

***Welcome to the 5<sup>th</sup>  
European Bifurcation Club  
16-17 September 2009 - BERLIN***

*October 16, 20:30-22:00*

**Role of lesion preparation in the  
treatment of bifurcation lesions  
Case Review Session**

*European Bifurcation Club*



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# Lesion Preparation: Cosmetic or Curative?

## Hypothesis

- Plaque modification before stent deployment may minimize arterial injury and subsequent neointimal proliferation /restenosis:
  - It minimizes plaque shifting between main branch and side branch and thus helps avoiding side branch stenting
  - It gives perfect stent apposition with reduced inflation pressure even if very long stents are deployed
  - With bioabsorbable stents it will be an essential tool to perform complete “vessel repair procedures”



# Pre-treatment options and consequences

## *Options*

CB

DCA

Rota

## *Consequences*

Minimize problems related to plaque shifting

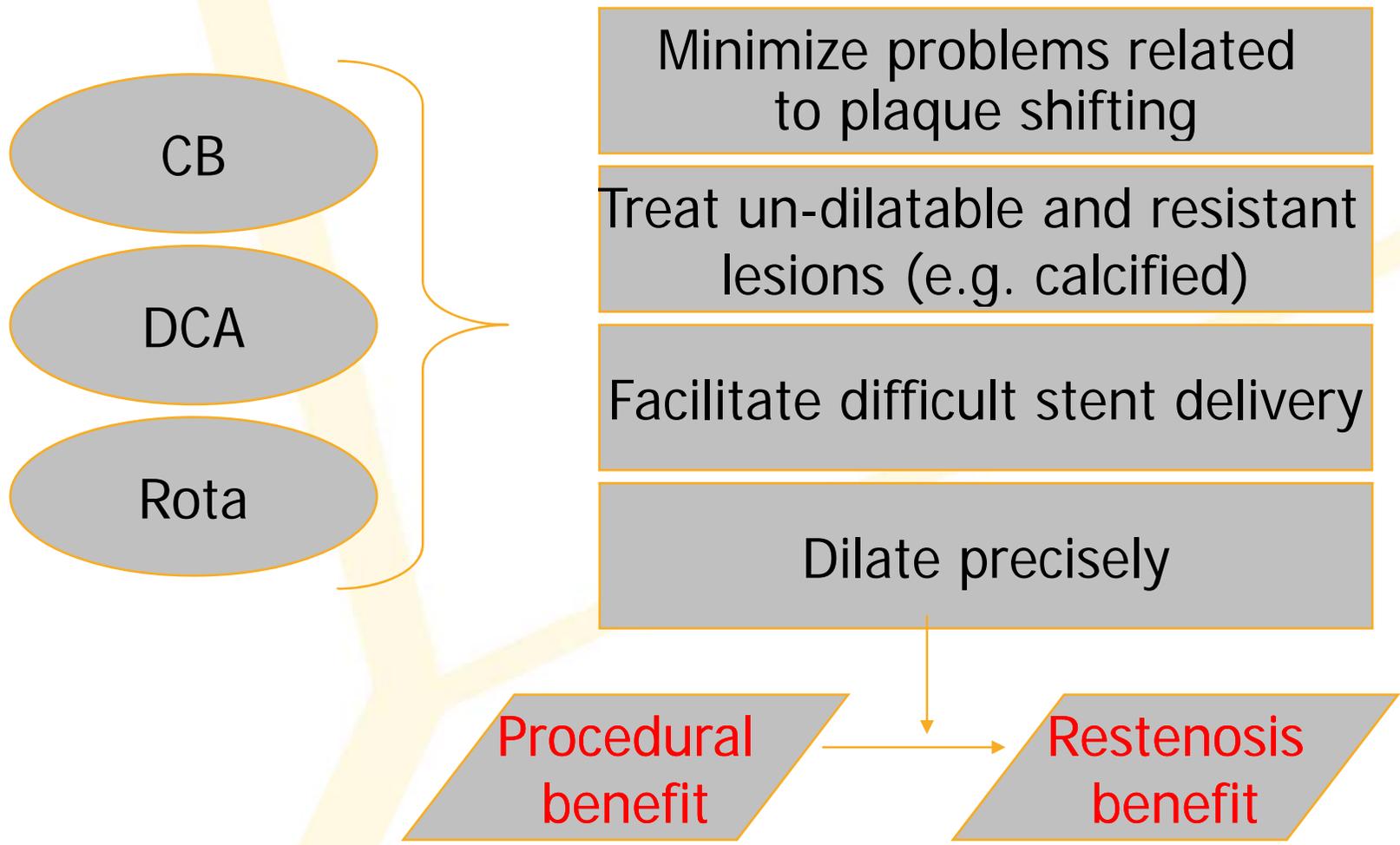
Treat un-dilatable and resistant lesions (e.g. calcified)

