

A novel technique for distal left main lesion treatment using DES & BVS

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

Company

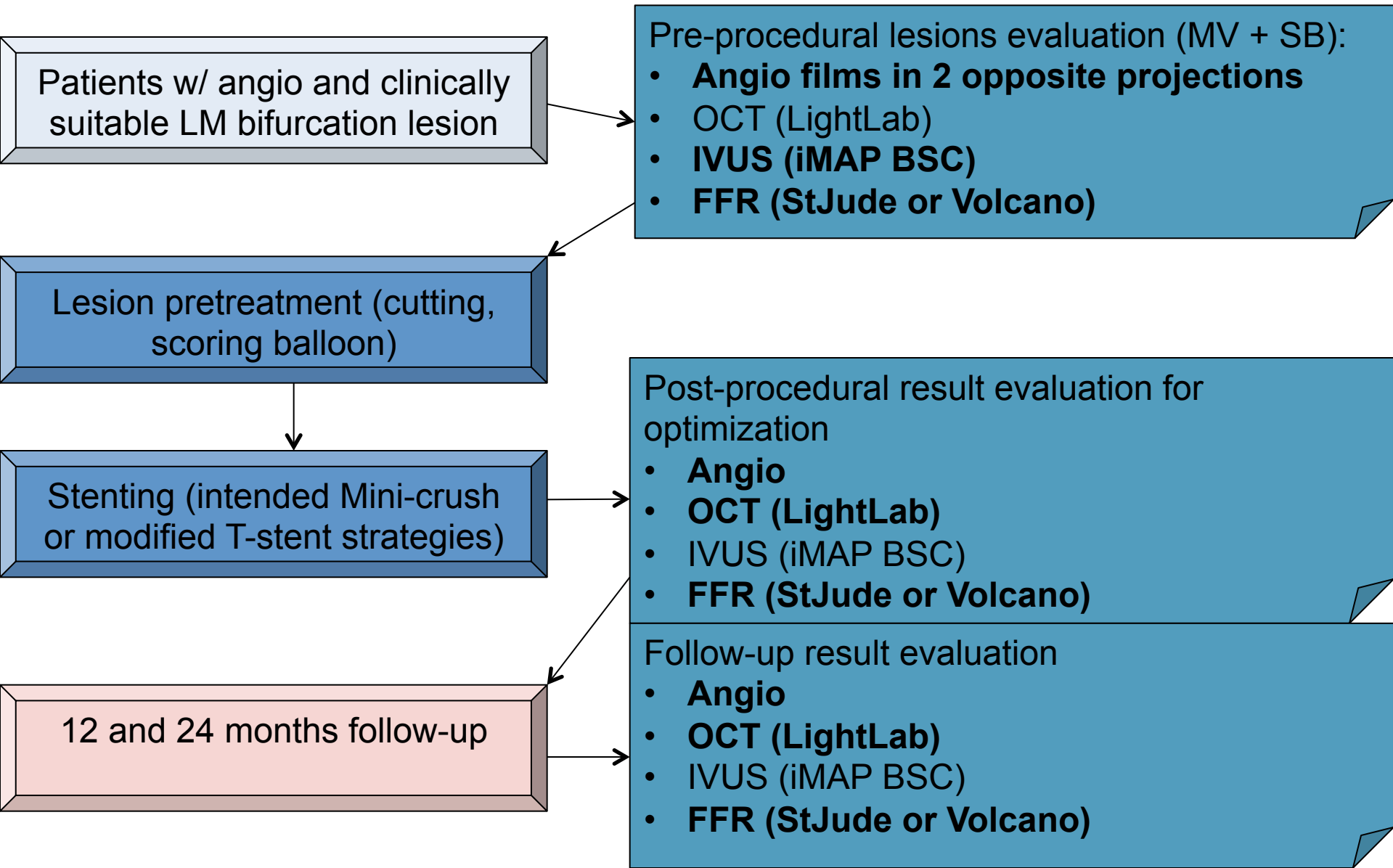
- Abbott Vascular, Boston Scientific
- Abbot Vascular, Biosensors, Boston Scientific, Cordis J&J, Medtronic

Novel technique for left main:

Unprotected LM Intervention by IVUS-guided and OCT-Optimized Combined BVS and DES stents Implantation Using 2- Stent Technique

- Pilot, prospective, consecutive, one center registry analyzing feasibility of IVUS-guided and OCT-optimized two stent technique (Mini-crush or T-stent strategy) using everolimus-eluting platinum chromium coronary stent with bioabsorbable polymer coating (Synergy) in LM/LAD and bioresorbable vascular scaffold (Abbsorb) in Cx for the treatment of distal ULMCA true bifurcation stenosis
- Study population: Elective patients with distal ULMCA true bifurcation stenosis
- Hypothesis:
 - Treatment of distal ULMCA true bifurcation stenosis with everolimus-eluting platinum chromium coronary stent with bioabsorbable polymer coating (Synergy) in LM/LAD and bioresorbable vascular scaffold (Abbsorb) in Cx using two stent techniques (Mini-crush or T-stent strategies) is safe and feasible with similar performance (non-inferior) to historical control with two DES.
 - Acute and long-term outcomes of ULMCA true bifurcation stenosis treatment with combined BVS and DES will be better than two DES treatment in historical control.

LM with BVS+DES flow chart



Stenting Techniques

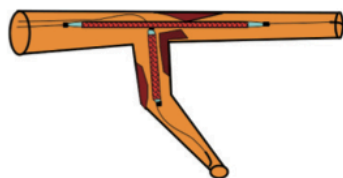
1. Plaque pretreatment with cutting balloon
2. SYNERGY at LM/LAD; ABSORB at Cx

Modified T stenting

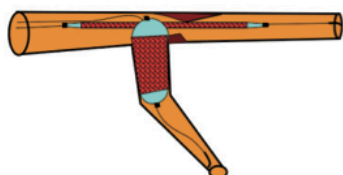
1. Wire both branches and predilate if needed.



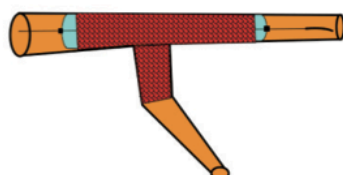
2. Advance the 2 stents. SB stent positioned with minimal protrusion into MB.



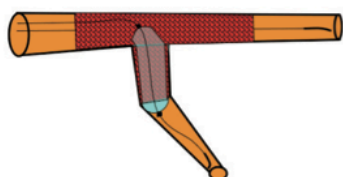
3. SB stent deployed at nominal pressure.



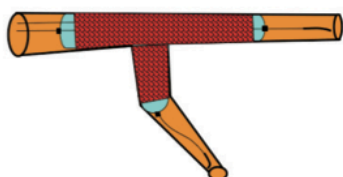
4. Check for optimal result in the SB and then remove balloon and wire from SB. Deploy the MB stent at high pressure.



5. Rewire the SB and perform high pressure dilatation.

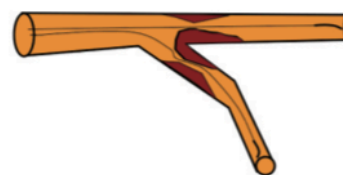


6. Perform final kissing inflation following advancement of a balloon into the MB.

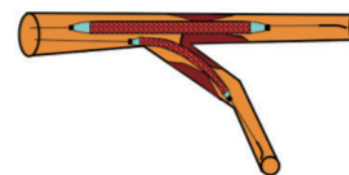


Minicrush stenting

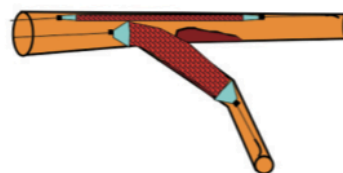
1. Wire both branches and predilate if needed.



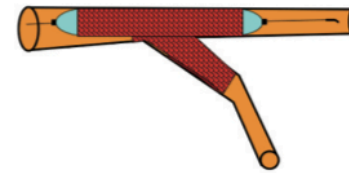
2. Advance the 2 stents. MB stent positioned proximally. SB stent will protrude only minimally into MB.



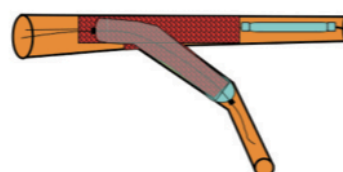
3. Deploy the SB stent.



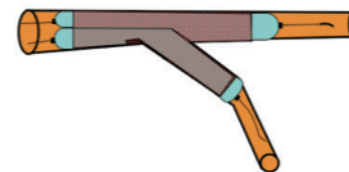
4. Check for optimal result in the SB and then remove balloon and wire from SB. Deploy the MB stent crushing the MB stent.



5. Rewire the SB and perform high pressure dilatation.



6. Perform final kissing balloon inflation.



Patient and Angiographic Characteristics

Patient clinical characteristics N=30 (%)

Age (years), mean \pm STD	64 \pm 8
Male, n (%)	24 (80)
Arterial hypertension, n (%)	29 (97)
Dyslipidemia, n (%)	26 (87)
Diabetes mellitus, n (%)	3 (10)
Current smokers, n (%)	9 (30)
Stabile angina diagnosis, n (%)	30 (100)
Previous MI, n (%)	10 (33)
Previous PCI, n (%)	14 (47)
PAD, n (%)	5 (17)
LVEF %, mean \pm STD	58 \pm 9

Patient angiographic characteristics N=30

Mean SYNTAX score	27.6 \pm 2.6
True bifurcation (Medina 111, 101, 011)	30 (100)

Procedural characteristics

Patient angiographic characteristics N=30	
Radial approach, n (%)	10 (33)
Cutting balloon pre-dilatation in LM-LAD, n (%)	23 (77)
Mean CB diameter, mm	3.38±0.32
Cutting balloon pre-dilatation in Cx, n (%)	23 (77)
Mean CB diameter, mm	3.17±0.36
Stenting technique:	
T stent technique	10 (33)
Minicrush technique	20 (67)
Mean SYNERGY stent length in LM/LAD, mm	22.80±7.64
Mean SYNERGY stent diameter in LM/LAD, mm	3.77±0.31
Mean ABSORB scaffold length in Cx, mm	16.27±4.32
Mean ABSORB scaffold diameter in Cx, mm	3.20±0.36
Final kissing, n (%)	30 (100)
Procedural success, n (%)	30 (100)

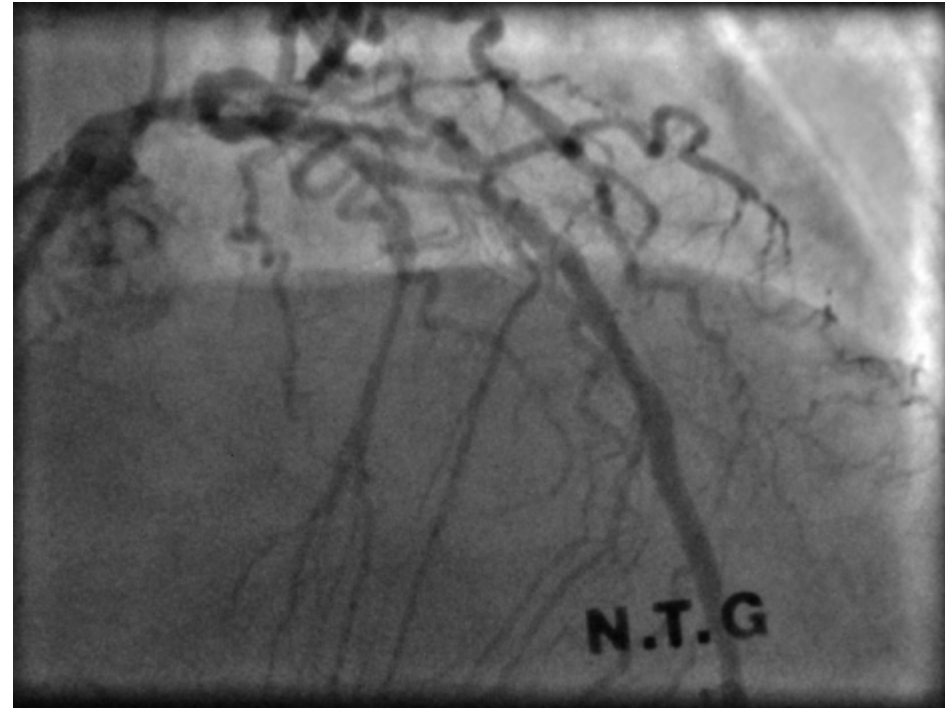
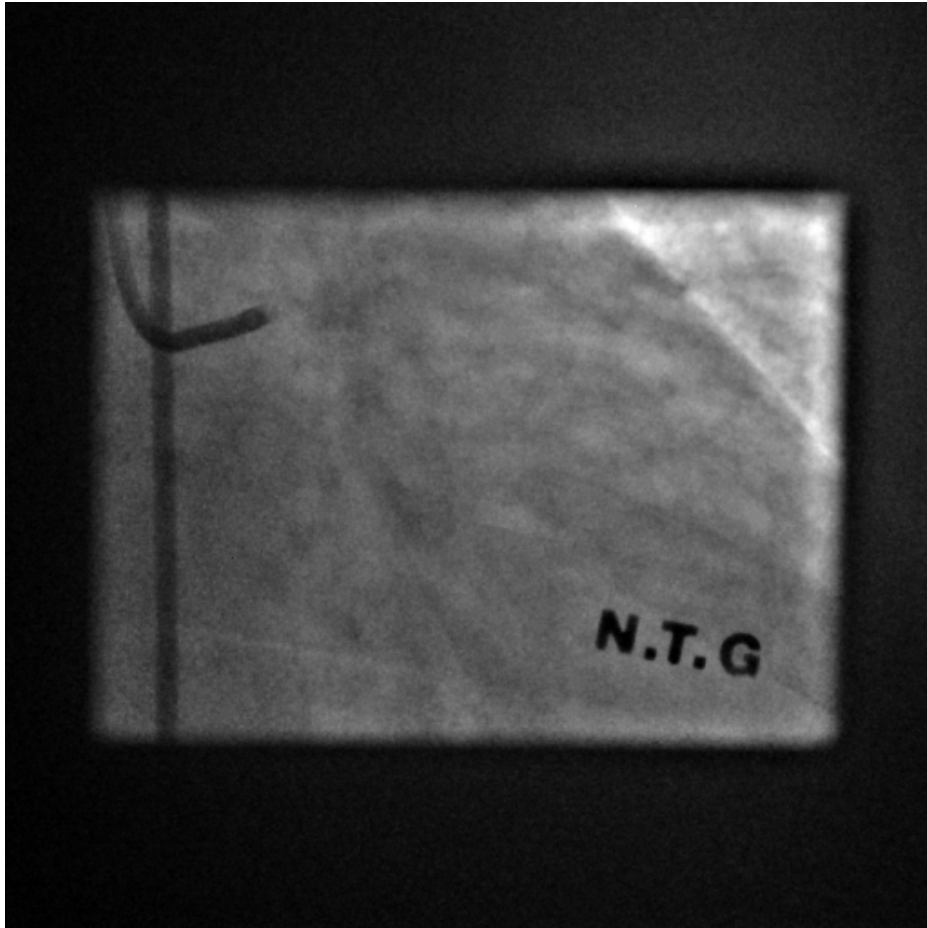
First results

30 days follow-up, N=30 (%)	
Death, n (%)	0 (0)
Cardiac death, n (%)	0 (0)
QMI, n (%)	0 (0)
TVR, n (%)	0 (0)
TLR, n (%)	0 (0)
ST, n (%)	0 (0)
MACE, n (%)	0 (0)

Case Example #1

LM distal bifurcation 75% stenosis to LAD and LCX.

