

# BRS: espoir et limites actuelles !

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# Conflits d'Intérêts

- Membre du Board – Abbott 2016 -2017
- P.I France Absorb pour le GACI
- Coinvestigateur Biosolve (Magmaris)



**NEWS • INTERVENTIONAL**

## Boston Scientific Scraps Biodegradable Scaffold Program

The thinner strut Renuvia scaffold won't be studied any further based on discouraging results from Abbott's Absorb BVS, the company confirmed.

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**GACI**

## FRANCE-ABSORB

- 2072 patients
- 09/2014 to 03/2016
  - 2502 lesions
  - 2818 BVS
  - 87 centers



**99% F/U à 1 an**  
**Mortalité : 0.7%**  
**MACE : 3%**  
**Thrombose: 1.5%**

**2017 / 2019 / 2020 / 2021**

# BRS: limites actuelles et espoir !

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**POURQUOI?**

**BVS- Abbott-Vascular**

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De Bruyne, B. TCT 2014

Cohort B CTA images - courtesy of RJ van Geuns, Erasmus Medical Center, Netherlands

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# Phases of Absorb™ Functionality





# LIMITES ACTUELLES DU BVS

- 1. Résultats initiaux équivalents aux DES ?**
- 2. Résorption progressive et graduelle?**
- 3. Restauration de la physiologie du vaisseau stenté?**
- 4. Amélioration des symptômes d'angor?**
- 5. Prévention des thromboses tardives de la prothèse / stents actifs classiques?**
- 6. Eviter un traitement prolongé par les antiagrégants plaquettaires ?**

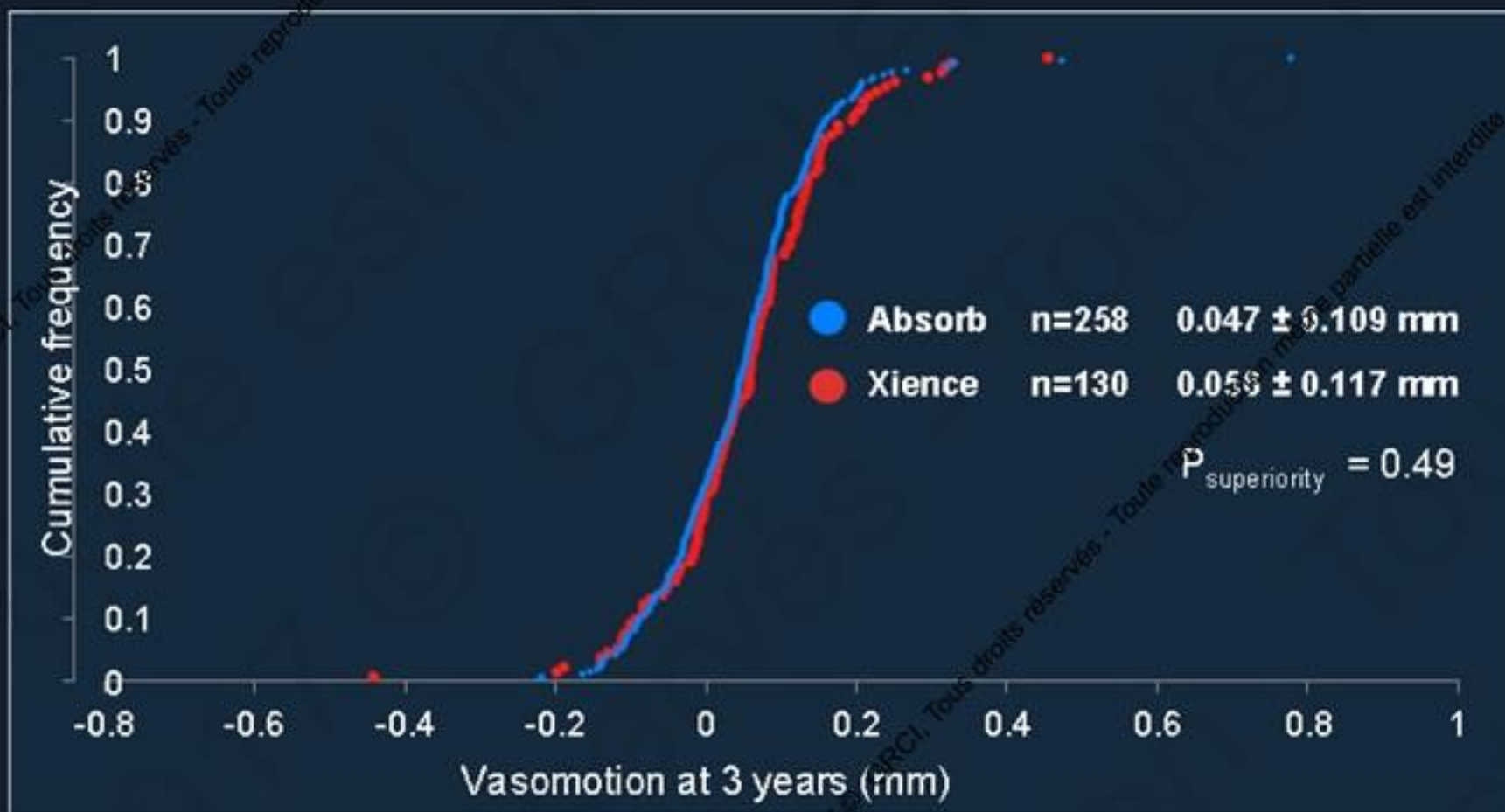
**ABSORB II - 501 patients randomized 2:1 to Absorb or Xience**

	Absorb	Xience	P value
<b>MLD (mm)</b>			
Pre-procedure	1.06 ± 0.33	1.06 ± 0.31	0.81
Post-procedure	2.22 ± 0.33	.250 ± 0.33	<0.0001
Acute gain	1.16 ± 0.38	.145 ± .037	<0.0001
3-Year follow-up	1.86 ± 0.54	2.25 ± .037	<0.0001
Net gain	0.80 ± 0.61	1.20 ± .044	<0.0001
Late loss*	0.37 ± 0.45	.025 ± .025	0.0003
Binary restenosis (%)	7.0%	0.7%	0.0031

