Clinical Experience of 3-Month DAPT in Coroflex ISAR® Stent

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Study Design and Aims

- A comparative Evaluation of Efficacy and Safety in the 3-Months DAPT Group vs. the 6-Months DAPT Group of Patients Treated with the Coroflex ISAR Stent; A Prospective, Multicenter, Randomized, Open-Label Clinical Trial

Study Population

- We will enrolled 906 patients
  - 3-Month DAPT group: 453 patients
  - 6-Month DAPT group: 453 patients
- We assumed about 5% of the patients with early drop out during 1-year clinical follow-up.

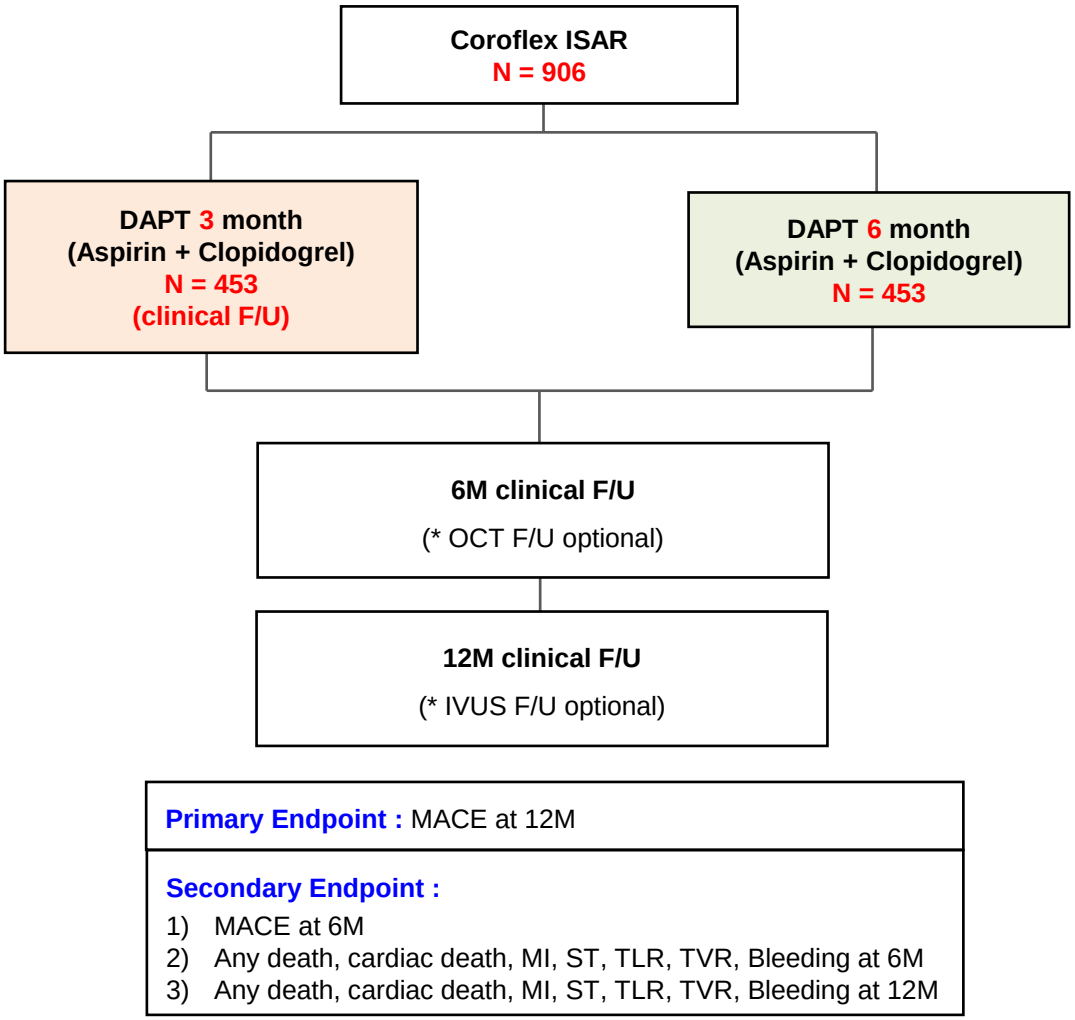
• **Non-inferiority margin (D)**	**Difference of primary outcome, 3%**
• **Type 1 Error**	p = 0.025
• **Randomization**	r = 1:1
• **Power of Test**	f = 80%

Patient Selection

- **Inclusion Criteria**
  - "De novo" lesions in native coronary arteries
  - Written informed consent

- **Exclusion Criteria**
  - Acute myocardial infarction (STEMI or NSTEMI)
  - Cardiogenic shock
  - Contraindication, intolerance, or hypersensitivity to aspirin, clopidogrel
  - CTO or ISR lesion
  - Hemorrhagic problem
  - PCI with BMS or DES in non-target lesions less than 6 months prior to the index procedure
  - Scheduled elective surgery within 12 months after the index procedure requiring to stop antiplatelet medication more than 2 weeks
  - Comorbidities with a life expectancy < 12 months

