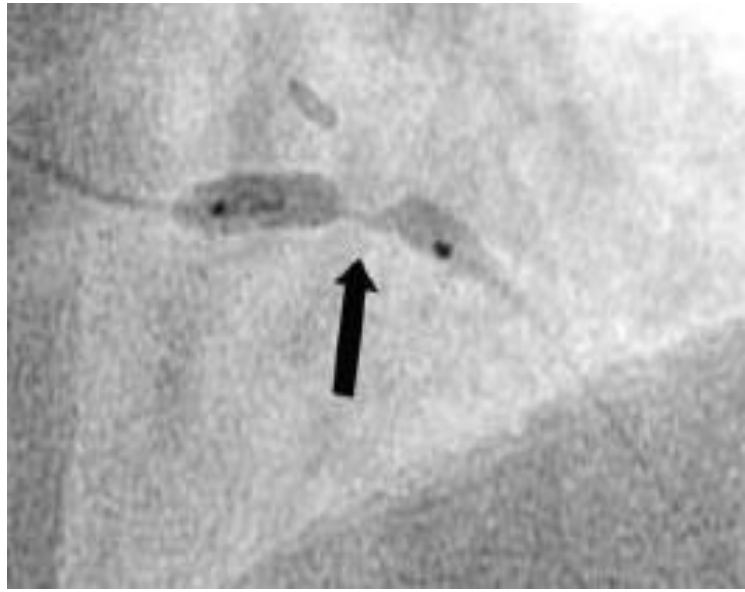
Non-dilatable coronary lesions- a practical approach to optimizing outcomes in PCI

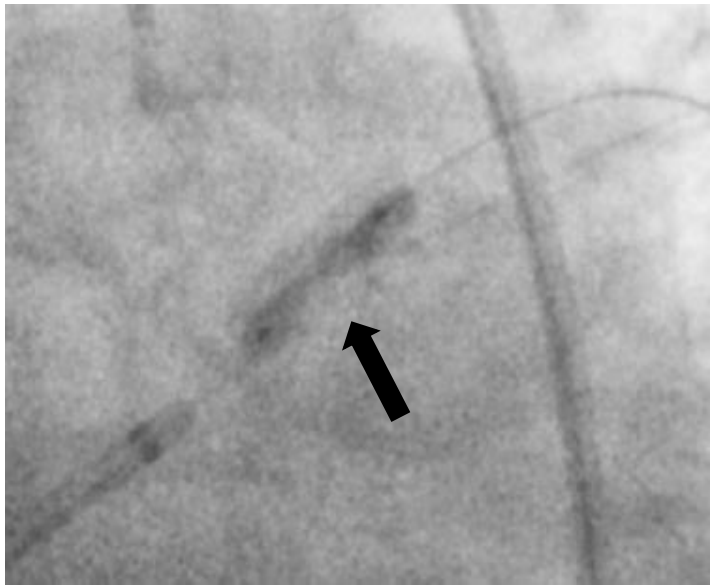
Ivayla Zheleva

Acibadem City Clinic Tokuda Hospital
Sofia, Bulgaria

Definition of non-dilatable coronary lesion

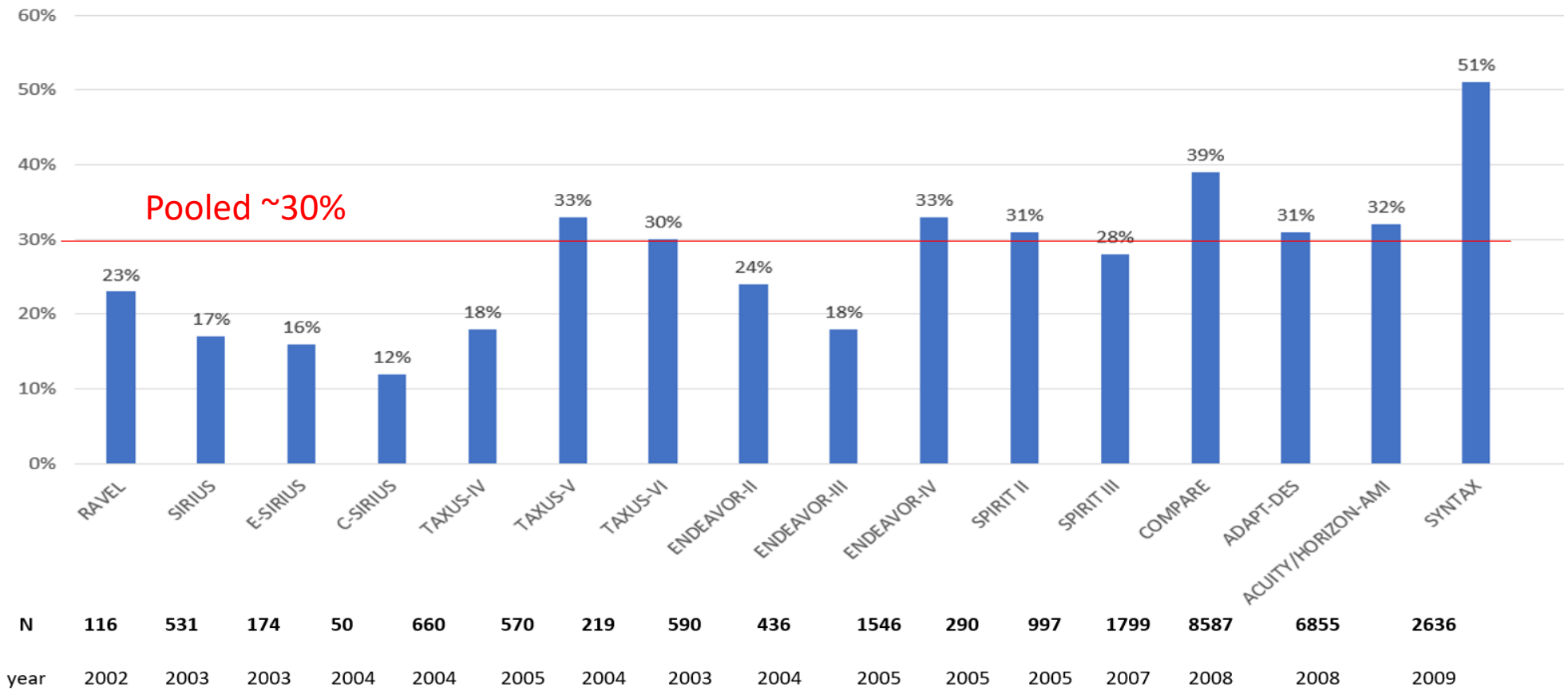
- Lesions that fail to expand despite multiple balloon inflations after successful guidewire crossing.
- An ongoing challenge in interventional cardiology
- Usually heavily calcified





Moderate –severe calcification in DES studies

According to the studies, moderate-to-severe calcification is estimated to be present in 12% to 51% of coronary lesions and is likely to grow.



Results from different studies are not directly comparable. Adapted from Kirtane CHIP DC 2017; ADAPT-DES: Genereux,P. et al., Int.J.Cardiolol;2017 (231):61-67 ; Farooq V, et al. the SYNTAX trial. J Am Coll Cardiol. 2013 Jan 22;61(3):282-941Généreux P, et. al. J Am Coll Cardiol 2014;63:1845–54.; Waters, et al. JACC 2014;63:1855-1856.

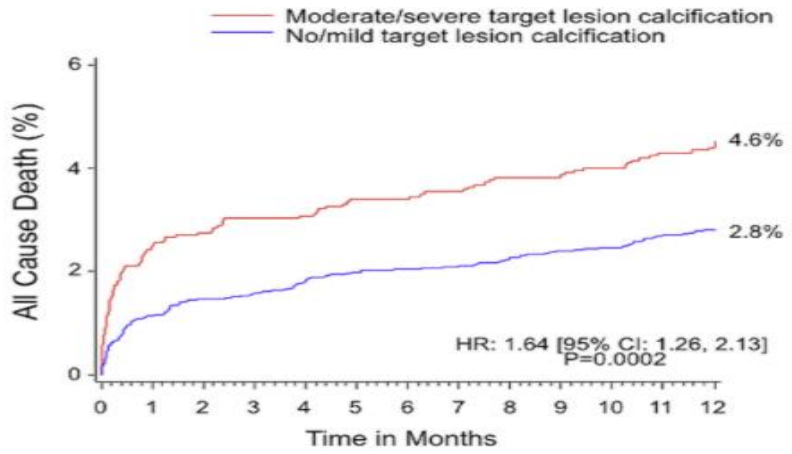
Why Calcium Matters

Increases the complexity of the PCI

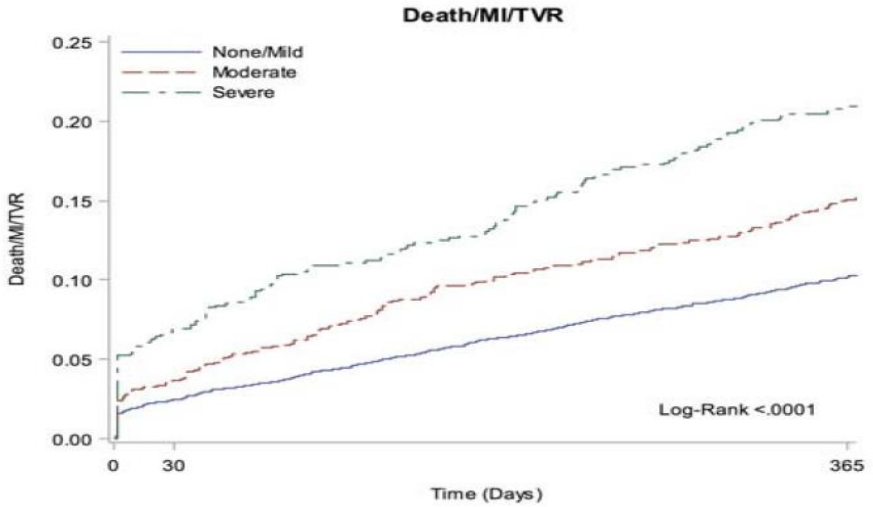
- affect the crossing of the lesion
- affect proper stent expansion and apposition
- damage the drug-eluting polymer
- increase the risk of stent thrombosis and restenosis
- increase the risk of procedural complications

Why Calcium Matters

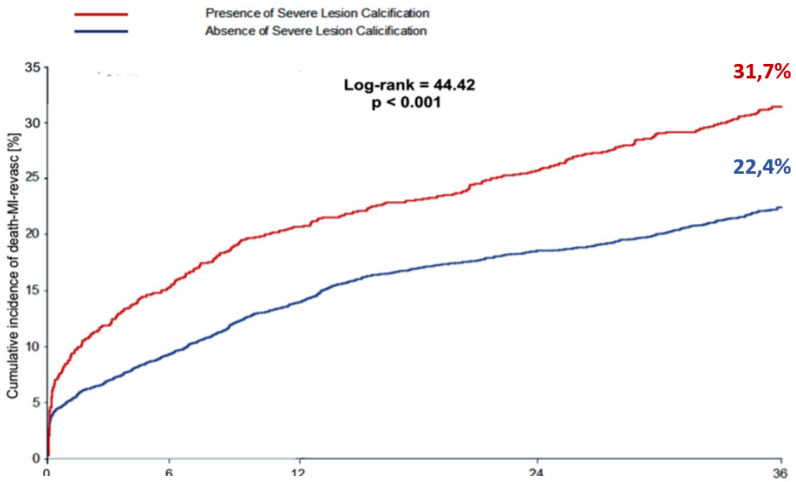
Poor outcomes (↑mortality, ↑MACE)



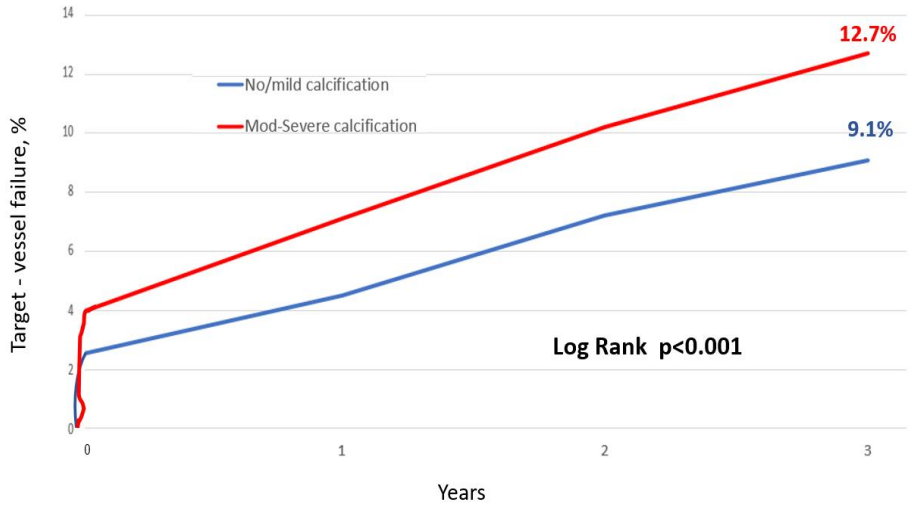
Généreux P,et al. J Am Coll Cardiol. 2014 May 13;63(18):1845-54.