\*Co-primary endpoint. MLD = minimal lumen diameter

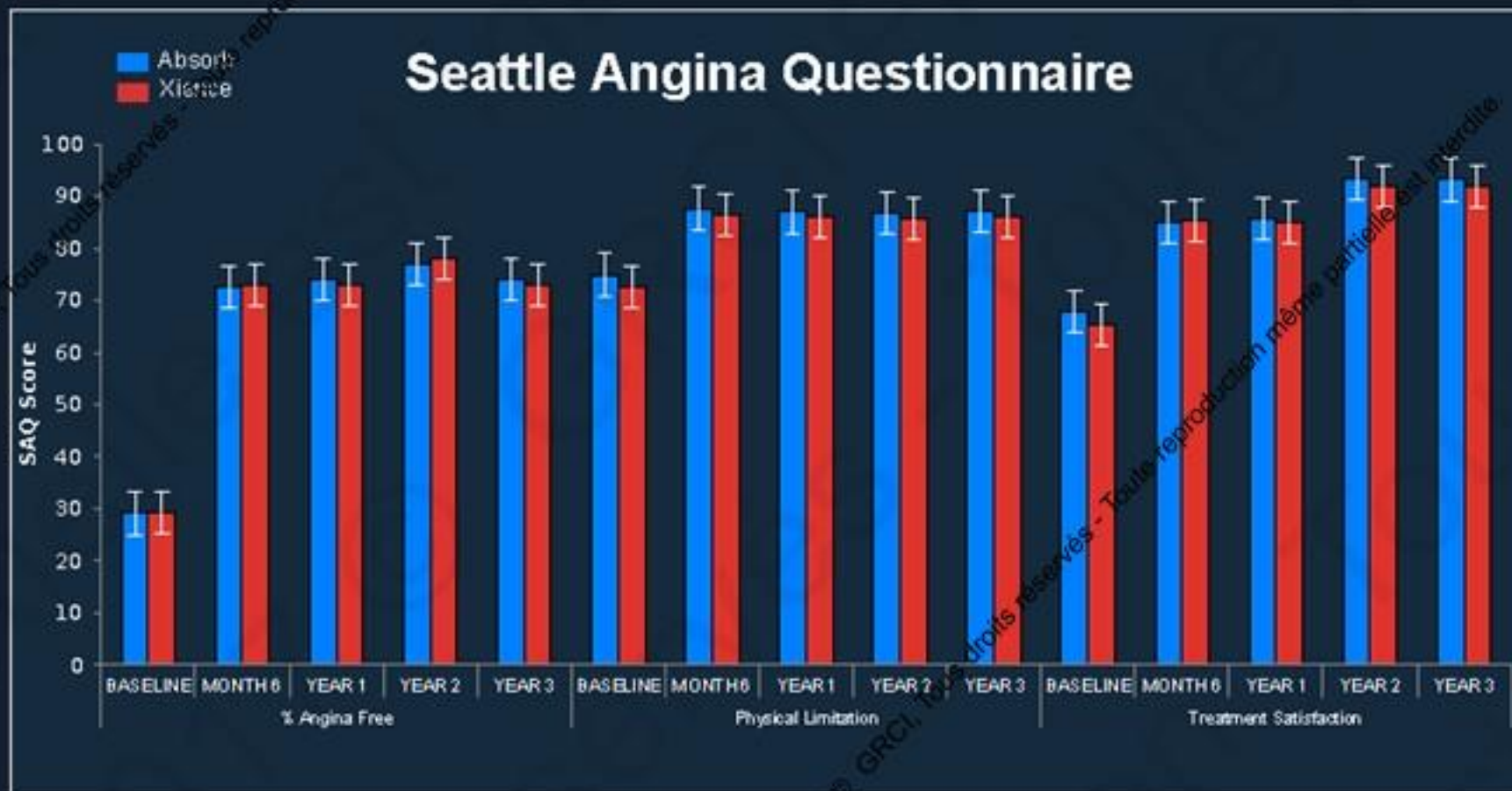
# Comparative Vasomotion of BVS and EES

**ABSORB II - 501 patients randomized 2:1 to Absorb or Xience**



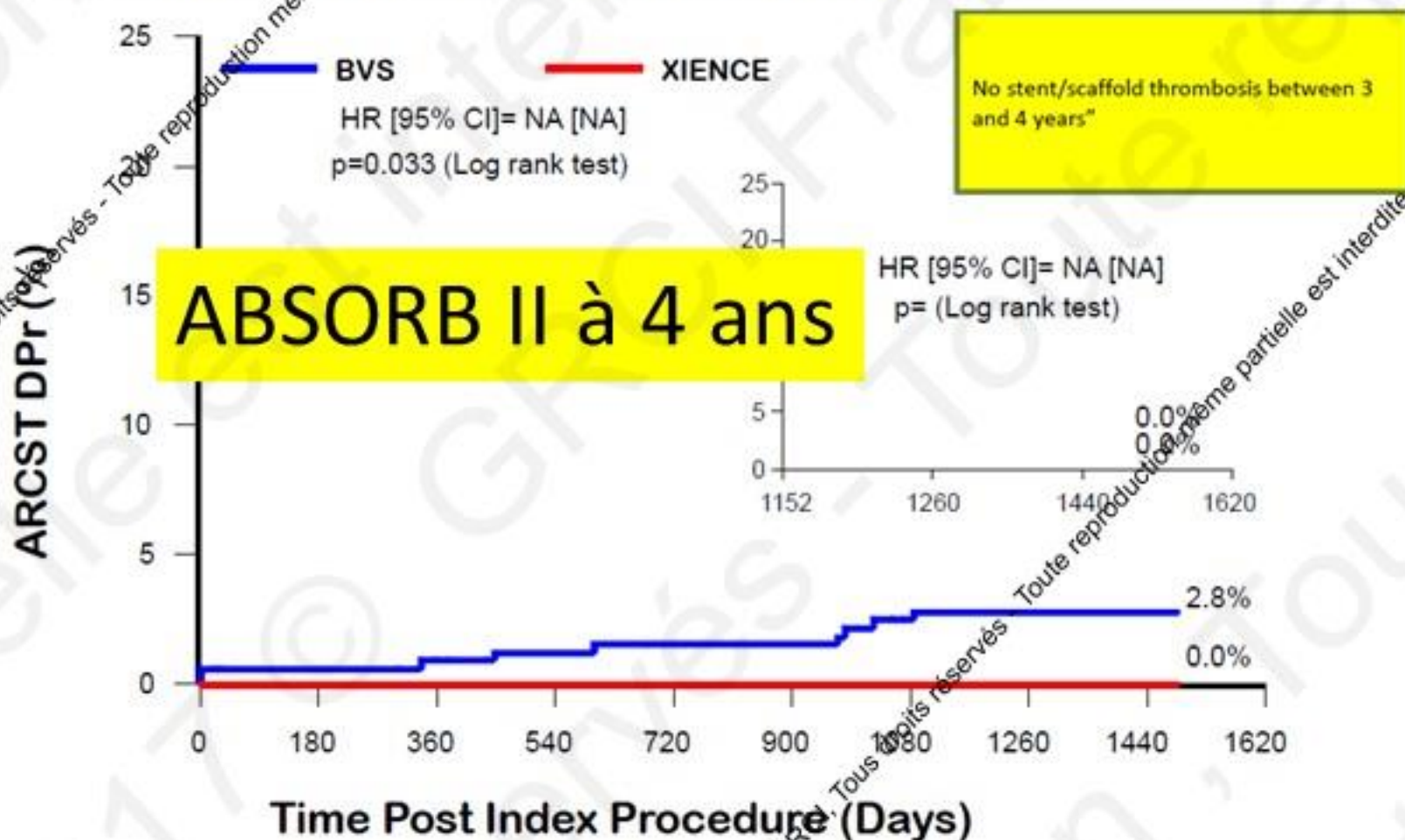
# Comparative Angina of BVS and EES

**ABSORB II - 501 patients randomized 2:1 to Absorb or Xience**



Serruys PW, et al. Lancet. 2016;388:2479-2491

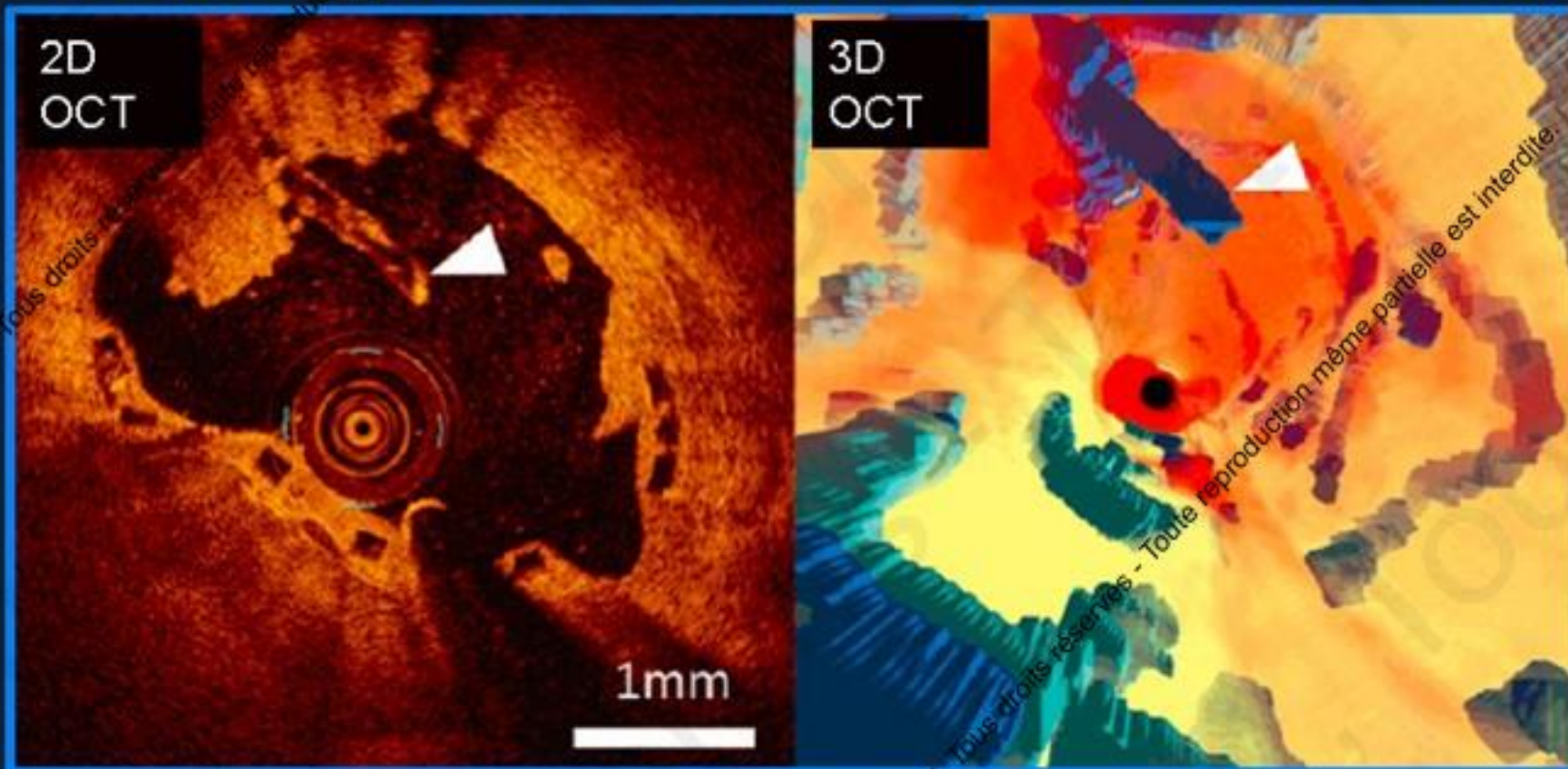
## Definite/Probable Scaffold/Stent Thrombosis\*



