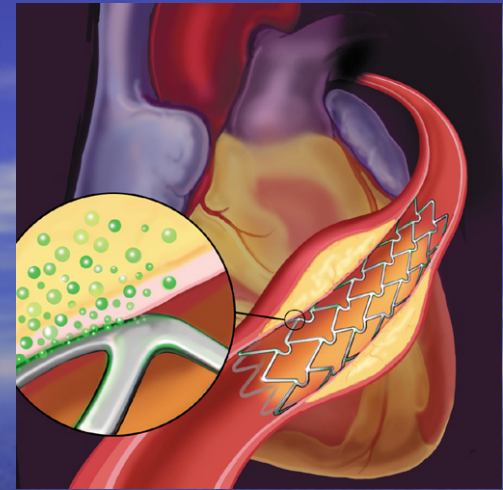
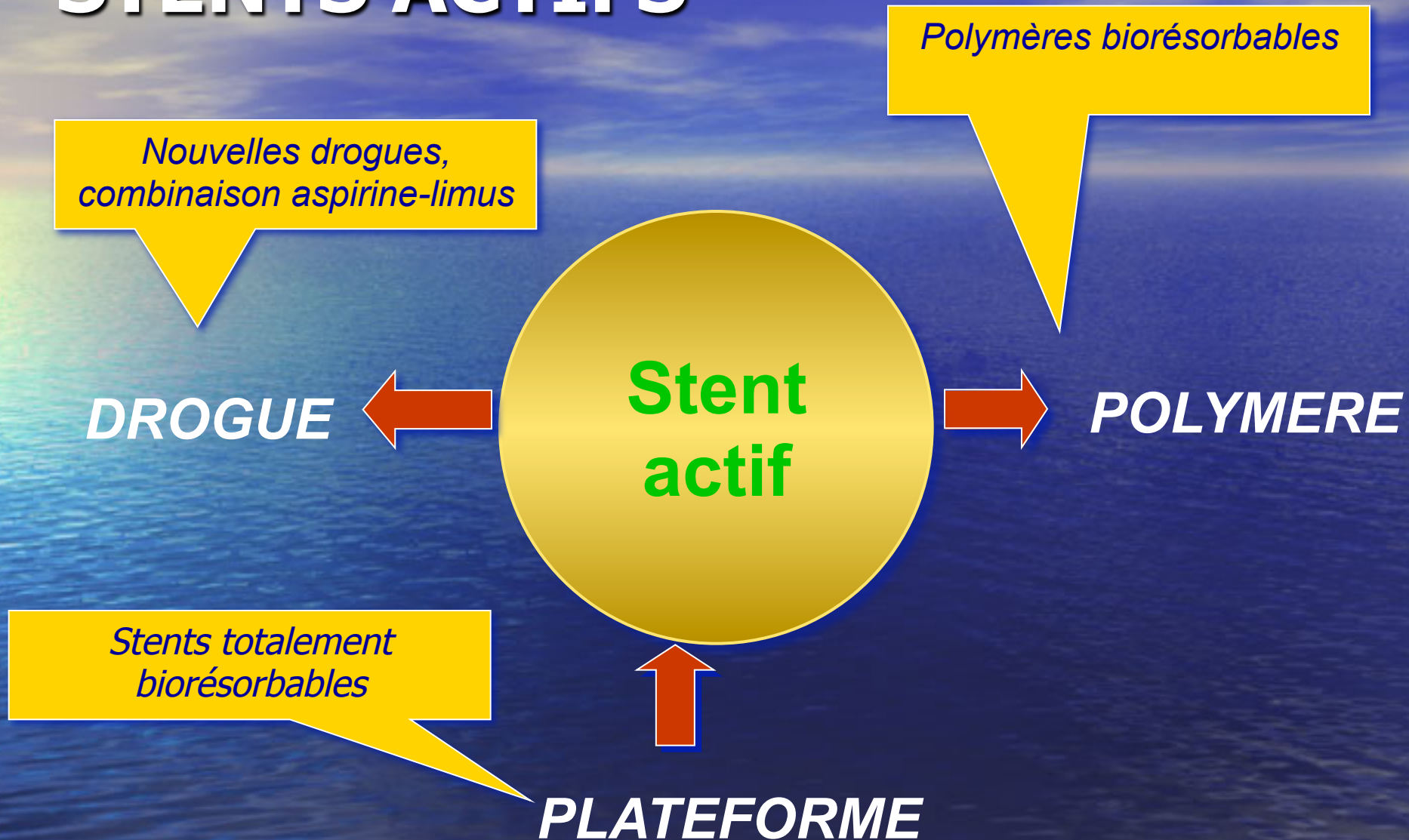


