Biomime
Bulgarian experience and clinical data

Georgi Mazhdrakov, MD
"St. George" Hospital,
Pernik, Bulgaria

Results from a single-centre, all-comer retrospective registry of the use of BioMimeTM coronary stent system.

- The conducted study was a retrospective, non-randomised, single-arm, clinical registry of the performance of the BioMime SES in the treatment of **all-comer patient population** in a single cardiovascular PCI capable institution.
- The objective was to determine the long-term safety, feasibility and efficacy of this stent system in patients indicated for percutaneous coronary intervention (PCI). All patients were treated in a single institution (Multiprofile hospital for active treatment MHAT “Blagoevgrad” AD, Blagoevgrad, Bulgaria).
- Coronary native and graft vessels with reference diameter (RD) 2.25 to 4,5 mm (by visual estimation); with diameter stenosis (DS) of 50% to 100% were treated. The study had approval from the local ethics committee of MHAT “Blagoevgrad” AD.

Design of the registry, follow-up and endpoints

A total number of 262 patients were treated with PCI solely with BioMime stent implantation starting 01/Nov/2011. The end of the Follow-up period was up to 01/Nov/2013. The following variables were analysed:

- Patients' baseline characteristics, including co-morbidities, ejection fraction at admission, type of anti platelet medication.
- Interventional procedure variables (indications for PCI, vessels treated, total number of stents per patient, type of stenting technique, total number of stents evaluated, stent length and diameter, mean deployment pressure).
- Details about the performance of the device were especially sought, e.g. (shaft breakage, balloon rupture, stent fracture, stent loss, stent thrombosis, in-stent restenosis).
- The clinical follow-up included assessment of major adverse cardiovascular events (MACE) **based on patient survival**; target lesion revascularization. The time points at which events were assessed were at the end of the PCI, at hospital discharge, every 3 month at year 1 and then every 6 months.

Patient population and baseline characteristics

- Patients included - 262
- Mean age - 65,4 years (38-87). Males - 141 (53.81%); Females - 121 (46.19%).
- The mean ejection fraction (EF) at admission was 54.1%.

Table 1 - Patients' Baseline characteristics-1

	Absolute number of patients	Percentage
Diabetes Mellitus	120	45.80
Hypertension	228	87.02
Dyslipidemia	224	85.49
Ejection fraction (EF) at admission		
EF<40%	14	5.34
EF-41-49%	48	18.32
EF>50%	200	76.33

PCI procedure

- PCI appropriateness was based on ESC guidelines
- Radial approach 5-7 F was preferred, although switch to femoral was done in isolated cases.
- The target lesions could be pretreated with a regular balloon angioplasty. Direct stenting was allowed. Postdilation was left on operator's discretion.
- BioMime SES device was available in the

Clinical scenario and lesions

- Stable forms of coronary artery disease (SCAD) - in 70 patients (26.72%);
- Unstable angina (UA) / non ST-elevation myocardial infarction (NSTEMI) - in 128 patients (48.85%);
- ST-elevation myocardial infarction (STEMI) - in 64 patients (24.43%).
- Total number of PCI procedures analysed - 294, of which 262 as a first (index) one and 32 - staged due to multivessel coronary disease

Vessels treated and lesion subtypes

	Number of lesions	Percentage
Vessels treated		
Left main (LM)	9	2.82
Left Anterior descending (LAD)	160	50.16
Left circumflex (LCx)	92	28.84
Right coronary artery (RCA)	57	17.87
Sapheous venous graft (SVG)	1	0.31
Lesion types		
Chronic total occlusions (CTO)	11	4.62
Bifurcation (provisional 1 stent)	61	25.63
Direct stenting	125	52.52
PCI due to restenosis of BMS	41	17.23

Biomime stent parameters

399 BioMime stents were implanted in 319 arteries. Mean deployment pressure - 17,98 Bar.

Table 2 - Parameters of stents used

	Absolute number of stent implanted	Percent
Stent diameter (mm)		
2.5	77	19.3
2.75	110	27.57
3	110	27.57
3.5	73	18.3
4	22	5.51
4.5	7	1.75
Stent length (mm)		
8	26	6.52
13	49	12.28
16	58	14.54
19	67	16.79
24	63	15.79
29	61	15.28
32	32	8.02
37	31	7.77
40	12	3.01

Diagram 1 - Distribution of stent diameters

Stent and patient follow-up

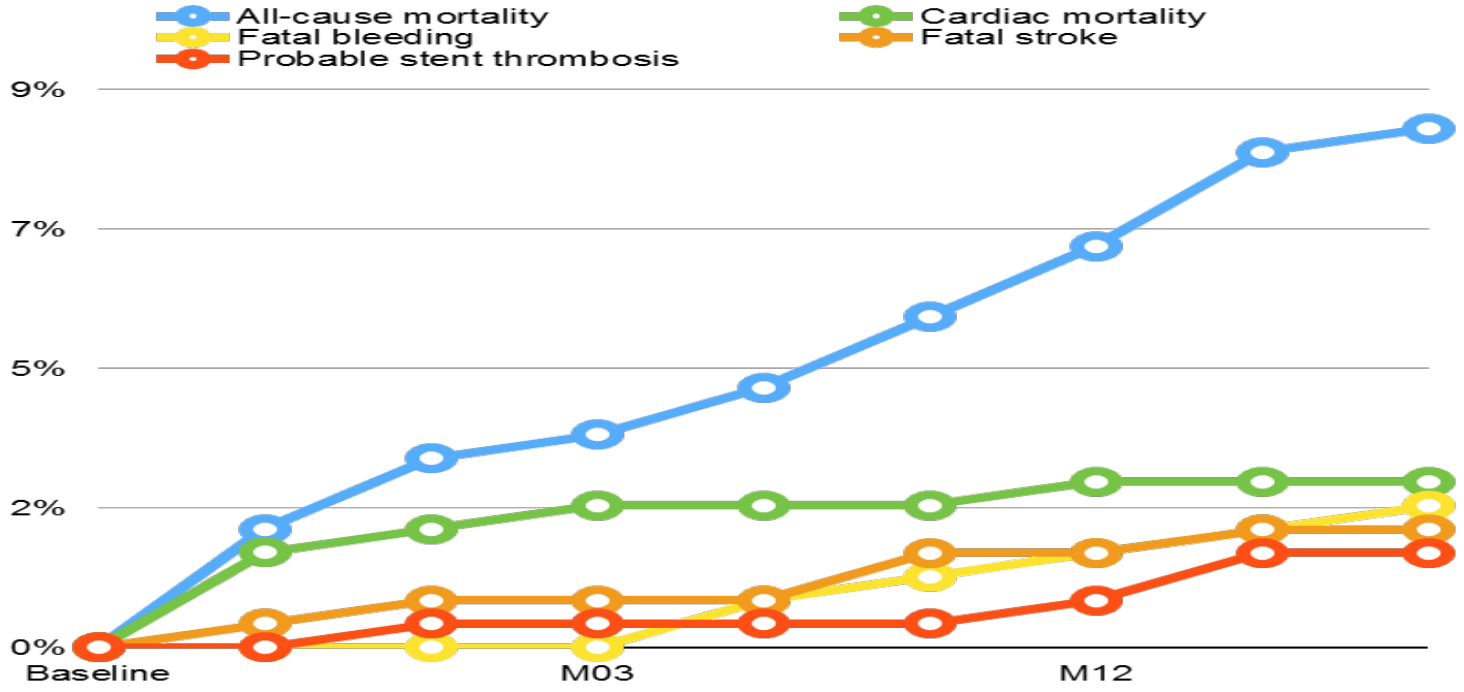
Stent performance: One case of shaft breakage. No cases of balloon rupture, stent fracture, stent migration or loss.

