Erasmus MC
Universitair Medisch Centrum Rotterdam

Symposium: Update on Vulnerable Plaque

Long-Term Effect of BVS on Plaque Morphology

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Thoraxcenter
Erasmus Medical Center
Rotterdam, NL

BVS ABSORB Clinical Trial Program
Long-Term Follow-up ≥ 5 Years

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COHORT A

First in Men, n=30

Single de-novo lesion

OCT:
Single center,n=16

Academic analysis
Thoraxcenter

Ormiston et al. Lancet 2008
Serruys et al. Lancet 2010
Simsek et al. Eurointerv 2014
Karanasos et al JACC 2014

COHORT B

First in Men, n=101

Single de novo-lesion

OCT:
Multi-center,n=55

Corelab analysis
Cardialysis

Serruys et al. TCT 2015

BVS ABSORB Clinical Trial Program
Long-Term Follow-up ≥ 5 Years

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COHORT A

First in Men, n=30

Single de-novo lesion

OCT:
Single center,n=16

Academic analysis
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Ormiston et al. Lancet 2008
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Karanasos et al JACC 2014

COHORT B

First in Men, n=101

Single de novo

OCT:
Multi-center,n

Corelab analysis
Cardialysis

Serruys et al. TCT 2015

Imaging follow-up

- QCA
- Echogenicity
- IVUS, IVUS-VH
- Palpography
- OCT
- MSCT

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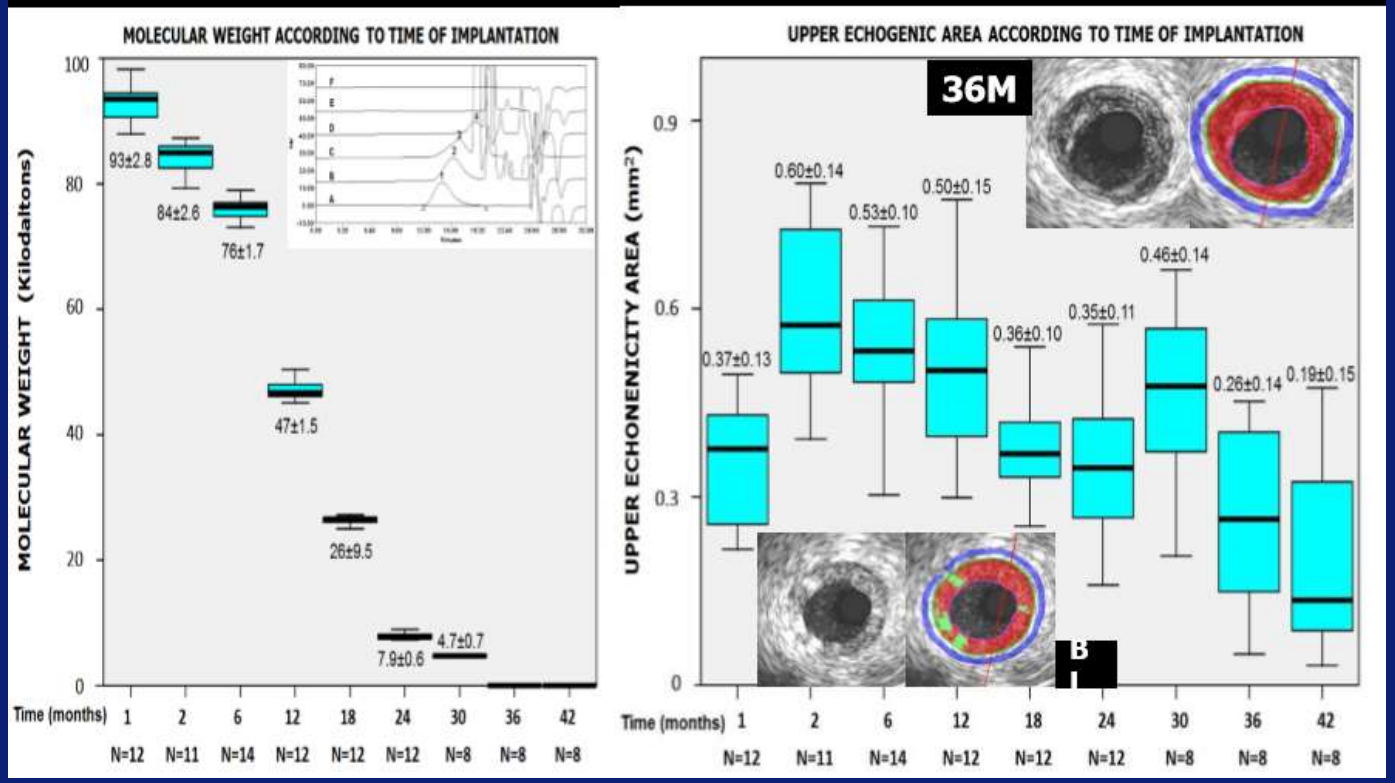
IVUS Echogenecity Can Visualize Depolymerization of PLLA

The echogenecity on IVUS allows us to follow the Depolymerization of PLLA scaffold (preclinical)



