

Selection of drug-eluting balloons (DEB) vs drug-eluting stents (DES) for in-stent restenosis

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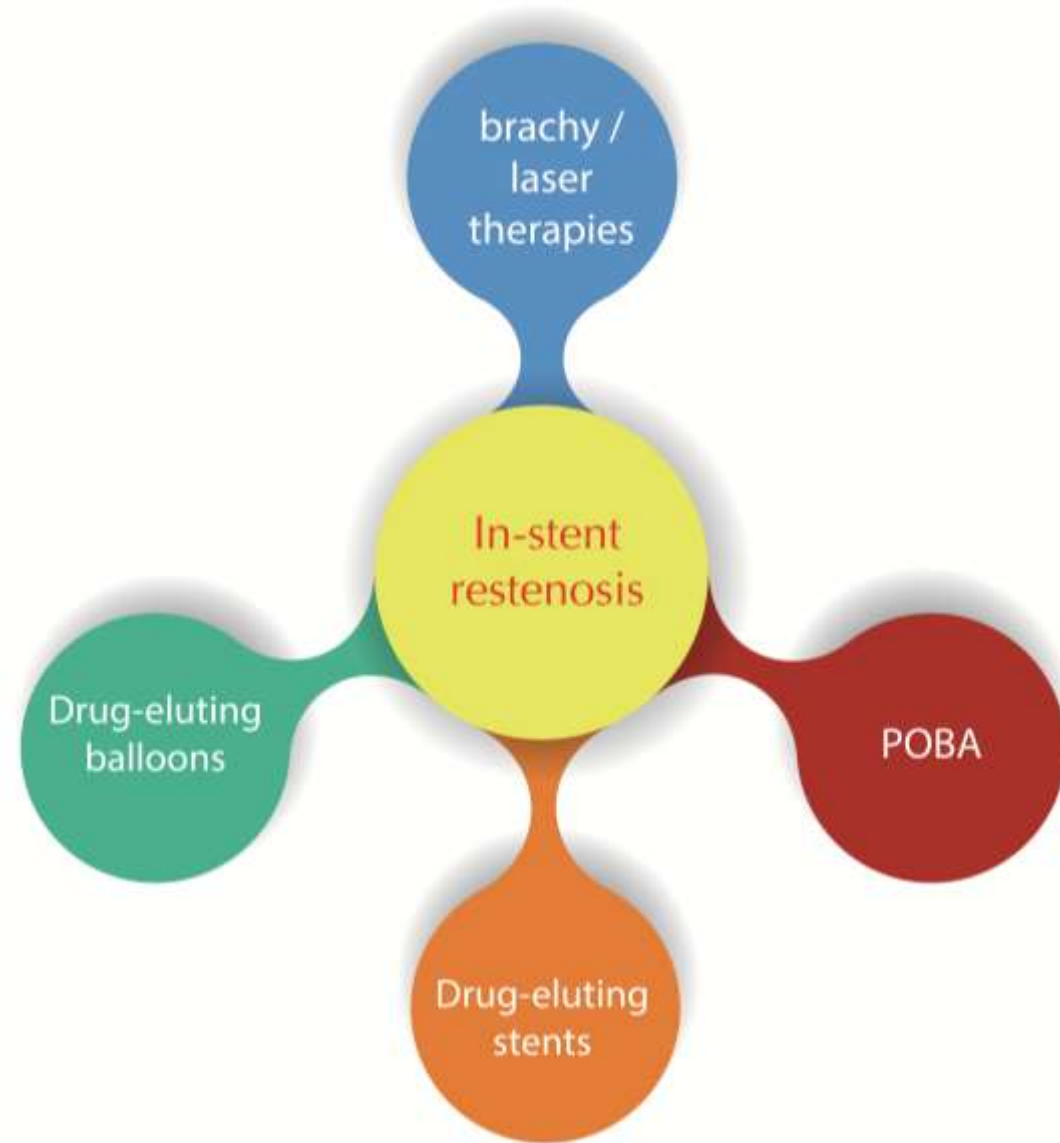
Outline

1. Brief Overview
 2. Case illustrations
 3. Take-home messages
- 

What we know

- Compared to the BMS era, the rate of in-stent restenosis (ISR) has been reduced by the introduction of DES
 - With DES however, the rate of ISR is still about 5-10%, but higher in diabetics, small vessels, and bifurcations
 - The first-line challenge is to reduce the frequency of ISR by using modern DES with a proper implantation techniques
 - In cases where ISR develops, more therapeutic options are available
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Therapeutic options for in-stent restenosis



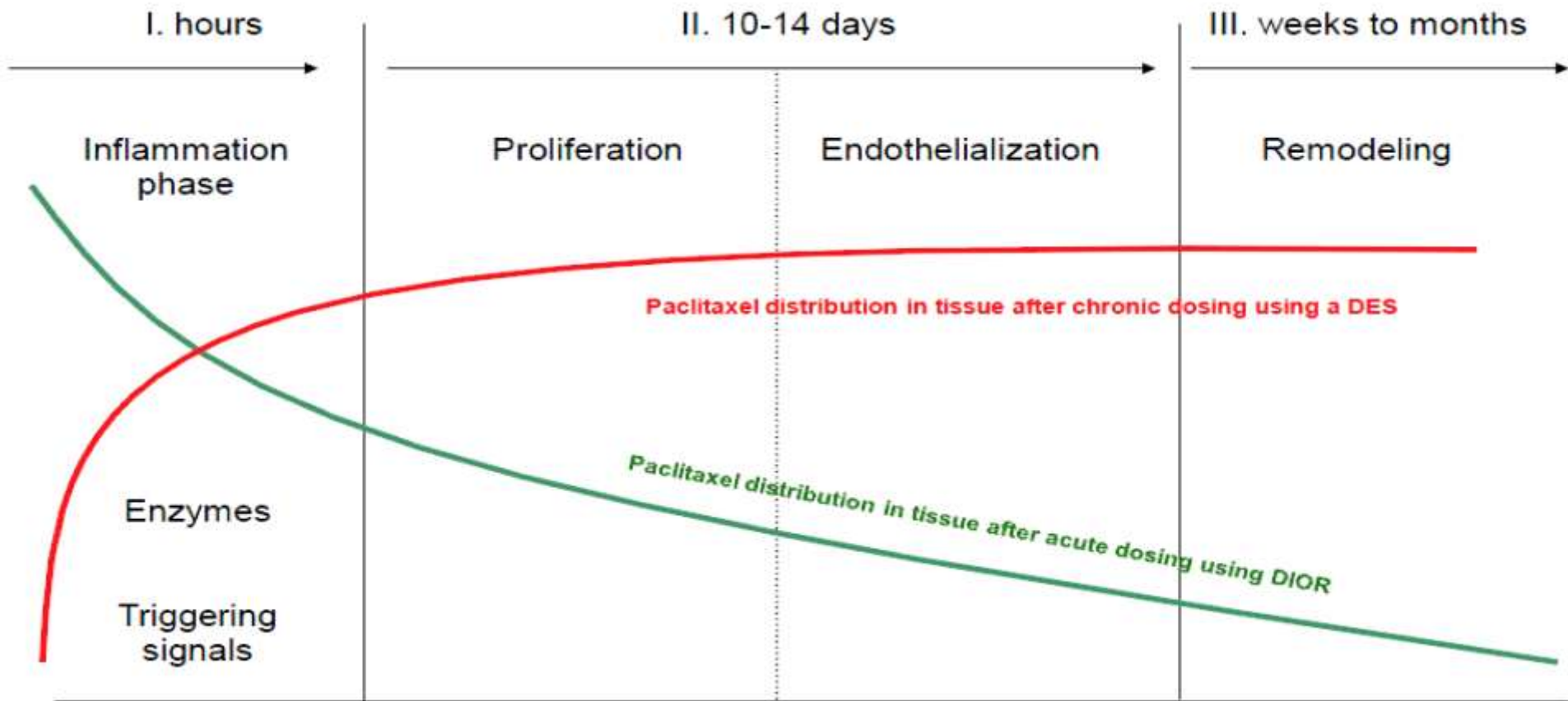
Why drug-eluting balloons?

