Use of Adjunctive Tools in Complex PCI: Laser Atherectomy/Specialty Balloons

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ARCH ELITE FELLOWS PROGRAM

DISCLOSURES

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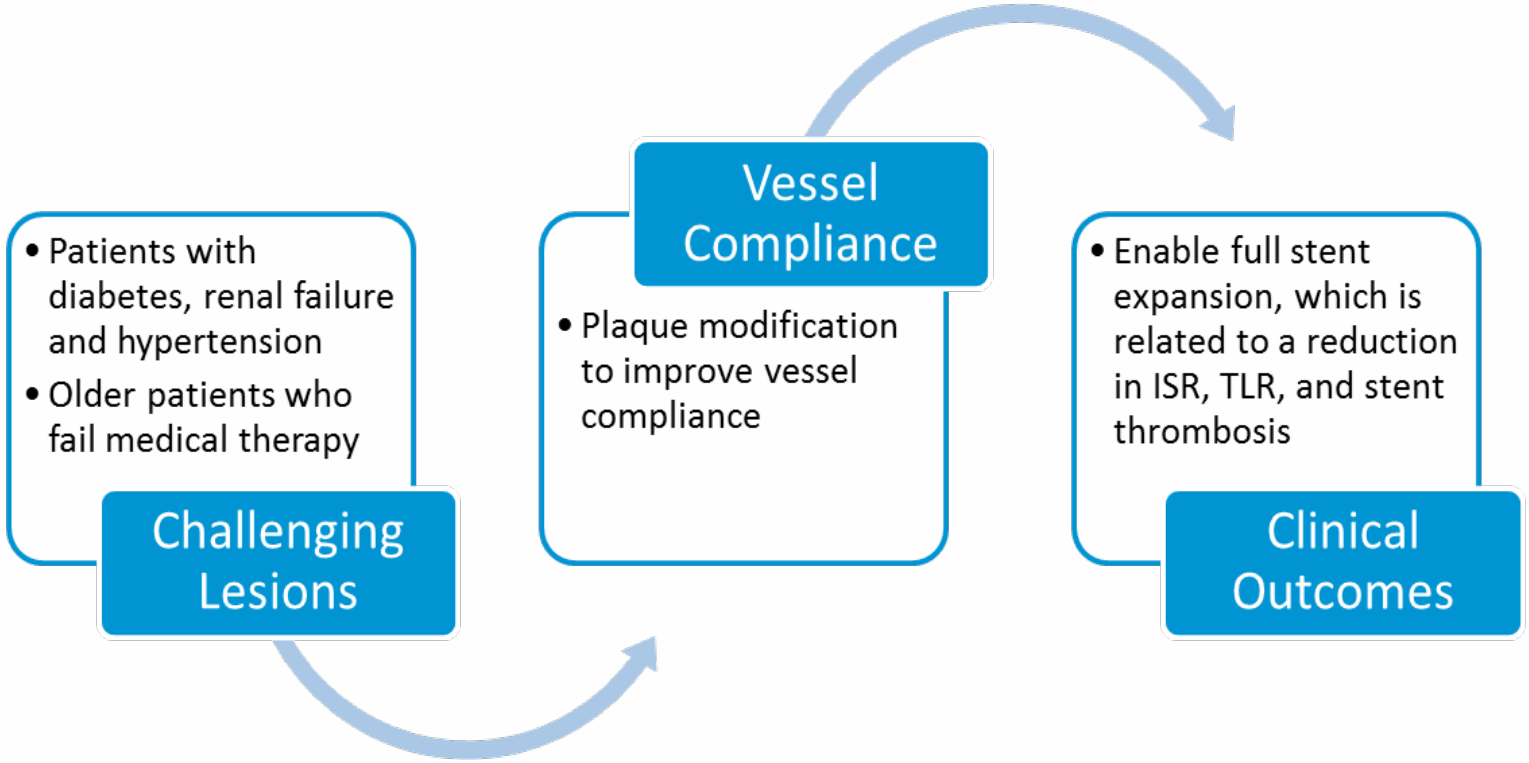
Speaker, Advisory Board, Consultant, Research Support **Philips**

Lesion Preparation



Virmani R, Farb A, Burke AP. Coronary angioplasty from the perspective of atherosclerotic plaque: Morphologic predictors of immediate success and restenosis. Am Heart J. 1994;127:163–79.

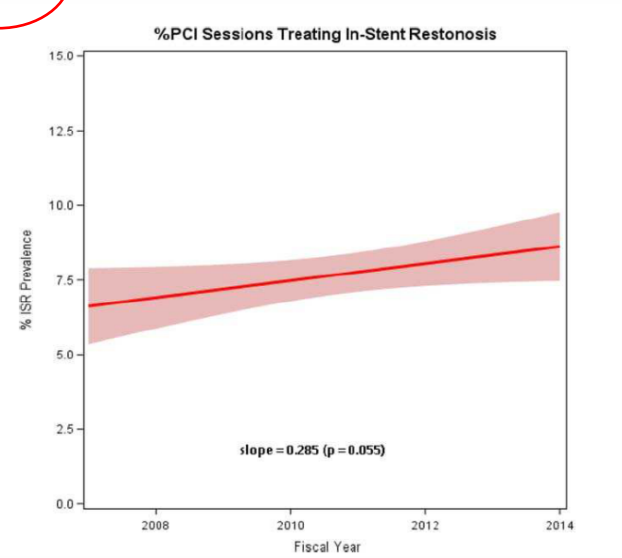
ISR Case June 2018

- 82 year old male, diabetic, hypertension, prior PCI in RCA 2001 (BMS)
- Returned with ISR - 2nd BMS and brachytherapy in 2002
- Returned with chest pain 2018

Optimizing PCI in Complex Procedures: June 1-2, 2018 Live Case St. Francis Hospital , NY Operator: Dr. Allen Jeremais

Several sources highlight real-world incidence rates

- According to the NCDR database 10% of PCI's are for in-stent restenosis (ISR)
- Insights from the National VA CART Program shows 10.5% PCI are for ISR
- Routine angiographic surveillance after unrestricted use of newer-generation devices demonstrates rates of angiographic restenosis of approximately 12%[7].



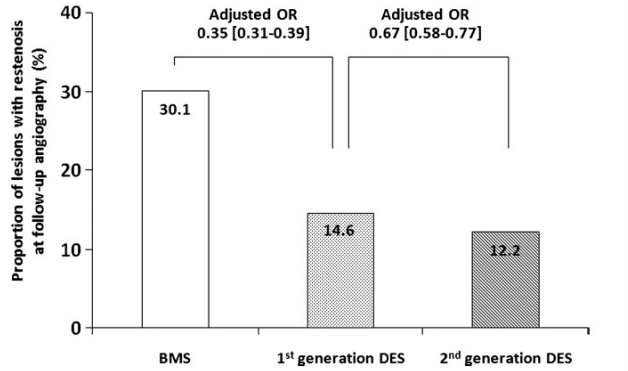


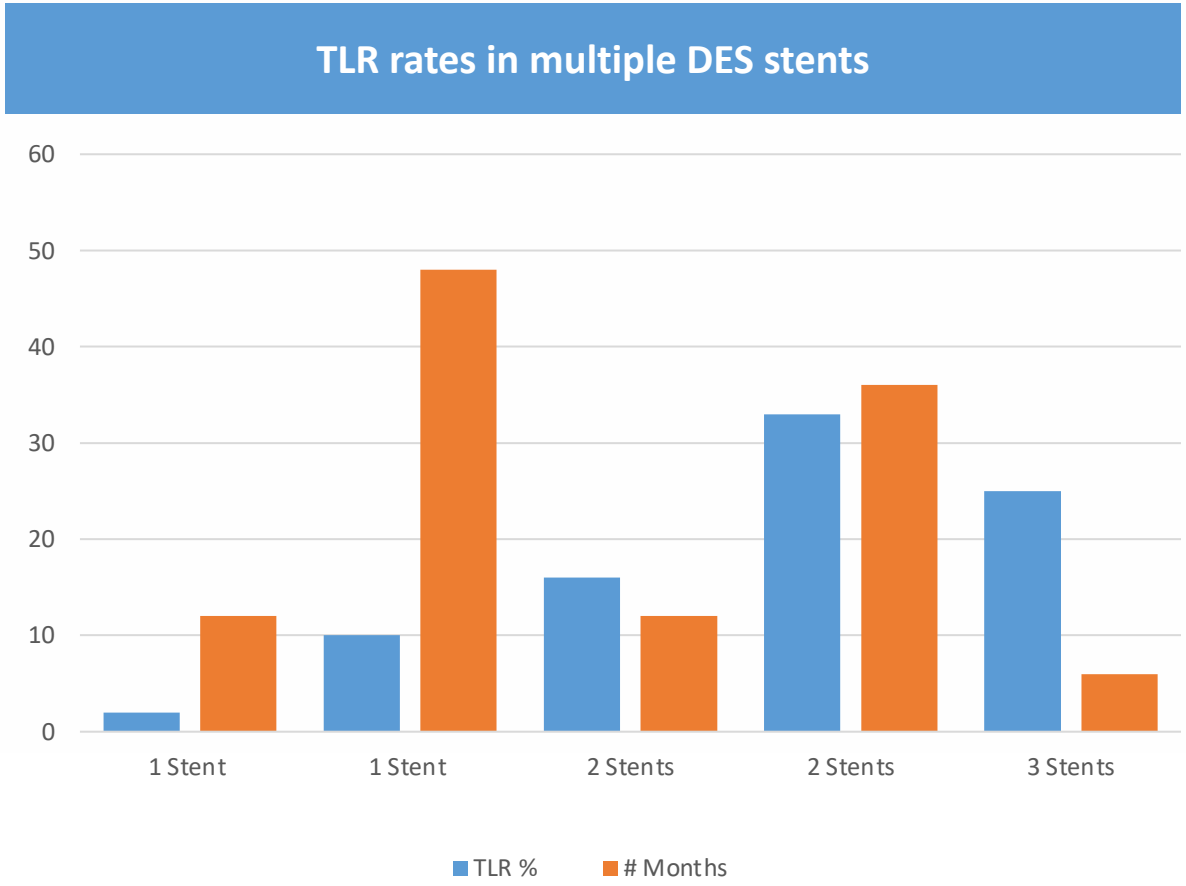
Figure 4 Proportion of lesions with restenosis at follow-up angiography according to stent cohort. Lesions presenting restenosis at follow-up angiography are described as proportion. The adjusted OR for restenosis is provided. BMS, bare metal stent; DES, drug eluting stent.

Cassese S, *et al*. *Heart* 2013;**0**:1–7. doi:10.1136/heartjnl-2013-304933

10-12% Cumulative ISR of prior 5 yrs. of stents is 100,000 patients/ per yr.

Croce K,MD. 2018 SCAI Presentation "How to deal with ISR and Multilayer ISR."
Incidence, procedure management, and clinical outcomes of coronary in-stent restenosis: Insights from National VA CART program; Catheter Cardiovasc Interv. 2017; 1-9

With low TLR rates why not just add another stent?



2nd stent 12-16% at 12 months and 33% at 3-5 years

3rd stent 25% at 6 months [8-12]

Causes of in-stent restenosis

Biologic

Reaction to metal or polymer
Drug resistance
Thrombosis

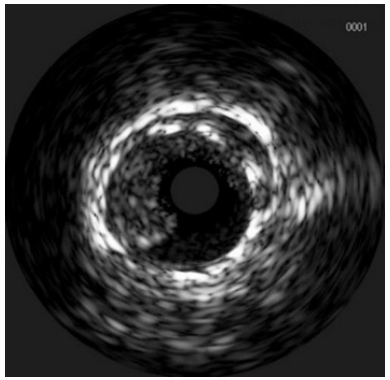
Technical or mechanical

Stent under-expansion/mal-apposition
Stent fracture
Edge trauma
Geographical miss

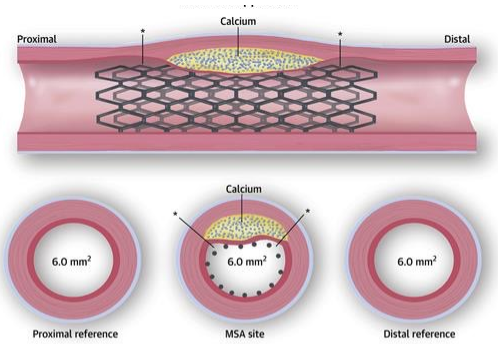
Major risk factors

Stent length
Smaller lumen
Diabetes

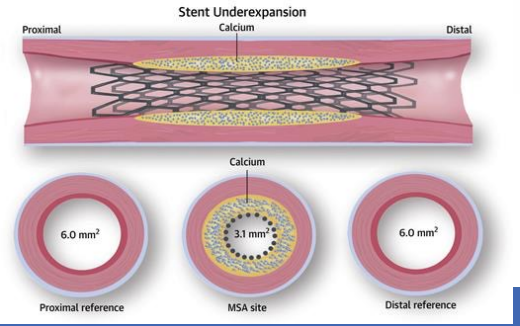
Thrombosis



Mal-apposition



Under-expansion



Reference.: http://circ.ahajournals.org/content/107/17/2175.full (ISR types)

Mintz, G. JACC 201464:2

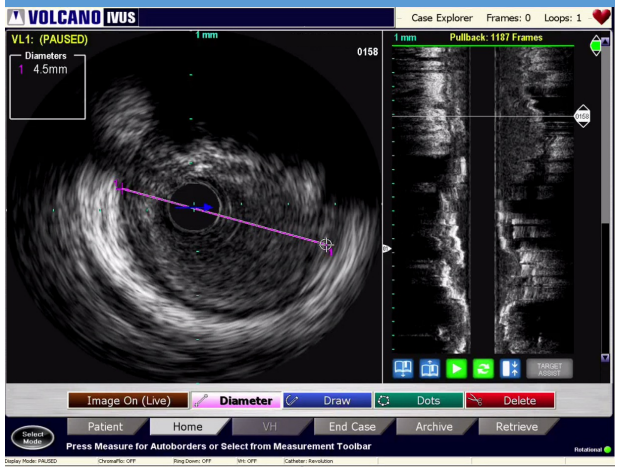
ISR case June 2018

Due to the high degree of in-stent restenosis. Physician passed a 1.4mm ELCA catheter to create a channel for imaging, single pass at setting of 60/40. (Figure 1)

Physician determined:

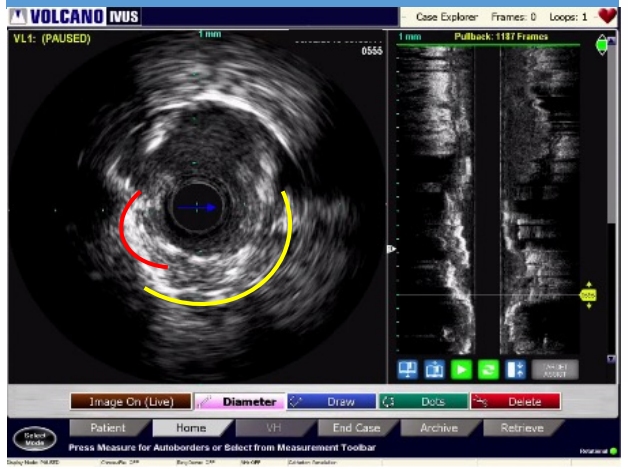
Under-expansion due to calcium behind stents and neo-atherosclerosis in-stent.

Distal reference site



(Figure 2)

Vessel size determined as 4.5mm
but the 2nd stent was under-expanded distal



(Figure 3)

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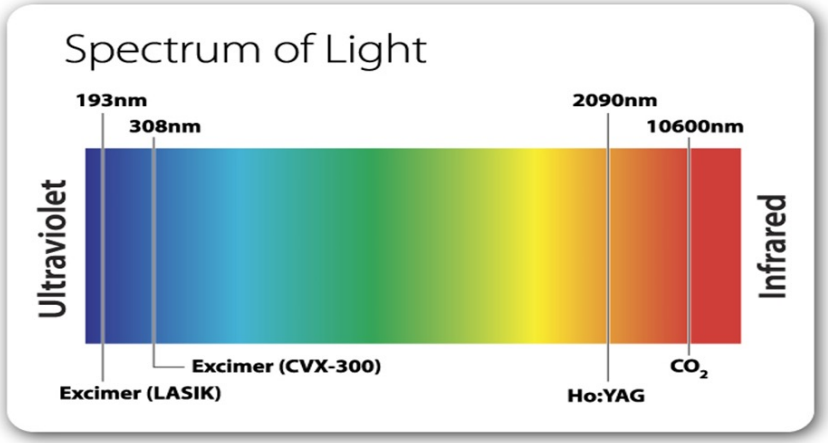
Why use coronary laser atherectomy for ISR?

