Stenting Design Is a Major Determinant of Outcomes in CAS

Pro!

Max Amor M.D

Cardio-Vascular Department

Clinic Louis Pasteur

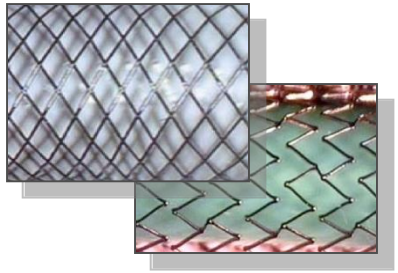
Essey Les Nancy . France

8 The determinants of outcomes in CAS

- Good patient selection
- Good patient preparation
- Technical skill and virtuosity to access
- Good selection of the protecting device
- Good stent selection
- True and complete post dilatation under protection
- Fast procedure
- Good patient surveillance post procedure

Closed Cell Concept

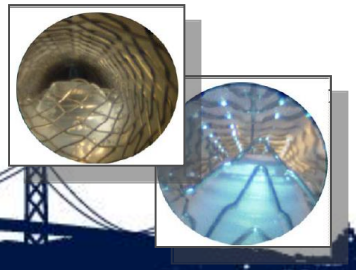
Scafolding



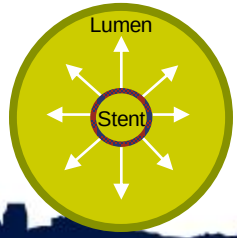
Stroke

Prevention

Structure



Radial Force



How to choose the most appropriate stent ?

Emmanuel Houdart

Department of Interventional Neuroradiology
Hôpital Lariboisière
Paris, France

Personal experience

- 125 Carotid Wall Stent (closed cells stent)
  1 delayed ischemic stroke due to Clopidogrel resistance

- 40 Nitinol stents (open cells stent) : 2 delayed ischemic complications without Clopidogrel resistance

Mr Rai…left symptomatic stenosis

After nitinol stent implantation under filter deployment (no debris)

Pré

Post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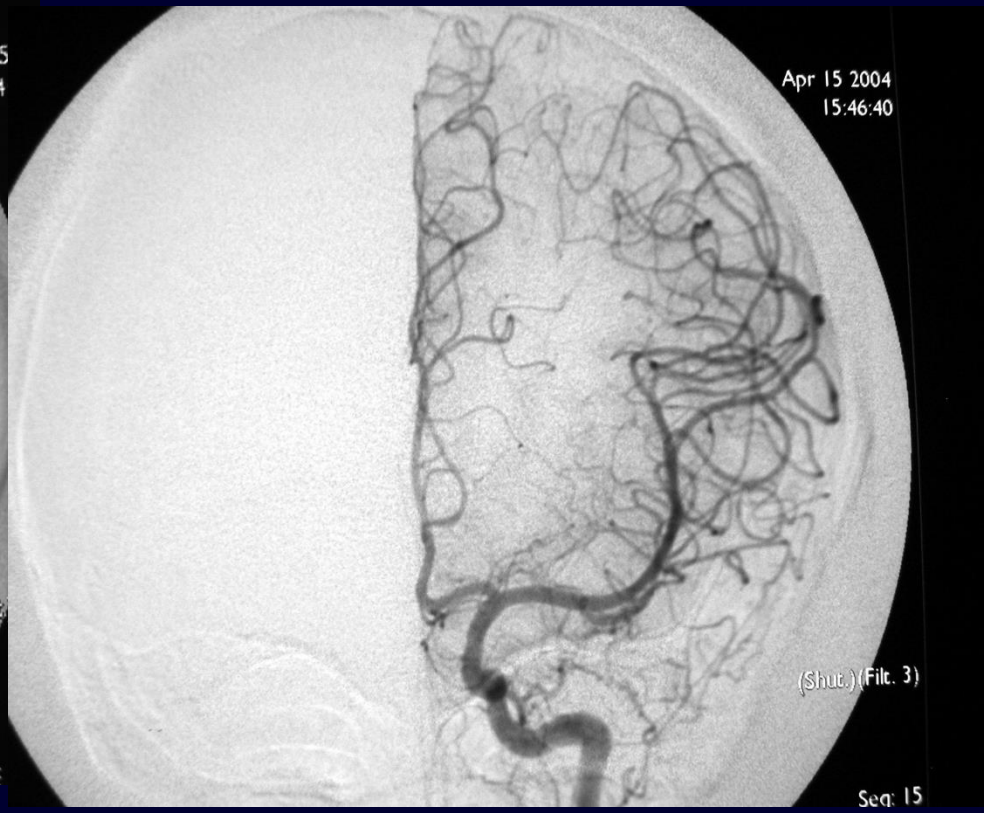
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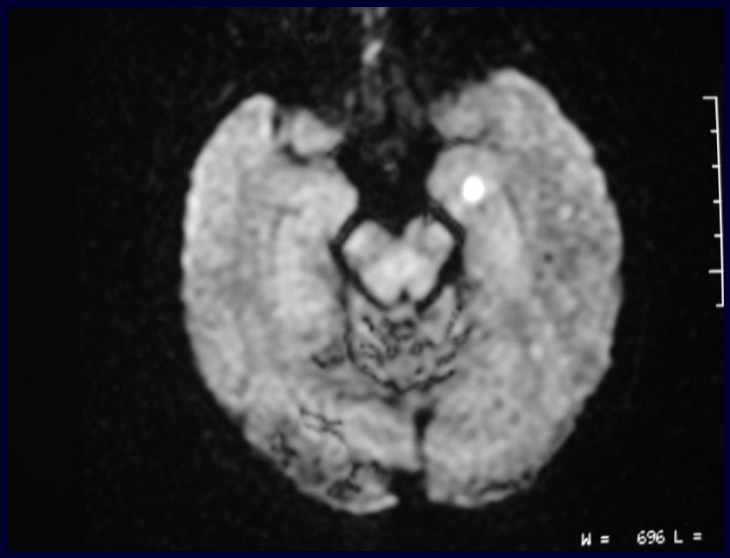
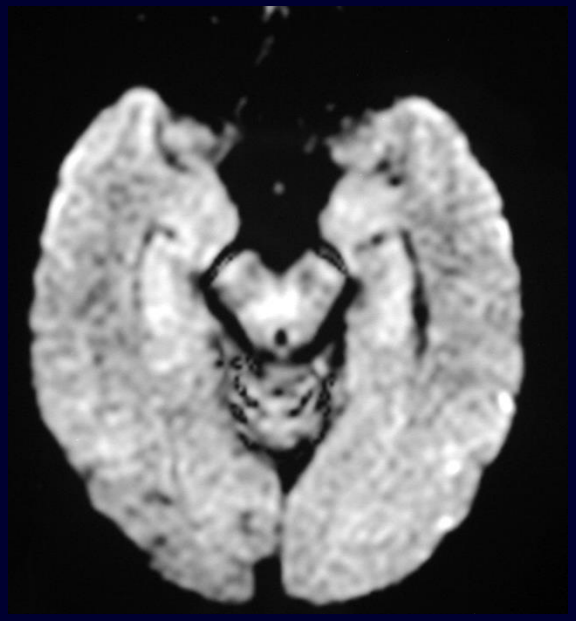
Evolution

- Patient was discharged
- Recurrent TIA at day 8
- Echo-Doppler : normal stent patency, no intra-stent thrombosis



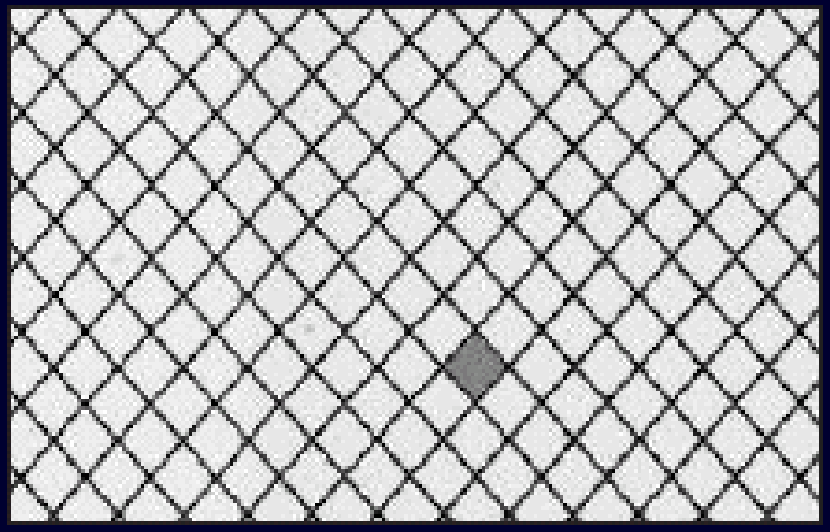


Failure of plaque exclusion was the suspected mechanism of delayed stroke in our patients

- Delayed embolism could occur if plaque (block of butter) protrudes through stent struts (wire able to cut the butter)