Six patients underwent target vessel revascularization (TLR) - 5 by PCI and 1 by CABG.

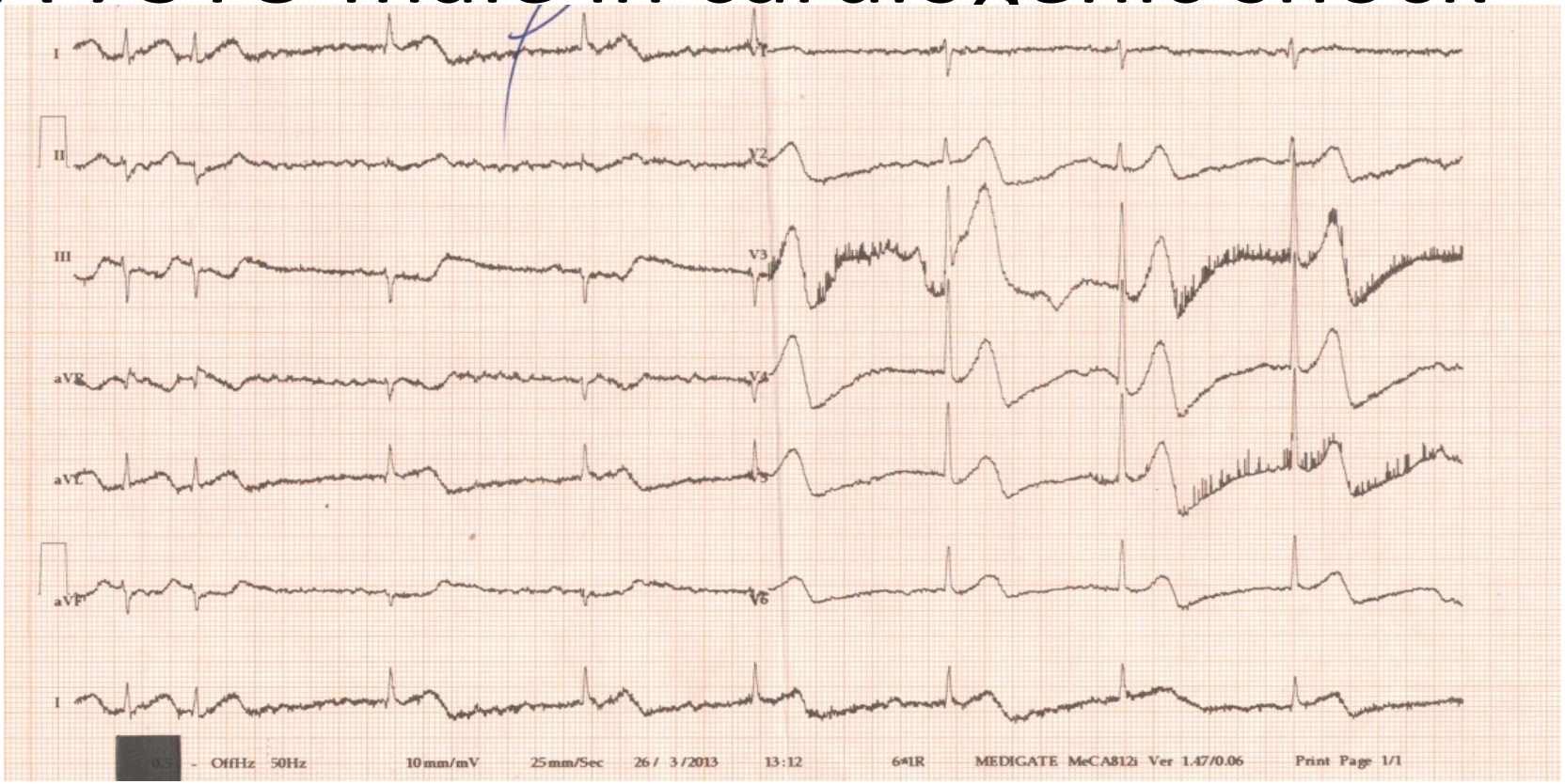
- 2 cases presented with definitive stent thrombosis and underwent urgent re-PCI.
- 4 cases presented with instent restenosis treated by PCI (balloon angioplasty, paclitaxel-eluting stent) in 3 cases and 1 had successful CABG. The restenosis cases were detected by a recurrence of angina.

The hard endpoints – survival

	Baseline	In hospital/Periprocedure	M01	M03	M06	M09	M12	M18	M24
All-cause mortality									
Cardiac mortality	#cases	4	1	1	0	0	1	0	0
Fatal bleeding	#cases	0	0	0	2	1	1	1	1
Fatal stroke	#cases	1	1	0	0	2	0	1	0
Probable stent thrombosis	#cases	0	1	0	0	0	1	2	0
All-cause mortality	0%	2%	3%	3%	4%	5%	6%	8%	8%
Cardiac mortality	0%	2%	2%	2%	2%	2%	3%	3%	3%
Fatal bleeding	0%	0%	0%	0%	1%	1%	2%	2%	2%
Fatal stroke	0%	0%	1%	1%	1%	2%	2%	2%	2%
Probable stent thrombosis	0%	0%	0%	0%	0%	0%	1%	2%	2%



Case presentation
A 73YO male in cardiogenic shock



Diagnosis, noninvasive evaluation and therapeutic strategy

Diagnosis

- CAD. STEMI – anterior. Cardiogenic shock.

