When and Why OAS Works Better for Calcified Lesions

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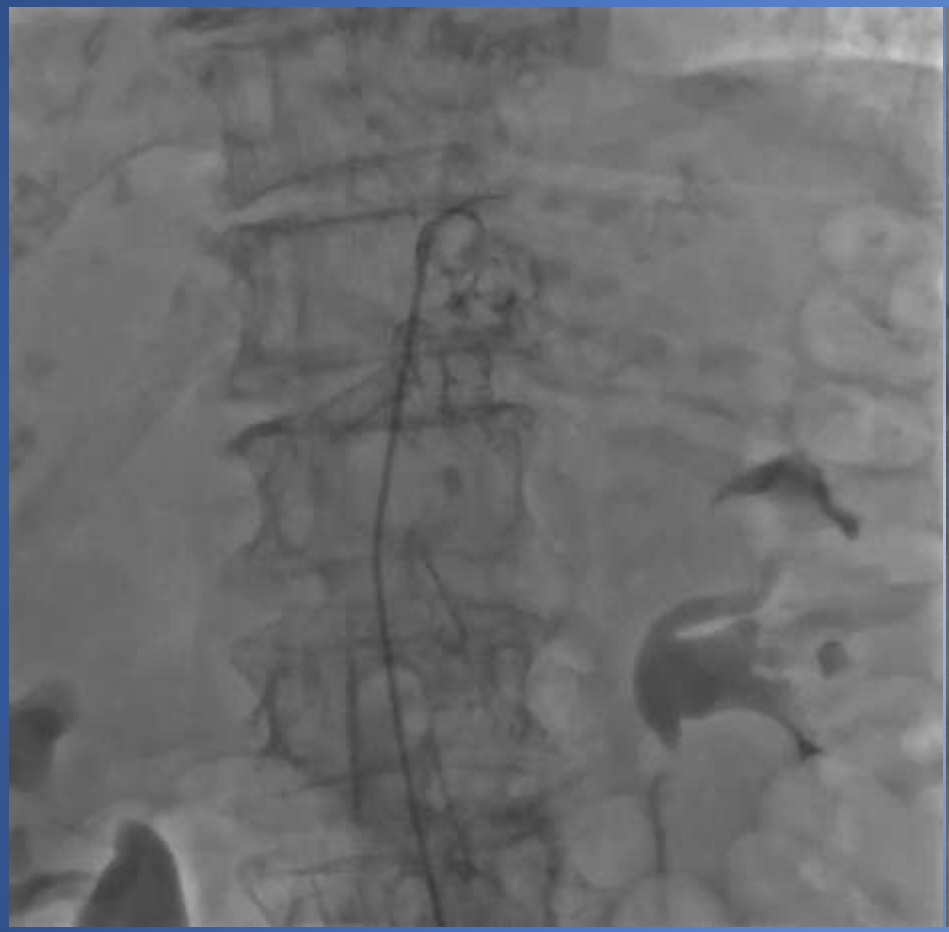
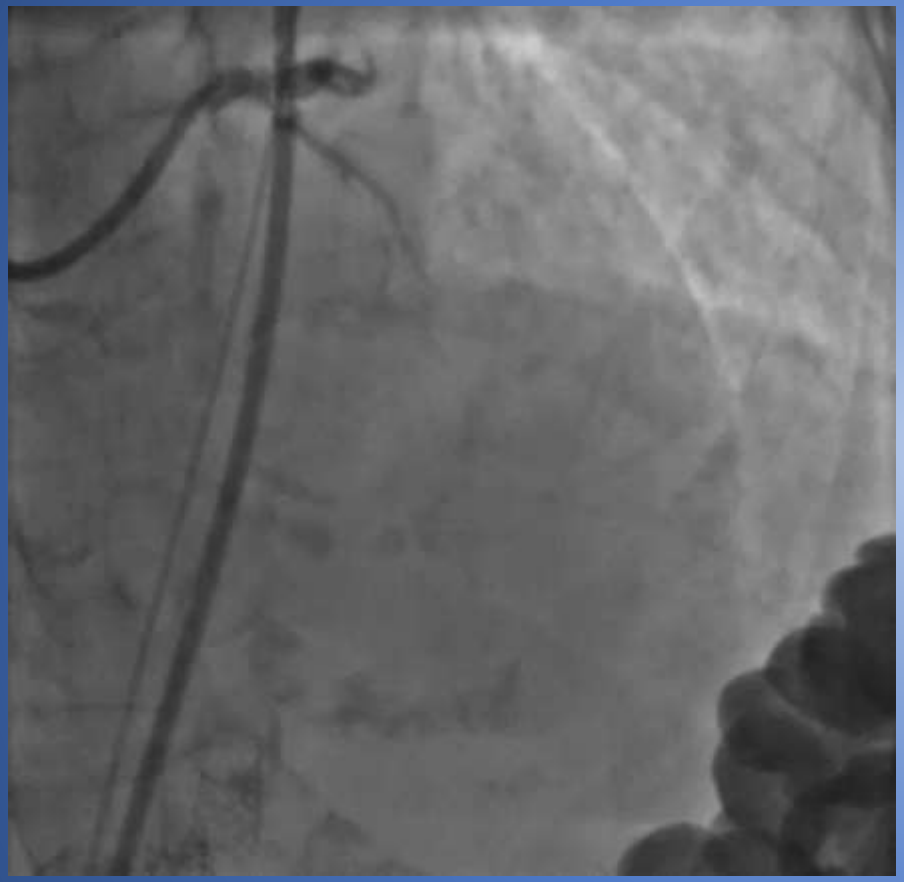
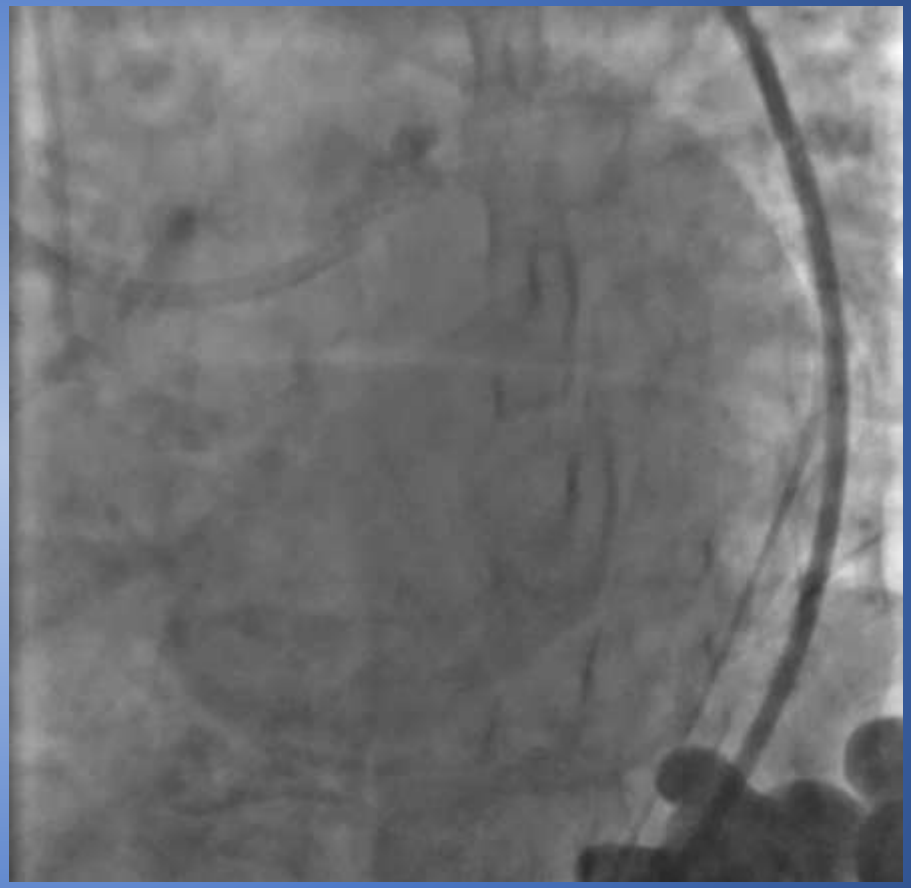
86 y.o. female with bronchiectasis, CMP with EF 35% presents with NSTEMI



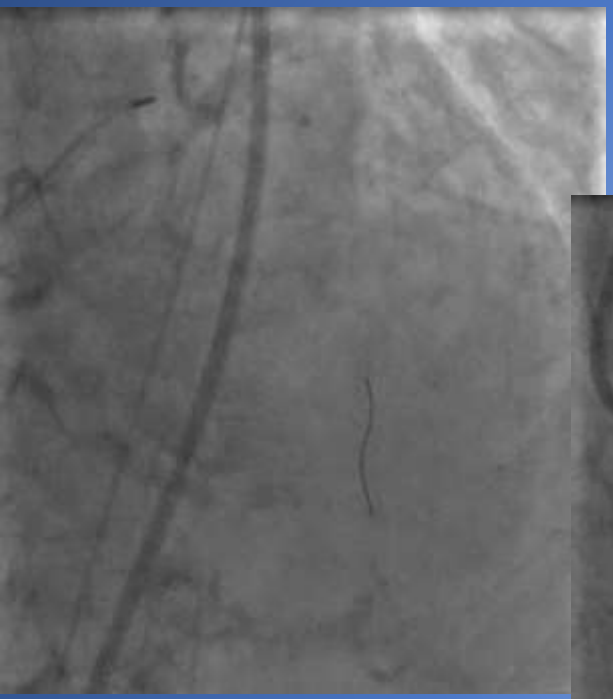
Severe mesenteric ischemia
s/p stent
Renal artery stenosis s/p stent