Facilitate difficult stent delivery

Dilate precisely

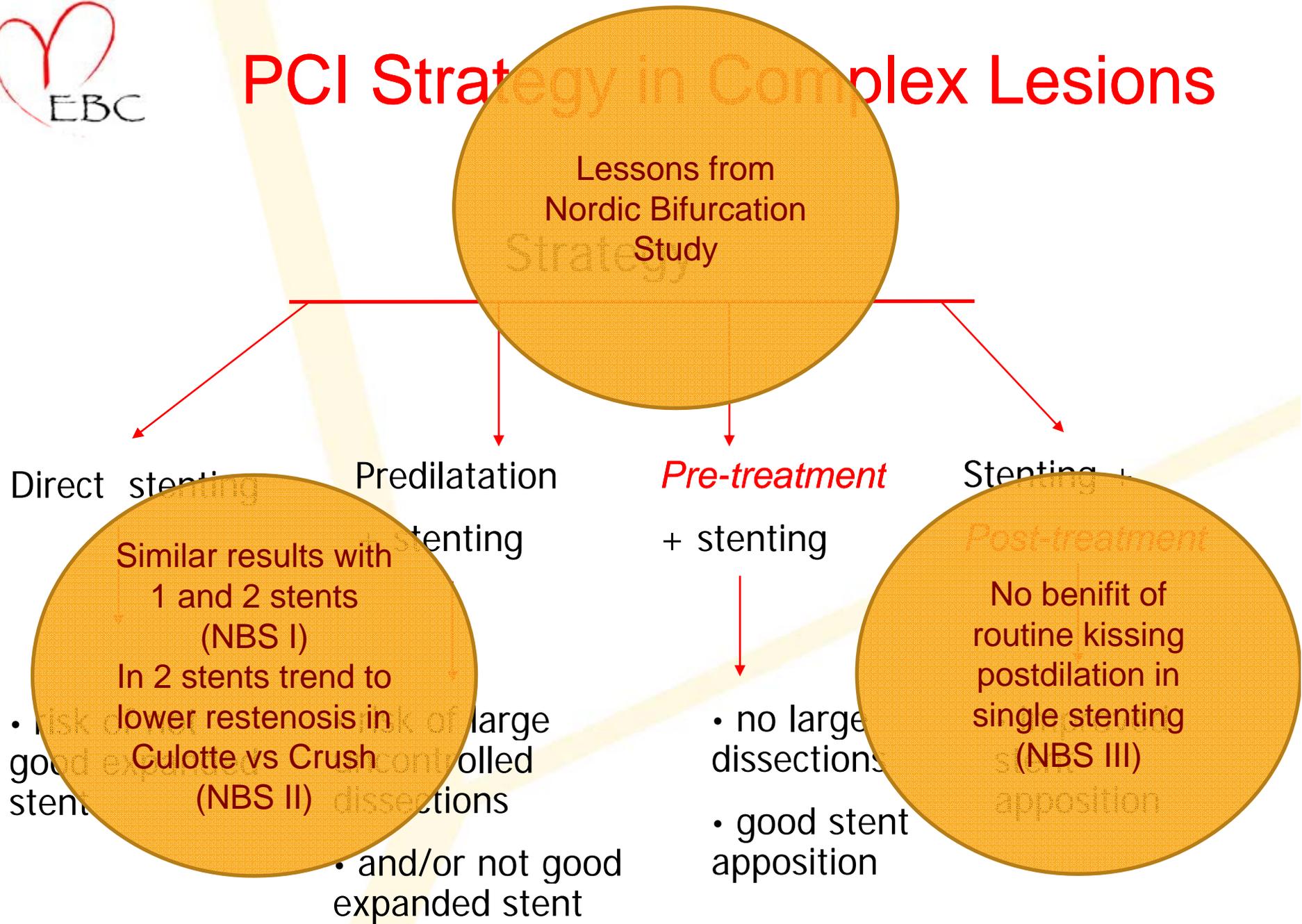
Procedural benefit

Restenosis benefit





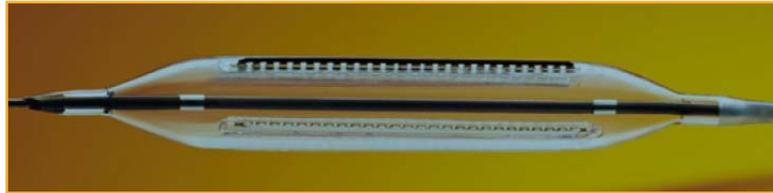
# PCI Strategy in Complex Lesions





# Scoring Balloon Types

## *Cutting Balloon Ultra*



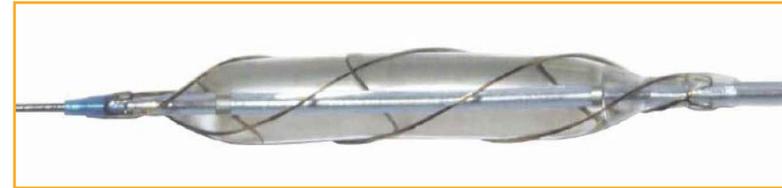
A non-compliant balloon with 3-4 microtomes mounted on its surface

## *Flextome Cutting Balloon*



Improved profile and flexibility

## *Angiosculpt*



A semi-compliant balloon with an external Nitinol shape memory helical scoring edge

### *Possible advantages:*

- Focused force PTCA with “Controlled” dissections
- Stent apposition improvement

### *Possible disadvantages:*

- Profile & limited length



# Acting Mechanisms of Regular and Cutting Balloons

## Regular balloon



- Entire balloon surface contact the vessel wall – arterial wall damage
- Multiple rips and tears in media
- Endothelium is completely disrupted, large hematoma has formed due to trauma

## Cutting balloon



- Injury localized to the scoring sites - reduced trauma
- Media with no visible disruption
- Endothelial layer remains intact



# Bifurcation CB Substudy

- Single centre substudy (Nordic Bifurcation Study I, II+ Riga bifurcation registry)
- **Goal:** The safety and efficacy of plaque modification with cutting balloon before main vessel stenting and/or side branch treatment in bifurcation lesion
- **Comparison:** CB vs non-CB interventions in bifurcation lesions
- **End-points:** cardiac death, myocardial infarction, stent thrombosis, target lesion revascularization (TLR), and target vessel revascularization (TVR) after 8 months.