## Scaffold/Stent Thrombosis

	4 years		
	Absorb BVS N=335	XIENCE N=166	p value
<b>Definite ST* 0-1488 days (%)</b>	<b>2.6</b>	<b>0.0</b>	<b>0.0583</b>
Acute/sub-acute (0-30 days)	0.6	0.0	1.0000
Late (31-365 days)	0.0	0.0	1.0000
Very late (365 – 14888 days)	1.8	0.0	0.1851
<b>Very late between 3 – 4 year follow-up (N)</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>Definite/Probable ST* 0-1488 days(%)</b>	<b>3.0</b>	<b>0.0</b>	<b>0.0347</b>
Acute/sub-acute (0-30 days)	0.6	0.0	1.000
Late (31-365 days)	0.3	0.0	1.0000
Very late (365 – 1488 days)	1.8	0.0	0.1851
<b>Very late between 3 – 4 year follow-up (N)</b>	<b>0</b>	<b>0</b>	<b>NA</b>

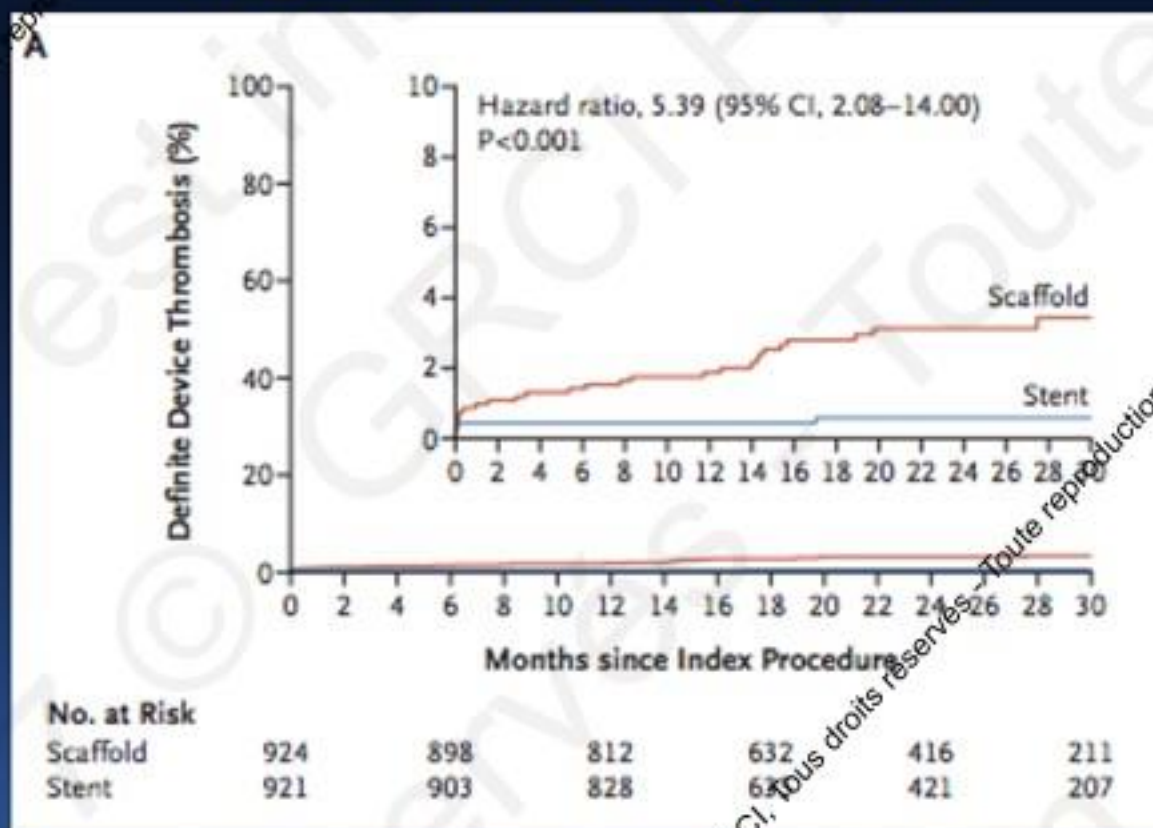
# Intraluminal Scaffold Dismantling A BRS-specific Thrombosis Mechanism



Strut discontinuity with marked suppression of neointimal hyperplasia resulting in prolapse of a scaffold segment into the vessel lumen before absorption is complete.

# BVS vs. EES in Routine Clinical Practice

## AIDA Investigators







**FIN DU CONCEPT  
BIORESORBABLE ?**

**ESPOIR !**

## 4-year Clinical Outcomes Composite Endpoints

	Absorb BVS N=335	XIENCE N=166	p value
PoCE (%)	23.6	26.7	0.4682
MACE (%)	12.4	8.0	0.1545
DoCE, TLF (%)	11.5	8.1	0.0628
TVF (%)	14.0	14.0	0.9970

**Pas de  
différence de  
mortalité**

**PoCE (Patient oriented Composite Endpoint):**

All death, all myocardial infarction, and all revascularisation

**MACE (Major Adverse Cardiac Events):**

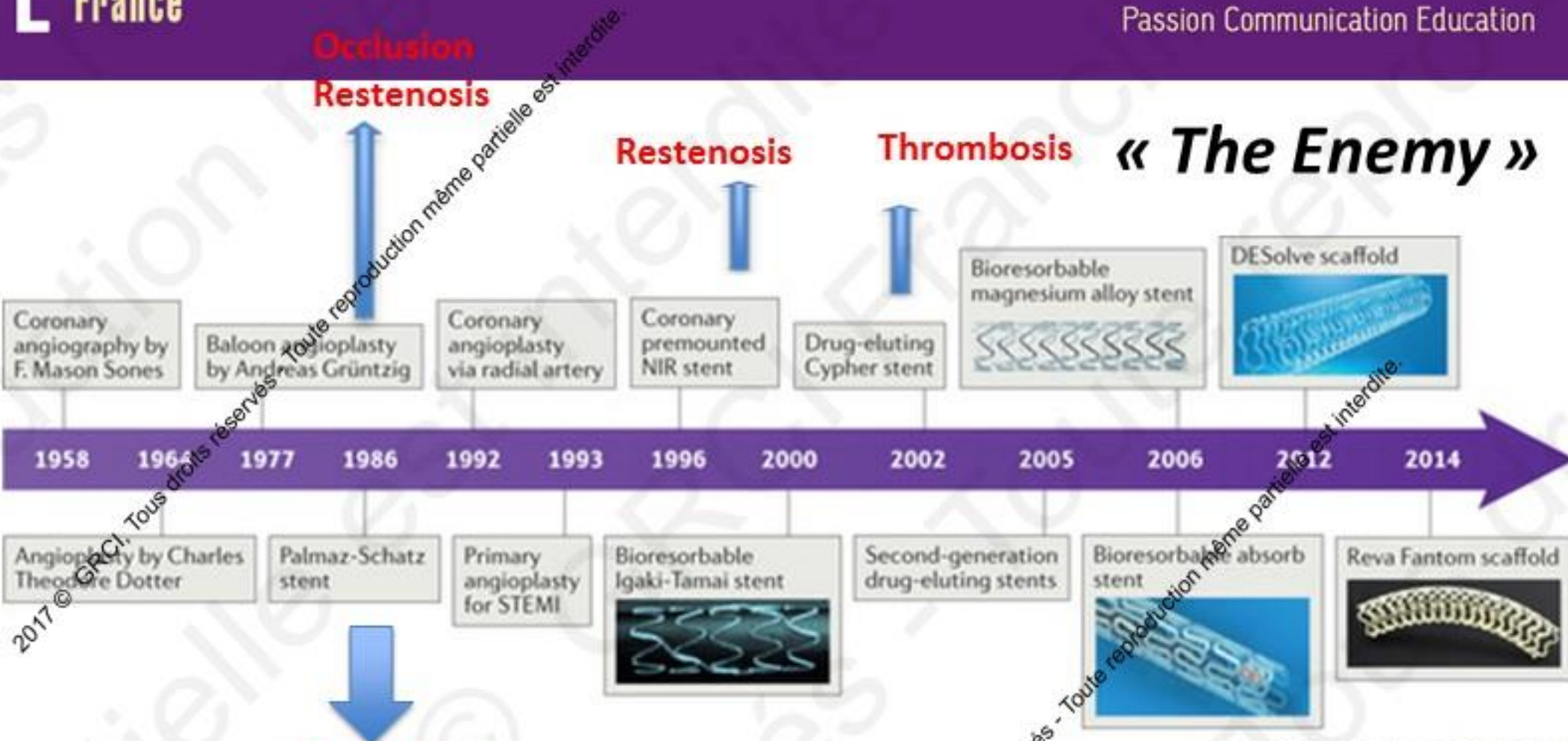
Cardiac death, all myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)