Copeland-Halperin R.S. et al., Catheter Cardiovasc Interv., 91 (2018), pp. 859-866.



Bourantas CV, et al. Heart. 2014 Aug;100(15):1158-64



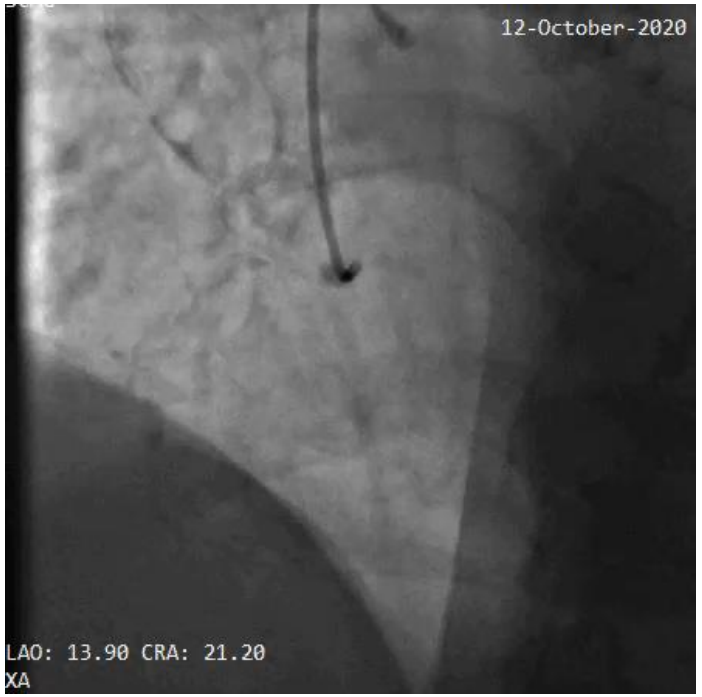
Lee CH, et IRIS-DES Registry Investigators. Coron Artery Dis. 2021 Jan;32(1):42-50.

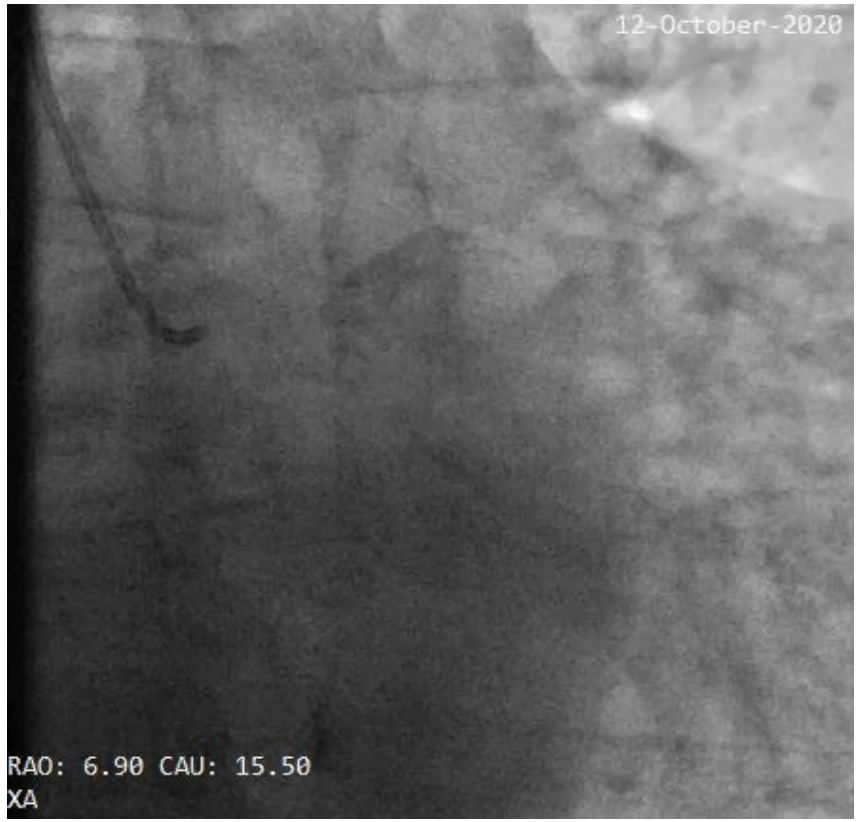
Case Dx

62 y/o male , chest pain, HTM

Right radial artery

Severely calcified RCA

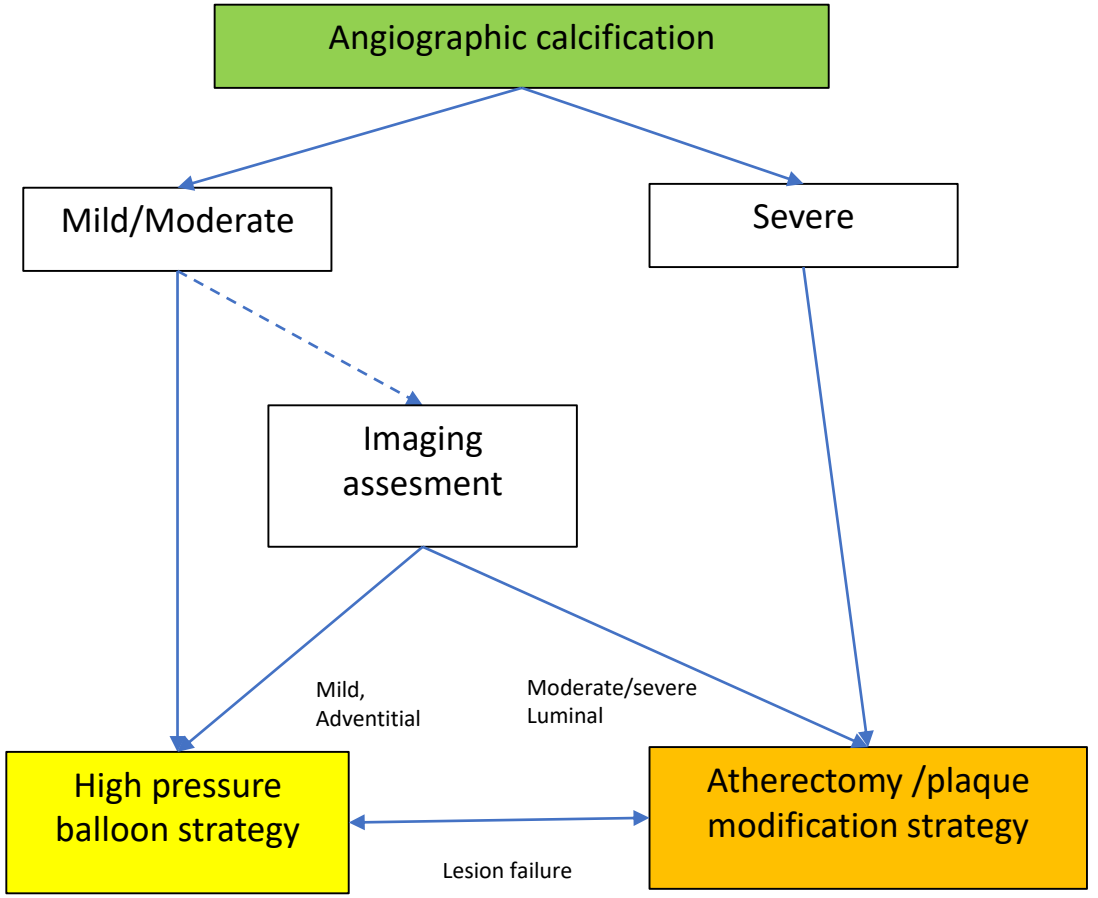




Severely calcified proximal LAD

Approach to calcified lesions

Conventional balloon options	**Atherectomy approach (plaque scoring)**	**Atherectomy approach (plaque debulking and/or modification)**
Noncompliant balloons / OPN	Longitudinal focused force angioplasty (buddy wires)	Rotational atherectomy
High pressure inflations	Cutting balloon	Orbital atherectomy
Larger balloon diameter	Scoring balloon	Excimer laser
		Coronary lithoplasty



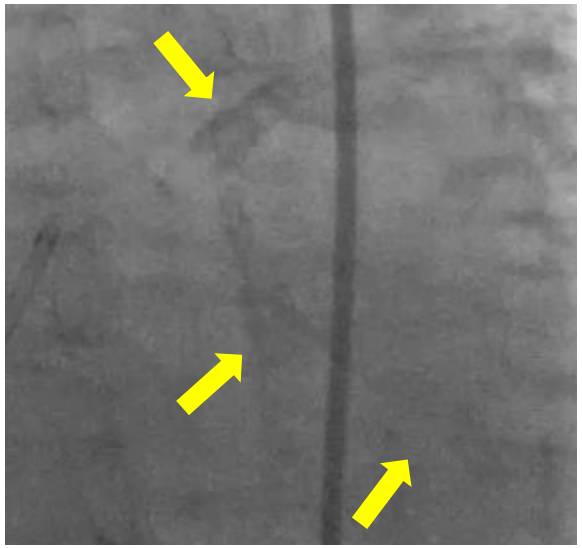
Imaging Coronary Calcification

- Fluoroscopy/cineangiography
- IVUS (gray-scale and radiofrequency)
- OCT

	IVUS (+)	IVUS (–)
Angio (+)	176	1
Angio (–)	188	75

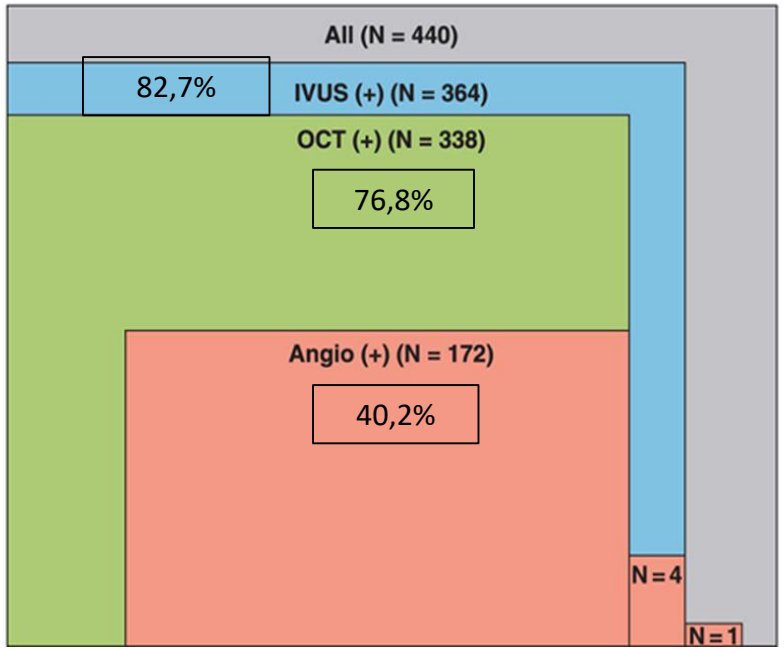
	OCT (+)	OCT (–)
Angio (+)	172	5
Angio (–)	166	97

