

# **Procedural and Follow-up Assessment of BVS by Multimodality Imaging**

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**Robert-Jan van Geuns, MD, PhD**

**Evelyn Regar, MD, PhD**

**Erasmus MC, Rotterdam, the NL**

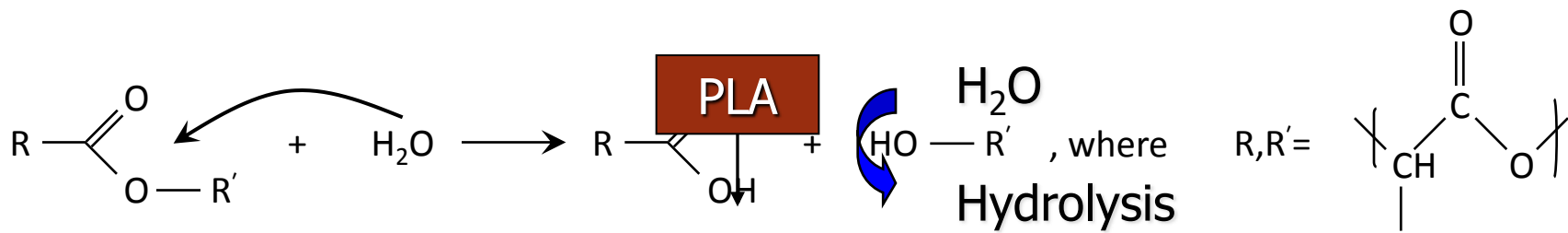
**Patrick W. Serruys, MD, PhD**

**Imperial College, London, UK**

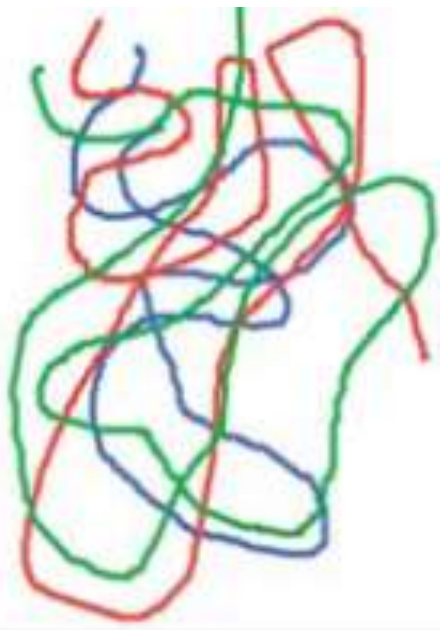
**7:24-32, May 1, 2015, TCTAP**

# Polylactide Degradation Mechanism

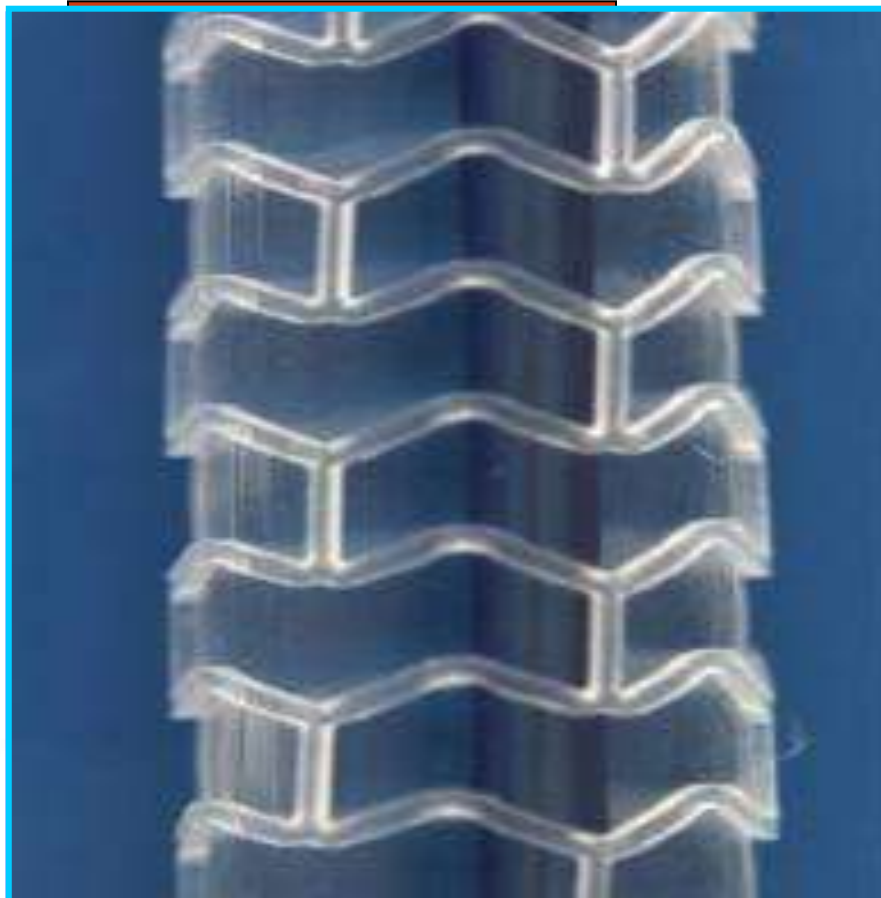
Hydrolysis via Random Chain Scission of Ester Bonds