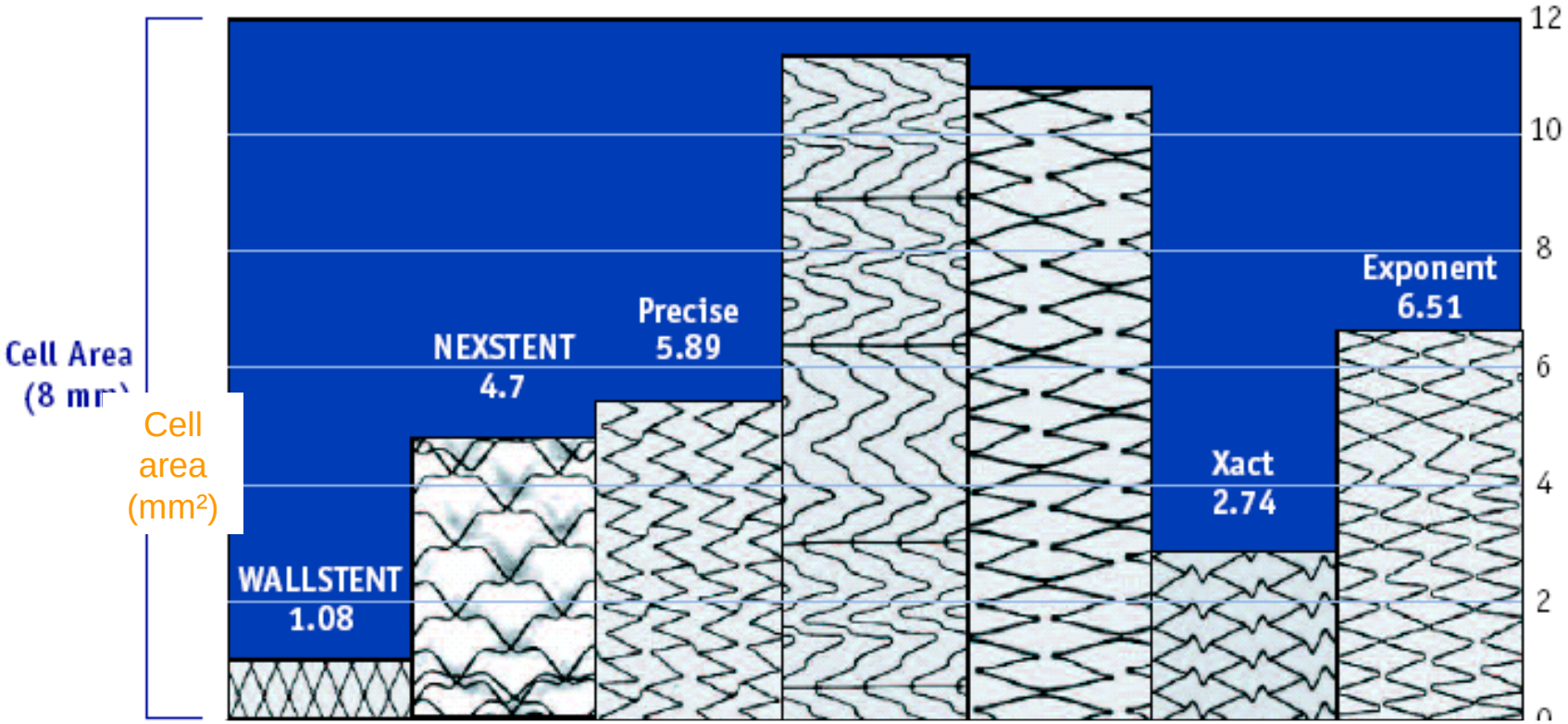
Cell's definition

- Elementary unit of a stent including the metallic struts and its void surface



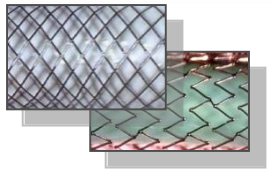
Closed cells
interdependent cells

Open cells
independent cells



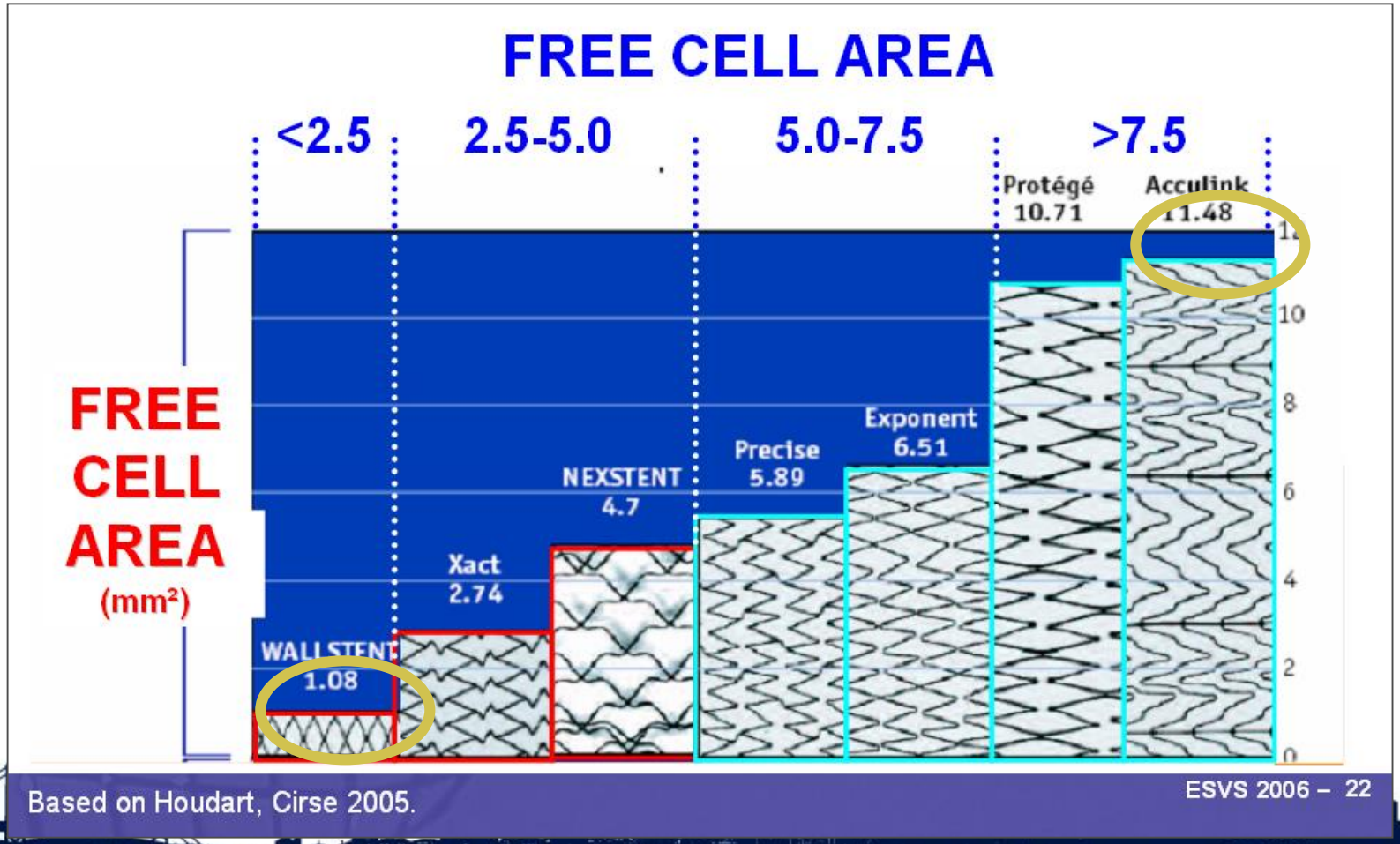
Surface of cells in mm^2

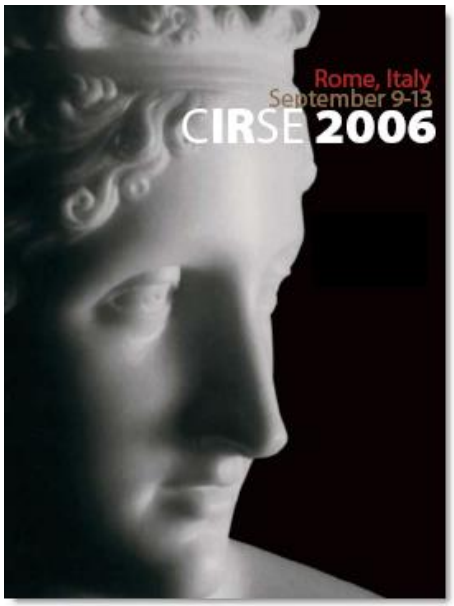
Scafolding



Stents are not equal, …

the CWS cell size is 10 times smaller than the Acculink





CAS device selection

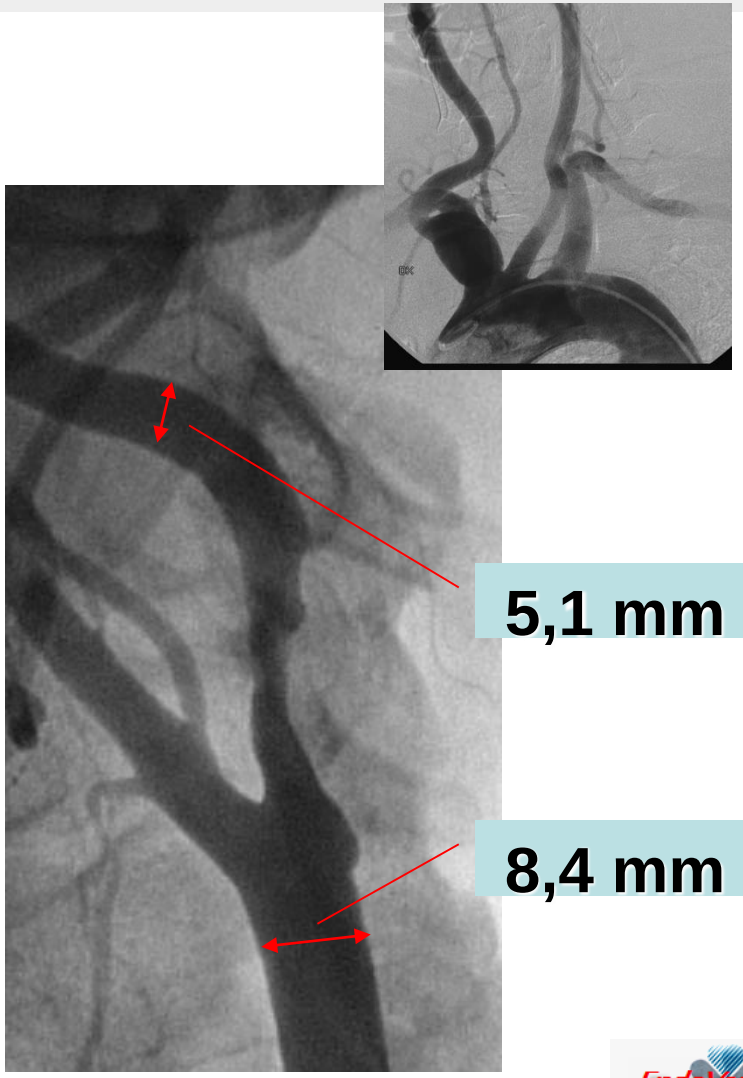
A. Cremonesi *

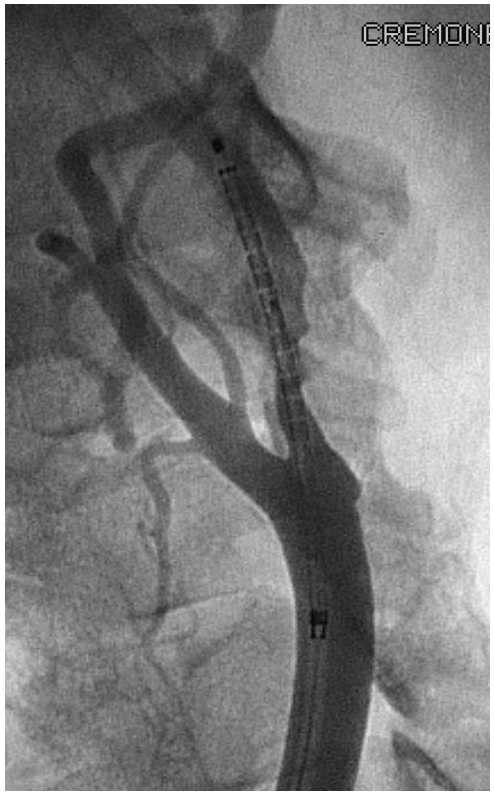
F. Castriota*

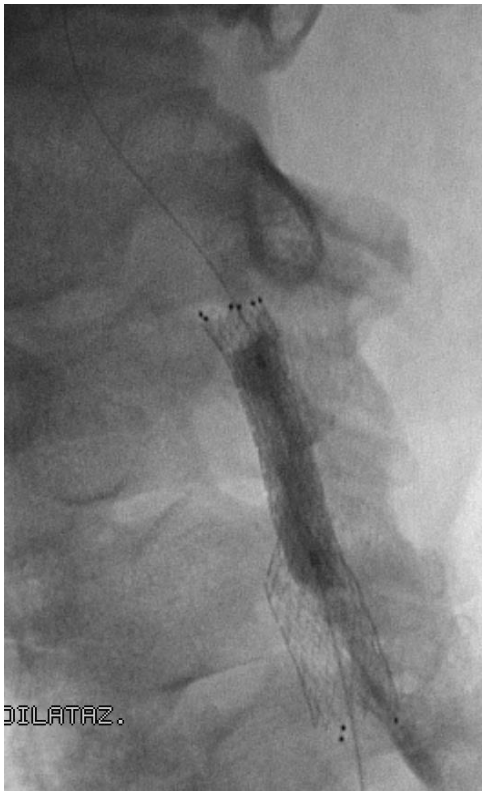
* Interventional Cardio-Angiology Unit
Villa Maria Cecilia Hospital
Cotignola (RA) - Italy

Symptomatic left ICA stenosis

- Male 85
- CVRF:
  - diabetes, hypertension
- Symptoms:
  - recurrent TIAs
- Eco-Doppler:
  - Left ICA 75% long lesion, PFV 2.3 m/sec
  - Dishomogeneous plaque, partially ulcerated, with significant soft component
- Medical therapy
  - Beta-blocker
  - Plavix 75 mg
  - Aspirin 100 mg

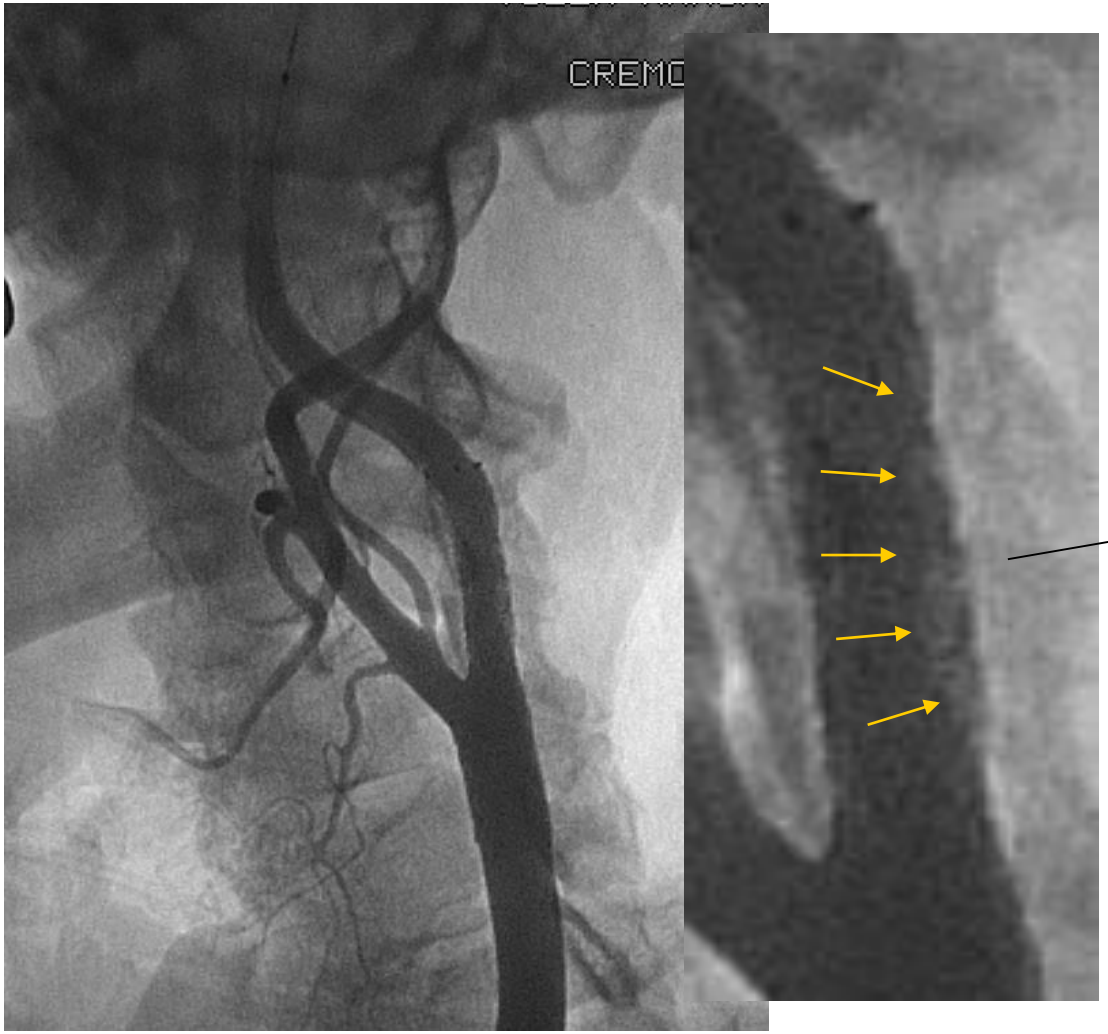






- EPD: Accunet 6.5 concentric filter
- Direct stenting: Protégé 7-10/40 mm
- Balloon: Maveric 5.0/20 mm @ 7 bars

