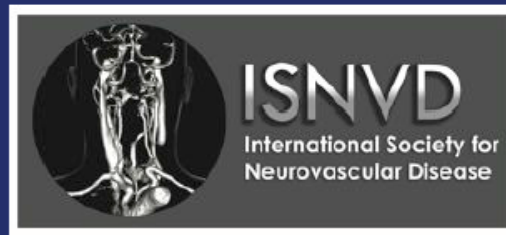


ISNVD



INTERNATIONAL SOCIETY OF NEUROVASCULAR DISEASE

9th annual meeting

May 30-31, 2019, University of Ferrara - Italy

AULA MAGNA - S. ANNA UNIVERSITY-HOSPITAL, CONA VIA ALDO MORO 8

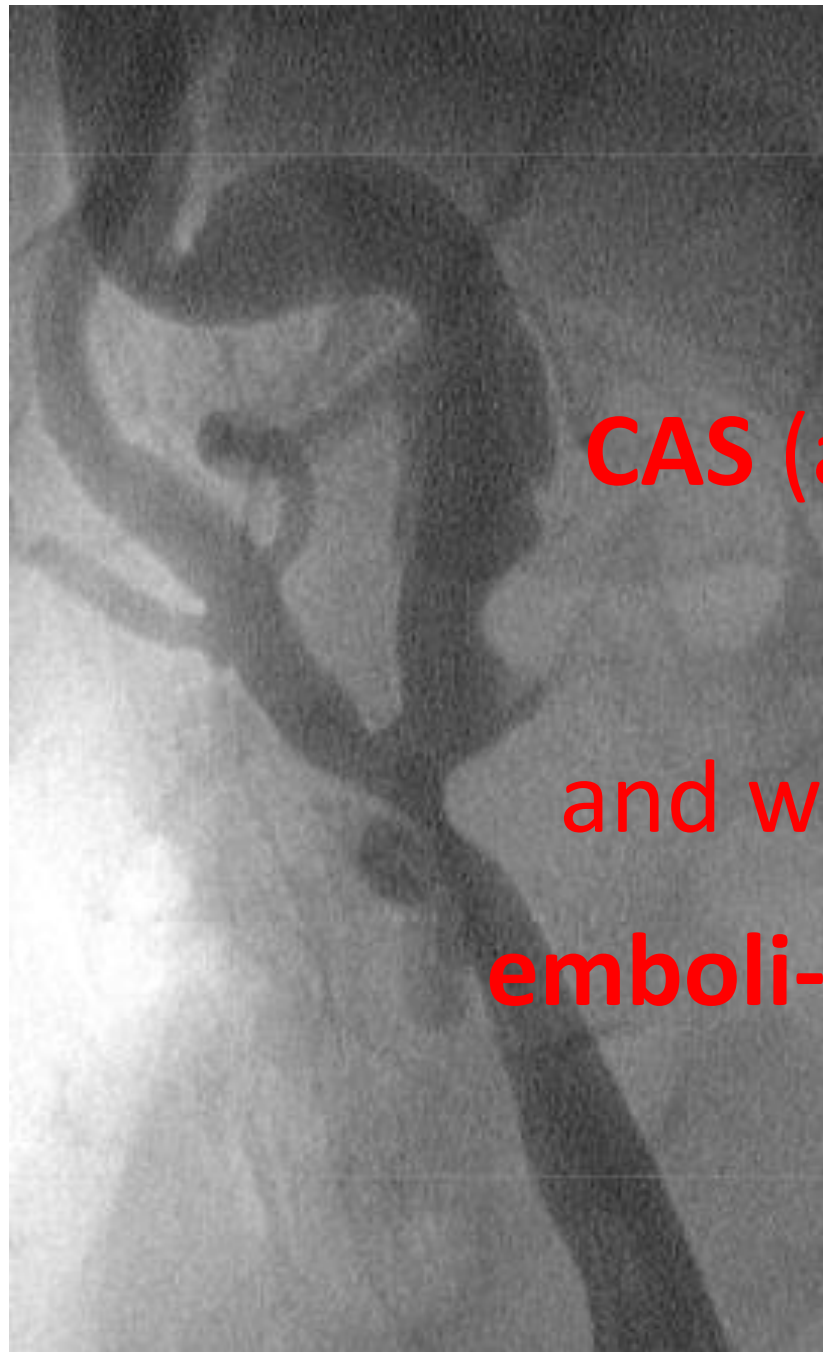
**Better embolic protection may reinvigorate
CAS?**