1. Ease of use in coronaries and peripheral (especially below knees)
2. Cost – balloon catheters have traditionally been less expensive than stents (and potential cost saving with less duration of DAPT)
3. Potential for improved safety – no chronic polymer effects, reduced drug exposure
4. Can be used in situations where DES can be problematic e.g. ISR, bifurcations (ostium side branch), diabetics, small vessels, diffuse disease, cant deliver stent (distal, tortuous etc)

Drug-eluting balloons for ISR

- Able to modulate neointimal proliferation, while avoiding the presence of platforms and polymers responsible for vascular inflammation, which may lead to late deleterious consequences
- Presently, DEBs utilize paclitaxel as the drug of choice
- However other drugs will likely come to market
- E.g. Limus drug options are more expensive than paclitaxel, particularly as they require new carrier agents to control their delivery into the vessel wall

Wound healing and drug distribution (DES vs DEB)



DEB versus DES for ISR

CLINICAL RESEARCH

CORONARY

Comparison Among Drug-Eluting Balloon, Drug-Eluting Stent, and Plain Balloon Angioplasty for the Treatment of In-Stent Restenosis



A Network Meta-Analysis of 11 Randomized, Controlled Trials

Joo Myung Lee, MD, MPH,* Jonghanne Park, MD,* Jeehoon Kang, MD,* Ki-Hyun Jeon, MD,* Ji-hyun Jung, MD,* Sang Eun Lee, MD, PhD,* Jung-Kyu Han, MD, PhD,* Hack-Lyoung Kim, MD, PhD,† Han-Mo Yang, MD, PhD,* Kyung Woo Park, MD, PhD,* Hyun-Jae Kang, MD, PhD,* Bon-Kwon Koo, MD, PhD,* Hyo-Soo Kim, MD, PhD*‡

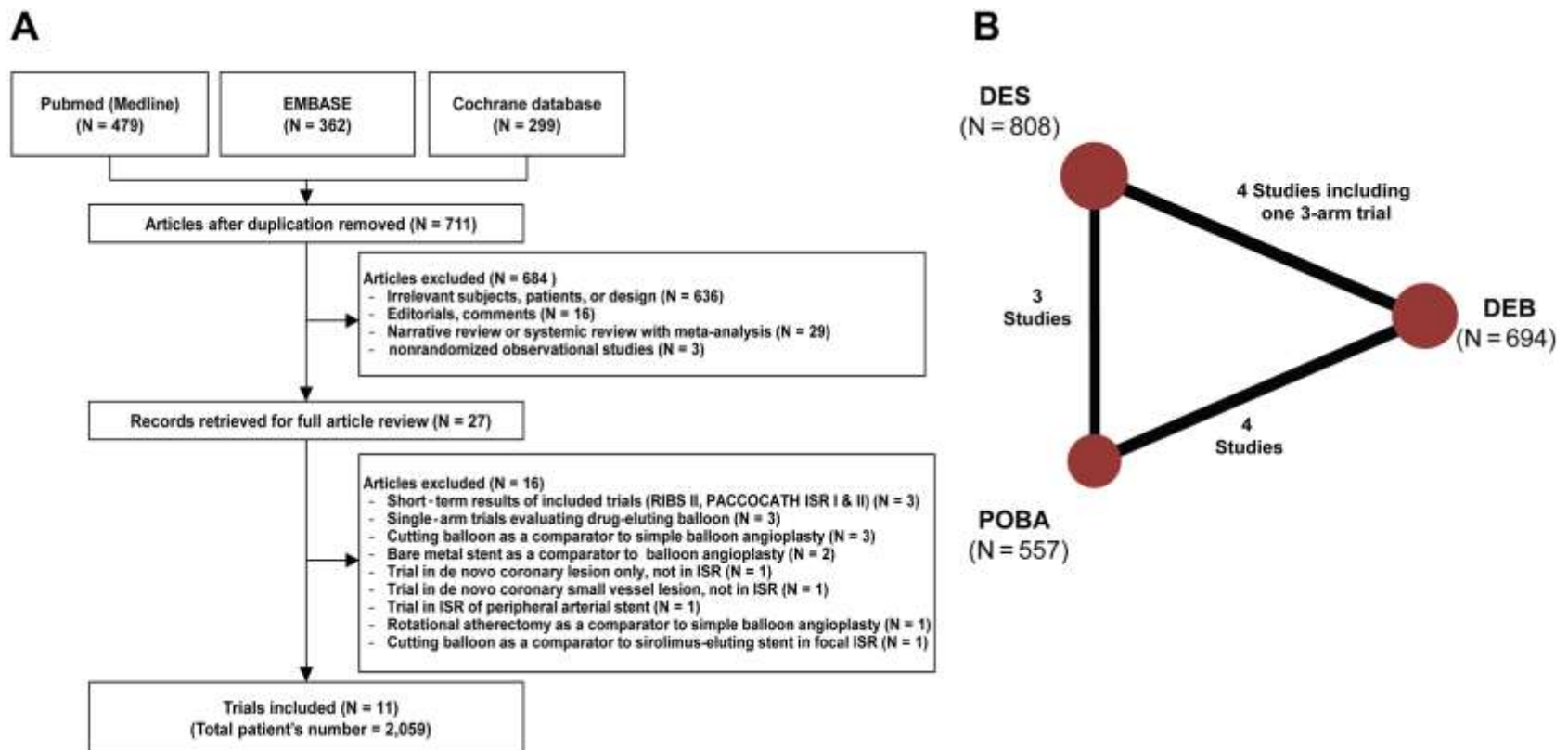


Figure 1 Flow Diagram of Trial Selection and Network Plot of Meta-Analysis Model (A) The study flow diagram depicted following the PRISMA guidelines. (B) Network plot of meta-analysis model. DEB = drug-eluting balloon; DES = drug-eluting stent; ISR = ...

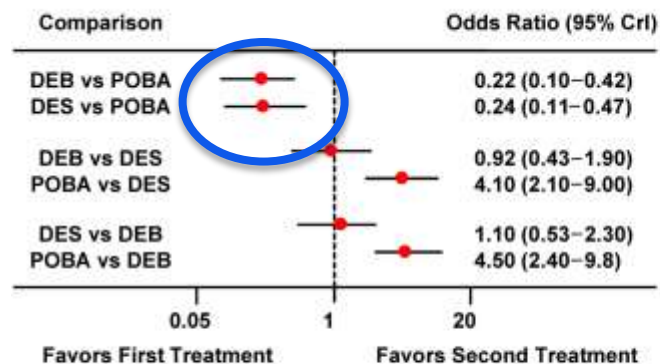
Joo Myung Lee , Jonghanne Park , Jeehoon Kang , Ki-Hyun Jeon , Ji-hyun Jung , Sang Eun Lee , Jung-Kyu Han , Hack-...

Comparison Among Drug-Eluting Balloon, Drug-Eluting Stent, and Plain Balloon Angioplasty for the Treatment of In-Stent Restenosis : A Network Meta-Analysis of 11 Randomized, Controlled Trials

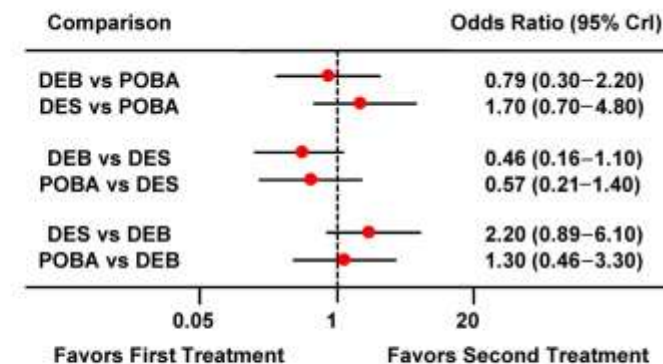
JACC: Cardiovascular Interventions, Volume 8, Issue 3, 2015, 382 - 394

<http://dx.doi.org/10.1016/j.jcin.2014.09.023>

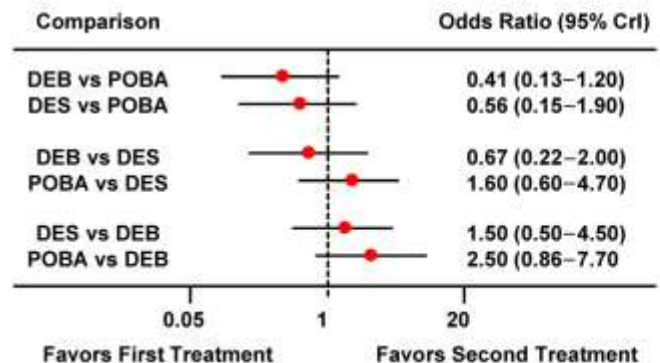
A Target Lesion Revascularization



B Myocardial Infarction



C All-cause Mortality



D MACE

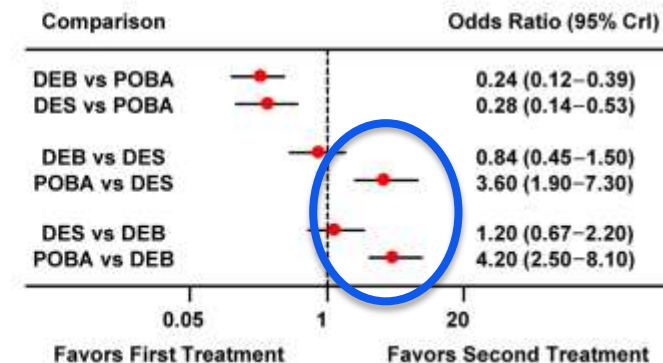


Figure 2 Results of Bayesian Network Meta-Analysis for Overall Rates of Clinical Outcomes in a Random Effects Model Results of a Bayesian network meta-analysis with a random-effects model for the risk of target lesion revascularization (A) , myocardial i...

Joo Myung Lee , Jonghanne Park , Jeehoon Kang , Ki-Hyun Jeon , Ji-hyun Jung , Sang Eun Lee , Jung-Kyu Han , Hack-...

