It Should Be Off-Labeled So Far

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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	Company
• Grant/Research Support	• Abbott Vascular, Boston Scientific
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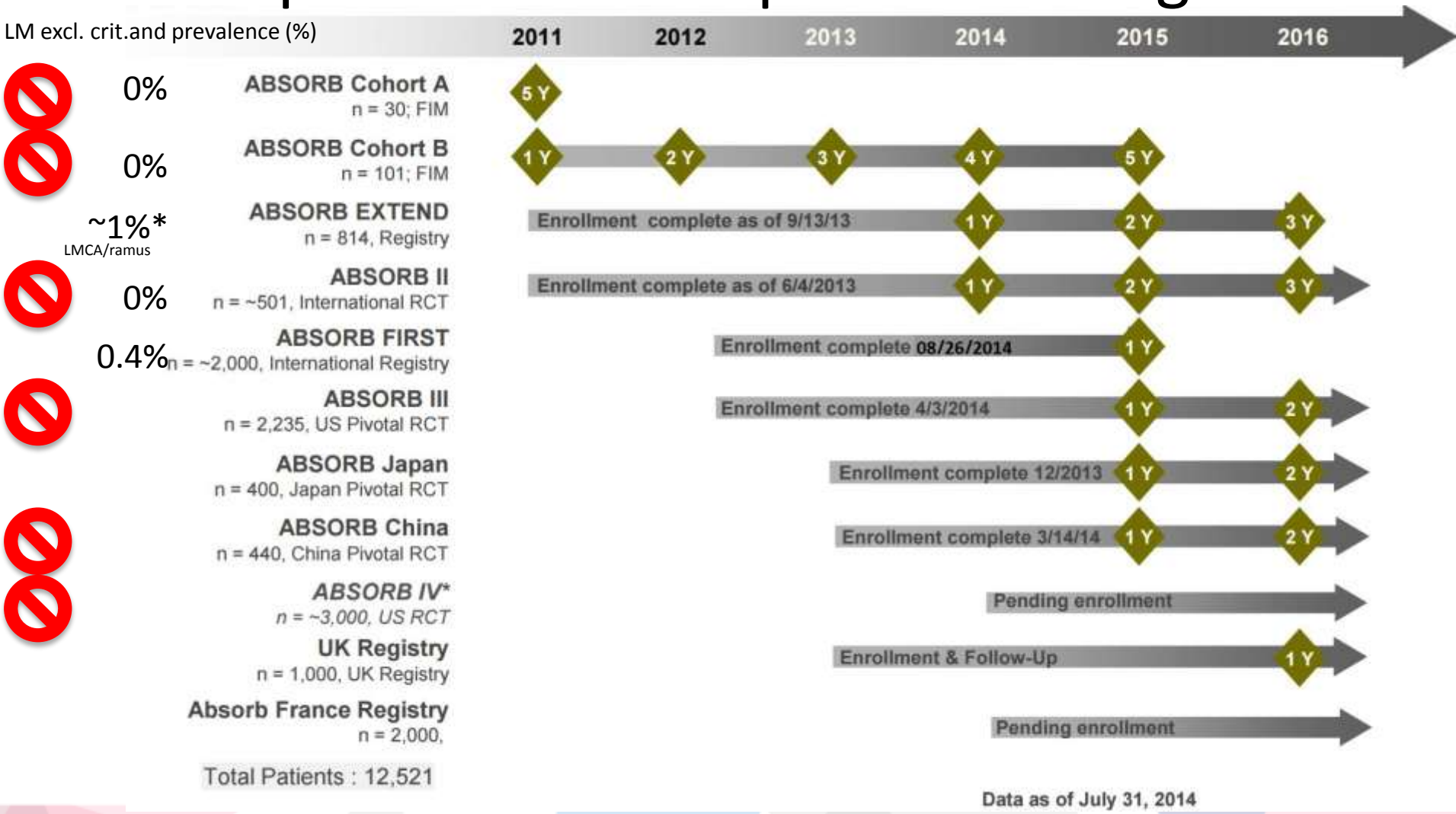
Absorb Clinical Trials

Comprehensive AV-Sponsored Program



Adapted from Jan J. Presented at AsiaPCR 2015

EuroIntervention 2014;10-online publish-ahead-of-print July 2014

Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry

Davide Capodanno[1], MD, PhD; Tommaso Gori[2], MD, PhD; Holger Nef[3], MD; Azeem Latib[4], MD; Julinda Mehilli[5], MD; Maciej Lesiak[6], MD; Giuseppe Caramanno[7], MD; Christoph Naber[8], MD; Carlo Di Mario[9], MD; Antonio Colombo[4], MD; Piera Capranzano[1], MD; Jens Wiebe[3], MD; Aleksander Araszki
Toru Naganuma[4], M

Variable	Patient-based	Lesion-based
Average of scaffolds implanted (n)	1.5±0.9 (1,189)	–
Target vessel		
LMCA	–	1.2% (17/1,427)
LAD	–	46.8% (668/1,426)
LCX	–	24.8% (353/1,426)
RCA	–	25.2% (359/1,425)

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1. Bailout **left main bioresorbable** vascular scaffolding for the treatment of iatrogenic coronary dissection induced by guiding catheter and sticky ABSORB **bioresorbable** vascular scaffold balloon.
Yew KL.
Int J Cardiol. 2015 Apr 1;187:527-529. doi: 10.1016/j.ijcard.2015.03.432. [Epub ahead of print] No abstract available.
PMID: 25846666
Related citations

2. Optical coherence tomographic image of dynamic **left main** coronary artery compression caused by intramural haematoma due to spontaneous coronary artery dissection - degloved artery managed with **bioresorbable** vascular scaffold.
Sengottuvelu G, Dattagupta A.
EuroIntervention. 2014 Dec 16. pii: 20131007-06. doi: 10.4244/EIJY14M12_05. [Epub ahead of print] No abstract available.
PMID: 25499831
Related citations

3. In-scaffold restenosis in a previous **left main** bifurcation lesion treated with **bioresorbable** scaffold v-stenting.
Miyazaki T, Panoulas VF, Sato K, Kawamoto H, Naganuma T, Latib A, Colombo A.
JACC Cardiovasc Interv. 2015 Jan;8(1 Pt A):e7-e10. doi: 10.1016/j.jcin.2014.08.009. Epub 2014 Dec 10. No abstract available.
PMID: 25499306
Related citations

4. A case of true **left main** bifurcation treated with **bioresorbable** everolimus-eluting stent v-stenting.
Sato K, Latib A, Panoulas VF, Naganuma T, Miyazaki T, Colombo A.
JACC Cardiovasc Interv. 2014 Aug;7(8):e103-4. doi: 10.1016/j.jcin.2013.12.208. Epub 2014 Jul 30. No abstract available.
PMID: 25086841
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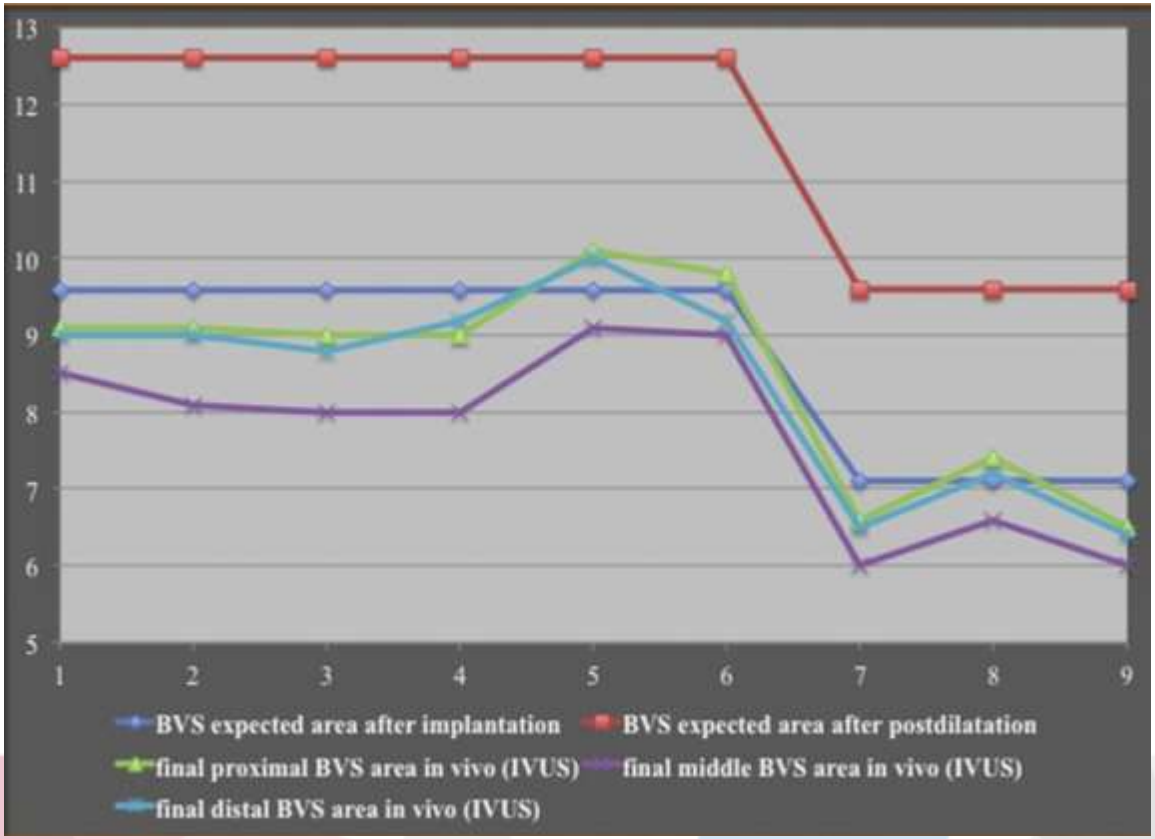
Letter to the Editor