4F JL4
Severe ostial LM, LAD, and LCX



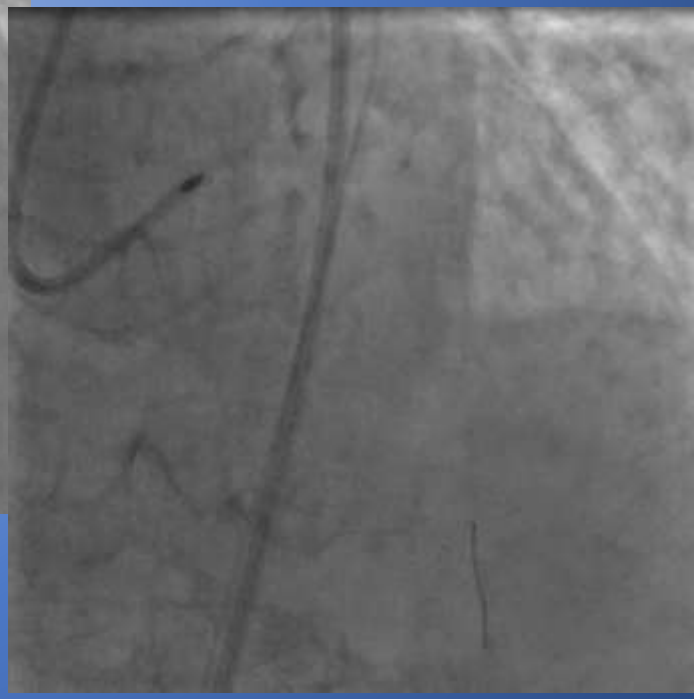


Rotational Atherectomy of LM and LAD



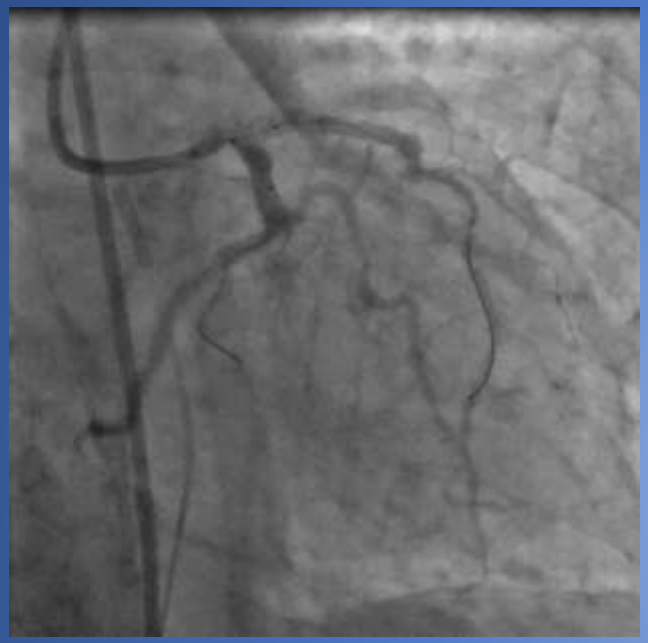
1.25 mm burr

1.5 mm burr

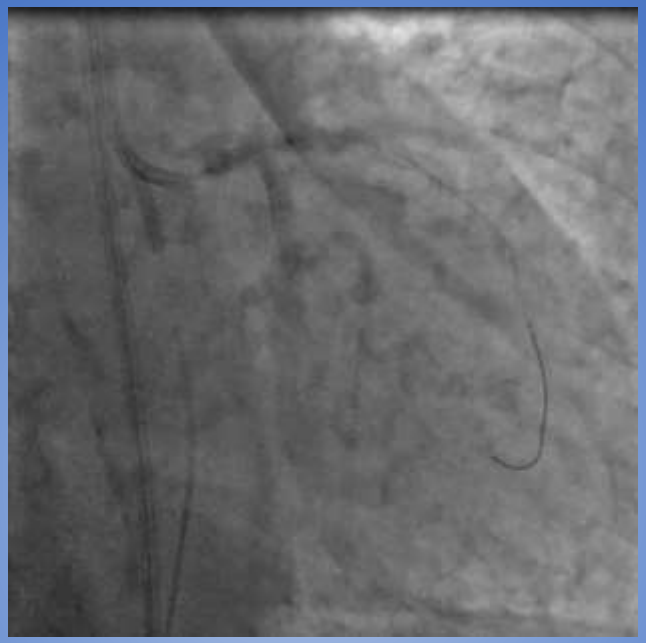


1.75 mm burr

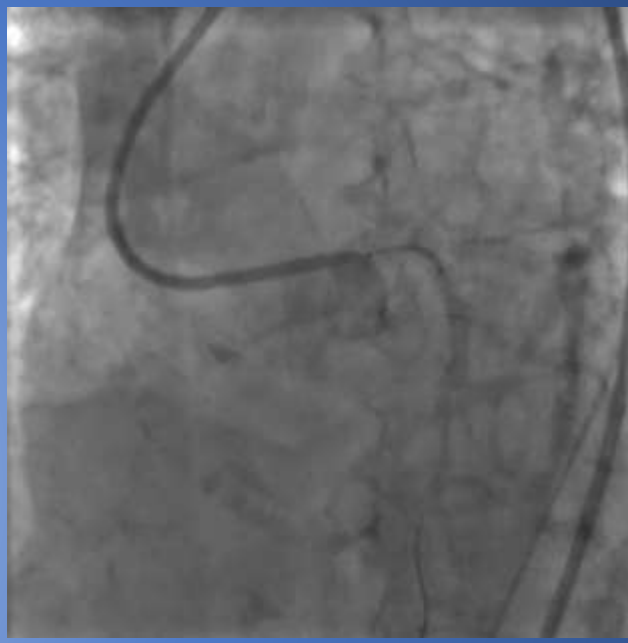
3.5x28 mm EES



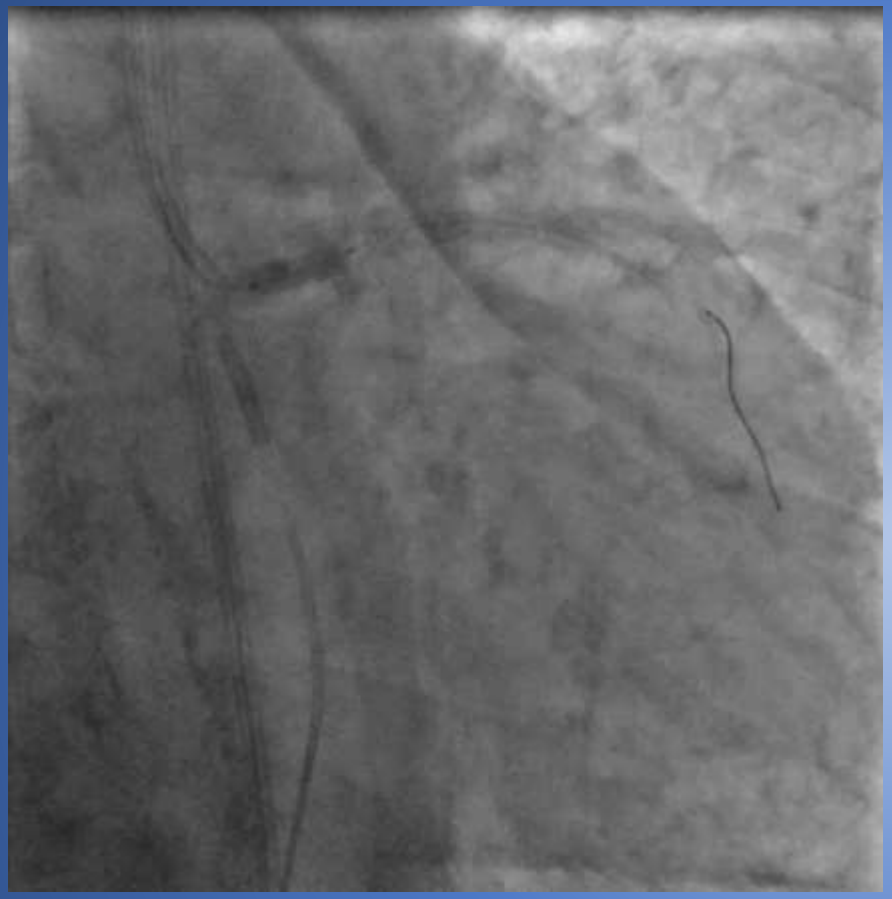
LCX: 3.5x15 mm EES
LAD: 3.5x15 mm balloon



