



What the data is telling us: the first 30 days need to be safer after any carotid repair, but how?

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Disclosure

Speaker name:

.....CARLO SETACCI

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

CEA Vs CAS Trials: Current Evidence

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Vs.



Meta-analysis of RCTs – updated 2011

CONCLUSION

For every 1000 patients opting for stenting rather than endarterectomy:

19 more patients would have strokes,
3 more patients would be dead

10 fewer would have MIs

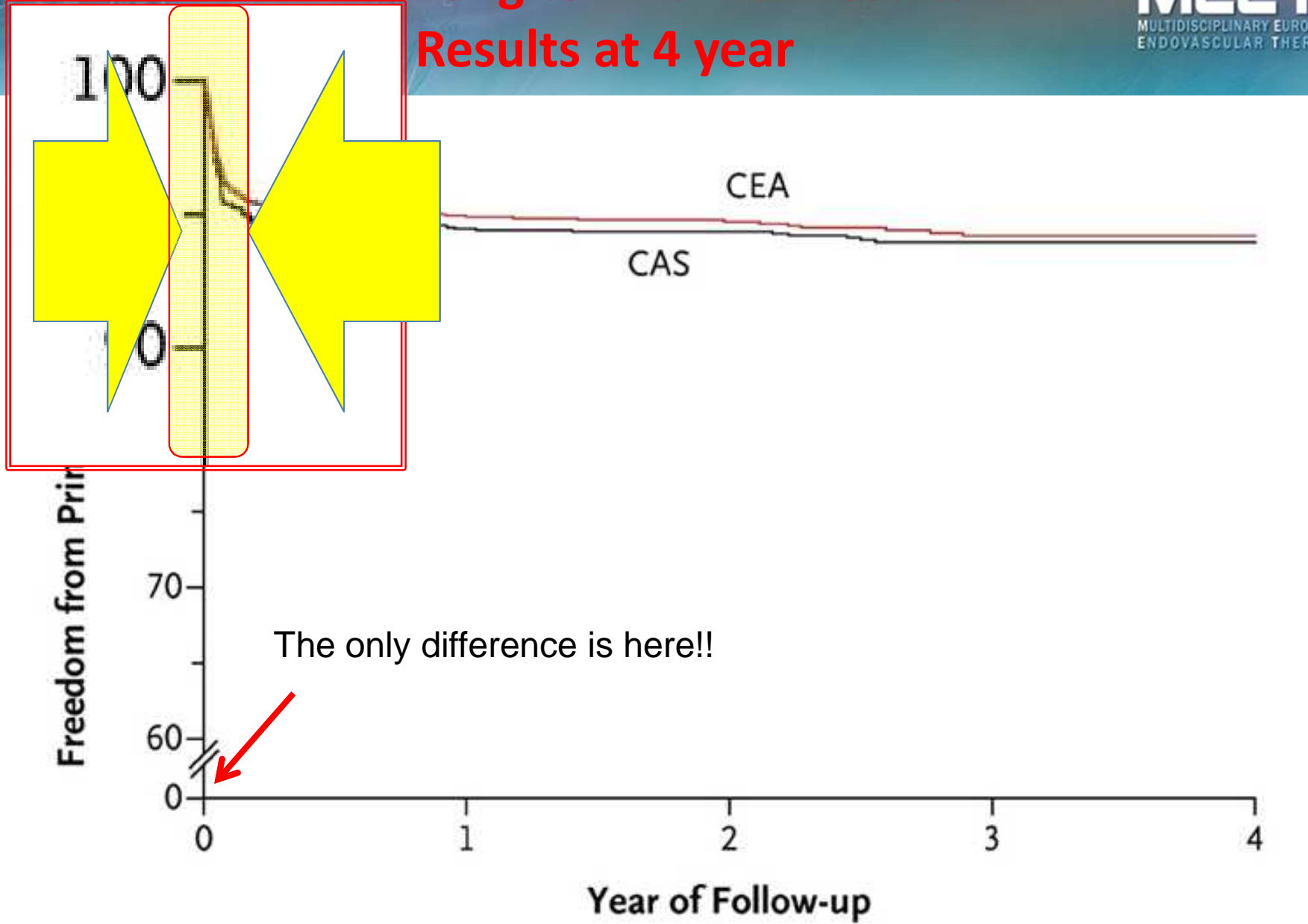
CAROTID ARTERY STENTING

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As an endovascular oriented vascular surgeon
I believe in the Renaissance of CAS



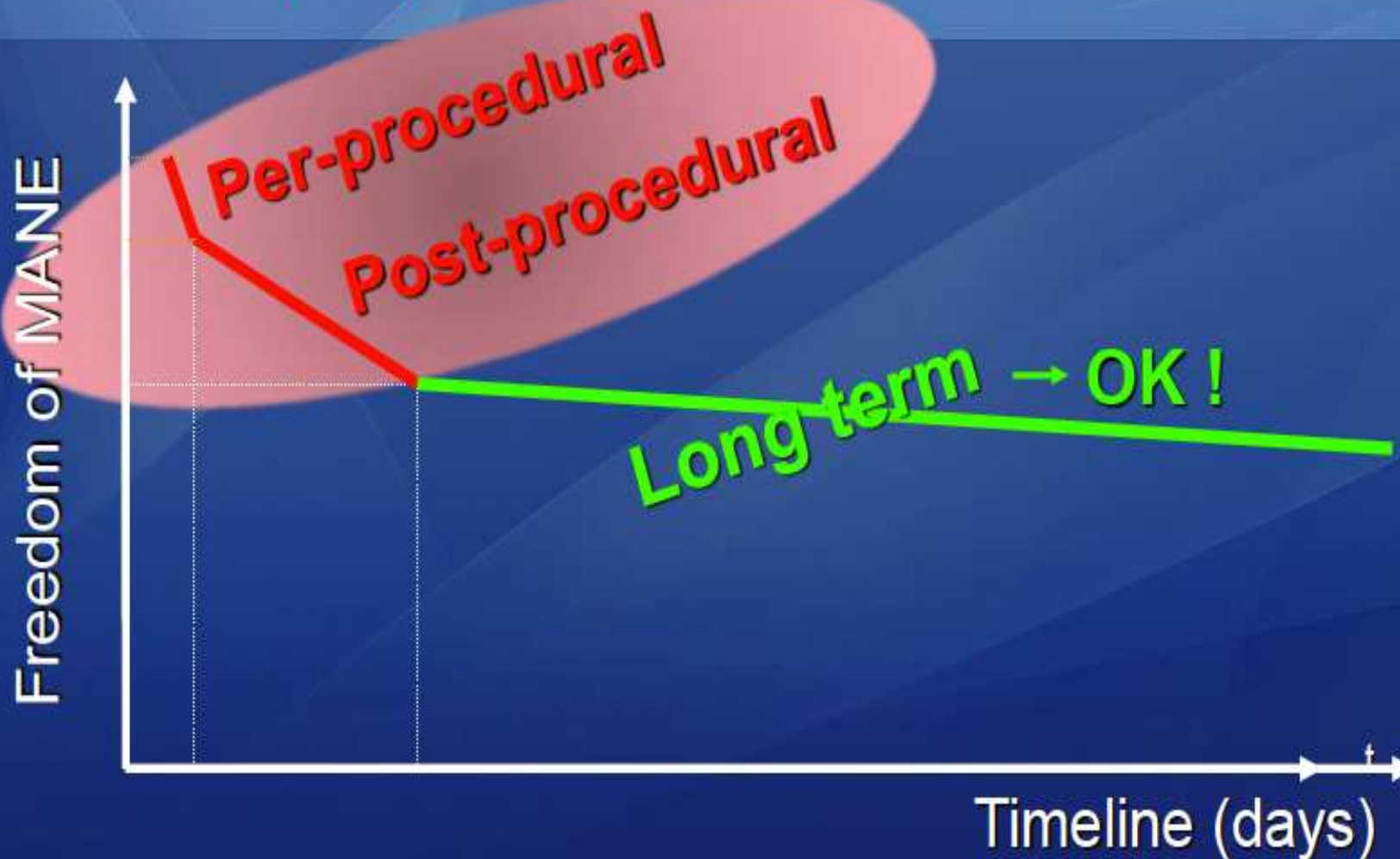
Long term CREST results : Results at 4 year



The only difference is here!!

