

**Erasmus MC**

Universitair Medisch Centrum Rotterdam



**TCTAP 2014 Session: Drug-eluting stents – bioresorbable scaffolds**

**5 Year Follow-Up After  
Bioresorbable Vascular Scaffold Implantation  
Insights from OCT**

**E. Regar, A. Karanasos  
Thoraxcenter  
Erasmus Medical Center  
Rotterdam, NL**

# History at Thoraxcenter: Clinical Trial Program **ABSORB**

## COHORT A

First in Men, n=30  
Single de-novo lesion  
OCT:  
Single center, n=16  
Academic analysis  
Thoraxcenter

A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial

Ormiston et al. Lancet 2008  
Serruys et al. Lancet 2010

## COHORT B

First in Men, n=101  
Single de-novo lesion

## EXTEND

Clinical trial, n=1000  
Multiple de novo-lesions  
Long lesions  
OCT:  
Multi-center, n=50  
Corelab analysis  
Cardialysis

## ABSORB II

Clinical trial, n=500  
Multiple de novo-lesions  
Stable angina & ACS  
RANDOMIZED 2:1  
(BVS vs Xience)

## B-SEARCH

Thoraxcenter Registry  
All-comer  
Real-world use  
Simsek et al. Eurointerv 2013  
Diletti et al. Eur Heart J 2014



# Clinical Trial Program **ABSORB A**

## COHORT A

First in Men, n=30

Single de-novo lesion

OCT:

Single center, n=16

Academic analysis

Thoraxcenter

The prospective, multicenter trial  
evaluated

the **safety and performance of the BVS\***  
everolimus eluting coronary stent system  
in the treatment of patients with single, *de  
novo*, native coronary artery disease.

A bioabsorbable everolimus-eluting coronary stent system  
for patients with single de-novo coronary artery lesions  
(ABSORB): a prospective open-label trial

Ormiston et al. Lancet 2008; Serruys et al. Lancet 2010

Ormiston et al. Lancet 2008

Serruys et al. Lancet 2010



# Clinical Trial Program **ABSORB A**

## COHORT A

**First in Men, n=30**

**Single de-novo lesion**

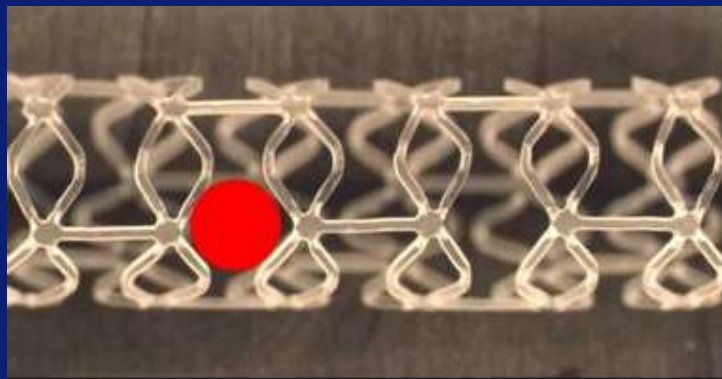
**OCT:**

**Single center, n=16**

**Academic analysis**

**Thoraxcenter**

## **BVS Gen 1.0**



### **Everolimus / PLA Matrix Coating**

- Thin coating layer
- Amorphous (non-crystalline)
- 1:1 ratio of Everolimus/PLA matrix

### **PLA Stent Backbone**

A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial

Ormiston et al. Lancet 2008

Serruys et al. Lancet 2010



# Clinical Trial Program **ABSORB A**

## COHORT A

**First in Men, n=30**

**Single de-novo lesion**

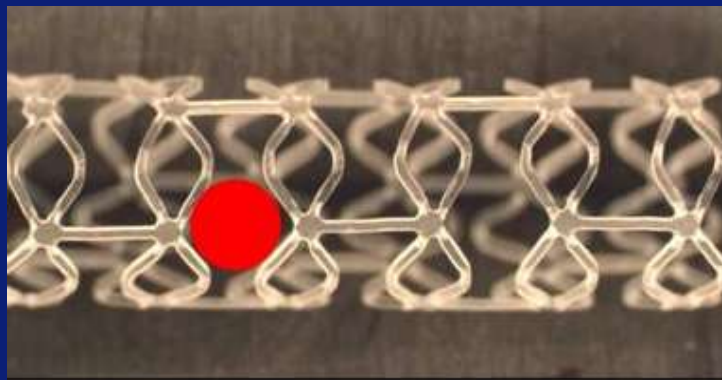
**OCT:**

**Single center, n=16**

**Academic analysis**

**Thoraxcenter**

## **BVS Gen 1.0**



**Diameter: 3.0 mm**

**Length: 12 and 18mm**

A bioabsorbable everolimus-eluting coronary stent system  
for patients with single de-novo coronary artery lesions  
(ABSORB): a prospective open-label trial

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**Ormiston et al. Lancet 2008**

**Serruys et al. Lancet 2010**





# Clinical Trial Program **ABSORB A**

## COHORT A

First in Men, n=30

Single de-novo lesion

OCT:

Single center, n=16

Academic analysis

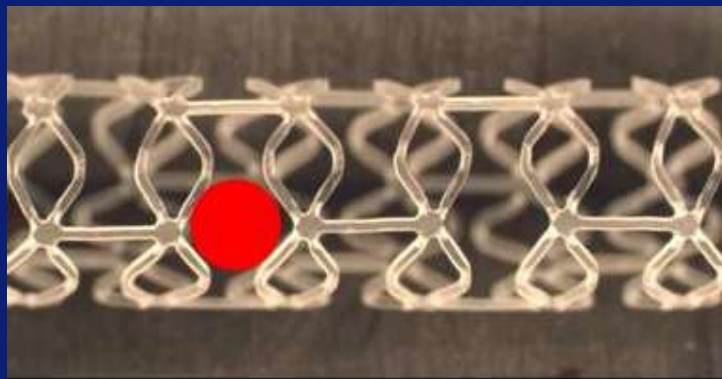
Thoraxcenter

A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial

Ormiston et al. Lancet 2008

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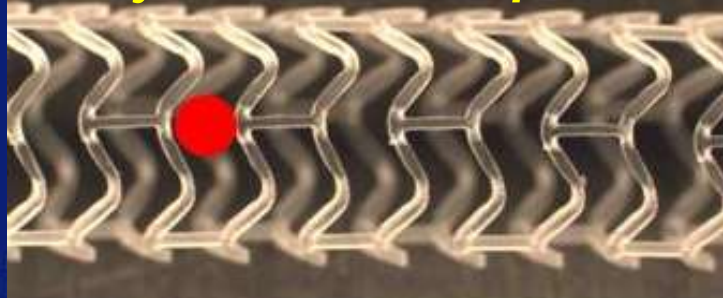
## BVS Gen 1.0



*maximal unsupported coronary area*

## BVS Gen 1.1

*Today's commercial product*





# Clinical Trial Program ABSORB A

## COHORT A

First in Men, n=30

Single de-novo lesion

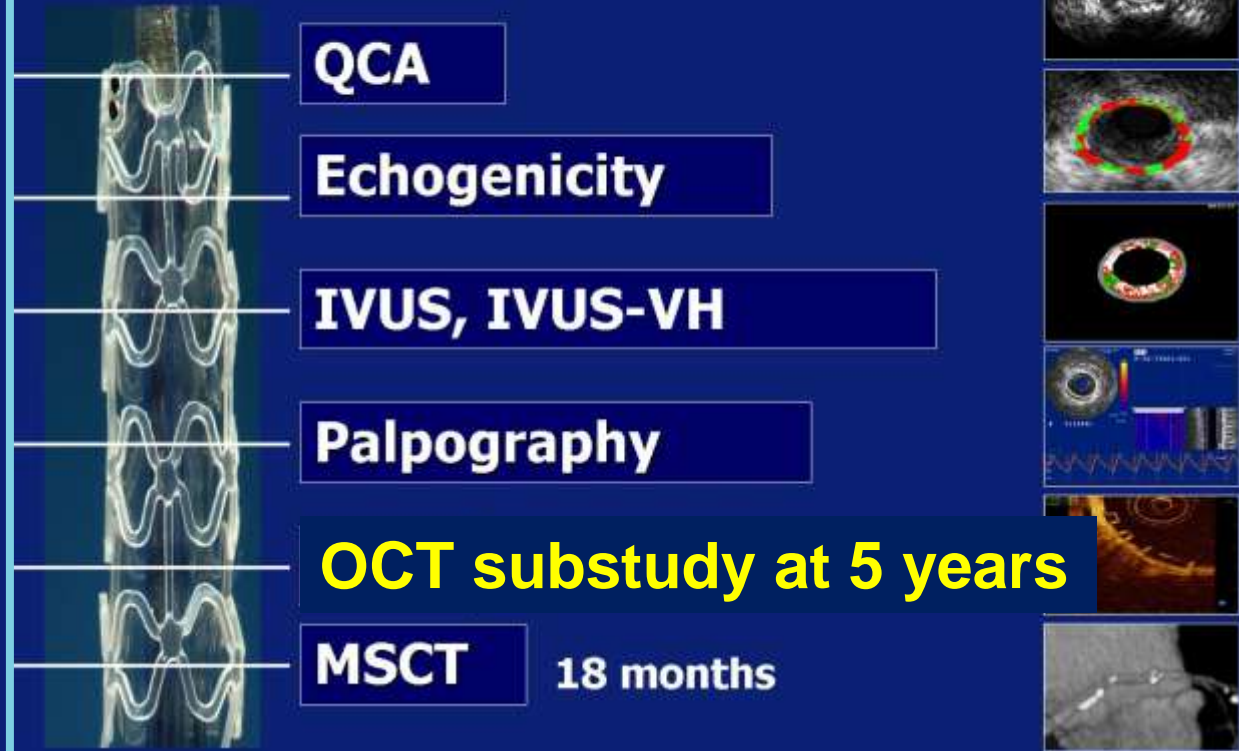
OCT:

Single center, n=16

Academic analysis

Thoraxcenter

### ABSORB Cohort A - Study Design Imaging Follow-Up (6m and 2y)



A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial

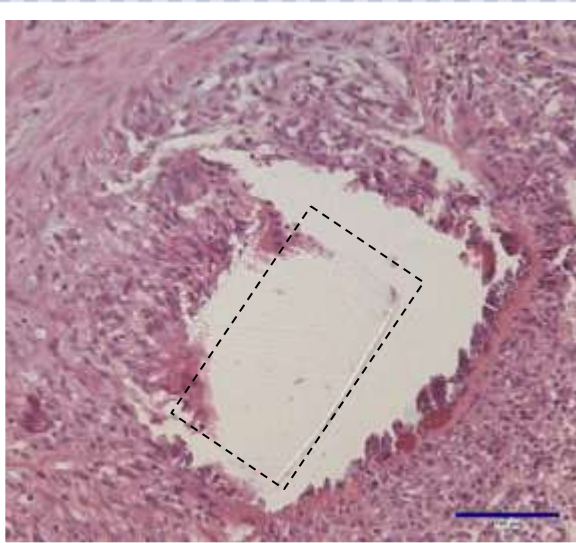
Ormiston et al. Lancet 2008

Serruys et al. Lancet 2010

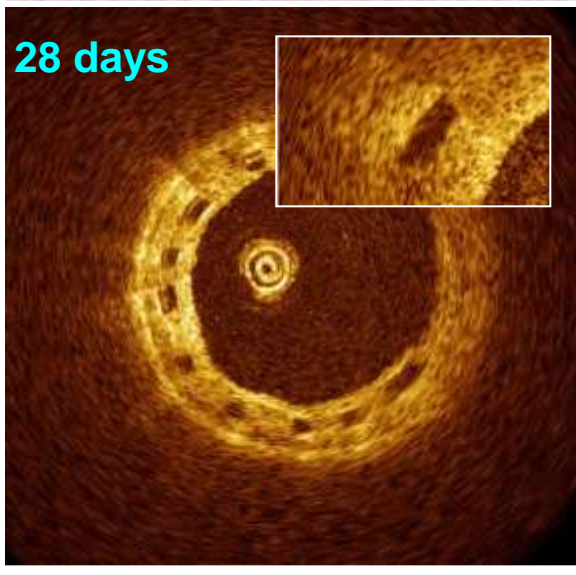
# BVS in a Porcine Model Histopathology vs. OCT

Early

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28 days





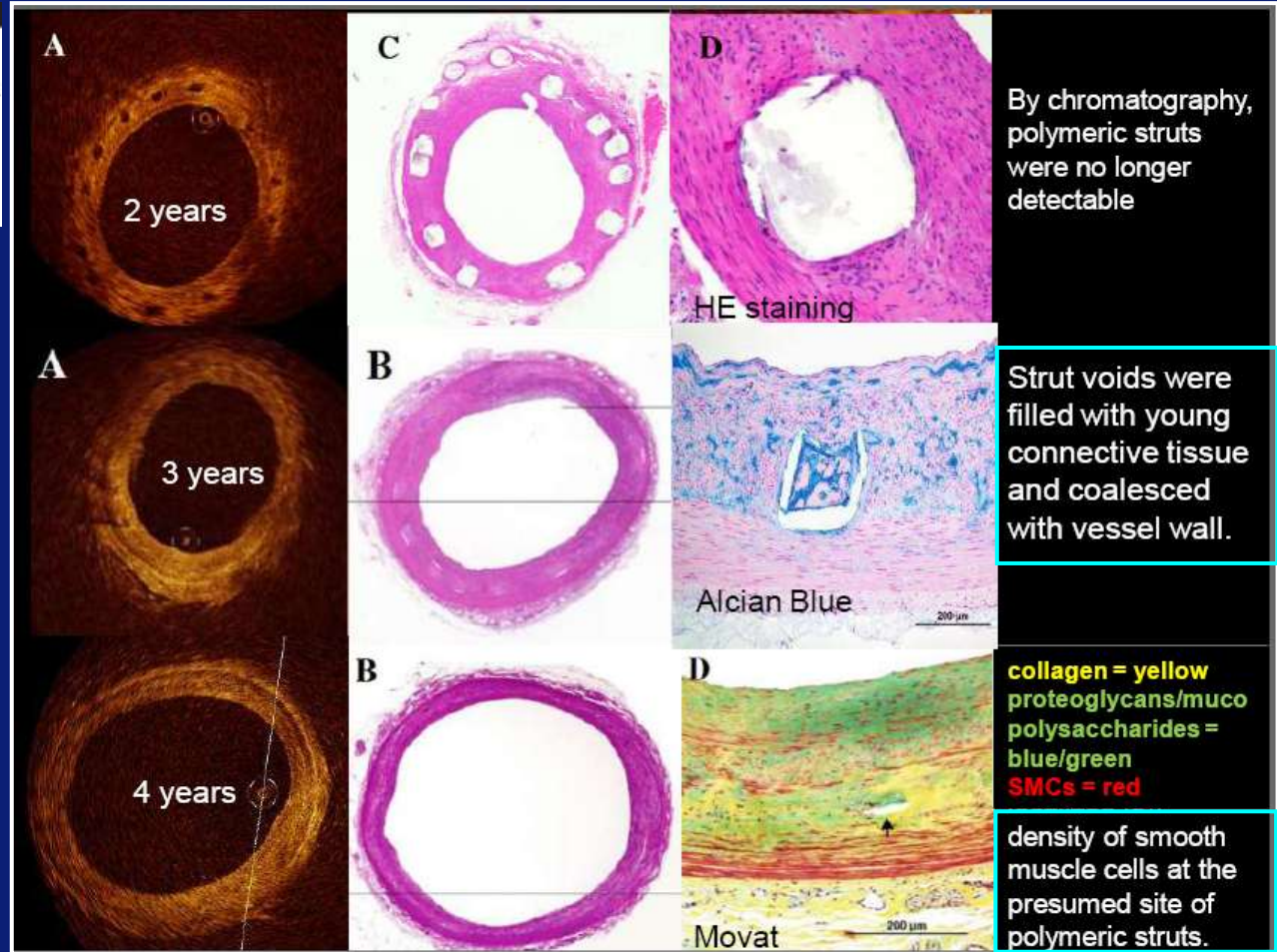


# BVS in a Porcine Model Histopathology vs. OCT Late

**Interventional Cardiology**

**Intracoronary Optical Coherence Tomography and Histology at 1 Month and 2, 3, and 4 Years After Implantation of Everolimus-Eluting Bioresorbable Vascular Scaffolds in a Porcine Coronary Artery Model: An Attempt to Decipher the Human Optical Coherence Tomography Images in the ABSORB Trial**

Yoshiro Onuma, MD\*, Patrick W. Serruys, MD, PhD\*, Laura E.L. Perkins, DVM, PhD, Takayuki Okamura, MD, Nieves Gonzalez, MD, Hector M. Garcia-Garcia, MD, PhD, Evelyn Rogge, MD, PhD, Mafalda Kambouzi, PhD, Ismael C. Pooser, BS, Richard Raposo, PhD, Heleen van Beusekom, PhD, Willem van der Giessen, MD, PhD, Remu Vlietman, PhD





# Patient Characteristics

<b>Patient number</b>	<b>n=8</b>	
<b>Demographic characteristics</b>		
<b>Age, years (<math>\pm</math>SD)</b>	<b>65.1</b>	<b>(<math>\pm</math>8.6)</b>
<b>Male, %</b>	<b>75</b>	<b>(6/8)</b>
<b>Cardiac history (%)</b>		
<b>Prior target vessel intervention</b>	<b>12.5</b>	<b>(1/8)</b>
<b>Prior myocardial infarction</b>	<b>12.5</b>	<b>(1/8)</b>
<b>Risk factors (%)</b>		
<b>Current smoking</b>	<b>12.5</b>	<b>(1/8)</b>
<b>Hypertension</b>	<b>50</b>	<b>(4/8)</b>
<b>Hypercholesterolemia</b>	<b>37.5</b>	<b>(3/8)</b>
<b>Diabetes</b>	<b>12.5</b>	<b>(1/8)</b>



# Lesion Characteristics

## Treated vessel (%)

<b>RCA</b>	<b>12.5</b>	<b>(1/8)</b>
<b>LAD</b>	<b>37.5</b>	<b>(3/8)</b>
<b>LCX</b>	<b>50.0</b>	<b>(4/8)</b>

## ACC lesion type (%)

<b>A</b>	<b>0</b>	<b>(0/8)</b>
<b>B1</b>	<b>50</b>	<b>(4/8)</b>
<b>B2</b>	<b>50</b>	<b>(4/8)</b>
<b>C</b>	<b>0</b>	<b>(0/8)</b>

