STENTYS
STENT AUTOEXPANSIF

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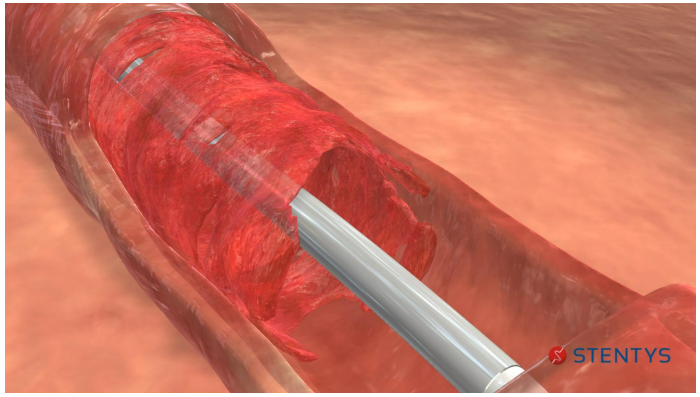
APPAC, BIARRITZ JUIN 2013

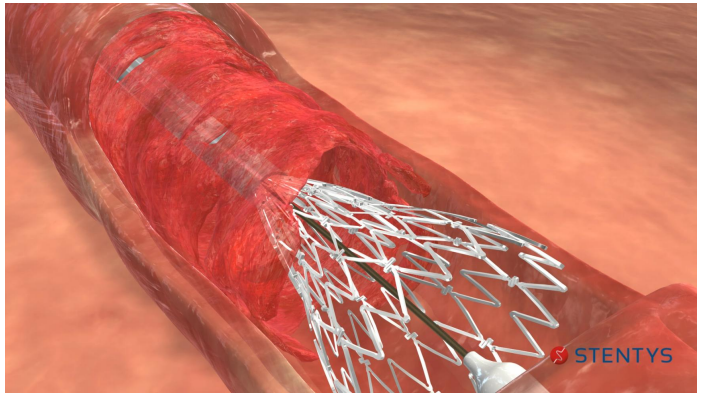
AUTO EXPANSIF = IL TRAVAILLE ‘SEUL’ !?

AUTO EXPANSIF ? = IL TRAVAILLE ‘SEUL’!

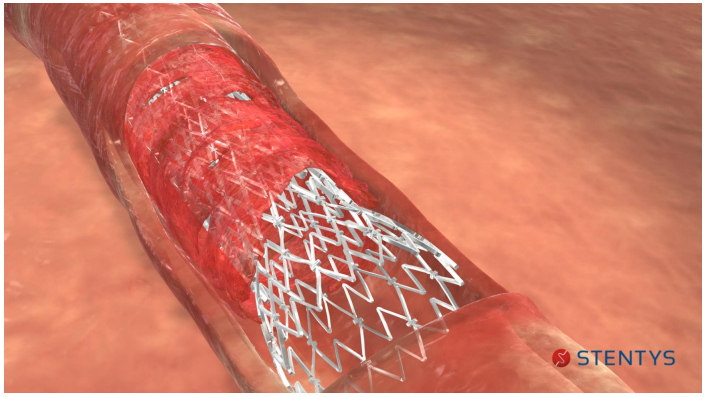
Deploying a STENTYS self-apposing stent



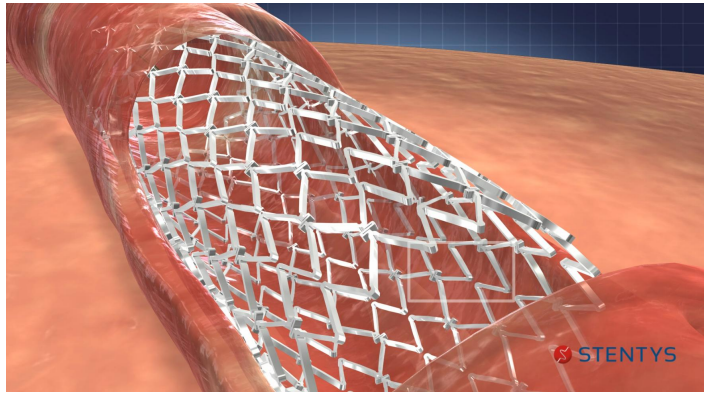
1. Position the STENTYS® stent over the lesion



2. Retract the outer sheath to deploy the stent from distal to proximal

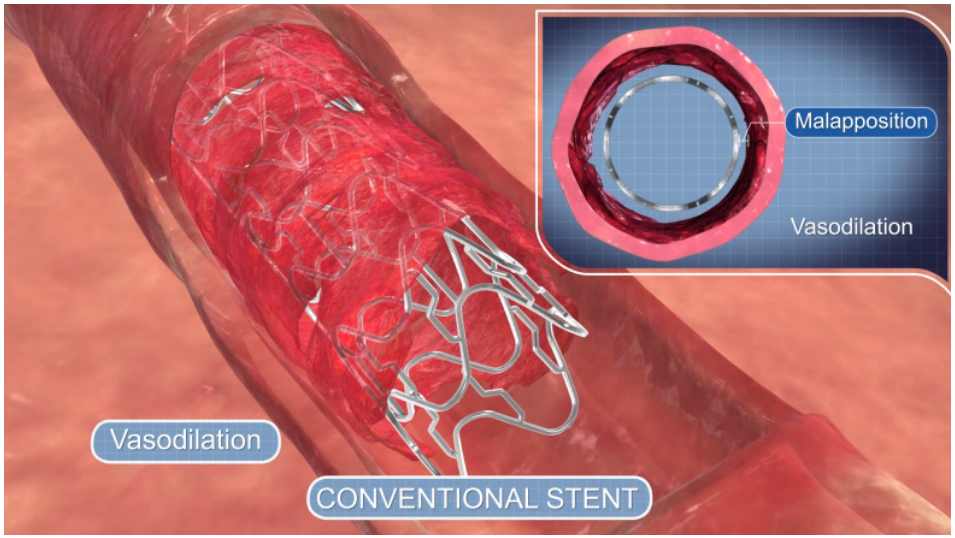


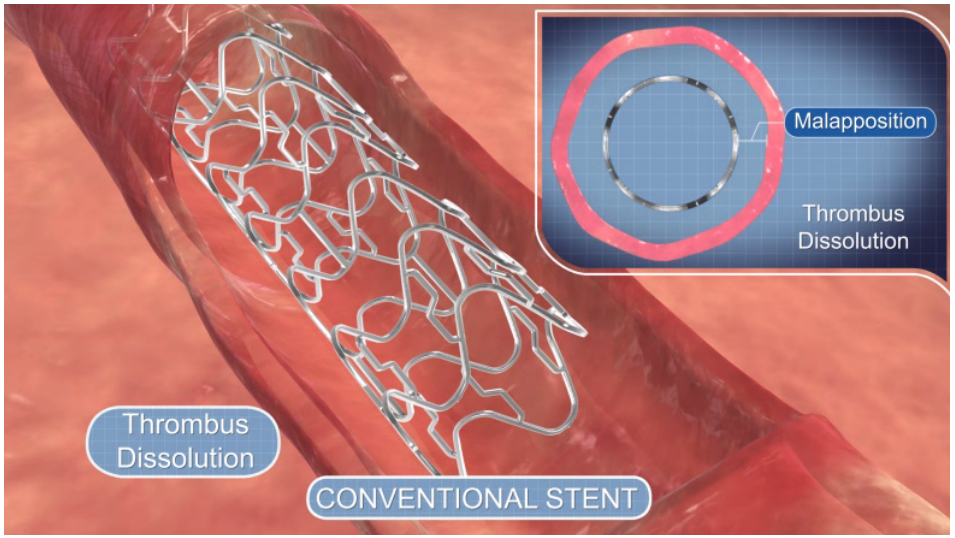
3. The stent is fully deployed in the vessel of the AMI patient with good apposition. Low pressure post-dilation is required