Challenges with mechanical atherectomy

- The unique SOFT, AQUEOUS morphology of neointimal hyperplasia tissue present a challenge to mechanical intervention. [15]

Ultraviolet → Infrared

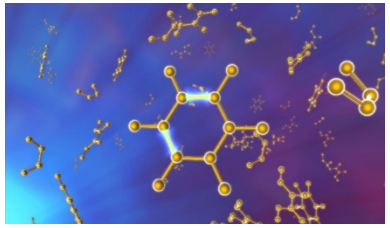
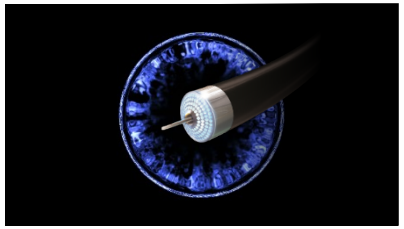
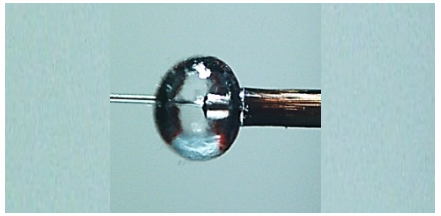
Cool → Hot



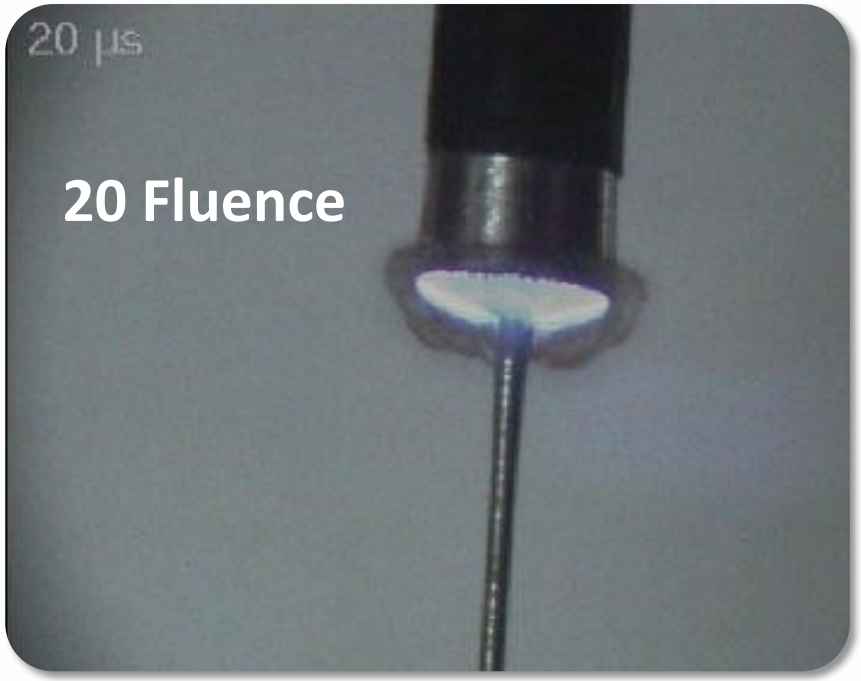
Unique benefits of coronary ELCA

- Effective and safe de-bulking allowing potential for greater vessel and stent expansion[13,15]
- Vapor Bubble expands beyond the stent struts
- Decrease risk of distal emboli[14]
- No mechanical moving parts
- Potentially decrease the placement of additional stents

Versatile mechanism of action-photoablation

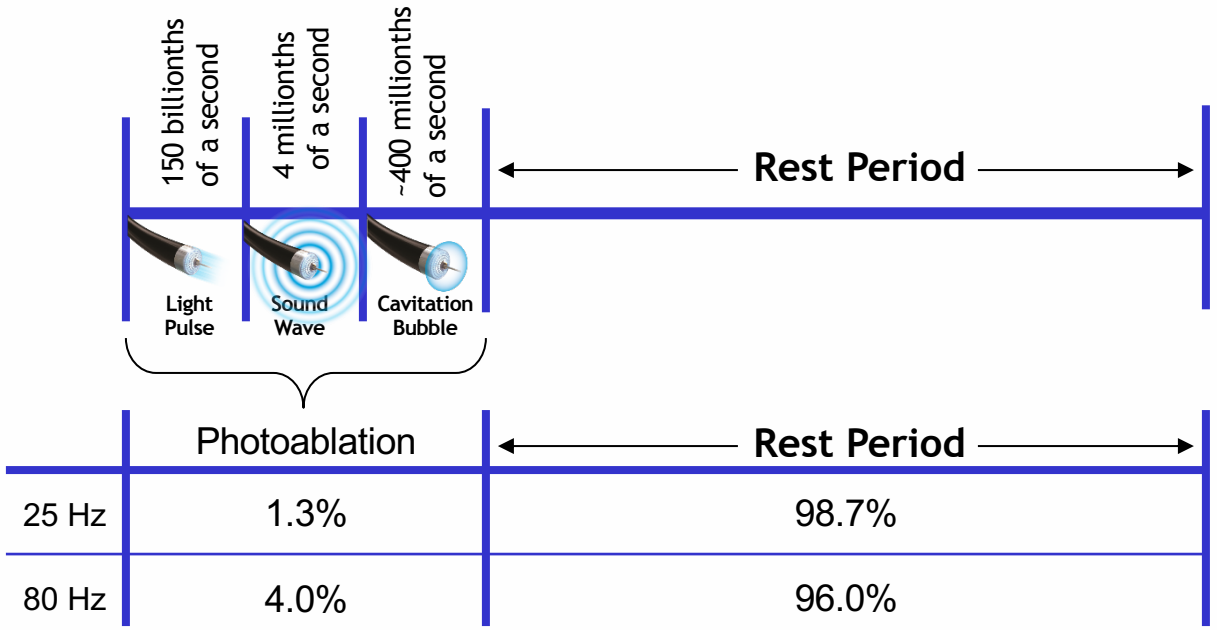
1 Light Pulse	2 Sonic Wave	3 Vapor Bubble
Ablates mixed morphologies at molecular level.	Impacts hard materials and changes vessel compliance	Debulks mixed morphologies and breaks down materials
		
Safe in all lesion types	Affects both luminal and medial disease	Debulking for luminal gain

Effective plaque modification



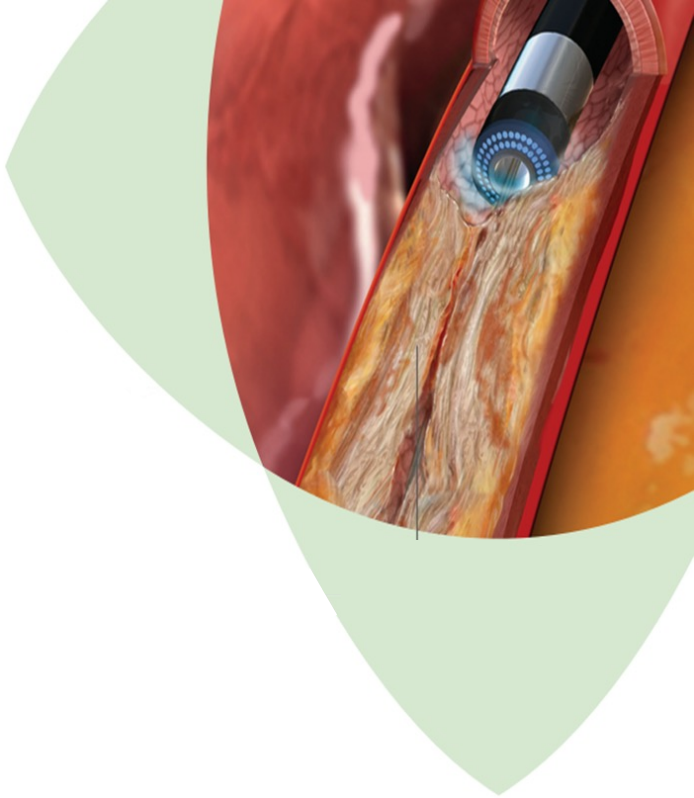
- Expansion and collapse of vapor bubble breaks down plaque and clears by-products away from tip
- The energy is pulsed to prevent thermal damage and allows the acoustic pressure wave to modify hard/fibrous morphologies

Timeline of a Single Laser Pulse



ELCA

Excimer Laser Coronary Atherectomy



Indications

- Total Occlusions – traversable by guidewire
- In-Stent Restenosis
- Saphenous Vein Grafts
- Moderately Calcified
- Failed Balloon
- Ostial Lesions
- Long Lesions

Contraindications

- Unprotected Left Main
- Beyond acute bend lesion where catheter cannot traverse
- Guidewire cannot pass through lesion
- Lesion located within bifurcation
- Patient not acceptable for bypass graft surgery

ELCA

Excimer Laser Coronary Atherectomy

Settings:

- Fluence (mJ/mm^2)
- Frequency (Hz)

Two Third's Rule for Vessel Sizing

Laser Sizes:

	Fluence	Repetition	On/Off
6 Fr Guide- 0.9 mm	30-80 mJ / mm²	25-80 Hz	10/5 sec
6 Fr Guide- 1.4 mm	30-60 mJ / mm²	25-40 Hz	5/10 sec
7 Fr Guide- 1.7 mm	30-60 mJ / mm²	25-40 Hz	5/10 sec
8 Fr Guide- 2.0 mm	30-60 mJ / mm²	25-40 Hz	5/10 sec

Bilodeau, L., et. al. (2004). Novel use of a high-energy excimer laser catheter for calcified and complex coronary artery lesions. Catheterization and Cardiovascular Interventions, 62, 155-161.

Why Prep with Laser?

- Easier delivery of balloons and stents[1]
- Potential for better stent apposition, leading to reduction in restenosis and stent thrombosis[2,3]
- Potential reduction of distal embolization[1,3]
- Balloon at lower pressure

1 - Pratsos, A. (2009). Atherectomy and the role of excimer laser in treating CAD. Cardiac Interventions Today, January/February, 27-34.
2 - Mehran, R., Mintz, G., et. al. (1997). Treatment of in-stent restenosis with excimer laser coronary angioplasty. Circulation, 96(7), 2183-2189.
3 - Dahm, J., Kuon, E. (2000). High energy eccentric excimer laser angioplasty for debulking diffuse in-stent restenosis leads to better acute and 6-month follow-up results. Journal of Invasive Cardiology, 12, 335-342

Published complication rates for ELCA (2000-2015)

Lead Author	# of Patients	Perforation Rate	MACE Rate
Giri[27]	93	0	1.1%
Singh[31]	56	0	0
Fernandez[7]	58	1.7%	1.7%
Nishino[26]	10	0	0
Bilodeau[13]	95	0	5.3%
Ajani[28]	208	0	0
Dorr[9]	14	0	0
Chen[1]	35	0	0
Liu[2]	20	0	0
Shishikura[32]	50	0	0
Ambrosini[33]	80	0	1.3%
Pratsos[15]	101	0	0
Badr[34]	119	1.7%	NR
Tarsia[35]	100	2.0%	2%
Niccoli[36]	60	0	0%
Total	**1099**		
Weighted Average		**0.46%**	**1.1%**

Results of In-stent restenosis outcomes with ELCA laser

Author Year	Intervention/ Study	Pts N	Procedural success	In hospital complication and MACE						
				Dissection	Perforation	Q-wave MI	No reflow	30-d MACE	Mortality	Emergent CABG
Hamburger[30] 2000	ELCA + PTCA	16	100	2	n/a	n/a	n/a	n/a	1	n/a
Koster[24] 1999	LARS	440	92	4.8	0.9	0.5	2	n/a	1.6	n/a
Liu[25] 2000	ISR, China	20	100	0	0	0	0	0	0	0
Mehran[14] 2000	ELCA vs. Rotational	119	77	n/a	0	0	0	4	0.7	3.3
Dahm[23] 2000	ELCA + PTCA	39	99.8	17.9	n/a	n/a	n/a	n/a	n/a	n/a
Ajani[28] 2001	ISR	33	98.5	10	n/a	0	n/a	n/a	0	0
Giri[27] 2001	LARS ELCA vs. BA	93	98.9	n/a	n/a	0	n/a	1.1	0	1.1
Nishino[26] 2012	Focal ISR	10	100	0	0	0	n/a	0	0	n/a
Badr[29] 2013	ISR	15	86.7	6.7	0	0	6.7	n/a	0	0
Weighted Average			**91.40%**							

MI = Myocardial Infarction, MACE = Major Adverse Cardiac Event, CABG = Coronary Artery Bypass Graft

How has ELCA changed over the years?

Improved catheter design

- More fibers, optimally placed
- Improved flexibility
- Hydrophilic coating
- Improved tracking and pushability
- 0.9 X 80 with higher settings and more fibers

Improved technique

- Saline infusion
- Slow advancement
- Settings
- Multiple passes, increasing settings with each pass

ISR case June 2018

Needed precise placement at the ostium of the RCA

- **CoreVision's Device Detection enable precise placement of the device without using cine**
- **AngioSculpt PTCA's precision ensured no slippage during inflation**

Used a 3.5x15 AngioSculpt PTCA at 18 ATM

Post AngioSculpt PTCA result

Images from: Optimizing PCI in Complex Procedures: June 1-2, 2018 Live Case
St. Francis Hospital , NY

ISR case June 2018

Laser with AngioSculpt RX PTCA final results

- **Delivered a 4.0 x 38 DES and post-dilated with a 4.0 NC balloon at 20 ATM**

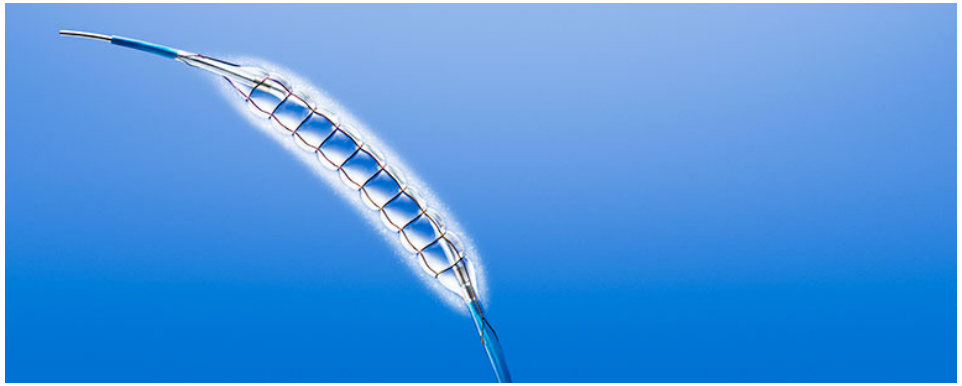
Images from: Optimizing PCI in Complex Procedures: June 1-2, 2018 Live Case St. Francis Hospital , NY

Operator: Dr. Allen Jeremias

Specialty Balloons

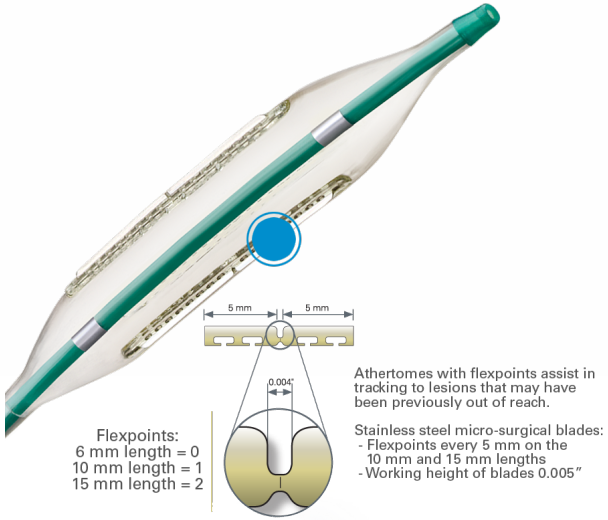
Focal Force Balloons

- Apply high force focally (Unlike NC balloons)
- Limit dissections
- Examples: Angiosculpt EVO, Chocolate



Cutting Balloons

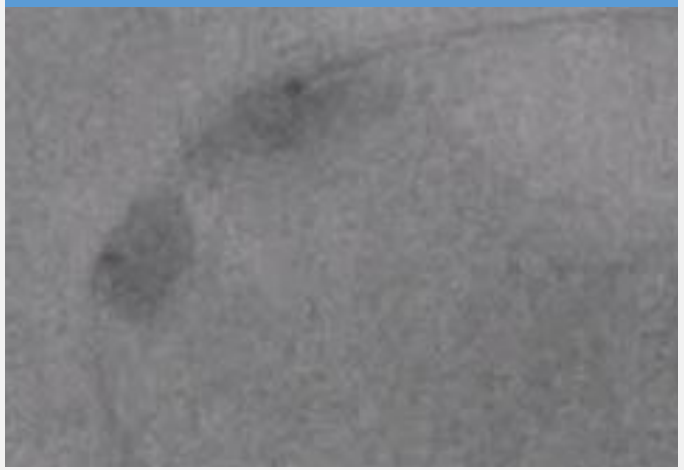
- Blades/Atherotomes to cut into plaque
- Risk of perforation/dissection
- Examples: Wolverine



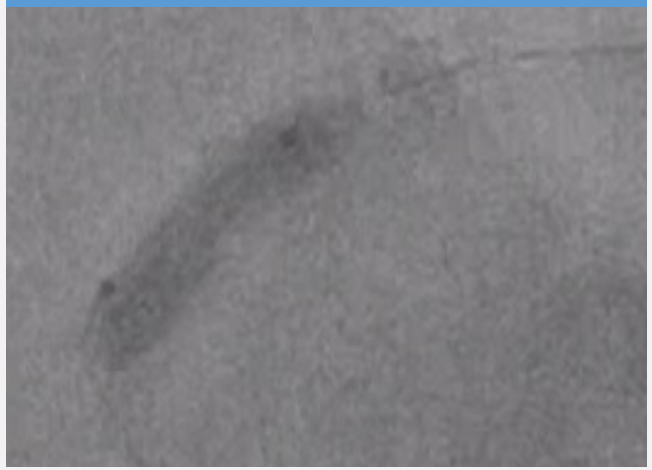
Plaque Modification Balloons

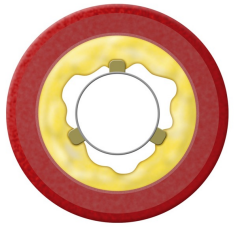
AngioSculpt RX PTCA scoring balloon

Balloon (dog-bone)

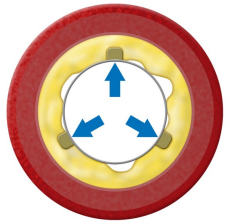


AngioSculpt at 20 ATM same lesion





Rectangular edges "lock "the device into challenging lesions like ISR and ostial.[16]



Leading edges drive outward force 15-25 times that of POBA.[17] The helical nitinol cage creates concentric scoring to engage plaque regardless of device orientation.

