

APPAC 2013

ABSORB

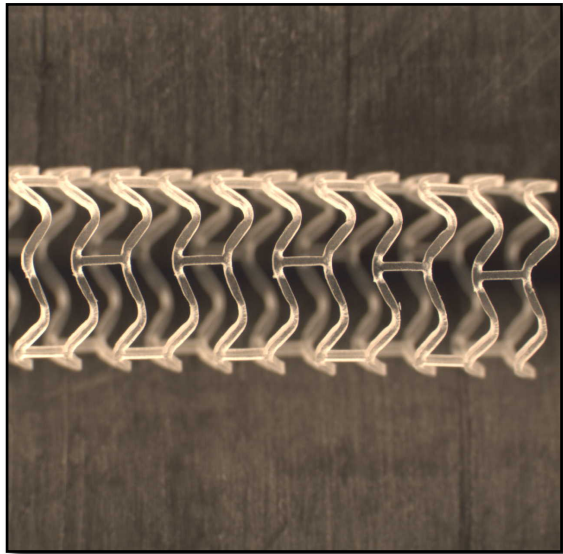
BVS POLY-L-Lactic Acid Everolimus Stent

JP Monassier

Fondation du Diaconat – Mulhouse

Hopital Albert Schweitzer - Colmar

CONCEPT



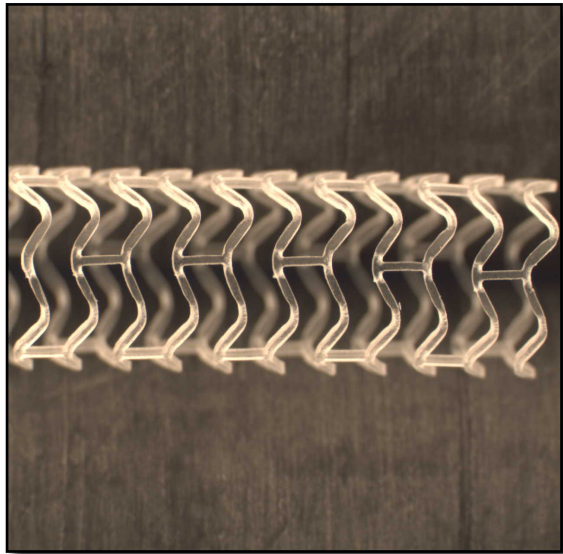
Prothèse non métallique (2 marqueurs)
Biologique
Pansement artériel

ABSORB

Objectifs :

- prévenir la resténose
- Maintenir la lumière artérielle
- Tirer sa révérence

STRUCTURE



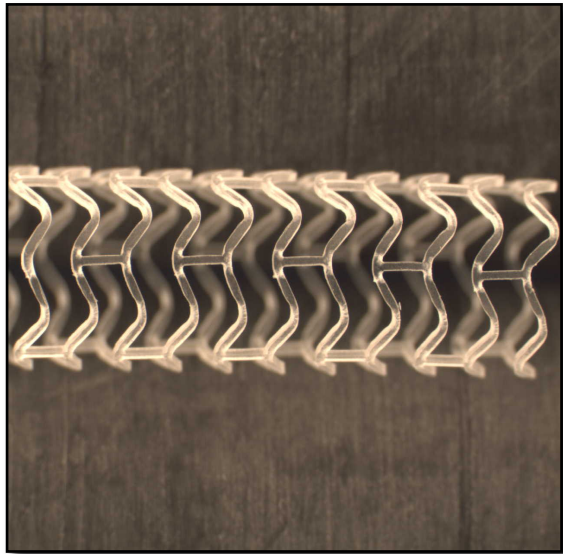
Acide Poly Lactique
Everolimus

ABSORB

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OBJECTIFS



Gain de lumière

Absence de resténose

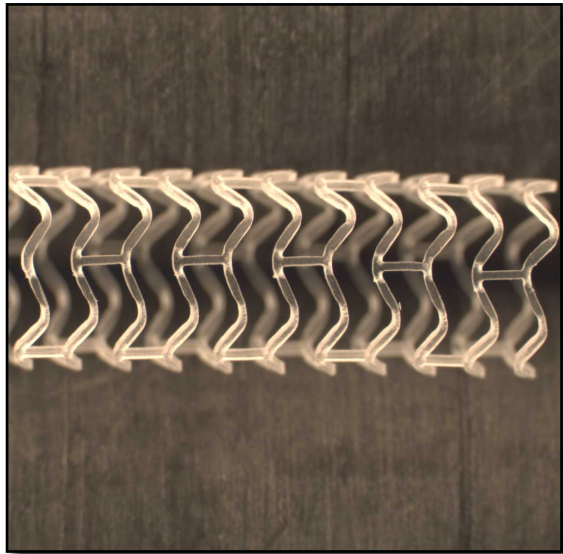
Rétablir une paroi « physiologique »

ABSORB

Objectifs :

