Case-Based Approach for Coronary Physiology Eval: Ostial Disease, Multiple Lesion, Bifurcation, and ACS

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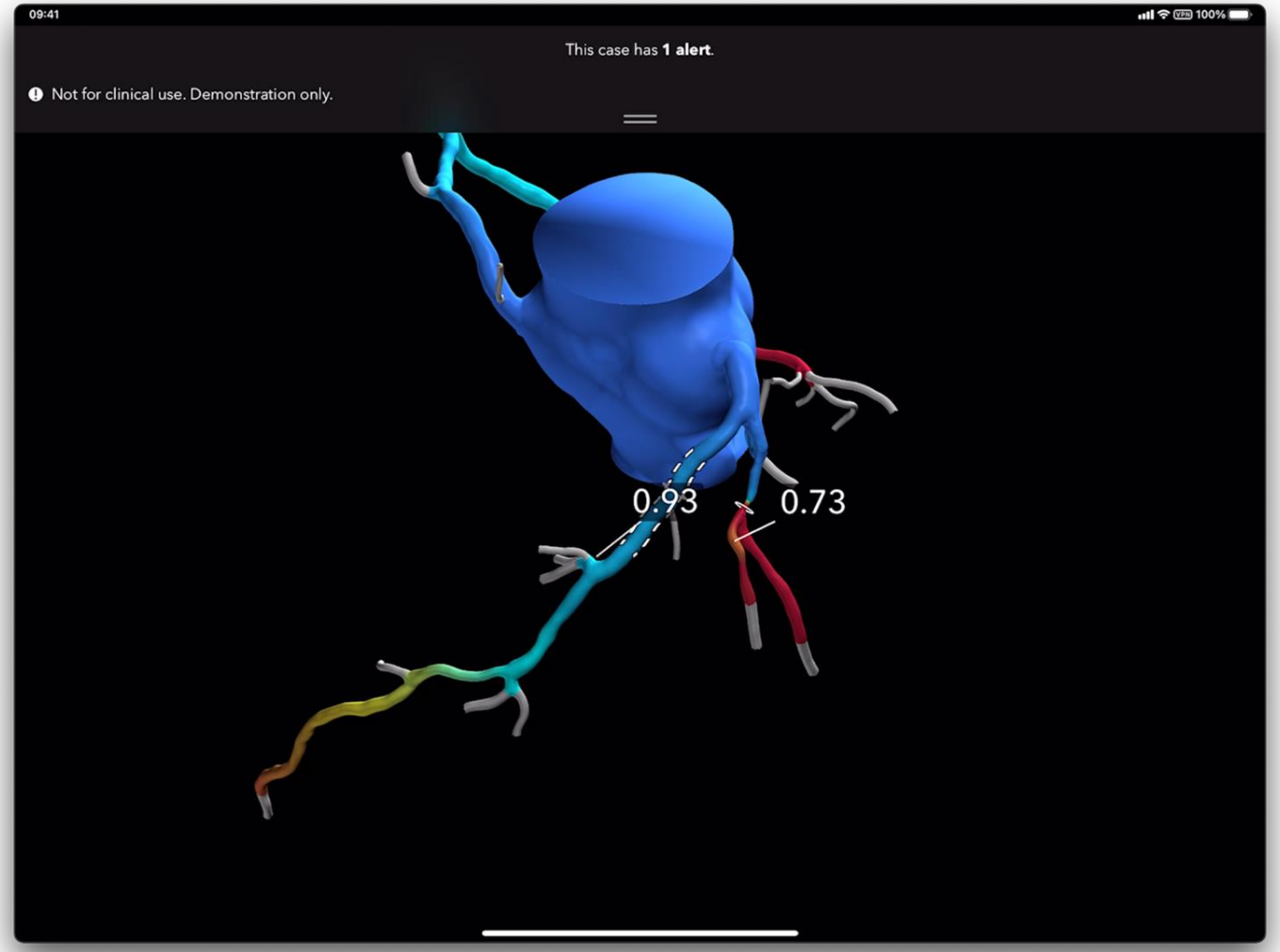
The HeartFlow Planner

The HeartFlow Planner is a non-invasive, interactive pre-procedure planning tool that uses an *idealized* coronary anatomy model and physiology simulation from the HeartFlow Analysis to assess FFR_{CT} changes as a result of anatomic modification to the coronary lumen boundary.

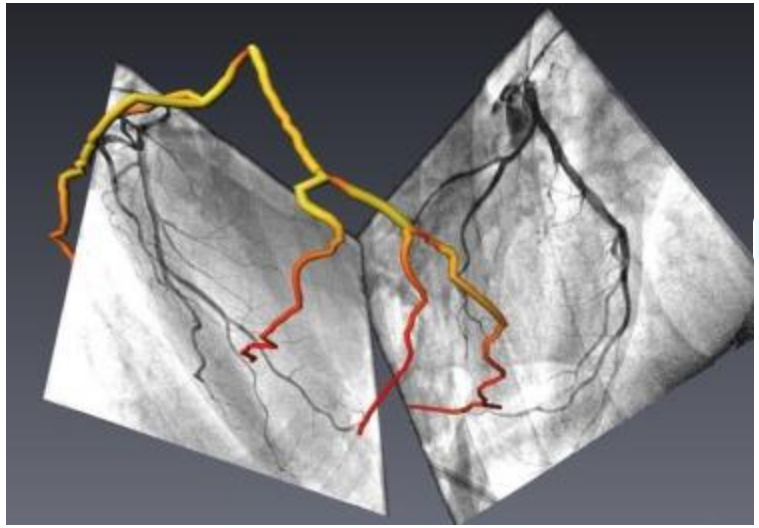


THE CATHWORKS FFRANGIO™ SYSTEM

WIRE-FREE 3D FFR GUIDANCE, PRACTICAL FOR EVERY CASE

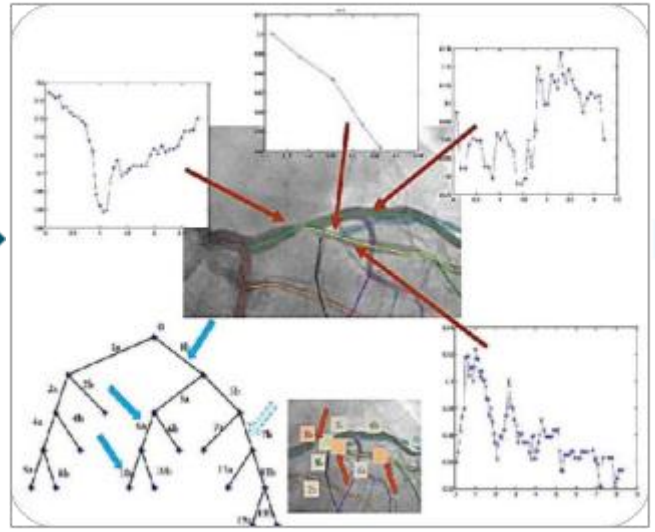
CATHWORKS™

Wire-Free FFR: The CathWorks FFRangio™ System



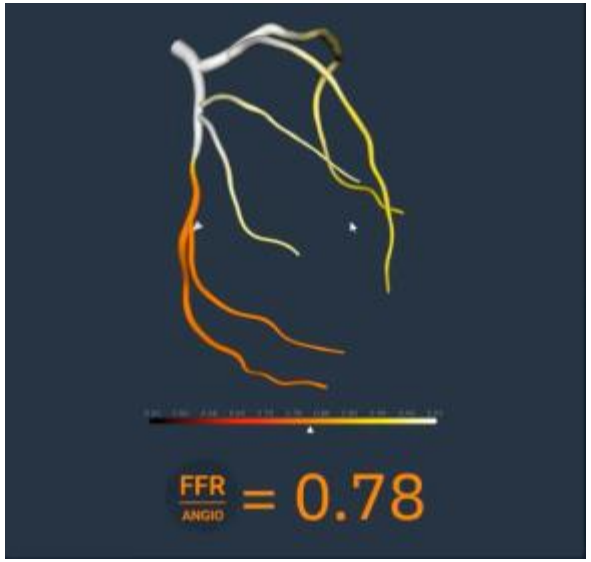
3D Reconstruction

and QCA from routine angiograms without an invasive wire



Resistance Analysis & FFR

from resistance mapping and computational FFR modeling



3D Physiology

with superimposed, color-coded FFR values in multiple vessels

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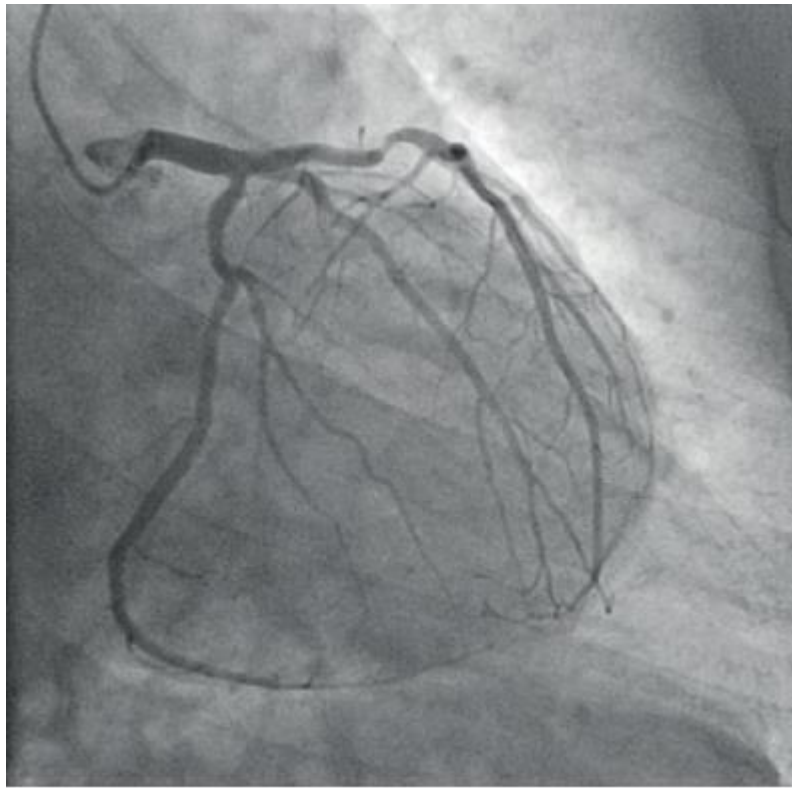
FFRangio Angiogram Requirements

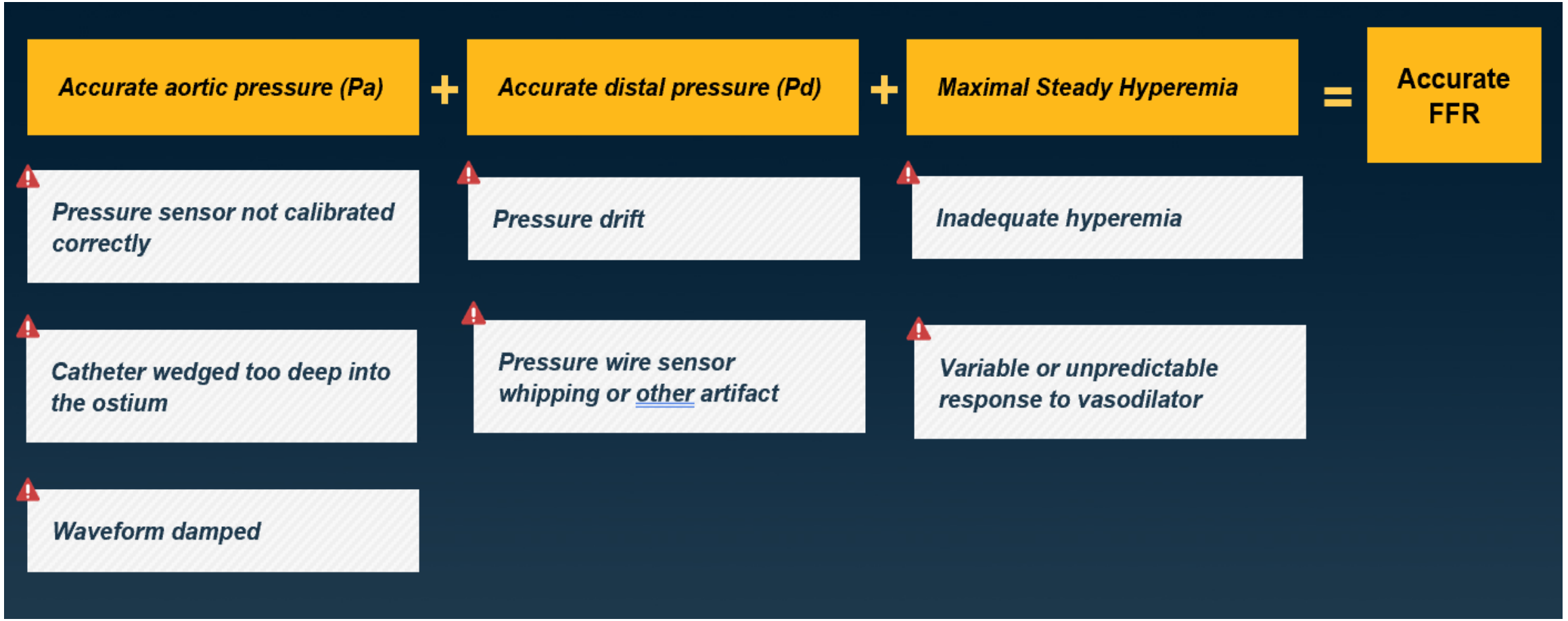
- **3 Images from different angles** (or views)
- **Full tree in view** (minimize panning, de-mag if needed).
- **Full opacification** (ostium to distal tip of vessels) for 2 cardiac cycles.
- **Clear view of lesion in at least 2 images** (avoid overlap and foreshortening as much as possible).




FFR SIZE
FFR PULLBACK
RAO 30.5 | CRAN 30.9
LAO 10.1 | CRAN 40.1
RAO 30.4 | CAUD 29.5
FFR | IMPACT
25% volume
FFRangio ≤0.8
FFRangio PULLBACK
47%
0.77
FFRangio
Length [mm]
FFR ANGIO = 0.77
Review vessel color matching
SAVE

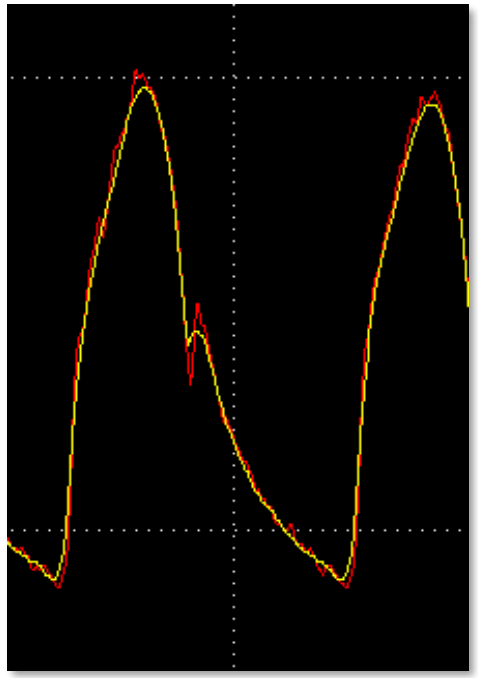
CATHWORKS

Requirements for Invasive Physiology & Sources of Error



Tips and tricks for iFR/FFR measurement

- Ensure good normalization
  - Flush the guide catheter with heparinized saline[1]
  - Remove the needle introducer[1]
  - Close the Touhy[1]
  - At normalization Pd and Pa waveforms should overlap
  - If Pa and Pd do not overlap well, simply renormalize
- Nitrates and contrast can induce temporary artificial hyperemia[2]
  - If you suspect transient hyperemic response (lower than expected iFR/FFR value), flush with saline, wait a few seconds and repeat iFR/FFR measurement until it has stabilized at a consistent value



Good Normalization

1. Al-Lamee, iFR tips & tricks, presented at TCT 2016
2. Nijjer, SS et. al. Improvement in coronary haemodynamics after percutaneous intervention: assessment using instantaneous wave-free ratio. Heart. 2013 Dec;99(23):1740-8.

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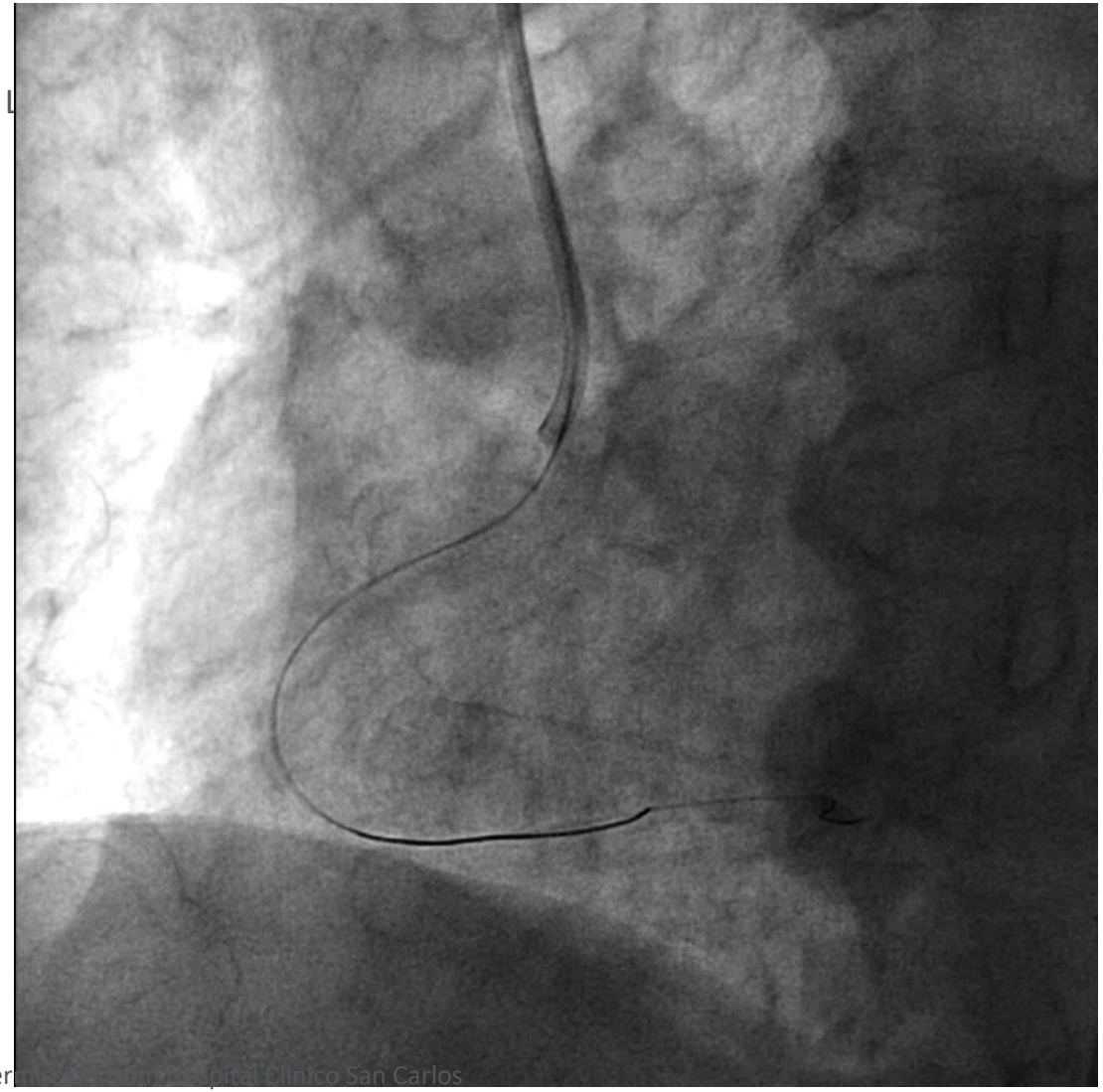
Ostial Lesions

1. Guide and normalizing must occur in aorta proximal to ostial stenosis.

How would you treat this RCA?

L

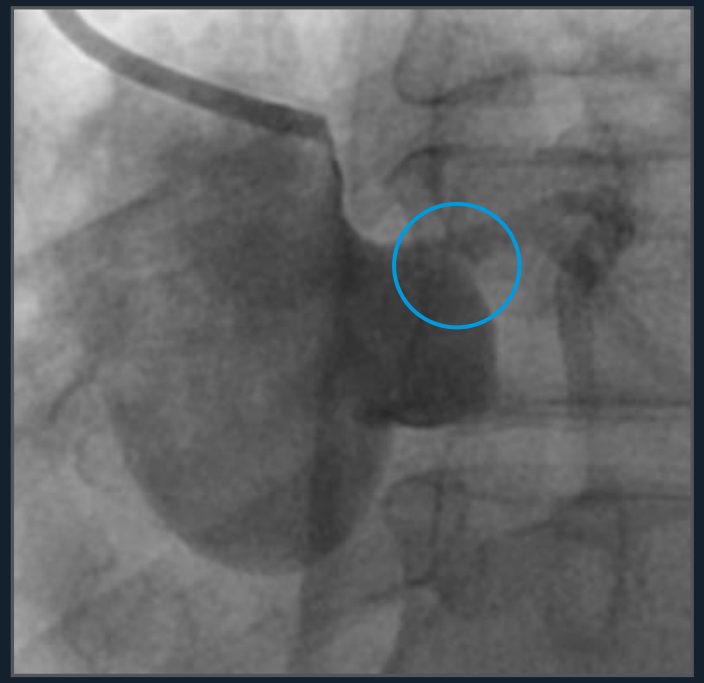


RCA

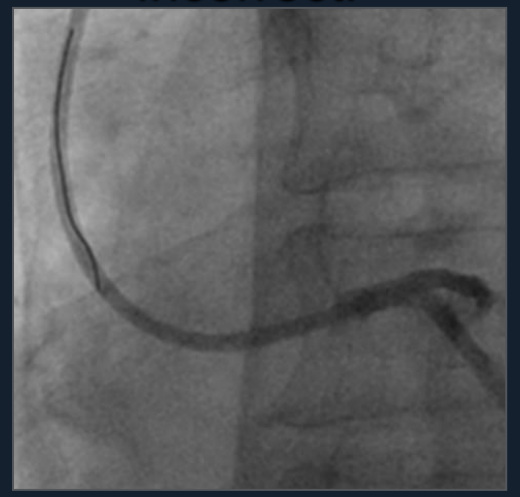
Images used with per[illegible] Hospital Clínico San Carlos

Catheter Position

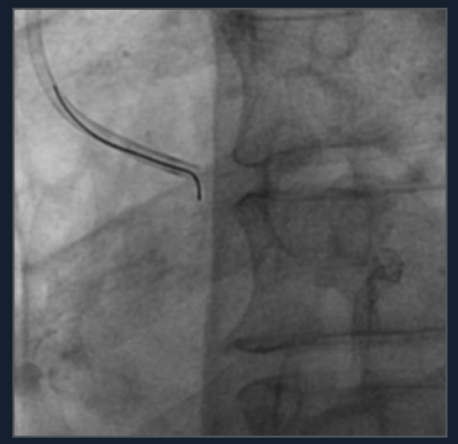
Is there a hemodynamically significant ostial stenosis?



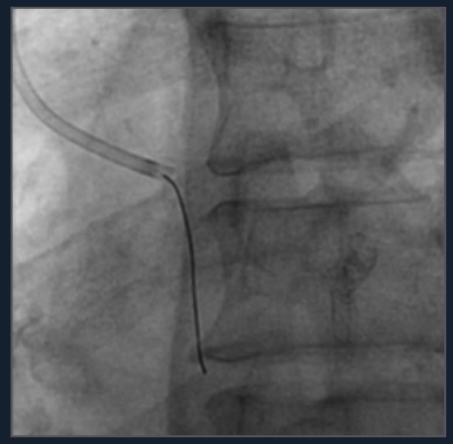
Incorrect!



