

12h00 / 12h40 *Salle plénière*



Il n'y a qu'ultra fine maille qui m'aille

Modérateur : B. KARSENTY (Pessac)

Les données scientifiques

L'apport d'un polymère biodégradable

Le stent couvert : état des lieux

A. BELLEMAIN-APPAIX (Antibes)

T. CUSSET (Marseille)

G. CAYLA (Nîmes)



Il n'y a qu'ultra fine maille qui m'aille

Les données scientifiques

Dr Anne BELLEMAIN-APPAIX
CH d'Antibes, France



Potential conflicts of interest

Speaker's name: Anne Bellemain-Appaix

I have the following potential conflicts of interest to report:

Honorarium: BIOTRONIK, DAIICHI SANKYO and ELI-LILLY

Institutional grant/research support: Fédération Française de Cardiologie, Société Française de Cardiologie

LES DESSOUS DE L'APPAC



Cayla's style



Cuisset's style



Après une bonne journée de travail

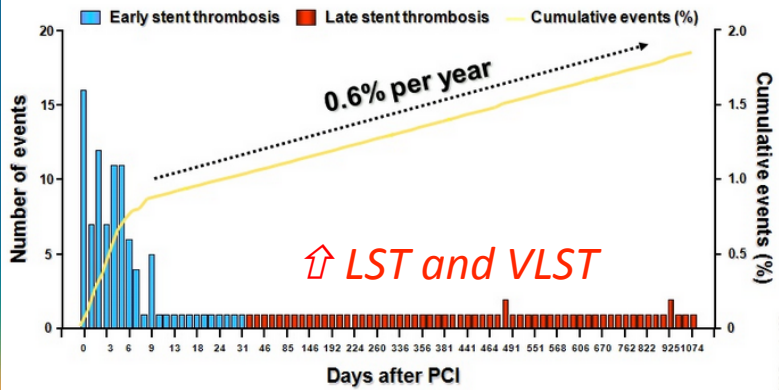
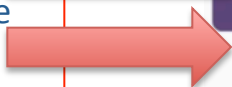
STENTS ACTIFS



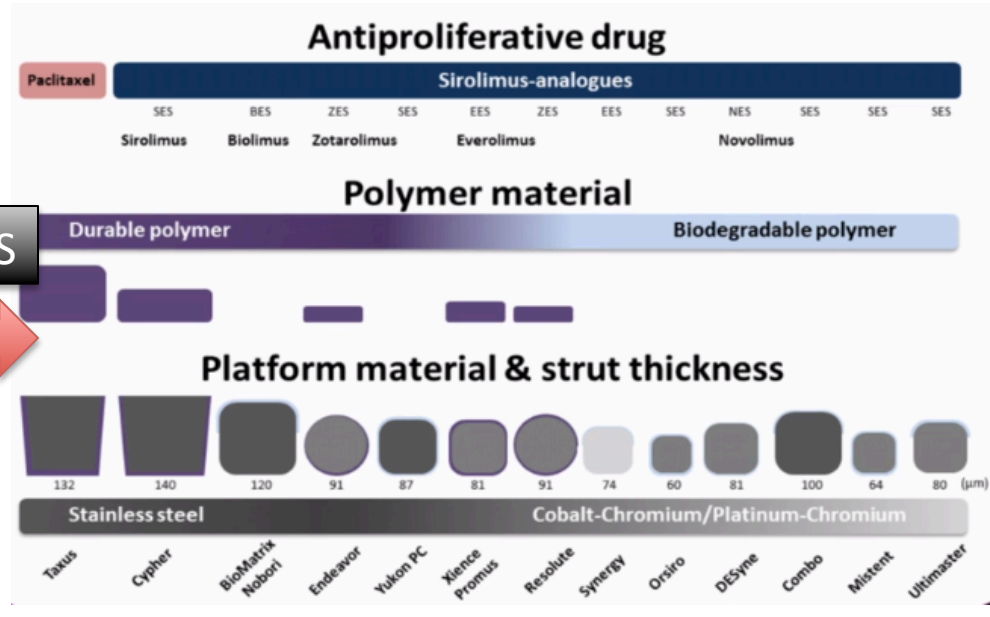
REF pour tout patient et toute situation

- ↑ Couverture incomplète des struts
- ↑ Retard de cicatrisation
- ↑ Faible endothélialisation
- ↑ Hypersensibilité au polymère
- ↑ Inflammation

NEW DES



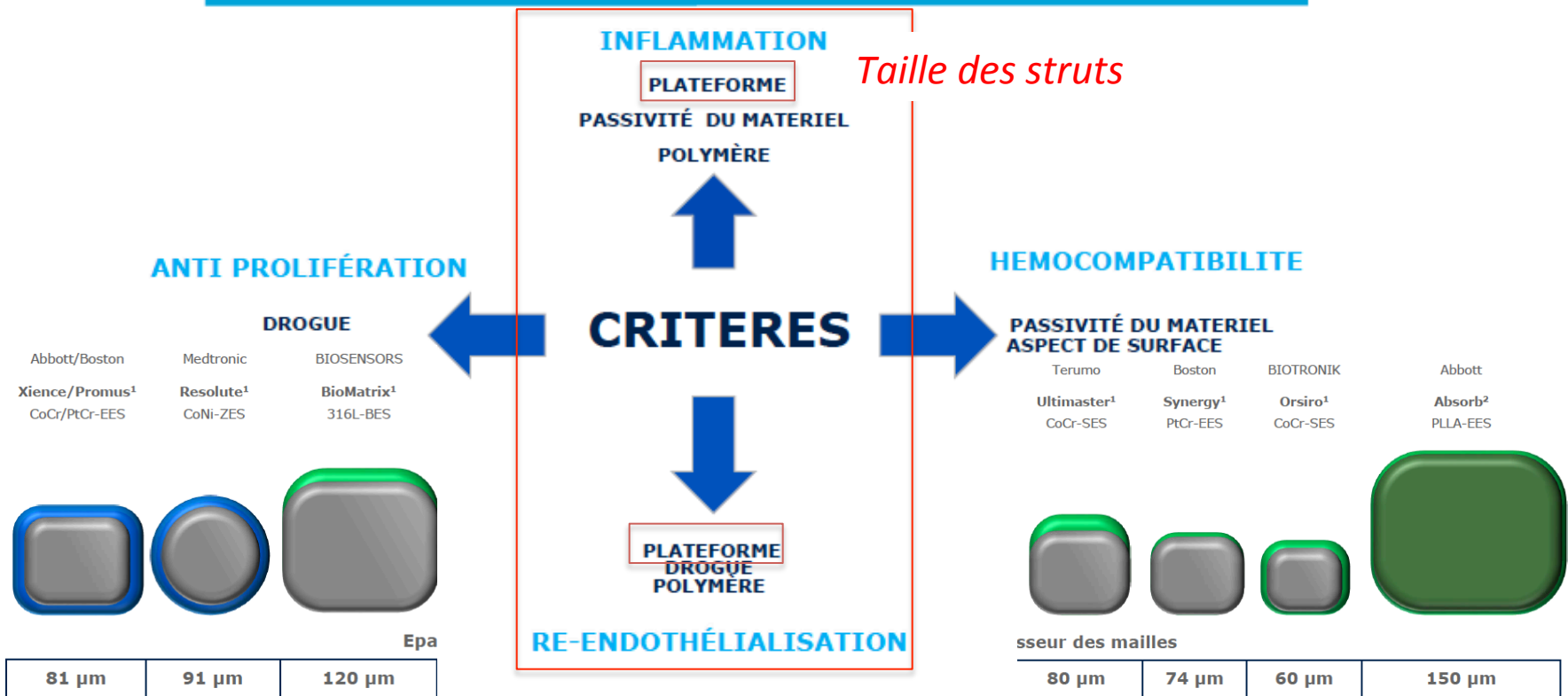
PROGRÈS FAITS SUR LES DES MÉTALLIQUES



Pilgrim et al; ESC 2014

Mc Fadden et al; Lancet 2004, p.364(15):9-21
 Daemen et al; Lancet; [Vol 369, Issue 9562](#), 2007, p. 667-678
 Camenzind et al; [Circulation](#). 2007 Mar 20;115(11):1440-55
 Nebeker et al; [J Am Coll Cardiol](#). 2006 Jan 3;47(1):175-81.
 Farb et al; [Circulation](#). 2003 Oct 7;108(14):1701-6