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ENSUITE



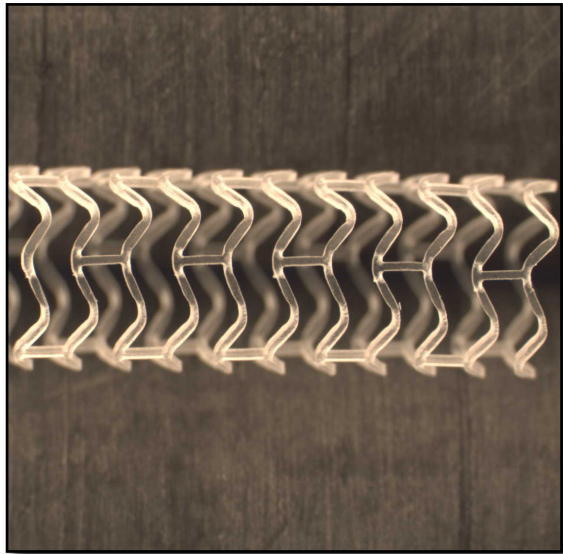
La Paroi s' est autoguérie
Le Gain de lumière est maintenu
L' Acide Lactique s' Hydrolyse Lentement

ABSORB

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ENSUITE



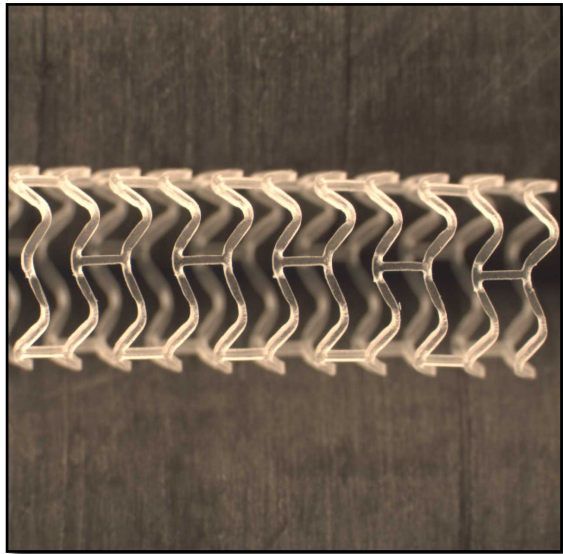
L' Endothélium se reconstruit
Le Phénotype Adulte de la Media est de Retour
Cellules Musculaires Lisses
L' Acide Lactique s' Hydrolyse Lentement

ABSORB

Objectifs :

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COMMENT ?



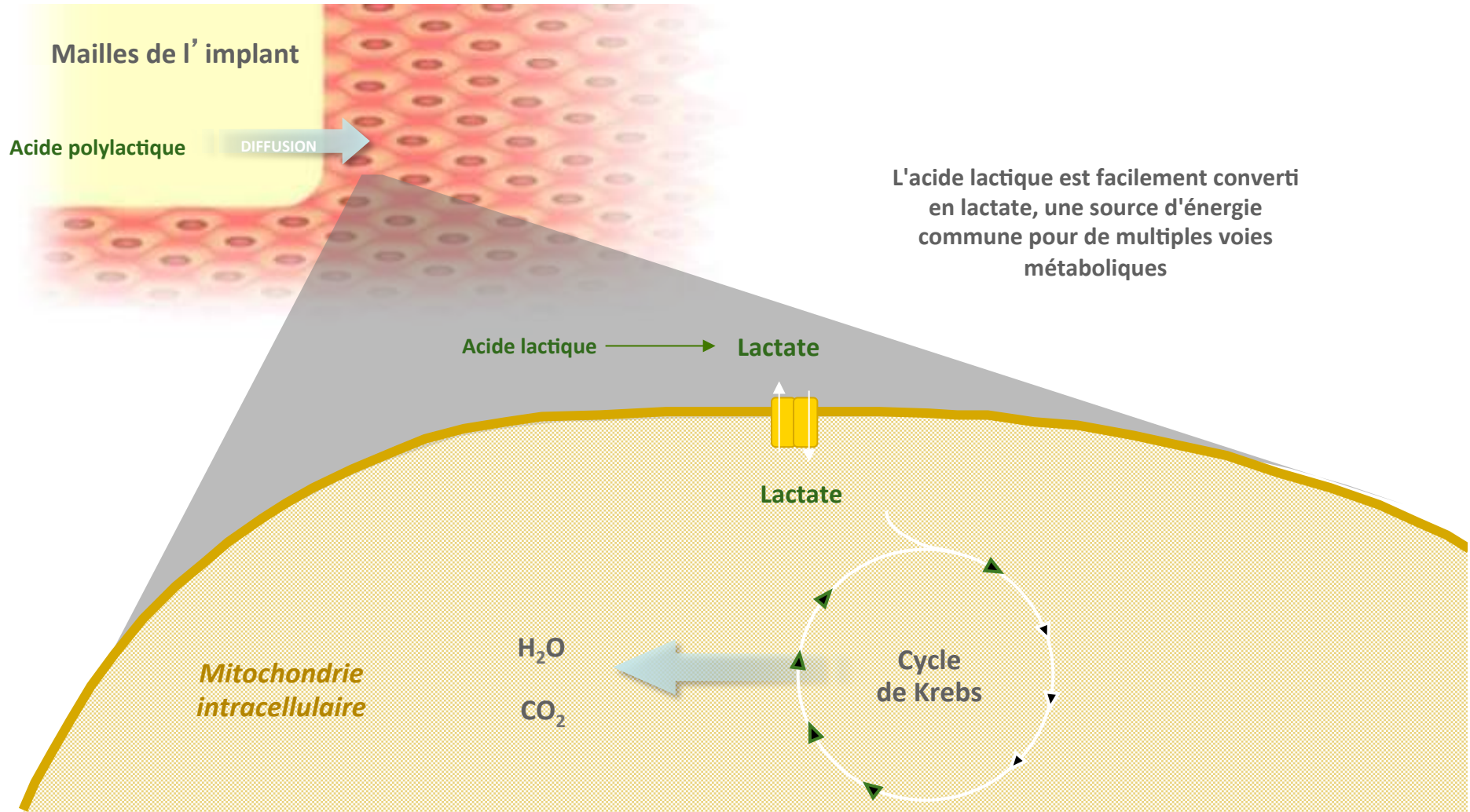
LA STENOSE = BALLON
LA RESTENOSE = EVEROLIMUS
LUMIERE : FORCE RADIAIRE
PUISSANCE DES LAISONS MOLECULAIRES