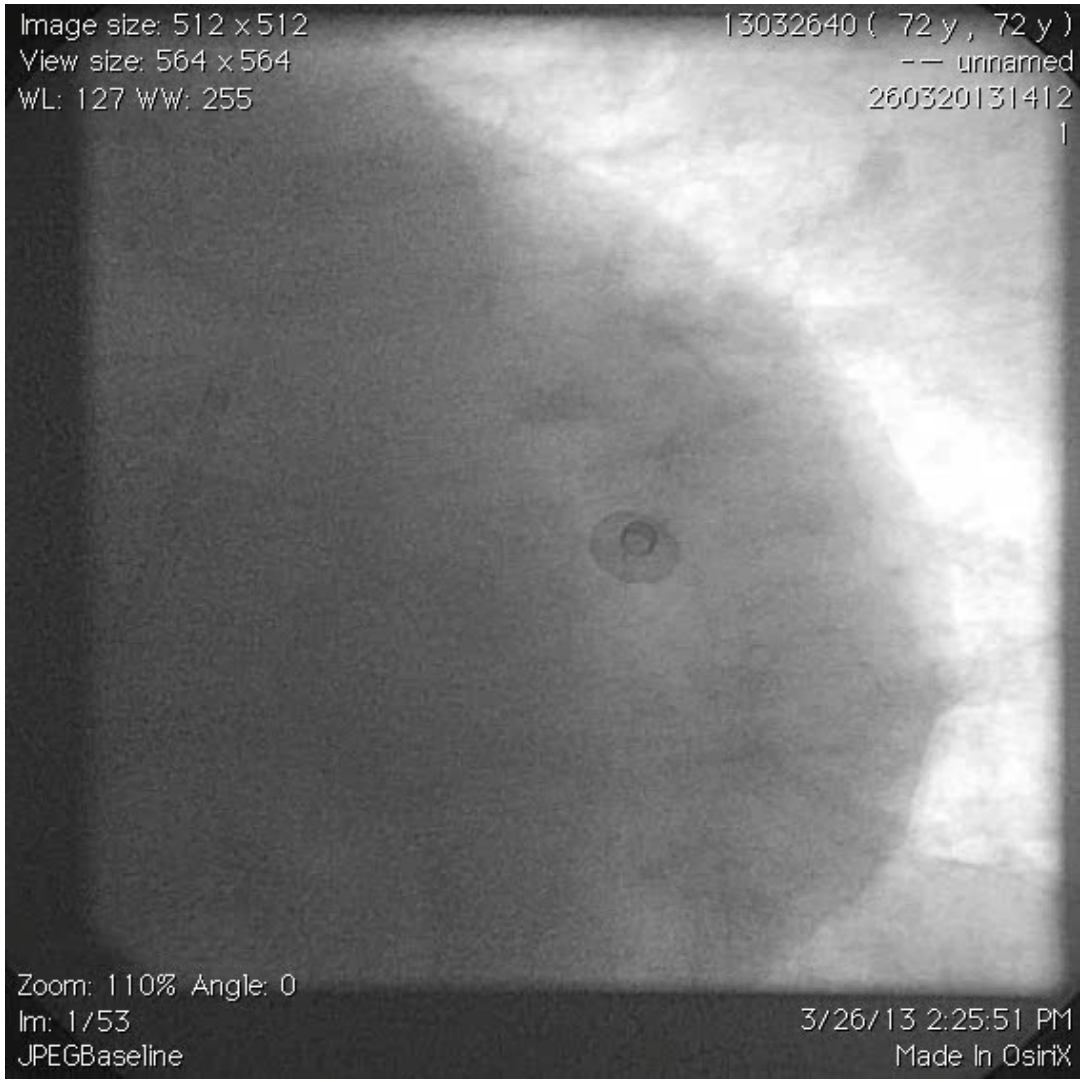
Initial lab evaluation

- eGFR – 59,9ml/min/1,73m2; Hb – 124g/l; CK, CK-MB – still negative

Therapeutic strategy

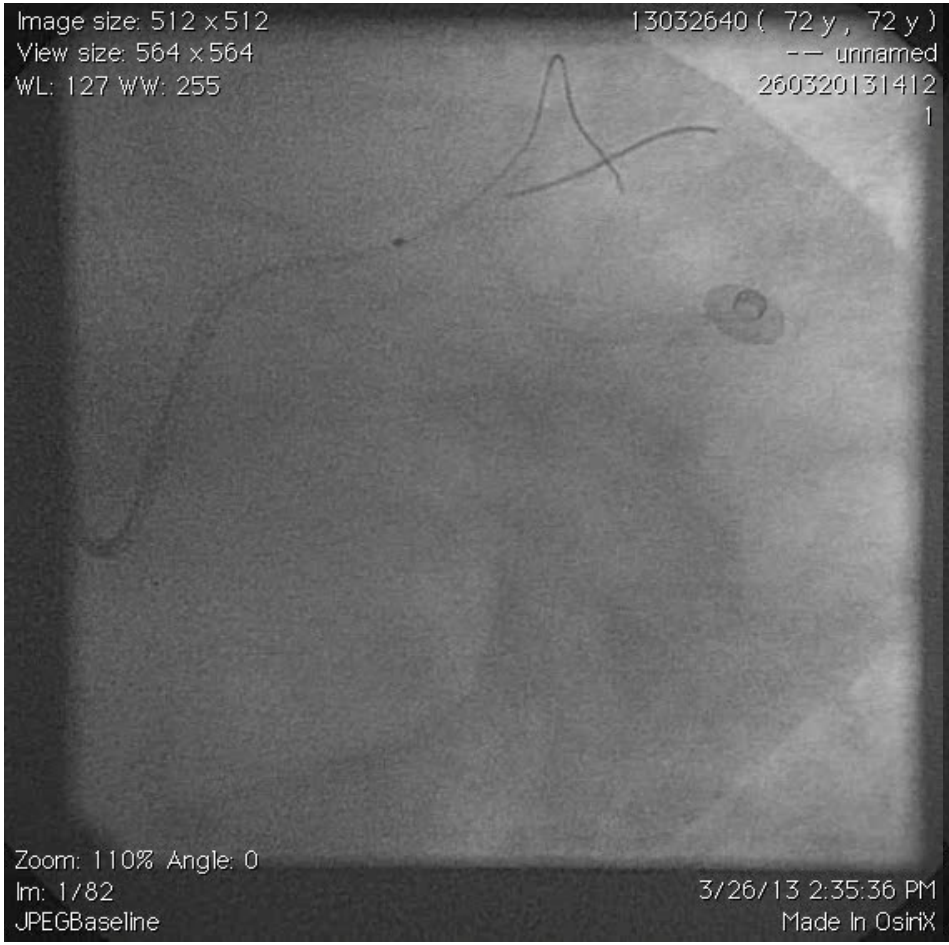
- Immediate loading with antiplatelets and and anticoagulants - Brilique – 180mg, ASA – 250mg, Heparin 5000 IU bolus
- Hemodynamic stabilization – Dopamin 5mcg/kg/min,

