

Introduction of IVL (Shockwave™) with case presentation

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Approaches to Calcified Lesions

1. High (Very High)
Pressure Balloons

2. (Balloon or Stent)

3. (Balloon or Stent)

B.L.

5. Laser

1. High Pressure Balloon

A.L.

3. Atherectomy

Intravascular Lithotripsy (IVL) System



○ Integrated 12mm SC Ballon

- Facilitates energy transfer
- IVL=4atm; Nominal=6atm; RBP=10atm

○ Distal and proximal marker bands

○ 2 Emitters

- One pulse per second (80 pulses/catheter)

IVL Generator

- Portable and rechargeable
- No external connections
- Quick & easy setup with no settings

IVL Connector Cable

- Simple magnetic connections
- Push-button activated

○ IVL Catheter

- Standard PCI technique
- RX System
- 0.014" guidewire of your choice

IVL - Technique

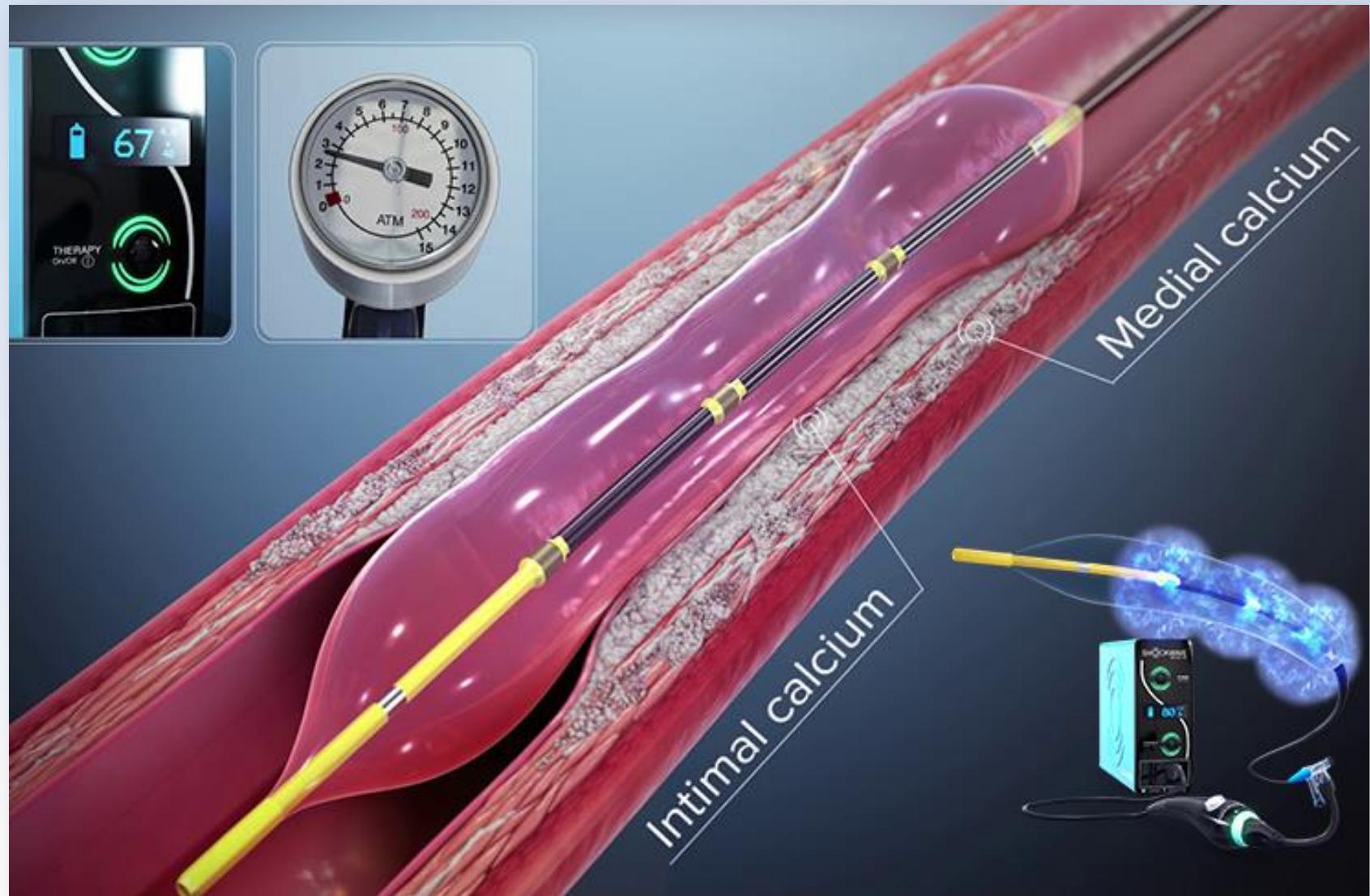
- 1. Sizing:** Equal to intented stent size
- 2. 1:1 Saline/Iodine prep;** Purge at least 3x
- 3. Inflate** to 4 atm
- 4. Deliver** 10 pulses
- 5. Inflate** to 6 atm until accoustic signal
- 6. Deflate** and repeat step 3 and onwards