Biovascular scaffolding of distal left main trunk Experience and follow up from the multicenter prospective RAI registry (Registro Italiano Absorb)

Bernardo Cortese [a,*], Pedro Silva Orrego [a], Rodrigo Sebik [a], Marco Sesana [b], Francesco Pisano [c], Dennis Zavalloni [d], Giuseppe Steffenino [e], Romano Seregni [a], on behalf of the, RAI registry investigators



Conclusion

Our study, despite the small sample size (n=9), describes the first experience with IVUS-guided BVS implantation at the distal LM with mid-term follow up. Our preliminary results show a high rate of device underexpansion/recoil, whose clinical meaning should be addressed in a dedicated and adequately powered study.

BVS for left main: Major concerns

- Lack of evidence based data
- Sizing: The largest BVS available is 3.5mm with max postdilatation diameter 4.0mm - too small for some LM?
- Dilatation of struts into side-branch may result in scaffold disruption

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.

Step-by-Step Approach

- ≥7F guiding catheter
- Wire both branches and predilate if needed
- FFR, Intravascular imaging (IVUS, OCT) for PCI guiding
- Plaque modificiation with cutting/scoring balloon
- Stenting: new generation DES LM to LAD and BVS LM to LCX
- Optimization:
  - Final kissing
  - Proximal optimisation technique (POT)
- Intravascular imaging (IVUS, OCT) for evaluation of stent expansion

First Results

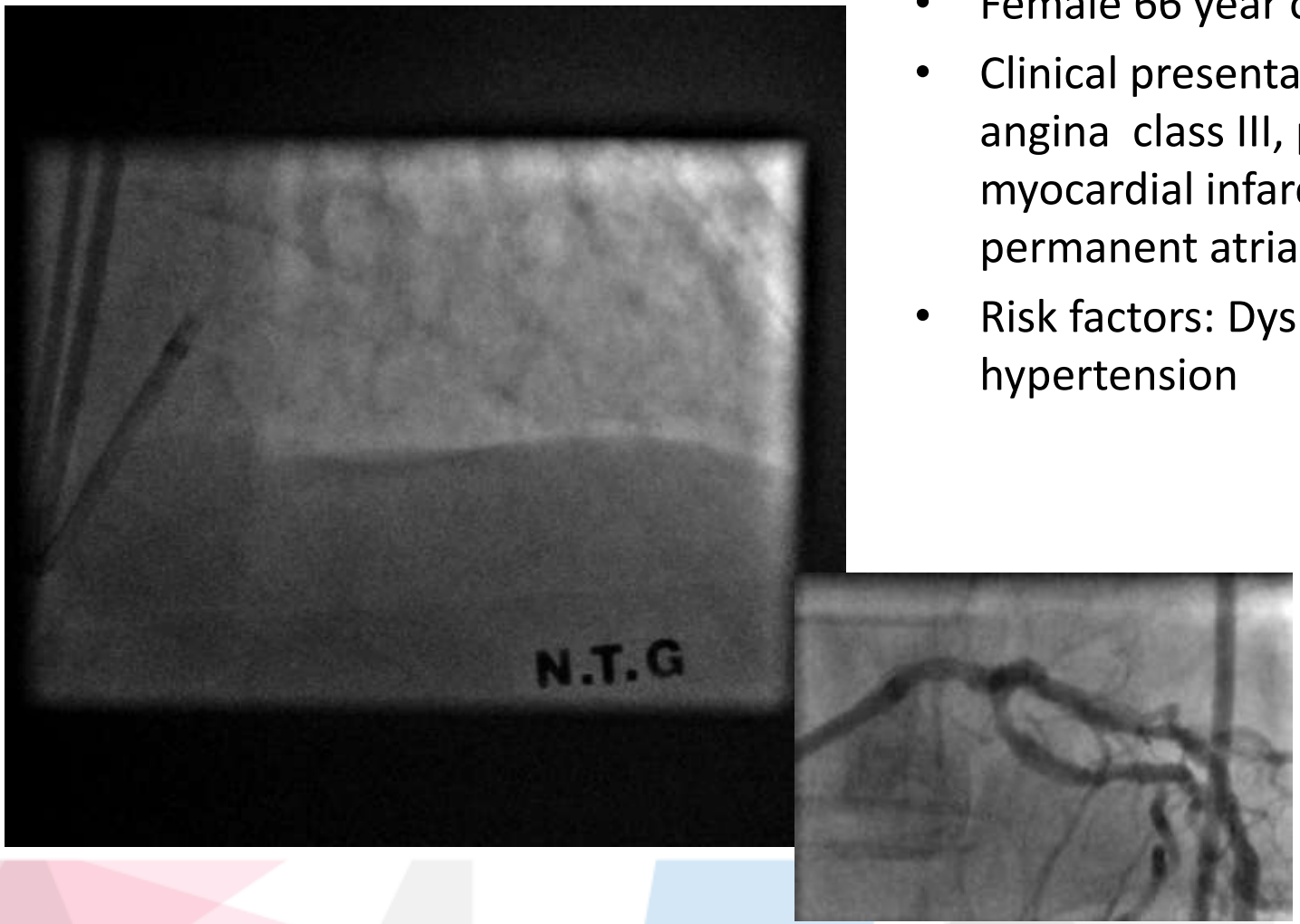
1 year follow-up, N=25 (%)	
Death, n (%)	0 (0)
Cardiac death, n (%)	0 (0)
QMI, n (%)	0 (0)
TVR, n (%)	4 (16)
TLR, n (%)	3 (12)
ST, n (%)	0 (0)
MACE, n (%)	4 (16)

Case Example #1

Case Example #1

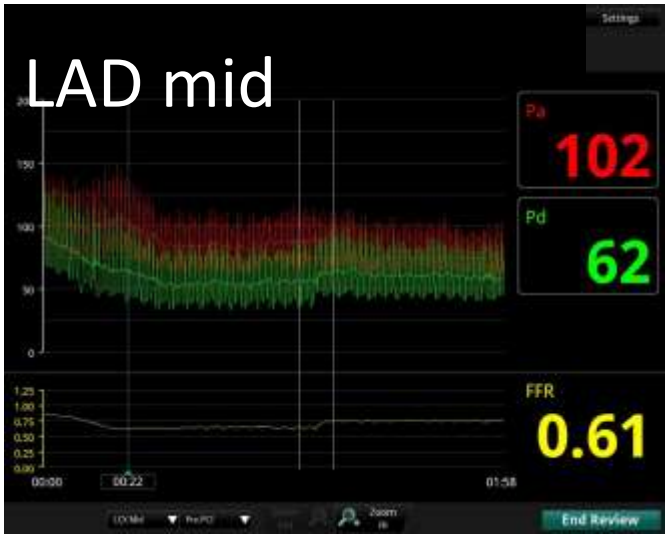
LM distal bifurcation 75% stenosis to LAD and LCX.