preclinical data; Serruys P.W., presentet at TCT 2015

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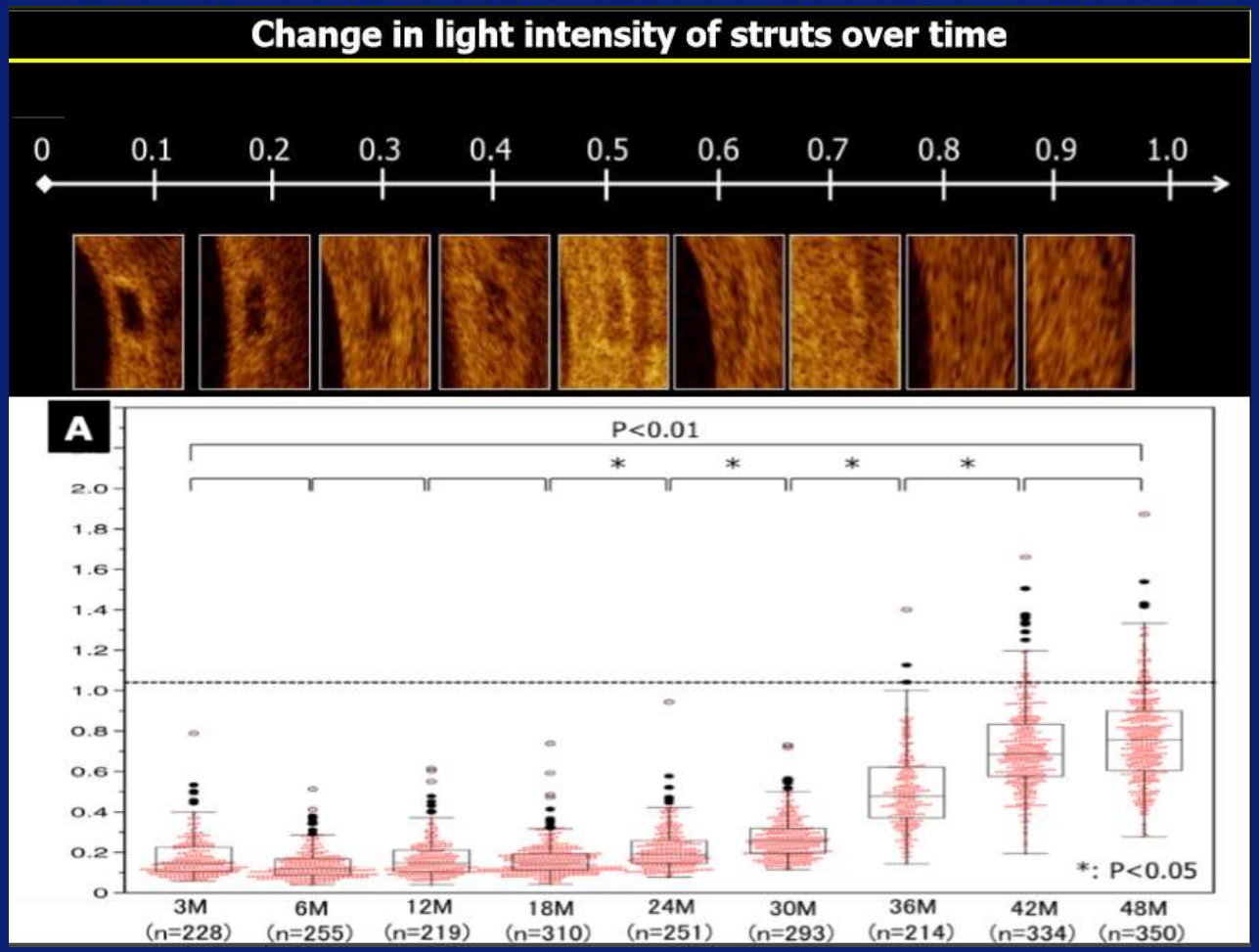
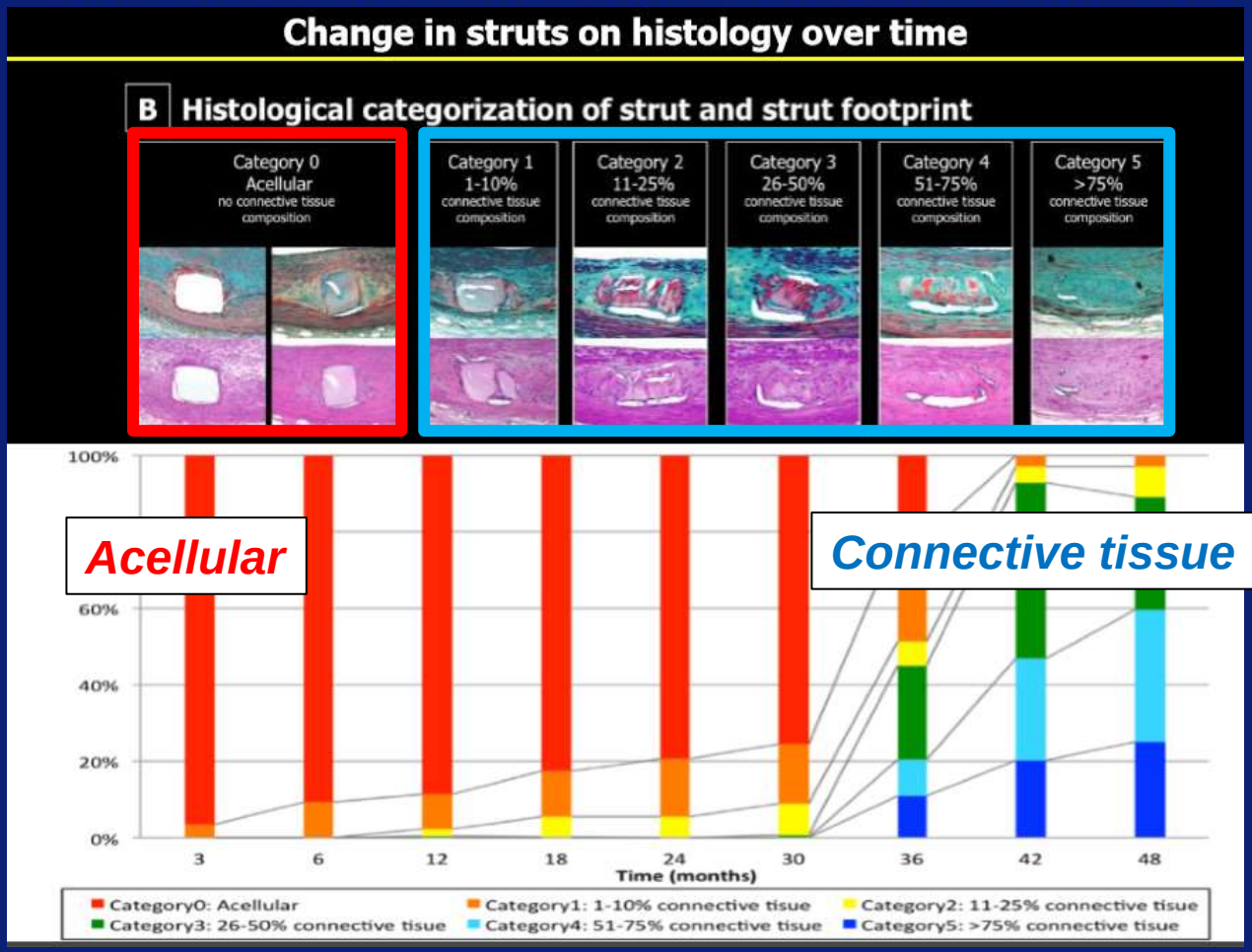
OCT Can Visualize Biointegration of PLLA Scaffold



Serruys P.W., presentet at TCT 2015

BVS ABSORB
OCT Can Visualize Biointegration of PLLA Scaffold



1-10%
11-25%
26-50%

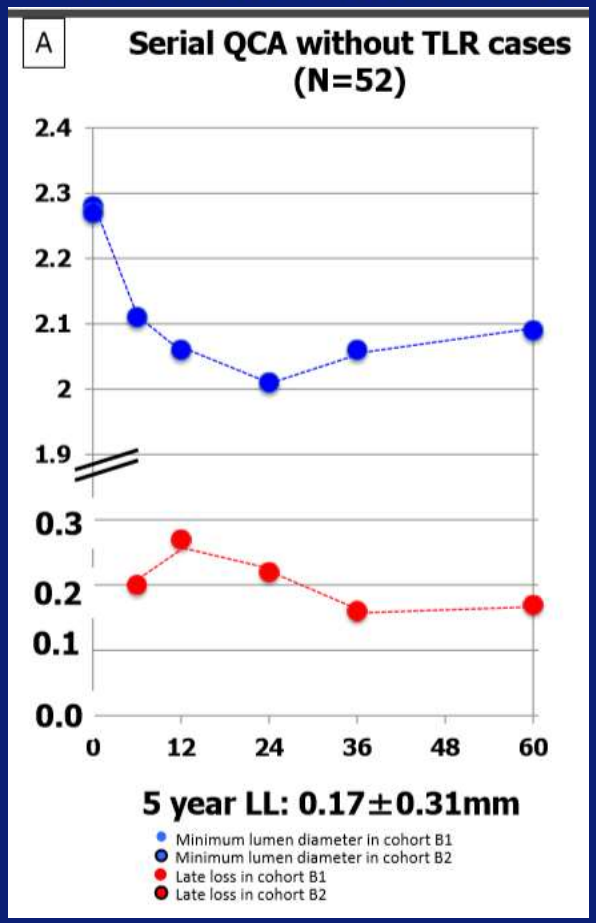
51-75%

> 75%

Serruys P.W., presentet at TCT 2015

BVS ABSORB COHORT B

BVS ABSORB COHORT B
Late Lumen Loss



Serruys P.W., presentet at TCT 2015

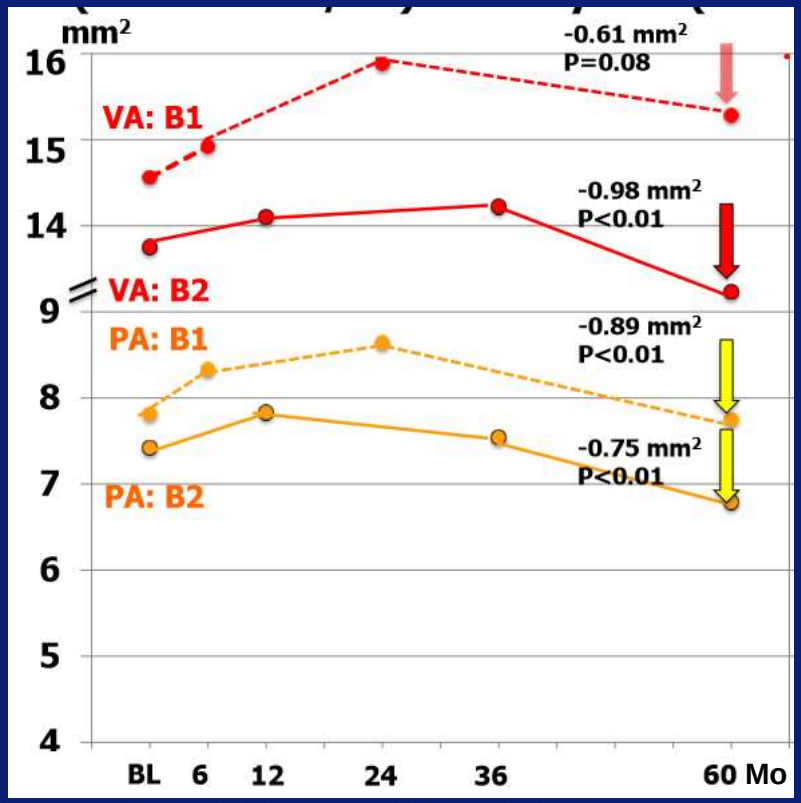
BVS ABSORB COHORT B

Effect on Plaque Morphology?

