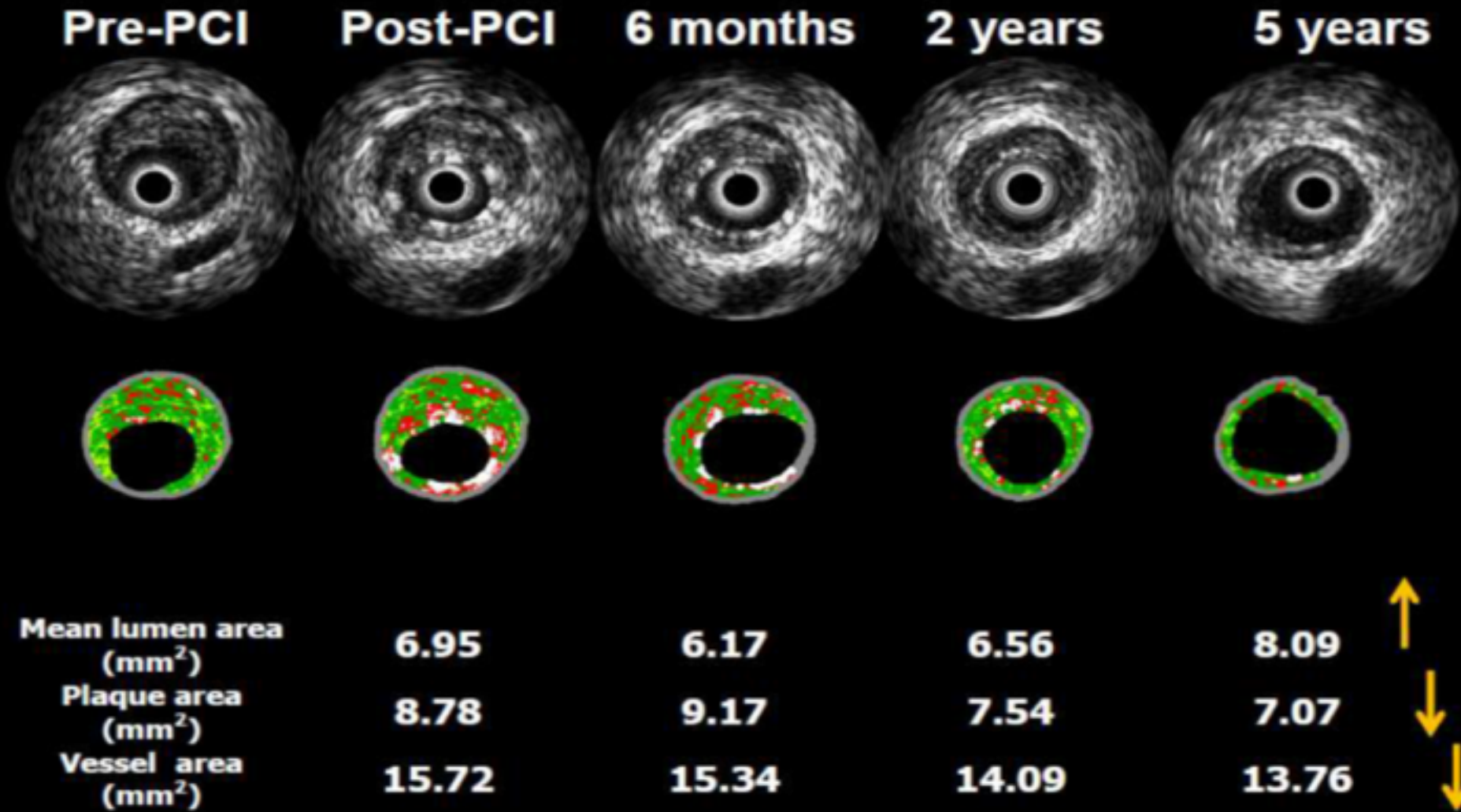


# IVUS through 5 years



Koen Nieman et al. *Circulation*. 2011;124: A10570

# MSCT through 5 years

Vessel Area:

$13.2 \pm 4.6 \text{ mm}^2$

[ 7.1 - 22.6 ]

Plaque Area:

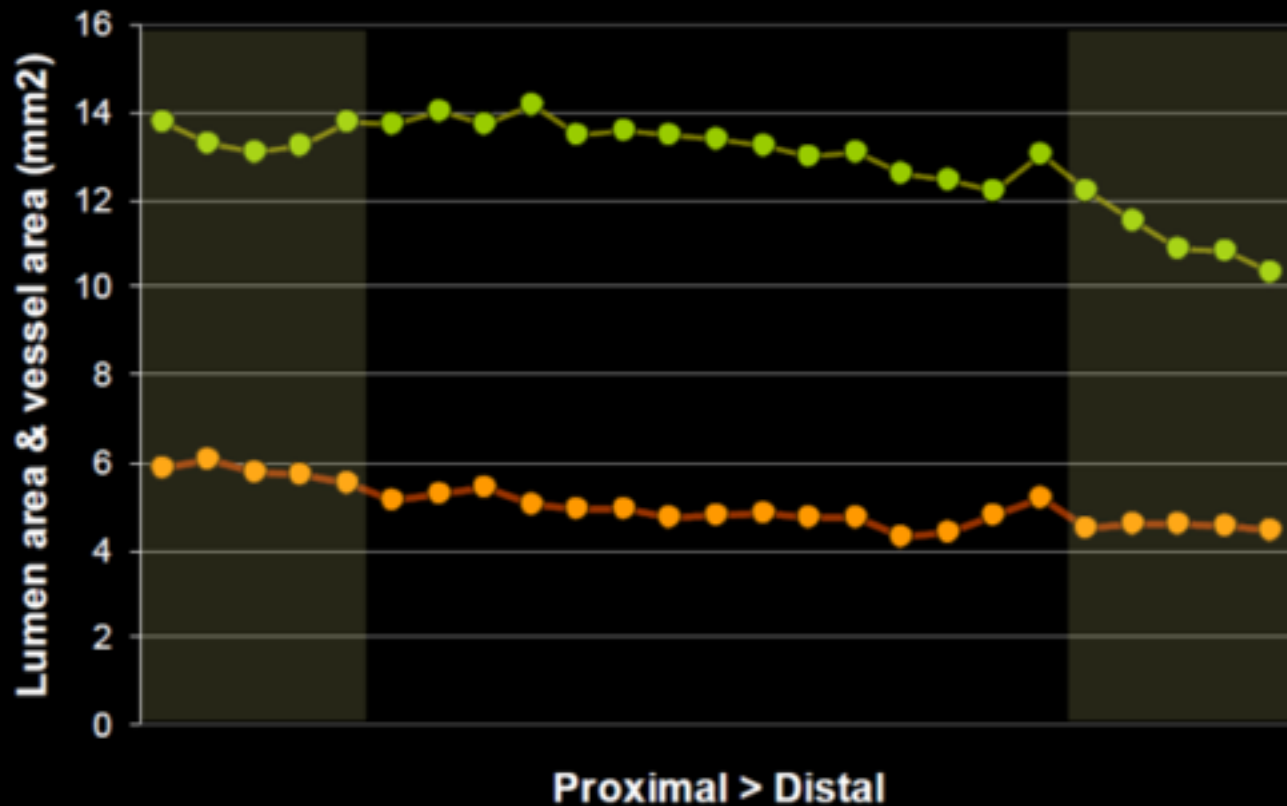
$8.4 \pm 3.9 \text{ mm}^2$

[ 3.0 - 17.3 ]

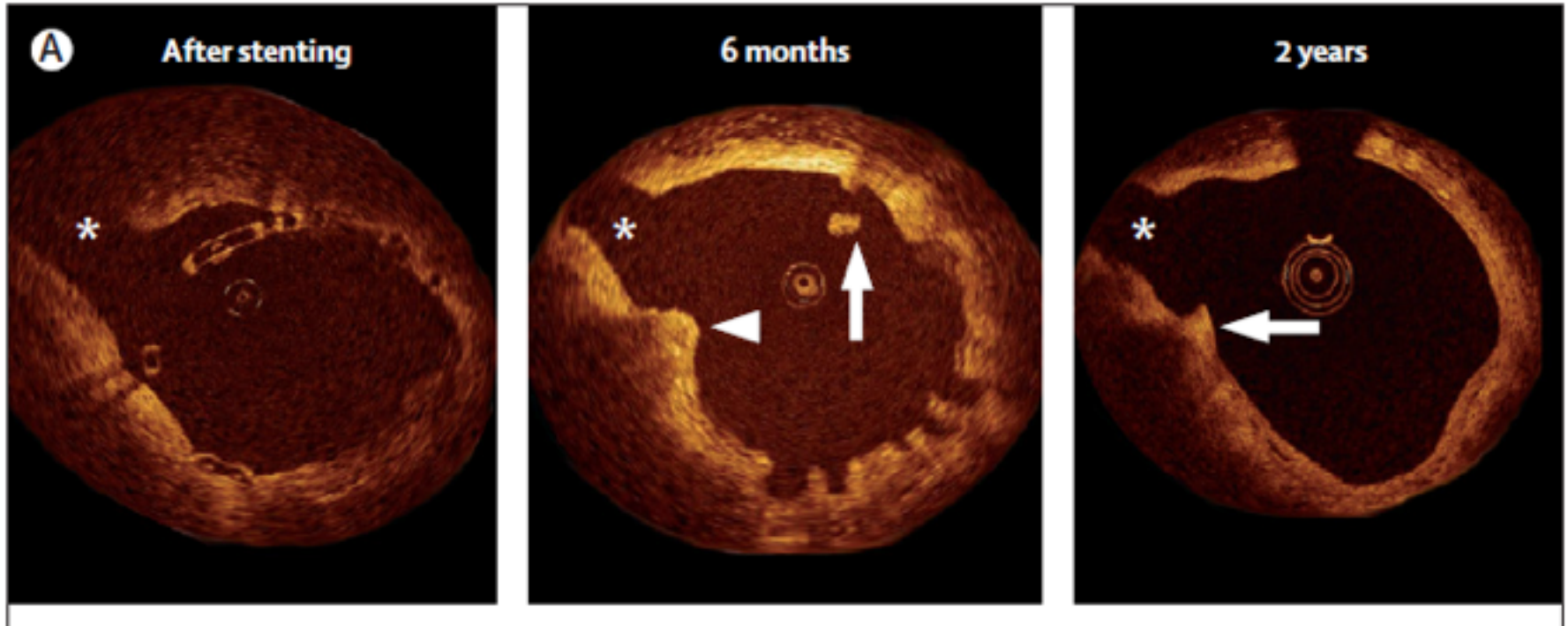
Lumen Area:

$4.7 \pm 1.8 \text{ mm}^2$

[ 2.7 - 9.9 ]

