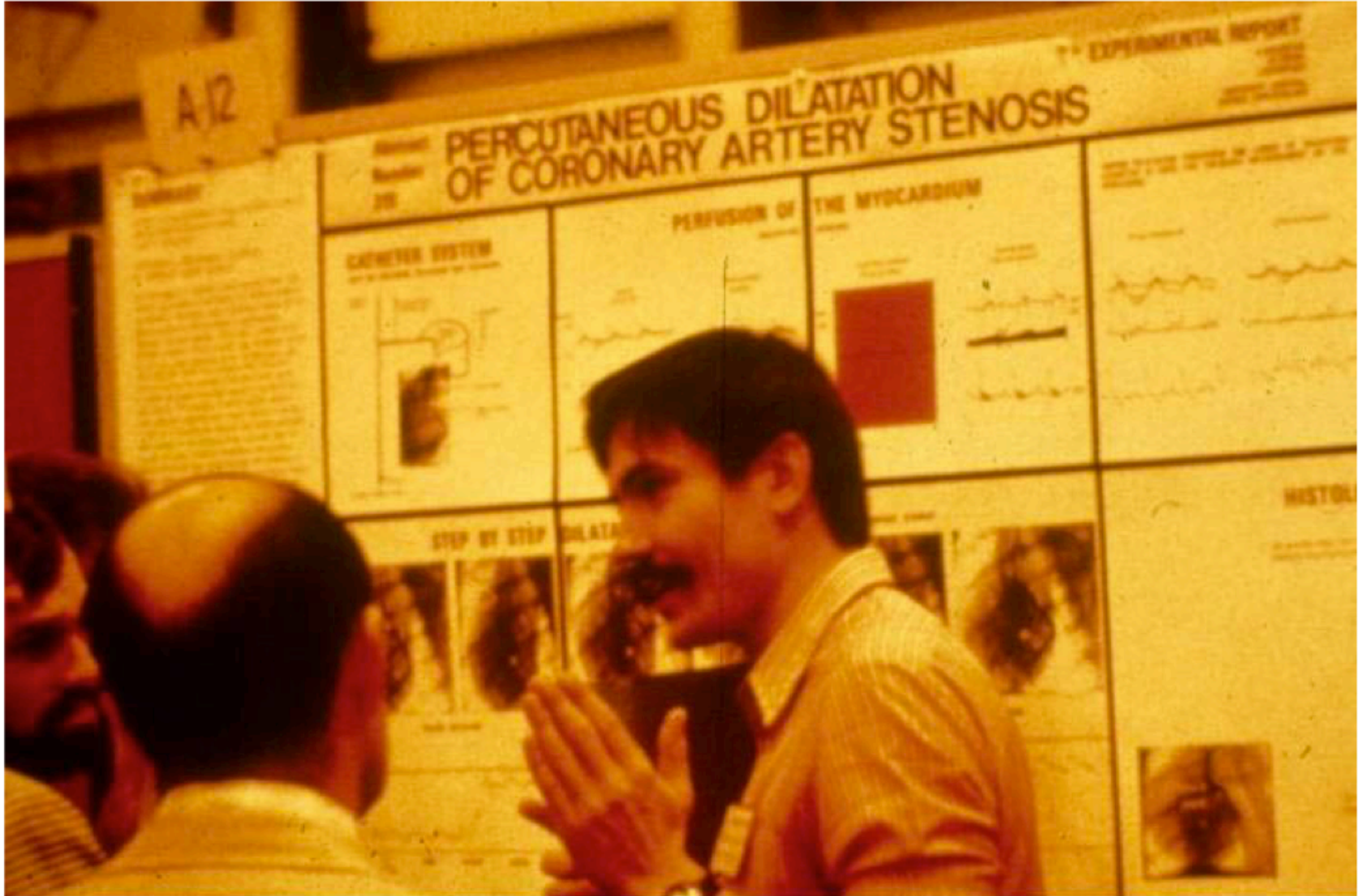


I HAVE A DREAM !

R. KONING - ROUEN - 2015

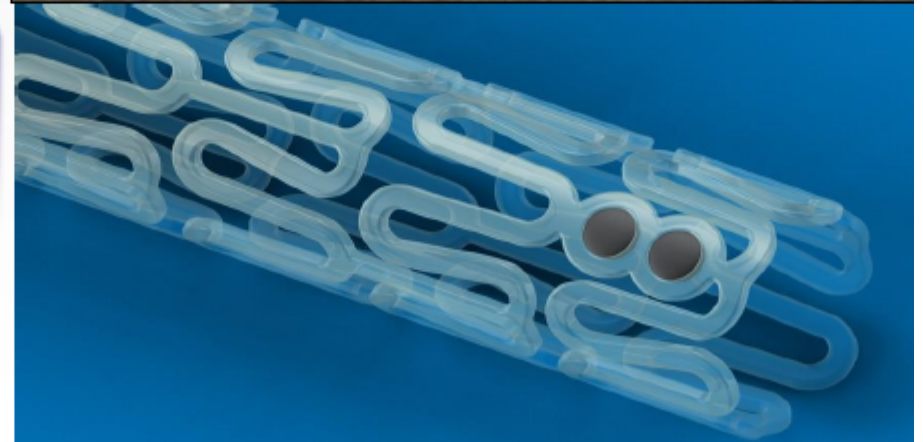
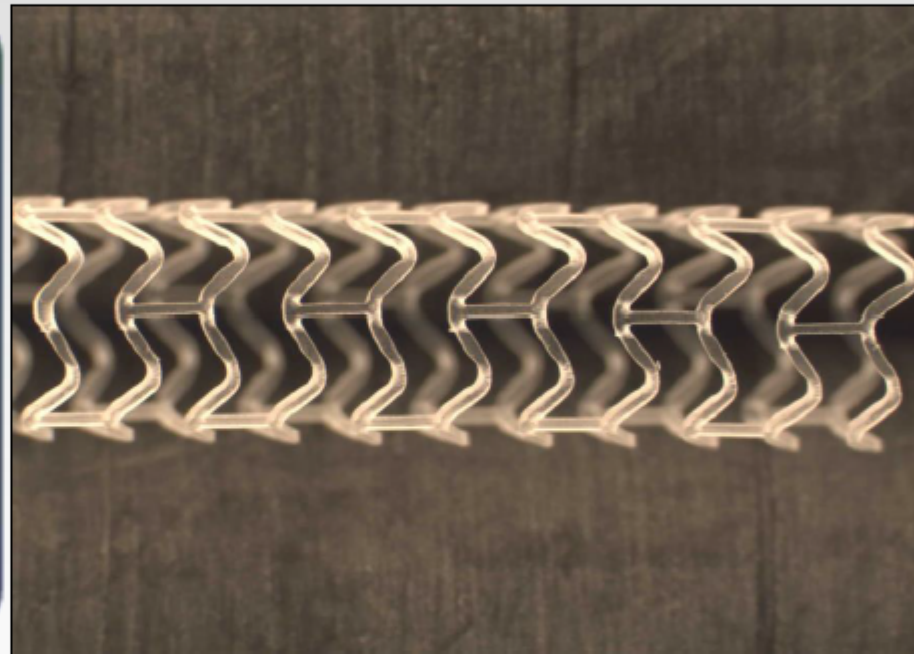
A. GRUENTZIG, AHA, 1977



STENT BIORESORBABLE



BVS is a balloon expandable, drug-eluting device with a backbone of poly-L-lactide coated with poly-D, L-lactide. Poly-D lactide backbone solidifies into a crystalline and amorphous phases with a strut thickness of 150 μm . The coating poly-D, L-lactide on the surface of BVS elutes slowly everolimus