BVS ABSORB COHORT B

Effect on Plaque Morphology: Plaque Reduction Over Time

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



Vessel area & plaque area show biphasic change with

- *Increase between 1st & 2nd year*
- *Significant plaque reduction between 2nd & 5th year accompanied by an adaptive & constrictive remodeling of the vessel area*

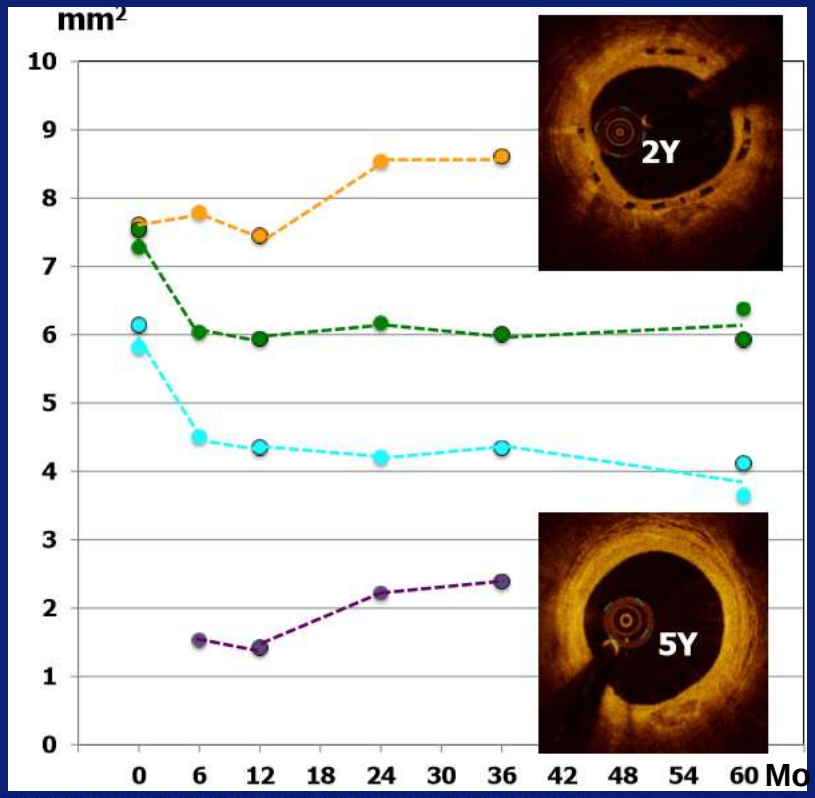
Vessel area

Plaque area

Serruys P.W., presentet at TCT 2015

BVS ABSORB COHORT B
Effect on Plaque Morphology: Stable Lumen Area

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



Mean and minimum scaffold area increased significantly in the first 3 years.

Thereafter struts are no longer discernible at 5 years.

Mean lumen area & minimal lumen area were stable from 1 year to 5 years.

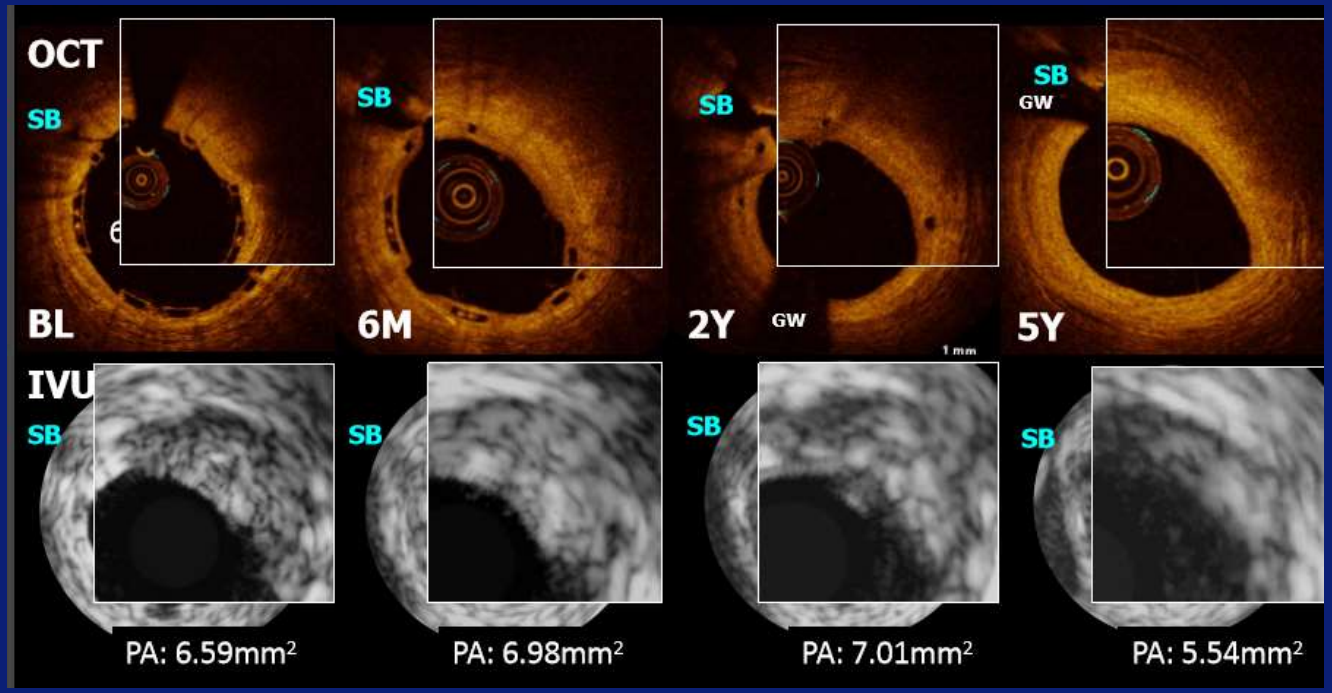
Neointima between and on top of struts are no longer measurable at 5 years since the struts are not discernible on OCT at 5 years

Serruys P.W., presentet at TCT 2015

BVS ABSORB COHORT B

Effect on Plaque Morphology: Media Visible at 5 Years

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



Change in plaque morphology which makes the media visible at 5 years

Serruys P.W., presentet at TCT 2015

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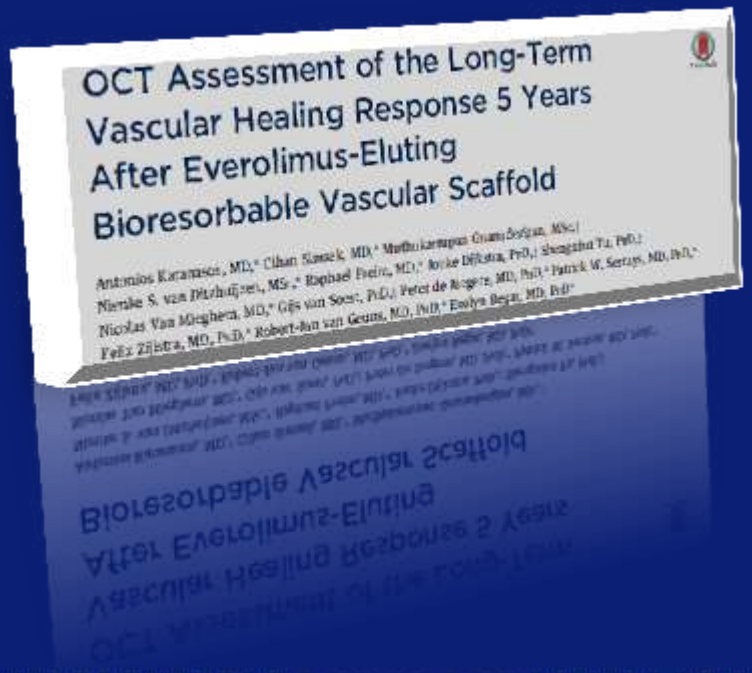
Effect on Plaque Morphology – More details?

BVS 1.0 (ABSORB A)



Karanasos A et al. JACC 2014

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Effect on Plaque Morphology – More details?

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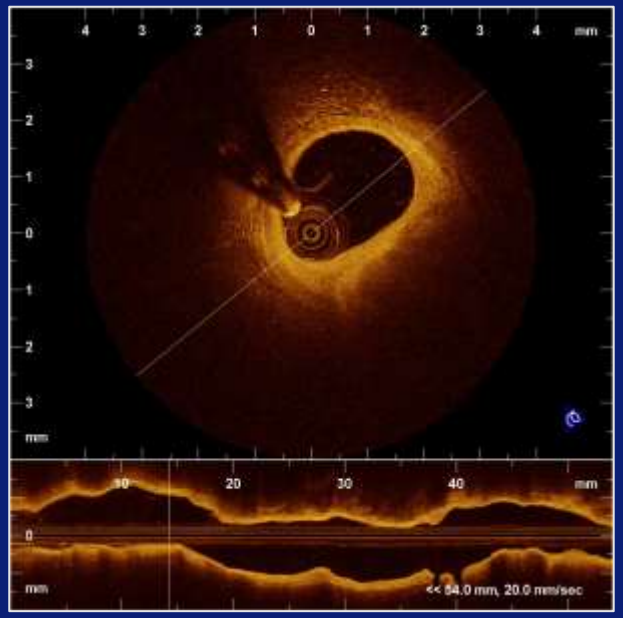
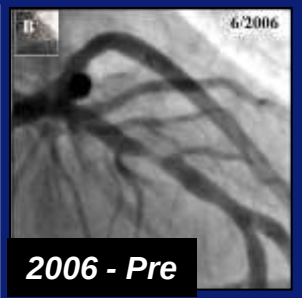
BVS 1.0 (ABSORB A)

Complete strut resorption &
Formation of a signal-rich layer





2006 - Pre

2006 - Final

2007 - FUP 6m

2012 – FUP 5y

Karanasos A et al. JACC 2014

BVS ABSORB
Effect on Plaque Morphology – More details?