ABSORB

Objectifs :

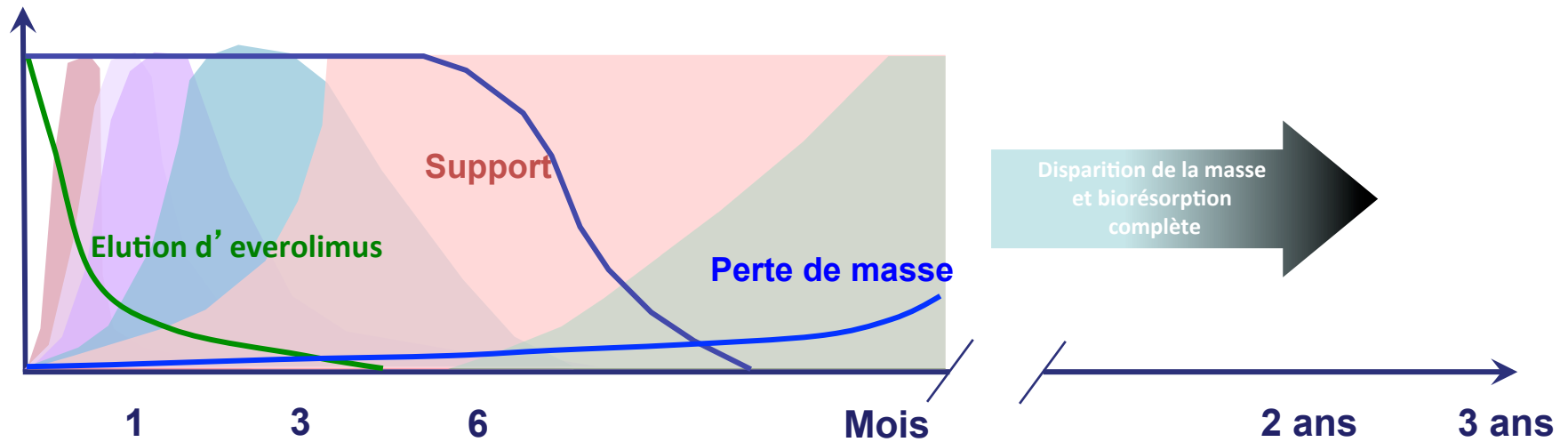
- prévenir la resténose
- Maintenir la lumière artérielle
- Tirer sa révérence

