# Optimal Lesion Preparation Strategy with Rotational Atherectomy and Cutting Balloon

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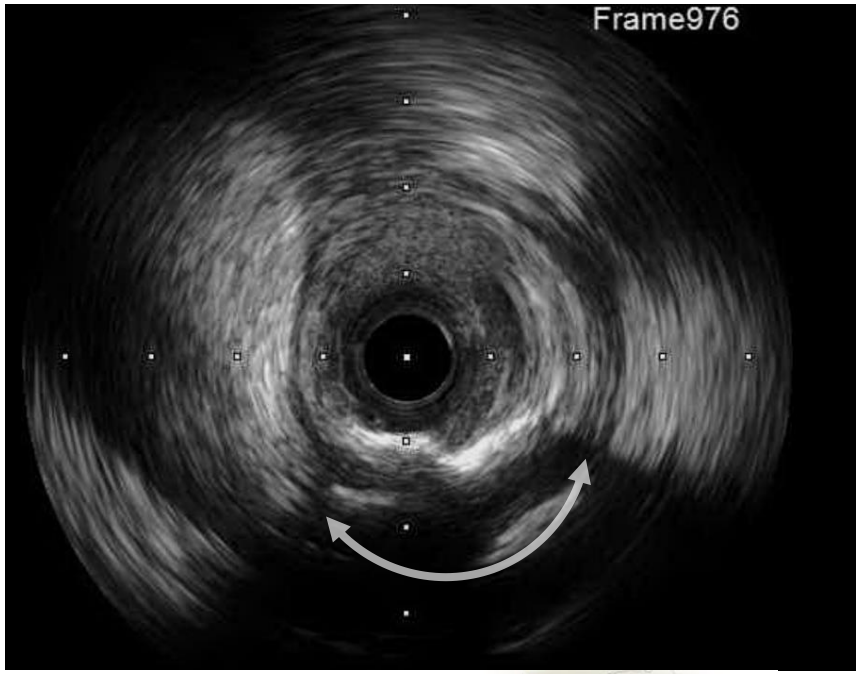
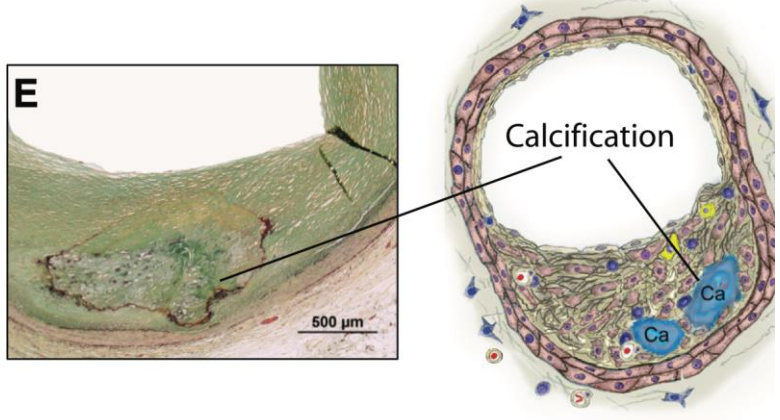
# Disclosures

I, Ju Hyeon Kim, have NO conflict of interest related to this presentation.

# Calcified Plaque



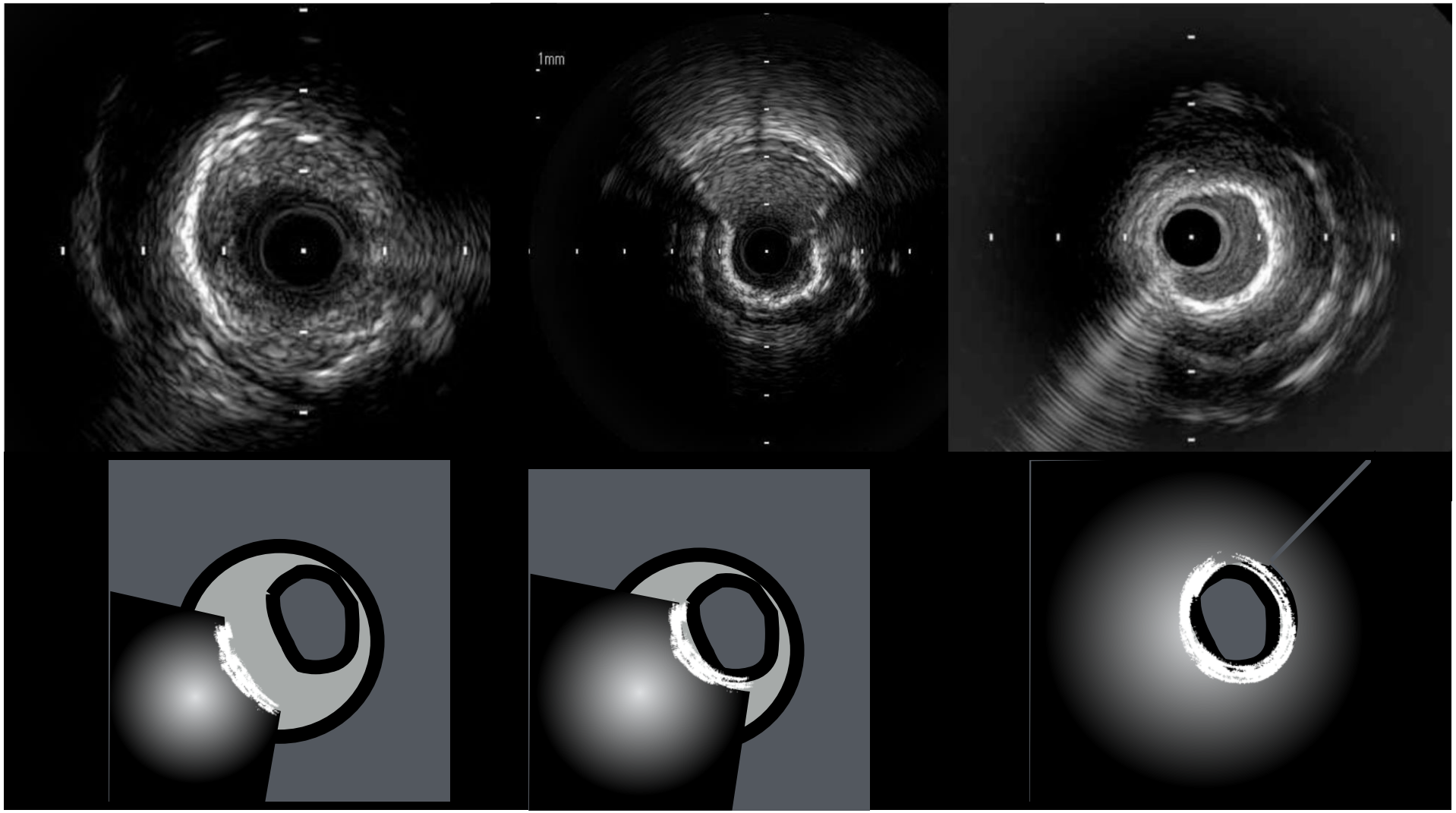

Very bright echoes (brighter than the reference adventitia) with acoustic shadowing of deeper tissue zones.

Since only the leading edge of calcium can be detected, thickness of calcium cannot be determined by IVUS.

Quantified in arc (and length)

Bentzon, Otsuka, Virmani, et al. Circulation Research. 2014;114:1852-1866

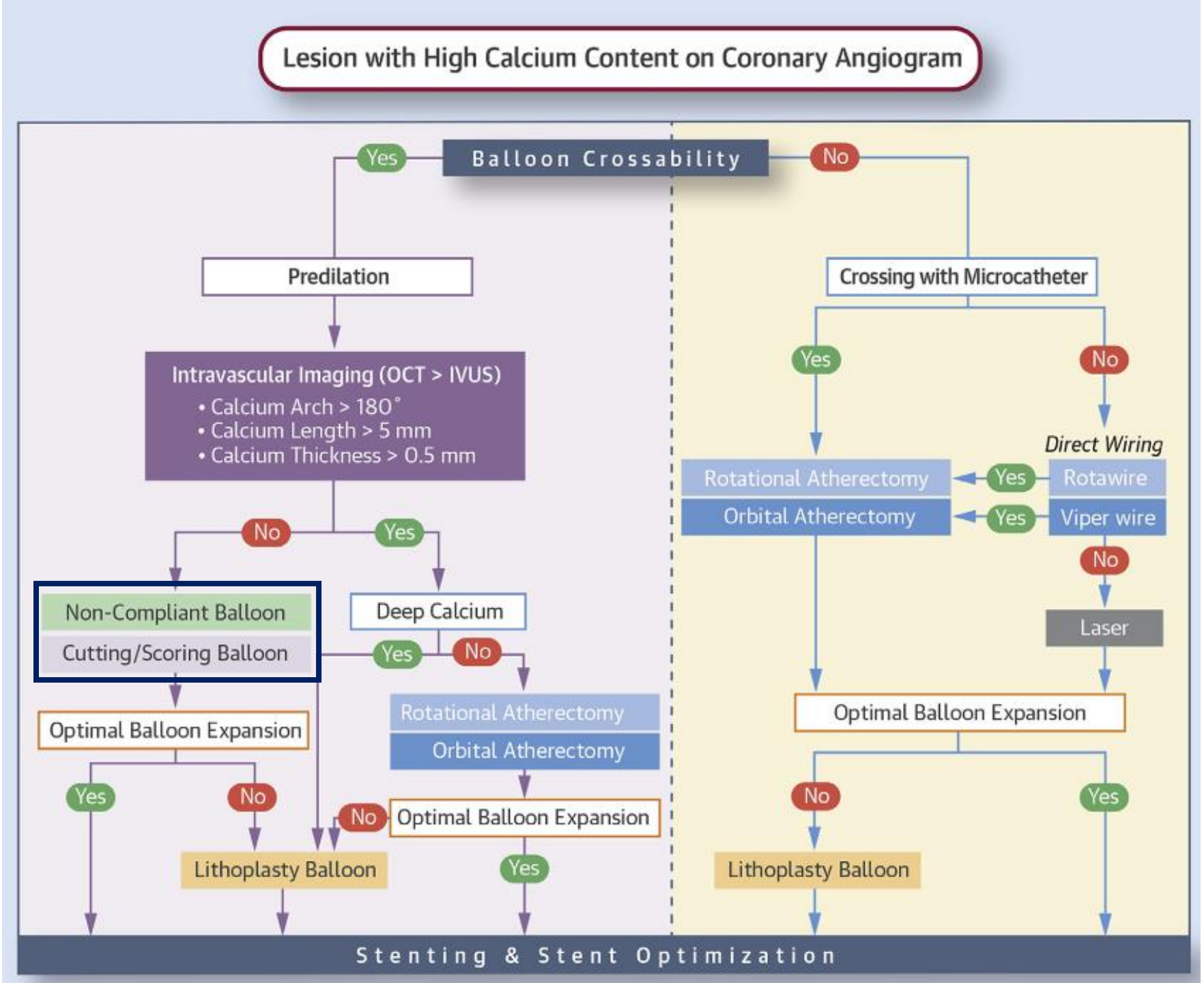
# Distribution of Calcium




Deep

Superficial

Superficial &
Circumferential




J Am Coll Cardiol Intv. 2019;12(15):1465-78.

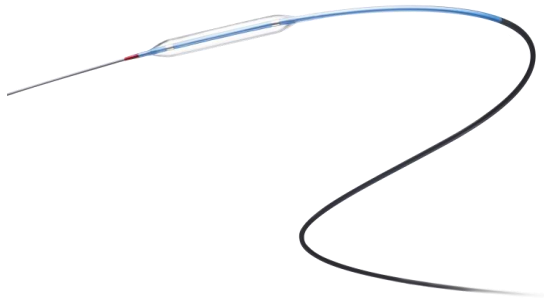
**Soft/fatty** **Fibrotic/Fibro-Calcific** **Calcific**