Erasmus MC

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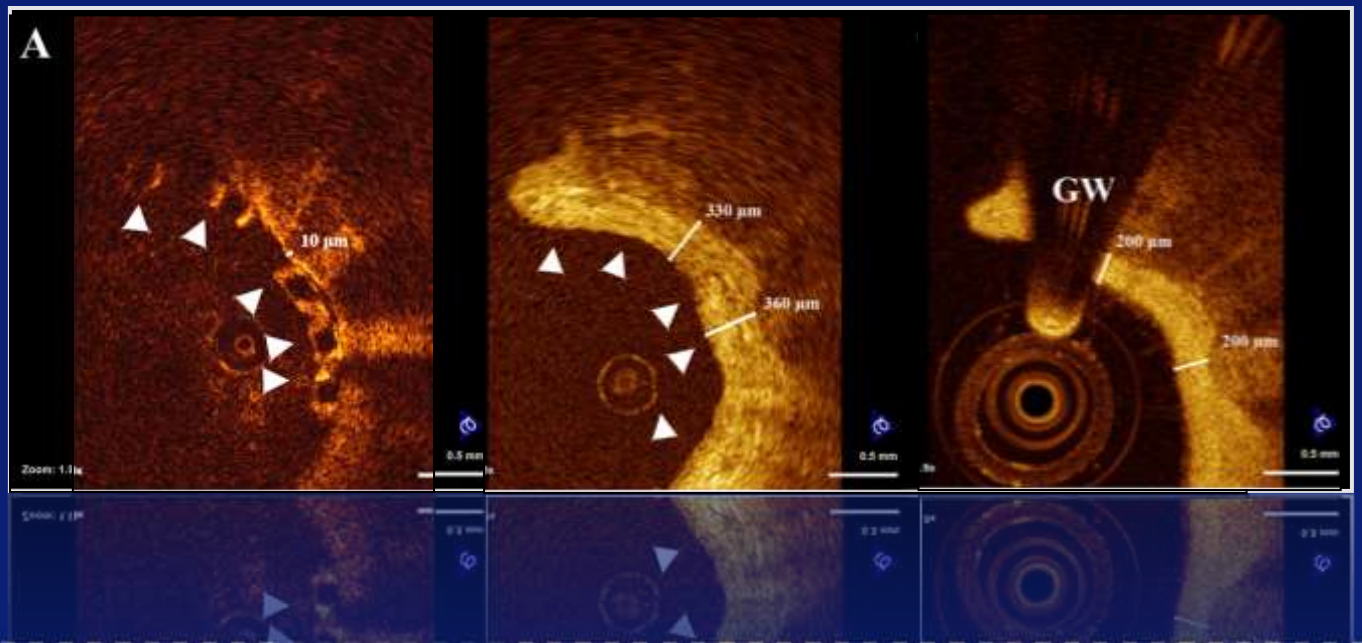
Complete strut resorption &
Formation of a signal-rich layer



Karanasos A et al. JACC 2014

BVS ABSORB

Effect on Plaque Morphology – More details?

Erasmus MC

BVS 1.0 (ABSORB A)

Complete strut resorption &
Formation of a signal-rich layer

How can we characterize this signal-intense layer and the underlying plaque?

Karanasos A et al. JACC 2014

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Effect on Plaque Morphology – More details?

BVS 1.0 (ABSORB A)

OCT Attenuation Imaging

Fibrous	low
Calcium	low
Necrotic core	HIGH
Macrophages	very HIGH

Relation between tissue type & attenuation coefficient

van Soest G et al, J. Biomed. Opt. 2010

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Effect on Plaque Morphology – More details?

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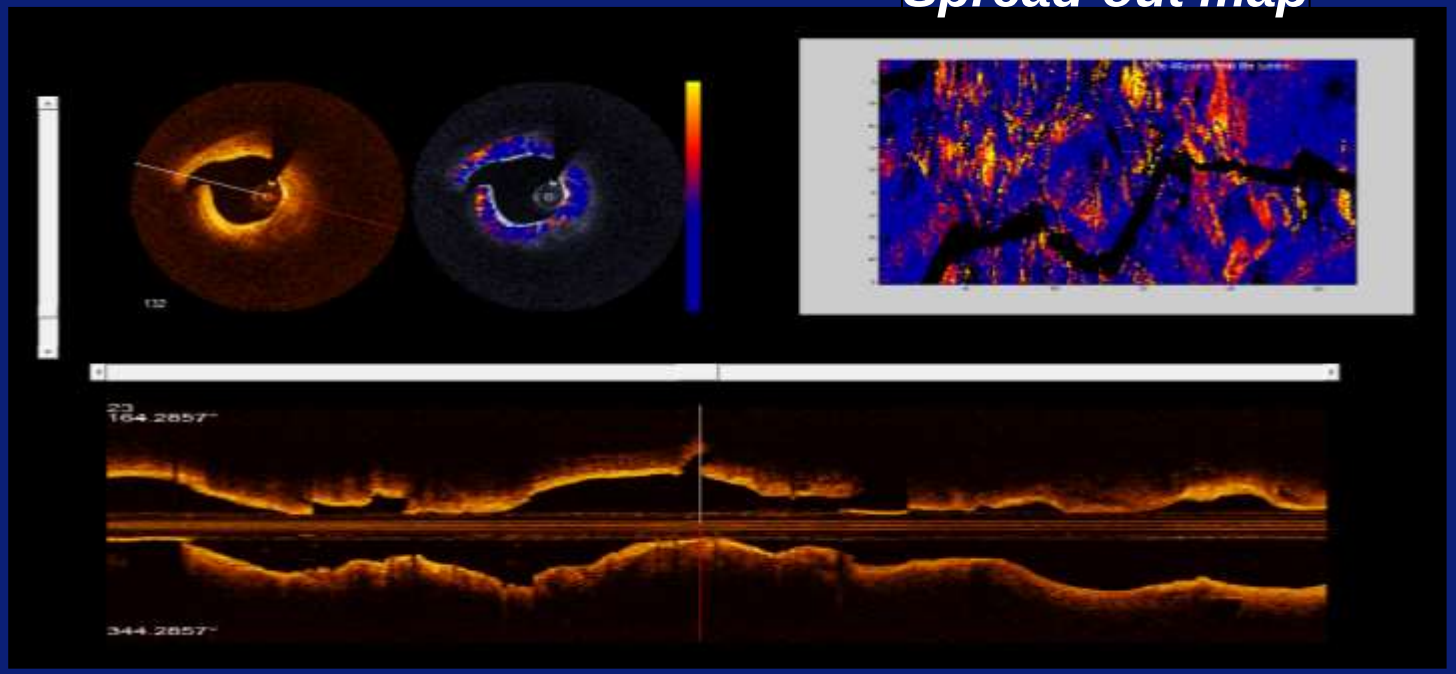
BVS 1.0 (ABSORB A)

OCT Attenuation Imaging

Spread-out map



Courtesy
M. Gnanadesigan
T. Kameyama

van Soest G et al, J. Biomed. Opt. 2010

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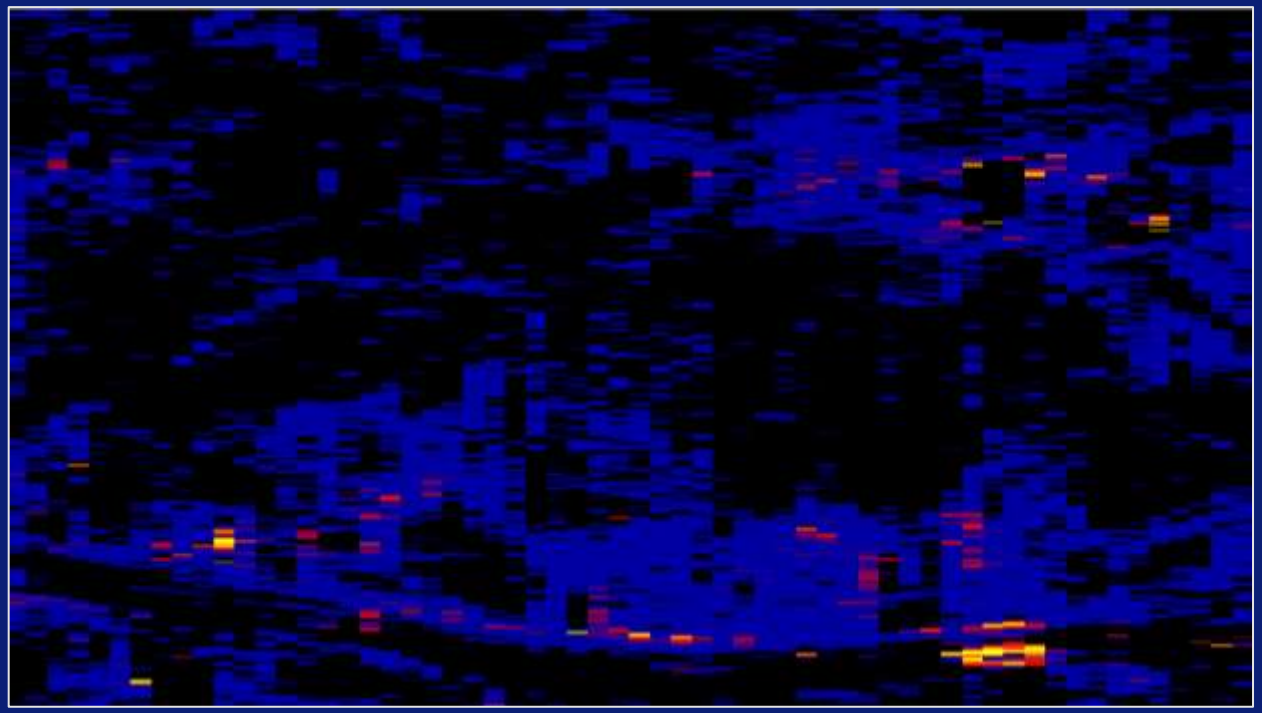
Effect on Plaque Morphology – More details?