Les stents biorésorbables

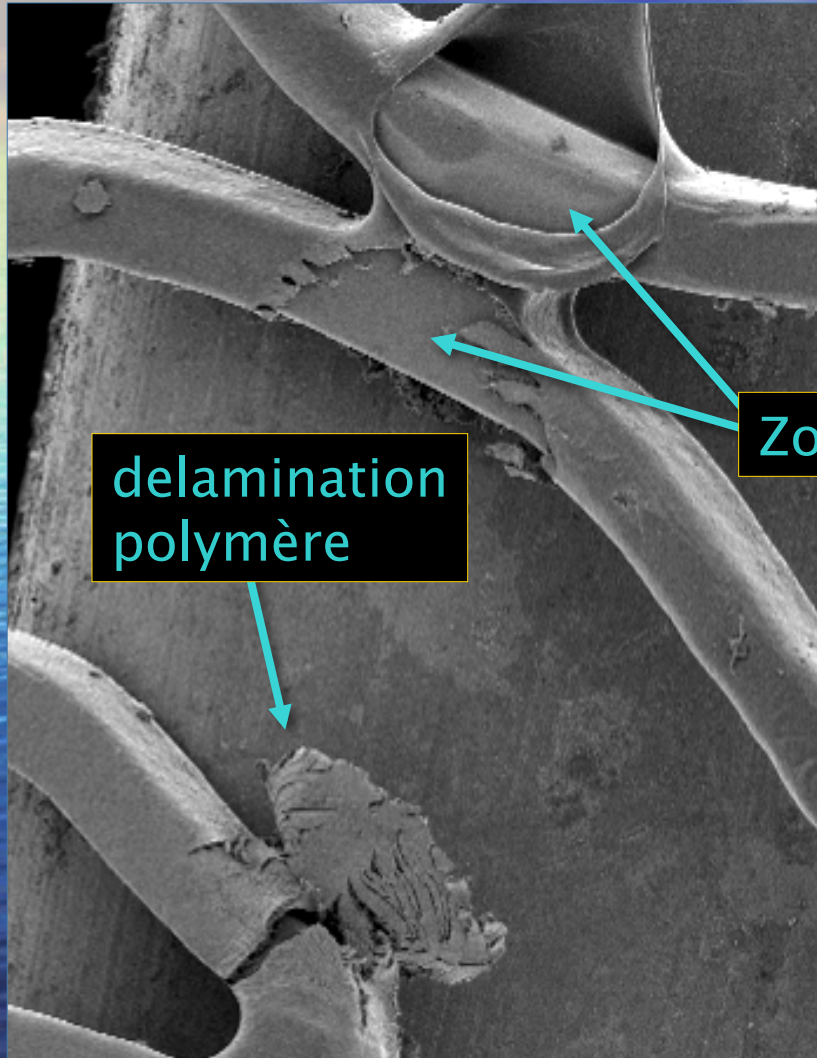
DR E.LAMMENS
CH CANNES



STENTS ACTIFS

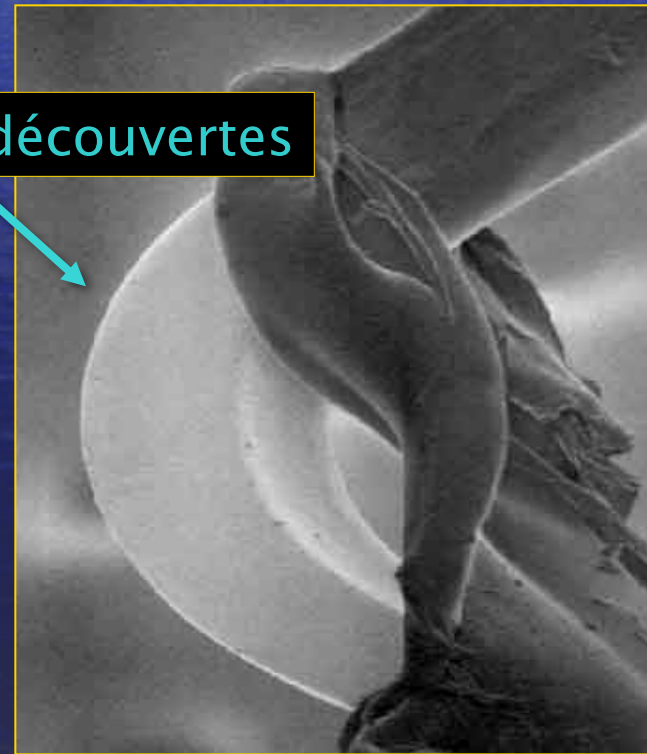


Problèmes liés aux Polymères



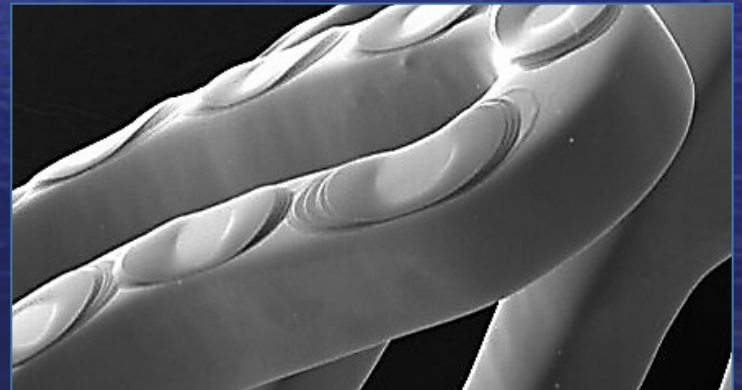
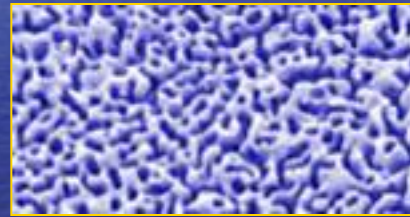
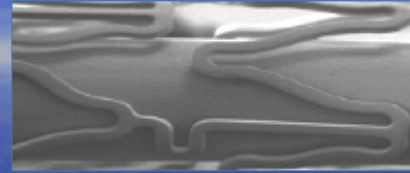
Complication à court terme parfois liées aux polymères recouvrant le tissu métallique du stent

Zones découvertes



Nouveaux polymères & Coatings

- Polymères bioresorbables
- Absence de polymère





ABSORB

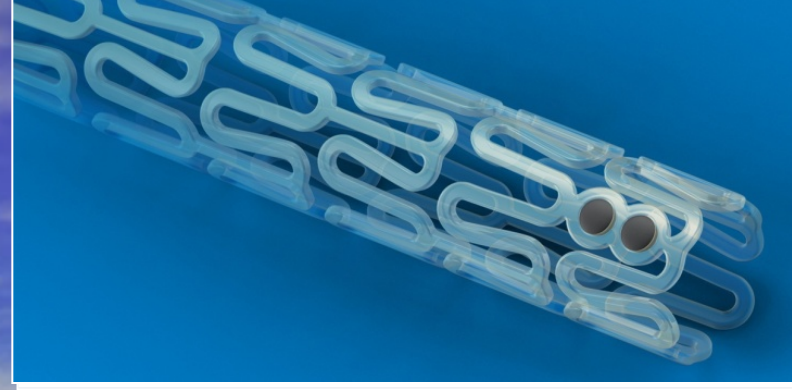
**totalelement
Biorésorbable**

Everolimus

**Acide polylactique
(PLA)**

- Epaisseur de maille : 150 μm (80 μm stent actif seconde generation)
- Marqueurs en platine à chaque extrémité

Acide polylactique ?



- Plastique
- fermentation de l'amidon sous l'effet de bactéries synthétisant l'acide lactique puis polymérisé
- Utilisé depuis 10 ans en chirurgie
- Sacs plastique biodégradables
- Peu onéreux : 3000 euros / tonne

Mailles de l'implant

Acide polylactique

DIFFUSION

L'acide lactique est facilement converti
en lactate, une source d'énergie
commune pour de multiples voies
métaboliques

