

# Nobori

Biodegradable Polymer **Biolimus-Eluting Stent**

Daily Practice in JAPAN  
-BIFURCATION LESION-

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# Contents

- ④ Nobori Recent Clinical Trials
  - ▶ COMPARE II / SORT OUT V
  - ▶ NEXT
  - ▶ NOBORI 2 -Left Main & Bifurcation
- ④ Nobori: Components / Features
- ④ Case presentation
- ④ Summary

# Contents

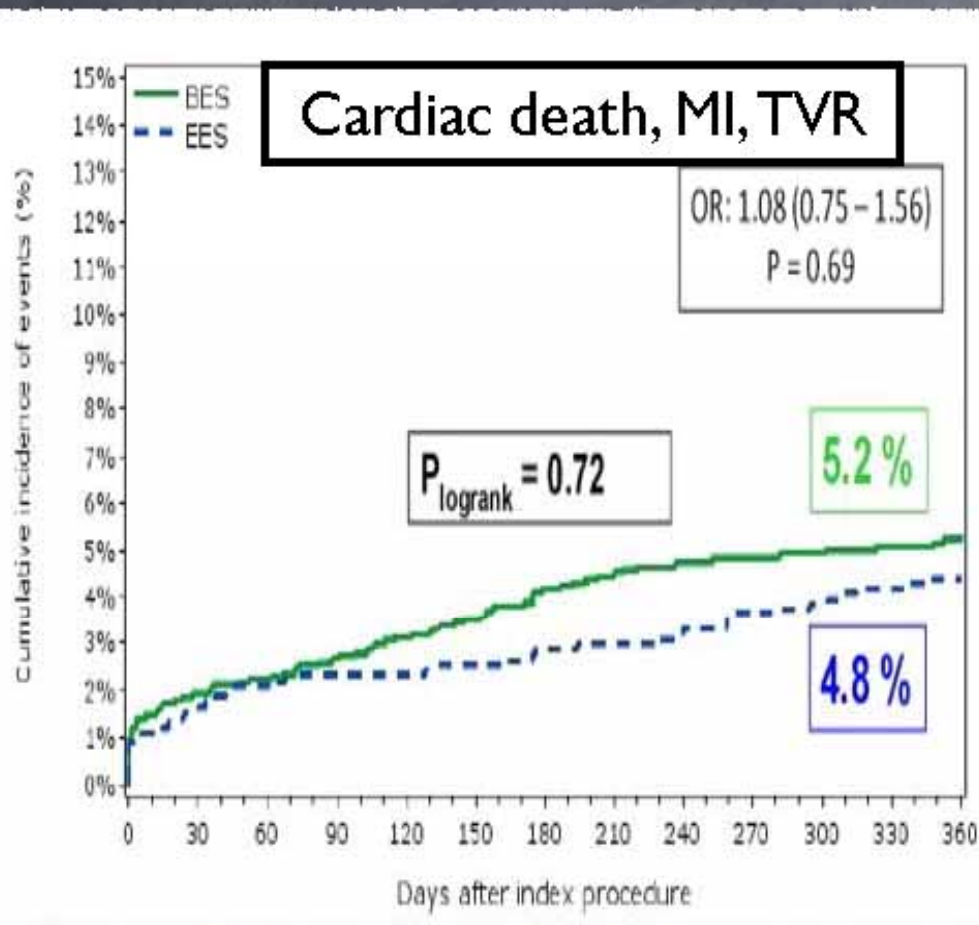
- ① Nobori Recent Clinical Trials
  - ▶ COMPARE II / SORT OUT V
  - ▶ NEXT
  - ▶ NOBORI 2 -Left Main & Bifurcation
- ① Nobori: Components / Features
- ① Case presentation
- ① Summary