Erasmus MC

BVS 1.0 (ABSORB A)
OCT Attenuation Imaging



100µm intervals starting from lumen surface

Karanasos A et al. JACC 2014

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Effect on Plaque Morphology – More details?

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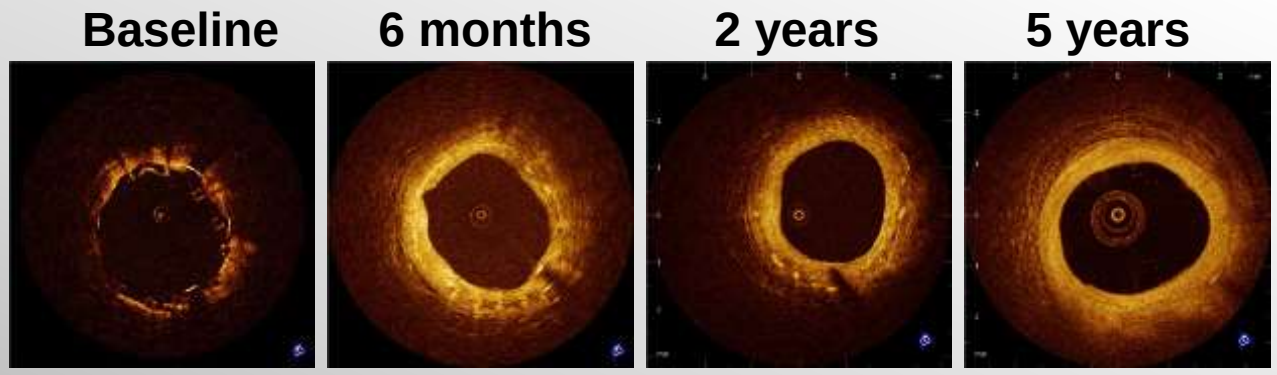
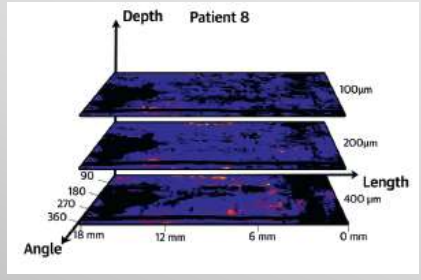
BVS 1.0 (ABSORB A)
OCT Attenuation Imaging



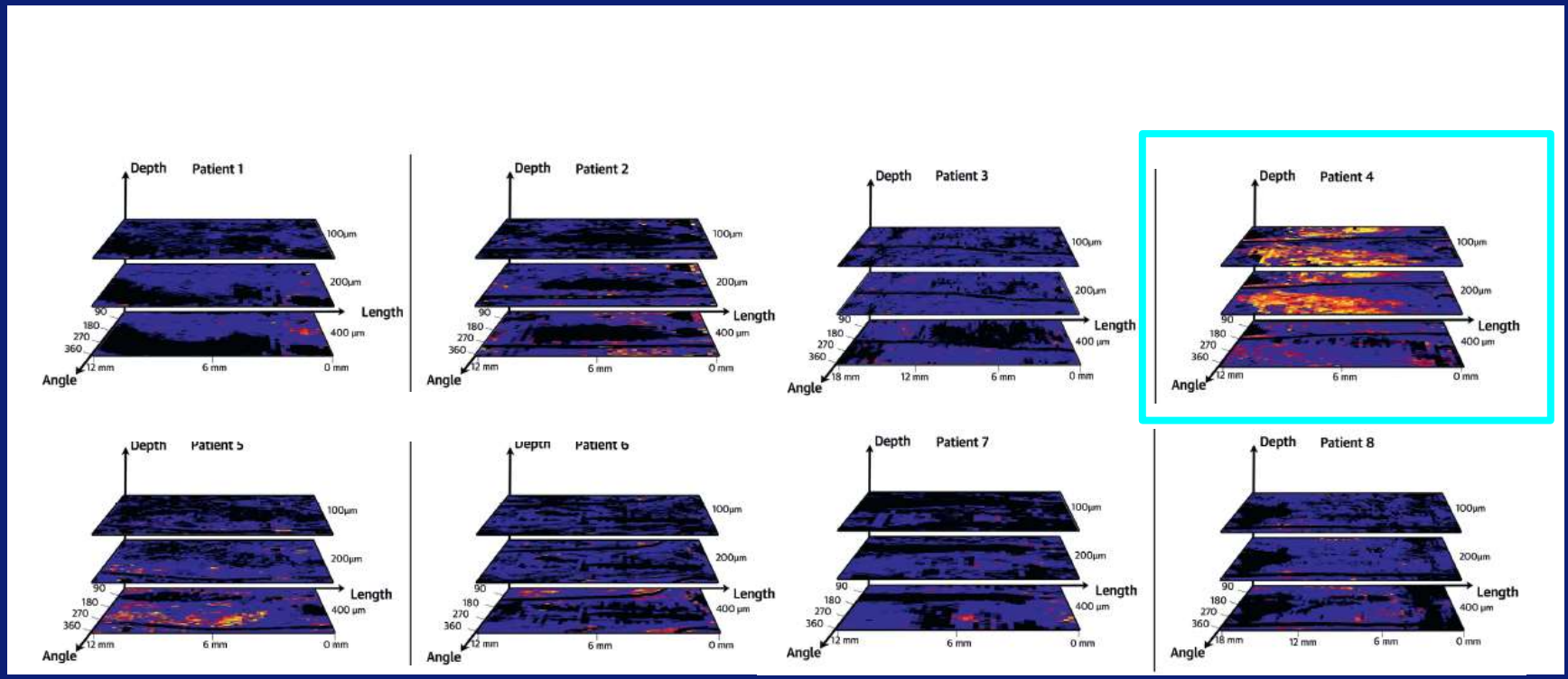


Karanasos A et al. JACC 2014

BVS ABSORB
Effect on Plaque Morphology – More details?

Erasmus MC Zafung

BVS 1.0 (ABSORB A)
OCT Attenuation Imaging



Karanasos A et al. JACC 2014

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Effect on Plaque Morphology – More details?

