

CHOIX CLINIQUE DU DISPOSITIF MEDICAL DANS LA REVASCULARISATION CORONARIENNE

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Service de Cardiologie Rangueil

**Euromat Toulouse
12 Octobre 2010**

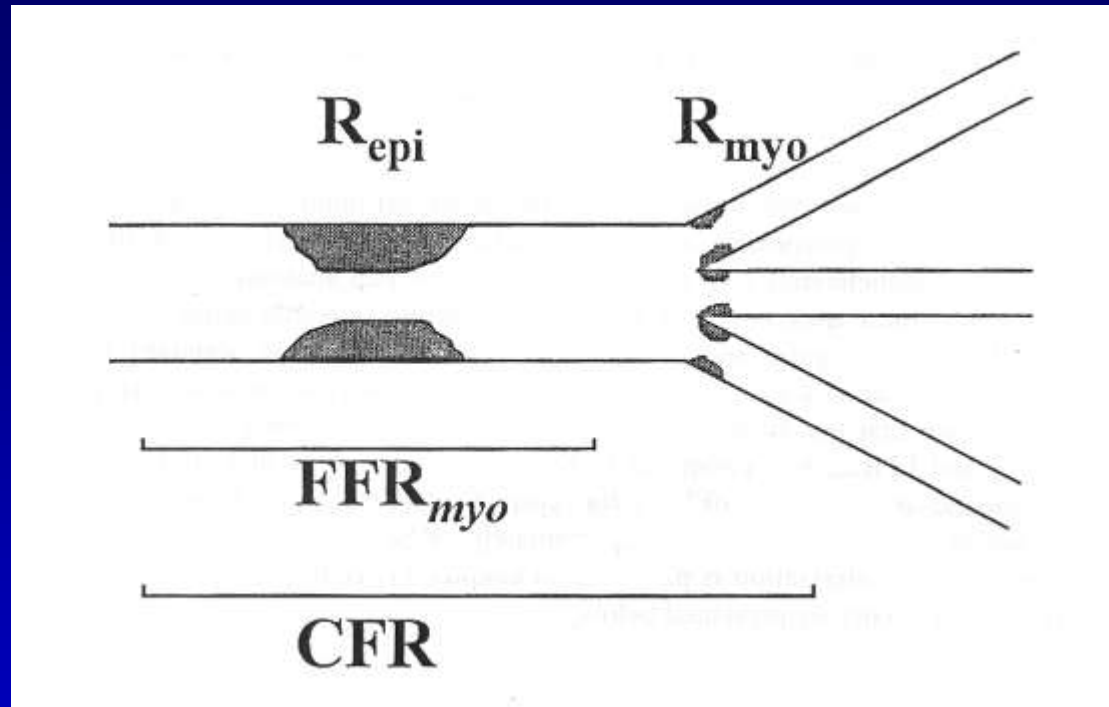


What is FFR (Fractional Flow Reserve) ?

- FFR compares the aortic pressure to the blood pressure distal to a stenosis during maximum hyperemia.
- FFR represents the fraction of blood flow that has still been preserved despite the stenosis.

$$FFR_{\text{myo}} \approx P_d / P_a$$

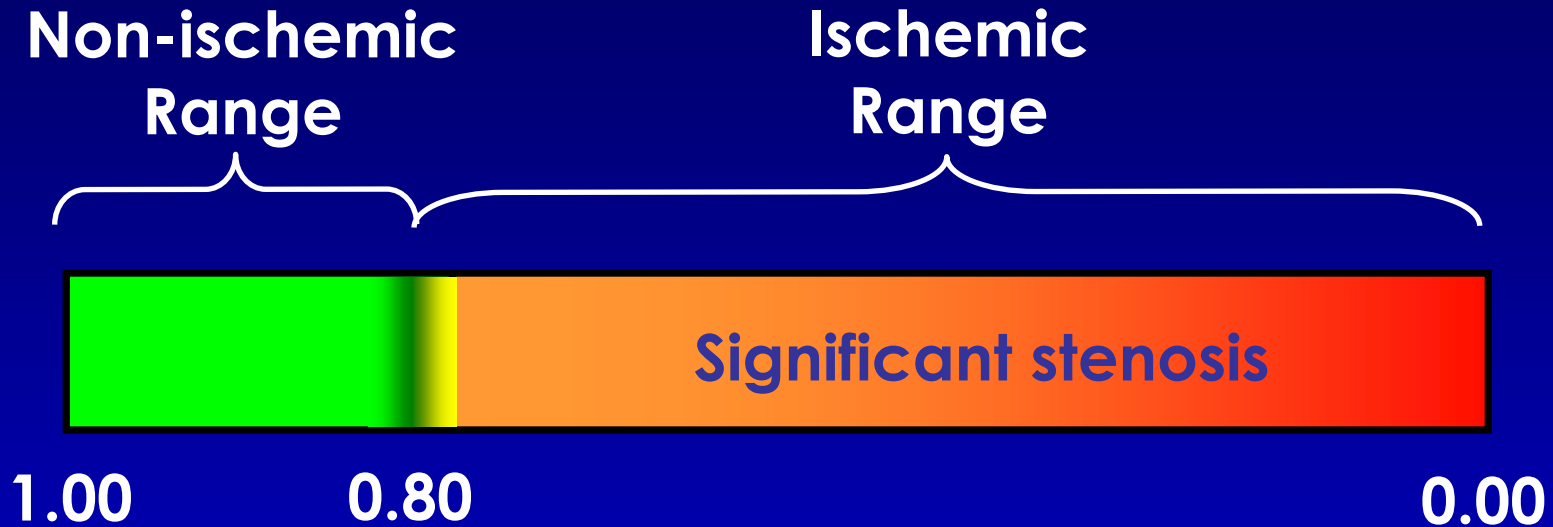
Flow and Pressure



Flow (CFR) examines the effects of disease on the microvascular bed.

Pressure (FFR) focuses on lesions within the main vessels.

FFR Threshold for Ischemia



FFR < 0.80 → inducible ischemia

FFR > 0.80 → no inducible ischemia

Hyperemia

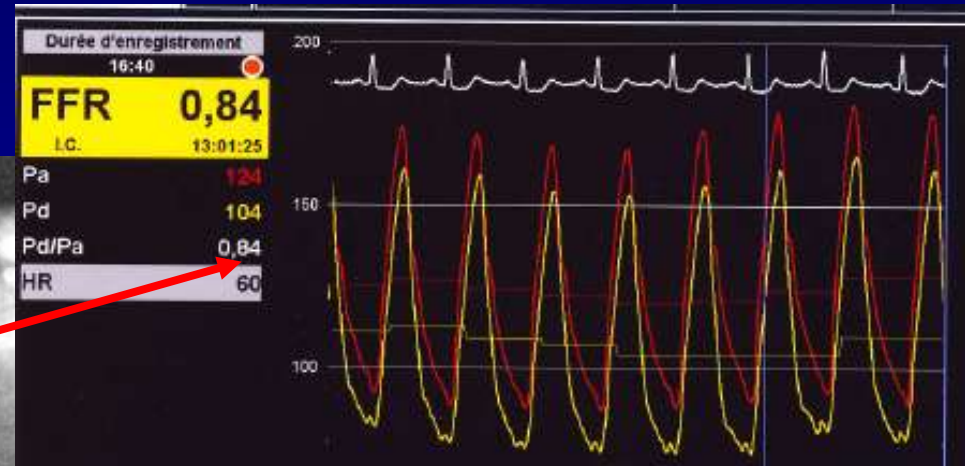
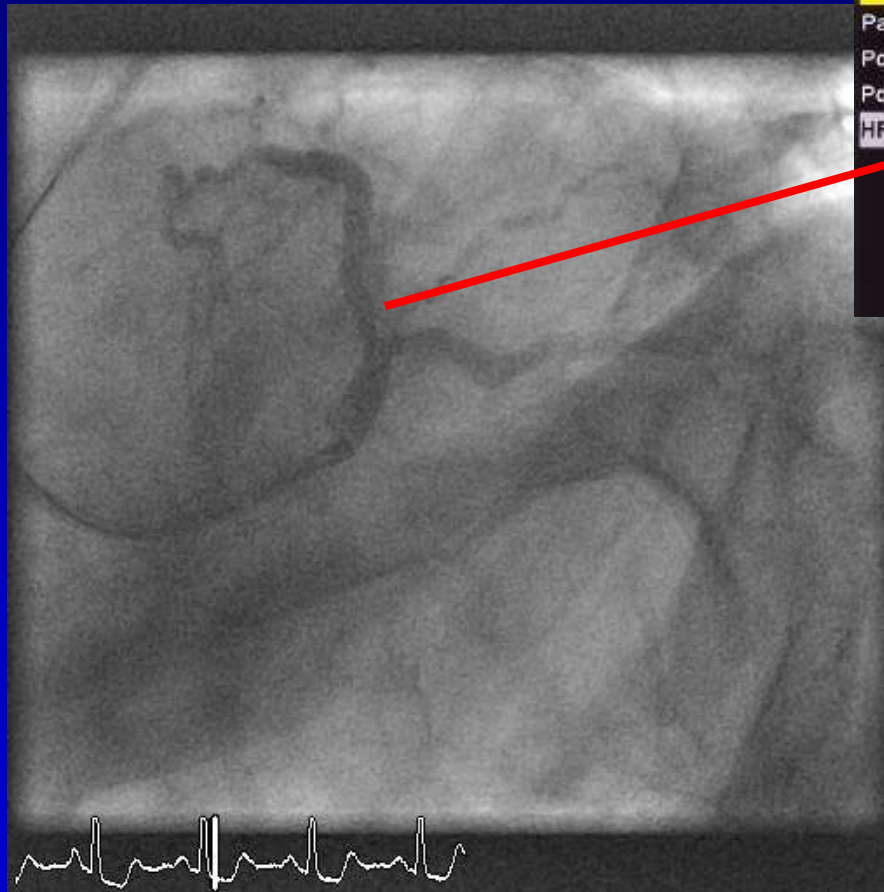
Induce hyperemia and press 'Measure' to obtain the FFR result.

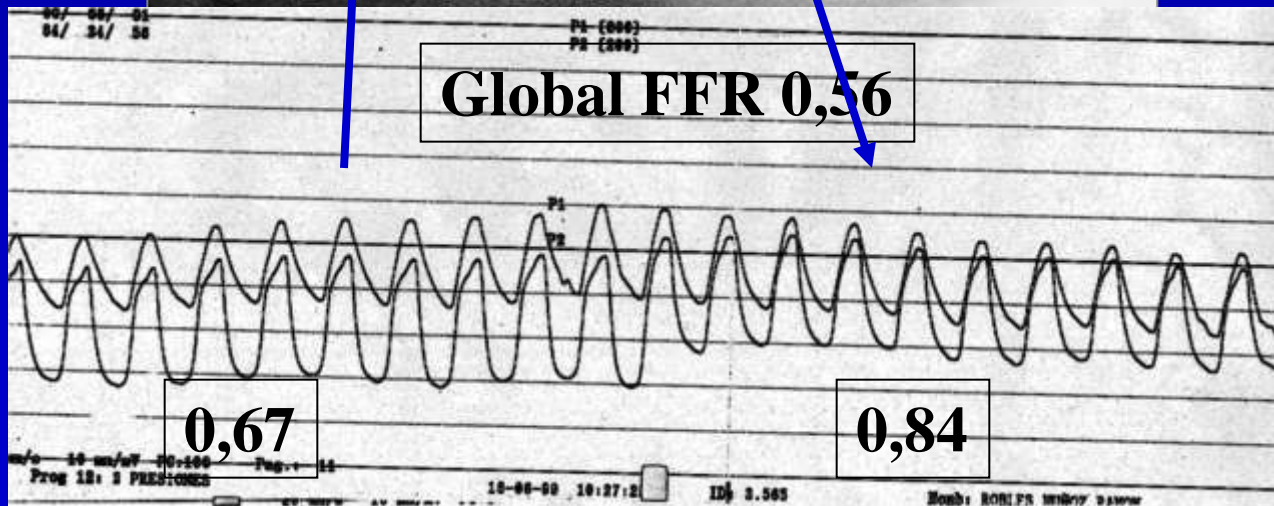
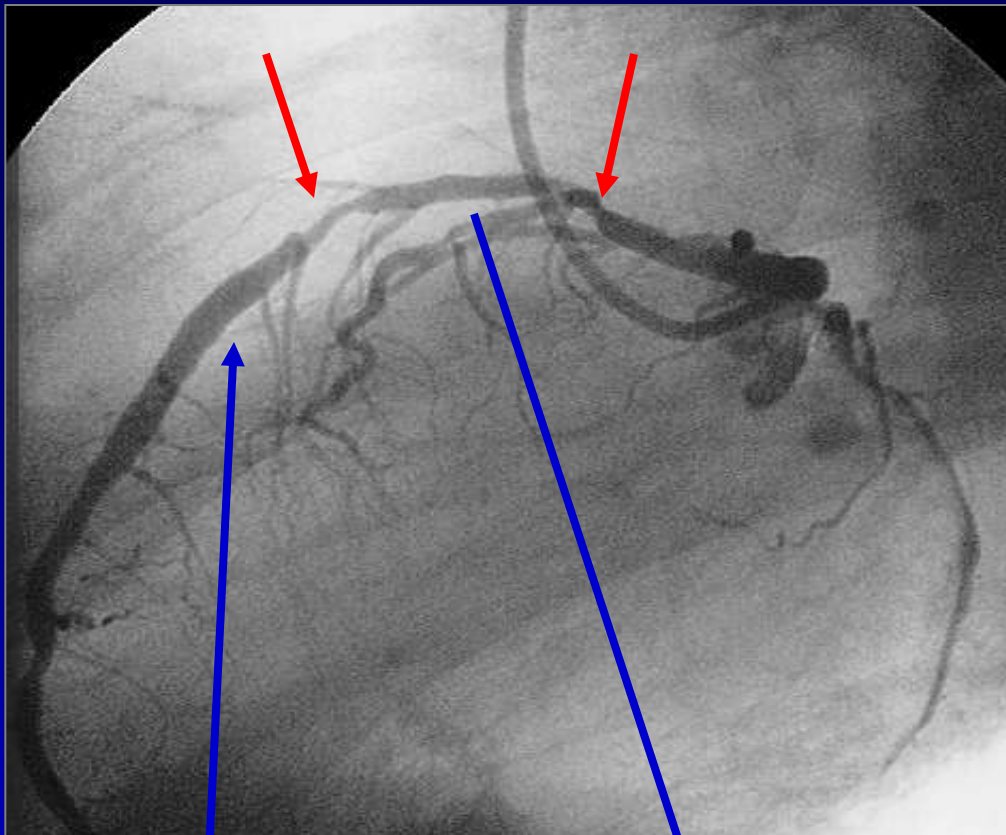