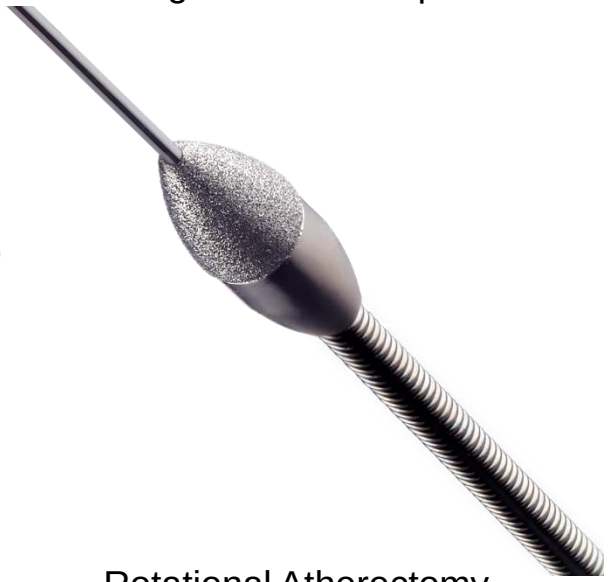
Optimize stent placement

Avoid Slippage

Avoid Plaque Shift

Change Lesion Compliance





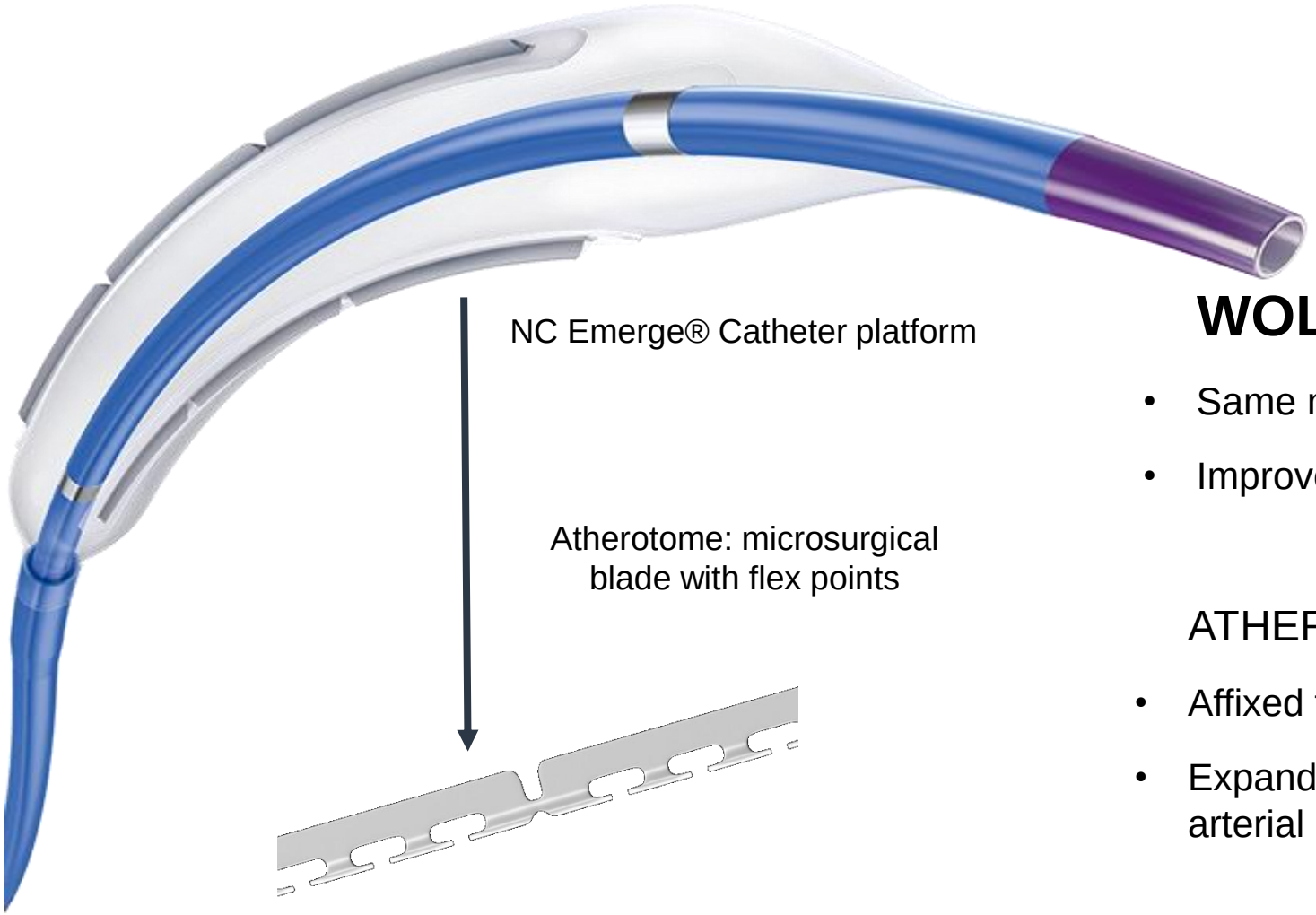
POBA

WOLVERINE™ Cutting Balloon Device

Rotational Atherectomy

# Wolverine™ Cutting Balloon™ Device

Conventional Angioplasty + Microsurgical Technology




## **WOLVERINE** vs. FLEXTOME

- Same mechanism of action
- Improved deliverability and reduced profile

ATHEROTOMES

- Affixed to a nylon non-compliant balloon
- Expand radially as balloon is inflated to score arterial plaque

# The COPS Trial

## Cutting balloon to Optimize Predilatation for Stenting


**Primary Investigators**

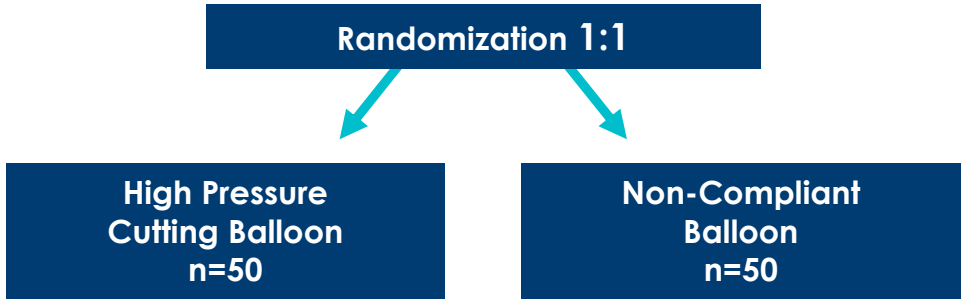
Dr. Antonio Mangieri, Dr. Antonio Columbo

**Three hospitals in Italy**

Maria Cecilia Hospital, Humanitas Rozzano, Clinica Mediterranea

### Study Design

- Prospective, randomized, multicenter open-label trial which enrolled 100 patients with significant calcified lesions evaluated at IVUS




### Primary Endpoint

- Minimal Stent Area (MSA) at Calcium Site

### Secondary Endpoint

- Eccentricity Index : (LD max – LD min) / LD max
- MSA
- Device Failure
- Safety: Procedural Complications & One-Year MACE

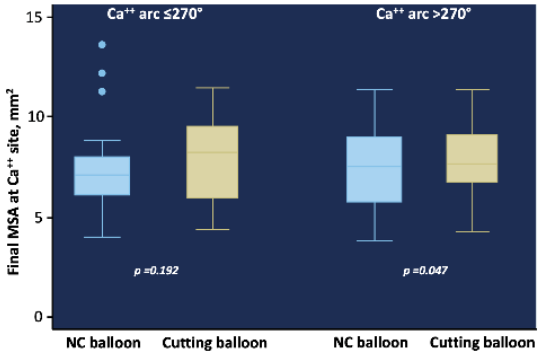
# The COPS Trial: Results

## Study contained a range calcium 100 – 360° and 29.4% avg of deep calcium

| | Overall | CB (n=44) | NCB (n=43) | P value |
|---|---|---|---|---|
| Lesion Type | | | | |
| Type B1 | 25 (28.7) | 14 (32.5) | 11 (25) | |
| Type B2/C | 62 (71.2) | 29 (67.4) | 33 (75) | |
| Calcium distribution | | | | 0.482 |
| Mixed Calcium | 34 (40) | 15 (34.8) | 19 (45.2) | |
| Deep Calcium | 25 (29.4) | 15 (34.8) | 10 (23.8) | |
| Superficial Calcium | 26 (30.5) | 13 (30.2) | 13 (30.9) | |
| Arch of calcium (degrees) | 266±84 | 274±84 | 258±85 | 0.373 |
| Calcium length (mm) | 12±6.6 | 11.9±7.3 | 12.5±6 | 0.667 |
| Lesion length (mm) | 24.3±9.7 | 23.5±9.6 | 25.1±9.8 | 0.442 |
| Minimal lumen area ($mm^2$) | 3.2±0.9 | 3.4±1.1 | 3±0.7 | 0.02 |
| QCA evaluation | | | | |
| Reference vessel diameter (mm) | 3.4±0.4 | 3.51±0.3 | 3.39±0.4 | 0.112 |
| Percentage of stenosis (%) | 81.2±8.1 | 79.4±7.6 | 82.7±8.3 | 0.97 |

## WOLVERINE is clinically proven to provide superior MSA at the calcium site compared to POBA

| | CB (n=44) | NCB (n=43) | P value |
|---|---|---|---|
| Final MSA ($mm^2$) | 7.1±1.7 | 6.5±2.1 | 0.116 |
| Minimal Stent Diameter | 2.7±0.4 | 2.5±0.4 | 0.064 |
| Maximal Stent Diameter | 3.2±0.4 | 3.1±0.4 | 0.189 |
| Final MSA at calcium site | 8.1±2 | 7.3±2.1 | 0.035 |
| Minimal stent diameter at calcium site | 2.9±0.7 | 2.7±0.4 | 0.016 |
| Maximal stent diameter at calcium site | 3.5±0.5 | 3.3±0.4 | 0.132 |
| Eccentricity index at calcium site | 0.84±0.7 | 0.8±0.8 | 0.013 |




**The benefit was magnified in presence of severe calcifications**

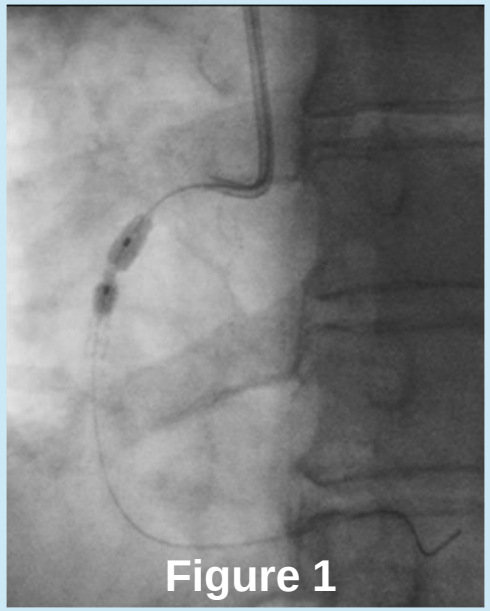
# Cutting balloon to optimize predilation for stent implantation: The COPS randomized trial

*Catheter Cardiovasc Interv.* 2023;101:798–805.

**TABLE 3** Baseline procedural features of the per-protocol population.

| | Overall *n* = 87 | CB *n* = 44 | NCB *n* = 43 | *p* |
|---|---|---|---|---|
| Predilatation atmospheres | 18.6 ± 4.7 | 18.3 ± 5 | 19 ± 4.5 | 0.463 |
| Diameter of the balloon for predilation | 3.1 ± 0.4 | 3.02 ± 0.3 | 3.2 ± 0.4 | 0.031 |
| Balloon to artery ratio | 0.89 ± 0.2 | 0.86 ± 0.1 | 0.92 ± 0.2 | 0.057 |
| Number of stent implanted | 1.3 ± 0.4 | 1.3 ± 0.5 | 1.2 ± 0.4 | 0.314 |
| Total stent length (mm) | 32.9 ± 12 | 31.6 ± 12 | 34.2 ± 12 | 0.837 |
| Stent diameter (mm) | 3.3 ± 0.4 | 3.4 ± 0.3 | 3.3 ± 0.4 | 0.737 |
| Postdilatation | 67 (77) | 33 (75) | 34 (79) | 0.885 |
| Diameter of the balloon for postdilation | 3.5 ± 0.5 | 3.6 ± 0.6 | 3.5 ± 0.4 | 0.497 |
| Postdilatation atmospheres | 20.9 ± 0.6 | 20 ± 5.2 | 21.7 ± 5.4 | 0.201 |

# Avoid Rota Regret!




Single 2.75 mm stent placed

Post Dilatation: 3.5x9 mm non- compliant balloon for 30 seconds at 22 ATM followed by 4.0x9 mm non- compliant balloon for 30 seconds at 16 ATM.
*(figure 1)*


Results sub-optimal.
*(figure 2)*

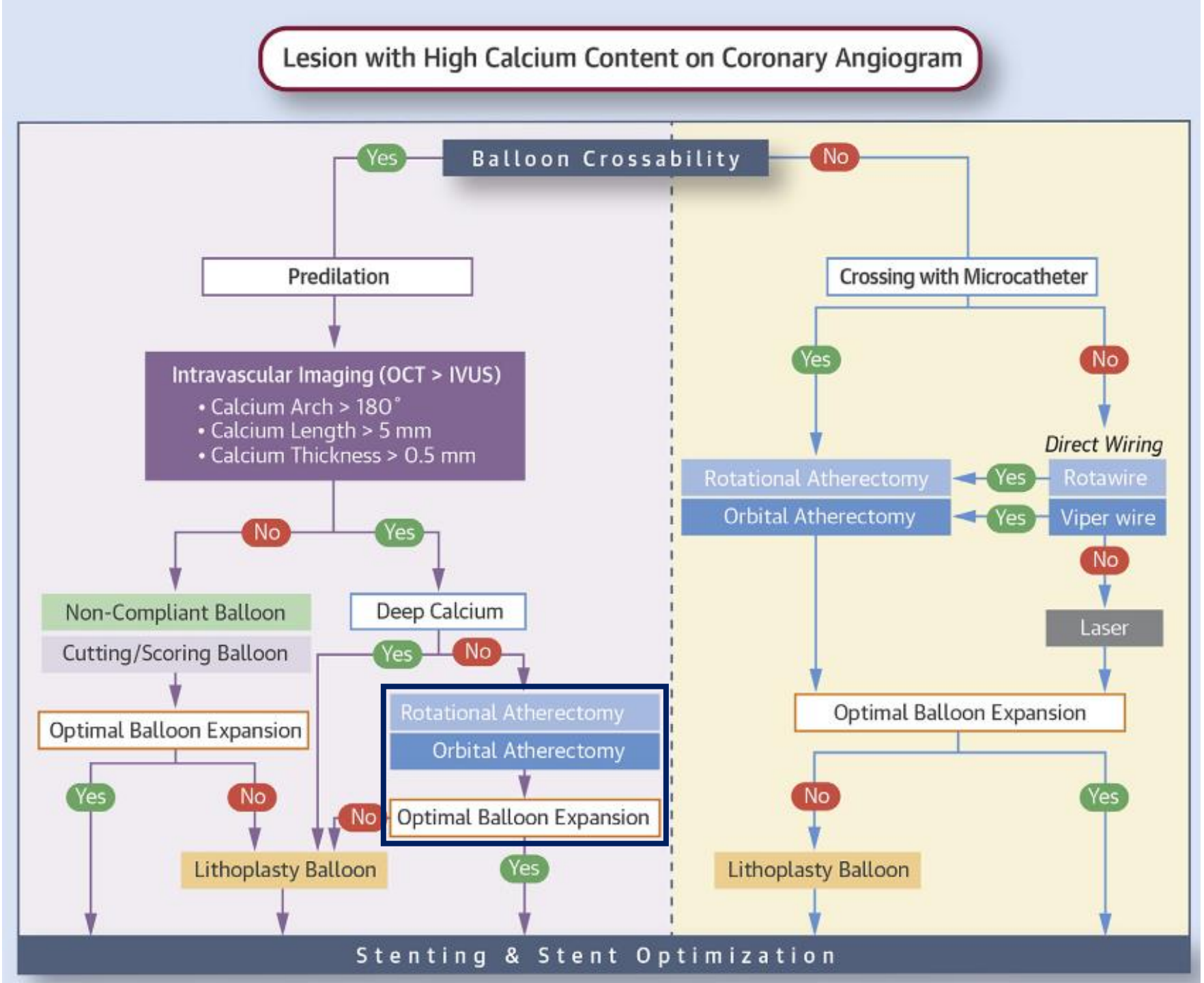
**Lesions which initially appear as either treatable with PTCA or by stenting may benefit from pre-treatment with the ROTABLATOR™ Rotational Atherectomy System.**