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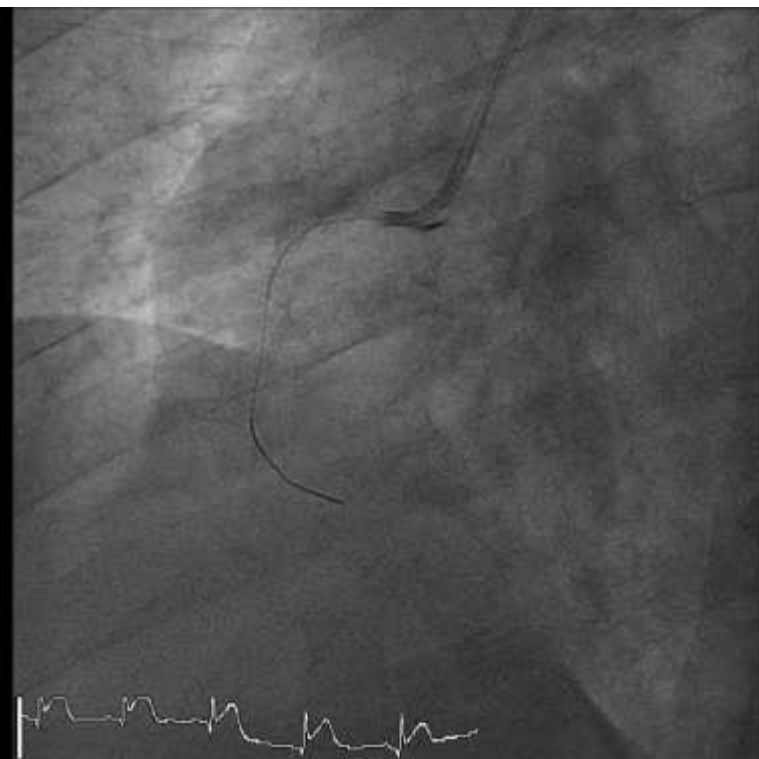
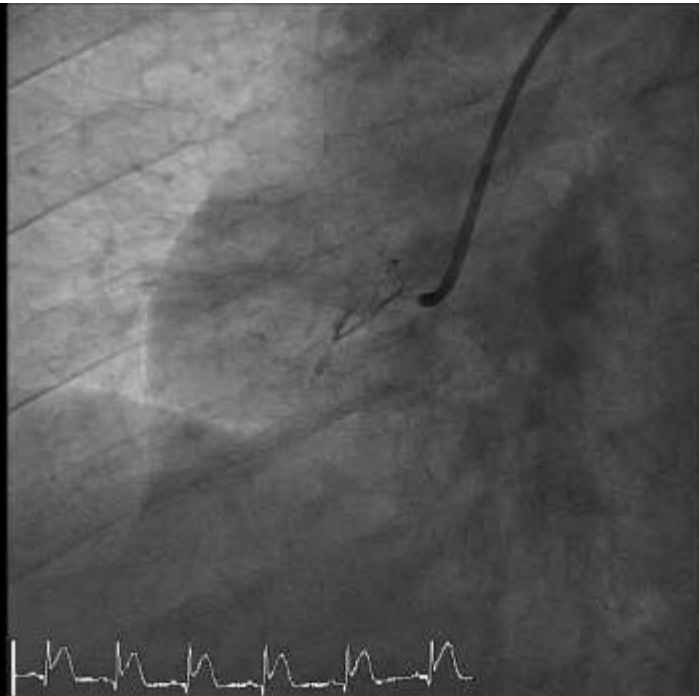
DEB vs DES for ISR

- Although DEB was comparable to DES in reducing TLR, it should be noted that the DEB group showed a significantly smaller post-procedural minimal lumen diameter (therefore less acute gain) and more severe residual %DS than the DES group in the individual trials
- Comparable efficacy even with smaller acute gain suggests that late loss after DEB would be less than that of DES
- Interestingly, an additional metal structure in the ISR lesion may induce a substantial degree of new tissue deposition, which would be less after using DEB
- Further clinical trials will help clarify these mechanisms and long-term outcomes

Case illustration 1

- 51 year-old male
- Hypertension, dyslipidaemia, prior smoker
- 2011: inferior STEMI – treated with 3 bare metal stents to the RCA
- 2015: New onset chest pain, positive inferior ischemia on stress echocardiography

Inferior STEMI 2011

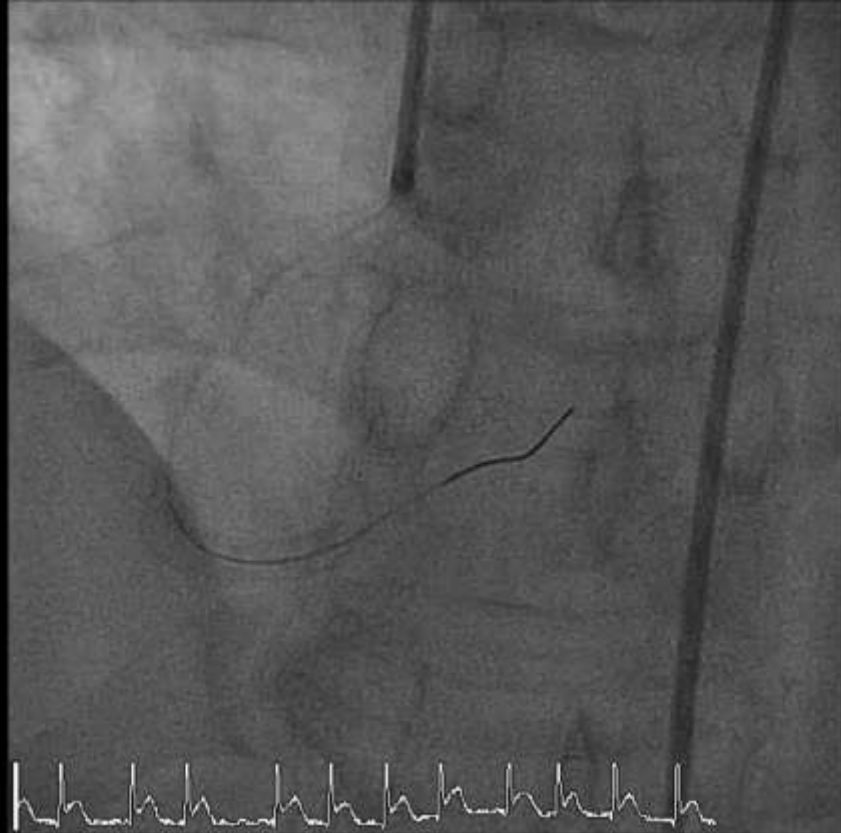


Post 3 bare metal stents

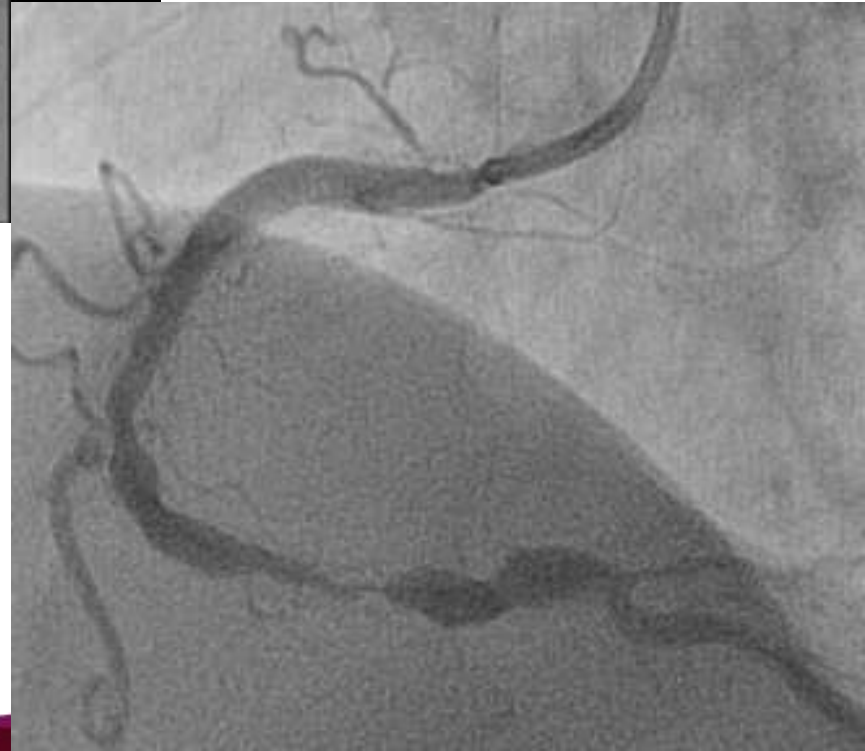
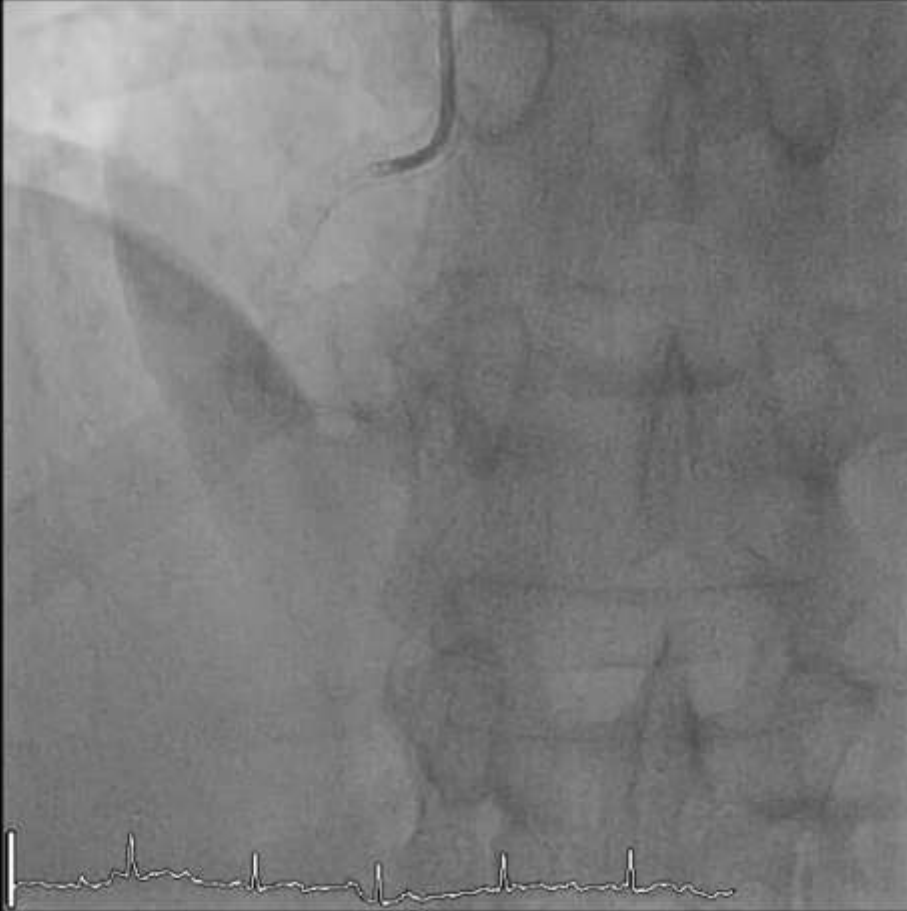
4.0x35mm

