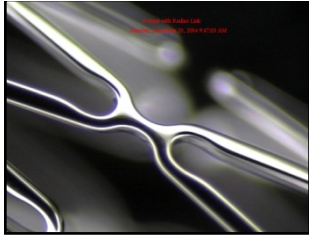


# Experience of Nobori Stent Implantation for Bifurcation Coronary Lesions

Young-Hak Kim, MD, PhD

Cardiac Institute, University of Ulsan College of Medicine  
Asan Medical Center, Seoul, Korea

# Drug-Eluting Stents



**Cypher**  
**Taxus (Express)**

**Taxus (Liberte)**  
**Endeavor**

**Pico Elite**  
**Coroflex Please**

**Xience V /**  
**Promus**  
**Endeavor**

**Xience Prime LL, SV**  
**Promus Element**  
**Resolute Integrity**

**Biomatrix**

**Nobori**

**Genous**

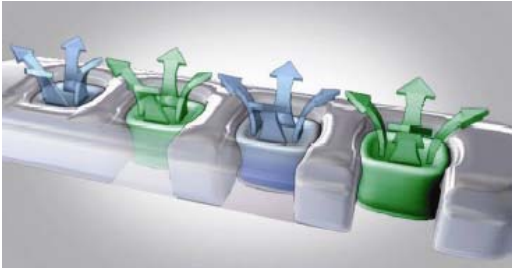
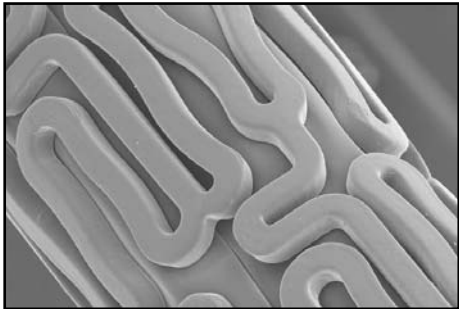


Sirolimus-eluting stent

Drug-free polymers

Sirolimus and polymers

Sirolimus

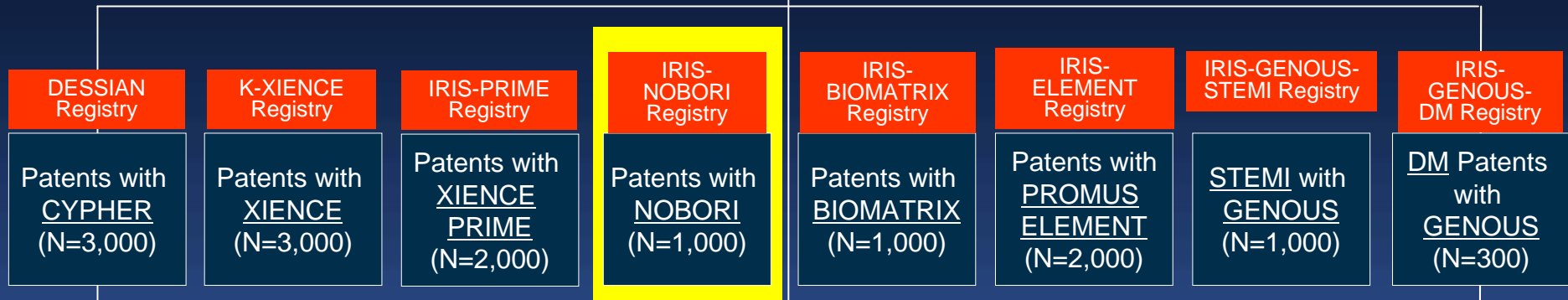


# Evaluation of Effectiveness and Safety of the First, Second, and New Drug-Eluting Stents in Routine Clinical Practice

## IRIS-DES Registry

Consecutive PCI patients receiving New DES in 55 centers without a mixture of other DES

Prospective Enrollment



Clinical follow-up at 1-, 6-, and 12-months, and annually up to 5 years

PI: Seung-Jung Park, MD, PhD

Funded by CVRF and Korean Ministry of Health and Welfare

# IRIS-DES Registry

## Inclusion Criteria

- Patients receiving Nobori (or other default DES) as the PCI devices.
- No limitation of clinical or lesion characteristics
- Agreement to the study protocol and informed consent

## Limited Exclusion Criteria

- Patients with a mixture of other DESs
- Terminal illness with life expectancy <1 year
- Patients with cardiogenic shock

# Study Outcomes

## Primary End Points

Major cardiac adverse event (MACE); a composite of death, non-fatal MI, or TVR at 12 months post procedure.

## Secondary End Points

- Death
- MI
- Composite of death or MI
- Repeat revascularization
- TVR
- Stent thrombosis (ARC criteria)
- Procedural success

# IRIS-NOBORI Registry

## From June 2010

- 586 patients were enrolled in 28 investigating sites in Korea

# Baseline Characteristics

Variables	586 patients
Age, year	63.6 ± 10.7
Male	68.3%
Hypertension	64.5%
Diabetes mellitus	35.2%
Smoking	48.4%
Hyperlipidemia	47.0%
Prior CABG	1.4%
History of MI	5.4%
Prior PCI	10.2%
Family history	4.0%
Prior heart failure	1.4%
Prior stroke	7.7%
Peripheral disease	1.4%

# Baseline Characteristics

Variables	586 patients
Chronic renal failure	2.8%
Chronic lung disease	2.8%
Ejection fraction, %	59.3 ± 9.0
Symptom	
Stable angina	39.2%
Unstable angina	31.7%
NSTEMI	17.8%
STEMI	11.3%
Diagnosis	
1 vessel	59.2%
2 vessel	27.2%
3 vessel	13.3%
Left main	2.1%



# Procedural Characteristics

Variables

586 patients

Target lesion

LAD

58.6%

LCX

24.9%

RCA

29.3%

Left main

1.3%

IVUS guidance

90.8%

Urgent procedure

16.2%

Use of IABP

3.2%

Number of stents per patients

1.4 ± 0.8

Length of stents per patients, mm

33.8 ± 21.1

# Nobori in Bifurcation Lesions

- 106 patients (18.7%) had bifurcation lesions with side branches  $> 1.5$  mm which were treated with Nobori stents.
- 1-year outcomes will be available at the end of this year.
- The outcomes will be compared with others DES in all patients and subgroups including bifurcation lesions.

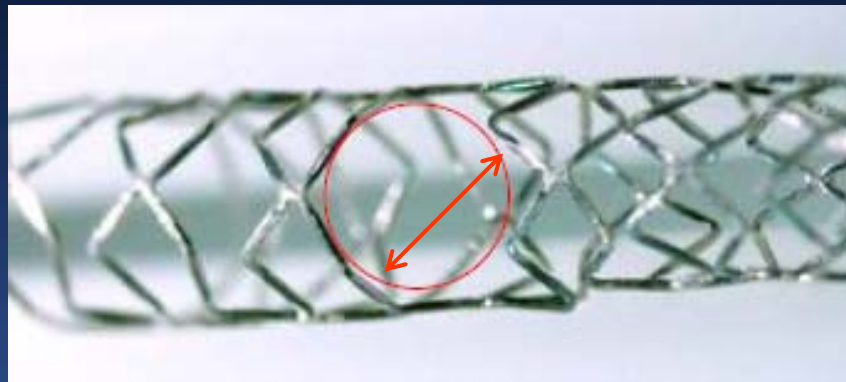
# Selection of Stent for Bifurcation

- Strut width and thickness
- Potential stent deformation
- Conformability
- Diameter of the open cell
- Comparative results with other DESs

