

# **Serial Follow-up **5-year** Imaging of Bioresorbable Vascular Scaffolds and Clinical Implication**

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**On behalf of the investigators of ABSORB cohort B**

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Erasmus University MC, Netherlands  
14:40-48, April 29**

# Comprehensive imaging of Bioresorption and Integration process: Histology, OCT, IVUS-greyscale and IVUS echogenicity (preclinical)

3M

Histology



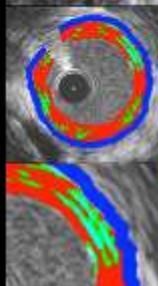
OCT



IVUS-GS

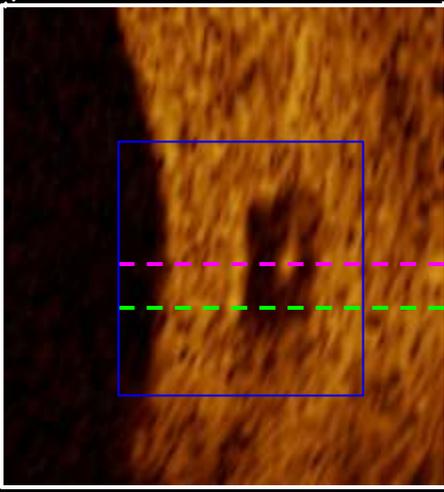
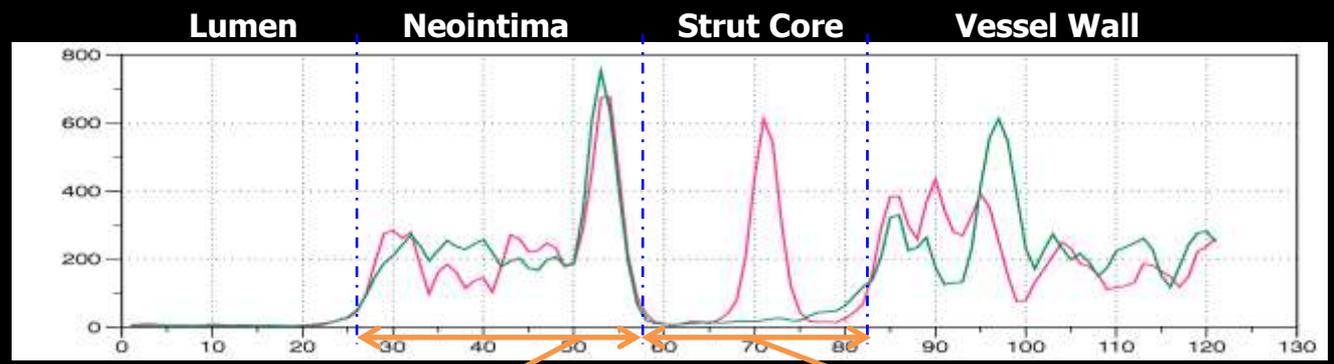
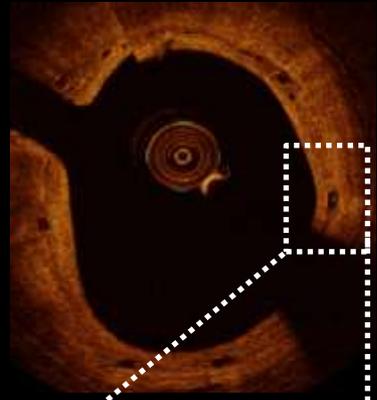


IVUS-  
Echogenicity



# How can the light intensity analysis be applied to bioresorbable scaffolds?

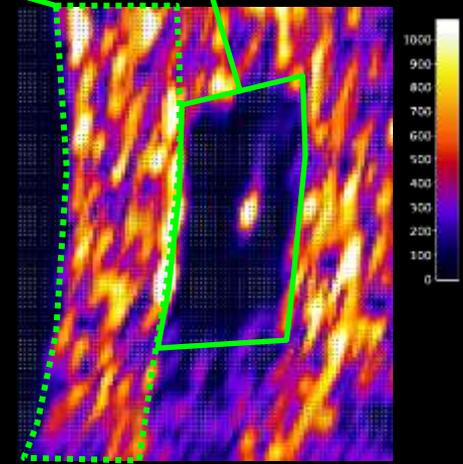
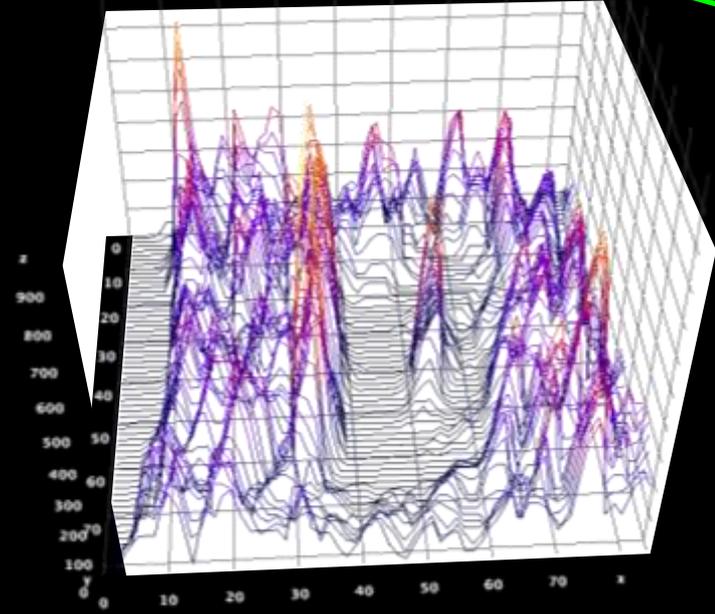
## 1. Line Plot Profile