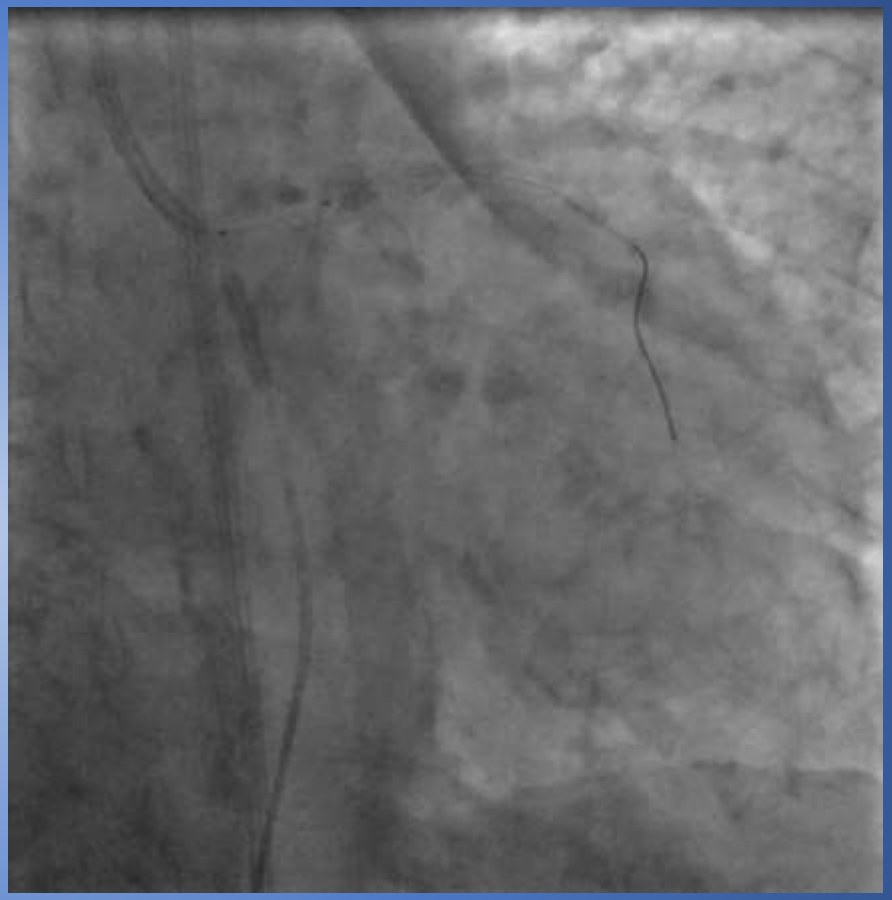
Crush technique



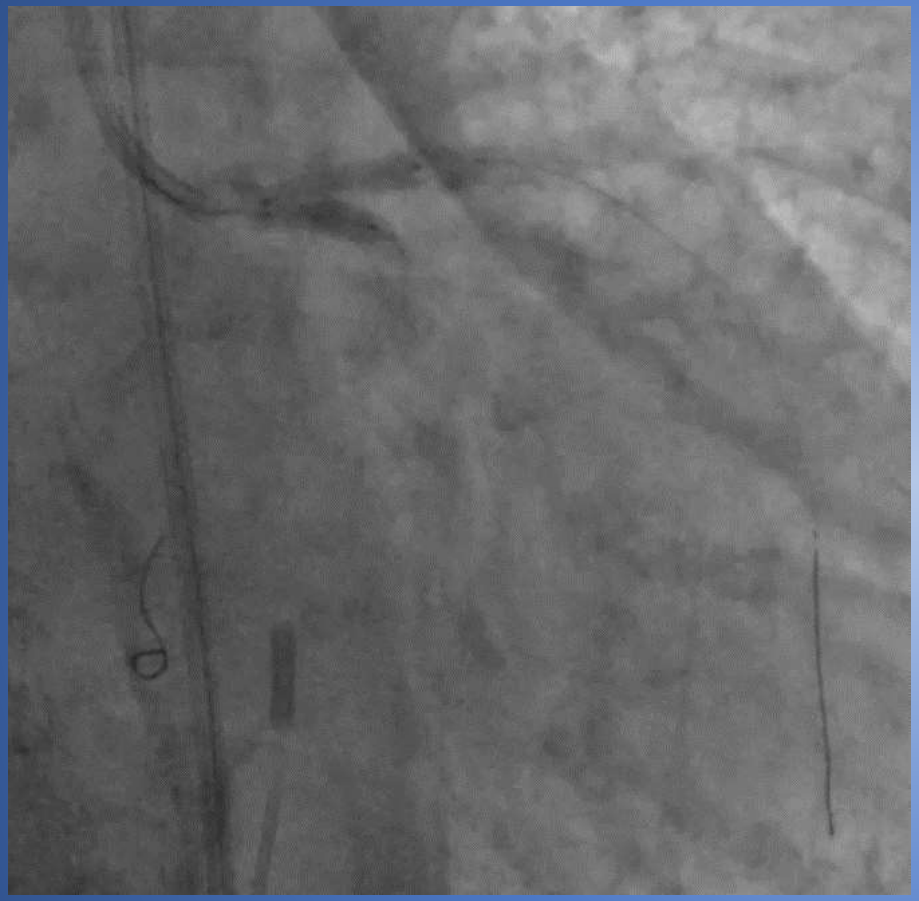
LM: 4.0x18 mm EES

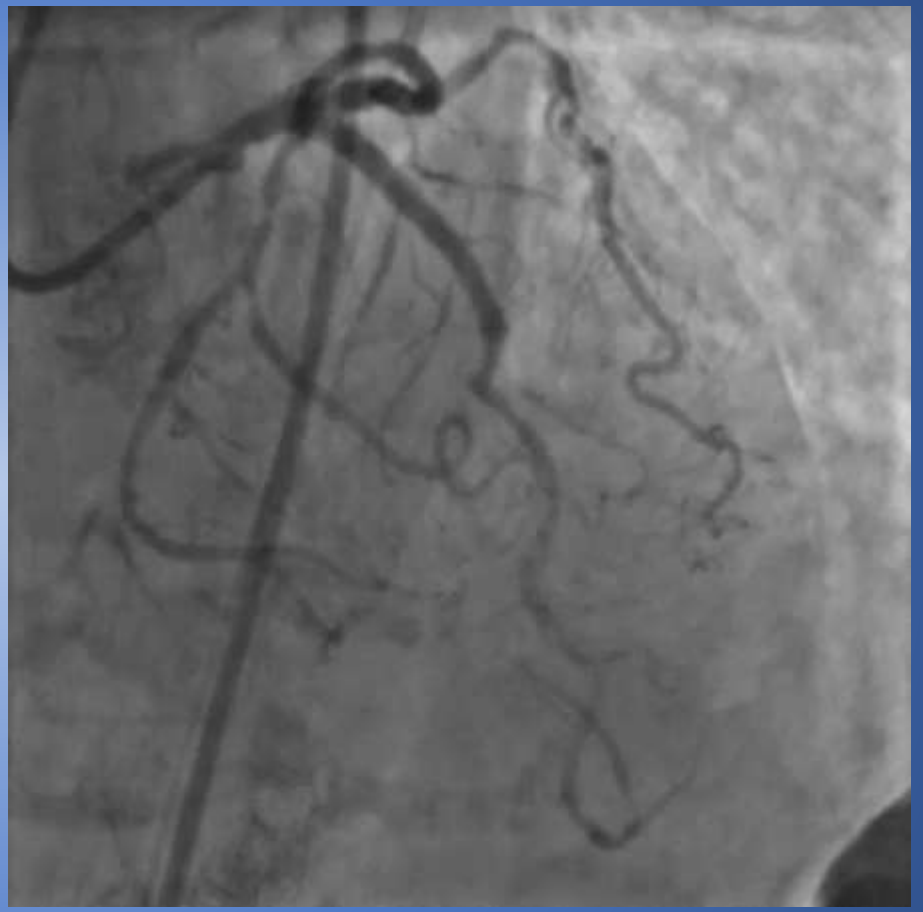


POT with 4.0x12 mm NC balloon



Flare of ostial LM



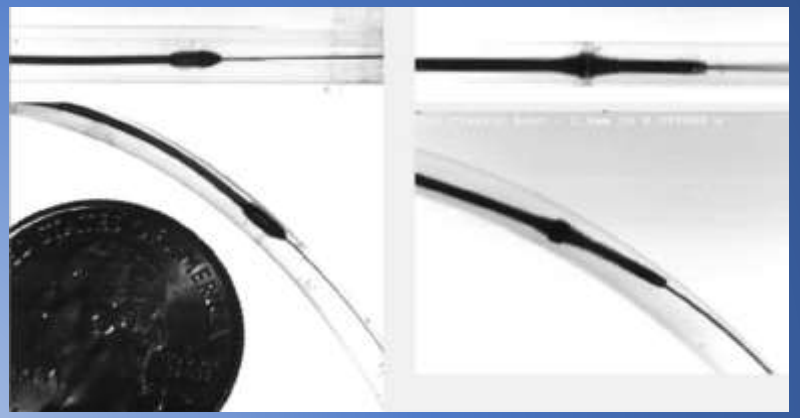


Kissing balloon:
LAD: 3.75x15 mm NC
LCX: 3.5x12 mm NC

Final angiogram

Orbital Atherectomy

Mechanism of Action



Differential Sanding:

- 30 micron diamond coating
- Bi-directional sanding, eccentric mounted crown
- Healthy elastic tissue flexes away minimizing damage to the vessel

Centrifugal Force:

- 360° crown contact designed to create a smooth, concentric lumen
- Allows constant blood flow and particulate flushing during orbit
- Increasing speed increases orbital diameter
- Ability to treat multiple vessel diameters with one crown (1.25 mm)
- Treat large vessels through small sheaths (6 French)

ORBIT II: Study Design

To evaluate safety and efficacy of the Diamondback Coronary OAS Classic Crown to prepare *de novo*, **severely calcified coronary lesions** for enabling stent placement

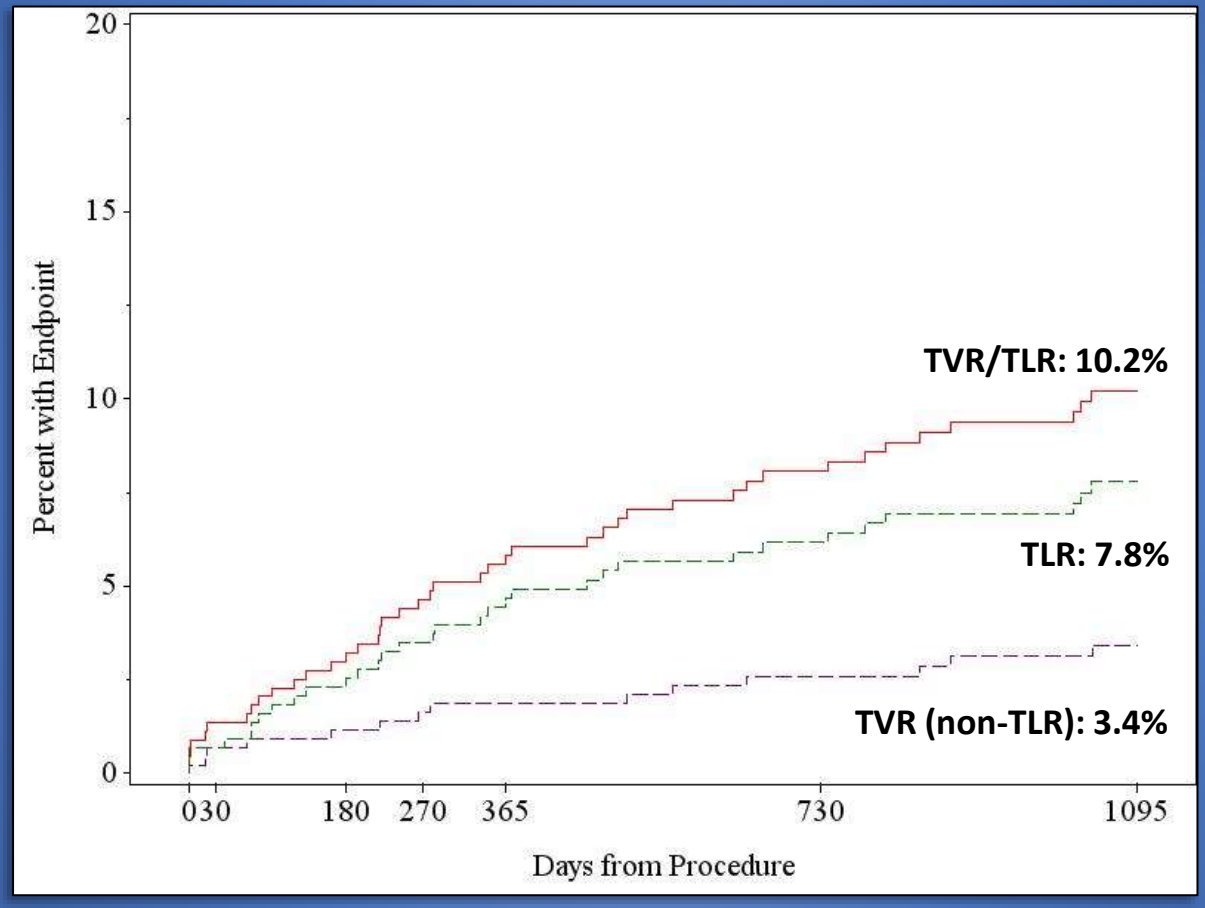
- Prospective, multi-center trial in the United States
- Single arm - As there were no FDA-approved percutaneous treatments specifically for patients with severely calcified coronary lesions.
- ***443 subjects enrolled at 49 U.S. Sites***

30 day follow-up* (N=437/440) → **1-year follow-up† (N=434/440)** → **2-year follow-up‡ (N=424/440)** → **3-year follow-up# (N=411/440)**

- **Primary Safety Endpoint: MACE (**MI= CK-MB>3x ULN, TVR, Cardiac Death)
- **Primary Efficacy Endpoint: Procedural Success**
  - Success in facilitating stent delivery with a final residual stenosis of <50% (as determined by Angiographic Core Lab) and free from in-hospital MACE

*438 subjects per Kaplan Meier were at risk/events for MACE
†432 subjects per Kaplan Meier were at risk/events for MACE
‡411 subjects per Kaplan Meier were at risk/events for MACE
#311 subjects per Kaplan Meier were at risk/events for MACE
Lee MS, et al. Cardiovasc Revasc Med. 2017;18:261-264.

ORBIT II
3-Year TVR/TLR

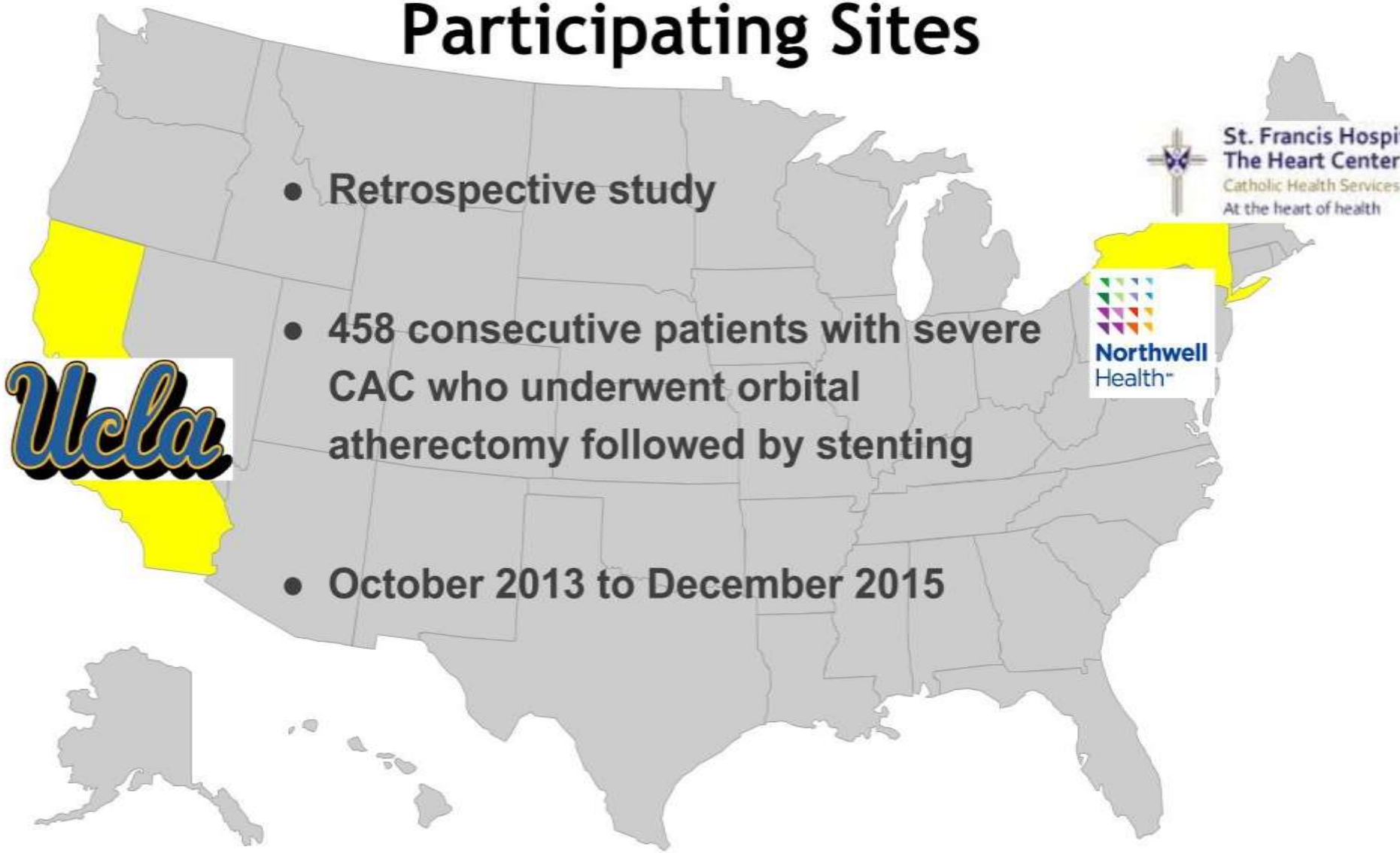


Number at risk (TVR/TLR)	443 430	413	403	392	356	228
Number at risk (TLR)	443 432	415	407	396	363	234
Number at risk (TVR)	443 433	421	416	407	377	242

