BVS: Experience and Clinical Data

Experience in Complex Coronary Lesions

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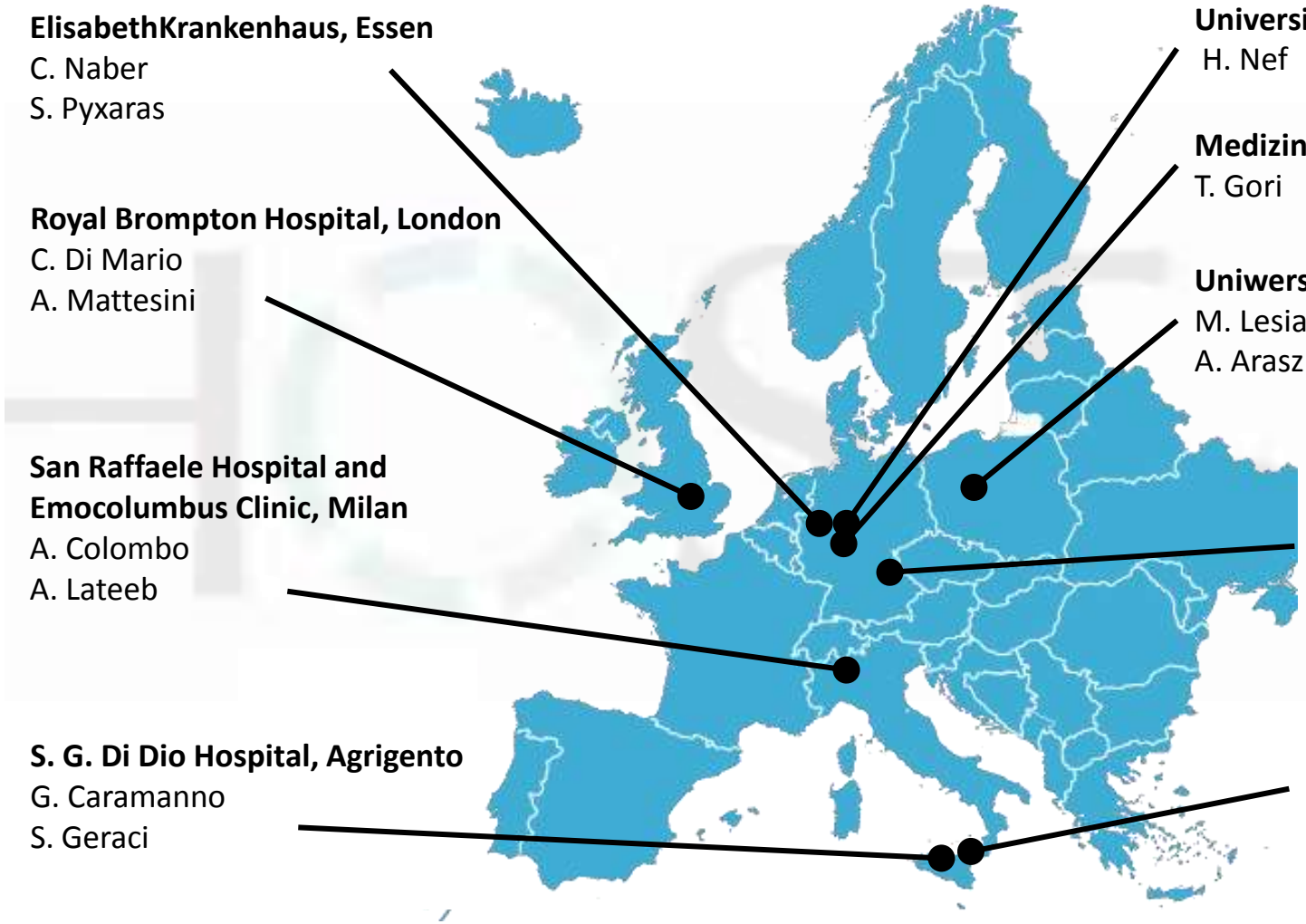

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GHOST-EU Extended Use* 1.189 patients

Clinical

Angiographic

NSTEMI/STEMI, N=406/1,189(34.1%)

LVEF<30%, N=32/980 (3.3%)

CKD (eGFR<60), N=111/743 (14.9%)

ISR, N=49/1,440 (3.4%)

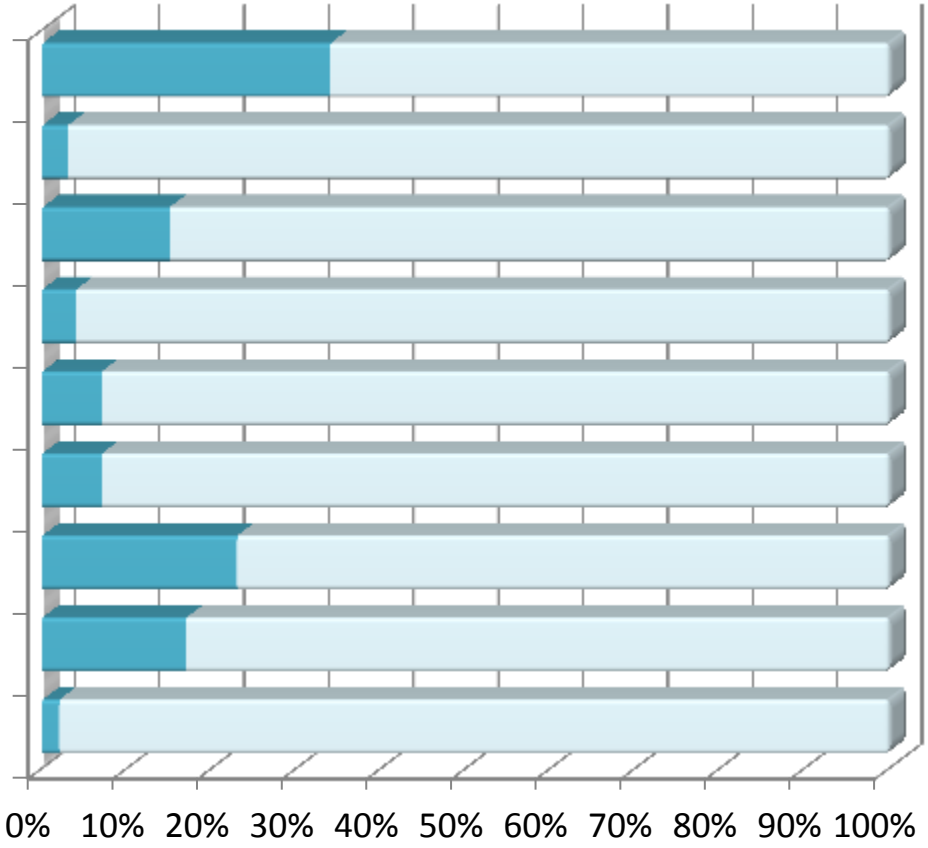
Ostial, N=90/1,282 (7.0%)

CTO, N=96/1,440(6.7%)

Bifucations, N=333/1,440(23.1%)

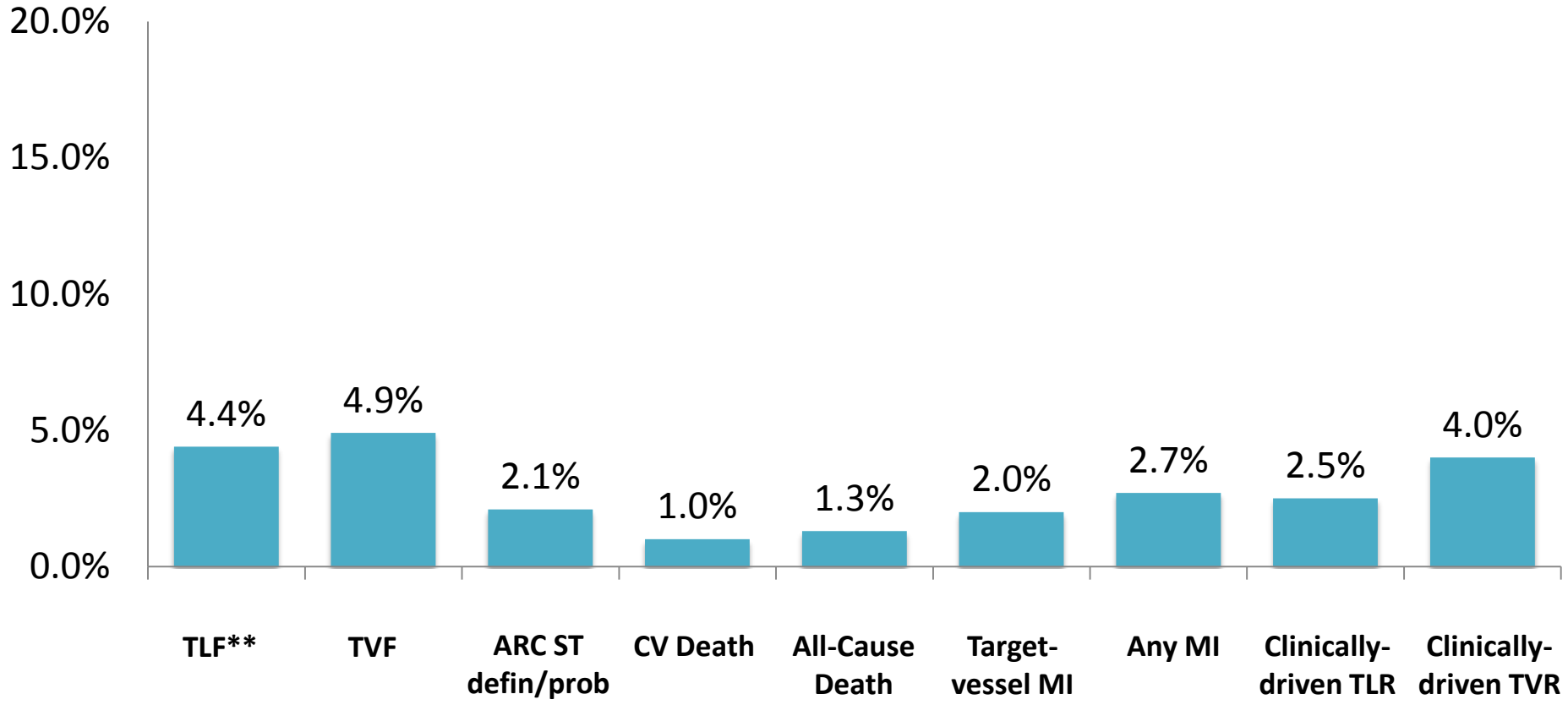
Thrombus, N=242/1,440(16.8%)

Left main, N=17/1,427(1.2%)



***Compared to ABSORB II eligibility (Diletti et al. Am Heart J. 2012;164:654-63)**

6-Month Outcomes*

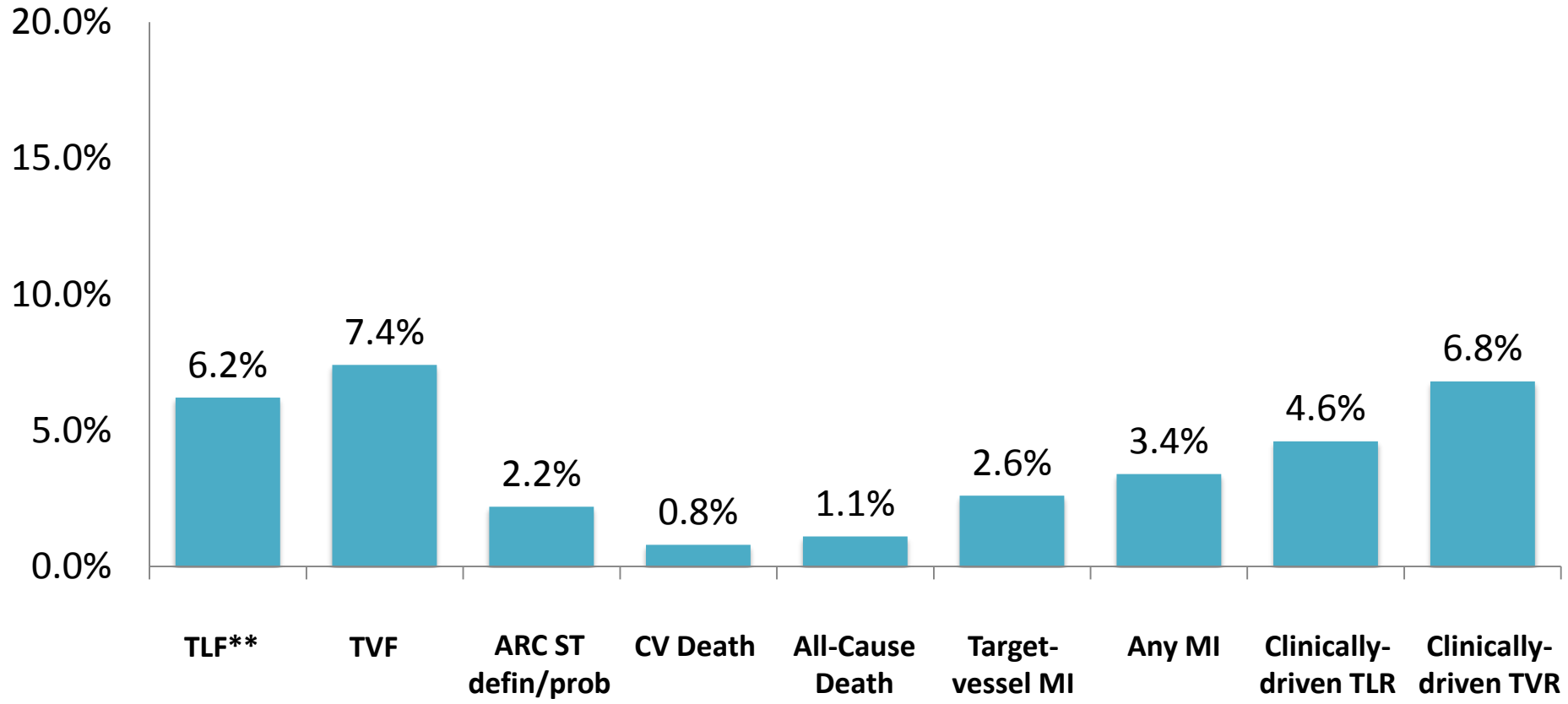


*Event rates are expressed as Kaplan Meier estimates

** Device-Oriented composite primiry endpoint

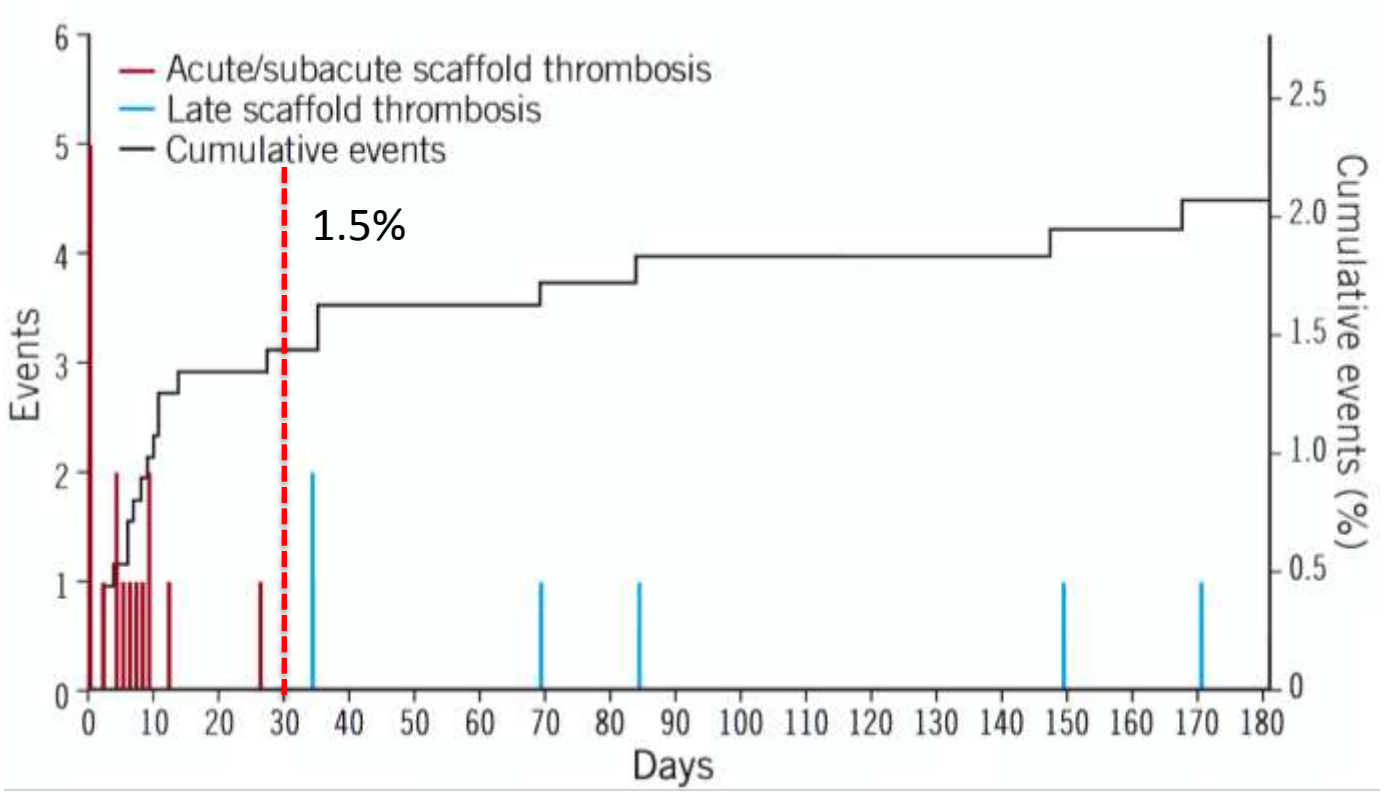
Capodanno D et at. EuroIntervention 2015;10:1144-53.

1-Year Outcomes* 1189 patients
1-year follow-up available in 86%



*Event rates are expressed as Kaplan Meier estimates
** Device-Oriented composite primary endpoint

GHOST-EU Scaffold Thrombosis : 1189 patients



- There were 20 cases of angiographically confirmed ST and three of probable ST.
- 70% occurred in the first month after PCI, **at a median of 5 days, suggesting the need for scrupulous lesion selection and PCI techniques when using BVS**
- Intravascular imaging was performed in only 9 of 23 patients who experienced ST
- 20 of 23 patients were on DAPT at the time of ST
- ST rates were numerically higher when more experience was accumulated and more complex patients were treated

Capodanno D et at. EuroIntervention 2015;10:1144-53.

Scaffold Thrombosis GHOST-EU: 1189 patients

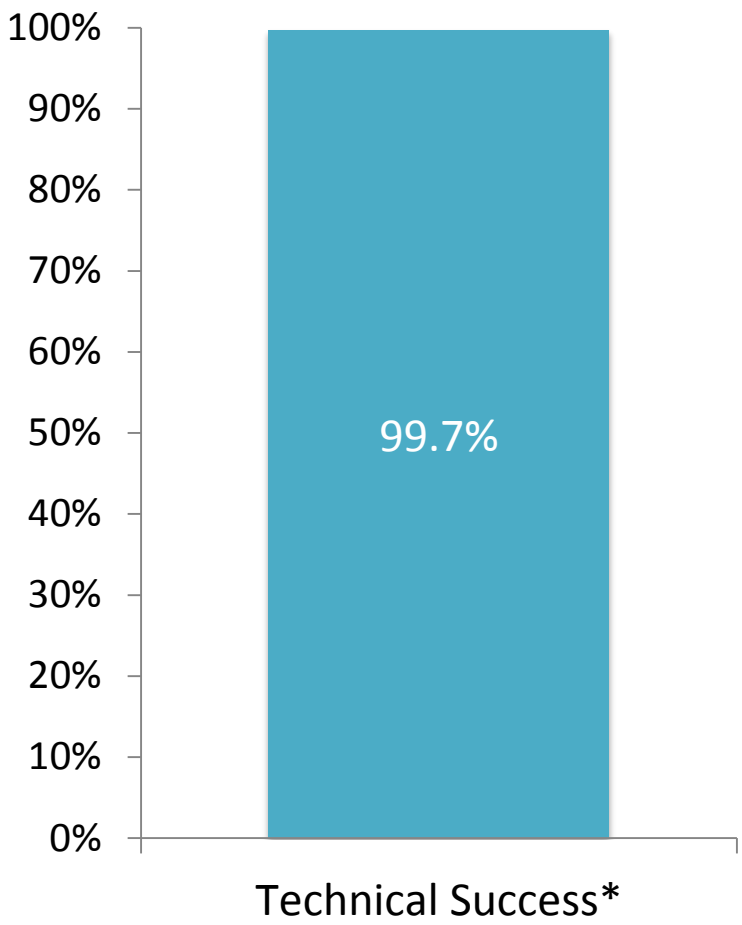
- There were 20 cases of angiographically confirmed ST and three of probable ST.
- 70% occurred in the first month after PCI, **at a median of 5 days,** suggesting the need for scrupulous lesion selection and PCI techniques when using BVS.
- Intravascular imaging was performed in only 4 of 23 patients who experienced ST, of whom 2 discontinued DAPT.
- 18 of 23 were on clopidogrel.
- 20 of 23 patients were on DAPT at the time of ST.

Capodanno D et al. Eurointervention 2014. In press

GHOST-EU Procedural Details :1189 patients

Lesion-based	
Pre-Dilatation	1,405/1,440 (98%)
Post-Dilatation	712/1,1440 (49%)

Patient-based	
No. Target Lesion/Pt	1.2±0.5
Multivessel Disease	485/1,186 (40.9%)
SYNTAX Score	11.3±7.9 (820)
Hybrid (BVS plus non-BVS)	219/1,189 (18.4%)
IVUS-guided	171/1,184 (14.4%)
OCT-guided	163/1,184 (13.8%)
Tot. Scaffold Length (mm)	32.6±23.0 (1,189)
Aver. Scaffold Diameter (mm)	3.0±0.5 (1,189)
Tot. Scaffold Implanted (n)	1731

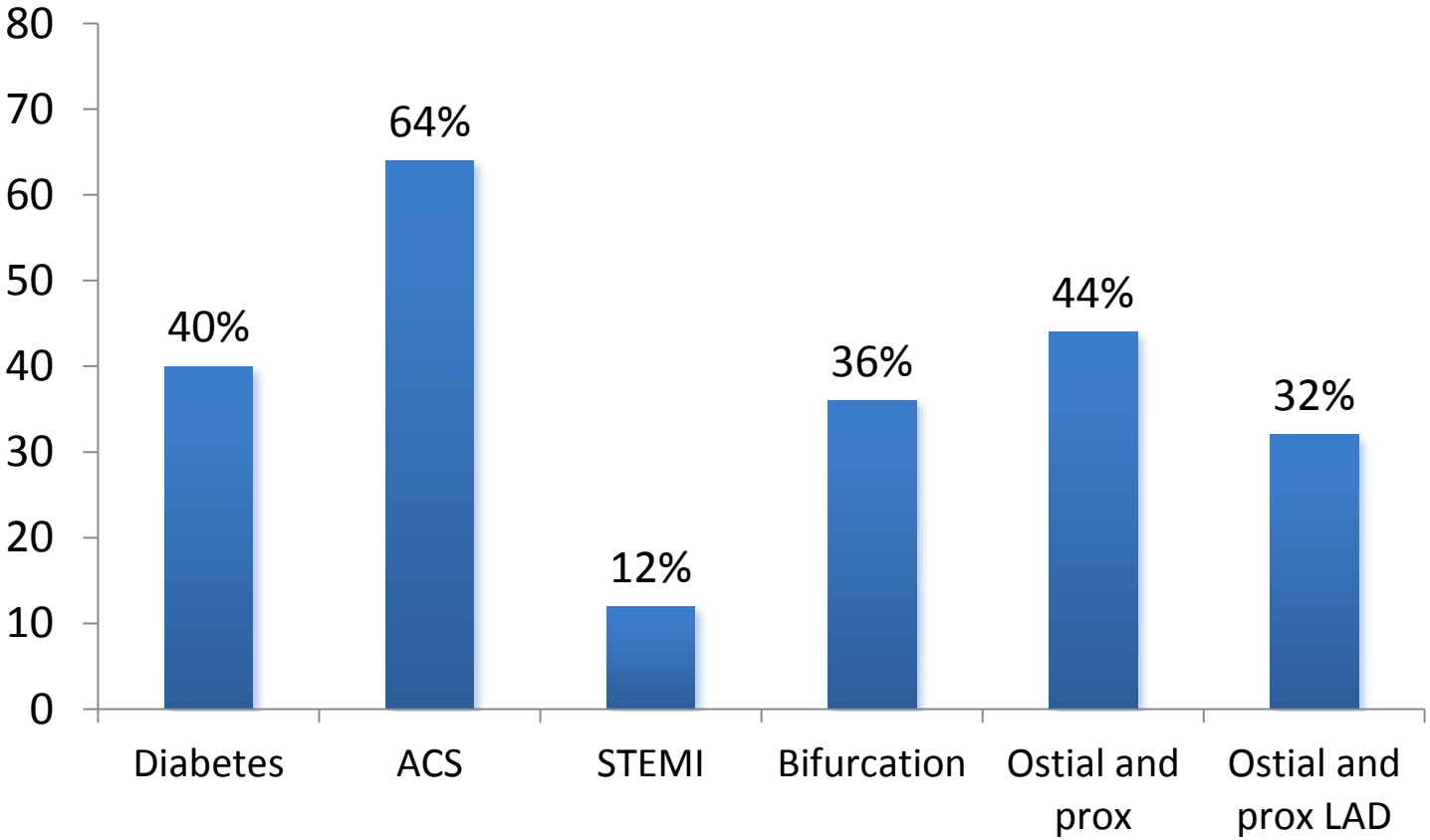


*** Residual in-scaffold diameter stenosis < 30%**

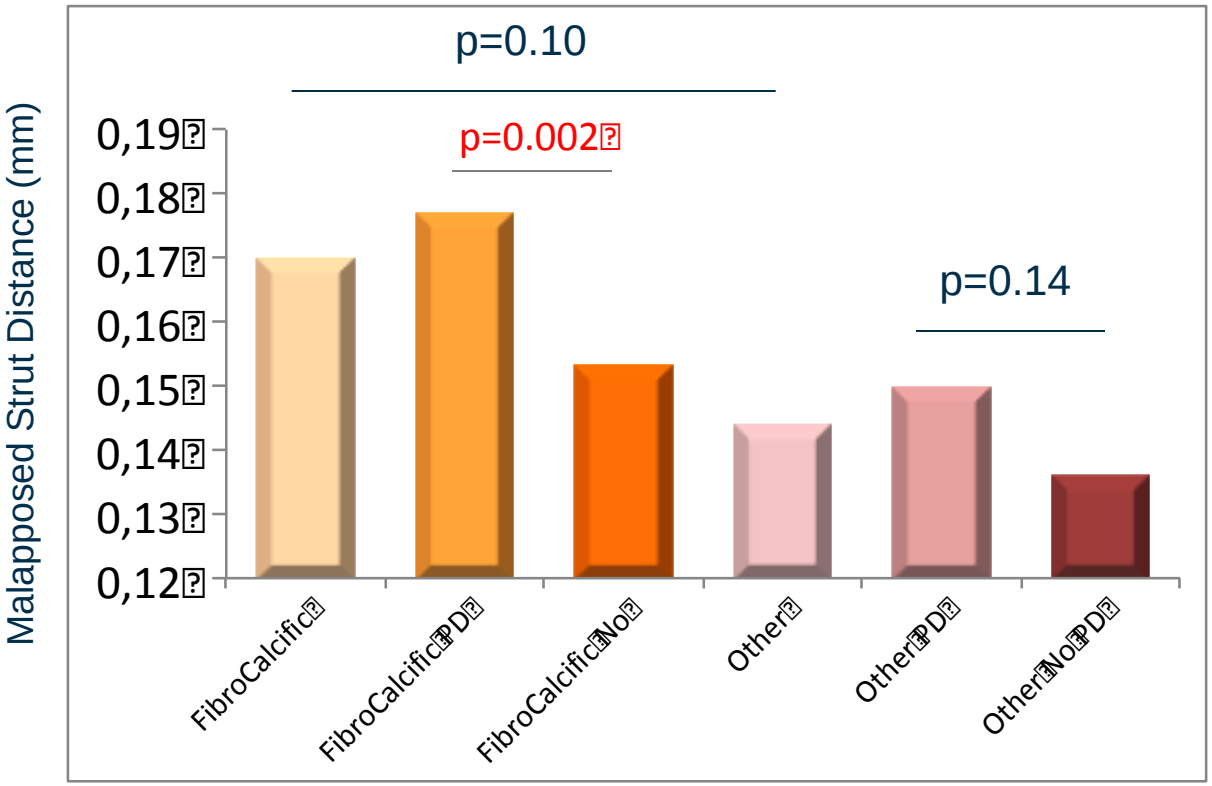
Capodanno D et at. EuroIntervention 2015;10:1144-53.