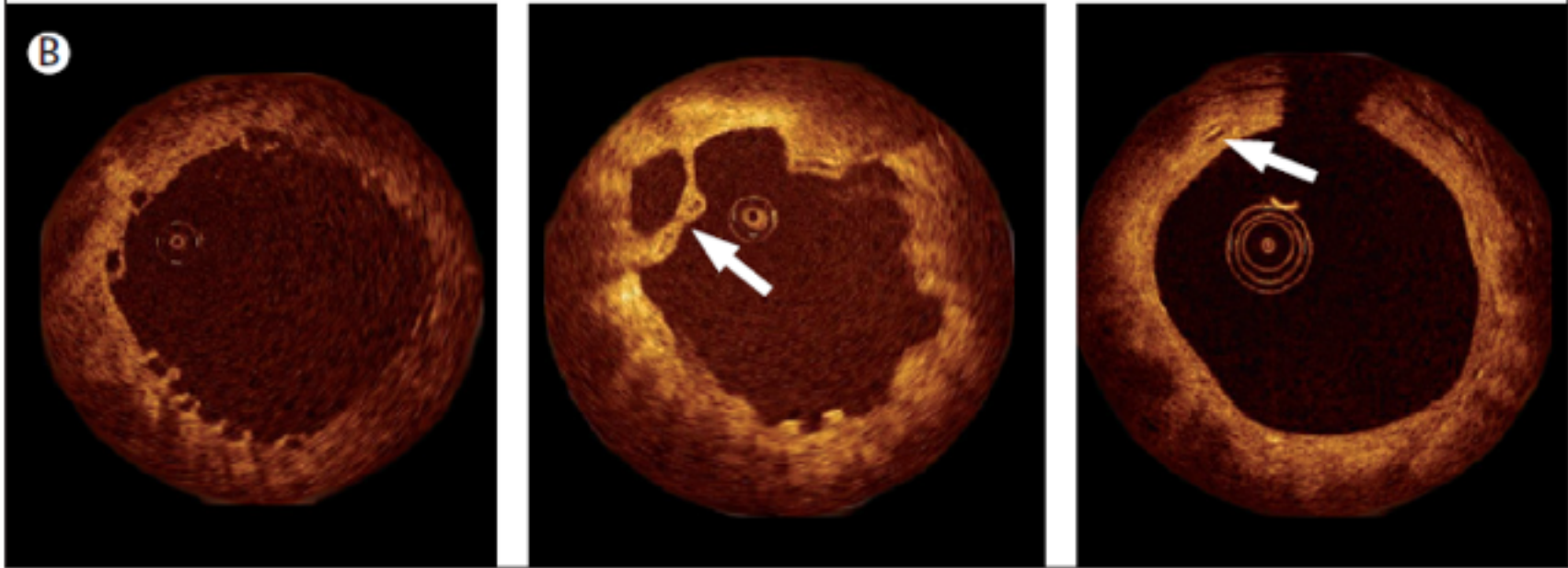


# OCT through 2 years



After stenting, incomplete stent apposition (ISA) in front of a side-branch ostium.  
At 6 mos, persistent ISA and resolved ISA.  
At 2 yrs, there is now smooth appearance of the endoluminal lining without ISA since struts have been absorbed.

# OCT through 2 years



Complete apposition of strut after the procedure.

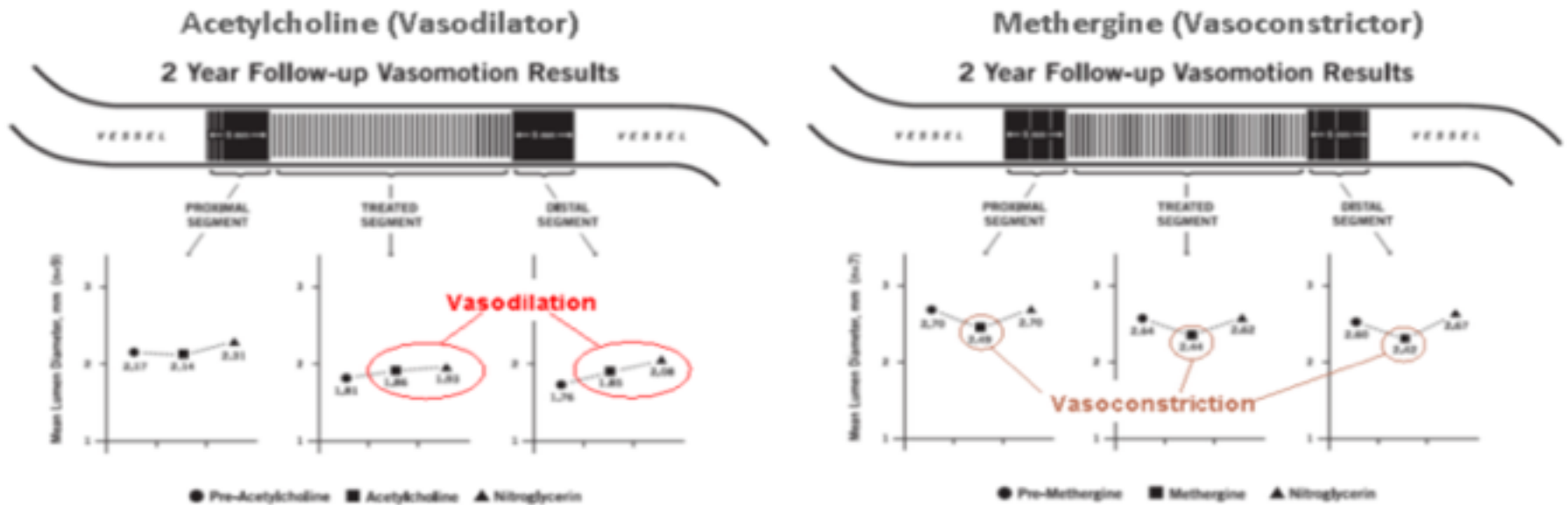
At 6 mos, there is late acquired ISA with tissue bridging connecting the struts. The endoluminal lining is corrugated.

At 2 yrs, smooth endothelial lining with almost circular cross section. Generally, the struts are no longer discernible, although there is a bright reflection that could indicate a strut. Asterisk indicates a side branch.



# Vasomotor function testing at 2 year

## ABSORB Cohort A at 2 years



The reappearance of vasomotion in the proximal, distal, as well as treated segments in response to methergine or acetylcholine suggests that **vessel vasoreactivity has been restored** and that **a physiological response to vasoactive stimulus might occur anew**.