# Open Cell Diameter of Nobori Stent

**2.9 mm**

in 3 mm Nobori stent



**3.0 mm**

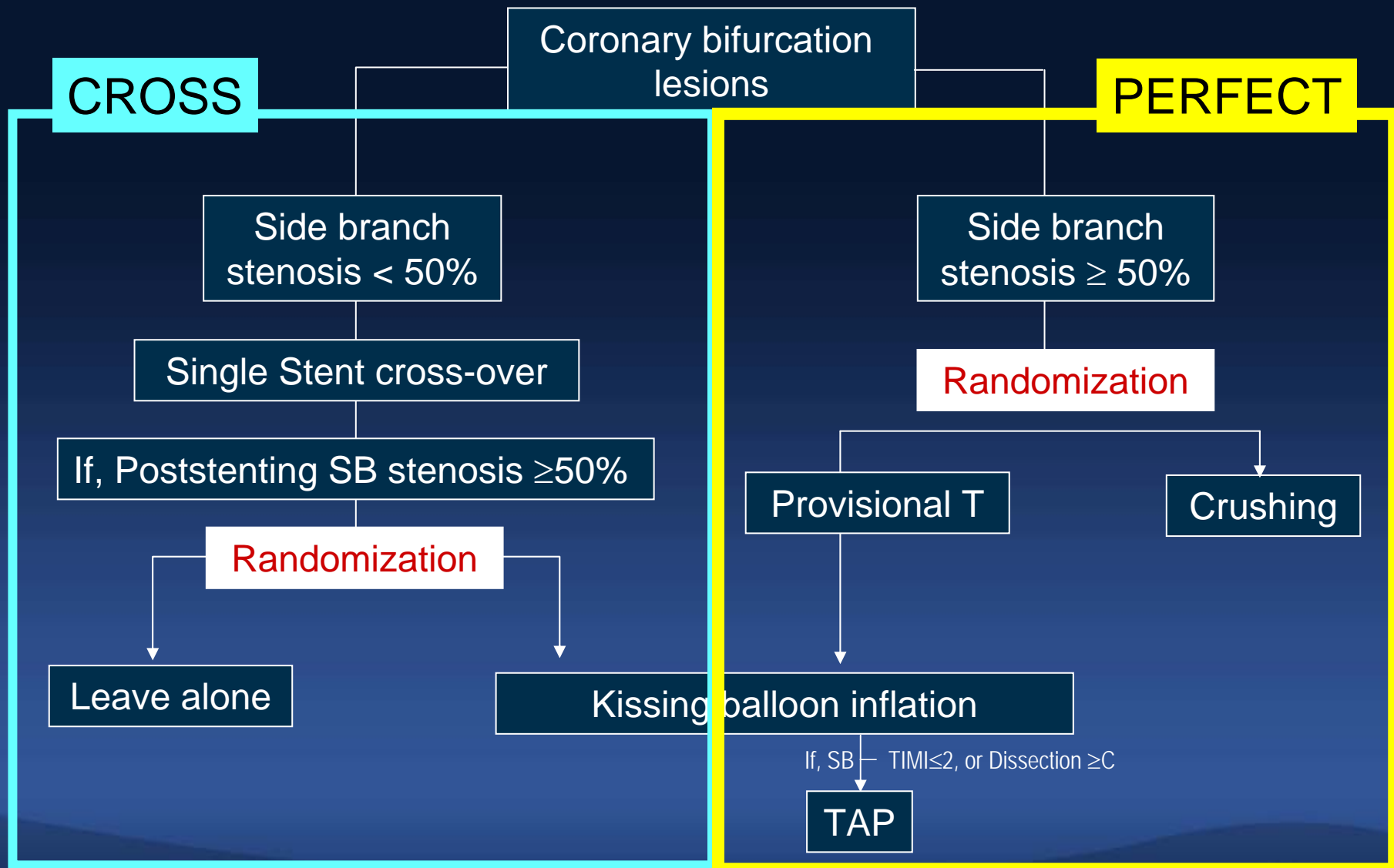
in 3.5 mm Nobori stent



# Case Examples

# CROSS & PERFECT Trials in Korea

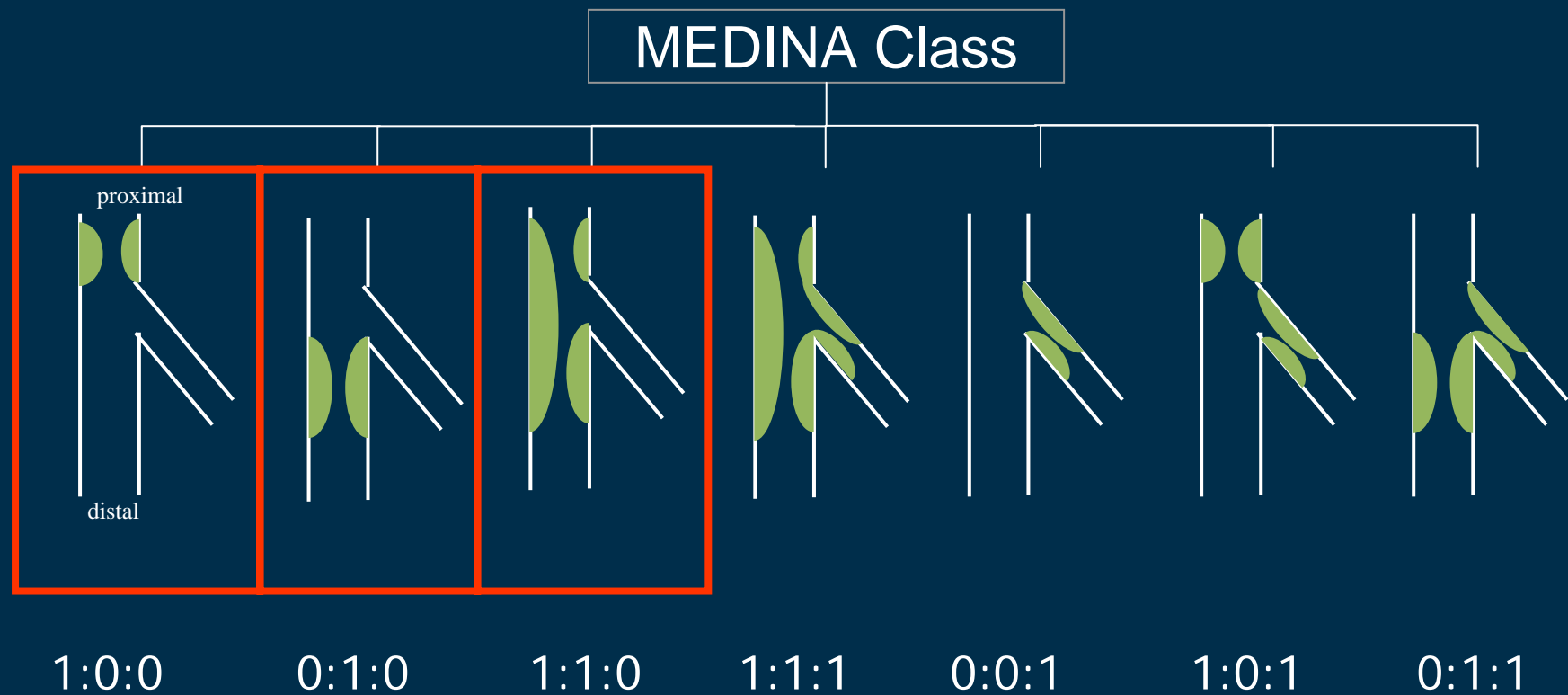
*to assess IVUS-Guided Bifurcation Stenting*



Choice of optimal strategy for bifurcation lesions  
with normal side branch

# CROSS Trial

Bifurcations without SB Stenosis



# CROSS

Bifurcation without SB stenosis by angiography

**Any DES**  
(N=600)

After MV stenting

SB DS  $\geq$  50% & TIMI 3 flow

2<sup>nd</sup> Randomization

• Stratified by sites

TIMI  $\leq$  2 flow

Registry

1. Treatment at the operator's discretion

SB DS < 50% & TIMI 3 flow

Registry

1. IVUS exam in MV
2. FFR in SB (selected sites)

**Kissing balloon group**  
(N=150)

1. FFR in SB before kissing balloon
2. Rewire into SB
3. Kissing balloon inflation

**Leave it alone group**  
(N=150)

1. IVUS exam in MV
2. FFR in SB (selected sites)

SB DS < 70% & TIMI 3  
Dissection none or  $\leq$  class B

1. IVUS in MV
2. FFR in SB (selected sites)

SB DS  $\geq$  70% or TIMI  $\leq$  2 or  
Dissection  $\geq$  class C

1. FFR in SB (selected sites)
2. Provisional T stenting in SB \*
3. IVUS in both branches

\* The decision can not be influenced by the value of FFR.

