

Nobori DES for calcified lesion

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Nobori DES Components



Modified S-Stent (stainless steel)

Excellent Flexibility and Scaffolding

Optimal Side Branch Access

Innovative delivery system with hydrophilic M-coating

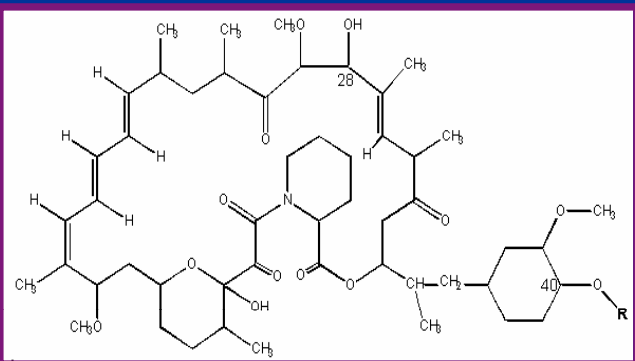


PLA Biodegradable Polymer

Abluminal coating

Controlled biodegradability

Precise drug release kinetics



Biolimus A9™ (rapamycin derivative)

A potent new “Limus” designed for stent applications

Highly lipophilic with optimal local tissue uptake

Characteristics of the Nobori stent

2Link structure

Radial force

Expansion performance

Stent design

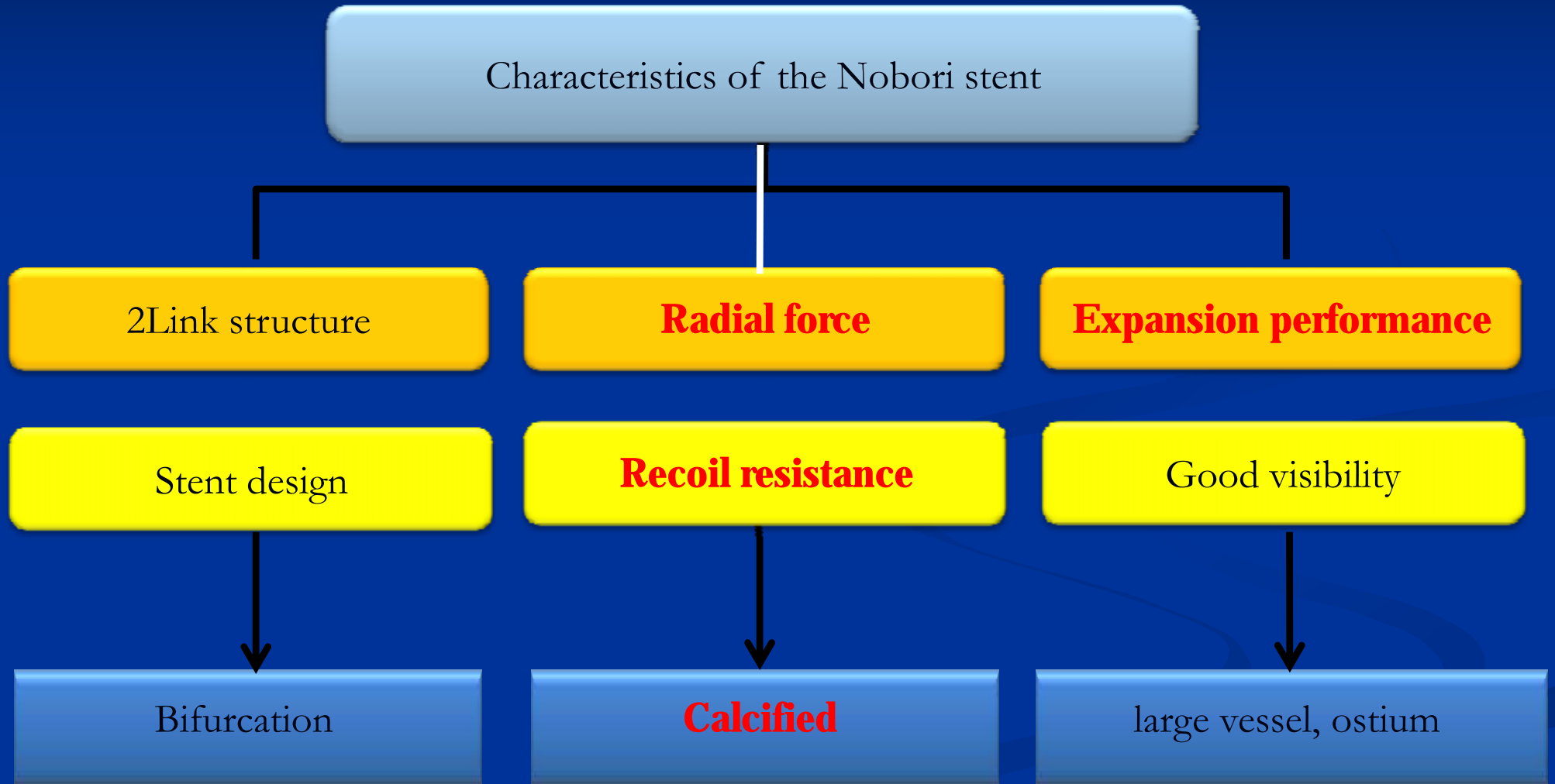
Recoil resistance

Good visibility

Bifurcation

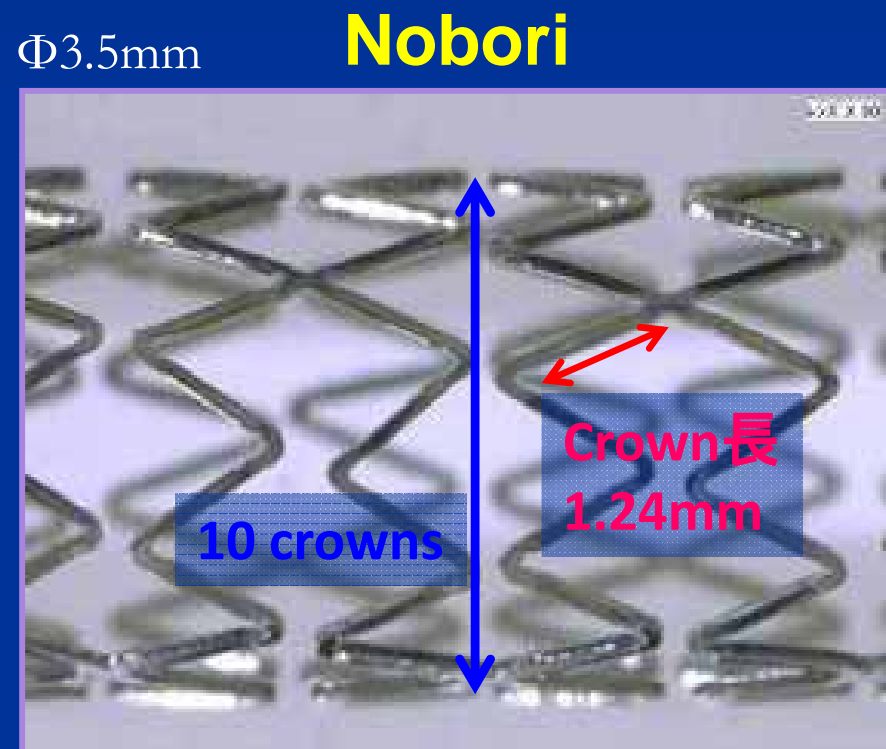
Calcified

large vessel, ostium



Excellent scaffolding

Nobori has a high expansion limit for the great vessels because of Long crown length and 10 crown design

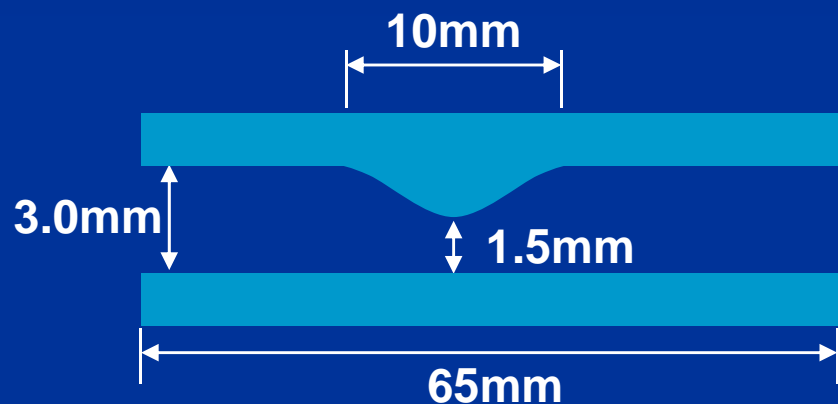


Stent expansion performance to the calcified lesion

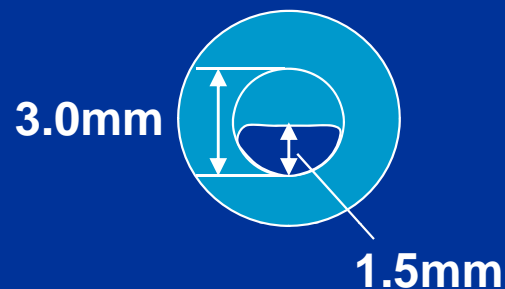
Easy to hold the vessel lumen in the calcified lesion because of strong radial force and low recoil

Estimation procedure

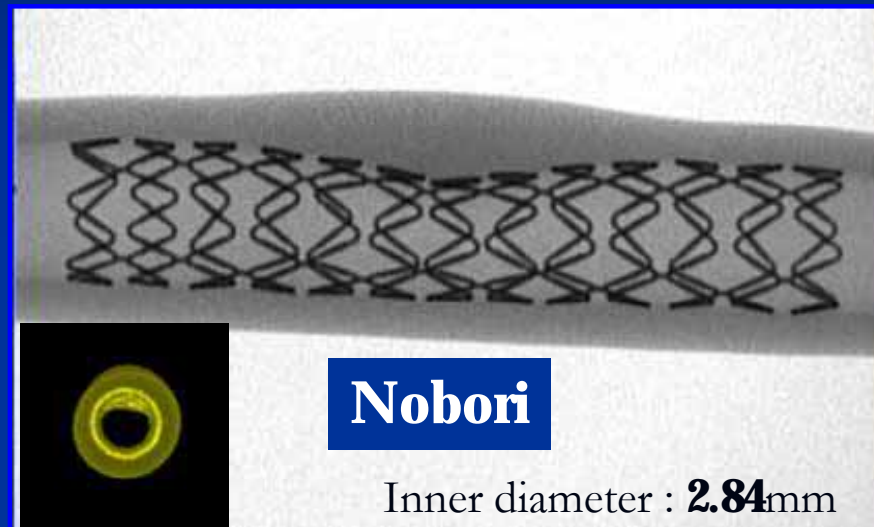
the $\phi 3\text{mm}$ stent was deployed at stenosis model by RBP16atm



