Contemporary Technique of PCI with BRS deployment

Chiung-Jen Wu M.D.
Chang-Gung M. Hosp.
Kaohsiung, Taiwan
Apr. 25, 2017 in TCT-AP BVS session, Seoul, S. Korea

Durable versus absorbable polymer and absorbable scaffold Stent Platform
Strut and Coating Thickness Varied

	Durable Polymer		Bioabsorbable Polymer		Bioabsorbable Stent
	Xience V™ PROMUS Element™	Resolute Integrity™	BioMatrix Flex™	SYNERGY™	BVS
Strut	81 µm (0.0032")	91 µme (0.0036")	112 µm (0.0044")	74 µm (0.0029")	150 µm (0.0059")
Coating	Conformable 8µm / side	Conformable 6µm / side	Abluminal 10µm	Abluminal 4µm	Conformable 3µm / side

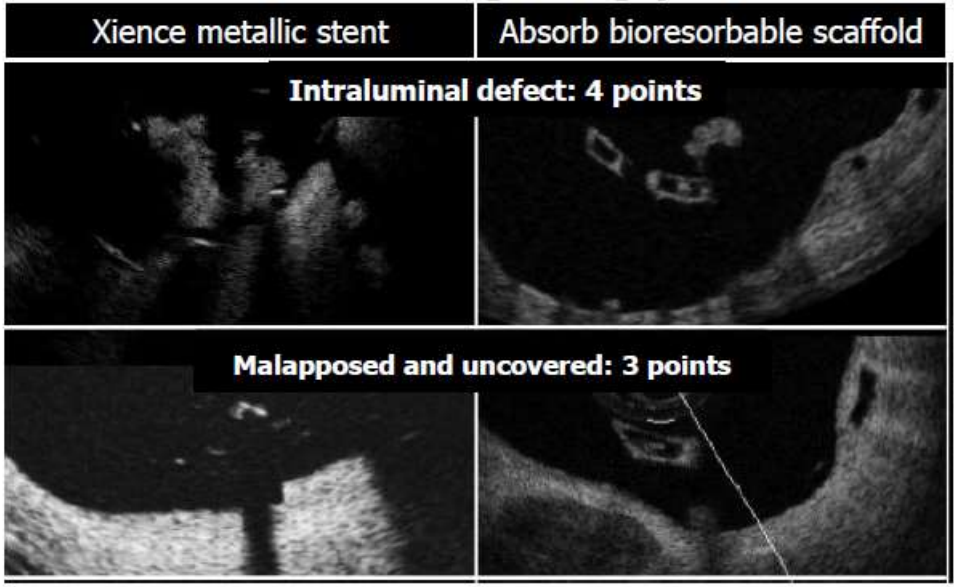
TROFI II
RANDOMIZED CLINICAL TRIAL IN STEMI

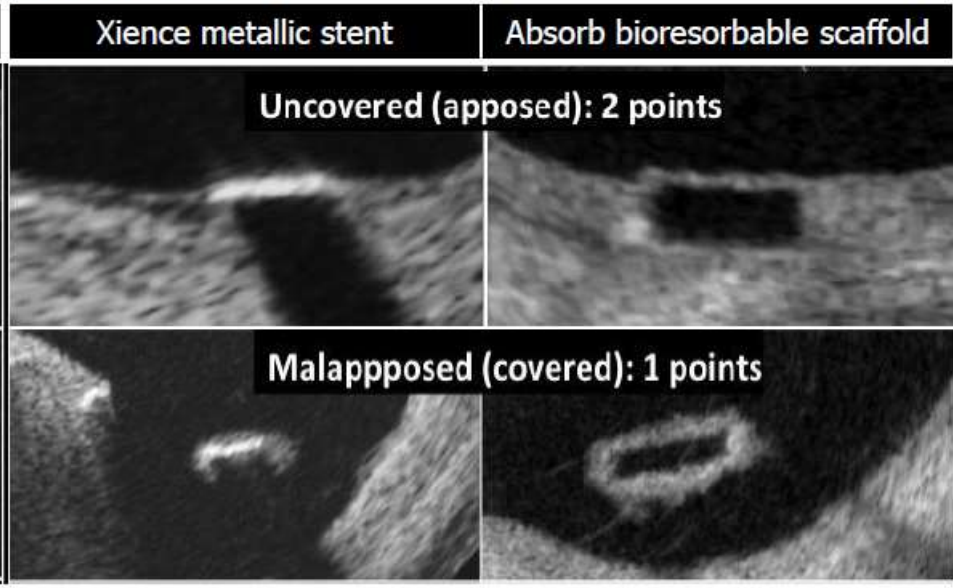
How to evaluate vessel healing after device implantation?

Healing score = [% ILDx4] + [% MUx3]+ [% Ux2]+ [% M]

ILD: intraluminal defect
MU: malapposed and uncovered
and their weighting points in the formula

U: uncovered
M: malapposed

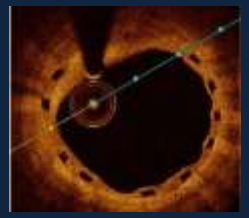




Reference: TROFI trial *Eur Heart J.*2013;34:1050-1060; *Eur Heart J Cardiovasc Imaging..* 2014;15:987-995
Leaders trial *Eur Heart J.* 2010;31:165-176; **Resolute all comers trial** *Eur Heart J.* 2011;32:2454-63
Absorb cohort B EuroIntervention 2015;10:1299-306; **NANO Plus** *AsiaIntervention* 2015; 1:57-70.

ABSORB Demonstrated Comparable Safety and Healing to XIENCE In STEMI Patients In TROFI II

6 month Results



Healing score at 6 months. Weighted index combining presence of:

1. % Intraluminal defect (presence of intraluminal mass) – assigned weight of "4"
2. % malapposed and uncovered struts - assigned a weight of "3"
3. % Uncovered struts (apposed) - assigned weight of "2"
4. % Malapposition struts (covered) - assigned weight of "1"

6 month OCT Analysis	Absorb N=95	XIENCE N=98	P-value
Healing Score	**1.74**	**2.80**	**<0.001[2] 0.053[3]**
% Uncovered & malapposed strut	0.0	0.1	0.036
% Covered & malapposed struts	0.6	1.5	0.011
Mean Neointimal area, mm^2	1.52	1.35	0.018
Mean neointimal strut thickness of strut coverage, µm	110	90	<0.001

6 month QCA	Absorb (N=85)	XIENCE (N=89)	P-value
In device RVD	2.76	2.79	0.68
In device MLD	2.26	2.38	0.07
In device %DS	18.3	14.5	0.02
In device LL	0.20	0.08	0.01
In segment LL	0.16	0.06	0.049

6-Month Clinical Results:

- Clinical Events: 1.1% Absorb vs. 0% for XIENCE
- There was one subacute definite ST leading to MI and clinically-driven TLR in the Absorb group

Absorb showed comparable safety and good endothelial coverage compared to best in class XIENCE

Absorb Clinical Update
ABSORB Cohort B – Imaging at 5 Years

De Bruyne, B. TCT 2014

Cohort B OCT images - courtesy of RJ van Geuns, Erasmus Medical Center, Netherlands

Scaffold or stent thrombosis

2 : 1 randomization

	Absorb 335 patients	Xience 166 patients	p value
Definite	**2·5% (8)**	**0·0% (0)**	**0·06**
Acute (0–1 day)	**0·3% (1)**	**0·0% (0)**	**1·0**
Sub-acute (2–30 days)	**0·3% (1)**	**0·0% (0)**	**1·0**
Late (31–365 days)	**0·0% (0)**	**0·0% (0)**	**1·0**
Very late (>365 days)	**1·8% (6)**	**0·0% (0)**	**0·19**
Definite or probable	**2·8% (9/320)**	**0·0% (0/159)**	**0·03**
Acute (0–1 day)	0·3% (1)	0·0% (0)	1·0
Sub-acute (2–30 days)	0·3% (1)	0·0% (0)	1·0
Late (31–365 days)	**0·3% (1)**	**0·0% (0)**	**1·0**
Very late (>365 days)	1·8% (6)	0·0% (0)	0·19

Secondary angiographic endpoints

	Absorb 298 lesions		Xience 151 lesions	p value
In-scaffold/stent assessment				
Minimum lumen diameter				
Pre-procedure diameter (mm)	1·06	=	1·06	0·81
Acute gain (mm)	1·16	<	1·45	<0·0001
Post-procedure diameter (mm)	2·22	<	2·50	<0·0001
Late loss (mm)	0·37	>	0·25	0·0003
Follow-up diameter (mm)	1·86	<	2·25	<0·0001
Net gain (mm)	0·80	<	1·20	<0·0001
Percent Diameter stenosis				
Pre-procedure (%)	59%	=	59%	0·83
Post-procedure (%)	15·6%	>	10·1%	<0·0001
Follow-up (%)	25·8%	>	15·7%	<0·0001
In-device binary restenosis (%)	7·0%	>	0·7%	0·003
In-segment binary restenosis (%)	8·4%	>	3·3%	0·042

PSP OBJECTIVES

P PREPARE THE LESION

OBJECTIVE
- Prepare lesion to receive scaffold
- Facilitate delivery
- Enable full expansion of pre-dilatation balloon to facilitate full scaffold expansion

S SIZE APPROPRIATELY

OBJECTIVE
- Accurately size the vessel
- Select appropriate scaffold for "best fit"

P POST-DILATE

OBJECTIVE
- Achieve **<10% final residual stenosis**
- Ensure full strut apposition

PRESCRIBE DAPT

Consider current ACC/AHA and ESC DAPT guidelines: Aspirin (*minimum 81 mg PO QD*), Clopidogrel (*minimum 300 mg load at procedure and 75 mg PO QD*)
As with any DES procedure, patients should be selected who will be able to comply with DAPT for the duration prescribed by their physician; the Absorb GT1 Instructions For Use (IFU) recommends a minimum of 6 months DAPT

Wright, RS, et al., Circulation. 2011; 123: 2022-2060. / Wijns, W, et al., European Heart Journal. 2010; 31: 2501-2555. / Levine, GN, et al., Circulation. 2011; 124: 2574-2651. / Steg, PG, et al., European Heart Journal. 2012; 33: 2569-2619. / O'Gara, PT, et al., Circulation. 2012; 127: e368-e425.

LEARNING CURVE

A BVS-SPECIFIC IMPLANTATION STRATEGY CAN IMPROVE OUTCOMES

P PREPARE THE LESION **S** SIZE APPROPRIATELY **P** POST-DILATE

2011 2012 2013 2014 2015 2016

4 Cities
International Registry
N~1,300

Enrollment & Follow-Up 1 Y

P Nitrates

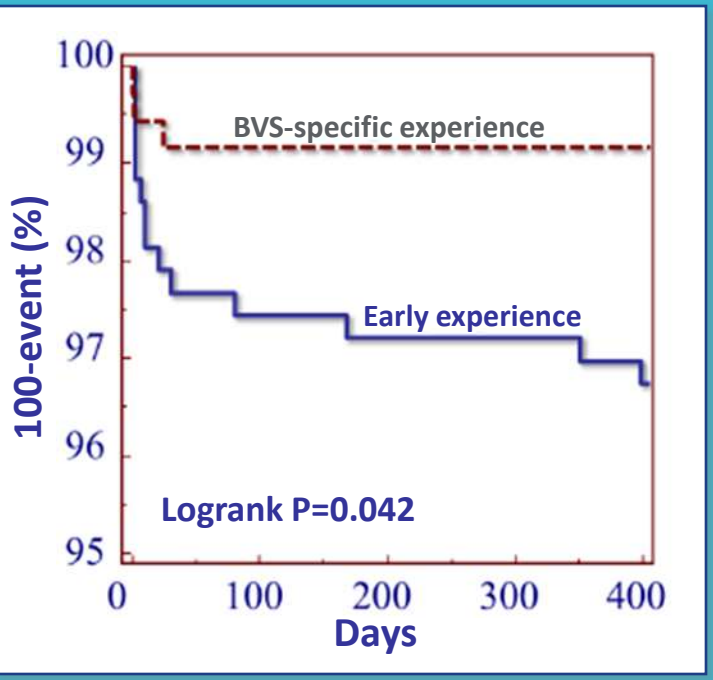
P Pre-dilate
Sizing with balloon (1:1:1)
2 angiographic planes

S Low threshold for
Intravascular imaging

Implant Following IFU

P NC post-dilatation (+0.5mm)

Do not accept:
MLD <2,5/2.9mm
MLA <4.9/6.6mm^2



One-year clinical outcomes: Taiwan Multi-center registry study of BVS pts

Table 5

One-year clinical outcomes of study patients and lesions

	Patients (N=945) Lesions (N=1342)
One-year clinical outcomes	
Target vessel revascularization (T	22 (2.32)
Target lesion failure (TLF) (%)	16 (1.19)
Myocardial infarction (%)	4 (0.42)
Definite or possible scaffold thro	2 (0.22)
Cardiovascular mortality (%)	3 (0.32)
All-cause mortality (%)	3 (0.32)

ABSORB III

Ghost EU

7.8%

4.4% at 6 mo

1.5%

2.0%

Millan

7.9%

1.2%

*Target lesion failure (TLF) was defined as cardiac death, target vessel myocardial infarction or ischemic-driven target lesion revascularization

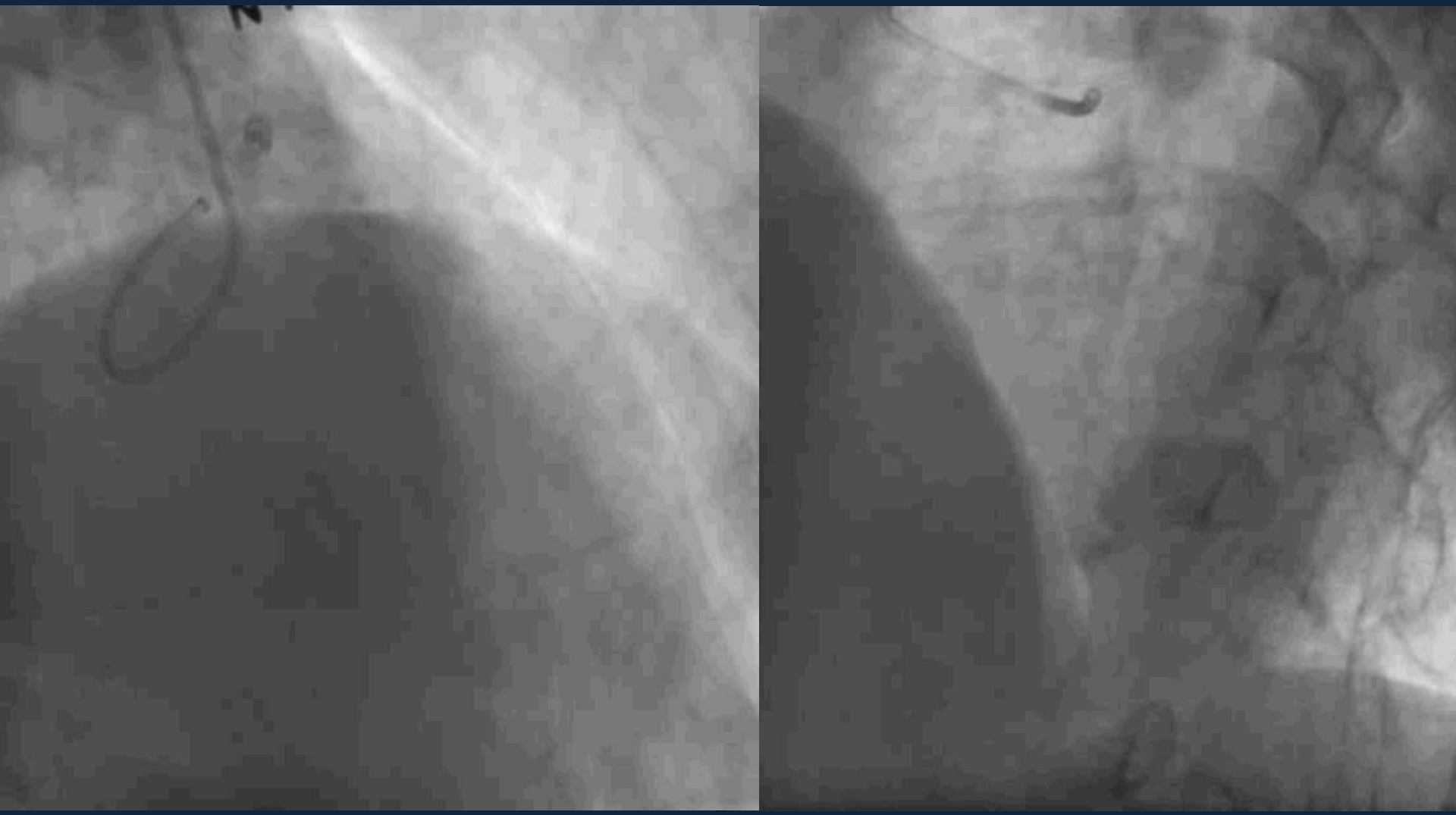
BVS deployment in LAD overlapping according to the study protocol & 19-mo angiographic and OCT f/u

(Case No. 1)