Renaissance of CAS

Room for **periprocedural** improvement



We need better protection against SMALL emboli

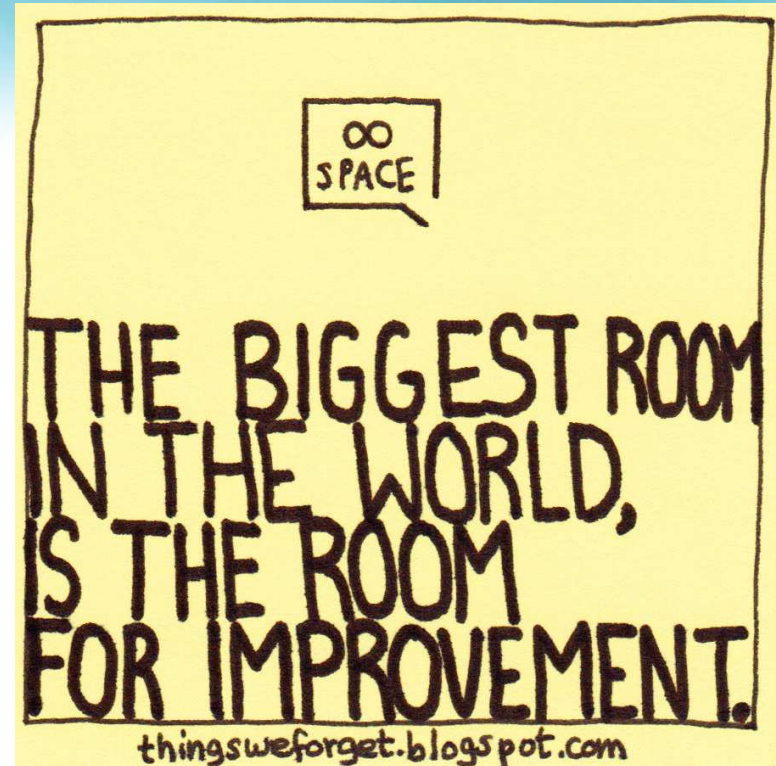
Per protocol	CAS N = 1,131	CEA N = 1,176	Difference	Unadjusted p-value*
All Death, Stroke, or MI	5.8% (65)	5.1% (60)	0.7%	0.5200
Death	0.53% (6)	0.26% (3)	0.27%	0.3335
Any Stroke	4.1% (46)	1.9% (22)	2.2%	0.0019
Major Stroke	0.9% (10)	0.4% (5)	0.5%	0.2005
Minor Stroke	3.2% (36)	1.5% (18)	1.7%	0.0088
MI	2.0% (22)	3.4% (40)	-1.5%	0.0387

Room for periprocedural improvement D0 → D30

Besides:

- Operator experience
- Patient selection
- Lesion selection

...we need a...

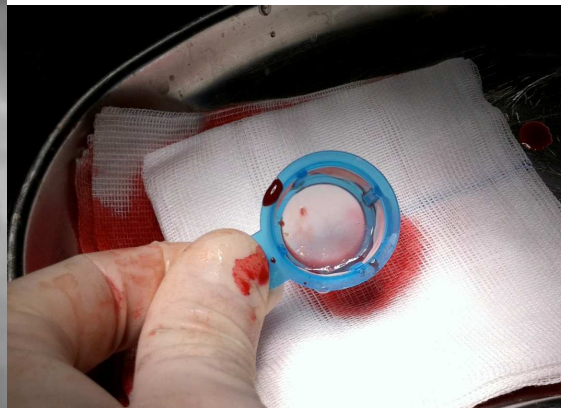
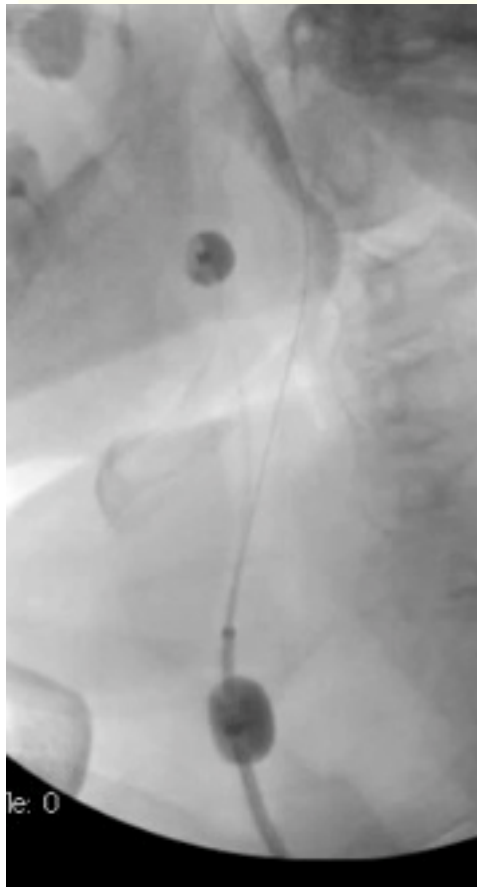


Scaffolding Stent to provide better protection
against **SMALL** and **LATE** embolisation

FOCUS ISSUE: TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

The PROFI Study (Prevention of Cerebral Embolization by Proximal Balloon Occlusion Compared to Filter Protection During Carotid Artery Stenting)

A Prospective Randomized Trial



Significant reduction in the incidence of new cerebral ischemic lesions (45.2% vs. 87.1%, $p = 0.001$).

- number ($p = 0.0001$)

- volume ($p = 0.0001$)

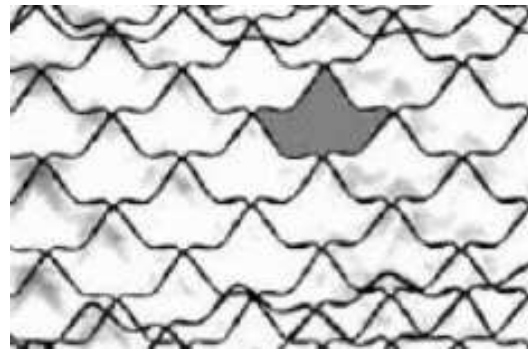
of new cerebral ischemic reduced by proximal balloon occlusion.

(J Am Coll Cardiol 2012;59:1383–9)

WHICH STENT?

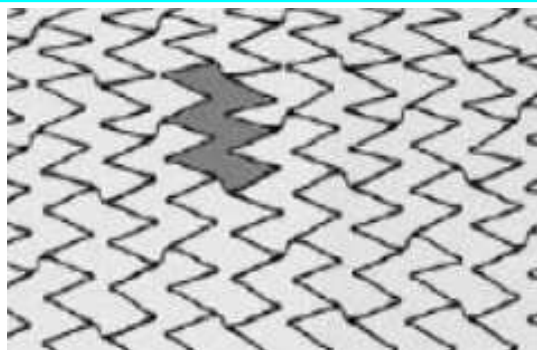


Wallstent (BSCI)



Adapt (BSCI)

closed cell



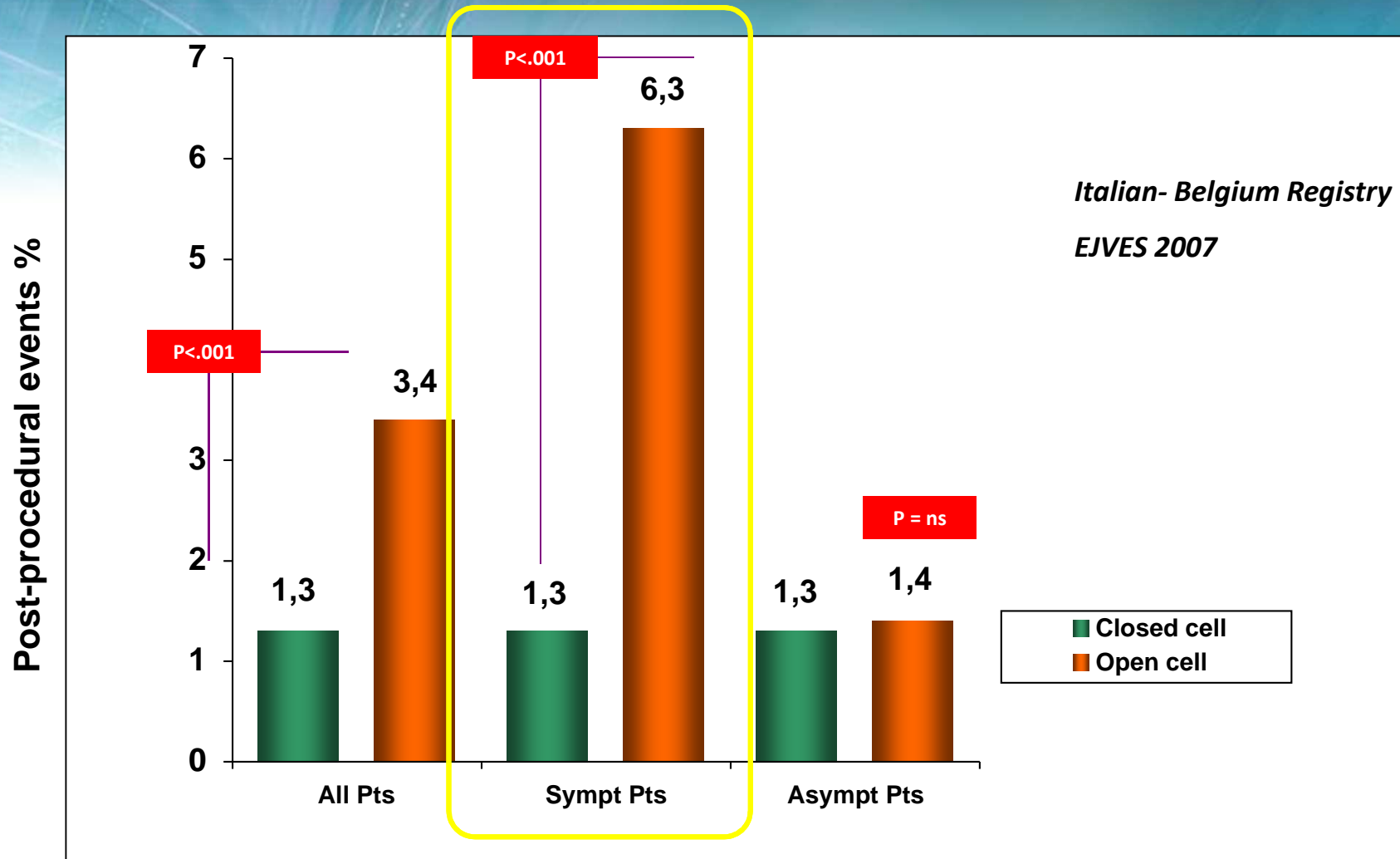
Precise (Cordis)