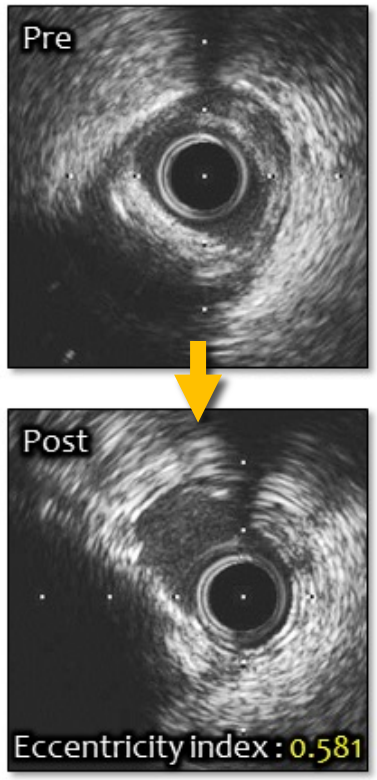
Minimal slippage

More dilatation force

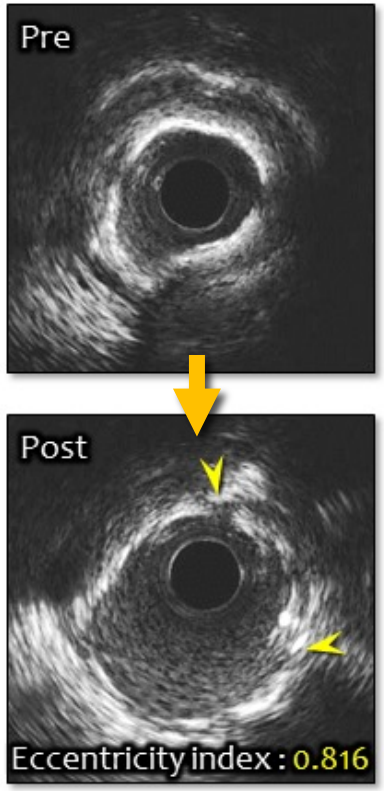
Images courtesy of Optimizing PCI in Complex Procedures: June 1-2, 2018 Live Case St. Francis Hospital , NY

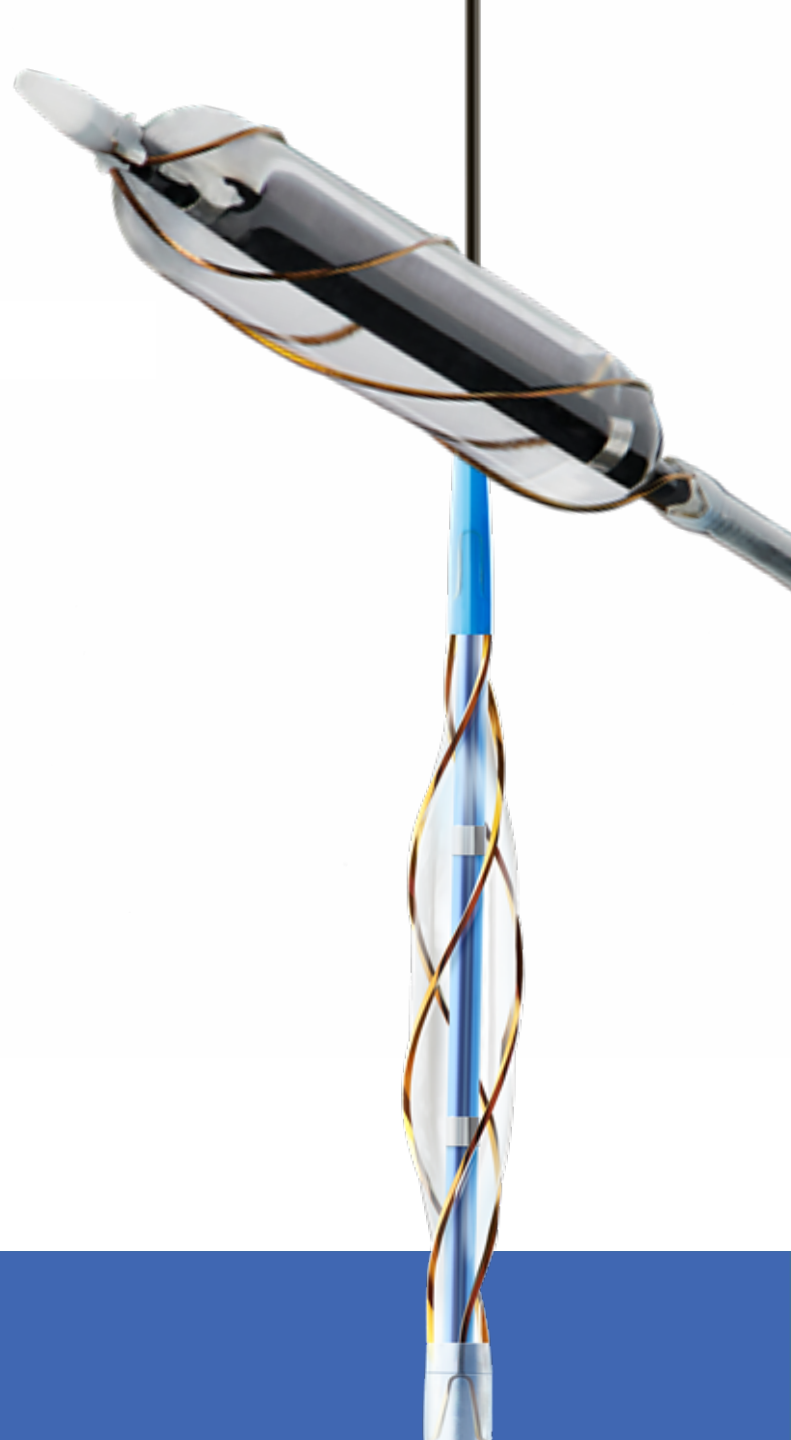
AngioSculpt PTCA scoring balloon

Conventional Balloon

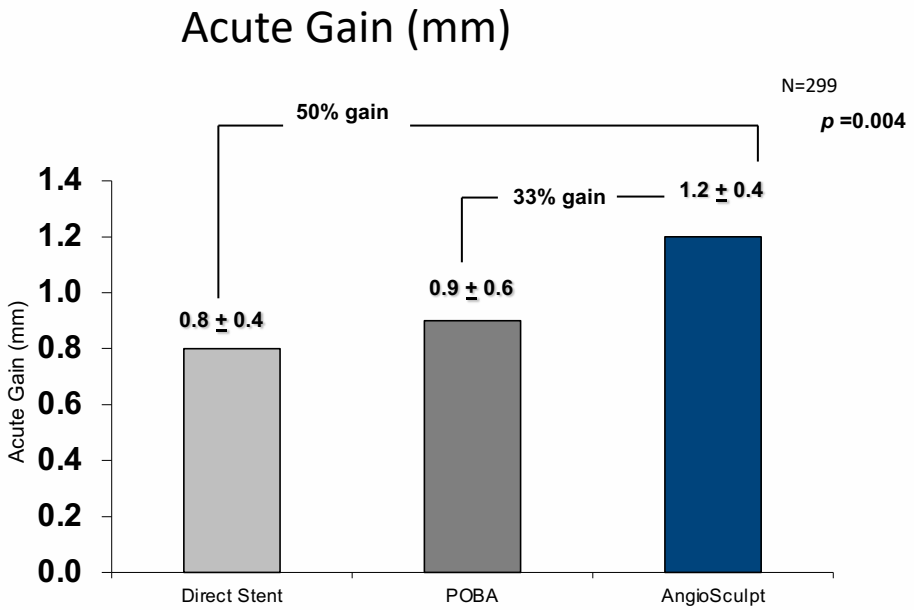


AngioSculpt





AngioSculpt delivers 33% acute gain vs POBA[18]



- **p = 0.004 applies to the comparison between Direct Stent vs. AngioSculpt**
- **comparison between Direct Stent vs. Pre-dil with POBA shows no statistical difference**

% Stent Expansion*

	Pre-dil with AngioSculpt	Pre-dil with POBA	Direct Stent
Soft	87%	75%	74%
Calcific	90%	75%	72%
Fibrotic	87%	82%	77%
Mixed	87%	77%	76%

AngioSculpt group exhibited greater % stent expansion than both POBA and direct stenting groups, regardless of plaque morphology

Plaque Modification

ShockWave C2

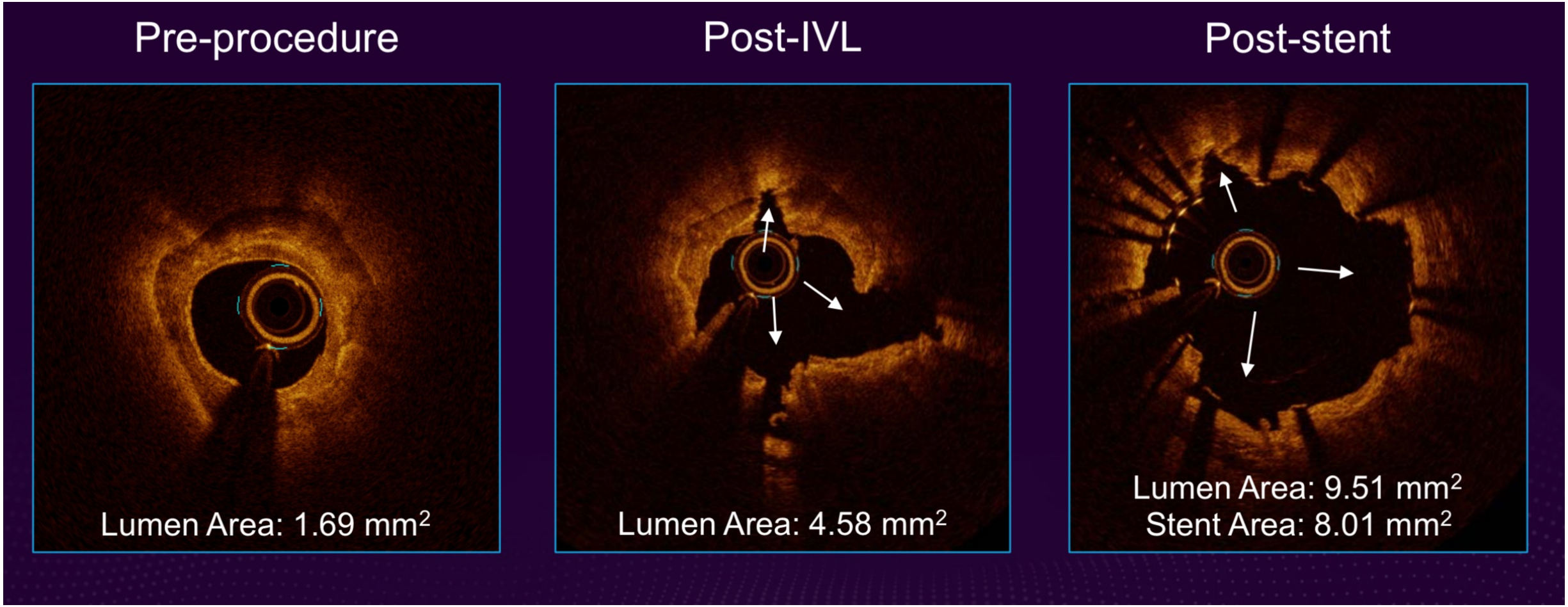
- 2 Emitters
- Saline/Contrast Mix
- Deliver one pulse per second (80 pulses/catheter)

DISRUPT CAD III

- 384 patients
- Long length (~50 mm or longer)
- Severe calcium
- Safety (30 Day MACE/1 Year)
  7.8%/13.8% (Driver by Periprocedural MI)
- Efficacy (Stent Delivery with <50% Stenosis without In-Hospital MACE)
  92.4% (355/384) <0.0001