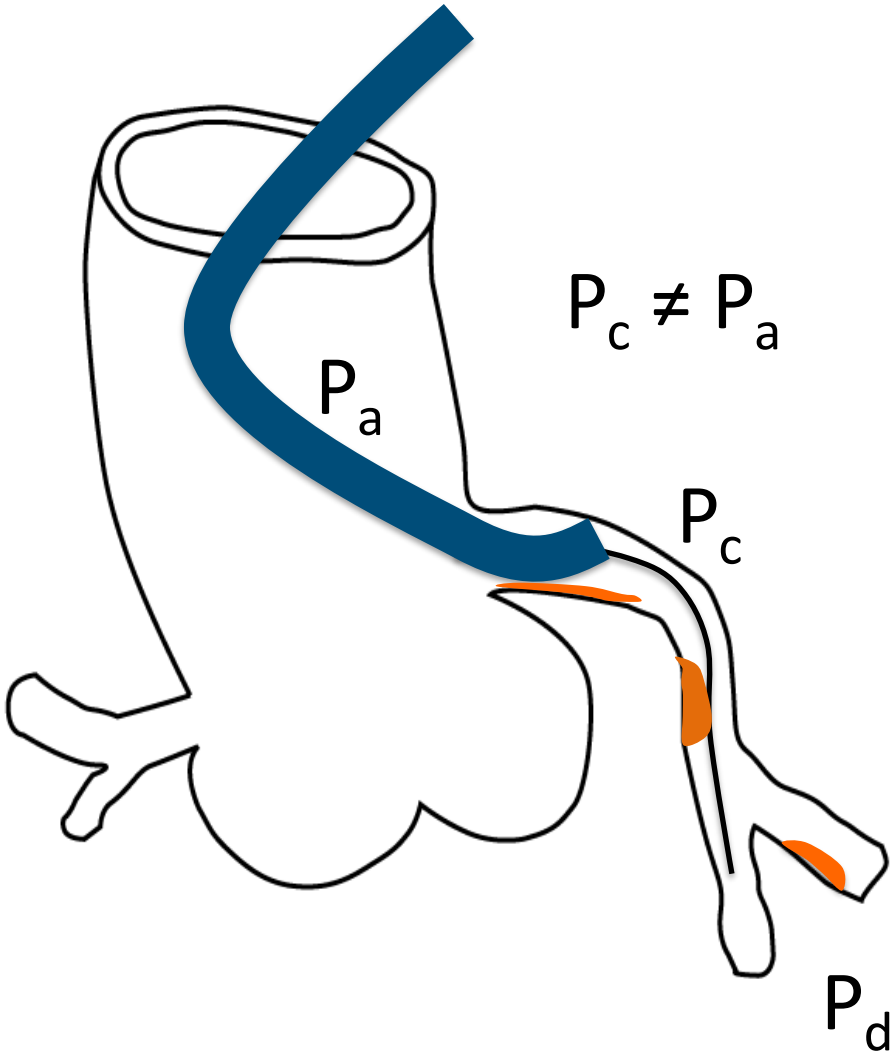
Correct



Correct



Dampened pressure - Wedging of guiding catheter



$P_c \neq P_a$

$$\frac{P_d}{P_a}$$

↑iFR/FFR

Stenosis severity:
Underestimated

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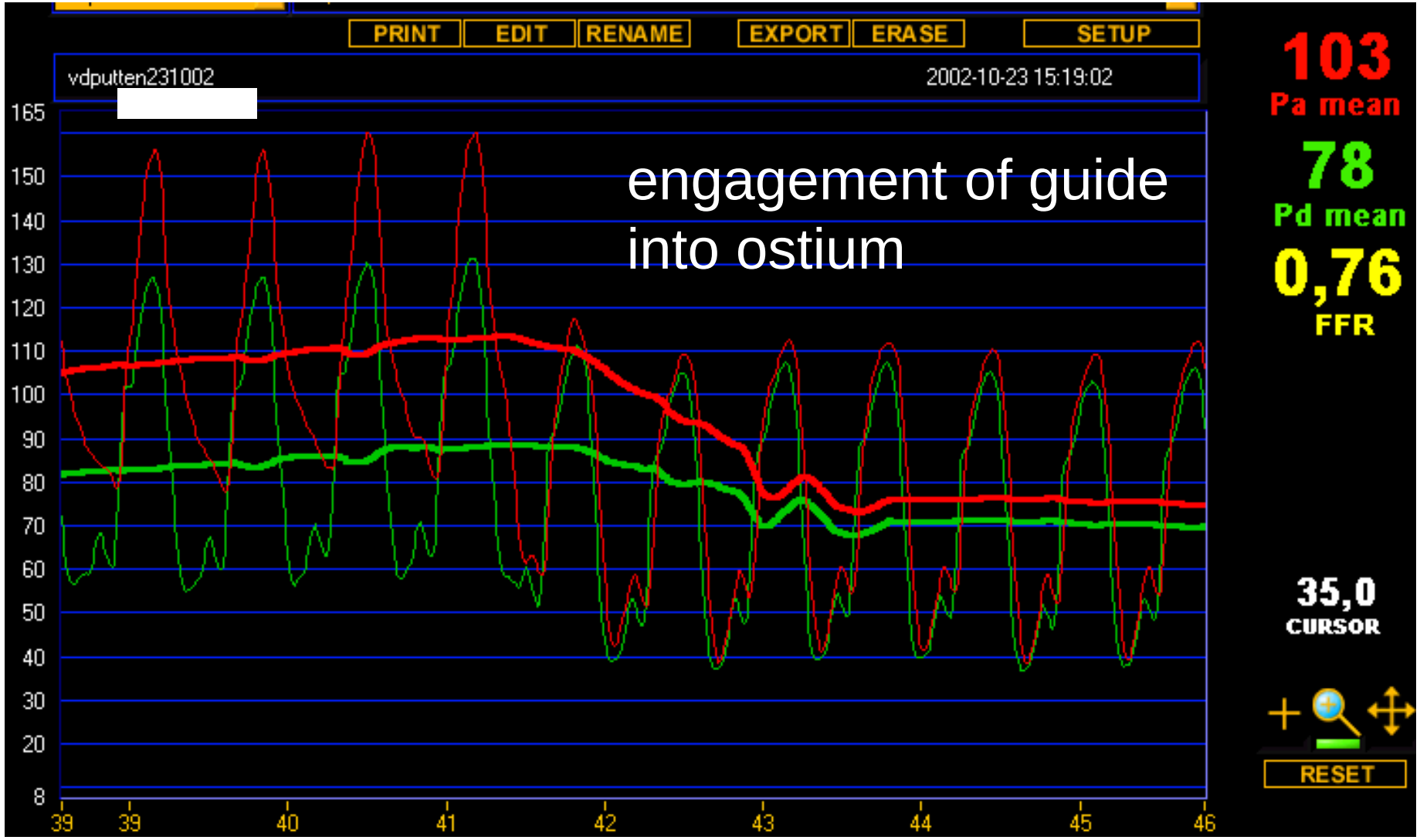
Watch Out For: “Wedging the Guide



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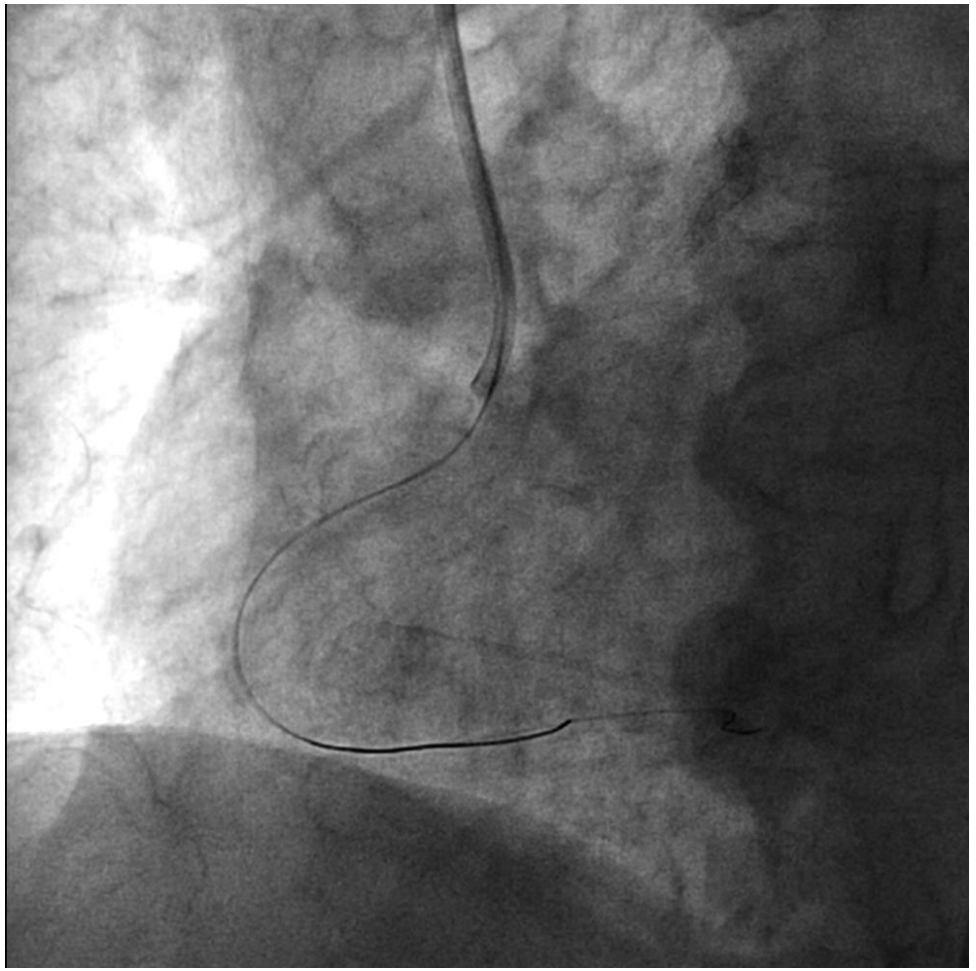
P. Tonino, TCT 2010

Physiological assessment

LAD

LCX

RCA



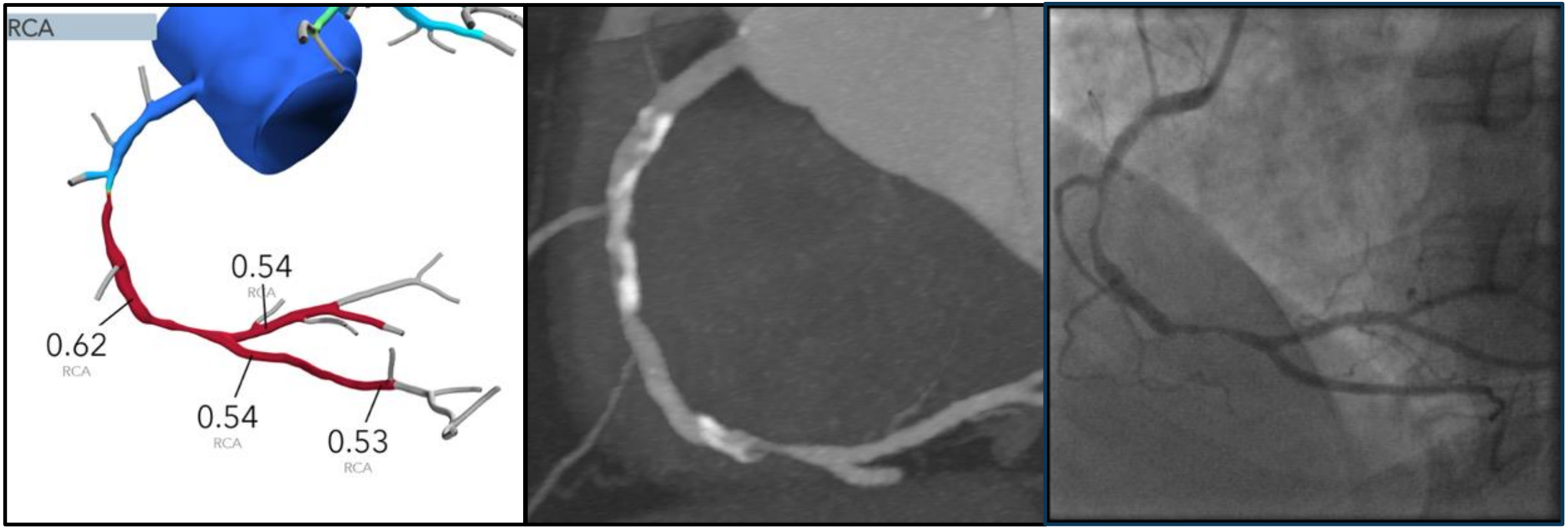
iFR 0.63

Images used with permission from Hospital Clinico San Carlos

Multiple Lesions

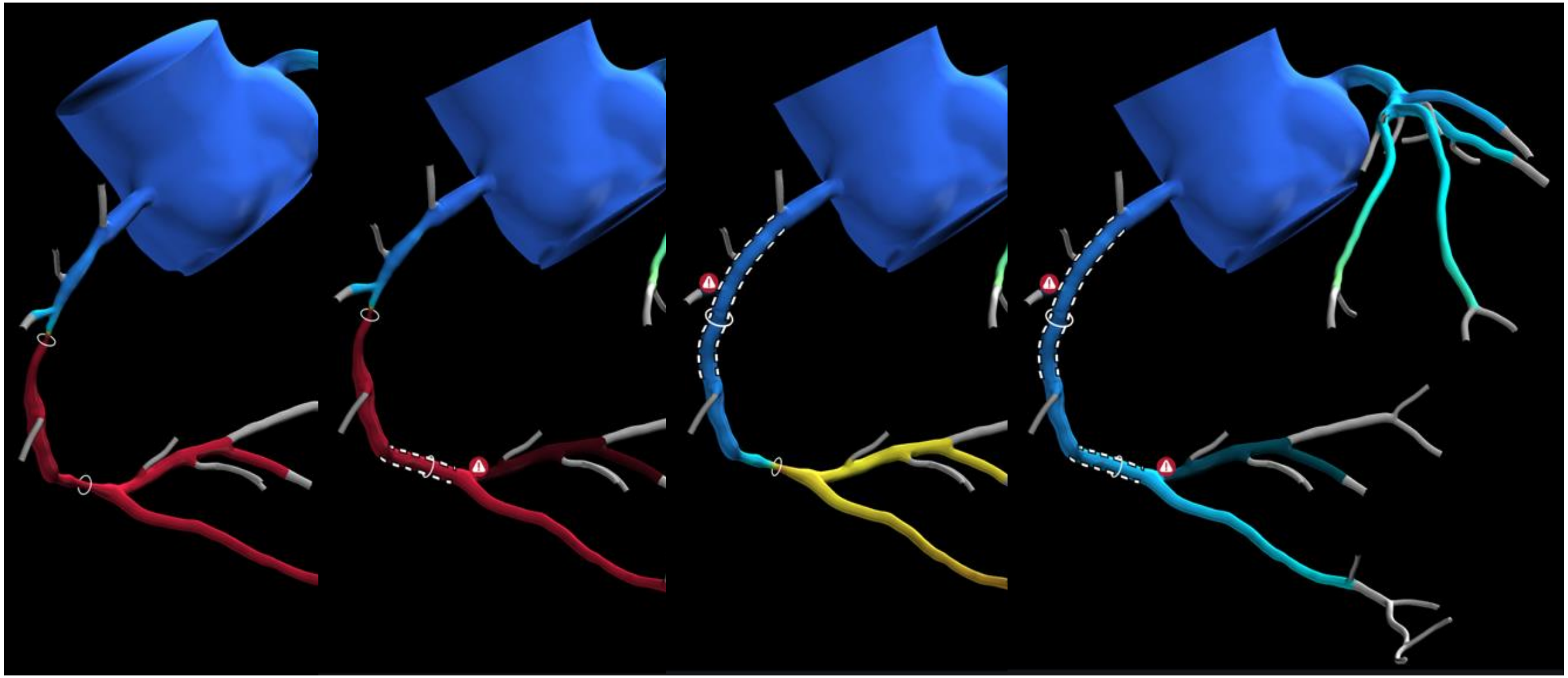
1. FFR/iFR considers contribution of multiple lesions in series
2. Some tandem lesions require all lesions to be revascularized while others require just one.
3. FFR/iFR pullback allows for assessment of tandem lesions with coregistration to pinpoint areas of most resistance.
4. Cathworks and Heartflow PCI planner also give this data.

Case Example: Tandem RCA

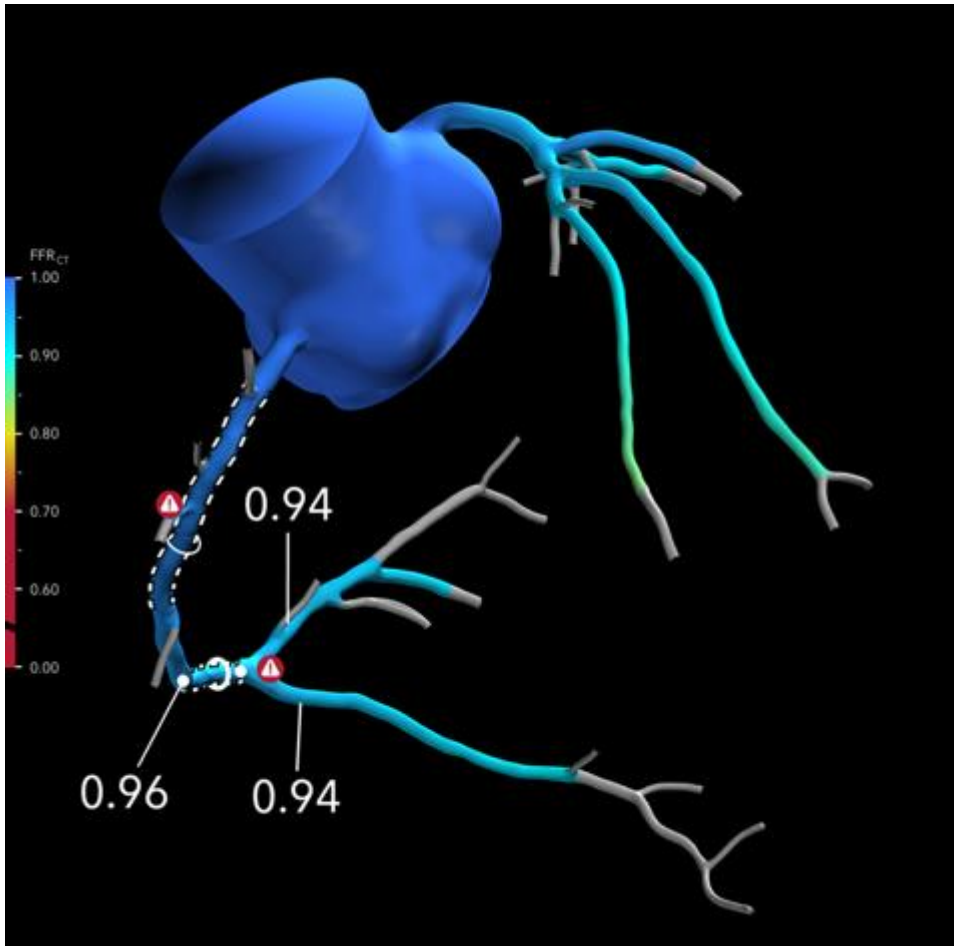


- CT Data: 20mm MIP, Calcium Window

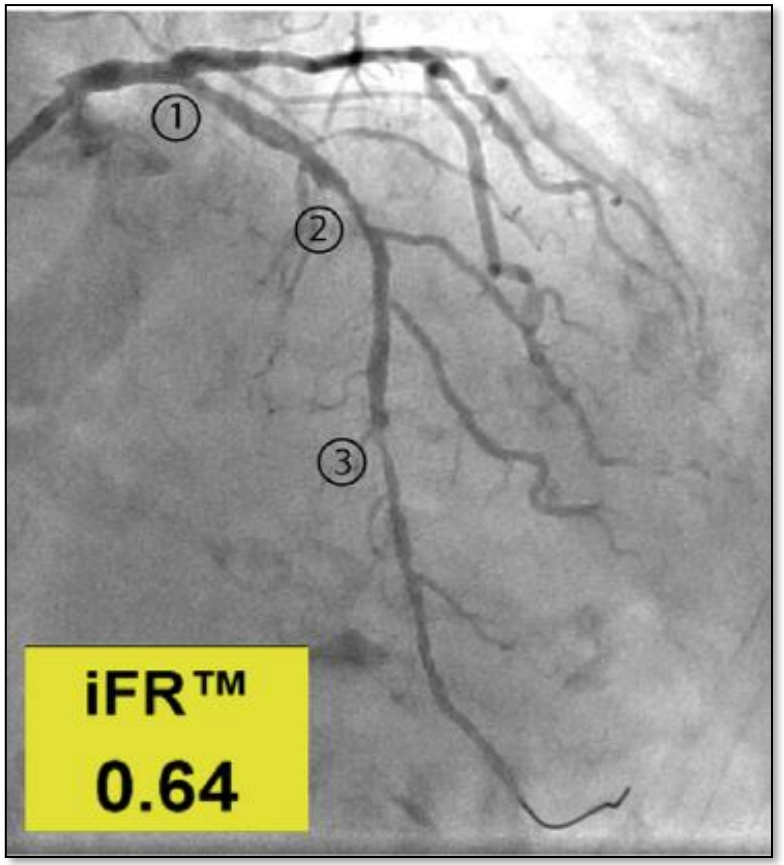
Potential value of Planner in pre-planning PCI



Tandem RCA Post PCI



FFR pullback



FFR can be used to make pullback measurements, but is seldom used. Why?