Acculink (Guidant)

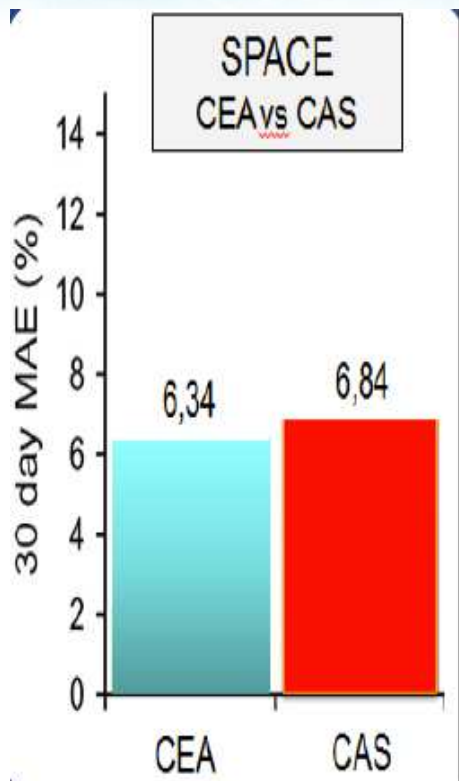
open cell

Comparison of post-procedural event rates by cell types - Sample 3179 Pts -



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 ; 33: 135-41.

Closed vs Open cell in RCT



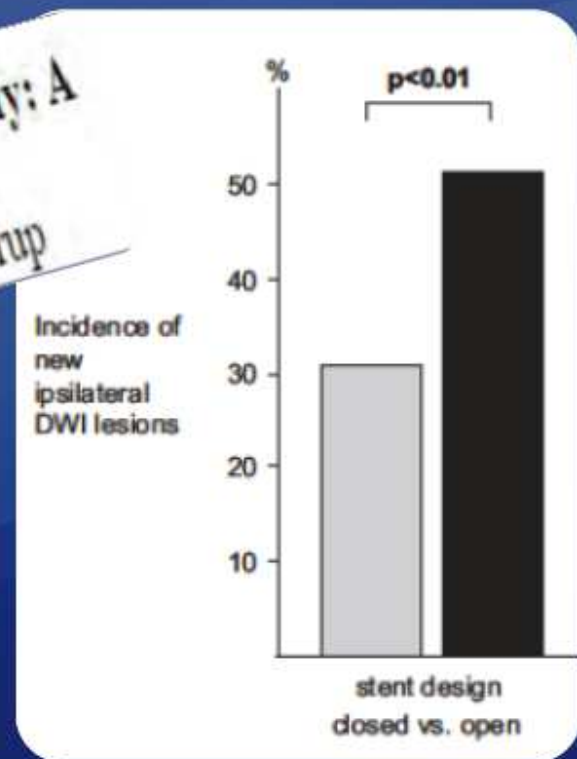
SPACE does confirm these findings!!!

Stent	Acculink	Precise	Wallstent
No. of patients	92	35	436
Pat. with OE	9	5	24
OE rate (95% CI)	9.8% (4.6–17.8%)	14.3% (4.8–30.3%)	5.5% (3.6–8.1%)
Combined OE rate: 11.0% (6.2–17.8%)			
	open cell / large free cell area		closed cell

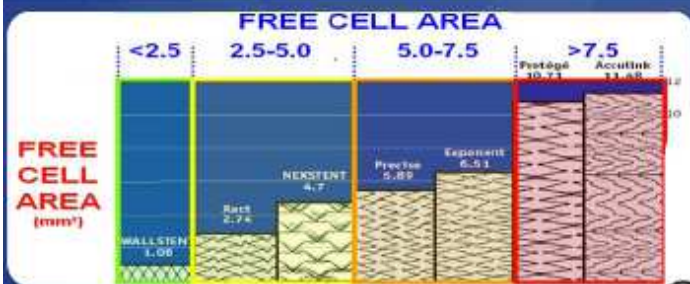
OR 2.13 [1.07-3.76]

We need better protection against **SMALL** emboli

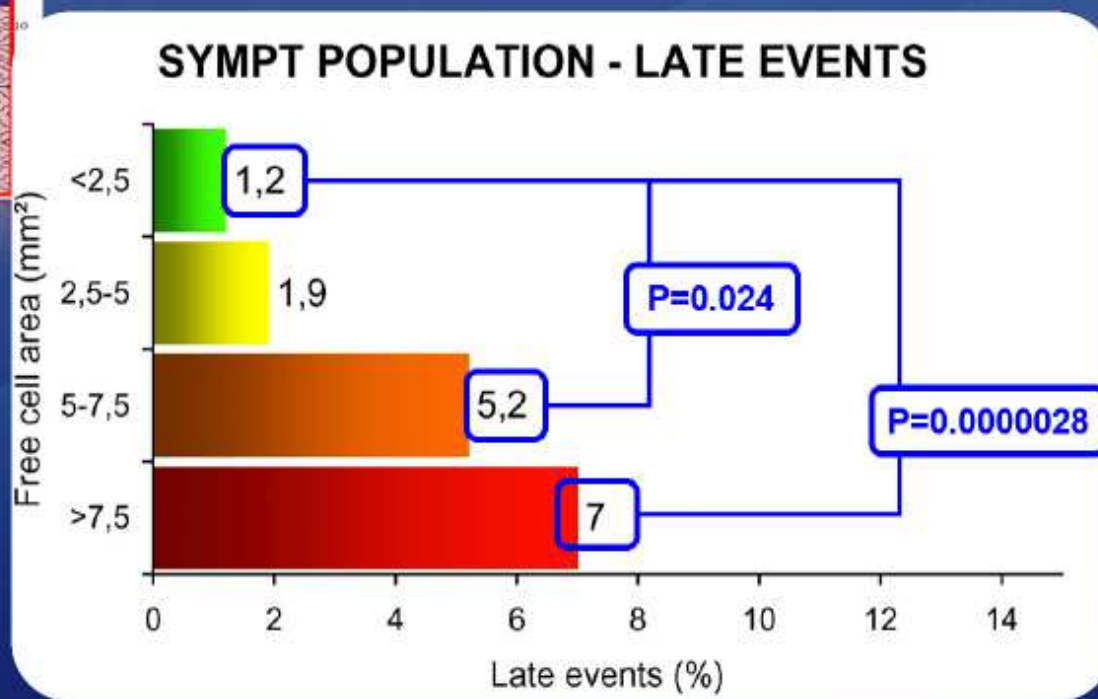
New Brain Lesions After Carotid Stenting Versus Carotid Endarterectomy: A Systematic Review of the Literature
Sonja Schnaudigel, Klaus Gröschel, Sara M. Pilgram and Andreas Kastrup



We need better protection against **SMALL & LATE** emboli



Symptomatic group
 "late" SDR 1,9%



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 ; 33: 135-41.

Ideal stent

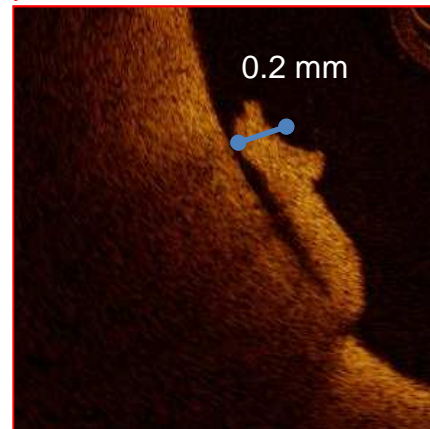


- Low profile
- High trackability & flexibility
- Complete plaque coverage
- Perfect vessel apposition

Answer by OCT

OCT for Stent Selection

Optical Coherence Tomography is an intravascular high-resolution (10 micron) imaging technology that employs near-infrared light



OCT for Stent Selection

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J ENDOVASC THER
2012;19:303-311

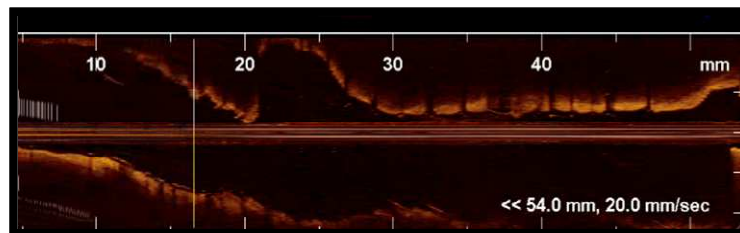
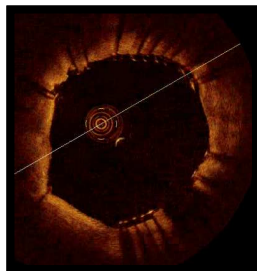
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◆ CLINICAL INVESTIGATION ————— ◆

Safety and Feasibility of Intravascular Optical Coherence Tomography Using a Nonocclusive Technique to Evaluate Carotid Plaques Before and After Stent Deployment

Carlo Setacci, MD; Gianmarco de Donato, MD; Francesco Setacci, MD; Giuseppe Galzerano, MD; Pasqualino Sirignano, MD; Alessandro Cappelli, MD; and Giancarlo Palasciano, MD

Department of Surgery, Vascular and Endovascular Surgery Unit, University of Siena, Italy.