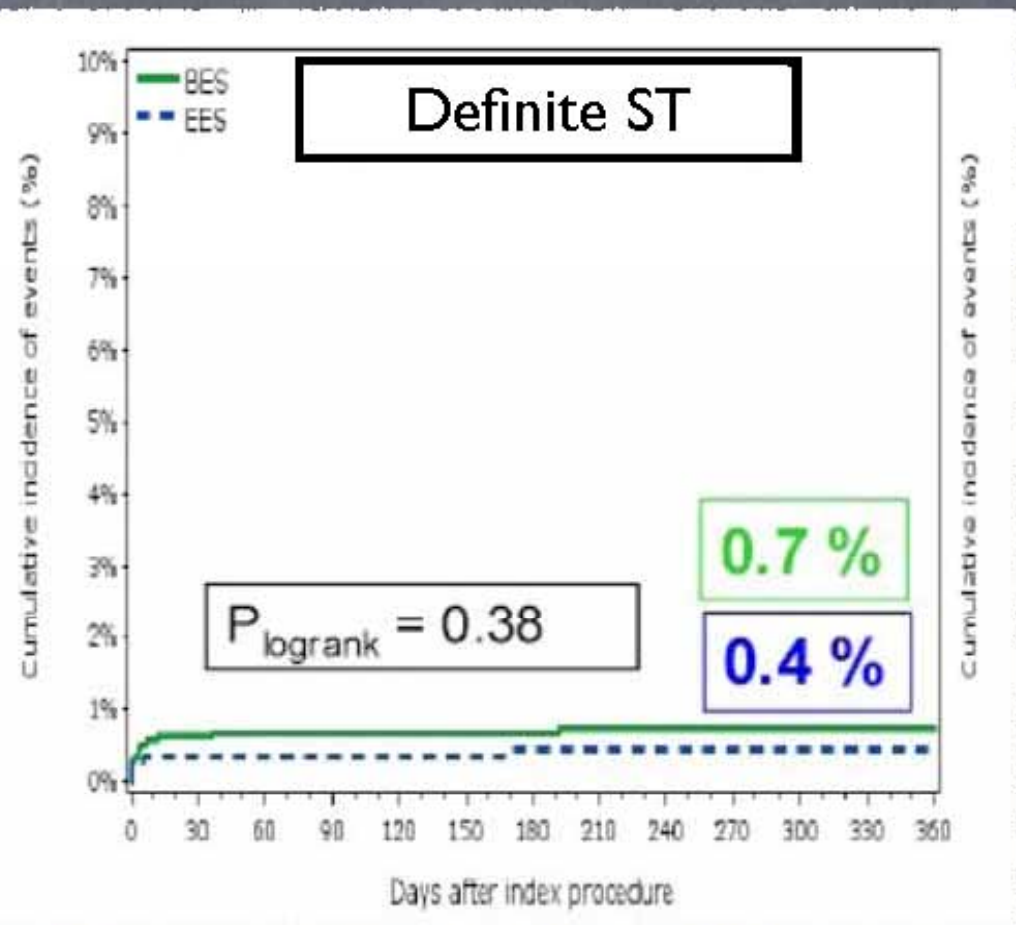
# COMPARE II

Prospective randomized all-comer trial: **BES vs. EES**

\*N=2702, age 63, DM 22%, ACS 58%, LM 1.5%, Bifurcation 6.4%, Type B2/C 64%



**BES was non-inferior compared to EES.**

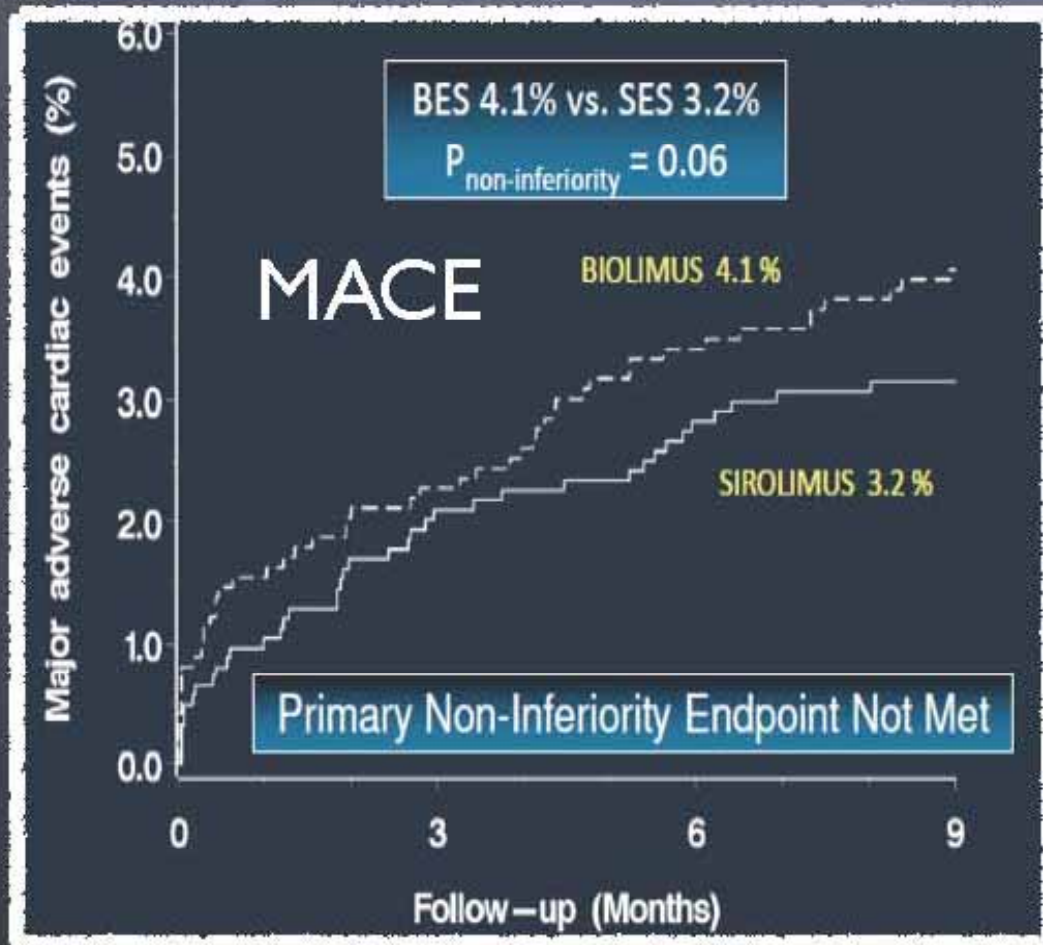


**There was no significant difference between BES and EES.**

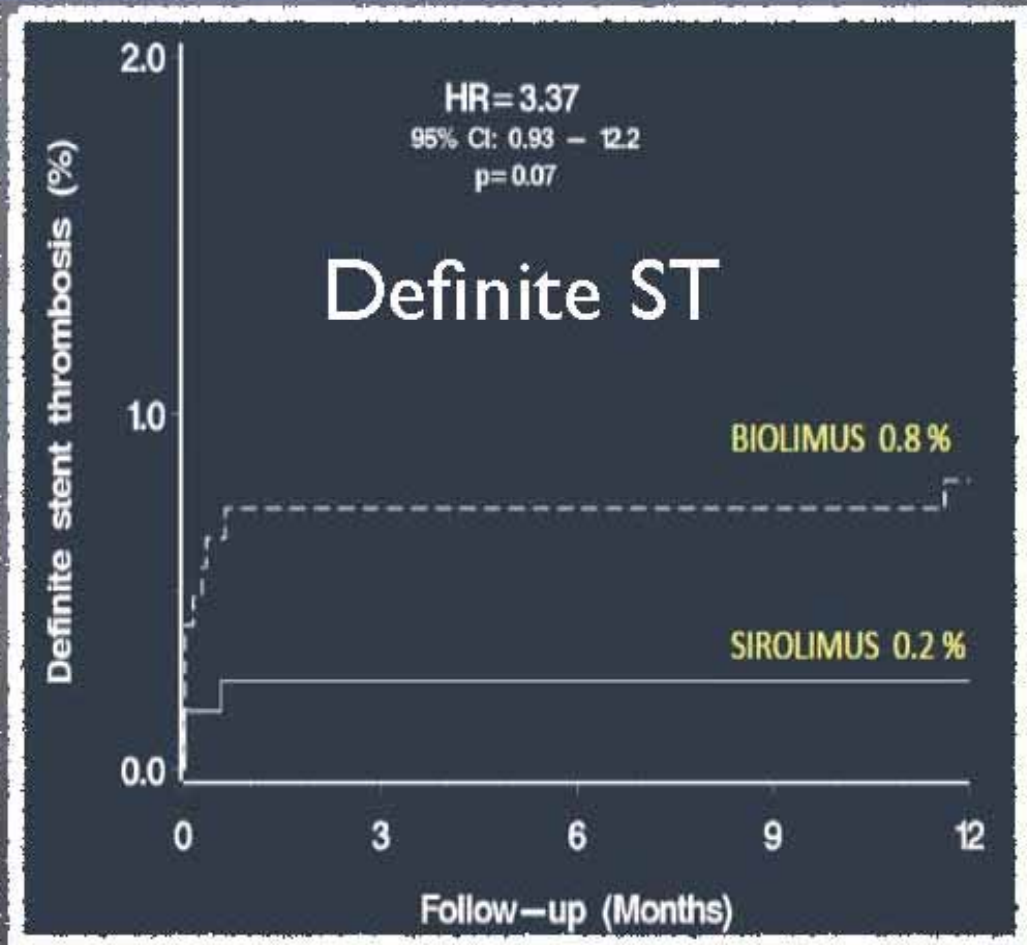
# SORT OUT V

Prospective randomized all-comer trial: **BES vs. SES**

\*N=2468, age 65, DM 15%, ACS 49%, LM 1.4%, Bifurcation 15%, Type B2/C 60%



**BES was not found to be non-inferior to SES.**



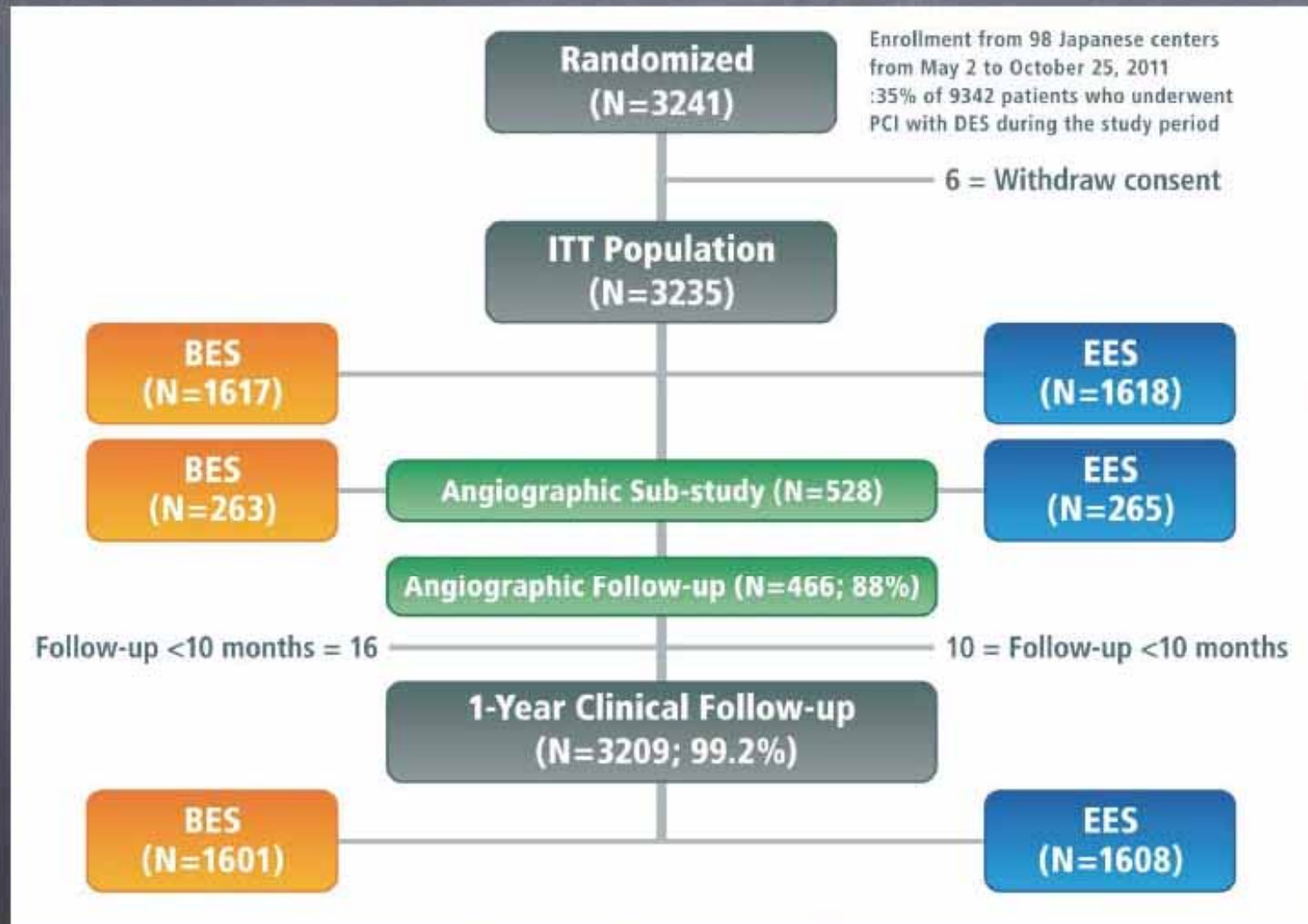
**There was no significant difference between BES and SES.**





# NEXT

## Multi-center, randomized, non-inferiority trial: BES vs. EES





# NEXT

## Patient Characteristics

	<i>Biolimus-eluting stent</i>	<i>Everolimus-eluting stent</i>	<i>P</i>
No. of patients	<b>1617</b>	<b>1618</b>	
Age (years)	<b>69.1 ± 9.8</b>	<b>69.3 ± 9.8</b>	0.49
Age ≥ 75 years	31 %	34 %	0.052
Male gender	77 %	77 %	0.76
Body mass Index (kg/m <sup>2</sup> )	24.1 ± 3.7	24.2 ± 3.5	0.55
Diabetes	<b>46 %</b>	<b>46 %</b>	0.85
Insulin-treated	10 %	11 %	0.73
Hypertension	81 %	82 %	0.81
Current smoker	19 %	18 %	0.71
Statin use	77 %	75 %	0.47
Prior PCI	50 %	51 %	0.9
Prior CABG	5.3 %	4.8 %	0.52

