

DES summit

**Insight into BVS  
from Multiple Imaging Studies**

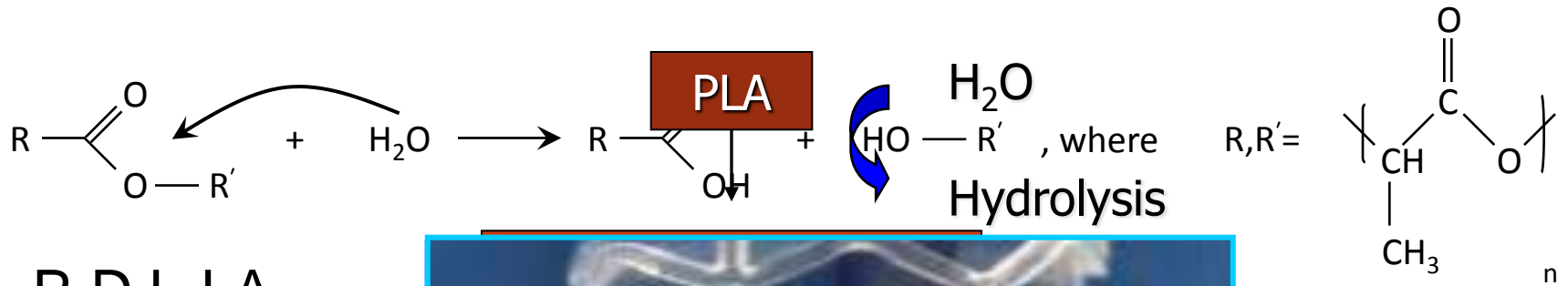
**Y. Onuma, MD, PhD  
Evelyn Regar, MD, PhD  
RJ. van Geuns, MD, PhD  
P. W. J. C. Serruys, MD, PhD  
Thorax Centre, Erasmus MC**

**TCTAP 2014**

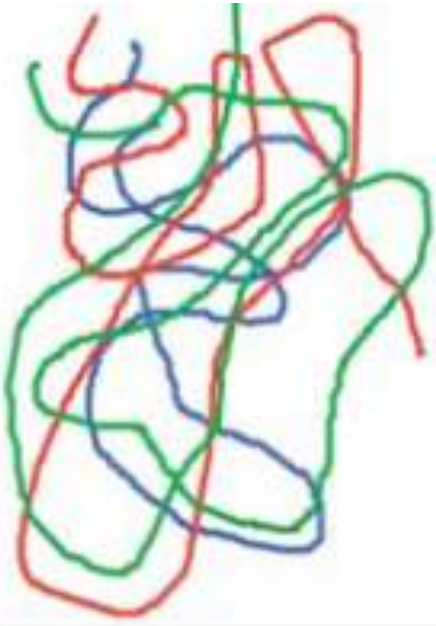
# #1. Overview

## Poly(lactide) Degradation Mechanism

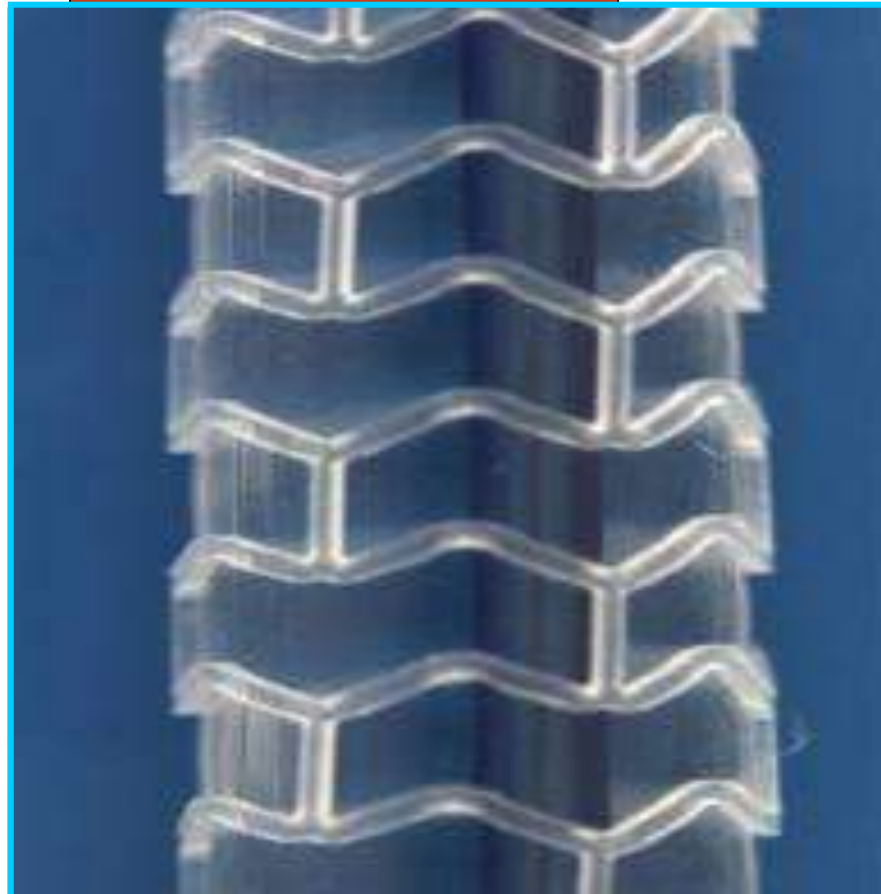
Hydrolysis via Random Chain Scission of Ester Bonds