**DoCE (Device oriented Composite Endpoint)/ TLF (Target Lesion Failure):**

Cardiac death, target-vessel myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)

**TVF (Target Vessel Failure):**

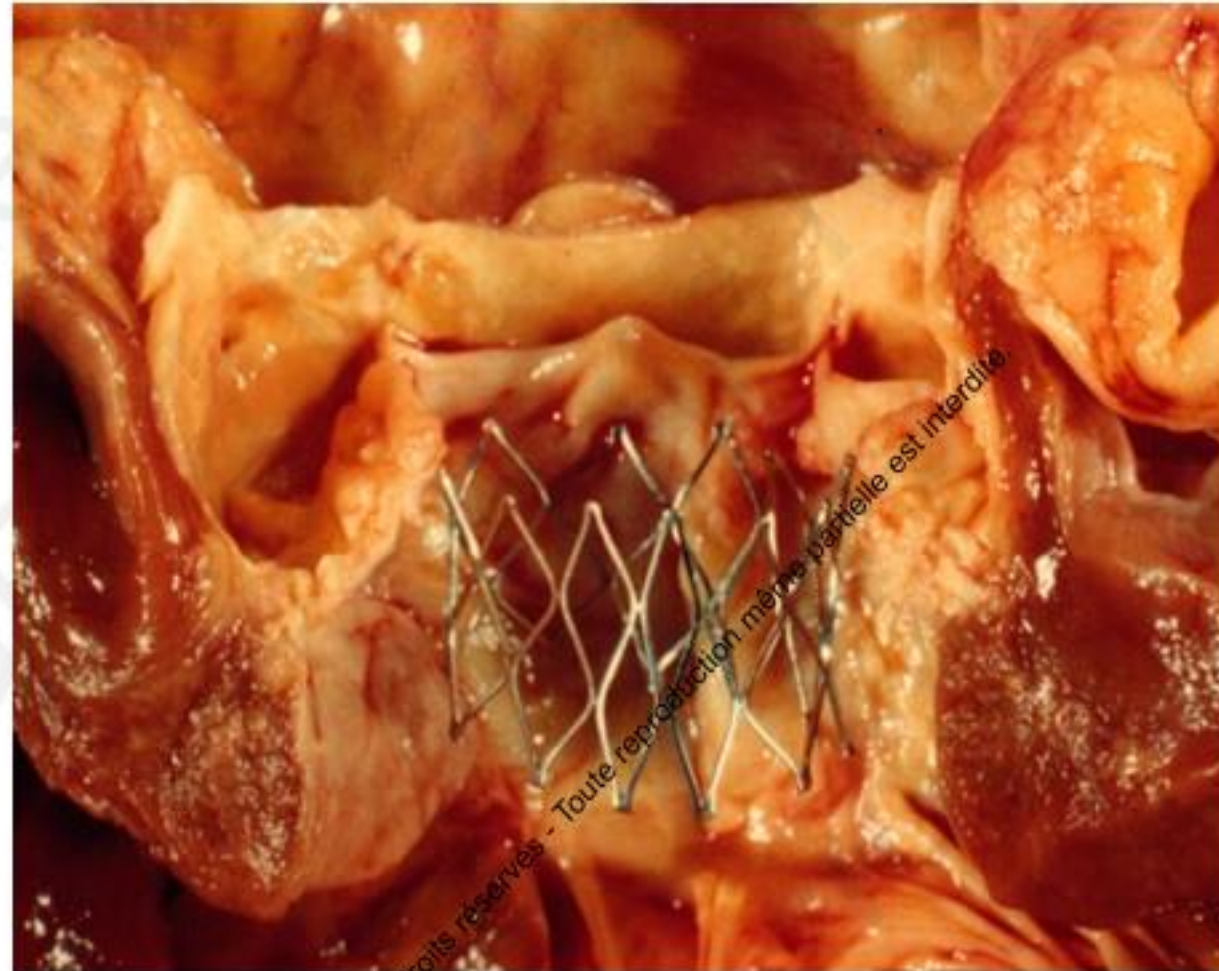
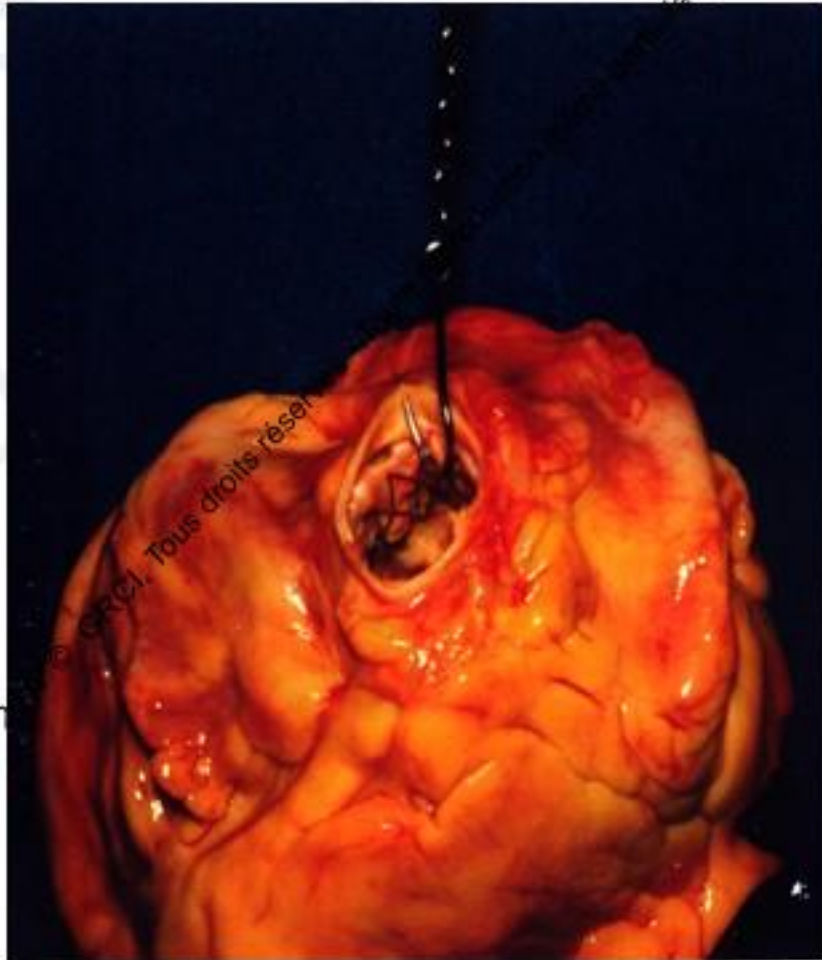
Cardiac death, all myocardial infarction, clinically indicated target-vessel revascularisation (TVR)