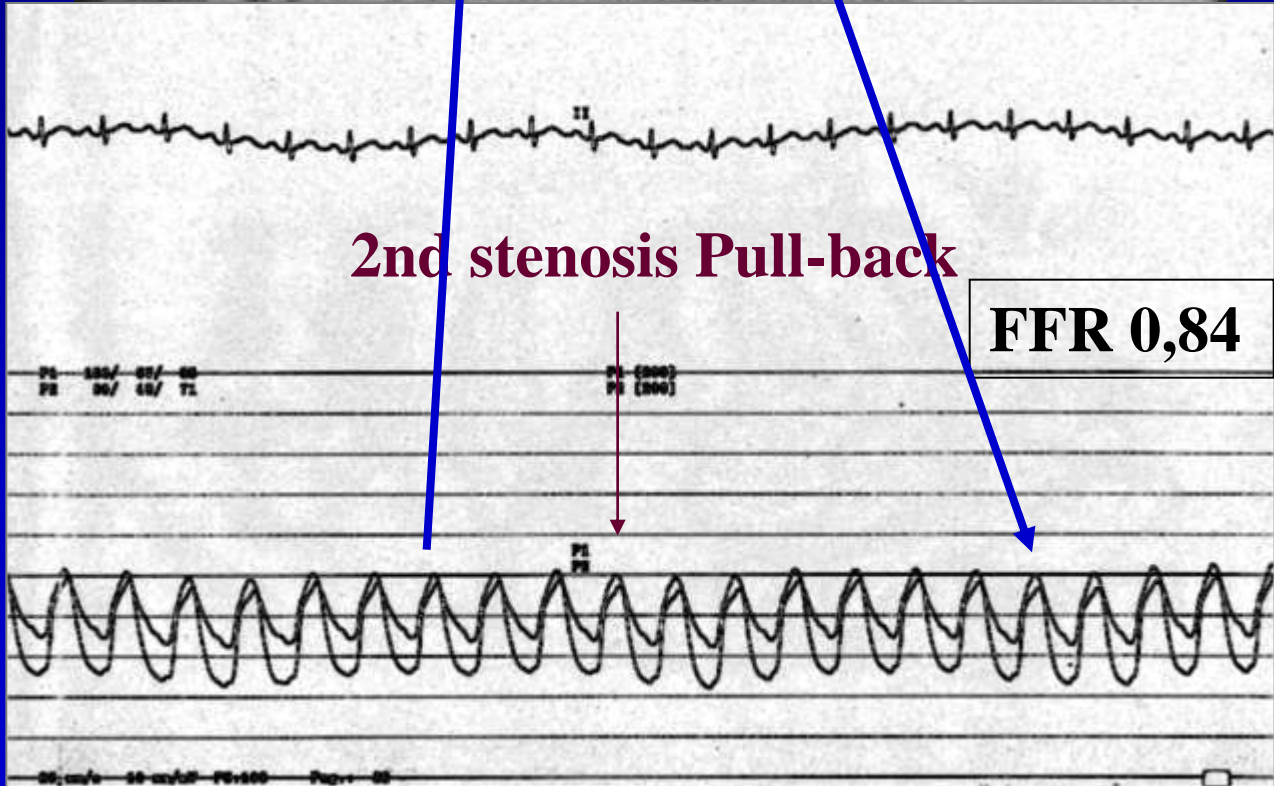
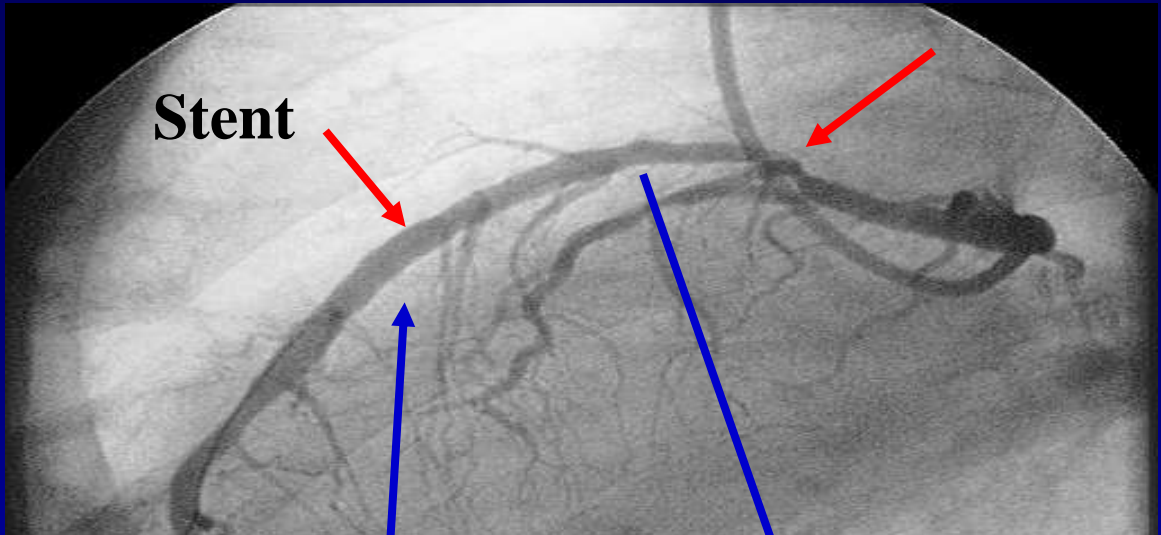
Intracoronary Adenosine

- More frequently used (safe and cheap)
 - Short Hyperemia, makes FFR overestimation
 - Usually low dose used: at least 40 μg in LCA
30 μg in RCA
 - 200 μg published data
- PULL BACK is not possible
- Sometimes makes incorrect interpretation
- It is not possible evaluate ostial or very proximal lesions

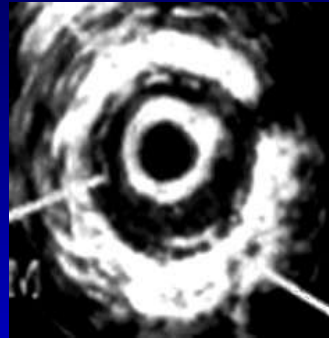
MESURE FFR IVA 0, EN AMONT STENT



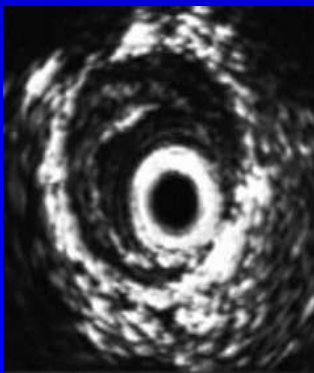




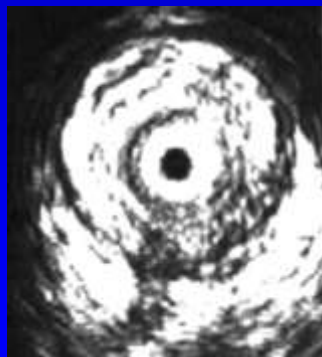
Sémiologie échographique endocoronarienne



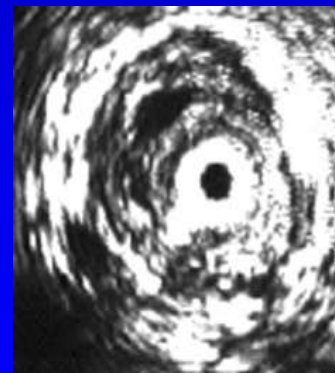
Paroi normale



Plaque molle



Plaque dure

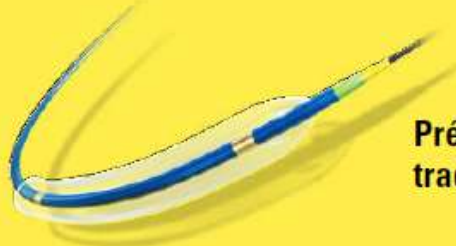




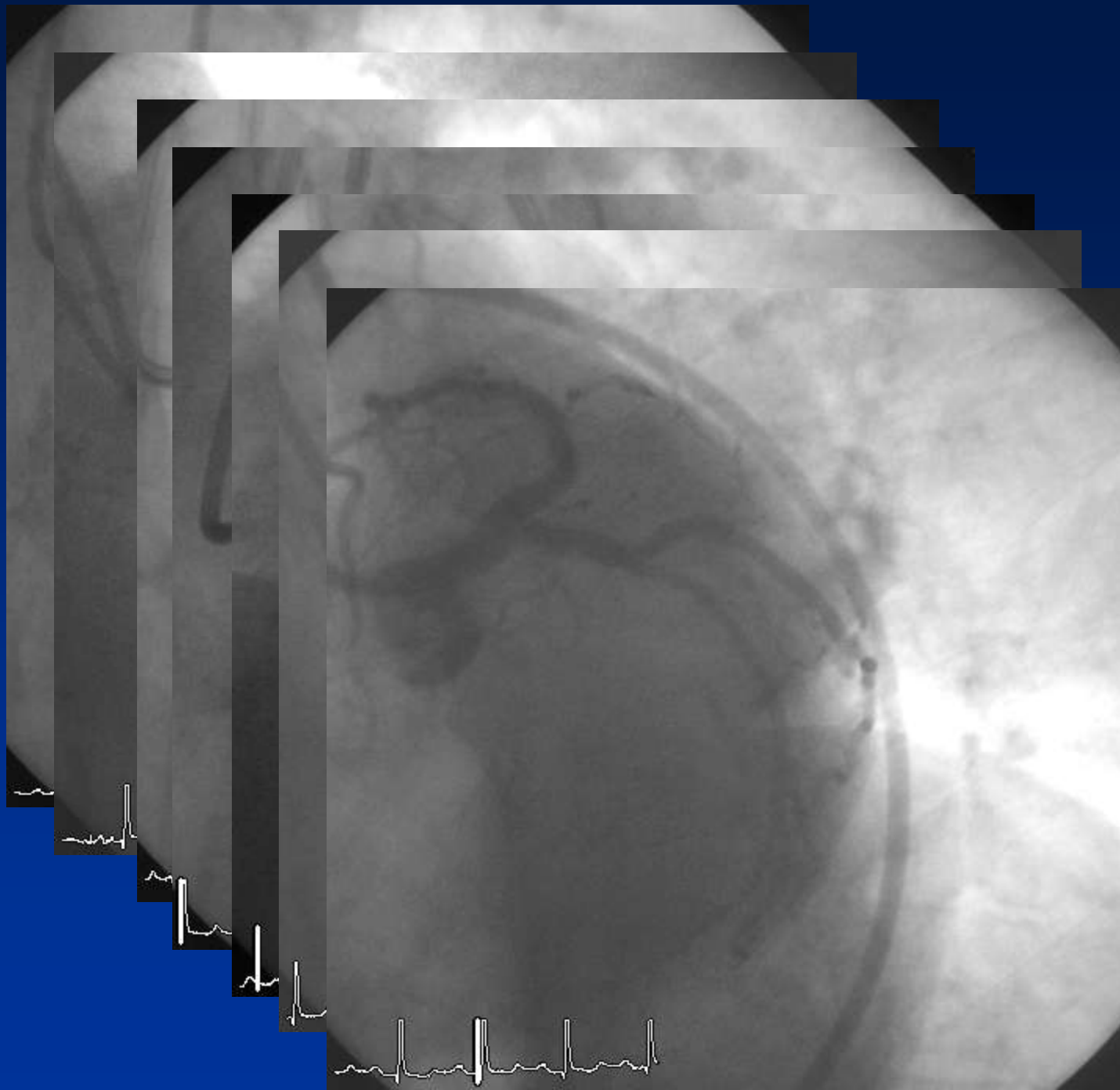
Plaque mixte



Thrombus

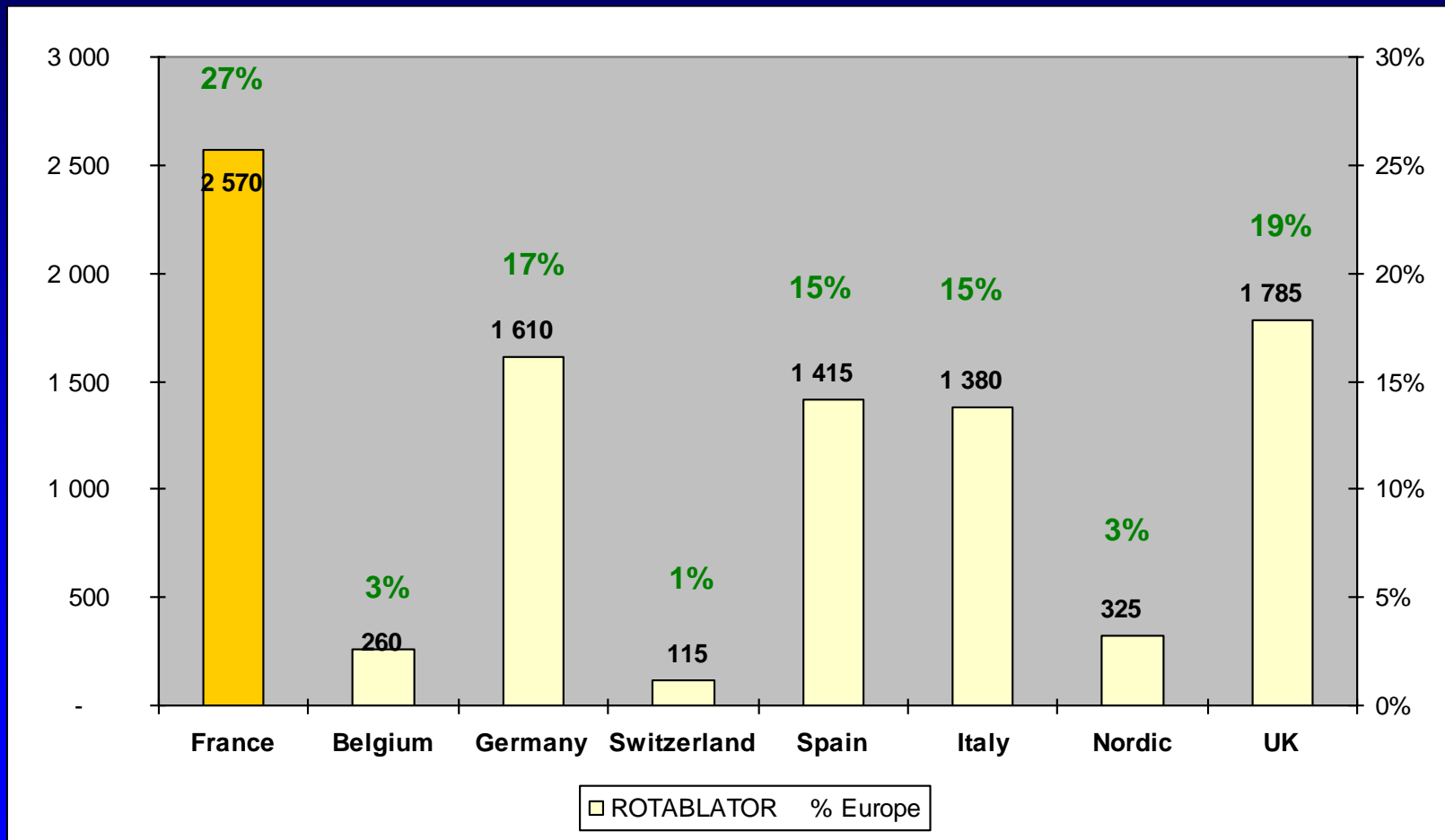
Positionnement produit

PLAQUE SOUPLE	Tout type de lésions	Optimise le positionnement du stent	 <p>Pré-dilatation traditionnelle</p> <p>Apex™ Cathéter de dilatation ACTP / Maverick2™ Cathéter à ballonnet Apex™</p>
	Lésions ISR	Évite les glissements	 <p>Incision de la plaque</p> <p>Dispositif Flextome™ Cutting Balloon™ Système de dilatation microchirurgical™</p>
	Lésions ostiales, Bifurcations**	Évite le basculement de la plaque	
PLAQUE RÉSISTANTE	Lésions fibreuses		
	Lésions calcifiées	Modifie la compliance des lésions	 <p>Modification / Diminution du volume de la plaque</p> <p>Rotablator™ Système d'athérectomie rotative</p>