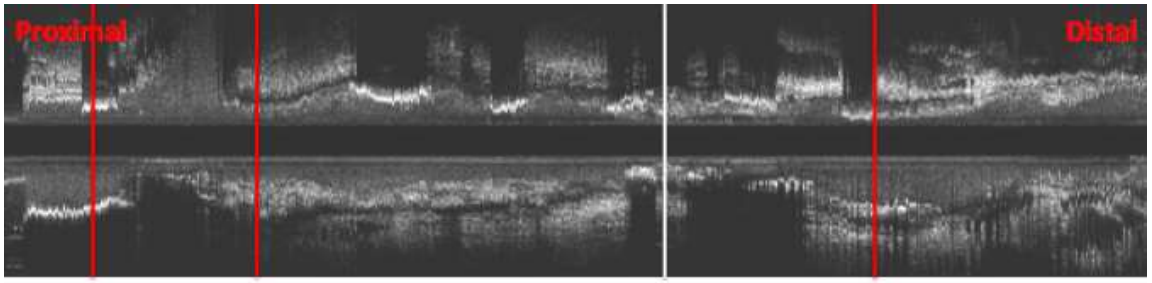
RCA chronic total occlusion

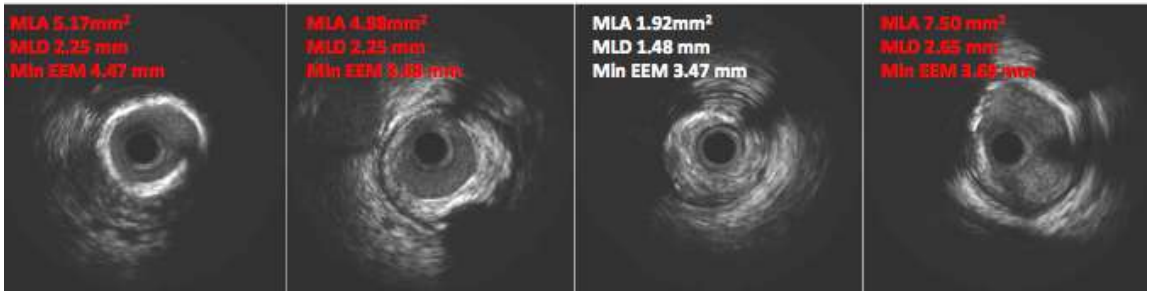


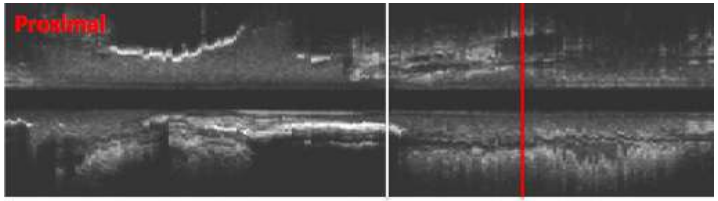
- Female 66 year old
- Clinical presentation: Stabile angina class III, previous myocardial infarction, permanent atrial fibrillation
- Risk factors: Dyslipidemia, hypertension

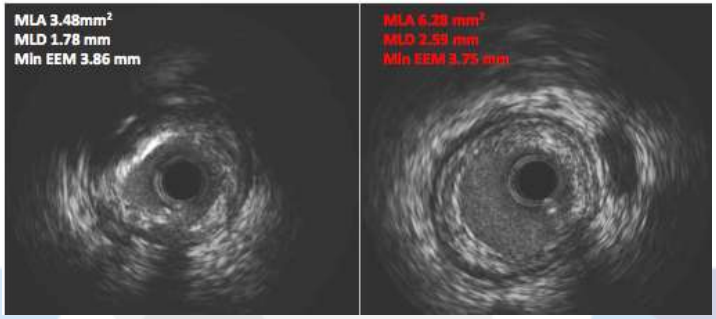
Case Example #1







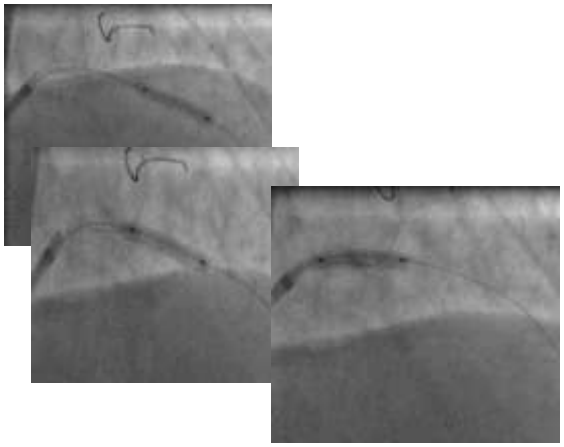




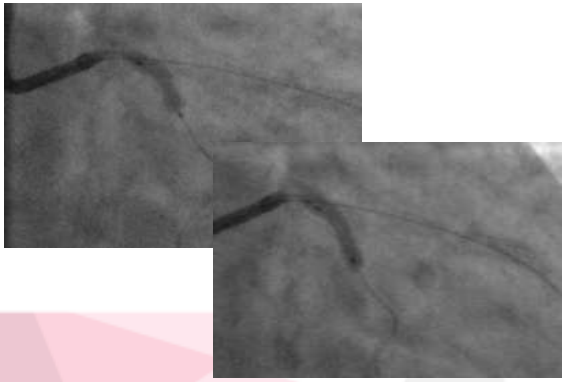
Case Example #1

Pretreatment

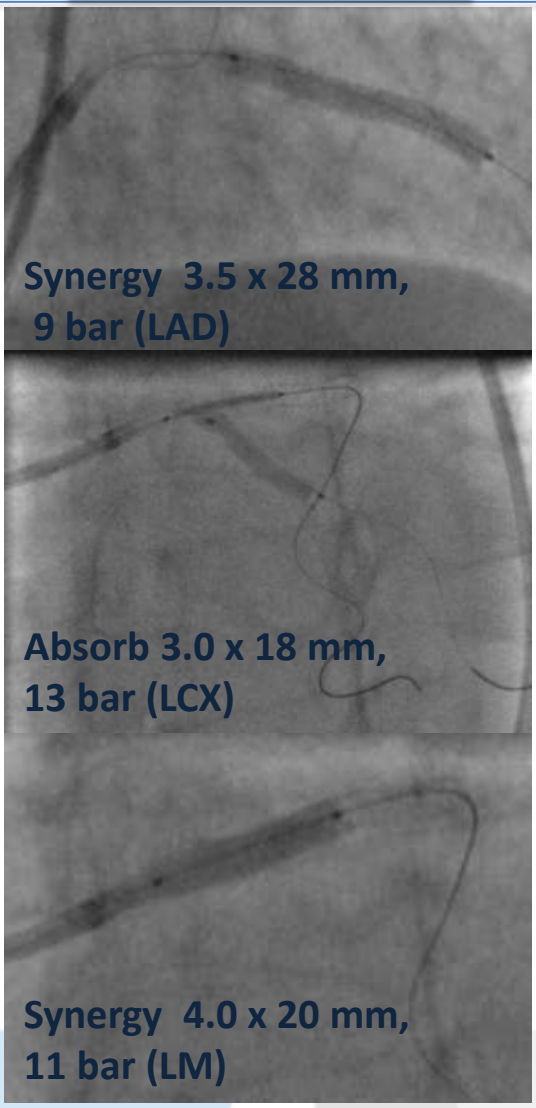
Predilatation of LM/LAD with cutting balloon 3.5 x 15 mm 5, 6, 7 bar



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



Stenting



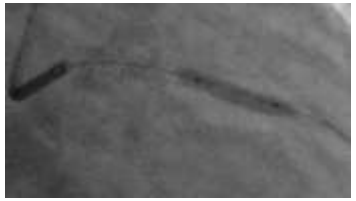
Synergy 3.5 x 28 mm, 9 bar (LAD)

Absorb 3.0 x 18 mm, 13 bar (LCX)

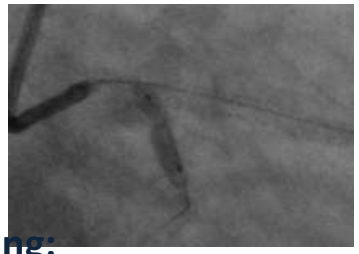
Synergy 4.0 x 20 mm, 11 bar (LM)