## QCA

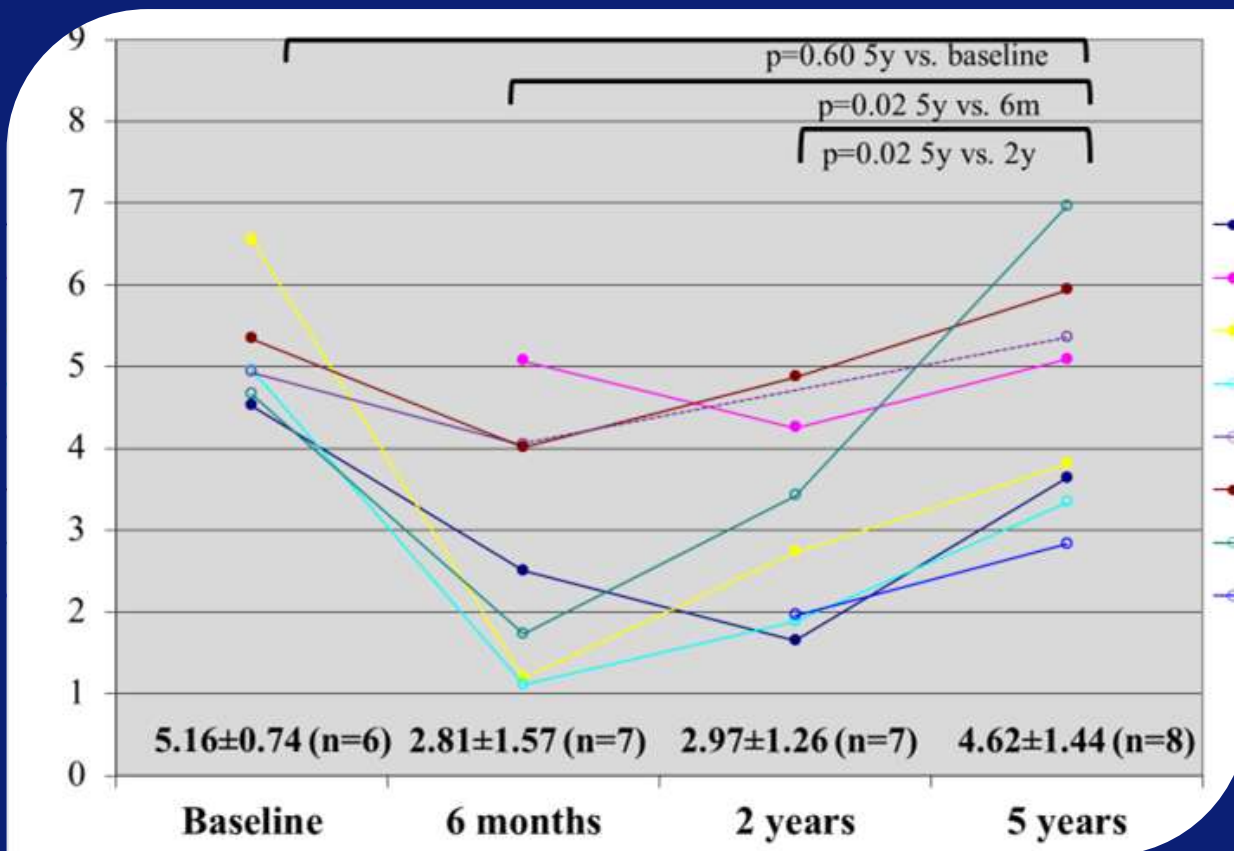
<b>Mean reference vessel diameter, mm (±SD)</b>	<b>3.0</b>	<b>(±0.6)</b>
<b>Minimum luminal diameter, mm (±SD)</b>	<b>1.1</b>	<b>(±0.3)</b>
<b>Diameter stenosis, % (±SD)</b>	<b>64.6</b>	<b>(±10.7)</b>
<b>Lesion length, mm (±SD)</b>	<b>10.8</b>	<b>(±4.0)</b>



# BVS Lumen Area Over Time

## 5 Years: Late Increase!

Minimal Lumen Area (mm<sup>2</sup>)

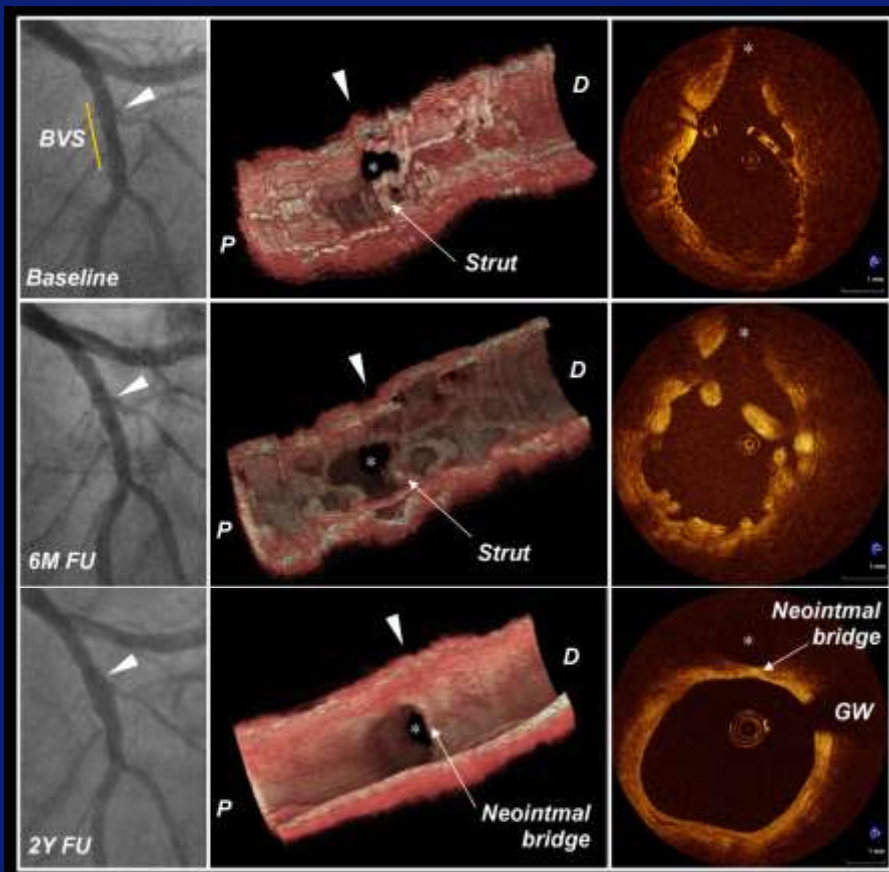


- Initial decrease due to acute recoil
- Consistent late increase in all patients !





# BVS – Fate of Jailed Side Branches? 2 Years: Neointimal Bridge



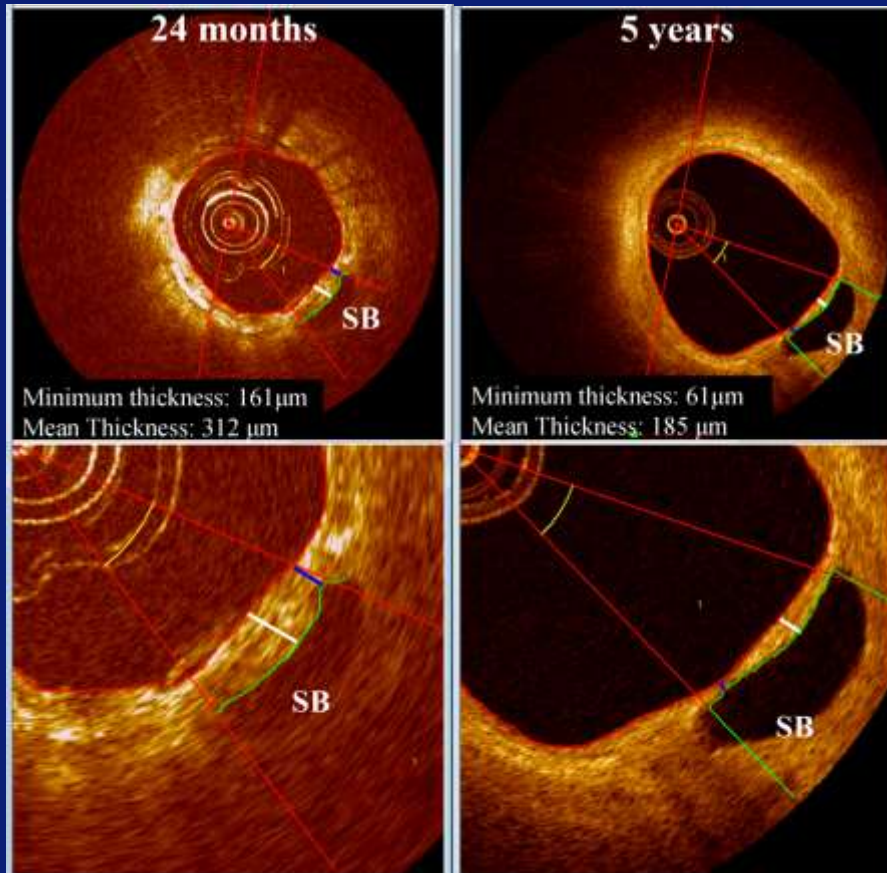
- Gradual bioresorption of SB struts
- Neointimal growth → neointimal bridge
- ‘Neo-carina’