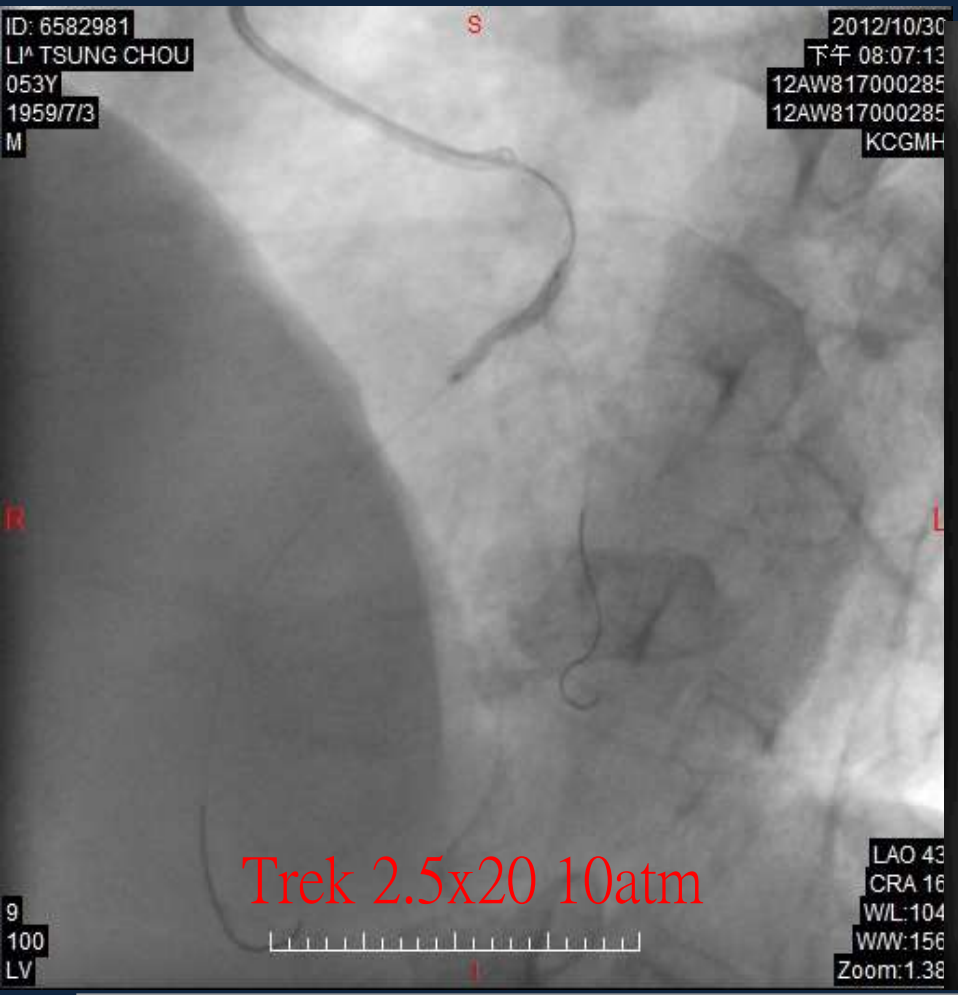
Case history

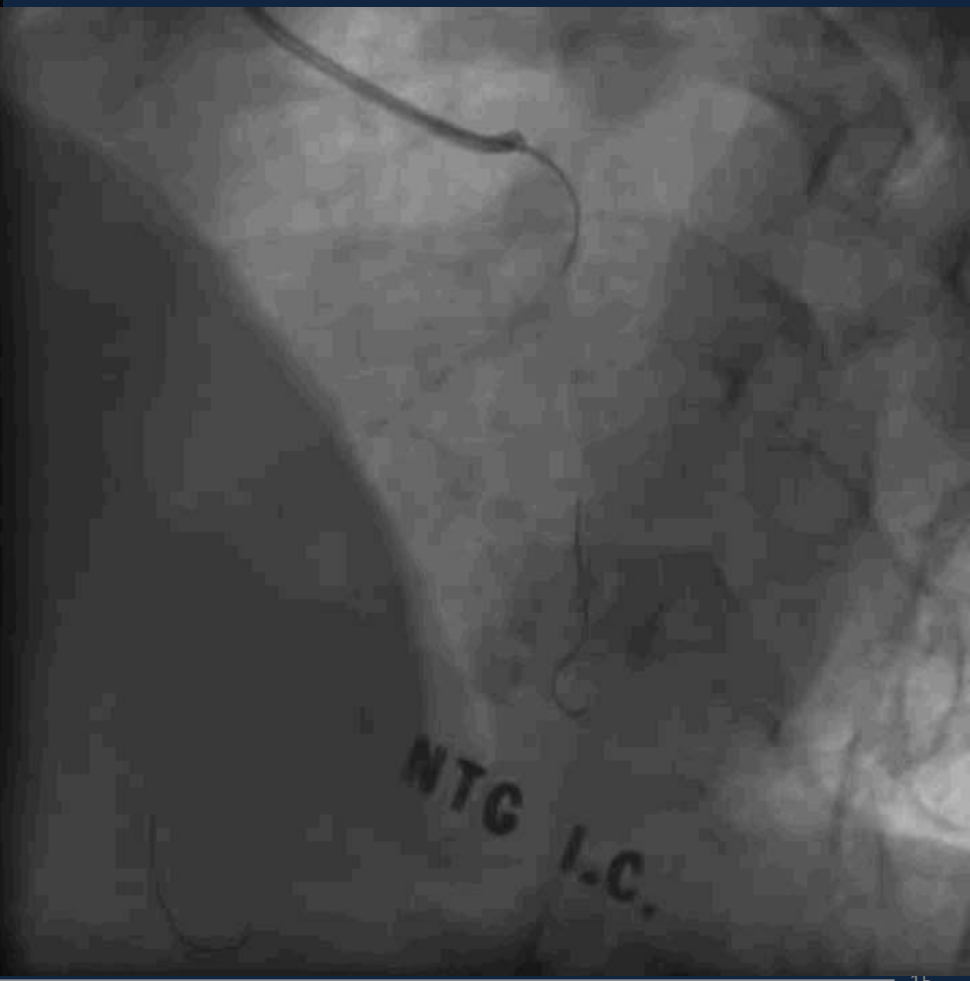
- A 51 y/o male, smoker,
- CC: Chest pain CCS2
- Hx: dyslipidemia, 3V-CAD
- PCI hx:
  - 2010/8: s/p DESx2 (Taxus Liberte 3.0x38, 2.75x38) to p-m-RCA & BMSx1 (Vision 2.5x23) to d-RCA
  - 2012/4,s/p BMS to m-LCX (Vision 2.5x28)
- TET:10.2 MET, positive of ischemia
- Echo: LVEF 75%, no wall motion abnormality