Acide lactique → Lactate



Lactate

Mitochondrie
intracellulaire

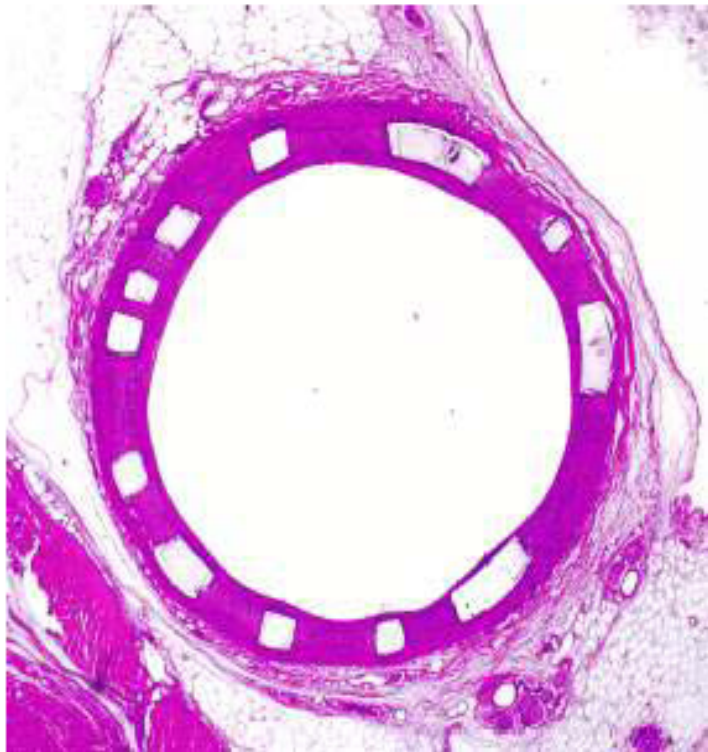
H_2O

CO_2

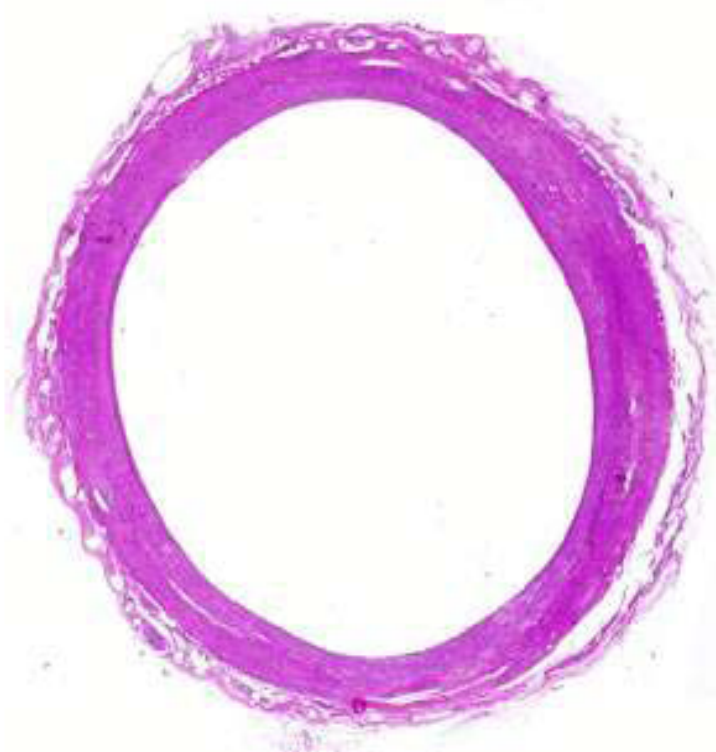
Cycle
de Krebs

Bioresorbable Vascular Scaffold (BVS): Un implant « idéal » pour ne laisser aucune trace* ...