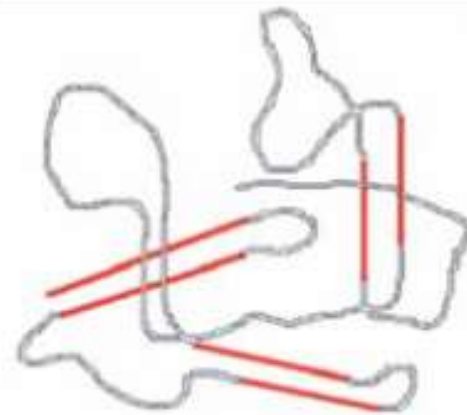
P-D,L-LA



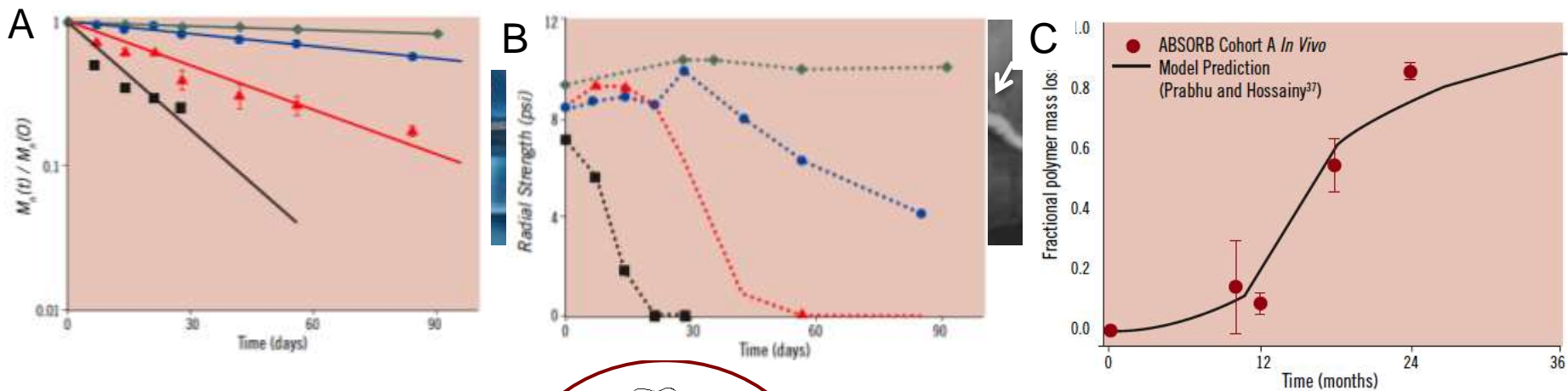
Amorphous



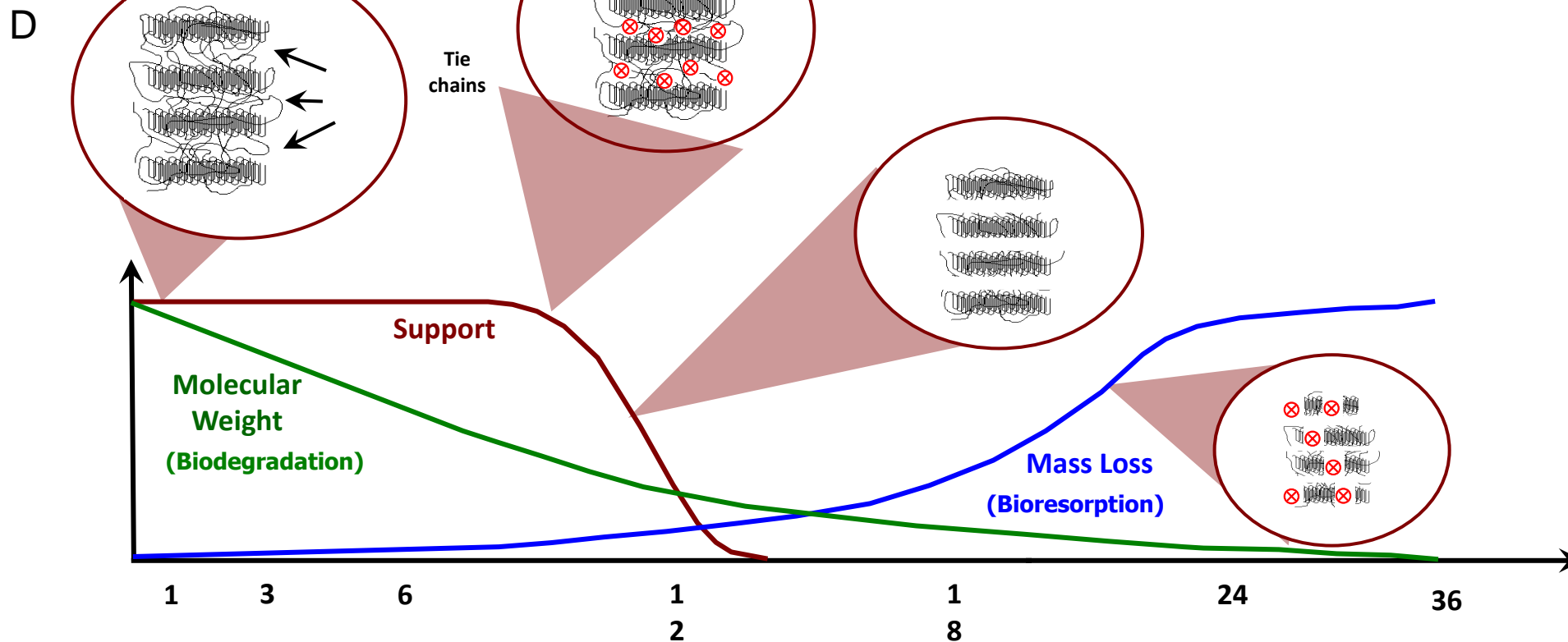
P-L,L-LA



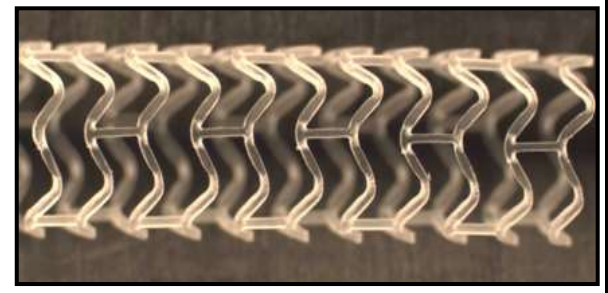
Semicrystalline



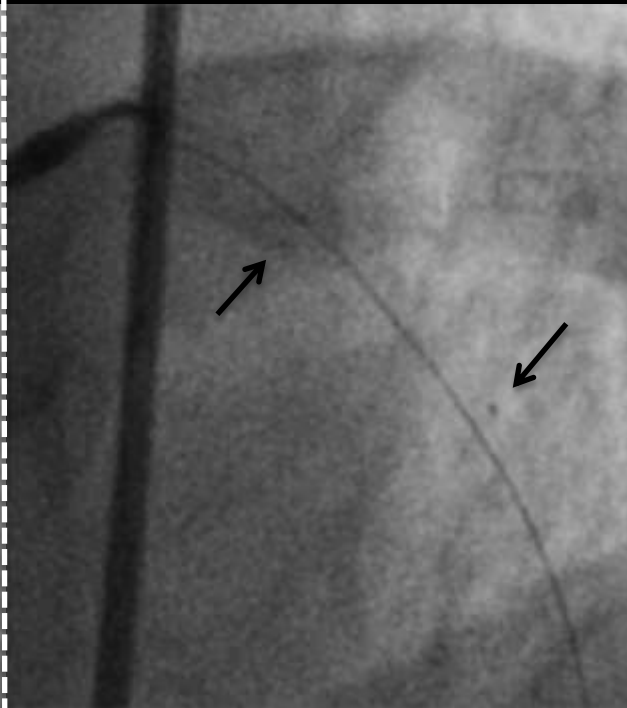
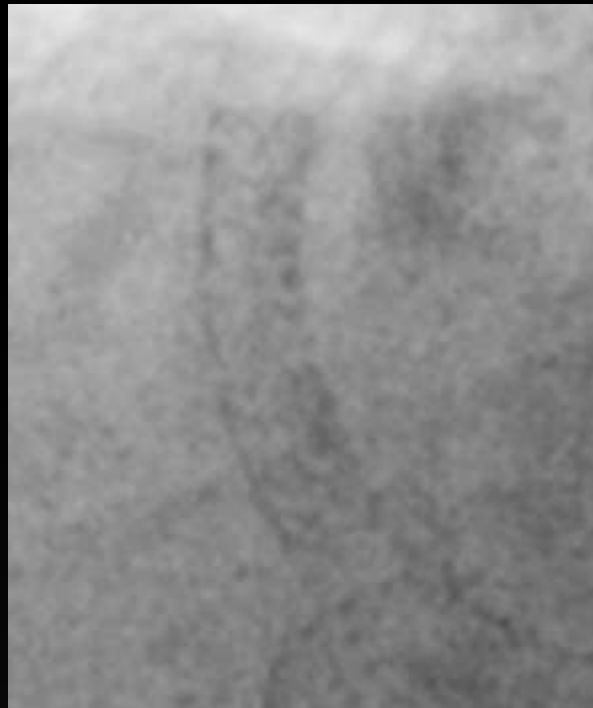
Onuma and Serruys, *Circulation* 2011



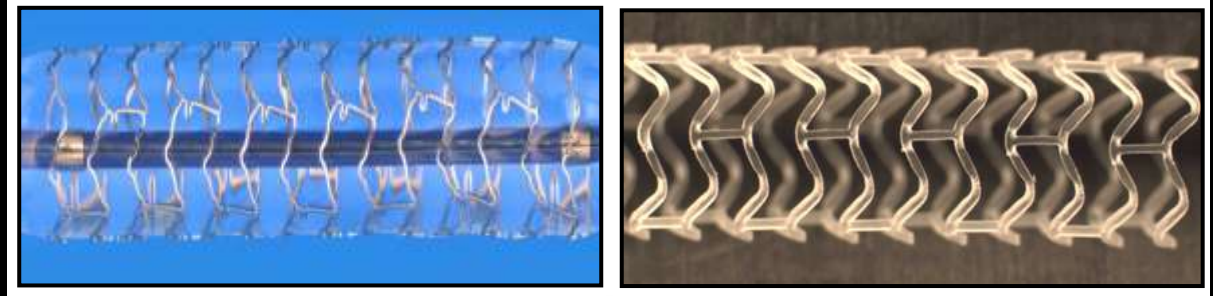
# Stents vs. Scaffolds



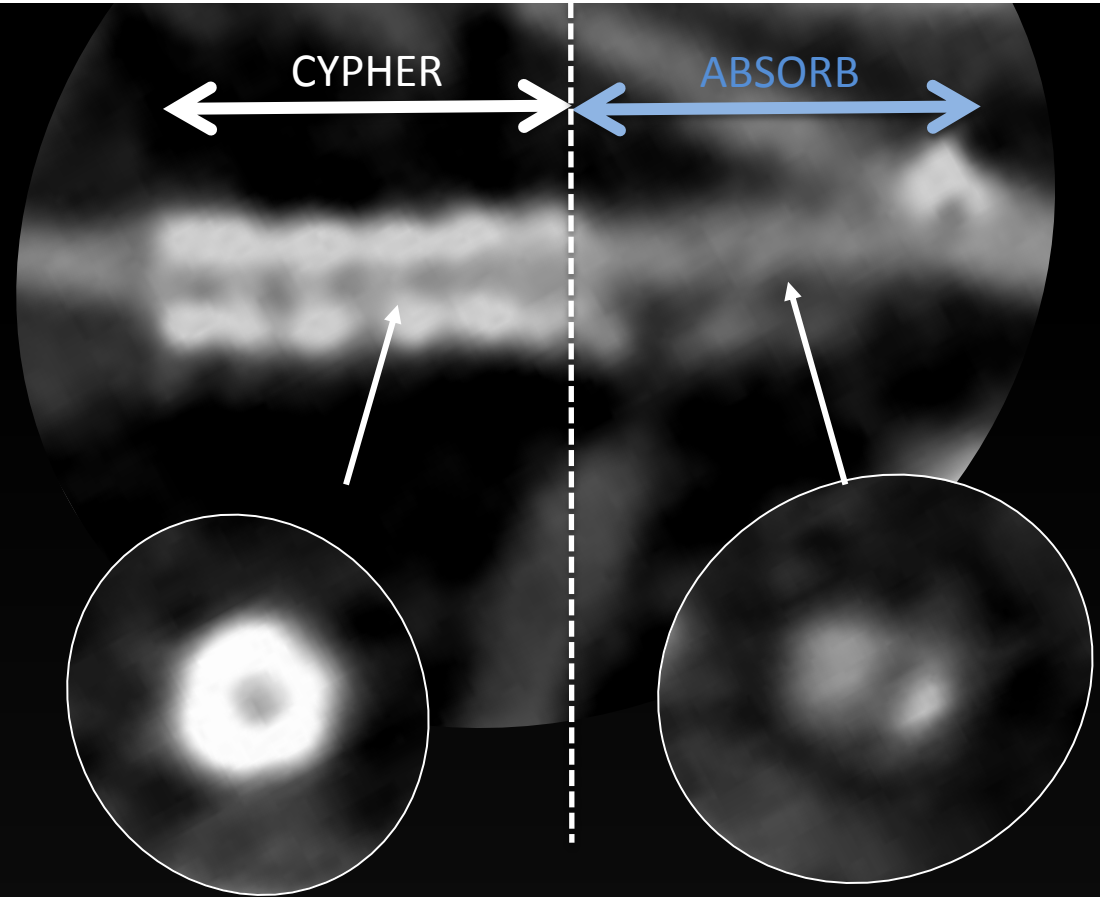
- **Angiography**
- **MSCT**
- **IVUS**
- **IVUS-VH**
- **OCT**



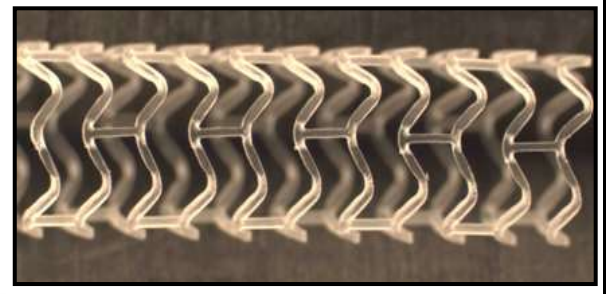
# Stents vs. Scaffolds



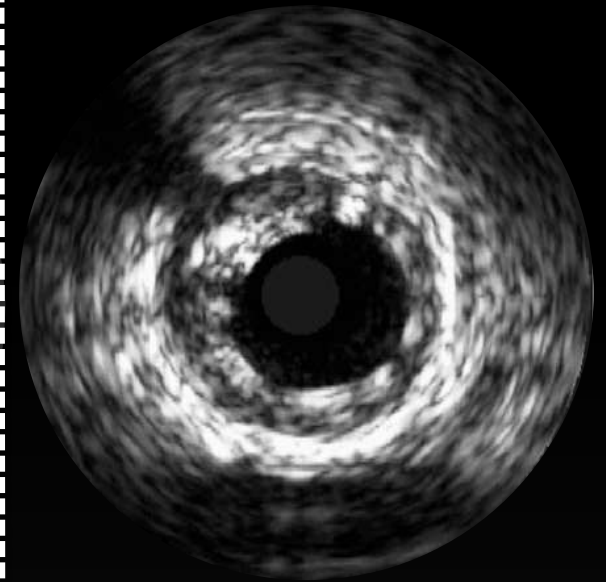
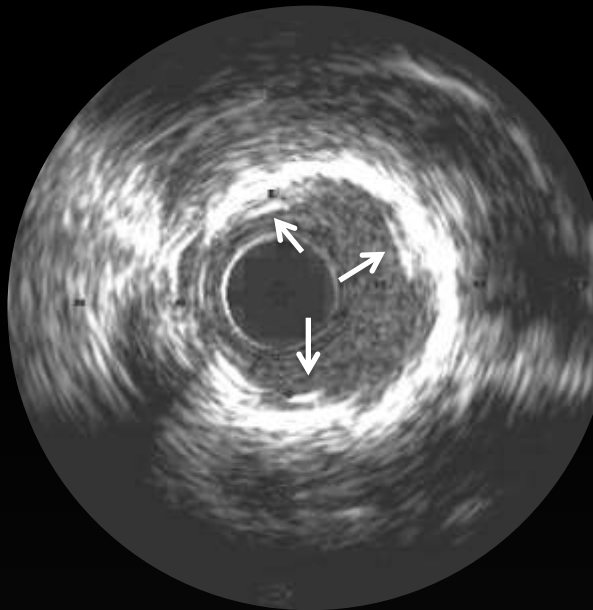
- Angiography
- **MSCT**
- IVUS
- IVUS-VH
- OCT



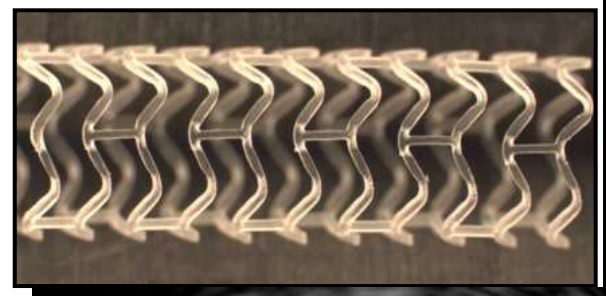
# Stents vs. Scaffolds



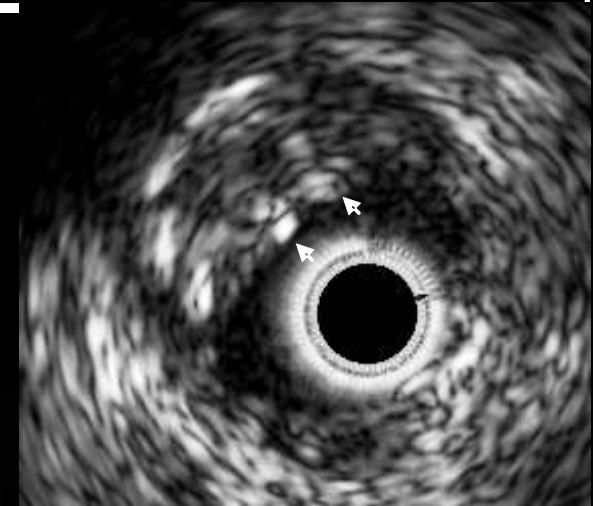
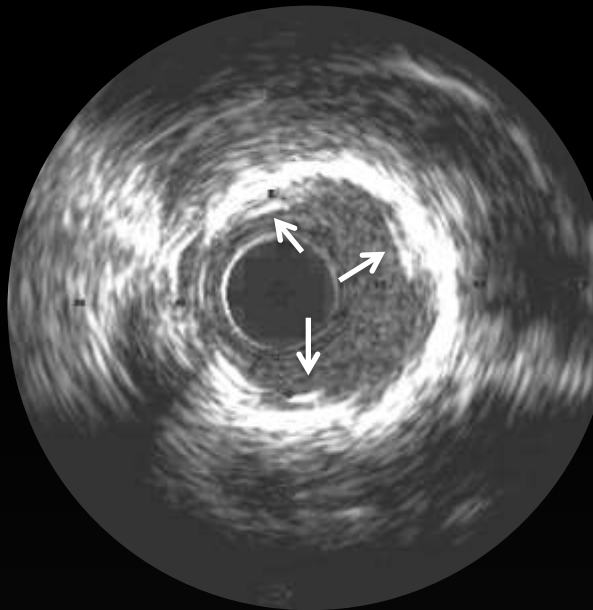
- Angiography
- MSCT
- **IVUS**
- IVUS-VH
- OCT