Study Flow



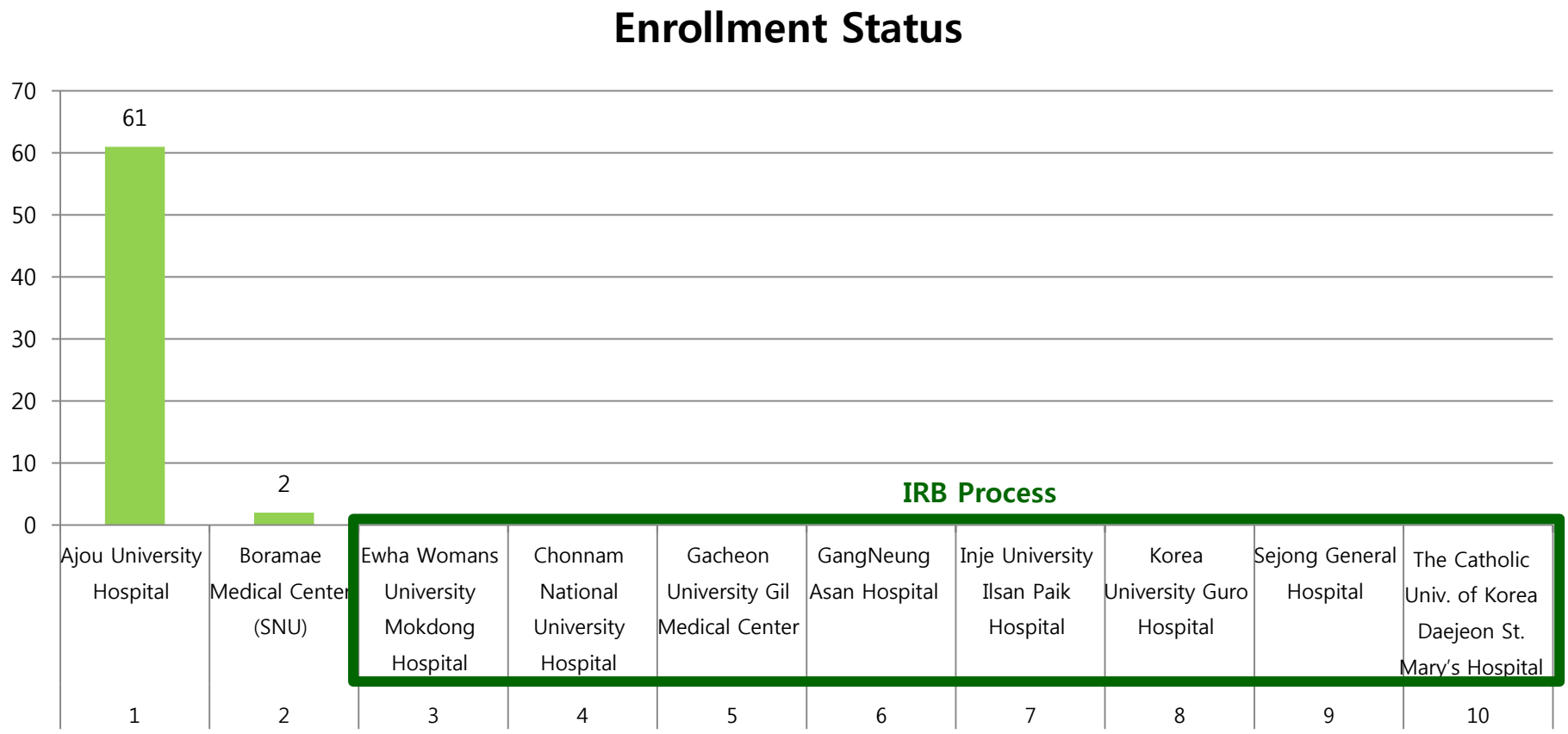
- MACE: cardiac death, myocardial infarction, stent thrombosis, TLR

DAPT

- **Aspirin**
  - Aspirin (100 mg daily) will be recommended for patients with chronic (>7 days) aspirin use prior to PCI.
  - Otherwise, a loading dose of 300mg will be given prior to the procedure.
  - Postprocedure use of aspirin (100 mg daily) should be prescribed indefinitely.
- **Clopidogrel**
  - A loading dose of clopidogrel (600mg) was given at least 2 hours prior to the procedure, if not already taken (75 mg daily, >7 days).
  - Postprocedural clopidogrel use (75mg daily) should be maintained according to the randomization scheme (3 vs. 6 months).

