

# HOW TO DISAPPEAR COMPLETELY AND NEVER BE FOUND

By Flin Kennedy



“DISAPPEARING STENT:  
IS THE TIME APPEARED?”

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FOUND  
NEVER BE



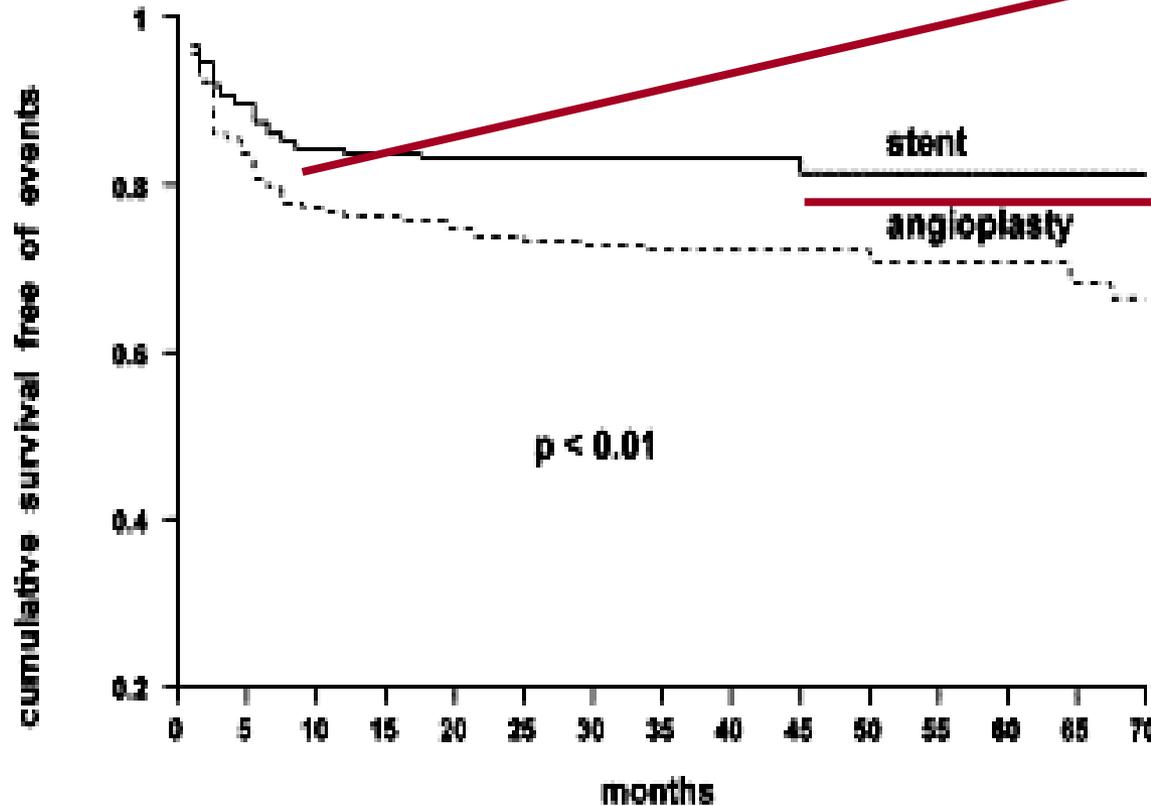
# THE BEGINNING.....

START randomized study (n=452)  
Long-term follow-up

The benefit of BMS is within the first months.

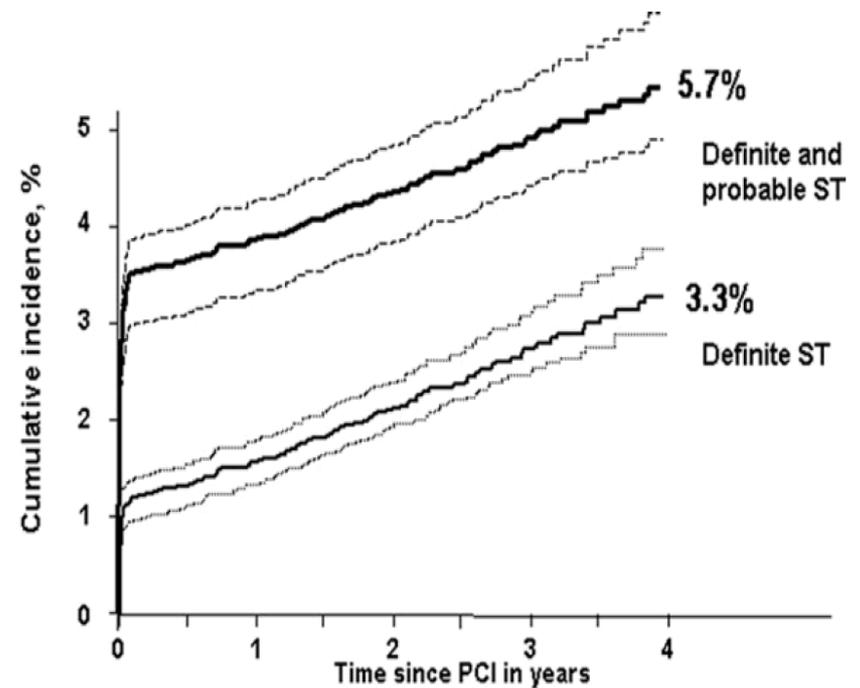
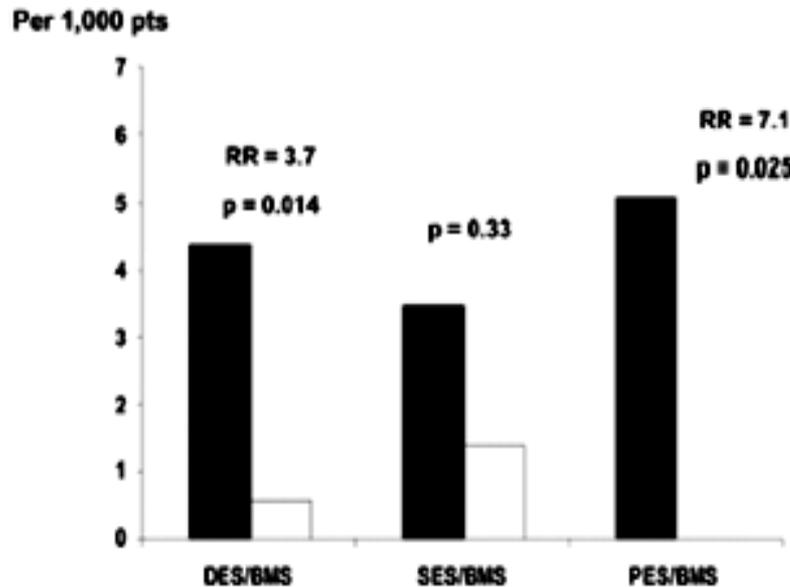
Is there any advantage of a permanent scaffolding?  
And any disadvantage?

Mechanical support is needed to avoid negative remodeling and vessel shrinkage, that occur during the first 6 mo.



# THE PROBLEM: VERY LATE STENT THROMBOSIS

## Incidence of Late Stent Thrombosis: > 6 Months

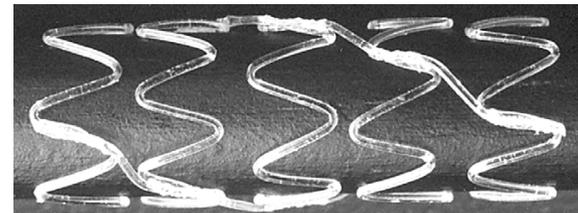


# POTENTIAL ADVANTAGES OF BIOASORBABLE SCAFFOLD

- Risk of stent thrombosis never completely disappears
- Potential limitation for future CABG
- Stent fracture
- Side branch compromise in bifurcations
- Aorto-ostial lesions
- Concerns about endothelial function.

# IGAKI-TAMAI stent (Kyoto Medical Planning)

- Strut Material: Poly-L-acid
- Coating Material: Nil
- Design: Zig-Zag helical that coils with straight bridges
- Absorption products: Lactic acid, CO<sub>2</sub> and H<sub>2</sub>O
- Drug: Nil



# IGAKI-TAMAI stent (Kyoto Medical Planning)

➤ **First in man study: 50 patients**

**1 in-hospital stent thrombosis and Q-wave MI**

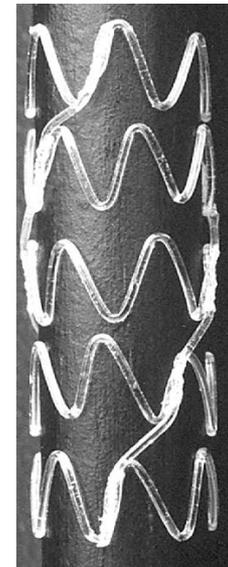
**1 non-cardiac death**

**TLR (all with PCI): @6 months 12%**

**@12 months 17%**

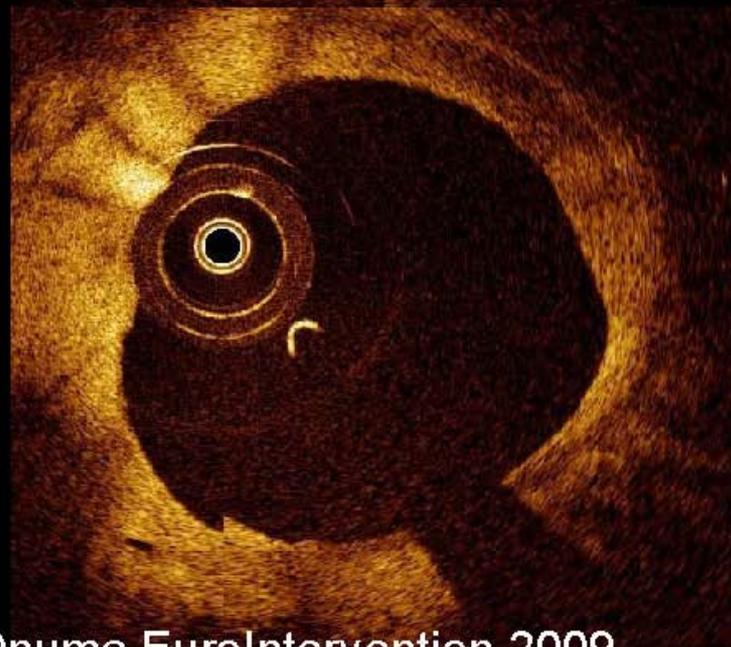
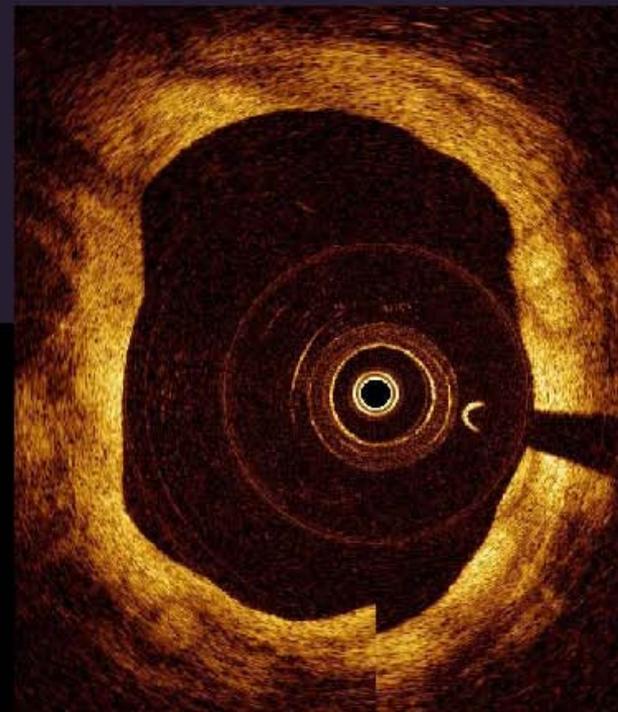
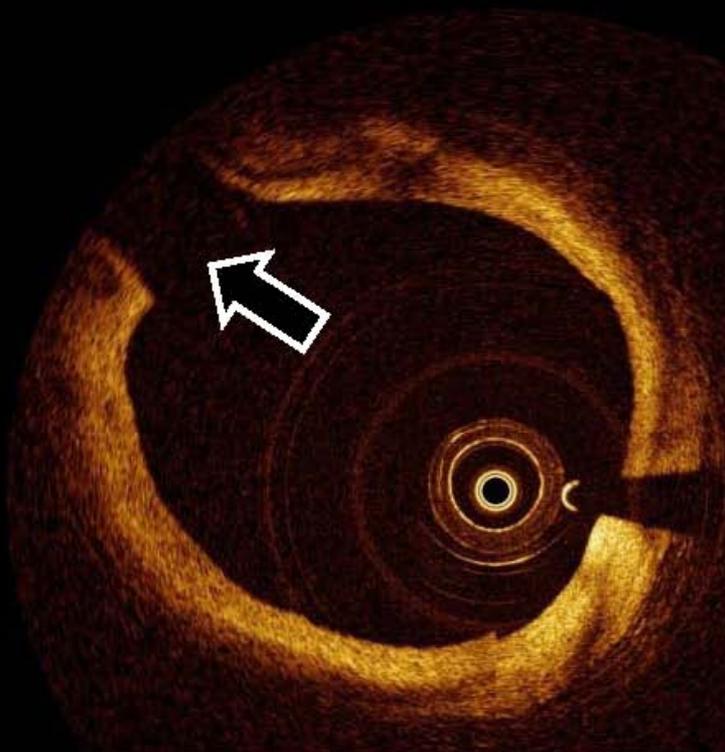
**@ 4 years 18%**

