



# Real World Experience of D+ Storm Drug-Eluting Stents

**Hyung-Mo Yang, MD,PhD**  
**Ajou University Hospital**  
**Suwon, Korea**





# Disclosure

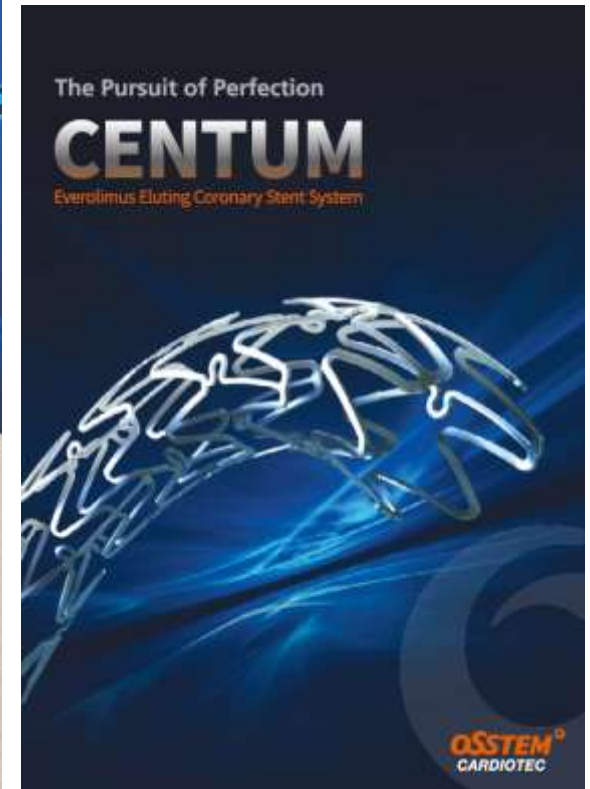
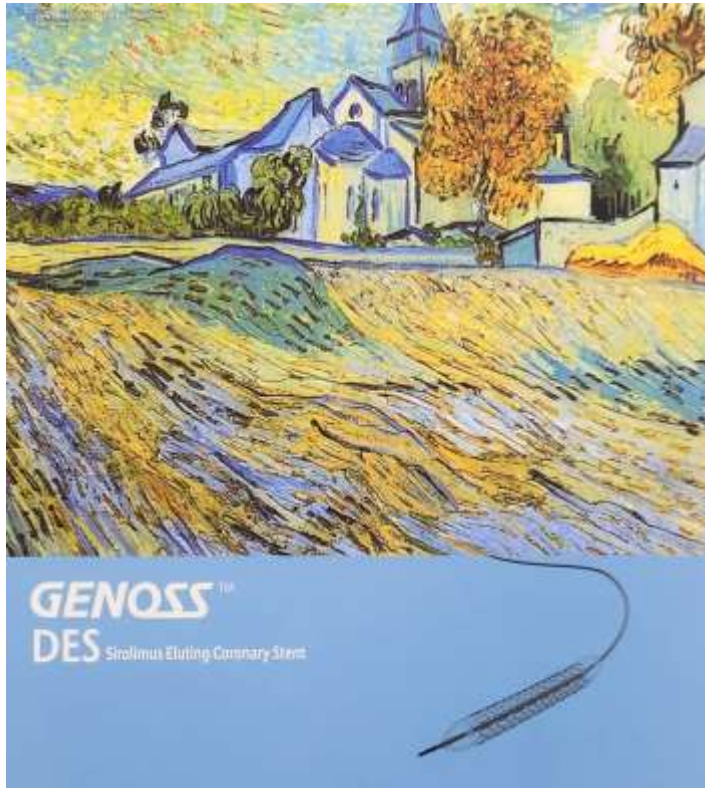
- Research grant: Microport, CG bio.
- Real world registry study

: Korea Medical Device Development Fund grant funded by the Korea government (the Ministry of Science and ICT, the Ministry of Trade, Industry and Energy, the Ministry of Health & Welfare, Republic of Korea, the Ministry of Food and Drug Safety) (Project Number: RS-2020-KD000246).





# DES in Korea





# D+storm DES

- Platform
  - Material: Co-Cr
  - Strut Thickness: 70  $\mu\text{m}$
  - Design: Waved Semi-Open cell
- Carrier
  - Material: Biodegradable PLA
  - Thickness: 5  $\mu\text{m}$

- Drug
  - Material: Sirolimus
  - Dose: 1.4  $\mu\text{g}/\text{mm}^2$
- Antioxidant
  - : Ascorbic Acid (Vitamin C)



# D+storm DES

## Coating Matrix

### Advanced Coating Technology

- Abluminal Drug Coating
- Controlled Drug Release
- Anti-thrombotic Properties

Coating thickness: 5  $\mu\text{m}$



## Stent Design

### Optimal Stent Platform

- Hybrid Stent Structure
- Lower Foreshortening <0.4%
- Lower Recoil <3.0%
- Higher Radial Force

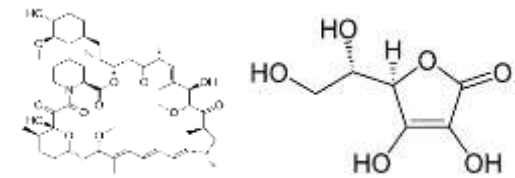
Strut thickness: 70  $\mu\text{m}$



## Drug

### Early Healing

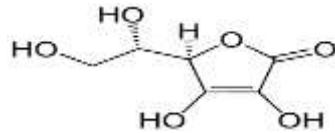
- Anti-inflammatory  
Ascorbic acid
- Anti-proliferative Sirolimus
- Excellent stent strut coverage



# D+storm DES



Drug

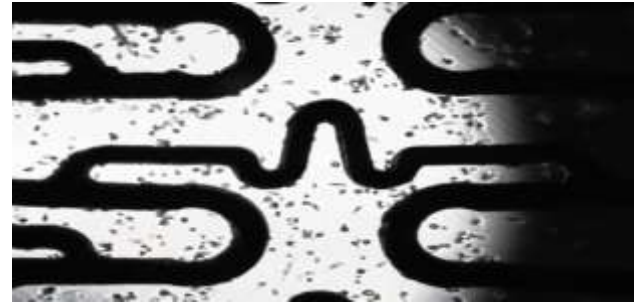


anti-aging  
low inflammation

Sirolimus



Ascorbic acid



Sirolimus+ Ascorbic acid(low)



Sirolimus+ Ascorbic acid(High)



When sirolimus inhibits vascular myocyte proliferation, Vit C helps vascular endothelial cell proliferation.

Contents lists available at ScienceDirect

Pharmacology & Therapeutics

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Associate editor: L.H. Lash

Inflammation in the vascular bed: Importance of vitamin C

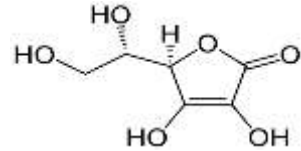
Rene Aguirre, James M. May <sup>✉</sup>

Department of Medicine, Vanderbilt University School of Medicine, Nashville, TN 37232-6303, United States

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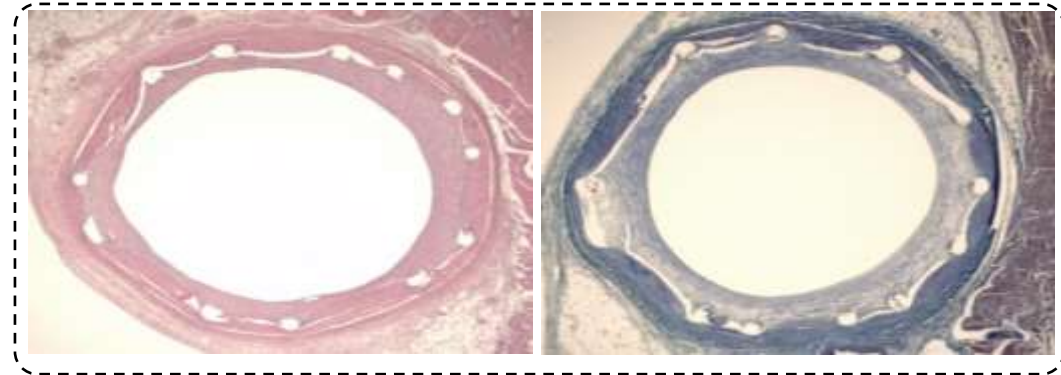
ARTICLE INFO	ABSTRACT
<p><b>Keywords:</b></p> <ul style="list-style-type: none"> <li>Atherosclerosis</li> <li>Antioxidant vitamins</li> <li>Endothelial cells</li> <li>Vascular smooth muscle cells</li> <li>Macrophages</li> <li>Vitamin E</li> </ul> <p><b>Abbreviations:</b></p> <ul style="list-style-type: none"> <li>AFR, ascorbate free radical</li> <li>ApoB, apolipoprotein B</li> <li>DNA, dehydroascorbate</li> <li>LDL, low density lipoprotein</li> <li>SVCT, sodium-dependent vitamin C transporter</li> <li>VSMCs, vascular smooth muscle cells</li> </ul>	<p>Despite decreases in atherosclerotic coronary vascular disease over the last several decades, atherosclerosis remains a major cause of mortality in developed nations. One possible contributor to this residual risk is oxidant stress, which is generated by the inflammatory response of atherosclerosis. Although there is a wealth of in vitro, cellular, and animal data supporting a protective role for antioxidant vitamins and nutrients in the atherosclerotic process, the best clinical trials have been negative. This may be due to the fact that antioxidant therapies are applied "too little and too late." This review considers the role of vitamin C, or ascorbic acid in preventing the earliest inflammatory changes in atherosclerosis; it focuses on the three major vascular cell types involved in atherosclerosis: endothelial cells, vascular smooth muscle cells, and macrophages. Ascorbate chemistry, recycling, and function are described for these cell types, with emphasis on whether and how the vitamin might affect the inflammatory process. For endothelial cells, ascorbate helps to prevent endothelial dysfunction, stimulates type IV collagen synthesis, and enhances cell proliferation. For vascular smooth muscle cells, ascorbate inhibits dedifferentiation, recruitment, and proliferation in areas of vascular damage. For macrophages, ascorbate decreases oxidant stress related to their activation, decreases uptake and degradation of oxidized LDL in some studies, and enhances several aspects of their function. Although further studies of ascorbate function in these cell types and in novel animal models are needed, available evidence generally supports a salutary role for this vitamin in ameliorating the earliest stages of atherosclerosis.</p>

# D+storm DES



**Reduces Early Inflammation**

**Without Ascorbic acid**



**Area restenosis (%)**

**With ASC**



- 7%

**Inflammation Score**



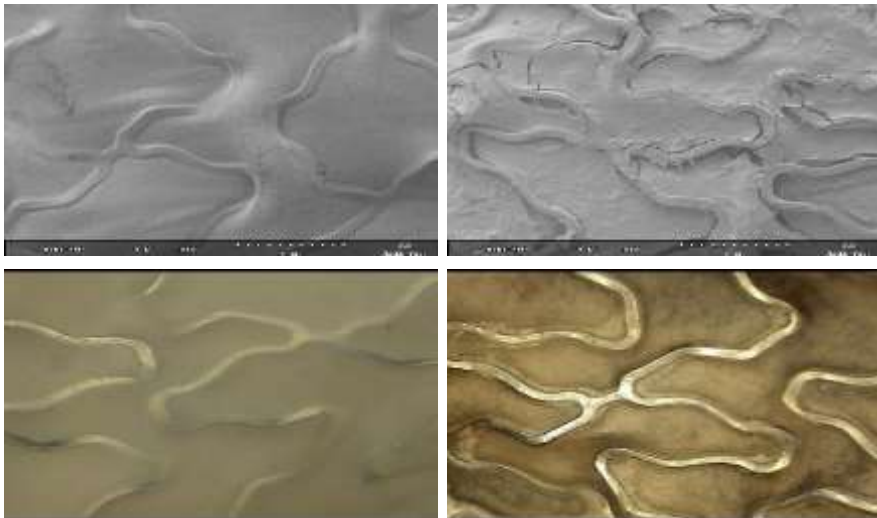
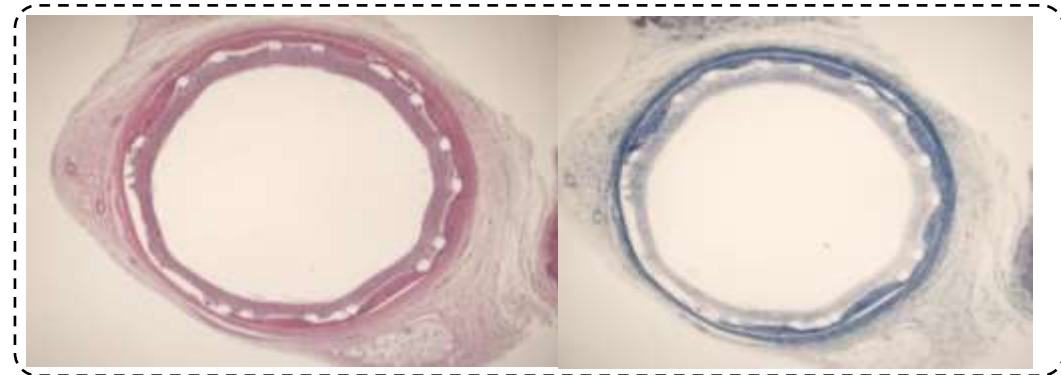
- 30%

**Platelet adhesion (%)**



- 33%

**with Ascorbic acid**





# D+storm DES

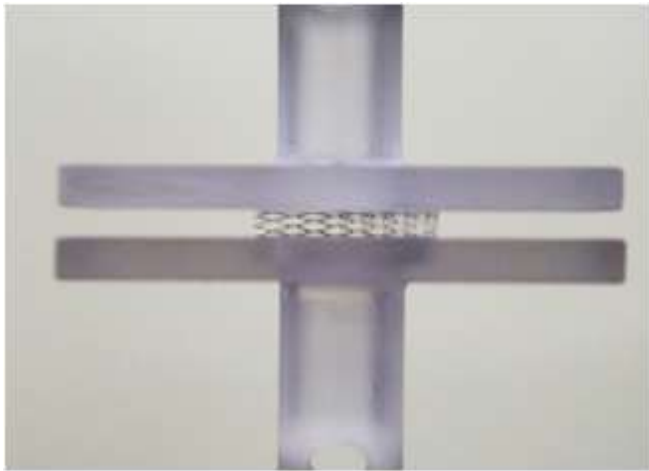
## Comparison with other DES

Product	Synergy	Xience sierra	Onyx	Ultimaster	Orsiro	D+STORM
Material	Pt-Cr alloy	Co-Cr alloy	Co-Cr alloy	Co-Cr alloy	Co-Cr alloy	Co-Cr alloy
Strut thickness	74 $\mu\text{m}$	81 $\mu\text{m}$	81 $\mu\text{m}$	80 $\mu\text{m}$	60 $\mu\text{m}$	70 $\mu\text{m}$
Drug	Everolimus	Everolimus	Zotarolimus	Sirolimus	Sirolimus	Sirolimus
Polymer	PLGA (Bioabsorbable Polymer)	PVDF-HFP (Biocomfortable Polymer)	Phosphorylcholine (BioLinx)	PDLLA-PCL copolymer	PLLA	PLA
Coating thickness	4 $\mu\text{m}$ (Abluminal)	8 $\mu\text{m}$ (Conformal)	6 $\mu\text{m}$ (Conformal)	15 $\mu\text{m}$ (Abluminal)	7 $\mu\text{m}$ (Conformal)	5 $\mu\text{m}$ (Abluminal)
Drug content	100 $\mu\text{g}/\text{cm}^2$	100 $\mu\text{g}/\text{cm}^2$	160 $\mu\text{g}/\text{cm}^2$	3.9 $\mu\text{g}/\text{mm}$	1.4 $\mu\text{g}/\text{mm}^2$	1.4 $\mu\text{g}/\text{mm}^2$