Longitudinal view of stenosis model

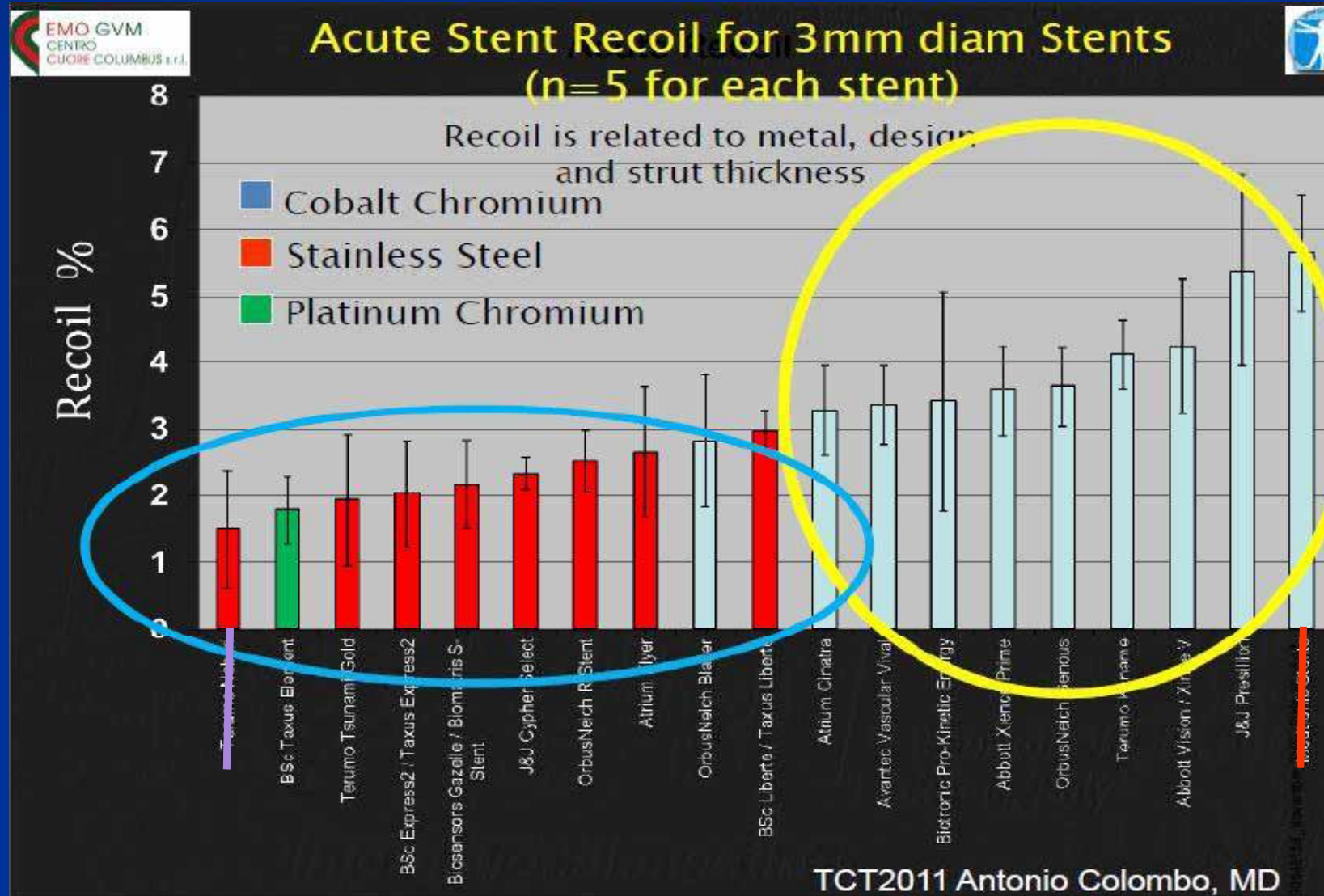


Cross-sectional view of stenosis model



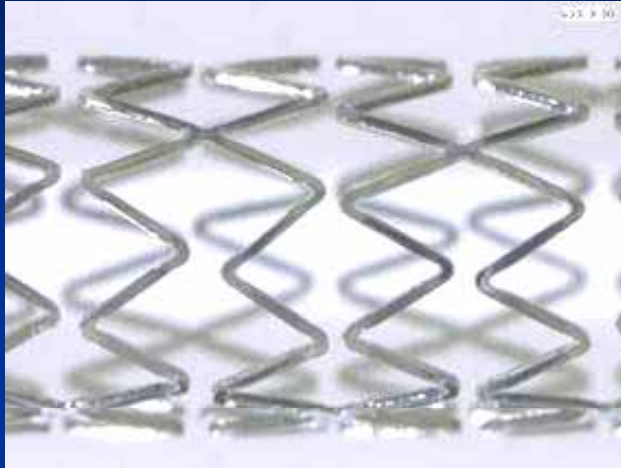
Stent expansion performance

Nobori could be promising by sufficient stent expansion because of less recoil



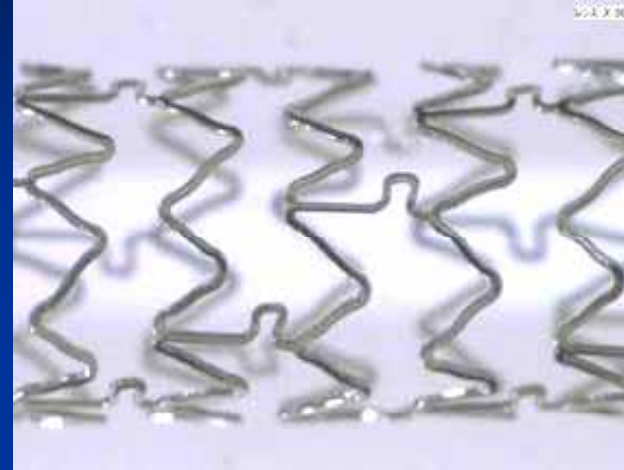
Stent structure of each company

Nobori



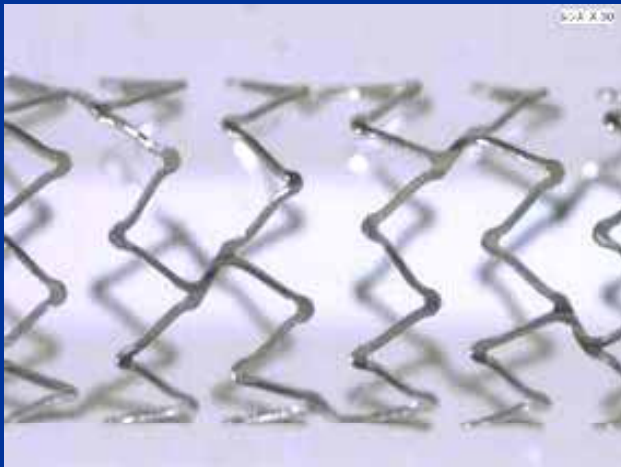
2Link Peak to Peak

XIENCE PRIME



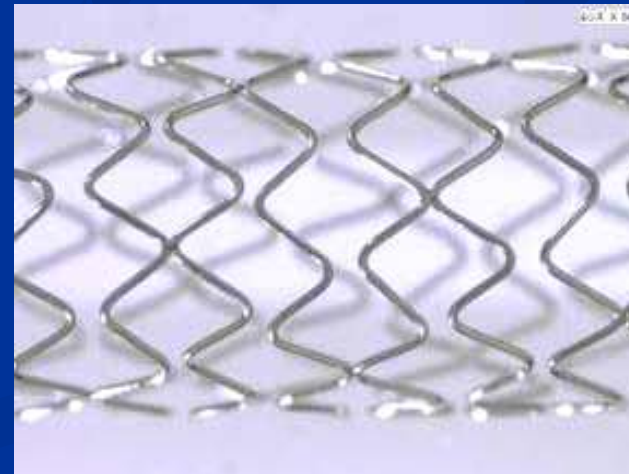
3Link Peak to Valley

PROMUS ELEMENT



2Link Peak to Peak offset

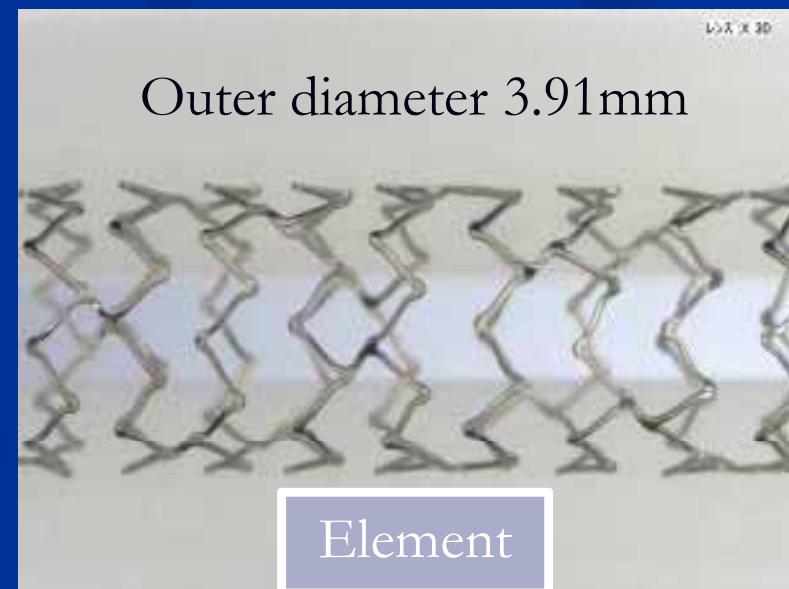
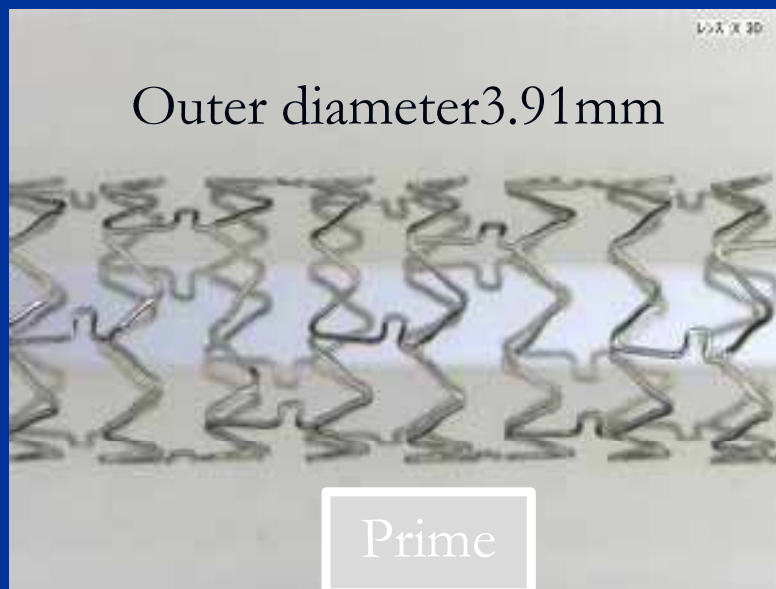
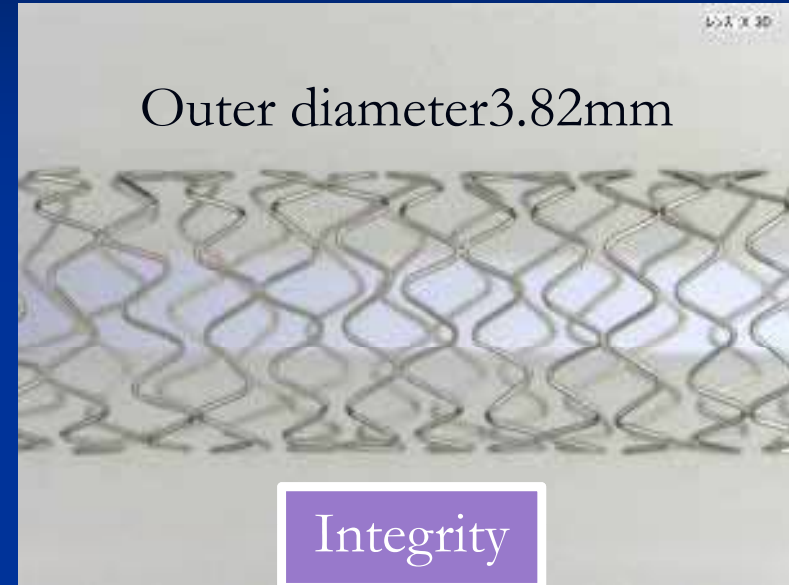
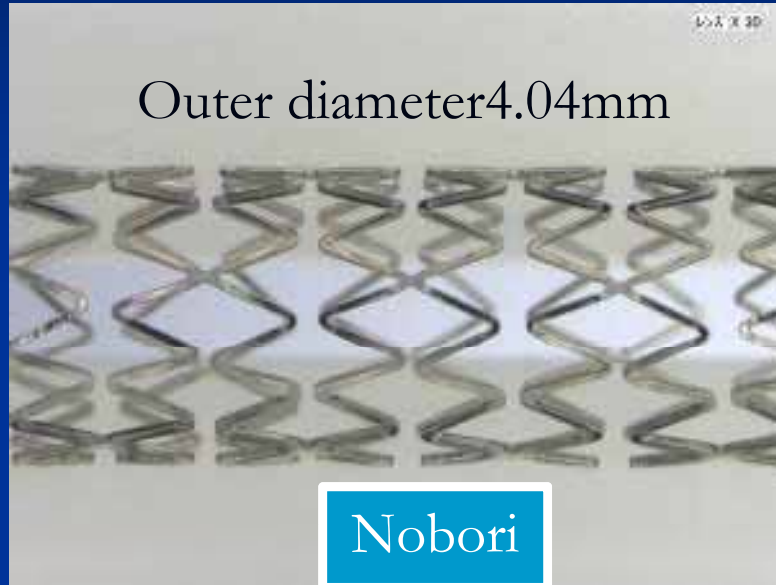
Integrity



2-3Link Peak to Peak

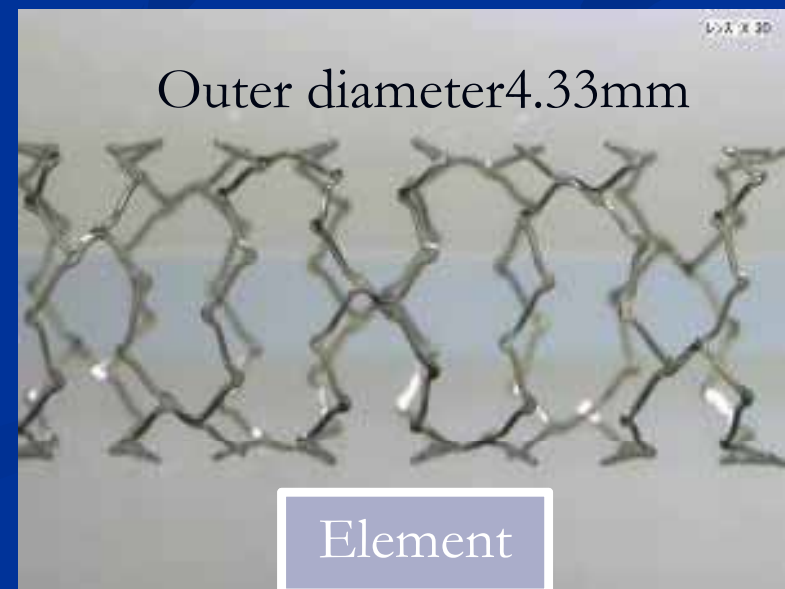
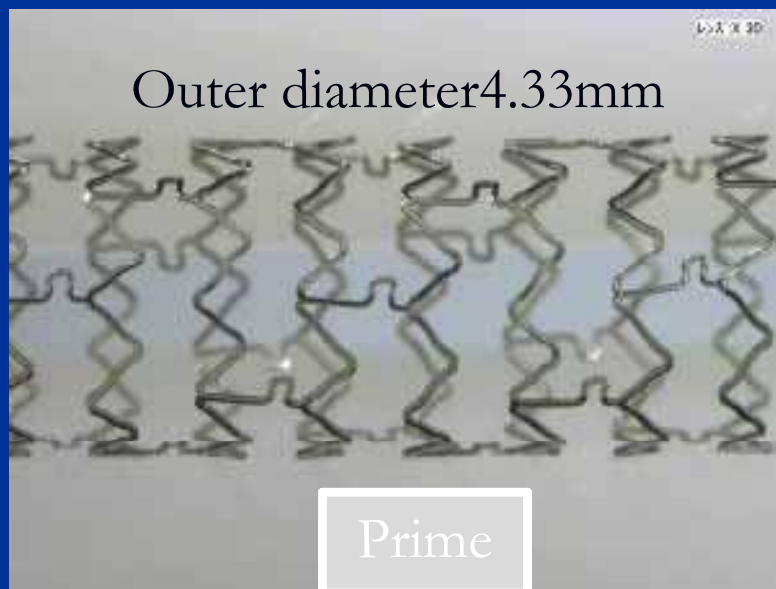
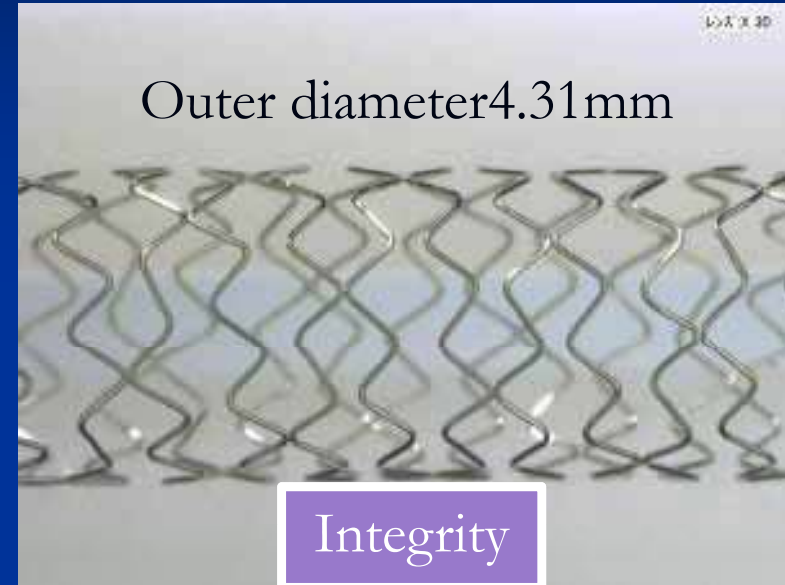
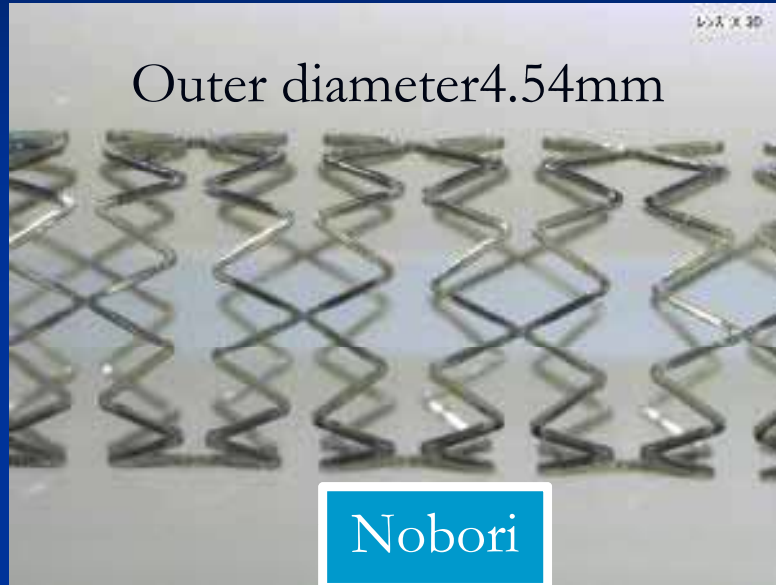
Response of each stents to the over-expansion (4.00mm balloon)

Φ3.5mm



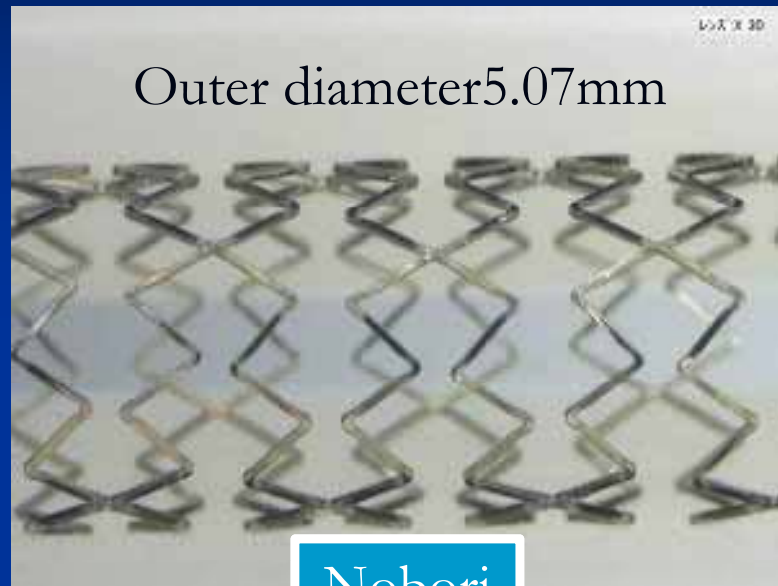
Response of each stents to the over-expansion (4.50mm balloon)

$\Phi 3.5\text{mm}$

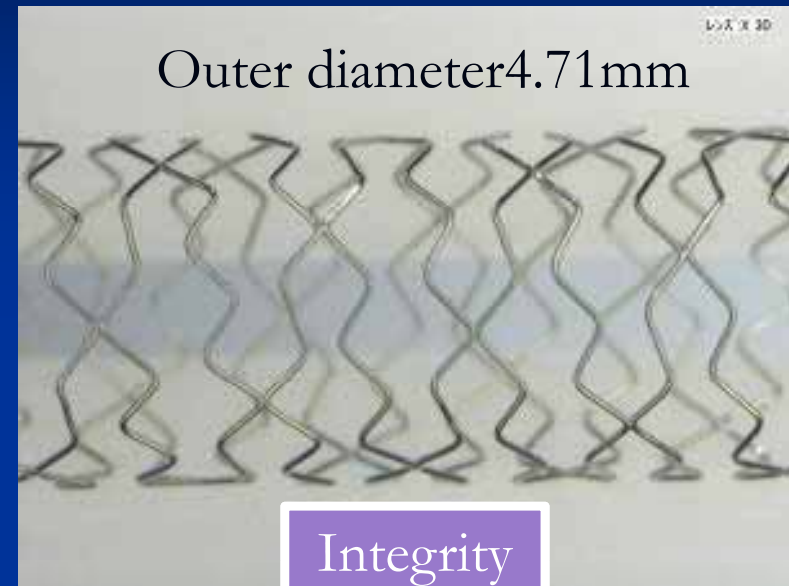


Response of each stents to the over-expansion (5.00mm balloon)

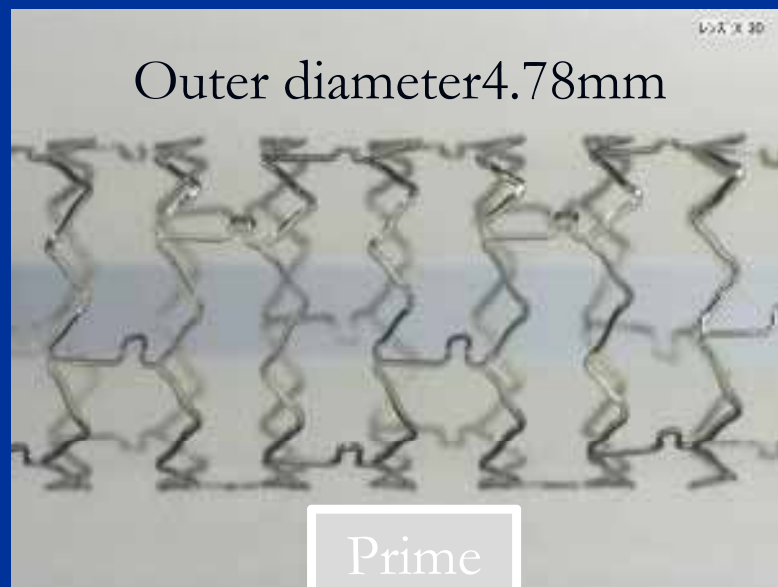
Φ3.5mm



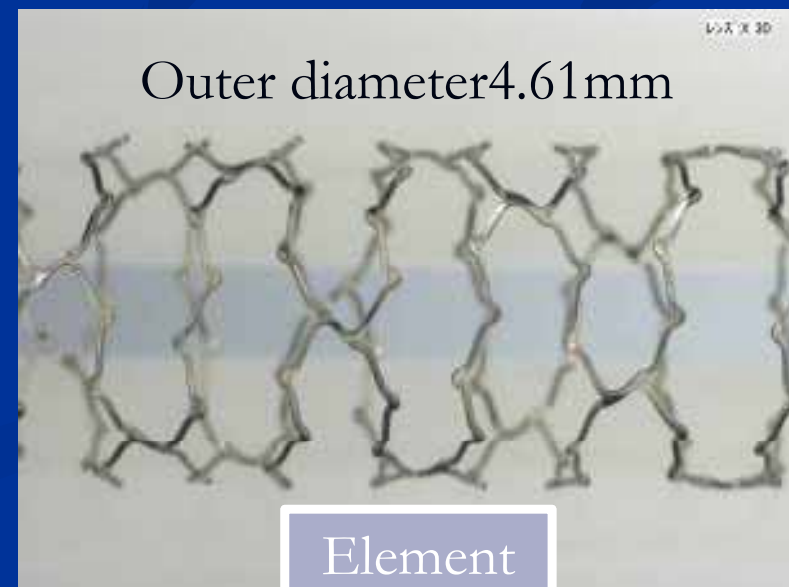
Nobori



Integrity



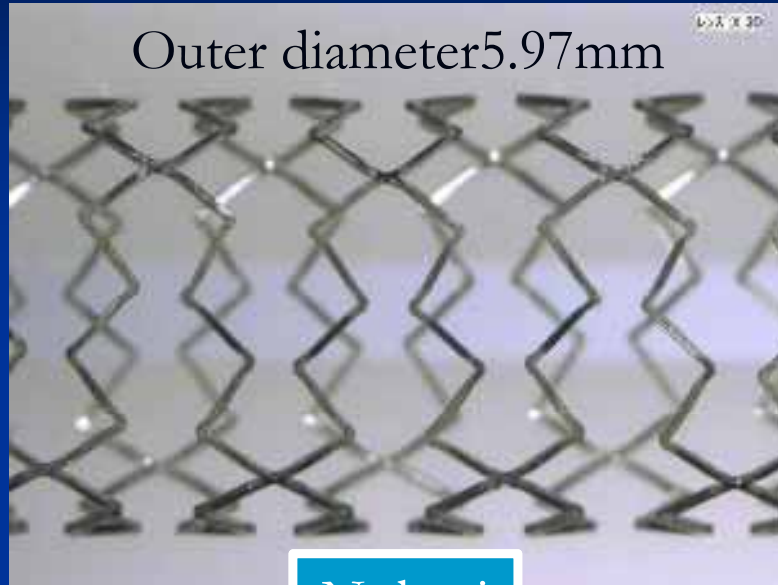
Prime



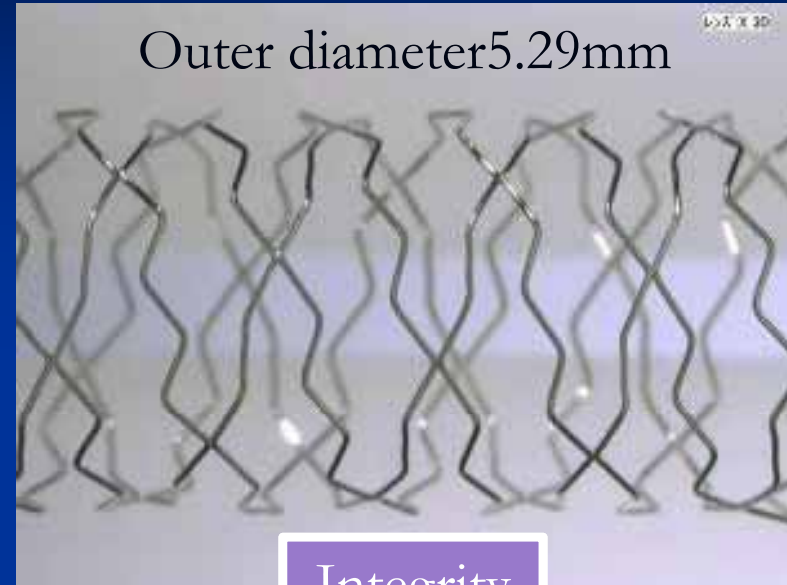
Element

Response of each stents to the over-expansion (6.00mm balloon)