	OCT (+)	OCT (–)
IVUS (+)	338	26
IVUS (–)	0	76



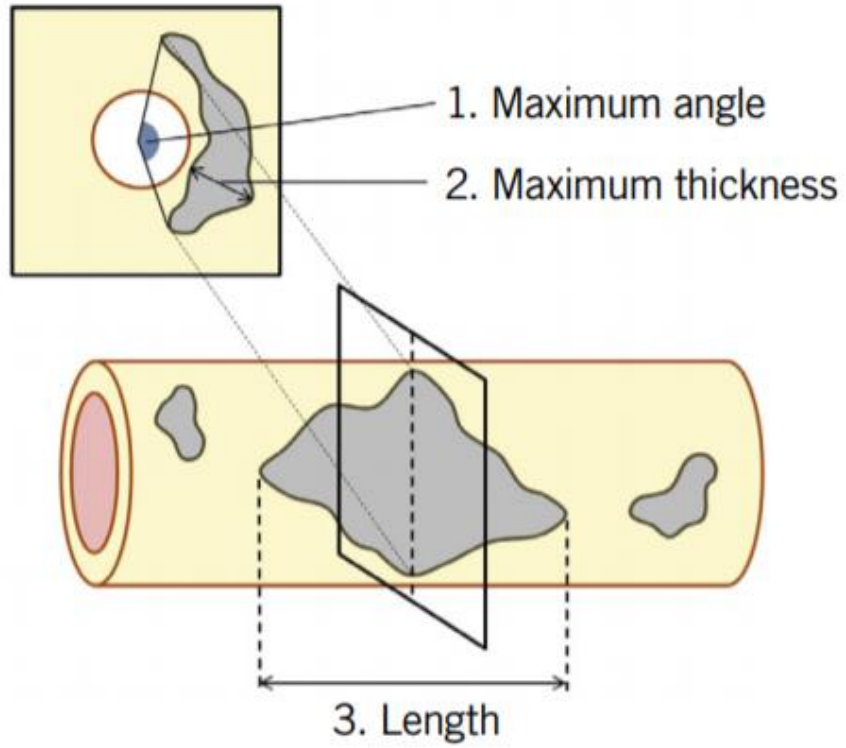
440 lesions with IVUS and OCT-guided stent implantation

Disagreement between angiography and other modalities was due to thinner layers of calcium that importantly did NOT appear to affect stent expansion



Wang X et al. In Vivo Calcium Detection by Comparing Optical Coherence Tomography, Intravascular Ultrasound, and Angiography. JACC Cardiovasc Imaging. 2017 Aug;10(8):869-879.

Imaging Coronary Calcification

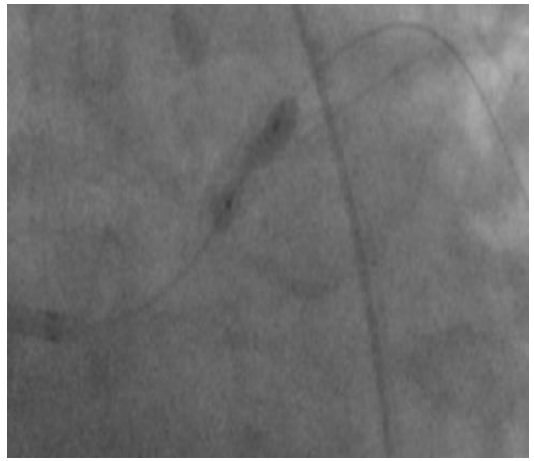


OCT-based calcium score	
1. Maximum calcium angle (°)	≤180° ➡ 0 point >180° ➡ 2 points
2. Maximum calcium thickness (mm)	≤0.5 mm ➡ 0 point >0.5 mm ➡ 1 point
3. Calcium length (mm)	≤5.0 mm ➡ 0 point >5.0 mm ➡ 1 point
Total score	**0 to 4 points**

Fujino A, et al. EuroIntervention. 2018 Apr 6;13(18):e2182-e2189.

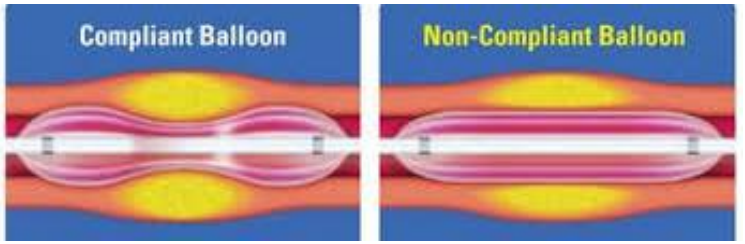
TIPS AND TRICKS FOR BALLOON INFLATION

Complex process involving plaque fracture, compression, and stretch.



- 1:1 sized balloons (or 0,5 mm undersized)
- high pressures – at least 26-28 atm
- long inflation time – 30 sec to 2-3 min
- short balloon length
- NC preferable

Beware! – risk of balloon rupture – vessel perforation



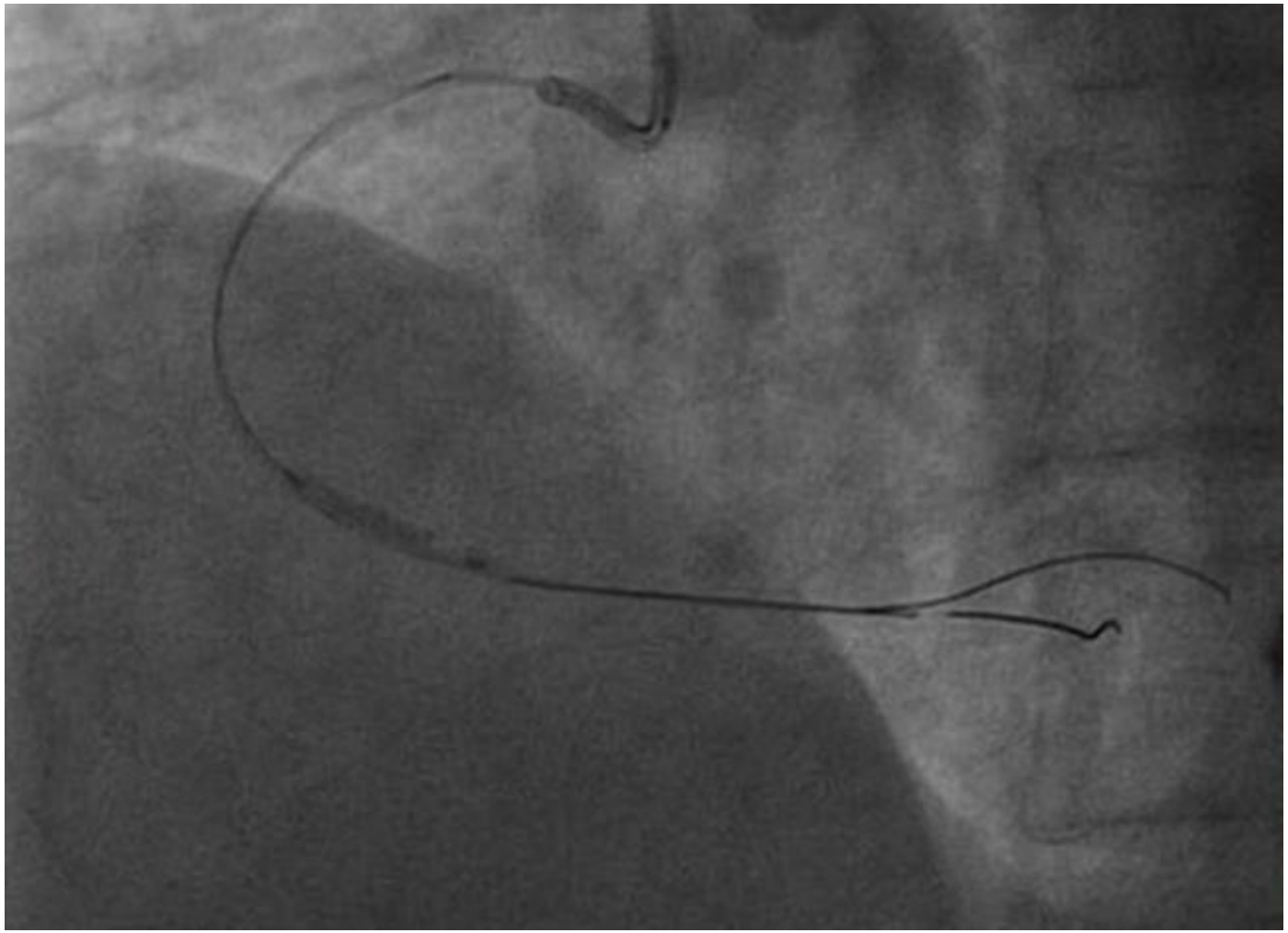
Ultra high pressure NC balloons

OPN balloon (SIS Medical, Switzerland)

- Twin layer balloon construction
- Long tapered tip design for a better crossability
- Super high pressure PTCA balloon (RPB 35-42 atm)
- Minimum guiding catheter: 5F
- Sizes available from 1.5 to 4.5mm diameter
- Very effective in postdilatation

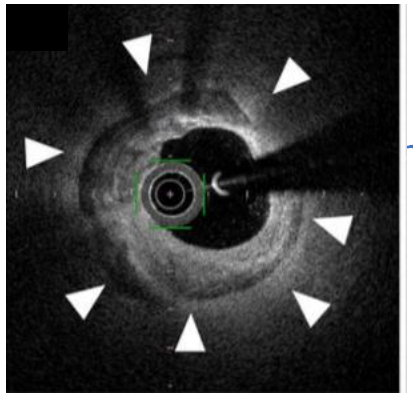
Buddy Wires

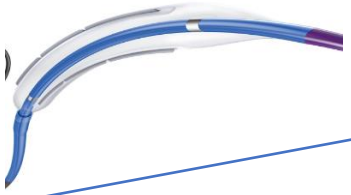
- Insertion of one (or more) buddy wires may improve the efficacy of high-pressure balloon inflations by causing longitudinal focused force angioplasty.

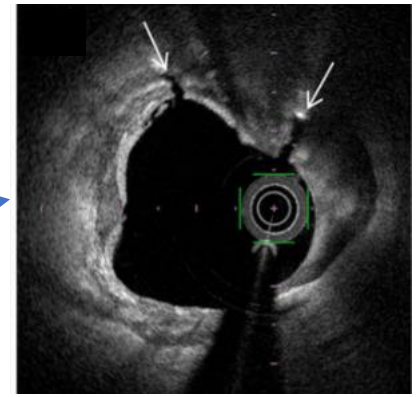


Cutting balloons

NC balloon with three or four metal microblades, placed longitudinally on it's surface and the balloon works by cutting the media with radial incisions, thus reducing elastic recoil and minimising neointima proliferation.