Postdilatation

LAD:NC Balloon 3.5 x 15 mm, 17 bar



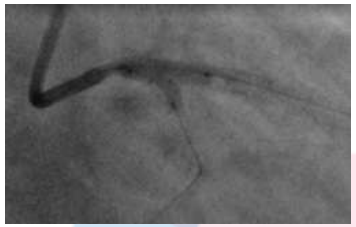
LCX: NC Balloon 3.5 x 15 mm, 15 bar



Kissing:

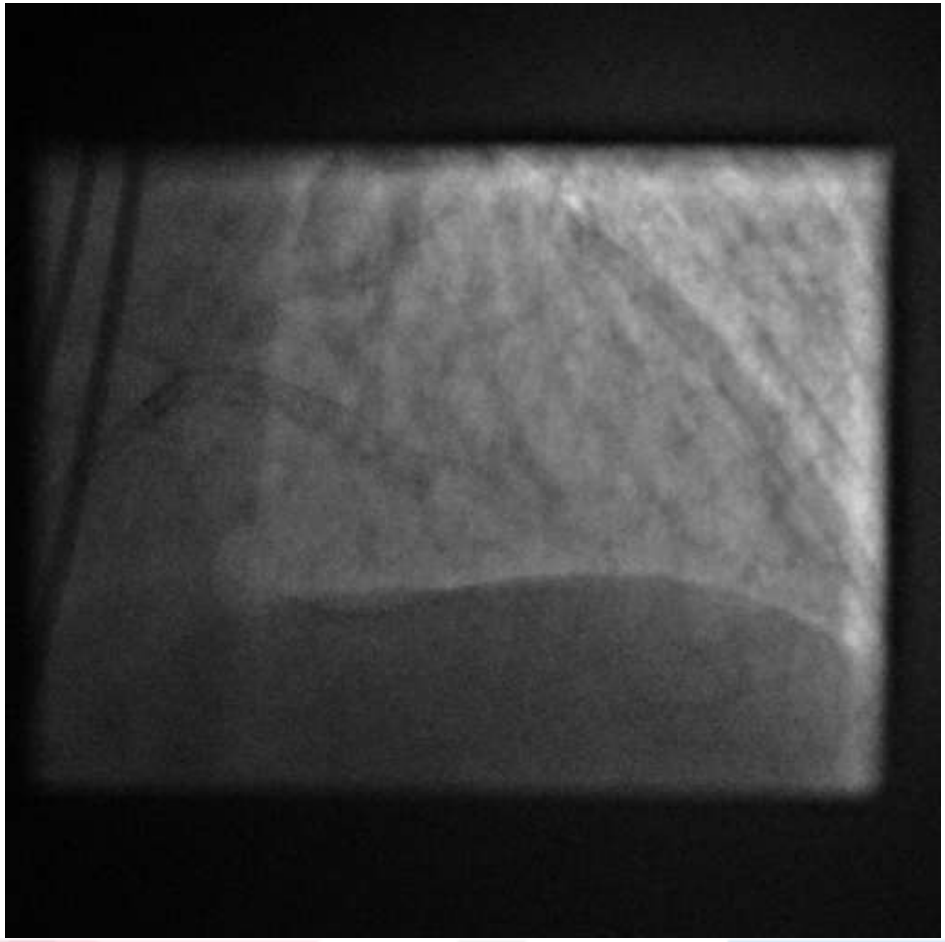
LAD 3.5 x 15 mm, 10 bar

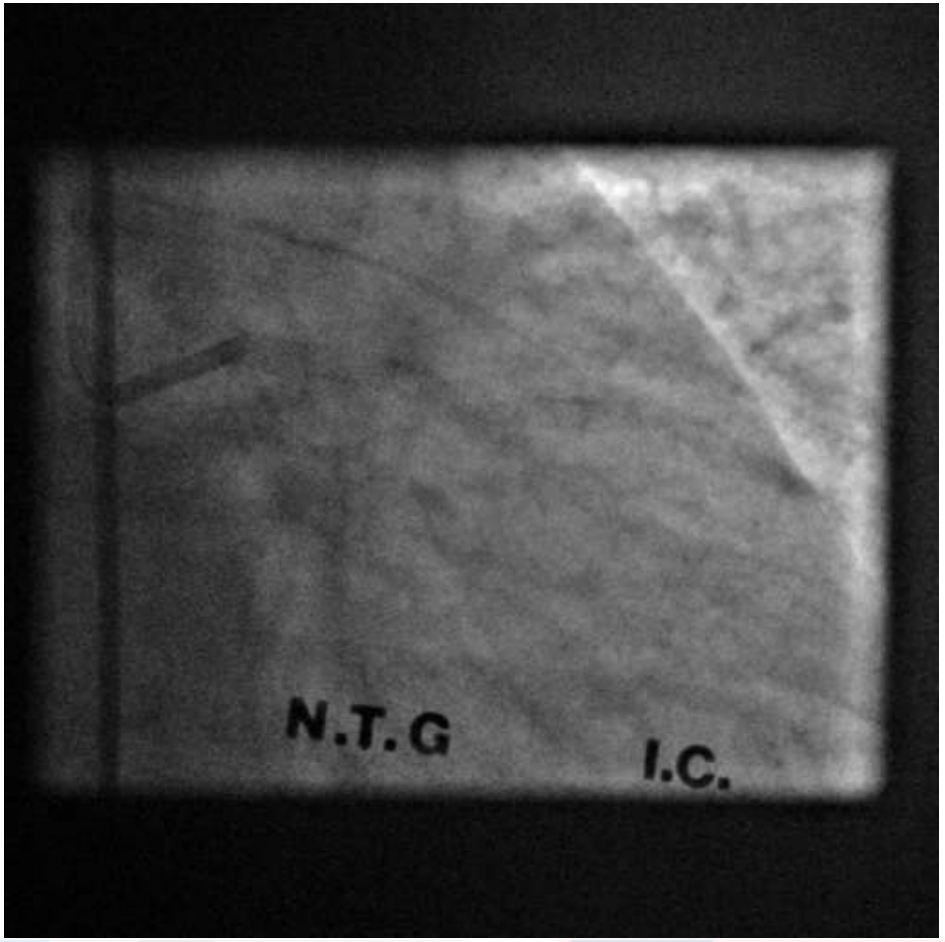
LCX 3.0 x 15 mm , 10 bar



Case Example #1

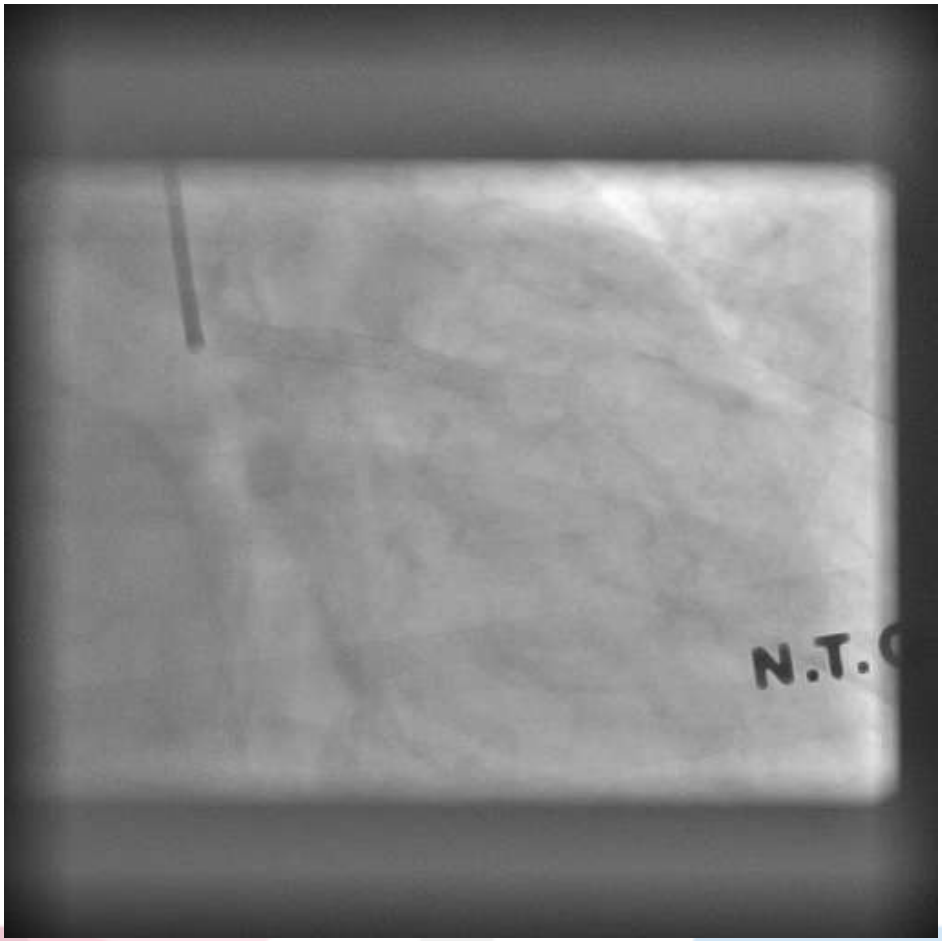
Final result

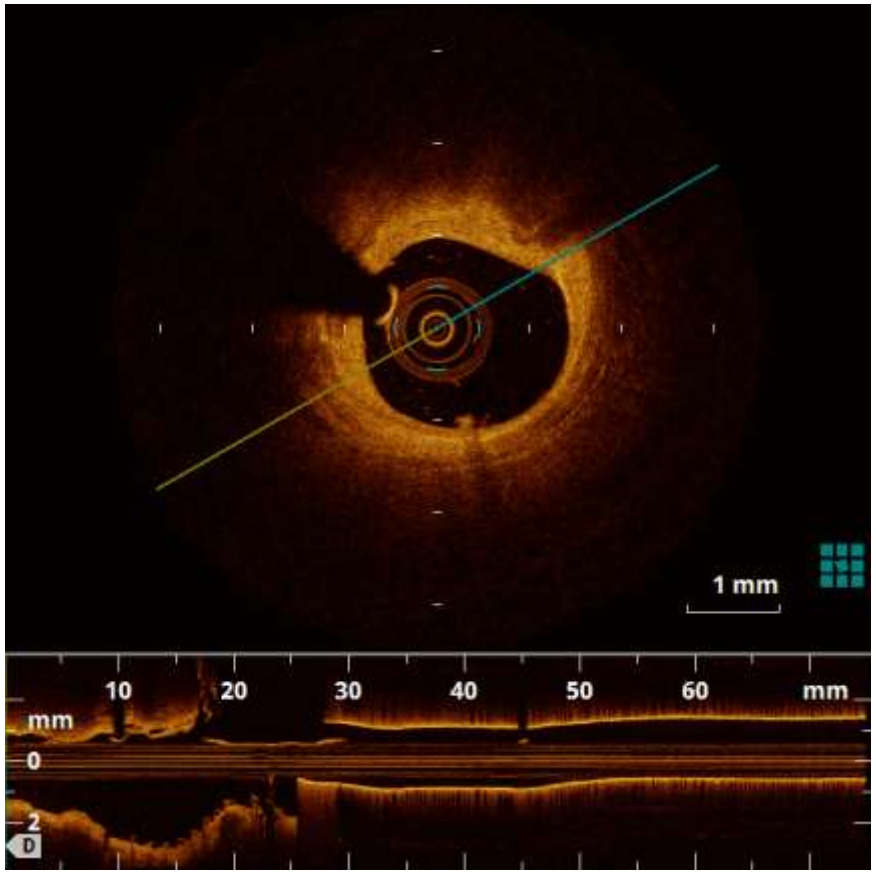