**Using ROTABLATOR System may favorably impact complications, acute angiographic results, TLR and angiographic restenosis in calcified and complex lesions.[1]**

**Asymmetrical stent expansion occurs in up to 50% of cases where calcium is not treated before stent deployment.[2]**

Results from case studies are not predictive of results in other cases. Results in other cases may vary.
Case images courtesy of Dr. Arthur Lee, Santa Clara Valley Medical Center, Kaiser Permanente, San Jose, CA

1.Hoffman R, et al. Comparative Early and Nine-Month Results of Rotational Atherectomy, Stents and the Combination of Both for Calcified Lesions in Large Coronary Arteries. *Am J. Cardiology*; March 1, 1998: vol. 81, :552-557
2.Moussa, Moses, Columbo et al. Coronary Stenting After Rotational Atherectomy in Calcified and Complex Lesions. *Circulation* 1997; 96:128-136




J Am Coll Cardiol Intv. 2019;12(15):1465-78.

# Who needs a ROTA?

- **Bail-out rotablation**
  - ✓ when device can not cross the lesion (calcification, CTO)
  - ✓ undilatable lesion or stent

- **Elective rotablation**
  - ✓ angiographically severely calcified or moderately calcified tortuous lesion
  - ✓ on IVUS

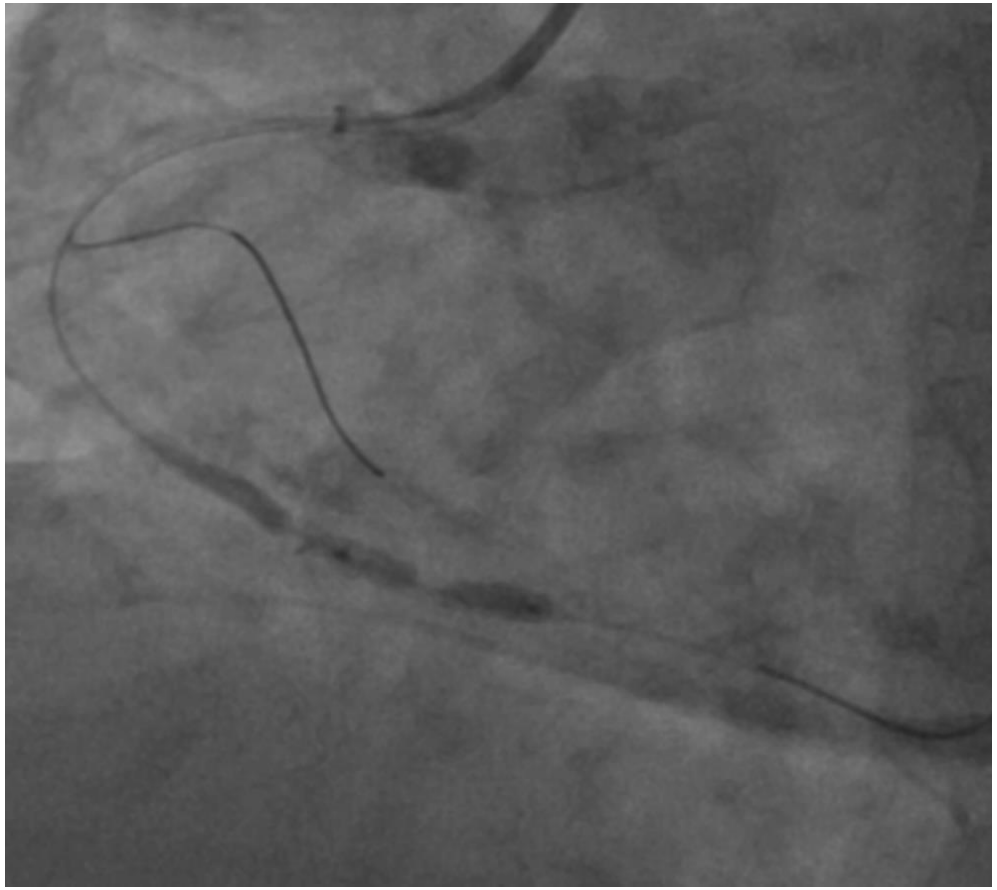
**Calcium >270°**
**longer than 5mm?**

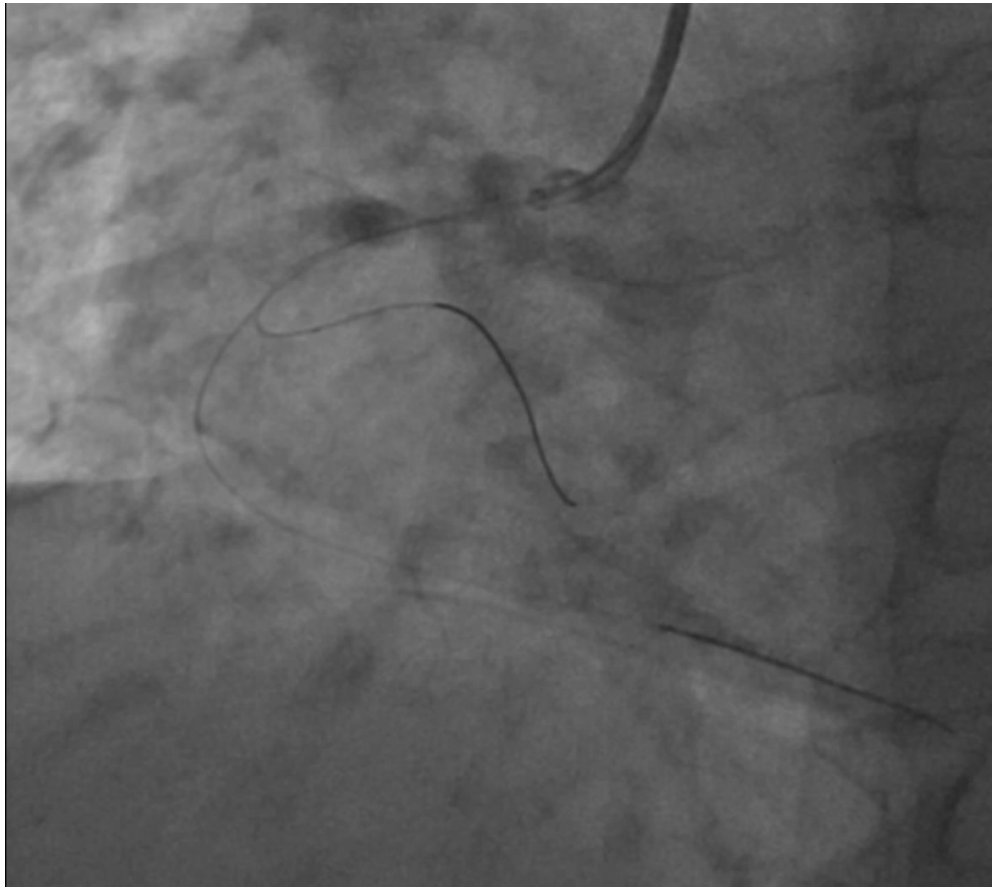
**360° of calcium?**

**Calcified nodule?**

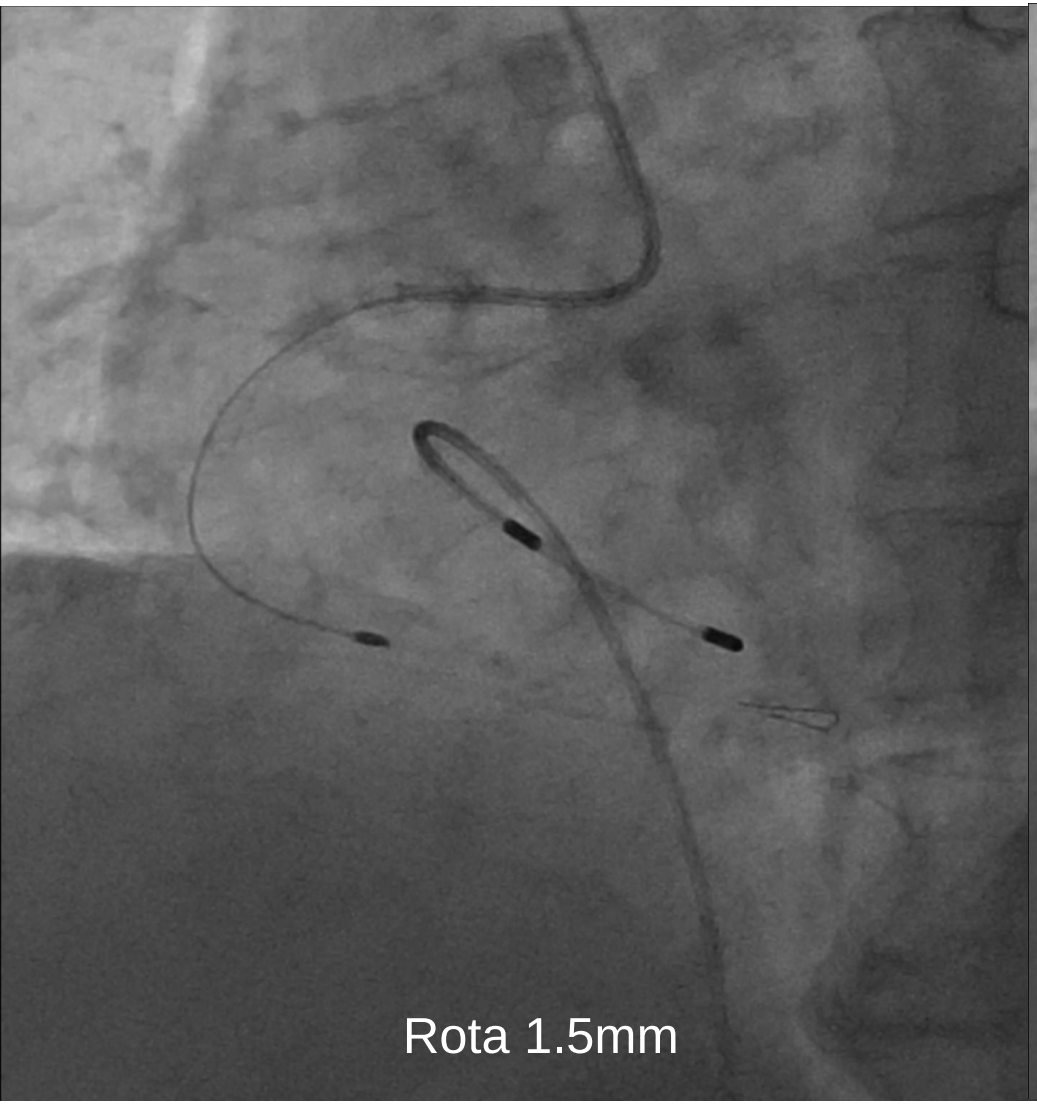
M/63, chest pain

