

# **ABSORB BVS scaffold: The disappearing scaffold is already here!**

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

**on behalf of the ABSORB investigators**

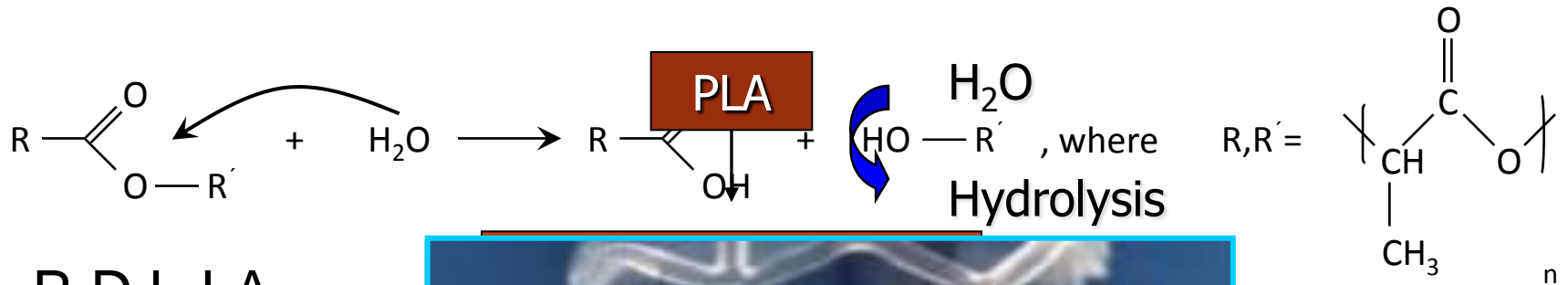
**Erasmus MC, the Netherlands**

**TCT-AP**

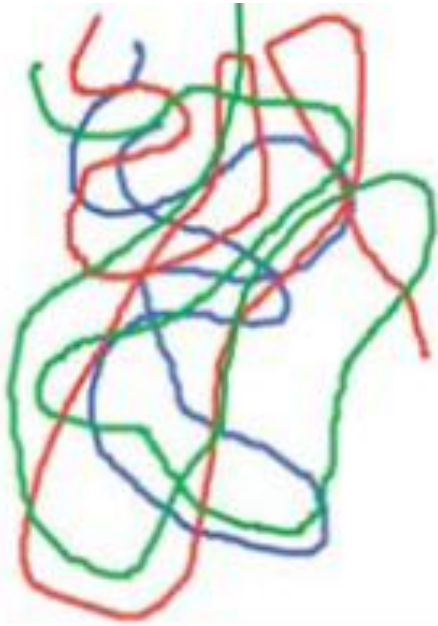
Company	Stent	Development	Pre-clinical	Clinical trials	Post-market
<b>Kyoto Medical</b>	<b>Igaki-Tamai</b>	✓	✓	✓	
<b>Biotronik</b>	<b>Dreams</b>	✓	✓	✓	
<b>Abbott</b>	<b>Absorb</b>	✓	✓	✓	✓
<b>Art</b>	<b>Art18AZ</b>	✓	✓	✓	
<b>Reva Medical</b>	<b>Resolve</b>	✓	✓	✓	
<b>Xenogenics</b>	<b>Ideal biostent</b>	✓	✓		
<b>Orbus Neich</b>	<b>Acute</b>	✓	✓		
<b>Elixir</b>	<b>DESolve</b>	✓	✓	✓	
<b>Amaranth</b>	<b>Amaranth PLLA</b>	✓	✓		
<b>Huaan Biotech</b>	<b>Xinsorb</b>	✓	✓	✓	
<b>S3V</b>	<b>Avatar</b>	✓	✓		
<b>Meril</b>	<b>MeRes</b>	✓	✓		
<b>Zorion Medical</b>	<b>Zorion BRS</b>	✓	✓		
<b>Lifetech</b>	<b>Lifetech Iron</b>	✓	✓		

# Polylactide Degradation Mechanism

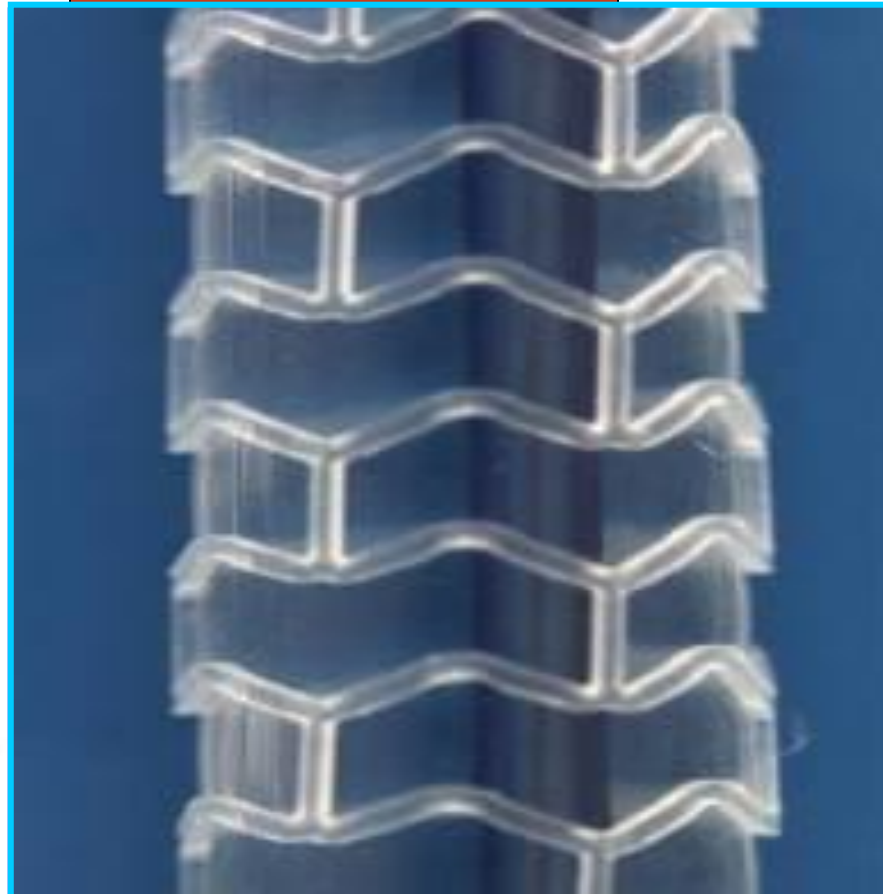
Hydrolysis via Random Chain Scission of Ester Bonds