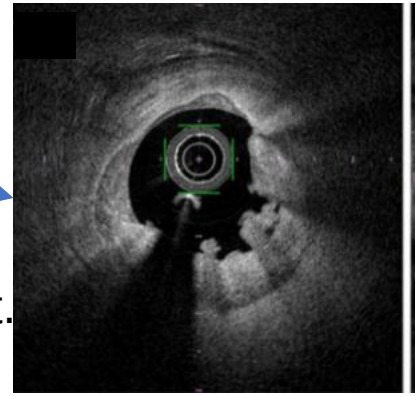




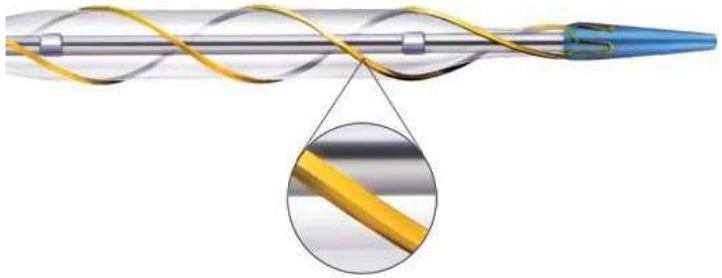


Creates controlled incisions and less often slips inside a narrowed lumen.

Tears the arterial wall at the weakest point.



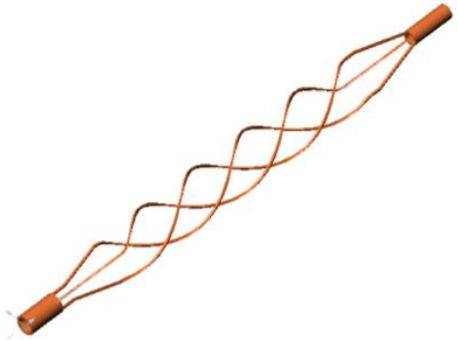
Scoring balloons

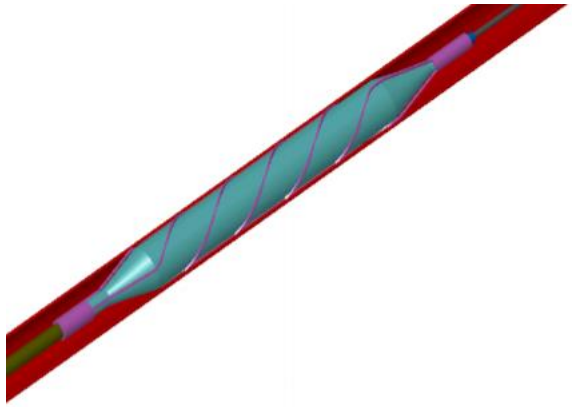


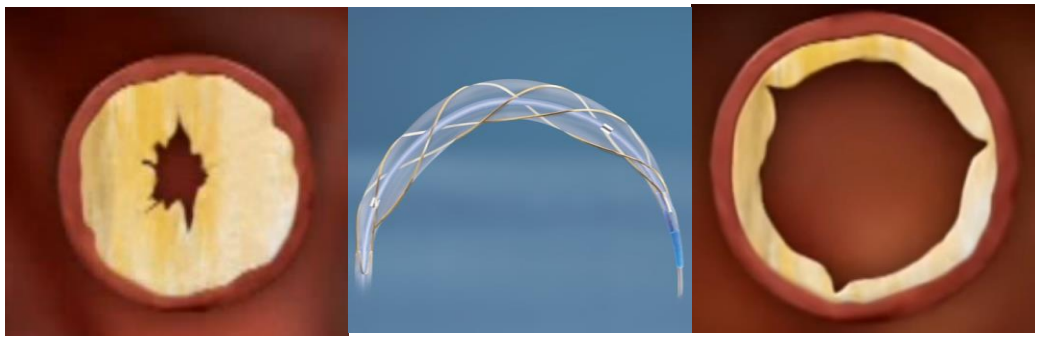
Semicompliant balloon encircled by scoring elements designed to anchor into fibrocalcific plaque

Allow focal concentration of the force during inflation and decrease balloon slippage.

More flexible, have a better profile and can achieve a full expansion with a low inflation pressure

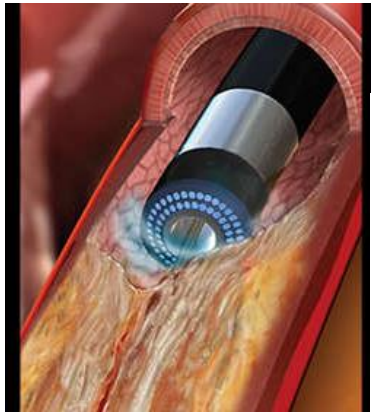






Ablation (non balloon) techniques

- rotational atherectomy (RA),
- orbital atherectomy,
- coronary laser.



Rotablation

stand-alone debulking therapy

bail-out technique of undilatable lesions

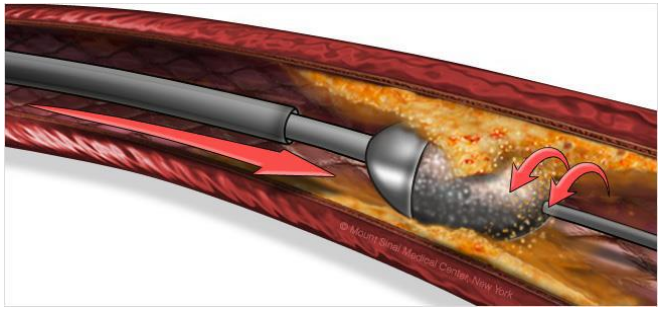
adjunct to balloon angioplasty

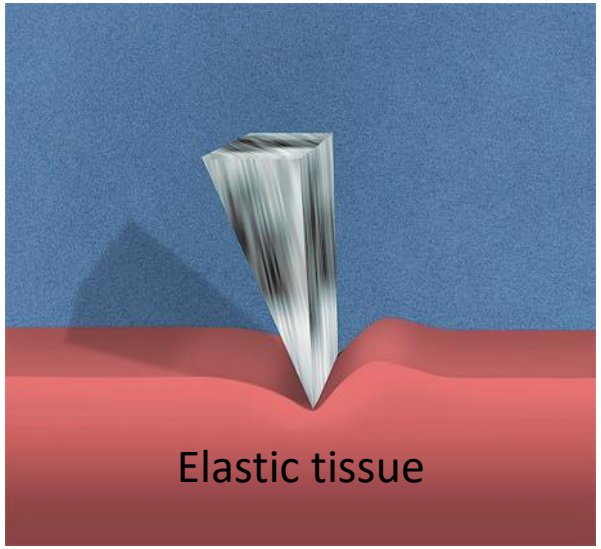
primary approach of intentional lesion preparation

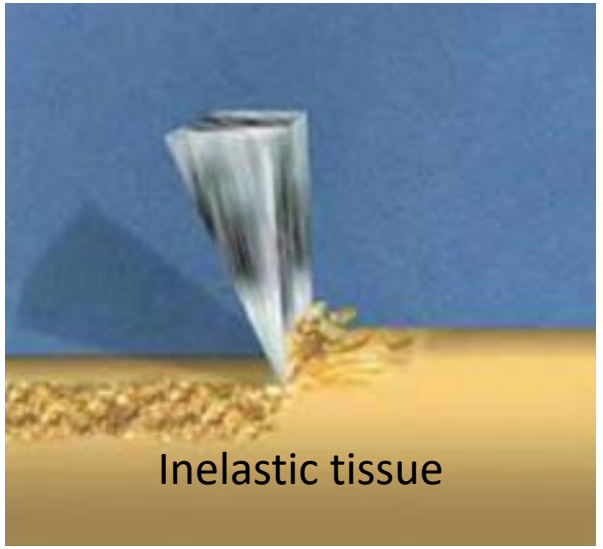
plaque modification

Aim : Lesion Modification, Not Calcium Removal

Mechanism of the action - RA







Results in preferential cutting of inelastic substrate

Mark Reisman,M.D, Guide to Rotational Atherectomy, 1997

RA TRIALs

	N pts		Results	
Rotaxus trial	240	RA+DES vs BP+DES	Higher success rate and initial luminal gain (P = .01), greater late stent luminal loss at the 9-month FU (P = .04). No significant differences in rate of stent restenosis or thrombosis, TLR and MACE.	Abdel-Wahab M,et al. JACC Cardiovasc Interv. 2013;6:10-19.
PREPARE-CALC	200	RA vs cutting/scoring balloons	Higher procedural success rate with the RA and a lower % of residual stenosis (P = .0001) No difference in stent luminal loss or clinical outcomes at the 9-month FU. (16% crossover)	Abdel-Wahab M,et al. Circ Cardiovasc Interv. 2018 Oct; 11(10) :e007415
ROTATE multicenter registry	1176	RA +DES	1 year MACE – 16%	Kawamoto H, et al. EuroIntervention. 2016;12:1448-1456.
European multicenter RA registry	966	RA + DES	1 year MACE – 13,2%	Bouisset F, et al. EuroIntervention. 2020 Jul 17;16(4):e305-e312.

What kind of lesions should be considered for RA

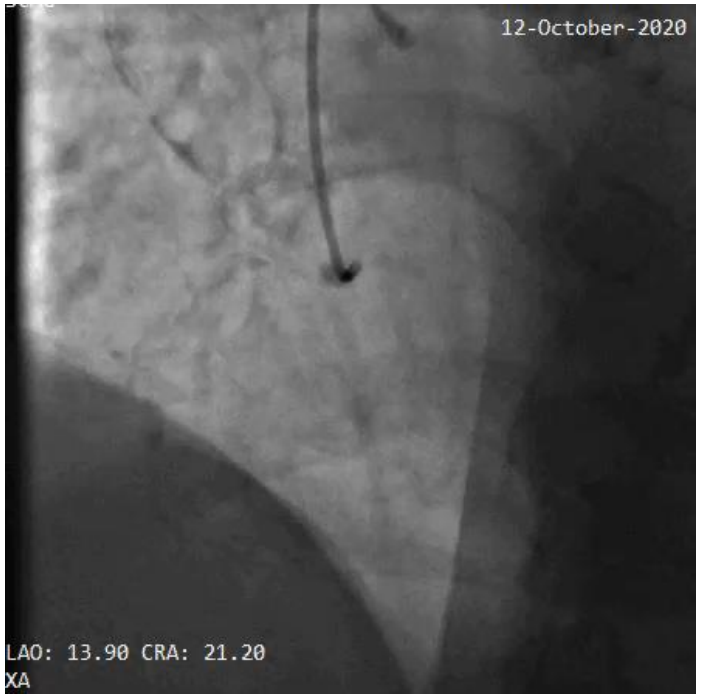
Severely calcified = clearly seen by fluoroscopy!