DJ Kereiakes, et al TCT Connect 2020

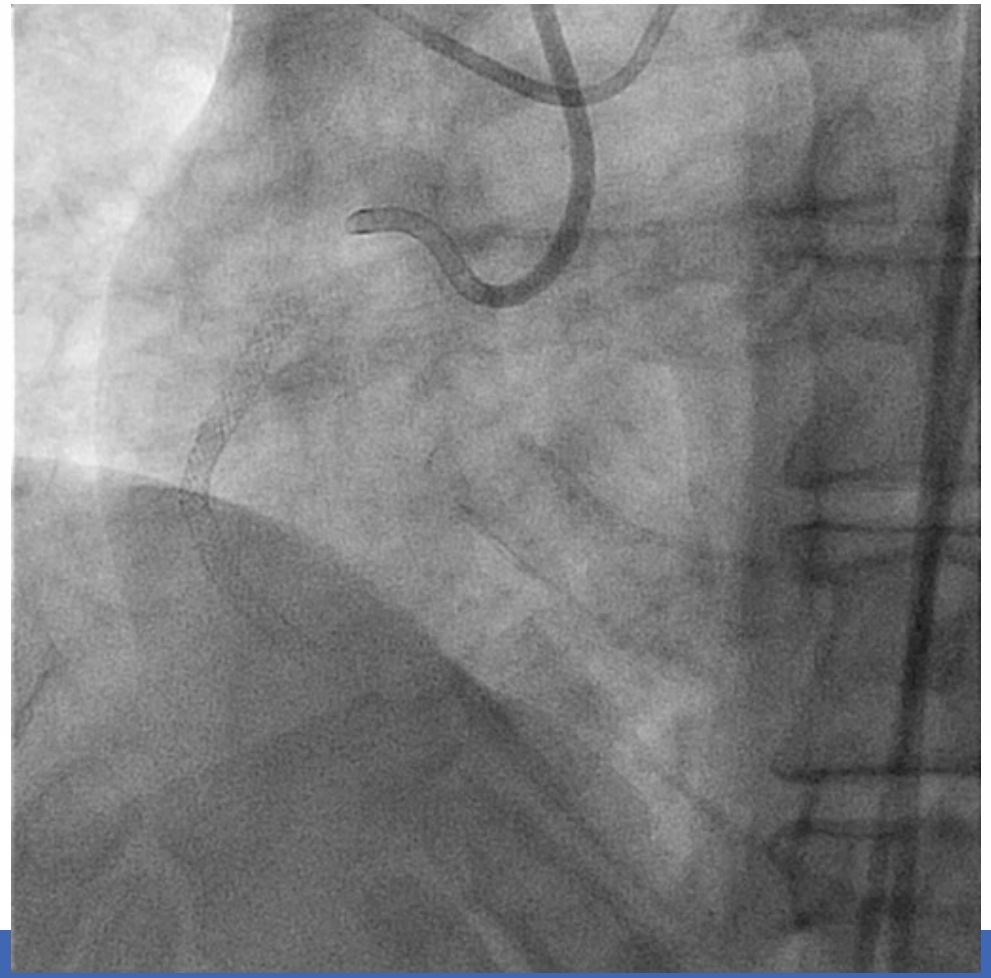
Plaque Modification

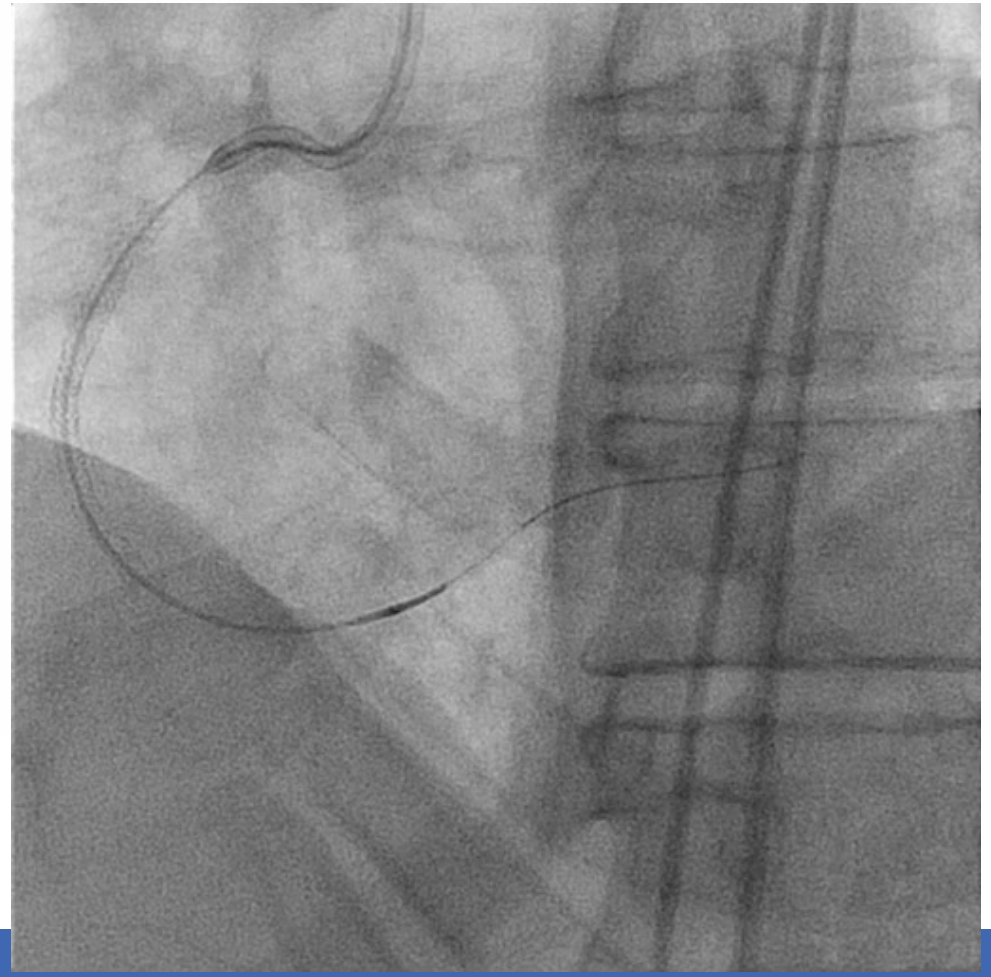


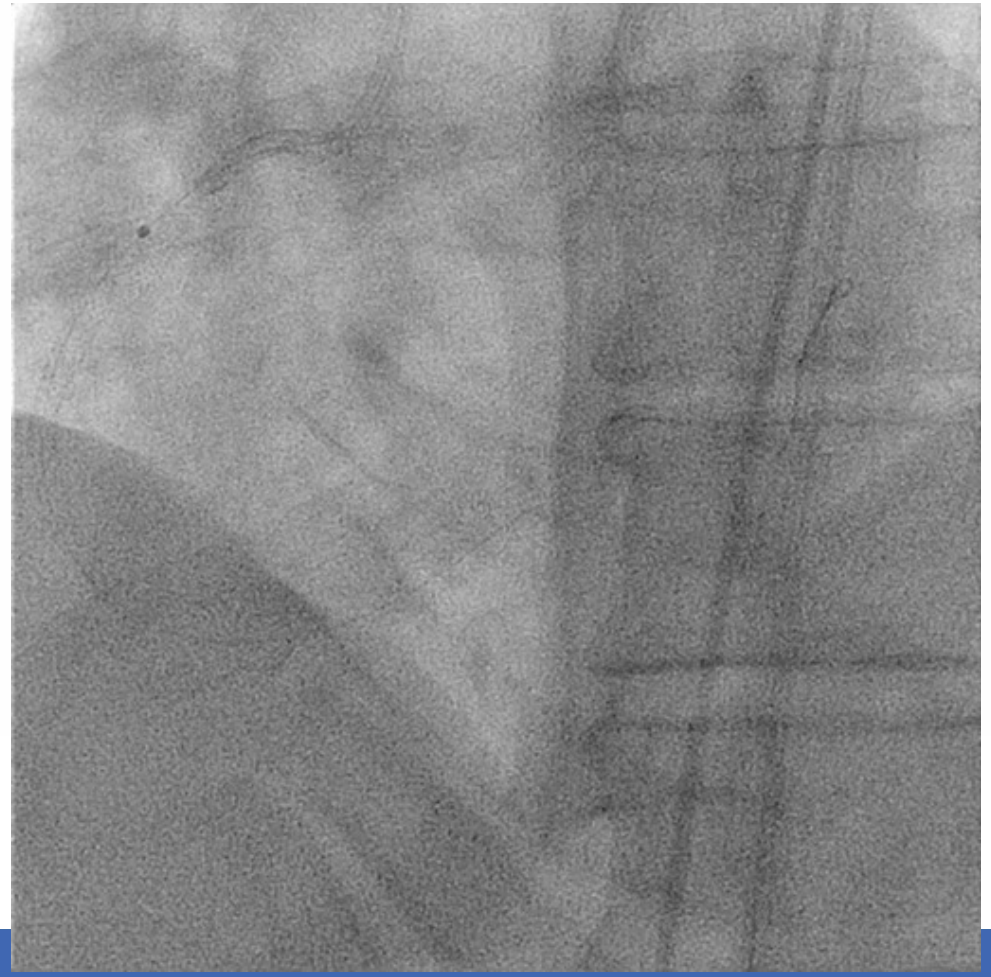
DJ Kereiakes, et al TCT Connect 2020

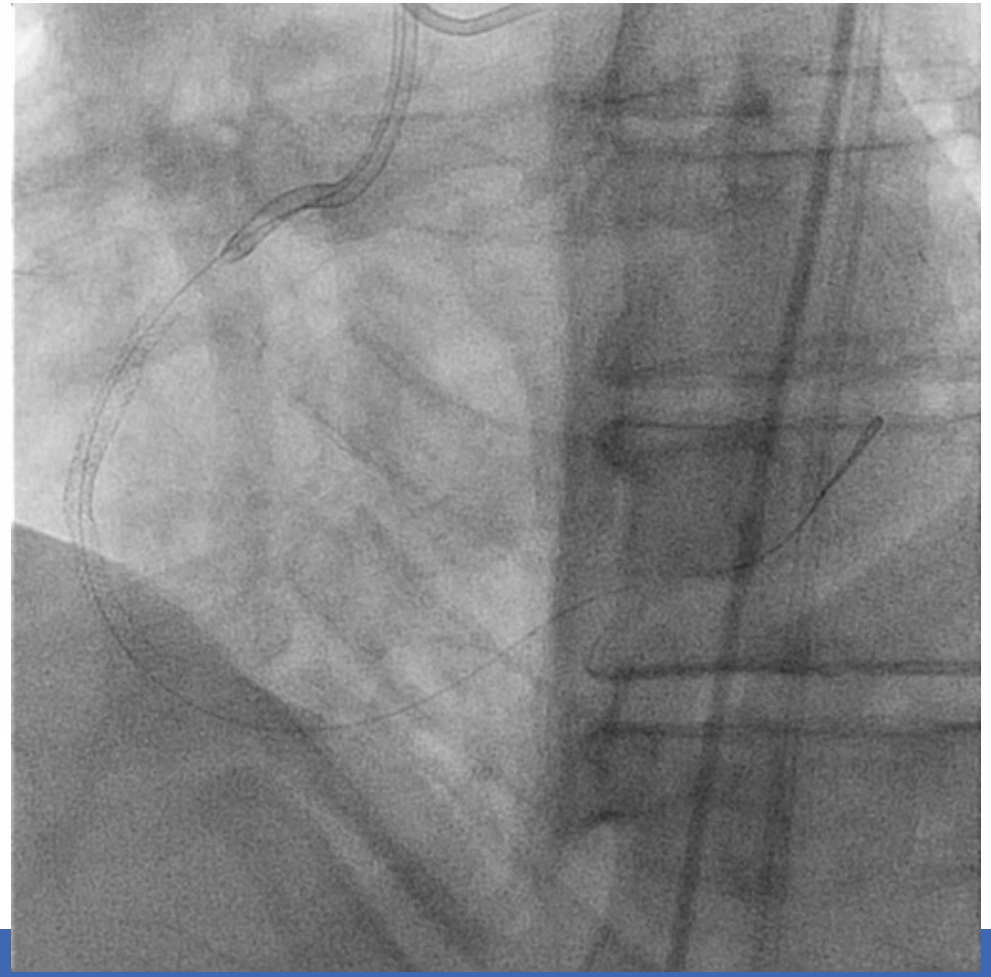
CASE: ISR

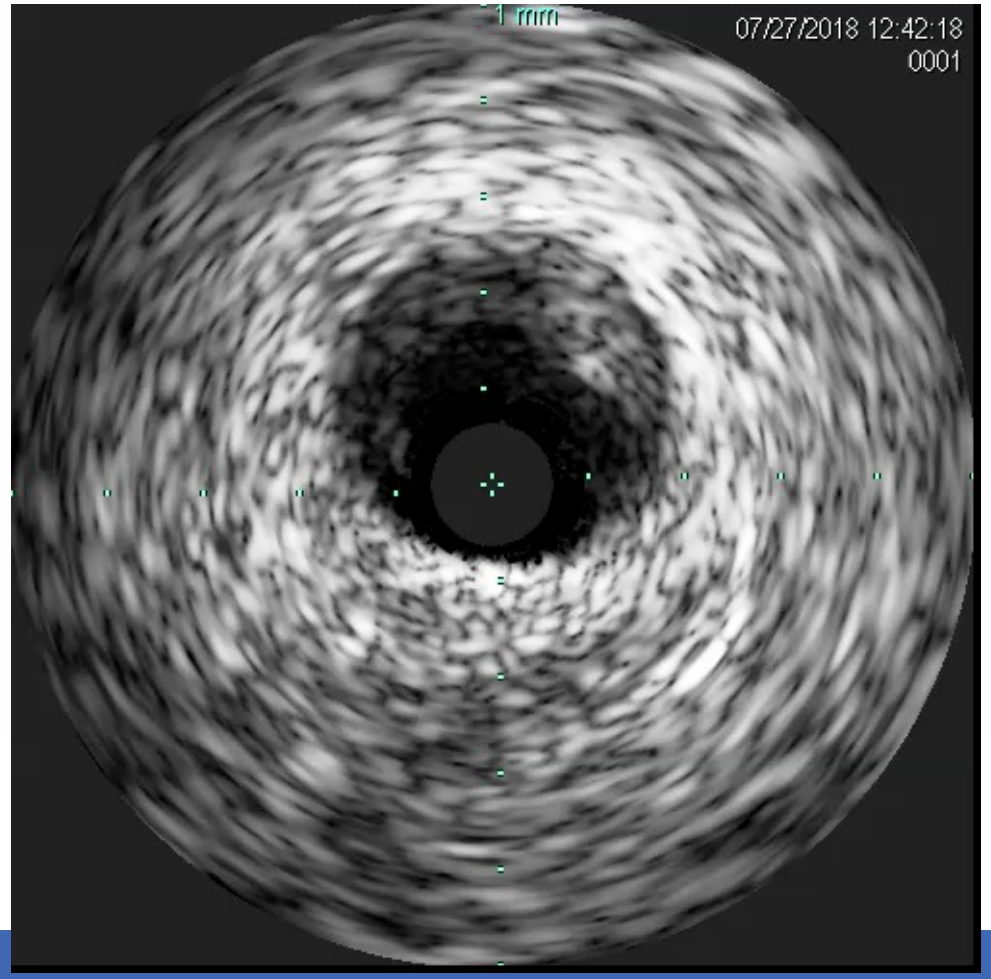
- 41 year old man
  - Presenting with Unstable Angina
  - CTO of the RCA Collateralized from the LCA
  - Prior Stents in the RCA







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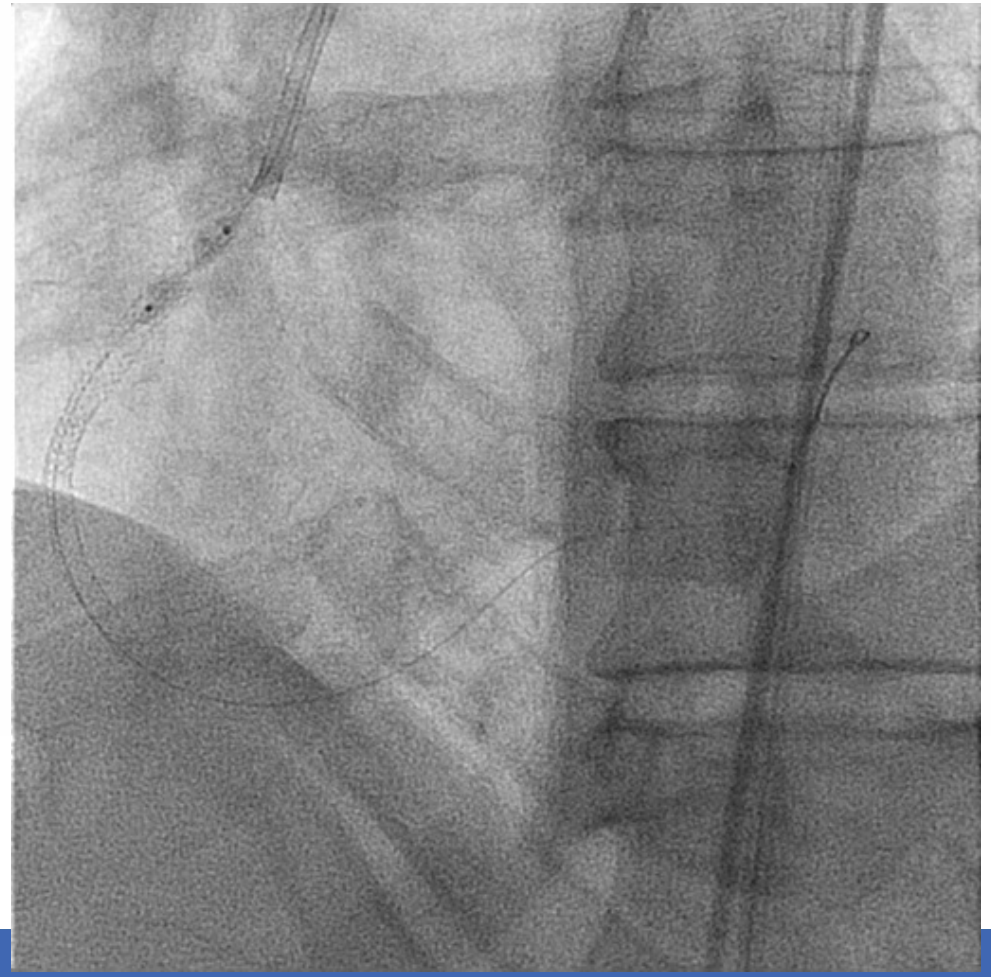