➤ **Late loss index: 0.48mm @ 6 months**



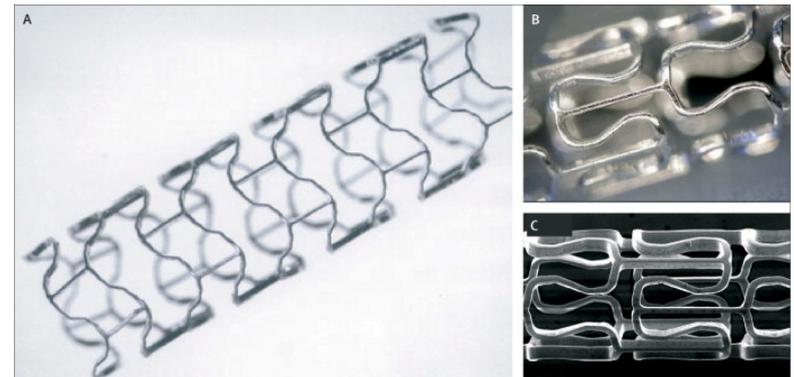
10 yr OCT follow-up after Igaki-Tamai  
PLA absorbable stent implantation  
(there was no OCT when study began)

1. Full absorption
2. No evidence toxicity
3. Smooth endolumen
4. No SB jailing



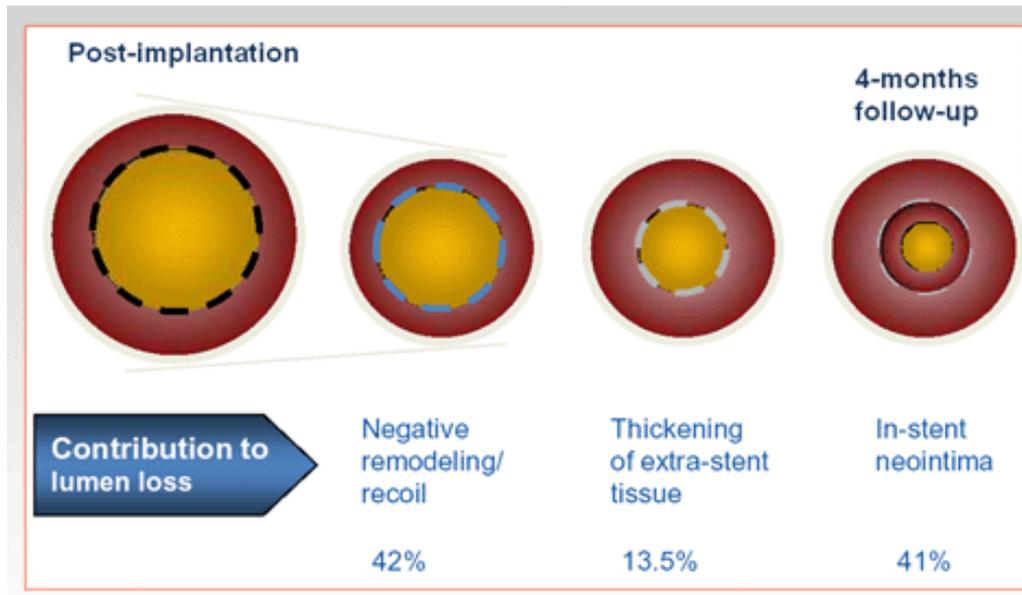
# MAGNESIUM STENT (AMS, BIOTRONIC)

- Strut Material: Magnesium-alloy
- Coating Material: Nil
- Design: sinusoidal in-phase hoops linked by bridges
- Absorption products: not applicable
- Drug: Nil



# MAGNESIUM STENT (AMS, BIOTRONIC)

- **PROGRESS-AMS: first in man study (63 pts)**
- **The primary endpoint was MACE at 4 months and ischemia-driven TLR**
- **Safe: no death, no MI, no stent thrombosis**
- **The stent was well-expanded on deployment with no immediate recoil**
- **High restenosis rate with an in-stent late loss of  $1.08 \pm 0.49\text{mm}$**



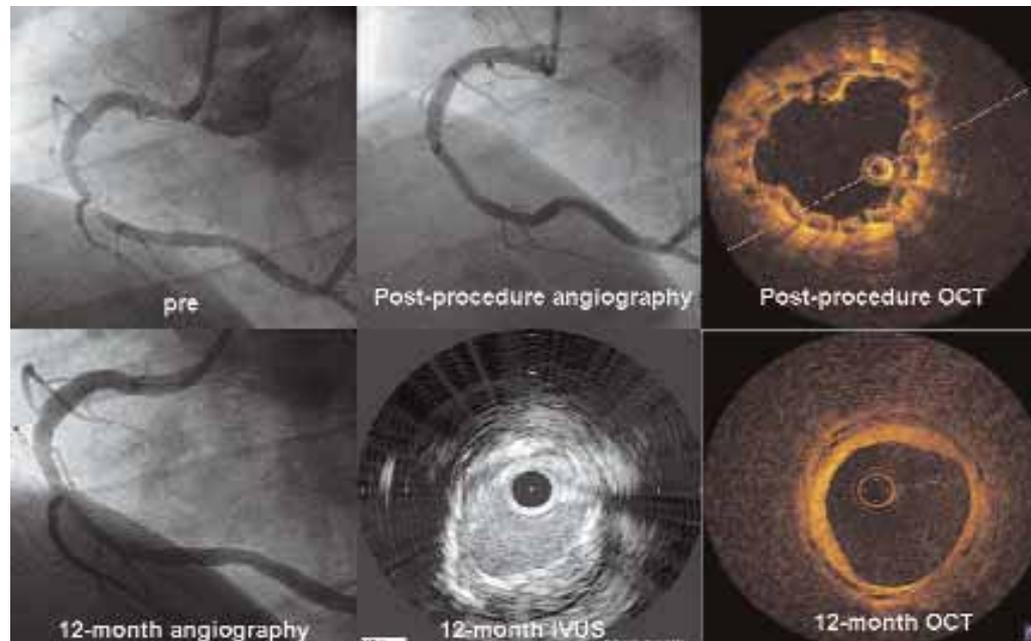
# REVA stent (Reva medical)

- Strut Material: Poly-L-Lactic acid
- Coating Material: Nil
- Design: Slide and lock design
- Absorption products: Amino acids, ethanol and CO<sub>2</sub>
- Drug: Paclitaxel



## REVA stent (Reva medical)

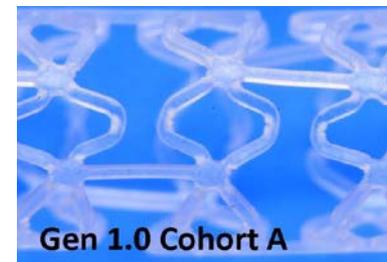
**Interim analysis of 27 FIM patients demonstrated “unfavourable results between 4 and 6 months with higher than expected TLR driven by reduced stent diameter”**



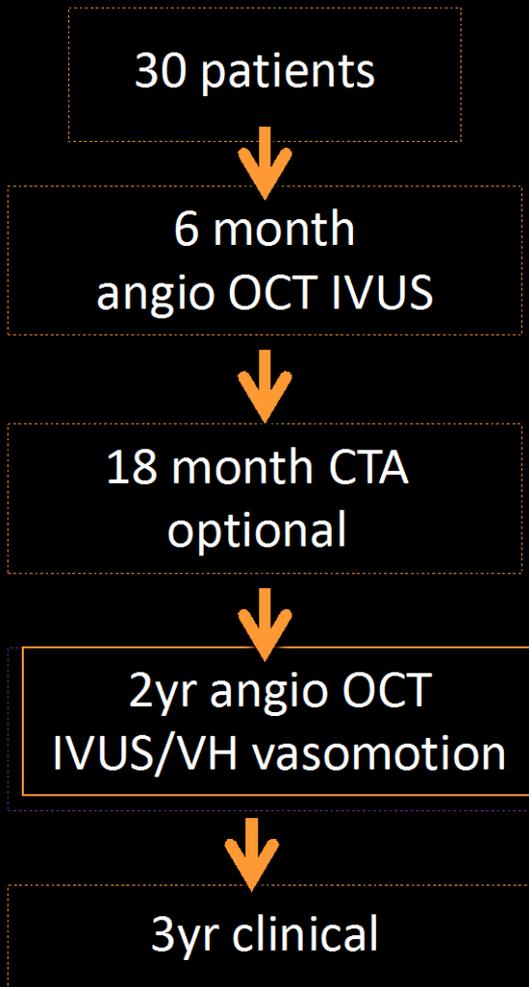
**OCT performed at 12 months demonstrated the presence of neointimal tissue covering the entire treated segment, and signs of stent absorption**

# BVS stent (Abbot Vascular)

- Strut Material: Poly-L-Lactic acid
- Coating Material: Poly-D,L-lactide
- Design: out of phase sinusoidal hoops with straight and direct links in cohort A and in-phase hoops with straight links in cohort-B
- Absorption products: Lactic acid, CO<sub>2</sub> and H<sub>2</sub>O
- Drug: Everolimus



# ABSORB Cohort A Trial



- Prospective, open label, FIM registry
- Single de novo native lesions
- 3.0 x 12 then 3.0 x 18mm BVS
- 4 sites in New Zealand and Europe
- Independent DSMB, CEC, CoreLab
- Fully monitored