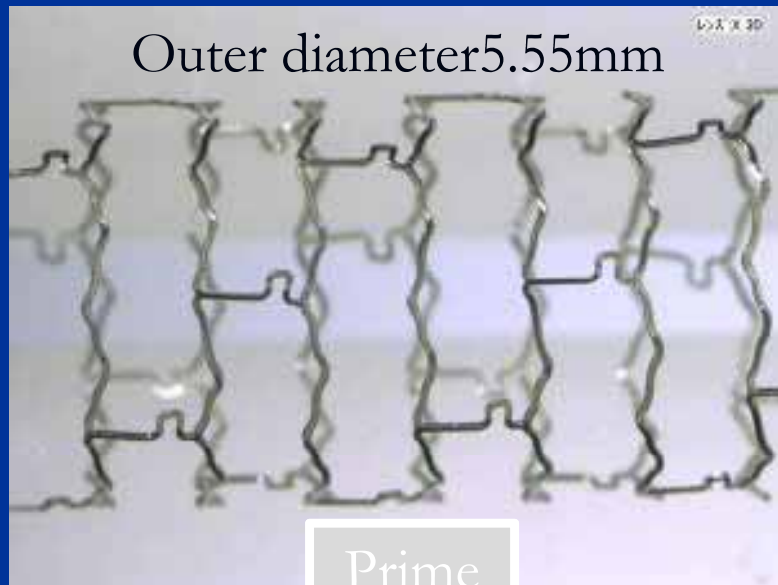
Φ3.5mm



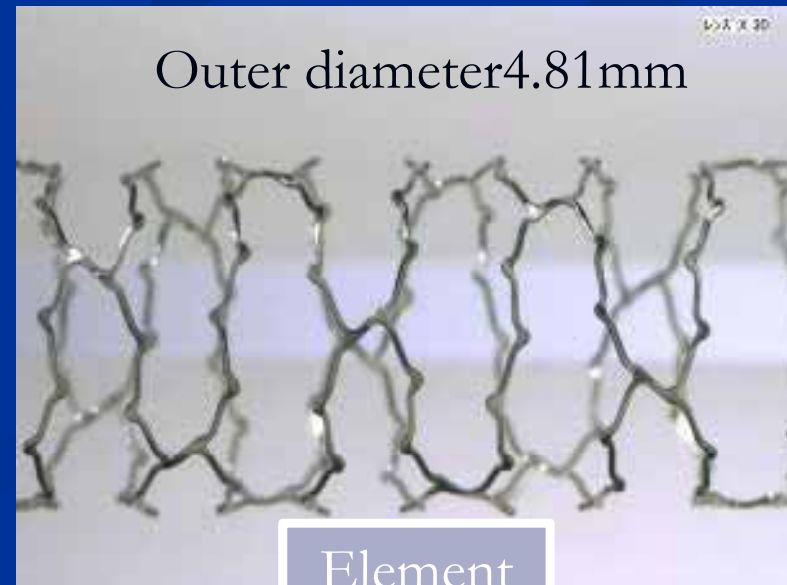
Nobori



Integrity

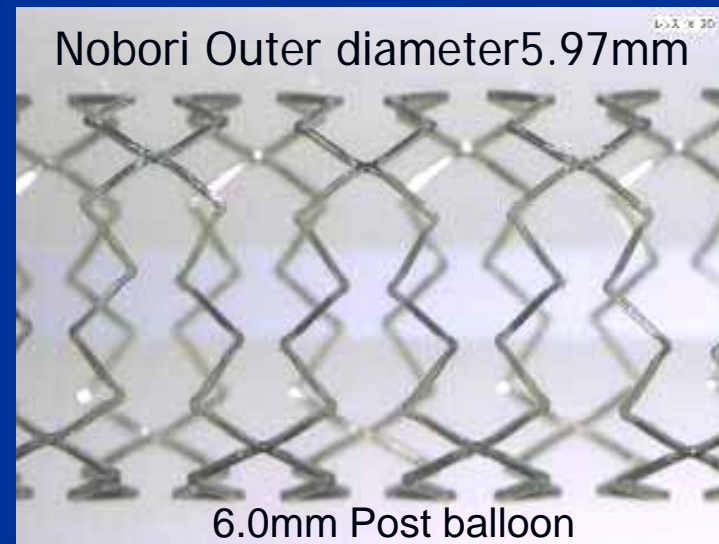
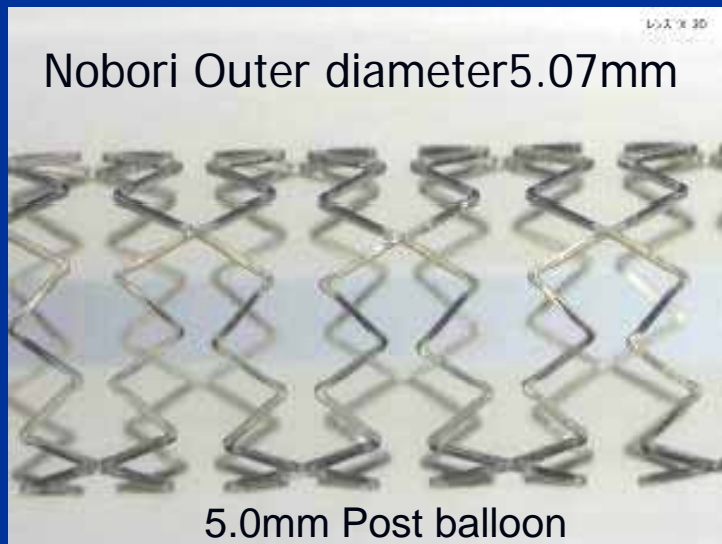
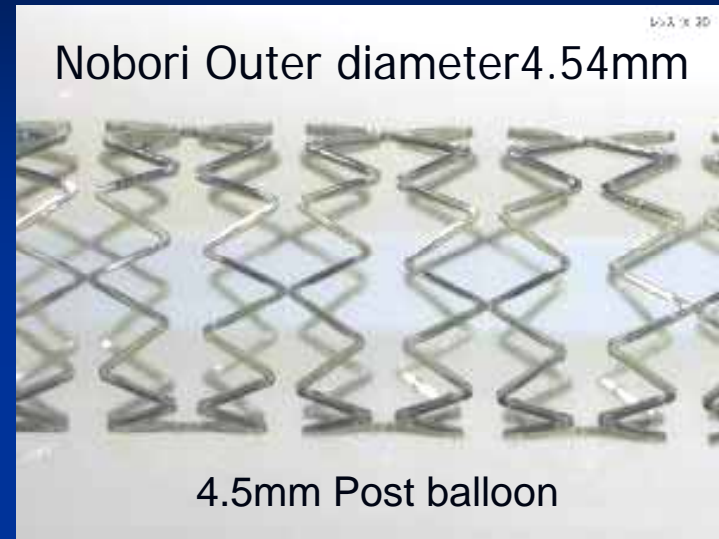
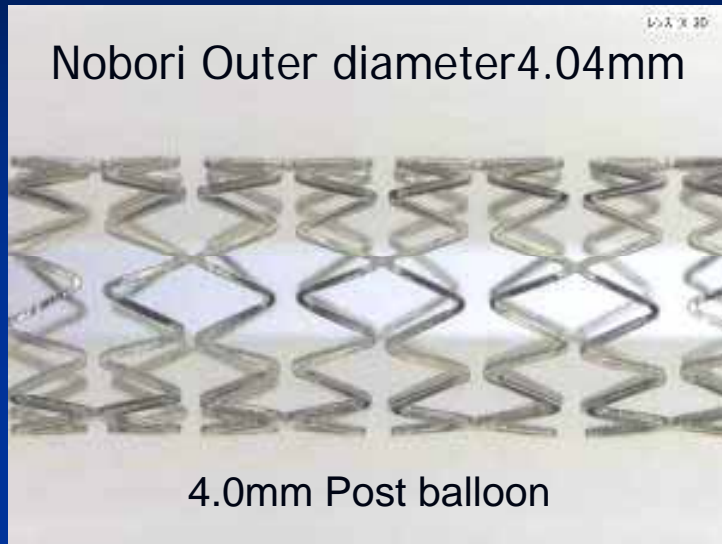


Prime



Element

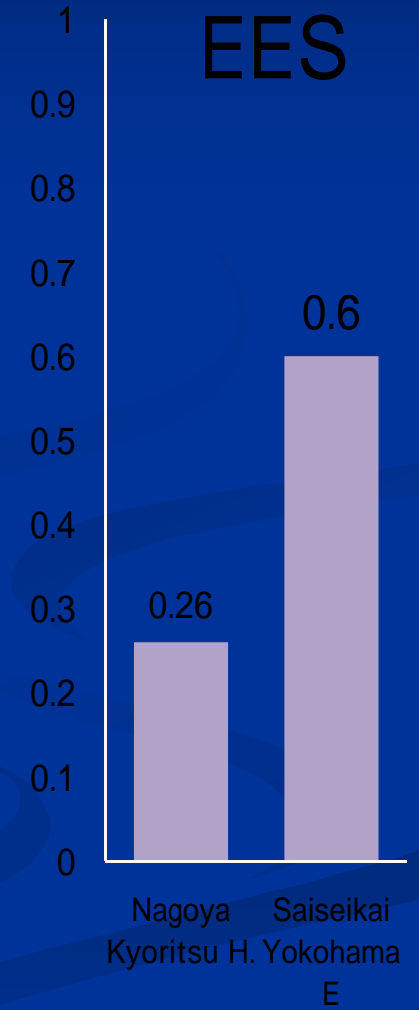
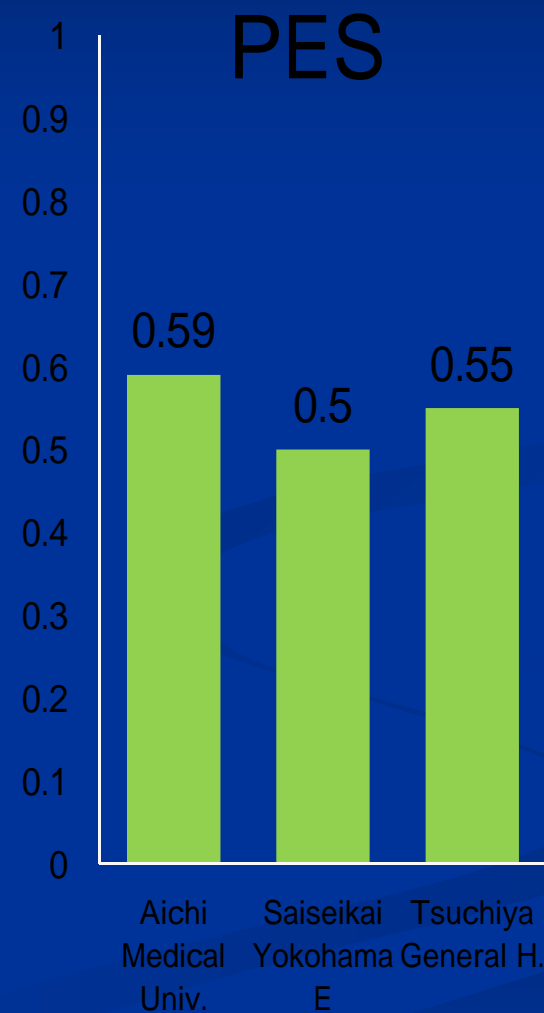
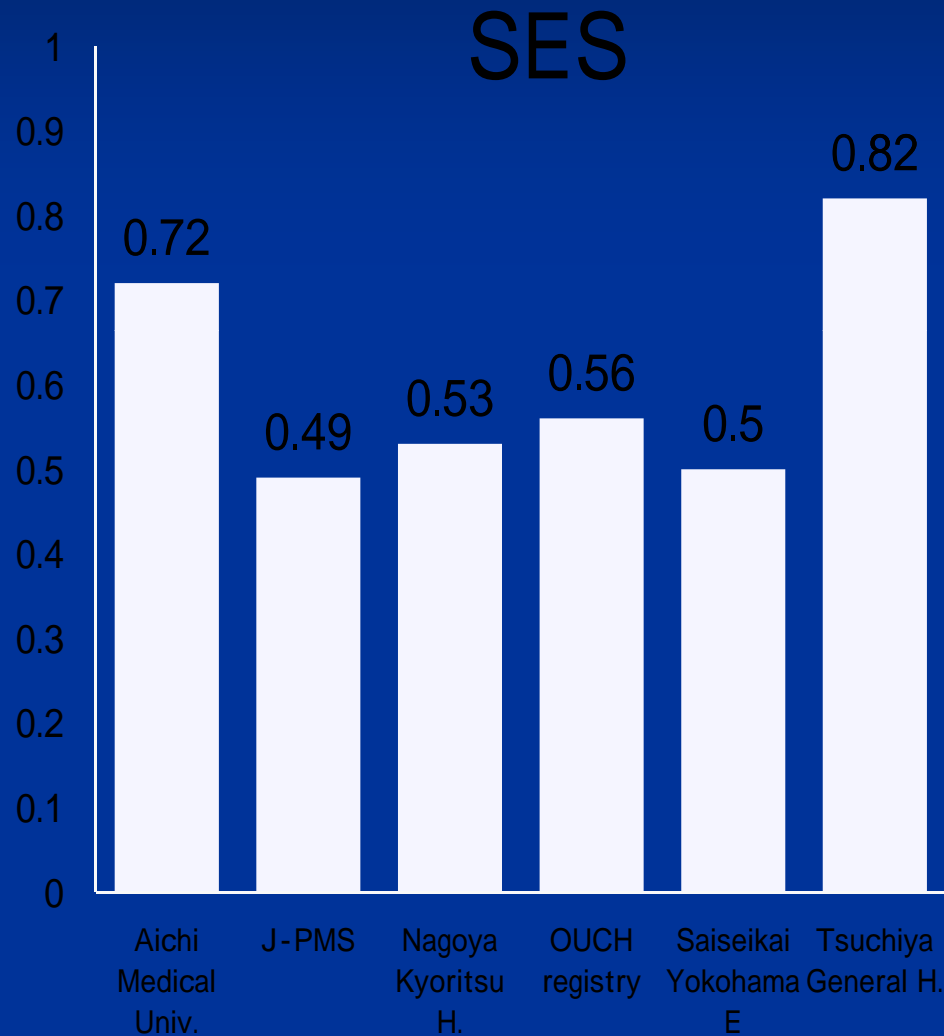
Response of $\phi 3.5\text{mm}$ Nobori stent to the over-expansion



Expanded diameter	3.5mm	4.0mm	5.0mm	6.0mm
Radial force (N/cm)	10.3	11.9	12.9	15.2

DES for Japanese HD patients

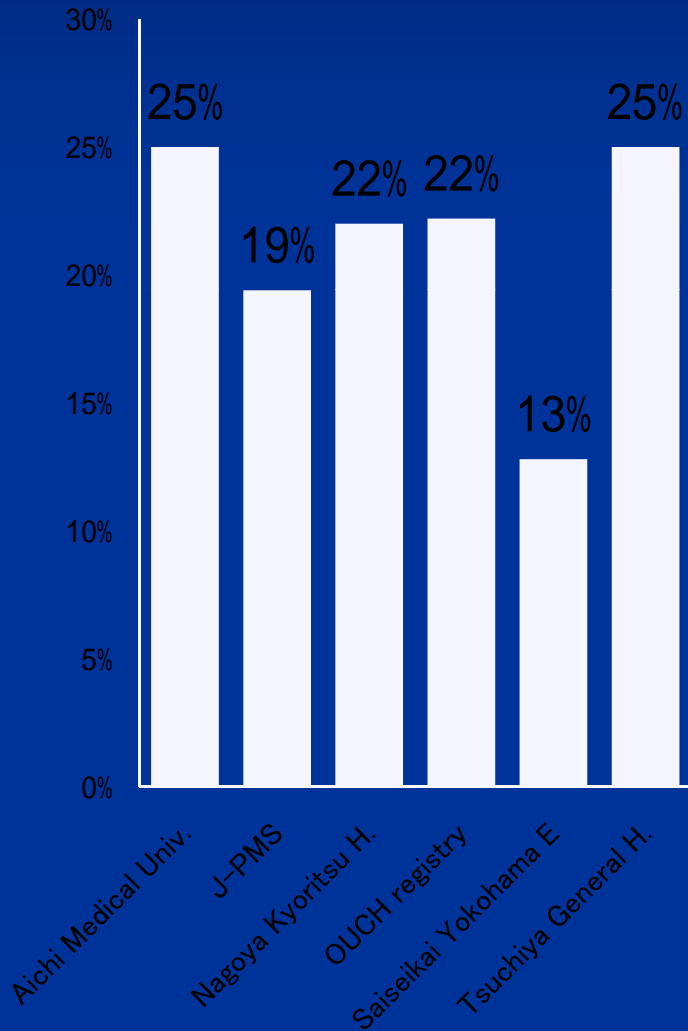
Late Loss (mm)



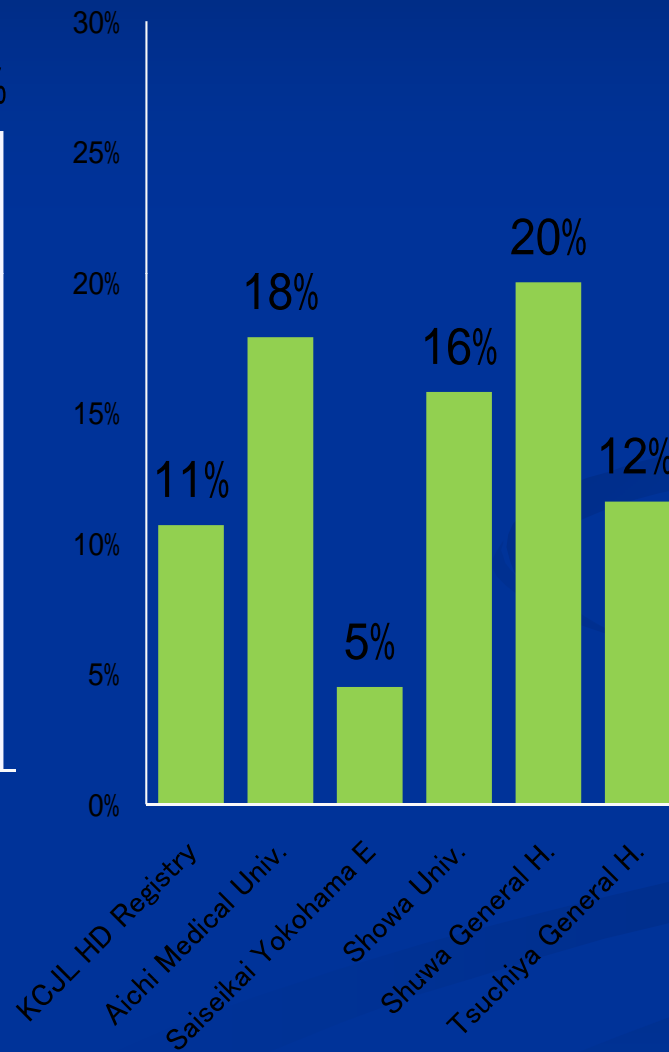
DES for Japanese HD patients

TLR

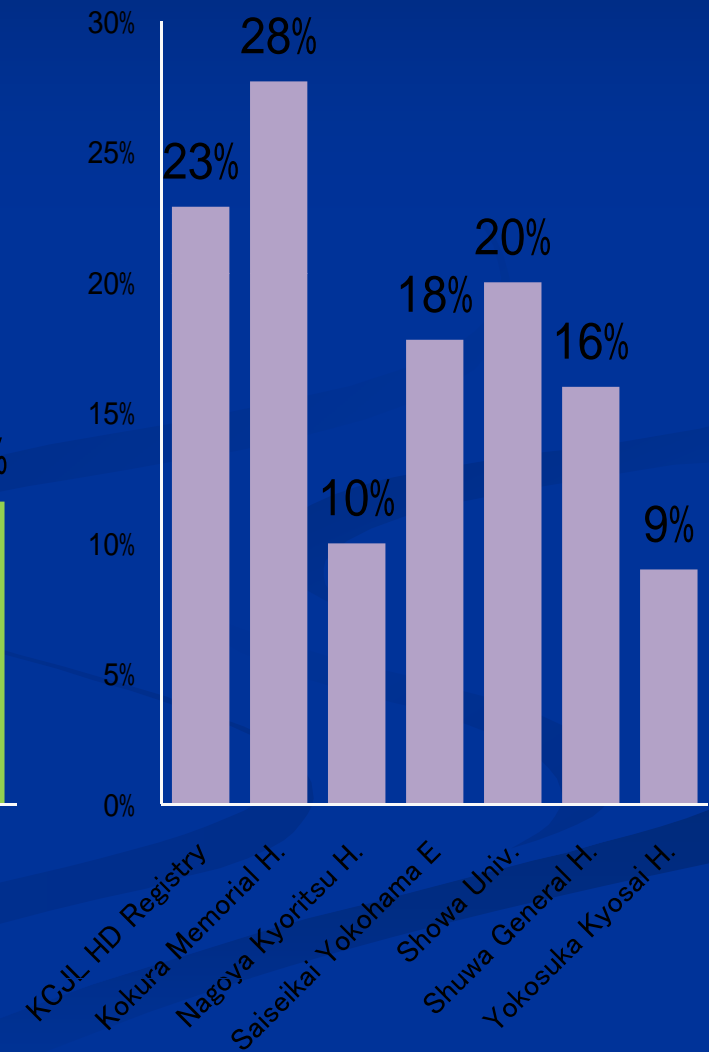
SES



PES



EES



DES for Japanese HD patients: SES

Institute	n of pts	LL (mm)	BAR	TLR	MACE
Aichi Medical Univ. ¹⁾	30	0.72	-	25.0%	36.7%
J-PMS ²⁾	106	0.49	26.4%	19.4%	46.9%
Nagoya Kyoritsu H. ³⁾	50	0.53	21.2%	22.0%	-
OUCH registry ⁴⁾	117	0.56	29.6%	22.2%	24.9%
Saiseikai Yokohama ¹⁾	102	0.5	-	12.8%	20.8%
Tsuchiya General H. ⁵⁾	184	0.82	30.1%	25.0%	28.3%

