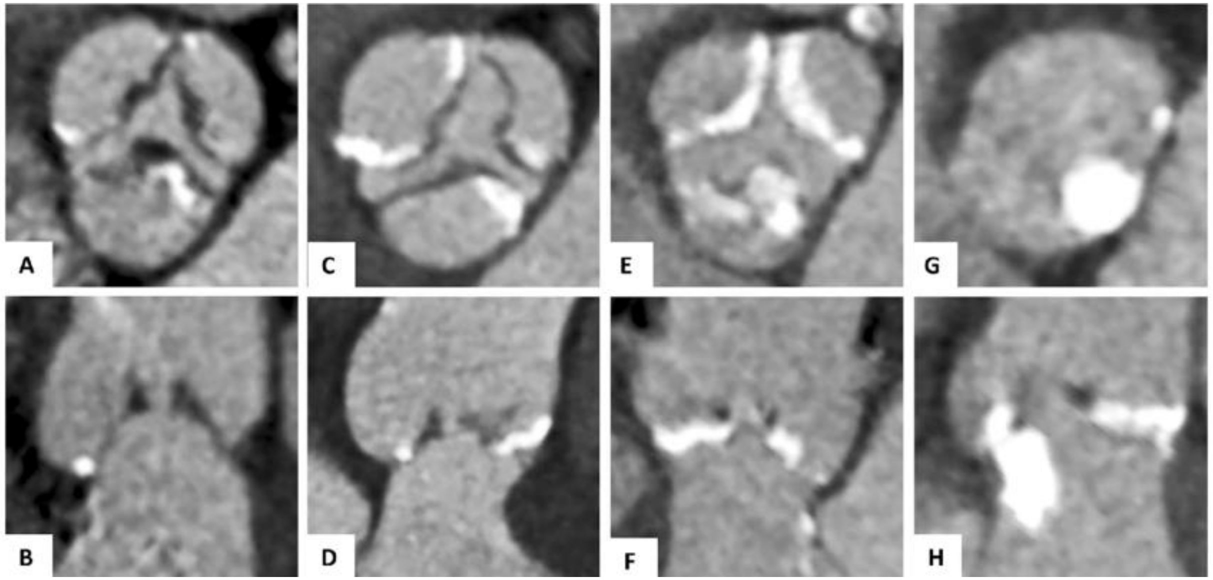
PCI of calcified lesions

Viktor Kočka
3rd faculty of Medicine
Charles University
University Hospital Královské Vinohrady
PRAGUE

Já, MUDr. Viktor Kočka, deklaruji, že:

	Nemám konflikt zájmů	Mám konflikt zájmů	Specifikace konfliktu (vyjmenujte subjekty, firmy či instituce, se kterými Vaše spolupráce může vést ke konfliktu zájmů)
Zaměstnanecký poměr	X		
Vlastník / akcionář	X		
Konzultant		X	Medtronic, Philips, Terumo, Abbott Vascular, Boston Scientific
Přednášková činnost		X	Medtronic, Philips, Terumo, Abbott Vascular, Boston Scientific
Člen poradních sborů (advisory boards)		X	Medtronic, Philips
Podpora výzkumu / granty	X		
Jiné honoráře (např. za klinické studie či registry)	X		

Calcium can be good ...



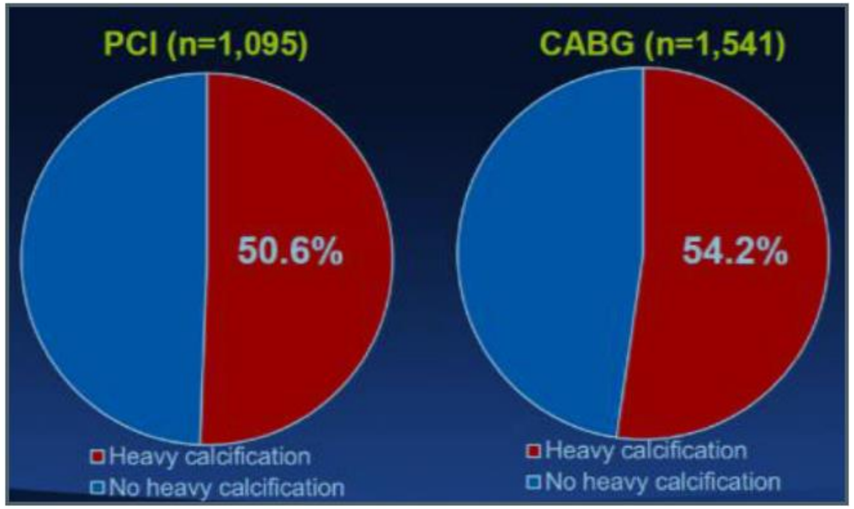
Coronary Artery Calcification (CAC)

- is common and is likely to become even more common in the future
- Intimal or Medial – defined by histology

Frequency of angio core lab 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)
Pooled	**29.0% (2,315/7,978**

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



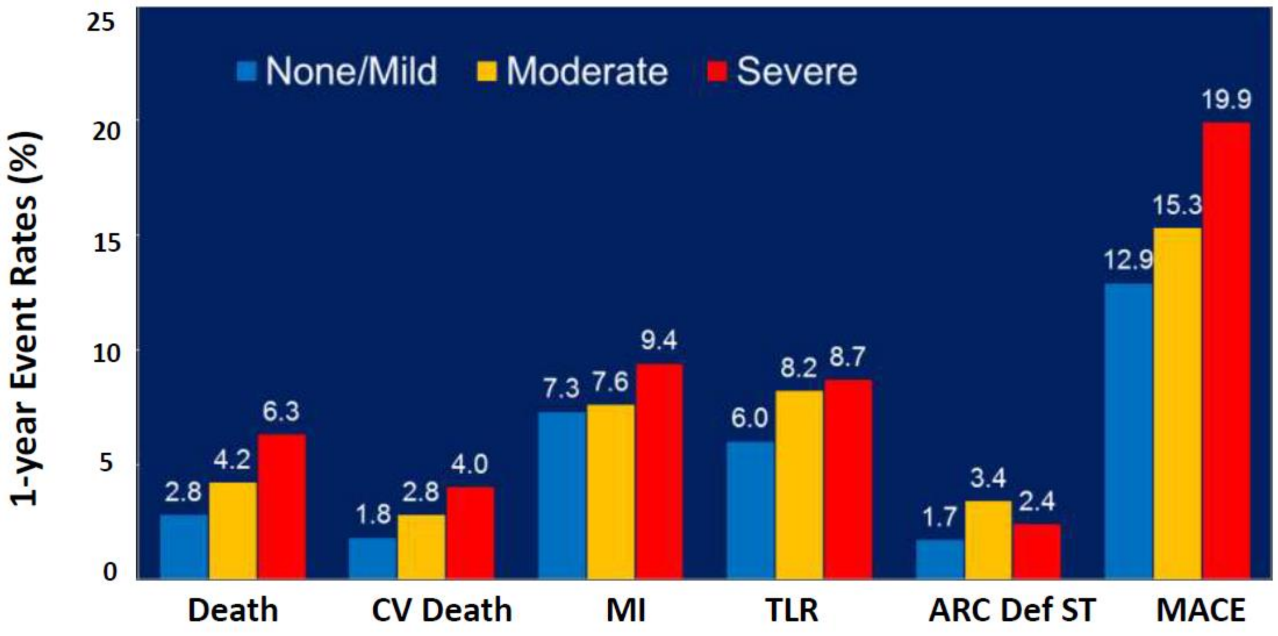
Farooq et al. J Am Coll Cardiol 2013;61:282–94

Coronary Artery Calcification (CAC)

Results in:
- Complicated procedure – difficult stent delivery, stent expansion
- Procedural complications – vessel dissection, perforation, slow-flow, stent thrombosis
- Long term consequences – MI, death, etc….