4. The STENTYS® stent expands with the vessel during vasodilation and as thrombus resolves ensuring perfect apposition

The Problem in ACS…

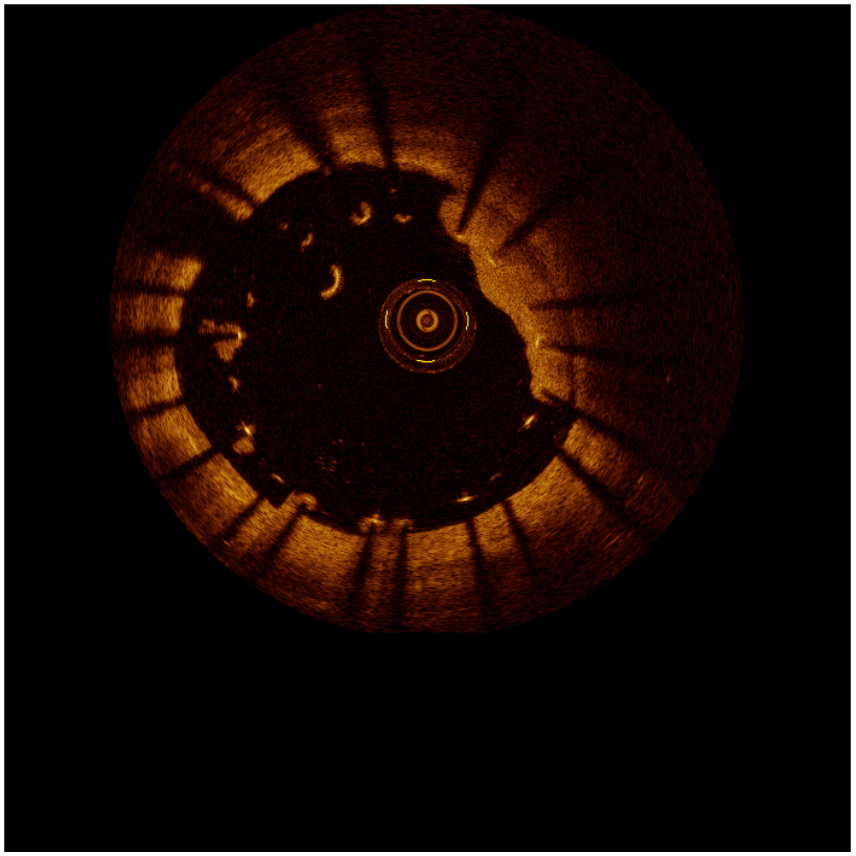


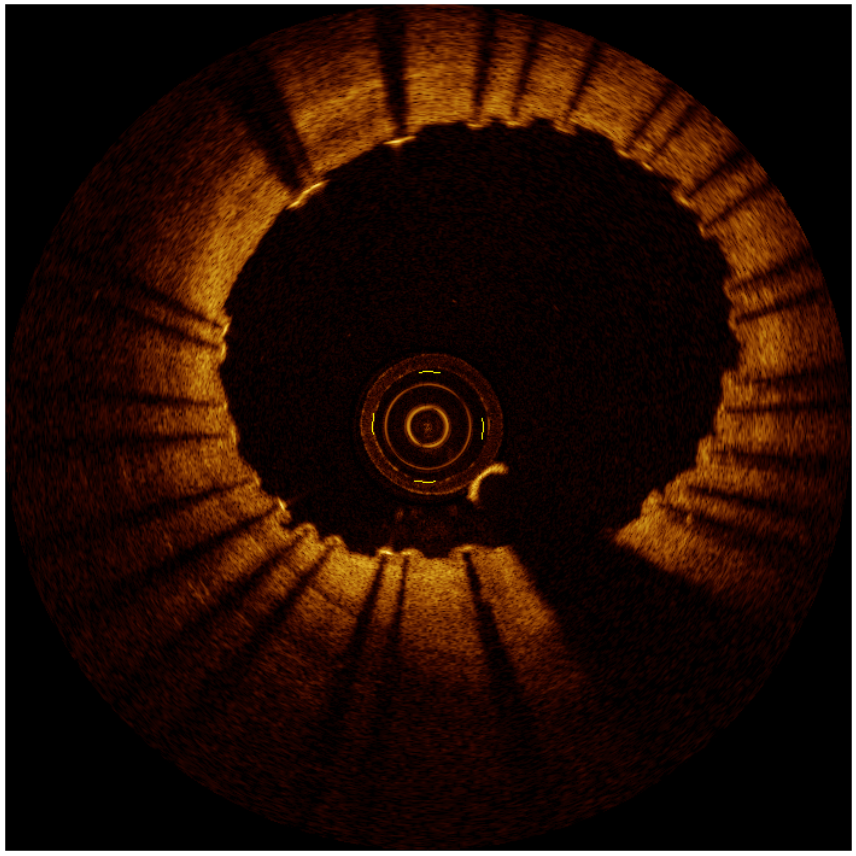


- BMS **malapposition** in AMI 35.2% post-procedure and 23.9% at 13 month follow-up[1]
- DES in STEMI → higher rates of **malapposition** on follow-up than in unstable or stable patients[2]
- **No-reflow** in >20% AMI patients → increased mortality[3]

1. Bare arm, Horizons-AMI IVUS sub-study, ACC 2009
2. B.Gonzalo, JACC: Cardiovascular Interventions Vol 2, Issue 5, May 2009, Pages 445-452
3. R. Jaffe, "Microvascular Obstruction and the No-Reflow Phenomenon After PCI" Circulation 2008:117;3152-3156

LE BON CONCEPT DANS L'INFARCTUS SCA ST PLUS?





ESC STEMI Guidelines 2012

"Operators performing primary PCIs in STEMI should be aware of the **importance of selecting an appropriate stent size**. Most patients with STEMI have some degree of **coronary spasm** and, thus, intracoronary administration of nitrates is recommended before starting the coronary angiographic sequence used for stent size selection. The **presence of thrombus** can also lead to **stent under-sizing** (or otherwise suboptimal deployment), which is a frequent **cause of re-stenosis or stent thrombosis** in real-life practice."

ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation, European Heart Journal 2012

Grosses variations de calibre

Résistance à la compression pour STENTYS Medium size (Ø3.0-3.5mm)

