New Designs in Carotid Stents: Micromesh Technology compared with Open or Closed Cell Design

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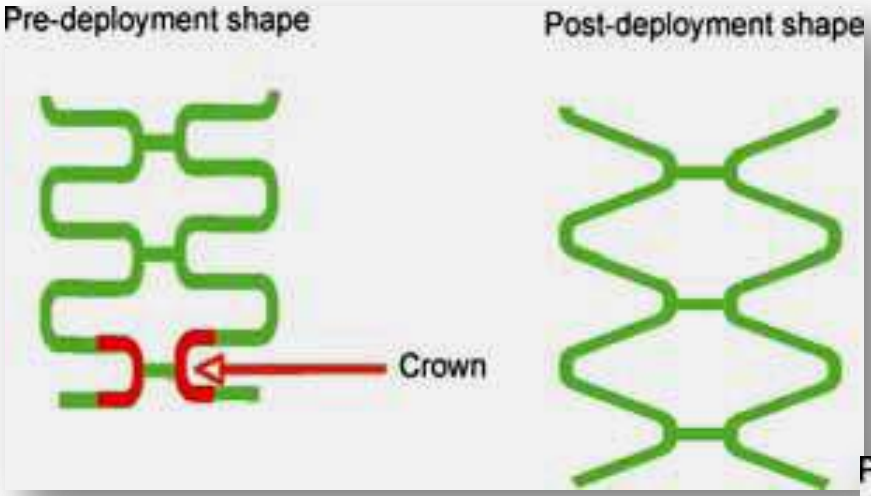
Disclosures

- Consultant to Silk Road Medical, Contego, Abbott Vascular, WL Gore, Medtronic, BSC

What are the possible causes of stroke in CAS?

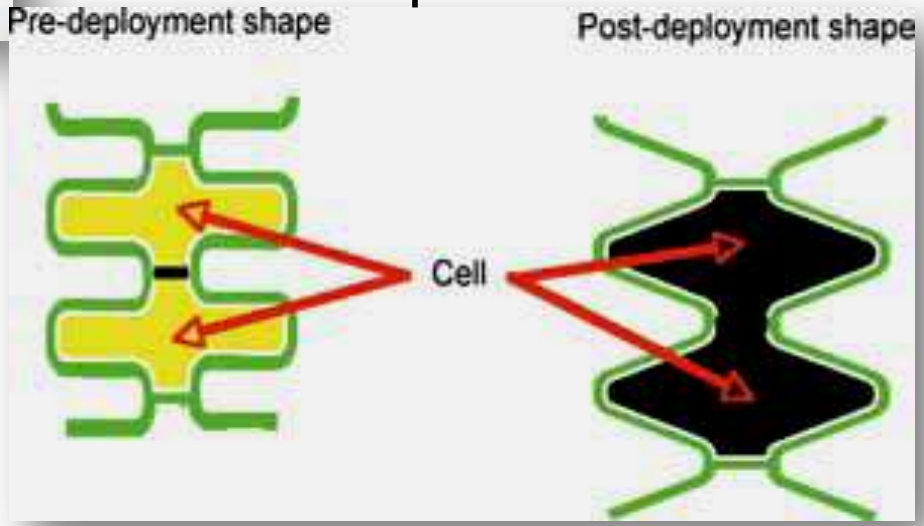
- Operator error
  - Technique (balloon sizing, wire misadventure, EPD error, etc.,)
- Patient factors
  - Vulnerable plaque (lesion, carotid, aorta)
  - Vascular anatomy or characteristics (calcium, thrombus, etc.,)
  - Genetics related to thienopyridine metabolism
- Inadequate technology
  - EPD, stent, procedural pharmacology