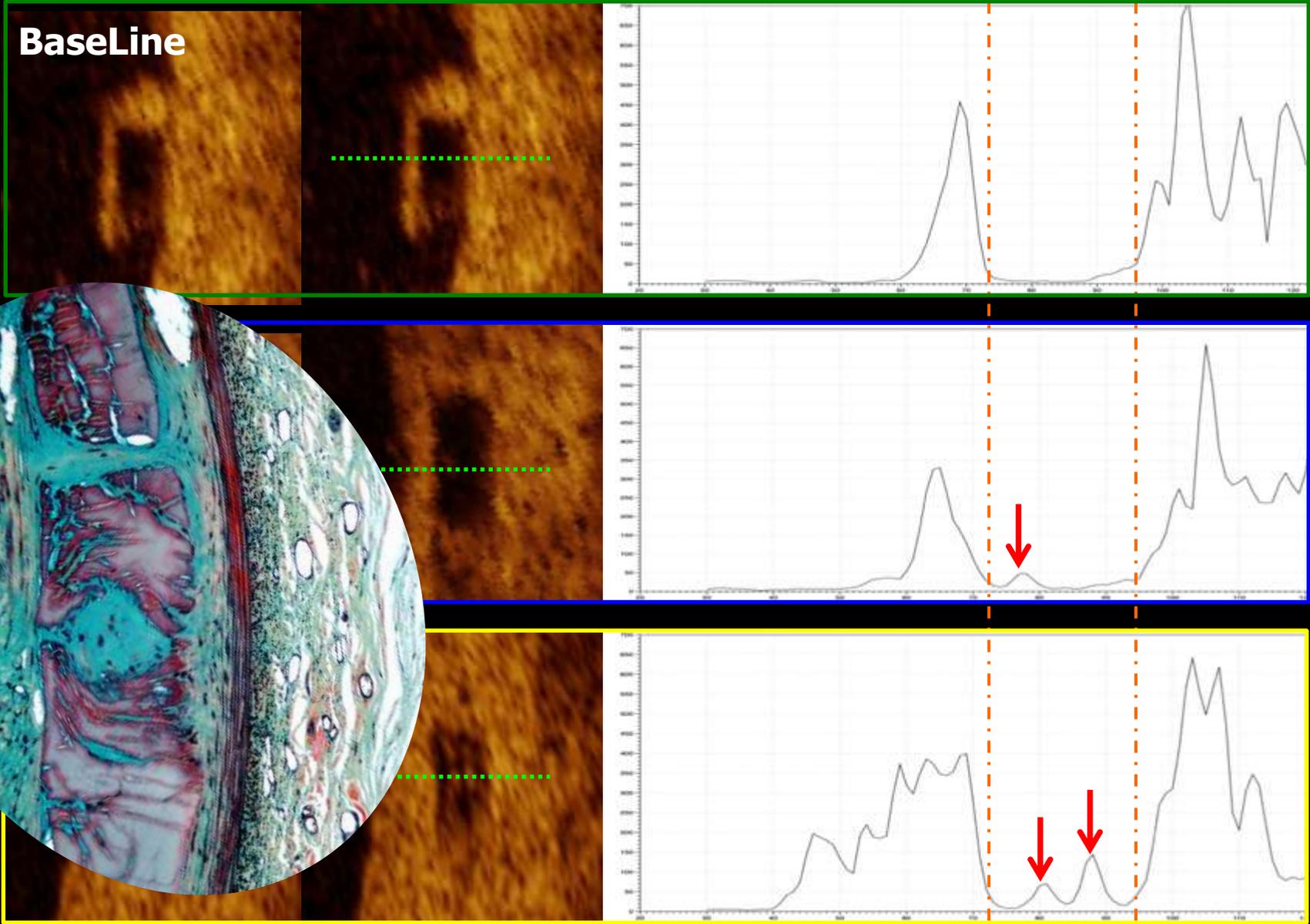
Neointimal Tissue

Strut Thickness  
Strut appearance

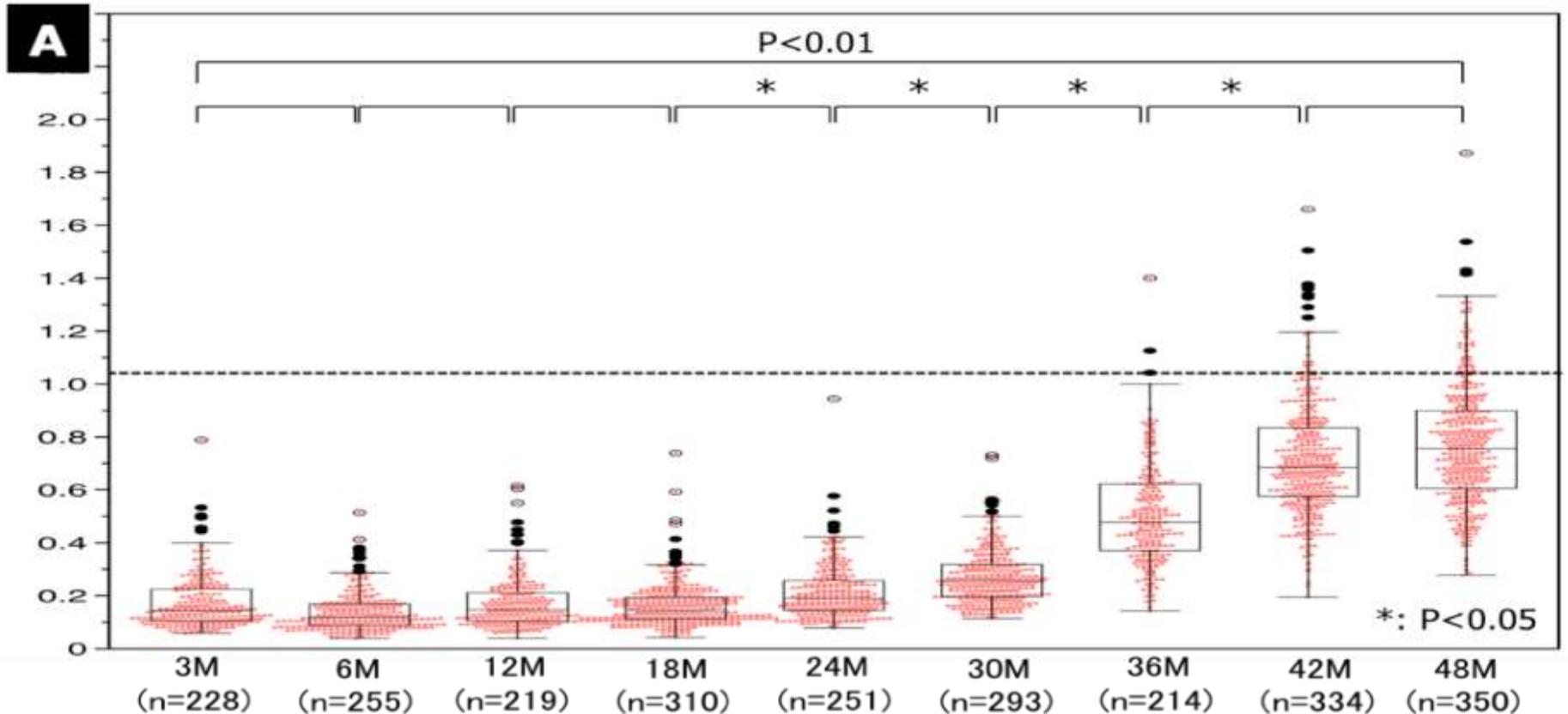
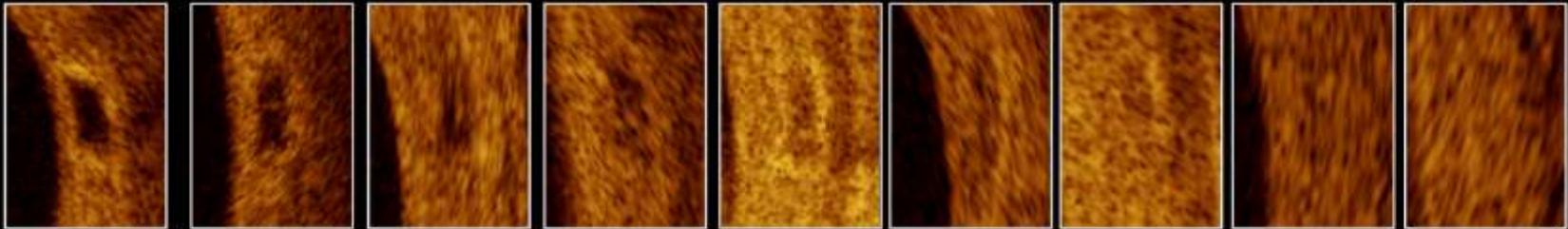
## 2. Area Profile



# Light reflectivity is effective to investigate the changes of strut core appearance

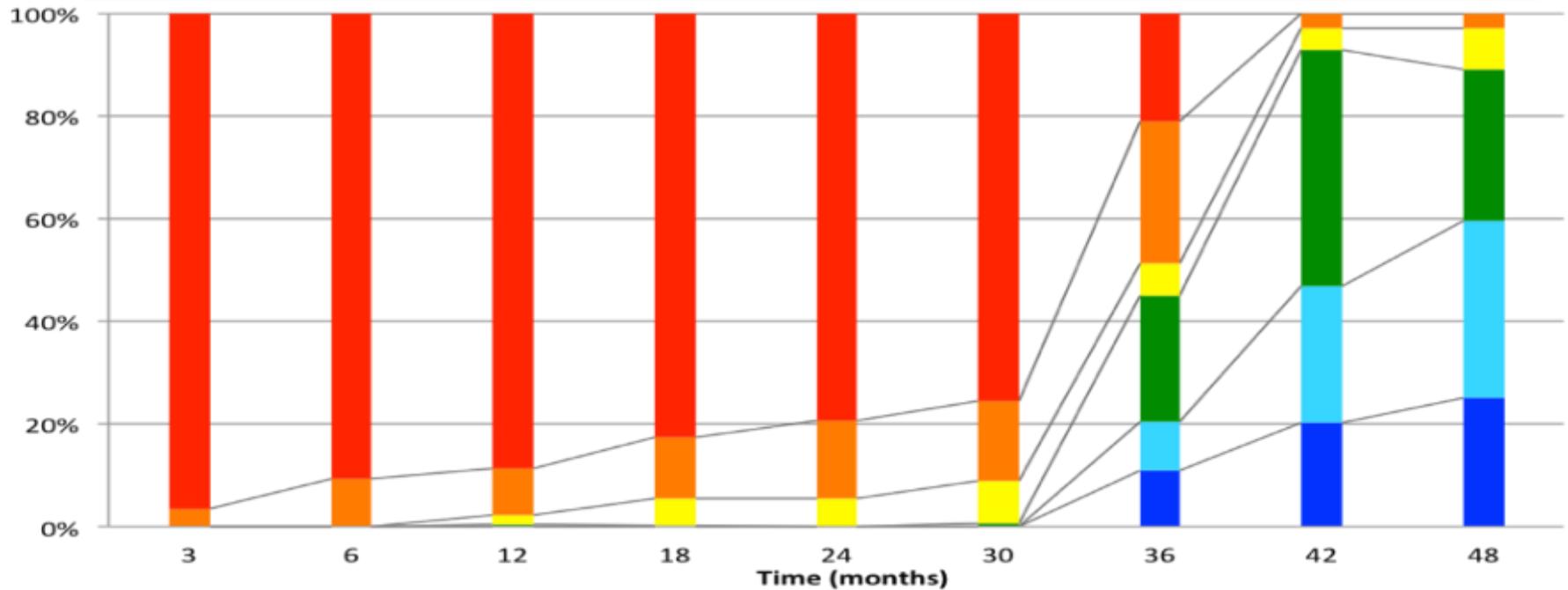
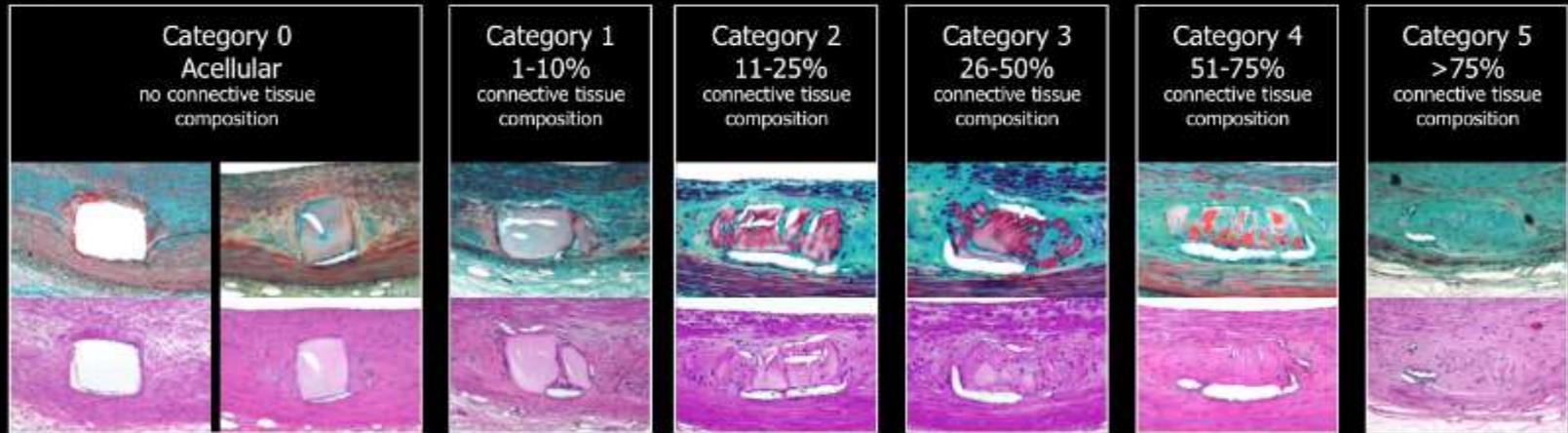