I. Quelques données chiffrées sur le ROTA

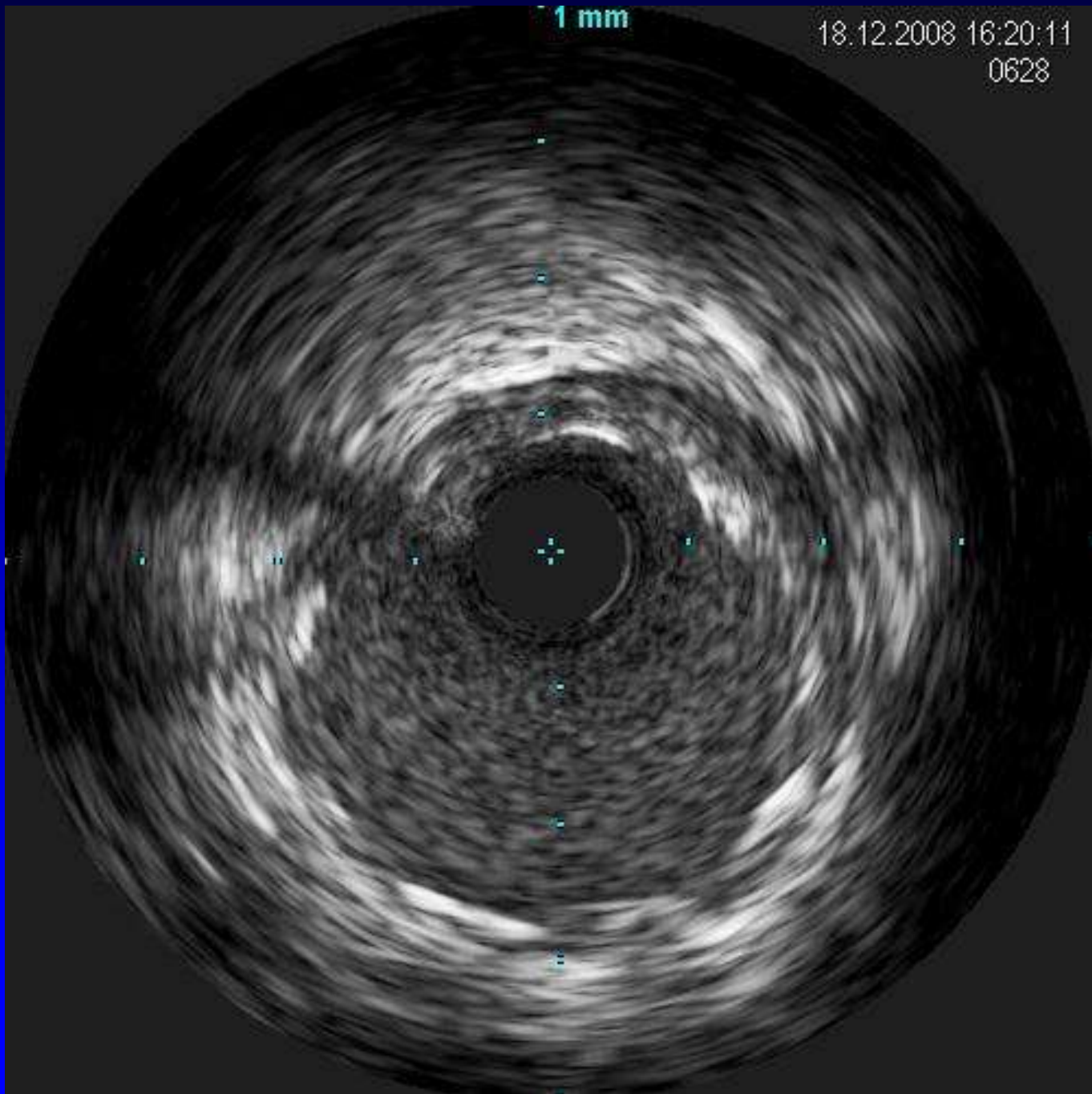
◆ A. Données Europe



1 mm

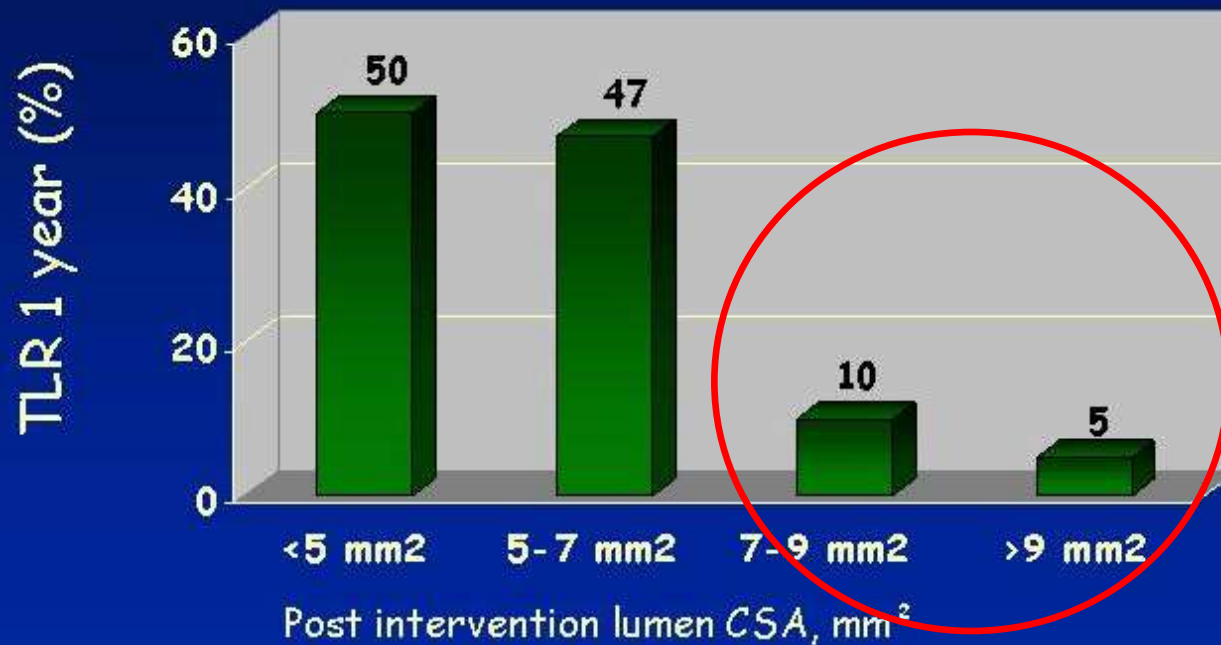
18.12.2008 16:20:11

0628



Intravascular Ultrasound

Left Main Disease



Hong et al Am J Cardiol 1999;83(2):175-9
Kornowski et al Am J Cardiol 1998 82:32-37

Predictors of Angiographic Restenosis After Stenting

Pooled analysis of 1197 patients from five randomized stent trials

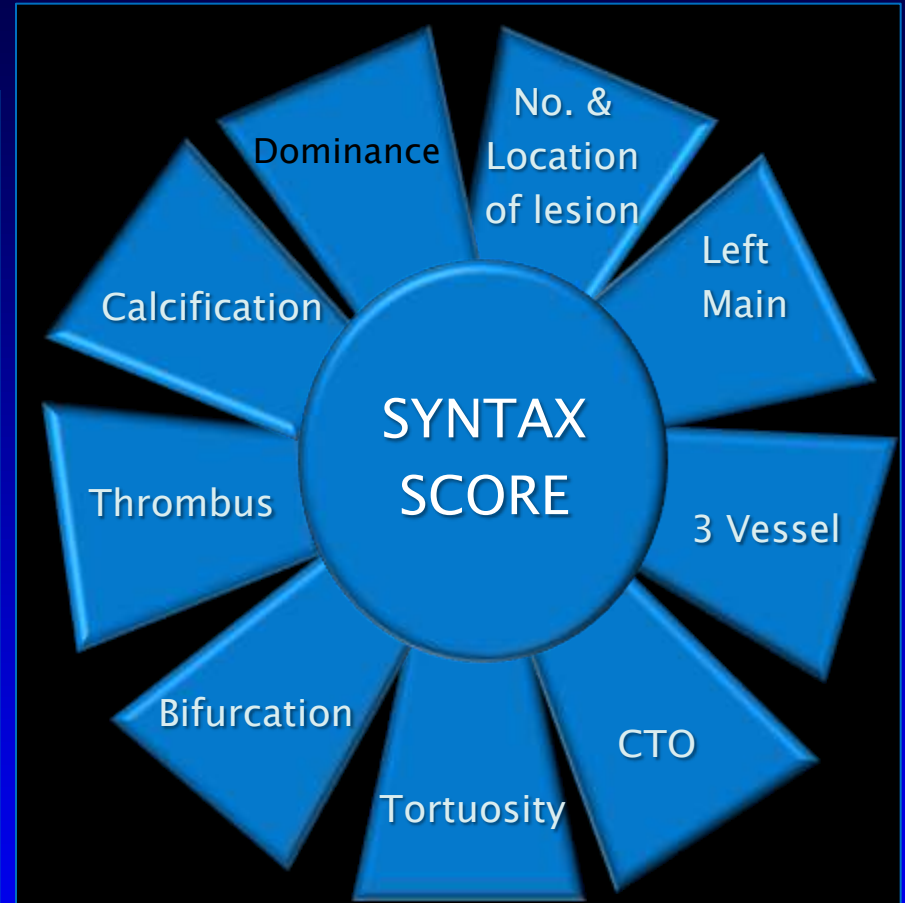
Post-Procedure In-Stent MLD	Lesion Length			
	10 mm	15 mm	20 mm	25 mm
<i>Non - Diabetics</i>				
4.0 mm	6%	7%	8%	10%
3.5 mm	10%	12%	14%	16%
3.0 mm	17%	19%	22%	25%
2.5 mm	27%	30%	33%	37%
<i>Diabetics</i>				
4.0 mm	9%	10%	12%	14%
3.5 mm	15%	17%	19%	22%
3.0 mm	23%	26%	30%	33%
2.5 mm	35%	39%	43%	46%

Risk factors for restenosis: MLD_{post}, lesion length, diabetes

Patient Profiling

Local Heart team (surgeon & interventional cardiologist) will assess each patient in regards to:

- Patient's operative risk (EuroSCORE & Parsonnet score)
- Coronary lesion complexity (Newly developed SYNTAX score)
- The goal of the SYNTAX score is provide a tool to assist physicians in their revascularization strategies for patients with high risk lesions



BARI classification of coronary segments

Leaman score, *Circ* 1981;63:285–299

Lesions classification ACC/AHA, *Circ* 2001;103:3019–3041 Bifurcation classification, *CCI* 2000;49:274–283

