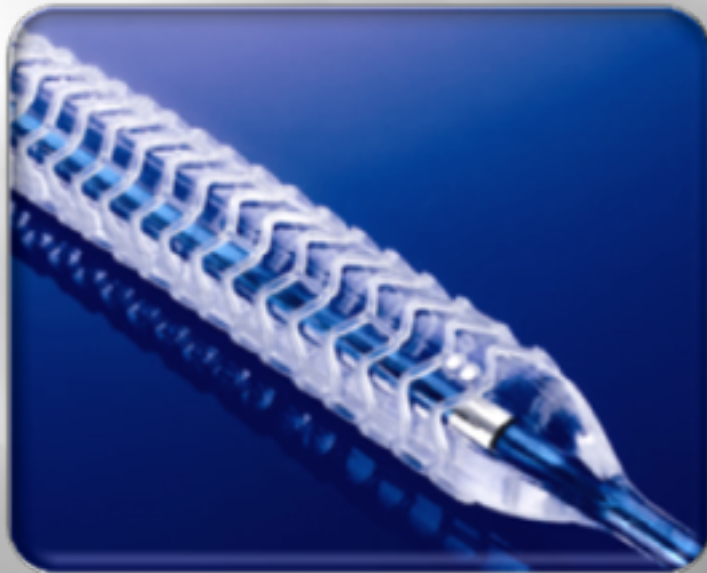


# **ABSORB Bioresorbable Vascular Everolimus Scaffold (BVS)**

## **in Complicated Coronary Intervention**

### **----Experiences from Macao**



生物可降解依维莫司聚乳酸模架在复杂冠脉中的运用-澳门经验

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# Revolutions in Interventional Cardiology

## Revolution One

Balloon Angioplasty  
(PTCA)



1977

## Revolution Two

Bare Metal Stents  
(BMS)



1988

## Revolution Three

Drug Eluting Stents  
(DES)