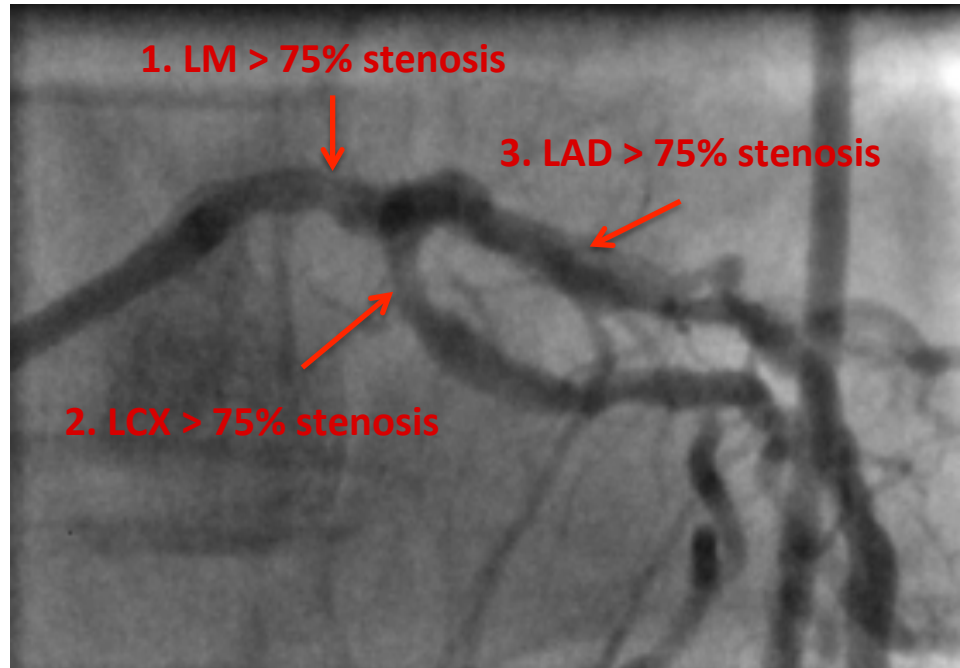
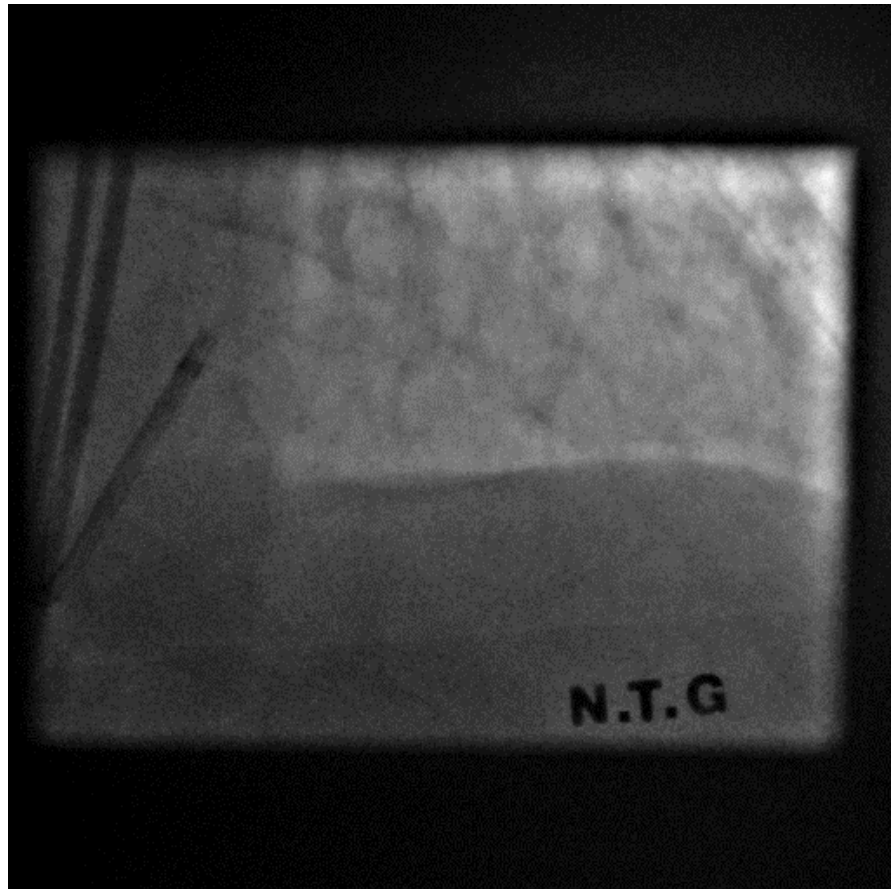
RCA chronic total occlusion



Coronary angiography

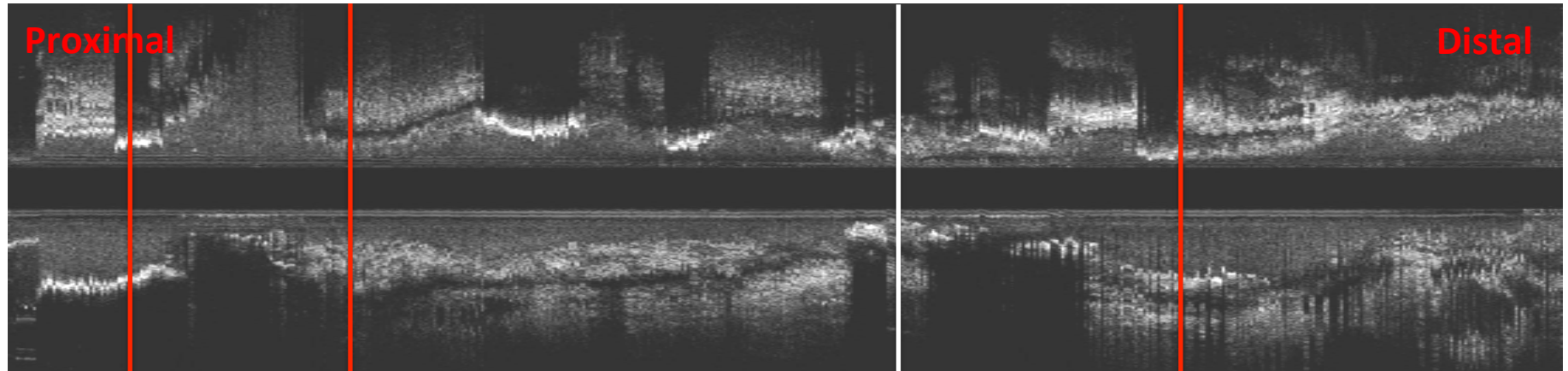
LM distal bifurcation 75% stenosis to LAD and LCX.

RCA chronic total occlusion



1. LM-Cutting balloon + DES
2. LCX-Cutting balloon + Bioabsorbable scaffold
3. LAD-Cutting balloon + DES

Preintervention IVUS LAD

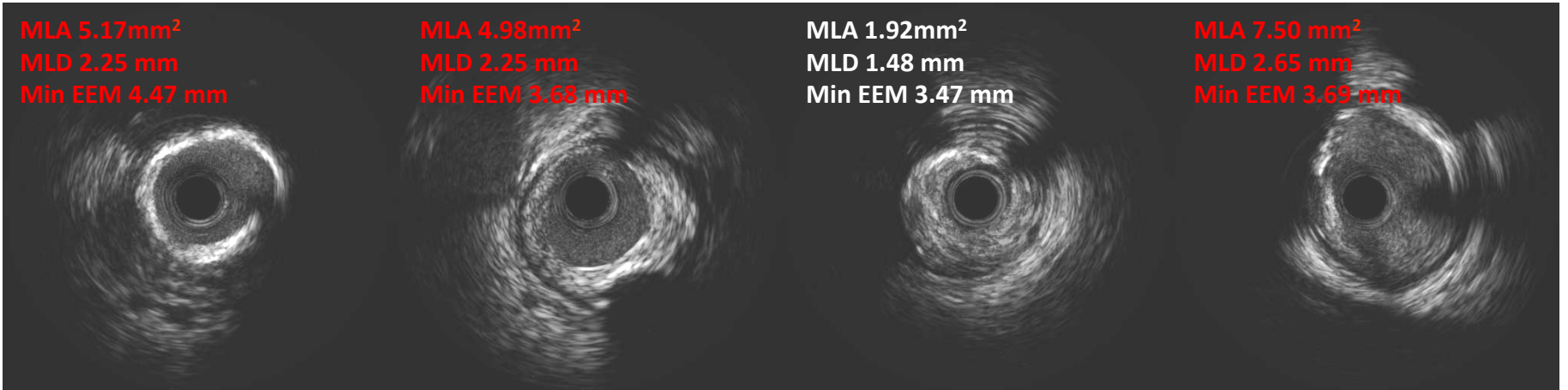


MLA 5.17mm²
MLD 2.25 mm
Min EEM 4.47 mm

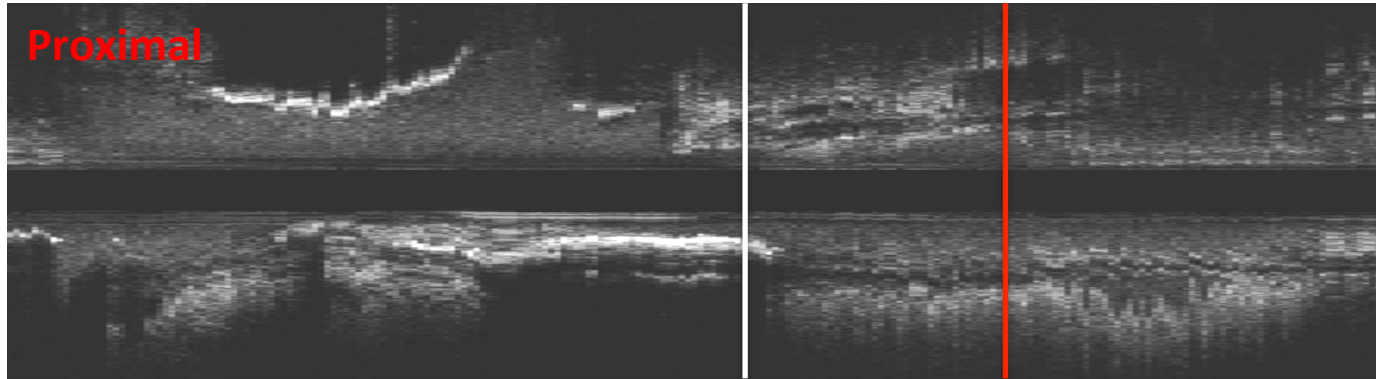
MLA 4.98mm²
MLD 2.25 mm
Min EEM 3.68 mm

MLA 1.92mm²
MLD 1.48 mm
Min EEM 3.47 mm

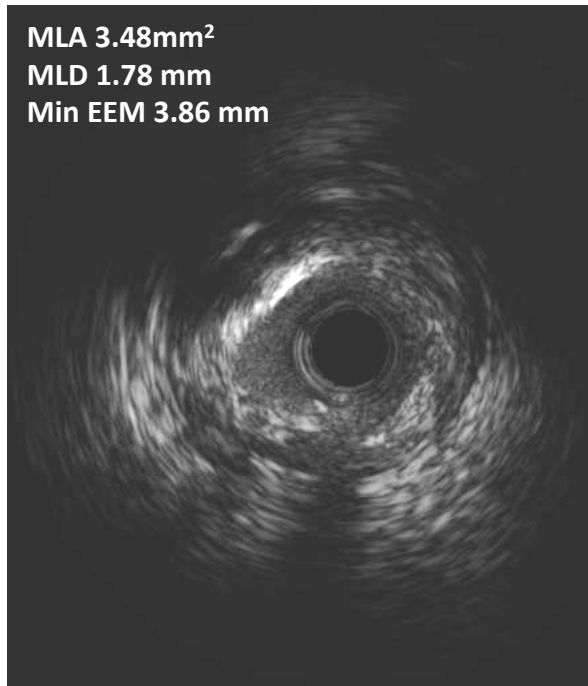
MLA 7.50 mm²
MLD 2.65 mm
Min EEM 3.69 mm