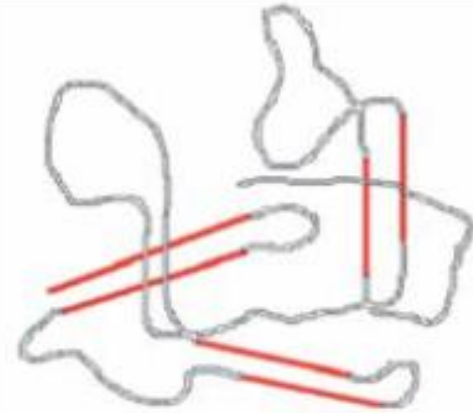
P-D,L-LA



Amorphous

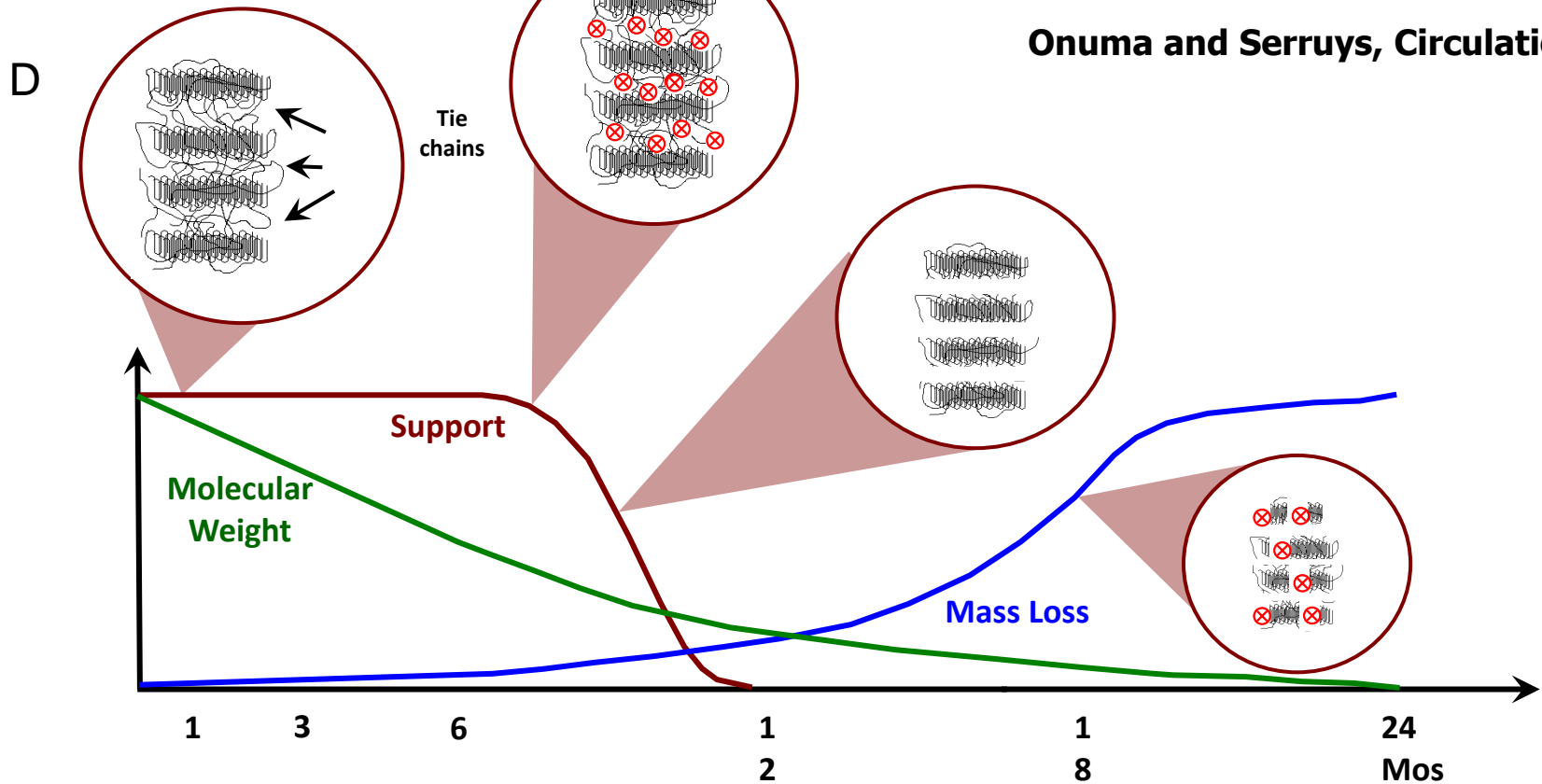
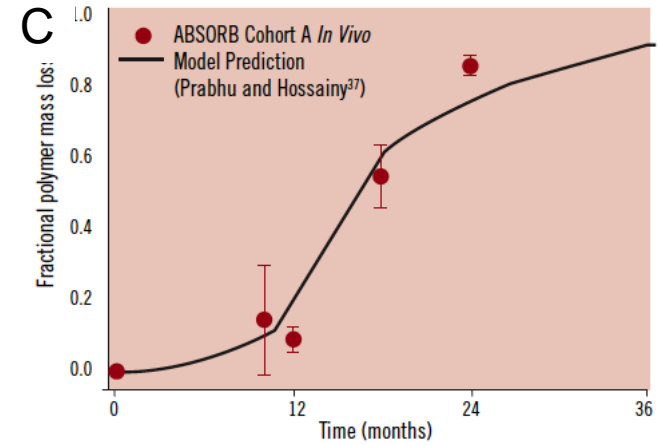
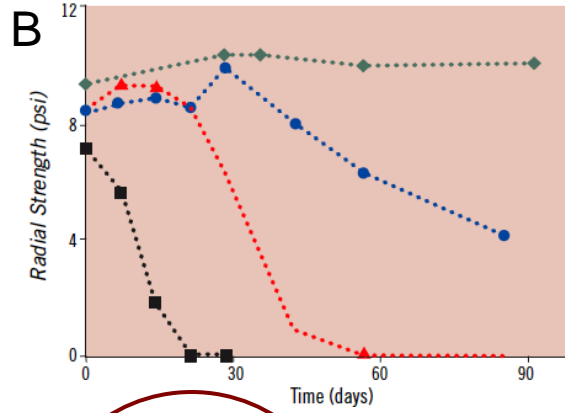
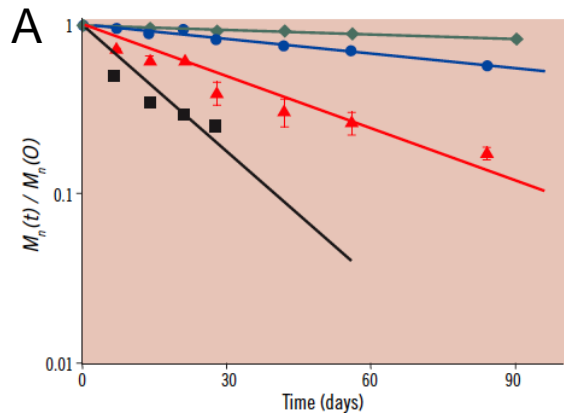