- ✓ Requires IV hyperemia
- ✓ Can be difficult to interpret
- ✓ Requires an additional FFR pullback assessment after treating the first lesion to assess the “updated” severities of the remaining two lesions
- ✓ Requires hyperemia for a final “post” FFR assessment to document success

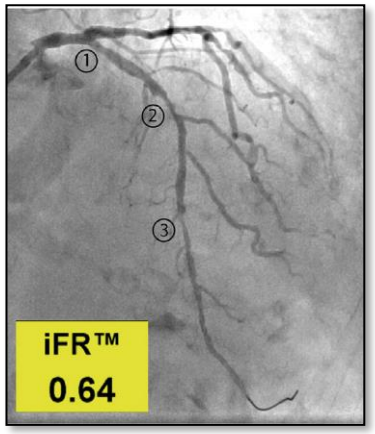
Kim, H-L, et al. “Clinical & Physiological Outcomes of Fractional Flow Reserve-guided Percutaneous Coronary Intervention in Patients With Serial Stenoses Within Once Coronary Artery. JACC:Cardiovasular Interventions; Vol. 5 (10) 2012, 1013-1018

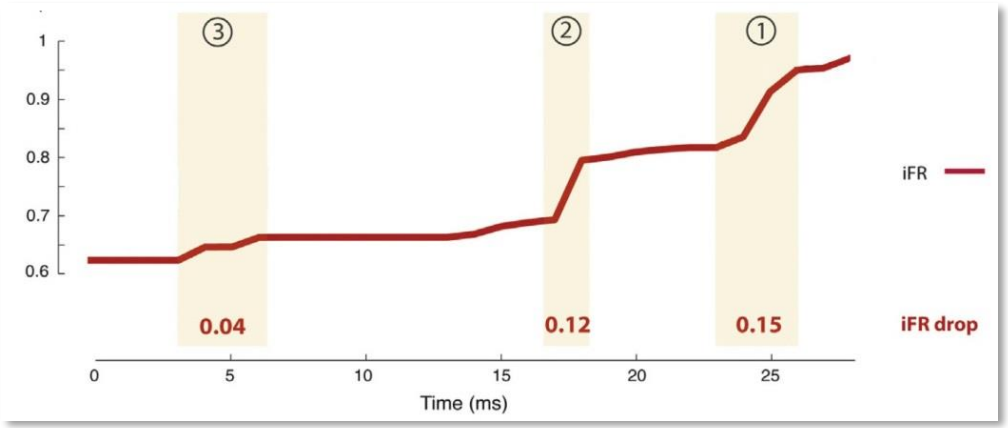
PHILIPS

…to Guidance

iFR pullback assessments map the ischemic contribution of each lesion without the confounding effect observed with FFR pullback assessments, providing **guidance** in the determination of a treatment plan

- Faster without IV hyperemic agents (pre- or post- PCI)
- Easier without interim reassessments as each lesion is treated





Adapted from Nijjer S, et al. "Pre-Angioplasty Instantaneous Wave-Free Ratio (iFR) Pullback Provides Virtual Intervention and Predicts Hemodynamic Outcome for Serial Lesions and Diffuse Coronary Artery Disease. JACC: Cardiovascular Interventions 2014; 12: 1386-1396

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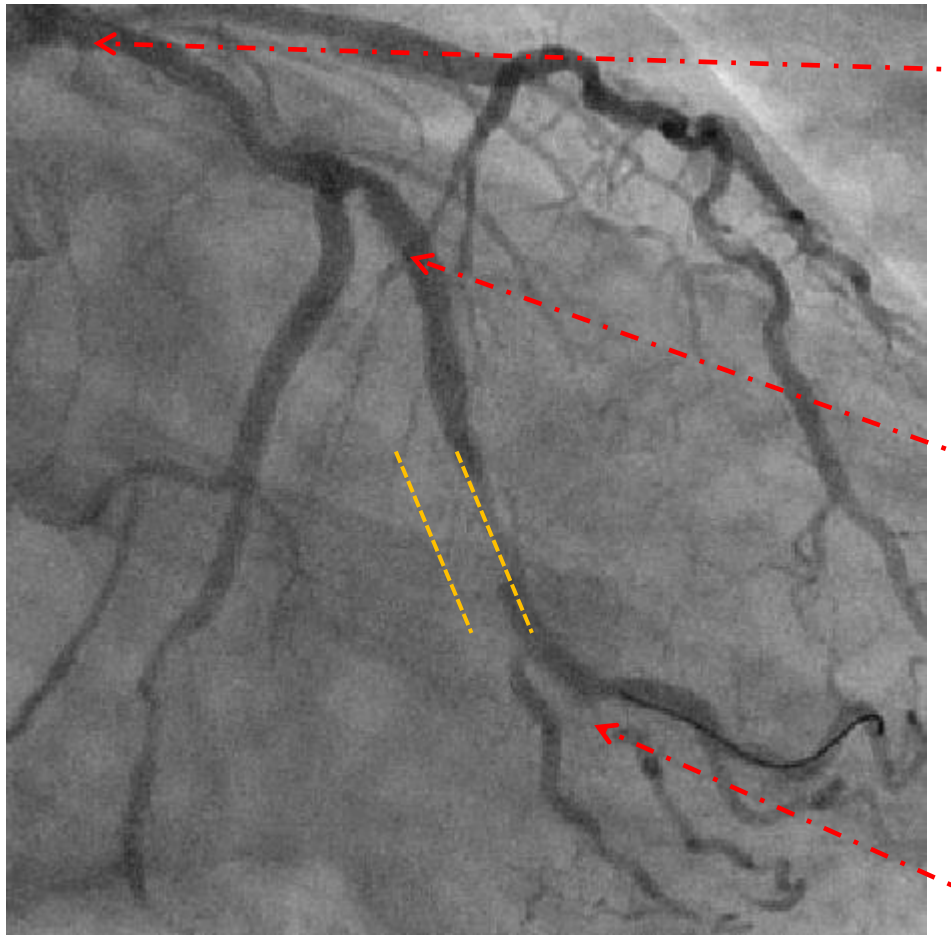
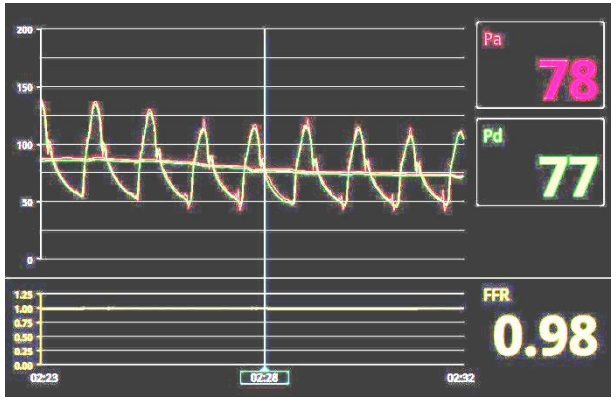
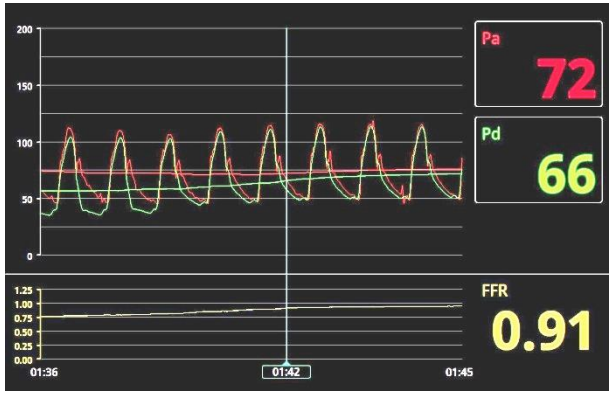
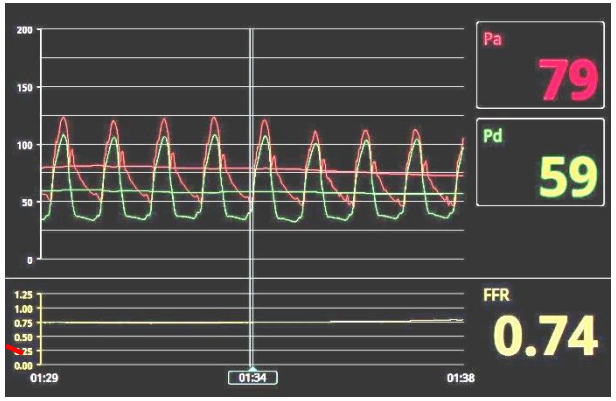
Serial Stenosis

FFR pull-back before treatment









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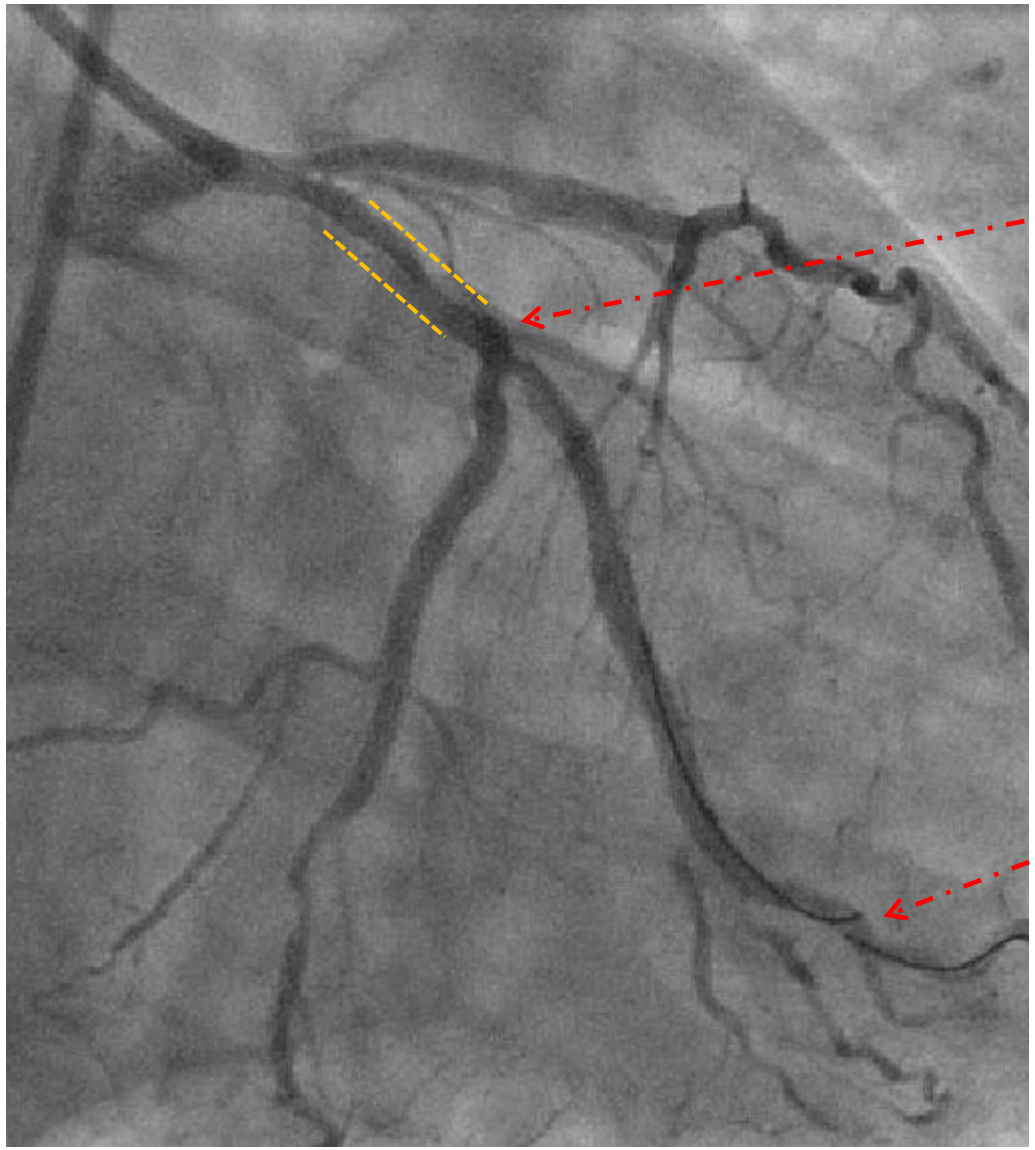
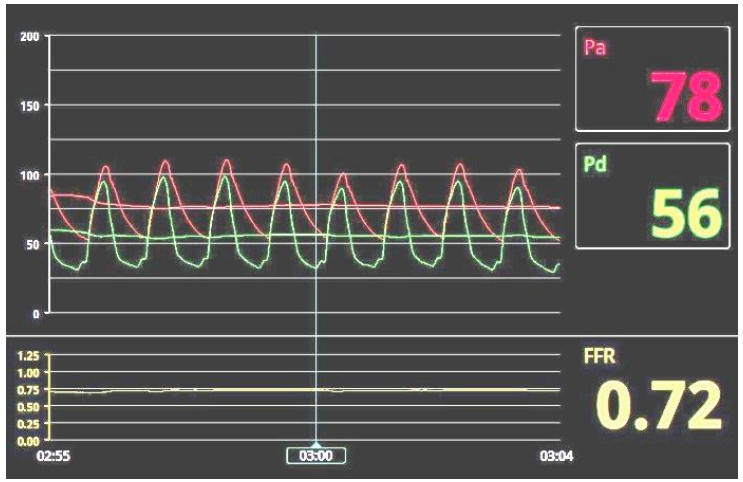
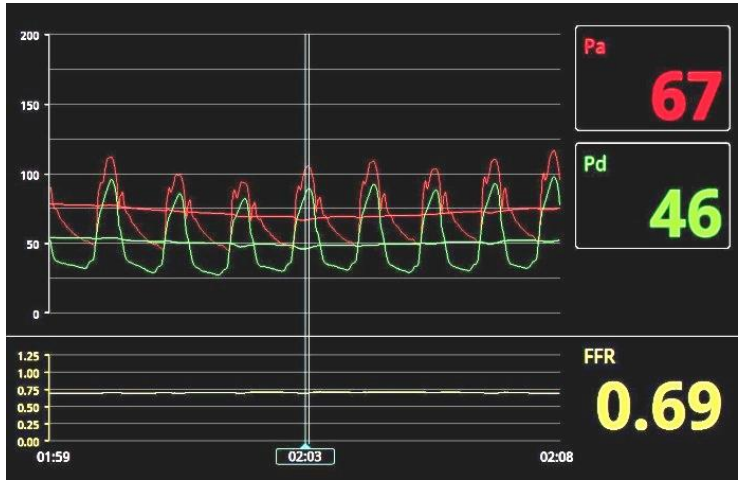
Stent to the Distal Lesion and New FFR assessment







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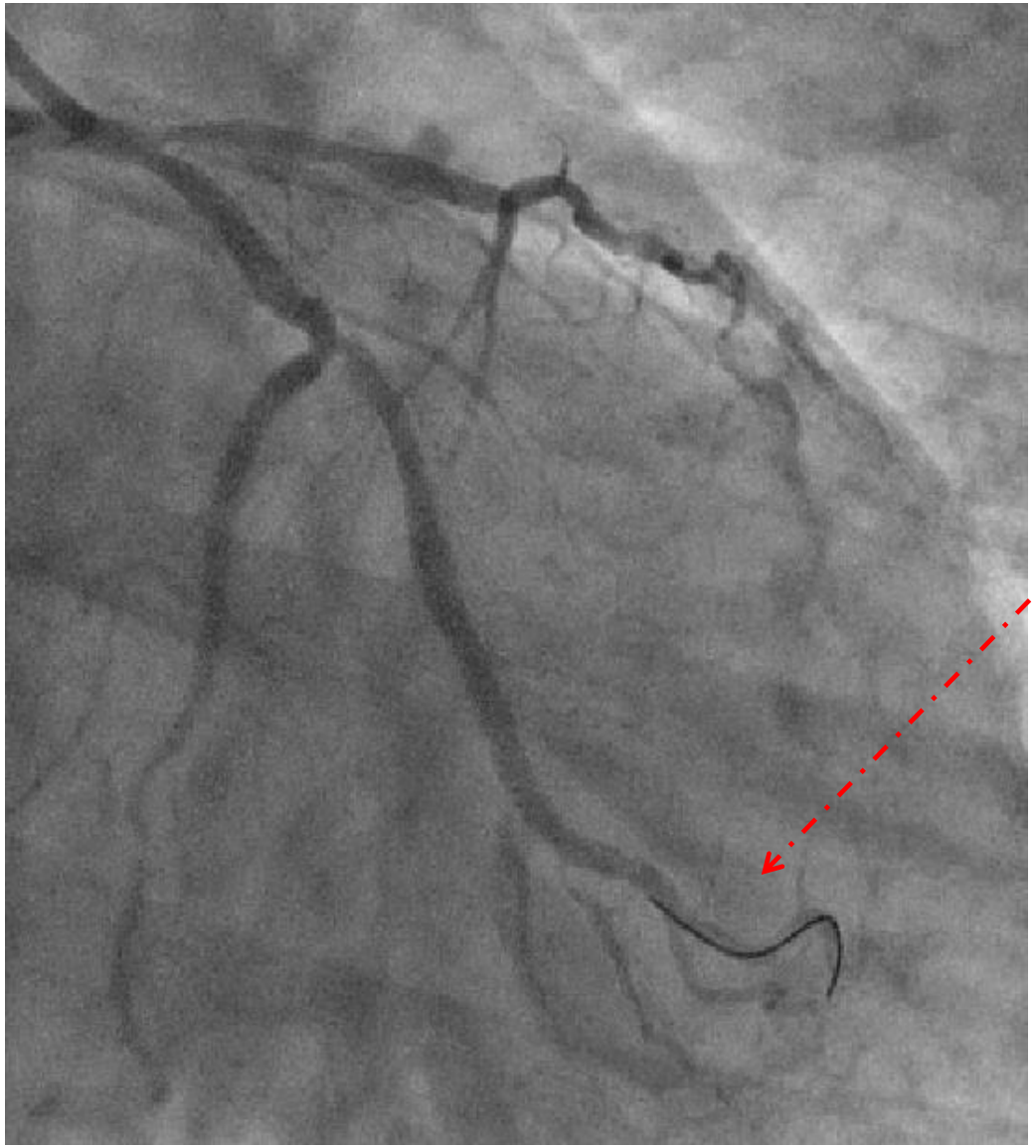
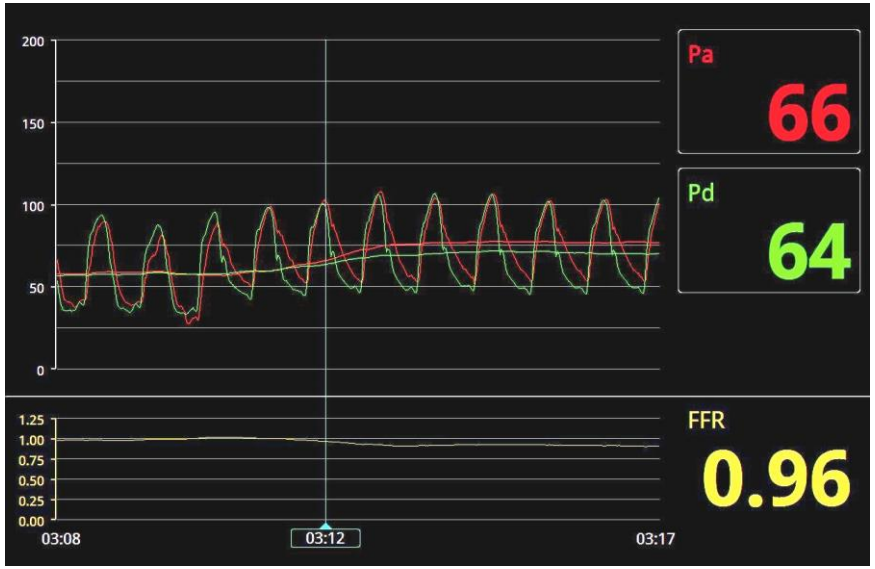
Distal FFR after OCT-Optimized Stent Deployment to the Proximal and Distal lesion





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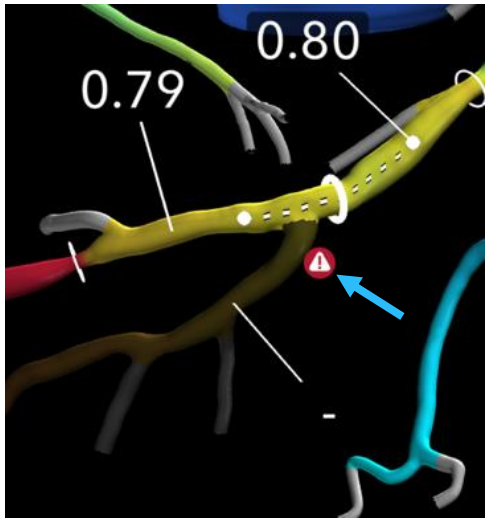
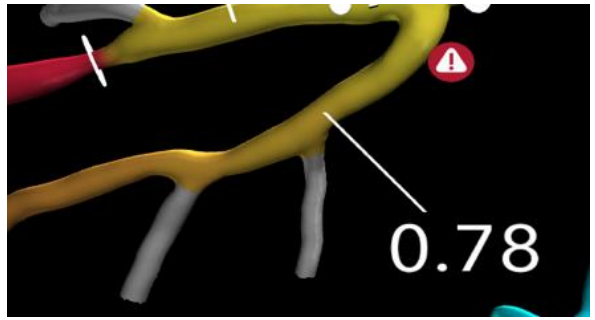
Slides courtesy of Carlo Di Mario: Advances in Coronary Physiology Course 2016

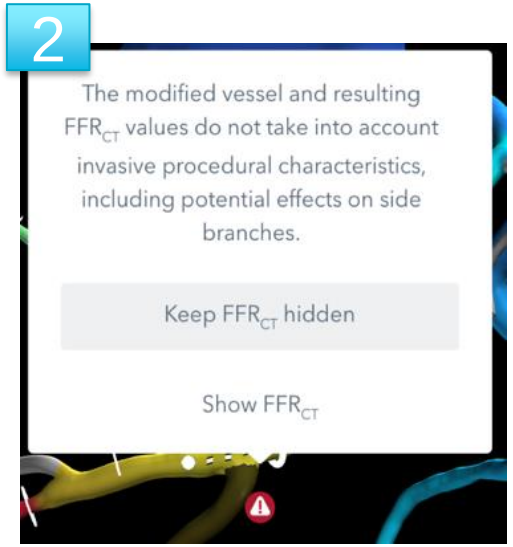
Bifurcation Lesions

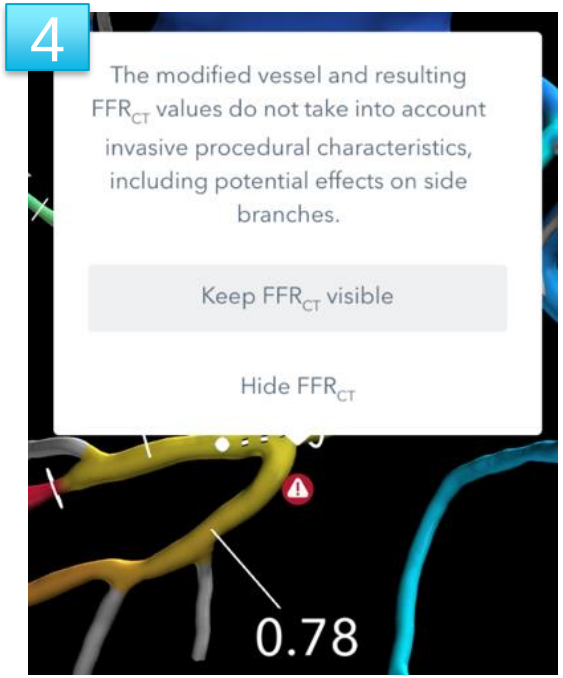
1. Difficult to determine how much of pressure drop in a sidebranch is from proximal lesion in main branch vs just disease in side branch.
2. It is impossible to know how the sidebranch FFR/iFR will be after you jail the sidebranch due to variations in plaque shift and carinal shift.
3. With wire based technology, it is best to determine values in both the side branch and main branch and use common sense.

Bifurcations









When you open a vessel across a bifurcation, the FFR$_{CT}$ values on the branching vessel are hidden by default. -- **the simulation does not simulate procedural effects across bifurcations.**

Tap the bifurcation icon on the branched vessel to expose or hide the FFR$_{CT}$.

What about ACS?