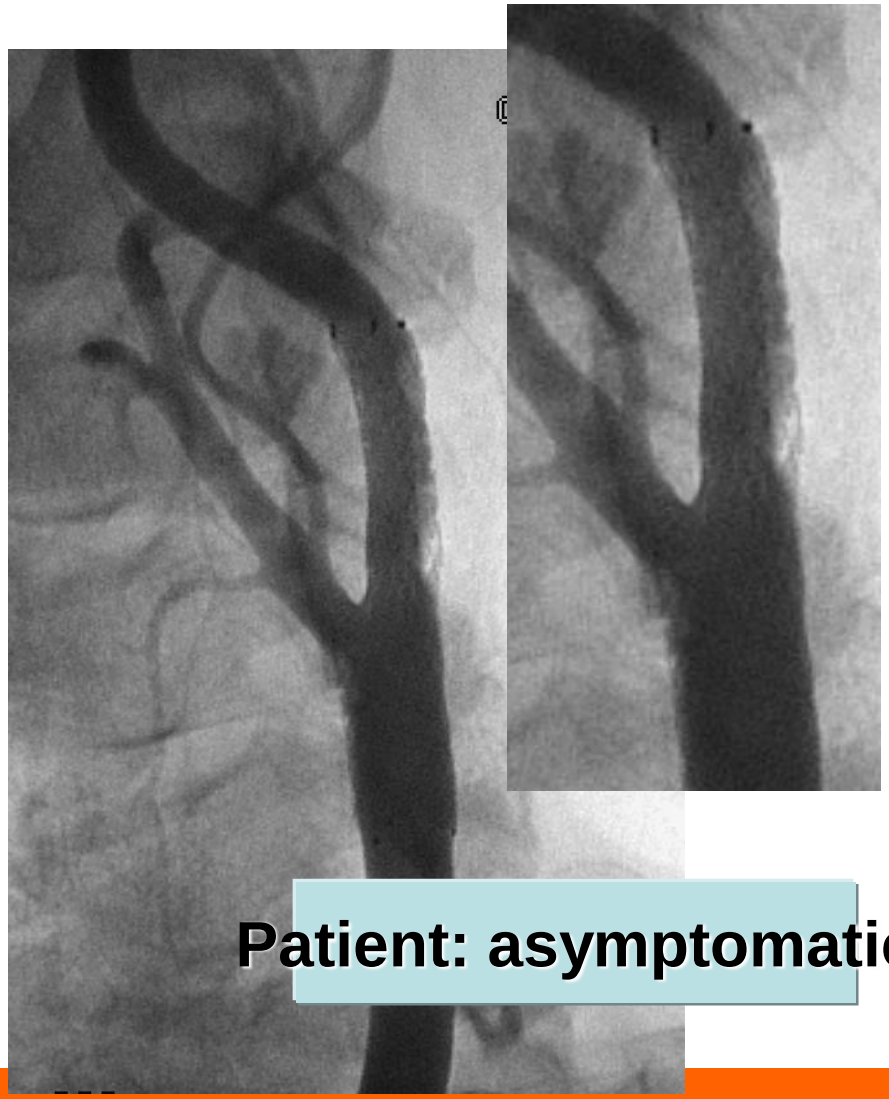
Final result

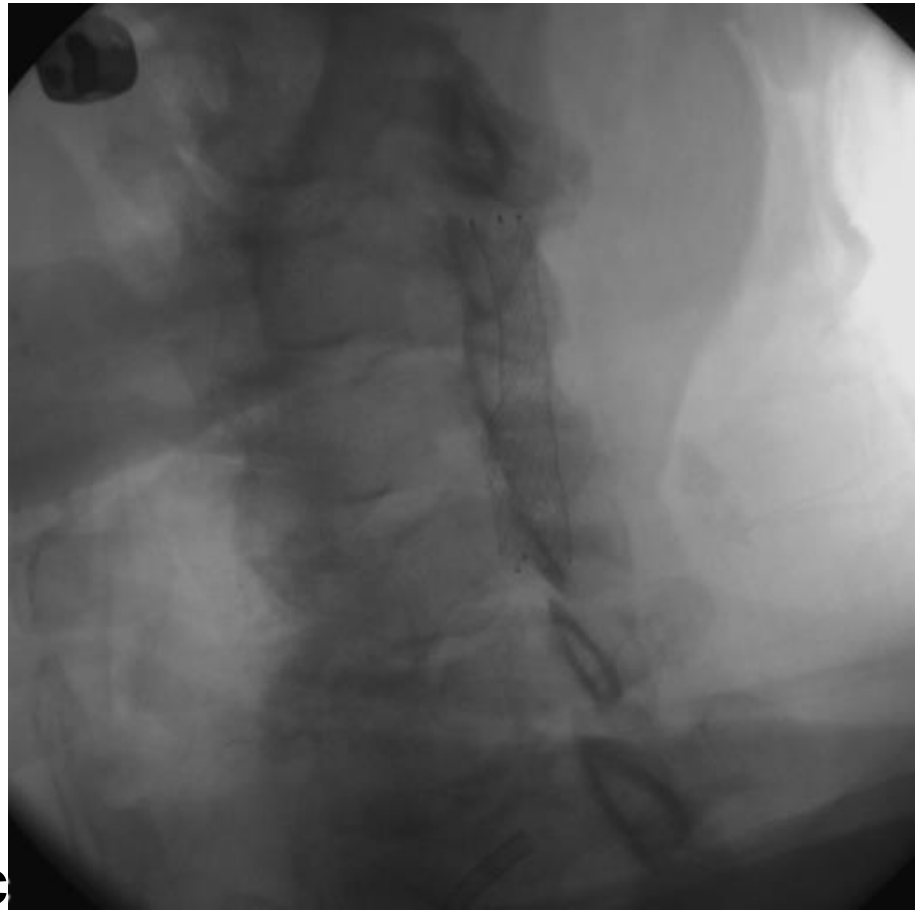


Filling defect?

The complication: progressive plaque prolapse

min. 8 after stenting

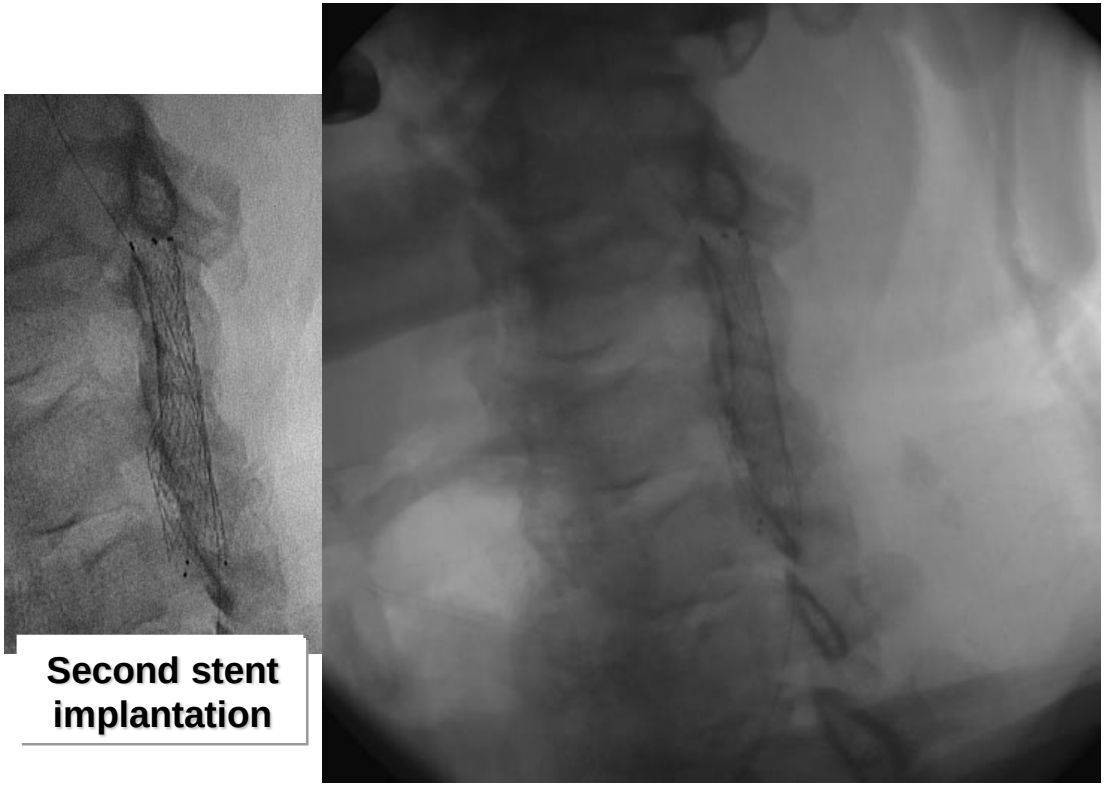




Patient: asymptomatic

Plaque prolapse treatment
min. 20 after stenting

- EPD: Accunet 6.5
- "Sandwich technique": stent in stent to fix the protruding plaque between the two frames
- Stent: XAct 8/30
- No post-dilatation



Second stent implantation

Patient: asymptomatic

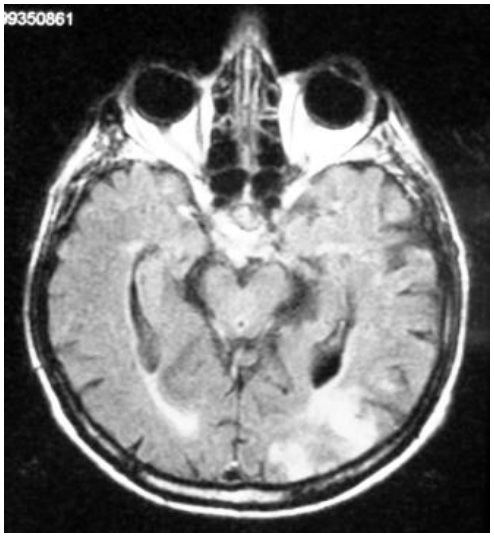
Plaque prolapse treatment
min. 21 after stenting

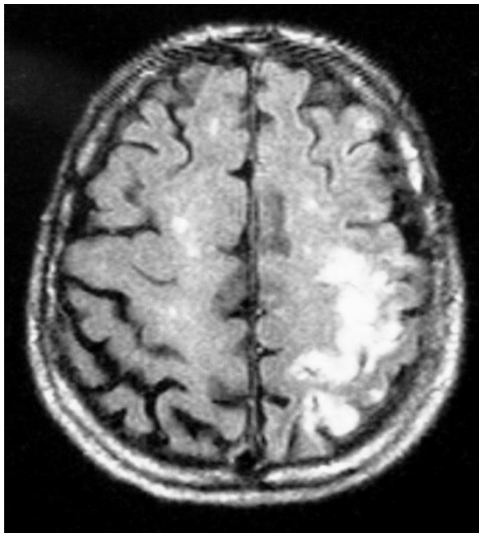
Patient: symptomatic for worsening right hemi-paresis!

Filter still in place!

In-hospital outcome

- The Patient developed a right hemi-paresis, successfully treated in ICU for two days.
- Neuro-rehabilitation for 20 days, with complete resolution of neurological deficits.
- Echo-Doppler: no evidence of significant plaque protrusion.





Stenting strategies to prevent peri-procedural complications

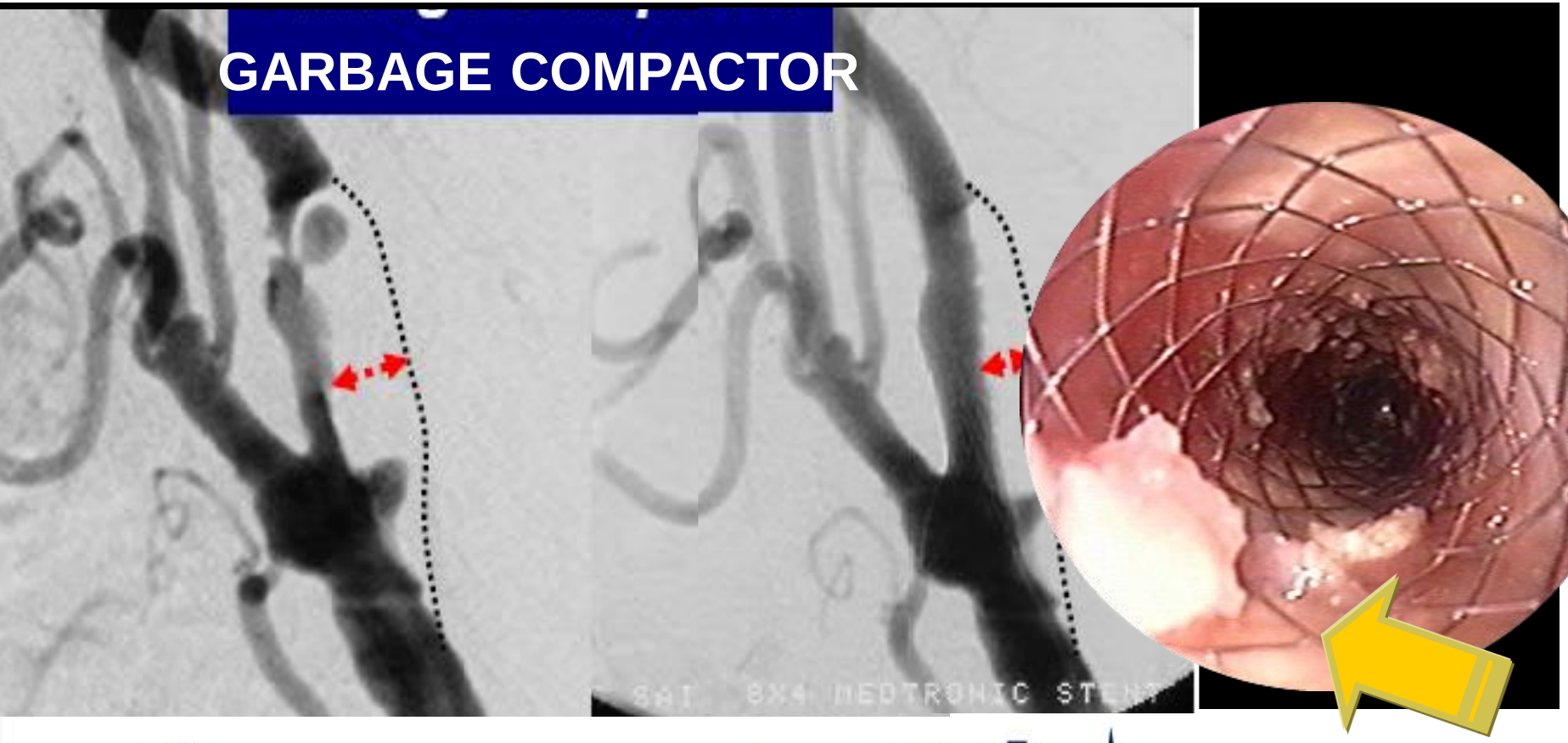
Carotid lesion / bifurcation issue	Type of stent
Plaque covering Long acting plaque prolapse prevention	Cobalt-alloy braided thread stent
In vessel flexibility Wall/plaque conformability	Nitinol open cell stents
Outward radial force Resistance to compression	Nitinol closed cell stents

Do device characteristic affect outcome in carotid artery stenting?

M. Bosiers – P. Peeters

Post-procedural phase (M.Bosiers)

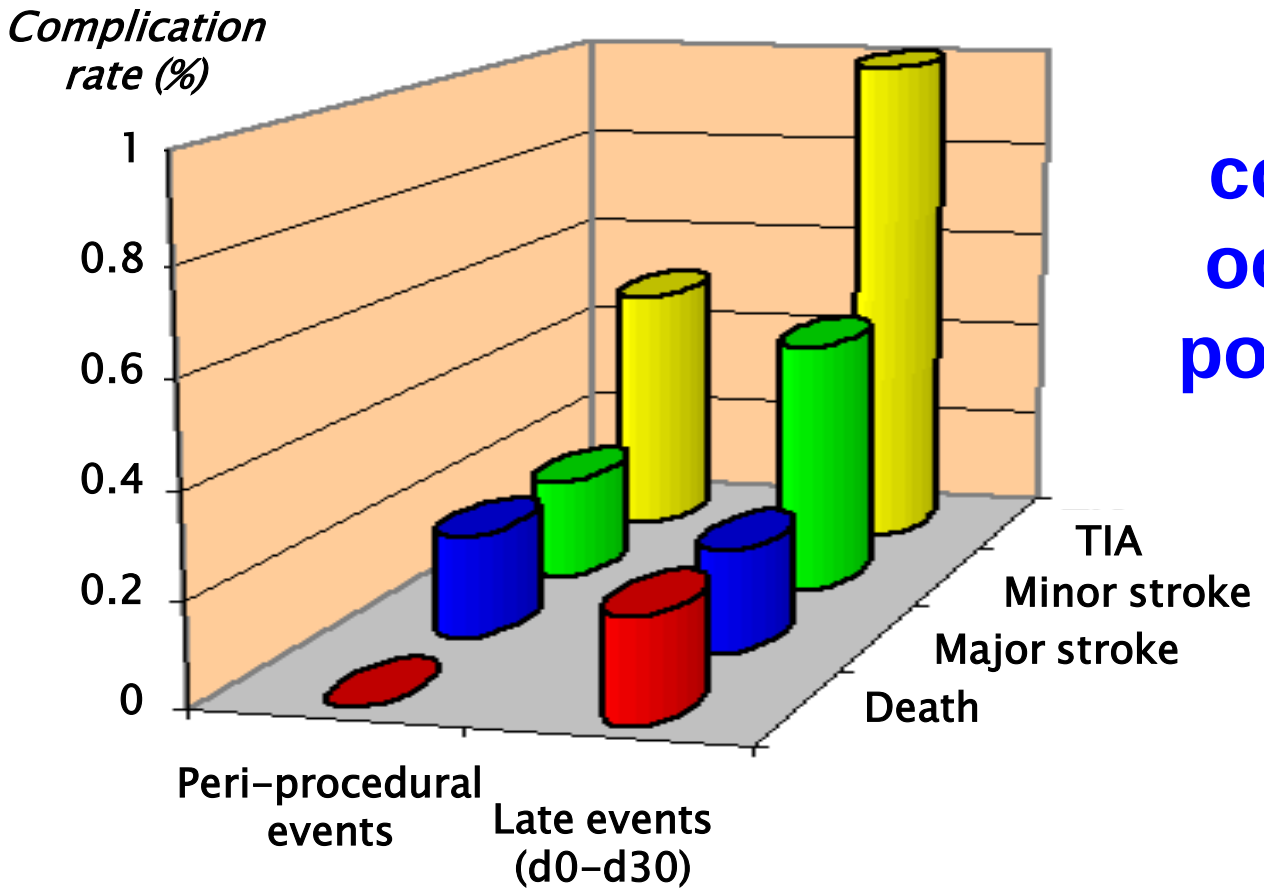
ENDOVASCULAR → Plaque containment!