Absorb se résorbe par un processus naturel



¹Philp A., et al., J. Exp. Biol. 2005; 208: 4561

Une nouvelle option thérapeutique qui agit en trois phases



■ Dépôt de plaquettes

■ Recrutement de leucocytes

■ Prolifération et migration de cellules musculaires lisses

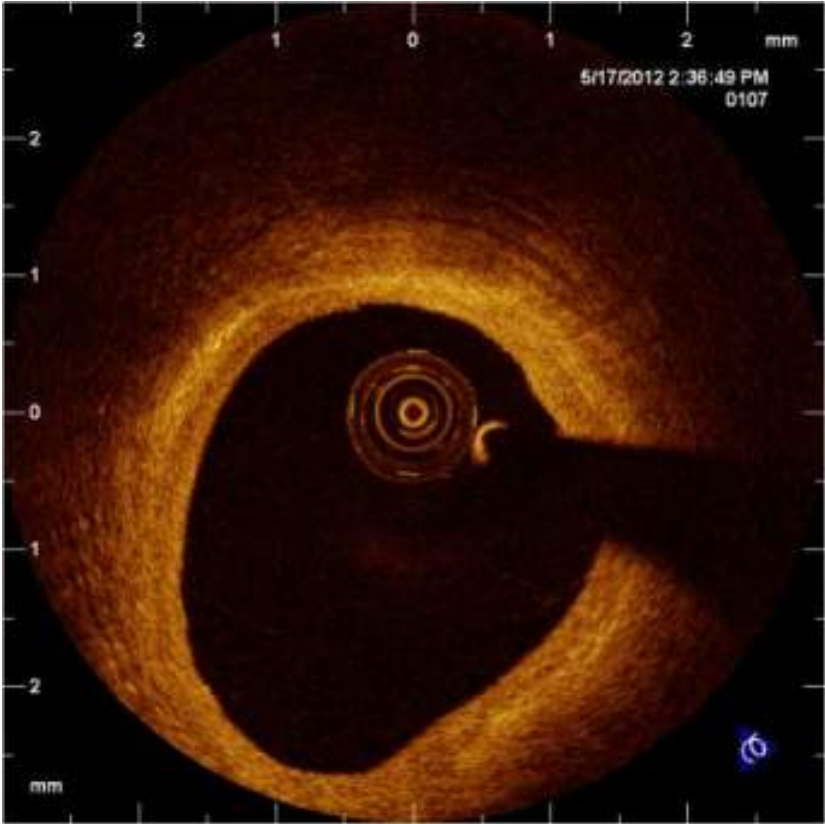
■ Dépôt de matrice

■ Réendothélialisation

■ Fonction vasculaire

Forrester JS, et al., J. Am. Coll. Cardiol. 1991; 17: 758. / Oberhauser JP, et al., EuroIntervention Suppl. 2009; 5: F15-F22.

L'ESPOIR



Images du Thoraxcenter, Erasmus MC, Rotterdam, Pays Bas, ABSORB A 5 ans

Absorb is authorized for sale in CE Mark and certain independently regulated countries outside the United States. Please check the regulatory status of the device in your geographical location before distribution. Information contained herein for presentation outside the U.S. and Japan only.

Le Premier

A completely absorbable stent may allow the vessel to react normally to pulsatile flow , to positively remodel and to respond normally to factors released by endothelium »

7 Mars 2007 - Auckland

64 ans - IVA 2

Ormiston JA et al

Cathet Cardiovas Interv 2007 ; 69 : 128-31

Etudes Pilotes

	6 Mois N=30	12 Mois N=29	2 ANS N=29	3ANS N=29
« MACES' s » Ischémiques.	3,3%	3,4%	3,4%	3,4%
Décès	0	0	0	0
STEMI	0	0	0	0
Non- STEMI	3,3%	3,4%	3,4%	3,4%
Resténoses Thromboses	0	0	0	0

ABSORB A - 5 Year Clinical Results

Hierarchical	6 Months 30 Patients	12 Months 29 Patients*	4 Years 29 Patients*	5 Years 29 Patients*
Ischemia Driven MACE, %(n)	3.3% (1)**	3.4% (1)**	3.4% (1)**	3.4% (1)**
Cardiac Death, %	0.0%	0.0%	0.0%	0.0%
MI, %(n)				
Q-Wave MI	0.0%	0.0%	0.0%	0.0%
Non Q-Wave MI	3.3% (1)**	3.4% (1)**	3.4% (1)**	3.4% (1)**
Ischemia Driven TLR, %				
by PCI	0.0%	0.0%	0.0%	0.0%
by CABG	0.0%	0.0%	0.0%	0.0%

No new MACE events between 6 months and 5 years
No scaffold thrombosis up to 5 years

*One patient withdrew consent after 6 months
**This patient also underwent a TLR, not qualified as ID-TLR (DS = 42%) followed by post-procedural troponin qualified as non-Q MI and died from his Hodgkin's disease at 888 days post-procedure.

QCA M 12 n = 57

mm	proximal	stent	distal	segment
diamètre	2,77	2,68	2,56	2,60
gain		1,20		
perte	0,12	0,22	0,08	0,16
sténose				
post	13%	15%	15%	22%
M 12	11%	20%	13%	23%
p	ns	0,001	0,10	0,24

ABSORB EXTEND : Résultats Cliniques

- Faible incidence de MACE à 1 an chez 450 patients (4,2%)

Non-Hierarchical % (n)	6 Months* (N=450)	12 Months* (N=450)
Cardiac Death % (n)	0.2 (1**)	0.2 (1**)
Myocardial Infarction % (n)	2.7 (12)	2.9 (13)
Q-wave MI	0.7 (3)	0.9 (4)
Non Q-wave MI	2.0 (9)	2.0 (9)
Ischemia driven TLR % (n)	0.4 (2)	1.8 (8)
CABG	0.0 (0)	0.2 (1)
PCI	0.4 (2)	1.6 (7)
Hierarchical MACE % (n)	2.9 (13)	4.2 (19)
Scaffold Thrombosis (ARC Def/Prob) % (n)	0.7 (3)	0.9 (4)

*Reflects an interim snapshot of patients with 12 month follow-up as of the cut-off date of 03 Dec 2012