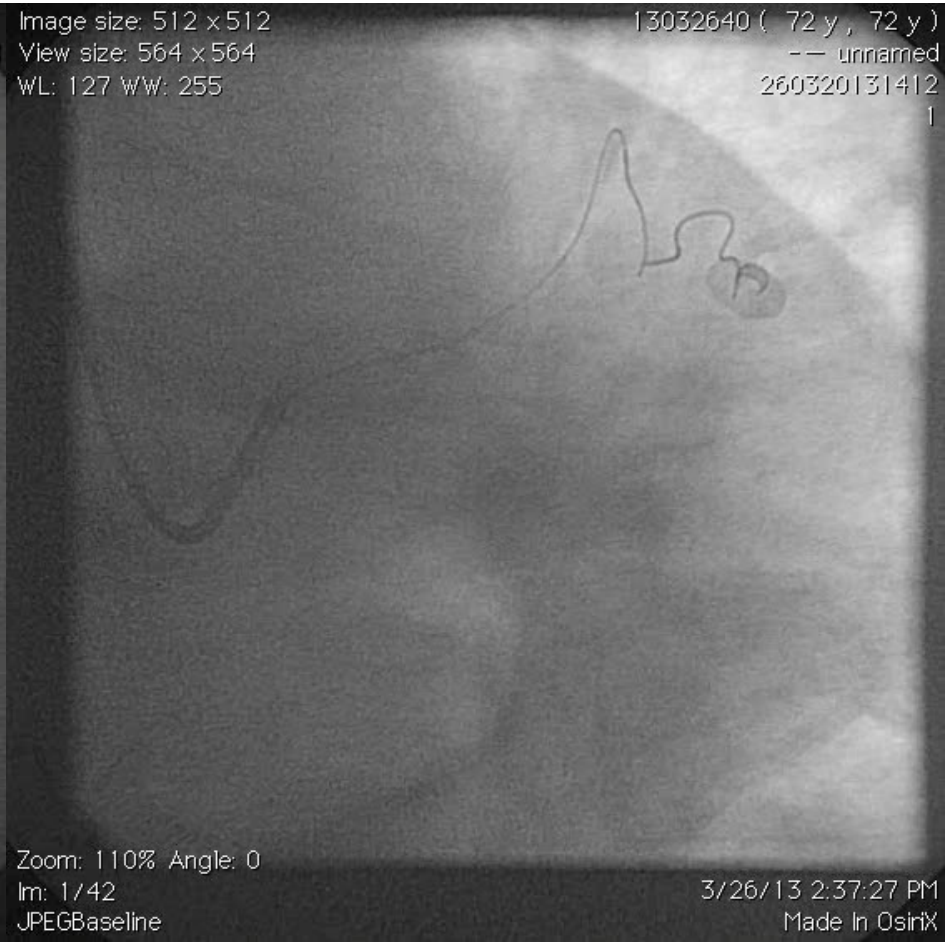
CAG – Proximal thrombosis of LAD, no significant stenoses of Cx and RCA



Invasive strategy

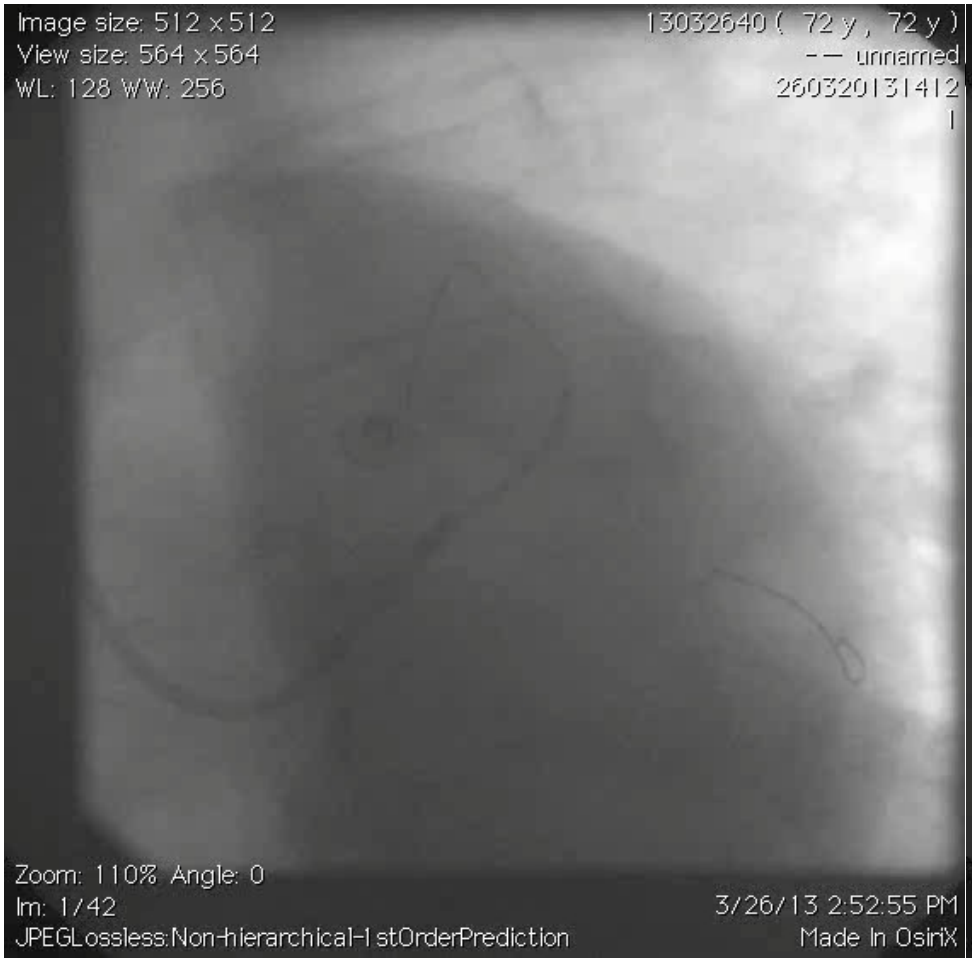
TA of LAD and D1. Decision for stenting of LM