2.75 * 15mm NC balloon upto 20atm

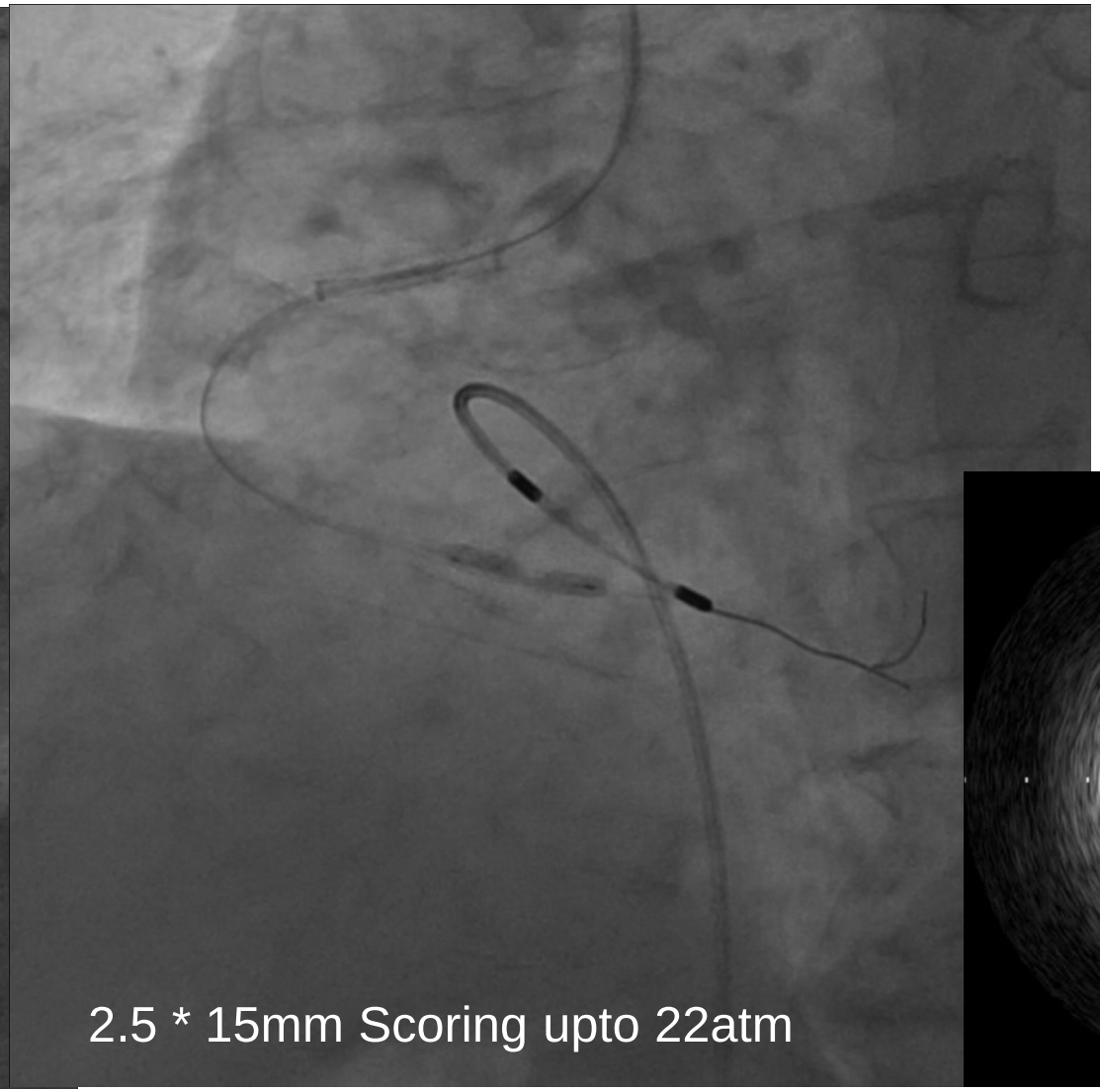




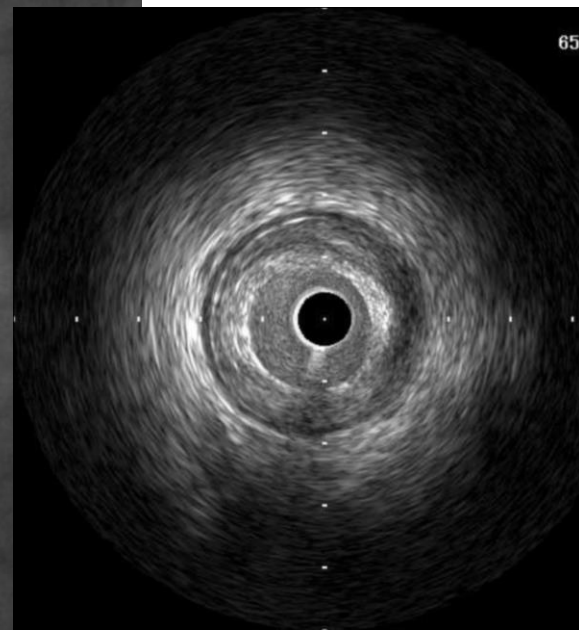
# ROTA 1.5 mm



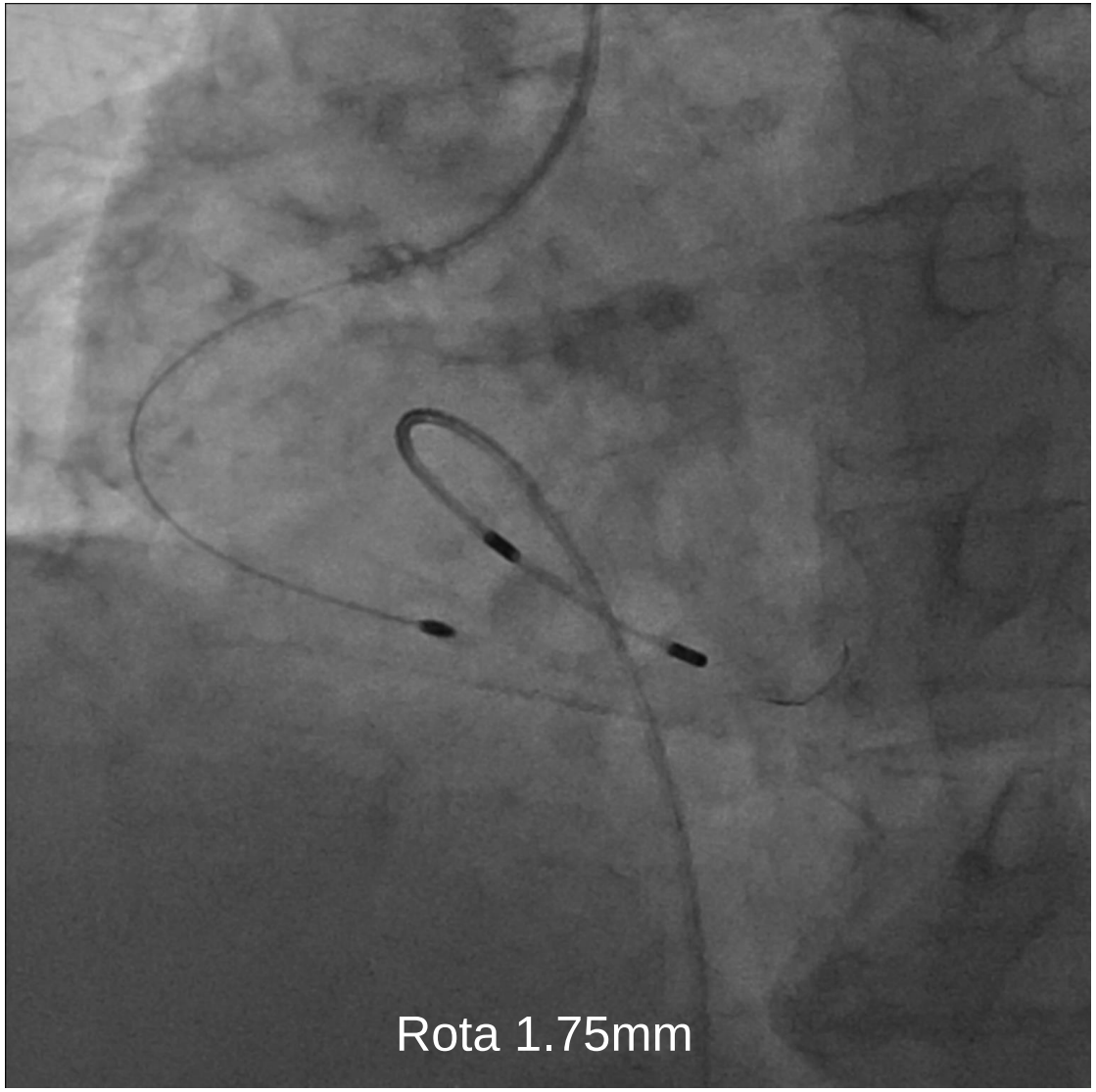
Rota 1.5mm



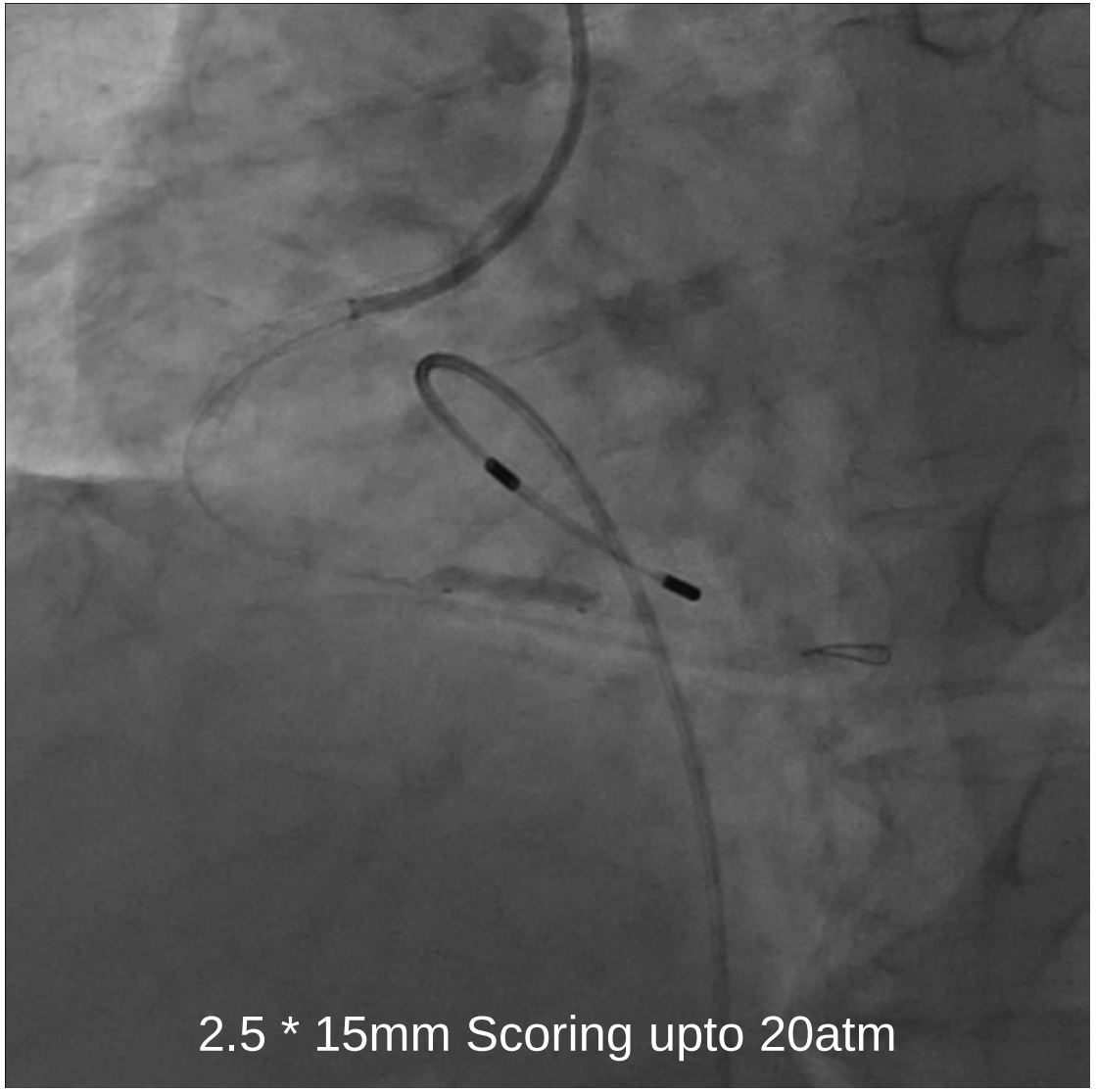
2.5 * 15mm Scoring upto 22atm



# ROTA 1.75 mm

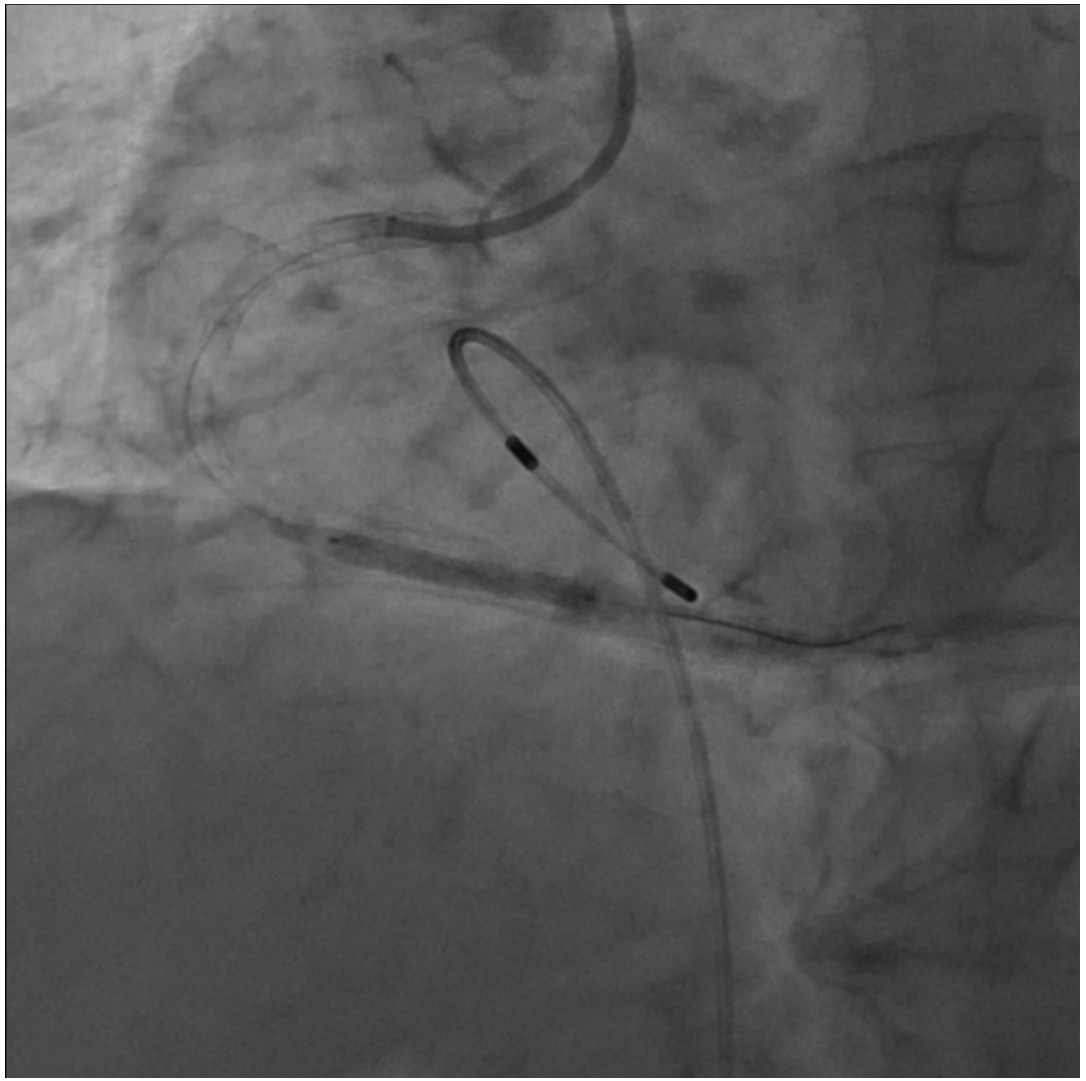


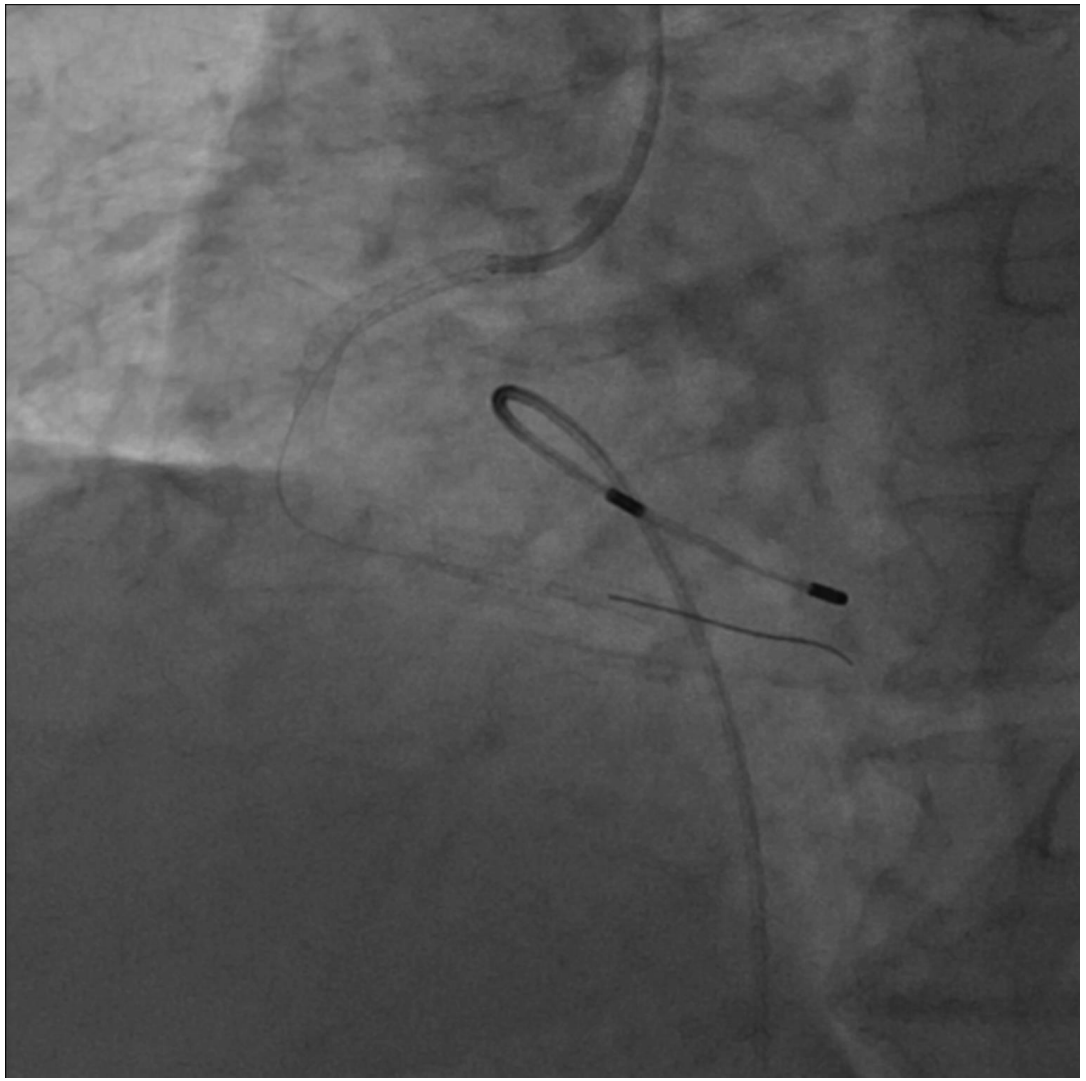
Rota 1.75mm



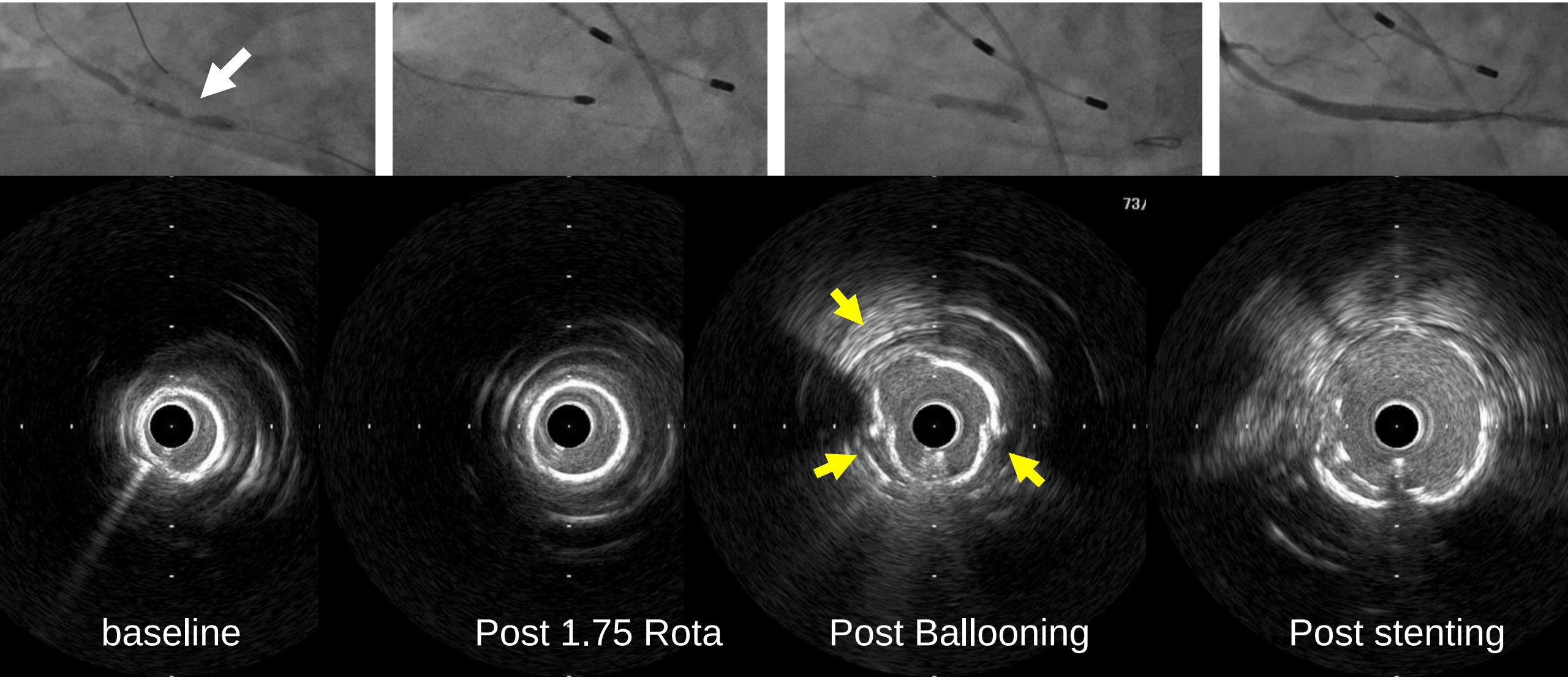
2.5 * 15mm Scoring upto 20atm

# DES implantation





# Calcium fracture




key to adequate stent expansion

If you have some doubts, try balloon first,

because you can always switch to Rotablation

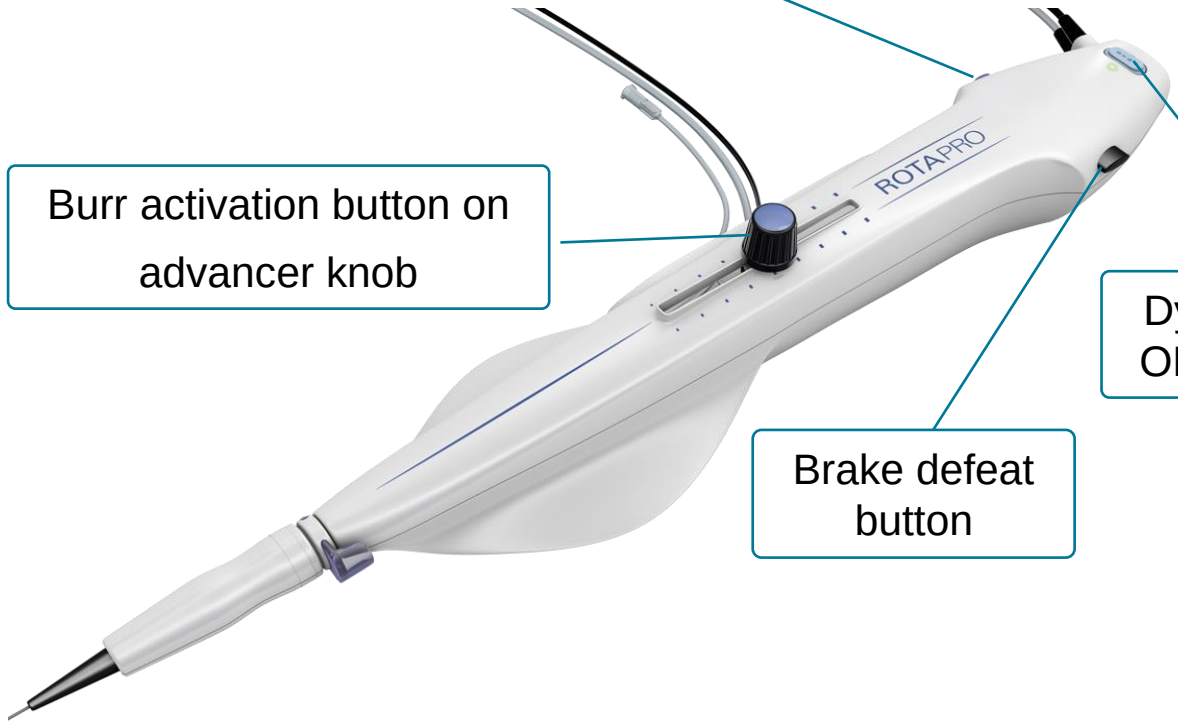
as long as you haven’t stented.