ISAR-DAPT Study Status

- Enrollment Status : 63 subjects
- Participate Centers : 10 centers



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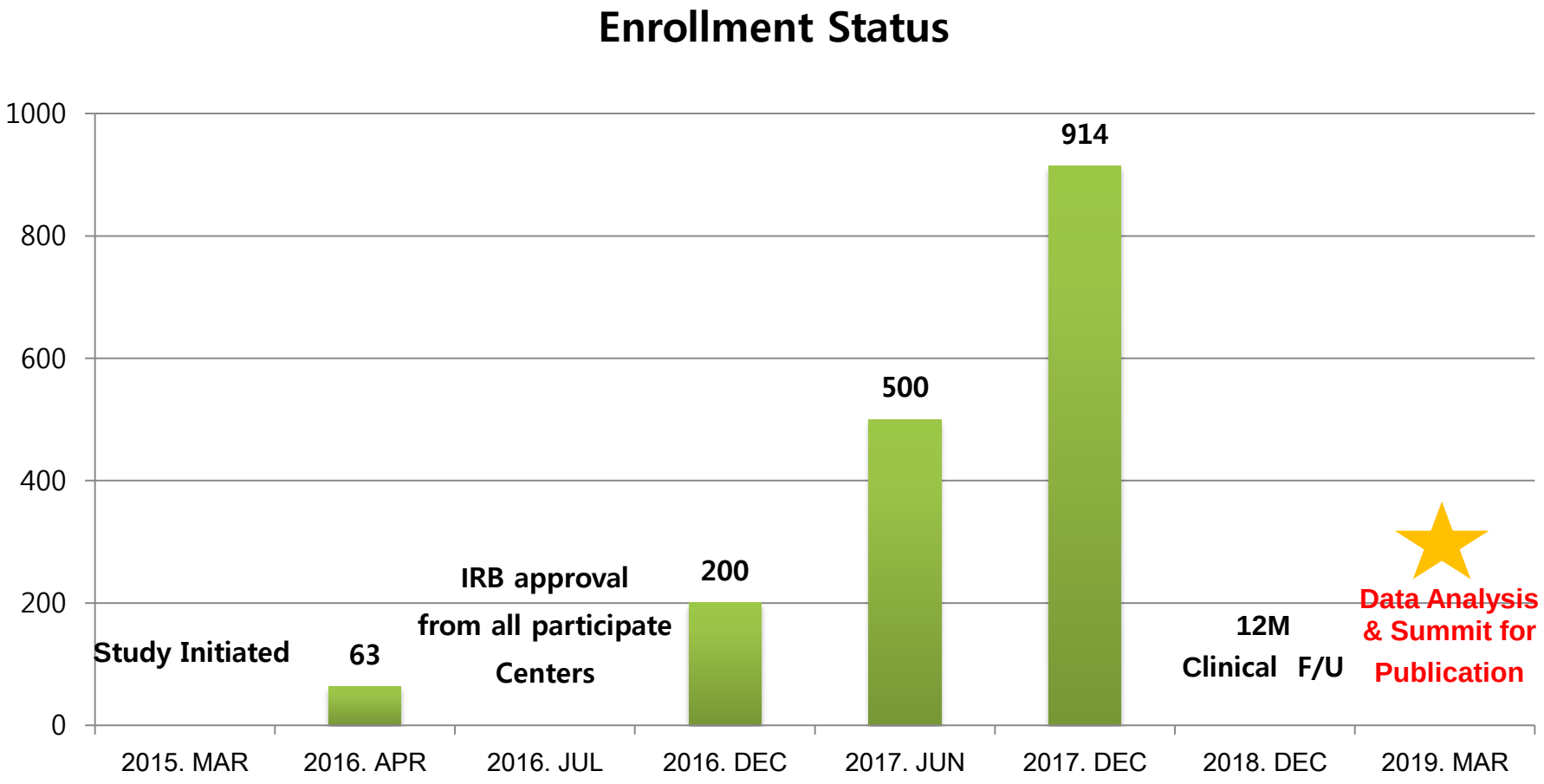


