MACE-Trial 1-year results



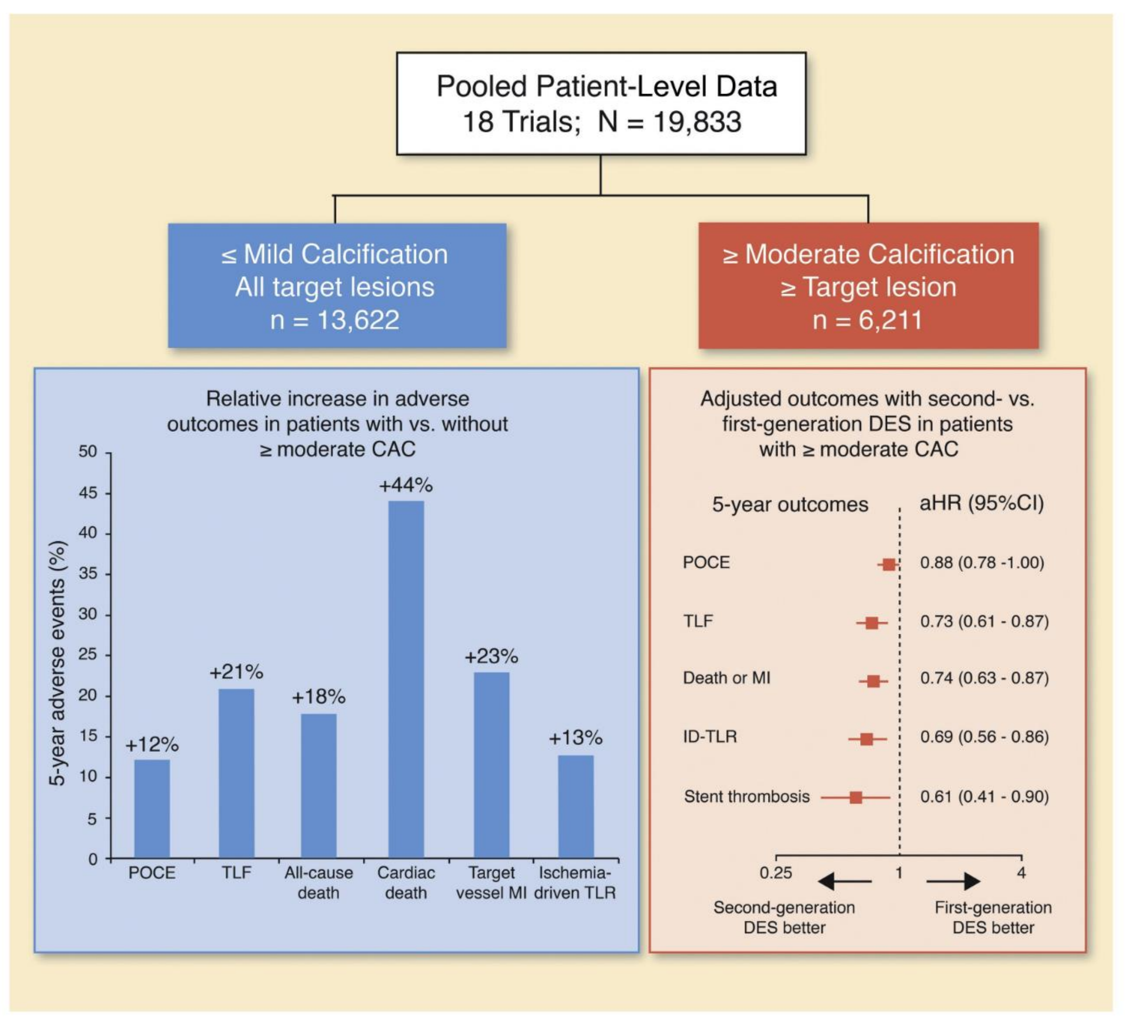
Sharma et al. Catheter Cardiovasc Interv.;1-8 https://doi.org/10.1002/ccd.28099

Coronary Calcification and Long-Term Outcomes According to Drug-Eluting Stent Generation



JACC Cardiovasc Interv. 2020 Jun 22;13(12): 1417-1428.

Coronary Calcification and Long-Term Outcomes According to Drug-Eluting Stent Generation

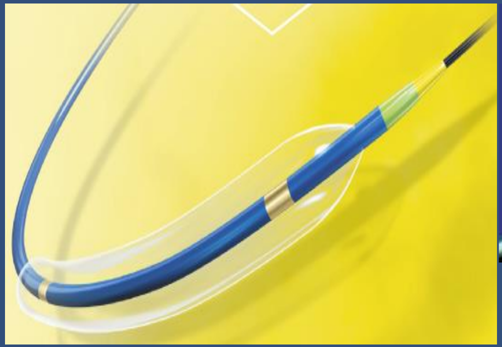


PCI of target lesion moderate or severe CAC was associated with adverse patient-oriented and device-oriented adverse outcome at 5 years

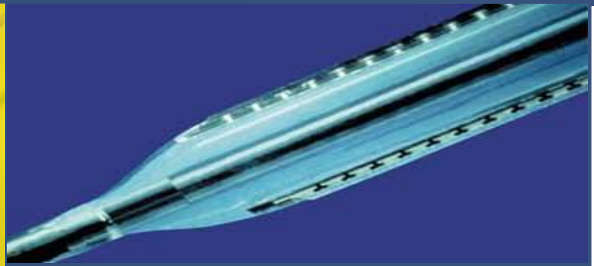
JACC Cardiovasc Interv. 2020 Jun 22;13(12): 1417-1428.

Treatment of Calcified Lesions

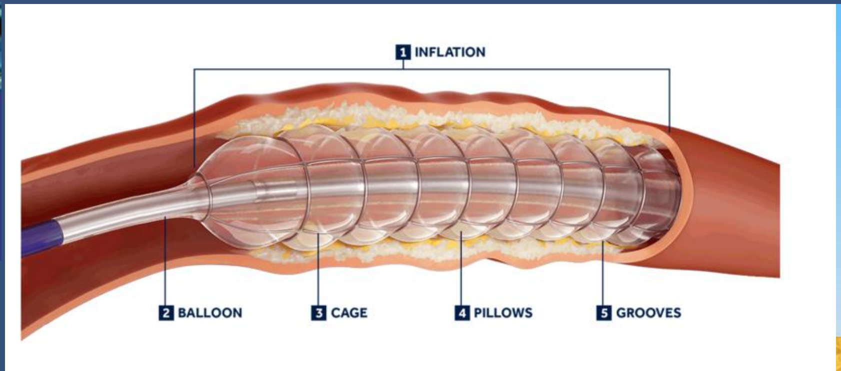
NC balloons



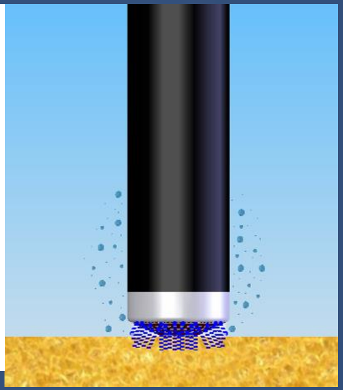
Cutting balloon



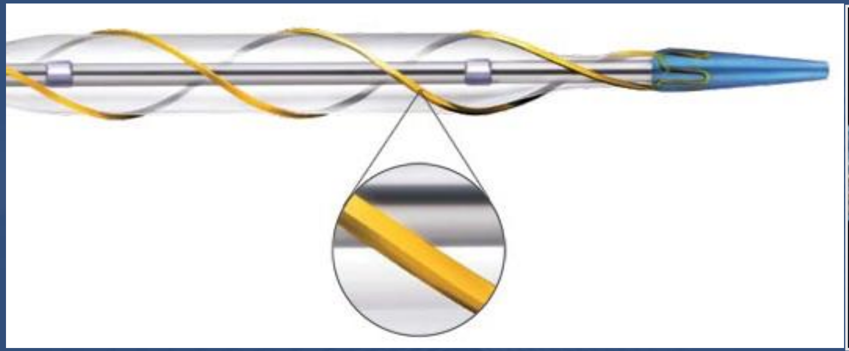
Chocolate PTCA balloon



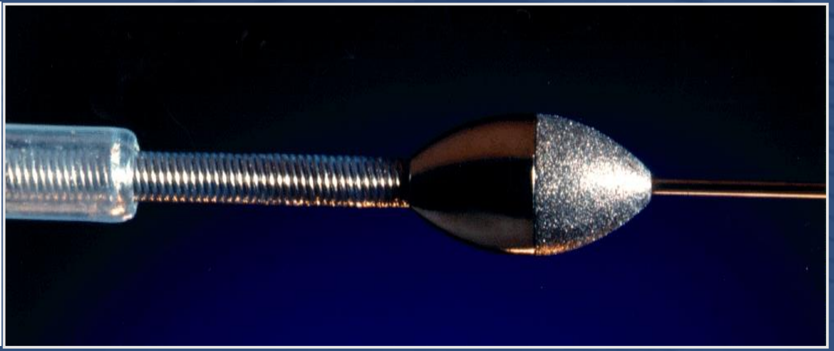
Laser



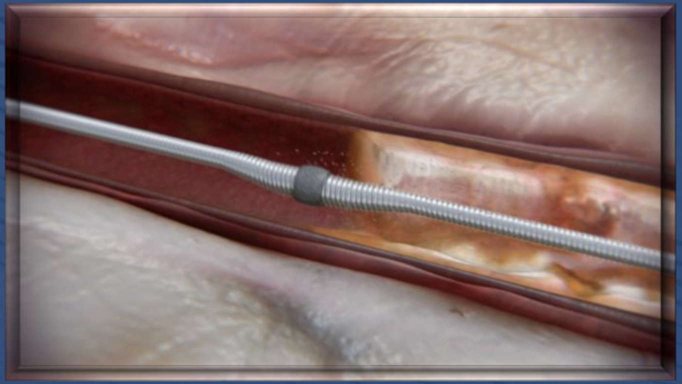
Angiosculpt



Rotational atherectomy



Orbital atherectomy



New Technics

Intravascular lithotripsy

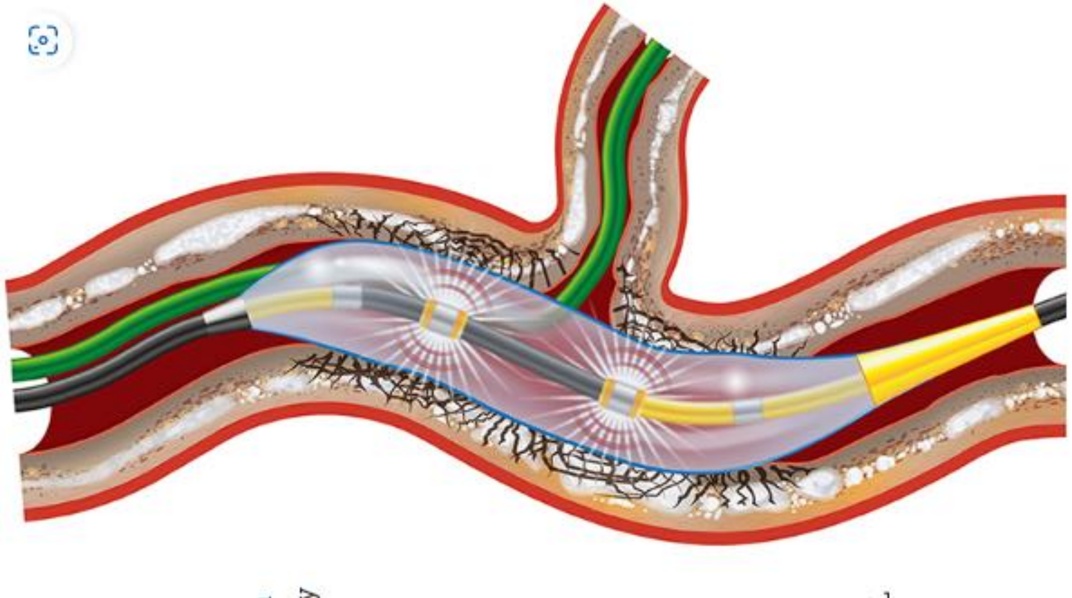
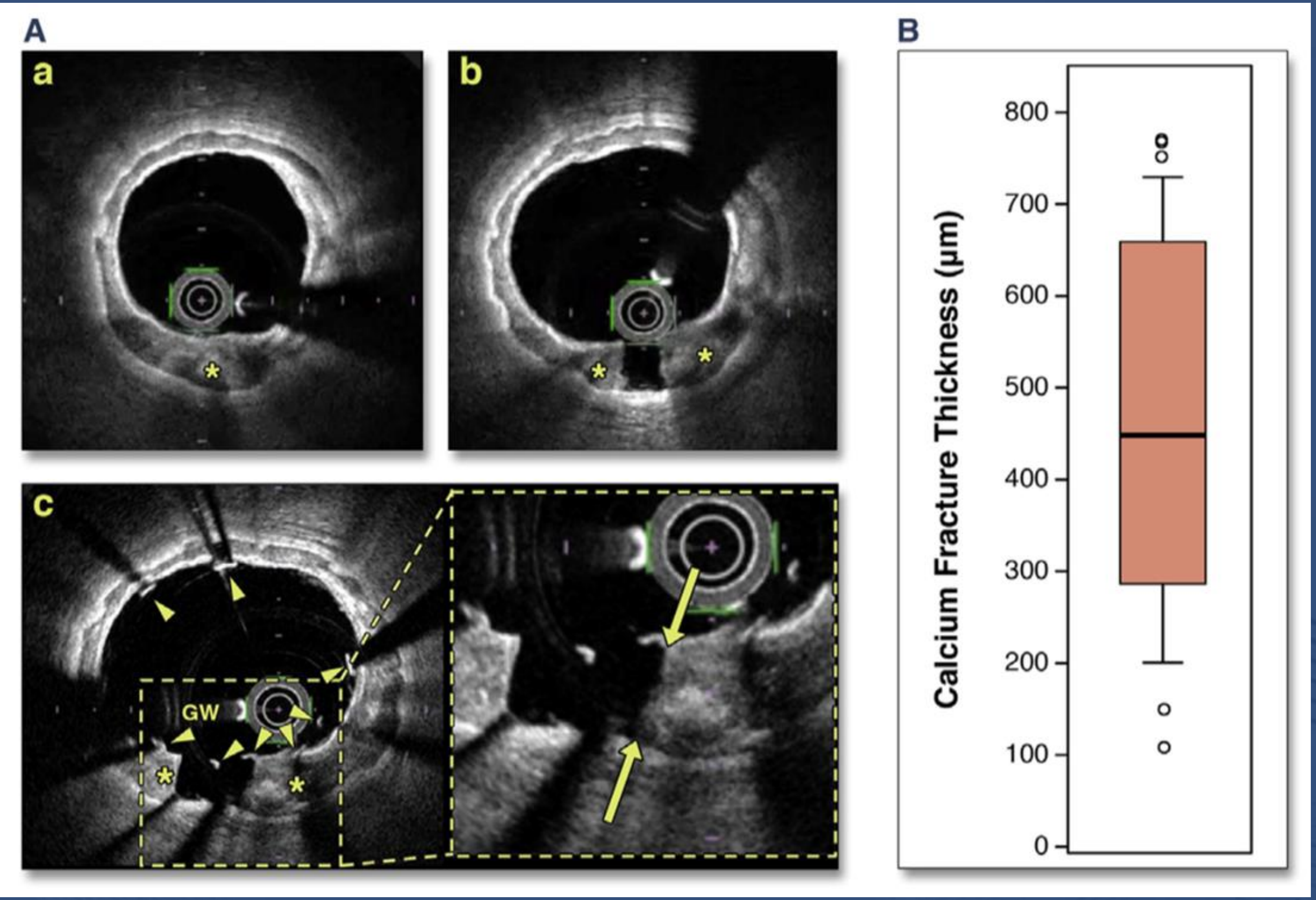


Photo Credit: Shockwave Medical

Catheter Cardiovasc Interv. 2021 Jan 1;97(1): 108-120.

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. T JACC Cardiovasc Imaging. 2015 Oct;8(10):1228-9

Optical frequency-domain predictor good stent expansion after atherectomy

50 de novo heavily calcified lesions that underwent OFDI-guided RA)

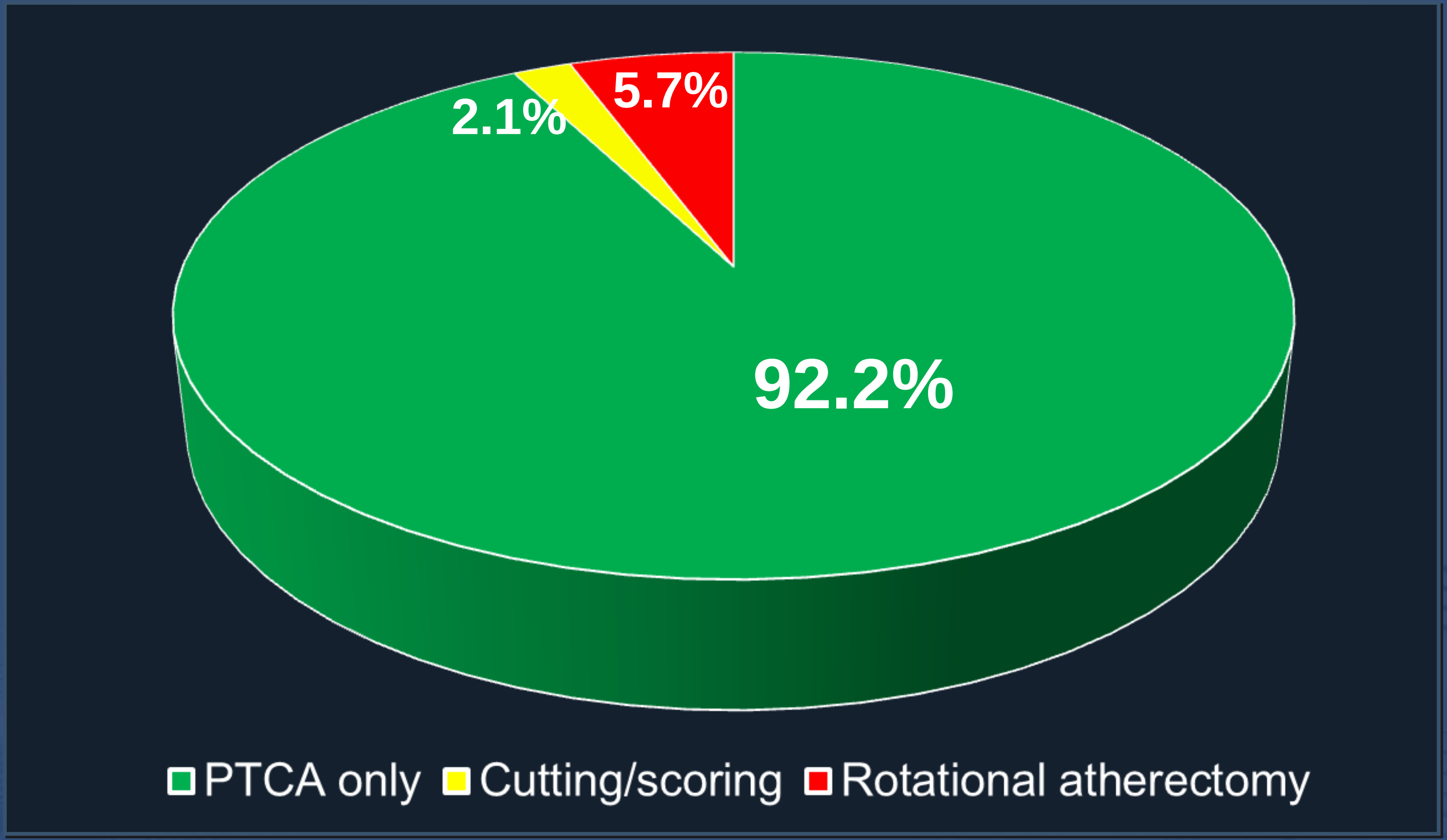
Variable	Univariate predictors		Multivariate predictors		
	Standardized coefficient (β)	P	Standardized coefficient (β)	t-statistics	P
Diabetes mellitus	0.058	0.69			
Hemodialysis	−0.073	0.61			
Burr-to-artery ratio	0.009	0.95			
Arc of calcium	0.075	0.60			
Minimum thickness of calcium	−0.53	< 0.001*	−0.45	−3.78	< 0.001*
Maximum thickness of calcium	0.50	0.50			
Length of calcium	−0.10	0.90			
Dissection formation	0.43	0.002*	0.32	2.65	0.011*

Minimum of thickness of calcification in the intima and dissection formation were positively associated with good stent expansion after RA.