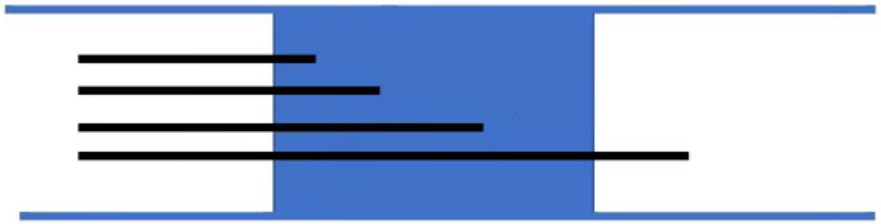
# ROTAPRO™ Rotational Atherectomy System



**Design Goals:**

- Easier to learn & use (no foot pedal)
- Easier to set up (consolidated cables)
- Allows single operator use

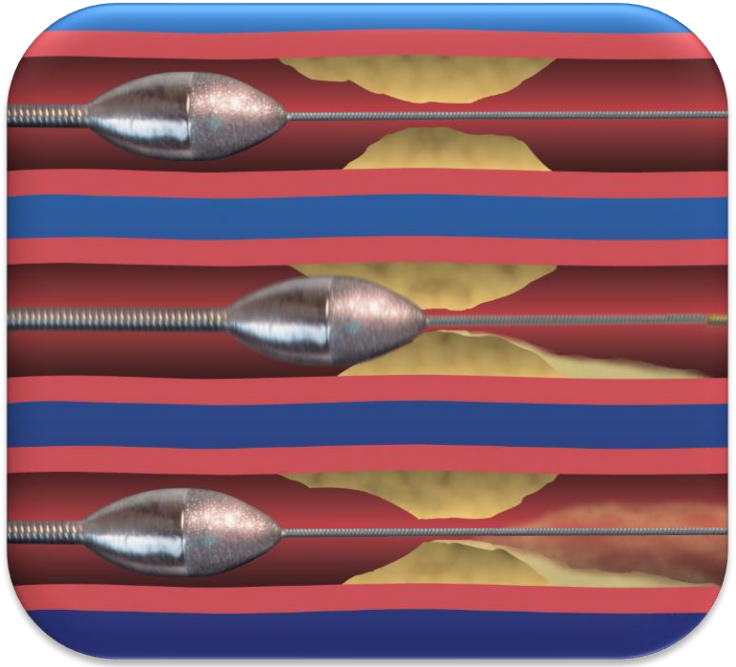


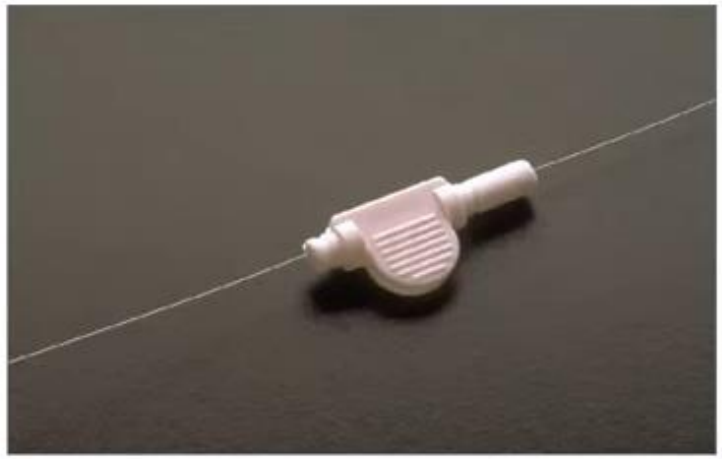


# Key Procedural Steps

**Ablation Procedure Tips** (Physician Considerations)

- Do not over-tighten Y-adapter
- Avoid dottering
- **Never stop burr in lesion**
- **Never stop burr distal to lesion**
- Never adjust RPMs during ablation
- Never advance rotating burr to point of contact with the guidewire spring tip
- Do not allow the burr to remain in one location while rotating at high speeds
- Gently advance or retract the burr while it is at high-speed rotary motion
- Avoid burring in the guide catheter





Wire: 0.009” that ends 0.014”

-Long, over-the-wire system
-No hydrophilic coating
-Difficult to torque and advance
-Generally, use workhorse wire then exchange for Rotawire

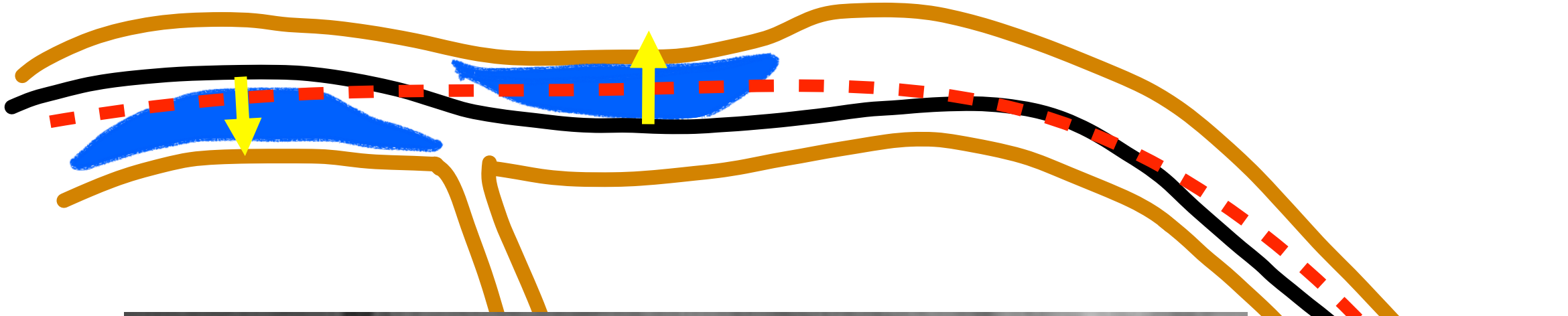

**2 types:**

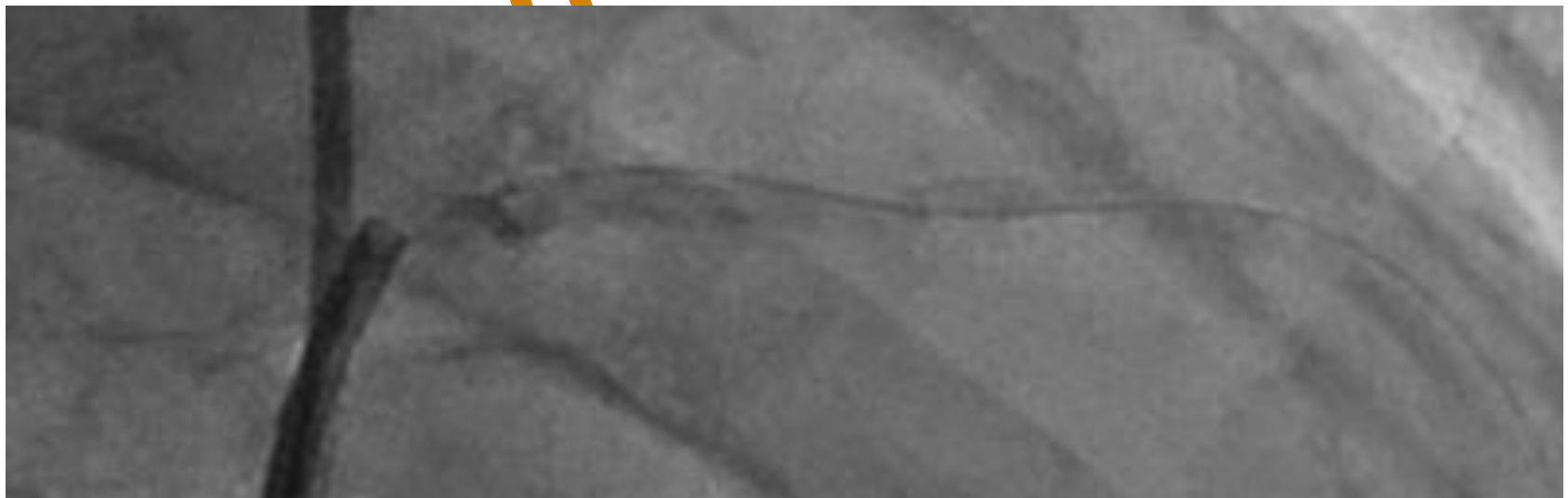
-Rotawire floppy: most commonly


-Rotawire extrasupport (heavier body)→more vessel straightening, wire bias, and ablation of plaque at the lesser curvature of angulated segments
→ Useful for ostial rotablation or distal

**The guidewire has a strong tendency to return to its normal shape**

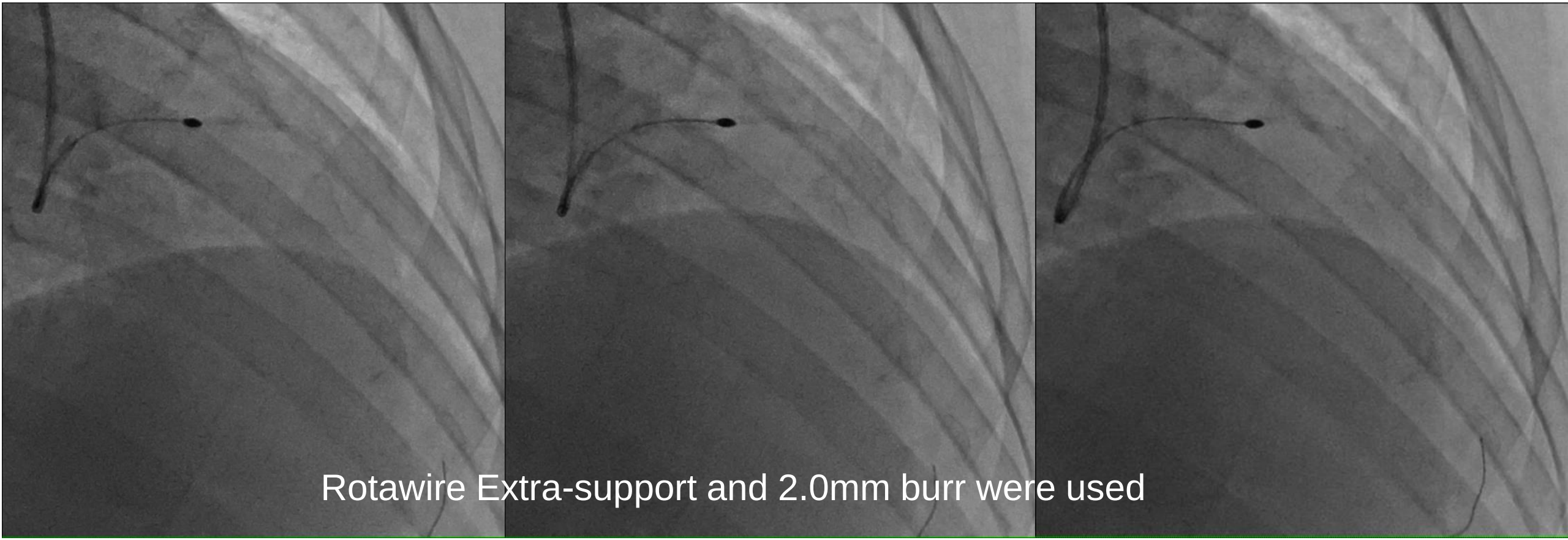
*more prominent for extra-support





## To maximize the guidewire bias

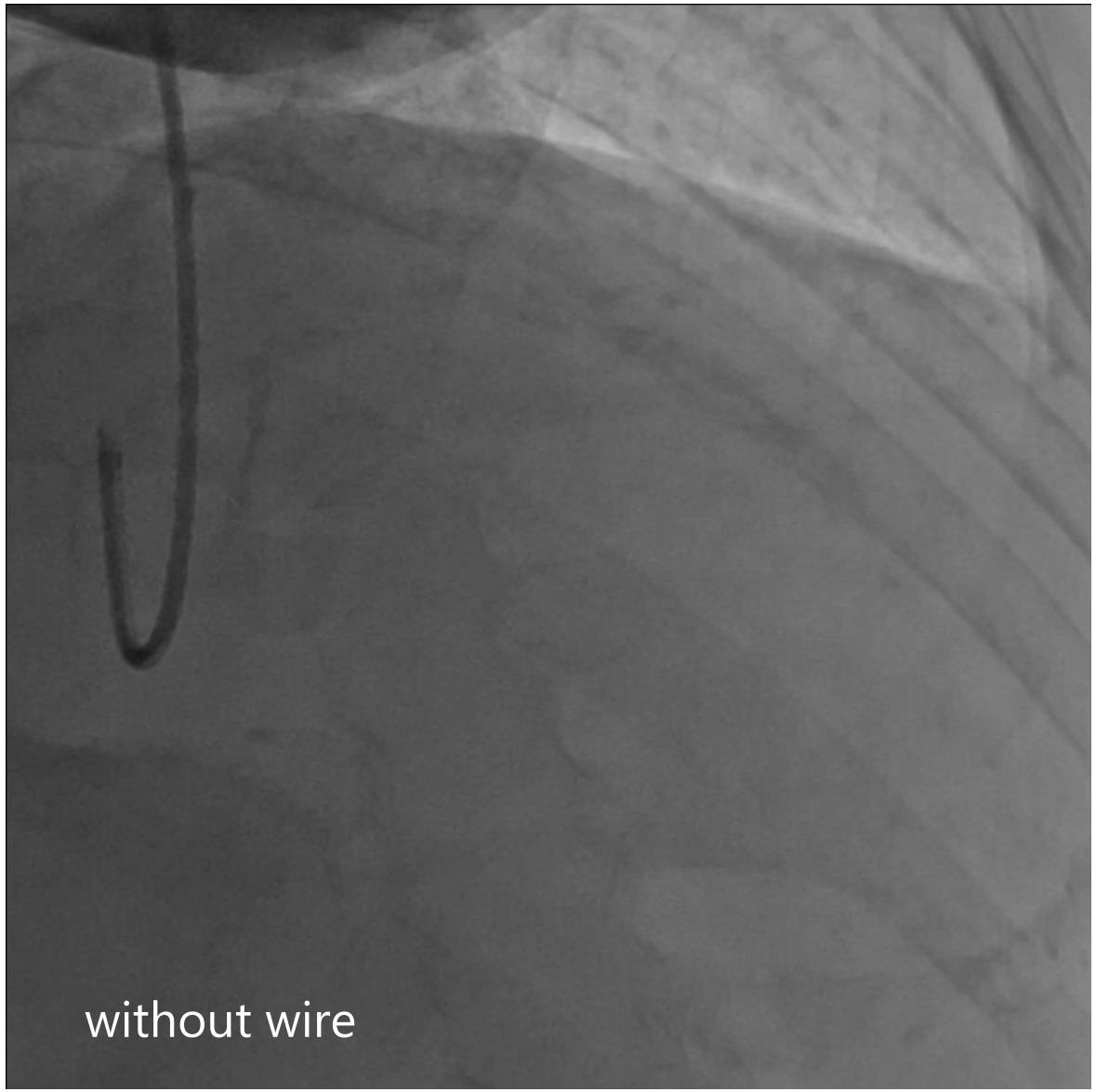
Don’t push too much and don’t go too fast!

