

Clinical Experience Using Onyx Frontier in CHIP PCI - In My Daily Practice -

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Disclosures

Relationships with commercial interests:

- **Grants/Research Support: Abbott Vascular, Boston Scientific, Philips Volcano, Terumo Corporation, Donga-ST, Zoll Medical, and Yuhan Pharmaceutical**
- **Speakers Bureau/Honoraria: Abbott Vascular, Boston Scientific**
- **Consulting Fees: Genoss**
- **Other: None**

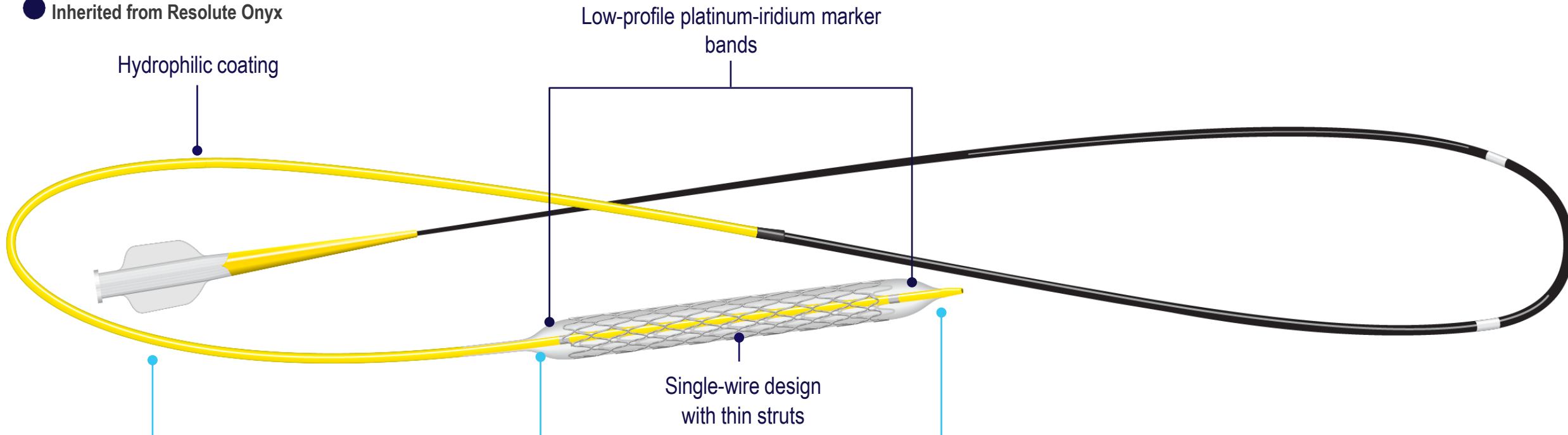
I have nothing to disclose with Medtronic.

Onyx Frontier

- Improved Feature Compared with Onyx -

● Unique to Onyx Frontier

● Inherited from Resolute Onyx



Increased catheter flexibility

Achieved through an updated manufacturing process and results in improved deliverability¹

Dual-flex balloon

Comprised of two layers:

- Inner layer enhances flexibility
- Outer layer maintains strength

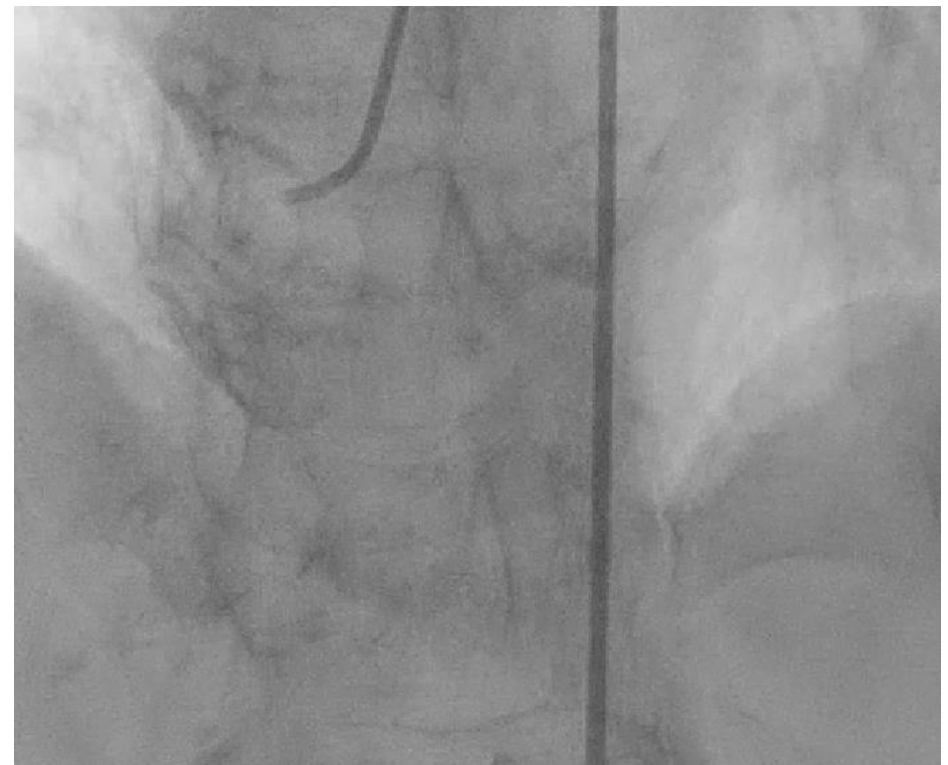
Results in a thinner balloon that maintains the same rated burst pressure as Resolute Onyx

7.5% lower crossing profile

Compared to Resolute Onyx, is enabled by the thinner dual-flex balloon

Onyx Frontier in I-CMP and Heavily Calcified Lesion

**F/75, Ischemic cardiomyopathy, EF 33% with RWMA in LAD/RCA territory
Admission due to congestive heart failure (NYHA IV with pulmonary congestion)**



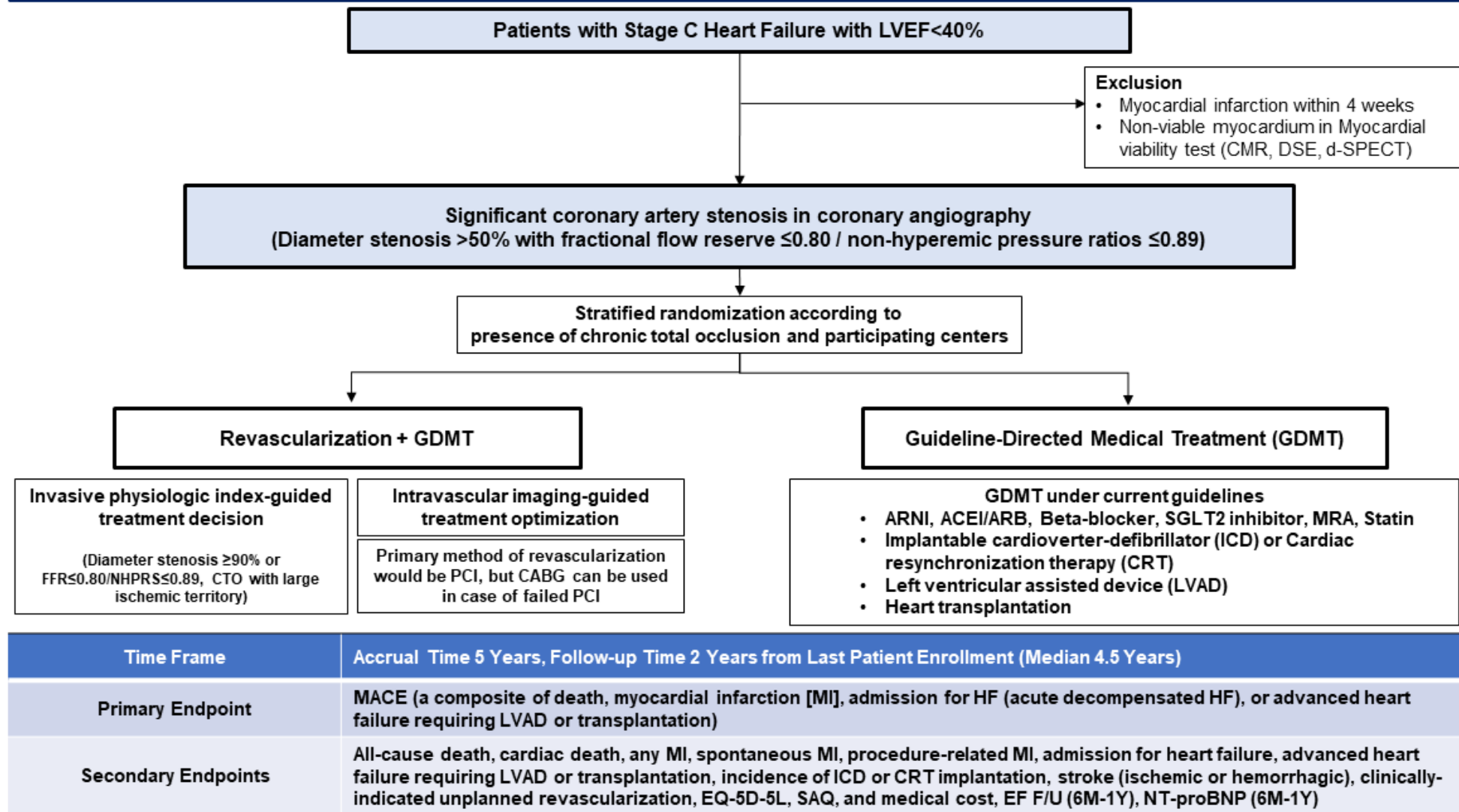
**pLAD diffuse 80% with heavy calcification, mLCX diffuse 70%, PDA tubular 90% stenosis
CABG was recommended but refused by patient.**

After Heart-team discussion, Patient was transferred to Cardiology Department.