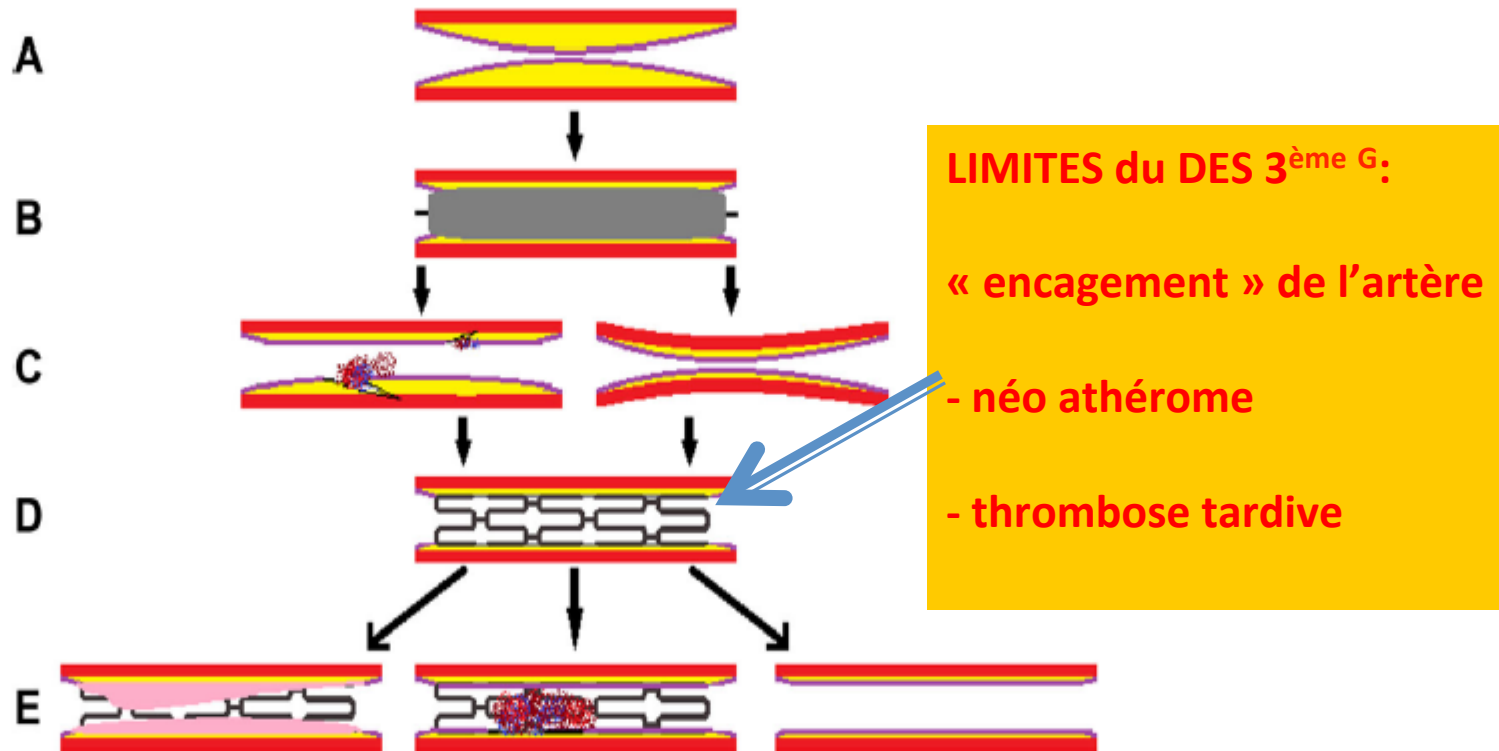


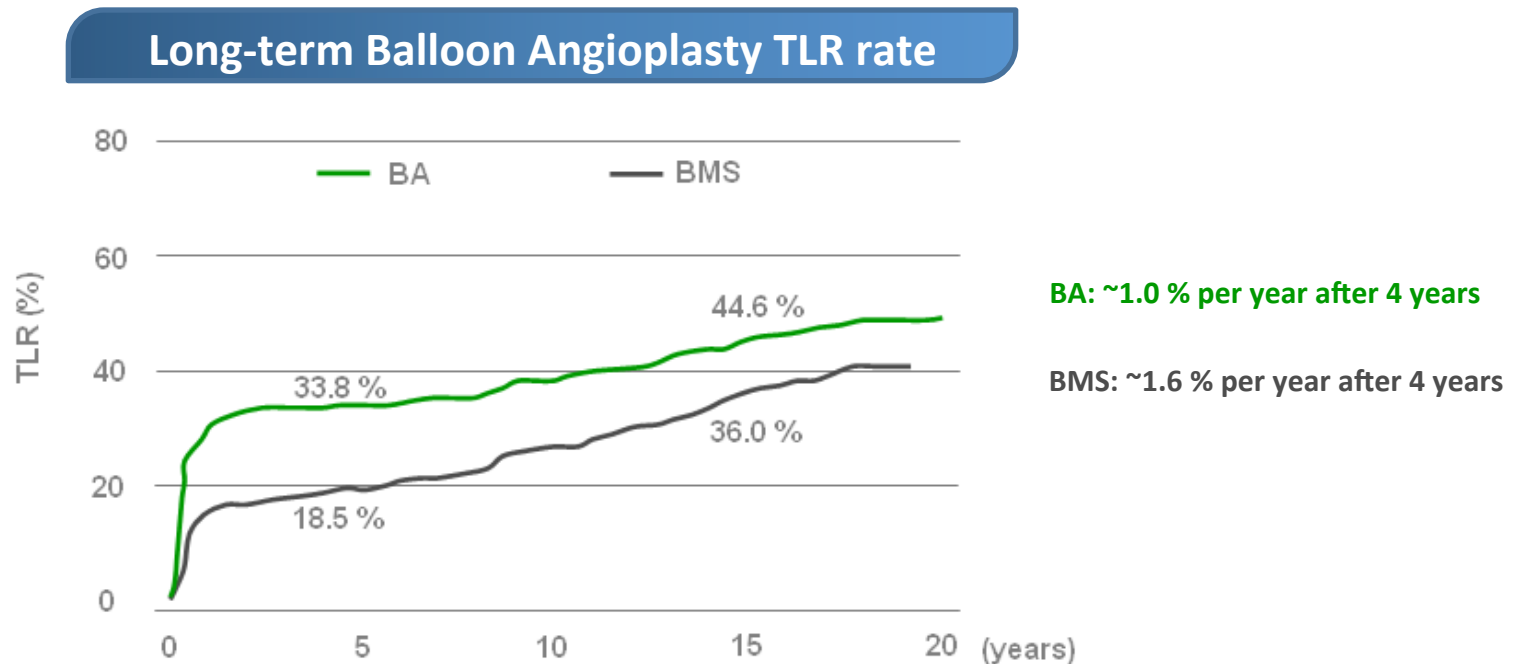
Fig. 1 Cartoon illustrating the major limitations of percutaneous coronary intervention (PCI) and potential benefit of metallic or polymeric bioresorbable scaffold (BRS). In **a**, there is a focal atherosclerotic lesion within a coronary artery. The lesion is treated with balloon angioplasty (**b**), which can result in intimal dissection with subsequent thrombus formation (**c, left**) or acute vessel recoil (**c, right**). The lesion can then be treated with placement of a bare metal stent (BMS), drug-eluting stent (DES), or BRS (**d**). In the case of BMS, restenosis remains a significant problem (**e, left**).

In the case of DES, the risk of restenosis is significantly reduced but stent thrombosis due to inadequate endothelialization remains a major concern (**e, center**). In the case of a BRS (**e, right**), the scaffold helps seal intimal dissection and prevent acute vessel recoil, but degradation of the scaffold prevents late stent thrombosis, and incorporation of antiproliferative drug within the biodegradable polymer helps prevent restenosis

POURQUOI UN STENT
BIORESORBABLE PLUTÔT
QU'UN
STENT ACTIF DERNIERE
GENERATION?

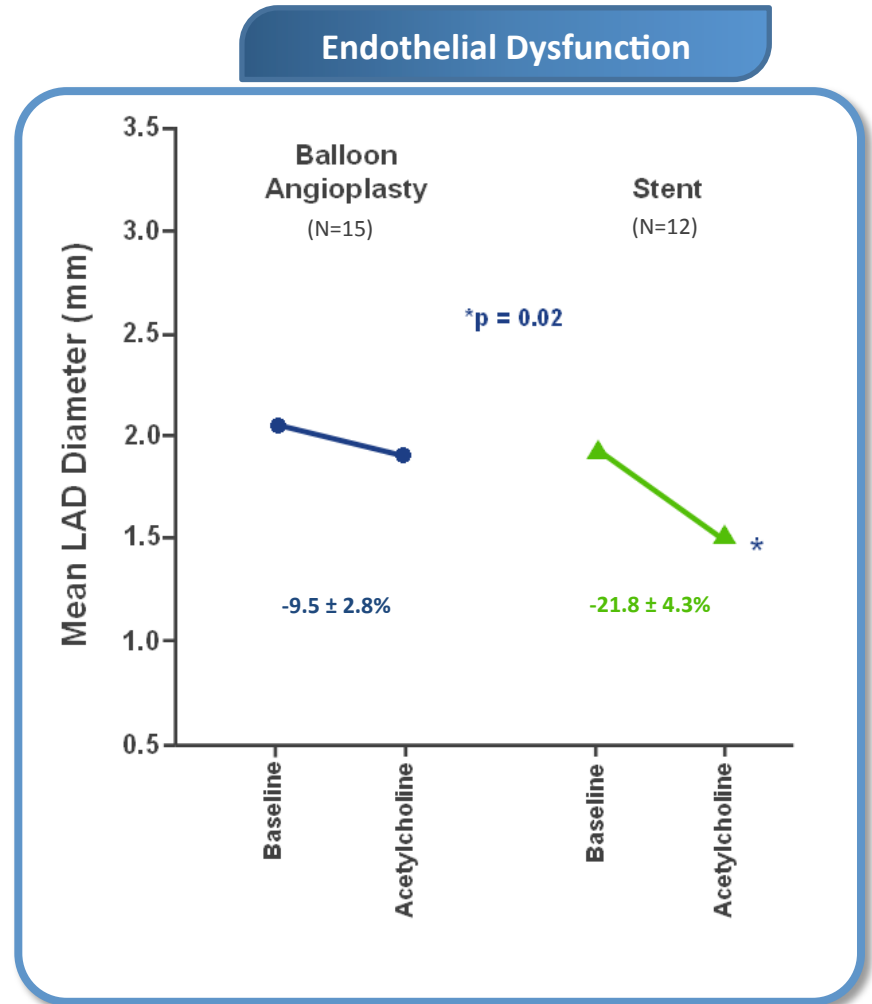
Impact of Late Disease Progression Following Balloon Angioplasty

- The cumulative incidence of late TLR beyond 4 years after balloon angioplasty (BA) tended to be lower than that after bare metal stent (BMS) implantation



Long-Term Endothelial Dysfunction After Coronary Stenting

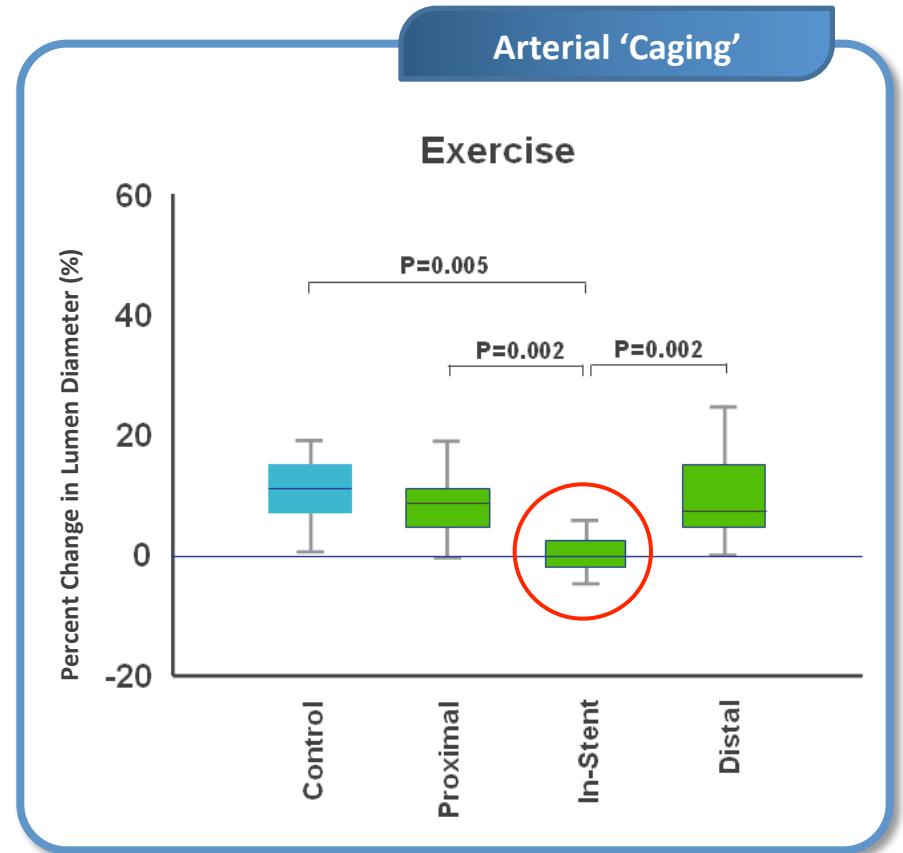
- More severe endothelial dysfunction is observed long term after stenting (BMS) as compared to balloon angioplasty in response to maximal intracoronary acetylcholine infusion¹



¹Caramori, P. et al. *J Am Coll Cardiovasc.* 1999; 34:1675-1679.