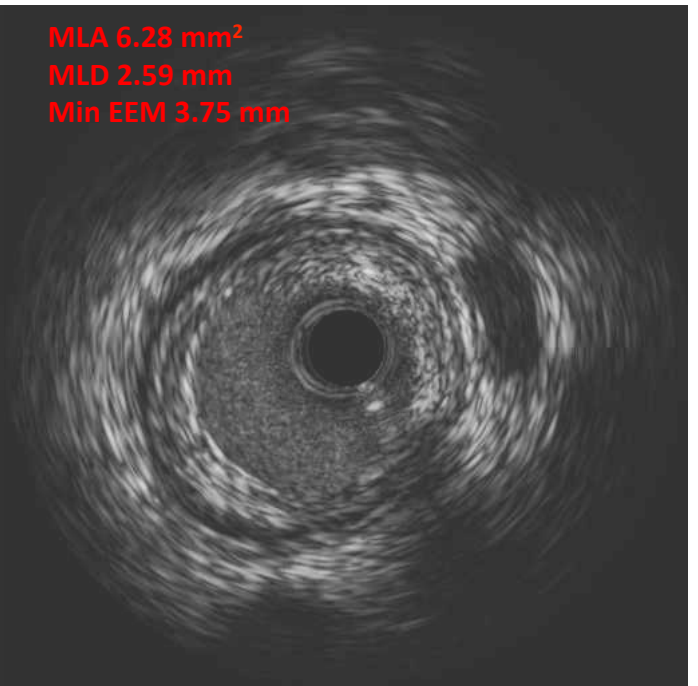
Preintervention IVUS LCX



MLA 3.48mm²
MLD 1.78 mm
Min EEM 3.86 mm

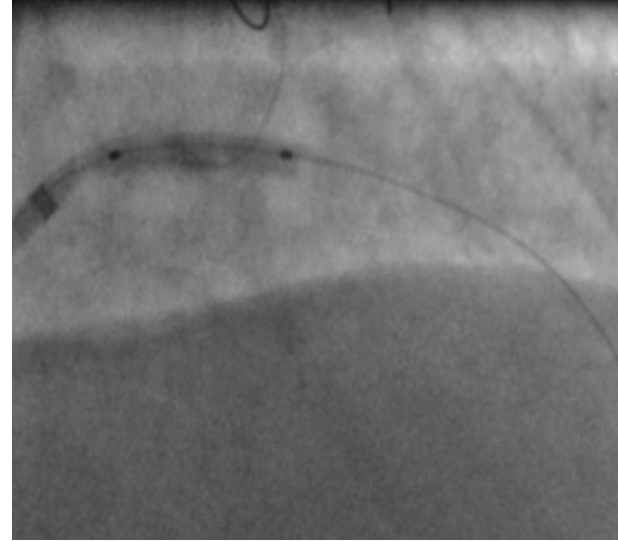
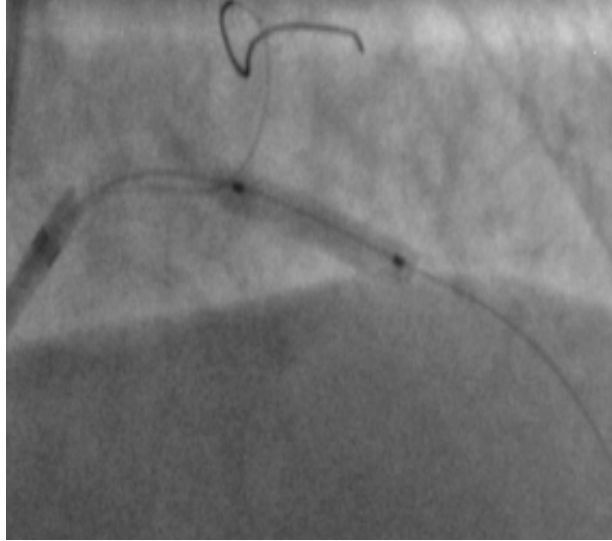
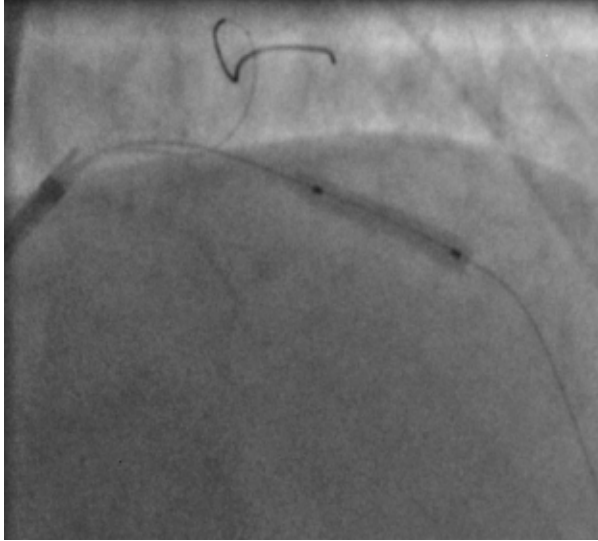


MLA 6.28 mm²
MLD 2.59 mm
Min EEM 3.75 mm

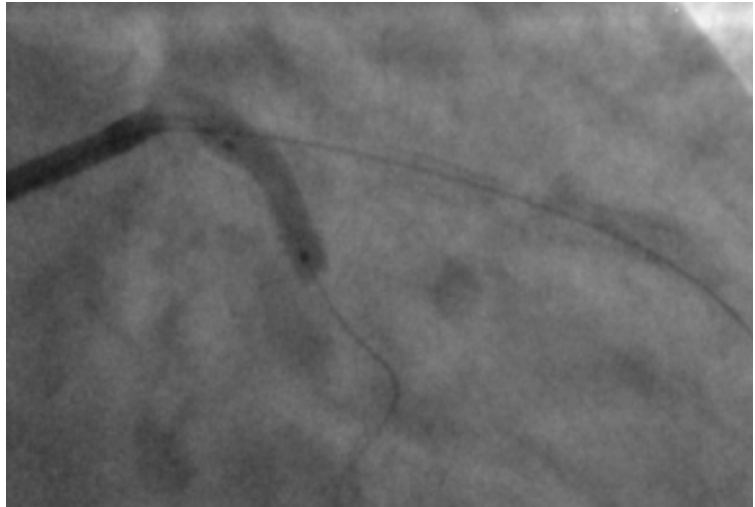
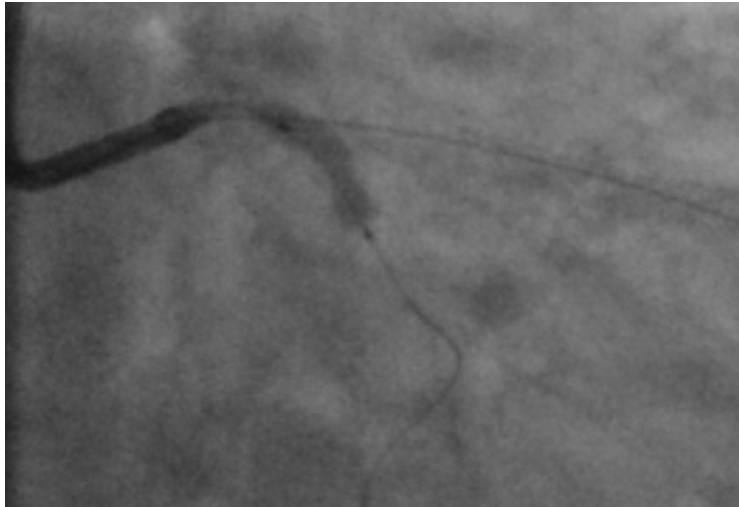


Plaque pretreatment

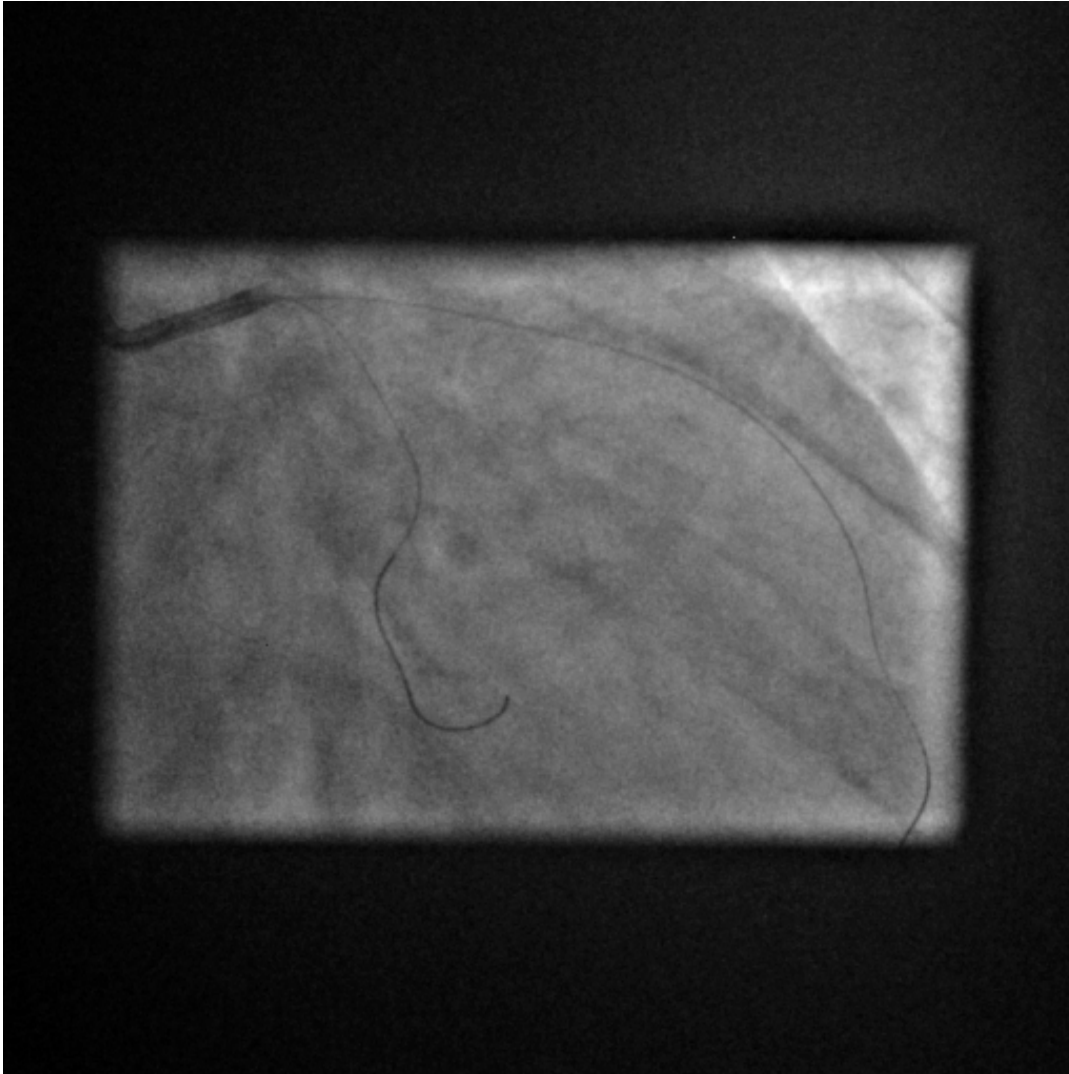
Predilatation of LM/LAD with cutting balloon 3.5 x 15 mm 5, 6, 7 bar



Predilatation of LCX with Regular balloon 3.0 x 12 mm 6, 7 bar



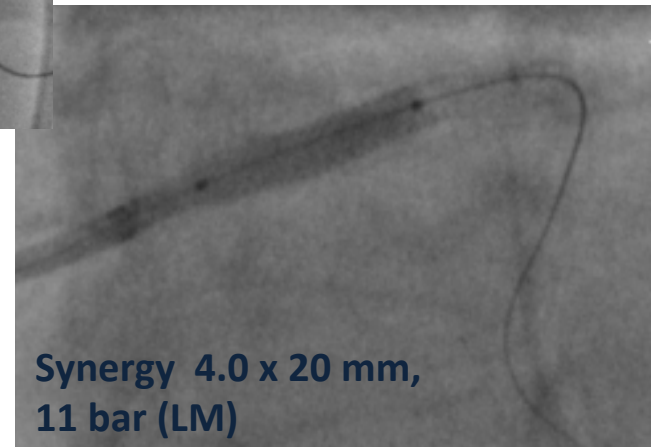
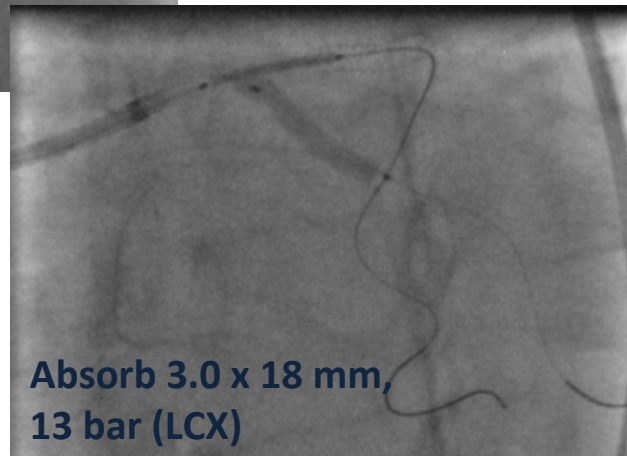
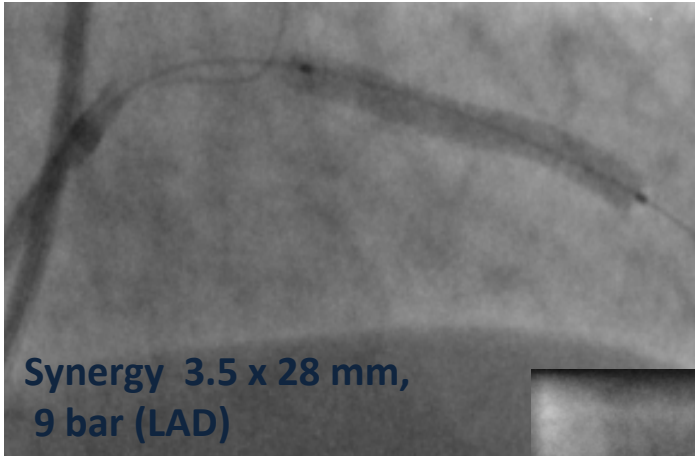
After predilatation