RESTORE-PCI Trial (NCT05828719)

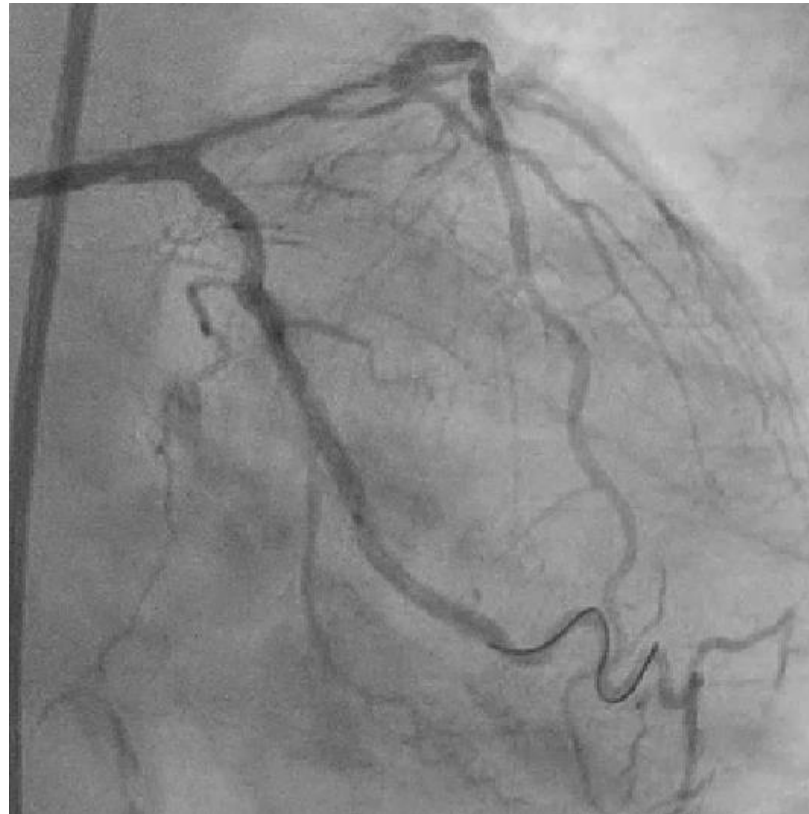


Randomized Controlled Trial of Revascularization Versus Medical Treatment on Clinical Outcomes in Patients with Reduced Left Ventricular Function

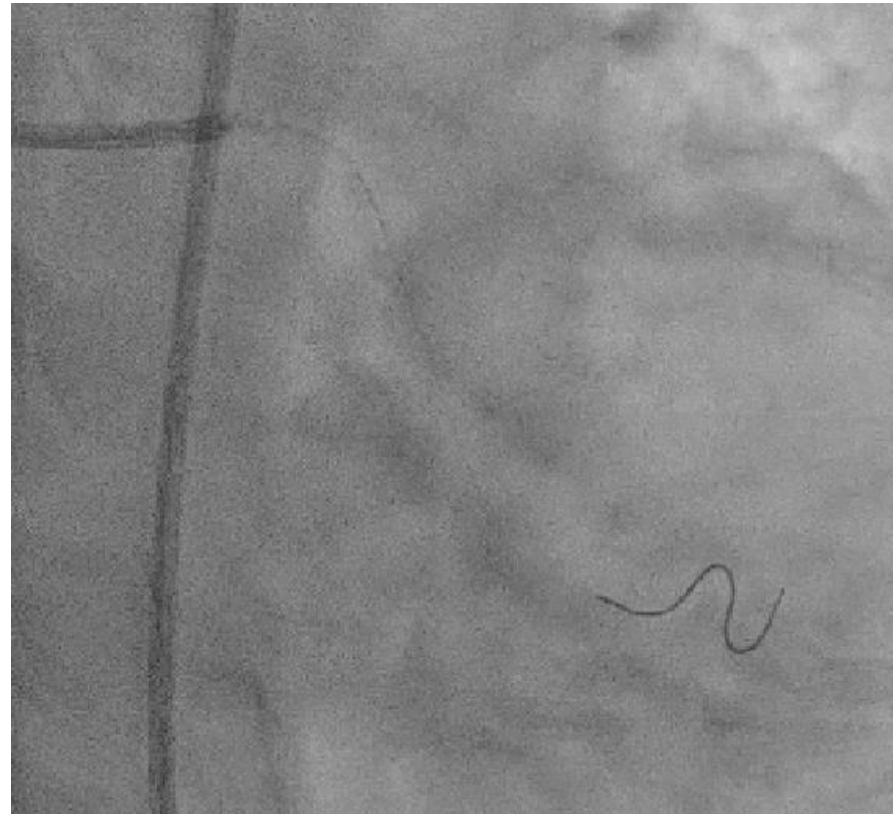


Onyx Frontier in I-CMP and Heavily Calcified Lesion

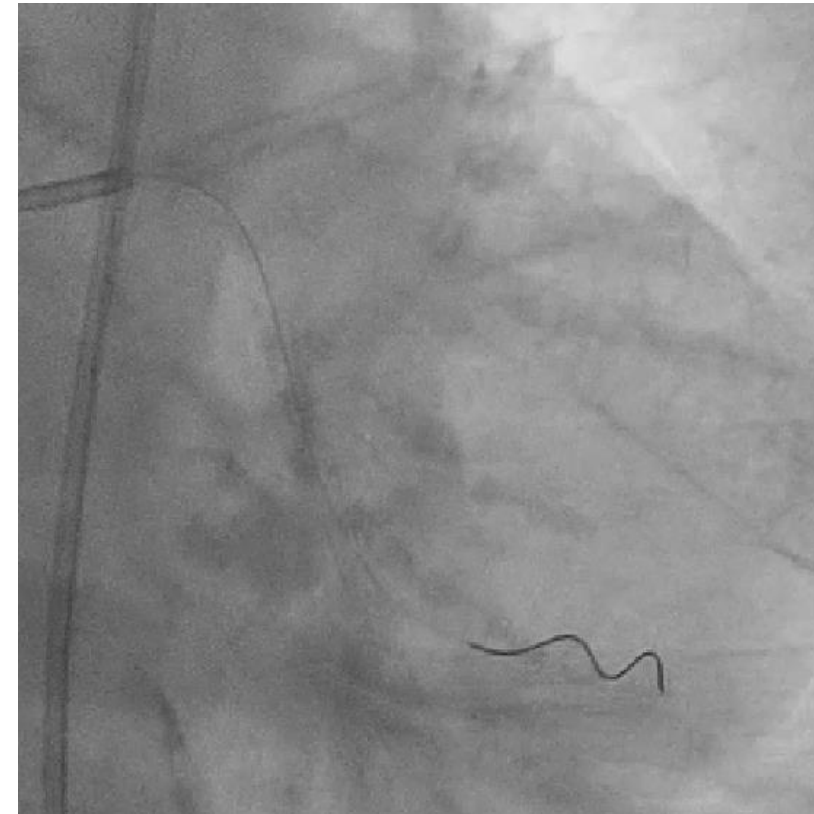
Allocated into Revascularization + GDMT group. Given the possible need of rota-ablation for LAD, sequence of PCI was decided as LCX → LAD → PDA



2.5x20mm NC balloon failed to cross
2.0x20mm high pressure balloon
2.5x20mm NC re-tried



Onyx Frontier 2.5x26mm
Inflation time 20 sec, up to 16atm



After 2.5x20mm Adjunctive balloon
IVUS MSA 4.43mm²

Onyx Frontier in I-CMP and Heavily Calcified Lesion

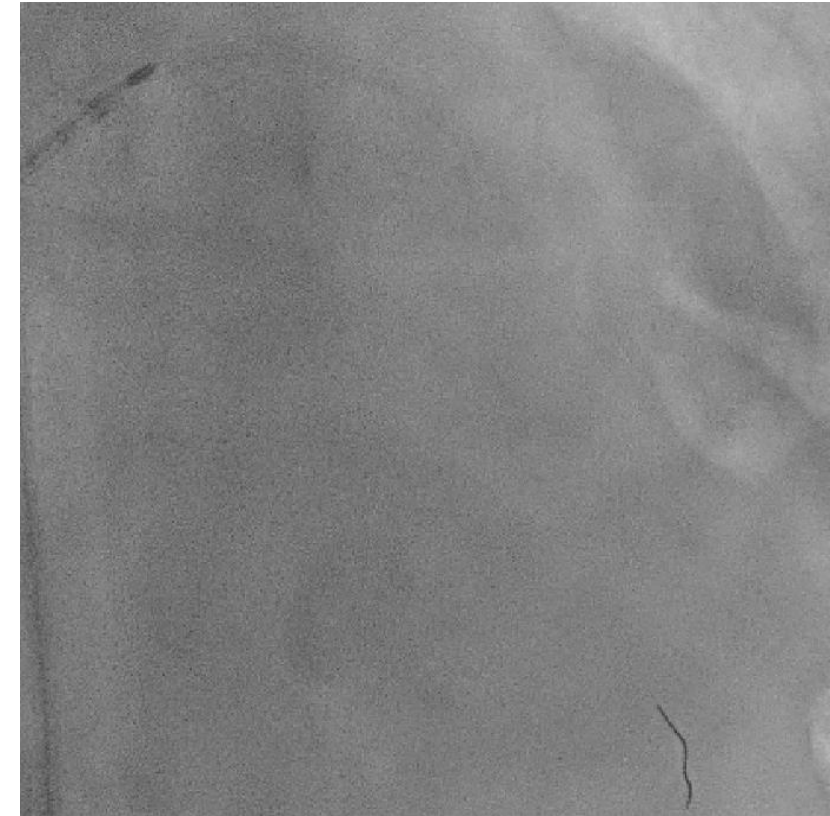
Rota-ablation with 1.5mm burr (Rota-Pro)