# BVS – Fate of Jailed Side Branches?

## 5 Years: All Side Branches Patent!

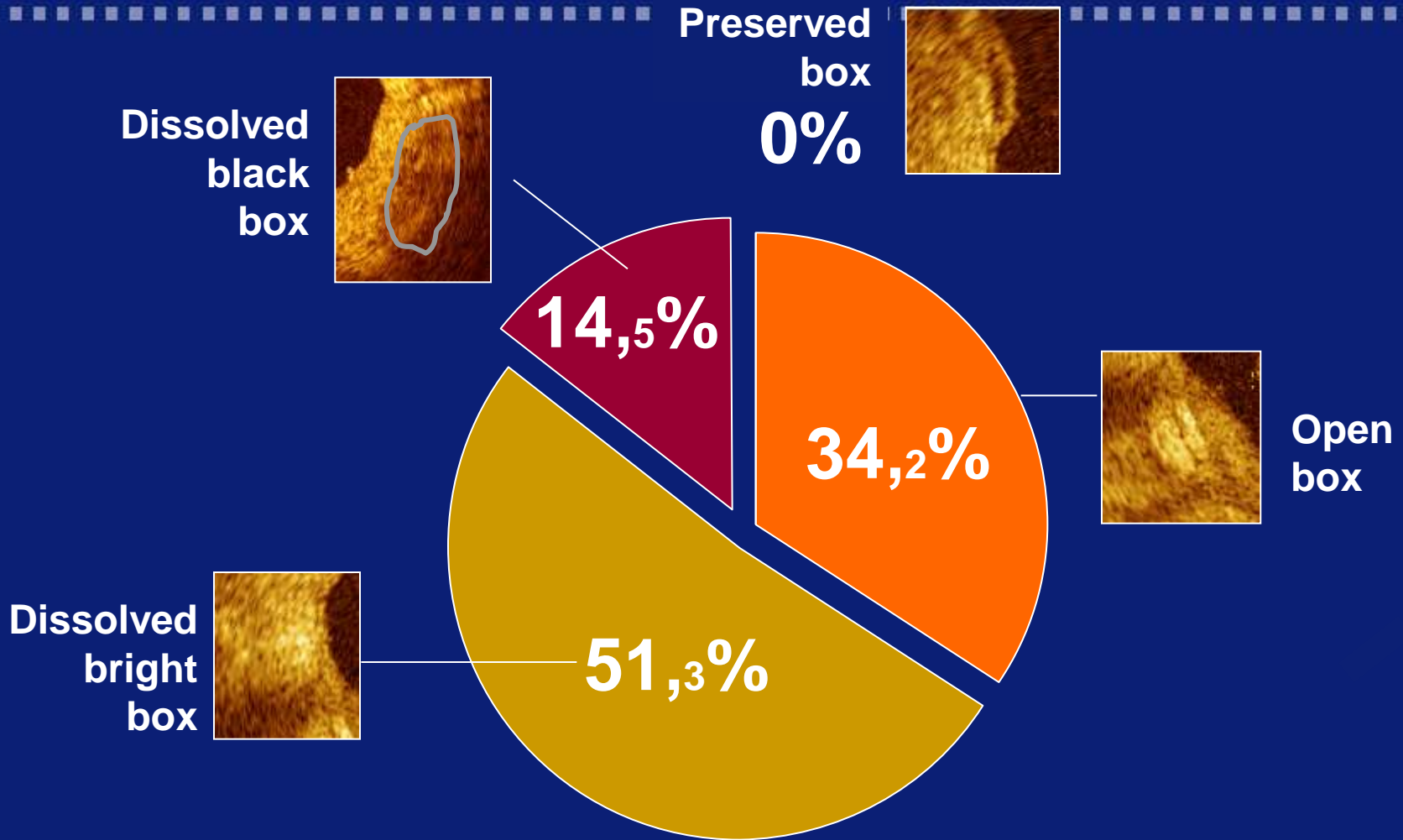


- Gradual bioresorption of SB struts
- Neointimal growth → neointimal bridge
- ‘Neo-carina’
- Further thinning of neointimal bridge