**Achieved good plaque modification
with cutting balloon**

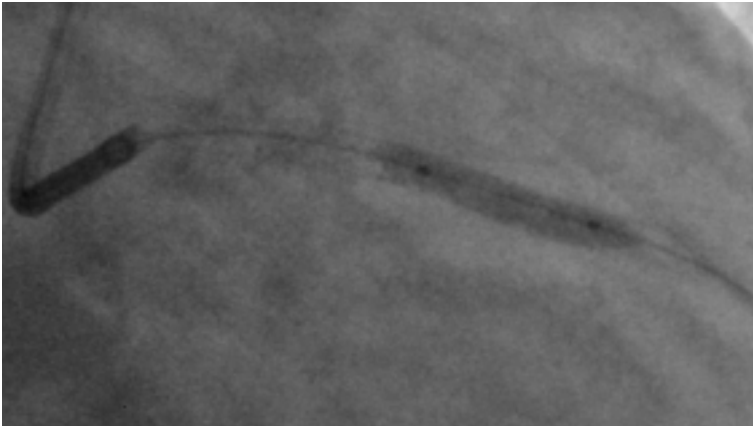


Stenting (minicrush)

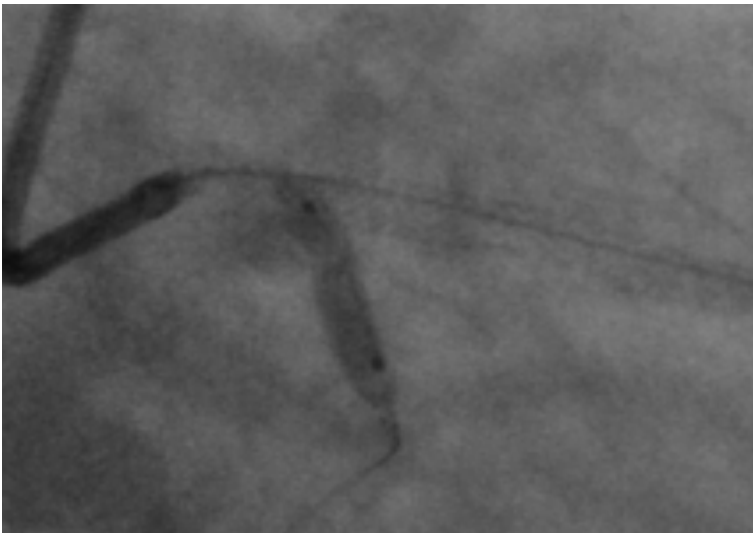


Postdilatation

1. LAD – NC Balloon 3.5 x 15 mm, 17 bar



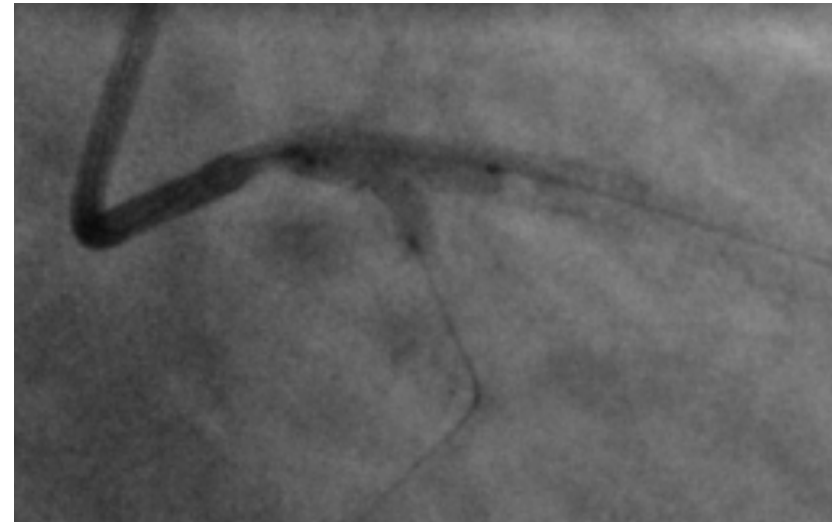
2. LCX – NC Balloon 3.5 x 15 mm, 15 bar



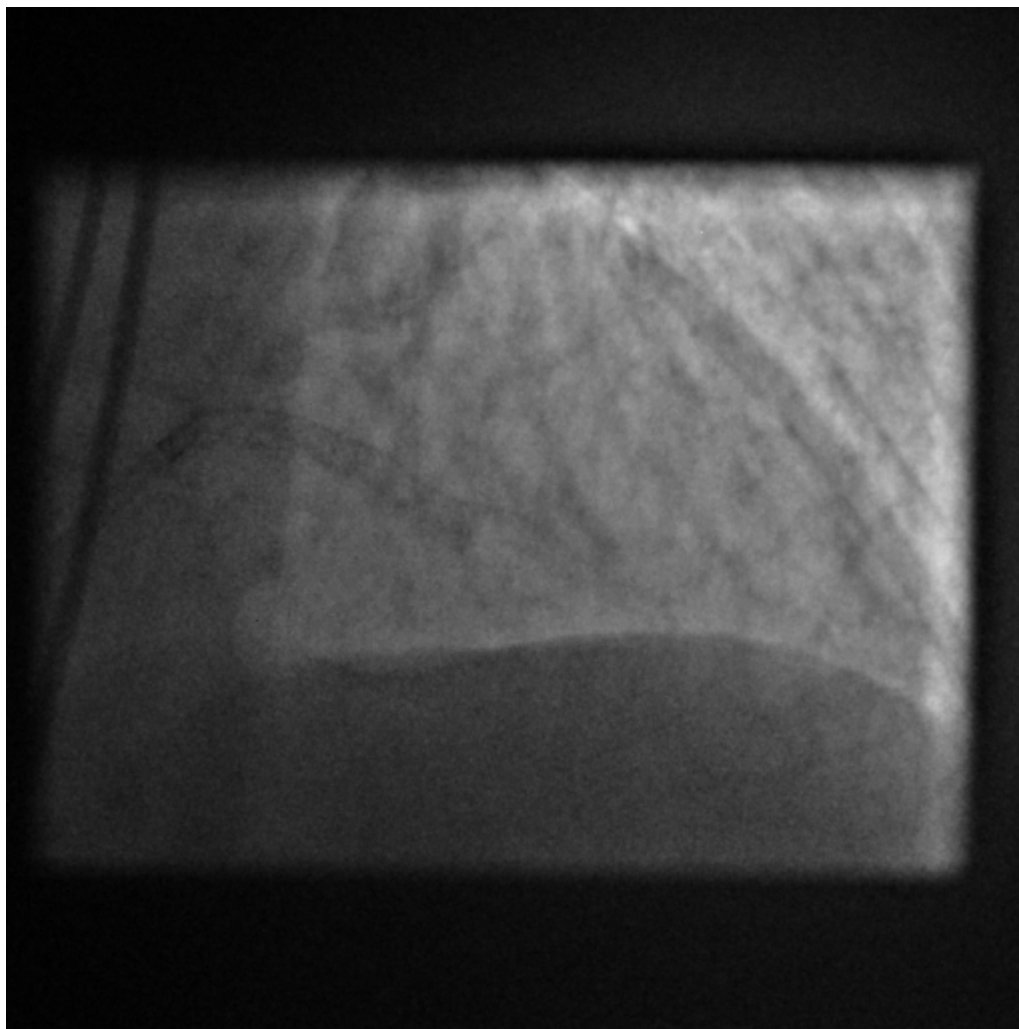
3. Kissing:

LAD 3.5 x 15 mm, 10 bar

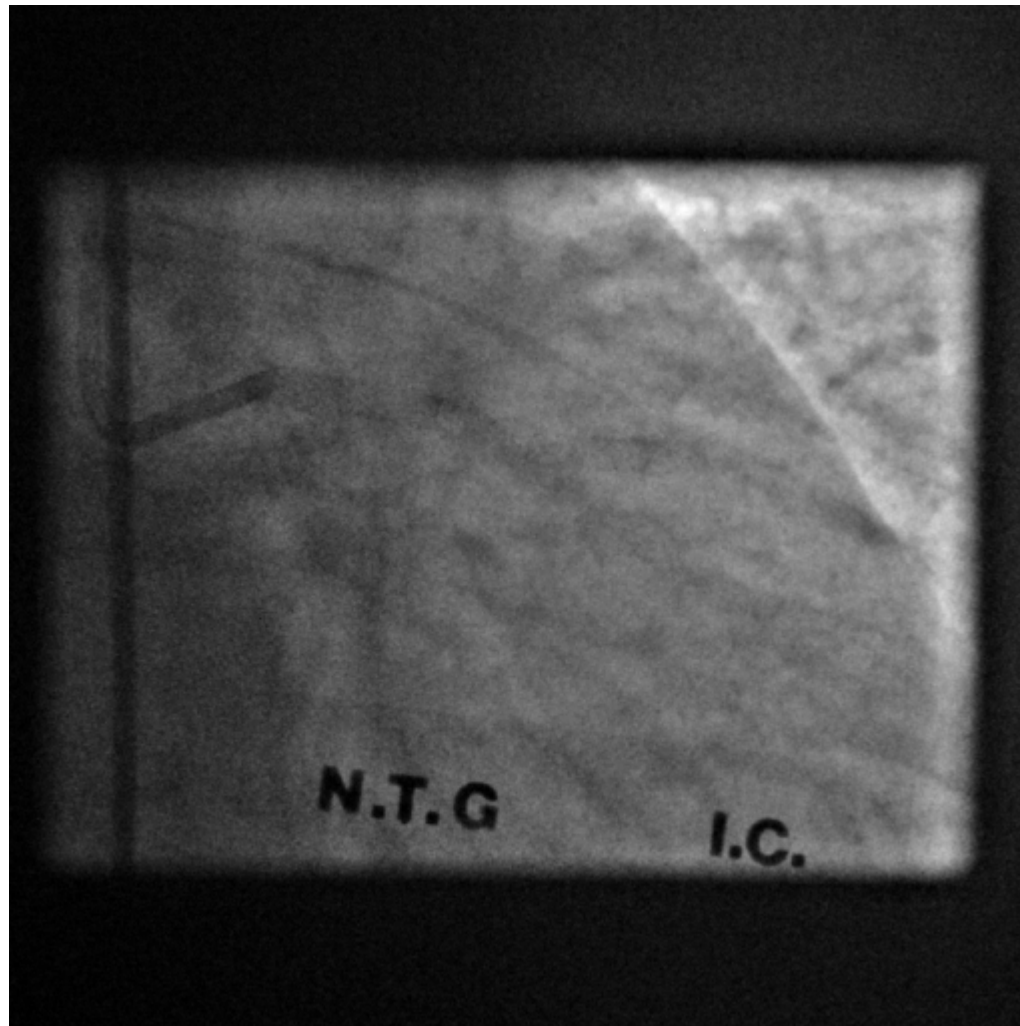
LCX 3.0 x 15 mm, 10 bar



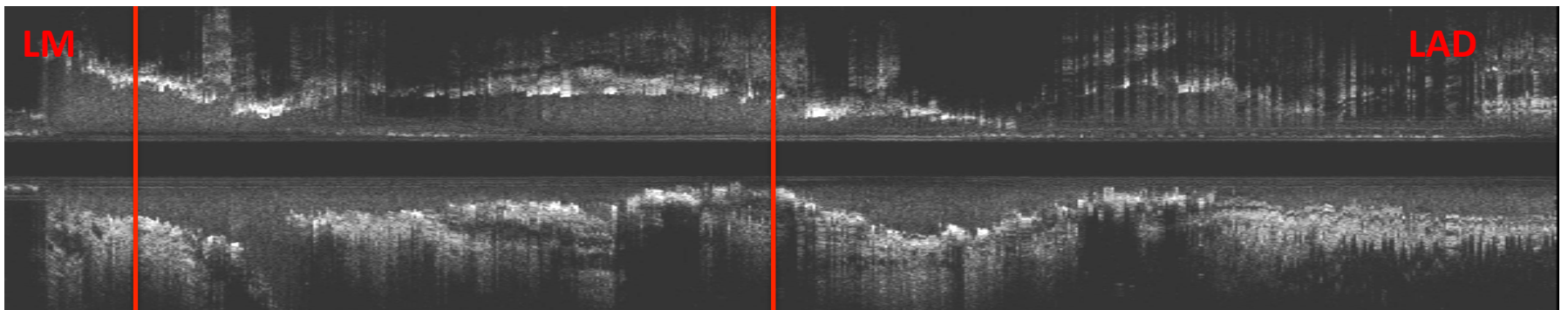
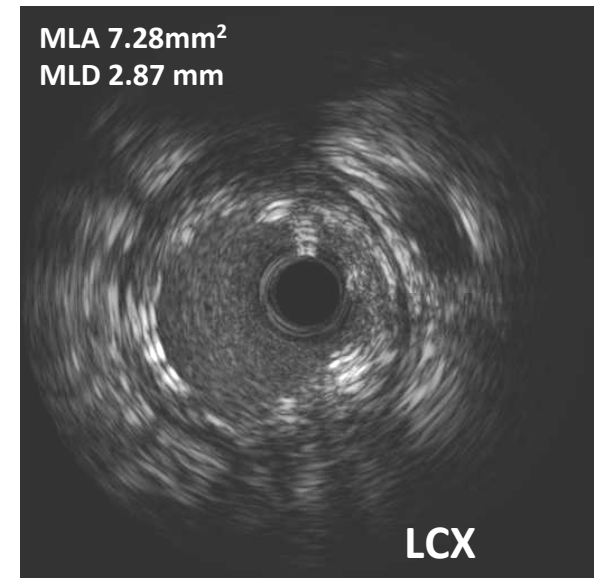
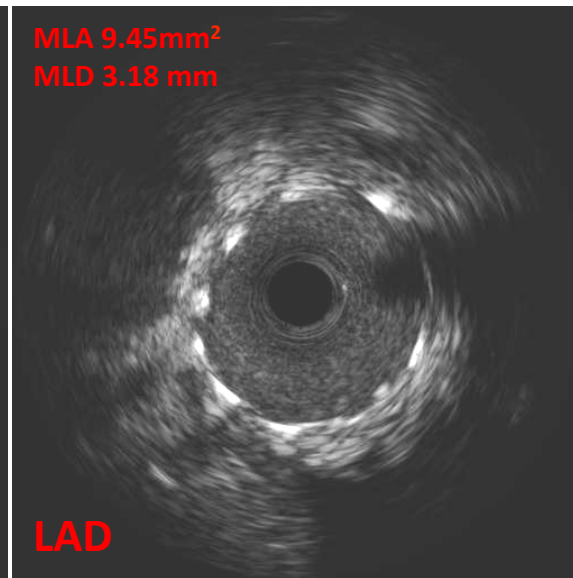
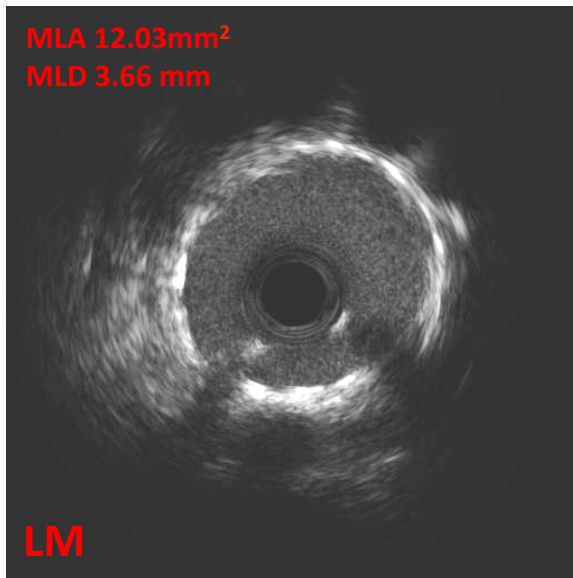
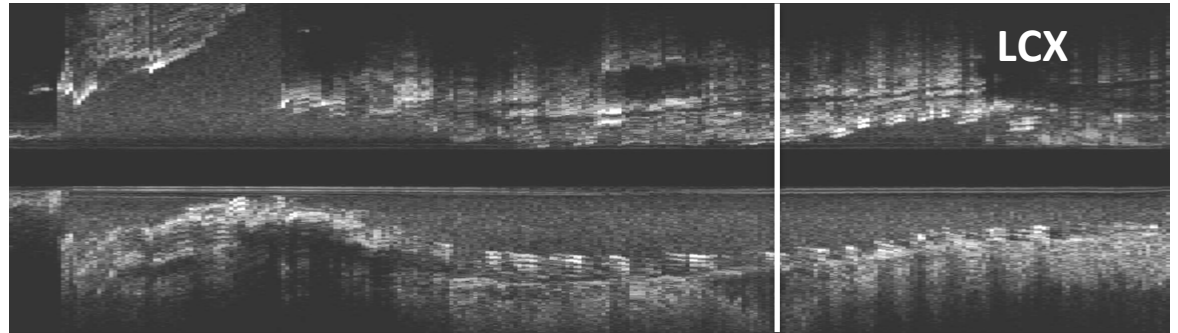
Final result



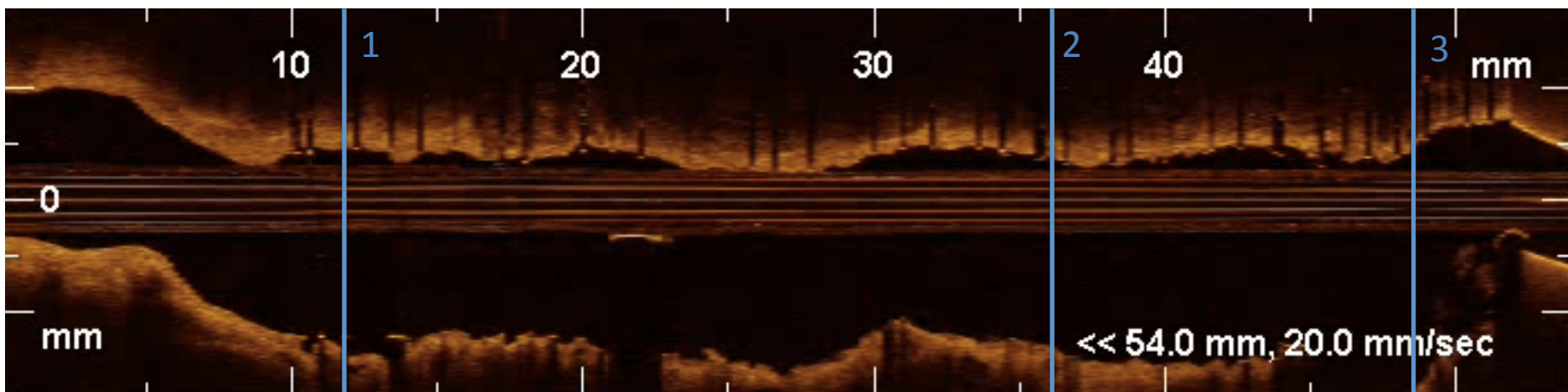
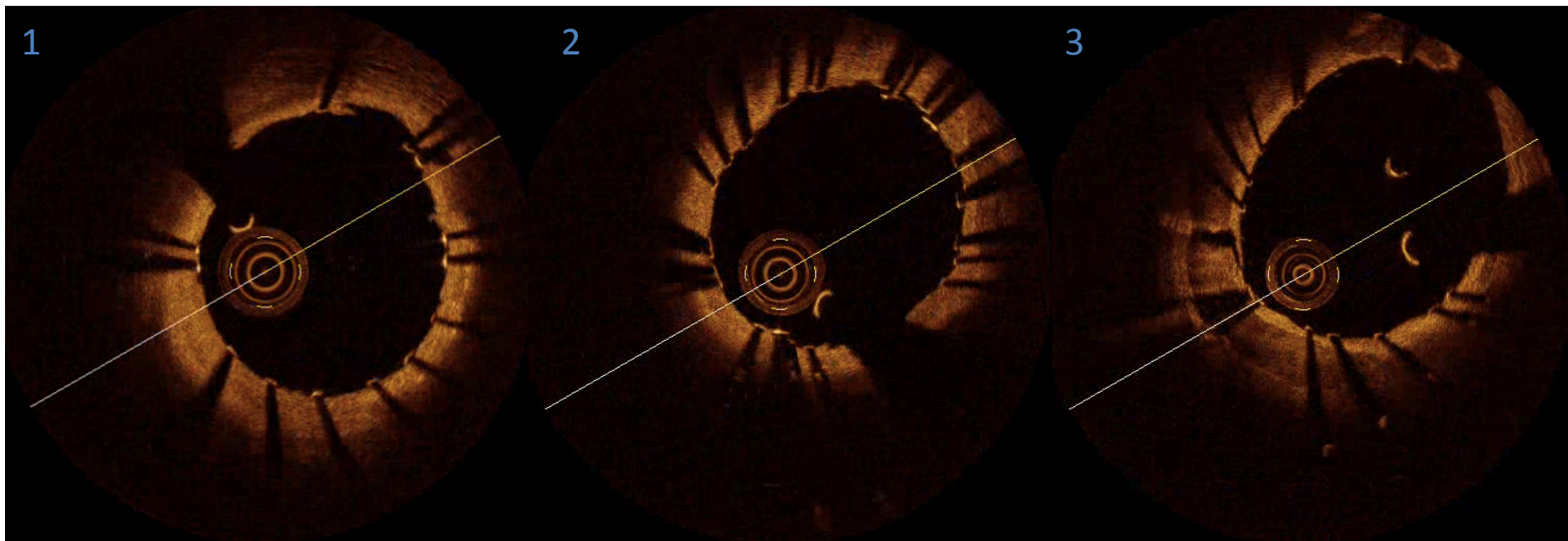
Final result



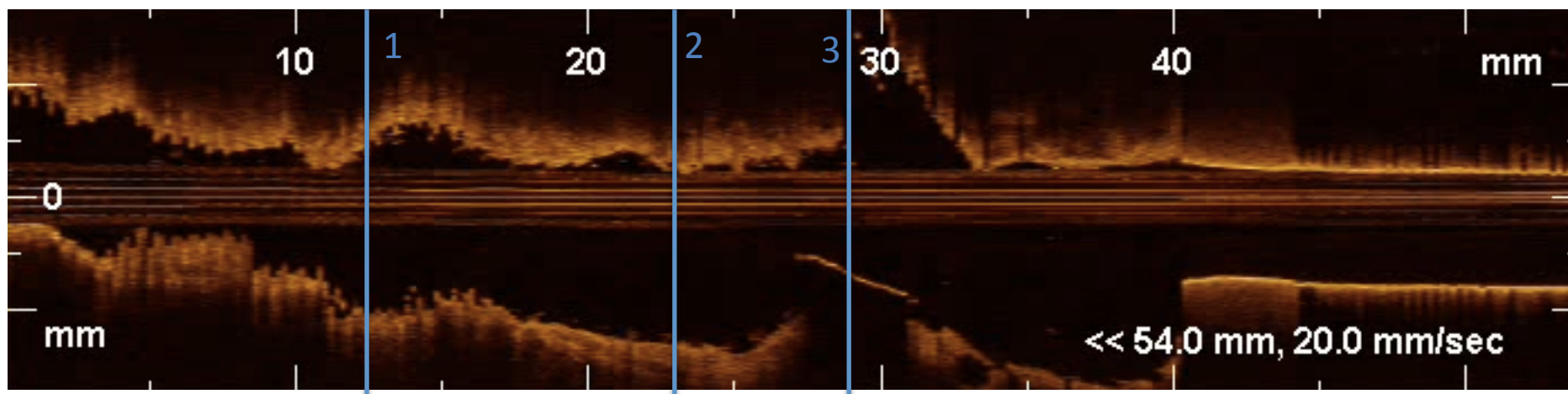
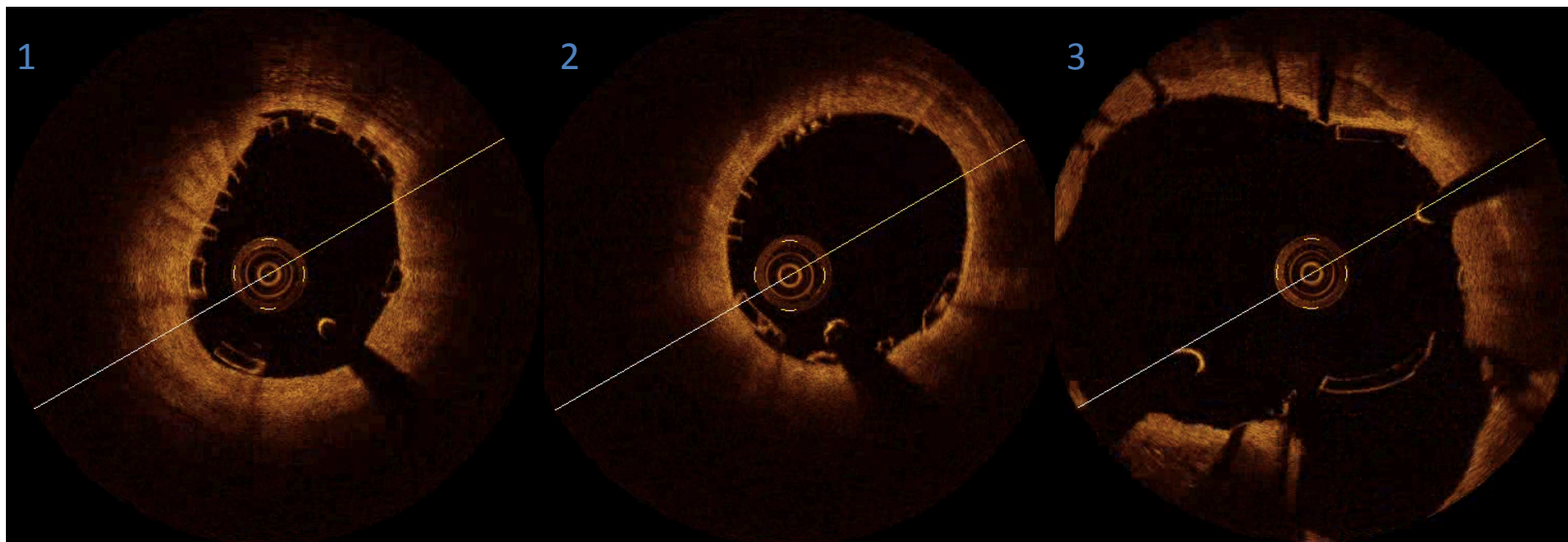
Final IVUS