190,000 RPM cross the lesion



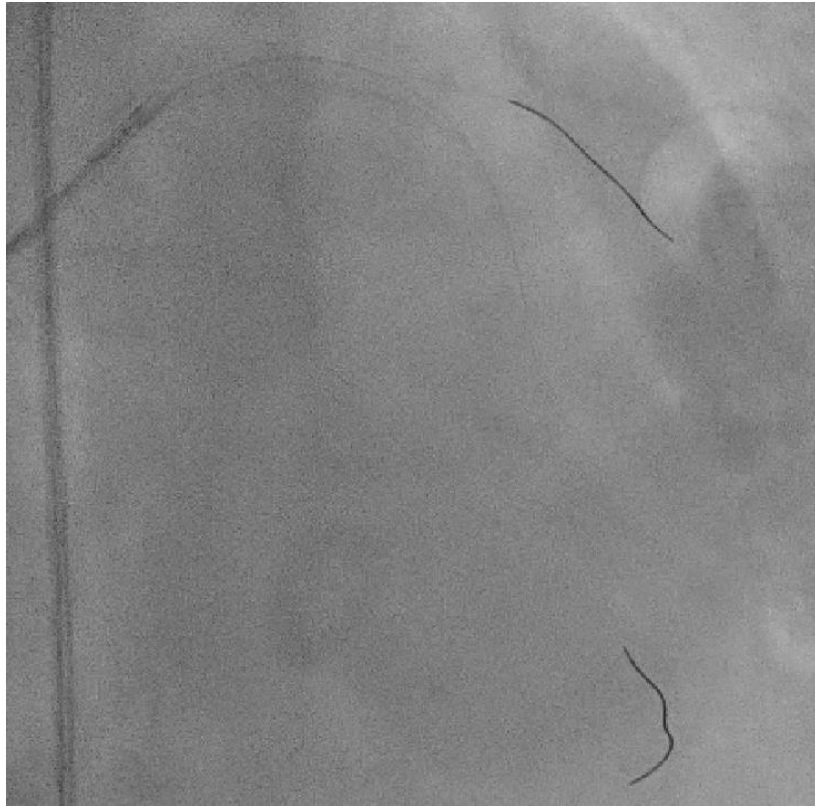
High speed polishing with 190,000 RPM



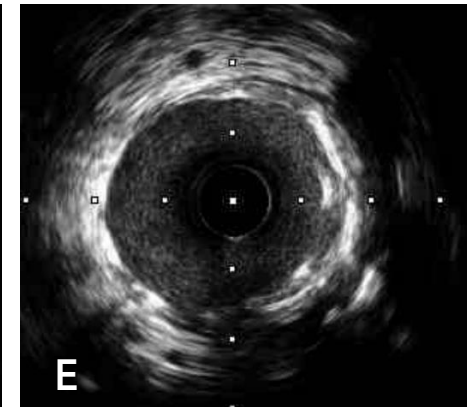
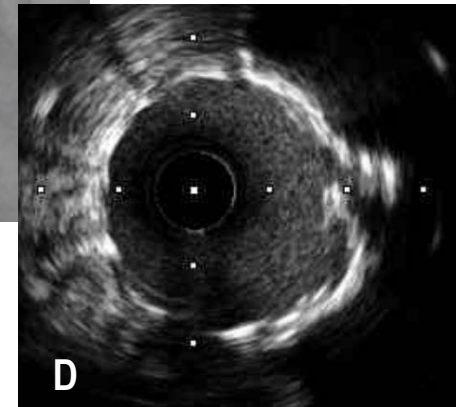
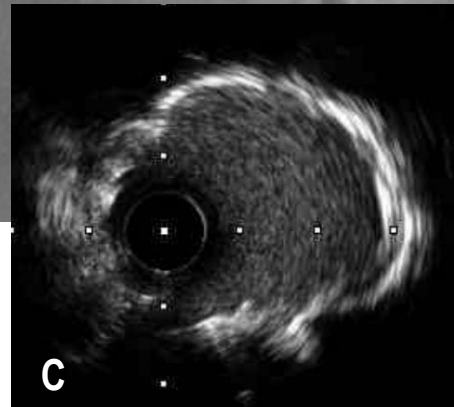
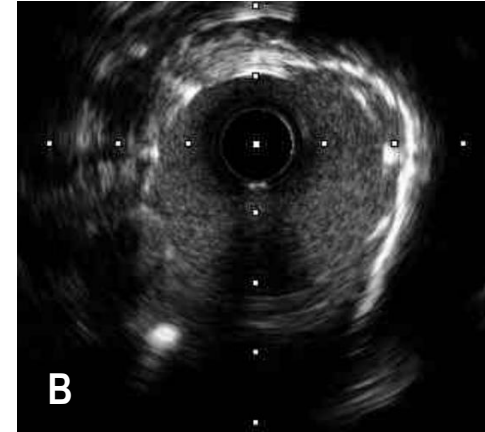
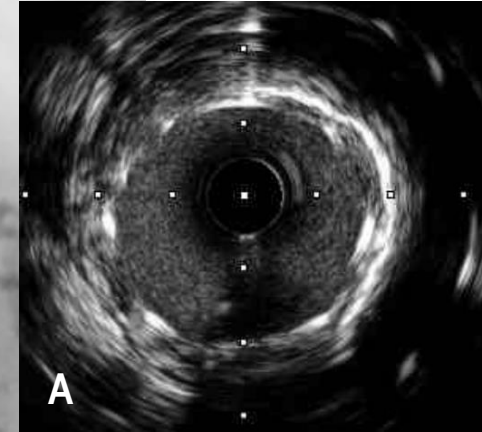
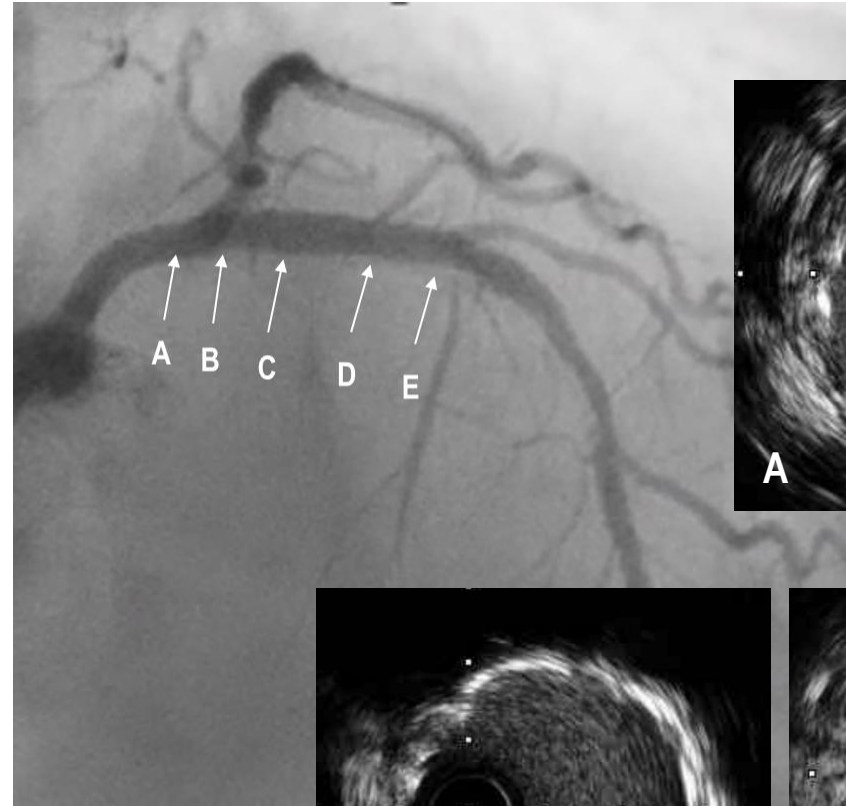
Low speed polishing with 150,000 RPM

Onyx Frontier in I-CMP and Heavily Calcified Lesion

Excellent deliverability and flexibility of Onyx Frontier
Even in heavily calcified lesion



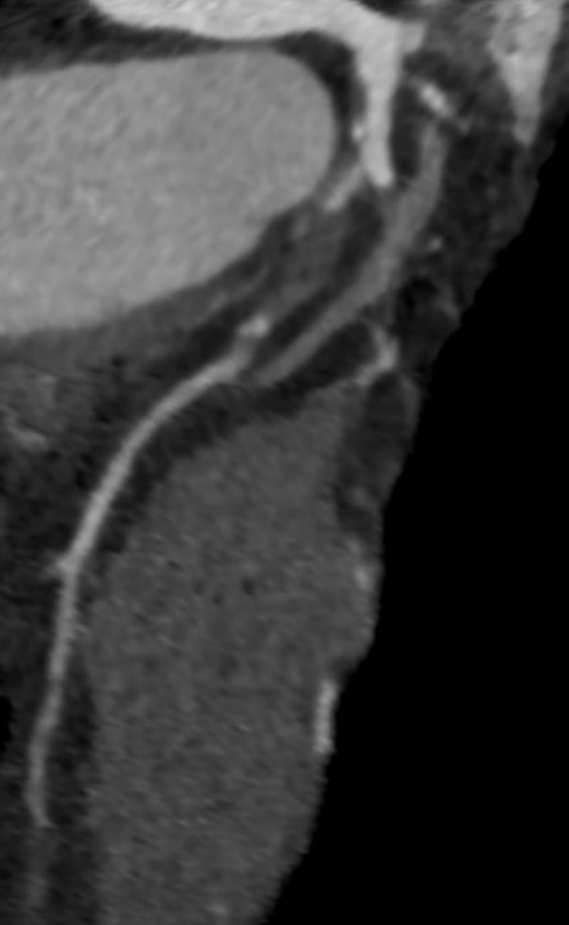
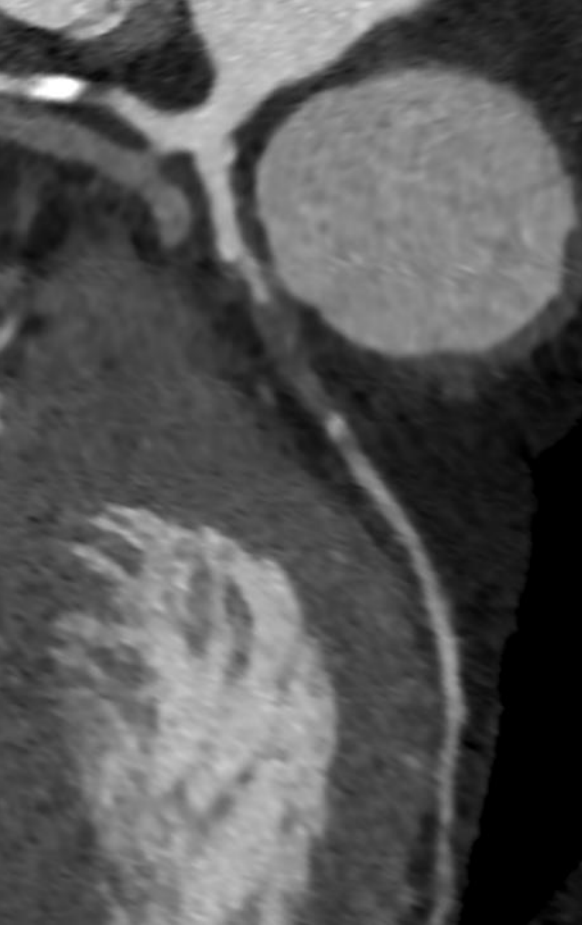
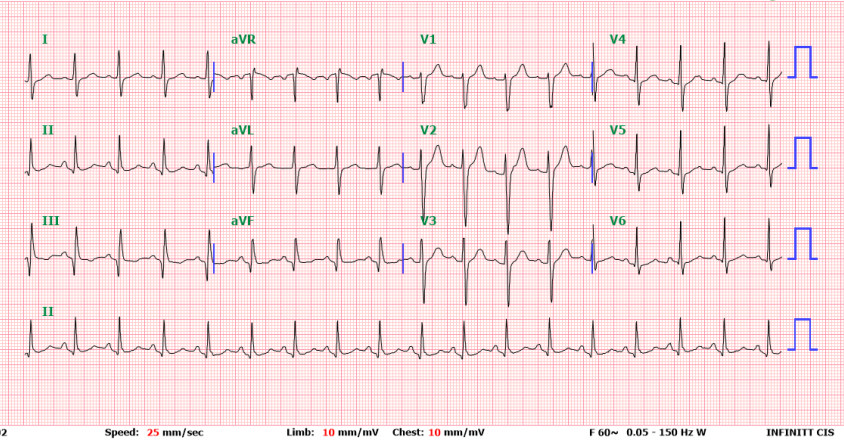
Onyx Frontier 3.0x30mm
3.25x20 NC Adjunctive balloon