1) CVIT2012

2) European Heart Journal 2011; 32:829

3) Circ J2012; 76:351

4) Circ J2012 in press

5) Euro Intervention 2011;6:754

DES for Japanese HD patients: PES

Institute	n of pts	LL (mm)	BAR	TLR	MACE
KCJL HD Registry ⁶⁾	44	-	17.5%	10.7%	22.7%
Aichi Medical Univ. ¹⁾	24	0.59	-	17.9%	37.5%
Saiseikai Yokohama ¹⁾	98	0.5	-	4.5%	6.3%
Showa Univ. ¹⁾	38	-	-	15.8%	26.3%
Shuwa General H. ¹⁾	14	-	-	20.0%	-
Tsuchiya General H. ⁵⁾	95	0.55	14.8%	11.6%	14.7%

1) CVIT2012

5) Euro Intervention 2011;6:754

6) CVIT2011, LBT

DES for Japanese HD patients: EES

Institute	n of pts	LL (mm)	BAR	TLR	MACE
KCJL HD Registry ⁶⁾	35	-	25.7%	22.9%	40.0%
Kokura Memorial H. ⁷⁾	32	-	-	27.7%	-
Nagoya Kyoritsu H. ³⁾	50	0.26	8.7%	10.0%	-
Saiseikai Yokohama E. ¹⁾	31	0.6	-	17.8%	20.0%
Showa Univ. ¹⁾	30	-	-	20.0%	26.7%
Shuwa General H. ¹⁾	23	-	-	16.0%	-
Yokosuka Kyosai H. ¹⁾	75	-	-	9.0%	25.3%

1) CVIT2012

3) Circ J2012; 76:351

6) CVIT2011, LBT

7) Chu-Shikoku Live

Design and Characteristics of the Four Limus DESs

	Cypher	Endeavor	Xience V	Nobori
Manufacturer	Cordis/J&J	Medtronic	Abbott	Terumo
Drug	Sirolimus	Zotarolimus	Everolimus	BiolimusA9
Stent platform	BX Velocity	Driver	Multi-Link Vision	S-Stent
Polymer	PBMA+PEVA (Persistent)	PC (Persistent)	PBMA+PVDF-HFP (Persistent)	PLA (Bioabsorbable/ Abluminal)
Stent strut thickness (μm)	140	91	81	125
Polymer thickness (μm)	12.6	5.3	7.6	25
Total thickness (μm)	152.6	96.3	88.6	150
Elution in animal model	>95% elution at 12 weeks	>95% elution at 1 week	>80% elution at 4 weeks	>45% elution at 12 weeks
Total drug dose of 18mm stent (μg)	150	180	88	293

PBMA: poly-n-butyl methacrylate; PEVA: polyethylene–vinyl acetate;
 PC: poly (phosphorylcholine-lauryl methacrylate);
 PVDF-HFP: vinylidene fluoride and hexafluoroisopropylene; PLA: poly-lactic acid.

Otsuka Y, et al. CCI 78:1078–1085 (2011) modified

Case1 : A 80 year old male

Effort AP (CCS)

ASO (Fontaine)

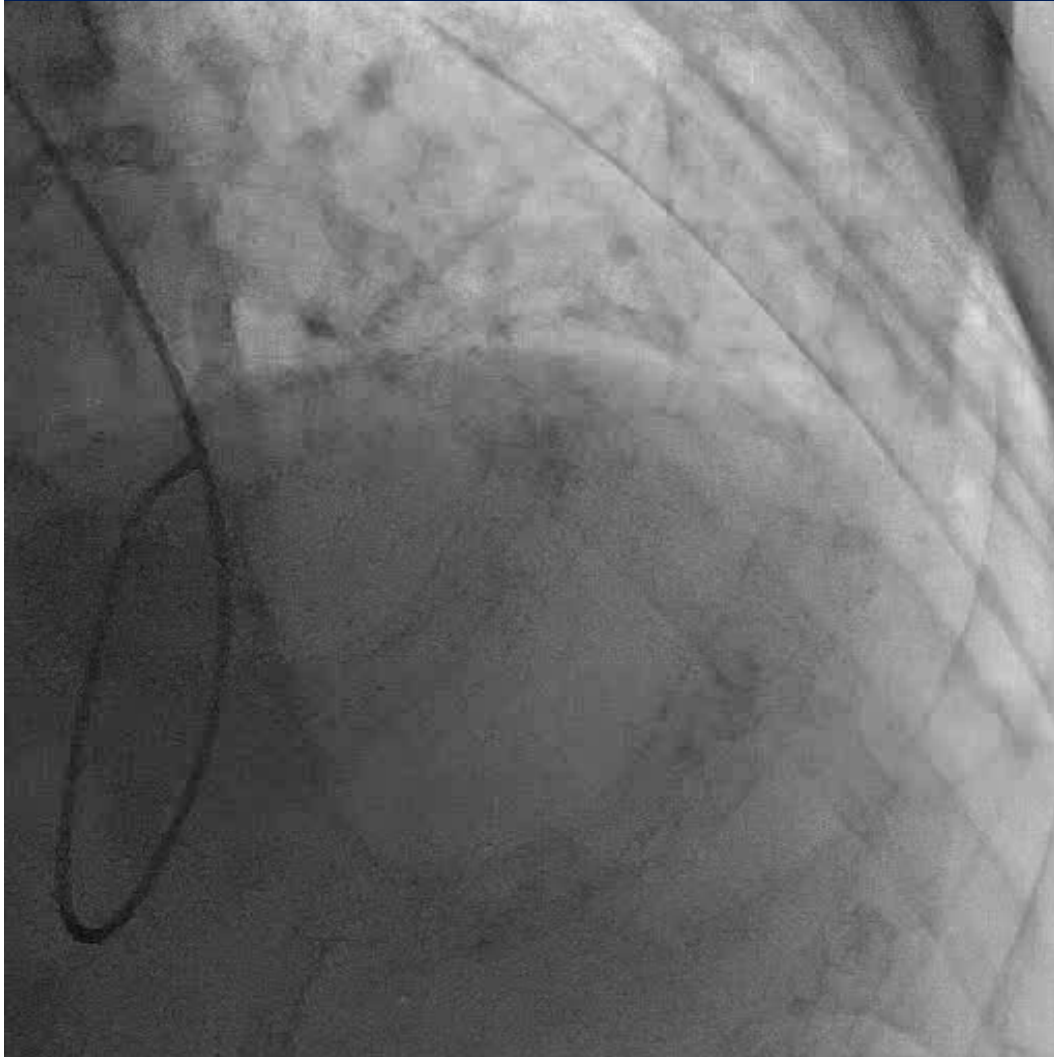
CRF on HD

DM

HT

Coronary angiogram

16th February 2012



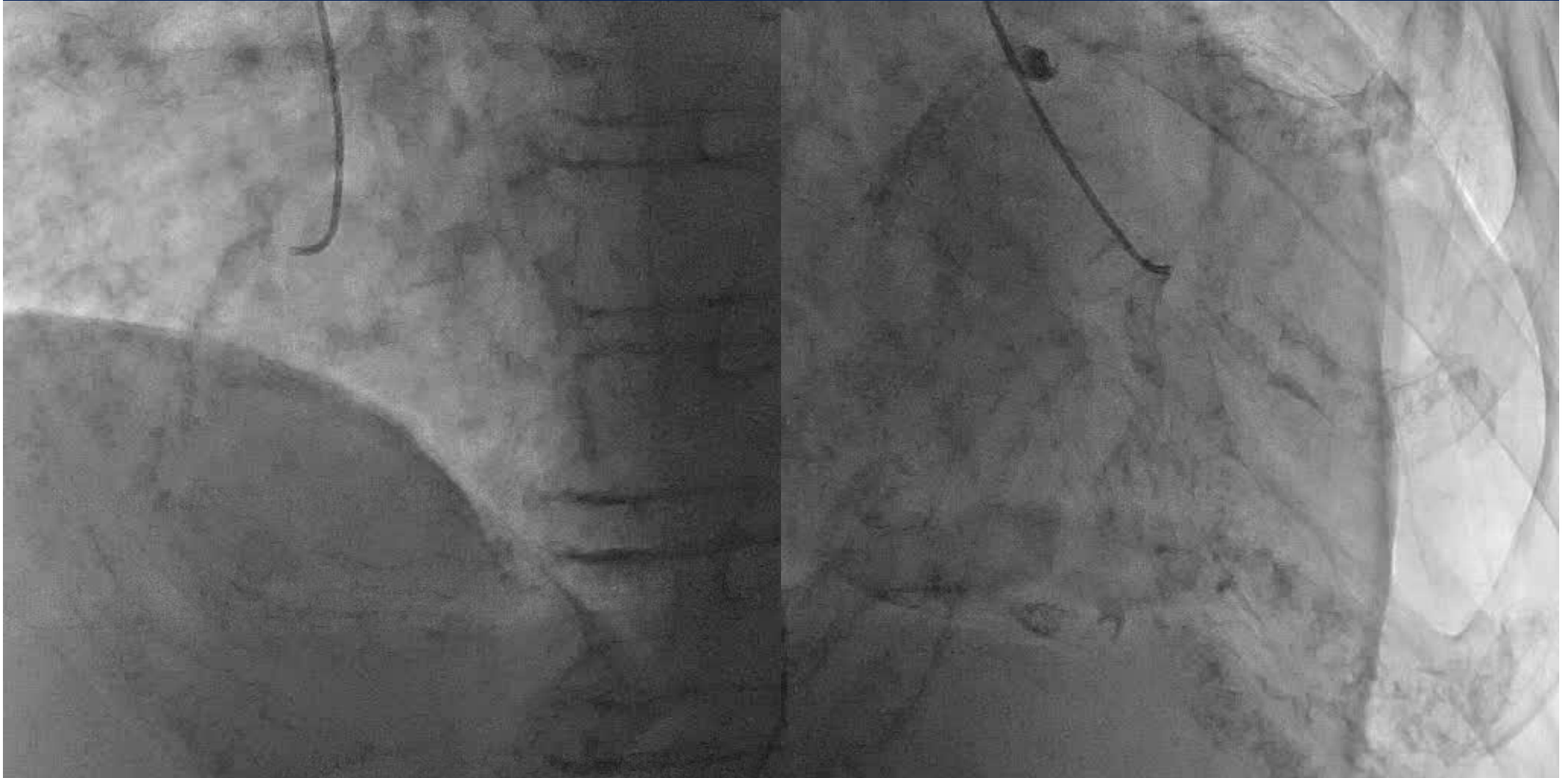
Left coronary angiogram in the RAO cranial view



Left coronary angiogram in the LAO cranial view

Coronary angiogram

16th February 2012



Right coronary angiogram in the LAO view

Right coronary angiogram in the RAO view

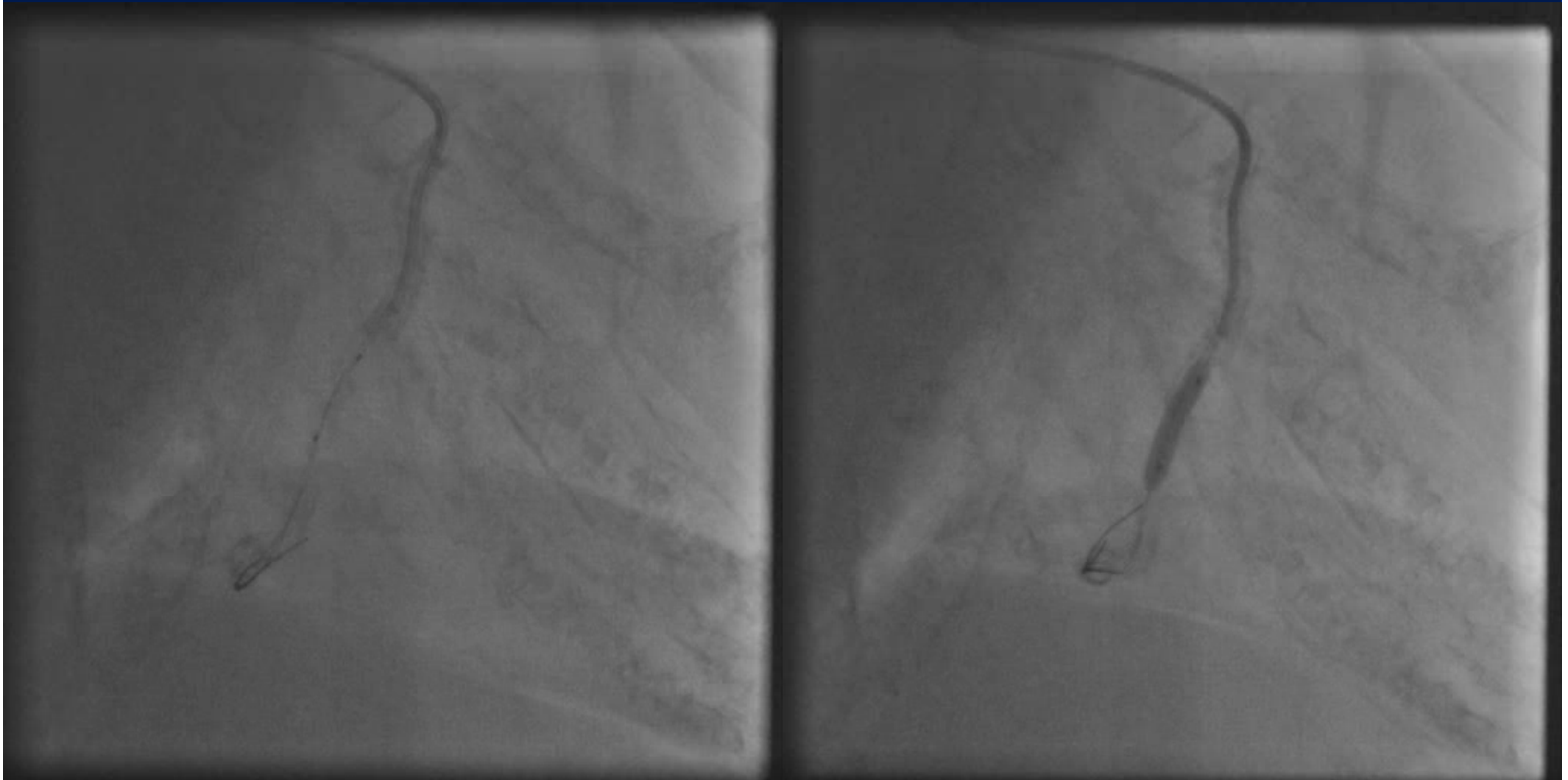
PCI for the severely calcified RCA

20th February 2012

20th February 2012

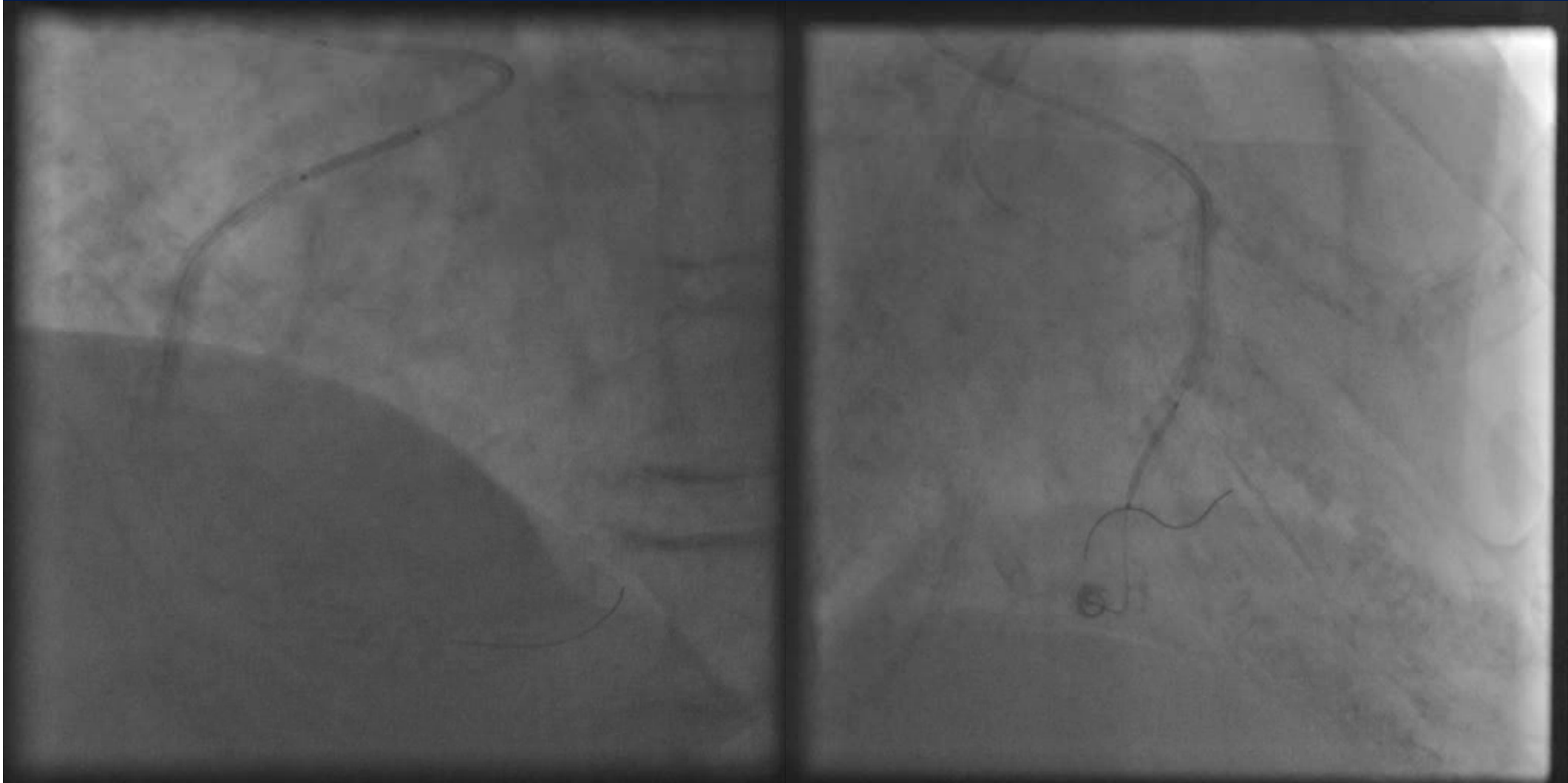


Approach was left femoral artery. But I could not induce the 6 Fr guiding catheter to the right coronary artery by using long sheath. And so I changed the 5Fr guiding catheter.



I tried to engage a 5 Fr guiding catheter (Heartrail : Terumo Co., Japan) into the right coronary artery by using balloon anchoring technique, and then I dilated the lesion with 3.0 × 15mm balloon.