Impact of Stenting on Vascular Function

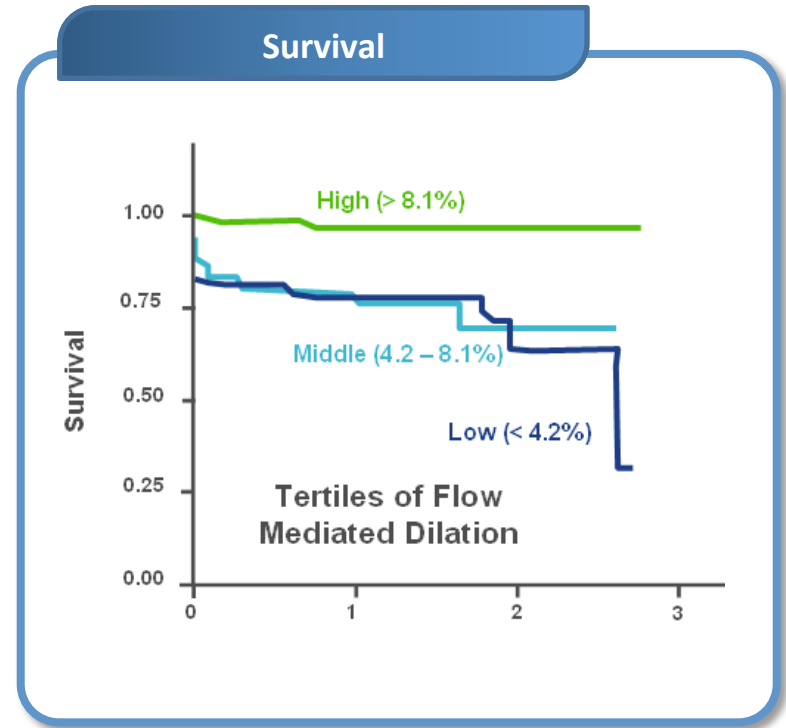
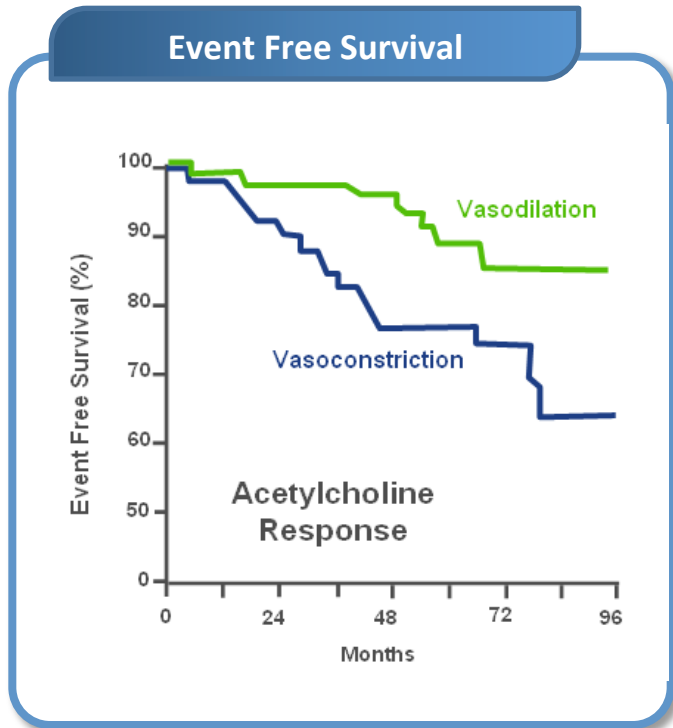
- Stenting abolishes vasomotor tone in the stented segment
- While normal vasomotor function was preserved proximal and distal to the stent in some studies¹; endothelial dysfunction has been seen in others²



Maier, W. et al. *Circulation*. 2002; 105:2373-2377.

¹Maier, W. et al. *Circulation*. 2002; 105:2373-2377. / ²Caramori, P. et al. *J Am Coll Cardiovasc*. 1999; 34:1675-1679.

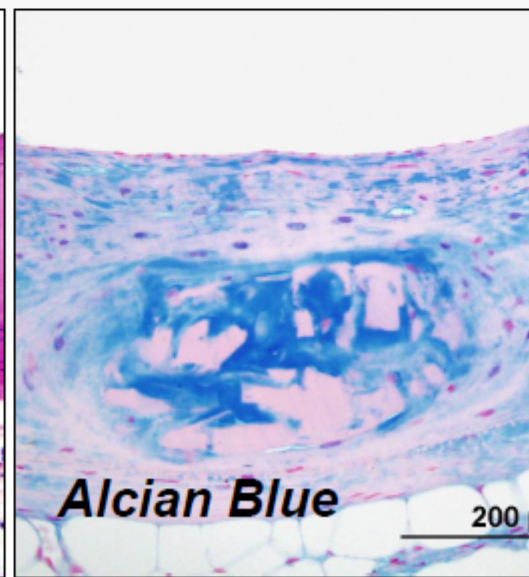
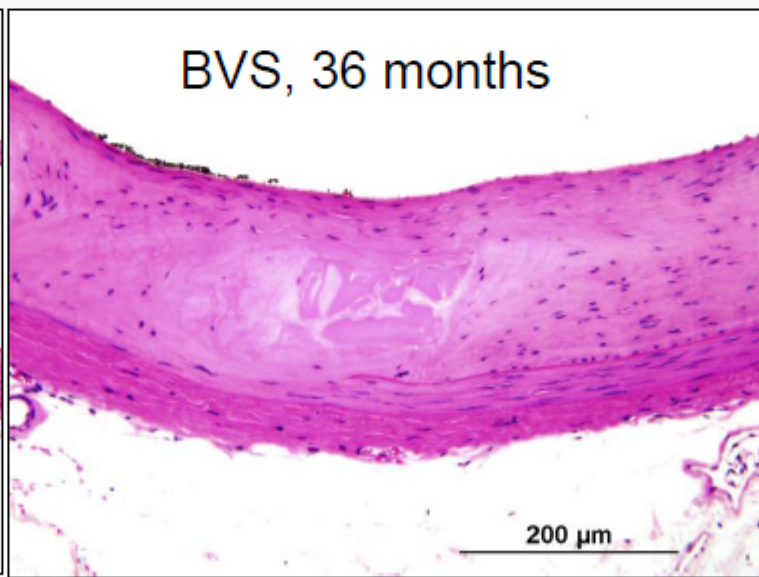
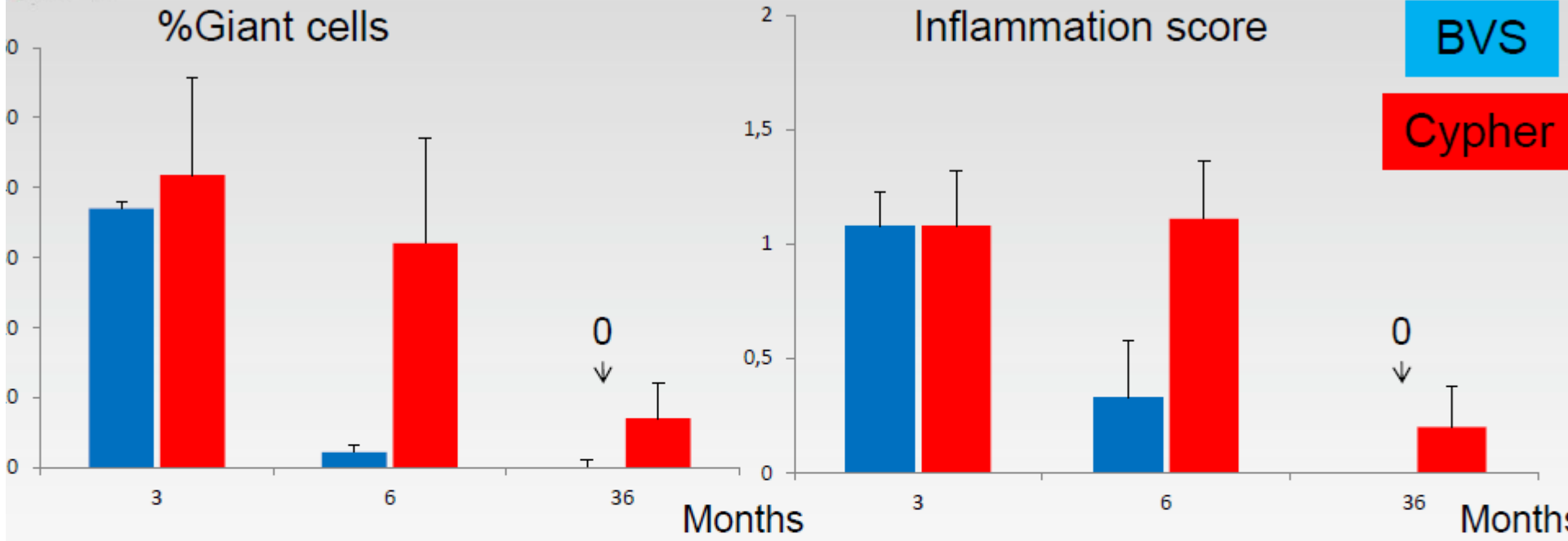
Impact of Endothelial Dysfunction on Long-Term Clinical Outcomes



Normal endothelial function is associated with improved survival and event-free survival compared with endothelial dysfunction.