## CB Substudy: 8 Months Outcomes

	CB n= 209	Non-CB n= 347	P value
Death, n (%)	7 (3.3)	10 (2.9)	0.802
MI, n (%)	7 (3.3)	9 (2.6)	0.609
Non Q-wave MI, n (%)	6 (12)	4 (8)	0.518
ST, n (%)	5 (2.4)	10 (2.6)	>0.99
TLR, n (%)	11 (5.3)	38 (11.0)	<b>0.021</b>
TVR, n (%)	17 (8.1)	48 (13.8)	0.056



# Arterial Scoring in LM (including distal bifurcation)

## Unprotected LM Registry

615 consecutive patients with unprotected LM disease undergoing PCI at Latvian Center of Cardiology were enrolled into the LM PCI registry since January 2002

*PCI on unprotected LM  
(IVUS guidance, cutting balloon pretreatment optional, BMS or DES implantation)*

**Between Feb 2004 and Nov 2005  
PCI on unprotected LM  
(IVUS guidance, cutting balloon pretreatment mandatory, randomization)**

**BMS  
n=50**

**PMS  
n=53**

## Intrahospital evaluation

n: 413 (100%)

n: 103 (100%)

## 6 months clinical, angiographic and IVUS follow-up

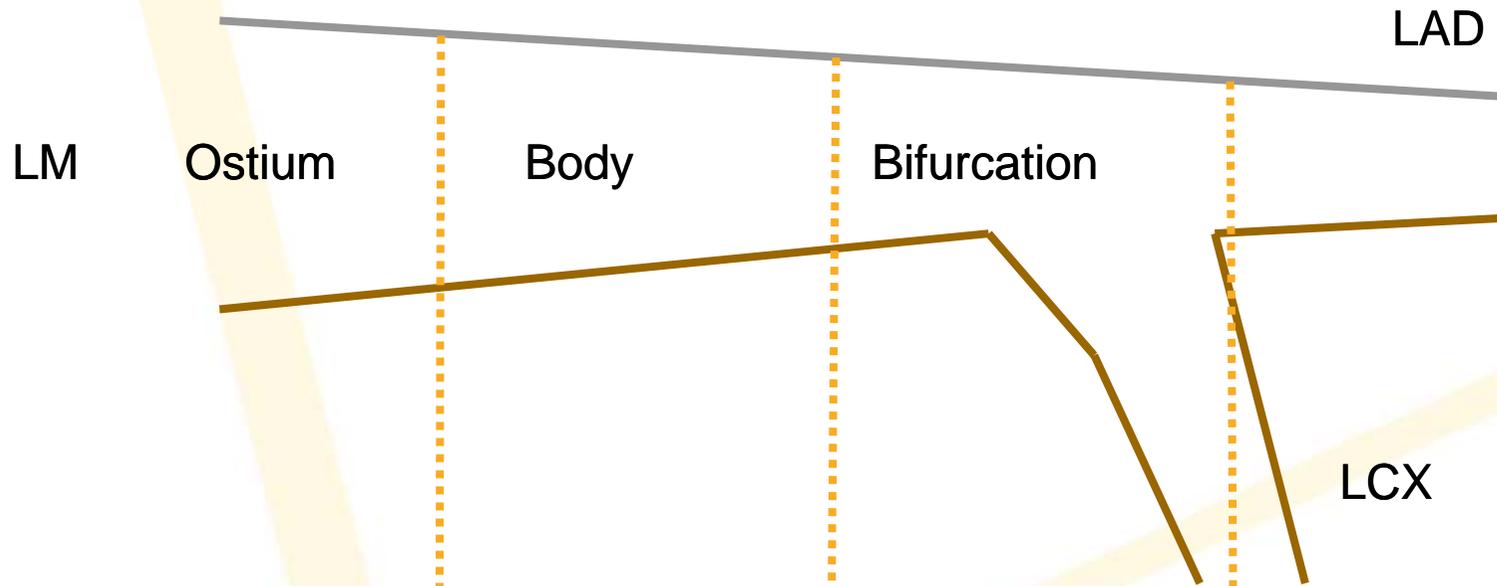
n: 276 (67%)

n: 103 (100%)

## 36 months clinical, angiographic and IVUS follow-up & OCT



# Lesion Location

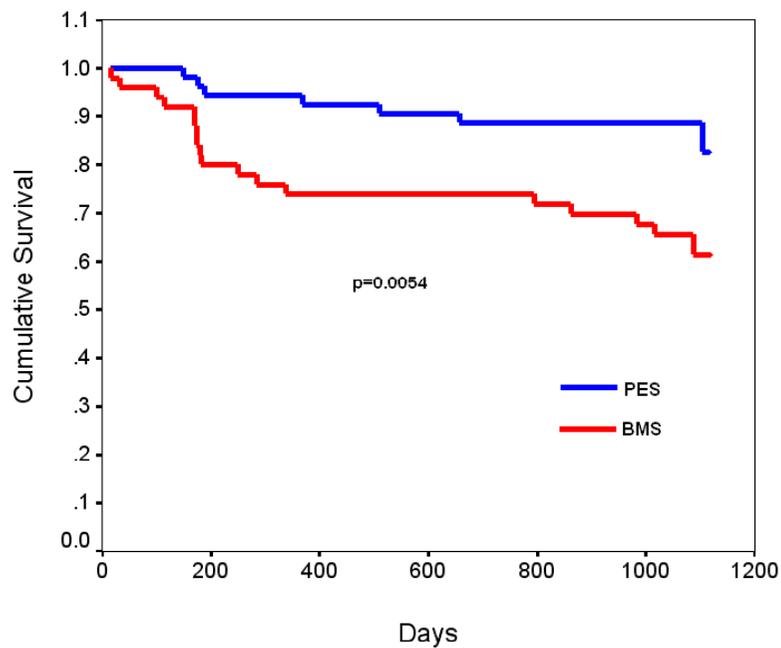


<b>BMS</b>	14%	18%	68%
<b>DES</b>	4%	15%	81%
<b>P value</b>	0.087	0.793	0.173



# 3 Years Clinical Results

MACE (death, MI, TLR) free survival



	BMS (n= 50)	PES (n= 53)	p-value	All (n=103)
Total death, n (%)	7 (14.0)	3 (5.7)	0.193	10 (9.7)
Cardiac death, n (%)	4 (8.0)	3 (5.7)	0.710	7 (6.8)
Q-MI, n (%)	1 (2.0)	3 (5.7)	0.618	4 (3.9)
TLR, n (%)	10 (20.0)	3 (5.7)	0.038	13 (12.6)
TLR-PCI, n (%)	9 (18.0)	3 (5.7)	0.067	12 (11.7)
TLR-CABG, n (%)	1 (2.0)	0 (0)	0.485	1 (1.0)
Total MACE, n (%)	18 (36.0)	7 (13.2)	0.011	25 (24.3)