# Change in light intensity of struts over time



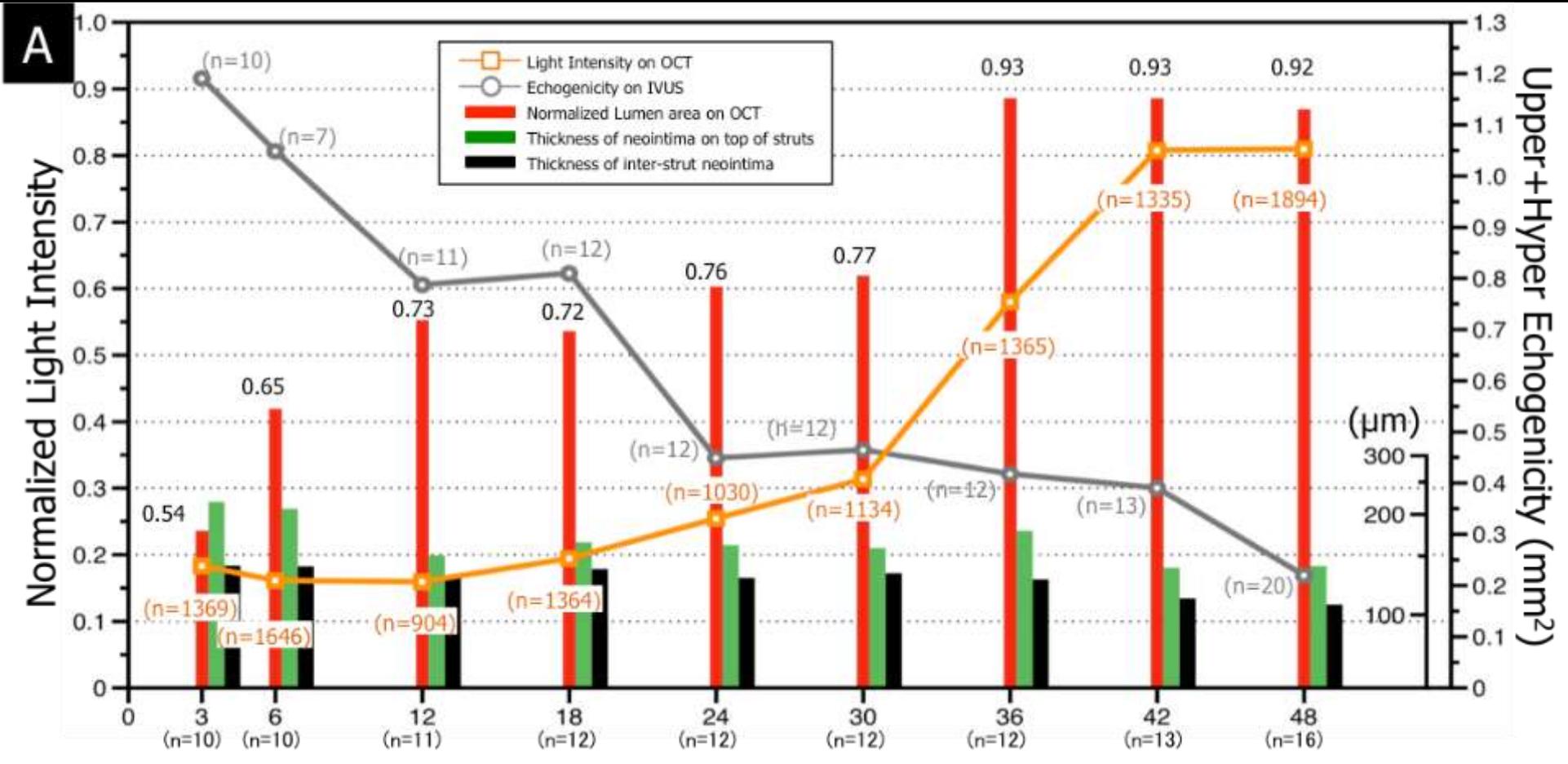
# Change in struts on histology over time

