

BioMatrix™ : The next generation biodegradable polymer technology – Korean Experience

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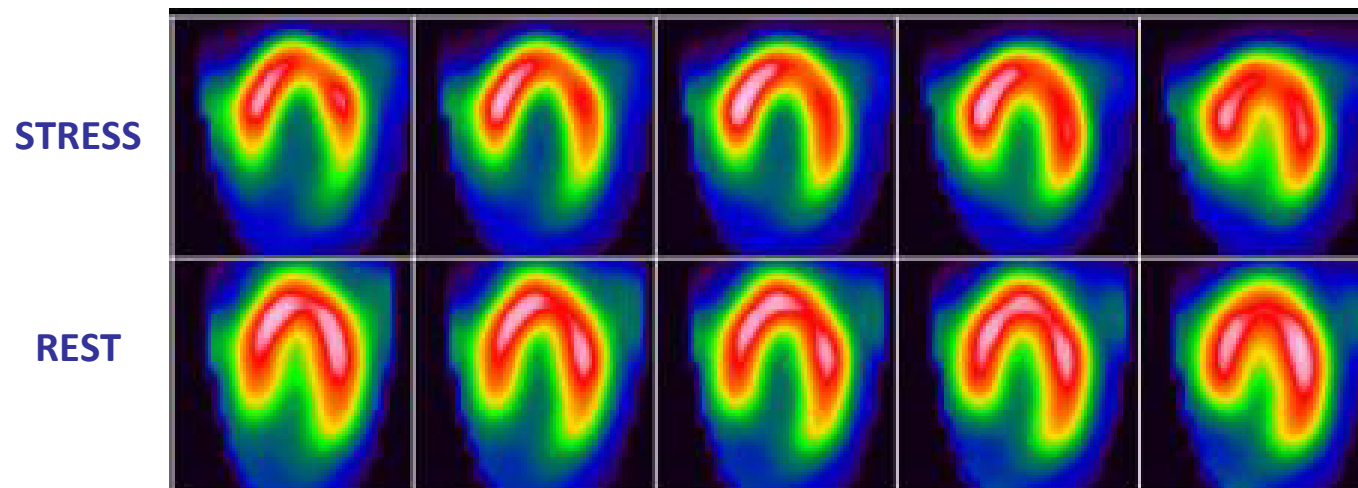


M/55 Silent ischemia

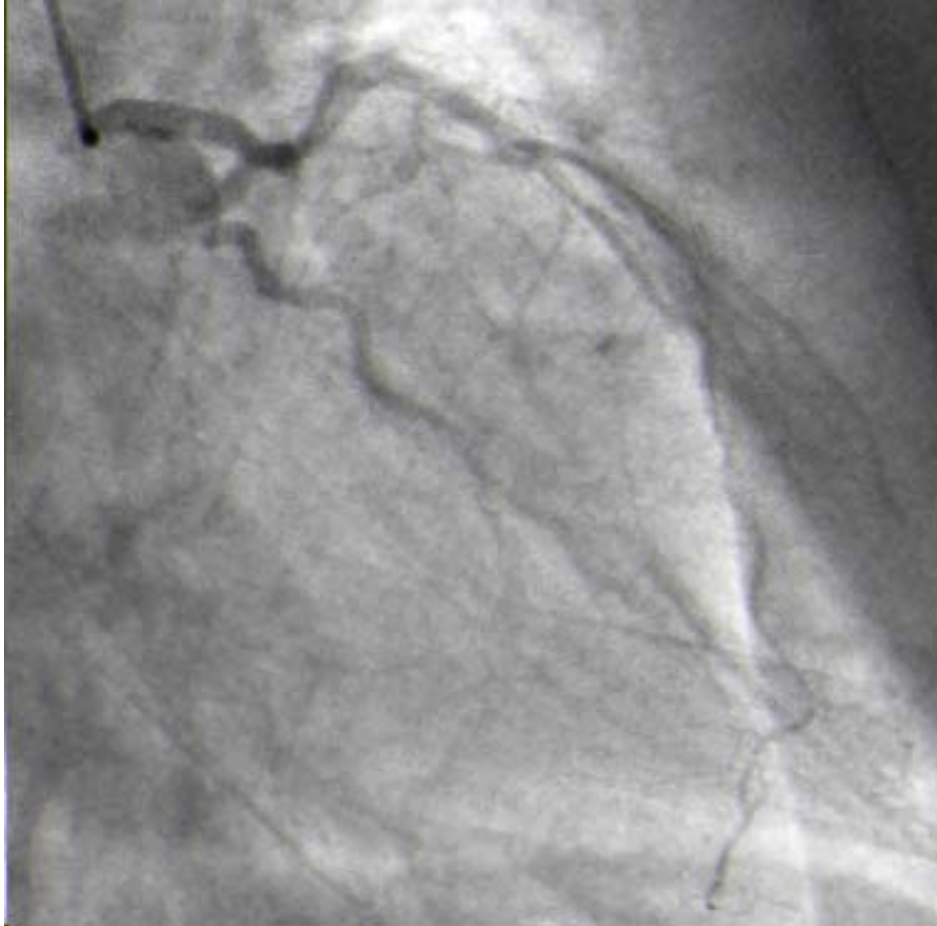
Risk factors: DM, Hypertension, Chronic renal failure

Lab

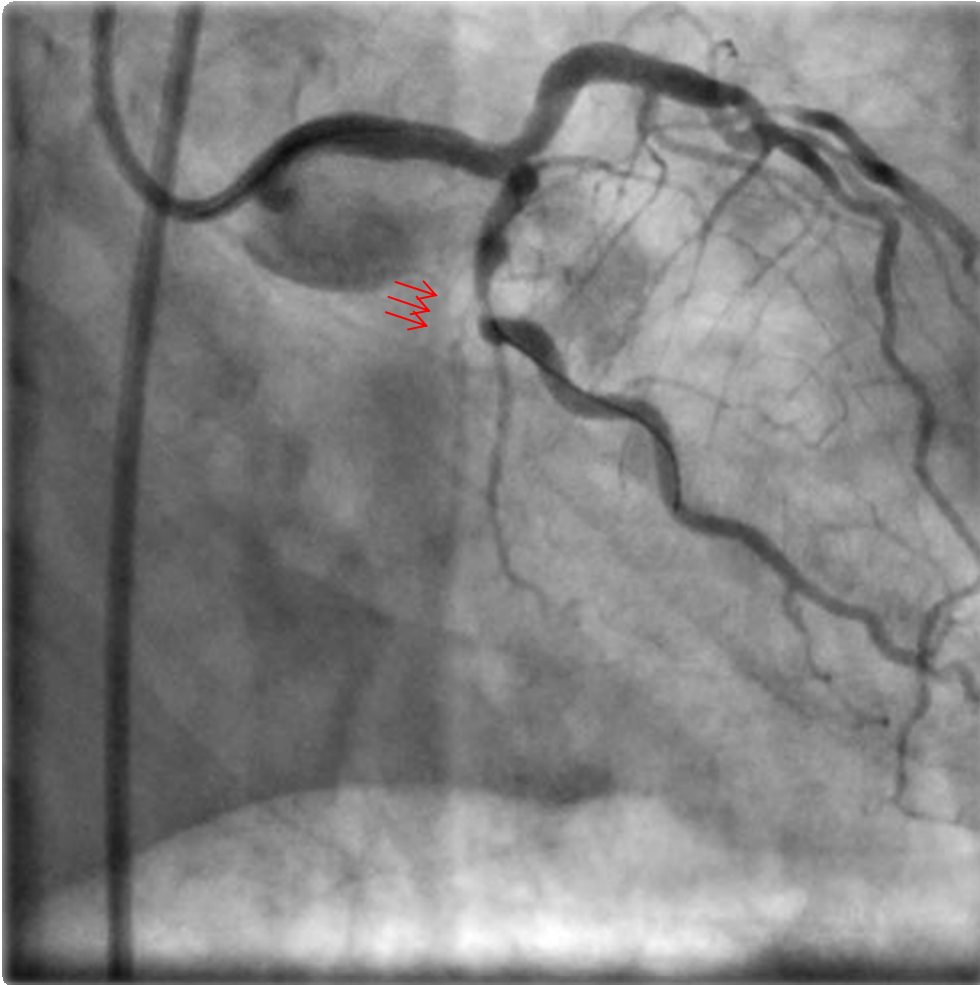
- EKG: LVH
- Echocardiography: Concentric LVH with normal LV function
- Myocardial SPECT: reversible perfusion defect in lateral wall