Case Example #1

Follow-up

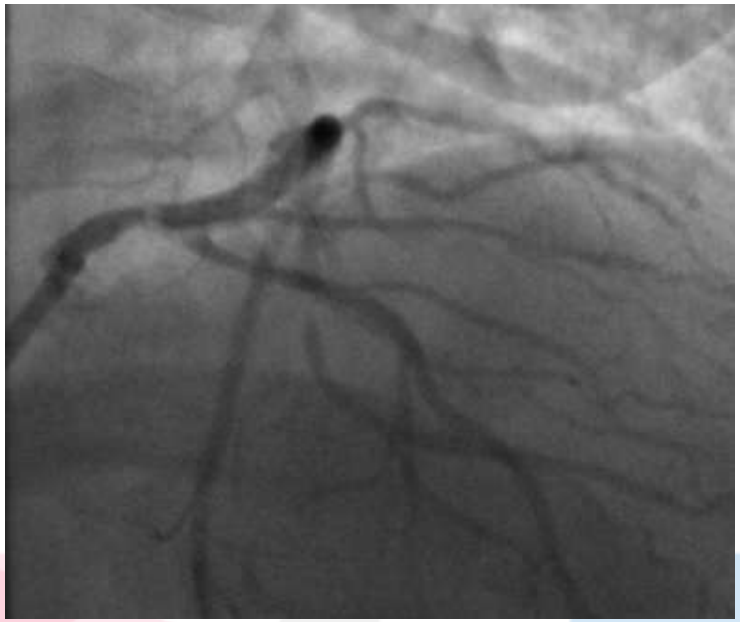


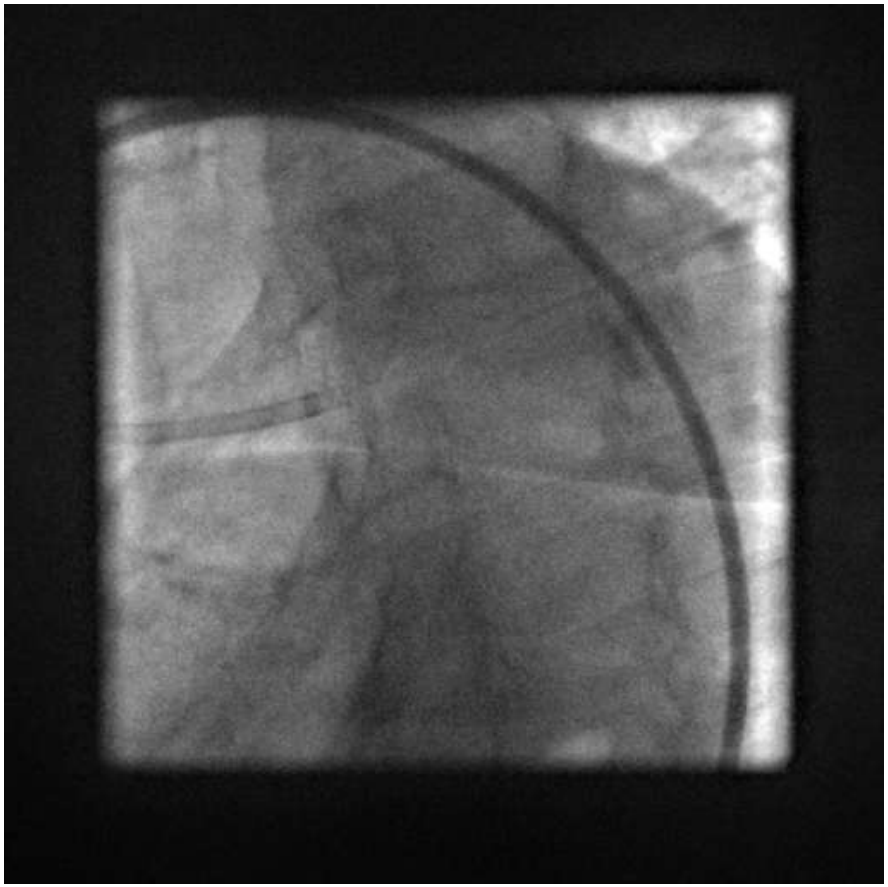


Case Example #2

Case Example #2

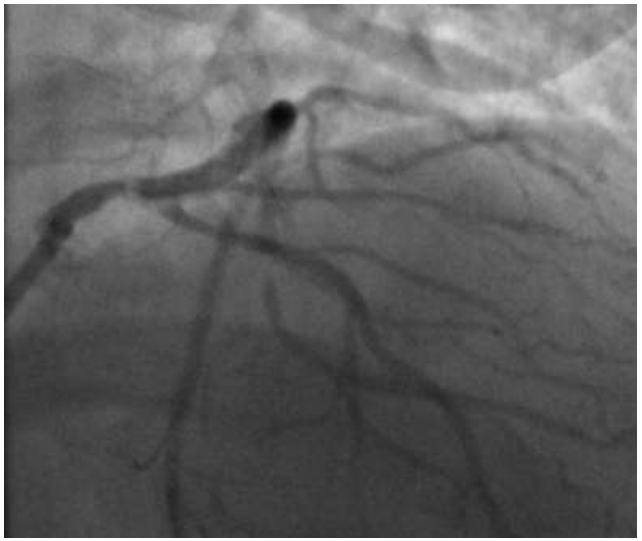
- 47 years old female
- Clinical diagnosis: Stable angina II, previous PCI RCA with DES
- Risk factors: smoker, hypertension, dyslipidemia, insulin dependent diabetes
- Echo: 60%