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Nature Reviews | Cardiology



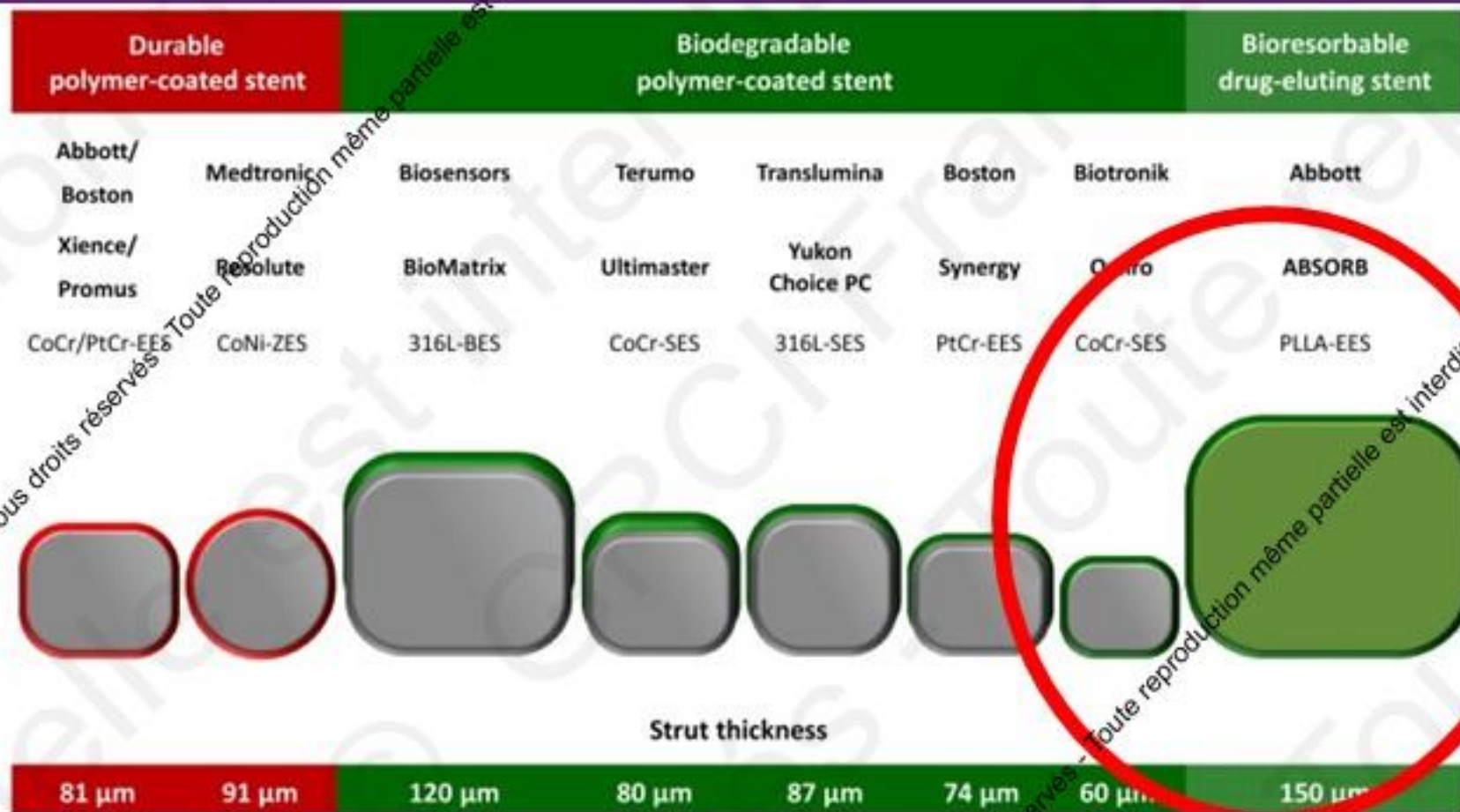
**Le concept existait déjà et 1<sup>er</sup> TAVI en 2001 !**



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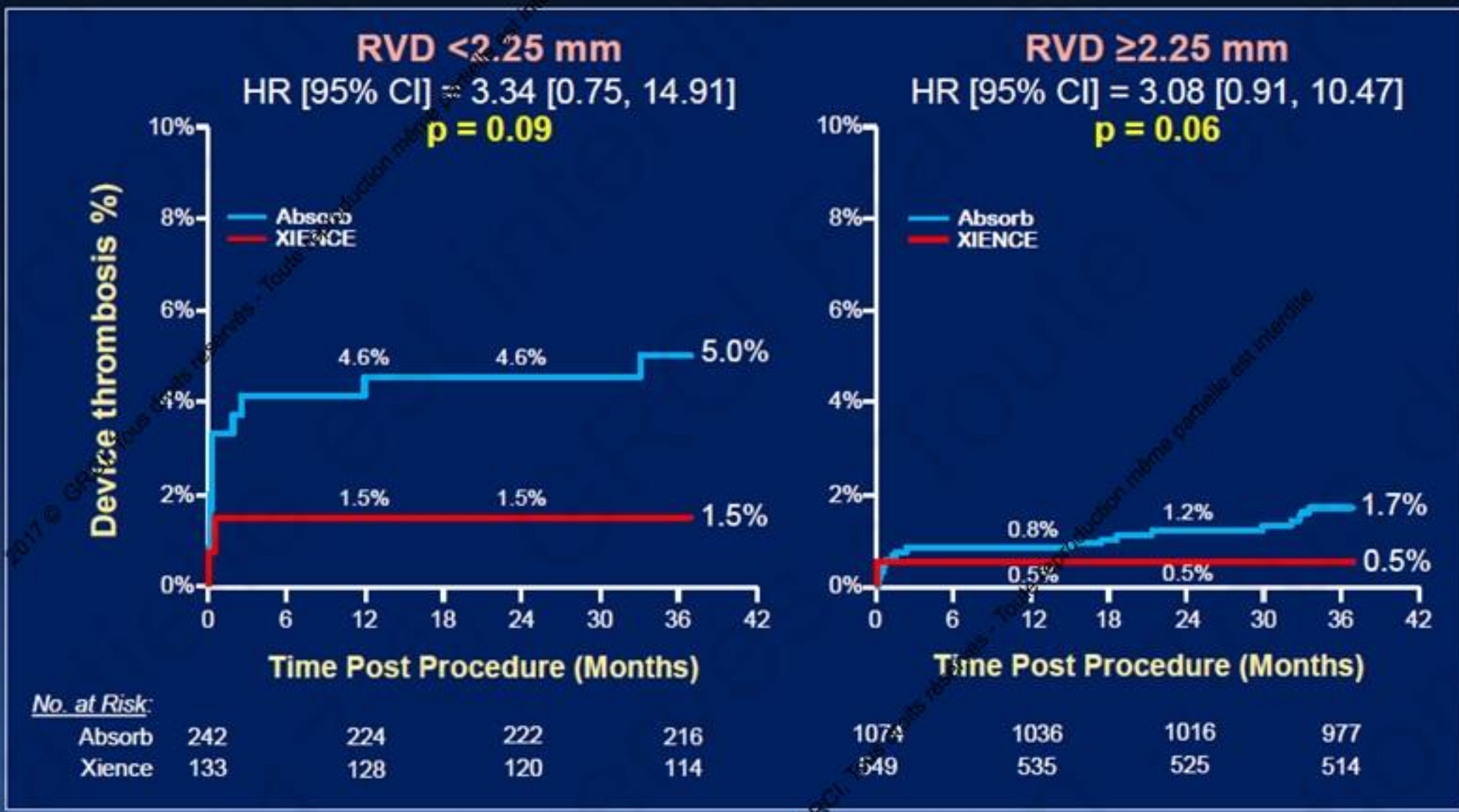
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**L'outil n'est pas OPTIMAL**

# Device Thrombosis: Stratified by Vessel Size







## Multivariable Predictors: Absorb

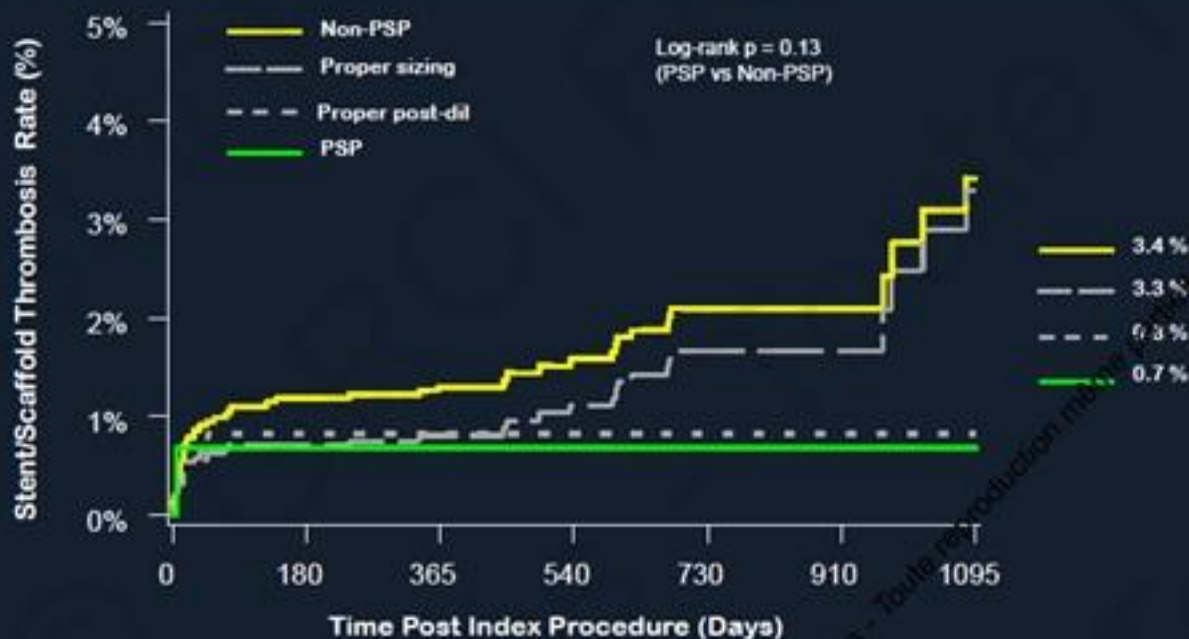
Outcome	Variable	0 – 3 Years	
		Relative Risk [95% CI]	P
TLF	Pre-procedure RVD <2.25 mm*	1.72 [1.28, 2.32]	0.0005
	Prior coronary intervention	1.37 [1.04, 1.81]	0.023
Scaffold thrombosis	Pre-procedure RVD <2.25 mm*	2.80 [1.37, 5.71]	0.006
	Diabetes mellitus	2.77 [1.36, 5.64]	0.006

\*By QCA

Variables entered into the TLF multiple model: ACC/AHA lesion class, age (median 64 years), treatment arm, calcification (moderate/severe), prior cardiac interventions, any diabetes, hypercholesterolemia requiring medication, sex, hypertension requiring medication, presentation (unstable angina and recent MI vs. stable ischemic syndrome), calcification, target vessel: LAD, target lesion length (mm, median), prior cardiac intervention, pre-procedure MLD (mm, median), number of target lesions, P2Y12 receptor antagonist (loading), pre-procedural RVD (<2.25 mm vs. ≥2.25 mm), current tobacco use.