1. CAHIER DES CHARGES DES

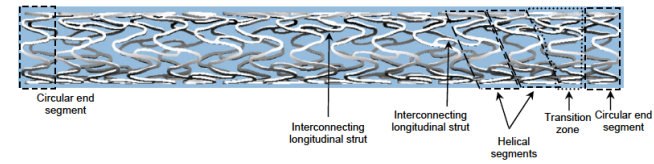
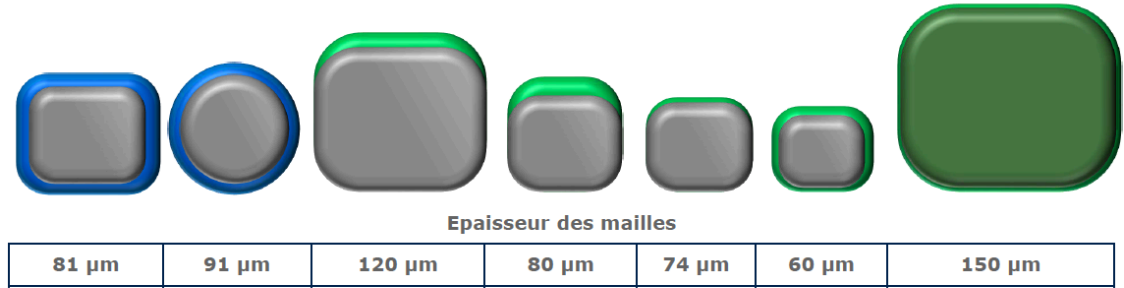


Intérêt MÉCANIQUE des struts ultra-fines

- | | | | | | | |
|----------------------------|-----------------------|------------------------|-------------------------|----------------------|---------------------|---------------------|
| Abbott/Boston | Medtronic | BIOSENSORS | Terumo | Boston | BIOTRONIK | Abbott |
| Xience/Promus ¹ | Resolute ¹ | BioMatrix ¹ | Ultimaster ¹ | Synergy ¹ | Orsiro ¹ | Absorb ² |
| CoCr/PtCr-EES | CoNi-ZES | 316L-BES | CoCr-SES | PtCr-EES | CoCr-SES | PLLA-EES |

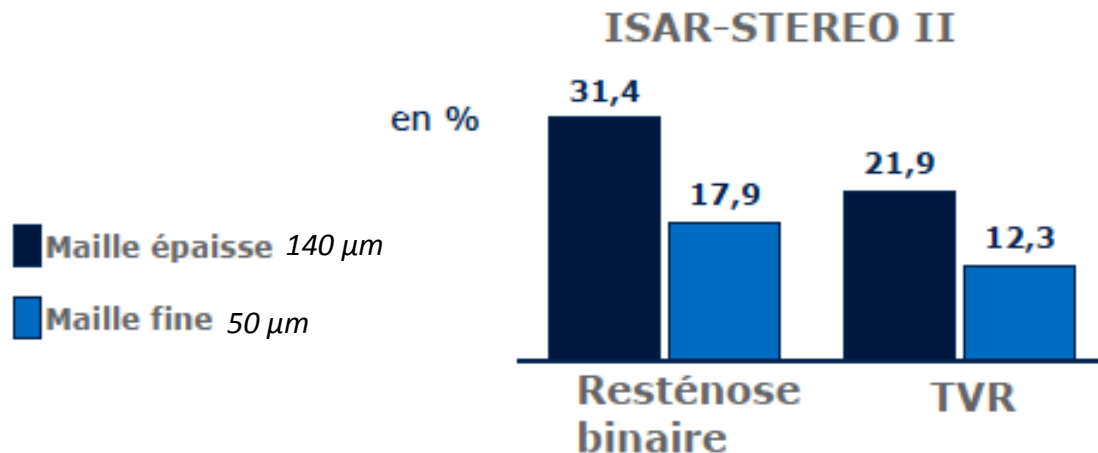
Profil de franchissement bas

Plateforme PRO-Kinetic Energy
 Double hélice (flexibilité)
 Alliage Chrome Cobalt, struts 60µm
 Sertissage, profil de franchissement 0,99mm



Des mailles plus fines sont plus efficaces cliniquement

Kastrati et al., *Circulation*. 2001;103:2816-2821
Pache et al. *JACC* 2003;41-8: 1283-1288



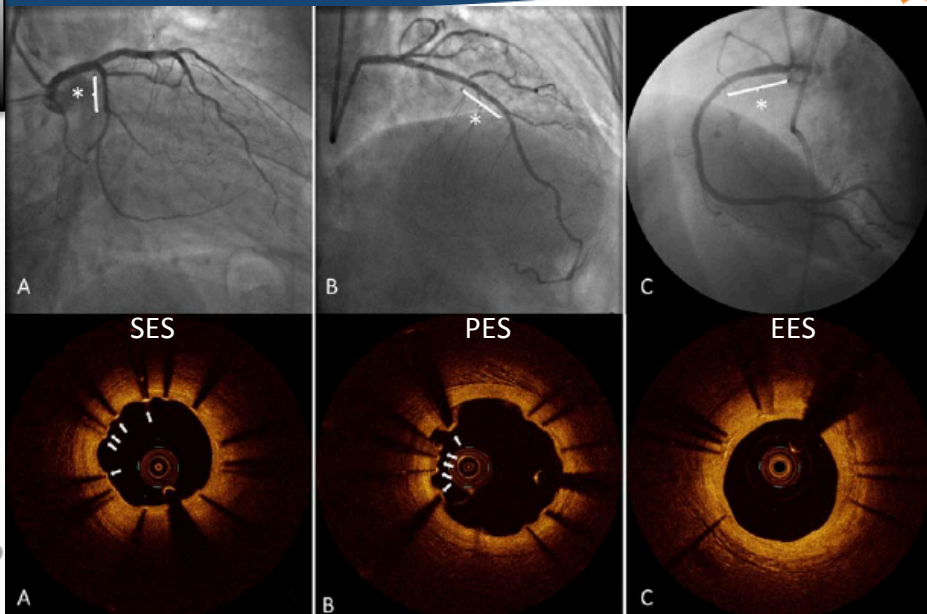
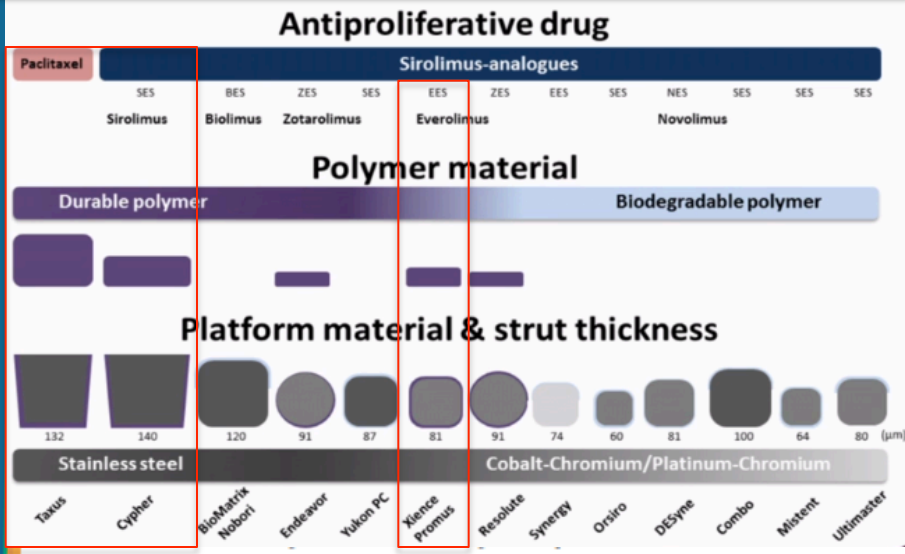
A 1 an; death and MI= NS

Conclusions

Les mailles fines (peu importe le design) réduisent de manière significative la resténose binaire et le TVR