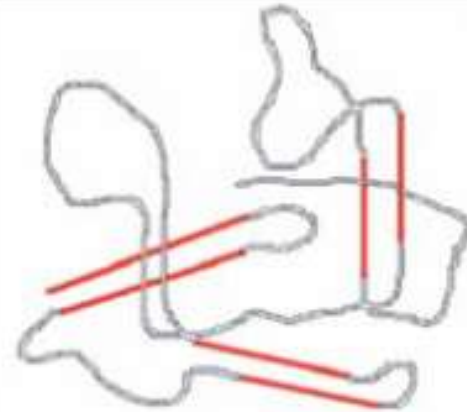
P-D,L-LA



Amorphous

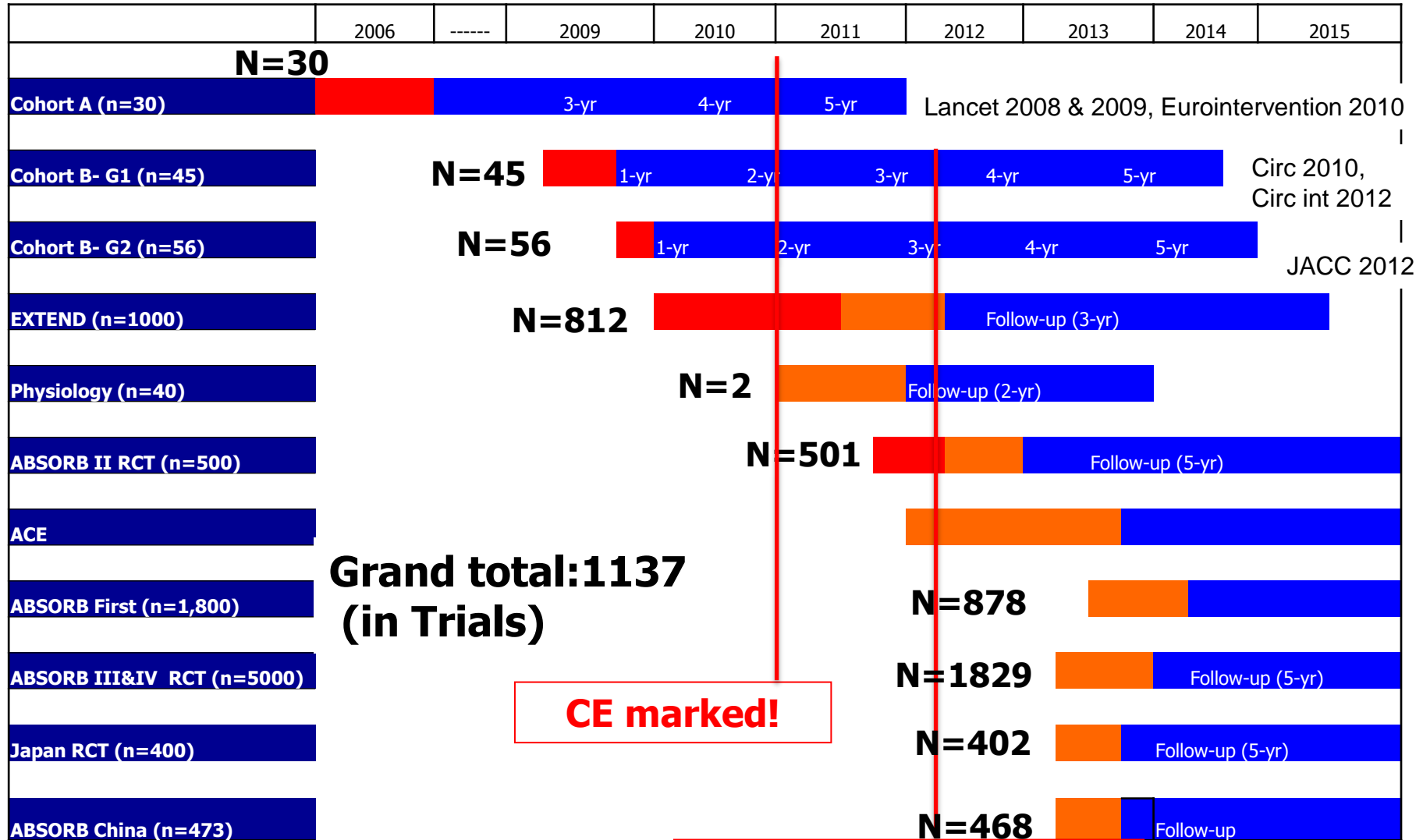


P-L,L-LA



Semicrystalline

# Overview of ABSORB Studies



**Grand total: 1137  
(in Trials)**

**CE marked!**

**Commercially available**

Follow-up

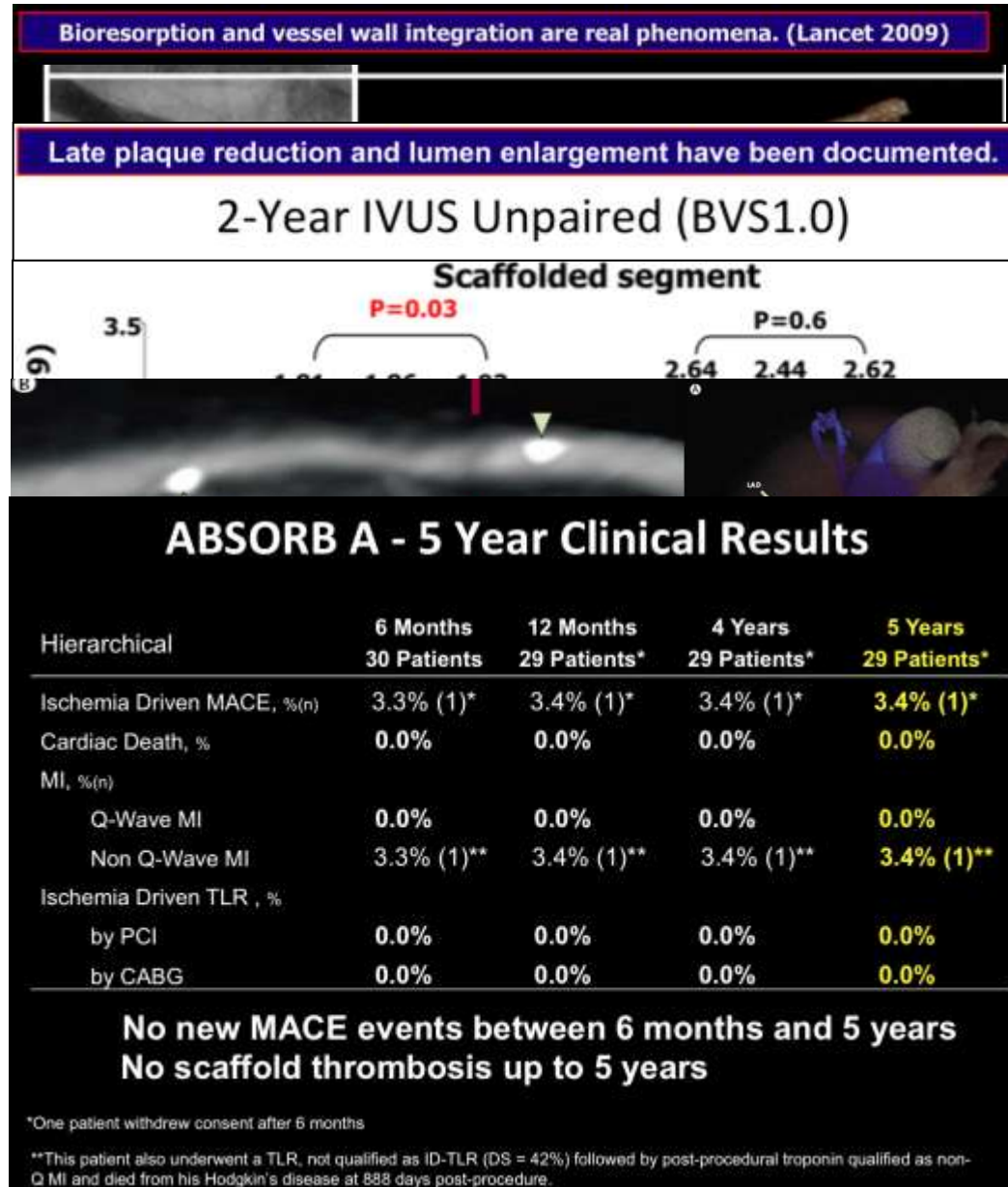
Enrolled

To be Enrolled

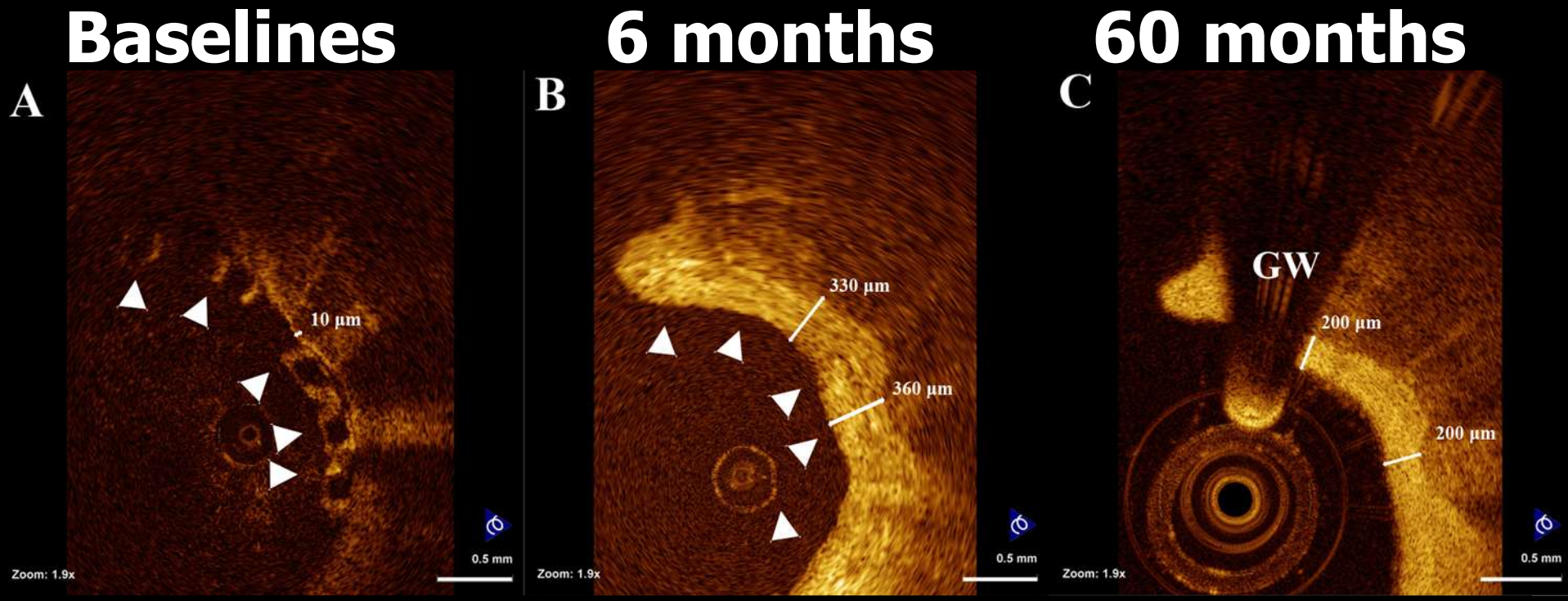
\* Timelines based on patient follow-up dates, not data availability

# What did we learn from 2-year follow-up of ABSORB cohort A ?

- Bioresorption does occur
- Late enlargement of lumen, as a result of plaque shrinkage, has been documented
- Vasomotion and endothelial function can be restored in the scaffolded segment
- Stented lesion can be assessed by non-invasive imaging
- Restenosis and thrombosis have not been seen up to 5 years, despite discontinuation of clopidogrel



**. Sealing and shielding of plaques as a result of scaffold implantation : can the scaffold cap the plaque? 60 Months Follow up**