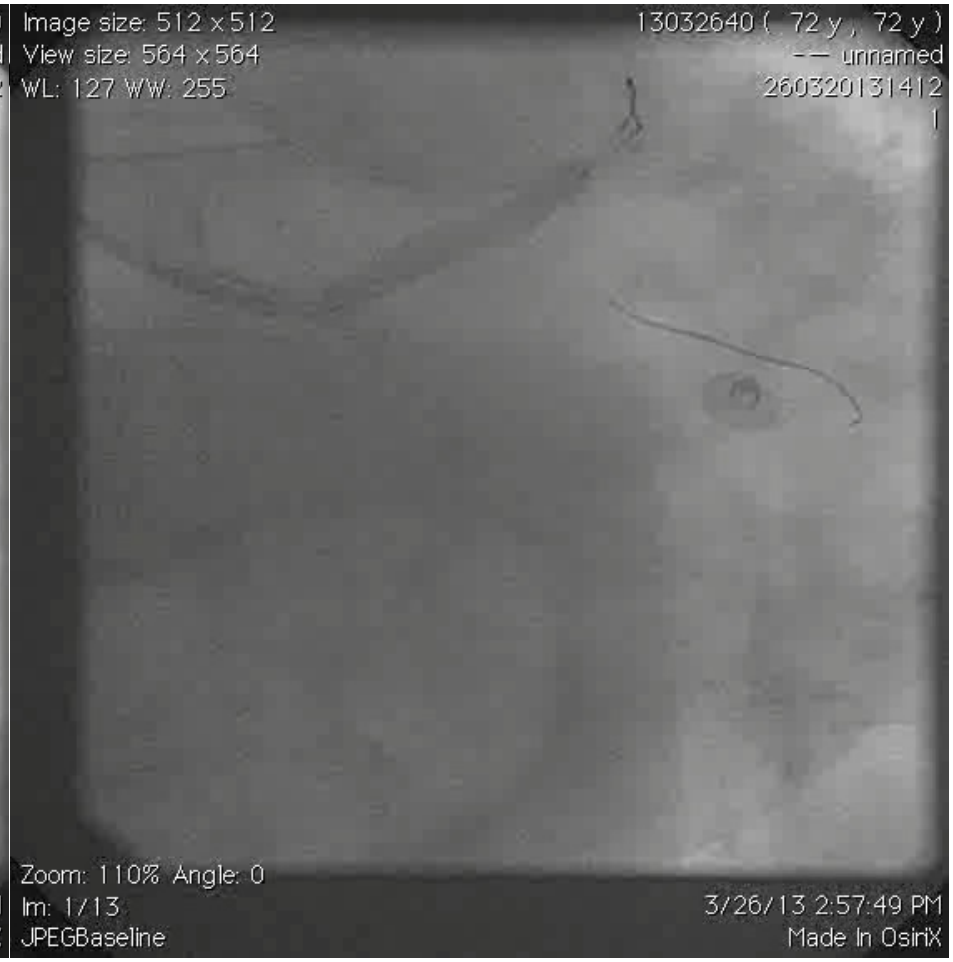




Invasive strategy (2)