J Endovasc Ther 2012 Jun;19(3):303-11

OCT & Carotid stent design

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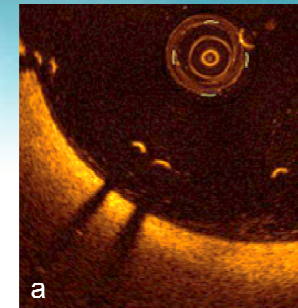
Design

Prospective single center study

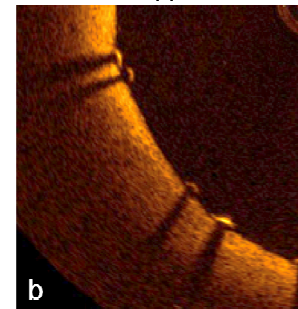
Objectives

To evaluate the rate of:

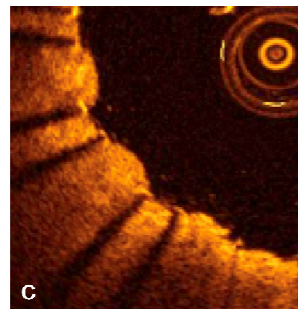
- **stent malapposition**
- plaque prolapse
- fibrous cap rupture



a
"Malapposed"



b
"Well apposed"



c
"Embedded"

G. de Donato, F. Setacci, P. Sirignano, G. Galzerano, A. Cappelli, C. Setacci.
OPTICAL COHERENCE TOMOGRAPHY AFTER CAROTID STENTING: RATE OF
STENT MALAPPOSITION, PLAQUE PROLAPSE AND FIBROUS CAP RUPTURE
ACCORDING TO STENT DESIGN. *Eur J Vasc Endovasc Surg* 2013;45:579-87

OCT & Carotid stent design

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Design

Prospective single center study

Objectives

To evaluate the rate of:

- stent malapposition
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G. de Donato, F. Setacci, P. Sirignano, G. Galzerano, A. Cappelli, C. Setacci.

OPTICAL COHERENCE TOMOGRAPHY AFTER CAROTID STENTING: RATE OF STENT MALAPPOSITION, PLAQUE PROLAPSE AND FIBROUS CAP RUPTURE ACCORDING TO STENT DESIGN. *Eur J Vasc Endovasc Surg* 2013;45:579-87

OCT & Carotid stent design

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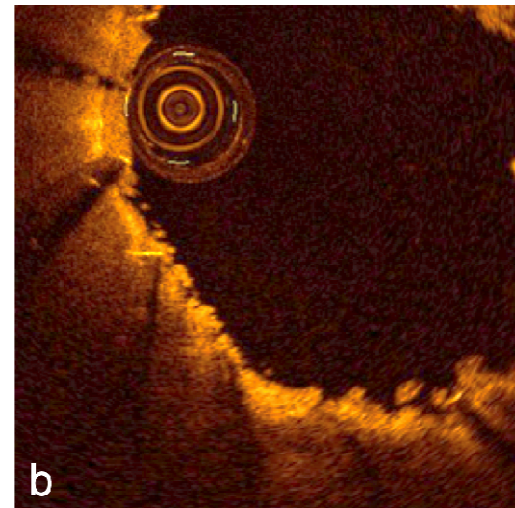
Design

Prospective single center study

Objectives

To evaluate the rate of:

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G. de Donato, F. Setacci, P. Sirignano, G. Galzerano, A. Cappelli, C. Setacci.

OPTICAL COHERENCE TOMOGRAPHY AFTER CAROTID STENTING: RATE OF STENT MALAPPOSITION, PLAQUE PROLAPSE AND FIBROUS CAP RUPTURE ACCORDING TO STENT DESIGN. *Eur J Vasc Endovasc Surg* 2013;45:579-87

OCT & Carotid stent design

Design

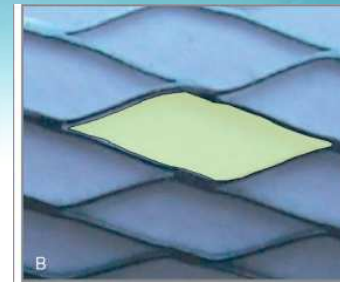
Prospective single center study

Objectives

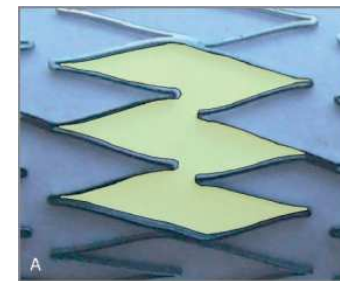
To evaluate the rate of:

- stent malapposition
- plaque prolapse
- fibrous cap rupture

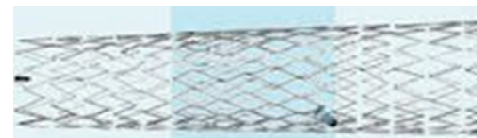
according to carotid stent design



Closed cell
(CC)



Open cell
(OC)



Hyb

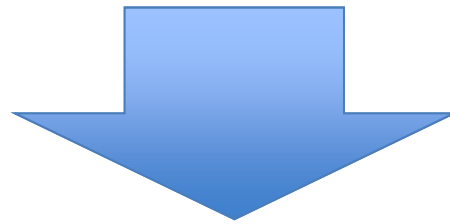
open closed open

G. de Donato, F. Setacci, P. Sirignano, G. Galzerano, A. Cappelli, C. Setacci.

OPTICAL COHERENCE TOMOGRAPHY AFTER CAROTID STENTING: RATE OF STENT MALAPPOSITION, PLAQUE PROLAPSE AND FIBROUS CAP RUPTURE ACCORDING TO STENT DESIGN. . *Eur J Vasc Endovasc Surg* 2013;45:579-87

Ideal stent - OCT answer

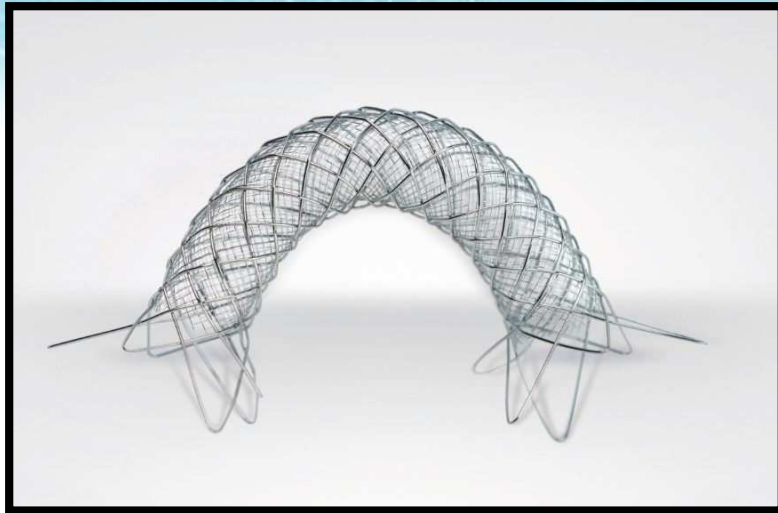
- Stent malapposition is more frequent with closed cell stent
- Plaque prolapse is more common with open cell stents



We need new stent design

We need MESH-STENT

New carotid stent design



Terumo - Roadsaver



Gore – Mesh carotid stent



Inspire – C-Guard

Impact of new stent design

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Roadsaver®

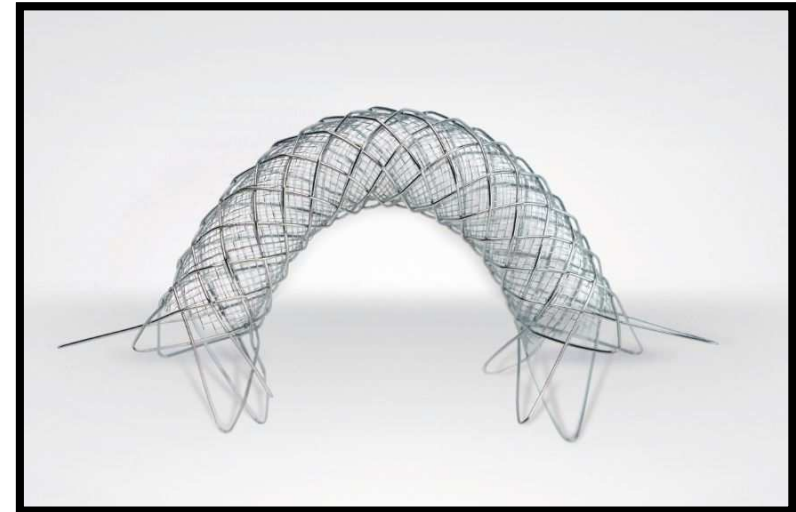
A novel carotid stent for sustained embolic protection