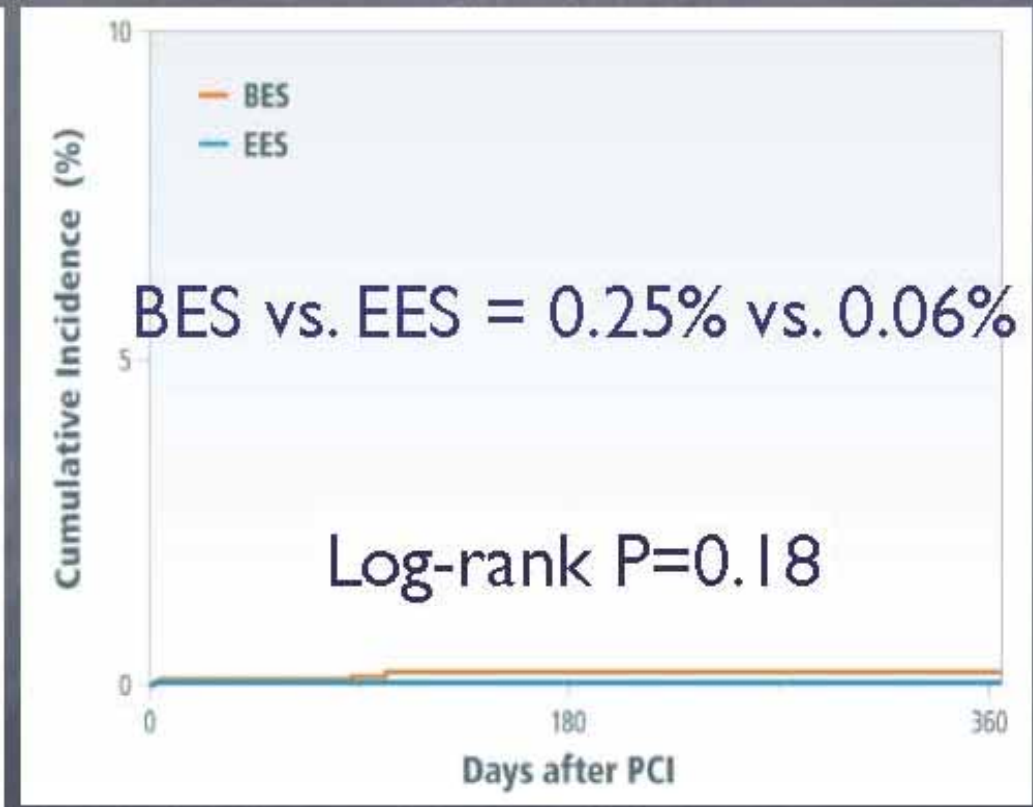
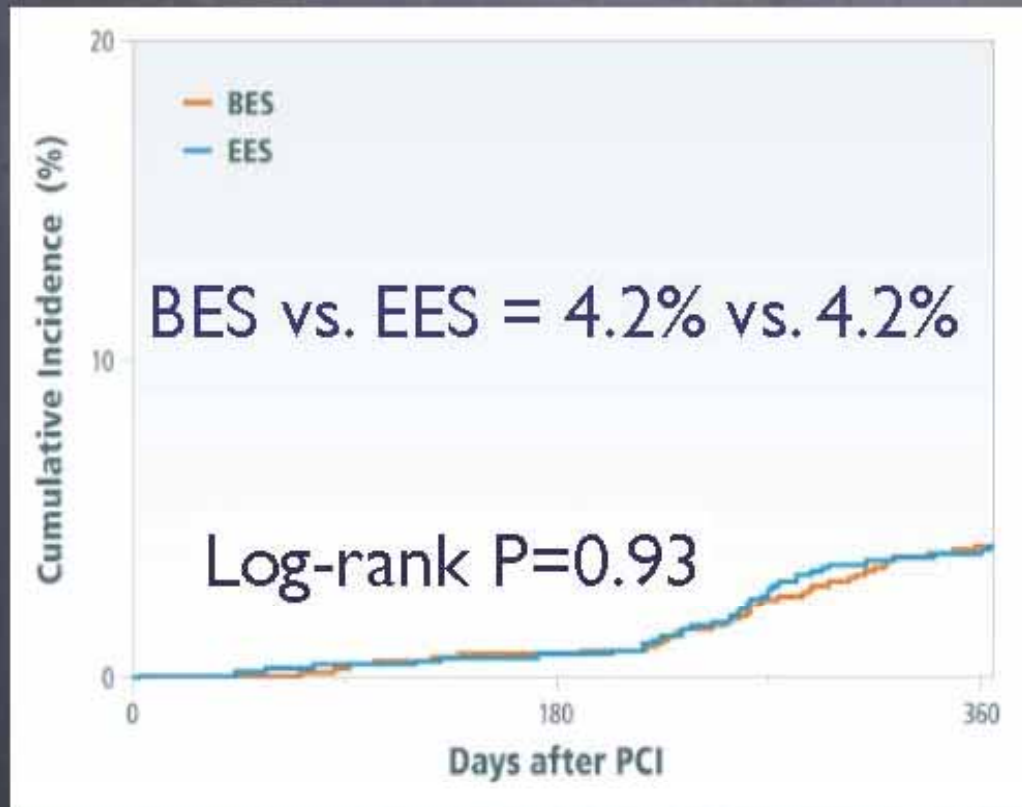
\*ACS 16%, SYNTAX score 10, LM 2.4%, Bifurcation 44%



# NEXT

Primary Efficacy Endpoint  
Any Target-Lesion Revascularization

Definite ST



- BES was demonstrated to be non-inferior to EES with respect to 1 year TLR rate.
- Clinical outcome after both BES- and EES-use was excellent with very low rate of stent thrombosis.



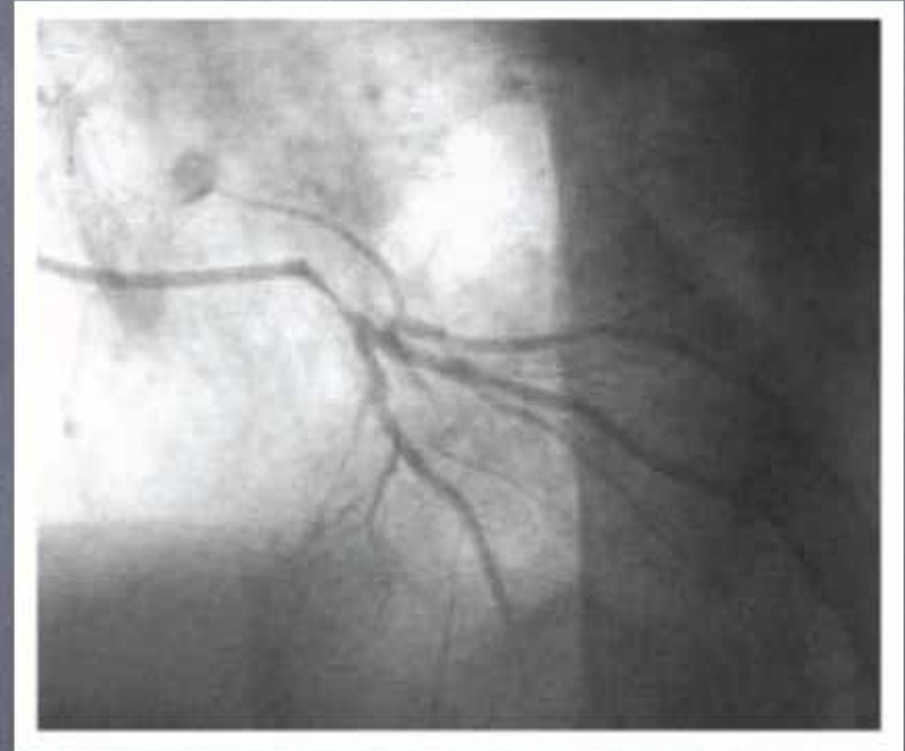
# NOBORI 2 -Left main & Bifurcation

- 3067 Patients enrolled in  
125 hospitals

Primary endpoint:

Target Lesion Failure (TLF) at  
12 months:

composite of cardiac death,  
myocardial infarction (MI)  
target vessel related and  
target lesion  
revascularisation (TLR)



62 pts had treatment of LM  
695 pts were treated for  
bifurcation lesions  
with a Nobori stent

# NOBORI 2 -Left main & Bifurcation

## Clinical presentation

%	LM N=62	Bifurcation N=695	No LM No Bifurcation N=2310
Age, years (mean $\pm$ SD)	66.7 $\pm$ 10.4	64.5 $\pm$ 10.8	64.3 $\pm$ 11.1
Male gender (%)	80.3	82.7	76.2
Prior MI (%)	33.3	31.8	34.3
Prior PCI (%)	30.0	30.4	32.5
Prior CABG (%)	33.3	6.4	9.3
Diabetes Mellitus (%)	31.2	27.1	29.9
Hyperlipidemia (%)	76.3	69.7	72.0
Hypertension (%)	65.0	68.3	69.3
Current smoker (%)	16.7	24.1	25.4



\*ACS 54%, LM isolated 25.8%, LM w/2VD 33.9%, LM w/3VD 40.3%



# NOBORI 2 -Left main & Bifurcation

## Clinical Outcomes at 3 years

%	LM N=62	Bifurcation N=695	No LM No Bifurcation N=2310
Cardiac Death	4.9	0.8	2.7
MI	3.3	3.4	3.0
TLR - CABG	1.6	0.8	0.6
TLR - PCI (not LM)	9.7	3.7	2.7
Left Main TLR	1.6	0.1	NA
TV non-TLR	3.3	1.7	2.3
TLF	14.8	6.7	6.4

## Definite/Probable ST at 3 years

	LM N=62	Bifurcation N=695	No LM No Bifurcation N=2310
Stent Thrombosis, % (Definite/ Probable)			
Acute	0.0	0.0	0.09
Subacute	0.0	0.41	0.51
Late	0.0	0.0	0.17
Very Late	0.0	0.27	0.17
<b>Total at 3 Years</b>	<b>0.0</b>	<b>0.69</b>	<b>0.94</b>

# Contents

- Nobori Recent Clinical Trial
  - ▶ COMPARE II / SORT OUT V
  - ▶ NEXT
  - ▶ NOBORI 2 -Left Main & Bifurcation
- **Nobori: Components / Features**
- Case presentation
- Summary

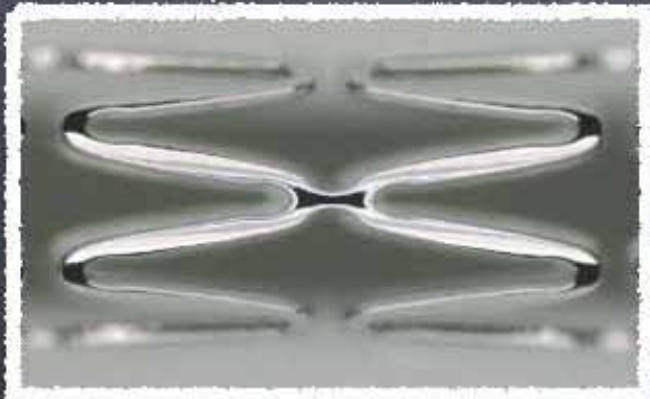
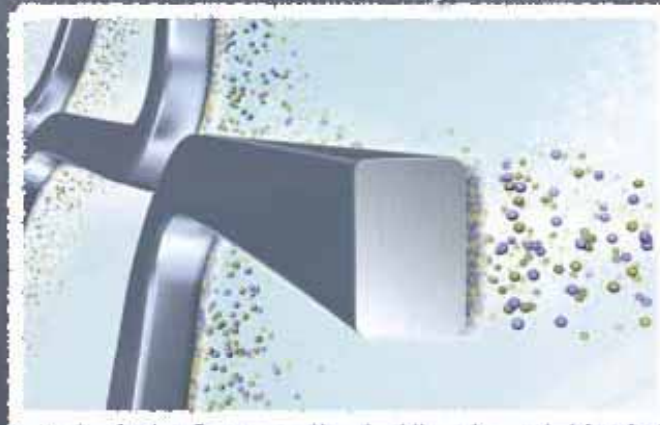
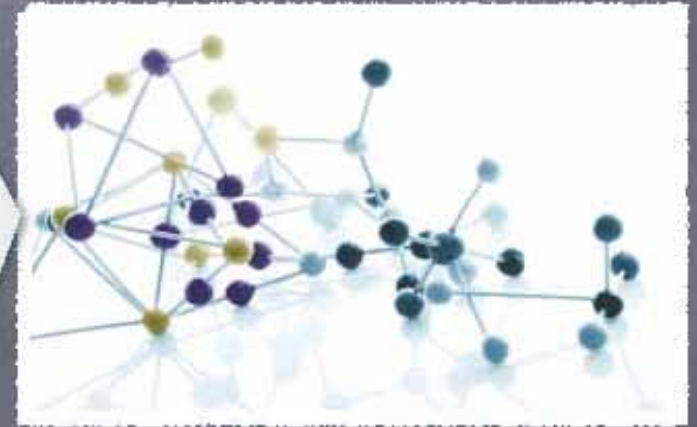


# Components and features

Drug and polymer

Biolimus A9<sup>TM</sup> and

Biodegradable Polymer (PLA)  
coated only Abluminal side.