Open and closed cell design elements

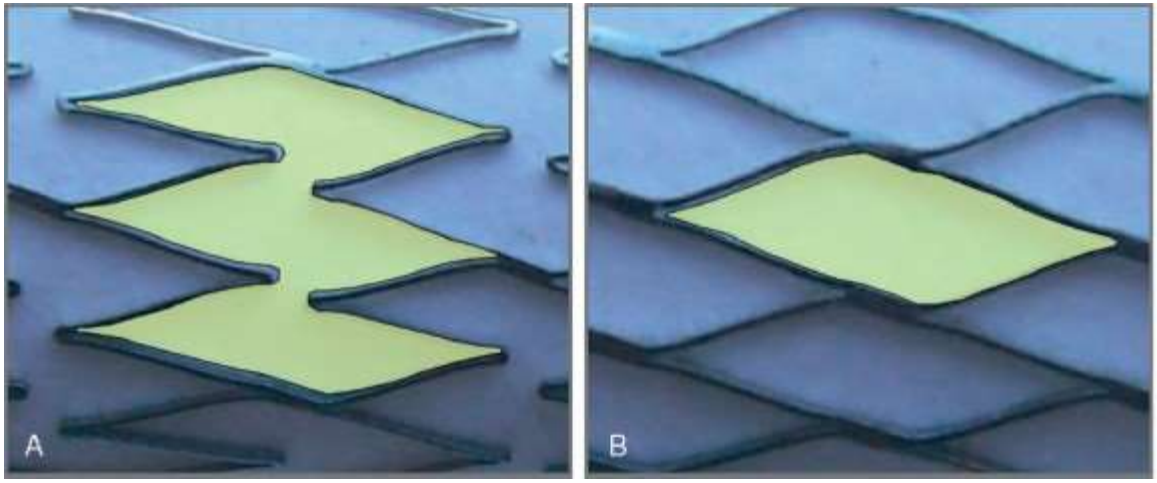


Closed cell

Open cell



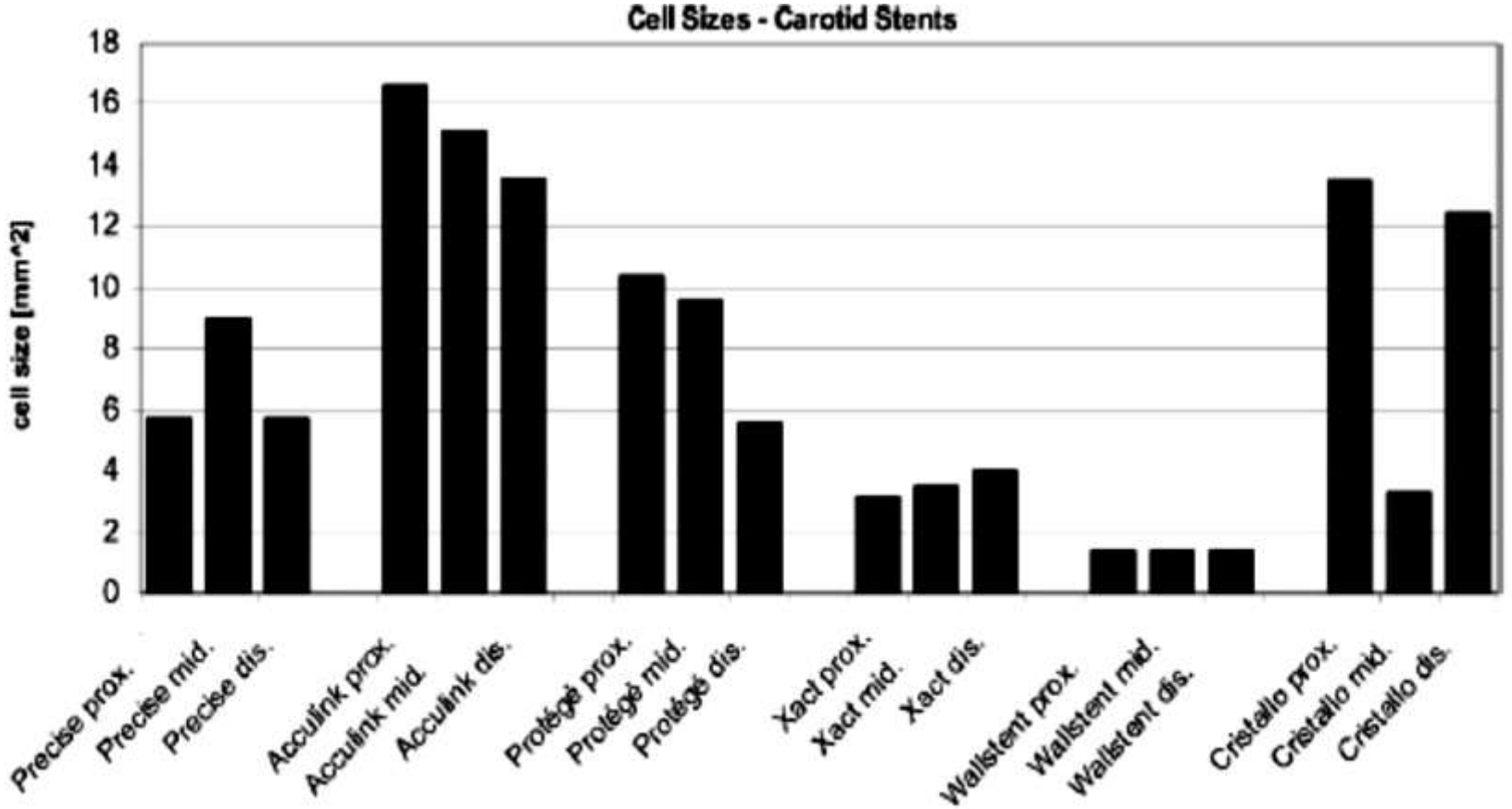
Stent design: open vs. closed cell



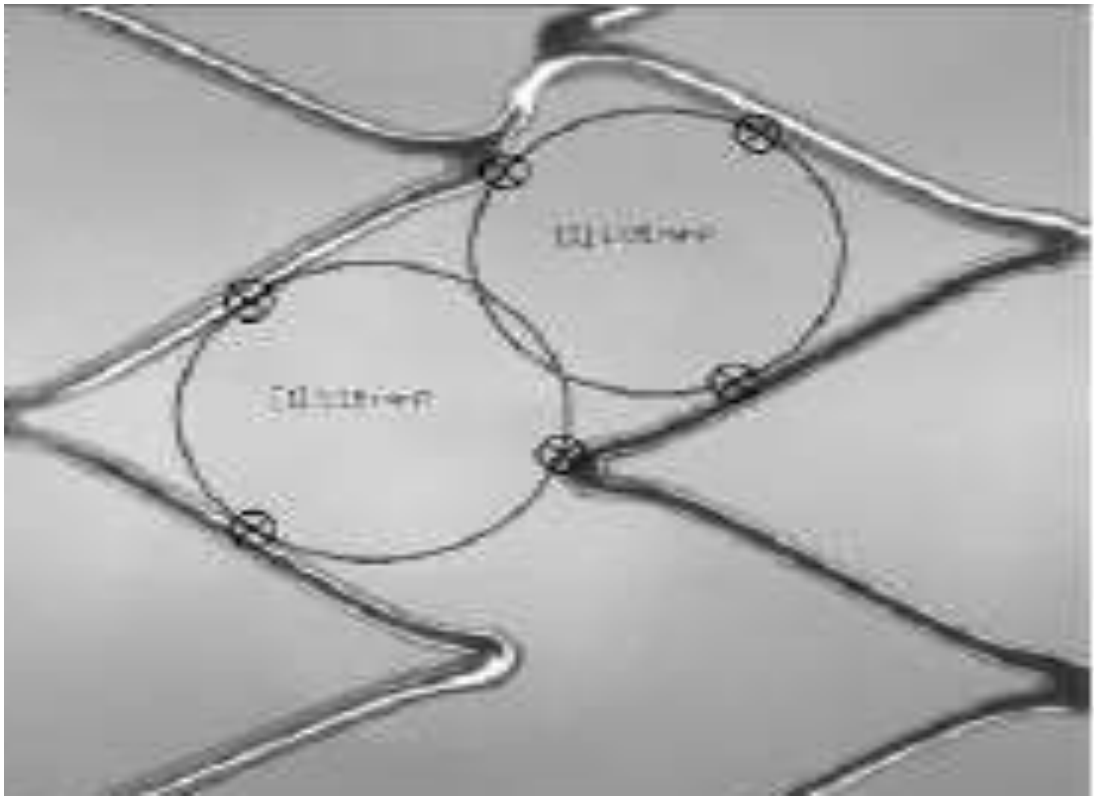
Closed cell stent leading to kinking

Open cell stent conforming to vessel

Differences in cell size by stent

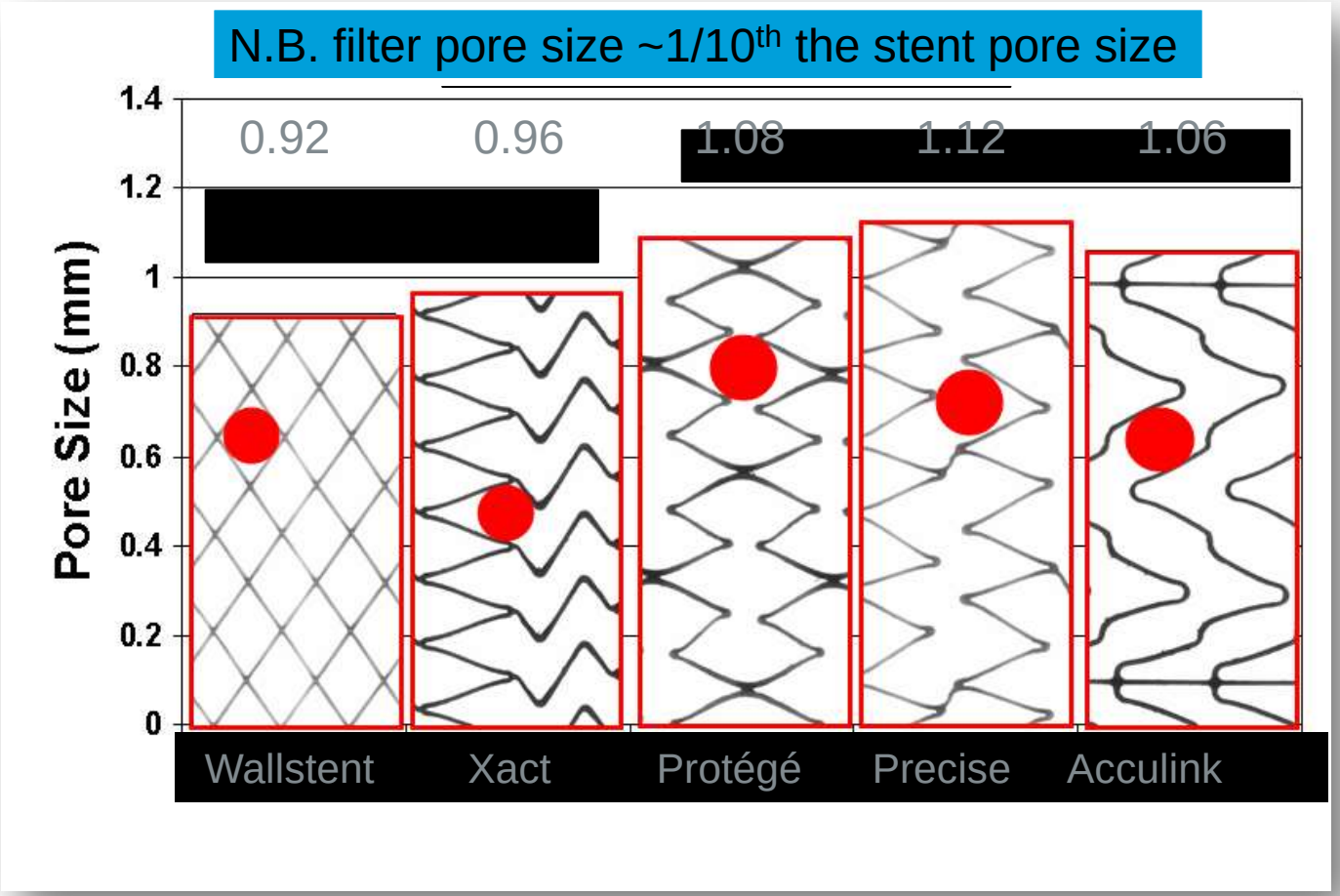


Also need to consider MCUSA



Pore (MCUSA) sizes

No significant difference between OC and CC stents



Xact, PROTÉGÉ RX and Acculink = 8-6mm tapered stents (distal portion)