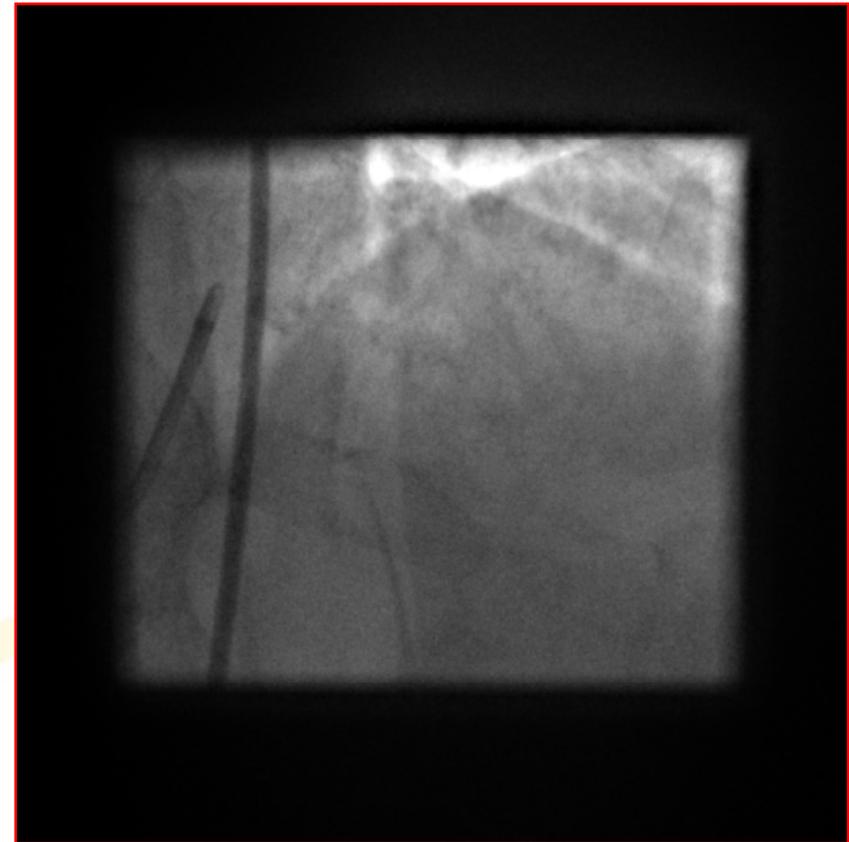
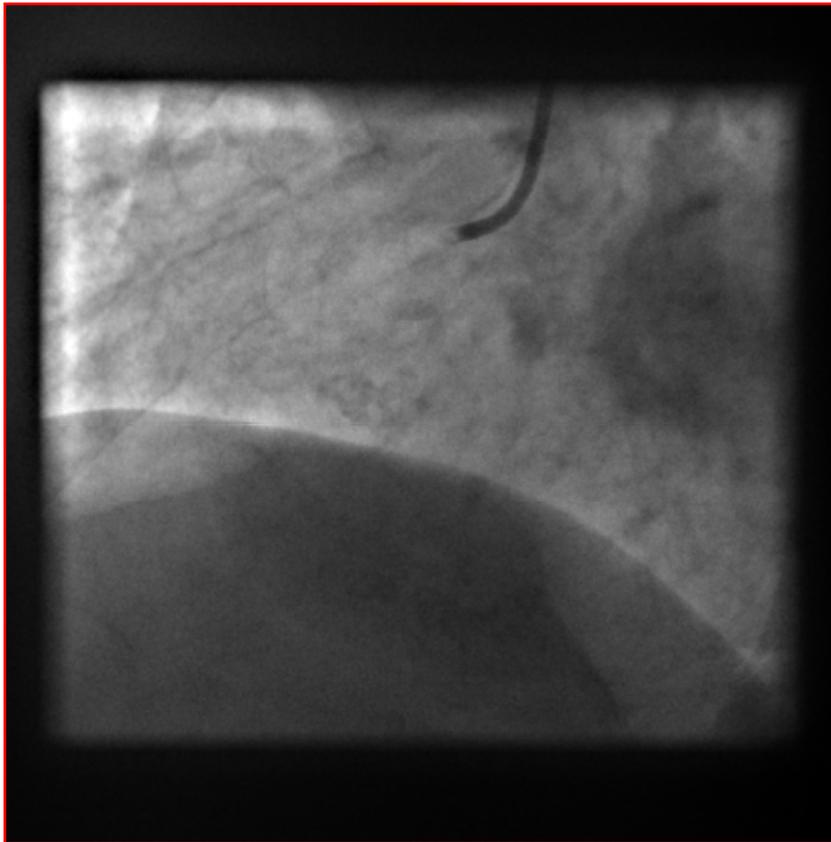
## Patient Characteristics

- 76 years old female admitted with stable angina CCS III on good medical therapy
- Factors of cardiovascular risk: dyslipidemia, arterial hypertension
- Previous history: Myocardial infarction (2007), Peripheral artery disease and lumbar sympathectomy (2008)