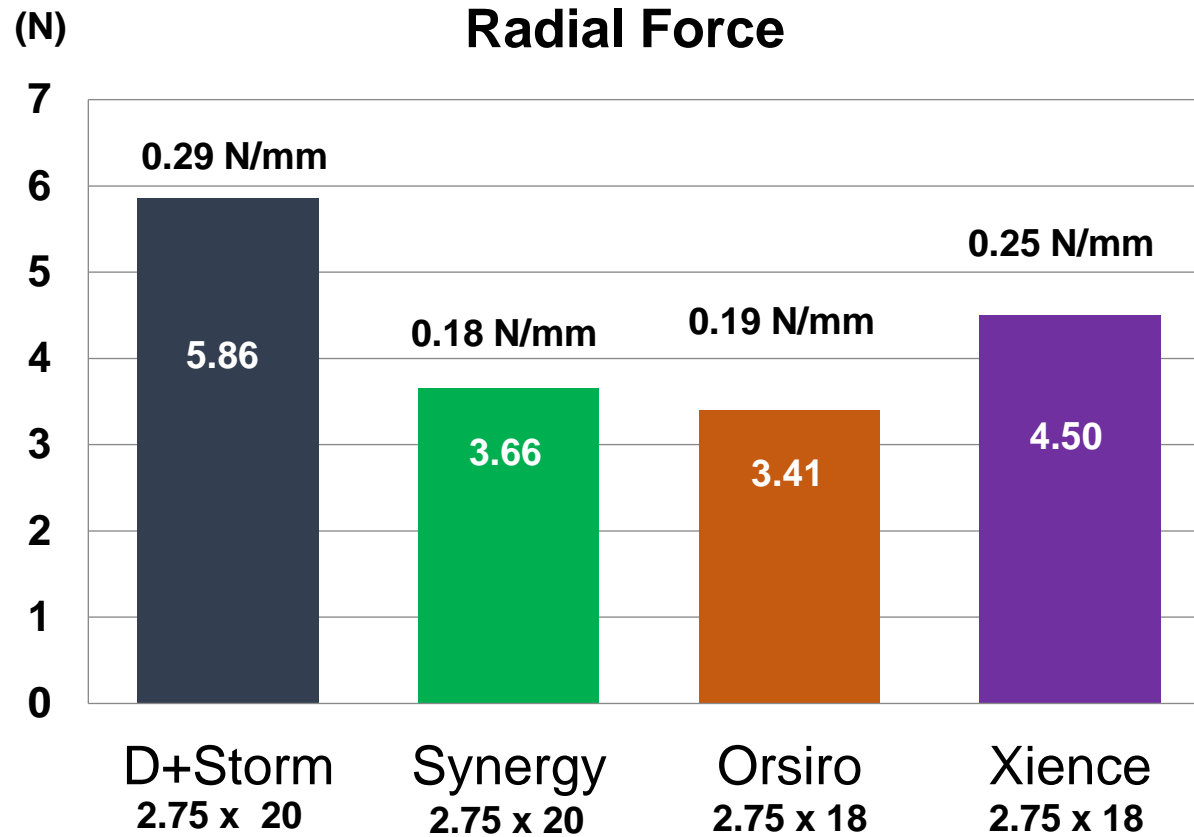




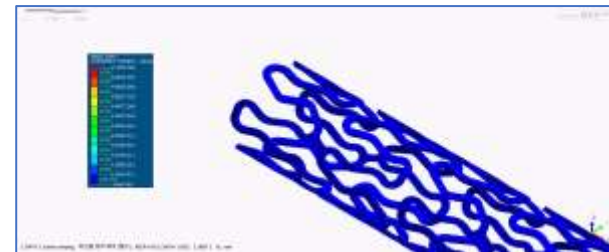
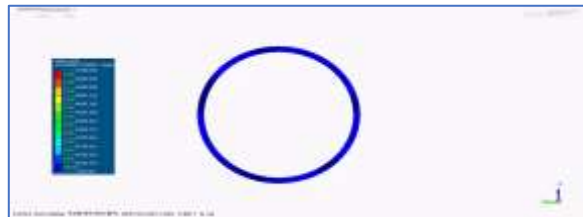
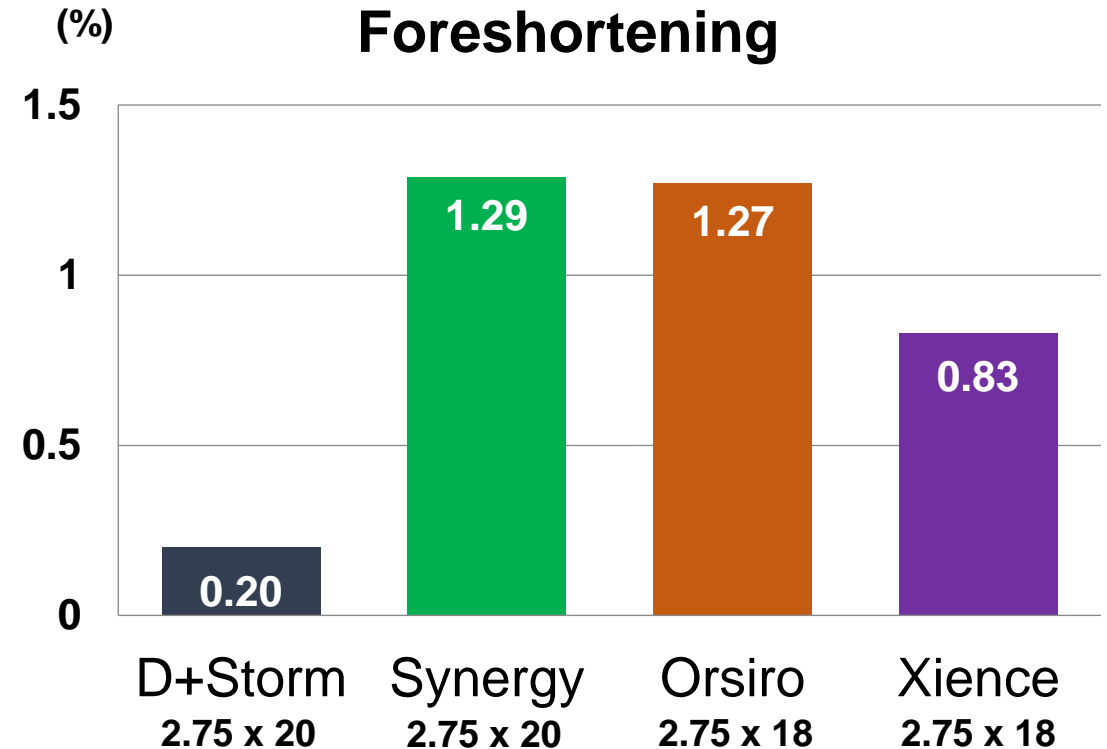
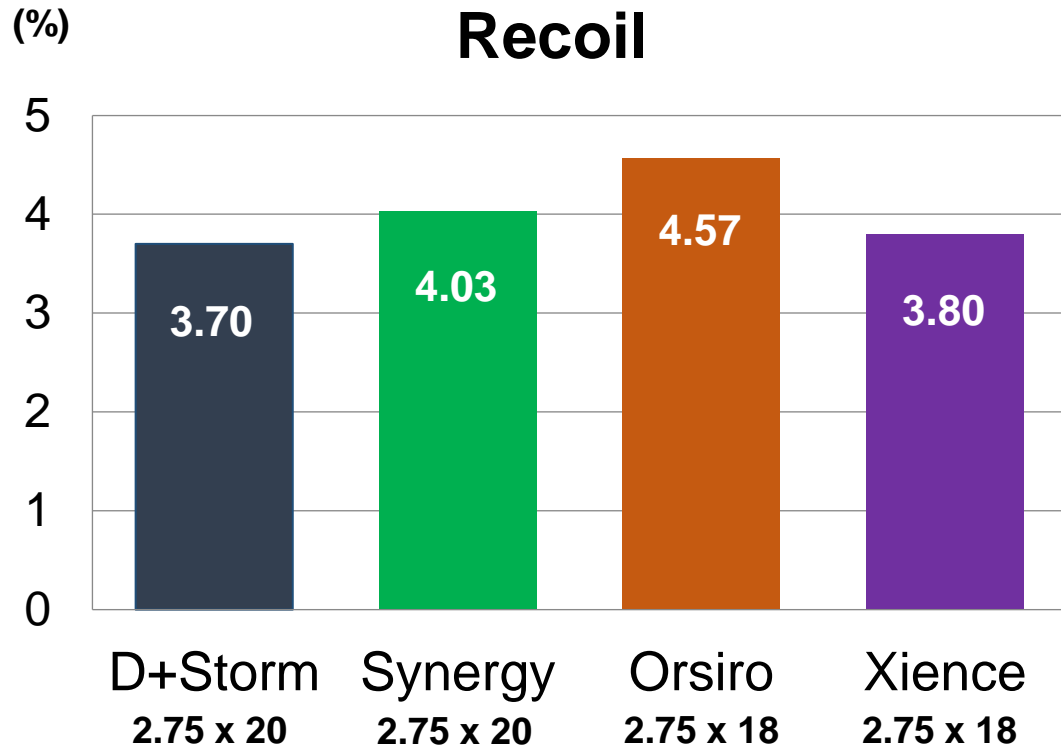
# D+storm DES