Good expansion and apposition of stent

Onyx Frontier in Retrograde CTO PCI

**M/51, Stable Angina (mainly DOE), CCS II since about 2 years ago
Referred from outside hospital due to LAD CTO in Coronary CT angiography**



**ECG showed no anterior Q wave
Echo – EF 54.5%, RWMA (+, LAD)
CCTA showed LAD CTO**

SMART-STEP Trial (NCT05799092)

Smart Angioplasty Research Team-Invasive versus non-invasive tests as next diagnostic STEP in symptomatic patient with non-high risk coronary artery stenosis (SMART-STEP)

**Patient with Significant CAD in CCTA ($\geq 50\%$ stenosis)
(CCTA according to the current guidelines)**

- Exclusion**
- High risk CAD (LM $\geq 50\%$ or 3VD $\geq 70\%$)
 - Biomarker (+) ACS

Stratified randomization according to diabetes mellitus and centers

Initial Invasive Approach

Invasive CAG (\pm Physiologic assessment)

Positive (%DS $\geq 70\%$ or FFR ≤ 0.80)

Negative

Revascularization (PCI or CABG)

GDMT

Initial Non-invasive Approach

Exercise ECG, Stress echo, SPECT, PET, stress CMR

Negative or Mild ischemia

Positive (Moderate-Severe ischemia)

GDMT

Invasive CAG and standard care

Time Frame	Accrual Time 4 Years, Follow-up Time 2 Years from Last Patient Enrollment (Median 4 Years)
Primary Endpoint	MACE (a composite of death, myocardial infarction [MI], clinically-indicated unplanned revascularization)
Secondary Endpoints	All-cause death, cardiac death, any MI, spontaneous MI, procedure-related MI, resuscitated cardiac arrest, clinically-indicated unplanned revascularization, rate of index coronary angiography, rate of index coronary revascularization by PCI or CABG, EQ-5D-5L (quality of life), SAQ (angina severity), medical cost, and procedure-related complications from invasive procedure

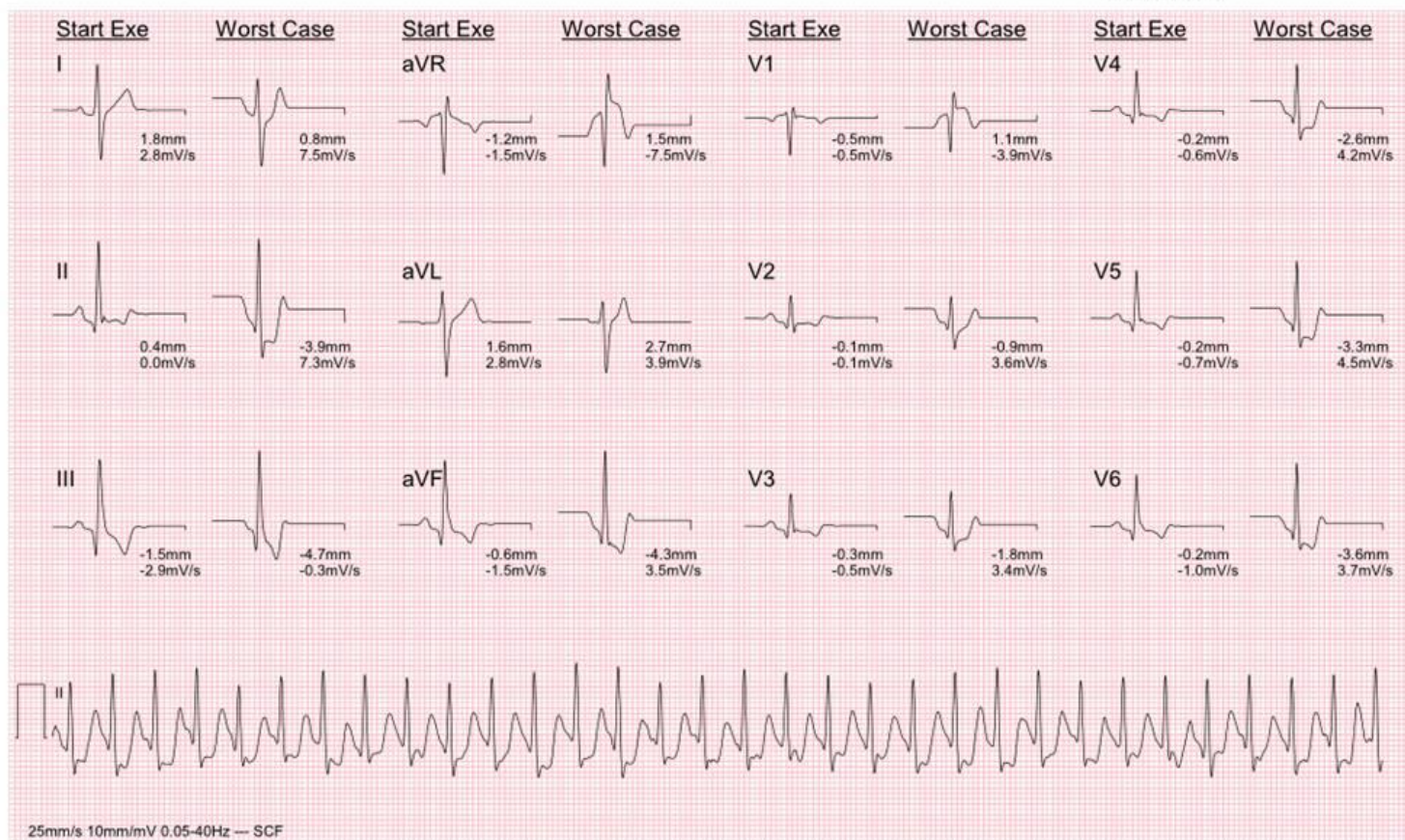
Onyx Frontier in Retrograde CTO PCI

M/51, Stable Angina (mainly DOE), CCS II since about 2 years ago
CCTA showed LAD CTO, **Allocated into Initial Non-Invasive Approach Group.**

CHO MOON SUNG
41014287
Bruce

Exam Start: 2024-02-07 오전 9:32:46
Event Time: 2024-02-07 09:47:32
Date of Birth: 1977-02-09
Gender: Male

10:10 EXER 6.7 km/h HR: 190
01:10 STAGE 4 16 % BP: 163/91
EXER 09:24



Positive Stress Echo – TMT (+), RWMA (+)

Onyx Frontier in Retrograde CTO PCI

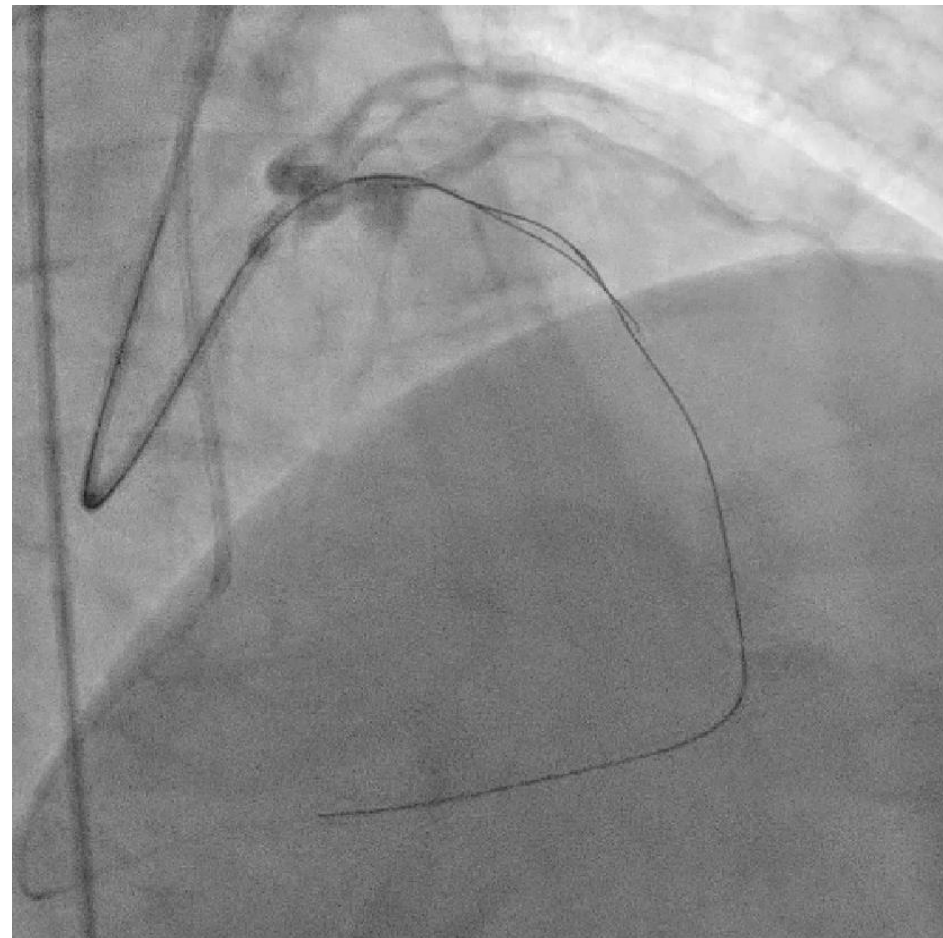
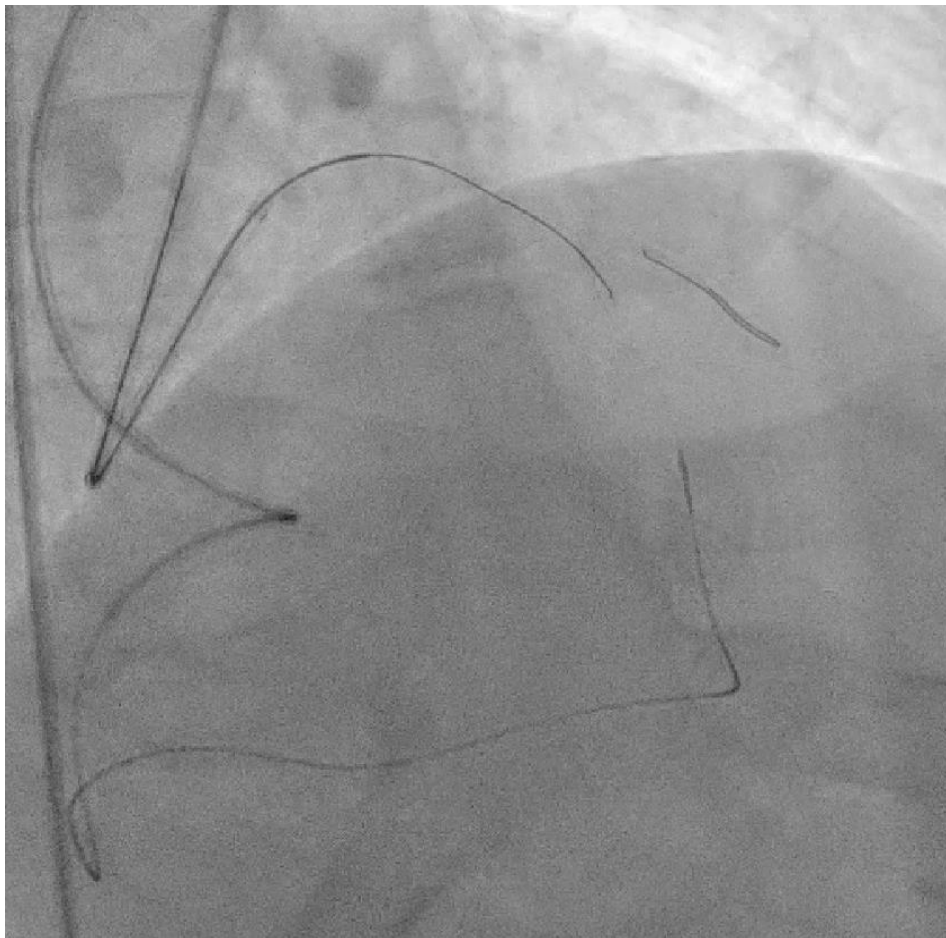
**M/51, Stable Angina, CCS II since about 2 years ago, LAD CTO
Based on the abnormal non-invasive stress test result, CAG was done.**