Aigu



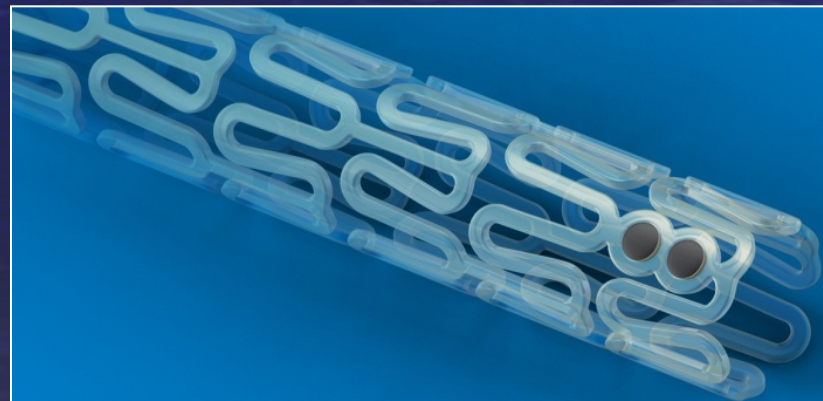
> 24 mois

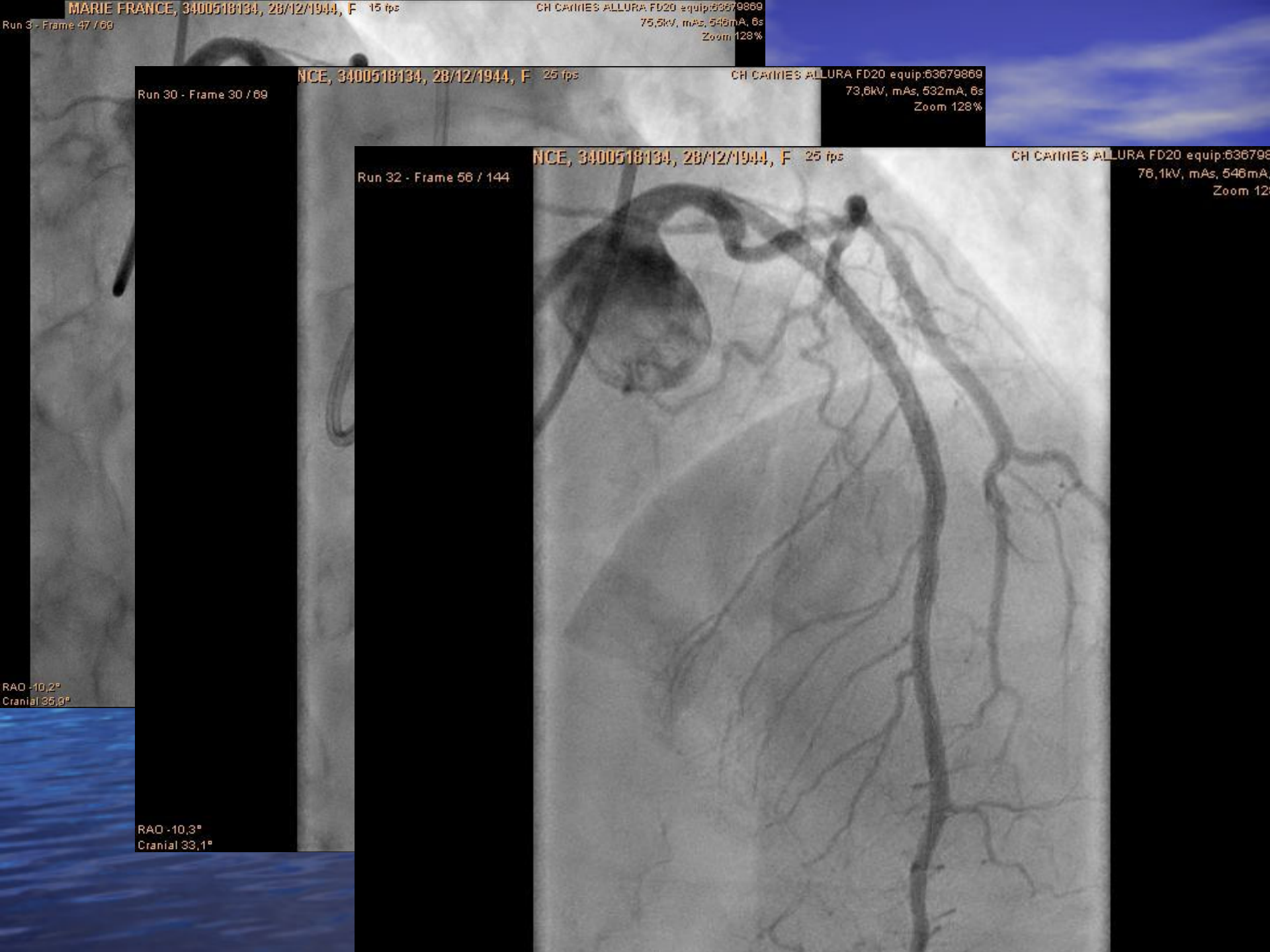


*Les marqueurs en platine demeurent pour le marquage radio-opaque.
Données et images Abbott Vascular. Images histologiques d'un model animal porcin.

CONCEPT / Biorésorbable

- Restauration de la fonction vasculaire
- Moins de thrombose tardive
- Moins d'inflammation / neoathérosclérose
- Disparition des mal appositions à distance
- Allègement du traitement AAP à long terme
- Possibilité de pontages
- Scanner





MARIE FRANCE, 3400518134, 28/12/1944, F 15 fps

CH CARINES ALLURA FD20 equip:63679889
75,5kV, mAs, 548mA, 6s
Zoom 128%

Run 3 - Frame 47 / 69

NCE, 3400518134, 28/12/1944, F 25 fps

CH CARINES ALLURA FD20 equip:63679889
73,6kV, mAs, 532mA, 6s
Zoom 128%

Run 30 - Frame 30 / 69

Run 32 - Frame 56 / 144

NCE, 3400518134, 28/12/1944, F 25 fps

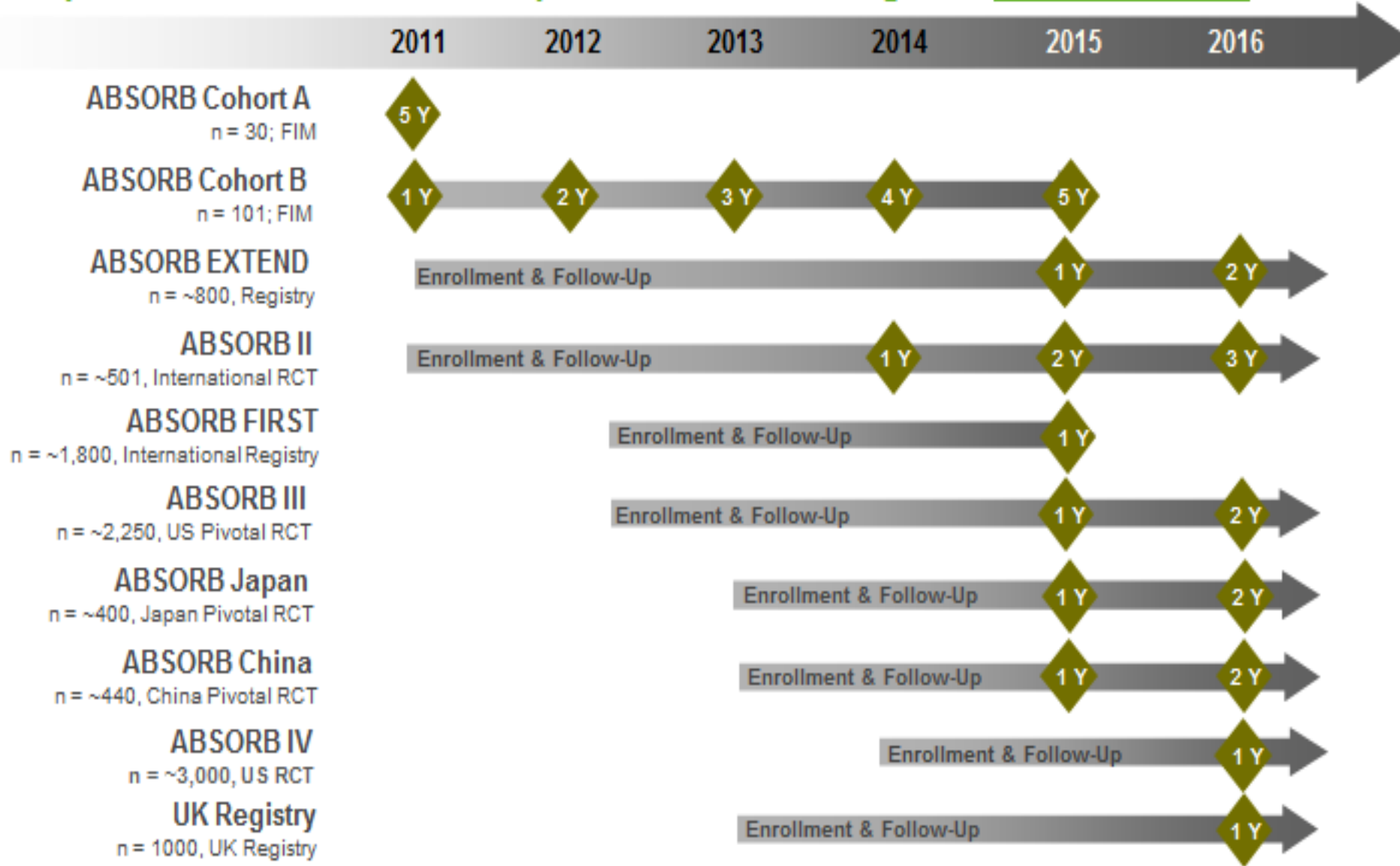
CH CARINES ALLURA FD20 equip:63679889
76,1kV, mAs, 546mA, 6s
Zoom 128%