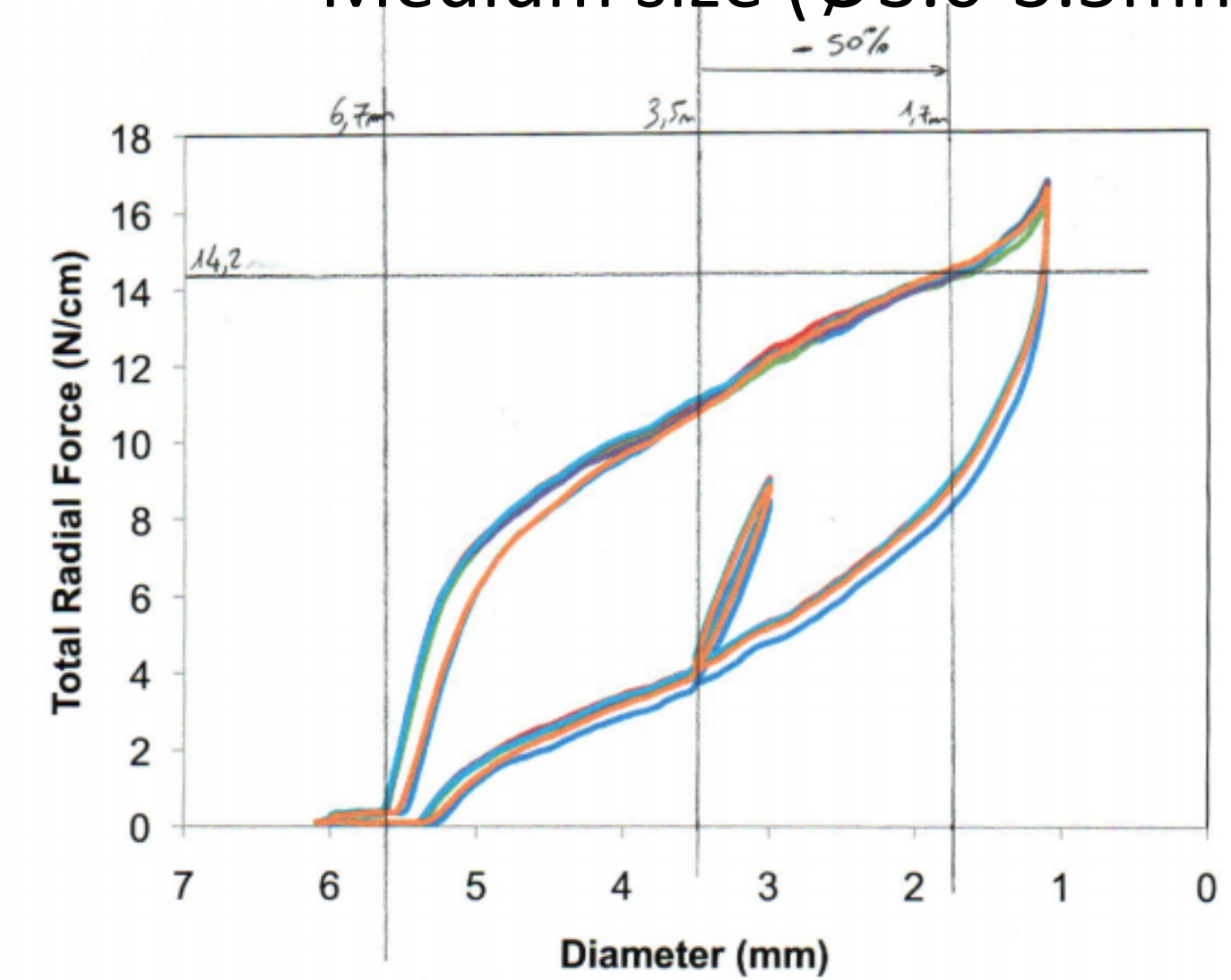


Figure 7: Total radial force vs. diameter curves for the six SX-6-009, Lot 247689 devices crimped at 37°C. Refer to Table IX for summary of the stent values.

STENTYS STEMI Clinical Program

APPOSITION (STEMI)

		Patients
I	**Feasibility trial**: Single Arm – STENTYS BMS → 3 day and 6 month QCA and IVUS	25
II	**Randomized trial**: STENTYS BMS vs VISION/Driver → 3 day QCA and OCT, 6 month clinical	80
III	**"Real life" study**: Single arm – STENTYS BMS & DES(P) → 30 day and 12, 24 month MACE	1000
IV	**Randomized trial**: STENTYS Sirolimus DES(S) vs Resolute → 4 and 9 month OCT – enrollment complete	150
V	**Randomized trial (US IDE)**: STENTYS BMS vs Multilink – enrollment in progress → 12 month TVF, IVUS/OCT sub-study	880

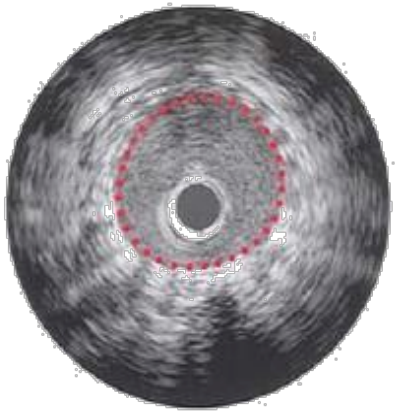
APPOSITION I

- 5 centres 2009, n=25
- Stentys Nu, ST+

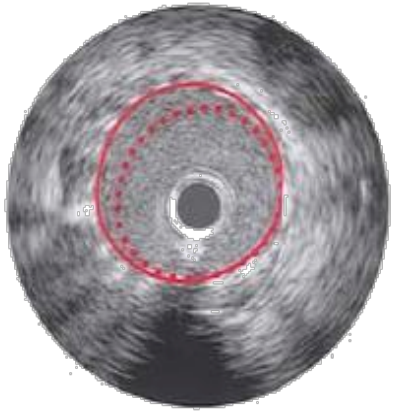
IVUS J0 J3 M6 ->apposition expansion J3

Mld J3 : +19%

- Clinique J 30
- Angio M6



Post-PCI IVUS image of a STENTYS stent in AMI patient



IVUS image 3 days after procedure in this patient: 19% increase in reference lumen area

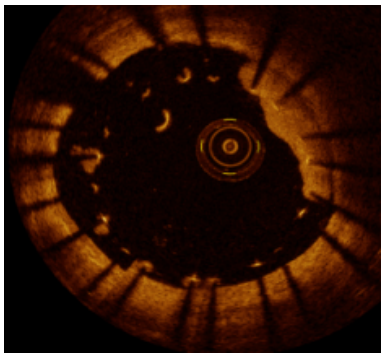
APPOSITION II

- 9 centres 2010, n=80
- Randomise Nu Stentys vs Expandable au ballon ST+

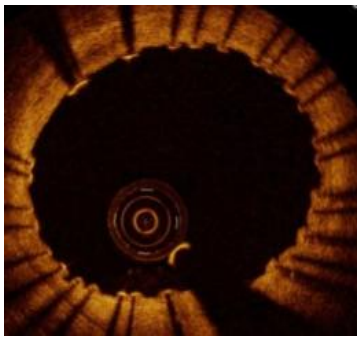
OCT Angio J3, ->apposition de maille OCT J3