Courtesy of M. Makaroun, University of Pittsburg / Courtesy of K. Balzer,

Distribution of Complications Over Time

Timing events

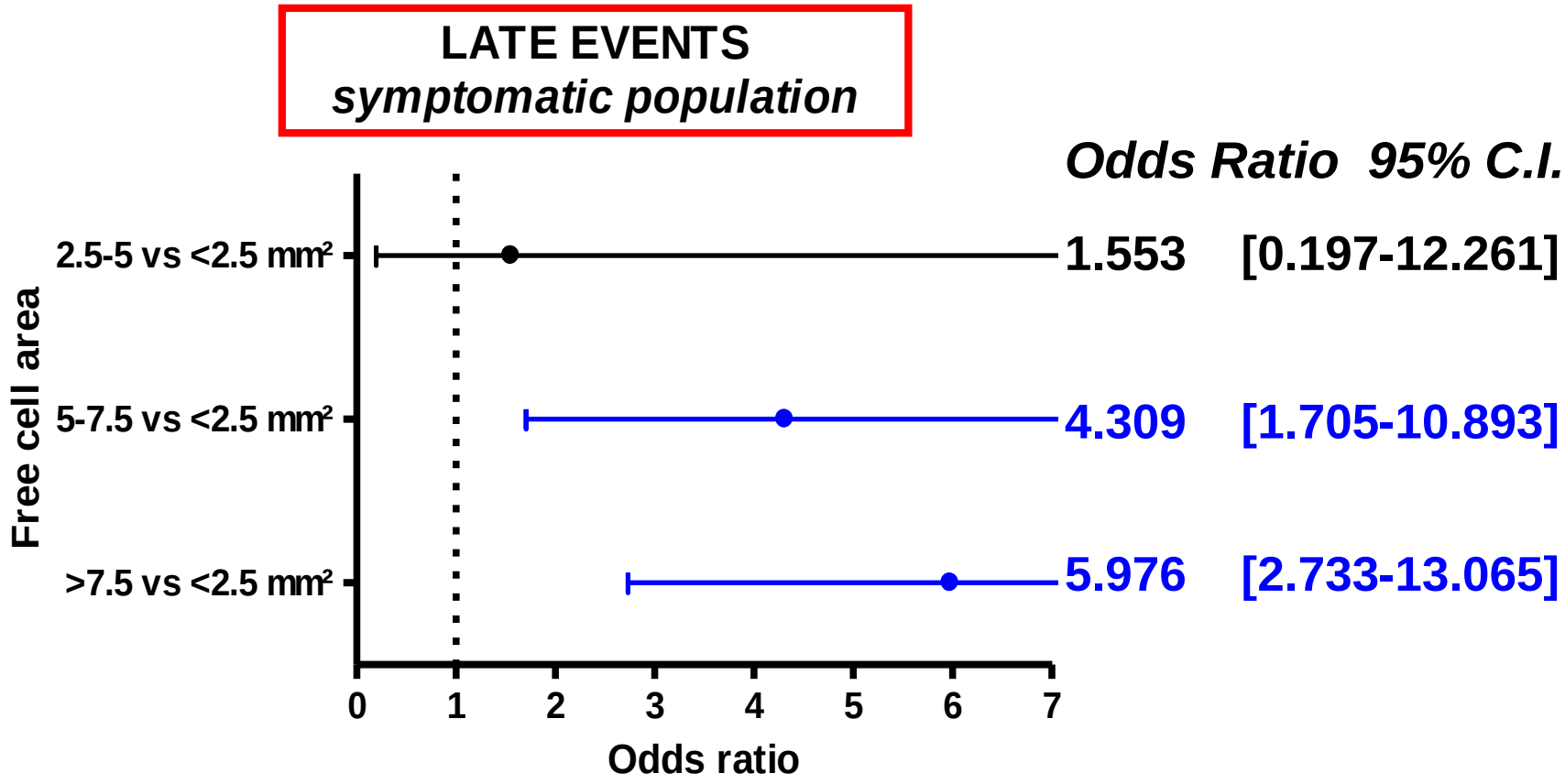


2/3 of all complications occured in the post procedural phase

“Stent design” based analysis

ALL EVENTS	Total population		Symptomatic		Asymptomatic	
	n/N	%	n/N	%	n/N	%
Closed	51/2242	*2.3%*	21/934	*2.2%*	30/1308	*2.3%*
Open	39/937	*4.2%*	27/383	*7.0%*	12/554	*2.2%*
TOTAL	**90/3179**	***2.8%***	**48/1317**	***3.6%***	**42/1862**	***2.6%***

“Free cell area” based analysis



Does Free Cell Area Influence the Outcome in Carotid Artery Stenting?

M. Bosiers,1* G. de Donato,2 K. Deloose,1 J. Verbist,3 P. Peeters,3
F. Castriota.4 A. Cremonesi4 and C. Setacci 4

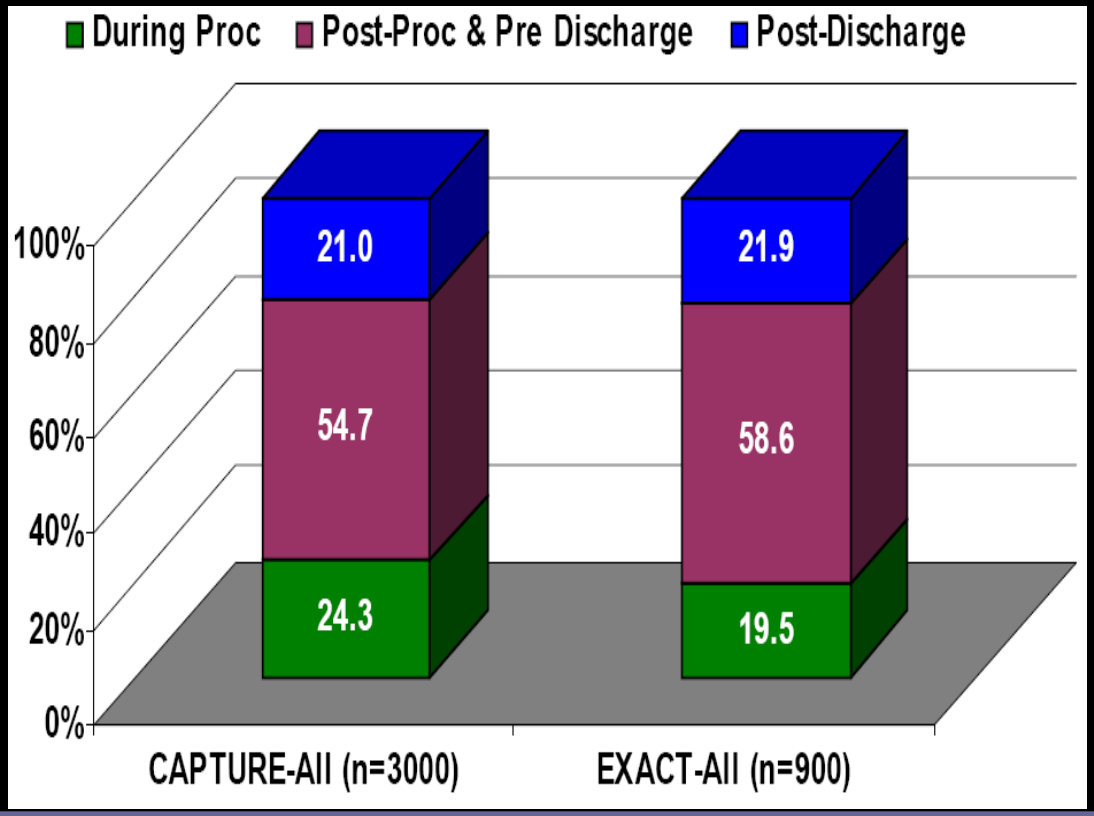
Material and methods. A CAS database of 3179 consecutive CAS patients was retrospectively assessed. The distribution of neurological complications were analysed for association with the different stent types and designs. Events where subdivided into procedural and postprocedural events.

Results. The overall combined rate of TIA, stroke and death was 2.8% at 30 days (late events 1.9%). The post-procedural event rate analyzed for differences stents varied from 1.2% using BSCI Carotid Wallstent to 5.9% using MedtronicExponent. The late event rates varied from 1.2% to 3.4% for free cell areas <2.5 mm^2 and >7.5 mm^2 respectively($p < 0.05$). Post-procedural event rate was 1.3% for closed cells and 3.4% for open cells. All these differences were highlypronounced among symptomatic patients ($p < 0.0001$).

Conclusions. After carotid stenting, complication rates vary according to stent type, free cell area and cell design. In the symptomatic population (and also in the total population), post-procedural complication rates are highest for the open cell types and increase with larger free cell area.

Post-procedural phase

- **The majority of strokes occur post-procedure (+/- 70%)**

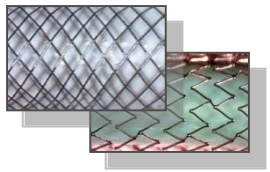


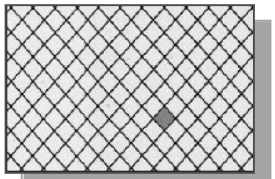
Prof. Jansen

sub-analysis

SPACE Clinical Trial

Sub Analysis



Procedure	Cell Design	MAE All Patients
Carotid Endarterectomy (CEA)		**6.3%** (37/584)
Carotid Artery Stent (CAS)	**Closed Cell** 	**6.0%** (26/434)
Carotid Artery Stent (CAS)	**Open Cell** 	**11.0%** (13/118)

“Stent design” based analysis

30-day MAE	Symptomatic	
	n/N	%
BIC		
Closed	21/934	*2.2%*
Open	27/383	*7.0%*
SPACE		
Closed	26/434	*6.0%*
Open	13/118	*11.0%*
CEA	37/584	*6.3%*

30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomised non-inferiority trial

*The SPACE Collaborative Group**

Summary

Background Carotid endarterectomy is effective in stroke prevention for patients with severe symptomatic carotid-artery stenosis, and carotid-artery stenting has been widely used as alternative treatment. Since equivalence or superiority has

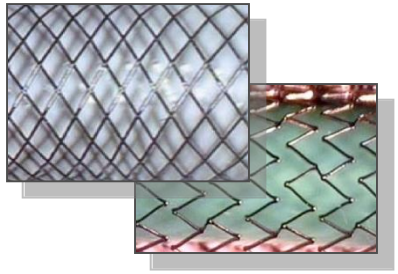
Results confirmed by subanalysis SPACE-trial

(Prof. Jansen)

for the periprocedural complication rate. The results of this trial do not justify the widespread use in the short-term of carotid-artery stenting for treatment of carotid-artery stenoses. Results at 6–24 months are awaited.