Variables entered into the ST multiple model: ACC/AHA lesion class, treatment arm, Any diabetes, presentation (unstable angina and recent MI vs. stable ischemic syndrome), target lesion length (mm, median), pre-procedural RVD (<2.25 mm vs. ≥2.25 mm).

## PSP Analysis – Def/Prob ST KM Through 3-Years (Absorb Patients, As-Treated Population)



	0	365	730	1095
Non-PSP	2549	2483	1354	291
Proper Sizing	2261	2211	1347	238
Proper post-dil	365	357	227	26
PSP	297	290	192	21

0-365 days population: A-EXTEND, A-II, A-Japan, A-China, A-III  
 366-730 days population: A-EXTEND, A-II, A-Japan, A-China  
 731-1095 days population: A-II

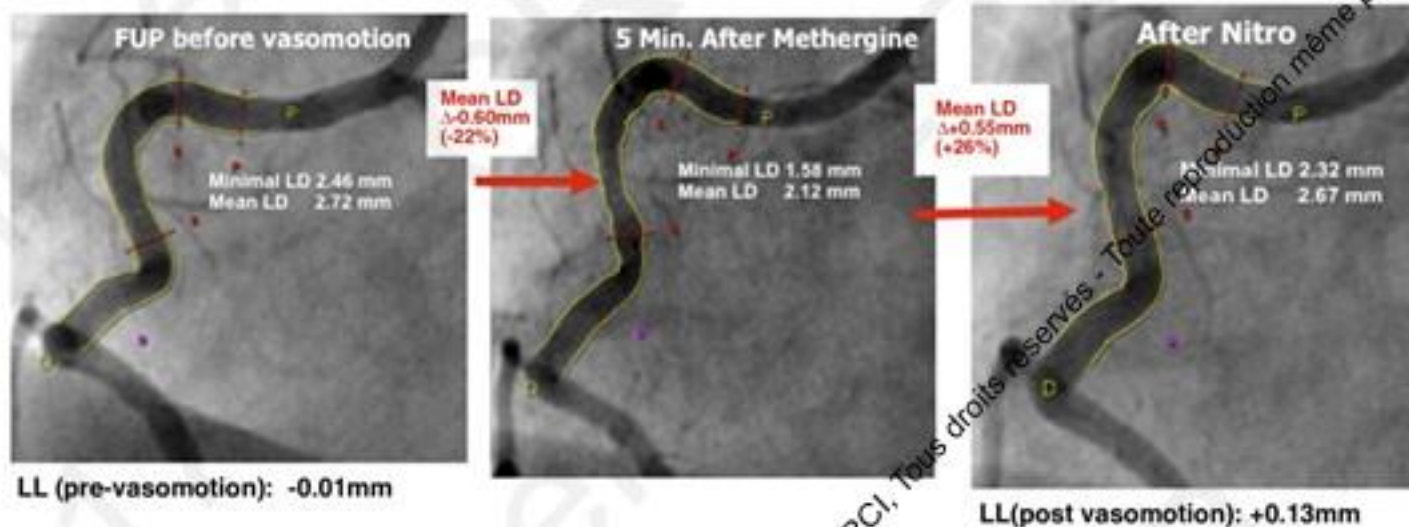
# LES LIMITES



**encagement**

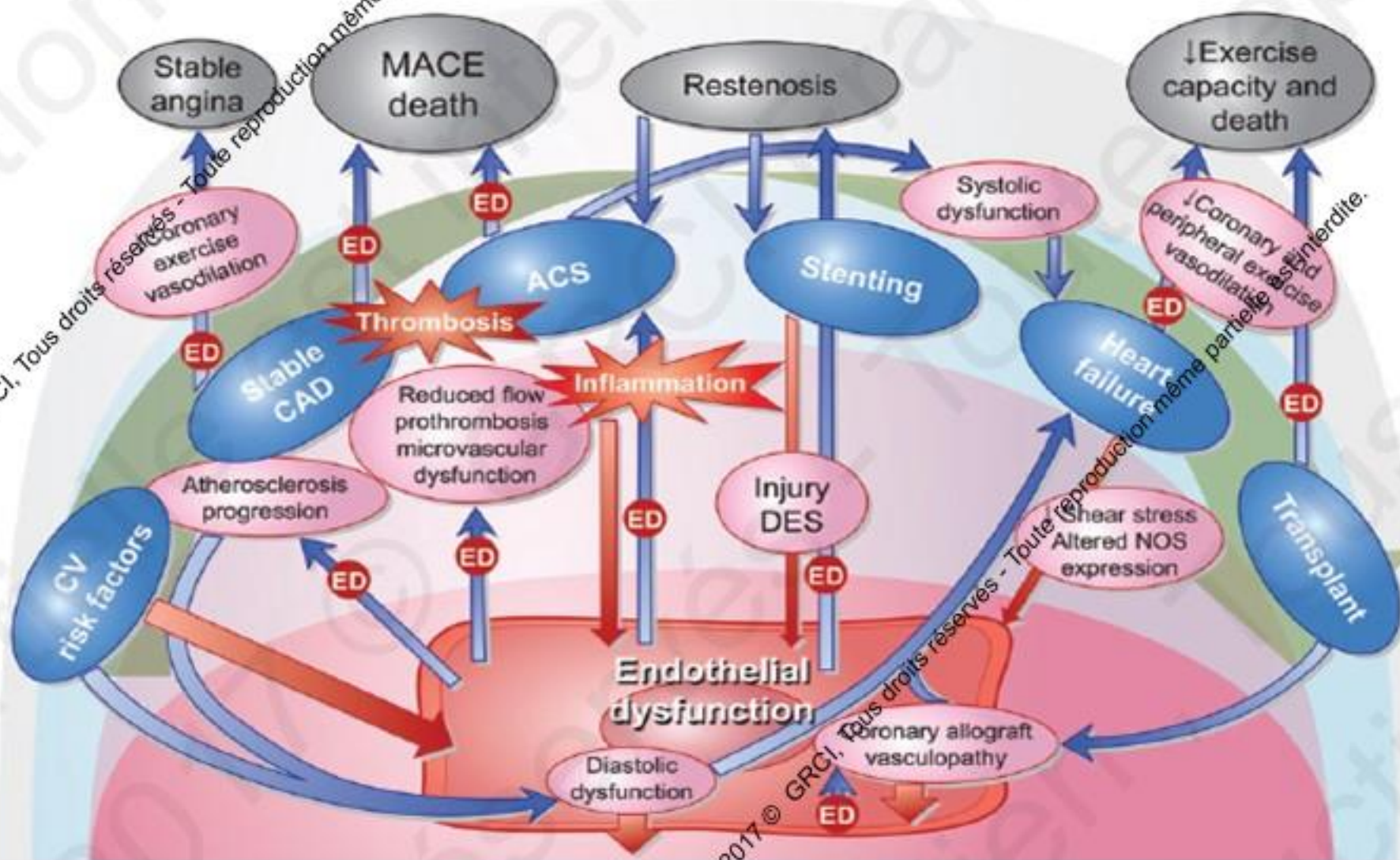
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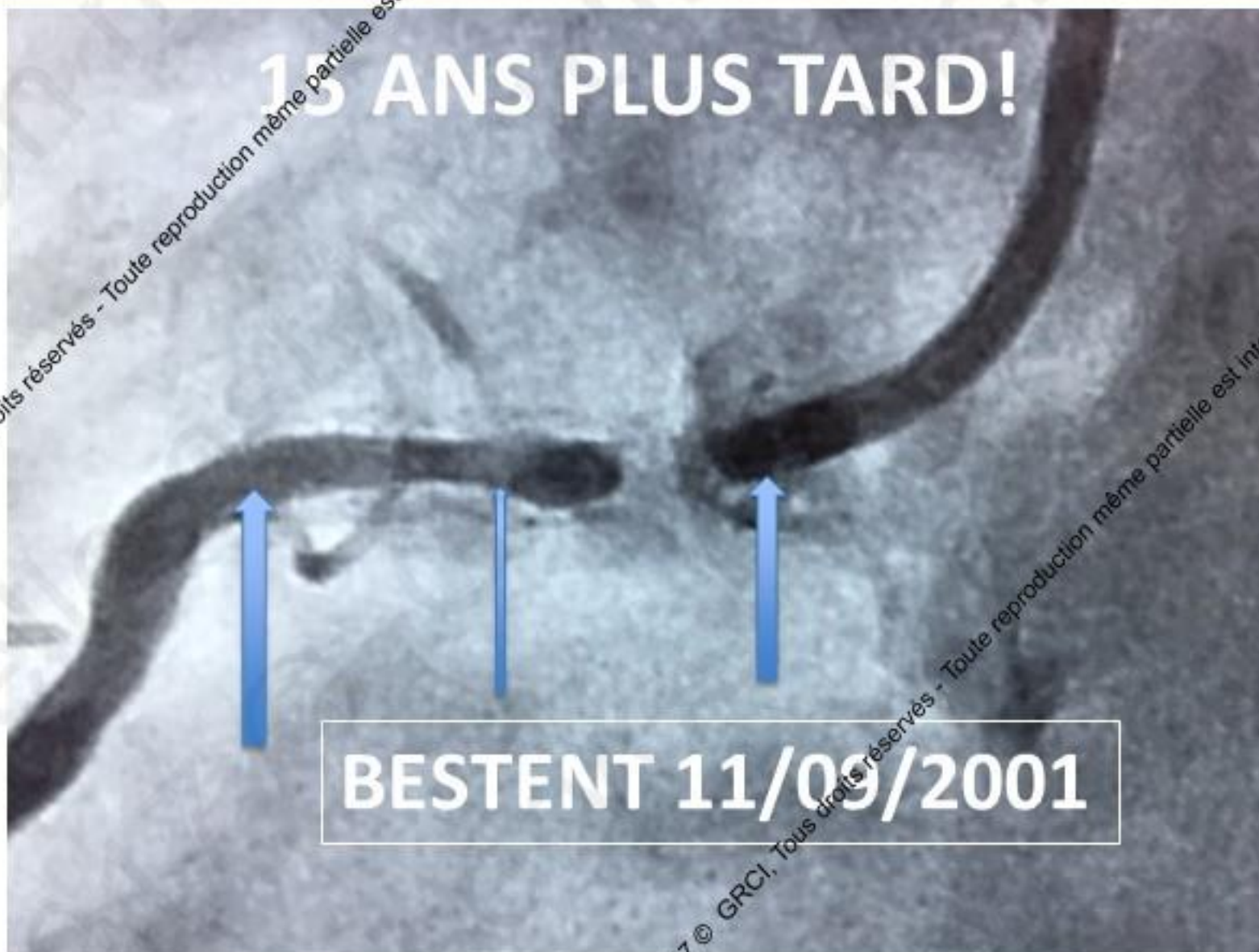