Kobayashi N. The International Journal of Cardiovascular Imaging (2018) 34:867–874

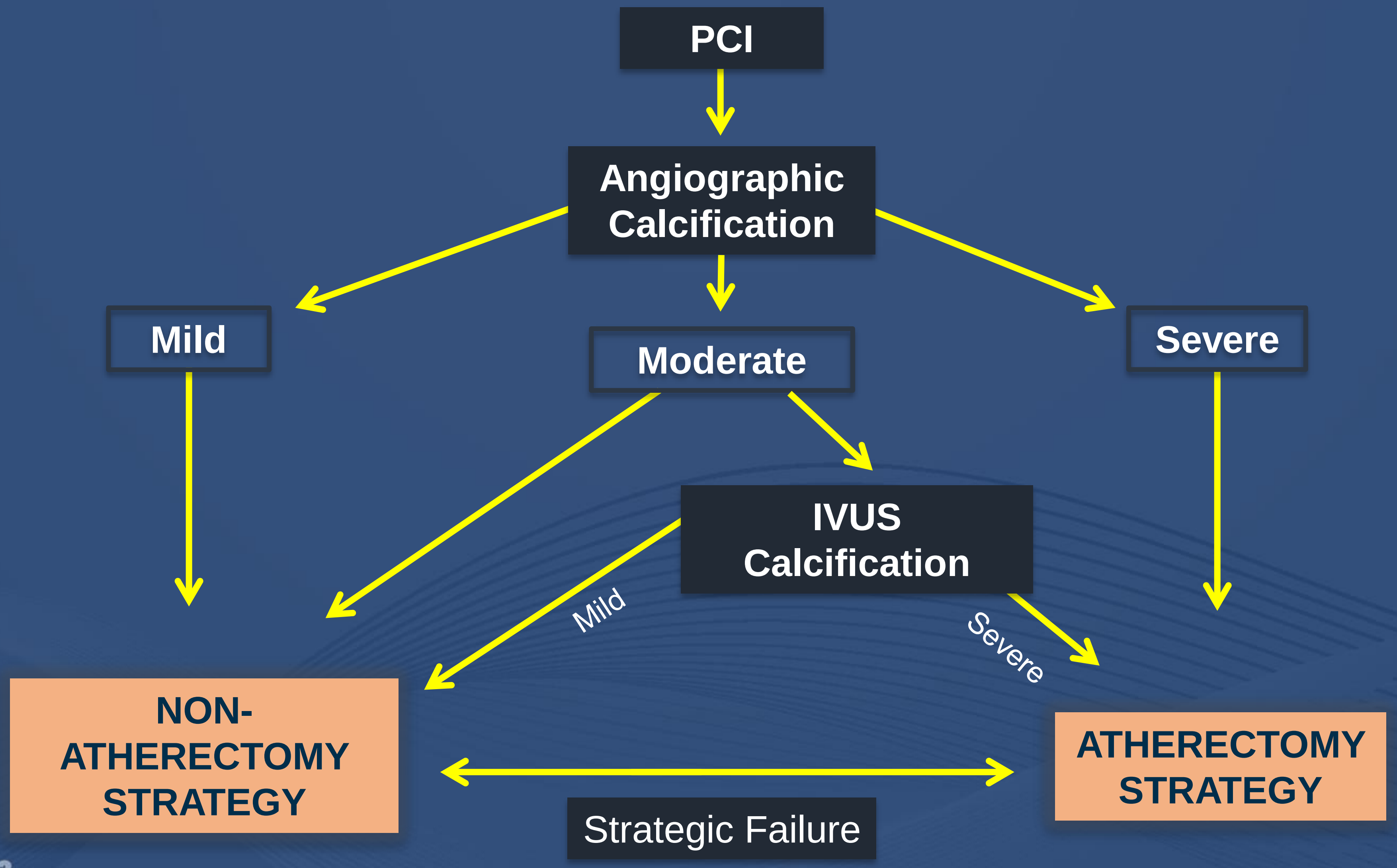
ADAPT-DES (11 center all-comers registry): Calcified lesion preparation

N = 2,644 patients



Généreux et al. Int. J. Cardiol 2017

Potential Strategy for Calcified Lesions



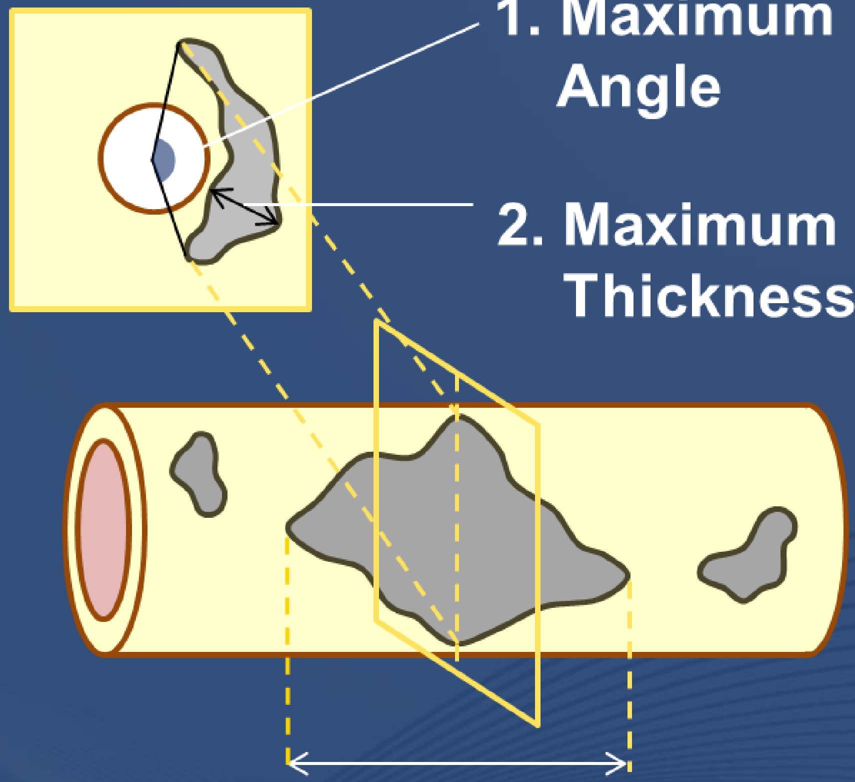
Tomey et al, JACC CV Intv 2014

PCI Guideline recommendation

- In patients with fibrotic or heavily calcified lesions, plaque modification with rotational atherectomy can be useful to improve procedural success. **(class 2a-B)**
- In patients with fibrotic or heavily calcified lesions, plaque modification with orbital atherectomy, balloon atherotomy, laser angioplasty, or intracoronary lithotripsy may be considered to improved procedural success. **(class 2b-B)**
- Cutting or scoring balloon angioplasty or rotational atherectomy may be required in selected lesions—particularly those with heavy calcification—in order to adequately dilate lesions prior to stent implantation
- However, studies investigating the systematic use of these adjunctive technologies have failed to show clear clinical benefit.

Circulation. 2022 Jan 18;145(3):e4-e17
Eur Heart J. 2019 Jan 7;40(2):87-165

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			

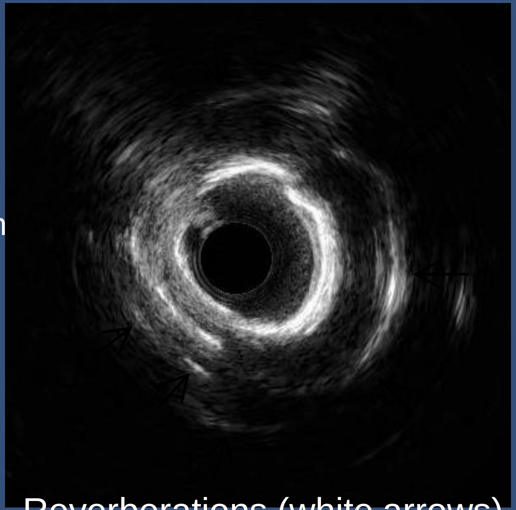
Fujino et al, Eurointervention 2018

IVUS-Based Calcium Scoring System

Example:
Calcium Score=0

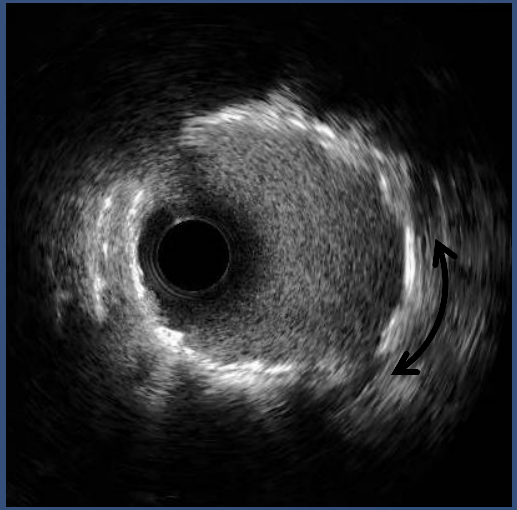
- Length of Ca >270º = 4.1mm
- Calcified nodule (-)
- Vessel diameter = 4.4mm
- Reverberation arc >90º

Pre-PCI



Reverberations (white arrows)

Post-PCI



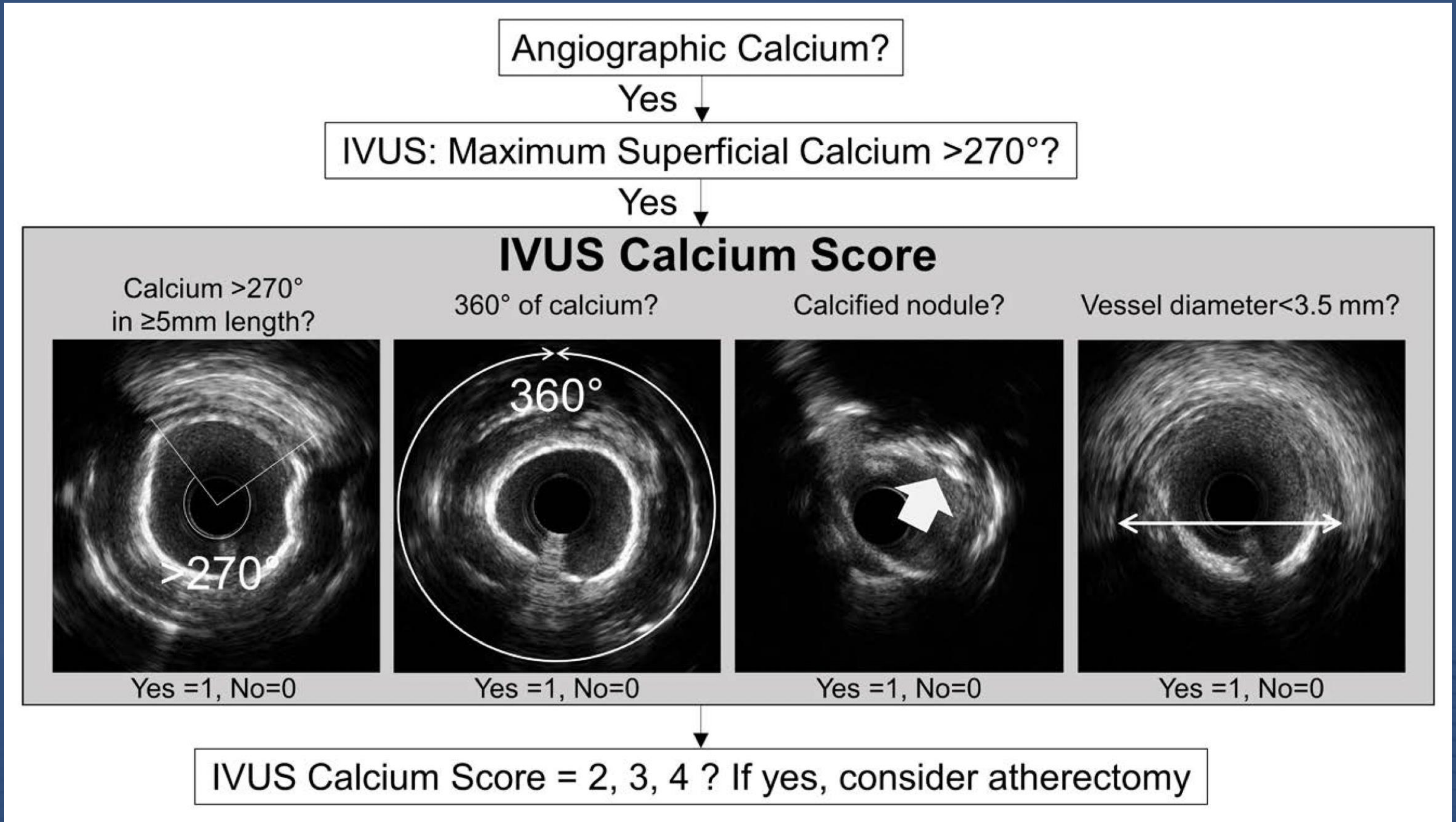
Excellent expansion despite severe Ca
Stent area= 9.7mm^2

Note Ca fracture (newly visible perivascular tissue, double-headed white arrow)

	Cut-off value	AUC	Score
Length of Calcium > 270º (per 5mm)	5.4	0.73	≤5mm → 0 point >5mm → 1 point
Vessel diameter (per 1mm)	3.4	0.74	>3.5mm → 0 point ≤3.5mm → 1 point
Calcified nodule	NA	NA	Absent → 0 point Present → 1 point
Reverberation arc (per 90º)	97º	0.81	>90º → 0 point ≤90º → 1 point

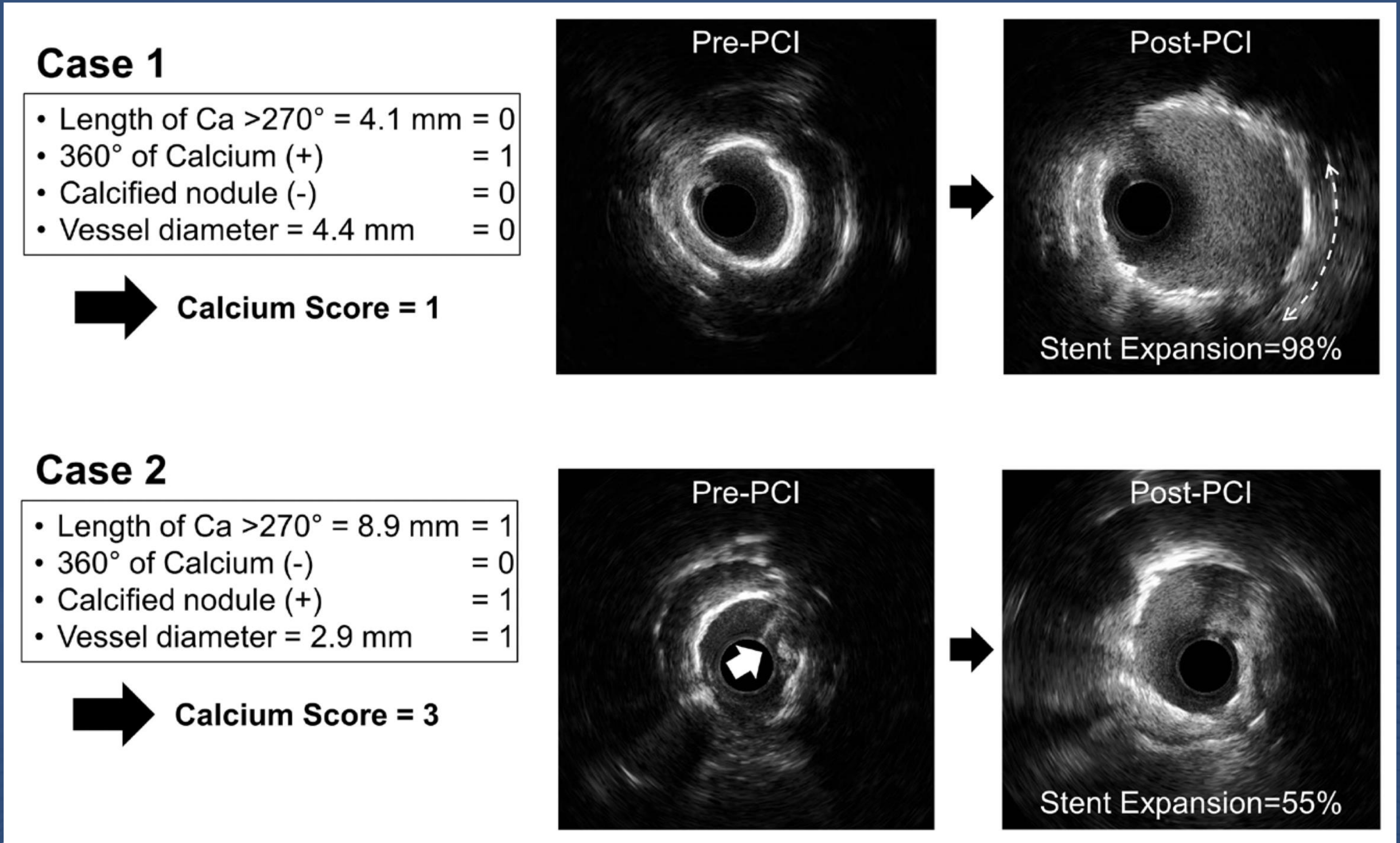
Zhang et al, TCT2019

IVUS-Based Calcium Scoring System



Zhang et al, Circ CV Intv 2021

Calcium Scoring System (examples)



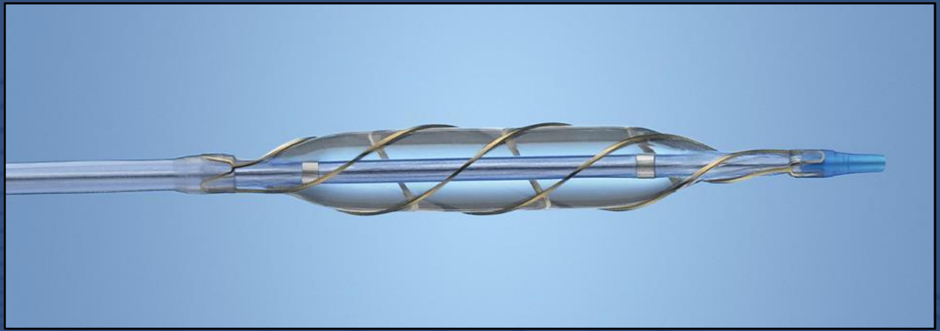
Zhang et al, Circ CV Intv 2021

Angiosculpt Balloon

AngioSculpt is a scoring balloon catheter comprised of two main components:

1. Angioplasty balloon catheter

- semi-compliant nylon balloon
- coaxial, nylon shaft
- 2 marker bands



2. Scoring element

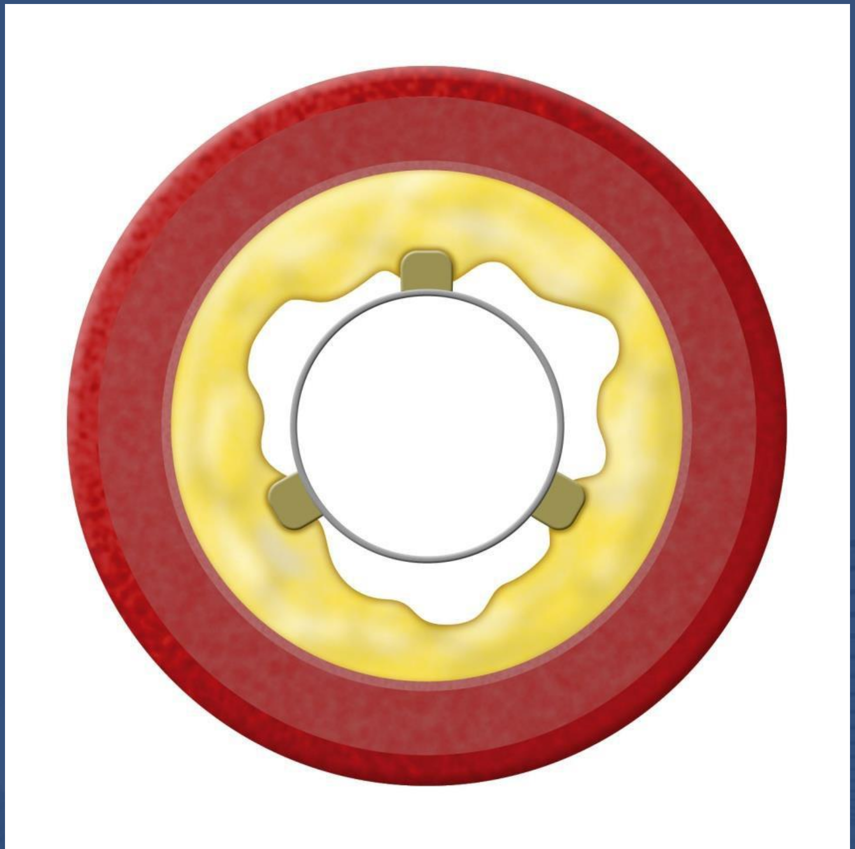
- laser-cut nitinol hypotube
- helical configuration

Scoring Mechanism of Action

AngioSculpt is the only device to offer 3 distinct benefits with one device:

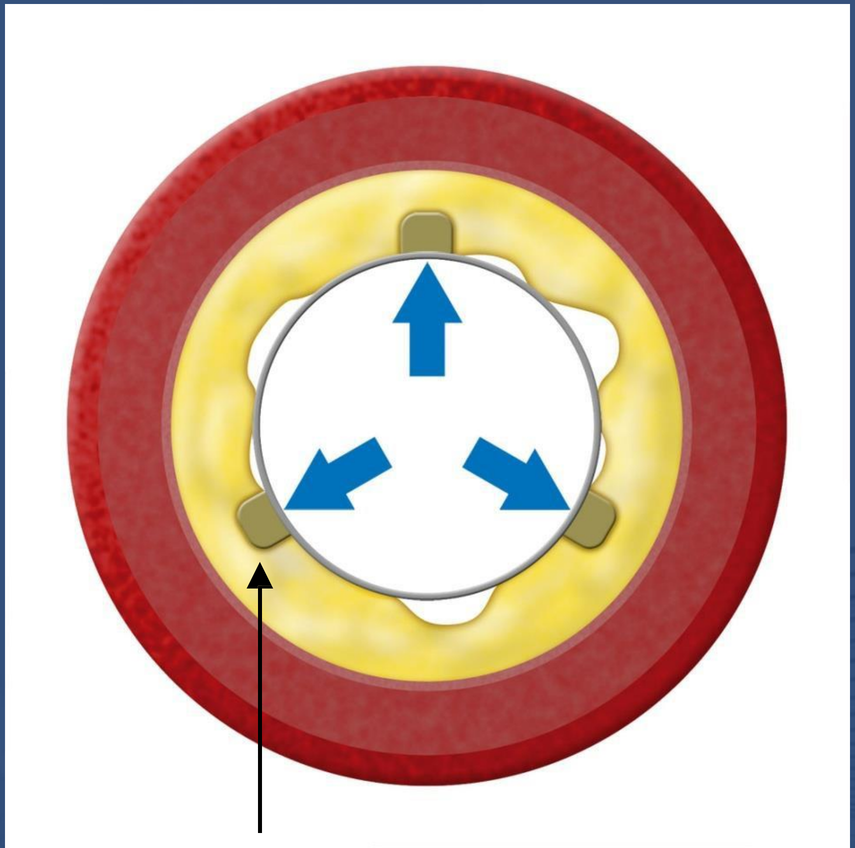
- Precision
- Predictable Power
- Safety

Precision – Minimal Slippage



- Rectangular edges “lock” the device into lesion
- No significant device slippage = less damage to healthy tissue