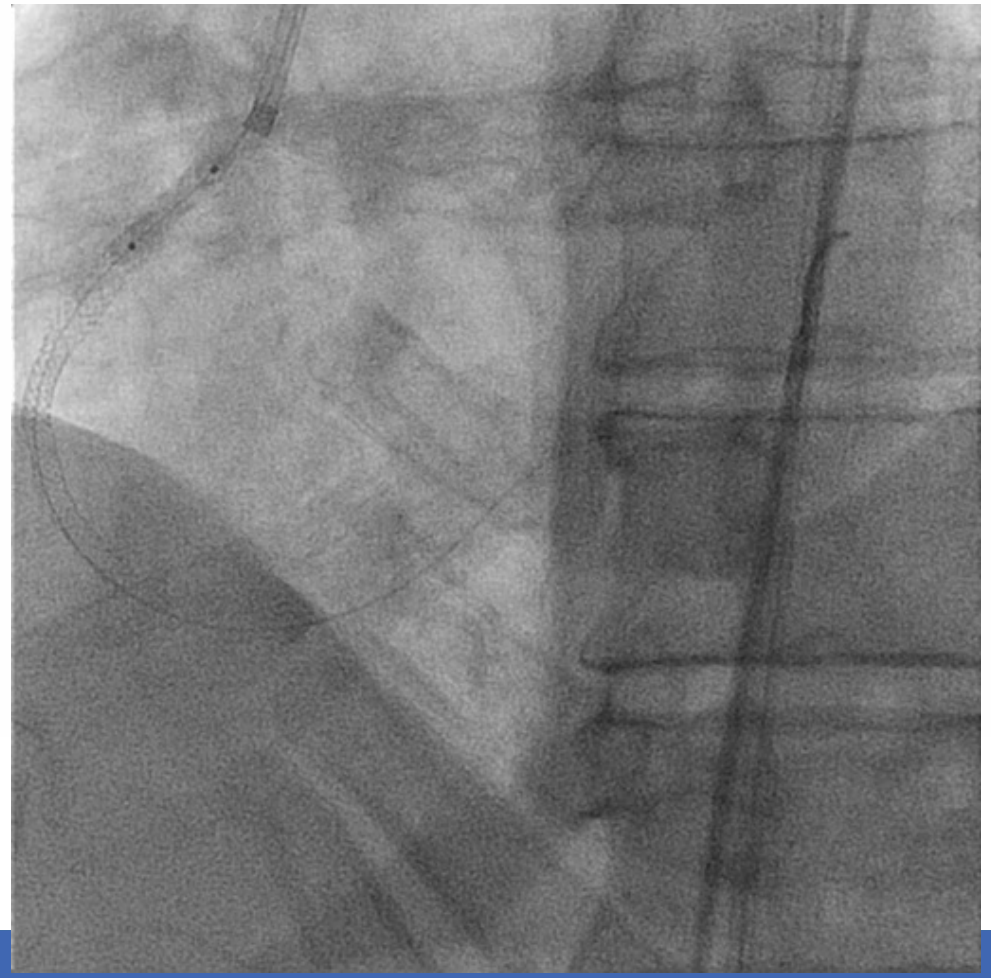

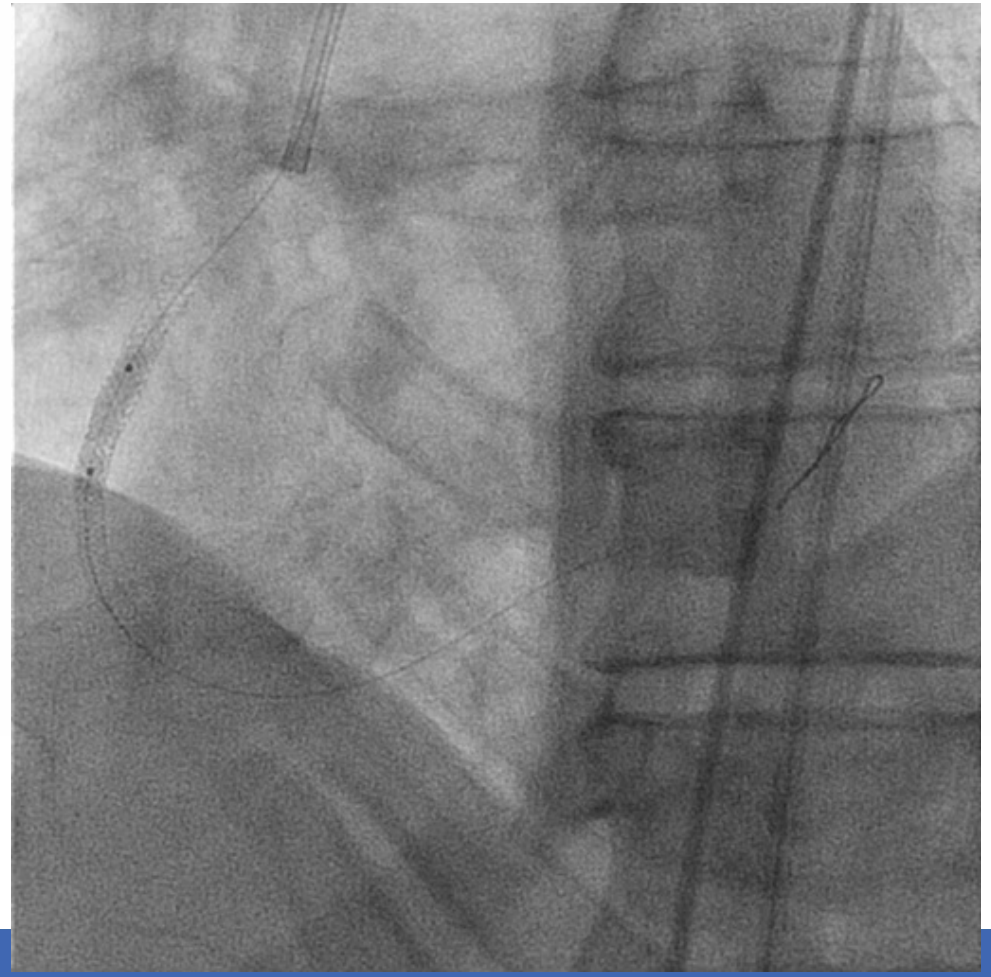

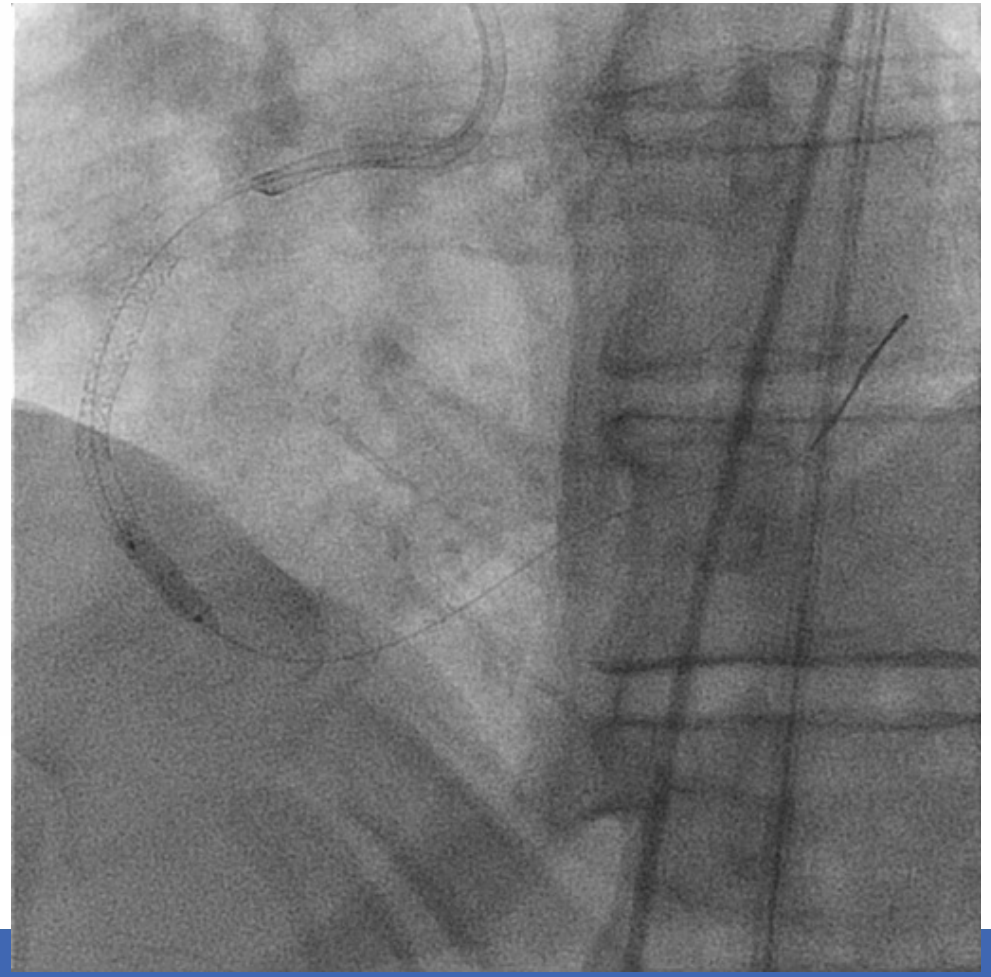

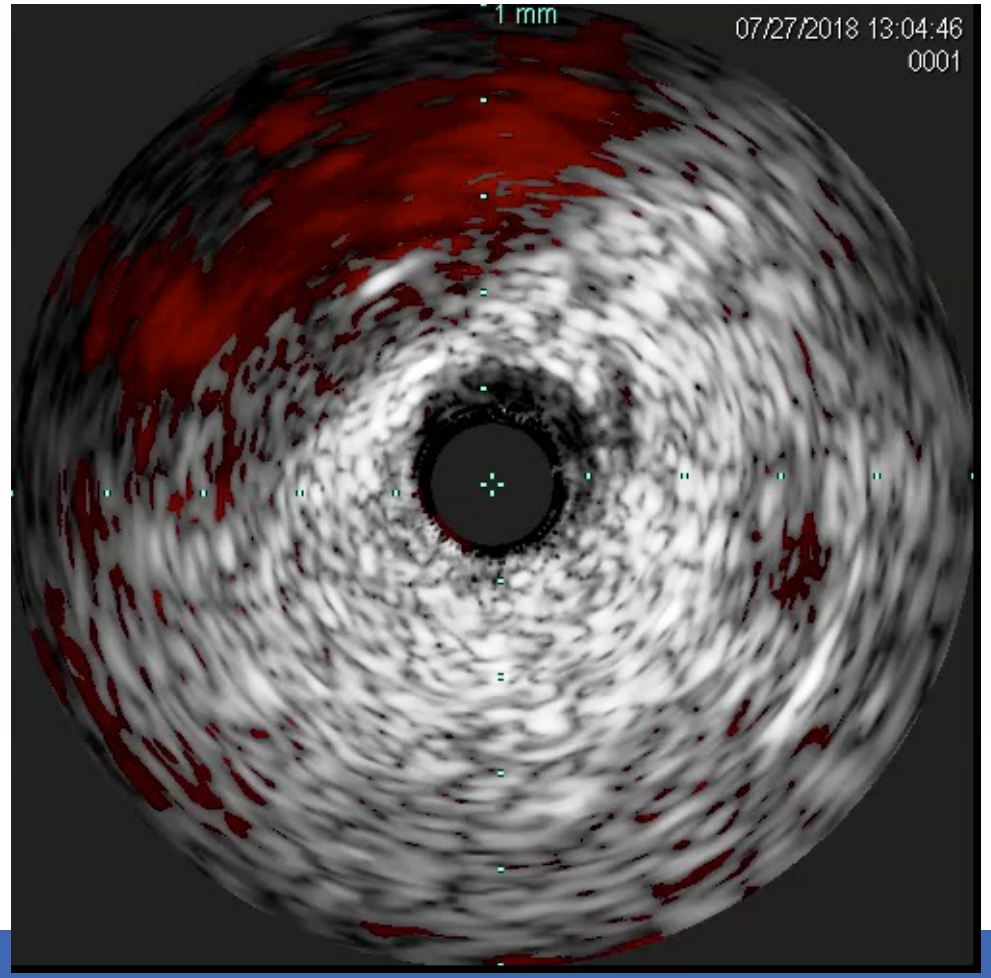
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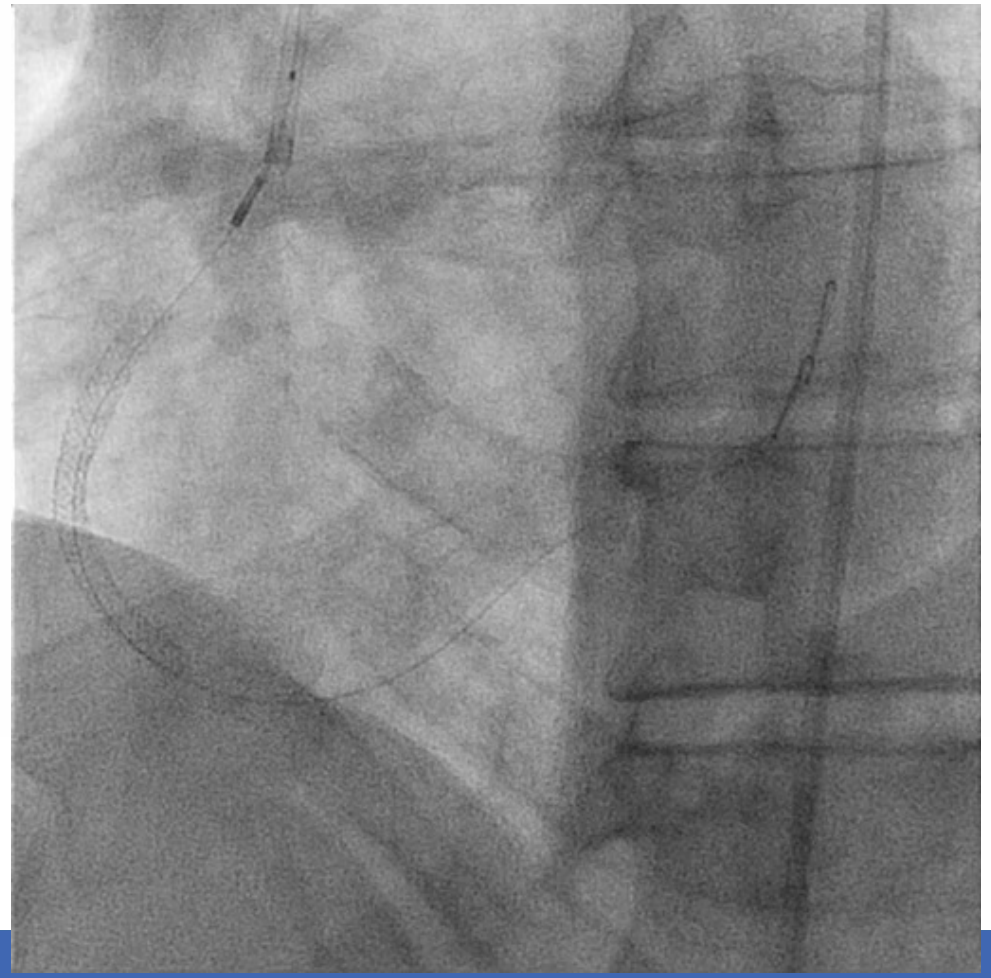
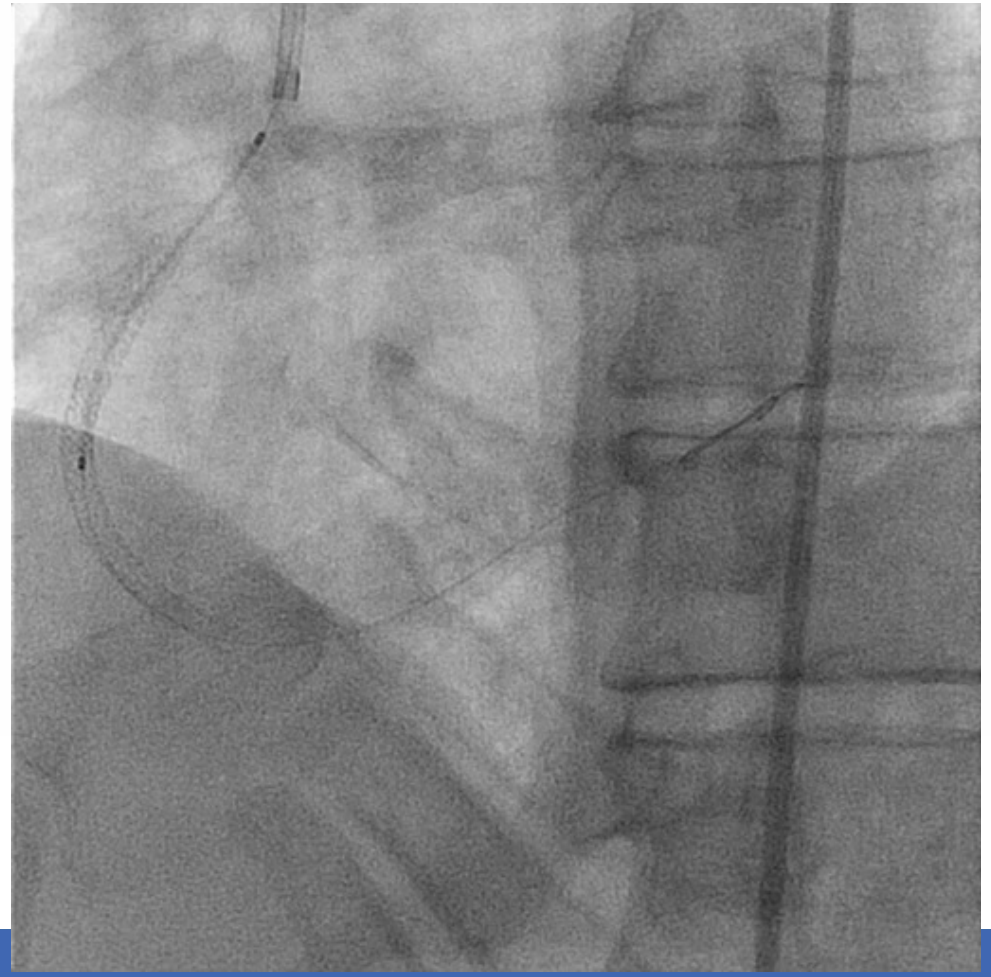
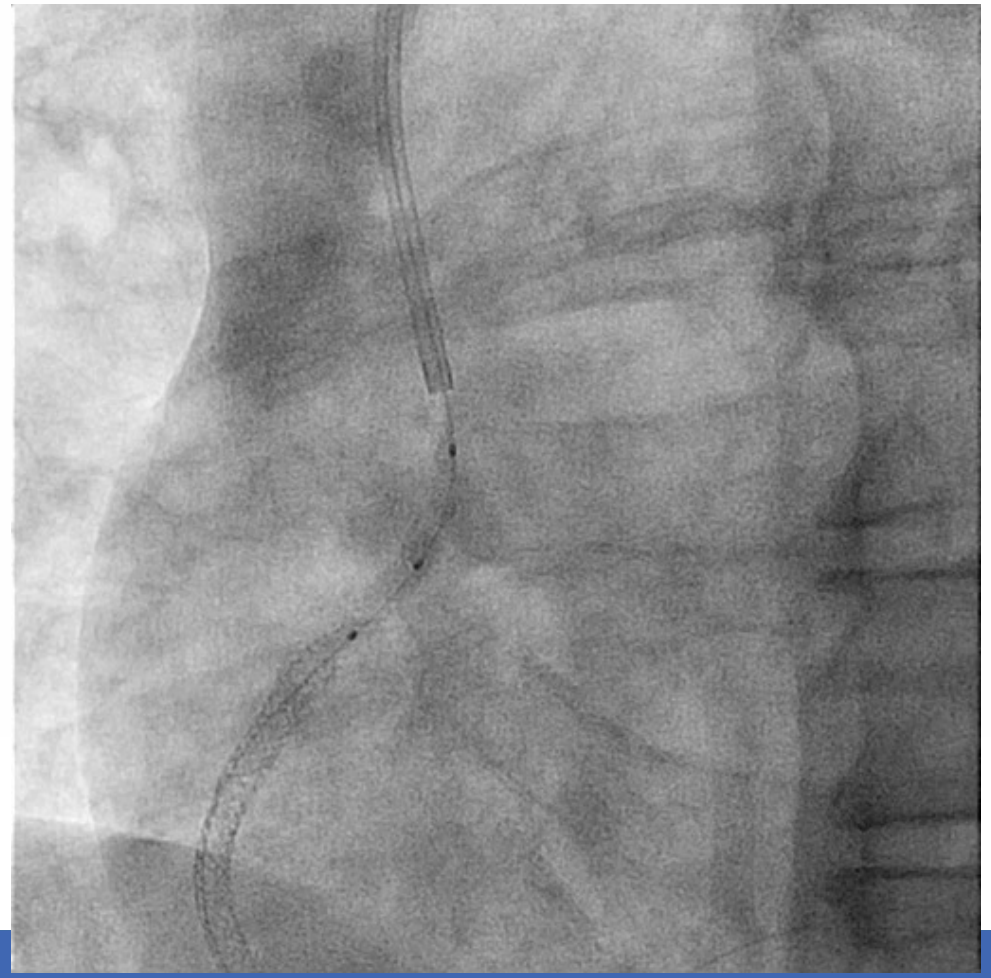
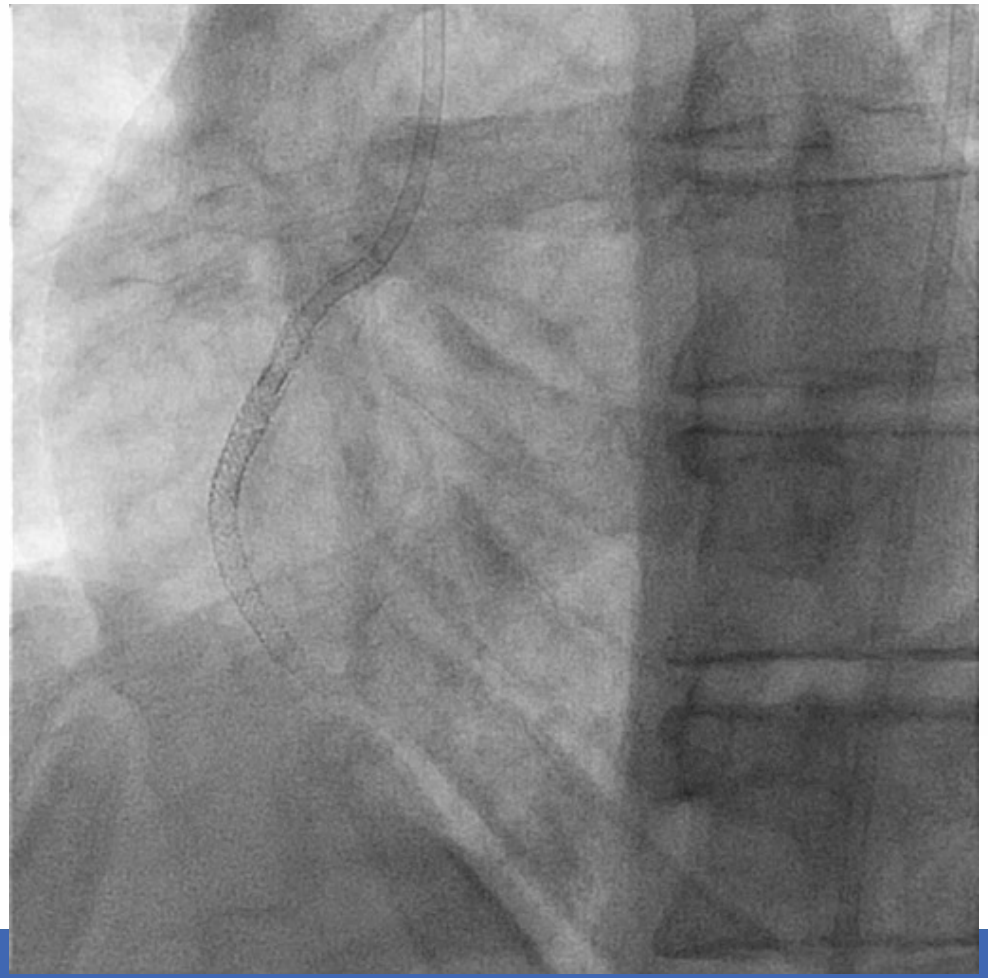