# Coronary Angiography

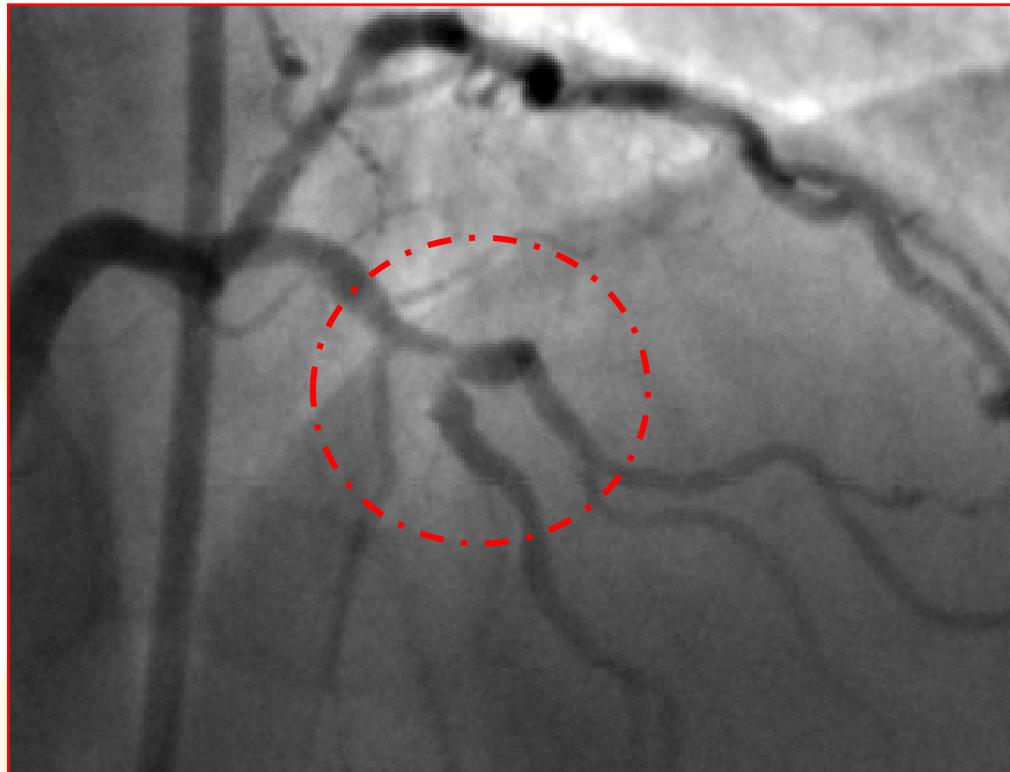
Diffusely diseased RCA + severely calcified LAD-D1 stenosis





## Intended Strategy for Bifurcation

IVUS guided PCI on LAD-D1 (plaque pre-treatment with cutting balloon + DES stenting)





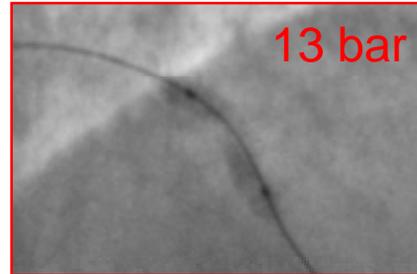
## Equipment

- Femoral approach - 7F Medtronic EBU 3.75
- IVUS guidance
- Choice floppy wires
- Predilatation balloon -  $\varnothing$  2.5 - 12 mm
- Cutting balloon -  $\varnothing$  2.75 - 6 mm
- CYPHER stent –  $\varnothing$  3.0 - 18 mm



# Predilatation

Apex 2.5-12 mm  
pre-treatment

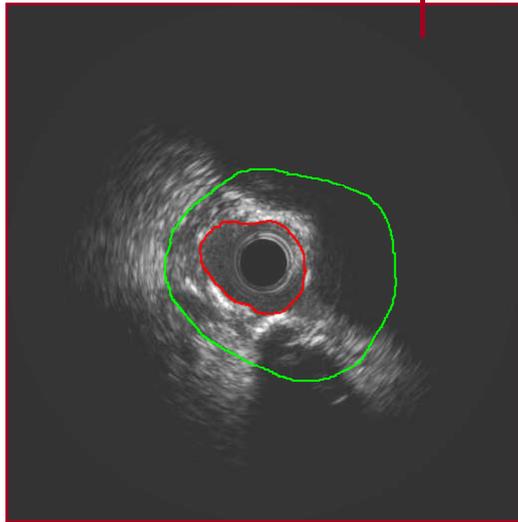
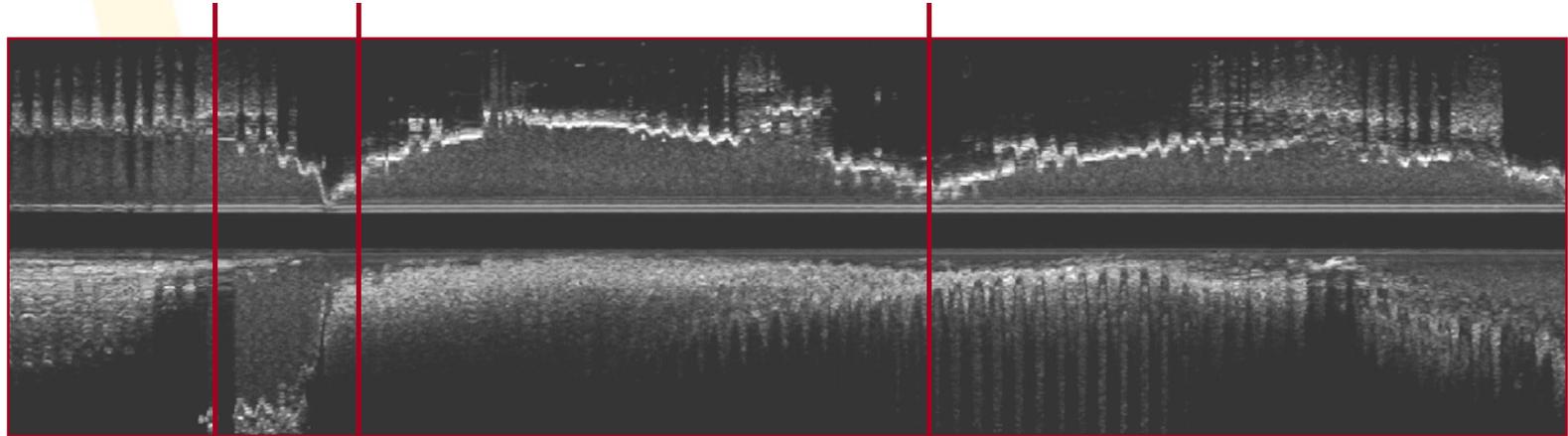