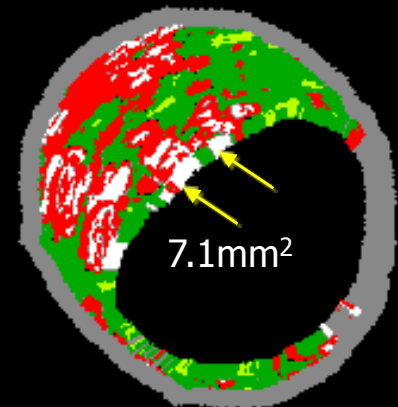
# Stents vs. Scaffolds



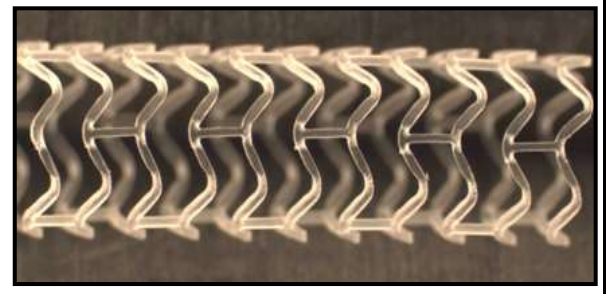
- Angiography
- MSCT
- IVUS
- **IVUS-VH**
- OCT