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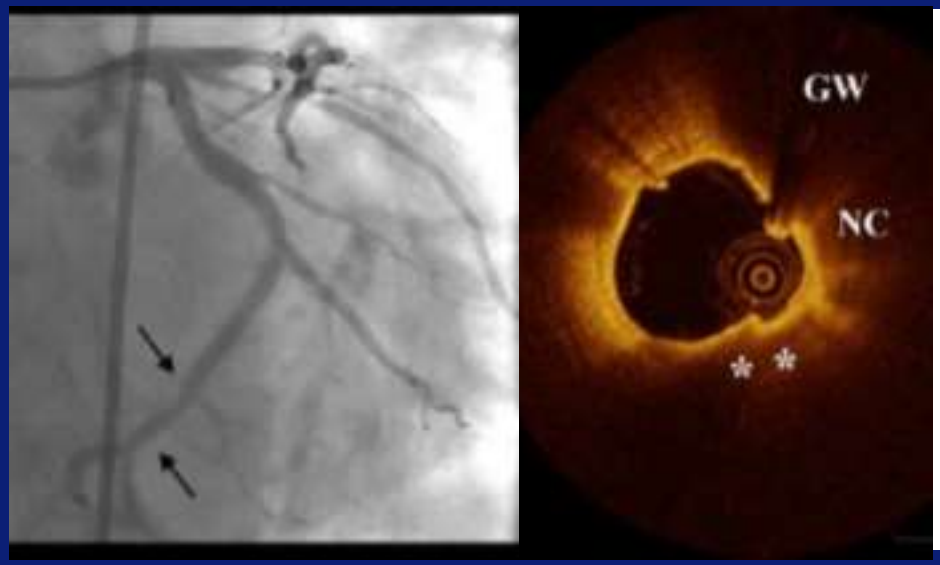
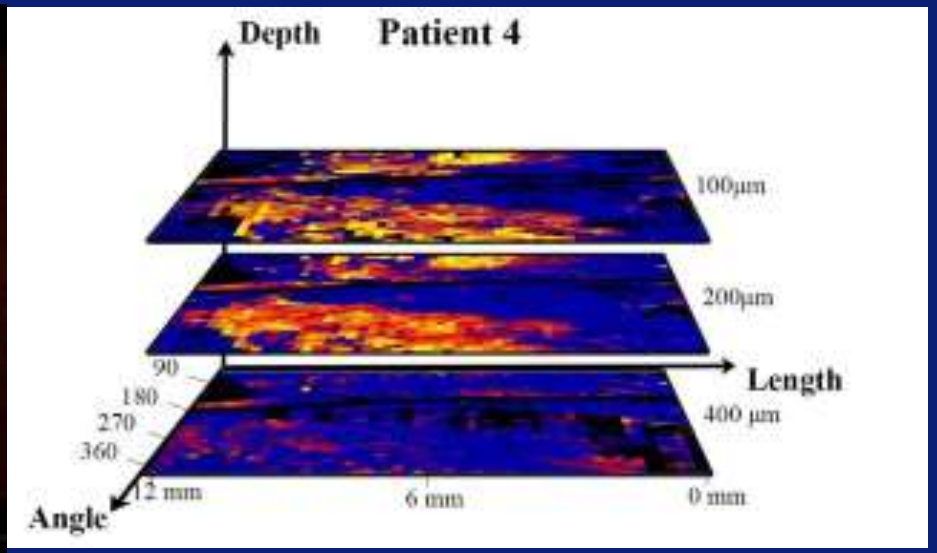
OCT Attenuation Imaging



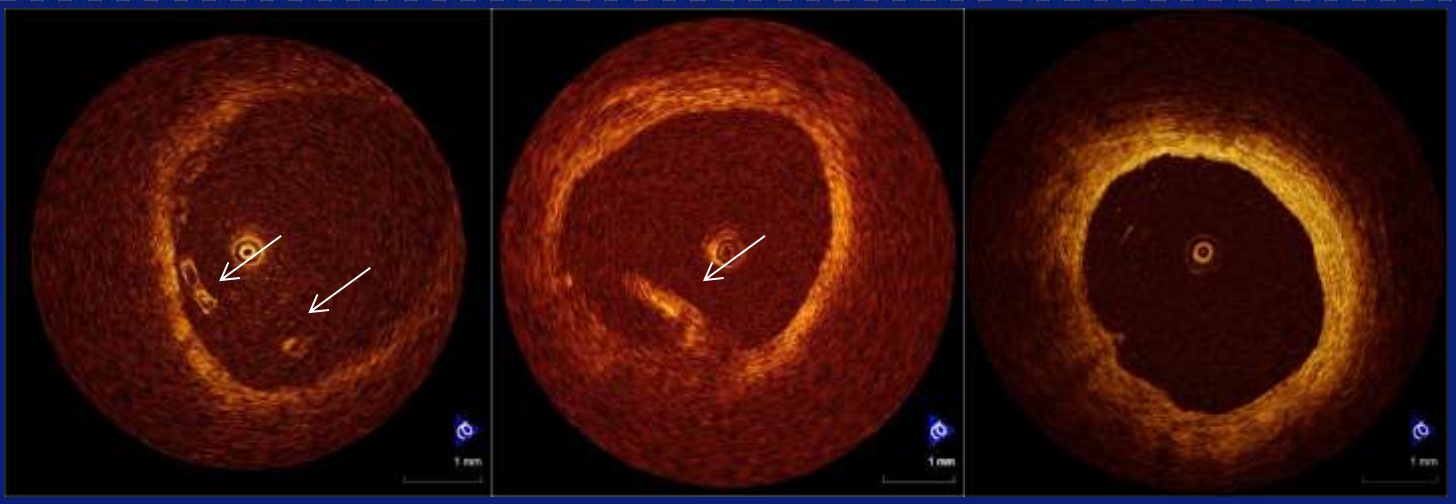


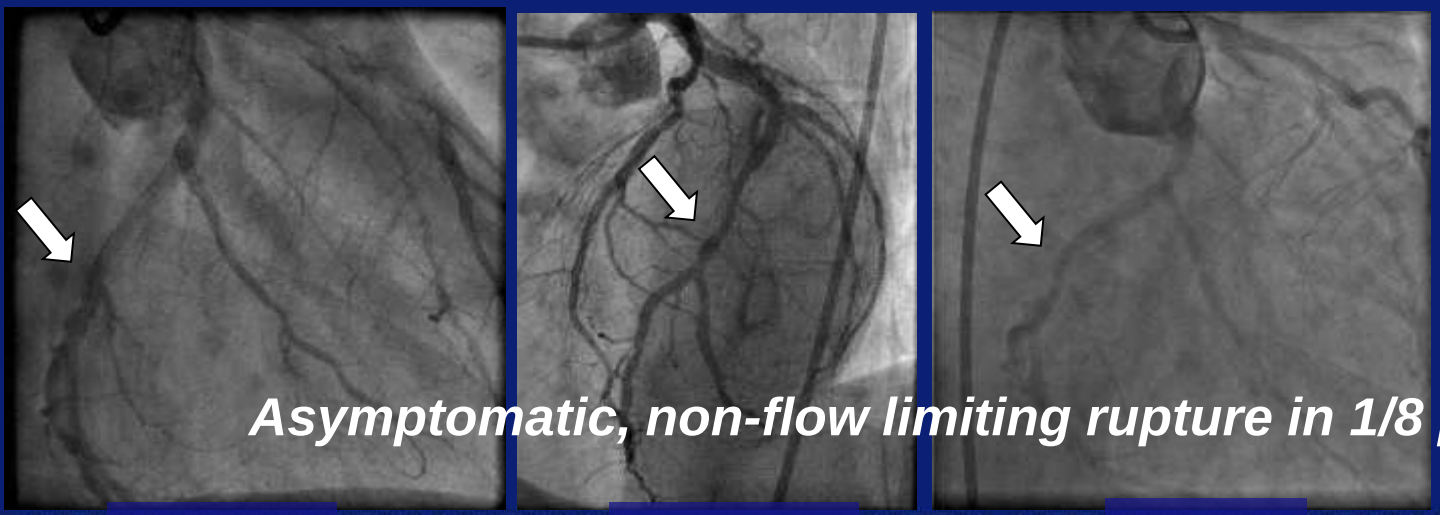
Asymptomatic, non-flow limiting rupture in 1/8 pts

Karanasos A et al. JACC 2014

BVS ABSORB

Effect on Plaque Morphology – More details?