# ABSORB Cohort A

## Excellent Long-Term Data Out to 5 Years

Hierarchical	RESTORATION	RESORPTION		
	6 Months 30 Patients	1 year 29 Patients**	2 Year 29 Patients**	5 Year 29 Patients**
<b>Ischemia Driven MACE***</b>	1 (3.3%)*	1 (3.4%)*	1 (3.4%)*	1 (3.4%)*
<b>Cardiac Death</b>	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
<b>MI</b>	1 (3.3%)*	1 (3.4%)*	1 (3.4%)*	1 (3.4%)*
<b>Q-Wave MI</b>	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
<b>Non Q-Wave MI</b>	1 (3.3%)*	1 (3.4%)*	1 (3.4%)*	1 (3.4%)*
<b>Ischemia Driven TLR</b>	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
<b>by PCI</b>	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
<b>by CABG</b>	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

No new MACE events between 6 months and 5 years  
 No scaffold thrombosis up to 5 years

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# Absorb Cohort B



# Absorb Cohort B

**101 subjects**

(Non-randomized) 12 sites in Europe, Australia, New Zealand

Group B1 (*n* = 45)

Imaging Follow-Up (Months)

6

12

18

24

36

Group B2 (*n* = 56)

QCA, IVUS, OCT, IVUS VH

MSCT

**Study Objective**

First In Man, Single Arm – safety/performance

**Endpoints**

Typical PCI clinical and imaging endpoints

**Treatment**

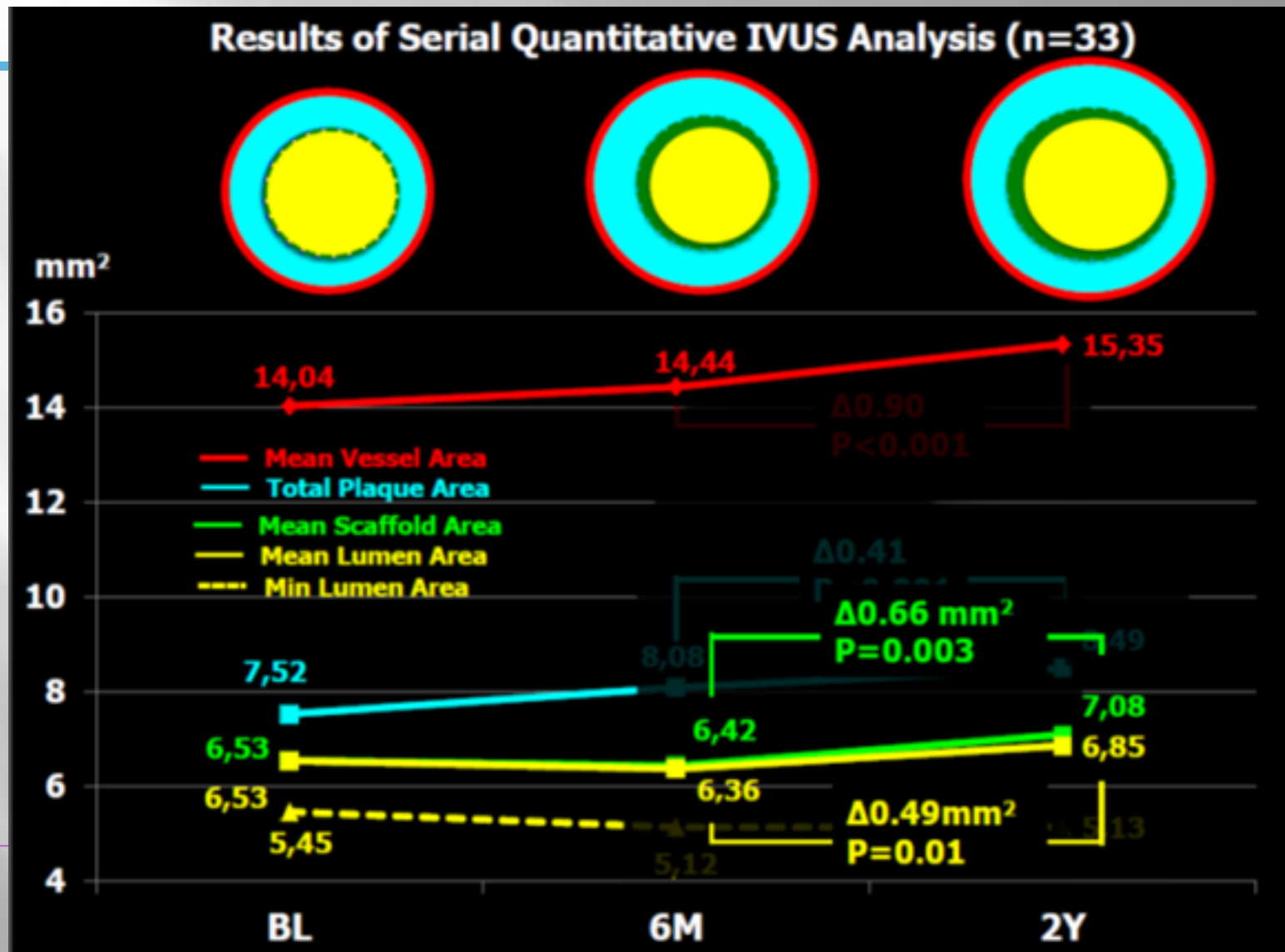
Up to 2 *de novo* lesions in different epicardial vessels  
Reference vessel diameter of 3.0 mm, lesions  $\leq$  14 mm in length