TAILLE DES STRUTS, COUVERTURE ET APPPOSITION

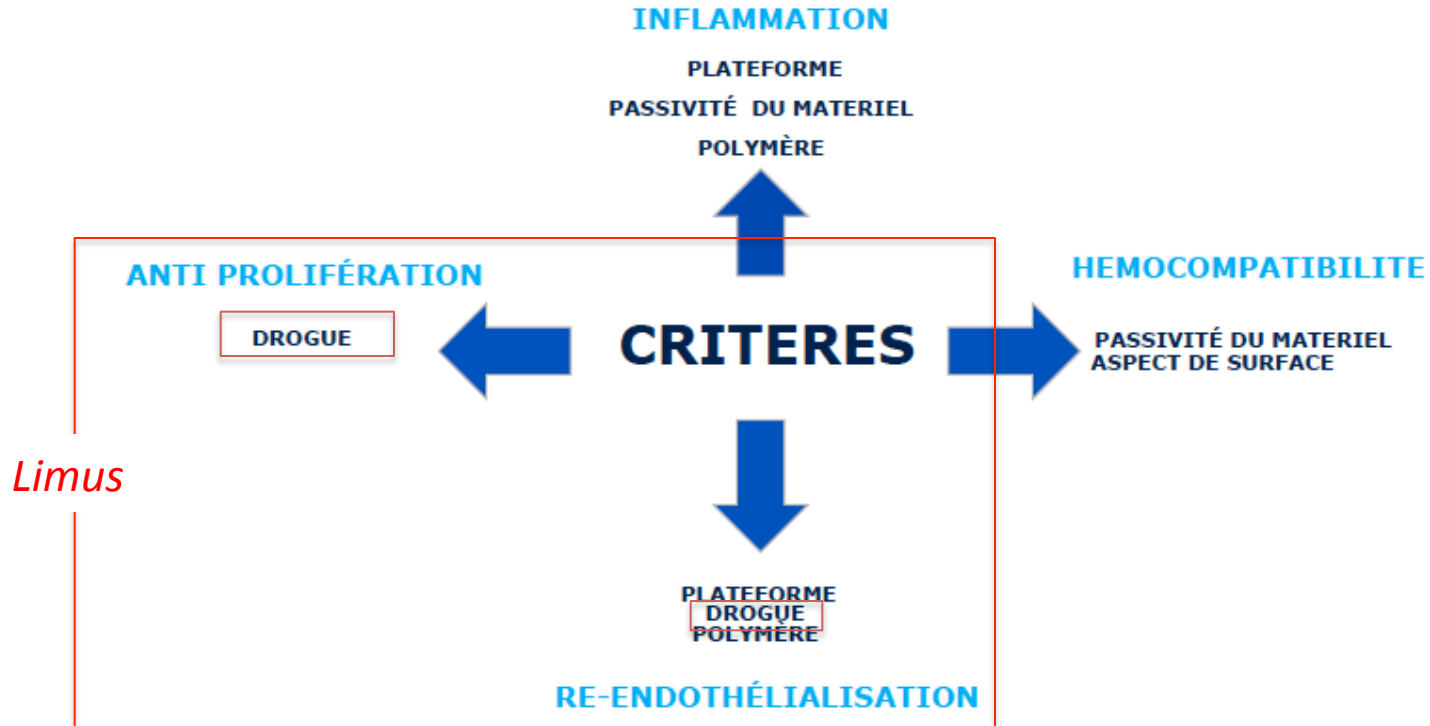
DP EES vs 1° génération DES



40 patients, OCT>1 an post implantation, stables

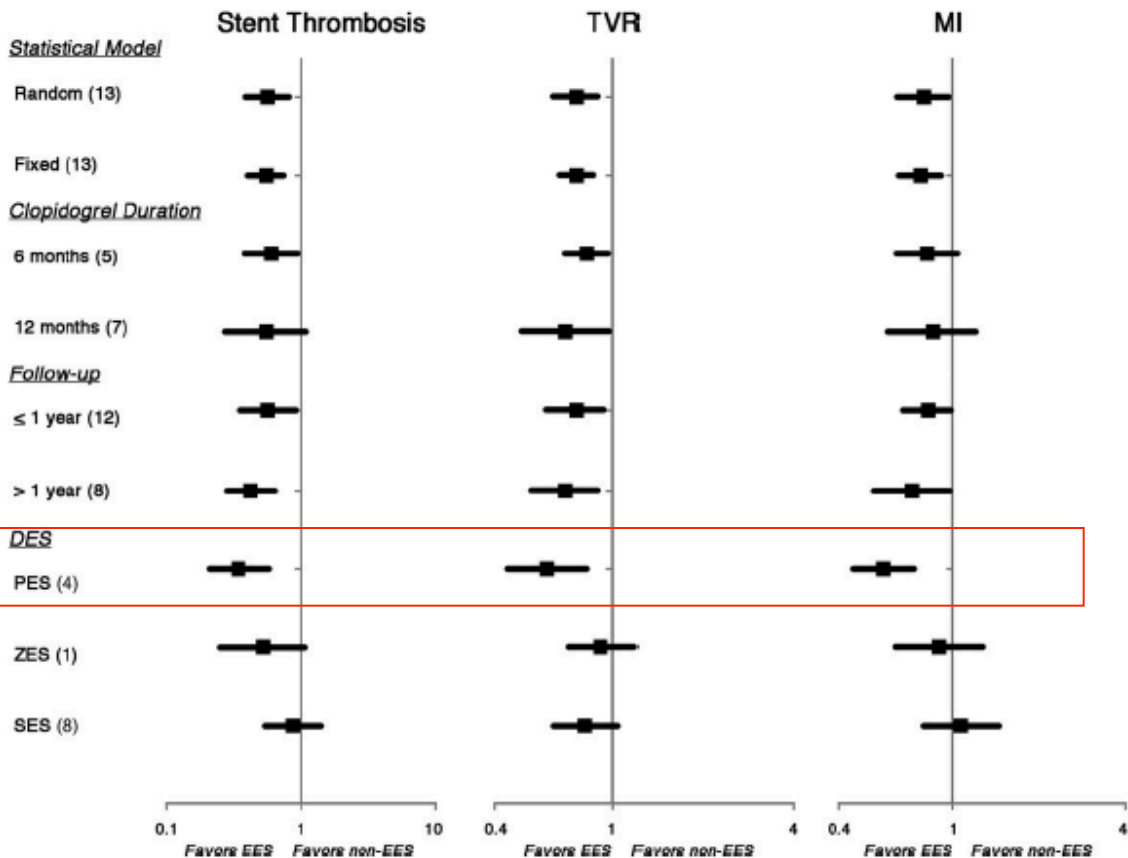
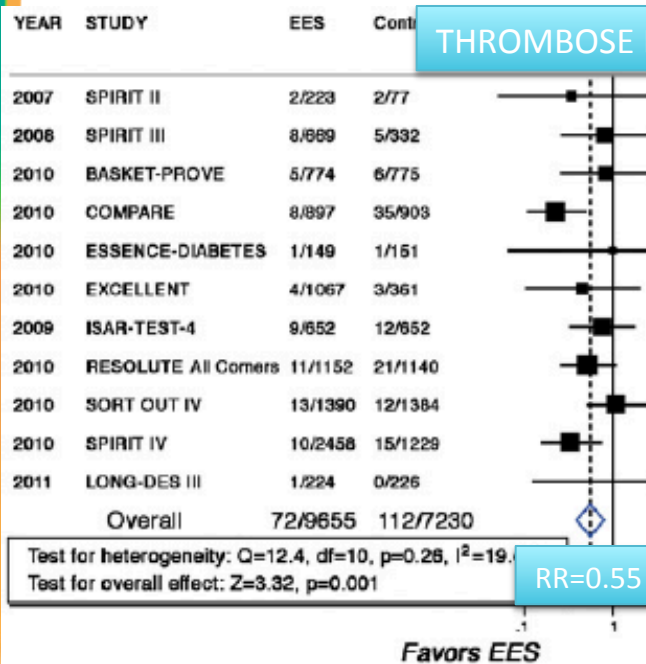
	Estimated marginal means (95% CrI)			Difference estimate (95% CrI) P		
	SES (n = 23)	PES (n = 22)	EES (n = 21)	EES versus SES	EES versus PES	SES versus PES
% Uncovered struts per stent	11.6 ± 12.7 (6.4–16.8)	7.1 ± 5.2 (4.8–9.4)	1.9 ± 4.1 (0.3–3.4)	-9.7 (-15.1 to -4.3) *0.001	-5.2 (-7.9 to -2.5) *<0.001	4.5 (-1.2 to 10.1) *0.12
% Malapposed struts per stent	1.8 ± 3.5 (0.6–3.1)	3.5 ± 5.1 (0.9–6.2)	0.1 ± 0.3 (0.01–0.3)	-1.7 (-2.9 to -0.5) *0.01	-3.4 (-6.1 to -0.7) *0.02	-1.7 (-4.6 to 1.2) *0.25