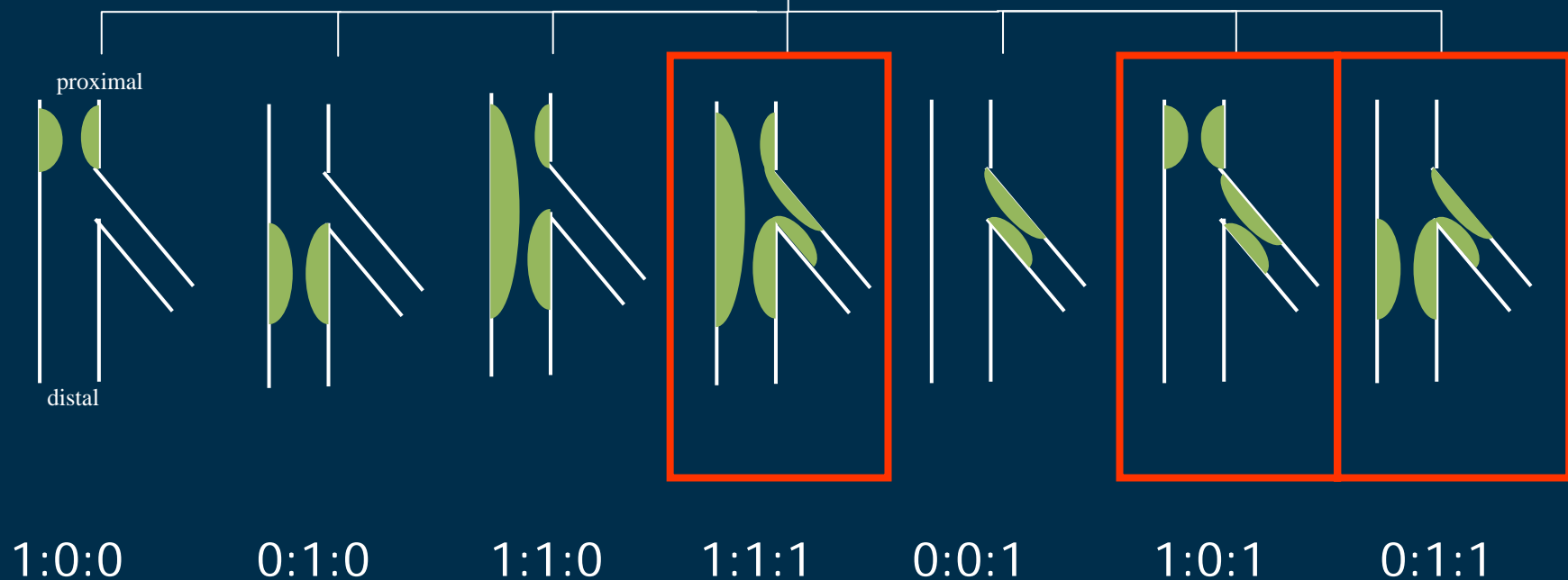


Optimal Stenting Strategy For True Bifurcation

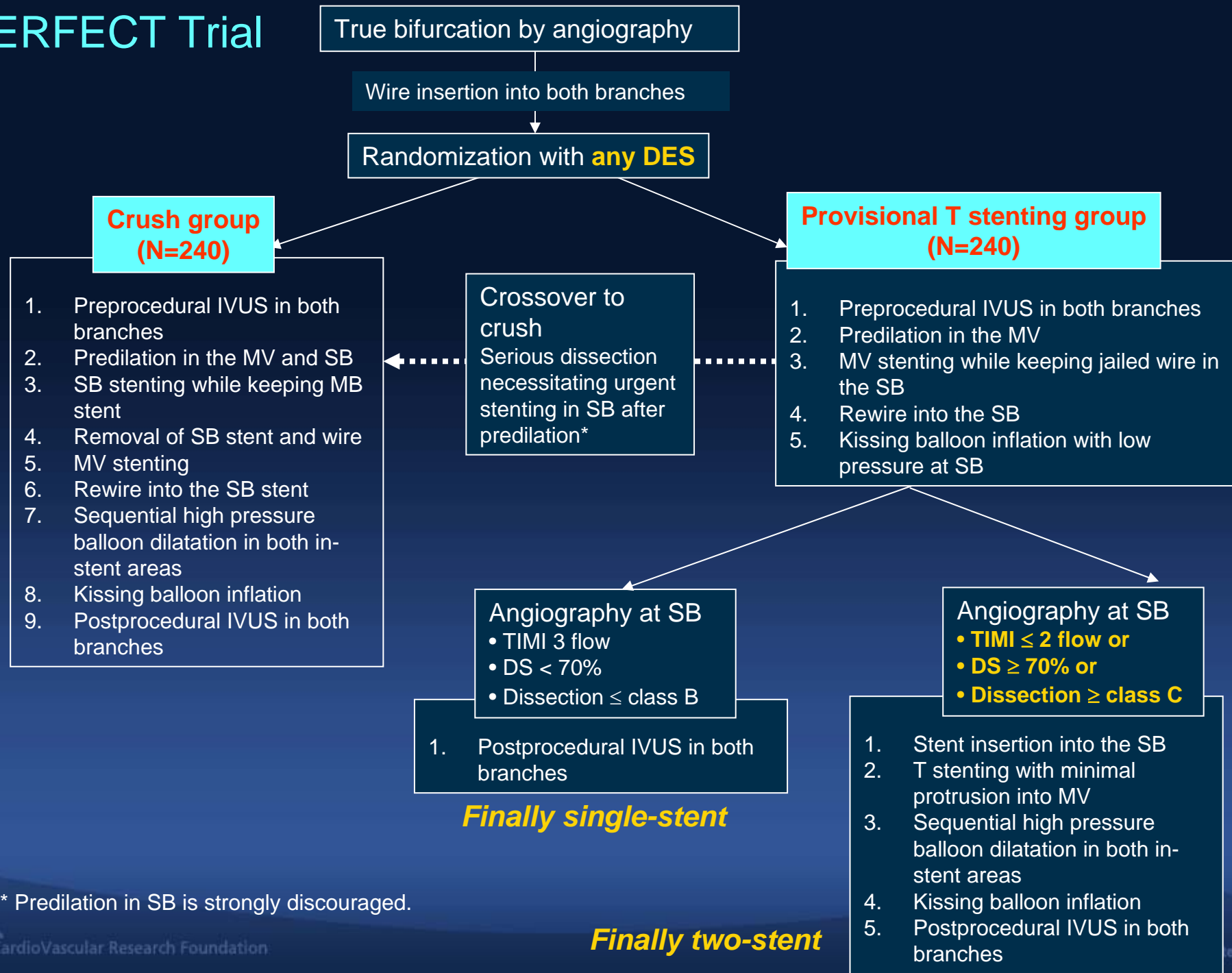
# PERFECT Trial

## Bifurcations with SB Stenosis

### MEDINA Class

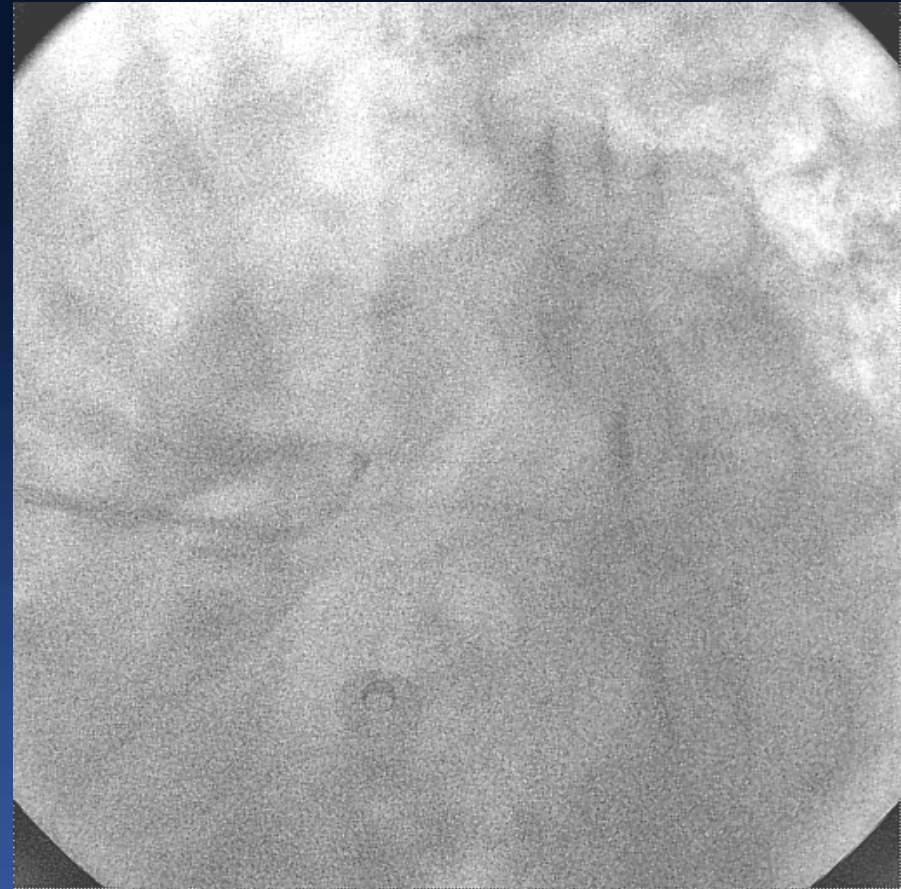
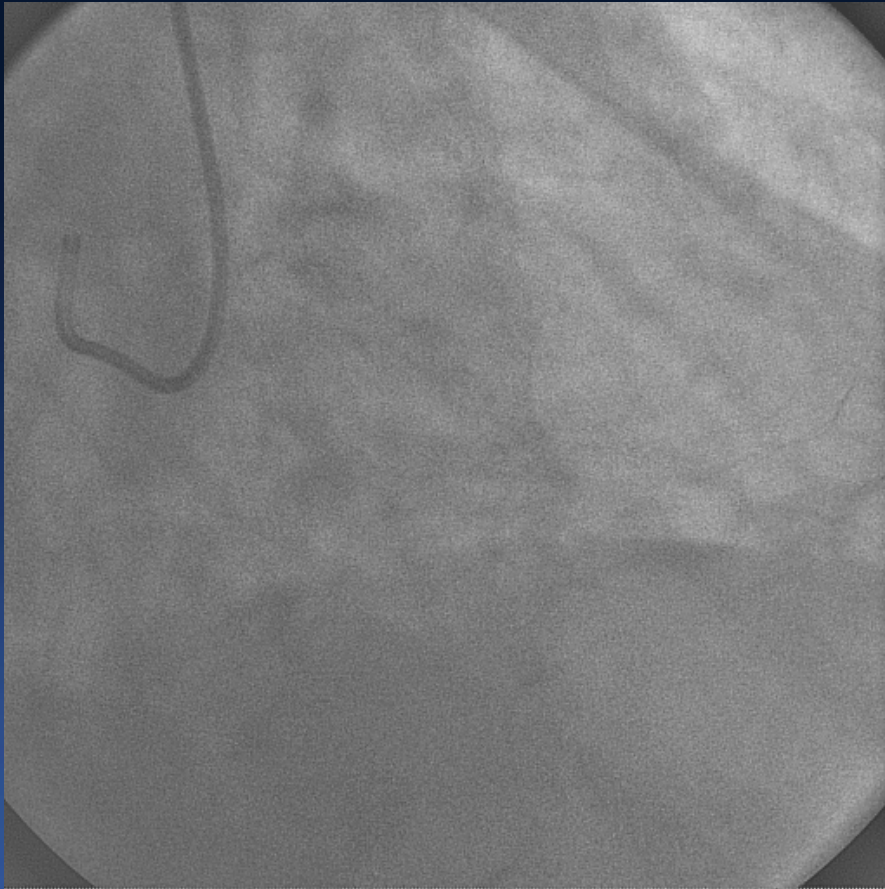


# PERFECT Trial



\* Predilation in SB is strongly discouraged.