2001

## Revolution Four

Bioresorbable  
Stent



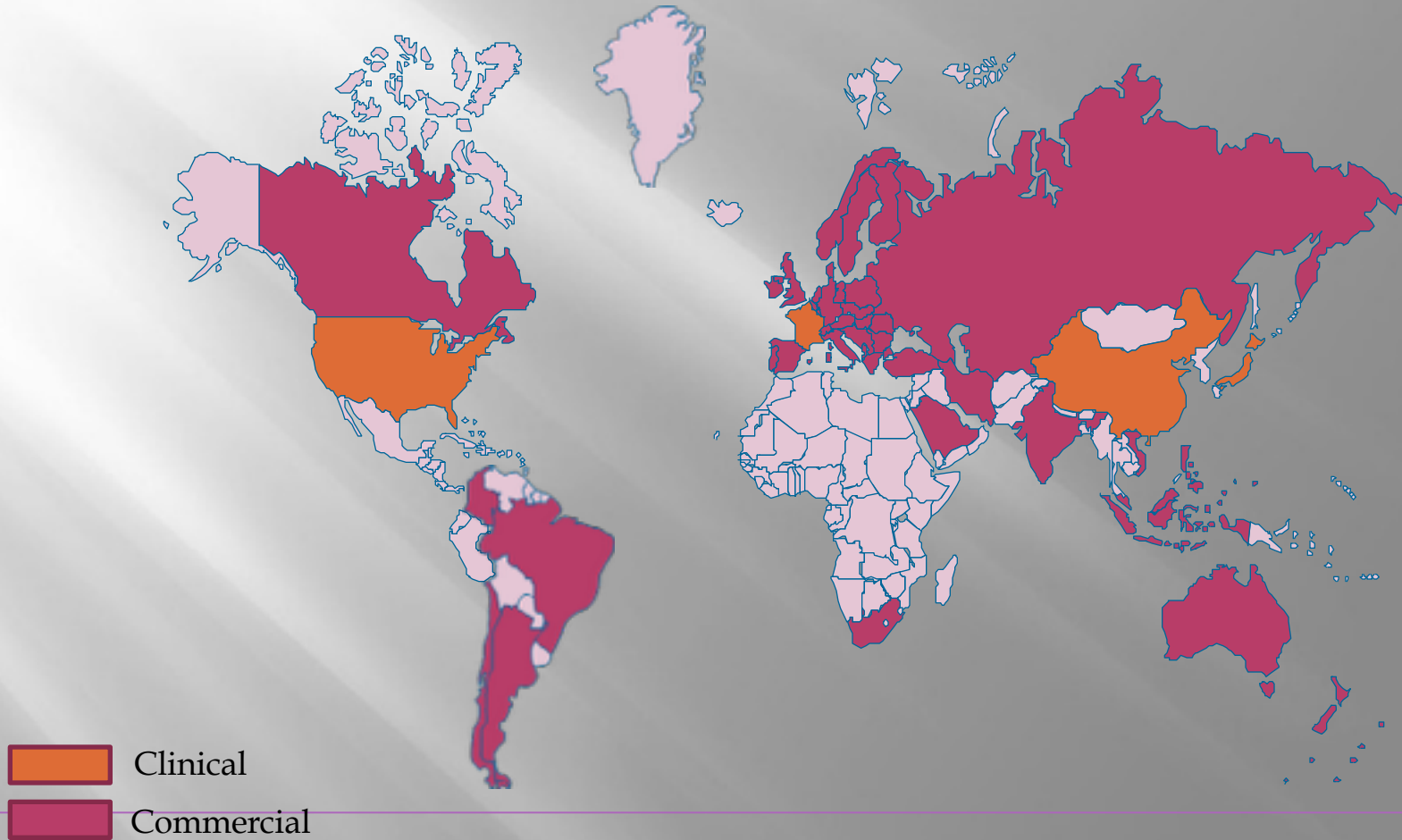
2011

## Revolution Four

ABSORB Bioresorbable Vascular Scaffold (BVS)



# Absorb Worldwide Exposure by End of 2013

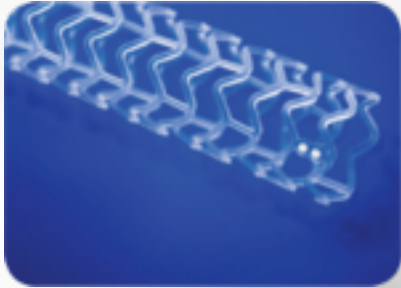


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# Characteristics of BVS

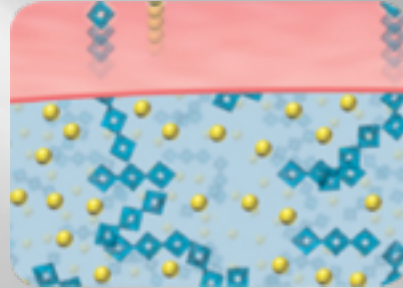


# BVS System Components



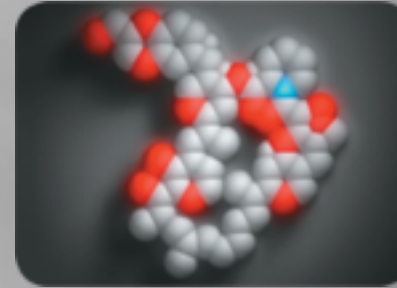
## Bioresorbable Scaffold (PLLA)

- Poly(L-lactide)
- Naturally resorbed, fully metabolized
- Fully resorbed in about 2 years



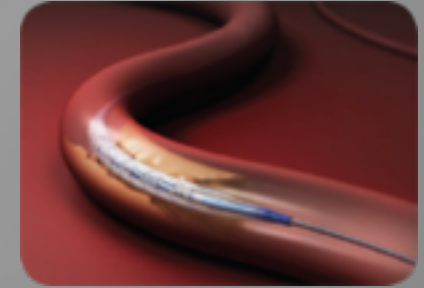
## Bioresorbable Coating (PDLLA)