**Mid-LAD CTO, Gr. 3 collateral from RCA, Ipsilateral collateral (+)
Blunt stump, CTO length around ~30mm, Good retrograde channel**

Onyx Frontier in Retrograde CTO PCI

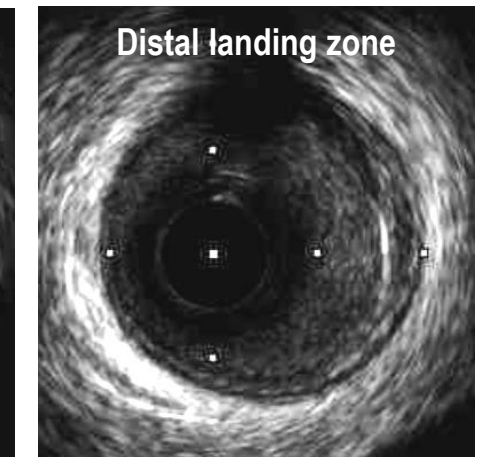
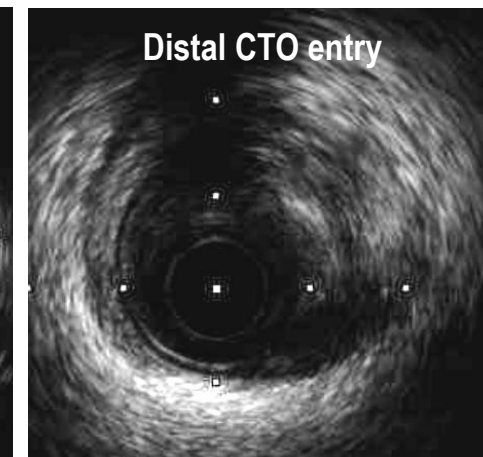
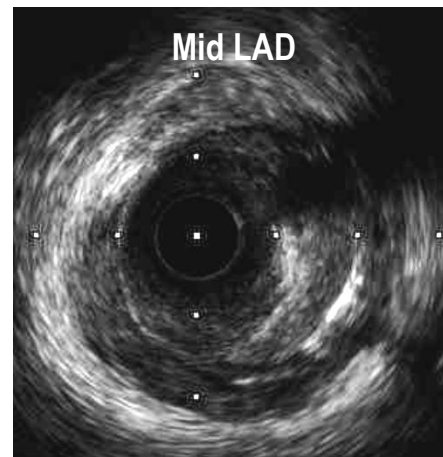
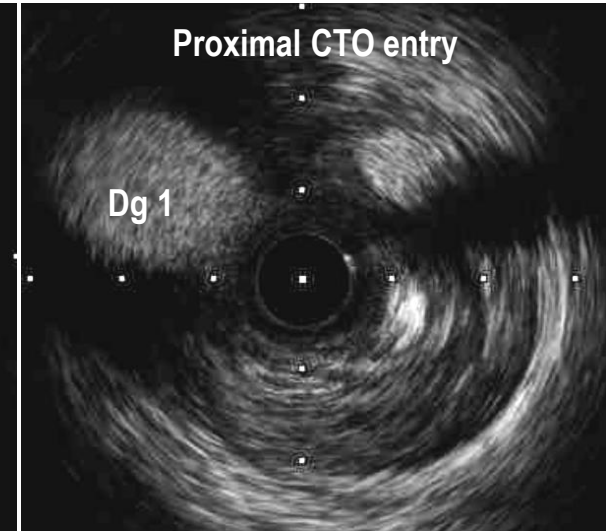
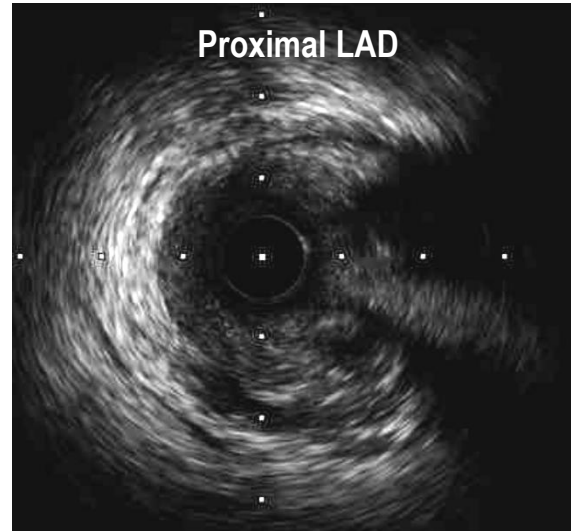
**M/51, Stable Angina, CCS II since about 2 years ago, LAD CTO
Given the ambiguous proximal stump, change to retrograde approach**



**Channel selection with Fielder → cross with Suoh 03 (with Caravel) → CTO cross with Gaia 2nd
→ Tip-in technique into Cosair Pro XS → wire exchange**

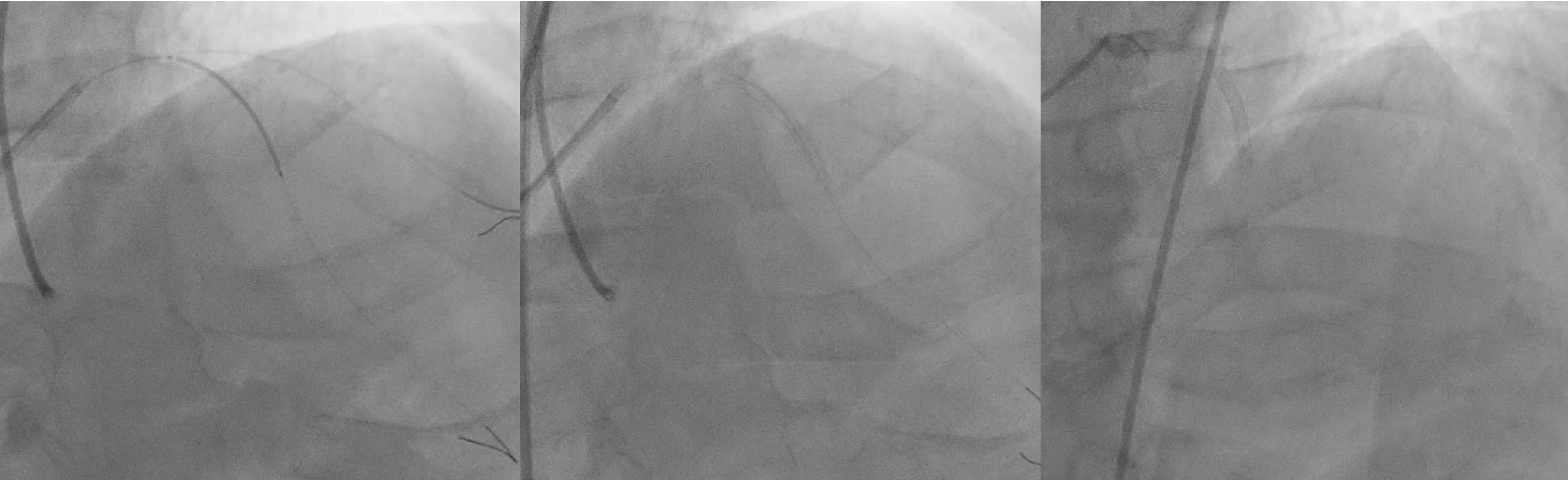
Onyx Frontier in Retrograde CTO PCI

After pre-dilatation with 2.5x20mm semi-compliant balloon
IVUS was done for stent sizing and selection of landing zones.