# Case 1 : Bifurcation Stenosis

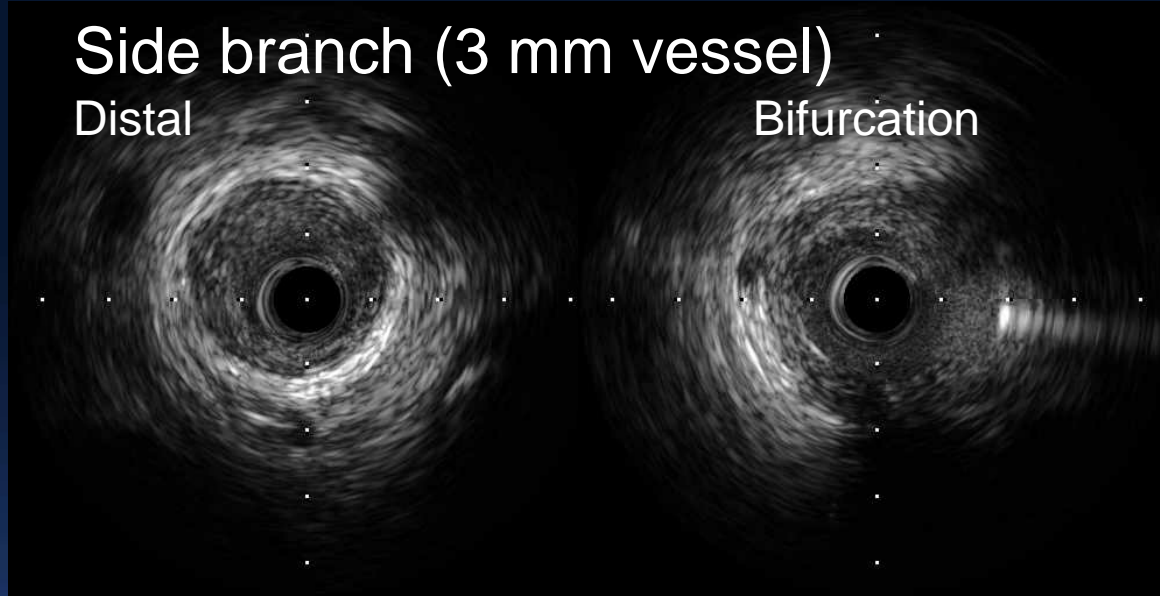


# IVUS Evaluation

Side branch (3 mm vessel)

Distal

Bifurcation

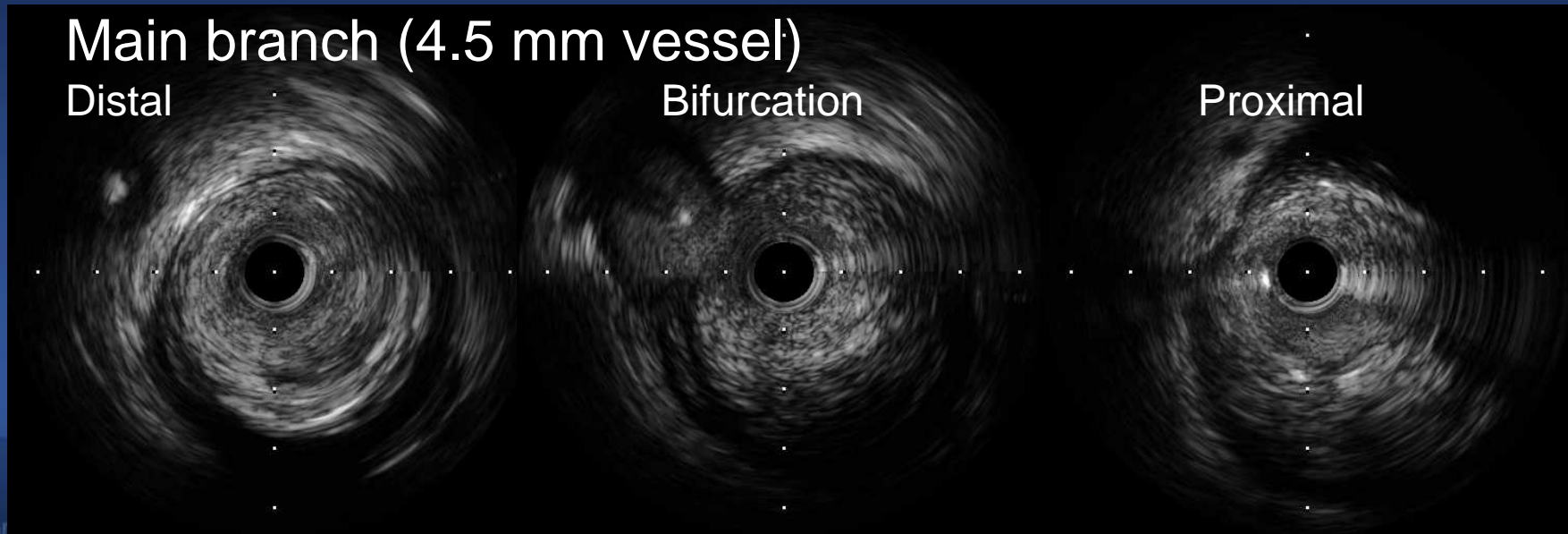


Main branch (4.5 mm vessel)

Distal

Bifurcation

Proximal



# Provisional Stenting Strategy

Compliant Balloon 2.5mm

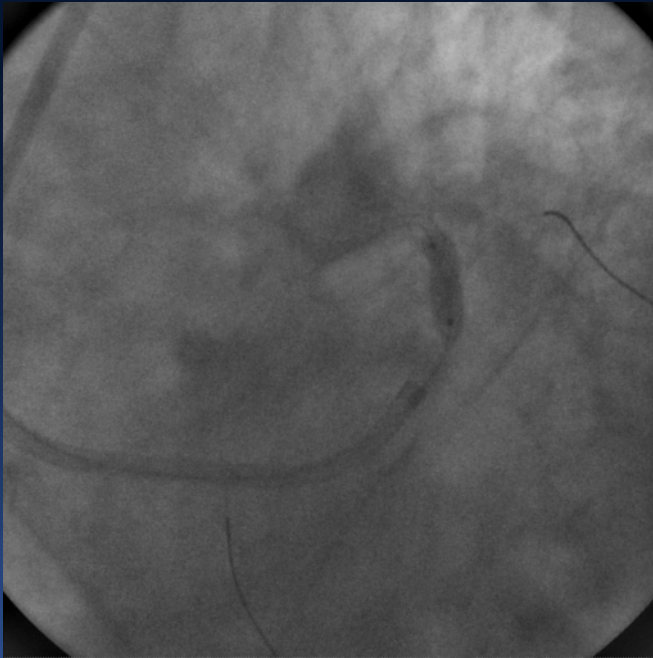
1<sup>st</sup> Nobori 3.5X23 mm

Stent Balloon

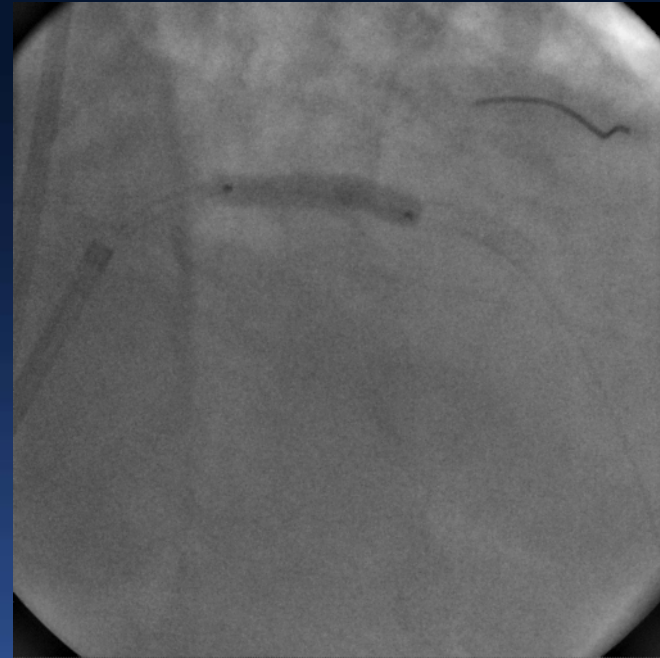


# Provisional Stenting Strategy

2<sup>nd</sup> Nobori 3.5x18mm



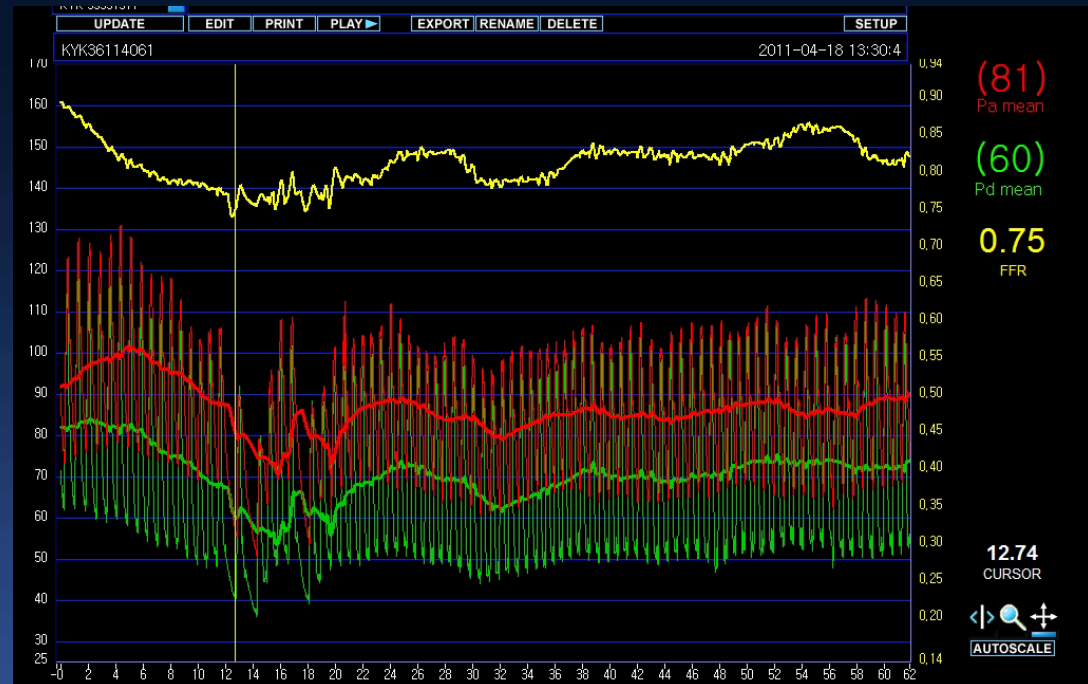
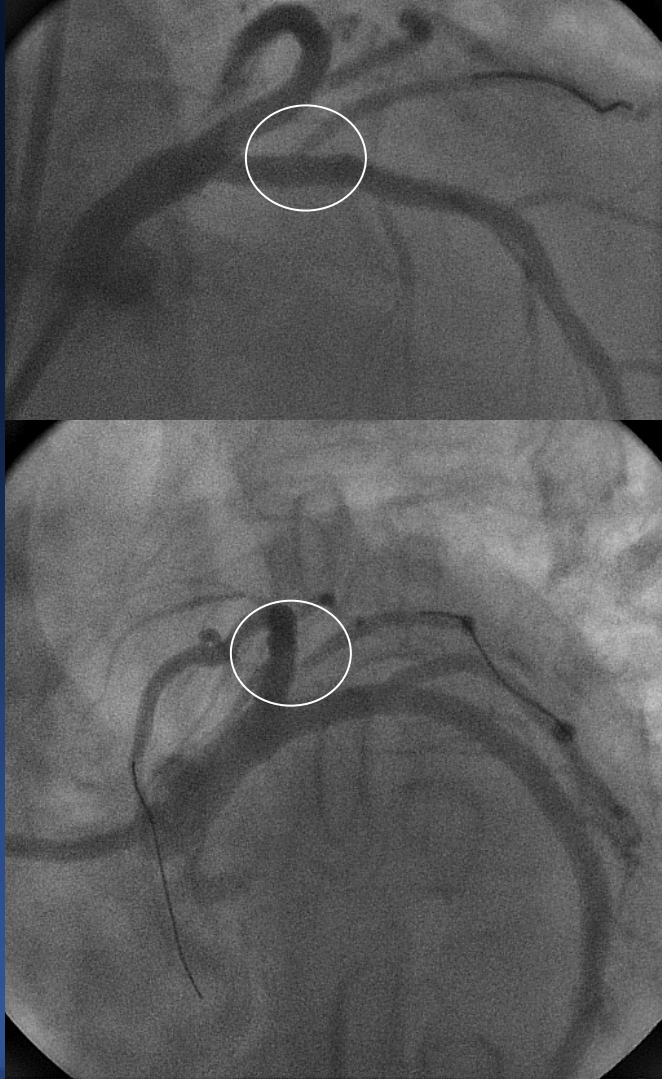
Non-compliant B 3.5mm