Closed Cell Concept

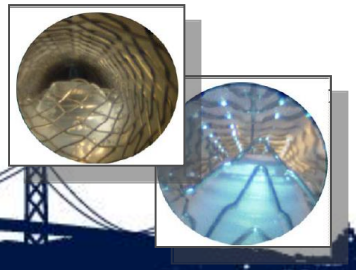
Scafolding



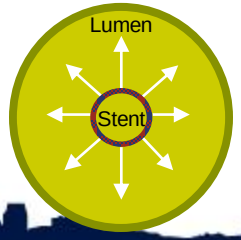
Stroke

Prevention

Structure

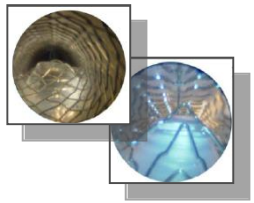


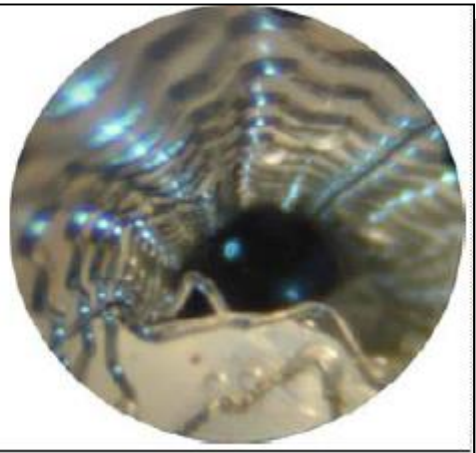
Radial Force

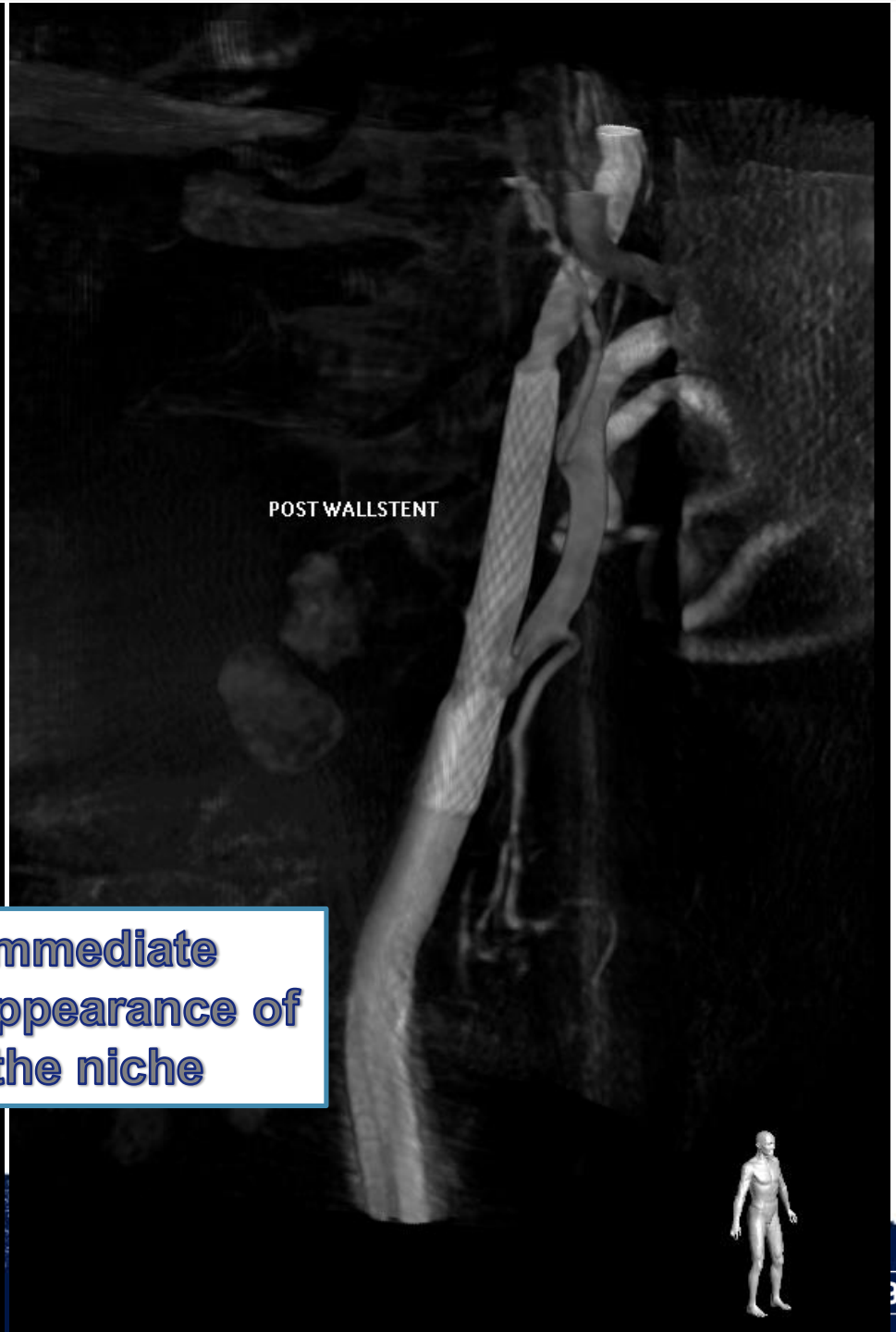


Closed and Open Cell Geometry

Inner Lumen Images

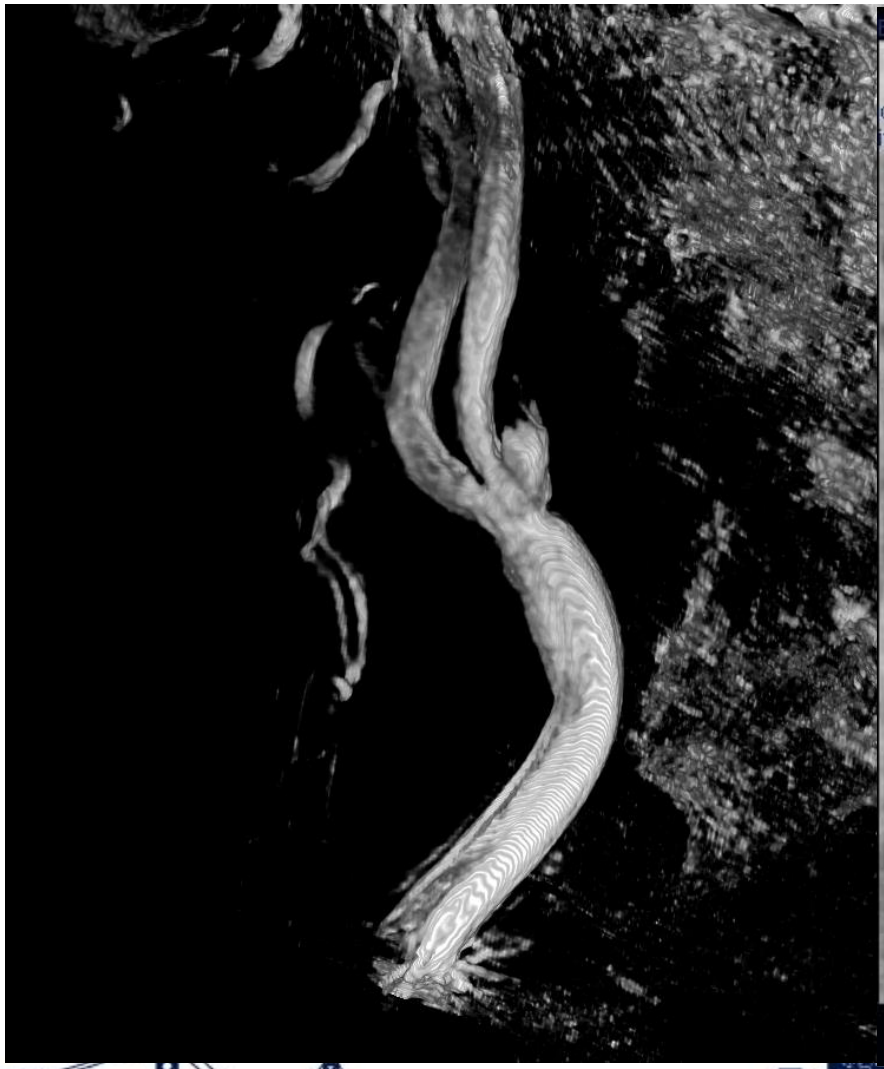


	Carotid Wallstent™	Acculink™ Carotid Stent
25% Lesion Stent deployed in lumen representative of a vessel with a plaque protrusion infiltrating 25% of the internal diameter		
70% Lesion Stent deployed in lumen representative of a vessel with a plaque protrusion infiltrating 70% of the internal diameter		



Immediate disappearance of the niche

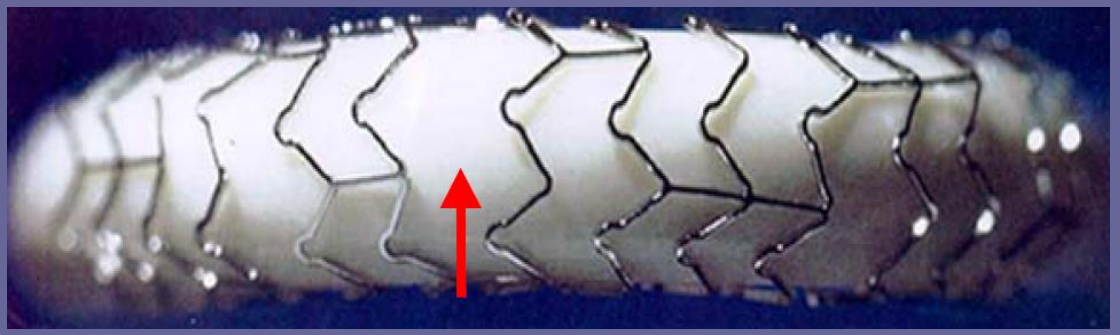
Open cells protruding in the the ulcerated niche

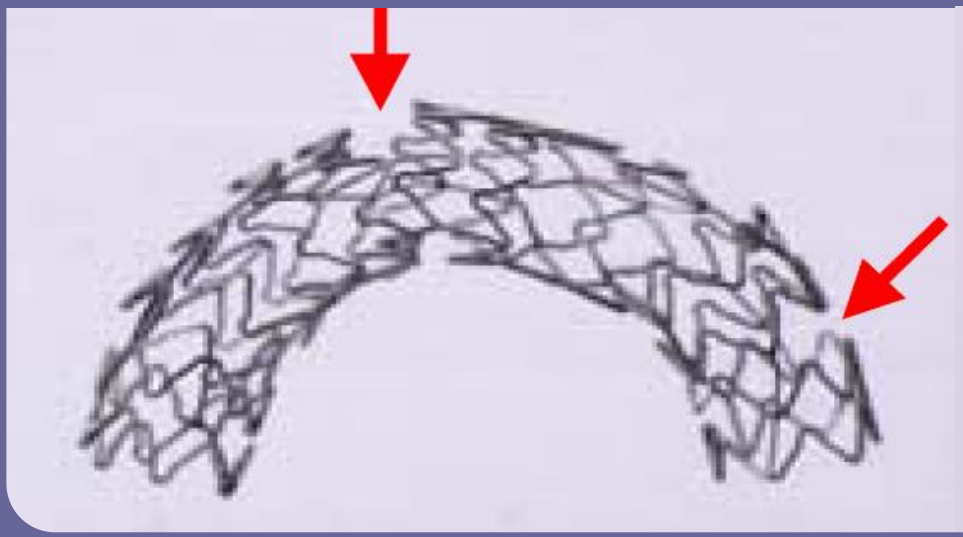


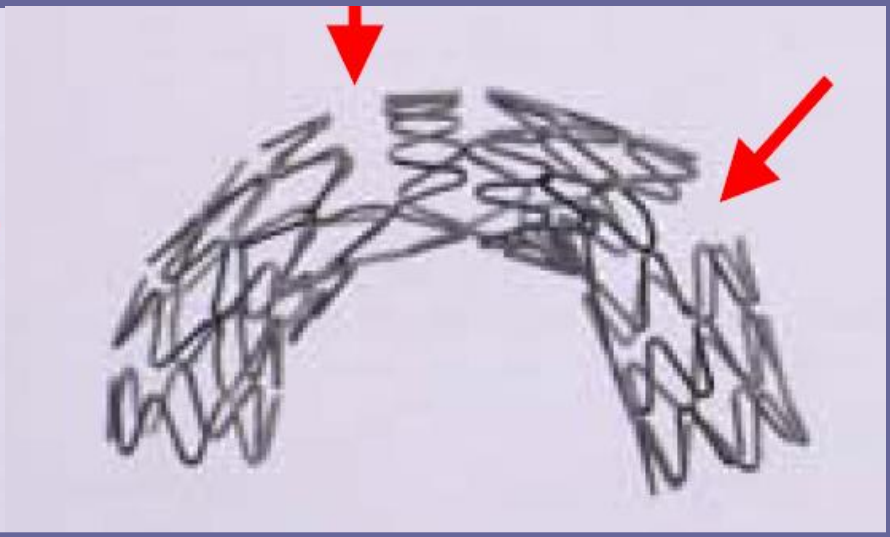
“Stent design”: why closed cell?