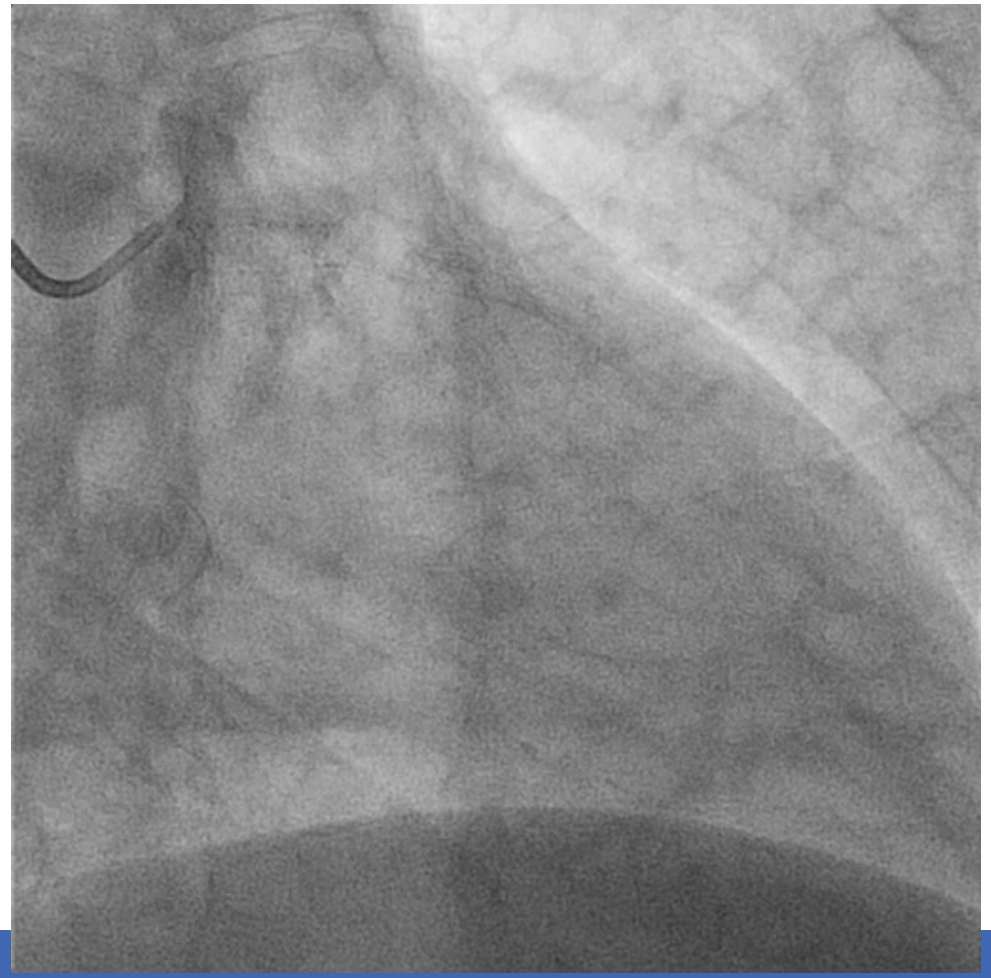


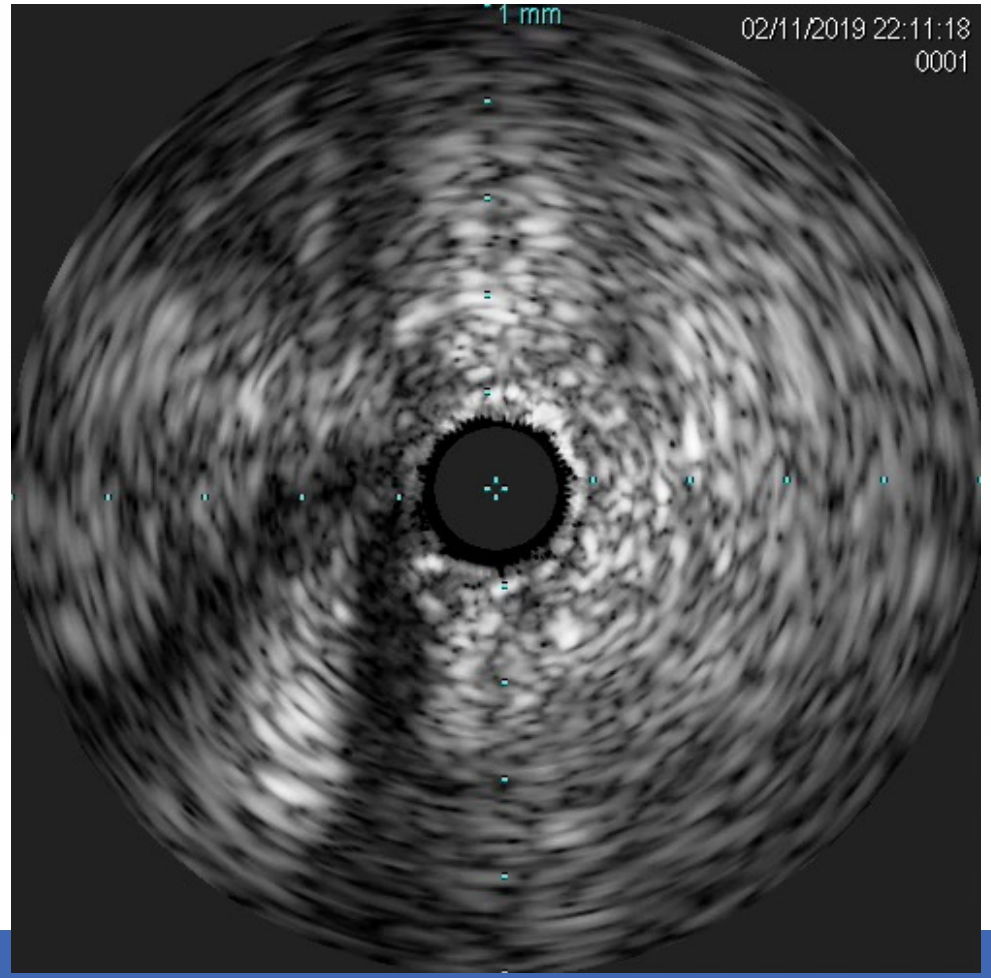




CASE: ISR

- 65 year old man
  - Presenting with Unstable Angina
  - Prior Stents in the LAD

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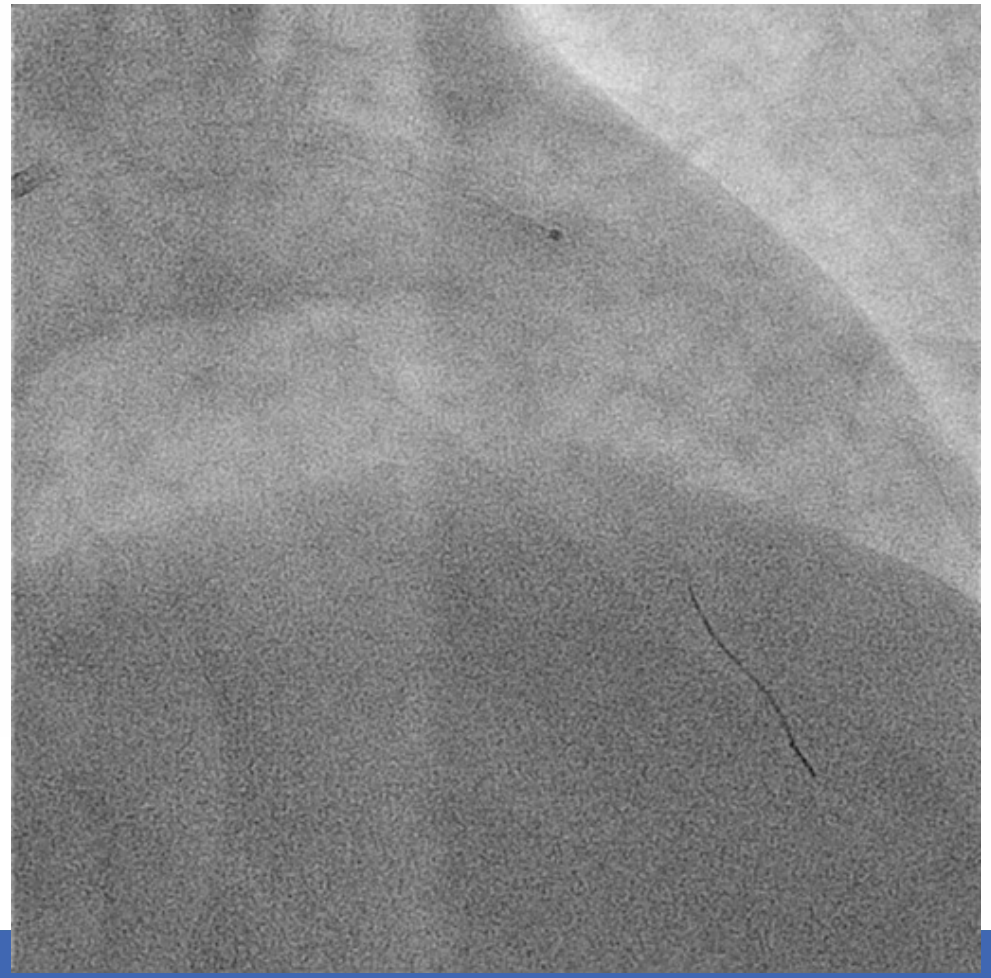

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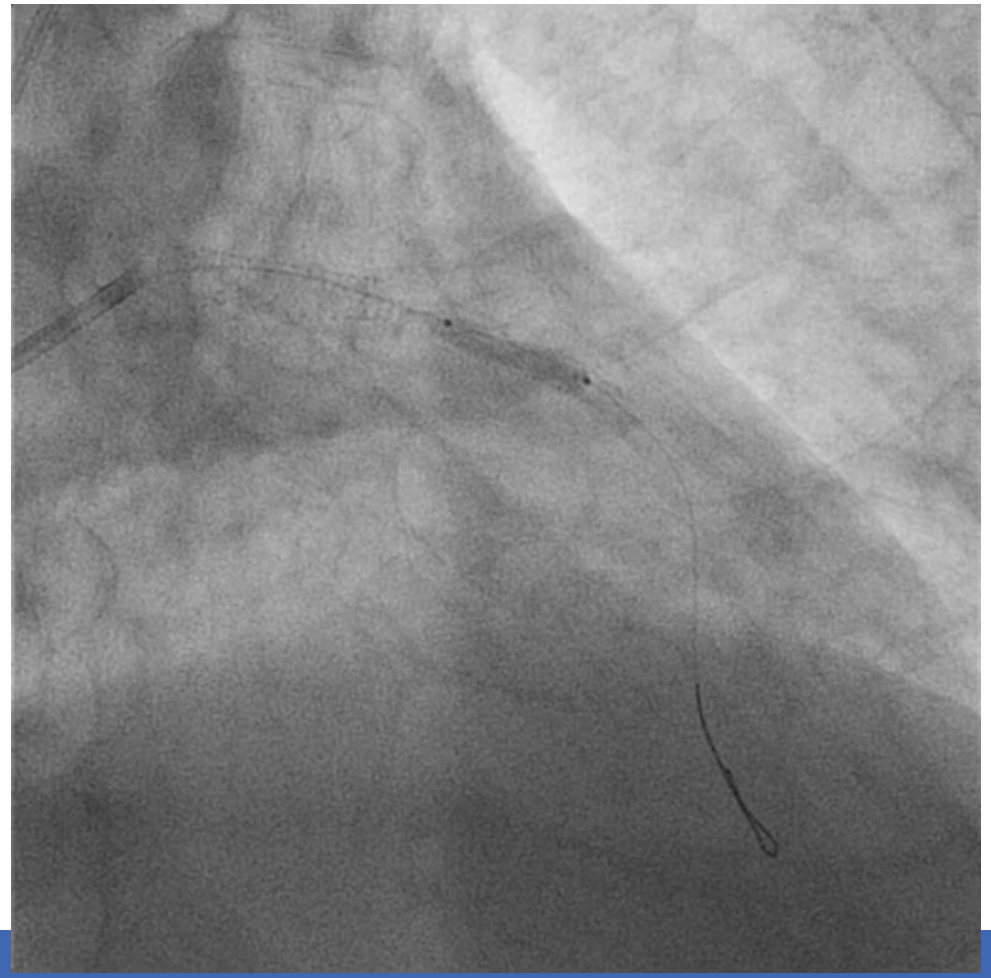
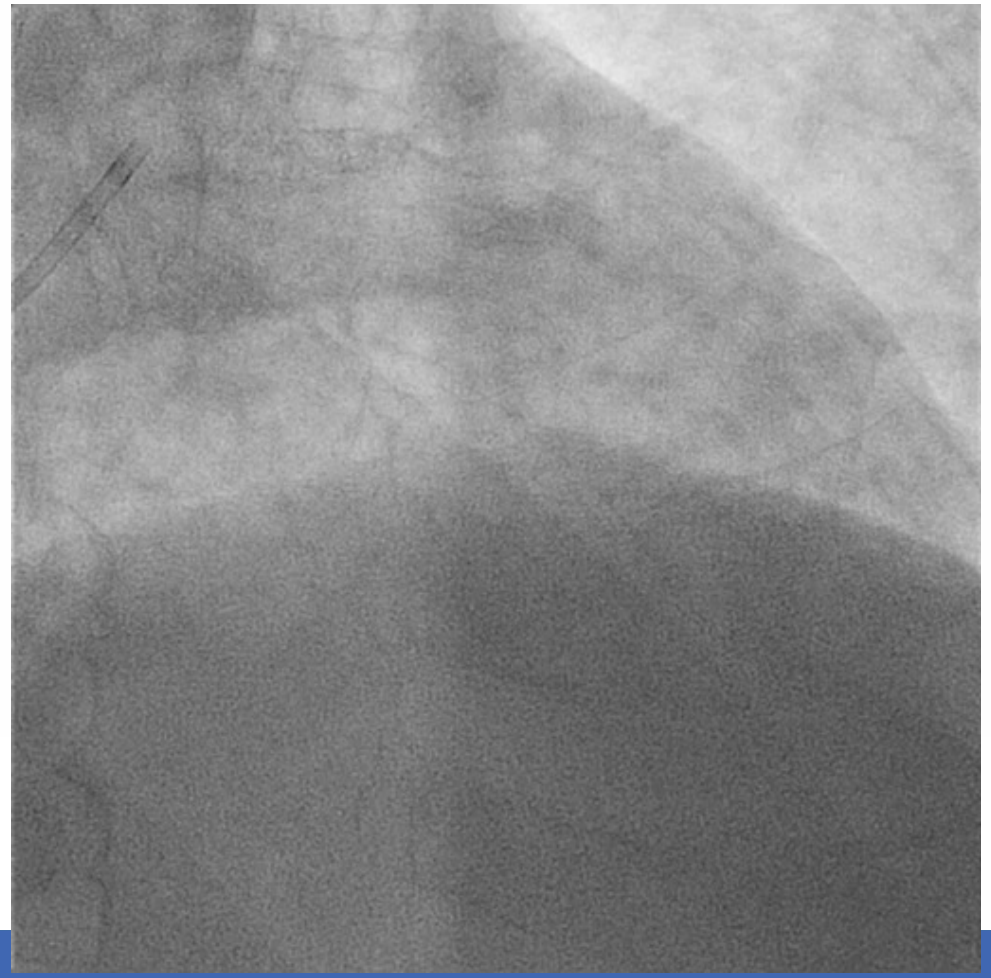
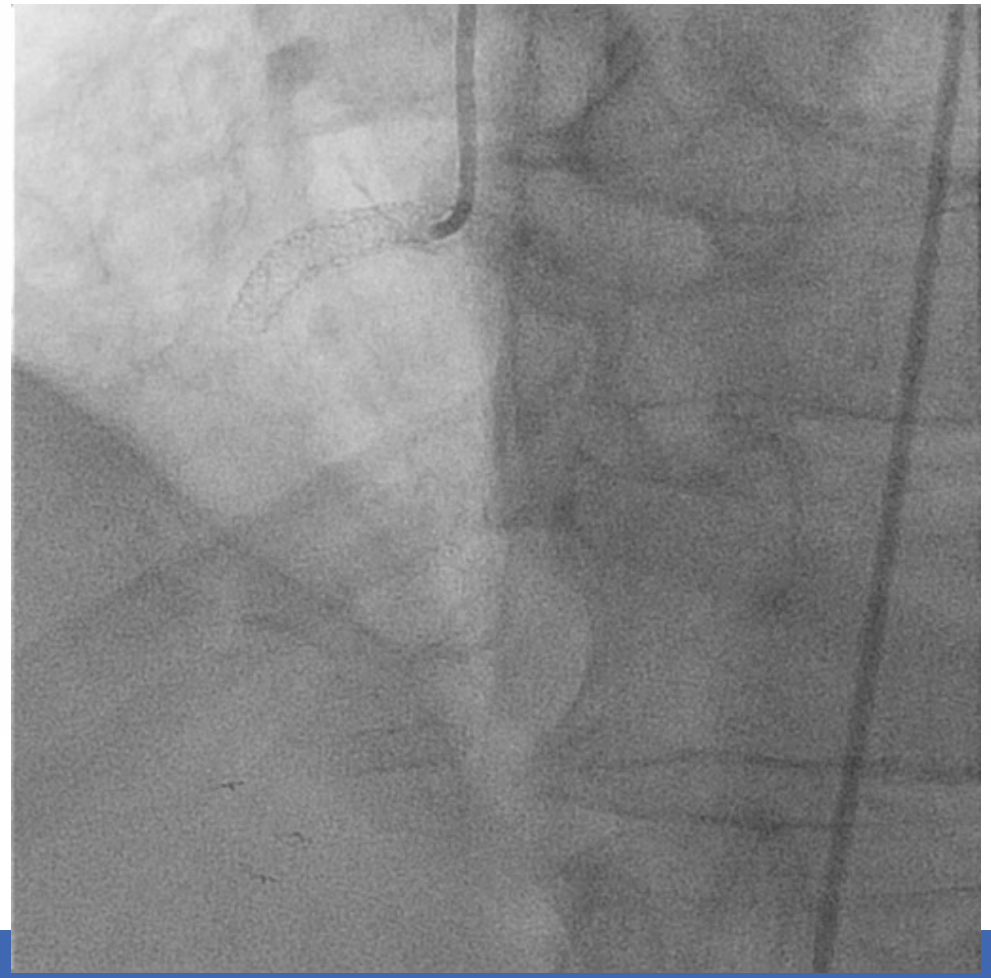




CASE: ISR

- 73 year old man
  - Presenting with Unstable Angina
  - Prior Stents in the RCA