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

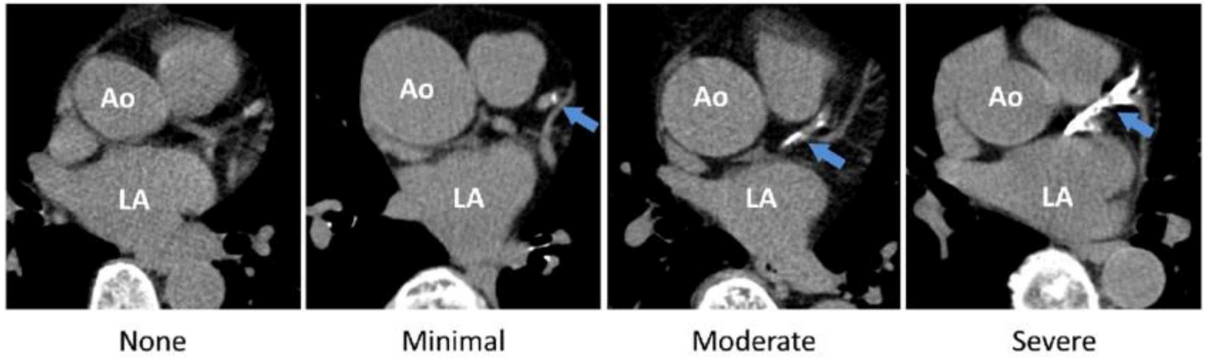
(1-year outcomes; n=6,855 pts)



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

Coronary Artery Calcification (CAC)

A) CT images of coronary arteries:



B) Calculation of CAC score (Agatston Method):

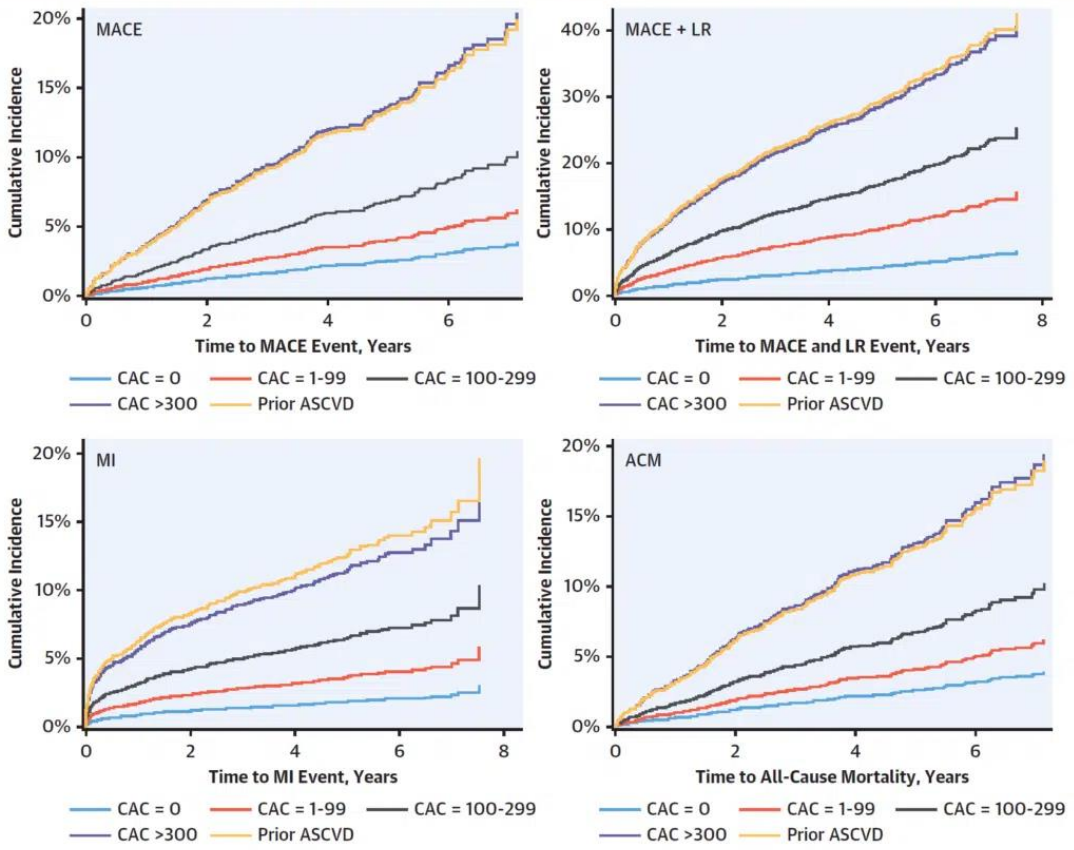
Definition of calcified lesion: (1) ≥130 Hounsfield Unit (HU) density
(2) ≥1mm^2 Area of lesion

Weights assigned to lesion density:

Lesion density	Weight	Lesion Score
130 to <200 HU	1	= Weight × Area of lesion (mm^2)
200 to <300 HU	2	
300 to <400 HU	3	
≥ 400 HU	4	

Total CAC Score: Sum of all lesion scores for all coronary CT slices (3mm)

CENTRAL ILLUSTRATION Event Rates by CAC Score Categories for MACE Compared to Prior ASCVD Patients