- Open cell designs in tortuous curvature

PROLAPSE

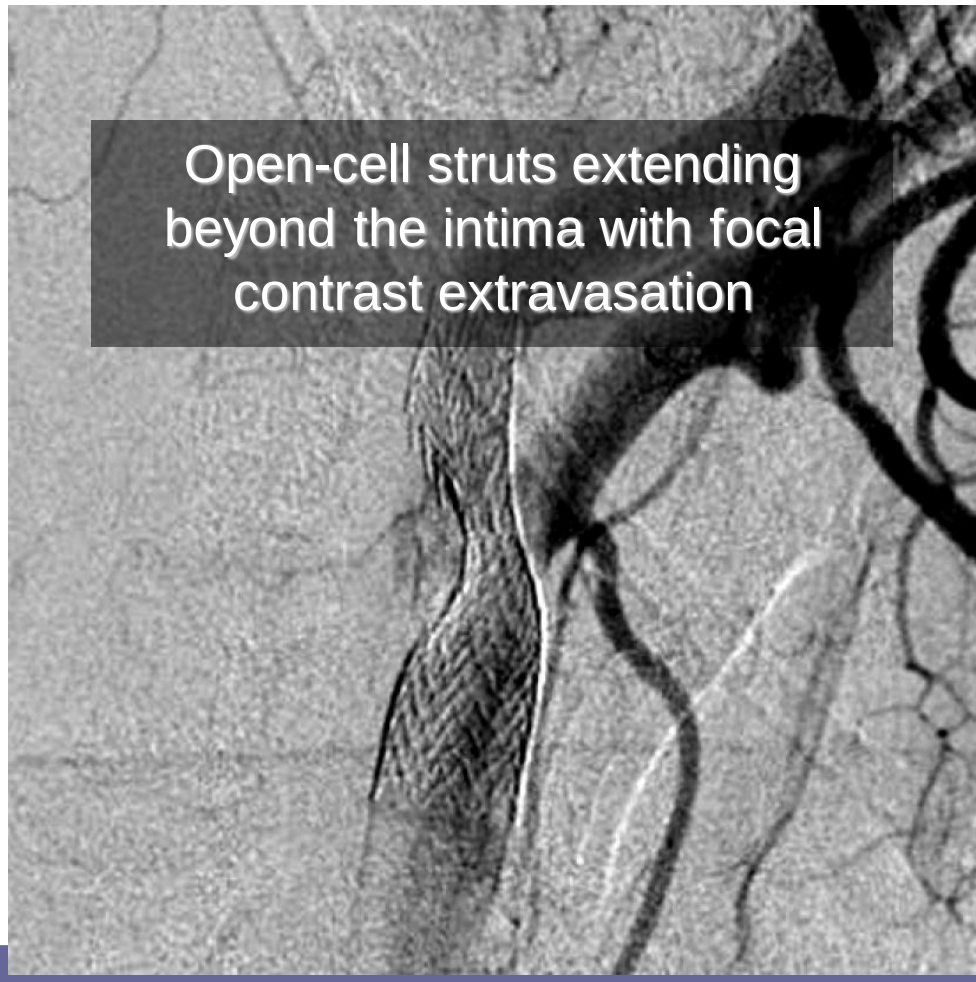




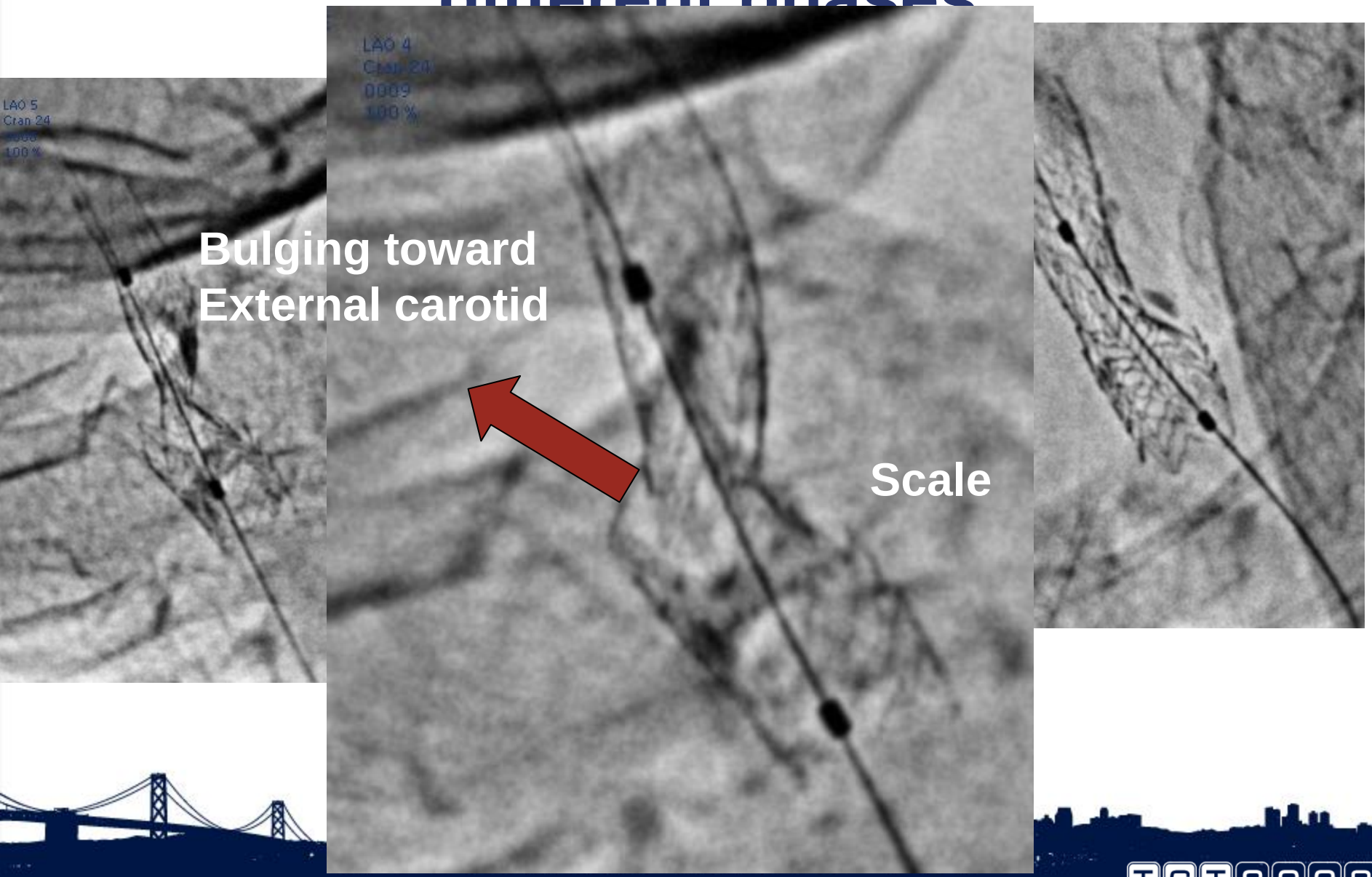


Courtesy of MH Wholey

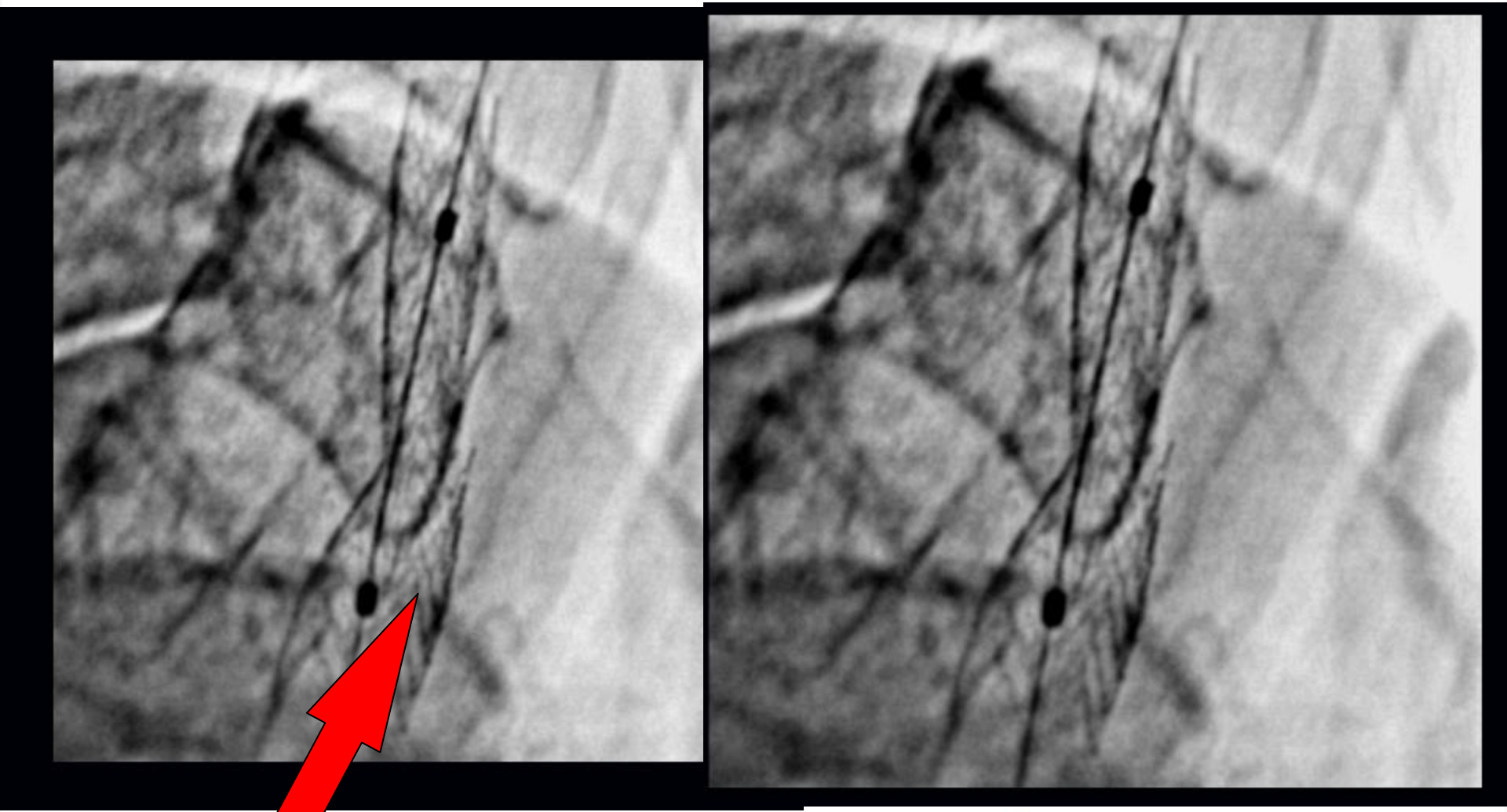
“Stent design”: why closed cell?



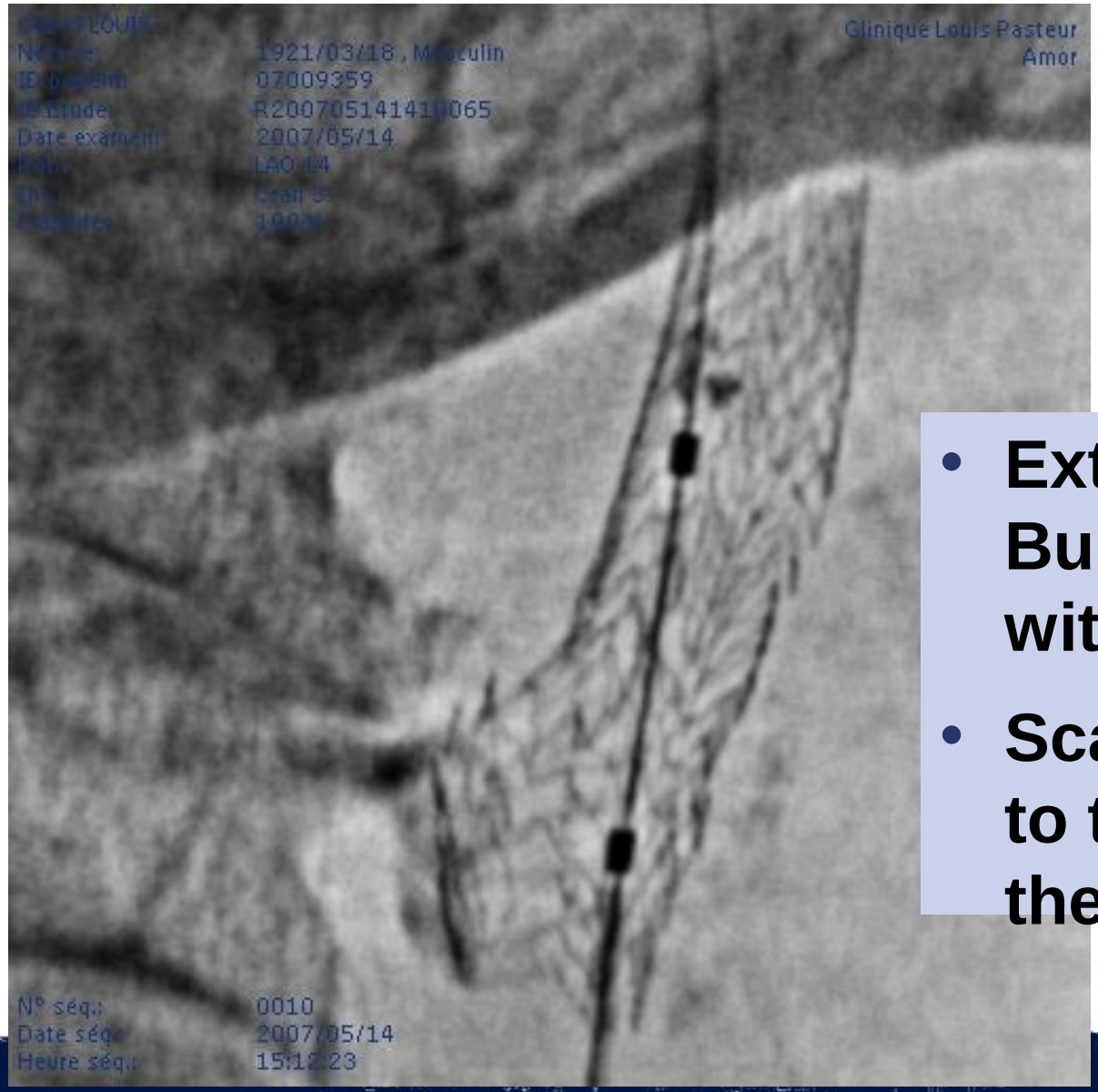
Stentboost of an open cell stent at different phases



Chimney !



The open cell stent signature



- **External Carotid Bulging with or without teeth**
- **Scale protruding to the lumen or the wall**

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MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
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BUILDING ENDOVASCULAR SYNERGIES

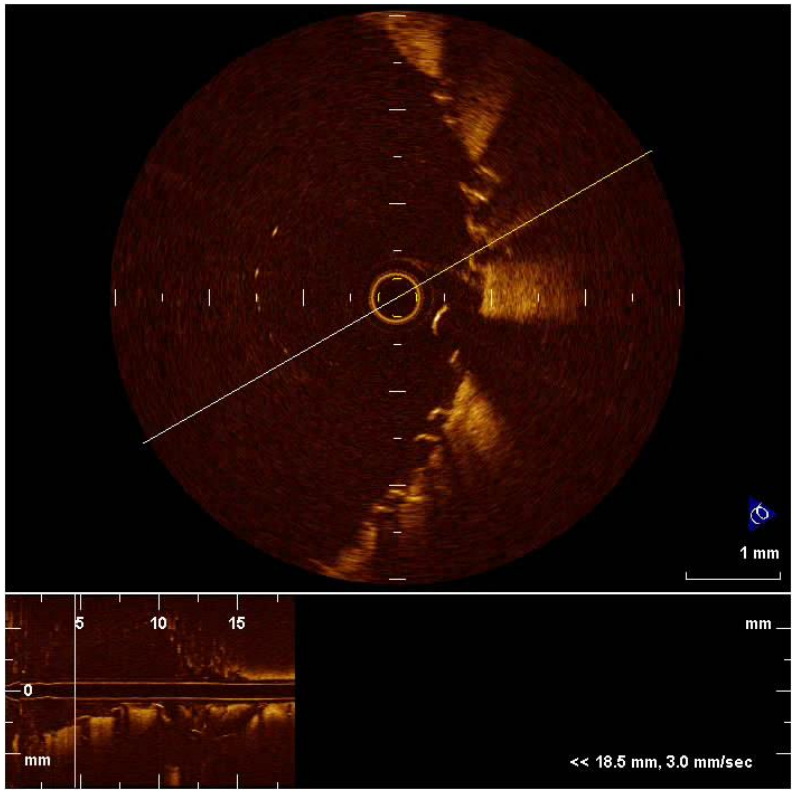
First OCT cases
Carotid Arteries Stents

Clinique Louis PASTEUR
Essey-les-Nancy / France
M.Amor –G.Ethevenot
F.Marty –J.P Simon –J Lemoine

Cases

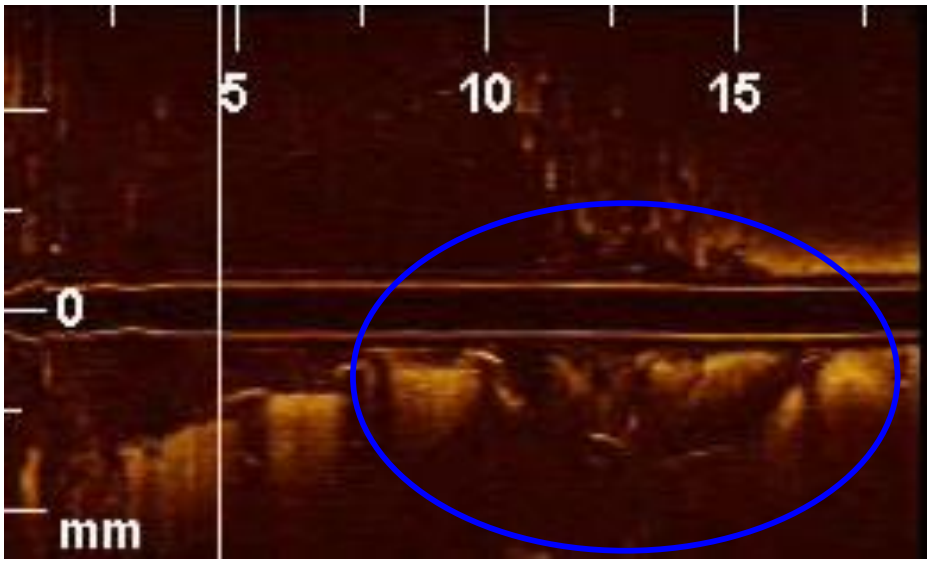
- Target : Control post stenting Wallstent (autoexp. Stent) in internal carotid
- Positions of the struts
- Presence of materiel between the struts post stenting
- Definition of protocol to obtain images
- Case report will be made