CTO classification, *J Am Coll Cardiol* 1997;30:649–656

Sianos et al, *EuroIntervention* 2005;1:219–227

Valgimigli et al, *Am J Cardiol* 2007;99:1072–1081

Serruys et al, *EuroIntervention* 2007;3:450–459

Drug-eluting Stents in 2004

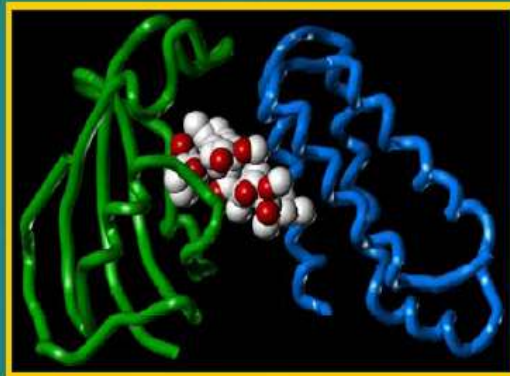
Safety and Efficacy Proven

Drug

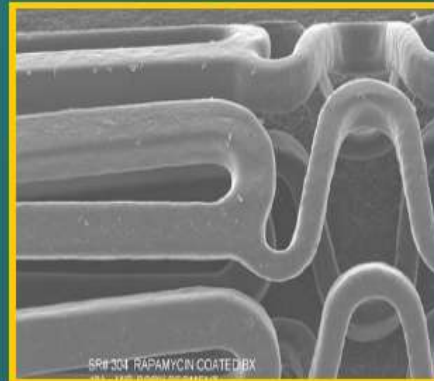
Polymer

Stent

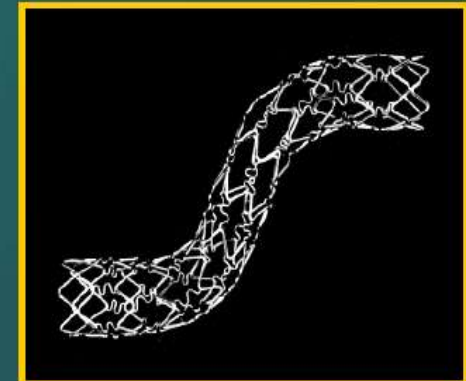
Cypher



Sirolimus

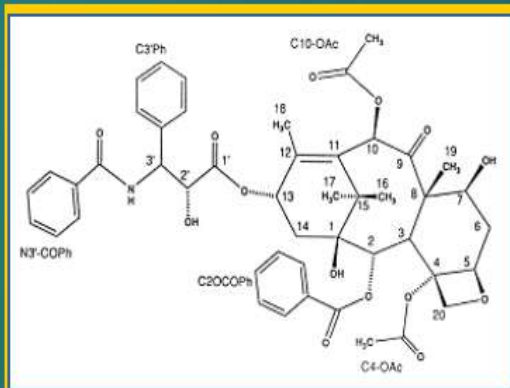


PEVA + PBMA blend

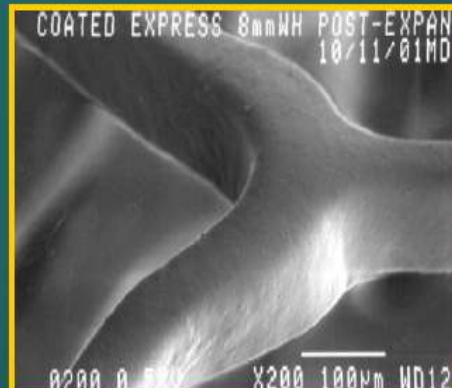


BX Velocity

TAXUS



Paclitaxel

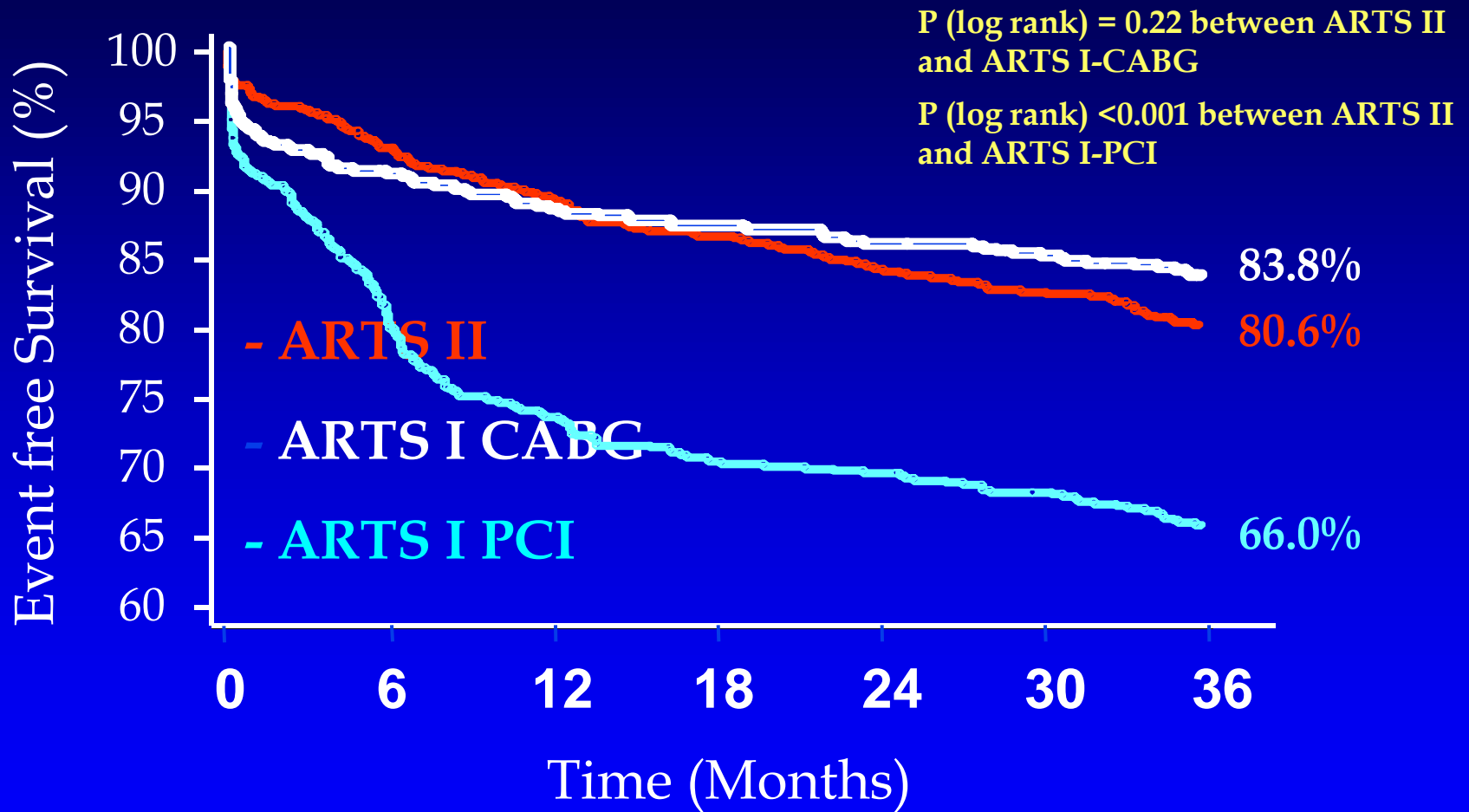


Polyolefin derivative



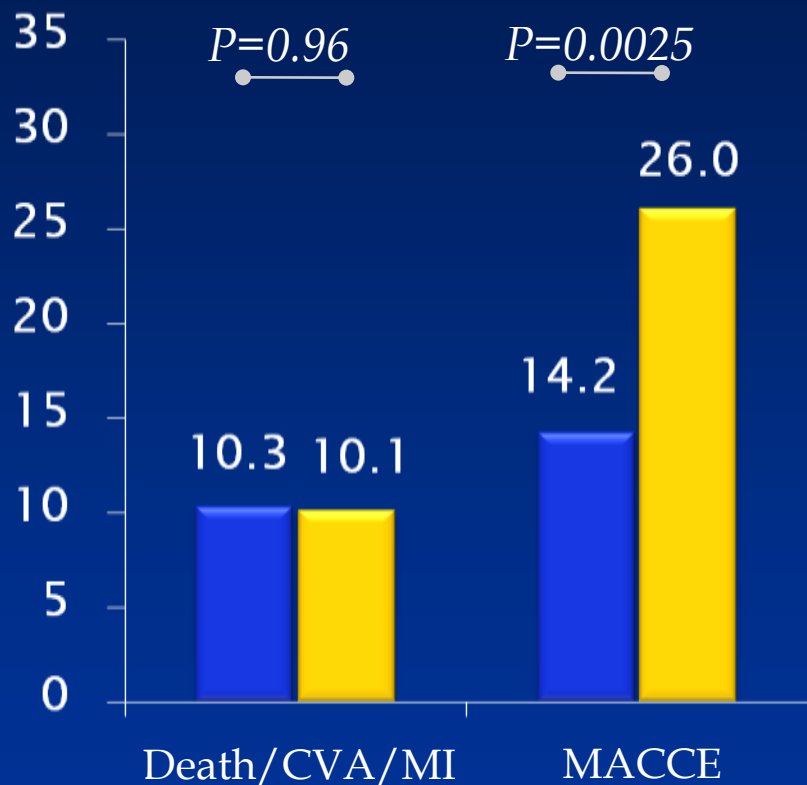
Express²

ARTS II - MACCE up to 3 years

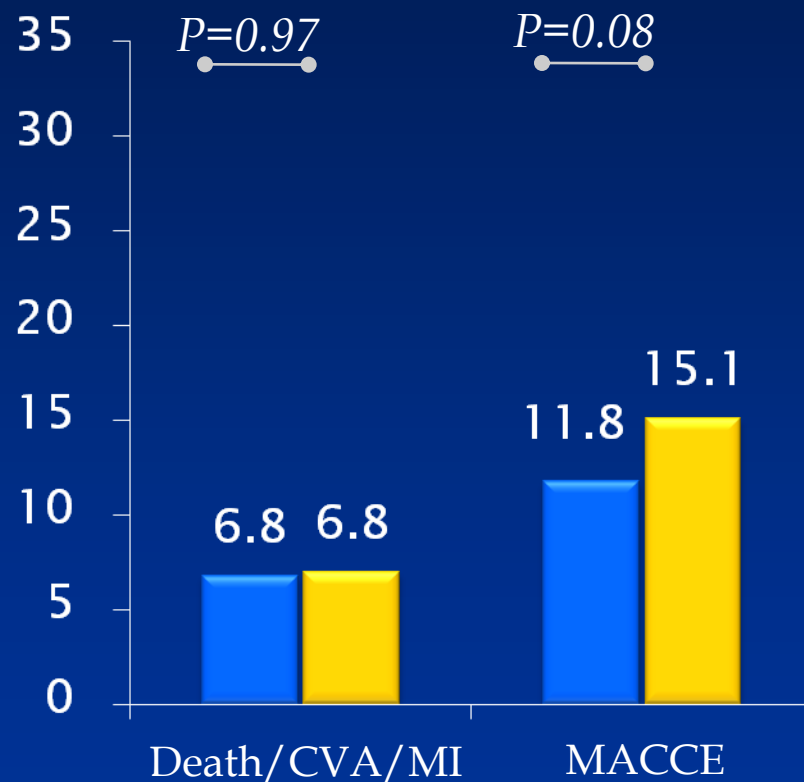


Outcome according to Diabetic Status

CABG TAXUS



Diabetes (Medical Treatment)
N=452



Non-Diabetic
N=1348

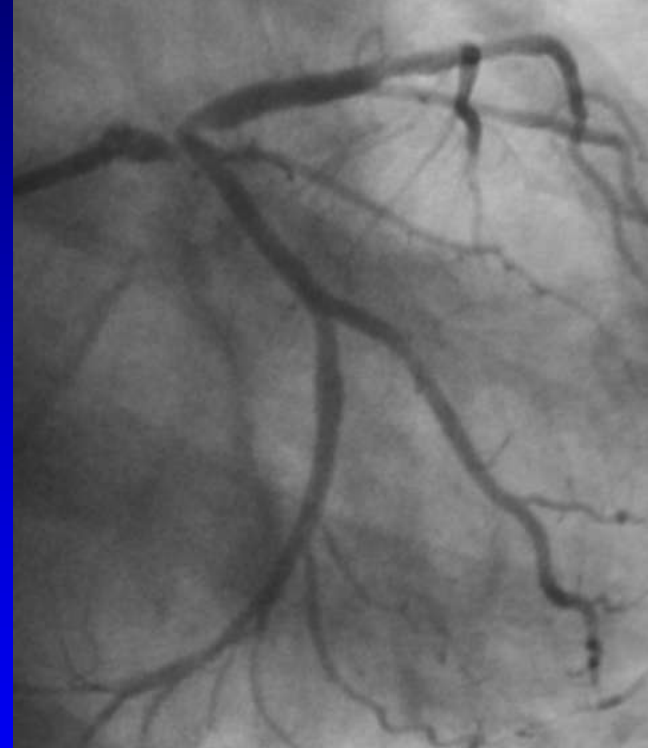
Localization of the LM Lesion



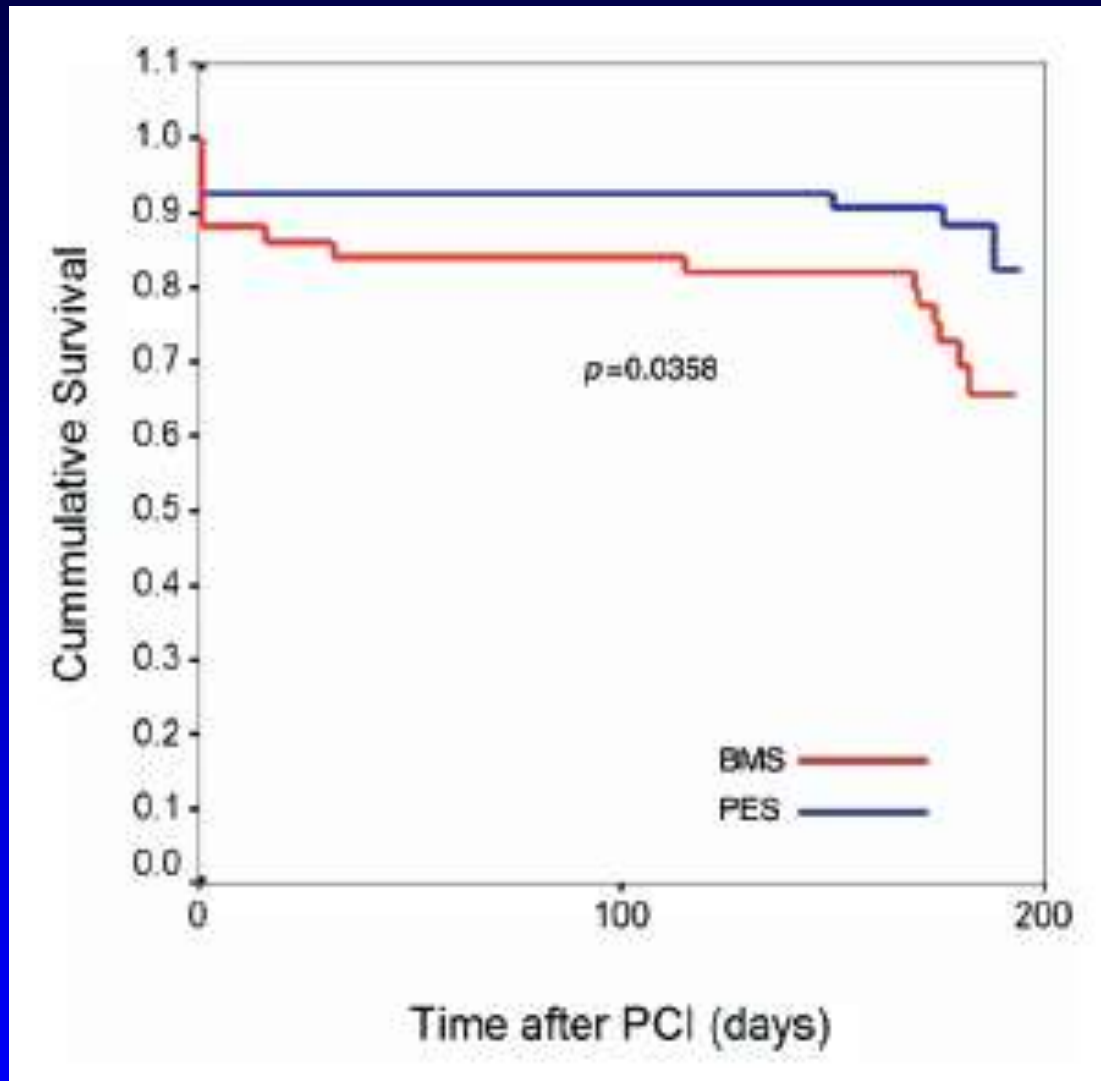
Ostial-proximal 19 %



Mid-segment 12 %

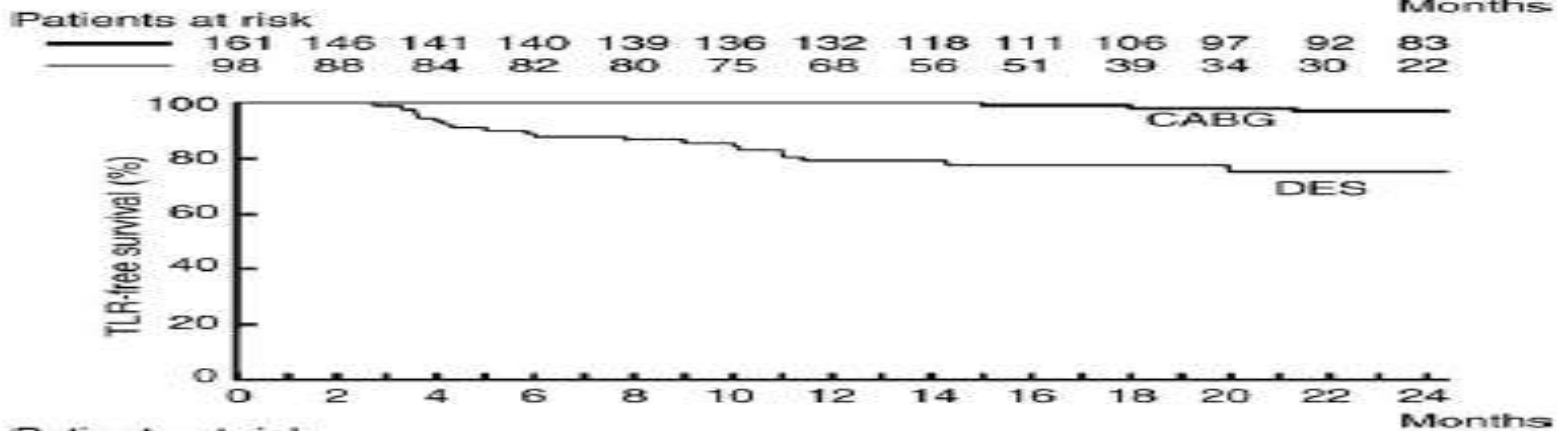
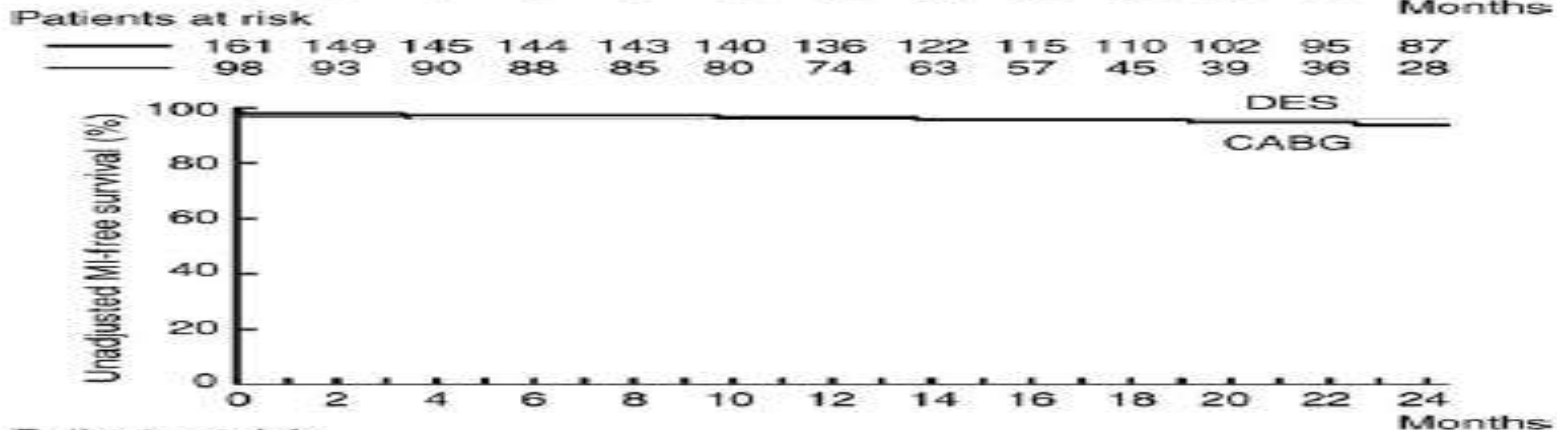
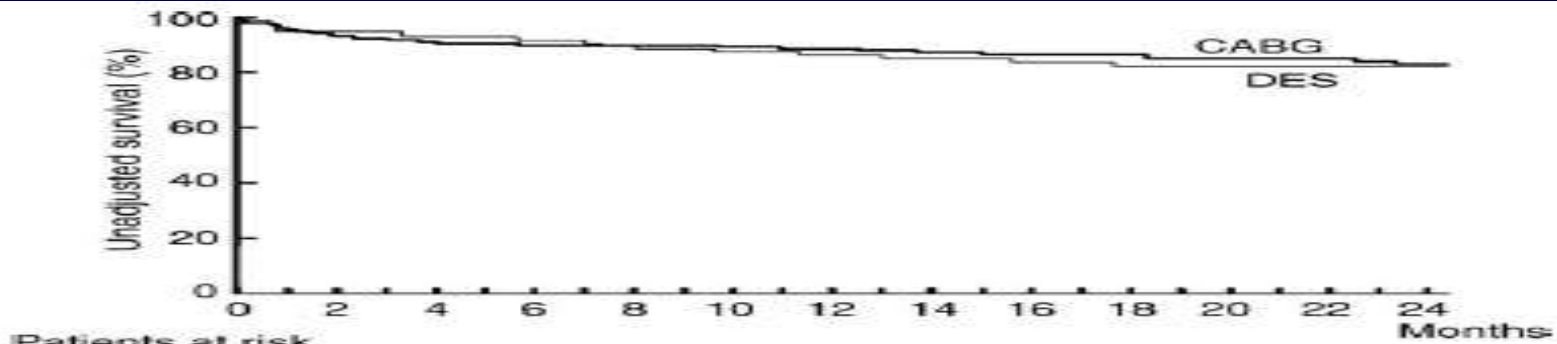


Distal 69 %



Kaplan-Meier Curves: Freedom From Major Adverse Coronary Events

Erglis JACC 2007;50:491-7.