Sustained embolic protection

- Double layer micromesh nitinol design
- Smallest cell stent size preventing embolic release

Lesion specific scaffolding:

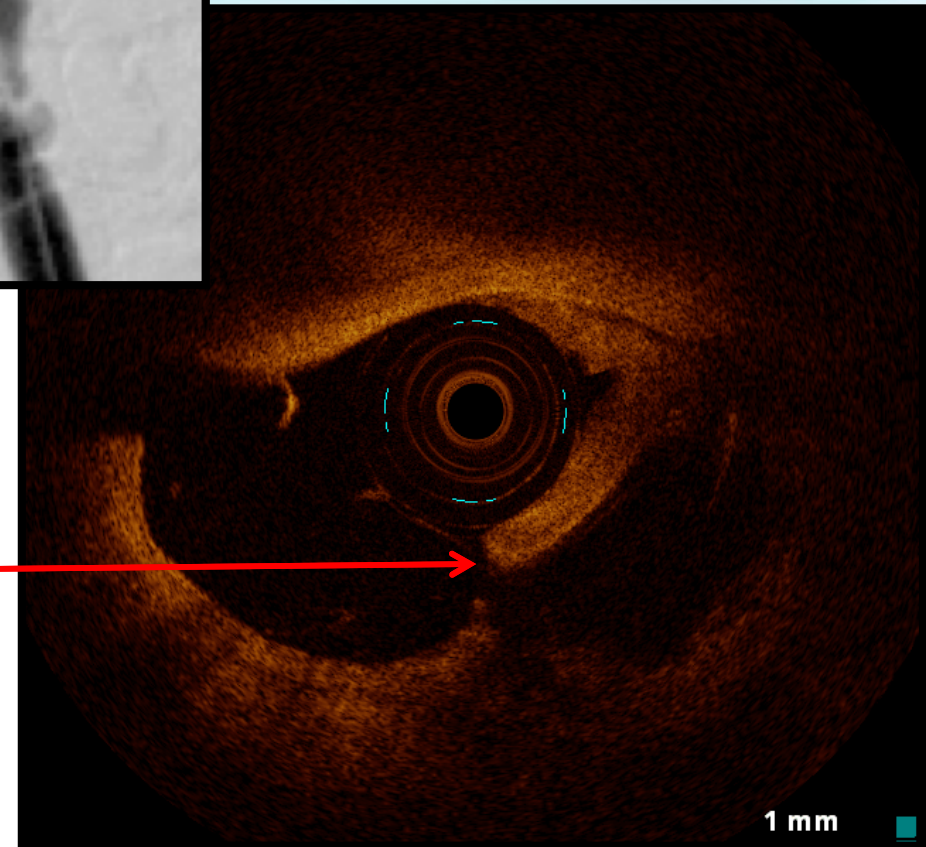
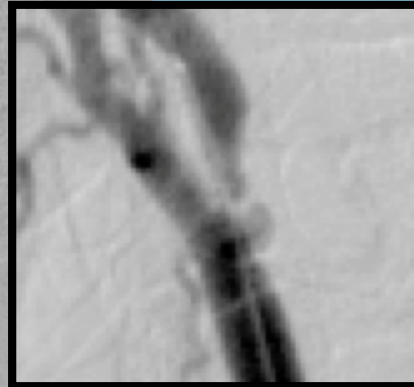
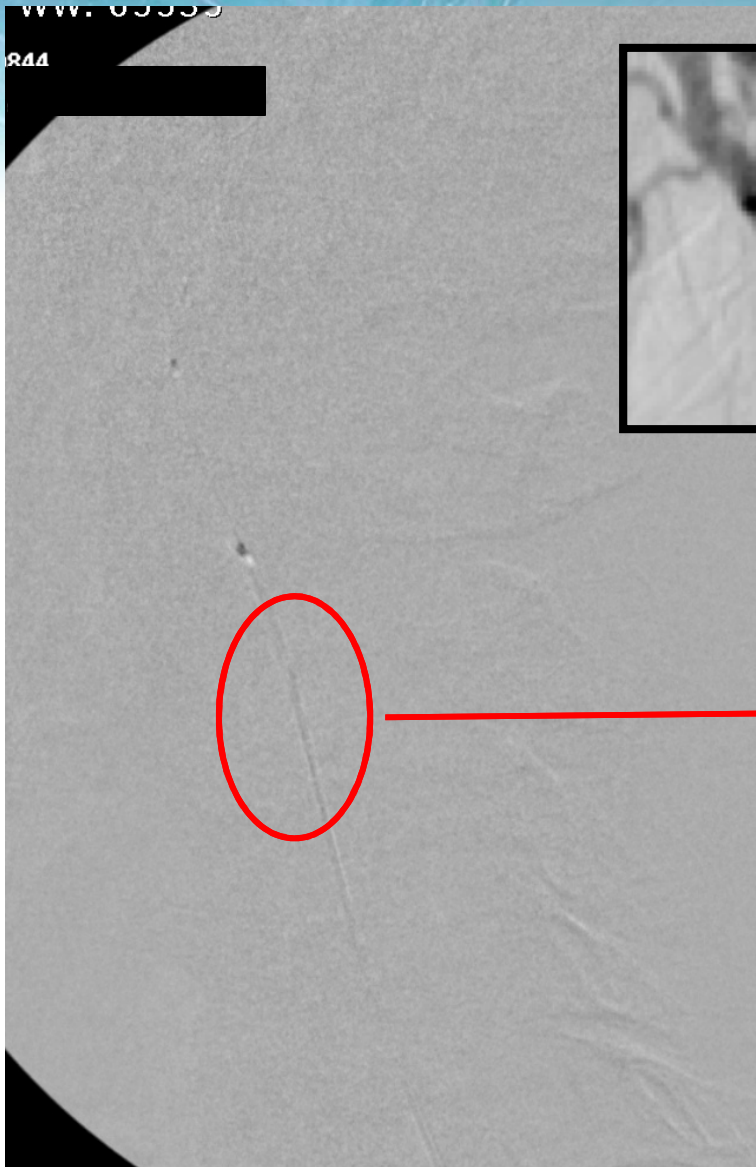
- Extremely high plaque coverage
- Superior in vessel flexibility
- Excellent wall apposition: the two mesh layers enable a flexible scaffold



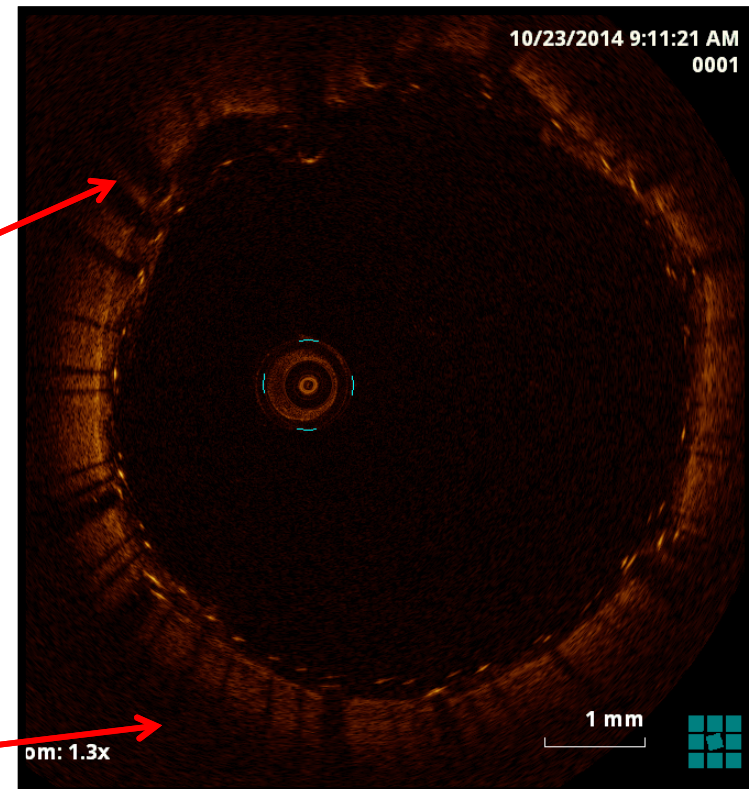
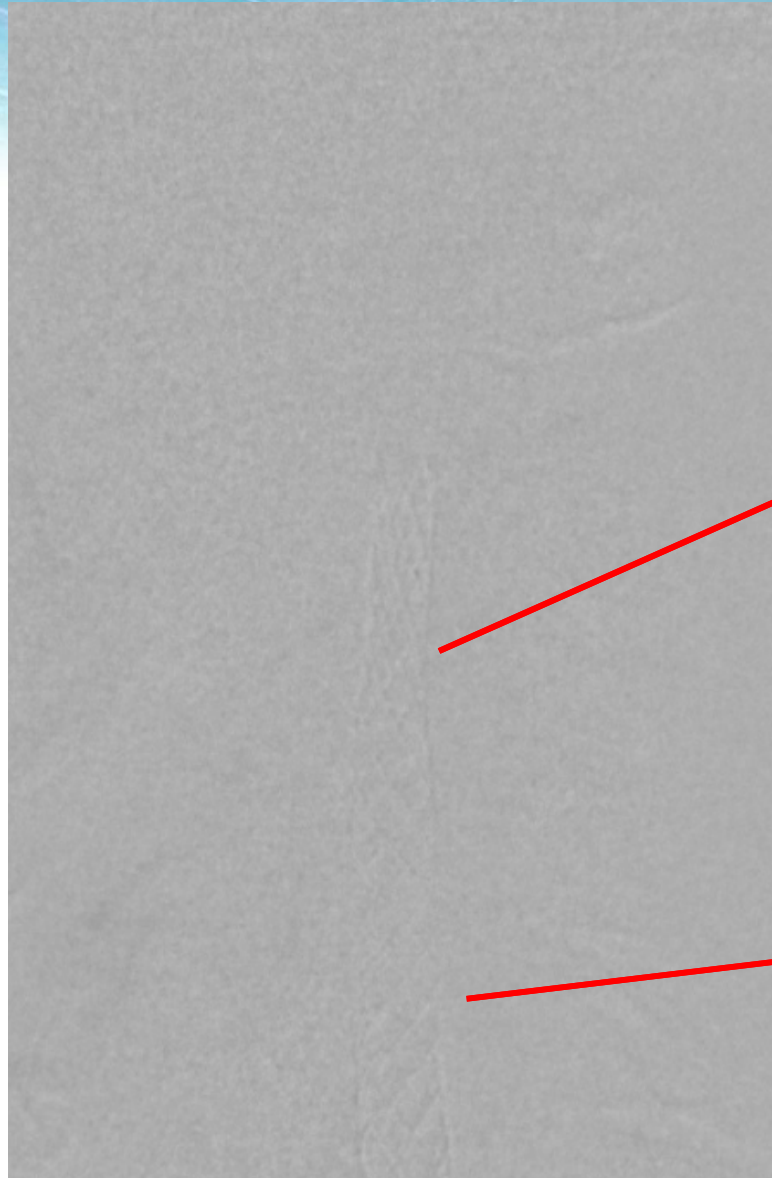
Impact of new stent design