# After Main Branch Stenting



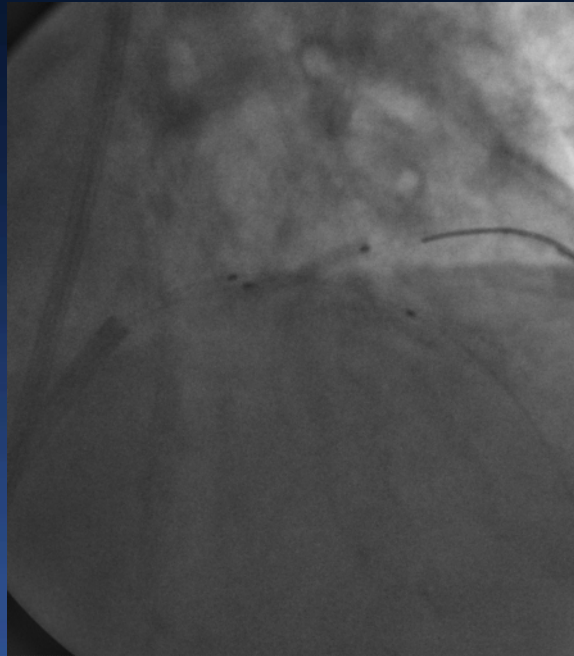
# FFR Assessment



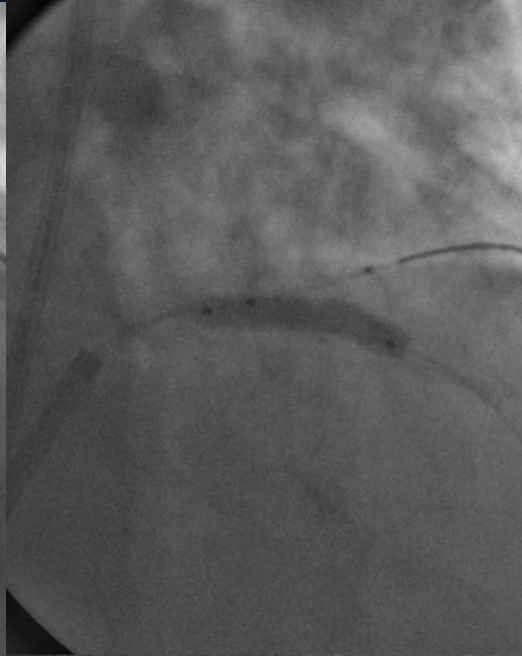


# Kissing Balloon Inflation

Compliant 2.5 mm



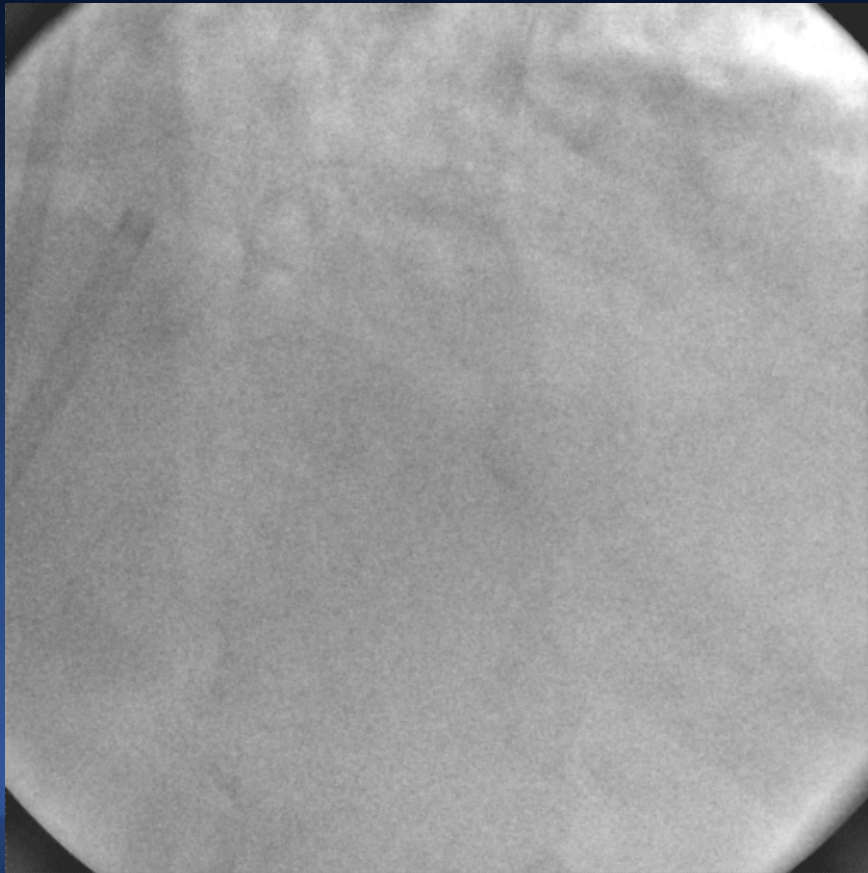
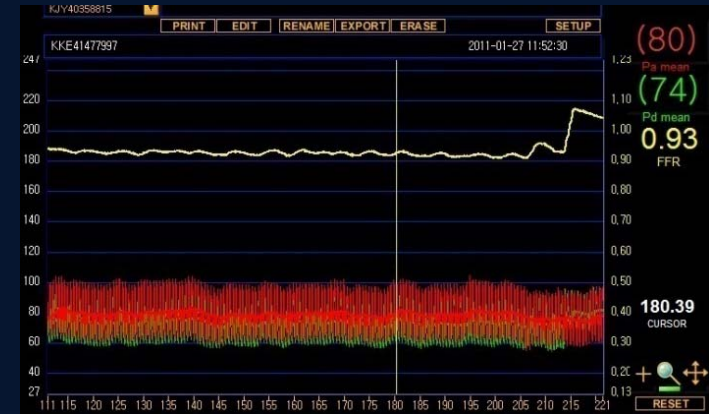
NC 3.5 mm