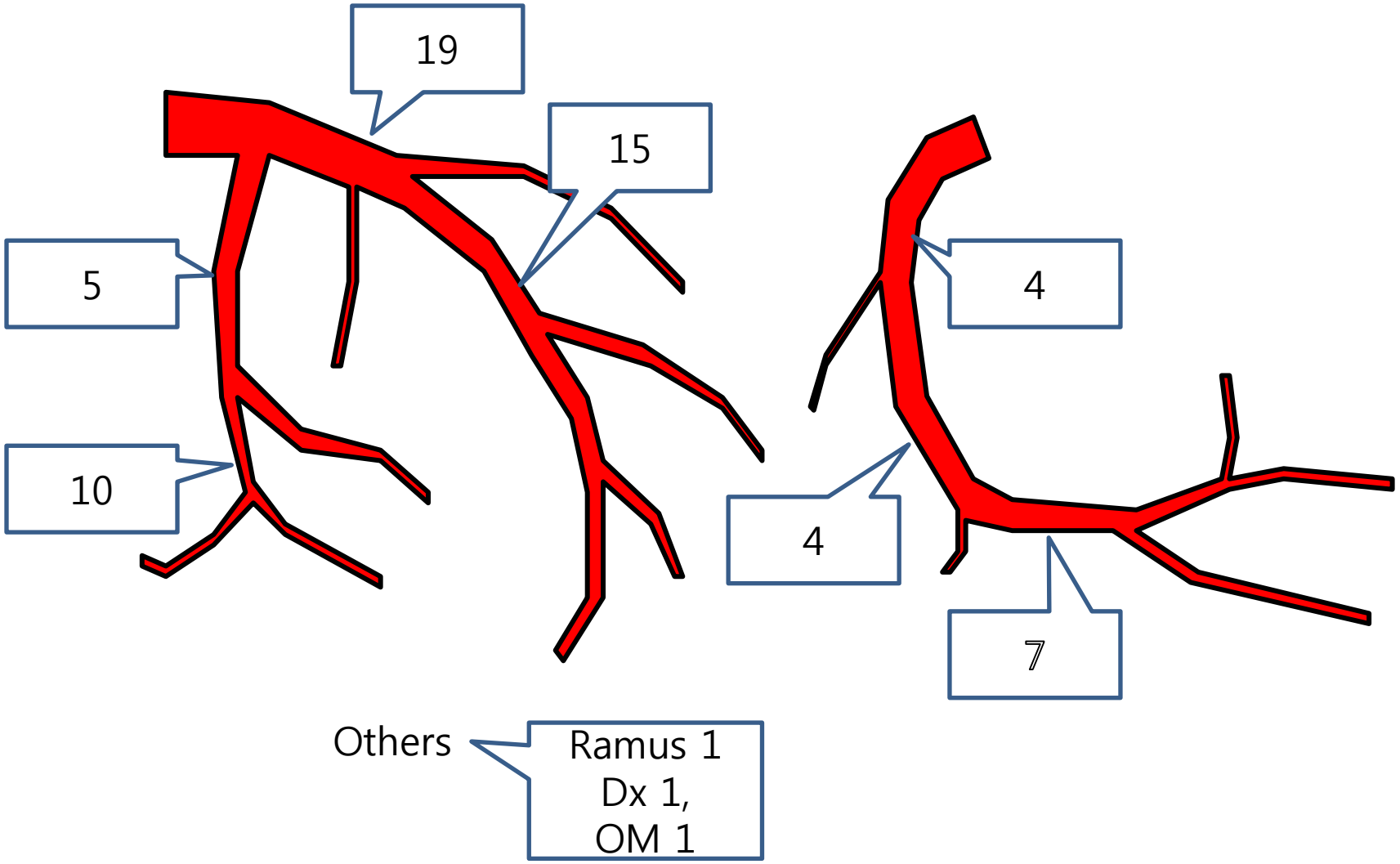
Patients Characteristics

		3 Month N=31	6 Month N=30	p Value
Age, years	63 ± 10	63 ±12	63 ±9	**0.910**
Gender, male	44 (72.1%)	22 (71.0%)	22 (73.3%)	**0.532**
Diagnosis				**0.544**
SA	26 (42.6%)	12 (38.7%)	14 (46.7%)	
UA	31 (50.8%)	16 (51.6%)	15 (50%)	
Others	4 (6.6%)	3 (9.7%)	1 (3.3%)	
Hypertension	24 (39.3%)	13 (41.9%)	11 (36.7%)	**0.795**
Dyslipidemia	25 (41.0%)	15 (48.4%)	10 (33.3%)	**0.300**
Diabetes Mellitus	15 (24.6%)	6 (19.4%)	9 (30%)	**0.384**
Current Smoker	18 (29.5%)	8 (25.8%)	10 (33.3%)	**0.582**
Pre-PCI Hx	7 (11.5%)	2 (6.5%)	5 (16.7%)	**0.255**
Cholesterol (mg/dl)	184 ± 43	191 ± 44	178 ± 12	**0.241**
Cr (mg/dl)	0.91 ± 0.23	0.85 ± 0.17	0.97 ± 0.26	**0.038**
EF (%)	64.4 ± 8.6	65.4 ± 8.4	63.4 ± 8.8	**0.387**

Angiographic Findings

		3 Month N=31	6 Month N=30	p Value
Vessel Severity				**0.557**
1 VD	34 (50.7%)	19 (55.9%)	15 (50.0%)	
2 VD	21 (34.4%)	10 (32.3%)	11 (36.7%)	
3 VD	6 (9.0%)	2 (6.5%)	4 (13.3%)	
Target Vessel				**0.100**
LAD	34 (55.7%)	15 (44.1%)	19 (57.6%)	
LCx	18 (26.9%)	13 (38.2%)	5 (15.2%)	
RCA	15 (22.4%)	6 (17.6%)	9 (27.3%)	