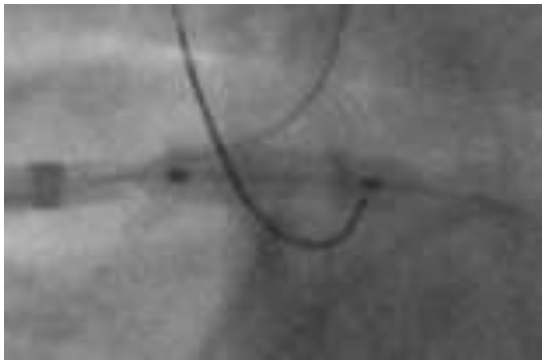
Case Example #2

- Femoral approach
- 6F EBU 3.75guiding catheter
- Angiographic guidance
- Wire both branches
- Plaque modificiation with cutting balloon
- BVS from LM to LAD across LCX
- NC postidilatation

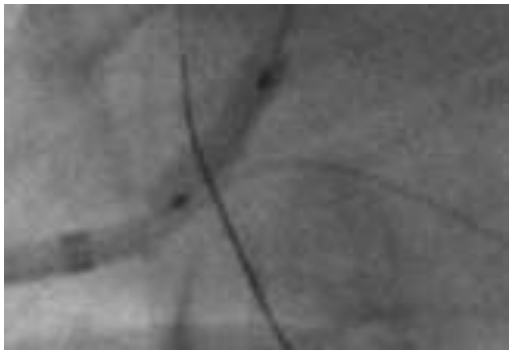


Case Example #2

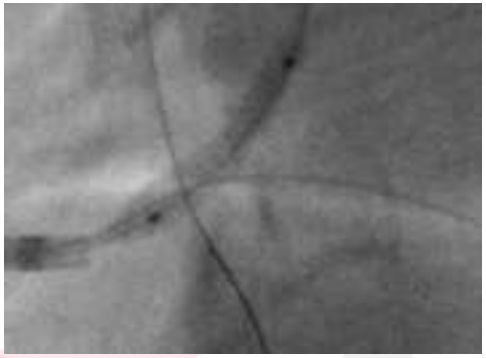
1. LM-LCX: Flextome Cutting balloon 3.5x10 mm 11 atm