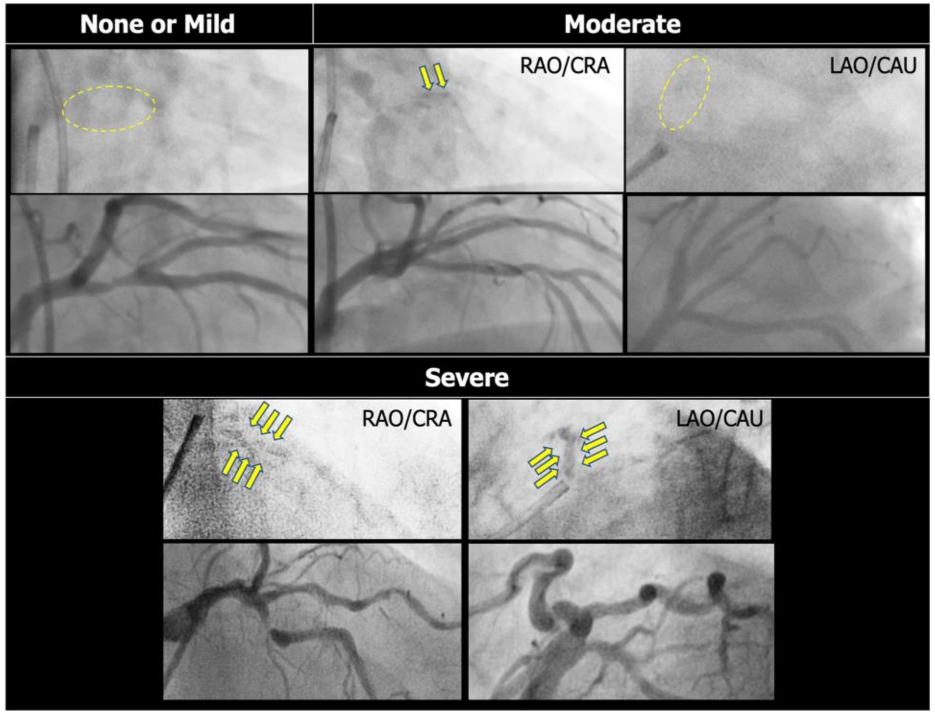


Budoff MJ, et al. J Am Coll Cardiol Img. 2023;16(9):1181-1189.

Event rates by coronary artery calcium (CAC) score distribution for major adverse cardiovascular events (MACE) **(upper left)**, MACE + late revascularization (LR) **(upper right)**, myocardial infarction (MI) **(lower left)**, and all-cause mortality (ACM) **(lower right)**. Follow-up was consistent for all endpoints, and each endpoint demonstrates that the event rates for CAC >300 are similar to those of patients who have established cardiovascular disease. ASCVD = atherosclerotic cardiovascular disease.

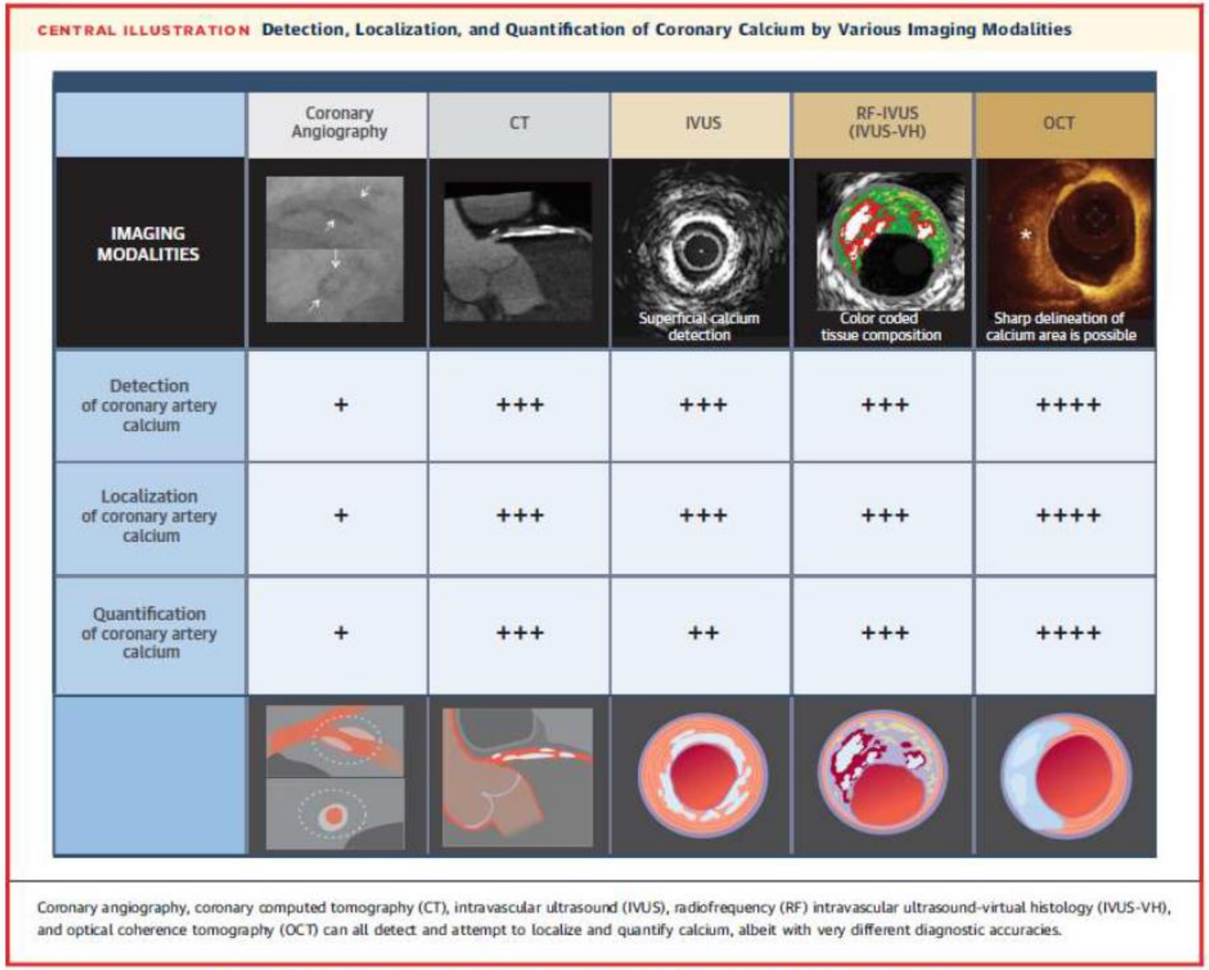
Coronary Artery Calcification (CAC)

Angiography is not the best tool to see CAC



Eur Heart J, Volume 44, Issue 41, 1 November 2023, Pages 4340–4356

Detection of Coronary Calcifications



	Coronary Angiography	CT	IVUS	RF-IVUS (IVUS-VH)	OCT
IMAGING MODALITIES					
Detection of coronary artery calcium	+	+++	+++	+++	++++
Localization of coronary artery calcium	+	+++	+++	+++	++++
Quantification of coronary artery calcium	+	+++	++	+++	++++

Coronary angiography, coronary computed tomography (CT), intravascular ultrasound (IVUS), radiofrequency (RF) intravascular ultrasound-virtual histology (IVUS-VH), and optical coherence tomography (OCT) can all detect and attempt to localize and quantify calcium, albeit with very different diagnostic accuracies.