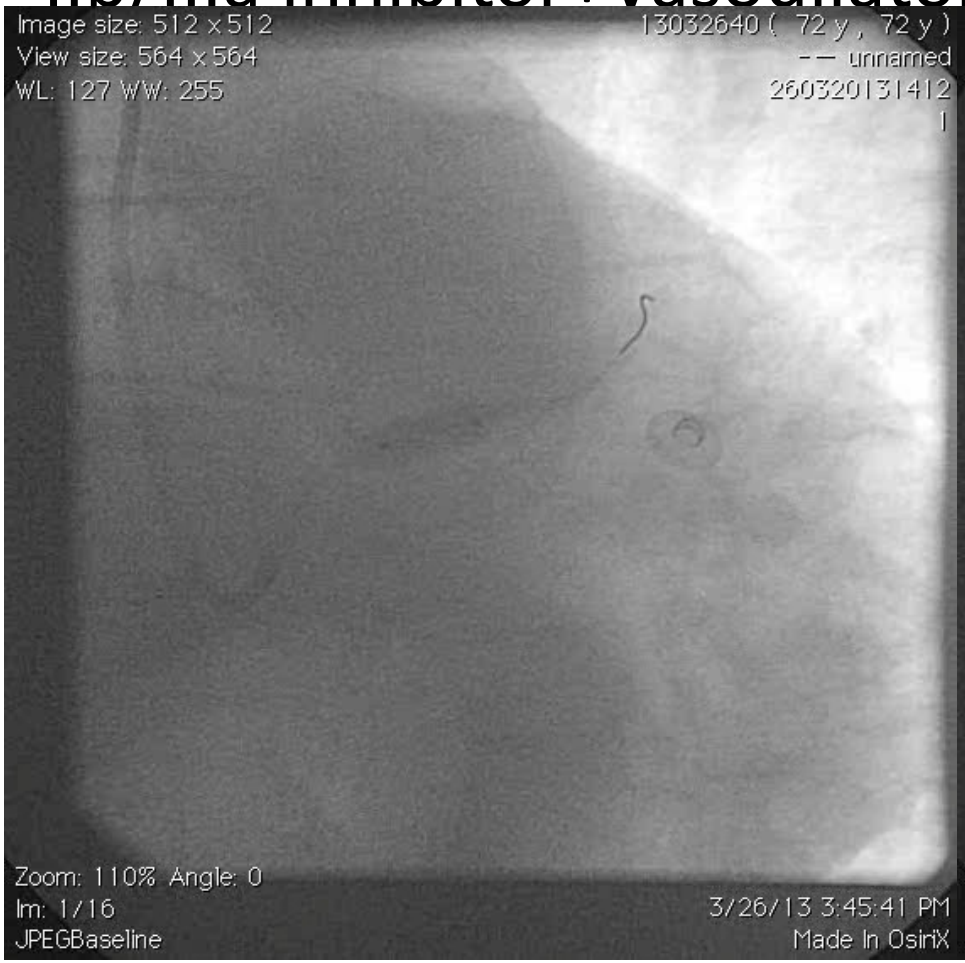
Implantation of Biomime 4,5x29mm in LM

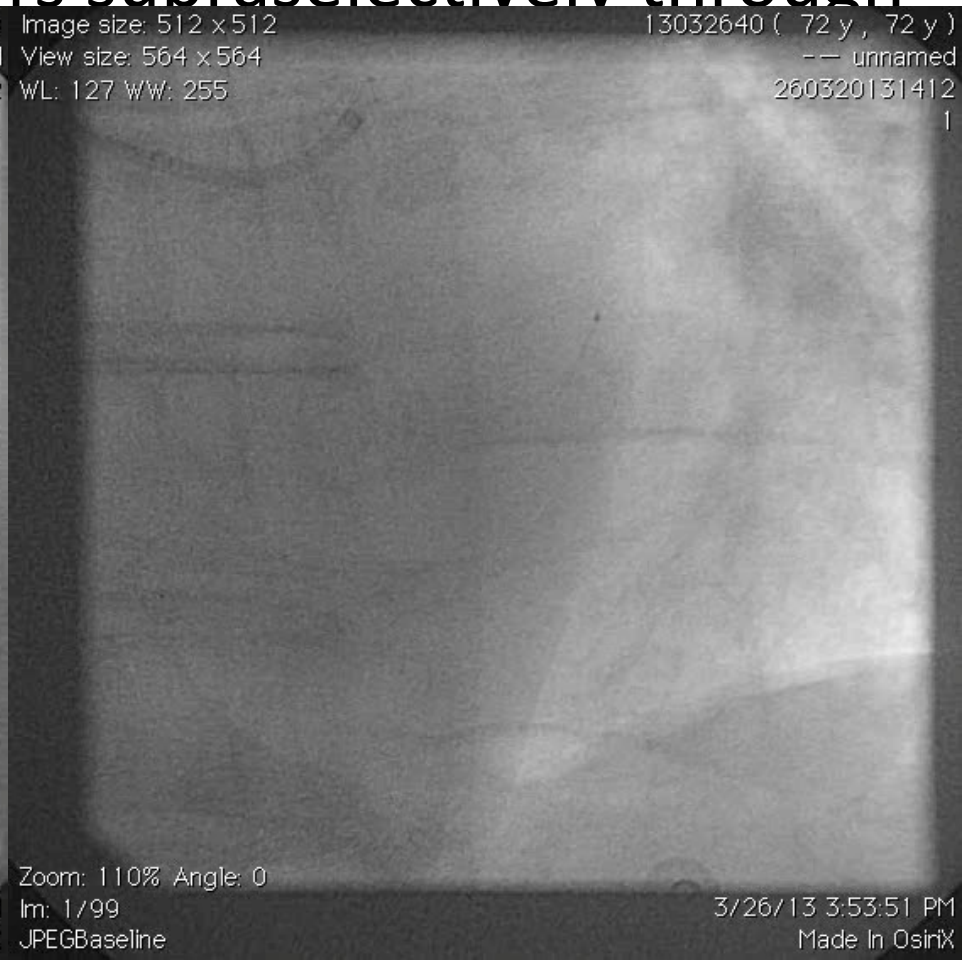




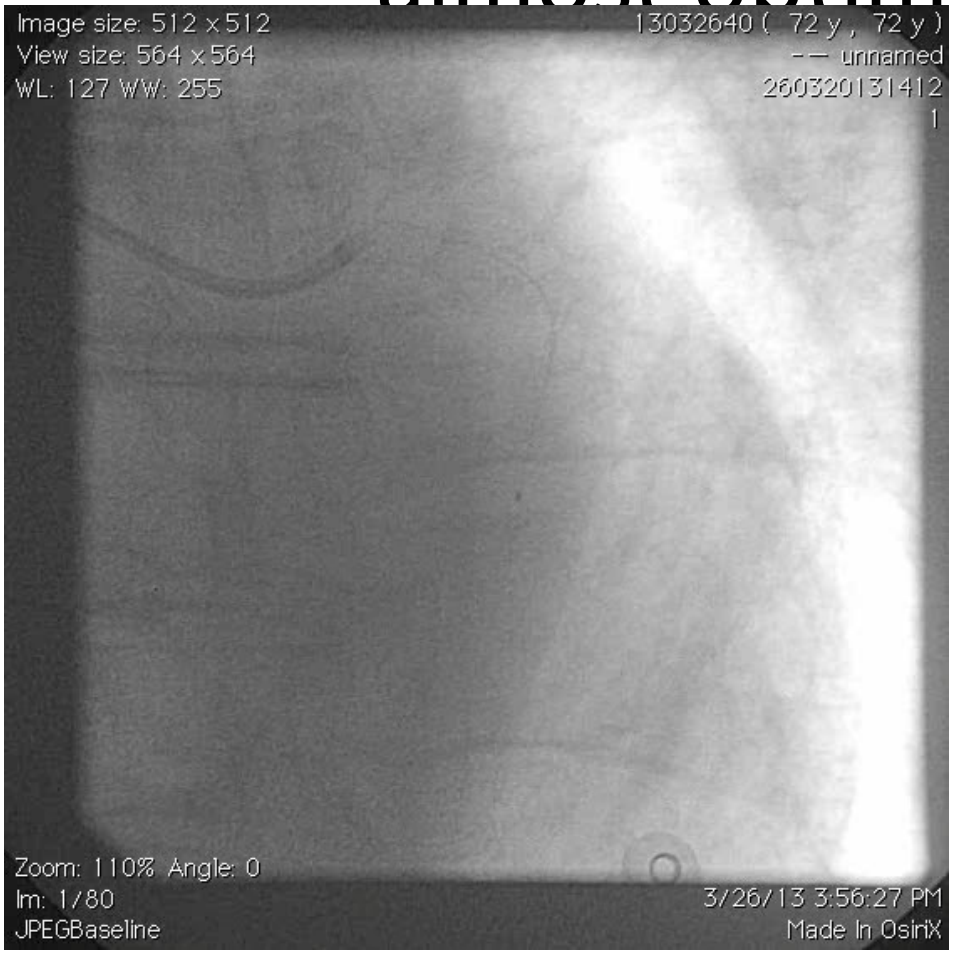
POT in LM

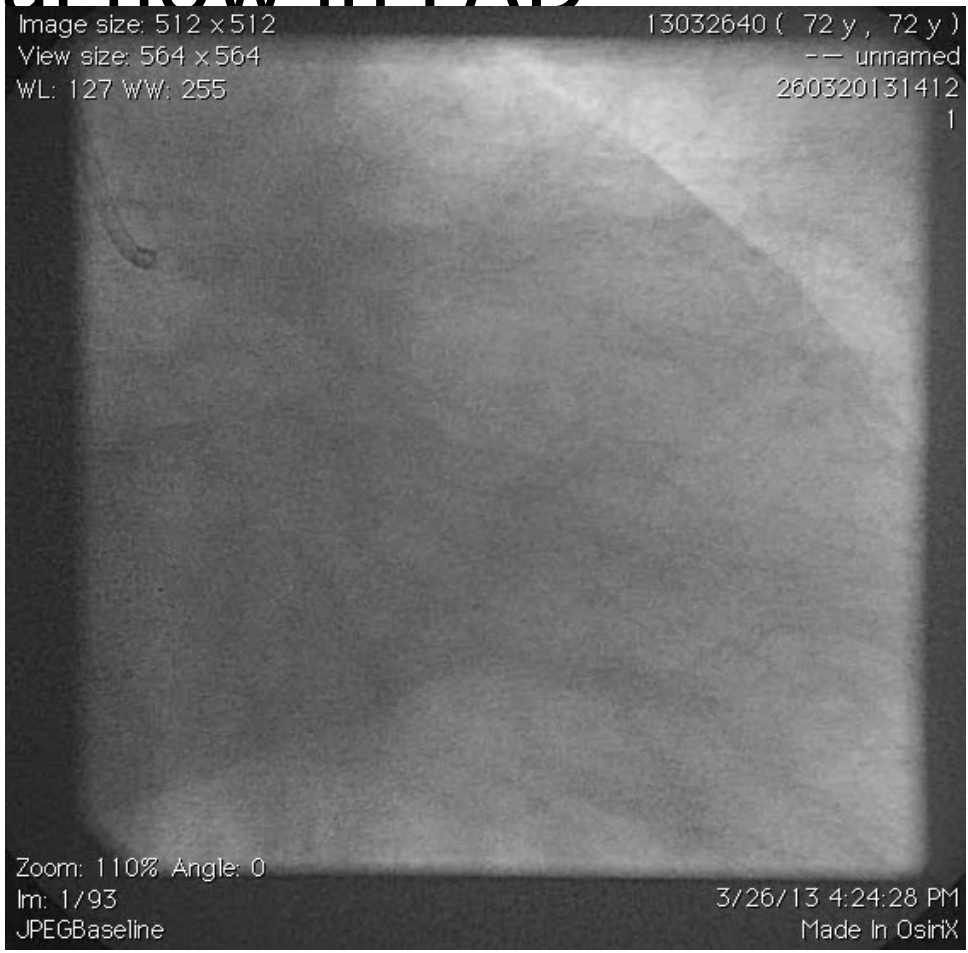