M/55 Silent ischemia



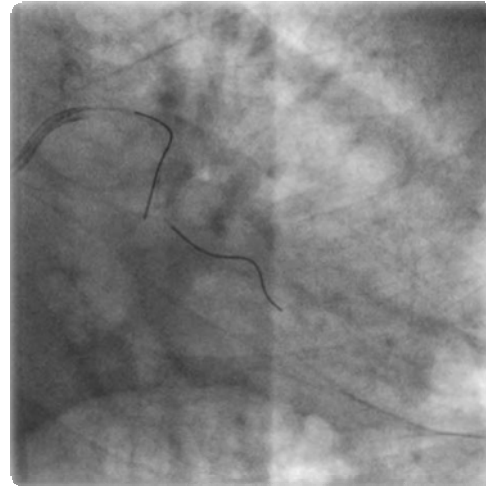
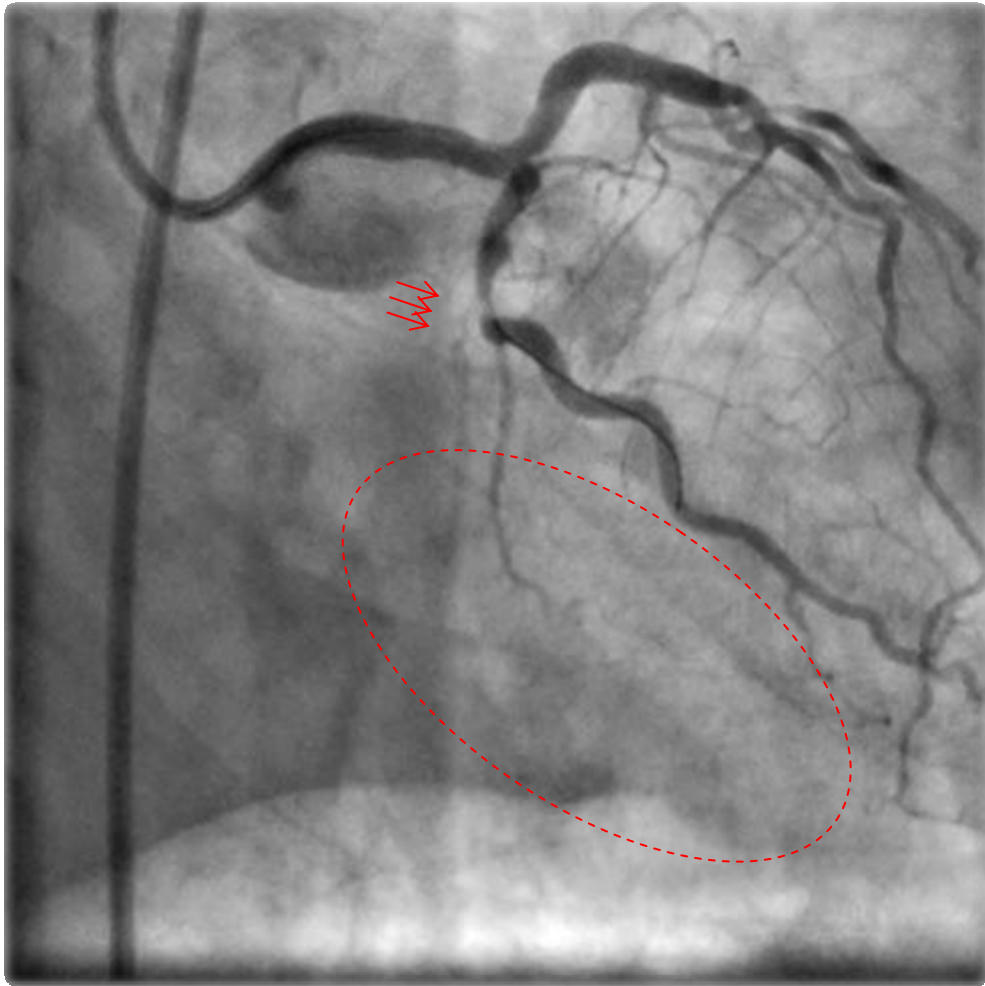
M/55 Silent ischemia



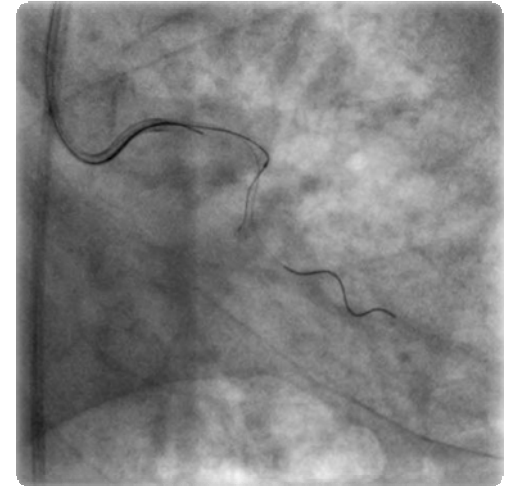
What's your strategy?

- Neglect small LCX branch
- Intentional 2 stenting
- Provisional 2 stenting

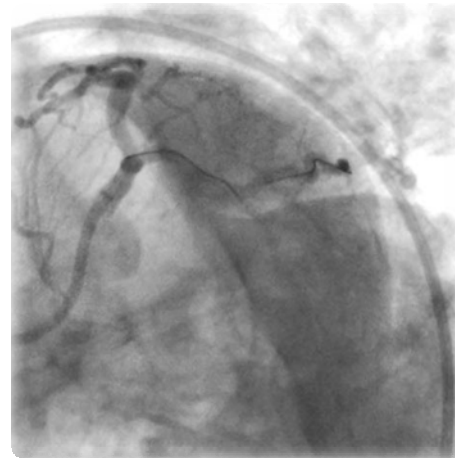
M/55 Silent ischemia



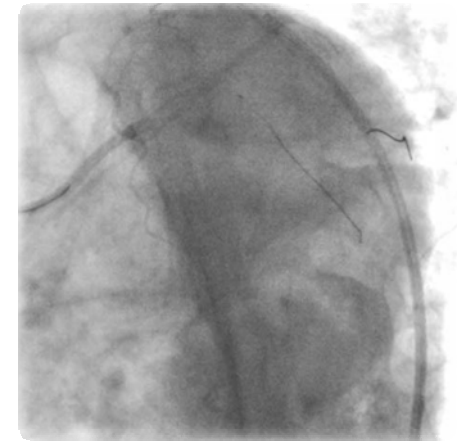
Runthrough: failed



Fielder XT: failed

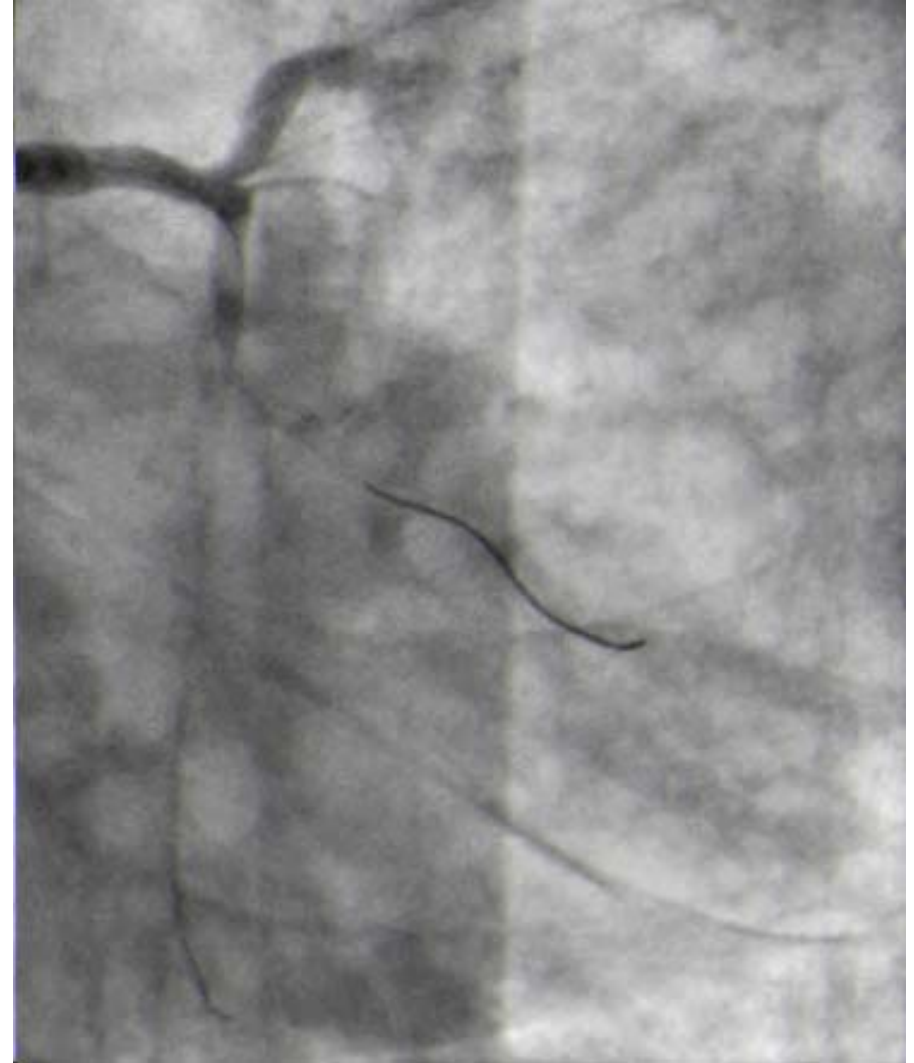
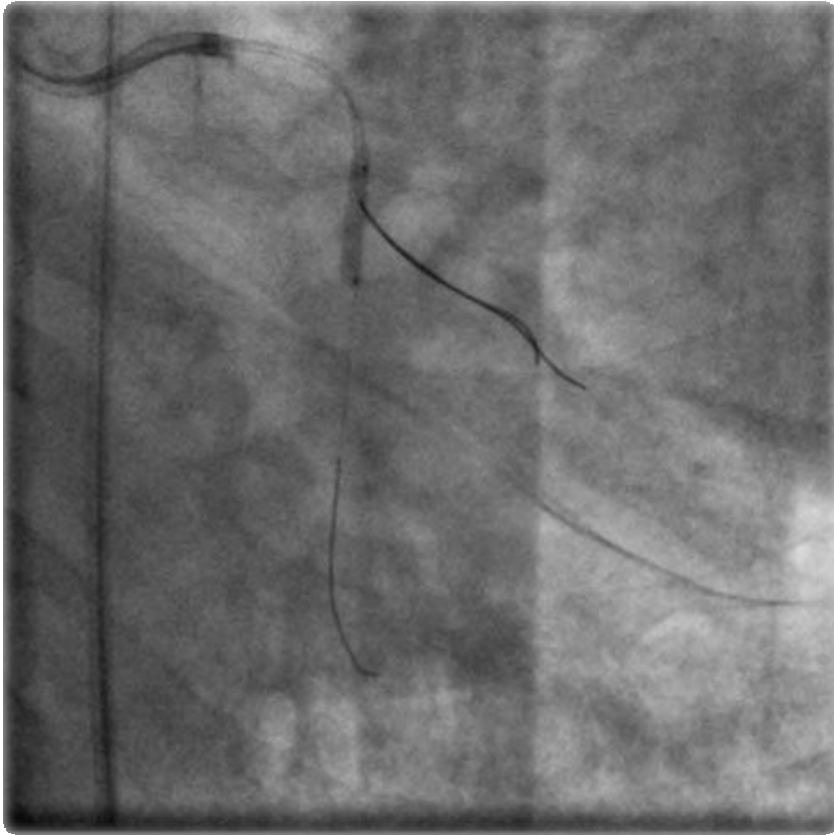