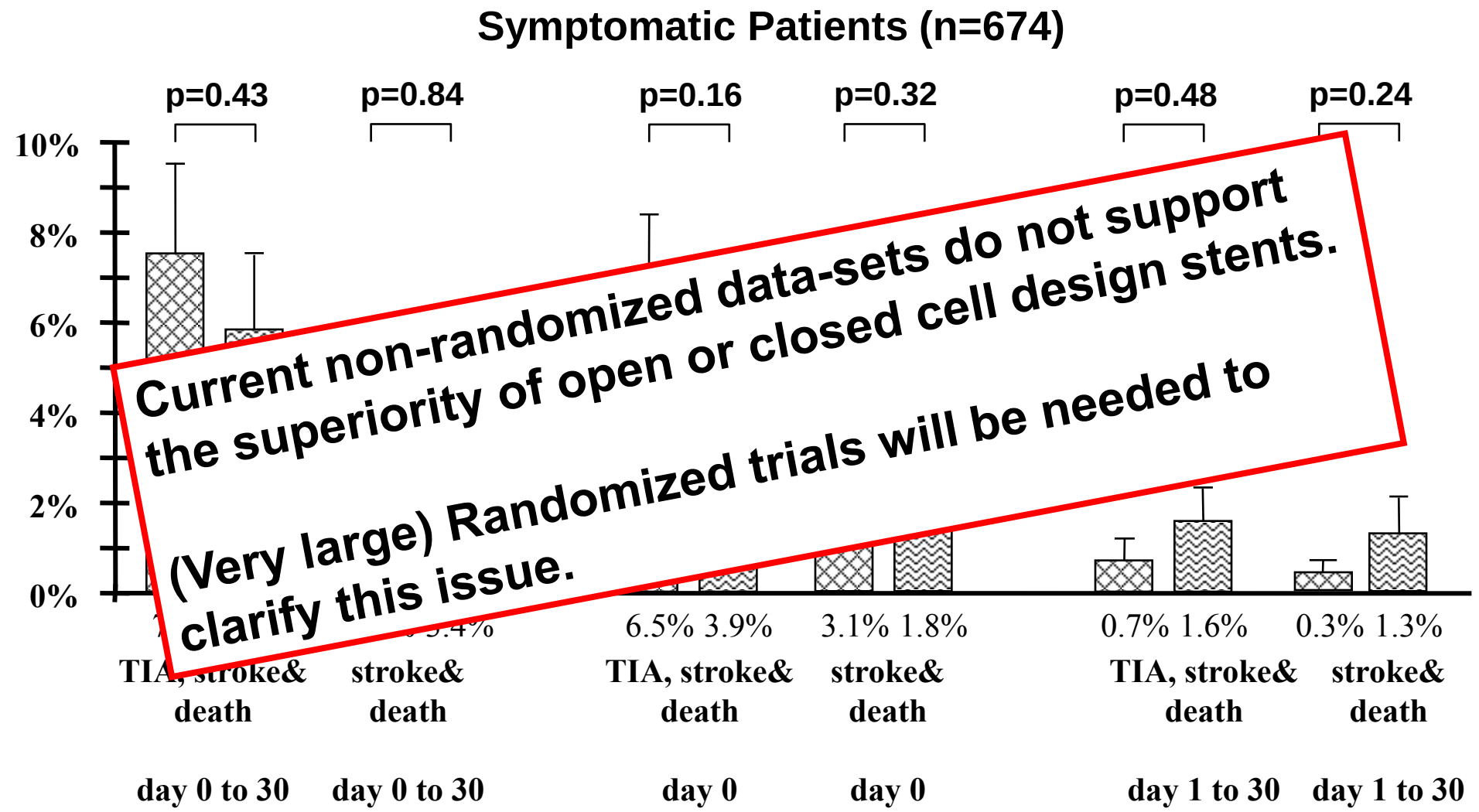
Precise and Wallstent = 8mm straight stent

Clinical event rates vary by free cell area?

	Total population			Symptomatic population			Asymptomatic population		
	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events
Free cell area									
<2,5 mm^2	2107	48	26	882	20	11	1225	28	15
2,5–5 mm^2	135	3	3	52	1	1	83	2	2
5–7,5 mm^2	327	16	11	155	10	8	172	6	3
>7,5 mm^2	610	23	21	228	17	16	382	6	5
Total	3179	90	61	1317	48	36	1862	42	25
Free cell area									
<2,5 mm^2		2.3%	1.2%		2.3%	1.2%		2.3%	1.2%
2,5–5 mm^2		2.2%	2.2%		1.9%	1.9%		2.4%	2.4%
5–7,5 mm^2		4.9%	3.4%		6.5%	5.2%		3.5%	1.7%
>7,5 mm^2		3.8%	3.4%		7.5%	7.0%		1.6%	1.3%
Total	3179	2.83%	1.9%	1317	3.6%	2.73%	1862	2.25%	1.3%

Bosiers M, de Donato G, Deloose K, Verbist J, Peeters P, Castriota F, Cremonesi A, Setacci C. Does free cell area influence the outcome in carotid artery stenting? Eur J Vasc Endovasc Surg. 2007 Feb;33(2):135-41;

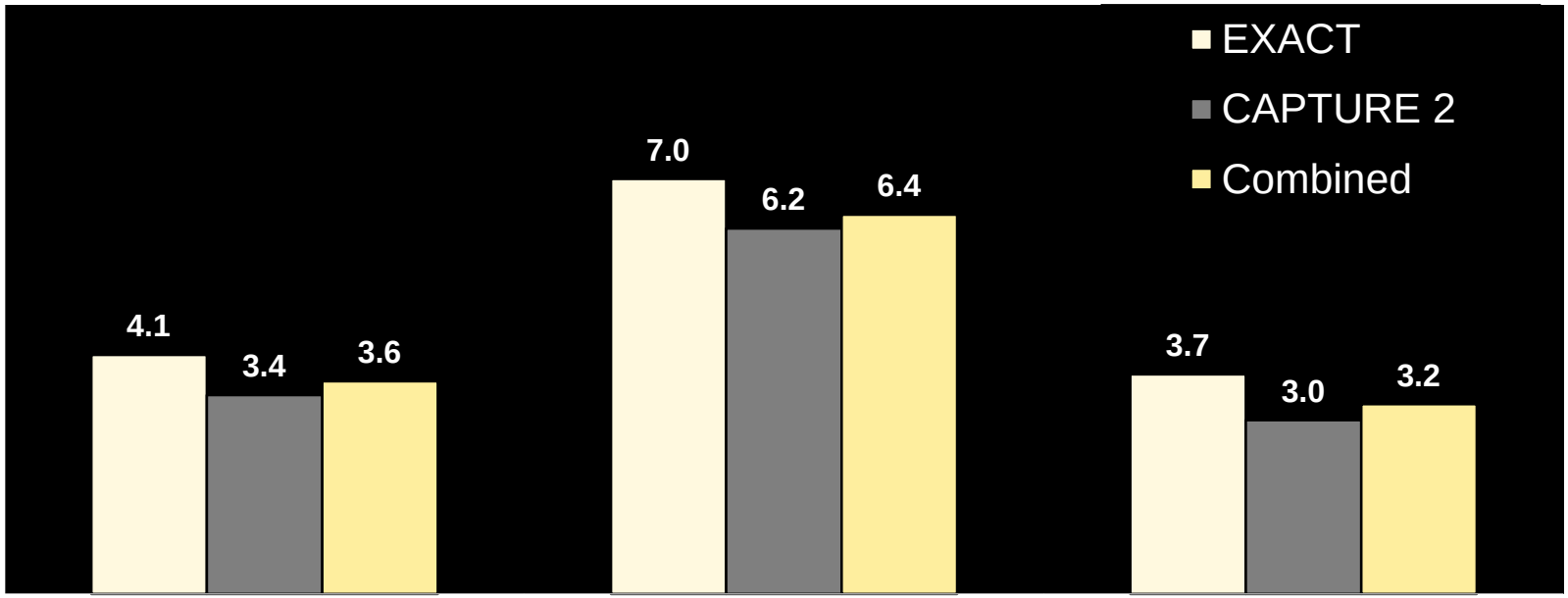
European Registry: no effect of stent type on outcomes



Current non-randomized data-sets do not support the superiority of open or closed cell design stents.

(Very large) Randomized trials will be needed to clarify this issue.