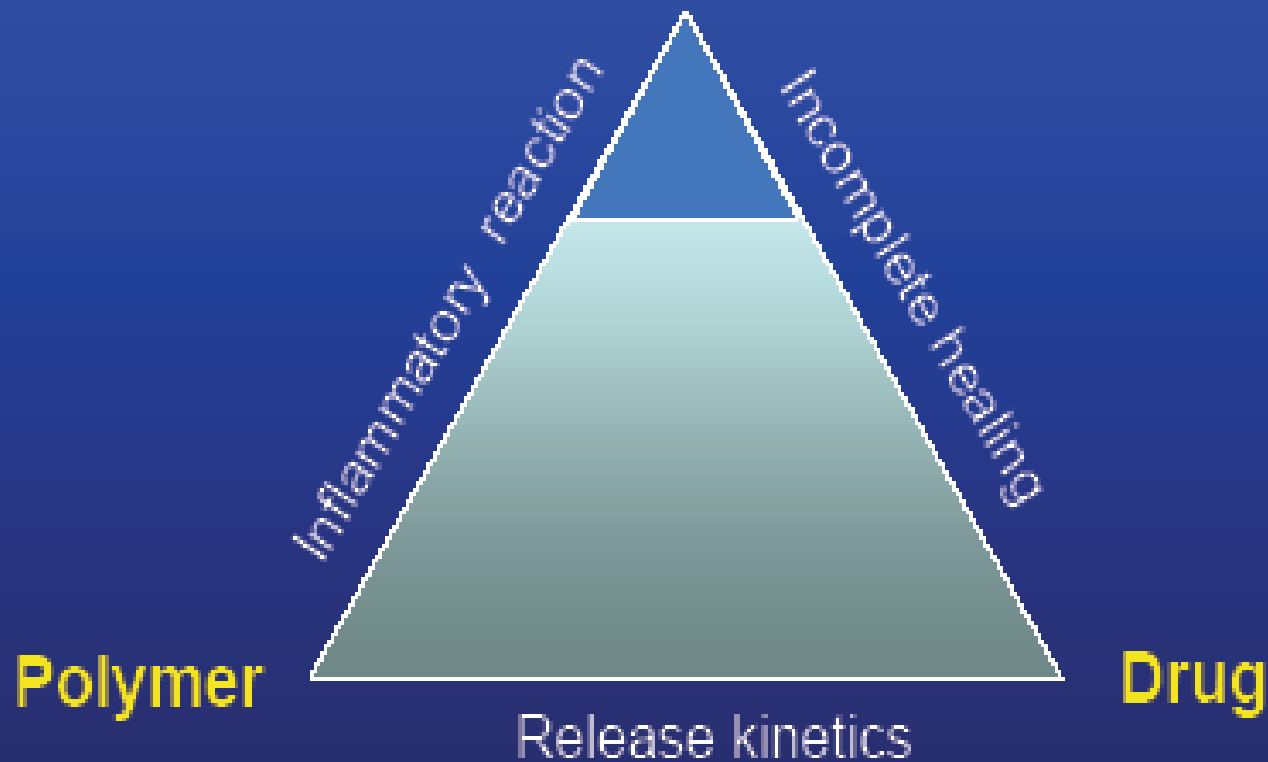


ULM CS > 75 years-old



Components of DES and Pathology

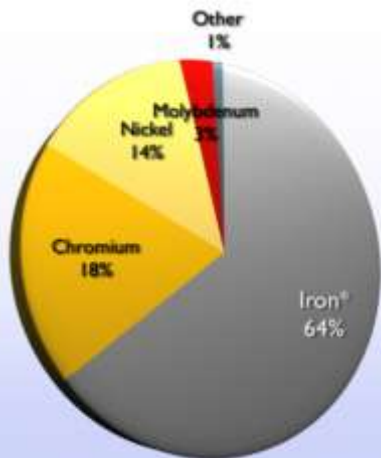
Metal/Design



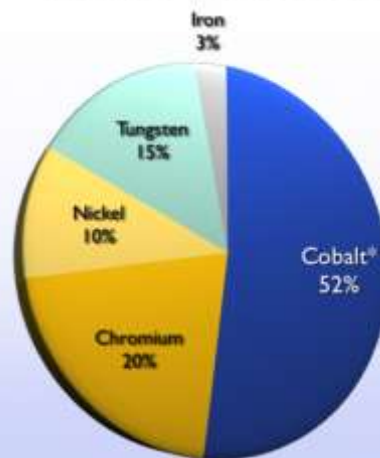
Les différents alliages disponibles

Nominal Metal Composition

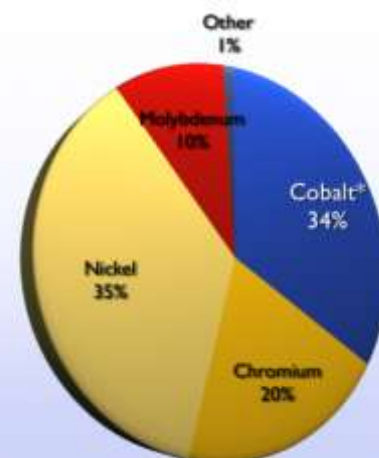
316L
Stainless Steel



L605
Cobalt Chromium



MP35N
Cobalt Nickel



TAXUS™,
Liberté™ Stent,
TAXUS Express™
Stent
CYPHER™ Stent

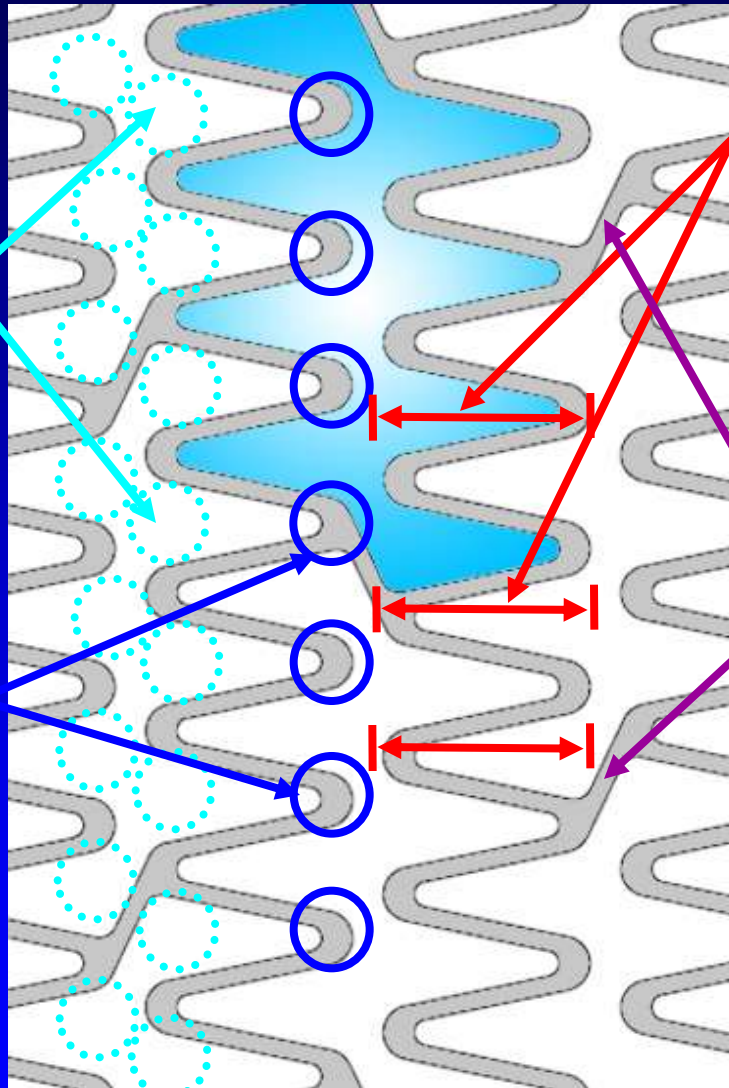
PROMUS™
Stent
XIENCE™ V
Stent

ENDEAVOR™
M Stent

Géométrie du stent Element™

Géométrie uniforme des cellules pour optimiser la libération de principe actif

Des courbures plus larges pour minimiser degré de retour

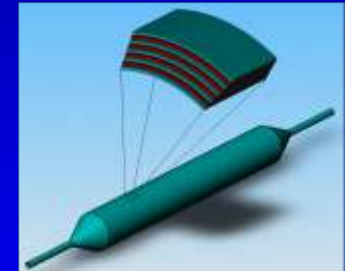
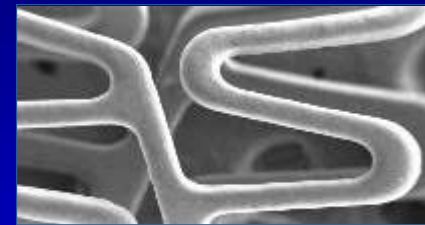


Segments courts pour améliorer la conformabilité

Deux connecteurs pour améliorer la flexibilité

Plate-forme Stent Element™

- **Alliage Platine Chrome**
 - Radio-opaque
 - Mailles fines
 - Résistance élevée à la compression
- **Géométrie conçue pour relargage de principe actif**
- **4 modèles de stents**
 - Ratio métal/artère bas
- **Système de pose basé sur le cathéter à ballonnet Apex™**
- **ballonnet Apex™**
 - Technologie corps du cathéter à 2 composants
 - Ballon multi-couches



Vision™ 0.0032"
(0.081 mm)



Driver™ 0.0036"
(0.091 mm)



Express™ 0.0052"
(0.132 mm)



Liberté™ 0.0038"
(0.096 mm)



Element 0.0032"
(0.081 mm)

Profil du stent Element™ 3 mm

Profil
de franchissement

Profil de
l'extrémité

0,042"

Stent TAXUS™ & Promus™ Element™

0,017"

0,046"

Stent TAXUS™ Liberté™

0,017"

0,042"

Stent PROMUS™

0,021"

0,044"

Stent ENDEAVOR™*



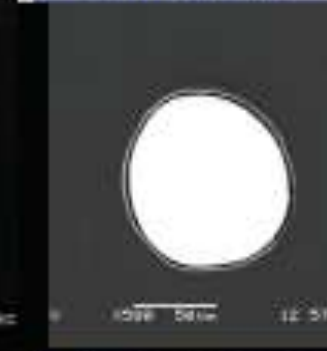
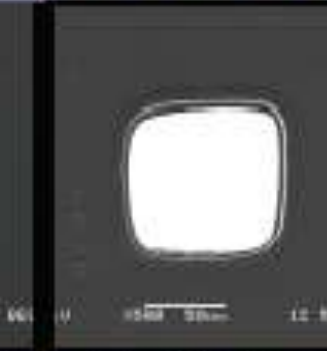
0,019"

0,047"

Stent CYPHER Select™

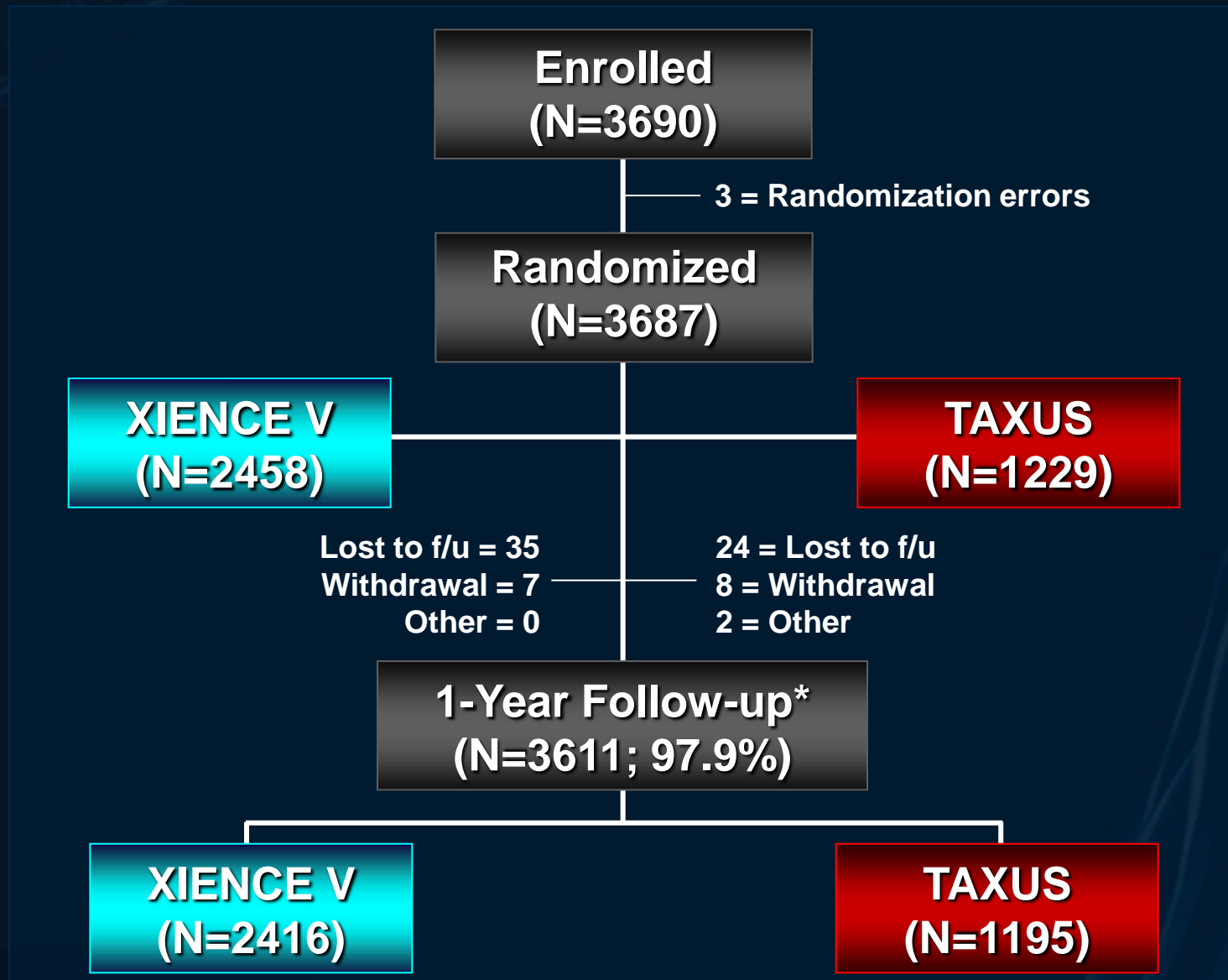
0,020"

Minimizing Strut and Polymer Thickness to reduce Injury and aid re-endothelialization

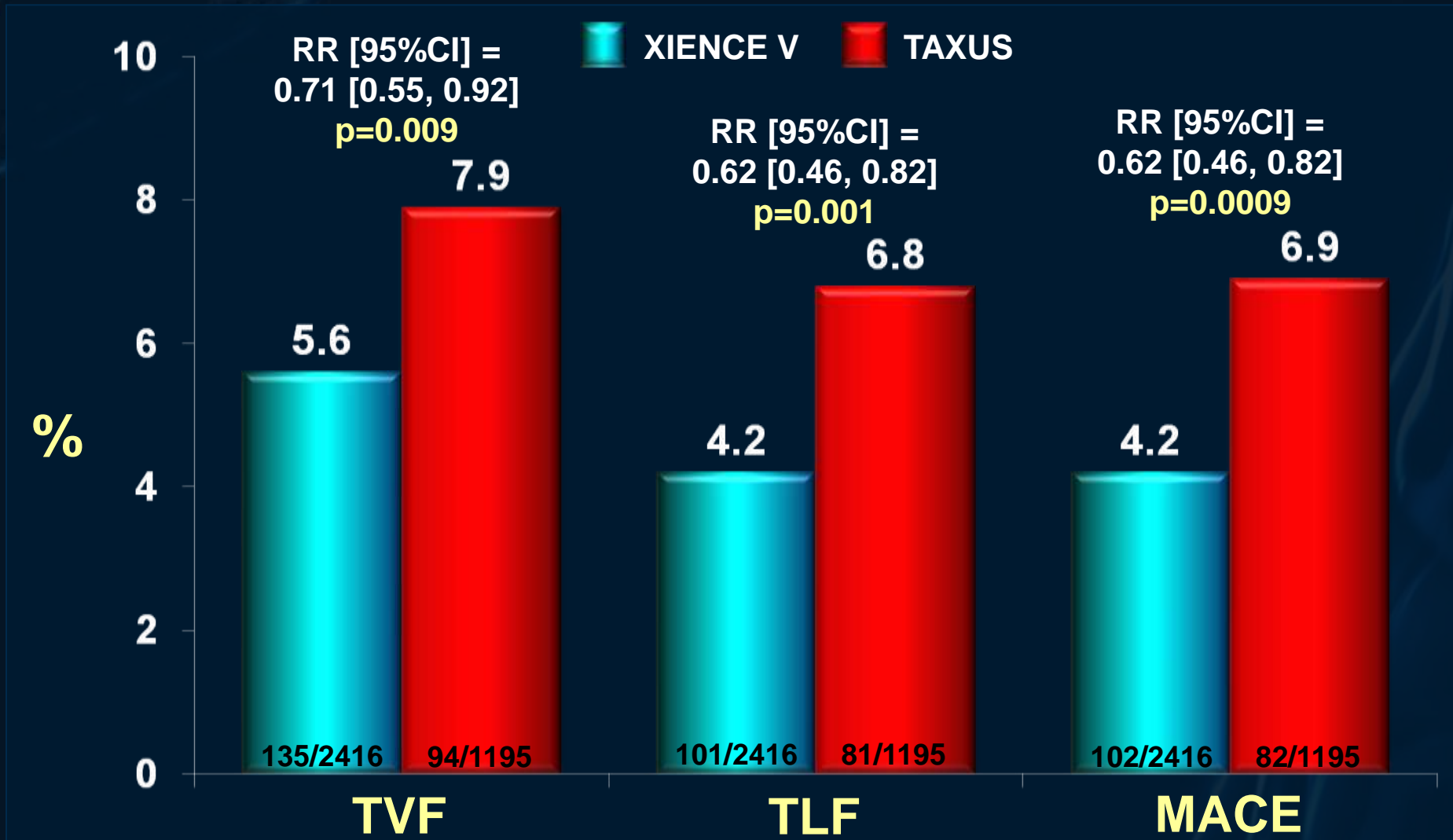
CYPHER®	TAXUS® EXPRESS	ENDEAVOR™	XIENCE™ V
			
Strut Thickness:	Strut Thickness:	Strut Thickness:	Strut Thickness:
140 µm	132 µm	91 µm	81 µm
Polymer Thickness:	Polymer Thickness:	Polymer Thickness:	Polymer Thickness:
12.6 µm	16 µm	5.3 µm	7.6 µm
PEVA+PBMA	SIBBS	PC	Fluoropolymer
Sirolimus	Paclitaxel	Zotarolimus	Everolimus
PEVA+PBMA	SIBBS	PC	Fluoropolymer

Photos & data on File at Abbott Vascular

SPIRIT IV Patient Flow



TVF, TLF, and MACE Through 1 Year

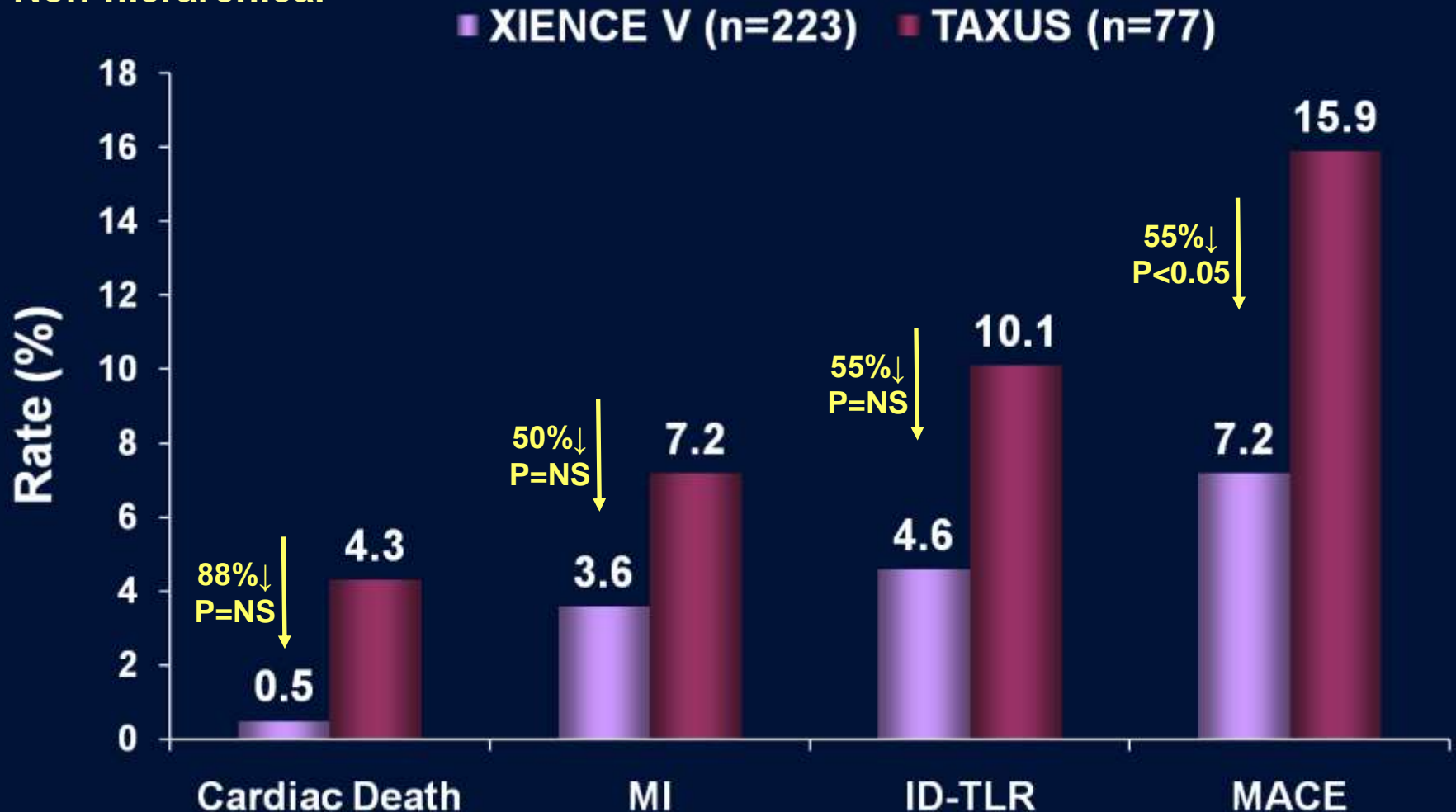


TLF = cardiac death, target vessel MI, or ID-TLR; MACE = cardiac death, all MI, or ID-TLR;
TVF = cardiac death, all MI, or ID-TVR. 1 Year = 365 ± 28 days