Stent Platform

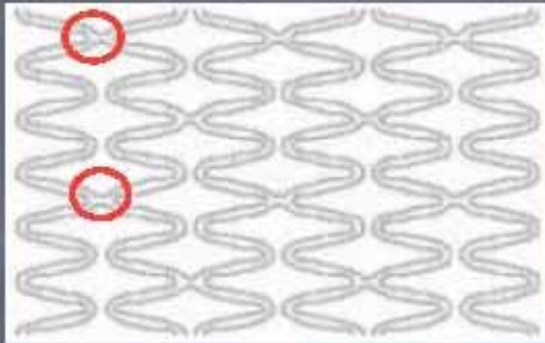
Flexible stent structure.



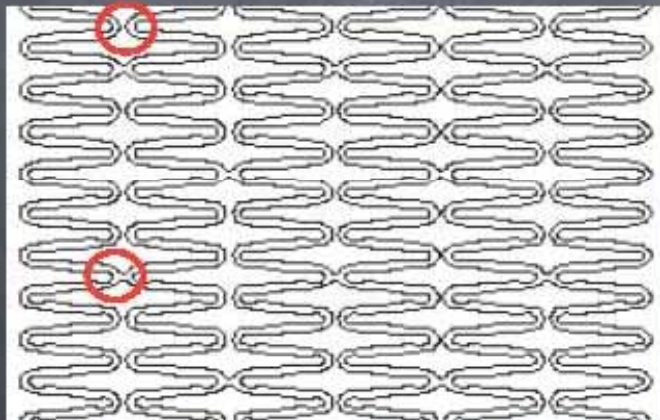


# Feasible strut structure for side branch access

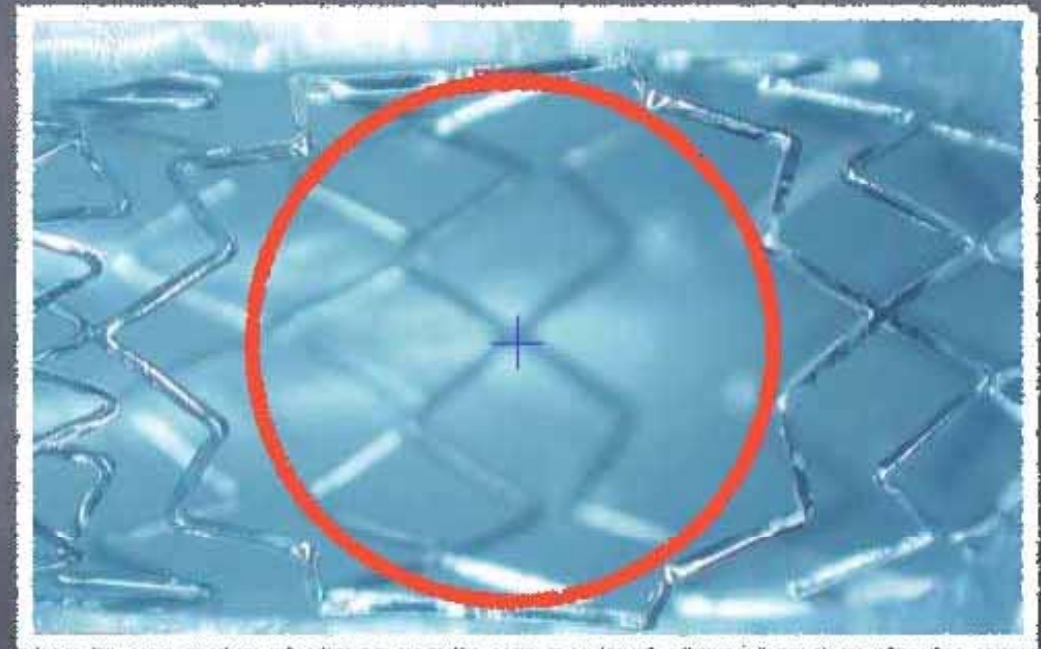
$\Phi 2.5\text{mm}$ ,  $2.75\text{mm}$ ,  $3.0\text{mm}$ : **2** links **6** crowns



$\Phi 3.5\text{mm}$ : **2** links **10** crowns



stent size:  $\Phi 3.5\text{mm}$



Diameter :  $4.2\text{mm}$

✓ **2 Link structure**  $\Rightarrow$  Easy to dilate up to around  $4\text{mm}$

✓ **Open cell area** provides wide side-branch access to treat bifurcation lesions

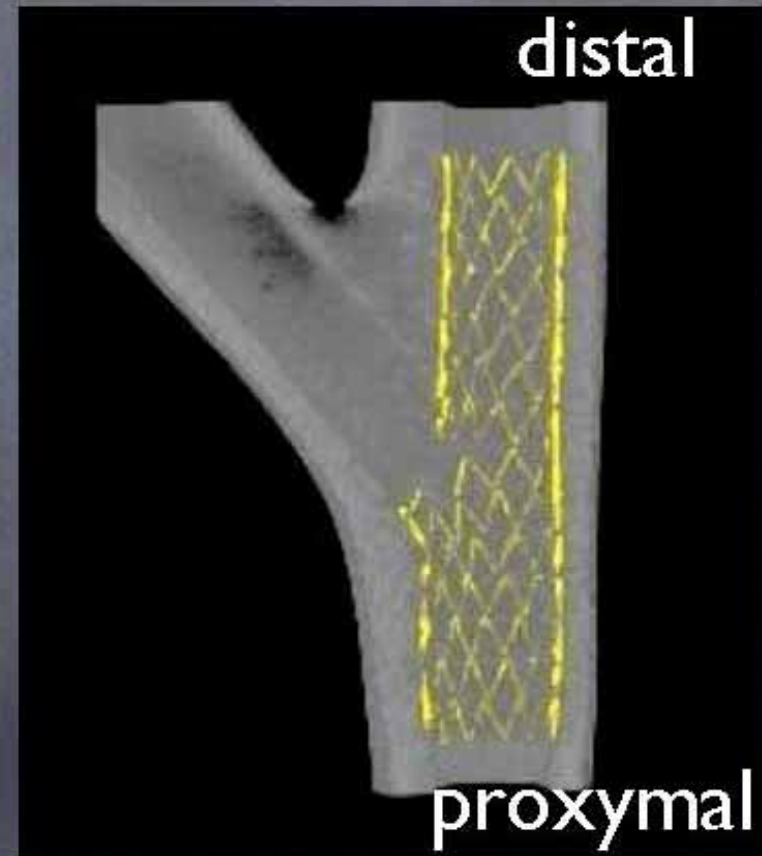


# Stent transformation after KBT (in vitro: $\varphi 3.5/18\text{mm}$ stent)

CT image

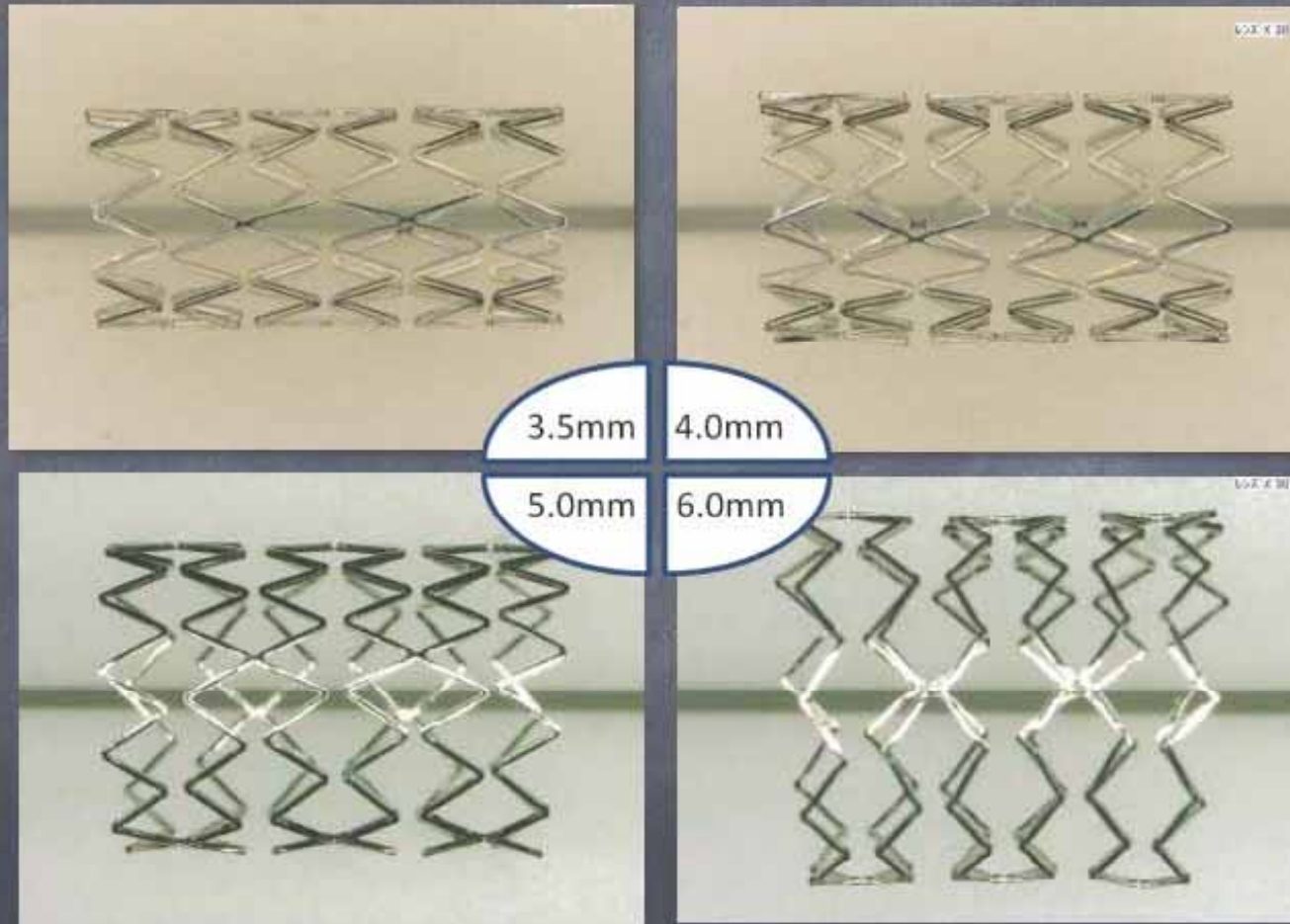
Vessel diameter  
main branch 3.5mm  
side branch 3.0mm