Runthrough interm: failed

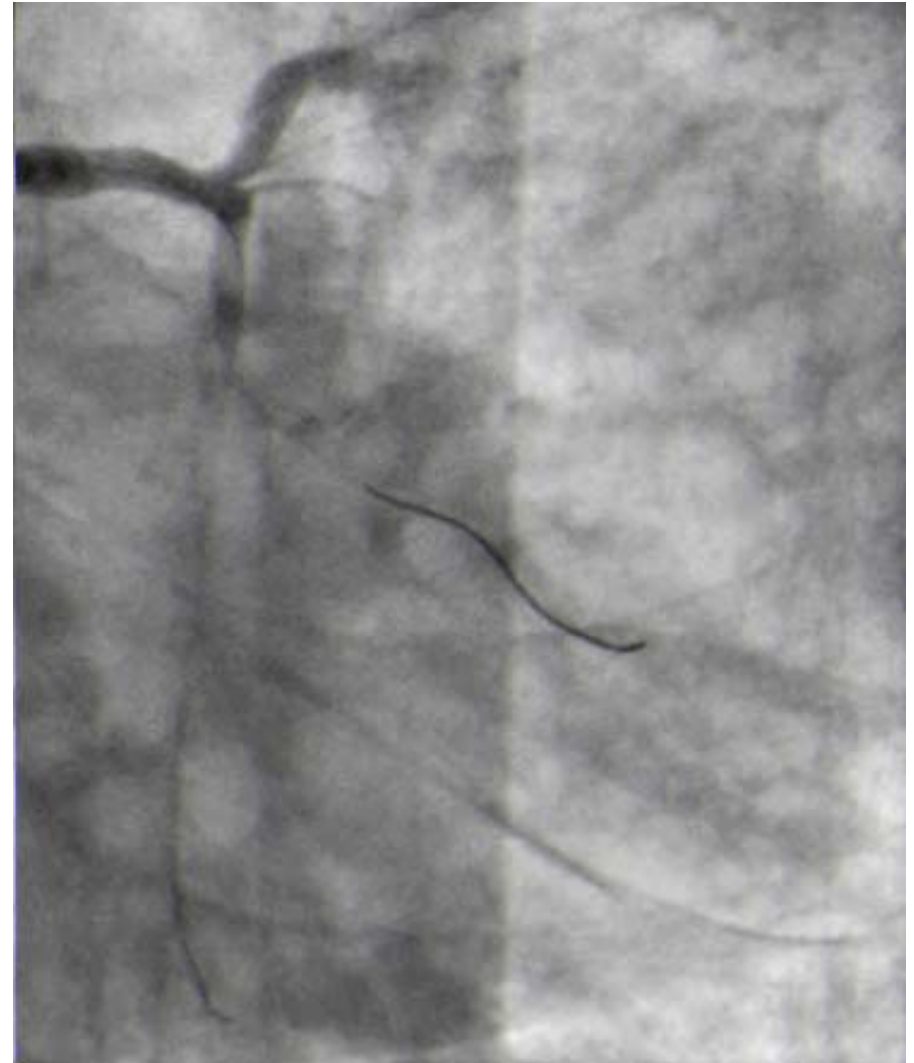
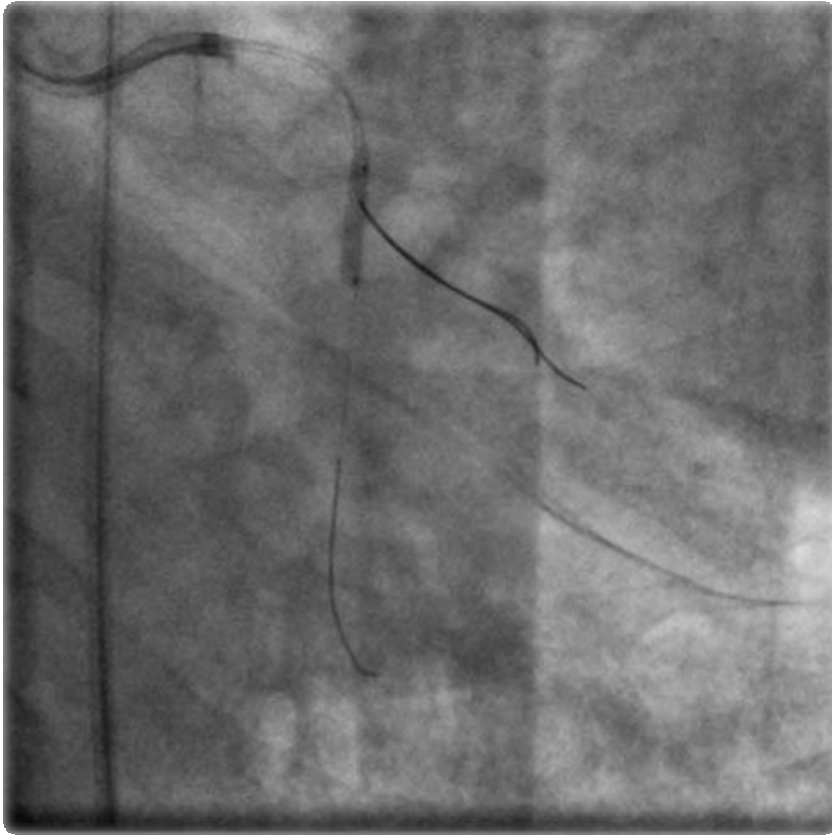