- Poly(D,L-lactide)
- Naturally resorbed, fully metabolized



## Everolimus

- Similar dose density and release rate to XIENCE V

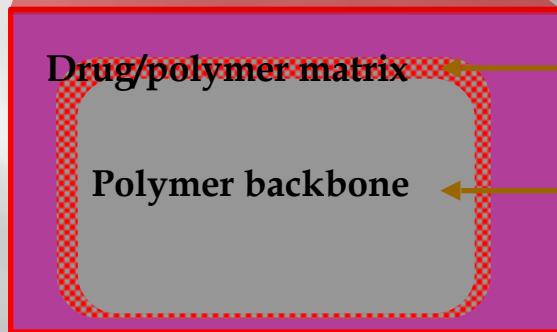


## XIENCE Delivery System

- World-class deliverability



# Bioresorbable Scaffold (PLLA) plus Bioresorbable Coating (PDLLA)



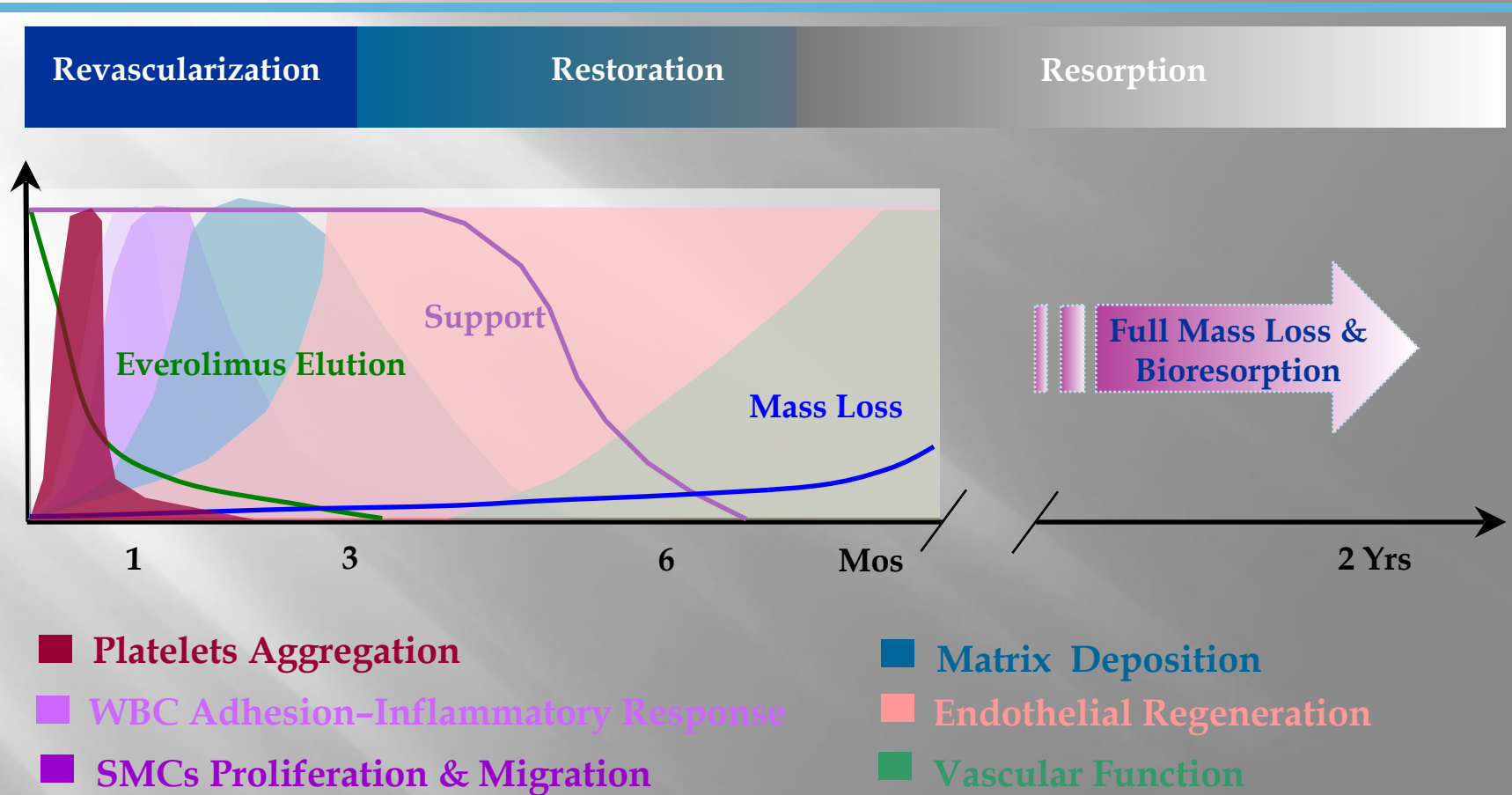
## Everolimus / PDLLA Coating

- Non-crystalline
- Everolimus: PDLLA = 1 : 1
- Polymer coating with thickness of 2-4  $\mu\text{m}$
- Controlled drug delivery system

## PLLA Scaffold

- High crystallinity
- Guarantee integrity of the system
- Sufficient radical strength

# BVS: Phases of Functionality



Forrester JS, et al., *J. Am. Coll. Cardiol.* 1991; 17: 758.  
 Oberhauser JP, et al., *EuroInterv.* 2009; 5: F15.