4.0x22mm

4.0x30mm



**2015:
recurrent
angina**



Procedure:
3.5mm NC balloon
BIOTRONIK Pantera Lux
DEBs
3.5x15mm
4.0x25mm
4.0x20mm



Case illustration 2

- 73-year-old male
- Hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnoea, chronic obstructive airways disease
- NSTEMI 2009 – triple vessel heavily calcified coronary disease
- CABG 2009 – LIMA to LAD, radial to OM, SVG-PDA

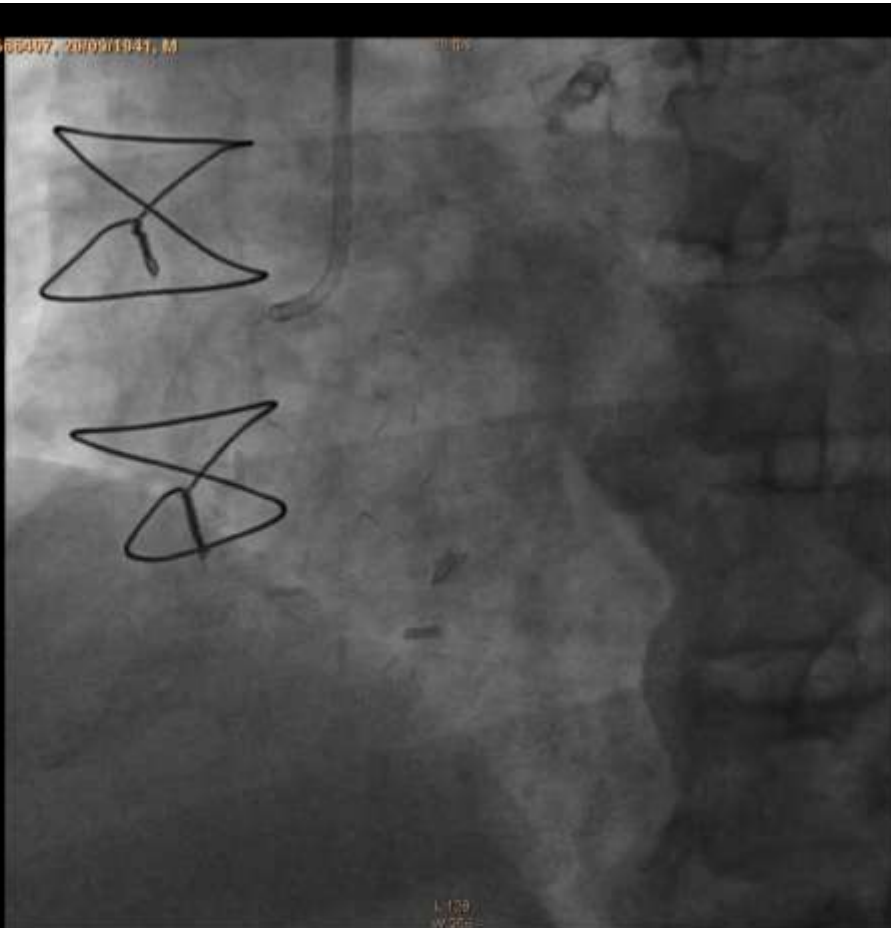
Medication

- Aspirin 100mg
- Clopidogrel 75mg
- Isosorbide mononitrate 120mg
- Nicorandil 10mg bd
- Metoprolol 100mg BD
- Ivabridine 7.5mg bd
- Insulin
- Rosuvastatin 40mg

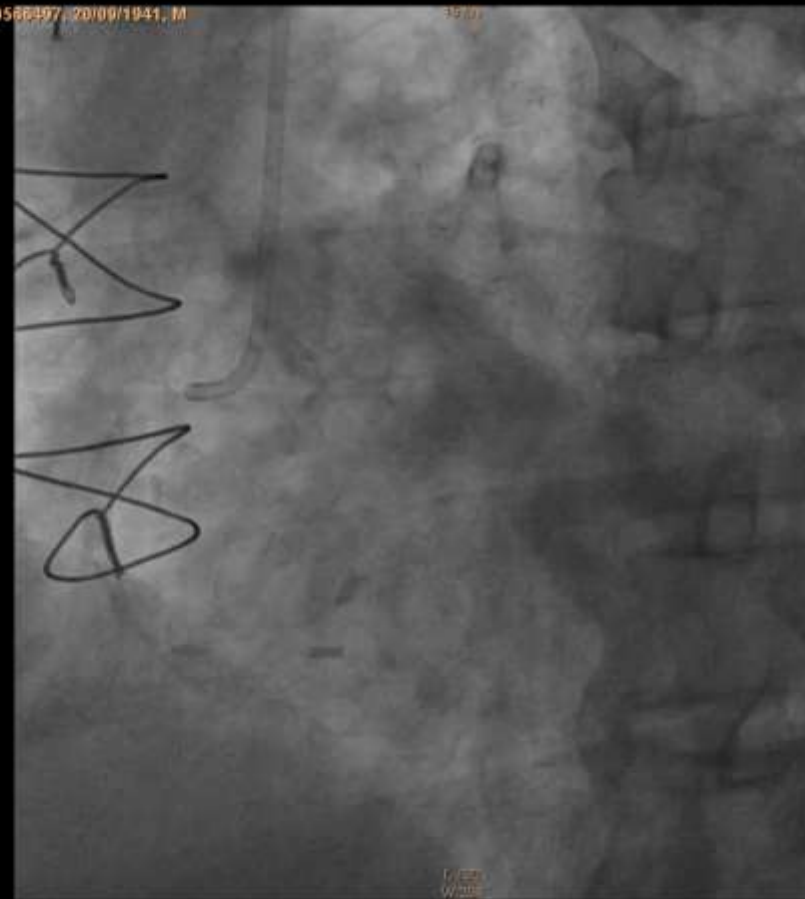
2009: NSTEMI, underwent CABGx3 (LIMA to LAD, RA-OM, SVG-PDA)



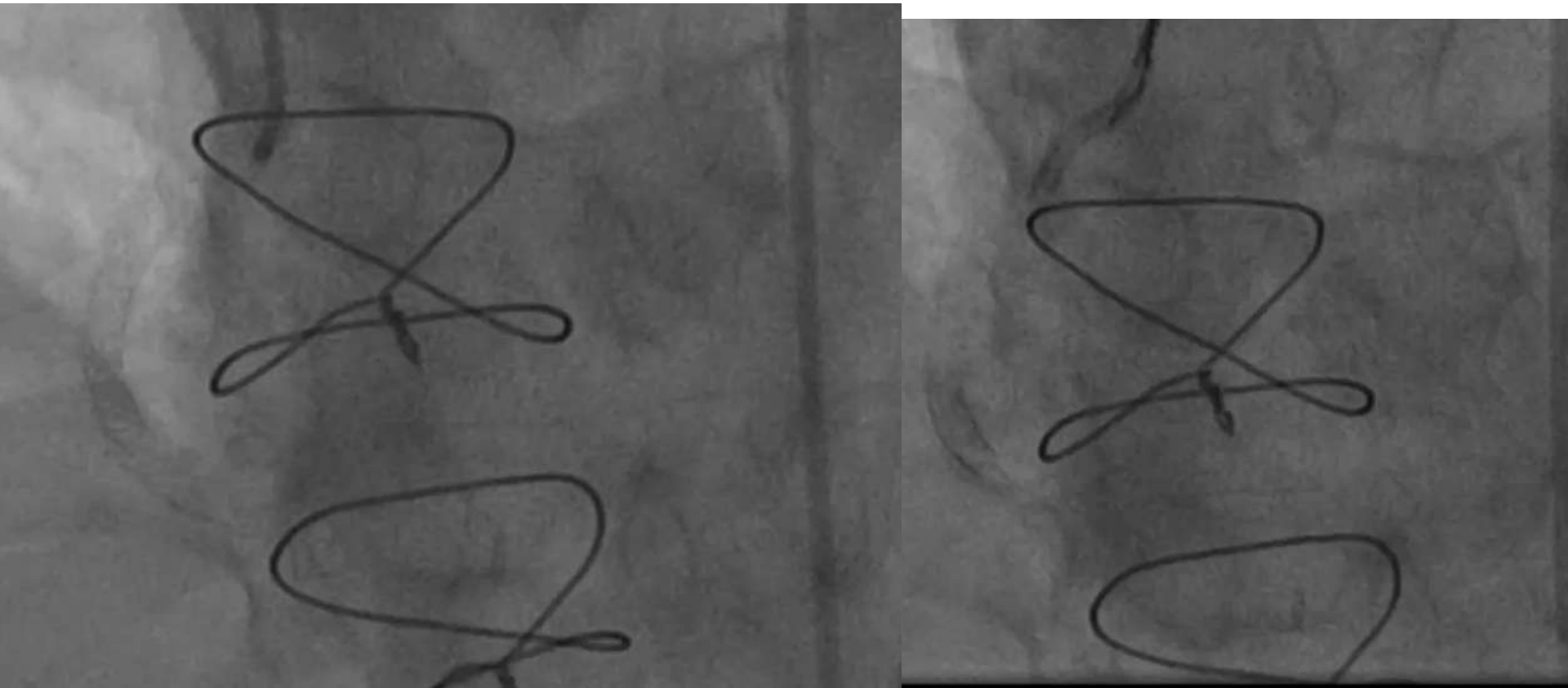
2011: Recurrent angina, NSTEMI
SVG graft occluded
PCI – RCA complex procedure,
eventually two stents implanted
3.0x12, 3.5x24 Resolute stents