2. LM-LAD: Flextome Cutting balloon 3.5x10 mm 11 atm



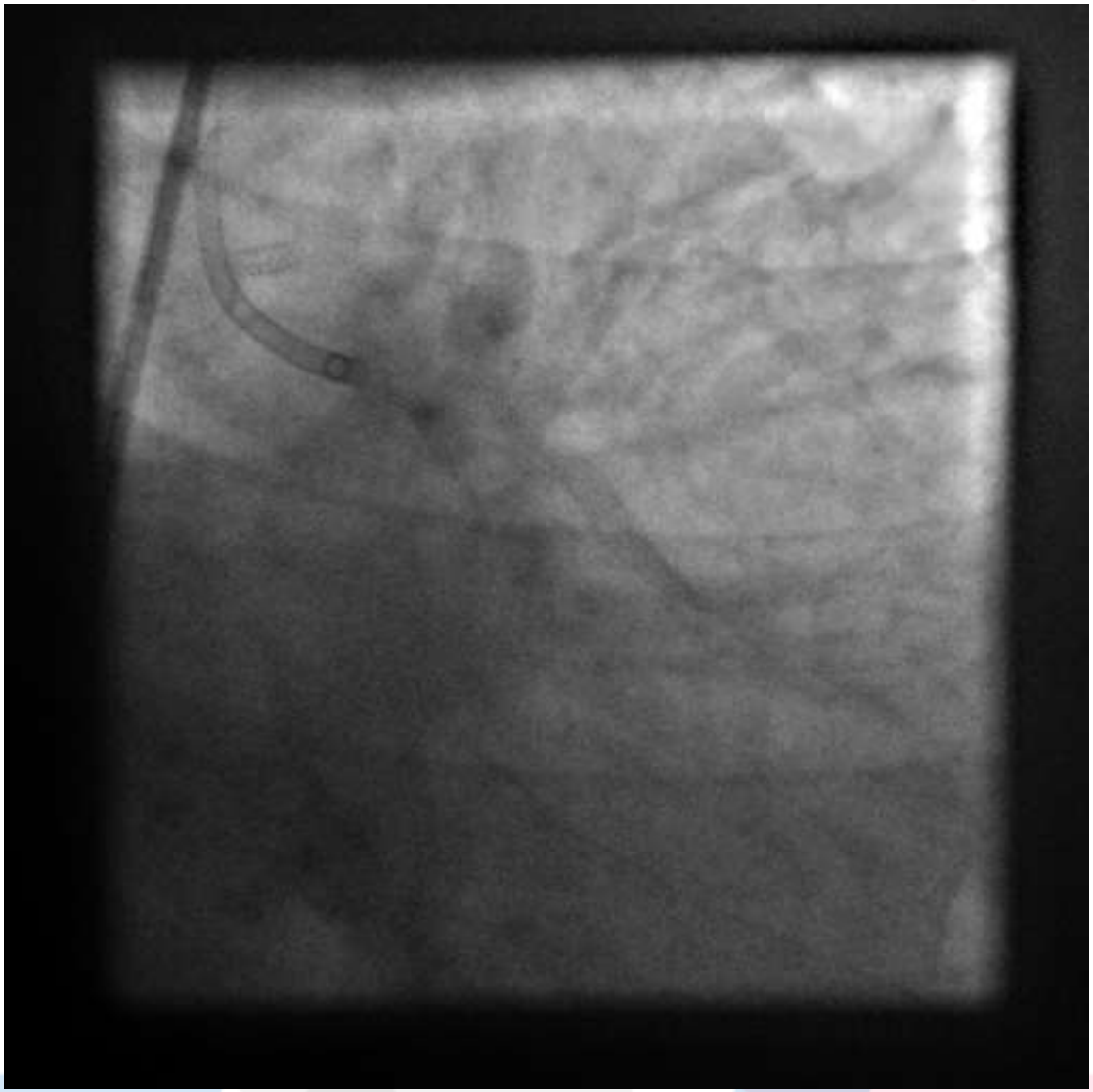
3. LM-LAD: BVS 3.5x18 mm 9 atm



4. LM-LAD: NC Quantum balloon 4.0x8 mm 21 atm

Case Example #2

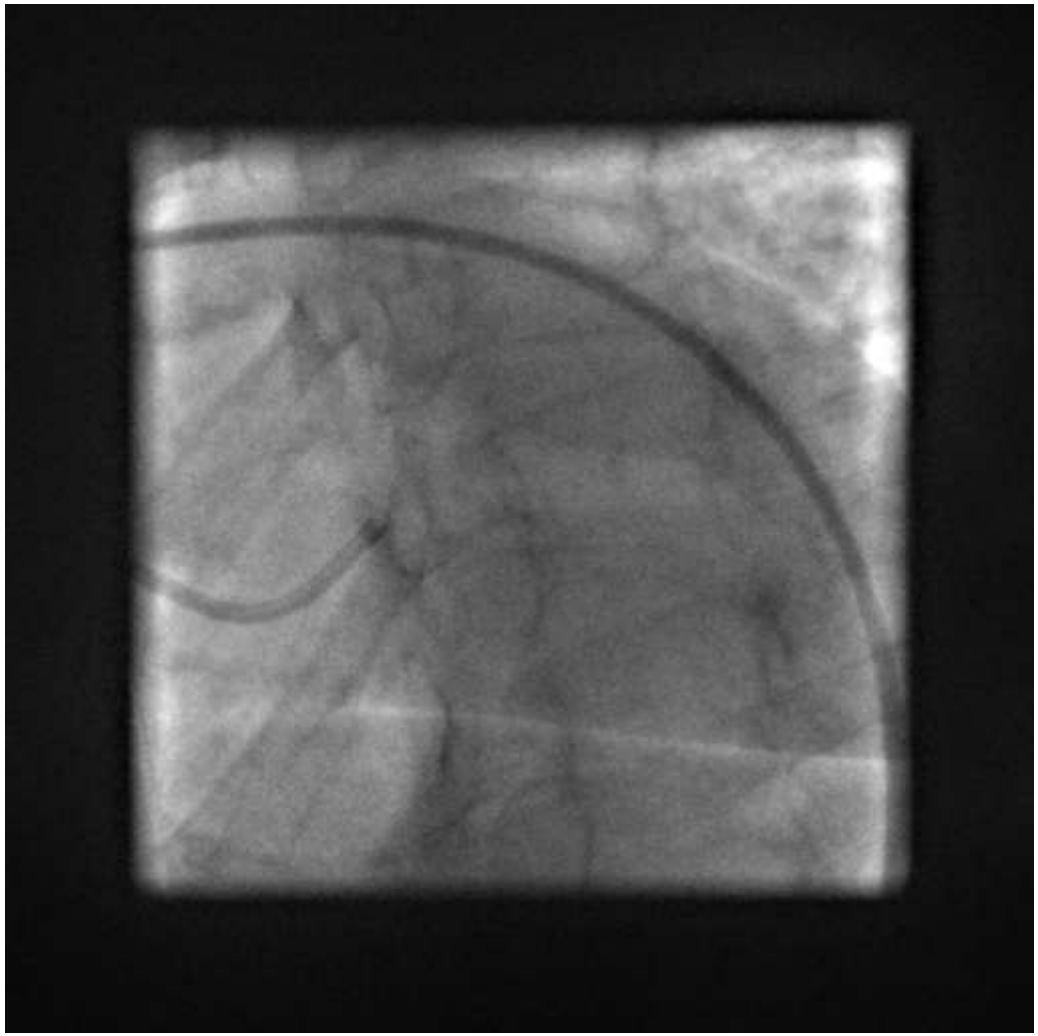
Final result



Case Example #2

1 Year follow-up

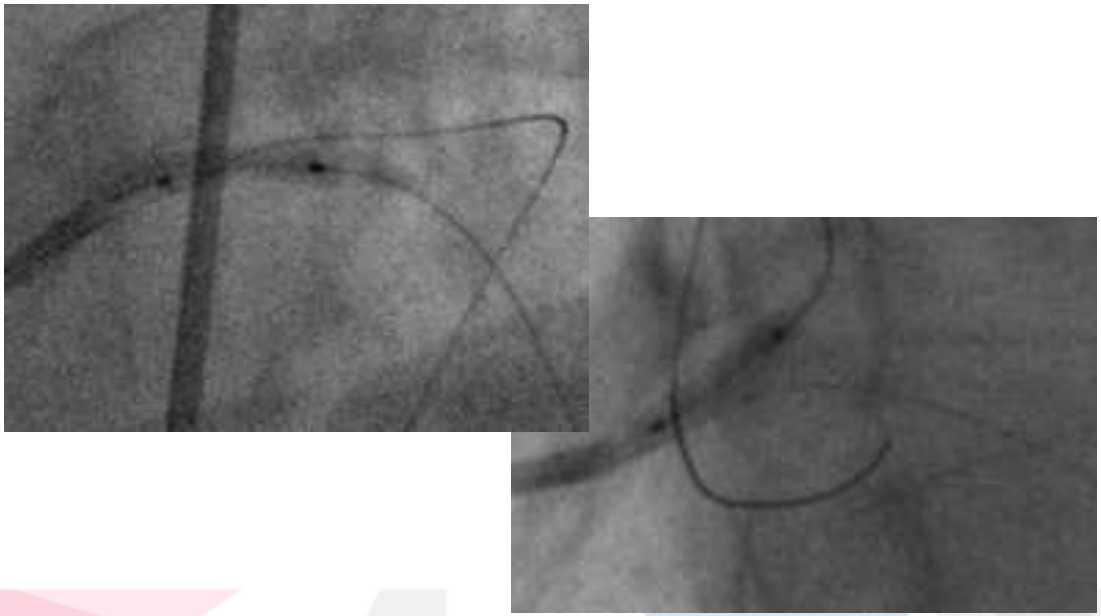
Clinical diagnosis:
Stable angina, class III (patient was symptom free for 6 months after PCI)



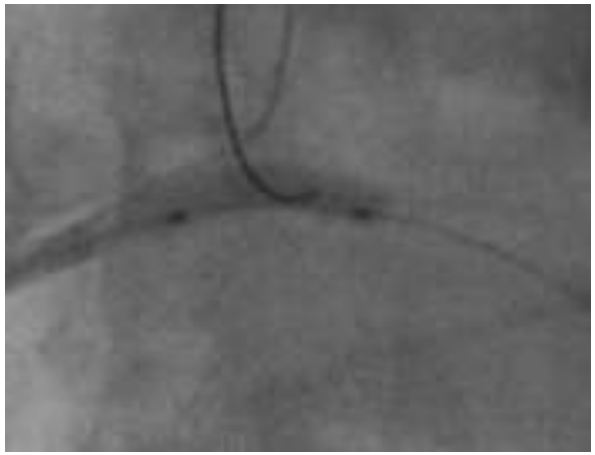
Case Example #2: TLR

TLR – Angiographic guidance

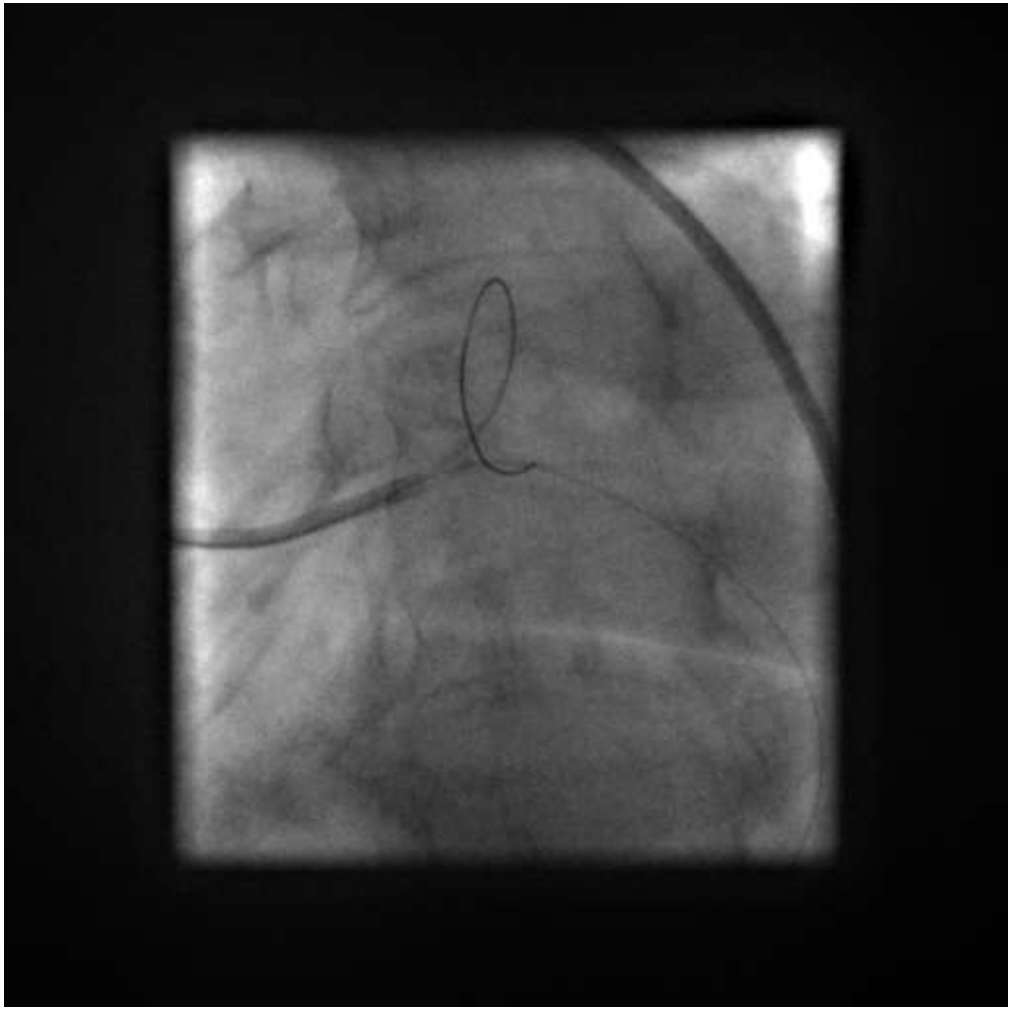
1. **Flextome Cutting balloon LM-LAD 2.75x10 mm 11 atm**