2. CAHIER DES CHARGES DES



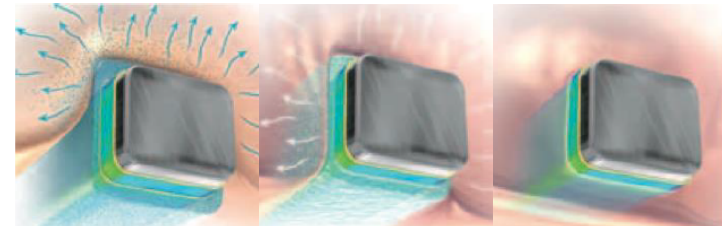
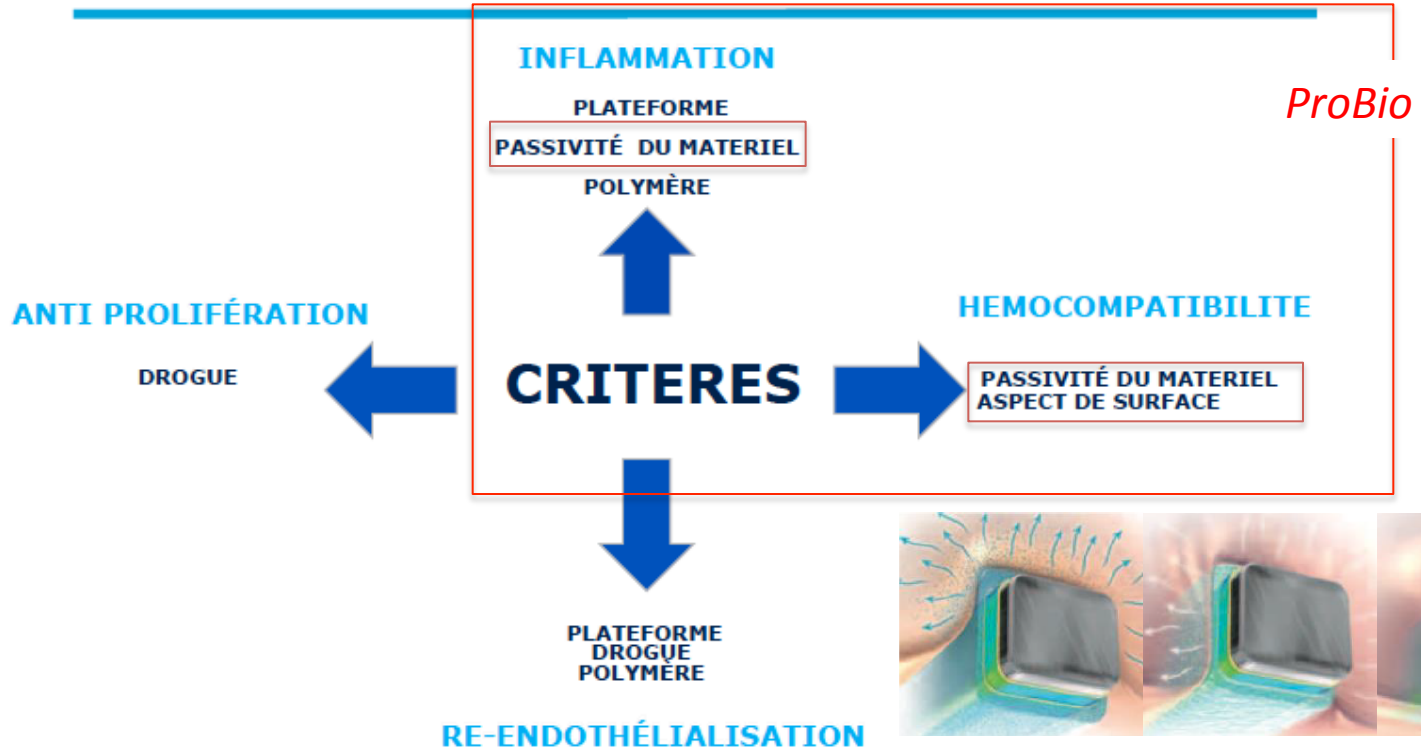
TS et TLF vs non EES

Méta-analyse EES vs non EES DES:



* Thrombose de stent DEFINITIVE

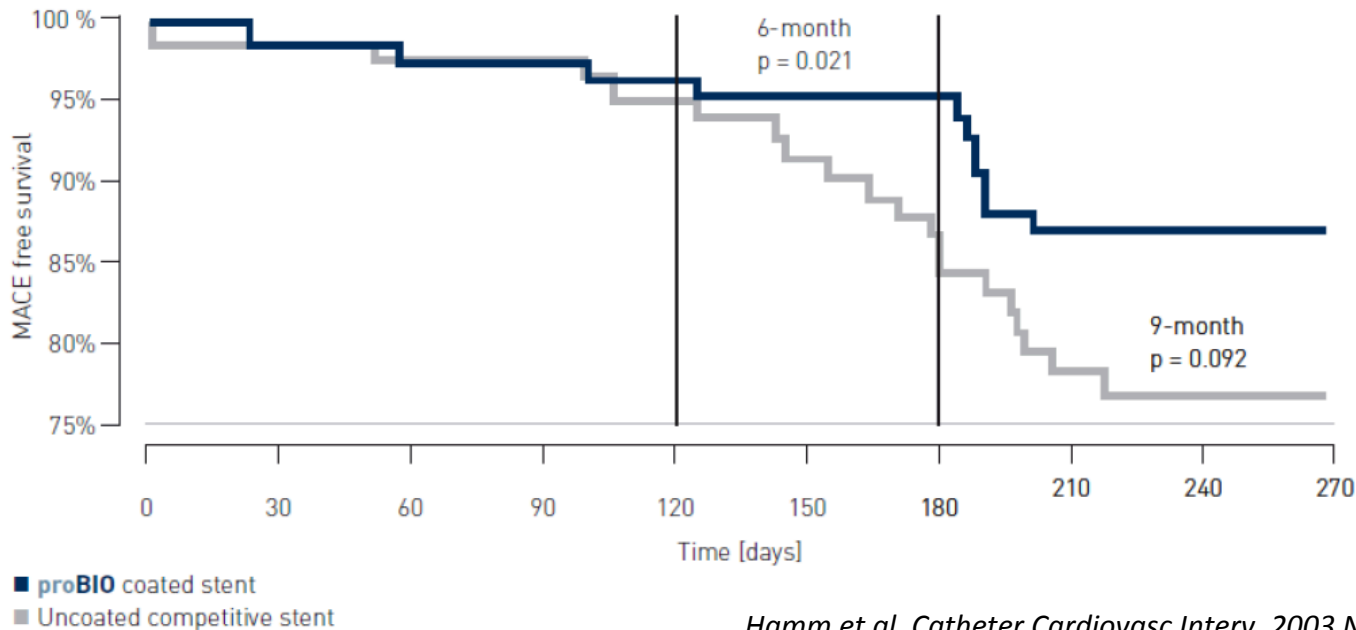
3. CAHIER DES CHARGES DES



Etude TRUST: BMS probio (Tenax: N=238) vs standard (N=247) SCA

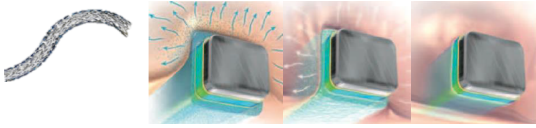
Analyse sous groupe Braunwald IIIB

- L'endoprothèse recouverte de BIOTRONIK montre un taux de survie sans MACE considérablement plus bas (TLR 4,7 %) VS les endoprothèses de référence (15,3 %)