**No ABSORB BVS was implanted in the target lesion.

Chevalier B, ABSORB EXTEND données préliminaires à 1 an, PCR Focus Group 2013

Faible taux de thromboses

ABSORB Cohorte A

0.0% ST durant 5 ans¹

ABSORB Cohorte B1

0.0% ST jusqu'à 3 ans²

ABSORB EXTEND

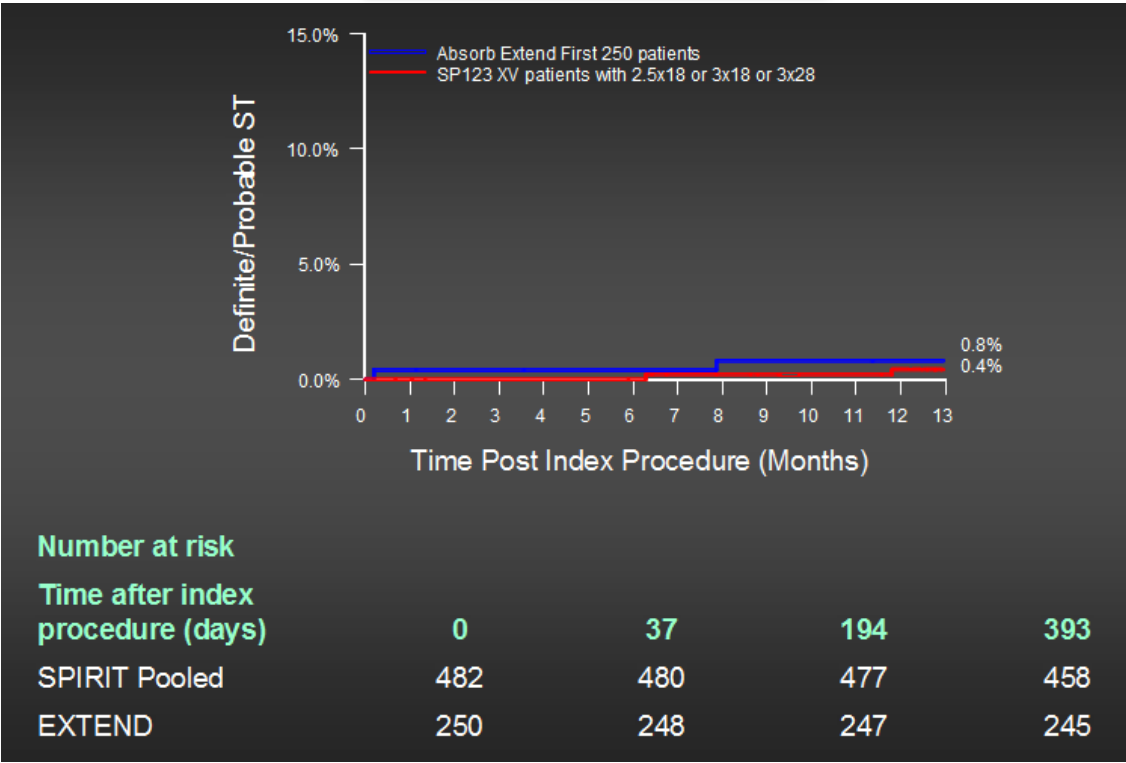
0.8% à 12 mois³

¹Serruys PW, Résultats Cohorte A à 5 ans et Cohorte B à 2 ans : Insights Intégrés, TCT2011

²Smits P. ABSORB Cohort B données à 3 ans, TCT 2012;

³Bartorelli, A, ABSORB EXTEND données préliminaires à 6 mois et 1 an, TCT 2012;