Lee MS, et al. Cardiovasc Revasc Med. 2017;18:261-264

Real-World Multicenter Experience on Patients with Severe Coronary Artery Calcification Undergoing Orbital Atherectomy

Participating Sites



- Retrospective study
- 458 consecutive patients with severe CAC who underwent orbital atherectomy followed by stenting
- October 2013 to December 2015

Lee MS, et al. J Interv Cardiol 2016

Angiographic Complications

DOI: 10.1111/joic.12310

ORIGINAL INVESTIGATION

Real-World Multicenter Registry of Patients with Severe Coronary Artery Calcification Undergoing Orbital Atherectomy

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Objectives: *We evaluated the safety and efficacy of orbital atherectomy in real-world patients with severe coronary artery calcification (CAC).*

Background: *The presence of severe CAC increases the complexity of percutaneous coronary intervention as it may impede stent delivery and optimal stent expansion. Atherectomy may be an indispensable tool for uncrossable or undilatable lesions by modifying severe CAC. Although the ORBIT I and II trials report that orbital atherectomy was safe and effective for the treatment of severe CAC, patients with kidney disease, recent myocardial infarction, long diffuse disease, severe left ventricular dysfunction, and unprotected left main disease were excluded.*

Methods: *This retrospective study included 458 consecutive patients with severe CAC who underwent orbital atherectomy followed by stenting from October 2013 to December 2015 at 3 centers.*

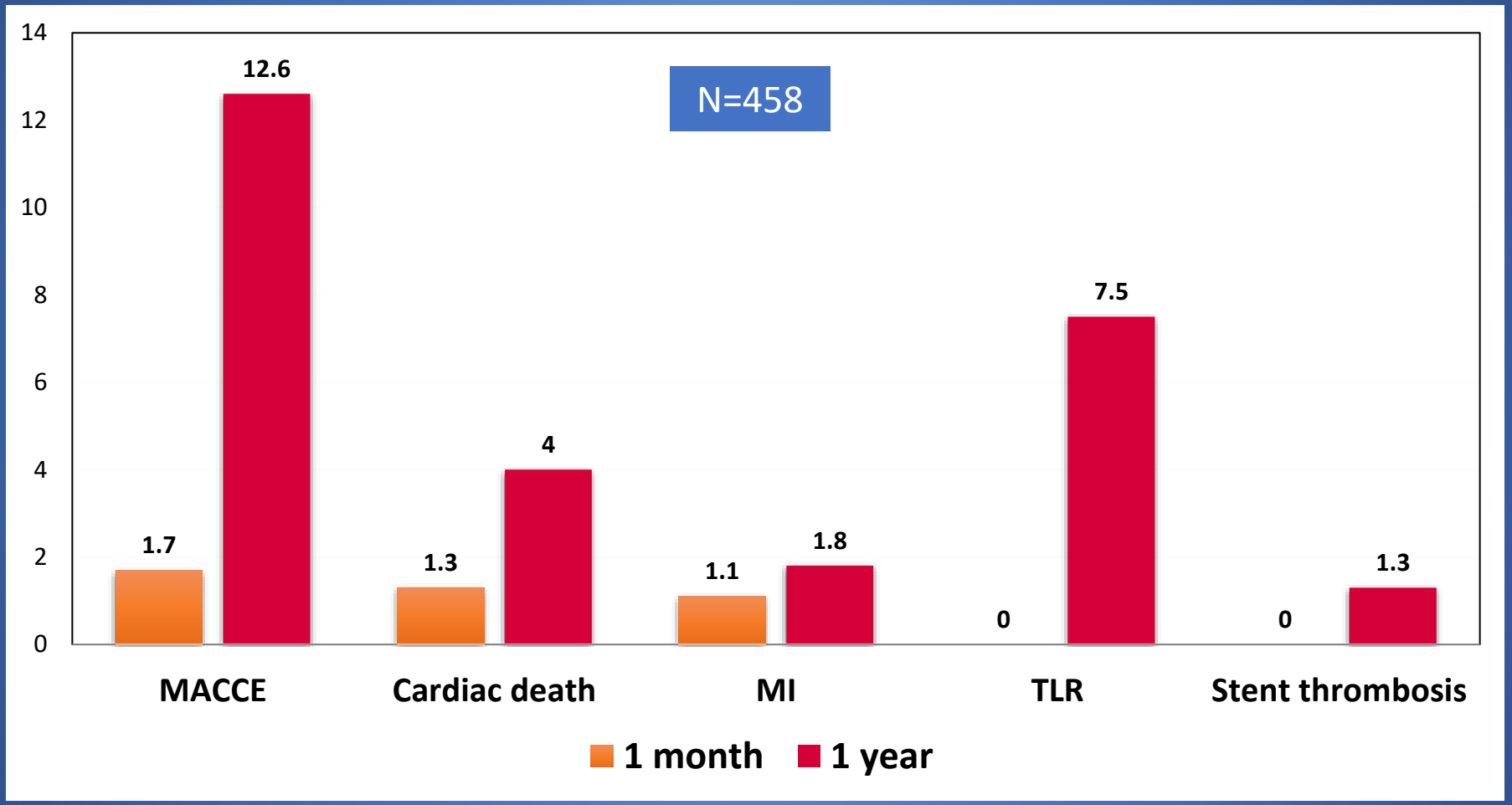
Results: *The primary endpoint of major adverse cardiac and cerebrovascular events at 30 days was 1.7%. Low rates of 30-day all-cause mortality (1.3%), myocardial infarction (1.1%), target vessel revascularization (0%), stroke (0.2%), and stent thrombosis (0.9%) were observed. Angiographic complications were low: perforation was 0.7%, dissection 0.9%, and no-reflow 0.7%. Emergency coronary artery bypass graft surgery was performed in 0.2% of patients.*

Conclusion: *In the largest real-world study of patients who underwent orbital atherectomy, including high-risk patients who were not surgical candidates as well as those with very complex coronary anatomy, acute and short-term adverse clinical event rates were low. A randomized clinical trial is needed to identify the ideal treatment strategy for patients with severe CAC.* (J Interven Cardiol 2016;9999:1–6)

	n=458
Perforation	3 (0.7%)
Dissection	4 (0.9%)
No reflow	3 (0.7%)

Lee MS, et al. J Interv Cardiol 2016.

Orbital Atherectomy
30-day and 1-year follow-up



Lee MS, et al. J Interv Cardiol 2016
Lee MS, et al. J Invasive Cardiol 2018

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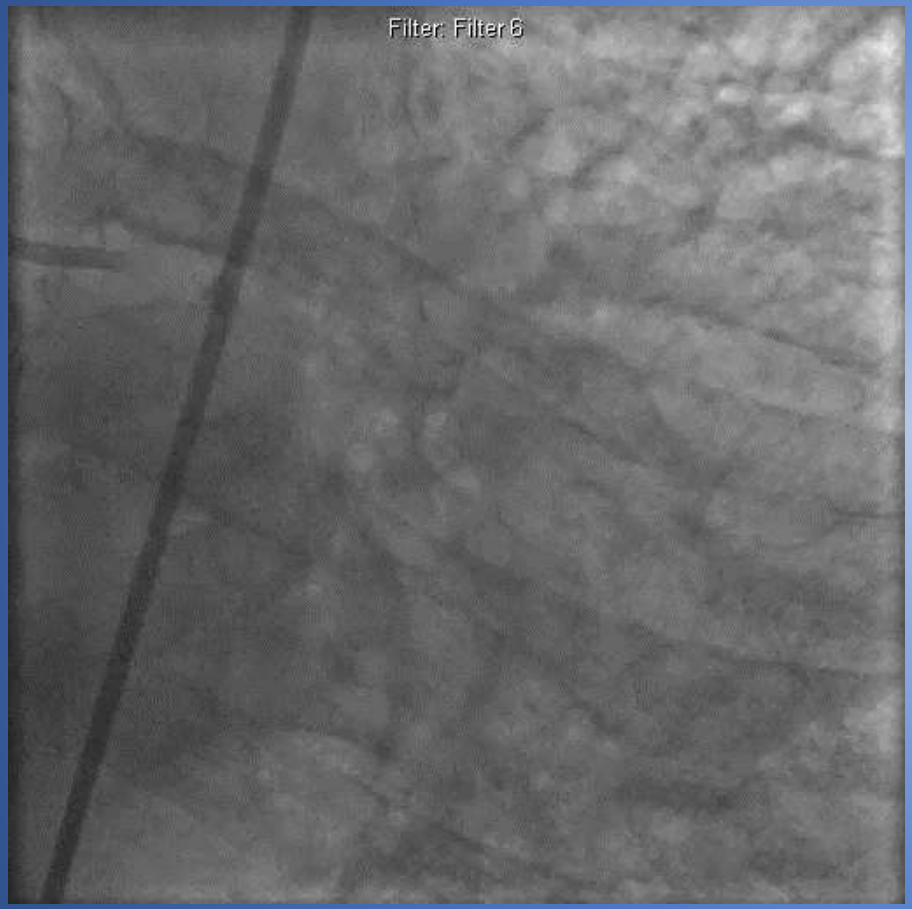
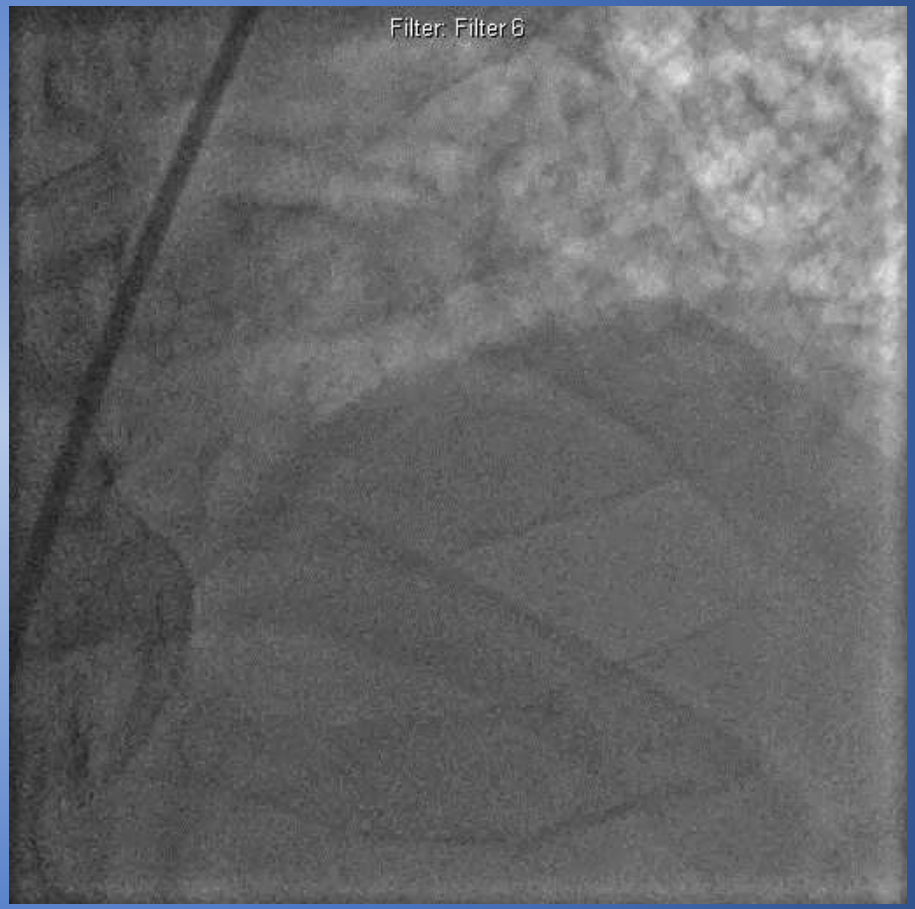
Calcified Left Main and LAD