Stentys : 0 malapposition

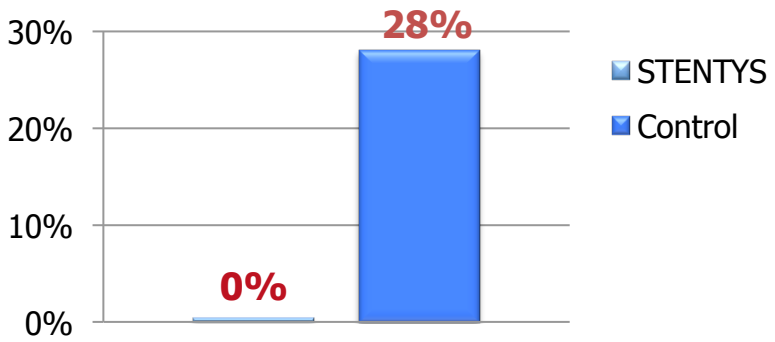
- Clinique J 30, M6



Balloon-expandable Stent - Day 3



STENTYS® Stent – Day 3



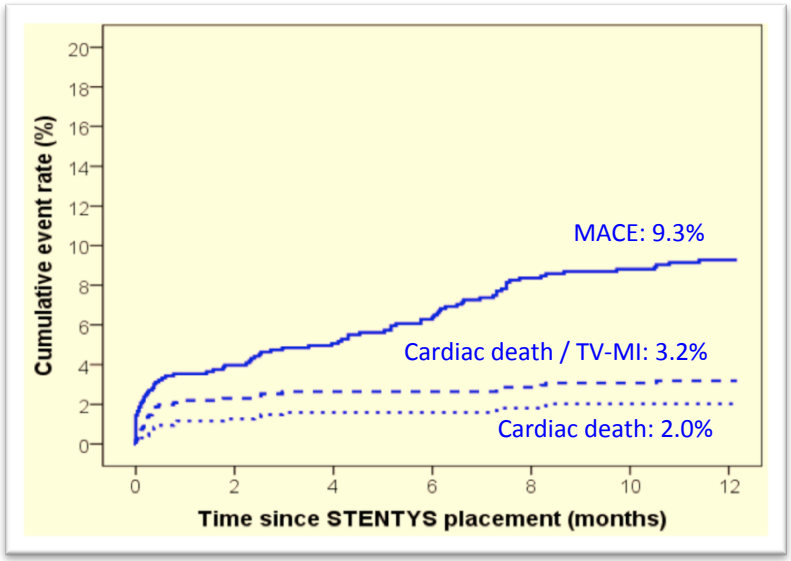
Patients avec malappositions

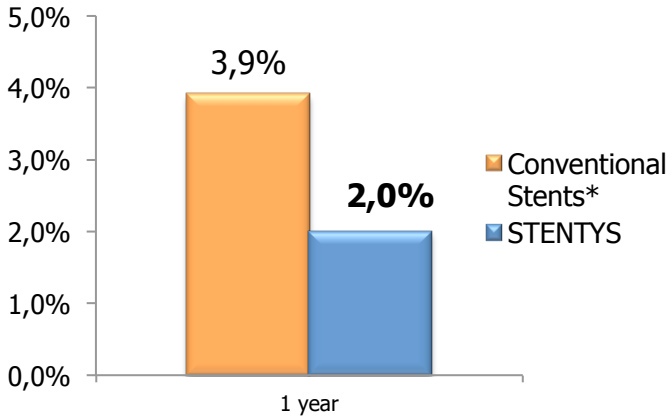
APPOSITION III

- 50 centres Europeens 2010-2012, n=1000
- Prospective non randomisee Stentys Nu en routine ST+

MACE M1 M12 M24

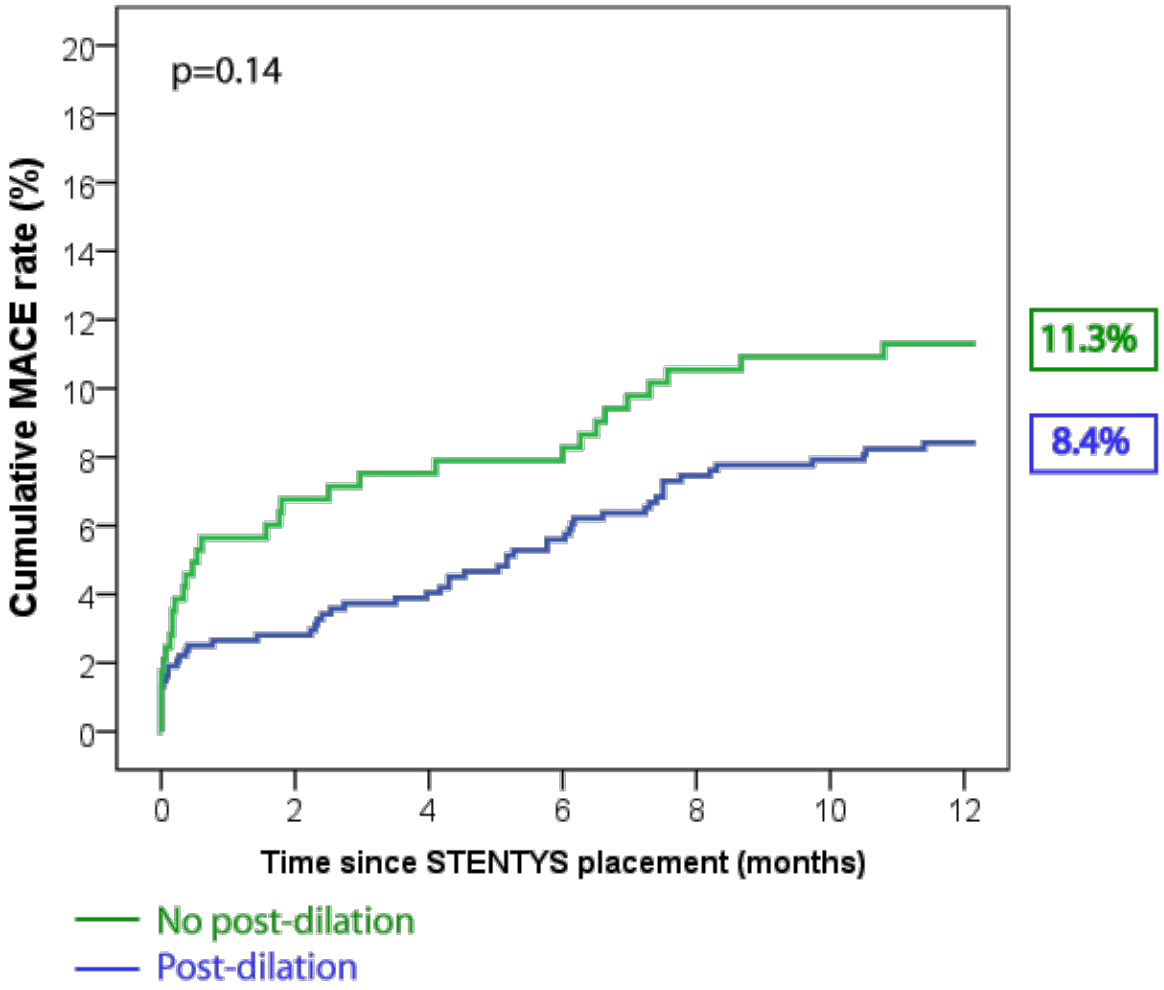
Deces Cardiaques 1 an : 2%



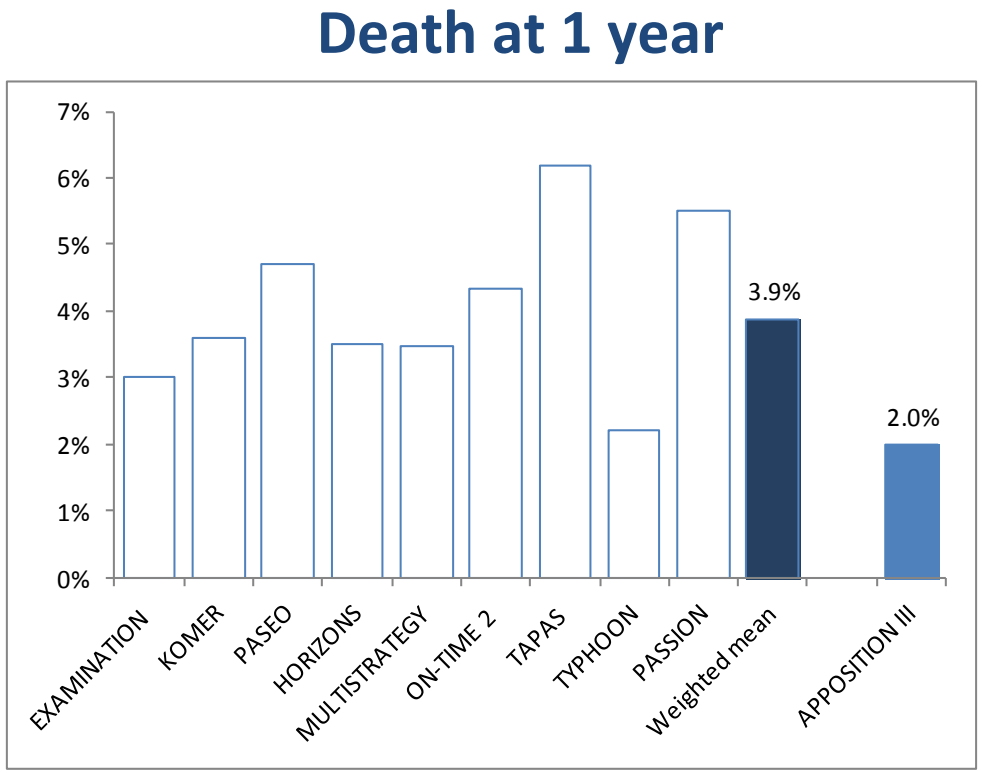


** Pooled analysis on 15 studies conducted by the ACTION Study group (Prof. G. Montalescot) representing 19,767 patients since 2006*

APPOSITION III : MACE according to post-dilation



Comparative Studies



Pooled analysis conducted by the ACTION Study Group (La Pitié-Salpêtrière Hospital, Paris)
on the most recent studies representing 19,767 patients since 2006

Some studies report all death, others cardiac death. APPOSITION III reports cardiac death.