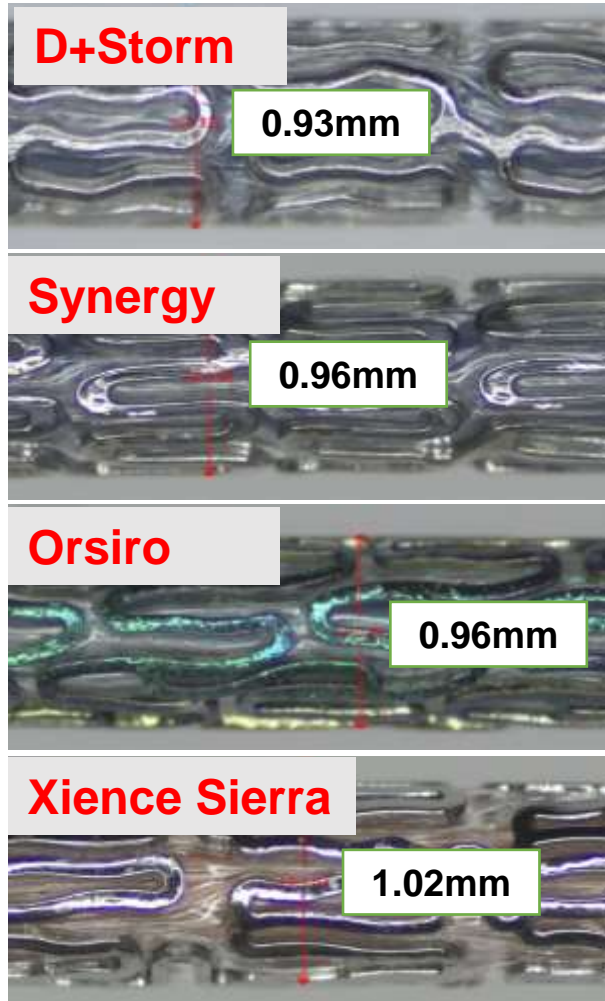
Flat Plate Compression



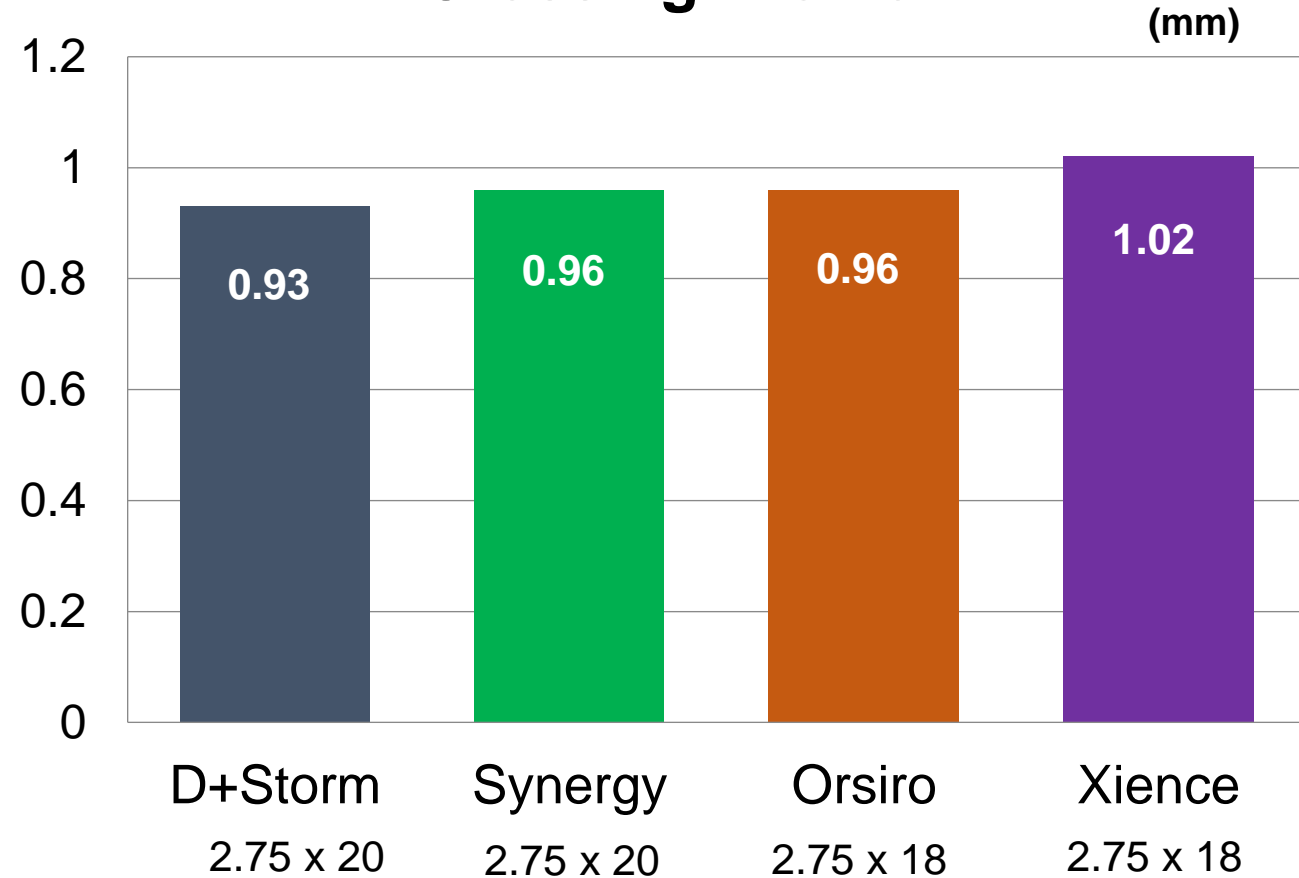
# D+storm DES



# D+storm DES



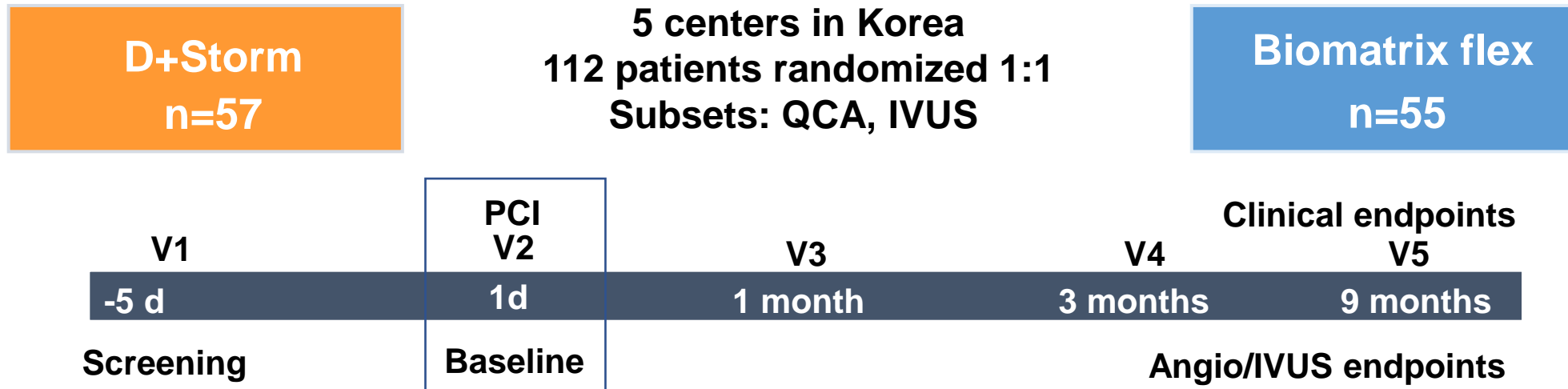
## Crossing Profile





# First-In-Human Trial

**A Multicenter, Subject-blinded, Randomized Study  
non-inferiority trial**



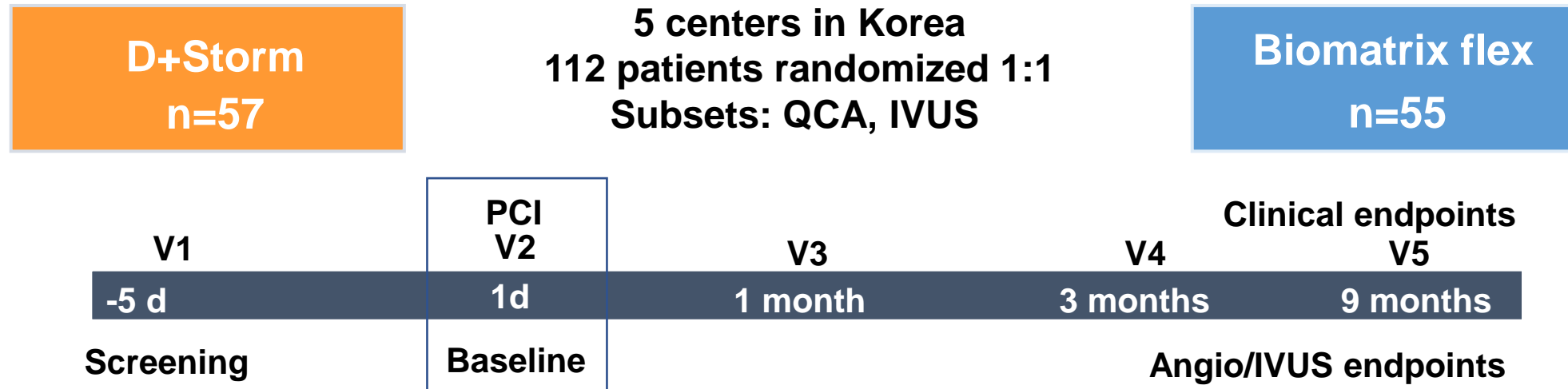
- Seoul National University College of Medicine
- Hanyang University College of Medicine,
- Yonsei University Wonju Severance Christian Hospital, Wonju
- Gachon University Gil Medical Center
- Korea University Anam Hospital





# First-In-Human Trial

A Multicenter, Subject-blinded, Randomized Study  
non-inferiority trial



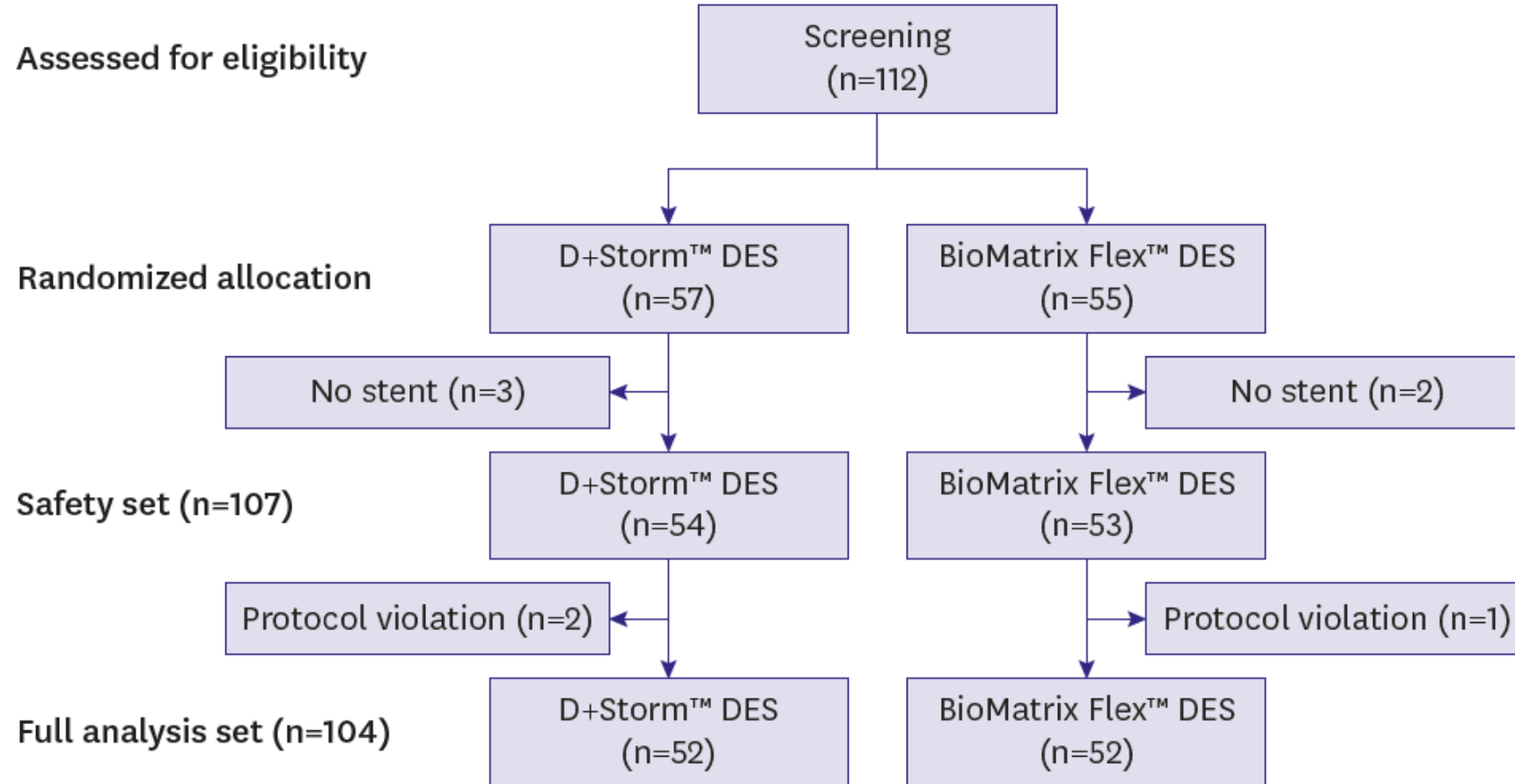
## Primary Endpoint: In-segment Late Lumen Loss (LLL) at 9 months

- 2° Clinical Endpoints: Cardiac death, MI, TLR, MACE, stent thrombosis, success rate
- 2° Angiographic Endpoint: in-stent LLL, % diameter restenosis at 9 months
- 2° IVUS Endpoints: Rates of incomplete stent apposition at 9 months, neointimal hyperplastic volume and % volume obstruction



# First-In-Human Trial

## Results





# First-In-Human Trial

## Results-Baseline clinical characteristics

	<b>D+Storm™ (n=54)</b>	<b>BioMatrix Flex™ (n=53)</b>	p value
Age (years)	64±10	64±10	NS*
Male	37 (68.52)	33 (62.26)	NS
Co-morbidities			
Hypertension	35 (64.81)	32 (60.38)	NS
Hyperlipidemia	26 (48.15)	32 (60.38)	NS
Diabetes mellitus	15 (27.78)	18 (33.96)	NS
Diagnosis			
Stable angina	11 (20.00)	20 (34.48)	NS
Unstable angina	32 (58.18)	25 (43.10)	NS
Silent ischemia	2 (3.64)	1 (1.72)	NS
NSTEMI	9 (16.36)	8 (13.79)	NS

The values are presented as n (%).

\* NS: not significant





# First-In-Human Trial

## Results- Angiographic & Procedural characteristics

	<b>D+Storm™ (n=54)</b>	<b>BioMatrix Flex™ (n=53)</b>	p value
Coronary artery disease			
1 vessel disease	44 (81.48)	45 (84.91)	NS
2 vessel disease	7 (12.96)	7 (13.21)	NS
3 vessel disease	3 (5.56)	1 (1.89)	NS
Target lesion			
LAD	40 (74.07)	33 (62.26)	NS
LCX	4 (7.41)	10 (18.87)	NS
RCA	10 (18.52)	10 (18.87)	NS
Stent diameter (mm)	3.22±0.44	3.30±0.41	NS
Stent length (mm)	23.08±7.32	23.00±6.56	NS
Stent overlap	3 (5.56)	2 (3.77)	NS

The values are presented as n (%).