RAO -10,2°
Cranial 35,0°

RAO -10,3°
Cranial 33,1°

Absorb

Comprehensive Abbott Vascular Sponsored Clinical Program: >10,000 patients



Each trial n reflects total patients. Data effective March 2015

ABSORB Cohorte B

Images OCT à 5 ans

Baseline



6 mois



2 ans



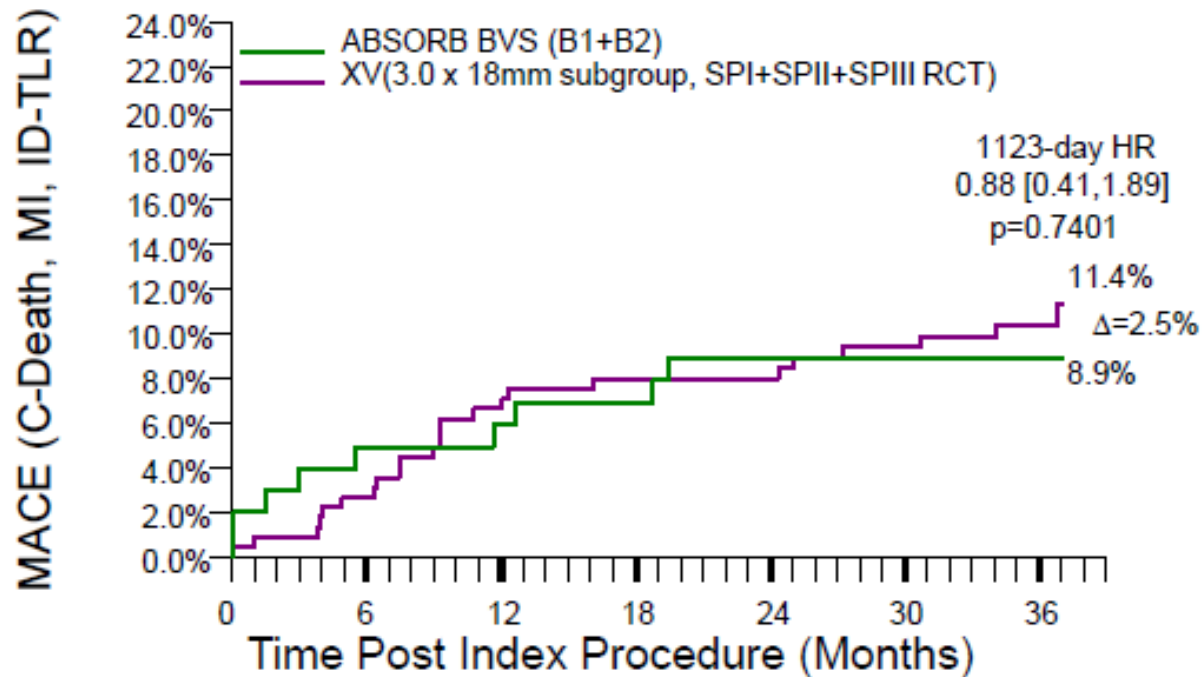
5 ans



De Bruyne, B. TCT 2014

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

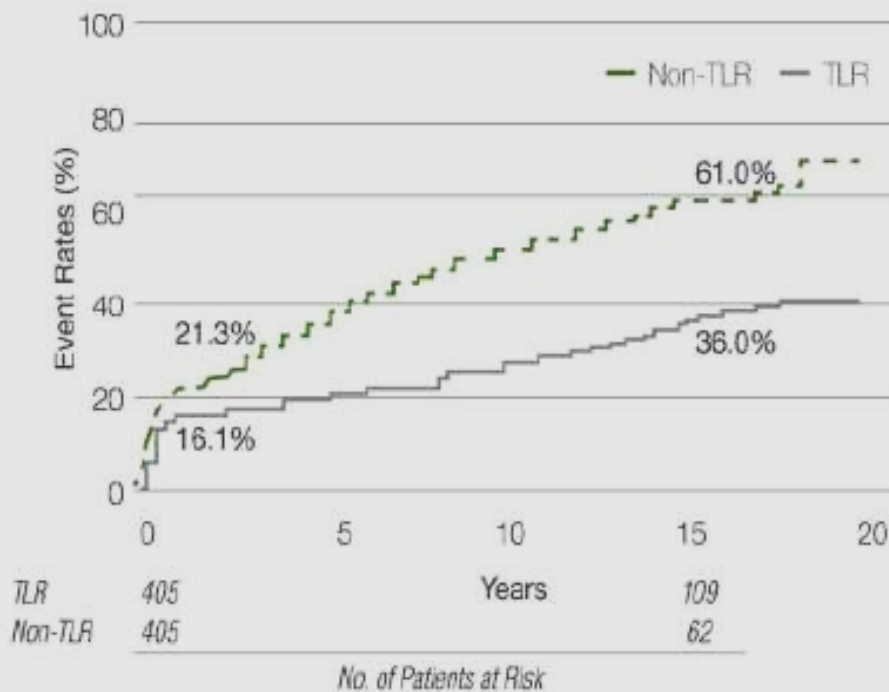
MACE rates in ABSORB cohort B vs XIENCE V (SPIRIT I+II+III Study)



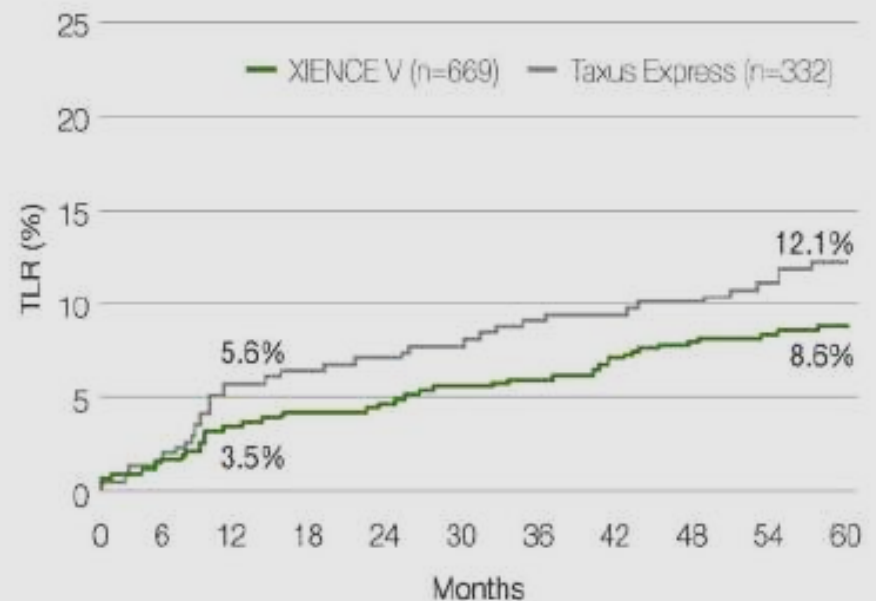
Time After Index Procedure (days)								
	0	37	194	284	393	573	758	1123
ABSORB BVS(B1+B2) At Risk	101	99	96	96	94	92	91	41
XV(3.0 x 18mm subgroup, SPI+SPII+SPIII RCT) At Risk	227	224	219	211	204	202	191	182