Asymptomatic, non-flow limiting rupture in 1/8 pts

Baseline | 6 months | 2 years

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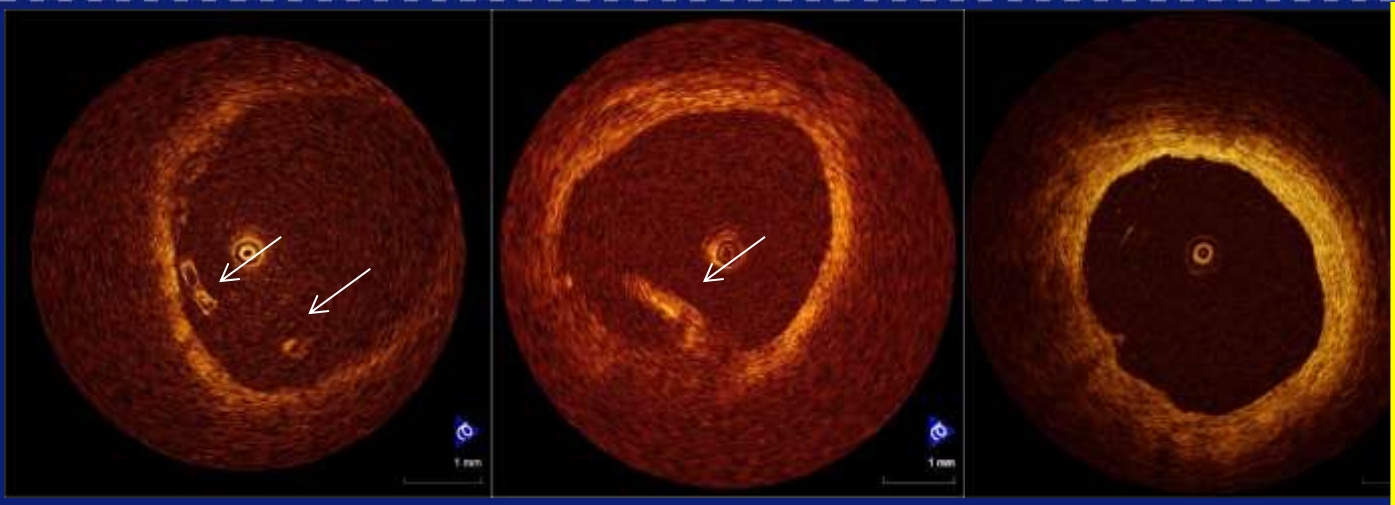
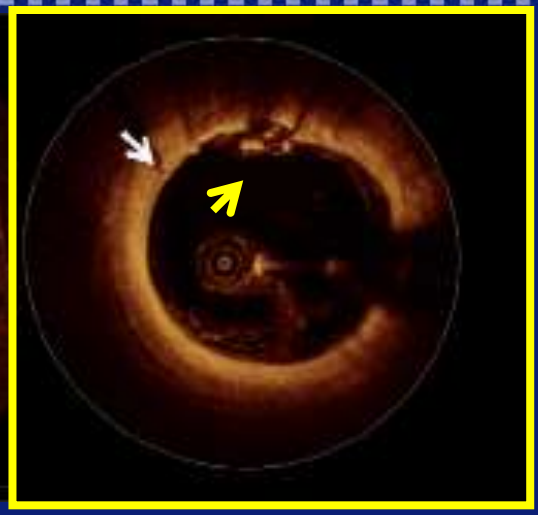
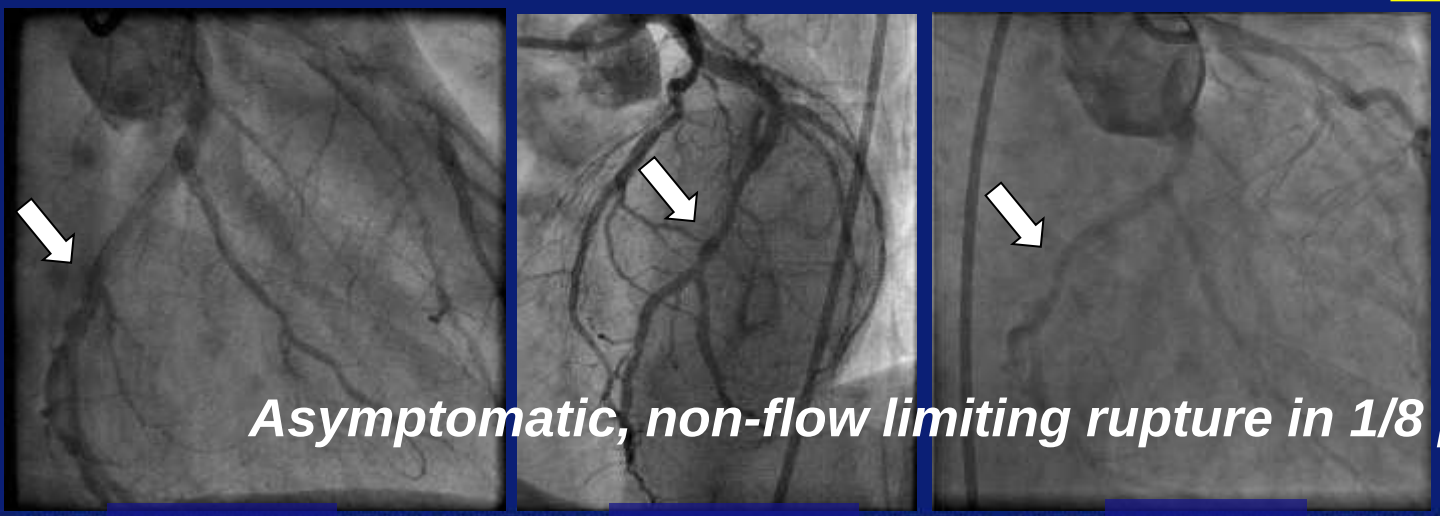
Effect on Plaque Morphology – More details?







Garcia Garcia HM et al. EuroIntervention 2013

Asymptomatic, non-flow limiting rupture in 1/8 pts

Baseline **6 months** **2 years** **5 years**

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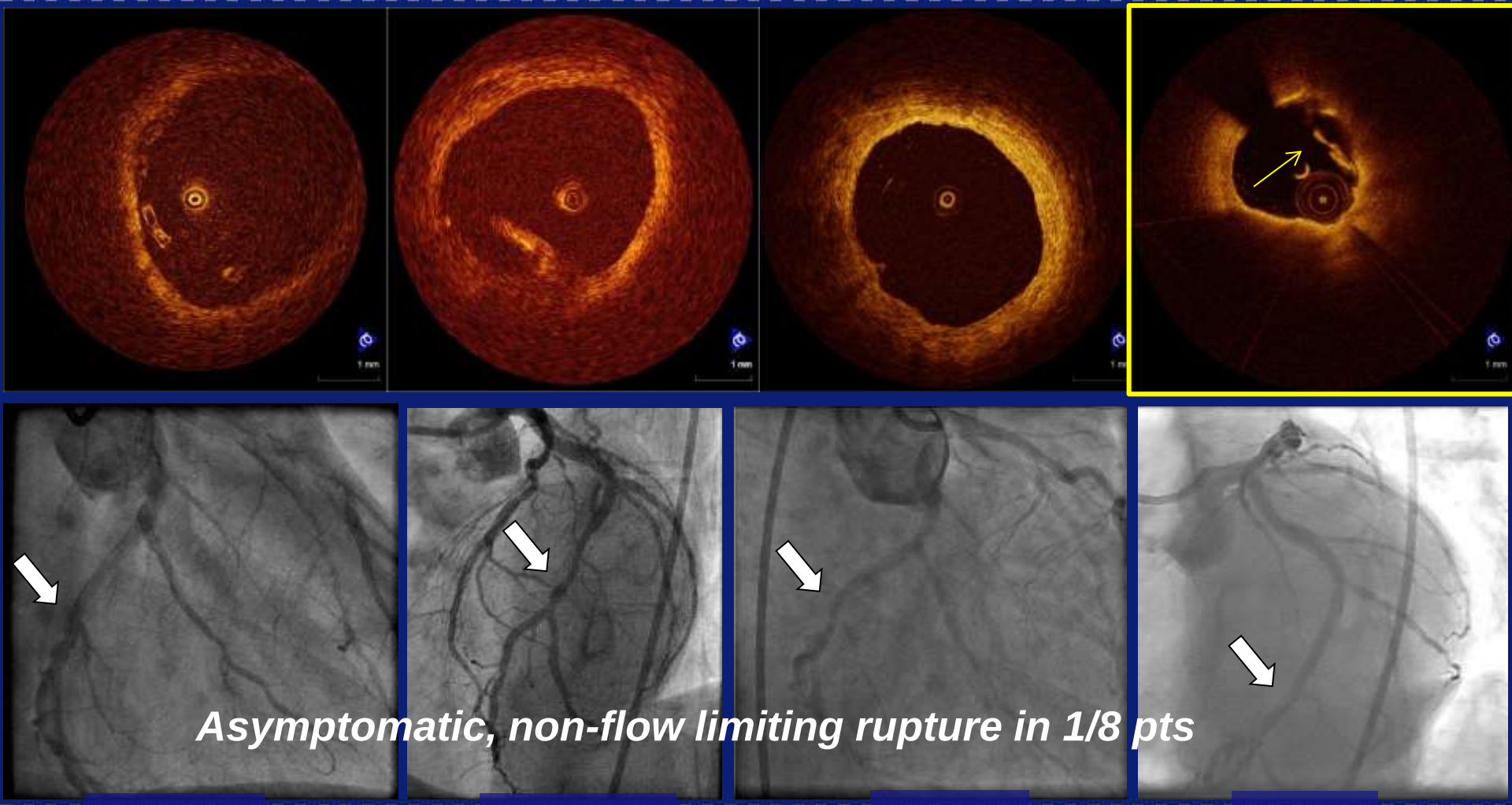
Effect on Plaque Morphology – More details?