SPiRiT II

3 Year Clinical Results

Non-hierarchical



Serruys PW. EuroPCR 2009

The LeMaX Pilot Study

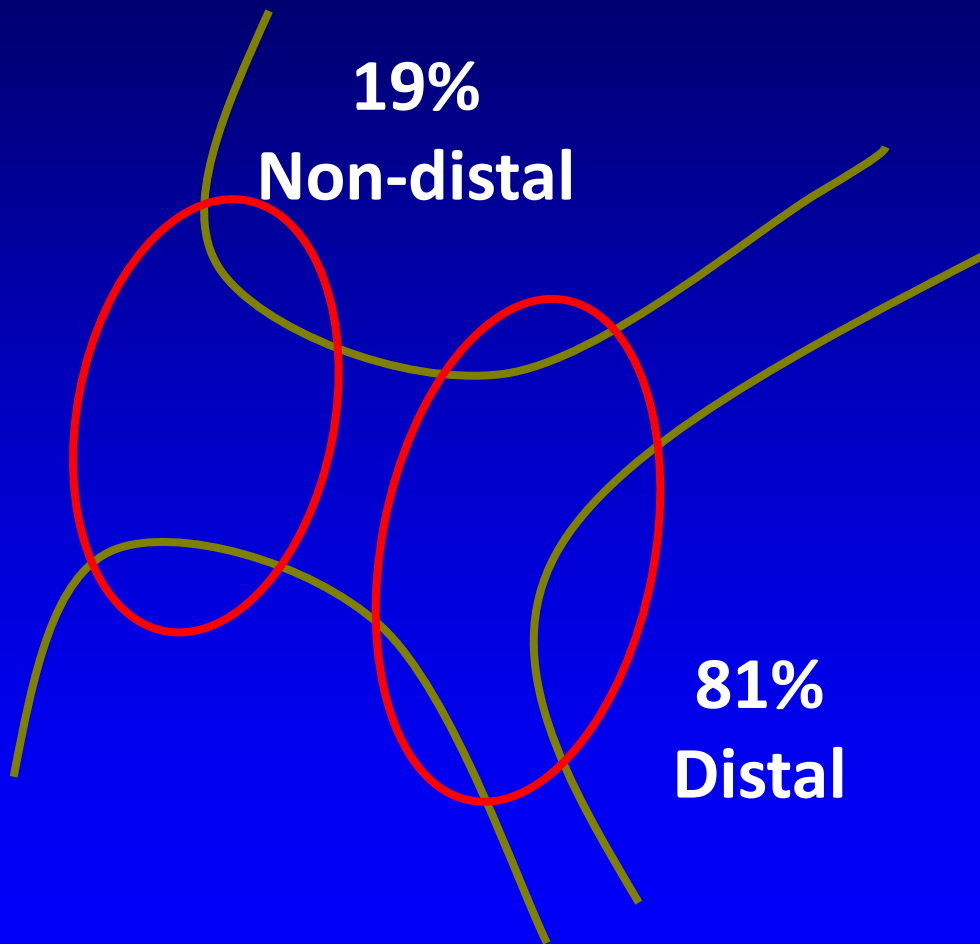
- 4 French centers
- Prospective observational study, December 07 to May 09
- Efficacy and safety of Xience V everolimus-eluting stent for unprotected de novo LM stenosis
- Primary end point : MACCE at 1 year
- e-CRF
- Angiographic analysis and adjudication of events by independent committee
- Clinical follow-up at 1 month, 1, 2 & 3 years

LeMaX
LEft MAIn Xience V



Pôle Cardiovasculaire et
Métabolique

Left Main Lesion Location



Medina for distal location:

1,1,1 : 15%

1,1,0 : 34%

1,0,0 : 31%

1,0,1 : 15%

0,1,1 : 1%

0,1,0 : 4%

French Multi-center Left Main studies with DES

	Pilot Taxus* 2004	FRIEND** 2006	LEMAX 2008
Nb patients	291	151	174
% distal lesion	78	69	81
% 2 stents	42	➔ 26	➔ 19
Mean LM stent diameter (mm)	3.44±0.39	➔ 3.59±0.49	➔ 3.63±0.33
12 month TLR	5.9%	2.7%	2.3%

*B. Vaquerizo et al. Circulation 2009;119:2349-56 **D.Carrié et al., Eurointerv 2009;4:449-56



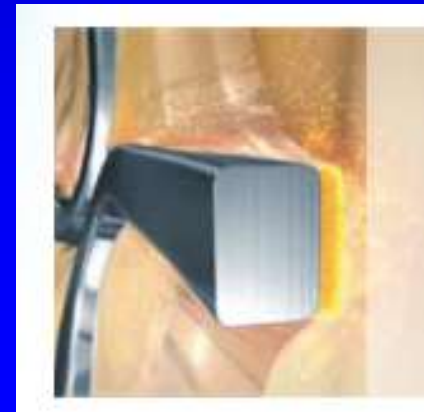
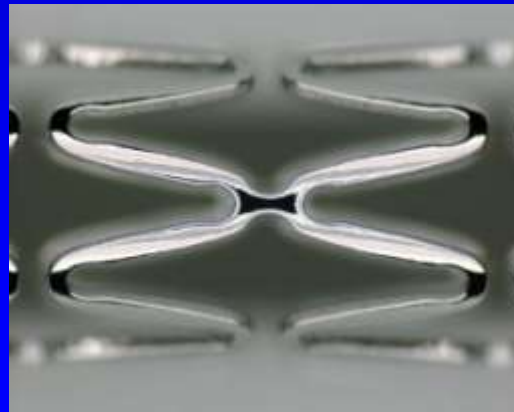
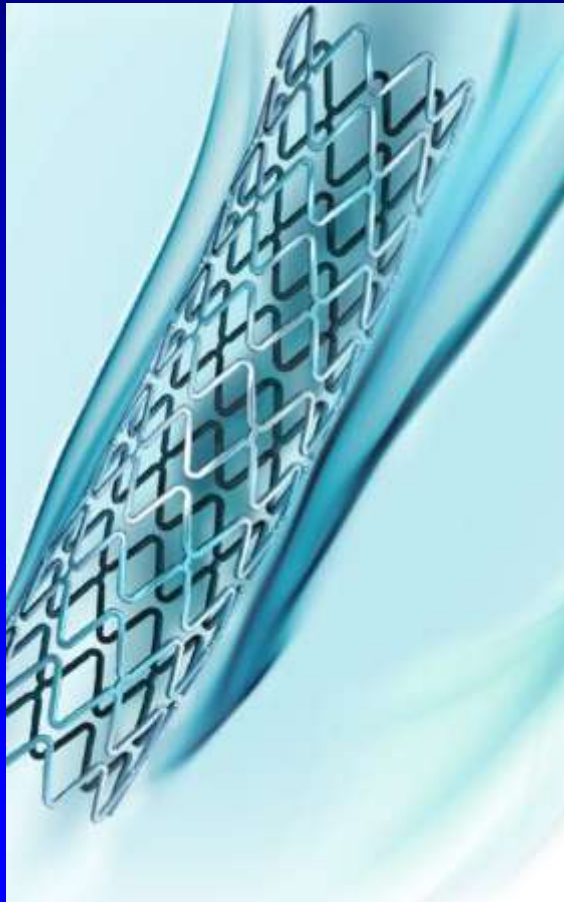
NOBORI DES

Highly Flexible
BMS Platform

Drug - Biolimus A9
Lipophilic
Specifically developed
for local applications

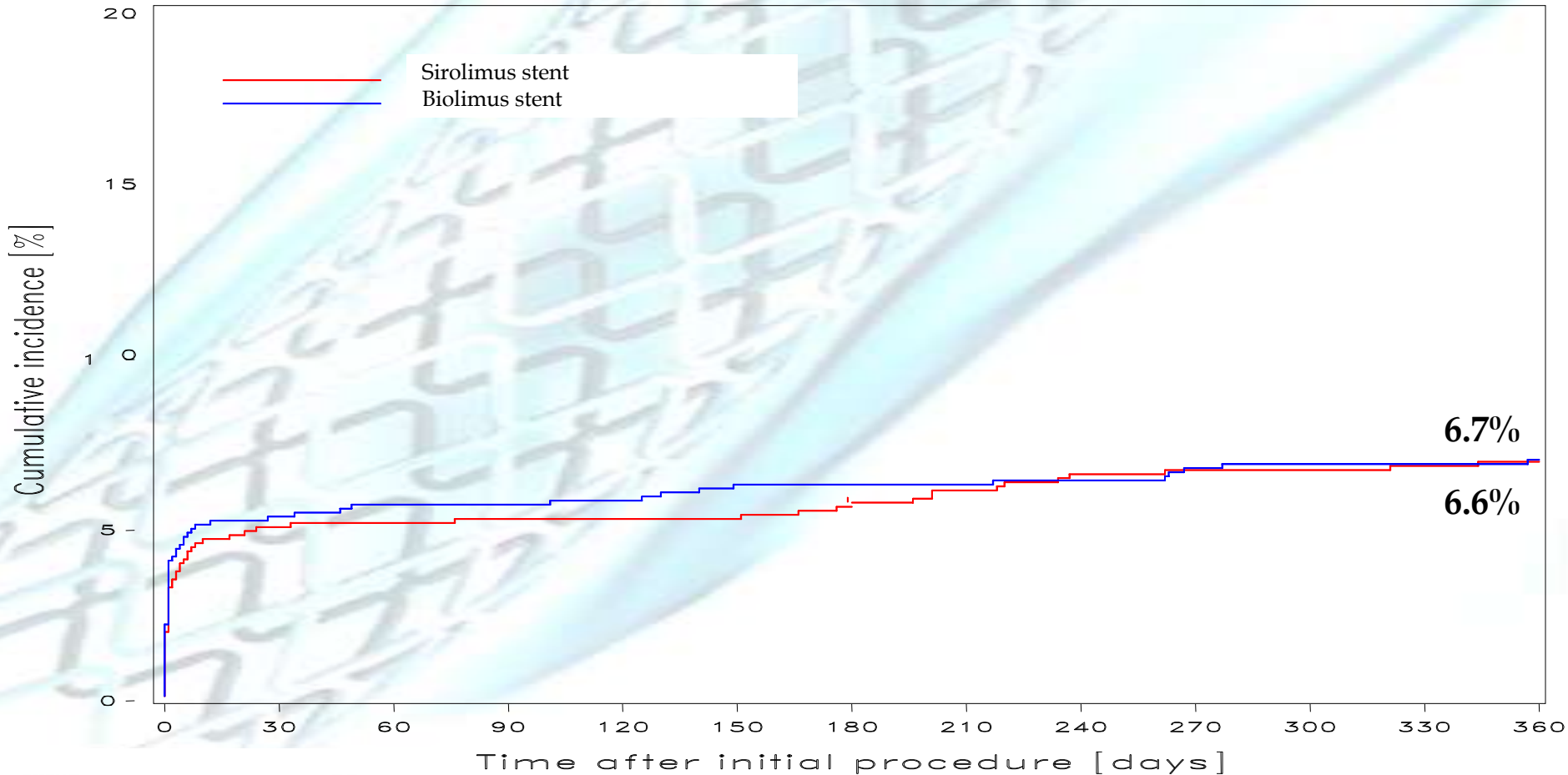
Polymer - PLA
Biodégradable

Coating
Only abluminal

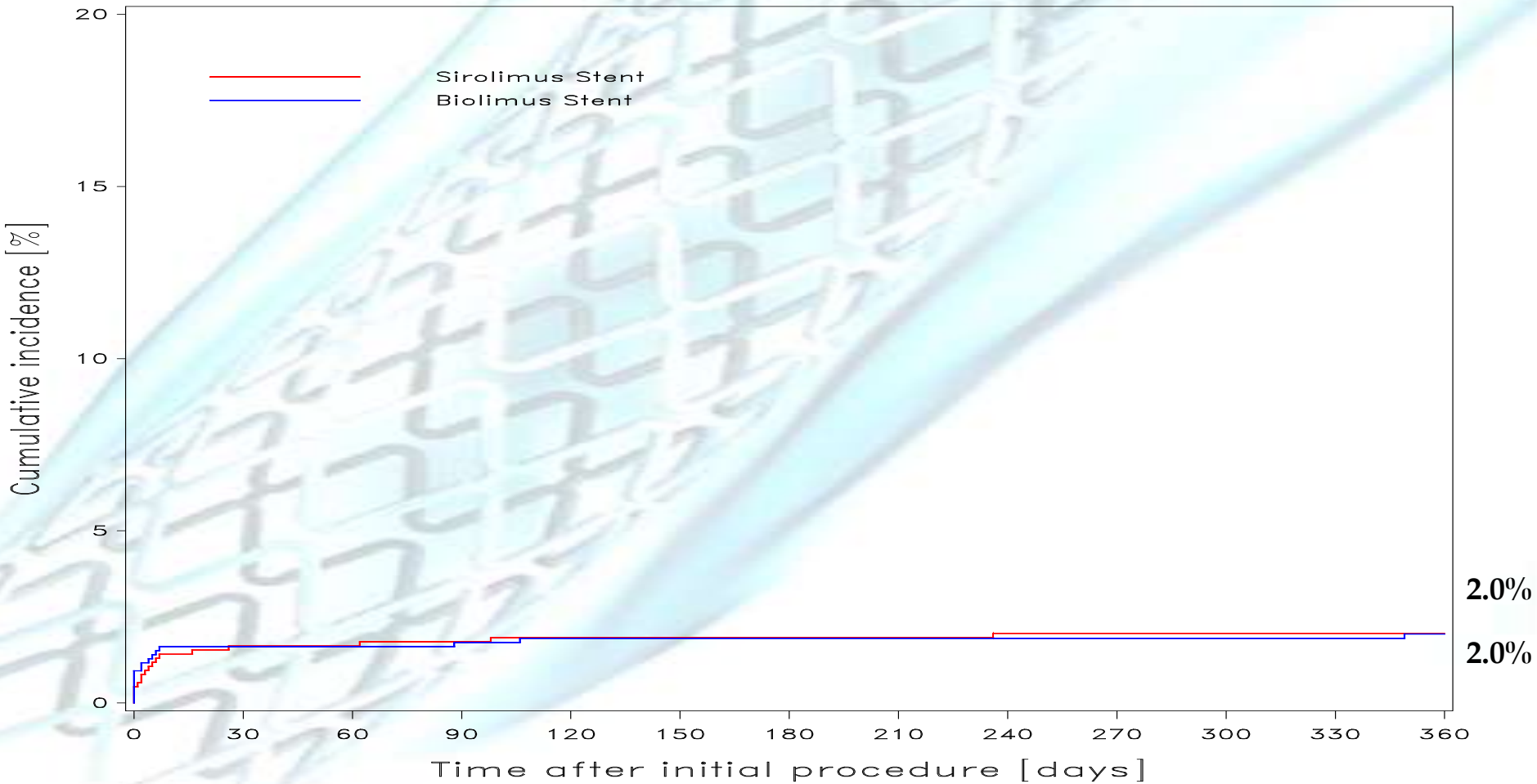


SAFETY ENDPOINT

Cardiac Death & Myocardial Infarction



DEFINITE STENT THROMBOSIS



NEVO™ Sirolimus-Eluting Stent : Cordis' 1st RES TECHNOLOGY™ Stent

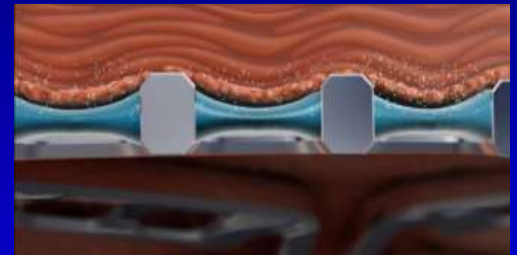
CoCr stent platform

- Flexible, conformable, thin struts, maximized vessel coverage, open cell design