Les stents actifs sont source de complications à long terme

Long-term BMS event rate¹



Long-term DES event rate²





ABSORB III Study Design

Prospective, multicenter, single blind, randomized 2:1
Absorb vs. Xience, in ~2000 patients

Clinical Follow-up

30 d

6 mo

12 mo

24 mo

36 mo

48 mo

60 mo

Primary
Endpoint

Target Lesion Failure at 1 year (CD,TV-MI,ID-TLR),
powered for non-inferiority in **2000 clinical follow-up subjects**

Power
Secondary
Endpoints

1.Angina at 1 year **for superiority test of Absorb to Xience**

2.ID-TVR at 1 year **for superiority test**

3.All Revascularization at 1 year **for superiority test**

Treatment

Up to 2 de novo lesions in different epicardial
vessels. No planned overlap; RVD (site)
2.5-3.75mm; LL $\leq$ 24mm

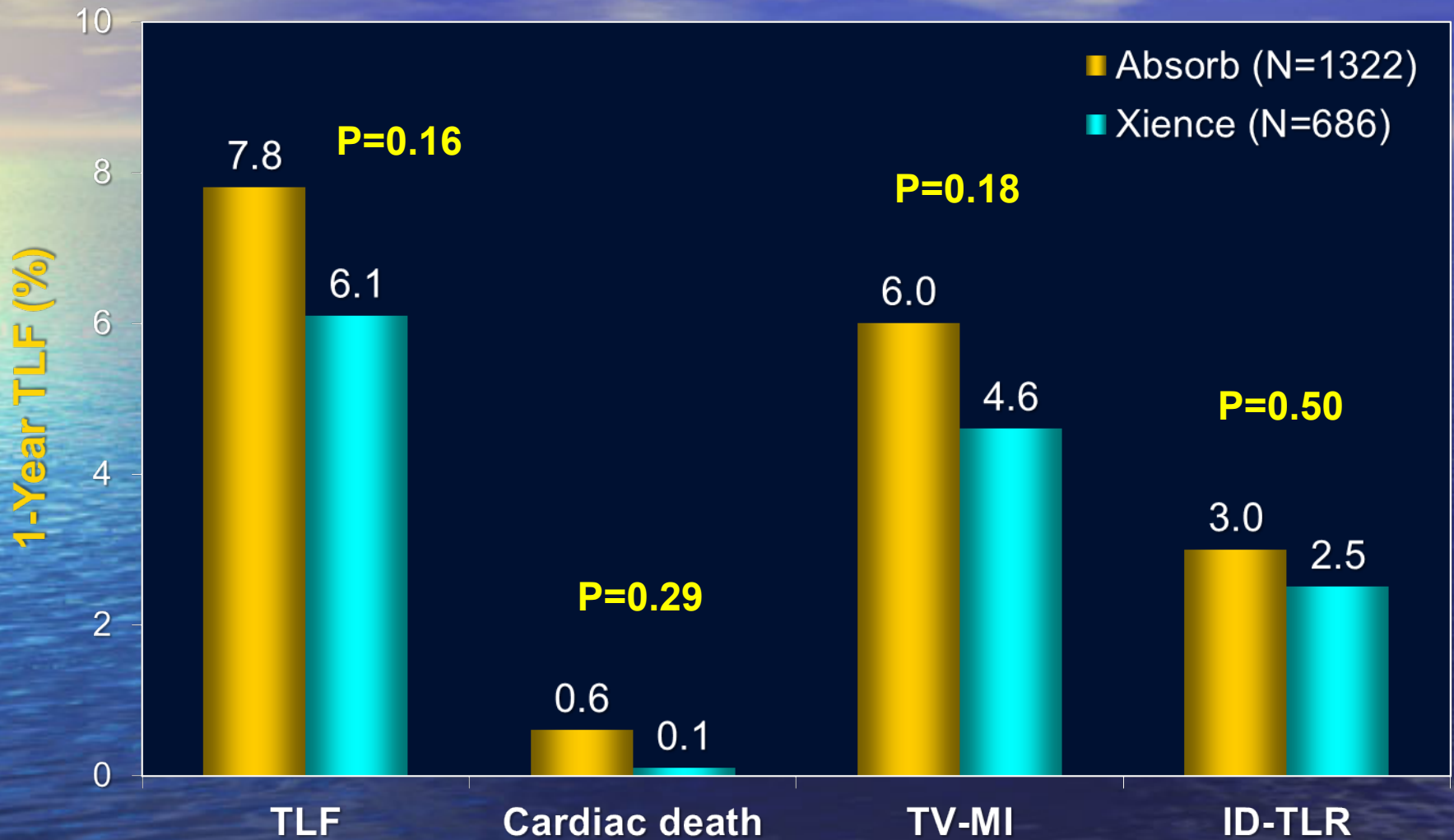


Summary and Conclusions (1)

- ABSORB BVS was non-inferior to Xience CoCr-EES for TLF at 1 year (**primary endpoint met**)
- TLF components (cardiac death, TV-MI, ID-TLR) were not significantly different between devices



1-Year TLF Components





Device Thrombosis to 1 Year

	Absorb (N=132)	Xience (N=686)	p-value
Device Thrombosis (def/ prob)	1.54%	0.74%	0.13
- Early (0 to 30 days)	1.06%	0.73%	0.46
- Late (> 30 to 1 year)	0.46%	0.00%	0.10
- Definite* (1 year)	1.38%	0.74%	0.21
- Probable (1 year)	0.15%	0.00%	0.55

*One “definite ST” in the Absorb arm by ITT
was in a pt that was treated with Xience

THE WALL STREET JOURNAL.

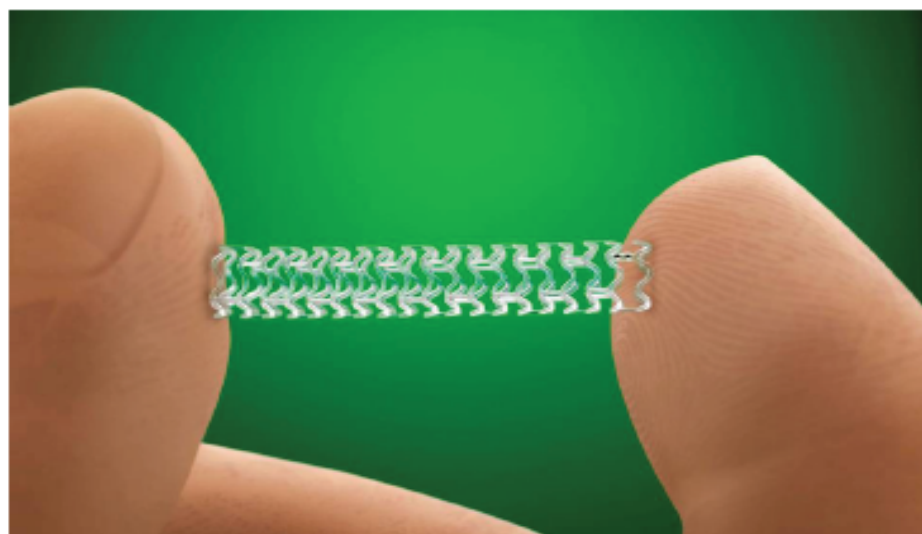
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<http://www.wsj.com/articles/abbott-laboratories-dissolving-stent-shows-mixed-results-in-study-1444678040>