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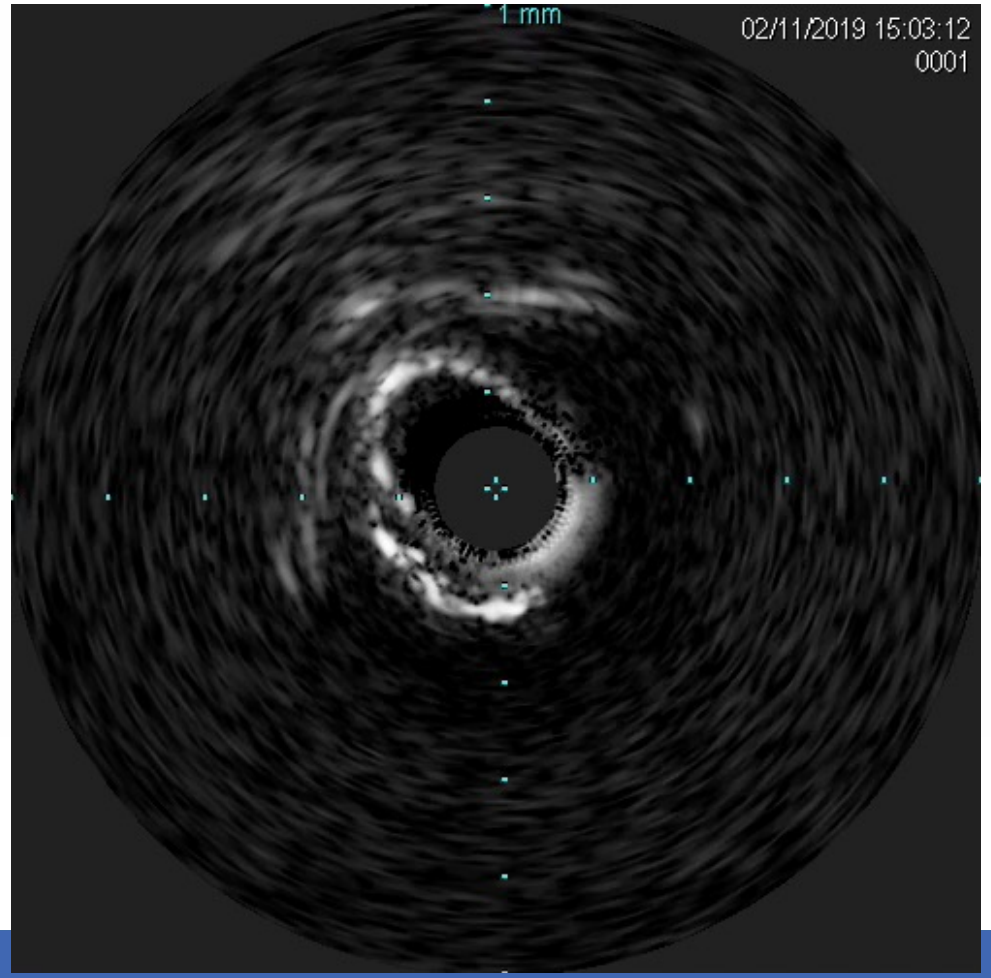
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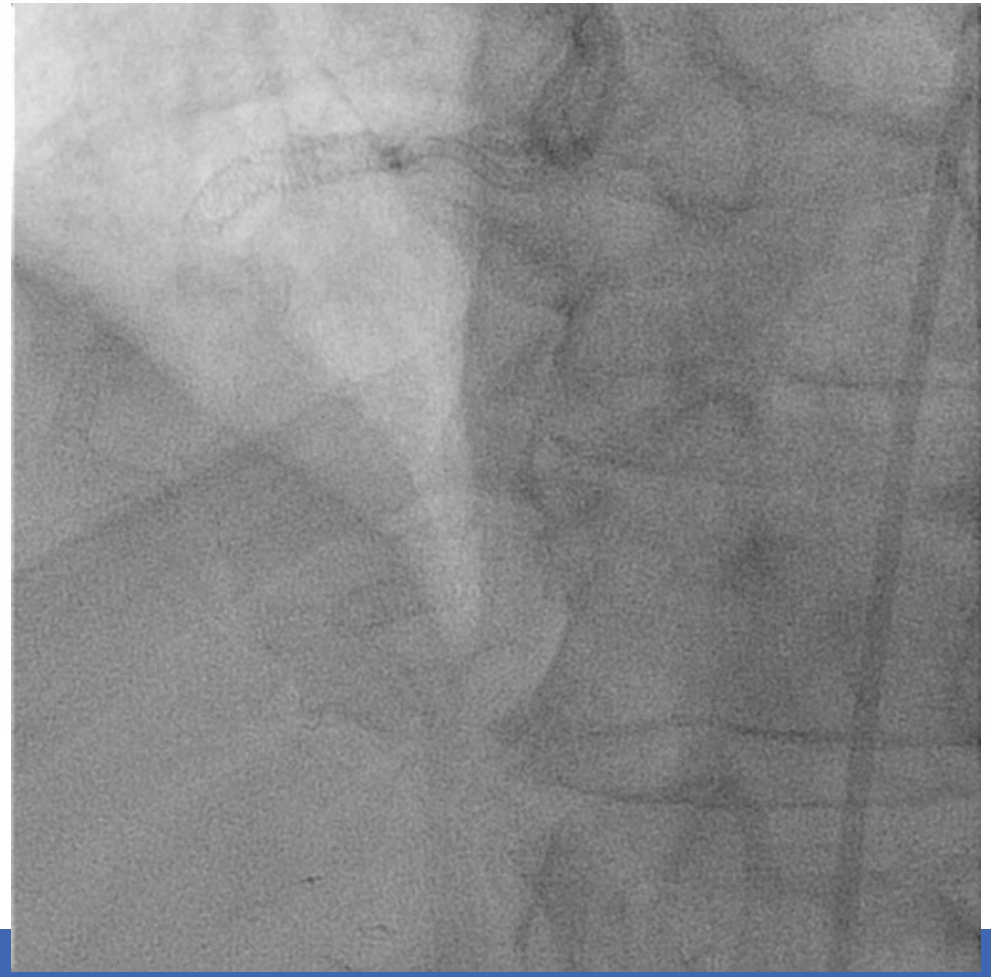

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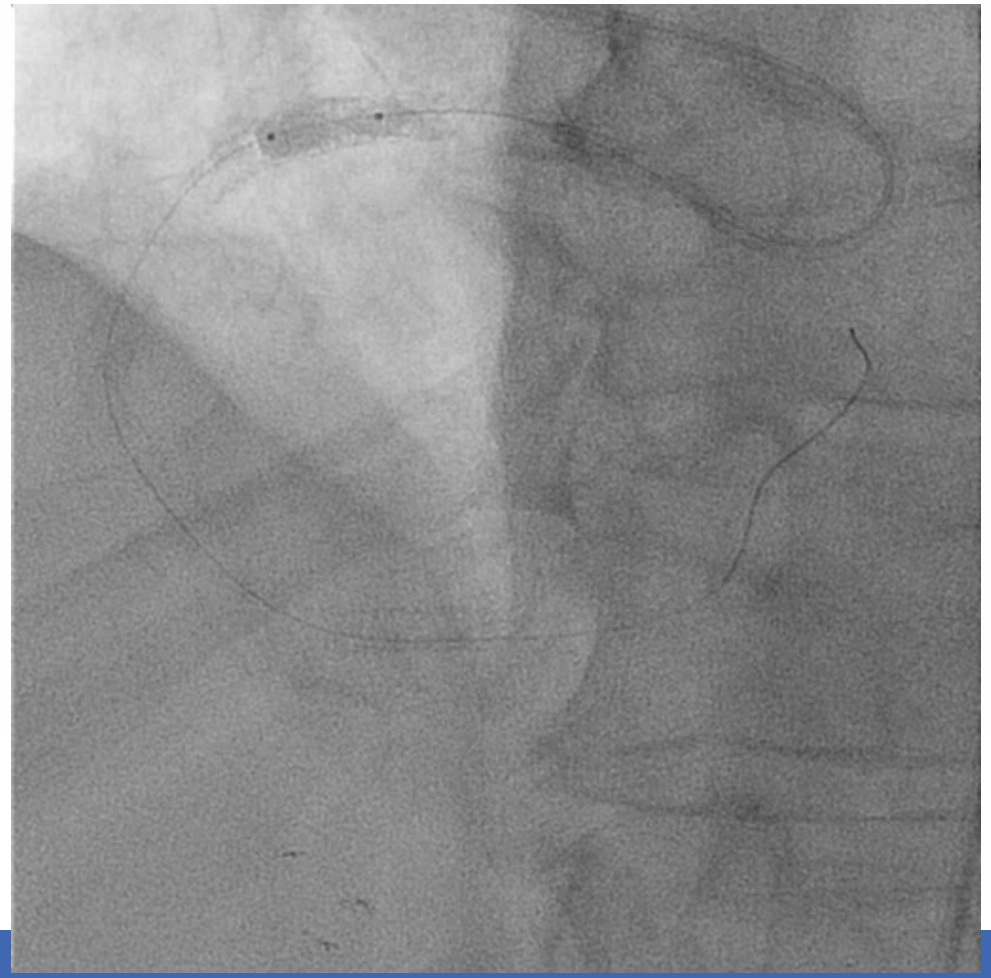

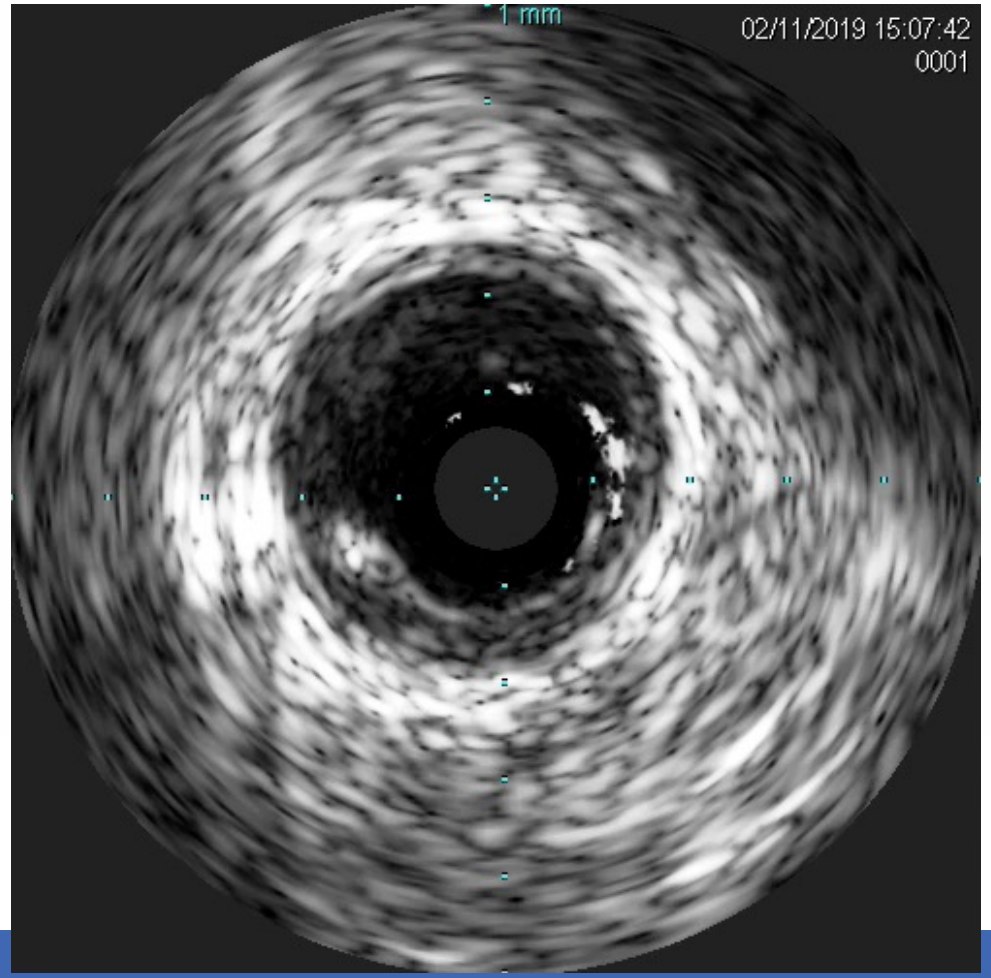
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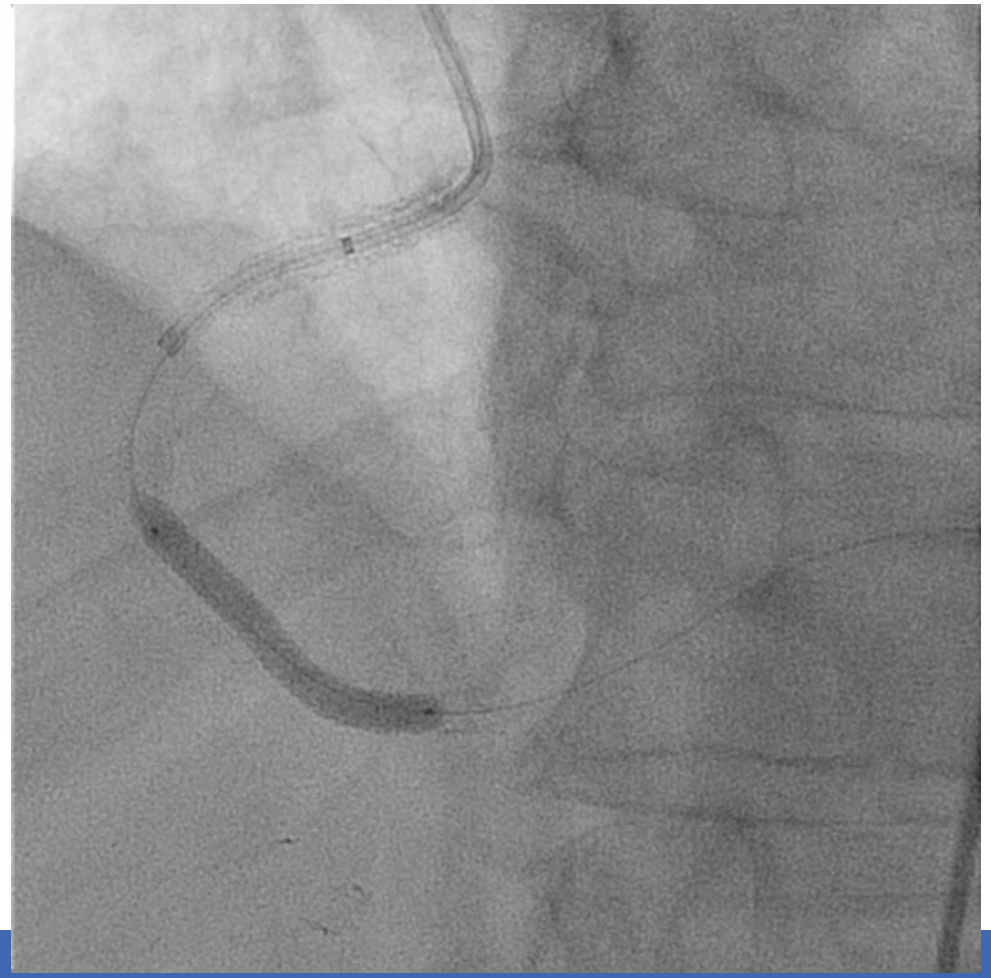
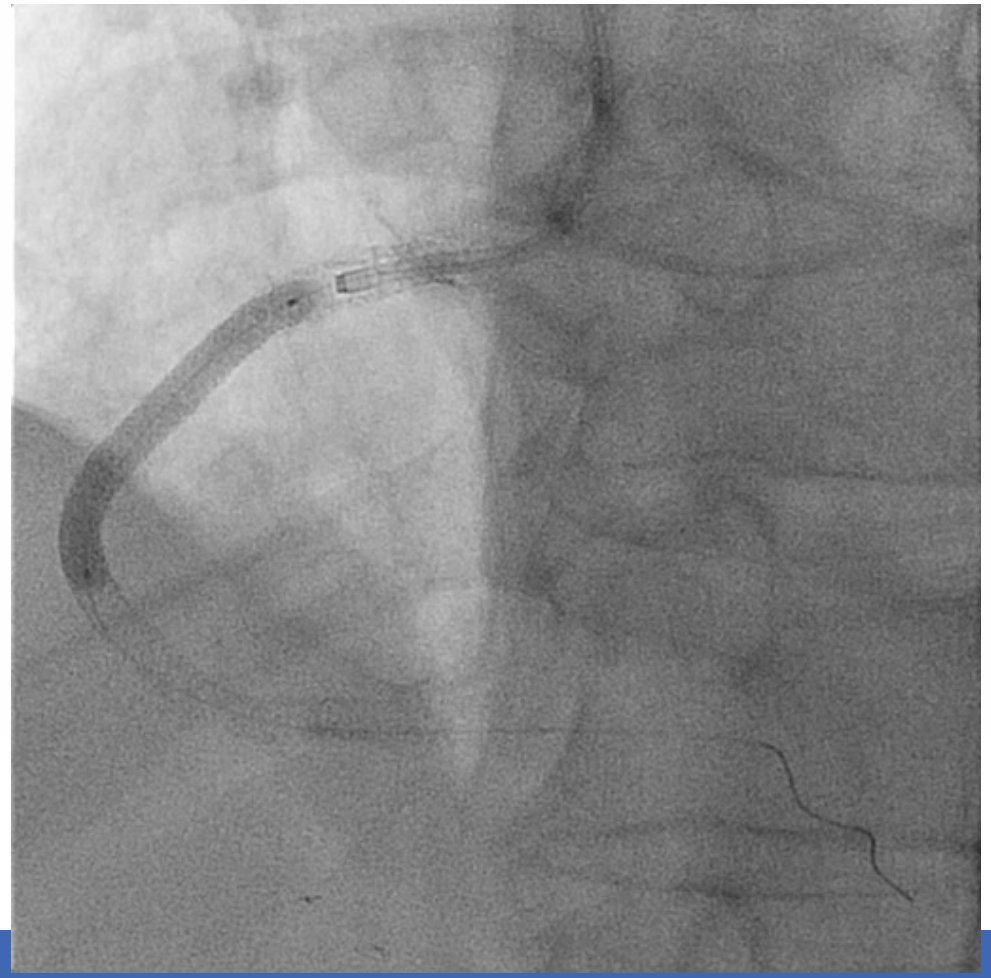
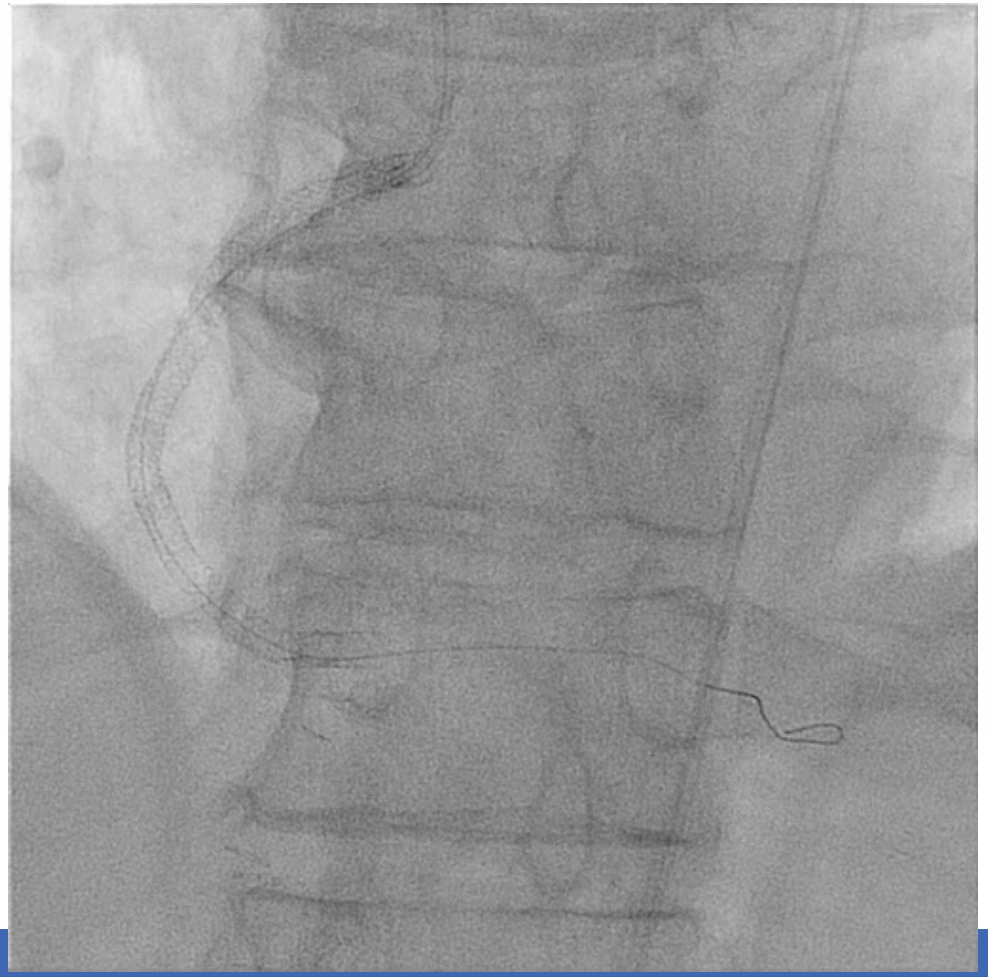
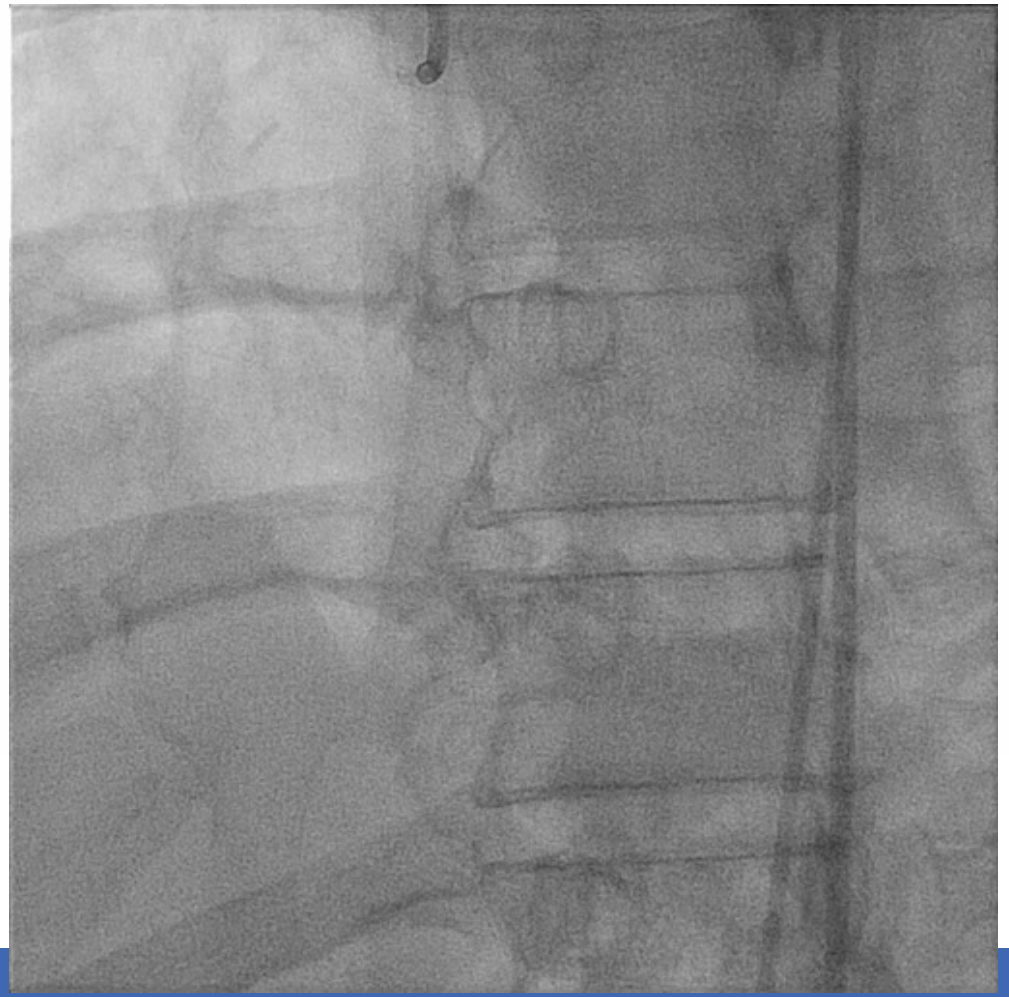