*Ormiston et al Lancet 2008*

*Serruys et al Lancet 2009*

# 3 Year Clinical Results – Intent to Treat

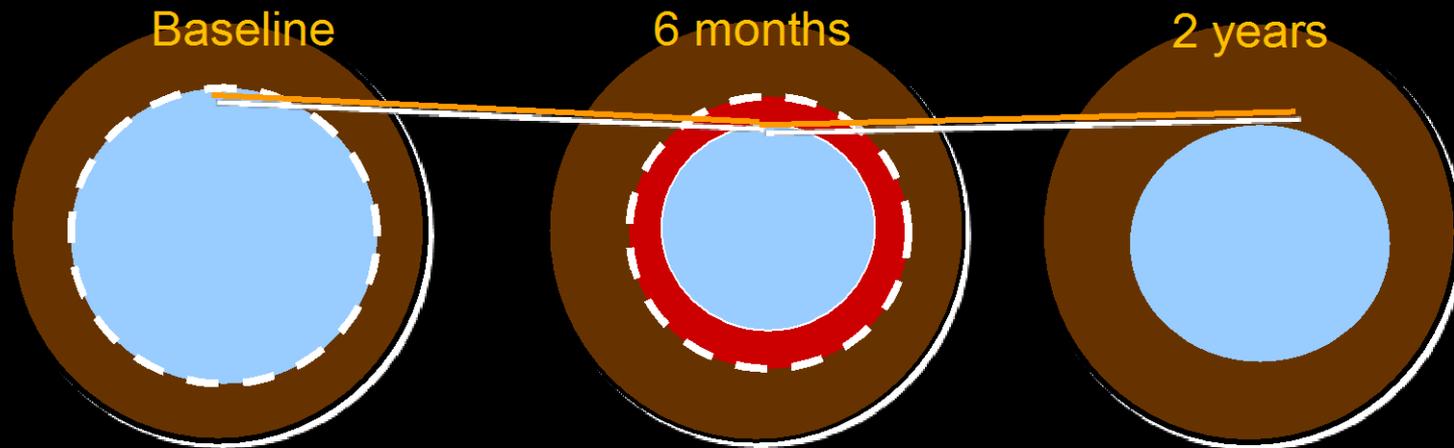
<b>Hierarchical</b>	<b>6 Months 30 Patients</b>	<b>12 Months 29 Patients*</b>	<b>2 Years 29 Patients*</b>	<b>3 Years 29 Patients*</b>
<b>Ischemia Driven MACE (%)</b>	<b>3.3% (1)*</b>	<b>3.4% (1)*</b>	<b>3.4% (1)*</b>	<b>3.4% (1)*</b>
<b>Cardiac Death (%)</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>
<b>MI (%)</b>				
<b>Q-Wave MI</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>
<b>Non Q-Wave MI</b>	<b>3.3% (1)**</b>	<b>3.4% (1)**</b>	<b>3.4% (1)**</b>	<b>3.4% (1)**</b>
<b>Ischemia Driven TLR (%)</b>				
<b>by PCI</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>
<b>by CABG</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>

**No new MACE events between 6 months and 3 years**  
**No stent thrombosis up to 3 years** (only one patient on clopidogrel)

\*One patient withdrew consent and missed the 9, 12, 18 month and 2 and 3 year visits but the vital status of the patients and absence of cardiac event is known through the referring physician.

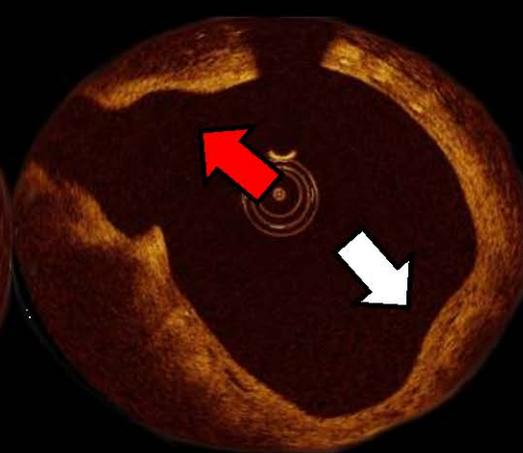
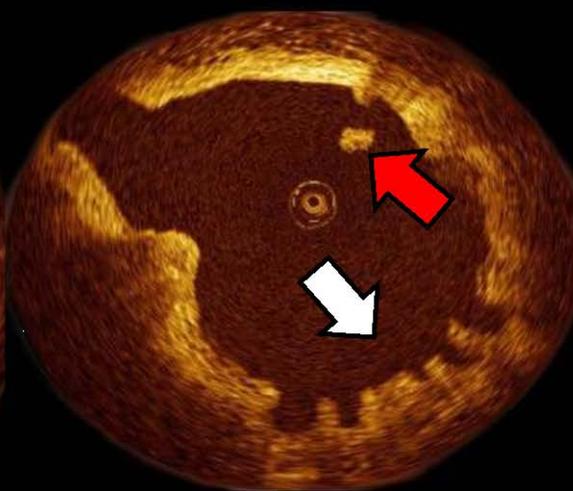
\*\*This patient also underwent a TLR, not qualified as ID-TLR (DS = 42%) followed by post-procedural troponin qualified as non-Q MI and died from his Hdr gkin’s disease at 888 days post-procedure.

# Absorb Trial Cohort A Trial IVUS



- Vessel size (EEL) did not change over 2 years on IVUS
- Scaffold (broken line) shrank 12% by 6 months then disappeared
- Lumen (blue) shrank in area by 17% by 6 mo (scaffold shrinkage and intimal hyperplasia) then increased by 11%
- Late loss of 0.43mm at 6 months due mainly to scaffold shrinkage

Serial OCT in an ABSORB Cohort A patient corrugated endolumen at 6 months due to scaffold shrinkage. Scaffold has gone by 2 years



**Baseline**

**6 months**

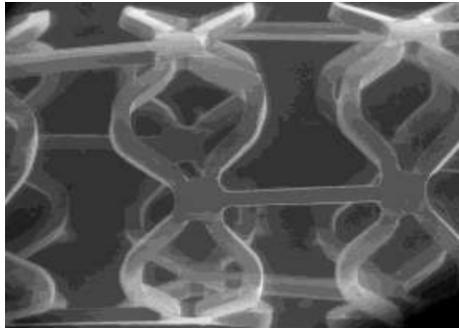
**2 years**

Corrugated endolumen  
? Due to scaffold shrinkage

Smooth endolumen, struts  
absorbed, no SB jail

## Summary & Conclusions for Cohort A

- MACE rate of 3.4% by 3 yrs
- 2 non-cardiac deaths by 3 yrs (Hodgkin disease & duodenal perforation)
- No cardiac deaths by 3 yrs
- No stent thrombosis by 3 yrs
- No ID-TLR up to 3 years
- No new MACE events between 6 months and 3 years
- Scaffold was largely resorbed by 2yrs
- Vasomotion present at 2 yrs

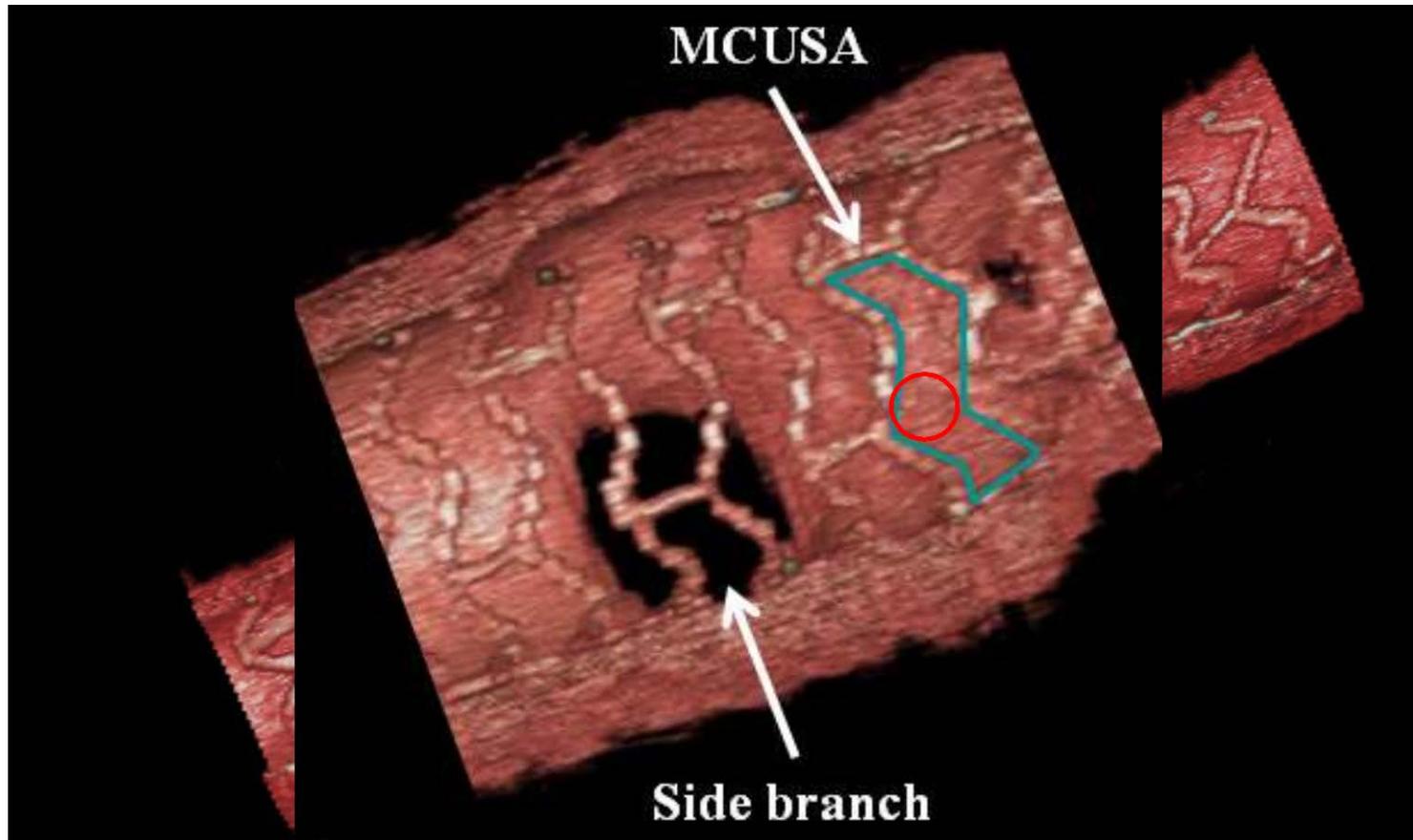


Clinical results were good but the Gen 1.0 device used in Cohort A had limitations and lessons have been learned