BUSINESS | HEALTH CARE | HEALTH

Abbott's Dissolving Stent Shows Mixed Results in Study

Device, made from biodegradable material, has been closely watched by physicians during its 15-year development



Abbott Labs' experimental heart stent, designed to gradually disappear after restoring blood flow to the heart, performed in a large clinical study about as well as an already marketed stent at preventing deaths, heart attacks and repeat stent procedures. PHOTO: ABBOTT



ABSORB

Acide polylactique (PLA)

- Epaisseur de maille : 150 μm
- Seule l'augmentation de l'épaisseur des mailles permet de compenser la faible force radiale inhérente au matériau utilisé



CONCEPT / REALITE

Thrombose aiguë : durée BIAAP ?
pose complexe

PLA : aucune capacité d'élongation (5%)

Absence de force radiale : lésions calcifiées

PROFIL 1.4 mm : délivrabilité

Remboursement ?

INDICATIONS

- Patients jeunes
- Lésions : courtes
non calcifiées
non bifurquées
non thrombotiques

Run 22 - Frame 4 / 26

, 9700096632, 20/09/1960, M 25 fps

CH CANNES ALLURA FD20 equip:63679869
74kV, mAs, 532mA, 6s
Zoom 128%

Run 30 - Frame 29 / 30

, 9700096632, 20/09/1960, M 25 fps

CH CANNES ALLURA FD20 equip:63679869
73,9kV, mAs, 531mA, 6s
Zoom 128%

Run 25 - Frame 13 / 85

, 9700096632, 20/09/1960, M 25 fps

CH CANNES ALLURA FD20 equip:63679869
73,3kV, mAs, 528mA, 6s
Zoom 128%

Run 35 - Frame 34 / 61

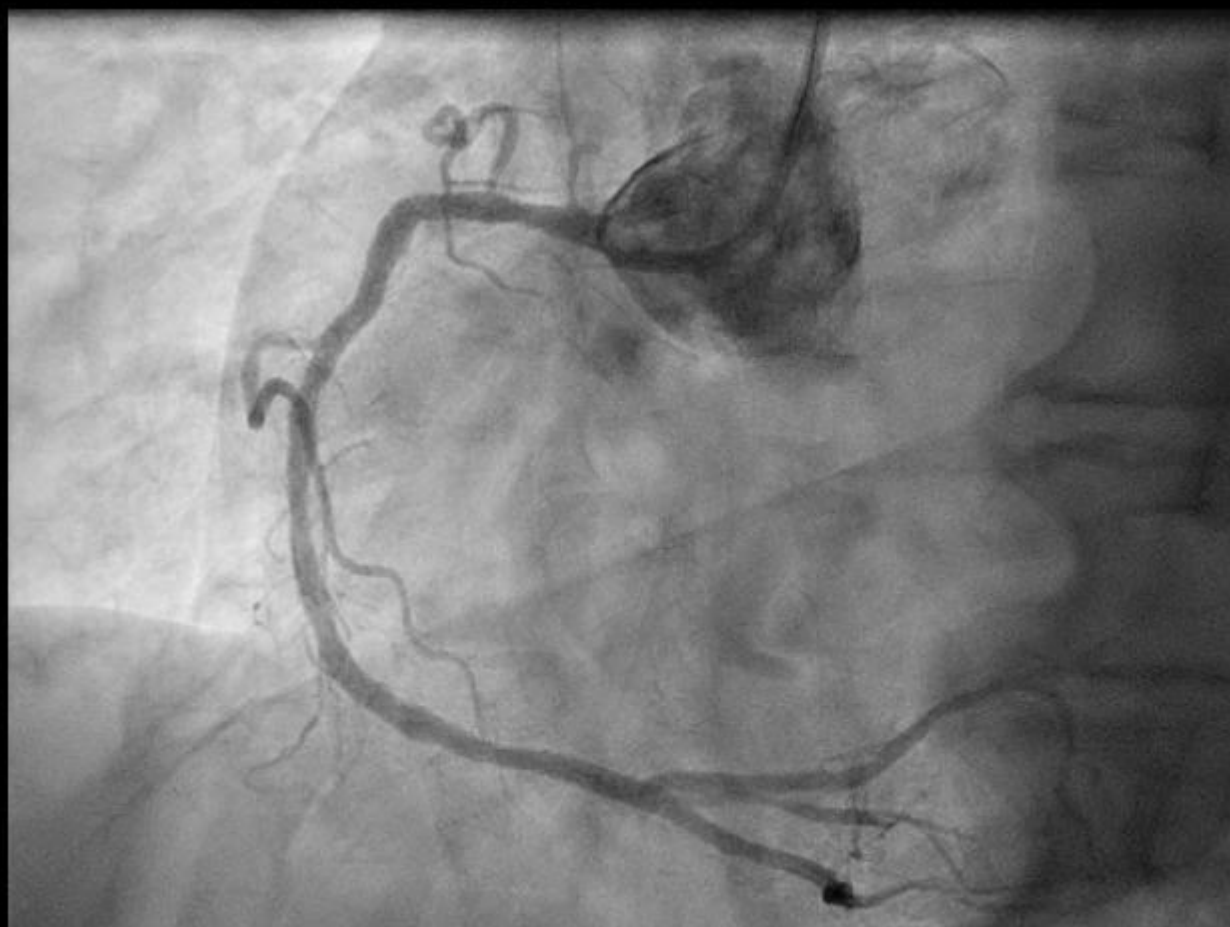
9700096632, 20/09/1960, M 25 fps

CH CANNES ALLURA FD20 equip:63679869
75,8kV, mAs, 531mA, 6s
Zoom 128%

0,4°
1-0,9°

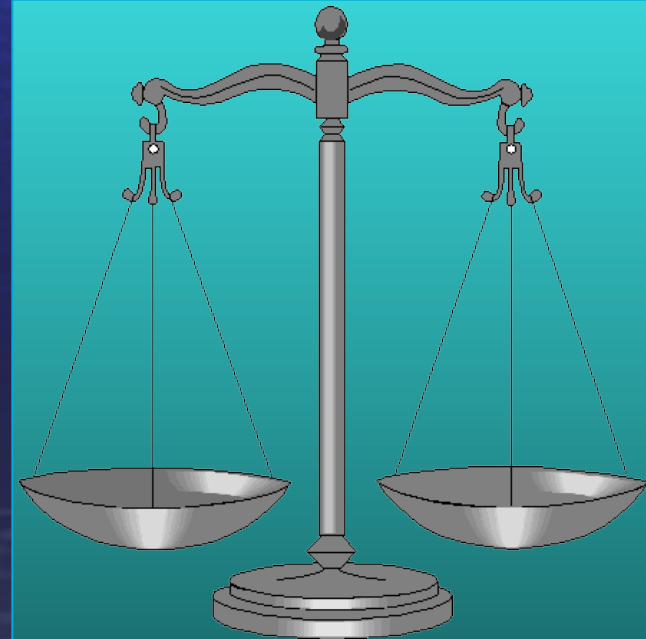
LAO 30,7°
Caudal -0,6°

LAO 29,7°
Caudal -0,6°



Conclusion

- Concept révolutionnaire / **OUI**
- Stent révolutionnaire / **NON**
- Première génération



Basic material	POLY-LACTIC ACID								
Scaffold name	Igaki-Tamai Stent	Absorb BVS 1.0	Absorb BVS 1.1	DESolve 1st generation	DESolve 2nd generation	Amaranth	ART18Z BRS	XInorb BRS	Acute BRS
Manufacturer	Kyoto Medical Planning Co, Ltd, Kyoto, Japan	Abbott Vascular, Santa Monica, CA, USA	Abbott Vascular, Santa Monica, CA, USA	Elixir Medical Corp., Sunnyvale, CA, USA	Elixir Medical Corp., Sunnyvale, CA, USA	Amaranth Medical Inc., CA, USA	Arterial Remodeling Tech., France	Shandong HuaAn Biotech., Co. Ltd., China	OrbusNeich, Fort Lauderdale FL, USA
Composition	PLLA	PLLA	PLLA	PLLA	PLLA	PLLA	PLLA, PDLA	Poly-lactic add, poly ϵ -caprolactone, poly-glycolic add	PLLA, L-latic-co- ϵ -caprolactone, PDLA
Design of the latest generation	Zigzag helical coil	Out-of-phase sinusoidal hoops with links	In-phase zigzag hoops, cross-linked by bridges	Tubularly arranged hoops, linked by bridges	Tubularly arranged hoops, linked by bridges	Zigzag hoops, linked by bridges	Creep-resistant hinge	–	Helically linked double ring
Thickness of strut, μ m	170	150	150	150	150	–	--	150–170	150
Visualization	Gold radio-paque markers at both ends	Radiopaque metal markers at both ends	Radiopaque metal markers at both ends	2 platinum radiopaque markers	2 platinum radiopaque markers	–	--	2 radiopaque markers	Radiopaque markers