**ABSORB cohort A (n=30)**

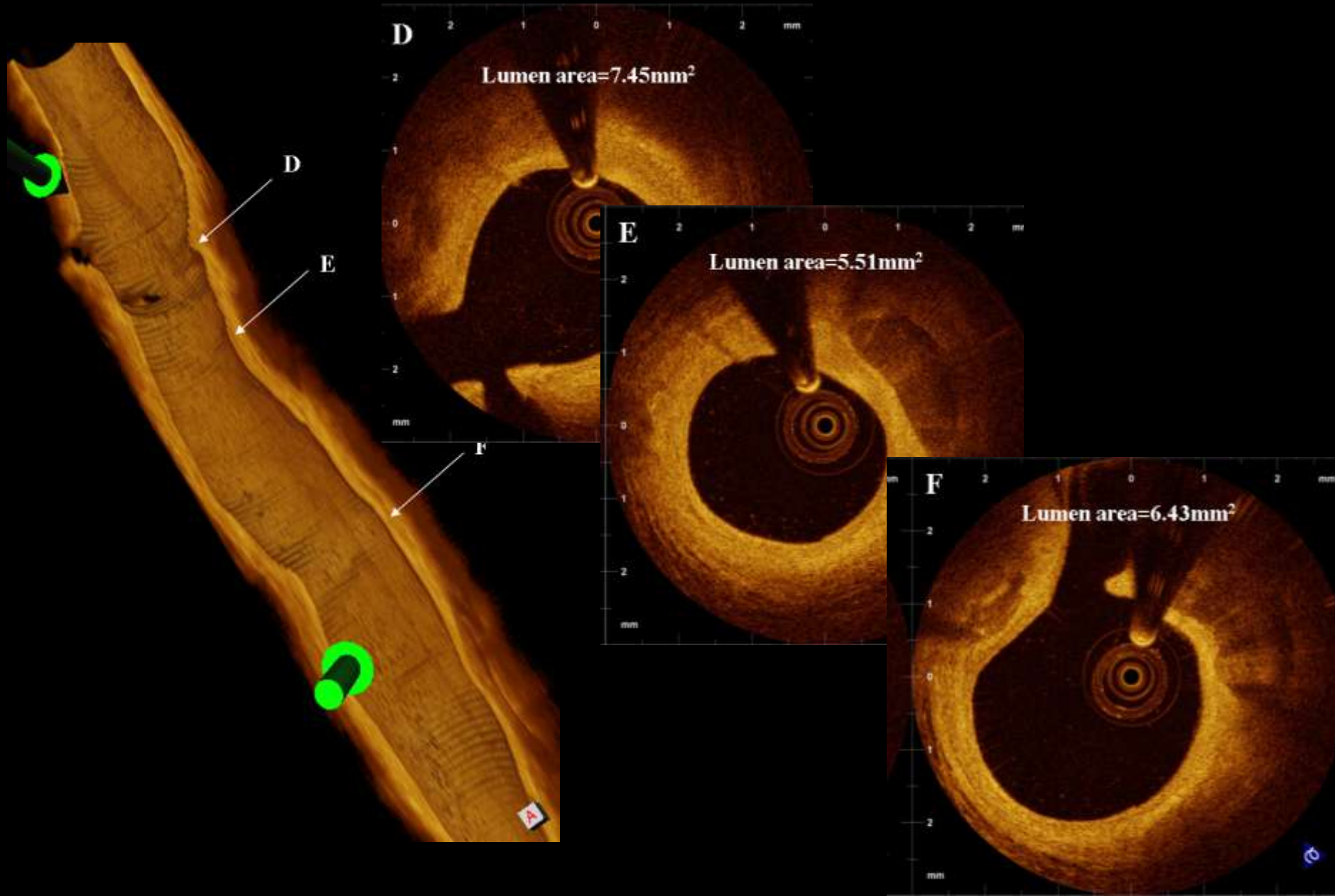
QCA, IVUS, OCT, IVUS VH



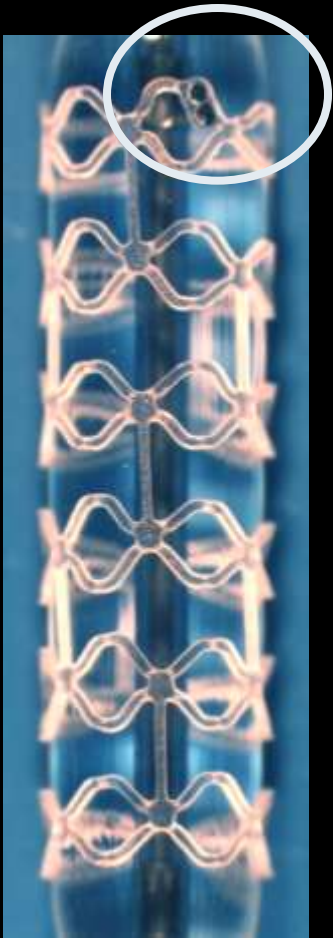
MSCT



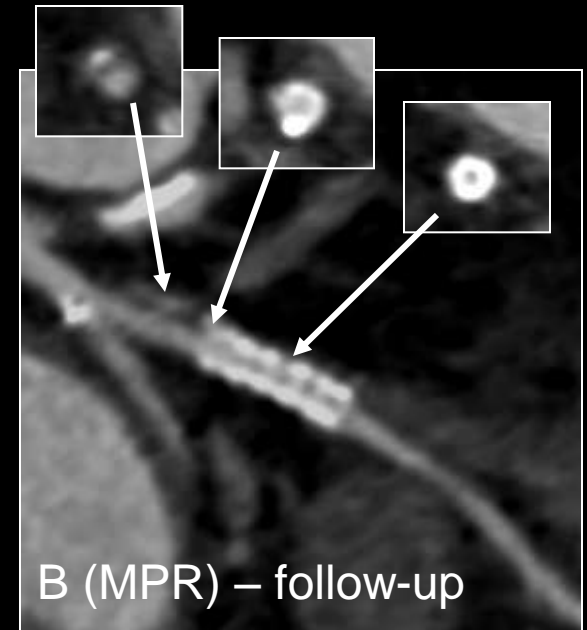
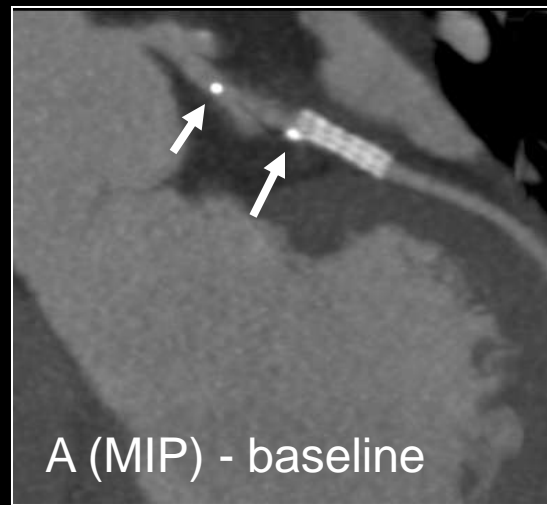
# 5-Year Follow-up OCT of ABSORB A



# Metal vs Bioresorbable scaffold by MSCCT

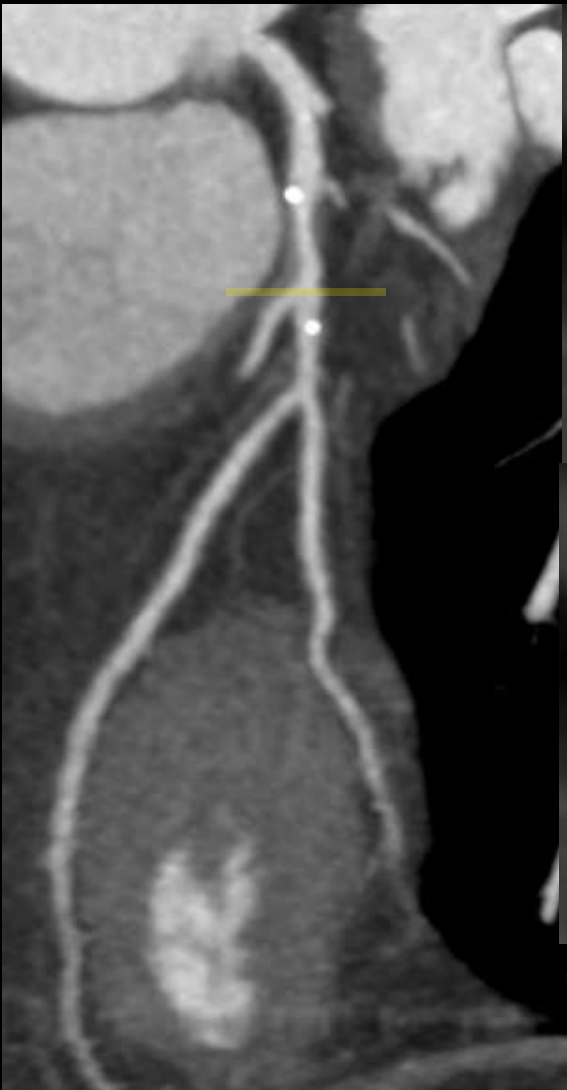
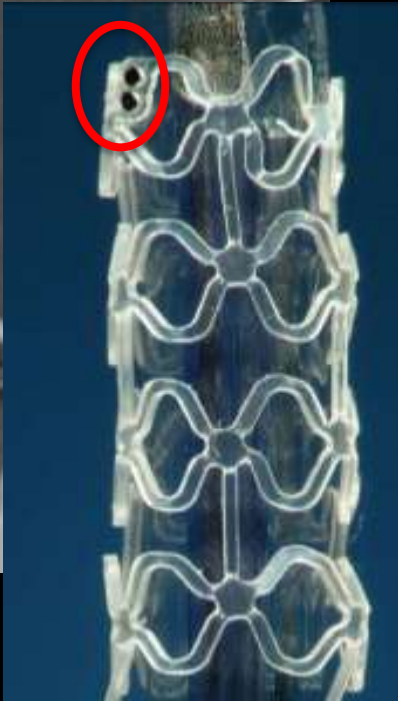
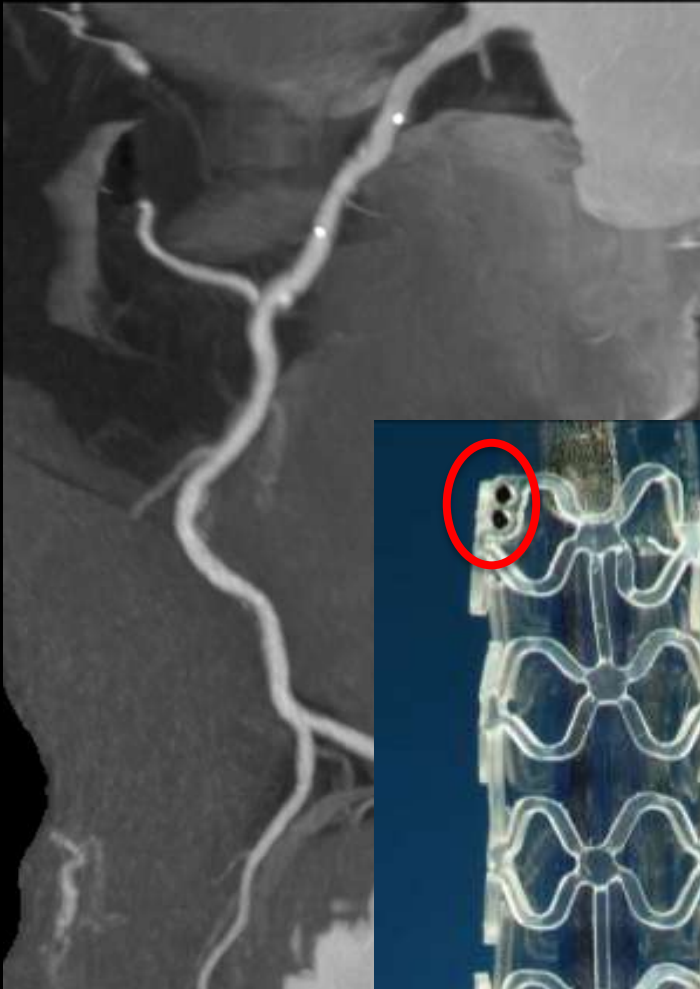


\*marker



- Absorbable and metal stent implantation (bail-out)
- Highly attenuating distal metal stent well visible
- Only prox./dist. markers absorbable stent detectable
- In-stent plaque remains visible