POLYMERE DP vs BP, COUVERTURE, APPOSITION et INFLAMMATION

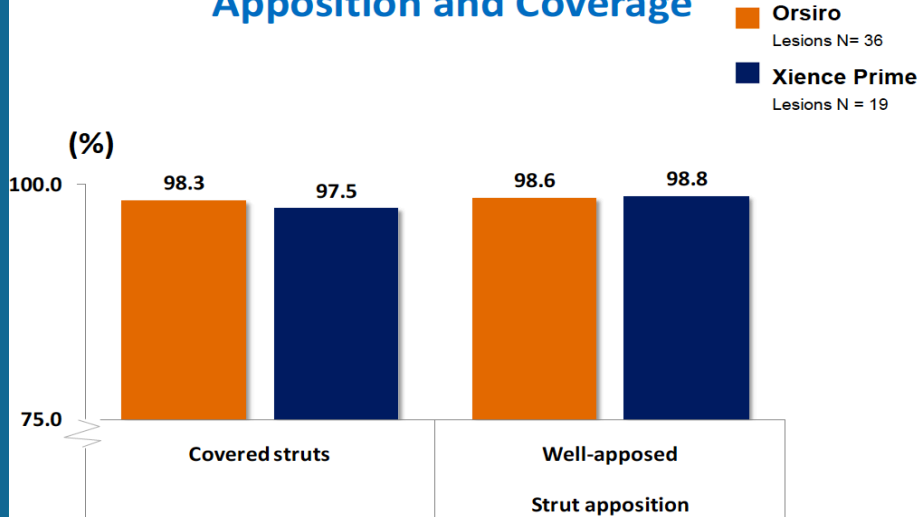
Fines struts DP EES (81 μm) vs BP SES (60 μm)



Stent **ORSIRO** (Biotronik), CoCh, 60μm): polymère PLLA
 Relargage sirolimus sur 12-14 semaines
 Dégradation en 1-2 ans
 (+ fine couche **PROBIO** (carbure de silicium) : biocompatibilité)

OCT / IVUS
 9 mois
 SCAD ou NSTEACS

Apposition and Coverage

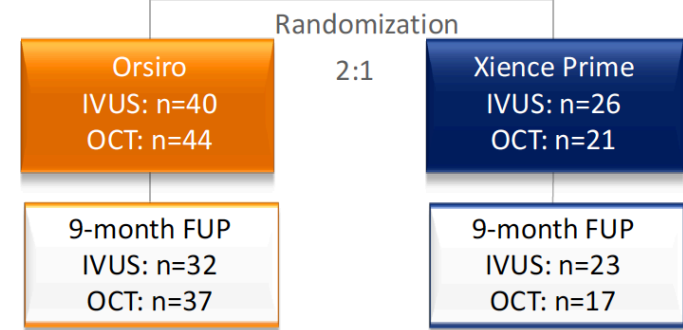


Source: M. Sabaté, EuroPCR, Paris, France. May 2013. Oral presentation.

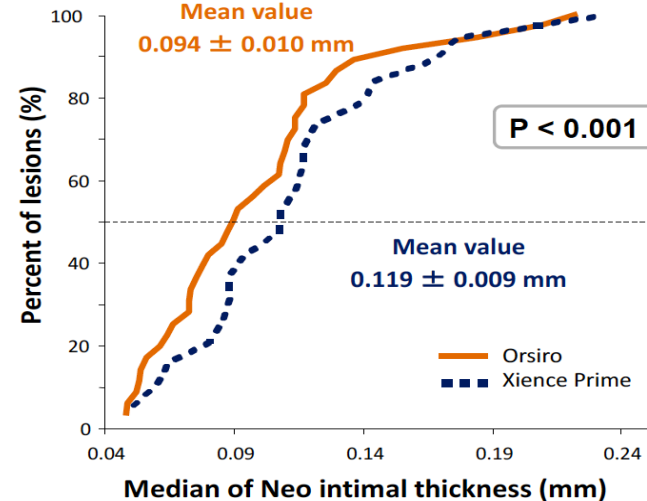
Pre-specified subgroups:

131 pts randomized between July 2011 and March 2012

IVUS & OCT Substudy

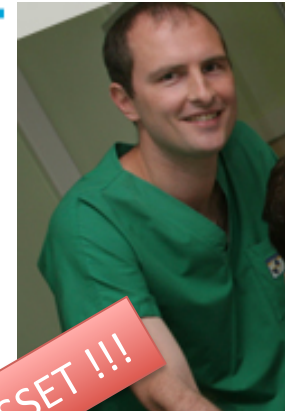
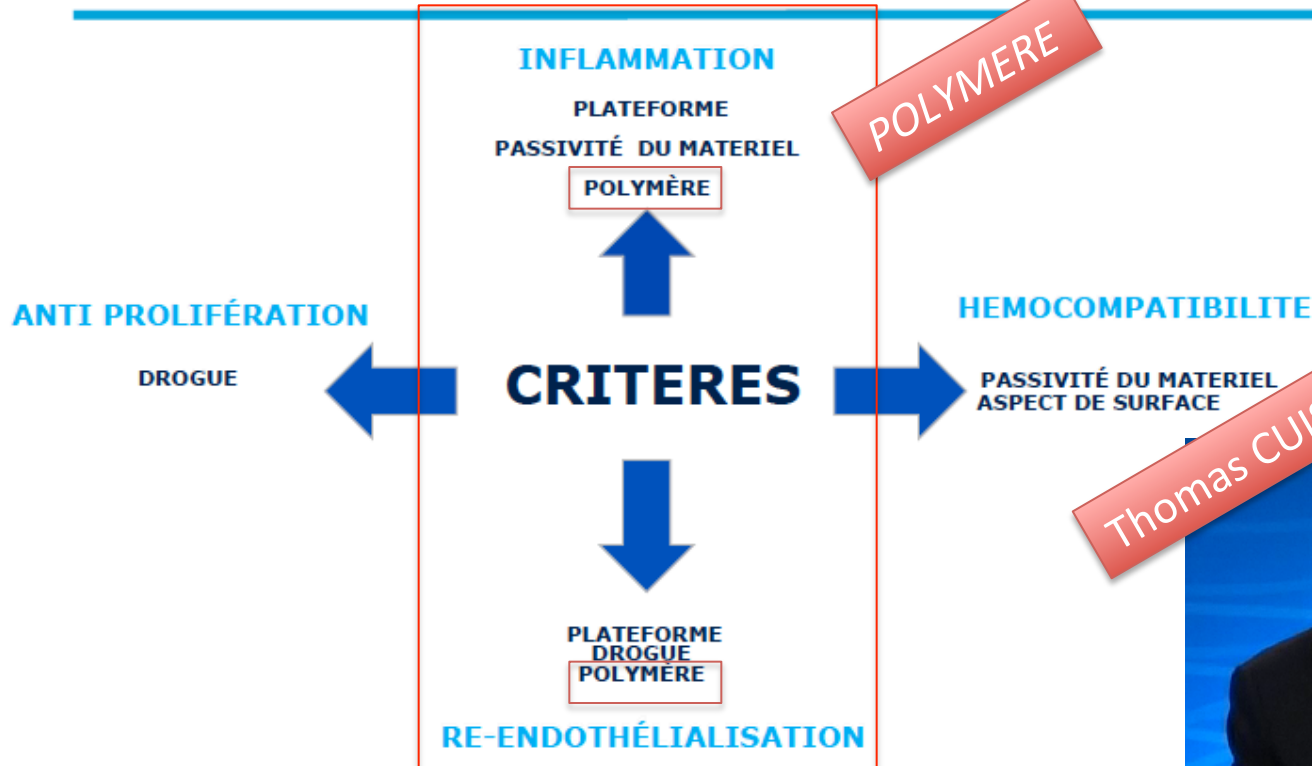


Neointimal Thickness



Source: M. Sabaté, EuroPCR, Paris, France. May 2013. Oral presentation.