Diameter (mm)	Length (mm)	Max Pulse Count	Guidewire Compatibility (in)**	Guide Catheter Compatibility	Working Length (cm)	Tip Profile (in)*	Crossing Profile (in)*
2.5	12	80	0.014	6F	138	0.023	0.042
3.0	12	80	0.014	6F	138	0.023	0.042
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*Refer to the Catheter IFU for full details and Warnings and Precautions. * ±0.001-in **RX platform

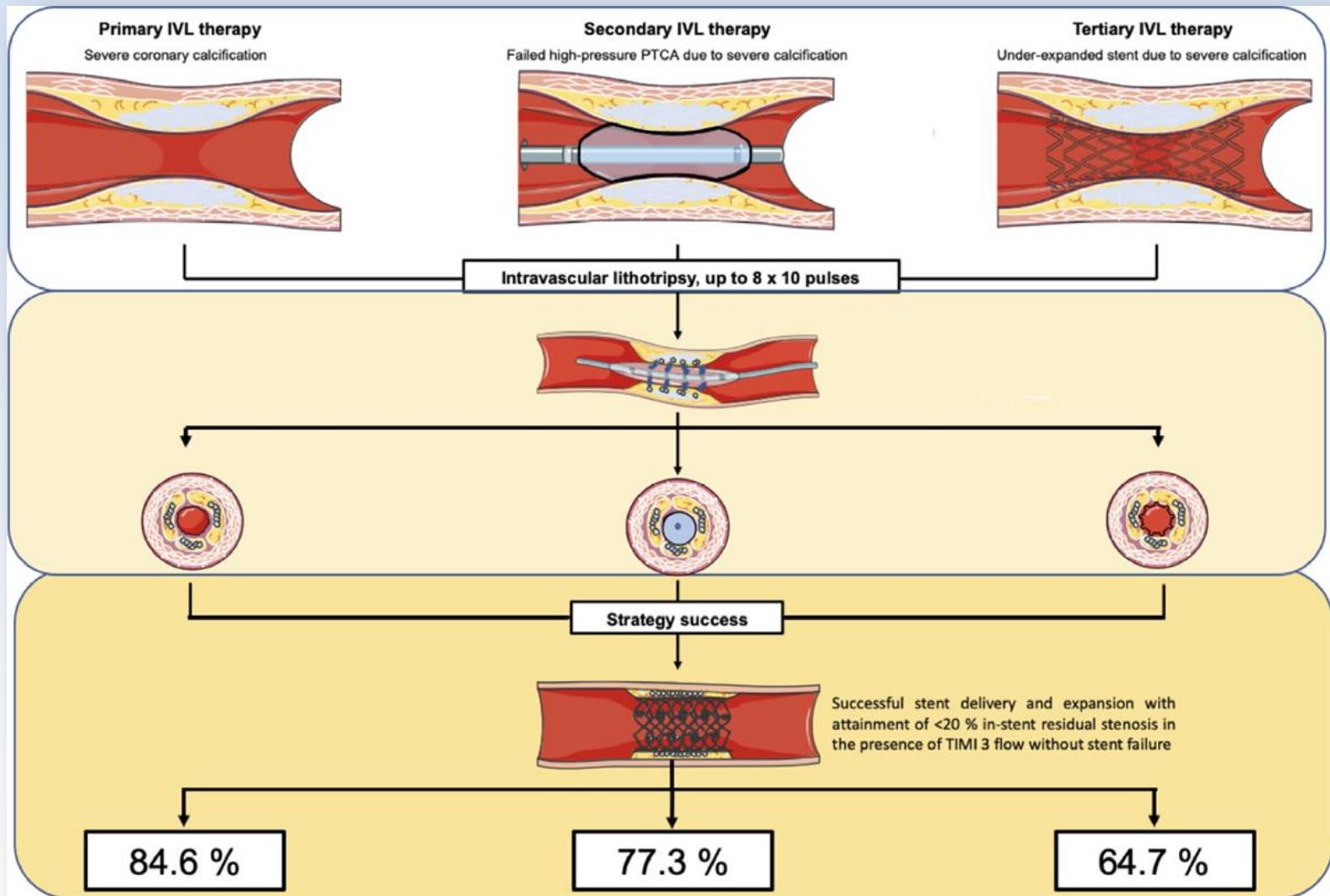
IVL - Mode of Action



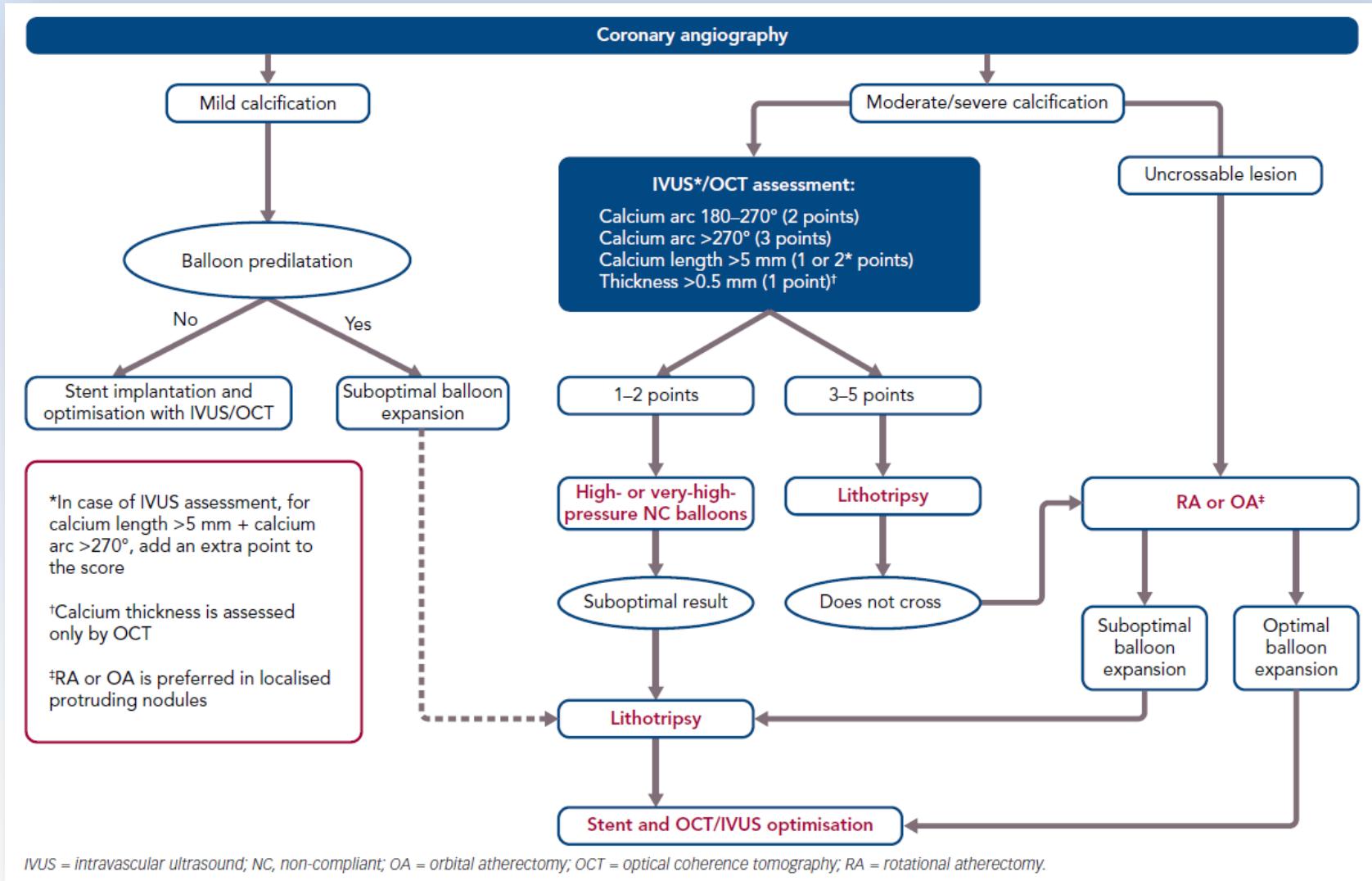
IVL Clinical Evidence

	Disrupt CAD I	Disrupt CAD II	Disrupt CAD III
n	60	120	392
Inclusion	RVD 2.5-4.0 mm (most non-LM) Length≤32 mm Severe Ca++	RVD 2.5-4.0 mm Length≤40 mm Severe Ca++	