Scaffold Thrombosis GHOST-EU: 1189 patients

Prevalence of clinical and angiographic factors among 25 patients with scaffold thrombosis



Malapposition after BVS Implantation



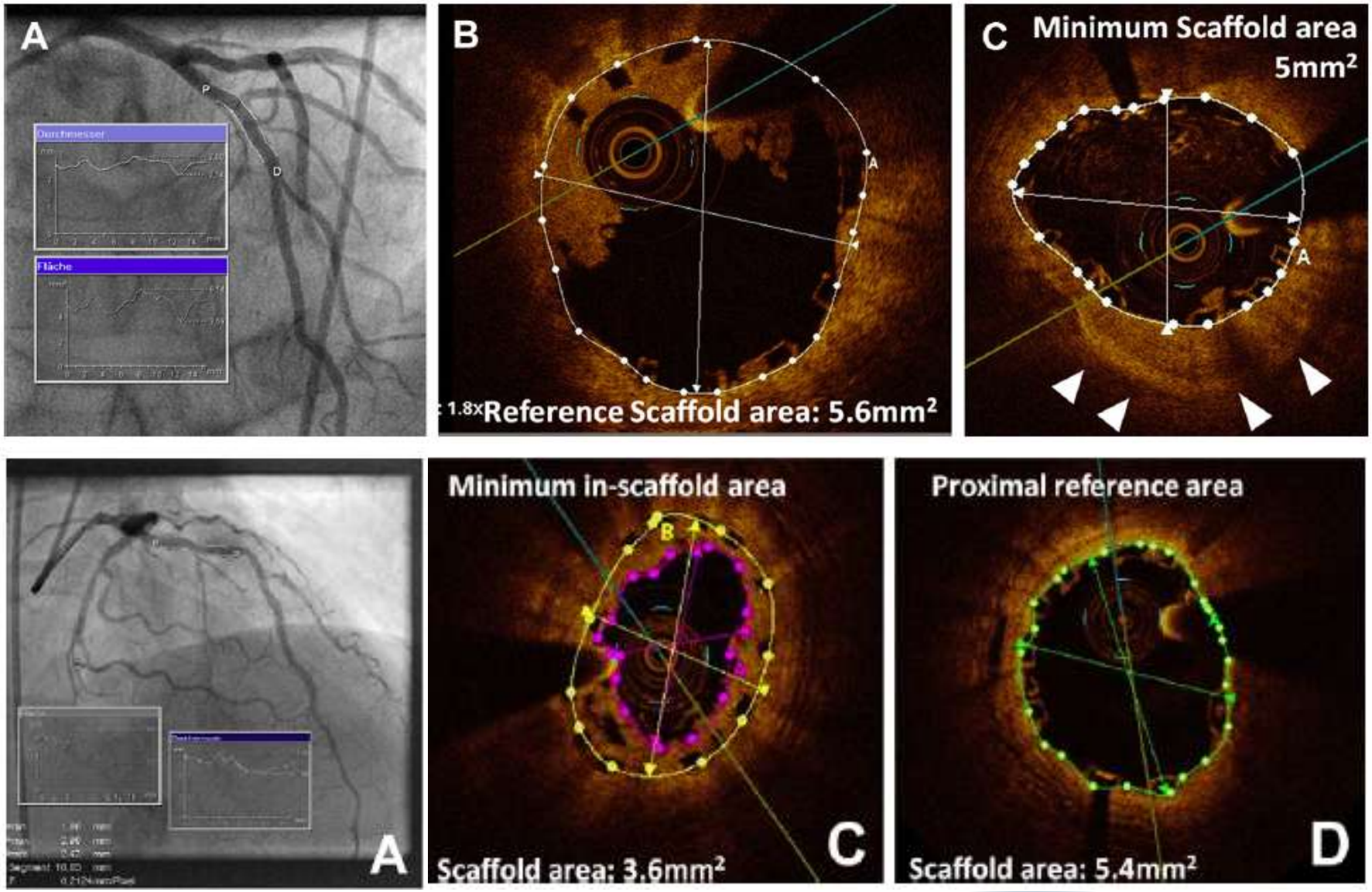
* 6.18% of all scaffold struts were malapposed

* Malapposition was observed more with fibrotic calcific plaque than with all other plaques

1:1 pre-dilatation did not impact malapposition distance but improved BVS expansion

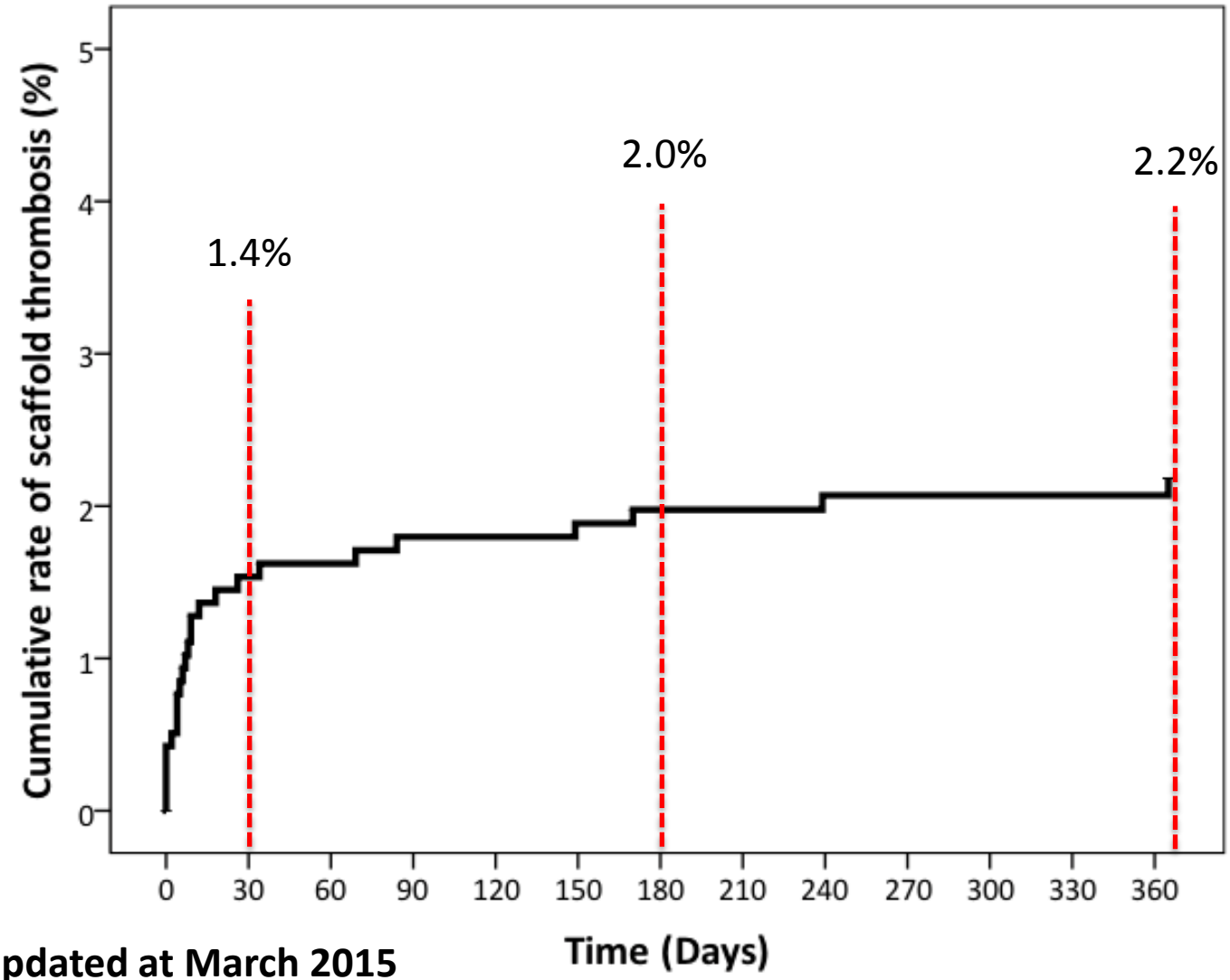
Brown AJ, et al. Catheter Cardiovasc Interv. 2014;84:37-45

Underexpansion and Early Scaffold Thrombosis

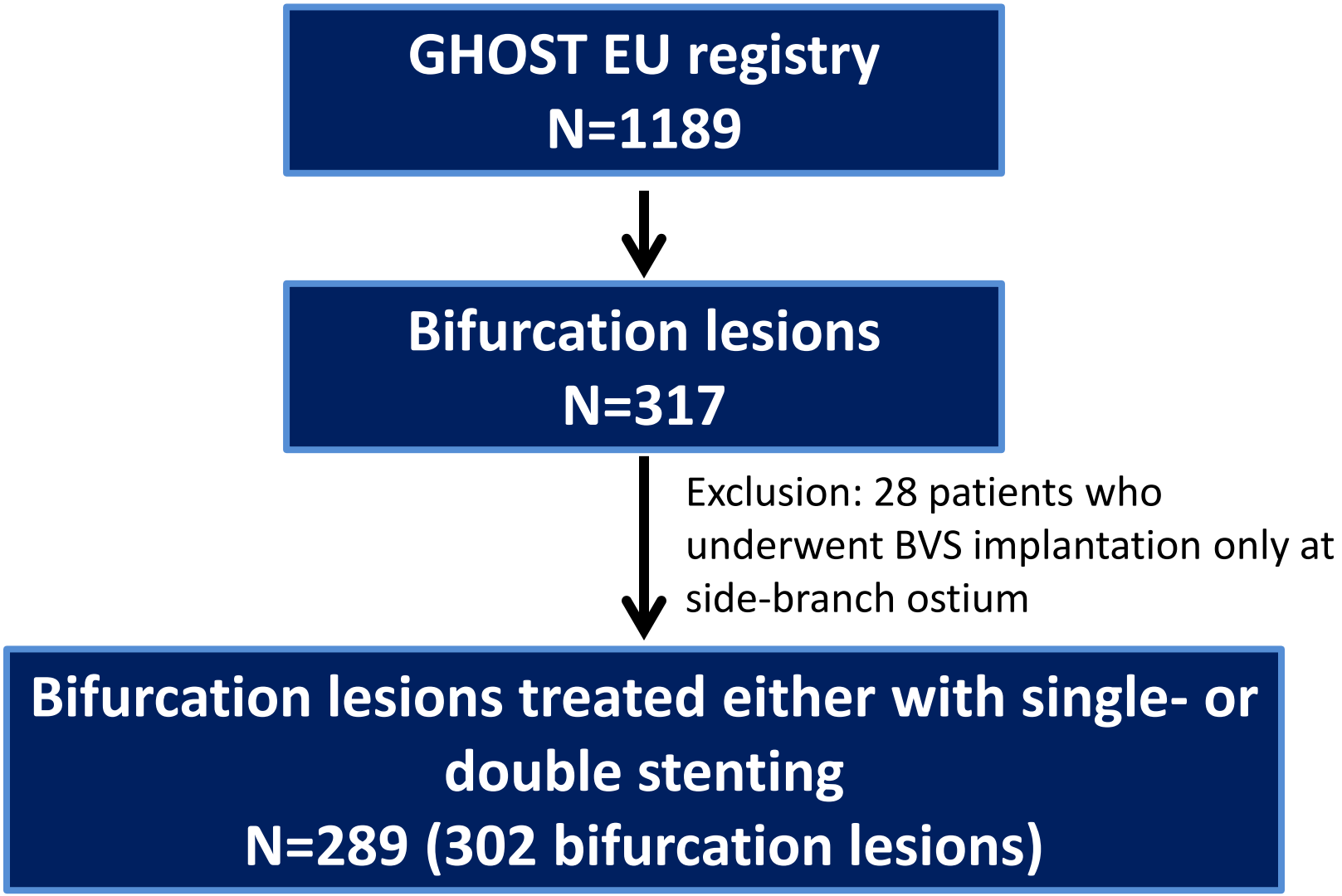


Gori T et al. JACC Cardiovasc Interv 2014;7:1194-5

Scaffold Thrombosis GHOST-EU: 1189 patients

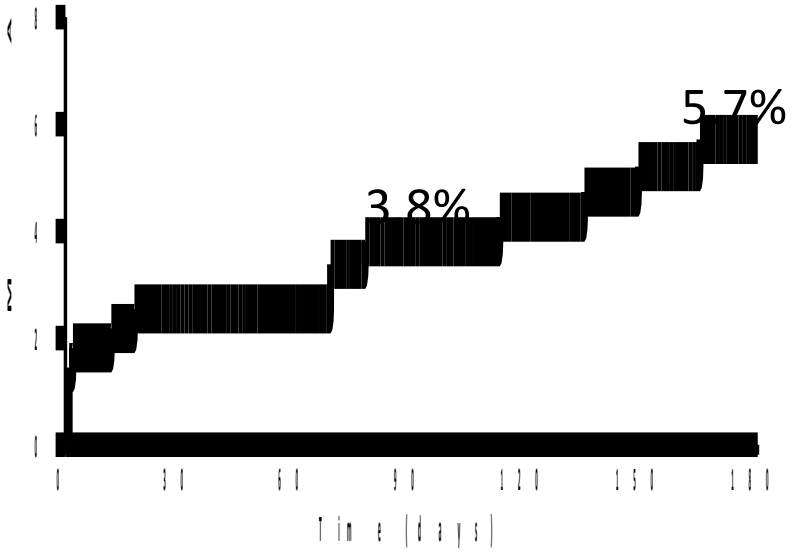


Follow-up updated at March 2015



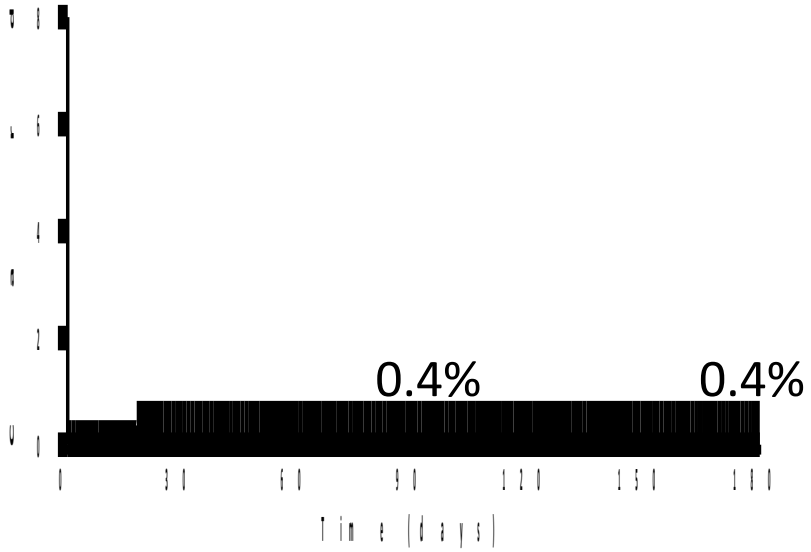
Naganuma T, Latib A, et al. GHOST-EU Investigators

Clinical Outcomes



Number at risk

289 262 240 221 207 200 170

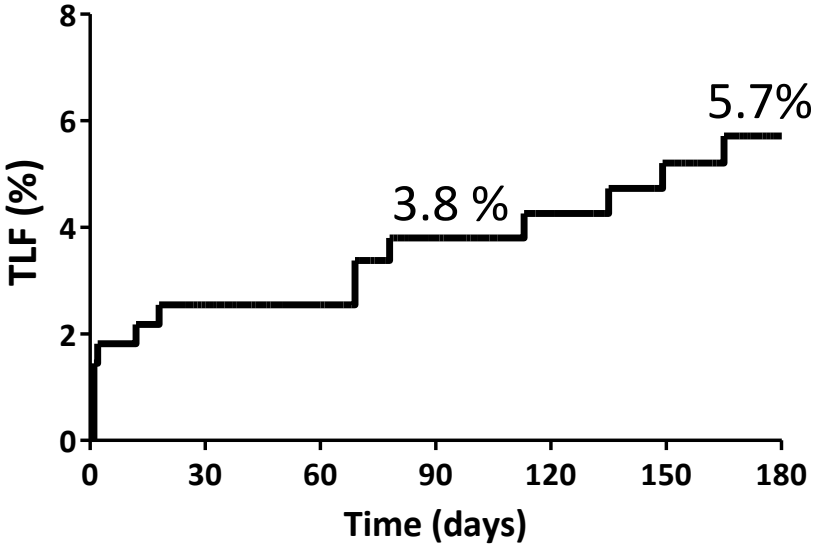


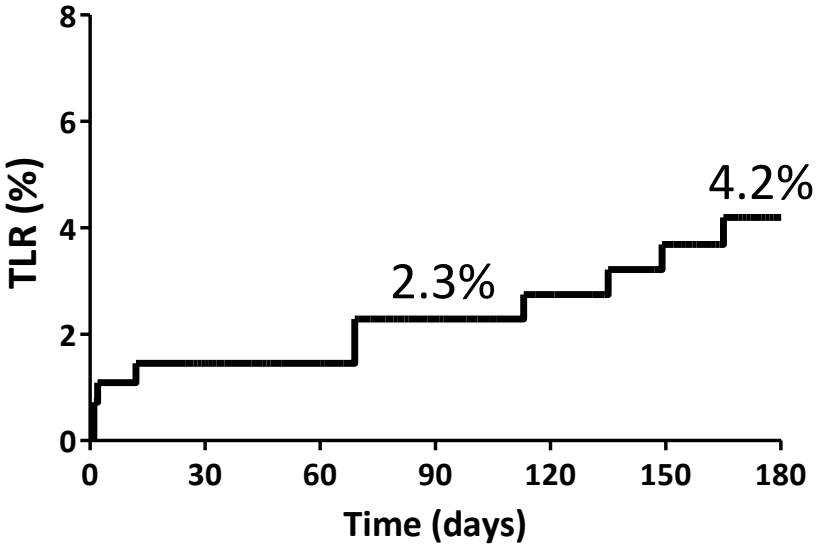
Number at risk

289 268 246 230 217 211 181

MACE includes all-cause death, MI and TVR

Clinical Outcomes





Number at risk

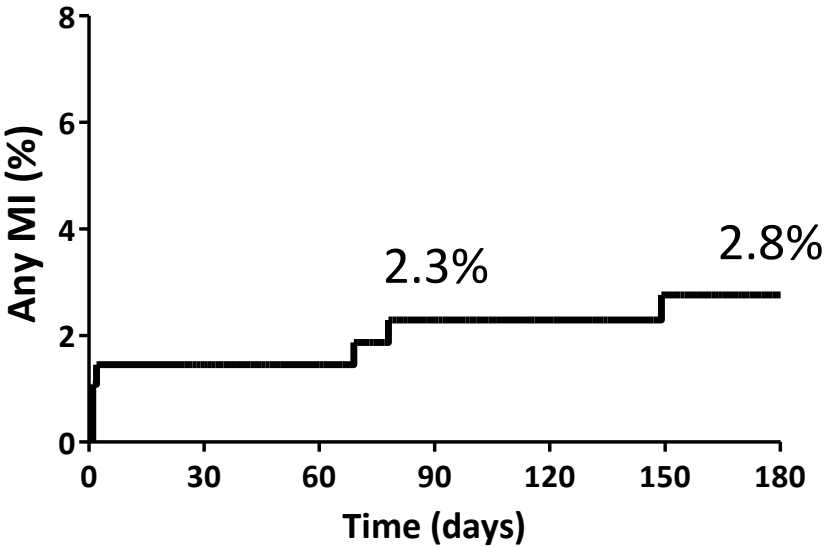
289	262	240	221	207	200	170

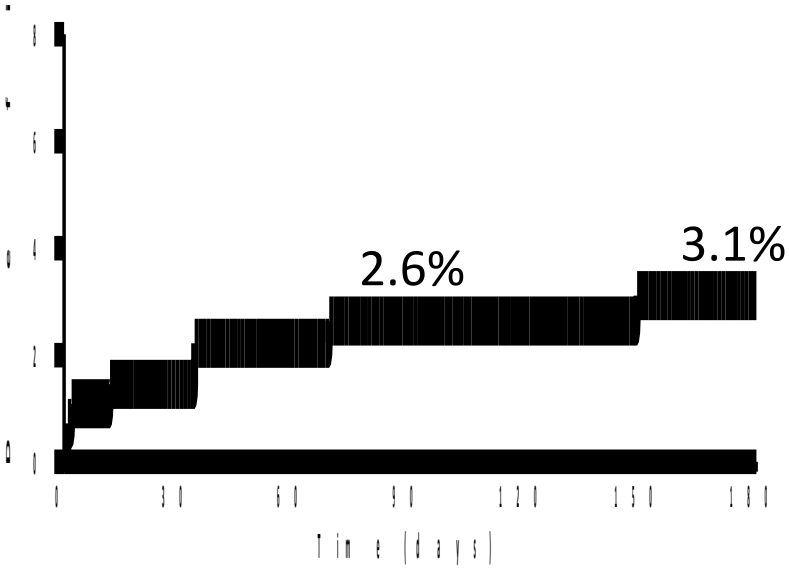
Number at risk

289	265	243	225	211	204	174

TLF includes cardiac death, target vessel MI and clinically driven TLR

Clinical Outcomes





Number at risk

265 243 225 212 206 175

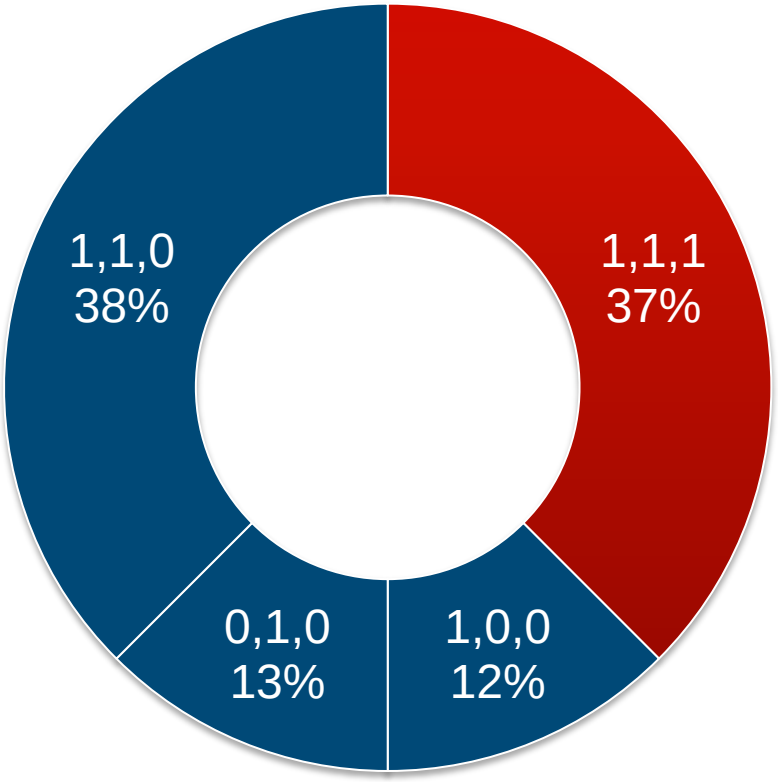
Number at risk

289 264 240 223 210 204 173

Prasugrel or ticagrelor was used in 55 (19.0%) patients.

GHOST-EU : 8/23 ST were in bifurcations

Kaplan-Meier 30-day and 6-mo ST in bifurcations: 1.5% and 3.1%, respectively



Medina classes in 8 bifurcations ST

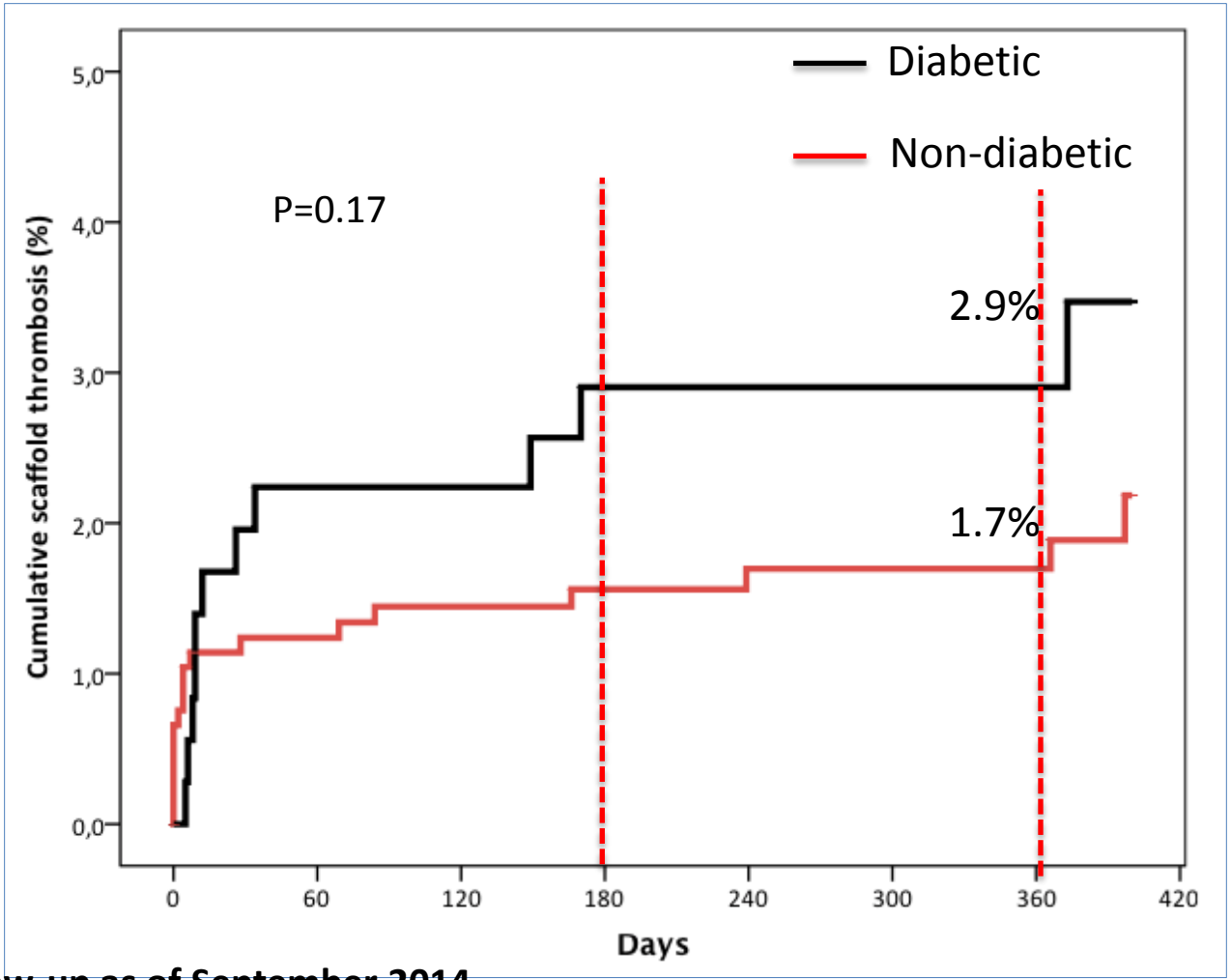
Case	Days	ACS	Strategy	PD	KBI	IG	DAPT
#1	149	No	Single	Yes	No	Yes	No
#2	69	No	Single	No	No	No	Yes
#3	2	Yes	Single	No	No	Yes	Yes
#4	0	Yes	Single	No	No	No	Yes
#5	34	Yes	Single	No	No	No	Yes
#6	34	Yes	Double	Yes	No	No	No
#7	0	Yes	Single	No	No	No	Yes
#8	12	Yes	Single	No	No	No	Yes

ACS = acute coronary syndromes; PD = main branch post-dilatation;
IG = intravascular guidance; DAPT = on dual antiplatelet therapy

GHOST-EU: Baseline Characteristics 1189 patients

Age, years±SD	62±11 (1,189)
Male	944/1,189 (79%)
Diabetes mellitus	295/1,189 (25%)
On insulin	106/1,189 (9%)
Hyperlipidemia	629/1,189 (53%)
Hypertension	874/ 1,189(74%)
Smoker	351/1,189 (30%)
Previous PCI	399/1,189 (34%)
Prior CABG	55/1,189 (5%)
Stroke/TIA	45/1,189 (4%)
ACS	563/1,189 (47%)
Unstable angina	157/1,189 (13%)
NSTEMI	214/1,189 (18%)
STEMI	192/1,189 (16%)

GHOST-EU: Diabetic vs. non-diabetic patients
Scaffold definite/probable thrombosis



Patients and Follow-up as of September 2014

GHOST | Ferrarotto Population

Patients enrolled N=319; lesions N = 406

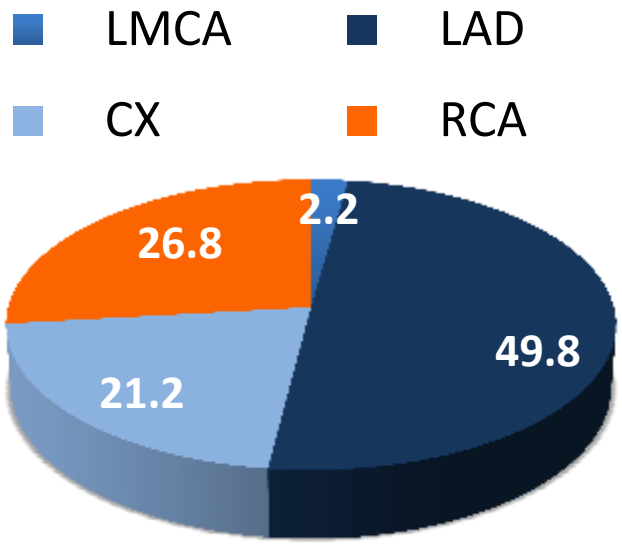
From 1/3/2013 to 30/06/2014

- **6-months FU in 305 patients 95.6%**
- **1-year FU in 281 patients: 88.1% of overall population and 95% of those eligible (n=296)**

Ferrarotto Population Clinical characteristics

Variable	Patient-based (N = 319)
Age, years±SD	60.7 ± 9.6
Male	272 (85.3%)
Diabetes mellitus	**79 (24.8%)**
On insulin	32 (10.0%)
Dyslipidemia	187 (58.6%)
Hypertension	221 (69.3)
Smoker	117 (36.7)
Previous PCI	102 (32.0)
Prior CABG	10 (3.1%)
ACS	**158 (49.5)**
NSTEMI	**46 (14.4%)**
STEMI	**58 (18.2)**