Angiographic Findings

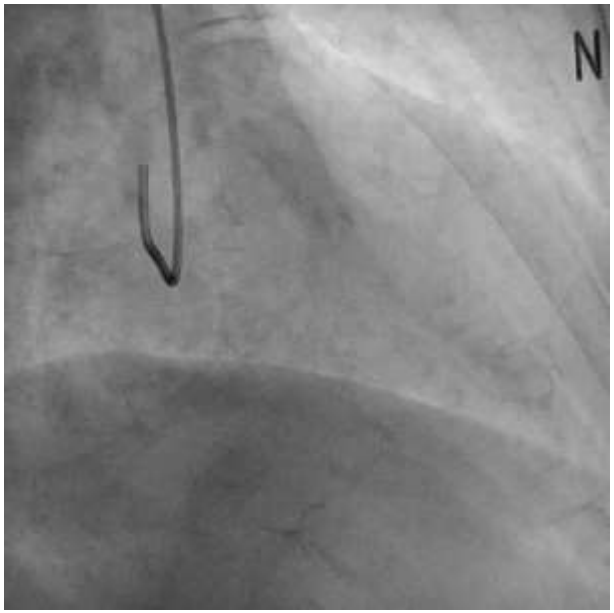


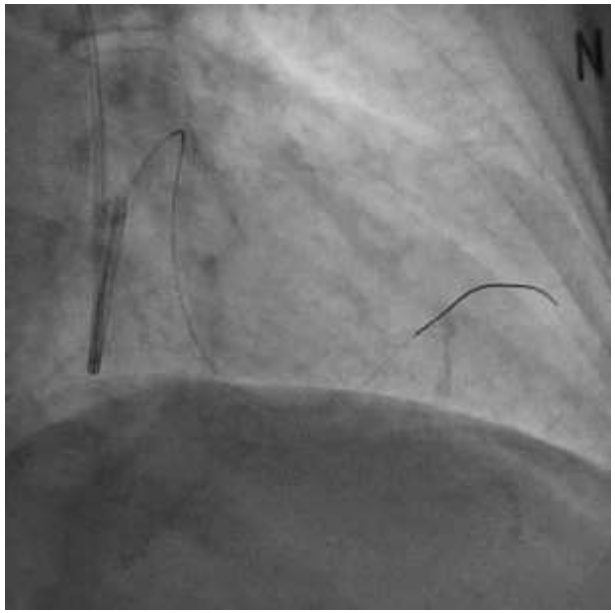
Angiographic Results

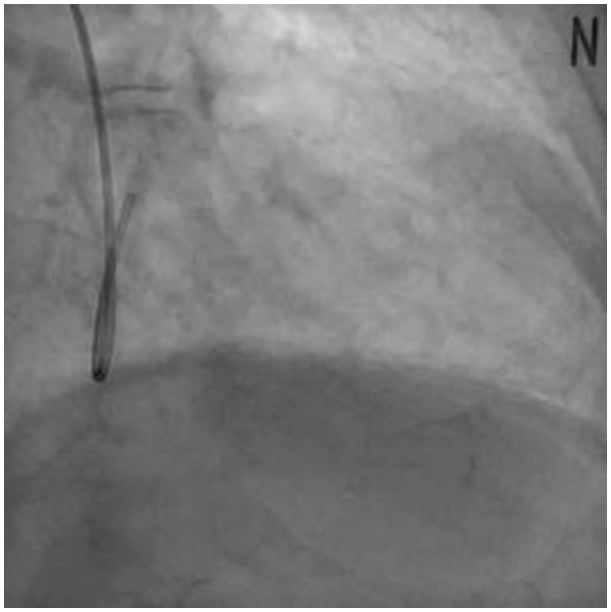
		3 Month N=31	6 Month N=30	p Value
Pre-PCI				
Ref. vessel size (mm)	3.13 ± 0.38	3.12 ± 0.36	3.14 ± 0.41	**0.769**
Lesion length (mm)	20.3 ± 6.9	19.3 ± 5.2	21.3 ± 8.3	**0.246**
MLD (mm)	0.6 ± 0.41	0.59 ± 0.49	0.60 ± 0.30	**0.919**