EXACT (CC) and CAPTURE 2 (OC)
No differences in prospective, adjudicated study

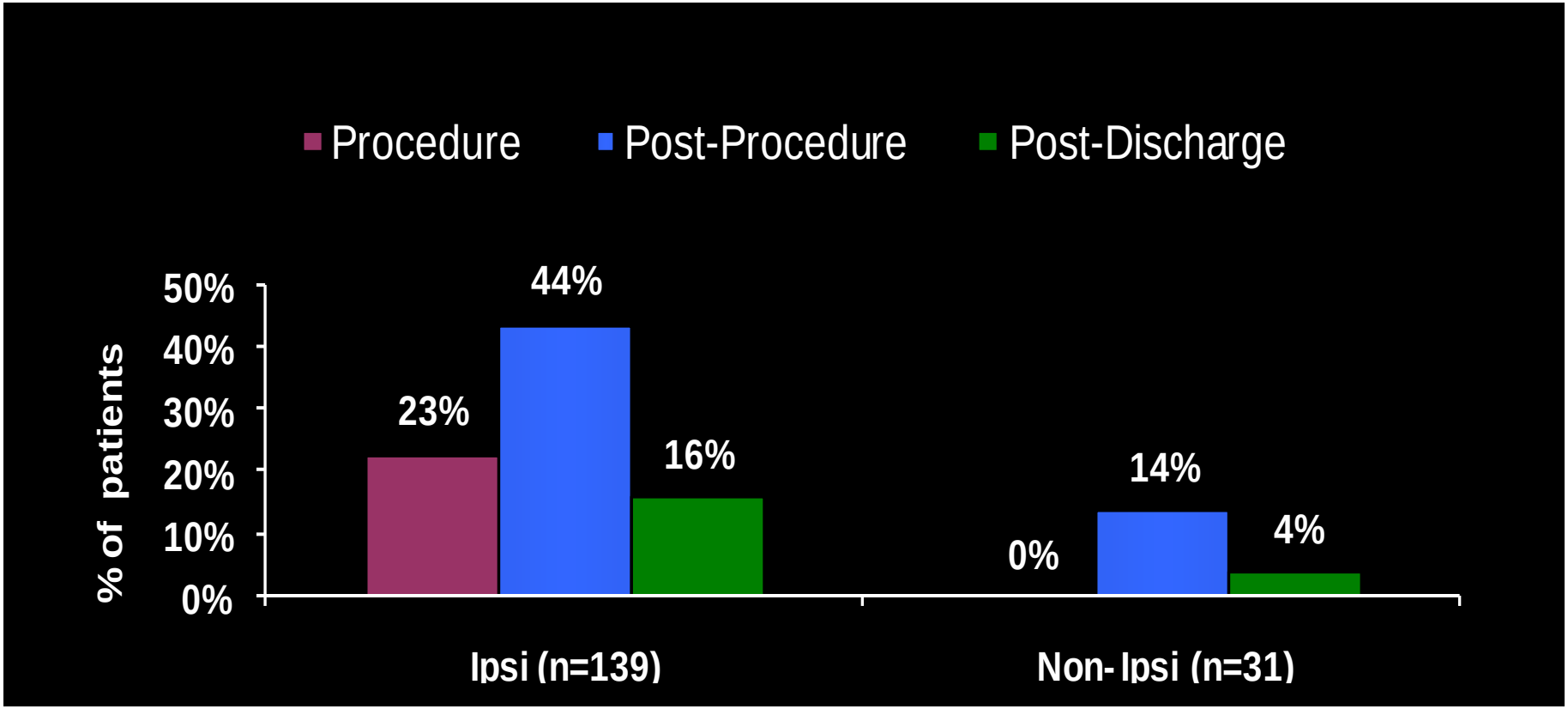


EXACT (N=2145)*
CAPTURE 2 (N=4175)
Combined (N=6320)

EXACT (N=213)
CAPTURE 2 (N=548)
Combined (N=761)

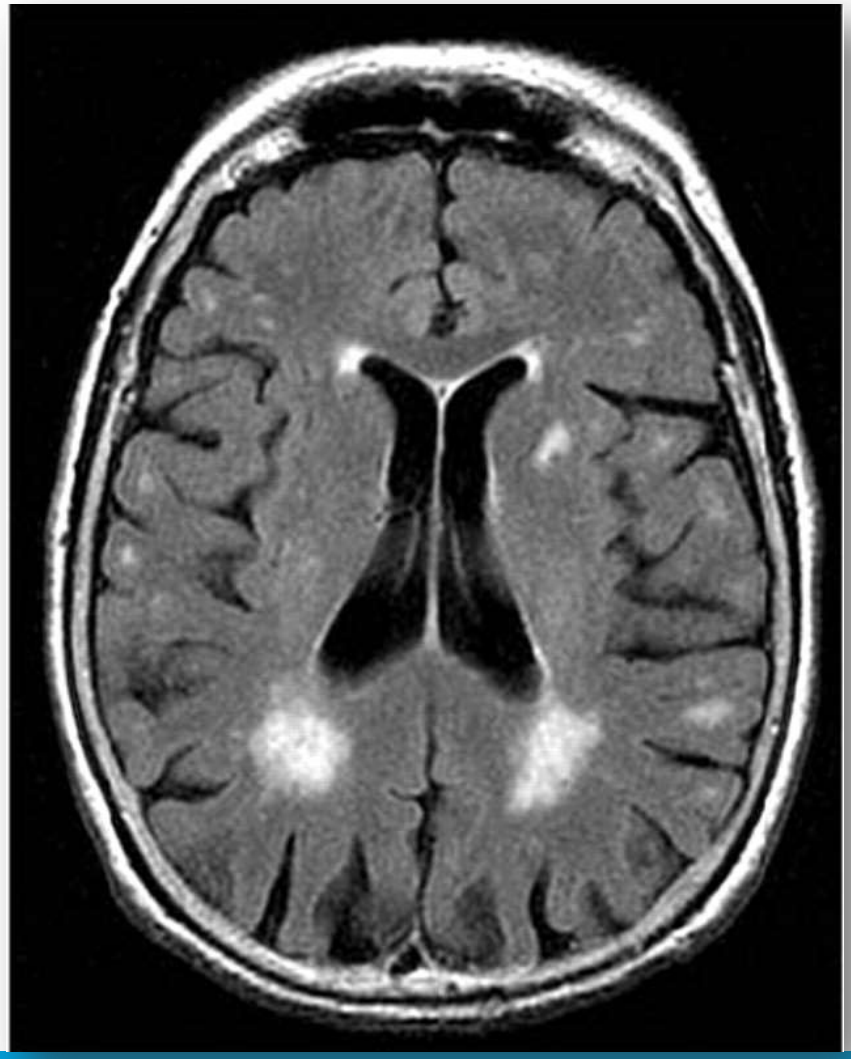
EXACT (N=1931)
CAPTURE 2 (N=3627)
Combined (N=5558)

Stroke timing paradox: Not all strokes appear on the day of the procedure



Fairman R, Gray W, Scicli A et al. Ann Surg 246 (4) Oct 2007

MRI DWI white matter changes post CAS are greater than CEA: numerically but not by volume



Fly-through of a conventional stent

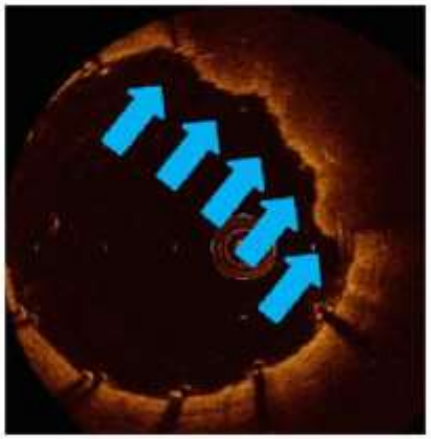
Post-procedural **PLAQUE PROLAPSE** through **conventional stent** struts

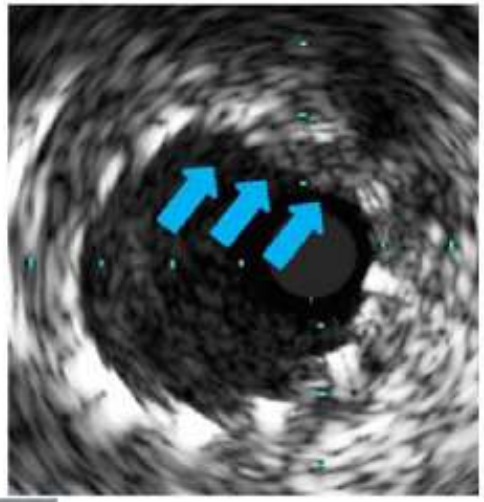
Suzuki M et al.
ESC 2014
Presentation
www.escardio.org