Ferrarotto Population
Lesions and procedural characteristics



Lesions B2/C: 51.2%
Bifurcations: 16.7%
CTO: 8.4%

*per patient

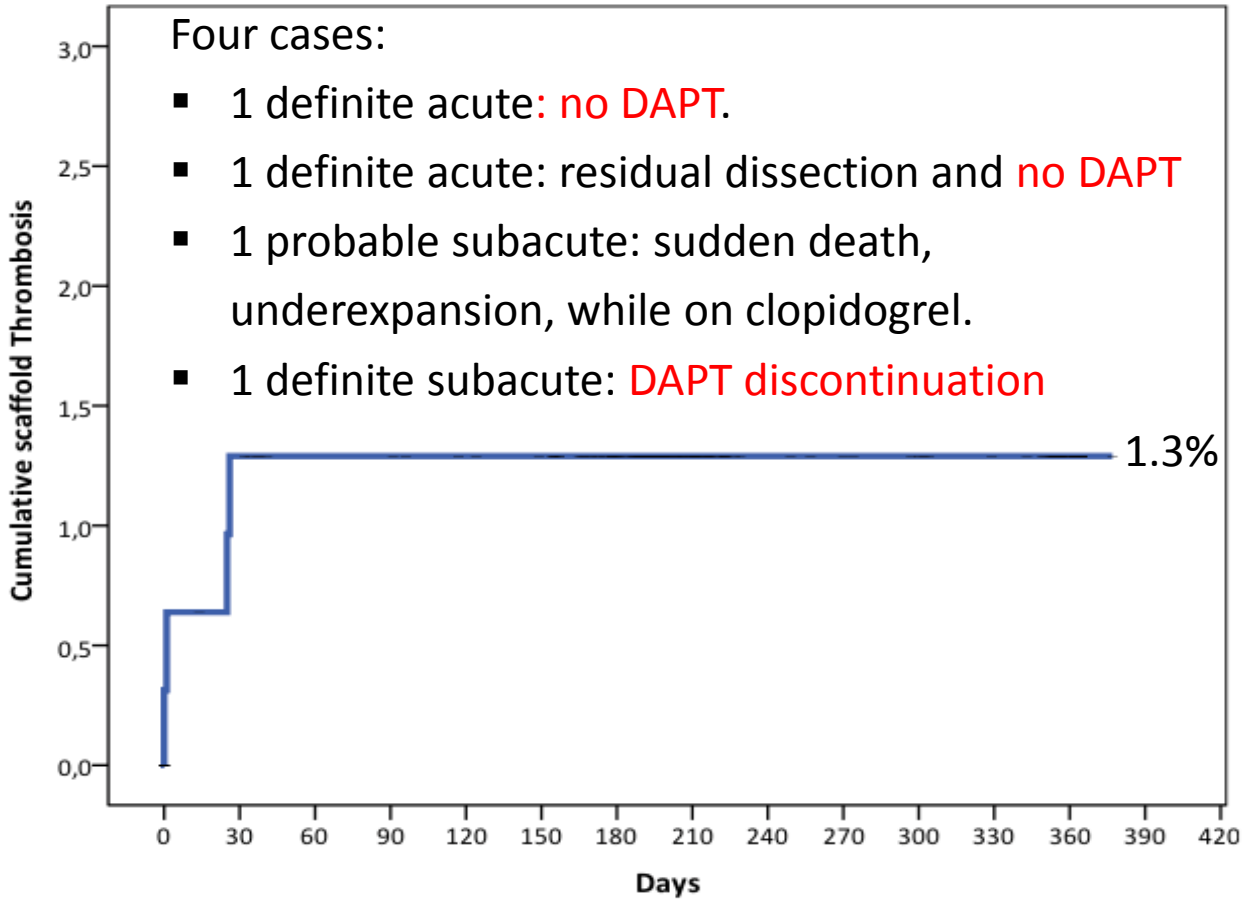
Variable	Lesions (N = 406)
Lesion Lenght	21.2 ± 16.8
Lesion length >34 mm	55 (13.5%)
Reference vessel diameter (mm)	2.9 ± 0.5
Total scaffold length (mm)	32.8 ± 21.6
Average scaffold diameter (mm)	3.1 ± 0.4
Avarage of scaffolds implanted (n)	1.9 ± 1.2*
Post-dilatation	**289 (71.2%)**
Post-dilation balloon pressure, atm	**16.6±4.3**
Scaffold implantation pressure, atm	13.5±3.4
Overlapping	132 (32.5%)
Optical coherence tomography use	80 (25.1)*
Intravascular ultrasound use	37 (11.6)*

GHOST | Ferrarotto Population 1-year outcomes

TLF (cardiac death, target-vessel MI, or clinically-driven TLR)	5.9%
TVF (cardiac death, target-vessel MI, or clinically-driven TVR)	6.4%
All Death	1.3%
Non-Cardiac Death	0.7%
Cardiac Death	0.3%
Any MI (all target vessel)	1.0%
TVR	6.0%
TLR	5.5%

Event rates are expressed as Kaplan Meier estimates.

Ferrarotto Population
1-year scaffold thrombosis



Investigator Sponsored Trials - Overview and Status Update

Study Title	S-I	Design	Number of patients enrolled	Primary Endpoint	Patient FU (Years)
Registries (>10,000 Pts) – Funded by Abbott Vascular					
BVS EXPAND	R.J. van Geuns	All – comers Registry (excl STEMI)	300/300	1 – Yr MACE	5
ASSURE	D. Mathey	All – comers Registry	180/180	Safety and Efficacy	3
ABSORB CTO	A. Serra	Feasibility in CTO	35/35	Safety and Performance	2
PABLOS	A. Colombo	Feasibililty in Bifurcations	23/30	Device, Procedural, Main and Side Branch Success	2
IT-DISSAPEARS	F. Bedogni / A.S. Petronio	MVD and Long Lesion Registry	175/1000	Safety and Efficacy	5
GABI-R	H. Nef	All – comers Registry	1417/5000	Safety and Efficacy	5
REPARA	F. Hernandez	All – comers Registry	1000/1500	1- Yr MACE	1
POLAR ACS	D. Dudek	ACS Registry	100/100	Safety, clinical device, procedure success and in-hospital MACE	1
France ABSORB	R. Koning	Feasibility in de novo lesions	160/2000	1 – Yr MACE	1
Registries – w/o Abbott Funding (not all information is available)					
GHOST EU	C. Tamburino	All – comers Registry	1433	Target Vessel Failure (TVF)	1
GHOST-Ferrarotto	C. Tamburino	All – comers Registry	319	Target Vessel Failure (TVF)	1
Prague 19	P. Widimsky	STEMI (STEMI Killip I/II)	98/100	Clinical Outcomes	1

ASSURE REGISTRY (n=183)
Population characteristics

Patients	N=183
Age (years)	63.5±9.3
Male gender, n (%)	146 (79.8)
Hypertension, n (%)	150 (82.0)
Diabetes, n (%)	47 (25.7)
Diabetes requiring insulin, n (%)	19 (10.4)
Dyslipidaemia, n (%)	139 (76.0)
Prior myocardial infarction, n (%)	48 (27.1)
Heart failure (NYHA I-IV), n (%)	88 (48.1)
NYHA I	29 (15.8)
NYHA II	43 (23.5)
NYHA III	12 (6.6)
NYHA IV	4 (2.2)
Angina pectoris, n (%)	104 (56.8)
Stable	65 (35.5)
Unstable	39 (21.3)

Target lesions		N=198
Lesion location, n (%)	LAD	84 (42.4)
	LCX	44 (22.2)
	RCA	47 (23.7)
	Other	23 (11.6)
ACC/AHA lesion morphology, n (%)	A	26 (13.1)
	B1	44 (22.2)
	B2	86 (43.4)
	C	42 (21.2)
Calcification*, n (%)	None	62 (31.3)
	Mild	105 (53.0)
	Moderate	27 (13.6)
	Heavy	4 (2.0)
Side branch involved, n (%)		28 (14.1)
Bifurcation (side branch ≥2 mm*)		6 (3)
* Determined by visual estimation		

Wöhrle J. Eurointervention 2014

ASSURE REGISTRY (n=183)
Lesion and procedural characteristics

Lesion length, mm, median (IQR)	11.6 (9.3-16.5)
Diameter stenosis, %	
Baseline	64.6±15.1
Final	16.1±7.7
Reference vessel diameter, mm	
Lesion/scaffold segment	
Baseline	2.6±0.5
Final	3.0±0.5
Proximal peri-scaffold segment, final	3.1±0.5
Distal peri-scaffold segment, final	2.9±0.5
Minimal lumen diameter (lesion/scaffold segment), mm	
Baseline	0.9±0.5
Final	2.5±0.4
Acute gain*, mm	1.54±0.51

Predilation, n (%)	196 (99.0)
Predilation balloon diameter, mm	2.7±0.4
Predilation balloon pressure, atm	13.8±2.7
Predilation balloon diameter/baseline reference vessel diameter	1.1±0.2
Predilation balloon length/scaffold length	0.8±0.2
Scaffold implantation	
Implantation pressure, atm	14.8±2.2
Number of inflations	1.1±1.0
Number of scaffolds per lesion	1.2±0.4
Scaffold length exceeding lesion length, mm*	7.1±3.8
Post-dilation, n (%)	25 (12.6)
Post-dilation balloon diameter, mm	3.2±0.3
Post-dilation balloon pressure, atm	17.3±3.7
Non-compliant balloon, n (%)	21 (84)
Number of inflations	1.6±0.8

Wöhrle J. Eurointervention 2014

ASSURE REGISTRY (n=183)
1-year Outcomes

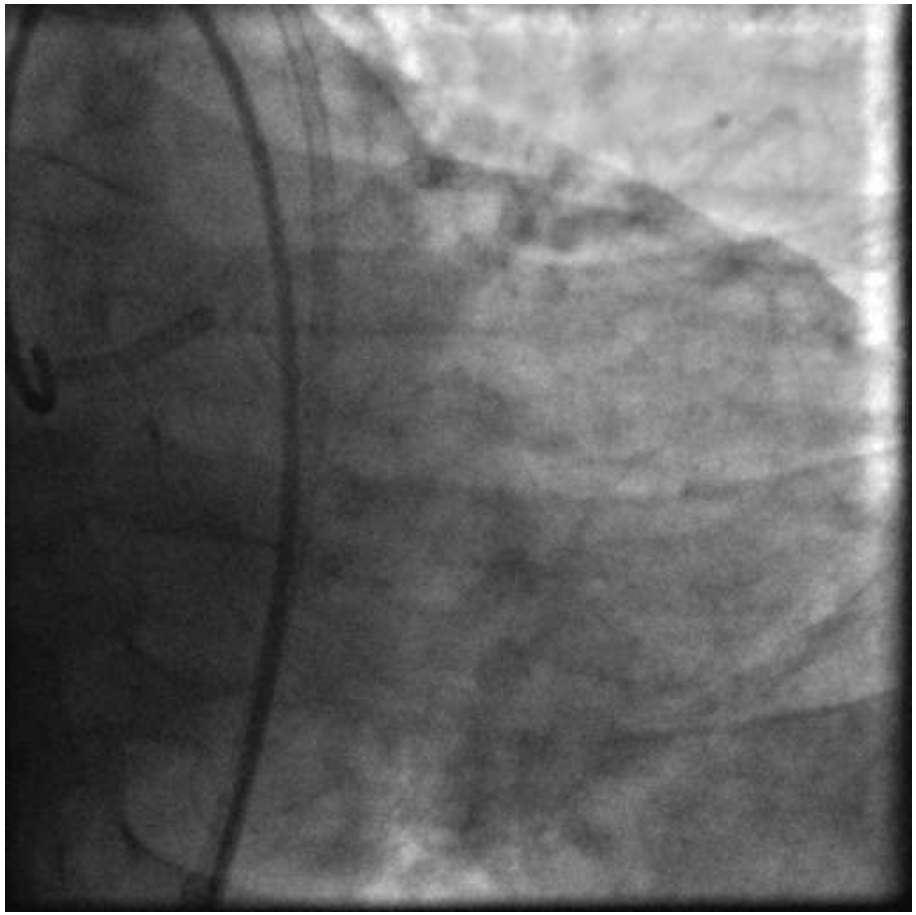
Outcome	6 months	12 months*
MACE¶ (hierarch.)	4 (2.2)	9 (5.0)
Cardiovascular death‡	1 (0.5)	1 (0.5)
Myocardial infarction§	2 (1.1)	3 (1.7)
Target lesion revascularisation	1 (0.5)	5 (2.8)
Target vessel revascularisation, non-TL	1 (0.5)	4 (2.2)
Target vessel failure, non-TVR	1 (0.5)	1 (0.5)

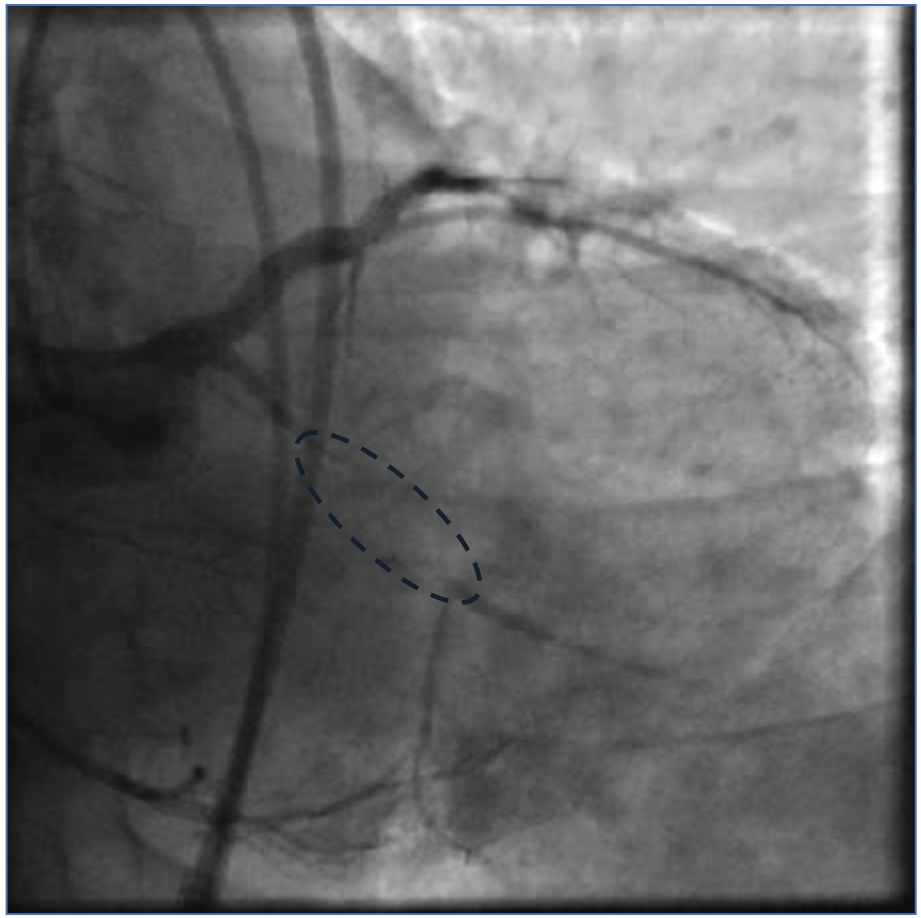
Wöhrle J. Eurointervention 2014

LCx CTO Clinical Case

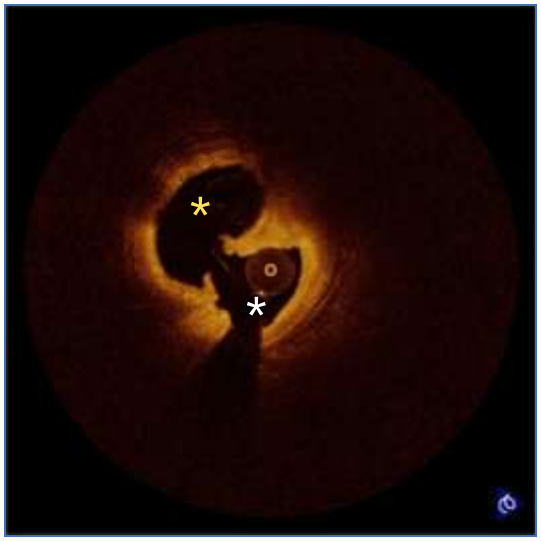
CTO clinical case

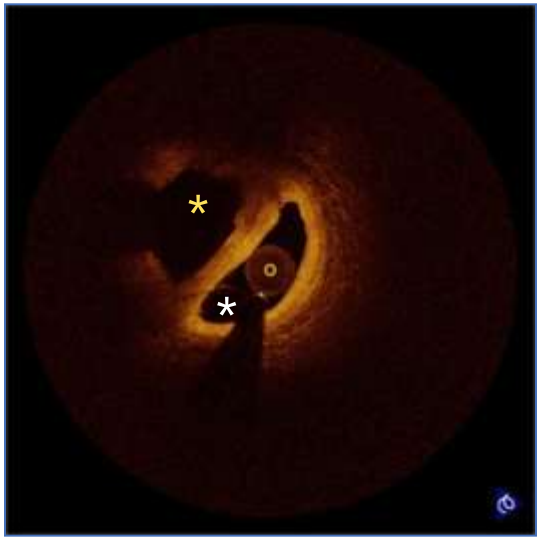
J-CTO score 2

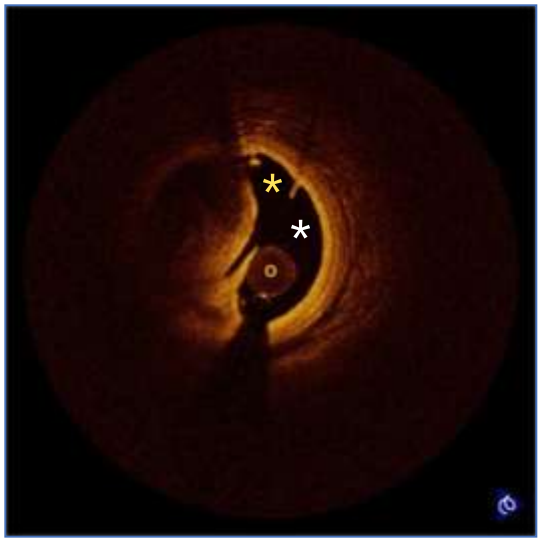


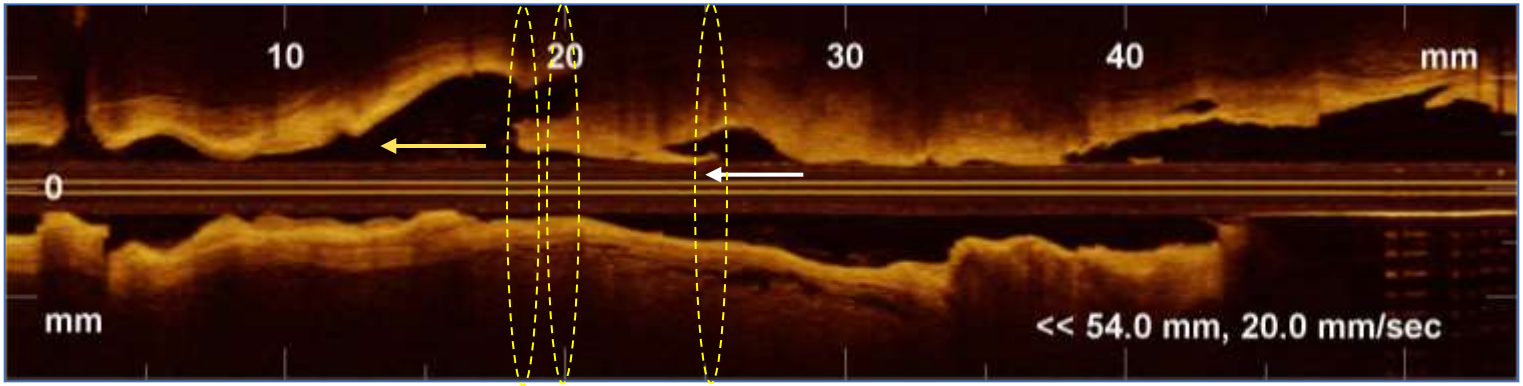


CTO clinical case



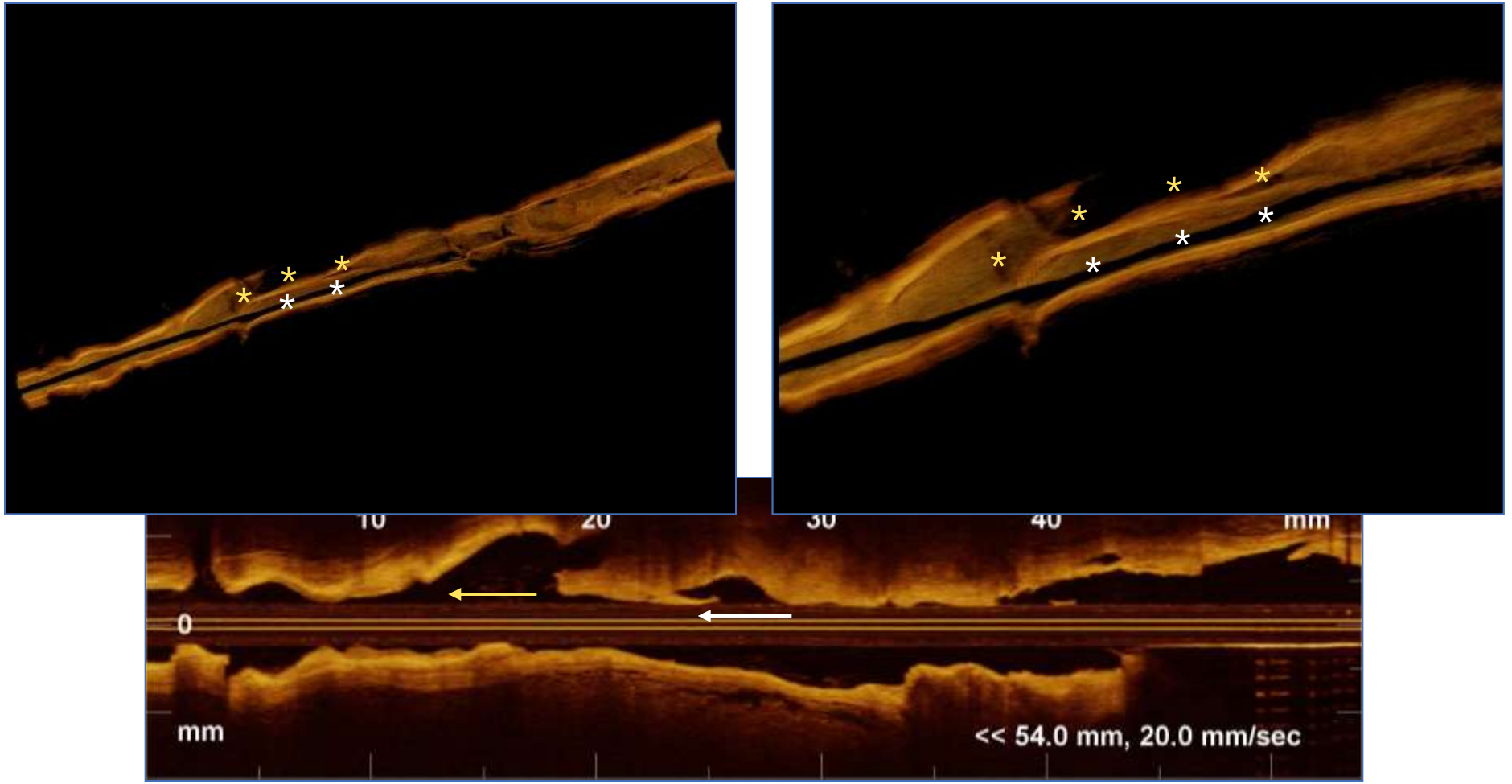






- OCT Long-view – exit (white arrow) and re-entry point (yellow arrow) of true lumen
- OCT cross-sections – false lumen (white asterisks) and true one (yellow asterisks)

CTO clinical case

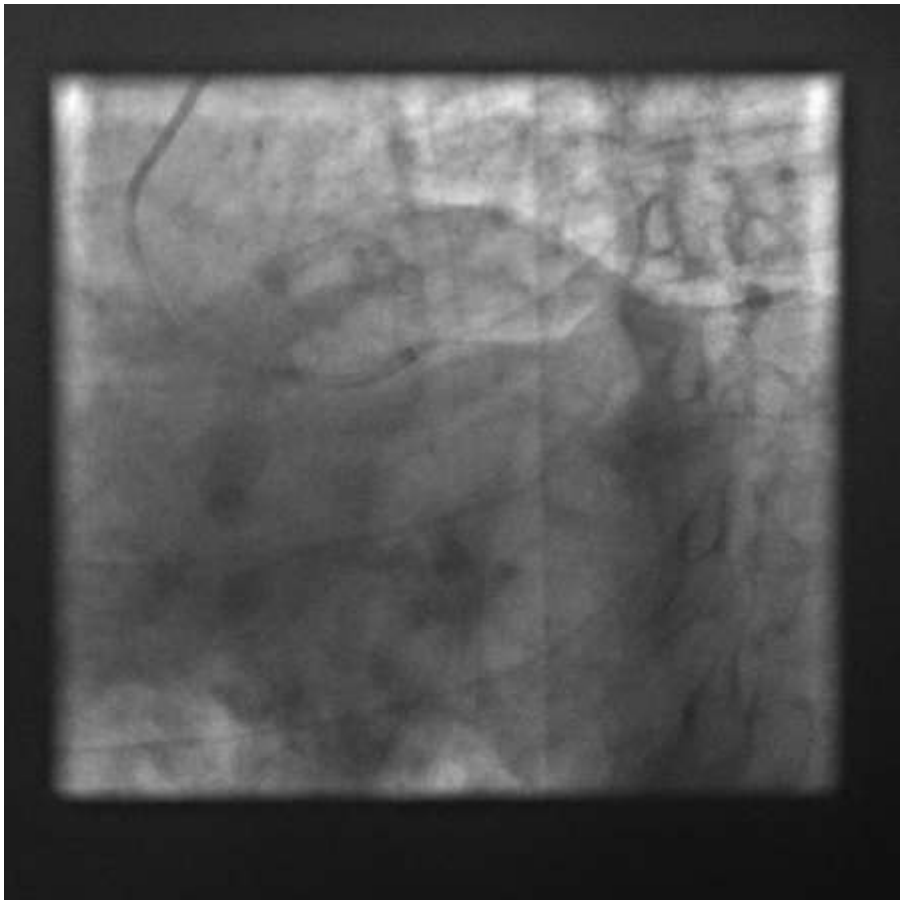


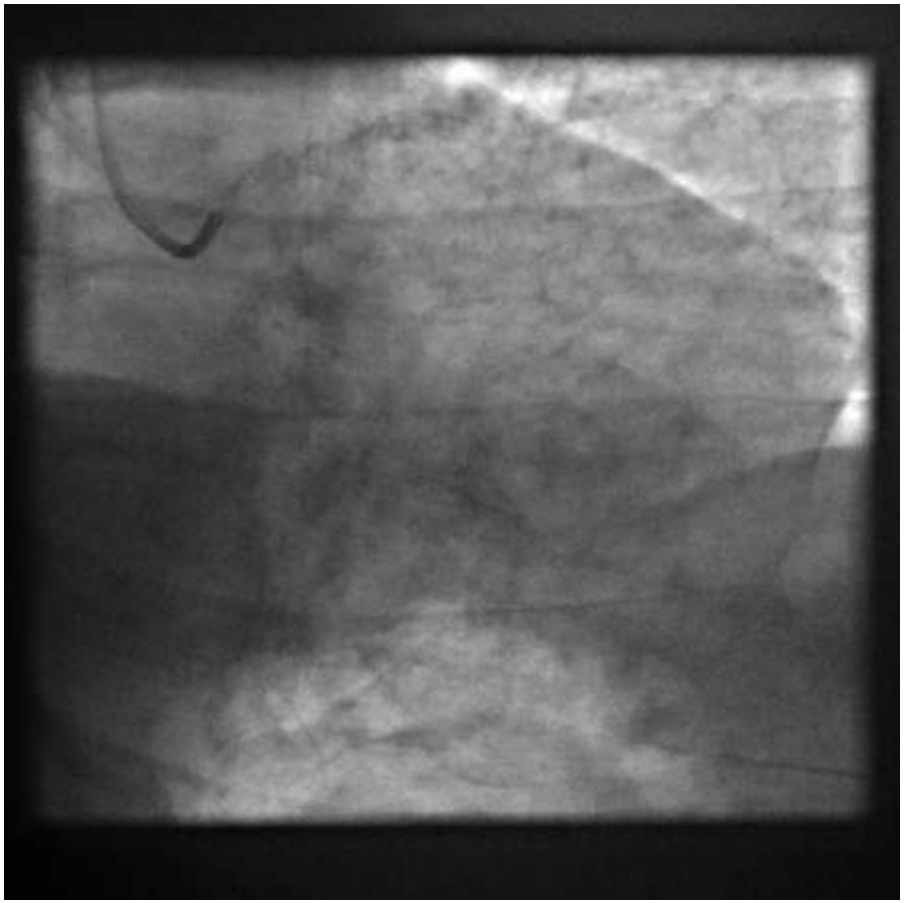
- 3D OCT – false lumen (white asterisks) and true one (yellow asterisks)