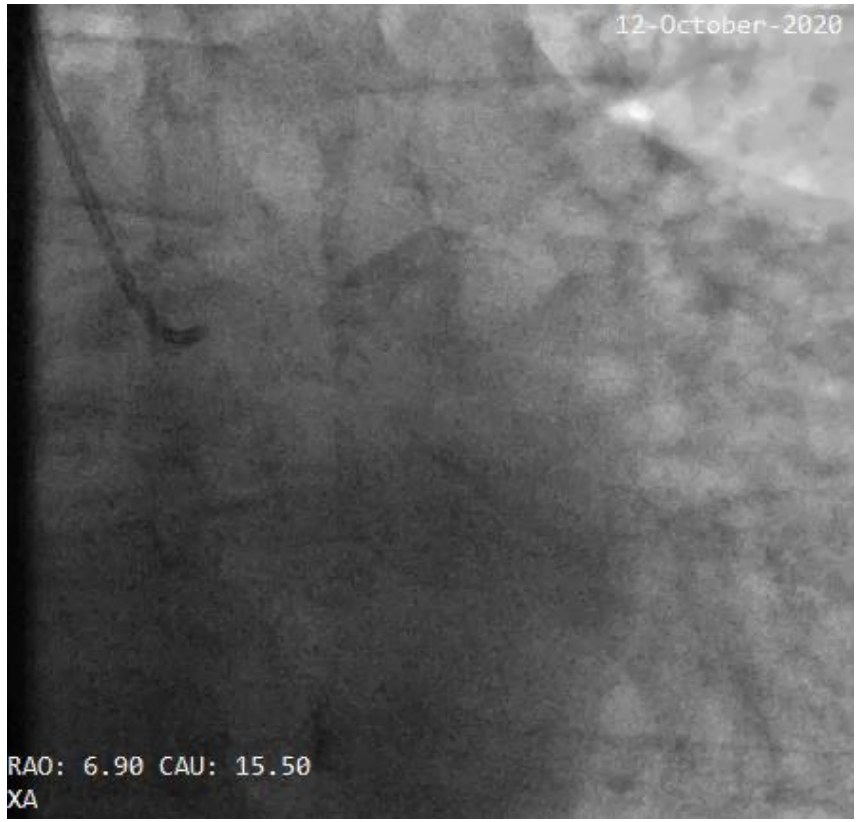
Case Dx

62 y/o male , chest pain, HTM

Right radial artery

Severely calcified RCA





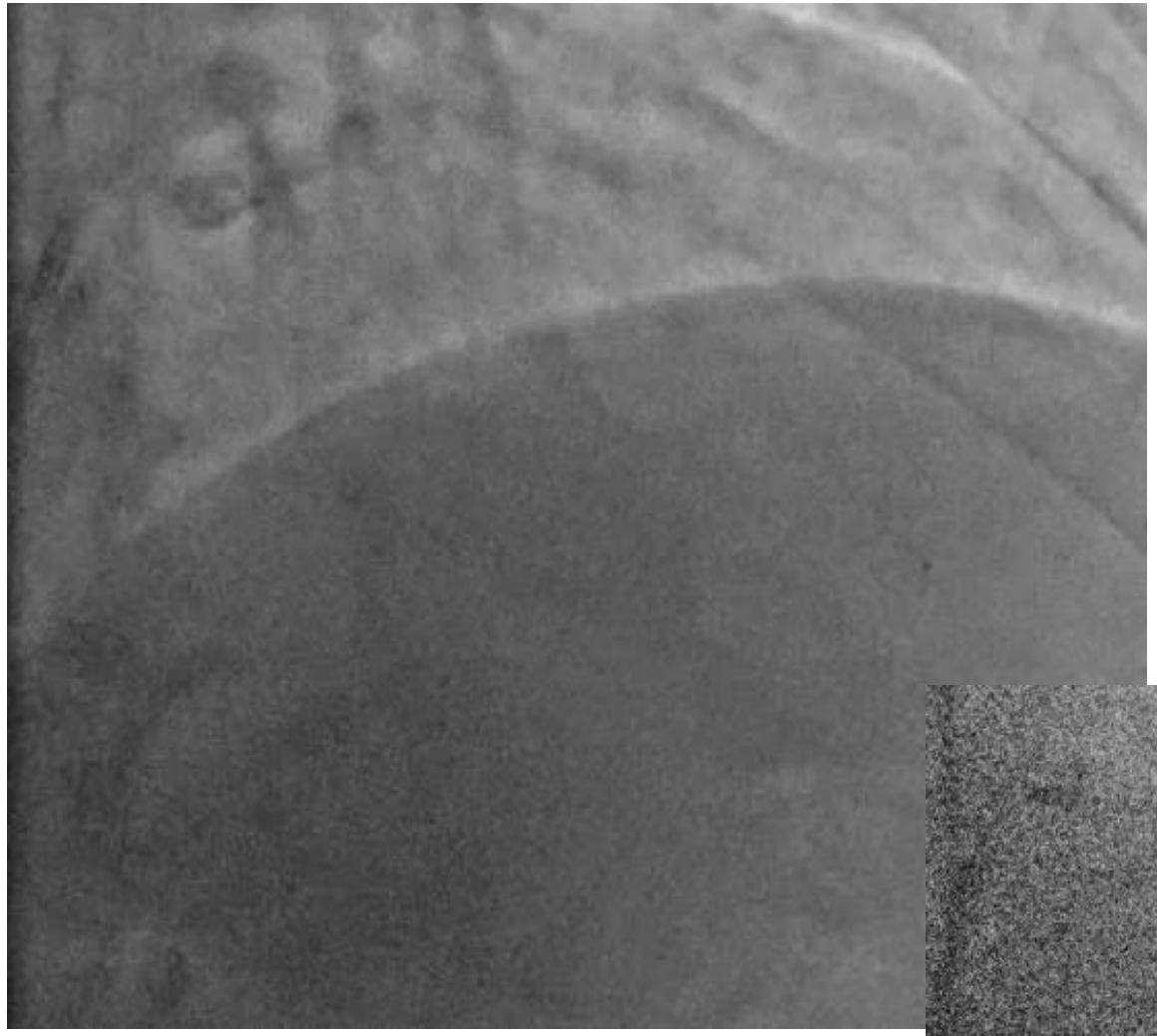
Severely calcified proximal LAD

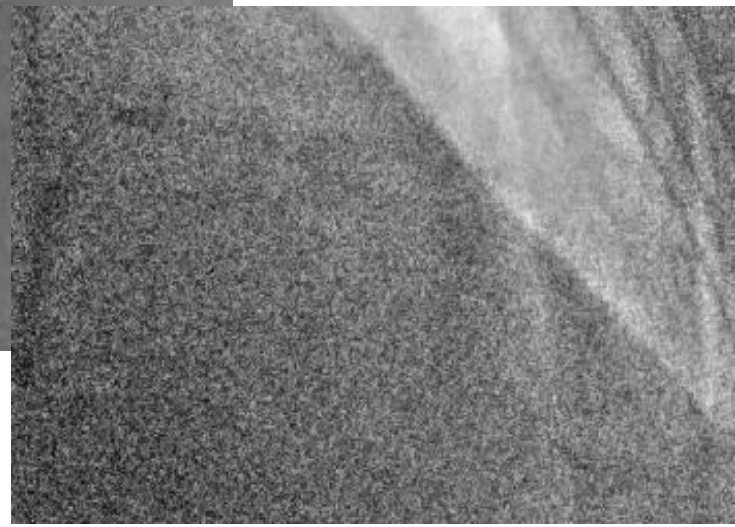
Case PCI procedure

Femoral access
7F EBU 4.0 GC

PCI procedure – RA for plaque modification

- Microcatheter
- Rotawire floppy
- Rotablation burr 1,5
- 180 000 rpm /4 runs





EuroIntervention 2015;11:30-36

European expert consensus on rotational atherectomy

Emanuele Barbato[1,2]*, MD, PhD; Didier Carrié[3], MD, PhD; Petros Dardas[4], MD, PhD; Jean Fajadet[5], MD; Georg Gaul[6], MD; Michael Haude[7], MD; Ahmed Khashaba[8], MD; Karel Koch[9], MD, PhD; Markus Meyer-Gessner[10], MD; Jorge Palazuelos[11], MD, PhD; Krzysztof Reczuch[12], MD, PhD; Flavio L. Ribichini[13], MD; Samin Sharma[14], MD; Johann Sipötz[6], MD; Iwar Sjögren[15], MD; Gabor Suetsch[16], MD; György Szabó[17], MD, PhD; Mariano Valdés-Chávarri[18], MD, PhD; Beatriz Vaquerizo[19], MD, PhD; William Wijns[1], MD, PhD; Stephan Windecker[20], MD, PhD; Adam de Belder[21], MD

This document is endorsed by the EAPCI.

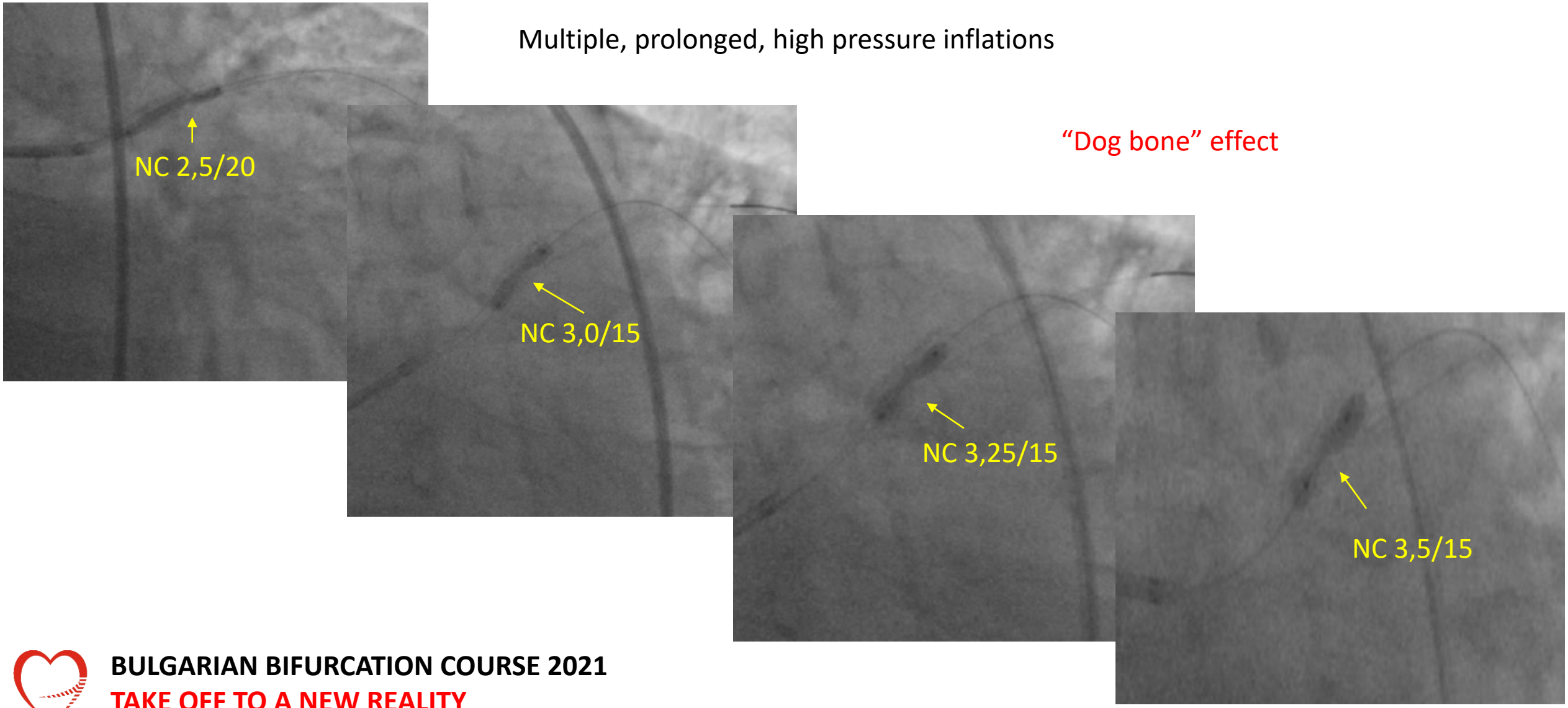
Contemporary rotational atherectomy.