Onyx Frontier in Retrograde CTO PCI

M/51, Stable Angina, CCS II since about 2 years ago, LAD CTO
Final Angiography



Onyx Frontier 2.75x38mm at p-mLAD, DCB 2.5x30mm at m-dLAD

Onyx Frontier in Complex CTO PCI

F/29, Polyarteritis Nodosa involving both renal and coronary arteries Diagnosed when she was 17 years old (2012)

- Referred to SMC due to New-onset HTN (BP 202/151)
- 2ndary HTN w/u – all negative
- ESR 90 mm/h, CRP 0.43 mg/dL
- FANA, ANCA, HBV Ag – all negative

- Multiple fusiform and saccular aneurysms in renal artery
- Ectatic changes and aneurismal changes in RCA, LCA.
- Stress echocardiography – negative

- Cyclophosphamide and Prednisolone
- 2012 ~ 2022 Stable Clinical Course

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IMAGES IN CARDIOLOGY

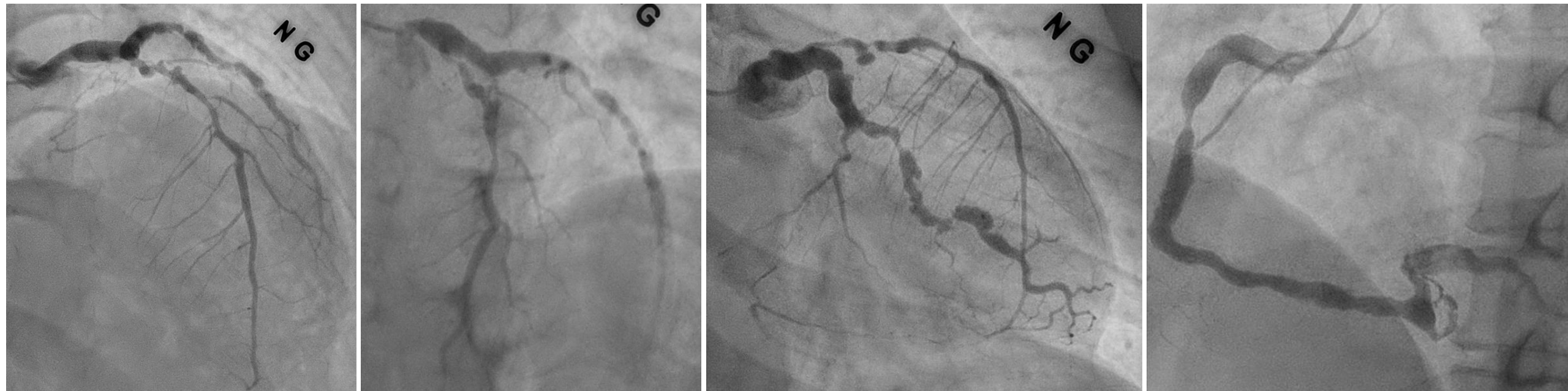
Polyarteritis Nodosa Involving Renal and Coronary Arteries

Jiwon Hwang, MD,* Jeong Hoon Yang, MD,† Duk-Kyung Kim, MD,† Hoon-Suk Cha, MD*
Seoul, Republic of Korea



Onyx Frontier in Complex CTO PCI

**F/29, Polyarteritis Nodosa involving both renal and coronary arteries
Exertional chest pain, Stress echo positive, CAG 2023-07**



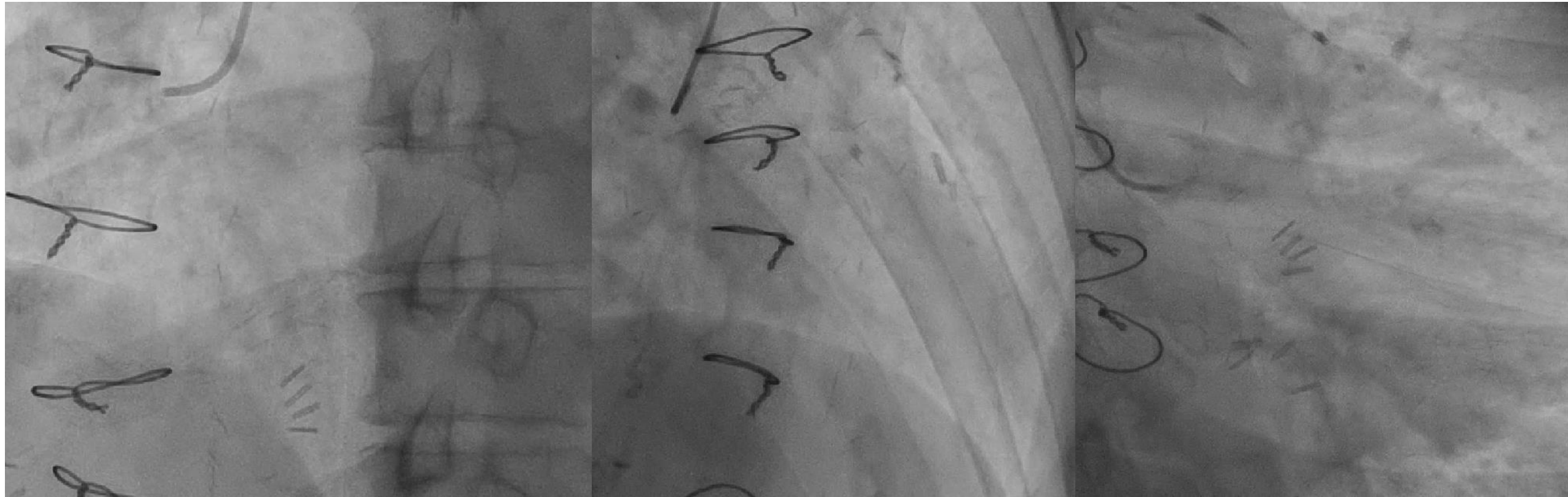
CABG was performed. During bilateral IMAs harvest, surgeon noticed that both IMAs were also involved by PAN and lumen was obliterated.

Saphenous vein grafts to LAD and OM was anastomosed.

Onyx Frontier in Complex CTO PCI

F/29, Polyarteritis Nodosa involving both renal and coronary arteries

After CABG 2023-07, patient was admitted due to orthopnea and pulmonary congestion at 2024-04



**ECG showed myocardial ischemic change.
Echo – EF 52%, new RWMA in LAD territory**

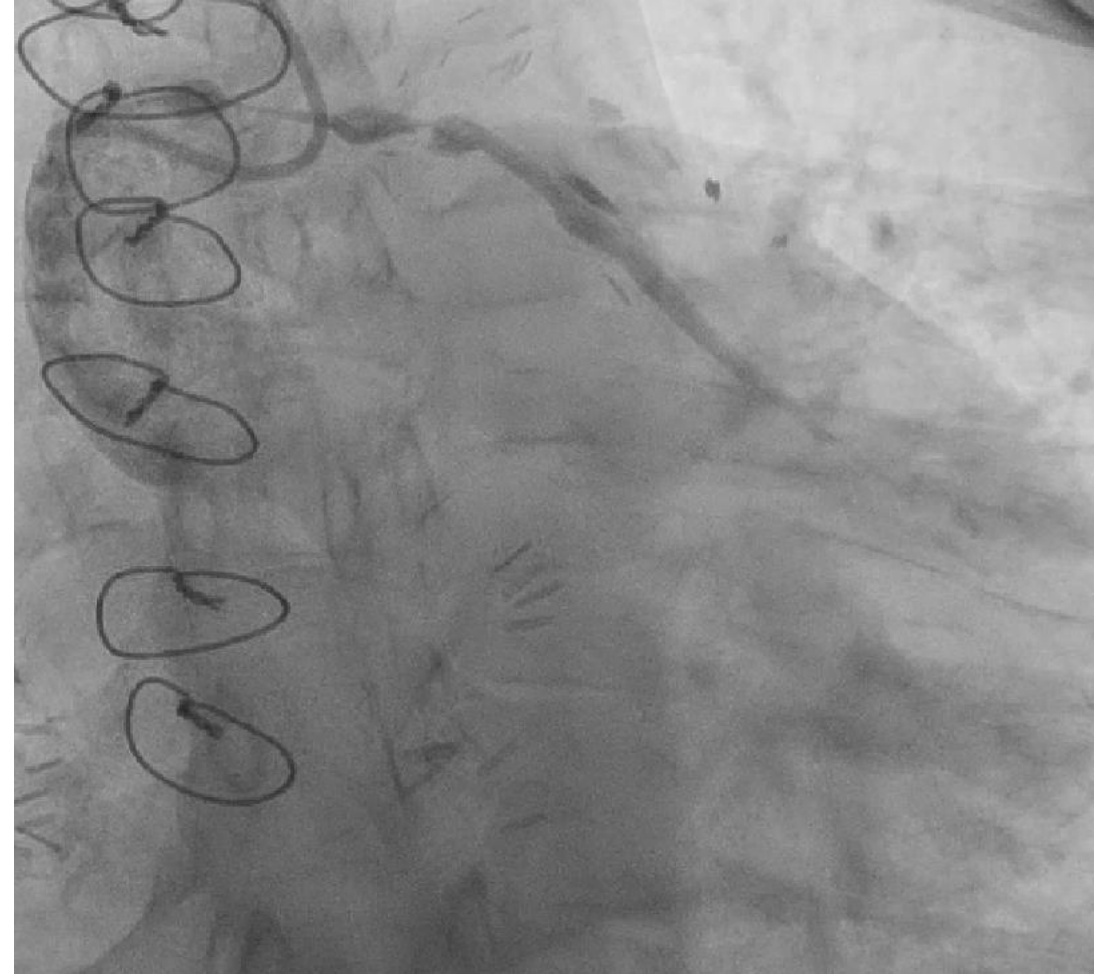
LAD os total occlusion, much progressed OM stenosis, RCA stationary

Onyx Frontier in Complex CTO PCI

SVG-LAD graft



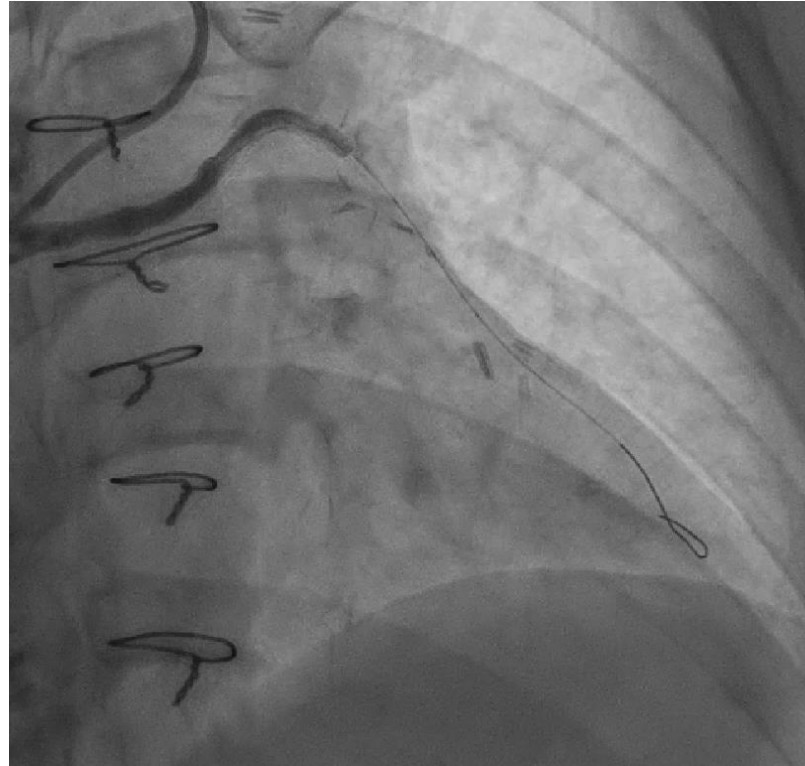
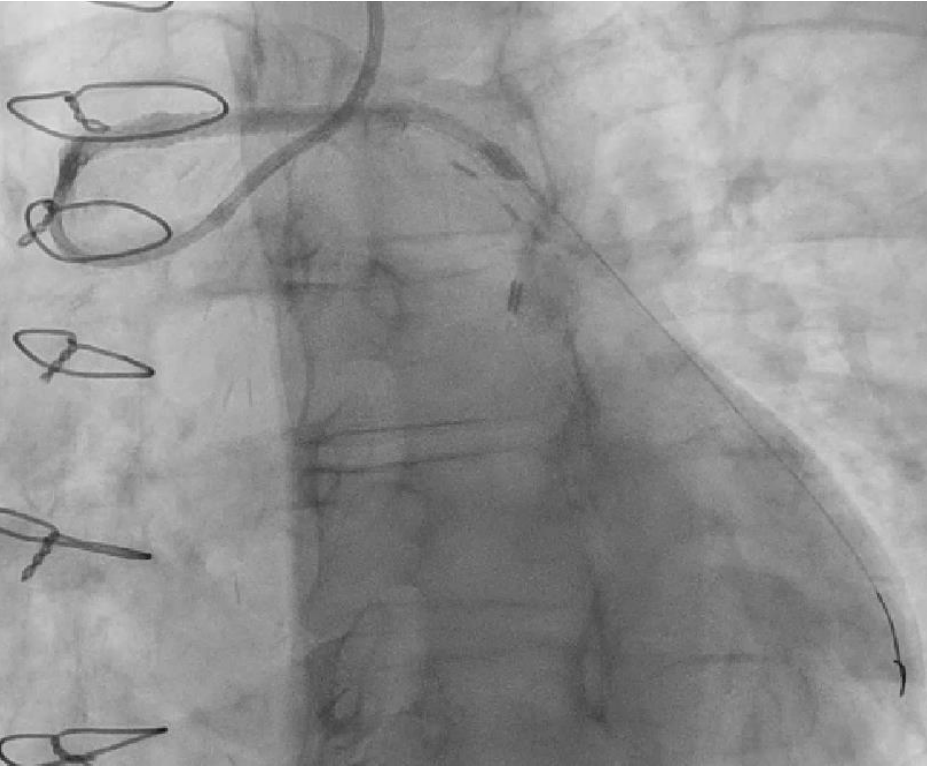
SVG-OM graft