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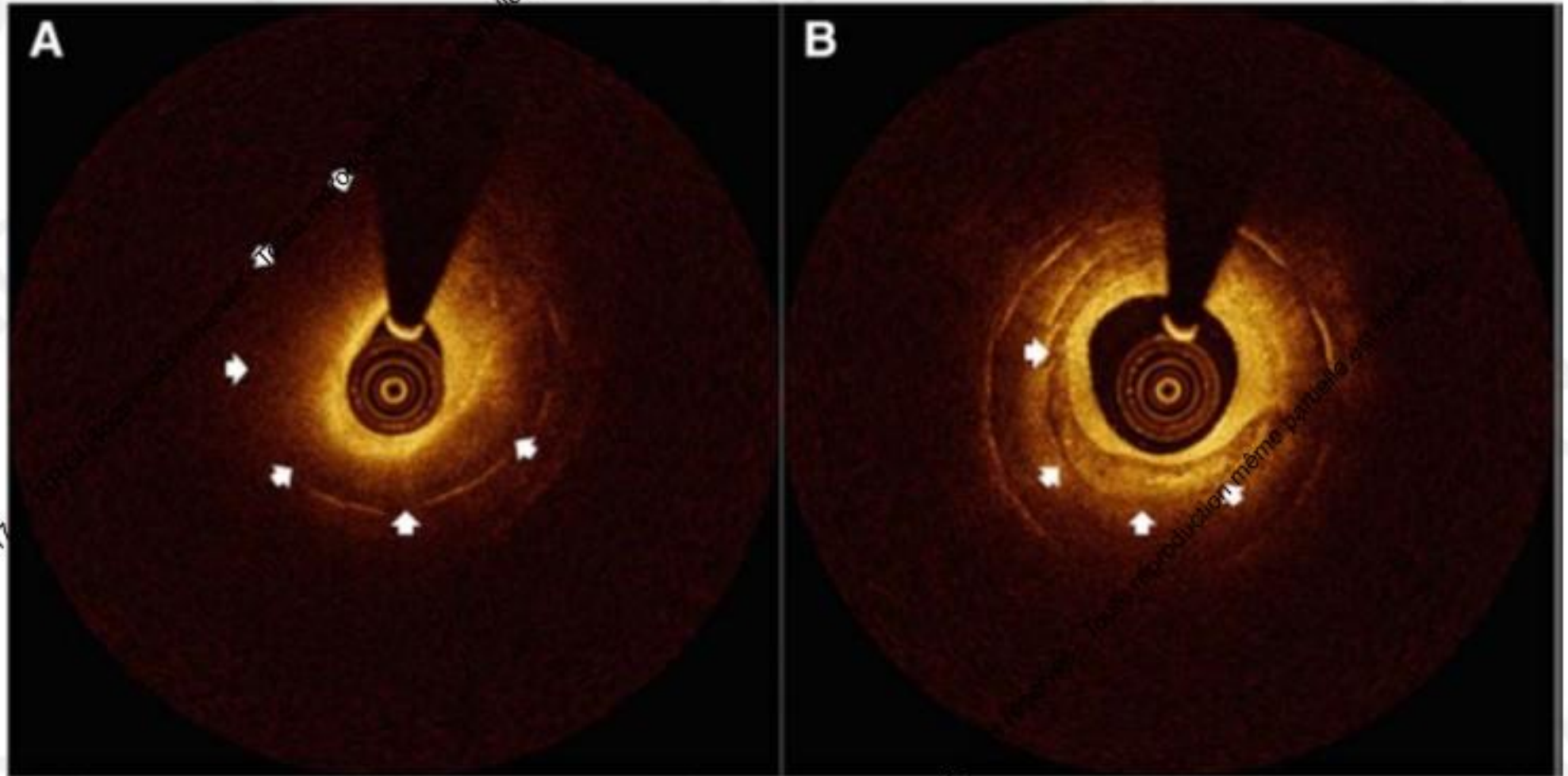