# BVS Strut Appearance Over Time

## 6 Months



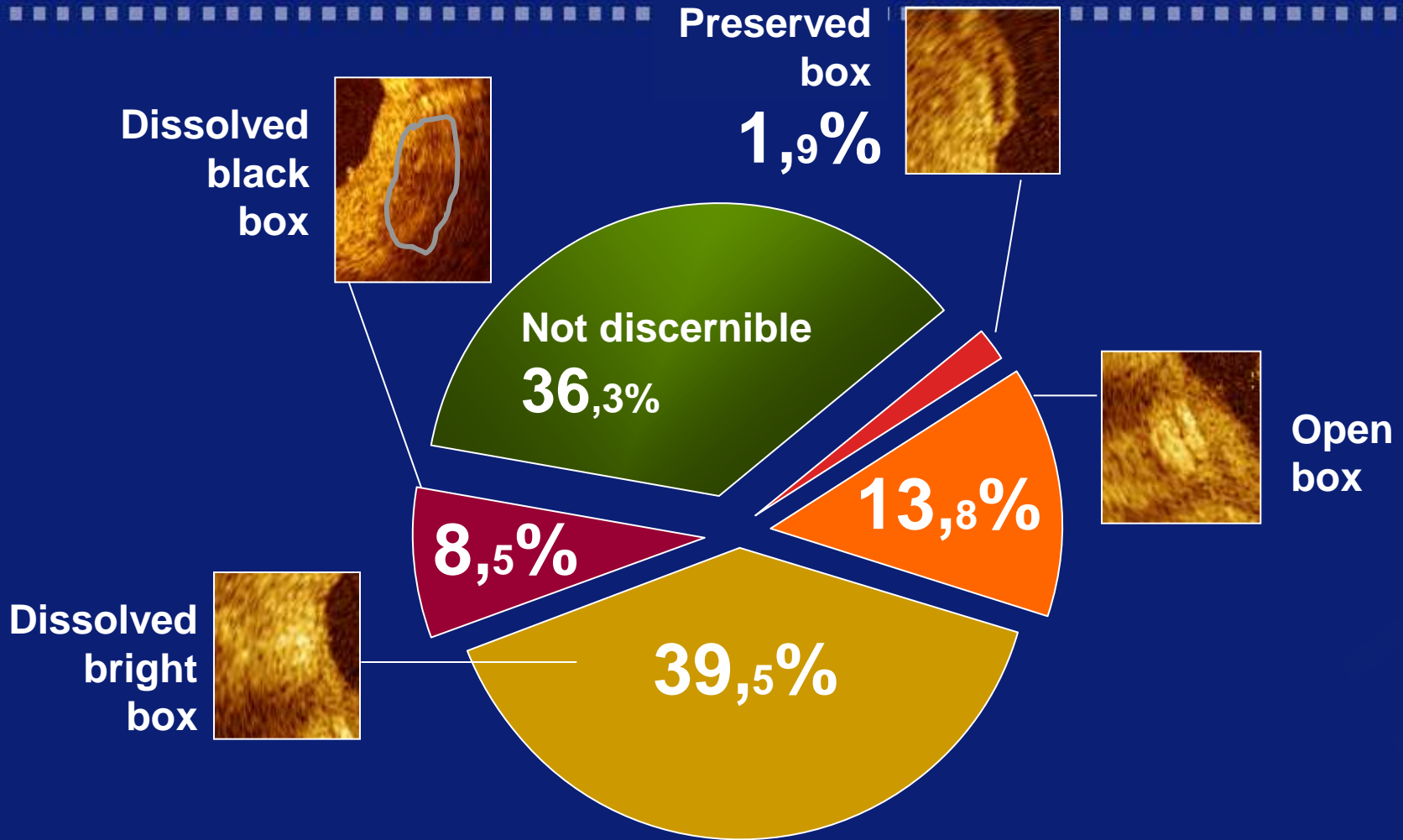
*Semiquantitative analysis*

*N=7, matched*



# BVS Strut Appearance Over Time

## 2 Years



*Semiquantitative analysis*

*N=7, matched*



# BVS Strut Appearance Over Time

## 5 Years



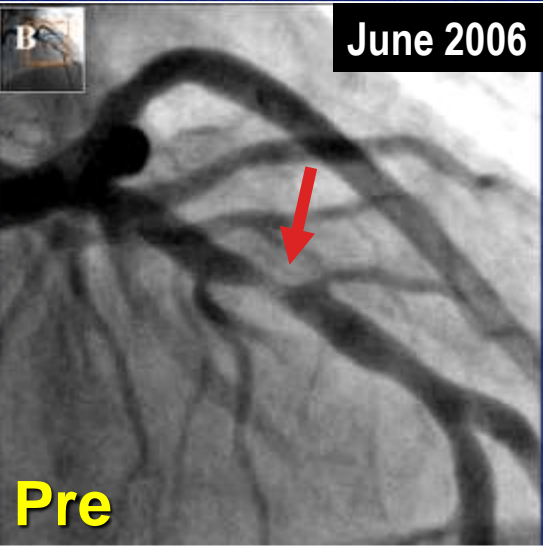


# BVS Strut Appearance Over Time

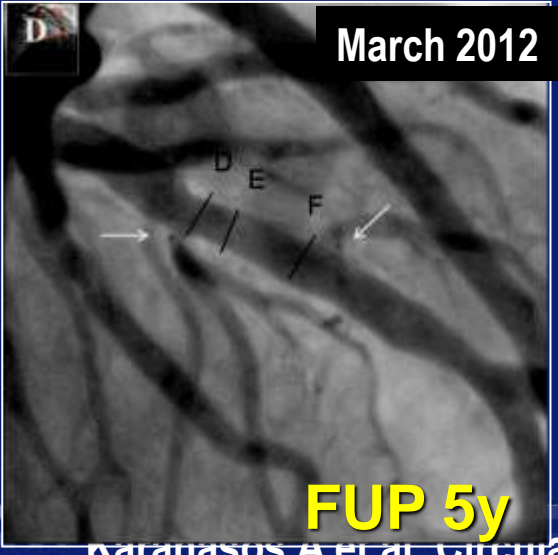
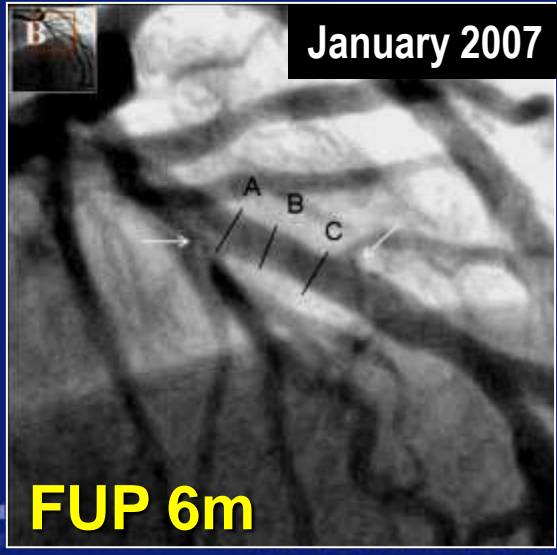
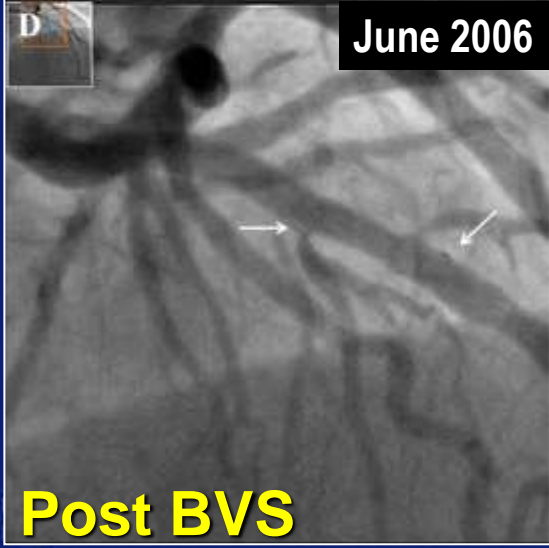
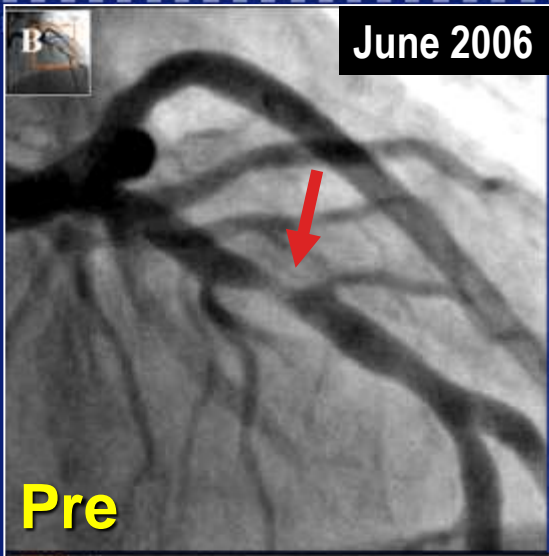
## 5 Years

ALL STRUTS  
ARE RESORBED  
**100%**

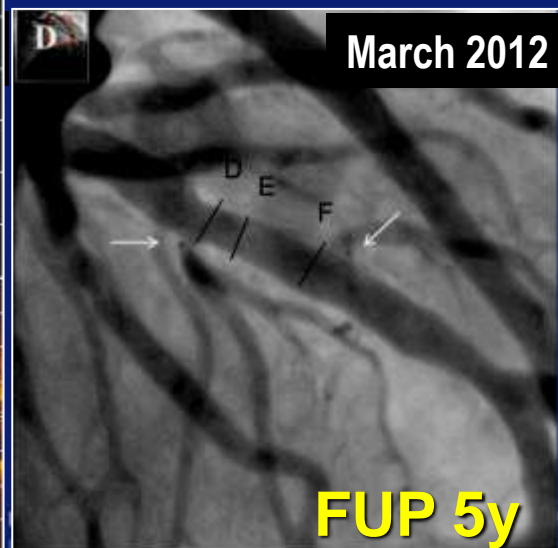
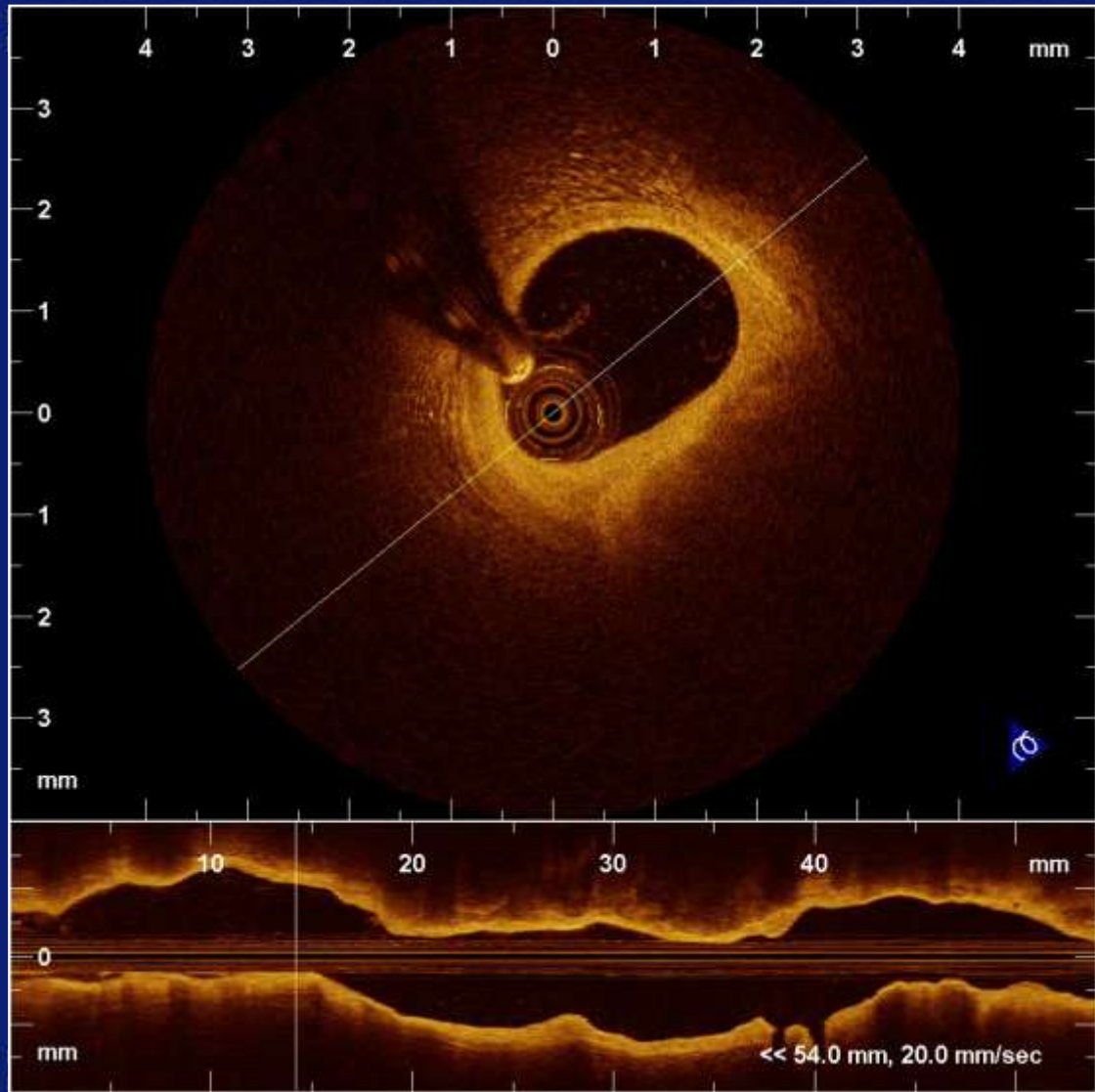




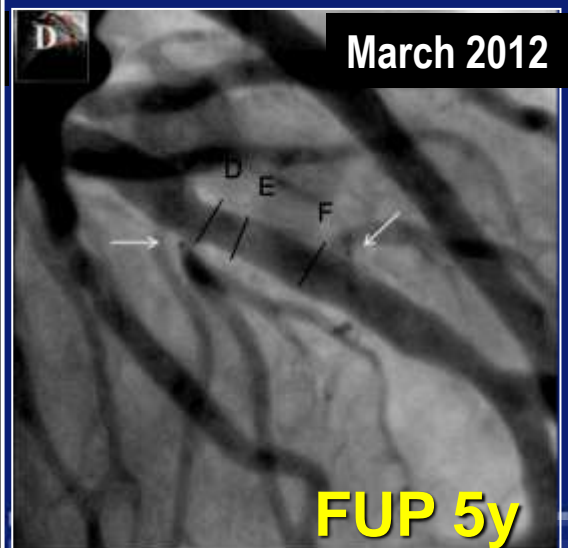
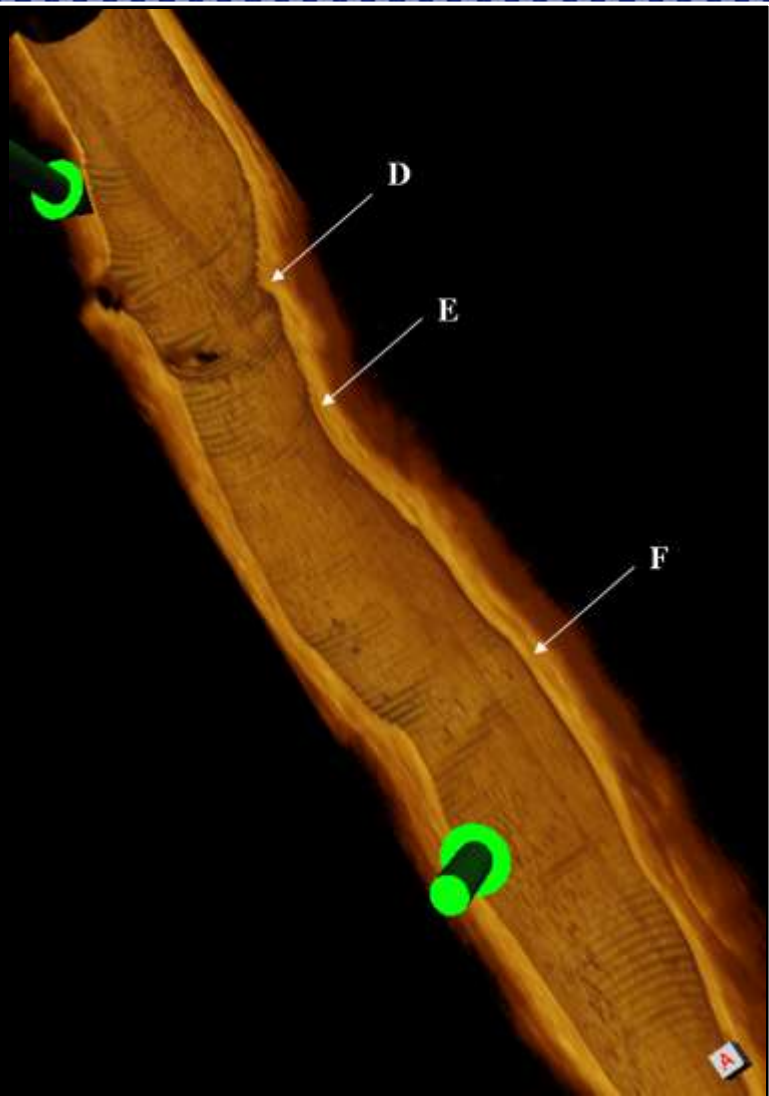
# ABSORB Cohort A – 5 Year FUP