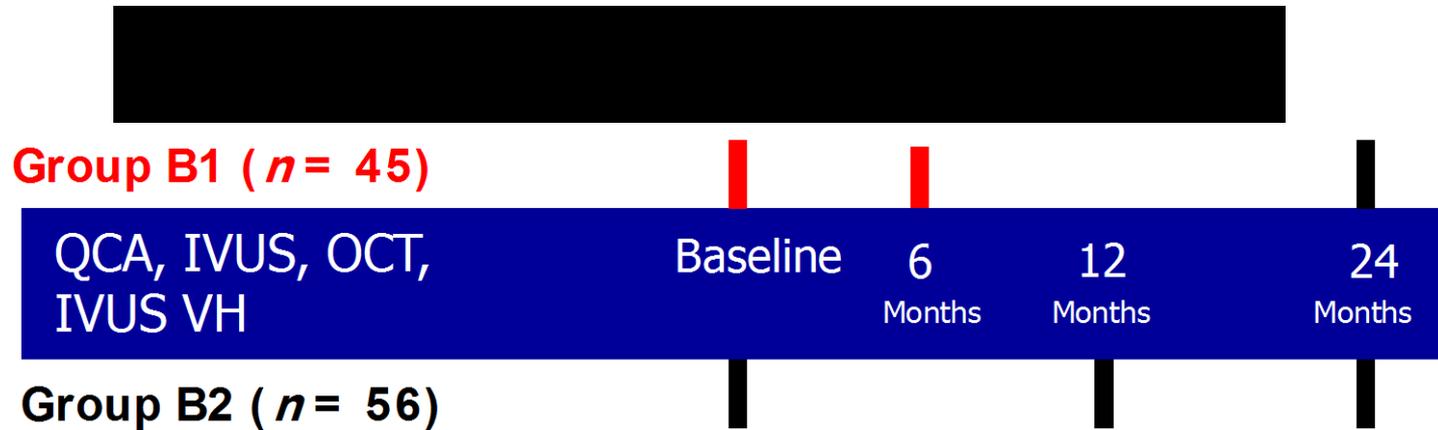
- Initial radial strength less than a metallic DES
- Unexpectedly, the duration of radial support may have been only weeks and insufficient to resist the negative remodelling after PCI
- Scaffold shrinkage by 6 months
- Late loss at 6 months was 0.44 mm due mainly to scaffold shrinkage
- Late lumen enlargement between 6 months and 2yrs occurred

# BACKGROUND.....

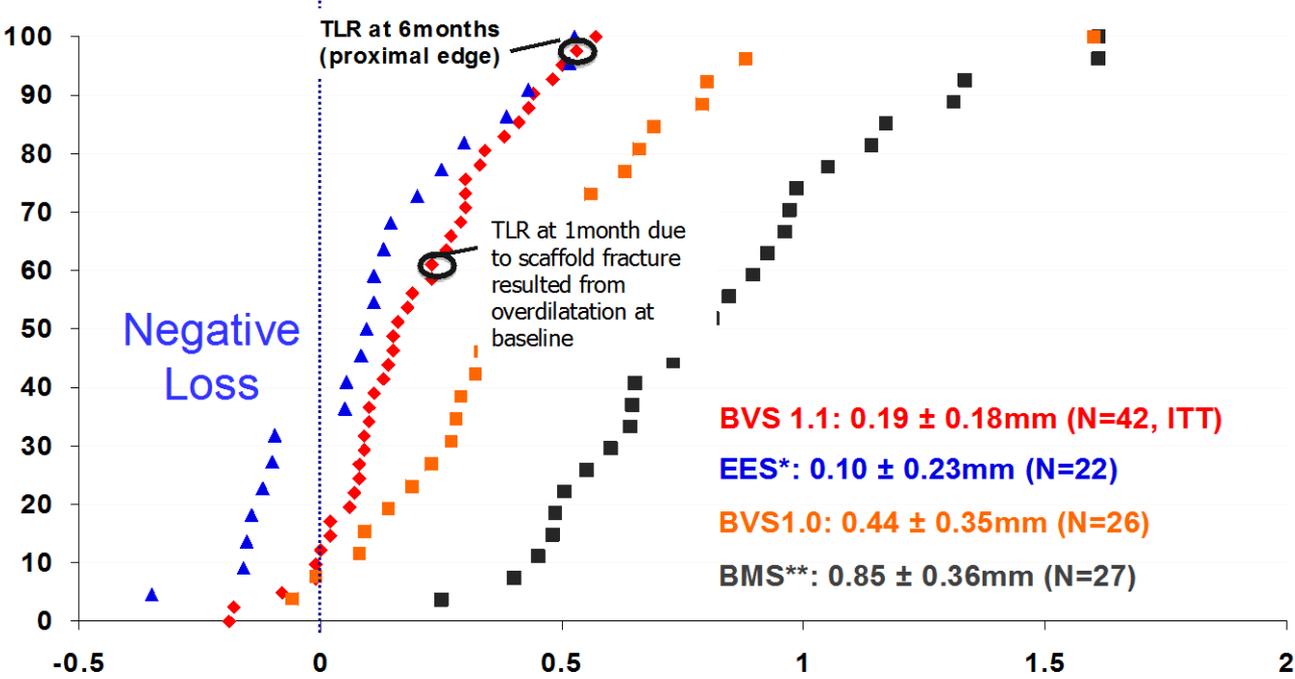
The second generation (BVS 1.1) has a modified platform designed with a reduced maximal circular unsupported scaffold area (MCUSA) and a different proprietary manufacturing process of the polymer



# Study design: ABSORB Cohort B



# Comparison of LL between BMS, Xience V, BVS 1.0 and BVS 1.1



# Clinical results @ 6 month

	30 Days	6 Months
<b>Non-Hierarchical</b>	<b>N = 45</b>	<b>N = 45</b>
Cardiac Death %	0	0
Myocardial Infarction % (n)	2.2 (1)	2.2 (1)
Q-wave MI	0	0
<b>Non Q-wave MI</b>	<b>2.2 (1)</b>	<b>2.2 (1)</b>
Ischemia driven TLR %	0	2.2 (1)
CABG	0	0
PCI	0	2.2 (1)
Hierarchical MACE % (n)	<b>2.2 (1)</b>	<b>4.4 (2)</b>
Hierarchical TVF % (n)	2.2 (1)	4.4 (2)

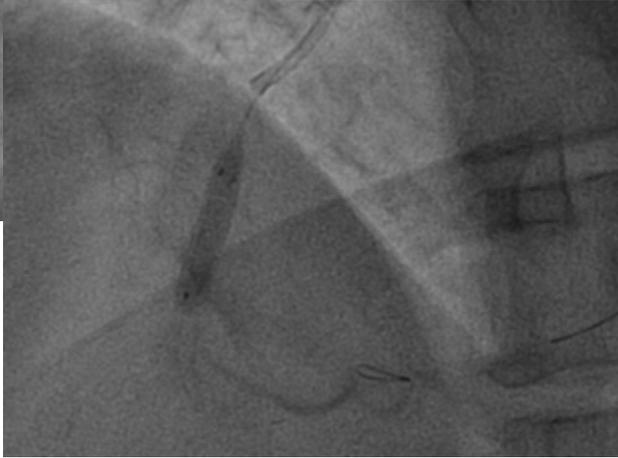
## No stent thrombosis by ARC or Protocol

MACE: Cardiac death, MI, ischemia-driven TLR

TVF: Cardiac death, MI, ischemia-driven TLR, ischemia-driven TVR

Real life.....