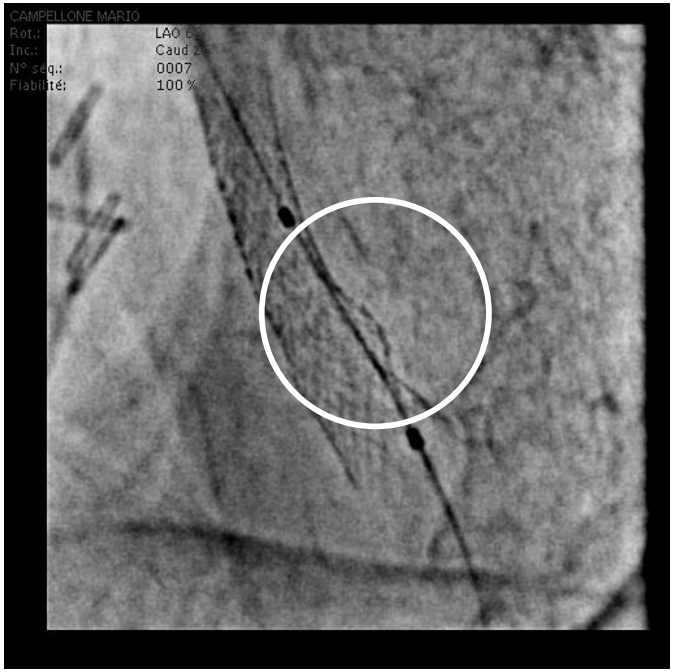
Case 1


1 mm
5
10
15
mm
0
mm
<< 18.5 mm, 3.0 mm/sec

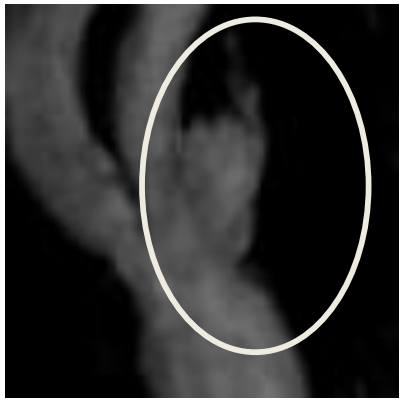

CAMPELLONE MARIO
Rot.: +81°
Inc.: -24°

Case 1

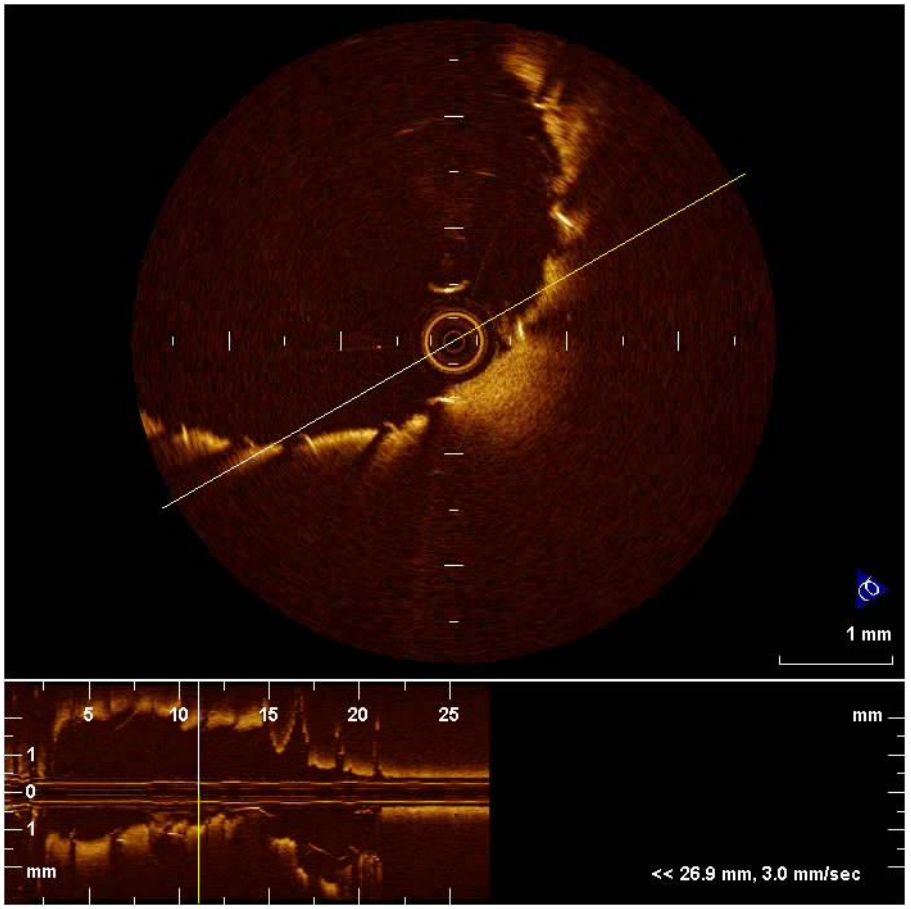




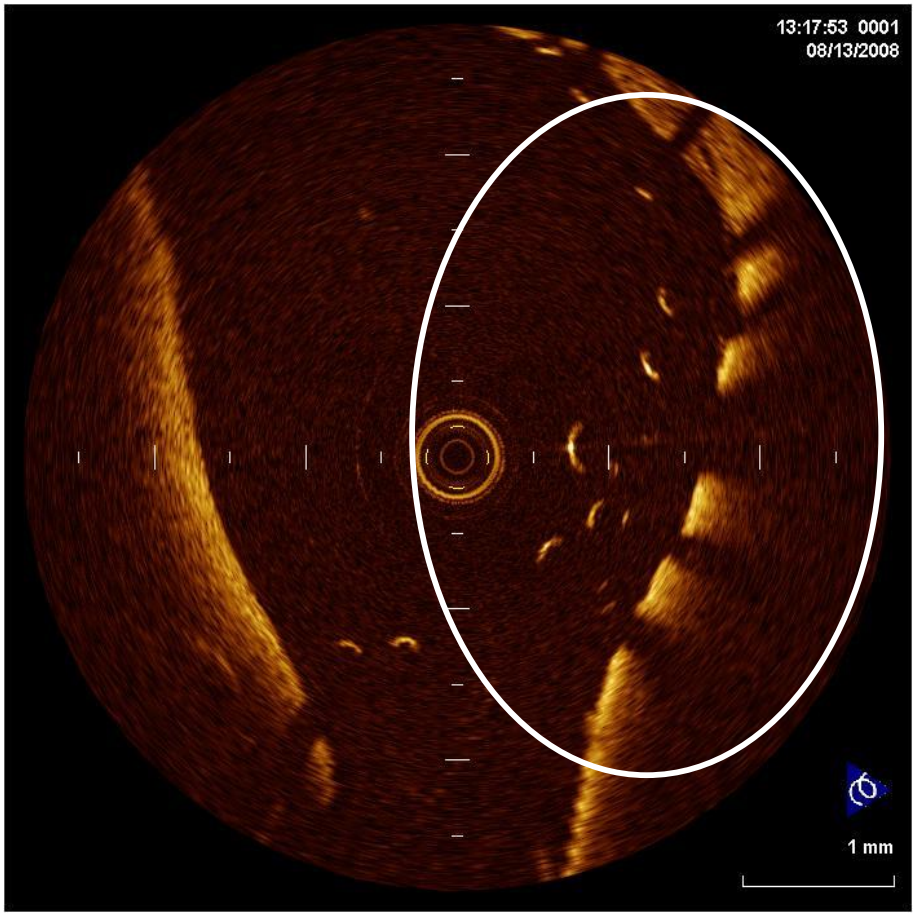
Protrusion of the struts in the ulceration niche.

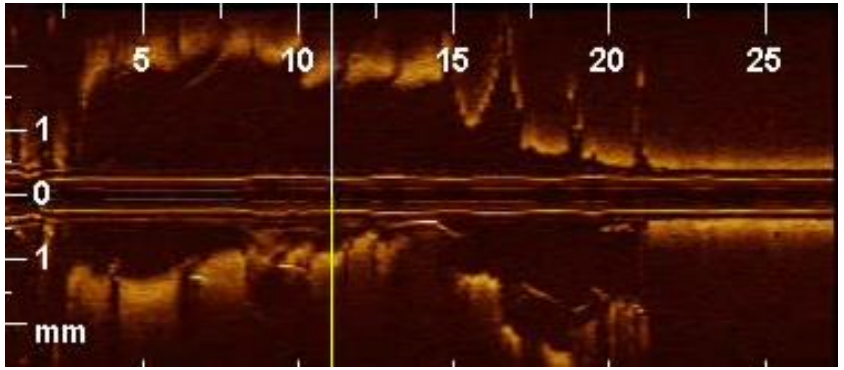


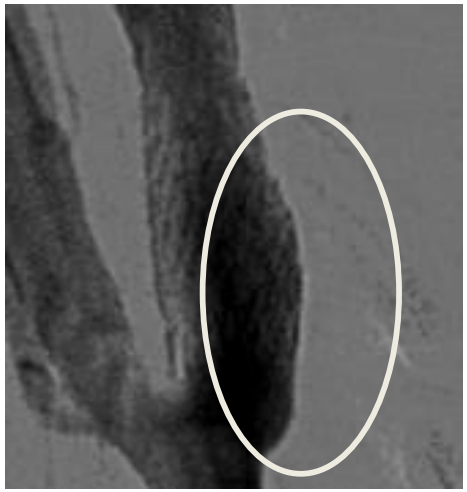
Case 2



Control post stenting



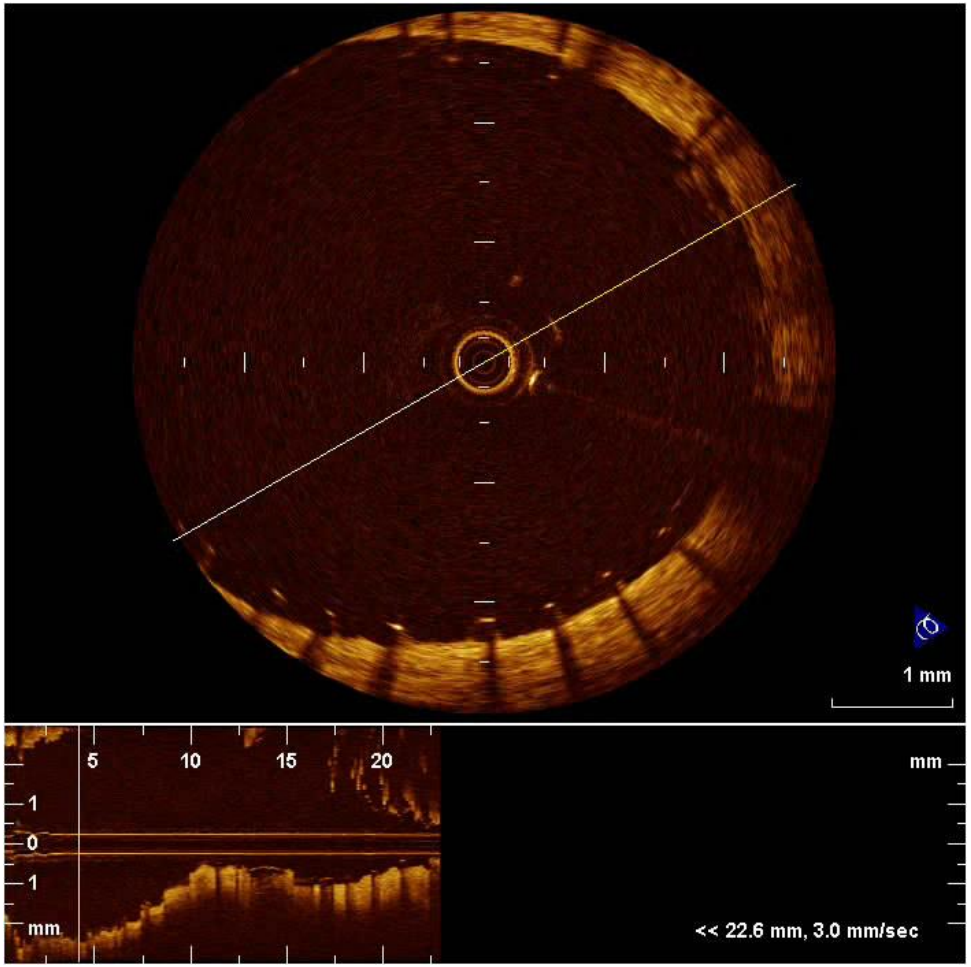




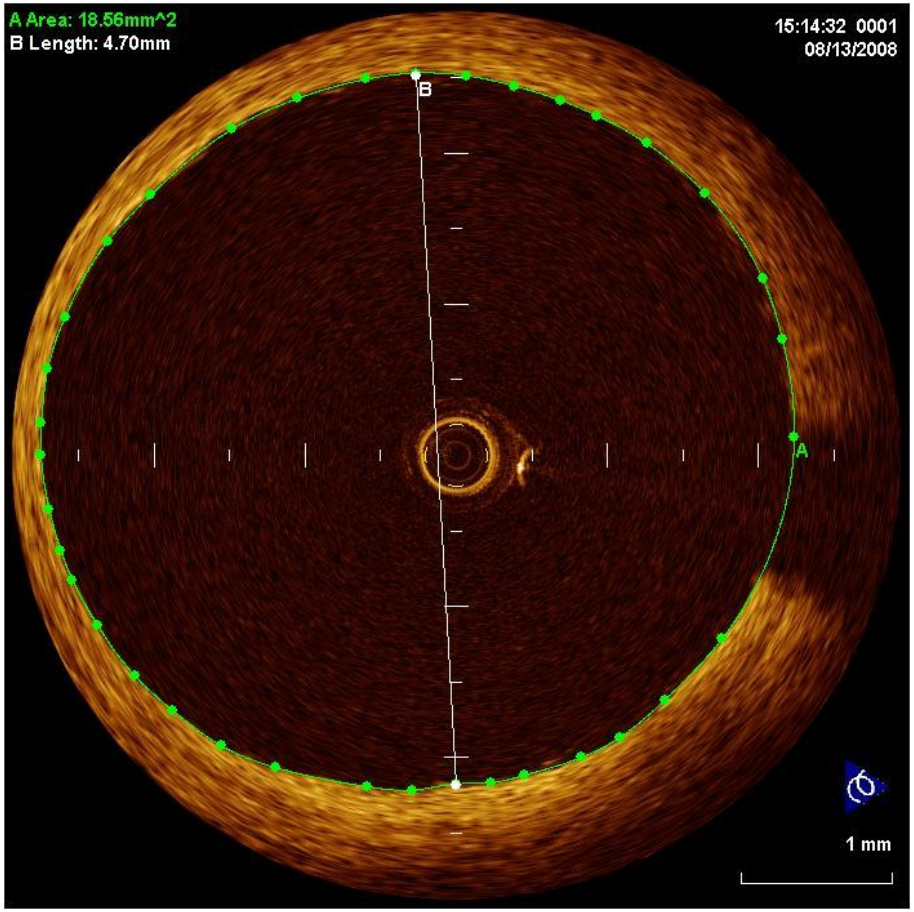
Floating struts and longer pullback – Protocol to obtain better flush is working.