4. CAHIER DES CHARGES DES

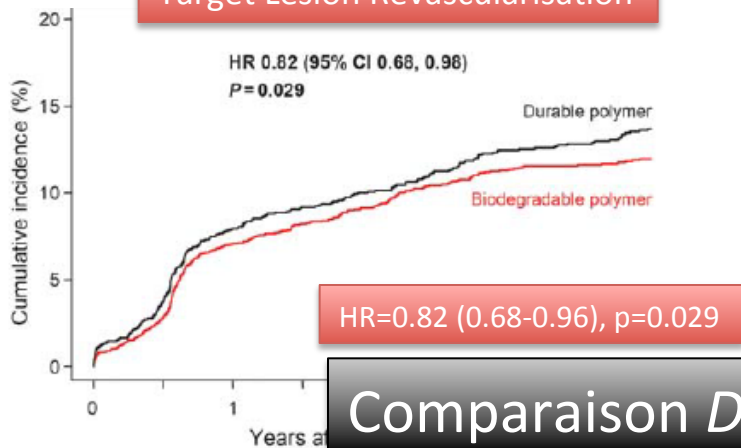


DES POLYMÈRE BIODÉGRADABLE (BP DES): ↘ inflammation, ↗ endothérialisation

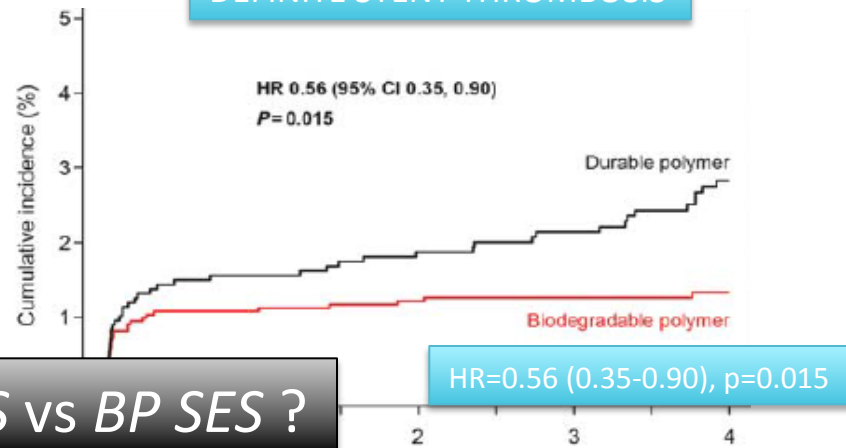
↘ TS (+ VLST) et TLR vs 1° génération DES MA 3 RCT, 4 062 pts, suivi 4 ans

Stefanini et al, EHJ 2012 (10)1214-22

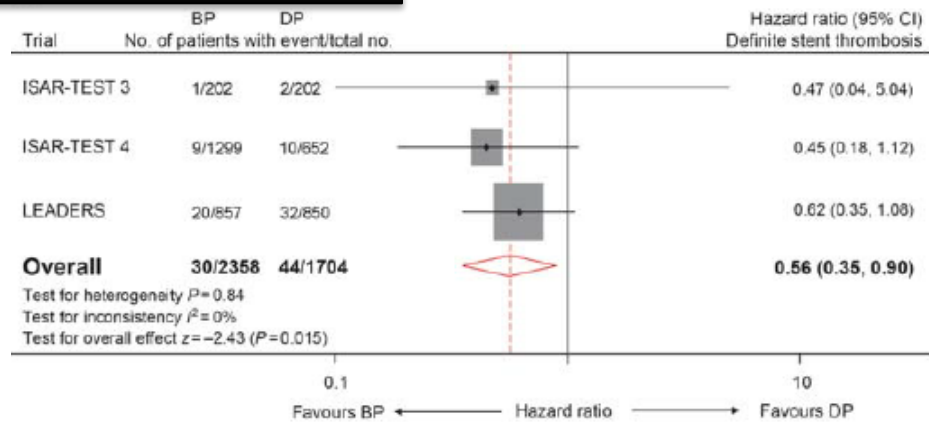
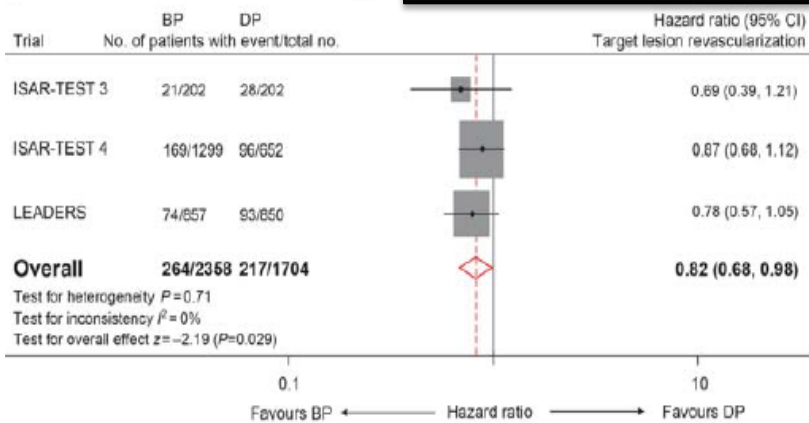
Target Lesion Revascularisation



DEFINITE STENT THROMBOSIS



Comparaison DP EES vs BP SES ?



ORSIRO

XIENCE PRIME/ XPEDITION



Ultrathin strut biodegradable polymer sirolimus-eluting stent versus durable polymer everolimus-eluting stent for percutaneous coronary revascularisation (BIOSCIENCE): a randomised, single-blind, non-inferiority trial



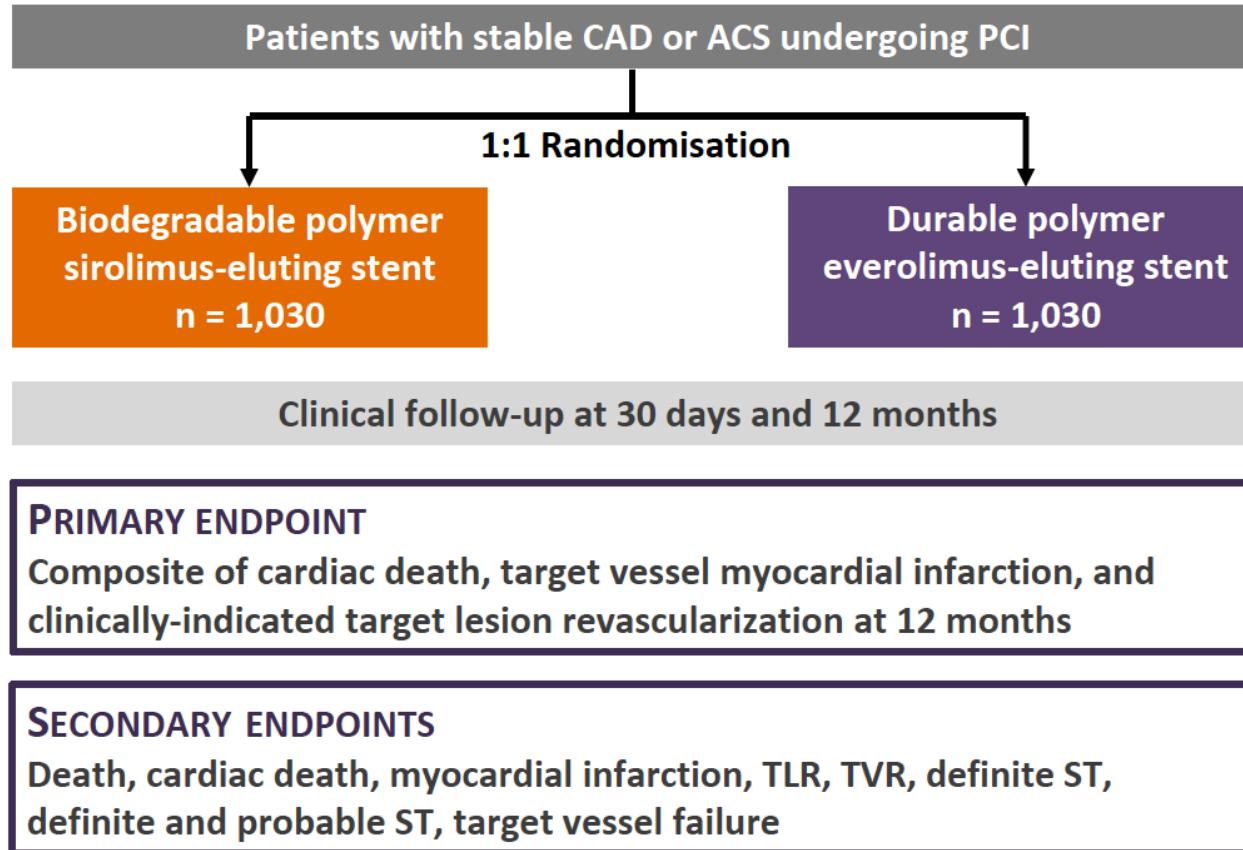
THE LANCET

Thomas Pilgrim*, Dik Heg*, Marco Roffi, David Tüller, Olivier Muller, André Vuilliomenet, Stéphane Cook, Daniel Weilenmann, Christoph Kaiser, Peiman Jamshidi, Therese Fahrni, Aris Moschovitis, Stéphane Noble, Franz R Eberli, Peter Wenaweser, Peter Jüni, Stephan Windecker

Lancet. 2014 Dec 13;384(9960):2111-22.