DS (%)	81.1 ± 9.5	82.4 ± 9.4	79.7 ± 9.6	**0.240**
Post-stent				
MLD (mm)	2.89 ± 0.36	2.87 ± 0.35	2.92 ± 0.38	**0.568**
DS (%)	8.14 ± 2.51	8.5 ± 2.5	7.8 ± 2.5	**0.222**
Stent Number per person	1.21 ± 0.45	1.19 ± 0.40	1.23 ± 0.50	**0.734**
Stent length per person (mm)	25.2 ± 11.2	25.4 ± 10.4	25.0 ± 12.1	**0.885**

3-Month F/U

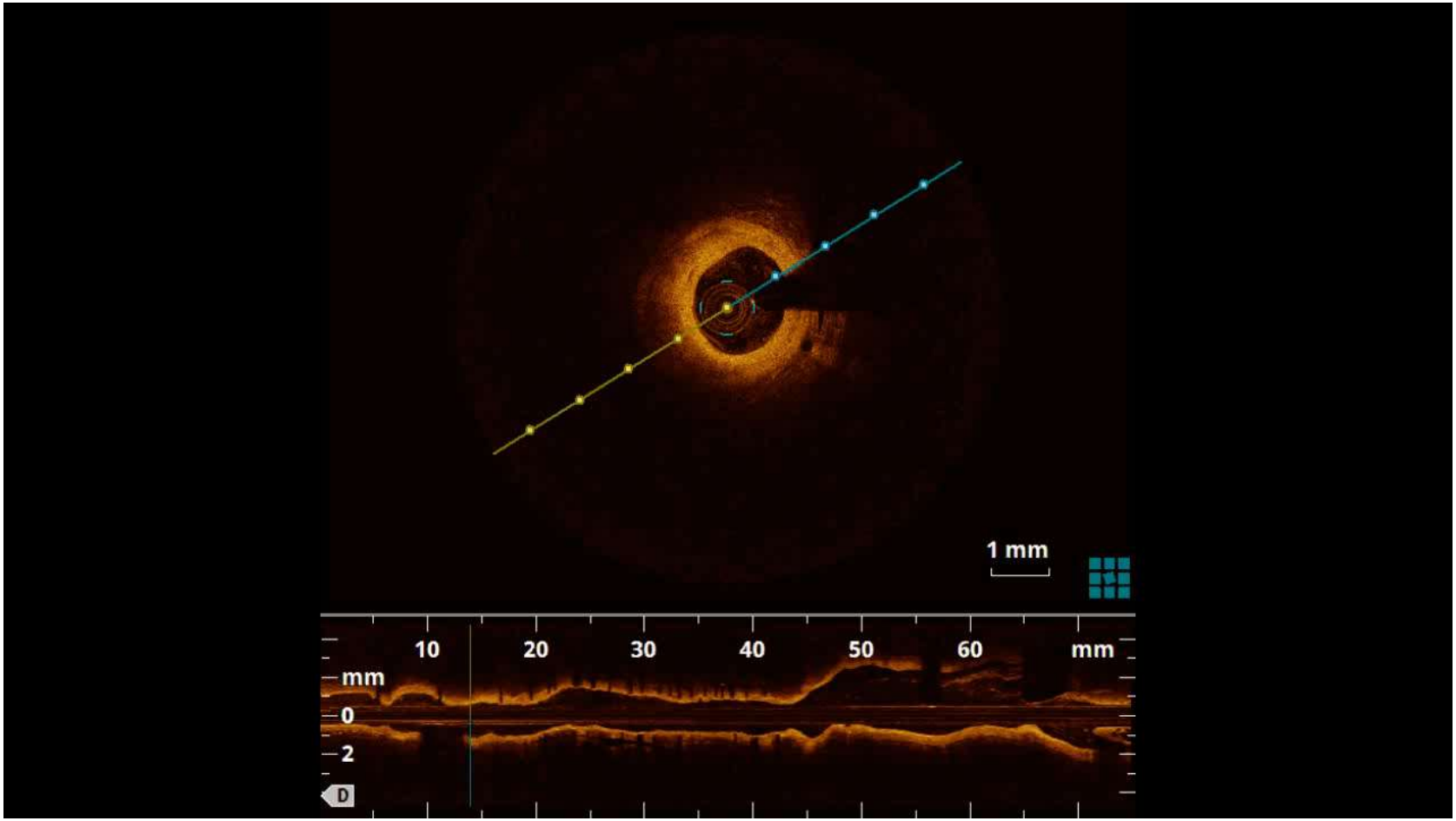
- **77/F, UA, HTN,**
- **2VD, dLCx to OM, stent: 2.5/27 mm**