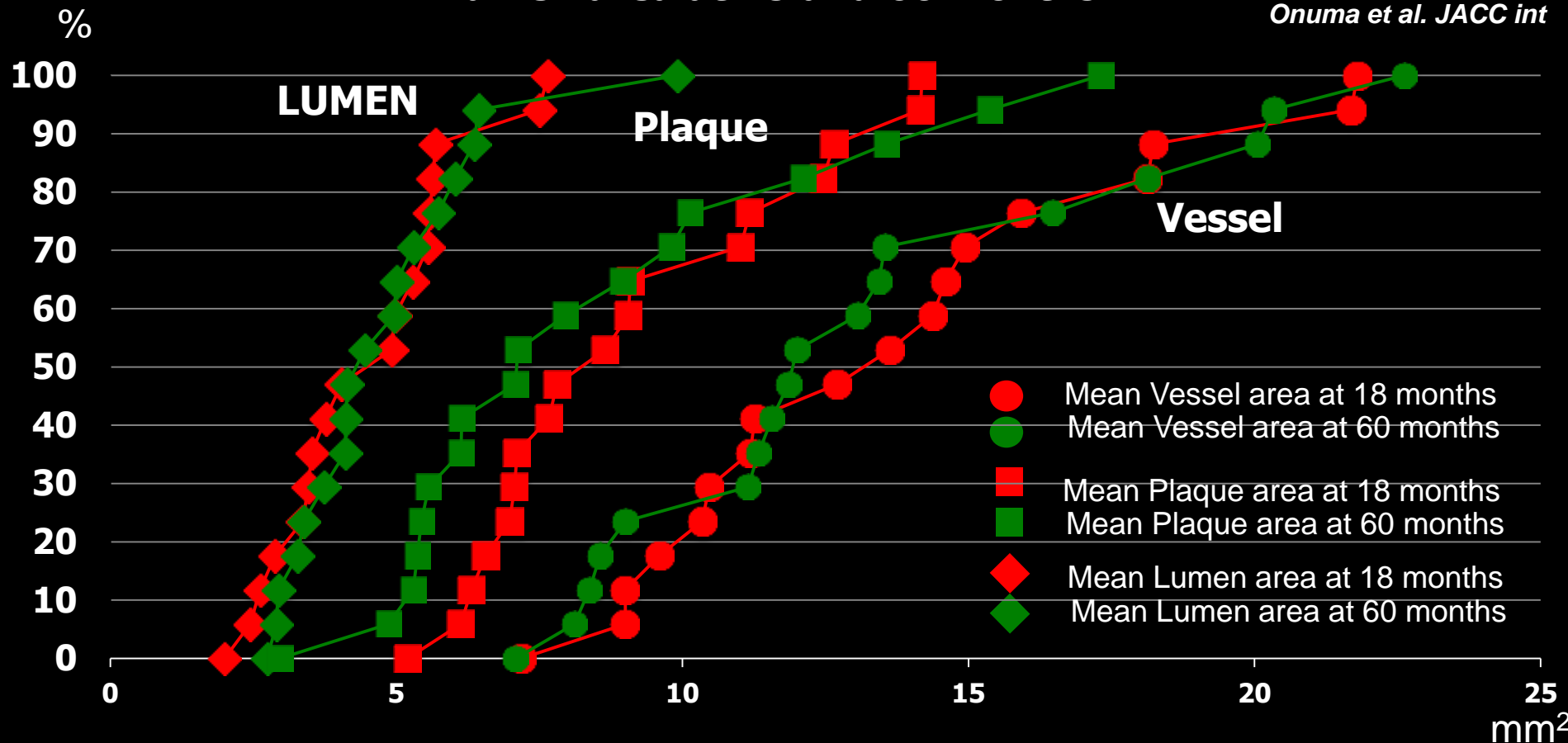
# Quantitative Assessment of MSCT





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

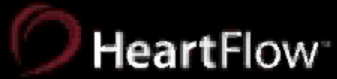
*Onuma et al. JACC int*



- Mean Vessel area at 18 months
- Mean Vessel area at 60 months
- Mean Plaque area at 18 months
- Mean Plaque area at 60 months
- ◆ Mean Lumen area at 18 months
- ◆ Mean Lumen area at 60 months

| Scaffolded segment (Median values)  | 18 months (n=18) |   | 5 year (n=18) | p    |
|-------------------------------------|------------------|---|---------------|------|
| Minimum Lumen area, mm <sup>2</sup> | 3.10             | = | 3.25          | 0.21 |
| Mean lumen area, mm <sup>2</sup>    | 4.47             | = | 4.29          | 0.11 |
| Mean vessel area, mm <sup>2</sup>   | 13.17            | ↘ | 11.93         | 0.26 |
| Mean plaque area, mm <sup>2</sup>   | 8.23             | ↘ | 7.10          | 0.23 |

# How we do it: MSCT- noninvasive FFR

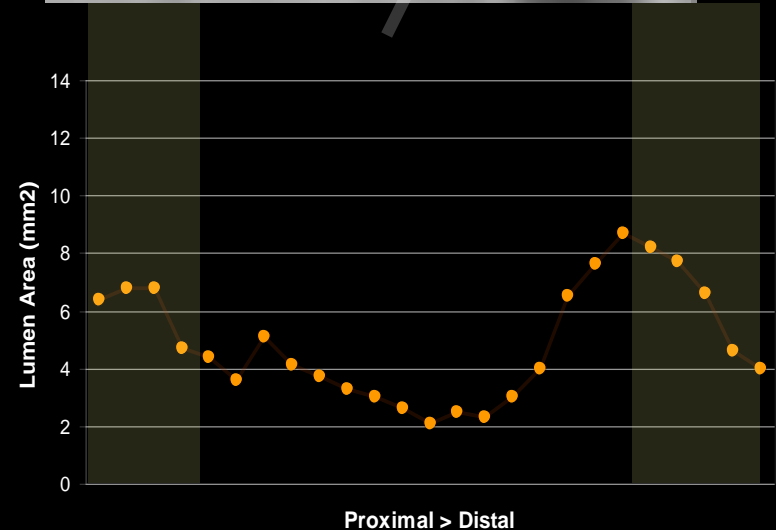


## Overview of the $FFR_{CT}$ Process

# Why we do it: MSCT- noninvasive FFR

## Moderate restenosis

Onuma et al. JACC interv 2013



**Why** we do it: MSCT- noninvasive FFR

# Moderate restenosis

Onuma et al. JACC interv 2013

HeartFlow



simulation

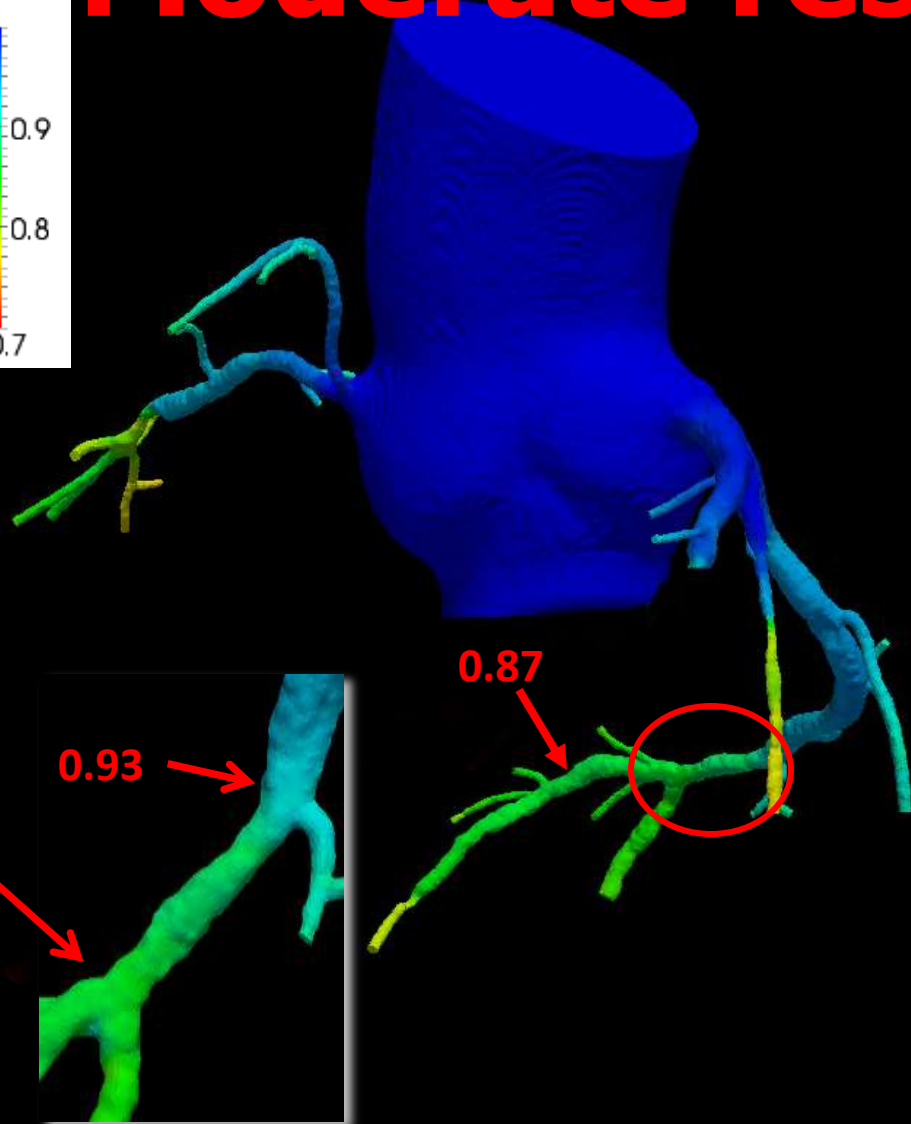
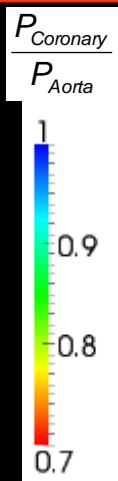
HeartFlow