	Biodegradable	Durable
Polymer material	 PLLA: poly-L-lactic acid	 PBMA/PVDF-HFP
Antiproliferative drug	Sirolimus (1.4 µg/mm ²)	Everolimus (1.0 µg/mm ²)
Epaisseur du coating	7µm	8µm

TRIAL DESIGN



ANGIOGRAPHIC CHARACTERISTICS

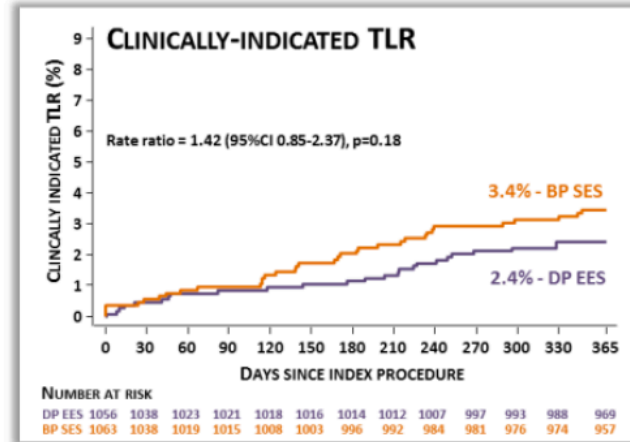
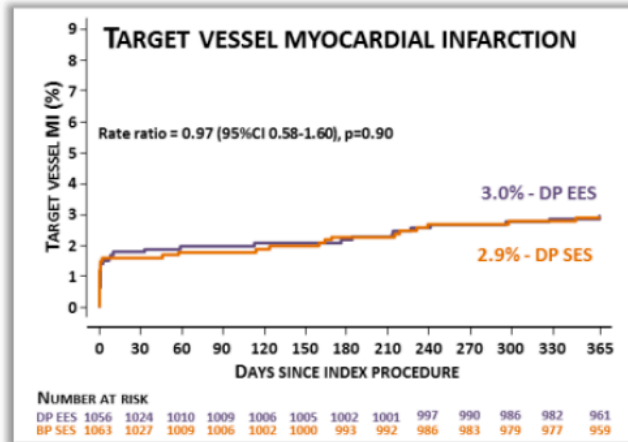
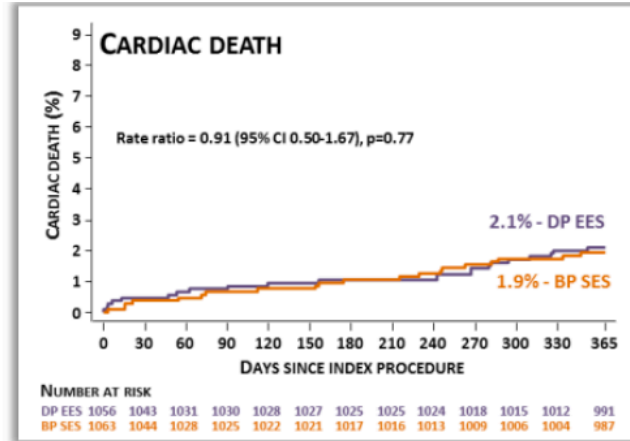
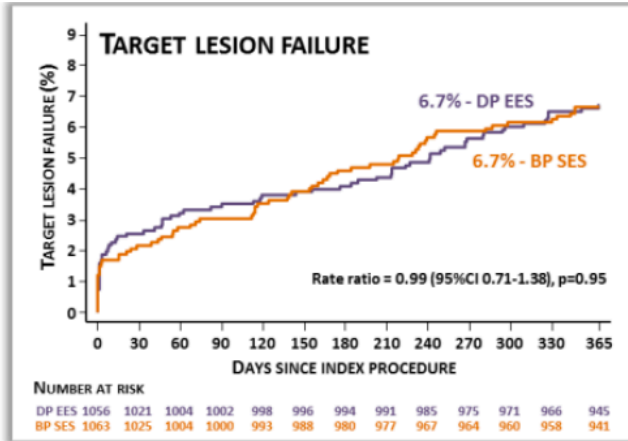
BP SES (n=1,594)

DP EES (n=1,545)

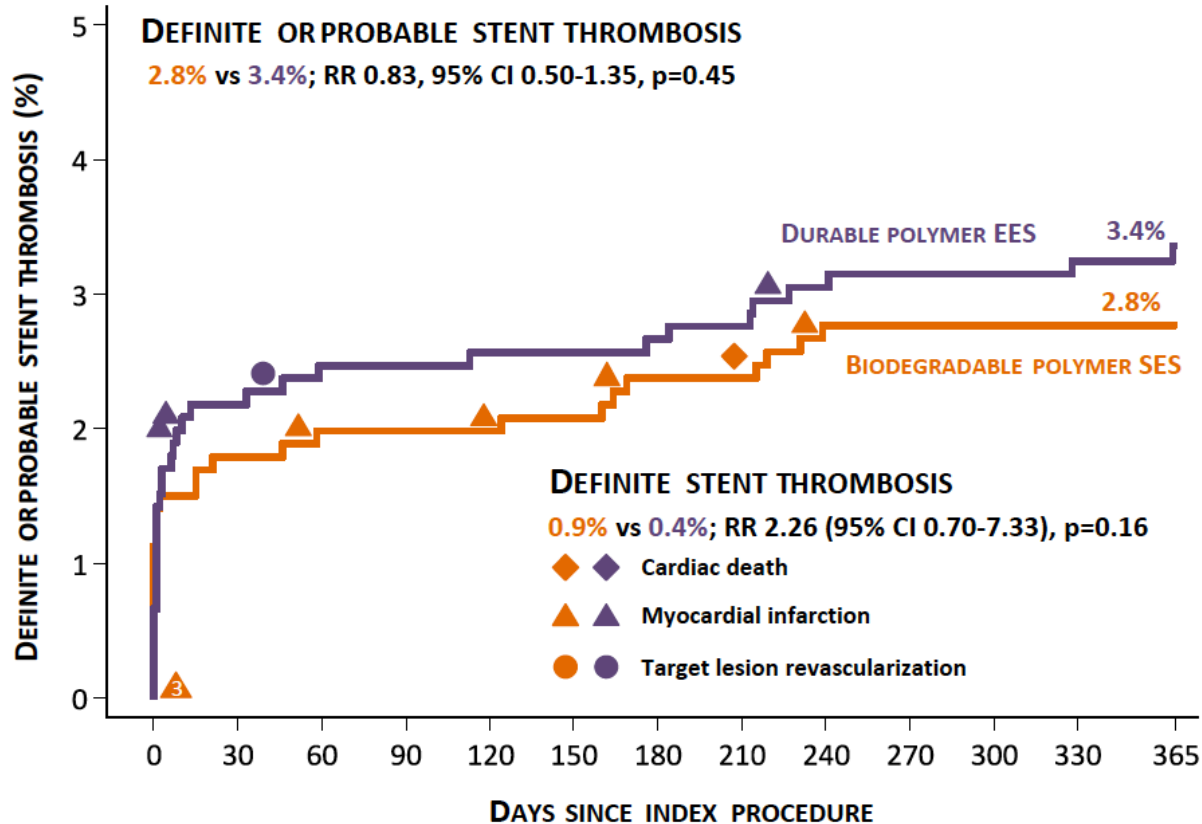
Target-vessel location per lesion — n (%)

Left main artery	29 (2%)	27 (2%)
Left anterior descending artery	649 (41%)	679 (44%)
Left circumflex artery	370 (23%)	341 (22%)
Right coronary artery	505 (32%)	452 (29%)
Saphenous vein graft	38 (2%)	40 (3%)
Arterial graft	3 (0.2%)	6 (0.4%)
Number of treated lesions per patient — mean ± SD	1.50 ± 0.79	1.46 ± 0.73
Number of stents per lesion — mean ± SD	1.31 ± 0.61	1.34 ± 0.64
Total stent length per lesion (mm) — mean ± SD	25.91 ± 15.40	27.45 ± 16.77
Maximum stent diameter per lesion (mm) — mean ± SD	3.05 ± 0.49	3.03 ± 0.49
Off-label stent use per lesion — n (%)	690 (46%)	735 (50%)
Long lesion per lesion (>20 mm) — n (%)	826 (54%)	839 (57%)
Small-vessel per lesion (<2.75 mm) — n (%)	439 (29%)	468 (32%)