**Device Sizes**

3.0 x 18 mm devices



# IVUS through 2 years



# Mean Lumen Area

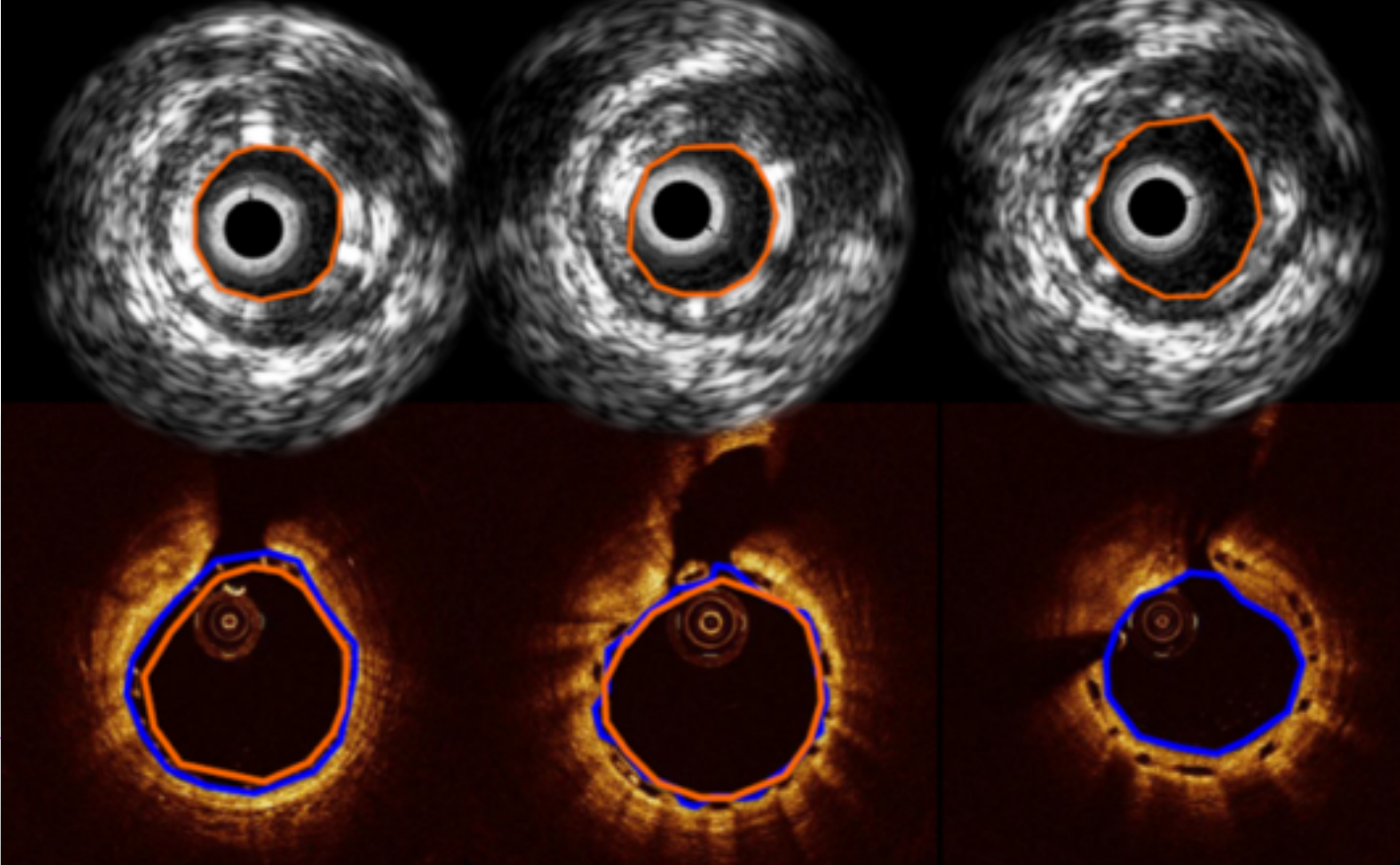
N=19

	IVUS	OCT	Difference	P-value
Mean Lumen area at Baseline	6.25±1.20	7.19±1.34	-0.93	<0.001
Mean Lumen area at 6M	6.06±1.15	5.98±1.45	0.083	0.55
Mean Lumen area at 2Y	6.58±1.50	5.81±1.59	0.76	<0.001