BVS preparation at 2012/10 baseline angiography via left radial approach

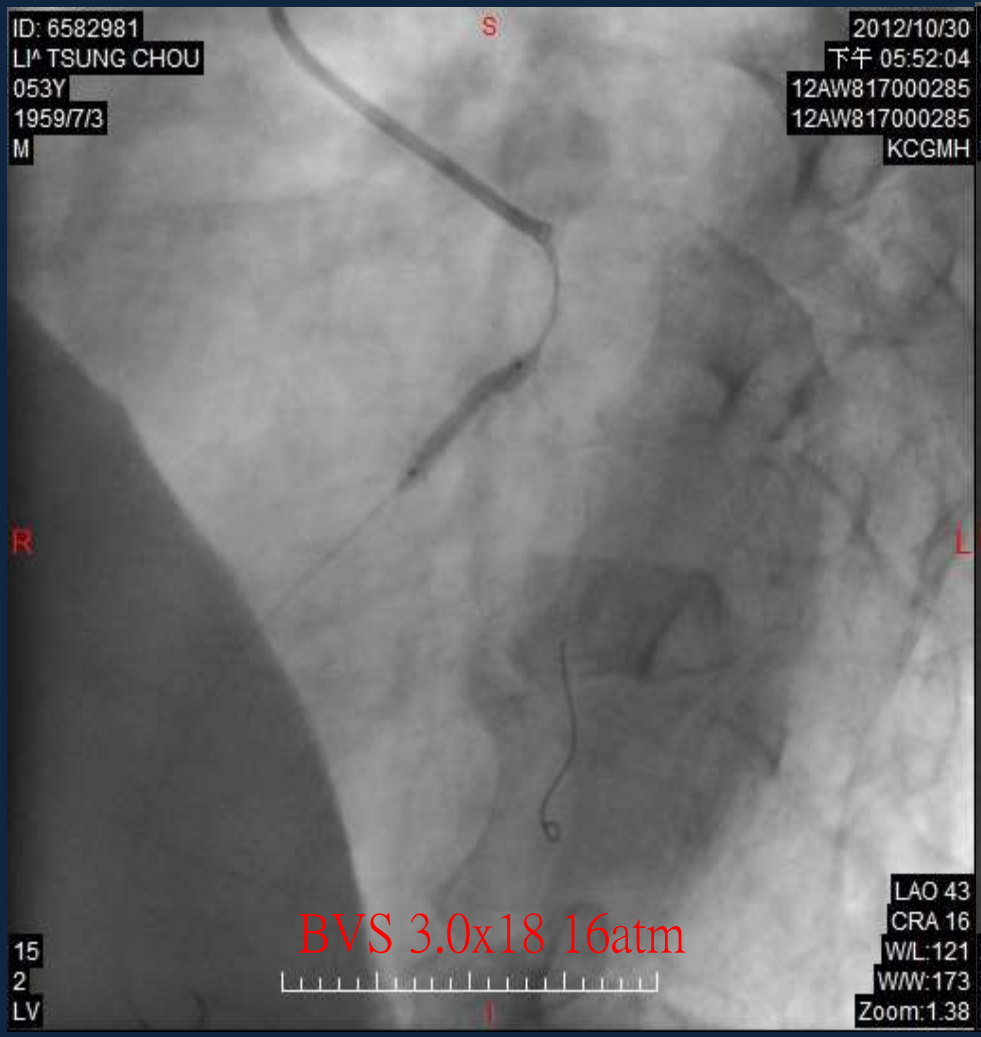


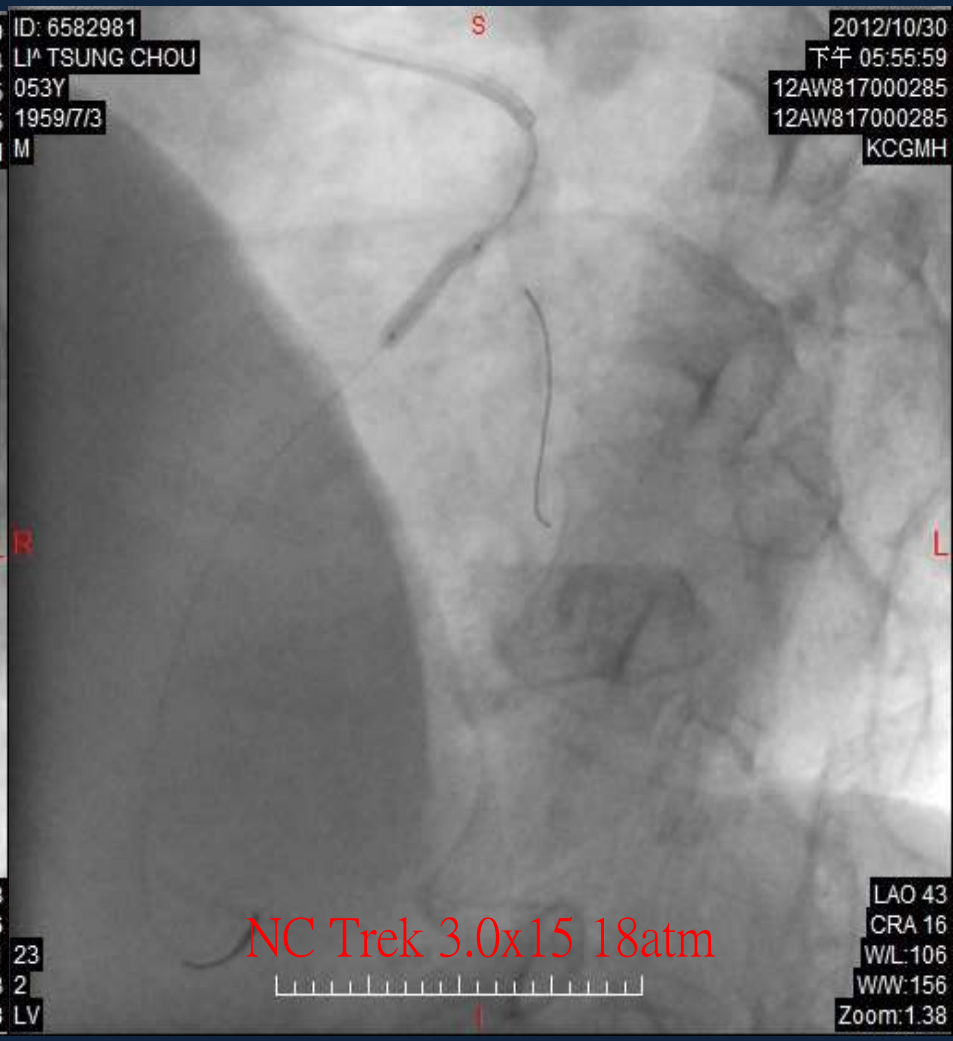
Pre-dilation



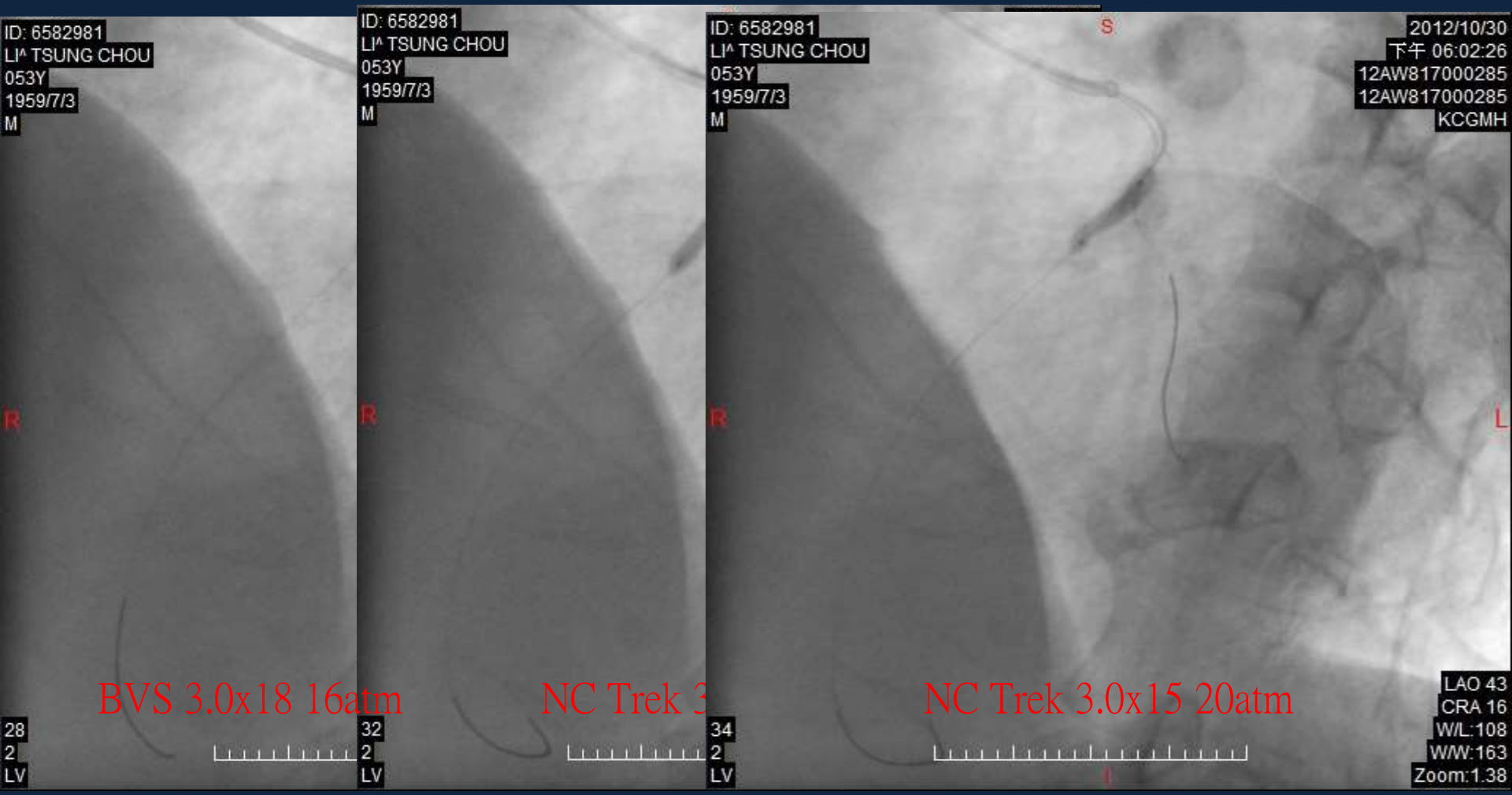


BVS-1 deployment and post HPB dilatation prepare for BVS-2

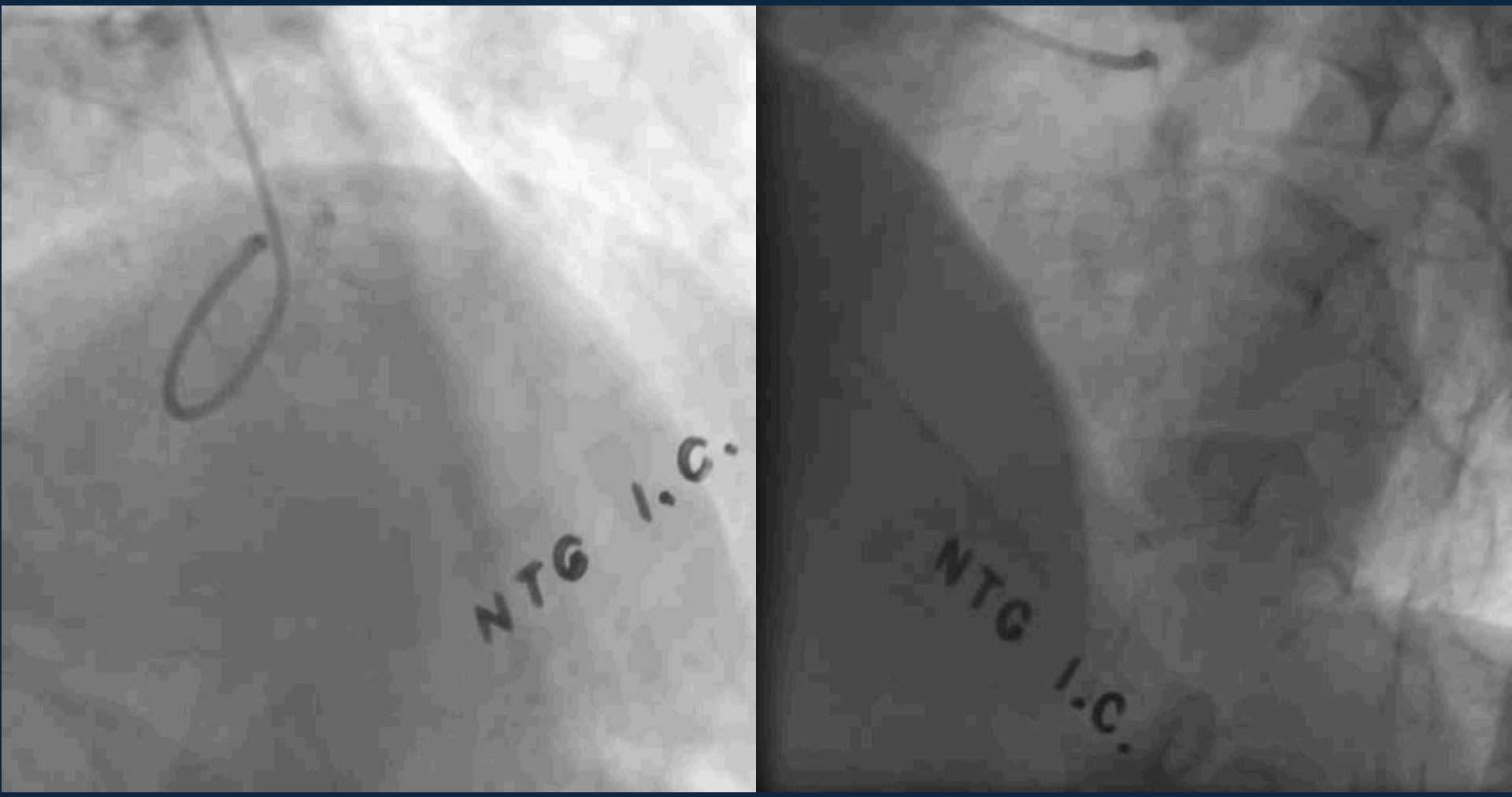




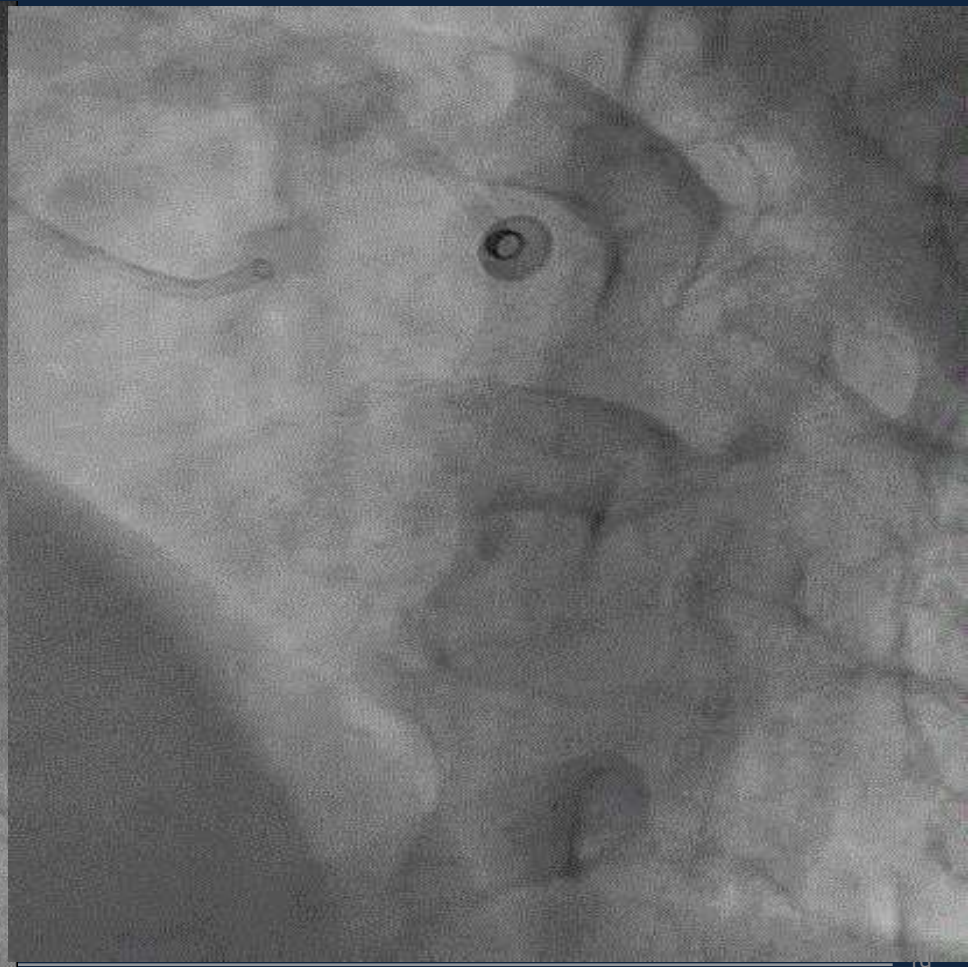
2nd BVS deployment and post dilation with non-compliant HPB



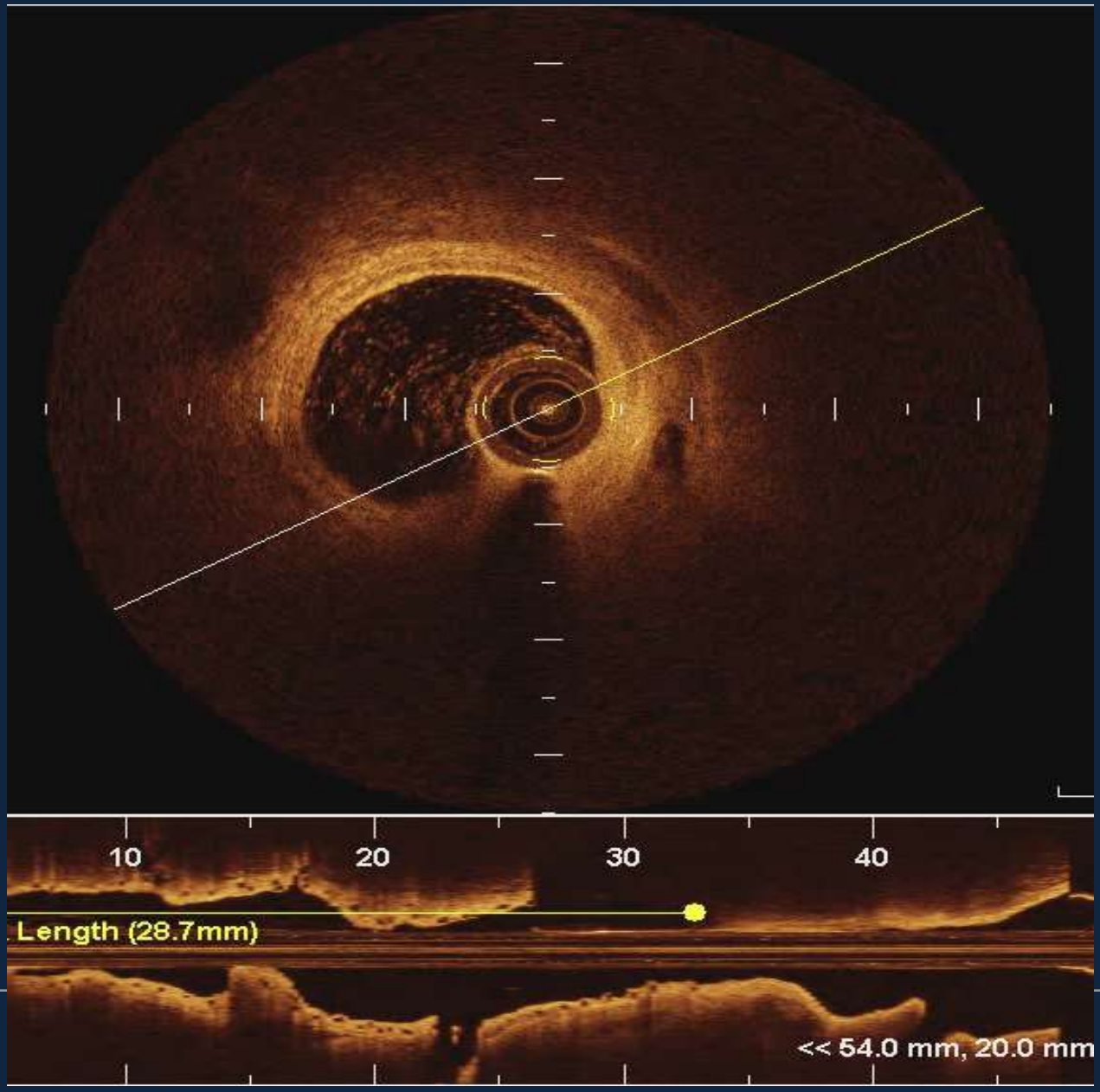
Final Angiography



19 m/o CAG & OCT f/u

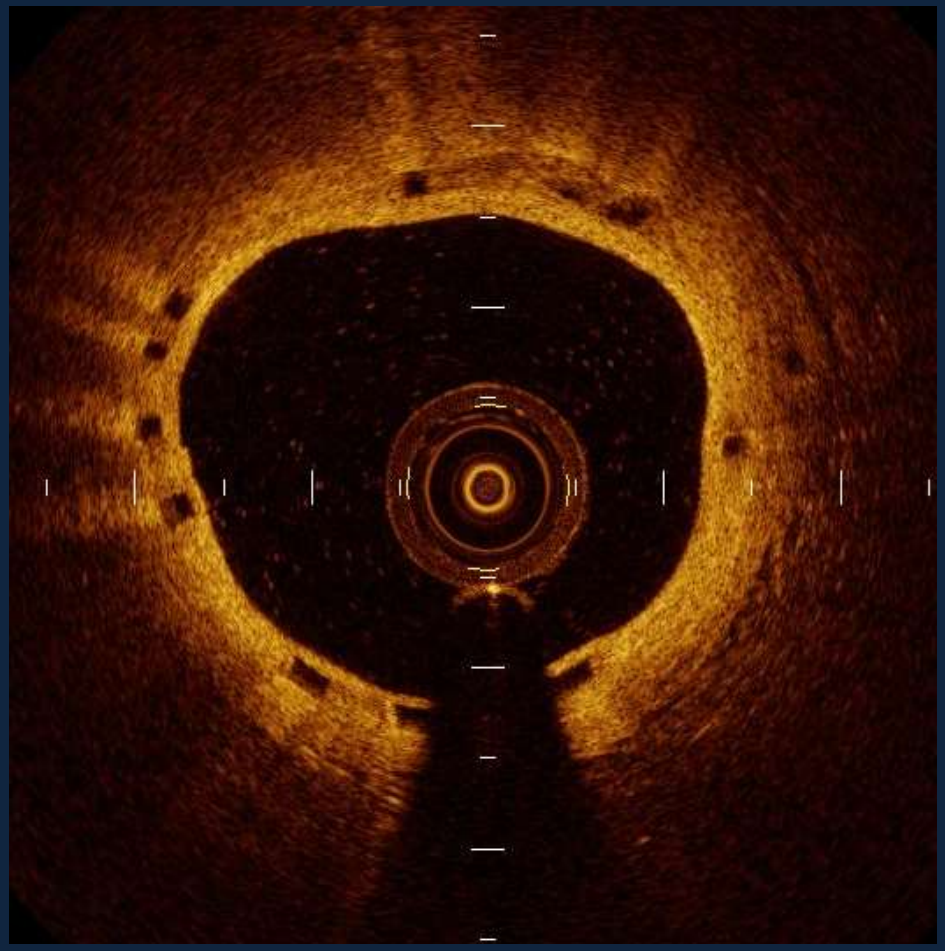


LAD BVS 19-mo OCT F/U

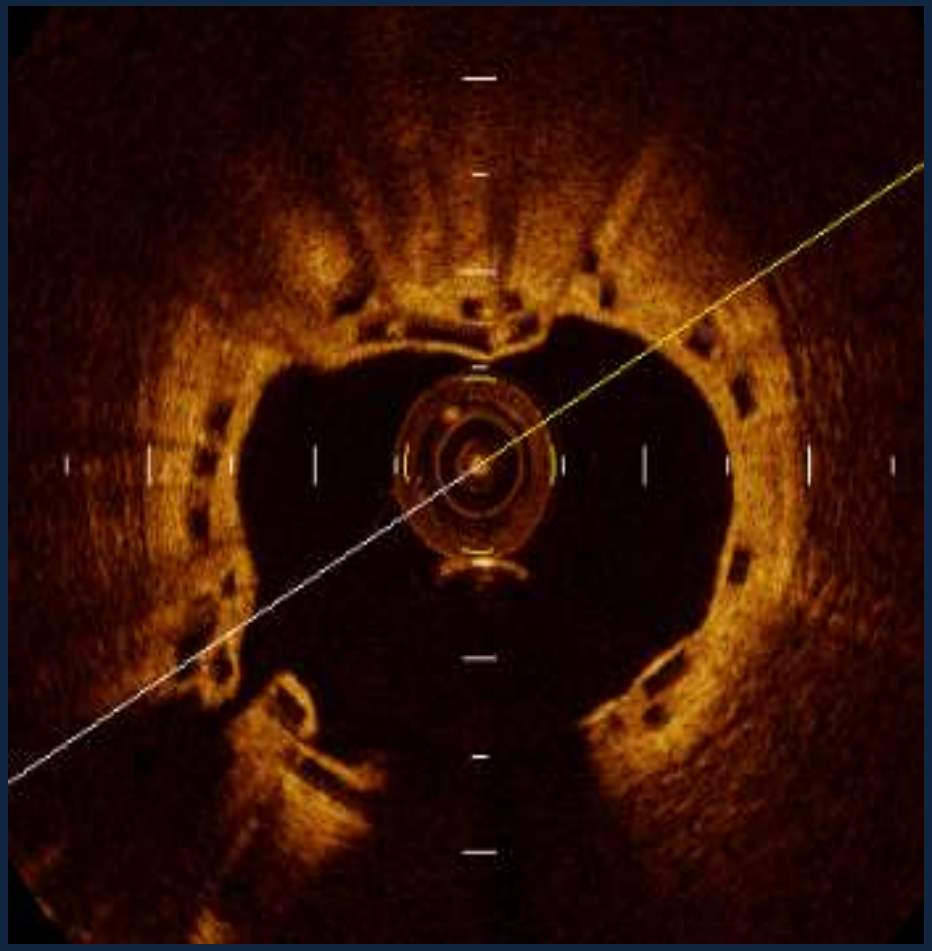


LAD BVS 19-mo OCT f/u

P-m-LAD BVS single layer

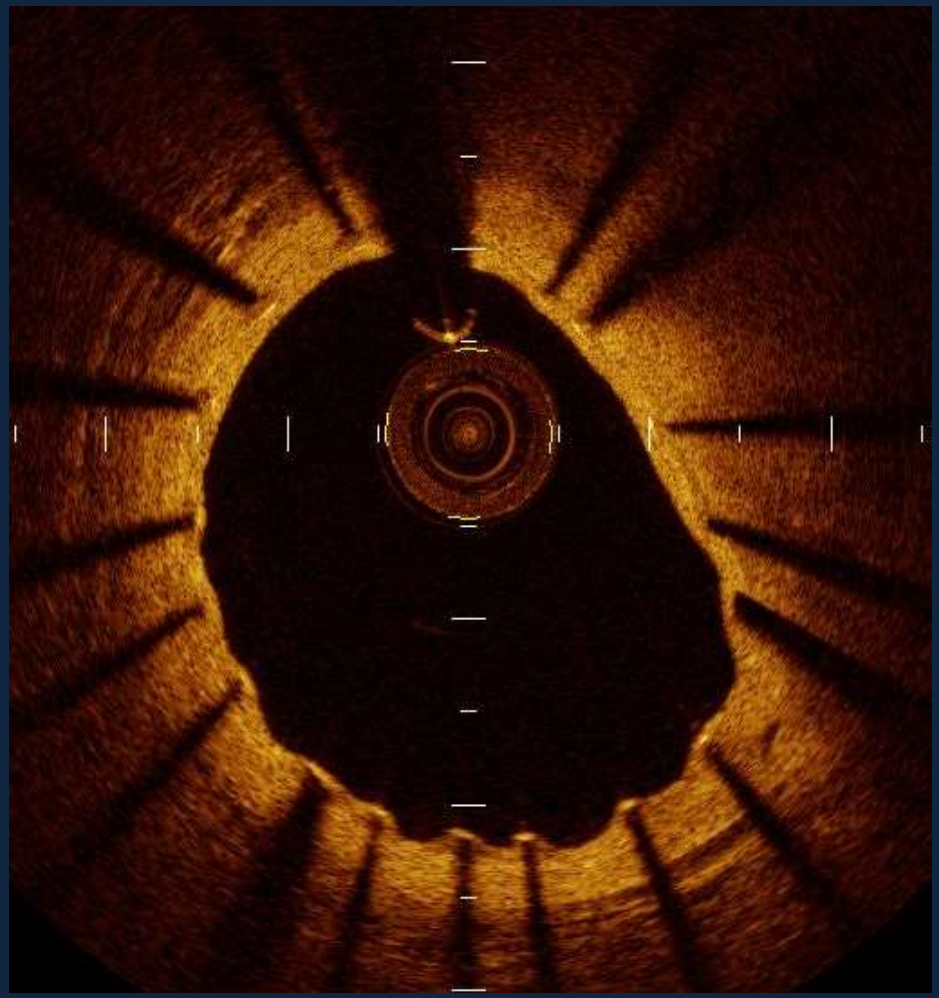


BVS overlapping zone



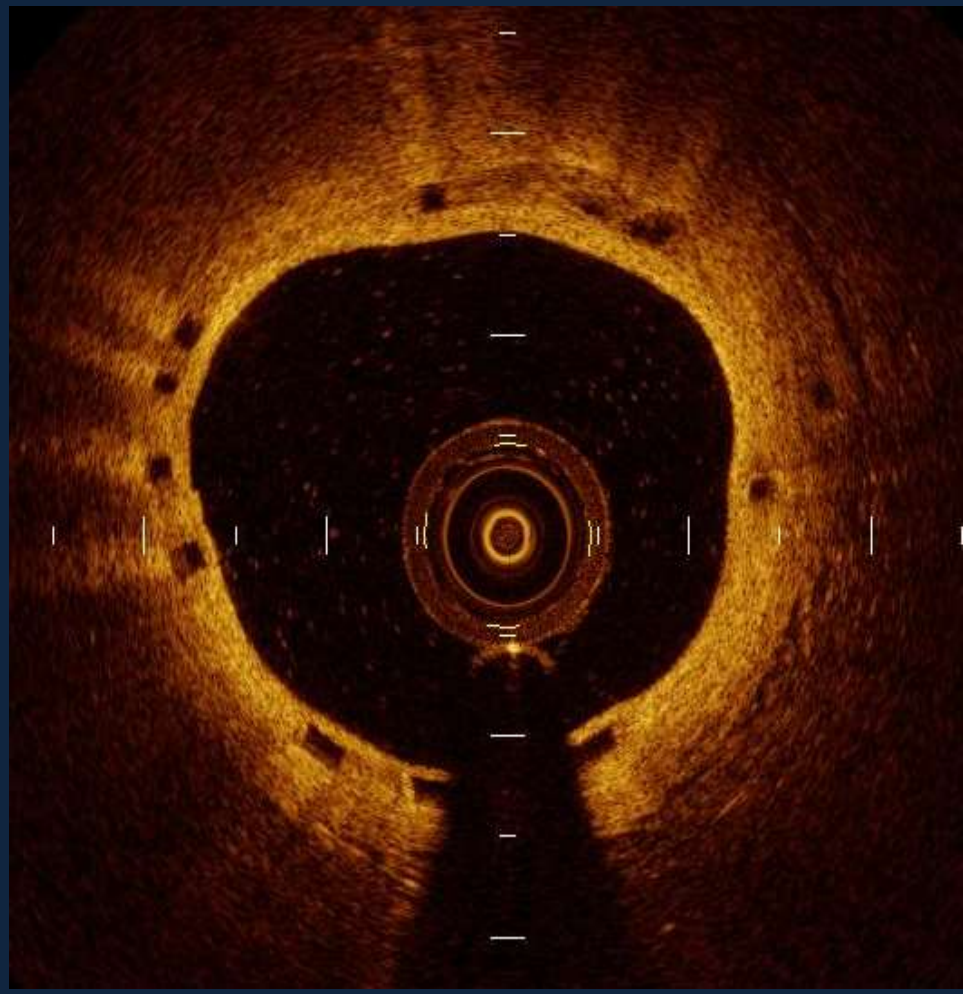
OCT DES

(RCA prior Taxus stent 49-mo)