SVG-LAD total occlusion, SVG-OM subtotal occlusion.

Onyx Frontier in Complex CTO PCI

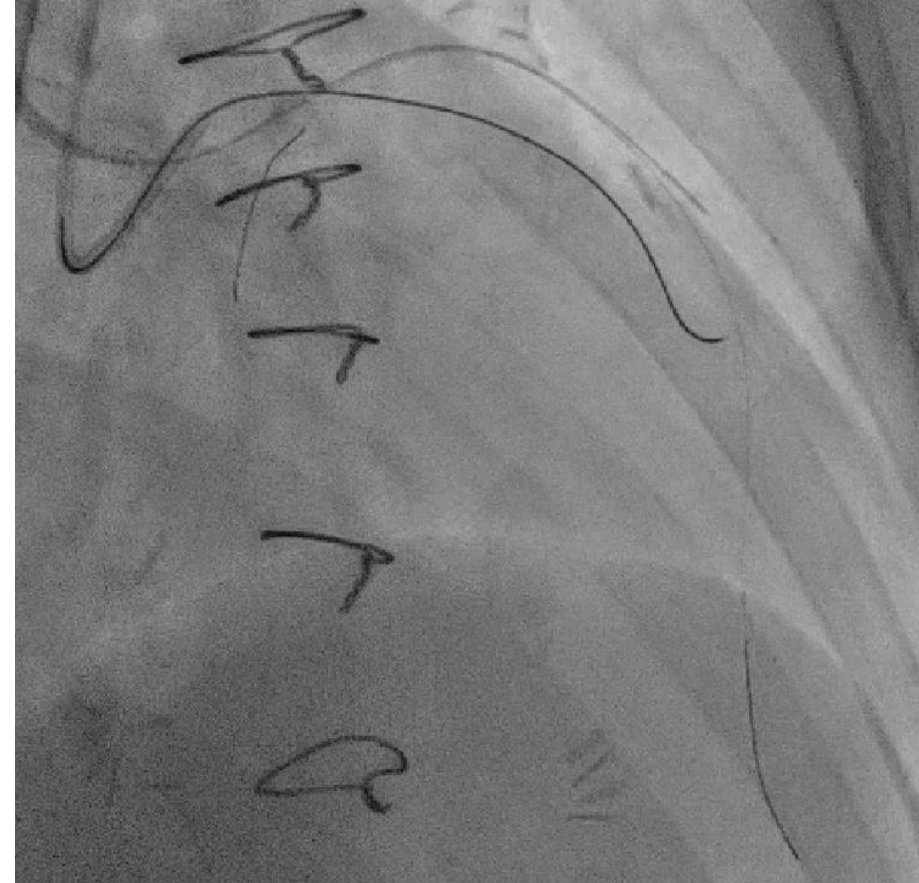
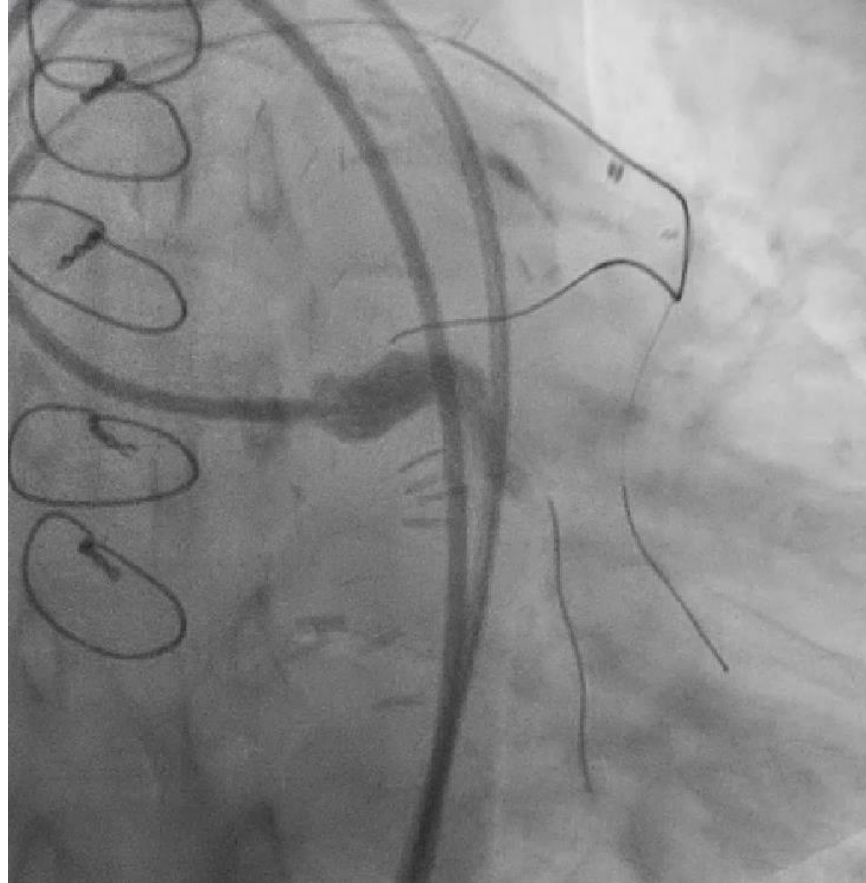
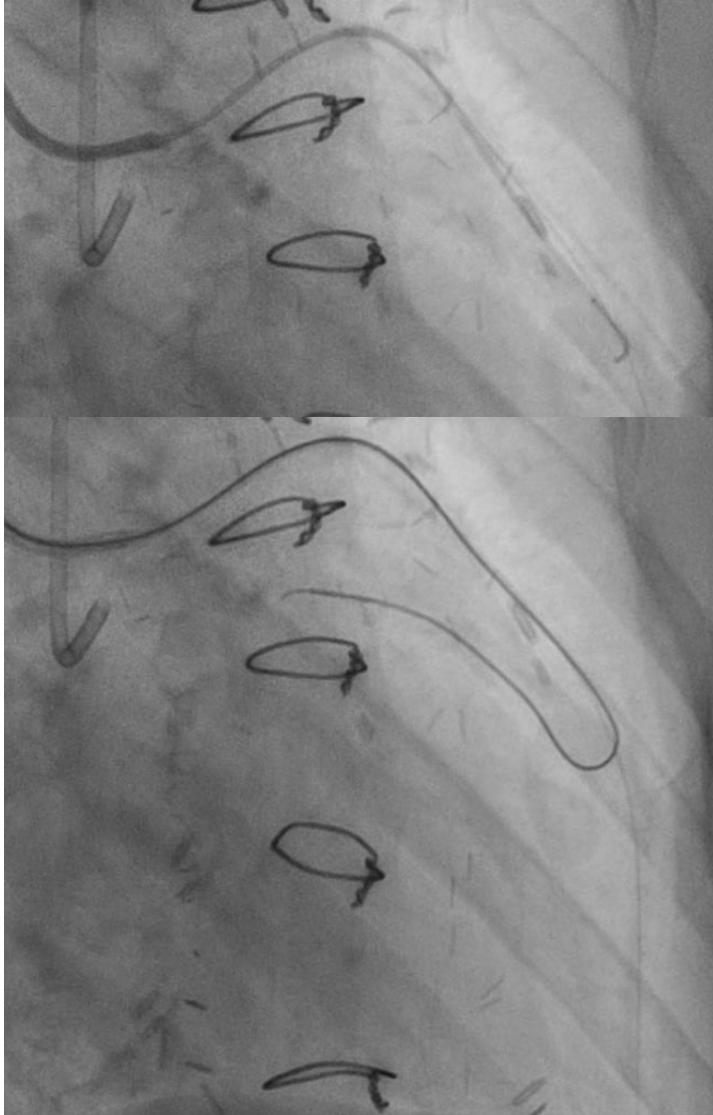
**F/29, Polyarteritis Nodosa involving both renal and coronary arteries s/p CABG, Graft failure.
SVG-OM graft was revascularized first.**



Onyx Frontier 3.5x38mm at proximal SVG graft, DCB 3.0x30, 2.5x30mm at distal SVG-OM