\* NS: not significant

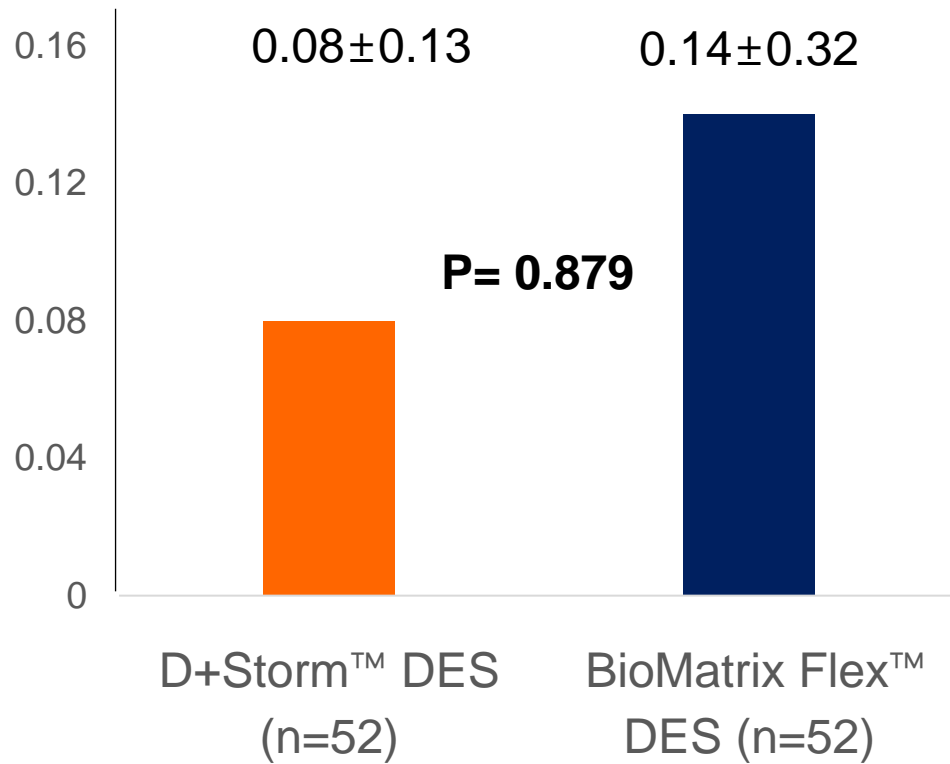




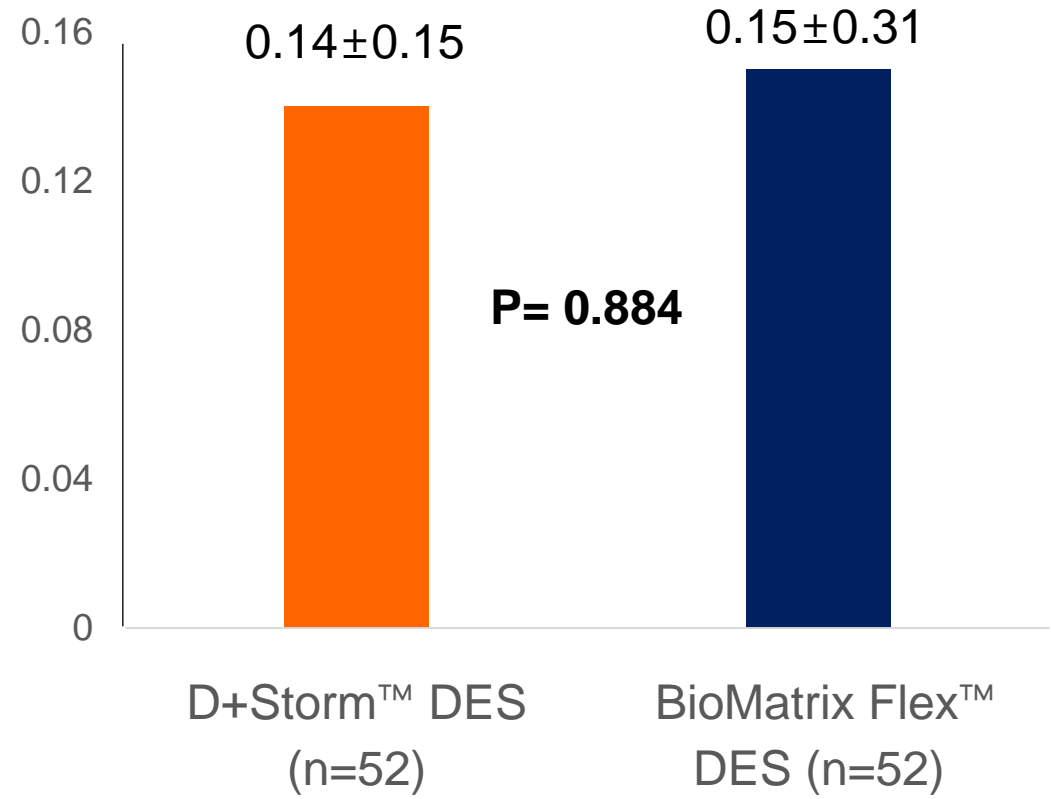


# First-In-Human Trial

## In-segment late lumen loss (mm)



## In-stent late lumen loss (mm)





# First-In-Human Trial

## Clinical Outcomes

n (%)	<b>D+Storm (N=52)</b>	<b>Biomatrix Flex (N=52)</b>	p
Death	0	0	NA
MI	0	1 (1.9%)	NA
TVR	0	1 (1.9%)	NA
TLR	0	1 (1.9%)	1.00
Stent thrombosis	0	1 (1.9%)	1.00
Success rate	52 (100)	50 (96.2%)	0.49



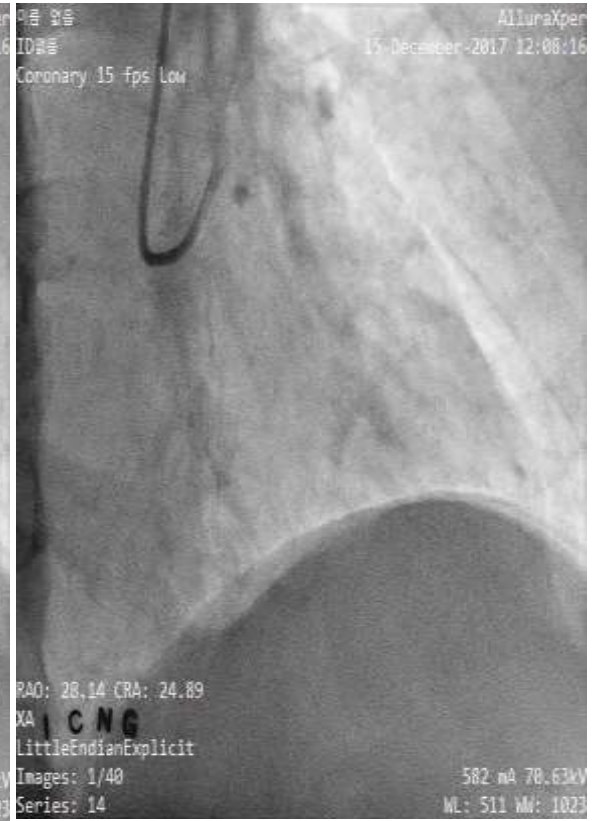
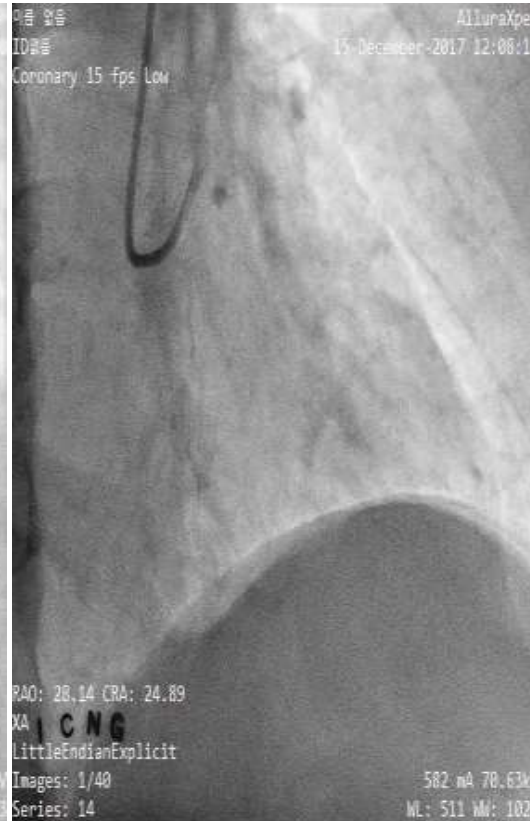
# First-In-Human Trial

*Index pre-PCI*

*Stenting*

*Index post-PCI*

*9 months FU*





# Real world Experience study

## 임상시험계획서

D+storm 스텐트의 효과와 안전성 평가를 위한  
다기관, 연구자 주도 임상시험

시험의료기기	D+Storm DES stent
시험계획서번호	Protocol No. O2005 (Version 1.0)
시험계획서작성일	2020.06.22

- Ajou University Hospital  
Inha University Hospital
- Prospective multicenter registry
- 206 patient, 264 lesions
- 12 months clinical follow-up
- This work was supported by the Korea Medical Device Development Fund grant funded by the Korea government (the Ministry of Science and ICT, the Ministry of Trade, Industry and Energy, the Ministry of Health & Welfare, Republic of Korea, the Ministry of Food and Drug Safety) (Project Number: RS-2020-KD000246).





# Real world Experience

## *Results-Baseline clinical characteristics*

### **D+Storm™ (n=206)**

Age (years)	65±9
Male	143 (69.4%)
Co-morbidities	
Hypertension	114 (55.3%)
Hyperlipidemia	95 (46.2%)
Diabetes mellitus	74 (35.9%)
Current smoker	57 (27.7%)
Prior MI	13 (6.3%)
Prior PCI	39 (18.9%)





# Real world Experience

## *Results-Baseline clinical characteristics*

### **D+Storm™ (n=206)**

#### Clinical diagnosis

Stable angina	35 (17.0%)
Unstable angina	114 (55.3%)
STEMI	10 (4.9%)
NSTEMI	11 (5.3%)
others	36 (17.4%)

#### Coronary artery disease

1 vessel disease	43.0%
2 vessel disease	36.7%
3 vessel disease	20.3%





# Results- QCA and Procedural results

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	<b>D+Storm™ (n=264)</b>
Reference vessel diameter, mm	3.08 ± 0.42
Pre-PCI	
Diameter stenosis, %	84.6 ± 9.8
Minimal lumen diameter, mm	0.48 ± 0.28
Post-PCI	
Diameter stenosis, %	5.8 ± 3.8
Minimal lumen diameter, mm	2.90 ± 0.40
Lesion length, mm	25.99 ± 11.17
Stent number per a lesion, n(%)	
1	245 (92.8)
2	18 (6.8)
3	1 (0.4)
Stent diameter, mm	2.97 ± 0.38
Stent length, mm	26.19 ± 7.68
Procedural success,%	99.6

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# Real world Experience

## *Clinical Outcomes*

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	<b>D+Storm (N=206)</b>
Major adverse cardiac events (death, MI, TLR)	3 (1.85%)
Death (cardiac death,1)	3 (1.85%)
Myocardial infarction	0
Target lesion revascularization	0
Target vessel revascularizationn	1 (0.48%)
Stent thrombosis	0

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# Case 1

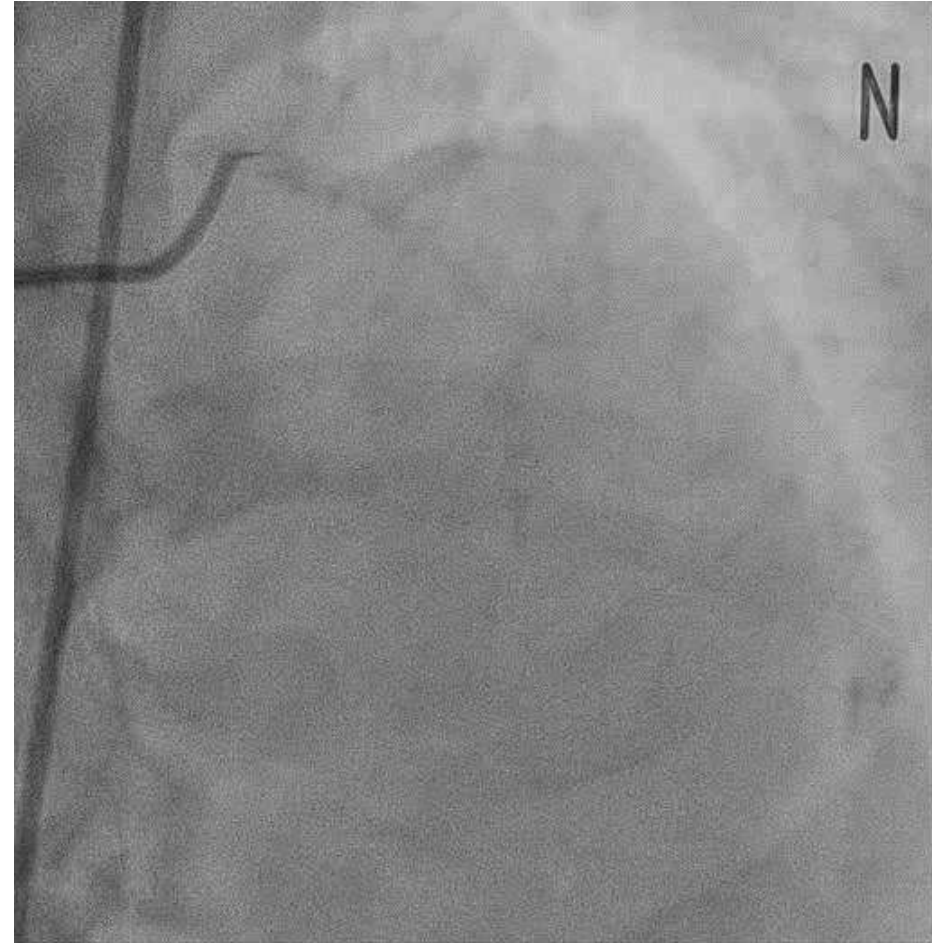
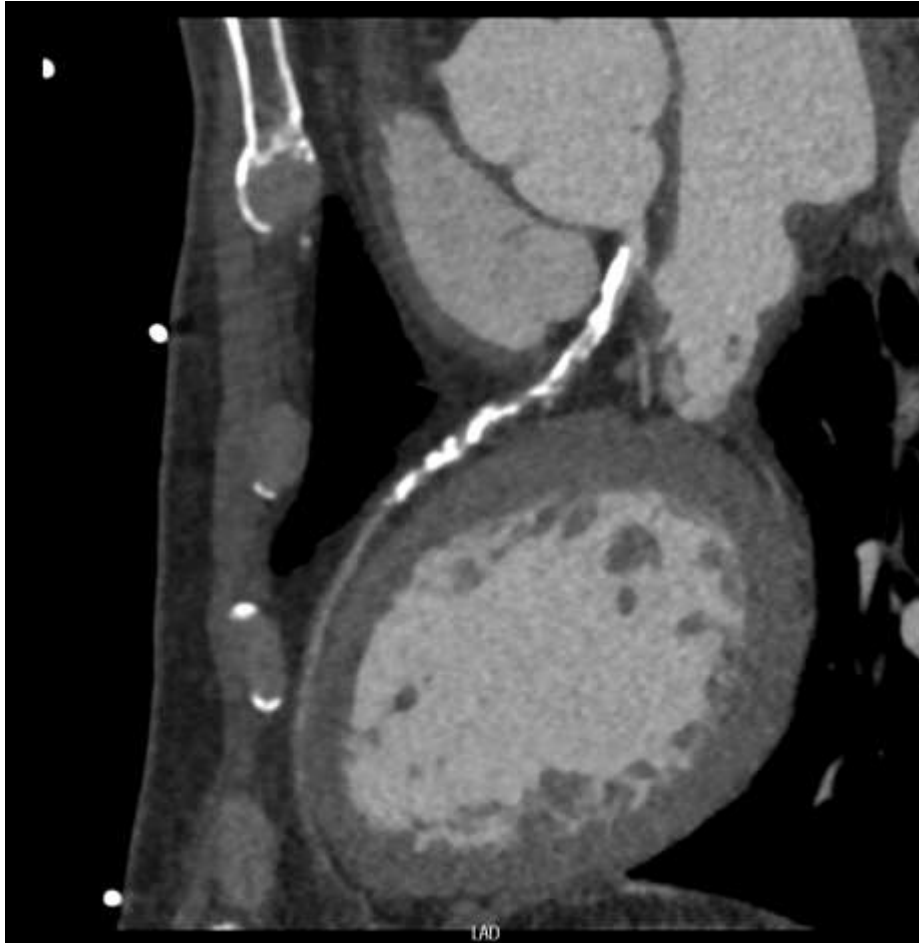
## *Calcified lesion*

- Male/ 69 years old
- Abnormal echocardiography for the evaluation cerebral infarction
- Echo: EF 50%, RWMA at apical anterior and septum
- Past medical Hx  
:HTN, Hyperlipidemia, current smoker