Deferral of PCI in Moderate Stenoses in ACS (NSTEMI and UA) pts vs SIHD

- Monocentric retrospective analysis
- FFR cut-off = 0.75
- Culprit stenoses
- Stenoses severity ≈ 50% DS
- Deferral in ACS vs SIHD

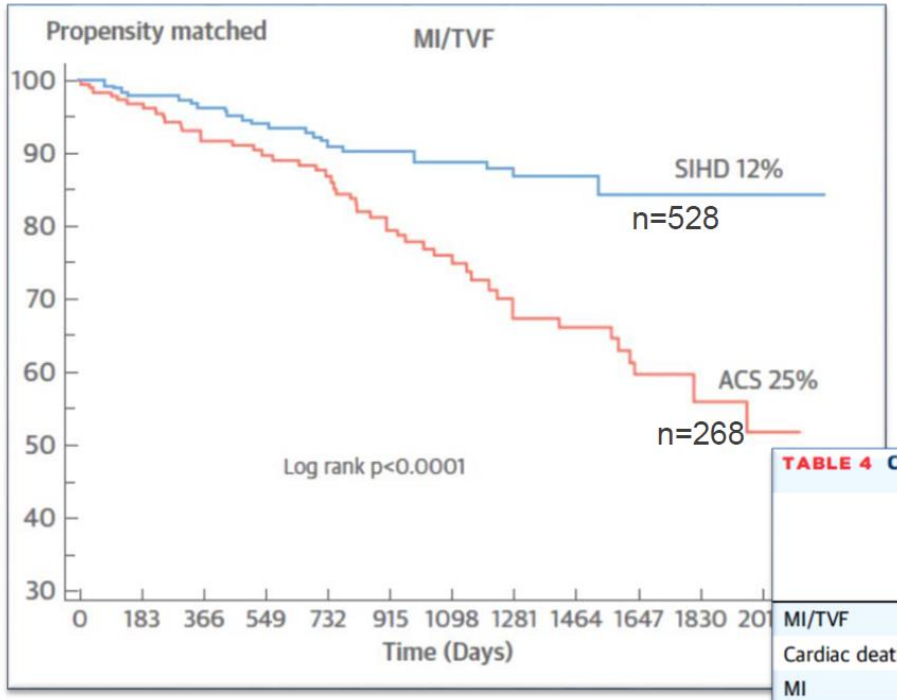


TABLE 4 Cumulative Events at Follow-Up

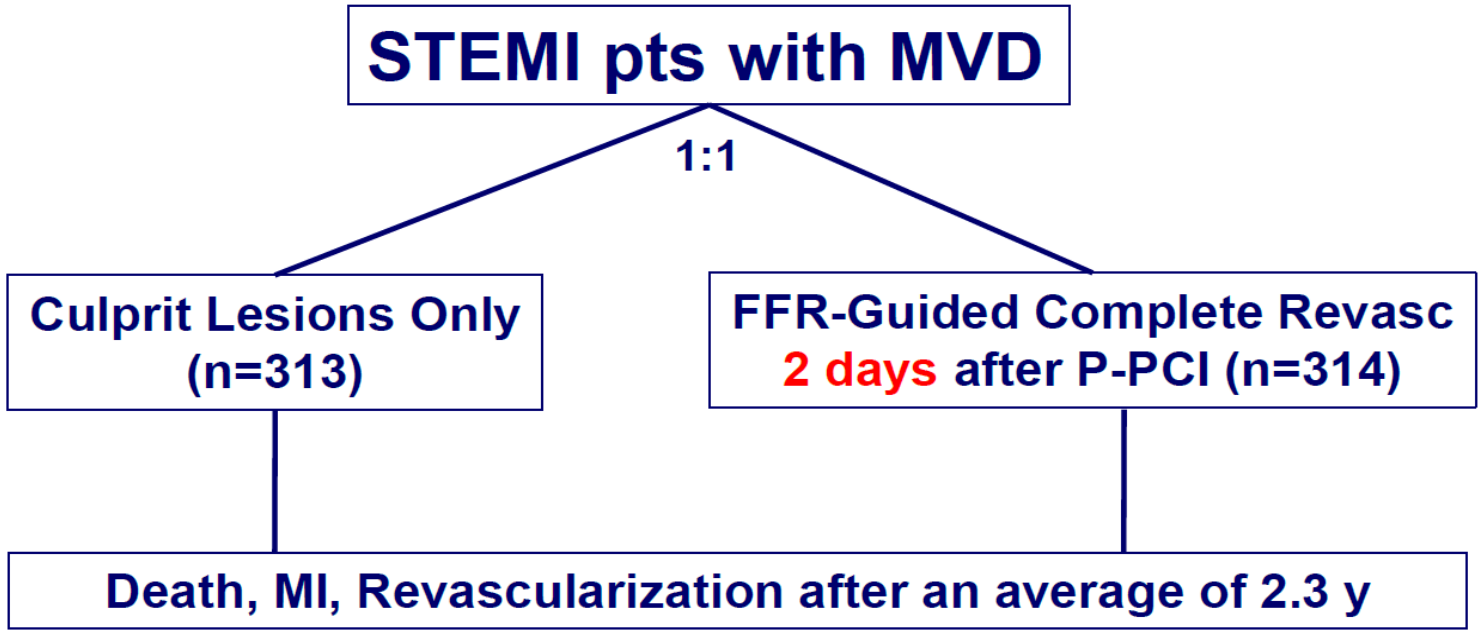
	Entire Cohort			Matched Cohort		
	SIHD (n = 370)	ACS (n = 206)	p Value	SIHD (n = 200)	ACS (n = 200)	p Value
MI/TVF	40 (11.0)	50 (24.0)	<0.001	24 (12.0)	50 (25.0)	<0.001
Cardiac death	30 (8.0)	9 (4.4)	0.1	12 (6.0)	9 (4.5)	0.5
MI	11 (3.0)	16 (7.8)	0.009	7 (3.5)	16 (8.0)	0.05
TLR	29 (7.8)	36 (17.5)	0.004	19 (9.5)	36 (18.0)	0.01
TVR	14 (4.0)	15 (7.3)	0.08	8 (4.0)	15 (7.5)	0.1

A Hakeem et al JACC 2016

DANAMI-3-PRIMULTI

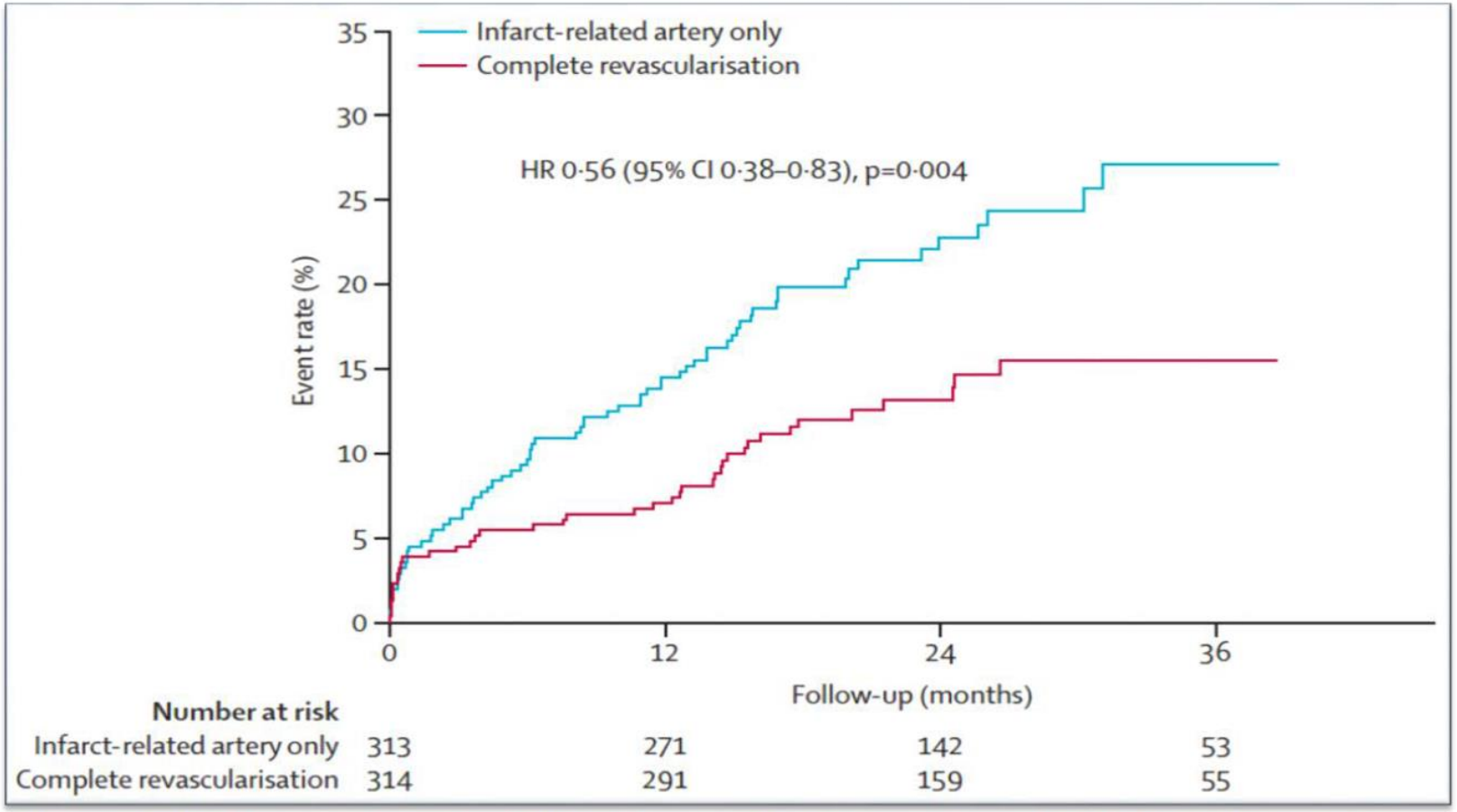
Complete revascularisation versus treatment of the culprit lesion only in patients with ST-segment elevation myocardial infarction and multivessel disease (DANAMI-3—PRIMULTI): an open-label, randomised controlled trial

*Thomas Engstrøm, Henning Kelbæk, Steffen Helqvist, Dan Eik Høfsten, Lene Kløvgaard, Lene Holmvang, Erik Jørgensen, Frants Pedersen, Kari Saunamäki, Peter Clemmensen, Ole De Backer, Jan Ravkilde, Hans-Henrik Tilsted, Anton Boel Villadsen, Jens Aarøe, Svend Eggert Jensen, Bent Raungaard, Lars Køber, for the DANAMI-3—PRIMULTI Investigators**



Engstrom T. et al Lancet 2015

DANAMI-3-PRIMULTI



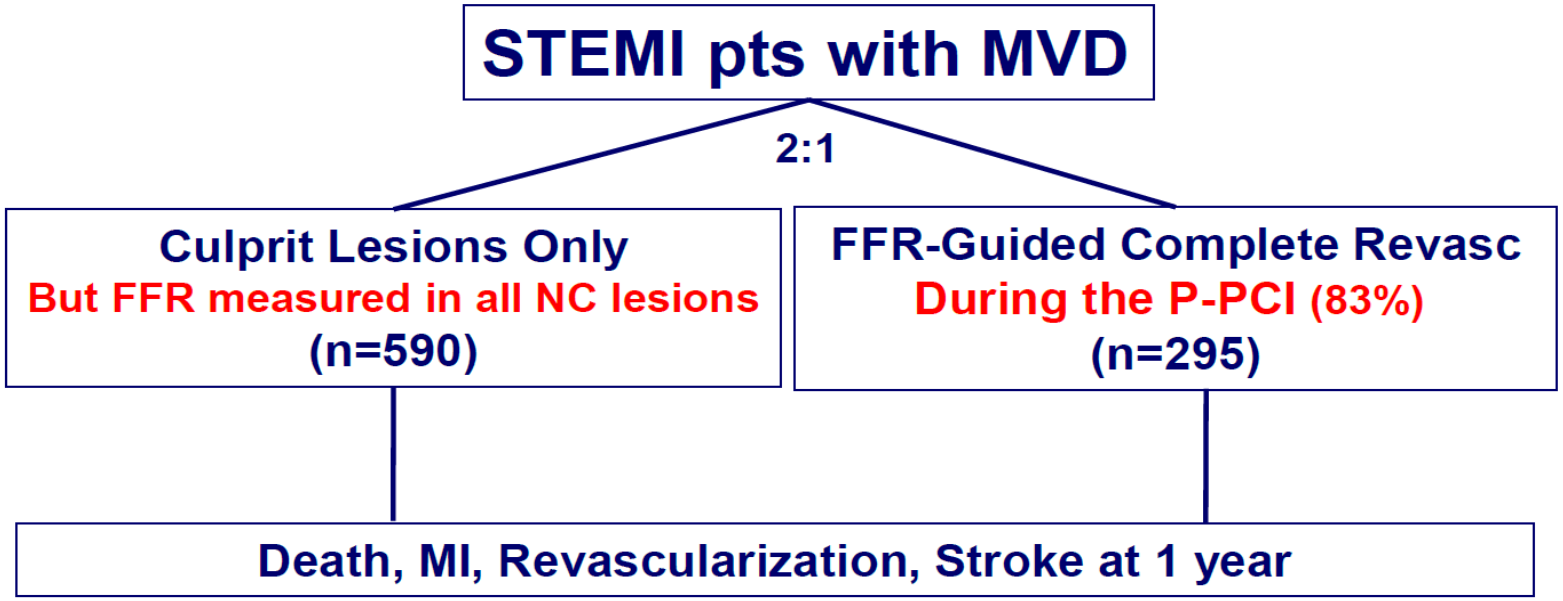
Primary endpoint*	68 (22%)	40 (13%)	0·56 (0·38–0·83)	0·004
All-cause mortality	11 (4%)	15 (5%)	1·40 (0·63–3·00)	0·43
Non-fatal reinfarction	16 (5%)	15 (5%)	0·94 (0·47–1·90)	0·87
Ischaemia-driven revascularisation	52 (17%)	17 (5%)	0·31 (0·18–0·53)	<0·0001

Engstrom T. et al Lancet 2015

COMPARE-ACUTE

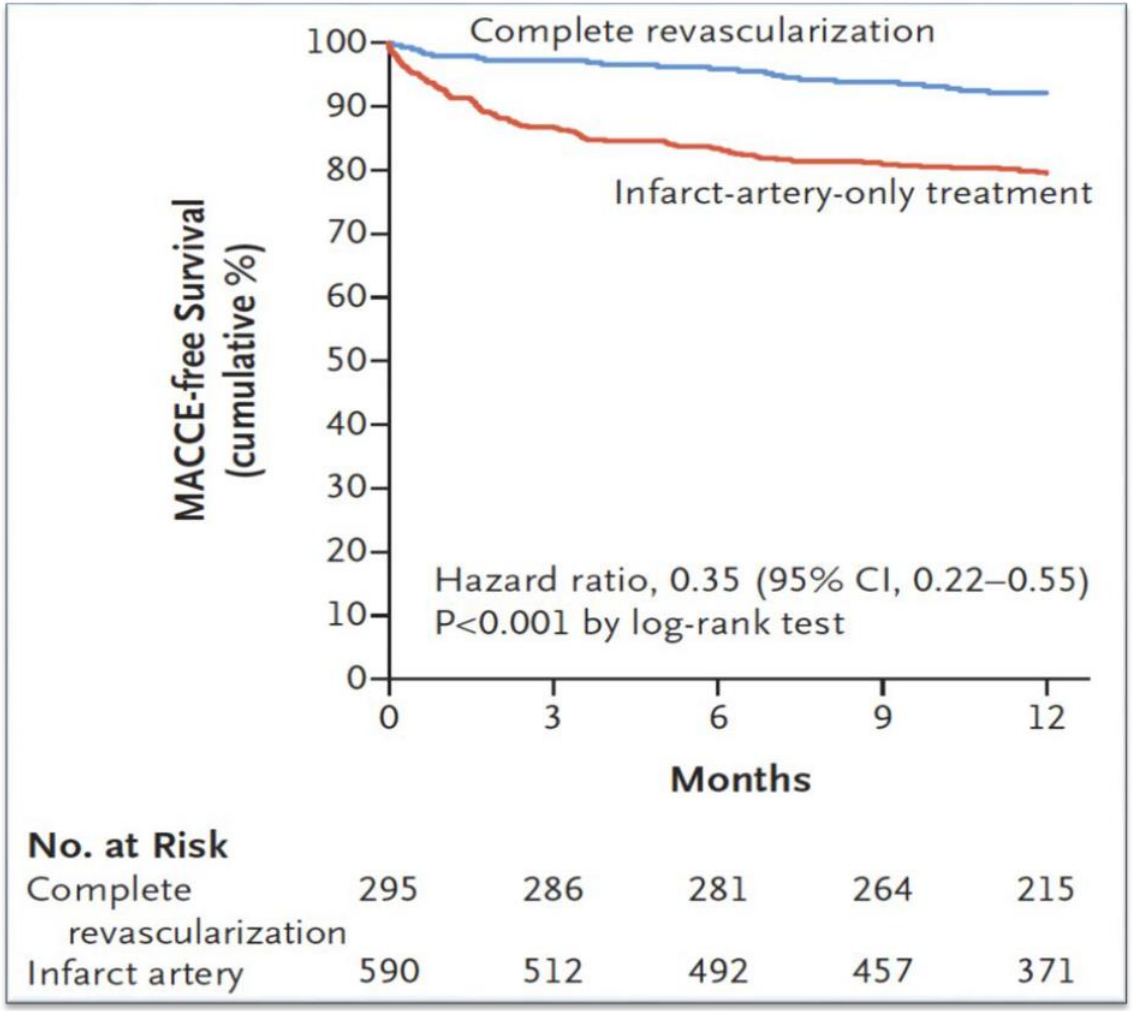
Fractional Flow Reserve–Guided Multivessel Angioplasty in Myocardial Infarction

Pieter C. Smits, M.D., Ph.D., Mohamed Abdel-Wahab, M.D., Franz-Josef Neumann, M.D., Bianca M. Boxma-de Klerk, Ph.D., Ketil Lunde, M.D., Carl E. Schotborgh, M.D., Zsolt Piroth, M.D., David Horak, M.D., Adrian Wlodarczak, M.D., Paul J. Ong, M.D., Rainer Hambrecht, M.D., Oskar Angerås, M.D., Gert Richardt, M.D., Ph.D., and Elmir Omerovic, M.D., for the Compare-Acute Investigators*



Smits P. et al New Engl J Med 2017

COMPARE-ACUTE



Smits P. et al New Engl J Med 2017

FFR in ACS Patients: Summary

1. In acute STEMI: no FFR in the culprit lesion

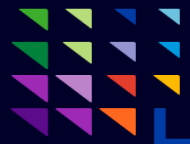
2. In “old” infarction: FFR like in stable patients

3. In the NSTEMI and UA:

   - ✓ high rate of reclassification.
   - ✓ FFR-guided appears safe as (PRIME),
   - ✓ CAVEAT for “clear culprit lesions” (Little Rock)

4. In Non culprit of STEMI and Non-STEMI ACS:

   - ✓ FFR = reliable during the acute phase (CAVE high LVEDP)
   - ✓ Clinically useful: needs confirmation



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Why Modify Calcific Plaque?

- MODIFICATION
  - Change lesion compliance
  - Minimize vessel trauma
  - Create larger MLDs
- ACCESS
  - Enable lesion access
  - Facilitate procedural success

The Truth

- 90% of lesions can be modified equally well by rotational, orbital atherectomy, or intracoronary lithotripsy.

Click to add text

- Thank you very much for the invitation to speak!

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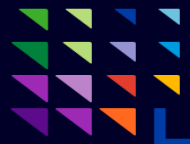

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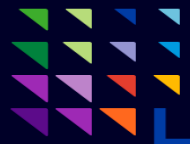

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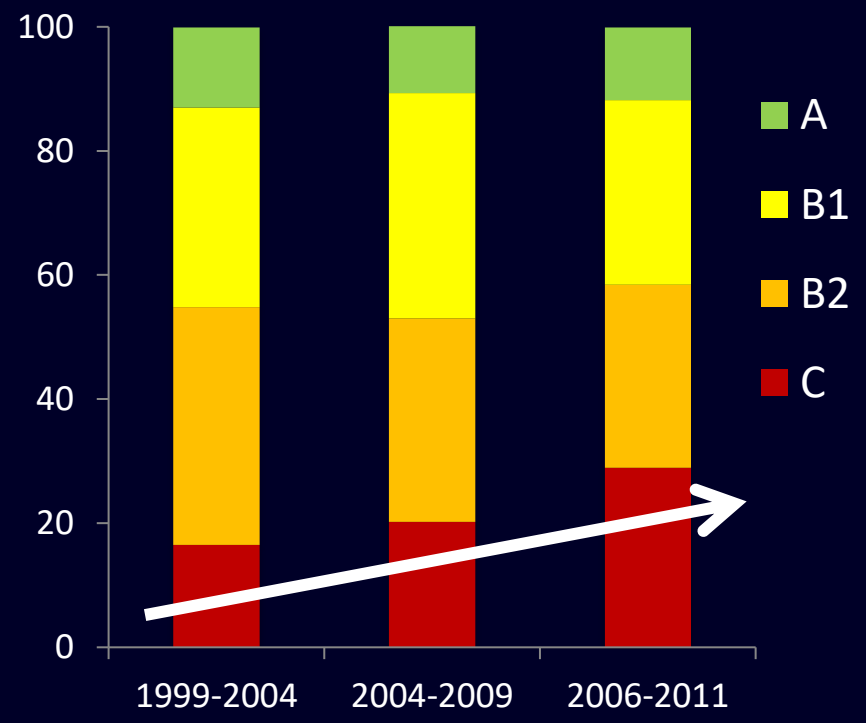
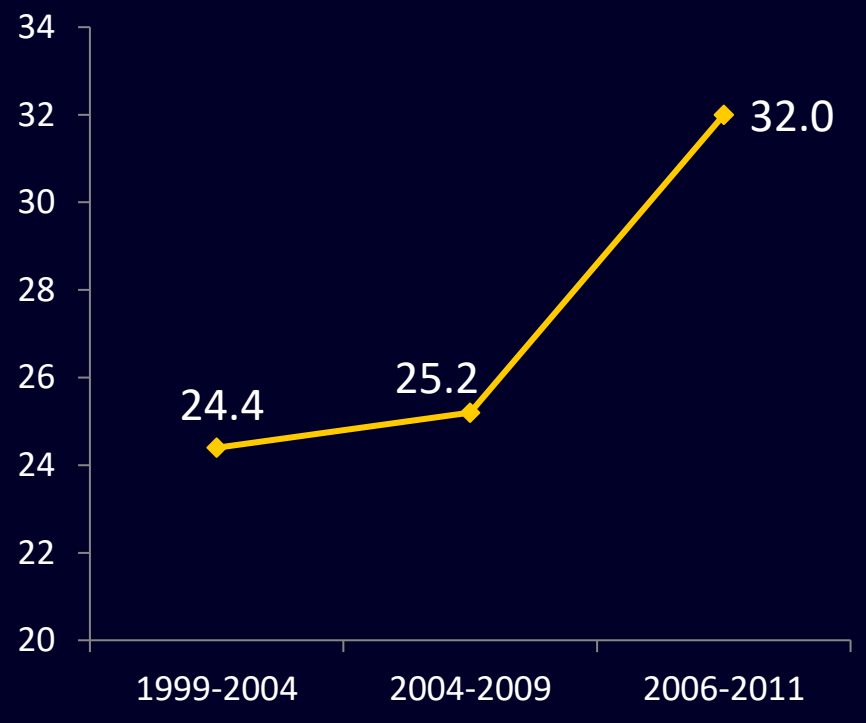
Calcium is Out There!
Increasing Complexity and Calcification of PCI Patients

INCREASING PREVALENCE OF TYPE C LESIONS



ACC/AHA Lesion Classification

INCREASING PREVALENCE OF CALCIFICATION

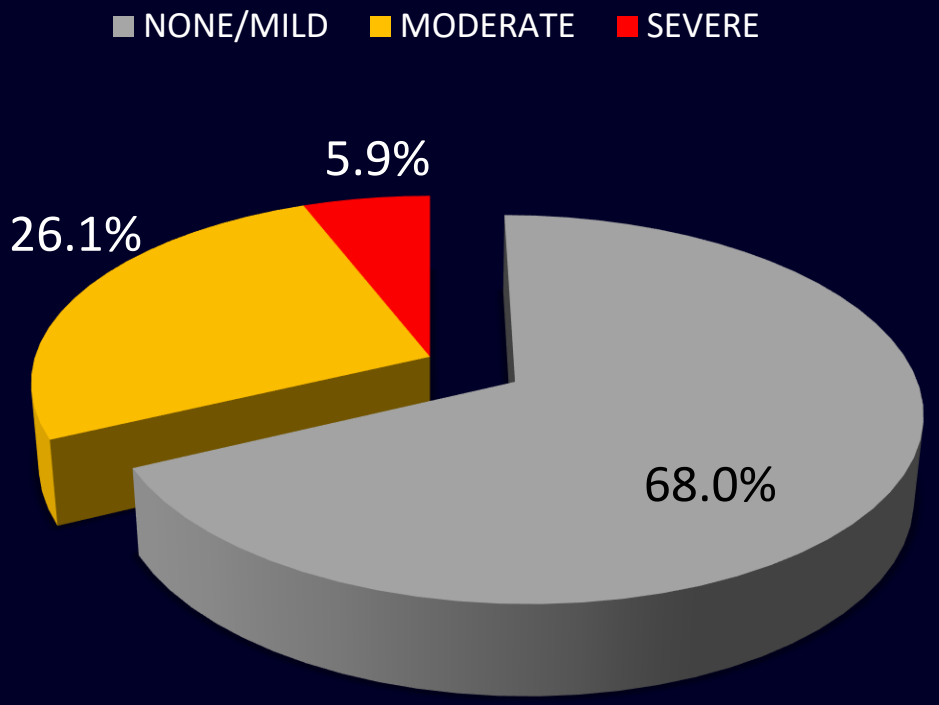


% Of Patients With Calcified Lesions*

*as reported to NHLBI Dynamic Registry.
Bortnick, et. al. Am J Cardiol 2014;113:573-579.