Post-scaffolding



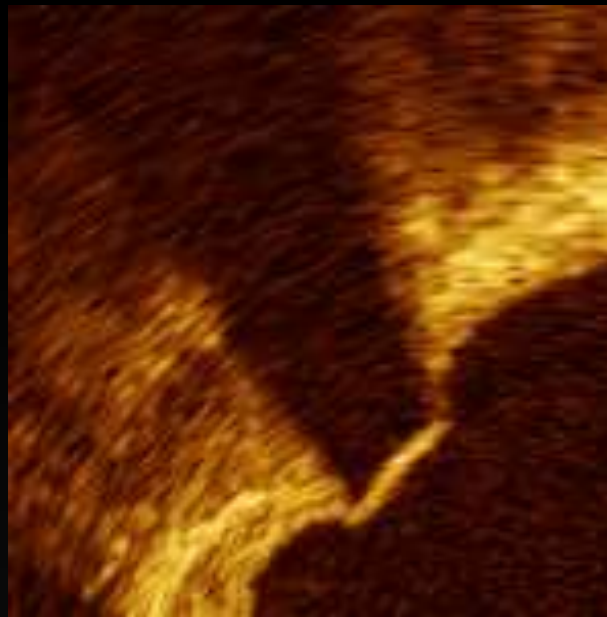
# Stents vs. Scaffolds



**With  
shadowing**

**Without  
shadowing**

- **Angiography**
- **MSCT**
- **IVUS**
- **IVUS-VH**
- **OCT**





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

3M

Histology



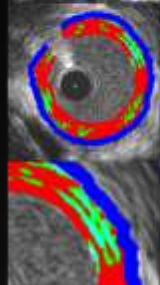
OCT



IVUS-GS

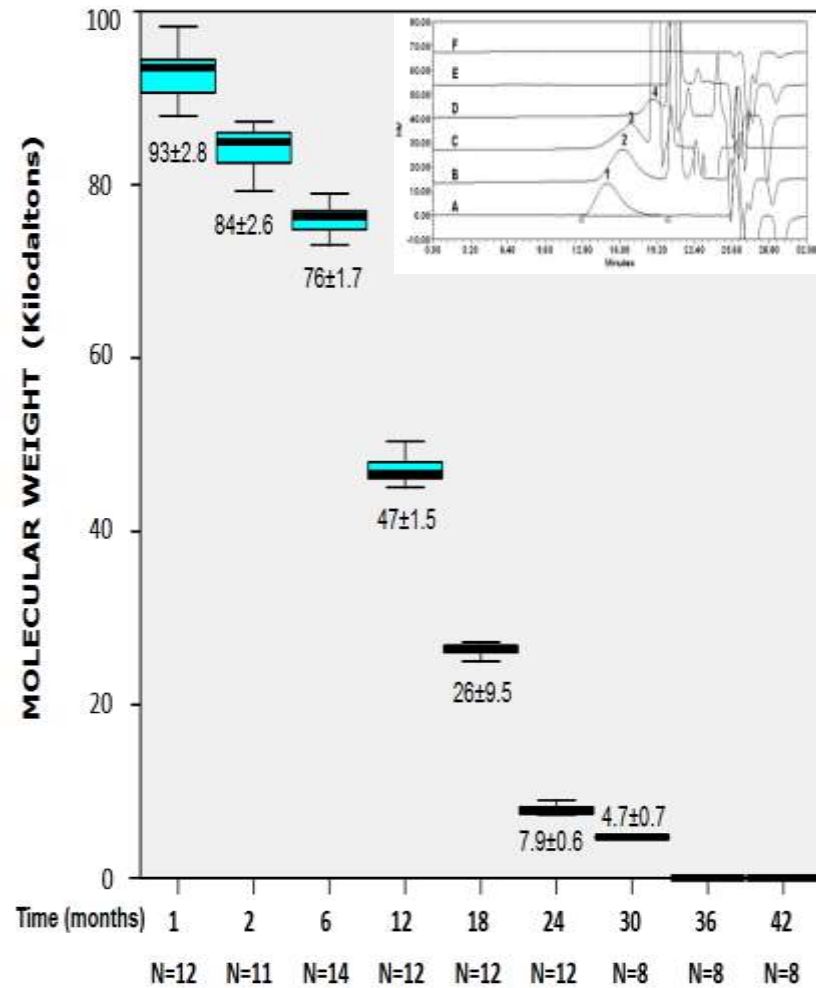


IVUS-  
Echo Genicity

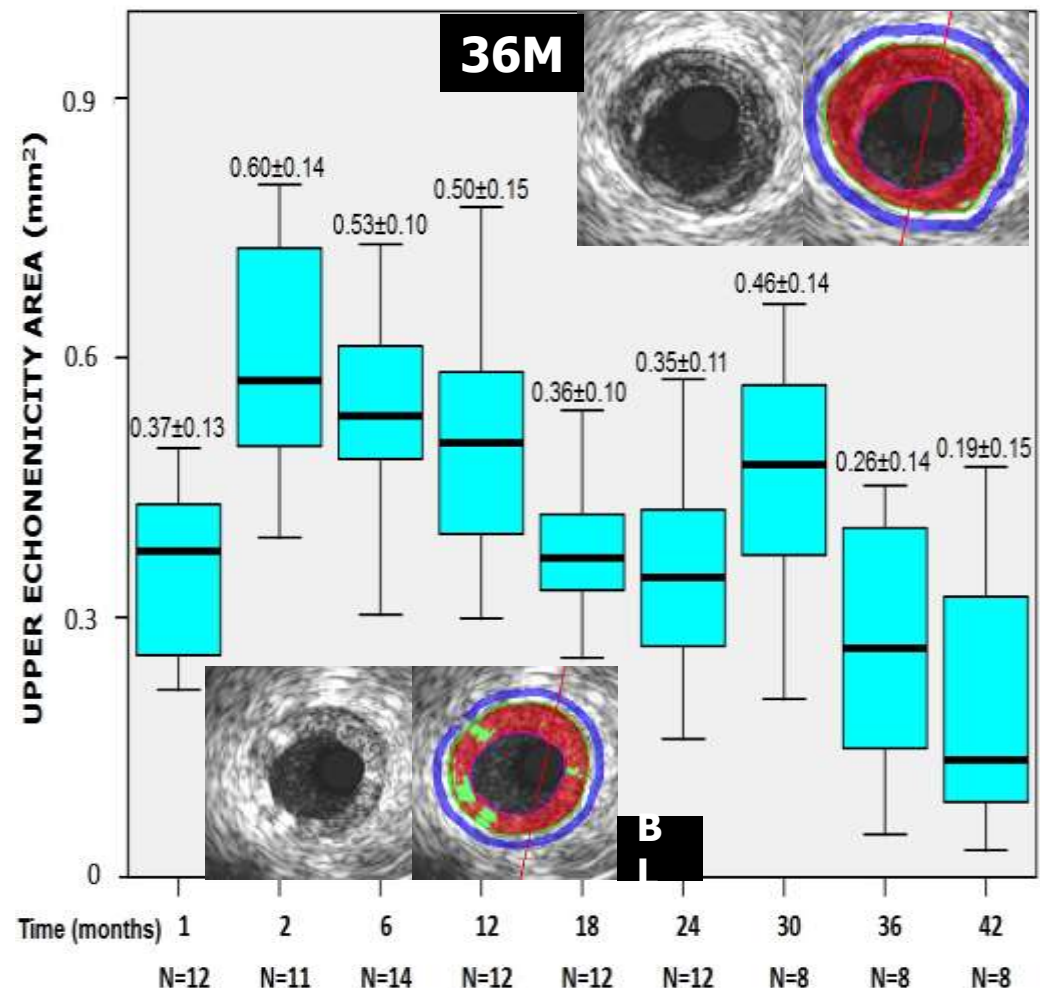


# Correlation of echogenicity with molecular weight of PLLA (Gel Permeate Chromatography) in a porcine model

MOLECULAR WEIGHT ACCORDING TO TIME OF IMPLANTATION

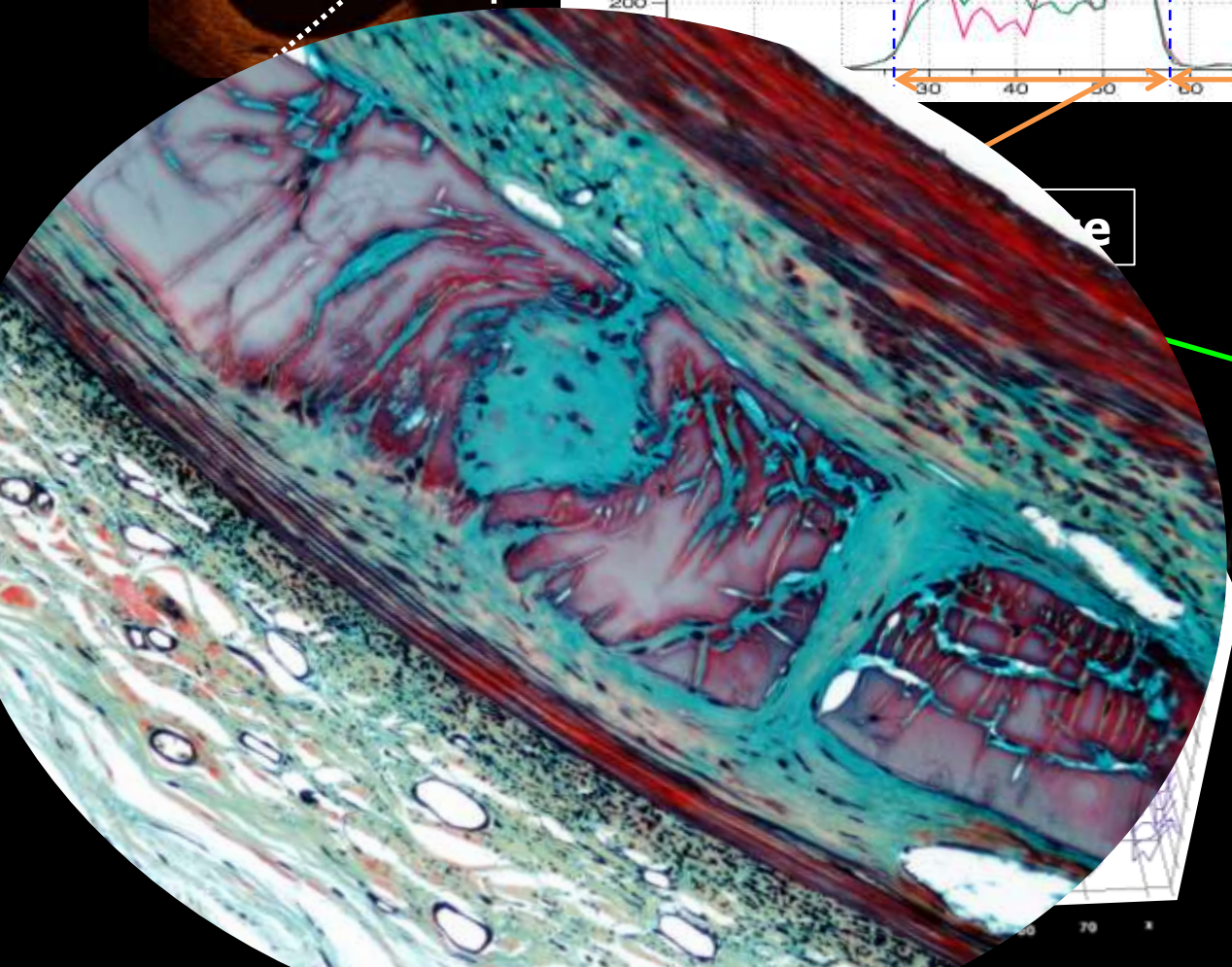
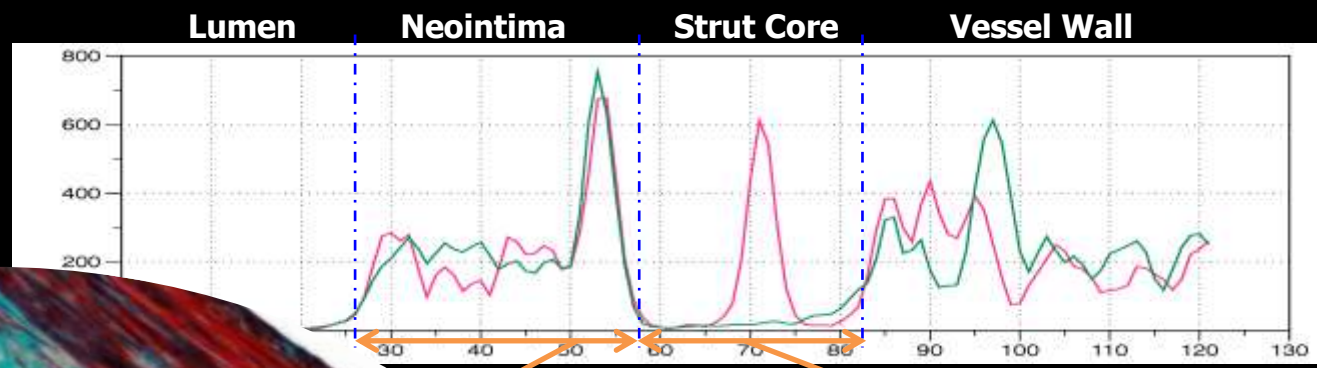
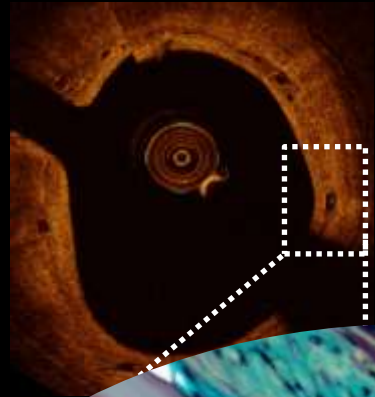


UPPER ECHOGENIC AREA ACCORDING TO TIME OF IMPLANTATION

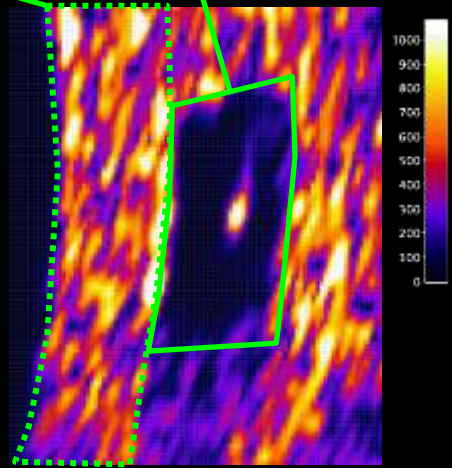


# How can the light intensity analysis be applied to bioresorbable scaffolds?

## 1. Line Plot Profile

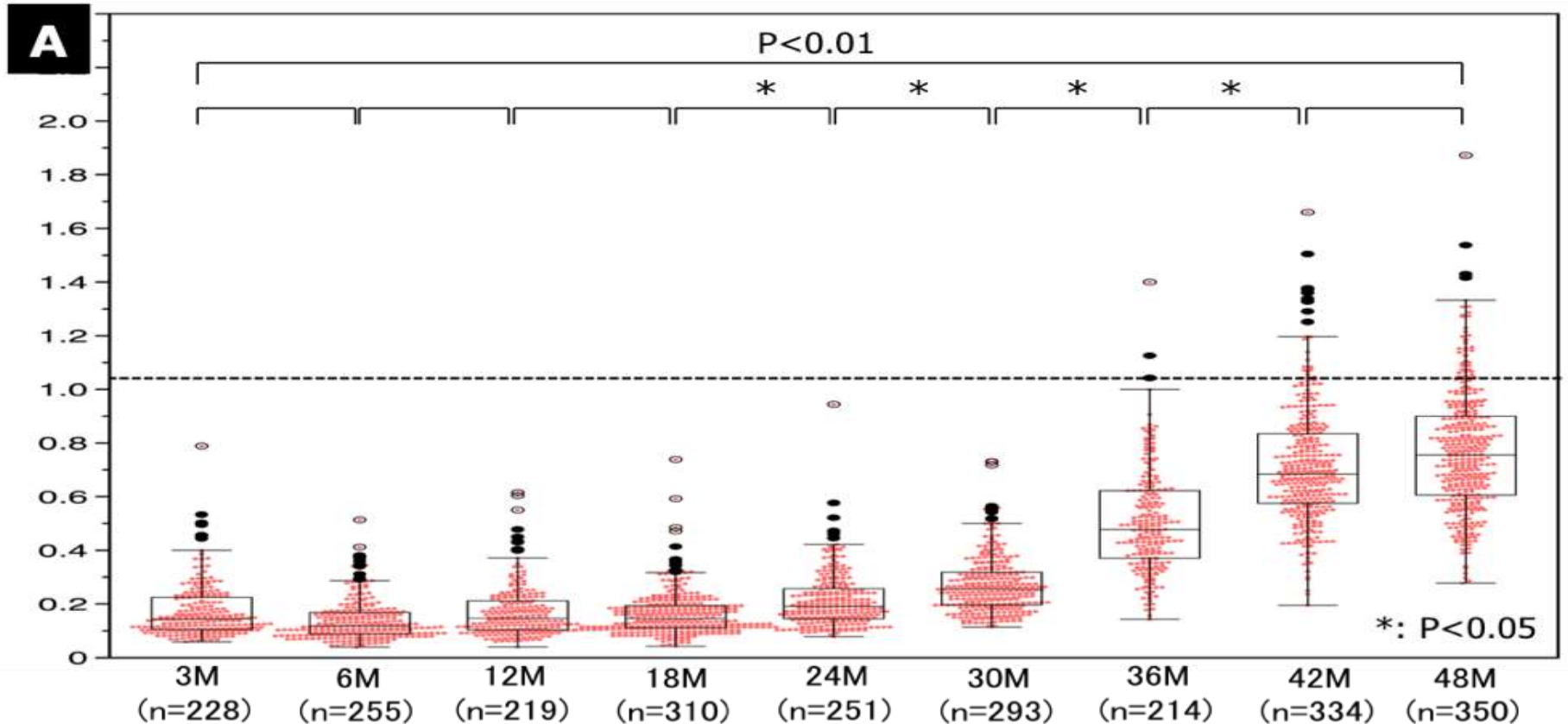
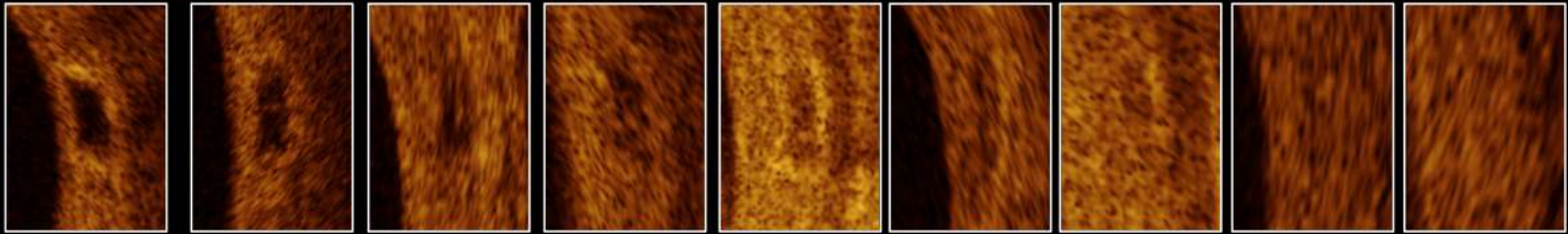


**Strut Thickness**  
**Strut appearance**



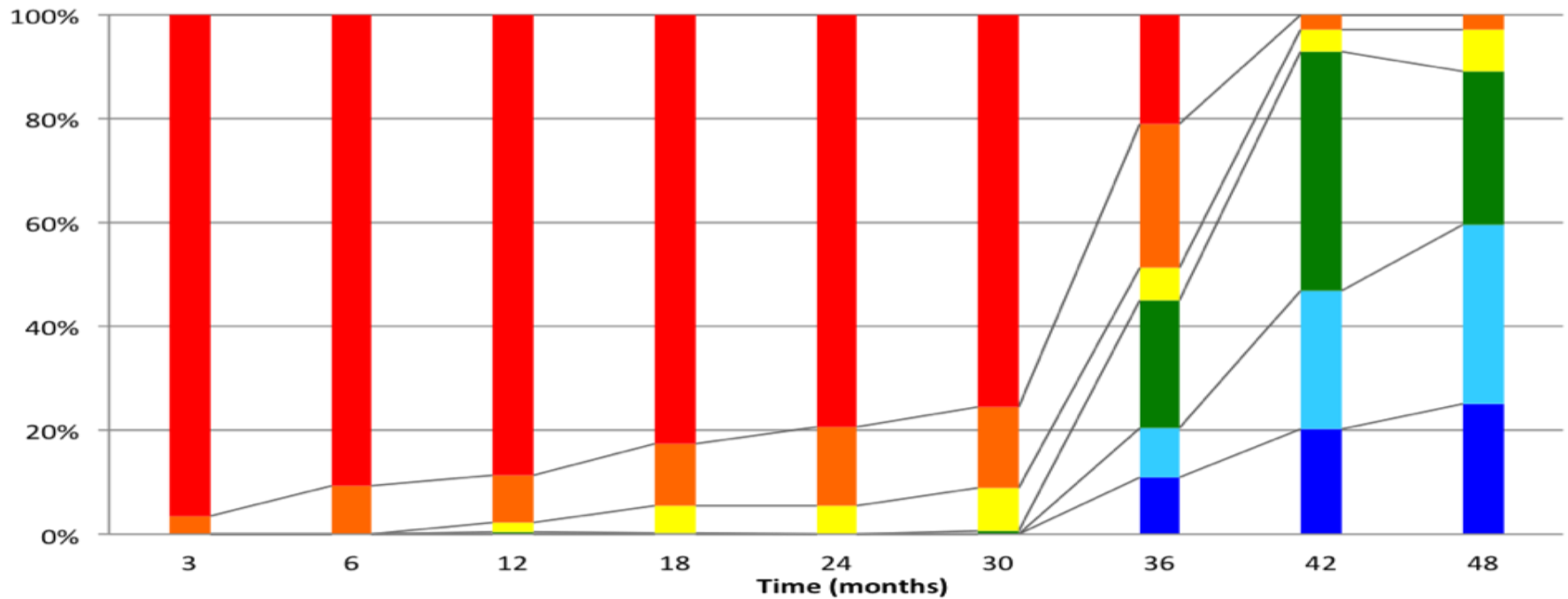
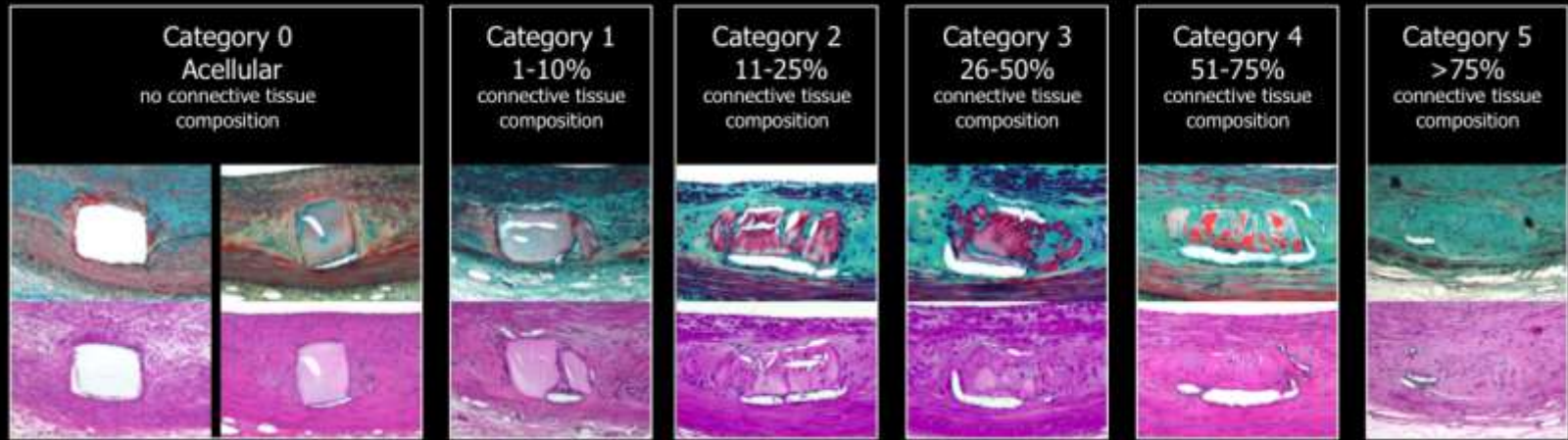
# Change in light intensity of struts over time