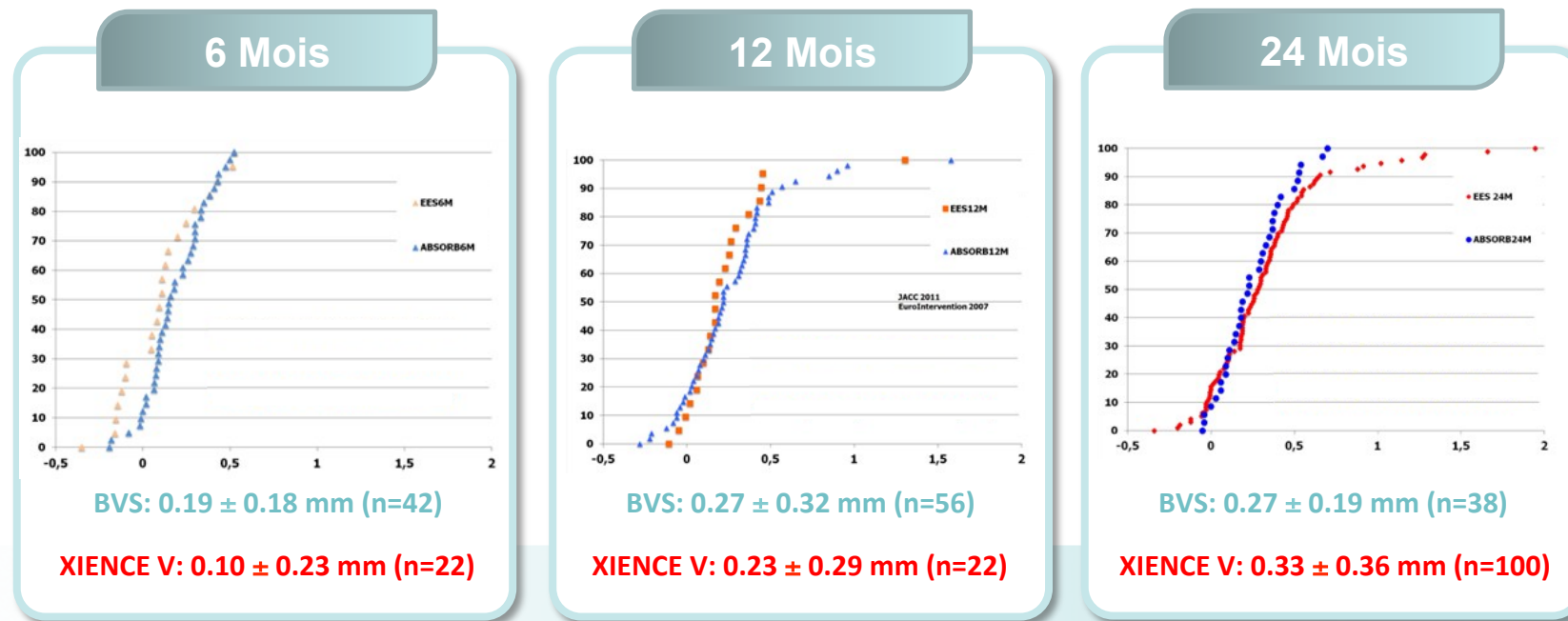
ABSORB EXTEND



Les bases de données sont issues de différentes études et présentées dans un but descriptif uniquement.

Revascularise comme un DES de référence

- Evolution des courbes de distribution de fréquences cumulées du Late Loss en fonction du temps : Absorb Cohort B et XIENCE V (Non-Matched Population, ITT)



- Absorb fournit le support radial aussi longtemps que nécessaire (Perte tardive inchangée entre 12 et 24 mois*)

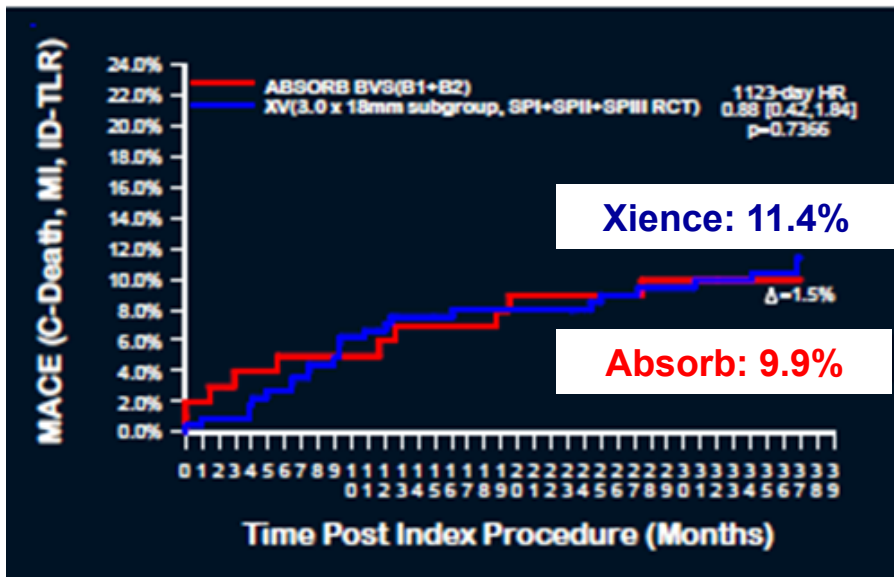
Serruys, PW., TCT 2011.

*Données à 1 an issues de ABSORB Cohort B Group 2 (n=56) et données à 2 ans de Cohort B Group 1 (n=45)

RESULTATS COMPARATIFS A XIENCE

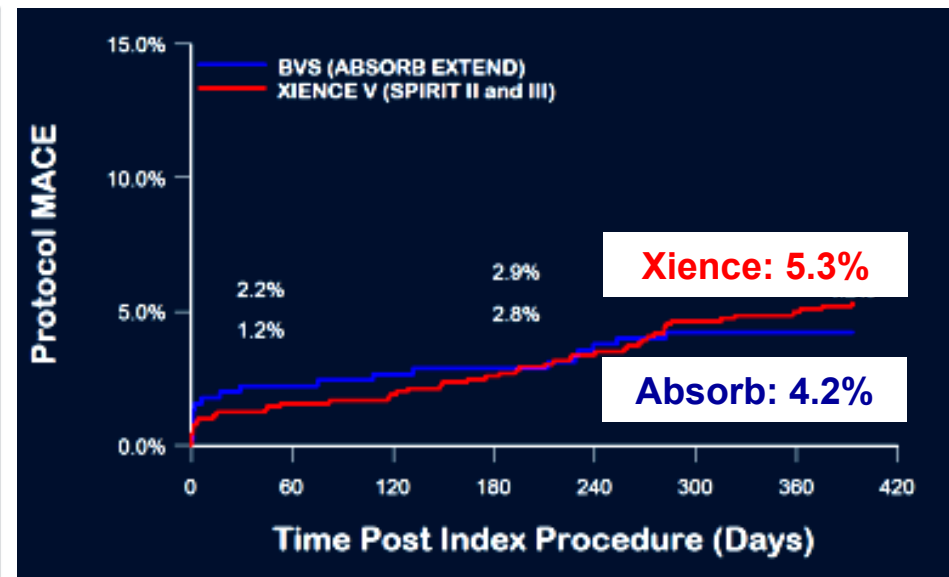
- Taux de MACE Absorb comparable et numériquement inférieur à celui observé avec XIENCE

A 3 ans dans ABSORB Cohorte B



Au sein d'une population similaire de patients - Analyse poolée SPIRIT I+II+III. PW Serruys ACC 2013