Even inACS Lesions – More Calcified than You'd Think

Presence of Calcium in ACS Patients



6,855 ACS pts pooled from ACUITY and HORIZONS-AMI [1]

[1]Généreux P, et. al. J Am Coll Cardiol 2014;63:1845–54. [2]Waters, et al. JACC 2014;63:1855-1856.

Complications due to Calcification

PRE-PCI

- Dissection during balloon angioplasty or pre-dilatation[1]
- Difficulty with complete dilation[2]

PERI-PCI

- Inhibition of adequate stent expansion[3]
- Prevention of stent delivery to the desired location[4]
- Stent malapposition[5]

POST-PCI

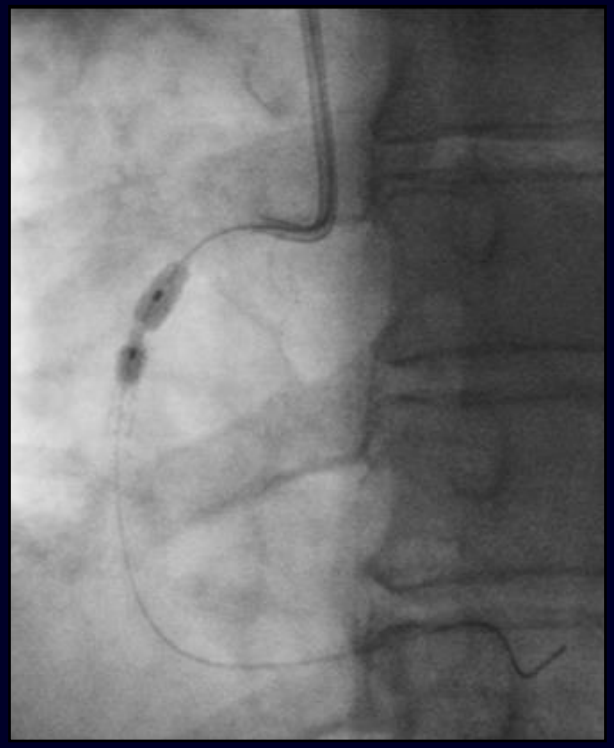
- Insufficient drug penetration and subsequent restenosis[6]

1 Fitzgerald PJ, et al.. Circulation. 1992:86;64-70. Kahn J, et al. Cathet Cardiovasc Diagn. 1990;21:89-91. 2 Cavusoglu E, et al. Cathet Cardivasc Intervent. 2004;62:485-498. 3 Moussa I, et al. Circulation. 1997;96(1):128-136. 4 Gilutz H, et al. Cathet Cardiovasc Intervent. 2000;50:212-214. 5 Mosseri M, et al. Cardiovasc Revasc Med. 2005;6:147-53. 6 Nakano M, et al. Eur Heart J. 2013 Jul 3.

Clinical Application

Case Example – “Atherectomy Regret”

Single 2.75 mm stent placed



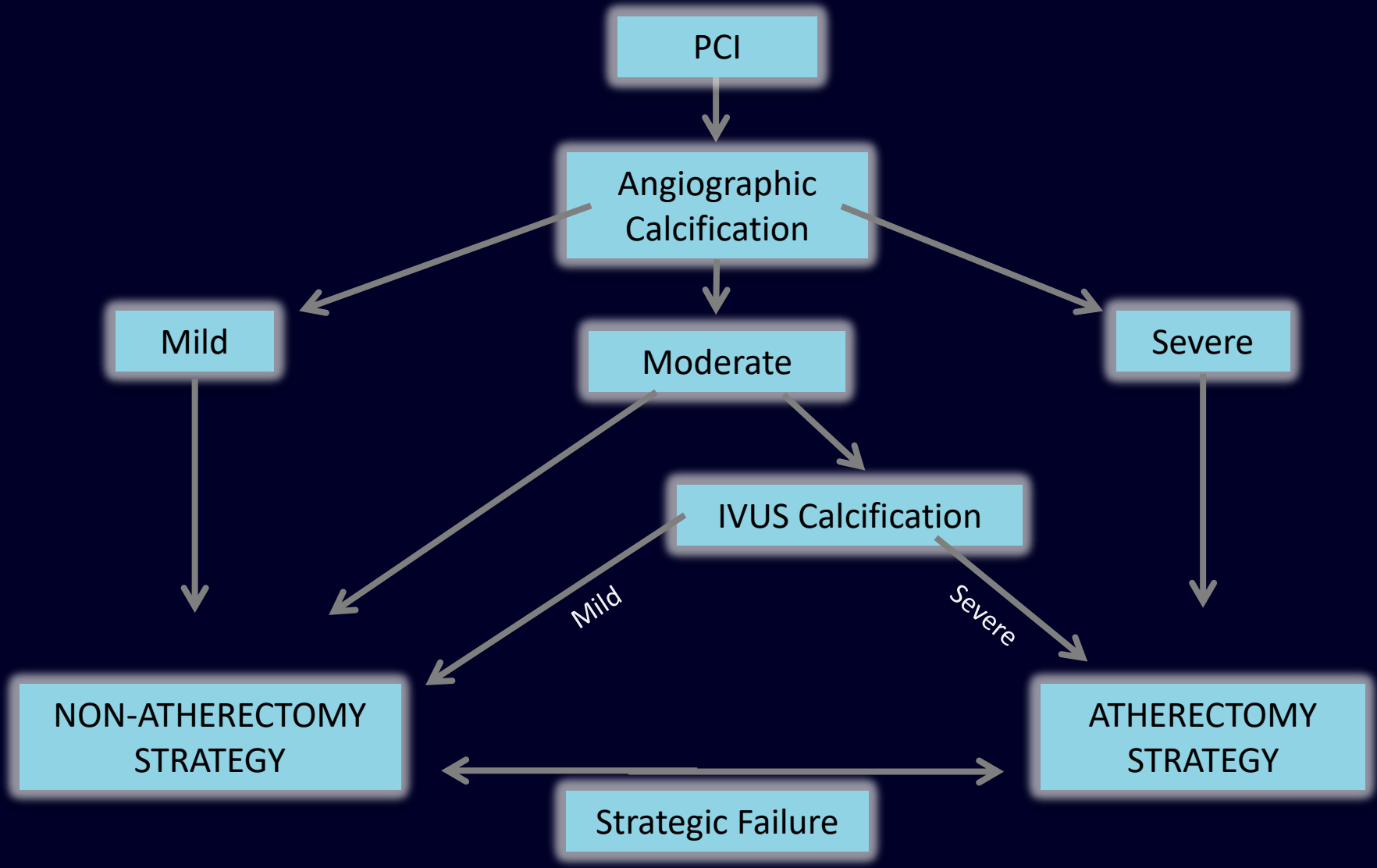
Post Dilatation:

- 3.5x9mm NC balloon x 30 sec @ 22 atm
- 4.0x9mm NC balloon x 30 sec @ 16 atm

Results sub-optimal

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

Strategy for Approaching Calcified Lesions



Adapted from Tomey, et. al. Current Status of Rotational Atherectomy. J Am Coll Cardiol Intv. Online ahead of print.

ECLIPSE Trial-Is Atherectomy superior to PTCA?

ECLIPSE

*E*valuation of Treatment Strategies for Severe *C*a*L*cif*I*c Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty *P*rior to Implantation of Drug Eluting *S*t*E*nts

~2000 pts with severely calcified lesions; ~60 US sites

Randomize 1:1

Orbital Atherectomy Strategy	Conventional Angioplasty Strategy
(1.25 mm Crown followed by non-compliant balloon optimization)	(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 (N~400 in imaging study)
2) 1-year TVF (all patients)

2° endpoint: Procedural Success (stent deployed w/RS<20% & no maj complications)

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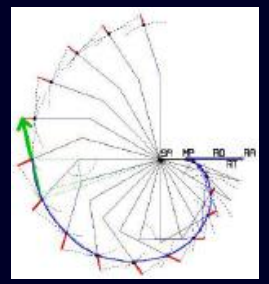
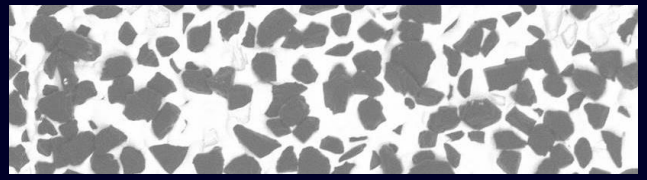
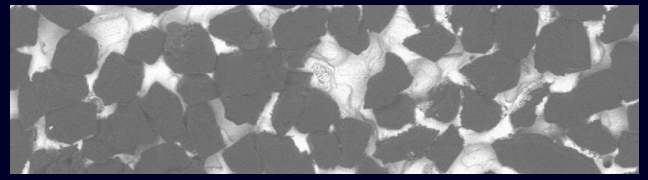
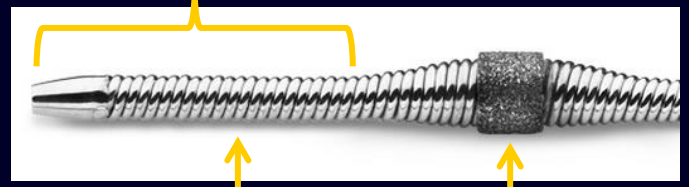
Atherectomy:
Rotational vs Orbital

Rotational vs. Orbital Atherectomy

	Rotablator®	CSI Diamondback
Burr Action	 Burr spins concentrically on wire	 Crown oscillates in orbital path
Lumen Sizing	Lumen size = burr size	Lumen size = f(time, speed, passes)
Grit Size	5 µ exposed diamonds 	10 µ exposed cutting surface 

Data presented by J. Moses at CRF Fellows 2014.

Rotational vs. Orbital Atherectomy

	Rotablator®	CSI Diamondback
Profile		
Cutting Mechanism	Front cutting	Circumferential cutting
Target Lesion Opening	0 - < 1.25 mm	0 - < 1.25 mm
	1.25 mm-1.84 mm	1.25 mm-1.84 mm
	> 1.84 mm	> 1.84 mm

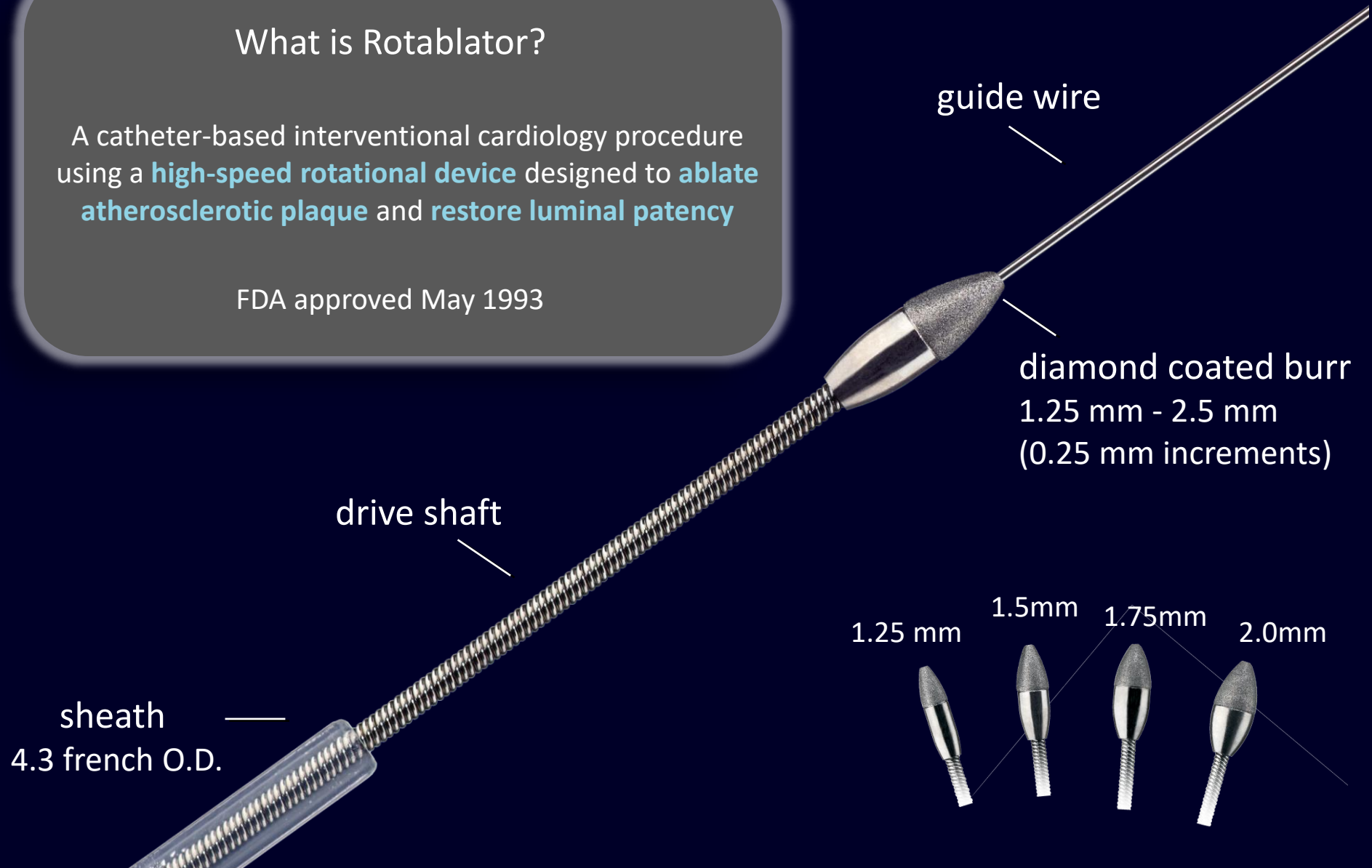
*CSI Classic Crown. Data presented by J. Moses at CRF Fellows 2014. Diamondback 360 Coronary Orbital Atherectomy System IFU.

Rotablator® Rotational Atherectomy System

What is Rotablator?

A catheter-based interventional cardiology procedure using a **high-speed rotational device** designed to **ablate atherosclerotic plaque** and **restore luminal patency**

FDA approved May 1993

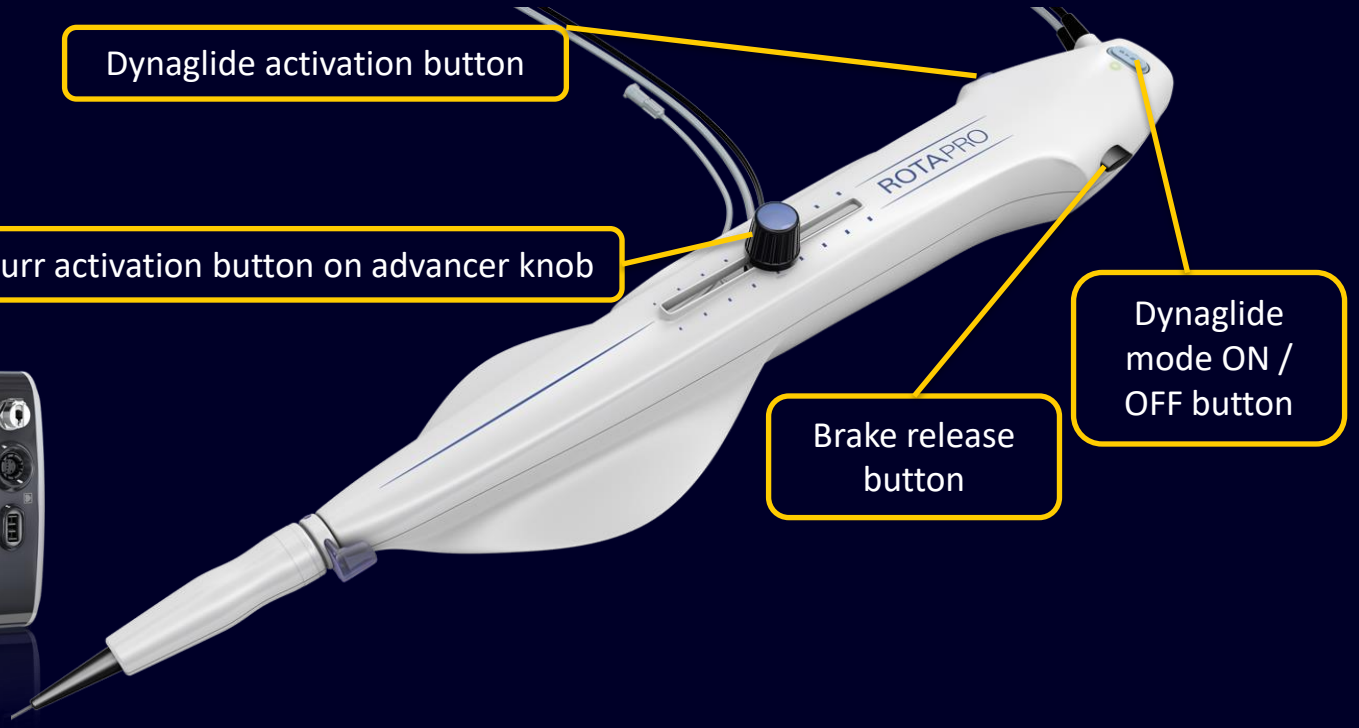


ROTAPRO™ Rotational Atherectomy System

Currently in Development

Design Goals:

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



*ROTAPRO is under development not available for sale

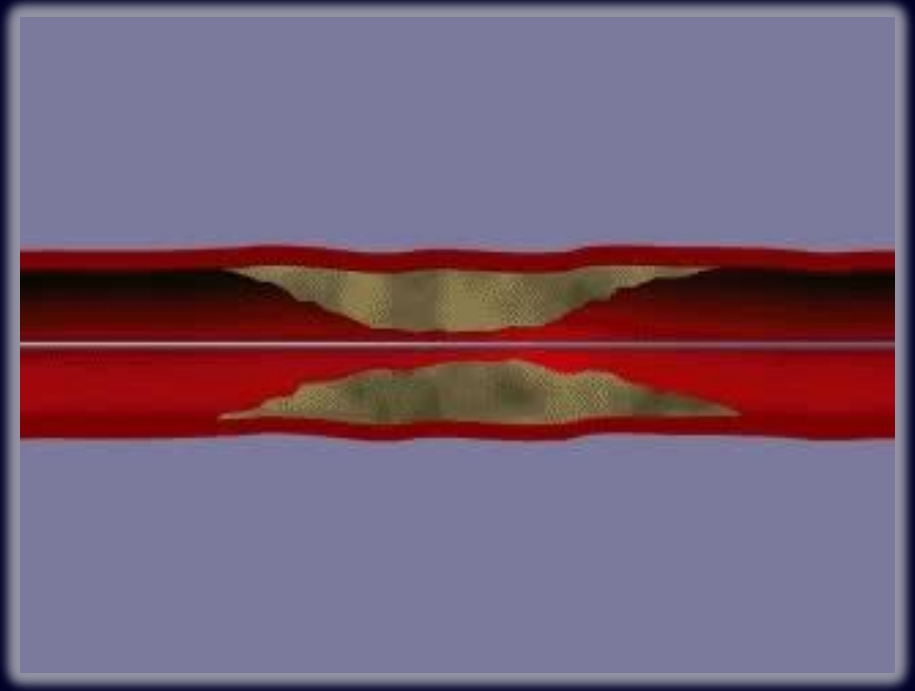
Optimal Technique

TECHNICAL CONSIDERATIONS

- Single burr with burr-to-artery ratio of 0.5 to 0.6
- Rotational speed of 140,000 to 150,000 rpm

OPERATOR TECHNIQUE

- Gradual burr advancement using a pecking motion
- Short ablation runs of 15 – 20 sec
- Avoidance of decelerations > 5,000 rpm
- Final polishing run



Tomey, et al. Current Status of Rotational Atherectomy. 2014. JACC Cardiovasc Int. epub ahead of print.

Advantages

- Great for severely calcified and very tight lesions due 1.25 burr option and drilling mechanism.
- Navigates tortuosity better than orbital athrectomy
- Once you have the “polish run” you know you’re ready to deliver the stent
- Paves pathway for long stents better than orbital atherectomy
- Fellows like it as it is exciting to use.
- Hospital makes money as cheaper than CSI but gets calcium DRG.