Reservoir technology

- Drug and polymer recessed within reservoirs in the stent strut - no surface-coating.
- Reduced vessel wall - polymer contact



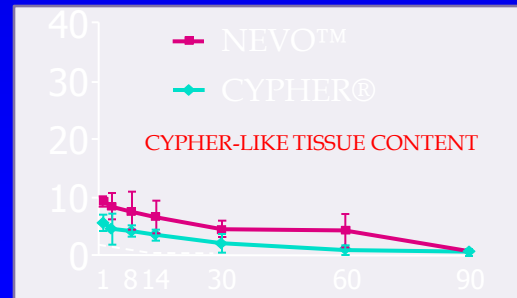
Bioabsorbable polymer

- Designed for complete bioabsorption in as little as 90 days

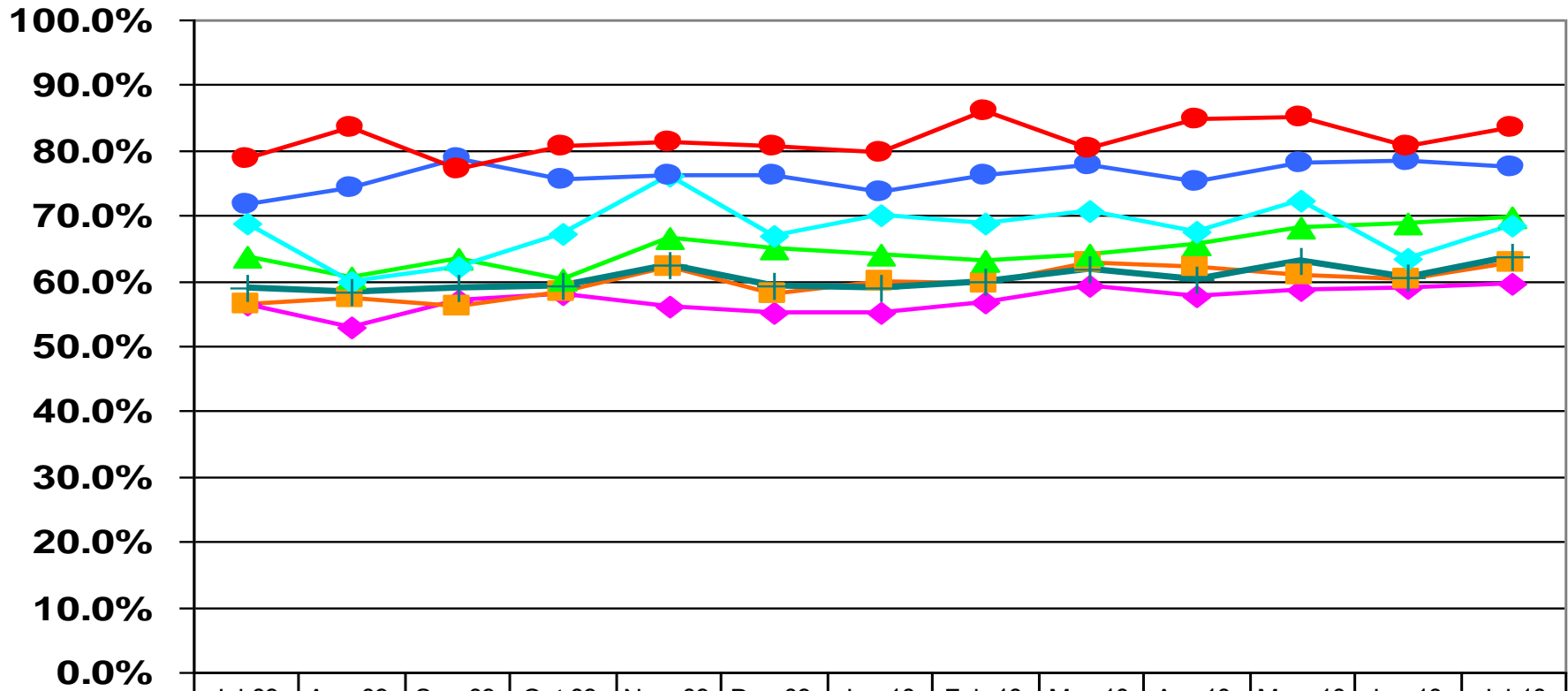


Proven Sirolimus Evidence

- CYPHER®-like tissue content
- Largest body of evidence with safety data out to 10 years



Evolution de la pénétration DES en Europe



◆ France	56.4%	52.9%	56.9%	57.9%	56.0%	55.2%	55.2%	56.7%	59.3%	57.6%	58.8%	58.8%	59.5%
■ Germany	56.3%	57.2%	56.2%	58.2%	62.2%	58.0%	59.7%	59.6%	62.9%	62.2%	60.7%	60.2%	62.6%
▲ Italy	63.8%	60.4%	63.5%	60.2%	66.5%	65.0%	64.1%	63.0%	63.9%	65.6%	68.2%	68.7%	69.8%
◆ Spain	68.8%	60.0%	61.9%	67.3%	76.1%	67.0%	70.2%	68.8%	70.8%	67.6%	72.3%	63.4%	68.4%
● UK	71.8%	74.3%	78.8%	75.6%	76.3%	76.2%	73.6%	76.2%	77.7%	75.2%	78.0%	78.3%	77.4%
● Netherlands	78.6%	83.3%	77.0%	80.6%	81.2%	80.6%	79.5%	85.9%	80.3%	84.8%	85.0%	80.6%	83.4%
+ EU	59.0%	58.3%	58.8%	59.4%	62.3%	59.4%	59.0%	59.8%	61.9%	60.2%	63.0%	60.4%	63.8%

Prise en Charge des Stents Actifs

PRISE EN CHARGE DES STENTS ACTIFS EN France - source: Journal Officiel

	TAXUS	PROMUS ELEMENT	PROMUS	XIENCE V	XIENCE PRIME	CYPHER	ENDEAVOR	BIOMATRIX	NOBORI
Nombre de stents par artère	1 ³	1 ³	1 ³	1 ³	1 ³	1 ³	1 ³	1 ³	1 ³
Nombre de stents par patient	3	1 ³	1 ³	1 ³	1 ³	3	3	3	3
1- Lésions de novo chez les patients à haut risque de resténose (L > 15mm ou D < 3mm ou diabétiques)	LPPR	LPPR	LPPR	LPPR	LPPR	LPPR	LPPR	LPR	LPR
2- Resténose Intrastent (BMS)	LPPR	NON	NON	NON	NON	LPPR	NON	NON	NON
3- Occlusion Chronique Totale	LPPR	NON	NON	NON	NON	LPPR	NON	NON	NON
4- Lésions de novo pluritronculaires en cas de risque chirurgical élevé (L > 15mm ou D < 3mm ou diabétiques)	LPPR	NON	NON	NON	NON	LPPR	LPPR	NON	NON
5- Tronc commun gauche non protégé	NON	NON	NON	NON	NON	LPPR	NON	NON	NON
Prise en charge en phase aiguë si IDM <72H et lésion correspondant à 1 des 5 indications LPPR ci-dessus	OUI	NON	NON	NON	NON	OUI	NON	NON	NON

INDICATIONS

¹ jusqu'à 3 en cas de dissection occlusive aiguë

² Avis CNEDIMTS favorable, non paru au JO donc pas LPPR pour le moment

possible d'en faire une indication avant d'avoir levé la contre-indication figurant dans la notice d'utilisation du marquage CE

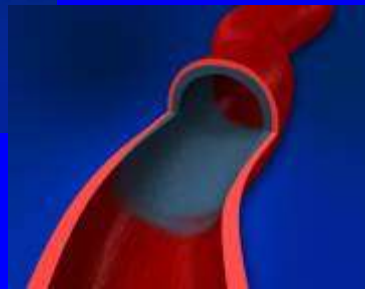
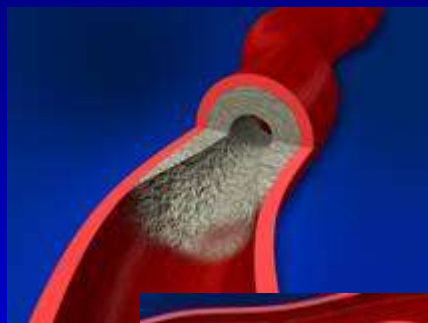
CODE	DÉSIGNATION	TARIF en € TTC jusqu'au 31 août 2010	PLV en € TTC jusqu'au 31 août 2010	NOUVEAU tarif en € TTC à compter du 1 ^{er} septembre 2010	NOUVEAU PLV en € TTC à compter du 1 ^{er} septembre 2010	NOUVEAU tarif en € TTC à compter du 1 ^{er} septembre 2011	NOUVEAU PLV en € TTC à compter du 1 ^{er} septembre 2011	NOUVEAU tarif en € TTC à compter du 1 ^{er} septembre 2012	NOUVEAU PLV en € TTC à compter du 1 ^{er} septembre 2012
3158144	Endoprothèse coronaire, stent à lib. de sirolimus, Cordis, CYPHER SELECT PLUS, DIAM 3 mm	1 220,00	1 220,00	1 150,00	1 150,00	1 050,00	1 050,00	1 050,00	1 050,00
3182852	Endoprothèse coronaire, stent à lib. de sirolimus, Cordis, CYPHER SELECT PLUS, DIAM 3,5 mm.	1 220,00	1 220,00	1 150,00	1 150,00	1 050,00	1 050,00	1 050,00	1 050,00

CODE	DÉSIGNATION	TARIF en € TTC jusqu'au 31 août 2010	PLV en € TTC jusqu'au 31 août 2010	NOUVEAU tarif en € TTC à compter du 1 ^{er} septembre 2010	NOUVEAU PLV en € TTC à compter du 1 ^{er} septembre 2010	NOUVEAU tarif en € TTC à compter du 1 ^{er} septembre 2011	NOUVEAU PLV en € TTC à compter du 1 ^{er} septembre 2011	NOUVEAU tarif en € TTC à compter du 1 ^{er} septembre 2012	NOUVEAU PLV en € TTC à compter du 1 ^{er} septembre 2012
3134988	Endoprothèse coronaire, stent lib. d'everolimus, B O S T O N , P R O M U S ELEMENT, DIAM 2,25 mm	1 220,00	1 220,00	1 100,00	1 100,00	990,00	990,00	925,00	925,00
3107081	Endoprothèse coronaire, stent lib. d'everolimus, B O S T O N , P R O M U S ELEMENT, DIAM 2,50 mm	1 220,00	1 220,00	1 100,00	1 100,00	990,00	990,00	925,00	925,00
3119747	Endoprothèse coronaire, stent lib. d'everolimus, B O S T O N , P R O M U S ELEMENT, DIAM 2,75 mm	1 220,00	1 220,00	1 100,00	1 100,00	990,00	990,00	925,00	925,00

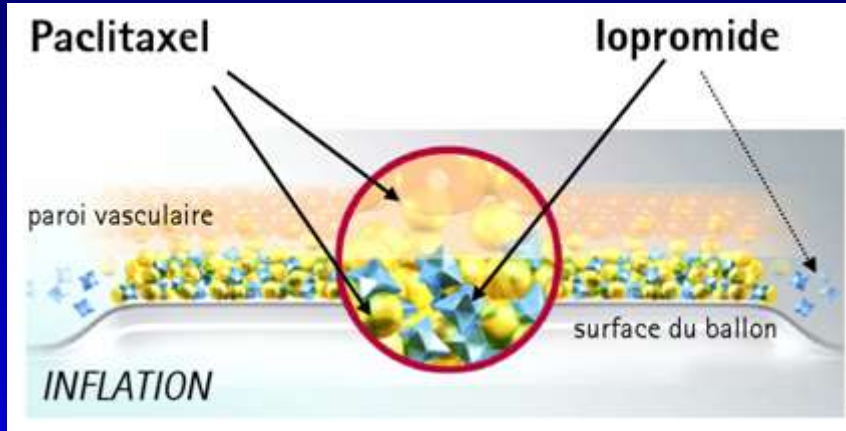
La technologie unique et originale de la Matrice

SeQuent® Please – la MATRICE est la différence

- 3 μ g/mm² Paclitaxel incorporés dans une matrice bio résorbable
- La matrice permet la libération du Paclitaxel de la surface du ballon et rend le transfert possible du Paclitaxel dans le tissu coronaire
- Les études pré-cliniques ont démontré qu'une inflation de 30 secondes permet une libération de la totalité de Paclitaxel
- La matrice est immédiatement résorbable après l'inflation du ballon. Il n'y a pas de libération à long terme (contrairement aux stents actifs)

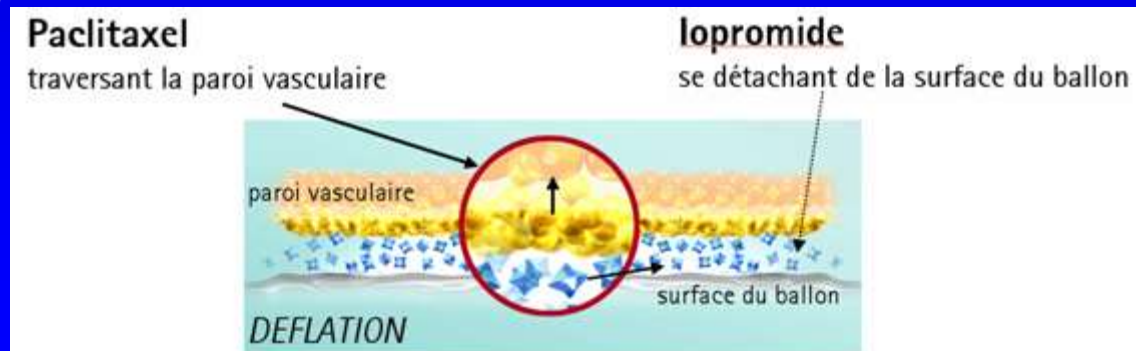


Mécanisme de diffusion de SeQuent® Please

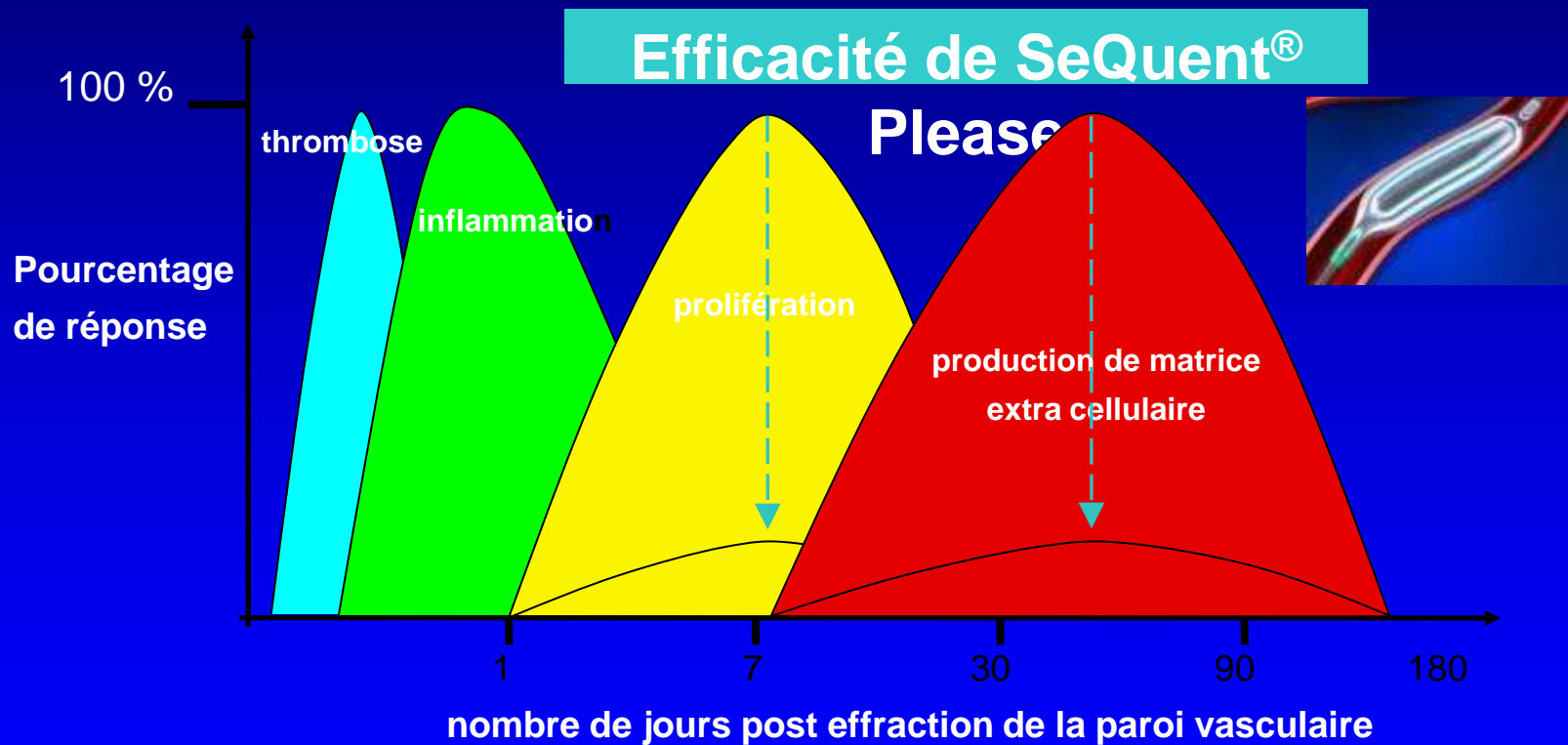


L'efficacité de la diffusion du principe actif est basée sur la combinaison de ces deux composants : la matrice hydrophile (soluble dans un liquide aqueux) libère le Paclitaxel lors de l'inflation du ballon ...