APPOSITION IV

- STEMI, n=150
- Prospective randomisee Actifs Stenty vs largable au ballon ST+
- OCT QCA M4 M9

Endothelialisation de mailles compares M4 M9

Malappositions tardives a 9 mois

MACE M12

APPOSITION V

- Prospective Randomisee, STEMI, n=880
- Non inferiorite du Stentys Nu vs Abbot Multilink Vision

TVF M12

Apposition aigue

Ss groupe IVUS OCT, n=120

TOUJOURS POST-DILATER?

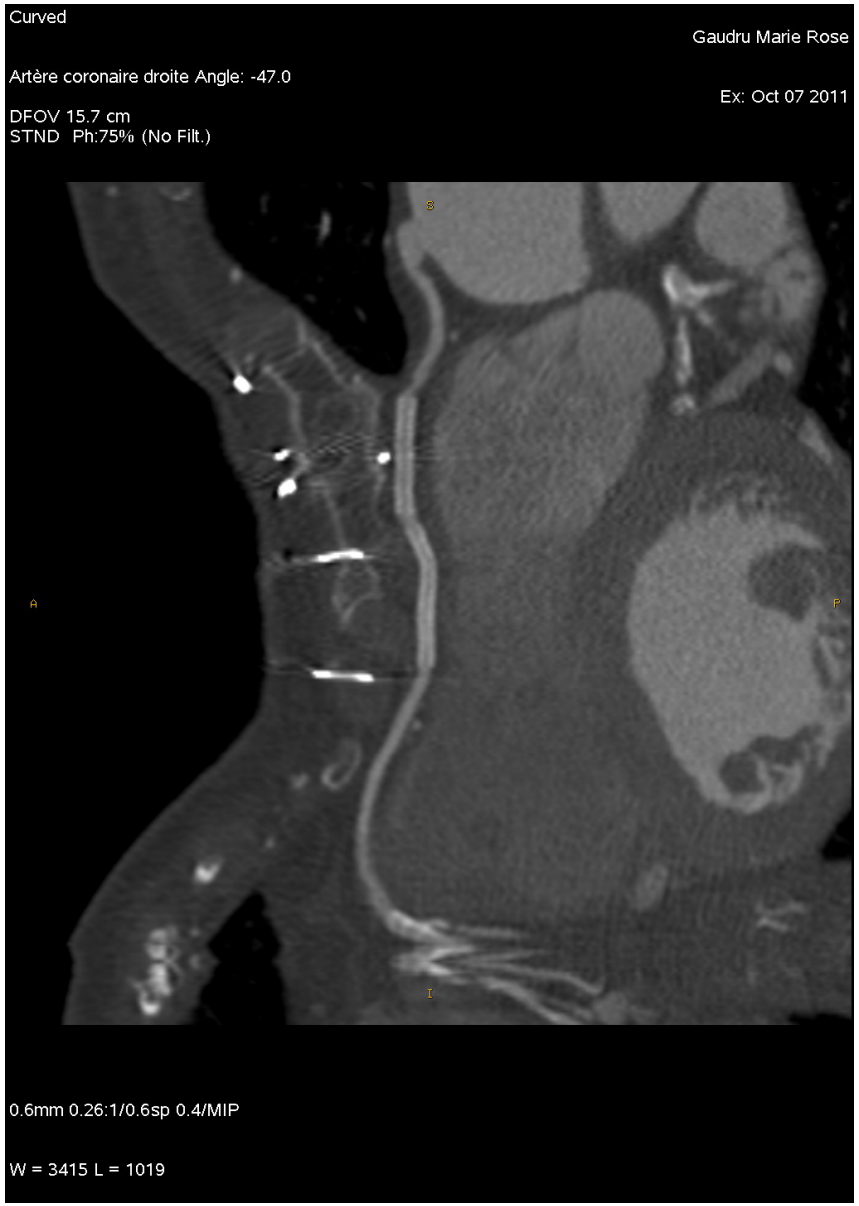
- Force developpee par le stent

- Force necessaire a lever une stenose
  - Resistante
  - Sans resistance particuliere

LE DILEMNE

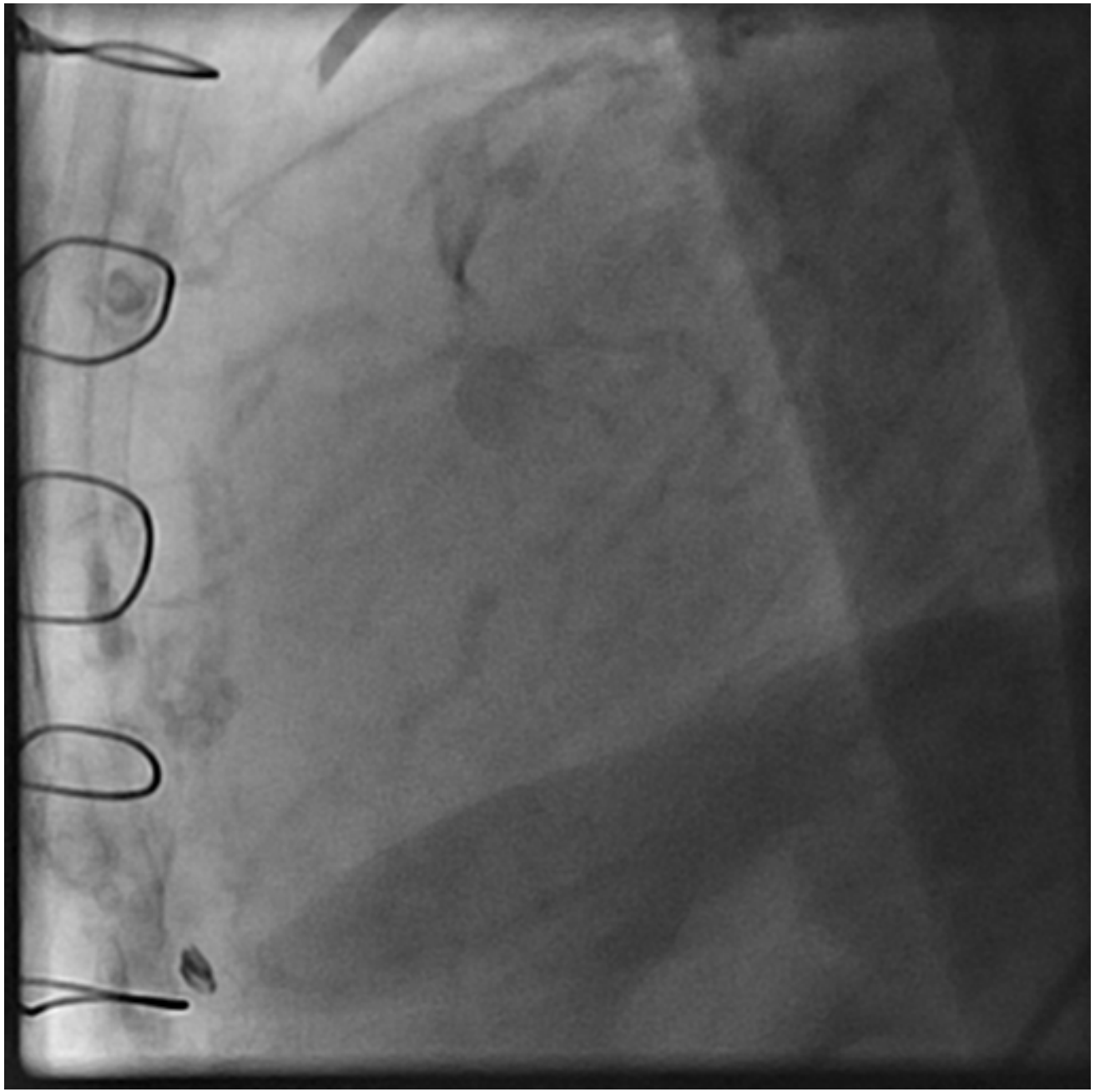
- Anevrysmes
- Discongruences
- Compresion externe
- …..