Final

- PCI – BVSs 3.0/18 and 3.5/28 in overlapping
- Post-dilatation – NC 3.5/20

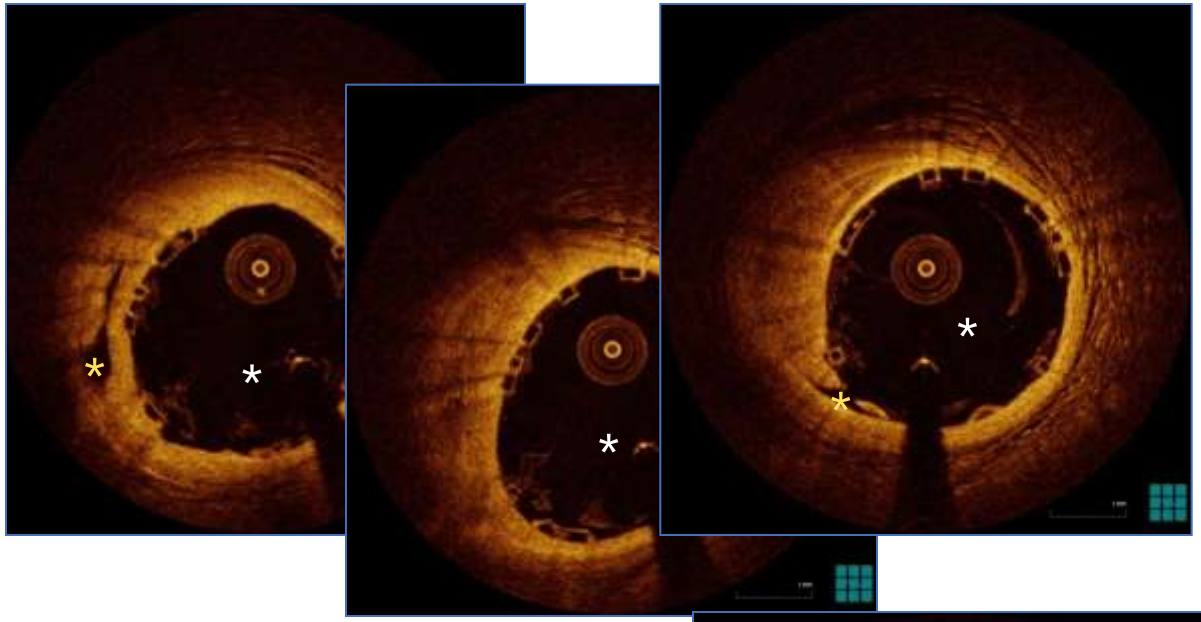
CTO clinical case – 1 y Follow-up

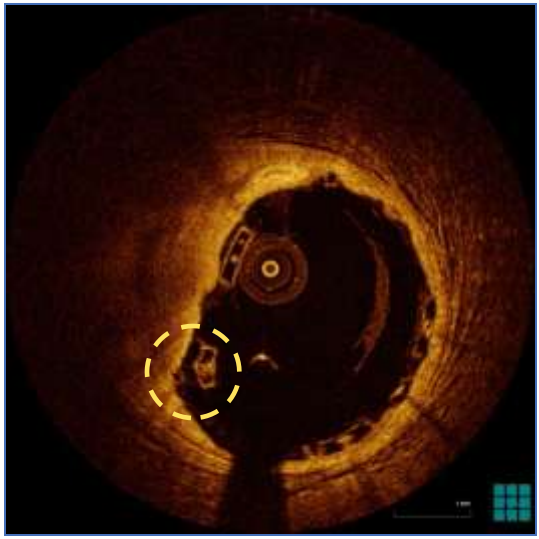


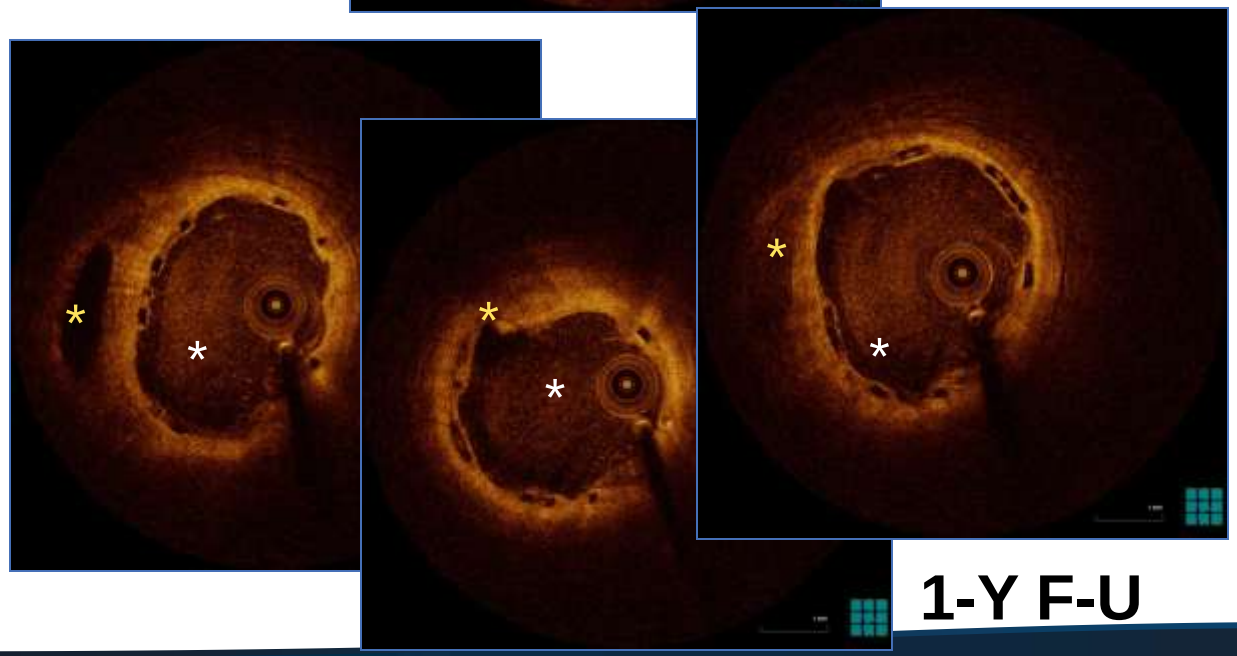


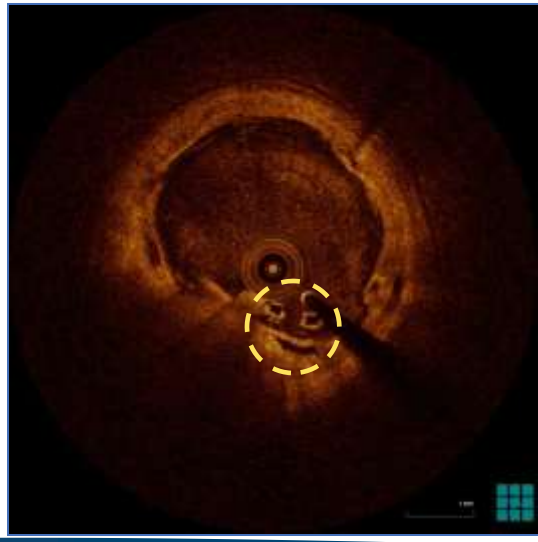
- Coronary angiography – good result of previous PCI on LCX-OM, TIMI 3 flow
- Coronary angiography – distal part of LCx still partly visible

INDEX PROCEDURE









1-Y F-U

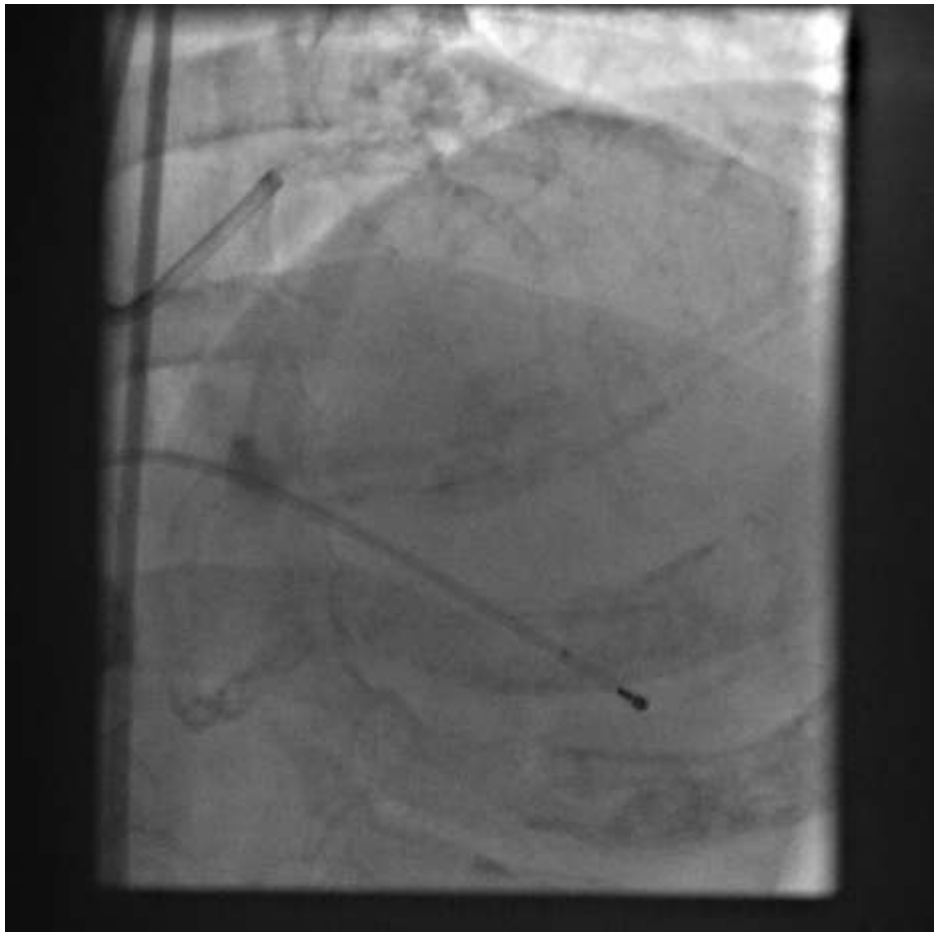
CLINICAL CASE
BVS implantation in highly calcified lesion

66 years old male,

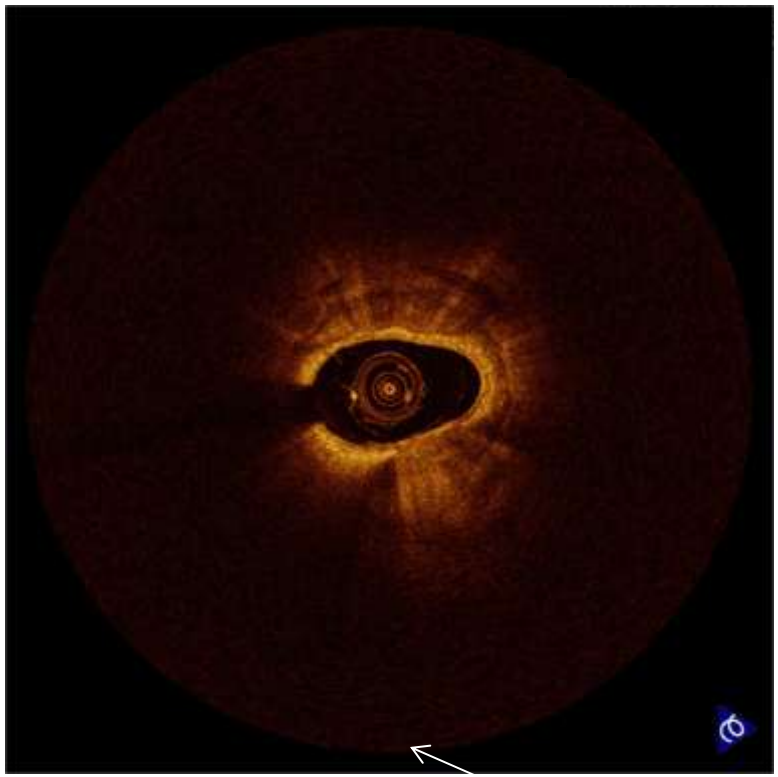
Hypertension, Diabetes, Dyslipidemia, Family history,

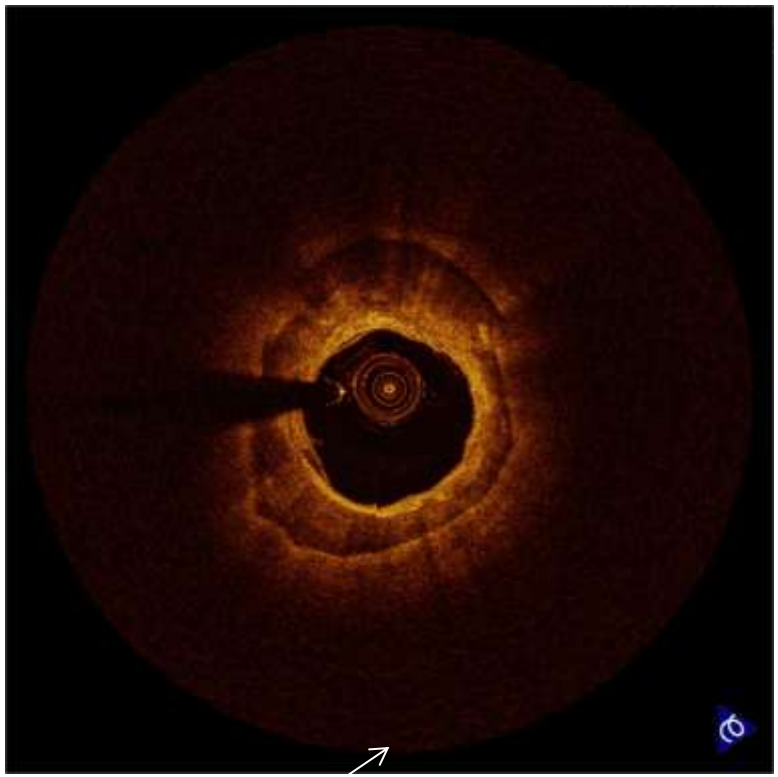
Stable angina (CCS II)

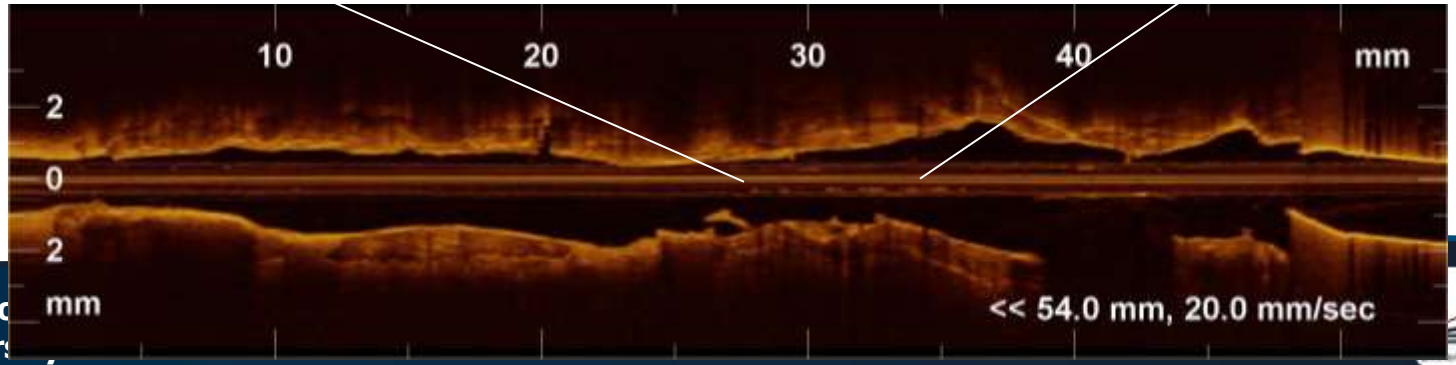
The Lesion



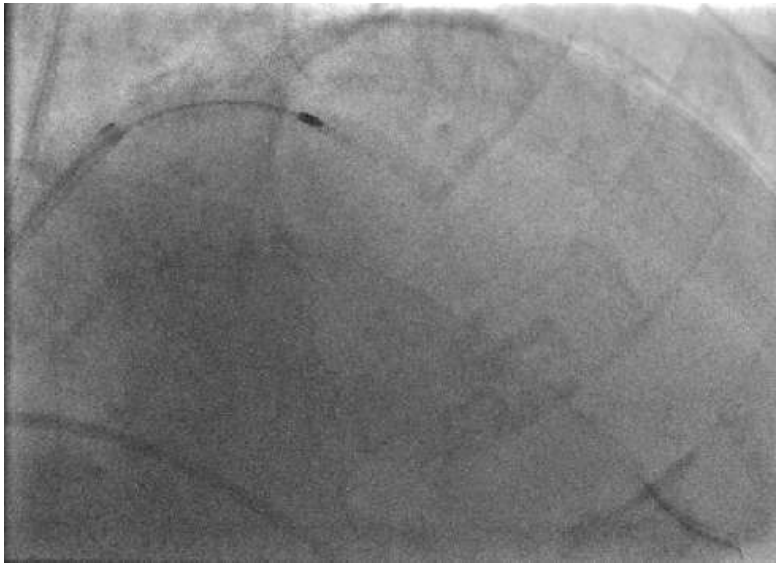
OCT PRE – Highly Calcified Segment



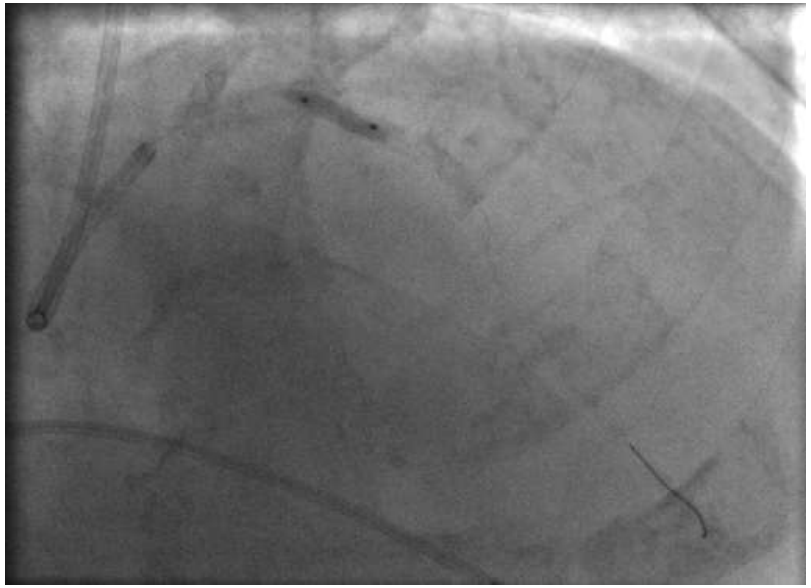




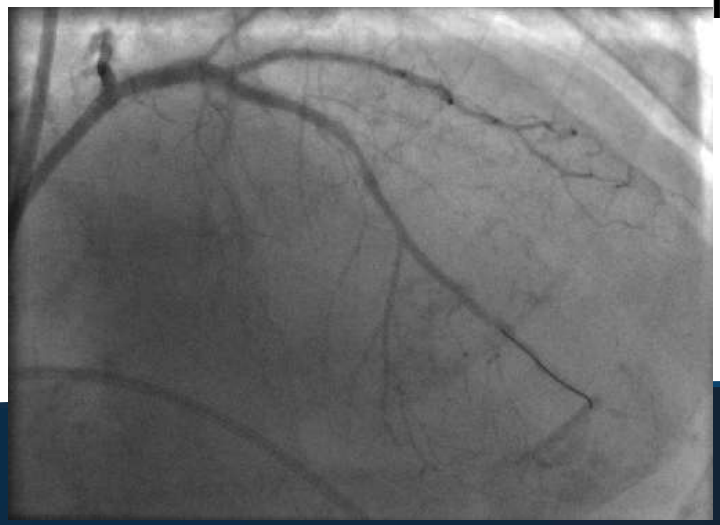
Lesion Preparation



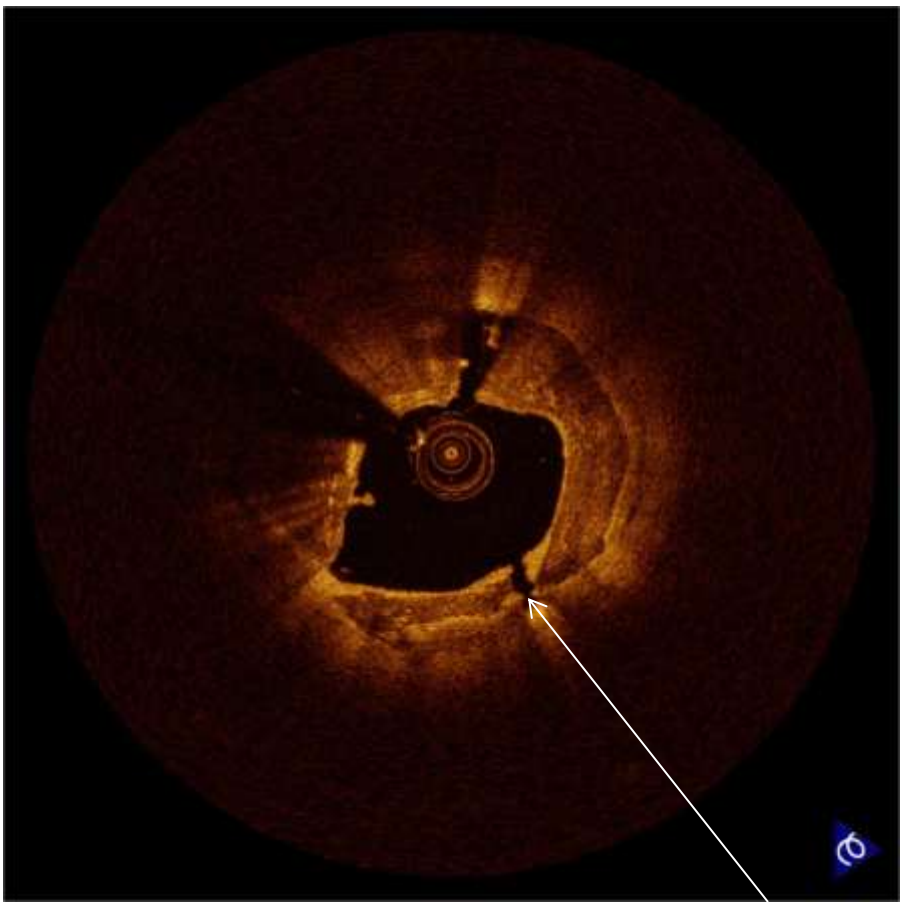
Rotational Atherectomy with 1.5mm burr

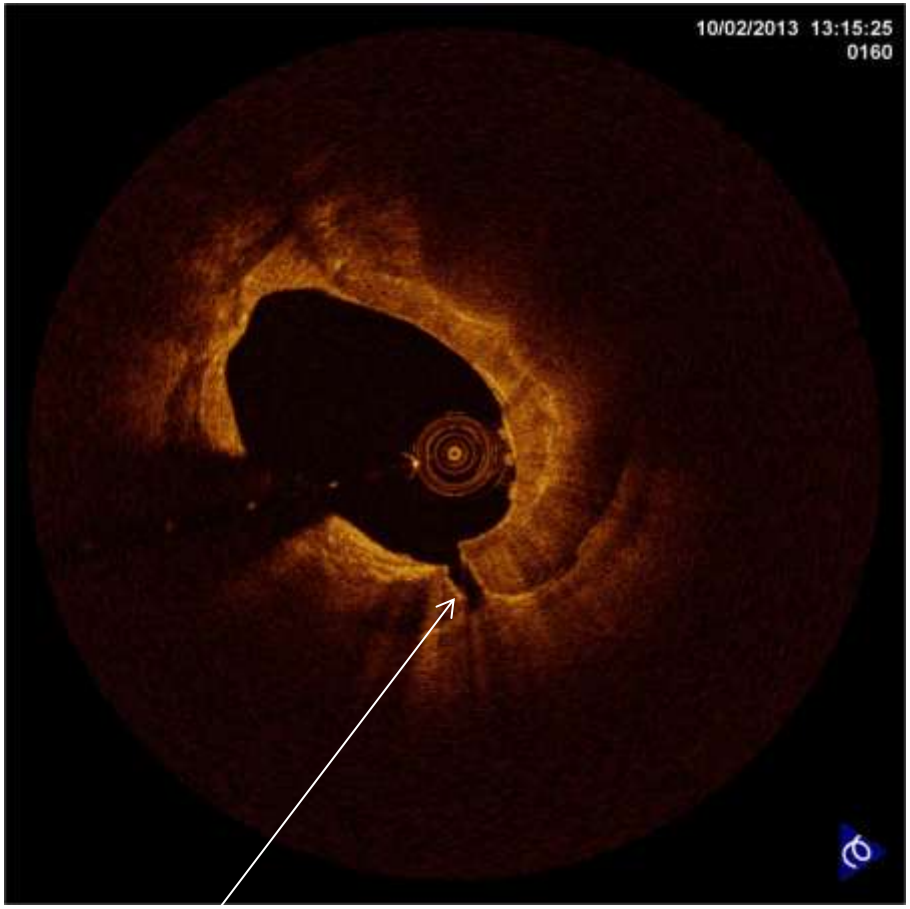


Scoring balloon 2.5x15mm + NC balloon 2.75x15mm



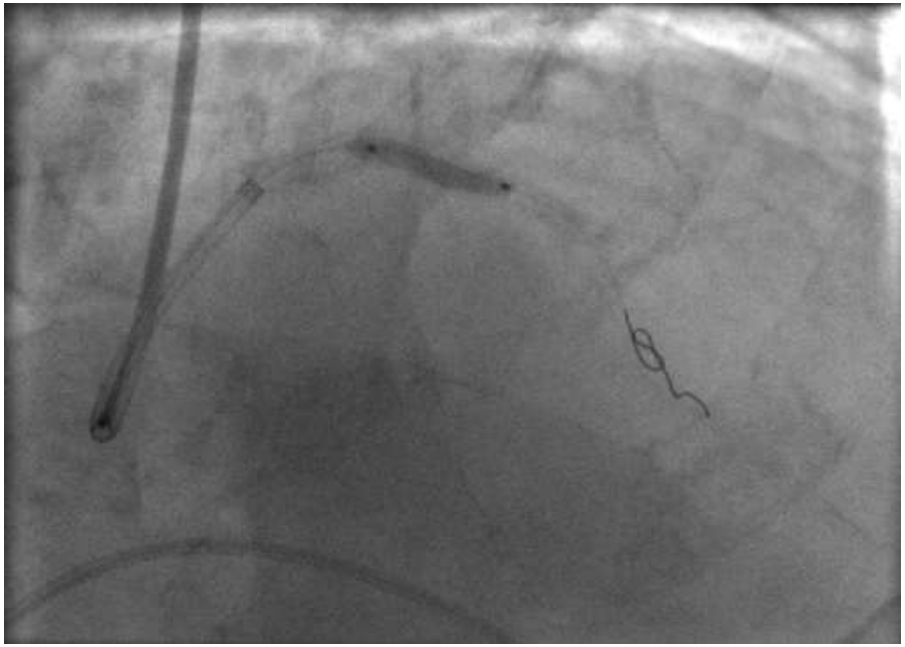
OCT after lesion preparation





Calcium Fracture

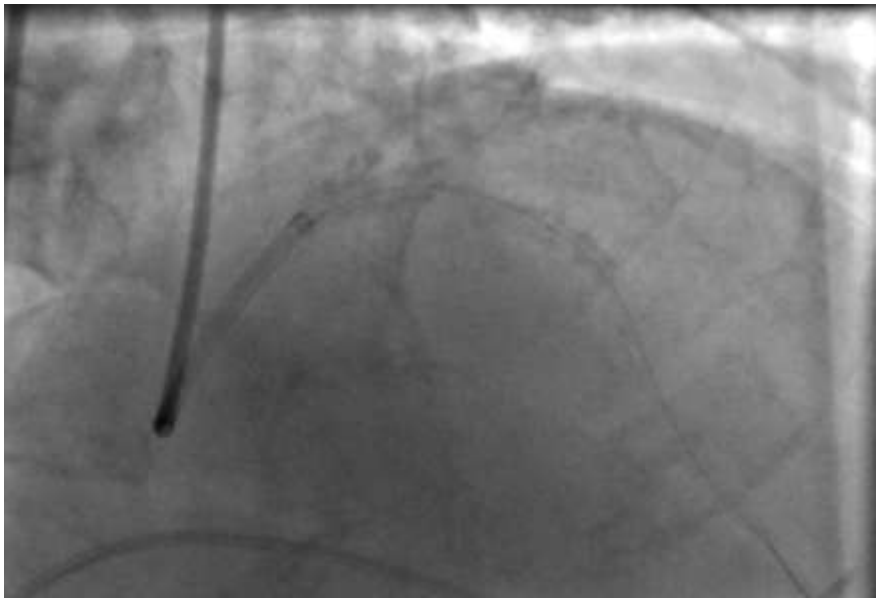
BVS Implantation and Post Dilation

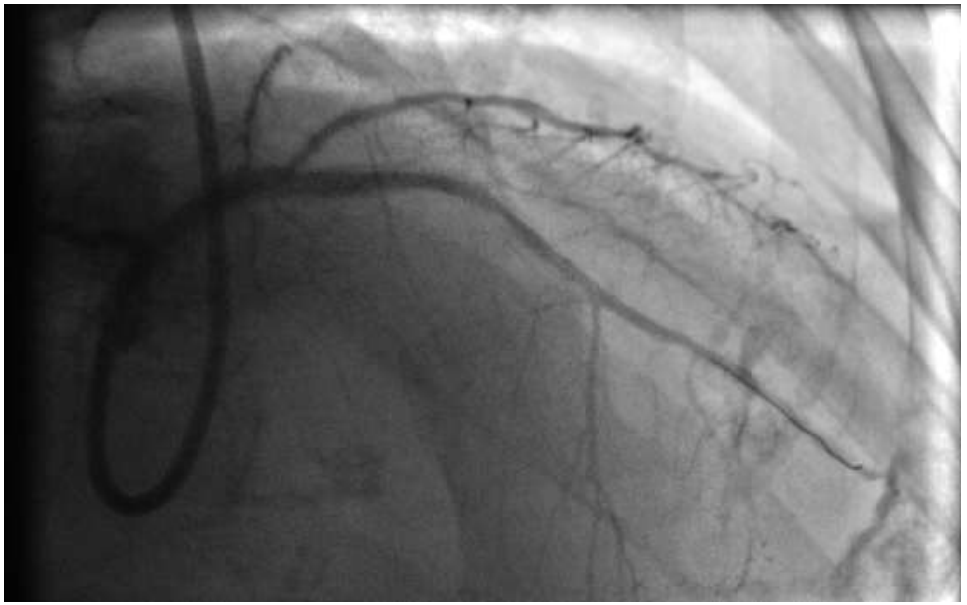


BVS 3.0x18mm @ 16atm

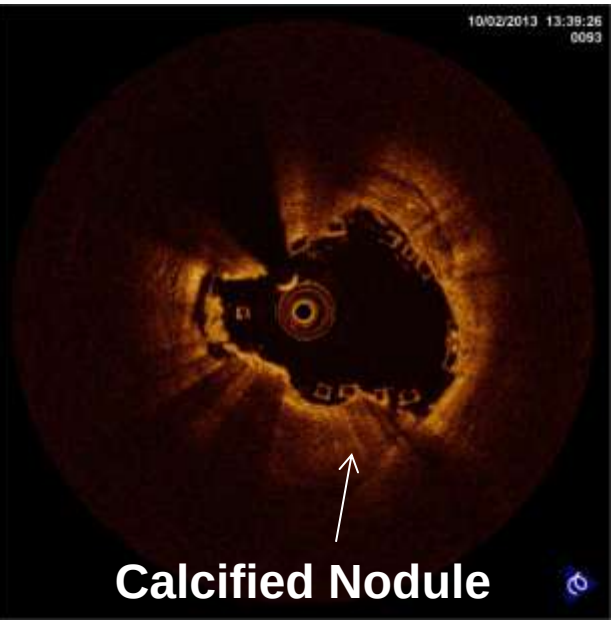
In-BVS post dilation with
3.5x15mm NC @ 24atm