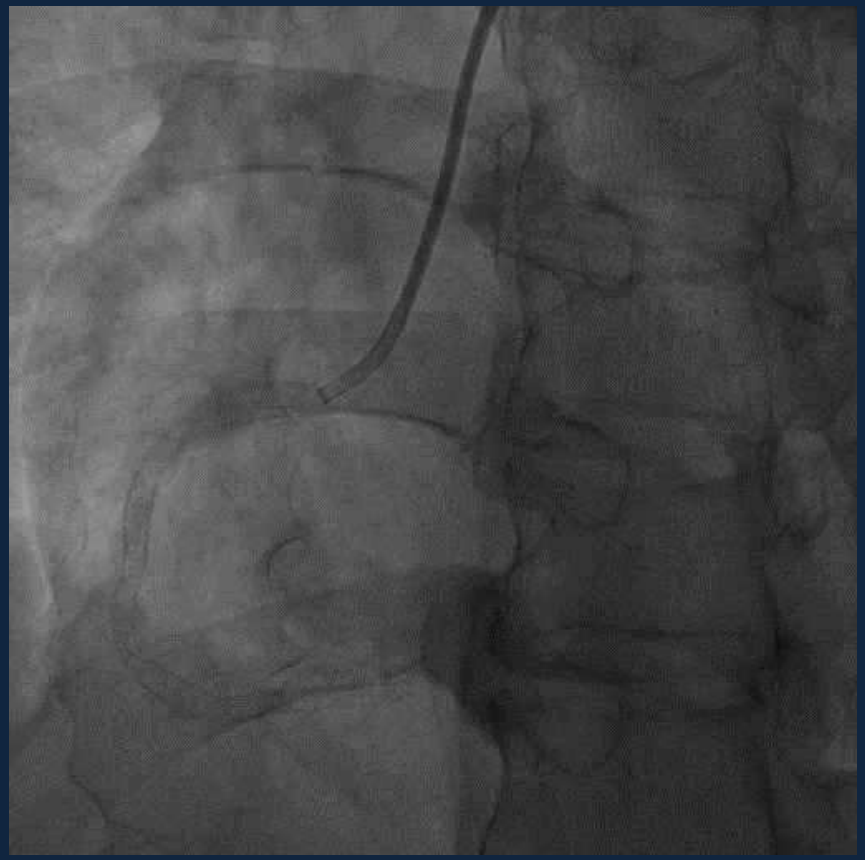


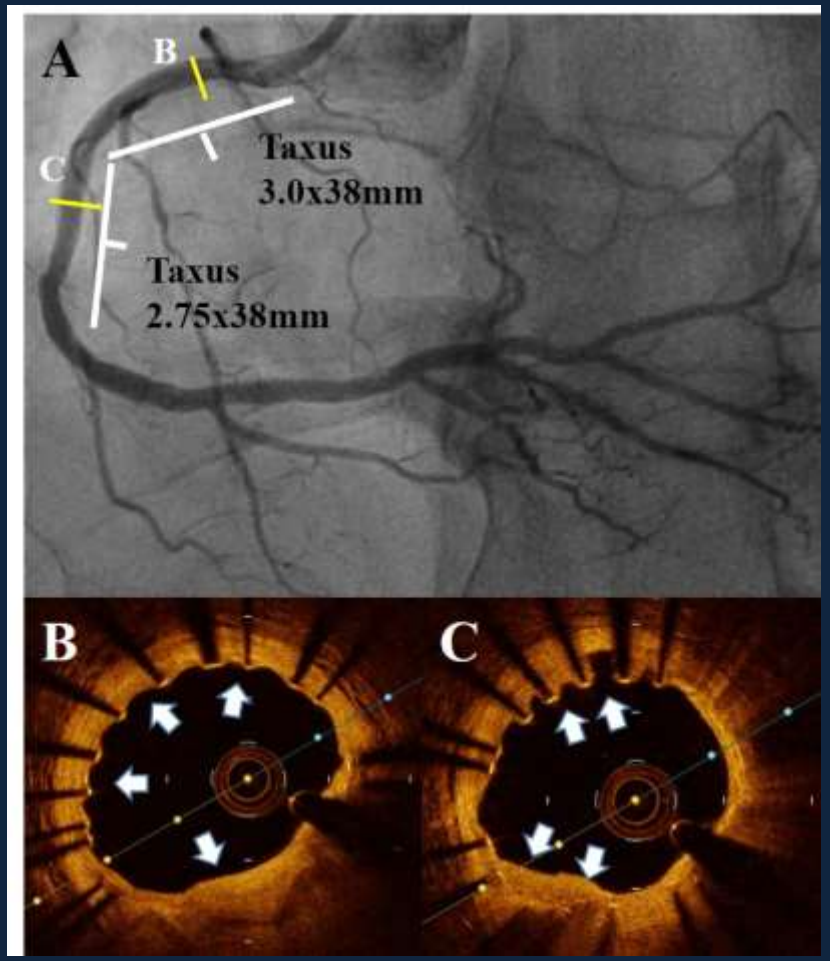
OCT BVS LAD

(19-mo)

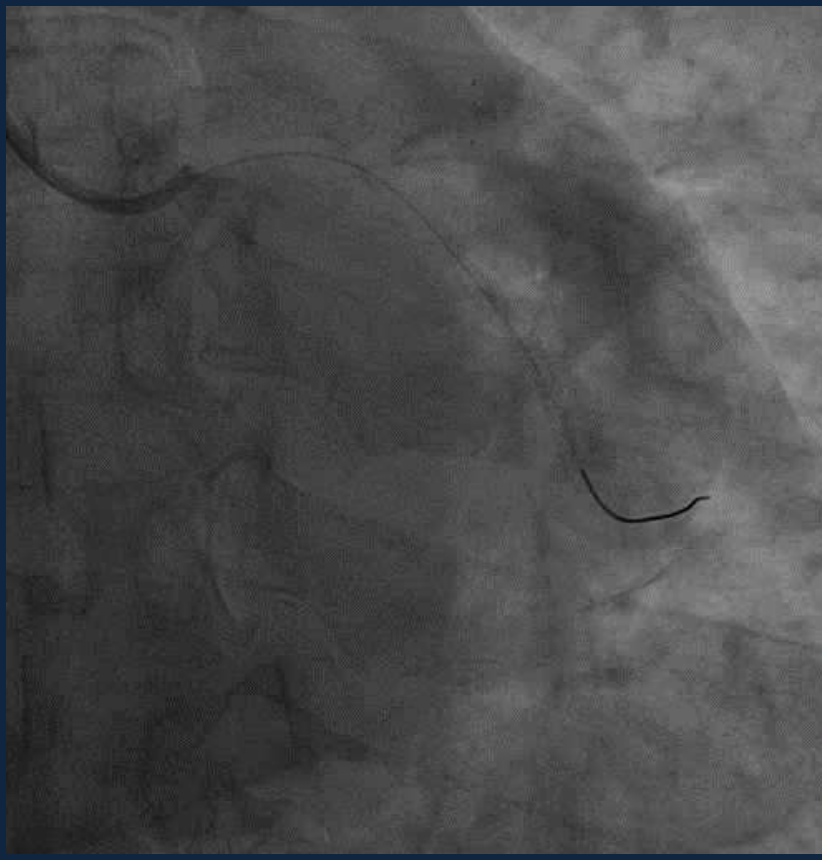


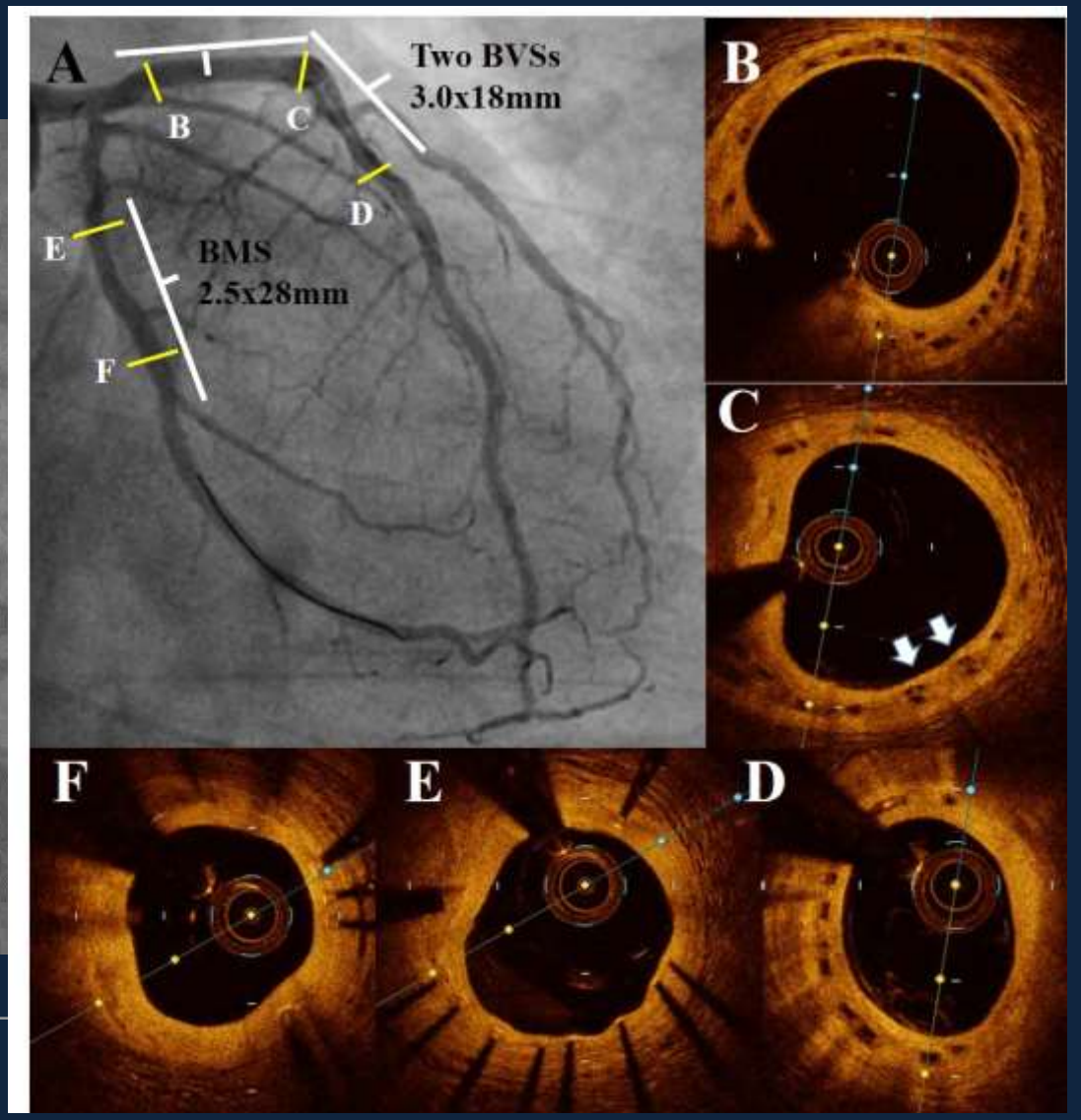
RCA f/u angio. at 2016-4-16 (67-mo post Taxus-Liberte DES)





LCA F/U angio. 2016-4-16 Absorb Extend Trial (3.5 yr s/p BVS 3x18 x II in LAD), MACE free for 4.5 yrs



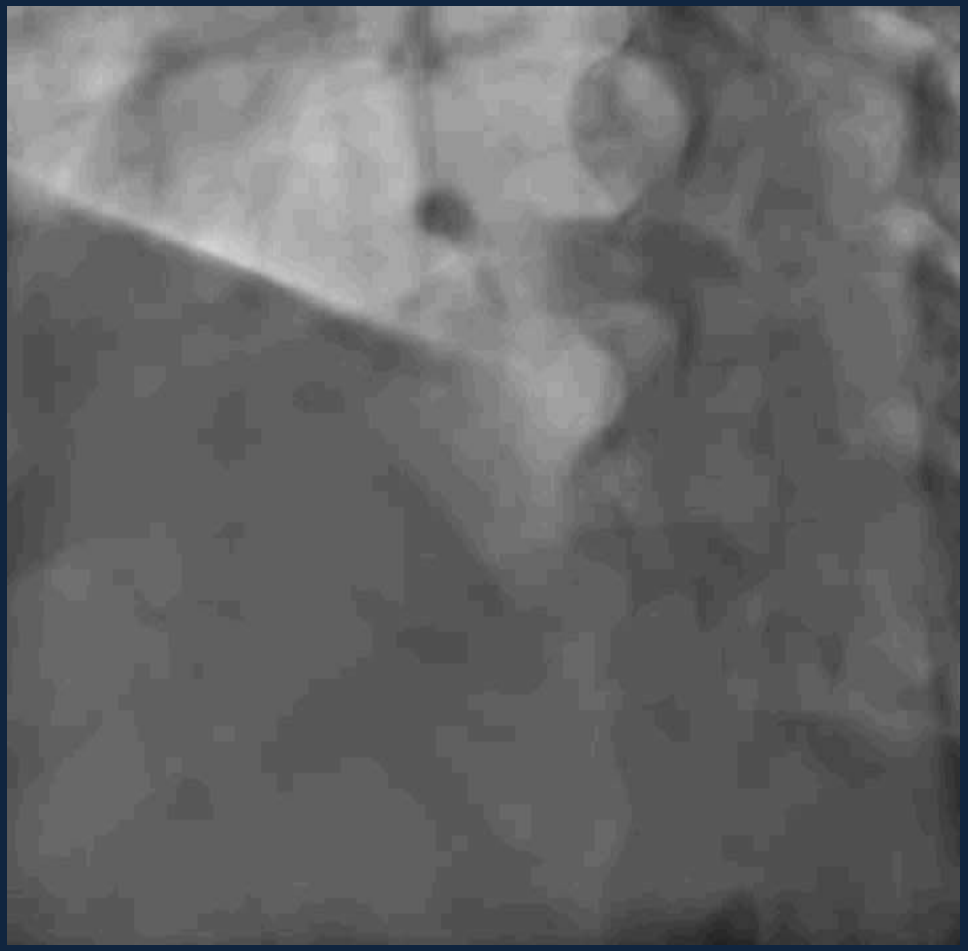


BVS deployment minimal overlap Contemporary approach (Case No. 2)

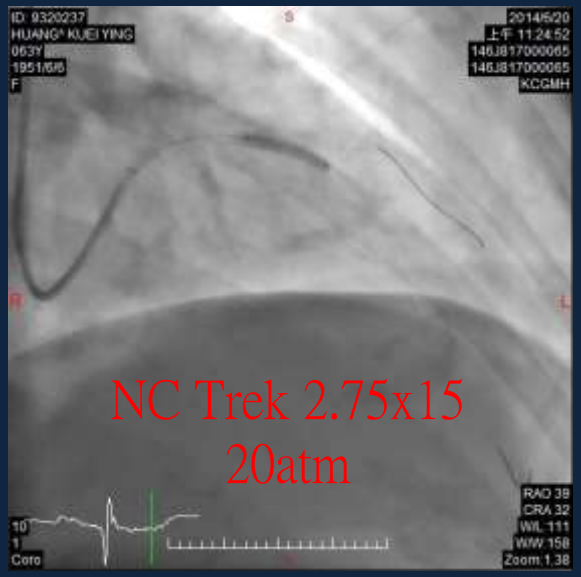
Case history

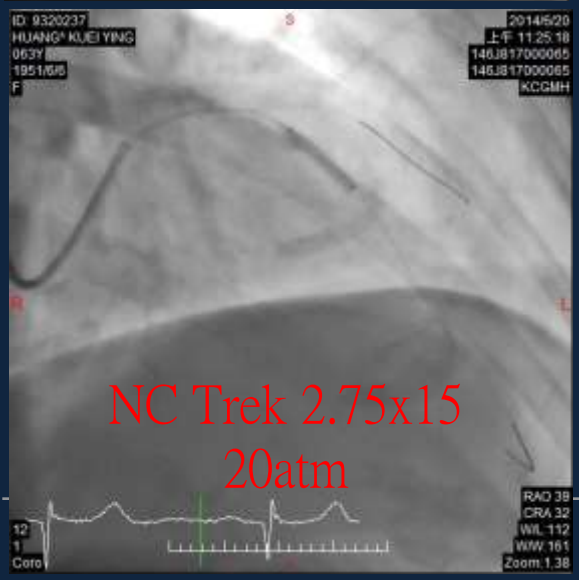
- A 63 y/o female, non-smoker
- CC: clinical Chest pain in CCS 2
- Hx: Dyslipidemia, DM
- TET: nil
- Echo: LVEF: 76%, normal LV wall motion
- MDCT: p-LAD 30-40% stenosis, m-LAD calcified plaque with 60-80% stenosis, RCA-PLB 70-90% stenosis