Special feature	Self-expandable when heated	--	--	Minor malapposition is self-corrected	Minor malapposition is self-corrected	Consists of multiple layers	--	Radial strength is comparable to that of DES	Dual elution
Anti-proliferative drug elution	No	Everolimus	Everolimus	Myolimus	Novolimus	No	No	Sirolimus	Abulimal side: sirolimus Luminal: CD34+ antibodies
Resorption time	3 yrs	Up to 3 yrs	Up to 3 yrs	1 yr	1 yr	1–2 yrs	1.5–2 yrs	–	--
Status	CE mark (for peripheral use)	CE mark (for coronary use); randomized-controlled trial BVS vs. DES) is currently enrolling patients		CE mark (for coronary use)		Clinical evaluation, new version under dev.	Clinical evaluation	30 patients enrolled in FIM study	Pre-clinical evaluation
Trials (no. in cohort and duration)	Igaki-Tamai-FIM 50 patients 127 $\pm$ 17 mos	Cohort A 30 patients 5 yrs	Cohort B 101 patients 24 mos ABSORB Extend 250 patients 24 mos	DESolve FIM 15 patients 12 mos	DESolve Nx Study 126 patients 12 mos	Amaranth FIM 13 patients 6 mos	Pre-clinical results ARTDIVA FIM -- --	Pre-clinical results	--

Basic material	MAGNESIUM			OTHER		
Scaffold name	AMS	DREAMS 1.0	DREAMS 2.0	REVA BRS	REVA ReZolve	Ideal BioStent
Manufacturer	Biotronik, Berlin, Germany	Biotronik, Berlin, Germany	Biotronik, Berlin, Germany	Reva Medical Inc., San Diego, CA, USA	Reva Medical Inc., San Diego, CA, USA	Xenogenics Corp., Canton, MA, USA
Composition	Magnesium and rare earth metals	Magnesium and rare earth metals	Magnesium and rare earth metals	Desaminotyrosine polycarbonate	Desaminotyrosine polycarbonate	Poly-lactic anhydride containing 2 salicylic acid molecules linked to 1 sebacic acid molecule
Design of the latest generation	4-crown design	6-crown design	6-crown design	Slide-and-lock ("ratchet")	Slide-and-lock ("ratchet")	Tube with laser-cut voids
Thickness of strut, µm	165	120	150	204	122	200
Visualization	Latest generation with radiopaque markers			Fully radiopaque	Fully radiopaque	--
Special feature	Electronegative charge that emerges during degradation process has an antithrombotic function			--	--	Polymer causes less inflammation
Anti-proliferative drug elution	No	Paclitaxel	Sirolimus	Paclitaxel	Sirolimus	Sirolimus
Resorption time	2 mos	9-12 mos	--	2-3 yrs	2-3 yrs	15 mos
Status	Clinical evaluation	Clinical evaluation	Clinical evaluation	Clinical evaluation; CE trial ongoing	Clinical evaluation; CE trial ongoing	Clinical evaluation, pre-clinical evaluation of the thinner 2nd generation
Trials (no. in cohort and duration)	PROGRESS AMS 63 patients up to 28 mos	BIOSOLVE-I 46 patients up to 3 yrs	BIOSOLVE-II -- --	FIM -- 15 mos	RESTORE 26 patients 12 mos	FIM 11 patients 1.5 yrs

A wide-angle photograph of a calm ocean under a vast, blue sky. The sun is low on the horizon to the left, creating a bright, hazy glow and a faint rainbow arching across the water. The water's surface is covered in gentle ripples, reflecting the light from the sky. The overall mood is peaceful and expansive.

QUESTIONS ?

Figure 5. The bioabsorbable therapeutics stent has absorbable backbone and coating polymers constructed from repeating salicylate molecules joined by linker molecules.