simulation

# Why we do it: MSCT- noninvasive FFR

## Moderate restenosis



**Non-invasive FFR could further improve the interpretation of quantitative MSCT results.**

# ABSORB cohort B

## Group B1 ( $n = 45$ )

QCA, IVUS, OCT, IVUS VH

QCA, IVUS,  
OCT, IVUS VH

Baseline

6  
Months

12  
Months

18  
Months

24  
Months

36  
Months

MSCT

## Group B2 ( $n = 56$ )

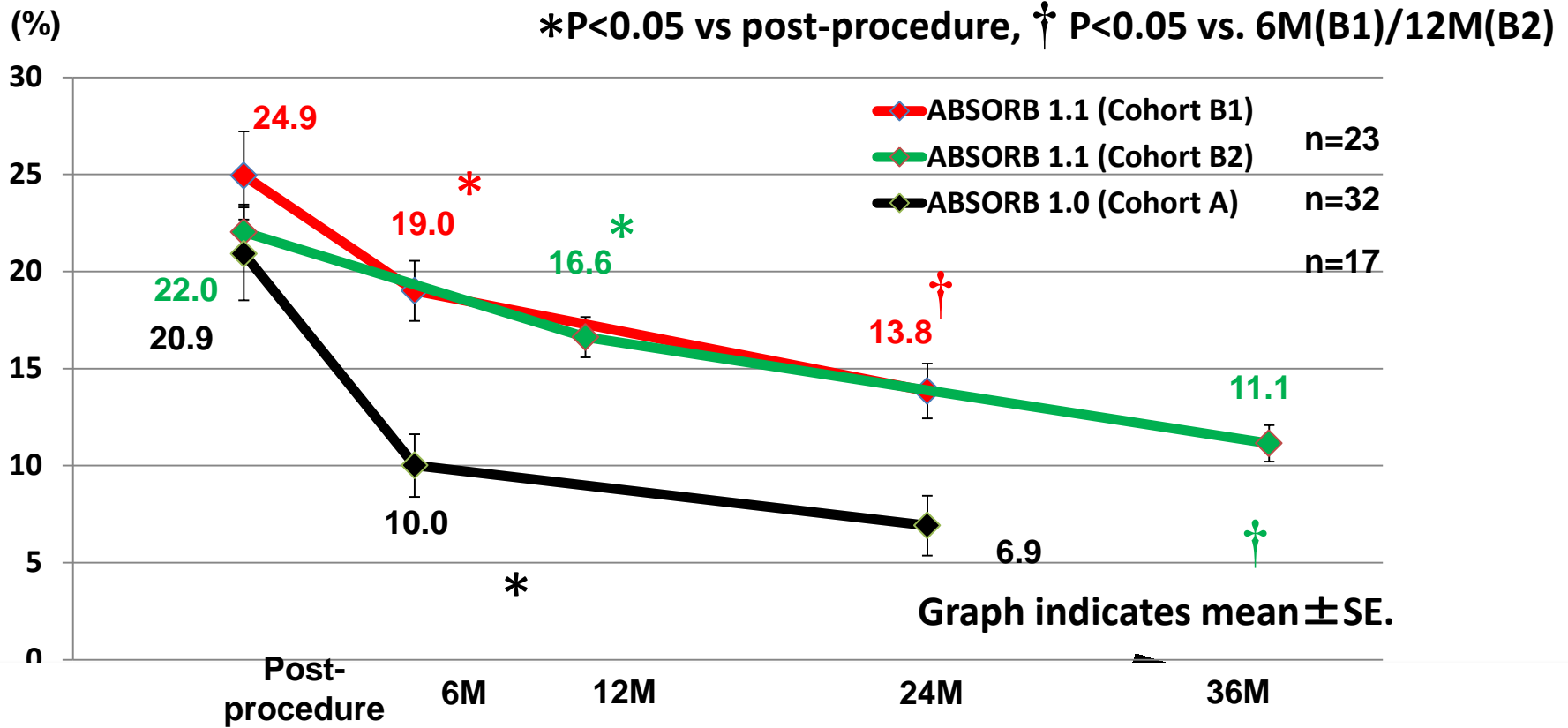
QCA, IVUS, OCT, IVUS VH

MSCT

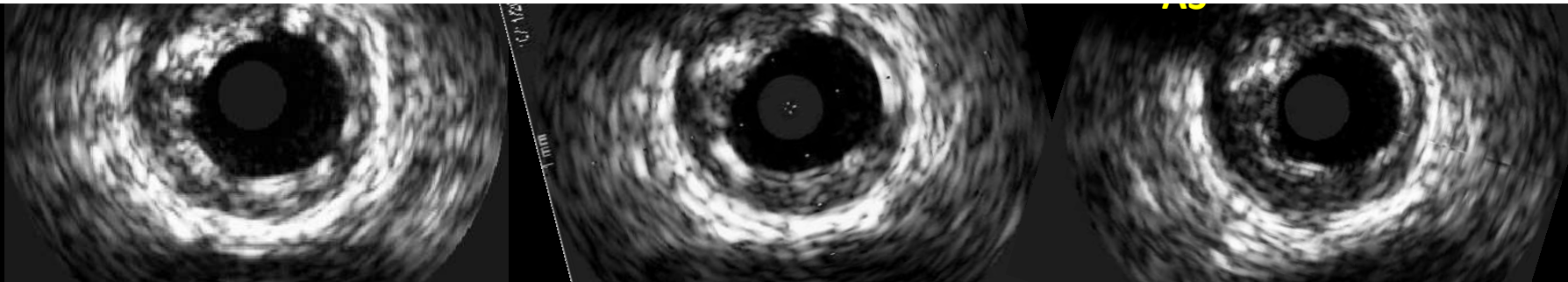
- Sponsor/ Funding: Abbott Vascular
- Primary Investigators:
  - PW Serruys MD, PhD
  - J Ormiston MD
- DSMB: J Tijssen PhD, M Wiemer MD, P Urban MD
- CEC: C Hanet MD, R Tölg MD, V Umans MD
- Angiographic, IVUS and OCT Corelab: Cardialysis
- Prospective, open label, FIM
- 3.0 x 18mm devices to treat up to 2 lesions  $\leq$  14mm in length

- 12 sites Europe, Australia, New Zealand
- B de Bruyne, MD, PhD
- D Dudek, MD
- L Thuesen, MD
- P Smits, MD, PhD
- B Chevalier, MD
- D McClean, MD
- J Koolen, MD, PhD
- S Windecker, MD
- R Whitbourn, MD
- I Meredith, MD, PhD
- 101 patients enrolled between 19 March and 6 November 2009

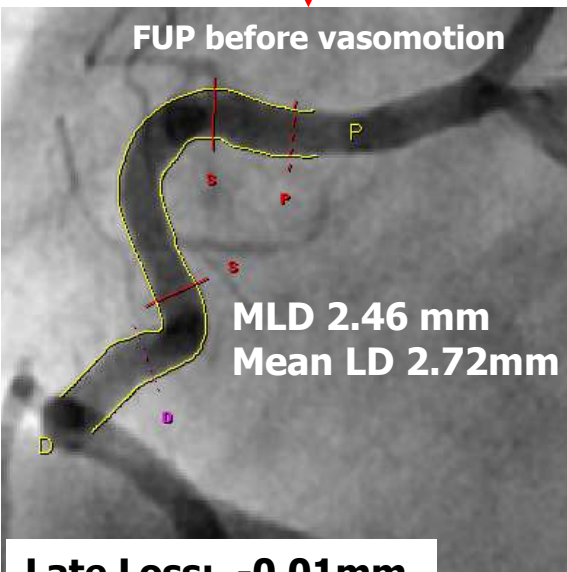
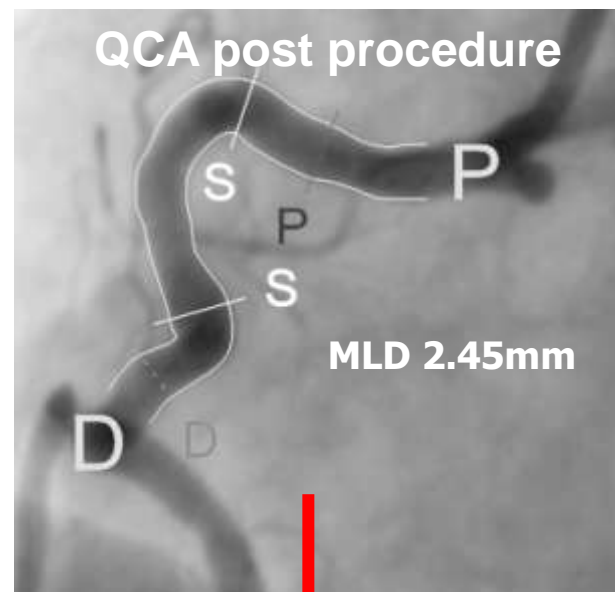
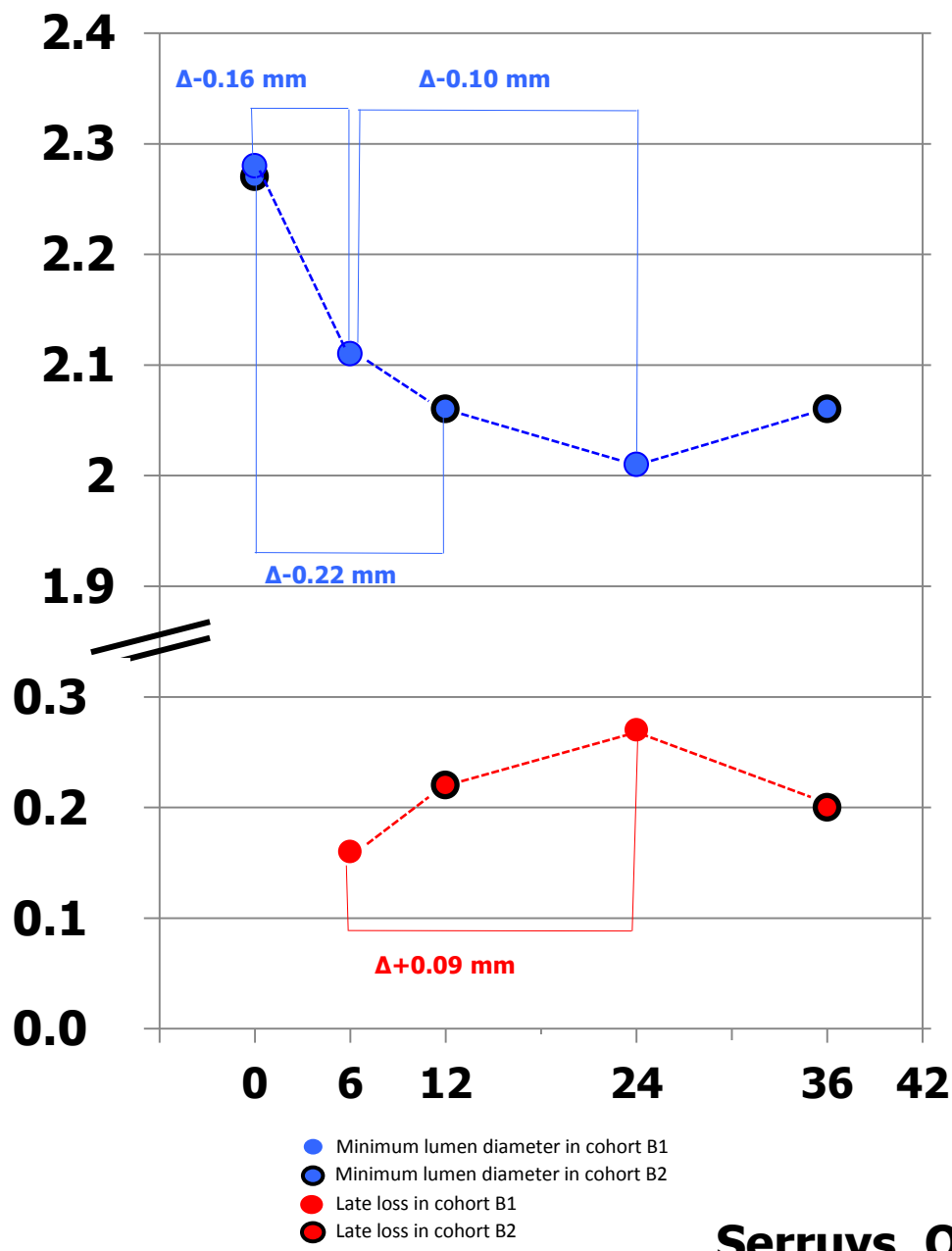
# True-serial changes in percentage hyper-echogenic area



The actual duration of resorption of the second generation is in vivo approximately **18 months longer** than the first generation, and the mass loss of 2<sup>nd</sup> generation ABSORB scaffold takes approximately 36 months