No pulses	72 (40-120)	70.7±43.4	
Predilation	37%	42%	
Postdilation	87%	79%	
Final DS, %	12 (7-21)	9.4±7.5	ONGOING
Final angio complications	0	1.6% (B/C dissections)	
30d MACE	5% (NQWMI)	7.6%	

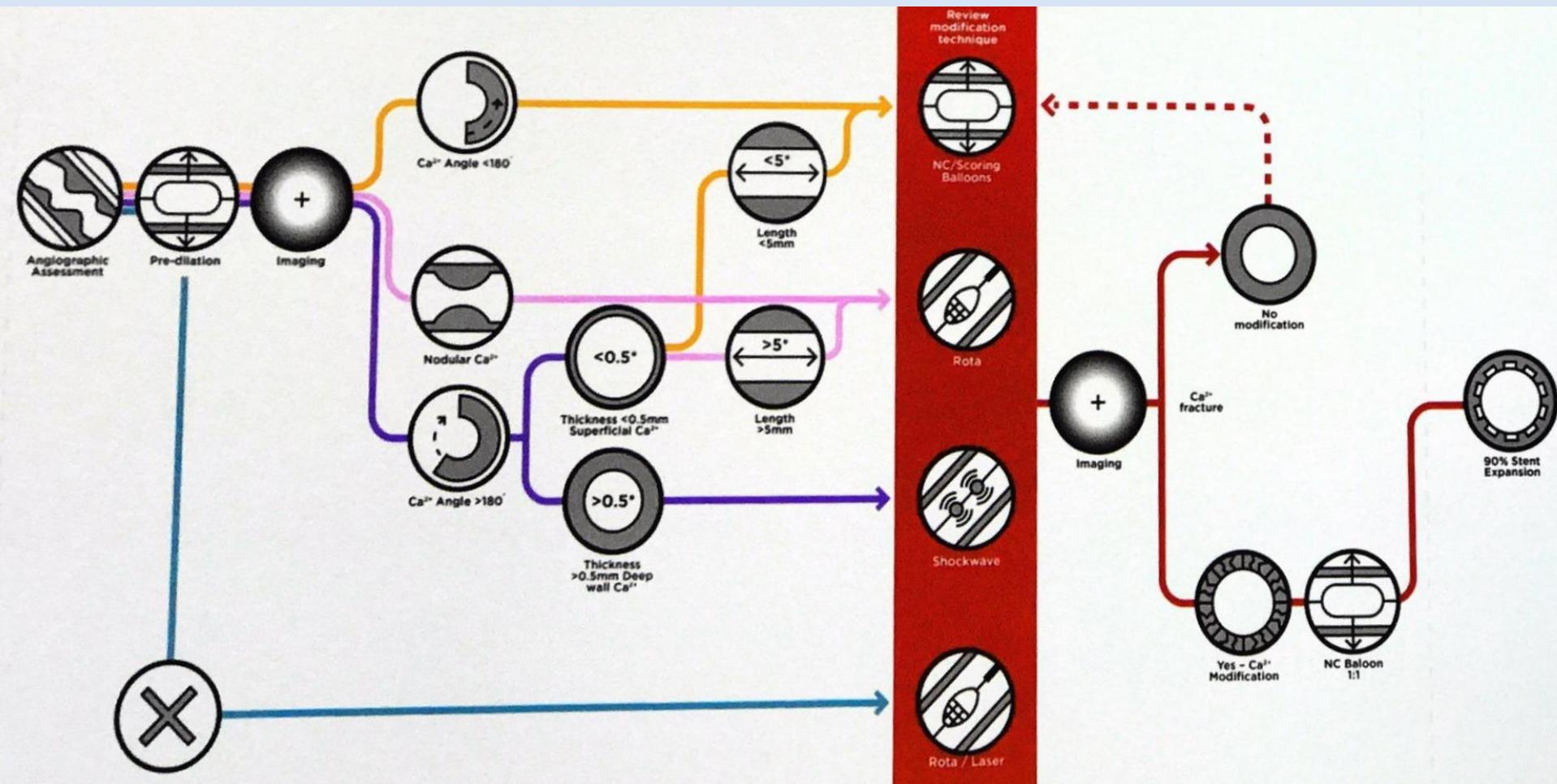
IVL Success and Safety in All-Corner Pts