# PPCI for INF STEMI 26.3.2013



Thromboaspiration

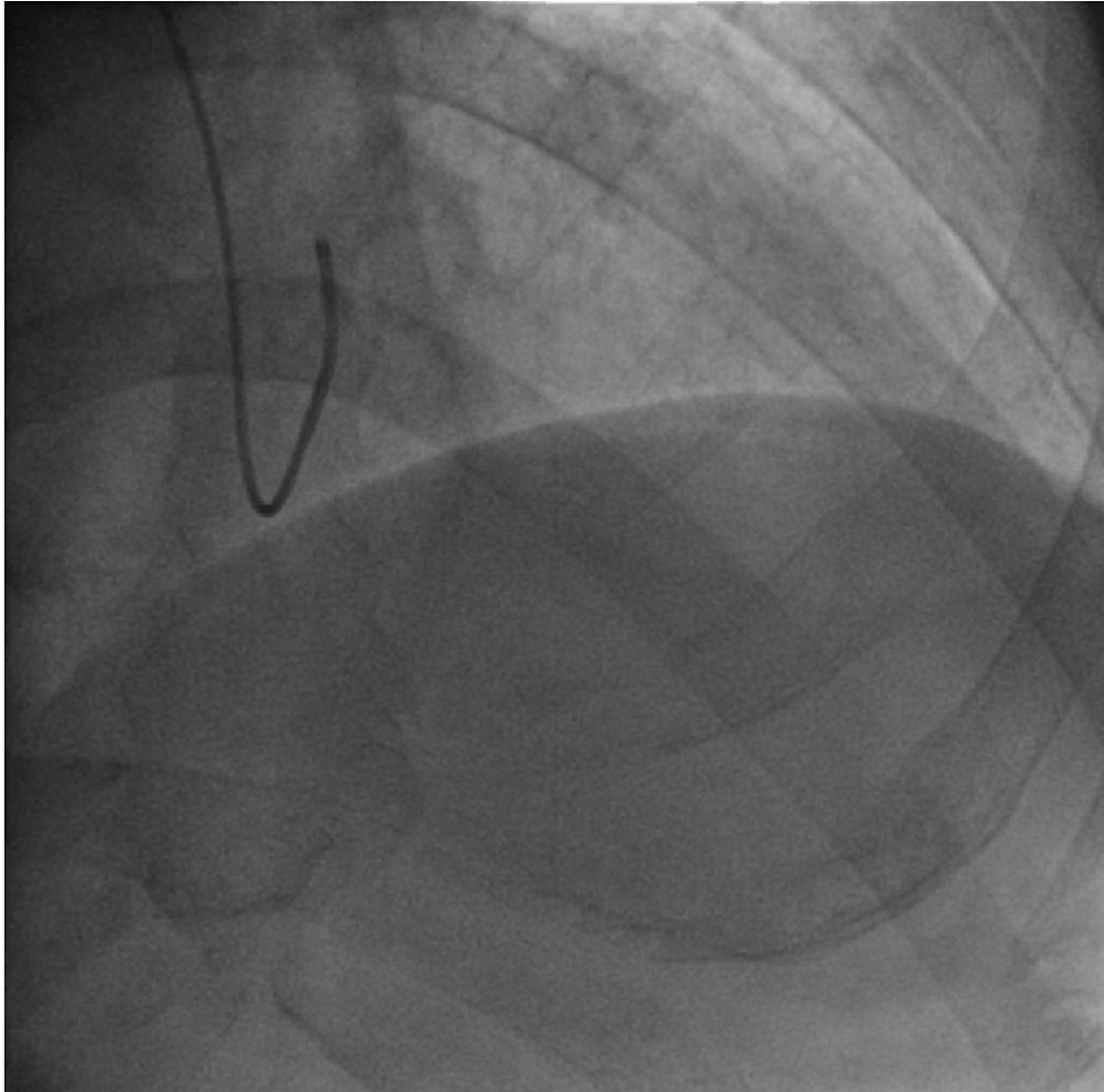
+

Distal Filter

+

**Chrono 4.5/16 @ 16 atm**

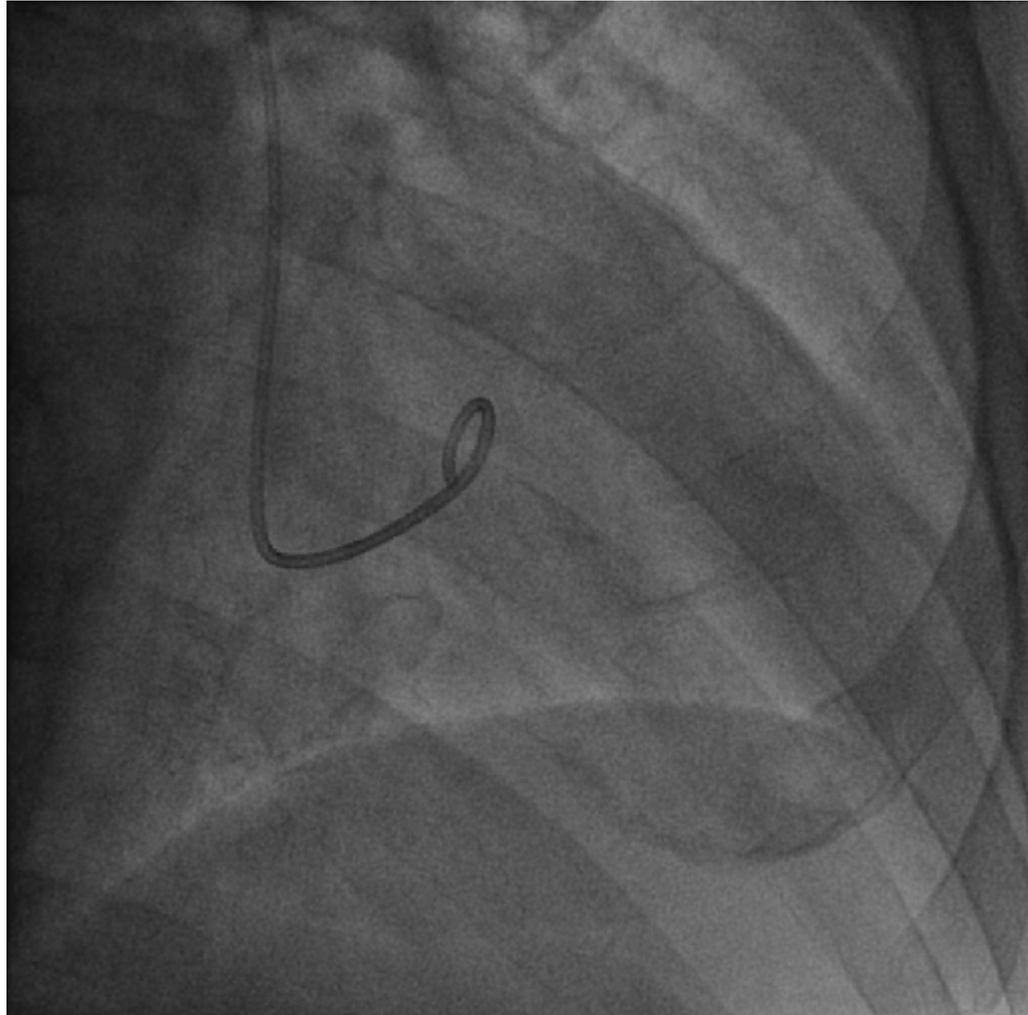
# Left CORO ANGIO 26.3.2013



# Left CORO ANGIO 26.3.2013

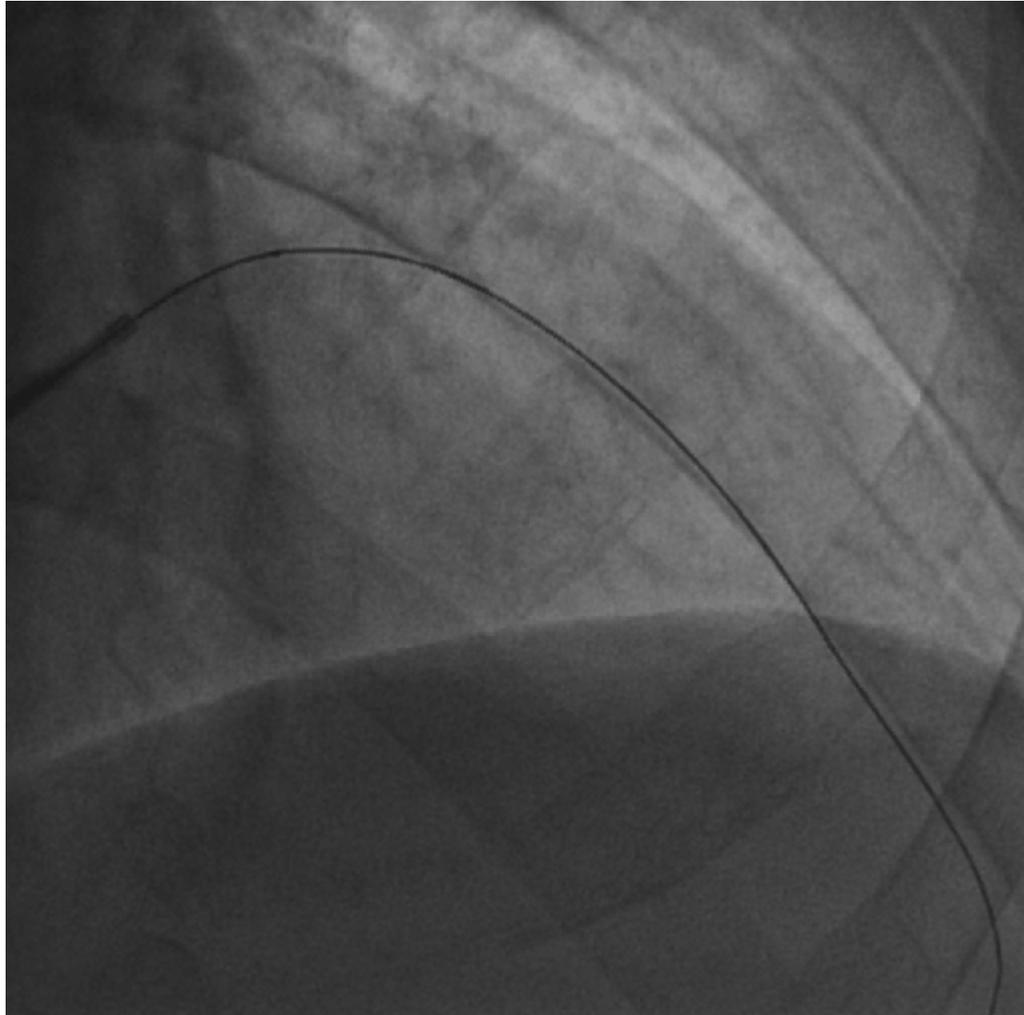


# LAD recanalization 2 M later



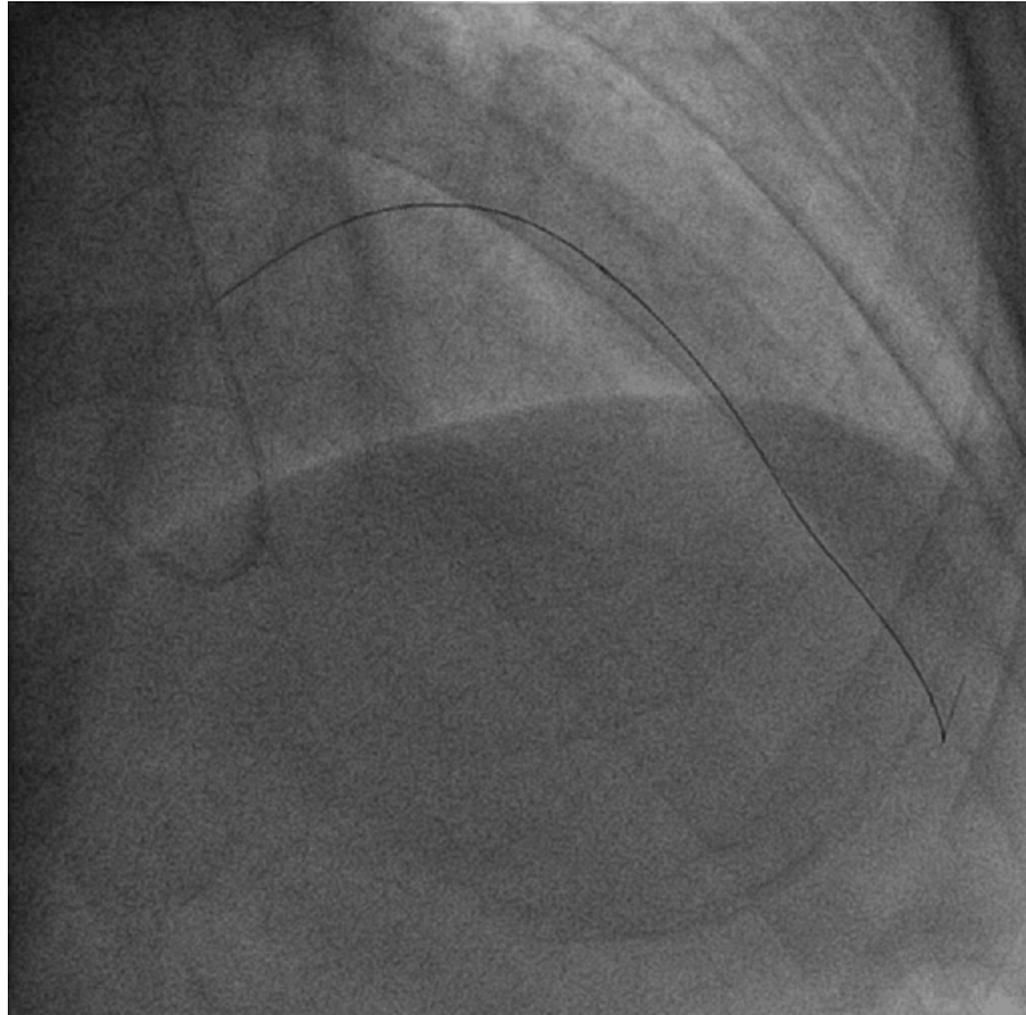
Left ventriculography confirms viable myocardium in anterolateral wall

# LAD recanalization 2 M later



- **Right Radial approach**
- **XB 3.5 6 French**
- **Fielder XT**
- **OTW Sprinter 1.25**

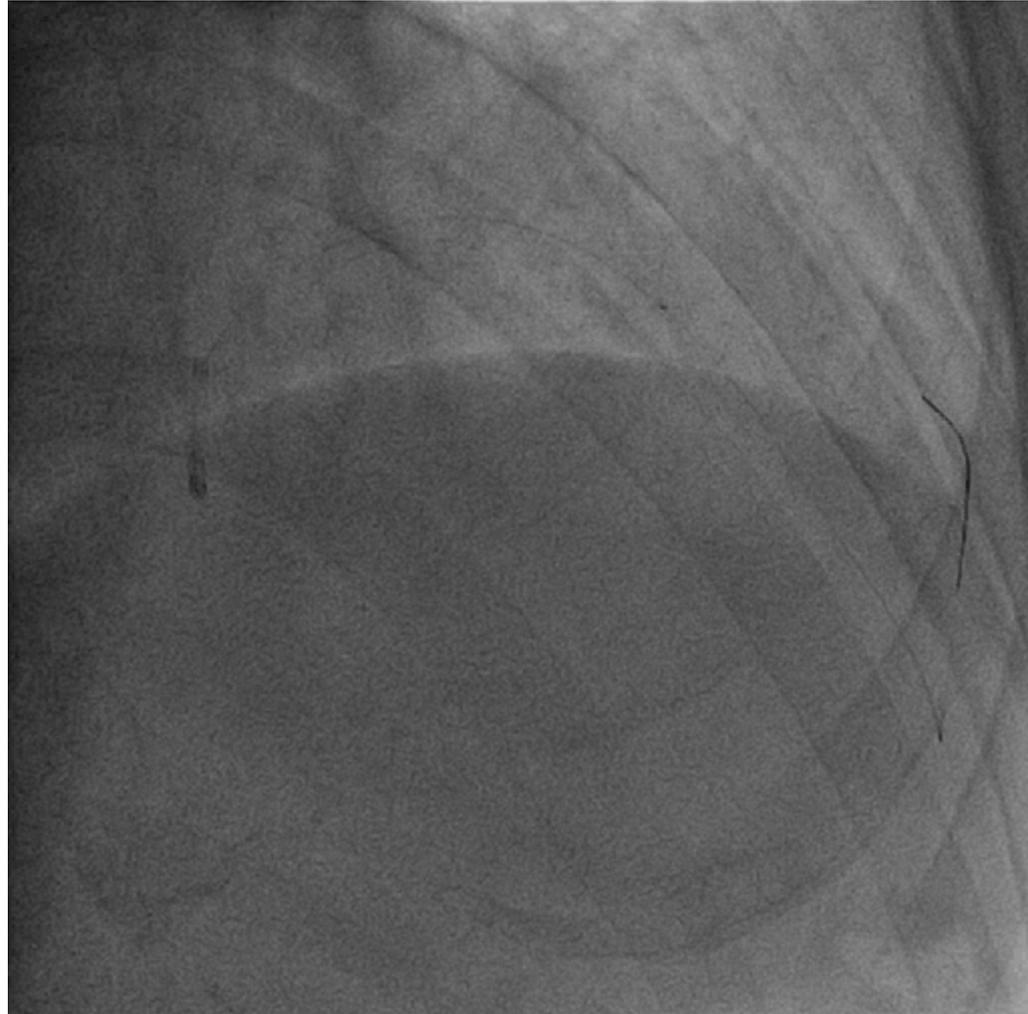
# LAD recanalization 2 M later



Predilatation with:

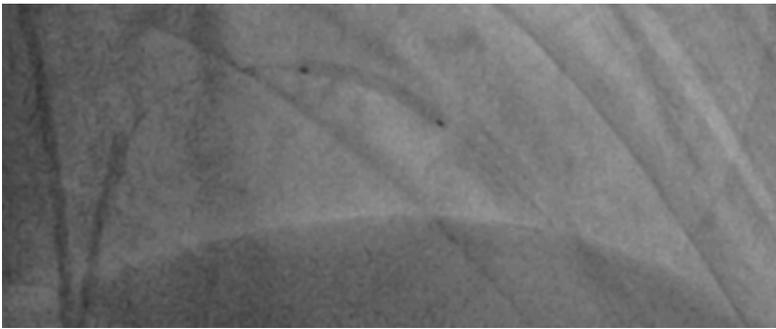
- **OTW Sprinter 1.25**
- **RE Sapphire 1.0**

# LAD recanalization 2 M later

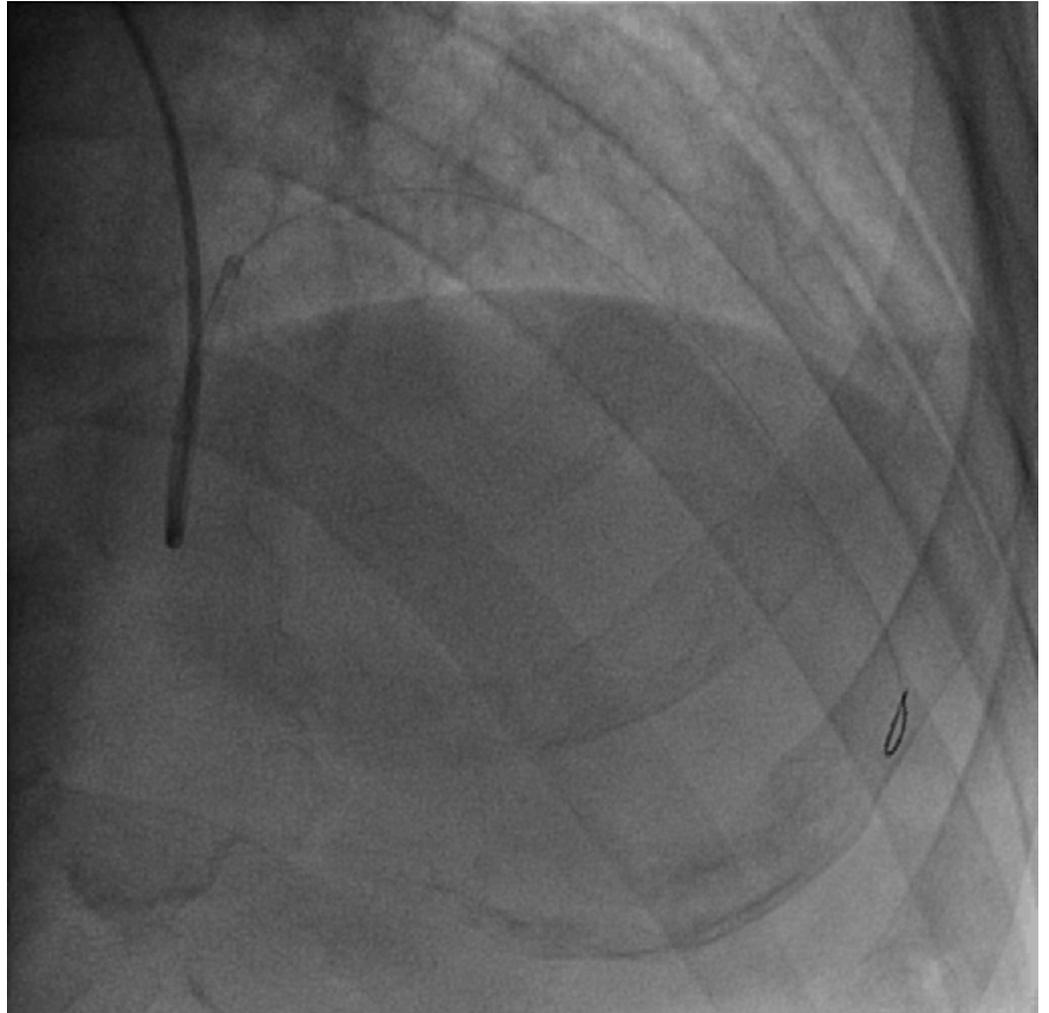


Filder XT exchanged for **BMW** through OTW  
Sprinter 1.25

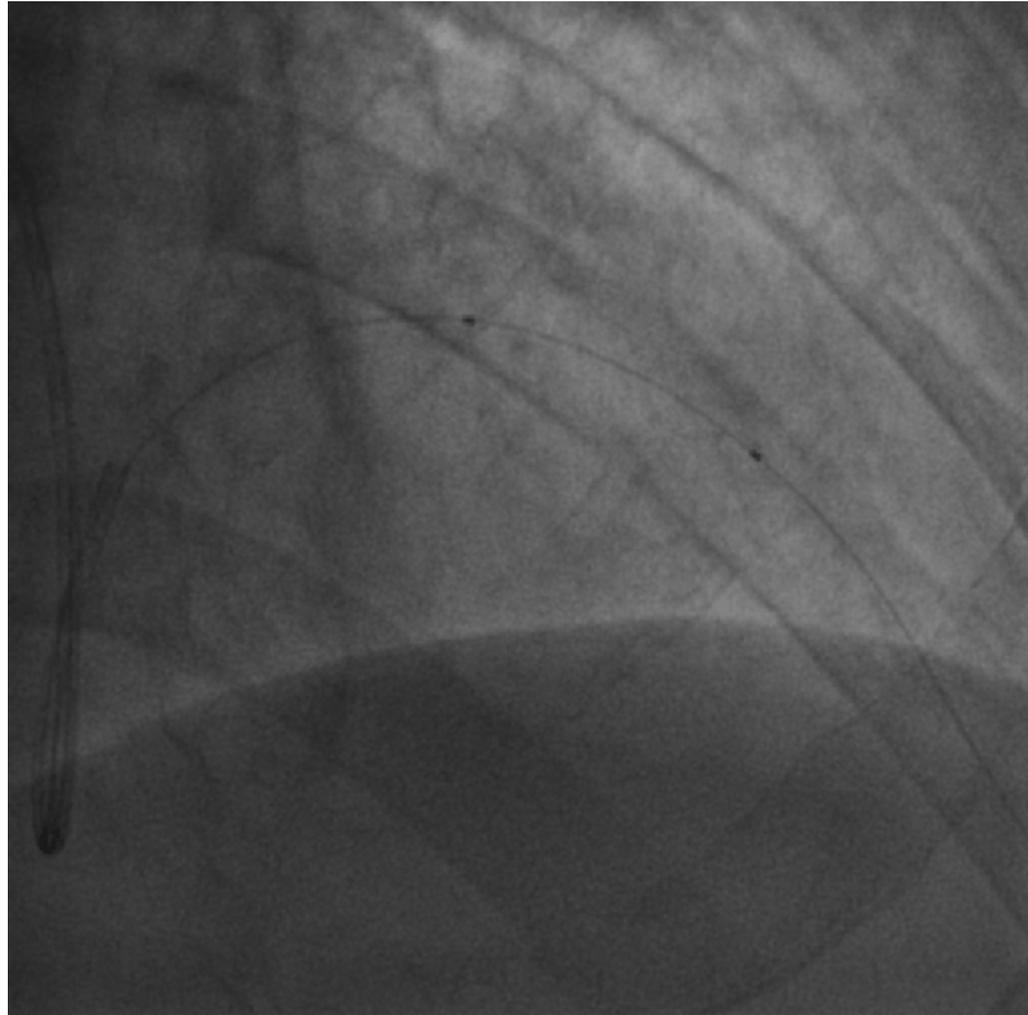
# LAD recanalization 2 M later



Predilatation with **Sapphire 2.0**

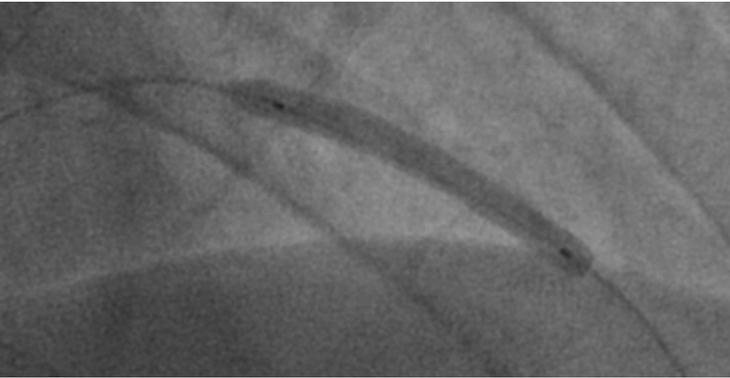