**A** Serial QCA without TLR cases

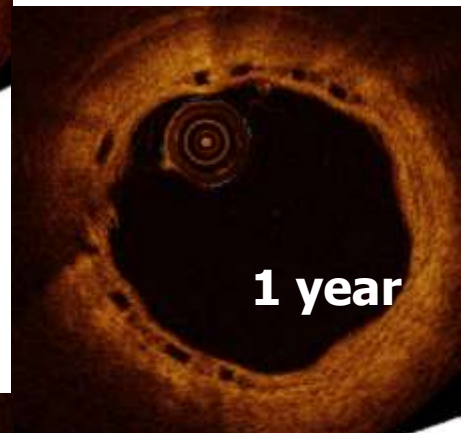
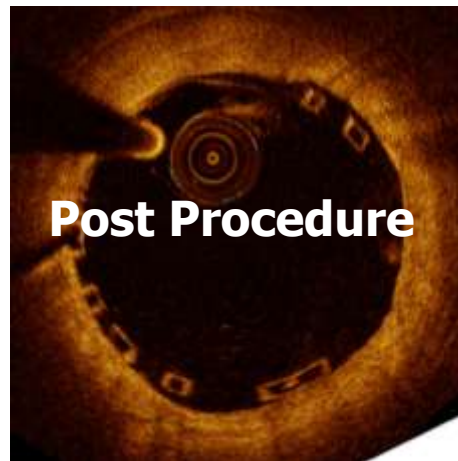
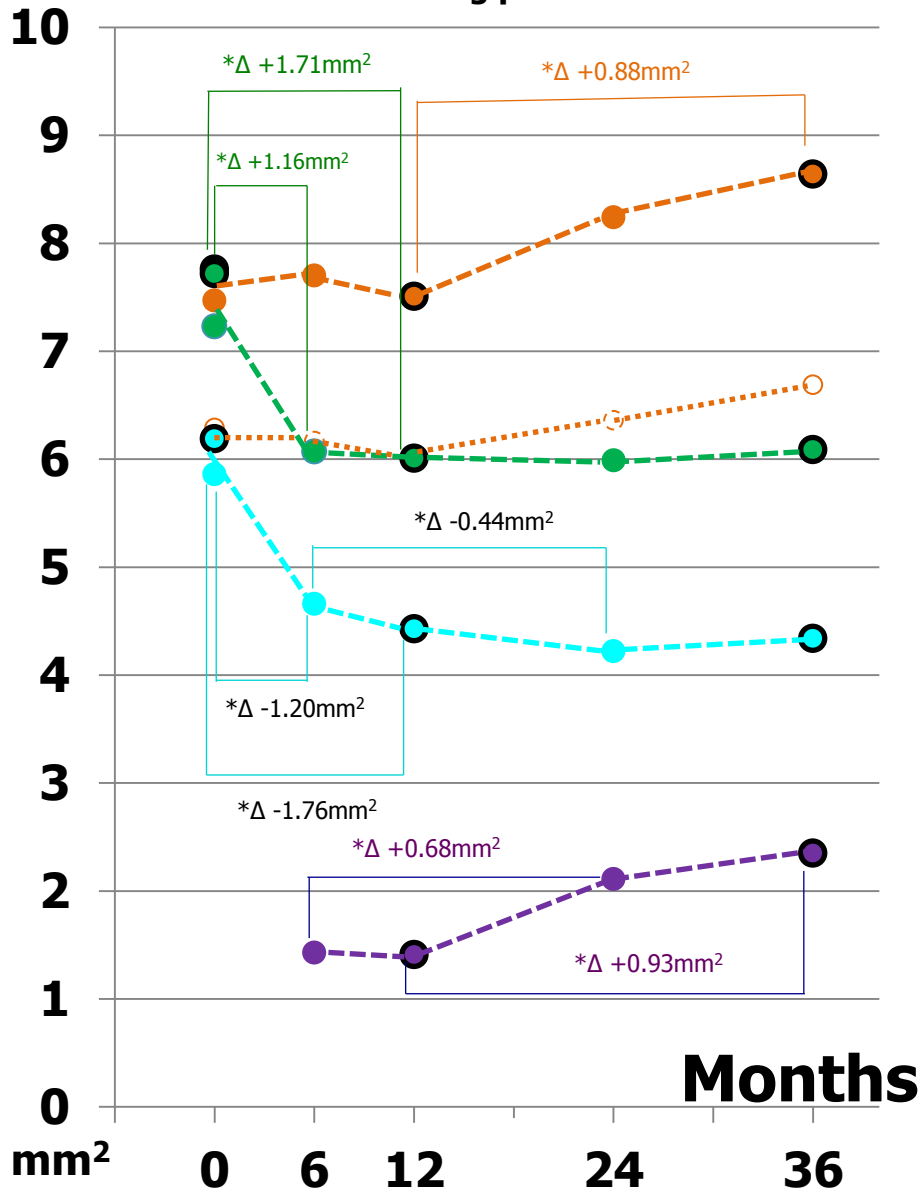


Late Loss: -0.01mm



# Serial OCT

OCT including pre TLR measurement

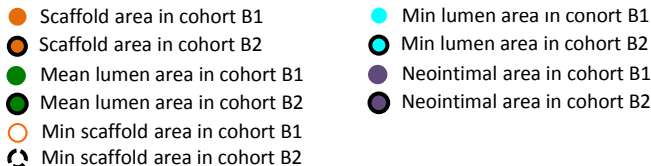
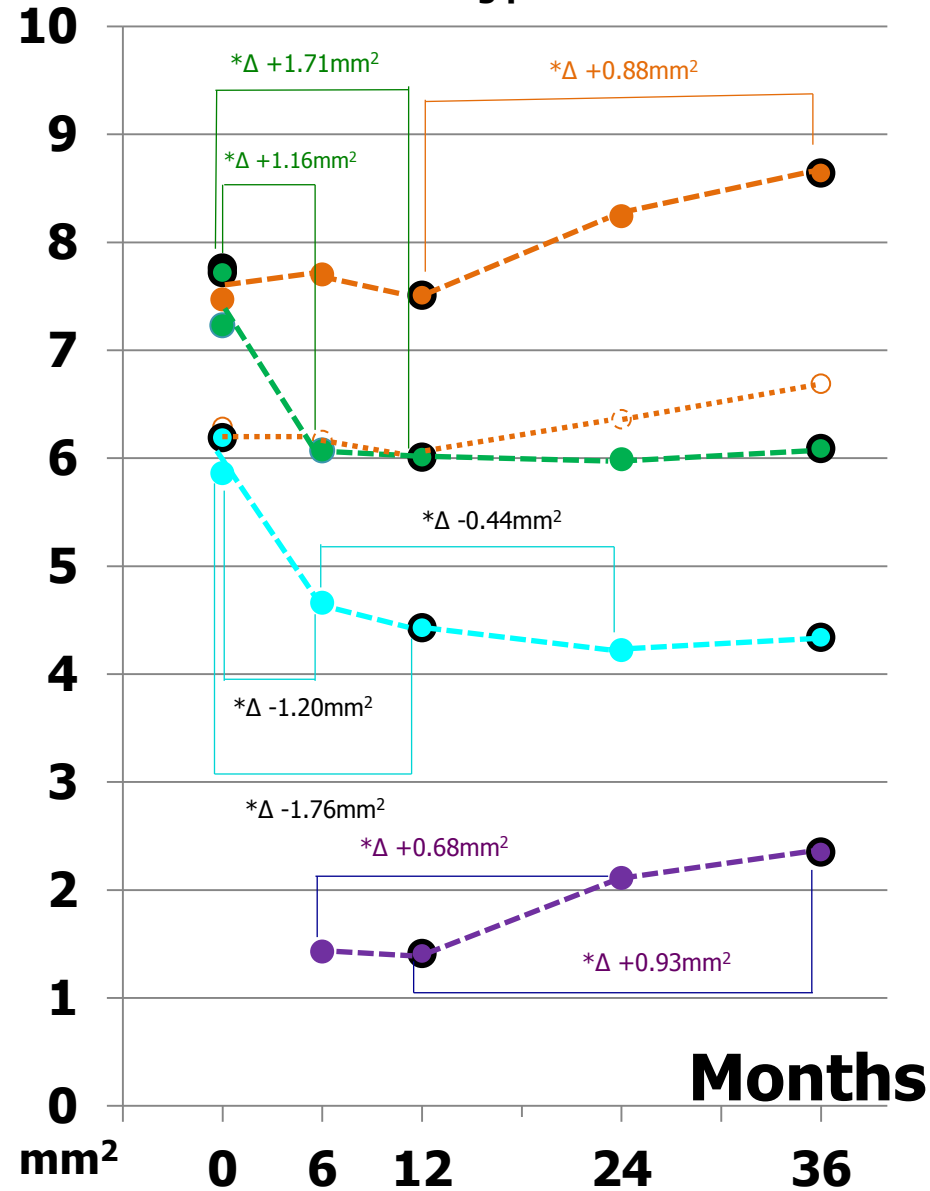


- Scaffold area in cohort B1
- Scaffold area in cohort B2
- Mean lumen area in cohort B1
- Mean lumen area in cohort B2
- Min scaffold area in cohort B1
- Min scaffold area in cohort B2
- Min lumen area in cohort B1
- Min lumen area in cohort B2
- Neointimal area in cohort B1
- Neointimal area in cohort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