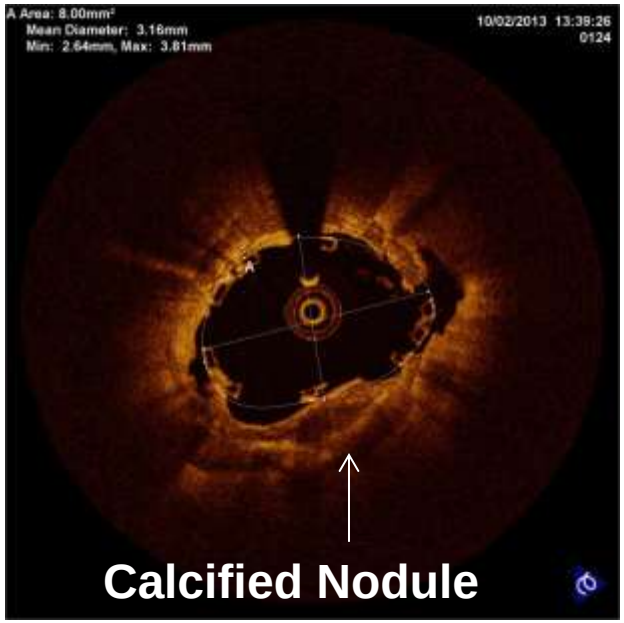
Final Angiography

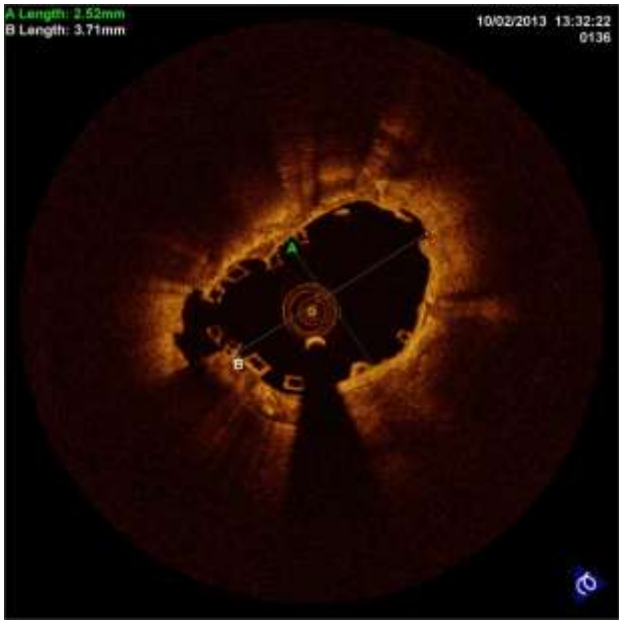




Final OCT







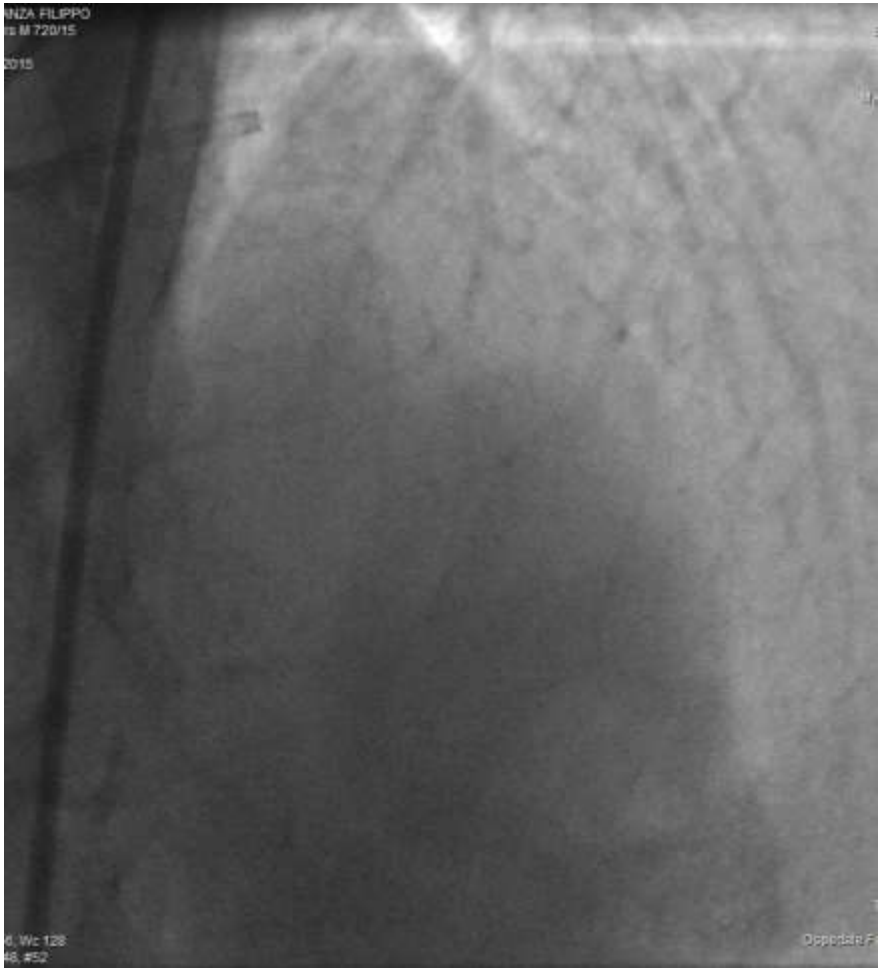
Uneven expansion with minimum malapposition but good final scaffold area

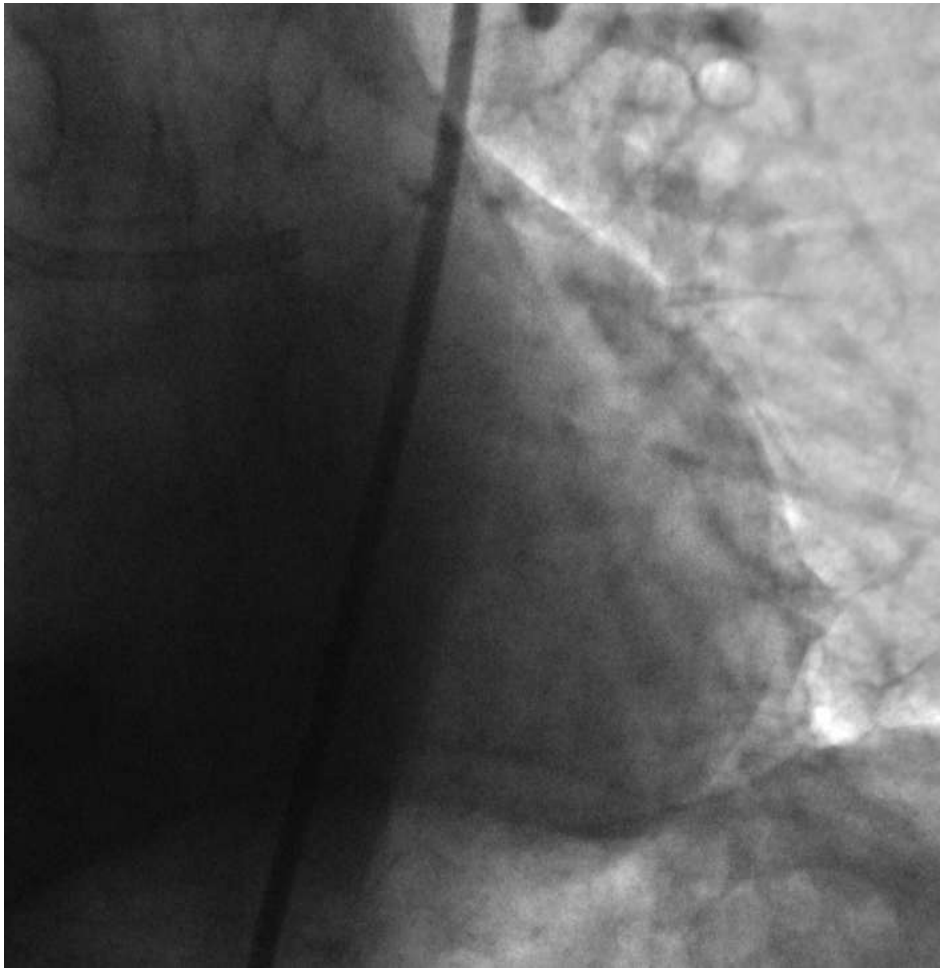
Patient's history

59 years old, Caucasian Male **2015, March**

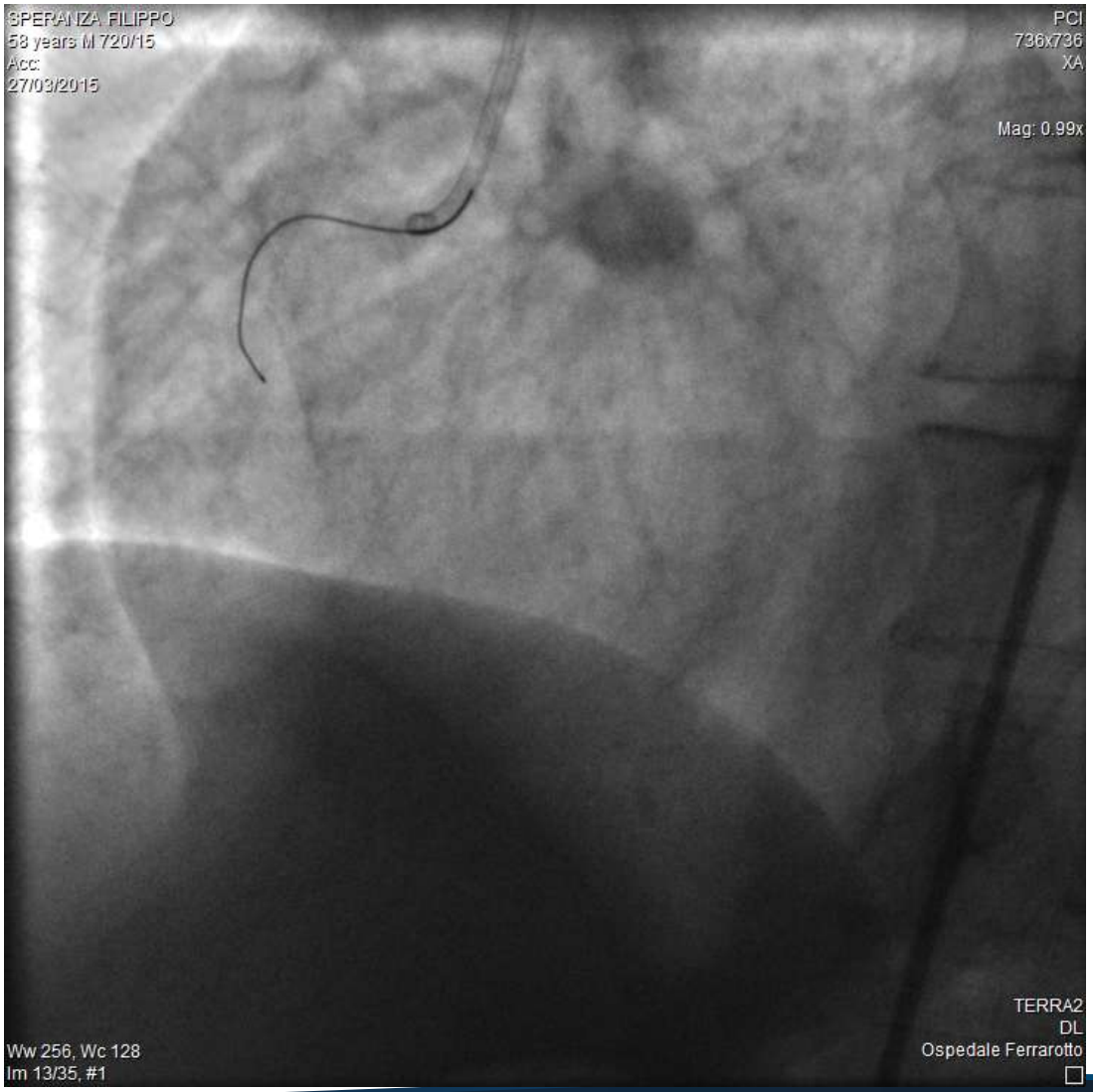
- **Cardiovascular risk factors:** hypertension, diabetes, smoker.
- **Co-morbidity: AOCP, BPCO stade III**
- **Presenting medical problem:** Angina CCS III, dyspnea
- **Physical exam:** arterial leg ulcers, diabetic retinopathy
- **Echocardiography:** akinesis of basal portion of inferior wall and distal portion of anterior septum; LVEF 47%. Trivial mitral regurgitation. E/A<1. sPAP 25 mmHg

Left coronary angiography

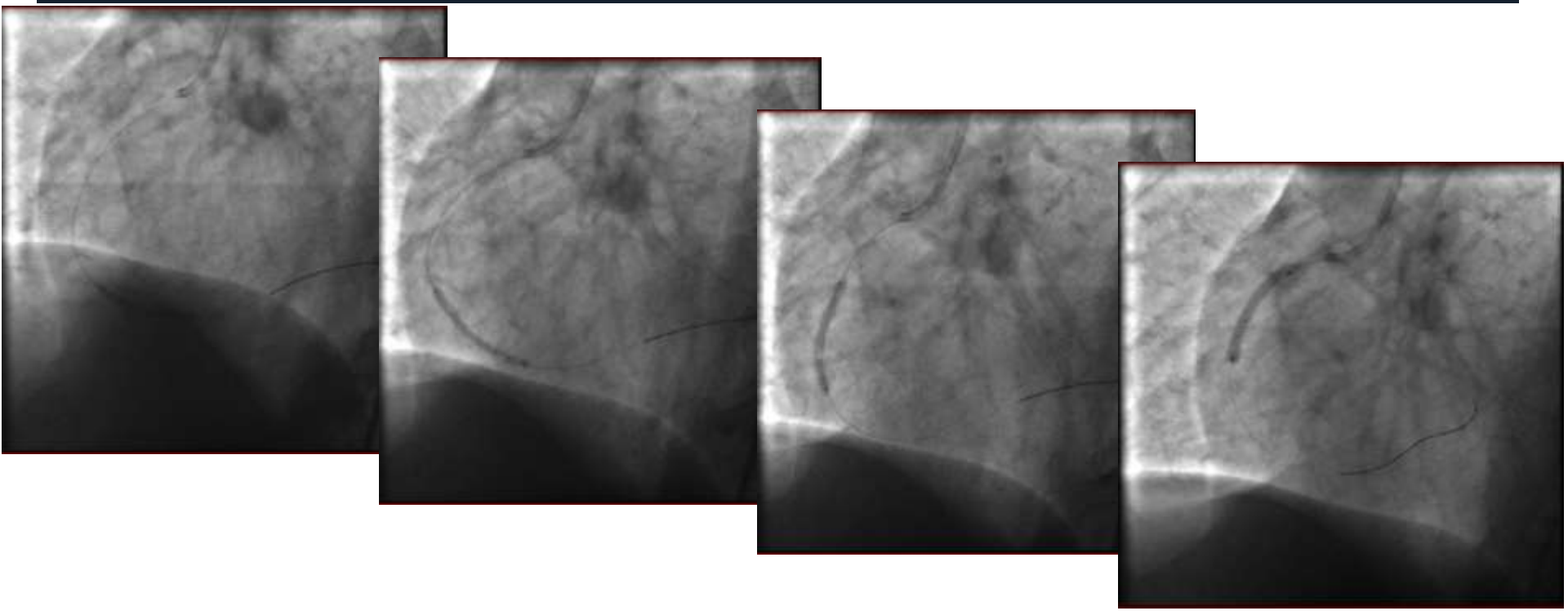




Right coronary angiography

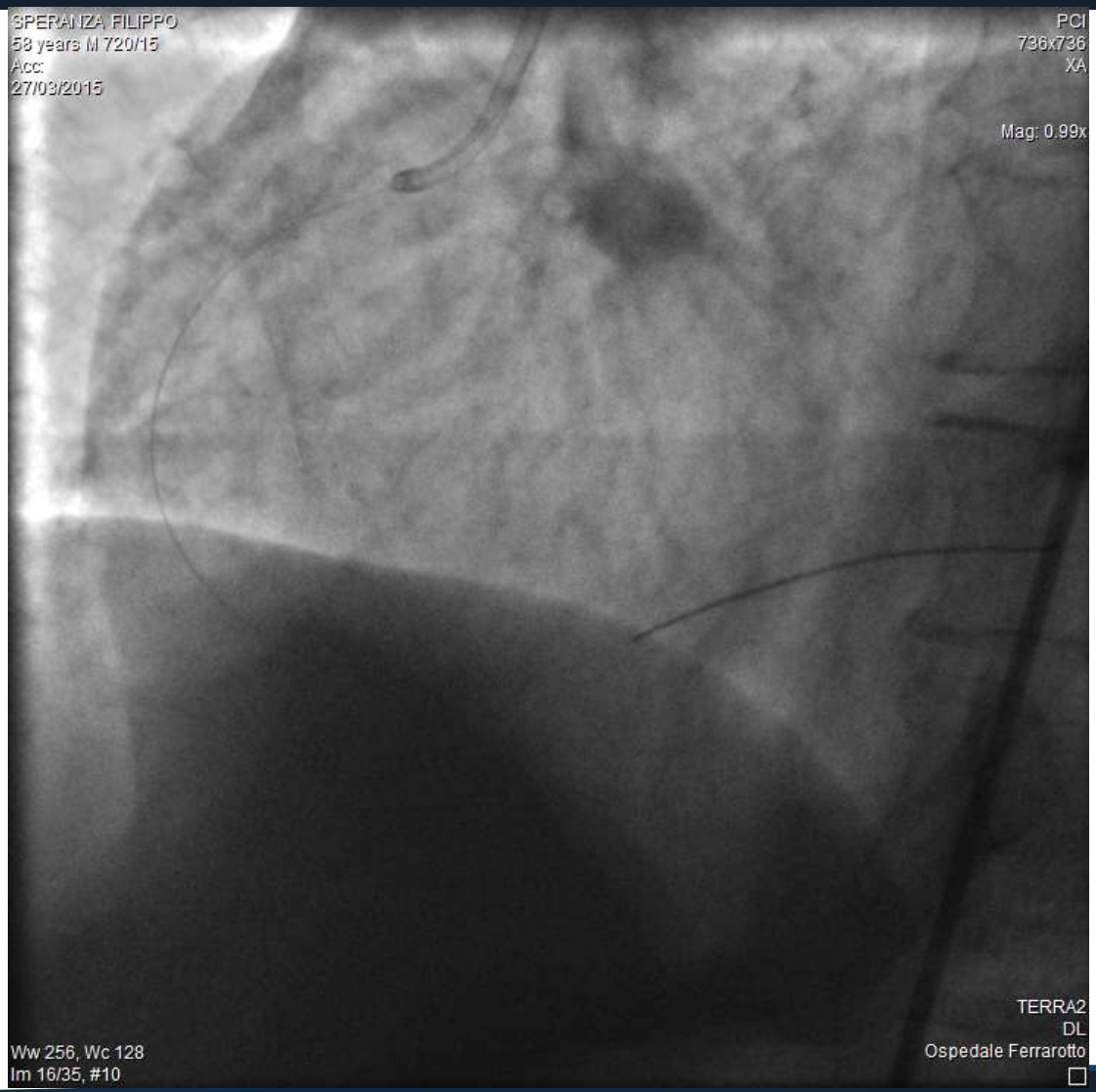


PCI on CDX: pre-dilatation



Pre-dilatation was performed using 2.75 s.c balloon and 3.0 N.C. balloon

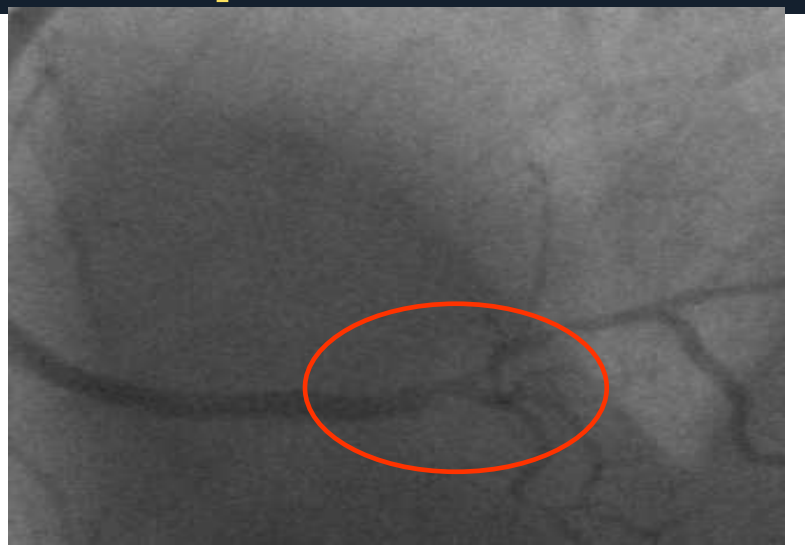
PCI on CDx after pre-dilatation

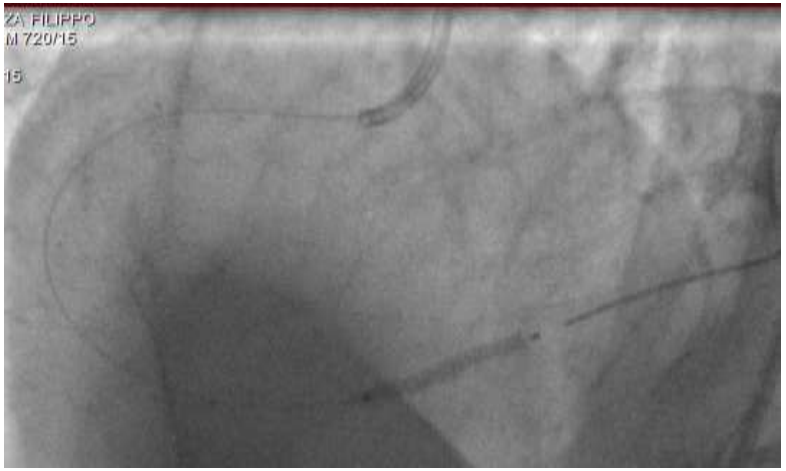


PCI on CDX: BVS implantation

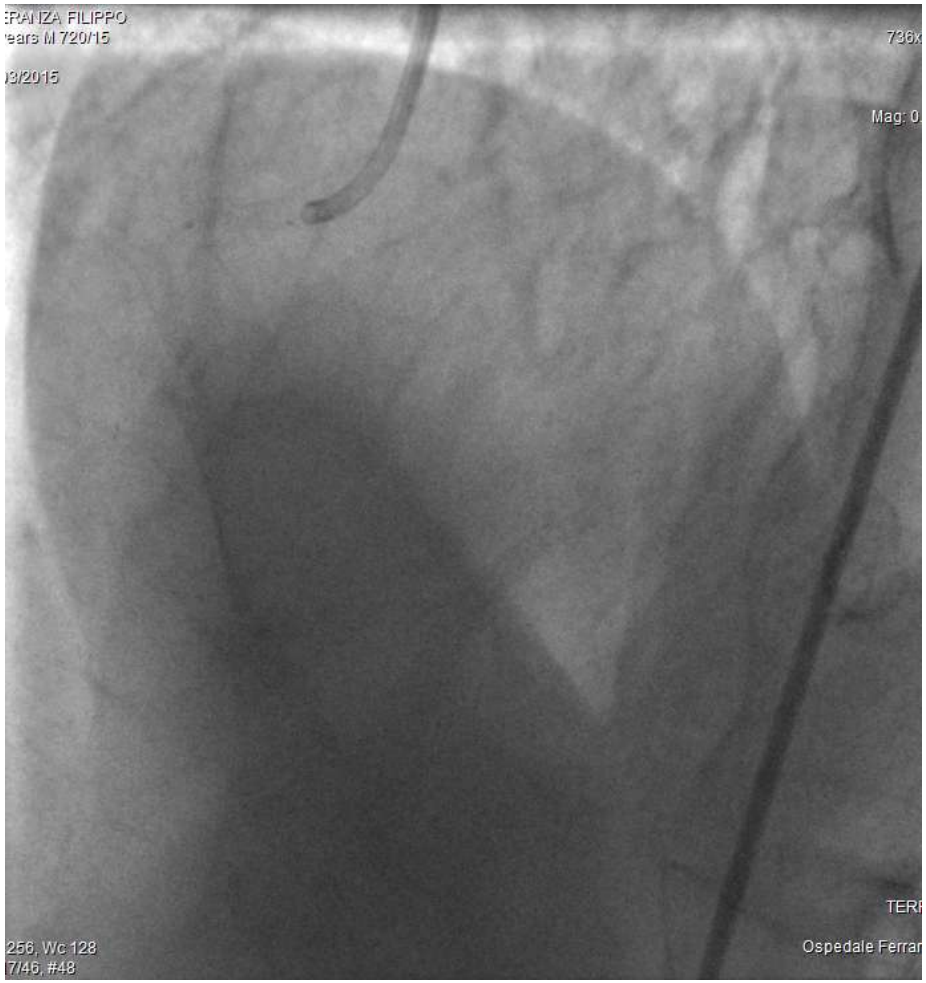
PCI was performed with implantation of 4 BVS : distal to proximal were 2.5x28 mm, 3.0x28 mm, 3.5x28 mm and 3.5x12 mm. Post-dilatation was performed using 3.0/30 N.C balloon