## B Histological categorization of strut and strut footprint

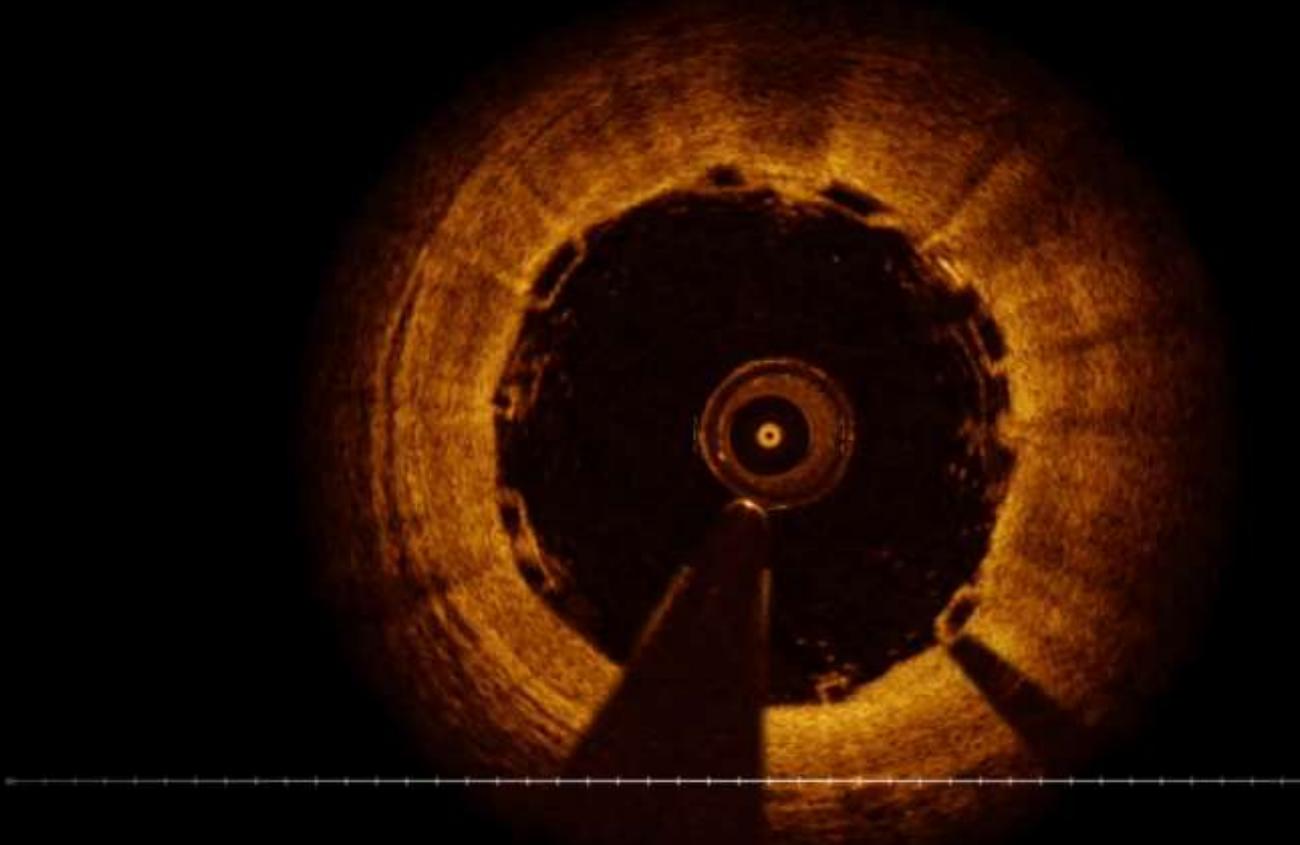


Category 0: Acellular  
Category 1: 1-10% connective tissue  
Category 2: 11-25% connective tissue  
Category 3: 26-50% connective tissue  
Category 4: 51-75% connective tissue  
Category 5: >75% connective tissue

# Change in IVUS-echogenicity, OCT light intensity, Lumen dimension and neointima

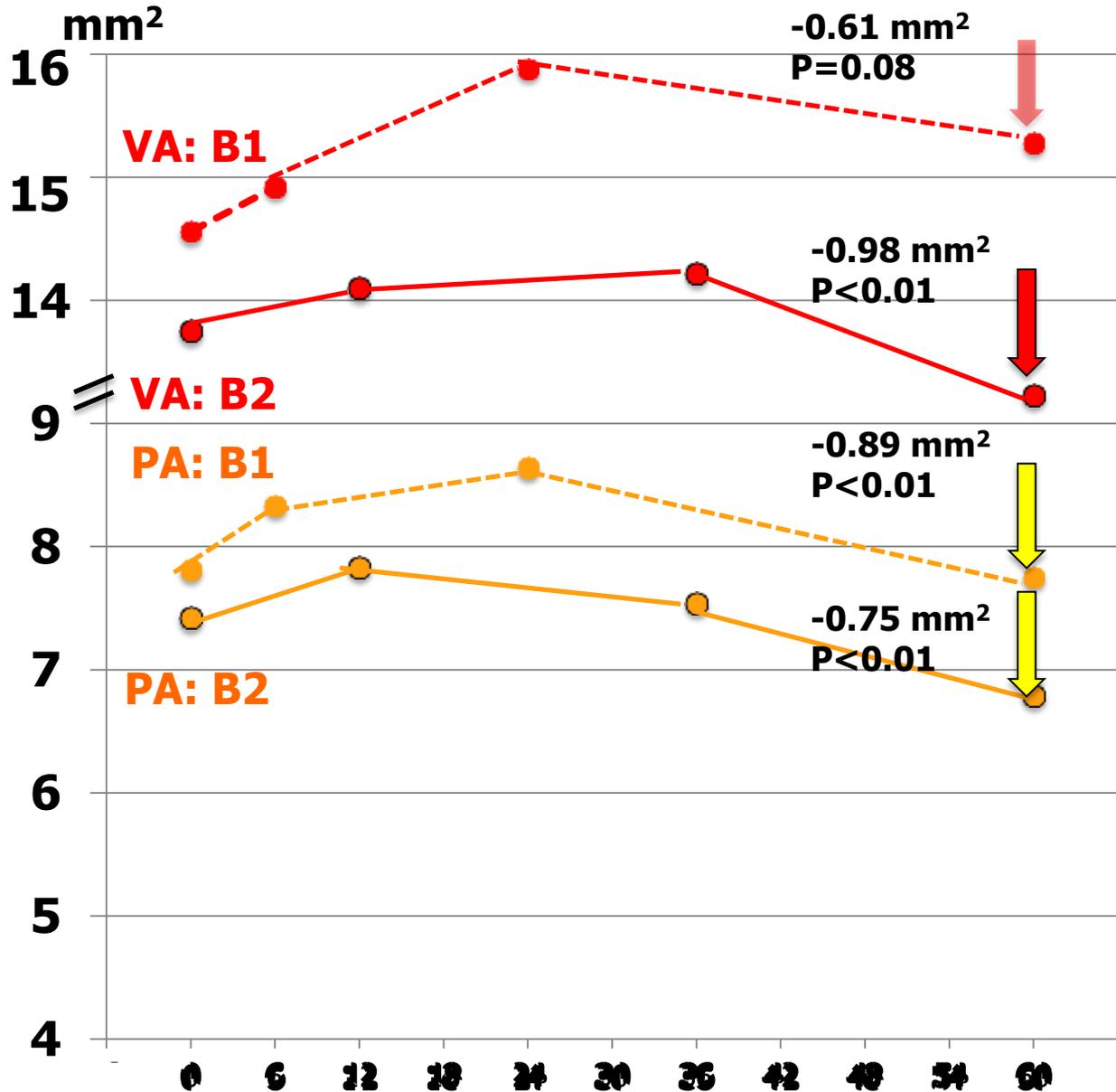


**Comprehensive imaging of Bioresorption and Integration process:  
OCT in human (BL, 6M, 2Y and 5Y)  
From apposition, to coverage, to scaffold expansion, to strut  
integration, to late lumen enlargement, to high reflectivity**



ABSORB Cohort B - Courtesy of RJ van Geuns, Erasmus Medical Center, Rotterdam

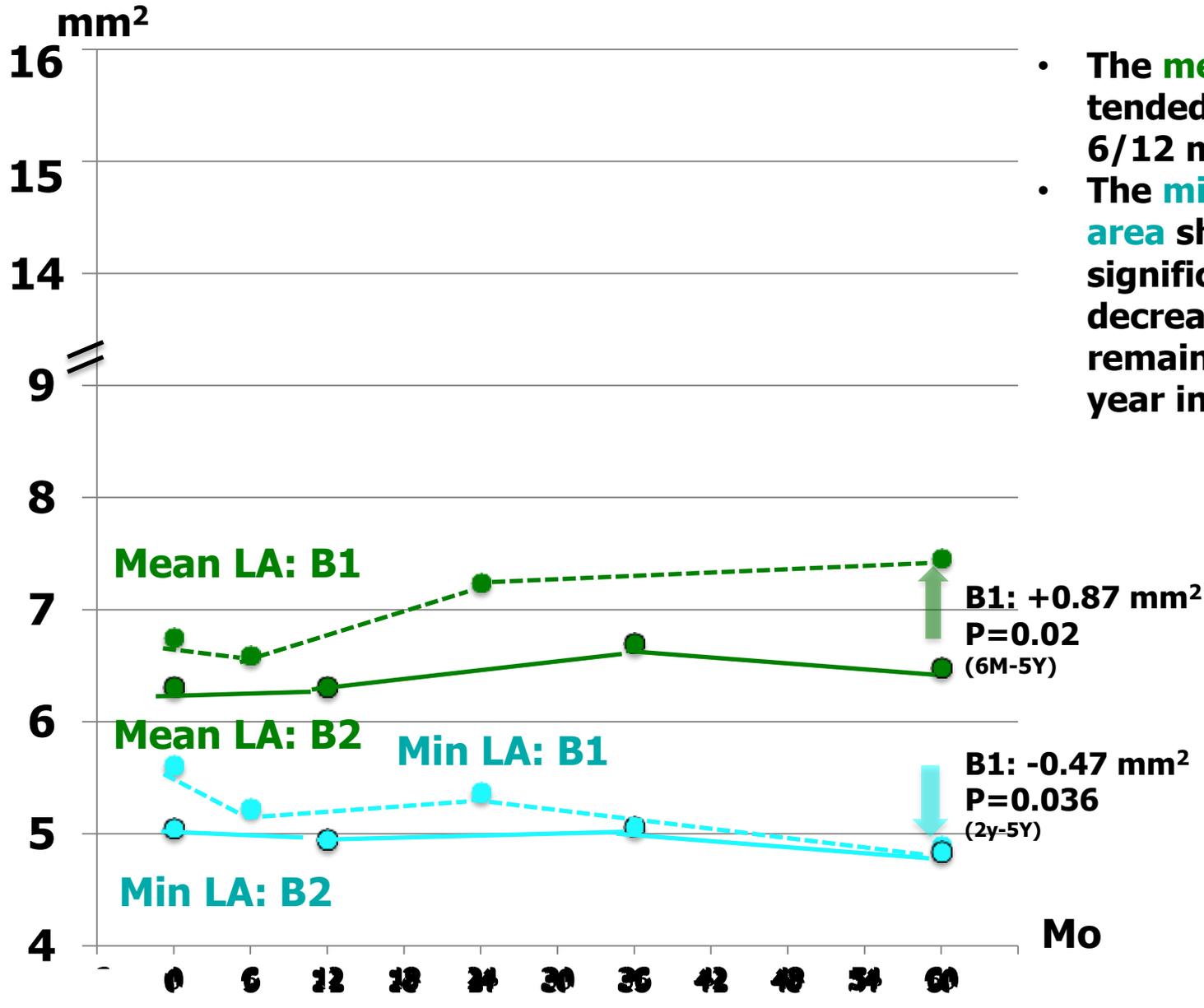
# IVUS follow-up of the First-in-man trial (ABSORB B1/B2) over 5 years (B1: n=21, B2: n=30)