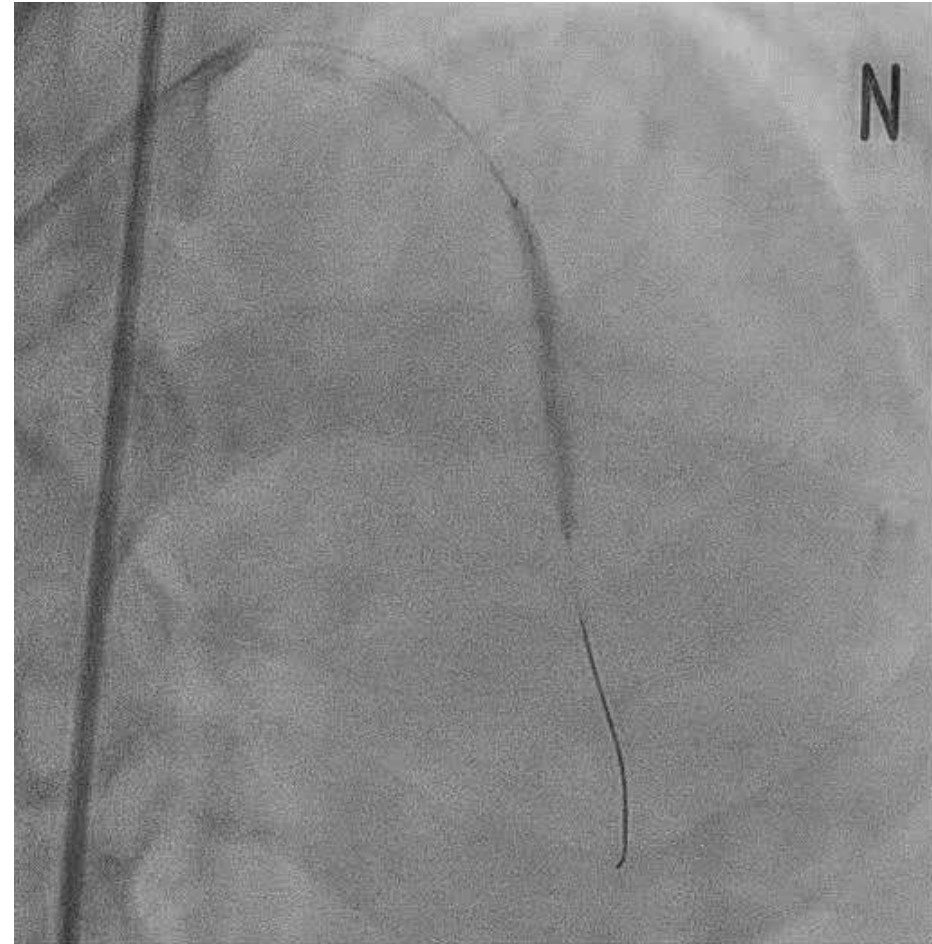
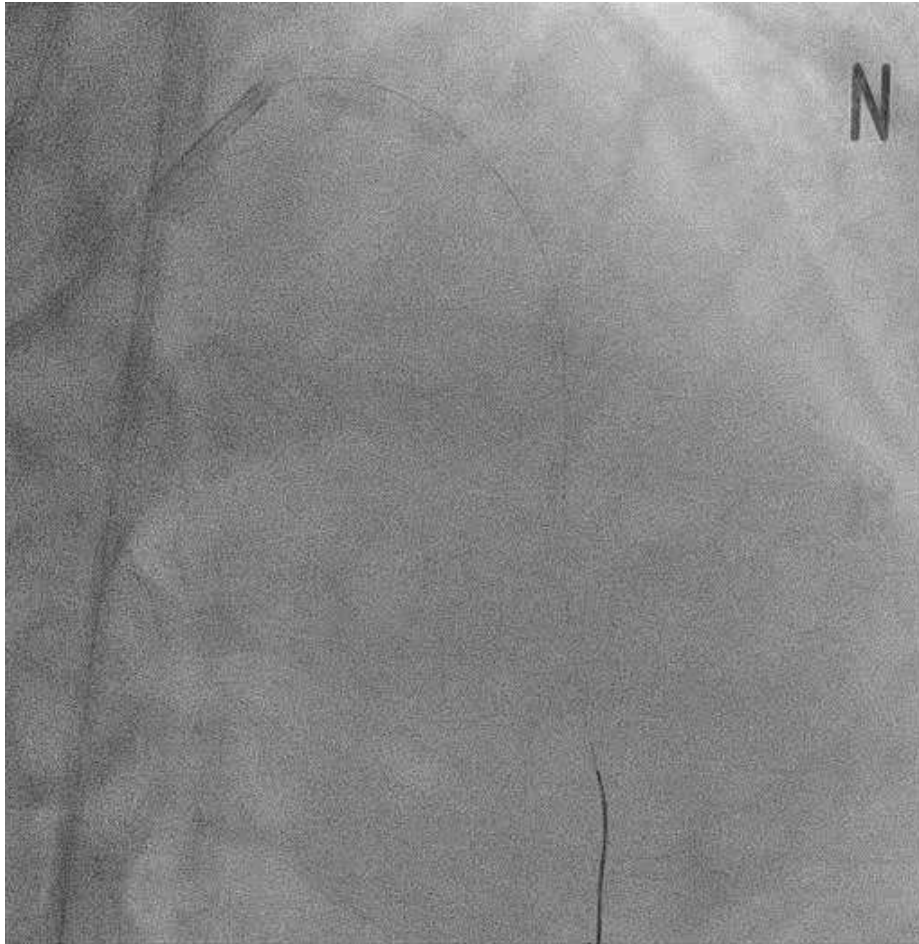
# Case 1

## *Calcified lesion*



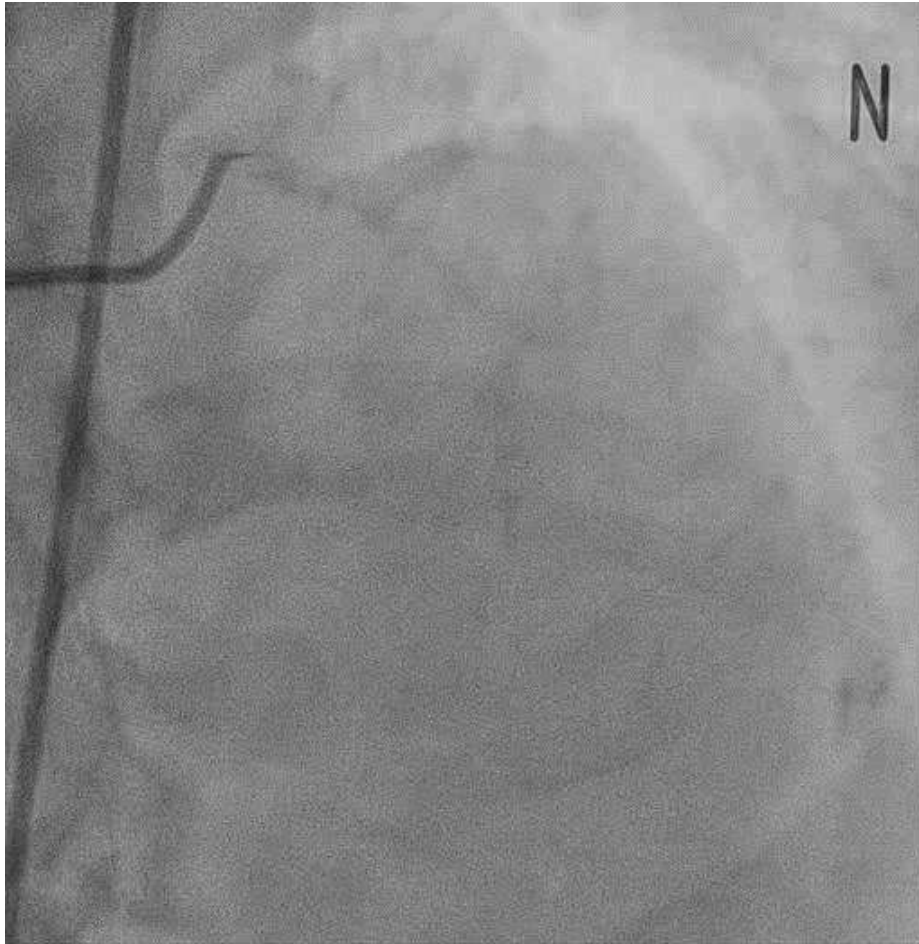
# Case 1

***Stent passage and inflation : D storm 2.5/33 mm***

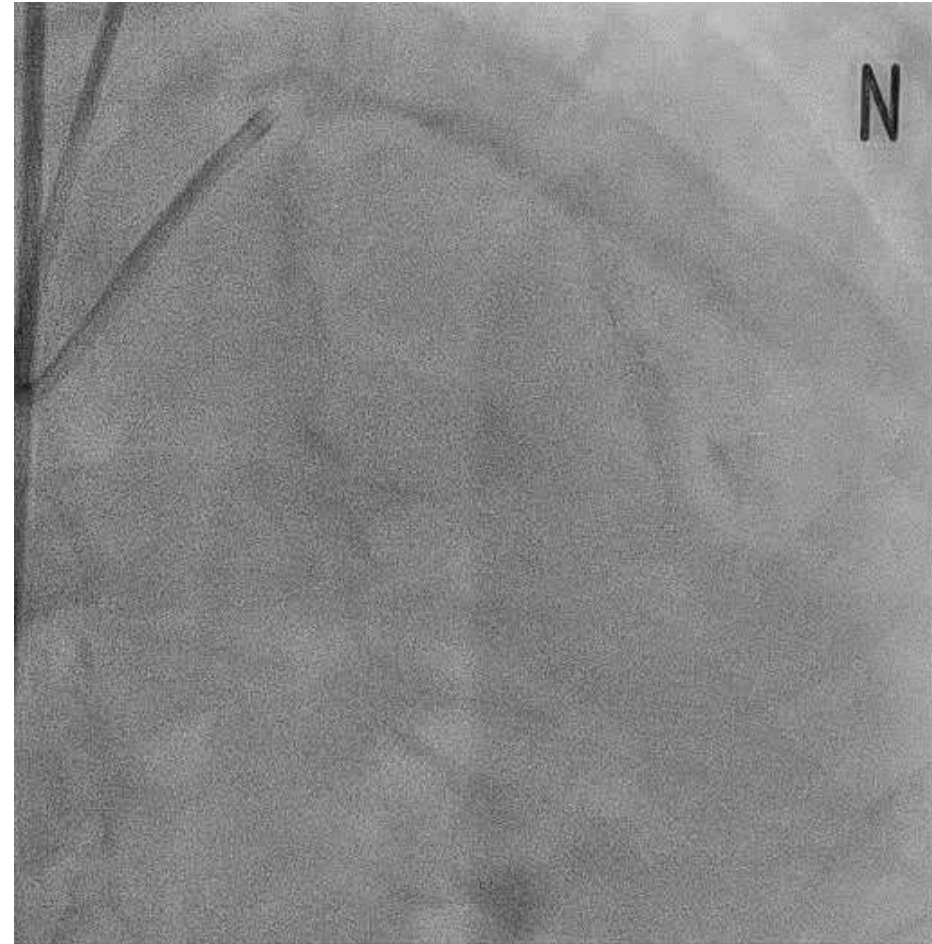


# Case 1

*Pre-PCI*



*Post-PCI*





# Case 2

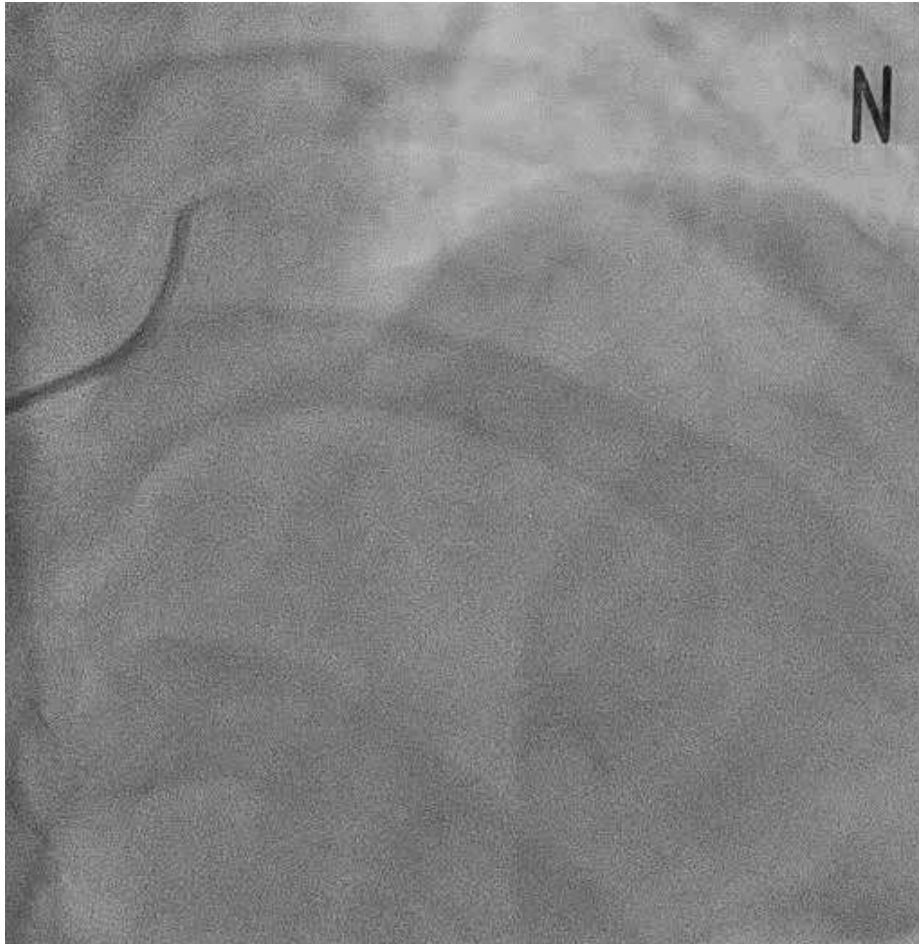
## *Unstable angina*

- Female/ 70 years old
- Exertional chest pain for 1 month
- Past medical Hx  
:HTN, Hyperlipidemia
- Echo: EF 78%, No RWMA