after which No-Reflow in LAD – treated with local IIb/IIIa inhibitor+Vasodilators supraselectively through





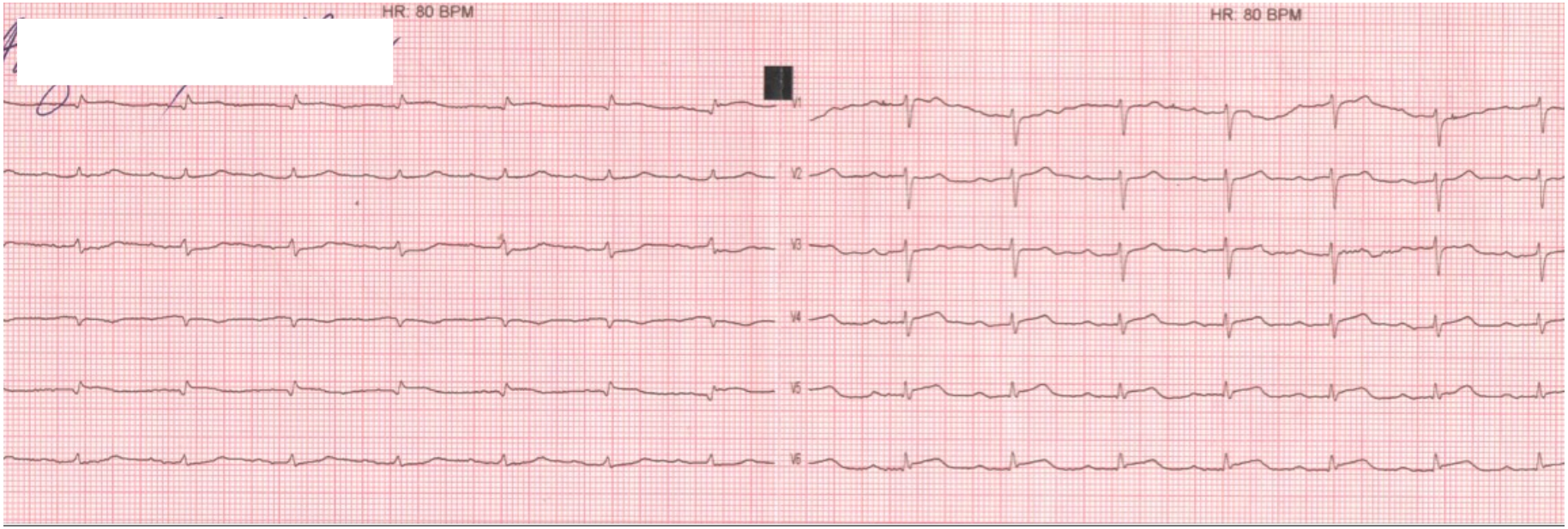
Optimal final angiografic result with almost optimal flow in LAD