www.65353

R44



Impact of new stent design



Italian registry _ Roadsaver

Torino: Dr. C.Rabbia
Radiologist

Cotignola: Dr. A.Cremonesi
Cardiologist



Siena: Prof. C. Setacci
Vascular Surgeon

3 Italian Vascular Centers

Preliminary results

3 Centers

Cotignola n = 51

Siena n = 17

Torino n = 9

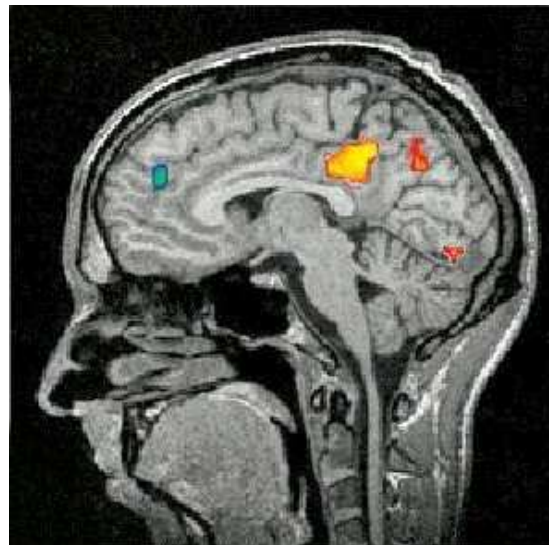
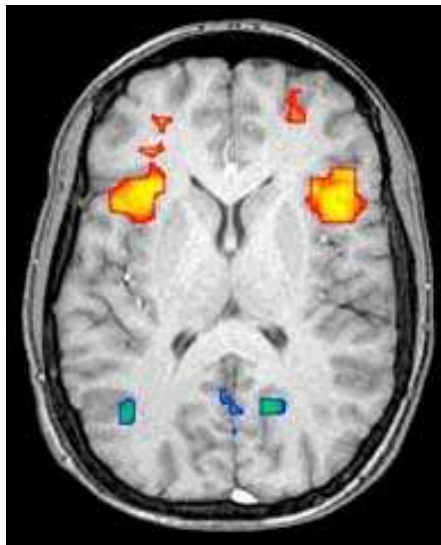
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Italian registry _ Roadsaver

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Subgroup analysis _ MR

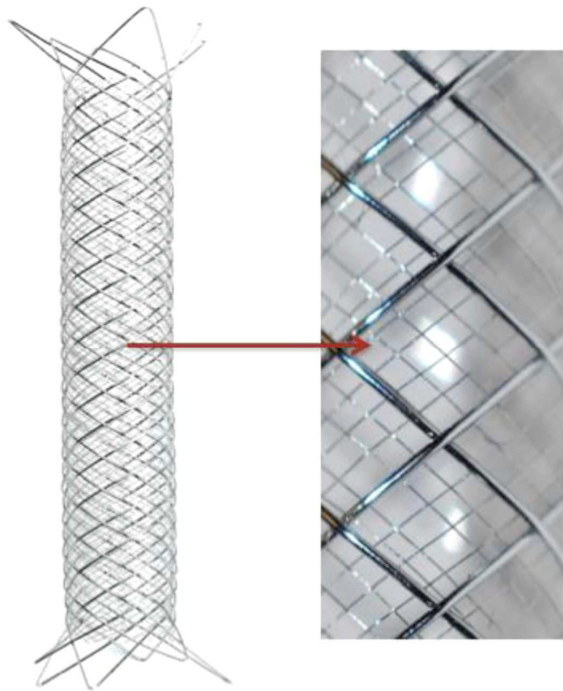
- Magnetic Resonance evaluation of cerebral parenchyma before and 24 hours post-op



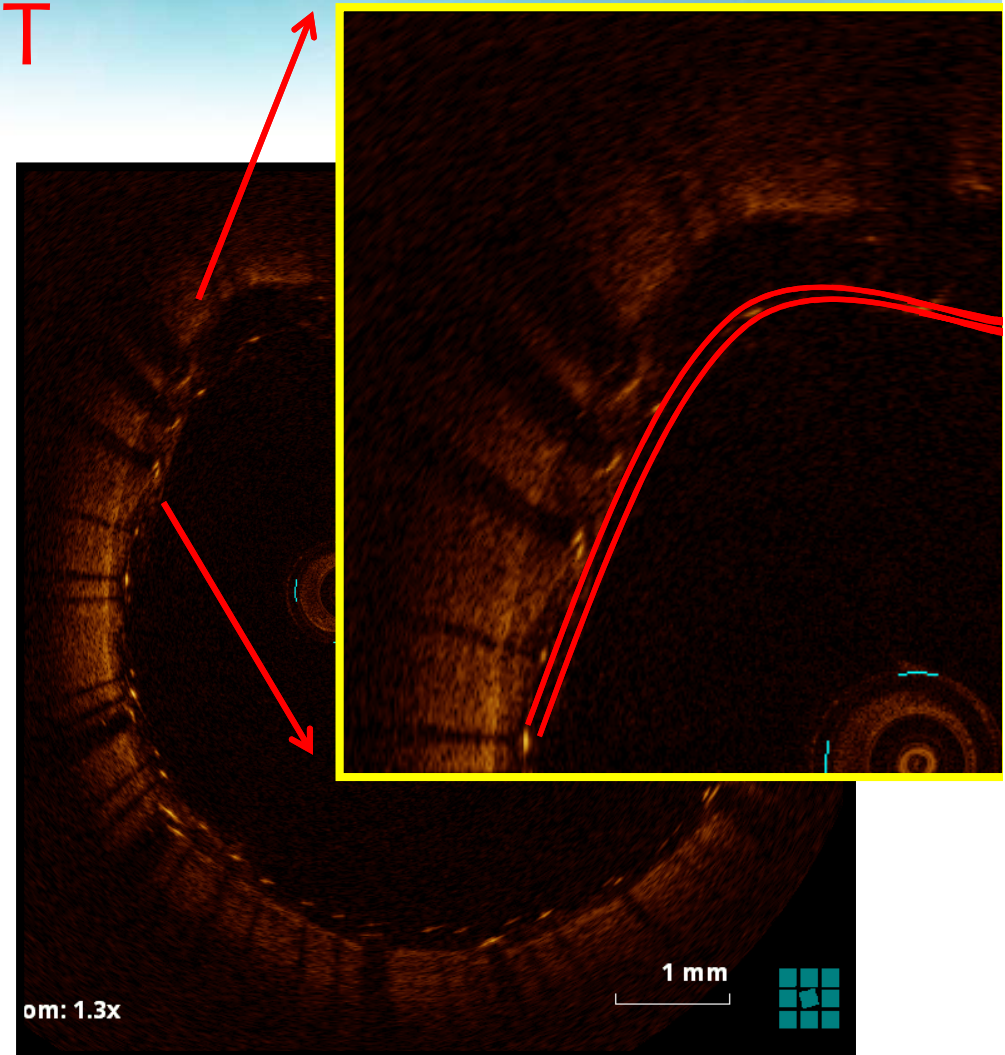
New lesions in **1 case** @ 24 hrs
(n=3 in the ipsilateral and
n=2 in contralateral hemisphere)