- **The Vessel area and total plaque area show a biphasic change with an increase between the first and second year. A significant plaque reduction occurs in B1 and B2 between the second and fifth year follow-up accompanied by an adaptive and constrictive remodeling of the vessel area.**

Mo

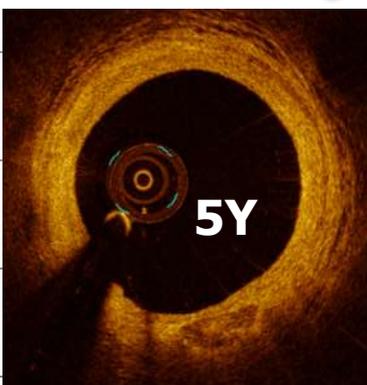
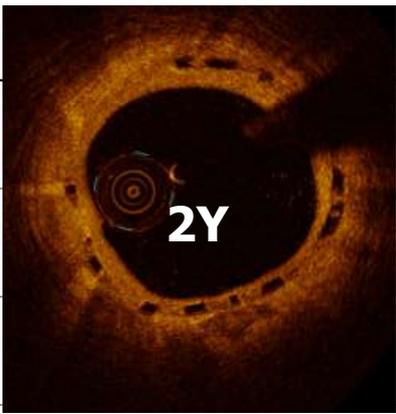
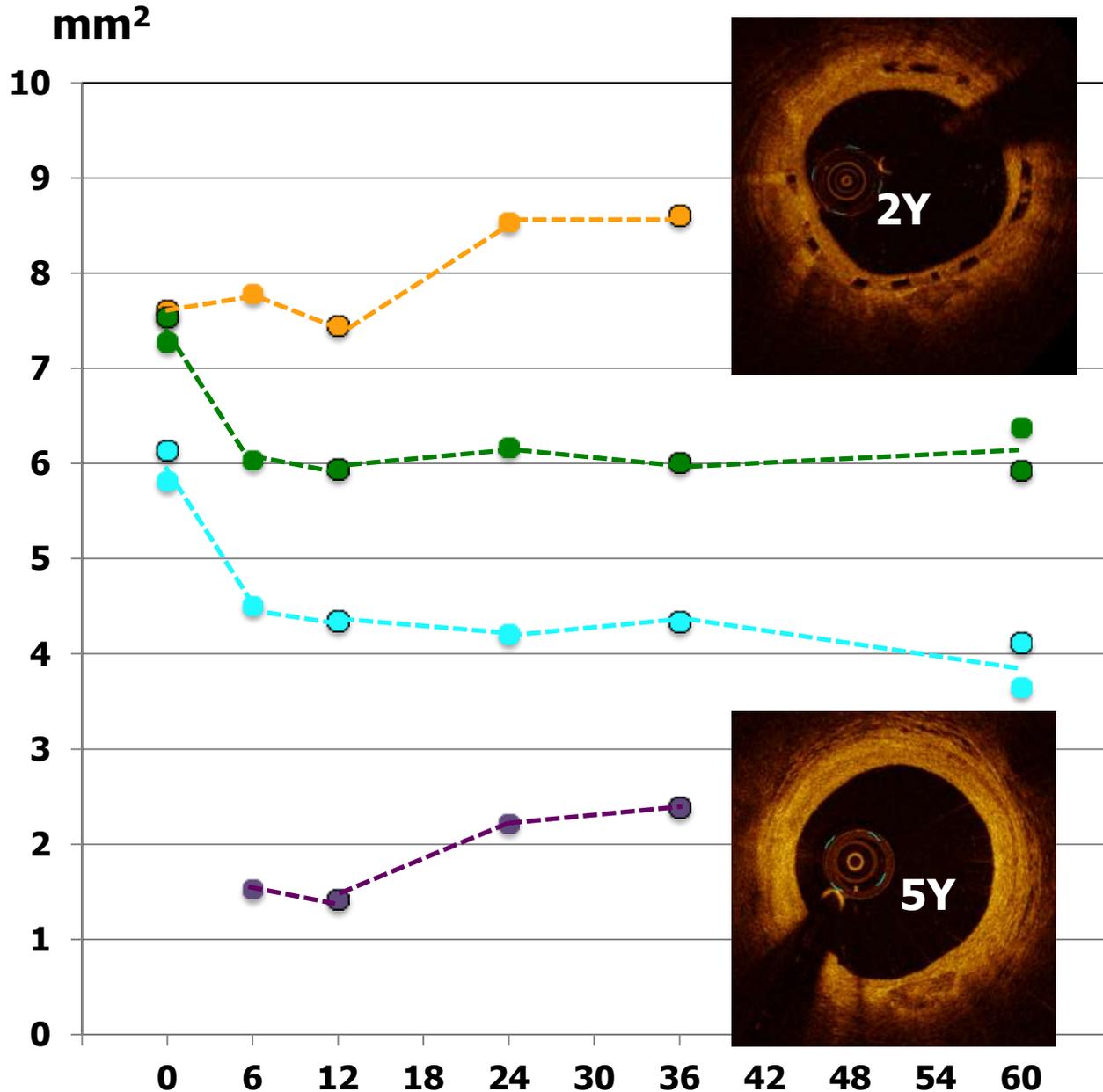
# IVUS follow-up of the First-in-man trial (ABSORB B1/B2) over 5 years (B1: n=21, B2: n=30)



- The **mean lumen area** tended to increase from 6/12 months to 5 years
- The **minimum lumen area** showed a significant modest decrease in B1 and remained stable after 1 year in B2.

- Scaffold area in cohort B1
- Scaffold area in cohort B2
- Mean lumen area in cohort B1
- Mean lumen area in cohort B2
- Min lumen area in cohort B1
- Min lumen area in cohort B2

# OCT follow-up of the First-in-man trial (ABSORB B1/B2) over 5 years (B1: n=13, B2: n=16)



- On OCT, the **mean and minimum scaffold area** increased significantly in the first 3 years. Thereafter struts are no longer discernible at 5 years.
- The **mean lumen area** and **minimal lumen area** were stable from 1 year to 5 years.
- The **neointima** between and on top of struts are no longer measurable at 5 years since the struts are not discernible on OCT at 5 years.

# Shielding of Plaque

## Sealing of plaques as a result of Bioresorbable Scaffold implantation: Can the scaffold cap the plaque?

CLINICAL RESEARCH

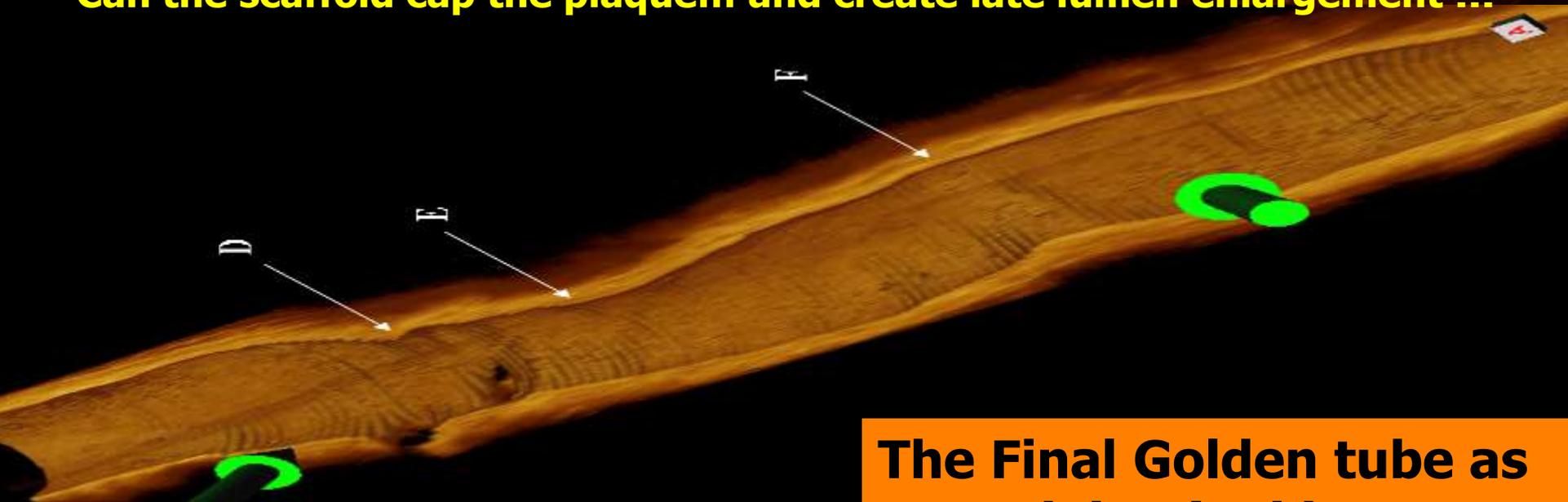
Eurointervention 2014

### **Bioresorbable vascular scaffold treatment induces the formation of neointimal cap that seals the underlying plaque without compromising the luminal dimensions: a concept based on serial optical coherence tomography data**