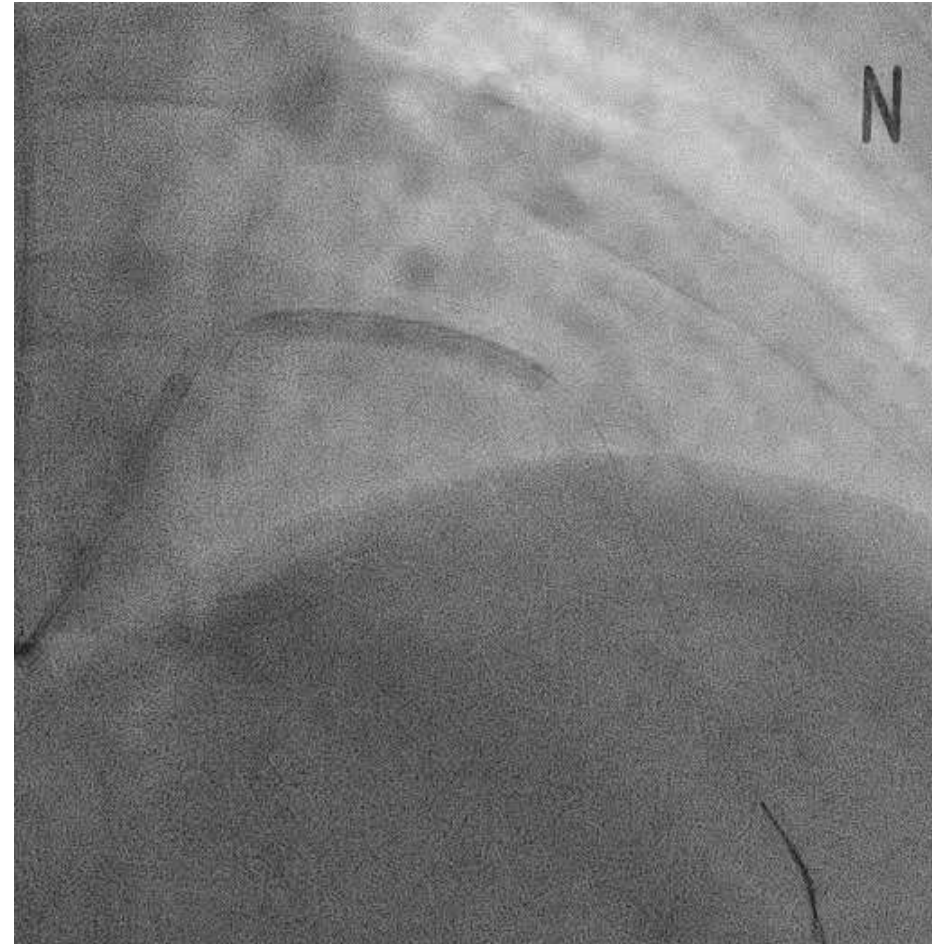


# Case 2

*Pre-PCI*



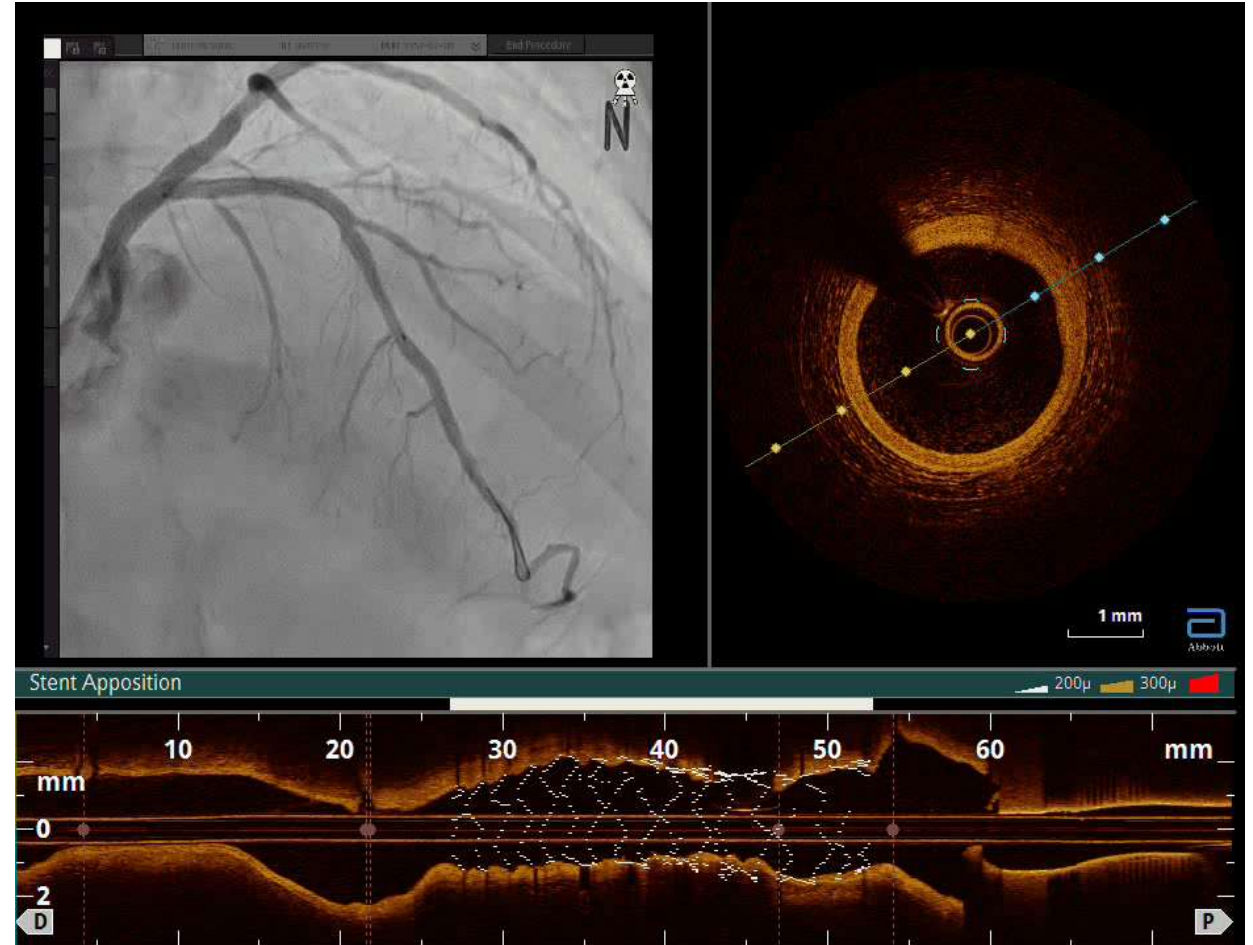
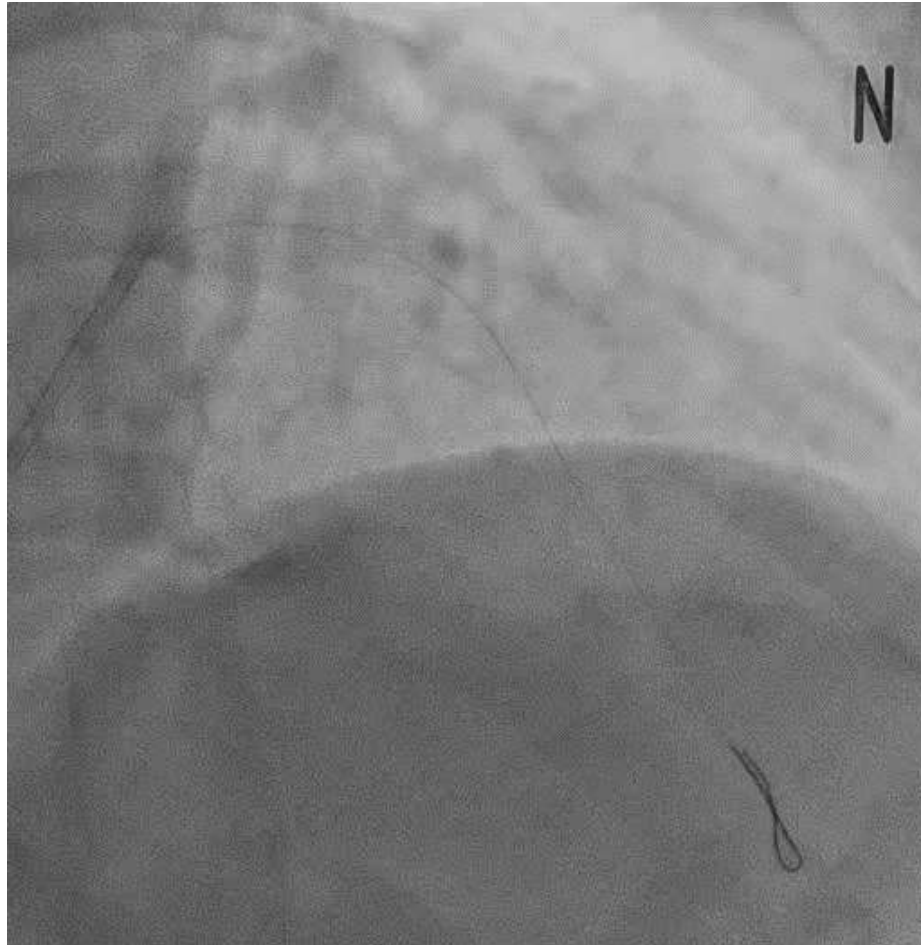
*D+storm 3.0/24*



# Case 2

*Post-PCI*

*OCT*





# Case 3

## *AMI*

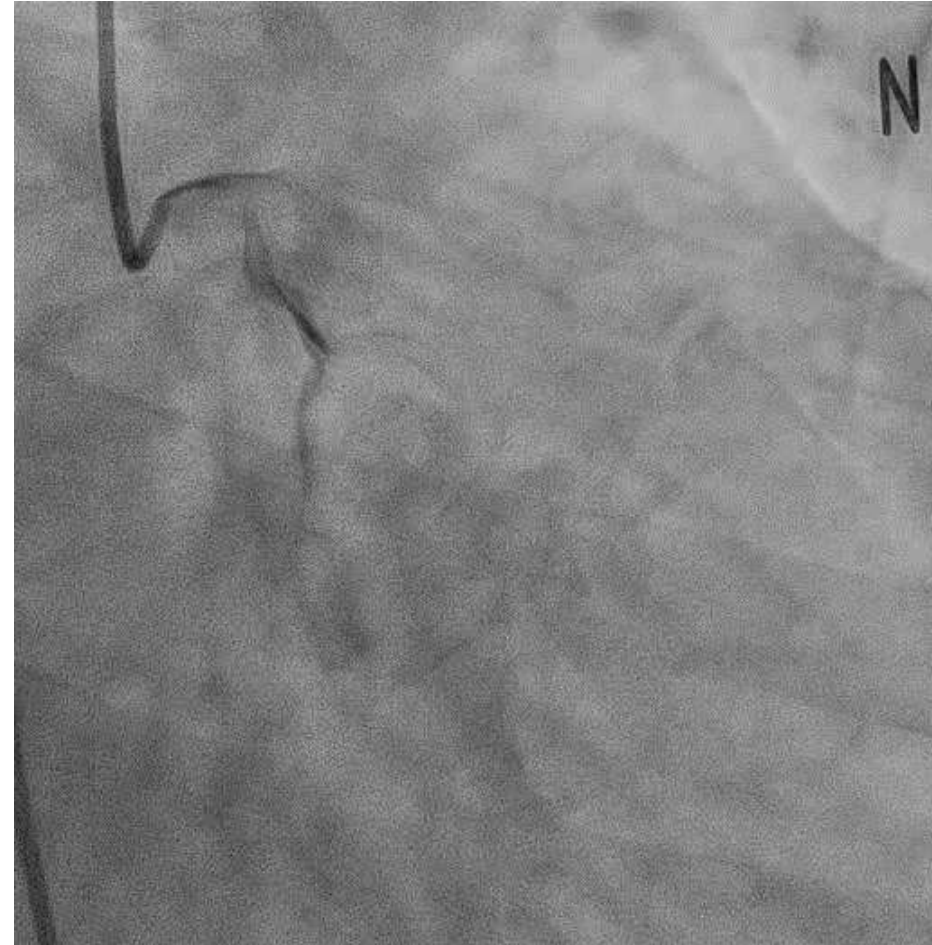
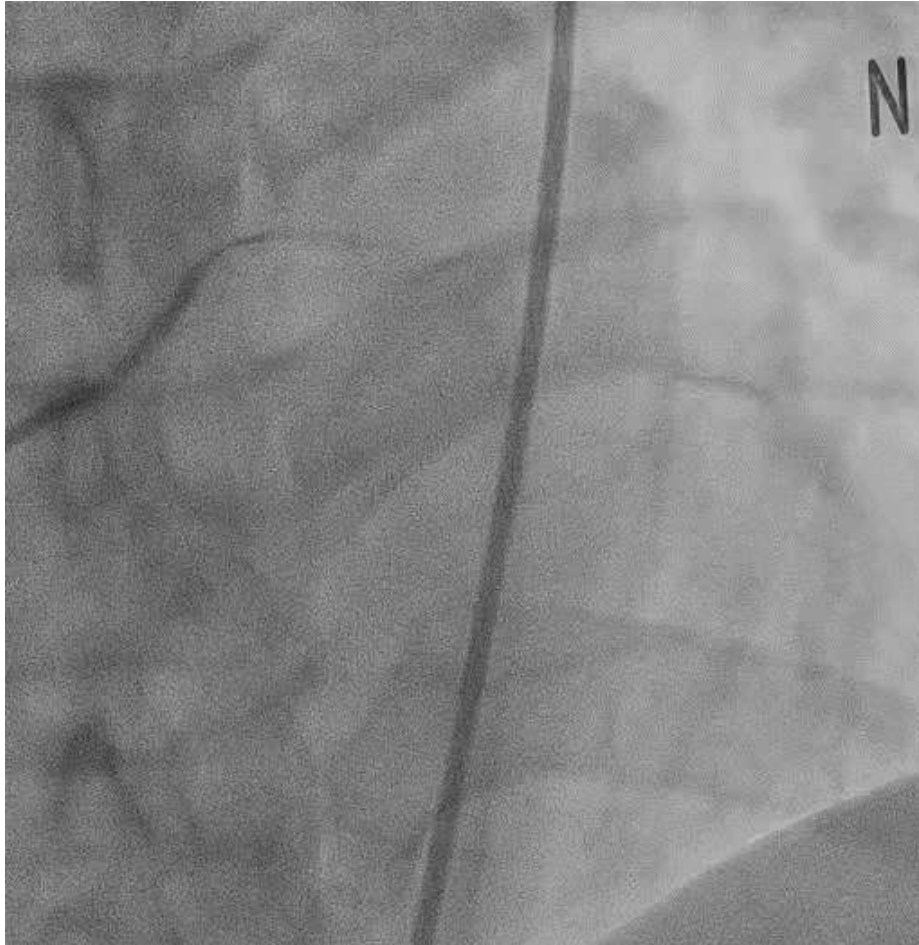
- Male/ 57 years old
- Intermittent exertional chest pain for 5 days  
aggravated chest pain for 6 hours
- Echo: EF 53%, RWMA at anteroseptum & anterior
- Past medical Hx  
: Hyperlipidemia, Current smoker