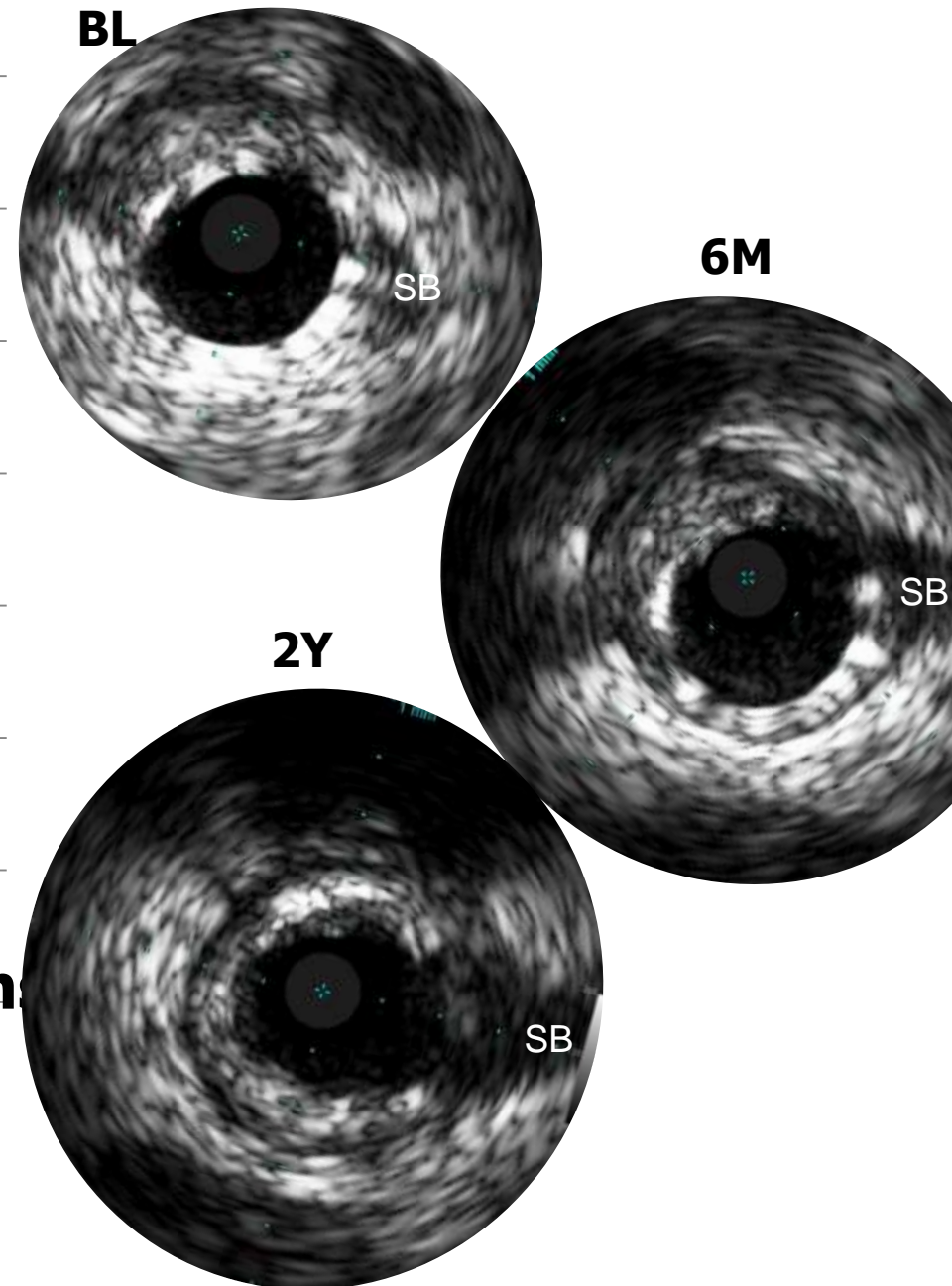
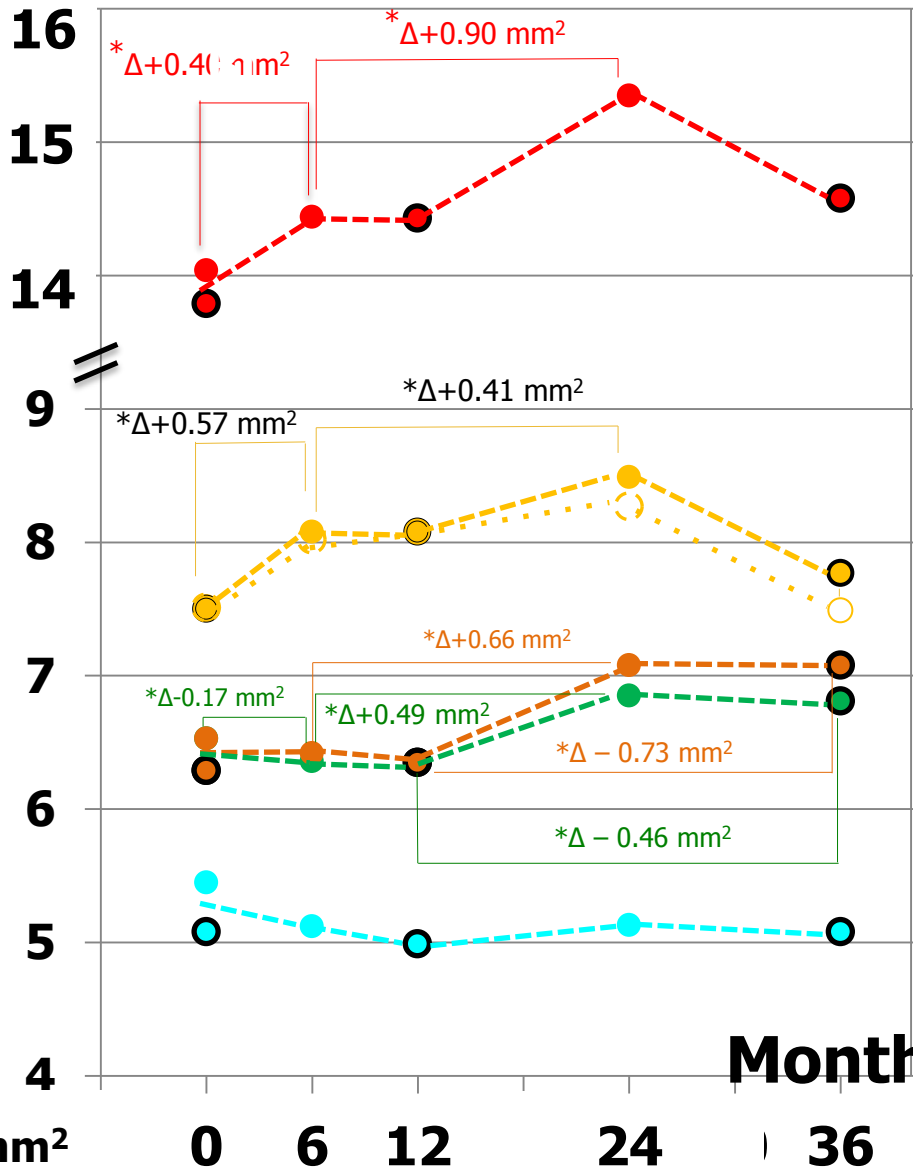
# Serial OCT

- The **mean and minimum scaffold area's** significantly increase between 1 and 3 years and compensate for the increase in **neointimal hyperplasia**
- As a consequence, **mean lumen area** and **minimal lumen area** remained unchanged between 1 year to 3 years.

OCT including pre TLR measurement

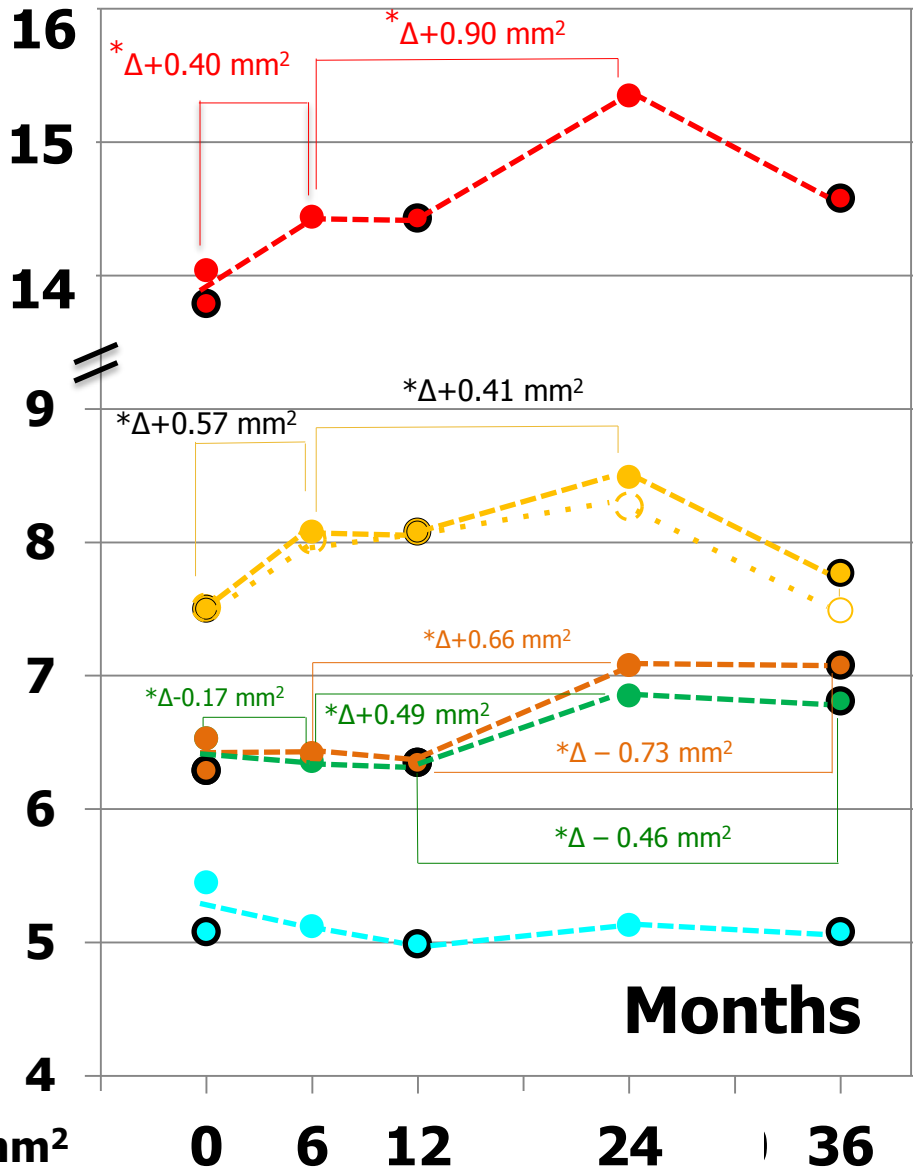


# Serial IVUS

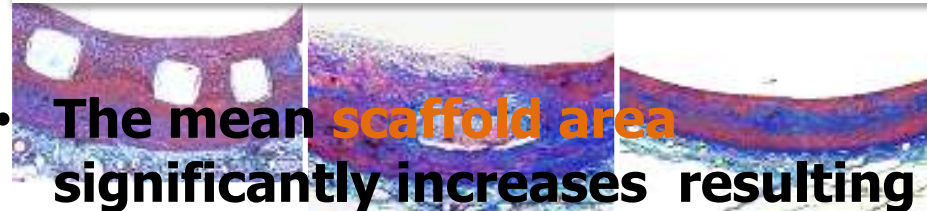


- Vessel area in cohort B1
- Vessel area in cohort B2
- Total plaque area in cohort B1
- Total plaque area in cohort B2
- Plaque behind scaffold in cohort B1
- Plaque behind scaffold in cohort B2
- Scaffold area in cohort B1
- Scaffold area in cohort B2
- Mean lumen area in cohort B1
- Mean lumen area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