Nakatani et al. submitted



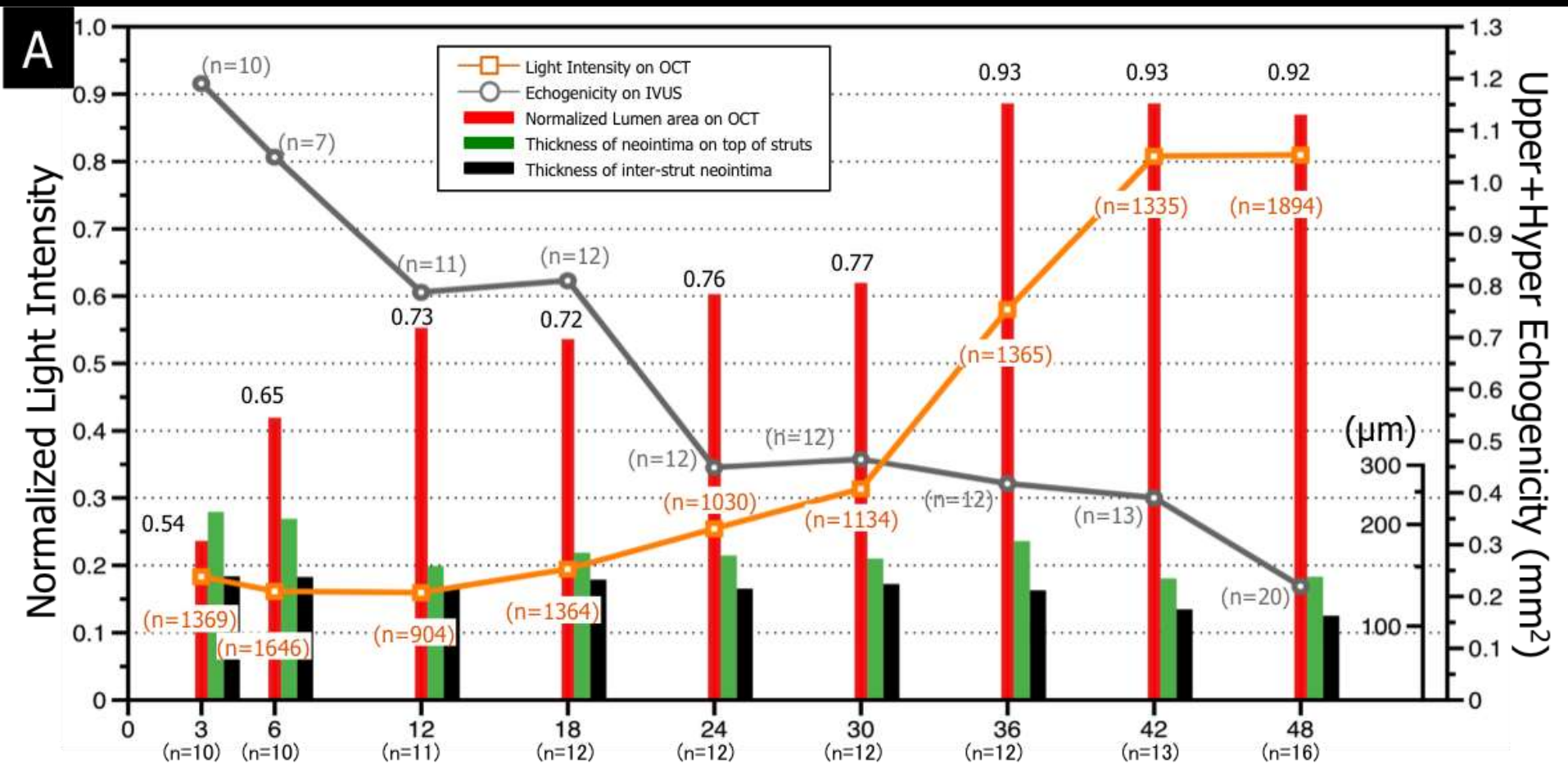
# Change in struts on histology over time

## B Histological categorization of strut and strut footprint

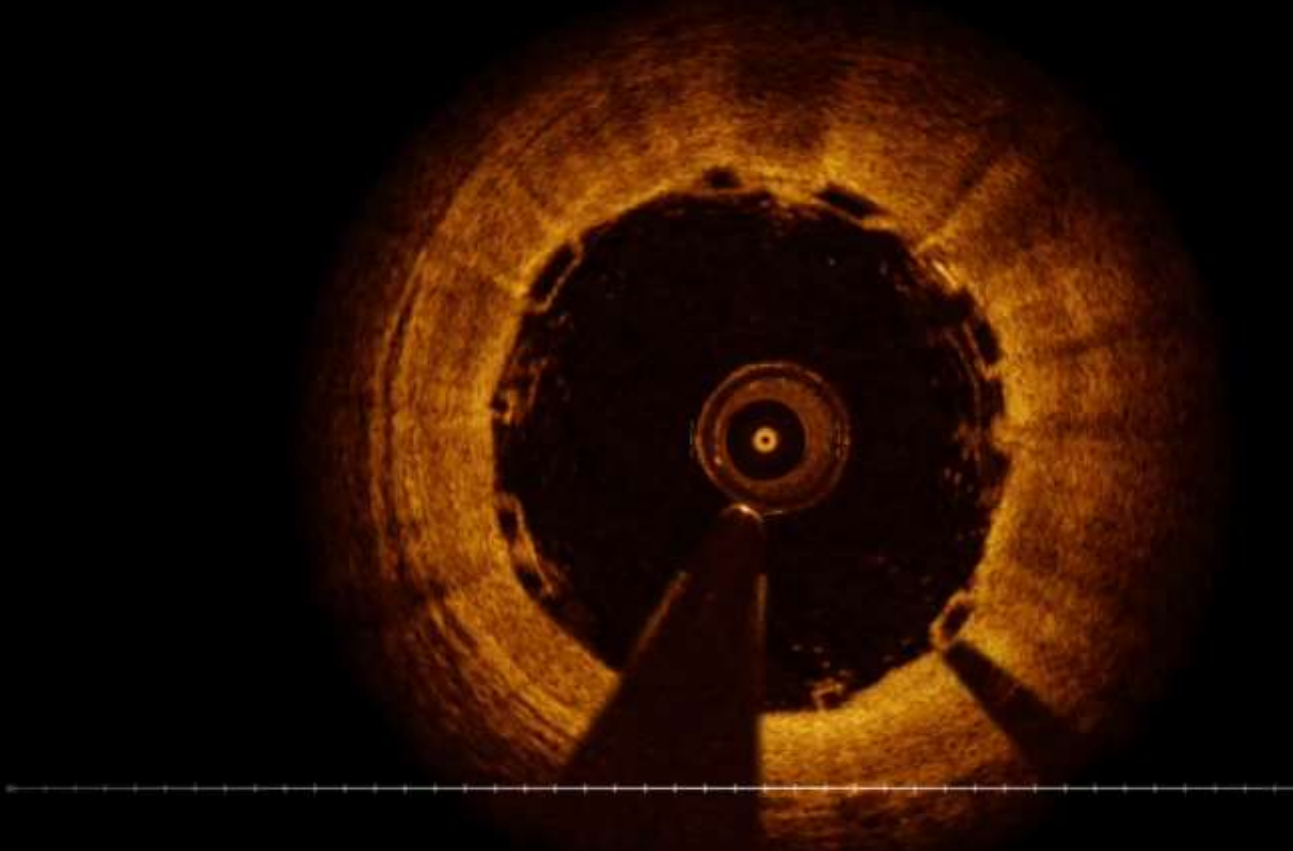


■ Category0: Acellular  
■ Category1: 1-10% connective tissue  
■ Category2: 11-25% connective tissue  
■ Category3: 26-50% connective tissue  
■ Category4: 51-75% connective tissue  
■ Category5: >75% connective tissue