P-L,L-LA



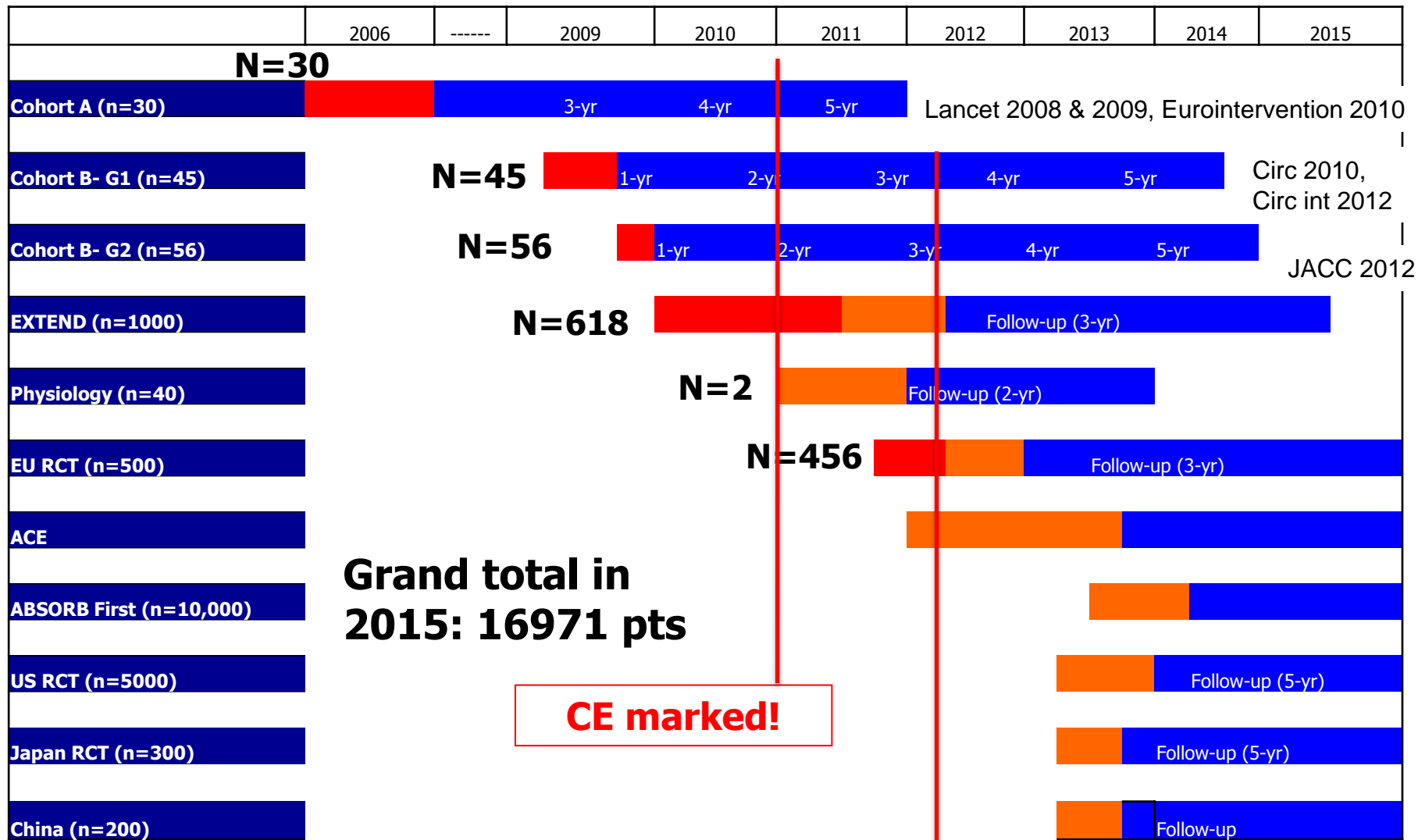
Semicrystalline

# #1. The PLLA fully disappears after 2 years, while the mechanical integrity lasts for 6 months



Onuma and Serruys, *Circulation* 2011

# Overview of ABSORB studies



**Grand total in 2015: 16971 pts**

**CE marked!**

**Commercially available**

Follow-up

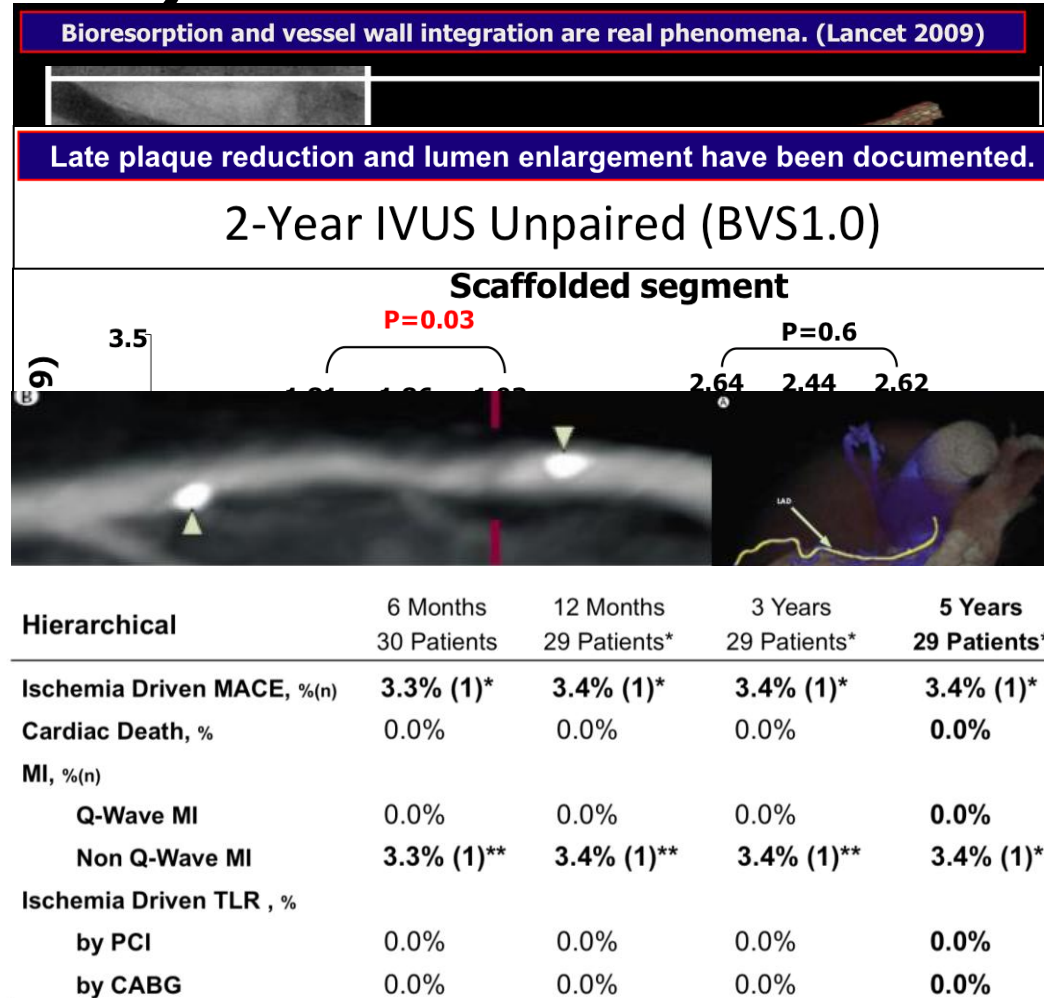
Enrolled

To be Enrolled

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

# What did we learn from ABSORB cohort A (2006-)?

- 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



**No new MACE events between 6 months and 5 years**  
**No stent thrombosis up to 5 years (All patients off clopidogrel)**

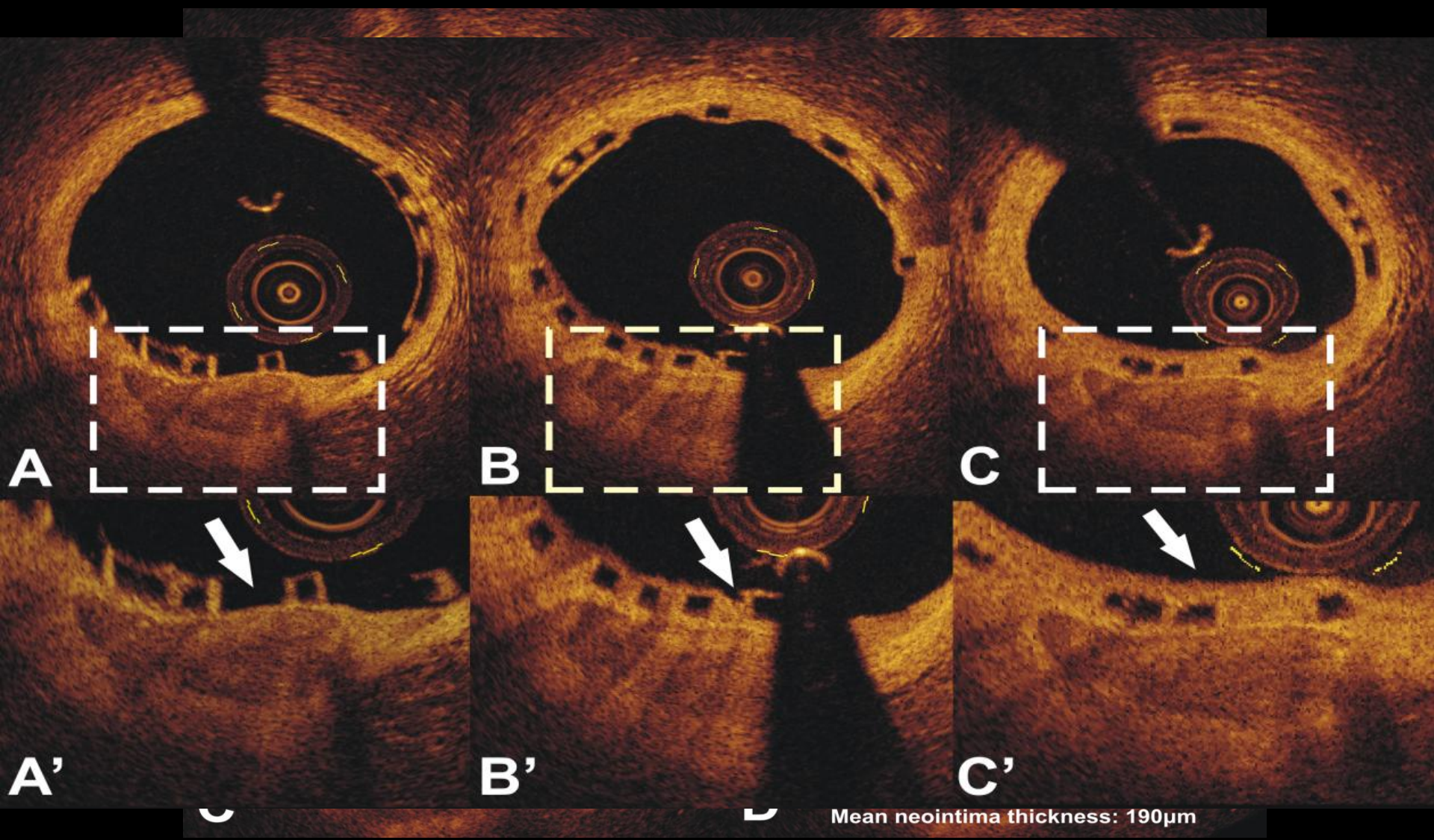
\*One patient withdrew consent after 6 months but the vital status of the patients and absence of cardiac event is known through the referring physician.

\*\*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 Hodgkin's disease at 888 days post-procedure.

**#What did we learn from cohort A and early FUP of cohort B?**

**Shielding of plaque**

**#9. Sealing and shielding of plaques as a result of scaffold implantation : can the scaffold cap the plaque?**



Serial OCT examinations in 20 patients

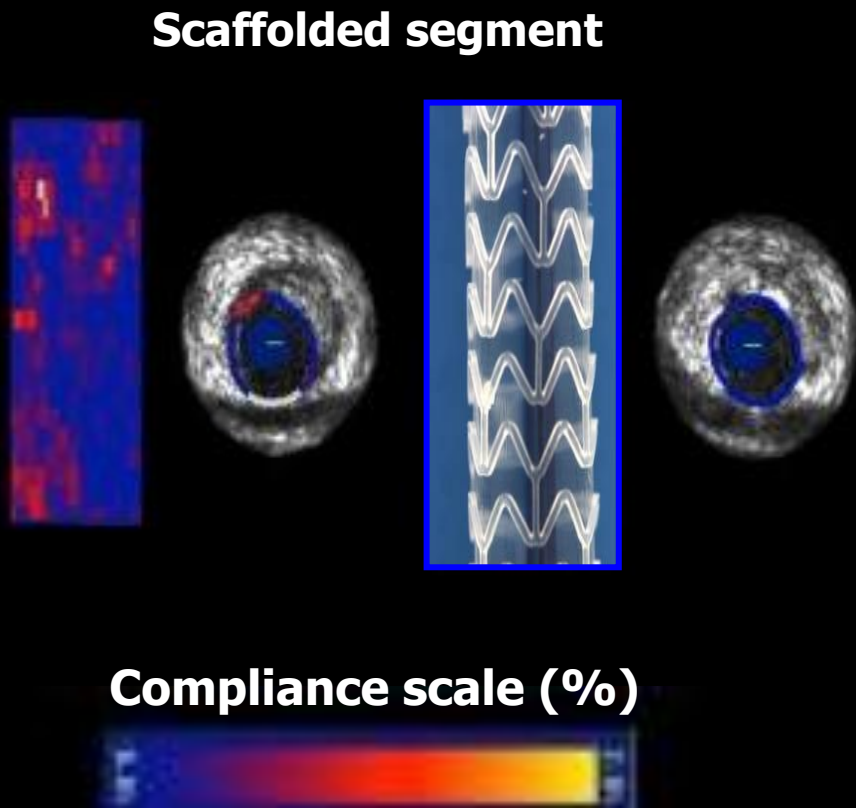


**#What did we learn from cohort A and early FUP of cohort B?**

# **Return of cyclic strain and mechano- transduction**

# ● #6. . Reappearance of physiological (cyclic) strain after bioresorption

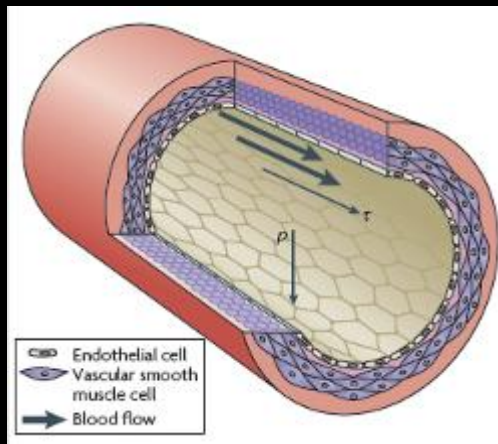
## Pre, Post, 6 and 24 months after bioresorbable scaffolding