Final OCT: LAD- LM



Final OCT: LCX- LM



Case Example #2

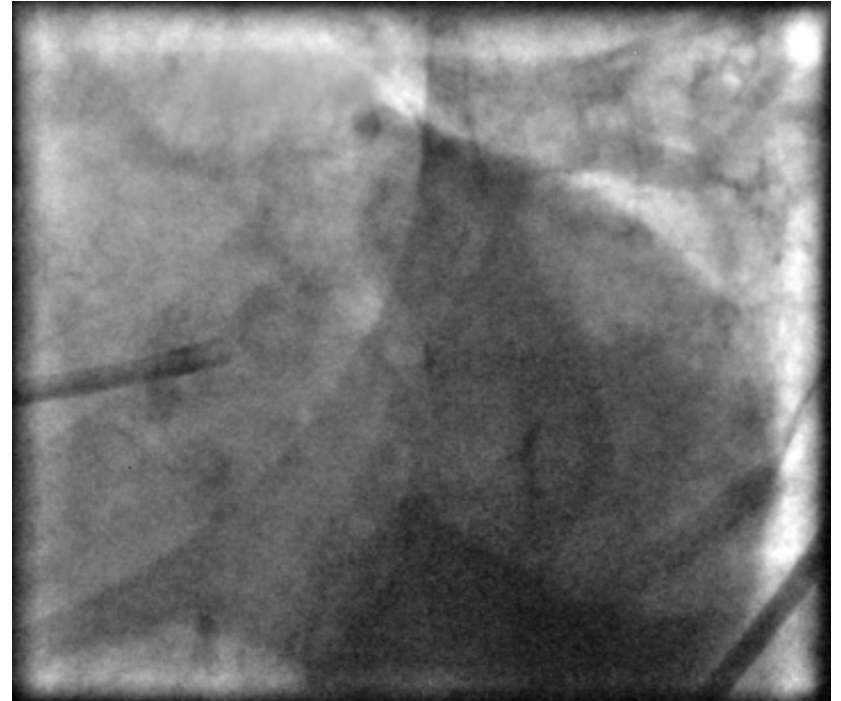
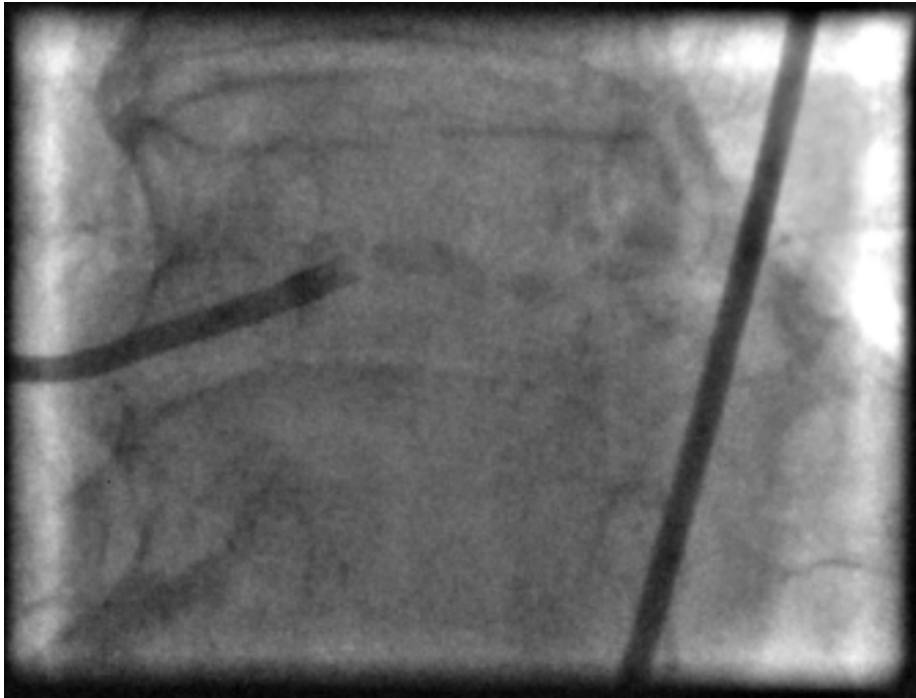
Male 68 years old with stable angina CCS III, risk factors: dyslipidemia, hypertension

Comorbidities: Previous stroke (two years ago without notable neurological deficit)

PTA - ACI dxt (1 year ago)

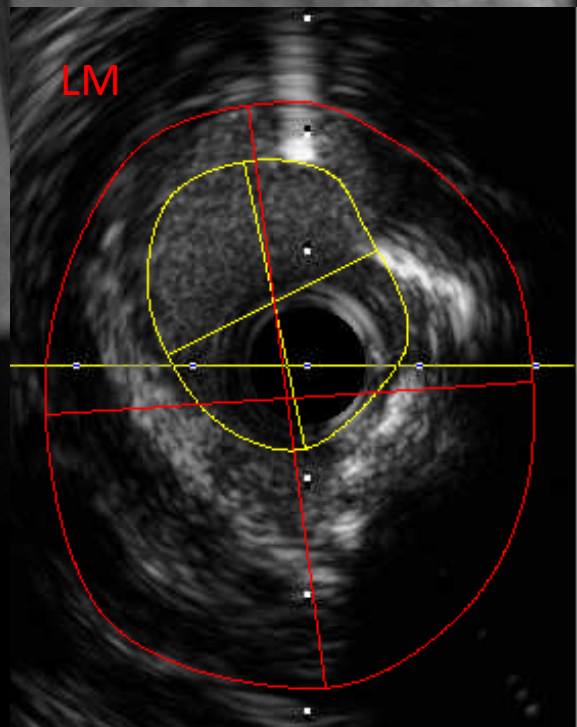
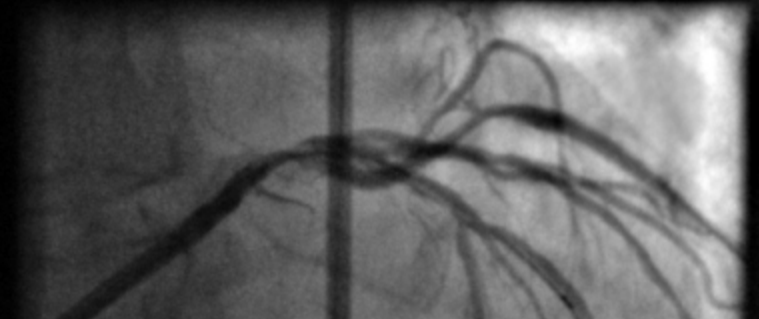
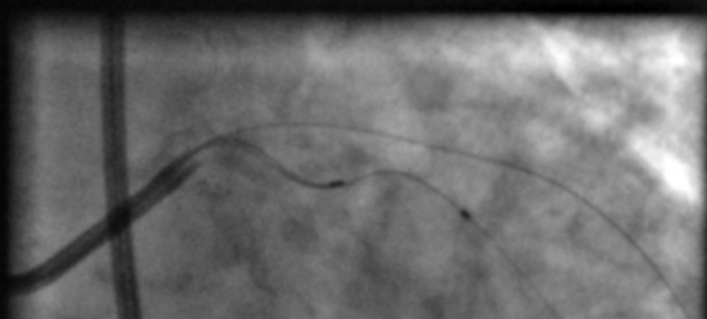
COPD

Echocardiography: Normal left ventricle function, no signs of valve dysfunction



Diffuse, severe coronarosclerosis on the left side, LM/LAD/LCX bifurcation stenosis > 75%, bifurcation stenosis in LAD mid 1/3 stenosis 50%, SYNTAX score 31

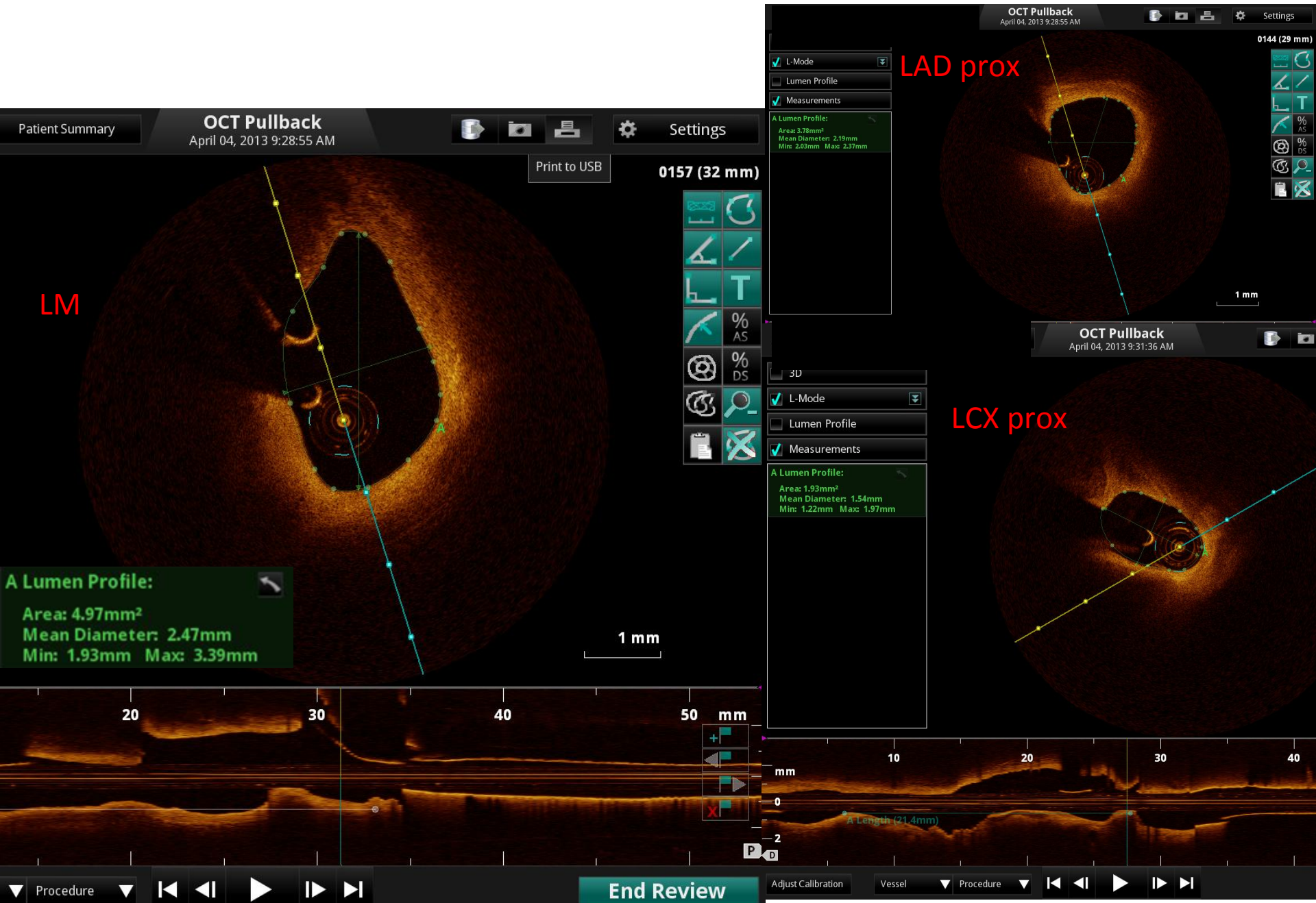
IVUS before intervention



Frame		Range and Volume		Stent Struts	
Area and Diameter					
	Area (mm ²)	Diameter (mm)			
		Mean	Min	Max	Min/Max
Lumen	4.11	2.30	2.00	2.53	0.79
Vessel	16.83	4.63	4.18	5.04	0.83
Stent					
Plaque	12.72 (75.6% of Vessel)				
NIH					
Malapp					

Intimal Thickness				
	Mean	Min	Max	Min/Max
Intimal Thickness	1.10	0.46	2.06	0.23
Neo-Intimal Thickness				