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# NEOATHEROME

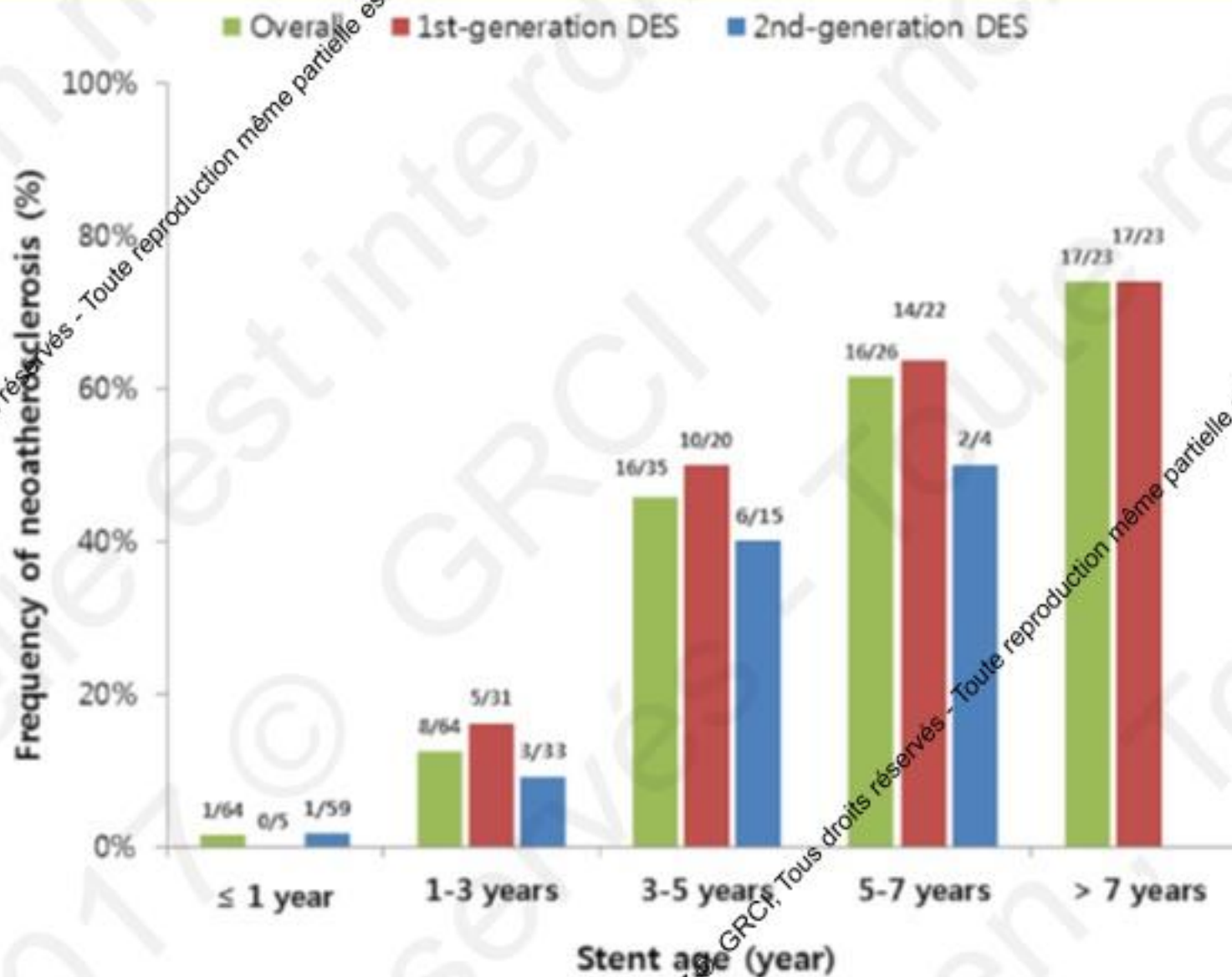
Passion Communication Education



**A Lipid-laden neointima. B Neointima with calcification**

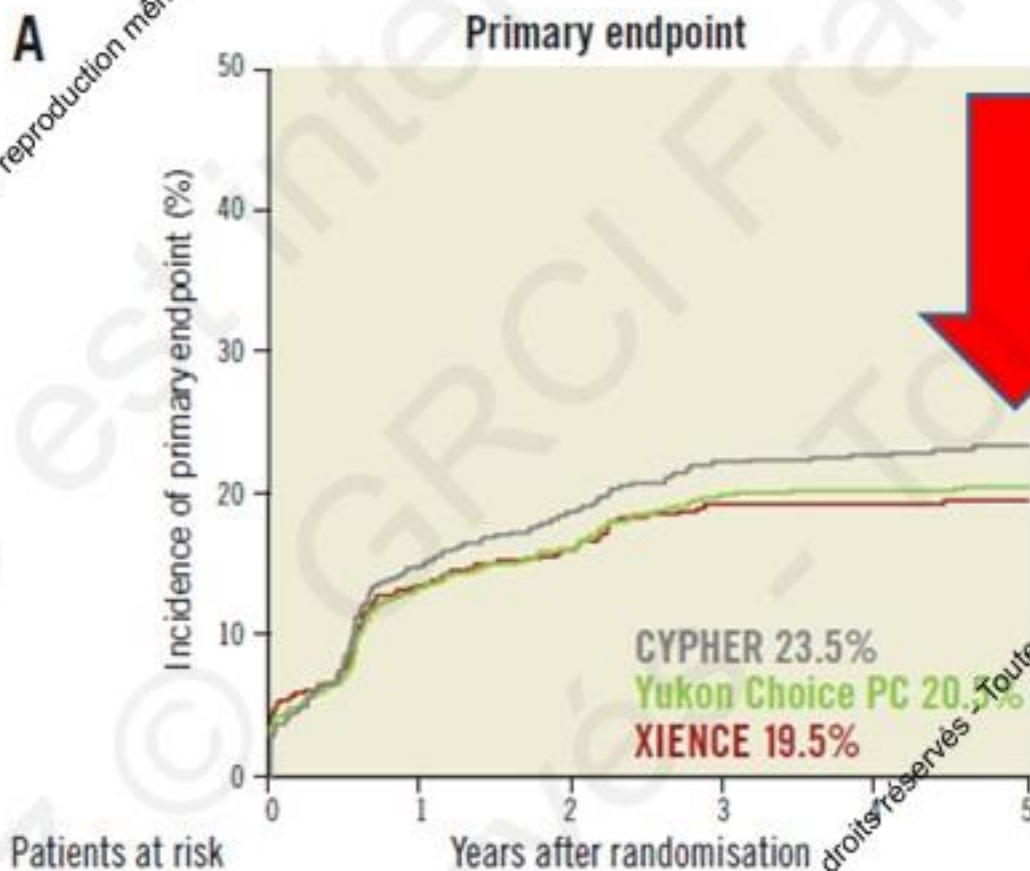
S.Y. Lee, Circ Cardiovasc Interv. 2015;





**MACCE/DOCE: cardiac death, TVRMI, TLR**

Passion Communication Education



Patients at risk

Yukon Choice PC	1,299	1,094	1,030	952	890	971
XIENCE	652	548	520	481	450	390
CYPHER	652	534	496	458	432	368

**ISAR-TEST 4, S. Kufner  
Eurointervention 2014**

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## Mammaire Interne Gauche – IVA implantée il y a 35 ans...



“And we know that metallic **DES from years 3 to 10, and probably for the life of the patient, have about a 2-3% per year rate of TLF**. So if Absorb or a bioresorbable scaffold can capture back a 1% or a half percent of those events on a per year benefit, then it won't be many years at all before it makes up that early difference.”



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**“The reason to persevere is not because of any expectation that scaffolds can beat metal stents in the intermediate term, but the concern that metal stents will begin to produce significant adverse events many years after implantation. That will have to become a demonstrated reality rather than a hypothetical speculation for bioresorbable scaffolds to replace metal stents.”**

**Fix the Technique, or Fix the Device?\***

Spencer B. King III, MD, Bill D. Gogas, MD, PhD

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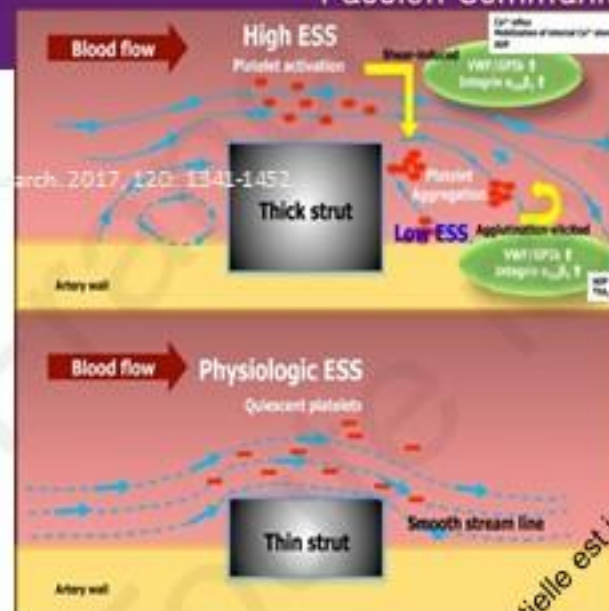
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Absorb GT1®

Next Gen  
Absorb



Reduced Strut  
Thickness



**Reduced Strut Thickness from 157 Microns to 99 Microns**

- May reduce acute thrombogenicity and achieve full endothelialization earlier
- Increases ease of use with substantially improved deliverability in simulated clinical models

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Cold spray coating



Coated rod

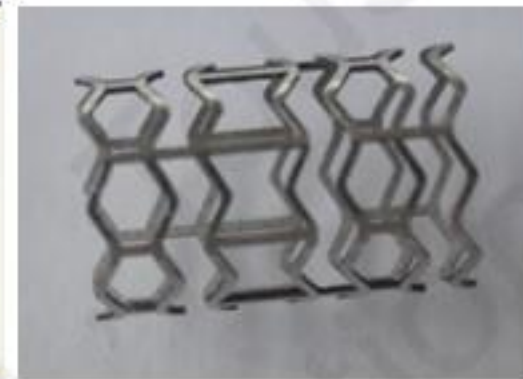


Centerless grinding

EDM



Laser cutting





**GRCI 2017**  
France

# Bien avant !

6 AU 8 DÉCEMBRE 2017  
Novotel Paris Tour Eiffel

Passion Communication Education



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