# ● #7. Impact of physiological cyclic strain and shear stress essential for the vessel wall biology

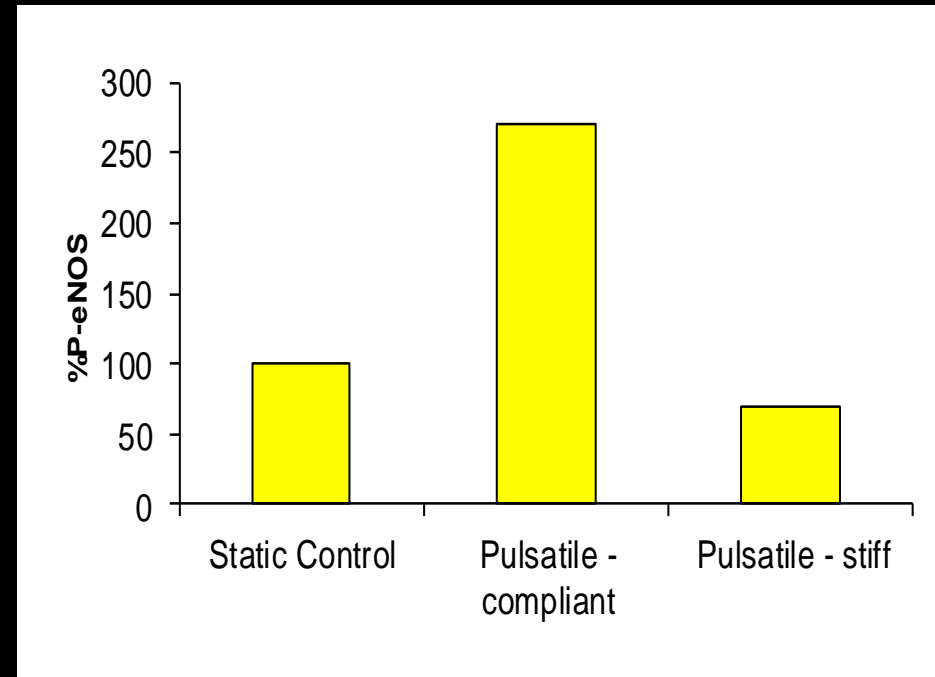
The translation of mechanical forces into chemical signals by cells is referred to as 'mechanotransduction'

Mechanical forces on the vessel wall



$\tau$  Shear Stress  $\rho$  Pressure

Hahn C and Schwartz M. *Nat Rev: Molec Cell Biol.* 2009;10:53-62.



↑↑Others

Normal responses to physiologic pulsatile cyclic strain and shear stress lead to cellular responses that stabilize the vessel

Gupta V and Grande-Allen K. *Cardiovasc Res.* 2006;72:375-383.

**#What did we learn from cohort A and early FUP of cohort B?**

## **Shielding of plaque at 2 and 5 years**

**“Golden tube”**

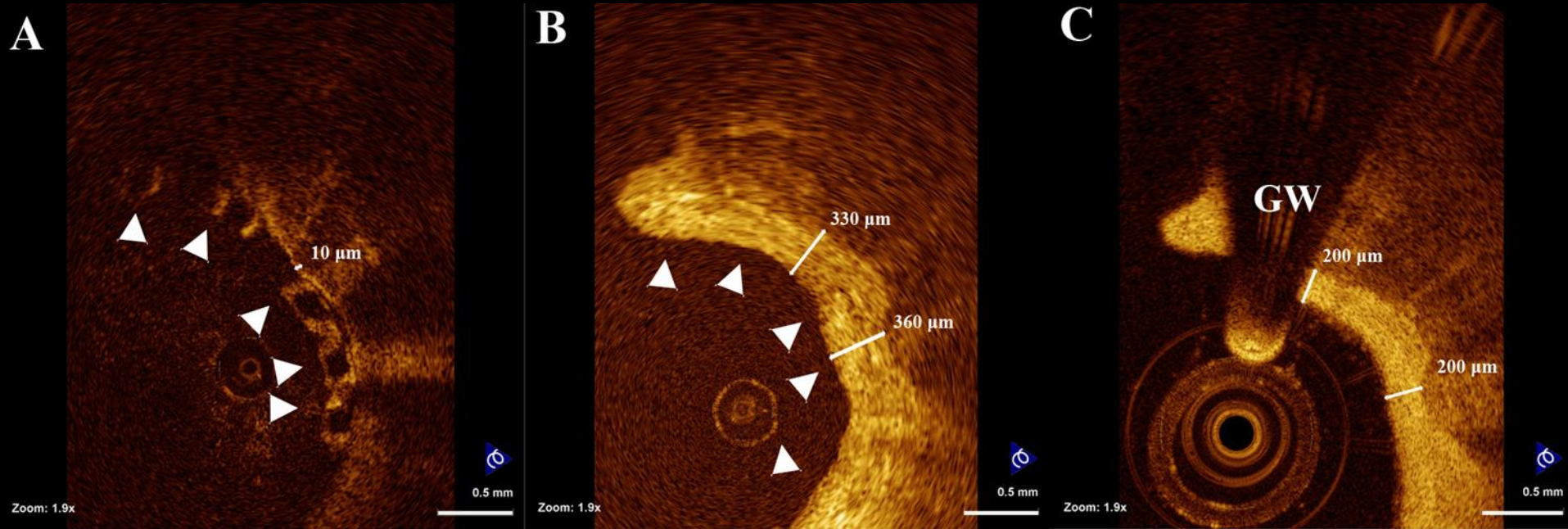
**(= late lumen enlargement on  
OCT + with homogeneous  
reflectivity of the light by the  
endoluminal lining + vasomotion)**

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

## Baselines

## 6 months

## 60 months



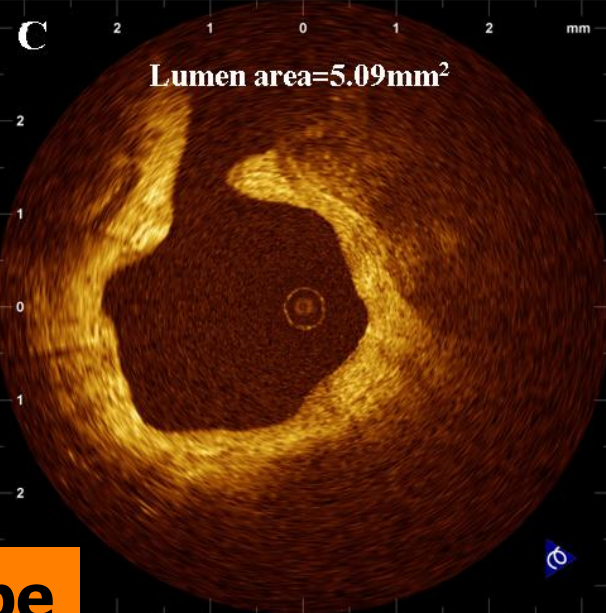
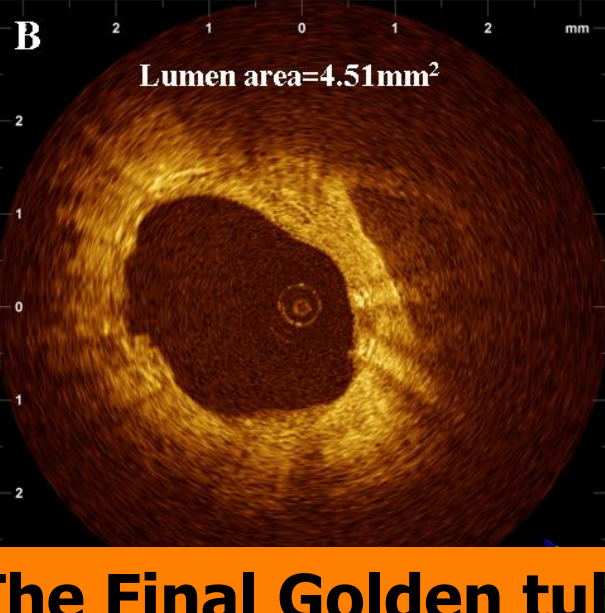
## Images in Cardiovascular Medicine

### Five-Year Optical Coherence Tomography Follow-Up of an Everolimus-Eluting Bioresorbable Vascular Scaffold Changing the Paradigm of Coronary Stenting?