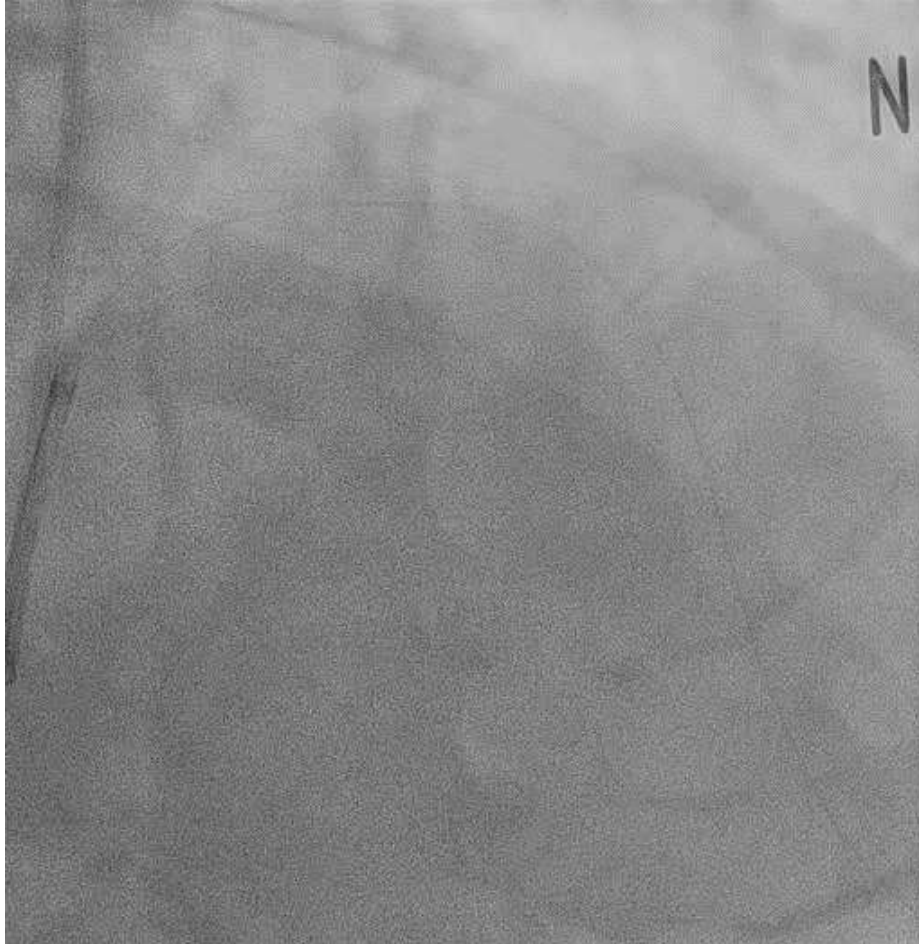
# Case 3 AMI large thrombus

*Pre-PCI*



# Case 3 AMI large thrombus

*After thrombosuction*



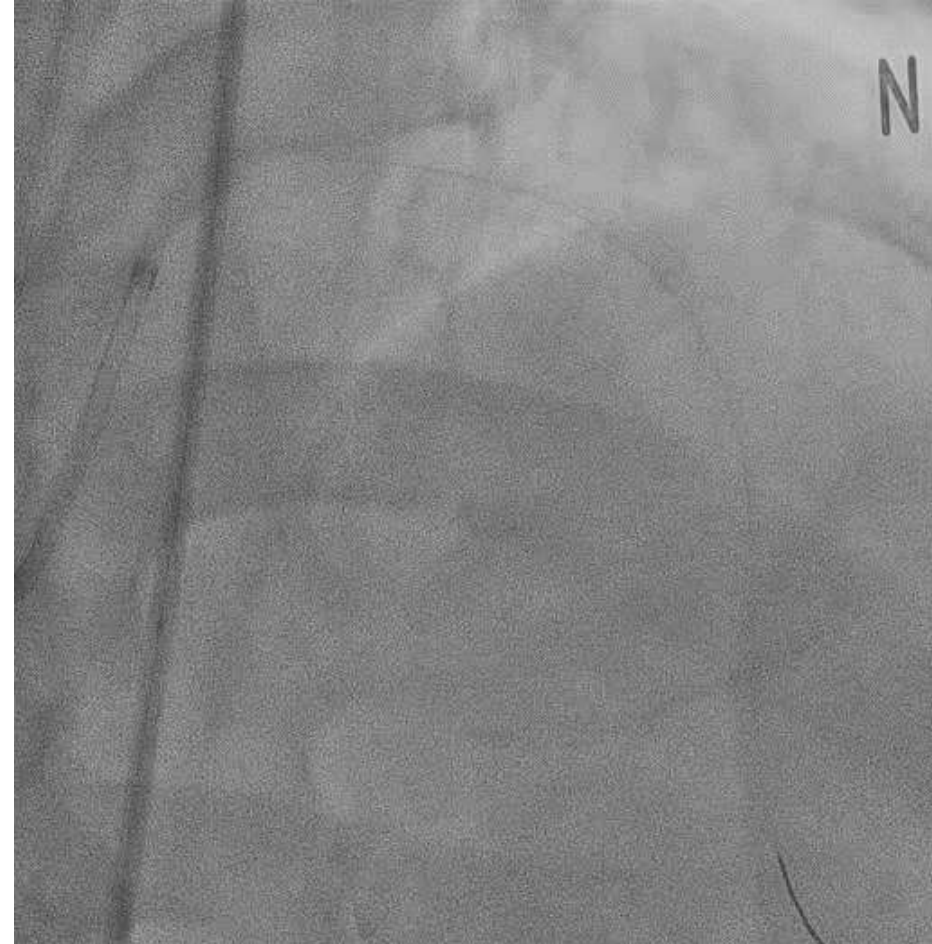
*After PTCA*



# Case 3 AMI large thrombus

*D+storm 3.5/28 mm*

*post stent*





# Case 4

- Male/ 65 years old
- Exertional chest pain with neck radiation and sweating for 1 month
- Admitted at Jun/2021
- Past medical Hx
  - : HTN, Ex-smoker
- Echo: EF 64%, No RWMA

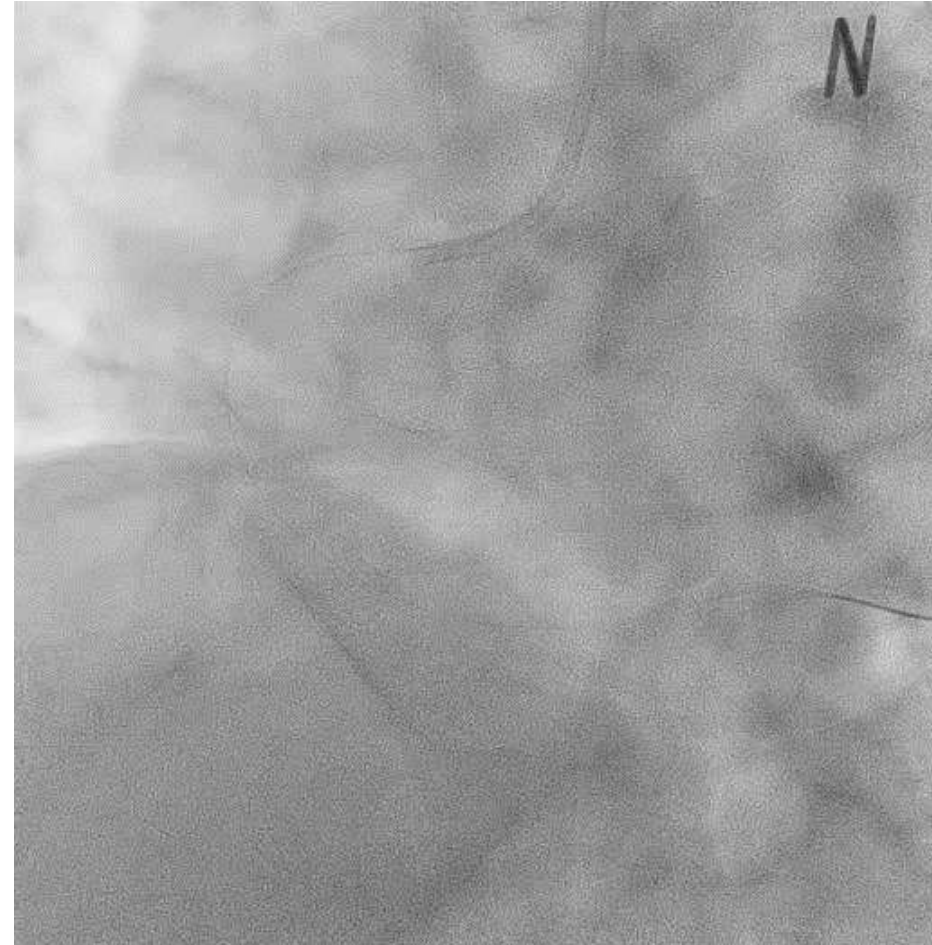
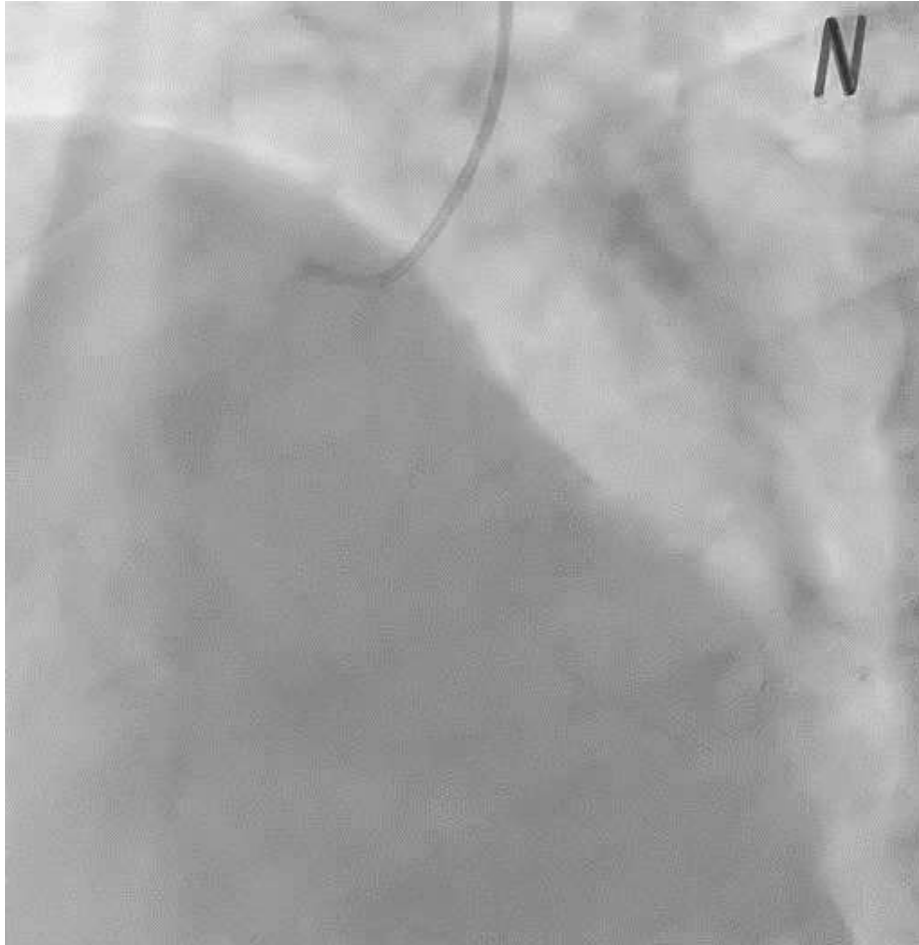


# Case 4 Index PCI

*Pre-PCI*

*D storm 2.75/18 mm*

*Post-PCI*

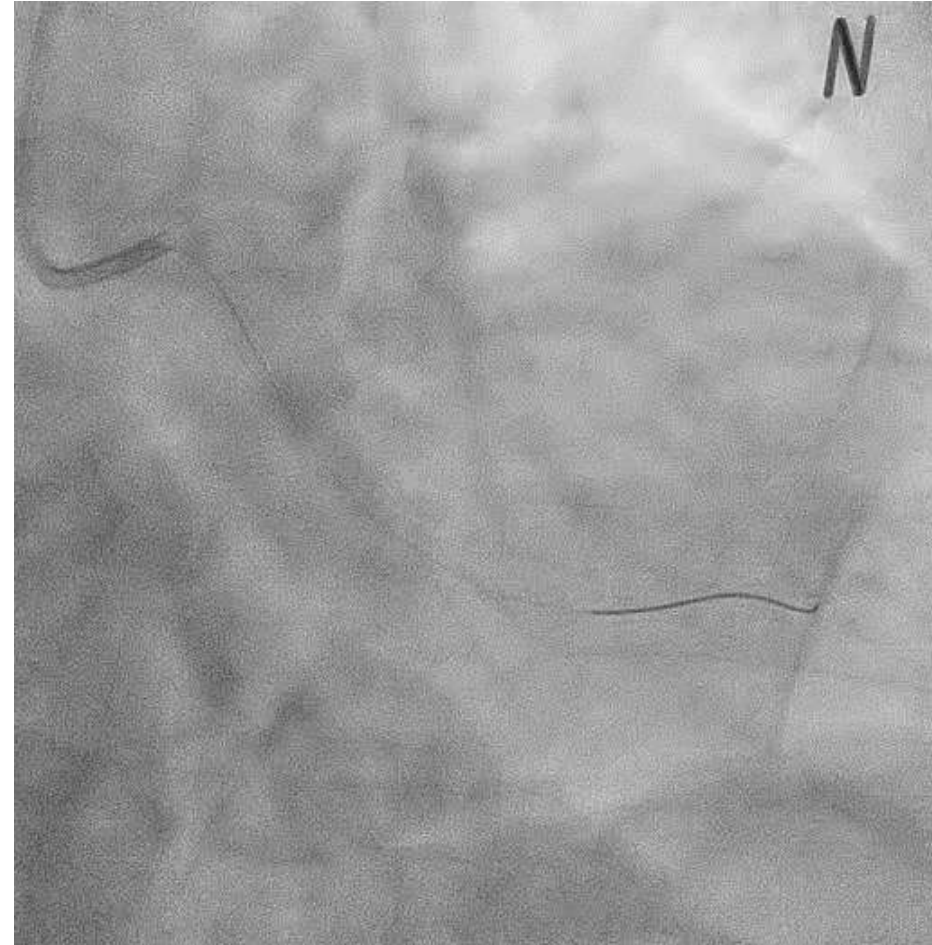
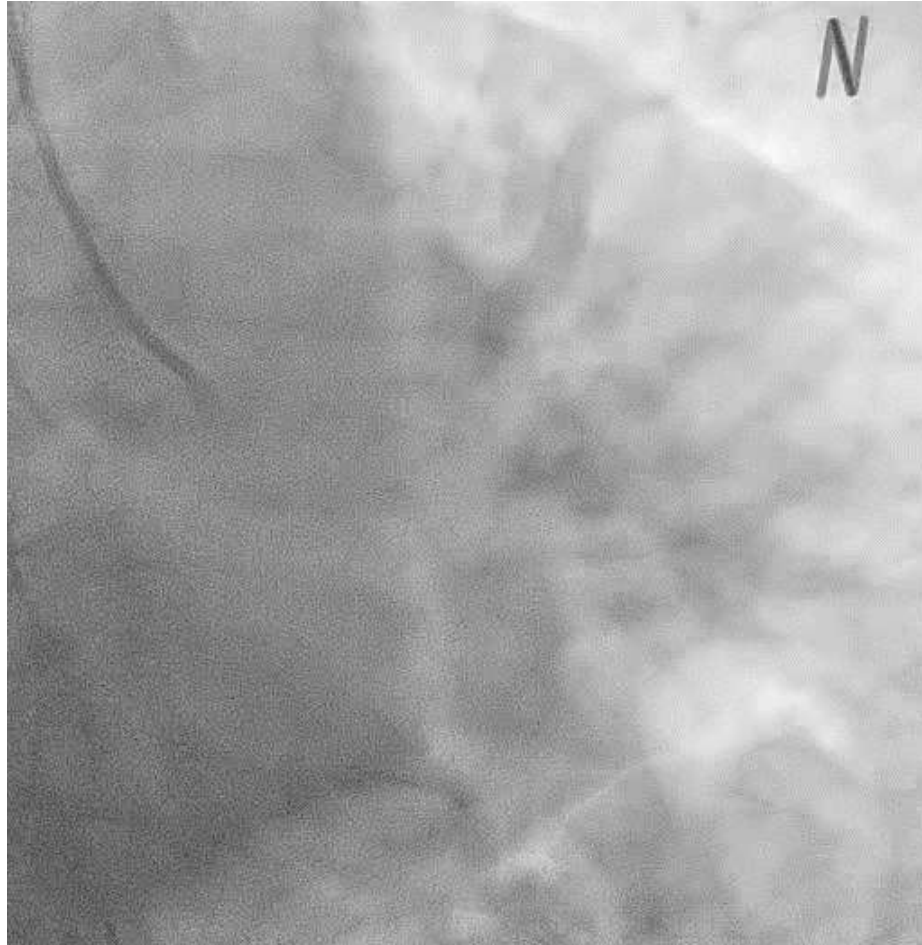