	Traditional	Contemporary
Arterial access	Femoral 8 Fr	Radial (6-7.5 Fr) or femoral (6-8 Fr), depending upon burr size requirement and operator experience
Guiding catheter	Judkins catheters	Single curve with strong support. Operator preference but stable catheter position required
Guidewire	Floppy rotawire or extra support rotawire for aorto-ostial lesions	Rotawire placement not always straightforward. Use of regular wire placement, with exchange using microcatheter placement often required
Burr size	Debulking up to 0.7 vessel ratio	Plaque modification with small burrs (1.25 mm to 1.5 mm) as initial strategy is default position. A step-up approach is encouraged to limit debris size and complications
Ablation speed	180,000 to 200,000 rpm	Plaque modification usually achieved at low speeds (135,000 to 180,000 rpm) to reduce risk of complications
Temporary pacemaker	Always for dominant RCA and left main PCI	Smaller burrs at lower speeds have led to lower incidence of transient heart block. Many operators use atropine to treat, avoiding any complications of temporary pacemaker placement
Rotablation flush	Rotablation cocktail with verapamil, nitrates and heparin in saline recommended	Rotablation cocktail with verapamil, nitrates and heparin in saline recommended

Barbato E,et al. EuroIntervention. 2015 May;11(1):30-6.

Preparing the lesion – high pressure balloon inflation

Multiple, prolonged, high pressure inflations



NEW TECHNIQUE

Lithoplasty system

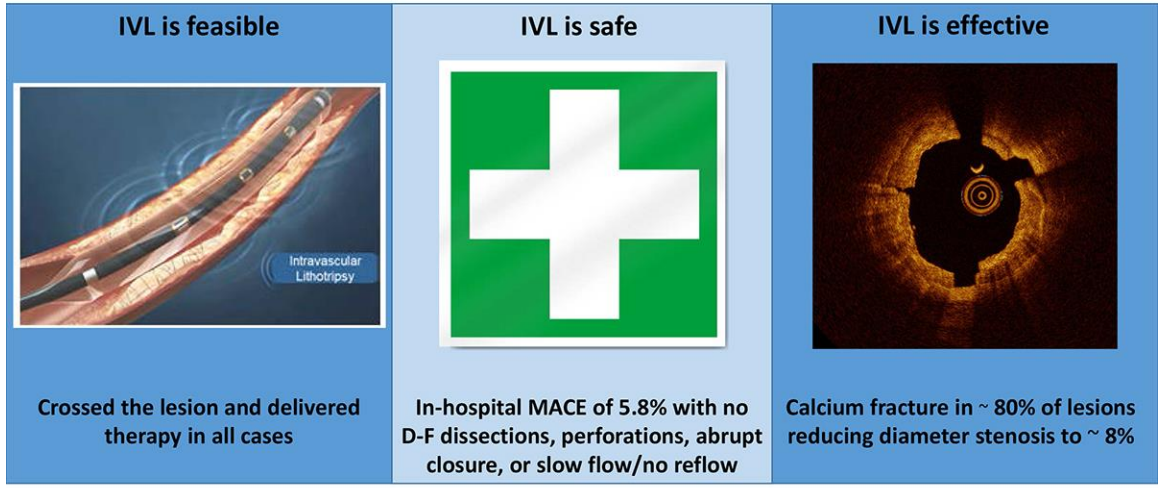
Shockwave Medical, Inc

- During low-pressure inflation the balloon emits acoustic circumferential pressure waves (1 pulse/sec) travel through tissue with an effective pressure of ~50 atm and fractures both superficial and deep calcium.
- Standard techniques are used to deliver and dilate the balloon.
- May also work on the calcium underneath the stent struts, due to its mechanism of action based on ultrasounds that are not prevented by a stent. presence.

CORONARY LITHOPLASTY

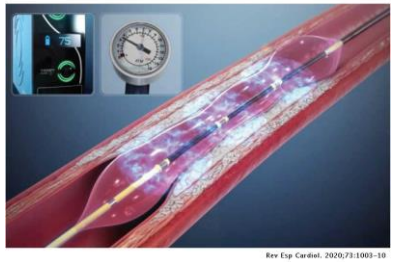
	STUDY	N of pts	Use of OCT
DISRUPT CAD I	CE MARK	60 pts (Europe)	OCT analysis in 31 pts (2016)
DISRUPT CAD II	Post marketing	120 pts (Europe)	OCT analysis in 47 pts (Sep 2019)
DISRUPT CAD III	FDA	442 pts (Europe, USA)	OCT analysis in 100 pts (TCT 2020)
DISRUPT CAD IV	Japanese	64 pts (Japan)	OCT analysis in all pts (Jan 2021)

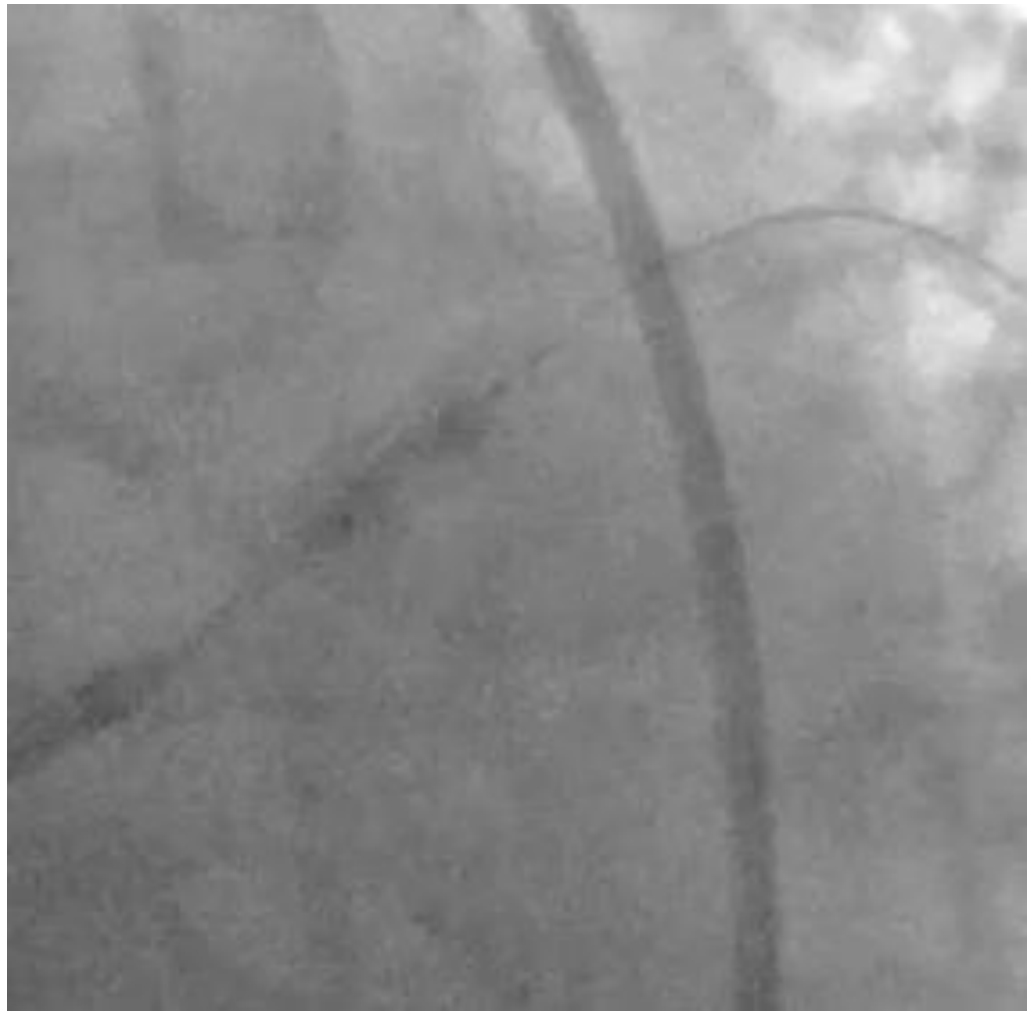
Safety and Effectiveness of Coronary Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Stenoses: The Disrupt CAD (Coronary Artery Disease) II study



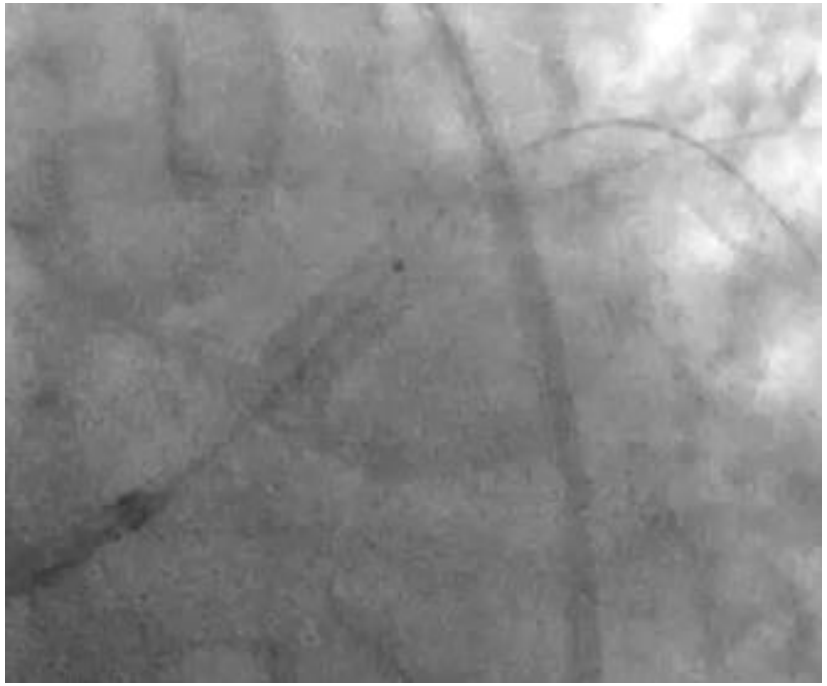
Ali et al. Circulation: Cardiovascular Interventions. Oct 2019

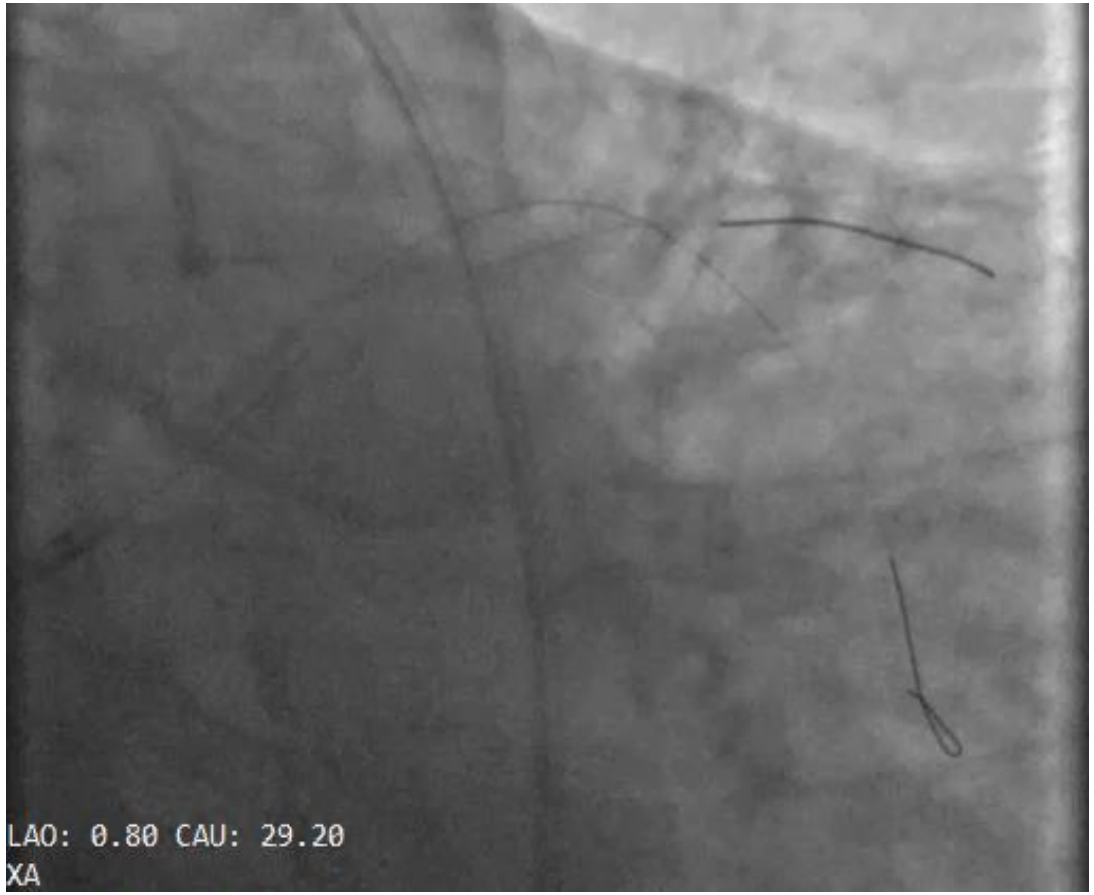
Lithoplasty balloon 3.5/12 for 3 cycles (10 seconds)