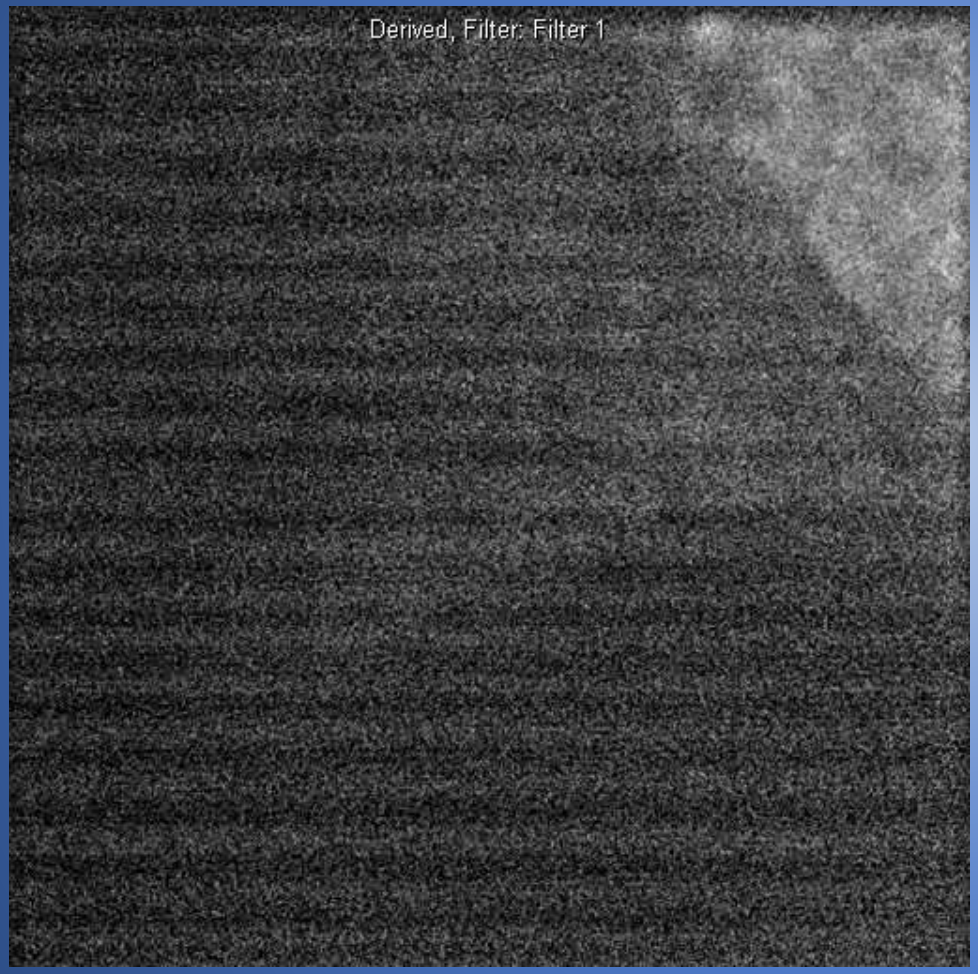




68 y.o. male pre-lung transplant

Calcified LM and LAD

Orbital Atherectomy
Left Main Artery

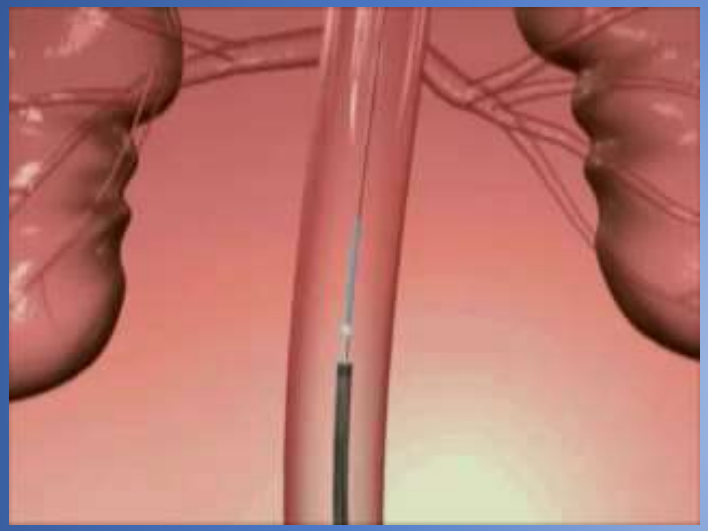


Treats 360˚ of the vessel. The diamond coated crown sands away calcium and allows healthy elastic tissue to flex away minimizing injury to the vessel.

Final Angiography

UCLA Health

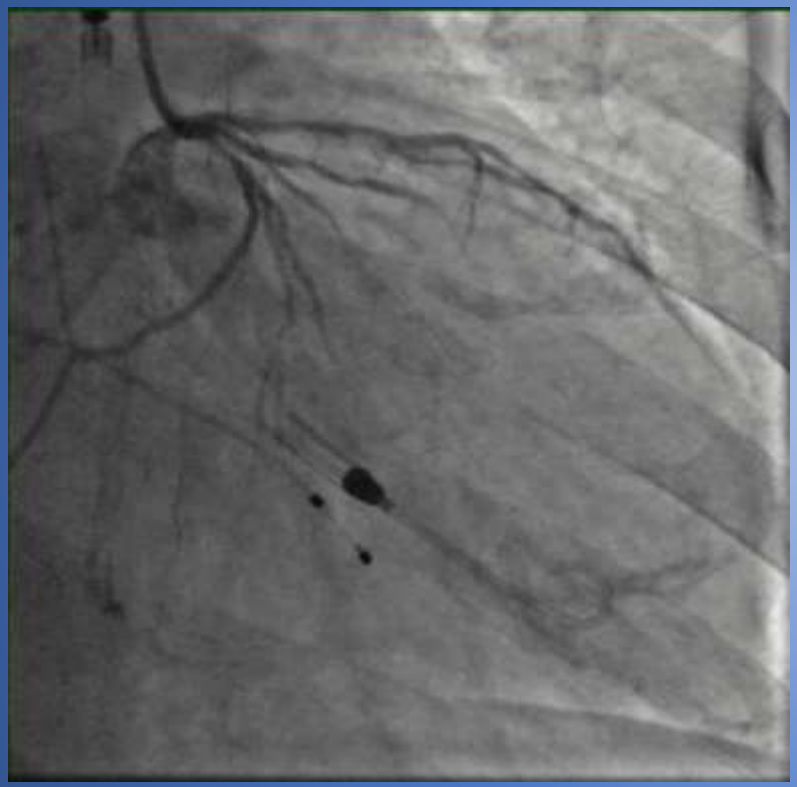
ANGIOGRAPHY



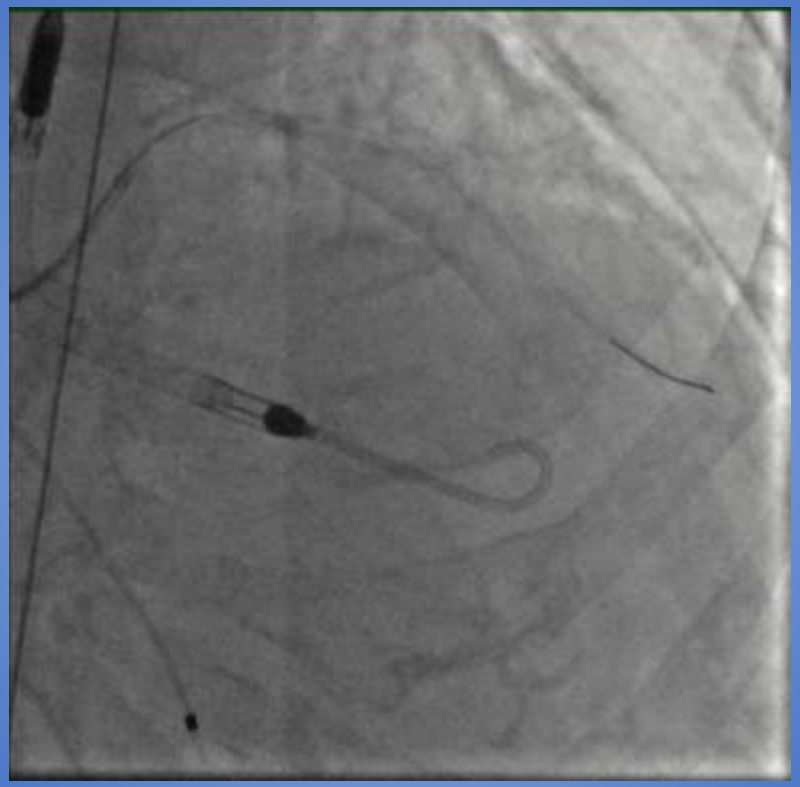
- 14F sheath
- Non-pulsatile flow
- Augment cardiac output by 3.5 L/min
- Does not require stable cardiac rhythm or native cardiac output/blood pressure signal for optimal function
- Unloads left ventricle
- $20,000

- Radial access
- BP 76/39 mmHg after radial cocktail
- LVEDP 27
- Bradycardia (HR 45)