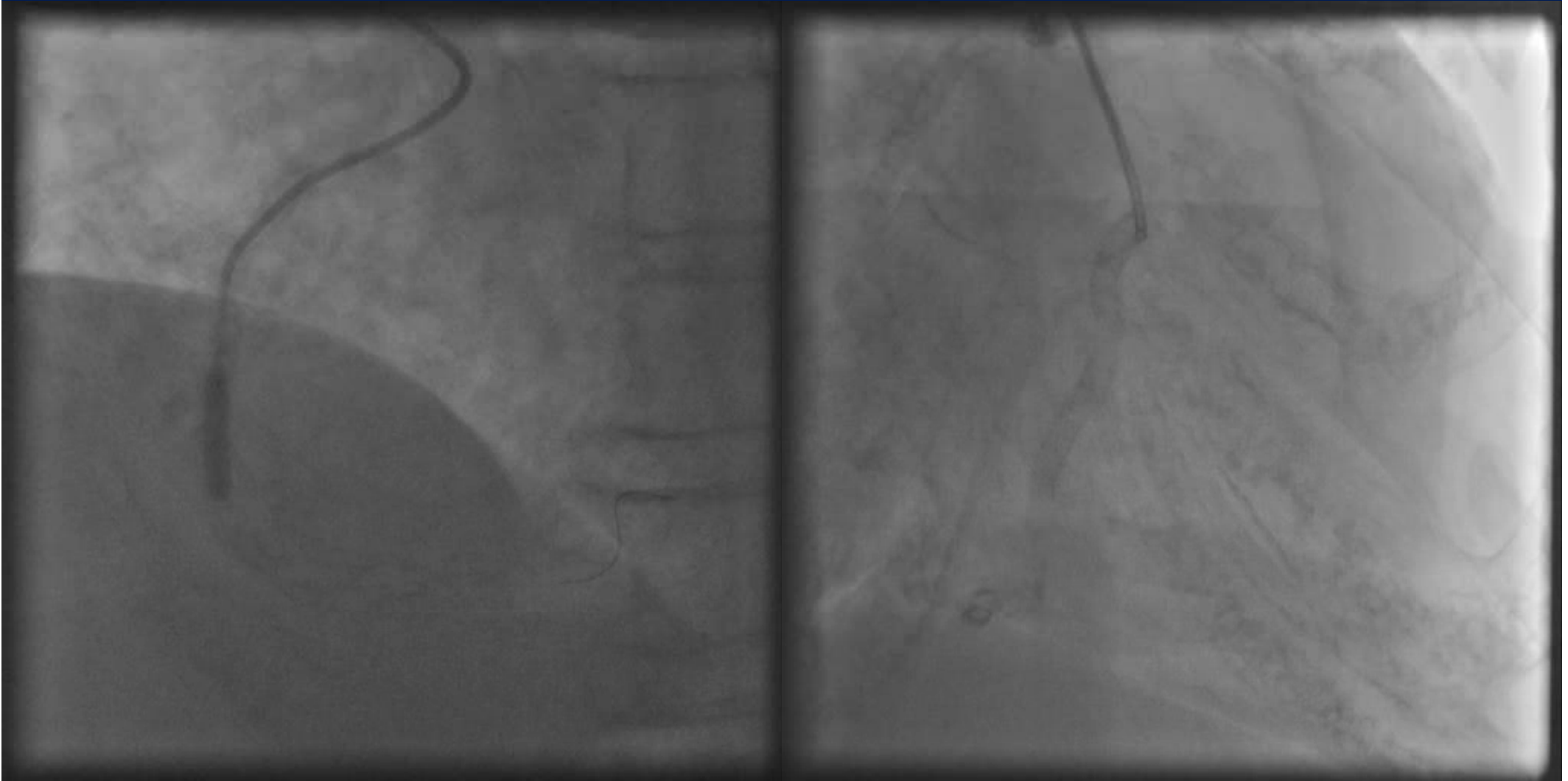
20th February 2012



I delivered Nobori stent (DES), which dimension was $3.5 \times 14\text{mm}$ (Terumo Co., Japan) to the mid RCA by deep engagement of 5Fr guiding catheter.

Final angiogram

20th February 2012



Finally, I deployed Nobori stent (DES), which dimension was 3.5×14 mm (Terumo Co., Japan) to the mid RCA.

Right coronary angiogram in the RAO view

PCI for the severely calcified and tortuous ULMCA and LAD

24th February 2012

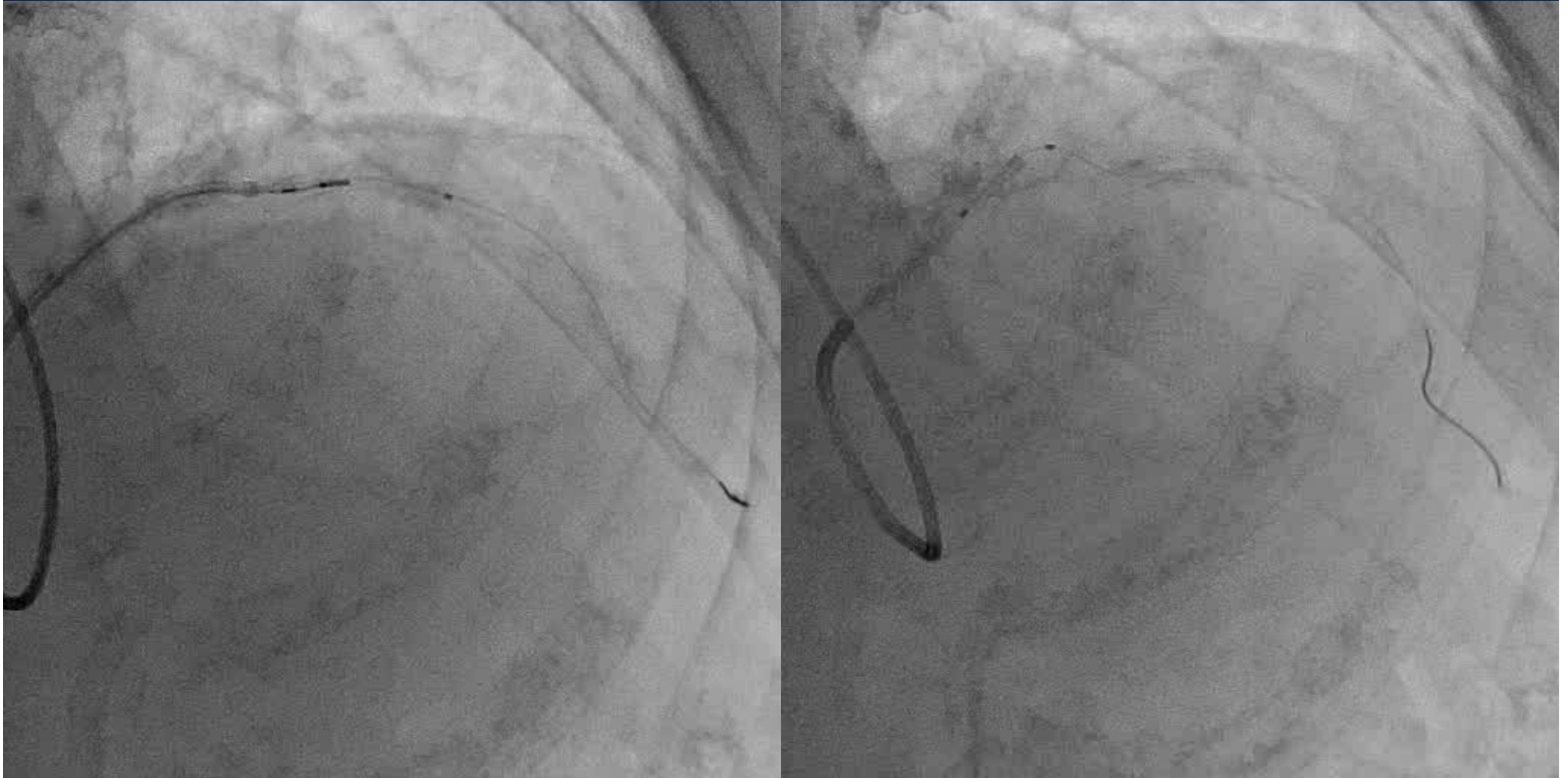
Baseline angiography

24th February 2012



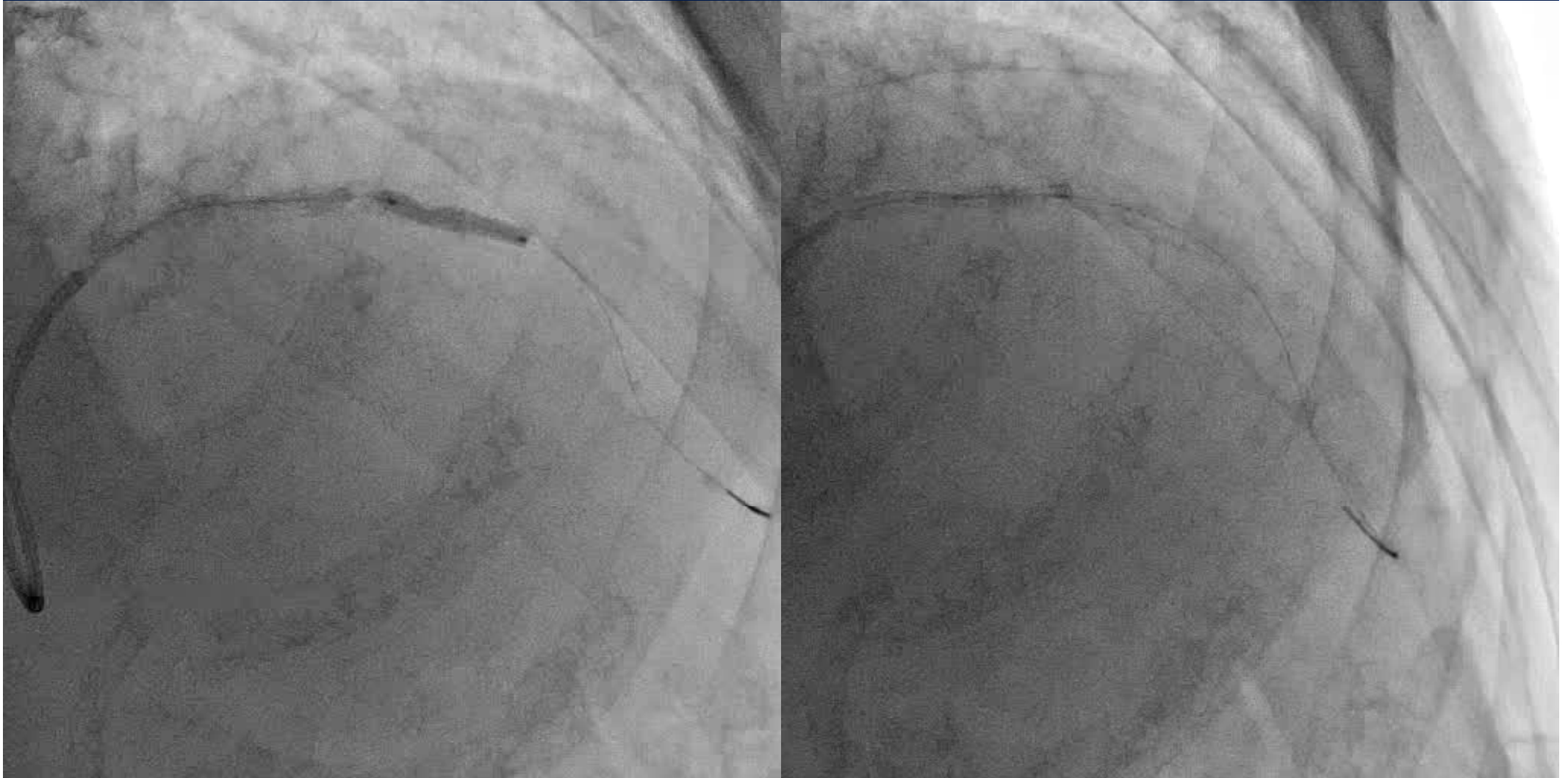
Left coronary angiogram in the RAO cranial view

24th February 2012



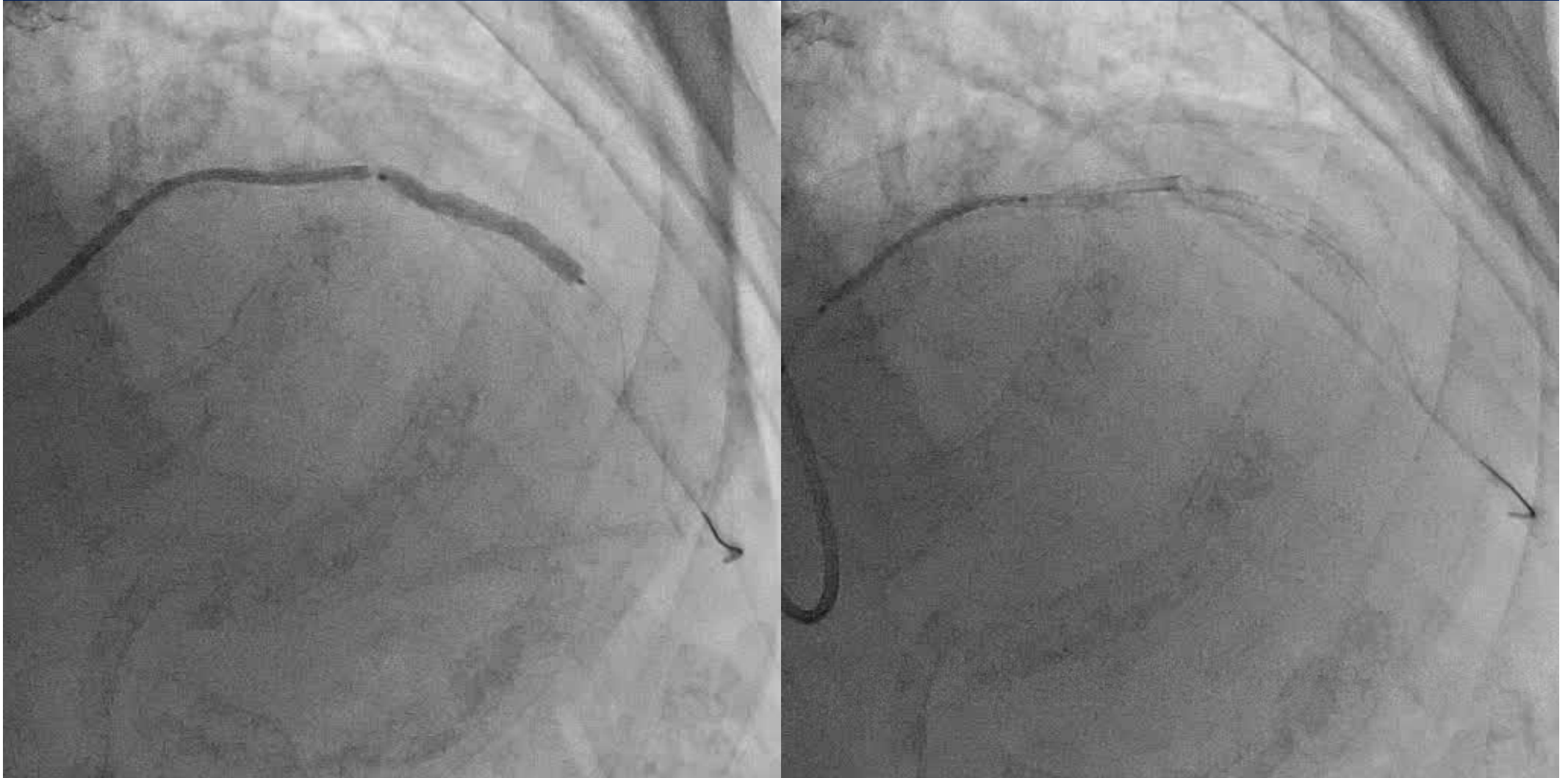
Approach was left brachial artery by using 6Fr sheath.

I tried to get the IVUS catheter and balloon catheter to pass the mid LAD calcified lesion, but I could not pass the mid LAD calcified lesion.



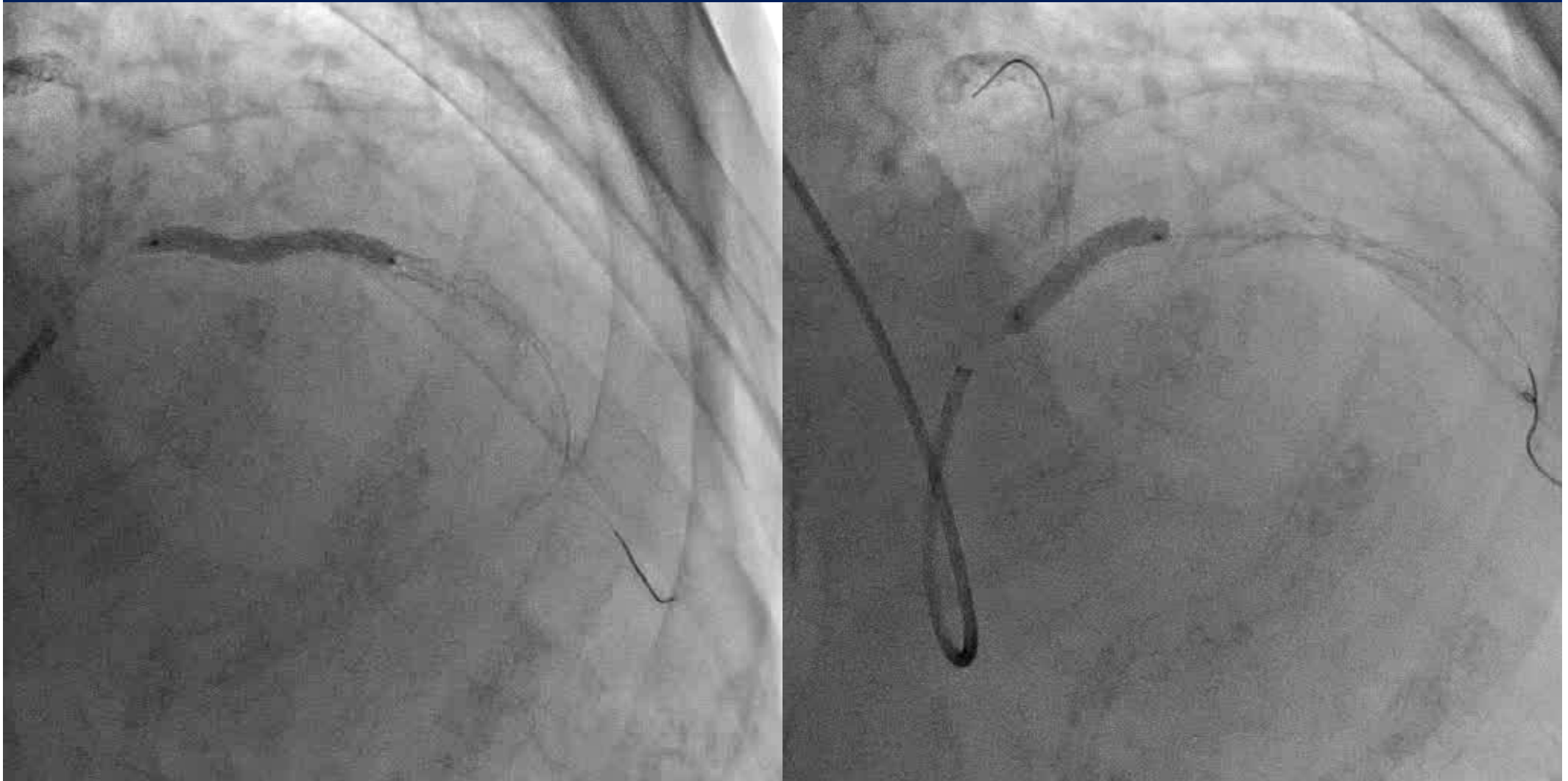
So, I tried to engage a 5 Fr guiding catheter deeply into the LAD, which was ST01 (Terumo Co., Japan) by balloon anchoring technique . I dilated the lesion with 3.0 × 15mm balloon, And then I delivered Nobori DES, which dimension was 3.0 × 28mm (Terumo Co., Japan) to the distal LAD by the 5 in 6 Fr technique.

24th February 2012



I deployed two Nobori stents (DES), which dimension were 3.0 × 28mm (Terumo Co., Japan) in the lesion from mid to distal LAD by the 5 in 6 Fr technique.