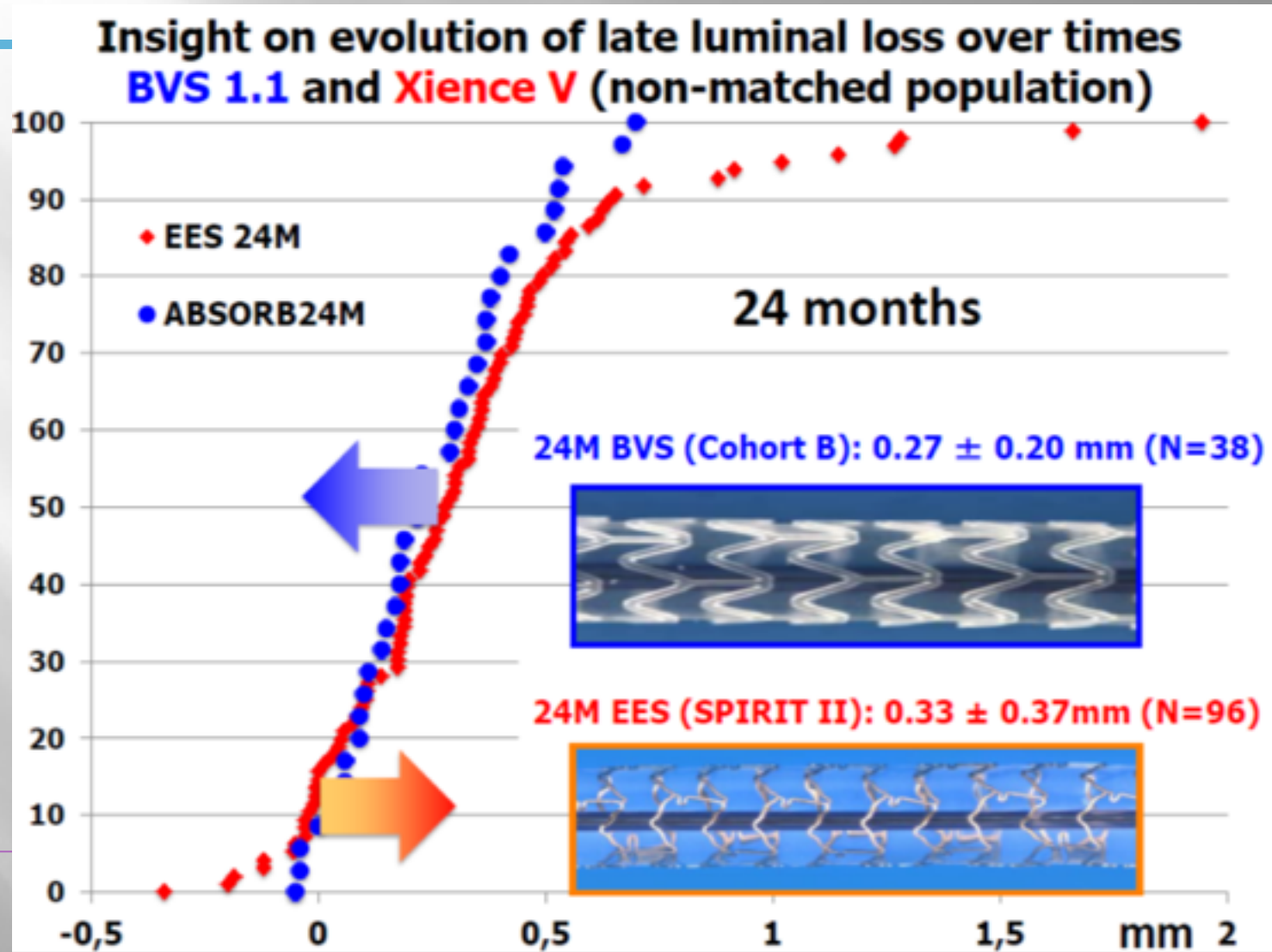
BL

6M

2Y



# BVS vs. Xience V



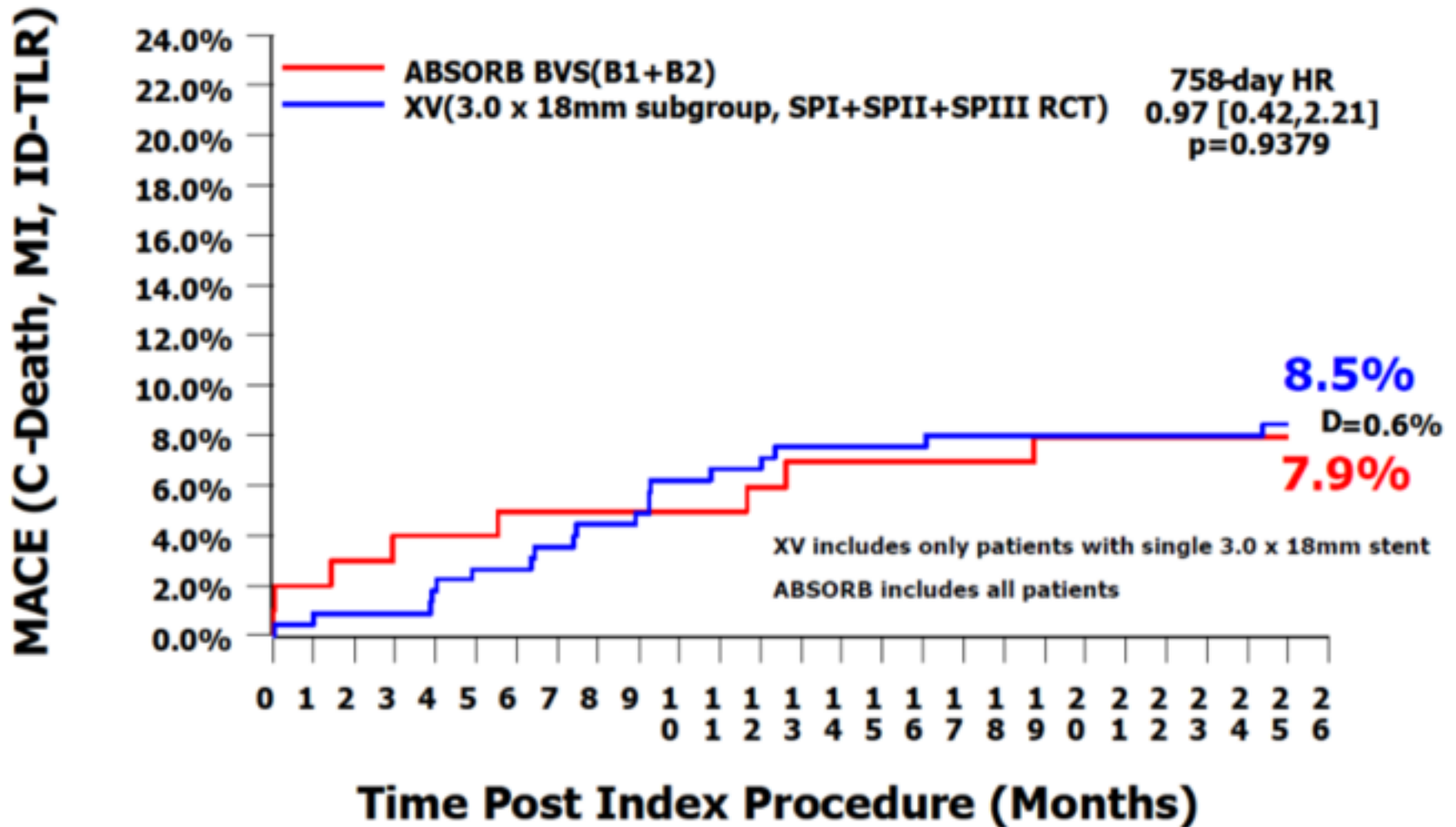
# ABSORB Cohort B

## Excellent Data Out to 2 Years

	30 Days	6 Months	1 Year	2 Years
<b>Non -Hierarchical</b>	n = 101	n = 101	n = 101	n = 100*
<b>Cardiac Death %</b>	0	0	0	0
<b>Myocardial Infarction % (n)</b>	2.0 (2)	3.0 (3)	3.0 (3)	3.0 (3)
Q-wave MI	0	0	0	0
Non Q -wave MI	2.0 (2)	3.0 (3)	3.0 (3)	3.0 (3)
<b>Ischemia driven TLR % (n)</b>	0	2.0 (2)	4.0 (4)	6.0 (6)
CABG	0	0	0	0
PCI	0	2.0 (2)	4.0 (4)	6.0 (6)
<b>Hierarchical MACE % (n)</b>	2.0 (2)	5.0 (5)	6.9 (7)	9.0 (9)