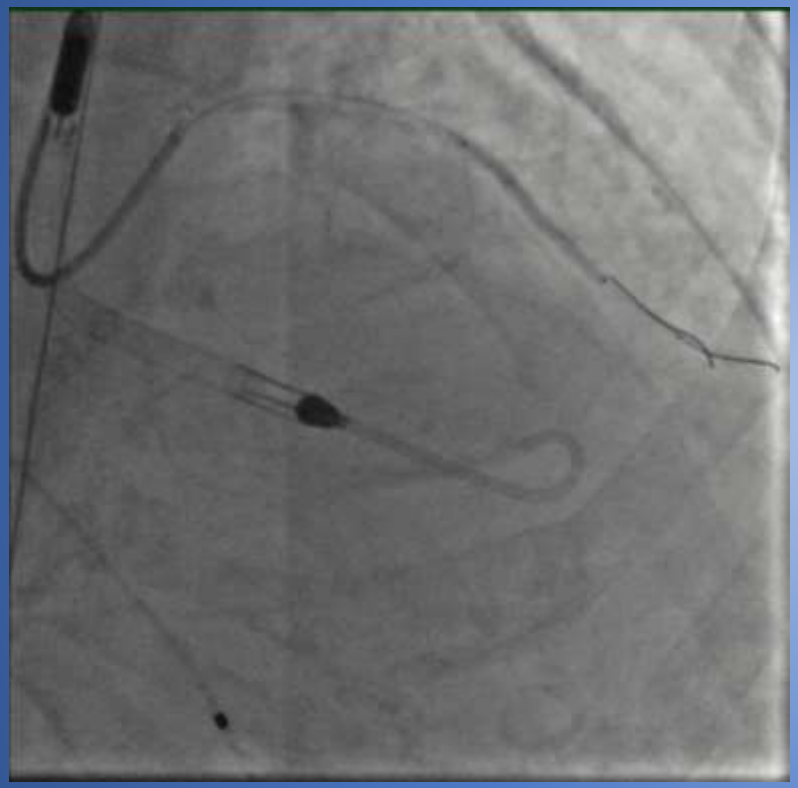
ANGIOGRAPHY



Orbital Atherectomy of LAD



Predilatation of LAD

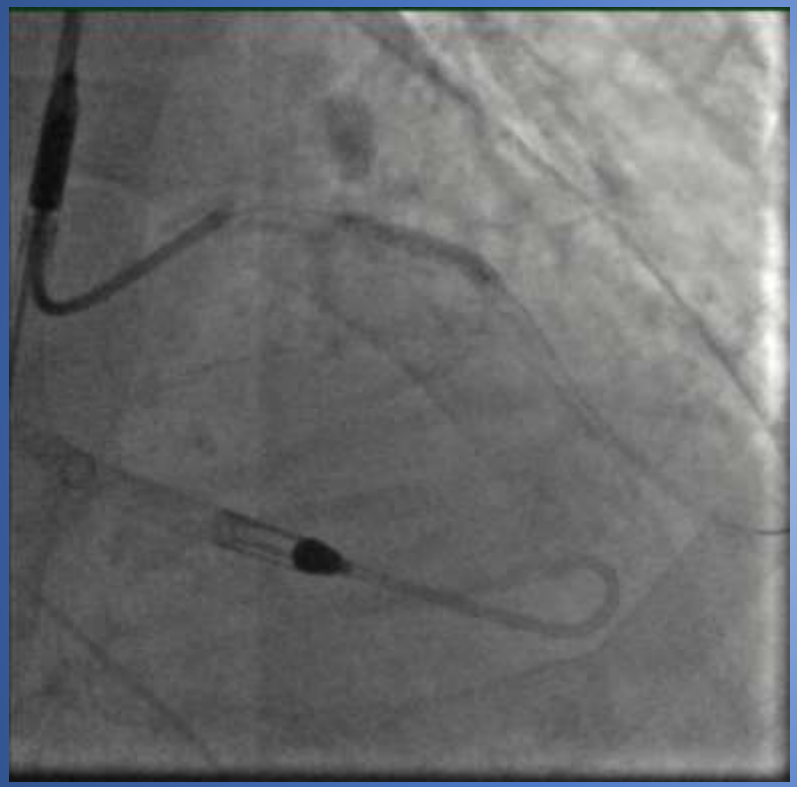


Predilatation with 2.5 x 30 mm balloon

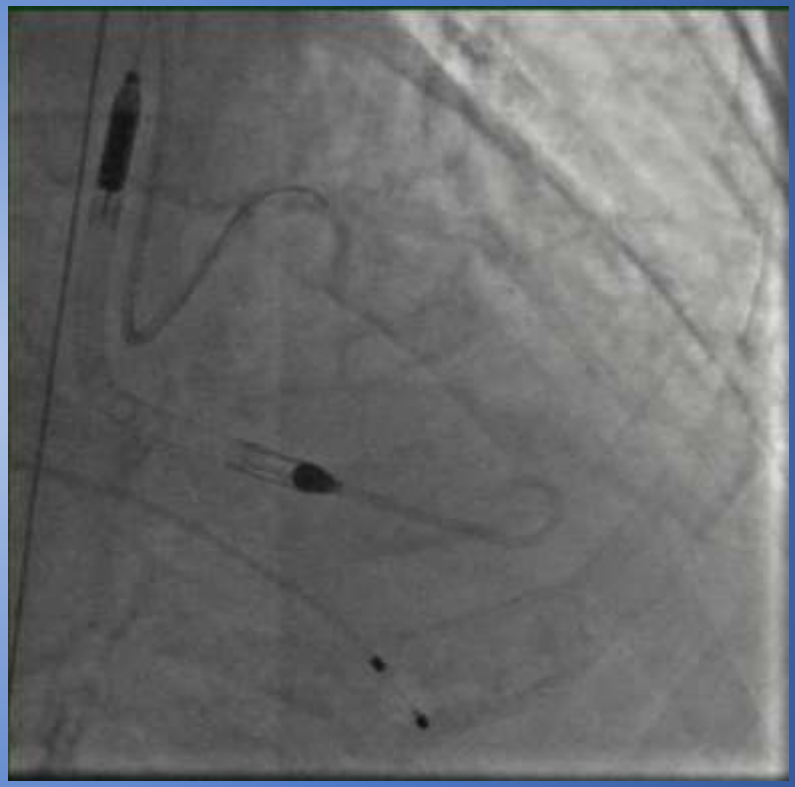
Stenting **of LAD**

2.75 x 38 mm Xience stent

3.25 x 38 mm Xience stent

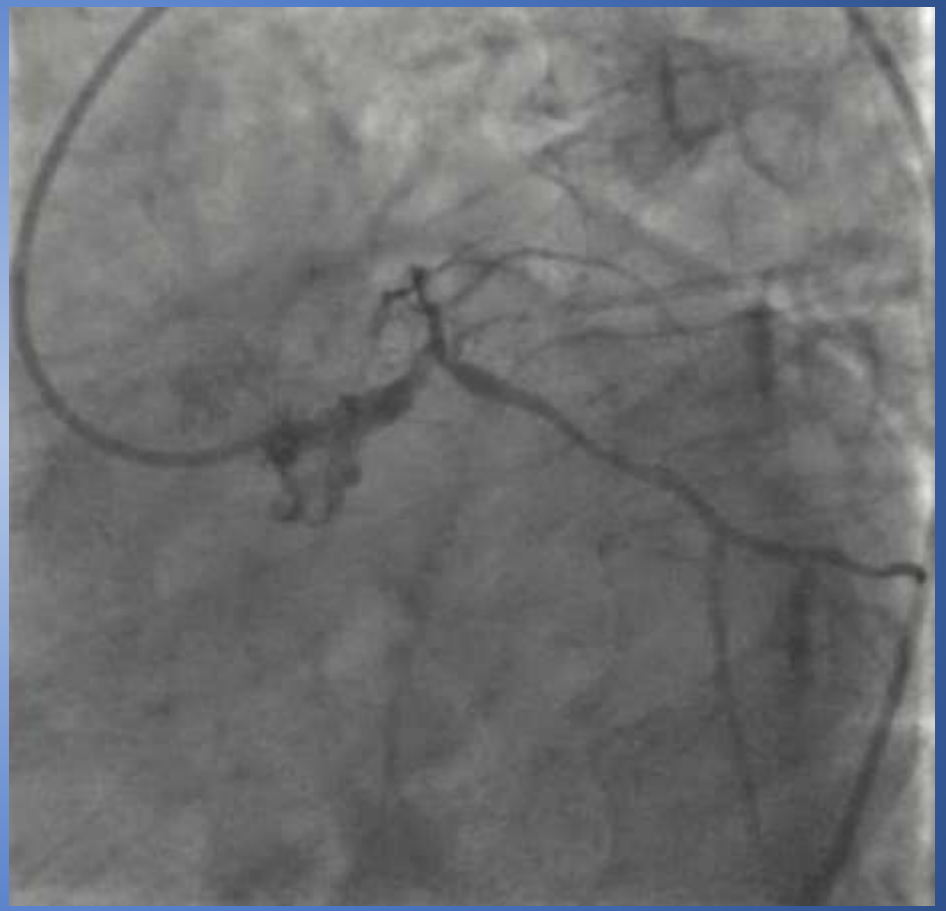


Post-dilate 3.5 x 20 mm NC



Final angiography

62 y.o. male with cardiomyopathy EF 30%
Severe PAD



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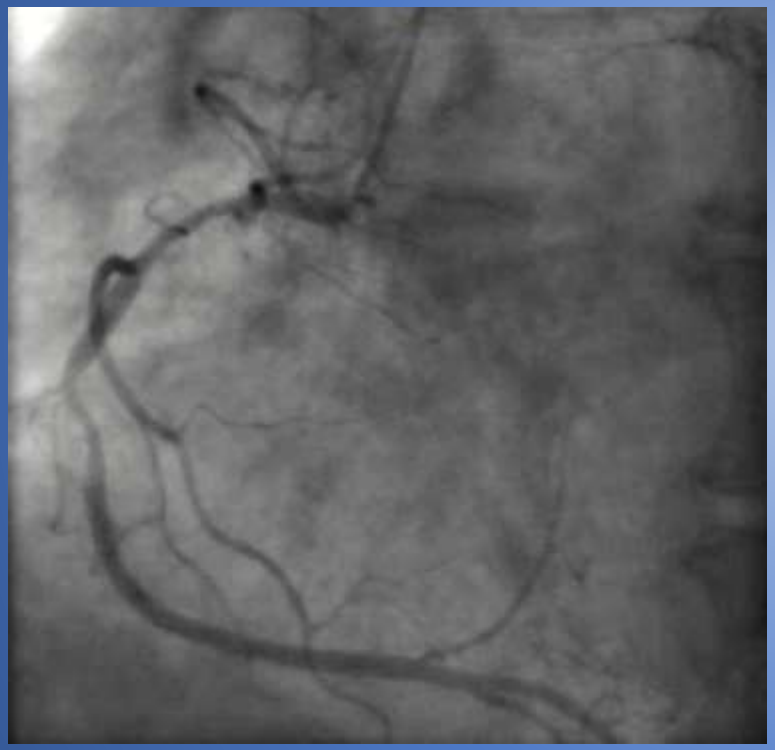