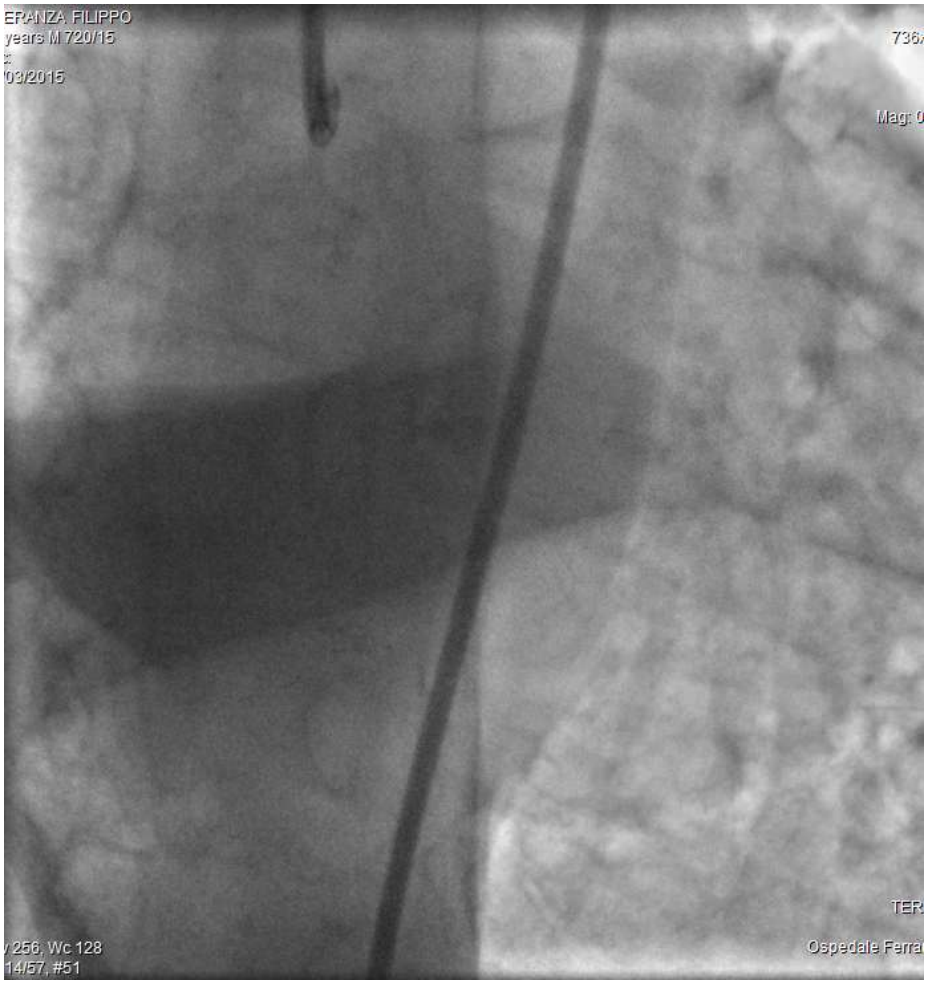
PCI on CDX: after BVS implantation



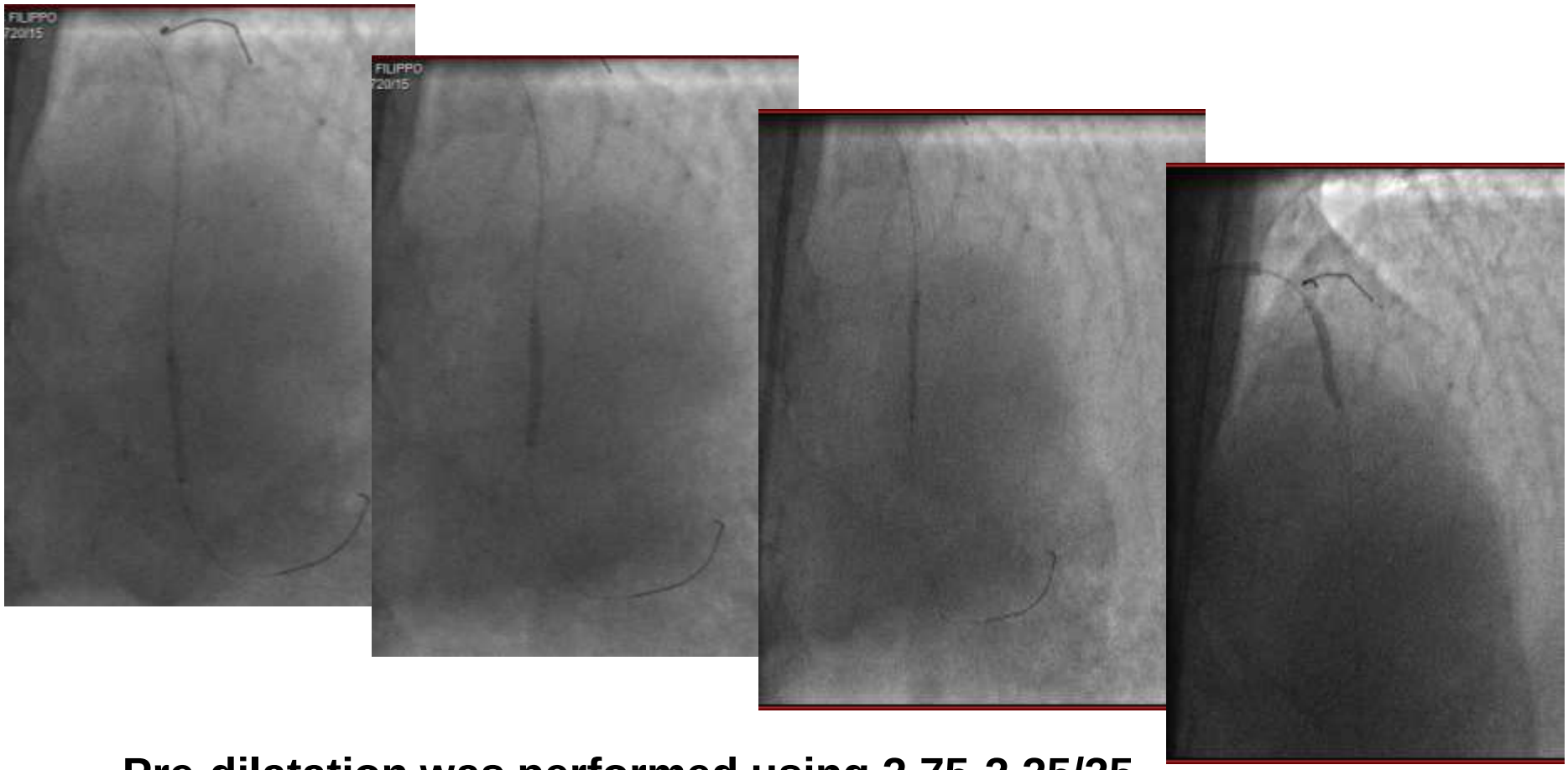


PCI on CDx: final result



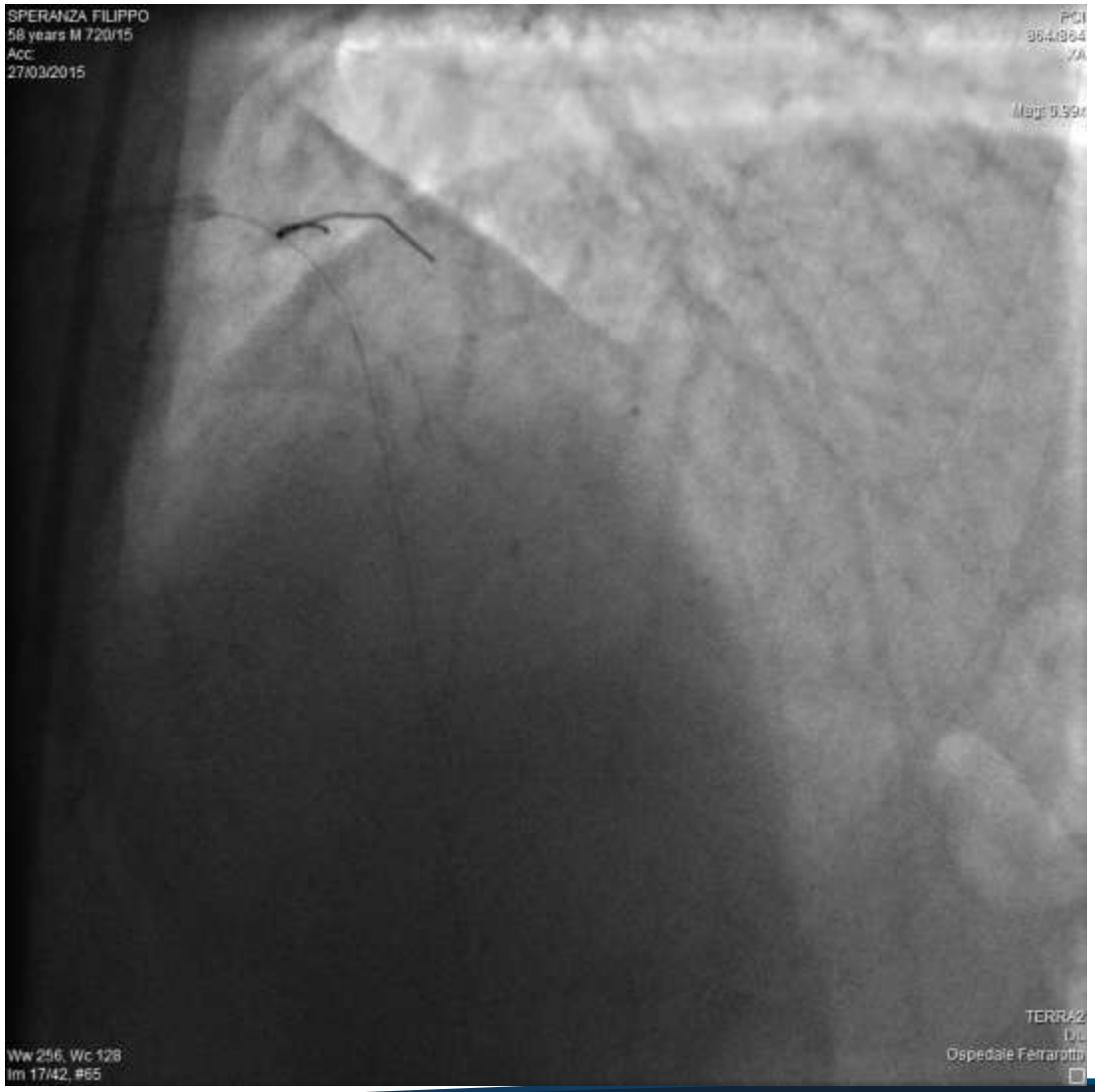


PCI on LAD: pre-dilatation



Pre-dilatation was performed using 2.75-2.25/25 mm conic balloon and 3.0/30 mm s.c. balloon

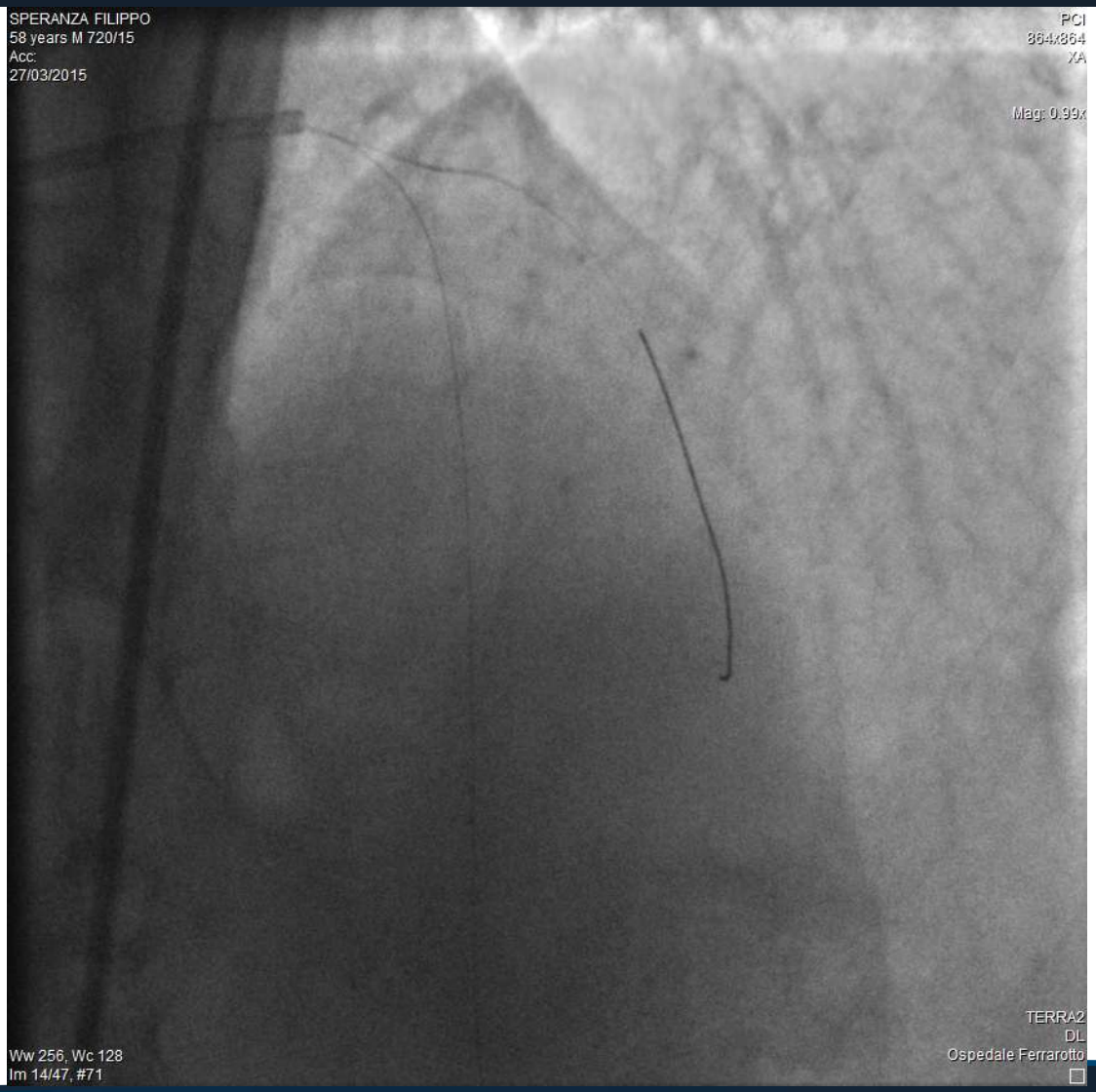
PCI on LAD after pre-dilatation



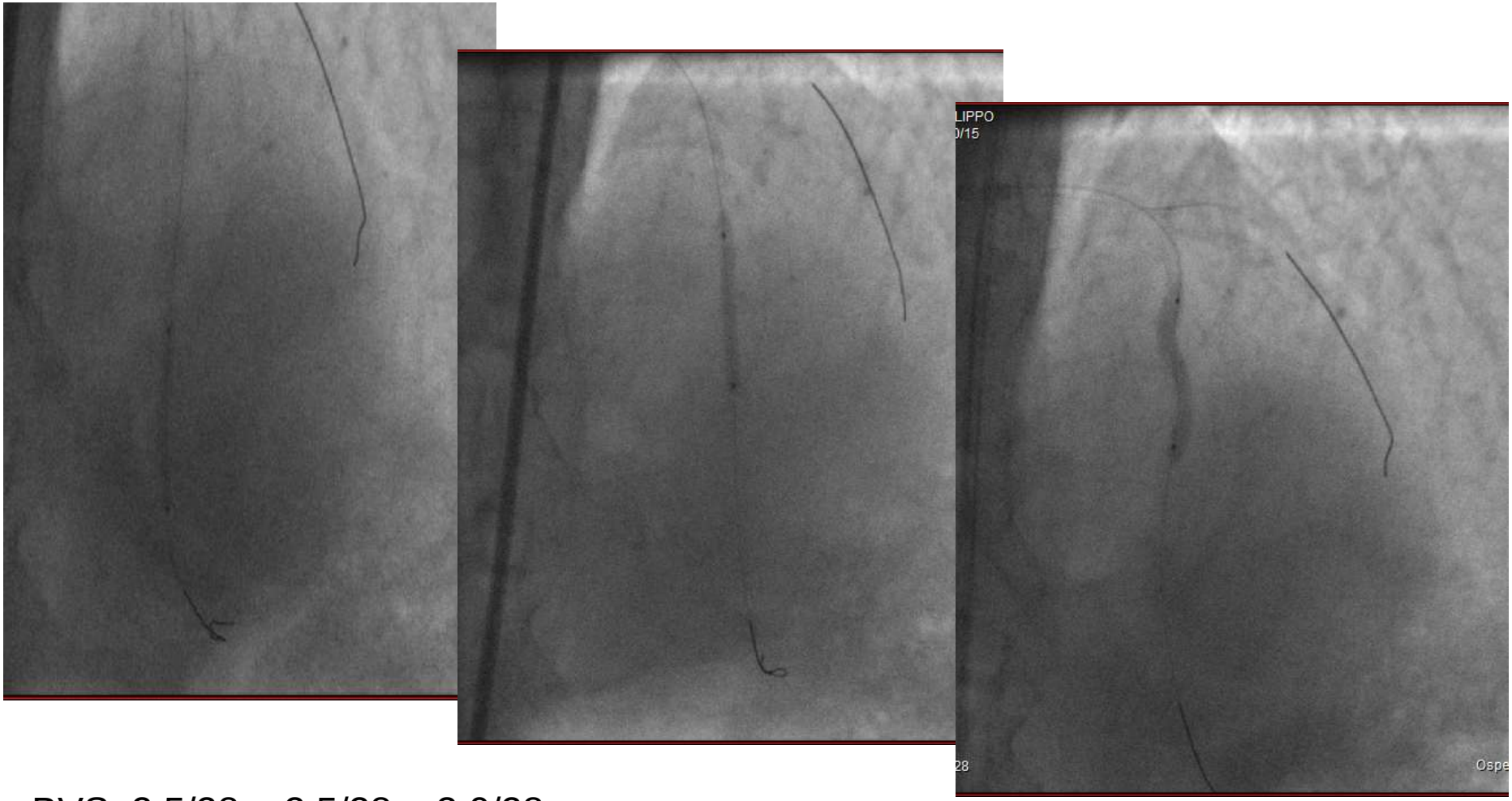
PCI on LAD: cutting balloon

Multiple dilatations with cutting balloon 2.5/15 mm

PCI on LAD: after cutting balloon

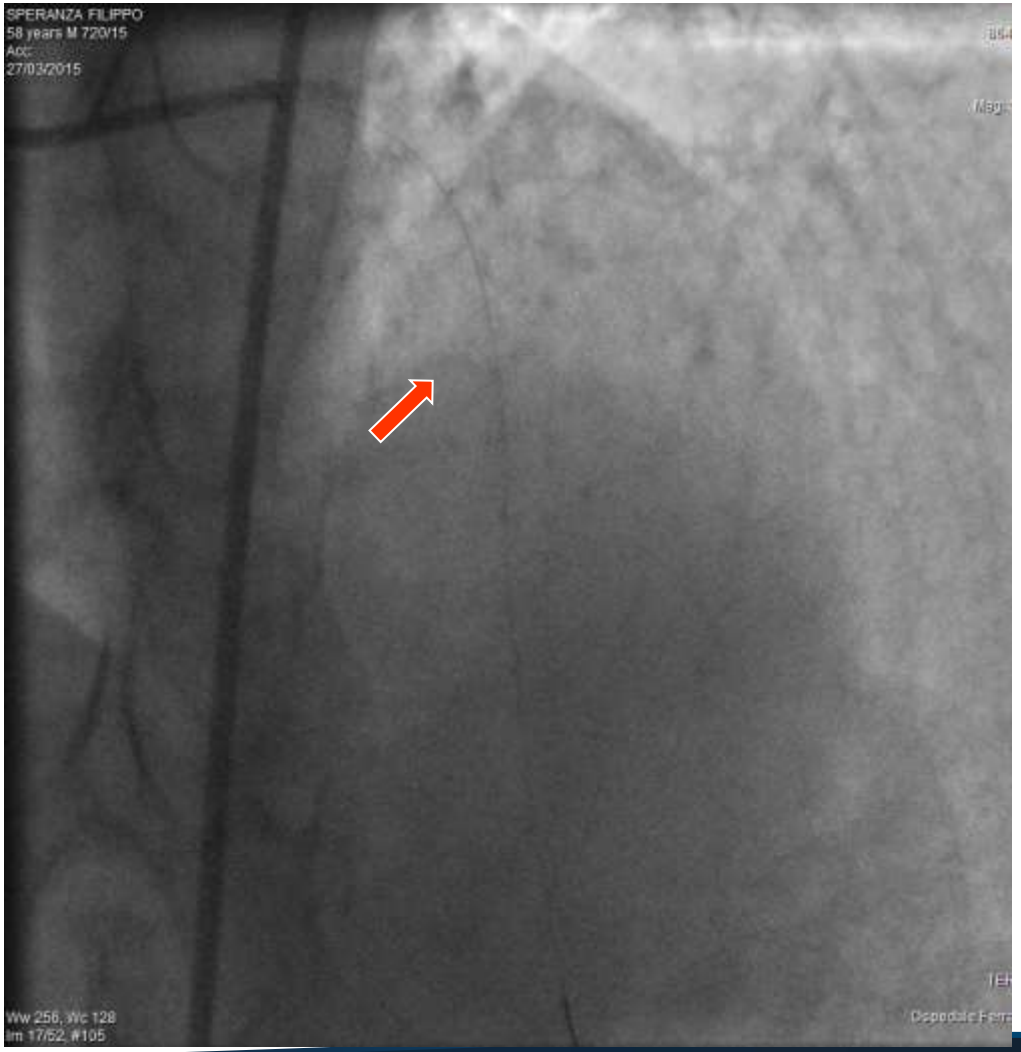


PCI on LAD: BVS implantation



BVS: 2.5/28 + 2.5/28 + 3.0/28

After BVS, angiogram showed luminal irregularities suggestive of intramural hematoma