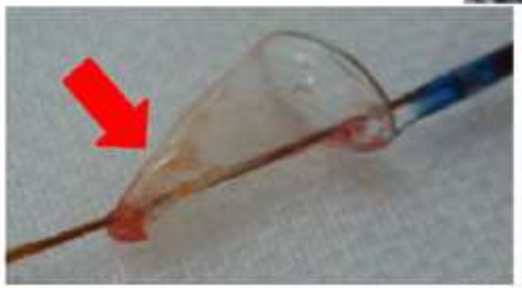
30.7%

1/3 stents = **Precise**
2/3 stents = **Carotid Wallstent**

81 y.o. Female, Symptomatic



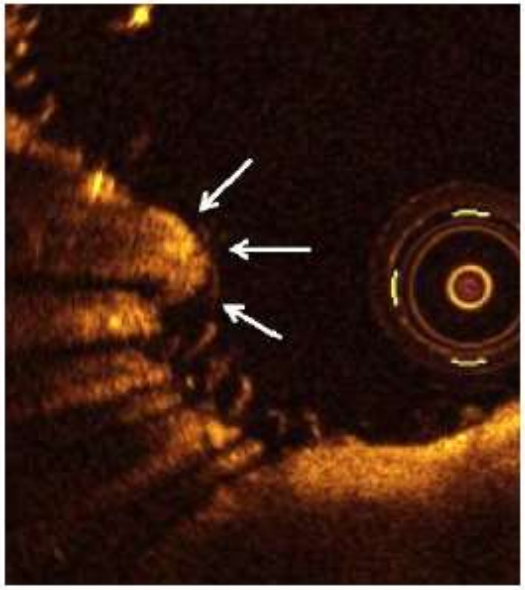




Images: Dr M. Suzuki
ESC 2014
www.escardio.org

Eur Heart J. 2014;35(Abstr Suppl):178

Plaque prolapse on OCT common



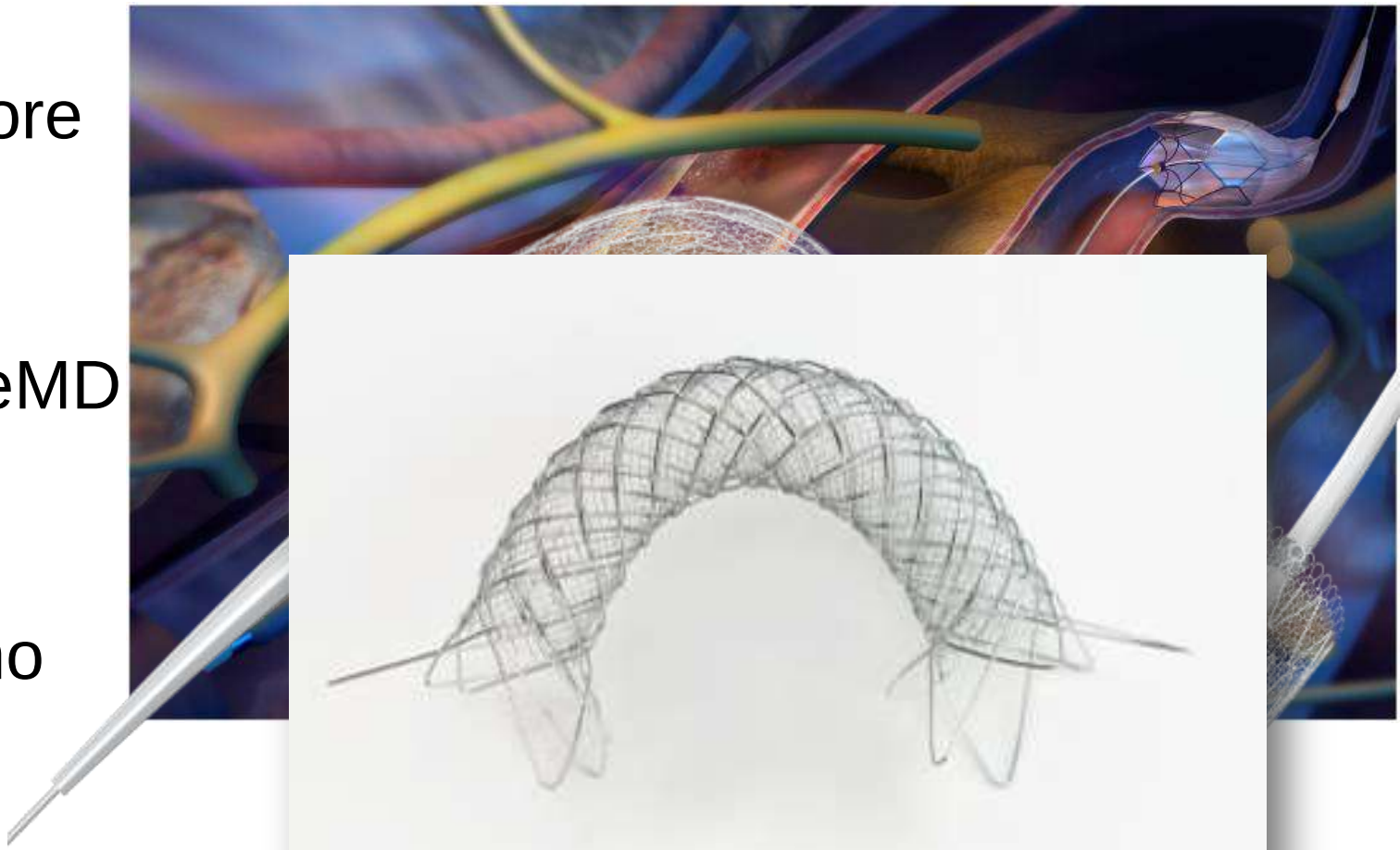
	Closed cell ($n = 17$)	Open cell ($n = 13$)	Hybrid cell ($n = 10$)
Plaque prolapse[b]	17.6%, (3)	61.5%, (8)	30%, (3)

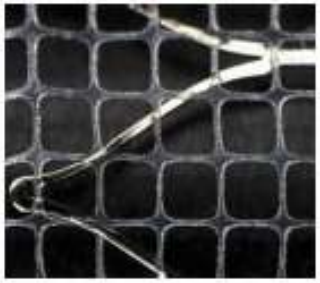
[b] At least 10 appreciable tissue prolapses between the stent struts per patient.

De Donato et al. *Eur J Vasc Endovasc Surg* 2013;45:579-587

New mesh stent designs

- WL Gore
- InspireMD
- Terumo



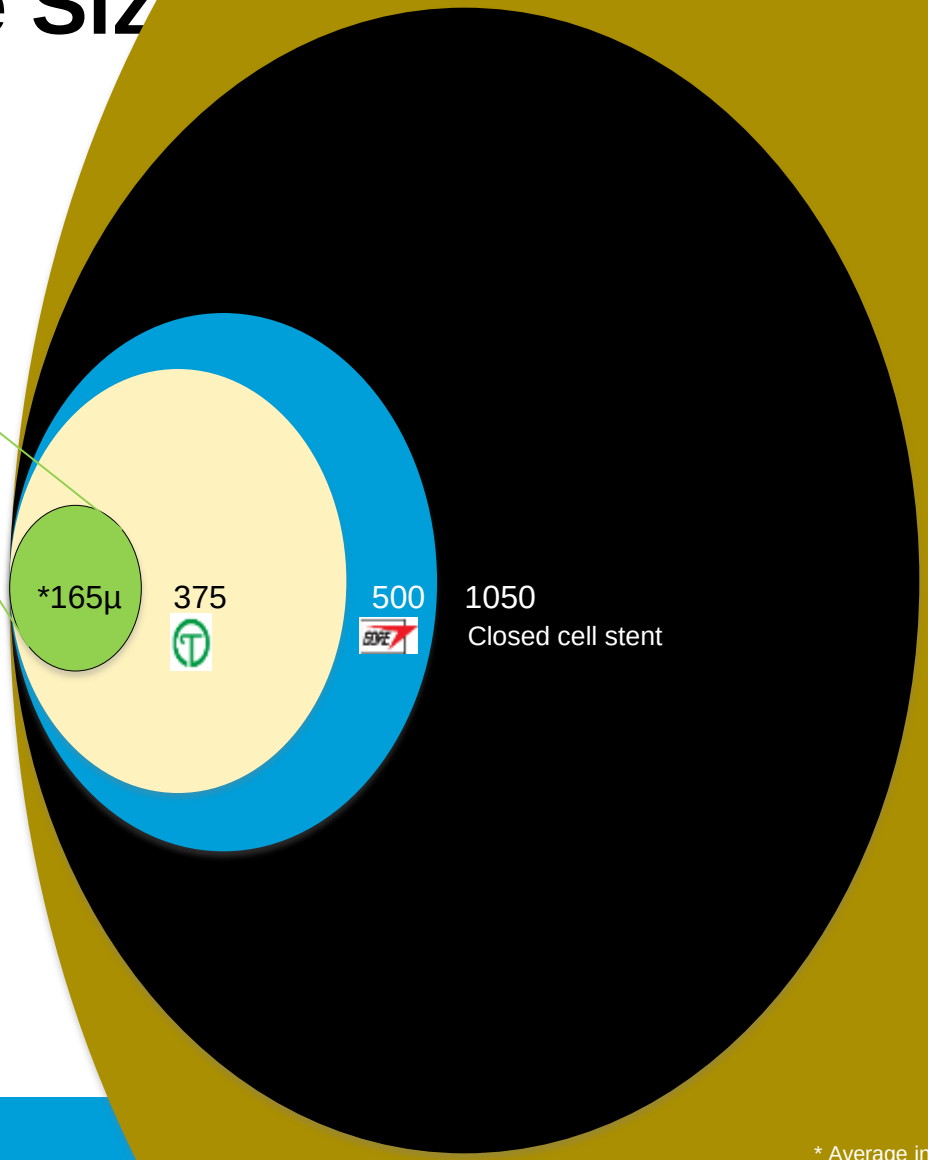
			
Name	RoadSaver *aka* Casper	Gore® Carotid Stent	CGuard™ Embolic Prevention Stent
Stent frame	closed-cell Nitinol	open-cell Nitinol	open-cell Nitinol
Mesh position in relation to frame	inside	outside	outside
Mesh material	Nitinol	PTFE	PET
Mesh structure	braided	inter-woven	single-fiber knitted
Pore size	375 µm	500 µm	150 - 180 µm

Ideal Pore Siz

CGUARD

TERUMO

GORE



* Average in lesion at expanded state

WL Gore SCAFFOLD stent

*CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.