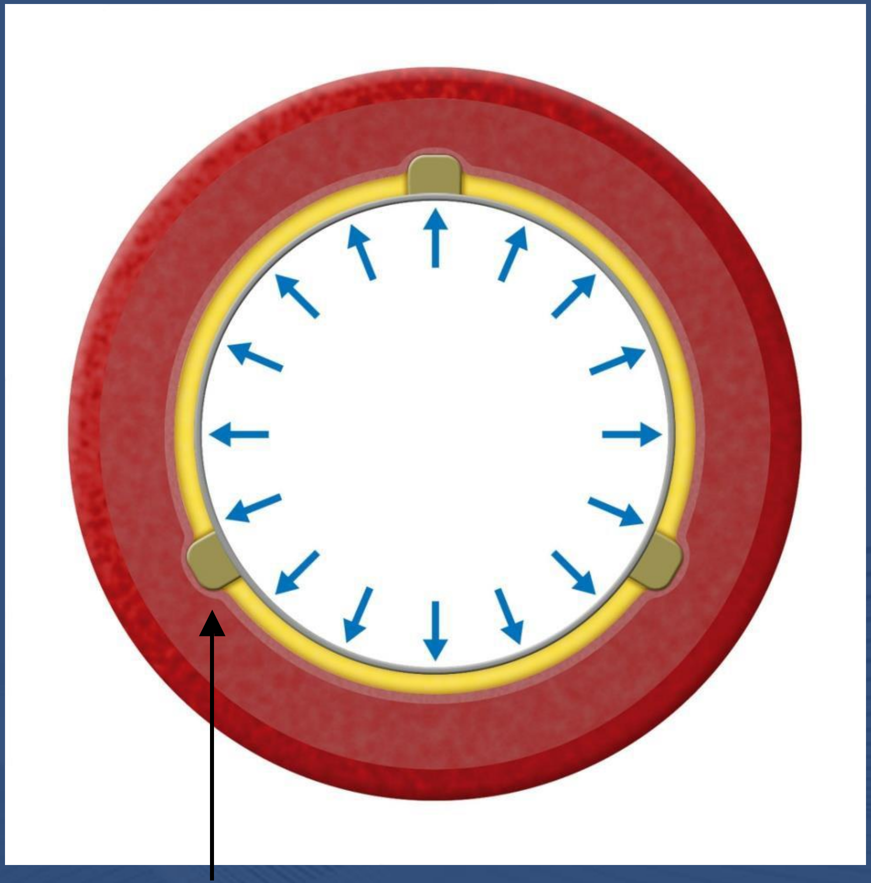
Power – More Dilatation Force



15-25X force of POBA*

- Leading edges drive outward force 15-25 times that of POBA
- Helical arrangement of scoring element creates uniform luminal enlargement

Safety – Low Dissection Rate



1X force post scoring*

- Post-scoring, outward forces are designed to be equivalent to POBA
- Low dissection rate
- Low rate of adjunctive stenting

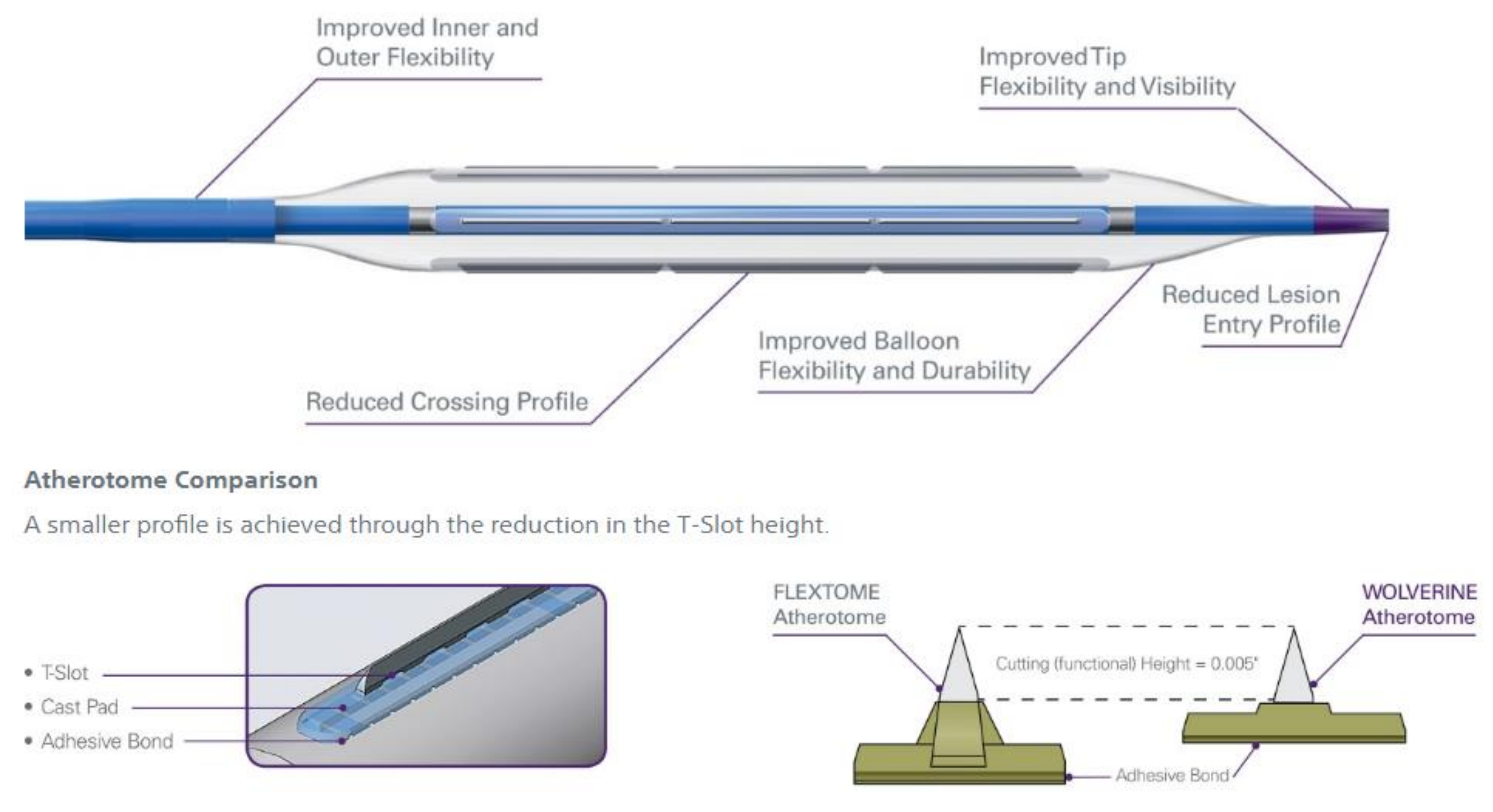
Features & Benefits - Scoring Element

Feature	Benefit
• Nitinol material	• Facilitates balloon deflation
• Helical shape	• Uniform, circumferential scoring • Reduces balloon slippage
• Electropolished rectangular edges	• Provides safe scoring – minimize dissections

Element strut height

.005” or .007”

Cutting Balloon



Cutting Balloon to Optimize Predilation for Stent Implantation: The COPS Randomized Trial

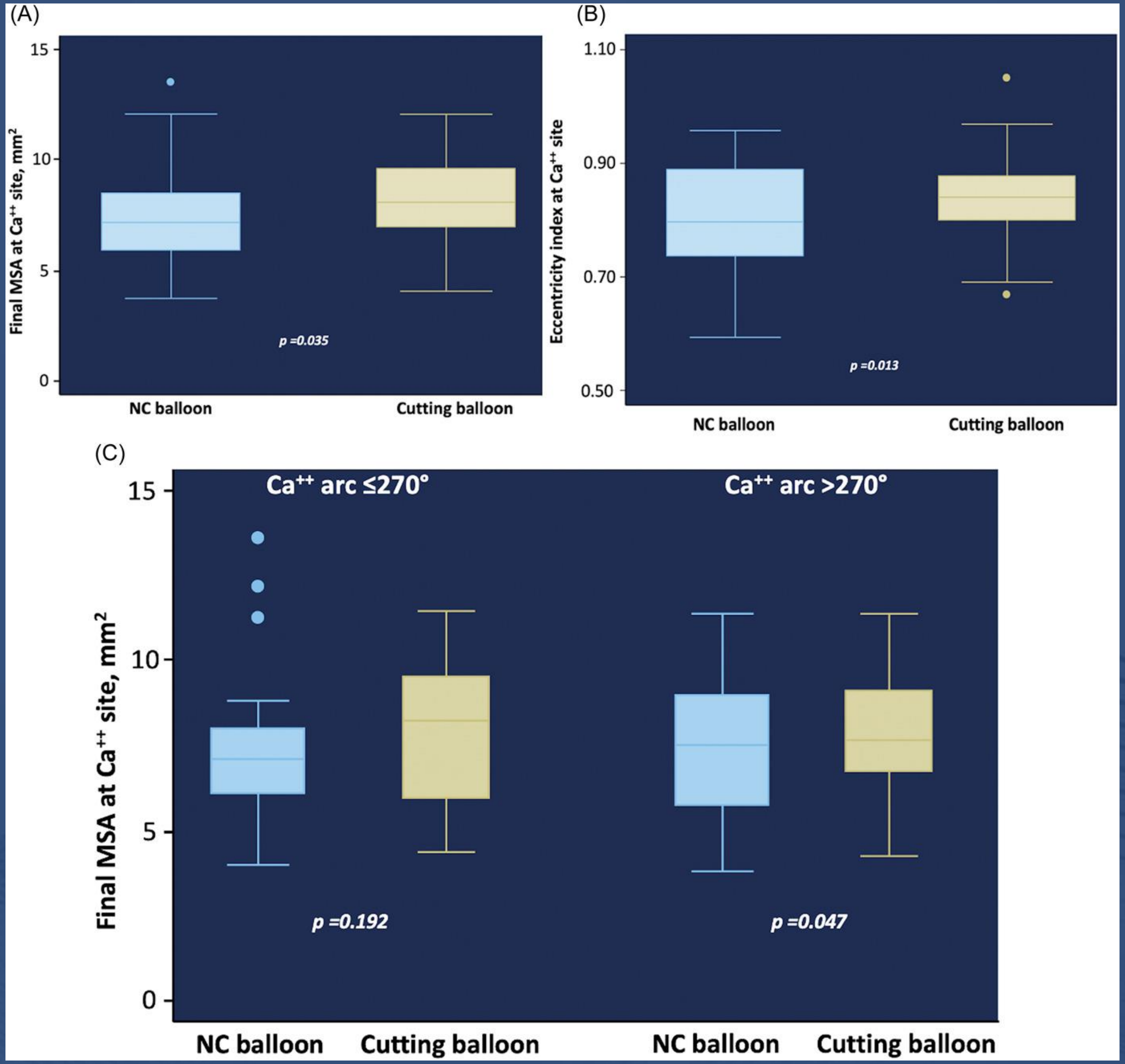
- 100 consecutive patients with calcified lesions
- Randomized to cutting balloon vs. non-compliant balloon

- Lesions excluded
  - In-stent restenosis
  - Graft restenosis
  - Thrombotic lesions

- Lesion characteristics
  - RVD 3.4 mm
  - Average calcium length: 12 mm
  - B2/C 71%

Mangieri A, Nerla R et al. Catheter Cardiovasc Interv. 2023 Mar;101(4):798-805.

Cutting Balloon to Optimize Predilation for Stent Implantation: The COPS Randomized Trial



Mangieri A, Nerla R et al. Catheter Cardiovasc Interv. 2023 Mar;101(4):798-805.

Israeli Registry -Baseline Characteristics

- 521 consecutive patients scheduled for PCI
- 521 patients and 745 lesions treated
- Lesions excluded
  - Without calcification
  - With untreated visible thrombus
- Lesion characteristics
  - RVD 2.48 mm
  - Average lesion length: 19.2 mm
  - Moderate/severe calcification: 75%
  - B2/C 53%
  - Bifurcations 18%
  - Angulated 43%

AR-
1154
Rev. A

Grenadier E, Kerner A et al. *Am J Cardiol*. 2008;102(suppl 8):53i.

Israeli Registry – Results (Acute)

	Pre-ASC	Post-ASC	Post-Stent
MLD (QCA) mm	0.22 ± 0.17	2.04 ± 0.57	2.49 ± 0.69
DS%	84.8 ± 13.9	21.7 ± 12.7	5.7 ± 2.4
CSA (IVUS) mm2	2.49 ± 0.39	3.72 ± 1.12*	5.30 + 2.05*

*p<0.001

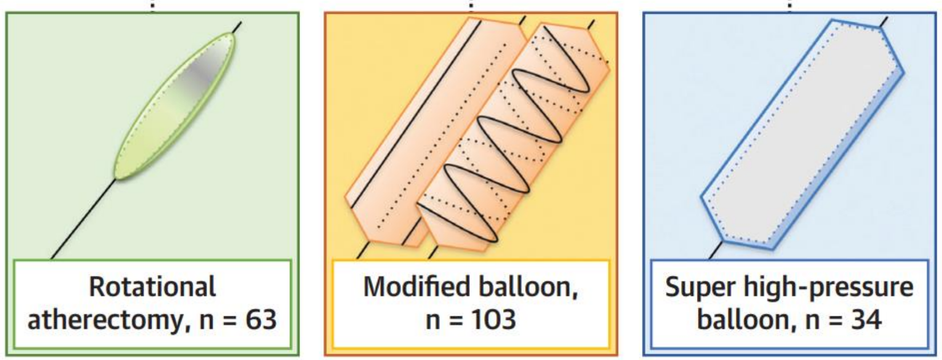
- Device slippage 1.2% lesions (9/745)
- Significant dissection (≥ type C) post ASC 1.5%
- No device-related perforations

Grenadier E, Kerner A et al. *Am J Cardiol*. 2008;102(suppl 8):53i.

Rotational Atherectomy or Balloon-Based Techniques to Prepare Severely Calcified Coronary Lesions

Patients With Severely Calcified Coronary Artery Lesions Amenable to Drug-Eluting Stent Implantation and Enrolled in the Randomized PREPARE-CALC and ISAR-CALC Trials (N = 274)

Patients with available OCT imaging after stenting included in the pooled analysis (n = 200)

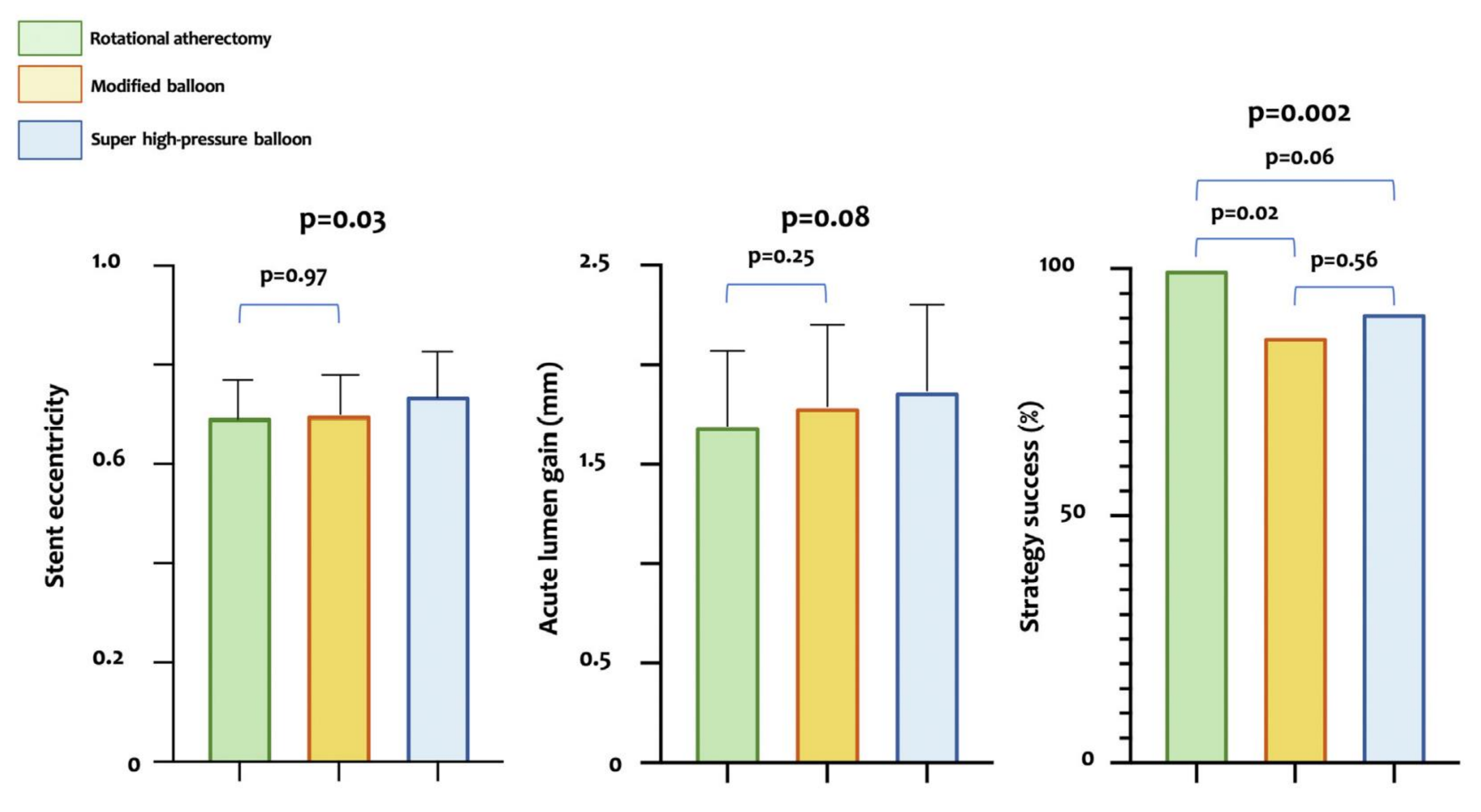


Main outcomes	Rotational atherectomy	Modified balloon	Super high-pressure balloon	Main findings
Stent expansion, %	73.2 ± 11.6	70.8 ± 13.6	71.8 ± 12.2	No significant difference
Maximal stent eccentricity	0.70 ± 0.06	0.70 ± 0.08	0.74 ± 0.09	Super high-pressure balloon better
Strategy success, %	100	86.4	91.2	Rotational atherectomy better

JACC Cardiovasc Interv. 2022 Sep 26;15(18):1864-1874.

Rotational Atherectomy or Balloon-Based Techniques to Prepare Severely Calcified Coronary Lesions

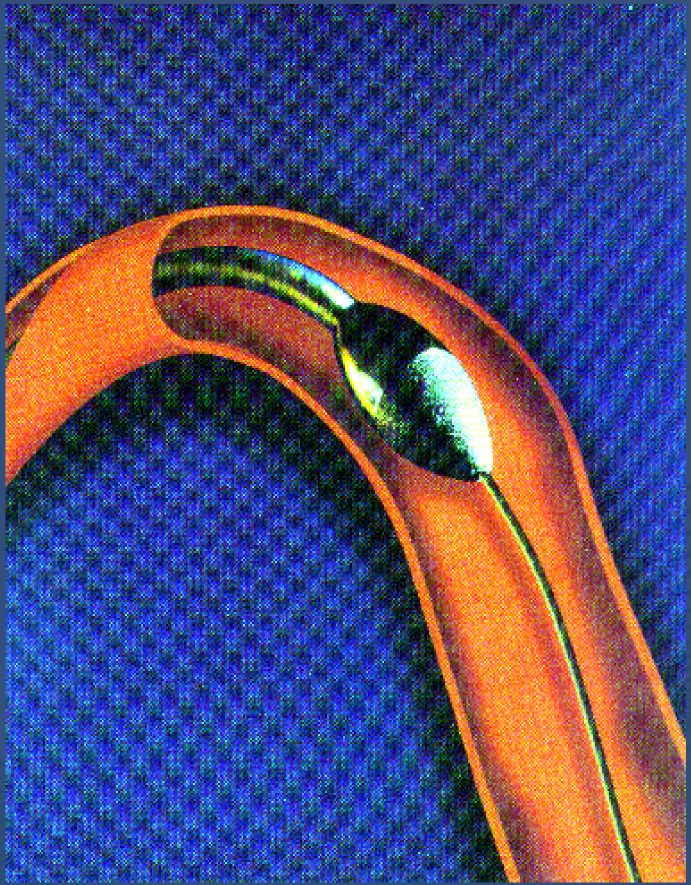
FIGURE 3 Stent Eccentricity, Acute Lumen Gain, and Strategy Success According to Lesion Preparation Strategies



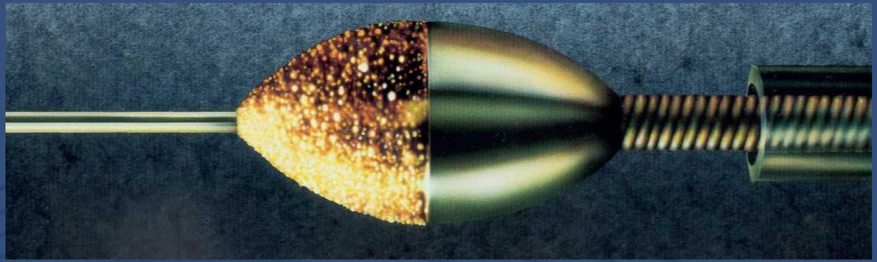
The height of the bars and the error bars display means and SDs, respectively.

JACC Cardiovasc Interv. 2022 Sep 26;15(18):1864-1874.