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



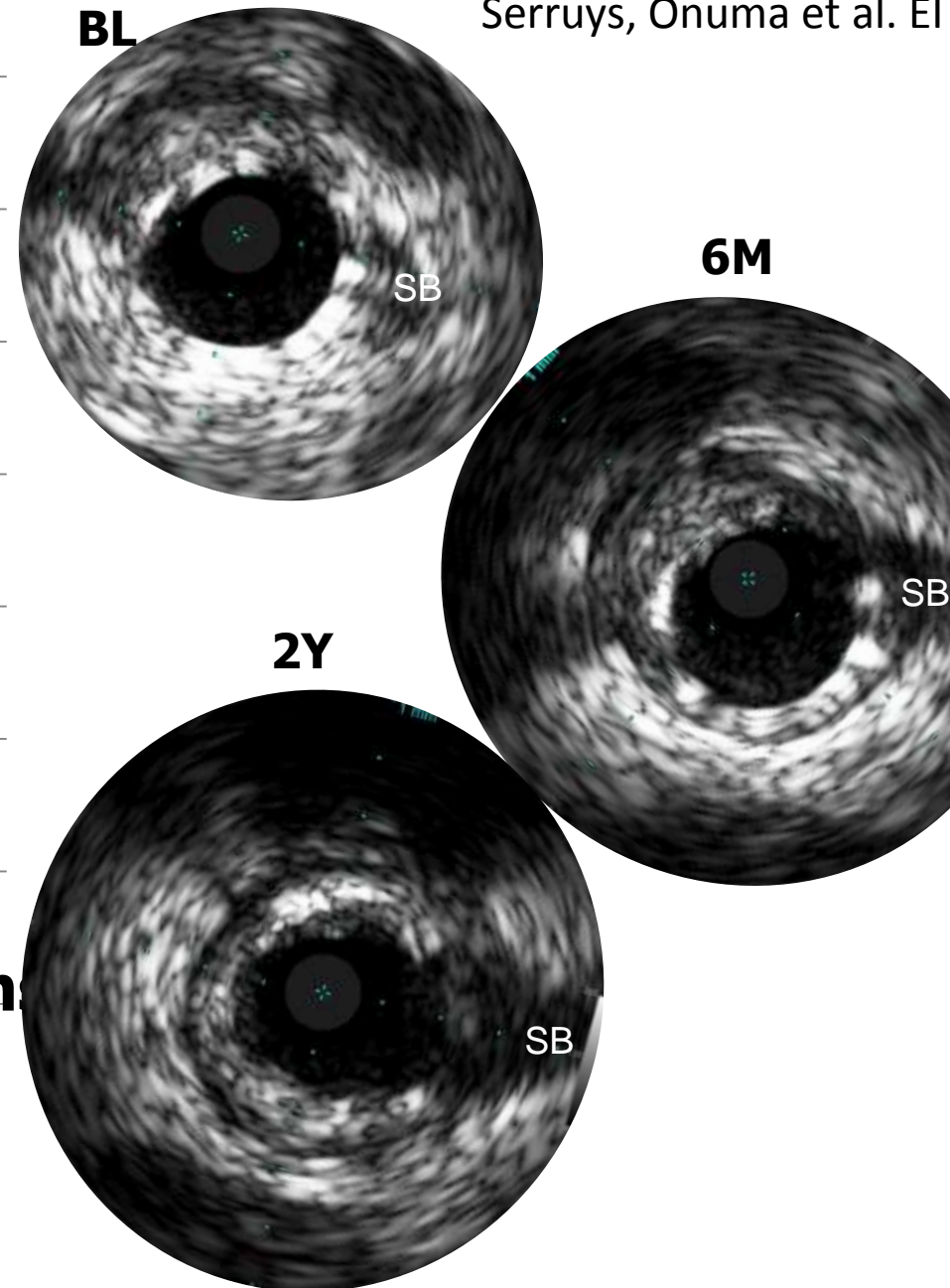
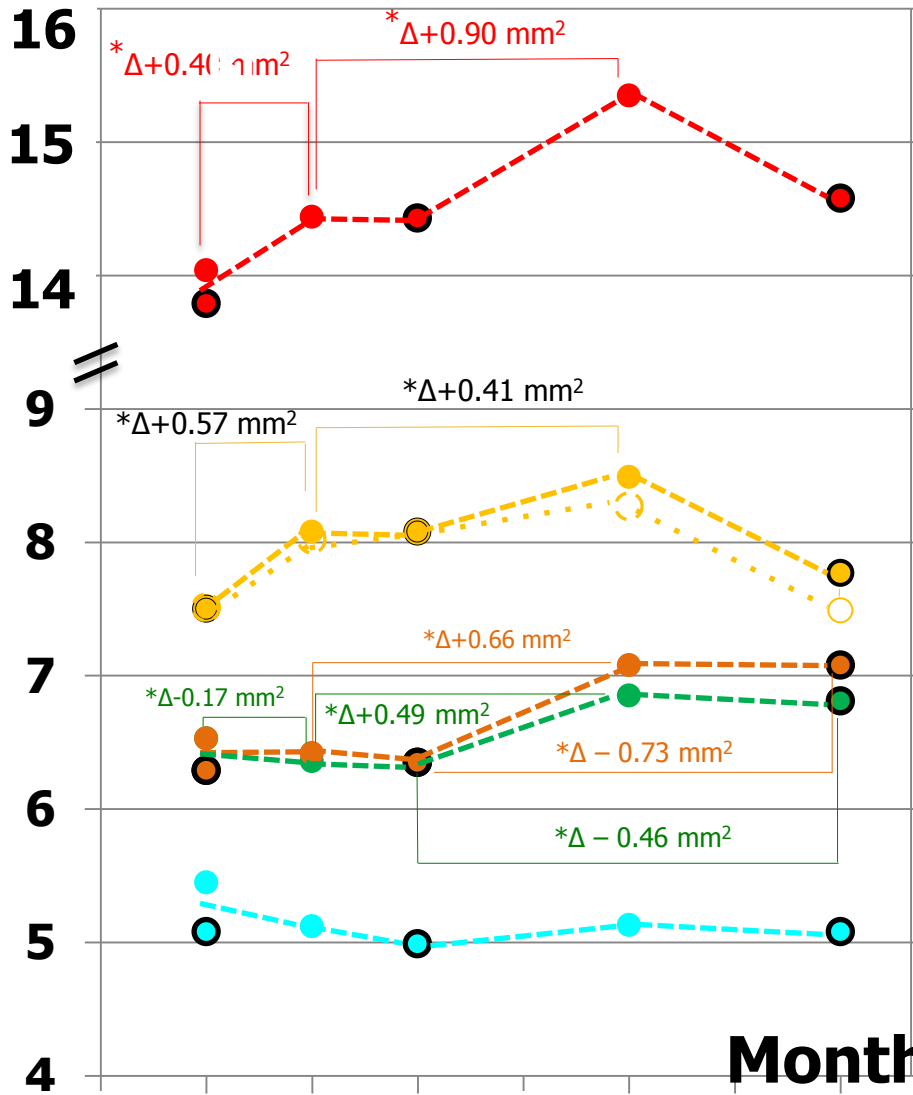
**Comprehensive imaging of Bioresorption and Integration process:  
OCT in human (BL, 6M, 2Y and 5Y)  
From apposition, to coverage, to scaffold expansion, to strut  
integration, to late lumen enlargement, to high reflectivity**



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

# Serial IVUS

Serruys, Onuma et al. E



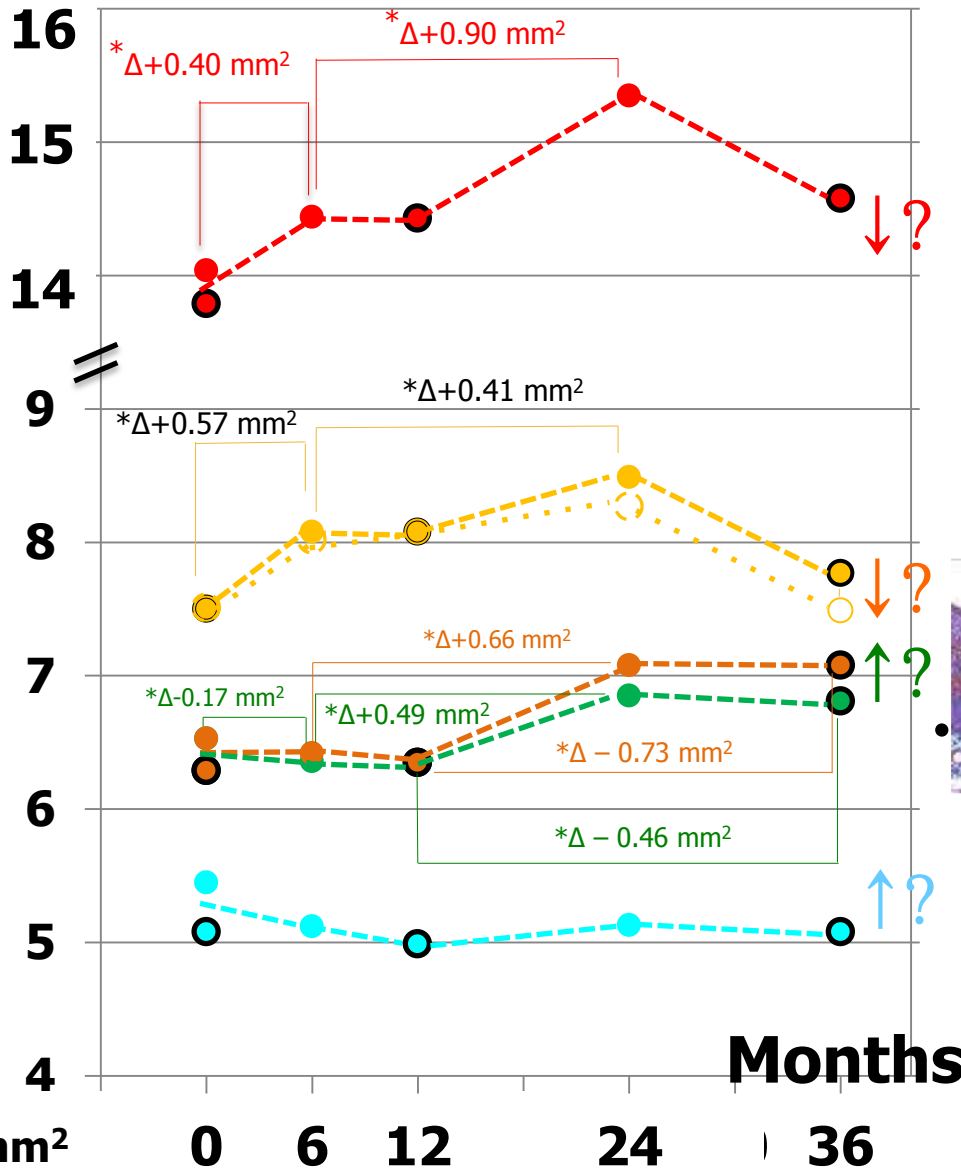
- Vessel area in cohort B1
- Vessel area in cohort B2
- Total plaque area in cohort B1
- Total plaque area in cohort B2
- Plaque behind scaffold in cohort B1
- Plaque behind scaffold in cohort B2
- Scaffold area in cohort B1
- Scaffold area in cohort B2
- Mean lumen area in cohort B1
- Mean lumen area in cohort B2
- Min lumen area in cohort B1
- Min lumen area in cohort B2



# Serial IVUS

Serruys, Onuma et al. Et

- **The Vessel area and total plaque area** show a biphasic change with an increase between the first and second year. A plaque reduction occurs between the second and third year follow-up.