Traitement d'une compression externe



UNITE-SOINS DE CARDIOLOGIE INTERVENTIONNELLE

GACI



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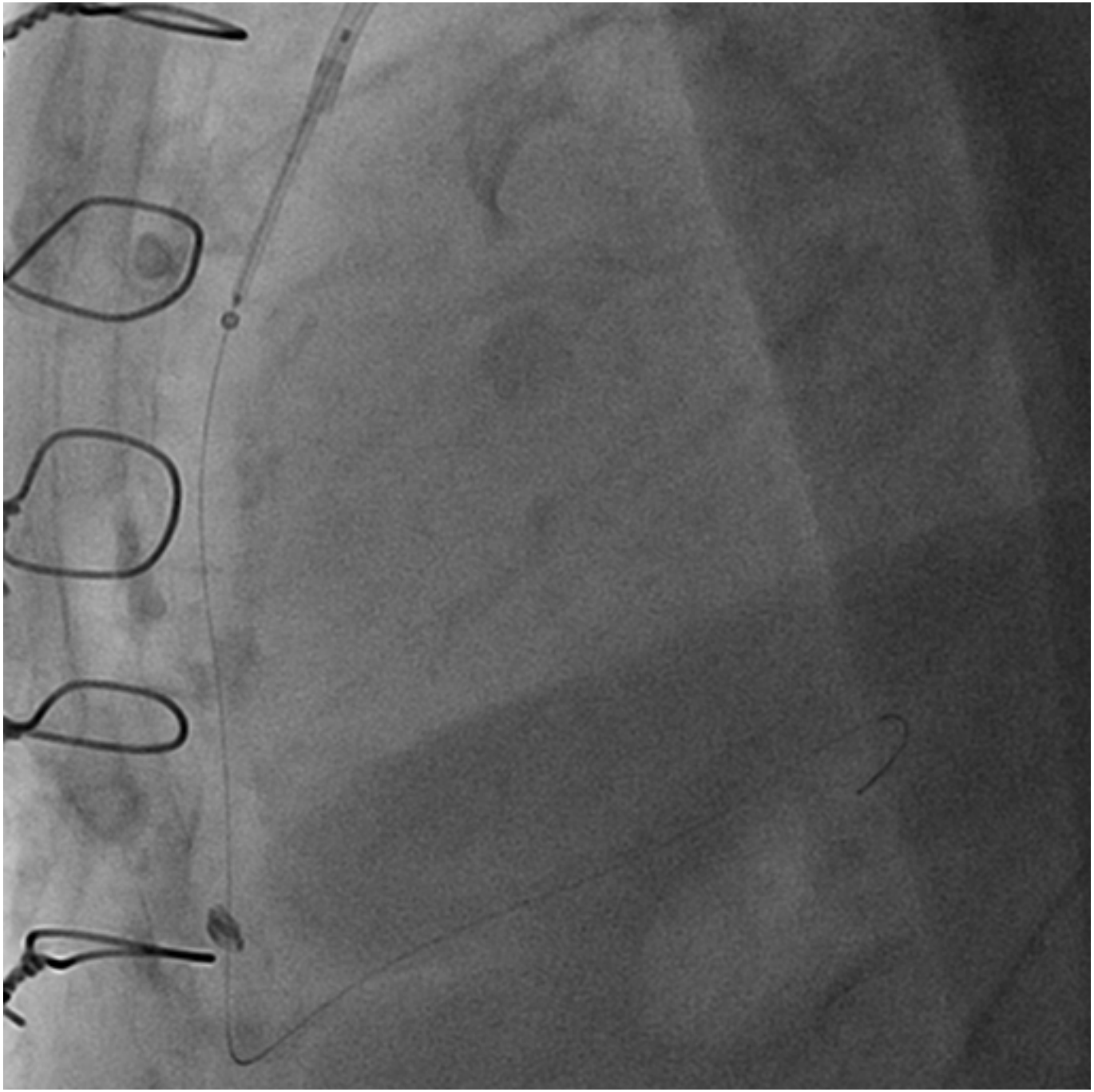