Rotational Atherectomy (Rotablator)



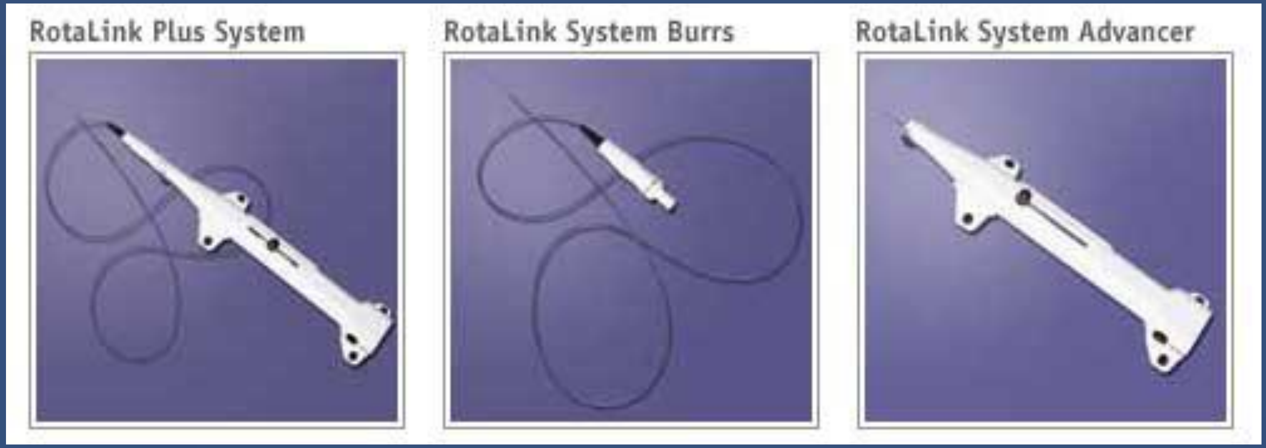
- Burr : covered with 20-30 um diamond chips
- Guidewire : 0.009 inch with 0.014 inch tip



Rotablator Rotational Atherectomy System

FDA approved May 1993

Rotalink and Burr

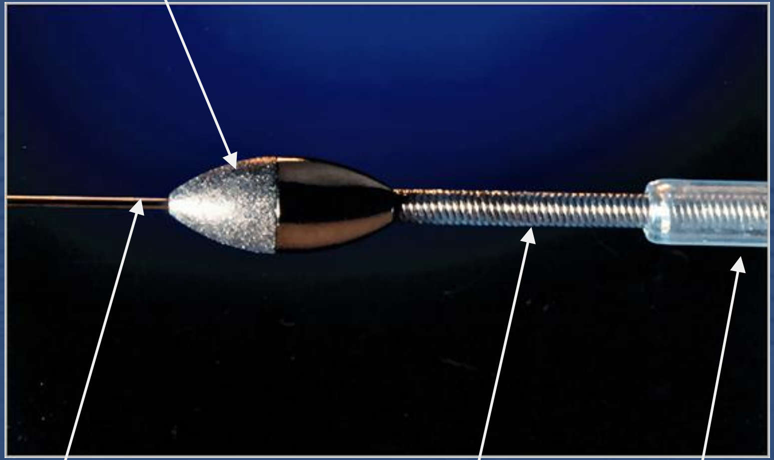


Pre-assembled

Separated

Diamond coated burr: 1.25 mm - 2.5 mm (0.25 mm increments)

To avoid damage to the burr, remove distal gripper after connection to Advancer



Rota-wire

Drive shaft

Sheath: 4.3 F O.D.

Console, Foot pedal, Gas, and Fluid

Procedure timer

Reset button

Dynaglide™ indicator

Rotational speed display (tachometer)

Turbine pressure gauge (delivered to advancer)

Turbine pressure control knob (adjusts RPM)

Event timer

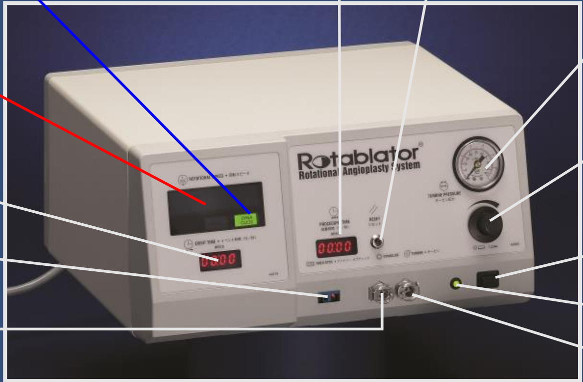
Advancer fiber optic tachometer connector

Power switch

Power lamp

DynaGlide™ connector

Advancer turbine pneumatic connector

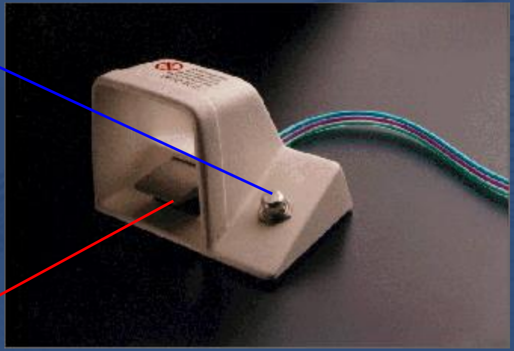


DynaGlide™ Connectors (blue color)

Compressed Air or Nitrogen connector

DynaGlide™ button (low/high speed selector)

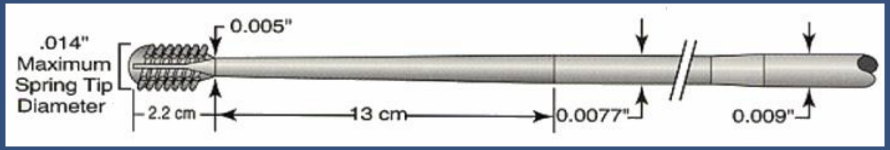
Foot switch



Power Cord

Rotawire

RotaWire floppy guidewire



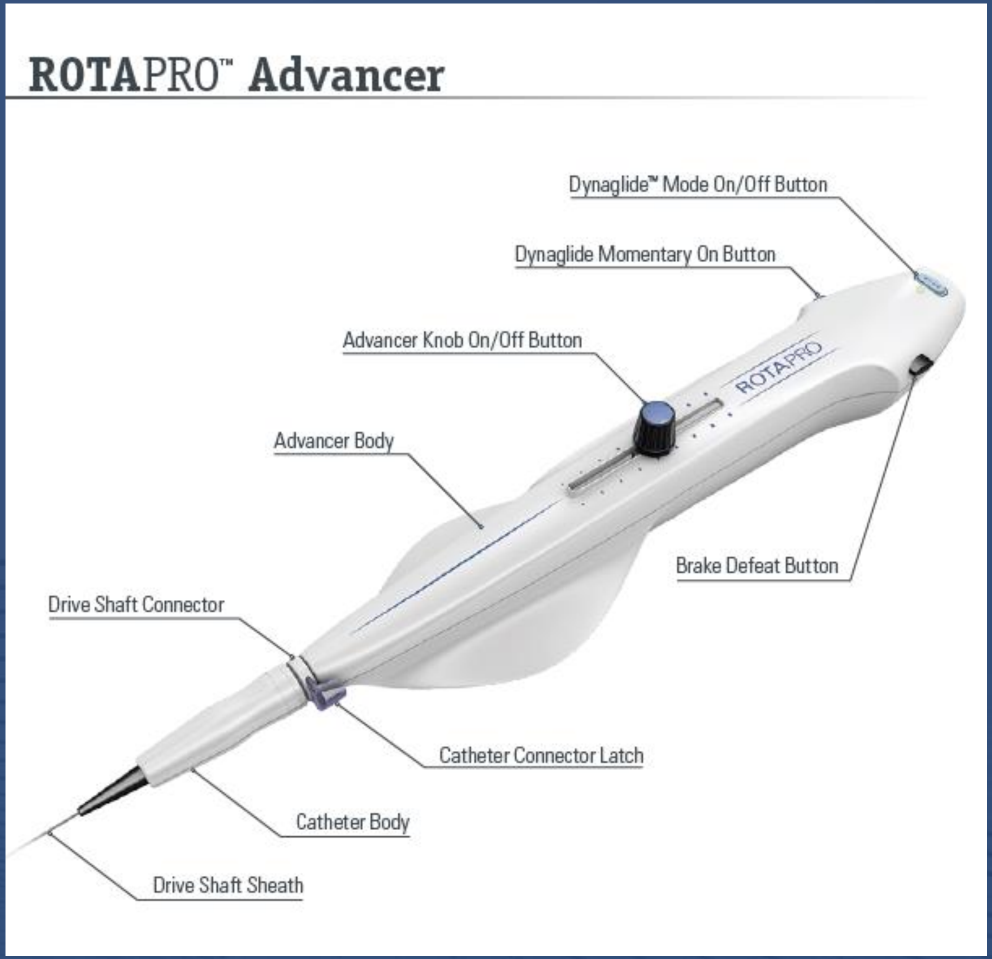
- Tip diameter= 0.014 inch, body diameter= 0.009 inch
- Spring tip length = 22 mm
- 'Long neck' segment: 130 mm, 0.005 – 0.0077 inch
- Total length 3300 mm

RotaWire extra support guidewire

- Tip diameter= 0.014 inch, body diameter= 0.009 inch
- Spring tip length = 28 mm
- 'Short neck' segment: 50 mm, 0.005 – 0.0077 inch
- Total length 3330 mm

Cf) Rotalink length = 1350 mm

ROTAPRO™ Rotational Atherectomy System

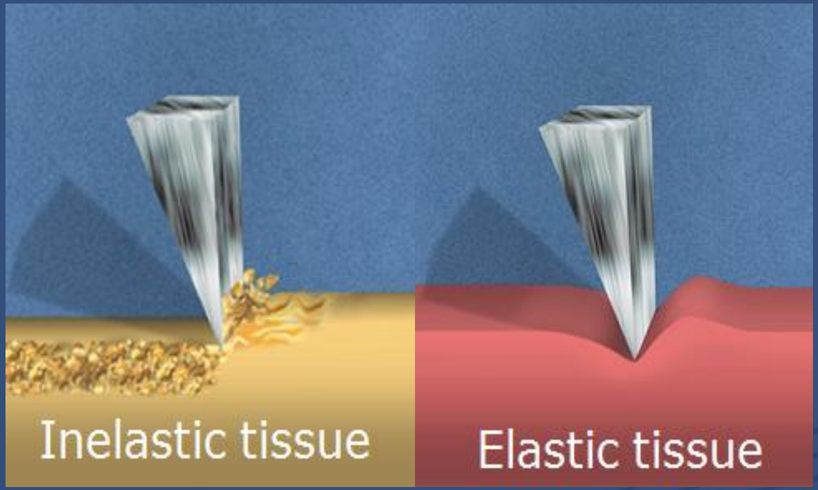


Current Indications of Rotablator

- **Indication: lesion modification**
  - Undilatable lesion or severely calcified lesion
  - Difficult to cross balloon or stent
  - Stent ablation

- **Relative contraindication**
  - Severe angulation
  - Extremely eccentric lesion
  - Vessel size is too small
  - Pre-existing severe dissection or vasospasm
  - High risk of no-reflow: thrombotic lesion, SVG

Principles of Rotational Atherectomy

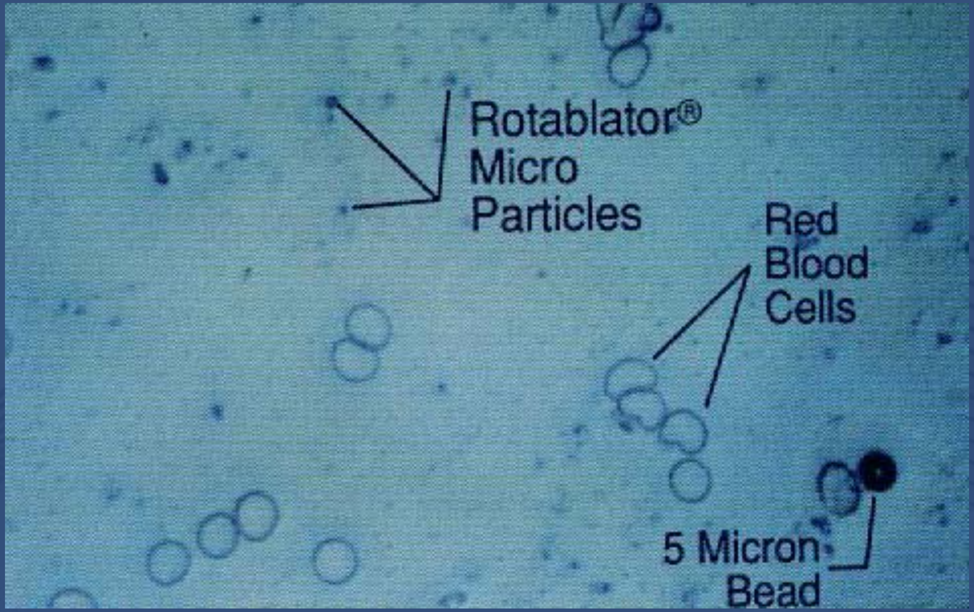


Differential Cutting

Orthogonal displacement of friction

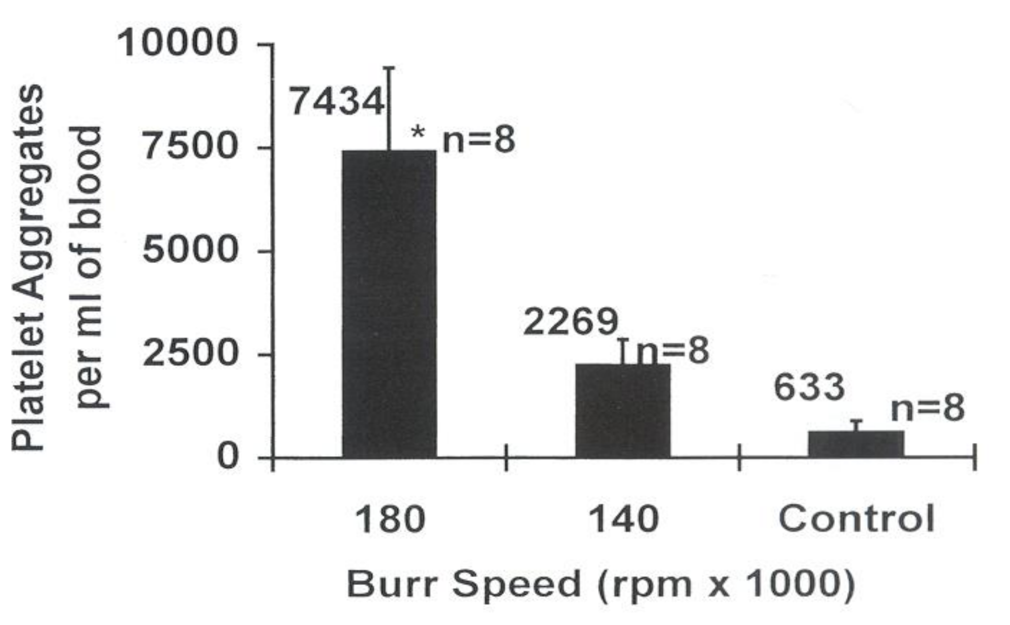
Microparticulate Debris

- Size: < 12 micron in 88%
- Increased size of debris when
  - Slow burr speed < 75,000 rpm
  - Deceleration by pushing hard > 5000 rpm



Burr Selection

- Burr-to-artery ratio: up to 0.5
- One-burr vs. two-burr approach
- Burr speed
  - Large burr (≥ 2.0 mm) : 150,000 rpm
  - Small burr (≤ 1.75 mm) : 180,000 rpm



Reisman, Cath Cardiovasc Diag 1998

Burr Size and Guiding Catheter

Rotablator Burr Size (mm)	Burr Diameter Inches/mm	Recommended Guide Catheter (Fr)	Minimum ID (Inches/mm)
1.25	0.049/1.245	5-6	0.053/1.346
1.50	**0.059/1.499**	**6**	**0.063/1.600**
1.75	**0.069/1.753**	**7**	**0.073/1.854**
2.00	0.079/2.007	8	0.083/2.108
2.15	**0.085/2.159**	**8**	**0.089/2.261**
2.25	0.089/2.261	9	0.093/2.362
2.38	0.094/2.388	9	0.098/2.489
2.50	0.098/2.489	10	0.102/2.591

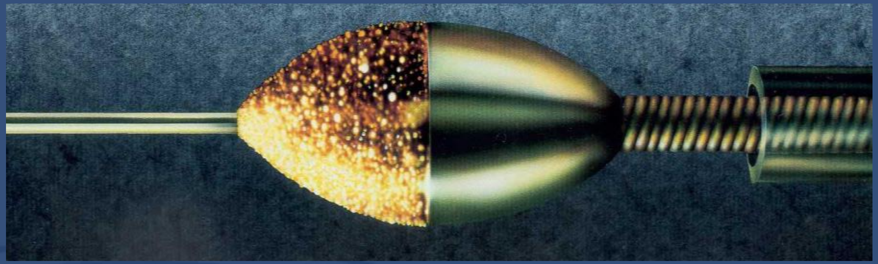
* Guiding catheters without abrupt primary or secondary curves are recommended (FR4, CLS, XB etc)

Cocktail solution

- Infused into Rotalink advancer by pressure-bag (50~100 mmHg above the blood pressure)
- Infusion speed 6-8 ml/30 sec
- Contents
  - Normal saline 500 ml
  - Nitroglycerin 2 mg
  - Heparin 2500 unit
  - Verapamil 5 mg
- Rotaflush study (Matsuo, AHJ 2007)
  - Nicorandil is better than verapamil in terms of ST resolution, and the risk of NQMI and QMI

Complications of Rotablation

- Slow or no-reflow
- Dissection
- Perforation
- Wire bias problems
- Lodged burr
- Spasm
- AV block



Slow Flow / No Flow

- Overview

- Slow flow and no flow are observed in 5% of patients undergoing PTCRA

- Slow flow is a diminution of flow by 1-2 TIMI grades from the baseline antegrade flow

- No reflow is a cessation of flow into the distal coronary bed

- Potential Course of Action

- Early recognition of flow disturbance is key

- Time

- IC Nitroprusside, verapamil or adenosine: careful of hypotension and bradycardia

- IABP if needed

- Intermittent injections of contrast media during ablation run for flow interrogation

- Appropriate burr run time for lesion and vessel complexity

Lodged Burr

- **Causes**

- Oversized burr in diffuse calcium and too much pressure can jam

- Small burr in eccentric lesion and too much pressure can cause watermelon seeding thru lesion and with no diamonds on proximal side of burr, no way to get back

- **Potential Course of Action**

- Do not attempt to start the burr spinning once it is stuck. Take an angiogram to determine burr position

- Nitro, cough and time

- DynaGlide™: Burp foot pedal while gently pulling catheter shaft. Brief spurt of energy and gentle pull back simultaneously

- Buddy wire with 1.5 mm ballooning if possible

- Pull the burr very hard, as the last resort!

- Surgery if required

AV Block

- Causes
  - No flow or slow flow for AV nodal branch
  - RCA > LCX > LAD

- Course of action
  - Cough CPR
  - Atropine
  - Temporary pacemaker

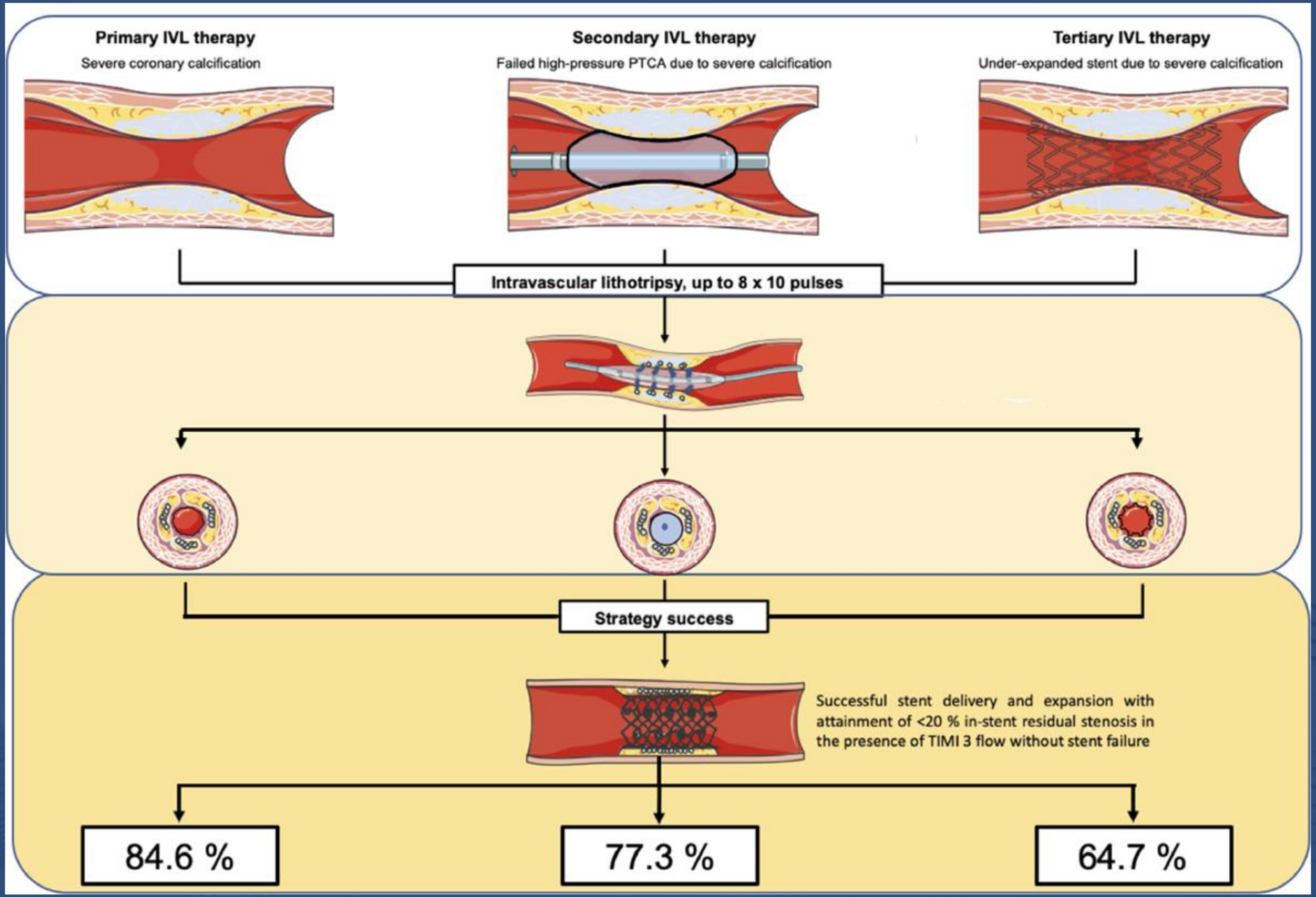
Incidence and Determinants of Complications in Rotational Atherectomy (J-PCI Registry)

In hospital death, cardiac tamponade, emergent surgery

	OR	95% CI	P Value
Age (1-y increase)	1.03	1.02–1.05	<0.001
Impaired kidney function	1.59	1.15–2.19	0.004
History of previous myocardial infarction	1.69	1.21–2.35	0.002
Emergent PCI	4.02	1.66–8.27	<0.001
Triple-vessel disease (vs single-vessel disease)	2.17	1.43–3.28	<0.001
Left main disease (vs single-vessel disease)	2.54	1.51–4.17	<0.001
High-volume institution (vs low-volume institution)	0.56	0.36–0.89	0.011