Antonios Karanasos, MD; Cihan Simsek, MD; Patrick Serruys, MD, PhD; Jurgen Ligthart, BSc; Karen Witberg, CCRN; Robert-Jan van Geuns, MD, PhD; George Sianos, MD, PhD; Felix Zijlstra, MD, PhD; Evelyn Regar, MD, PhD

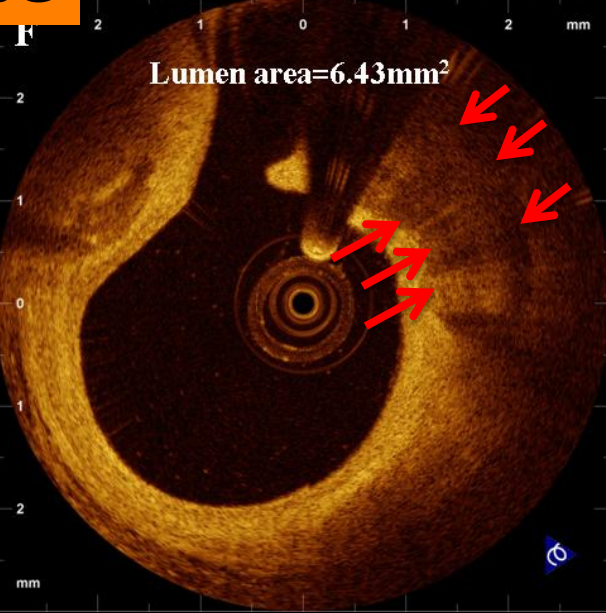
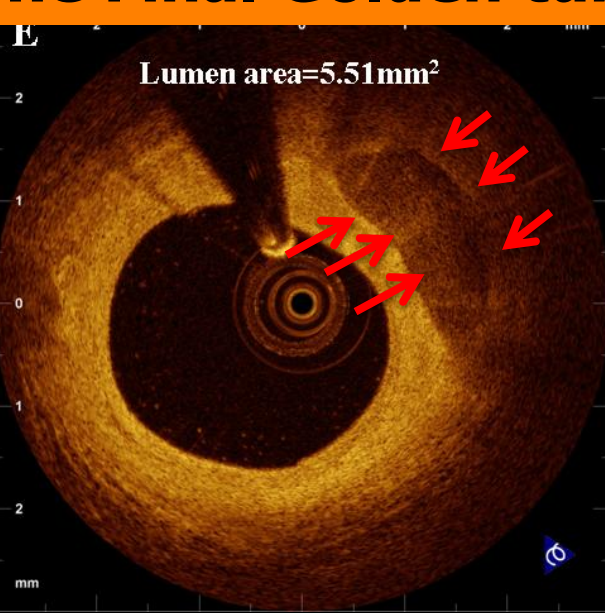
# Sealing and shielding of plaques as a result of scaffold implantation : can the scaffold cap the plaque... and late lumen enlargement !!!

6 months



**The Final Golden tube**

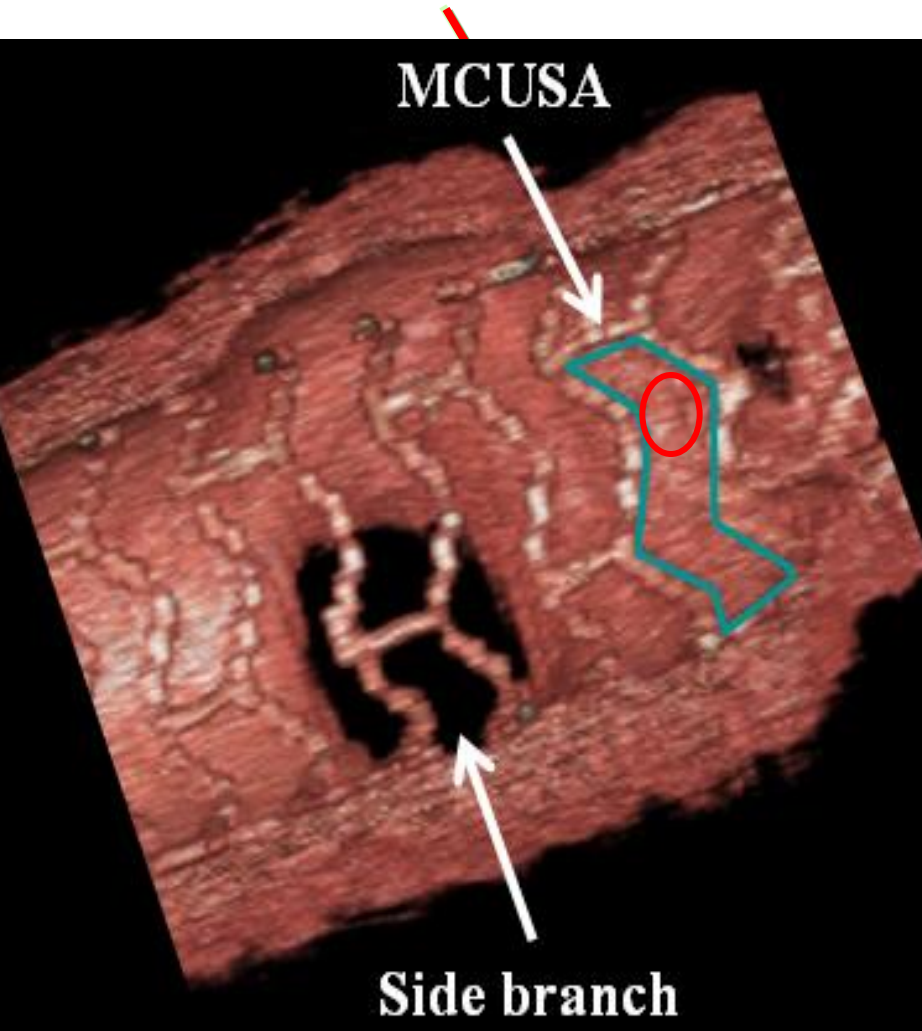
60 months



# **3-year imaging and clinical results of the ABSORB B**

# The second generation (BVS1.1) has a modified platform design and a different manufacturing process of the polymer.

Larger **Maximum Circular Unsupported scaffold area (MCUSA)**



## Revision 1.1 has

- More radial strength
- More uniform support and drug application
- Longer duration of support
  
- Profile less than Cypher
- Track test better than ML Vision
- No change in strut thickness