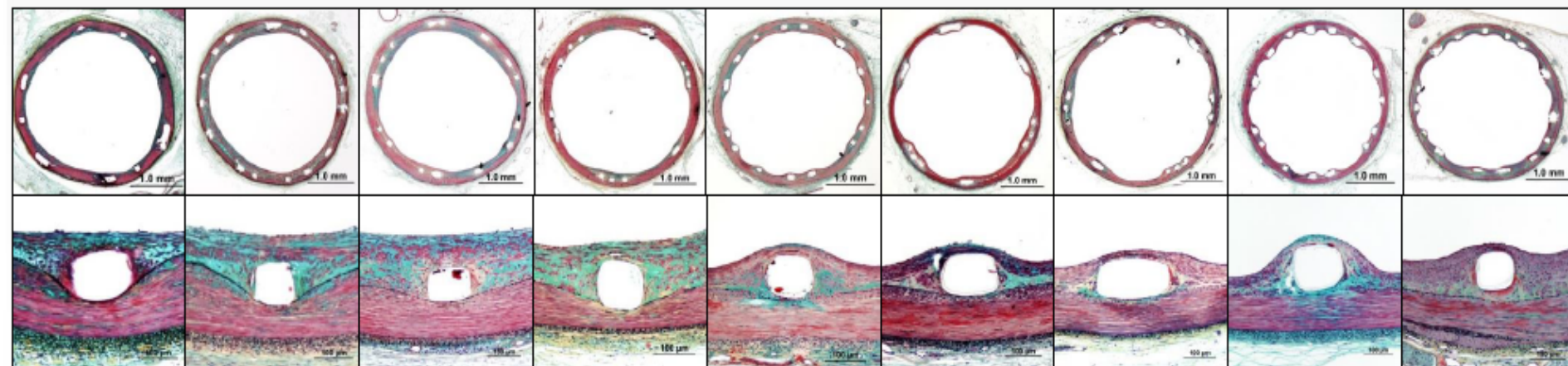
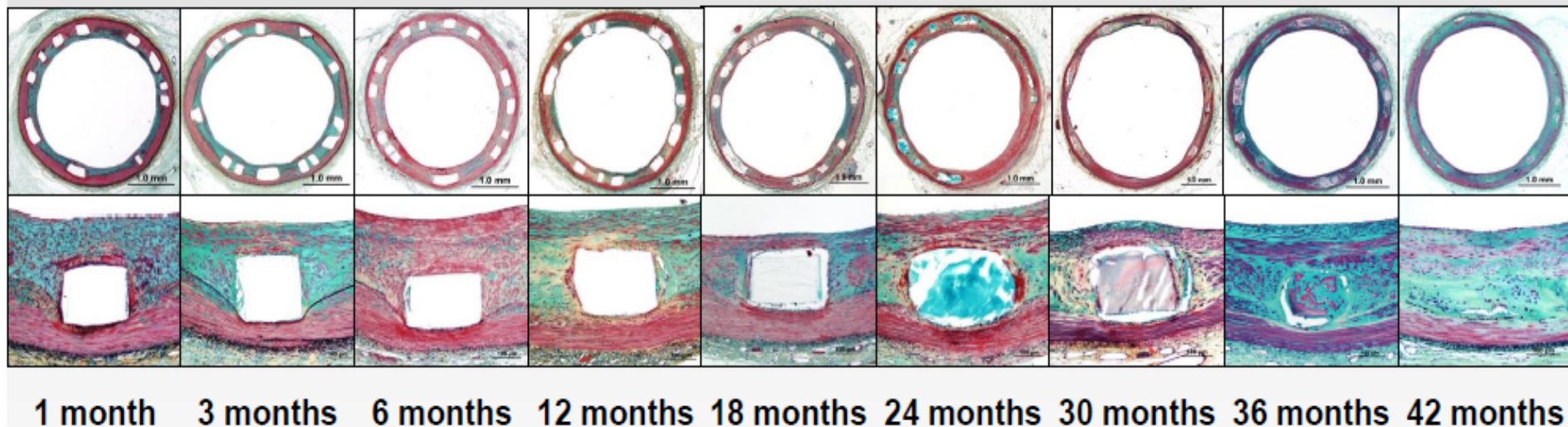
BVS disappears, then inflammation is gone...