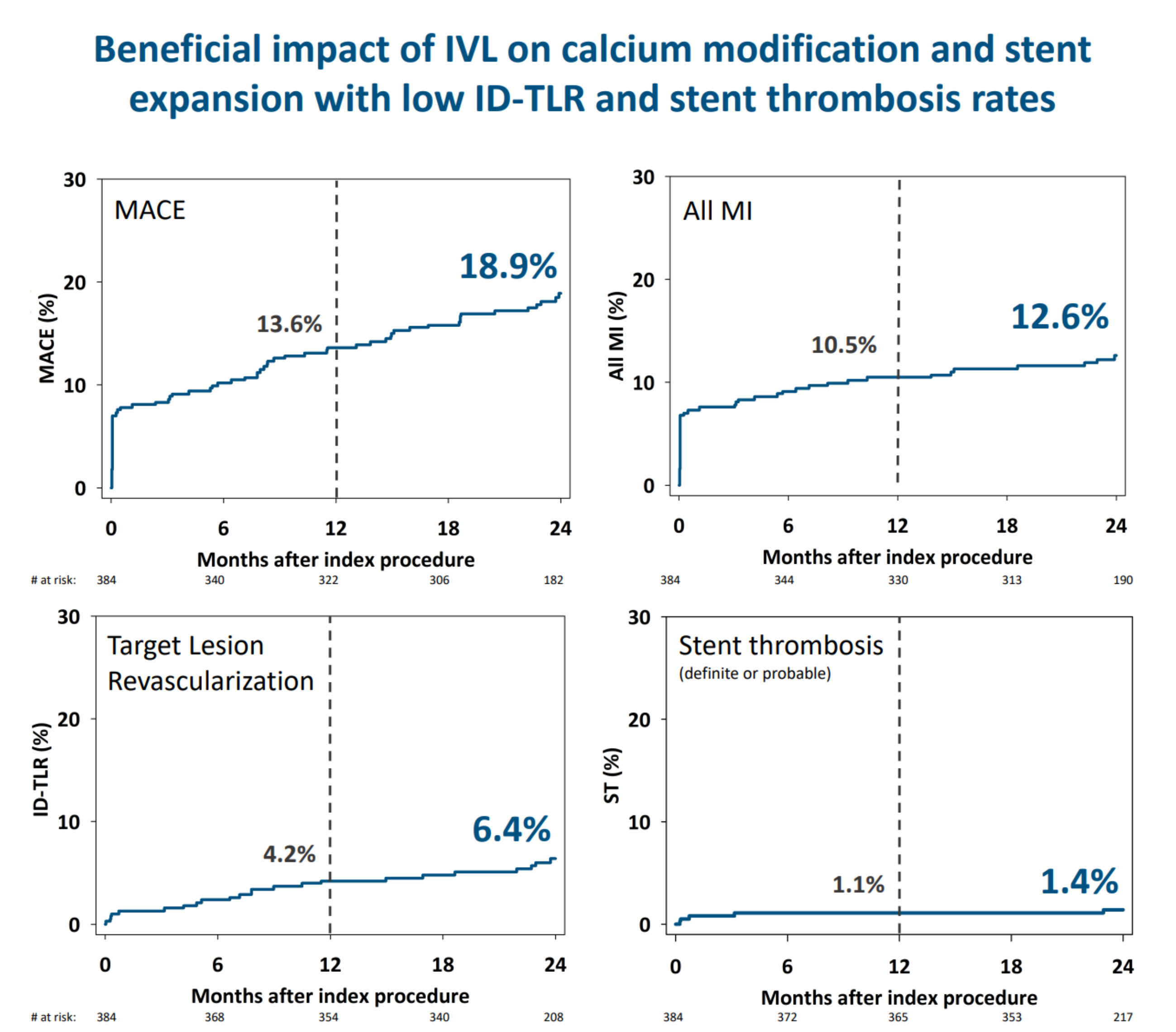
Kenichi, et al., Circulation Intv. 2016; 9: 11.

Intravascular coronary lithotripsy



Cir Cardiovasc Interv. 2019 Nov;12(11)

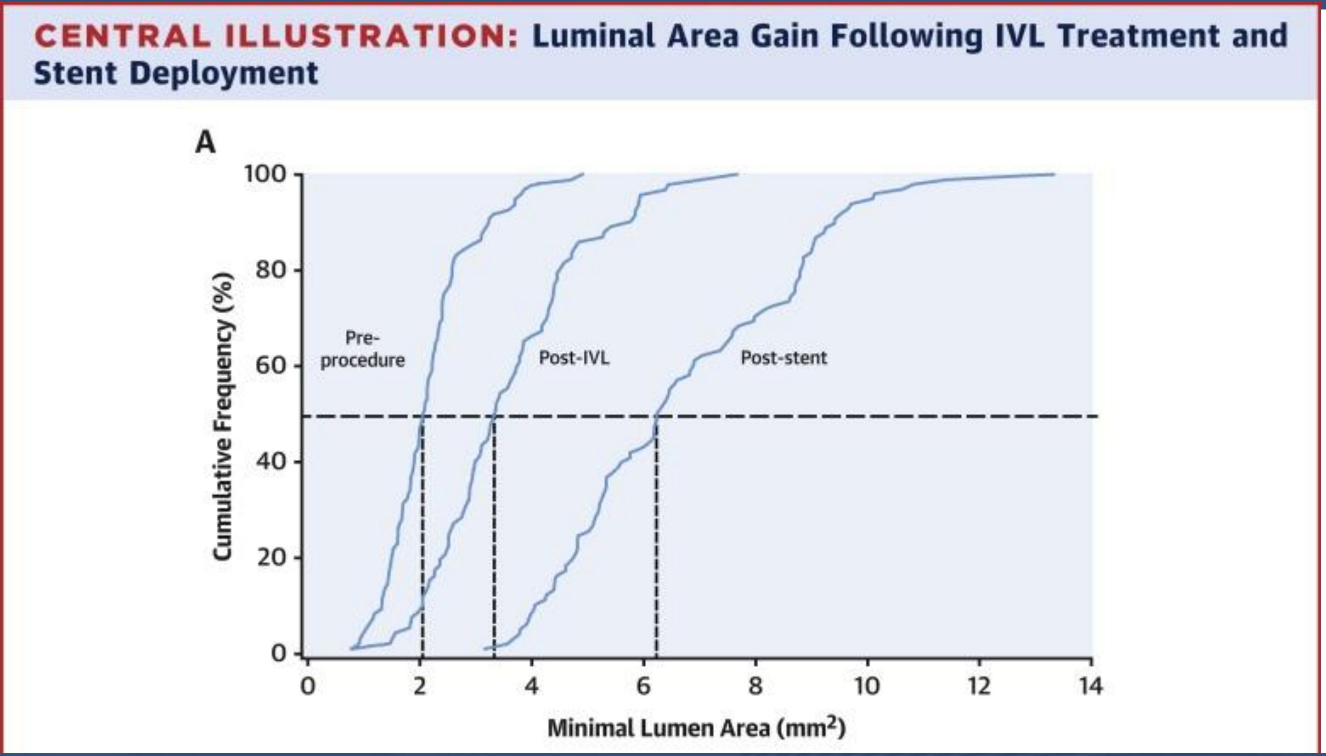
Intravascular coronary lithotripsy

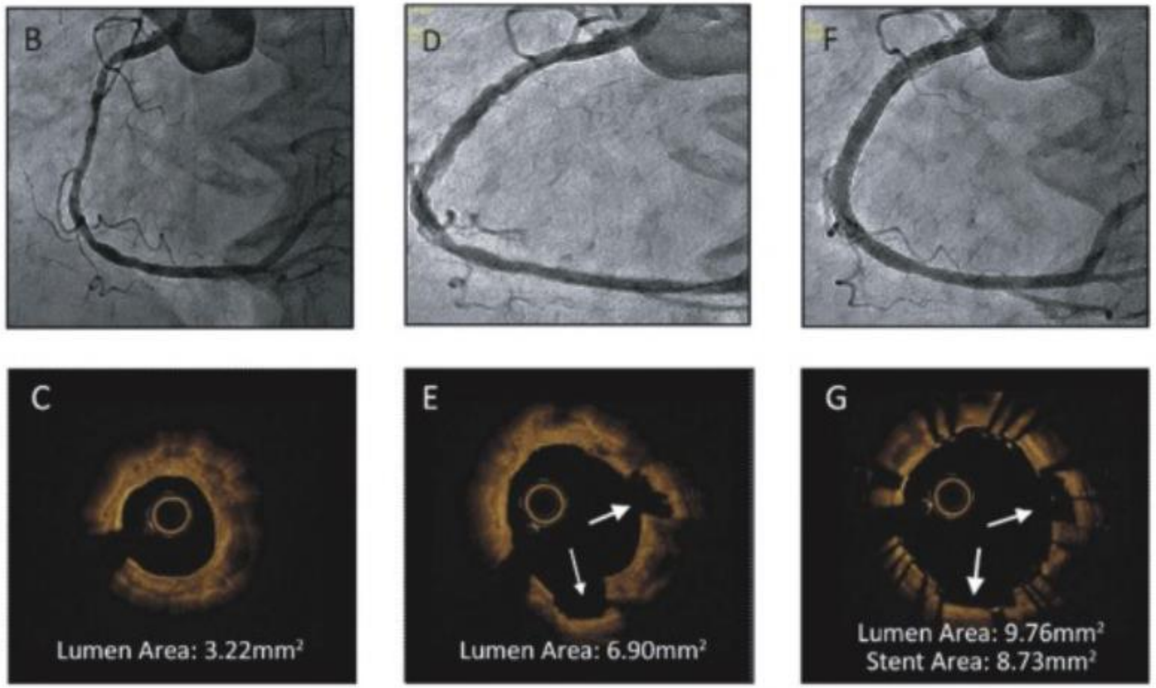


Beneficial impact of IVL on calcium modification and stent expansion with low ID-TLR and stent thrombosis rates
- Final 2-year result from the Disrupt CAD III study

J Am Coll Cardiol. 2022 Sep, 80(12_Supplement) B71-B72

Intravascular coronary lithotripsy



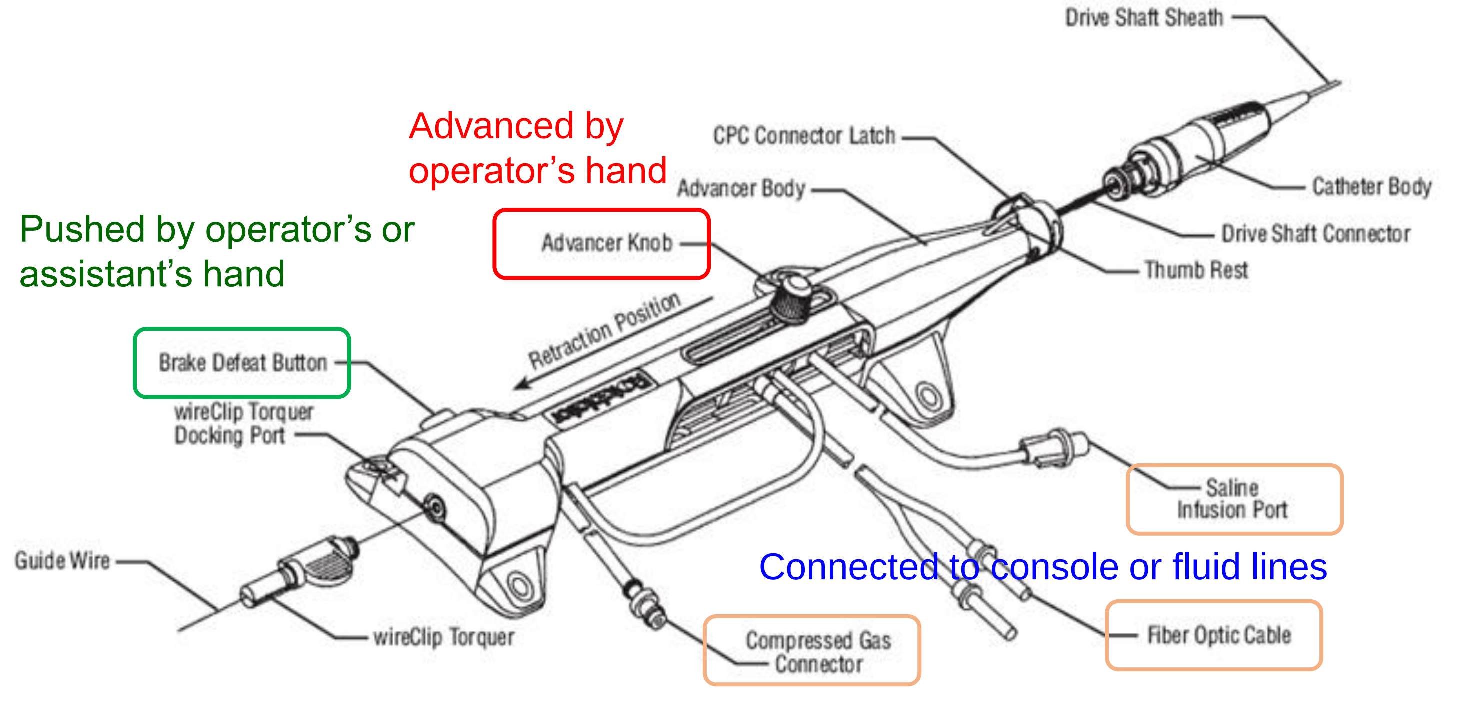


Coronary IVL safely and effectively facilitated stent implantation in severely calcified lesions

Hill, J.M. et al. J Am Coll Cardiol. 2020;76(22):2635-46.

Technical Issues

Rotalink advancer

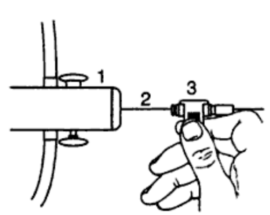


Basic procedural steps (1)

1. Place the rota-wire beyond lesion
    - Rota-wire is very delicate. No severe bends
    - Rota-wire has poor torque conduction. Use microcatheter or over-the-wire balloon to exchange with conventional guidewire.

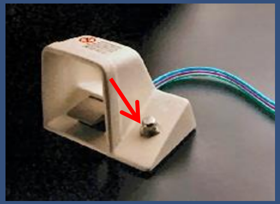
2. Select burr size: Burr-to-artery ration < 0.5 – 0.7

3. Backload and advance assembled burr + advancer unit over rota-wire. Place wire clip at the end of rota-wire.



4. <u>Lock advancer knob 2 to 3cm forward</u> before advancing burr into guiding catheter. Turn on the flush solution and do <u>brief RPM check</u> while holding the Y-connector firmly.
    - It removes tension/inertia on the burr (sudden burr advancement or jump)
    - *(Cover the burr with wet gauze to prevent damage)*

Basic procedural steps (2)



5. Press Dynaglide button to activate Dynaglide mode (60,000 – 80,000 rpm).

6. Advance the burr to the 'landing zone' (non-stenotic site proximal to the lesion) in the proximal coronary artery
    - Avoid tightening of Y-connector. The hemostasis valve should be closed just tight enough to prevent blood loss, but still allow the RotaLink Sheath to slide through the valve.

7. Remove residual tension/inertia of burr at landing zone
    - Move advancer knob back and forth to remove tension between drive shaft and Teflon sleeve
    - Release Y-connector and move burr back and forth to remove tension between guidewire and rota burr
    - Brief Dynaglide run under fluoroscopic guidance. If there is residual tension/inertia, sudden burr advancement or jump occurs.

Basic procedural steps (3)

8. Basics of rotablation

1. Burr motion: To-and-fro pecking motion > slow advancement
2. Burr run time: the shorter is the better, 15–20 sec
3. Burr speed: the higher is the better, > 180,000 rpm*
4. Advance burr no more than 3 cm back and forth. Moving forward only when there is light resistance.
5. Avoid running the burr in static position. Always keep the burr advancing or retracting while it is rotating.
6. Avoid significant drop in rpm (> 5000 RPM for > 5 sec)
7. Aggressively keep blood pressure and heart rate.
8. Do final 'polish run' (no rpm drop, no resistance) after completion of rotablation.
9. Long lesions were divided into segments and each segment was separately ablated.

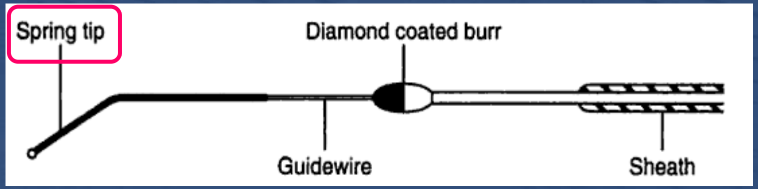
Basic procedural steps (4)

9. Get feedback of rotablation
    - Tactile: advancer knob resistance or driveshaft vibration
        - excessive load on burr
        - too rapid advancement
        - a kink in the drive shaft coil
        - too large burr
    - Visual: smooth advancement under fluoroscopy
    - Auditory: Pitch changes relative to resistance encountered by the burr

Basic procedural steps (5)

10. Tips for successful rotablation

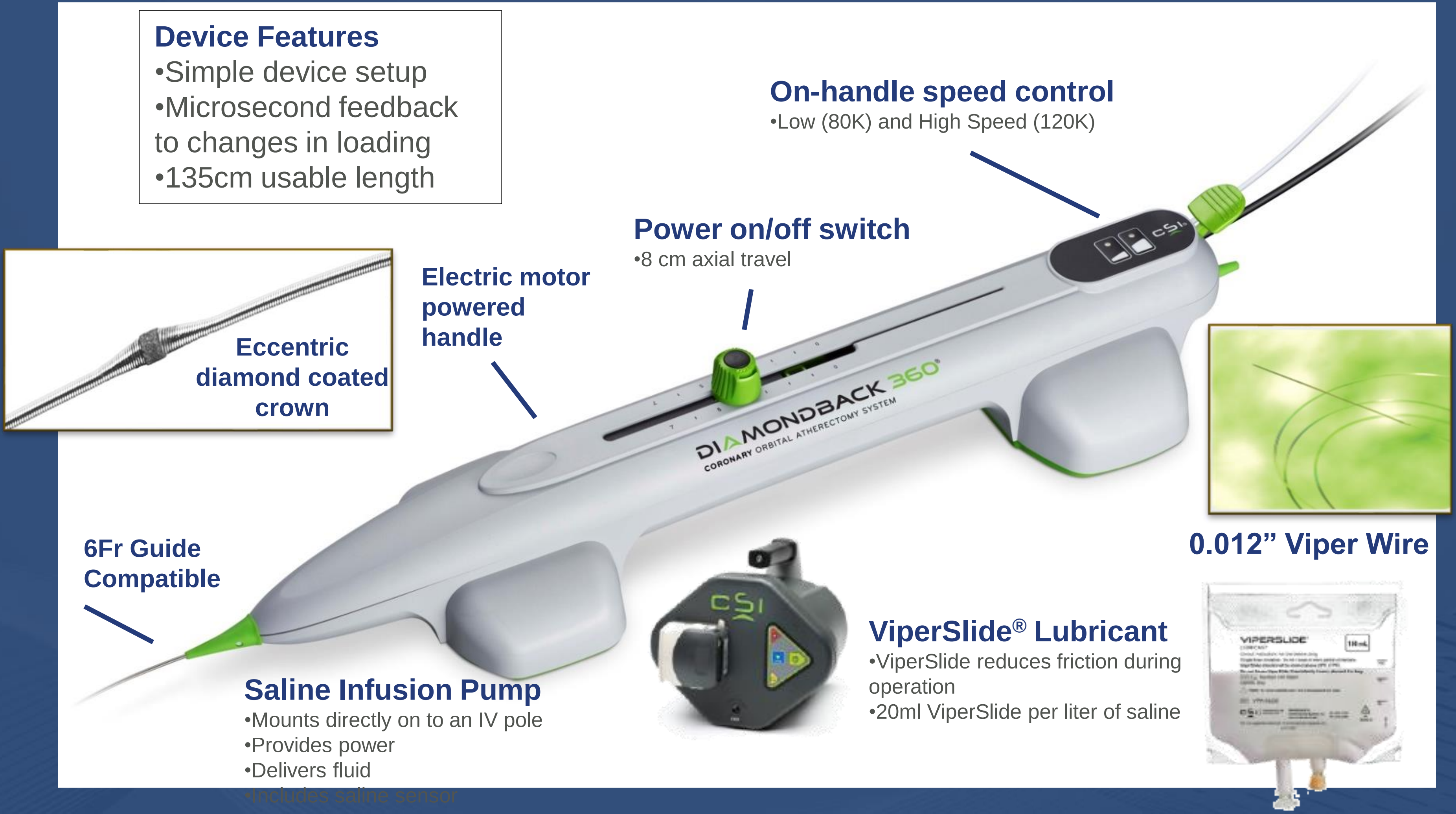
1. Never adjust RPMs during ablation.
2. Do not over-tighten Y-adapter.
3. Avoid dottering.
4. Avoid burring in the guide catheter (except Dynaglide mode).
5. Gently advance or retract the burr while it is at high speed rotary motion.
6. Never stop burr in lesion or distal to lesion. Burr should be located at the proximal ‘landing zone’ or within guiding catheter when not running.
7. Do not allow the burr to remain in any location while rotating at high speeds. Always keep the burr advancing or retracting while it is rotating.
8. Never advance rotating burr to point of contact with the guidewire spring tip. The guidewire can be destructed easily.