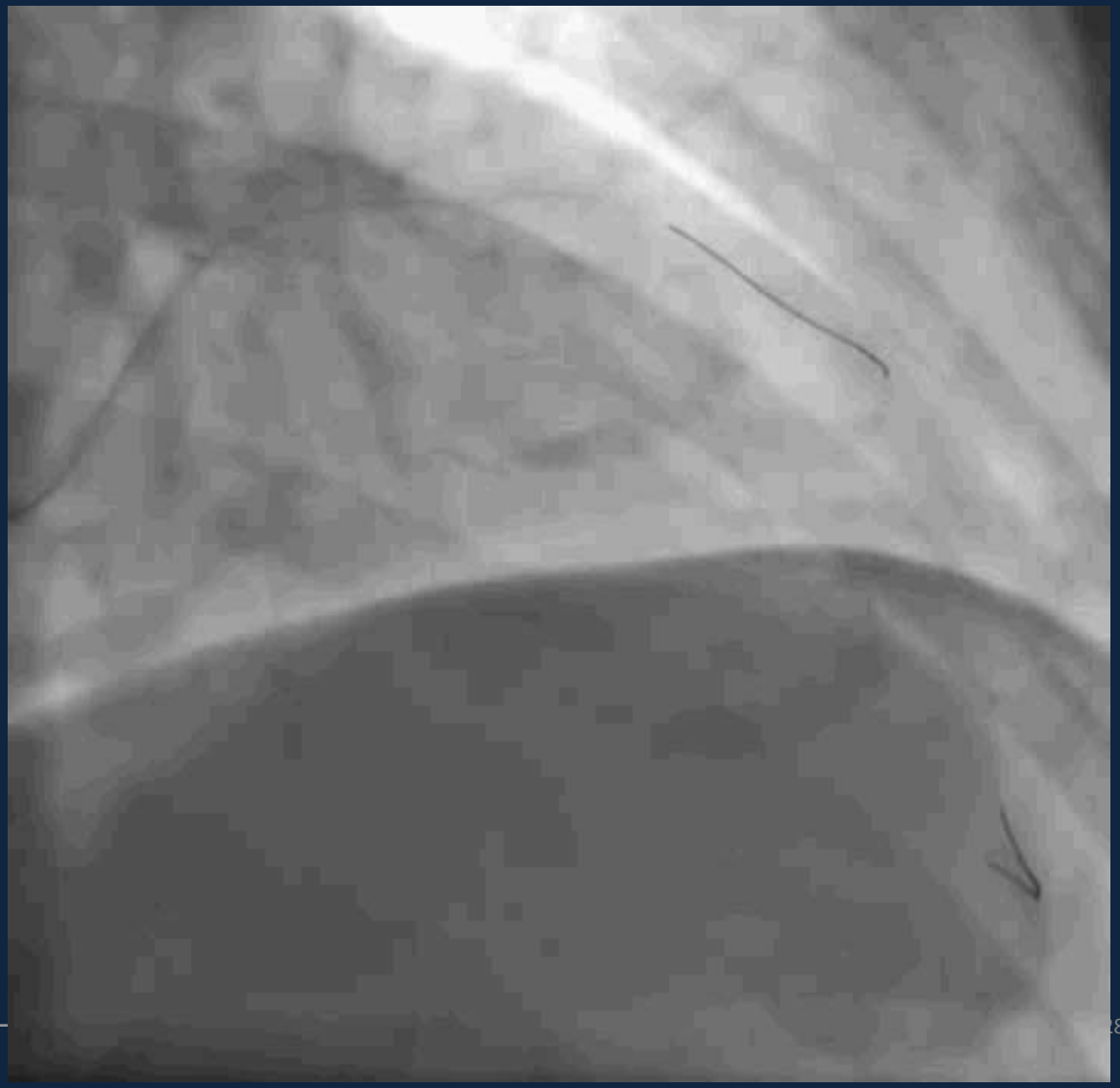
Baseline CAG



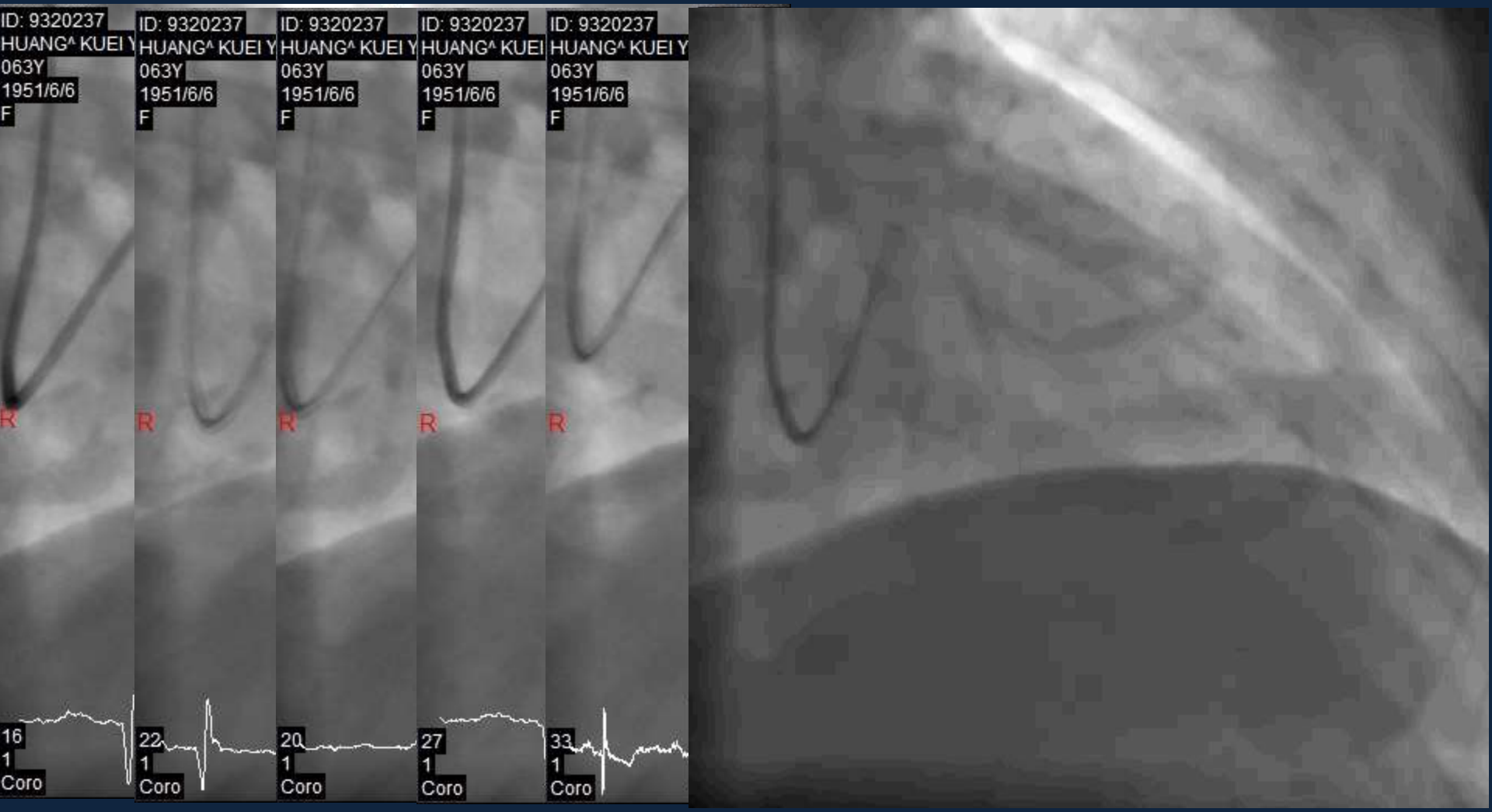
Pre-dilation under-IVUS guide



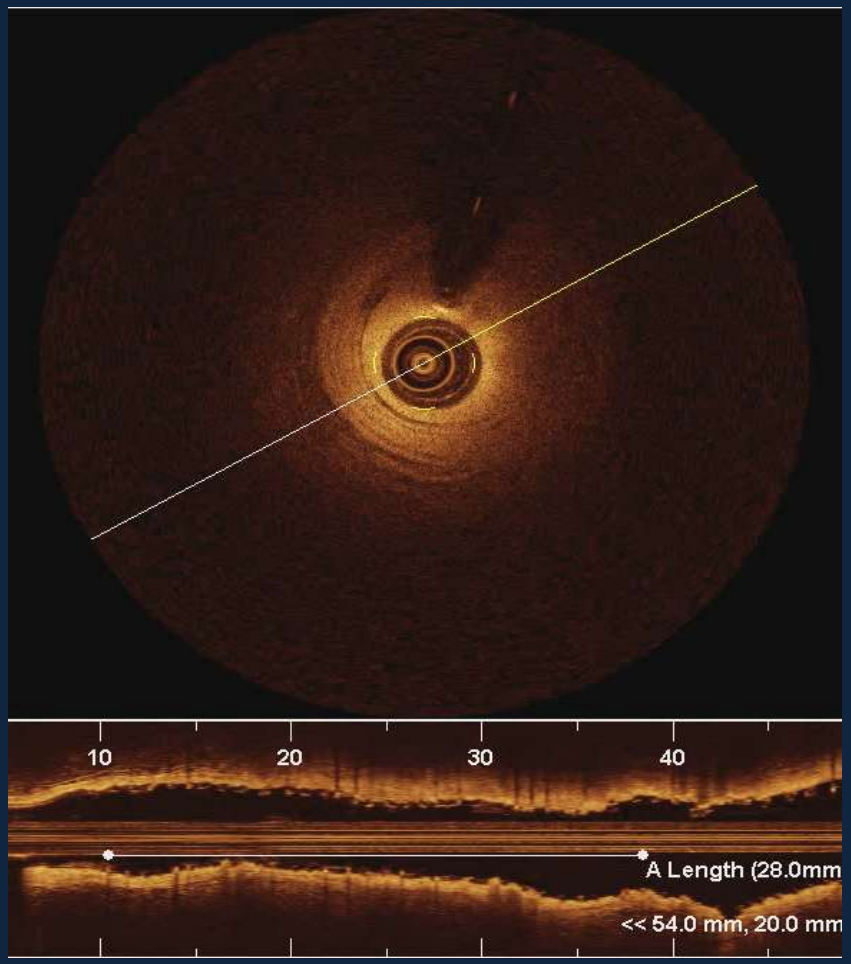




BVS deployment



OCT study post BVS X 2 edge to edge

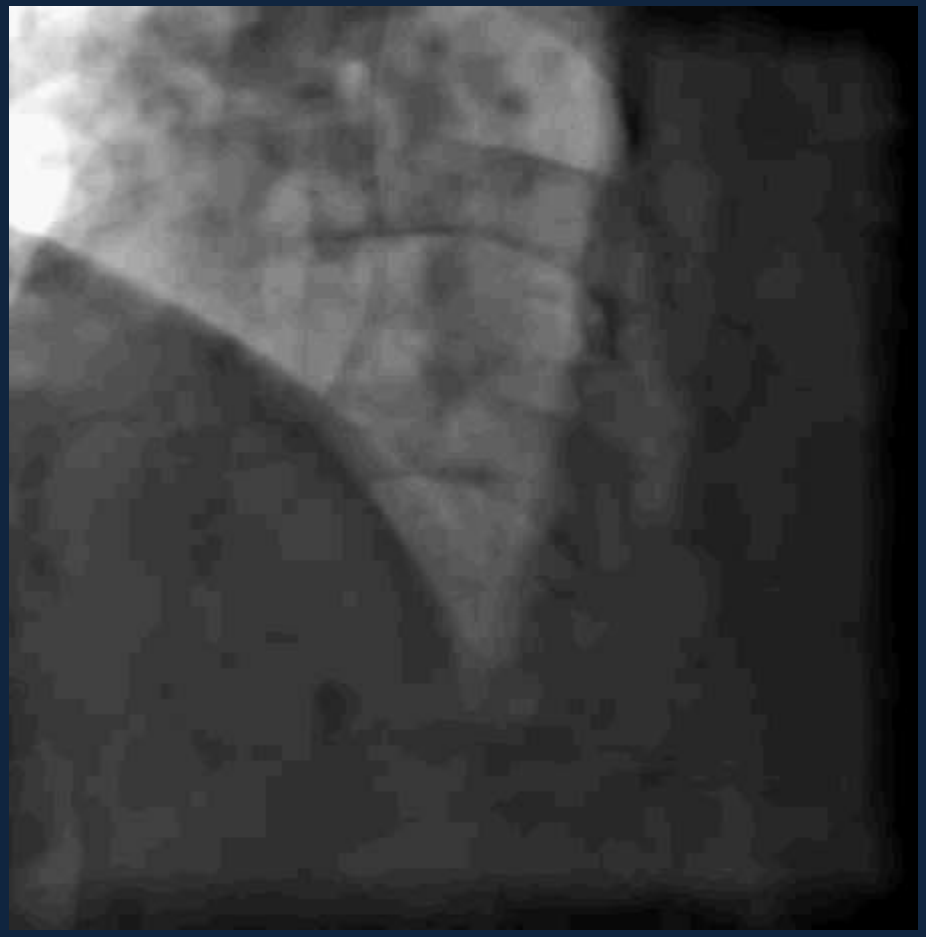


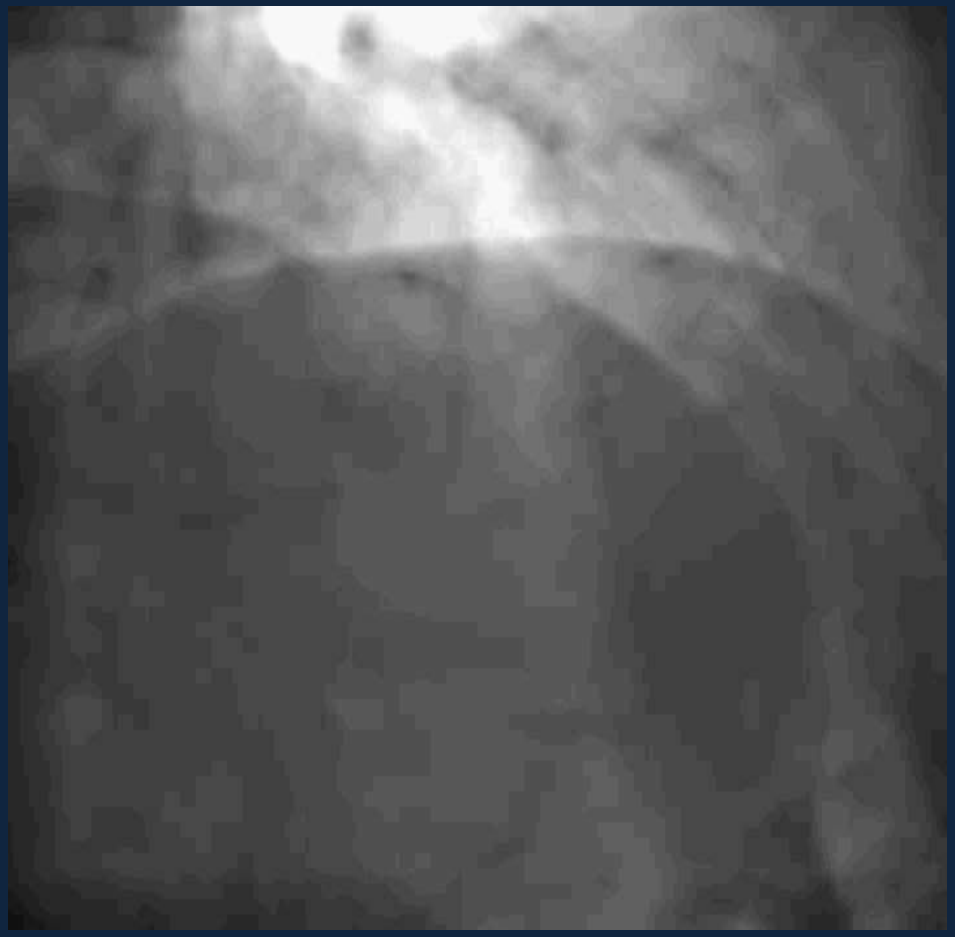
Trouble shouting of BVS delivery in angulated RCA, 18 m/o angiography & OCT f/u, (Case No. 3)