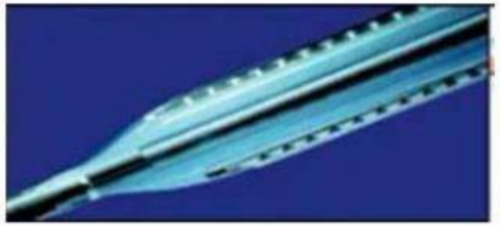
GS Minz ; JACC Cardiovasc Imaging 2015;8:461-471

Coronary Artery Calcification (CAC)

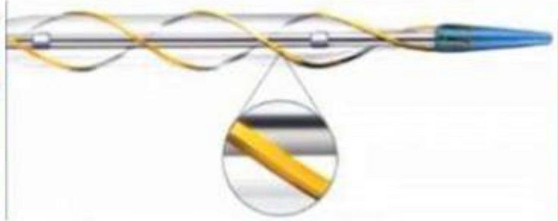
Tools for the management of coronary calcified lesions

NC Balloons

Cutting Balloon

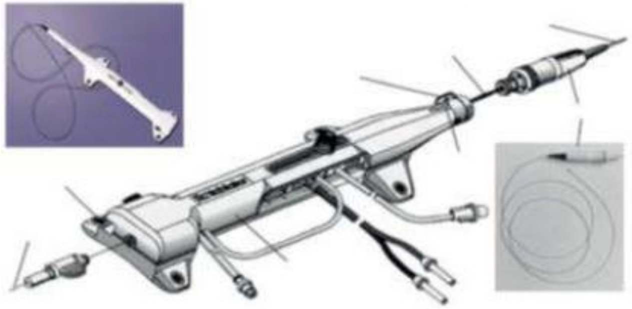


Anguiosculpt



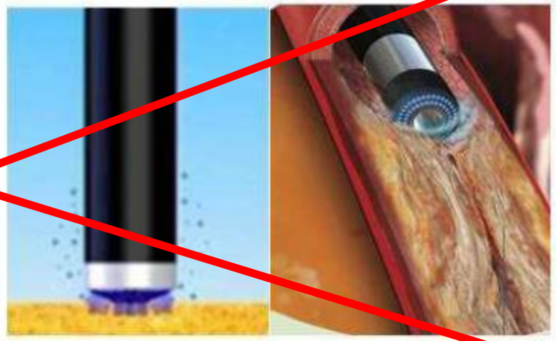
ShockWave Lithoplasty

Rotational-Ablation Atherectomy

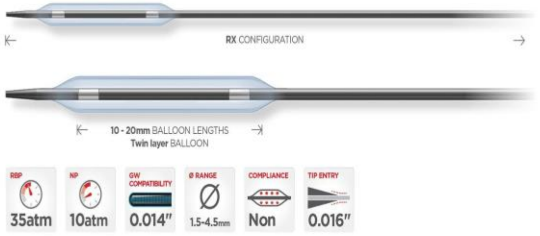


Orbital Atherectomy

Laser



SIS Medical OPN NC



CAC – balloons

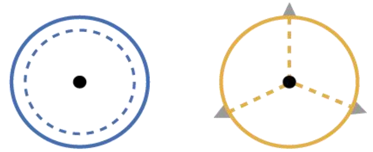
Conventional NC balloons:
- 2 projections to check full expansion, option to enhance – StentBoost
- after several high-pressure dilatations 0.014 in wire can adhere to the balloon potential for wire loss – buddy ??

Cutting balloons:
- slow inflation/deflation + undersize by 0.5 mm and move the target to reduce risk of perforation
- less slippage – especially Ca++ ostial lesions
- Wolverine designed to be more deliverable

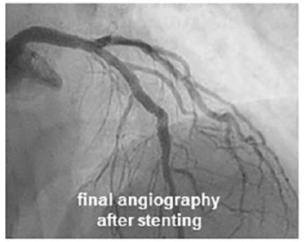
Scoring balloons:
- in theory more deliverable then cutting balloon

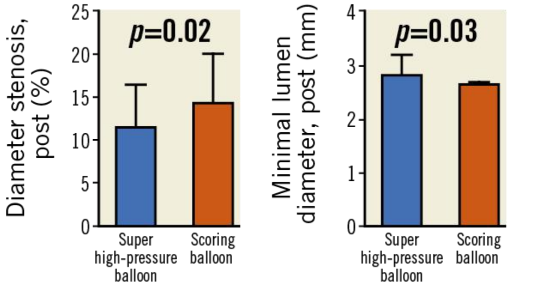
High-pressure balloons:
- double-layer strucure, rigid
- 53% of lesions achieve full expansion with 35 Atm, but remaining 47% require over 40 Atm.
- approx. 1% risk of vessel perforation
- undersize by at least 0.5 mm in native vessels, no undersizing in stent postdilatation

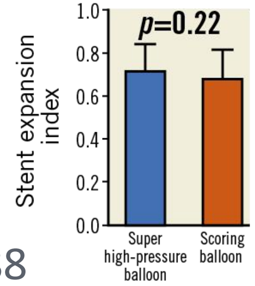
74 patients randomised 1:1 at 5 centres



	Super high-pressure balloon	Scoring balloon
Technology	Twin-layer construction	Nylon scoring elements
Diameter/length, range (mm)	1.5-4.5/10-20	2.0-4.0/13
Rated burst pressure (atm)	35	14







ISAR-CALC. 2021 Aug 27;17(6):481-488

CAC – when balloon are not enough?