# 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

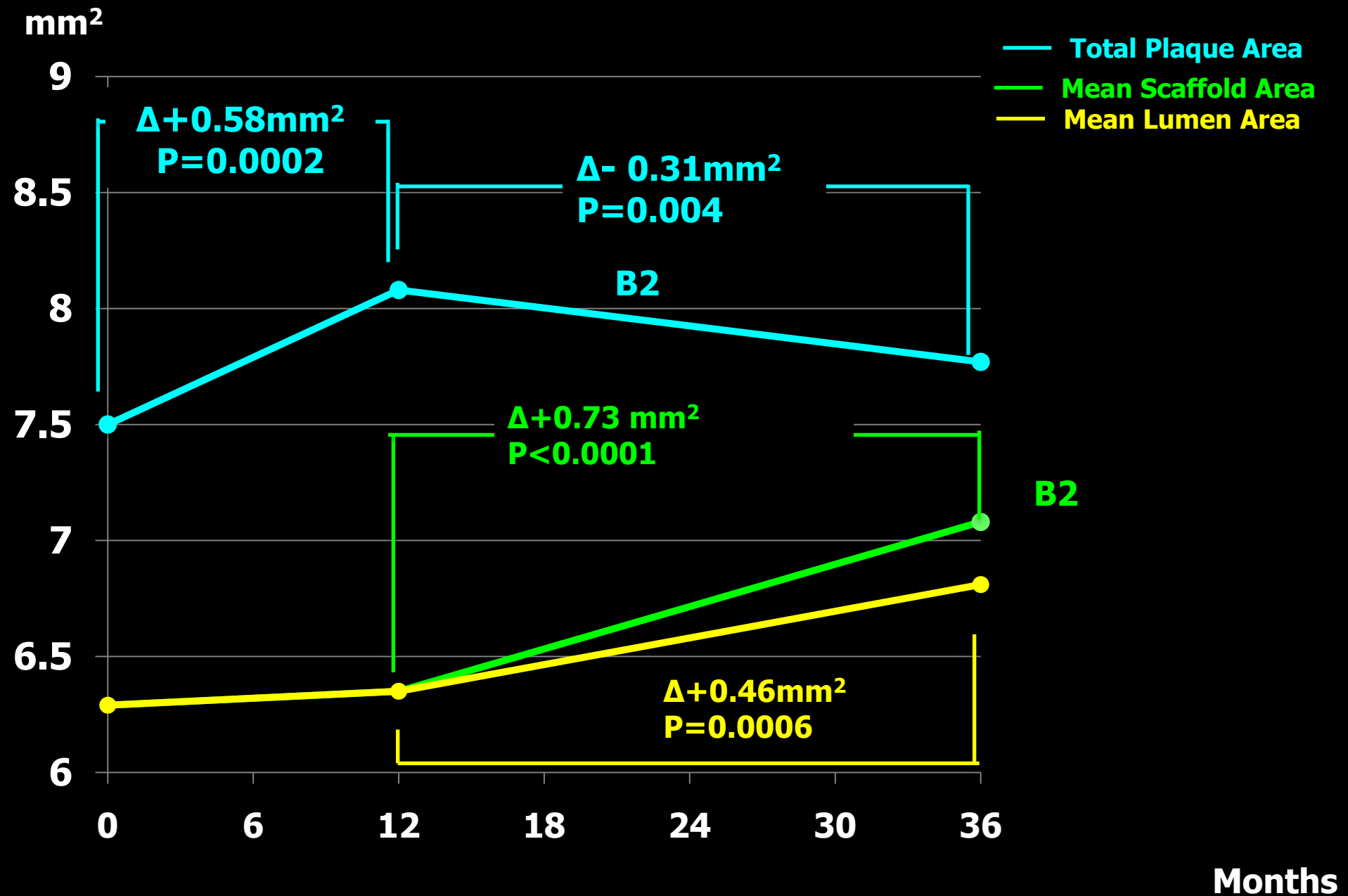


- **Sponsor/ Funding: Abbott Vascular**
- **Primary Investigators:**
  - PW Serruys MD, PhD
  - J Ormiston MD
- **DSMB: J Tijssen PhD, M Wiemer MD, P Urban MD**
- **CEC: C Hanet MD, R Tölg MD, V Umans MD**
- **Angiographic, IVUS and OCT Corelab: Cardialysis**
- **Prospective, open label, FIM**
- **3.0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

- **12 sites Europe, Australia, New Zealand**
- **B de Bruyne, MD, PhD**
- **D Dudek, MD**
- **E Christiansen, 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**

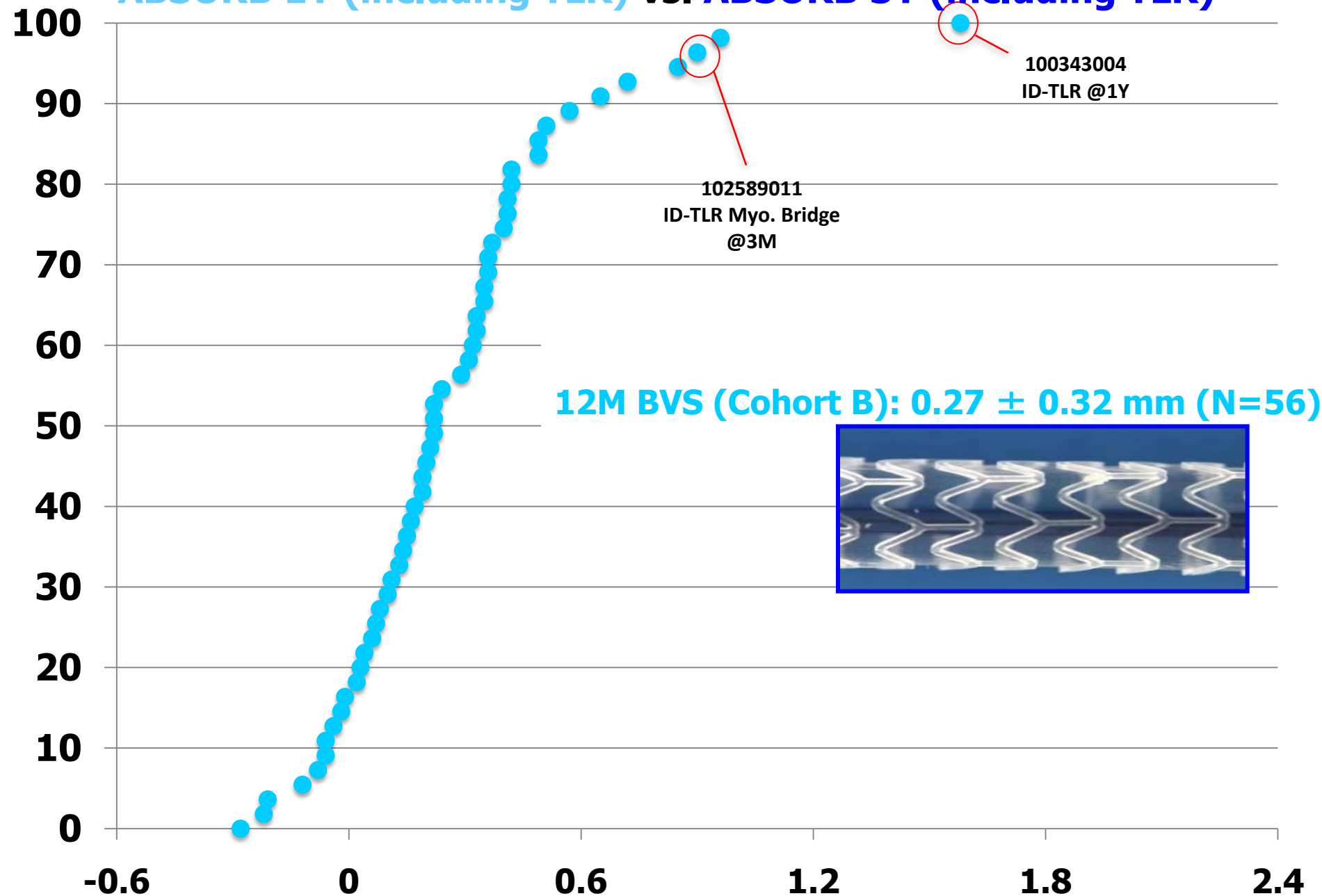


# Results of Serial Quantitative IVUS Analysis (n=45)



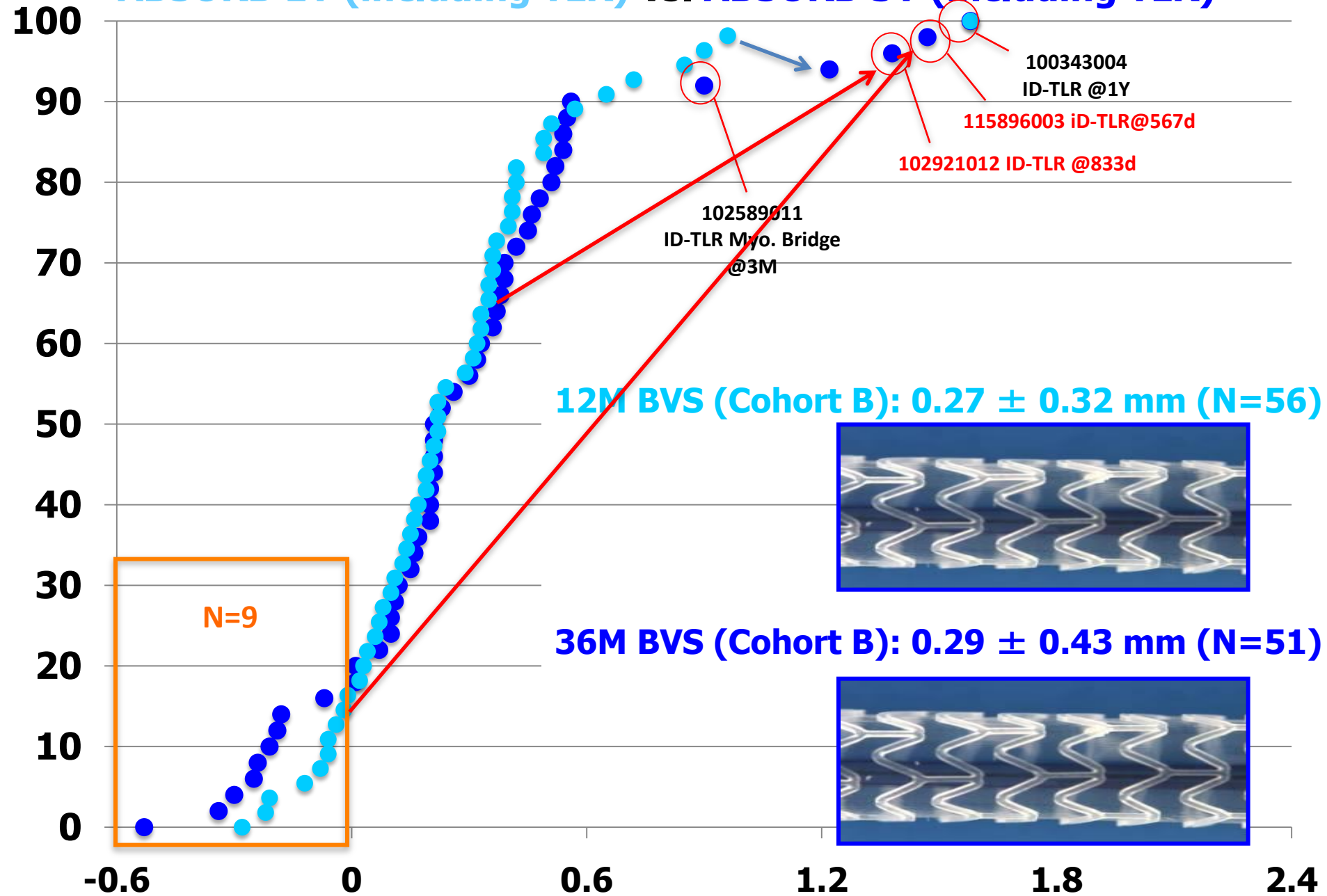
# Insight on evolution of late luminal loss over times