UNITE-SOINS
CARDIOLOGIE
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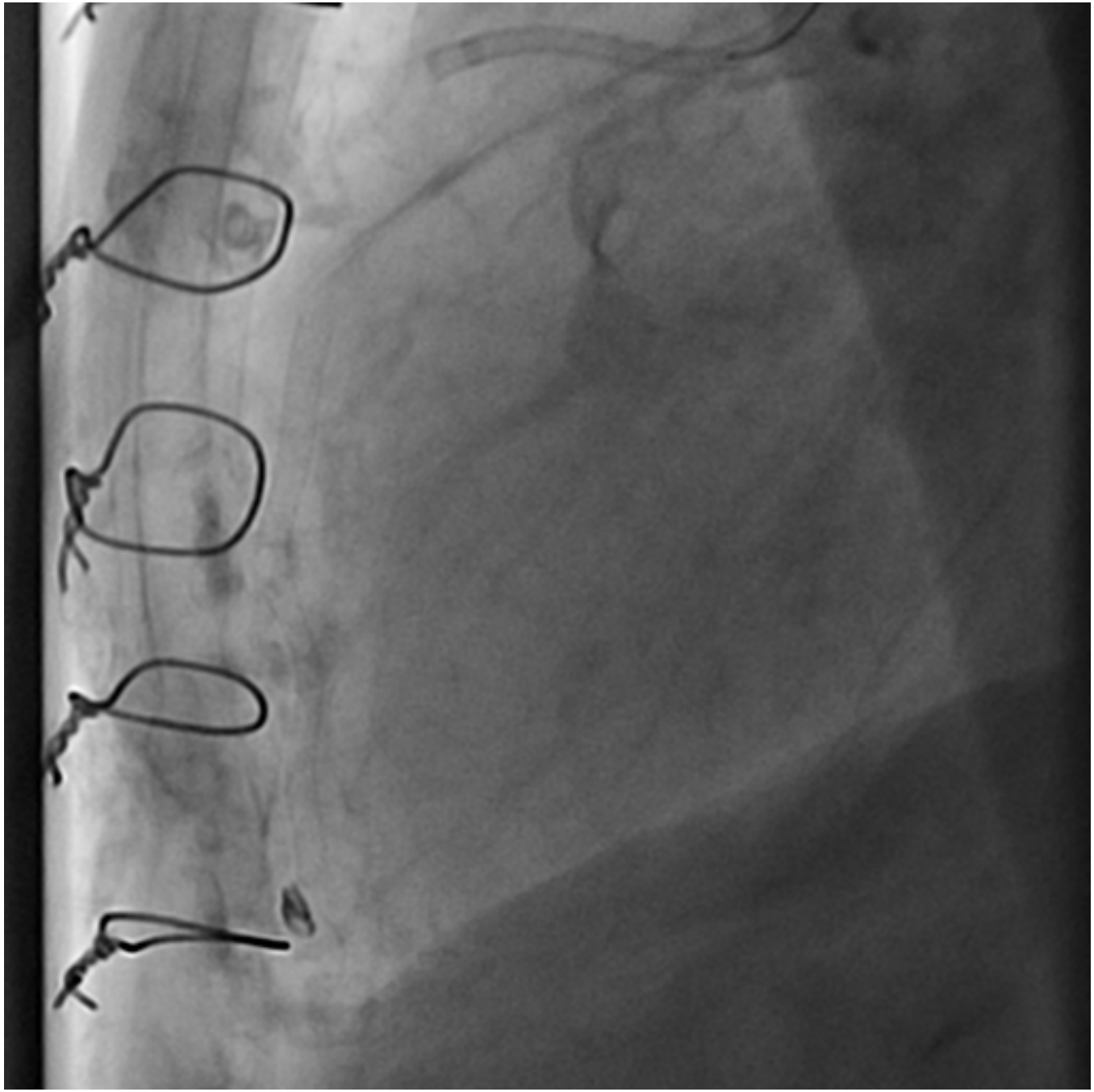
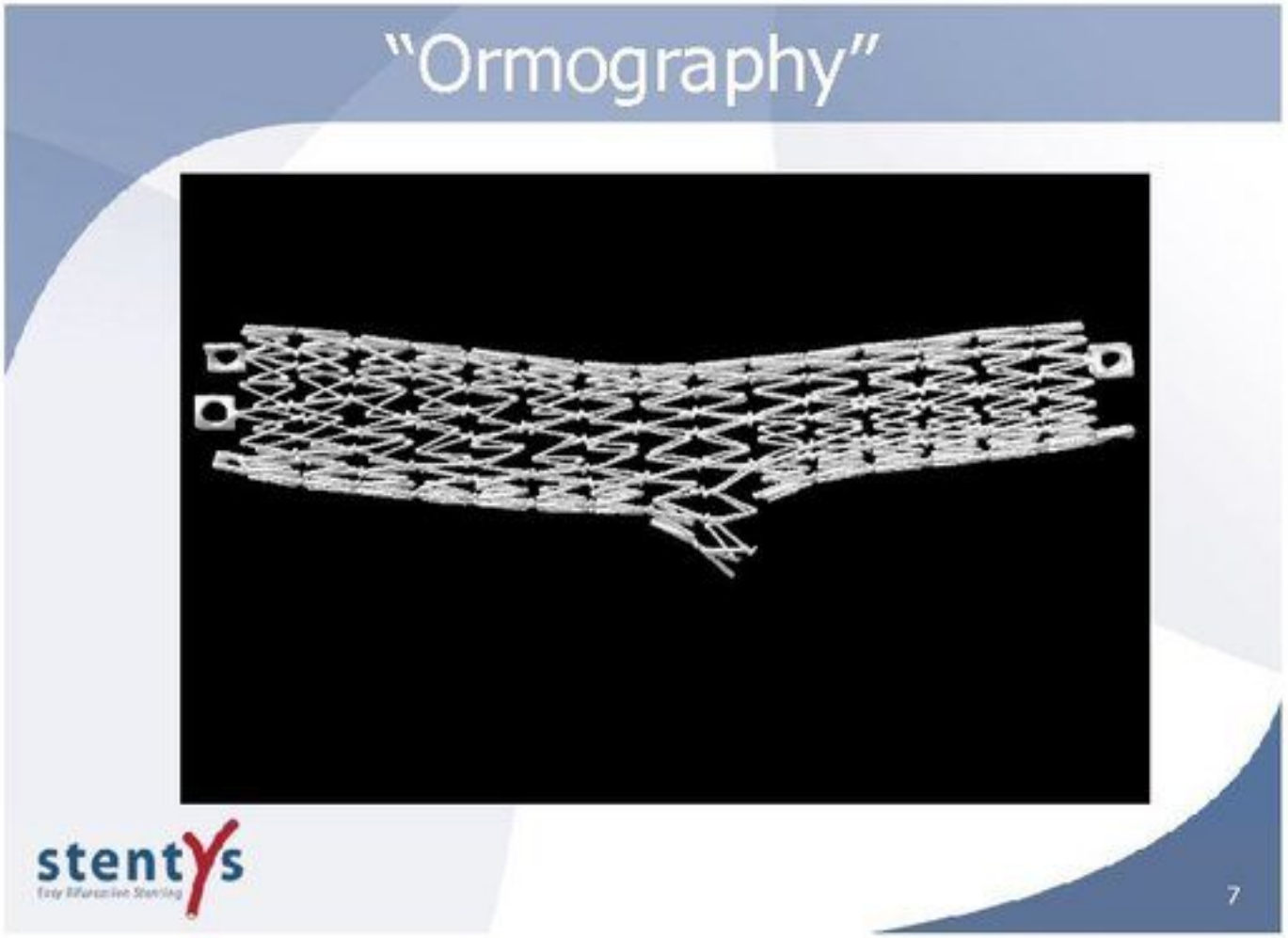


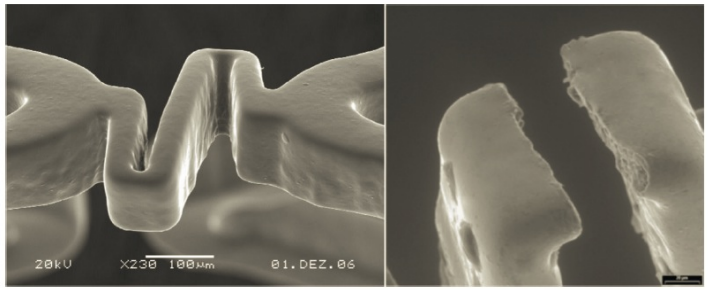
ET LES BIFURCATIONS OU LES BRANCHES

- 

LES CONNECTEURS NE SONT PAS PORTEURS DE CHARGE

The STENTYS® Self-Apposing Stent in bifurcation lesions **Eurointervention 2010 Dec,**

Verheye2*, MD, PhD, FESC *Antwerp, Belgium*



Conclusion : this stent is desirable because its design is simple enough not to compromise the patient' s safety and yet, at the same time, it can be **easily adapted to treat the bifurcation** and the side branch **should the need arise**

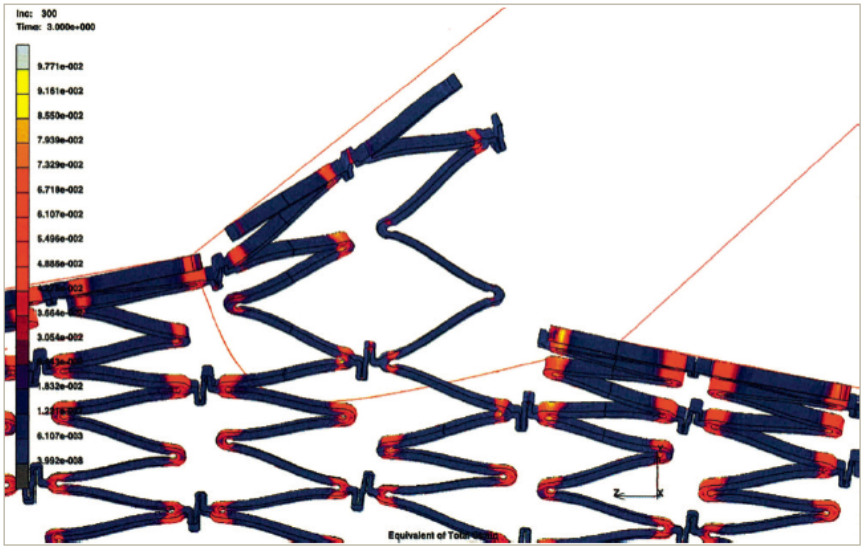


Figure 5. Finite element analysis (FEA) image in a bifurcation model demonstrating that the disconnectors are not load-bearing elements and thus a disconnection does not affect the radial force of the stent.

Y-A-T-IL VRAIMENT UNE BONNE ALTERNATIVE?

- Reprendre le stent ‘conventionel’, patient, pour une reapposition ulterieure?
- Ouverture d’artere en urgence, de ‘petit calibre’ et mise en place differee d’un stent?
- Aspiration seule?
- Stent resorbable?

Deferred stent implantation in patients with ST-segment elevation myocardial infarction: a pilot study

Henning Kelbæk et al, *Copenhagen, Denmark*

Eurointervention 2013

Table 2. Angiographic findings.