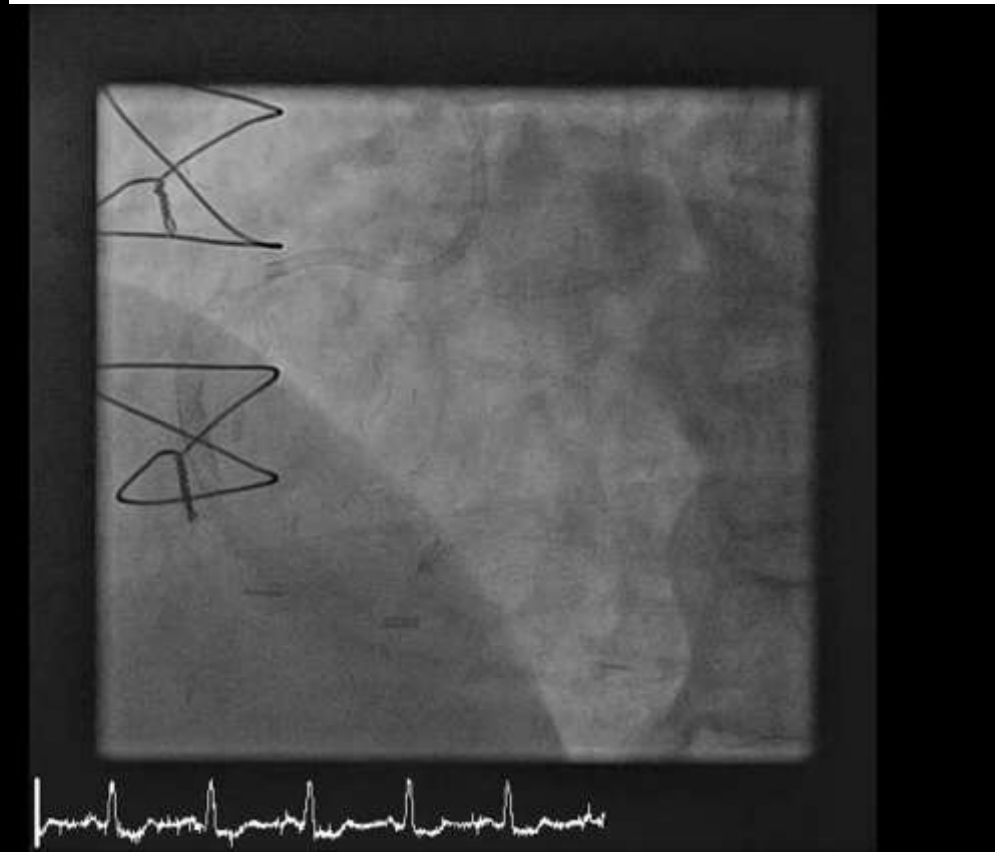
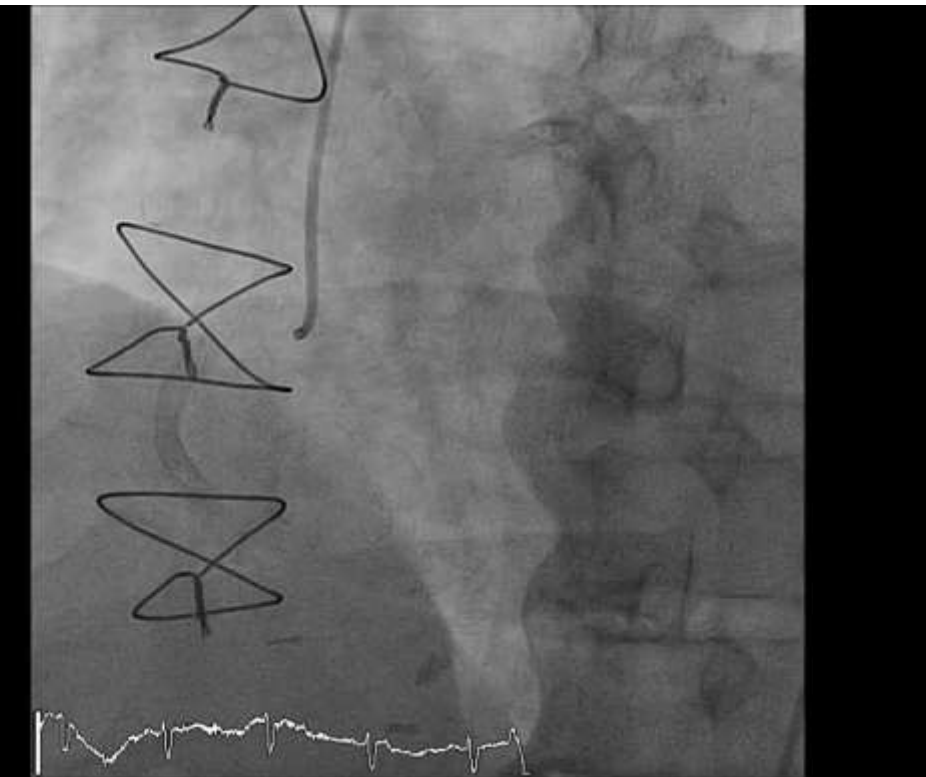
The Northern Hospital, 056497, 2010/10/41, M
70.8kV, 664mA, 6s



2012: 6 months post PCI, develops recurrent chest pain. Severe ISR – Xience 3.0x16mm stent deployed to ISR

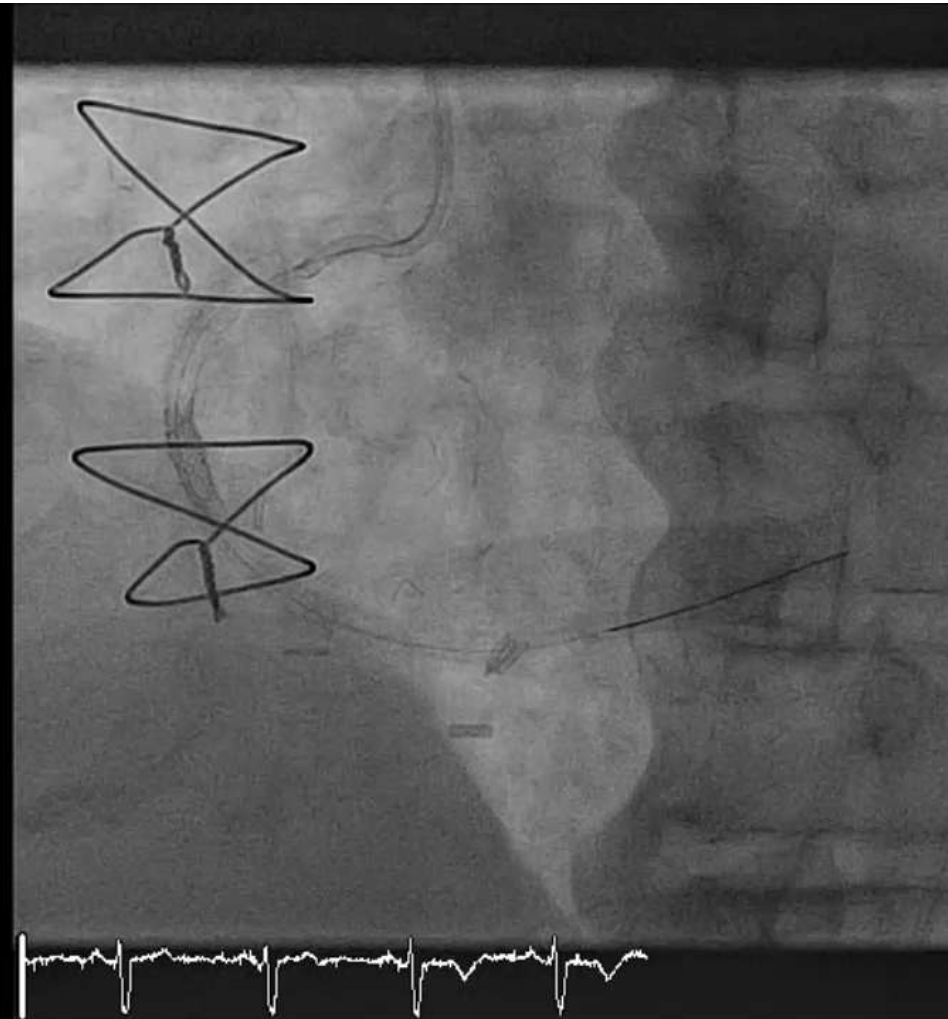
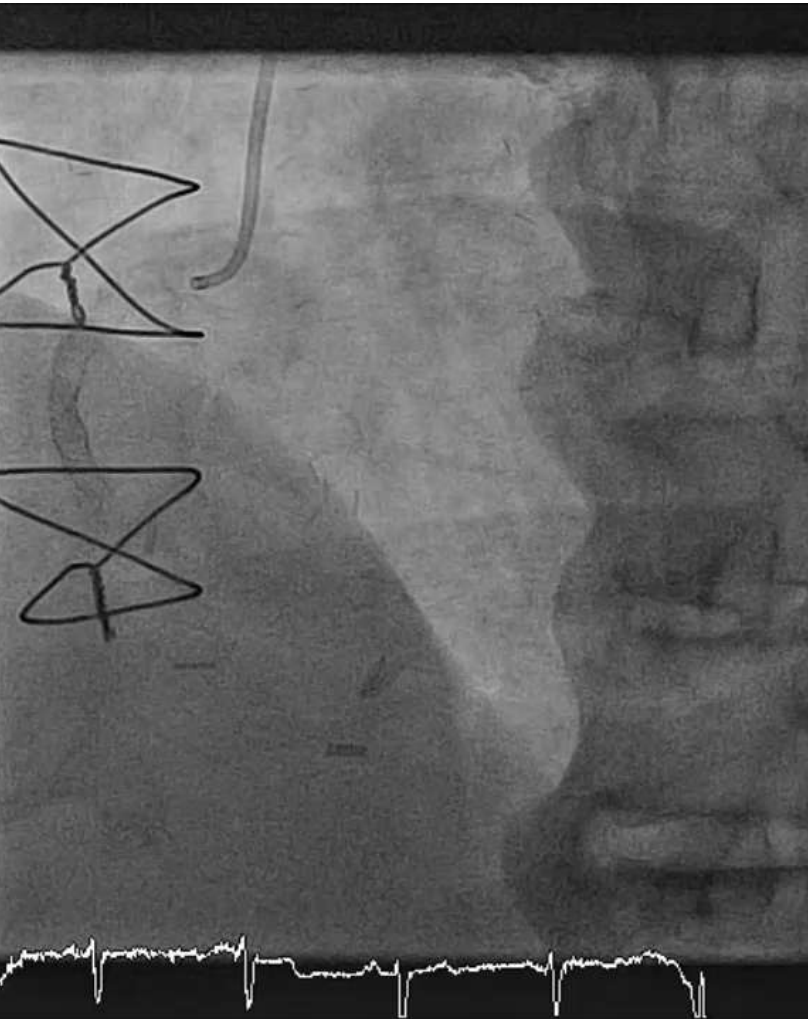