**ABSORB 1Y (including TLR) vs. ABSORB 3Y (including TLR)**



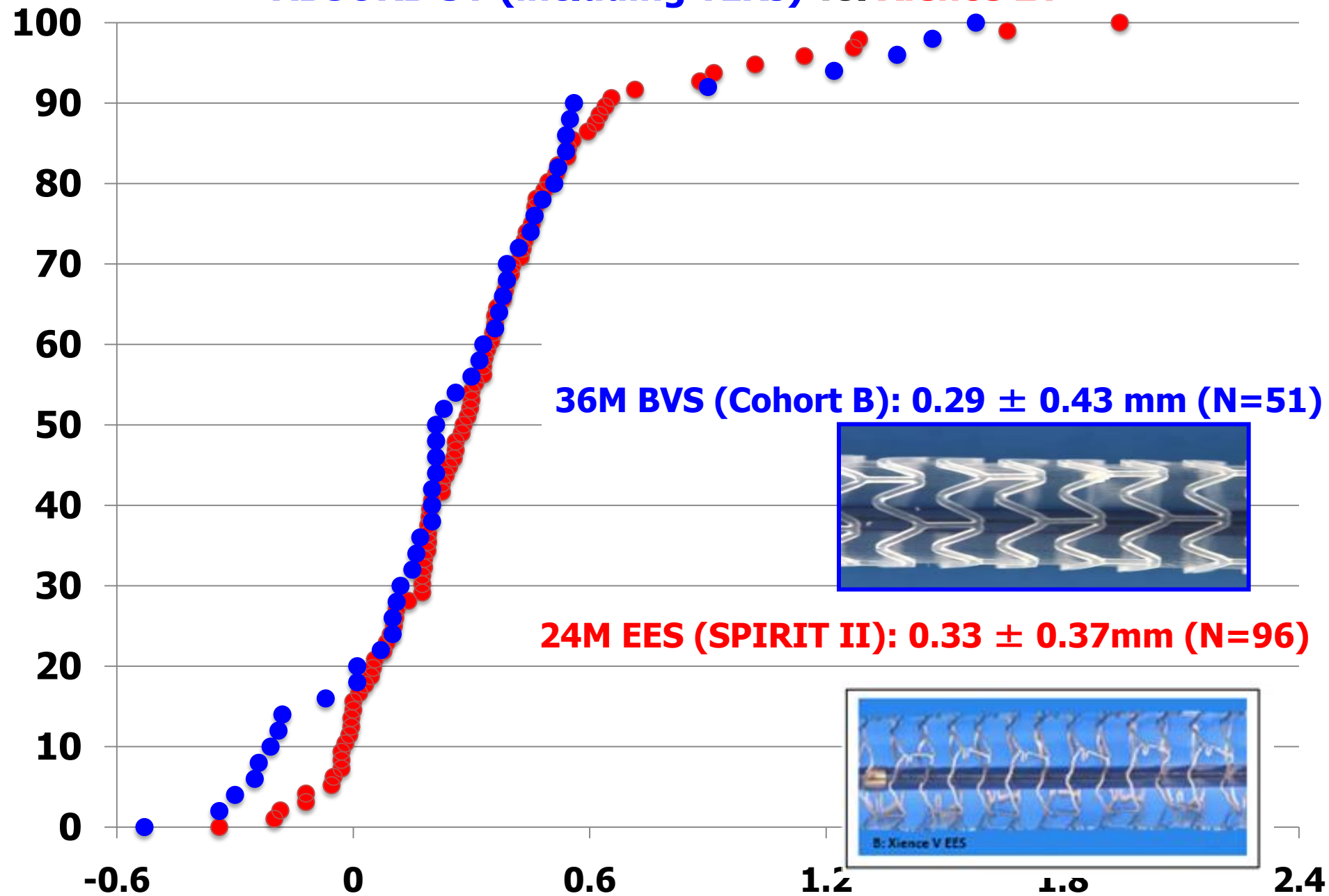
# Insight on evolution of late luminal loss over times

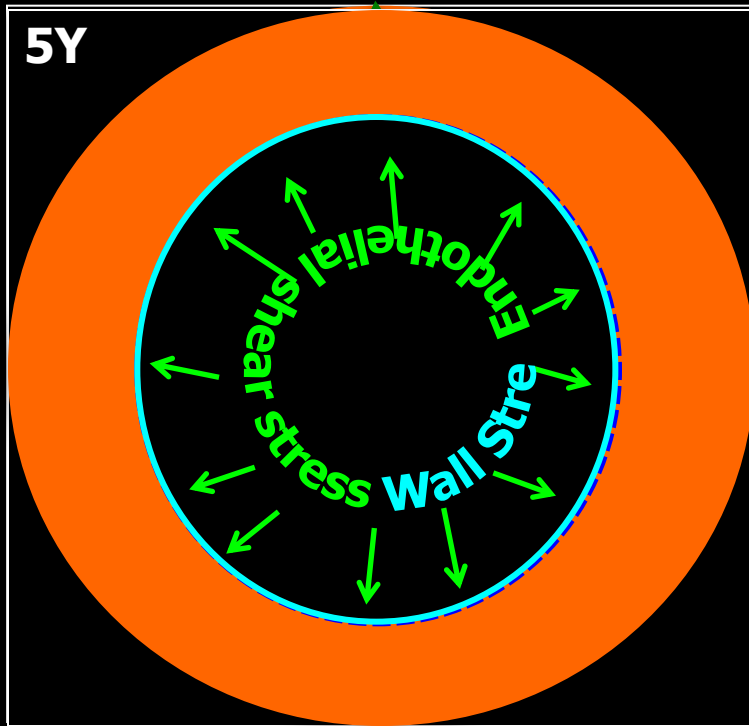
**ABSORB 1Y (including TLR) vs. ABSORB 3Y (including TLR)**



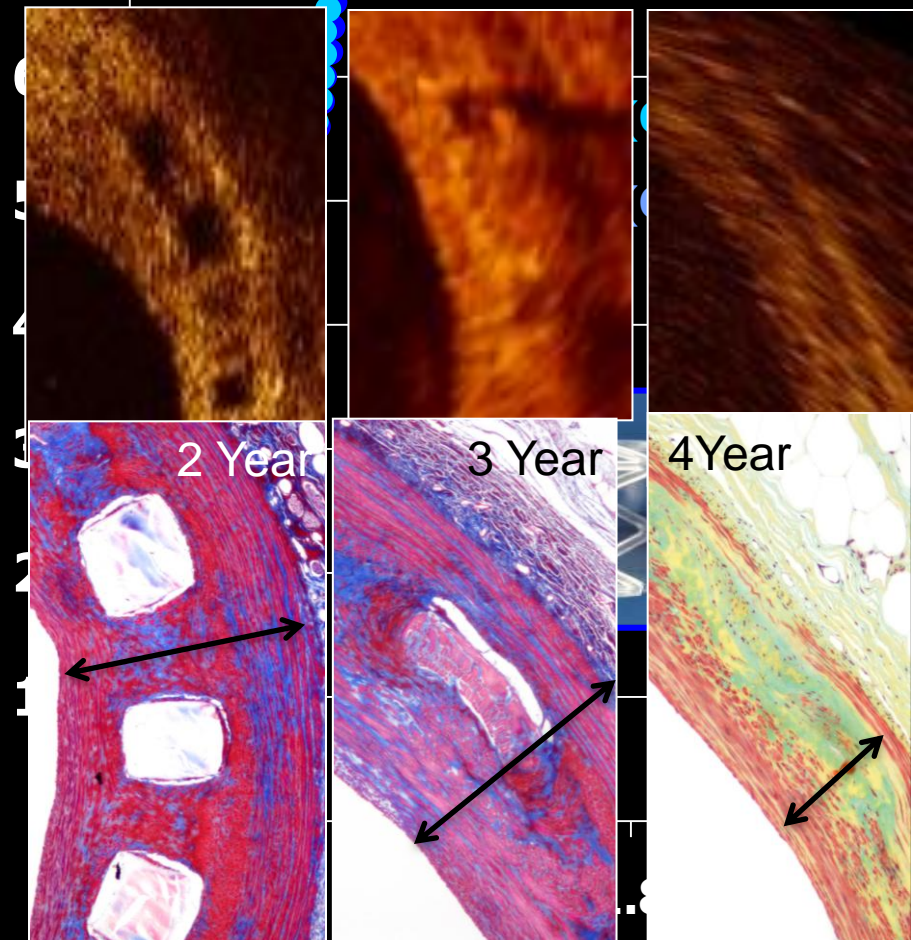
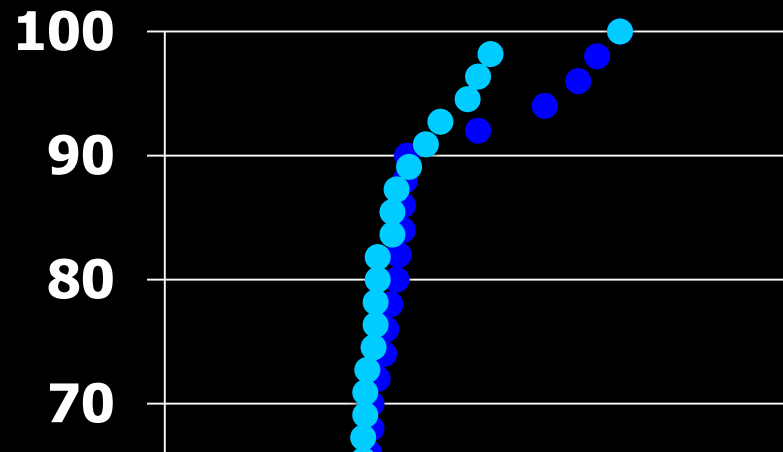
# Insight on evolution of late luminal loss over times