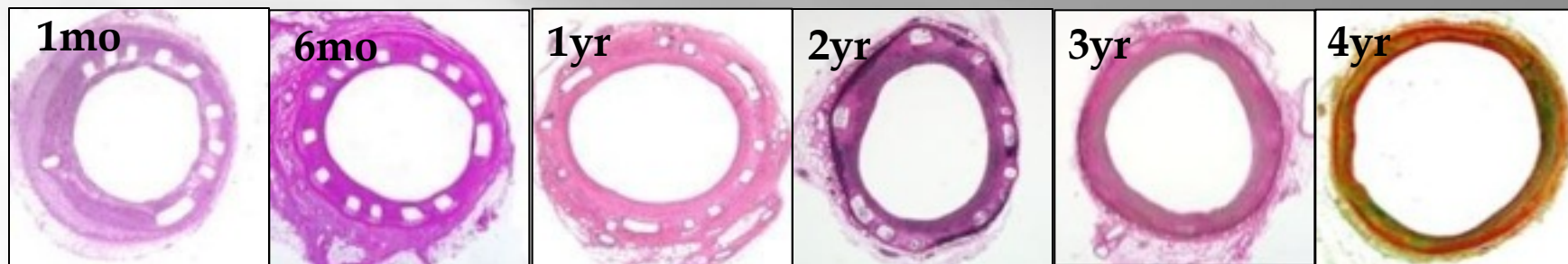
# Stent Feature Matrix

	Bare-Metal Stents	Drug-eluting Stent	Bioabsorbable drug-eluting Stent
Reduced Dual-Antiplatelet Therapy	✓	✓	✓
No neointimal hyperplasia		✓	✓
Restoration of Vasomotion			✓
Material (Biocompatible)			✓

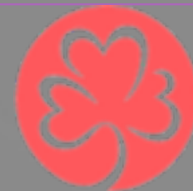
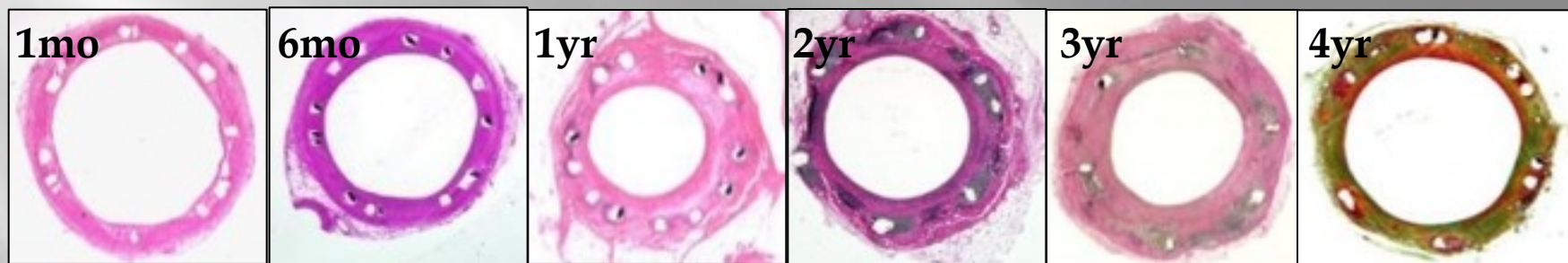