# Case 4 Index PCI

*Pre-PCI*

*D storm 2.75/18 mm*

*Post-PCI*





# Case 4

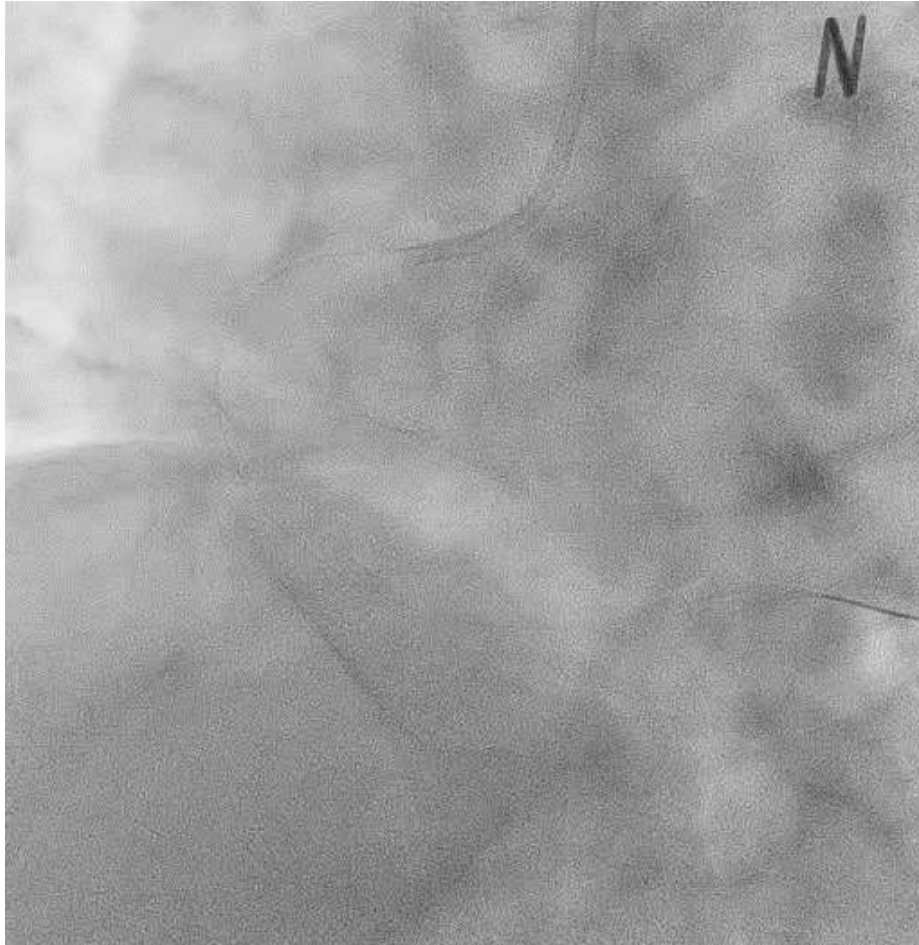
## *Medication withdrawal*

- The patient discharged without events.
- Medication : maintained medications for 2 months.  
stop medications and follow-up loss.
- Revisited hospital due to chest pain, 16 months after index PCI

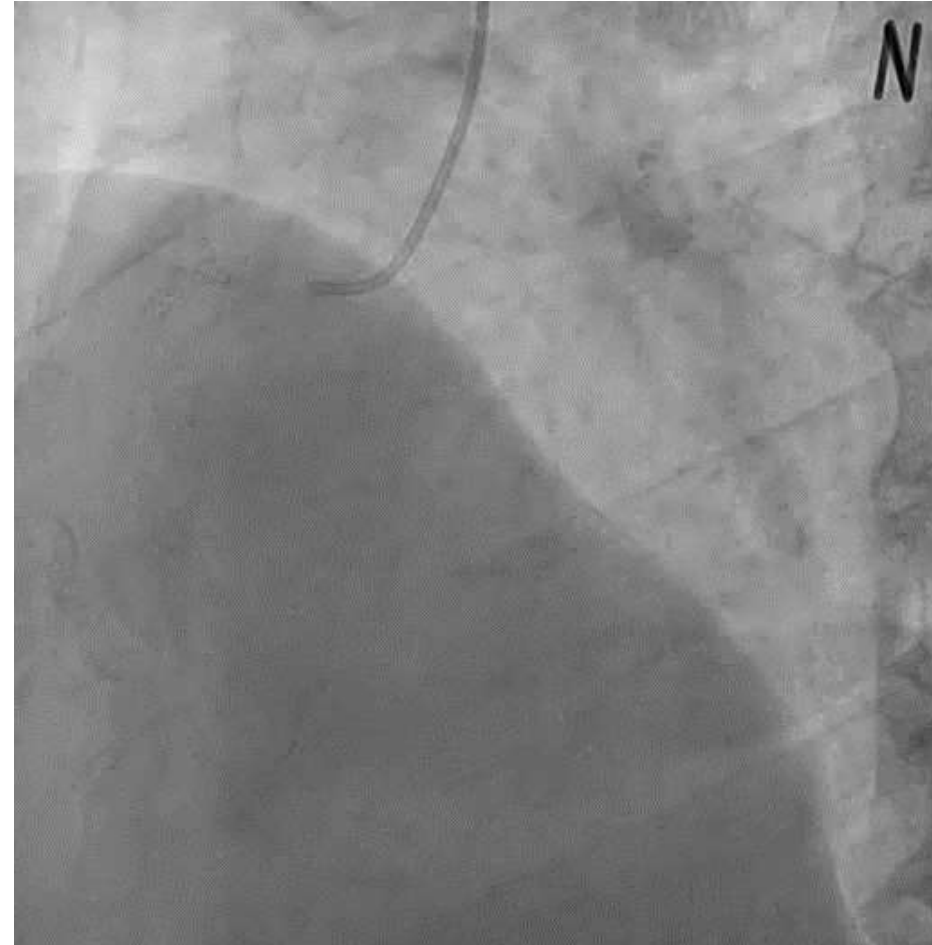


# Case 4: 16 mo follow-up CAG

*Index final CAG*



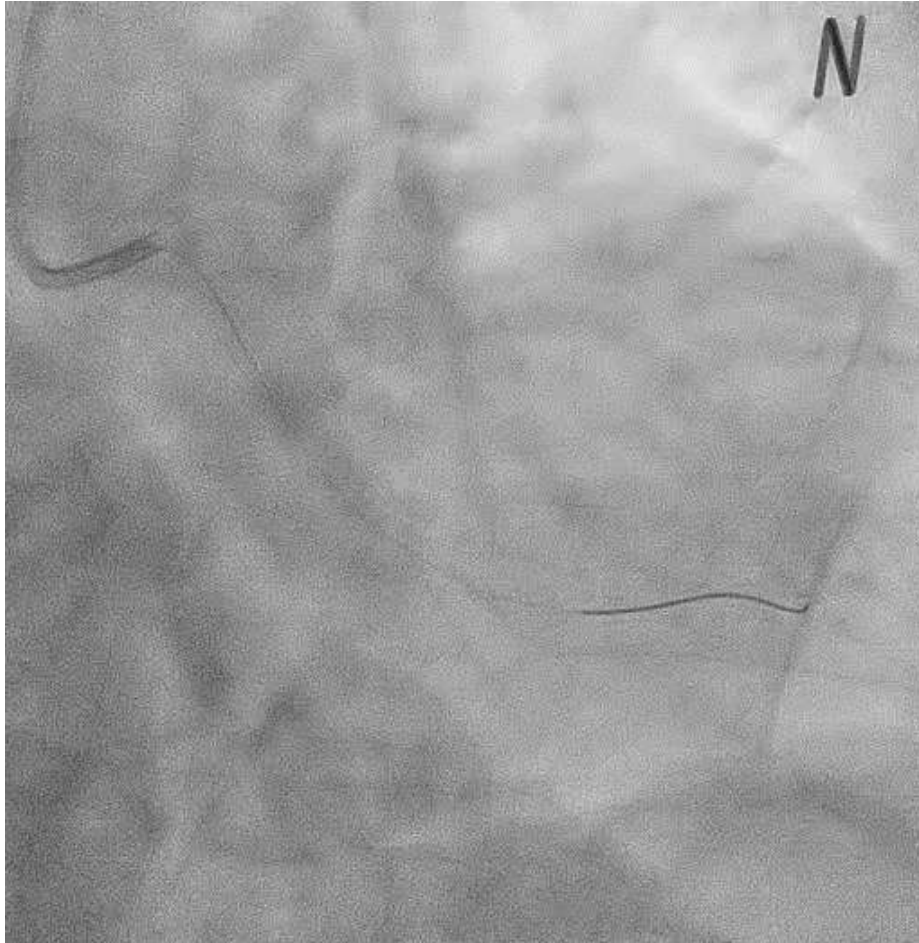
*FU CAG*





# Case 4: 16 mo follow-up CAG

*Index final CAG*

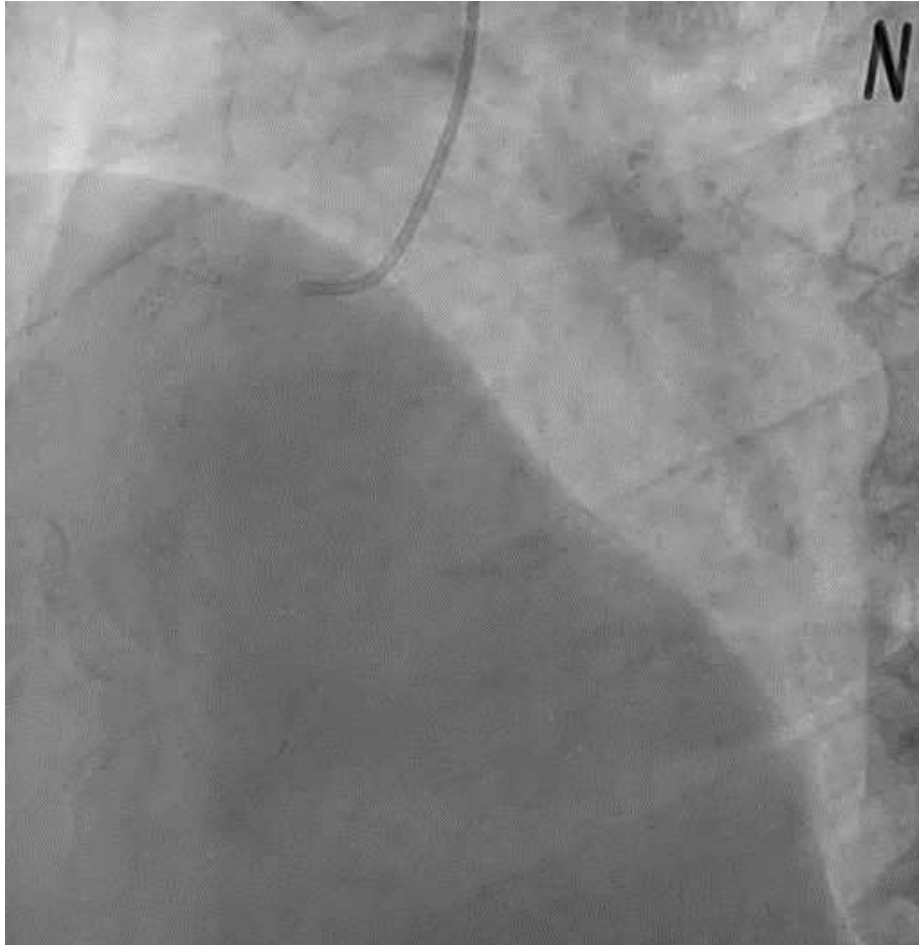


*FU CAG*



# Case 4: 16 mo follow-up CAG

*Pre-PCI*



*Post-PCI*





# Conclusion / Take-home Message

- D+ storm DES is a new DES made in Korea.
- The first-in-human trial of the D+Storm DES demonstrated excellent efficacy in both QCA and clinical outcomes during 9-month follow-up when compared to Biomatrix.
- Real world clinical trial showed excellent clinical outcomes in terms of death, MI and revascularization.
- There was no stent thrombosis.
- Further large-scale randomized clinical trials will be needed