CASE: RCA CTO

- 64 year old man
  - Progressive chest pain
  - Inferior wall ischemia by stress testing



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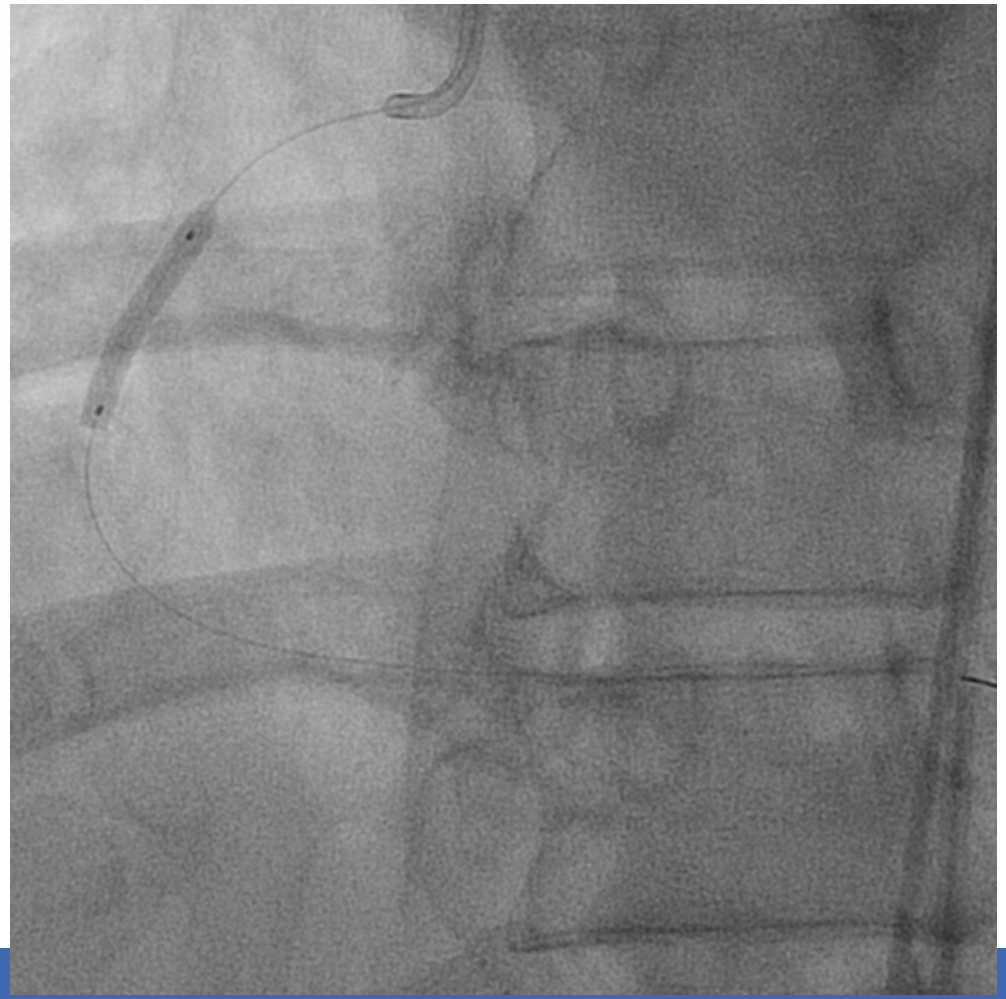

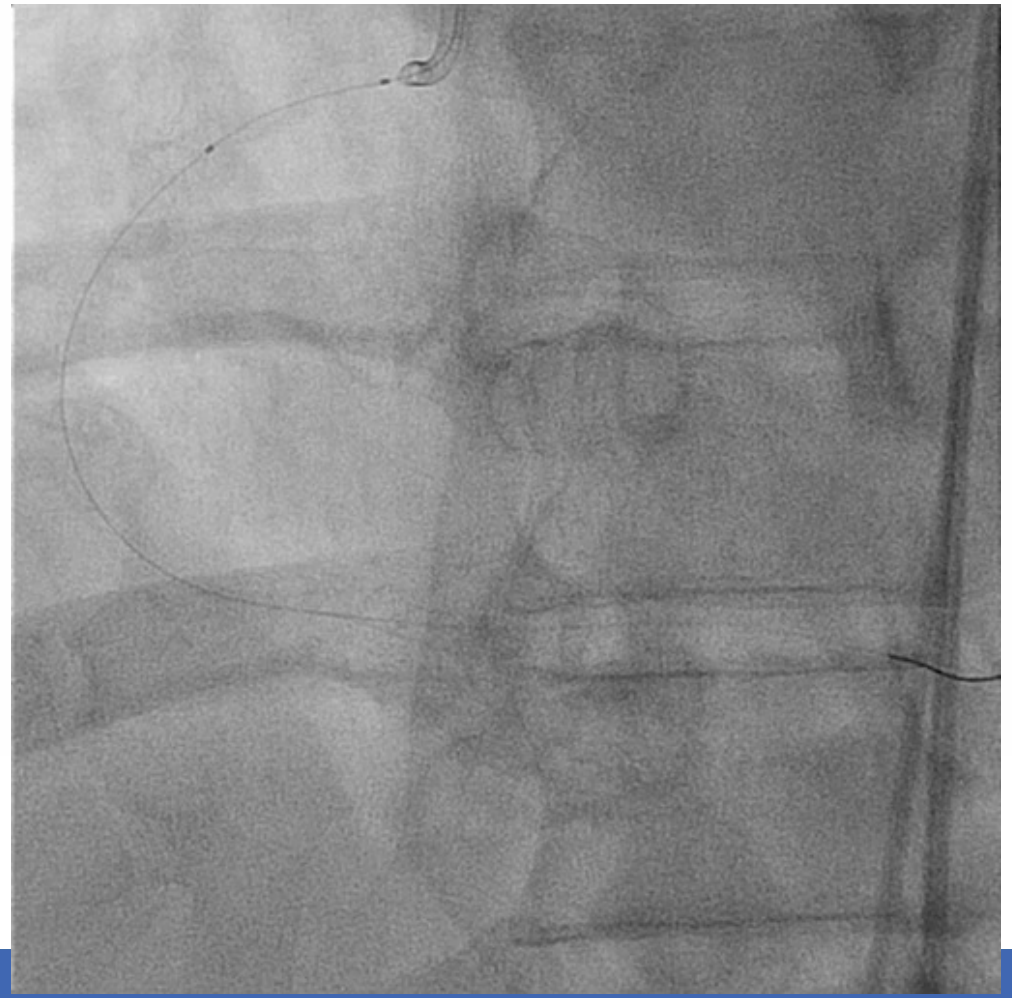

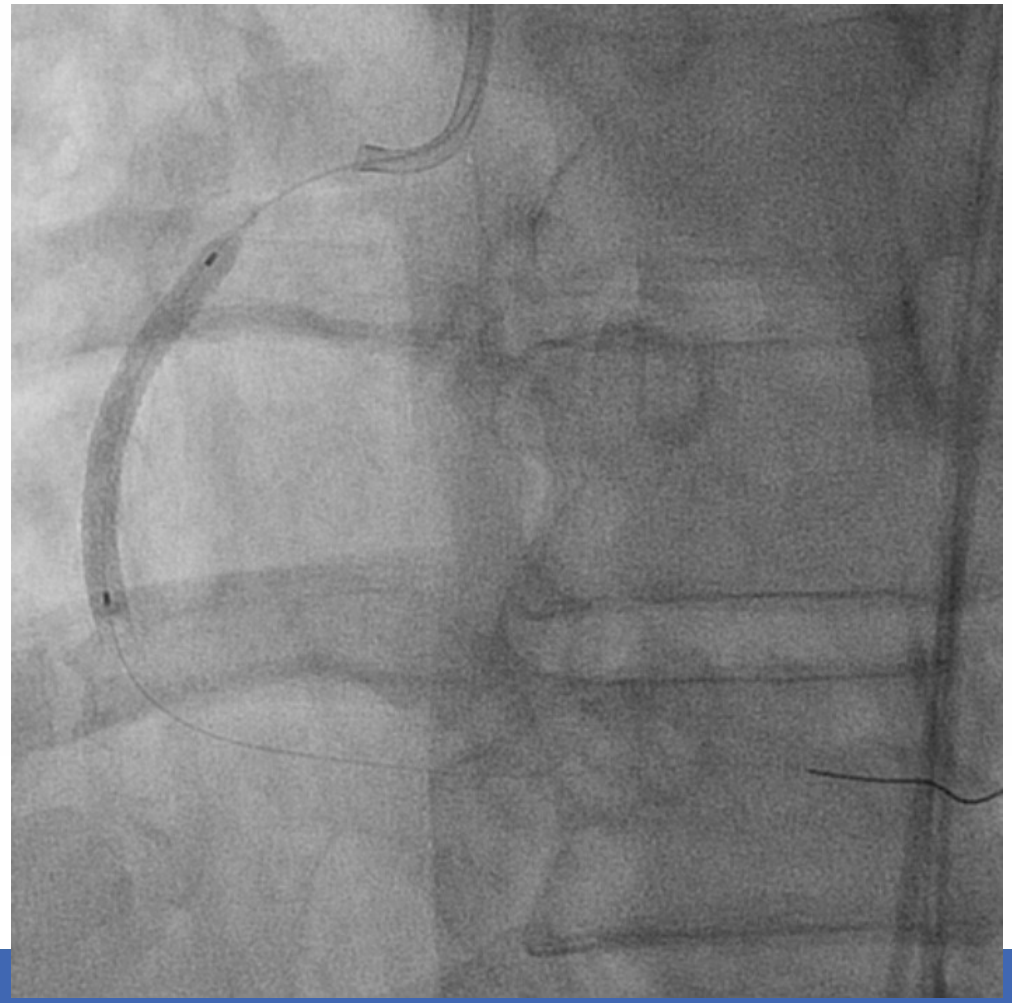

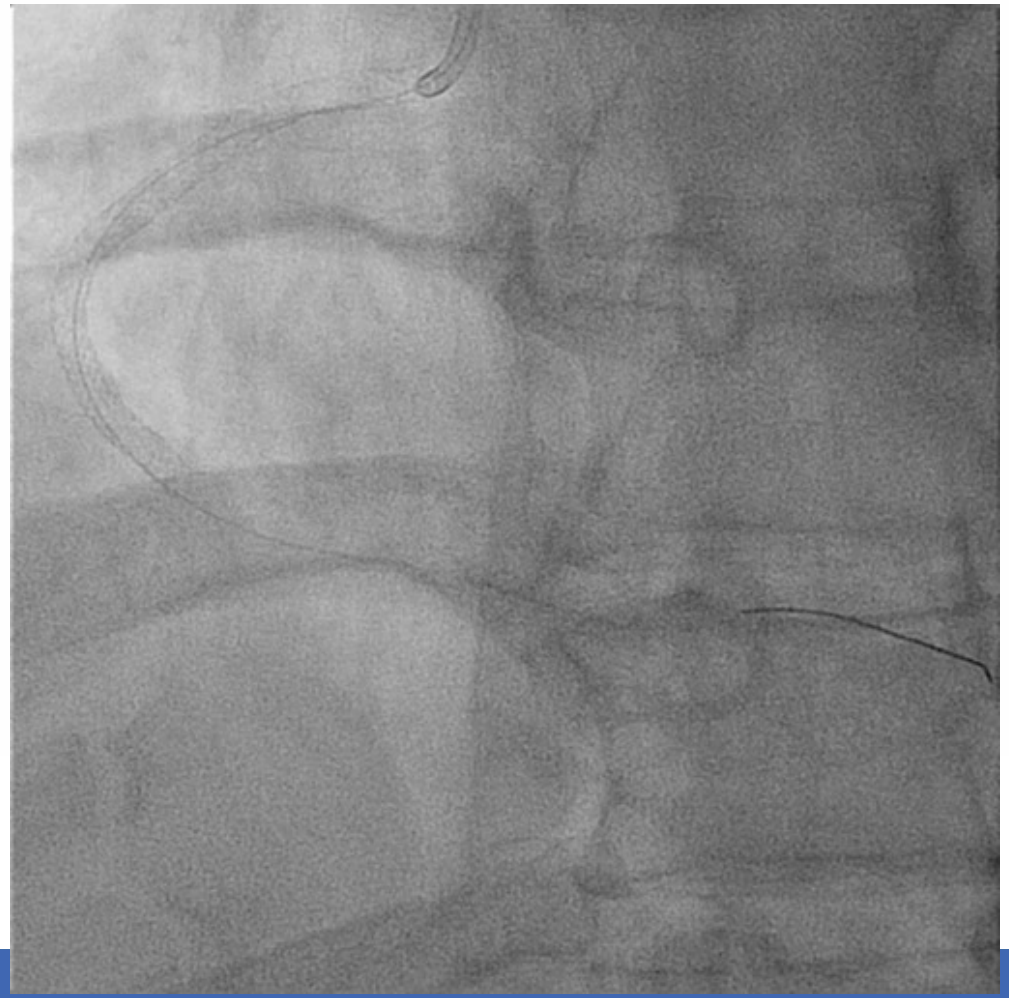

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SUMMARY

- Laser is effective and safe de-bulking allowing potential for greater vessel and stent expansion
- In addition to de-bulking, Laser also modifies the plaque even behind the struts making it more amendable to further stent expansion[5]
- Laser decreases the potential placement of additional stents inside the stenotic stent
- Laser decreases potential risk of distal emboli but proper technique is key!
- Specialty balloons may reduce risk of dissection and facilitate expansion in calcified vessels
- Role of plaque modification balloons remain undefined but early feasibility data seems promising

Use of Adjunctive Tools in Complex PCI: Laser Atherectomy/Specialty Balloons

S. Jay Mathews, MD, MS, FACC

Director, Cardiac Catheterization Lab, Structural Heart Program, & PERT

Manatee Memorial Hospital, Bradenton, FL

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