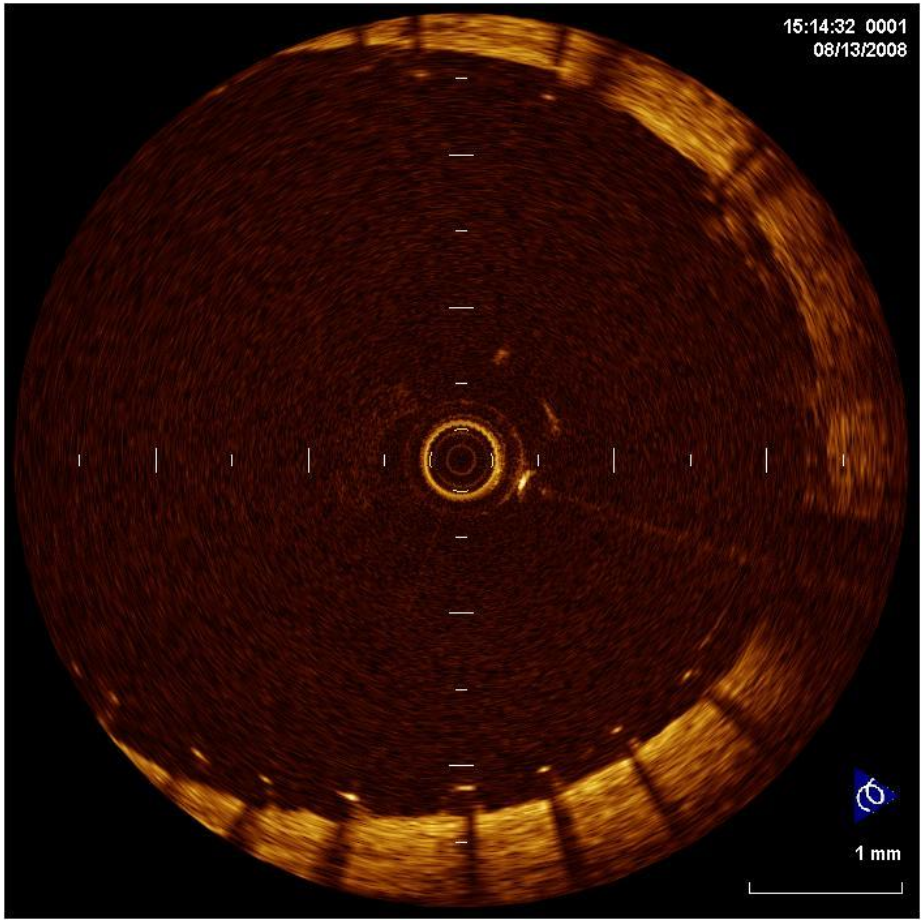
Surprise Surprise
Black & White

Case 3

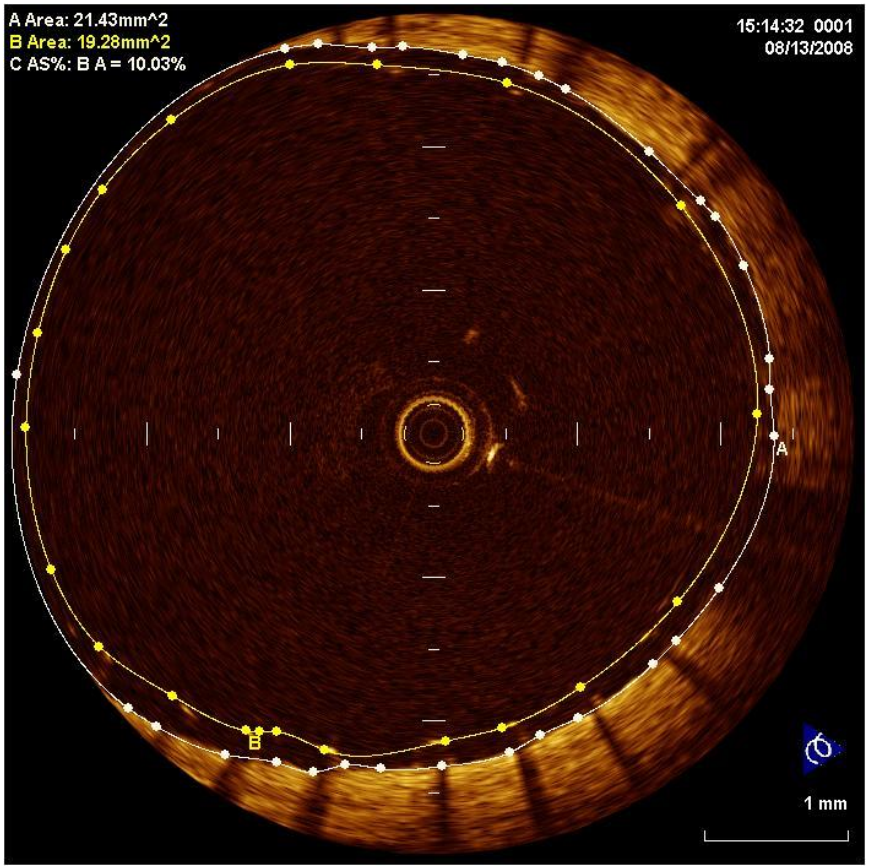


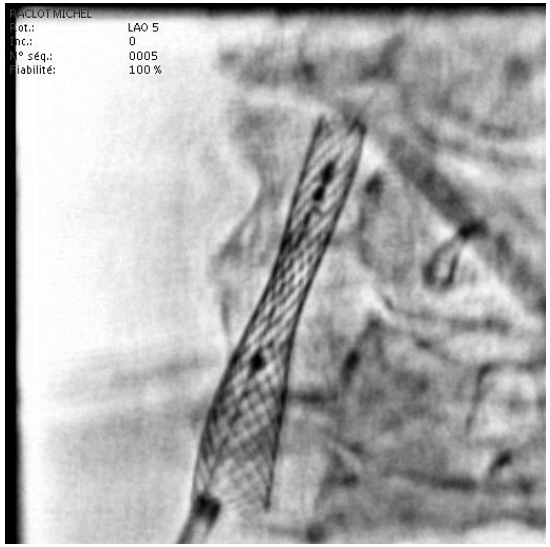
Control Post stenting

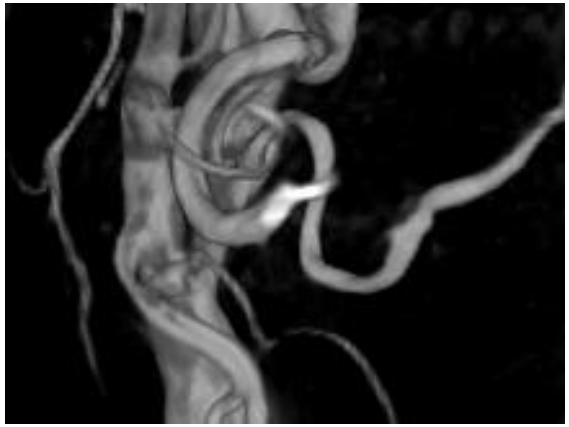




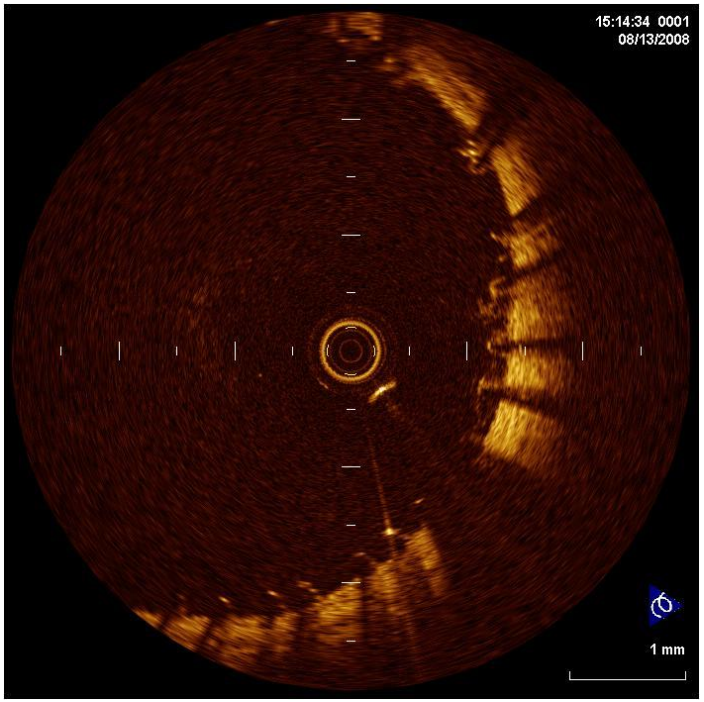
Visualisation of malposition





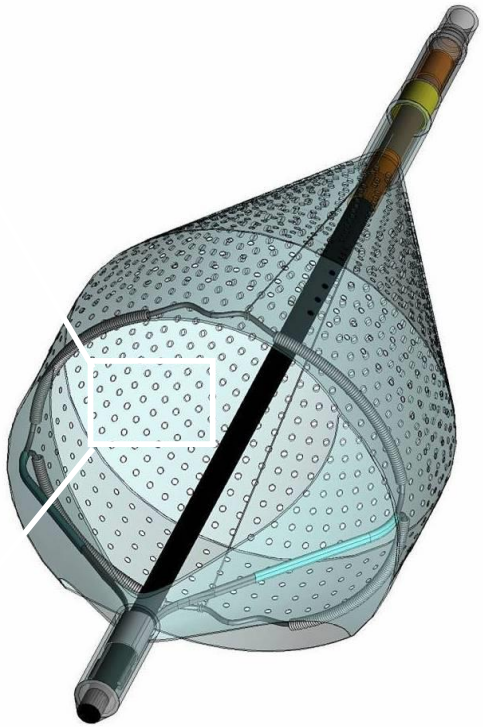


Protrusion and material between struts



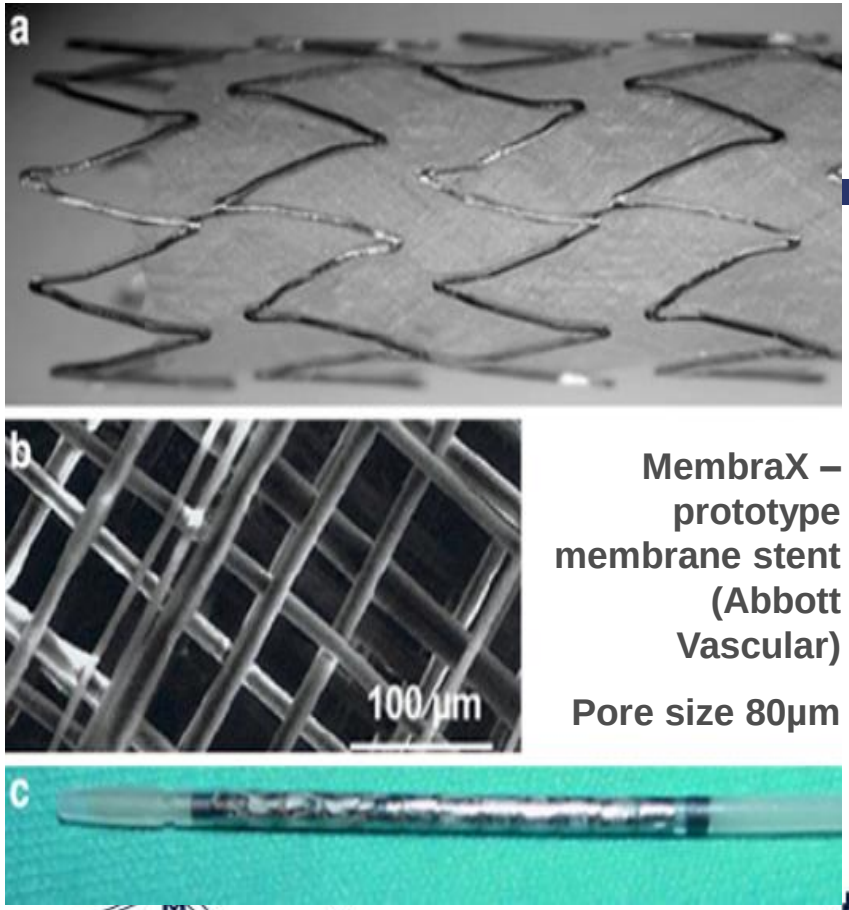
Future scaffolding solutions???

- **Flexible *porous membrane* stent *(+/- 100 µm ~ EPD)***



Future scaffolding solutions???

- **Flexible *porous membrane* stent**



MembraX – prototype membrane stent (Abbott Vascular)

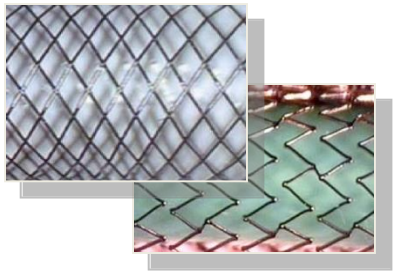
Pore size 80µm

Membrane stent has potential for reducing the late emboli

Müller-Hülsbeck et al. Cardiovasc Intervent Radiol 2006;29:630-636.

Closed Cell Concept

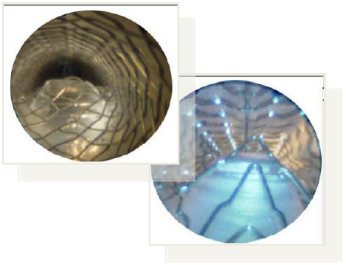
Scaffolding



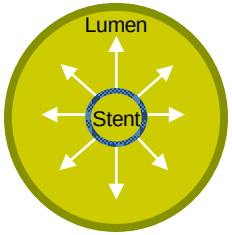
Stroke

Prevention

Structure



Radial Force



The relationship of post CAS hypotension to stent type – Dr. Katzen

Purpose

- To assess whether there is a significant difference in the incidence of peri-procedural hypotension requiring treatment related to stent type used in the carotid artery for de novo lesions.

Conclusion

Nitinol carotid stents exhibit 2x greater risk of peri-procedural hypotension than Carotid Wallstent.

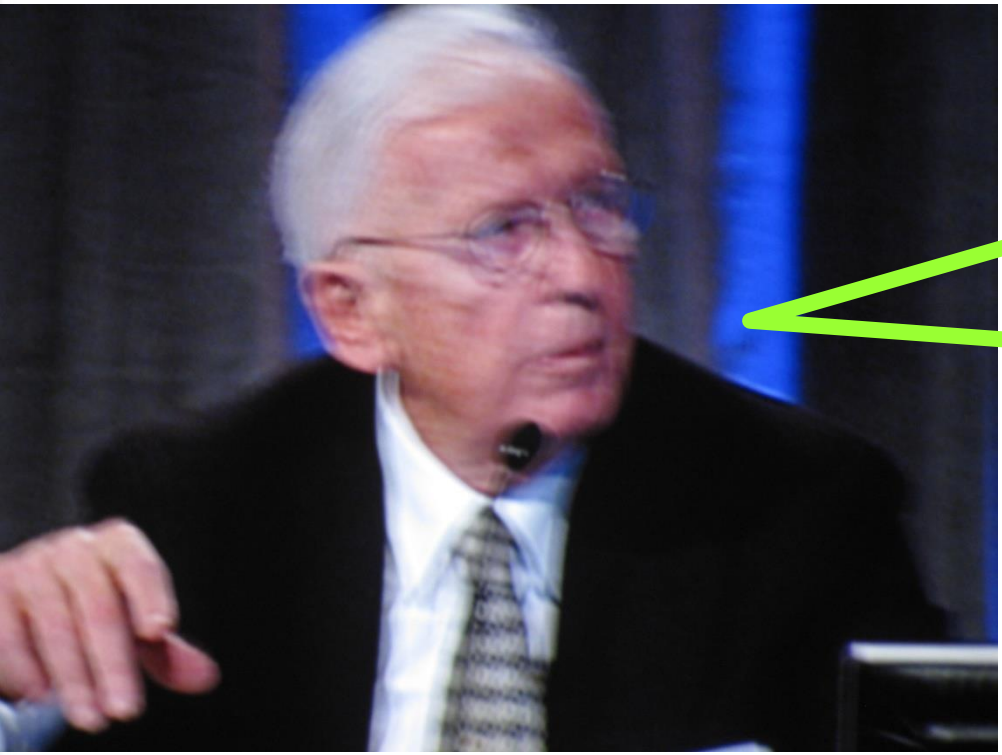
Incidence of Hypotension	Nitinol[1] (n=141)	Carotid Wallstent (n=31)	t-test
Periprocedural Hypotension	31.0%	12.9%	p=0.045
All Hypotension	40.4%	19.4%	p=0.014

The Pro M.H Wholey Esq

Outcome of carotid artery stenting at 2 years follow-up: comparison of nitinol open cell versus stainless steel closed cell stent design.

Maleux G, Marrannes J, Heye S, Daenens K, Verhamme P, Thijs V.
Department of Radiology, University Hospitals Leuven, Leuven, Belgium
J Cardiovasc Surg (Torino). 2009 Oct;50(5):669-75. Epub 2009 May 19

- **This was a non-randomized, retrospective study including 123 patients in whom 132 carotid stent-procedures were performed**
- **In 72 procedures a closed cell stainless steel stent was implanted, in the remaining 60 procedures an open cell nitinol stent was placed. In 8 patients with a stainless steel stent (11%) and in 6 patients with a nitinol stent (10%) a stroke occurred during the follow-up period (P=0.79).**
- CONCLUSIONS: **At 2-year follow-up after carotid artery stenting, there is no difference in clinical outcome or in stent patency among patients treated with open versus closed cell design stents. Subsequently the type of carotid stent design does not seem to impact the overall midterm outcome after carotid artery stenting.**



Size of the cells
Only matters !

Deformation of closed cells

A pocket is a deformable closed cell

FORGET THE DOG BEWARE OF OWNER!

TCT2009