24th February 2012



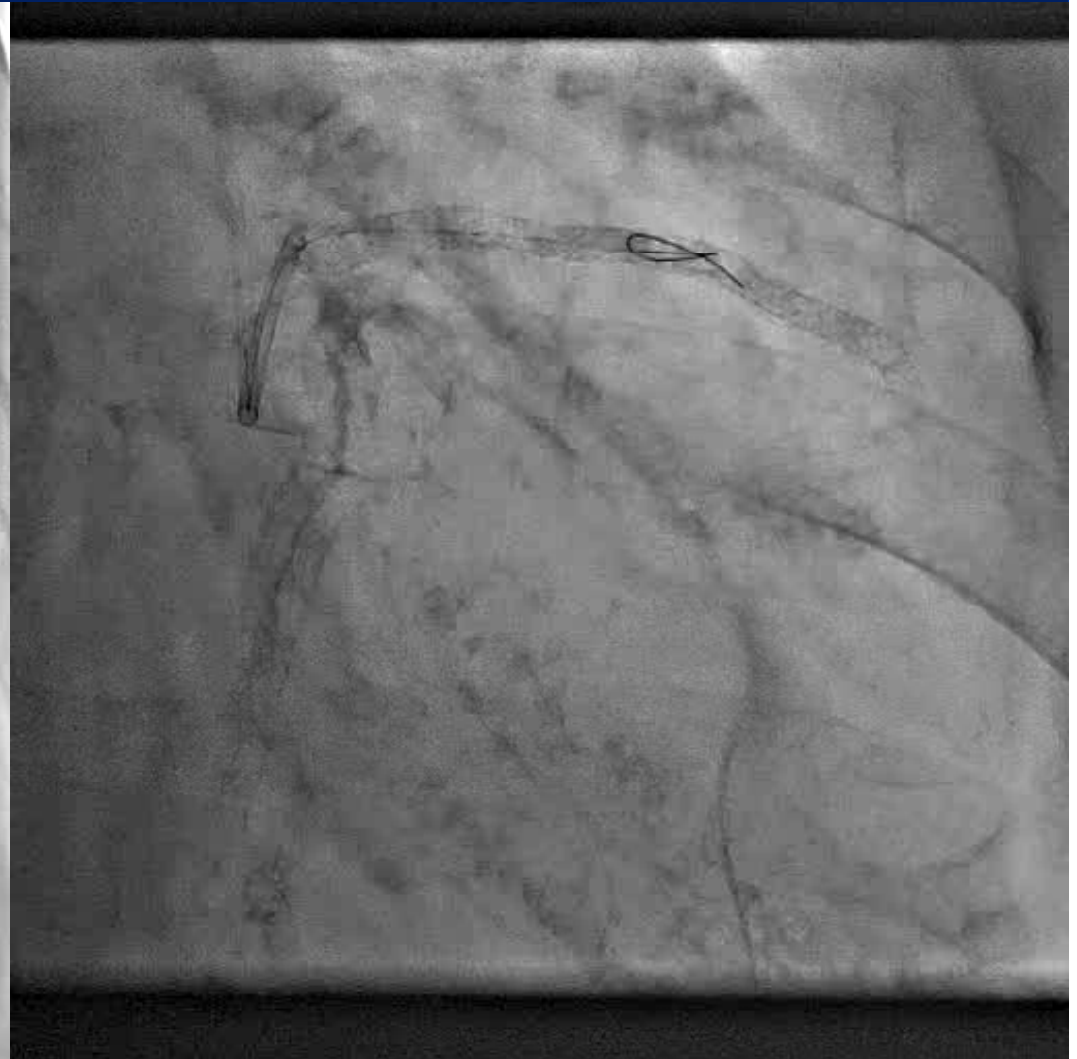
Finally, I deployed Nobori stents (DES), which dimension was $3.5 \times 18\text{mm}$ (Terumo Co., Japan) in the lesion from the ULMCA to proximal LAD.

Final angiogram

24th February 2012



Left coronary angiogram in the RAO cranial view



Left coronary angiogram in the RAO caudal view

Follow up CAG

7th March 2013

Coronary angiogram

7th March 2013

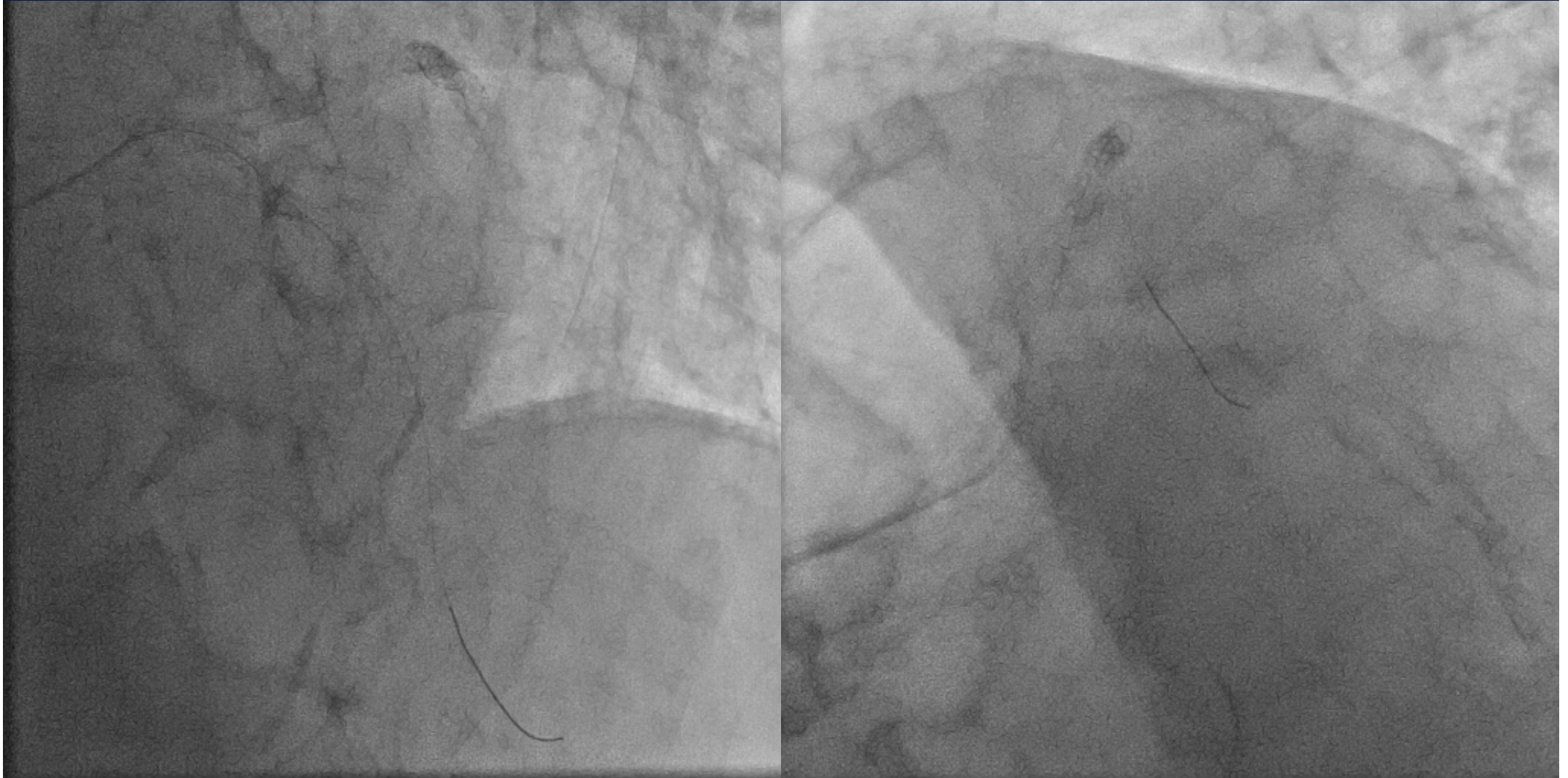


Left coronary angiogram in the RAO caudal view

Left coronary angiogram in the RAO cranial view

Coronary angiogram

7th March 2013

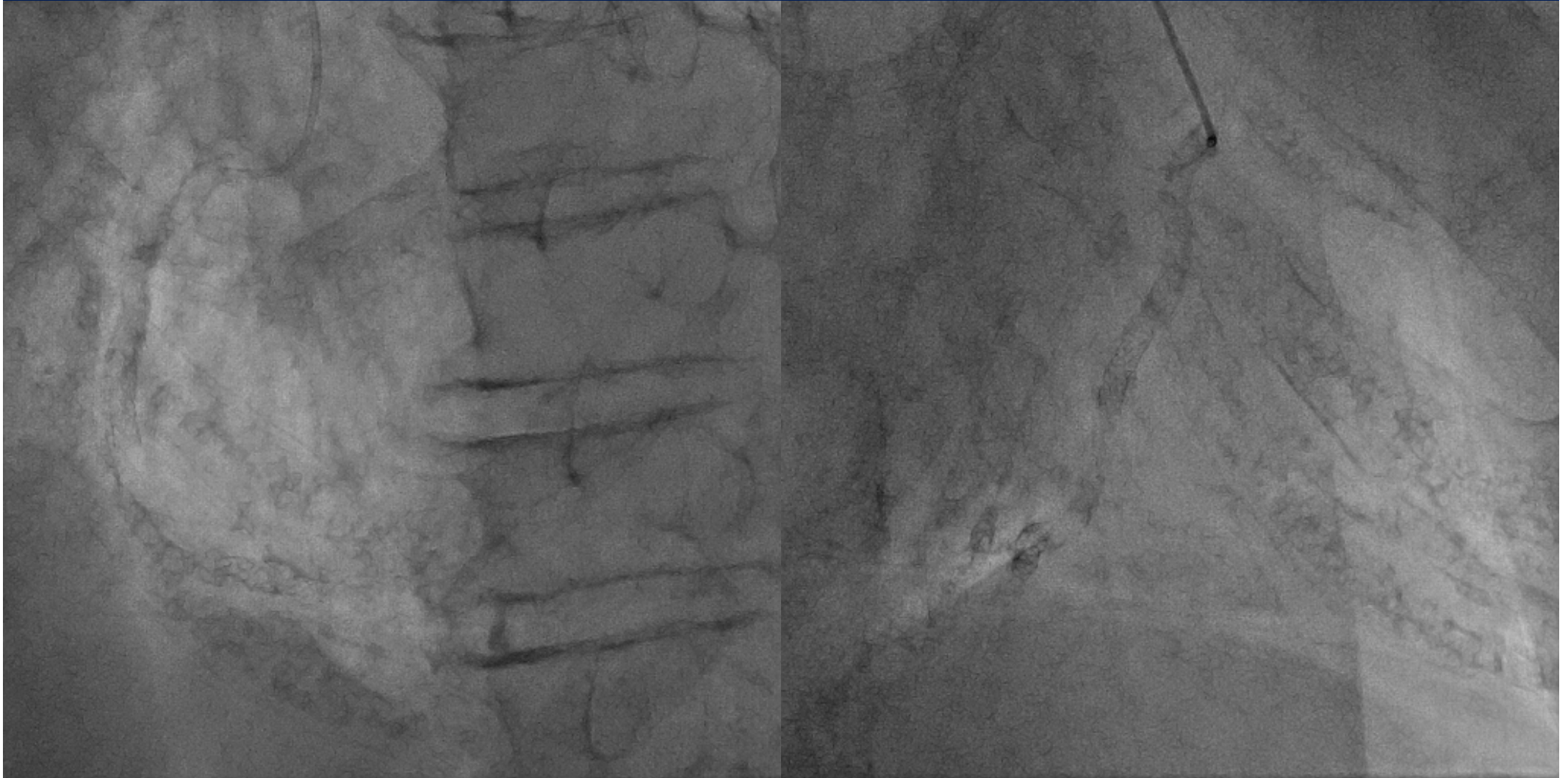


Left coronary angiogram in the LAO cranial view

Left coronary angiogram in the spider view

Coronary angiogram

7th March 2013



Right coronary angiogram in the LAO view

Right coronary angiogram in the RAO view

Case 2 : 79 year old Male

Effort AP (CCS)

ASO (Fontaine b)

DM

HT

Coronary angiogram

18th April 2012



Left coronary angiogram in the RAO cranial view

Right coronary angiogram in the LAO view

PCI for the severely calcified ULMCA

20th April 2012

Baseline angiography

20th April 2012

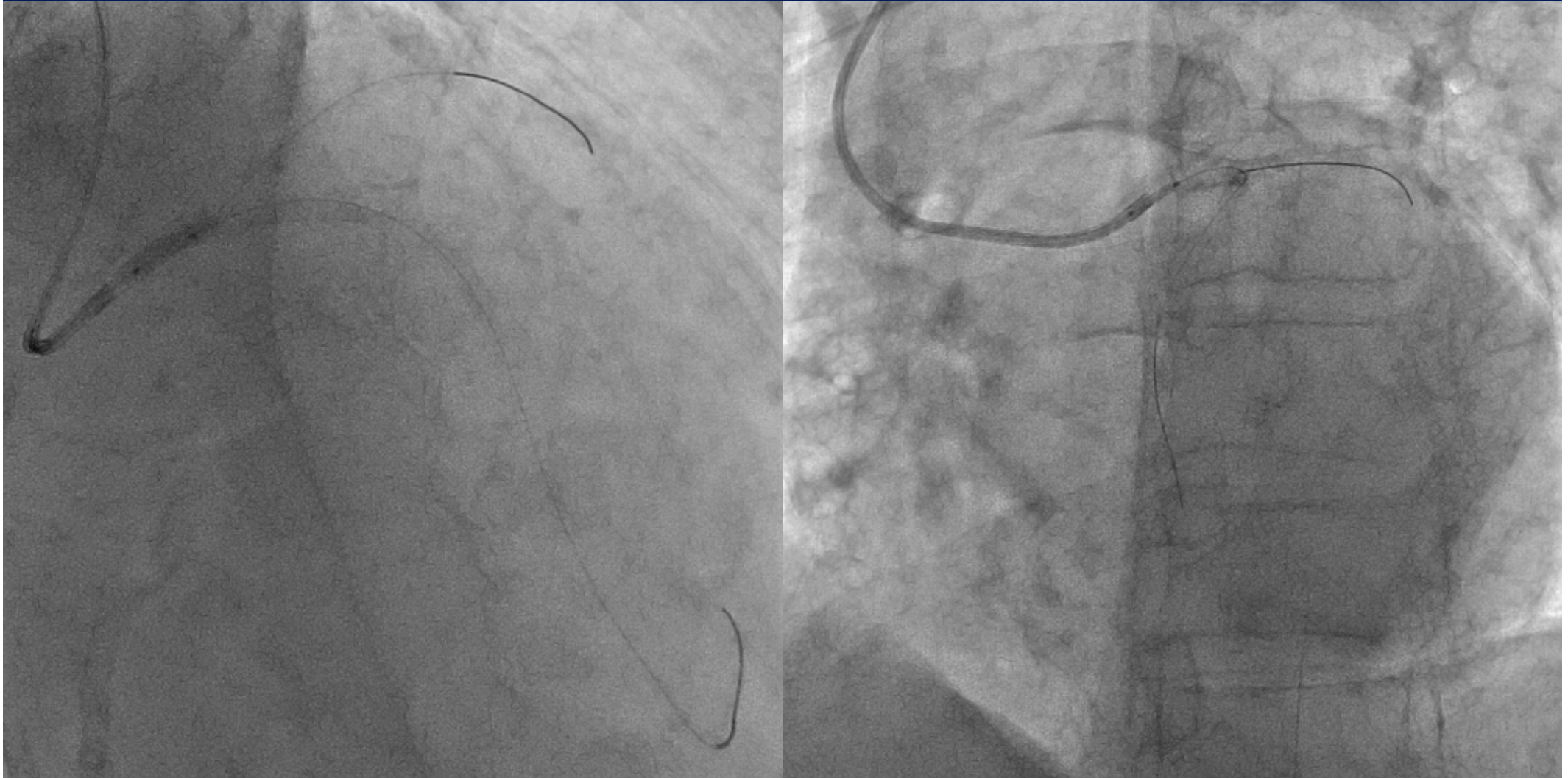


Left coronary angiogram in the RAO cranial view



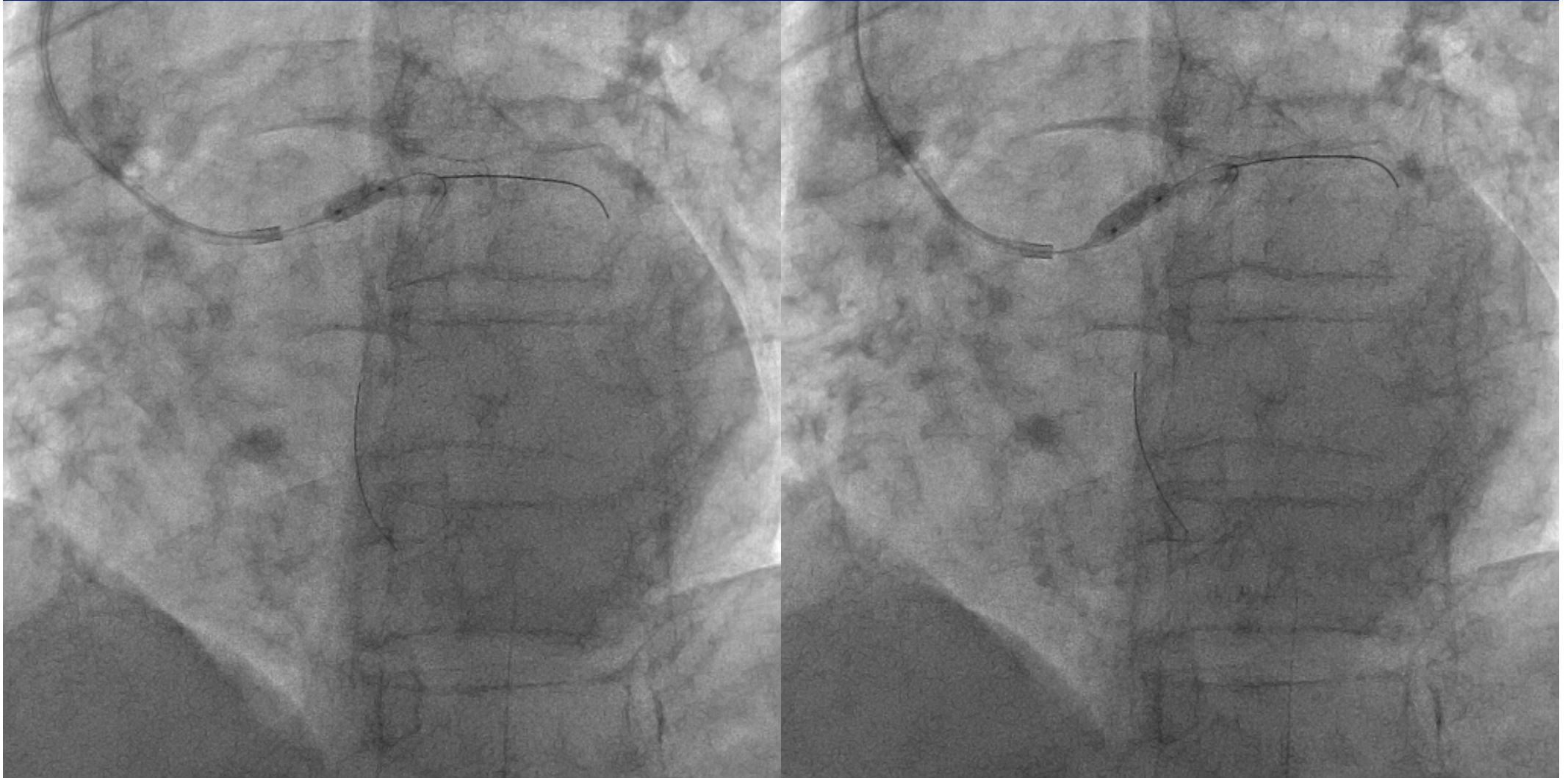
Left coronary angiogram in the LAO cranial view

20th April 2012



I dilated the lesion with 3.5×10 mm balloon, And then I delivered Nobori DES, which dimension was 3.5×8 mm (Terumo Co., Japan) to the ULMCA lesion.