CGUARD™

Carotid Embolic Prevention System

InspireMD

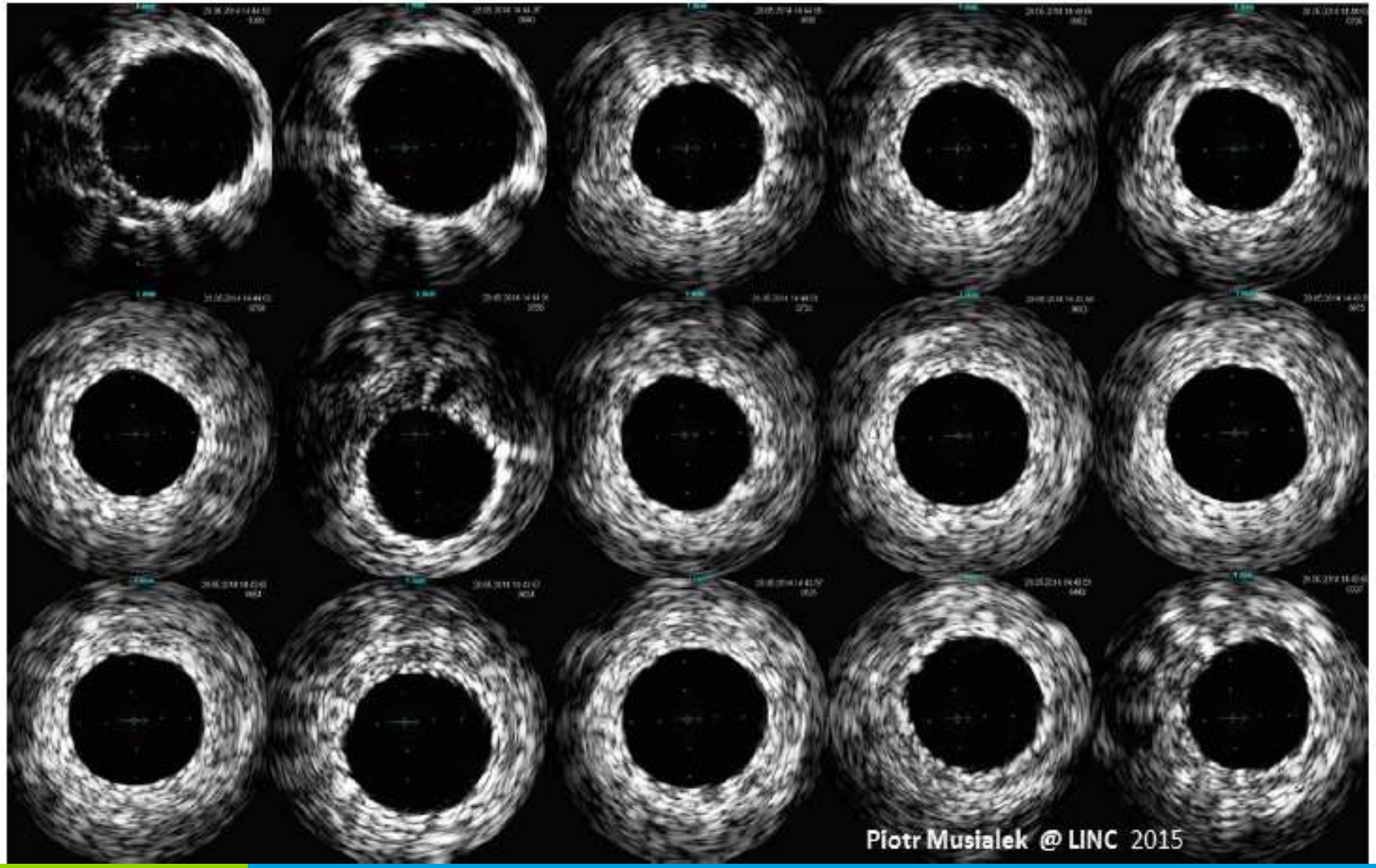
Lankenau Heart Institute
Main Line Health

CE Approved | Not available for sale in the USA

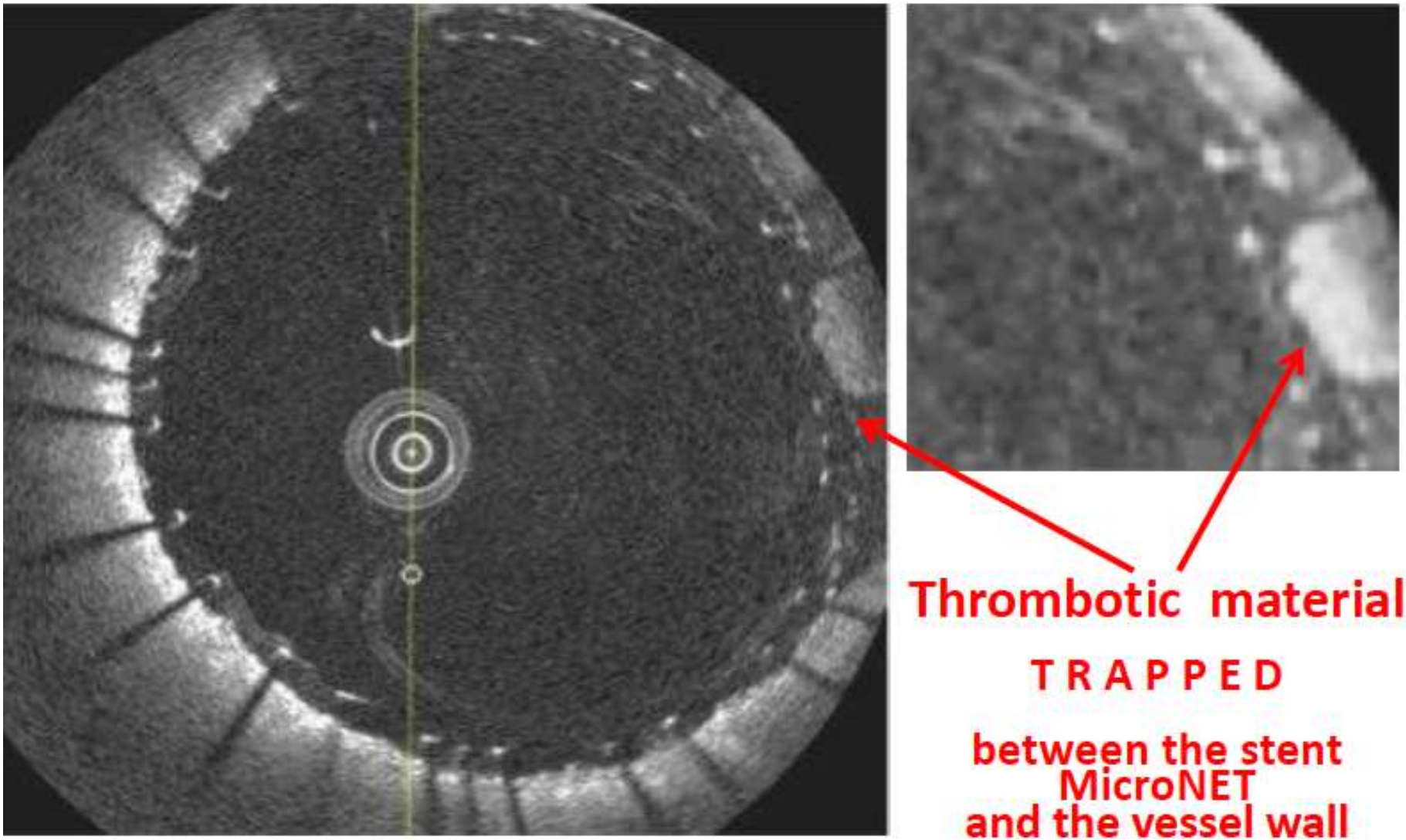
MAL-017-14-01

Initial series of CGuard™ IVUS studies indicates...