Asymptomatic, non-flow limiting rupture in 1/8 pts

Baseline | 6 months | 2 years | 6 years

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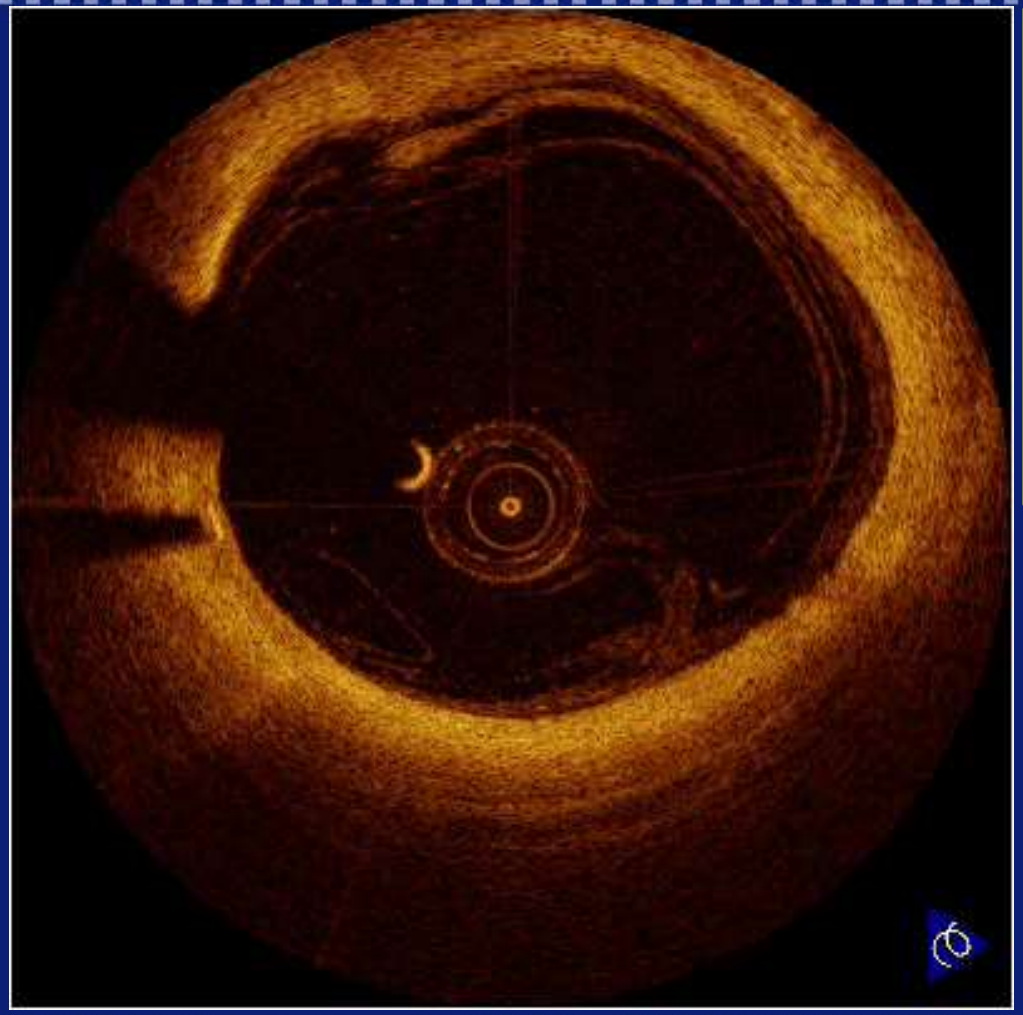
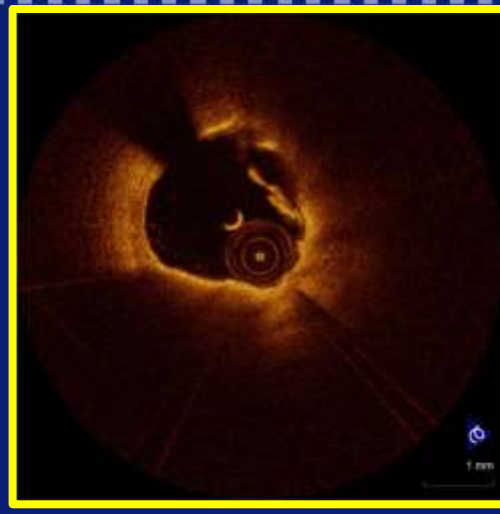
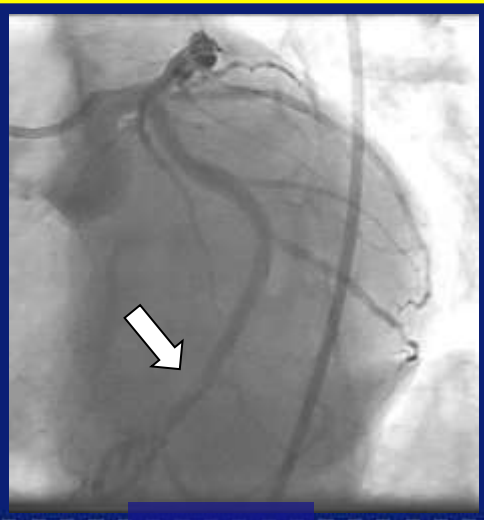
Effect on Plaque Morphology – More details?







6 years

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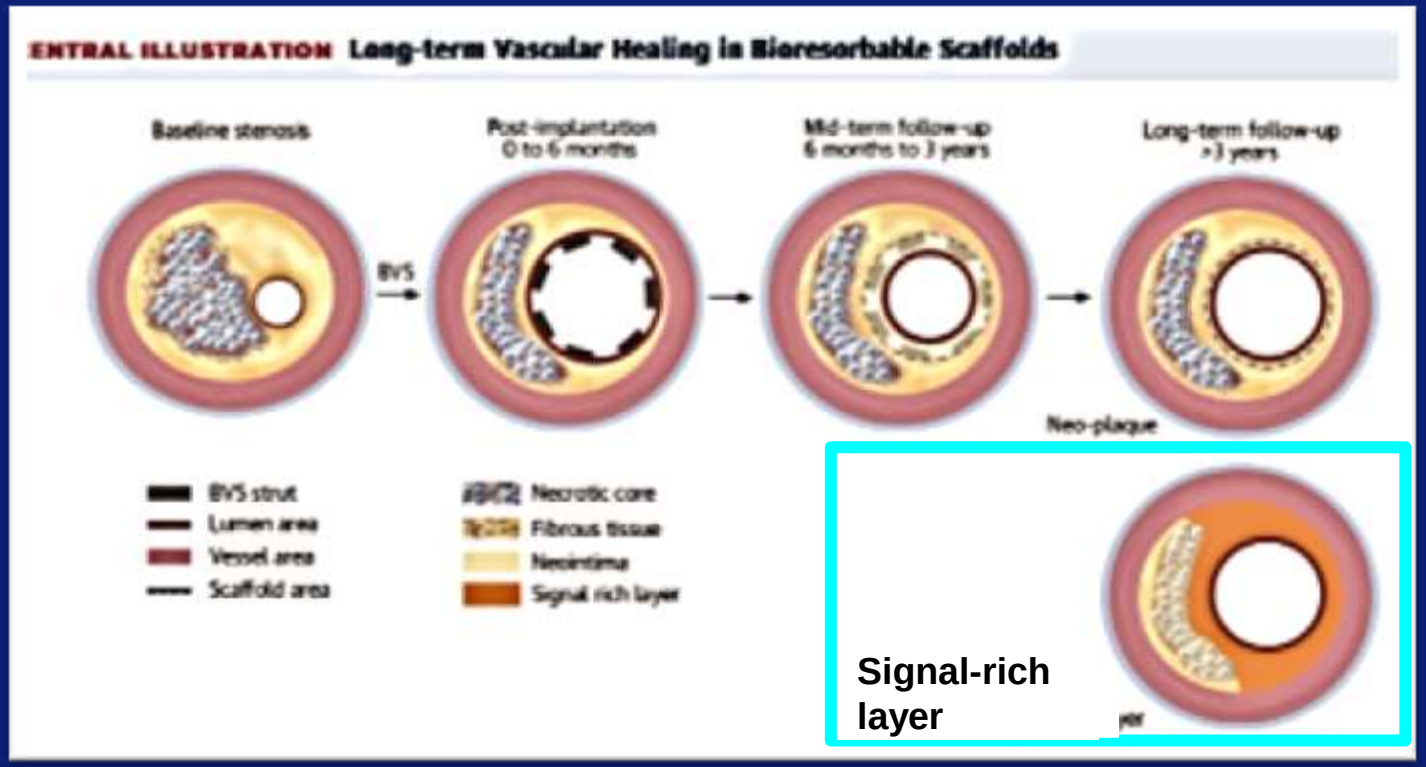
Effect on Plaque Morphology

Plaque composition & architecture can be modified.



Karanasos A et al. JACC 2014

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Effect on Plaque Morphology

- Both studies, Absorb Cohort A and Cohort B, show favourable effects on plaque morphology at 5 year follow-up:

- Complete bioresorption of BVS, with the formation of neoplaque and a sealing layer, which shows homogenous, low attenuating appearence in the majority of patiens.
- Stable lumen area between 2 years and 5 years
- Reduction in plaque area and vessel area.

- These results need to be interpreted with caution in light of the small number of patients and simple lesions.
- The observation of asymptomatic plaque rupture warrants further attention.

Thank you for your attention!

PhD Students

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- *J. van der Sijde*

Interventional Cardiology

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- *N. van Mieghem*
- *J.Daemen*
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