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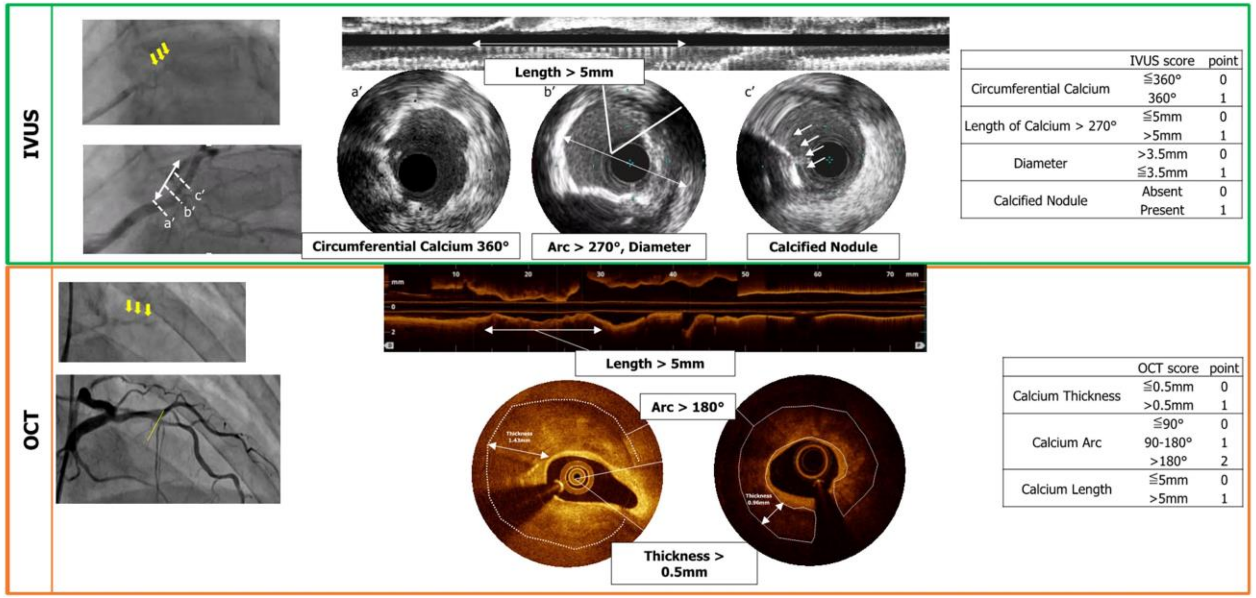
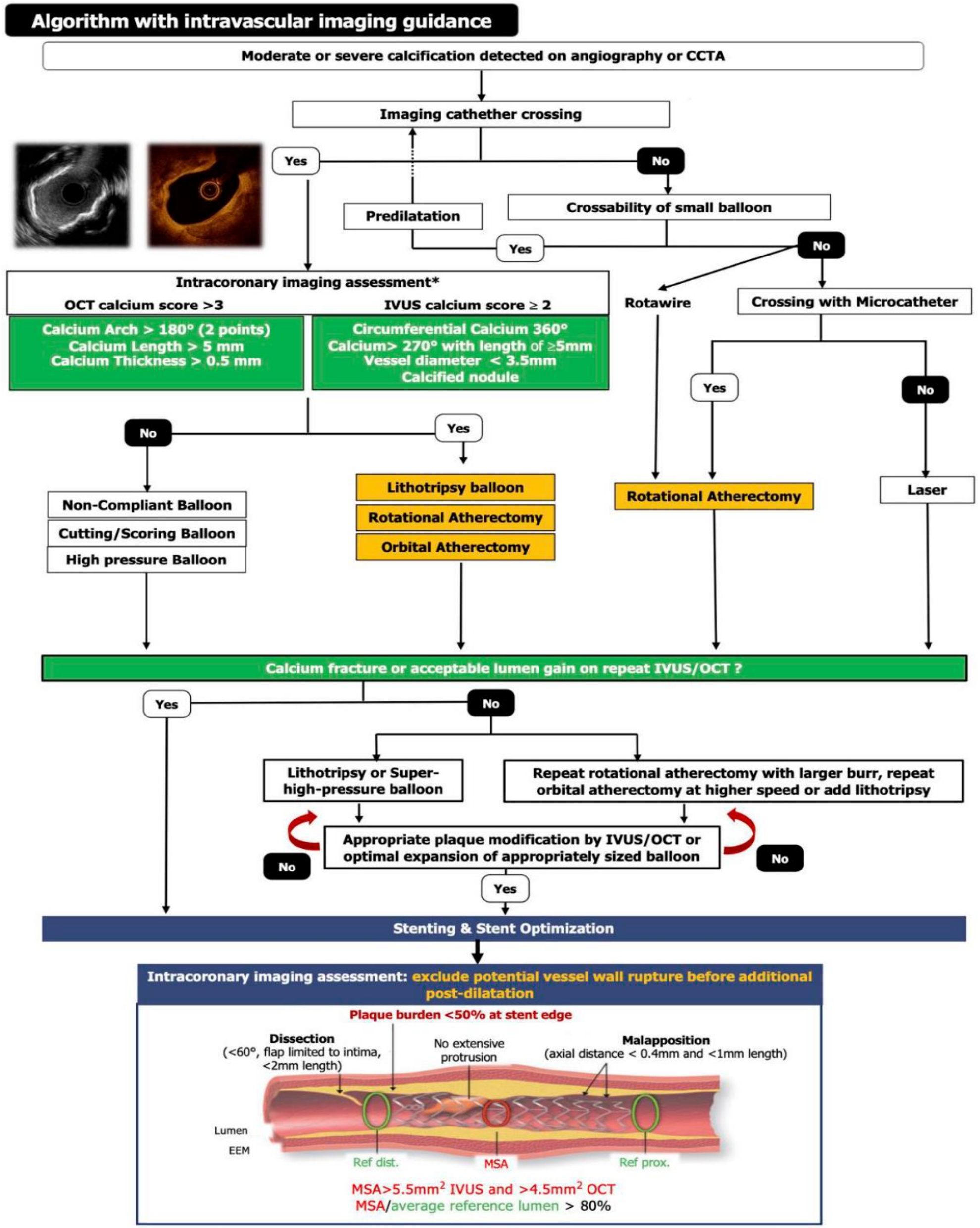
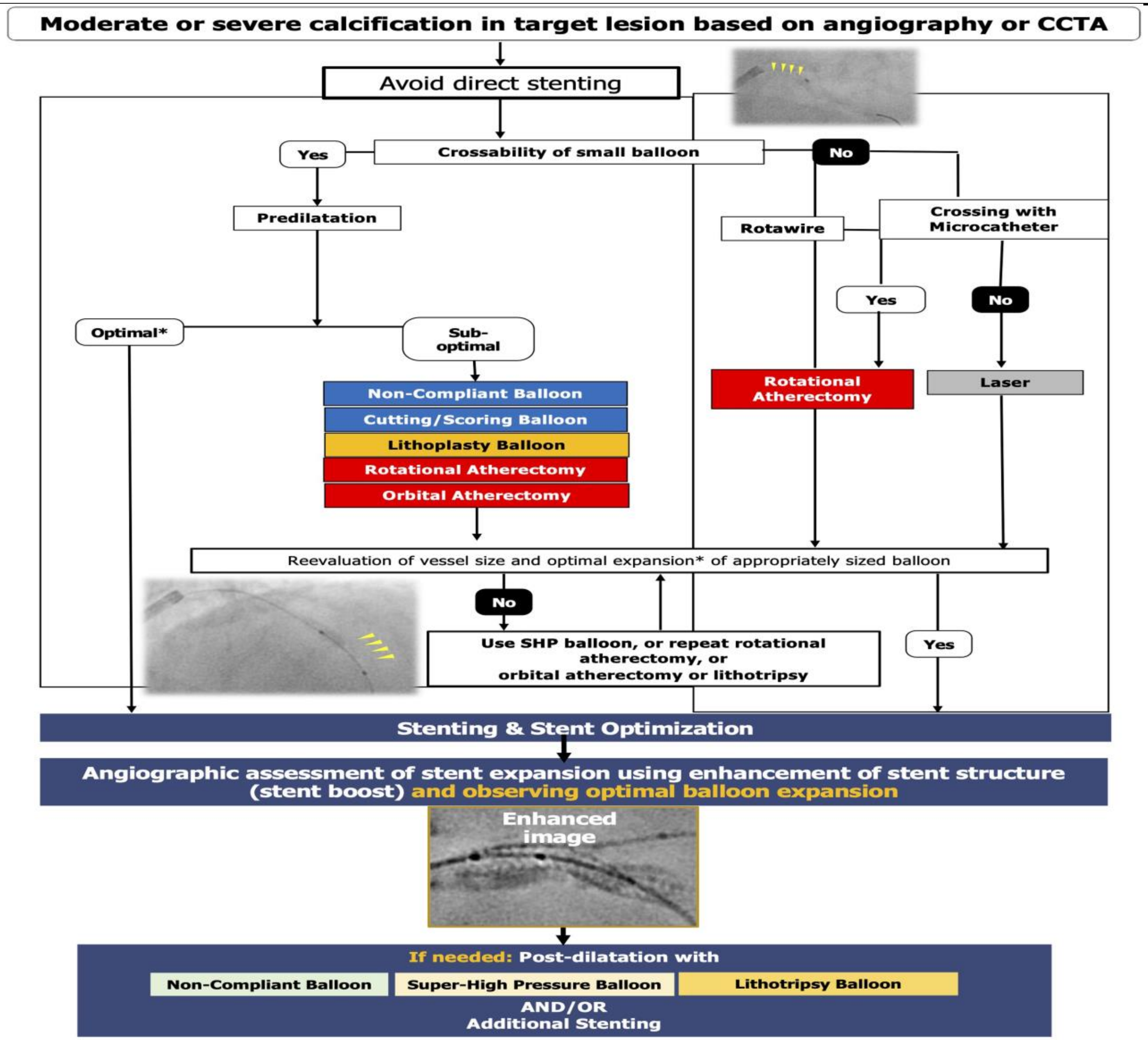