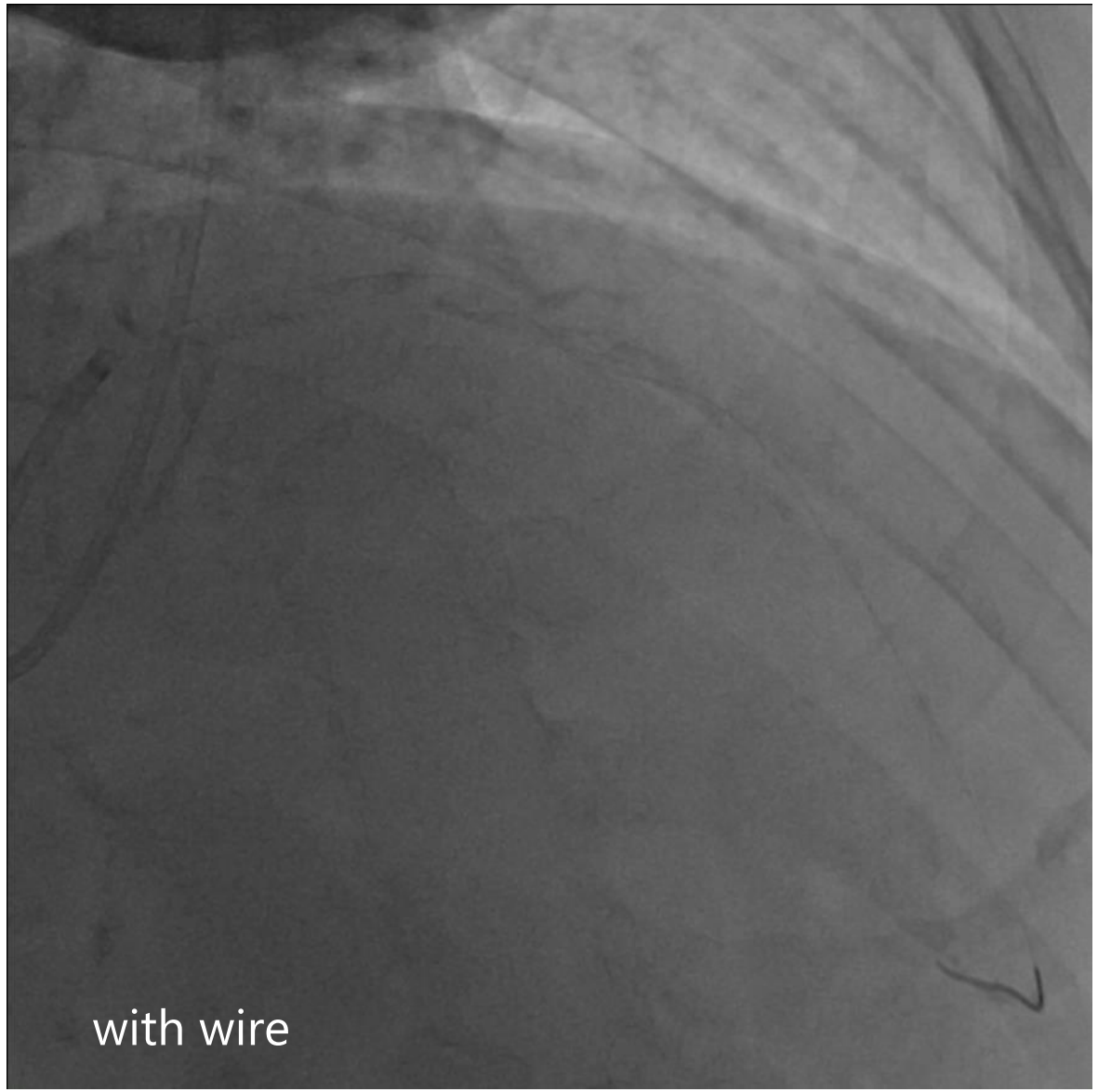



Lateral cut can be expected by advancing the burr very slowly if appropriate GW bias is present

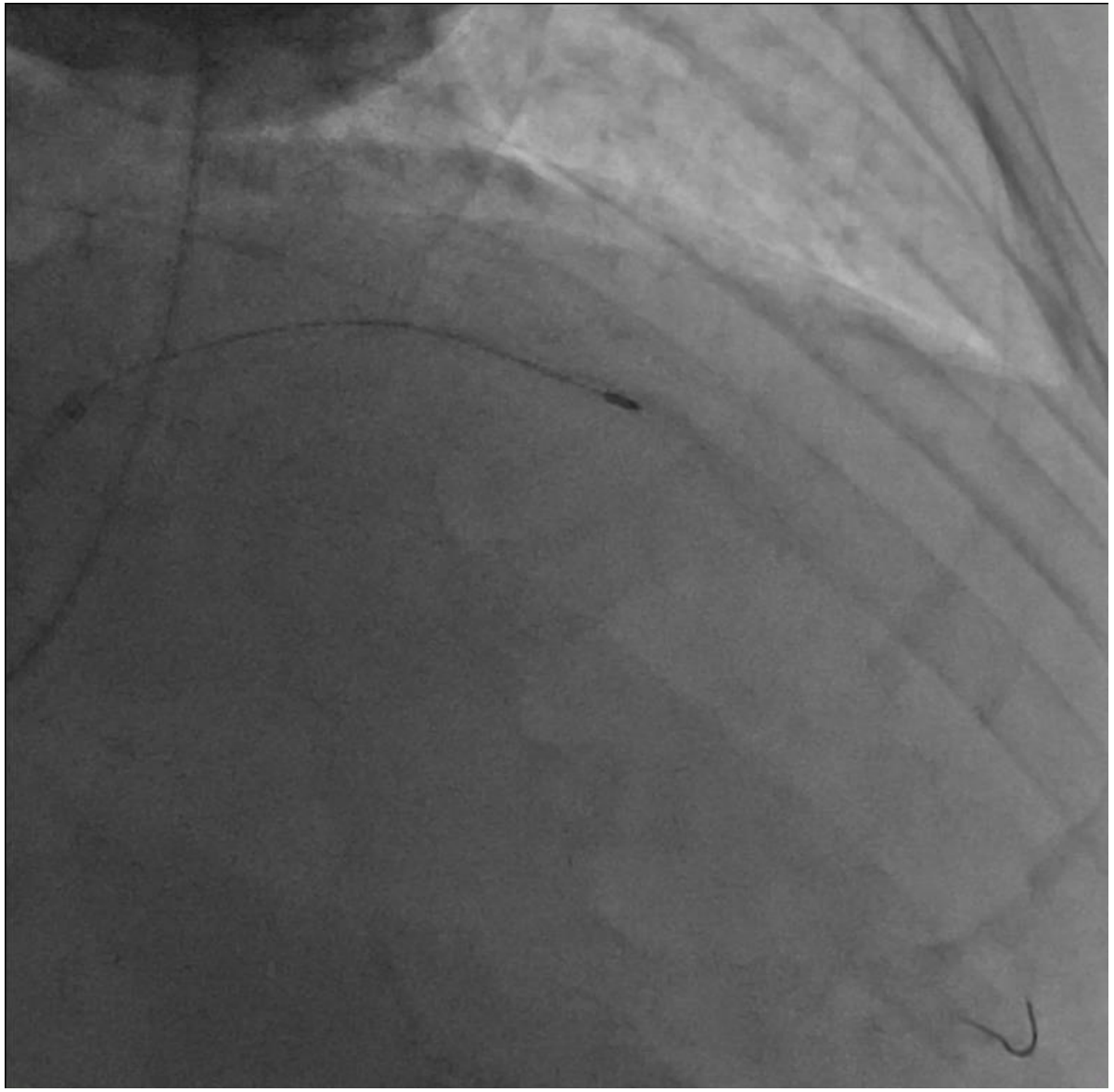
The stronger the wire, the greater the guidewire bias.

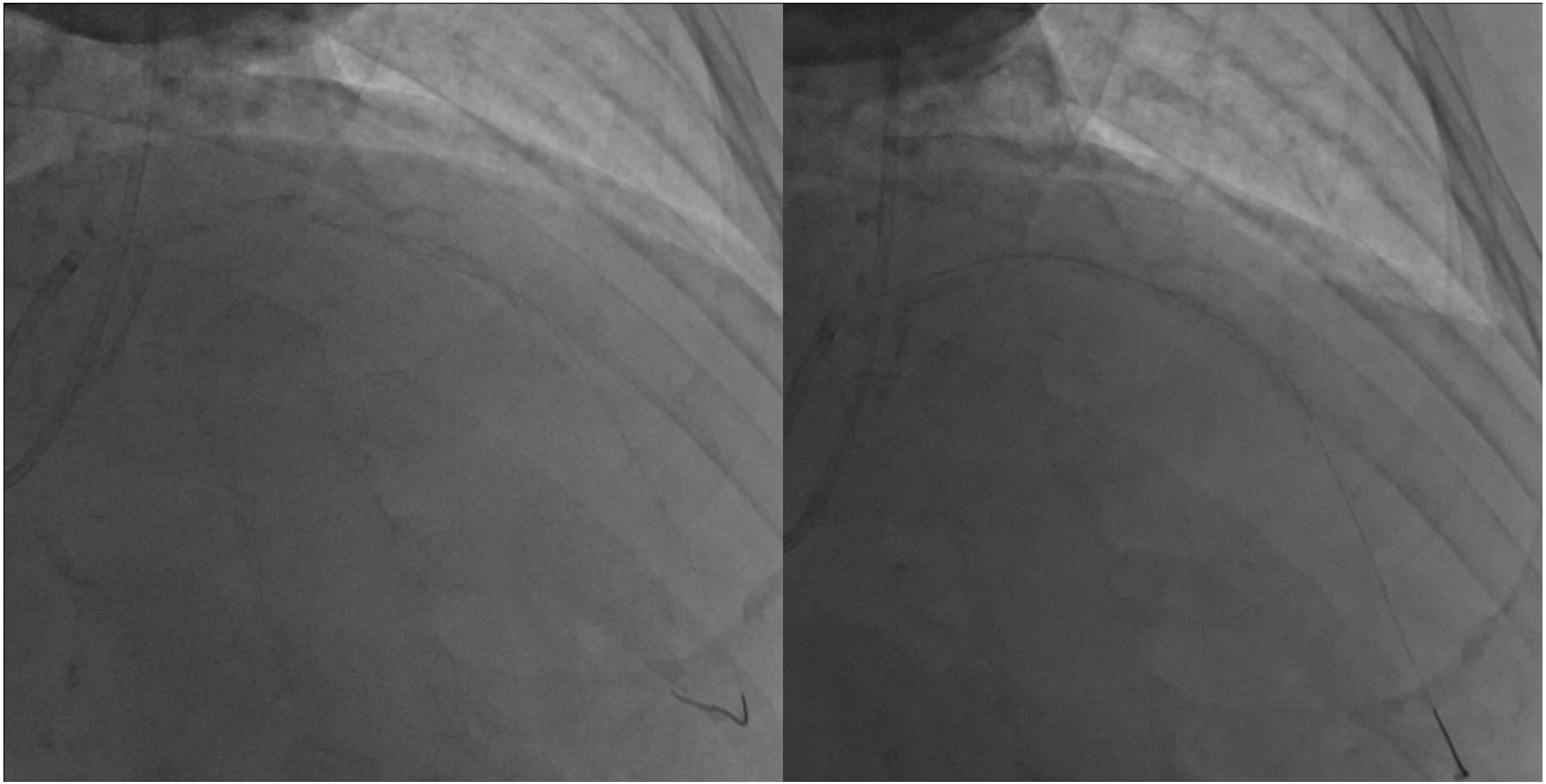
# depends on lesion tortuosity, rigidity, and the wire