**No scaffold thrombosis by ARC or Protocol out to 2-year  
only 2 additional TLR events between 1 year and 2 year**

# MACE rate in patients treated with BVS (n=101) Vs. Xience V (n=227)





# Why Absorb?

## Near & Long Term Results Similar to XIENCE & Unique Benefits Emerging

### *Similar Results vs. XIENCE → Unique Benefits Emerging*

- **Near term** results, measured in traditional endpoints, indicate Absorb performs as well as the standard of care (XIENCE V)\*
  - 12 month MACE: 4.2% EXTEND vs. 5.3% SPIRIT II/III; Chevalier, EXTEND 1 year 450 Pt follow-up, Rotterdam, PCR
- **Longer term** data demonstrates a numerical difference in favor of Absorb vs. the standard of care (XIENCE V)\*
  - 3 year MACE: 9.9% vs. 11.4% SPIRIT I/II/III; Serruys, Cohort B2 3 year Follow-up, Rotterdam PCR Focus on BVS, 2013
- The most **unique benefits** of Absorb are the results that would not be expected with a <sup>Clinical</sup> metallic implant
  - Patients {
    - 12-Month significant difference in favor of Absorb vs. XIENCE in reducing reported angina\*†
    - Long-term lumen enlargement
    - Reduced plaque area with Absorb over the long-term
    - More treatment options
    - Scaffold breaks down into water and carbon dioxide unlike a permanent implant‡

\*Data sets are from different trials and displayed for descriptive purposes only.  
†Small platinum markers at scaffold edges remain for fluoroscopic landmarking

‡ABSORB EXTEND vs. SPIRIT IV. Presented at EuroPCR 2013.

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# Absorb Extend



# ABSORB EXTEND

## Non-Randomized, Single-Arm, Continued Access Trial

~1000 subjects  
Up to 100 global sites (non-US)

### Clinical follow-up

Clinical Follow-up (months)	6	12	18	24	36
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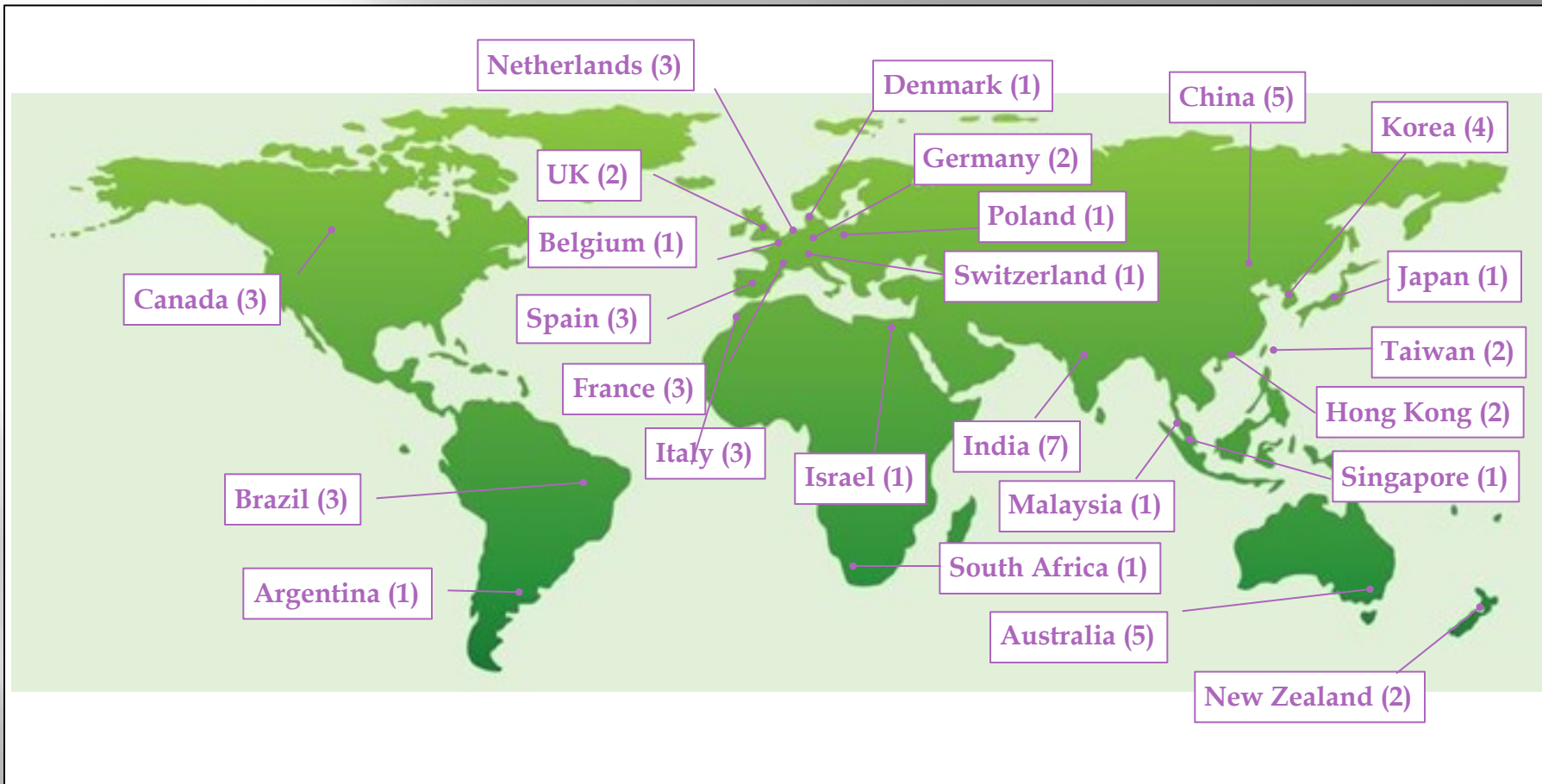
MSCT follow-up (n=100)