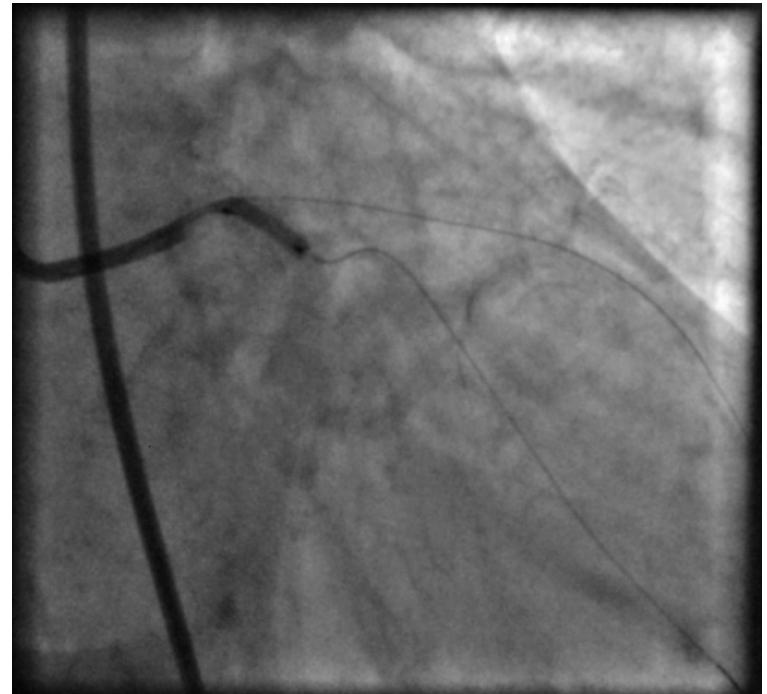
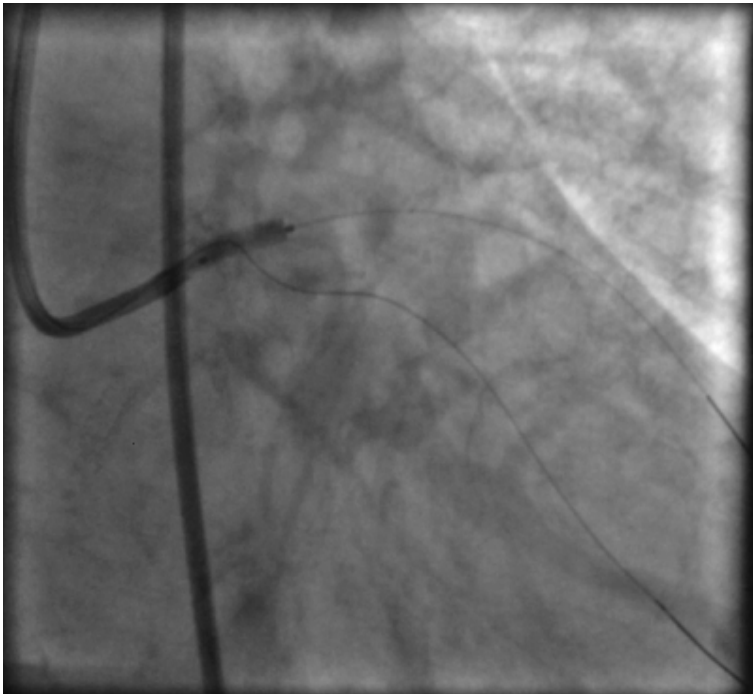
OCT– LM/LAD/LCX before Cutting balloon



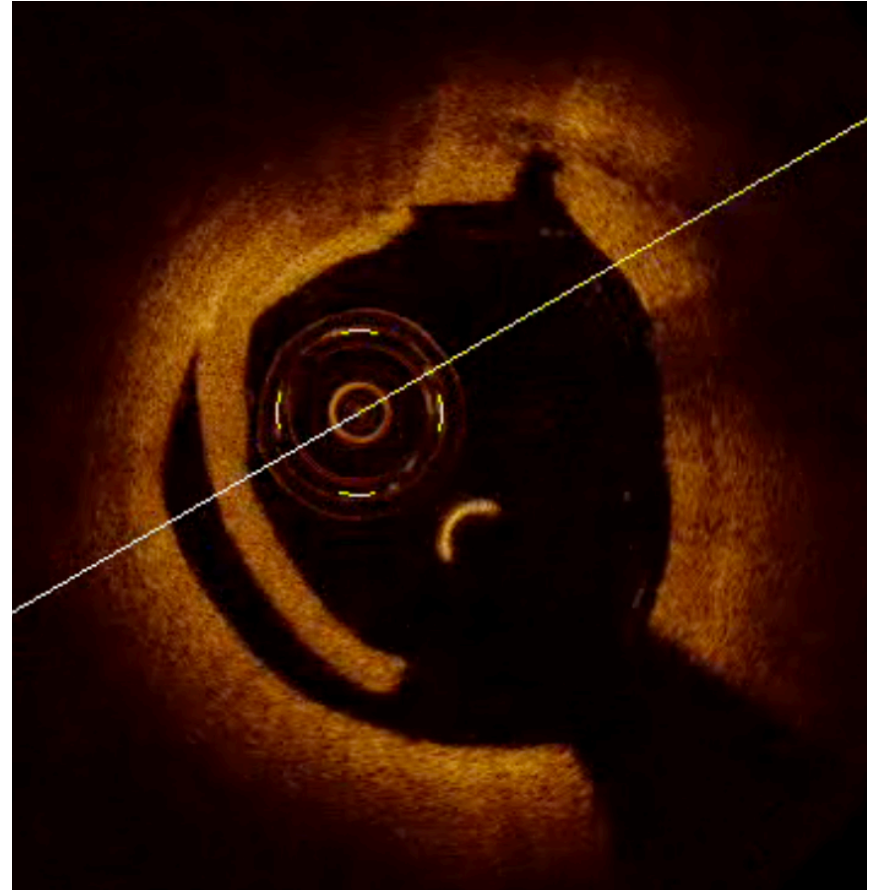
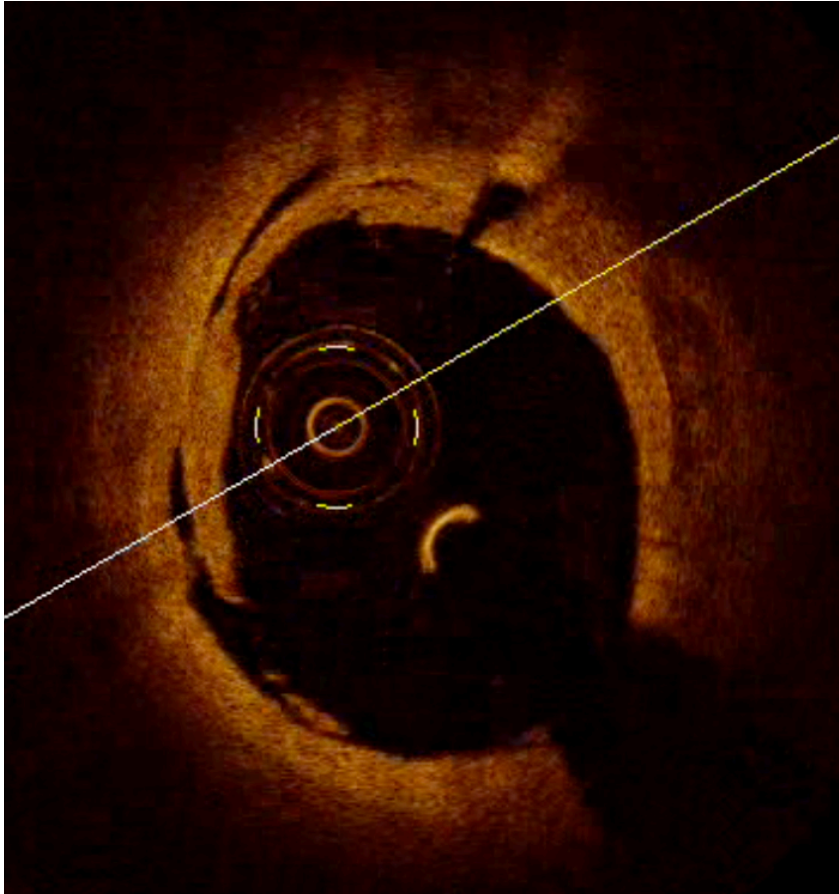
Pretreatment with Cutting balloon

Femoral approach – 7 F EBU 3.75

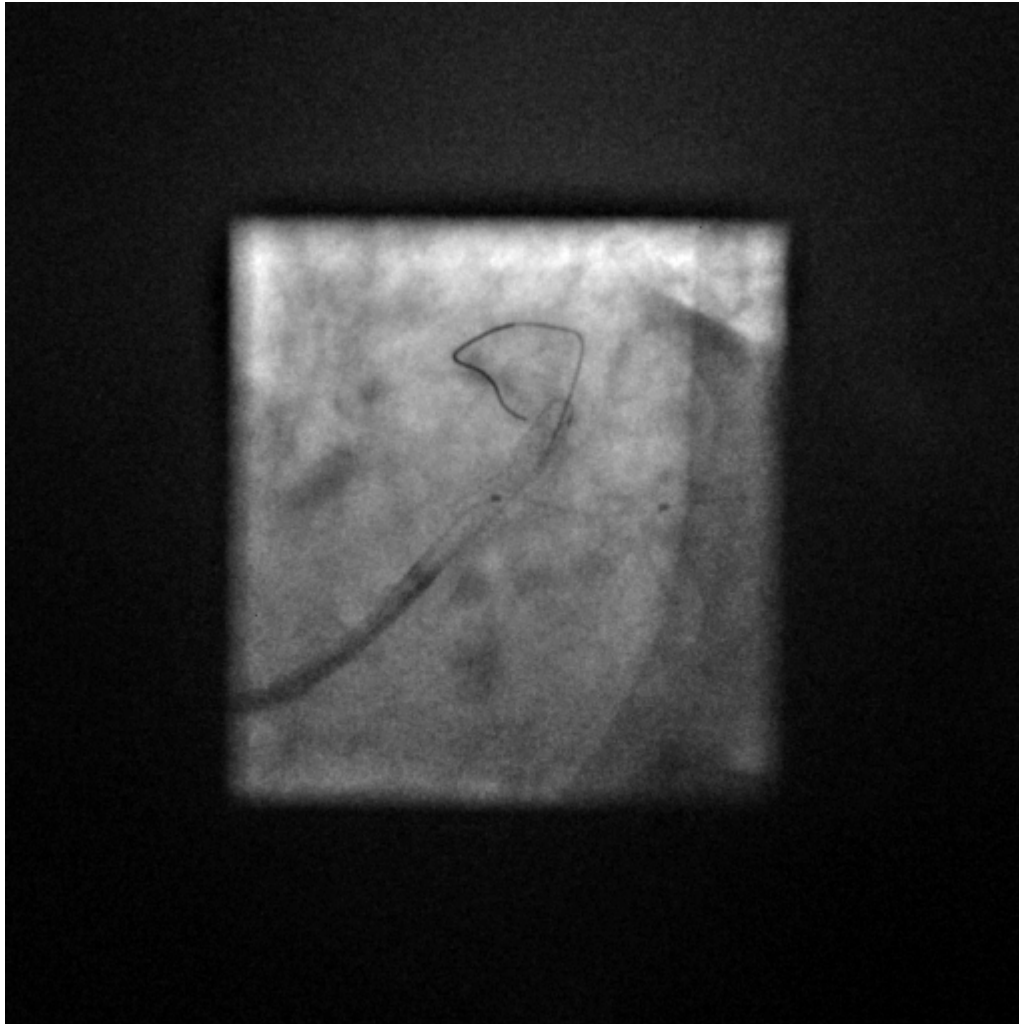
- Ch.Floppy wire in LM/LAD
- Predilatation of LM/ LAD with Cutting balloon 3.0 x 10 mm 9 bar
- Asahi Soft wire in LCX
- Predilatation of LCX with Cutting balloon 2.5 x 10 mm, 9 bar



OCT– LM/LAD after Cutting balloon



BVS positioning after SYNERGY implantation in LM/LAD (T-stenting)



■ Stents:

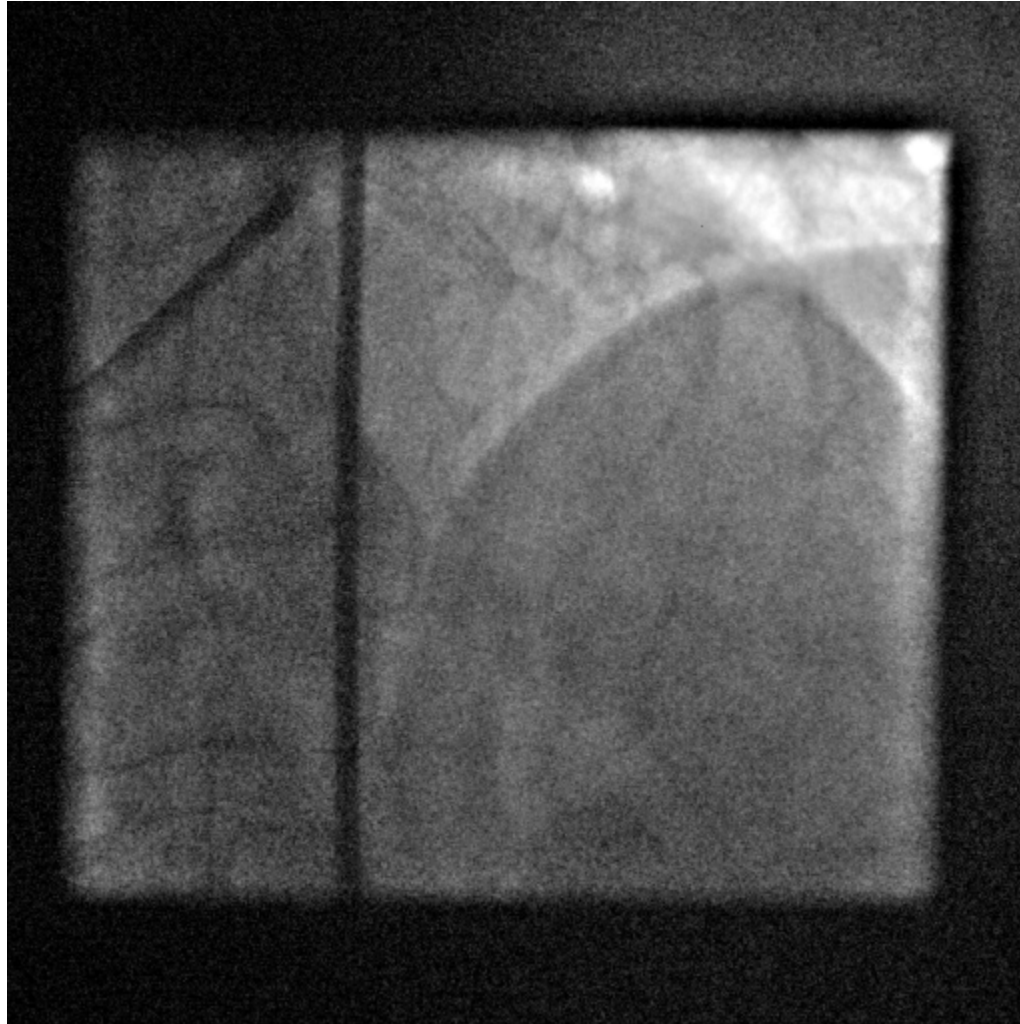
- DES (Synergy) 3.5 x 28 mm (LM/LAD)
- BVS (Absorb) 2.5 x 18 mm (LCX)