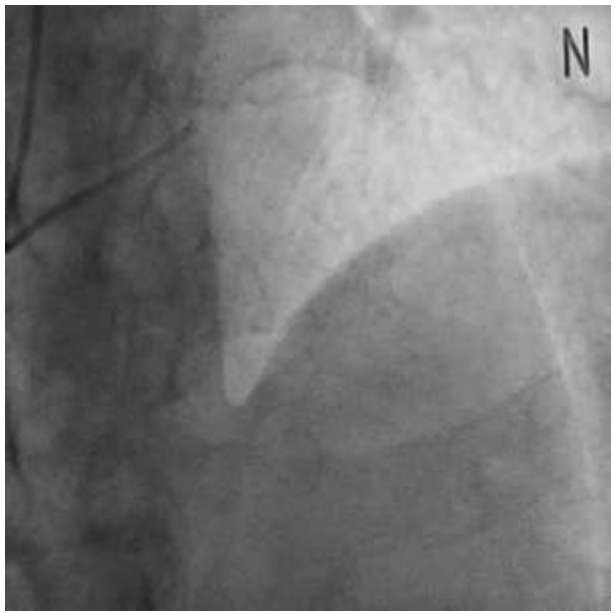


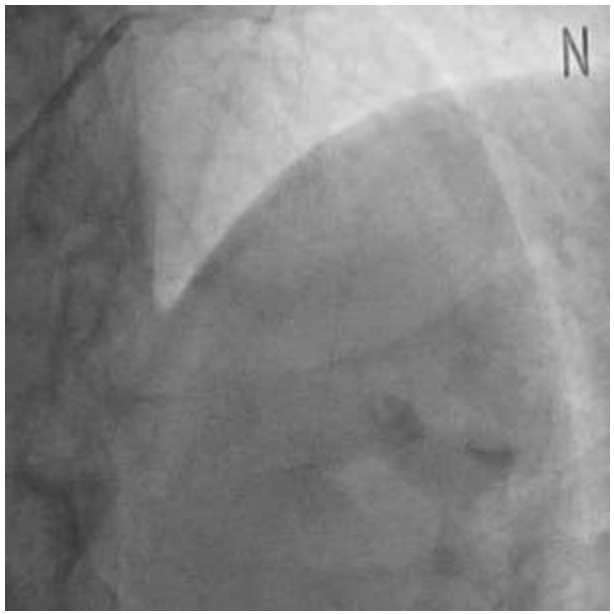
3-Month F/U OCT

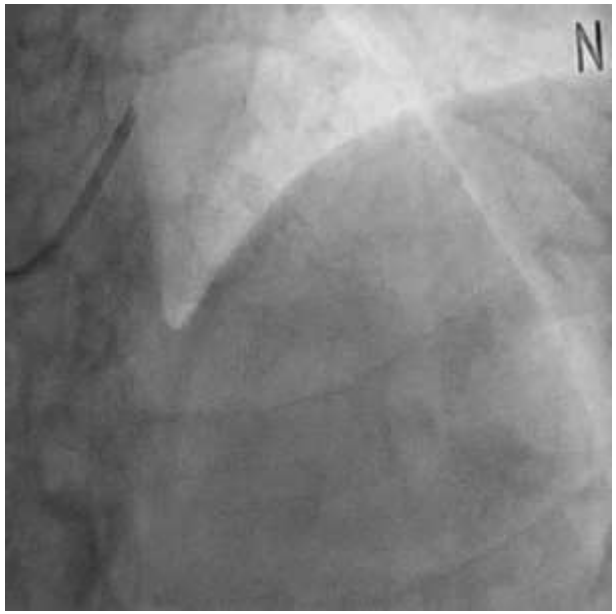


4.5-Month F/U

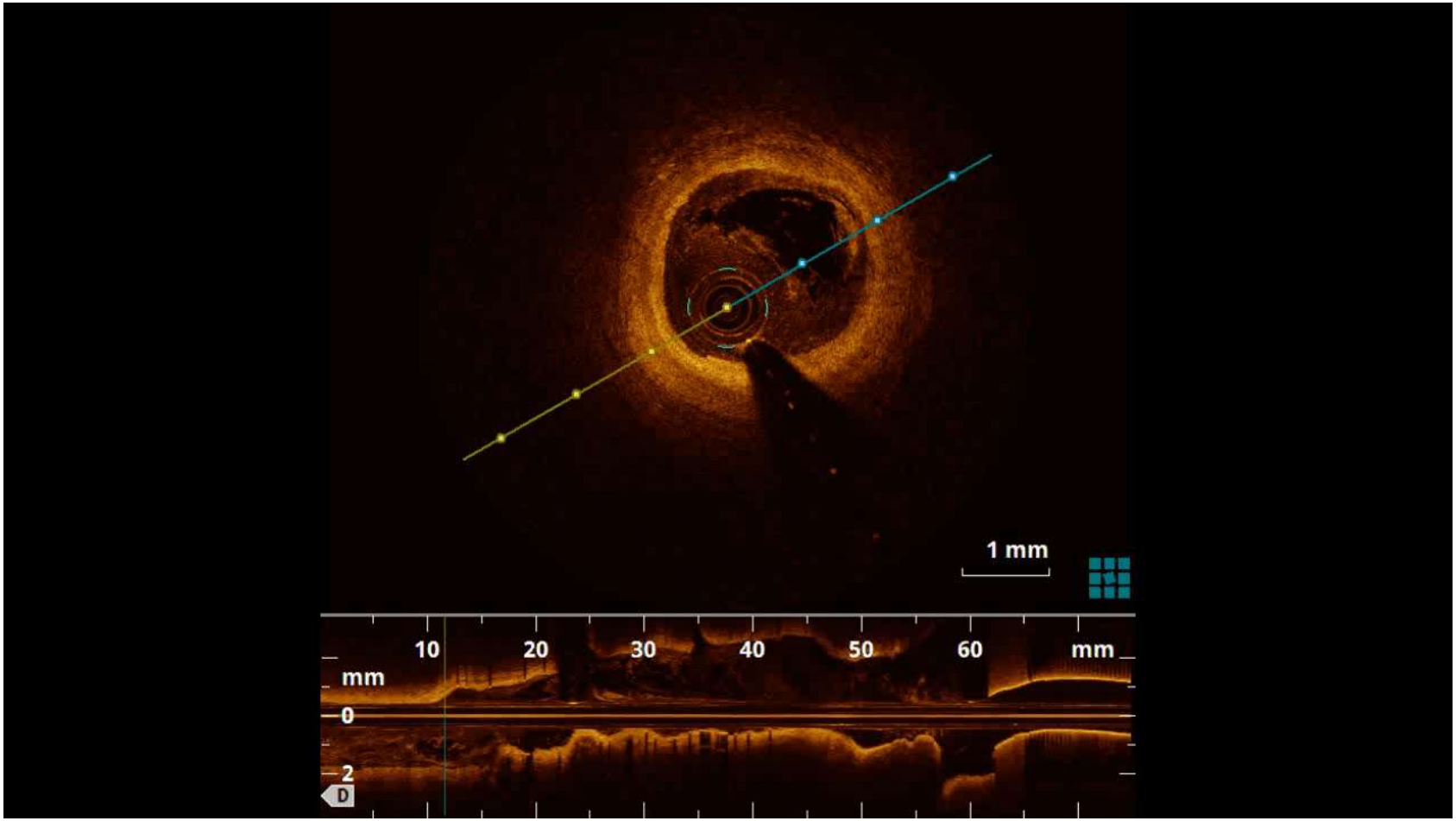
- **76/M, UA,**
- **1VD, mLAD, stent: 3.5/27 mm**