Crossit 200

M/55 Silent ischemia

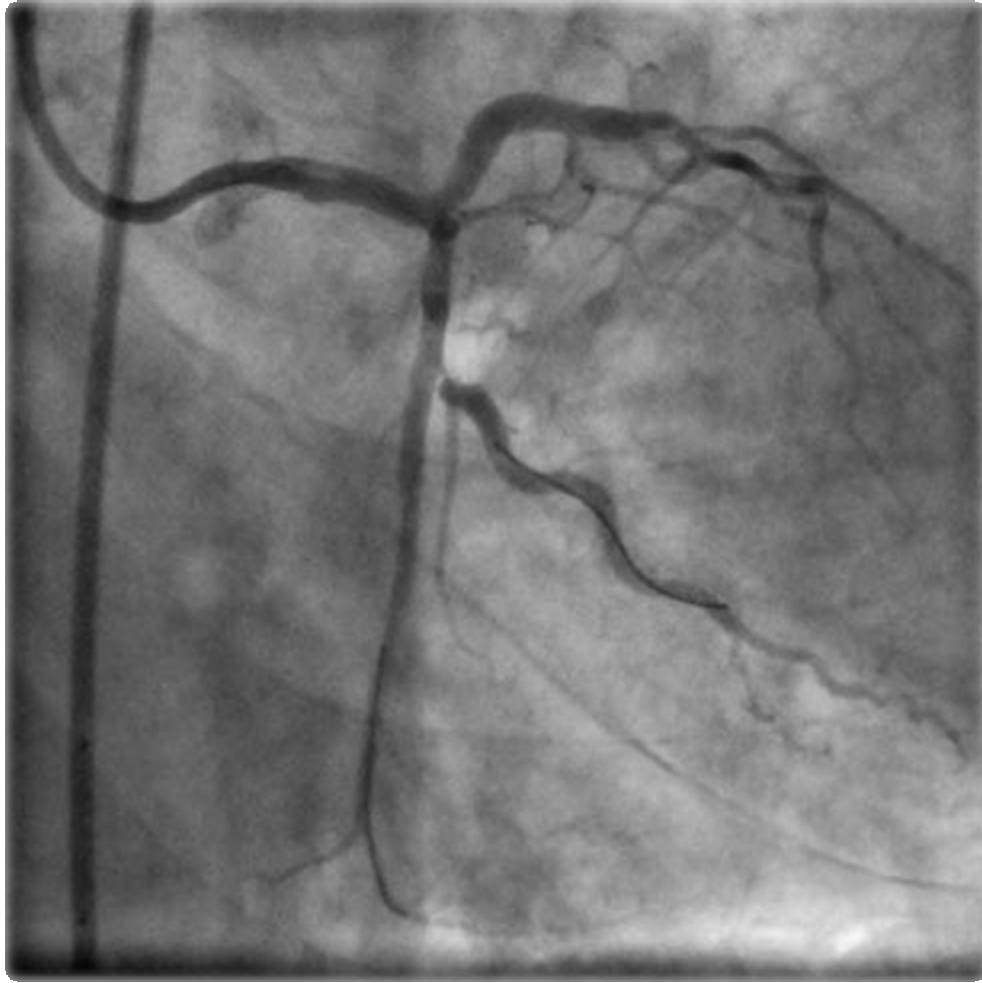


M/55 Silent ischemia

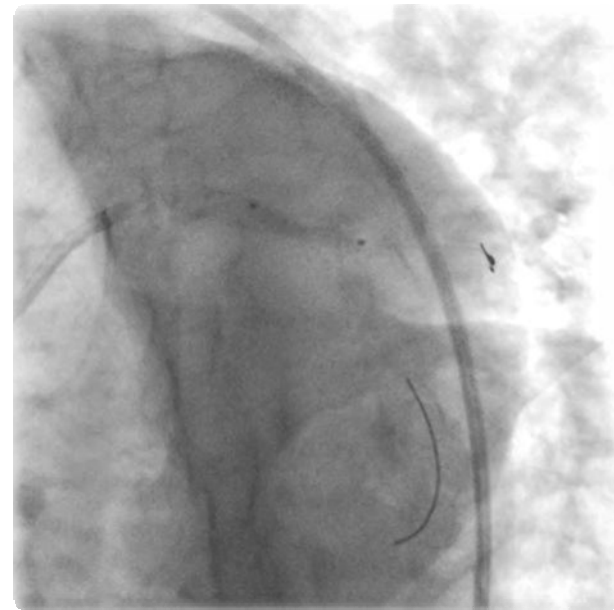
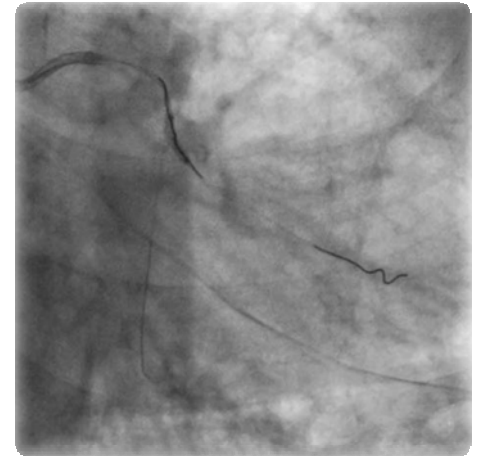
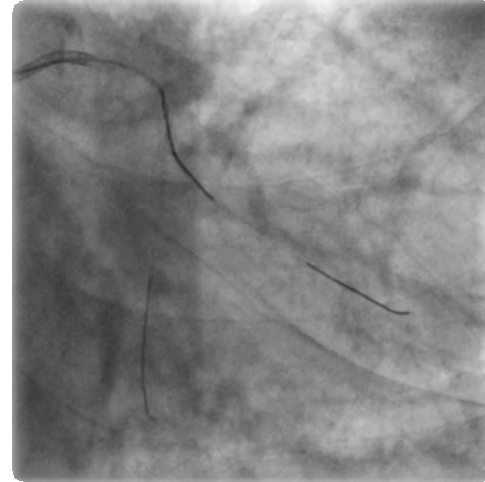


What would you do? *Crush? Provisional T? Culotte?*

M/55 Silent ischemia

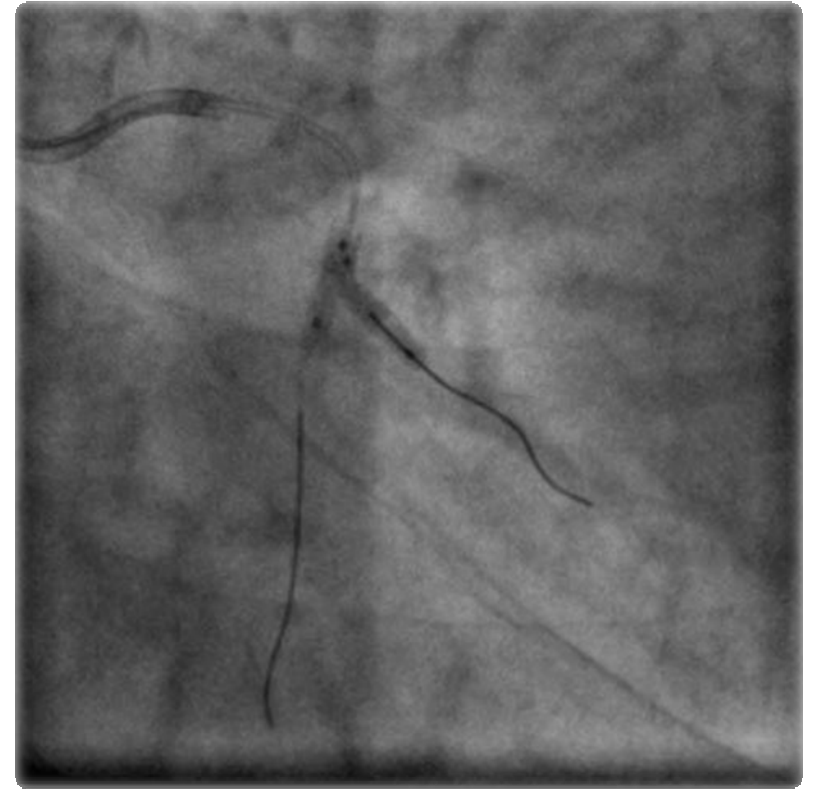
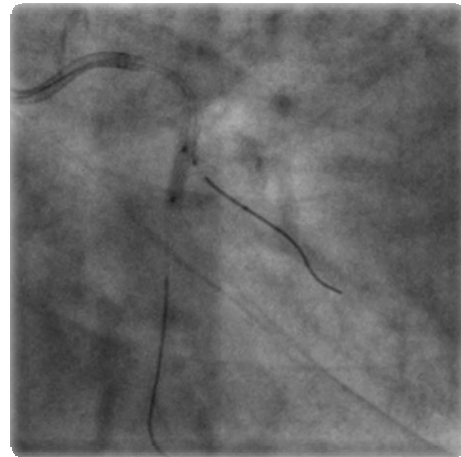
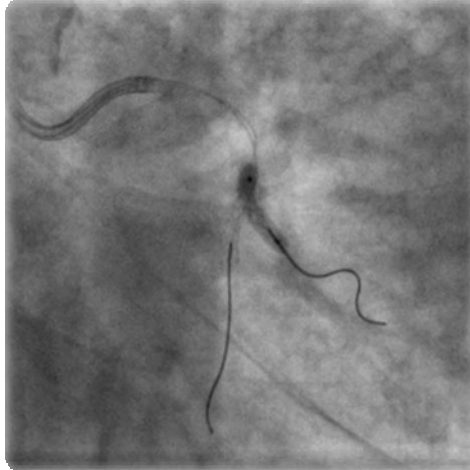
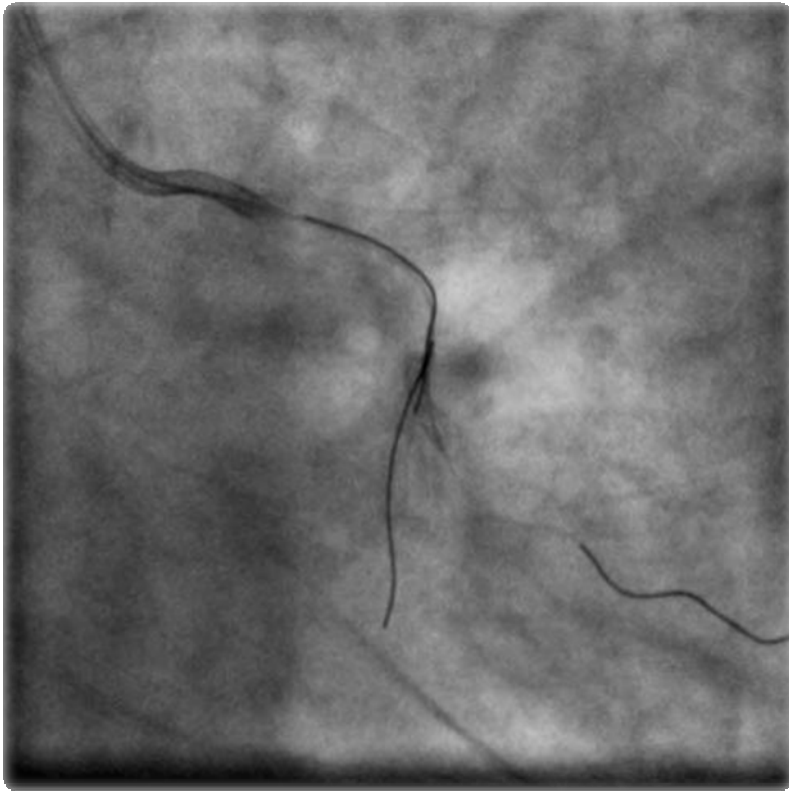