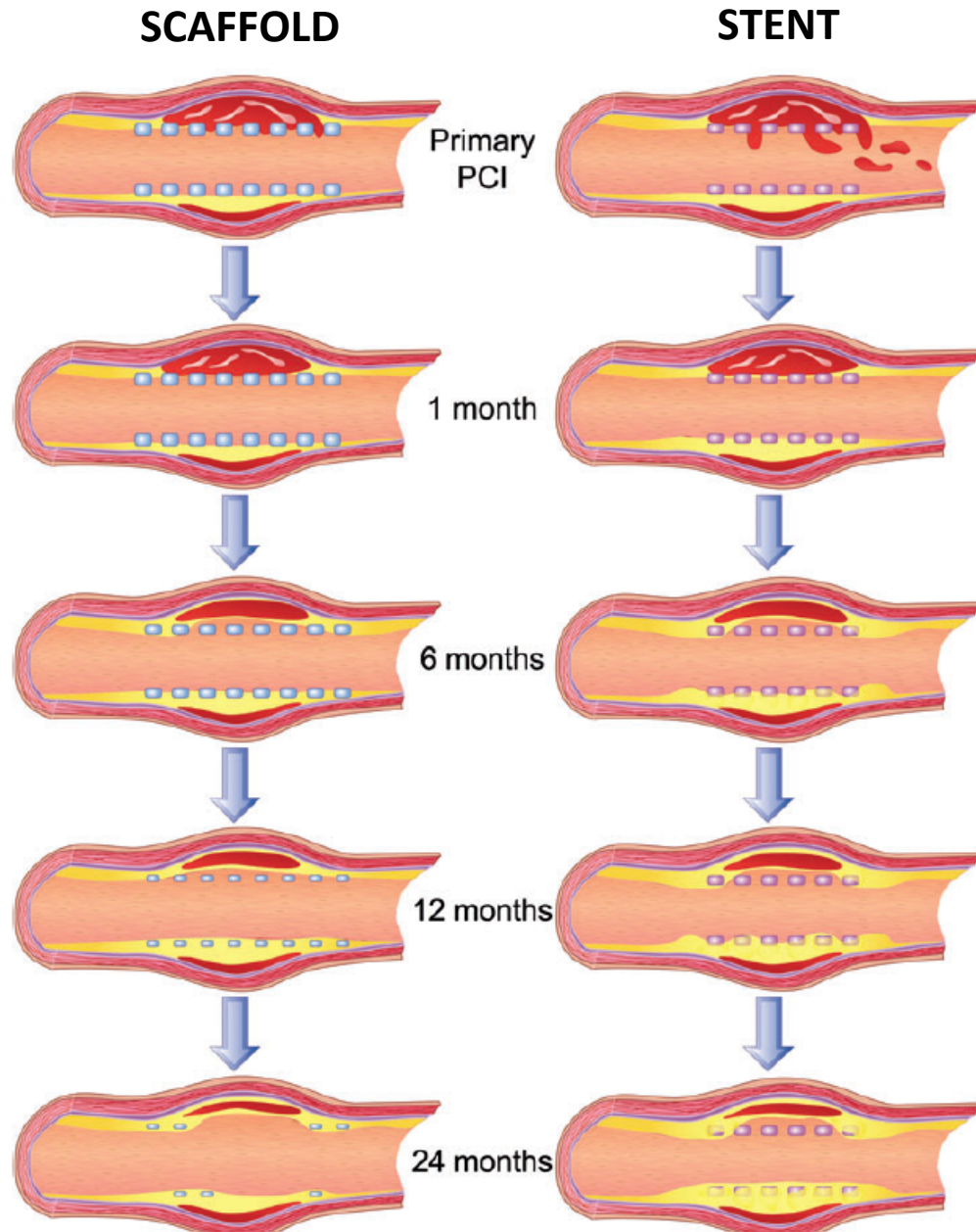




BVS (Cohort B) vs. XIENCE V in Porcine Coronary Arteries

BVS Cohort B

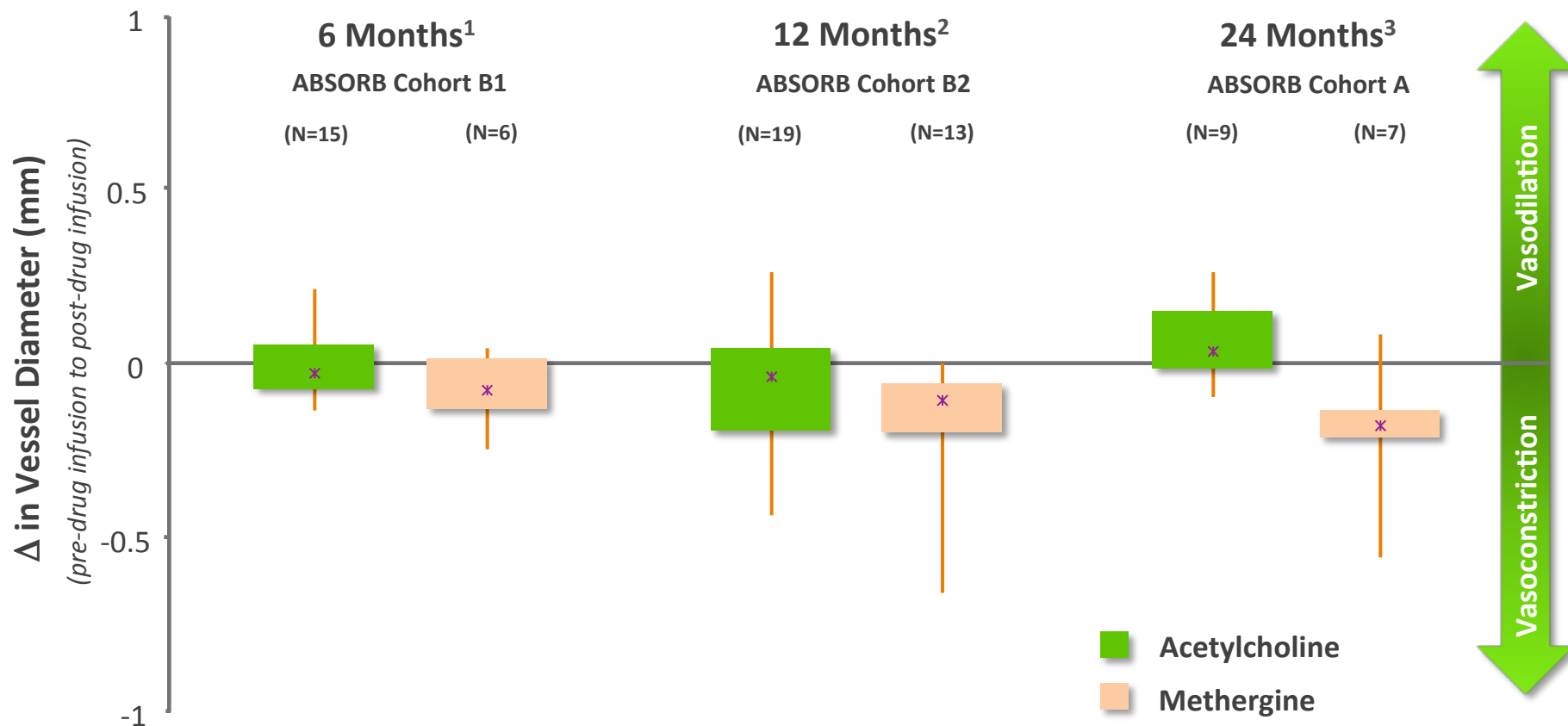




Plus de mal apposition dans les SCA

**QU'EST CE QUI EST DEMONTRE APRES
IMPLANTATION D'UN BVS
CHEZ L'HOMME EN 2014 ?**

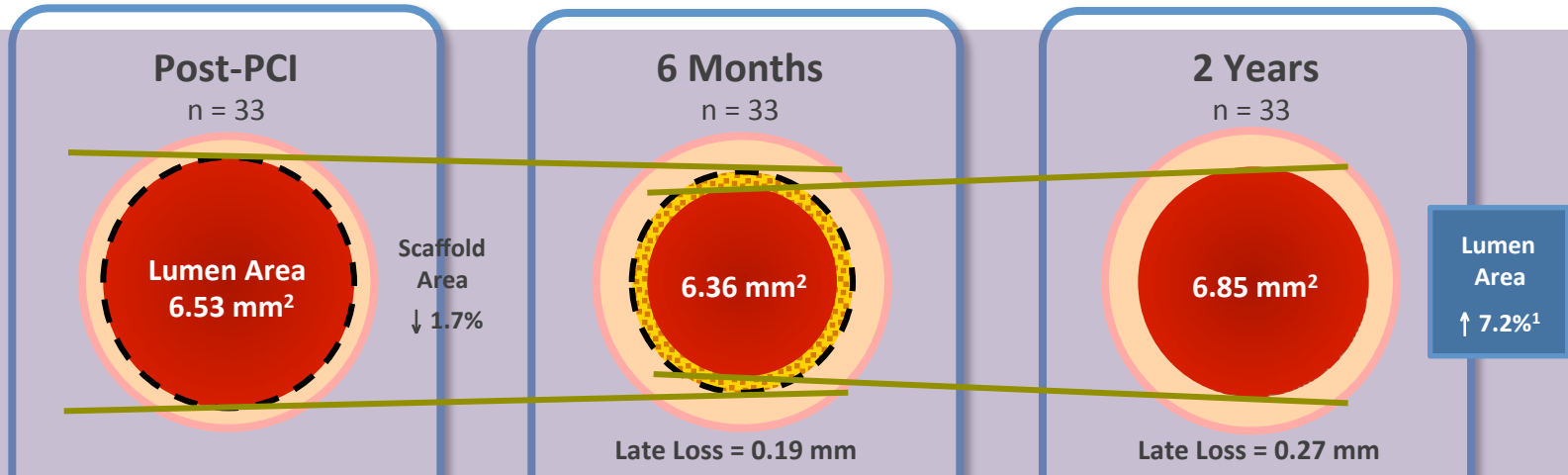
Preliminary Evidence of Vasomotion Suggests Improved Long-term Outcomes



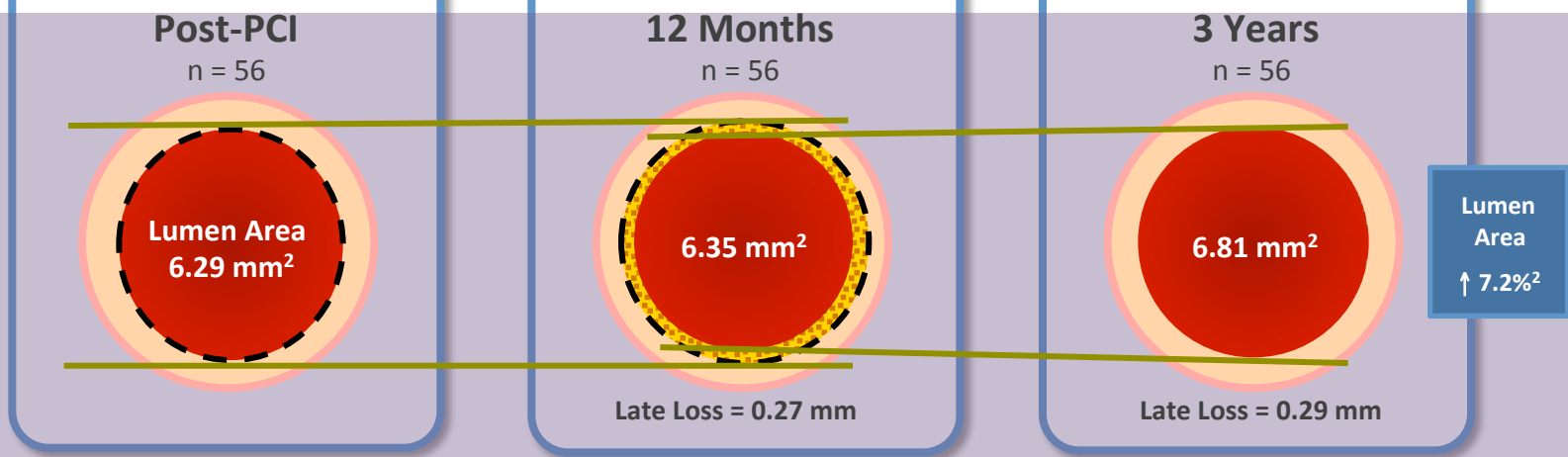
1. Data on file at Abbott Vascular/ 2. Adapted from Serruys, PW. et al. *J Am Coll Cardiol.* 2011; 58: 1578-88./ 3. Adapted from Serruys, PW, et al. *Lancet* 2009; 373: 897-910.

Late Lumen Gain Potential for Reduced TLR

**ABSORB
Cohort B1**
Serial Analysis*



**ABSORB
Cohort B2**
Paired Analysis**

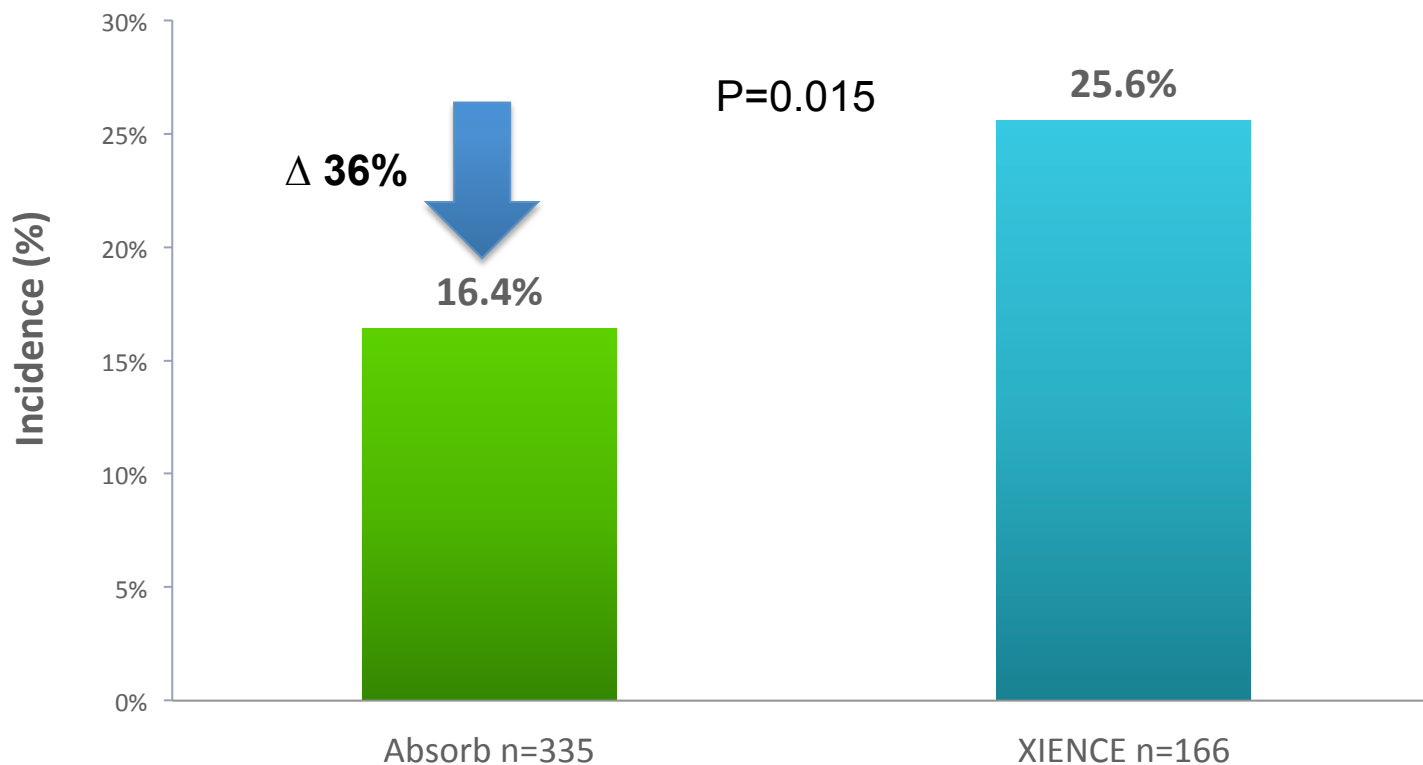


*Serruys, PW., ABSORB Cohort B 2-year results; TCT 2011
**Serruys, PW., ABSORB Cohort B 3-year results; ACC 2013