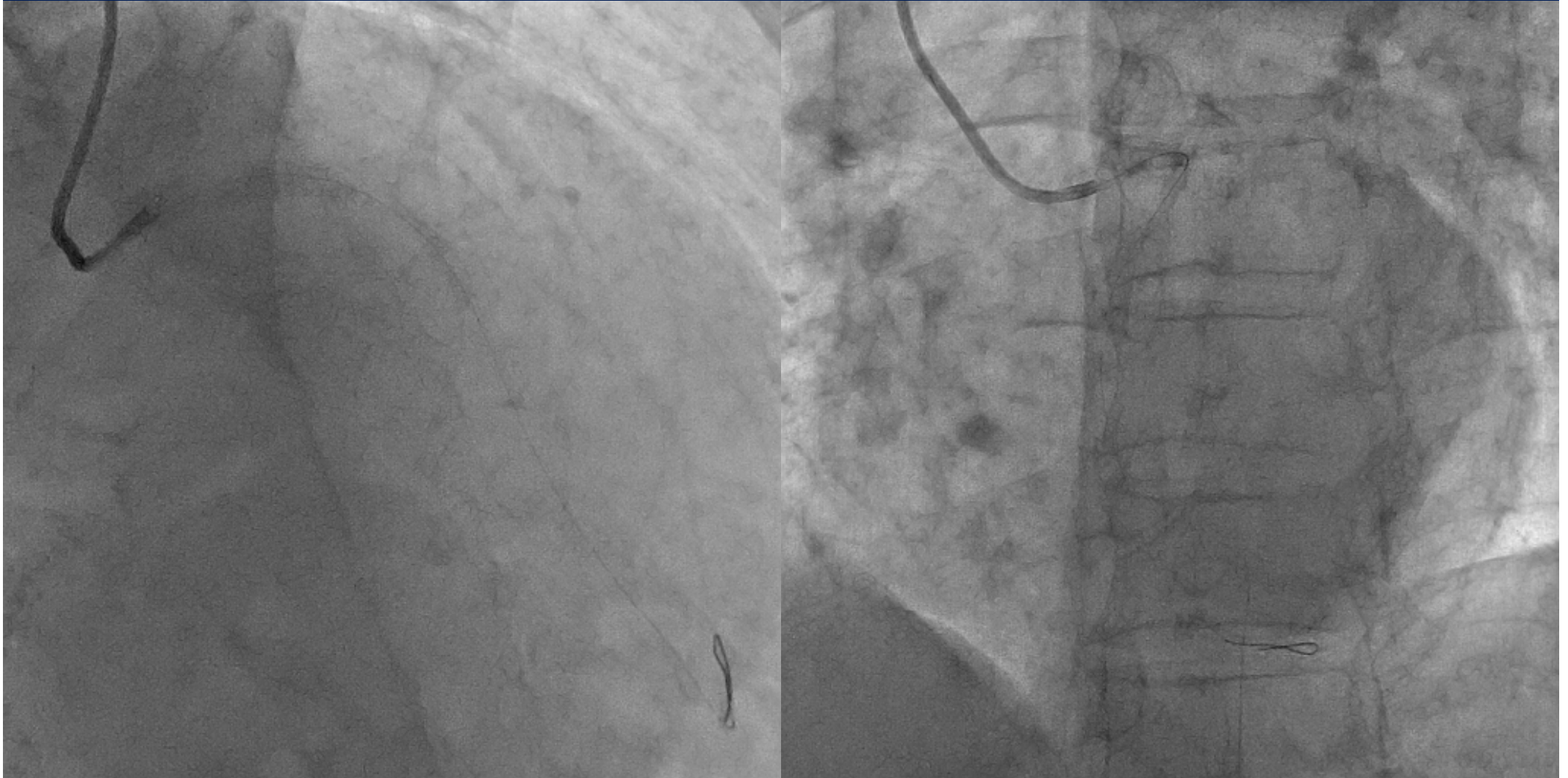
20th April 2012



I deployed Nobori stent (DES), which dimension was $3.5 \times 8\text{mm}$ (Terumo Co., Japan) to the ULMCA lesion.

Final angiogram

20th April 2012



Left coronary angiogram in the RAO cranial view

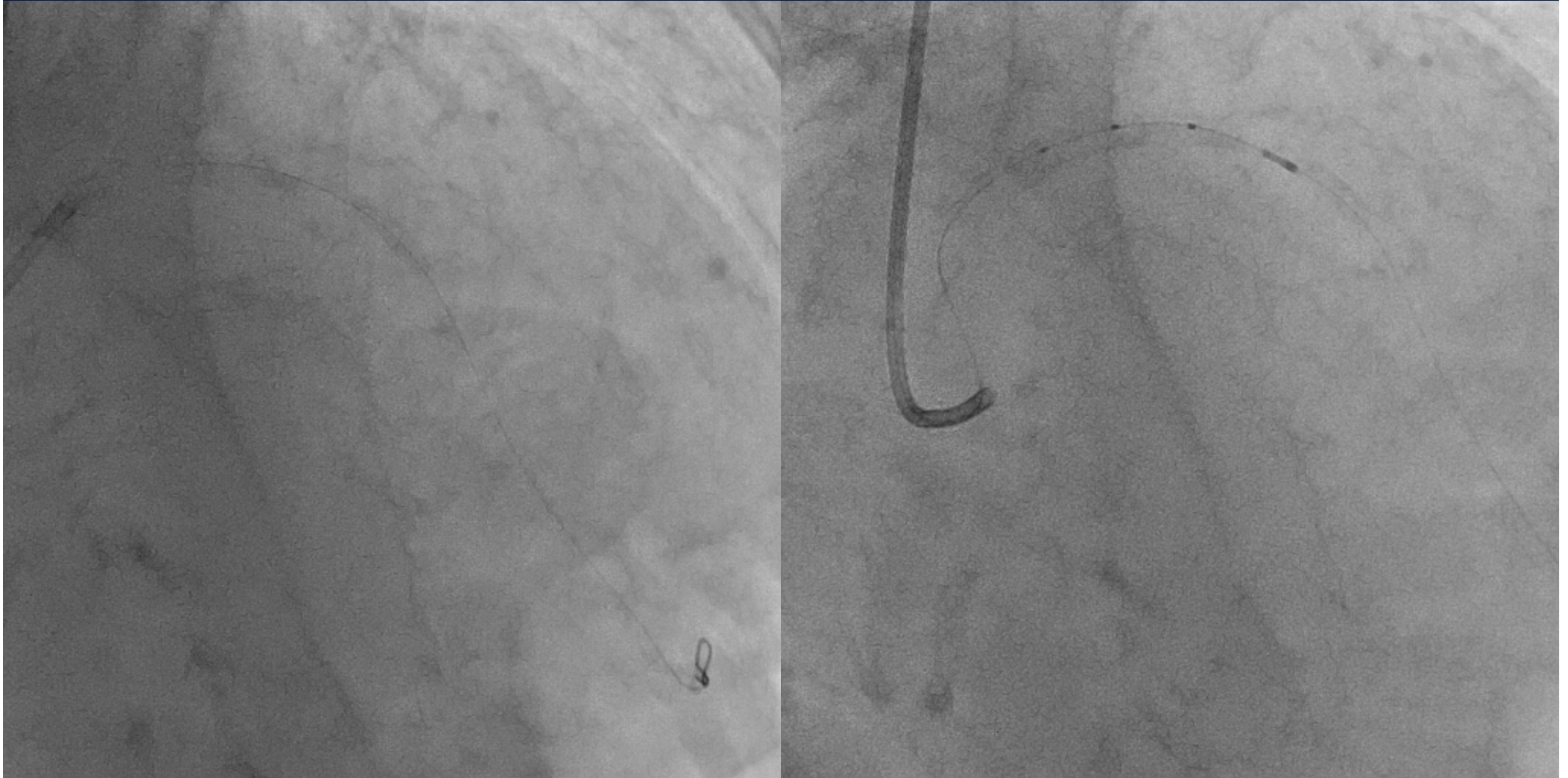
Left coronary angiogram in the LAO cranial view

PCI for the severely calcified LAD

25th May 2012

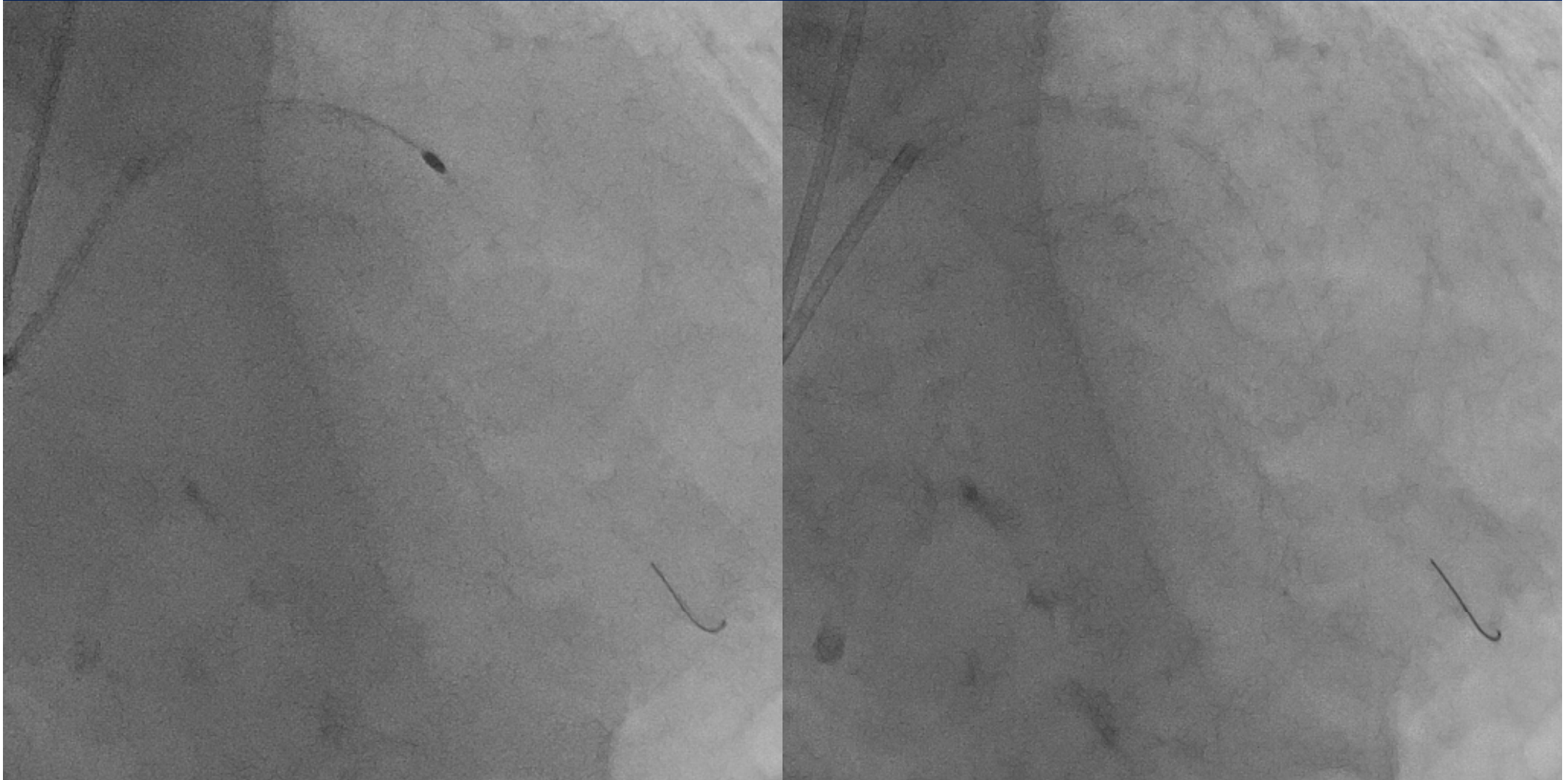
Left coronary angiogram in the RAO cranial view

25th May 2012



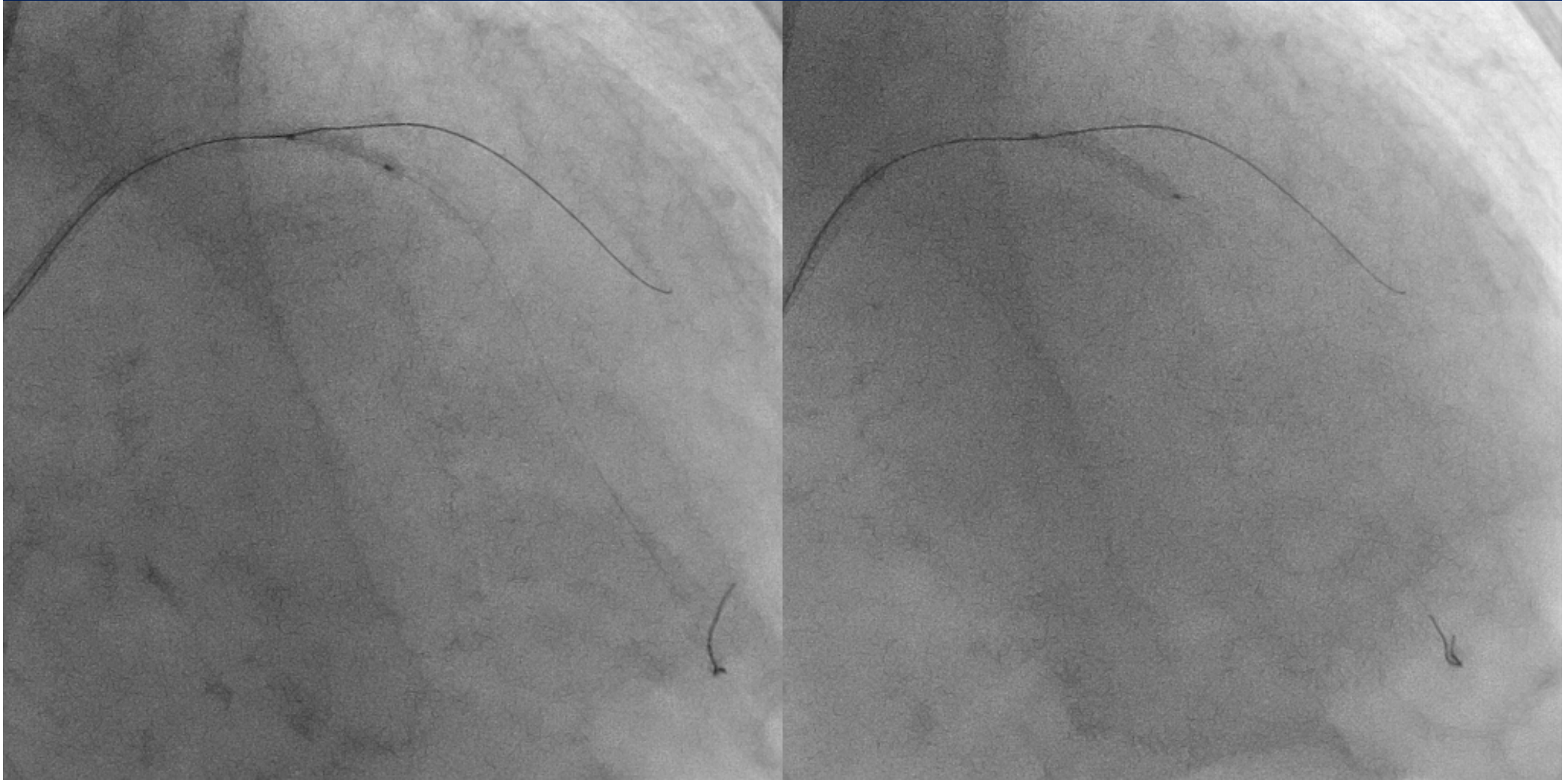
I tried to get the IVUS catheter to pass the mid LAD calcified lesion, but I could not pass the mid LAD calcified lesion.

25th May 2012



I chose the rotational atherectomy to modify the mid LAD calcified lesion.
I modified the mid LAD calcified lesion by 1.75mm burr.

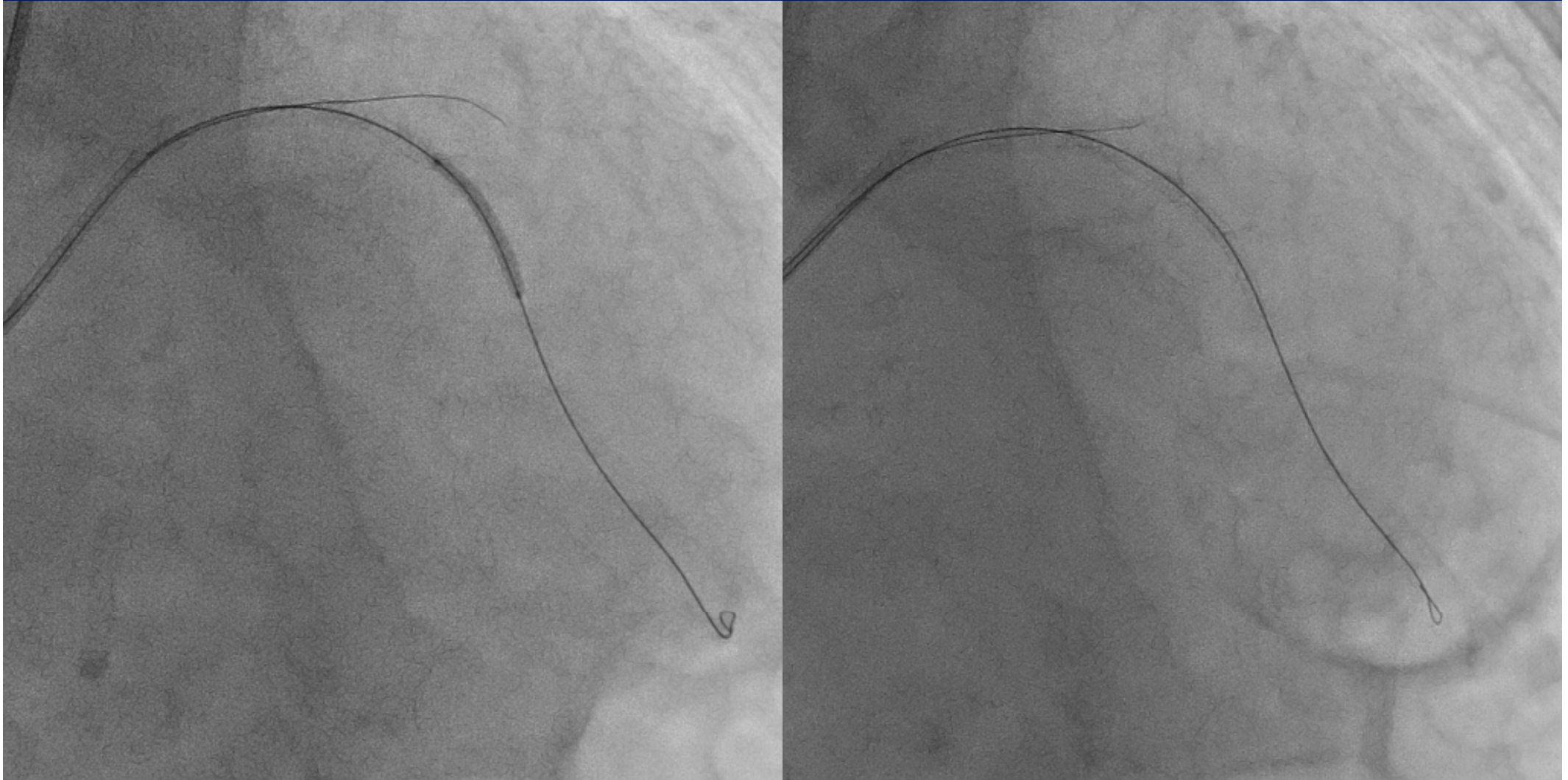
25th May 2012



I dilated the lesion with 2.5 × 15mm balloon.

And then I deployed Promus element DES, which dimension was 2.75 × 20mm (Boston Scientific Co., USA) to the proximal LAD.