Italian registry _ Roadsaver

Subgroup analysis _ OCT



No plaque prolaps at OCT



Preliminary results

30 days

0% stroke or deaths

0% postprocedural TIAs

Prospective international trial

CLEAR ROAD – participating centers



- PI: Dr. Bosiers, AZ Sint-Blasius, Dendermonde, Belgium
- Participating centers:
 - 5 Belgian centers
 - 4 German centers
 - 3 Italian centers



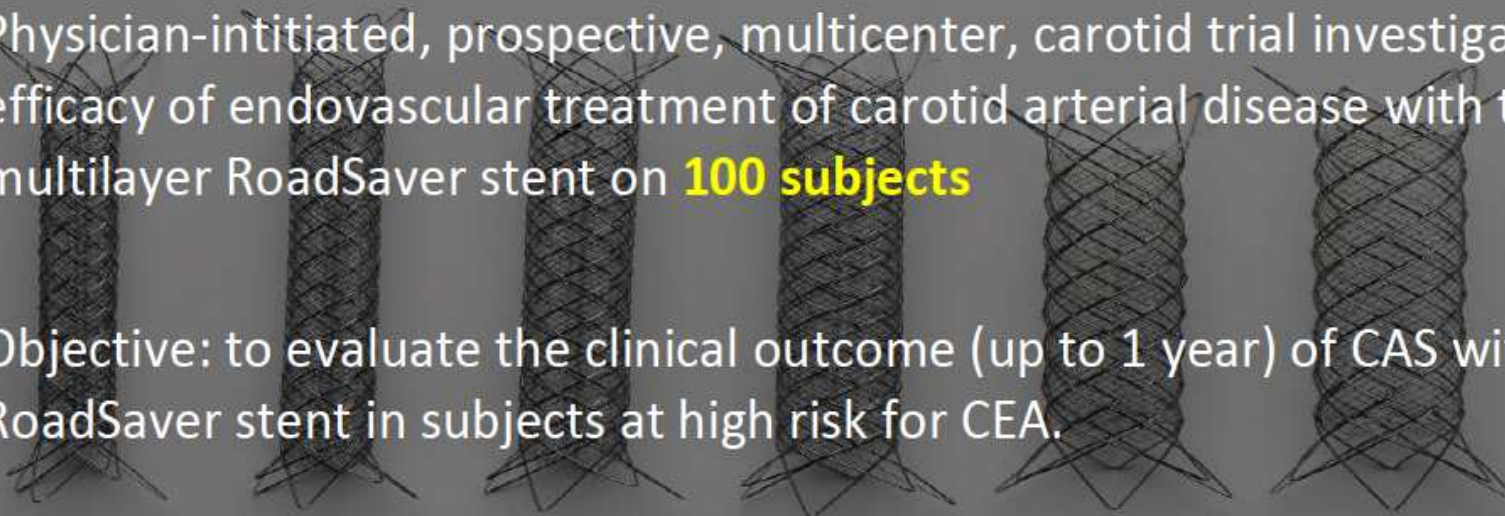
Prospective international trial

Sustained embolic protection device....



CLEAR ROAD TRIAL

- Physician-initiated, prospective, multicenter, carotid trial investigating the efficacy of endovascular treatment of carotid arterial disease with the multilayer RoadSaver stent on **100 subjects**
- Objective: to evaluate the clinical outcome (up to 1 year) of CAS with the RoadSaver stent in subjects at high risk for CEA.

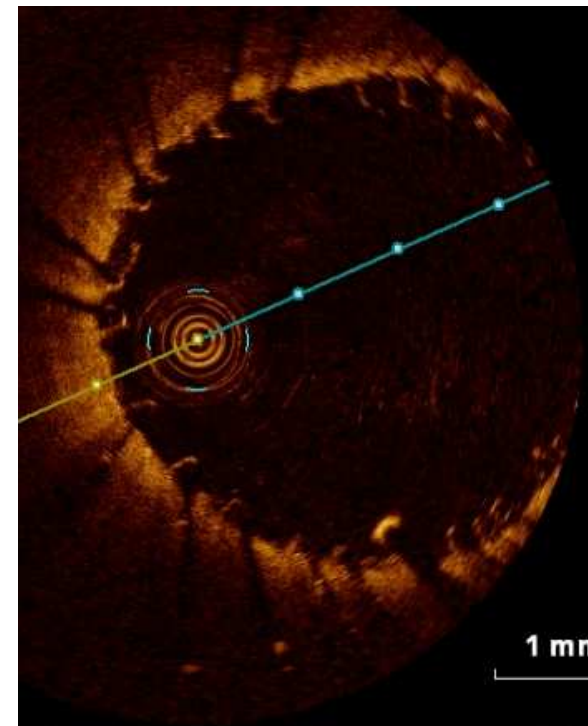
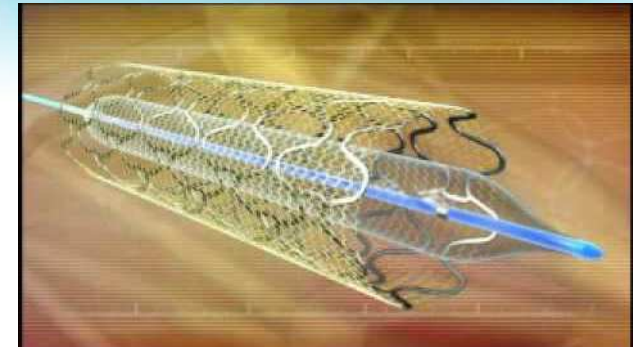


CLEAR ROAD trial



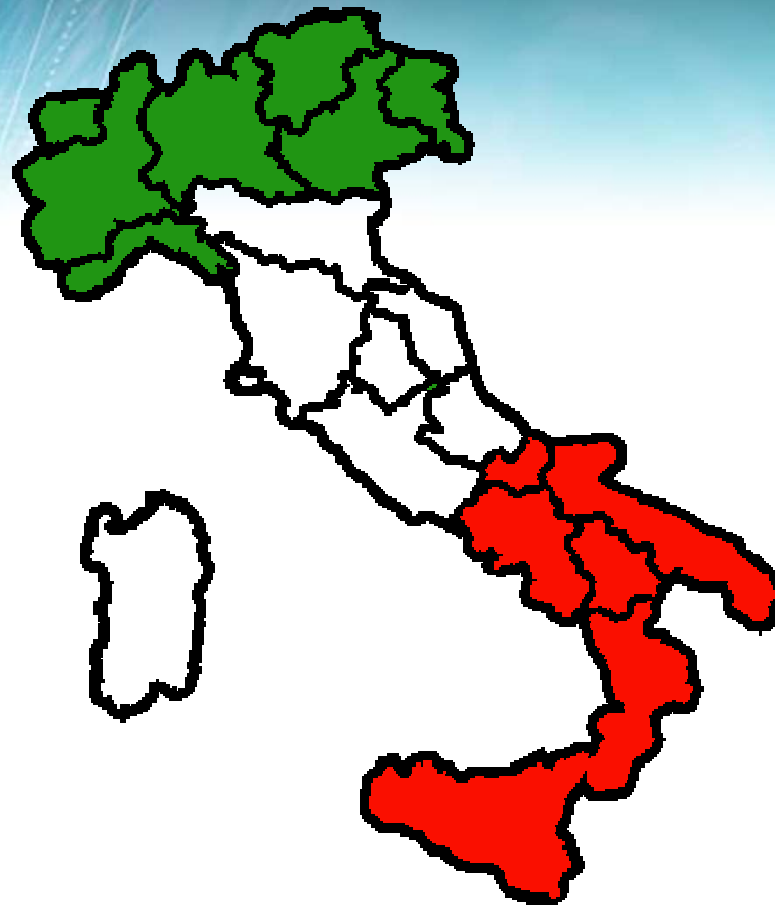
Impact of new stent design

Inspire CGuard is based on a stent which is wrapped with an expandable, MicroNet (mesh). The net is made of a single knitted PET fiber, and it is attached only to the proximal and distal edges of the stent.