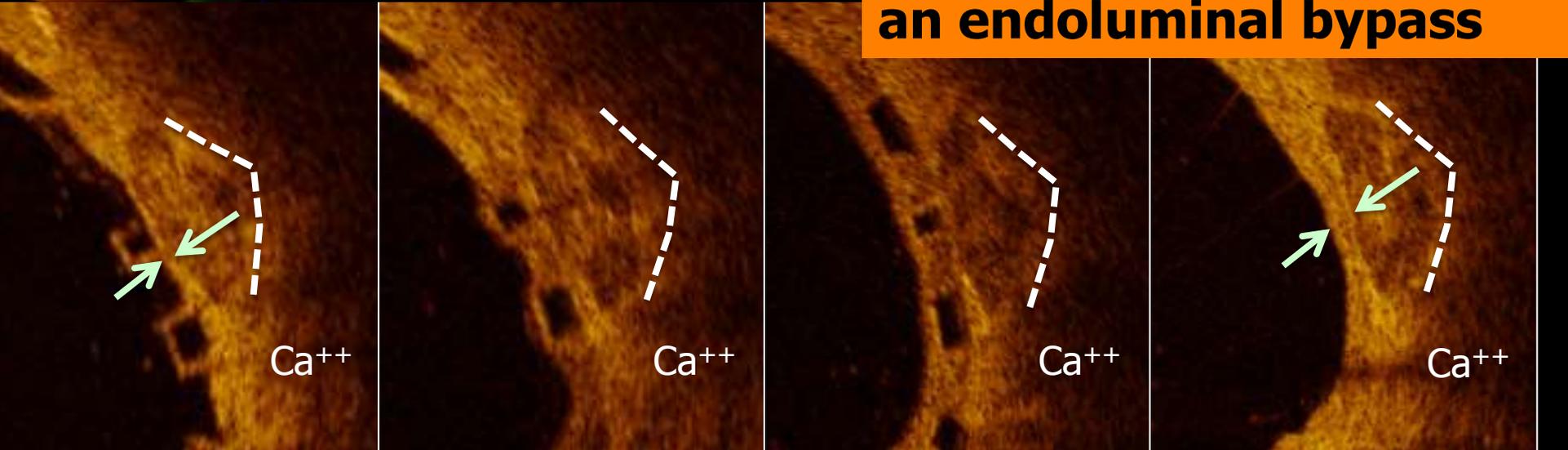
Christos V. Bourantas<sup>1</sup>, MD, PhD; Patrick W. Serruys<sup>1\*</sup>, MD, PhD; Shimpei Nakatani<sup>1</sup>, MD; Yao-Jun Zhang<sup>1</sup>, PhD; Vasim Farooq<sup>1</sup>, MBChB, MRCP; Roberto Diletti<sup>1</sup>, MD; Jurgen Ligthart<sup>1</sup>, BSc; Alexander Sheehy<sup>2</sup>, MSc; Robert-Jan M. van Geuns<sup>1</sup>, MD, PhD; Dougal McClean<sup>3</sup>, MD; Bernard Chevalier<sup>4</sup>, MD; Stephan Windecker<sup>5</sup>, MD; Jacques Koolen<sup>6</sup>, MD, PhD; John Ormiston<sup>7</sup>, MBChB; Robert Whitbourn<sup>8</sup>, MD; Richard Rapoza<sup>2</sup>, PhD; Susan Veldhof<sup>9</sup>, RN; Yoshinobu Onuma<sup>1</sup>, MD; Hector M. Garcia-Garcia<sup>1</sup>, MD, PhD

# Shielding of Plaque

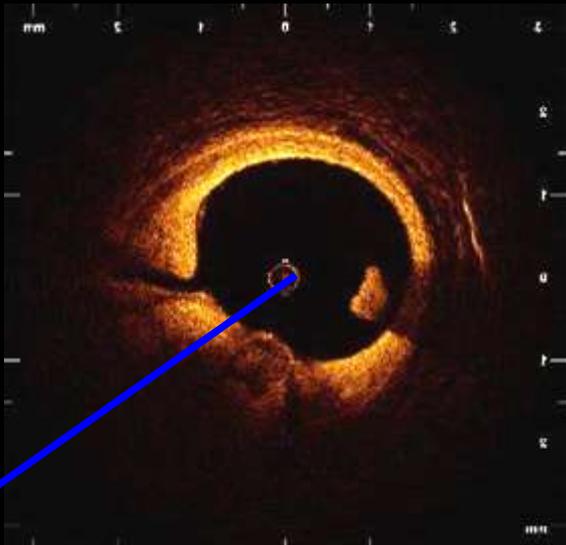
Sealing of plaques as a result of Bioresorbable Scaffold implantation:  
Can the scaffold cap the plaque... and create late lumen enlargement !!!



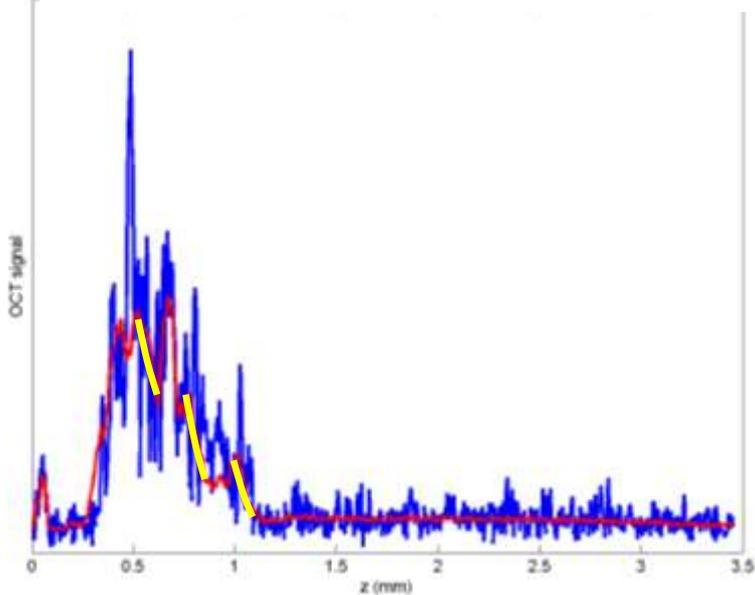
**The Final Golden tube as an endoluminal bypass**