A 1 an dans ABSORB EXTEND



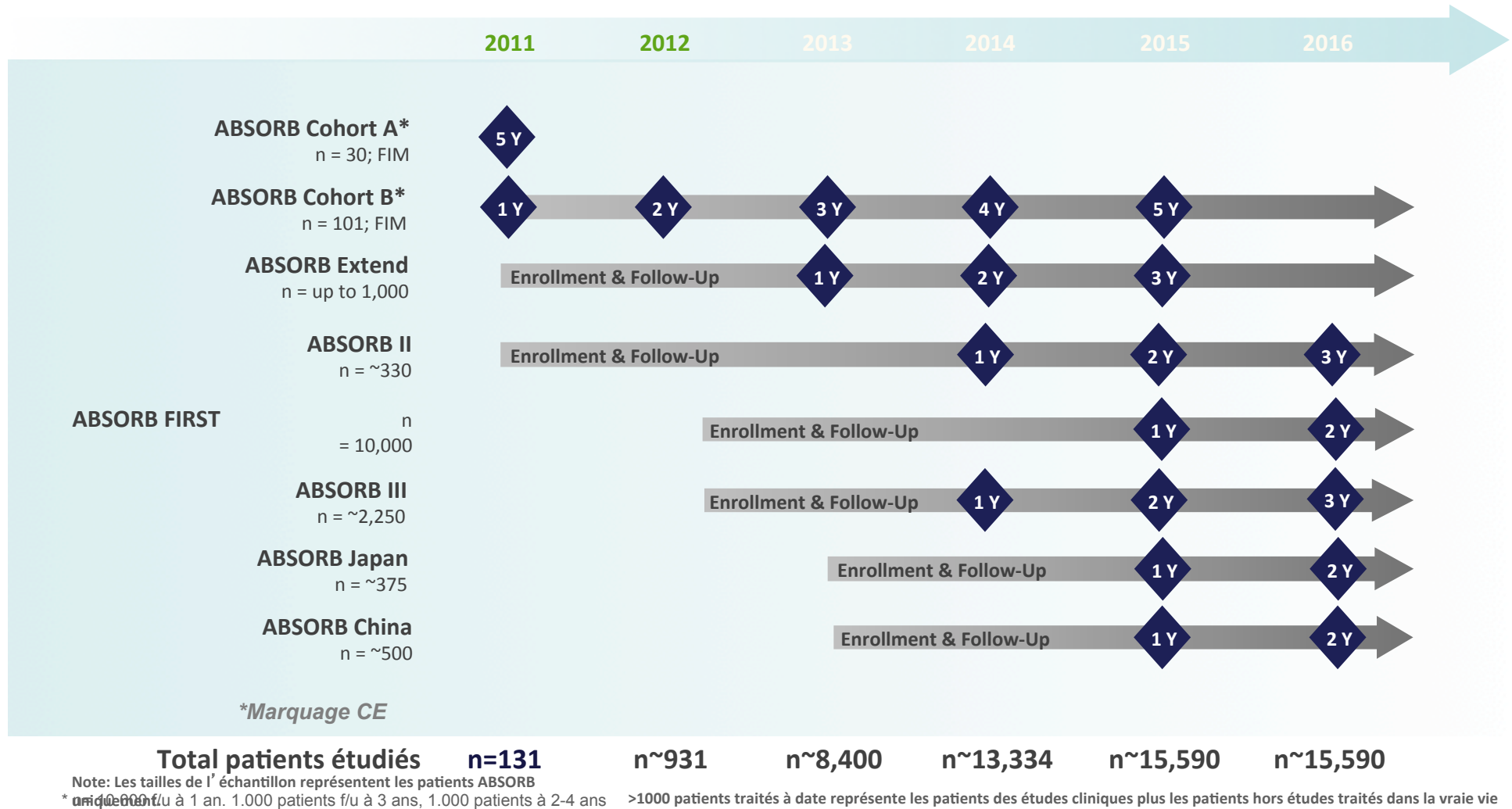
Au sein d'une population similaire de patients - Analyse poolée SPIRIT II+III. B Chevalier ACC 2013

Conclusion

- Results from ABSORB Cohort B continue to be encouraging with :

- Clinical Procedure Success 98%
- ABSORB B Group 1 – MACE rate of 6.8% at 2 and 3 years (1 peri-procedural MI & 2 TLR)
- No additional MACE between 1 year and 3 years
- No scaffold thrombosis event
- Clinical data very comparable to Xience-V data from SPIRIT I- III

Programme clinique – Les études



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INFARCTUS MYOCARDIQUE AIGU

Methods

- ***Academic*** (no industry support) prospective single center registry
- 87 consecutive STEMI pts underwent emergent CAG during 5 months period (Dec 16, 2012 – May 15, 2013)
- Study is planned for 3 years follow-up (incl. CTA at 1 year and CAG+OCT at 3 years)
- ***Early outcomes*** presented here