Disadvantages

Nitrogen tank – staff hate it

Rotapro system has more burr entrapment

If long lesion- size differential you may need 2 different size burrs

Always need a pacemaker for RCA and dominant LCX

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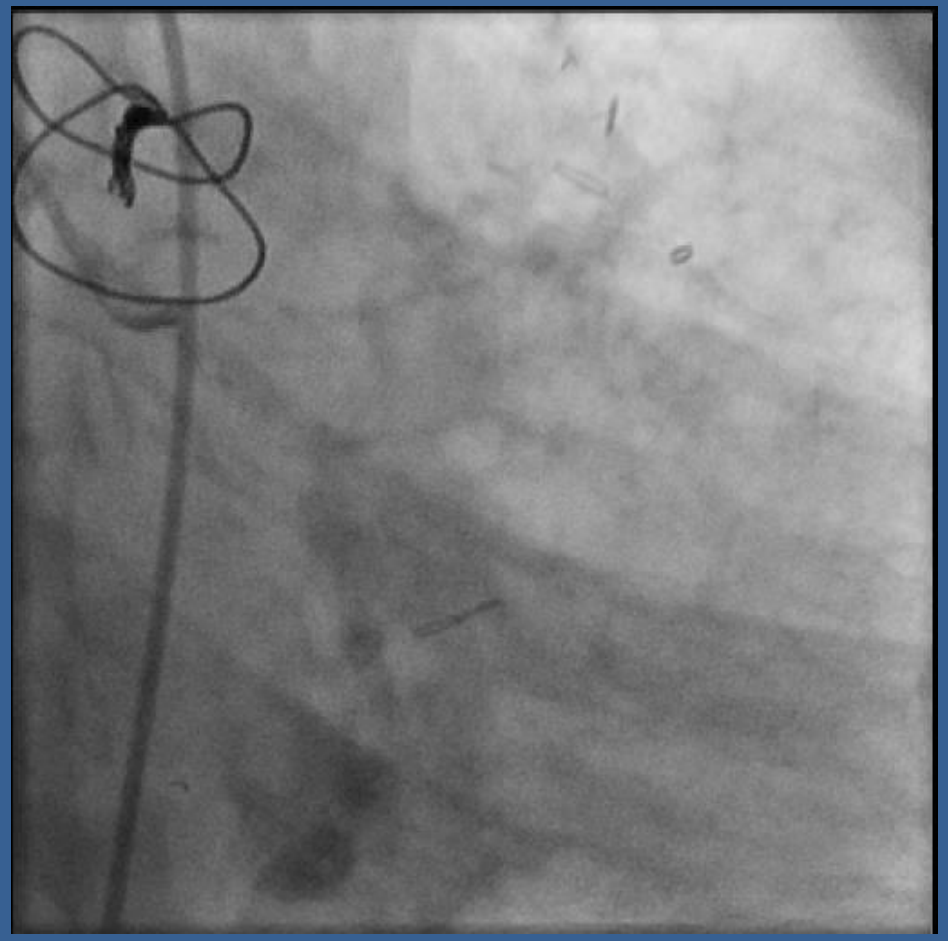
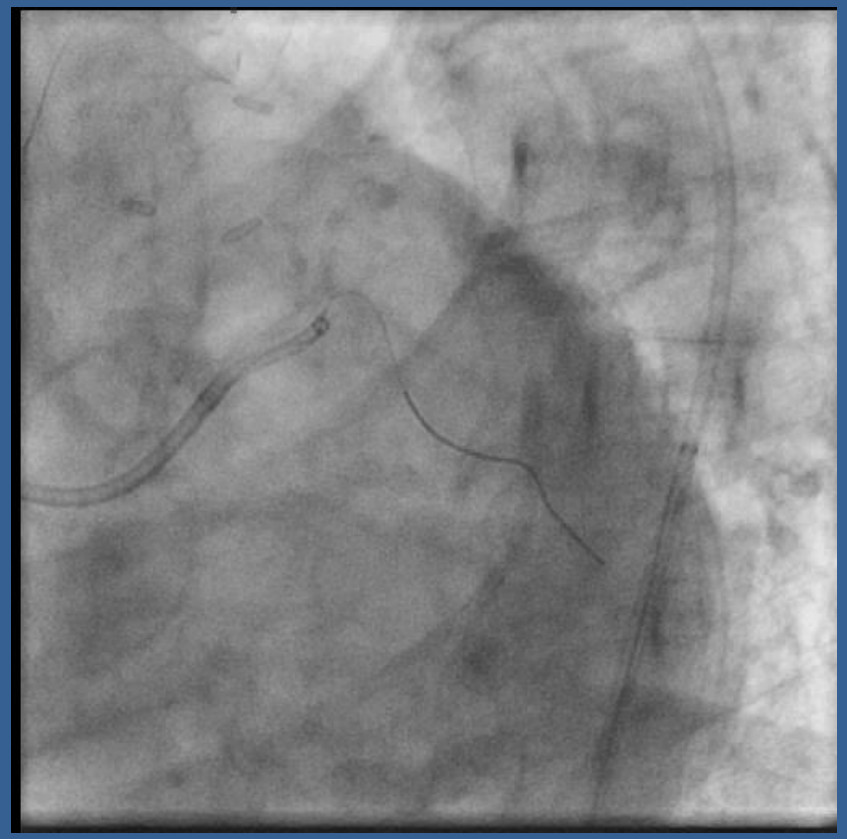
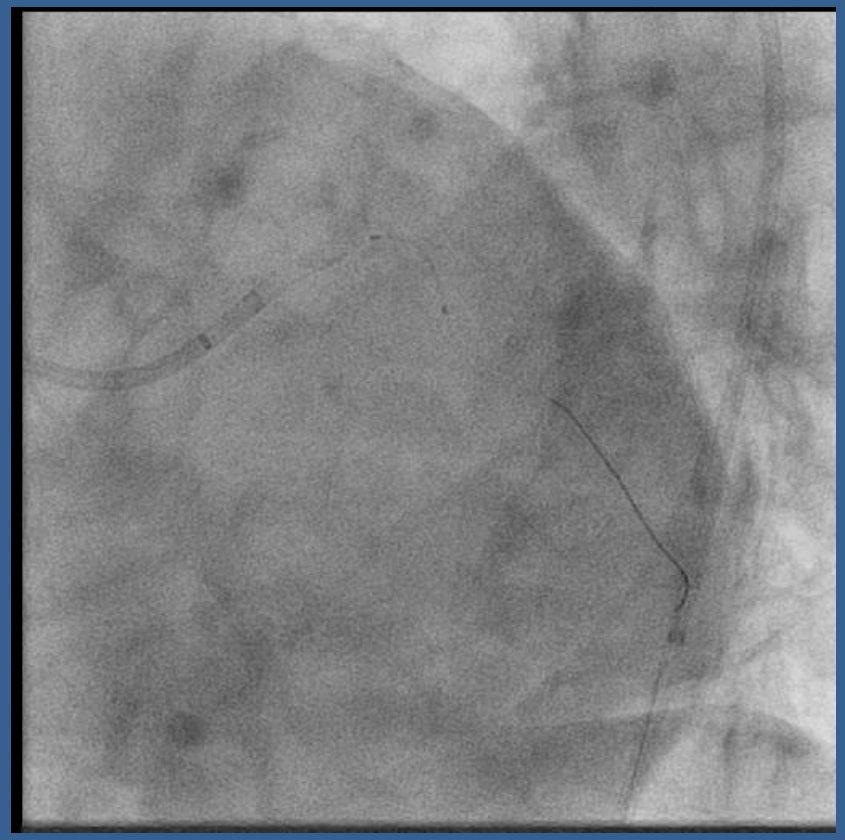
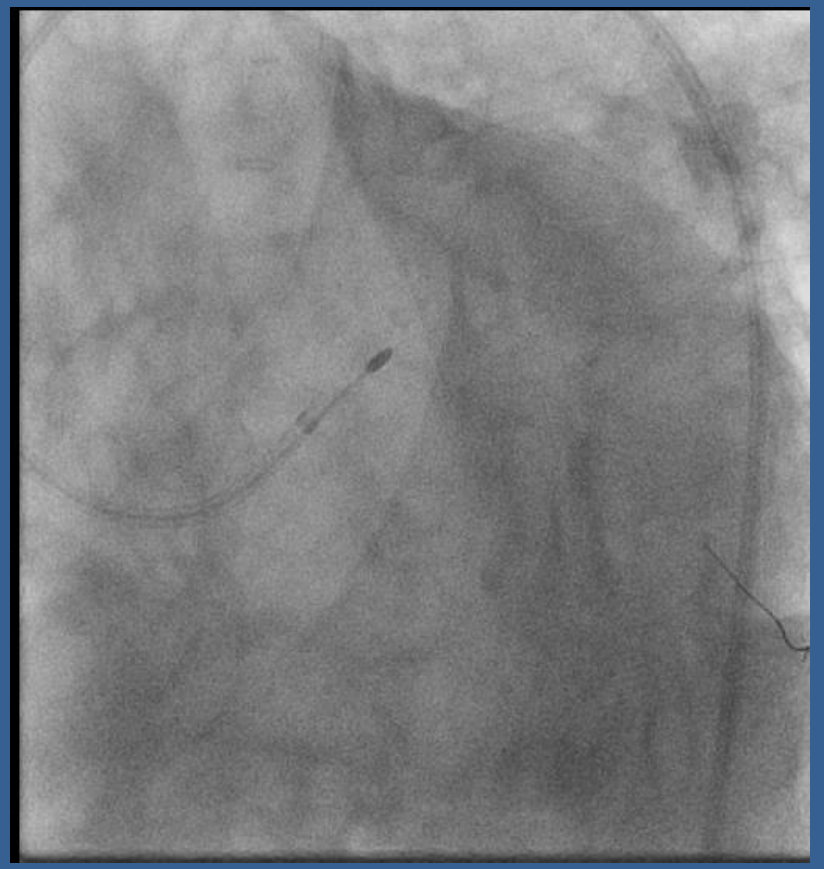


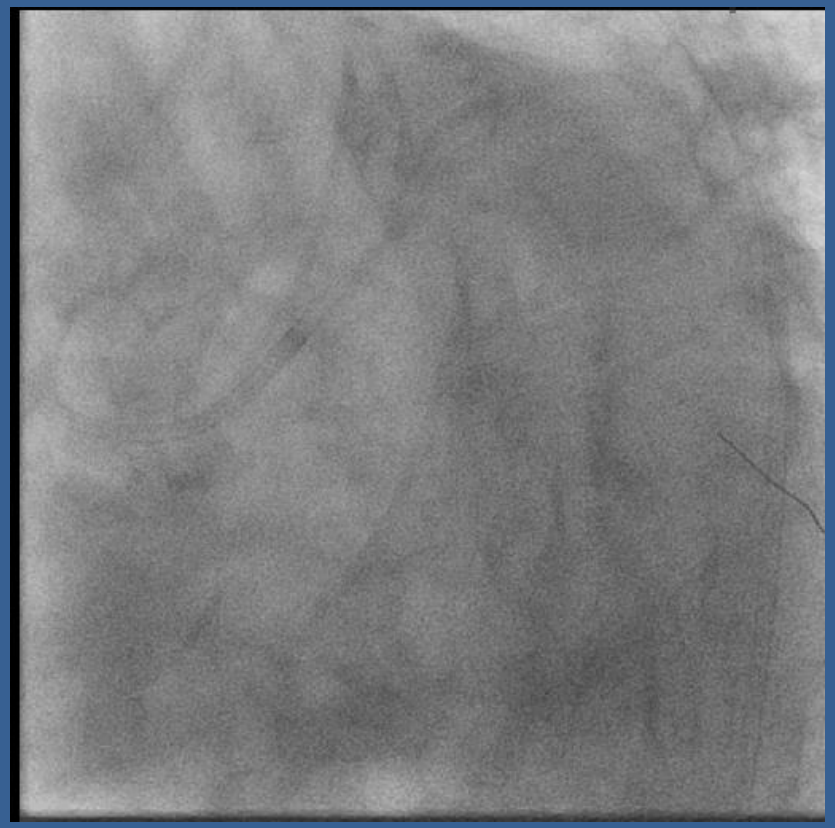
- Rota Case
- 74 yo male h/o CABG, HTN, DM presenting with chest pain to PMD. Nuc revealing severe lateral wall ischmia. Normal LVEF.

Rota Case





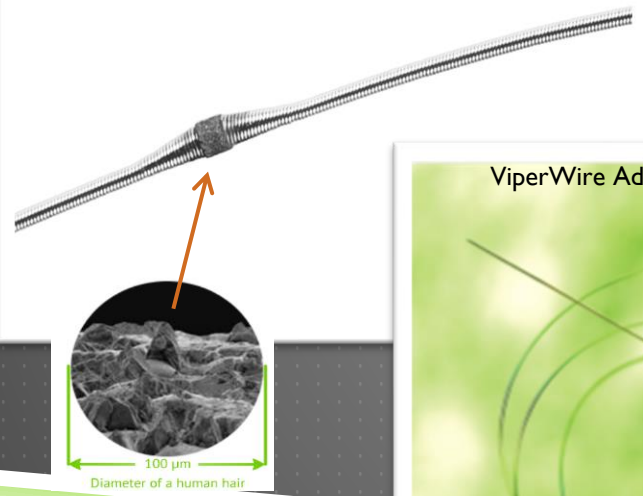




ORBITAL TECHNOLOGY: THE FIRST DEVICE FOR SEVERELY CALCIFIED CORONARY LESIONS

- First and only device specifically indicated for severe calcium
- Easy setup and use
- Control of device in operating field
- .012" OAS guide wire
- Compatible with 6 French guiding catheters

Eccentric Crown
1.25mm



30 Micron diamond grit

ViperWire Advance®

Electric OAS

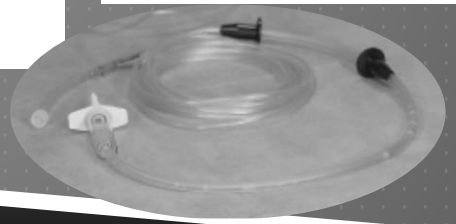
OAS Pump

SYSTEM COMPONENTS

Diamondback 360
Coronary Orbital Atherectomy Device

VIPERWIRE Advance® and ViperSlide®

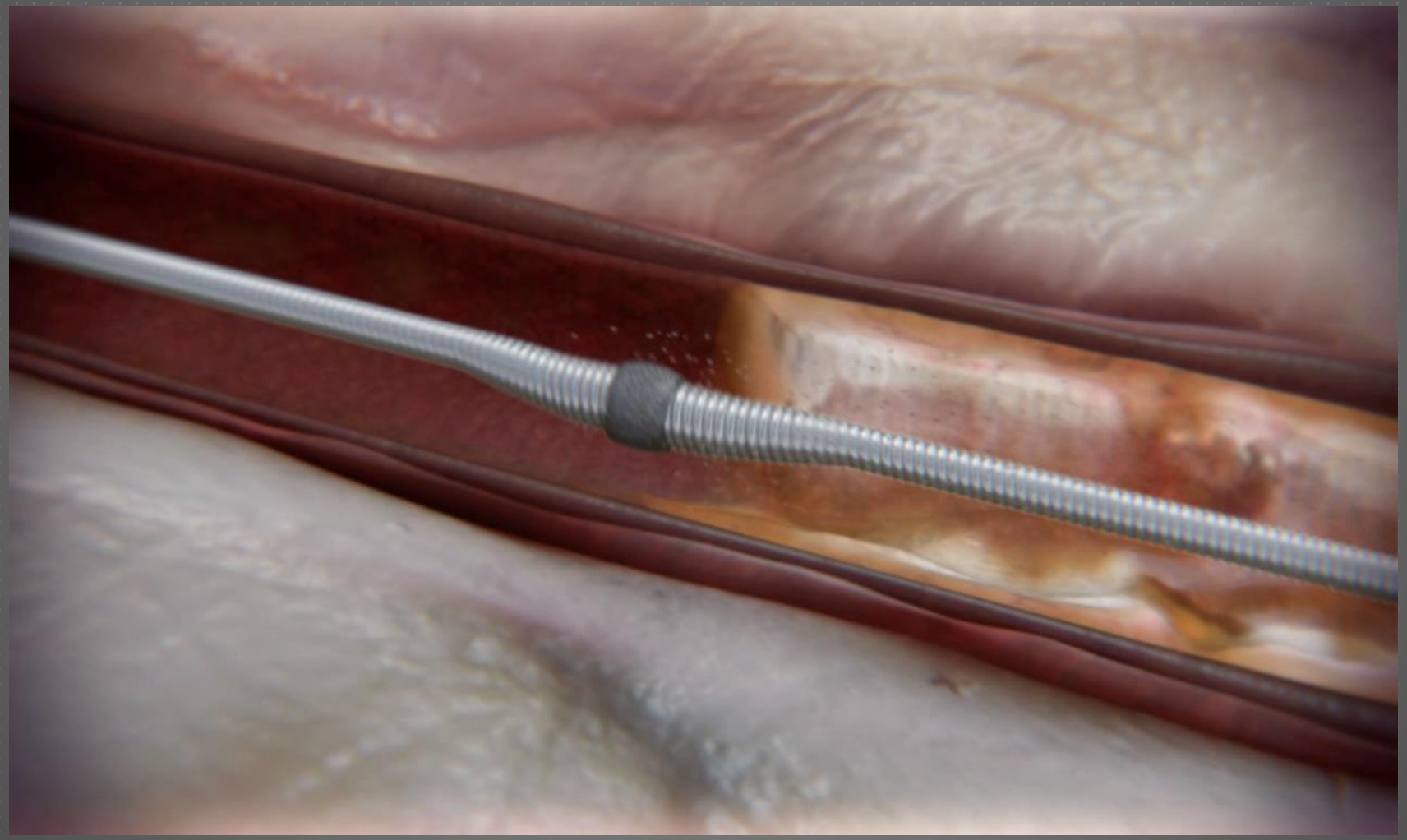
OAS Pump



Saline Tubing

ORBITAL TECHNOLOGY: MECHANISM OF ACTION

DIFFERENTIAL SANDING & CENTRIFUGAL FORCE



COMPLEX CASE PREP

- SPEED
  - Slow both ways! 1mm/ second
  - Slow eraser motion during initial pilot channel
- Limit run times even in long lesions and don't stop device in lesion
  - 20-30 seconds
- Rest times
  - Vasodilators periodically (at least every 2 runs if clinically able)
- If post-dilating or imaging after stent deployment over Viper, may need to place an 0.014" wire

Warning: Initial treatment for each lesion must start at low speed.

For every 30 seconds of treatment, a rest period of equal time is recommended with a maximum treatment time of **5 minutes** per OAD. The OAS pump will emit a beep after every 25 second interval of treatment time.

Precaution: Follow standard institution atherectomy policies and procedures, including those related to anticoagulation, channel blockers, and vasodilator therapy.

Advantages

- One size fits all – may save money
- Great for large and straight vessels
- Less no flow or slow flow
- No bulky nitrogen tank
- All control is in your hands
- Can potentially primary wire or work over the new viper wire
- No need for pacer for most cases

Disadvantages

Does not navigate severe tortuosity well

Be careful when using in small diameter vessels- 2.5 mm or smaller

Not great for delivering long stents as no modification to proximal calcified vessel

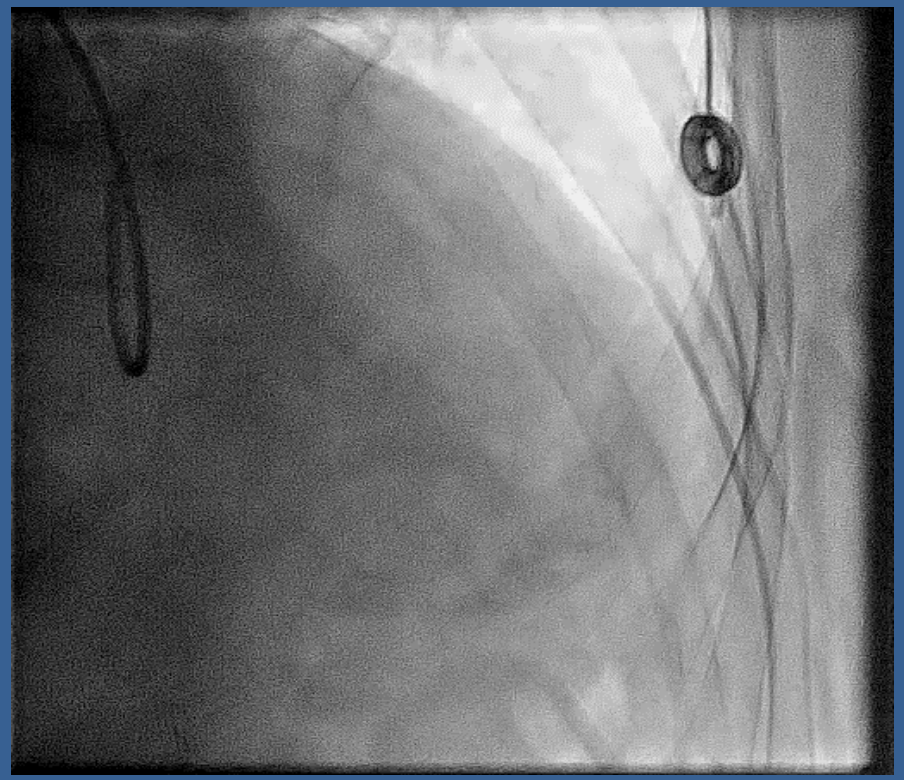
Its not exciting as you move very slowly within the vessel

CSI algorithm- when do you know you're done?

- Go on low speed and slow movement
- Only go on high speed if large diameter vessel 3.5 mm or greater
- Listen to the sound- constant pitch
- Tactile- smooth transition over the lesion- NO jumping
- That's equivalent to the "polish run"
- NC balloon- 1:1 ratio to artery diameter- Make sure balloon expands
- Deliver the stent- Normal to Normal

CSI Case

Severely Calcified Prox LAD in a 4.0 mm vessel



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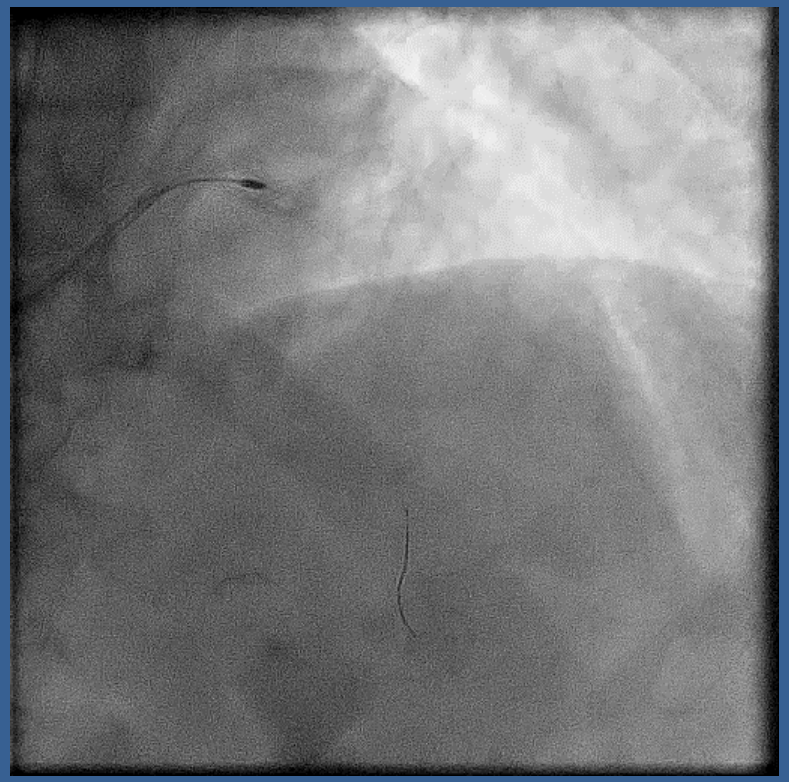
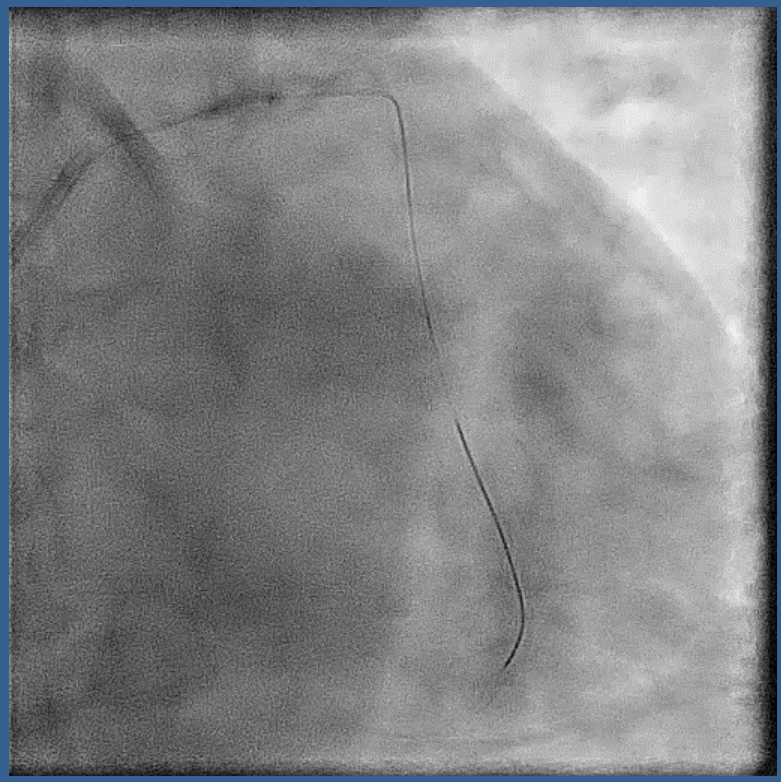
1.5 Burr used as primary atherectomy strategy