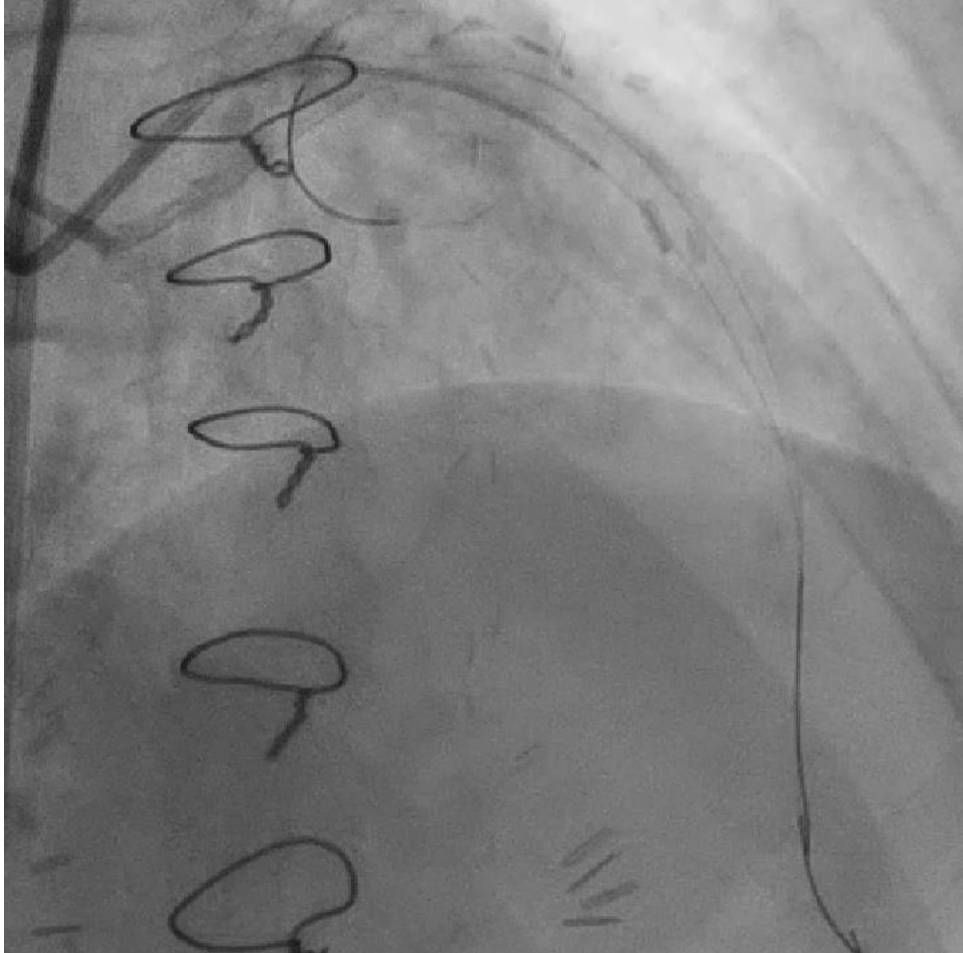
Onyx Frontier in Complex CTO PCI

Total occlusion of SVG-LAD and LAD os CTO PCI



Cosair Pro XS and UB3 wire into totally occluded SVG → cross to LAD → Supercross 120° → Fielder XT-R into distal LAD stump → CTO crossing with UB3 → Tip-in → Wire exchange into LAD

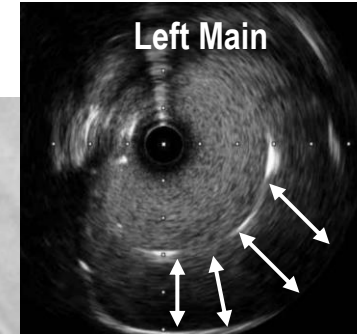
Onyx Frontier in Complex CTO PCI



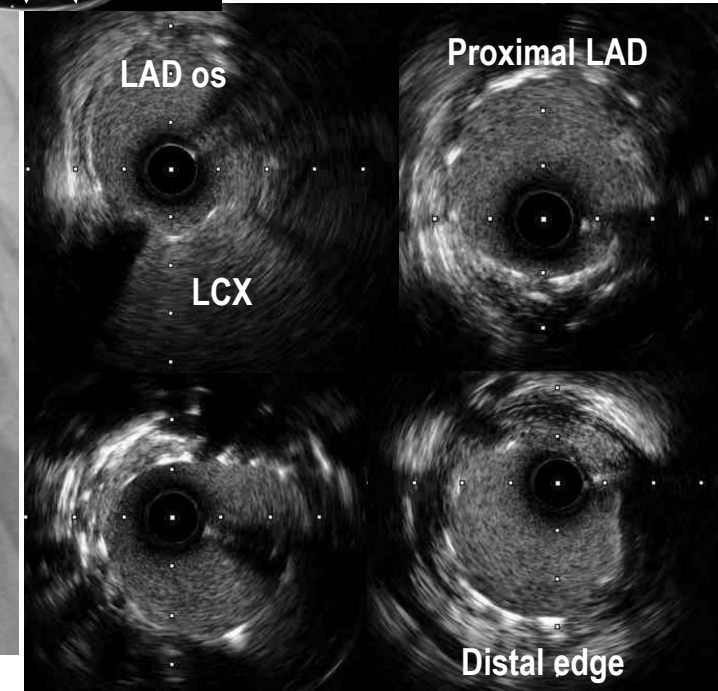
Onyx Frontier 3.0x38mm at LM - mLAD



Adjunctive balloon with 3.5x20mm NC

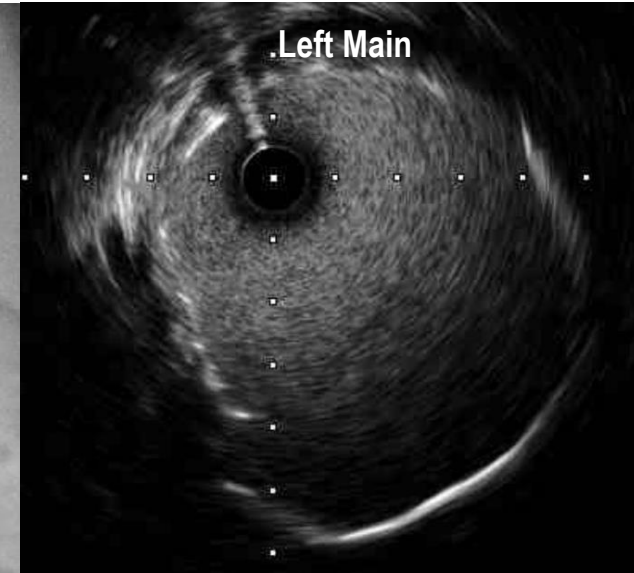
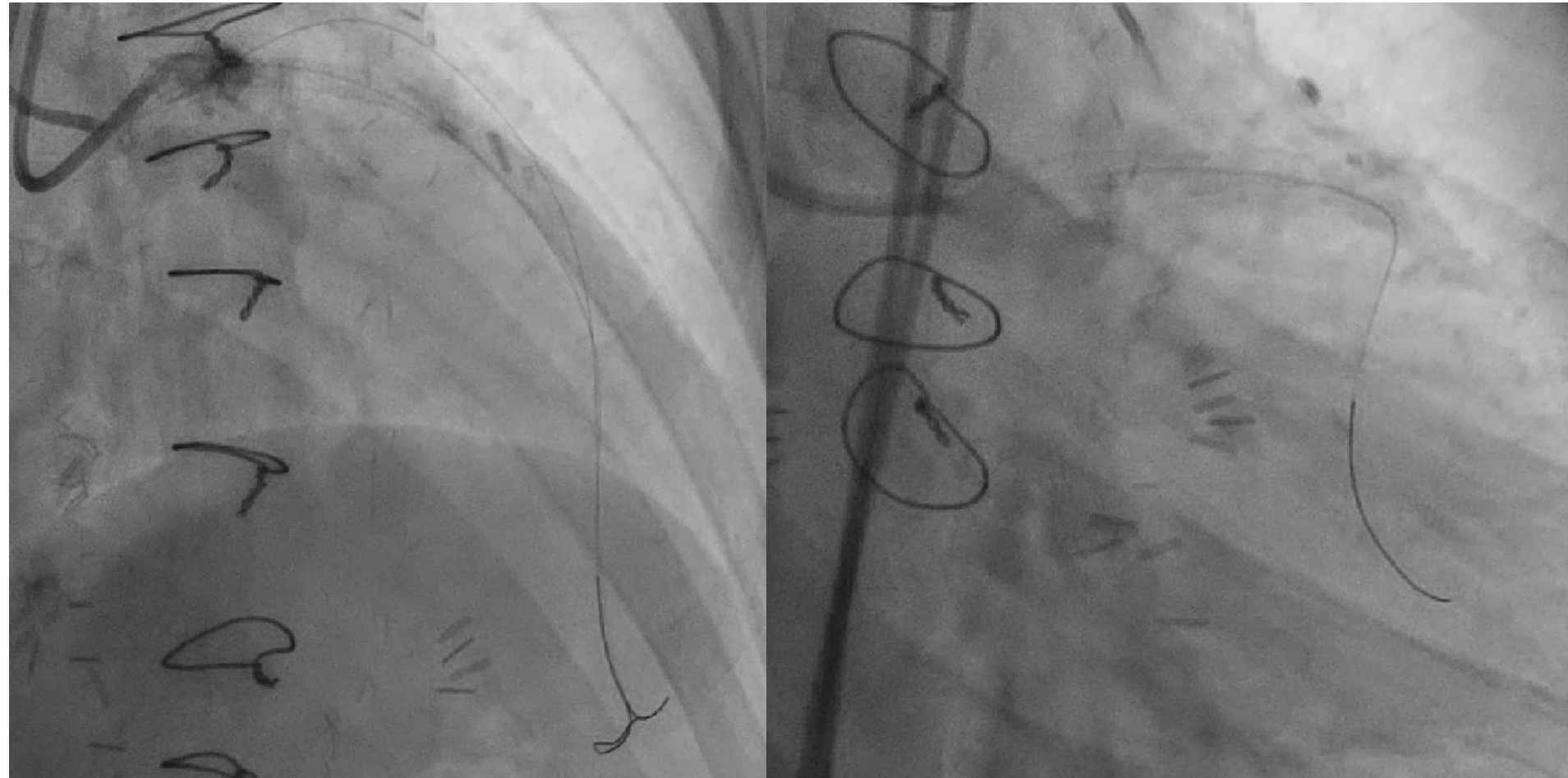


Under-apposition at LM



Onyx Frontier in Complex CTO PCI

Final Angiography and IVUS



Complete apposition at LM

Adjunctive balloon with 6.0x10mm at LM

Summary

- Optimal techniques and devices are essential in Complex Lesion PCI.
- **Onyx Frontier** facilitate Complex Lesion PCI based on its **lowest crossing profile, excellent deliverability and flexibility, dual-flex balloon technology, and wide expansion range.**
- **Onyx Frontier can cover any types of complex coronary artery lesions.**
- Intravascular Imaging-guided optimization is the key in Complex lesion PCI including CTO, heavily calcified lesion, unprotected left main, complex bifurcation lesion, long lesion, and multivessel disease.
- The value of Intravascular Imaging-guided optimization in Complex lesion PCI has been proved by multiple RCTs including **the RENOVATE-COMPLEX-PCI Trial.**