Result after 3 therapies



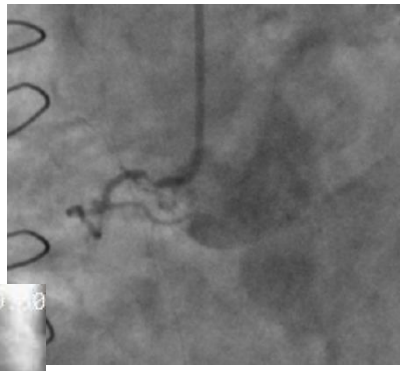


Final result

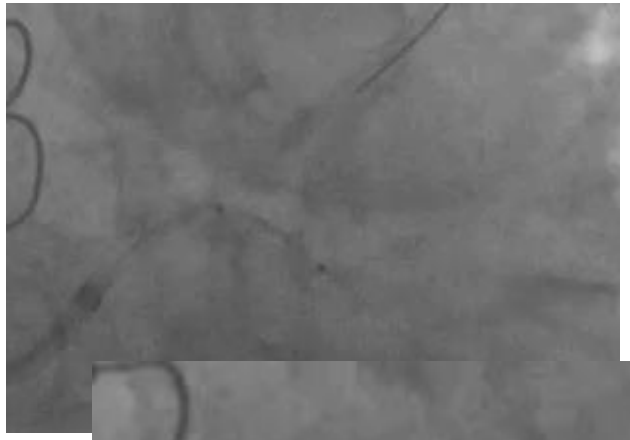
Provisional stenting of LAD with DES- 3.5/30,14 atm
Postdilatation NC 3.5/15, 20atm
POT – NC 4,0 /12 20atm

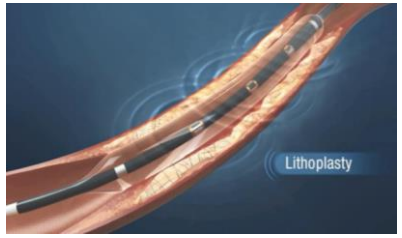
Case of 80 y/o male assessed for TAVI after CABG

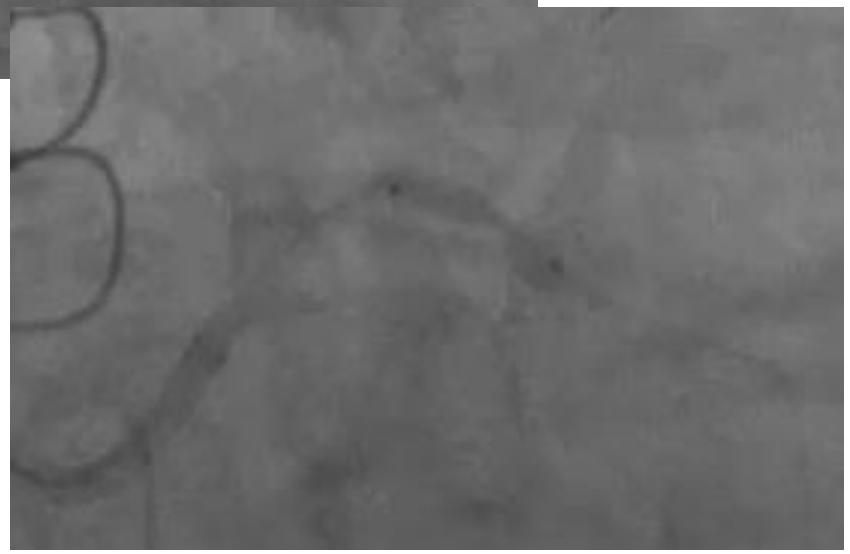
Severely calcified distal LM and ostioproximal Cx, occluded not dominant RCA
Occluded SVG to distal segments of Cx , patent to OM1 and LIMA to LAD
Large ischemia burden of infero-lateral segment (stressEcho)
After RA – burr 1,5



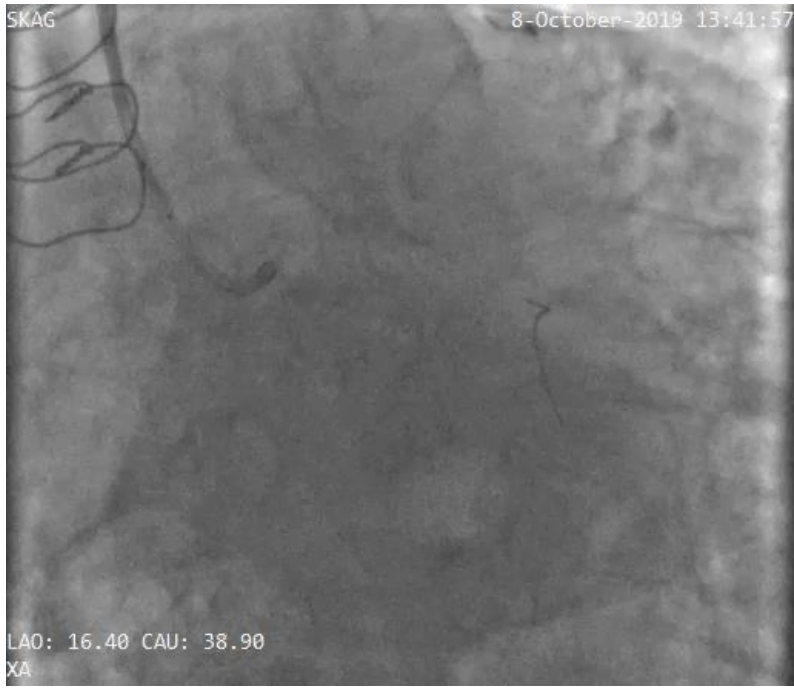
Lithoplasty – 3,0/12







LM-Cx - DES- 3.0/34,16 atm
Postdilatation NC 3,0/15; 3.5/15, 20atm
POT – NC 4,0 /12 20atm

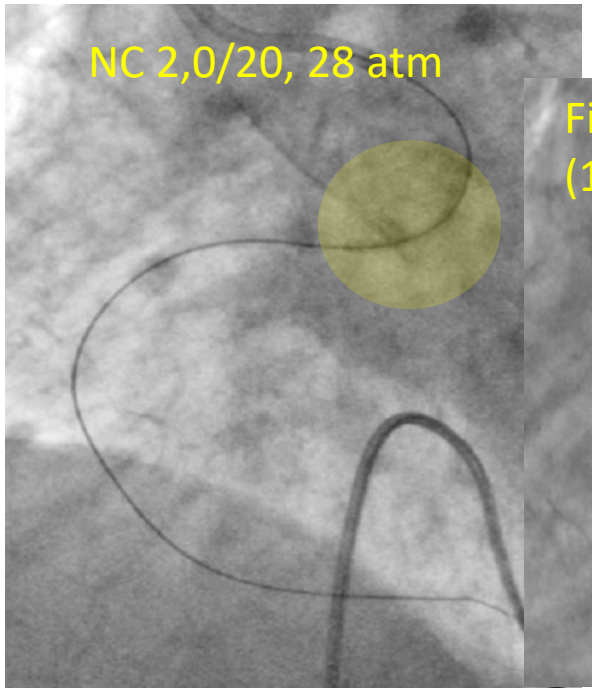


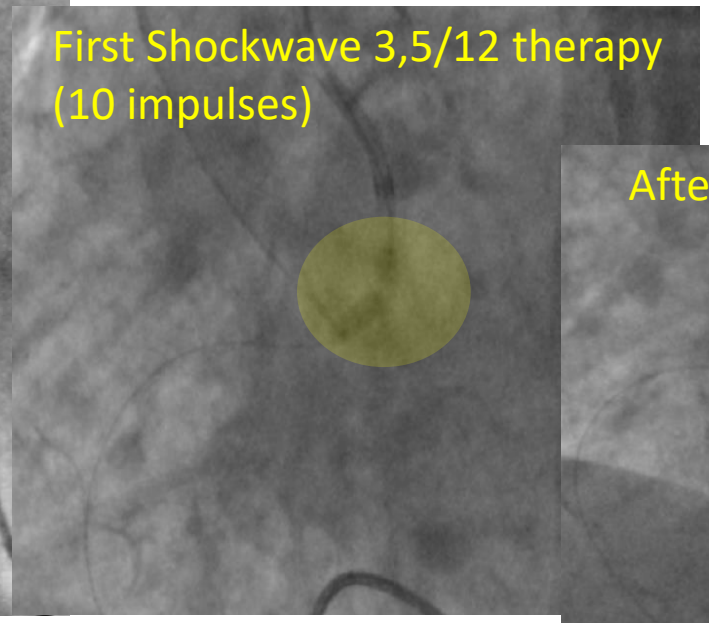
Case 60 y/o diabetic female

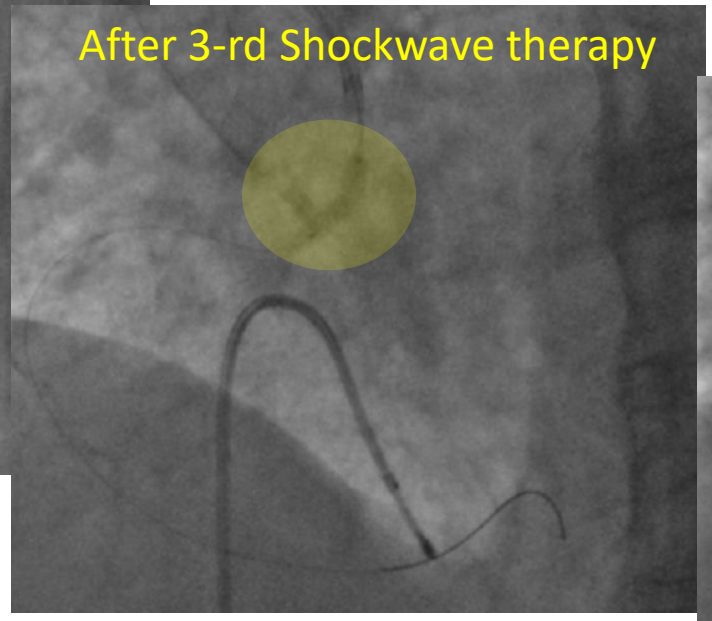
Chest pain for 3 months, heart failure symptoms, LV dysfunction with moderate MiR (Echo)
Dx – right radial artery