Only after  
predilatation it was  
possible to perform  
IVUS

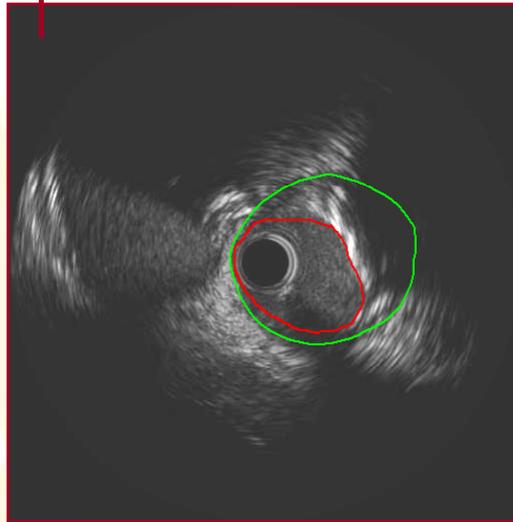




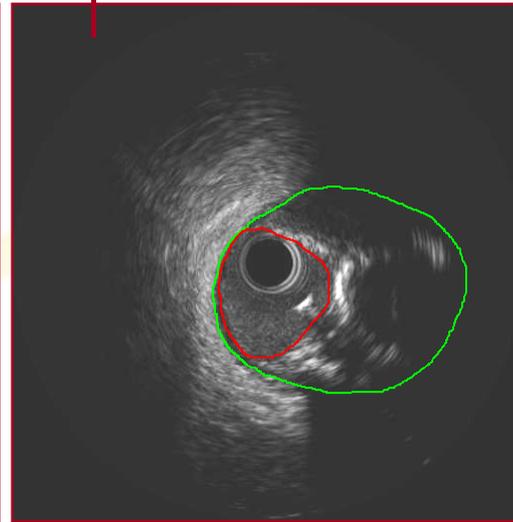
# Baseline IVUS - LAD



MLD 2.22 mm  
MLA 5.03 mm<sup>2</sup>



MLD 1.78 mm  
MLA 3.37 mm<sup>2</sup>

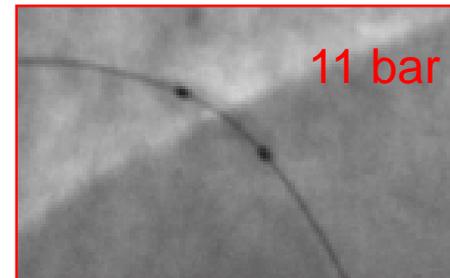
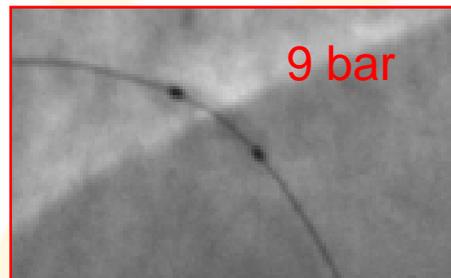
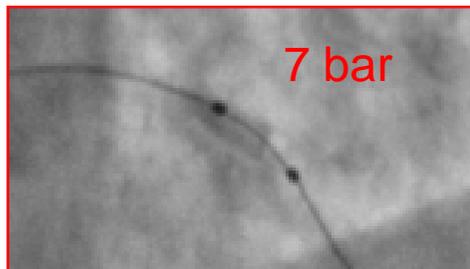


MLD 2.30 mm  
MLA 4.85 mm<sup>2</sup>



# Lesion Preparation with Cutting Balloon

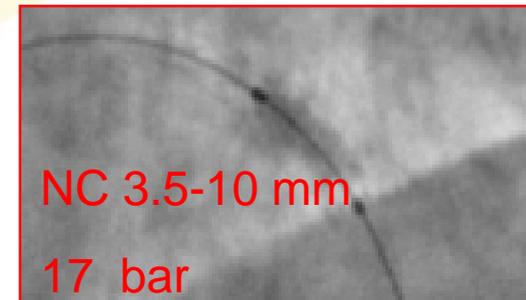
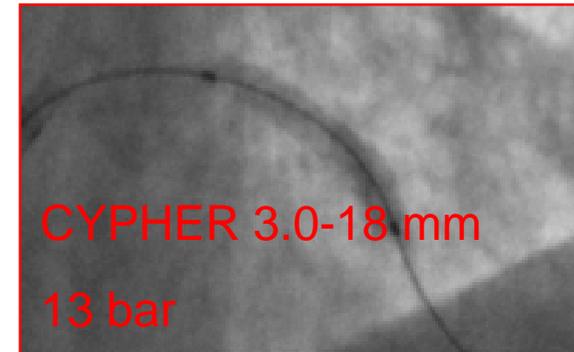
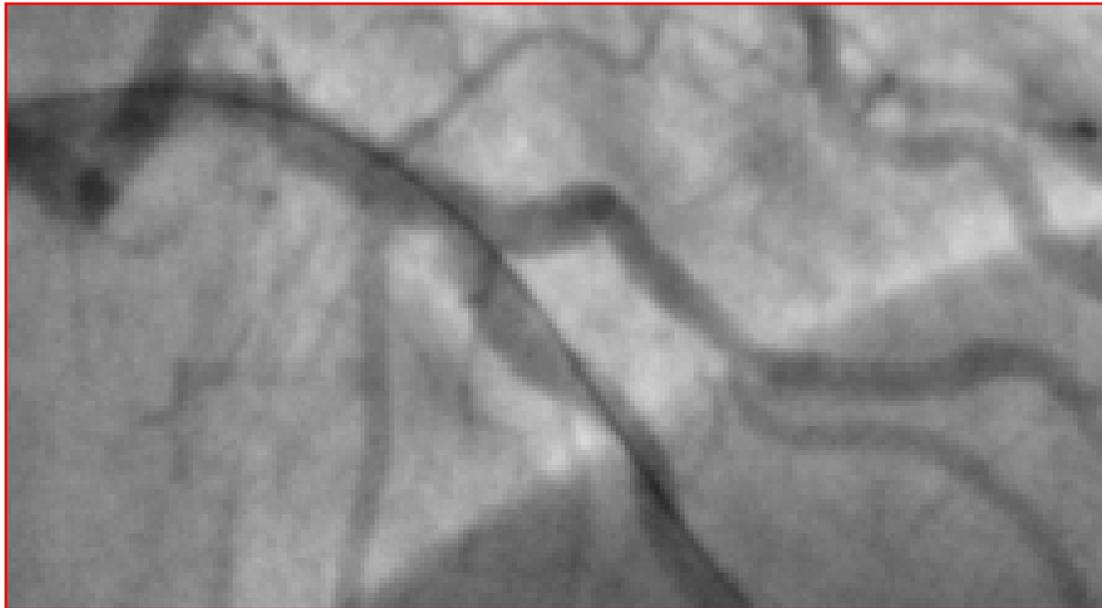
CB 2.75 – 6 mm three incisions performed with 7, 9, 11 bar