OCT follow-up (n=50)

Study Objective	Continued Access trial. FPI: Jan 11, 2011
Endpoints	Typical PCI clinical endpoints
Treatment	Up to 2 <i>de novo</i> lesions in different epicardial vessels Planned overlapping allowed in lesions >22 and ≤ 28 mm
Device Sizes	Scaffold diameters: 2.5, 3.0 mm Scaffold lengths: 18, 28 mm



# ABSORB EXTEND Planned Clinical Sites





- Up to two *de novo* lesions can be treated, each located in a separate native epicardial vessel
- Target vessel diameter range is  $\geq 2.0$  mm and  $\leq 3.3$  mm
- Target lesion length is  $\leq 28$  mm (planned overlapping allowed in lesions  $>22$  and  $\leq 28$  mm)
- Target lesion(s) meeting any of the following criteria are excluded:
  - Left main location;
  - Located within an arterial or saphenous vein graft or distal to a diseased arterial or saphenous vein graft;
  - Involves a bifurcation with a side branch  $\geq 2$  mm in diameter and ostial lesion  $> 40\%$  stenosed or side branch requiring predilatation;
  - Total occlusion (TIMI flow 0), prior to wire crossing;
  - Excessive tortuosity proximal to or within the lesion;
  - Heavy calcification.



# **ABSORB EXTEND**

**Preliminary Data from ABSORB EXTEND: A Report  
of the 6-month Clinical Outcomes from the First 269  
Patients Registered**

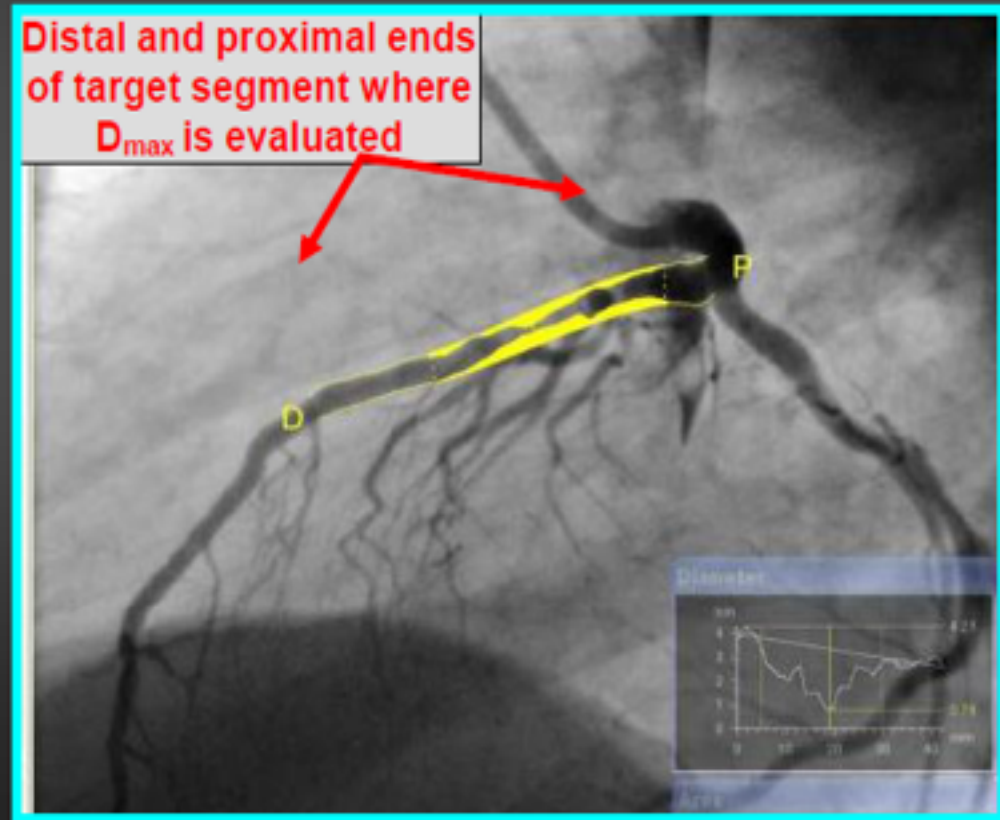
**Robert Jan van Geuns, MD, PhD, FACC  
on behalf of the ABSORB EXTEND Investigators**

**EuroPCR Focus on BVS 2012  
Rotterdam, The Netherlands**

# Quantitative Vessel Sizing - Online QCA

- The recommended range for target vessel diameter is assessed in terms of the online QCA parameters distal  $D_{max}$  and proximal  $D_{max}$ , which refer to maximum lumen diameter evaluated at the distal and proximal ends of the target segment to be scaffolded, respectively.

Target Vessel Diameter Distal and Proximal	ABSORB BVS Diameter to be Used
$\geq 2.0$ mm and $\leq 3.0$ mm	2.5 mm
$\geq 2.5$ mm and $\leq 3.3$ mm	3.0 mm



As of CIP Rev. 3.0, IVUS is now also permitted as a modality for vessel sizing.