BVS implantation and final Kissing balloons

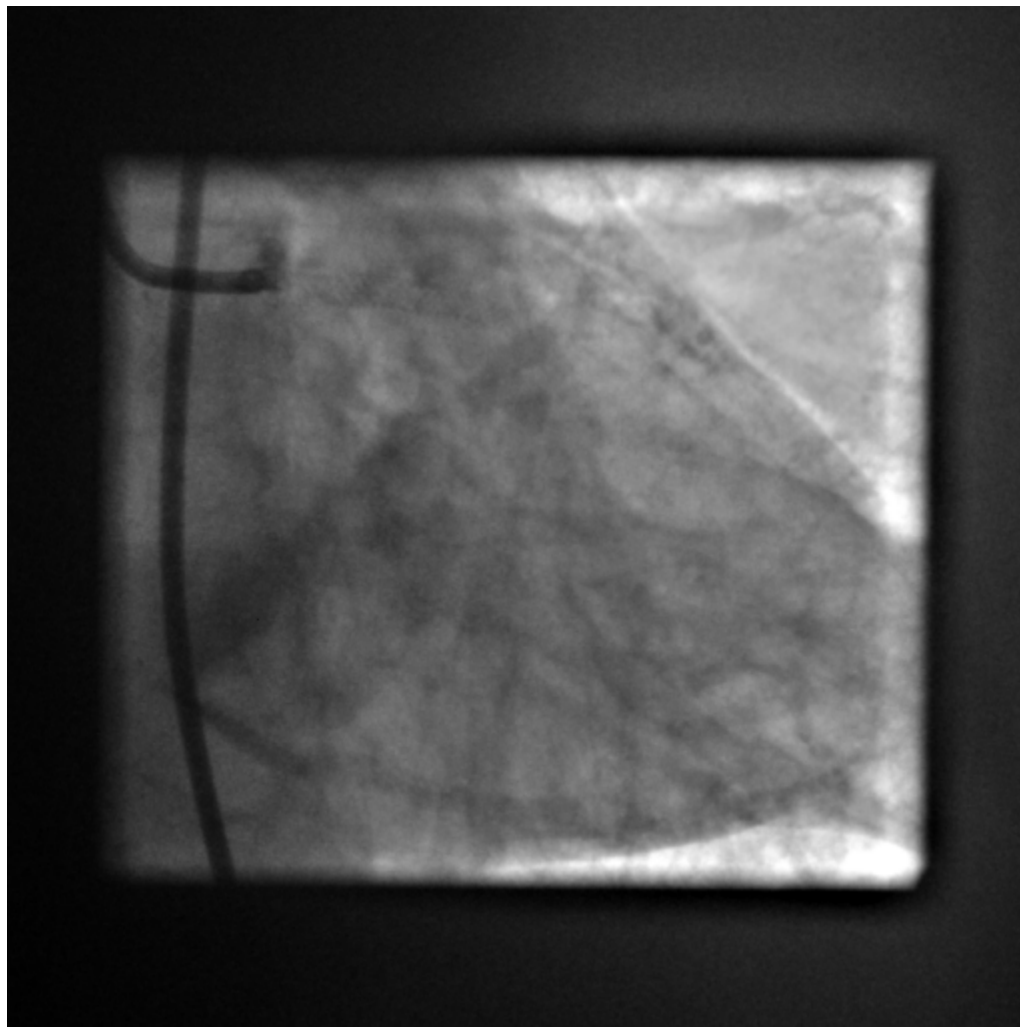


- Postdilatation
 - NC balloon 3.5 x 15 mm (LM/LAD), 2.75 x 12 mm (LCX)
 - Kissing balloons 3.0 x 15 mm, 2.75 x 12 mm

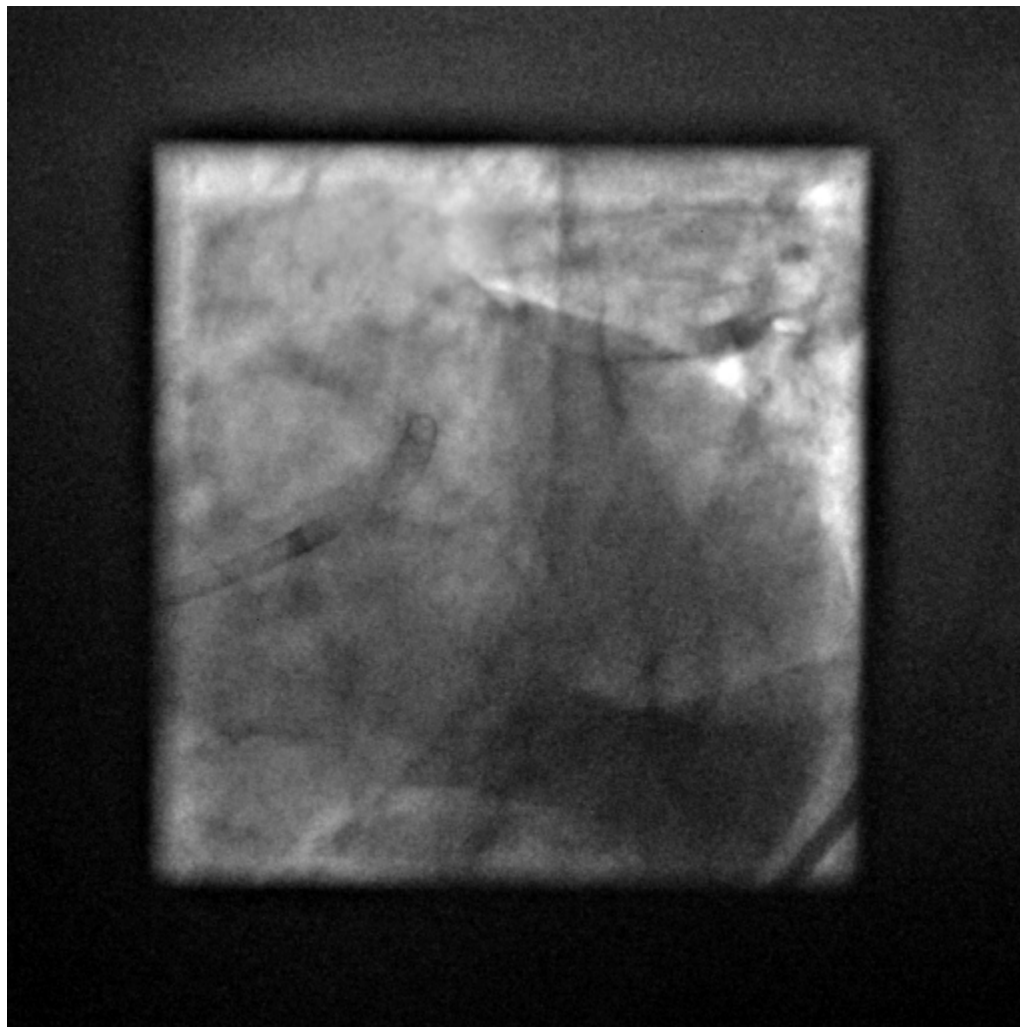
Final result



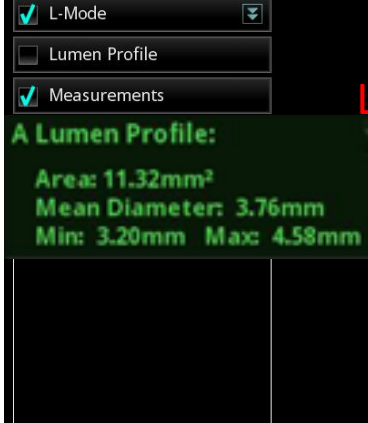
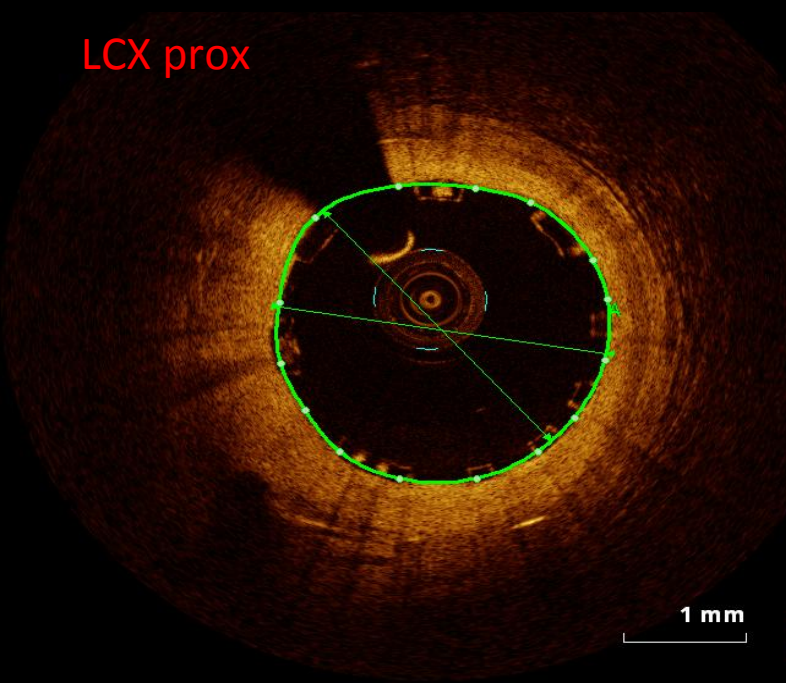
Final result



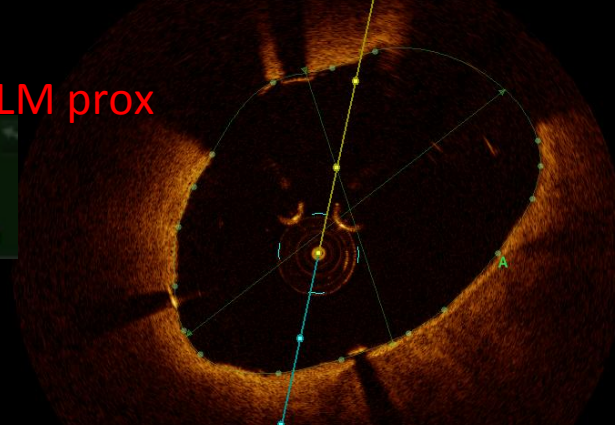
Final result



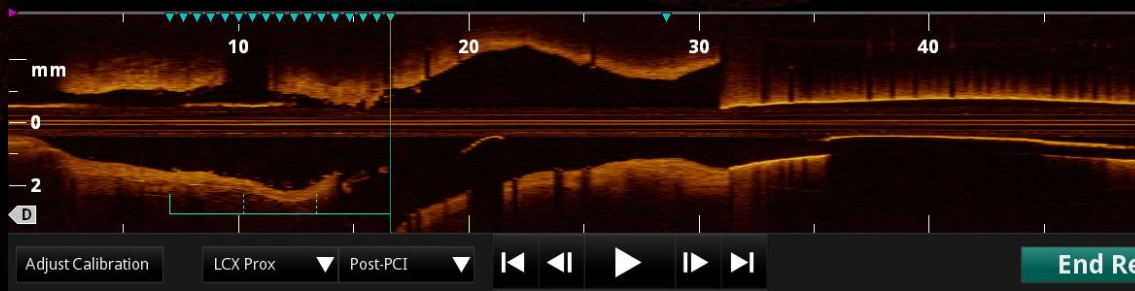
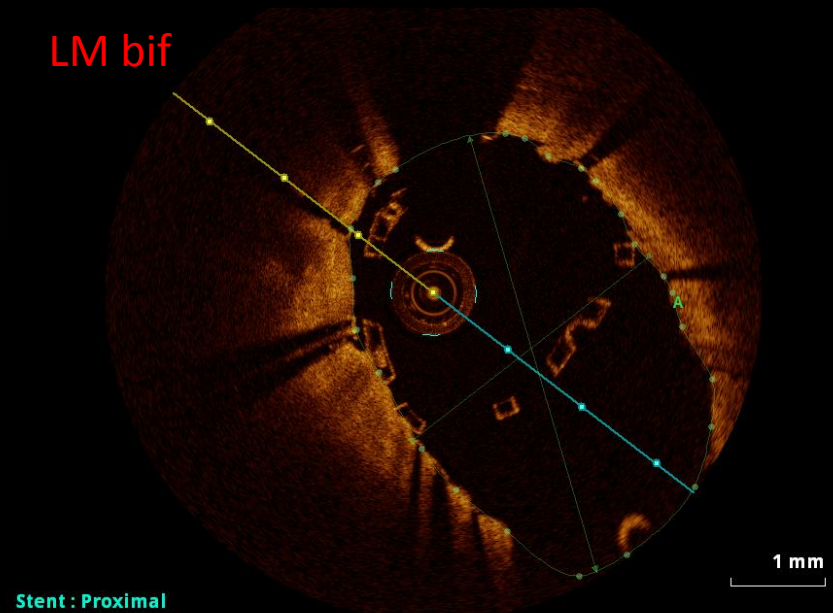
Final result by OCT



LM prox



LM bif



Conclusions

- The current study demonstrates that novel ULMCA stenting technique using SYNERGY stent and ABSORB scaffold is safe and feasible
- No serious procedure-related complications were observed, hospital and 30 day clinical outcomes appeared to be good
- However, further evaluation is needed