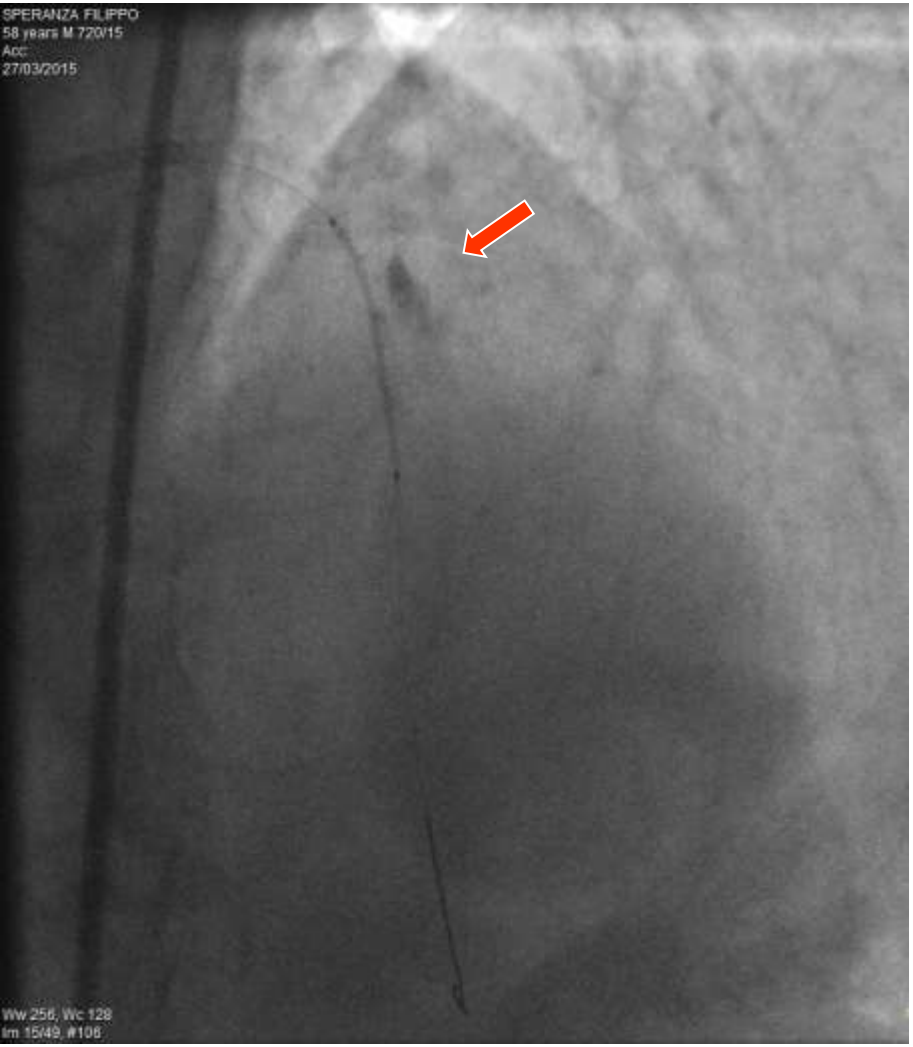


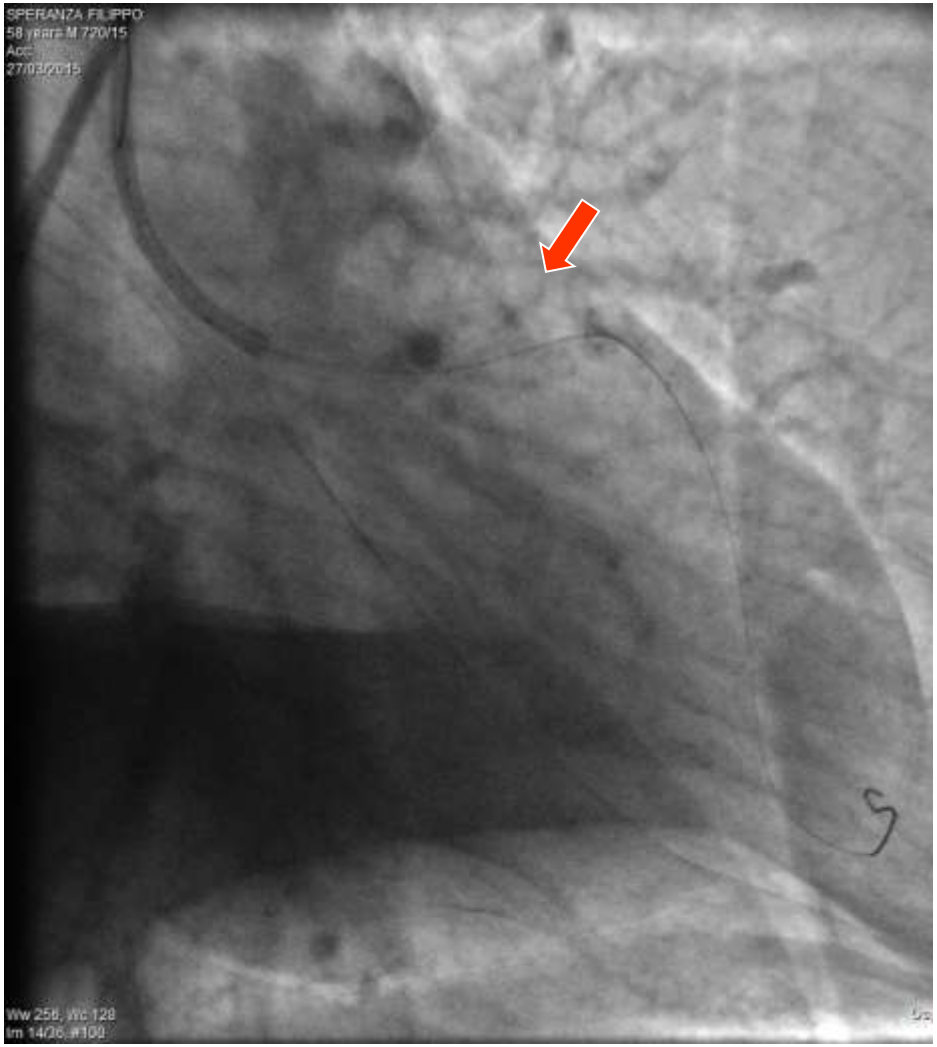
PCI on LM

Pre-dilatation with s.c. balloon 3.5/12 mm

DES 4.0/12 mm

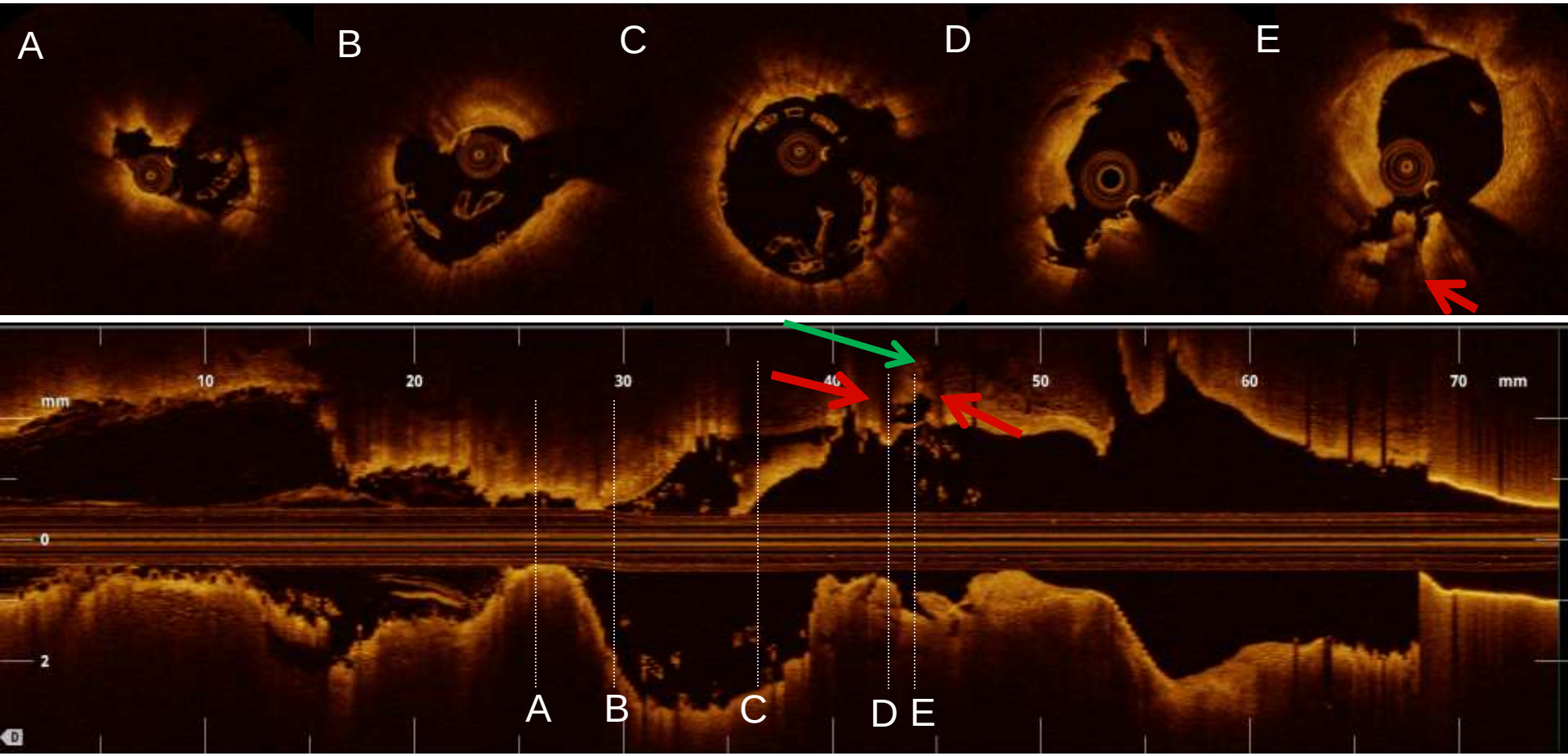
PCI on LM: result



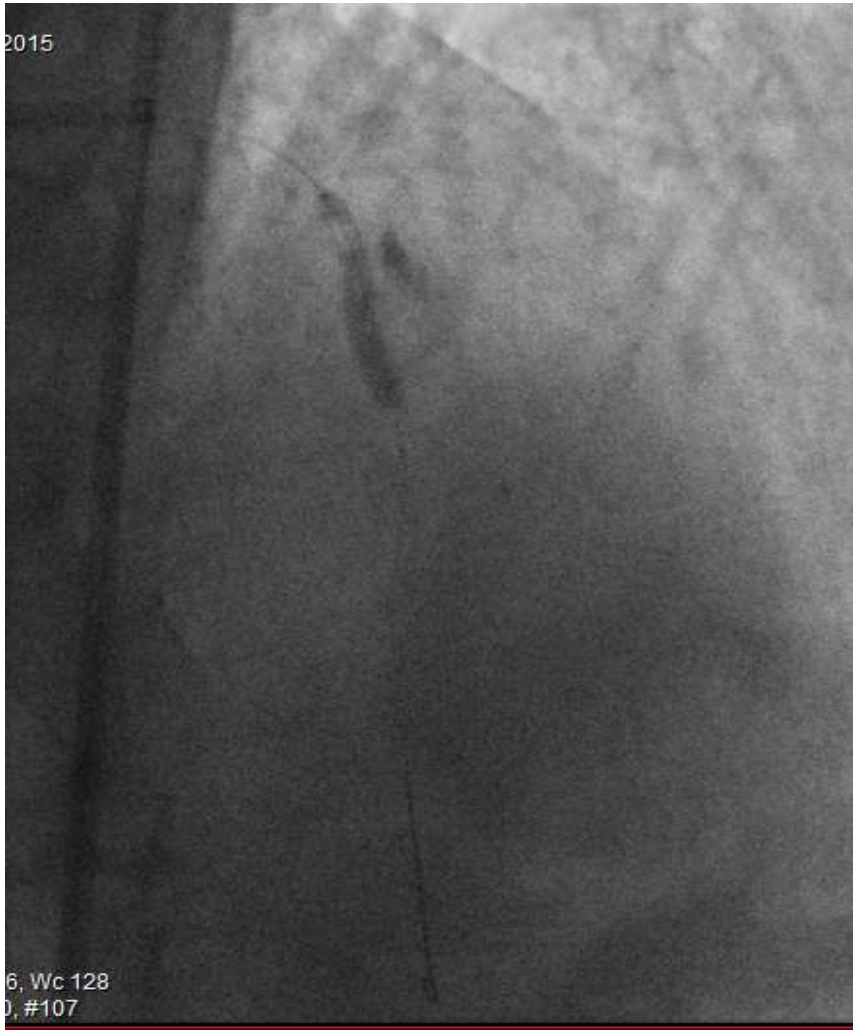


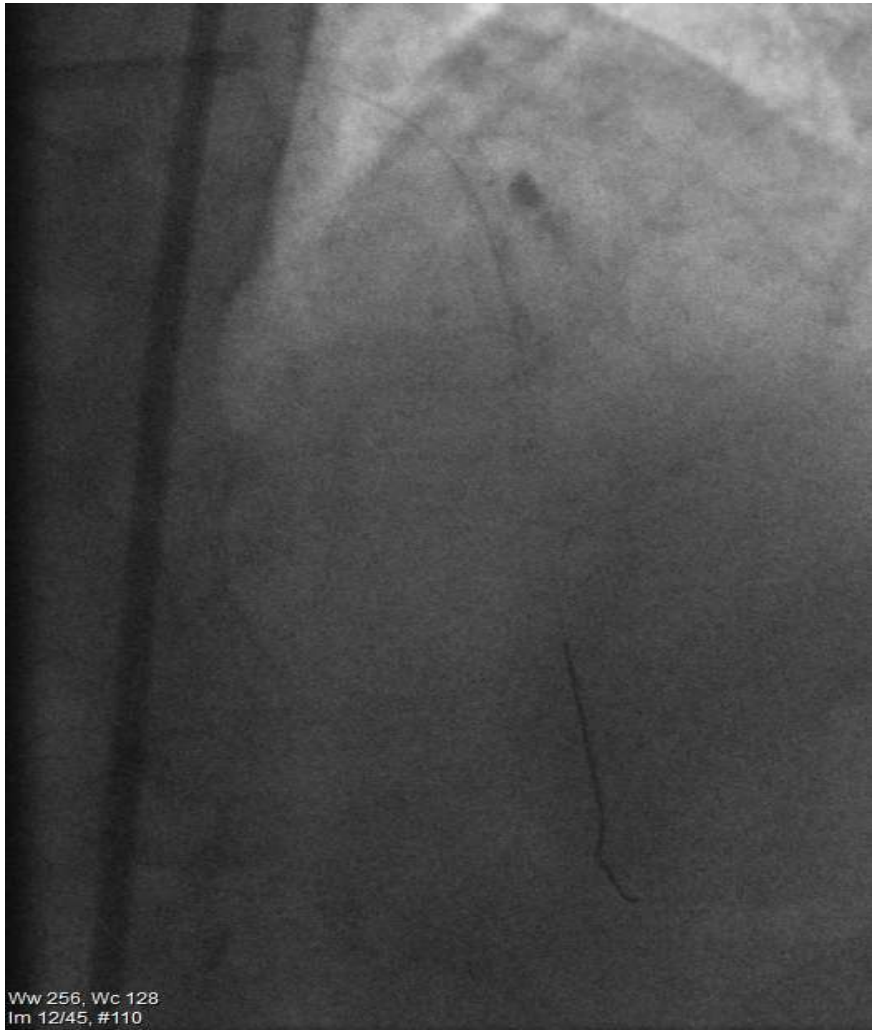
Angiogram showed contrast extravascular effusion suggestive of coronary perforation

OCT after BVS impantation



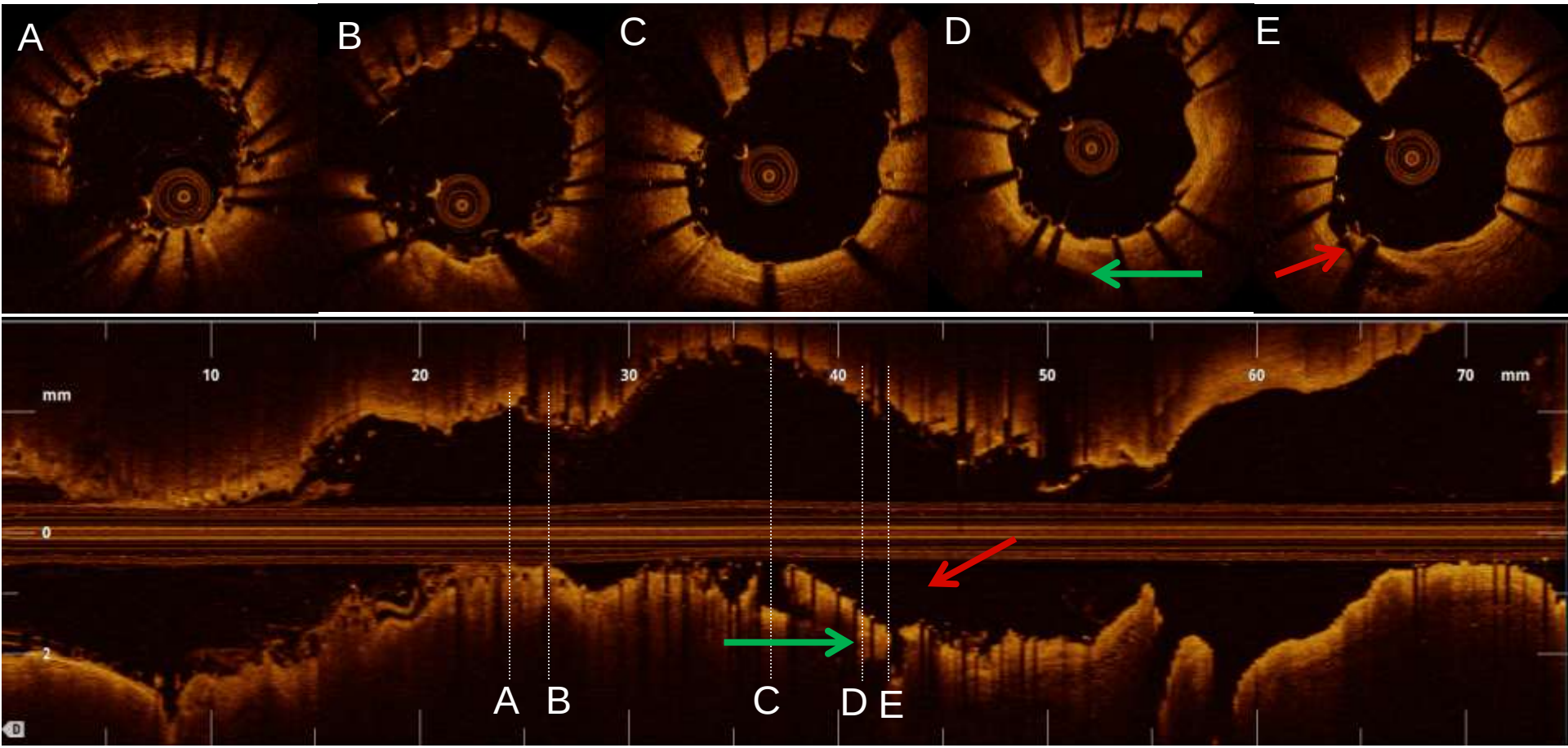
DES on LAD





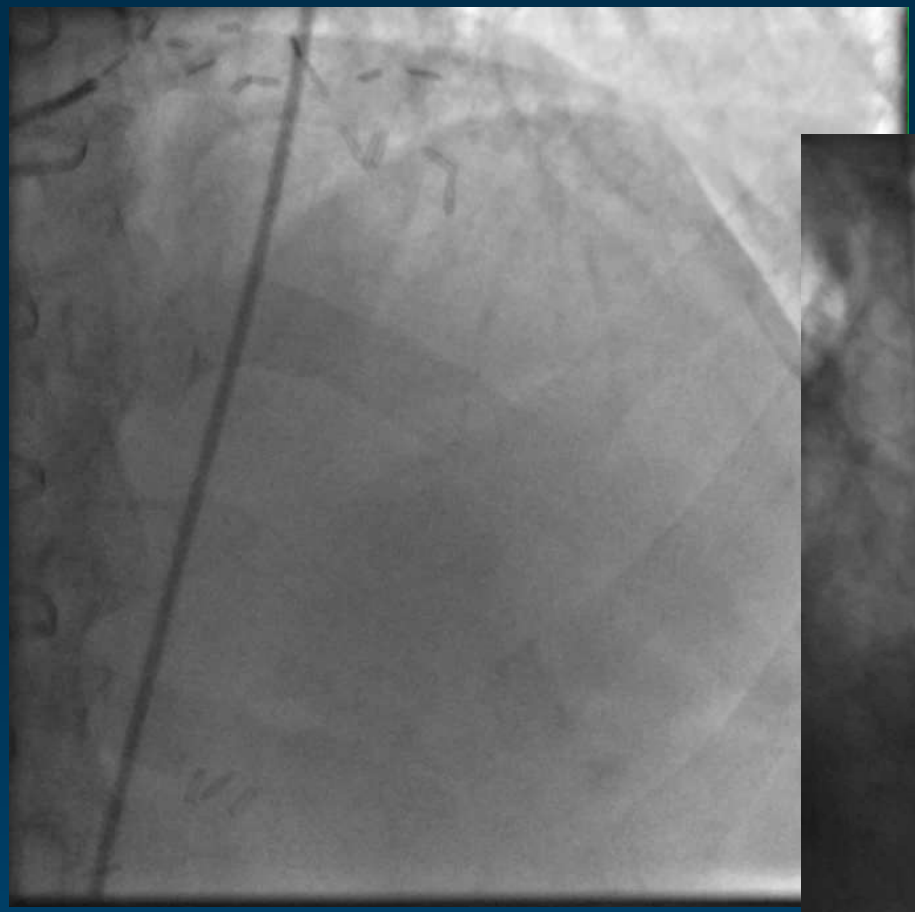
OCT showed that perforation was due to huge dissection, so we decided to use a normal DES (and not a covered stent) in order to close the «dissection tunnel».

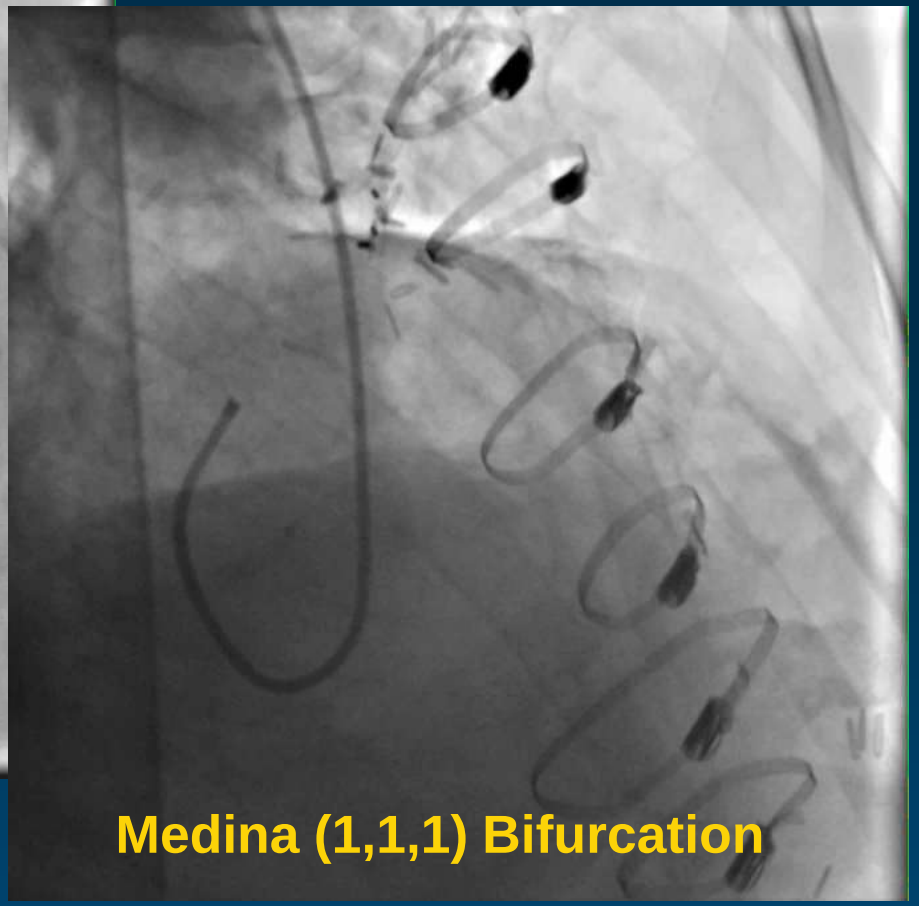
OCT after DES implantation



Case #4
BVS implantation in COMPLEX true bifurcation – 8m FU

The Lesion



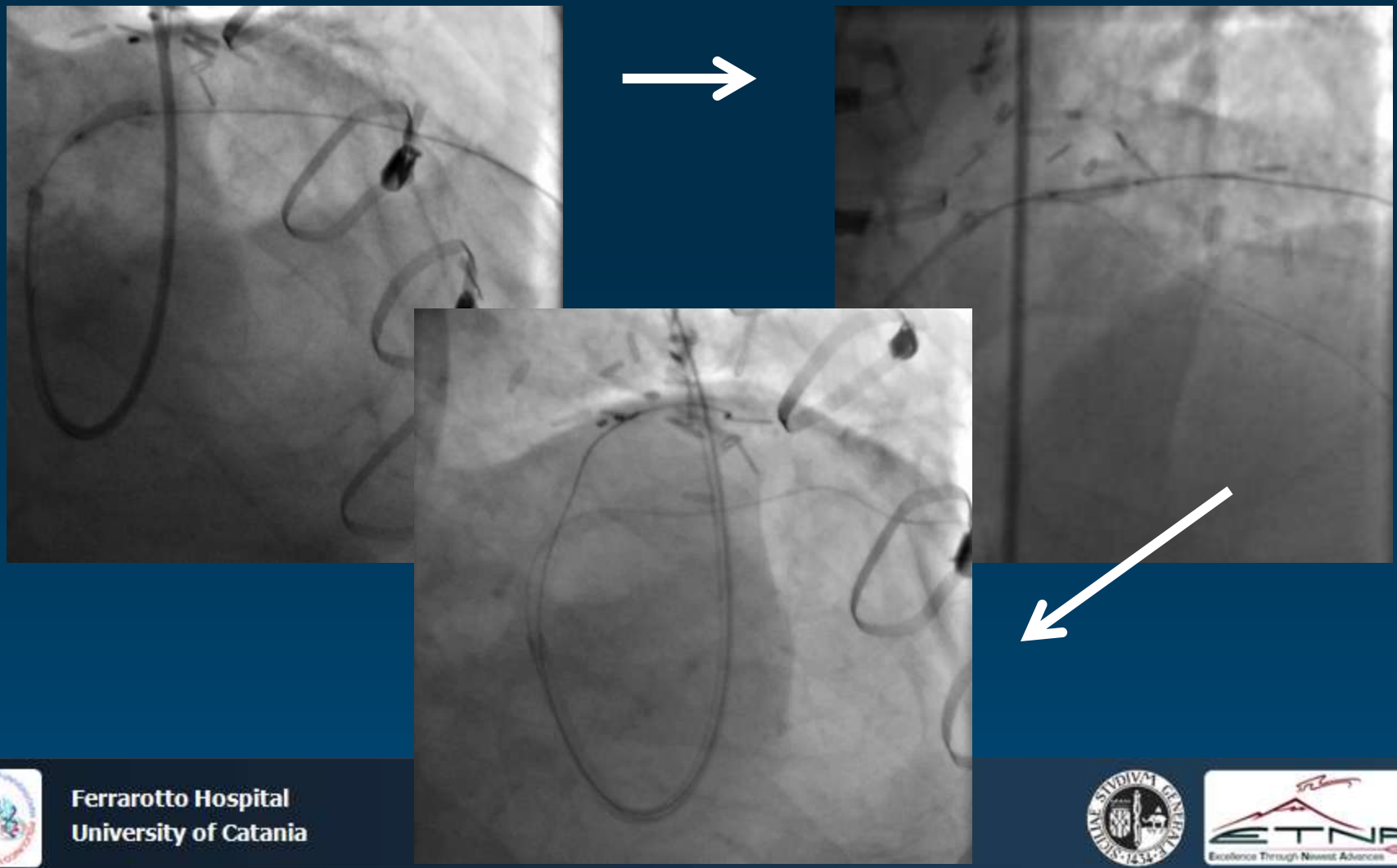


Medina (1,1,1) Bifurcation

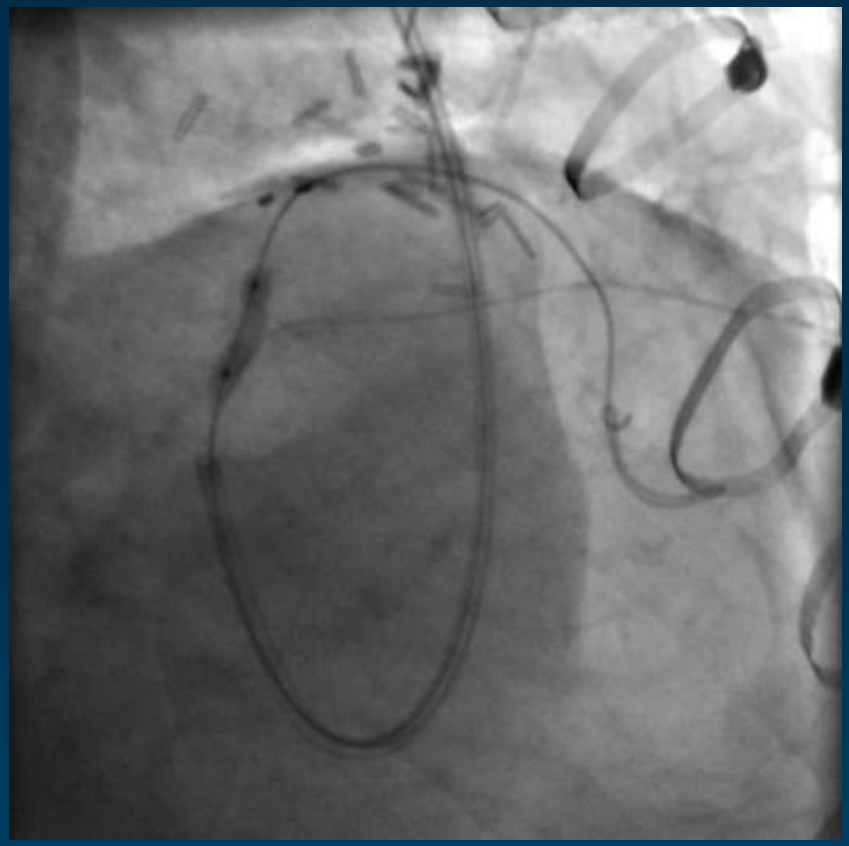
Lesion Preparation

POBA to LAD with SC balloon 2.5/12 mm

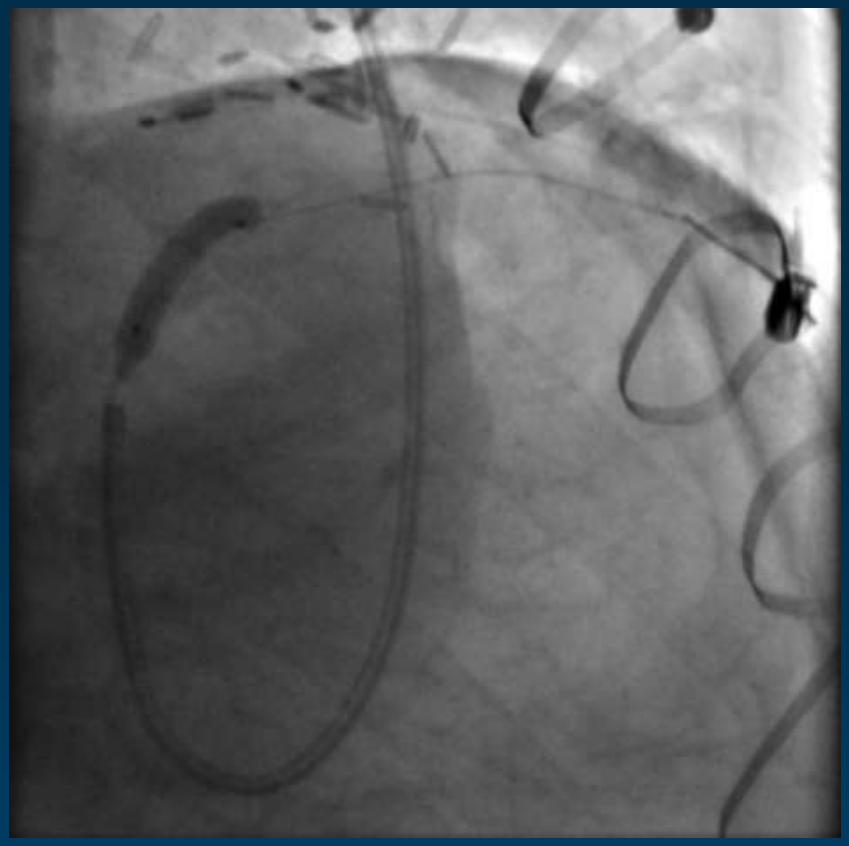
POBA to D1 with SC balloon 2.5/12 mm



BVS Implantation



BVS 2.5x12mm @ 14atm (D1)

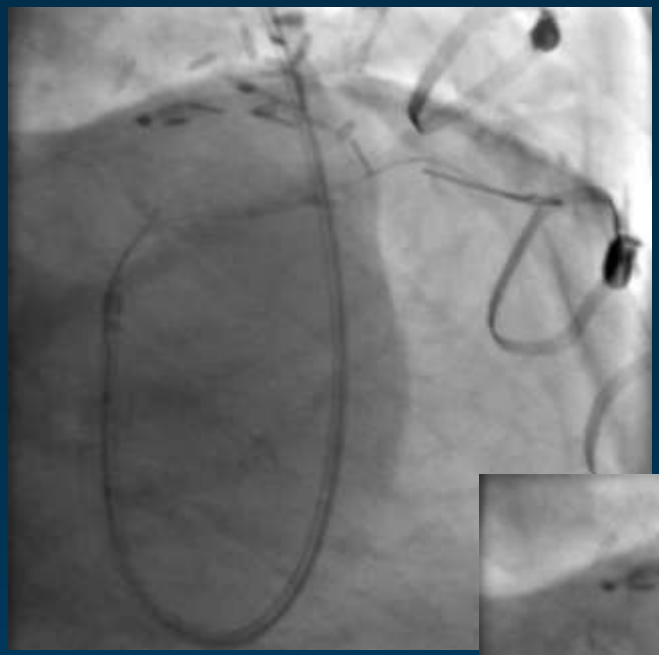


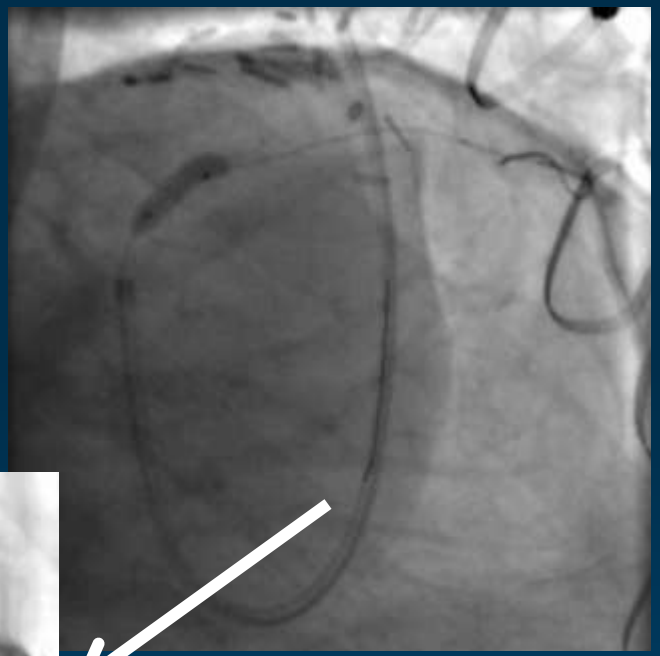
BVS 3.0x18mm @ 14atm (LAD)