# LAD recanalization 2 M later

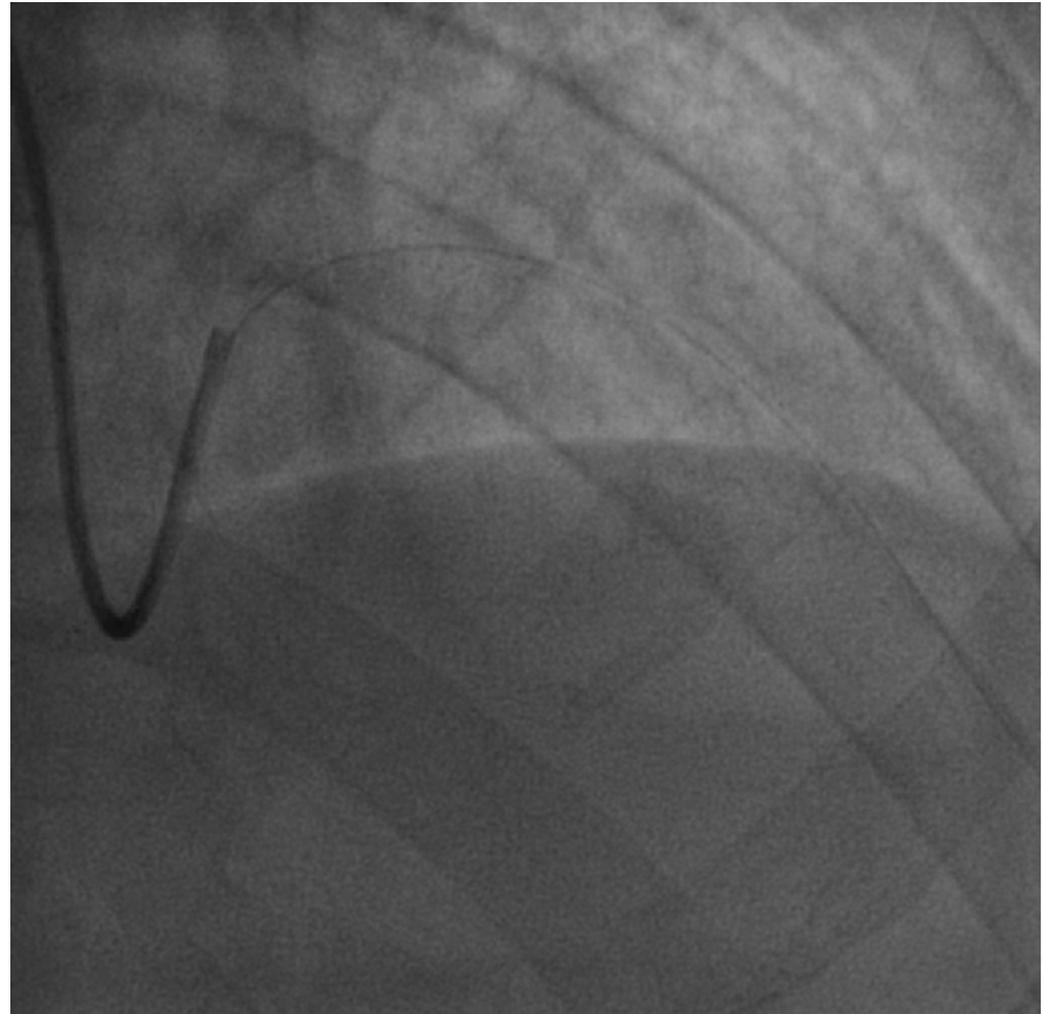


Positioning of the first **BVS 3.5/28 mm**

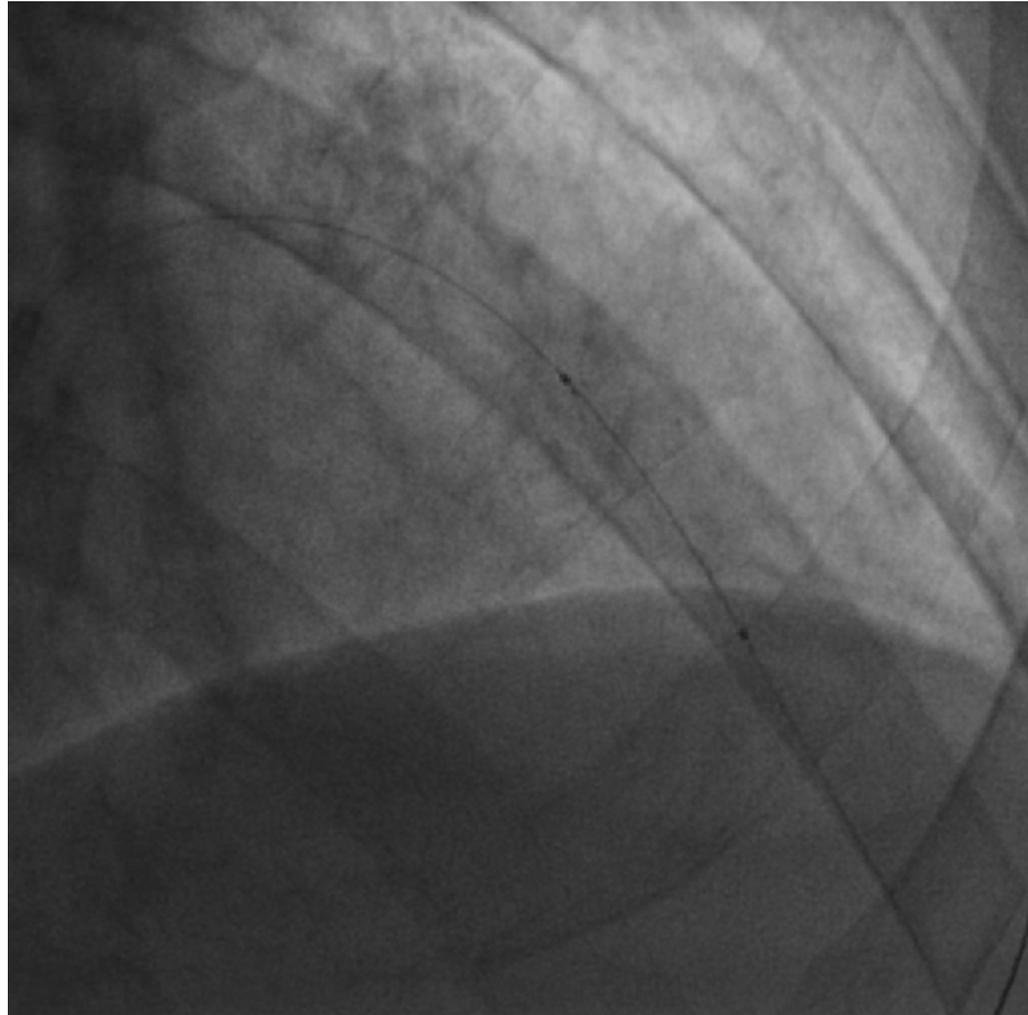
# LAD recanalization 2 M later



Implantation of the first **BVS 3.5/28 mm @ 16 atm**

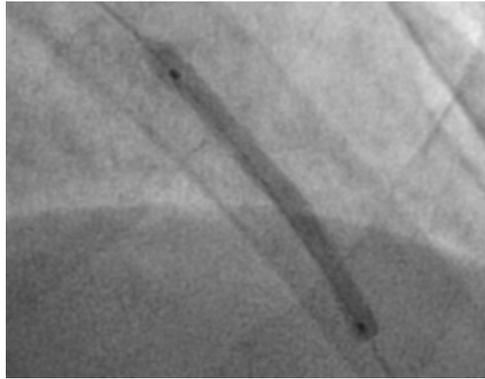


# LAD recanalization 2 M later

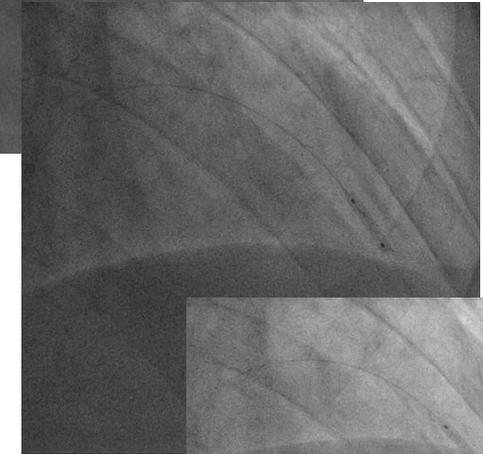
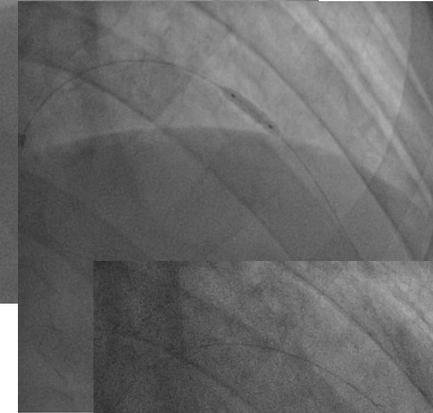
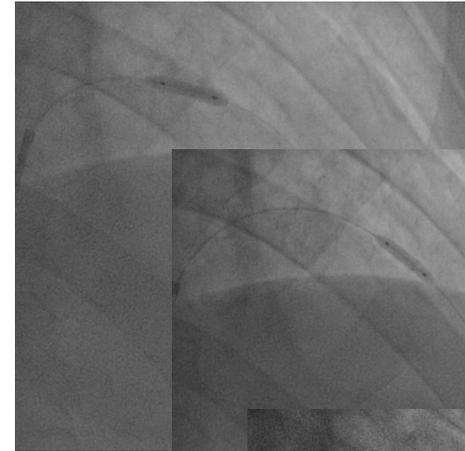