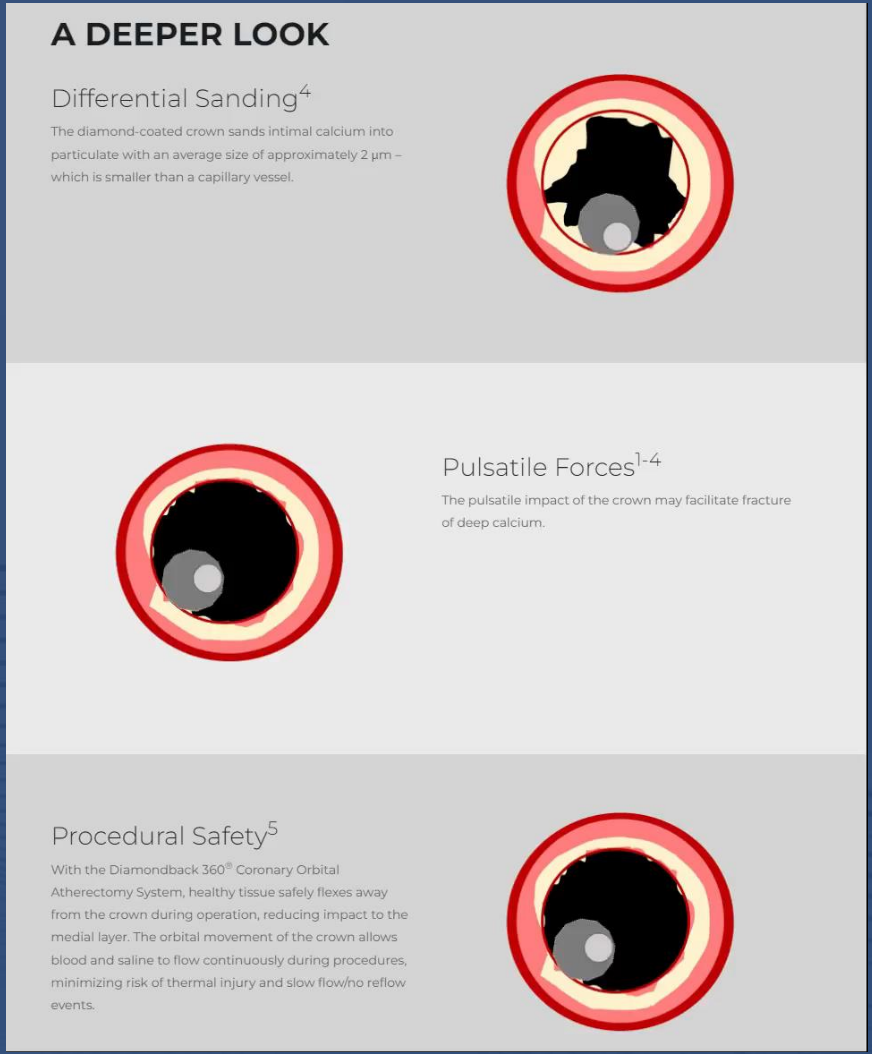
Procedure

1. Place the rota-wire beyond lesion
   Easy to bend, poor torque control
   Use microcatheter or OTW balloon for wire exchange
2. Select burr size: Burr-to-artery ration ≈ 0.5
3. Backload and RPM check
   150K RPM for 1.75 or larger burr, 180K for smaller burr
4. Advance the burr upto landing zone (with or without dynaglide)
5. Tension release and dye injection
6. Start ablation
   1) Burr motion: To-and-fro pecking motion for 15~20 sec
   2) Never stop burr in lesion or distal to lesion
   3) Get feedback: visual, auditory for drop in rpm > 5000 RPM for > 5 sec
   4) Intermittent dye injection for slow flow
   5) Polish run after cross
7. Remove burr using dynaglide

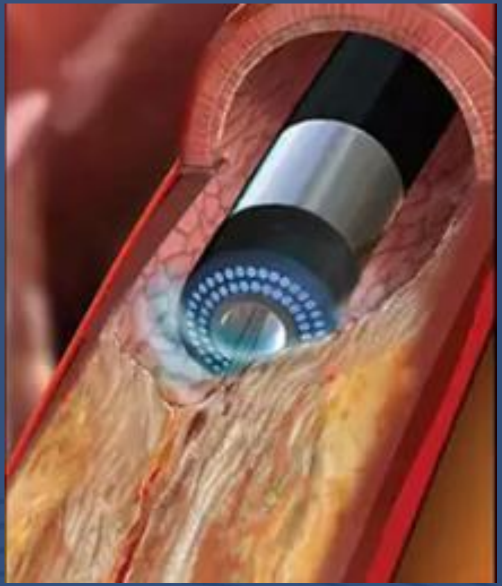
DIAMONDBACK 360: Coronary Orbital Atherectomy System



Orbital atherectomy

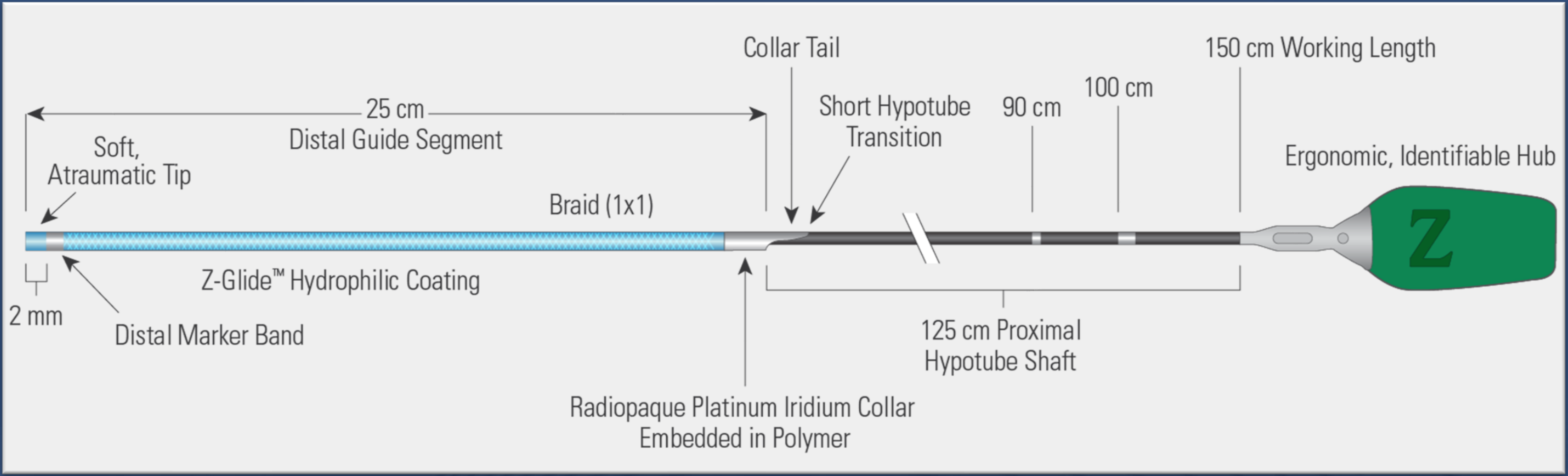


Laser atherectomy



PHILIPS Coronary laser atherectomy catheter

Guidezilla II



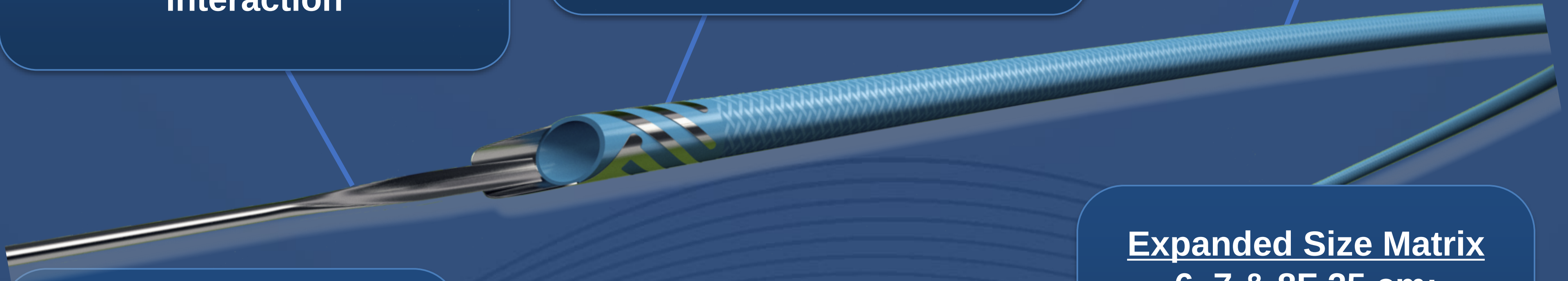
Guidezilla II

Powerful Reach. Predictable Performance.

Short Hypotube Transition
for reduced device interaction

Radiopaque Helical Collar
Designed for improved strength and visibility

Z-Glide™ Coating
For improved deliverability



Green Ergonomic Hub
Unique and easily identifiable

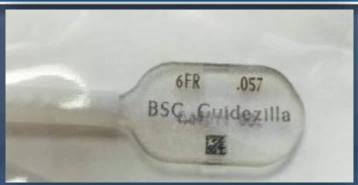
Expanded Size Matrix
6, 7 & 8F 25 cm;
6F 40cm
(Rapid Exchange Length Noted)

Design Changes

(Guidezilla to GUIDEZILLA™ II)

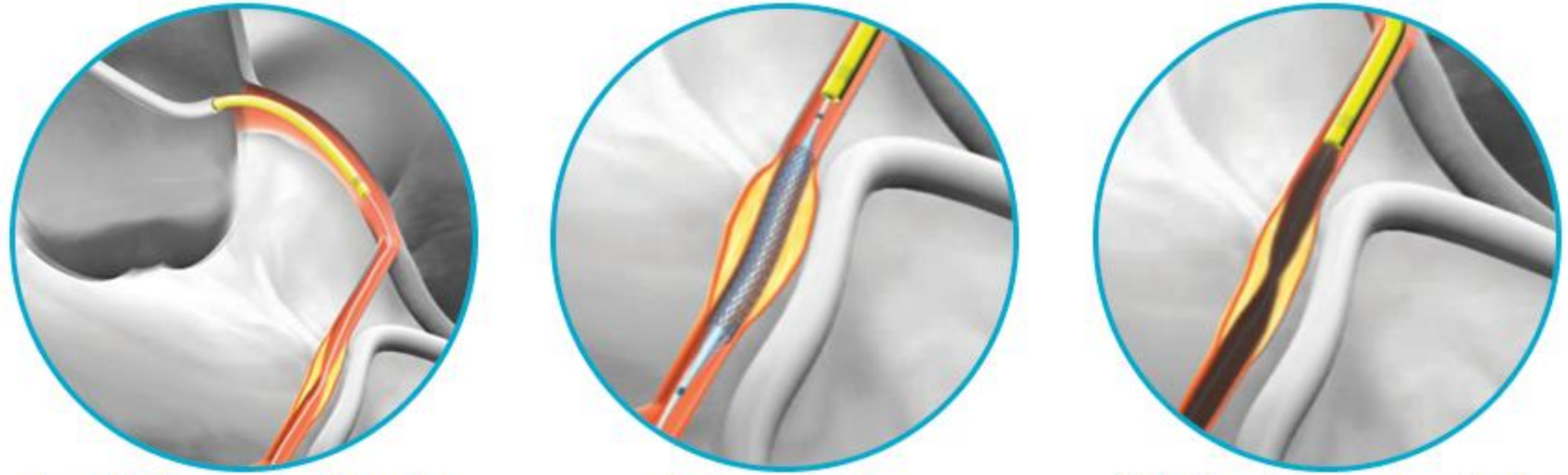
Features	Guidezilla	GUIDEZILLA II	Design Goal
Sizes	6F	6F, 7F, 8F, and 6F Long	Expanded Size Matrix
Guide Segment	25 cm	25 cm on 6F,7F,8F (40 cm on 6F Long)	40cm 6F Long Designed for TRI
Working Length	145cm	150cm	Extra 5 cm Proximal Hypotube Shaft
Collar	Stainless Steel	Helical Platinum Iridium	Visibility, Strength, and Smooth Device Interaction
Coating	Bioslide™	Z-Glide™	Deliverability
Radiopaque	Distal Marker Proximal Marker	Distal Marker band Radiopaque Collar	True Device Positioning with Added Visibility
Hypotube Transition	19mm	6mm	Optimized to Reduce Device Interaction
Hub Design			

Guidezilla



GUIDEZILLA II

GuideLiner

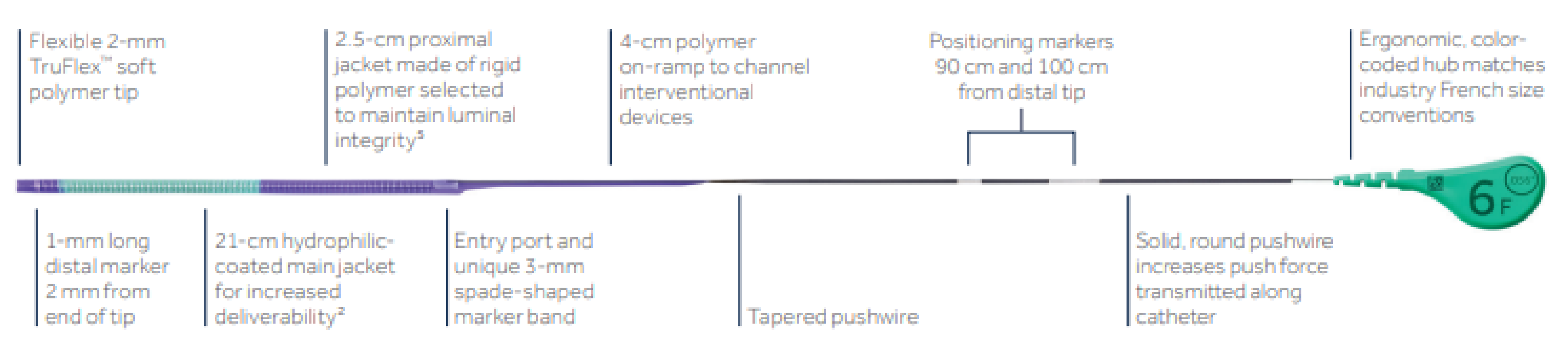


Coaxial alignment and backup support

Deep-seating for distal device delivery

Selective delivery of contrast

Telescope



TECHNICAL FEATURES

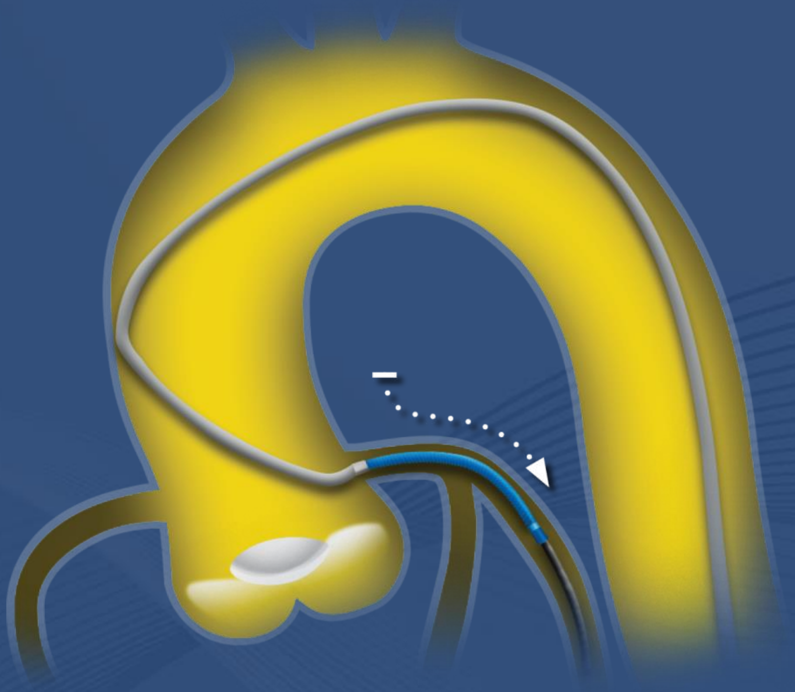
Technical Features	Telescope™ GEC
Catheter length	150 cm
Distal extension length	25 cm
Marker band material	Platinum iridium
Marker band lengths and locations	1 mm long, 2 mm from distal tip 3 mm long, spade-shaped at entry port
Coating	Hydrophilic, outer layer of distal 21 cm
Pushwire length	125 cm
Tapered pushwire portion	10 cm
On-ramp length	4 cm
On-ramp material	Nylon-based polymer
TruFlex™ tip	2 mm
Shelf life	2 years

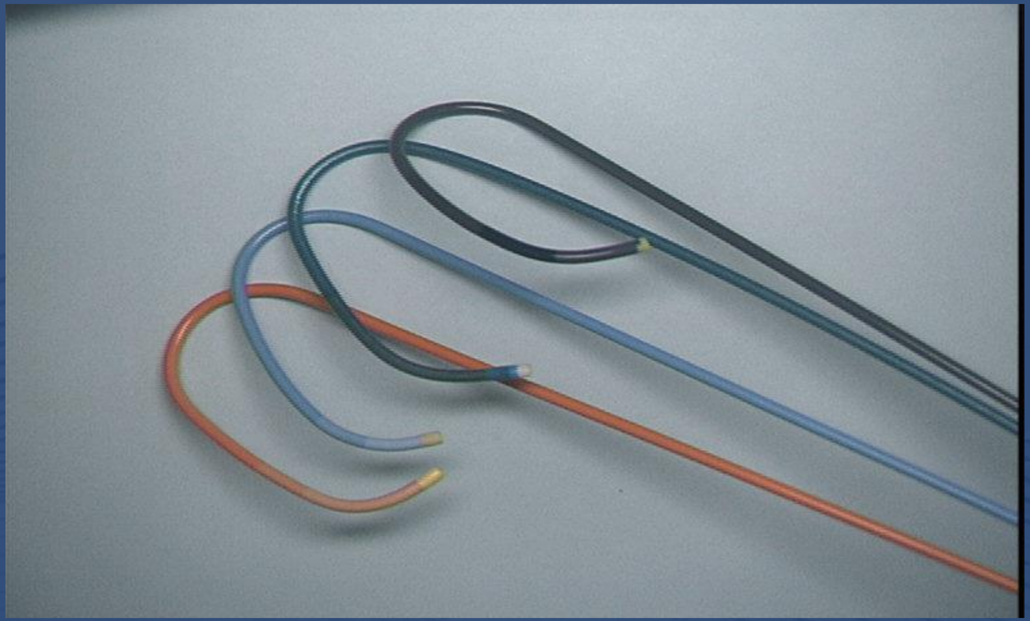
DIMENSIONAL COMPARISON

French Size (F)	GEC Name	I.D. (in)	O.D. (in)	Required GC I.D. (in)
5.5	GuideLiner™* V3 GEC[6]	0.051	0.063	6 F ≥ 0.066
6	Telescope™ GEC	0.056	0.067	6 F ≥ 0.070
6	GuideLiner™* V3 GEC[6]	0.056	0.067	6 F ≥ 0.070
6	Guidezilla™* II GEC[7]	0.057	0.067	6 F ≥ 0.070
7	Telescope™ GEC	0.062	0.075	7 F ≥ 0.078
7	GuideLiner™* V3 GEC[6]	0.062	0.075	7 F ≥ 0.078
7	Guidezilla™* II GEC[7]	0.063	0.073	7 F ≥ 0.078

Heartrail

Large I.D. & Superb Back up force





ARTIST trial

Balloon angioplasty (PTCA) vs. Rotablation in ISR (PTCR)

TABLE 4 Angiographic Outcome

	PTCA (n = 138)	PTCR (n = 139)	p Value
MLD after rotational ablation (mm)	—	1.33 ± 0.39	
Mean diameter after rotational ablation (mm)	—	1.7 ± 0.28	
Diameter stenosis after rotational ablation (%)	—	35 ± 15	
Final MLD (mm)	1.9 ± 0.3	1.9 ± 0.4	0.57
Final mean diameter (mm)	2.2 ± 0.35	2.2 ± 0.37	0.2
Final diameter stenosois (%)	29 ± 10	28 ± 12	0.38
Acute gain (mm)	1.3 ± 0.4	1.4 ± 0.4	0.45
Acute gain index	50 ± 16	52 ± 16	0.43
Final plaque area (mm^2)	6.4 ± 5.2	6.8 ± 5.4	0.55
Plaque area reduction (%)	69 ± 17	68 ± 17	0.68
Angiographic success	139/146 (95%)	144/152 (94%)	1.0
Diameter stenosis ≤30%	78/137 (57%)	87/143 (61%)	0.54

TABLE 5 Angiographic Outcome After Six Months

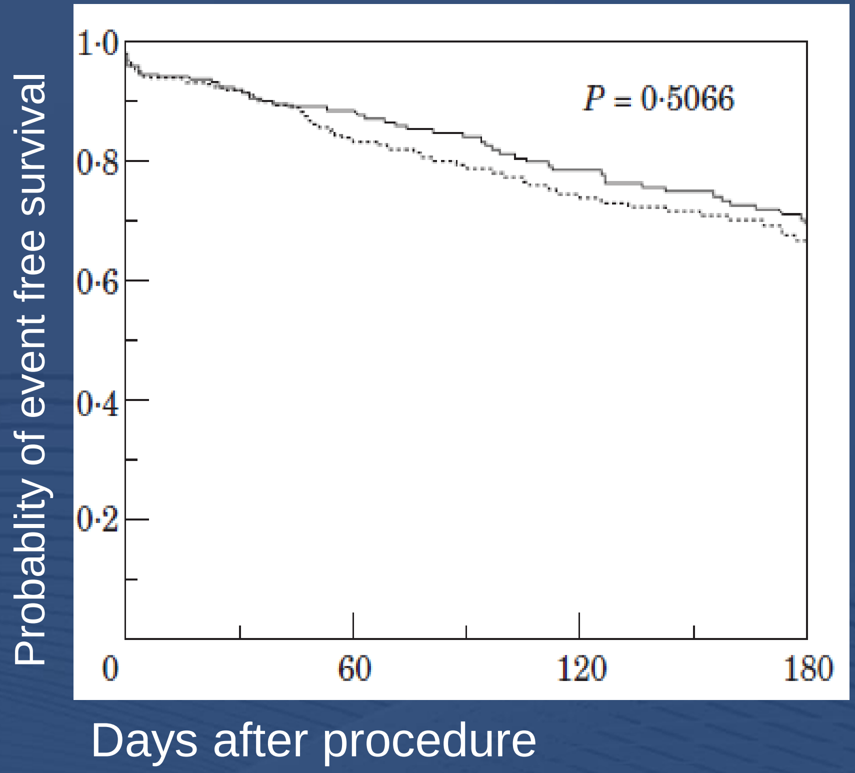
	PTCA (n = 123)	PTCR (n = 131)	p Value
Diameter stenosis (%)	56 ± 20	64 ± 22	0.005
MLD (mm)	1.2 ± 0.6	1.0 ± 0.6	0.008
Mean stenosis diameter (mm)	1.83 ± 0.74	1.7 ± 0.45	0.03
Late loss (mm)	0.68 ± 0.5	0.92 ± 0.6	0.0015
Loss index	50 ± 46	69 ± 42	0.0007
Net gain (mm)	0.67 ± 0.5	0.45 ± 0.6	0.0019
Net gain index	24.5 ± 20	16.8 ± 22	0.005
Neo-plaque area (mm^2)	5.1 ± 5.8	6.1 ± 6.3	0.25
Net plaque reduction (mm^2)	11.6 ± 14	7.9 ± 12	0.04
Restenosis rate (%)	51.2	64.9	0.027