# ABSORB Cohort A – 5 Year FUP



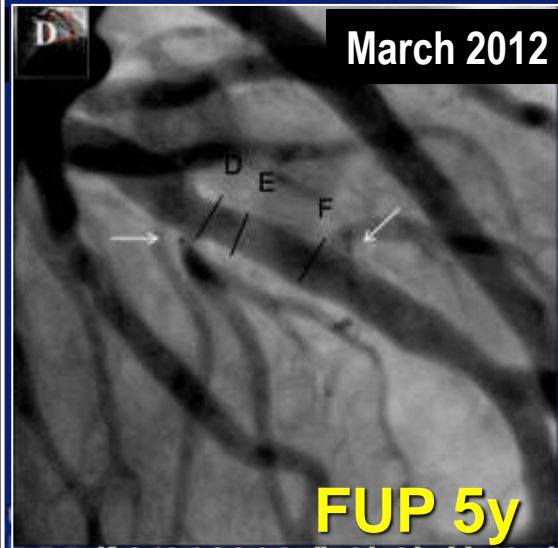
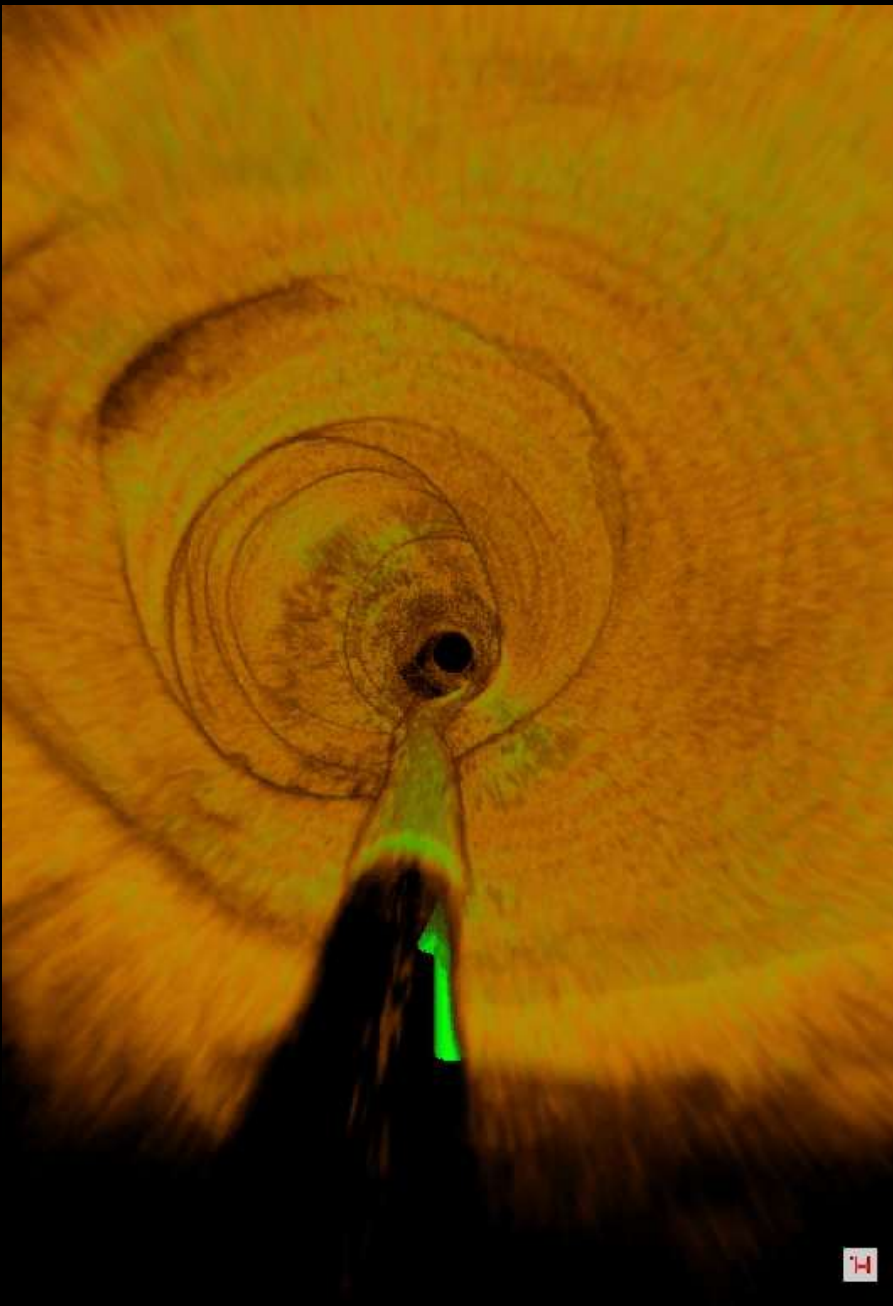
OCT 3D Rendering







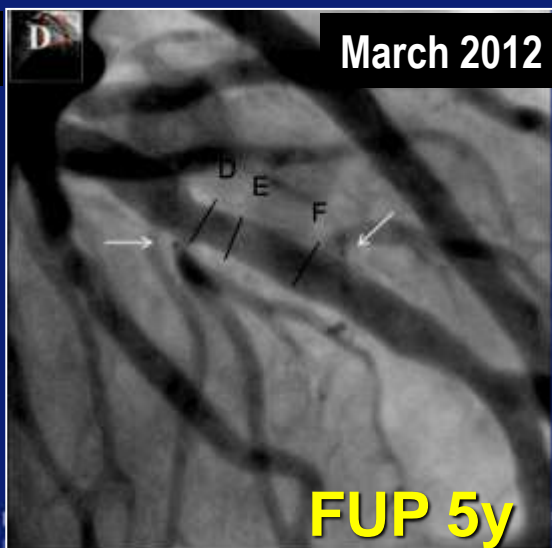
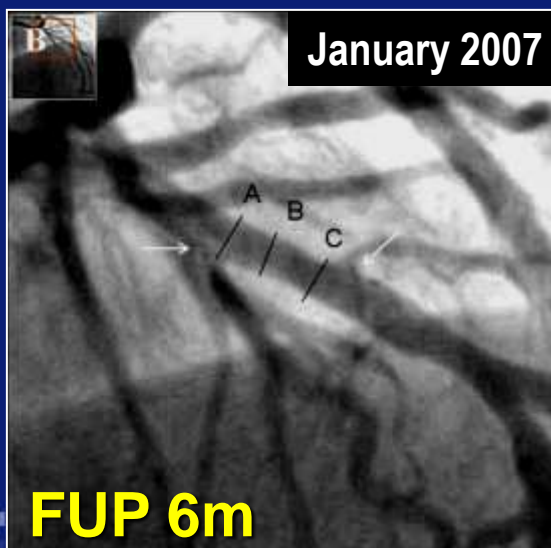
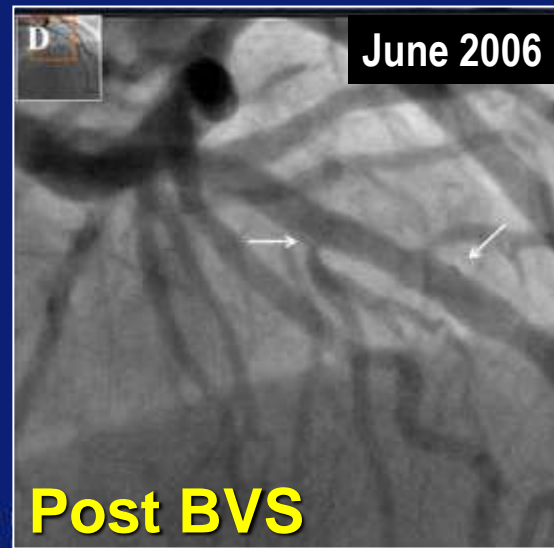
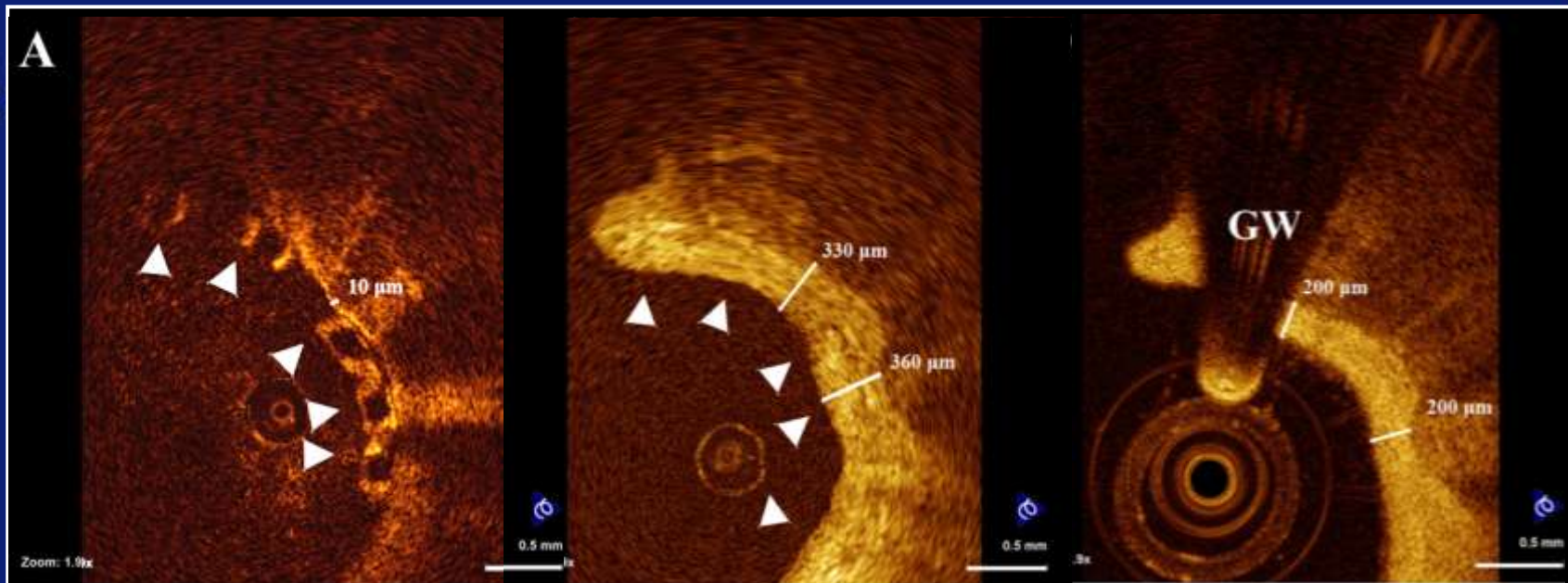
OCT 3D Rendering