Positioning of the second **BVS 2.5/28 mm**

# LAD recanalization 2 M later

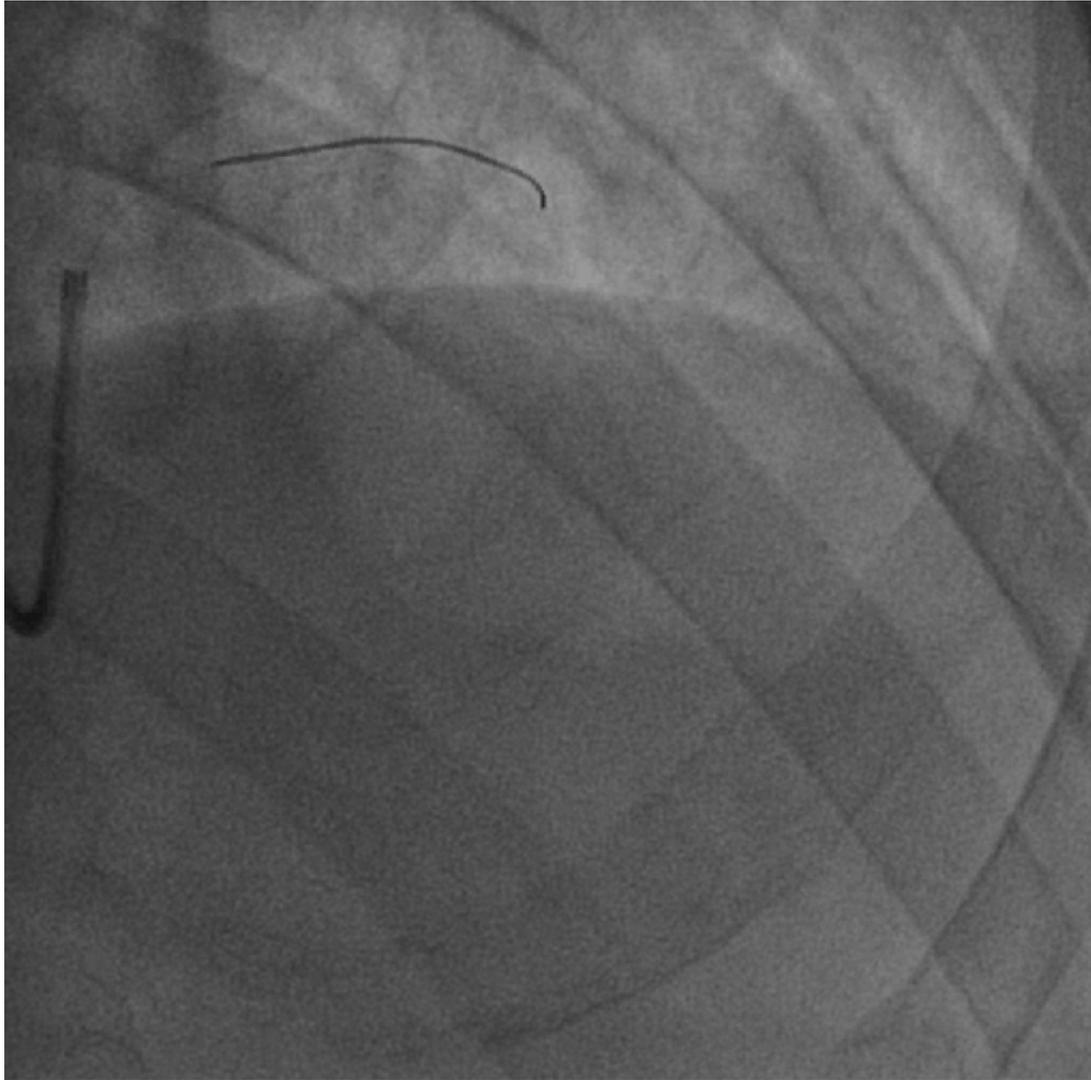


Implantation of the second **BVS**  
**2.5/28 mm @ 16 atm**



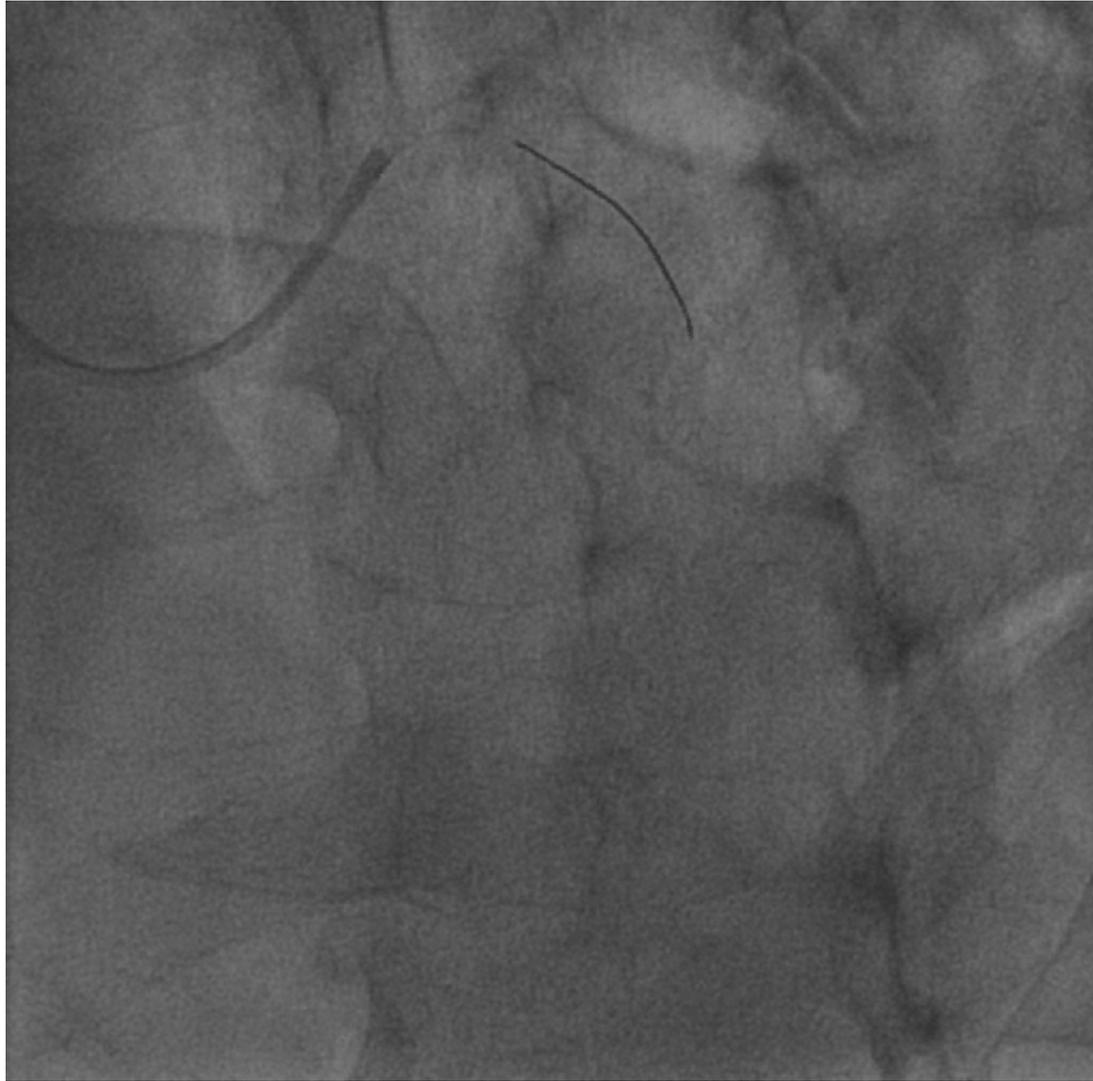
Postdilatation of the BVS with  
**Quantum 3/12 @ 12 atm**

# LAD recanalization 2 M later



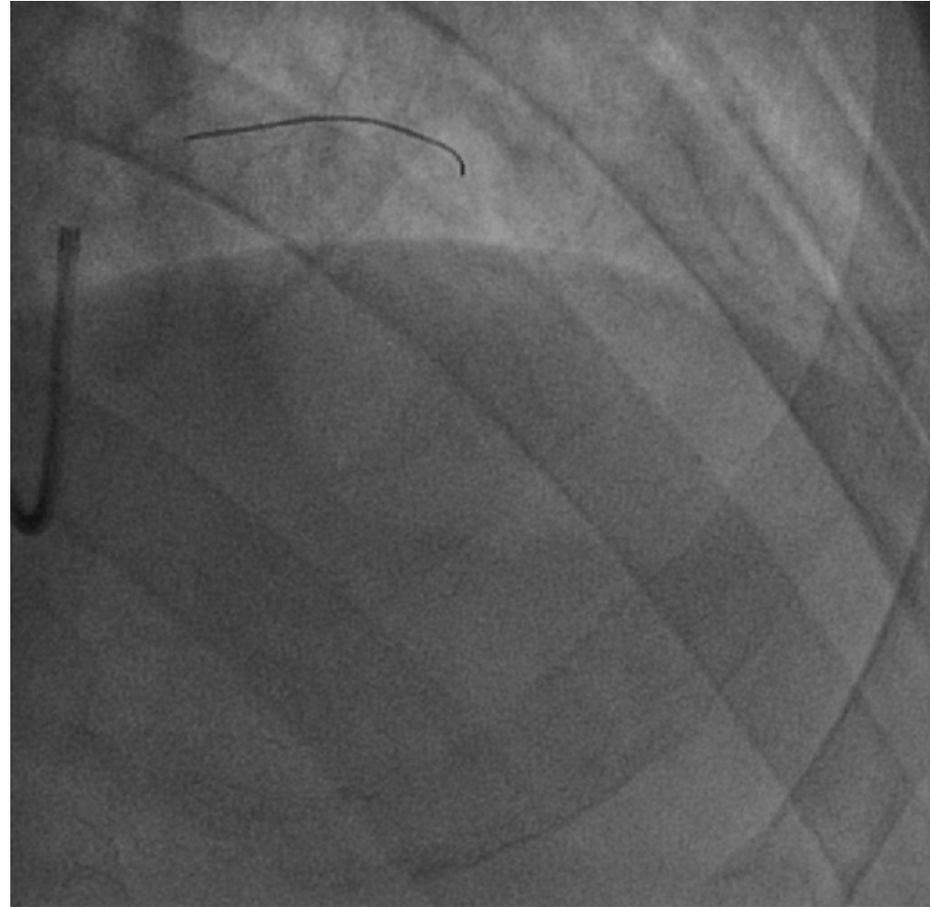
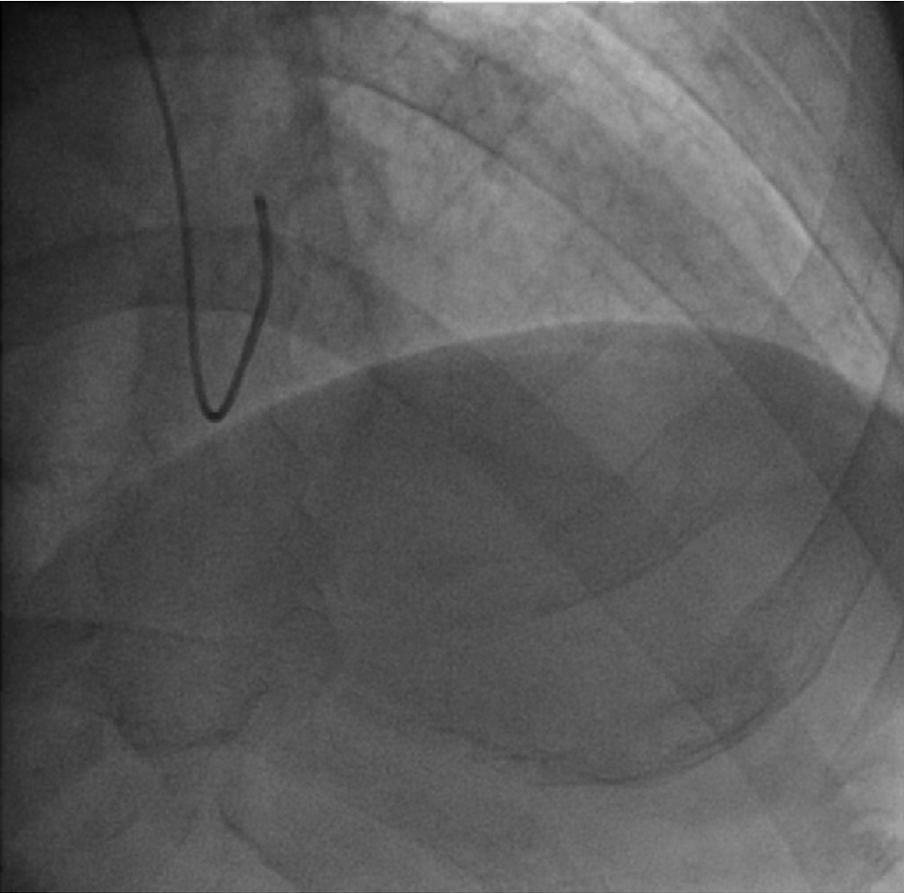
**Final result**

# LAD recanalization 2 M later



**Final result**

# LAD recanalization 2 M later



**Final result**

# Castelfranco Experience 2012/2013

<b>Patients</b>	<b>98</b>
<b>Age</b>	<b>46±12</b>
<b>Male sex</b>	<b>71 %</b>
<b>ACS @ presentation</b>	<b>38%</b>
<b>Procedural Success</b>	<b>100%</b>
<b>Target Vessel LAD</b>	<b>72%</b>
<b>BVS diameter 3.0 mm</b>	<b>72%</b>
<b>BVS/pt</b>	<b>1.8 (176 BVS)</b>
<b>Predilatation</b>	<b>100%</b>
<b>Ivus</b>	<b>27%</b>
<b>QCA</b>	<b>100%</b>
<b>Postdilatation</b>	<b>100%</b>
<b>Mace @ clinical FU</b>	<b>0</b>
<b>AngioFU</b>	<b>35%</b>
<b>Restenosis Angio</b>	<b>0,98%</b>

# Conclusion 1

- ❖ Utilization of BVS for treatment of de novo lesions is demonstrated.
- ❖ Utilization of BVS in settings such as CTO bifurcation appears feasible and safe.
- ❖ When BVS is used for CTO recanalization, meticulous lesion preparation is mandatory (predilatation with non-compliant balloon, Cutting balloon, Rotablator)
- ❖ BVS technology for CTO recanalization is particularly appealing in case of diffuse disease in which multiple overlapping stenting would be required («full metal jacket»)

# Conclusion 2

- ❖ CTO recanalization with multiple overlapping BVS allows real vessel reconstruction (not eliminating a possible subsequent surgical option), with the possibility of vasomotion restoration after 18 mo
- ❖ It is possible to hypotize that the risk of ST with multiple overlapping BVS is lower than multiple overlapping (metal) stents (may tend to ZERO !!!) but we need more data on that.