# Porcine Coronary Histologic Studies

## BVS (2X)

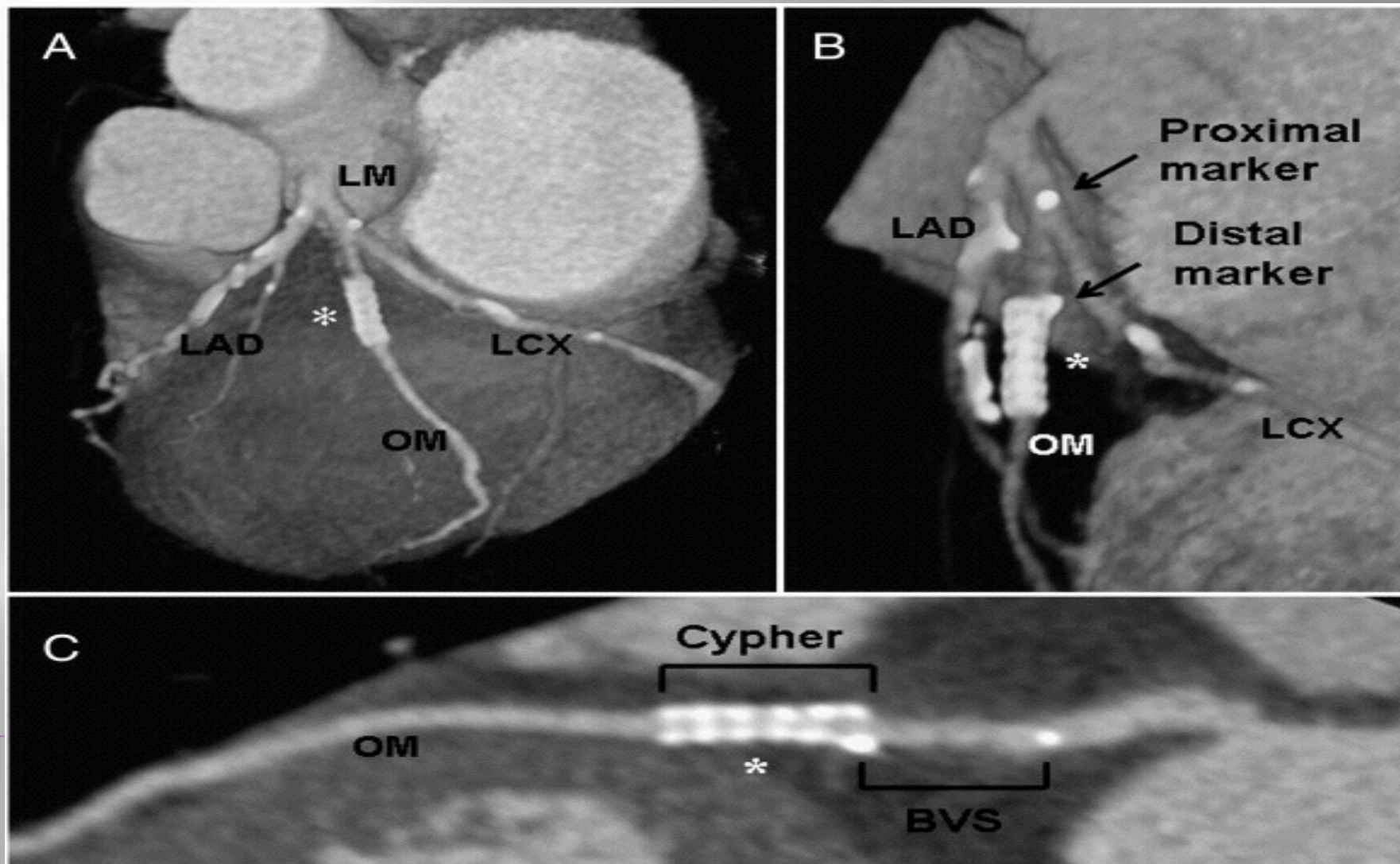


## CYPHER (2X)

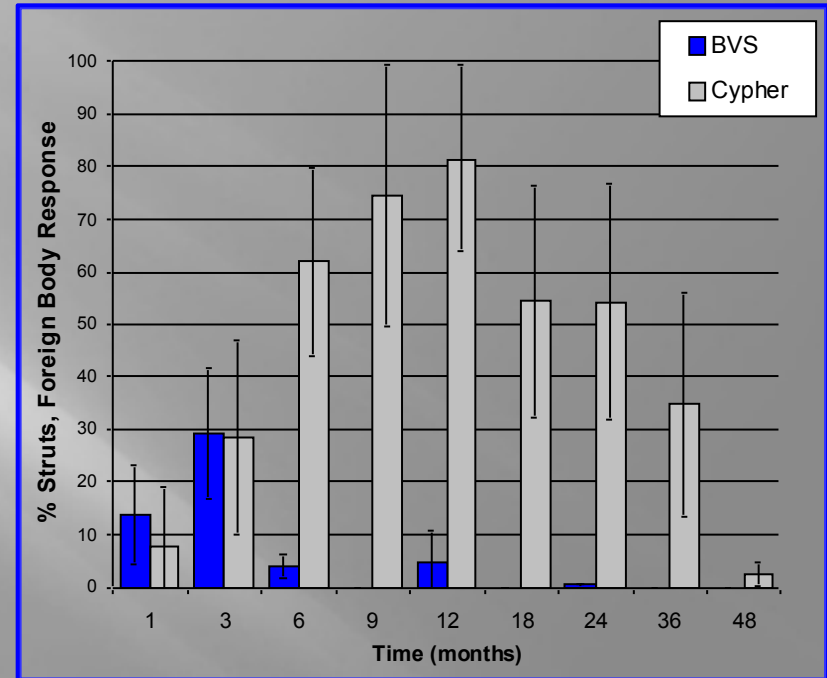
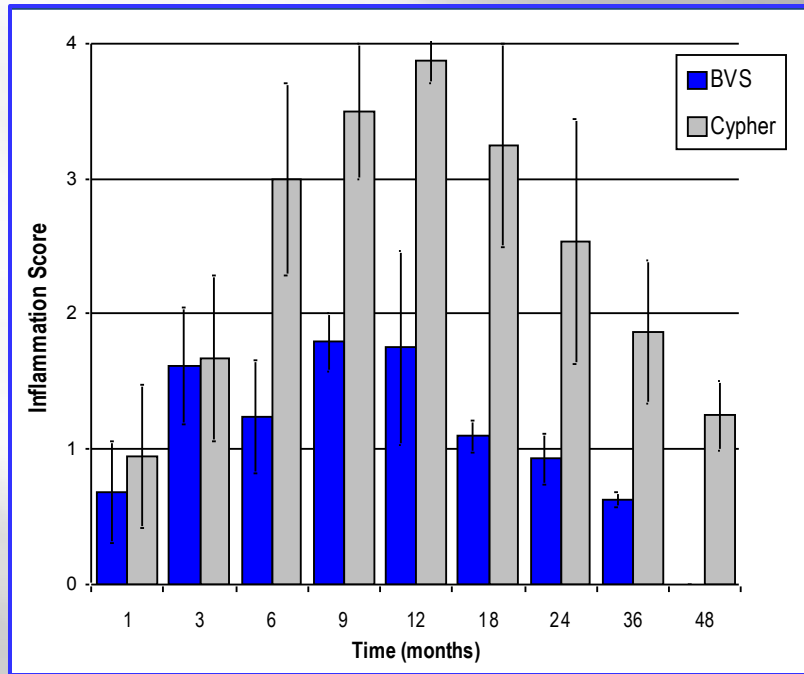