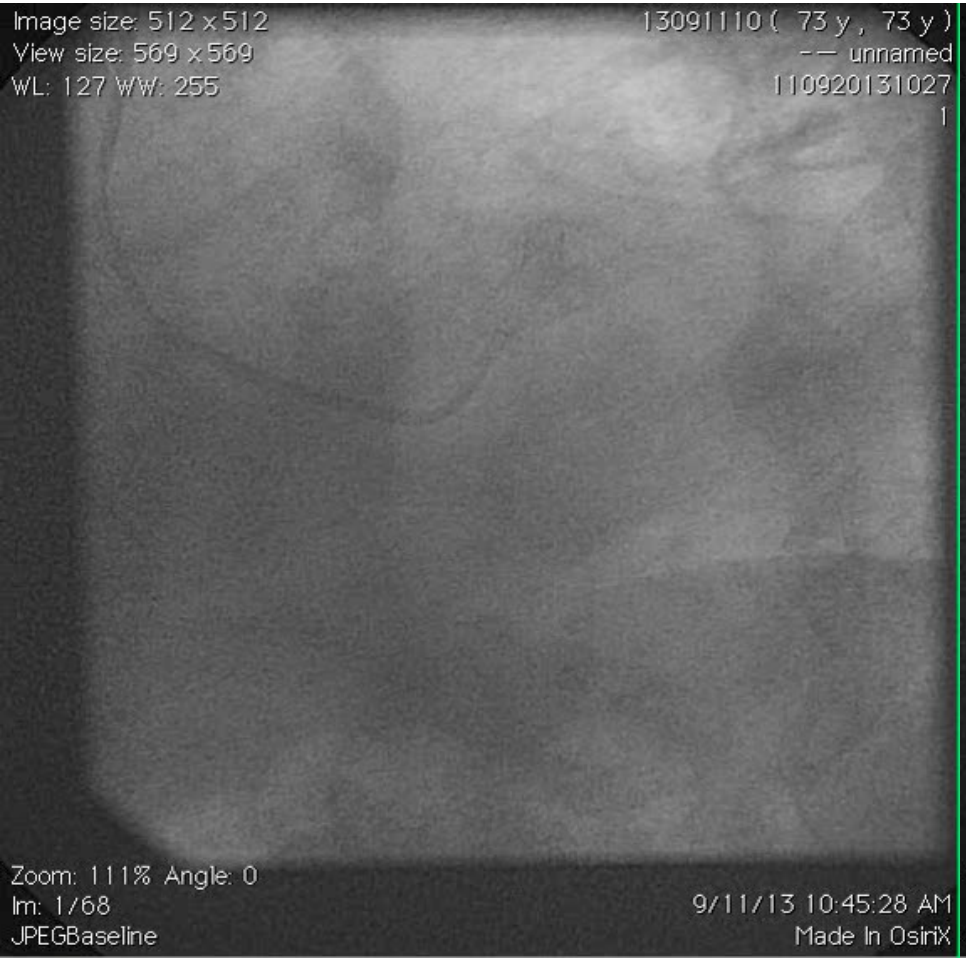


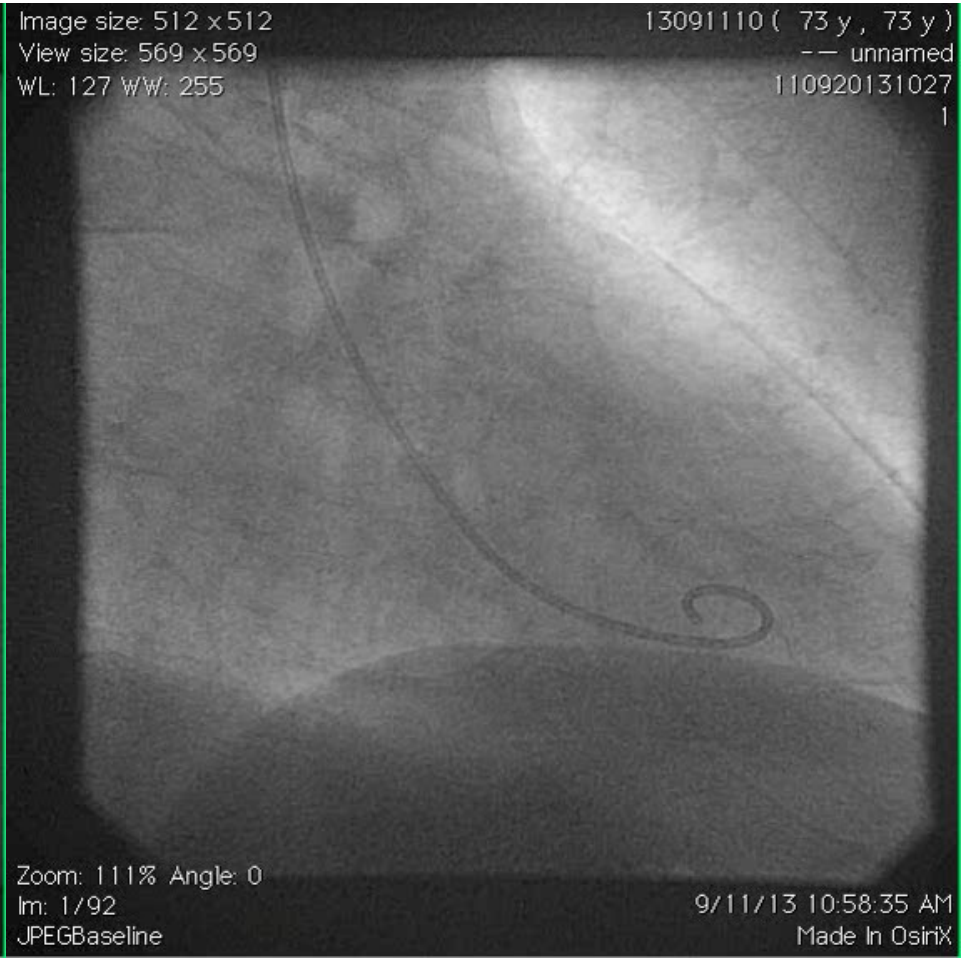
Postprocedure period

- Impressive ECG resolution after PPCI.
- Cardiac echo with LVEF – 35%.
- Peak of CK/MB – 3920/176 IU/L.



6Month angiographic follow-up
Optimal result of PCI. LVEF-56%





Thank you for your attention