BioMatrix 2.75x14mm

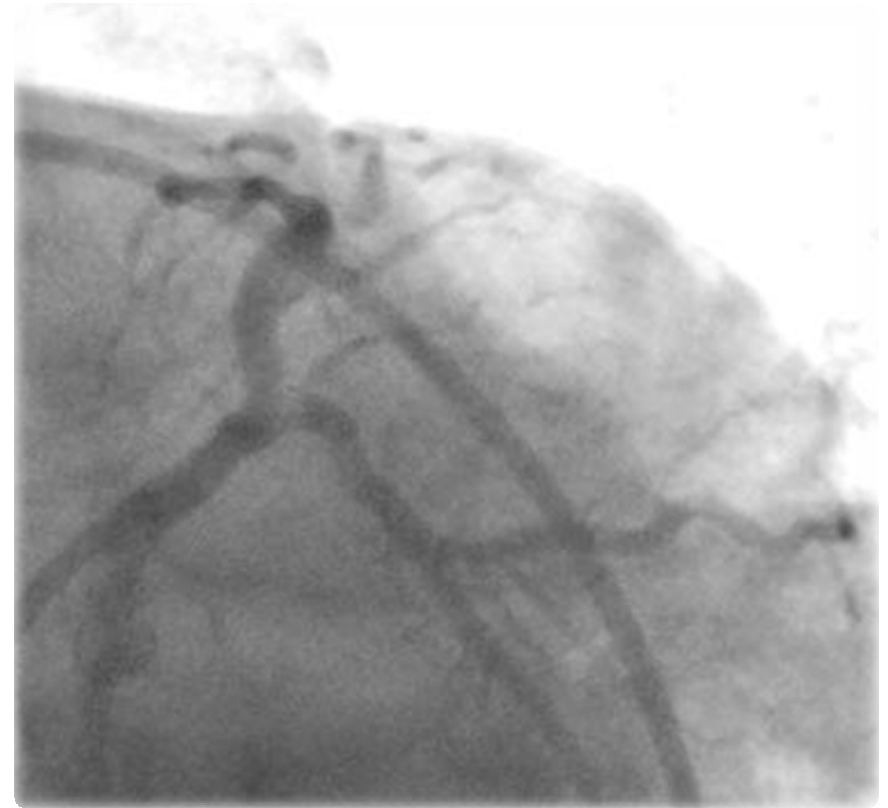
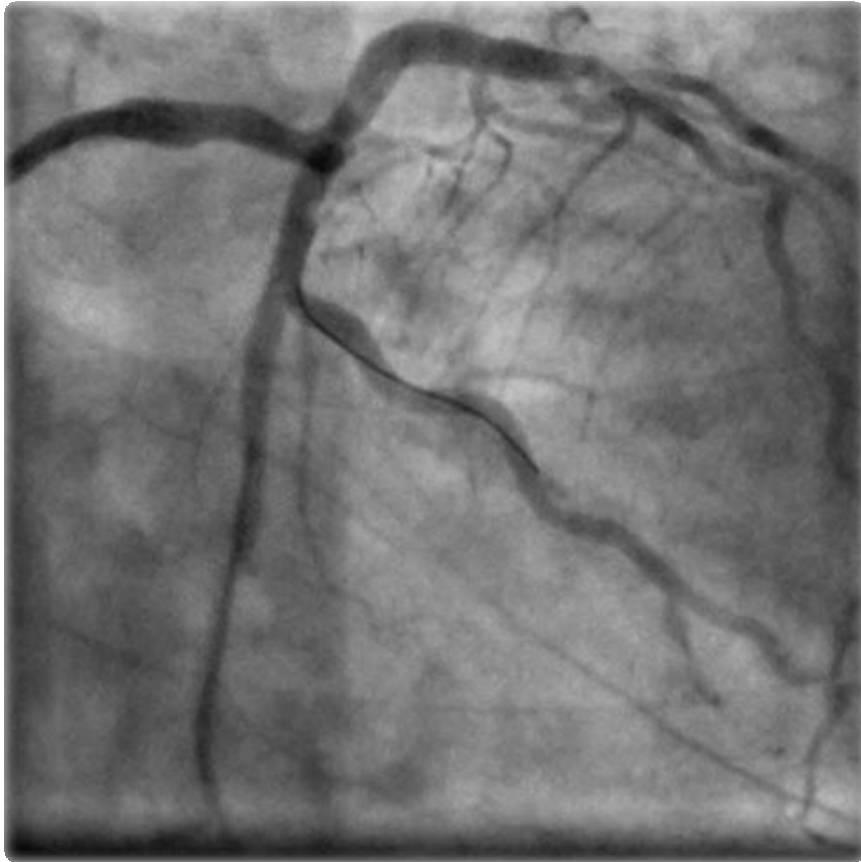


BioMatrix 2.75x14mm

M/55 Silent ischemia



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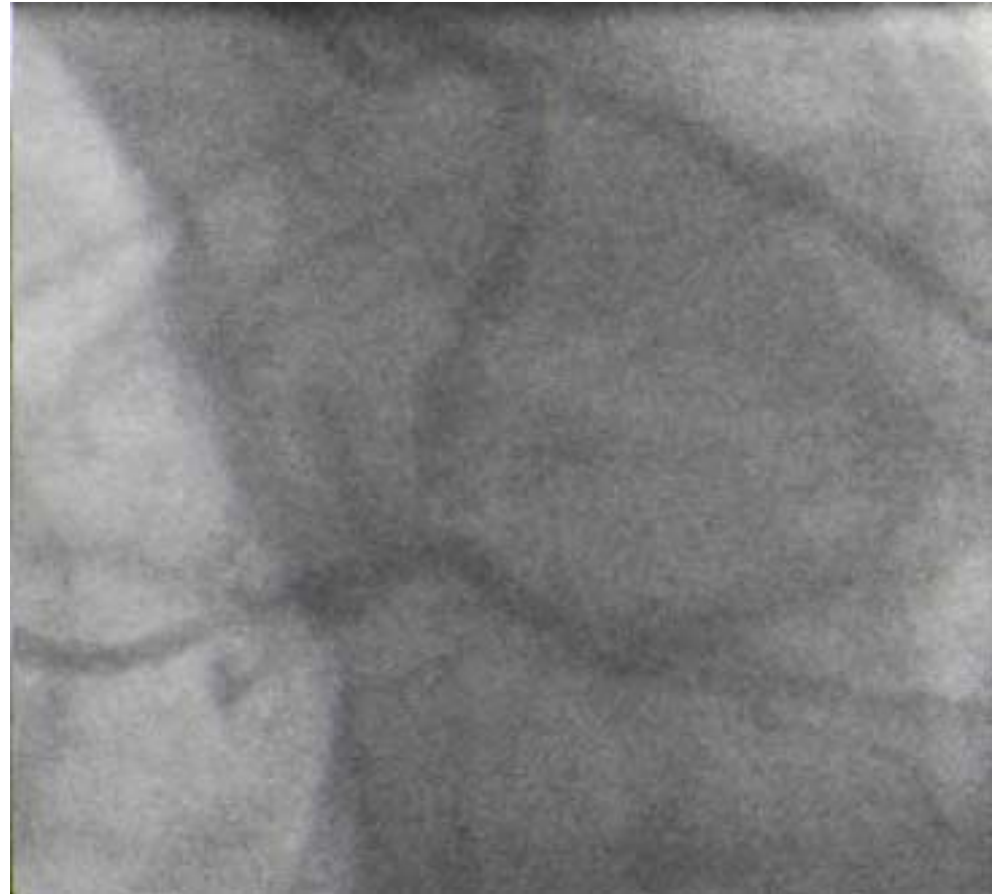
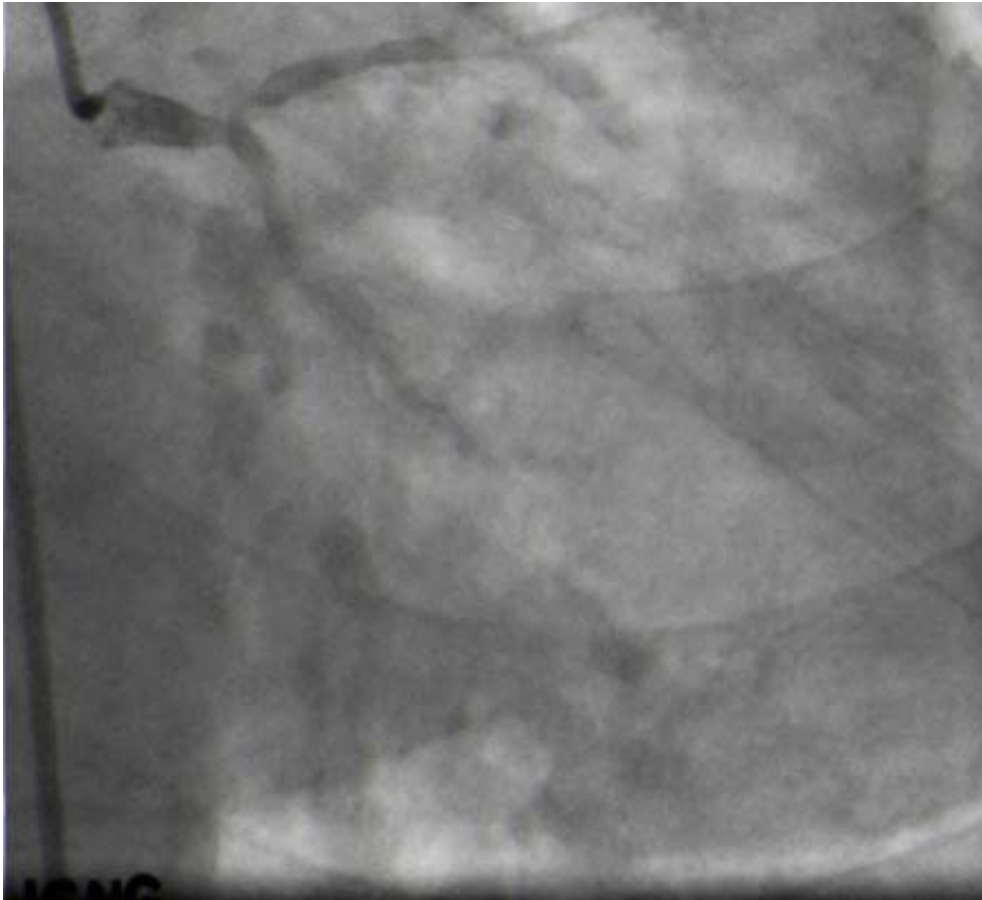