# BVS STENT

“Radio-lucent” and “radio-opaque” coronary stents characterized by multislice computed tomography



# Little vascular inflammatory response to BVS



**Weaker inflammatory response than Cypher**

**Inflammatory response can almost be ignored after one year.**

**Inflammation score  $\leq 1$  according to porcine coronary studies**

**Weak foreign body response (FBR) after implantation**

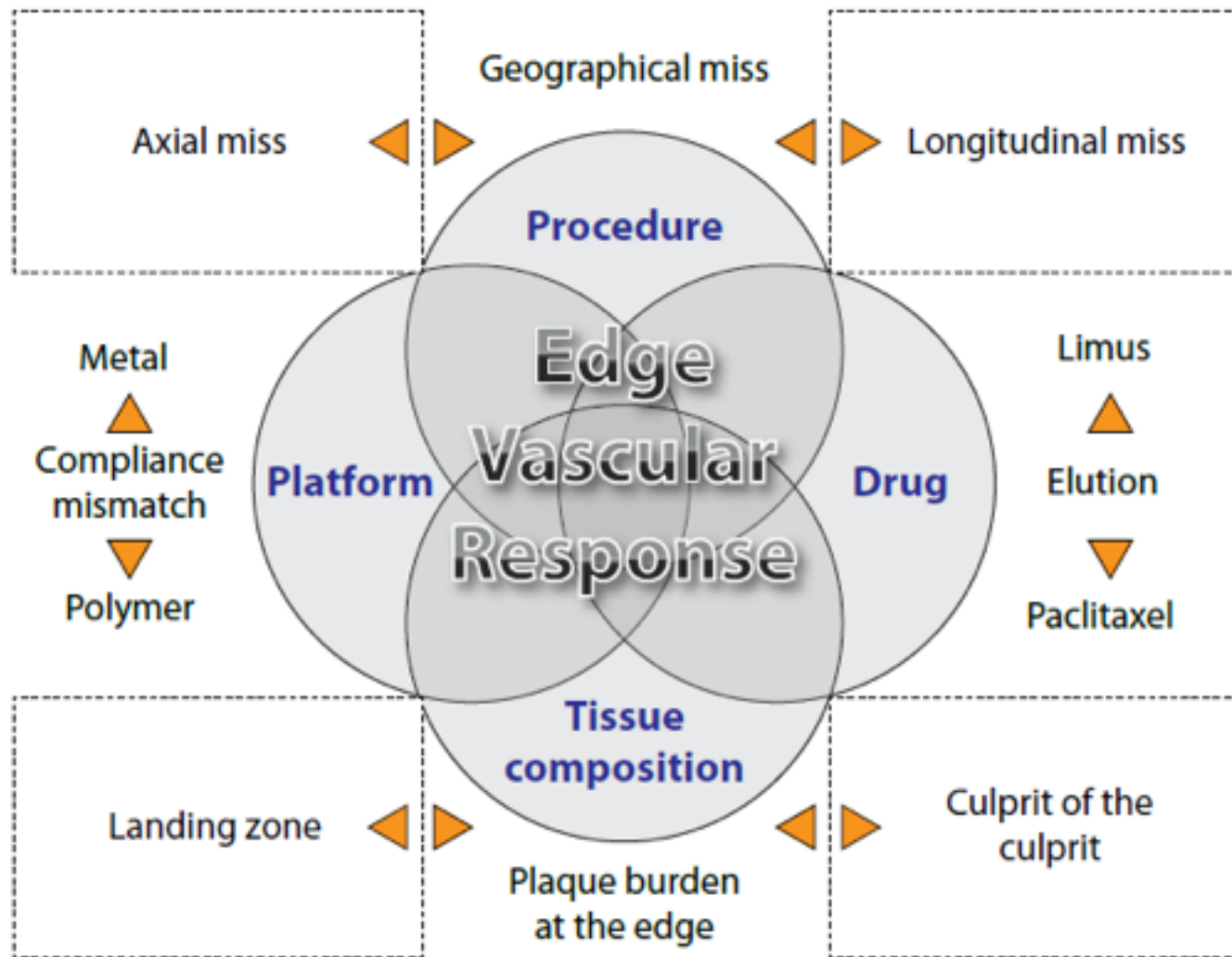
**FBR vanishes after 2yrs as BVS dissolves completely**