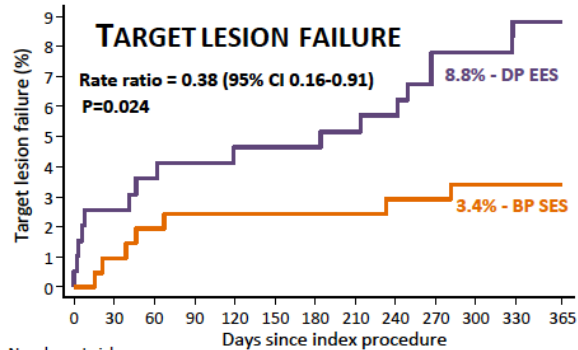
SECONDARY ENDPOINTS



STENT THROMBOSIS

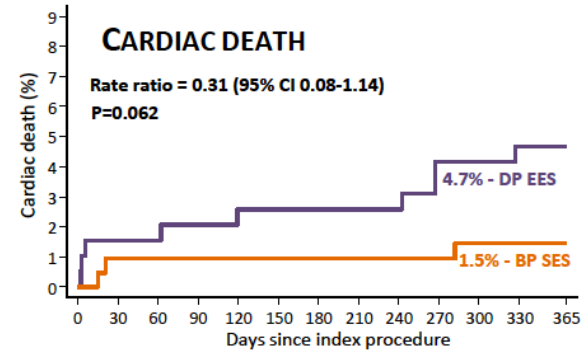


SUBGROUP ANALYSIS OF PATIENTS WITH ST-SEGMENT ELEVATION MI



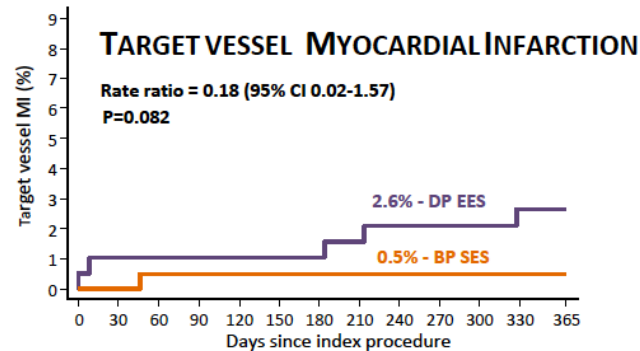
Number at risk

DP EES	196	189	185	184	183	183	183	182	181	177	177	175	172
BP SES	211	207	201	199	198	198	198	198	197	196	194	194	194



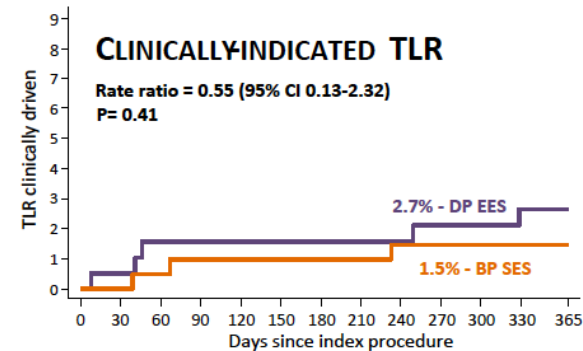
Number at risk

DP EES	196	191	188	187	187	187	187	187	187	184	184	183	180
BP SES	211	207	203	202	201	201	201	201	201	200	198	198	197



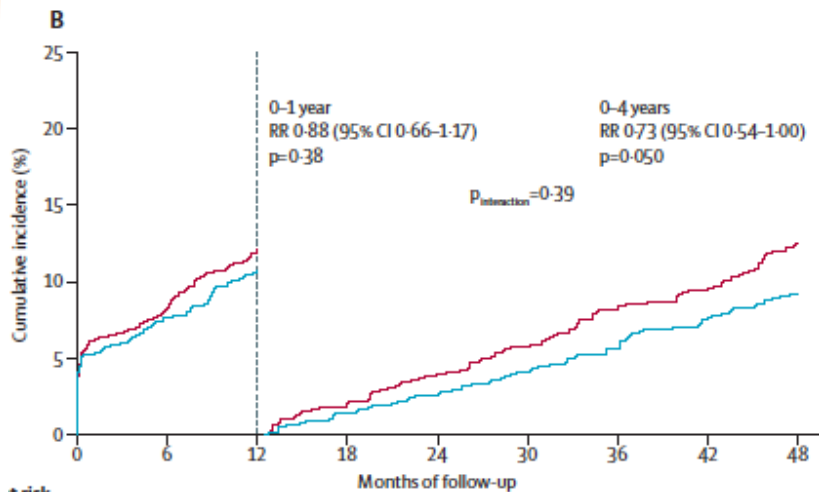
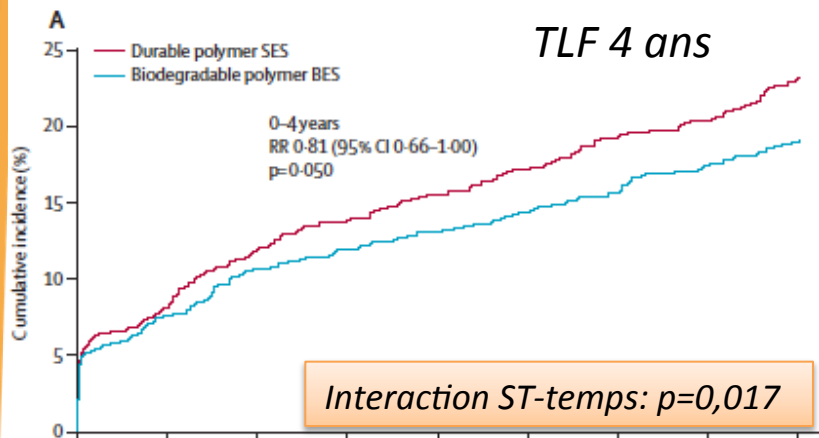
Number at risk

DP EES	196	189	187	186	185	185	185	184	183	180	180	178	175
BP SES	211	207	202	201	200	200	200	200	200	199	197	197	196



Number at risk

DP EES	196	190	186	185	184	184	184	184	184	184	180	180	178	175
BP SES	211	207	202	200	199	199	199	199	198	197	195	195	195	195



	Biodegradable polymer BES	Durable polymer SES	Risk ratio (95% CI)	p value	$P_{interaction}$
Not associated with stent thrombosis					
Cardiac death, MI, or clinically-indicated TVR					
≤1 year	78/857	87/850	0.89 (0.65-1.20)	0.44	0.70
1-4 years	67/749	79/738	0.81 (0.59-1.12)	0.21	
Cardiac death or MI					
≤1 year	48/857	47/850	1.02 (0.68-1.53)	0.94	0.43
1-4 years	43/779	52/781	0.80 (0.54-1.21)	0.30	
Cardiac death					
≤1 year	16/857	23/850	0.69 (0.37-1.31)	0.25	0.35
1-4 years	33/817	32/814	1.01 (0.62-1.65)	0.96	
MI					
≤1 year	39/857	28/850	1.39 (0.85-2.27)	0.19	0.11
1-4 years	18/779	24/781	0.73 (0.40-1.35)	0.31	
Clinically-indicated TVR					
≤1 year	37/857	45/850	0.81 (0.52-1.25)	0.33	0.64
1-4 years	39/776	40/760	0.94 (0.60-1.45)	0.77	
Associated with stent thrombosis					
Cardiac death, MI, or clinically-indicated TVR					
≤1 year	13/857	15/850	0.86 (0.41-1.80)	0.68	0.049
1-4 years	2/749	11/738	0.17 (0.04-0.78)	0.009	
Cardiac death or MI					
≤1 year	11/857	11/850	1.00 (0.43-2.30)	0.99	0.08
1-4 years	3/779	11/781	0.27 (0.08-0.95)	0.029	
Cardiac death					
≤1 year	2/857	0/850	4.97 (0.24-103.4)	0.50	0.14
1-4 years	0/817	2/814	0.20 (0.01-4.12)	0.25	
MI					
≤1 year	11/857	11/850	1.00 (0.43-2.30)	0.99	0.11
1-4 years	3/779	10/781	0.29 (0.08-1.06)	0.06	
Clinically-indicated TVR					
≤1 year	13/857	15/850	0.85 (0.41-1.80)	0.68	0.07
1-4 years	2/776	10/760	0.19 (0.04-0.87)	0.017	

CONCLUSION

DES Maille Ultra Fine

DES Polymère Biodégradable

Facilité de pos
 ↗ Crossabilité
 ↗ Trackabilité

ersensibilité
 lammation



In