**2013: 14 month later, develops recurrent chest pain,
objective inferior ischemia on thallium
Further 3.5x12mm Xience Prime stent deployed**

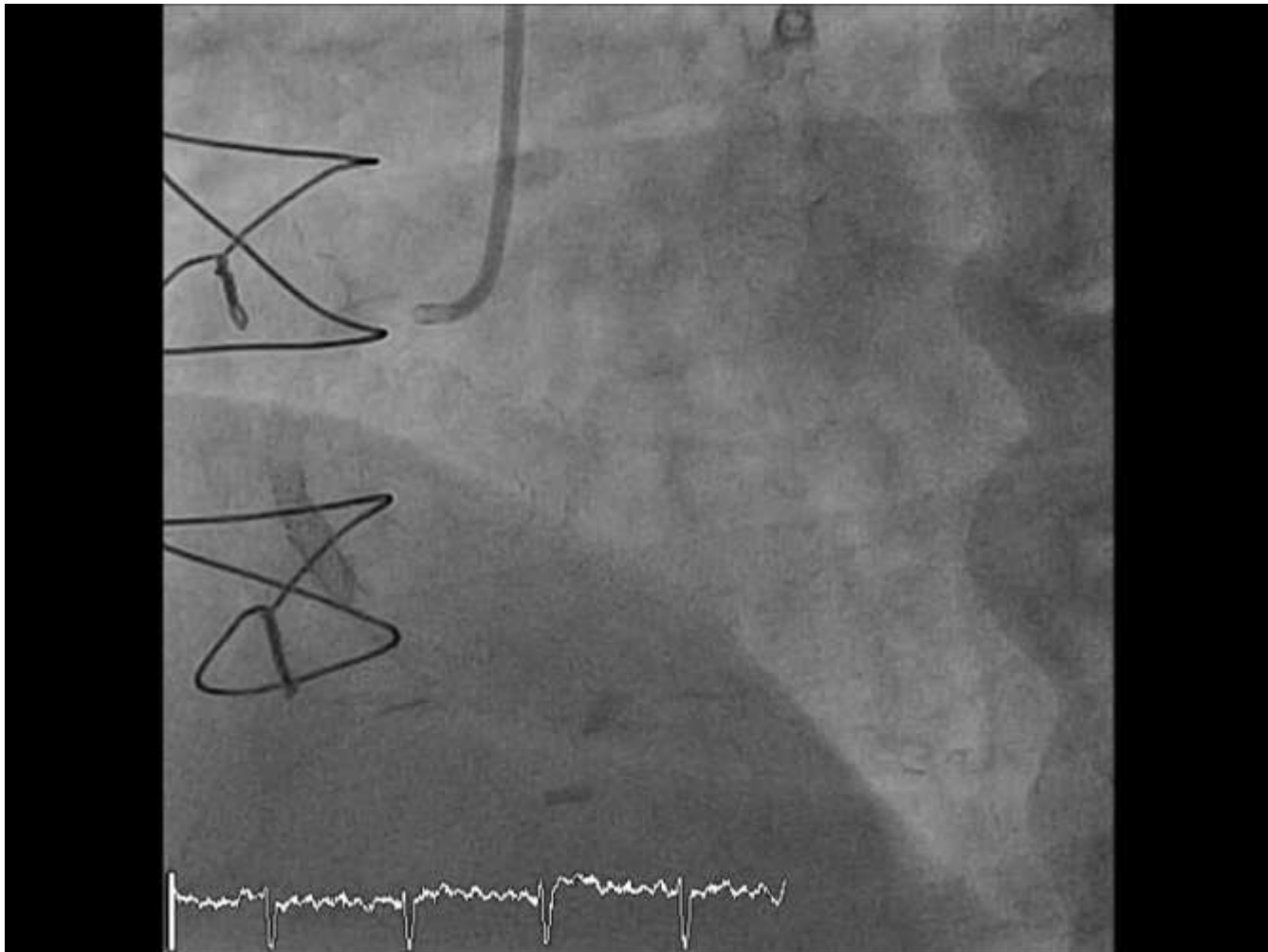


Sep 2014: Angina, 90% RCA restenosis

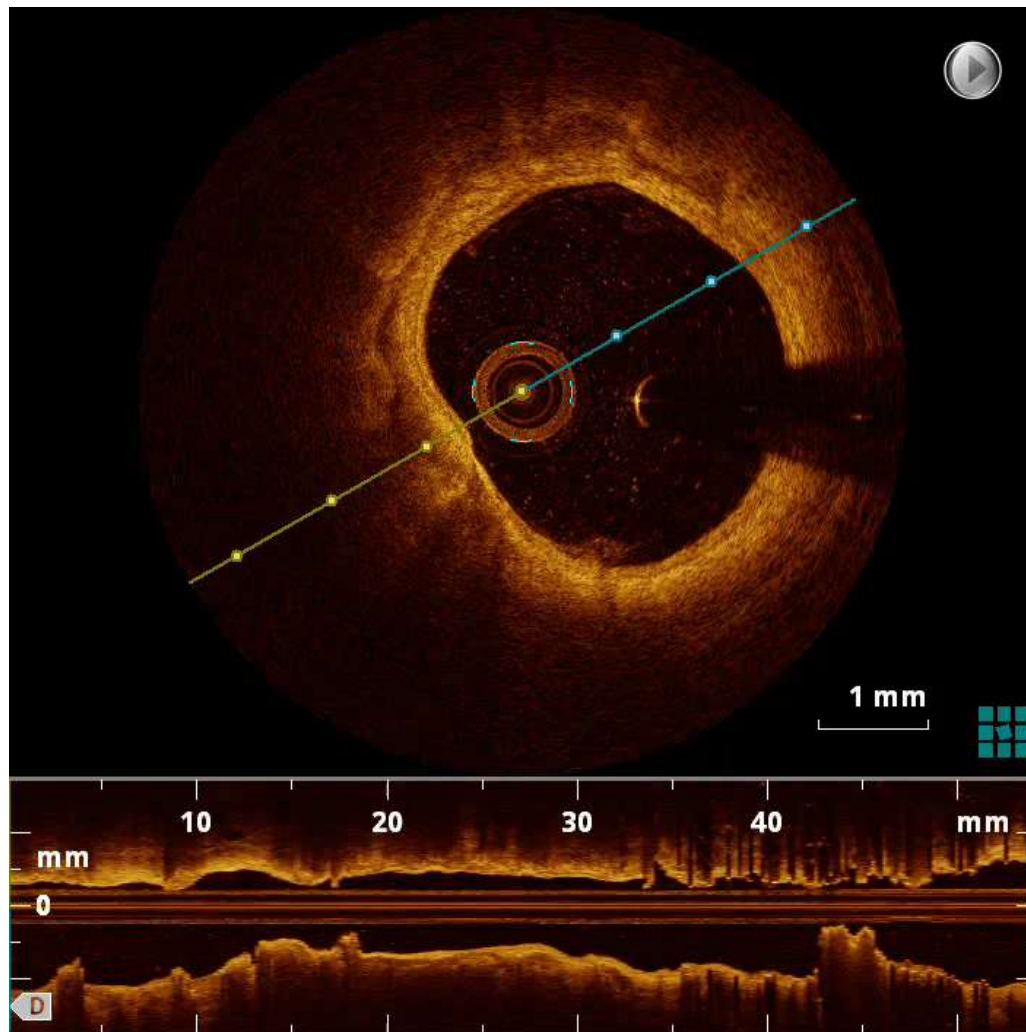