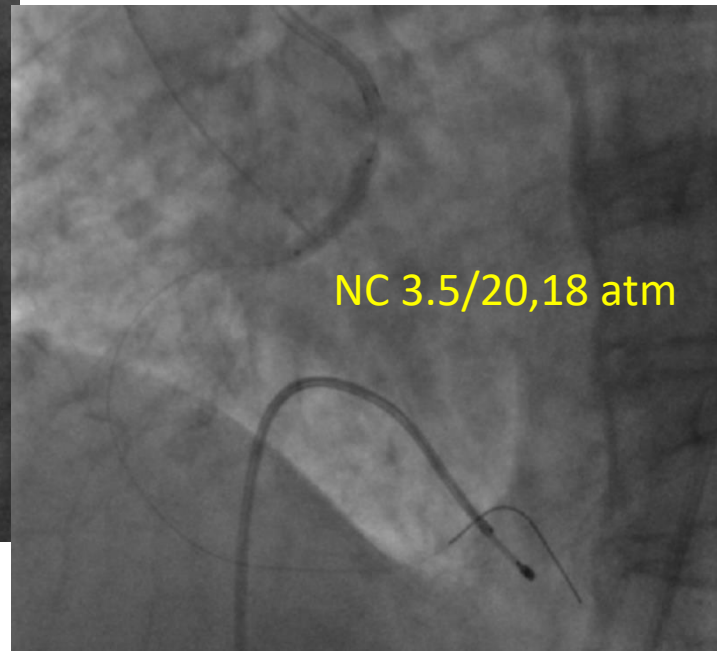
Case 60 y/o diabetic female

Right femoral artery, AL 2,0, 7F GC
Temporary PM was implanted
Miracle Ultimate wire succeeded to pass the lesion
Inadequate predilation with 2,0/20 NC balloon but made the possibility to place a lithoplasty balloon 3,5/12



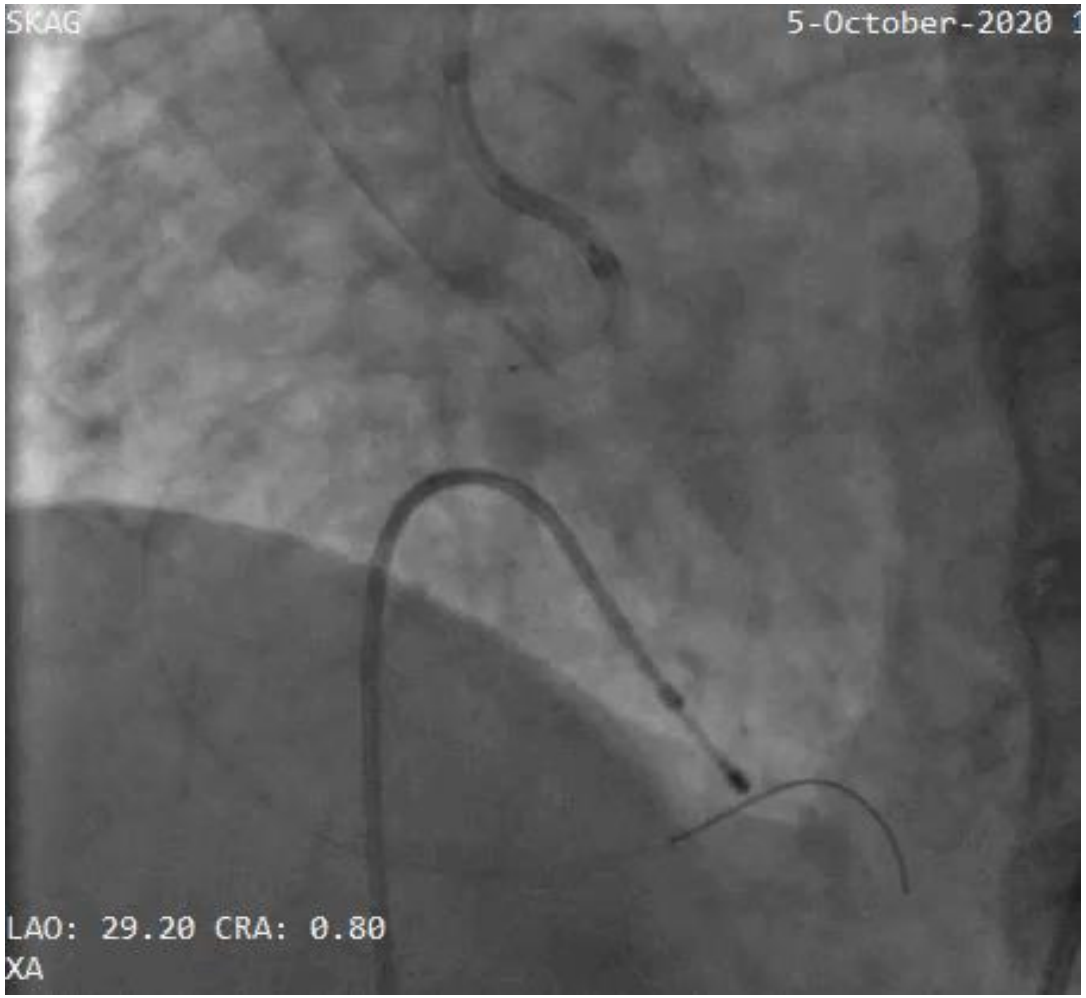






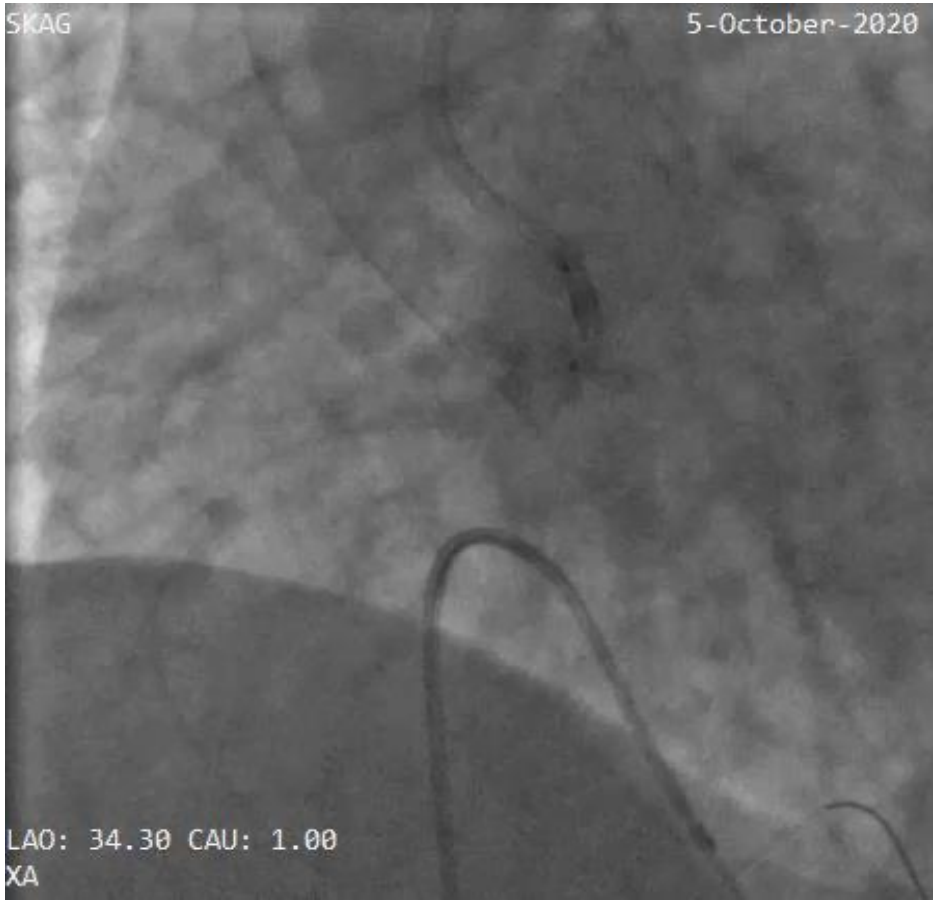
Case 60 y/o diabetic female

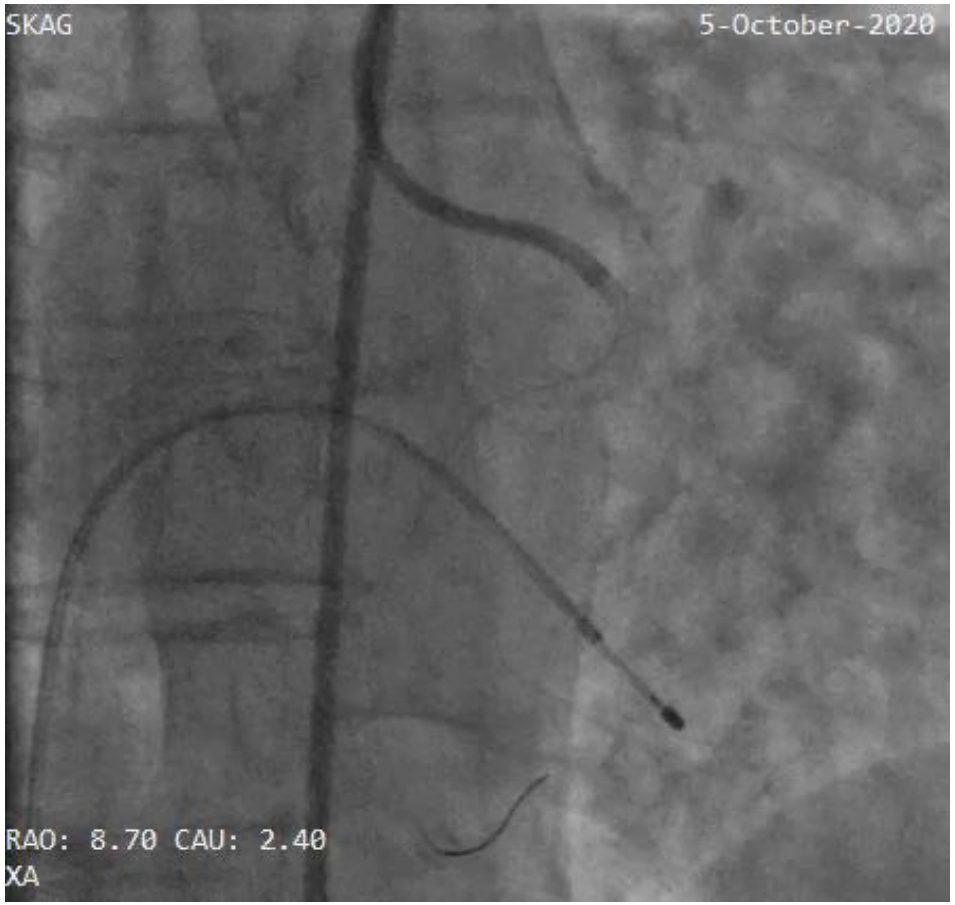
Result after 3 therapies (30 impulses)



Case 60 y/o diabetic female

Final result, after DES 3,5/23,20 atm, postdilated 4,0/15, 20 atm.
MSA of ost. RCA – 10,8mm2 (4,0/3,3mm)





Take home

- Balloon undilatable lesions can be challenging to treat but are also likely to be increasingly encountered given the increasing complexity of PCIs.
- Careful planning and implementation of a stepwise, algorithmic approach can help optimize outcomes in this challenging lesion subgroup.
- Although routine RA did not improve DES efficacy according to studies, RA remains an important tool for uncrossable or undilatable lesions and improves overall procedural success in this setting.
- Combination rotational atherectomy followed by intravascular lithotripsy may improve lesion preparation in undilatable lesions.
- The optimal approach is being knowledgable of the mechanism of action of every possible device or technique that can solve the problem.