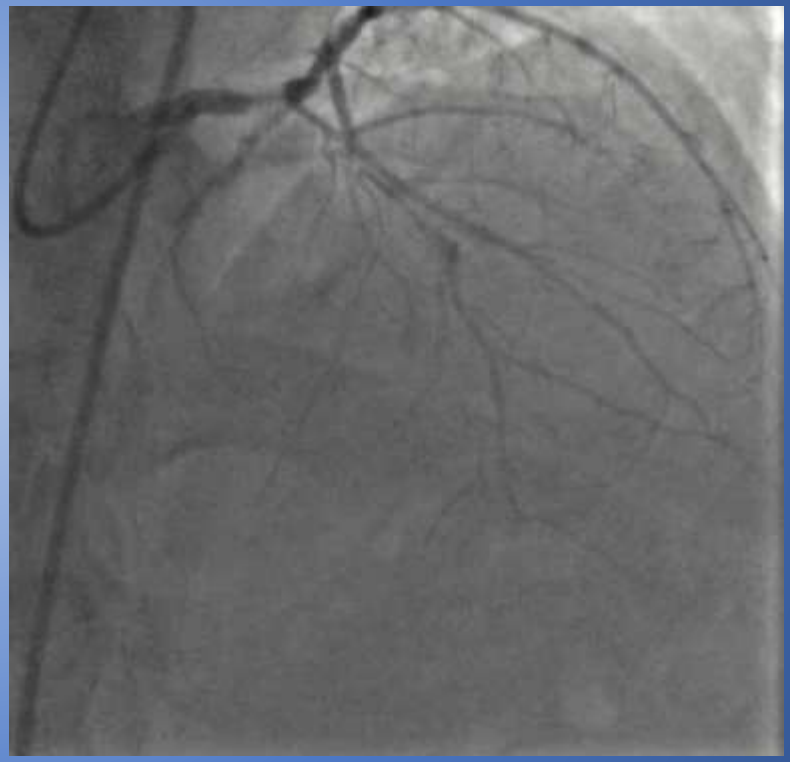

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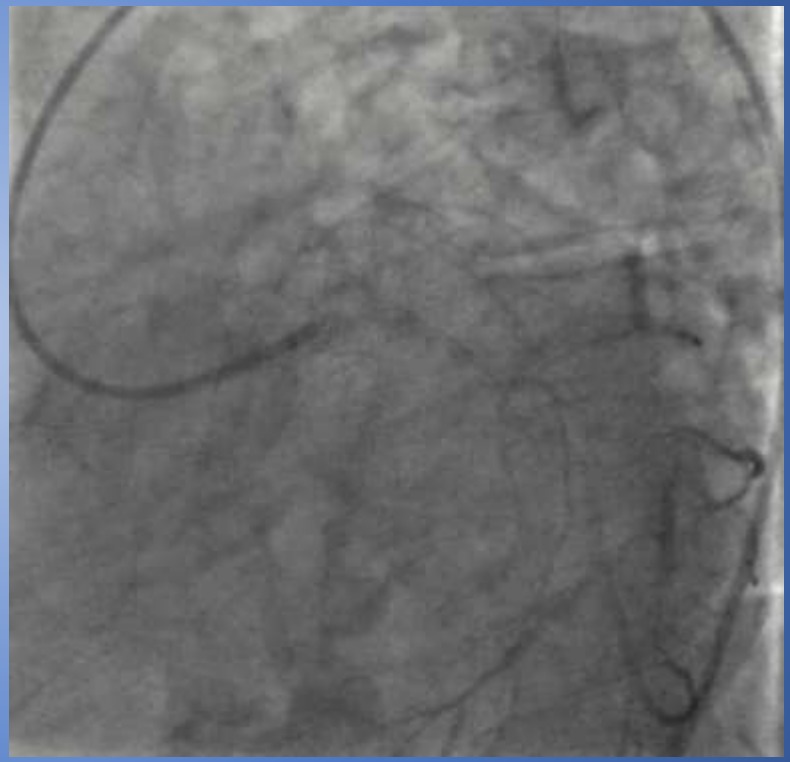
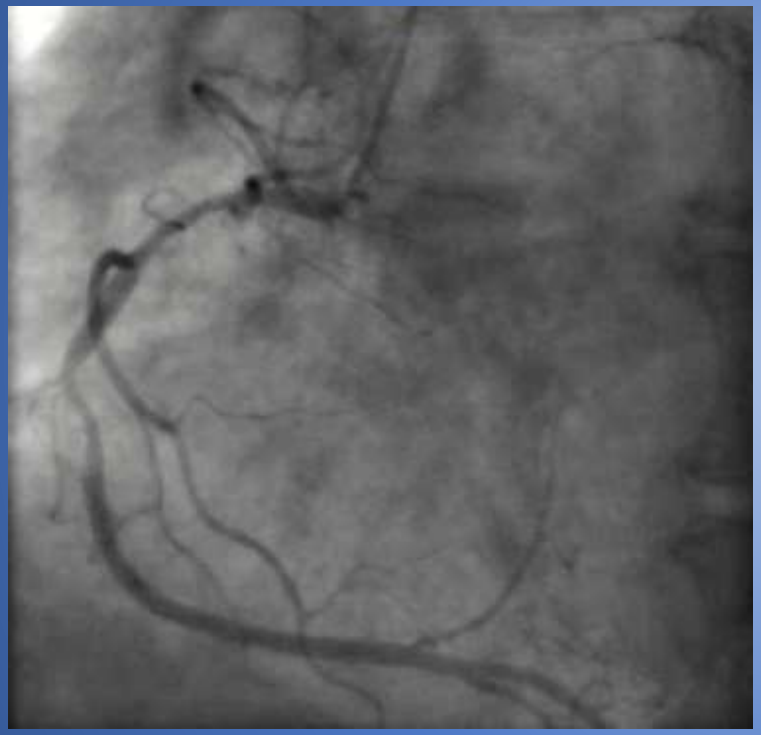
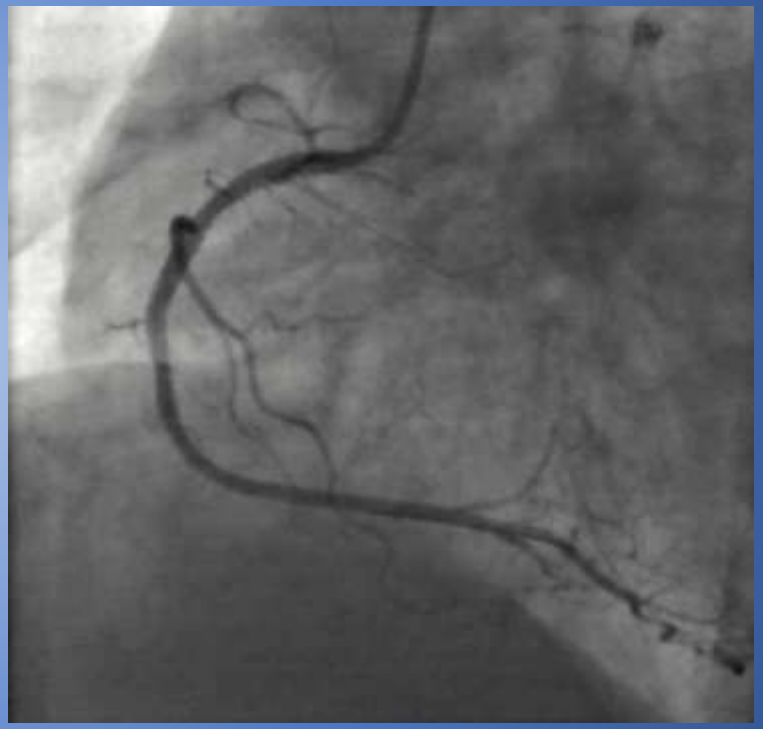


Peripheral Angiography of SFA

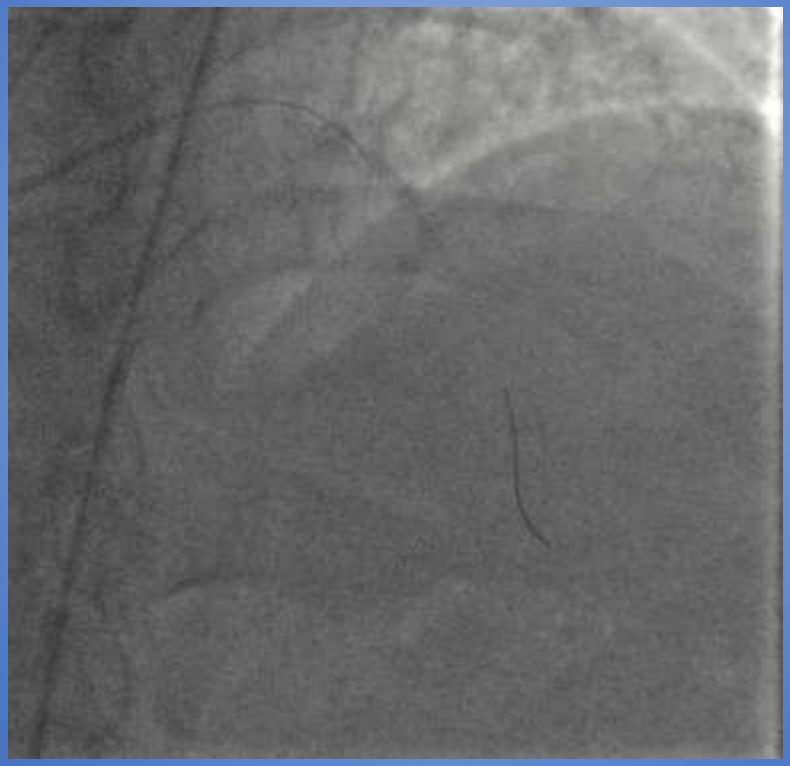
PCI of RCA



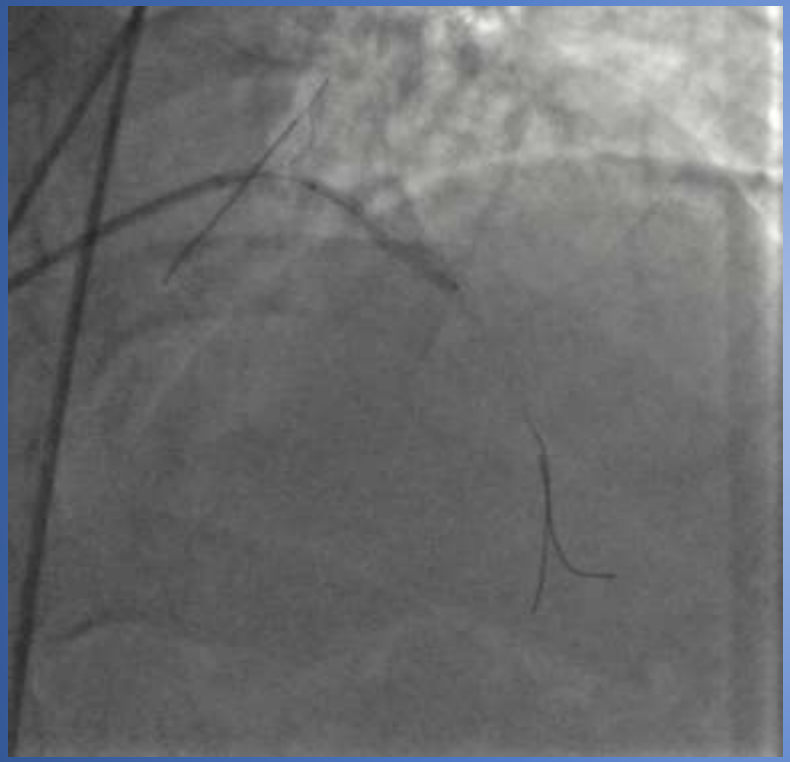


3.5x28 mm and 4.0x38 mm Xience stents

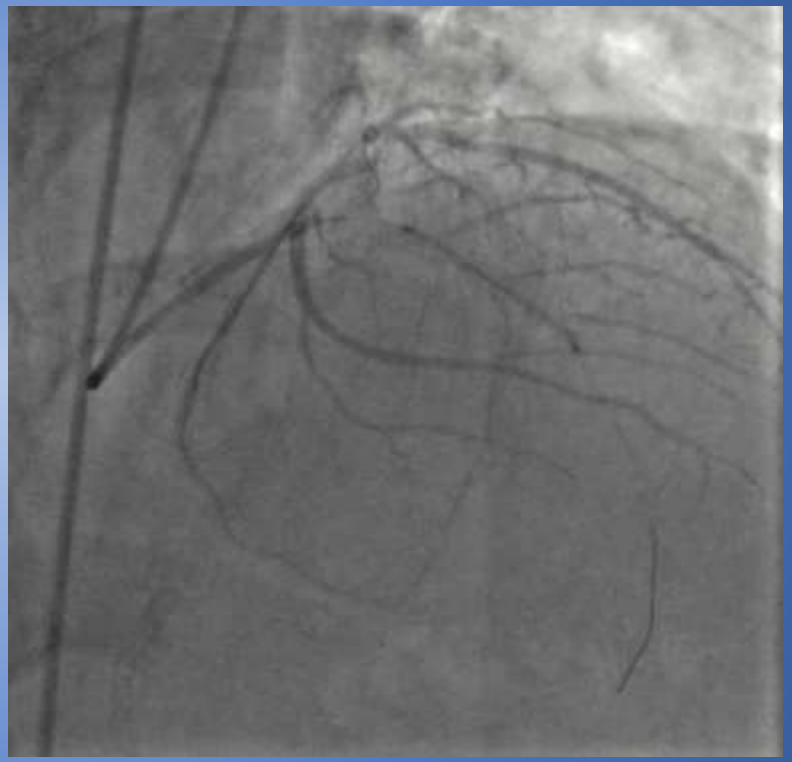
PCI of distal LM Bifurcation with Orbital Atherectomy and DK Crush Technique