... Une fois libéré, les propriétés lipophiles du Paclitaxel (forte affinité pour les lipides) lui permettent de traverser la paroi vasculaire; il diffuse alors vers les cellules musculaires lisses afin de réduire leur prolifération.



Impact de SeQuent® Please sur le processus en cascade de la resténose



Adapté de Nikol et al., Atherosclerosis' 123: 17-31, 1996



Optical Coherence Tomography

CT Angiography



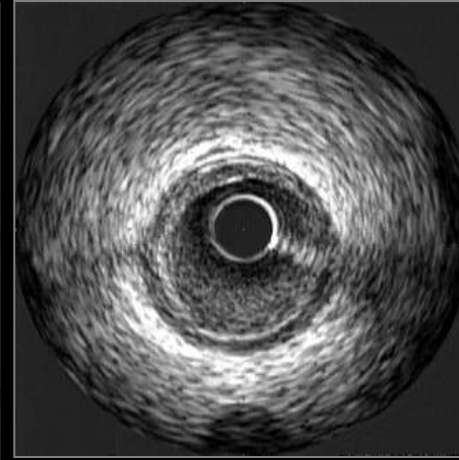
Resolution : 600 μ m

Angiography



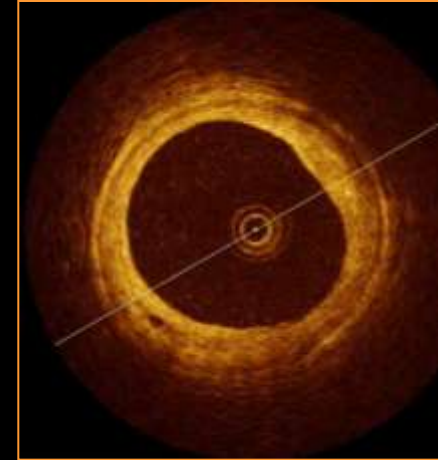
200 μ m

IVUS

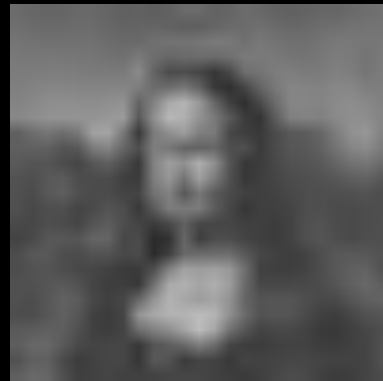
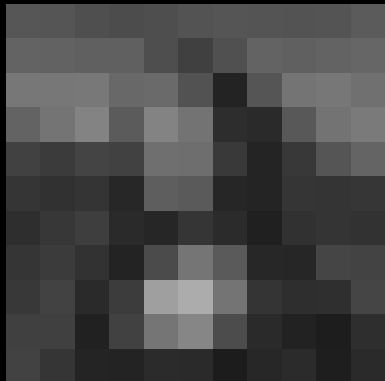


100 μ m

OCT



10 μ m

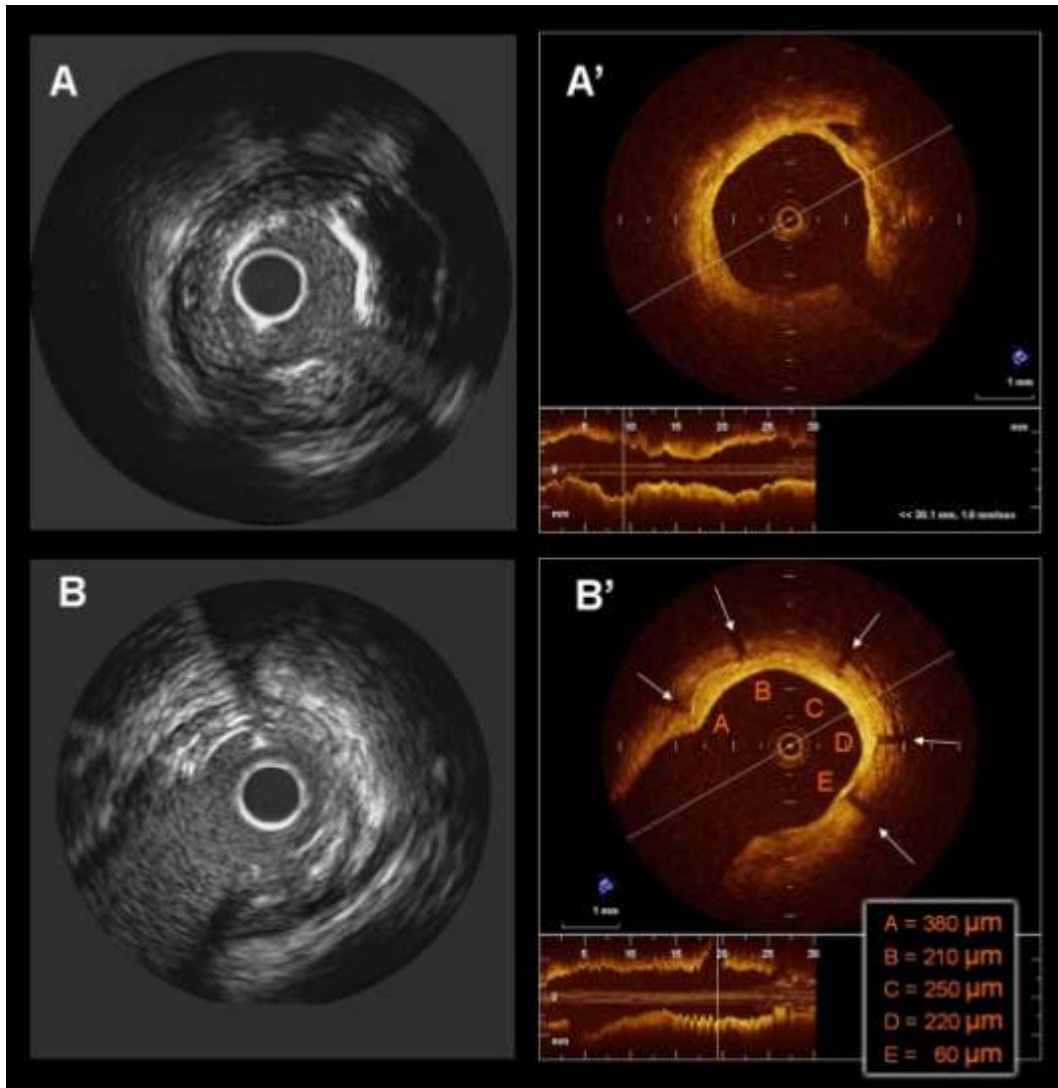




Optical Coherence Tomography

IVUS

OCT



- High-Resolution
- Most superficial layer analysis



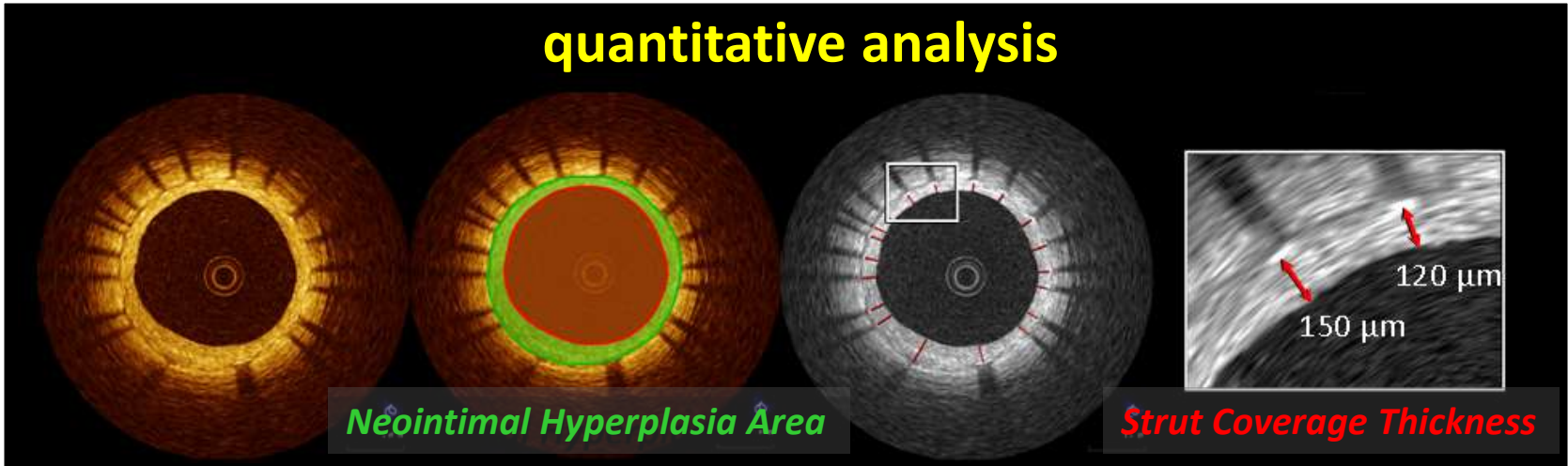
Indications

- Plaque analysis
- Stent assessment

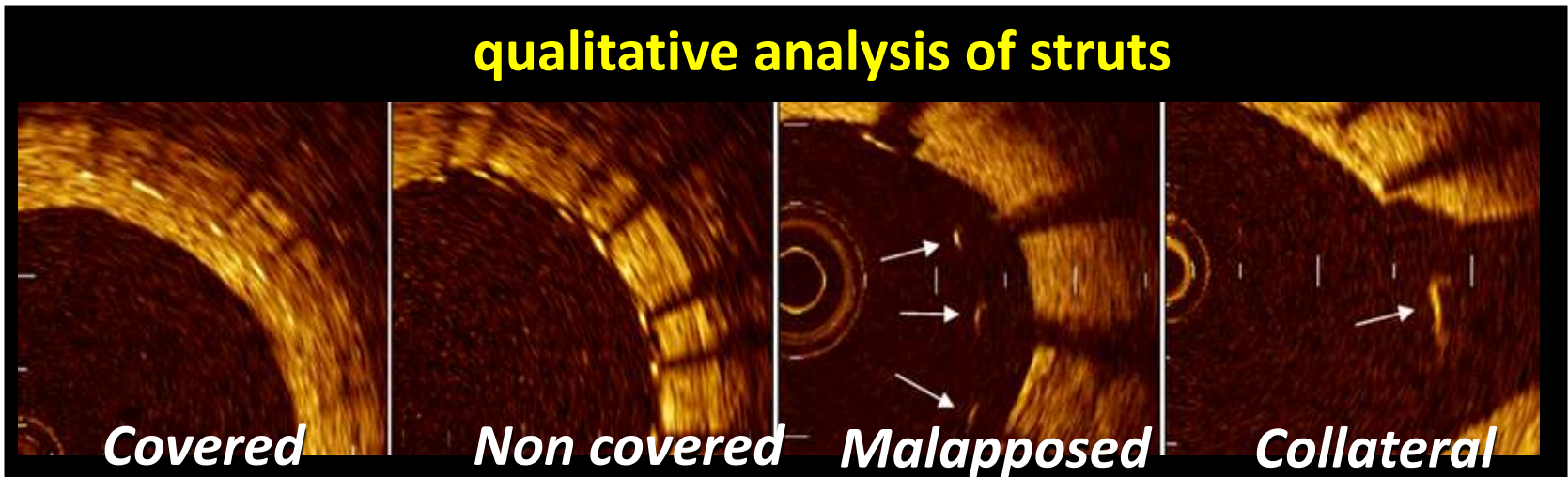


OCT

quantitative analysis



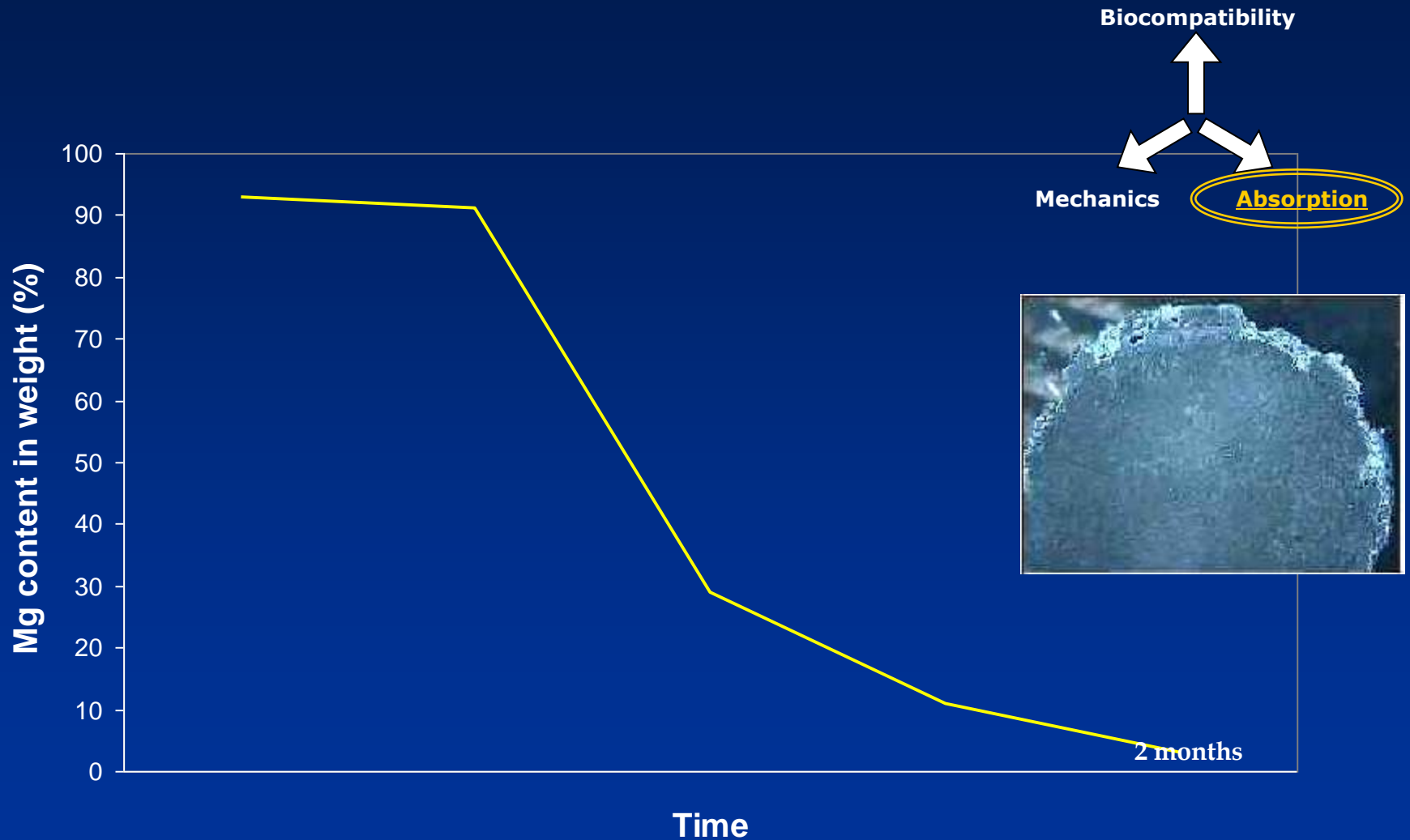
qualitative analysis of struts



Stent métallique résorbable



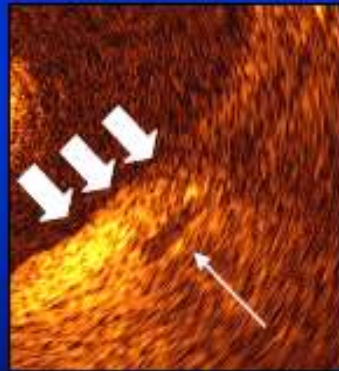
Schematic Mg Degradation Curve*



* Indicative values in porcine coronary artery model

6-Month Results – OCT Data

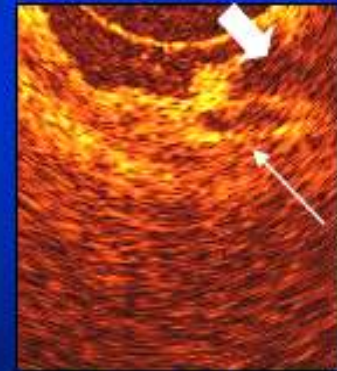
Stent Strut Coverage – 6 Mos. F/U



Complete

■ Complete ■ Incomplete

N = 13 stents, 671 struts



Incomplete

J Ormiston, et al, *Lancet* 2008; 371: 899-907.

CONCLUSION

OUTILS D'ÉVALUATION (FFR, IVUS, OCT)

STENTS ACTIFS (Plateforme, Polymère...)

STENTS BIODEGRADABLES