- Excellent stent expansion and apposition √
- ZERO tissue protrusion though mesh-and-struts √



CGuard™ EPS

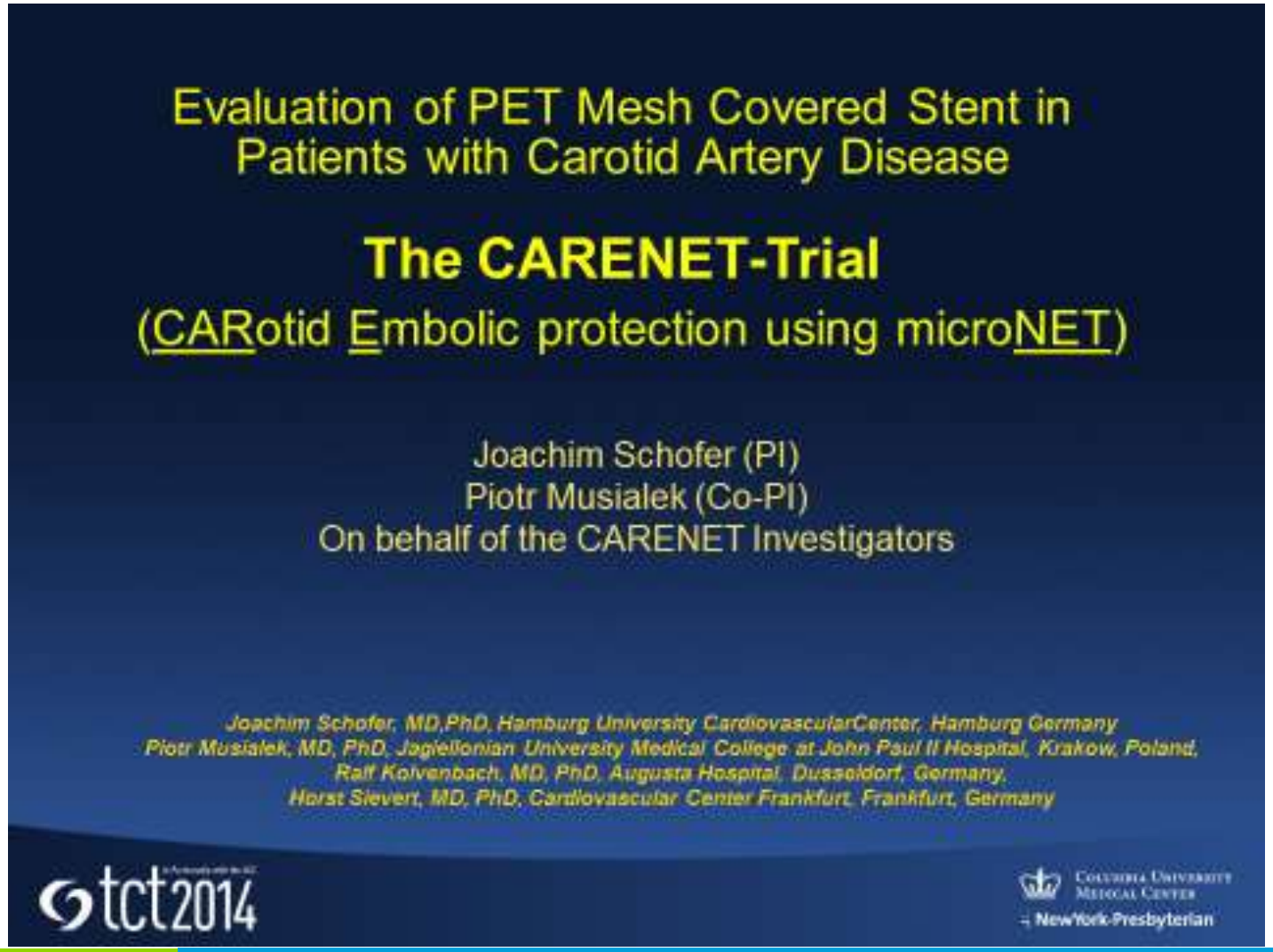


Thrombotic material

TRAPPED

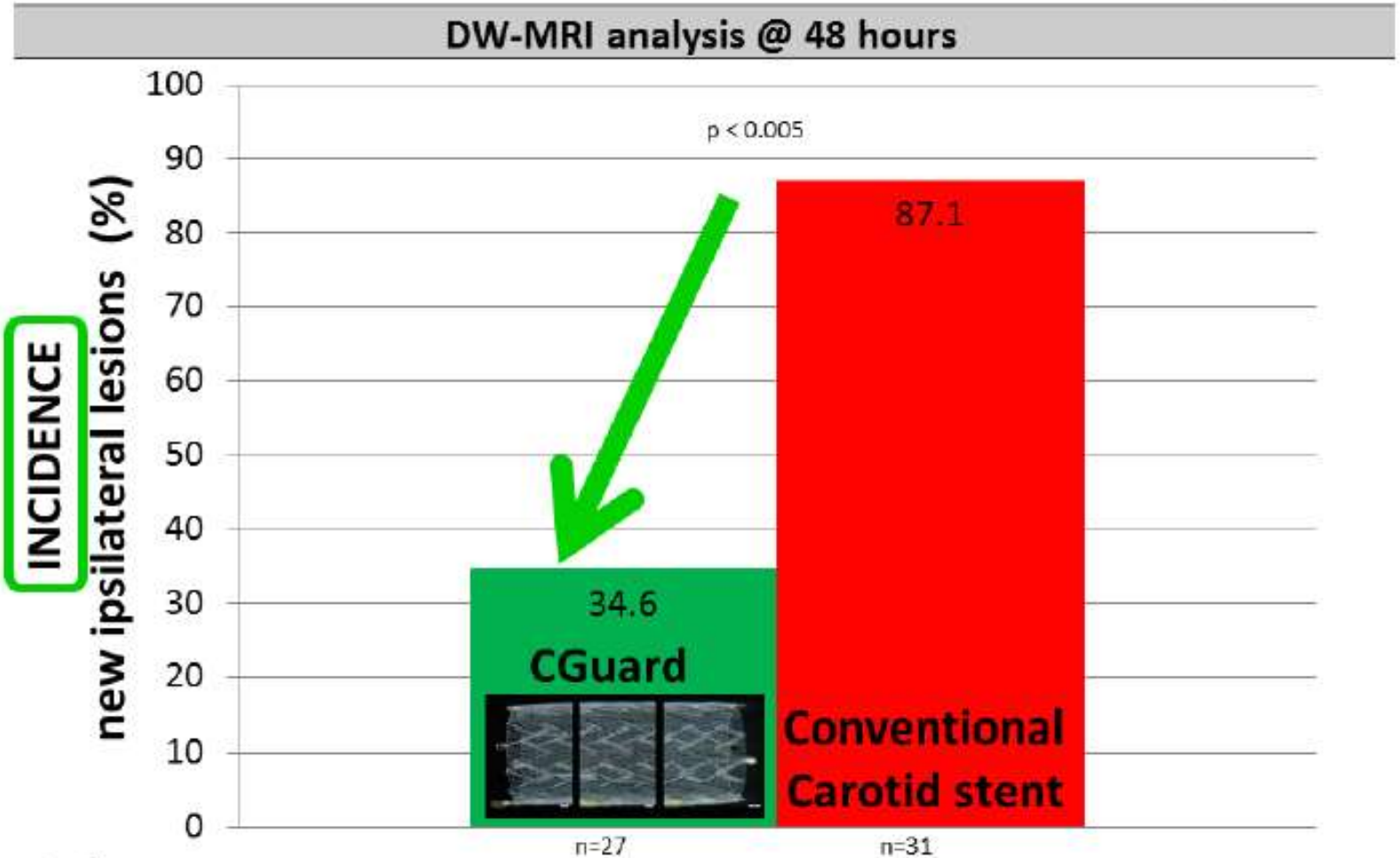
between the stent
MicroNET
and the vessel wall

CARENET I


Evaluation of PET Mesh Covered Stent in Patients with Carotid Artery Disease
The CARENET-Trial
(CARotid Embolic protection using microNET)
Joachim Schofer (PI)
Piotr Musialek (Co-PI)
On behalf of the CARENET Investigators
Joachim Schofer, MD,PhD, Hamburg University CardiovascularCenter, Hamburg Germany
Piotr Musialek, MD, PhD, Jagiellonian University Medical College at John Paul II Hospital, Krakow, Poland,
Ralf Koivenbach, MD, PhD, Augusta Hospital, Dusseldorf, Germany,
Horst Sievert, MD, PhD, Cardiovascular Center Frankfurt, Frankfurt, Germany
tct2014
Columbia University Medical Center
NewYork-Presbyterian