# Local optical attenuation coefficient can be found from the OCT signal

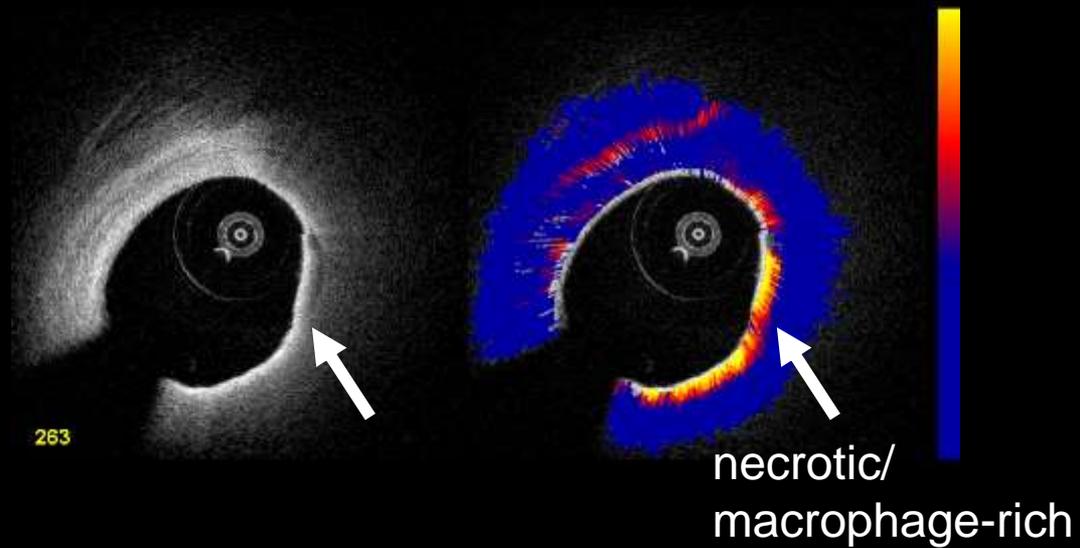


$$I(z) = T_{cath}(z) I_0 m_b \exp(-m_t z)$$



Fibrous  
Calcium  
Necrotic core  
Macrophages

low
low
HIGH
HIGH

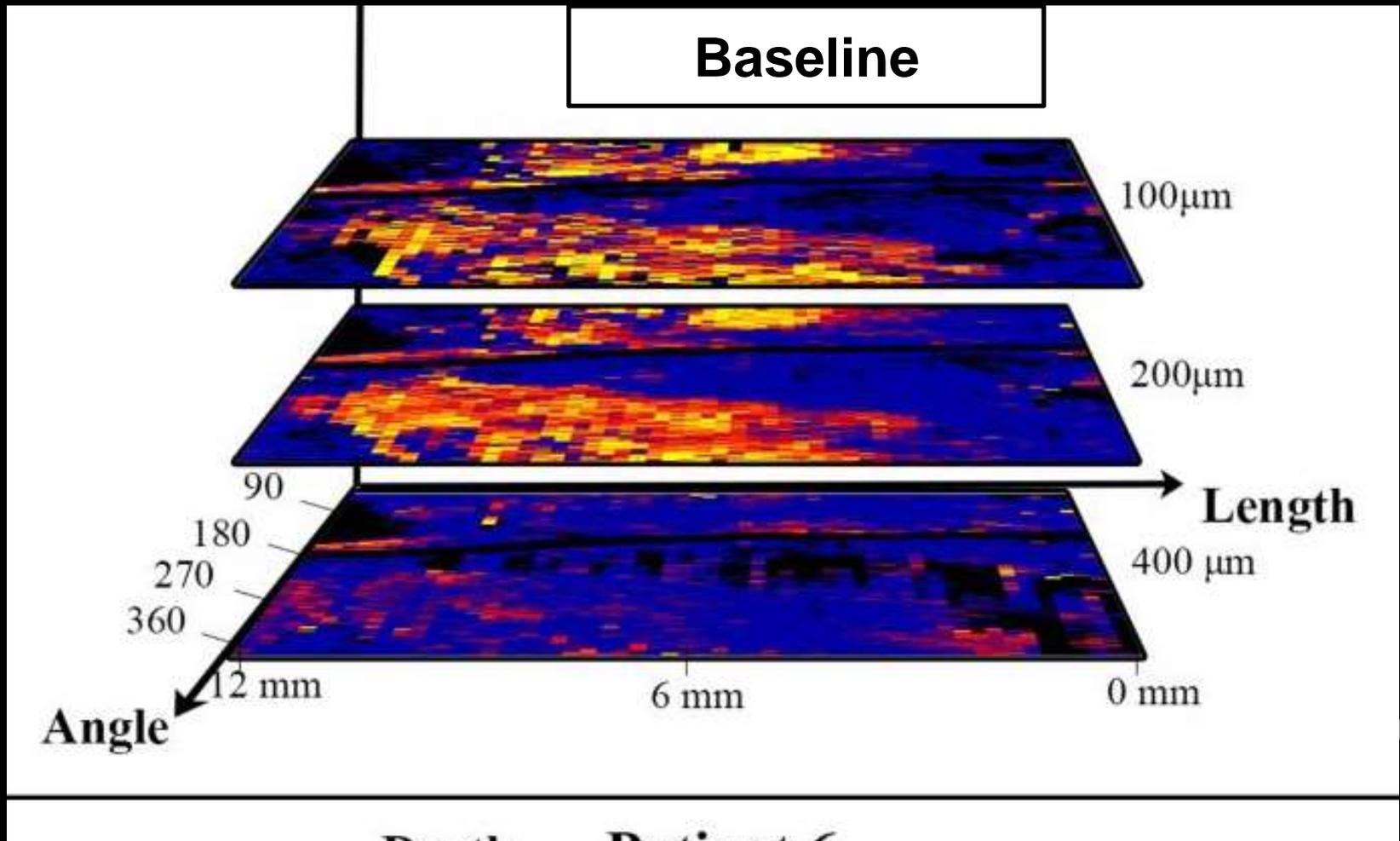


**Attenuation spread out maps in different depth from the vessel surface.**

Spread out maps demonstrate the attenuation coefficient in certain depth from the vessel surface (100, 200 and 400 micron) per patient.

In the majority of patients, there is a low attenuating layer of 200 micron, separating the underlying plaque (starting at -400micron) from the lumen.