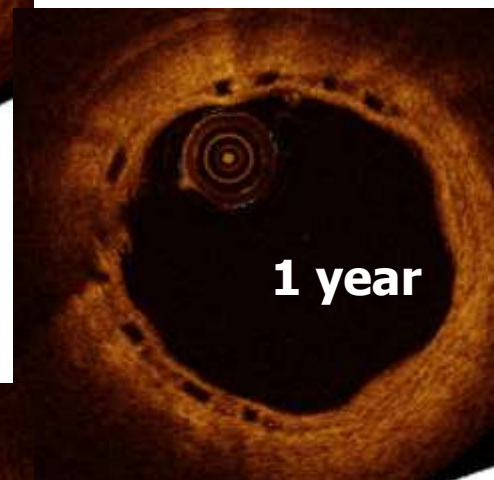
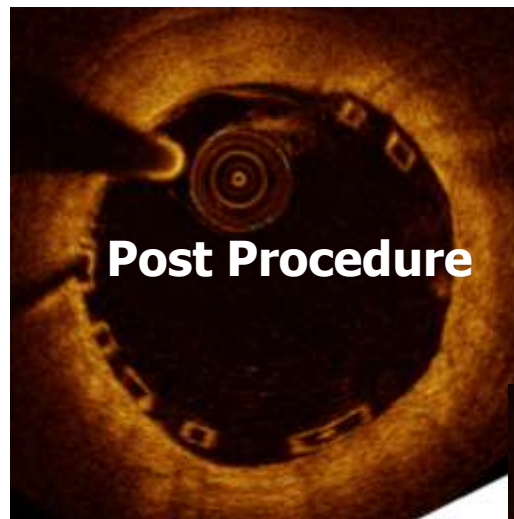
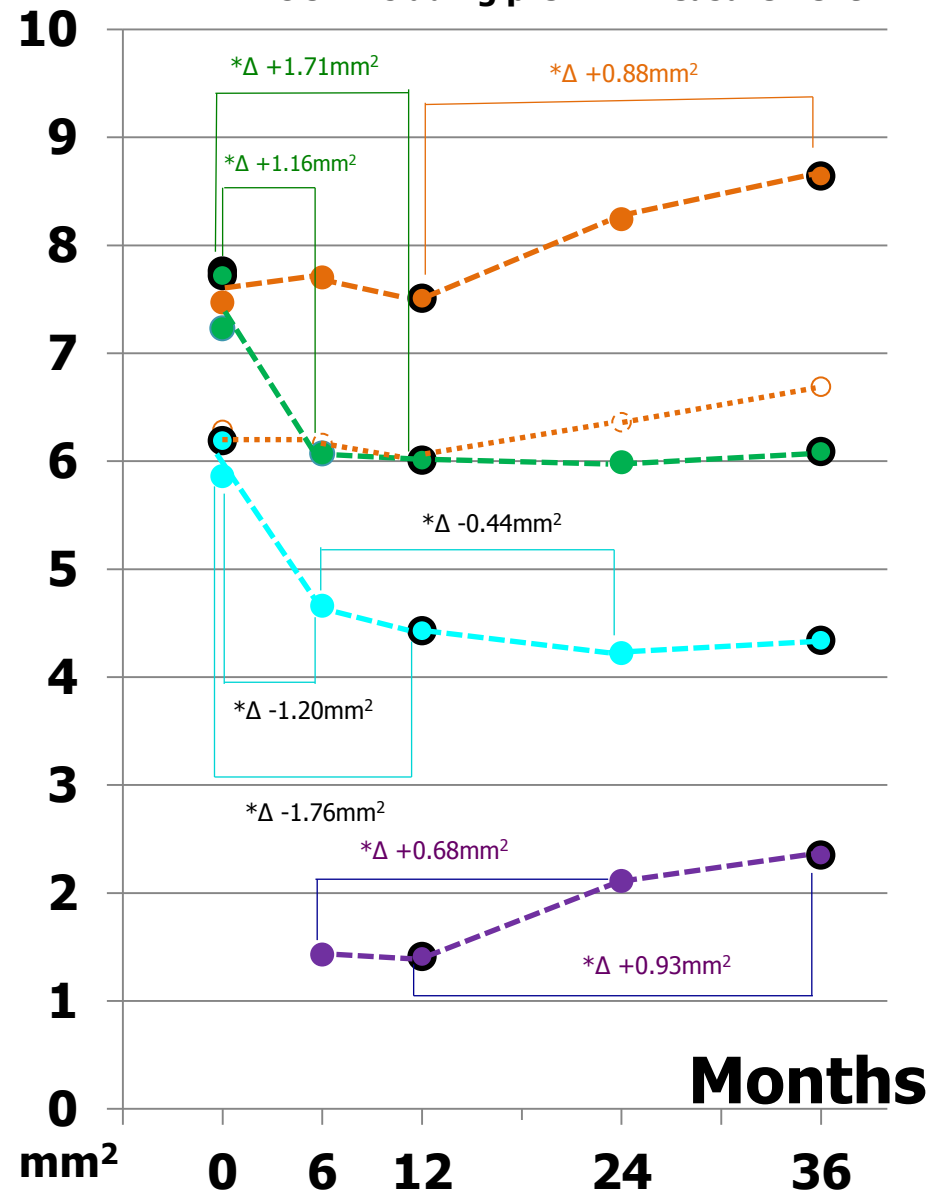
- The mean and minimum scaffold area significantly increase and compensate for the increase in neointimal hyperplasia, resulting in an increase of mean lumen area from 1 to 3 years with an unchanged minimal lumen area from 1 year to 3 years.

- Vessel area in cohort B1
- Vessel area in cohort B2
- Total plaque area in cohort B1
- Total plaque area in cohort B2
- Plaque behind scaffold in cohort B1
- Plaque behind scaffold in cohort 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

# Serial OCT

Serruys, Onuma et al. E

## OCT including pre TLR measurement

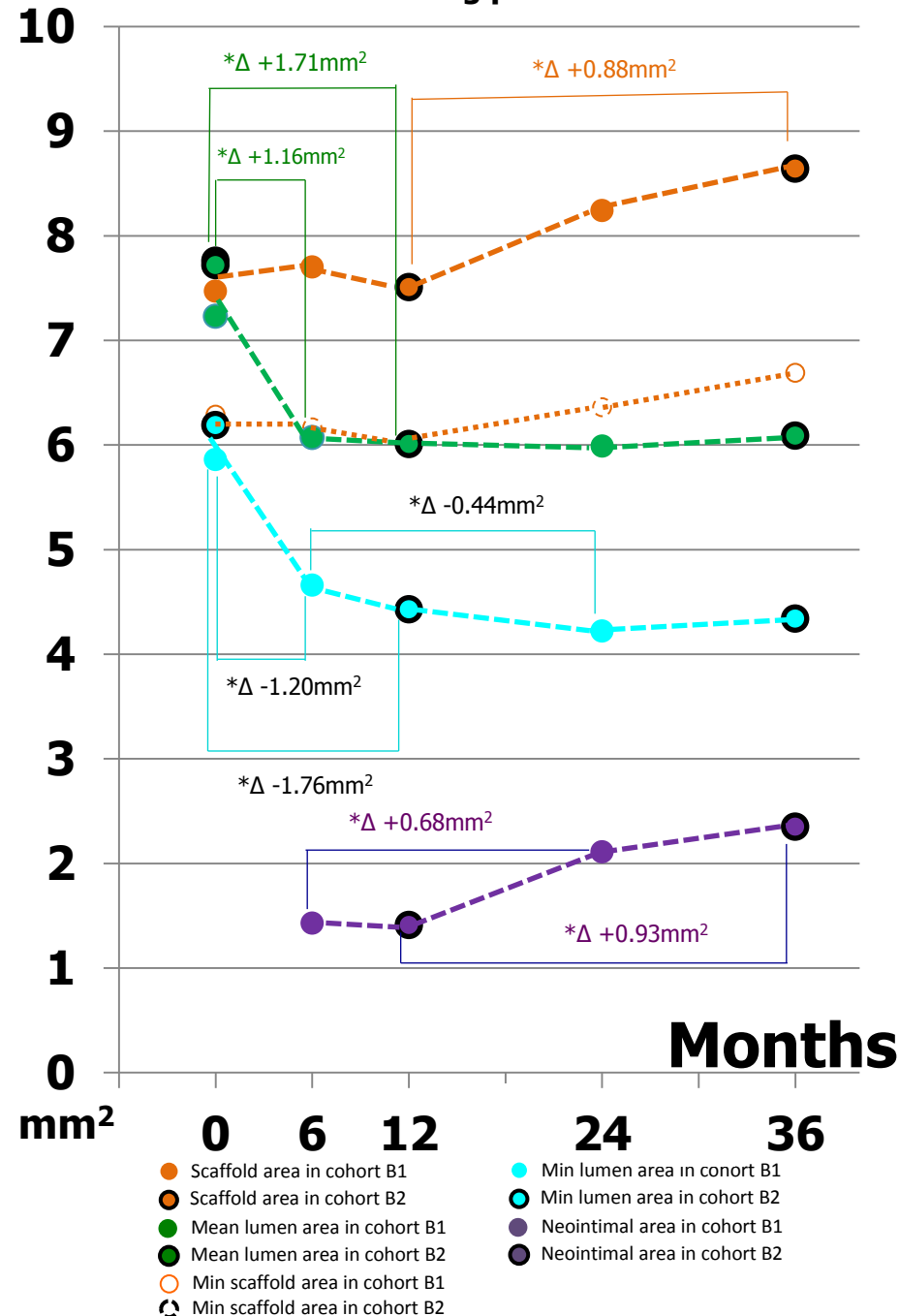


- Scaffold area in cohort B1
- Scaffold area in cohort B2
- Mean lumen area in cohort B1
- Mean lumen area in cohort B2
- Min scaffold area in cohort B1
- Min scaffold area in cohort B2
- Min lumen area in cohort B1
- Min lumen area in cohort B2
- Neointimal area in cohort B1
- Neointimal area in cohort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

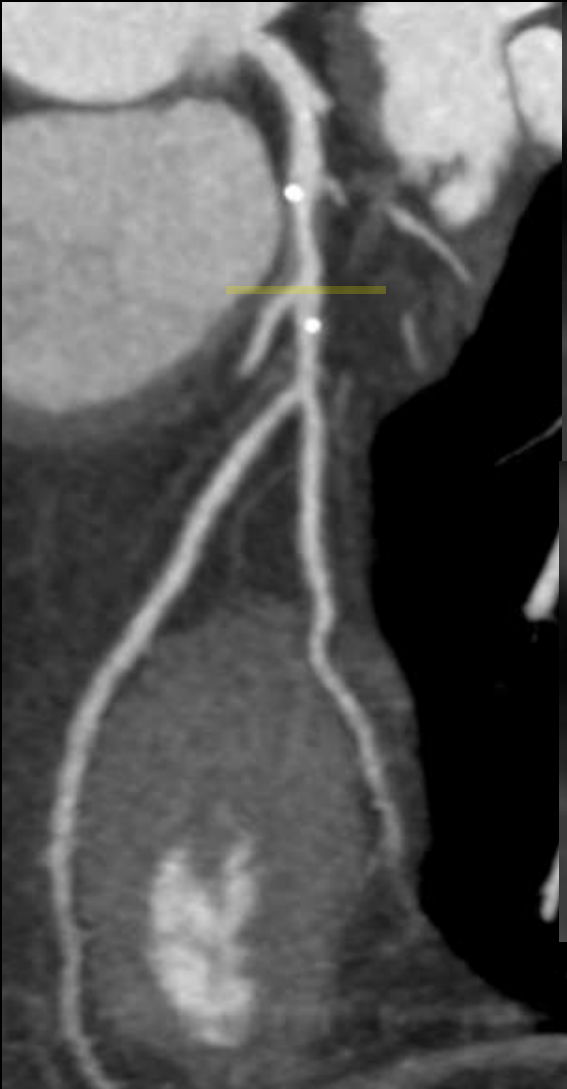
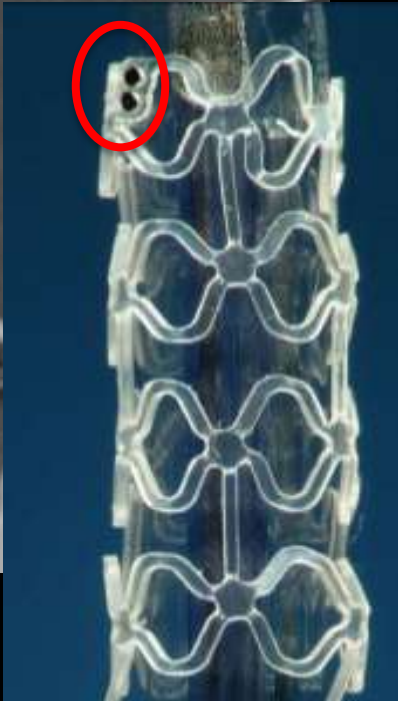
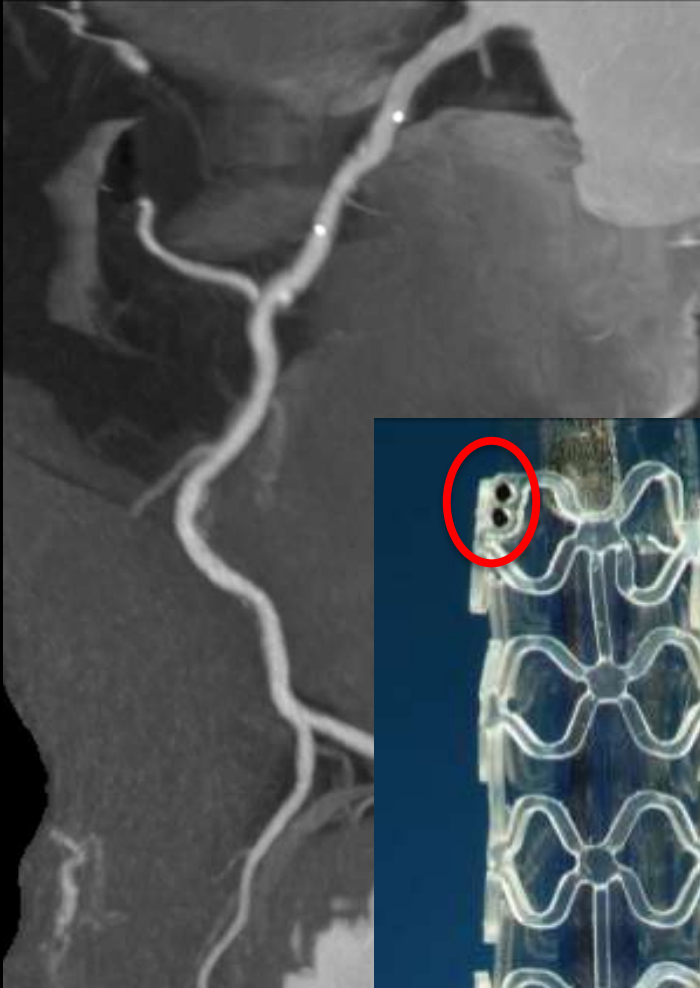
# Serial OCT

- OCT confirms the IVUS findings regarding the increase in the scaffold area and neointimal area from 1 to 3 years.
- The **mean and minimum scaffold area** significantly increase and compensate for the increase in **neointimal hyperplasia**. As a consequence, **mean lumen area** and **minimal lumen area** were unchanged from 1 year to 3 years.