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis

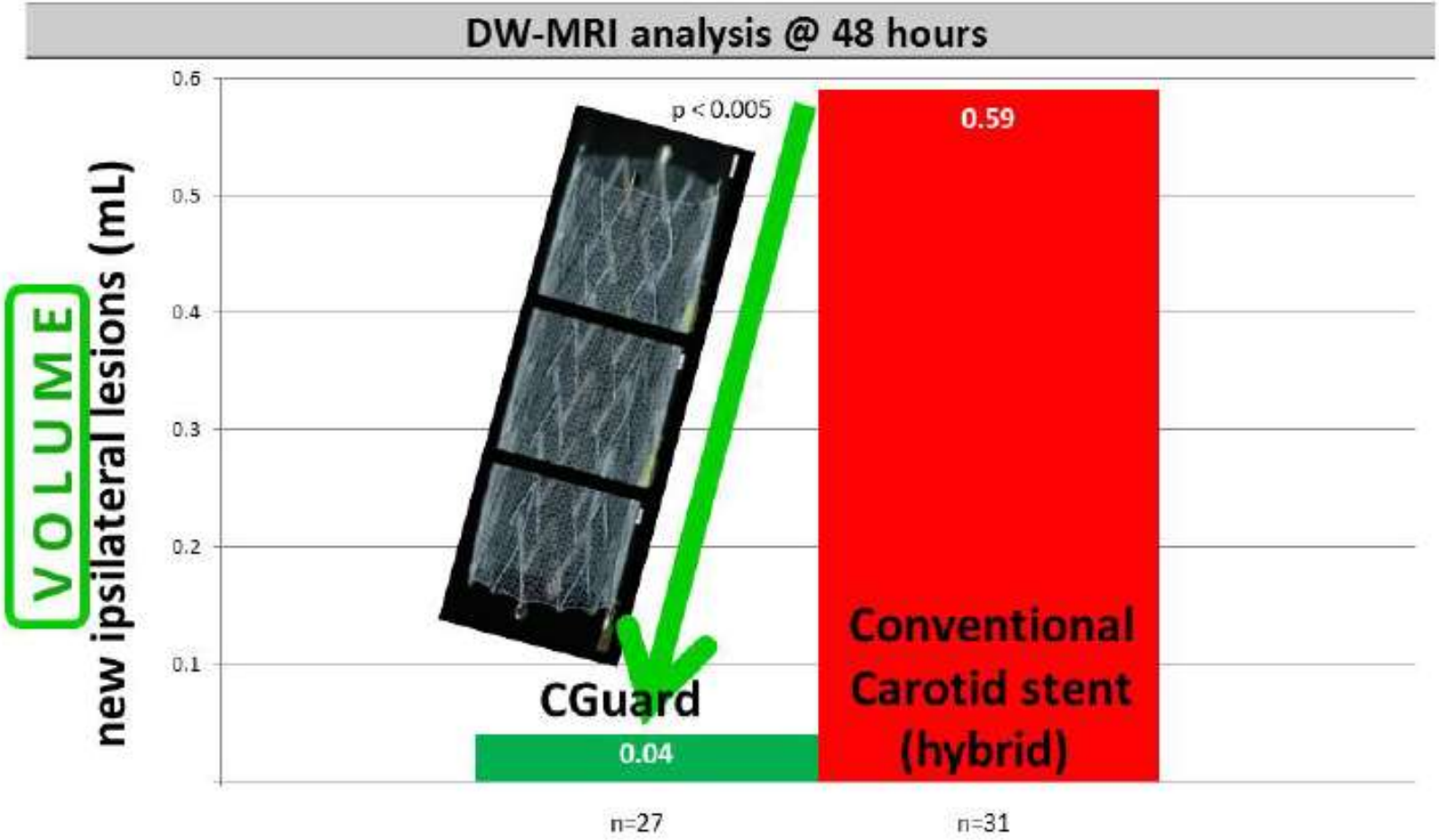


ee patient fluxogram
uklic et al. *JACC*, 2012;59

J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34
Bijuklic et al. (manuscript in preparation)

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis



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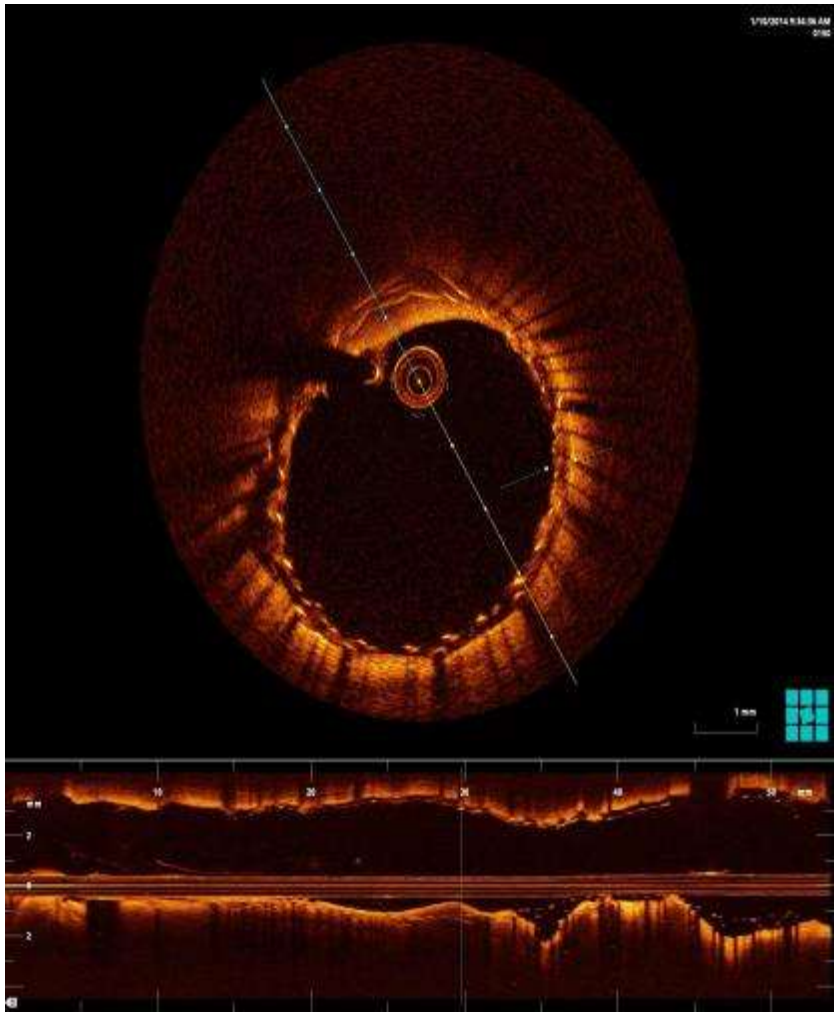
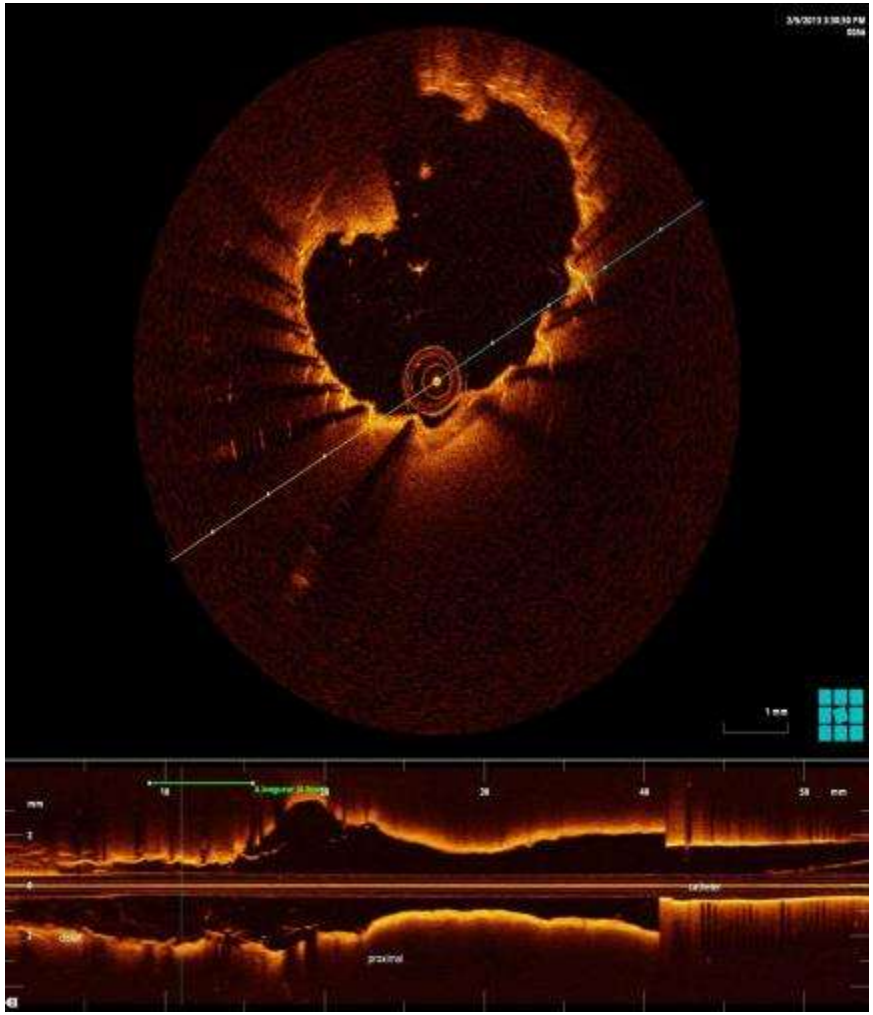
TERUMO: A Novel CAS Design

- Closed cell structure with flexible Nitinol weave
- Dual layer micromesh design for sustained embolic prevention
- Retrievable and repositionable

CASPER/Roadsaver vs. Other Closed Cell CAS OCT





Furnished by Dr. M Amor, Polyclinique Louis Pasteur, Nancy, France

Regulatory status of CASPER

- FDA IDE is in preparation for US investigation
- Initiation planned 2016

Summary

- Mesh-covered carotid stents likely to add benefit in terms of reducing not only clinical events but also surrogate DWI lesions
- As the stent becomes the “protector” and not the “provocateur”, CAS outcomes—already good—should improve further