**In this patient** , this layer is absent and the plaque is close to the lumen

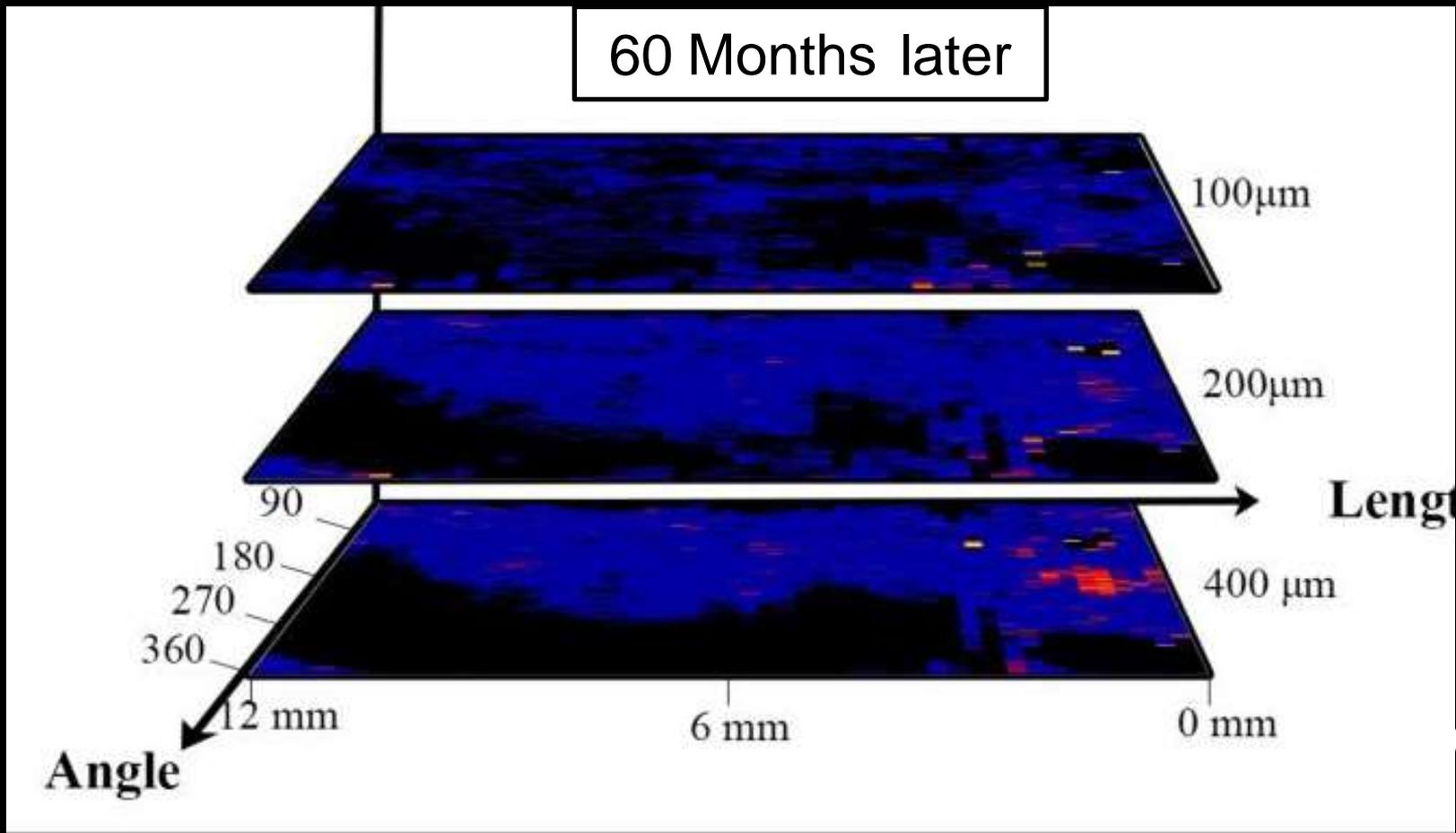


SMC  
*afms*

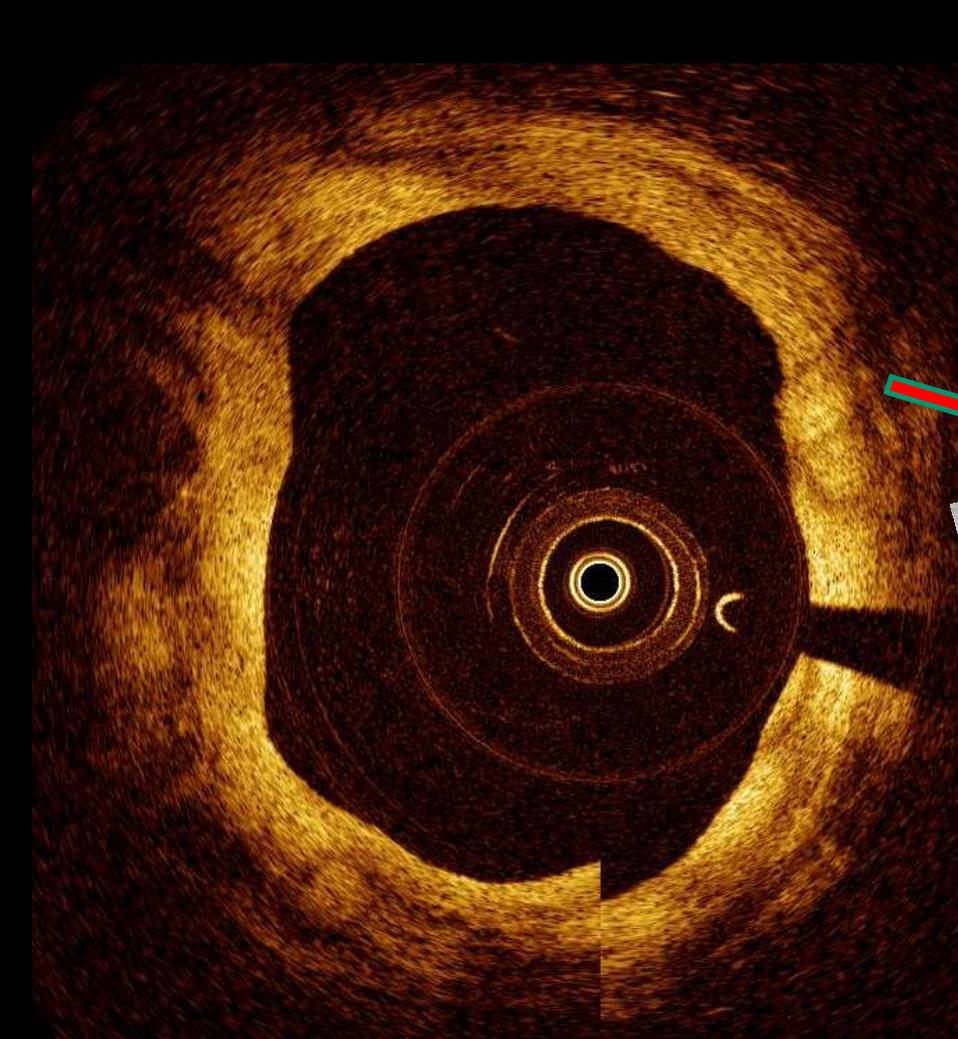
**Attenuation spread out maps in different depth from the vessel surface.**

Spread out maps demonstrate the attenuation coefficient in certain depth from the vessel surface (100, 200 and 400 micron) per patient.

**At 60 months in this patient**, there is a low attenuating layer of 200 micron, separating the underlying plaque (starting at -400micron) from the lumen.



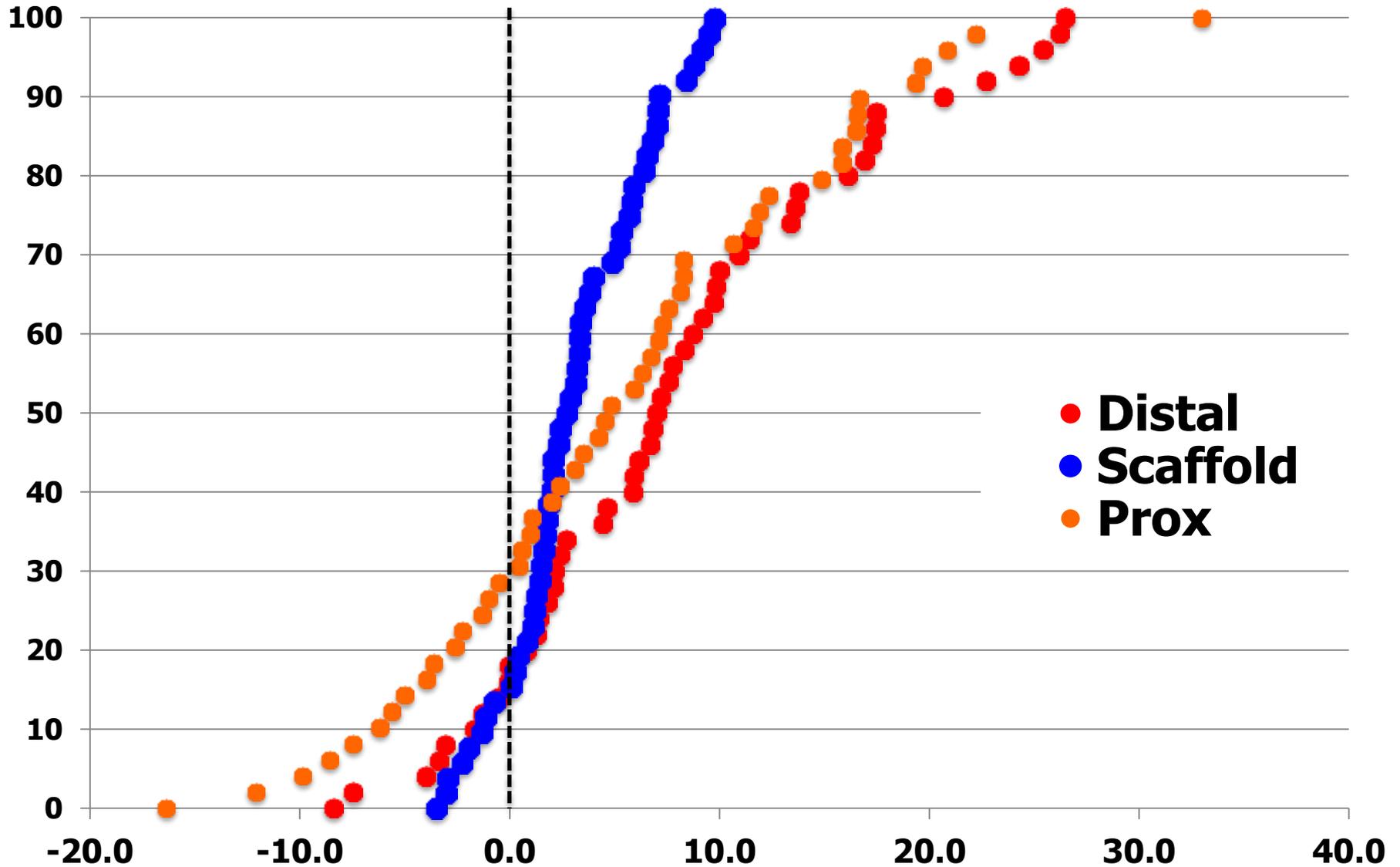
# OCT and Histology 10 years after implantation of Igaki-Tamai stent in human coronary artery



Onuma et al. Eurointervention 2010  
Nishio et al. Circulation 2014

**Neomedia?**

# Vasomotion test (Relative changes in mean LD) before and after nitrate administration at 5 years (n=53)



**A bioresorbable scaffold induces the formation of neointimal/neomedial cap which seals the underlying plaque without compromising lumen dimension but with persistence of vasomotion**

# Now two Interventional Journals

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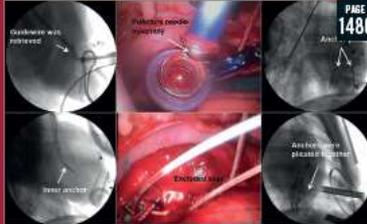
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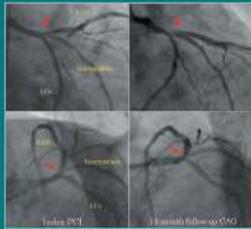
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