Case history

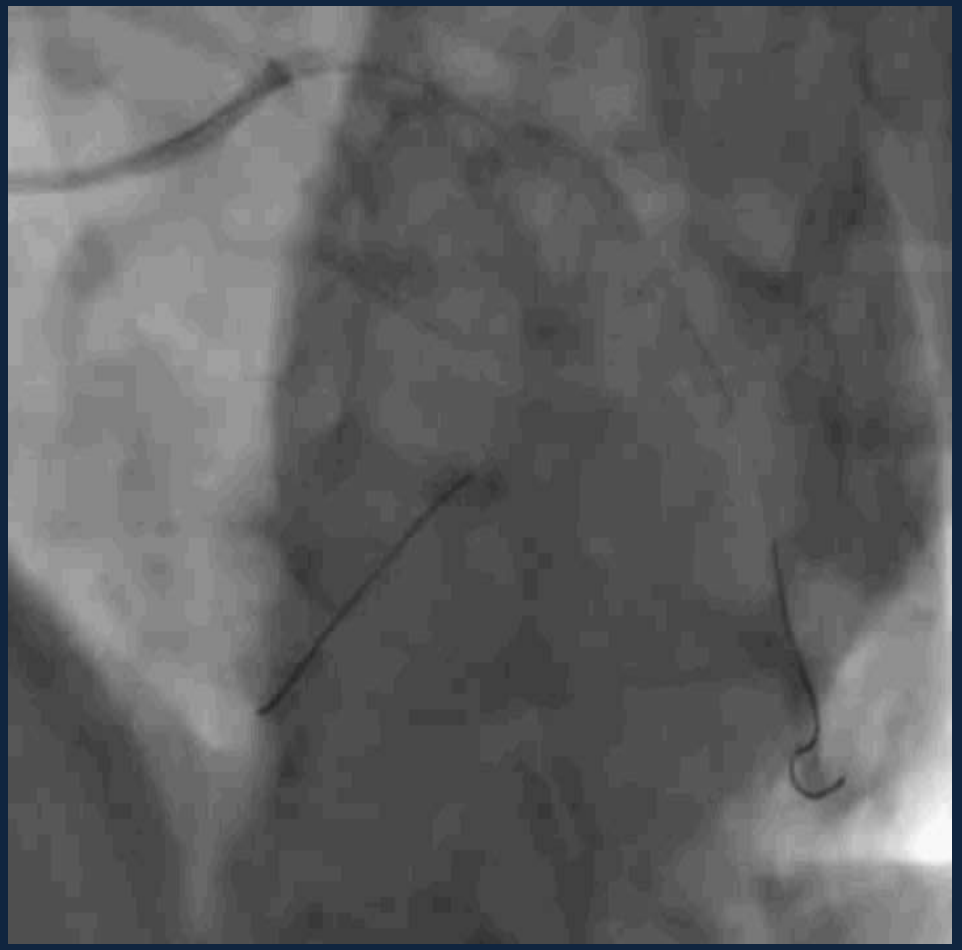
- A 65 y/o male, smoker
- CC: Chest pain in CCS 2
- Hx: Dyslipidemia, 3-V CAD s/p DES (Xience Prime 3.0x28) to m-RCA and BMS (Vision 2.5x23) to D1
- TET: Positive ischemia at 11-min 13.4 MET, (rapid upslope ST depression 2mm on III, AVF, V3-4)
- Echo: LVEF: 73%, normal LV wall motion

1st PCI (CAG)



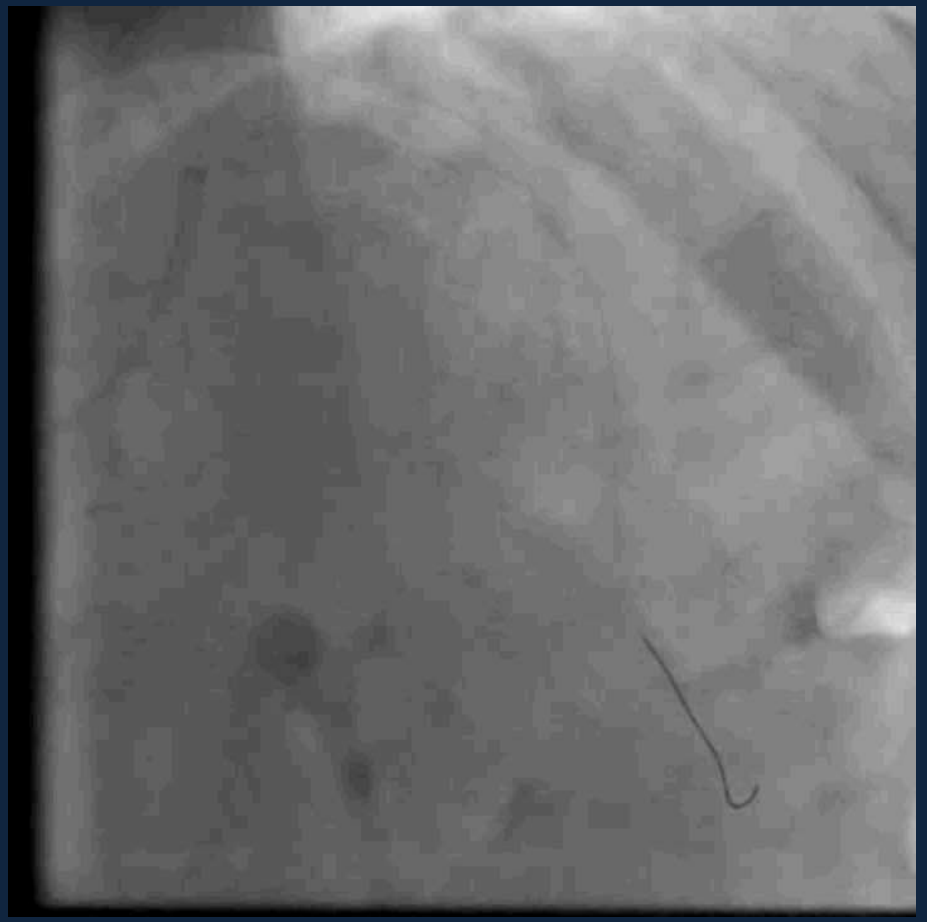


1st PCI (s/p PCI)

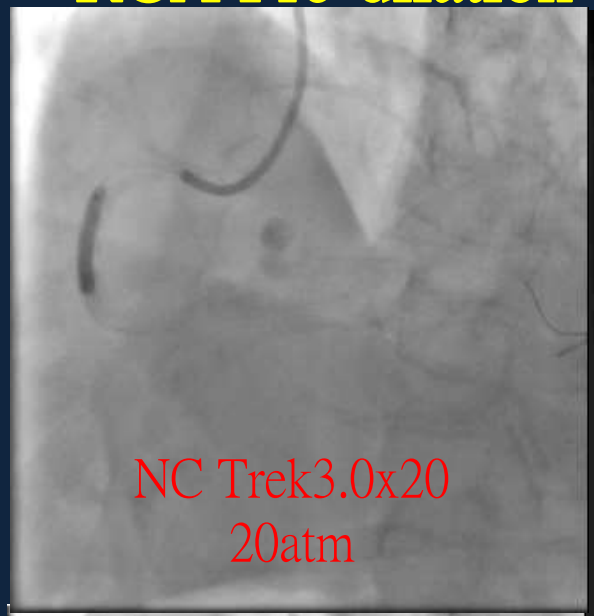


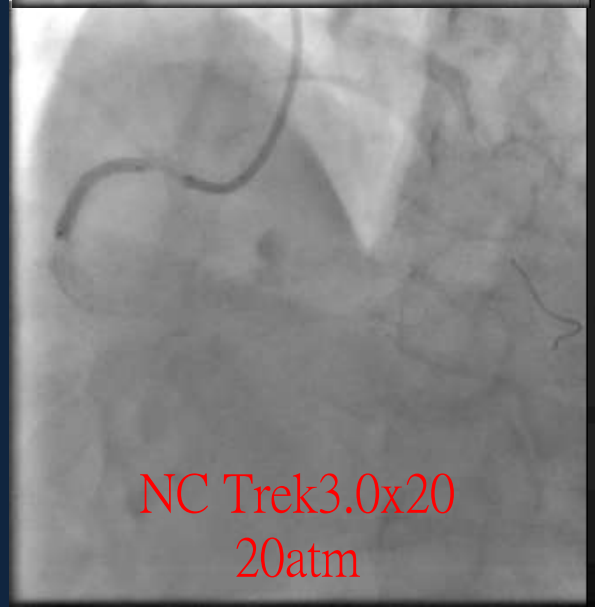
s/p Xience Prime 3.0x28 to m-RCA, Vision 2.5x23 to D1

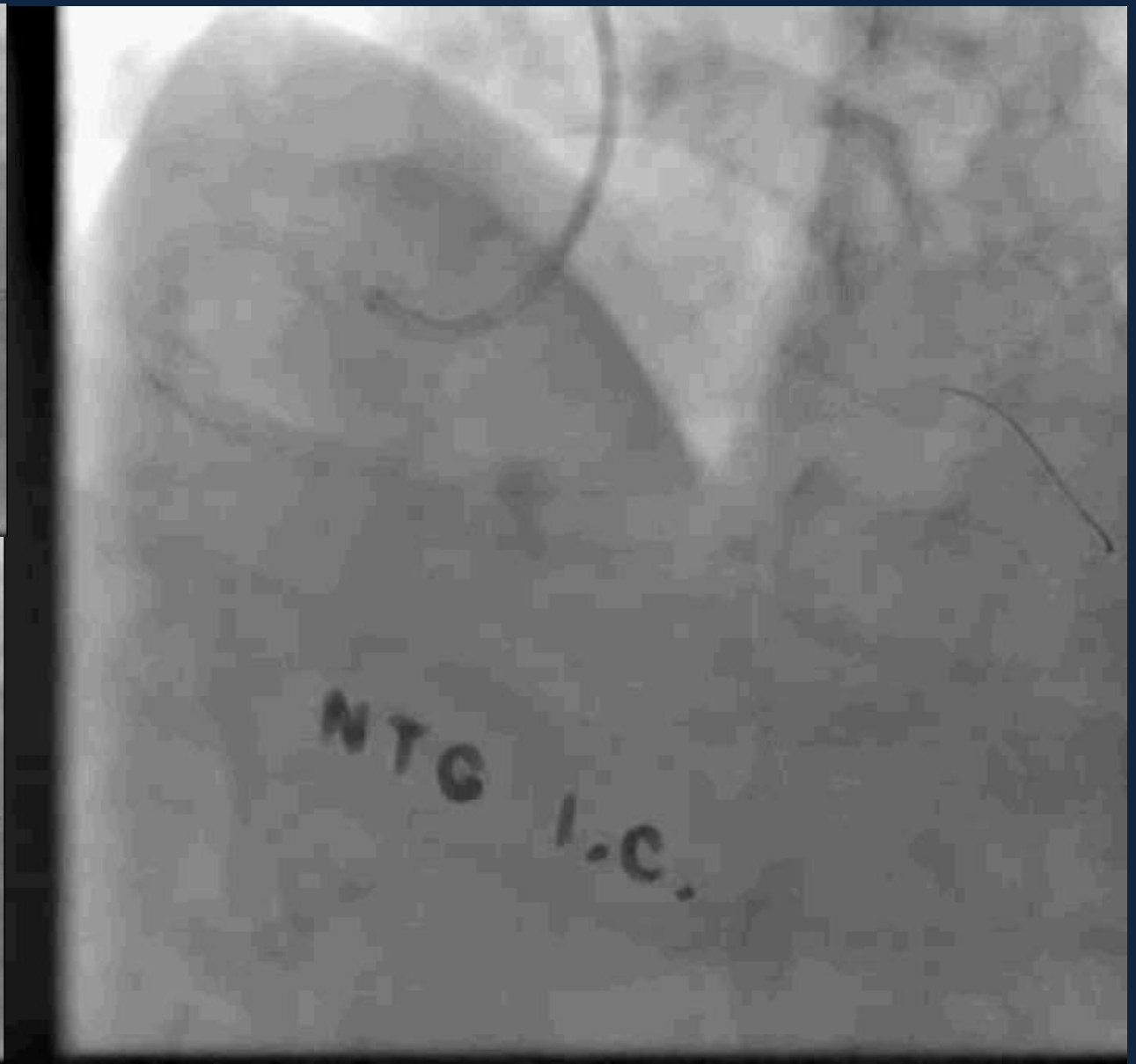
2nd PCI (CAG) 8 m/o later TR approach with Ikari-left 4 guiding



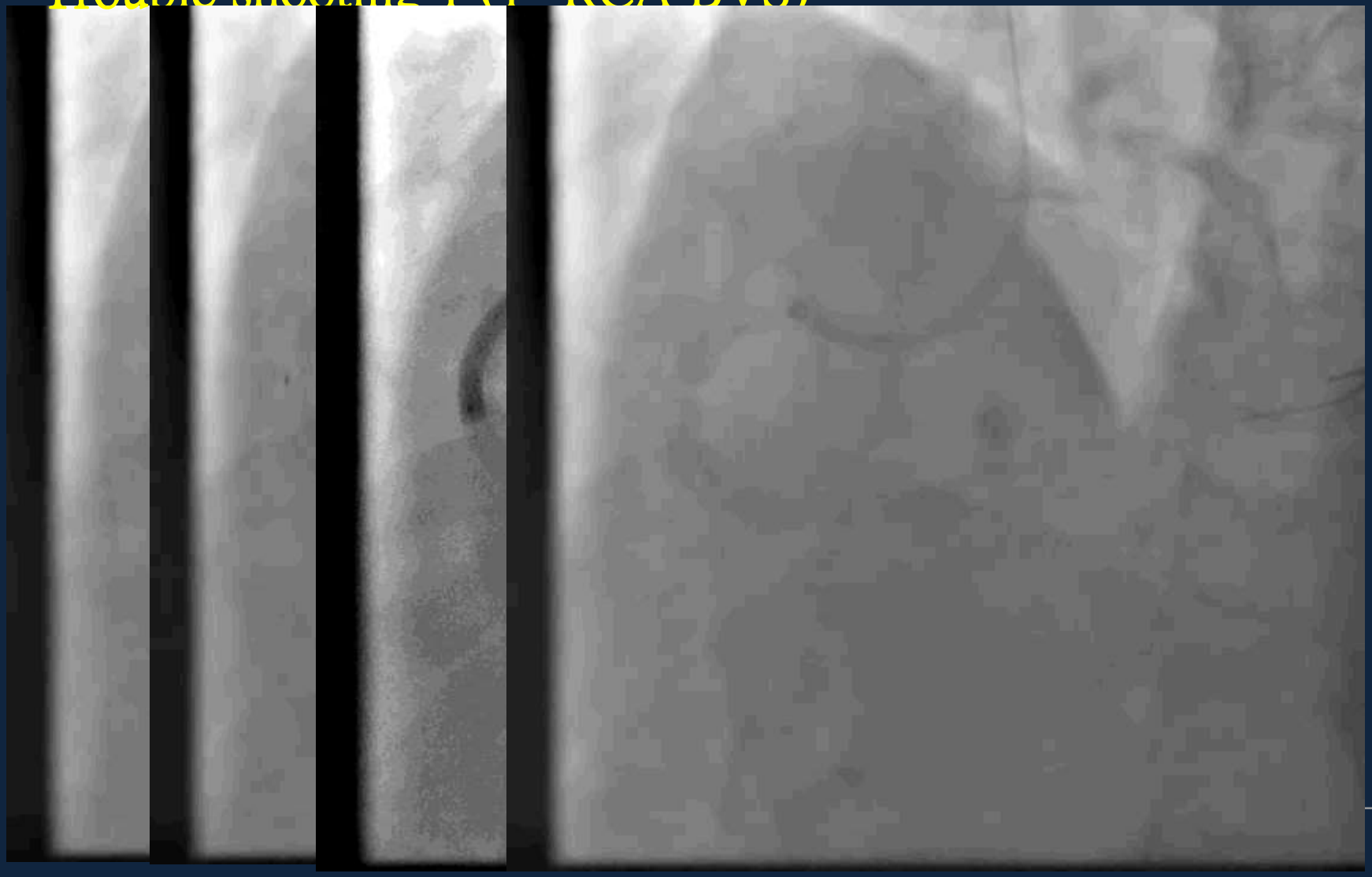
RCA Pre-dilation



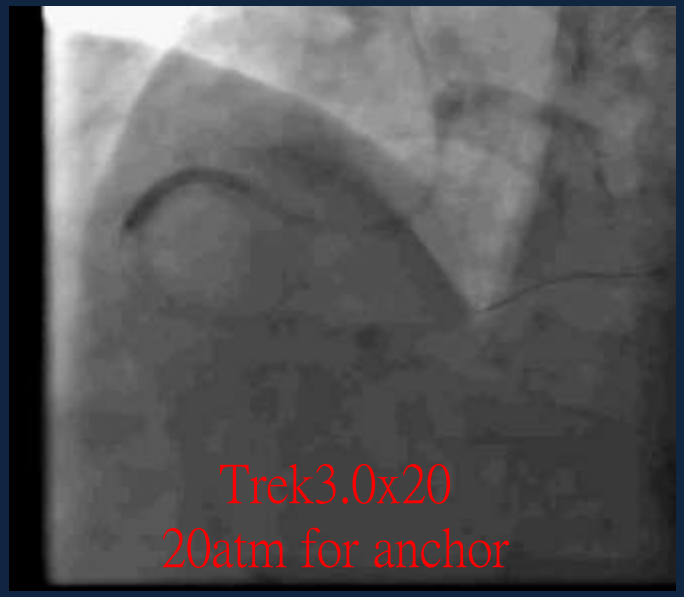




Trouble shooting 1 (1st RCA BVS)