PCI of distal LM Bifurcation with Orbital Atherectomy and DK Crush Technique

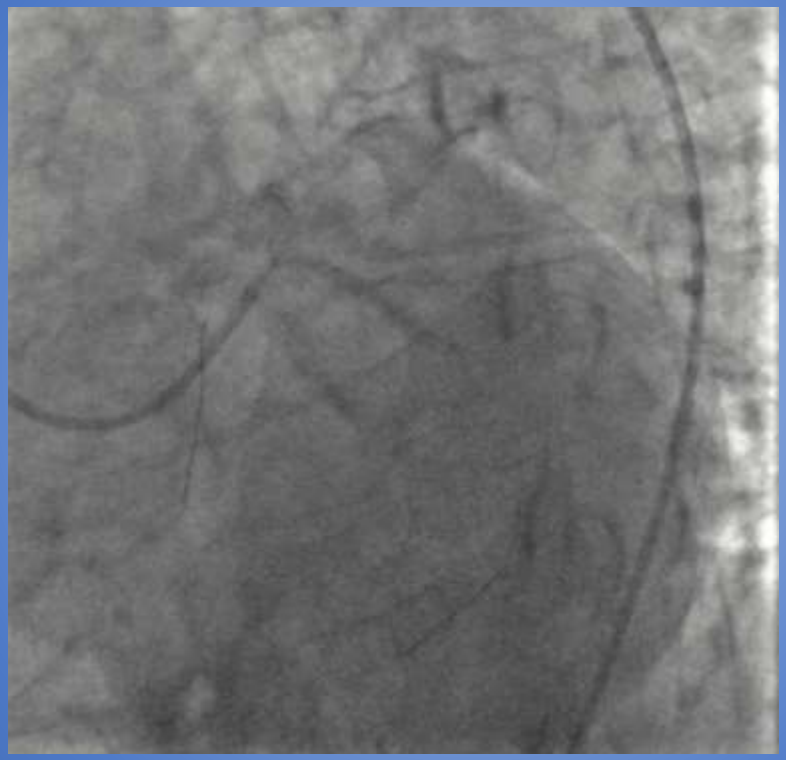


Predilate LAD with 3.25x20 mm balloon



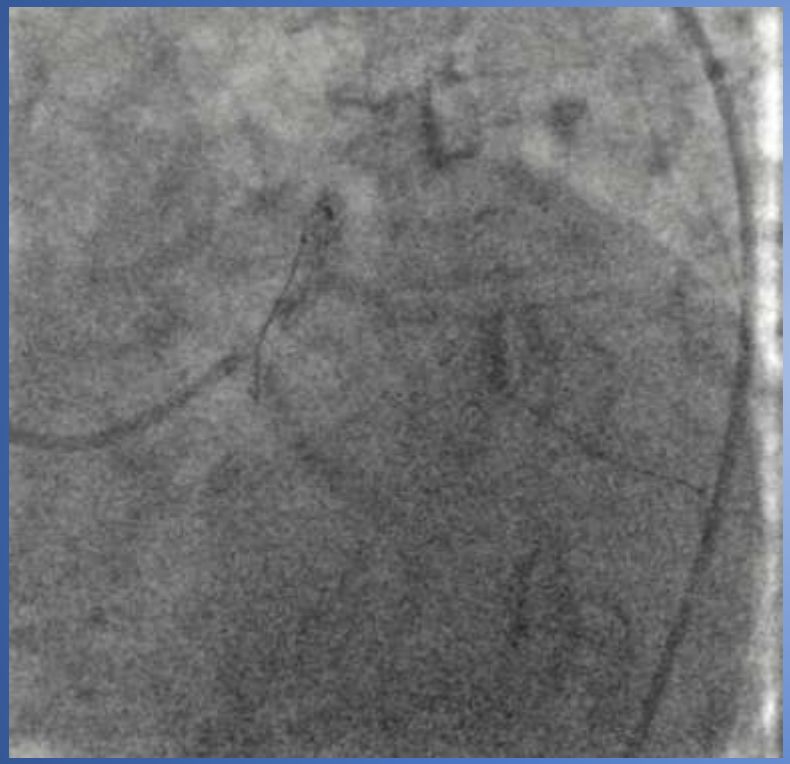
3.25x23 mm Xience

PCI of distal LM Bifurcation with Orbital Atherectomy and DK Crush Technique

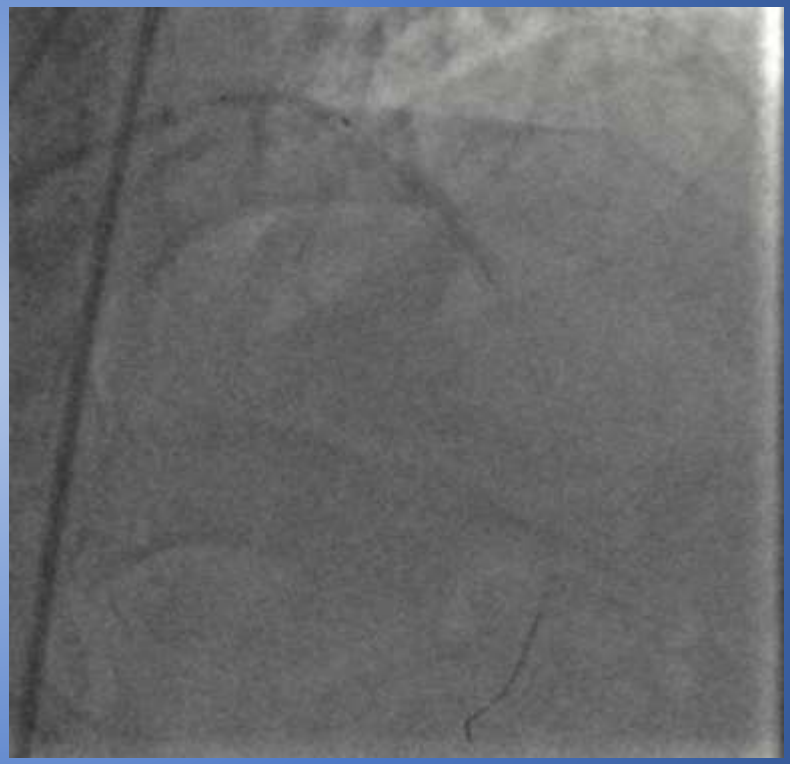


Predilate LCX with 2.75x20 mm balloon Hemodynamic collapse requiring phenylephrine 200 mcg and dopamine

PCI of distal LM Bifurcation with Orbital Atherectomy and DK Crush Technique



After 3.25x28 mm Xience in the ostial LCX, first kissing balloon angioplasty performed



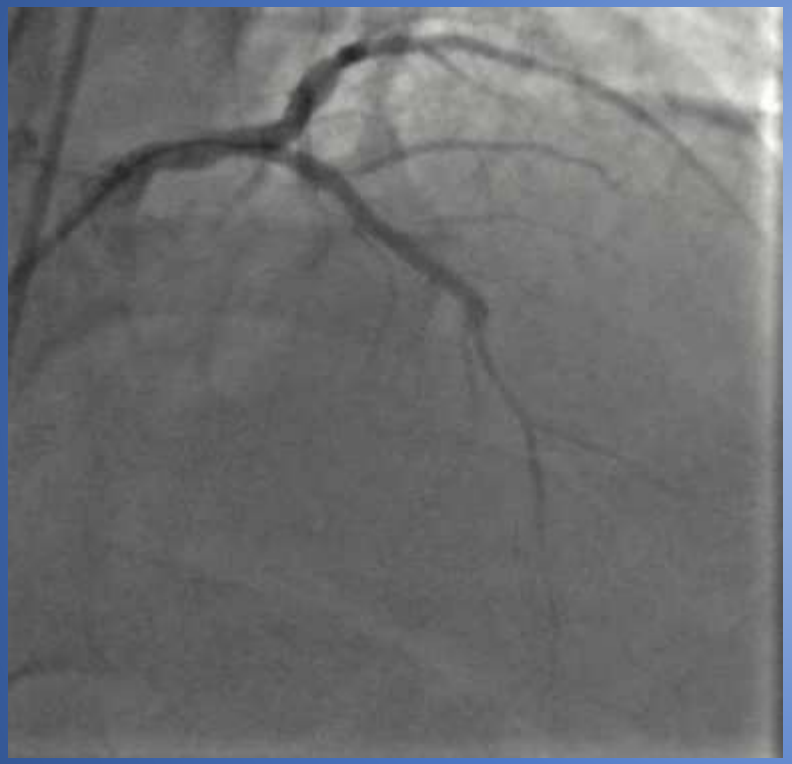
4.0x18 mm Xience in the LM

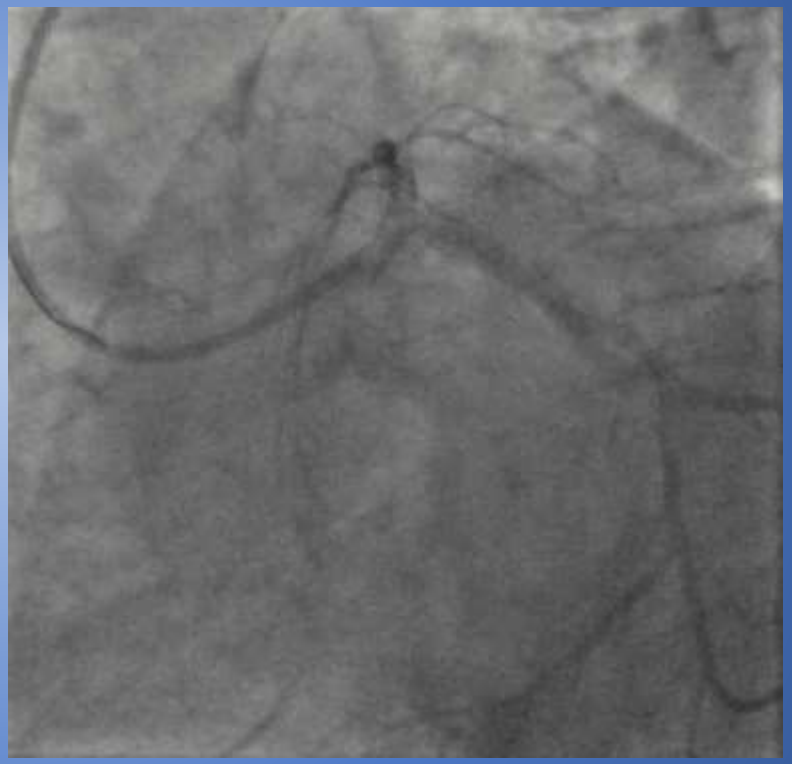
PCI of distal LM Bifurcation with Orbital Atherectomy and DK Crush Technique

Angiography after LM stent

Second kissing balloon inflation: 4.0x15 NC in LM and 3.5x15 mm NC in LCX

PCI of distal LM Bifurcation with Orbital Atherectomy and DK Crush Technique





“Failing to prepare is preparing to fail.”