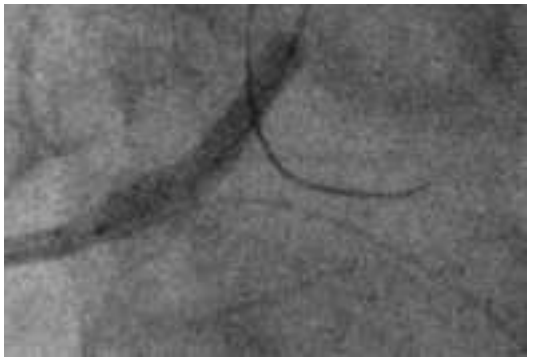
2. SC balloon LM-LCX 2.5x12 mm 17 atm



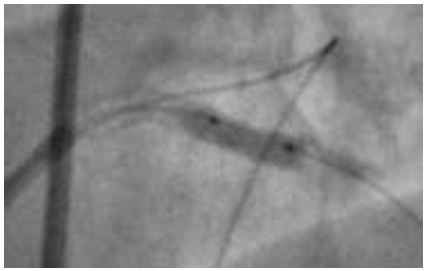
Case Example #2: TLR

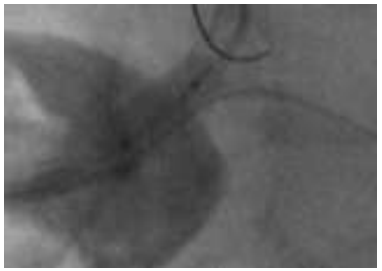


4. LM-LAD: EES 4.0x24 mm 10 atm

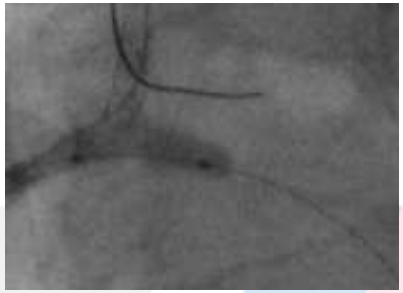


5. LM-LAD: NC balloon 4.5x8 mm 19 atm



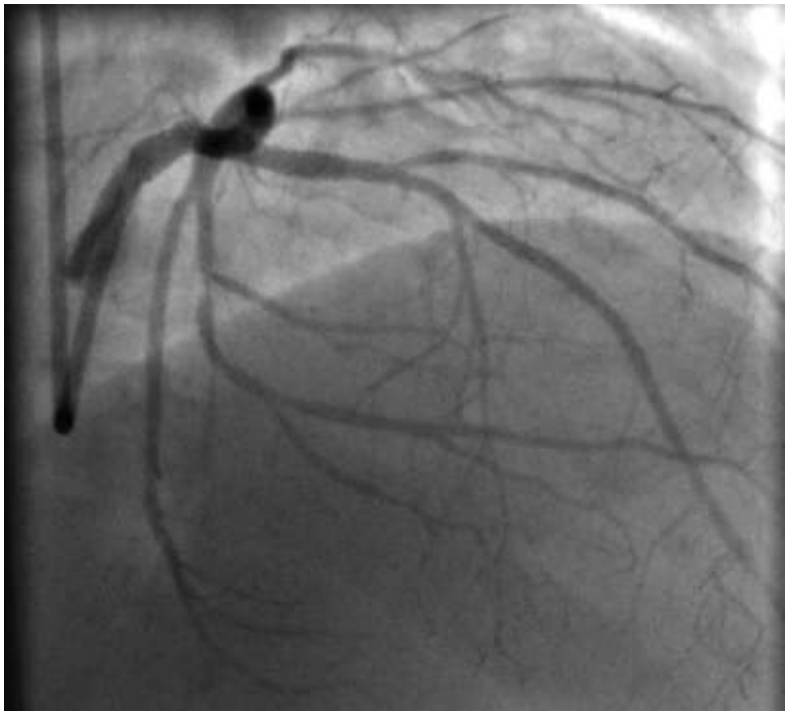


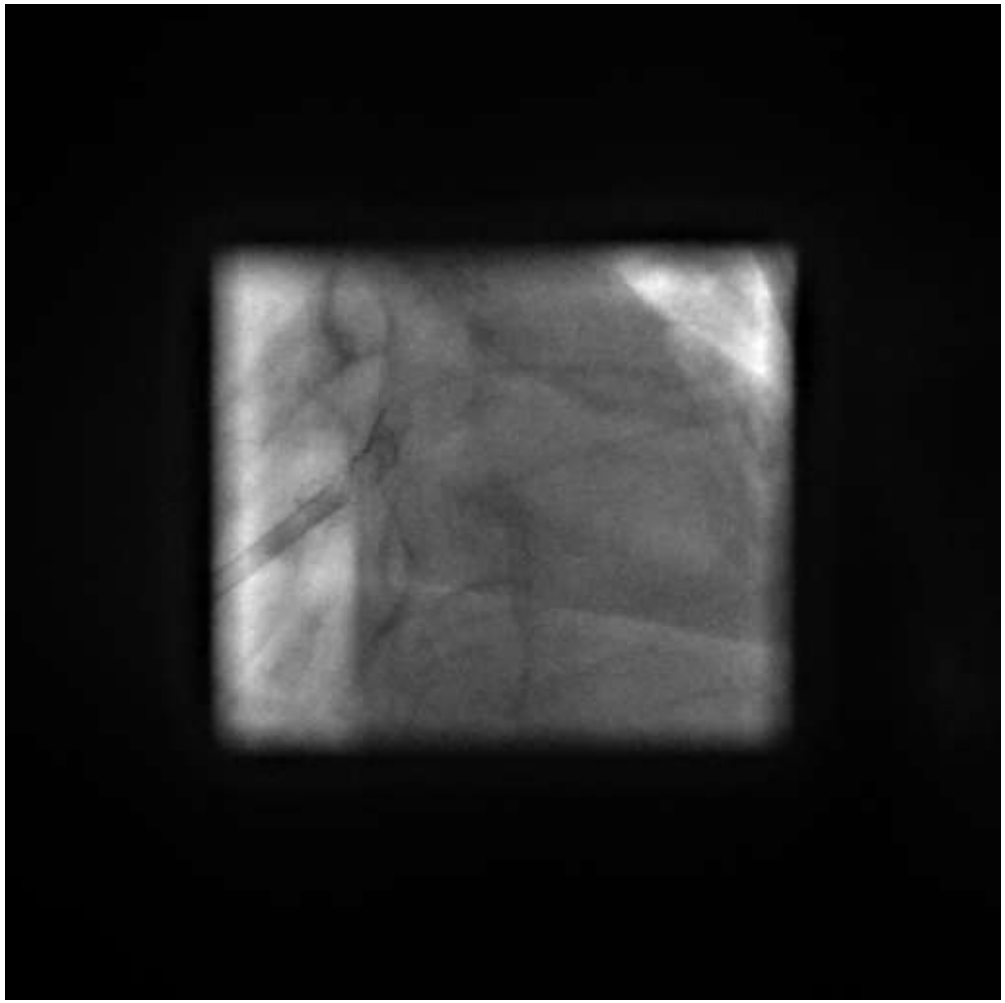
6. Open struts to LCX: SC balloon 3.0x12 mm 17 atm



Case Example #2: TLR

Final result after TLR





BVS for left main?

- No: Off-label indication
- Yes: It can be recommended after plaque pretreatment with intravascular guidance and optimization
- Maybe: Evidence based data is needed