European Heart Journal (2023) **44**, 4340–4356



CAC – when balloons are not enough 2? No IVI

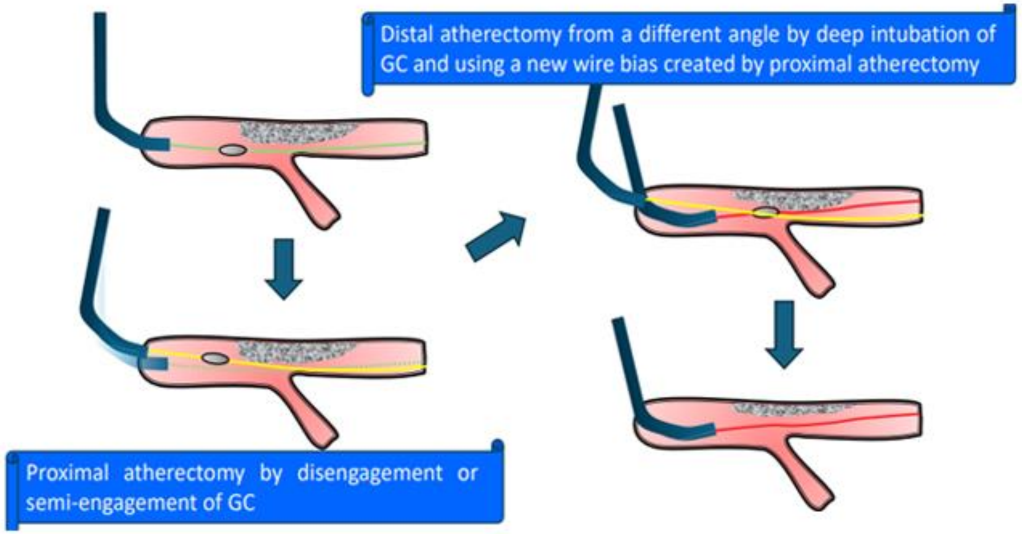


*Optimal expansion is defined as follows: i) during balloon inflation, homogenous full balloon expansion is achieved throughout the entire balloon length, as assessed visually in two orthogonal views, and ii) on angiography after dilatation there is no luminal constriction observed at the site of visible calcification

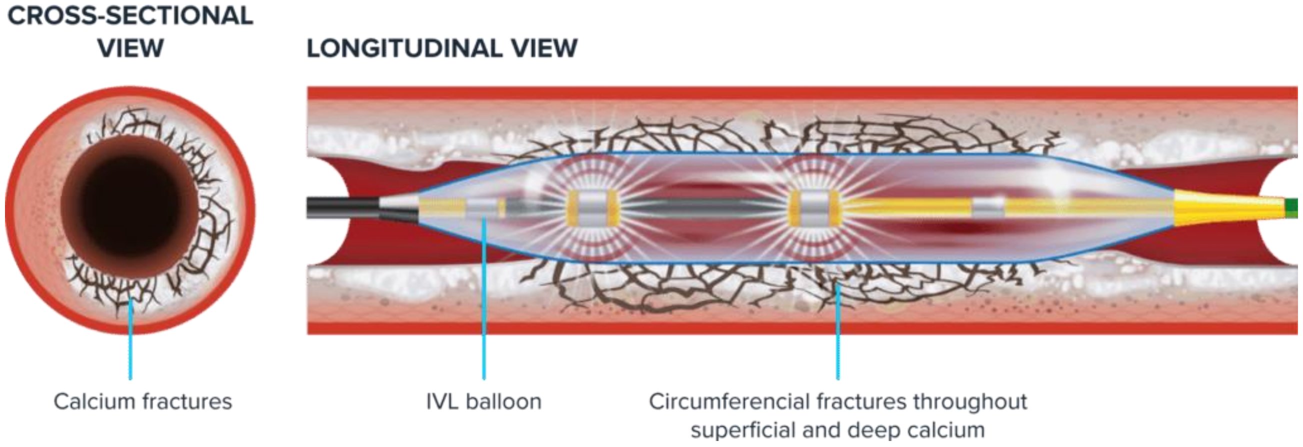
https://cardiologyapps.com/calcificaid-algorithm/

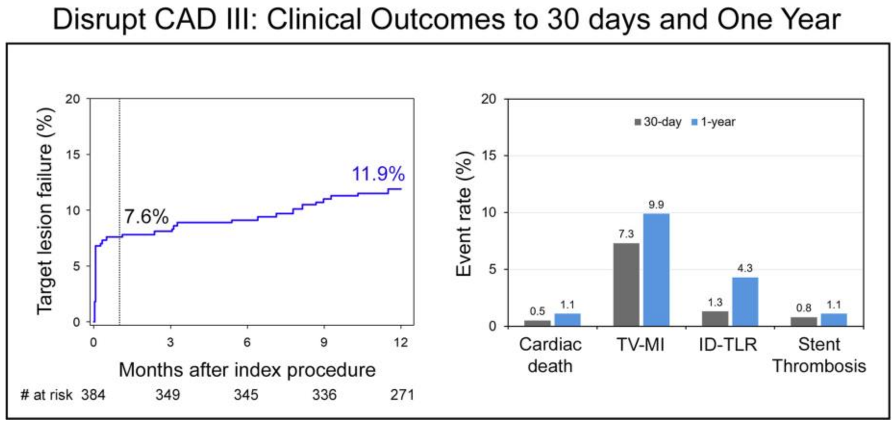
ROTABLATION

1. Guiding selection – good support, size based on burr size (burr/artery ratio 0.4-0.6) 1.5mm burr to 6-7Fr guiding, 2mm burr to 8 Fr guiding
2. Wiring – standard 0.014 in wire ….microcatheter…RotaWire Floopy or ES. Uncrossable lesions – microcatheter + direct wiring; watch the distal tip, keep the burr away from distal radiopaque tip
3. Ablation – flush with saline + heparin+nitrate + verapamil. Pecking motion with speed 135000-180000/min and duration under 30s, avoid decelerations over 5000/min
4. Take great care if you need to use guiding extensions
5. Randomized studies – PREPARE-CALC a ROTAXUS – no major benefit on clinical outcomes, but higher procedural success
6. Complications:
   a) slow-flow…no-flow…AV block. Higher speed, ic nitrate, ACT above 250s, Atropine, pacing.
   b) burr entrappment – feared and potentially serious issue. Slow pecking!! Beware tortuous segments. Cut the system, pull sheath and advance guiding extension over the system to protect proximal vessel from injury