**ABSORB 3Y (including TLRs) vs. Xience 2Y**

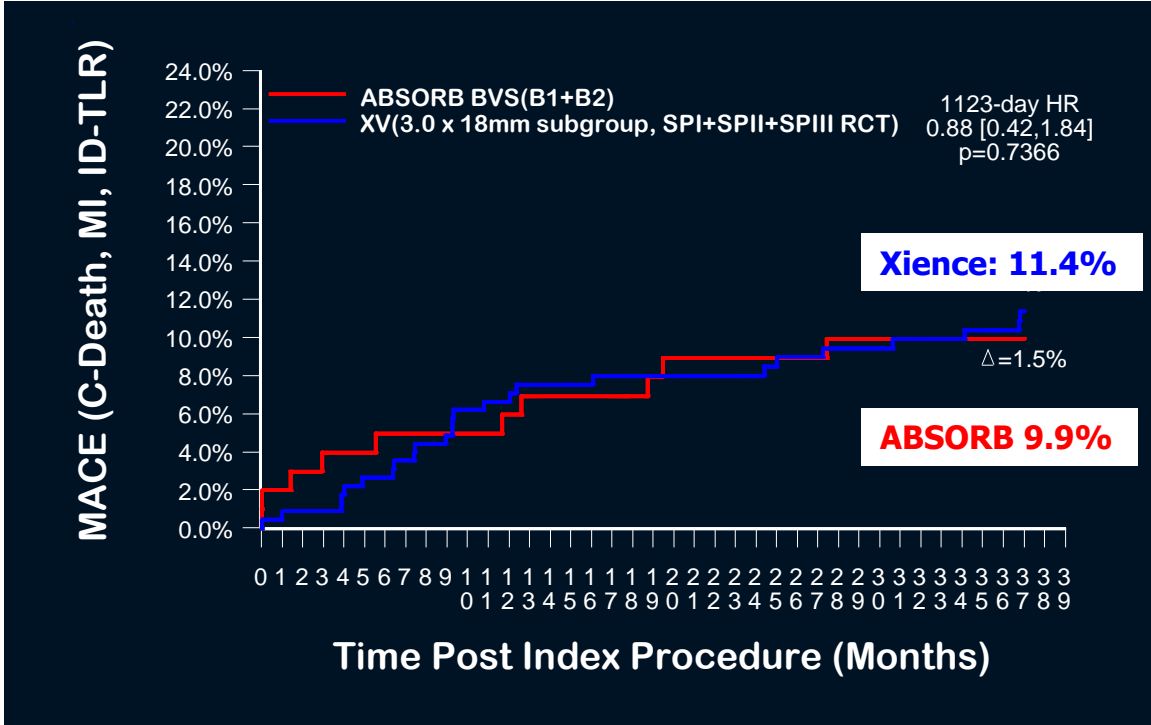




**At 5 years, the vessel wall thinning (plaque media reduction?) will result in late lumen enlargement.**



# KM estimate of MACE rate in patients treated with Absorb BVS (ABSORB Cohort B, n=101) vs. patients treated with a single 3.0x 18 mm metallic XIENCE V (SPIRIT FIRST+II+III, n=227)

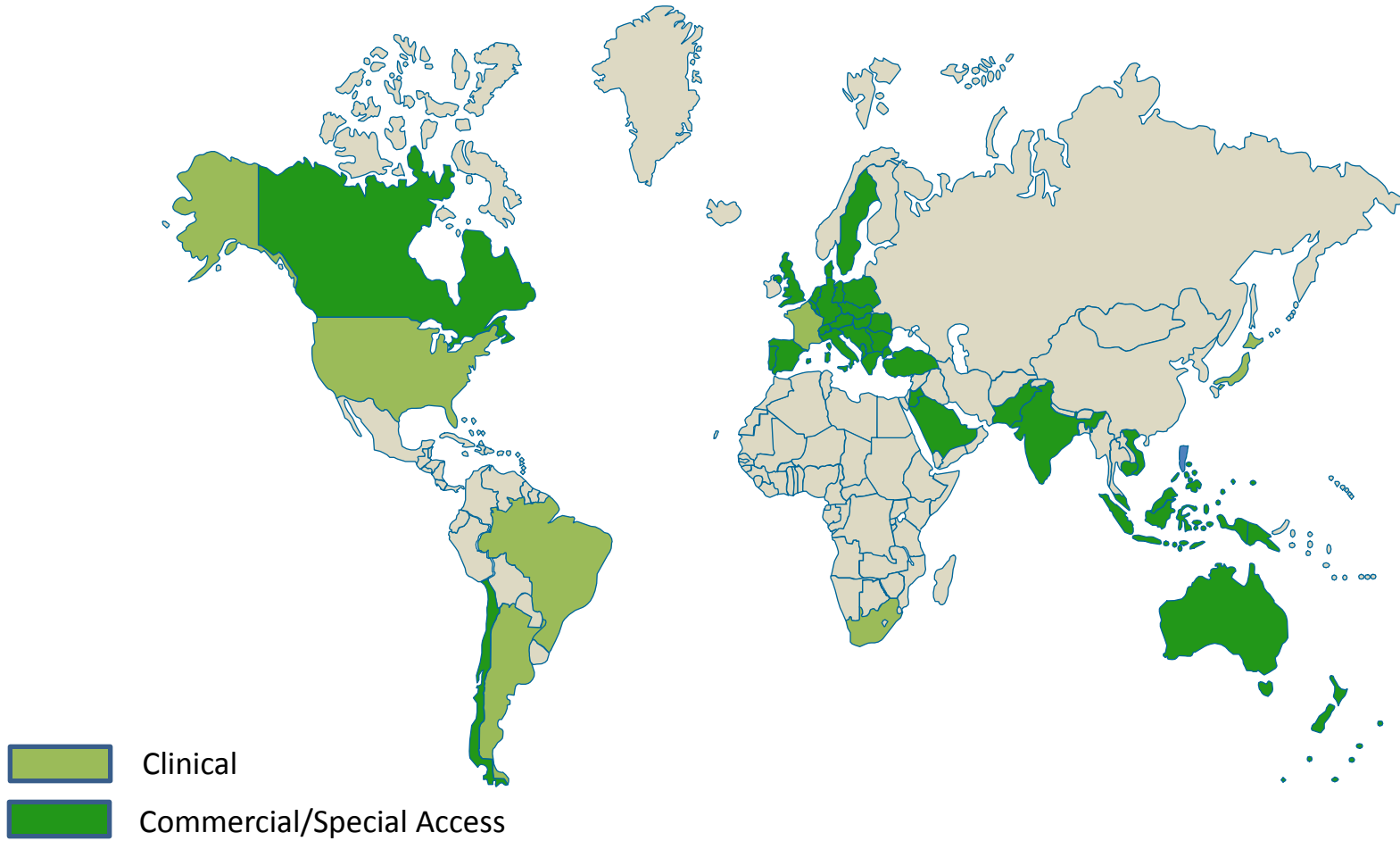


	Time After Index Procedure (days)							
	0	37	194	284	393	573	758	1123
ABSORB BVS(B1+B2) At Risk	101	99	96	96	94	92	91	89
XV(3.0 x 18mm subgroup, SPI+SPII+SPIII RCT) At Risk	227	224	219	211	204	202	191	182

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



# Bioresorbable Vascular Scaffold Worldwide Current Exposure by Country



# Conclusion

- **ABSORB cohort A (5 year FUP) demonstrated**
  - **Bioresorption of strut**
  - **Late lumen enlargement**
  - **Restoration of vasomotion**
  - **Feasibility of serial non-invasive follow-up**
  - **Long-term safety**
- **ABSORB cohort B (3 Year FUP) demonstrated**
  - **Consistent bioresorption between the two Cohorts examined at different time points (6 & 24 months vs. 12 & 36 months)**
  - **On OCT, enlargement of scaffold area that compensates for persistent increase of neointima**
  - **On IVUS, enlargement of scaffold area & lumen area with reduction of plaque area**
  - **On Angiography at 36 months, stable late loss over the last 24 months with vasodilation on intracoronary administration of nitrate**
  - **The 3-Y MACE rate of ABSORB is comparable to Xience (in a non-randomized post-hoc analysis)**
- **ABSORB scaffolds are now commercially available and starts to be used in complex lesions: LM, Bif, CTO, AMI and so on... Some preliminary acute results look promising**