1. Patient-level serial analysis
2. Calculated from overall mean values

ABSORB II

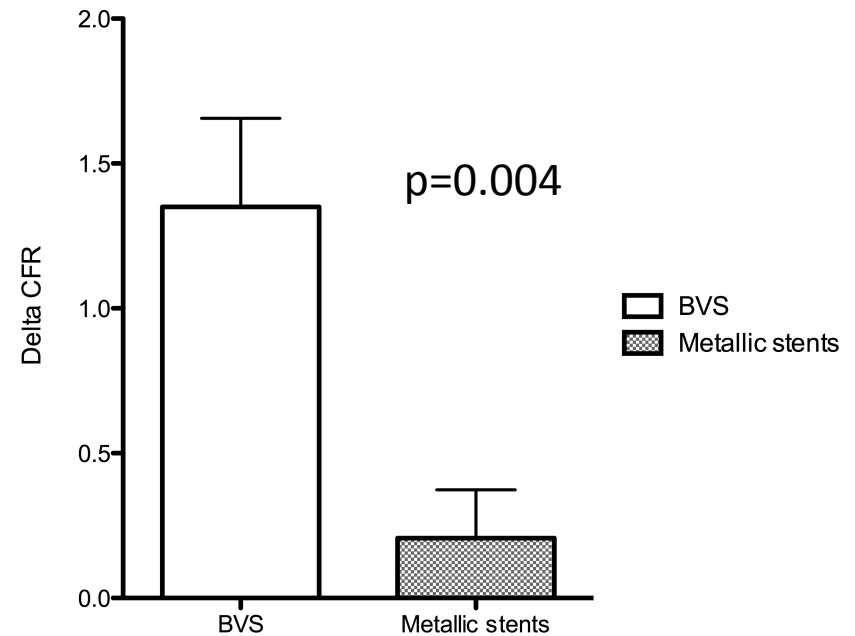
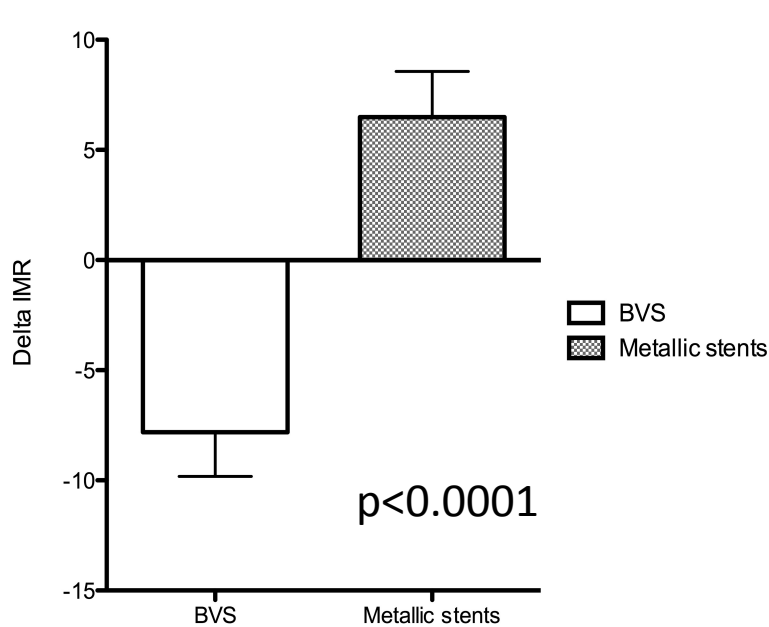
One Year Angina Outcome



Excludes in-hospital or the first 7 days, whichever is earlier

Adapted from ABSORB II, 1 Year Clinical Results, P.W. Serruys, TCT 2014.

Indices of microvascular function improve post-BVS implantation



n=21 each group; metallic stent controls
matched for stent length & diameter

Why is the site-diagnosed angina less in the ABSORB arm than in the Xience arm?

Early

- **Placebo effect in absence of blinding**
- **Better systolic and diastolic conformability of the scaffold to the vessel (angulation change)**
- **Less aggressive postdilatation – less stretching of adventitia (neurogenic theory)**
- **Wide scaffold struts with snow-boot effect vs. penetration of thin metallic struts with knife-in-butter effect**

Late

- **Vasomotion: better response to nitrate and shear stress**
- **Normal endothelial cell function in Absorb vs. dysfunctional endothelia in metal**
- **Cyclic Strain**
- **Impact of diastolic recoil (Cyclic strain) of scaffolded segment on microcirculation (forward pulse wave) vs. permanently stiff stented segment**
- **Reduction of microvascular resistance for unknown reason**
- **Absence of compliance mismatch at the edge of device**
- **Late lumen enlargement**
- **Local release of lactic acid molecule and metabolic interference to the vessel wall**

Goals of Vascular Reparative Therapy:

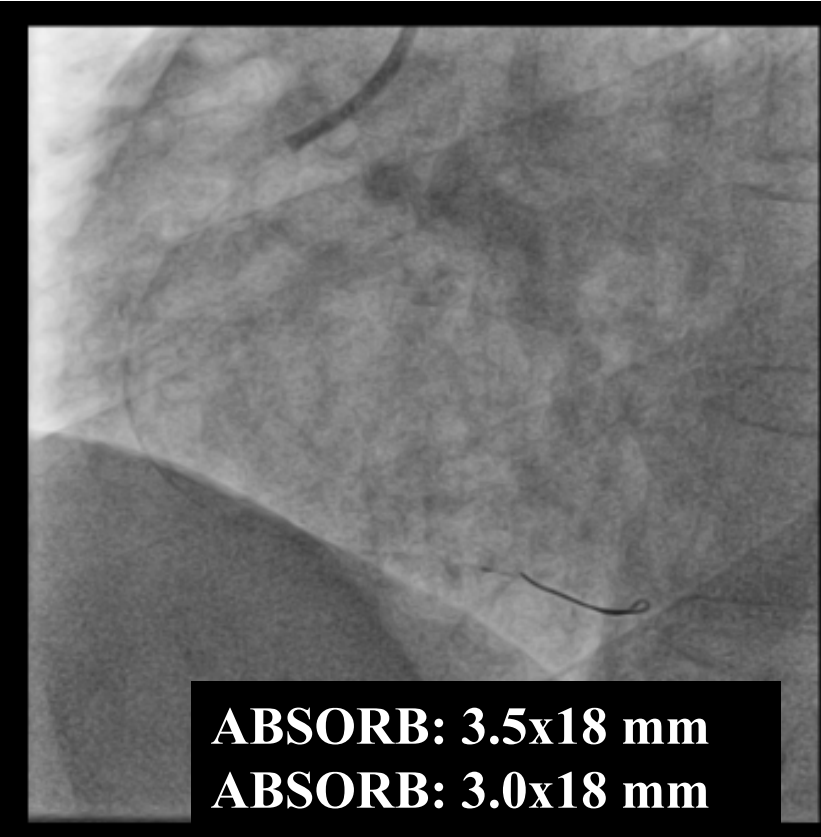
- **Restore vasomotor function** in some patients, for regulation of coronary blood flow
- **Restore vessel compliance** and cyclic strain in response to pulsatile flow
- **Beneficial remodeling**