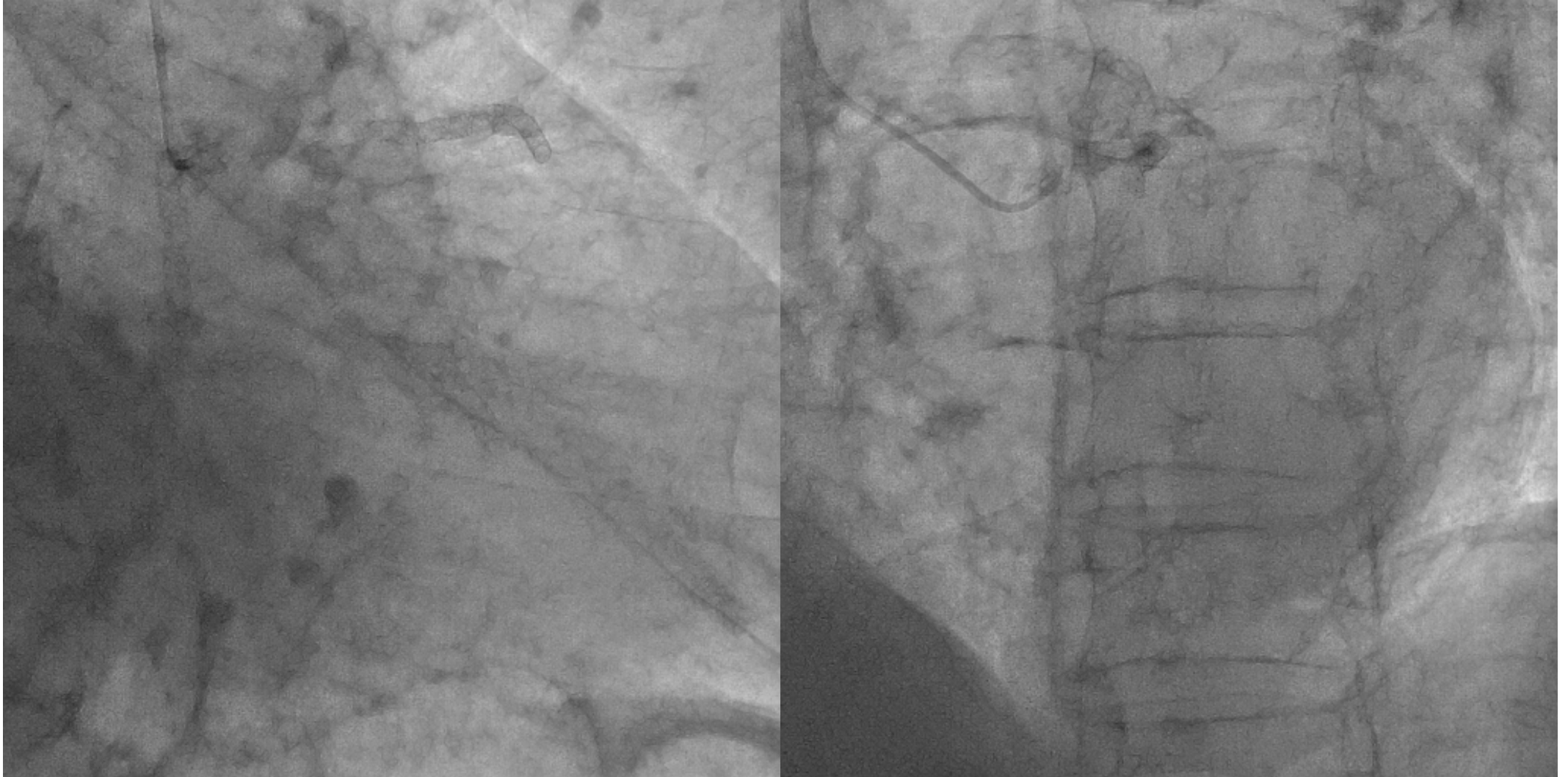
25th May 2012



After I dilated the mid LAD lesion with 2.5×15 mm balloon, I deployed Promus element DES, which dimension was 2.5×20 mm (Boston Scientific Co., USA) to the mid LAD.

Final angiogram

25th May 2012



Left coronary angiogram in the RAO caudal view

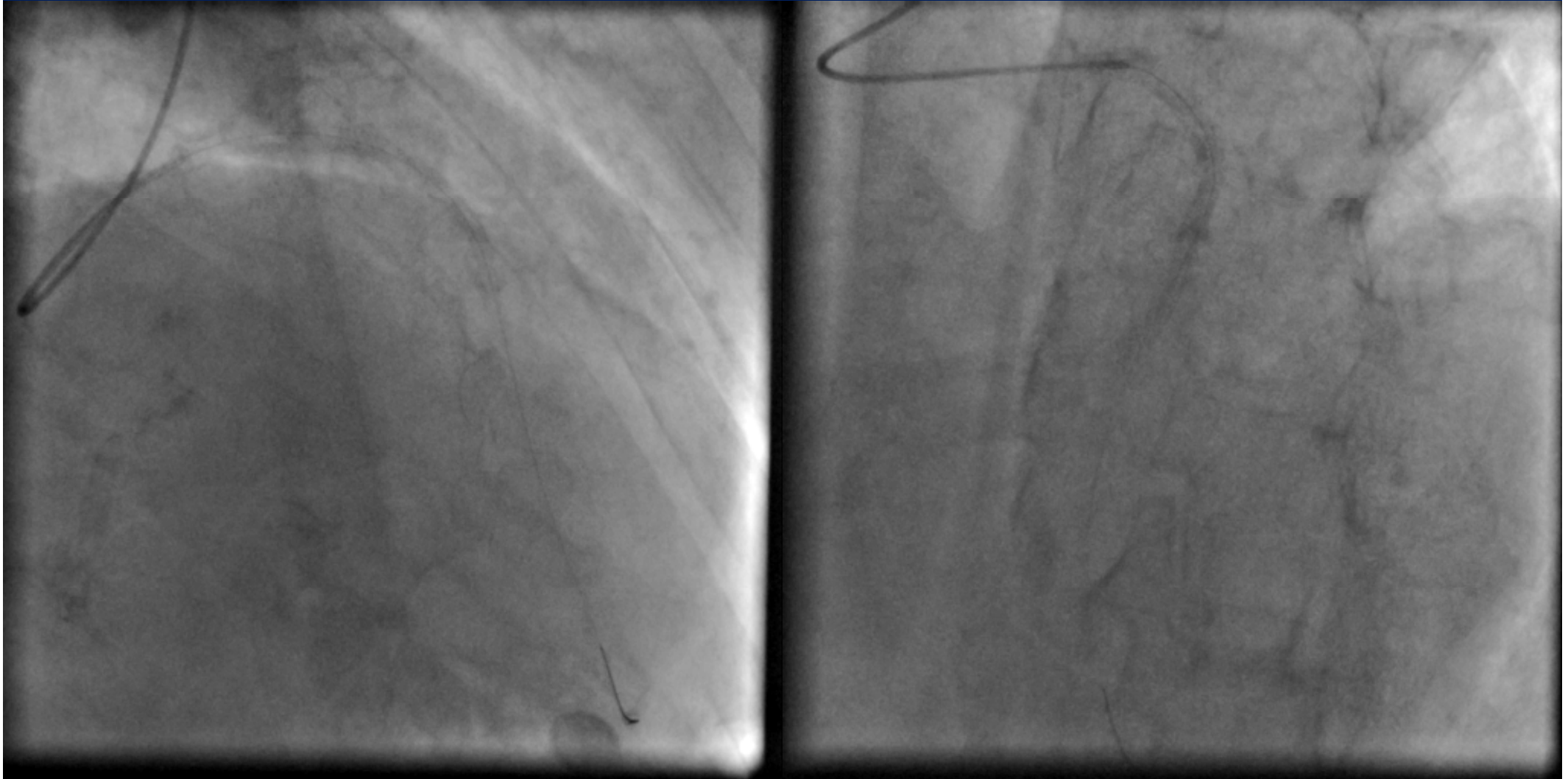
Left coronary angiogram in the LAO cranial view

Follow up CAG

1th April 2013

Coronary angiogram

1th April 2013



Left coronary angiogram in the RAO cranial view

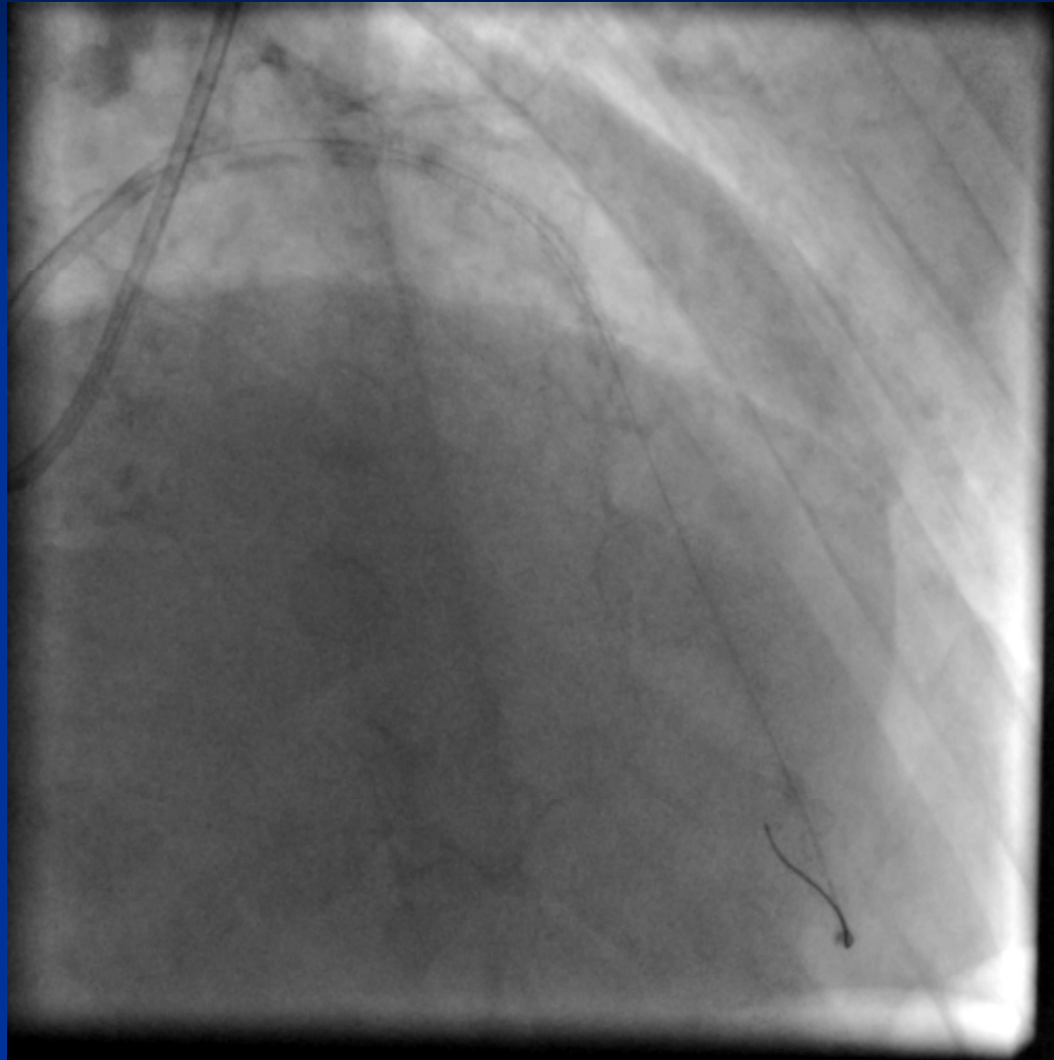
Left coronary angiogram in the LAO cranial view

Re-PCI for the severely calcified LAD ISR

3th April 2013

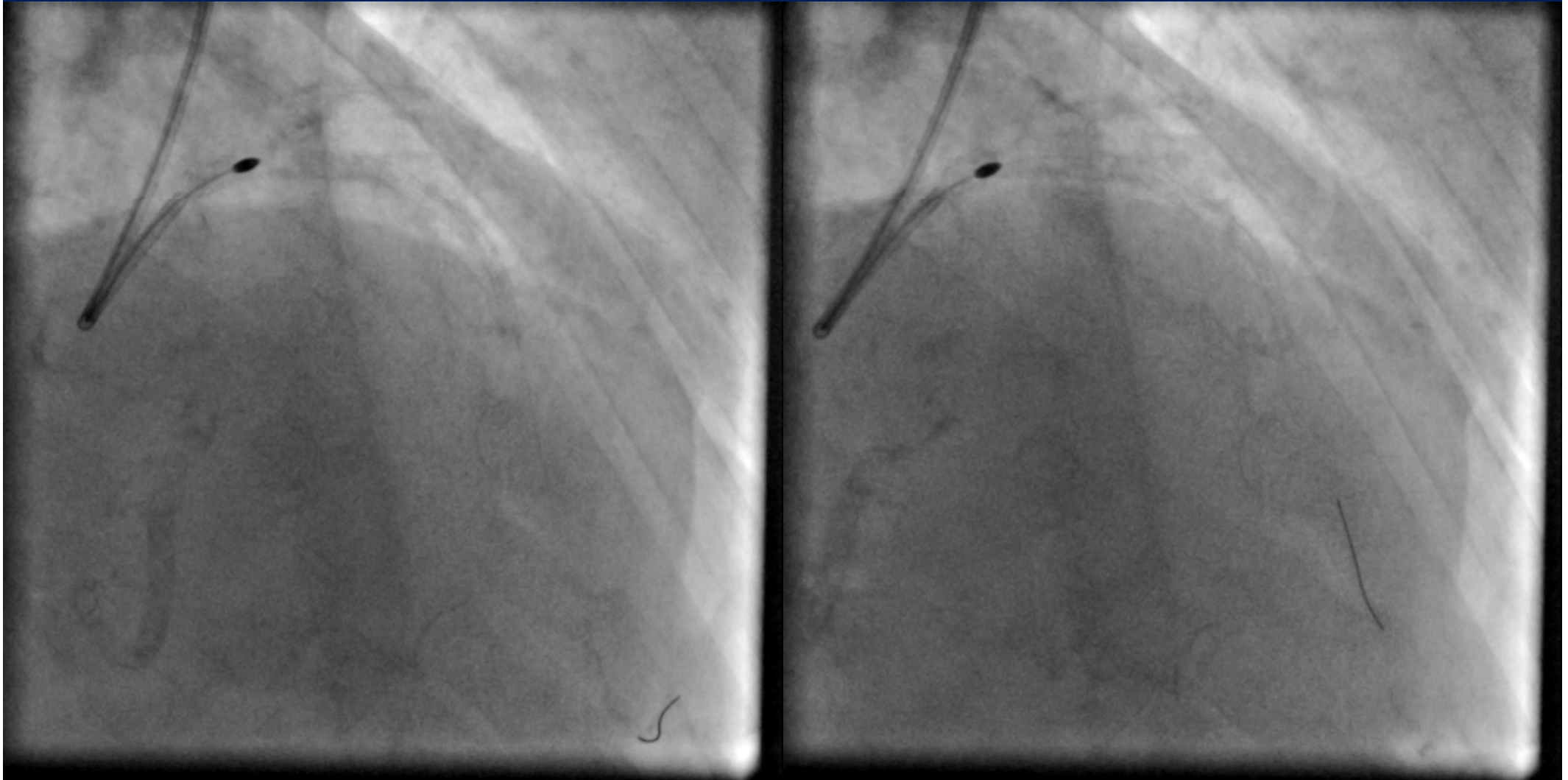
Baseline angiography

3th April 2013



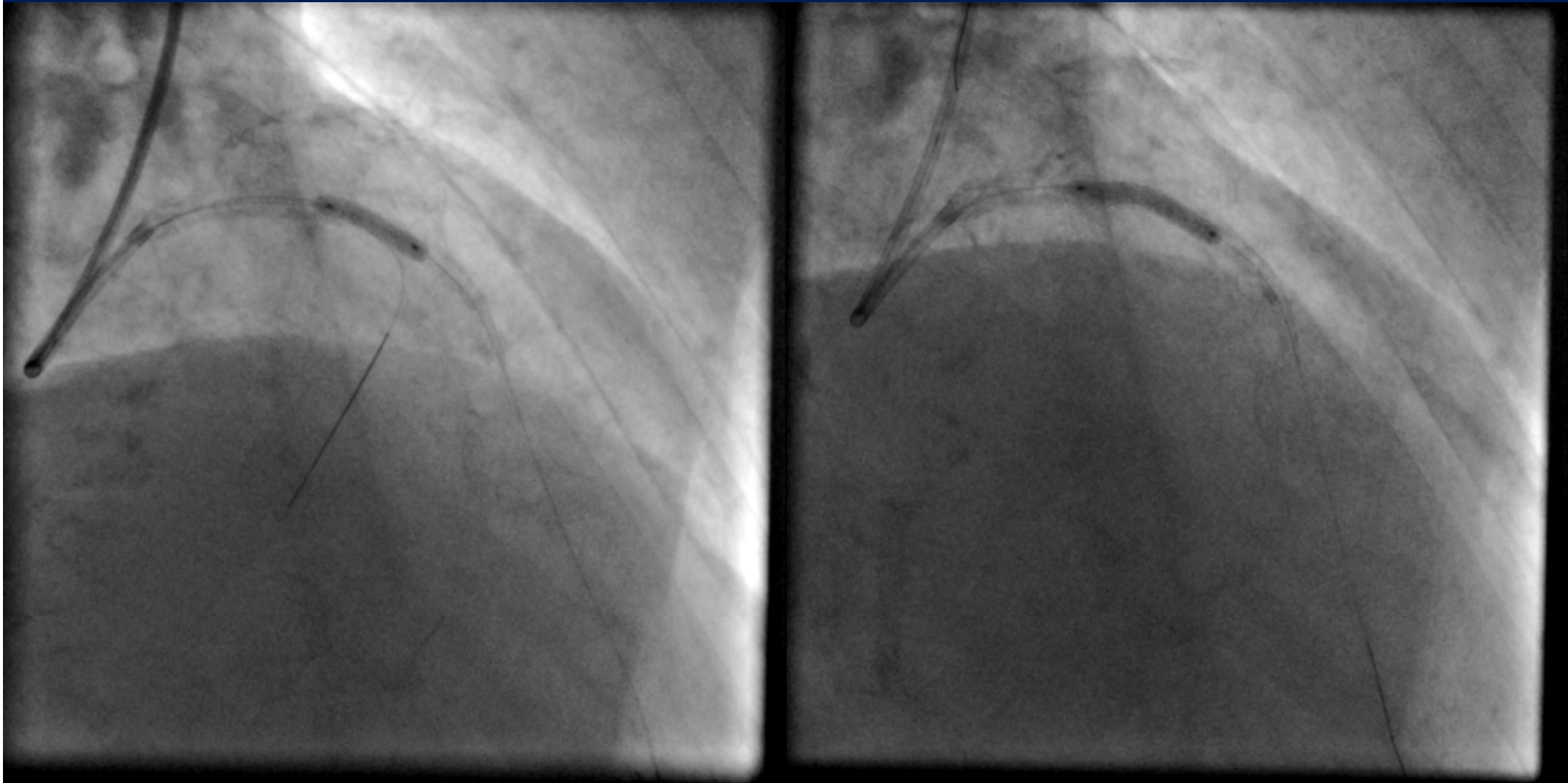
Left coronary angiogram in the RAO cranial view

3th April 2013



I chose the rotational atherectomy to modify the proximal LAD ISR lesion.
I modified the proximal LAD ISR lesion by 2.0 mm burr.

3th April 2013



I dilated the proximal LAD ISR lesion with $3.25 \times 15\text{mm}$ balloon, and then I deployed Nobori stent (DES), which dimension was $3.0 \times 18\text{mm}$ (Terumo Co., Japan) to the proximal LAD ISR lesion.

Final angiogram

3th April 2013



Left coronary angiogram in the RAO cranial view



Left coronary angiogram in the LAO cranial view

Summary 1

- The characteristics of Nobori DES platform are 2 link peak to peak structure, high radial force, and good expansion performance.
- The reason why excellent scaffolding of Nobori DES is because it has long crown length and 10 crown design.
- In the response of stent to the over-expansion, only the Nobori DES can be expanded well to the balloon size and the radial force of Nobori DES increases gradually depending on the expanded stent diameter.
- In the stent expansion performance to the hard stenosis model, Nobori DES is more easier to hold the vessel lumen in the hard stenosis model than another company's DES because of strong radial force and low recoil.

Summary 2

- Antonio Colombo reported that Nobori DES could be promising by sufficient stent expansion because of less recoil.
- I have experienced the efficacy of Nobori DES for two severely calcified cases.
- Good results of Nobori DES can be promising for the even calcified lesion because of not only PLA biodegradable polymer and biolimus A9, but also the good designed platform of high radial force and good expansion performance.