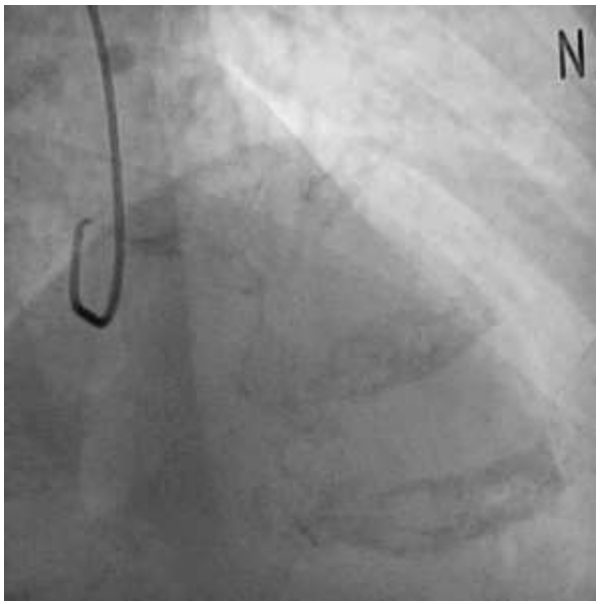


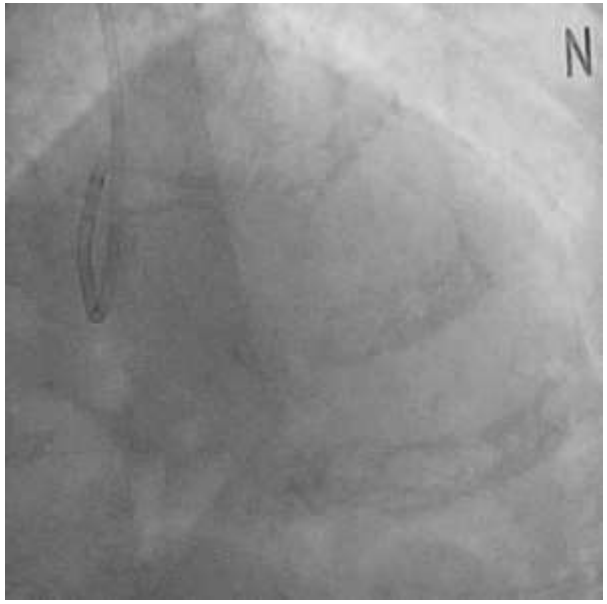
4.5-Month F/U OCT

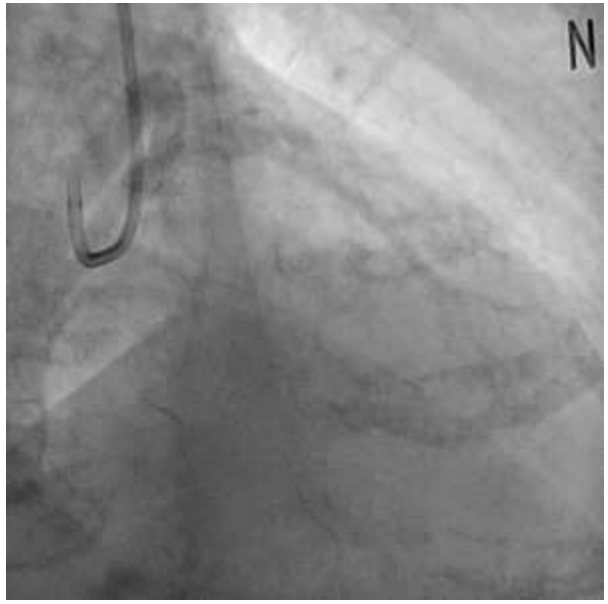


6-Month F/U

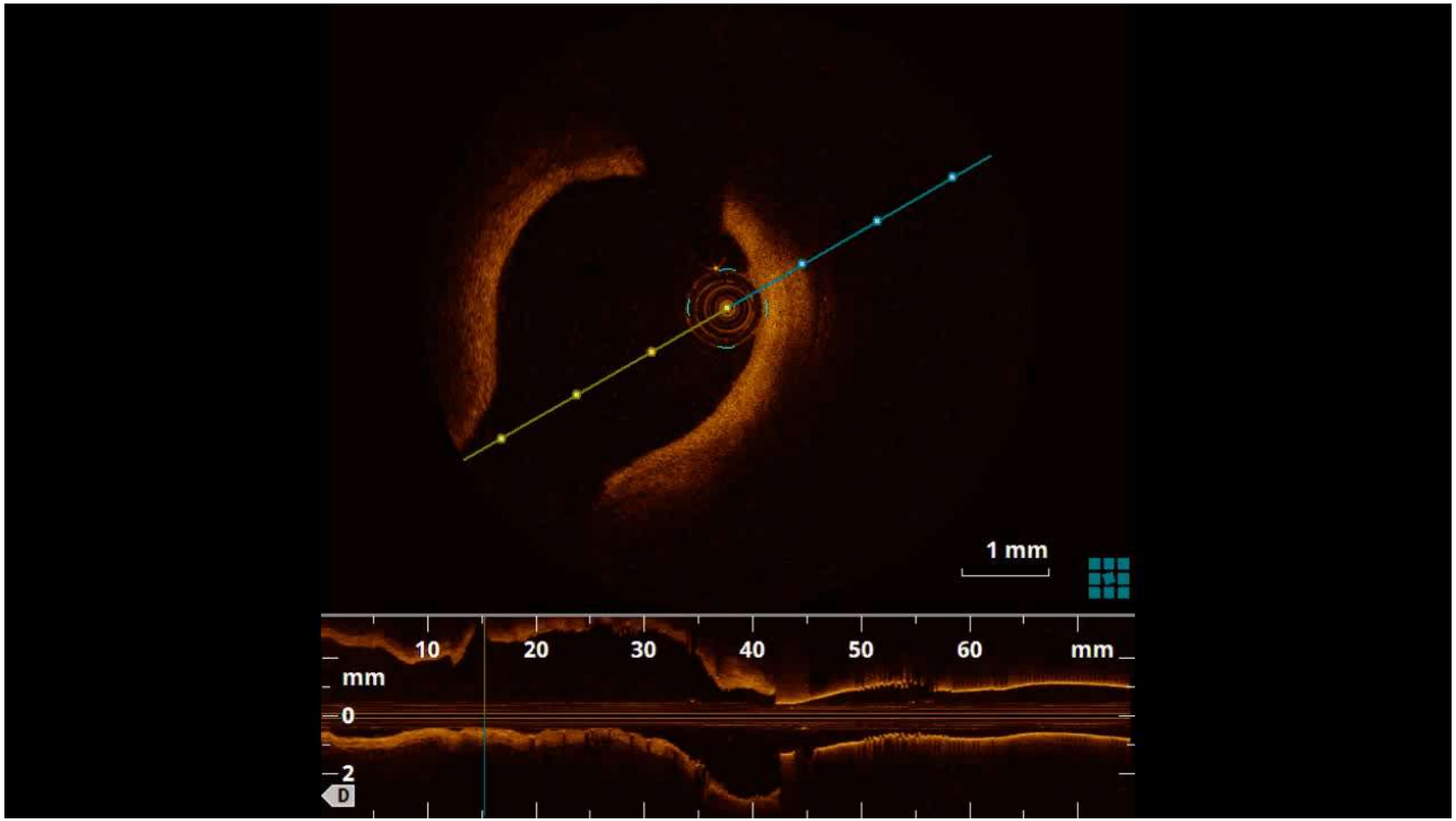
- **KKB, 75/F, SA,**
- **1VD, pLAD, stent: 3.5/16 mm**







6-Month F/U OCT



Clinical Outcomes

- Mean Follow-up duration: 4.3±3.0 M

- In Hospital Event
  - 61 patients
  - No MACE or bleeding
- 3-Month Follow-up
  - 44 patients
  - No MACE or Bleeding

Clinical Outcomes

- 6-Month Follow-up
  - 21 patients
  - MACE: 1 patient, ISR and TLR (3 month group)
  - No other events
- 1-Year Follow-up
  - No MACE or Bleeding during 7-12 months

Thank you for your attention