Italian Algorithm



British Algorithm



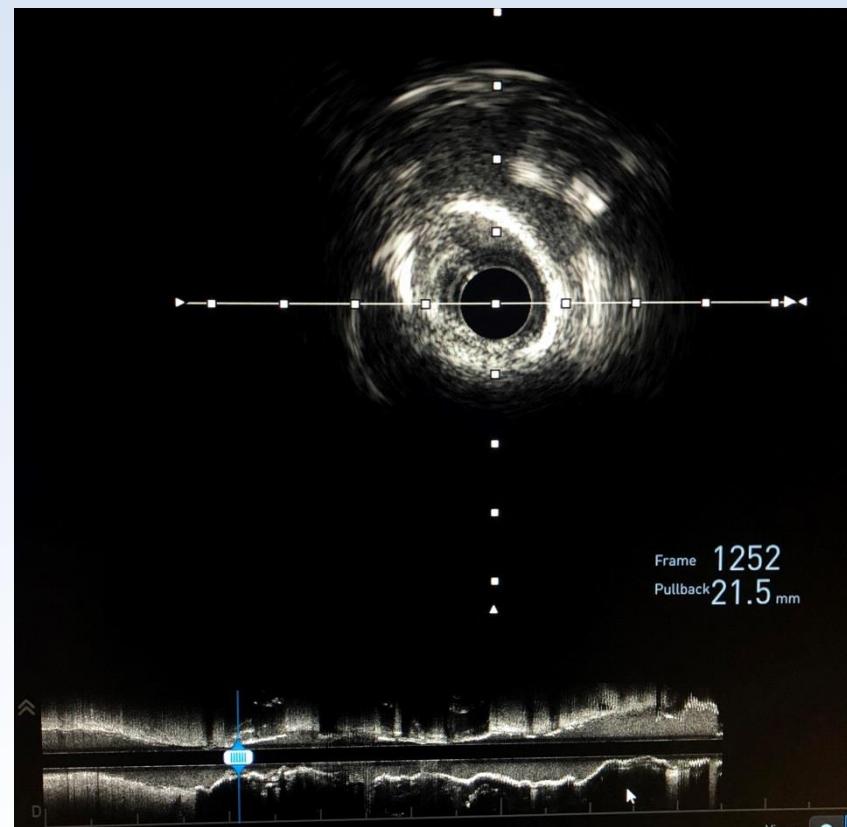
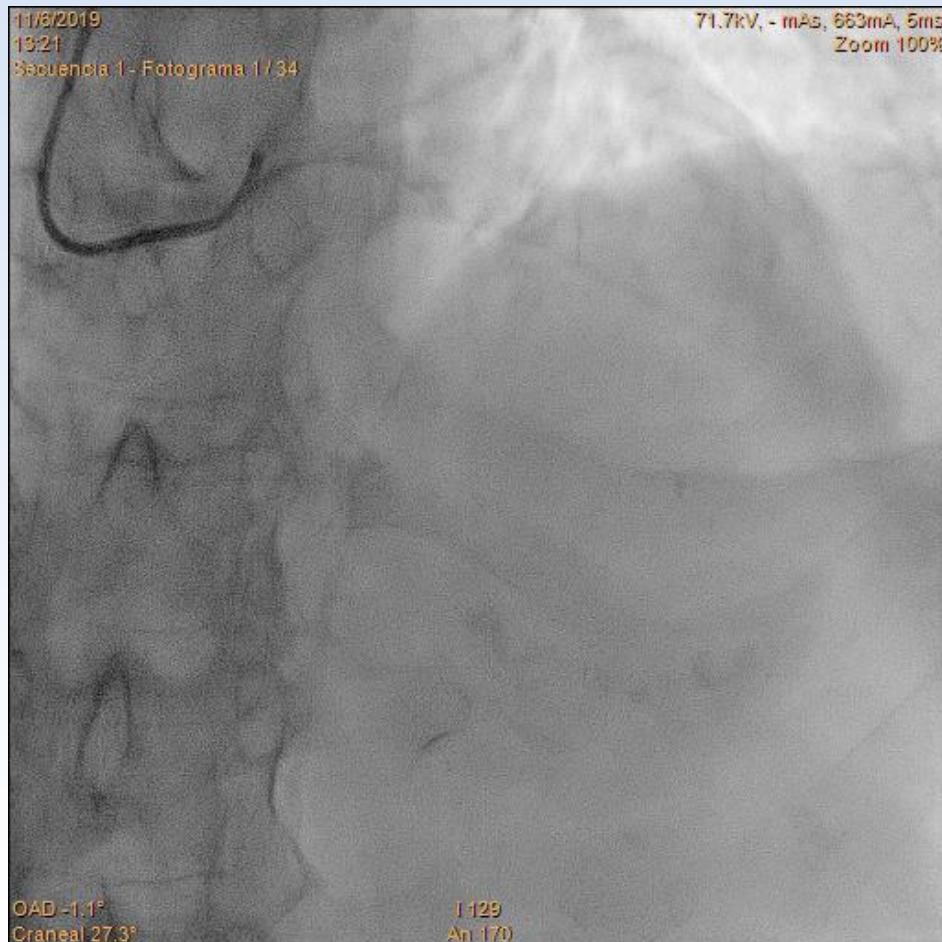
Courtesy of Dr. James Spratt

IVL vs. Atherectomy (Rotational/Orbitational)

	Lithotripsy	Atherectomy
Guidewire	Any PTCA wire	Proprietary wire
Lesion crossing	-	+++
SB protection	+++	N/A
Embolisation	-	++
Perforation	-	++
Effect on Ablation	-	++
Deep calcium	++	-