Potential for improved long-term outcomes

Mr M. 37 ans

SCA ST + Semi Récent

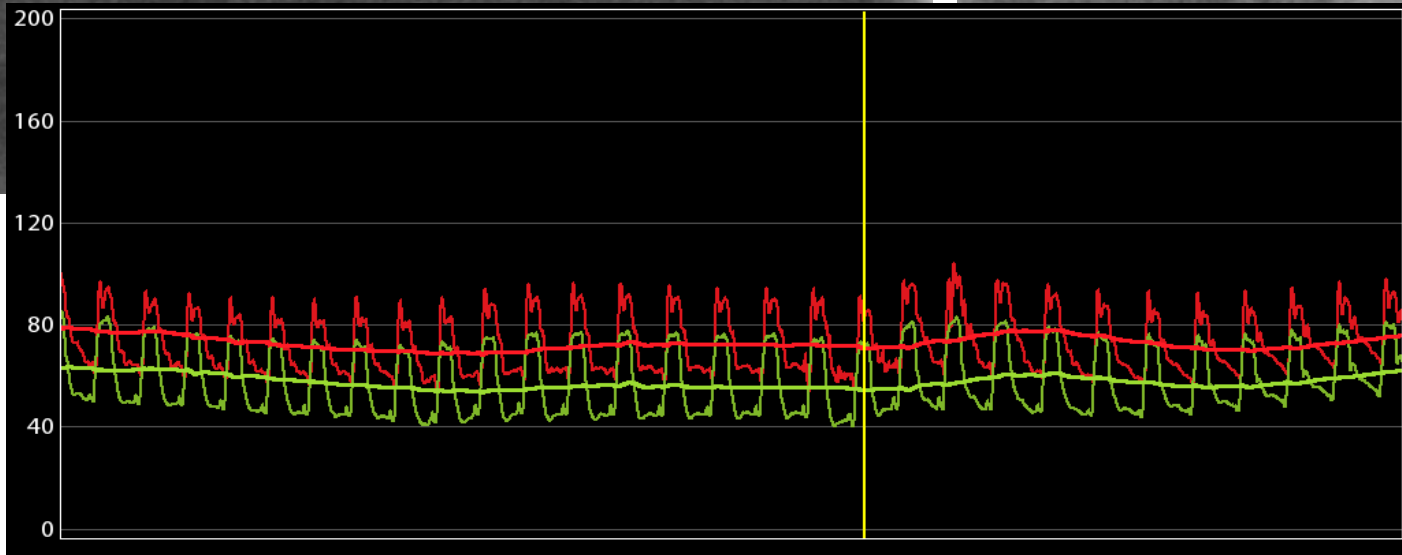
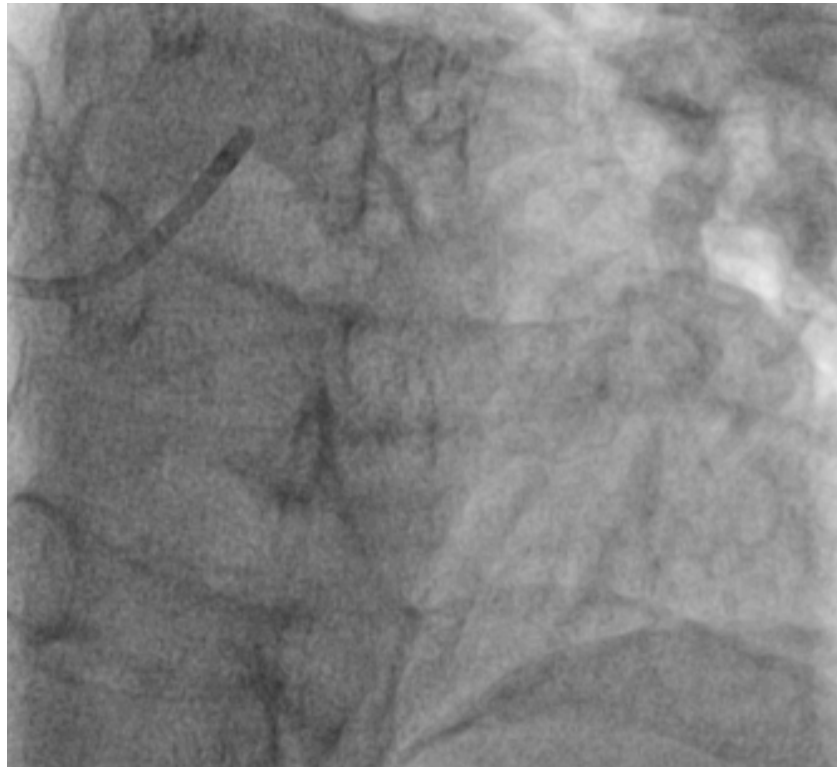
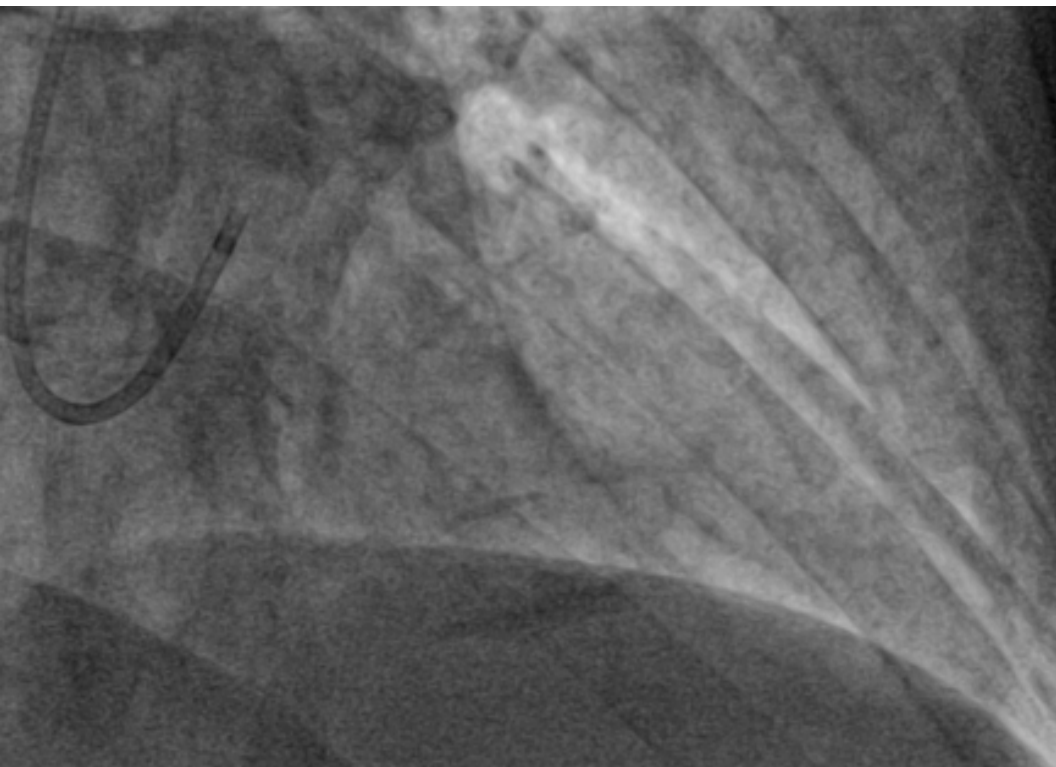
FUME DE TOUT



ABSORB: 3.5x18 mm
ABSORB: 3.0x18 mm



BMW Elite preforme



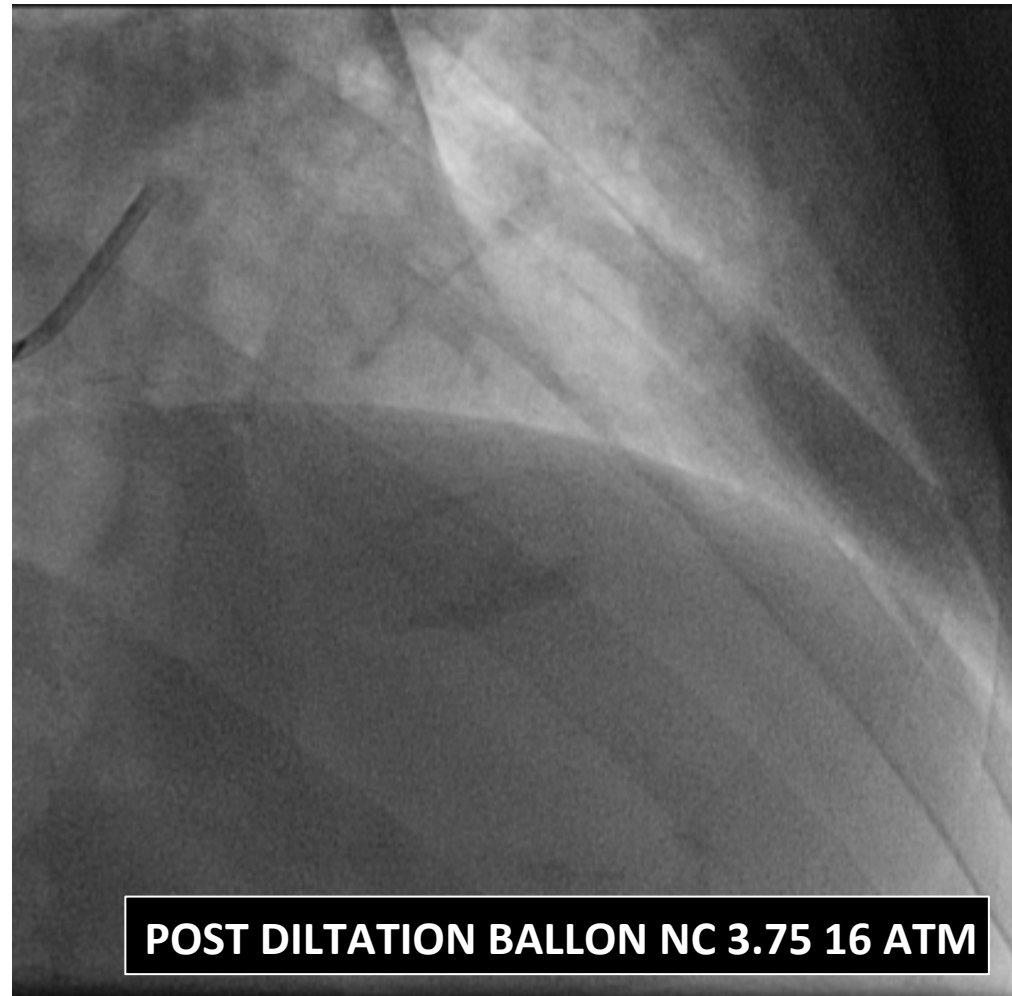
Pa
72

Pd
55

FFR
0.77

Temps
16.3

Predilatation, Bon Sizing



ST-Segment Elevation Myocardial Infarction

– Ideal Scenario for Bioresorbable Vascular Scaffold Implantation? –

Giancarla Scalone, MD; Salvatore Brugaletta, MD, PhD; Omar Gómez-Monterrosas, MD;
Shuji Otsuki, MD; Manel Sabate, MD, PhD

Bioresorbable vascular scaffolds (BVS) represent a breakthrough technology for percutaneous coronary intervention (PCI). In this context, because of the unique properties of bioresorbable devices, ST-segment elevation myocardial infarction (STEMI) may represent the ideal scenario for BVS implantation. Consistently, 57% of physicians declare they currently use BVS in this group of patients. However, continuous and growing evidence on the good performance of these devices has been actually shown only in small studies with short- and mid-term follow-up. For these reasons, we need data from sufficiently large observational studies, with long-term follow-up, to confirm that BVS can deliver the same results as 2nd-generation drug-eluting stents when using an appropriate implantation technique. In this review, we discuss the potential advantages of BVS implantation in STEMI patients, together with the most recent evidence from clinical studies, highlighting safety and procedural concerns. (*Circ J* 2015; **79**: 263–270)

Key Words: Bioresorbable scaffolds; Plaque sealing; ST-segment elevation myocardial infarction; Vascular response

Pourquoi un stent Bioabsorbable ?