# Advantages of BVS

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- ▣ Vasomotion
- ▣ Arterial remodelling and late lumen enlargement
- ▣ Side branch jailing
- ▣ Conformability
- ▣ Edge vascular response
- ▣ Incomplete stent apposition





**Figure 6.** The edge vascular response as a consequence of iatrogenic, device-related and biologic factors.



# Patient Considerations for Initiating Therapy with a Fully BVS

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## Younger patients facing their first revascularization procedure

- ▣ Younger patients could potentially have a treated vessel that is restored to a more natural state; absence of a permanent metal stent leaves the vessel segment unconstrained, enabling it to respond to physiological demands
  - Potential for reducing the need for prolonged DAPT
  - Generally more active with the potential for greater benefit from a naturally functional vessel
  
- ▣ Younger patients may need future interventions that can be complicated or compromised by a permanent metal stent
  - Absence of a permanent implant may preserve more options for future interventions, whether PCI or CABG
  - CABG is also complicated by the presence of stents<sup>1-3</sup>
  - MSCT imaging may allow non-invasive determination of potential retreatment strategies

1. Yap CH, et.al. JACC Interv. 2009, 2: 758-764

2. Taggart DP. EuroIntervention. 2009,5: D21-D24

3. Thielmann, M. Circulation. 2006,114 (Suppl I): I441-I447



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# Clinical Trials

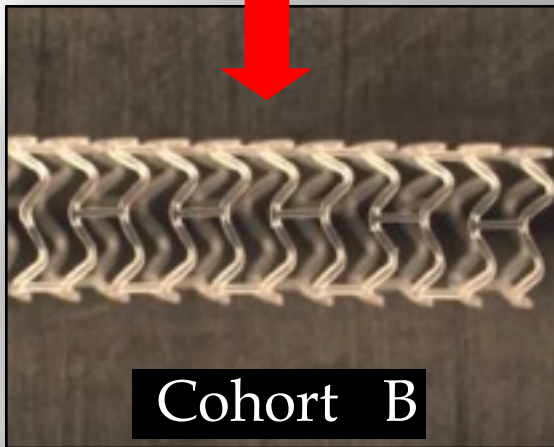
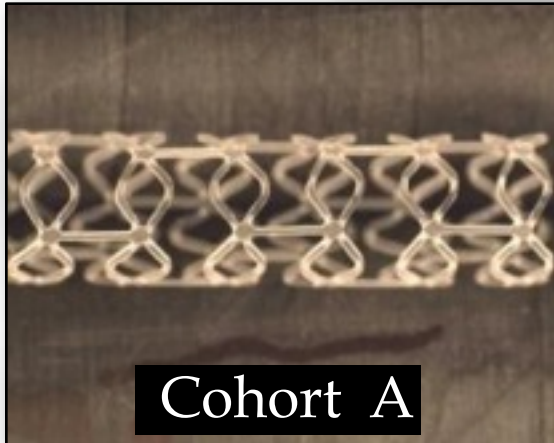