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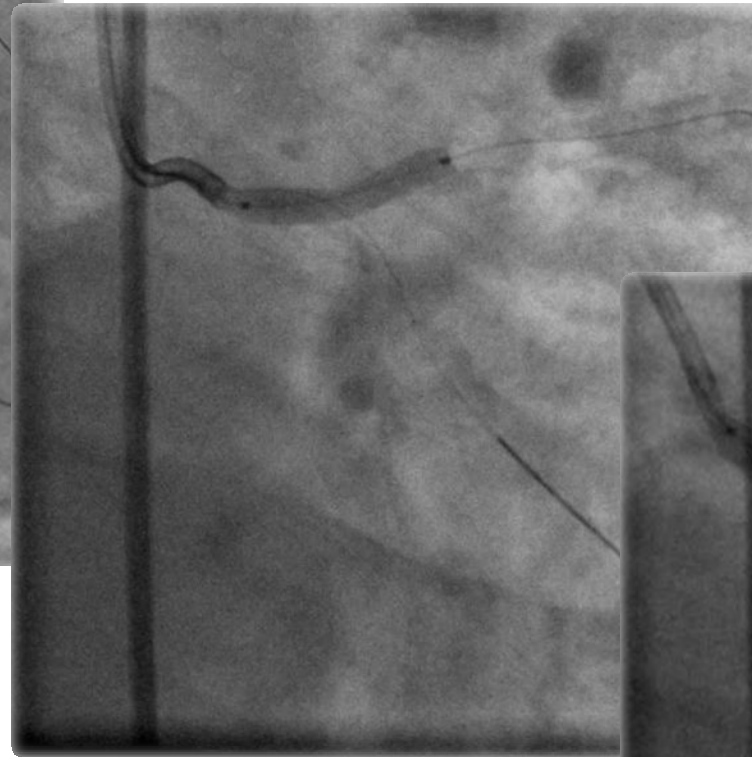
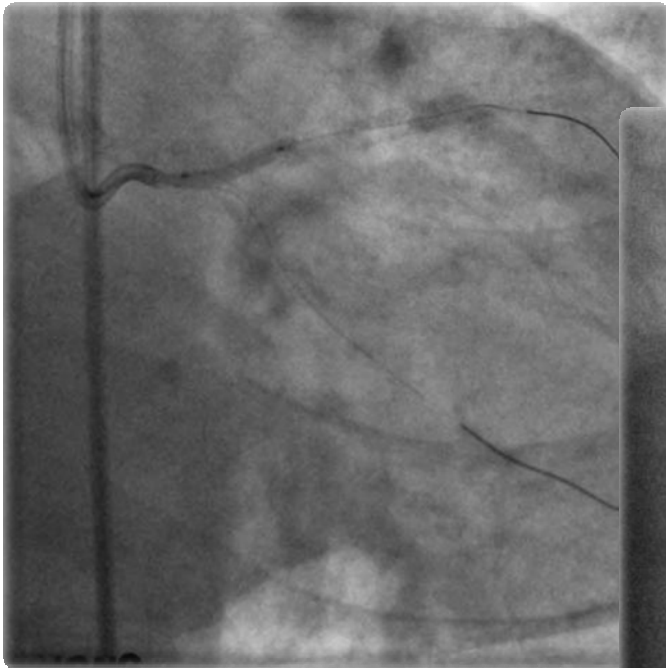
Progress note

- 12 mo after PCI
- No event, patient is doing good.