angle  
45-degree



※KBT with  $\varphi 3.5\text{mm}$  balloon for main branch and  
 $\varphi 3.0\text{mm}$  balloon for side branch

# Tolerant design for over-dilatation ( $\varphi 3.5/8\text{mm}$ )



balloon size

3.5mm

4.0mm

5.0mm

6.0mm

Radial force (N/cm)

**10.3**

**11.9**

**12.9**

**15.2**



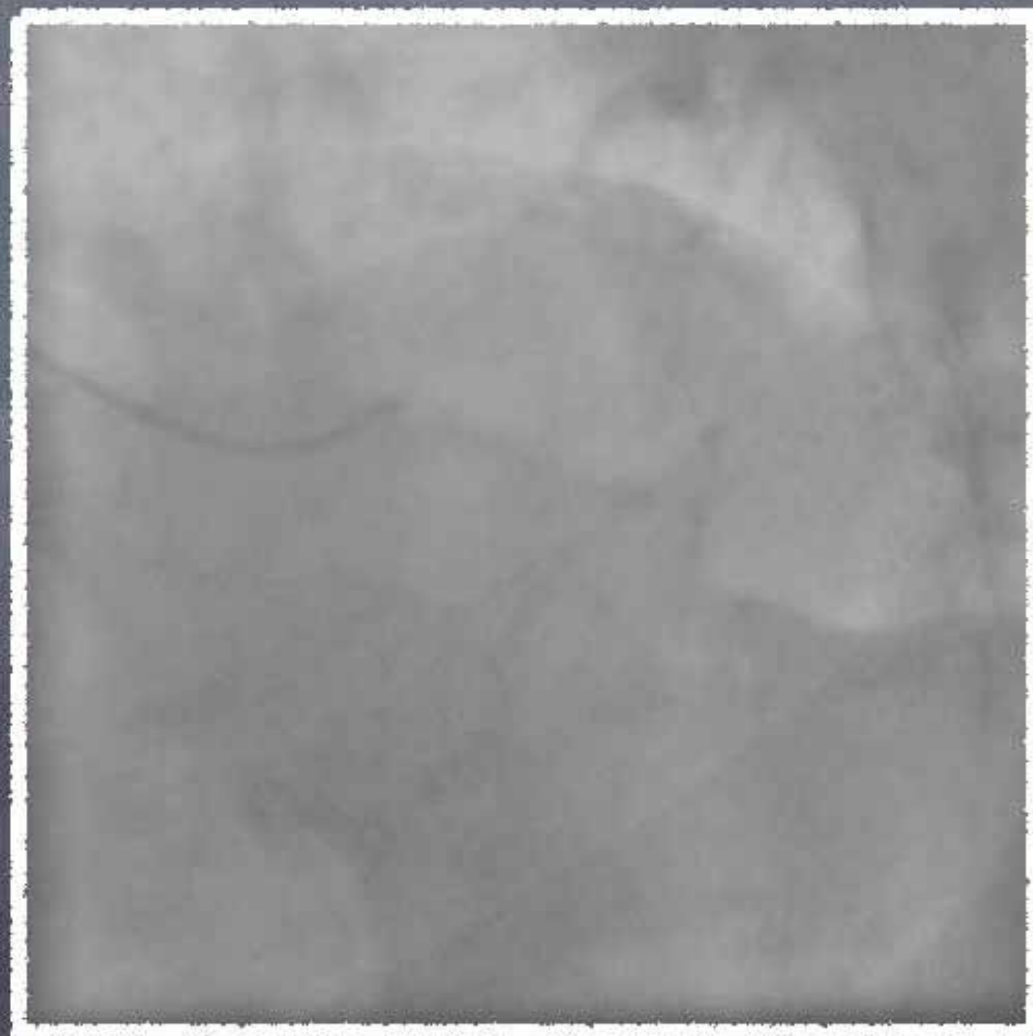
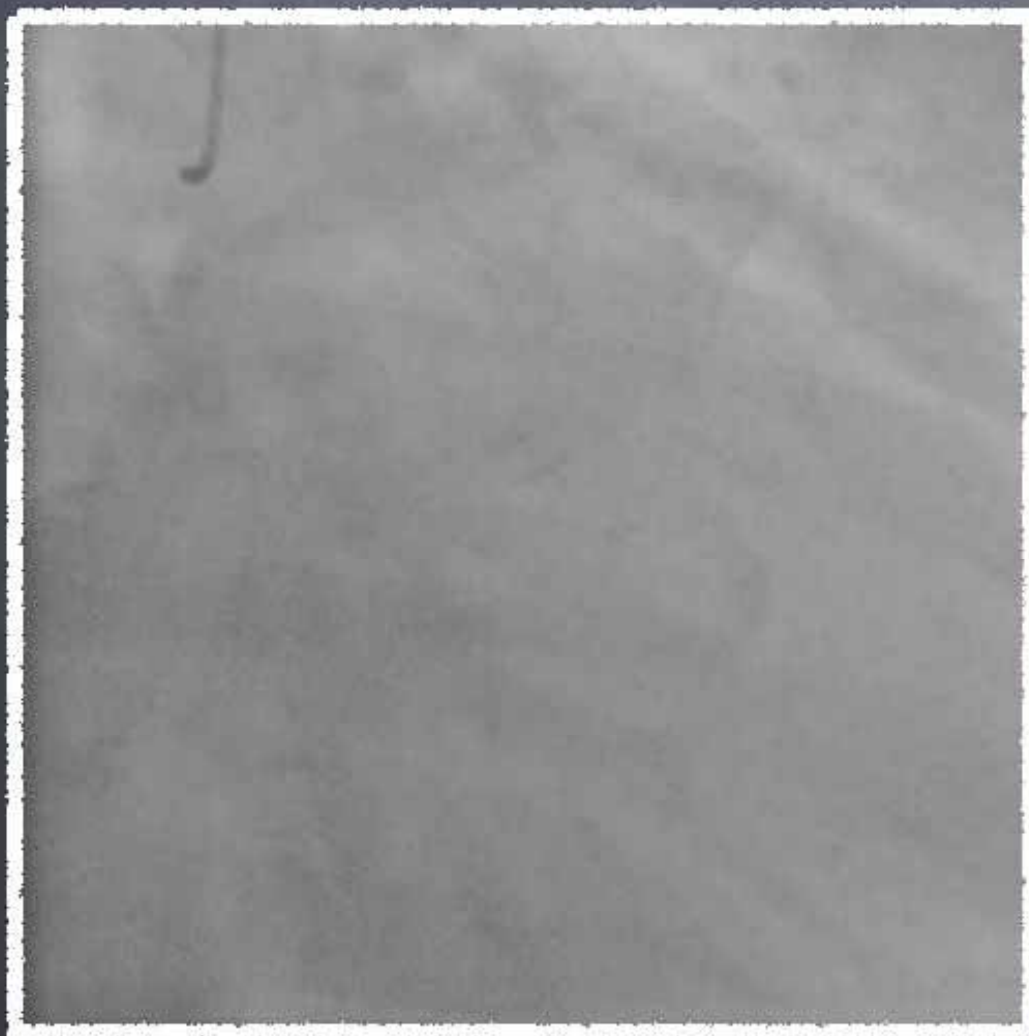
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Case 1 48 yrs male  
ACS DM HT DL