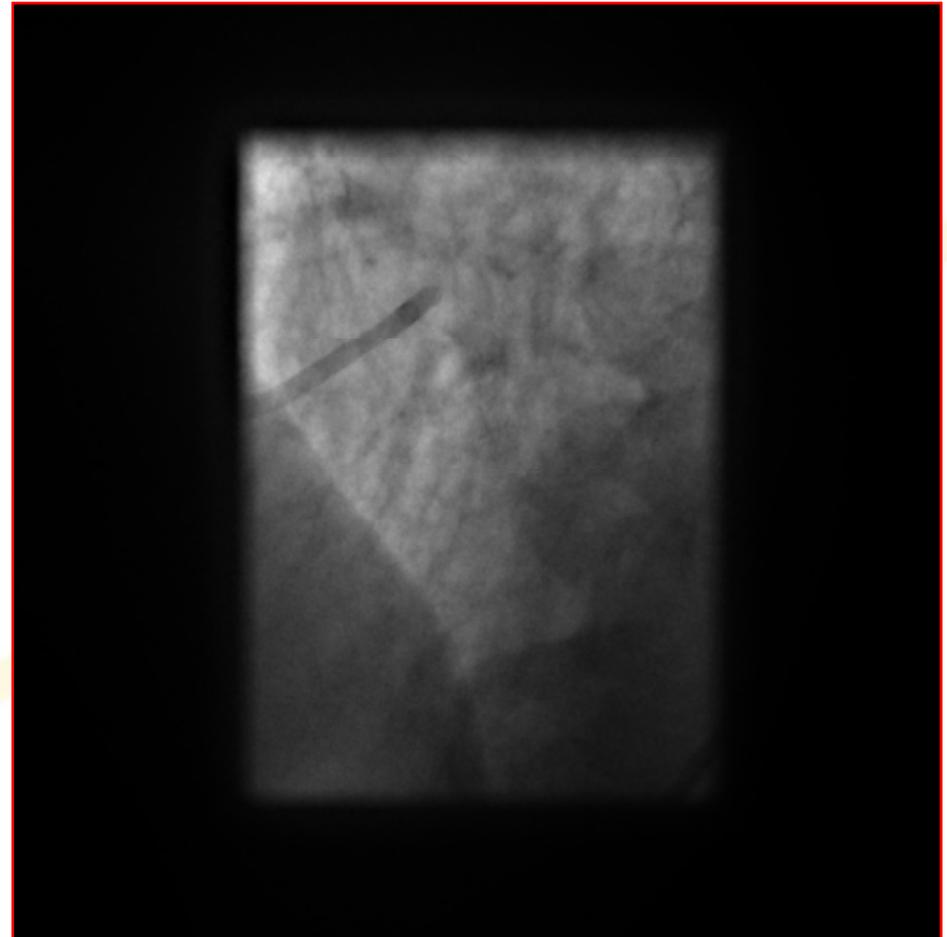
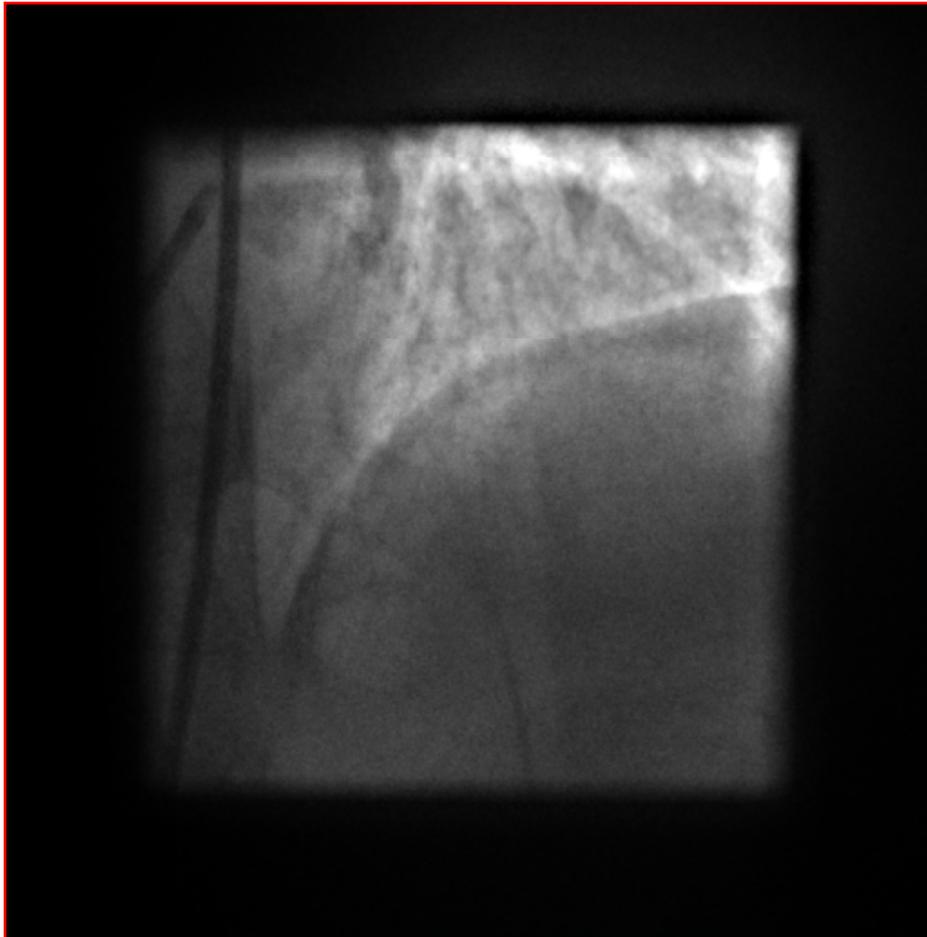
# Stenting and Postdilation