Kissing balloon



# FFR and Angiograms

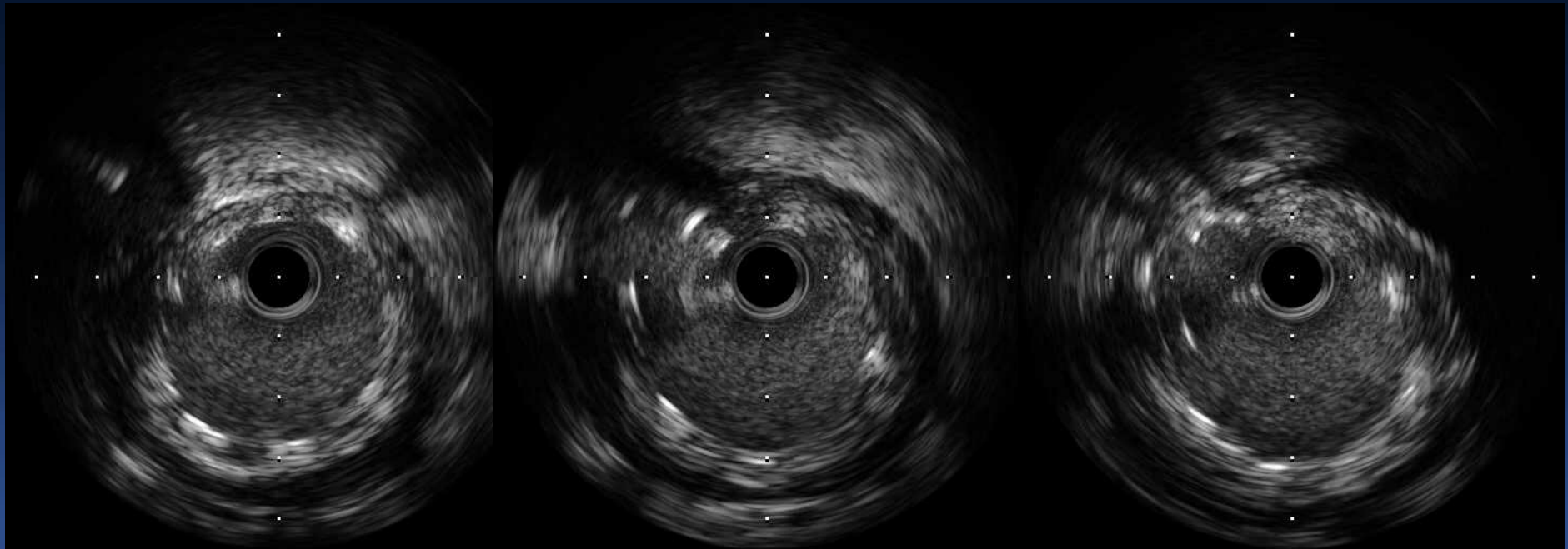


# Final IVUS in LAD

Distal segment

Bifurcation

Proximal segment

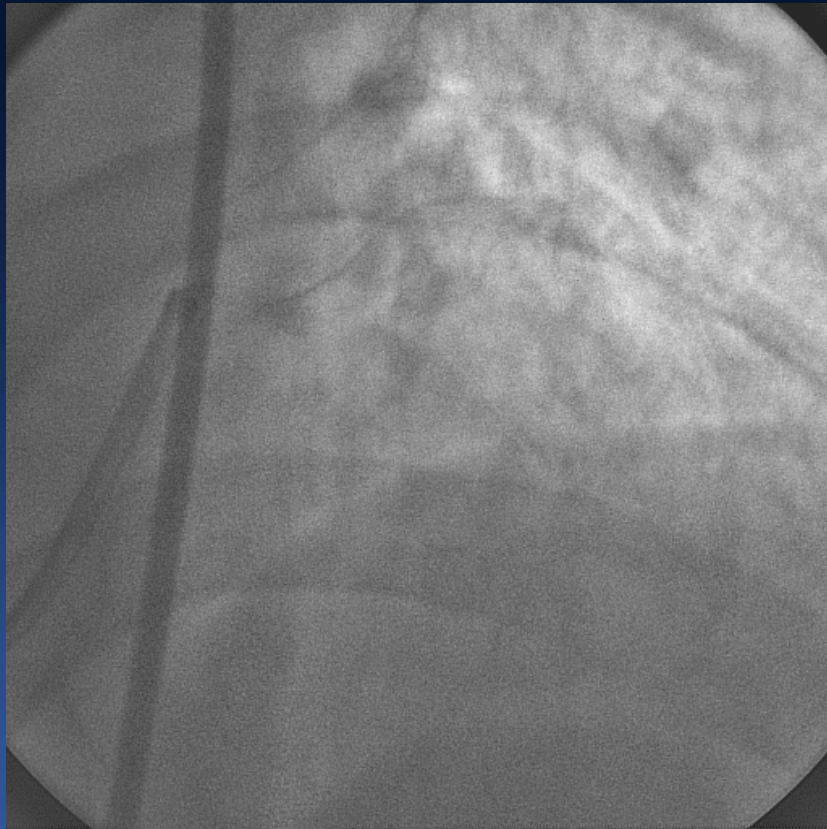


10.1 mm<sup>2</sup>

9.4 mm<sup>2</sup>

10.5 mm<sup>2</sup>

# Case 2 : True Bifurcation



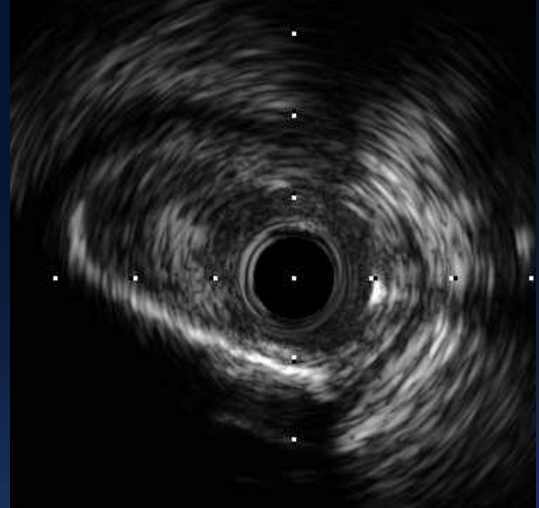
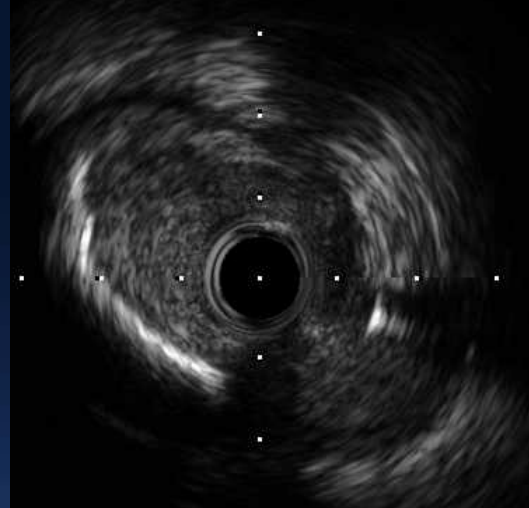
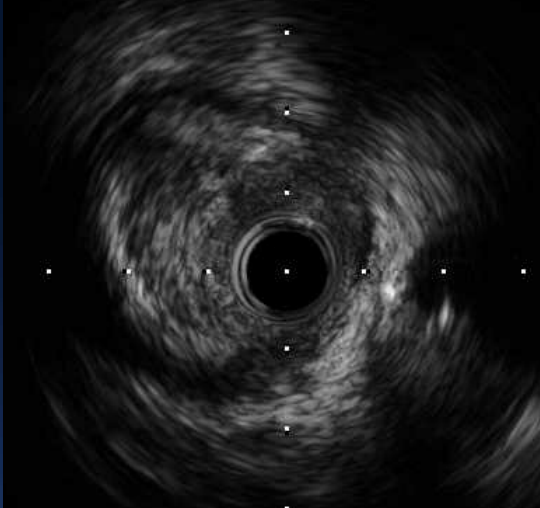
# IVUS Evaluation

Distal segment

Bifurcation

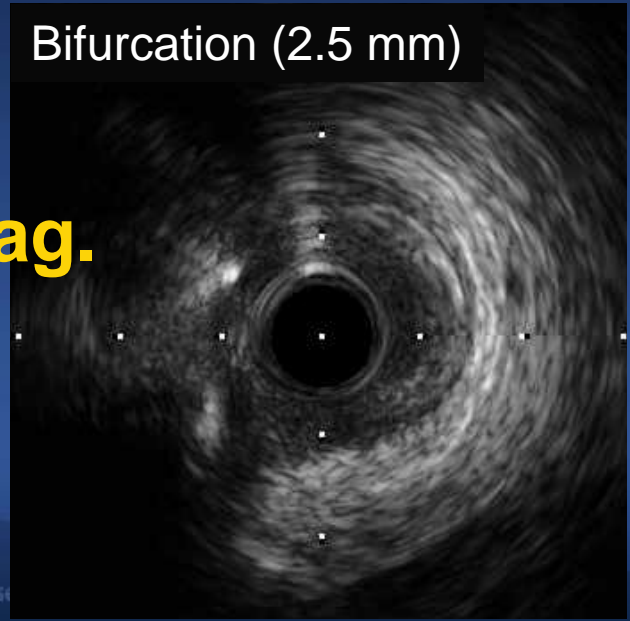
Proximal segment

LAD



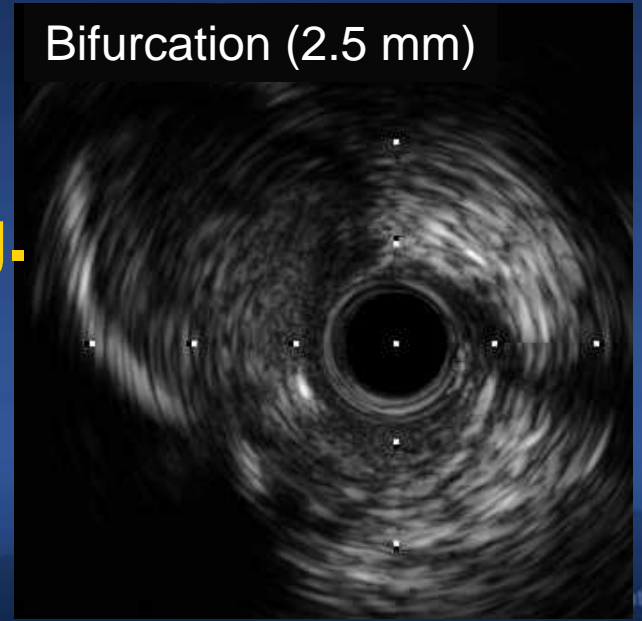
Bifurcation (2.5 mm)

1<sup>st</sup> Diag.