# ABSORB Cohort A – 5 Year FUP

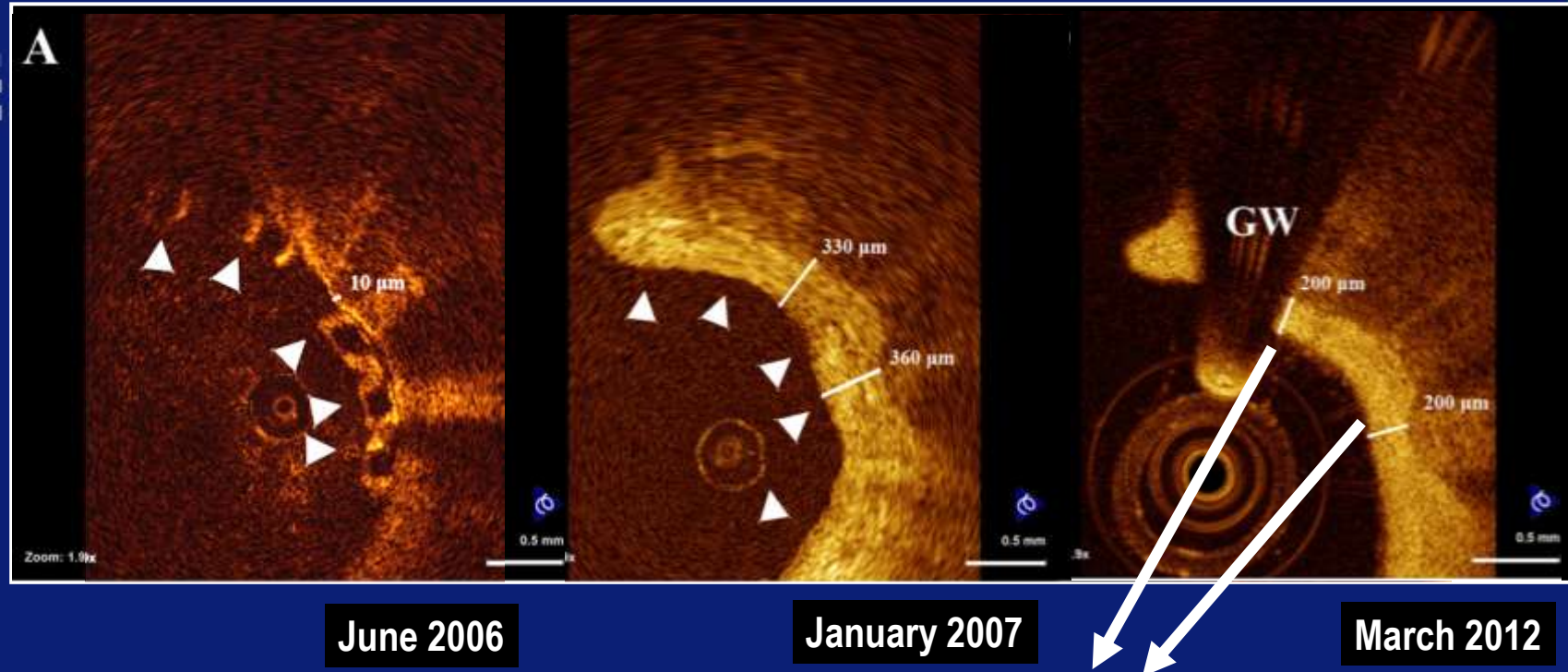
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# ABSORB Cohort A – 5 Year FUP

## # 1



**Late lumen enlargement**

**“ Sealing or Re-capping ”**

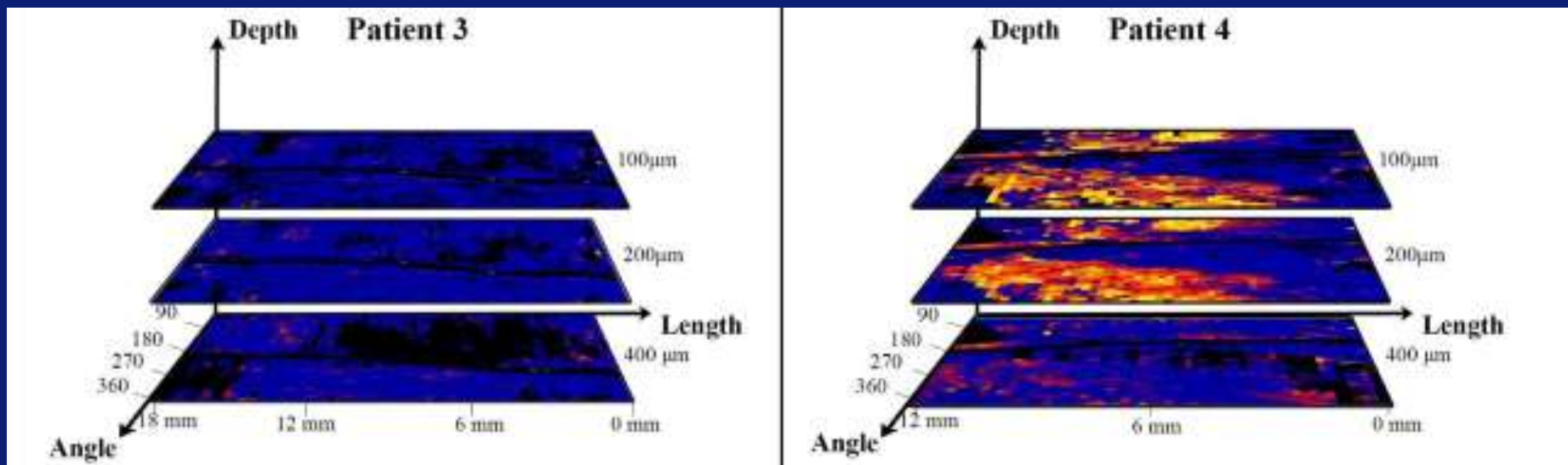
- Development of signal-rich layer
- Separation of thrombogenic plaque from the lumen



# BVS Sealing Layer Formation?

## 5 Years

### Quantitative tissue analysis:



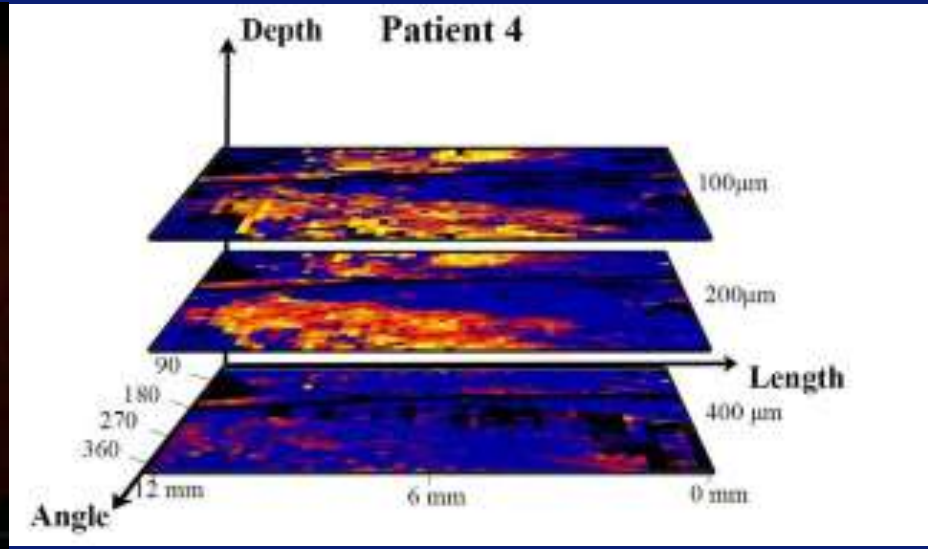
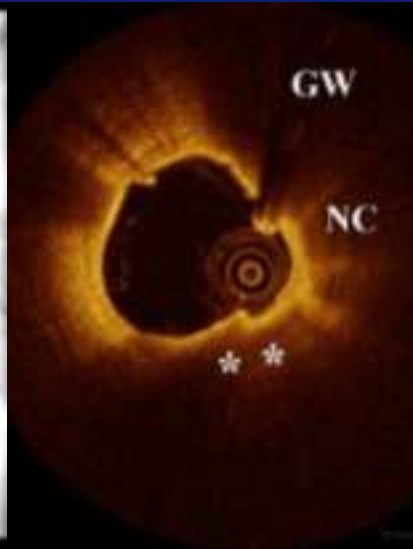
## Automated attenuation analysis of sealing layer