After CB pretreatment  
calcium is broken and  
vessel is ready for stent  
implantation



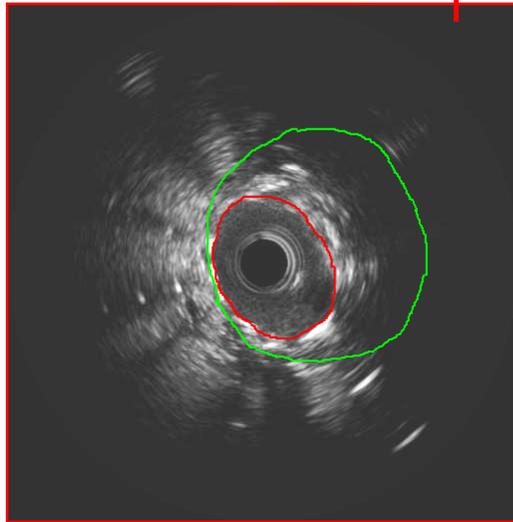
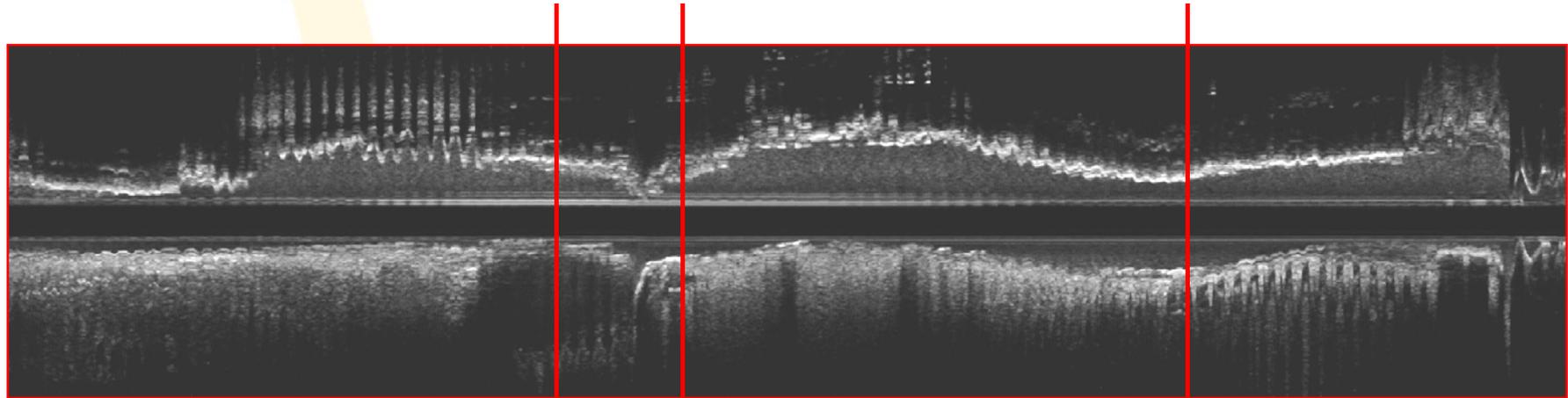


# Final Angio Result

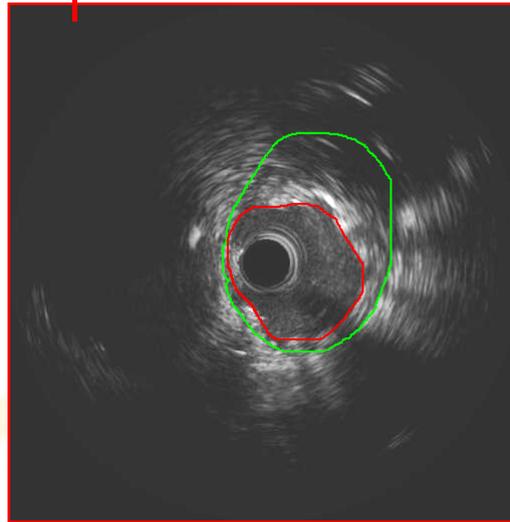




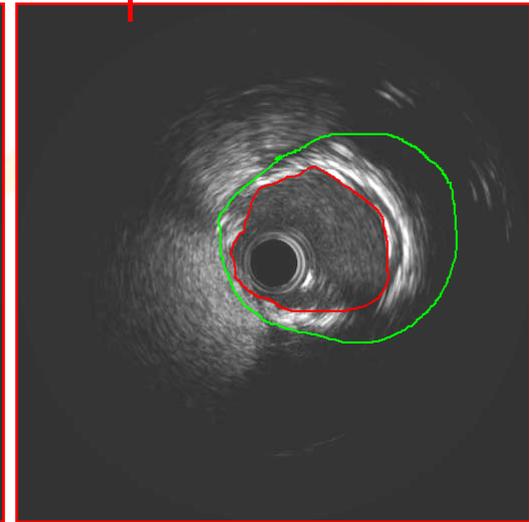
# Postintervention IVUS - LAD



MLD 2.48 mm  
MLA 6.45 mm<sup>2</sup>



MLD 2.34 mm  
MLA 5.85 mm<sup>2</sup>



MLD 2.89 mm  
MLA 7.86 mm<sup>2</sup>



## Conclusions

Good final result, well apposed stent confirmed by IVUS. No side branch flow limitation because of plaque shift which was prevented by lesion pretreatment with CB