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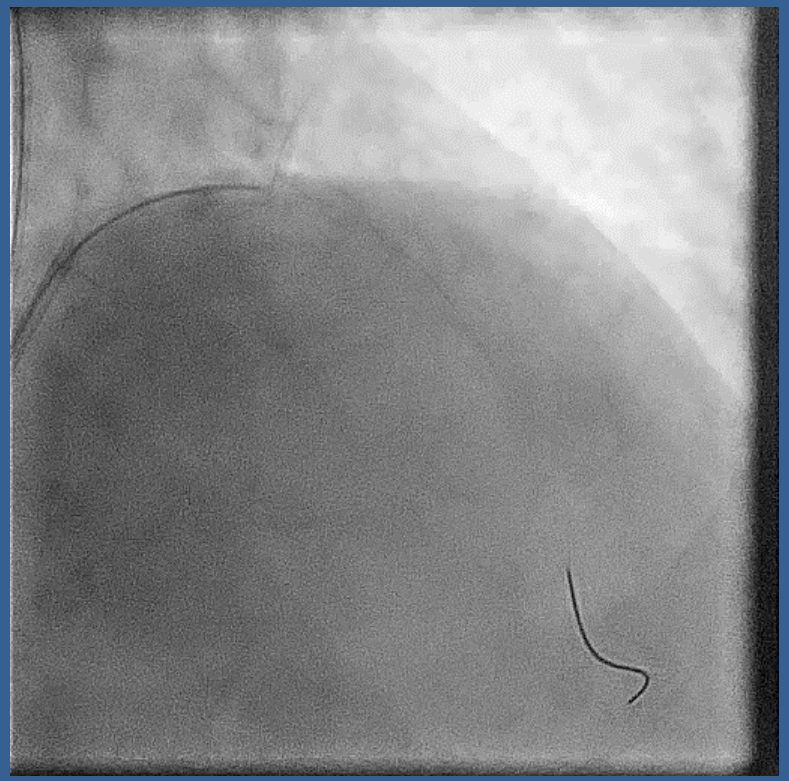
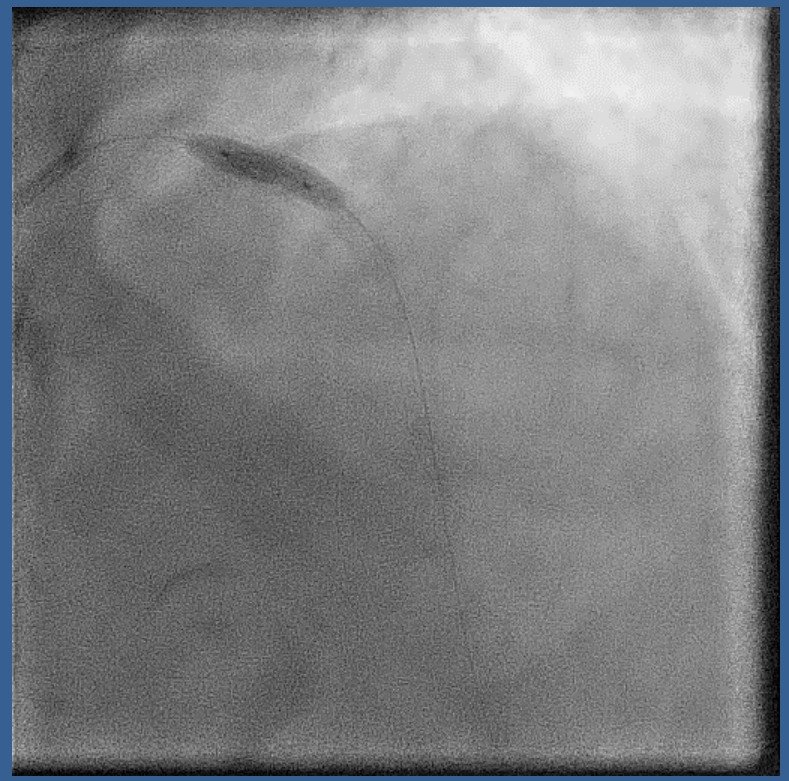
Used CSI both low speed 3 runs and 1 run on high speed





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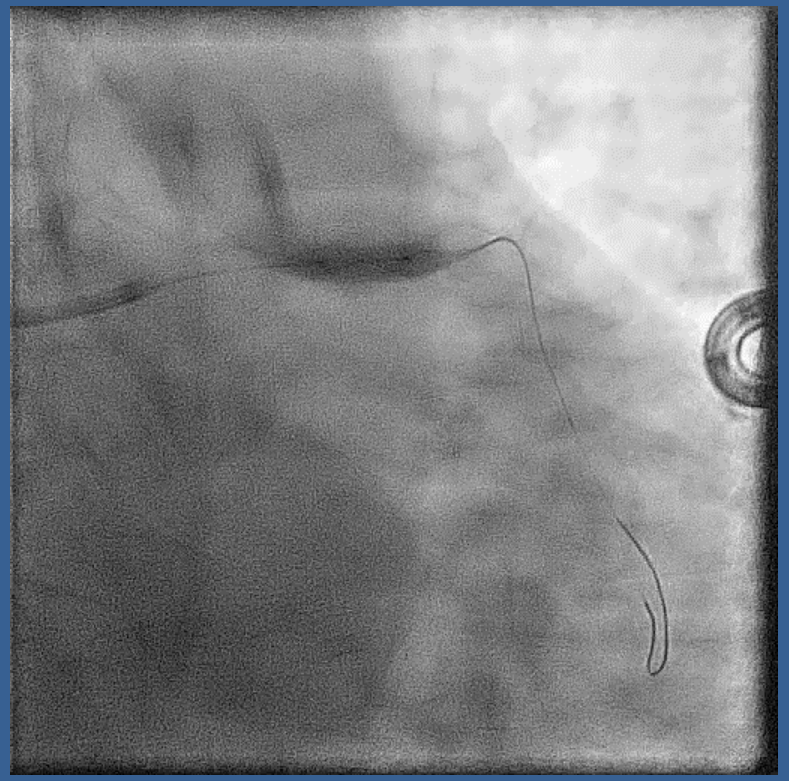
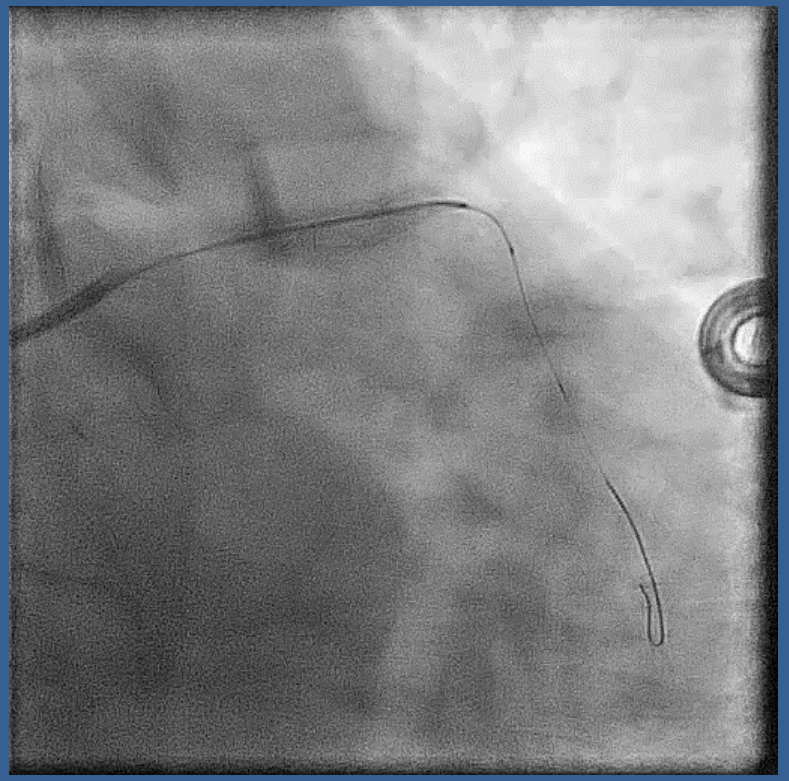
Post Dilatation and IVUS





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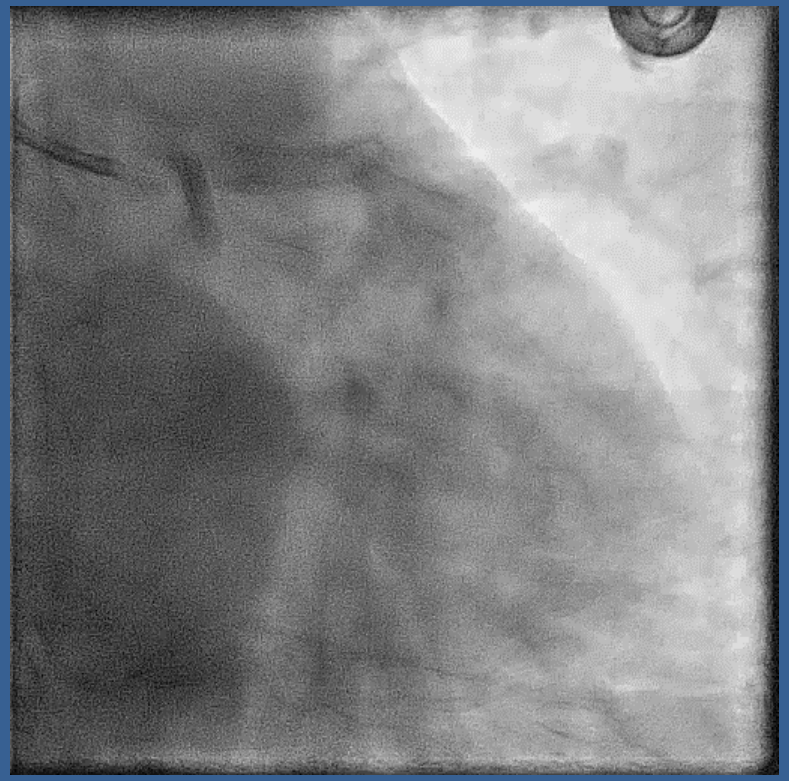
Final Result



Localized Lithotripsy For Coronary Arteries

Coronary Intravascular Lithotripsy (IVL)

A Novel Technology Addressing Severely Calcified Coronary Artery Disease By Fracturing Calcium in Preparation for Stent Placement

Intravascular Lithotripsy: A Novel Option

Mechanism of Action to Modify Calcium Proven

Extracorporeal Lithotripsy

30 years of safety data in kidney stone treatment

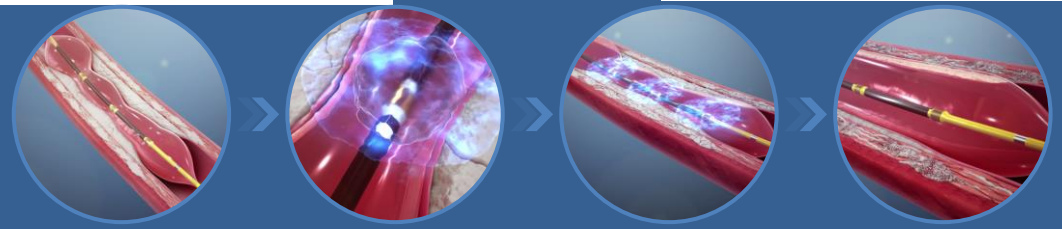
Sonic Pressure Waves preferentially impact hard tissue, disrupt calcium, leave soft tissue undisturbed

Intravascular Lithotripsy (IVL)

Miniaturized and arrayed lithotripsy emitters for localized lithotripsy at the site of the vascular calcium

Optimized for the treatment of coronary arterial calcium

How IVL Is Performed



Deliver catheter via standard technique and inflate to low pressure

Generate sonic pressure waves using lithotripsy

Crack superficial and deep calcium in the artery wall

Safely expand the vessel to prepare for stent implantation

- Advantages

- It is a balloon! So even scaredy-cats can tackle calcified leisons!
- Easy set up for staff
- Excellent for focal lesions
- Excellent for angulated lesions
- Excellent for ostial RCA lesions

Disadvantages

Is not a deliverable balloon. Wiggle wire helps

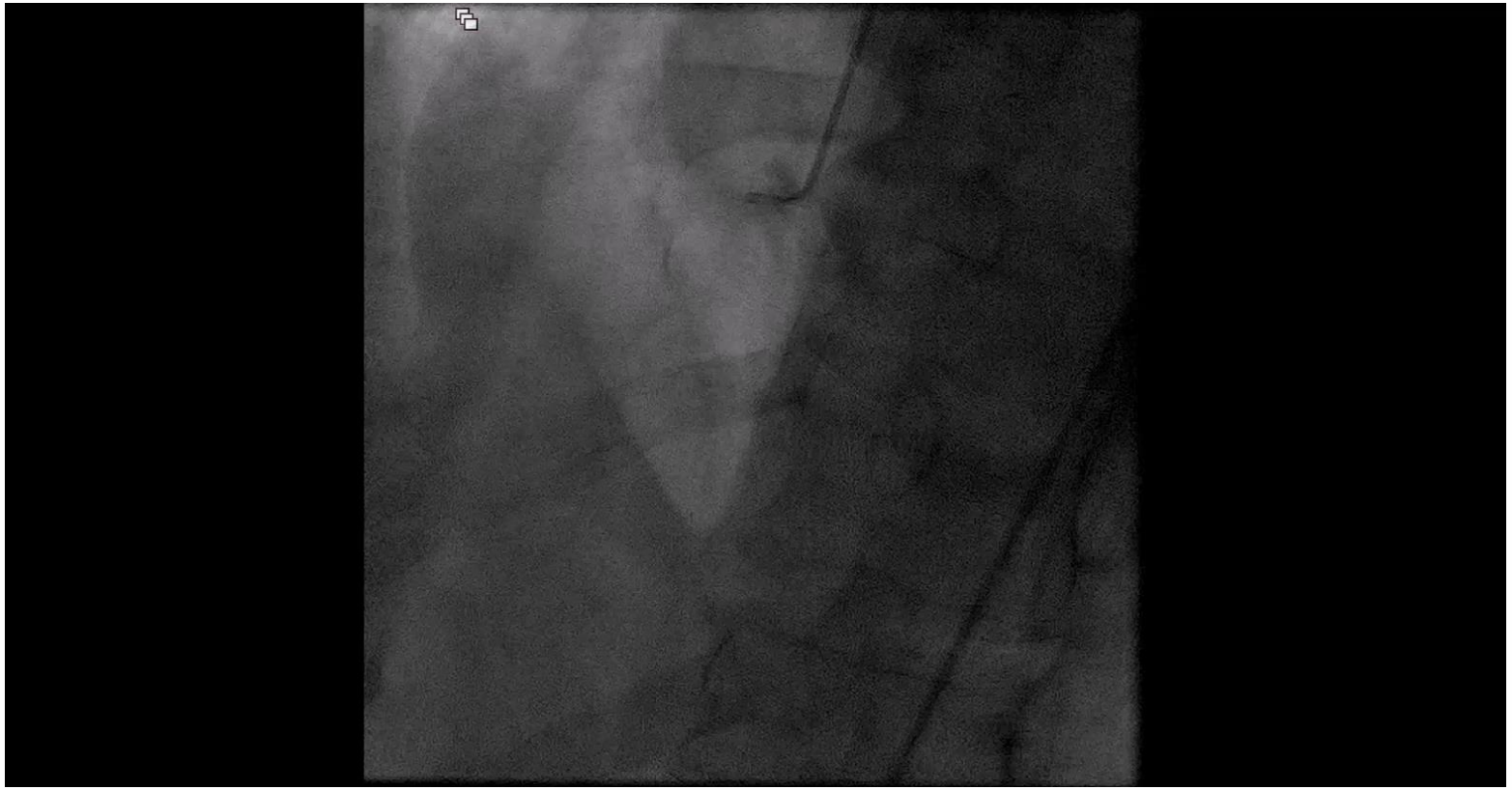
One balloon size per vessel. So not ideal for diffuse lesions that vary in size.

Only 8 x 10 second shocks per balloon

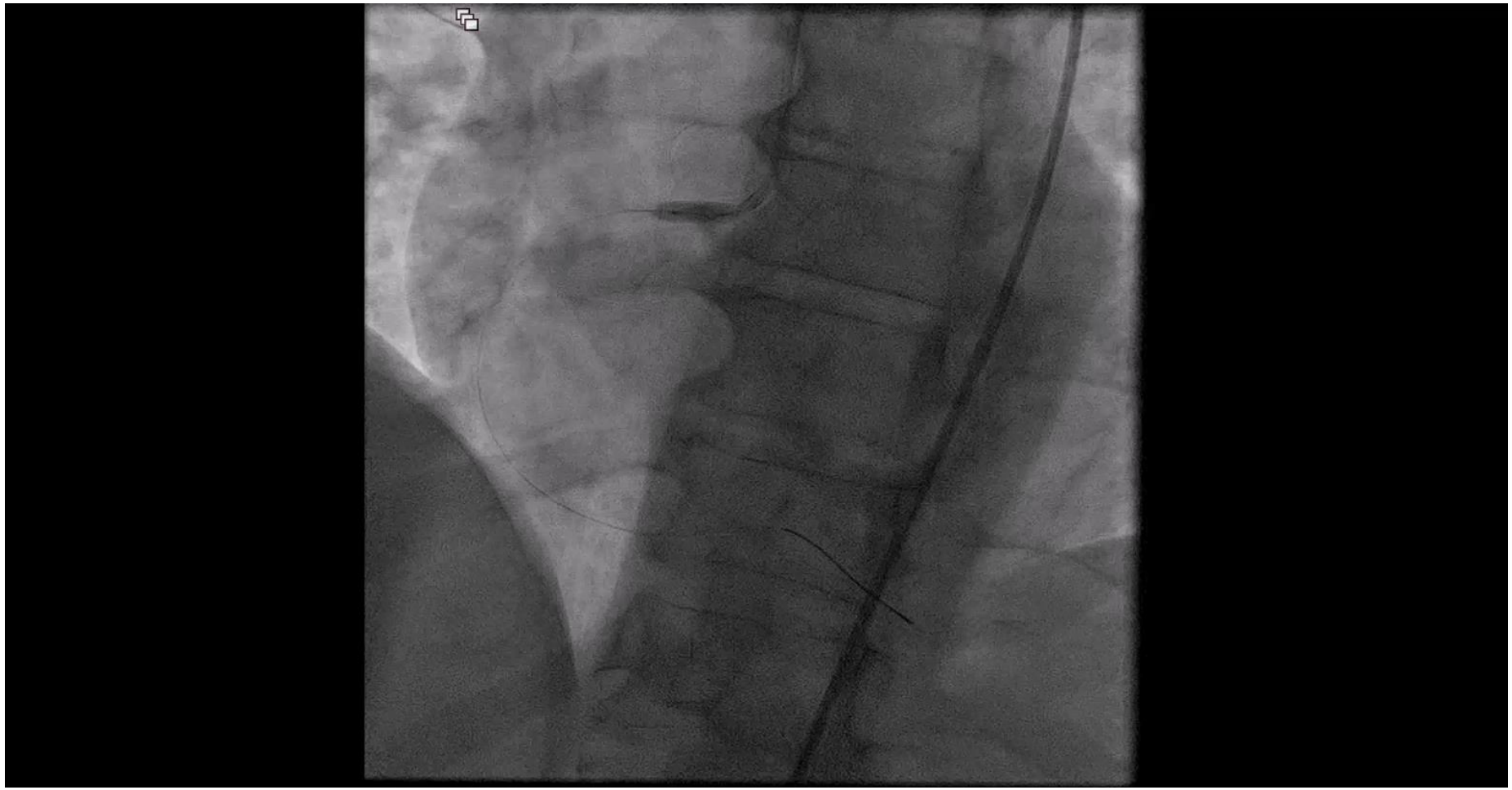
Not good for LM lesions due to balloon inflation x 10 seconds

May lose money per case.