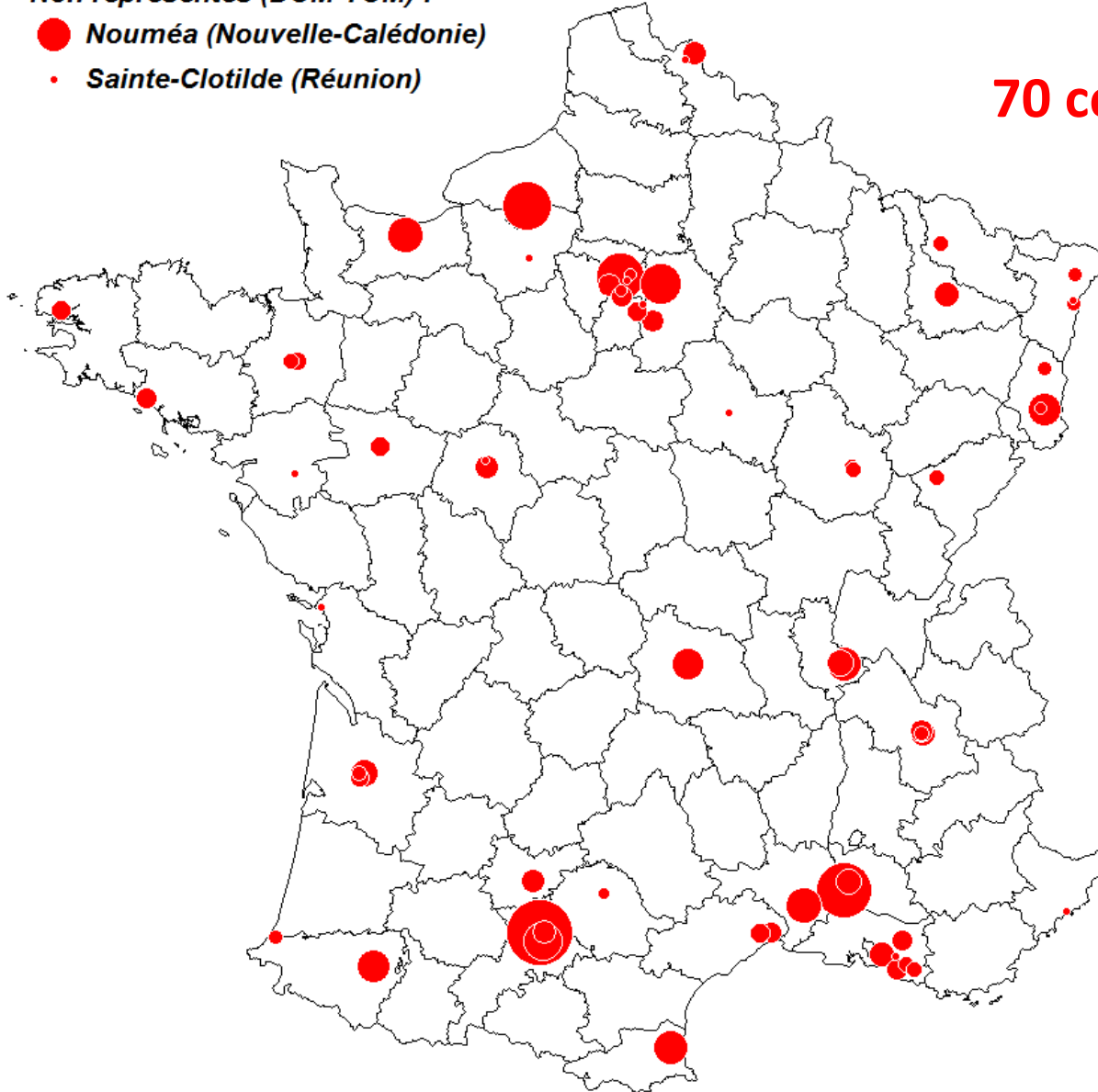
- « **Plaque sealing** »
- **Restauration de la fonction vasculaire.** (*chez le jeune et le diabétique +++*)
- **Moins de thrombose tardive** due à la disparition du stent
- **Moins d'inflammation** donc certainement moins de néo athérome
- Probable disparition de **la mal apposition** notamment dans les SCA à distance
- Possible **allègement du tt antiagrégant plaquettaire** à distance surtout chez le jeune
- Une artère native toujours **pontable.....** si besoin !
- Et aussipour**FRANCE-ABSORB**

918 patients (Oct 2014-Juin 2015)

Non représentés (DOM-TOM) :

- *Nouméa (Nouvelle-Calédonie)*
- *Sainte-Clotilde (Réunion)*

70 centres actifs



Caractéristiques de la procédure

Caractéristiques de la lésion	Pourcentage (%)
Pré-dilatation	94,6
Rotablator	0,4
Thrombo-aspiration	4,8
Nombre Absorb implantés:	
- 1	88,1
- 2	10,6
- 3	1,3
Longueur moyenne totale	23,6 mm +/- 10,3
Diamètre moyen	3,06 mm +/- 0,39
OCT	16,2
Post-dilatation	73,8
<i>Diamètre max du ballon post-dilat.</i>	<i>3,24 mm +/- 0,5</i>
<i>Rapport Diam max ballon / diam BVS</i>	<i>1,06 +/- 0,1</i>
Flux TIMI 3 final	99,7
Succès d'APTL	99,8

MACCE (n= 879)

HOSPITALIER

- **Mortalité: n=0**
- **INFARCTUS : n=6**
 - Homme 33 ans, NSTEMI le jour de la procédure, hematome intra-mural (traité avec edge to edge Xience)
 - Homme 43 ans, NSTEMI à J+1, sans relation avec la procédure
 - Femme 61 ans, STEMI à J+1. Occlusion d'une branche diagonale non protégée
 - **Homme 46 ans, thrombose de stent à J+1, staged procedure**
 - **Homme 46 ans, thrombose de stent à J+2, PCI ballon**
 - **Femme 45 ans, thrombose de stent à J+3,**
- **AVC : n=1**
 - Homme 69 ans, AVC le jour de la procédure
- **TLR / TVR : n=3**
 - Homme 33 ans, NSTEMI le jour de la procédure, hematome intra-mural (traité avec edge to edge Xience)
 - **Homme 46 ans, thrombose de stent à J+1, PCI**
 - **Homme 46 ans, thrombose de stent à J+2, PCI ballon**

MACCE Déclarés (n= 879)

(à 30 jours)

- Mortalité: n=3

- Homme 42 ans, décès inexpliqué à J+6
- Homme 60 ans, mort subite à J+7
- Homme 63 ans, décès inexpliqué à J+8

- INFARCTUS : n=8

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- **Femme 45 ans, thrombose de stent à J+3 (traitement non précisé)**
- **Homme 31 ans, thrombose de stent à J+10 (non observance), PCI ballon**
- **Homme 45 ans, thrombose de stent à J+18, PCI**

- AVC : n=1

- Homme 69 ans, AVC le jour de la procédure

- TLR/TVR : n=5

- Homme 33 ans, NSTEMI le jour de la procédure, hematome intra-mural (traité avec edge to edge Xience)
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THROMBOSE BVS

5 + 3 morts = 8/879 = 0.9%

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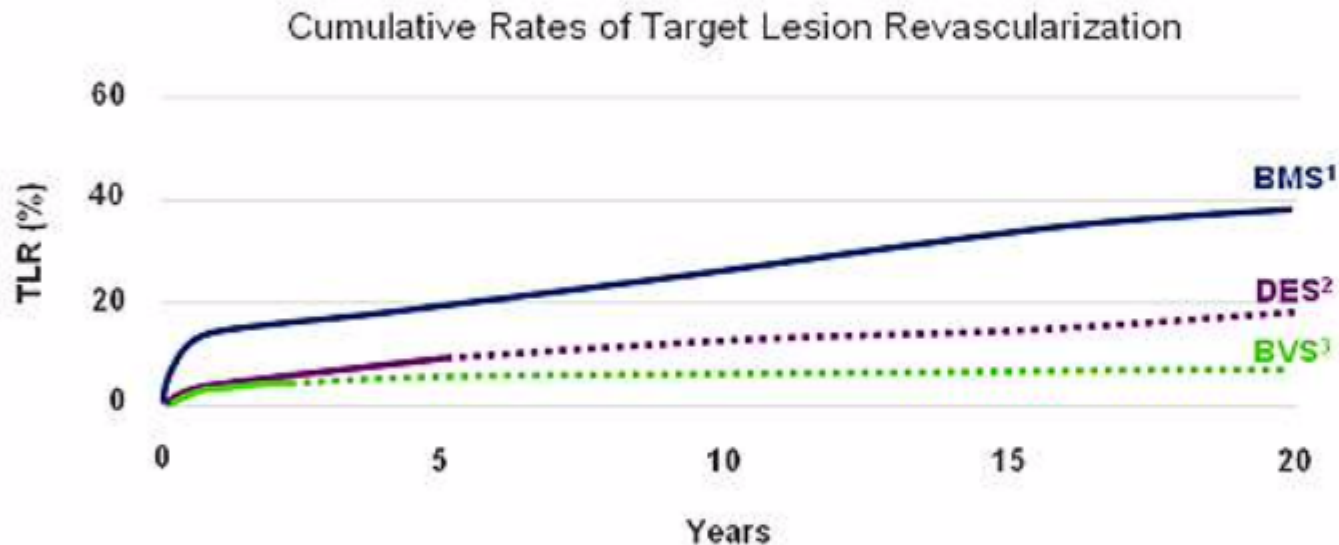
THROMBOSE BVS

$$5 + 3 = 8/879 = 0.9\%$$



(RESTE A DEMONTRER)

Could Absence of an Implant Reduce Long-Term Events?



- The goal of bioresorbable vascular scaffolds is to achieve the early benefits seen with DES, but improve on long-term outcomes by eliminating the implant