Intravascular Lithotrypsy (IVL) Shockwave





Kereiakes DJ, Hill JM, Shlofmitz RA, et al. Intravascular lithotripsy for treatment of severely calcified coronary lesions: 1-year results from the disrupt CAD III study. J Soc Cardiovasc Angiogr Interv. 2022;1(1):100001. https://doi.org/10.1016/j.jscai.2021.100001

1. Can be placed on any 0.014 in wire, with second wire able to protect bifurcation branch
2. Balloon needs to be well de-aired
3. Subanalysis of all DISRUPT studies did not find any difference between concentric, eccentric or nodular morphology
4. Requires long and reccurent inflations – problematic in LM – longer rest periods might help

ECLIPSE

Nicola Ryan

Source: PCRonline.com

2,005 patients with de-novo angiographically severe calcified lesions

Outcome: Post PCI in-stent MSA by OCT, 1-yr TVF

Orbital atherectomy	Balloon angioplasty
MSA 7.67mm²	**MSA 7.42mm²**
TVF 11.5%	**TVF 10.0%**
	

MSA diff 0.26, 95% CI -0.31-0.82, p=0.08, TVF HR 1.16, 95% CI 0.87-1.54, p=0.28

> A routine strategy of OA should not be adopted in patients with angiographically severely calcified coronary lesions.

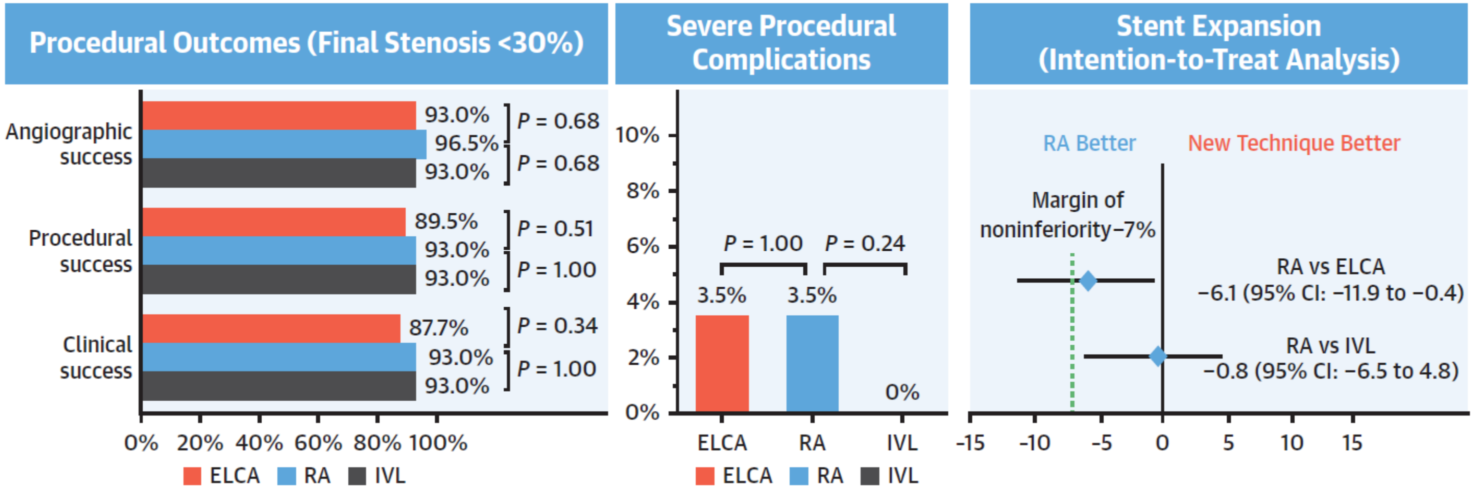
CENTRAL ILLUSTRATION RA vs IVL and ELCA for the Treatment of Patients With Calcified Coronary Lesions

The ROLLER COASTR-EPIC22 Trial: Rotational Atherectomy (RA) Versus IVL Versus ELCA for Treatment of Calcified Coronary Stenosis

PCI of angiographically moderate or severe calcified lesions

N = 171

n = 57 | n = 57 | n = 57



- IVL was noninferior to RA for stent expansion measured with OCT
- In the ITT analysis, ELCA did not reach the noninferiority margin compared with RA
- No significant differences were observed among the 3 groups for minimum stent area, procedural success rate or complications, although the latter were numerically lower with IVL

Jurado-Román A, et al. JACC Cardiovasc Interv. 2025;18(5):606-618.

ELCA = excimer laser coronary angioplasty; ITT = intention-to-treat; IVL = intravascular lithotripsy; PCI = percutaneous coronary intervention; RA = rotational atherectomy.