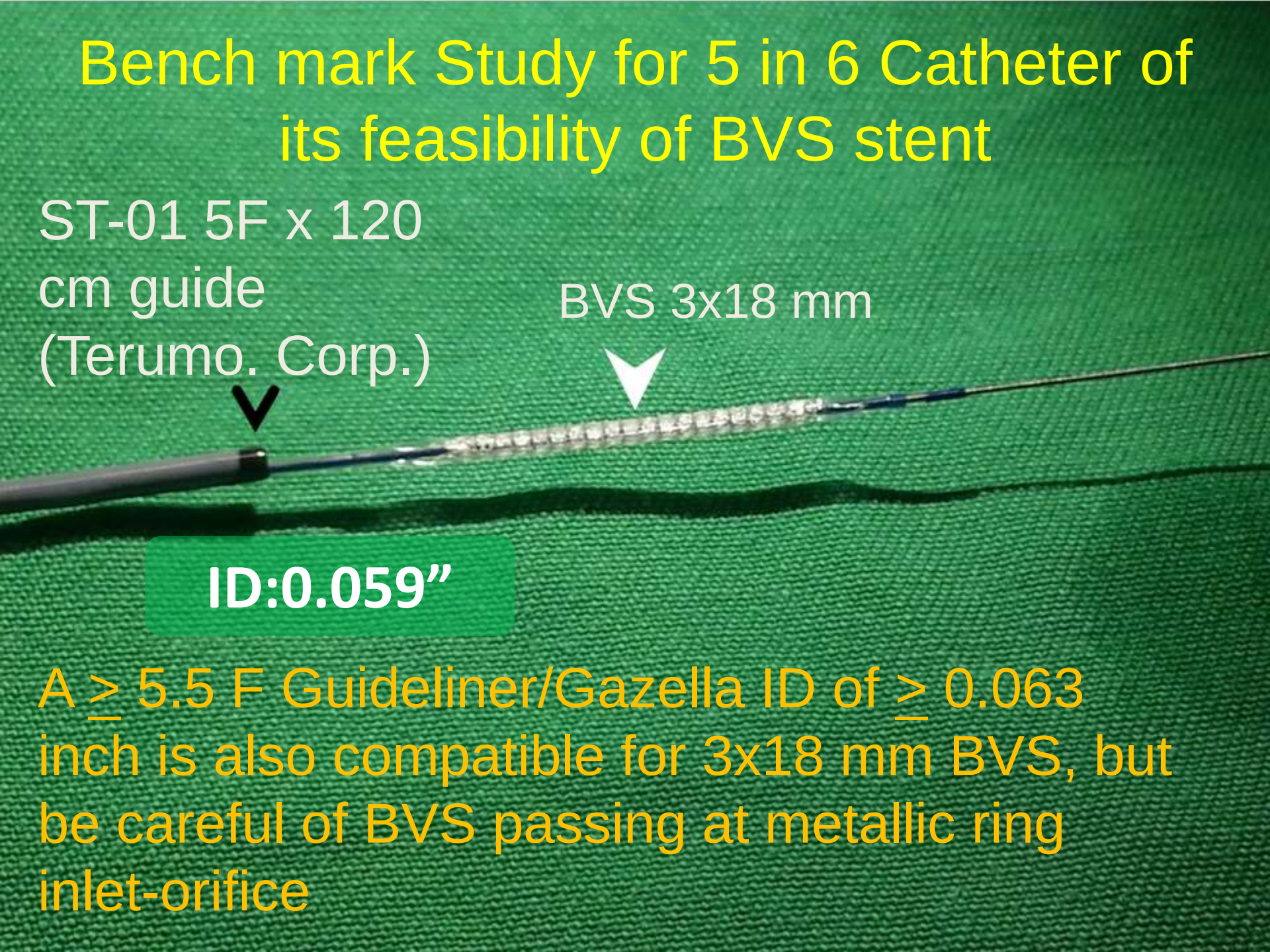


Trouble shooting 2 (2nd RCA BVS 3x18 mm)



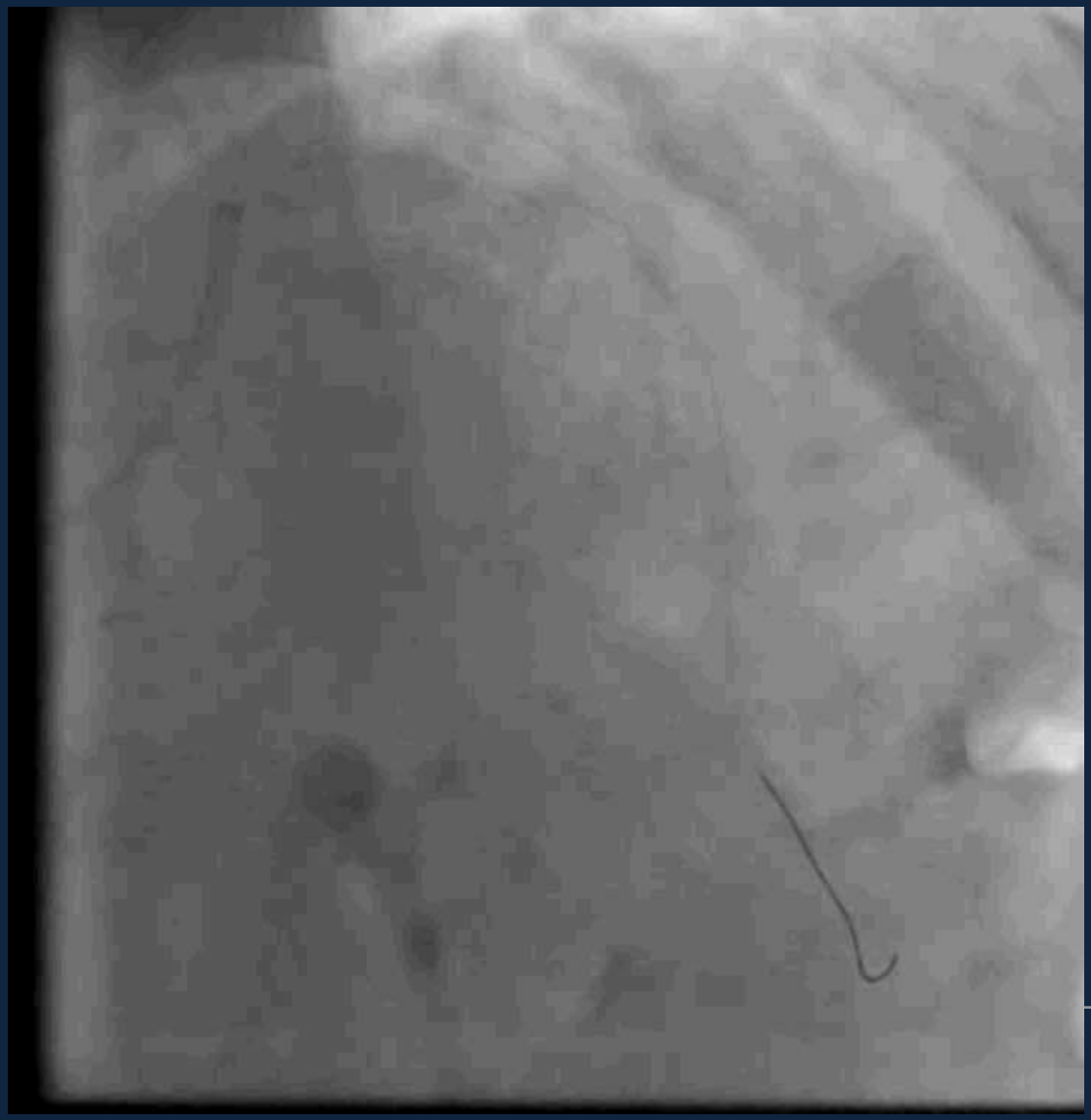
Trouble shooting 2 (2nd RCA BVS round 2)

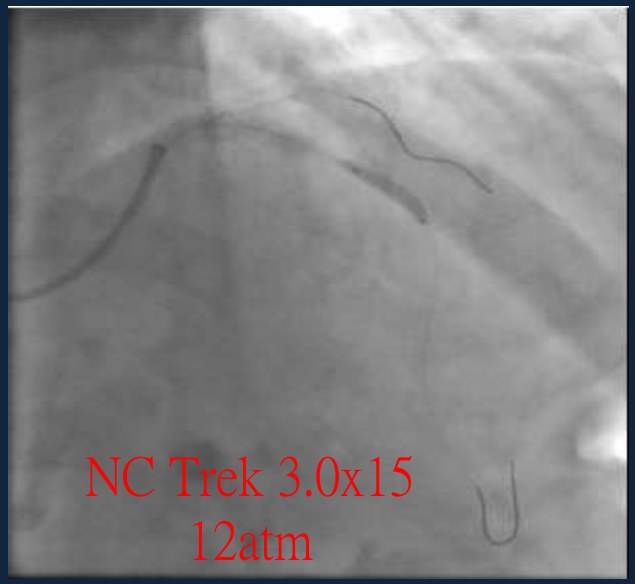
Bench mark Study for 5 in 6 Catheter of its feasibility of BVS stent

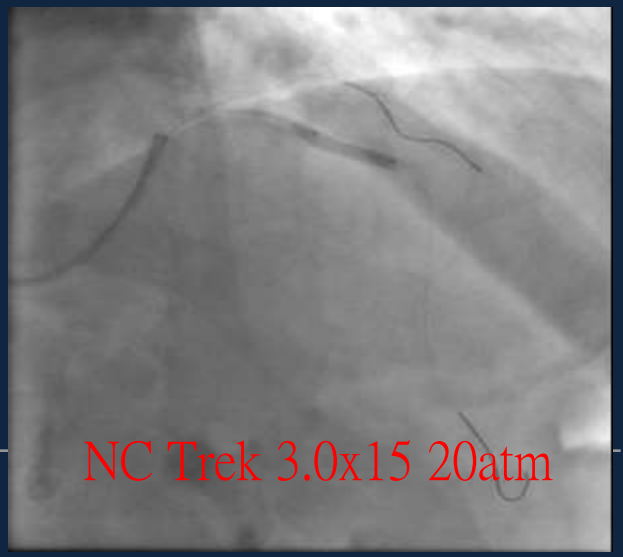


A ≥ 5.5 F Guideliner/Gazella ID of ≥ 0.063 inch is also compatible for 3x18 mm BVS, but be careful of BVS passing at metallic ring inlet-orifice