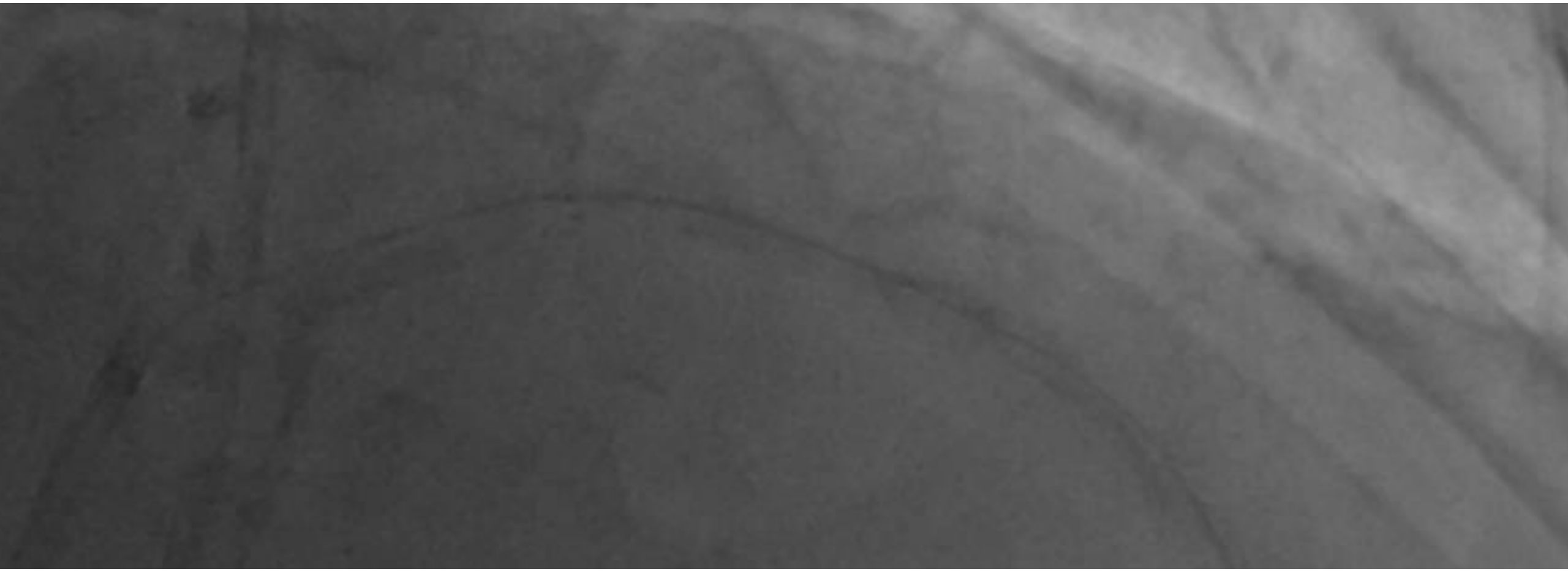
# Rotaburr 1.25mm on Rotawire Extra-support



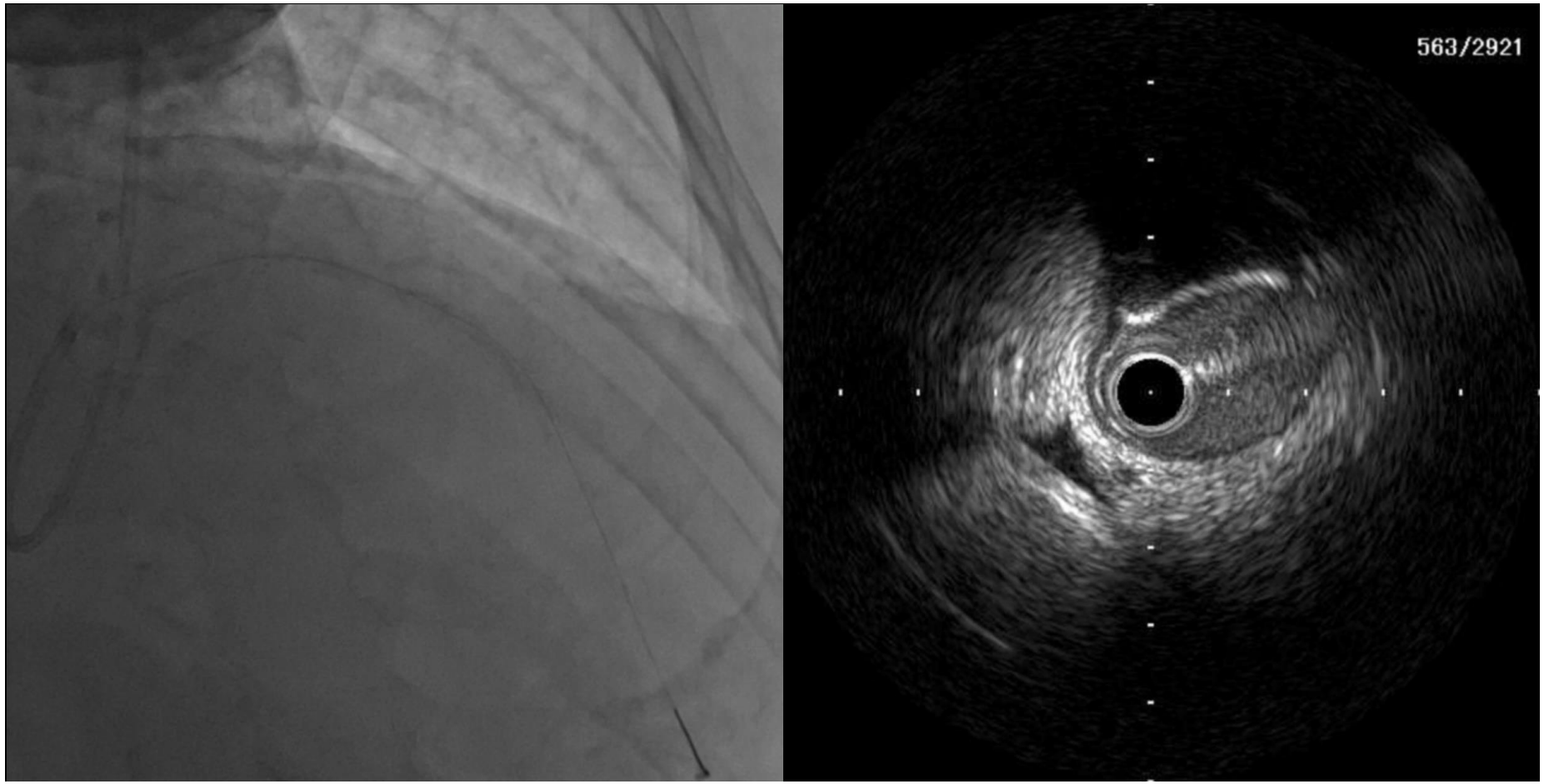


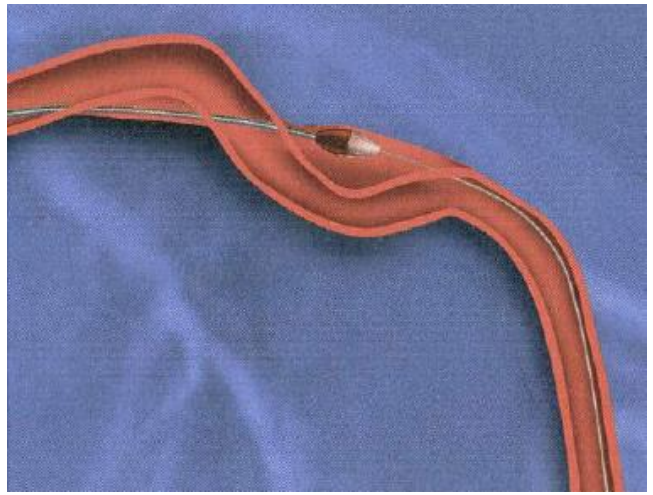
Baseline

Post ROTA



# The Floppy wire and larger burr might have been safer



Stiffer is not always better

Smaller is not always safer

# The new ROTAPRO study

*The 1st clinical data comparing the new ROTAPRO to legacy ROTABLATOR*

**Objective: Evaluate safety & feasibility of the new ROTAPRO system for lesion preparation in calcified coronary artery stenosis.**

All patient with severely calcified lesions undergoing PCI using RA with **either the new Rotapro system** or **conventional Rotablator**, followed by DES implantation included in the Bad-Krozingen rotablation registry (1 center, Germany) N= 597

- PCI using the new ROTAPRO system N= 264
- PCI using conventional Rotablator N= 351

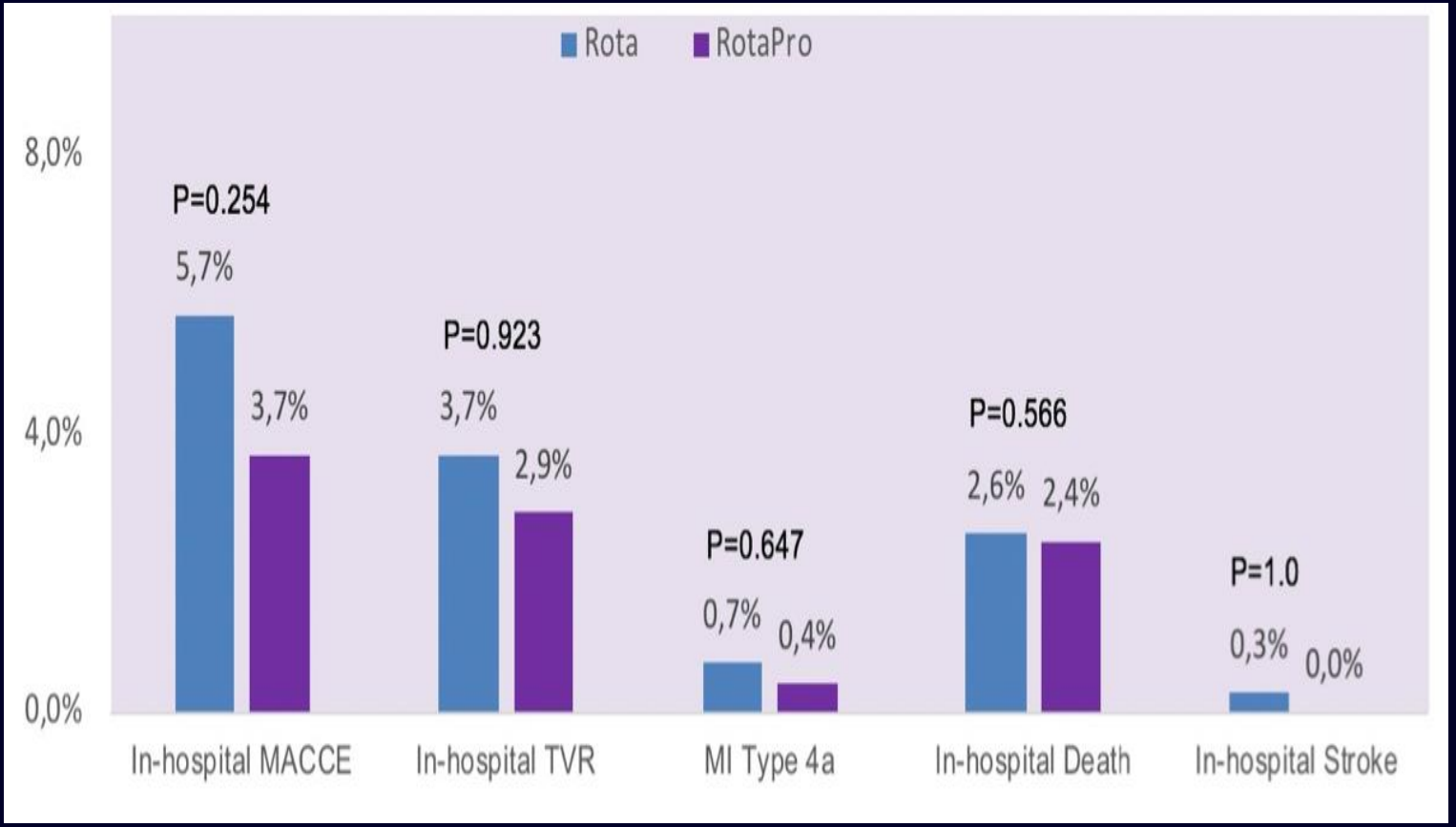
Primary Endpoint: **In-hospital MACCE** (in-hospital all-cause death, periprocedural MI, recurrent symptoms requiring urgent TVR with PCI or surgery, and stroke).

Secondary Endpoints: Procedural success (technical success without in-hospital MACCE), procedural time, fluoroscopy time, amount of contrast used, major complications.

*Mohamed Ayoub, Kambis Mashayekshi et al. Caridol. J. 2021*

# Results: No differences in in-hospital MACCE

*Similar in-hospital MACCE & its individual components*




ROTAPRO showed numerically lower in-hospital MACCE, TVR, MI, death or stroke vs. legacy Rota , but without any significant differences in p-values.

Ayoub et al. Cardiol J. 2021

# Results: Secondary Endpoints & Major Complications

| Secondary endpoint (n) % | Total number (n=597) | Rotapro (n=246) | Rota (n=351) | P-value |
|---|---|---|---|---|
| **Procedural endpoints** | | | | |
| Technical success | (589) 98.7% | (244) 99.2% | (345) 98.3% | 0.385 |
| Procedural success | (568) 93.8% | (237) 95.5% | (331) 92.6% | 0.318 |
| Procedural time (min) | 88 | 82.5 | 96 | **0.0003** |
| Fluoroscopy time (min) | 34 | 30 | 38 | **0.0001** |
| Constrast volume used (mL) | 250 | 210 | 290 | **0.0001** |
| Dose area product (cGy*cm$^2$) | 8011 | 6129.5 | 9827 | **0.0001** |
| **Major complications** | | | | |
| Perforation requiring pericardiocentesis | (8) 1.3% | (2) 0.8% | (6) 1.7% | 0.348 |
| Vascular access complication | (13) 2.1% | (8) 3.45% | (5) 1.46% | 0.206 |

- ROTAPRO showed significant **lower procedural & fluoroscopy times** as well as **contrast volume** use compared to conventional rotablator.
- ROTAPRO and Rota both demonstrated high rates of technical & procedural success, with **numerically higher success for ROTAPRO**.

Ayoub et al. Cardiol J. 2021

# The ROTAPRO Study: Key take-aways

Compared to conventional Rota, ROTAPRO showed:

- **Similar in-hospital MACCE**, including in-hospital all-cause death, peri-procedural MI, TVR and stroke.
- **Similar procedural success rates and major complication.**
- **Lower procedural time, radiation exposure and contrast use**
- This study demonstrated **safety and efficacy of using the new ROTAPRO system** for rotational atherectomy.

Ayoub et al. Cardiol J. 2021

# Summary

**Rotablator can facilitate procedural success, enabling the treatment of otherwise uncrossable or undilatable severely calcified lesions**