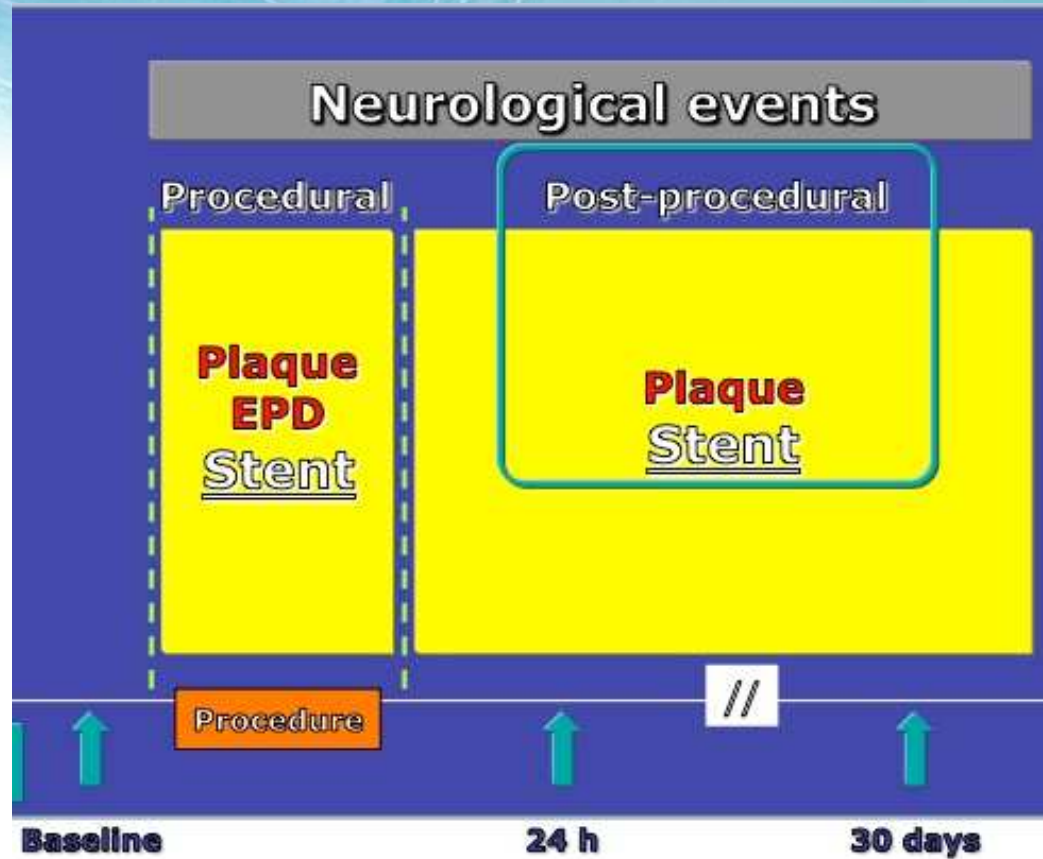
Impact of new stent design

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ITALIAN REGISTRY IN VASCULAR SURGERY CENTRES

Registry Rationale



AFTER 30 DAYS



CEA=CAS

**WE NEED SIMILAR OUTCOME OF CEA AND CAS
WITHIN 30 DAYS**

Registry

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Iron Guard

Physician-initiated prospective Italian Registry of carotid
stenting with the C-Guard mesh-stent.

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DI SIENA
1240



SAPIENZA
UNIVERSITÀ DI ROMA

JCVS In press

J Cardiovasc Surg (Torino). 2015 May 21. [Epub ahead of print]

Physician-initiated prospective Italian Registry of carotid stenting with the C-Guard mesh-stent: the IRON-Guard registry. Rationale and design.

Setacci C¹, Speziale F, de Donato G, Sirignano P, Setacci F, Capoccia L, Galzerano G, Mansour W.

⊕ Author information

Abstract

BACKGROUND: According to the World Health Organization, every year, 5 million peoples die for stroke and another 5 million are permanently disabled. Although there are many causes of acute stroke, a common treatable cause of acute stroke is atheromatous narrowing at the carotid bifurcation. Carotid endarterectomy is still the standard of care, even if carotid artery stenting (CAS) has become an effective, less invasive alternative. Unfortunately, CAS procedure is not yet perfect; regardless the use of an embolic protection device (EPD), percutaneous treatment has been correlated with a risk of cerebral ischemic events related to distal embolization.

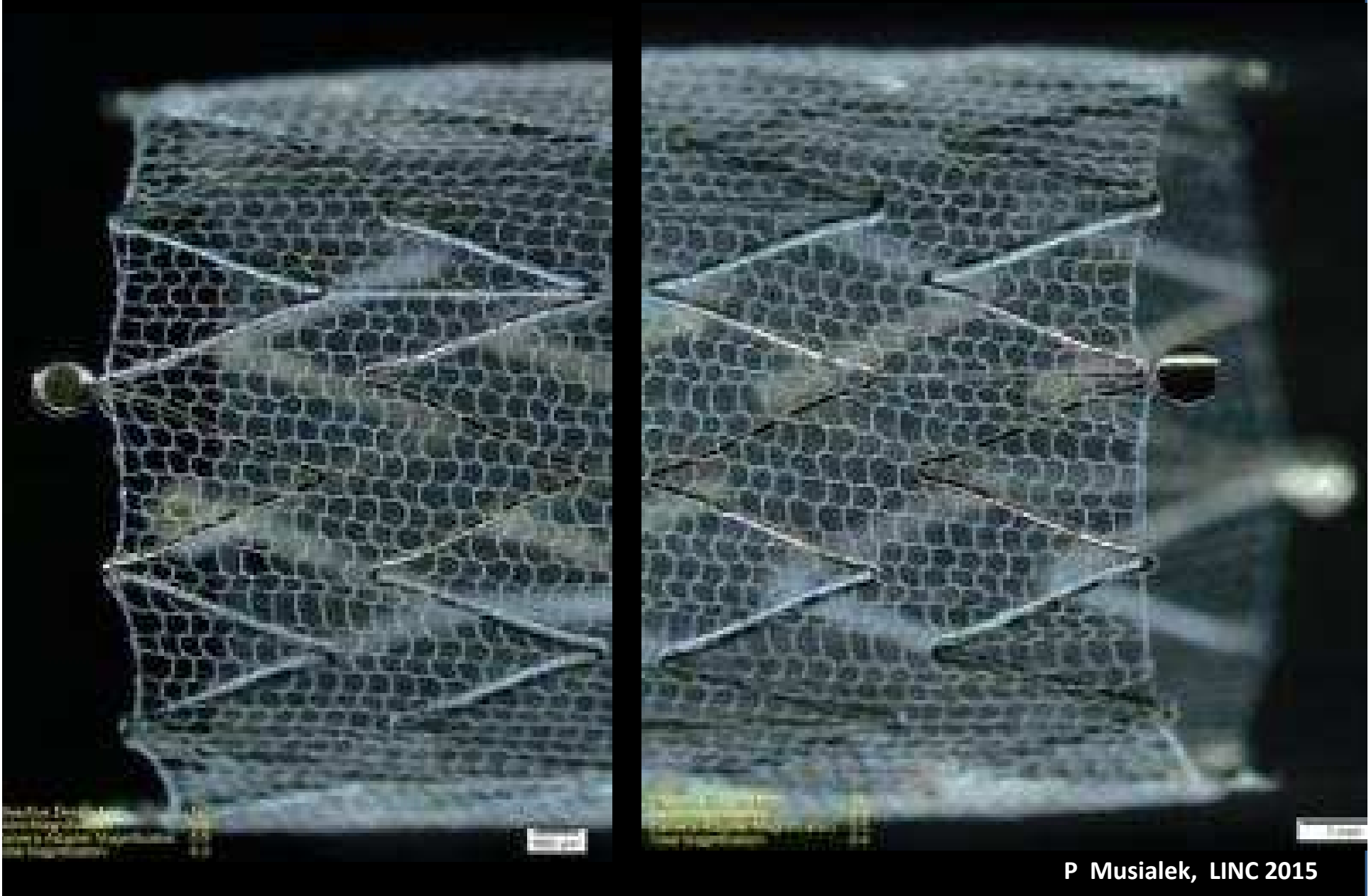
Registry



OBJECTIVES

The objective of this clinical investigation is to evaluate the clinical outcome (up to 12 months) of treatment by means of stenting with the C-Guard (InspireMD) in subjects requiring carotid revascularization due to significant extra-cranial carotid artery stenosis.

CGuard™ embolic prevention ster



Registry

ENDPOINTS



6.1 Primary Endpoint

The primary endpoint of this study is the 30-day rate of major adverse events (MAE), defined as the cumulative incidence of any peri-procedural (≤ 30 days post-procedure) death, stroke or myocardial infarction (MI).

6.2 Secondary Endpoints

1. Late ipsilateral stroke (31 through 365 days)
2. System Technical Success
3. Device malfunctions.
4. Major Adverse Events (MAEs)
5. Serious device-related and procedure-related Adverse Events (SAEs) as defined per ISO 14155-1:2011.
6. Target Lesion Revascularization (TLR).
7. In-Stent Restenosis (ISR).

What the data is telling us: the first 30 days need to be safer after any carotid repair, but how?

We have to avoid an inappropriate approach to CAS related to:

- 1. Poor specific competence**
- 2. Inadequate training**
- 3. Inadequate materials**

What the data is telling us: the first 30 days need to be safer after any carotid repair, but how?

Devastating sequelae:

- 1. Wrong patient selection and indication**
- 2. Incapacity to manage complications**

THANKS FOR THE ATTENTION

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SAVE THE DATE

SIVVEC / SIENA

SIENA VASCULAR AND ENDOVASCULAR COURSE - COURSE DIRECTOR: CARLO SETACCI

7-9
SEPTEMBER
2015

The poster for the SIVVEC / SIENA course features a blue background with a stylized, metallic-looking tower on the left. The tower has a crenellated top and a base that tapers into a series of white and blue geometric shapes, including squares and rectangles, arranged in a pattern that suggests a modern architectural or medical theme. The text is in white and black, providing clear information about the course and its dates.