Promus Element deployed 3.5x12mm



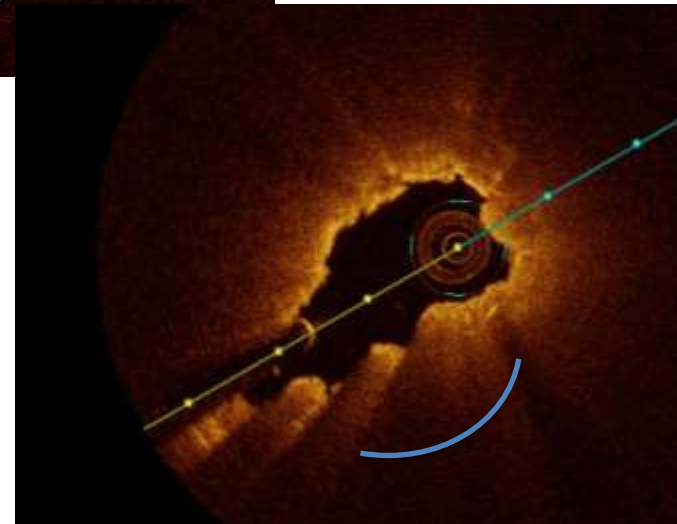
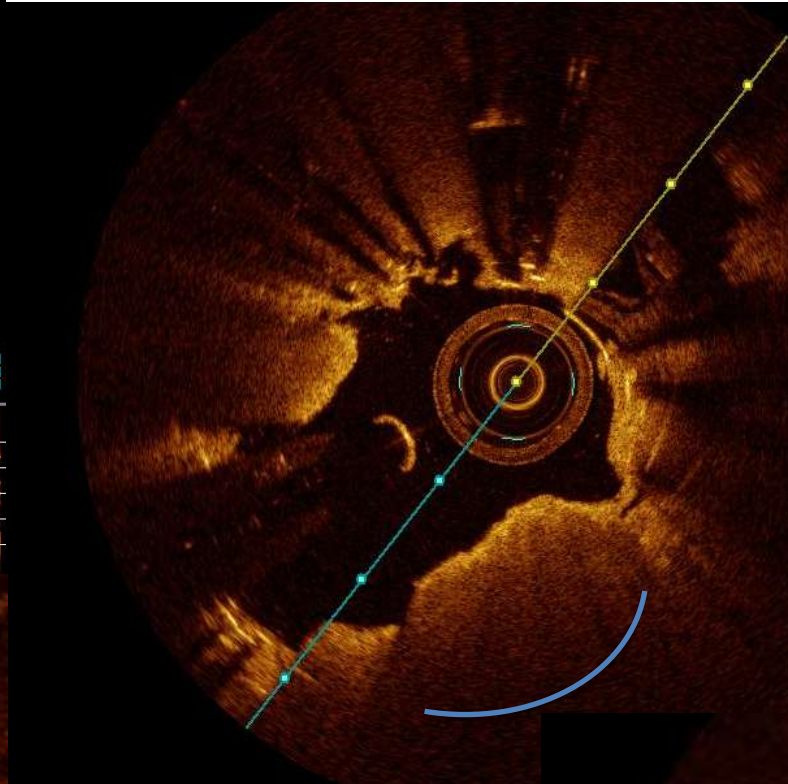
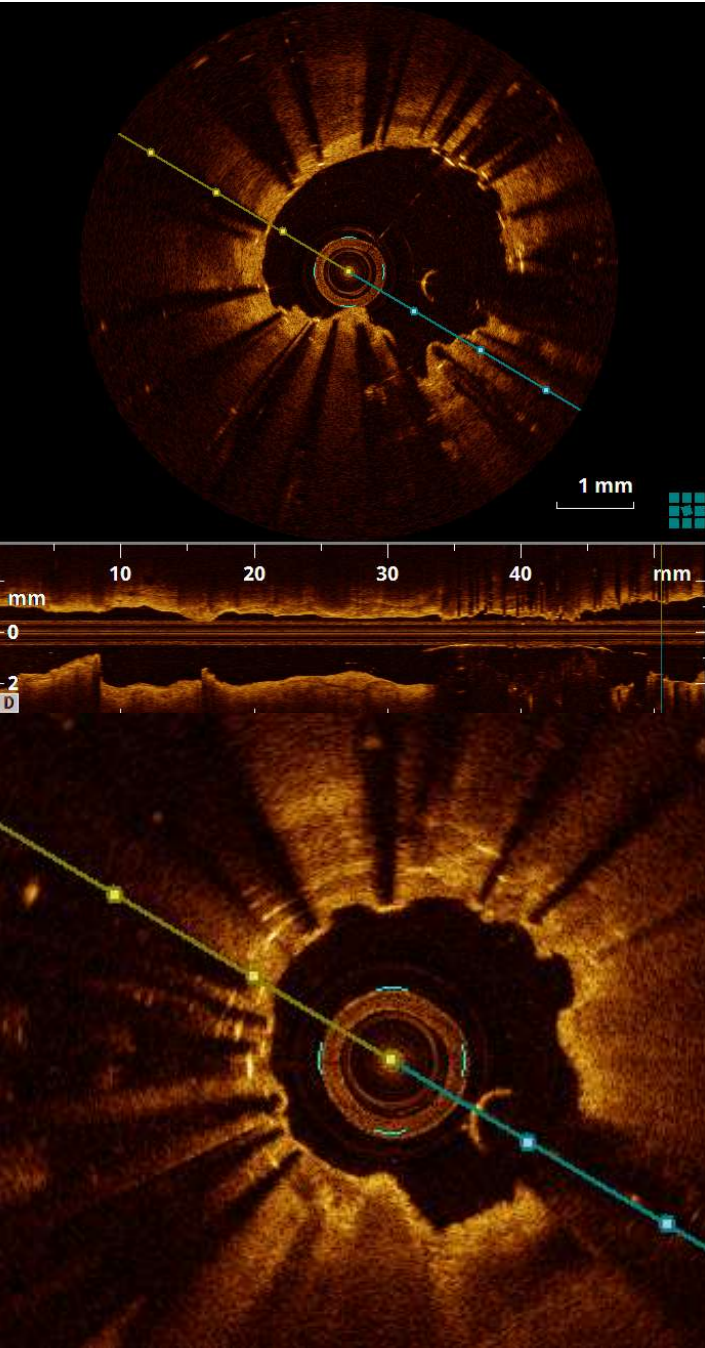
Last week: 2015
Having angiography to evaluate recurrent
angina and positive stress echo