Am J Cardiol 2002;90:843–847

COBRA study

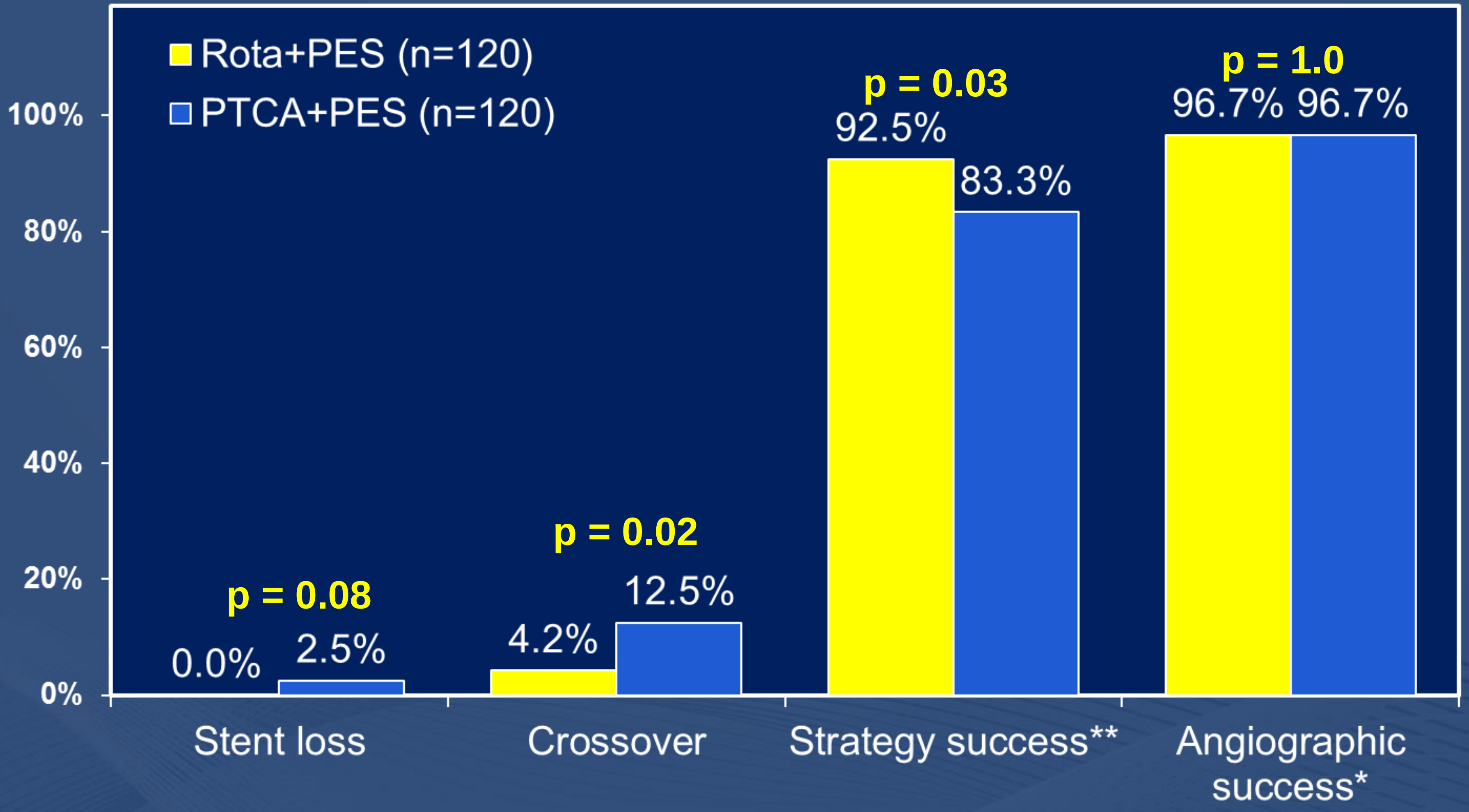
A randomized comparison of balloon angioplasty versus rotational atherectomy in complex coronary lesions

	RA (n=252)	PTCA (n=250)	P value
Procedural success	85%	78%	0.038
6 months success	48.9%	51.1%	0.333
Major cardiac events during follow up			
Q wave MI	0.5%	0%	
CABG	4.2%	6.5%	
Death	0%	0%	



T.Dill European Heart Journal (2000) 21, 1759–1766

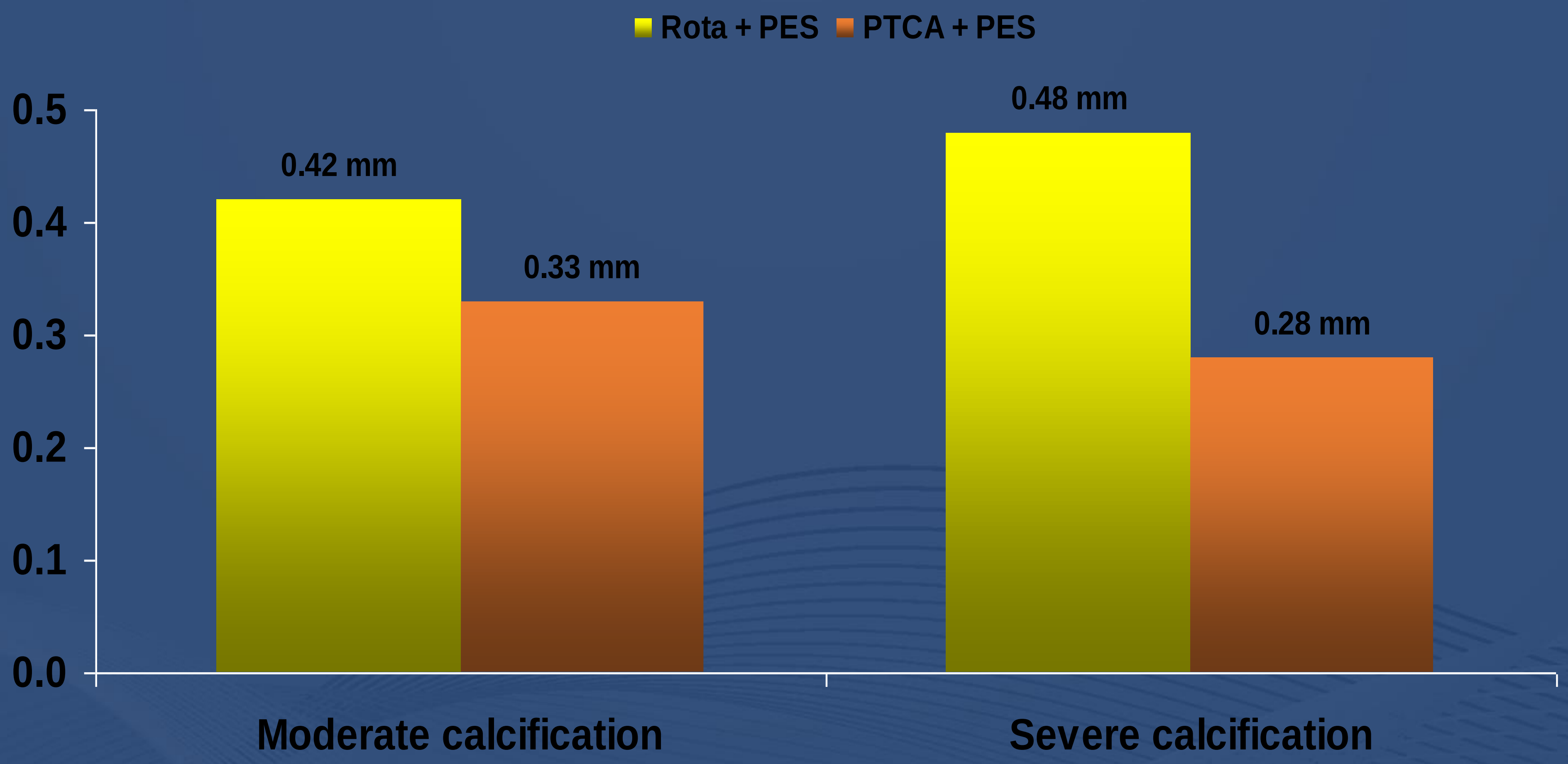
ROTAXUS; Procedural Outcomes



* Defined as <20% residual stenosis + TIMI 3 flow
** Defined as angiographic success with no crossover or stent loss

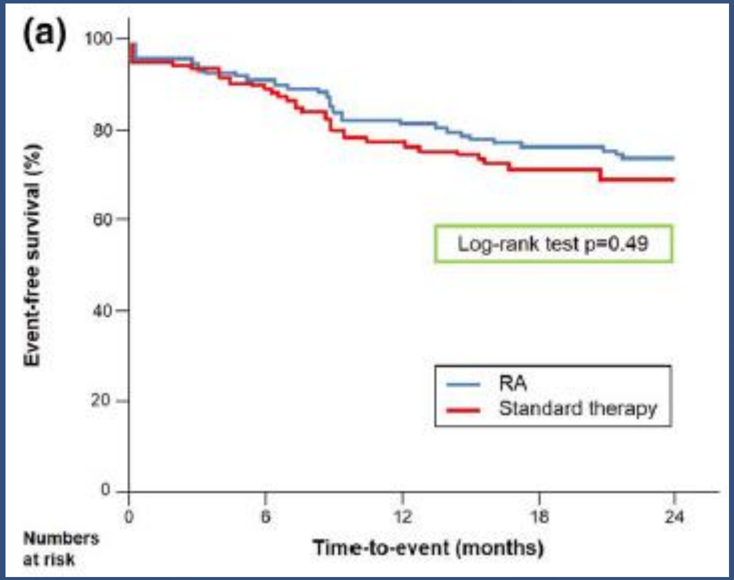
Abdel-Wahab M et al. JACC CV Interv 2013;6:10-19

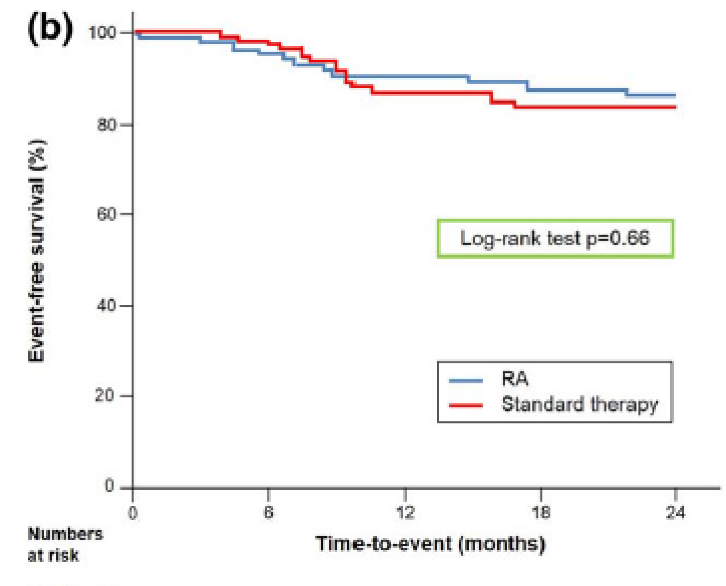
ROTAXUS
Strategy Success according to calcification



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

Rotaxus ; 2 year clinical outcome





	RA+DES (n=109)	DES (n=108)	P value
Procedure success	92.5%	83.3	0.03
MACE	29.4%	34.3%	0.47
Death	8.3%	7.4%	1.00
MI	8.3%	6.5%	0.8
TLR	13.8%	16.7%	0.58
TVR	19.3%	22.2%	0.62

Increse procedure success
But does not increase clinical outcome

Catheterization and Cardiovascular Interventions 2016; 87: 691–700

PREPARE-CALC Trial

Study design

Prospective, randomized, active controlled clinical trial in 2 German centers

PCI in 200 patients with severely calcified lesions

Lesion preparation with Modified balloon (scoring/cutting)	Randomization 1:1	Lesion preparation with rotational atherectomy

SES implantation (Orsiro)

↓

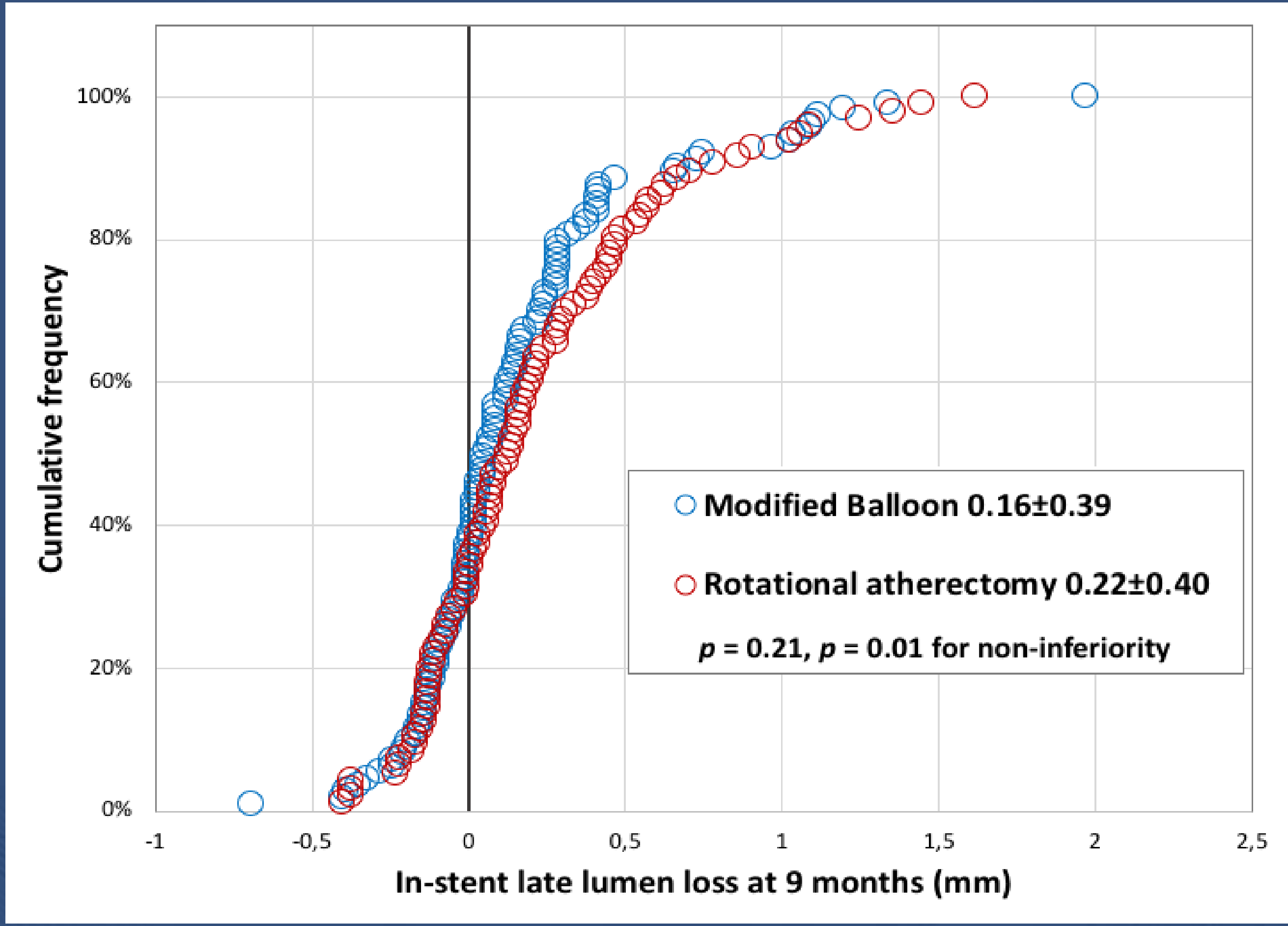
9 month angiographic & clinical follow up

↓

1 & 2 year clinical follow up

Gert Richardt TCT 2018
Circ Cardiovasc Interv. 2018;11:e007415

PREPARE-CALC Trial
Co-Primary Endpoint – In stent LLL at 9 Month



Gert Richardt TCT 2018
Circ Cardiovasc Interv. 2018;11:e007415

PREPARE-CALC Trial
QCA 9 months

	Modified balloon (n = 112 lesions)	Rotational atherectomy (n = 97 lesions)	p-value
Minimal lumen diameter (mm)			
In-stent	2.68±0.59	2.64±0.51	0.59
In-segment	2.50±0.54	2.50±0.55	0.96
Diameter stenosis (%)			
In-stent	18.83±13.42	19.75±11.54	0.49
In-segment	22.40±11.36	23.30±11.43	0.52
Late lumen loss (mm)			
In-stent	0.16±0.40	0.22±0.41	0.21
In-segment	0.07±0.52	0.18±0.74	0.25
Binary restenosis (%)			
In-stent	6 (5.3%)	2 (2.1%)	0.30
In-segment	5 (4.5%)	2 (2.1%)	0.32

Gert Richardt TCT 2018
Circ Cardiovasc Interv. 2018;11:e007415

PREPARE-CALC Trial
Clinical outcome 9 months

	Modified balloon (n = 100 pts.)	Rotational atherectomy (n = 100 pts.)	p-value
Death	2 (2%)	2 (2%)	1.00
Cardiac death	1 (1%)	1 (1%)	1.00
Non-cardiac death	1 (1%)	1 (1%)	1.00
Myocardial infarction	3 (3%)	2 (2%)	1.00
Target vessel MI	1 (1%)	2 (2%)	1.00
Periprocedural MI	1 (1%)	2 (2%)	1.00
Spontaneous MI	2 (2%)	0 (0%)	0.50
Stent thrombosis (def./prob.)	0 (0%)	0 (0%)	1.00
TVR	8 (8%)	3 (3%)	0.21
Target vessel failure	8 (8%)	6 (6%)	0.78

Gert Richardt TCT 2018
Circ Cardiovasc Interv. 2018;11:e007415

PREPARE-CALC-COMBO Study

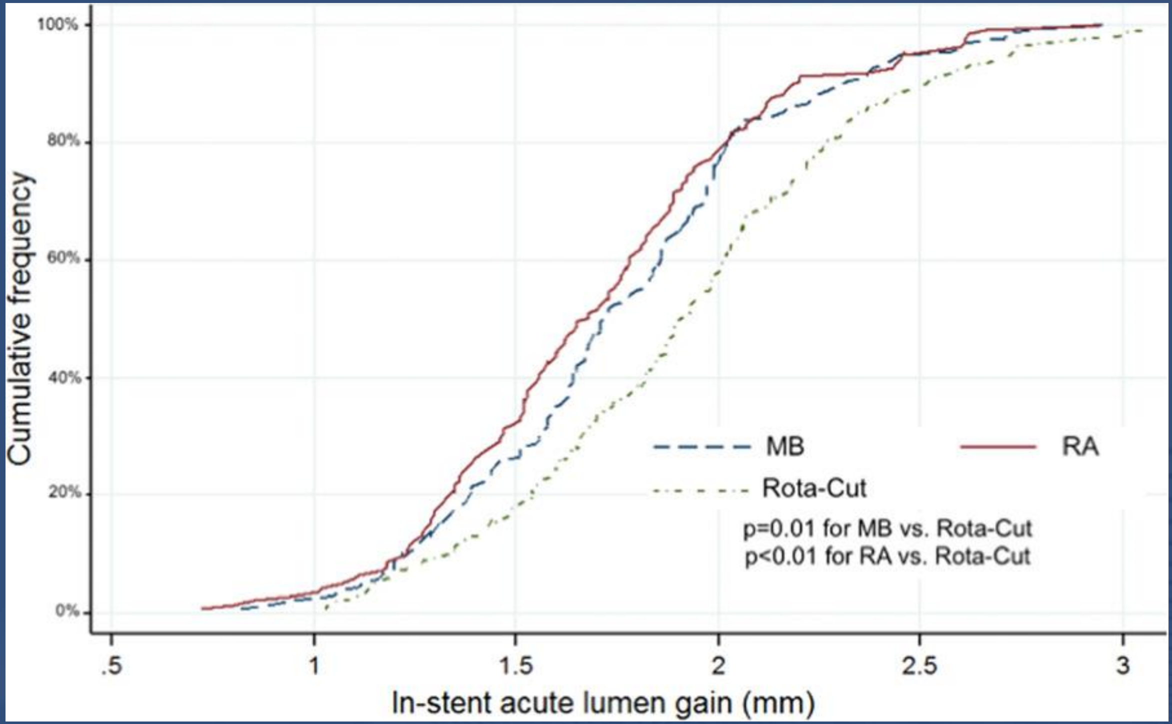
Combined rotational atherectomy and cutting balloon angioplasty prior to drug-eluting stent implantation in severely calcified coronary lesions

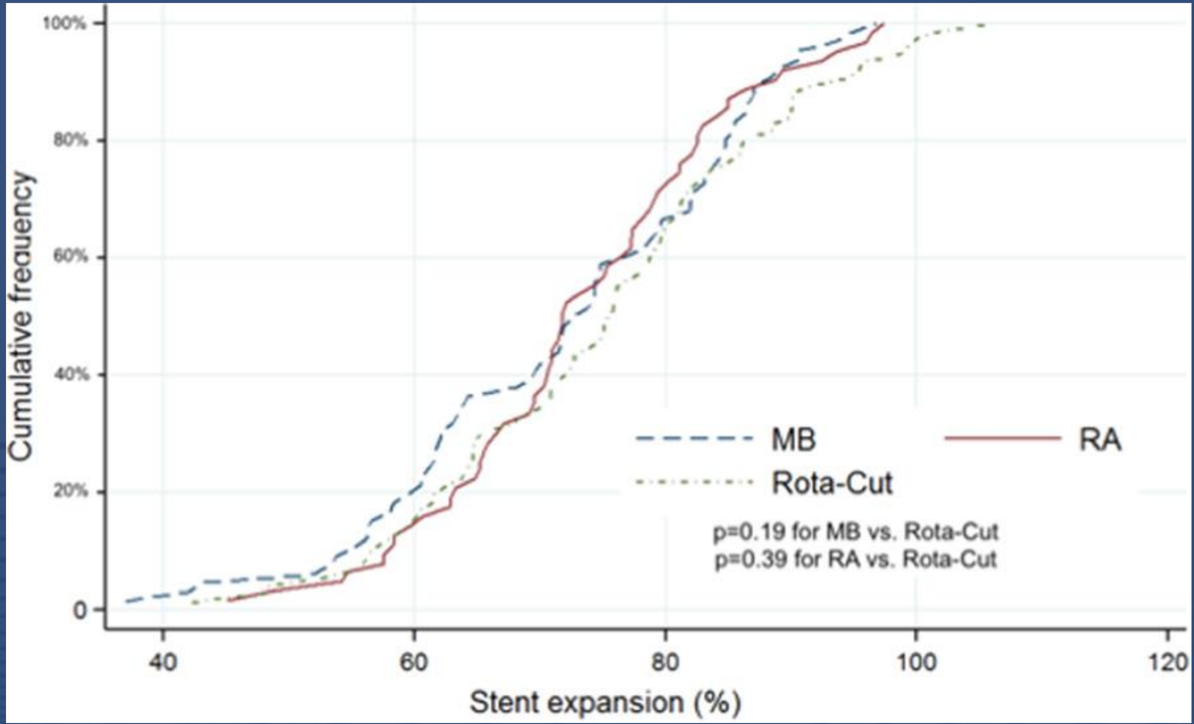
- **To assess whether the Rota-Cut combination improves stent performance in severely calcified coronary lesions**
- **Prospective, single-arm, single center study**
- **Primary endpoint : in-stent acute lumen gain(ALG), stent expansion(SE)**

Catheter Cardiovasc Interv. 2022 Nov;100(6):979-989..