Baseline characteristics

	BVS group Killip I-II only	Other stent group Killip I-II only	Patients with Killip III-IV and/or without stent
N=	22	31	34
Mean age ± SD	58,5 ± 9,96	60,8 ± 13,54	69 ± 13,3
Females %	18%	14%	45%
Mean Killip class ± SD	1,09 ± 0,29	1,14 ± 0,36	2,45 ± 1,26
LAD as infarct artery %	59%	42%	48,6%
LCX as infarct artery %	13,6%	7%	16%
RCA as infarct artery %	27,2%	46%	27%
LMCA as infarct artery %	0%	0%	0%
Diabetes mellitus %	4,5%	10,7%	32%
Prior MI %	4,5%	7%	16,2%
Prior CABG %	0%	7%	2,7%
Prior PCI %	4,5%	3,5%	21,6%

Conclusion

- Concept original
- Absence de métal
- Résorbable sans réaction inflammatoire
- Resténose identique à Xience
- Faible taux de thromboses
- **Il Fait le JOB !**
- A suivre Mais disponible (marquage CE)

« The Next Revolution ?

Bittl JA Circulation 2010 ; 122 : 2236-8

An Evolution or Revolution ?

Gogas BD et al Hellenic J Cardiol 2012 ; 533 : 301-9

ABSORB B Group 1&2

Clinical Results - Intent to treat

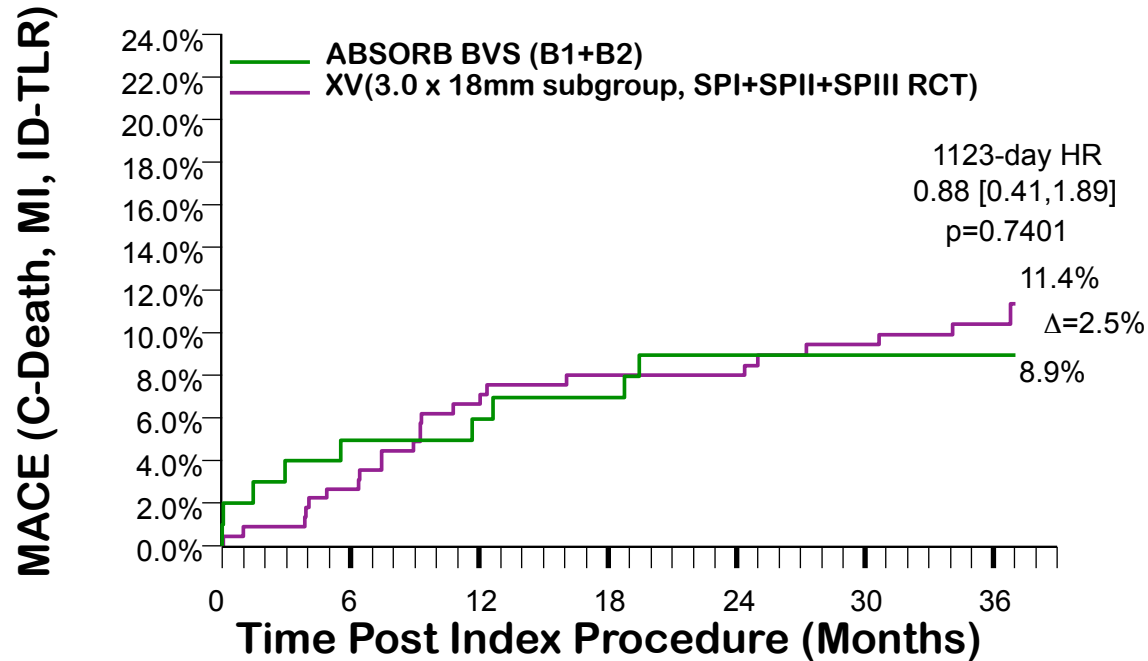
Non-Interventive
 30 Days N = 101 6 Months N = 101 12 Months N = 101 2 Years N = 100*

Cardiac Death %	0	0	0	0
Myocardial Infarction % (n)	2.0 (2)	3.0 (3)	3.0 (3)	3.0 (3)
Q-wave MI	0	0	0	0
Non Q-wave MI	2.0 (2)	3.0 (3)	3.0 (3)	3.0 (3)
Ischemia driven TLR % (n)	0	2.0 (2)	4.0 (4)	6.0 (6)
CABG	0	0	0	0
PCI	0	2.0 (2)	4.0 (4)	6.0 (6)
Hierarchical MACE % (n) <small>(n) One patient missed the 2-year FUP</small>	2.0 (2)	5.0 (5)	6.9 (7)	9.0 (9)

Hierarchical TVF % (n) **2.0 (2)** **5.0 (5)** **6.9 (7)** **11.0 (11)**
No scaffold thrombosis by ARC or Protocol

MACE: Cardiac death, MI, ischemia-driven TLR; TVF: Cardiac death, MI, ischemia-driven TLR, ischemia-driven TVR

KM estimate of MACE rate in patients treated with Absorb BVS (ABSORB Cohort B, n=101) vs. patients treated with a single 3.0x 18 mm metallic XIENCE V (SPIRIT FIRST+II+III, n=227)



	Time After Index Procedure (days)							
	0	37	194	284	393	573	758	1123
ABSORB BVS(B1+B2) At Risk	101	99	96	96	94	92	91	41
XV(3.0 x 18mm subaroup. SPI+SPII	227	224	219	211	204	202	191	182

P-values are not from formal hypotheses testing and are displayed for exploratory purpose only