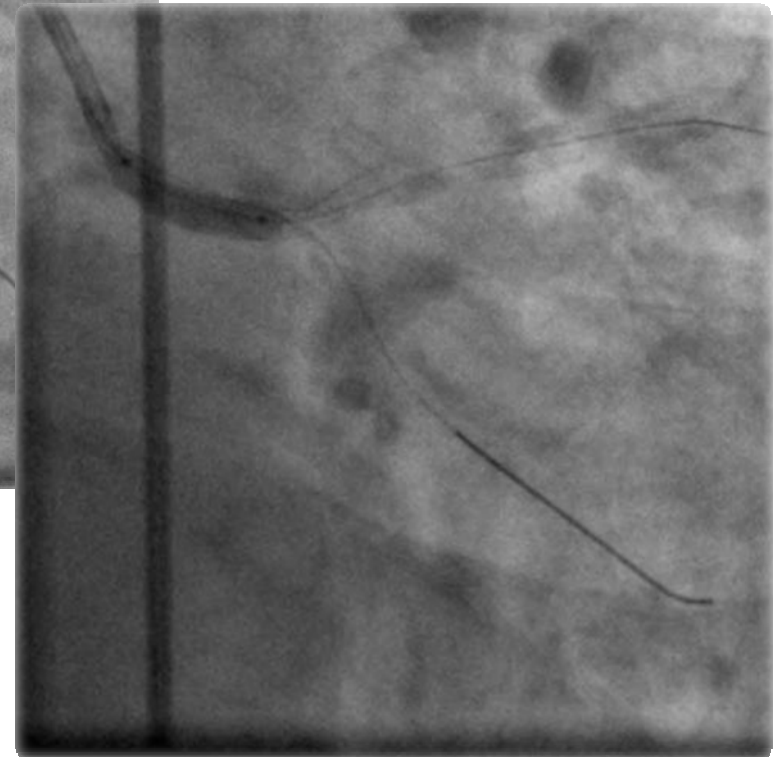
M/69 Crescendo angina



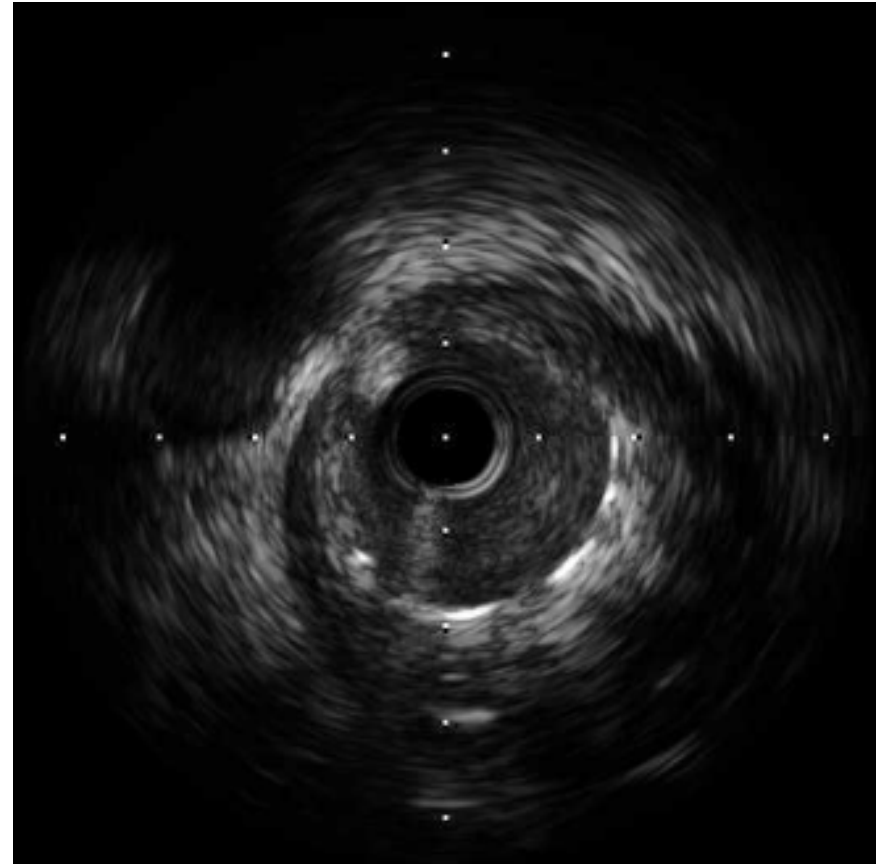
M/69 Crescendo angina



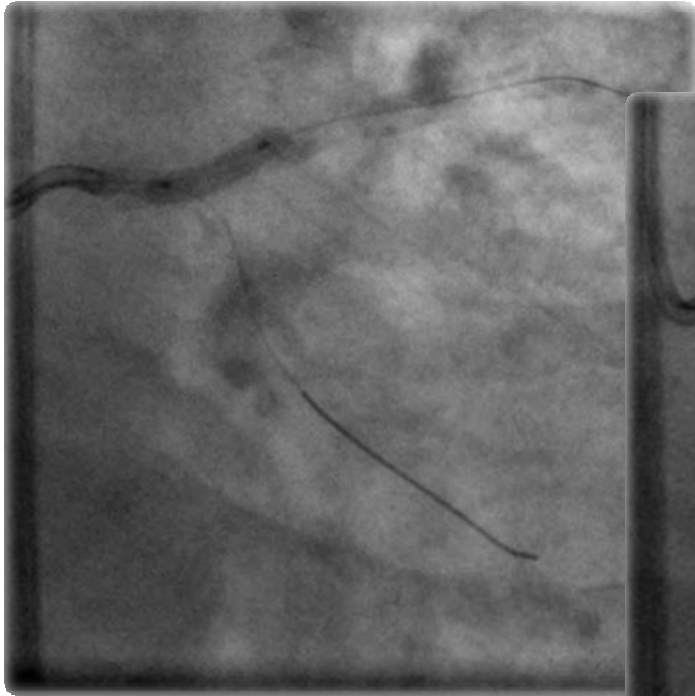
BioMatrix 3.5x18mm



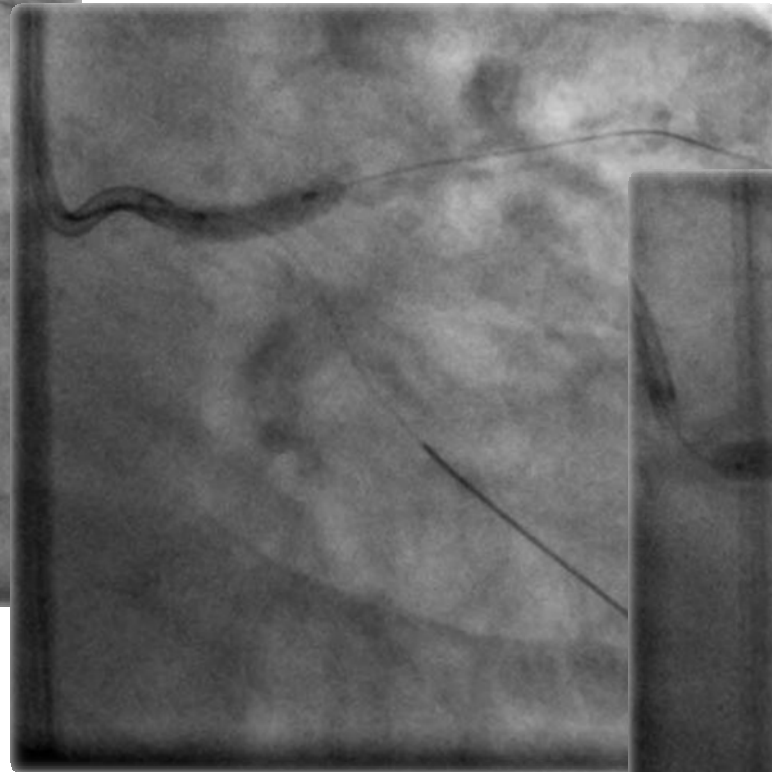
M/69 Crescendo angina



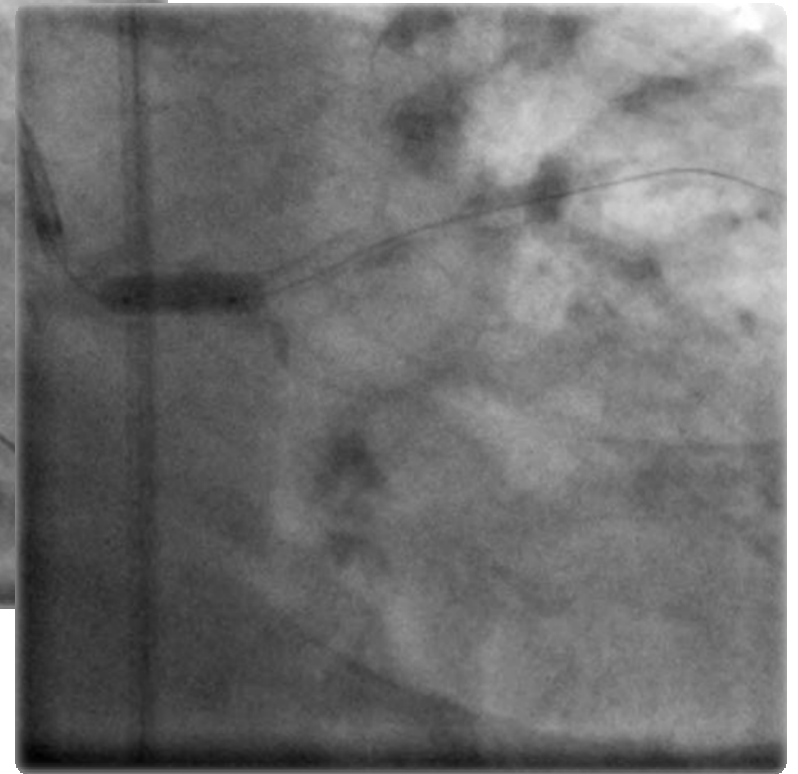
M/69 Crescendo angina



3x12mm, 20atm

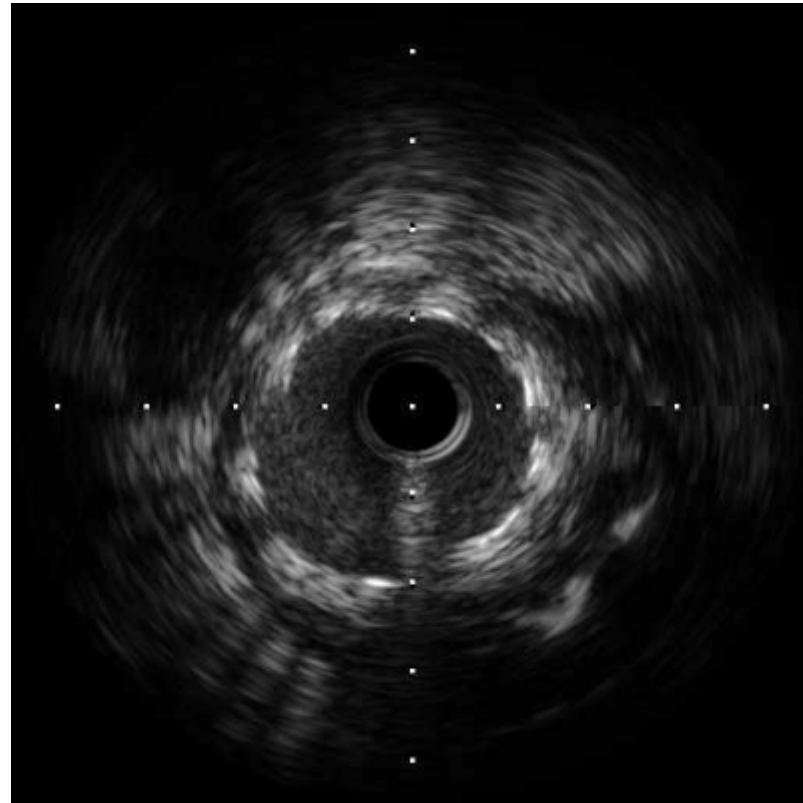


3x12mm, 20atm



3.5x15mm, 14atm

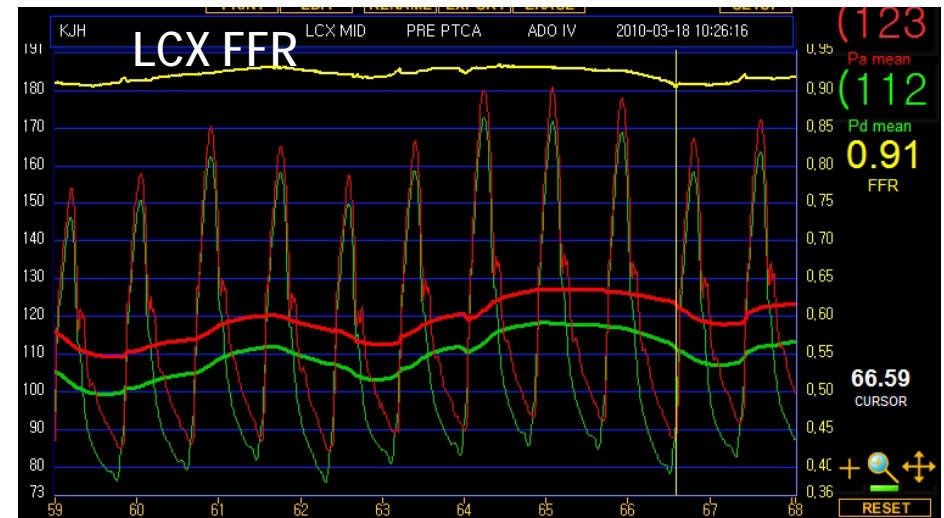
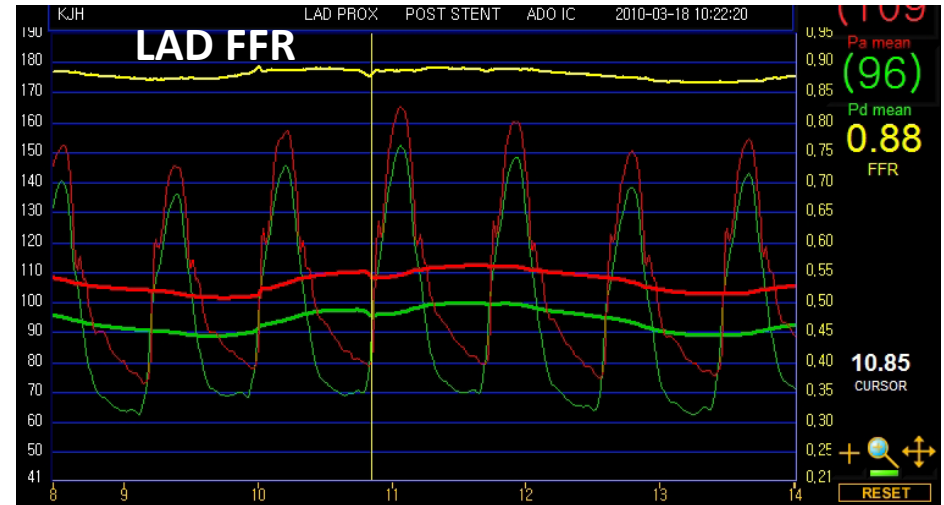
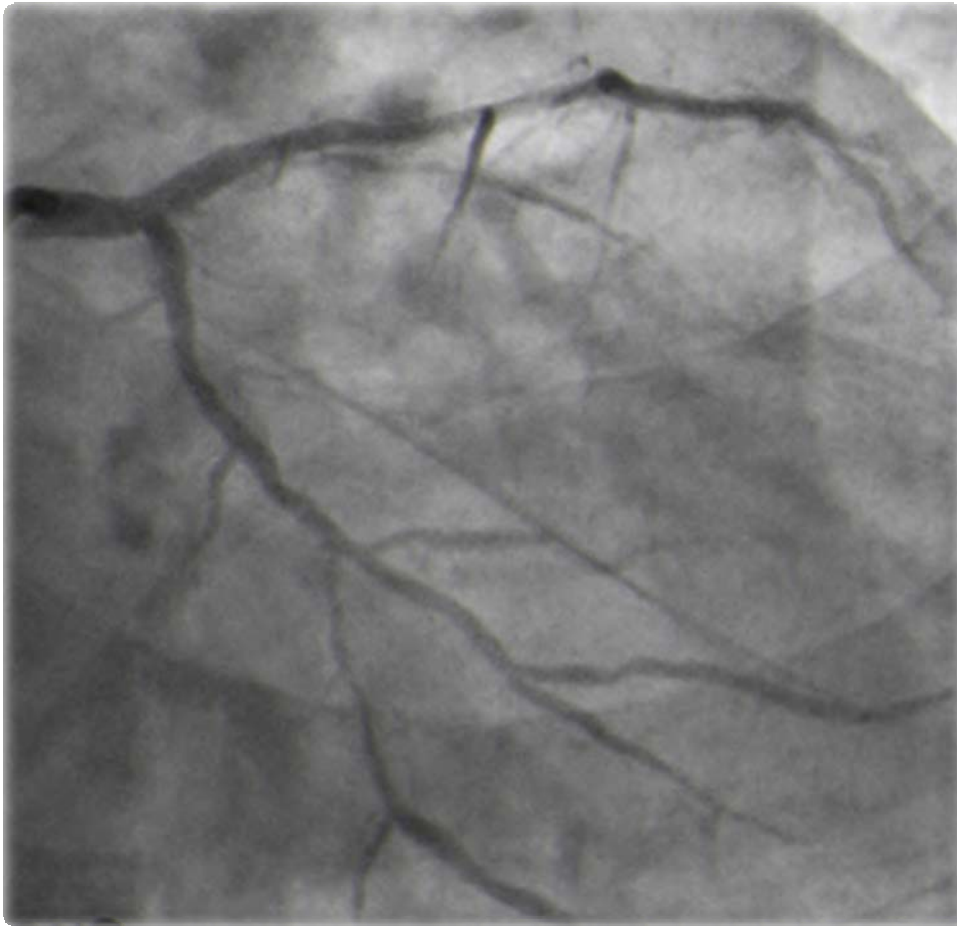
M/69 Crescendo angina