Table 2: Angioplasty, Atherectomy, and Lithotripsy Clinical Trial Data

Trial	Study Design	Sample Size	Study Arms	Outcomes/Results	Conclusions
LAVA Study (1997)[49]	Randomized controlled trial	215	117 laser versus 98 PTCA alone	No difference in procedural success or diameter stenosis after treatment	No benefits of laser-facilitated PTCA versus stand-alone PTCA Procedural complications significantly increased with laser
STRATAS (2001)[13]	Randomized controlled trial	497	249 aggressive RA burr sizing (burr/artery ratio >0.70) versus 248 routine RA burr sizing (burr/artery ratio <0.70)	6-month TLR 31% with aggressive RA strategy versus 22% with routine RA strategy Restenosis 58% with aggressive RA strategy versus 52% with routine RA strategy	Aggressive RA with burr/artery ratio >0.70 offers no advantage over routine RA strategy A decrease in rpm >5,000 from baseline associated with CK-MB elevation, and restenosis
CARAT (2001)[12]	Randomized controlled trial	222	104 RA burr/artery ratio >0.7 (lesion debulking) and 118 RA burr/artery ratio <0.7 (lesion modification)	Diameter stenosis at procedure end	No differences in procedural success, extent of immediate lumen enlargement, or late TVR Large burrs had more serious angiographic complications (12.7% versus 5.1%)
ROTAXUS (2013)[67]	Randomized controlled trial	240	120 RA + DES versus 120 PTCA + DES	9-month in-stent late lumen loss 0.44 RA versus 0.31 PTCA, despite higher acute lumen gain with RA	Balloon dilation with provisional RA preferred over routine RA
LEONARDO Study (2015)[50]	Prospective, single-arm	80	100 lesions (96 treated with ELCA)	Laser success 93.7%, procedural success 91.7%, clinical success 90.6% No major complications	LA is simple, safe, and effective for complex lesions
ROTATE (2016)[17]	Registry	985	1167 lesions treated with RA	In-hospital MACE 8.3%, driven by periprocedural MI	RA is safe and effective in severely calcified lesions
ORBIT II (2016)[40]	Prospective, single-arm	443	OA + BMS (43), OA + first-generation DES (74), OA + second-generation DES (312)	2-year MACE, 19.4% (BMS), 4.3% (first-generation DES), 8.1% (second-generation DES)	OA is safe and effective in *de novo*, severely calcified lesions
Registry of OA (2016)[44]	Multicenter registry	458	OA + DES	30-day MACCE 1.7%	Real-world patients to include high-risk and surgical turn-down Acute and short-term adverse rates were low
Disrupt CAD II Study (2019)[52]	Prospective, multicenter, single-arm	120	IVL on calcified coronary lesions	Calcium fracture identified in 78.7% of lesions In-hospital MACE, 5.8% with non-Q-wave MI	IVL safely performed with high procedural success
OA versus RA meta-analysis (2020)[58]	Meta-analysis	1,872	535 OA versus 1,337 RA	OA lower fluoroscopy times No difference in 30-day MI, complications, mortality, TVR, or MACE	No significant differences between OA versus RA except fluoroscopy time
ECLIPSE Trial NCT03108456 (ongoing)	Randomized controlled trial	2,000 (planned enrollment)	OA versus PTCA prior to DES implantation	Acute minimum stent area, procedural success, and 1-year TVF	
DISRUPT CAD III NCT03595176 (ongoing)	Prospective multicenter single-arm	392 (planned enrollment)	IVL prior to DES implantation	Adverse events, procedural success (residual stenosis <50%)	

BMS = bare-metal stent; DES = drug-eluting stent; ELCA = excimer laser coronary atherectomy; IVL = intravascular lithotripsy; MACE = major adverse cardiovascular events; MACCE = major adverse cardiovascular and cerebrovascular events; MB = modified balloon-cutting or scoring balloon; OA = orbital atherectomy system; PTCA = percutaneous coronary angioplasty; RA = rotational atherectomy; RCT = randomized clinical trial; TLR = target lesion revascularization; TVF = target vessel failure.

Table 1: Angioplasty, Atherectomy, and Lithotripsy Device Comparison

	Atherectomy and Laser Lesion Modification			Balloon-based Lesion Modification			
Device	Rotational atherectomy	Orbital atherectomy	Excimer laser coronary atherectomy	Intravascular lithotripsy	Cutting balloon	Scoring balloon	Super high-pressure non-compliant balloon
Mechanism of action	Differential cutting with mechanical ablation of inelastic plaque by concentric rotation and antegrade movement of an elliptical burr	Differential sanding of calcified plaque by elliptical rotation and antegrade and retrograde movement of an eccentrically mounted crown	Ablation and modification of recalcitrant lesions by catheter emitted pulses of ultraviolet light	Disruption of calcified lesions with unfocused circumferential pulsatile mechanical energy during low-pressure balloon inflation[63]	Creation of discrete incisions in fibrocalcific tissue by multiple longitudinally placed atherotomes	Controlled expansion with low dissection rates using a balloon with external nitinol scoring wires[6]	Uniform lesion expansion using a twin layer balloon design to very high pressure[29]
Device sizes	Burrs (mm): 1.25, 1.50, 1.75, 2.00, 2.15, 2.25, 2.38, and 2.50	Crown (mm): 1.25	Catheters (mm): 0.9, 1.4, 1.7, and 2.0	Balloons (mm): 2.5–4.0 diameter (in 0.25 mm increments) in 12 mm length	Balloons (mm): 2.0–4.0 (in 0.25 mm increments) in 6, 10, and 15 mm lengths	Balloons (mm): 2.0–3.5 (in 0.5 mm increments) in 6, 10, and 15 mm lengths	Balloons (mm): 1.5–4.5 (in 0.5 mm increments) in 10, 15, and 20 mm lengths
Guide catheter compatibility	6 Fr: 1.25 mm and 1.50 mm burr 7 Fr: 1.75 mm burr 8 Fr: 2.00 mm and 2.15 mm burr 9 Fr: 2.25 mm and 2.38 mm burr 10 Fr: 2.50 mm burr	6 Fr	6 Fr: 0.9, 1.4 mm 7 Fr: 1.7 mm 8 Fr: 2.0 mm	6 Fr	6 Fr	6 Fr	5 Fr
Device sizing	Burr-to-artery ratio: 0.4–0.6[34]	Single size crown	Catheter-to-vessel ratio: 0.5–0.6	1:1 sizing[63]	≤1:1 sizing	≤1:1 sizing	≤1:1 sizing
Technique	Rotational speed of 140,000–180,000 rpm using a 'pecking' motion with gradual burr advancement, short ≤30 s runs, and avoidance of decelerations >5,000 rpm[31,34]	Rotational speed options of 80,000 and 120,000 rpm with higher speed translating to a larger crown orbit, slow crown advancement (1–3 mm/s), short ≤30 s runs[32]	Laser activation of 10 s with a 5 s pause prior to next pulse, very slow catheter advancement (0.5 mm/s), manual flush saline infusion before and during ablation required[47]	Delivery of 1 cycle of 10 pulses (1 pulse/s) for total of 8 cycles per catheter[63]	Rapid exchange balloon with very slow and controlled inflation and deflation	Rapid exchange balloon with very slow and controlled inflation and deflation	Rapid exchange balloon designed to deliver high-pressure inflation ≥35 atm[47]
Complications	No-reflow, dissection, perforation, burr entrapment, AV block[34]	No-reflow, dissection, perforation, abrupt closure[44]	Dissection, perforation[7]	Dissection, electric signals similar to pacing spikes, asynchronous cardiac pacing[63]	Dissection, perforation[6]	Dissection[32]	Dissection[29]
Wire	RotaWire Floppy (0.014/0.009"), RotaWire Extra Support (0.014/0.009")	ViperWire (0.014/0.012"), ViperWire Advance with Flex Tip (0.014/0.012")	Standard 0.014" coronary guidewire	Standard 0.014" coronary guidewire	Standard 0.014" coronary guidewire	Standard 0.014" coronary guidewire	Standard 0.014" coronary guidewire
Particle size	5–10 μm	<2 μm	<10 μm	–	–	–	–
Regulatory approval	FDA, CE mark	FDA, CE mark	FDA, CE mark	CE mark	FDA, CE mark	FDA, CE mark	CE mark

CE = Conformité Européenne; ELCA = excimer laser coronary atherectomy; FDA = Food and Drug Administration; IVL = intravascular lithotripsy.

Thank you