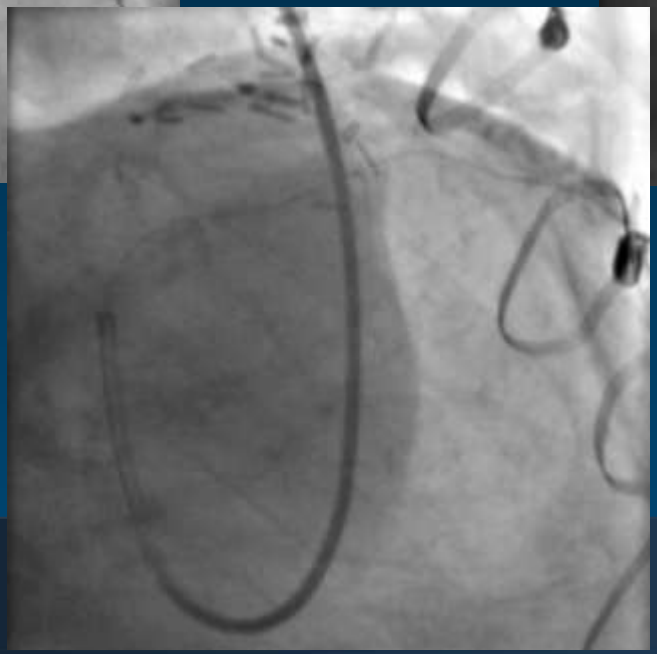
Complication

Difficult to re-wire D1

In-BVS post dilation with 3.0x15mm NC

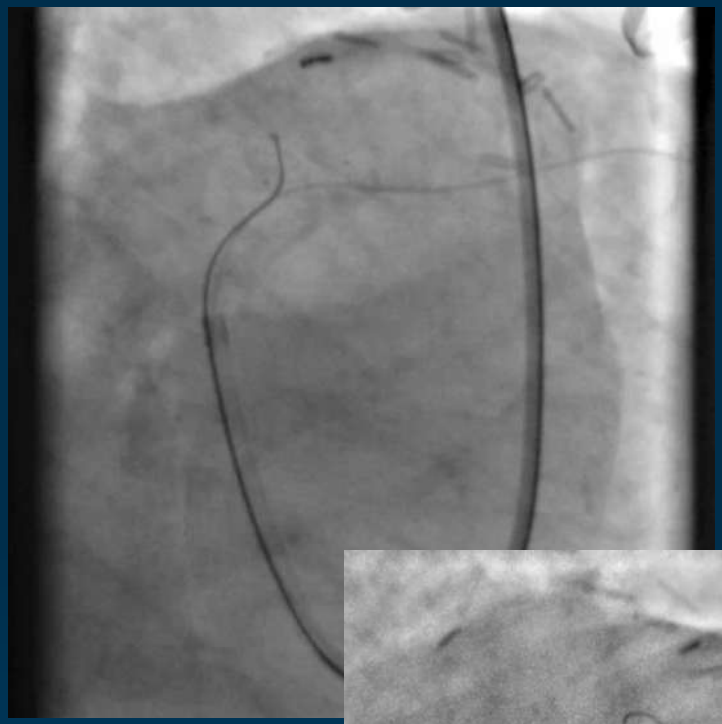




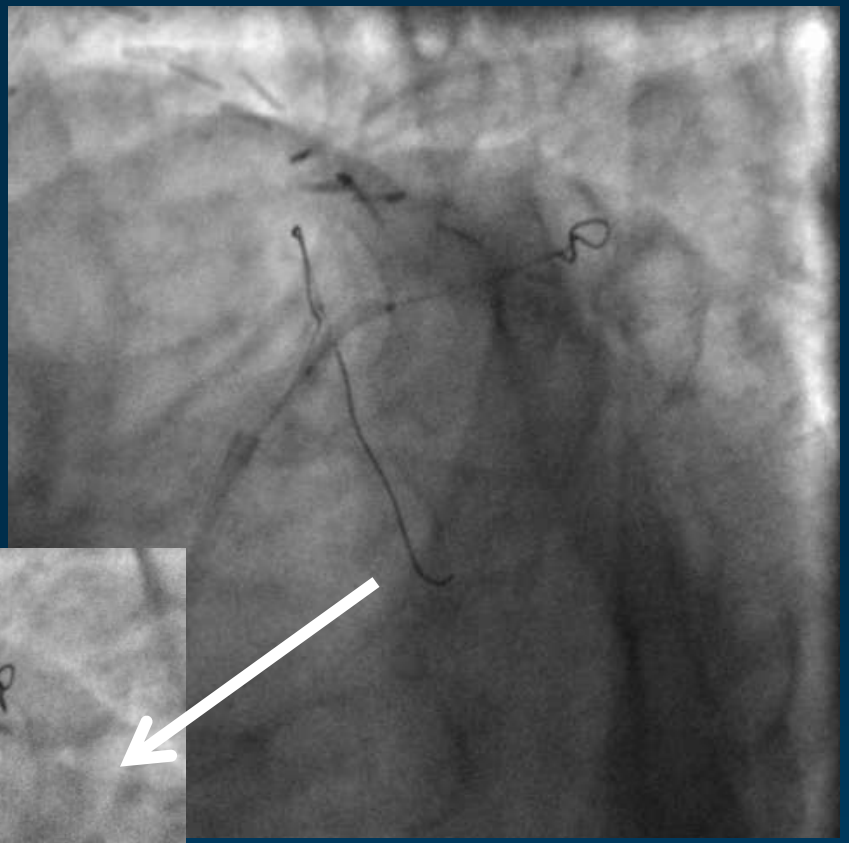


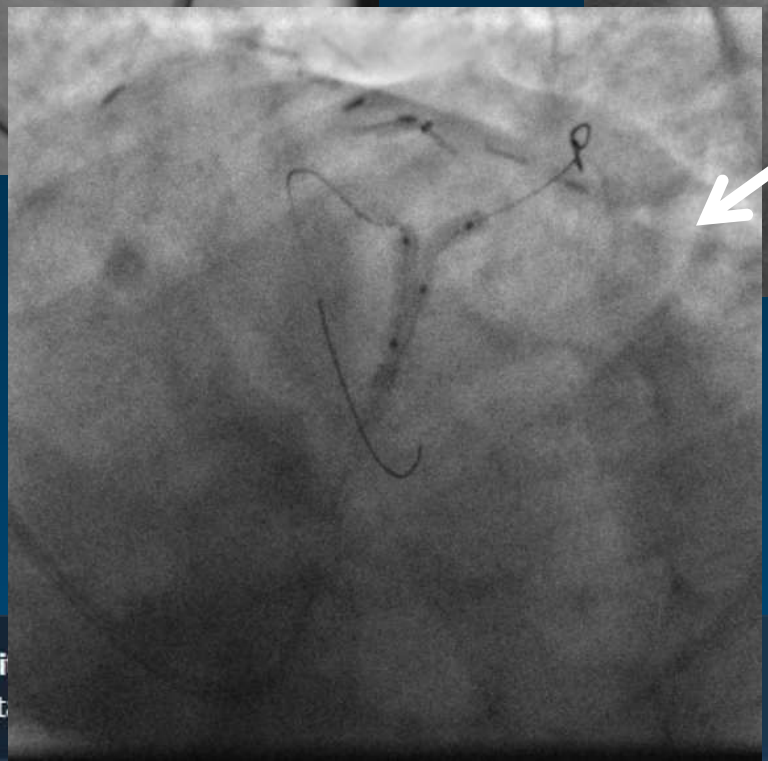
TIMI 0 in D1 (side branch occlusion)

Side branch wiring with hydrophilic wire



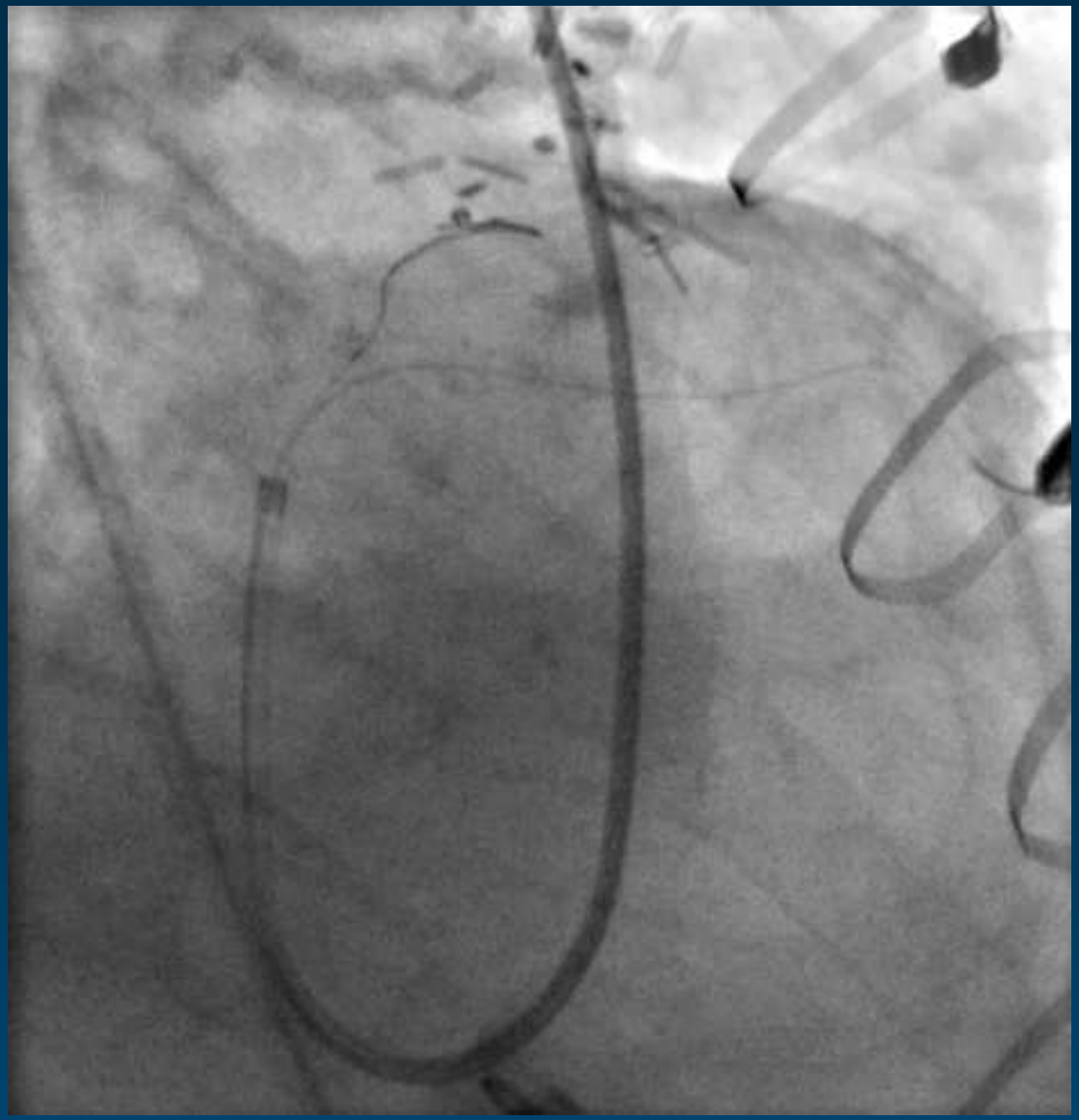
POBA to D1 with balloon 2.0/15 mm



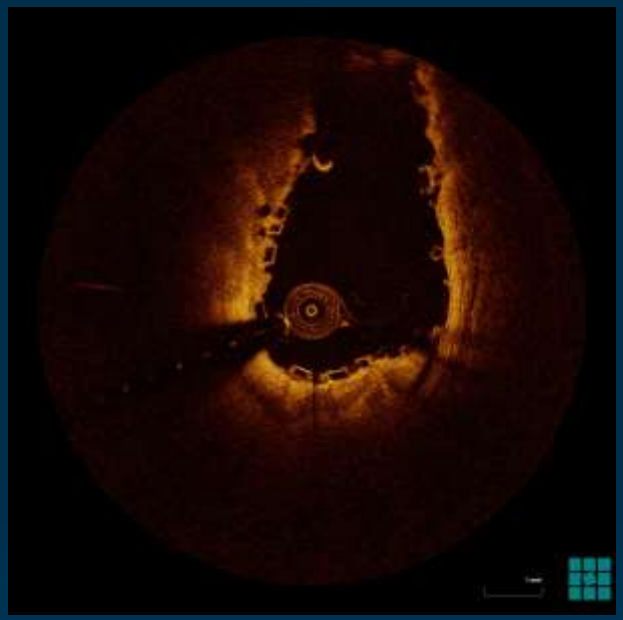


Mini KBT with
3.5+2.5 mm @ 8atm

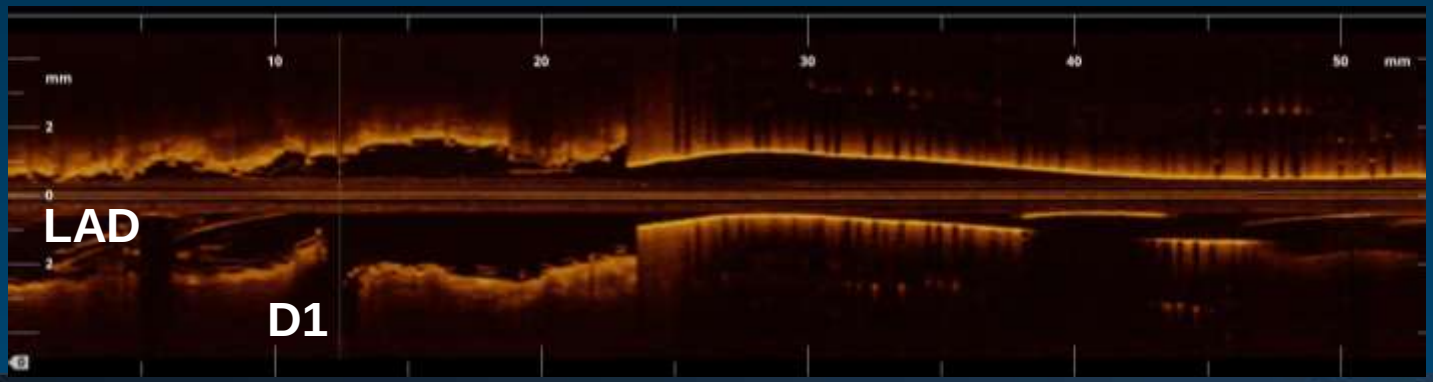
Final Angiography



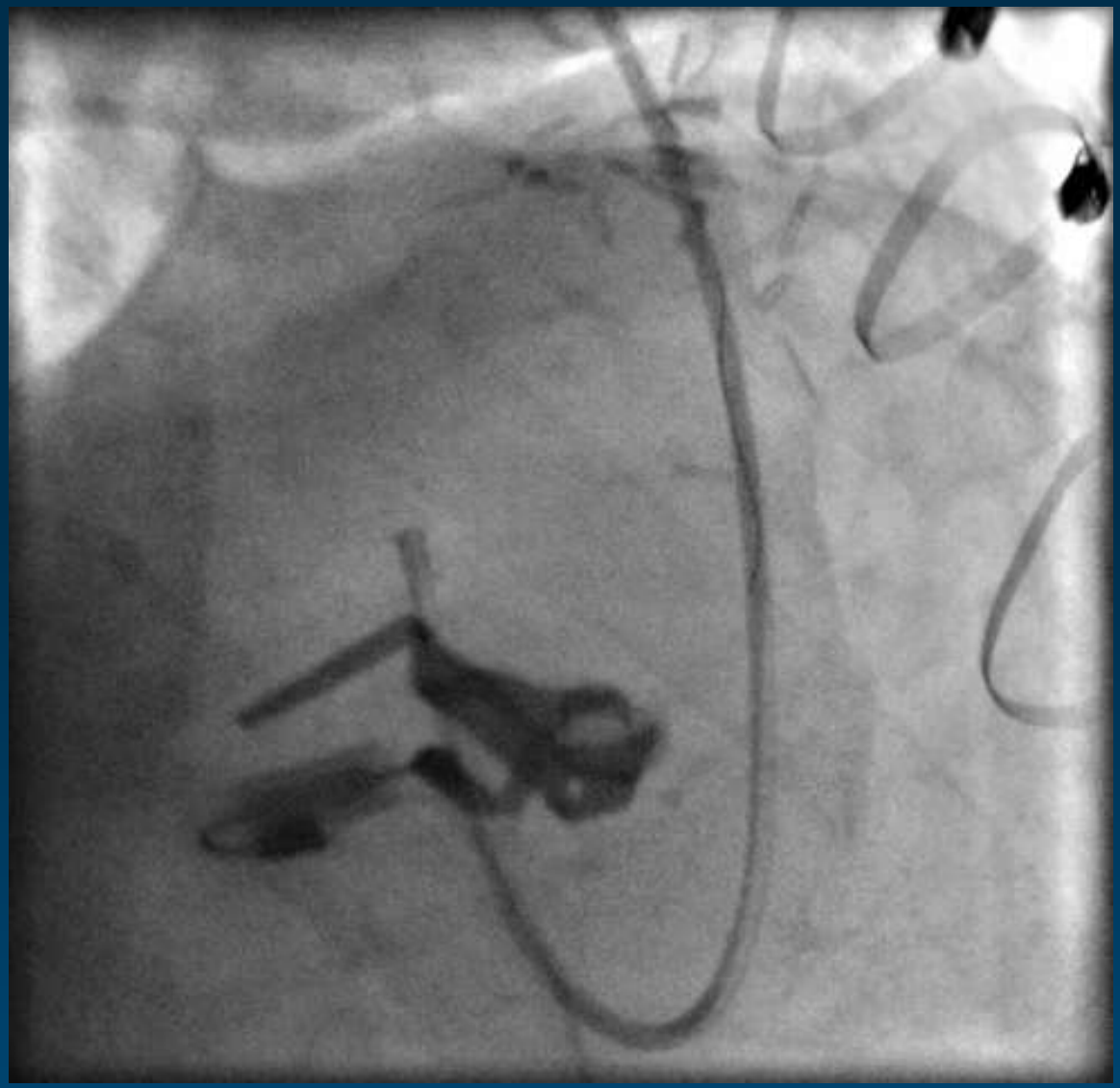
OCT after mini-KBT



Struts are nicely open and well apposed to the vessel wall.

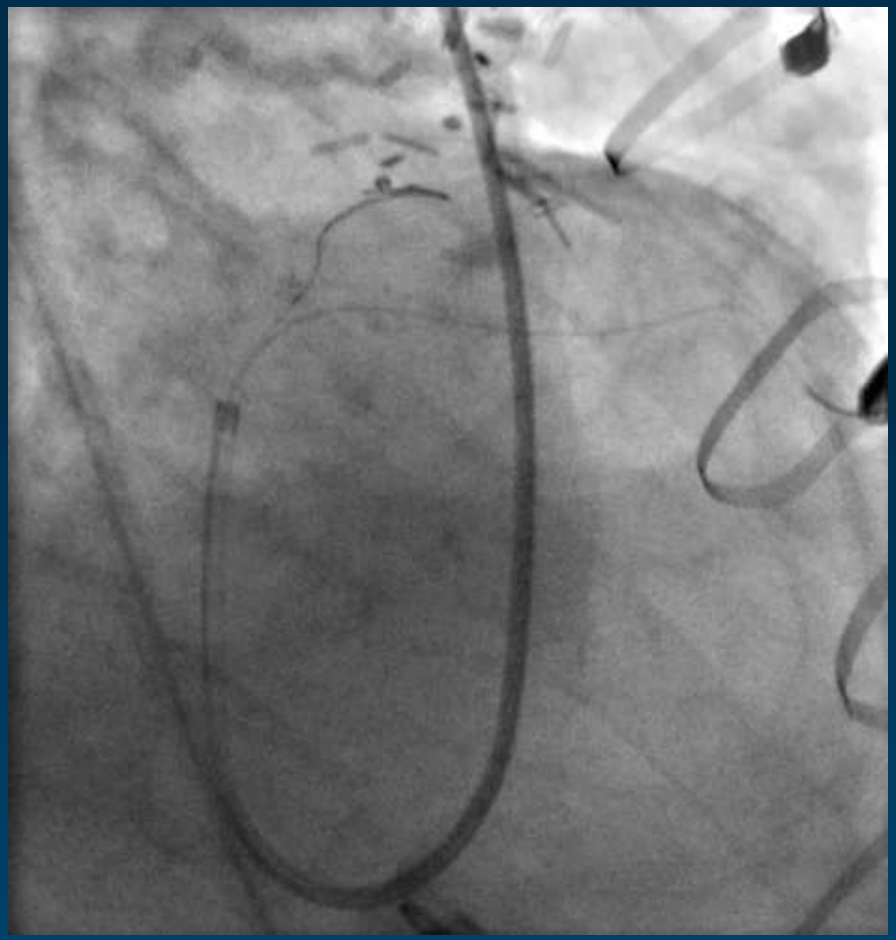


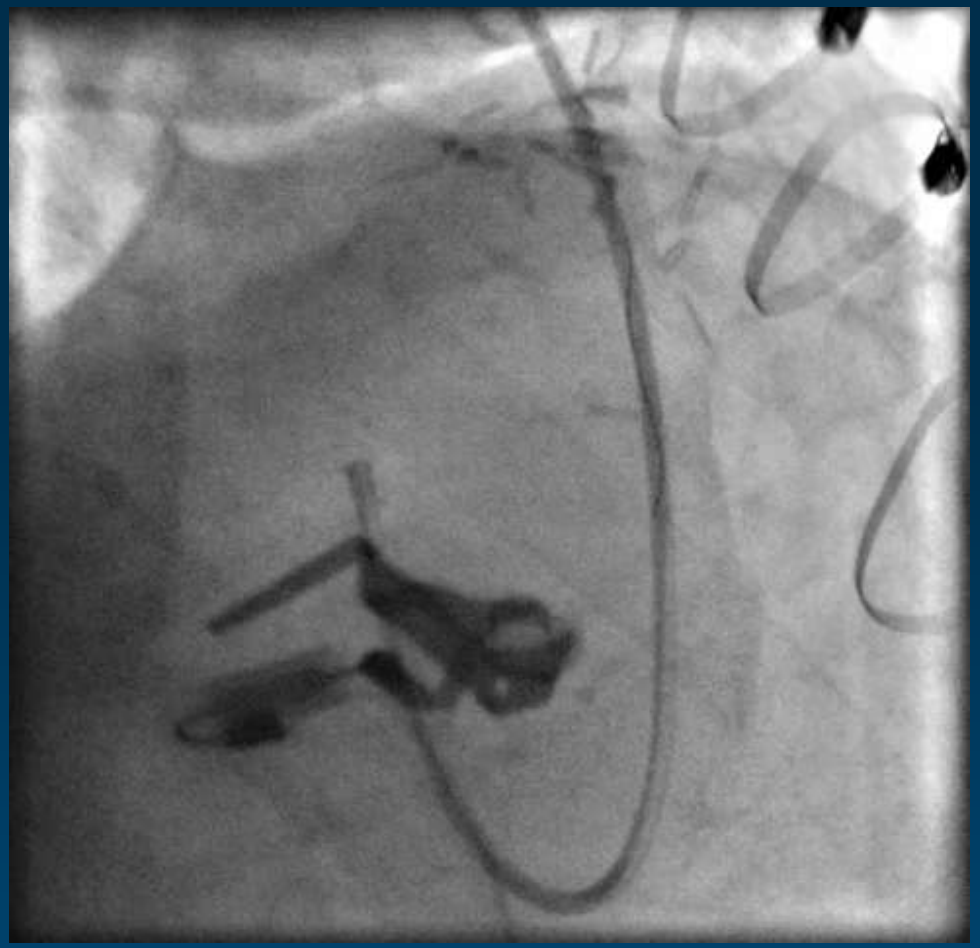
After 8 months, atipical chest pain, angiography



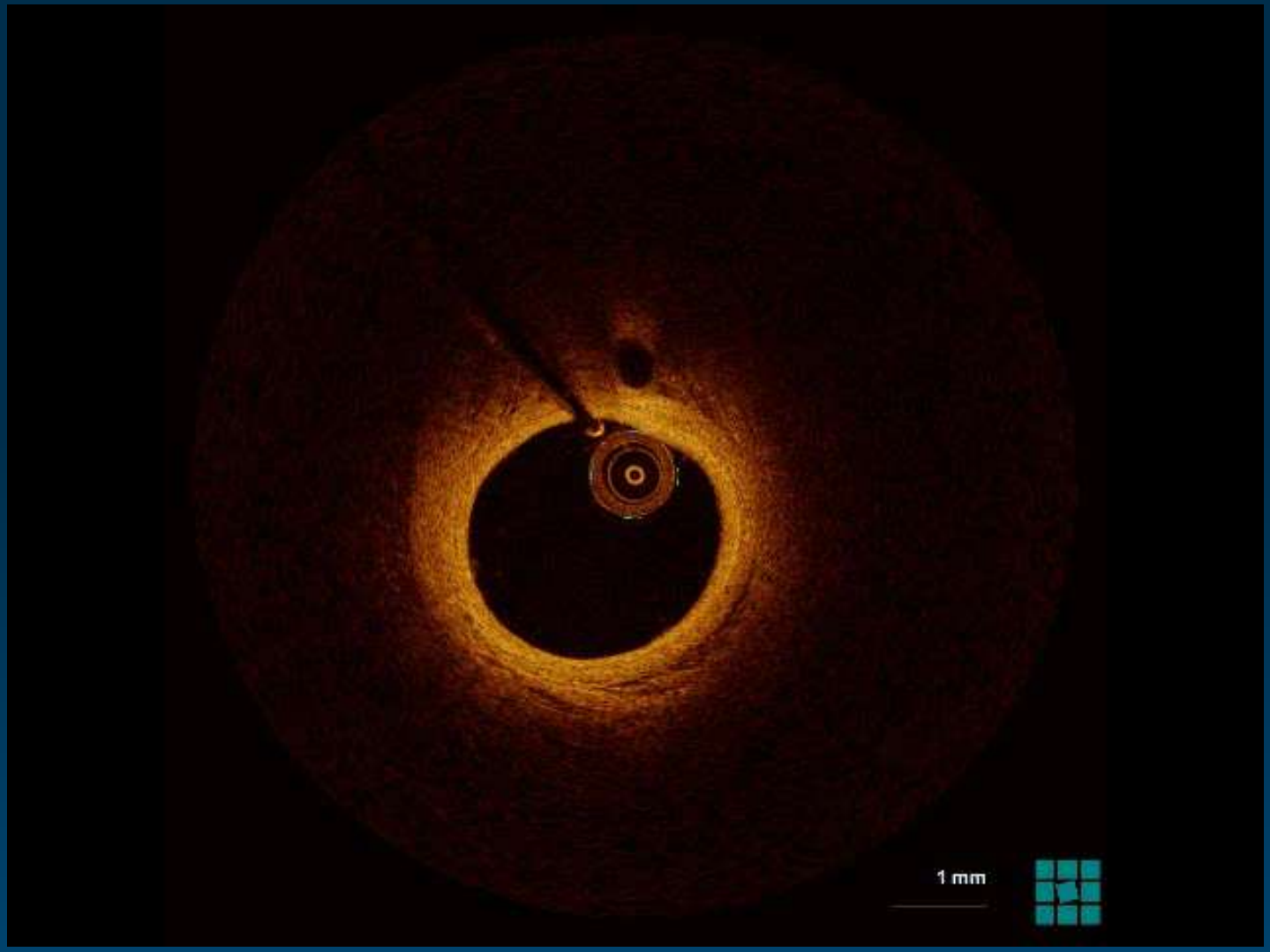
Index procedure

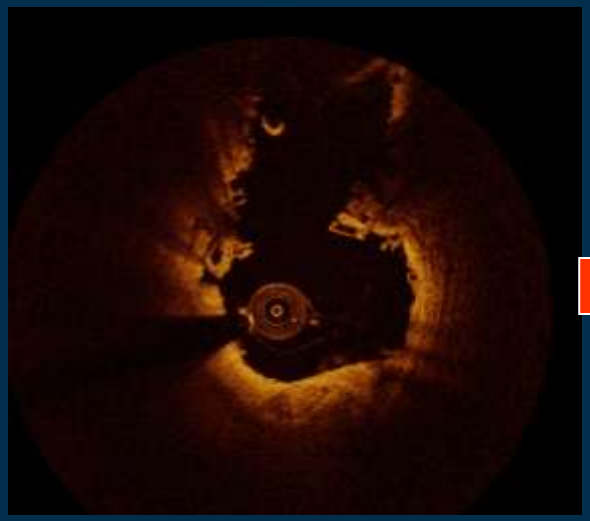
8 months



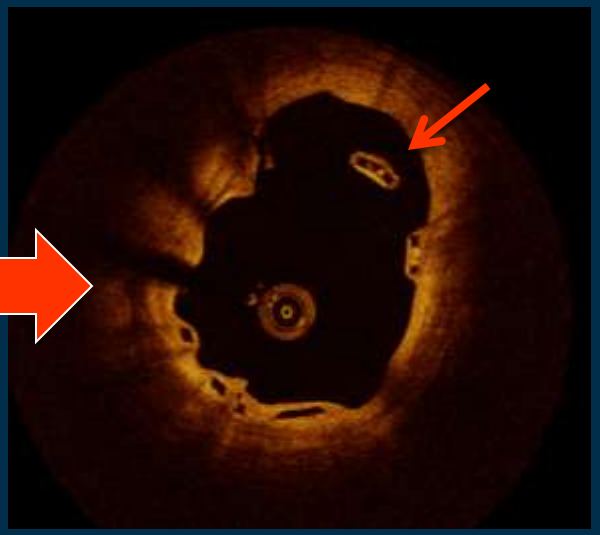


8 months FU: OCT run at the site of BVS

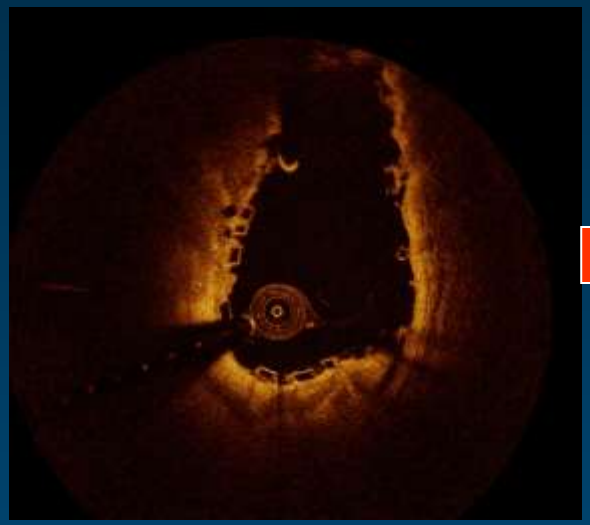


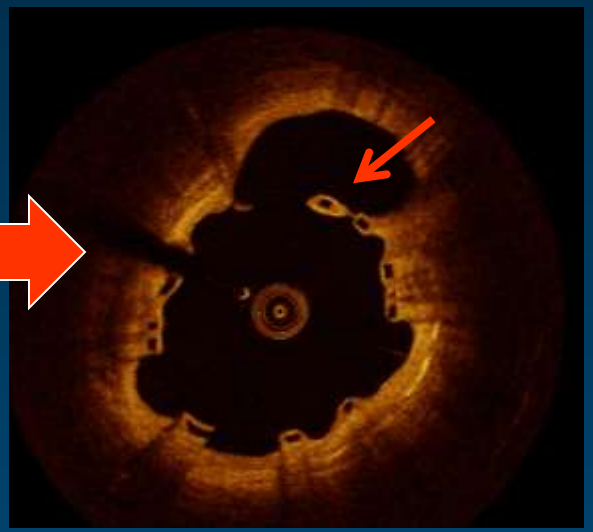


Index procedure OCT



8 months follow-up OCT





At 8 months f.u. OCT showed good result of PCI at the bifurcation. Floating-covered struts are still visible in the side branch lumen (arrows)

Lessons from Absorb registries

1. Accurate Patient and Lesion assessment and selection (more data are needed to define the best candidate for BVS)
    1. 20% of cath-lab PCI volume
2. Lesion preparation: stent-like result
3. Accurate sizing (tend to slight oversizing)
4. Adeguate Scaffold Implantation and Result optimization
    1. 2 atm every 5 seconds. Keep inflated 30 seconds, at high pressure
    2. post-dilatation (NC balloon + 0.5 nominal size), at high pressure
    3. Meticulous Ovelapping
5. More Liberal Imaging use, especially in complex setting
6. Optimal antiplatelet therapy