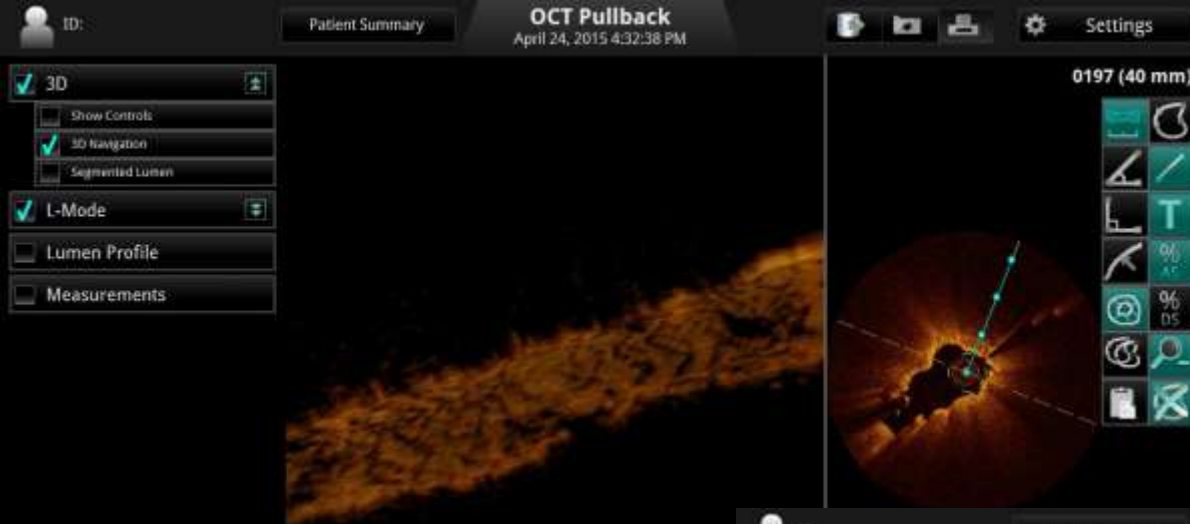


OCT Imaging - baseline

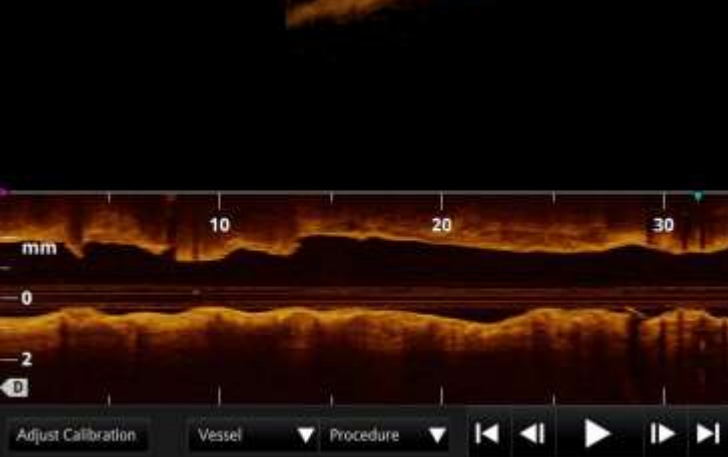


OCT – baseline – stent fracture

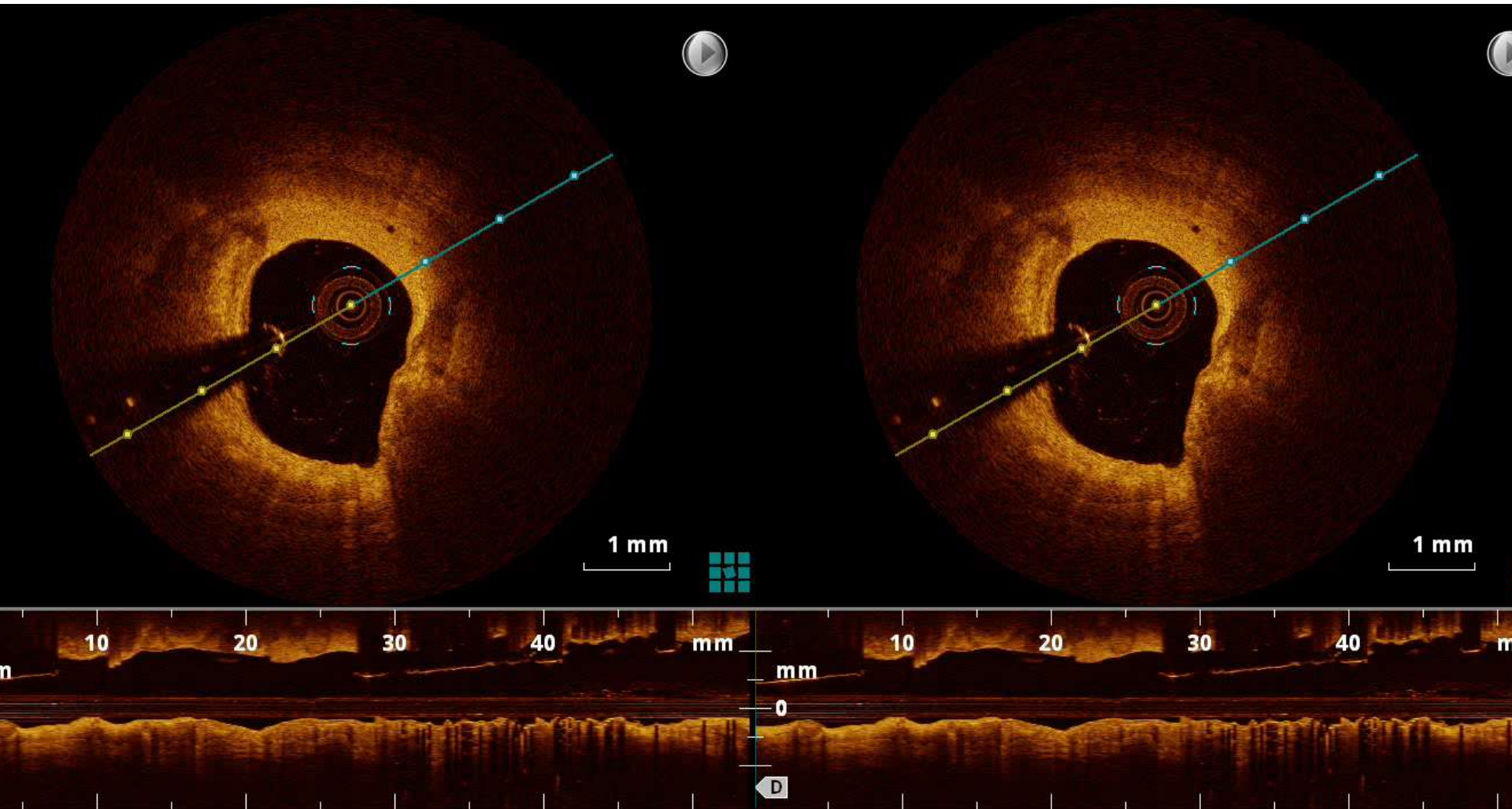




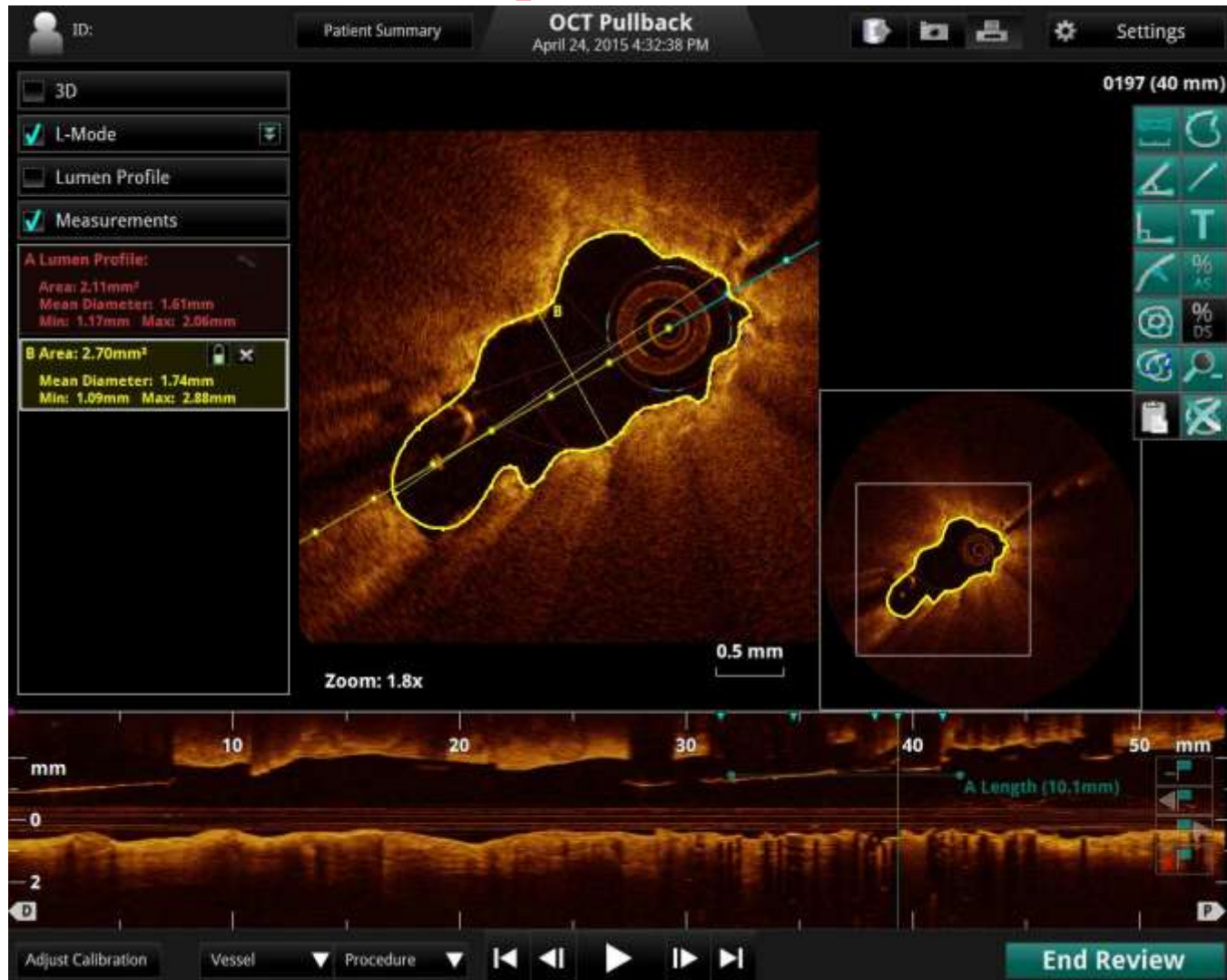
3d OCT reconstruction



Post DEB



MLA post DEB



**What next when he
represents with angina?**

Take Home Messages

- Each case of ISR needs to be considered individually as there are several factors to think about including:
 - Patient characteristics (e.g. diabetes, ability to take prolonged DAPT)
 - Lesion/vessel factors (e.g. vessel geometry, calcification, distal versus proximal ISR, small vs large vessel, angulation, tortuosity)
 - Stent factors (e.g. stent type, likely mechanism for ISR such as fracture, versus neointimal proliferation versus malapposition)
- Findings of intracoronary imaging (OCT) are useful and can inform the clinical decision making process
- DEBs are a novel and genuine technology that can be applied to most cases of restenosis and negate the need for prolonged anti-platelet therapy and the problems incurred by implanting multiple stents thereby leaving implantation of another DES as a last resort