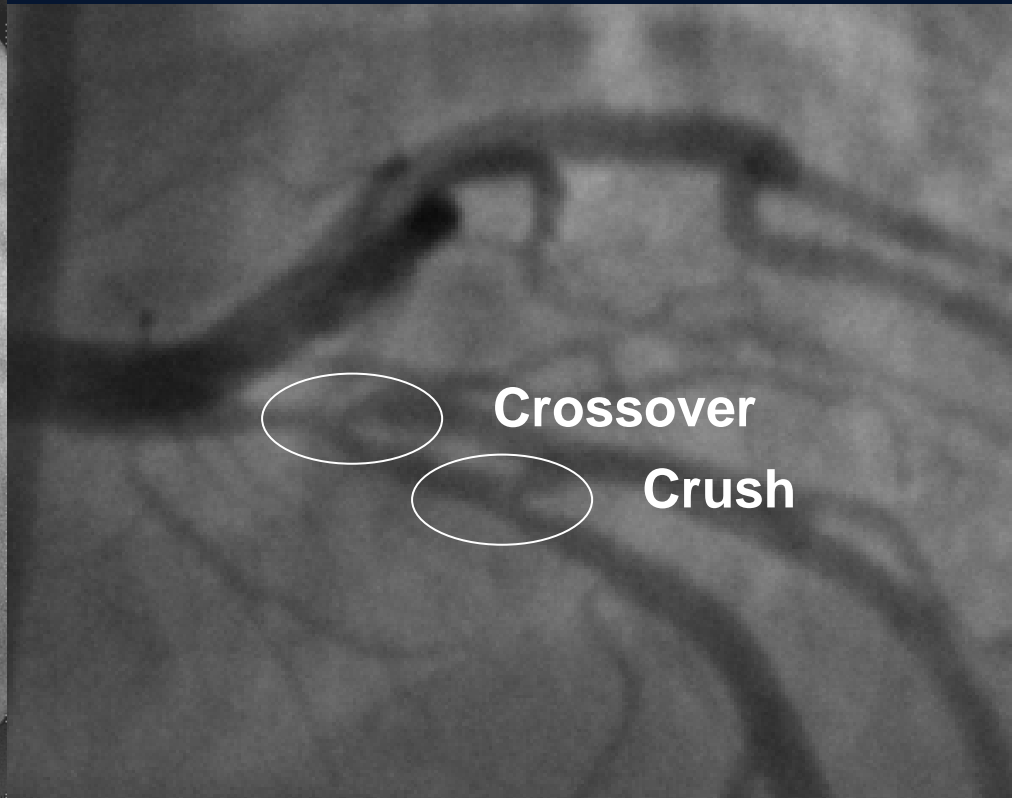
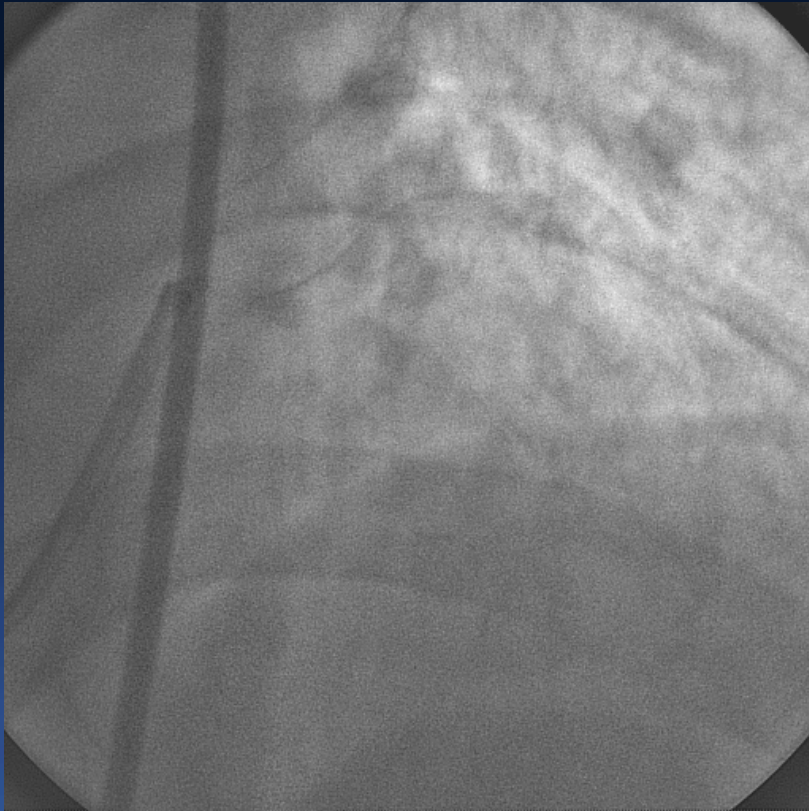


2<sup>nd</sup> Diag.

Bifurcation (2.5 mm)