	Index		Day 3		3 months
	Pre	Post	Pre	Post	
	n=113		n=110		n=13
Diameter stenosis, %	95 (10.2)	58 (20.9)	49 (21.6)	16 (22.6)	28 (17.0)
Thrombus score, Δ-value	4.4	2.5	1.4	–	0
TIMI flow 3, % of patients	42	100	100	100	100

Mean values (SD); TIMI: Thrombolysis In Myocardial Infarction

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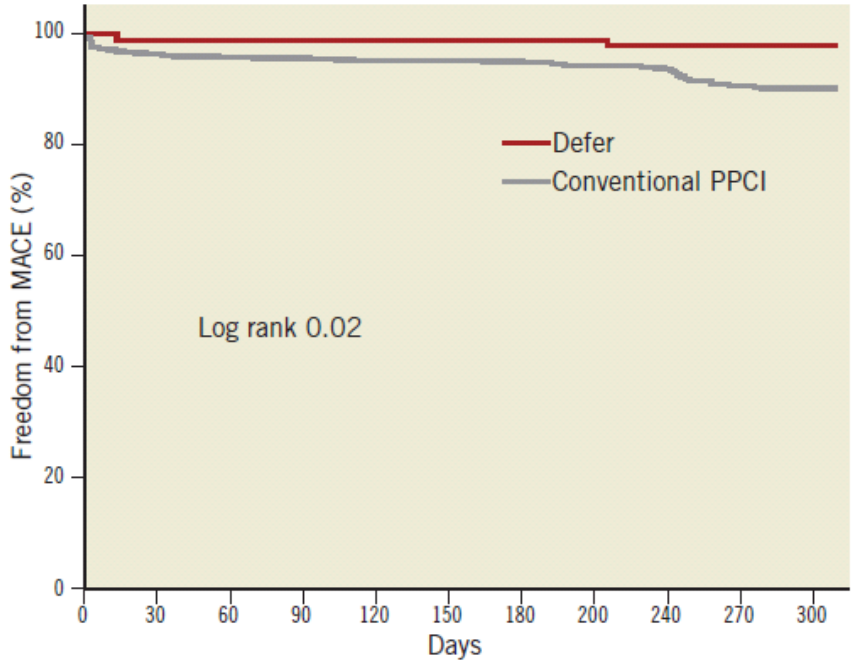

Figure 4. *Kaplan-Meier estimates of MACE-free survival of patients treated with conventional primary PCI in a previous trial (grey line)[6], and patients treated with deferred stent implantation in the present study (red line).*

Safety of lone thrombus aspiration without concomitant coronary stenting in selected patients with acute myocardial infarction

Javier Escaned*, MD, PhD; Carlos Macaya, MD, PhD
Cardiovascular Institute, Hospital Clinico San Carlos, Madrid, Spain

EUROINTERVENTION 2013 8 1149

ble 2. Angiographic thrombus burden modification with aspiration, n=28, n (%).

		Before TA	After TA	*p*-value*
TIMI flow grade	0	18 (64)	–	<0.001 (overall)
	1	2 (7)	–	
	2	5 (18)	5 (18)	
	3	3 (11)	23 (82)	
TIMI thrombus grade	0		12 (43)	<0.001 (overall)
	1	–	9 (32)	
	2	–	5 (18)	
	3	3 (11)	2 (7)	
	4	7 (25)	–	
	5	18 (64)	–	
Angiographic analysis	Coronary stenosis, %	87.2±21.3	11.3±0.9*	<0.001
	Minimum lumen diameter, mm	0.89±1.01	2.4 2±0.70*	<0.001
	Lesion length, mm	9.1±6.7	7.1±4.5	0.206

LAD: left anterior descending coronary artery; LCx: left circumflex coronary artery; LMCA: left main coronary artery; RCA: right coronary artery; TA: thrombus aspiration. *Expressed as mean±SD; *Paired t-test or Wilcoxon test.

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Suivi :

3 deces, deux non cardiaques, une mort subite
1 NSTMI pas de nouvelle revascularisation

STENT RESORBABLE ST+
PRAGUE 19

Vidimsky, PCR 2013

- n=22/85 ST+MI, 2013
- 2,3 3,7mm, calcifications, tortuosites, 24mm
- 5 re IDM, 1 thrombose de 'BVS'

DES PROBLEMES AVEC LE SYSTEME DE POSE?

- La pratique du peripherique
- Un systeme ameliore

NOUVELLE GENERATION-NOUVELLE POIGNEE

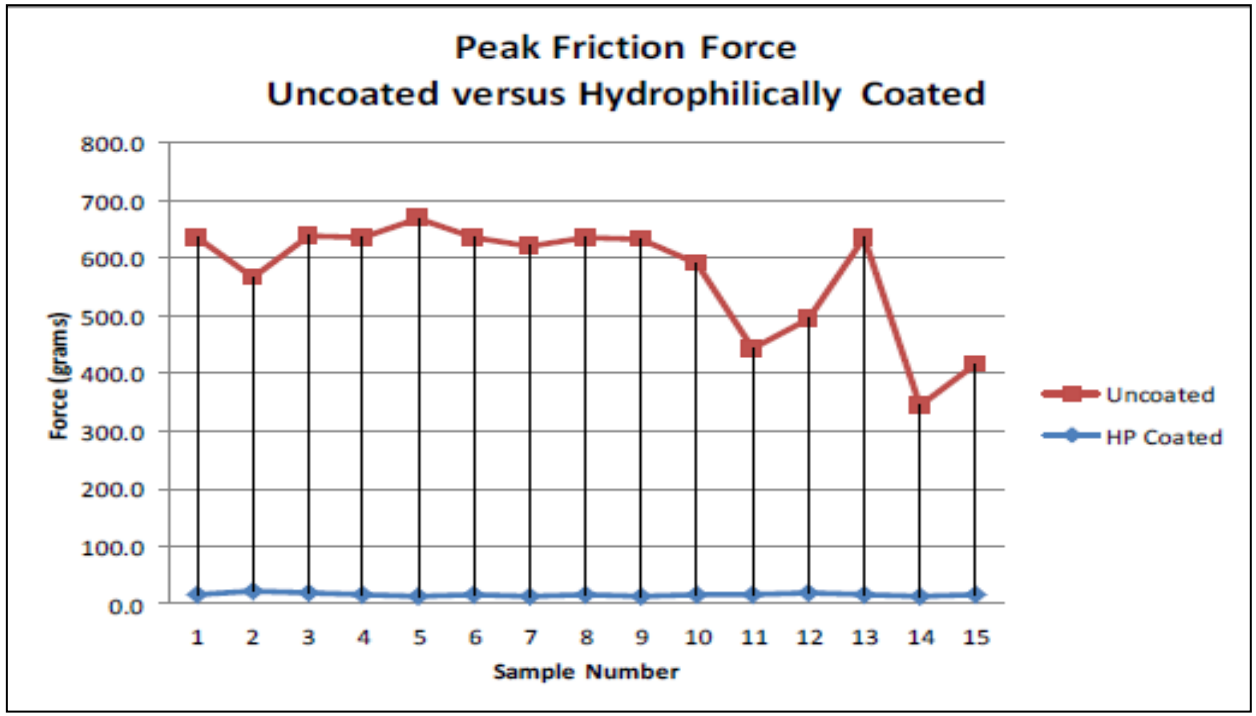
Current Handle

Next Gen Handle

More control over deployment

Reminder to flush and to open valve before deployment

Improved deliverability with Hydrophilic Coating



A total of 15 uncoated samples and 15 hydrophilically coated samples were tested for peak friction force. The peak friction force was measured to demonstrate that the hydrophilically coated samples are more lubricious than the uncoated samples.

STENT AUTO-EXPANSIF CORONAIRE : CONCLUSION

- Permet une conformation proximale et distale
- Quand doute sur le vrai calibre (ex. ST+)+++
- Bonne apposition
- Adaptation aux modifications temporelles de l'anatomie, y compris a long terme, (remodelage positif?)

STENT AUTO-EXPANSIF CORONAIRE : CONCLUSION

- Design permettant le traitement des branches de bifurcation

- Maintient du gain luminal a long terme
- Bons resultats cliniques
- Systeme de pose ameliore

MERCI


GROUPE DE CARDIOLOGIE
INTERVENTIONNELLE
FONTAINE LES DIJON

WALLSTENT

- Acier inoxydable
- Tresse