2013/1/16

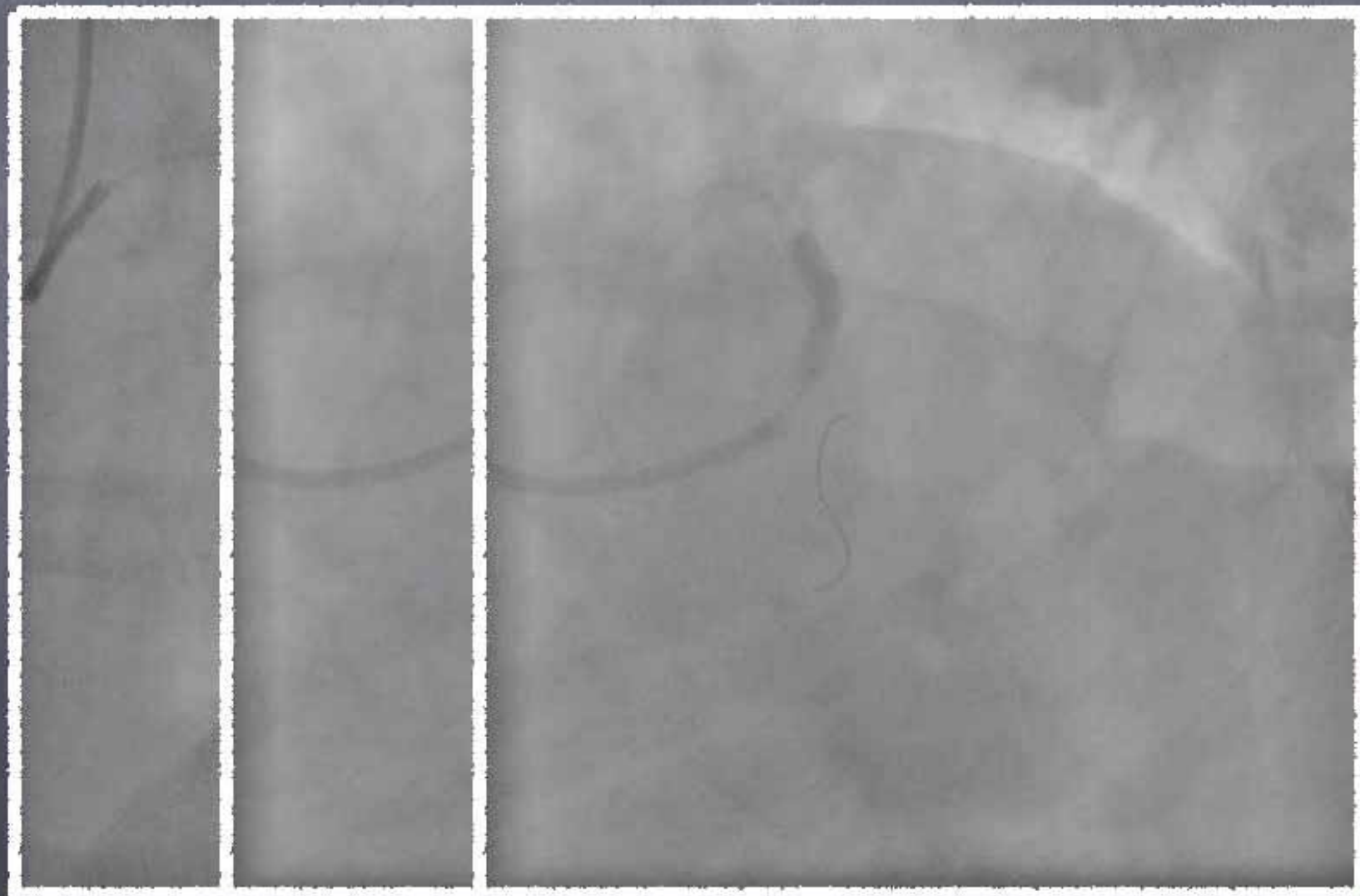
CAG: #5 90% #6 75%





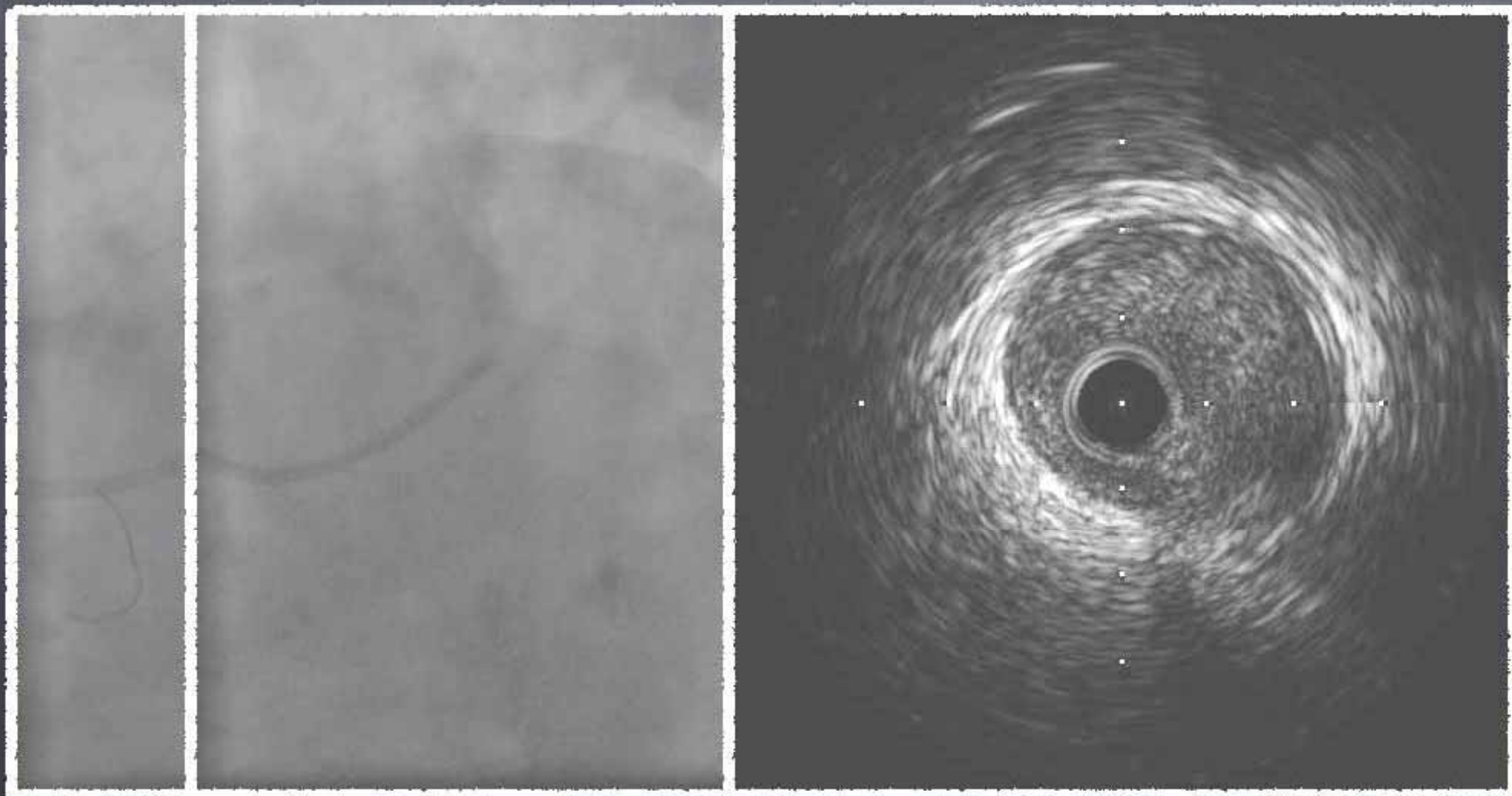
Case I 48 yrs male  
ACS DM HT DL

6F TRI  
GC:CLS3.5  
GW: Sion



LAD-LMT: Xience Prime 3.5x33mm/Nobori 3.5x24mm

Case I 48 yrs male  
ACS DM HT DL



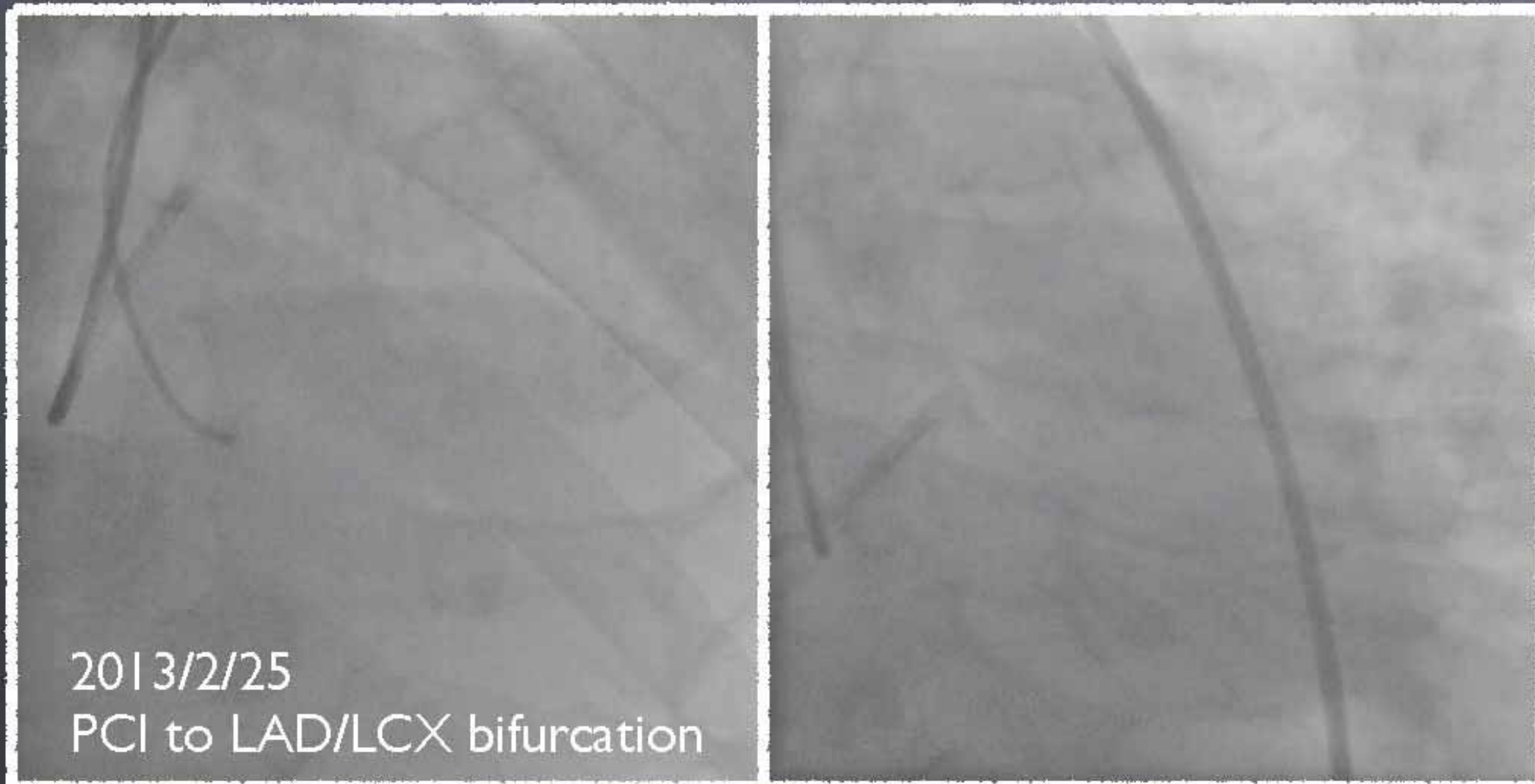
KBT: LAD Hiryu 4.0 x 12mm/LCX Tazuna 3.0 x 15mm at 14 atm