# Serial IVUS



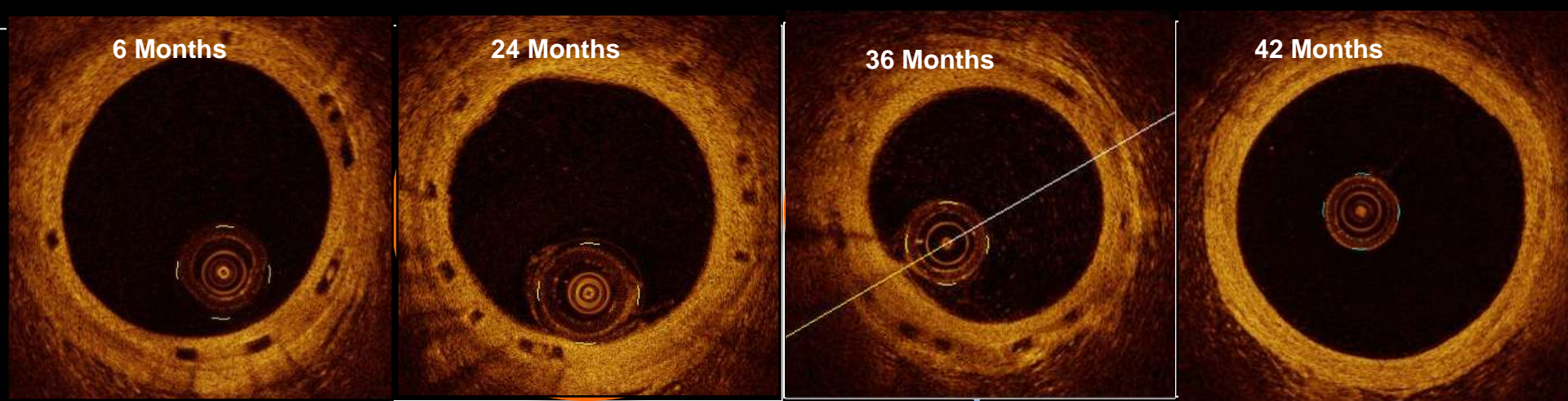
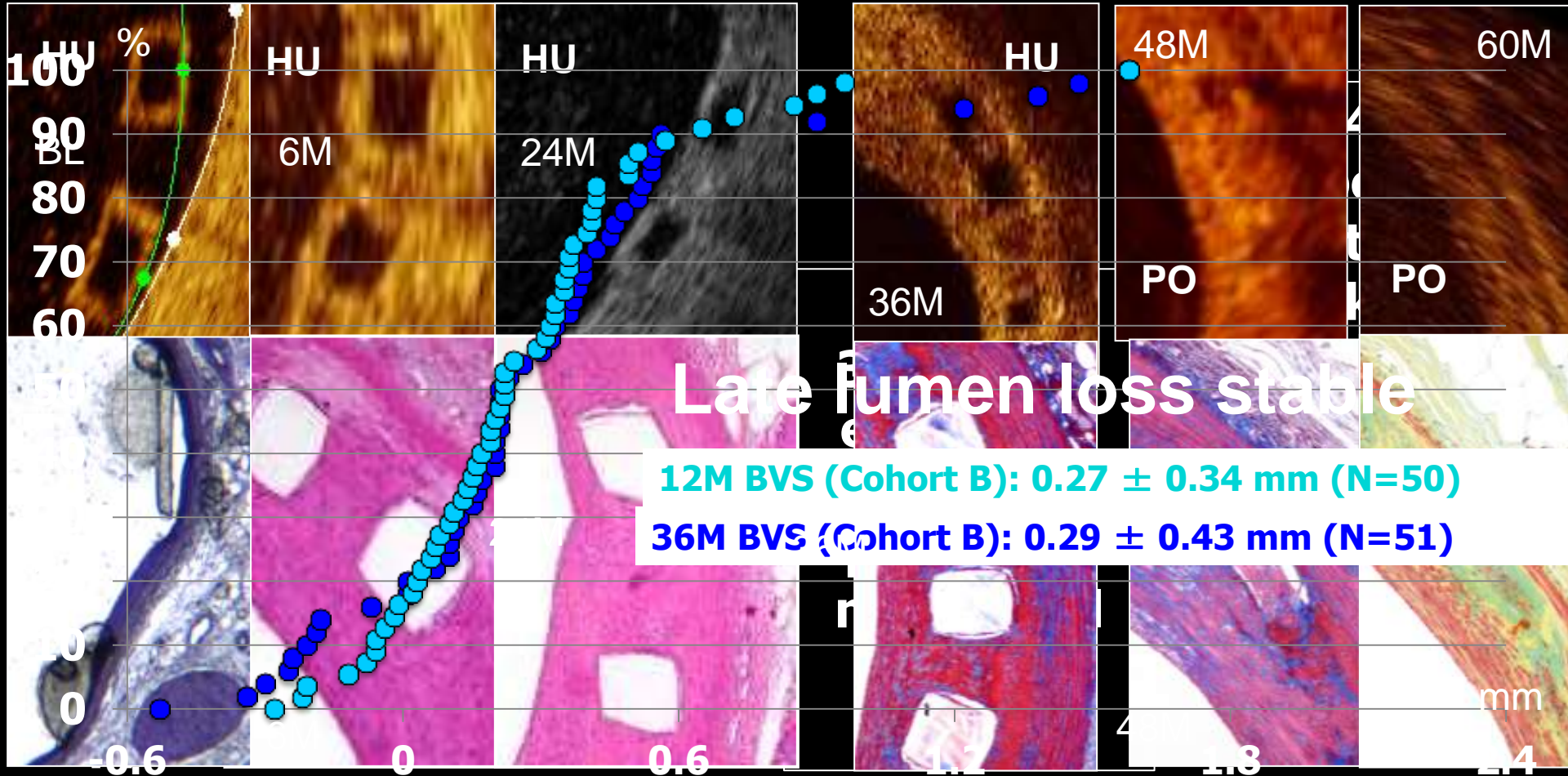
- The **Vessel area** and **total plaque/media area** show biphasic changes with an increase between BL and the second year and a **plaque/Media /Vessel area** reduction between the second and third FUP.



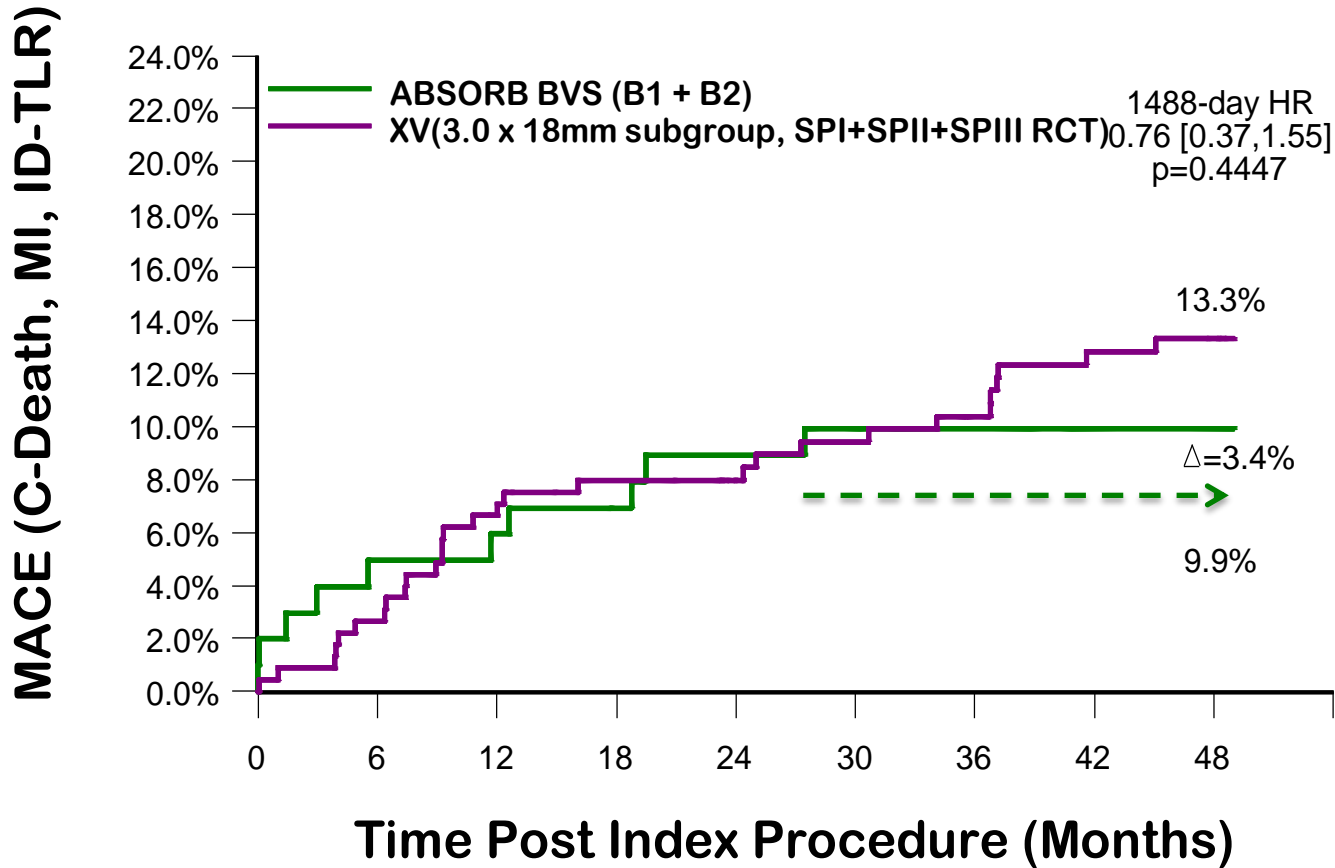
- The mean **scaffold area** significantly increases resulting in an increase of **mean lumen area** from 1 to 3 years with an unchanged **minimal lumen area** from 1 year to 3 years.

The next cartoon summarizes the evolution

- 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



# KM Estimate of MACE Rate in Patients Treated with Absorb vs Patients Treated with a Single 3.0x18mm Metallic XIENCE V



|   | Time After Index Procedure (days) |     |     |     |     |     |     |      |      |
|---|-----------------------------------|-----|-----|-----|-----|-----|-----|------|------|
|   | 0                                 | 37  | 194 | 284 | 393 | 573 | 758 | 1123 | 1488 |
| ABSORB BVS (B1 + B2) At Risk                        | 101                               | 99  | 96  | 96  | 94  | 92  | 91  | 88   | 86   |
| XV(3.0 x 18mm subgroup, SPI+SPII+SPIII RCT) At Risk | 227                               | 224 | 219 | 211 | 204 | 202 | 191 | 182  | 174  |

P-values are not from formal hypotheses testing and are displayed for exploratory purposes only

# Conclusion

**In cohort A, serial imaging at 6M, 24M and 60M showed:**

- **Serial non-invasive MSCT is feasible with an option of functional assessment**
- **Golden tube: Homogeneous light reflectivity on OCT, Capping of the underlying plaque, Late lumen enlargement, plaque reduction and Vasomotion**

**In cohort B, imaging at 3 years showed:**

- **Advanced bioresorption of the polymeric device (IVUS echogenicity/VH)**
- **Unchanged angiographic late luminal loss between 1 and 3 years (Binary Reste: 6%)**
- **Increase of the mean and minimum scaffold area, compensating for the increase in neointimal hyperplasia (IVUS and OCT)**
- **Increase of mean lumen area from 1 to 3 years (IVUS)**
- **The total plaque area shows a biphasic change with an increase between 1 and 2 years (IVUS) and decrease between the 2<sup>nd</sup> and 3<sup>rd</sup> year follow-up (IVUS)**