# BVS Sealing Layer Formation?

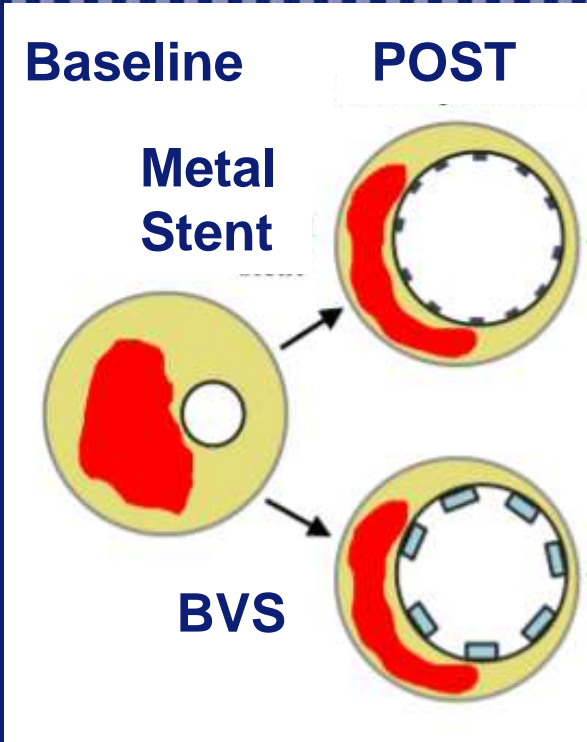
## 5 Years



*Asymptomatic, non-flow limiting rupture in 1/8 pts*



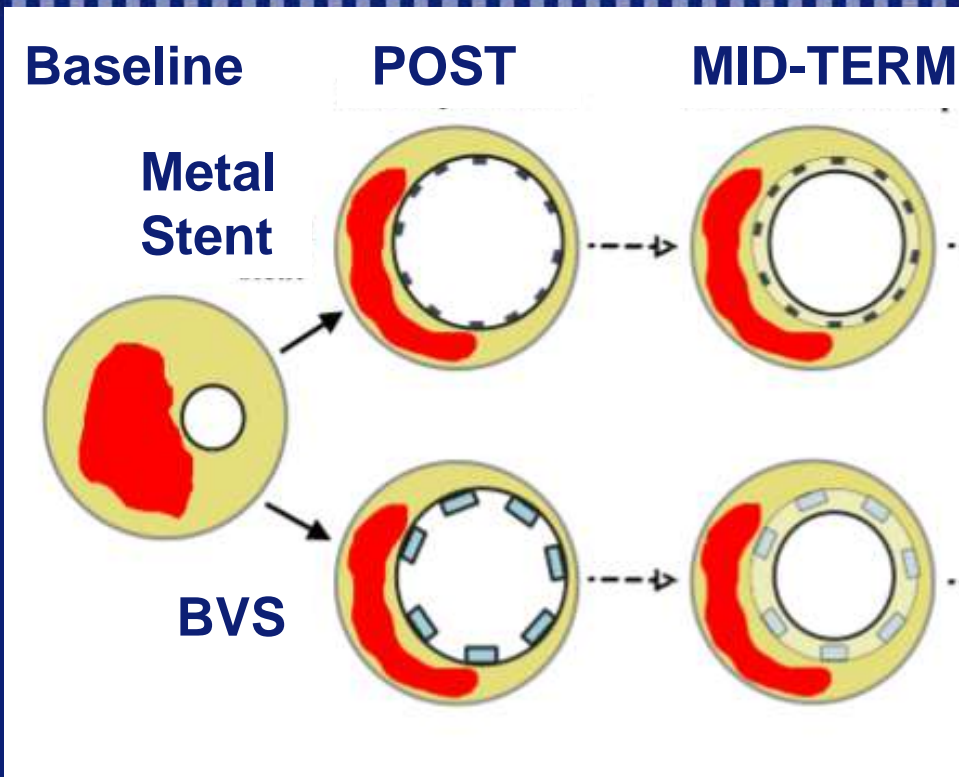
# Complete BVS Resorption Over Time Time for a New Paradigm?







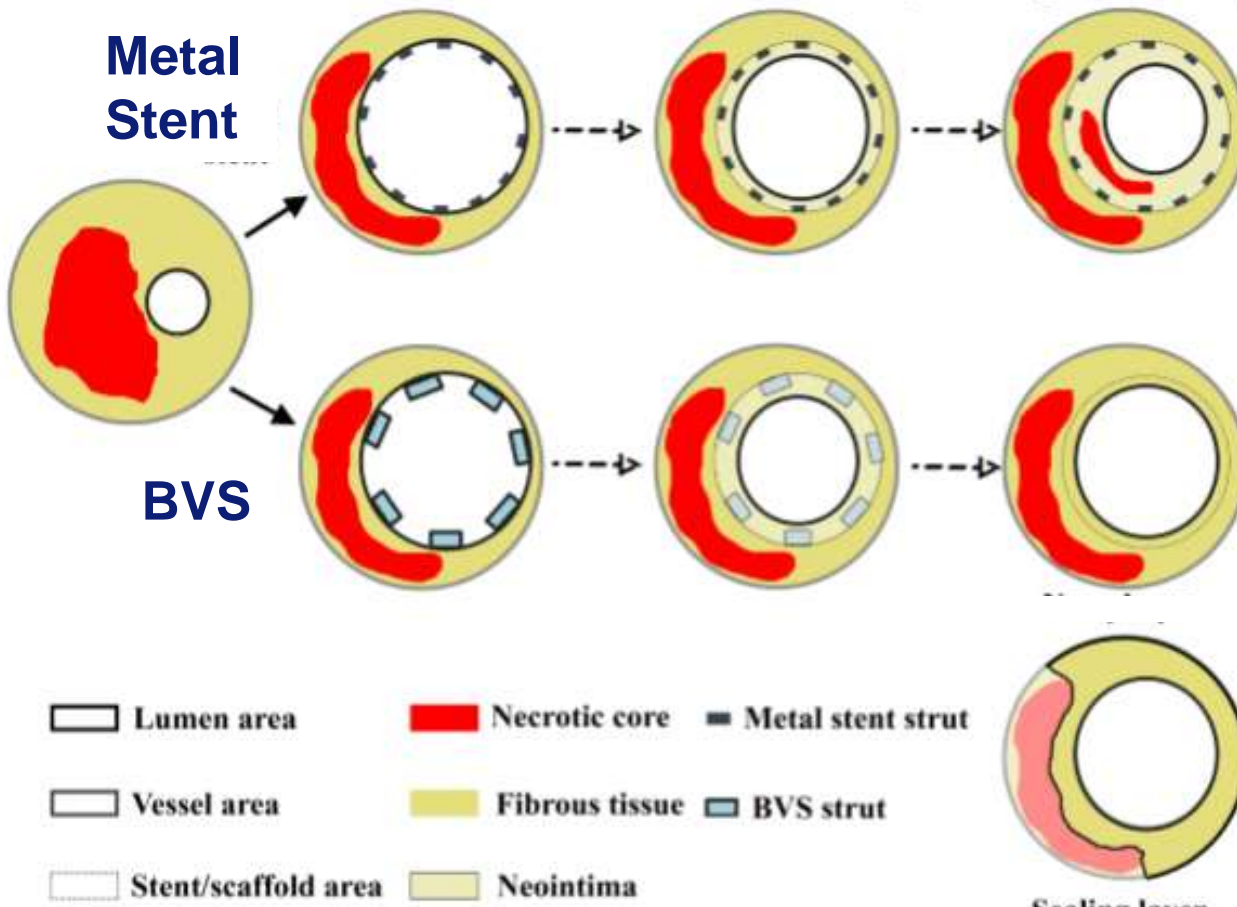
# Complete BVS Resorption Over Time Time for a New Paradigm?





# Complete BVS Resorption Over Time Time for a New Paradigm?

Baseline POST MID-TERM LONG-TERM



Neointima  
with/without  
neoatherosclerosis

NEOPLAQUE

SEALING LAYER



# **OCT Follow-up Summary & Conclusion**

- **Intracoronary OCT is an excellent tool to assess the delicate stent strut – vessel wall interaction and structural changes of the BVS stent over time.**
- **Late lumen area enlargement was observed in all patients.**
- **All jailed side branches were patent with thinning of the neointimal bridge.**
- **Complete bioresorption of BVS was observed, with the formation of neoplaque and a sealing layer, which shows homogenous, low attenuating appearance in the majority of patients.**
- **These results need to be interpreted with caution in light of the small number of patients and the use of Gen 1.0 BVS.**



# Thank you for your attention!

## *PhD Students*

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*N. van Ditzhuijsen*

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## *Interventional Cardiology*

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*P. de Jaegere*

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