# Planning



# Stent Crush

Compliant 2.0mm

Compliant 2.0mm

Nobori 2.5x18mm

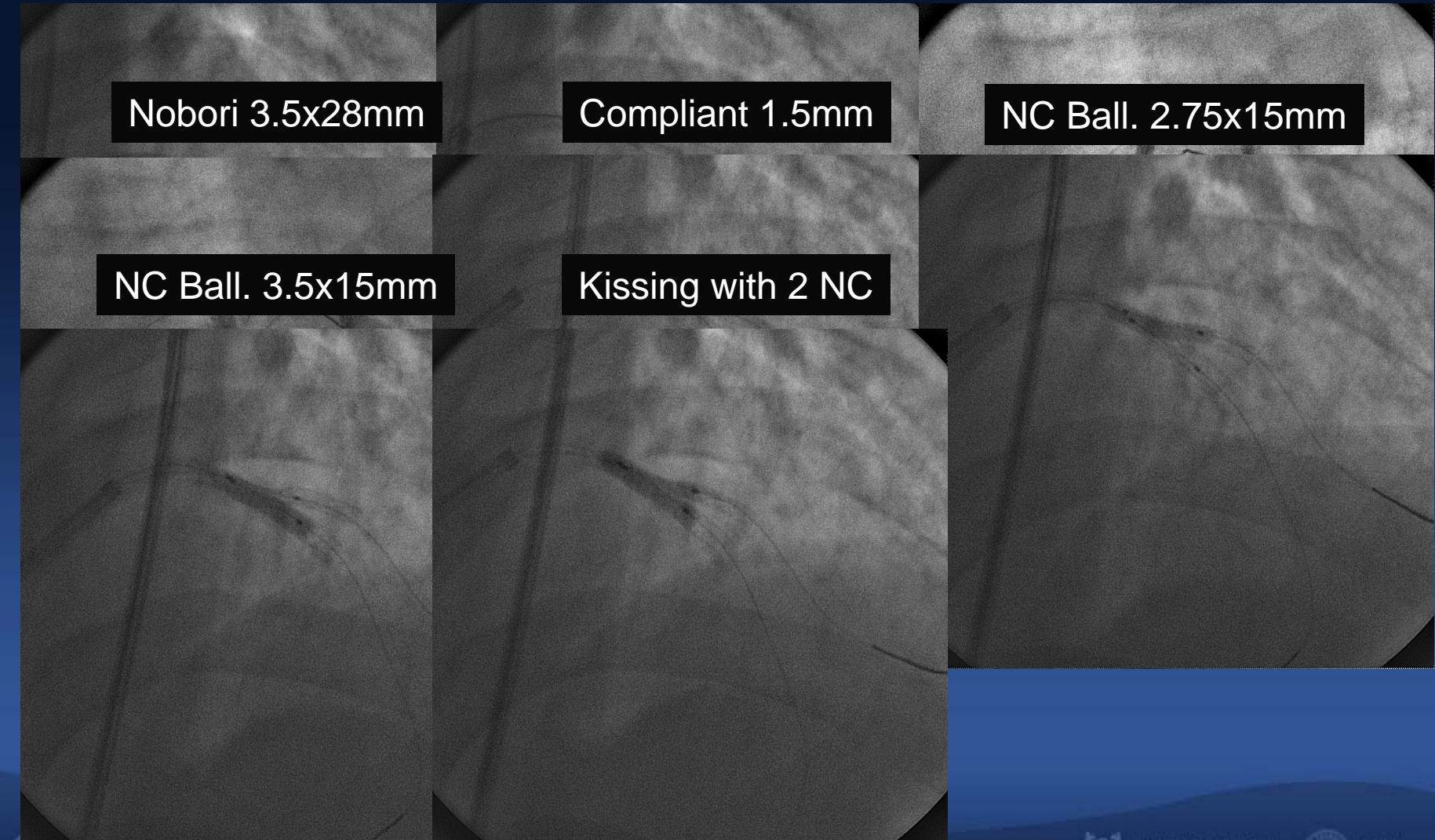
Nobori 3.5x28mm

Compliant 1.5mm

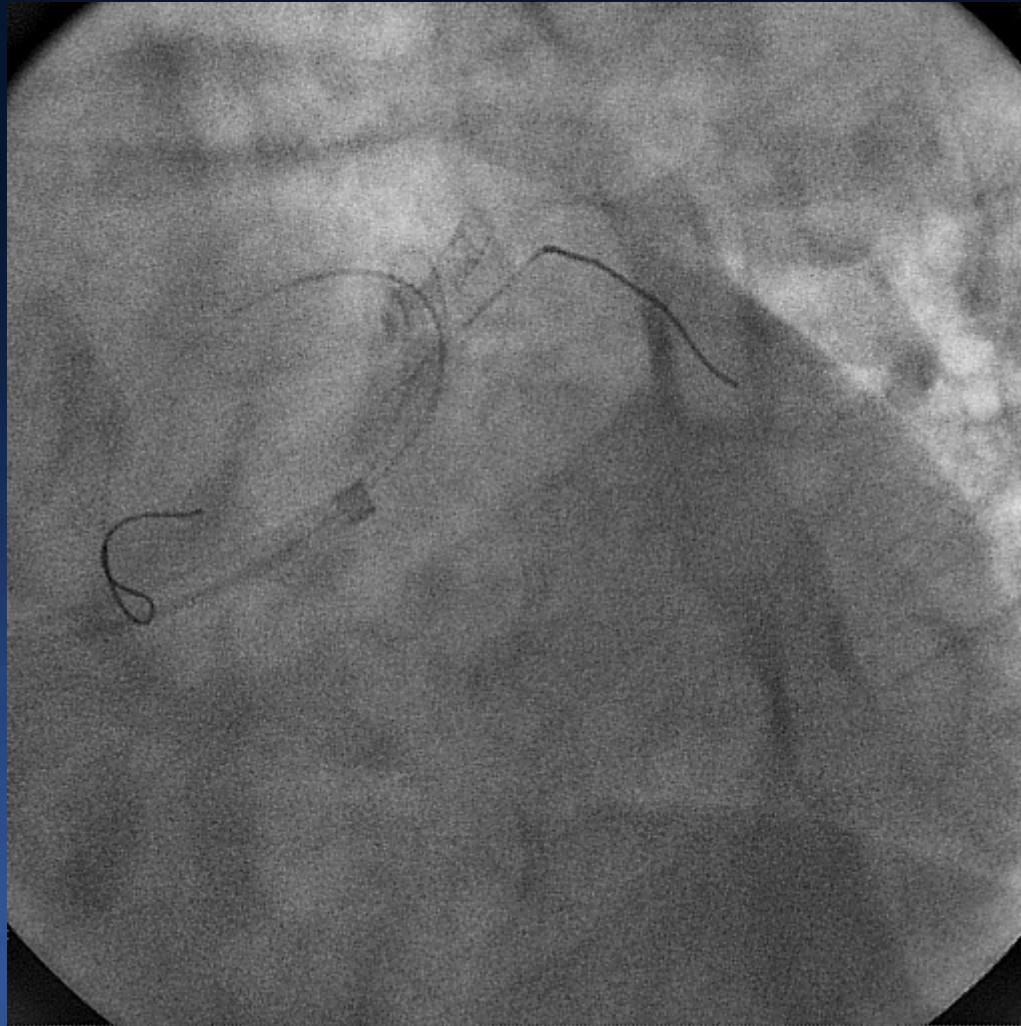
NC Ball. 2.75x15mm

NC Ball. 3.5x15mm

Kissing with 2 NC



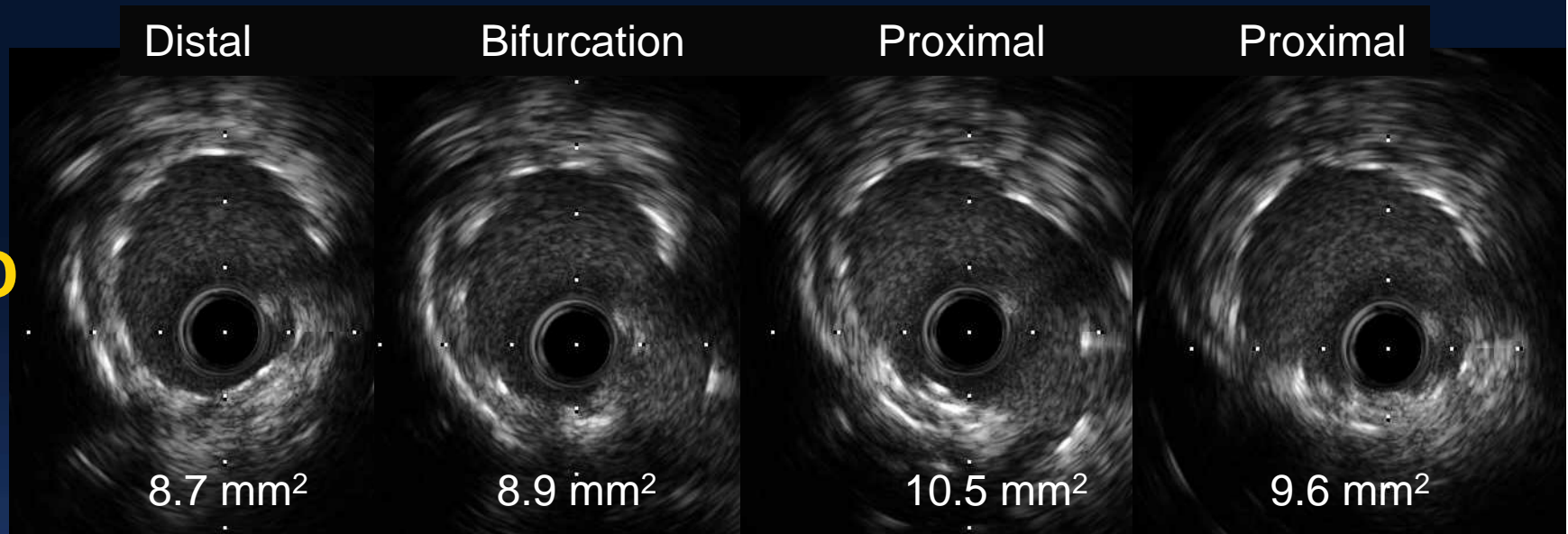
# Finals without Touch for the 1<sup>st</sup> Diag.



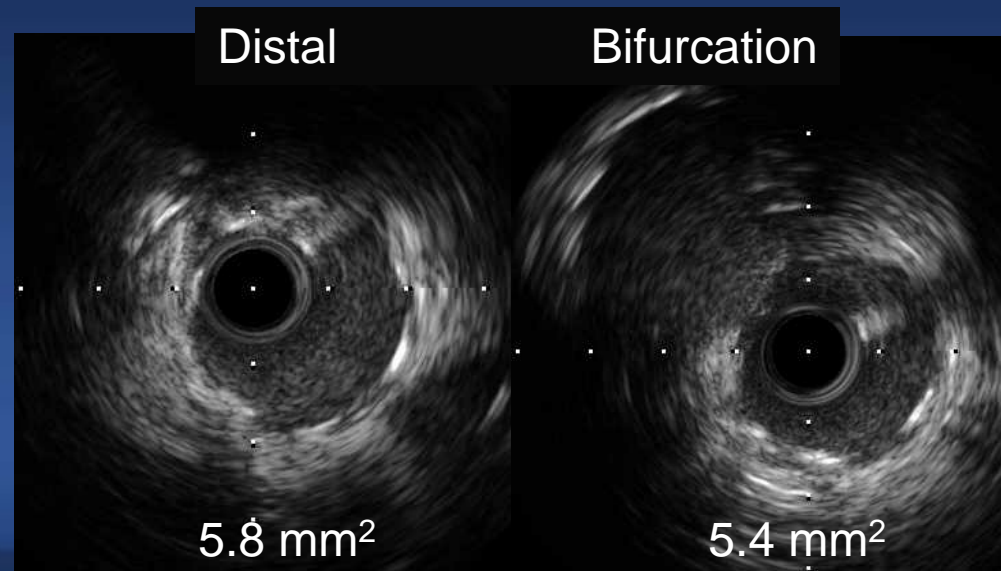


# Final IVUS Evaluation

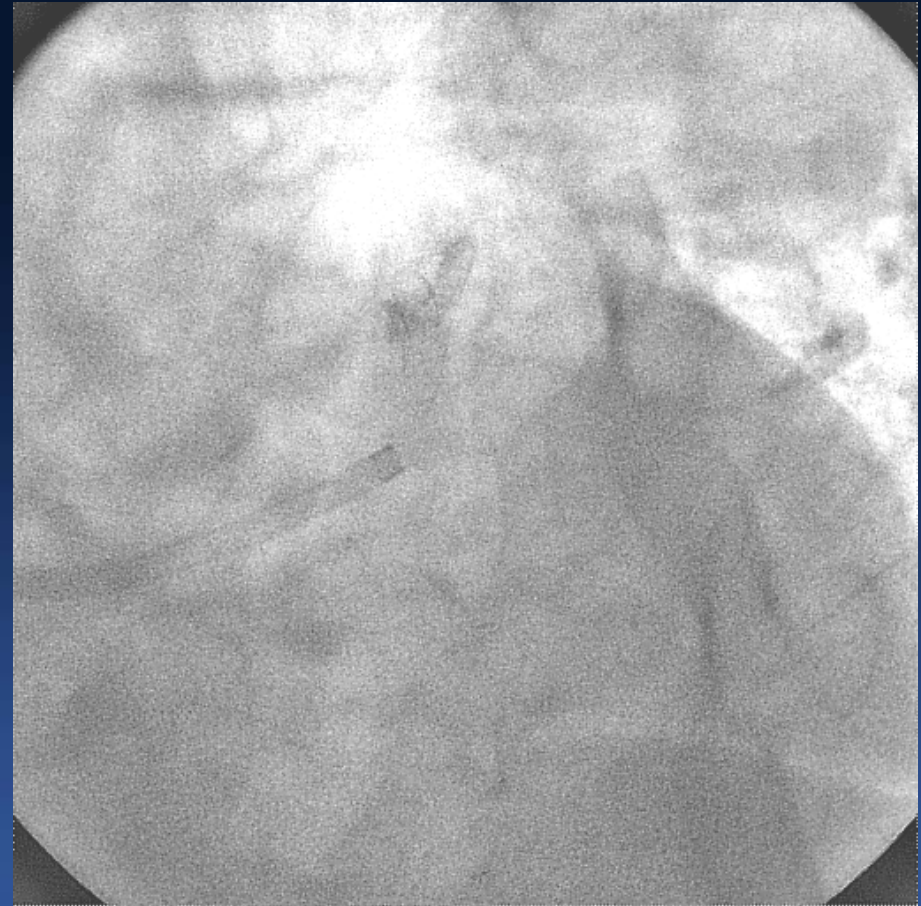
LAD



2<sup>nd</sup> Diag.



# Final Angiograms



# Conclusion

- Nobori stent with open cell and larger side branch access makes procedure safe and successful in PCI for bifurcation lesions.
- Nobori stent may be a good option for bifurcation lesions treated with either single- or two-stent strategies because of its procedural feasibility and favorable long-term safety and efficacy.