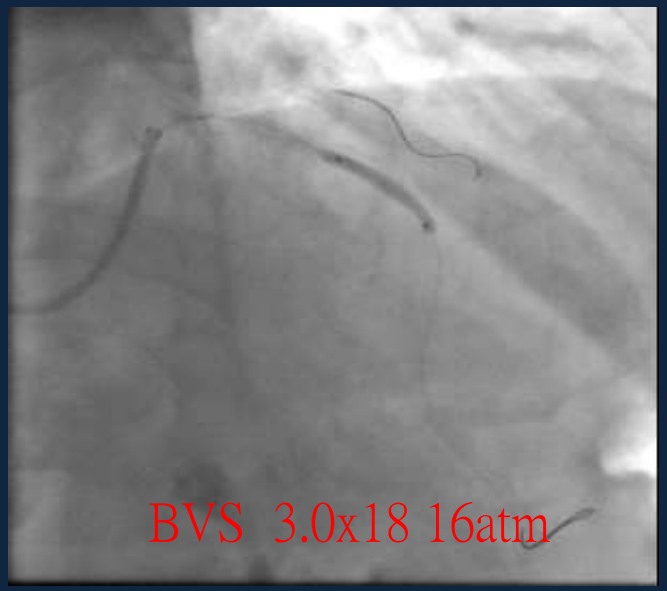
LAD Pre-dilation

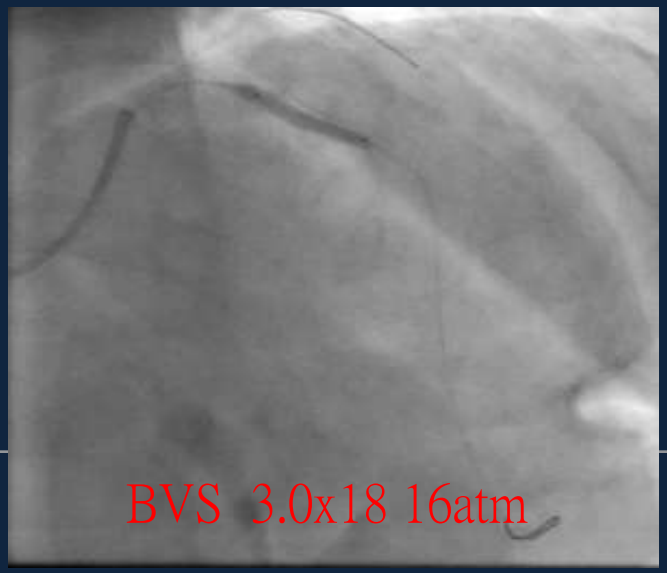




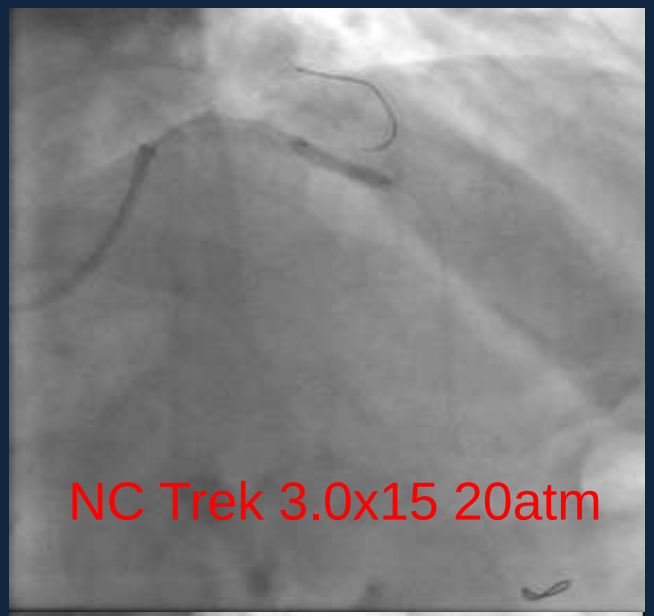


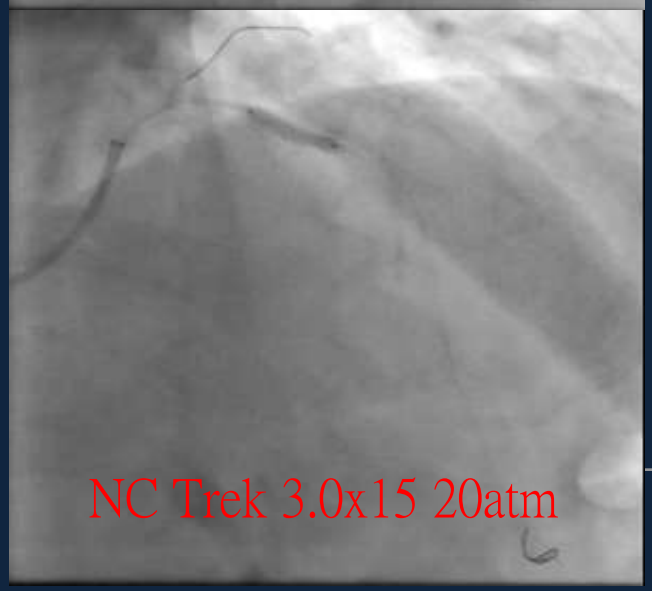
LAD BVS deploy





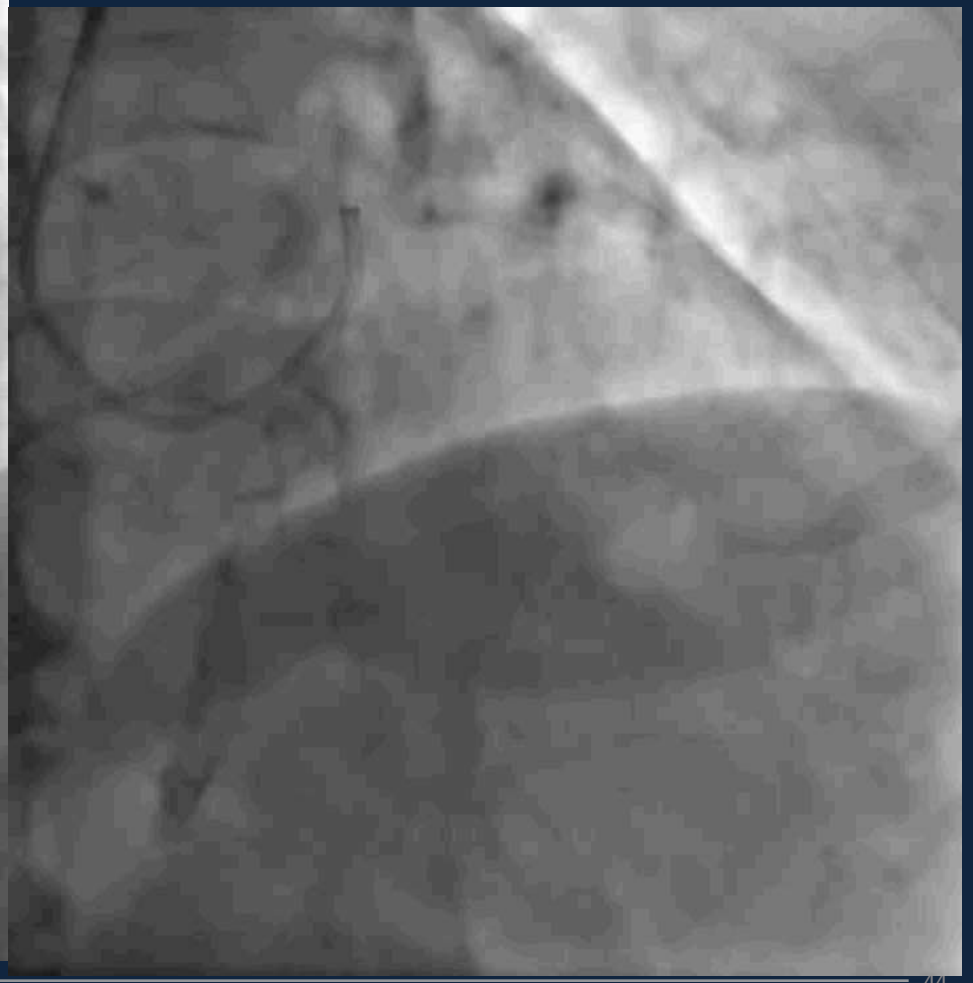
LAD Final



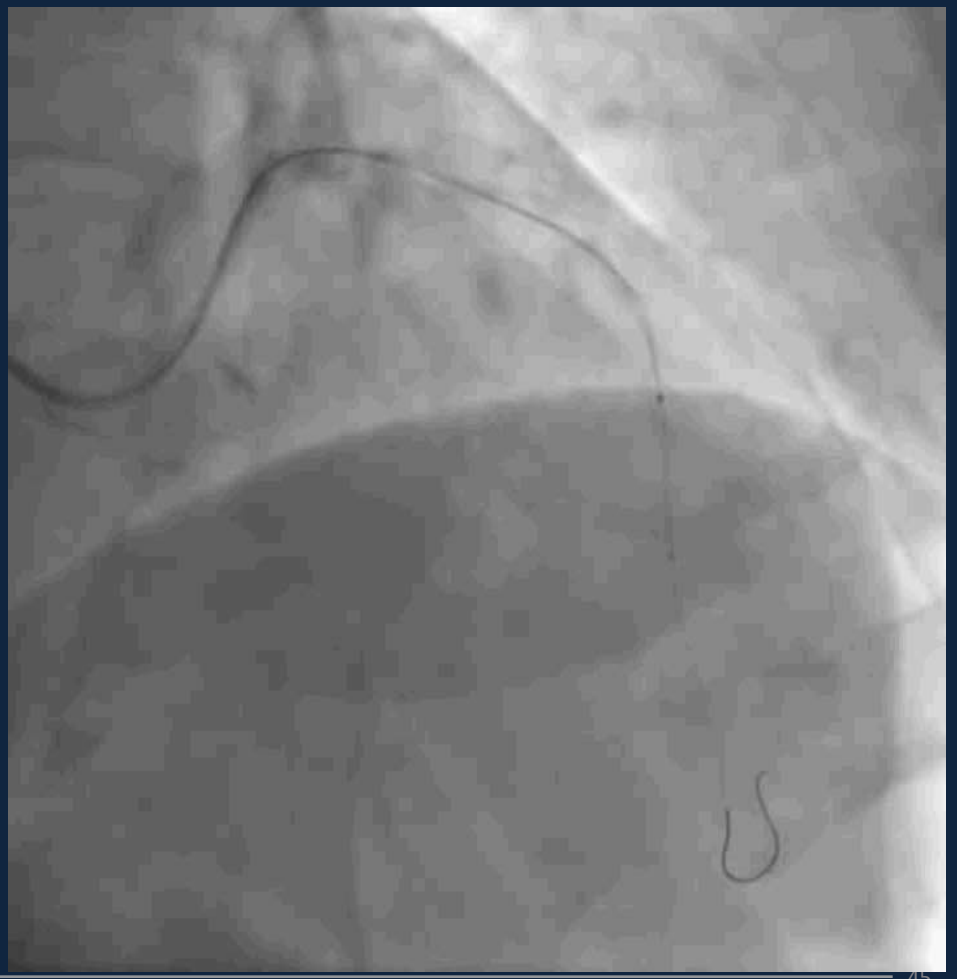


CAG F/U of BVS in RCA-p LAD-p

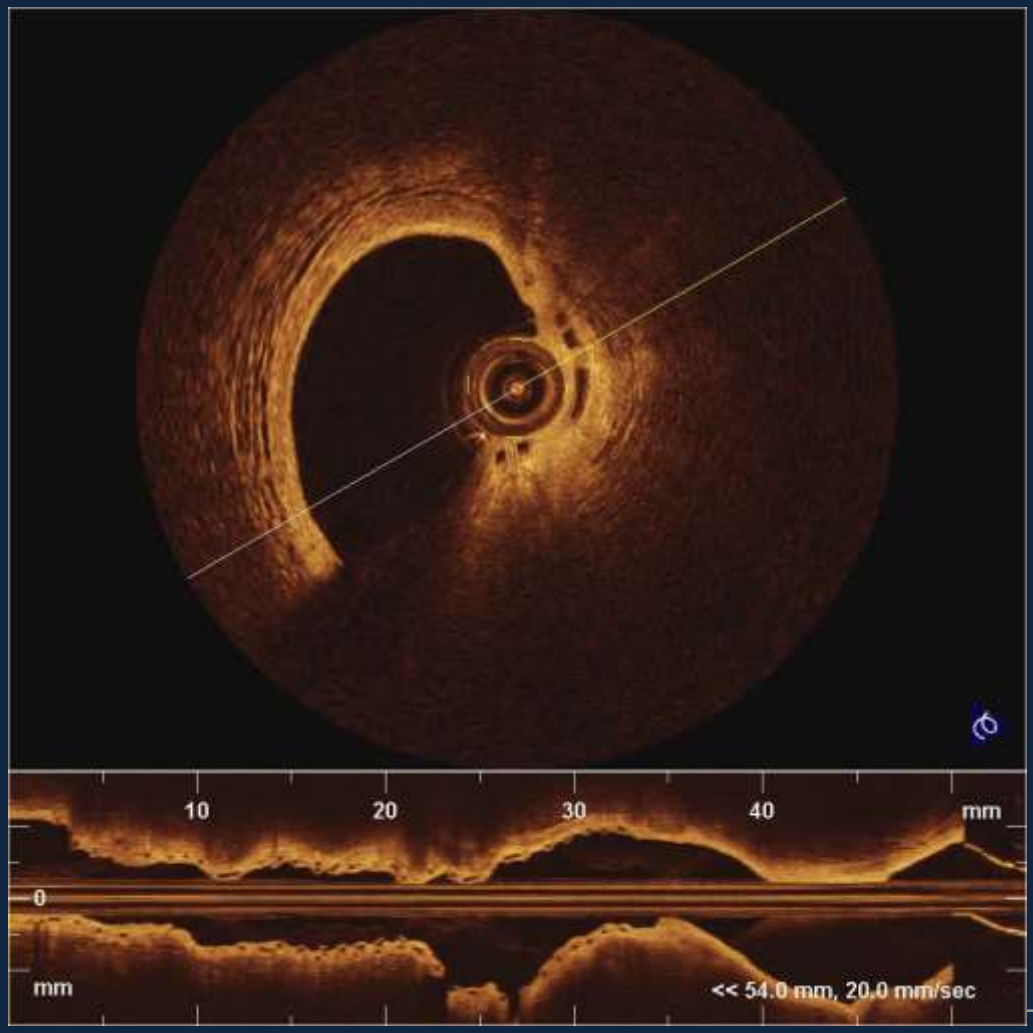
(18 m/o f/u)

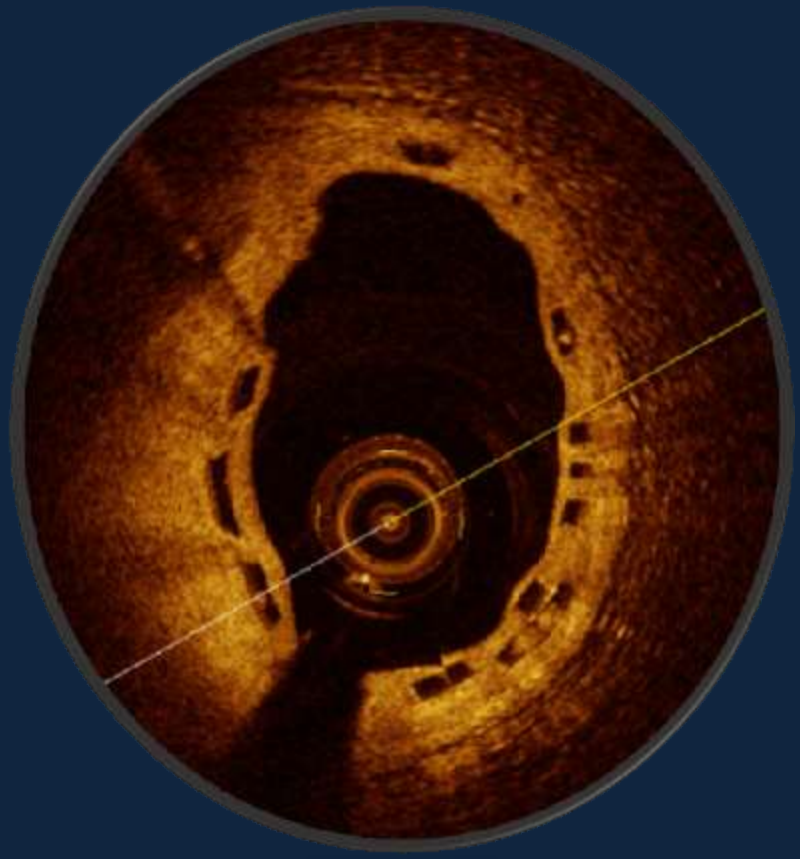


OCT f/u Post BVS for 18m/o

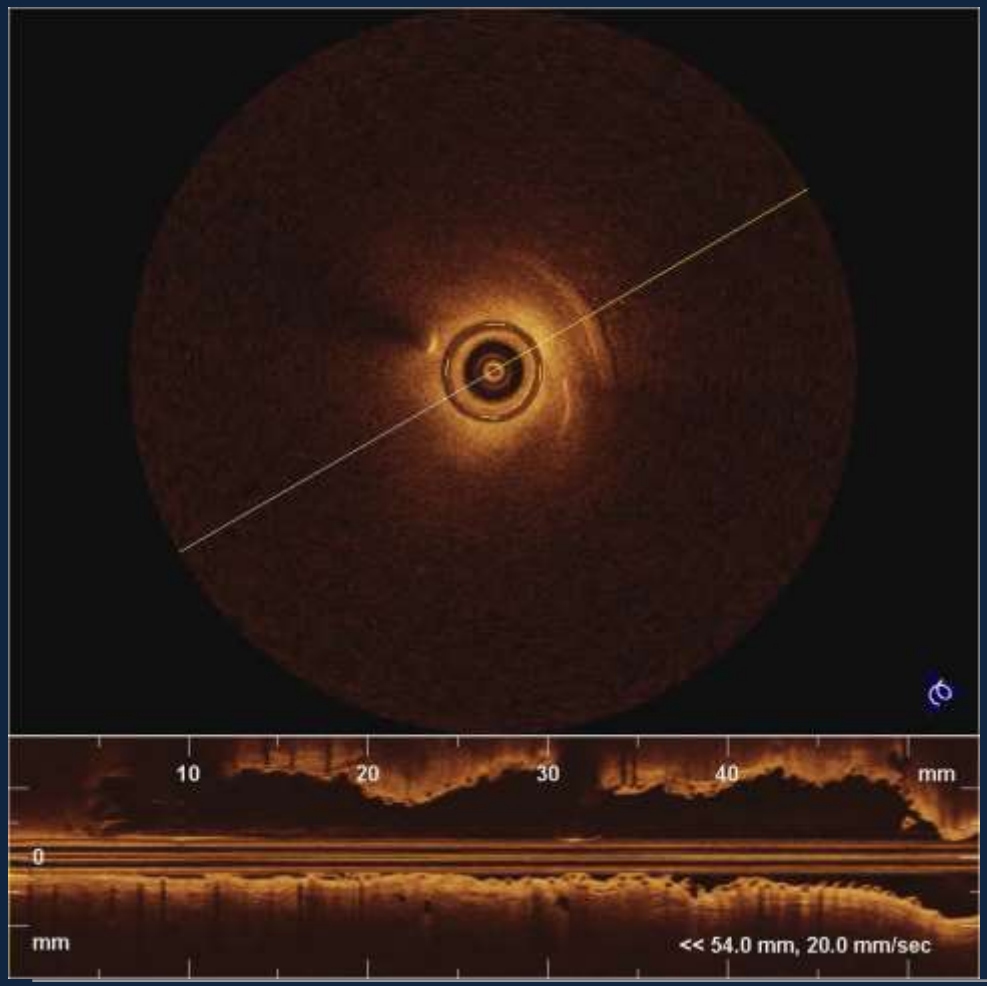


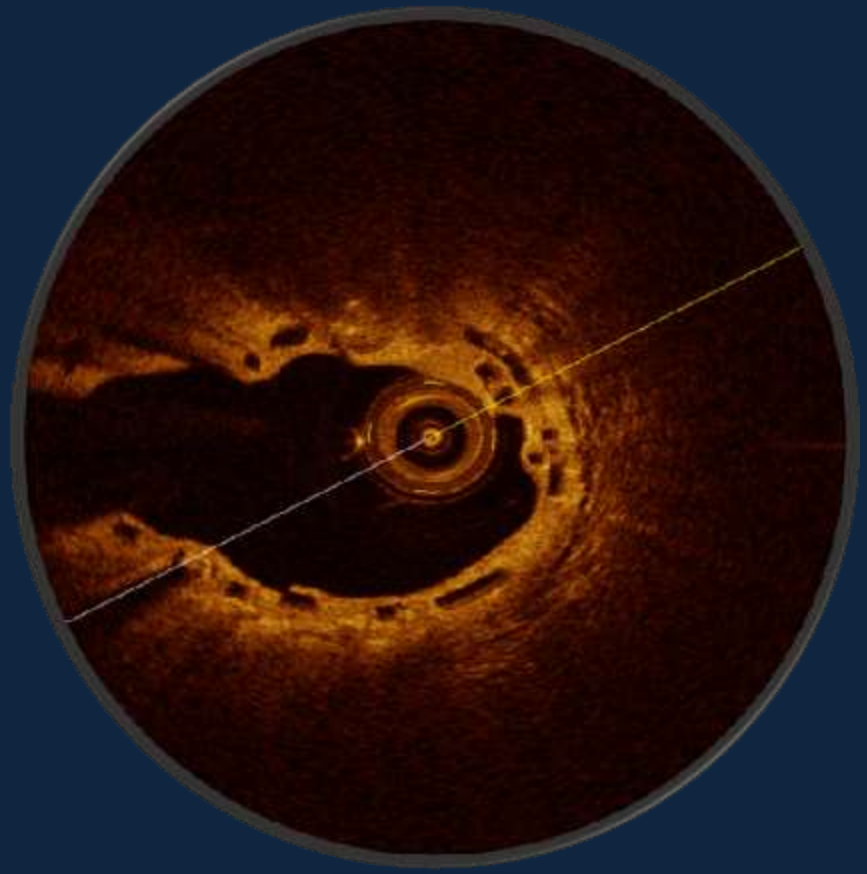
LAD BVS 18-mo F/U OCT



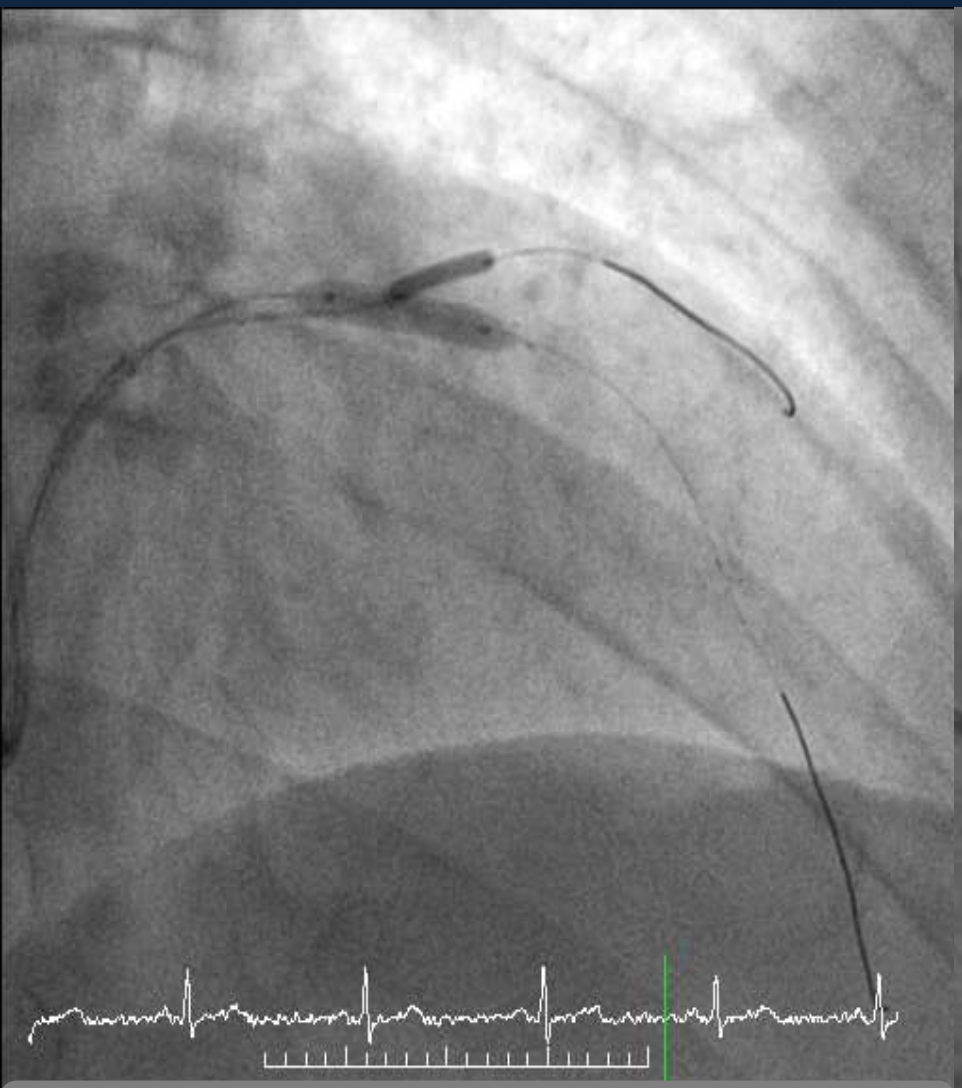


RCA-P BVS 18-mo F/U OCT: remain asymptomatic & MACE free for > 3 yrs





Final snuggle kissing balloon: case Example



Trek 2.0x12-NC/NC Trek 3.5x15 16/16 atm

Conclusions:

- From the most updated prospective randomized studies of Absorb - Japan, II, III, China and post market clinical registry studies, we know that of its safety, feasibility and non-inferiority, however, somewhat higher VLST in Absorb-Japan and Absorb-II, III, AIDA most likely causing by less aggressive post-dilatation and lower incidence of PSP
- Good clinical practice of BVS deployment needs follow device instruction of "PSP" , and more emphasize of imaging study (IVUS, OCT) for sizing, lesion preparation & optimization of scaffold by non-complaint high pressure balloon, start from simple then complex lesions
- Off-label indications for more complex lesions also based on good practice at the beginning period of BVS usage
- Good BVS deployment in any lesions can lead to a lower MACE rate and avoid Late or Vary late Scaffold Thrombosis


THANKS FOR YOUR ATTENTION !
LAD-os BVS ISR
s/p cutting and DEB


TTT
2017
TAIWAN
TRANSCATHETER
THERAPEUTICS
LIVE COURSE
JAN 07-08, 2017
NTUH International
Convention Center,
Taipei, Taiwan


Thank for your
Attention &
Welcome to
Kaohsiung, Taiwan