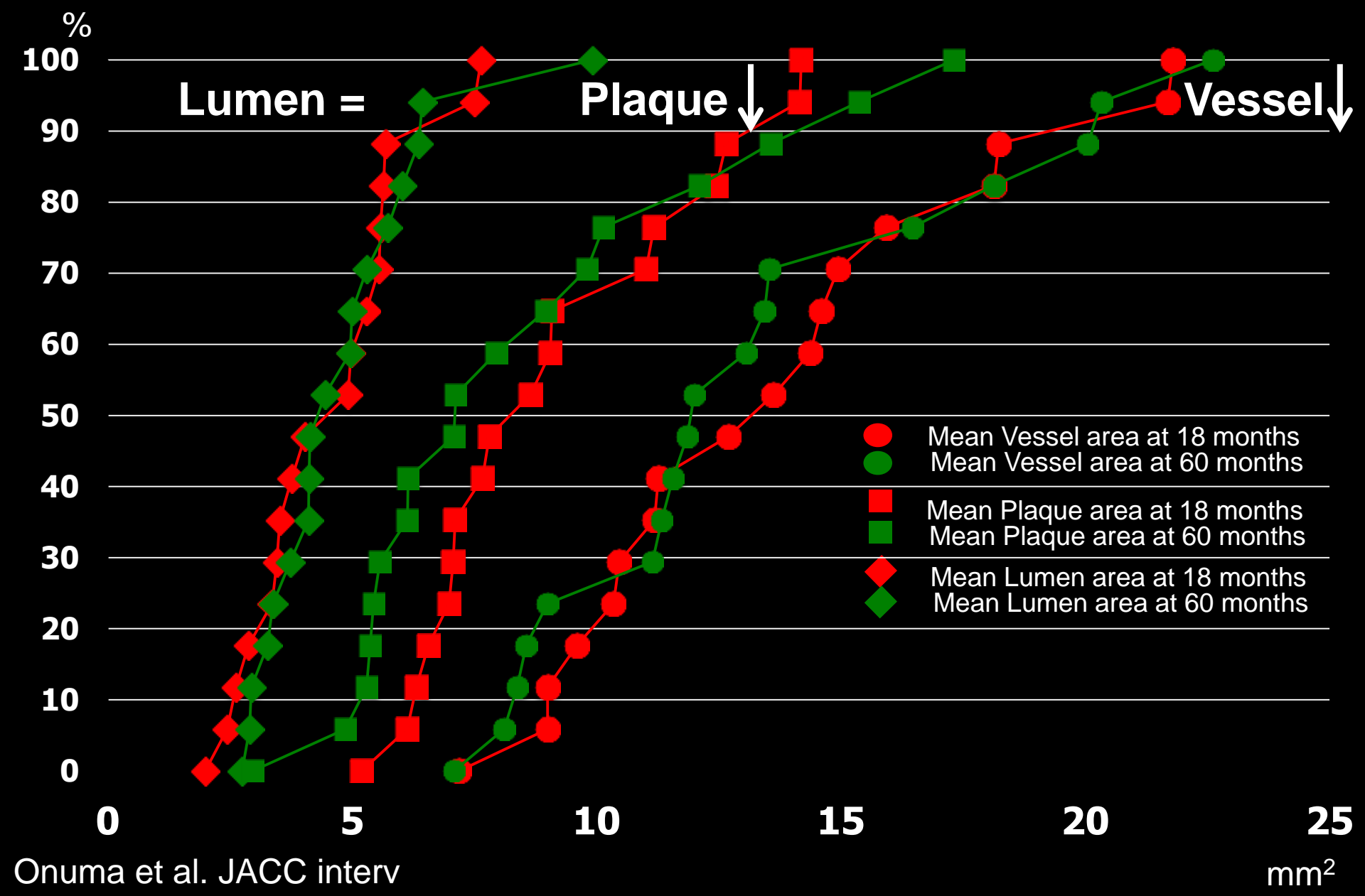
OCT including pre TLR measurement



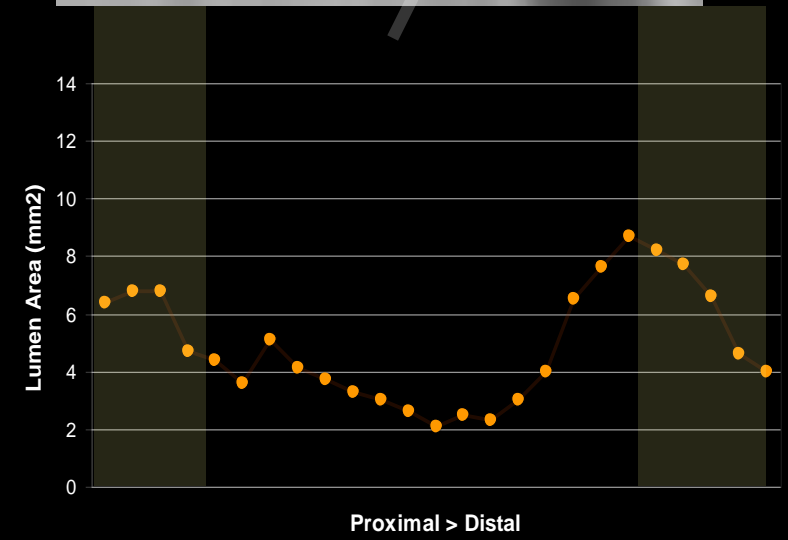
# Quantitative Assessment of MSCT



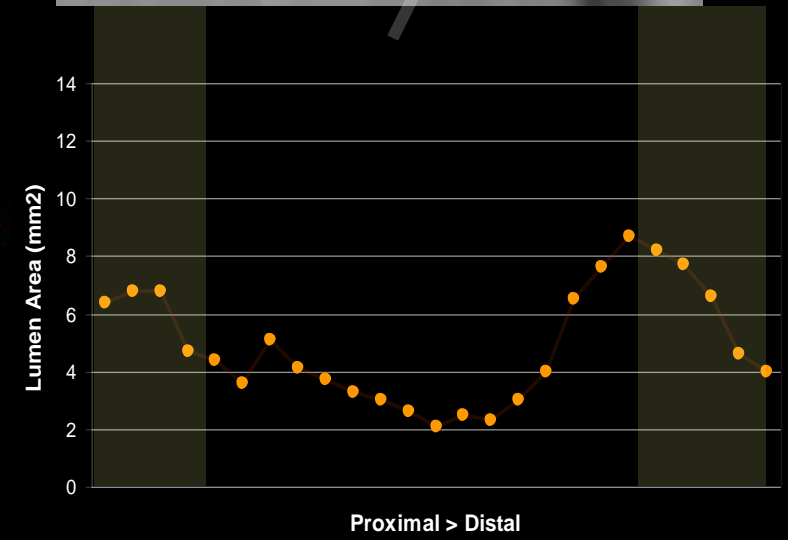
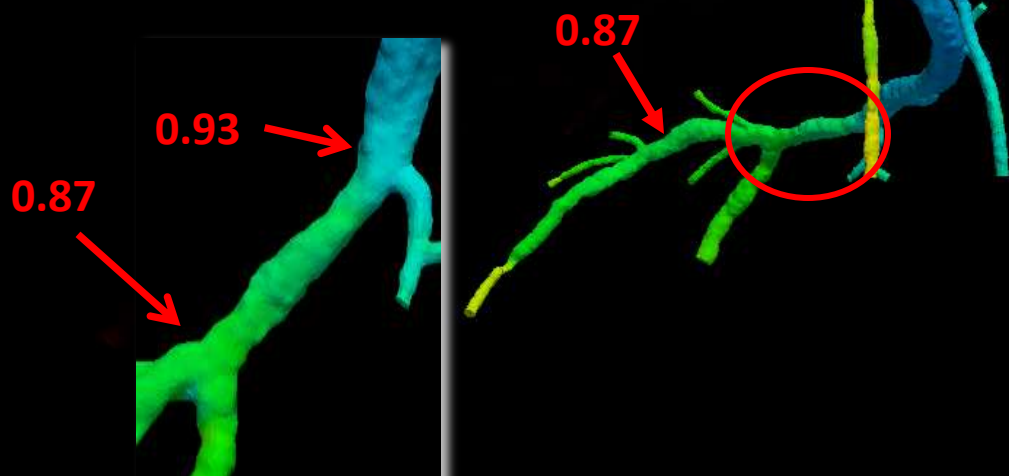
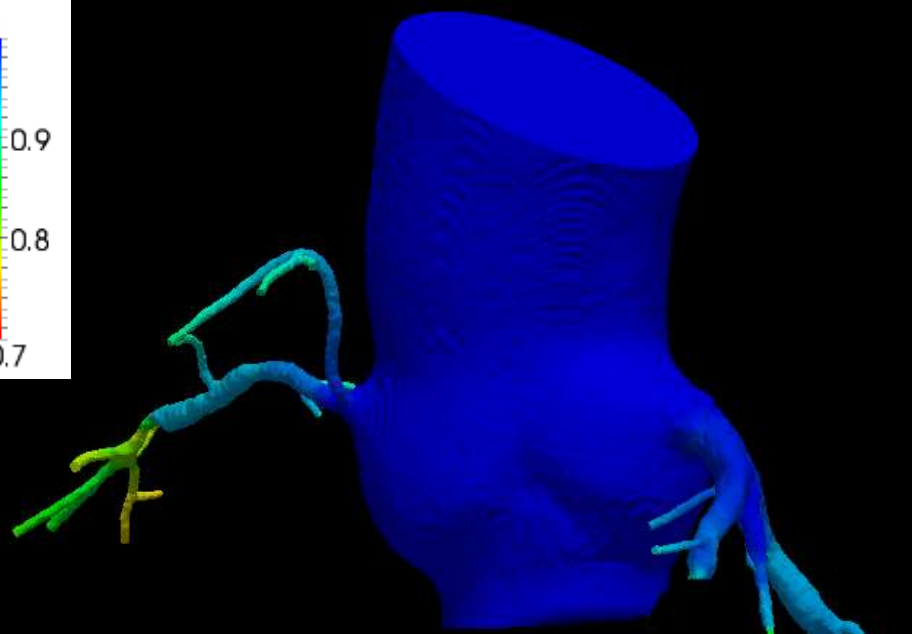
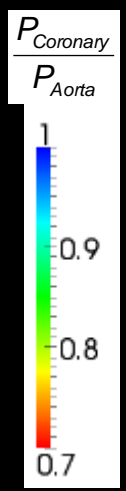
# Cumulative frequency distribution curves of vessel area, plaque area and lumen area on MSCT at 18 months and 60 months



# Moderate restenosis



# Moderate restenosis



# Conclusion

- **The Absorb PLLA scaffold is radiolucent and translucent.**
- **At the time of implantation, struts of an ABSORB scaffold look:**
  1. **On MSCT and Angiography, invisible except for metallic markers**
  2. **On IVUS, hyperechogenic stripe, IVUS-VH, Dense calcium**
  3. **On OCT, black box**
- **The appearance of struts on IVUS and OCT changes over time due to bioresorption**
  1. **IVUS: Molecular weight loss**
  2. **OCT: integration process after bioresorption**
- **In a serial fup of human**
  - **IVUS showed late lumen enlargement with changes in plaque area**
  - **OCT showed scaffold enlargement**
  - **MSCT FUP with functionality assessment is feasible**