# The ABSORB Clinical Trial Program



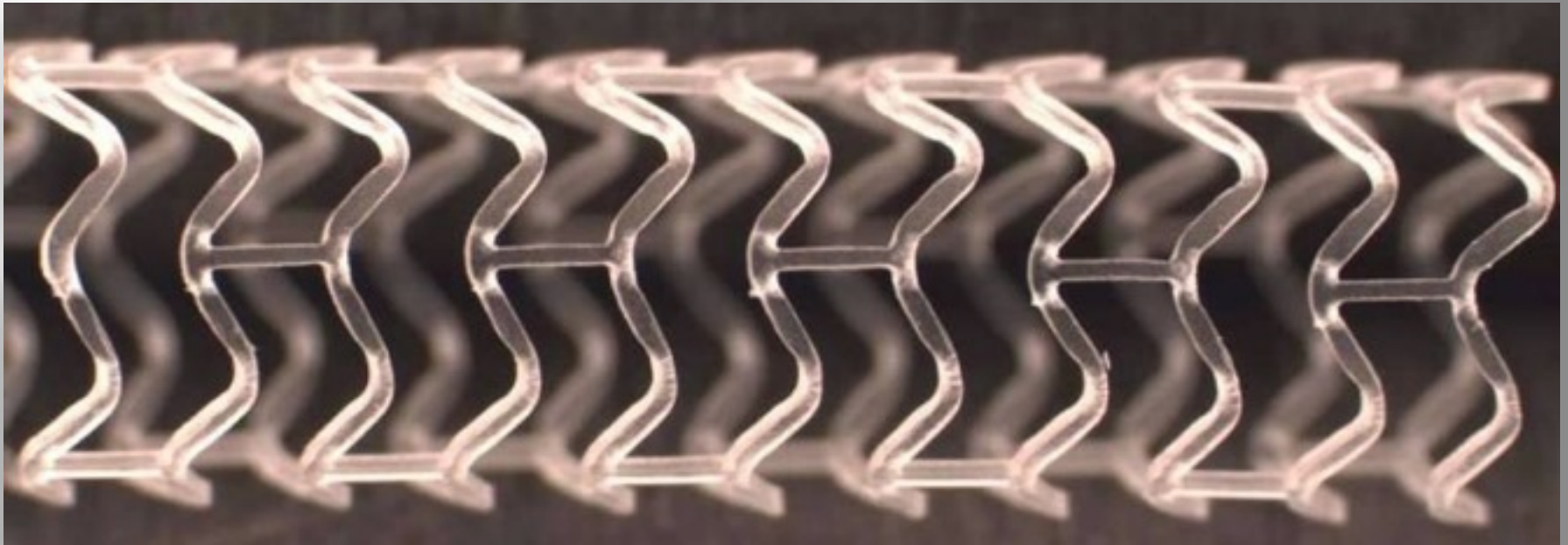
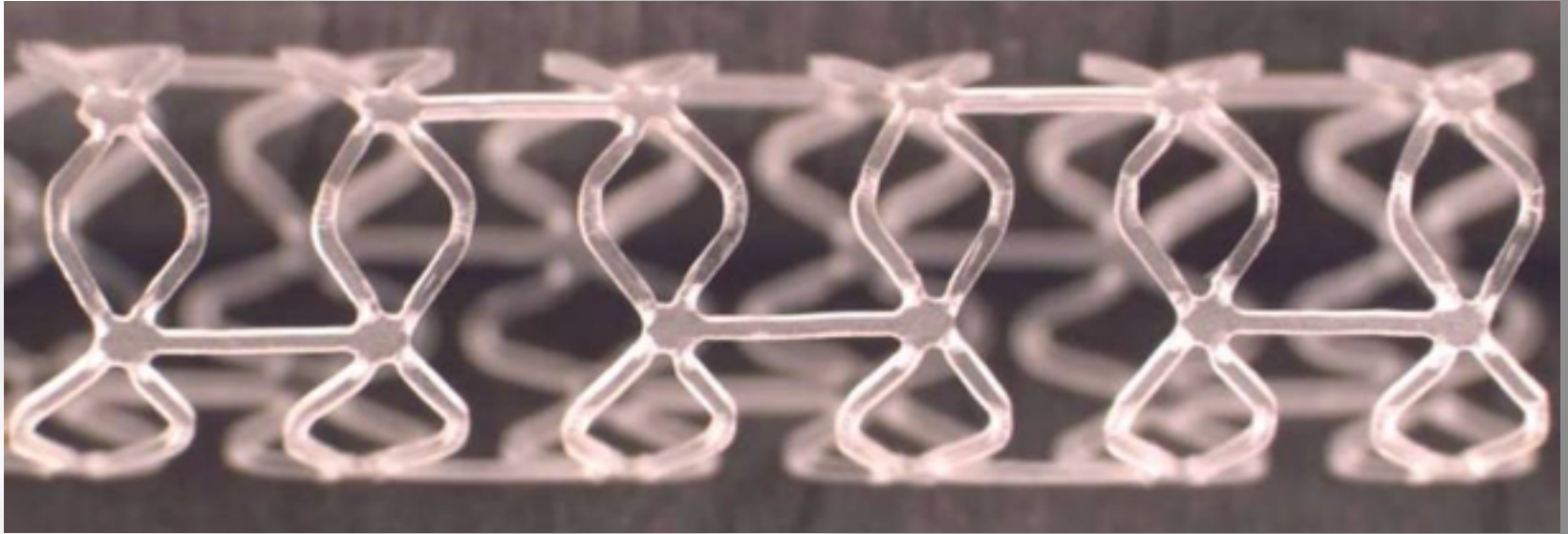


# Optimization of BVS design



Photos taken by and on file at Abbott Vascular.

- Uniform stent struts distribution
- More balanced vascular wall support
- Sufficient radial strength
- Lower late stent area loss
- Stored under indoor temperature
- Improved in controllability of delivery system
- Preserved:
  - Material of coating & backbone
  - Thickness of struts
  - Velocity of drug release
  - Time of complete absorption



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# Absorb Cohort A



Device ---- 3.0 x 12mm scaffolds  
(3.0 x18mm\* scaffolds available after enrolment start)