M/69 Crescendo angina



M/69 Crescendo angina



M/69 Crescendo angina

Progress note

- 13 mo after PCI
- No pain, no event

Harmonizing **O**ptimal **S**trategy for **T**reatment
of CAD using **Biolimus**-eluting stents
: **The HOST-Biolimus Registry**

**HOST-Biolimus
Registry**

(21 Participating Centers)

**BES
(Biomatrix[®] / Nobori[®])
3000 pts
Prospective registration**

“all comer” registry

1° Endpoint: MACE at 12 mo

2° Endpoint: in stent & segment LL

Stent thrombosis, Target Vessel Failure

Total 3 years of follow up

Objectives

1. To evaluate the **safety and long-term effectiveness** of coronary stenting with the **biolimus eluting stent (BES)** in a cohort of “real world” patients and lesion subsets.
2. To determine clinical device and procedural success during commercial use of **BES**.

Trial Design

1. Prospective, open label, multi-center, real world, observational registry

2. One arm registry : **Biomatrix[®] / Nobori[®]**

Active prospective registration of pts receiving Biomatrix[®] / Nobori[®]

Total number of patients

: 3000 patients

All comers undergoing percutaneous coronary intervention with more than one coronary stents for significant coronary artery disease

1) **Primary endpoint**: Major Adverse Cardiac Events (MACEs, composite of cardiac death, non-fatal MI, target lesion revascularization) at 12 months

2) **Secondary endpoint**:

In-stent & In-segment Late Loss at 9 months

ST at 24 hrs (acute), 30 days (subacute), 1 yr (late), yearly up to 3 years (very late)

Target Vessel Failure at 12 months (composite of cardiac death, MI, and TVR)

Any death, cardiac death, MI, TLR, TVR at 30 days, 9months, 1 year, 2 years and 3 years

Composite rate of cardiac death and any MI up to 3 years

Composite rate of all death and any MI up to 3 years

Composite rate of all death, any MI (Q-wave and non Q-wave) and any repeat revascularization up to 3 years

Compliance and therapy interruptions with adj antiplatelet therapy up to 3 years

Clinical device and procedural success

Risk of MACE according to baseline level of CRP and Hb will be assessed at 1 year, 2 years and 3 years

Inclusion & Exclusion Criteria

- **Inclusion : “All comer” registry**

The patient agrees to participate in this study by signing the informed consent form. Alternatively, a legally authorized patient representative may agree to the patient’s participation in this study and sign the informed consent form.

- **Exclusion**

There are no exclusion criteria.

Follow up

1. **Clinical follow-up:** 30 days, 9 months, 1, 2, 3 years
2. **Angiographic follow-up:** A 9-month follow up angiography will be recommended (standard clinical practice in Korea) but this will not be mandatory.

Timeline

Jan, 2010 – March, 2011 : Preparation

March, 2010 – February, 2012 : Registry enrollment

– February, 2015 : Clinical Follow-up

March, 2015 – May, 2015 : Close out

reporting of final results

Study Parameters

	Baseline	Follow Up		
		30 d	9mo	Yearly
Medical/Clinical/ History (age, sex, risk factors, clinical dx, angina status, cardiac hx)	×			
Informed Consent	×			
Inclusion/Exclusion Criteria	×			
Brief Physical Examination	×			
Vital status	×	×	×	×
Weight, height	×			
Angiogram	×		×	
CBC	×			
Baseline blood chemistry	×			
Serum creatinine	×			×
Fasting plasma TG, HDL, total cholesterol	×			×
Pregnancy test (if applicable)	×			
Medications	×	×	×	×

•Baseline blood chemistry: electrolyte, AST, ALT, fasting glucose, HbA1C, hs-CRP, uric acid, (proBNP)

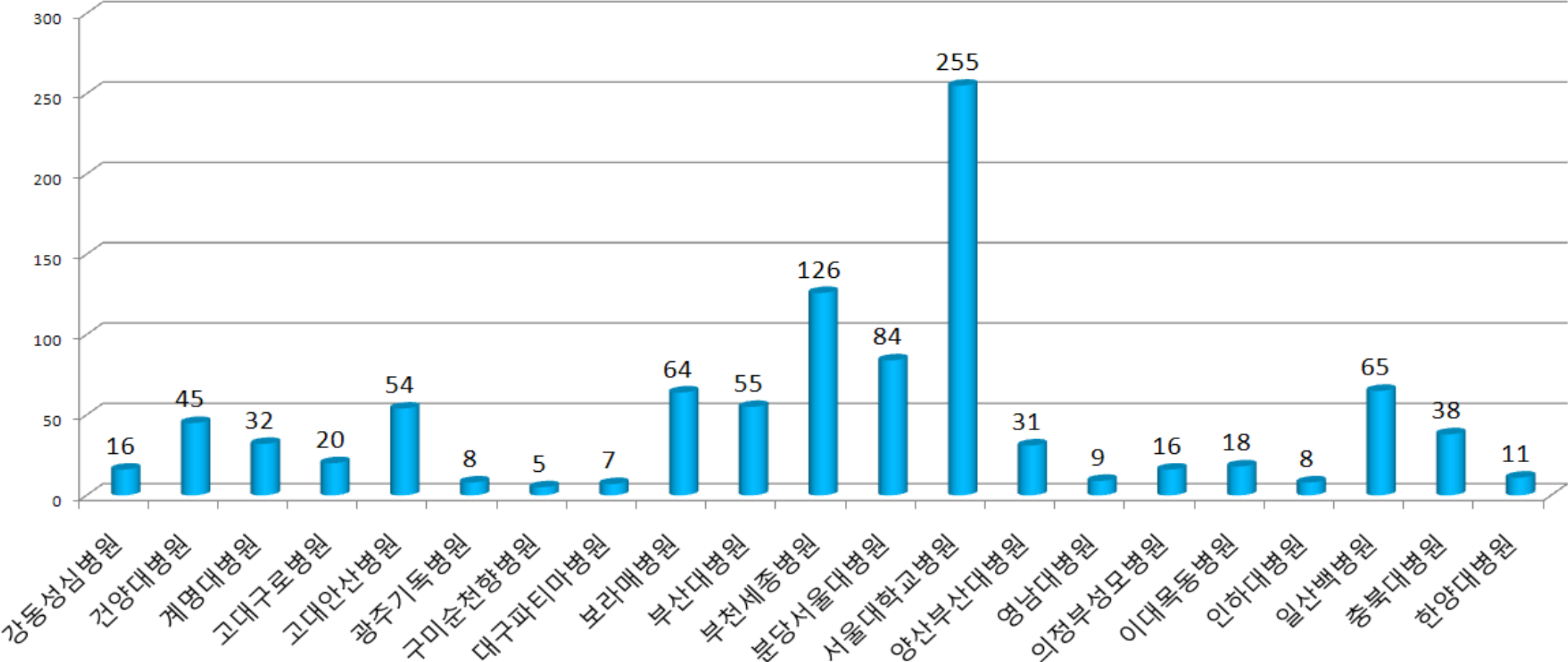
Enrollment Status

■ Enrollment started in March of 2010.

■ Up to last week, total enrolled patients = 967

Biomatrix[®]/Nobori[®] = 585 (60.5%) / 382 (39.5%)

HOST-Biolimus Registry : Total N=967



Baseline Characteristics

N (Biomatrix/nobori)	967 (585 /382)
Age, y	64.2 ± 10.9
Male	669 (69.2%)
Initial diagnosis	
Stable angina	281(36 %)
Unstable angina	224(28.7%)
NSTEMI	111 (14.2%)
STEMI	113(14.5%)
Silent MI	52(6.7%)
Previous CABG	12(1.2%)
Previous peripheral vascular disease	18(1.9%)
Hypertension	520 (53.8%)
Diabetes Mellitus	271(28 %)
Statin naïve Hyperlipidemia	274 (28.4%)

Baseline Characteristics

Smoking 41(4.1%)

Previous MI 53 (5.5%)

Family history of CAD 38(3.9%)

Multi-vessel coronary artery 48.9. %

disease

Target lesion coronary artery

LAD 429(48.6%)

LCX 156(18.3%)

RCA 242(28%)

LM 33(4.23%)

Raumus 7(0.9%)

Clinical outcomes (first 181 patients)

n=181	
MACE	2(1.1%)
Cardiac death	1(0.6%)
MI	0(0%)
CVA	1(0.6%)
TLR	1(0.6%)
Stent thrombosis	0(0%)
Bleeding complication	0(0%)

Take home message

- 1. Biomatrix[®] stent showed great actual performance in complex complex left main and bifurcation lesions, with good accessibility in the side branch.**
- 2. The HOST-Biolimus registry is expected to show the performance of the next generation bioabsorbable polymer technology based BES in a 'real-world' cohort of Asian (Korean) patients.**
- 3. So far up to 180 patients followed up for 9 months, BES shows good clinical outcome.**