Case2 80 yrs male  
eAP HT DL CKDstage3

2013/1/21

CAG: #6 90% #7 100% #9 90% #11 90%



2013/2/25

PCI to LAD/LCX bifurcation

Case2 80yrs male  
eAP HT DL CKDstage3

7FTFI

GC:CLS3.5

GW: Sion / Sion blue

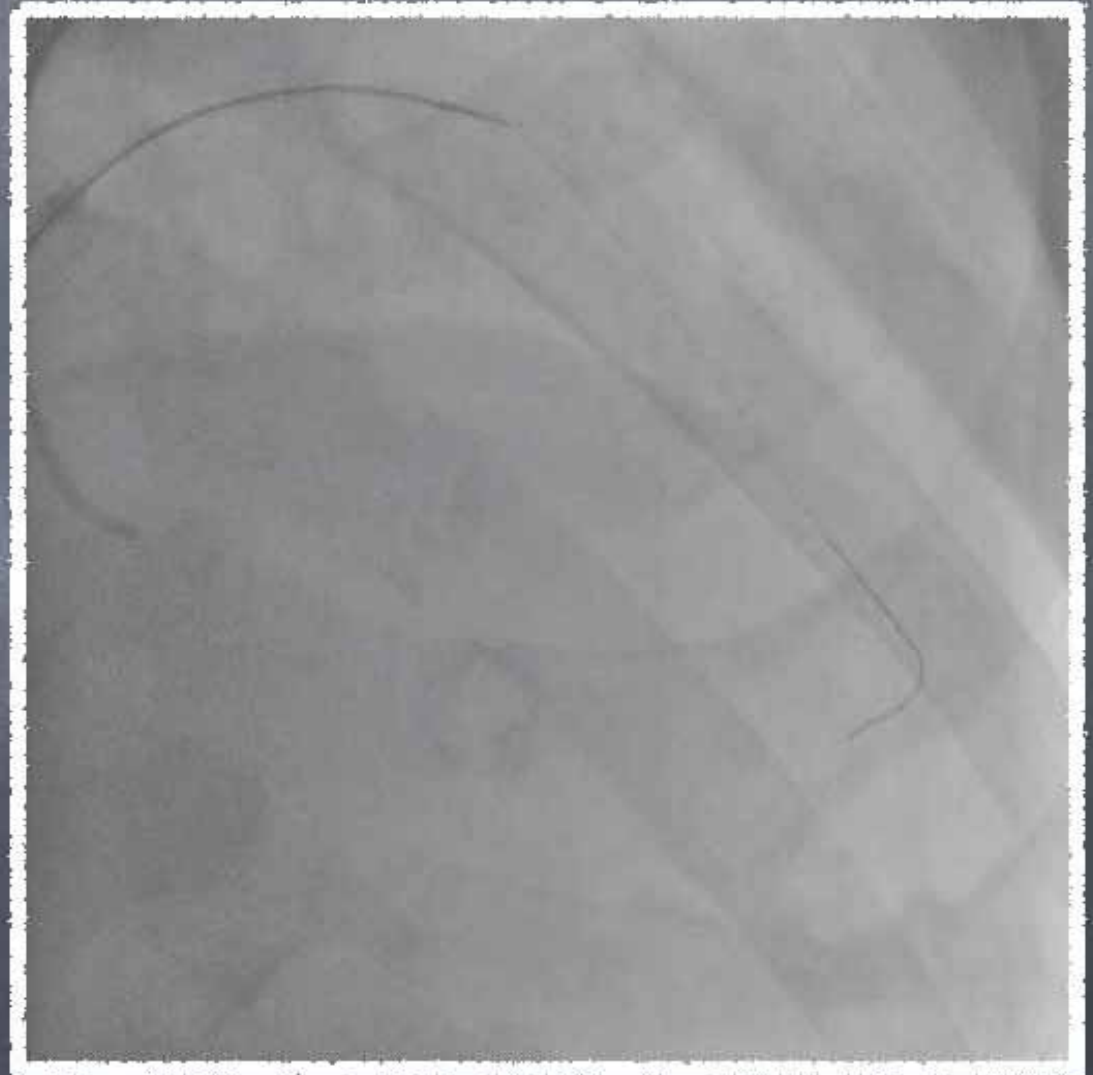
Gaia I st / Runthrough

CTO site:

Corsair support

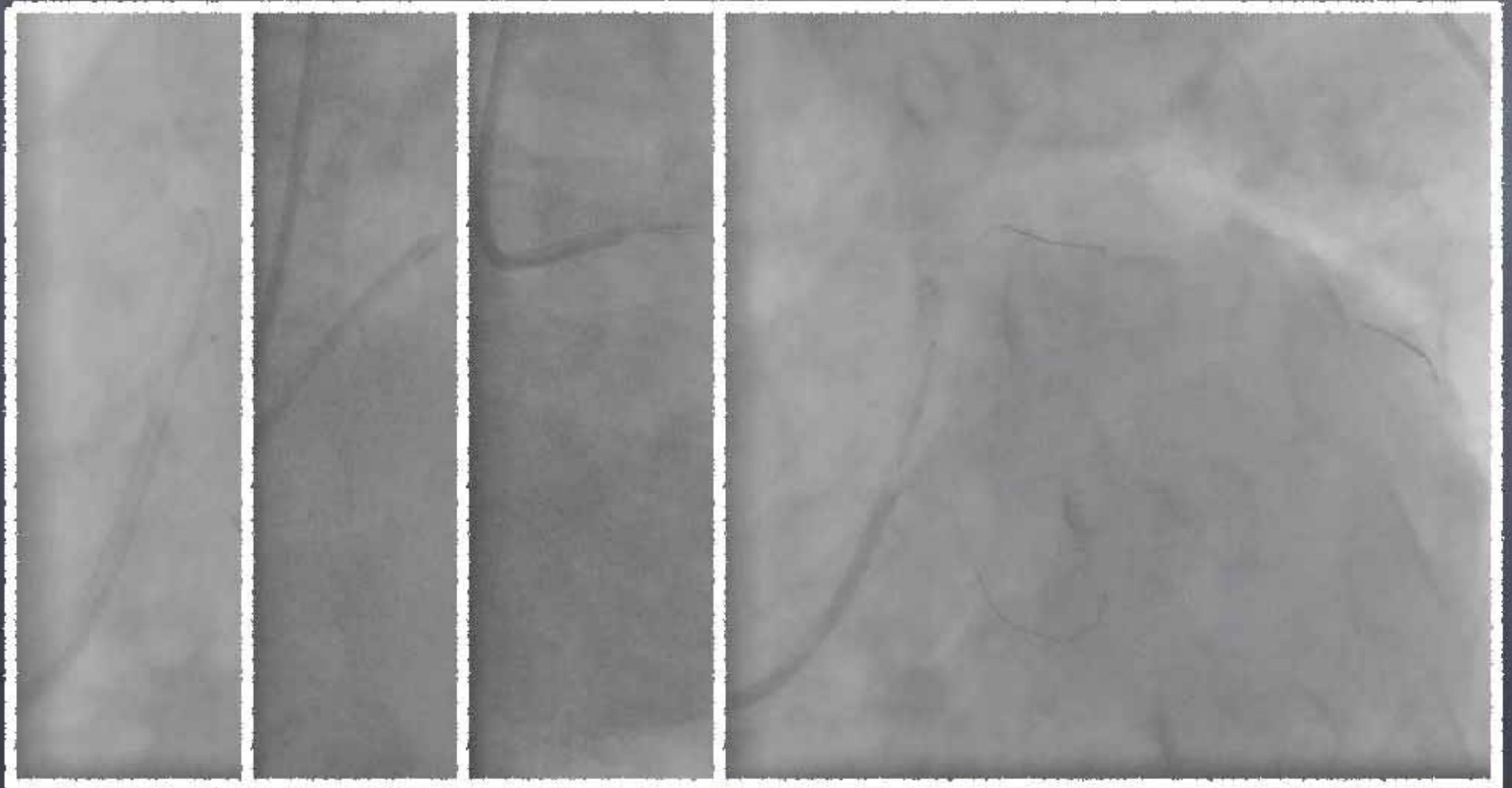
See-Saw wire technique

w/Sion, Gaia I st



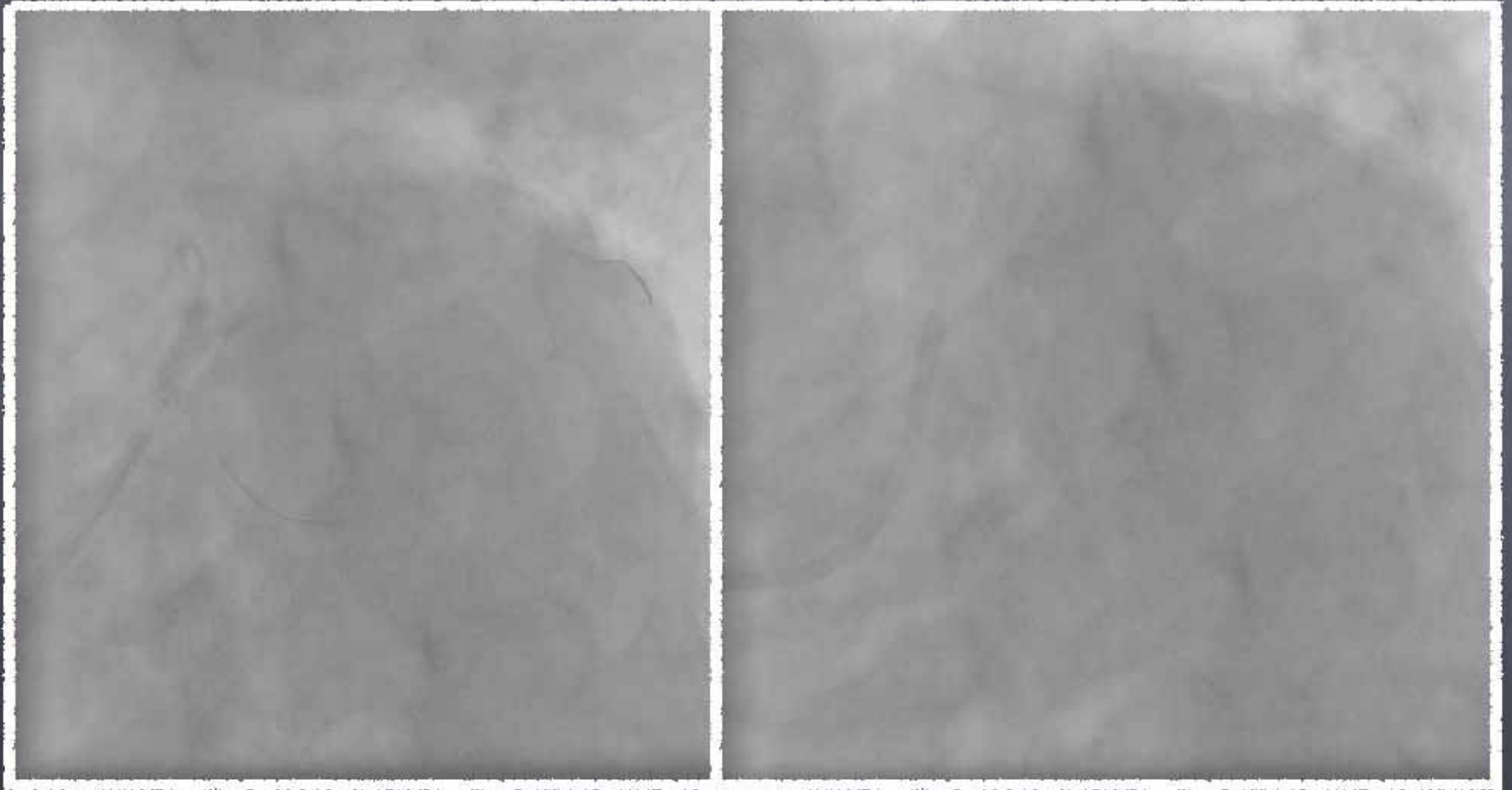


Case2 80yrs male  
eAP HT DL CKDstage3



LCX: Nobori 3.5x8mm → LAD: Nobori 2.5x28/3.0x24mm/3.5x20mm

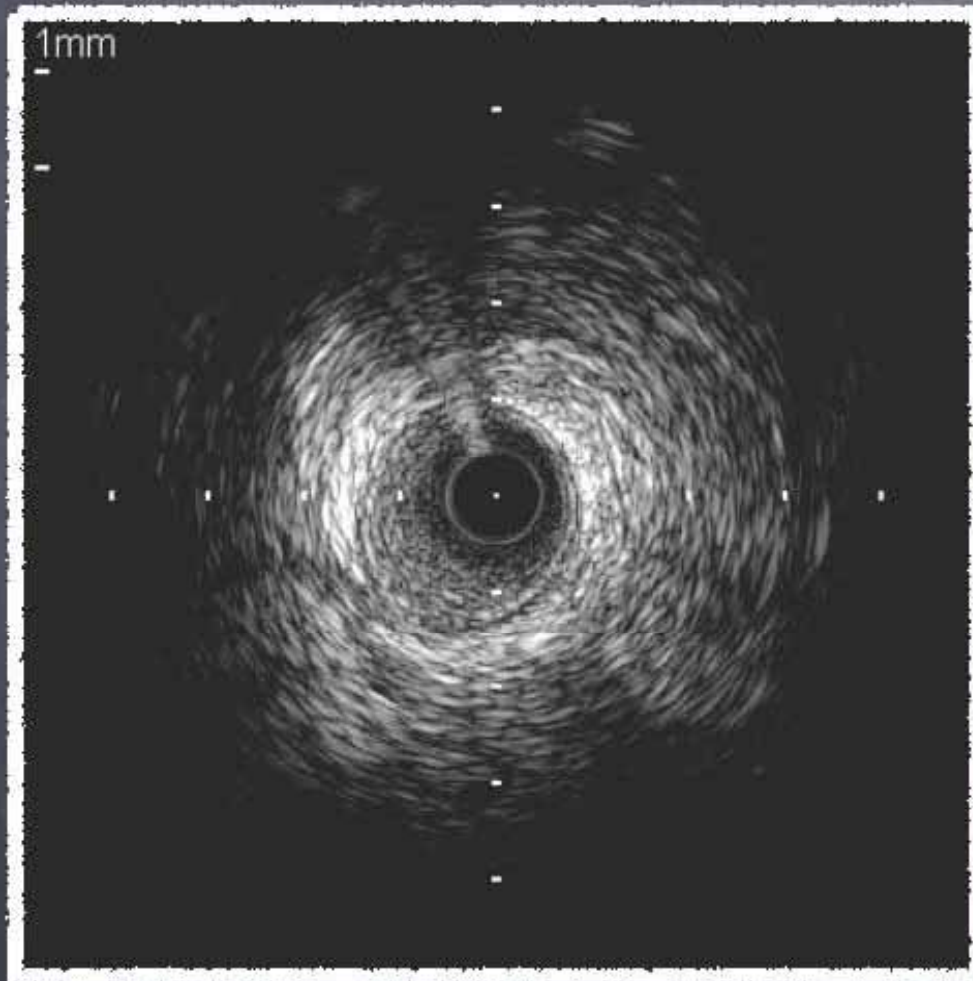
Case2 80yrs male  
eAP HT DL CKDstage3



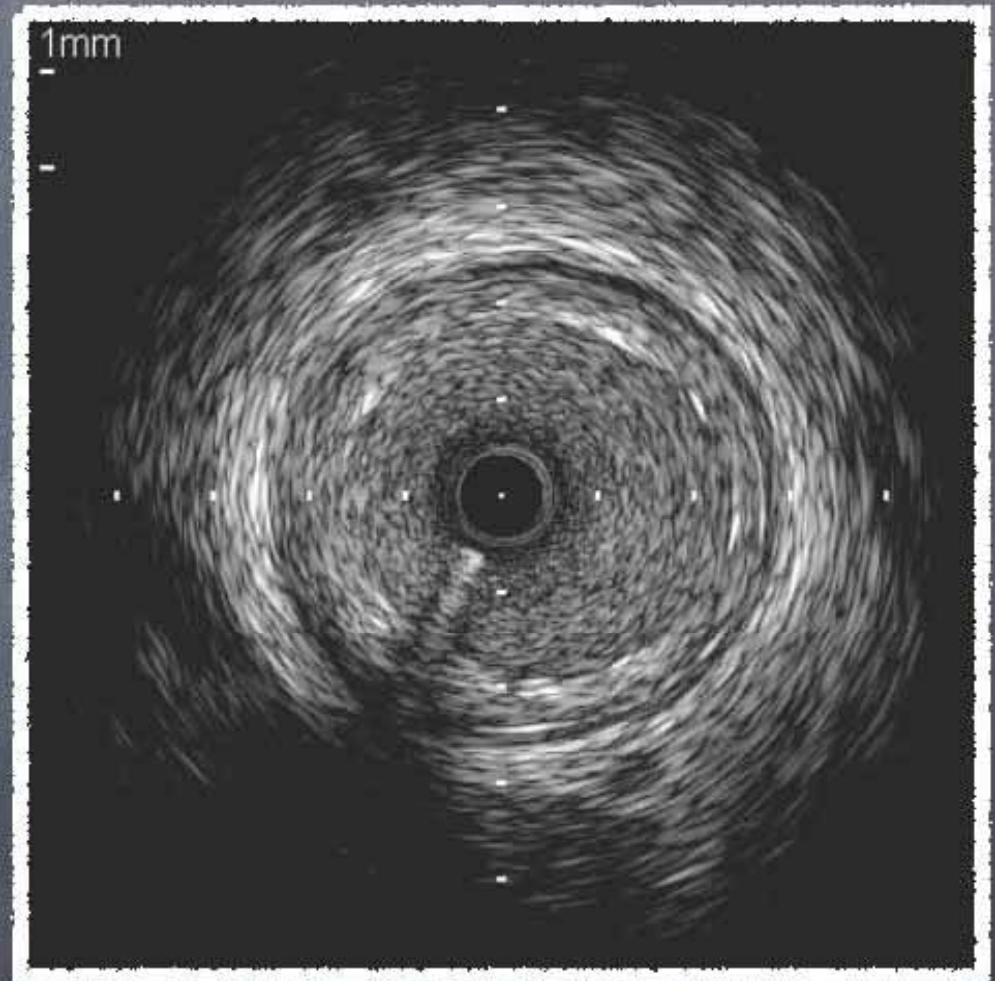
KBT: LAD Hiryu 3.5 x 12mm/LCX Tazuna 2.5 x 15mm at 18 atm



Case I 80yrs male  
eAP HT DL CKDstage3



IVUS: LAD-LMT



IVUS: LCX

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  - ▶ SORT OUT V
  - ▶ NEXT
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# Summary

- Nobori is the only biodegradable polymer, abluminal coating stent in JAPAN.
- One-year clinical outcome after both BES- and EES-use was excellent with low rate of TLR and very low rate of stent thrombosis in Japanese patients. (NEXT trial)
- Abluminal coating maximizes drug release into the vessel wall and minimizes systemic effect for better stent endothelialization with possible positive impact on safety.
- Degradation of the polymer may improve long term safety by reducing chronic sensitivity and eliminating the potential problem of remnant drug inside the coating.
- From the point of view in stent design, Nobori stent has an advantage in bifurcation lesion and large vessel.

**One of the Feasible  
Lesions for Nobori**



**Bifurcation lesion,  
especially in LMT**