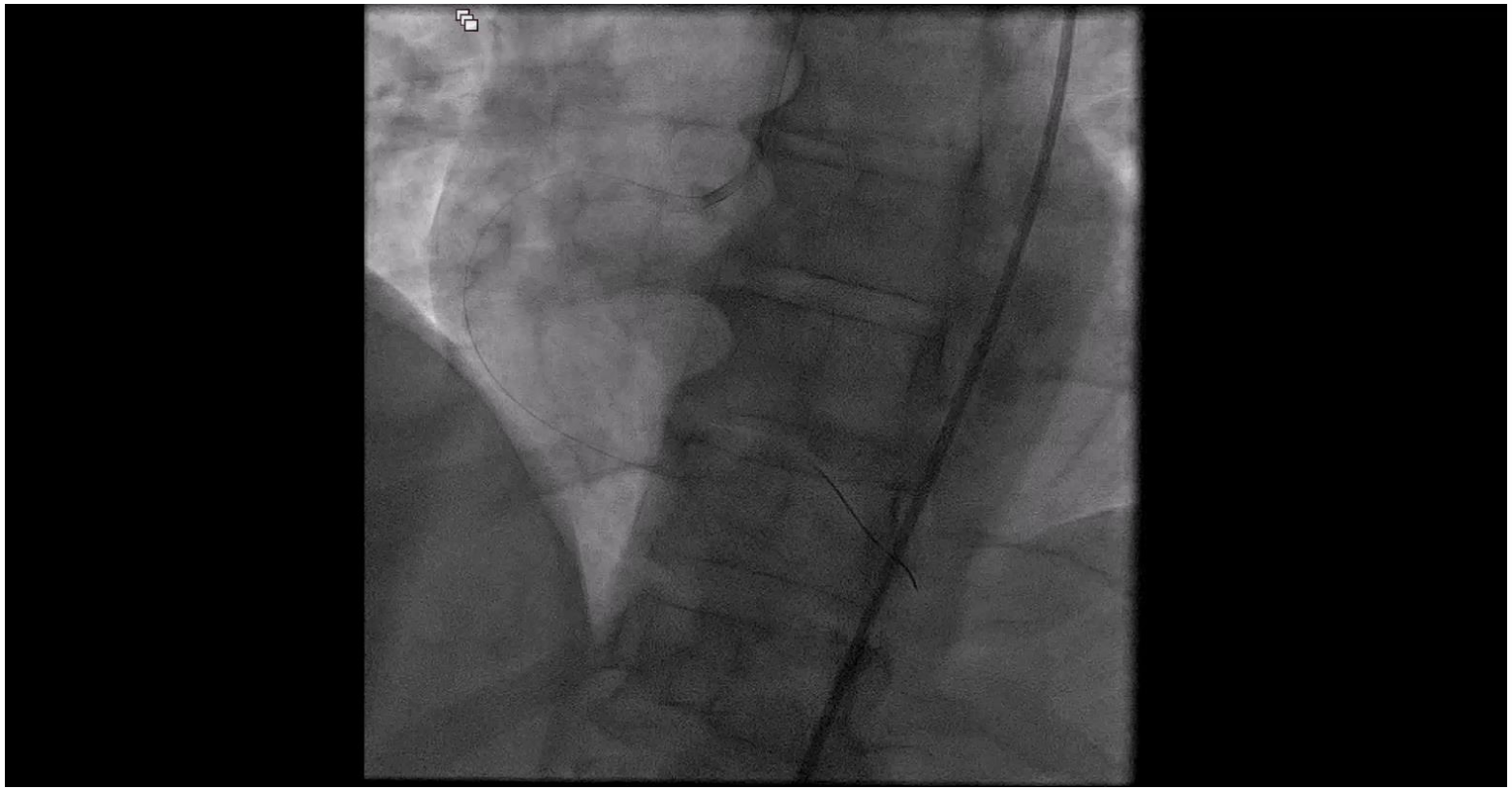
Shockwave Case- Heavily calcified ostial RCA



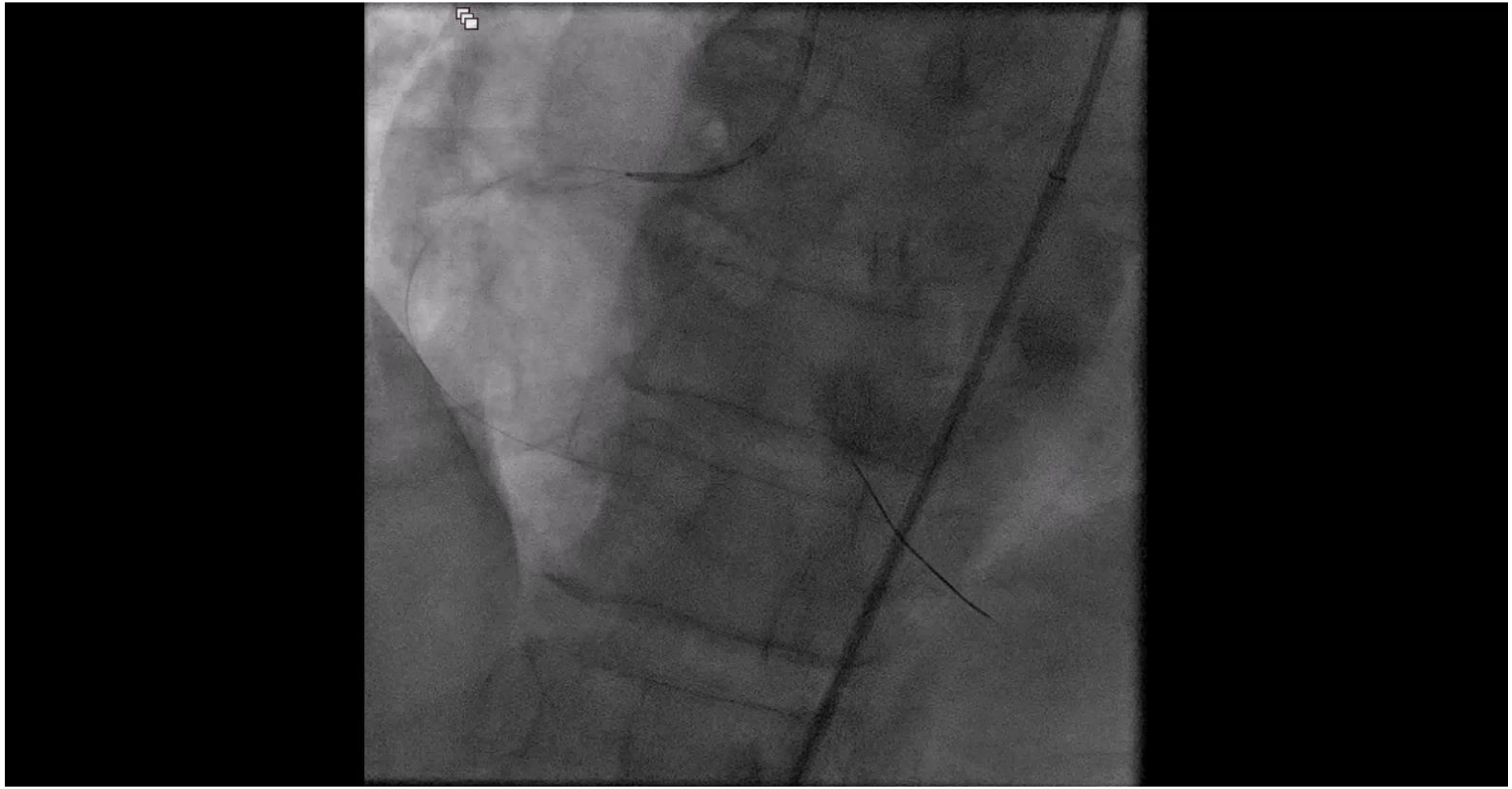
Shockwave 4.0/12 IVLT



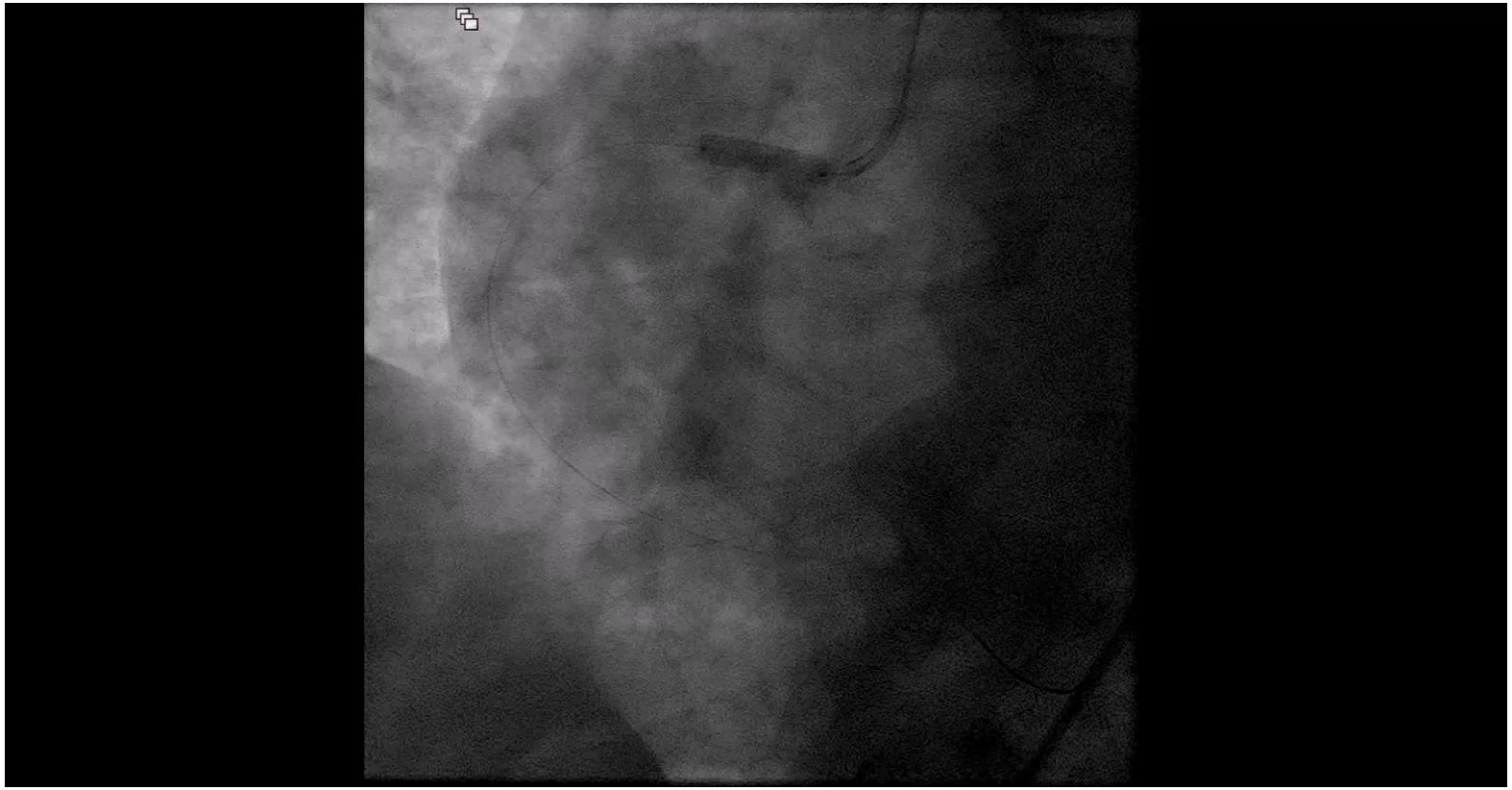
Post Shockwave 4.0/12 x 4

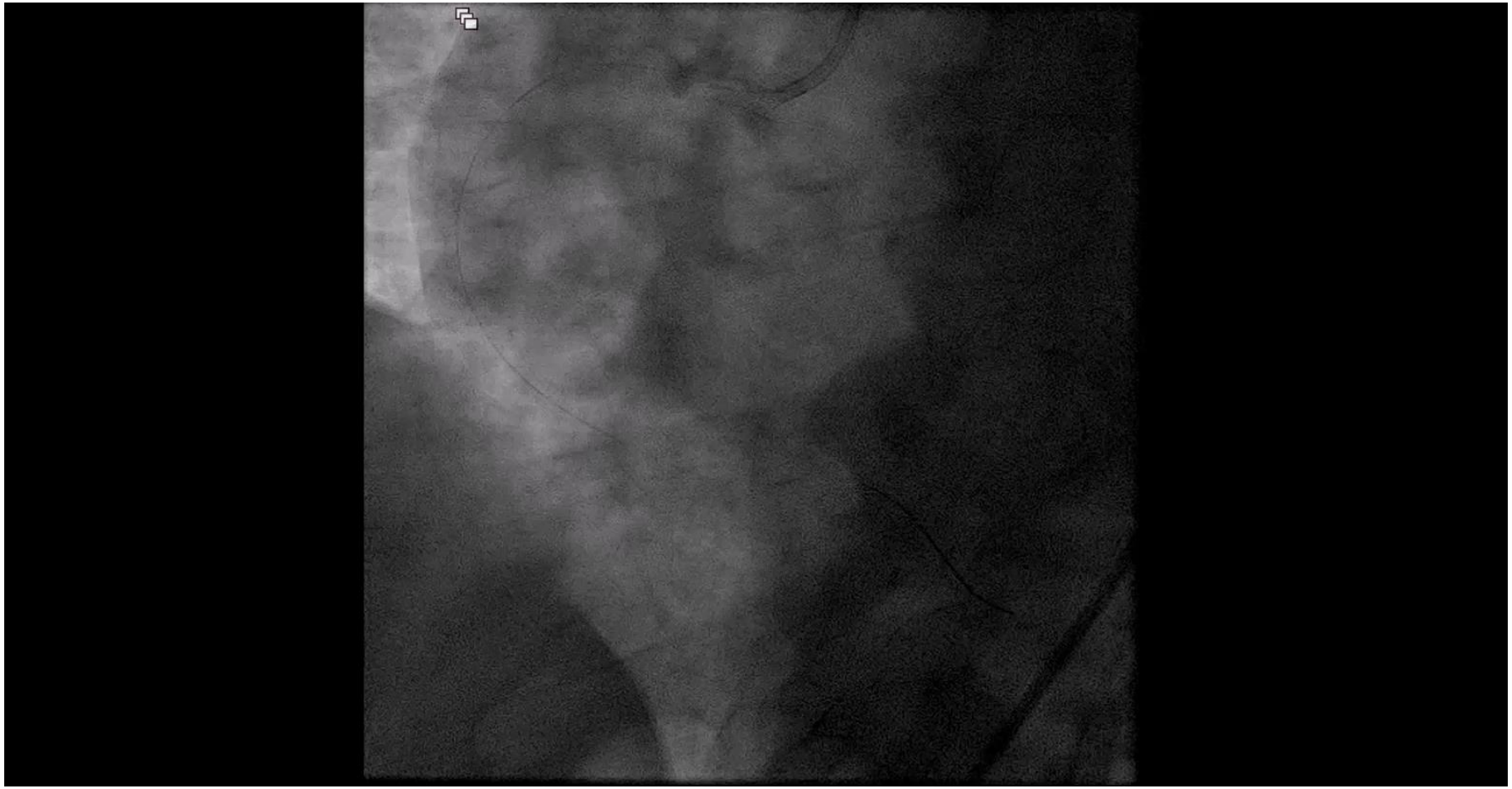


Stent Placed

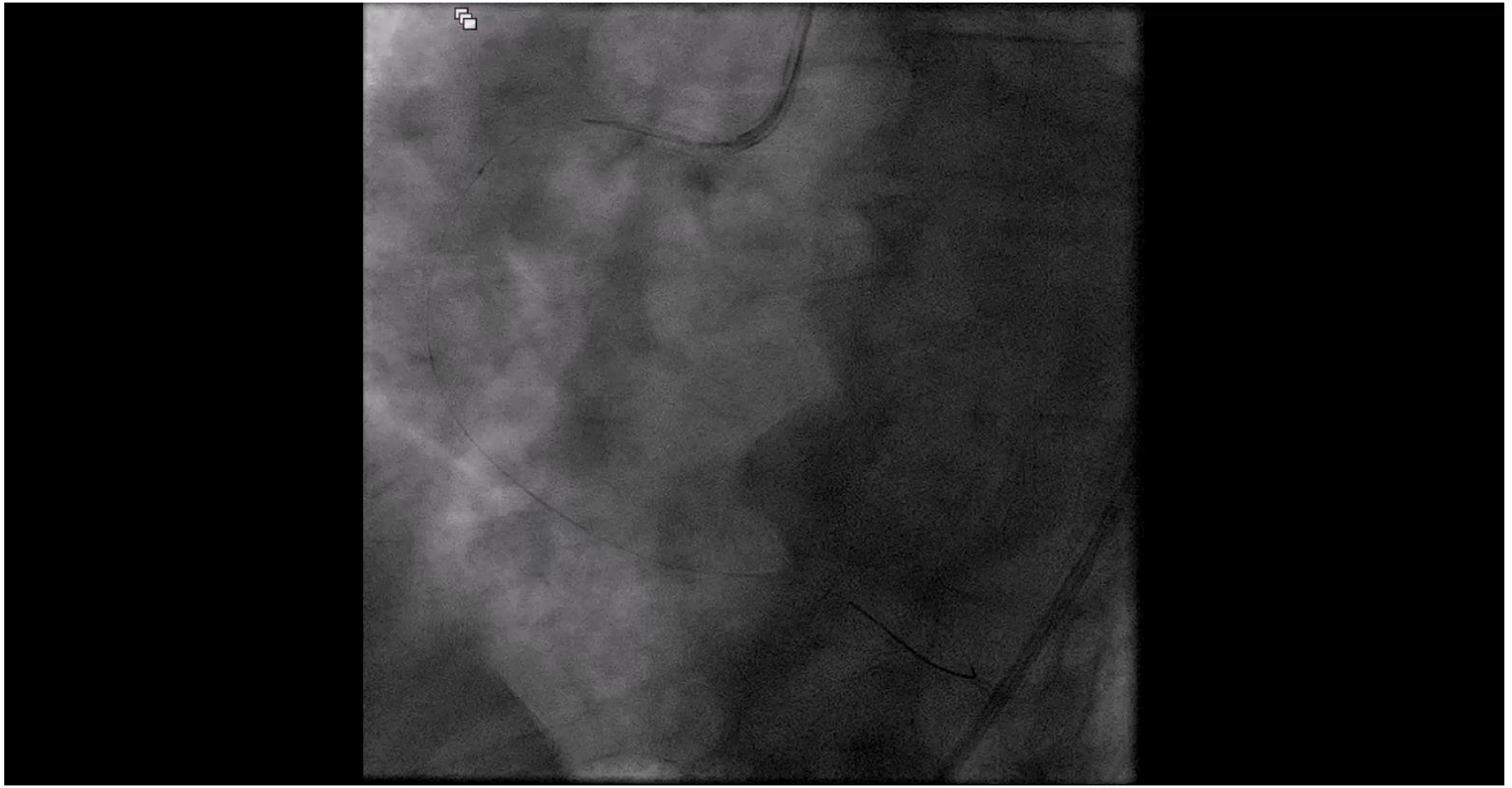


Stent well expanded

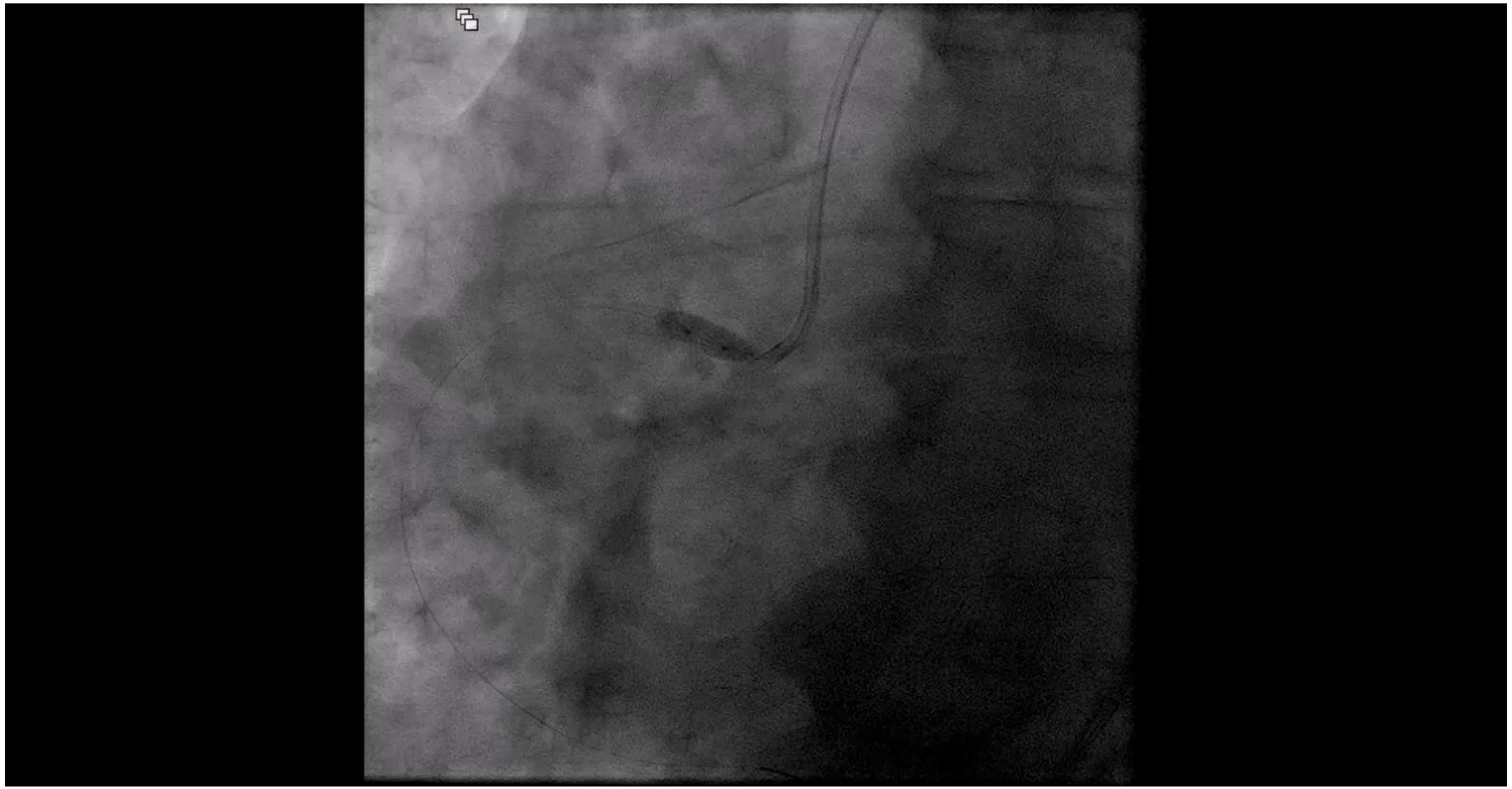




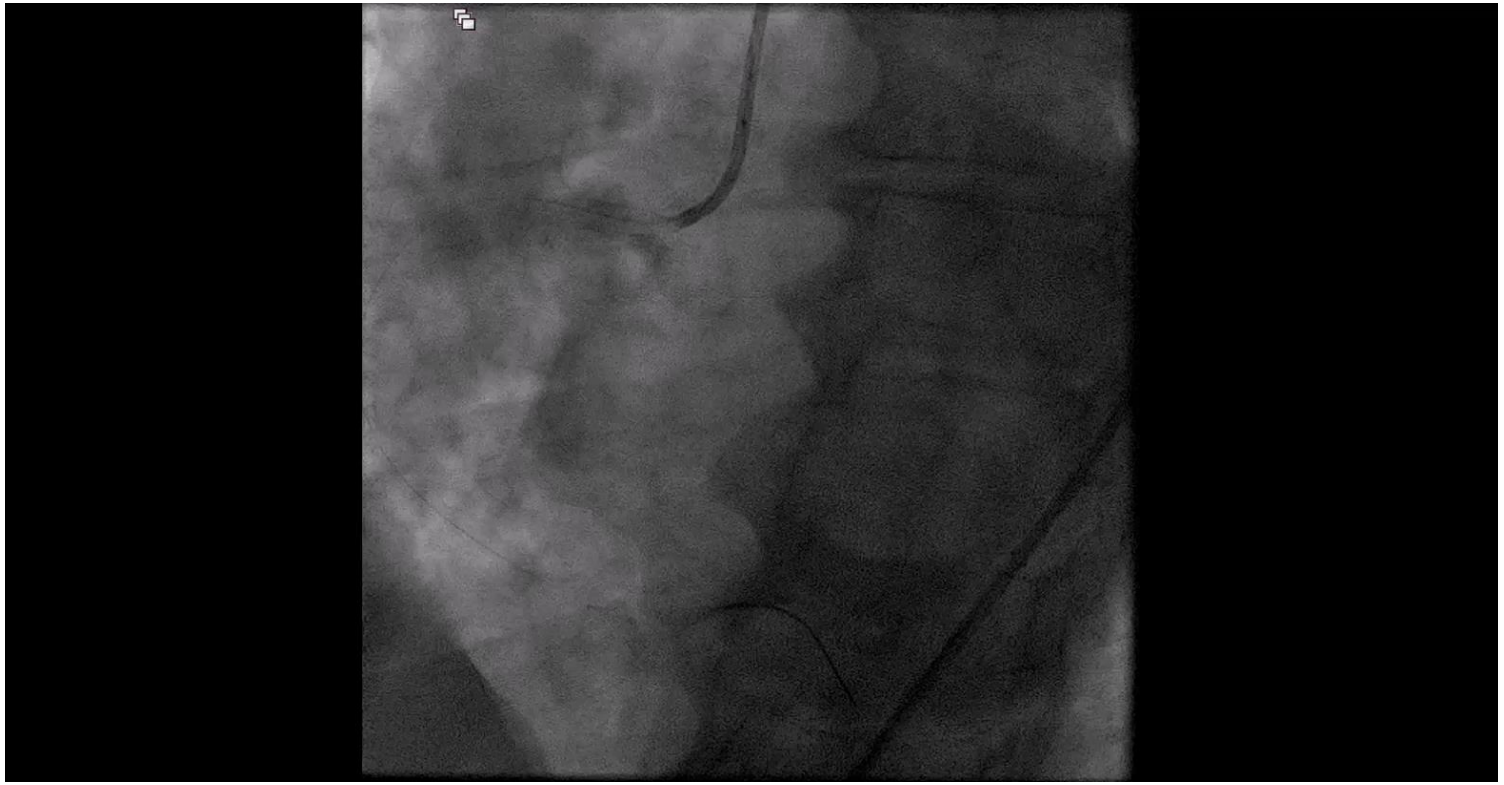
IVUS



Post dilatation with 4.5 mm NC balloon



Final Result



Conclusion

- Be aware of calcium- if you don’t look for it, you will miss it up front
- If you need to use an athrectomy device use it
- Be comfortable with at least one device but try to be comfortable with all- each have their unique advantages and disadvantages
- Know the pitfalls of each device to avoid complications

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Which device would you use?