PREPARE-CALC-COMBO Study

Combined rotational atherectomy and cutting balloon angioplasty prior to drug-eluting stent implantation in severely calcified coronary lesions

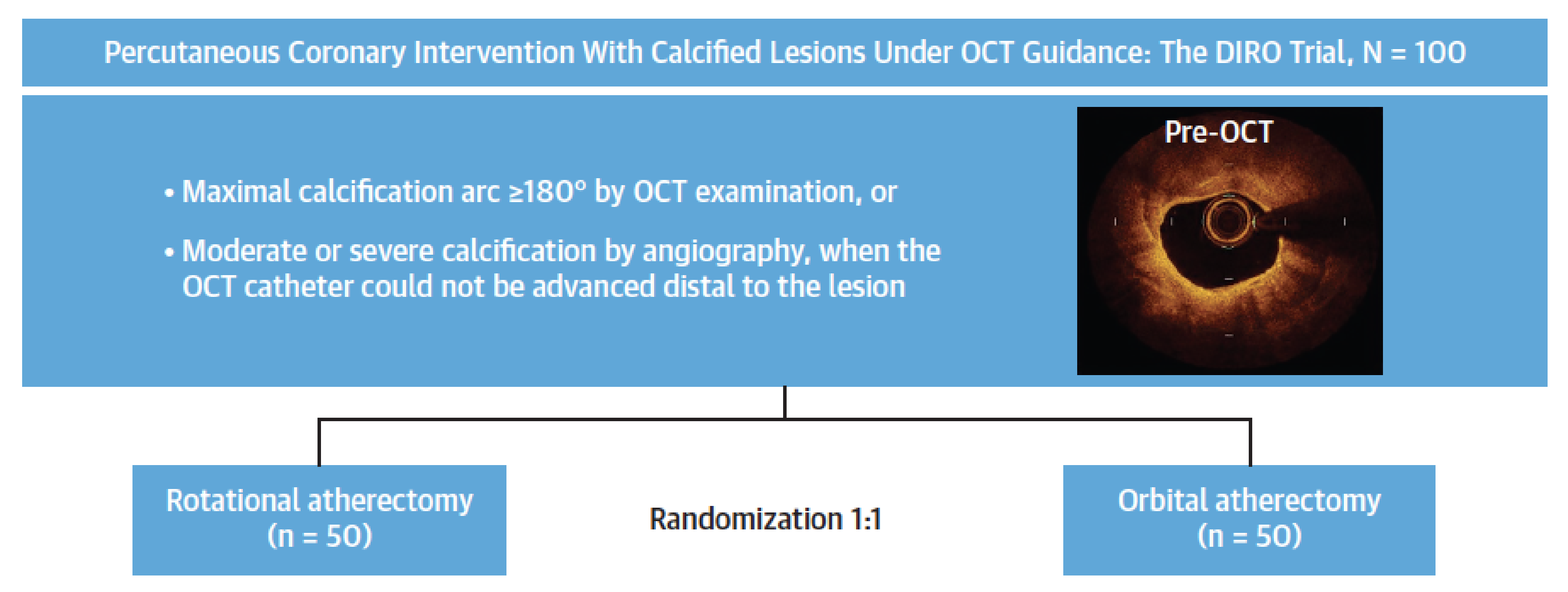




Catheter Cardiovasc Interv. 2022 Nov;100(6):979-989..

DIRO Study

- Direct Comparison of Rotational vs Orbital Atherectomy for Calcified Lesions Guided by Optical Coherence Tomography



Okamoto N, et al. J Am Coll Cardiol Intv. 2023;16(17):2125–2136.

DIRO Study

The blue area indicates the tissue modification area. A dotted two-way arrow shows the atherectomy width and the solid two-way arrow indicates the atherectomy depth.

	RA	OA	*P* Value
Maximum tissue modification area, mm^2	1.24 (0.84-1.74)	0.89 (0.59-1.11)	<0.01
Atherectomy width, mm	1.50 (1.32-1.89)	1.22 (1.12-1.40)	<0.01
Atherectomy depth, mm	0.54 (0.39-0.83)	0.55 (0.31-0.73)	0.62
Percentage of lumen area increase, %	72.2 (49.0-98.3)	39.2 (17.0-48.1)	<0.01
Ratio of atherectomy width to burr size	0.94 (0.79-0.98)	0.98 (0.89-1.12)	0.03
Stent expansion assessed by distal reference, %	99.5 (89.3-107.3)	90.6 (80.0-102.3)	0.02
Stent expansion assessed by mean reference, %	72.2 (60.6-86.3)	64.1 (54.0-77.7)	0.05

- Procedural outcomes including periprocedural MI were comparable
- Clinical outcomes at 8 months were similar

Okamoto N, et al. J Am Coll Cardiol Intv. 2023;16(17):2125–2136.

ECLIPSE
Clinical Trial

ECLIPSE

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; ~150 US sites

Randomize 1:1

Orbital Atherectomy Strategy (1.25 mm Classic Crown followed by balloon pre-dilation)	**Conventional Angioplasty Strategy** (Conventional and/or specialty balloons per operator discretion)
2nd generation DES implantation and optimization	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)

Ajay J. Kirtane ACC 2019

Disrupt CAD III

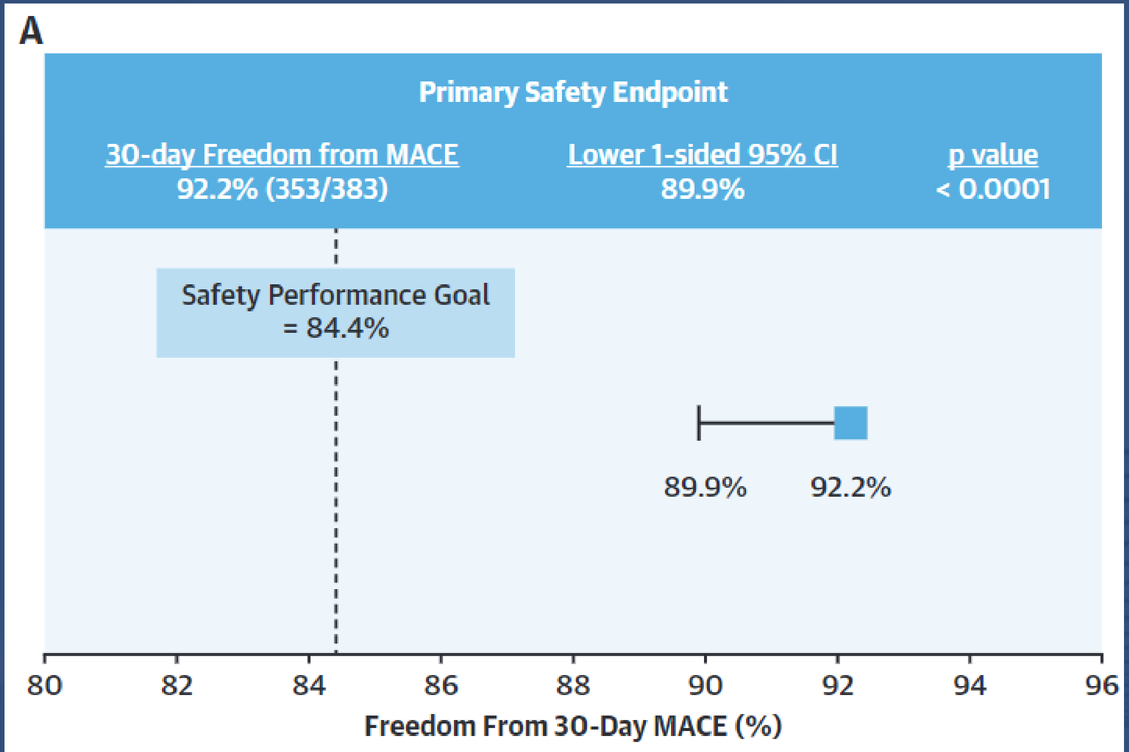
Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease

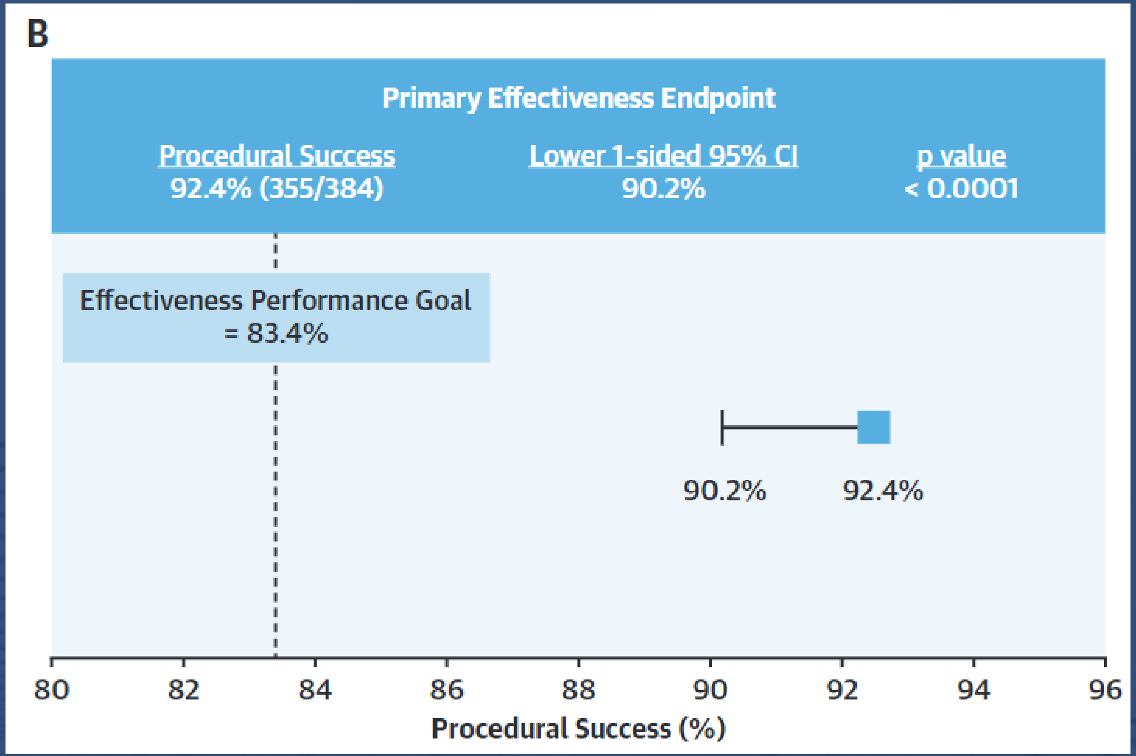
- **To assess safety and effectiveness of IVL in severely calcified de novo coronary lesions**
- **Prospective, single-arm multicenter study**
- **Primary safety endpoint : freedom from major adverse cardiovascular events (cardiac death. MI, or target vessel revascularization) at 30 days**
- **Primary effectiveness endpoint : procedural success**

Hill, J.M. et al. J Am Coll Cardiol. 2020;76(22):2635–46.

Disrupt CAD III

Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease





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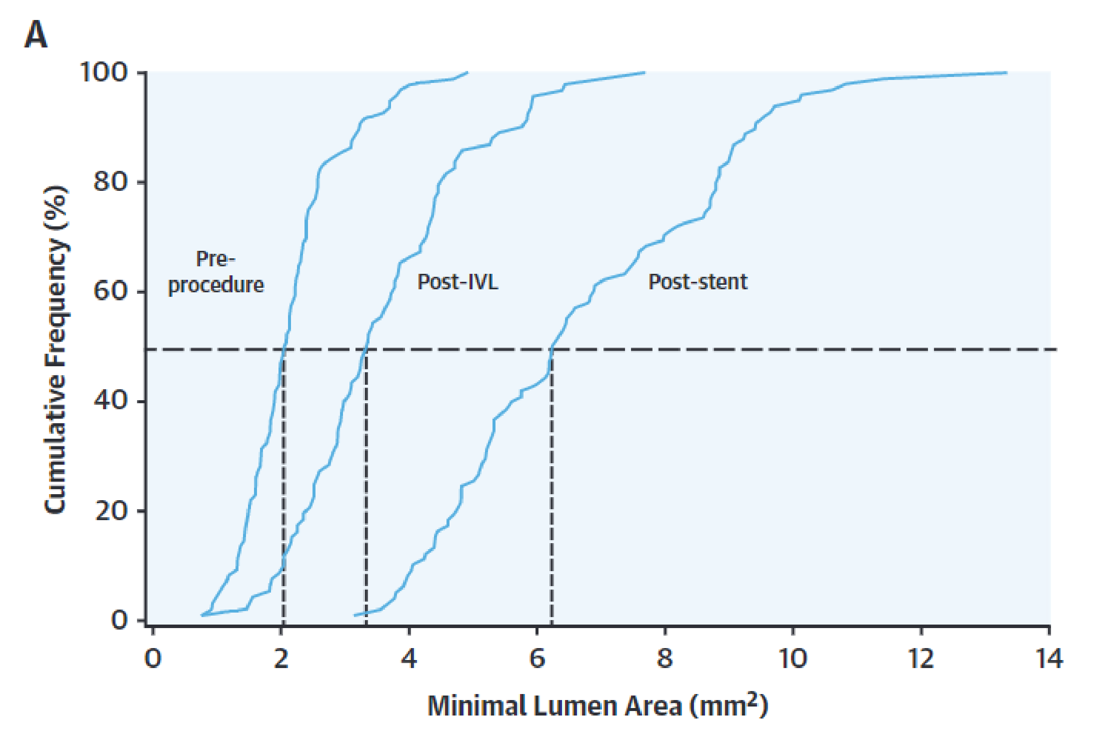
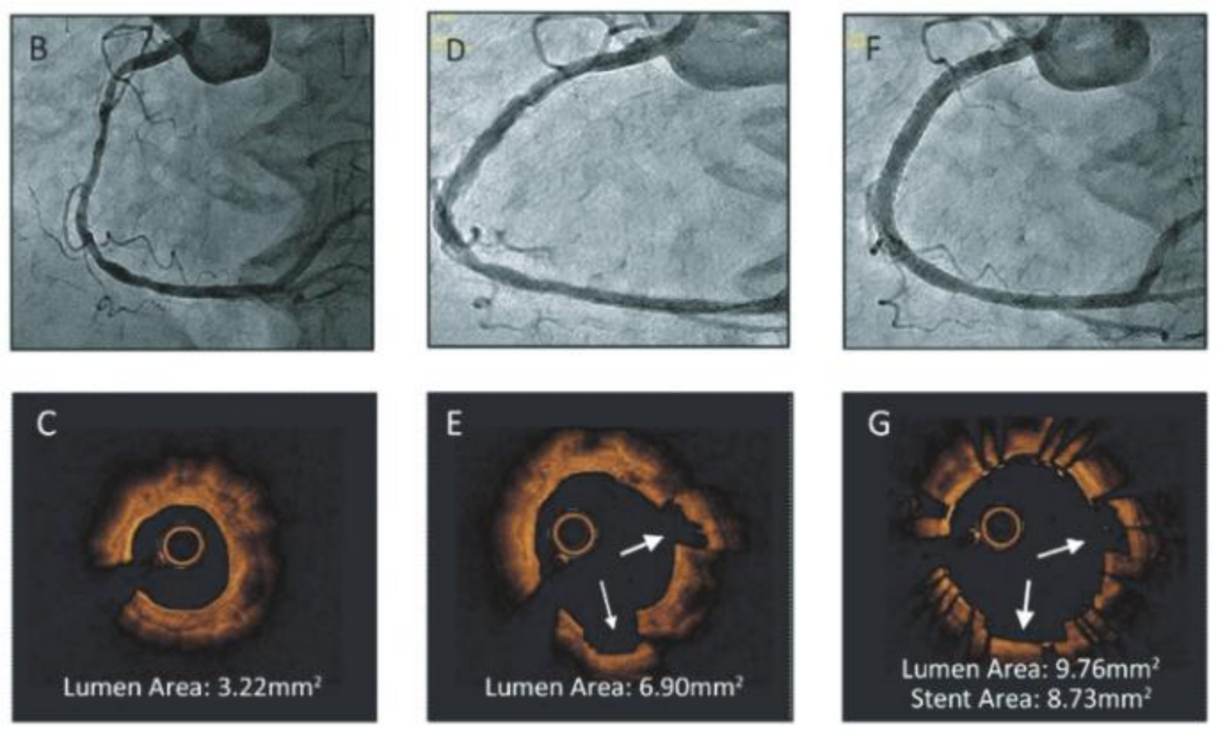




Hill, J.M. et al. J Am Coll Cardiol. 2020;76(22):2635–46.

DISRUPT-CAD Studies

	DISRUPT-CAD I	DISRUPT-CAD II	DISRUPT-CAD III	DISRUPT-CAD IV	Pooled result
Patients	60	120	384	64	628
Procedural success	95%	94%	92.4%	93.8%	92.4%
Stent delivery	100%	100%	99.2%	100%	99.5%
Severe dissection	0%	0%	0.3%	0%	0.2%
Perforation	0%	0%	0.3%	0%	0.2%
Abrupt closure	0%	0%	0.3%	0%	0.2%
Slow/no flow	0%	0%	0%	0%	0%

Kereiakes, D.J. et al. J Am Coll Cardiol Intv. 2021; 14 (12) 1337–1348.

ISAR-CALC 2 trial

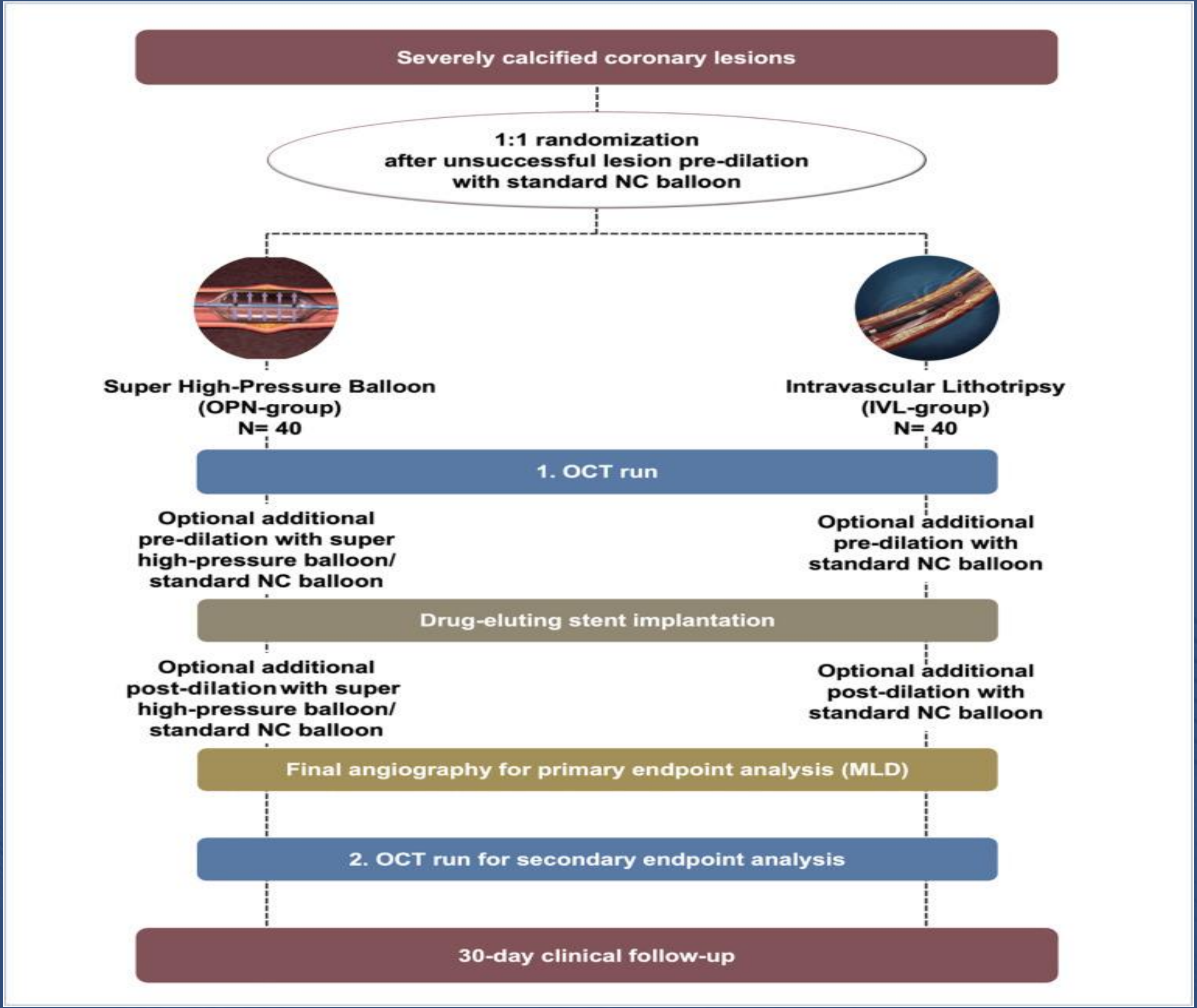
Randomized Comparison of Strategies to Prepare Severely Calcified Coronary Lesions 2

- **To compare a lesion preparation strategy with either super high-pressure balloon or intravascular lithotripsy in severely calcified undilatable coronary lesion**
- **Prospective, randomized, multicenter, assessors-blind, open-lable study**
- **Primary end point : final angiographic minimal lumen diameter after stent implantation**

Cardiovasc Revasc Med. 2023 Apr;49:22-27.

ISAR-CALC 2 trial

Randomized Comparison of Strategies to Prepare Severely Calcified Coronary Lesions 2



Cardiovasc Revasc Med. 2023 Apr;49:22-27.