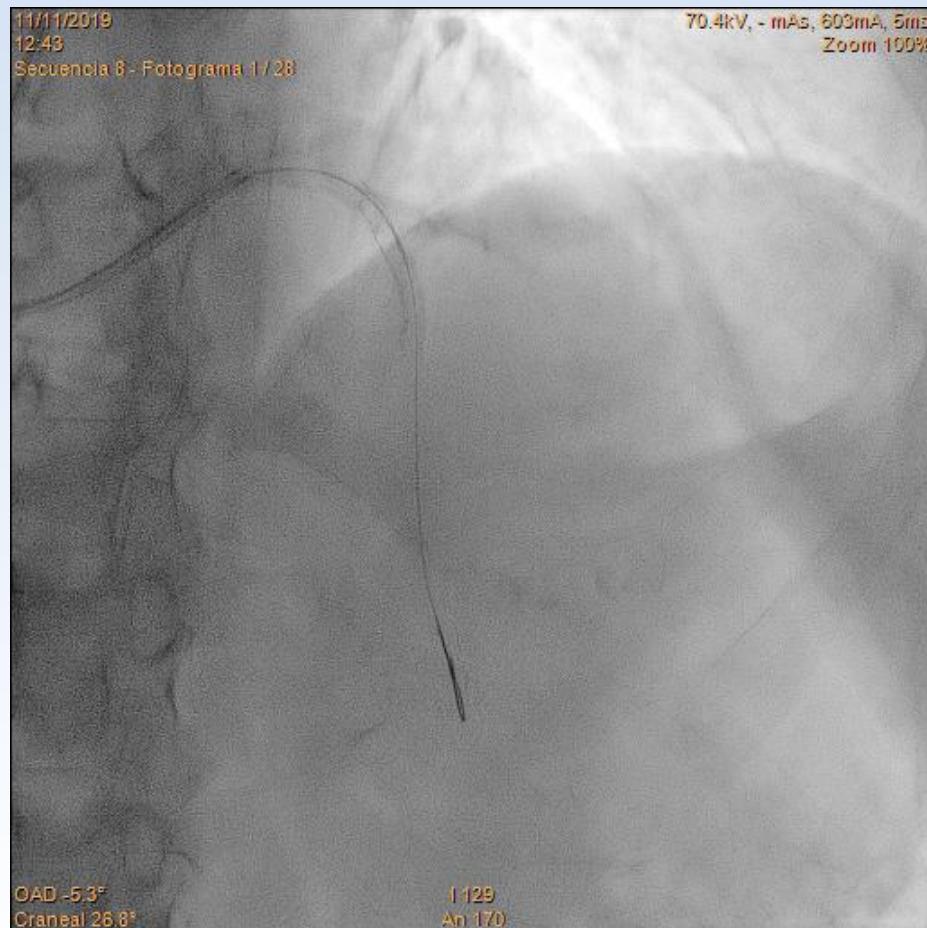
IVL: Case

Huge LAD Calcification



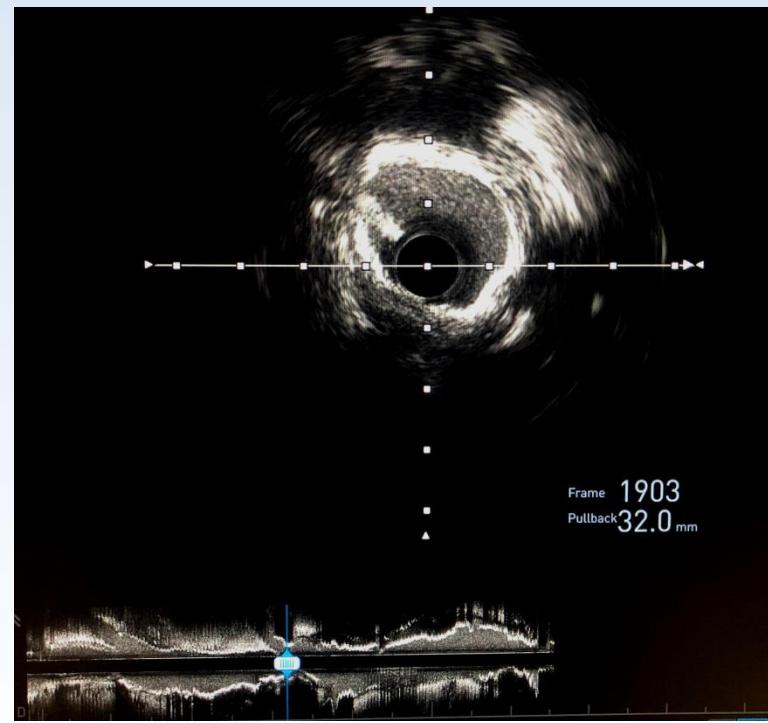
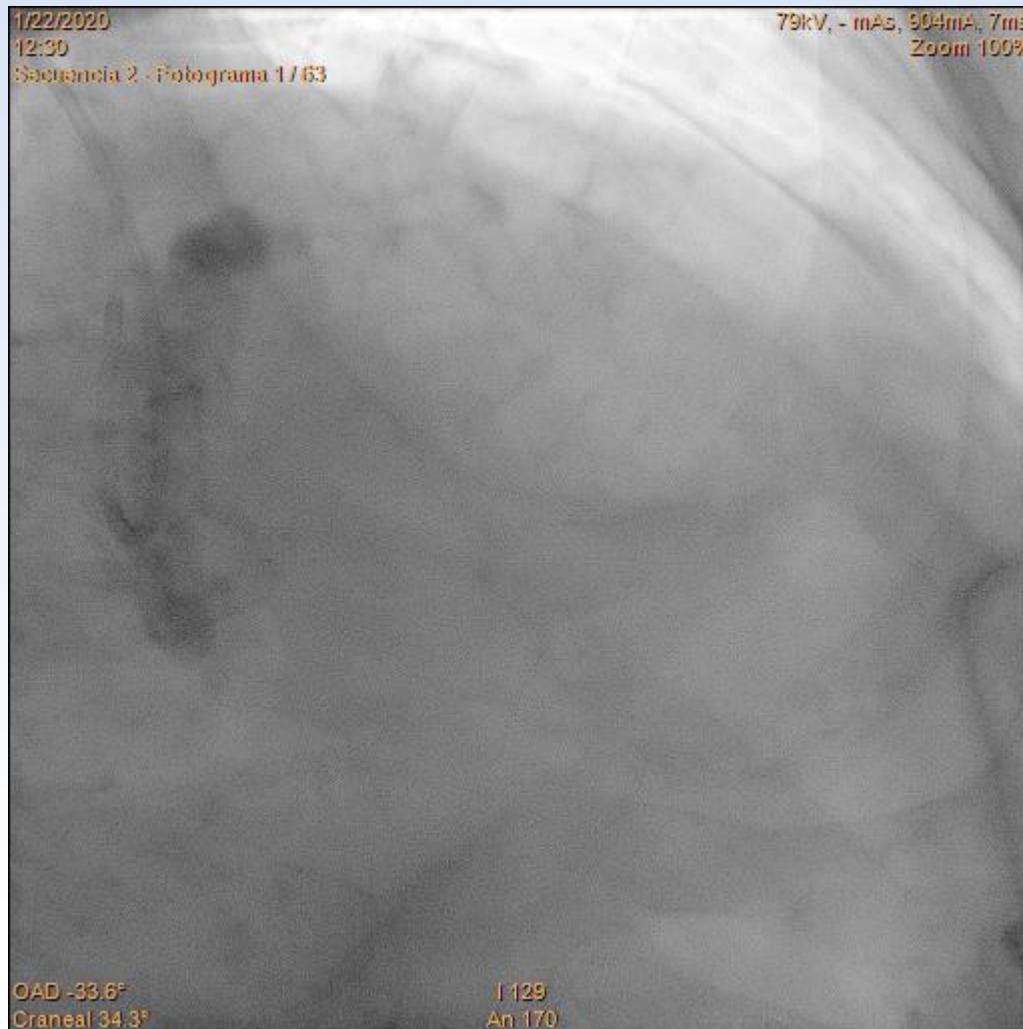
IVL: Case

- ✓ MV & SB wiring
- ✓ SHOCKWAVE C2 3.0/12
- ✓ 80 pulses (30+30+20)
- ✓ NC 3.0 predil
- ✓ BFR 3.0/33 @ 14 atm
- ✓ NC 3.0 postdil @30 atm



IVL: Case

Severe AS and difusse LM-LAD calcified disease



Gracias!!

Thank you!!

Merci!!