Carlo Setacci

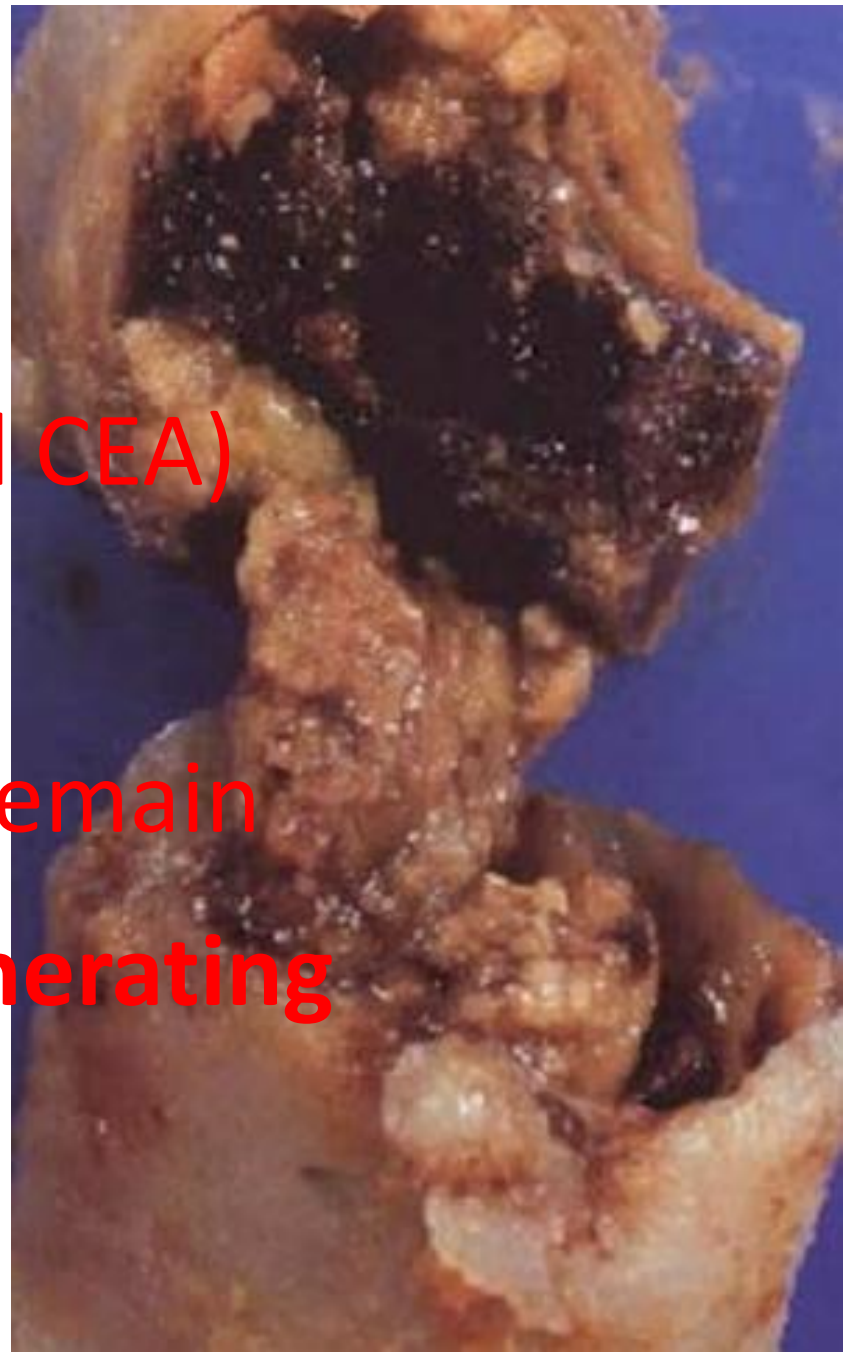
Vascular and Endovascular Surgery Siena

Disclosures

- **Consultant/Advisor**
- **Boston Scientific**
- **Endologix**
- **Terumo**



CAS (and CEA)
are
and will remain
emboli-generating



Effect of the Distal-Balloon Protection System on Microembolization During Carotid Stenting

Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD

CAS (and CEA) are –and will remain– emboli-generating procedures

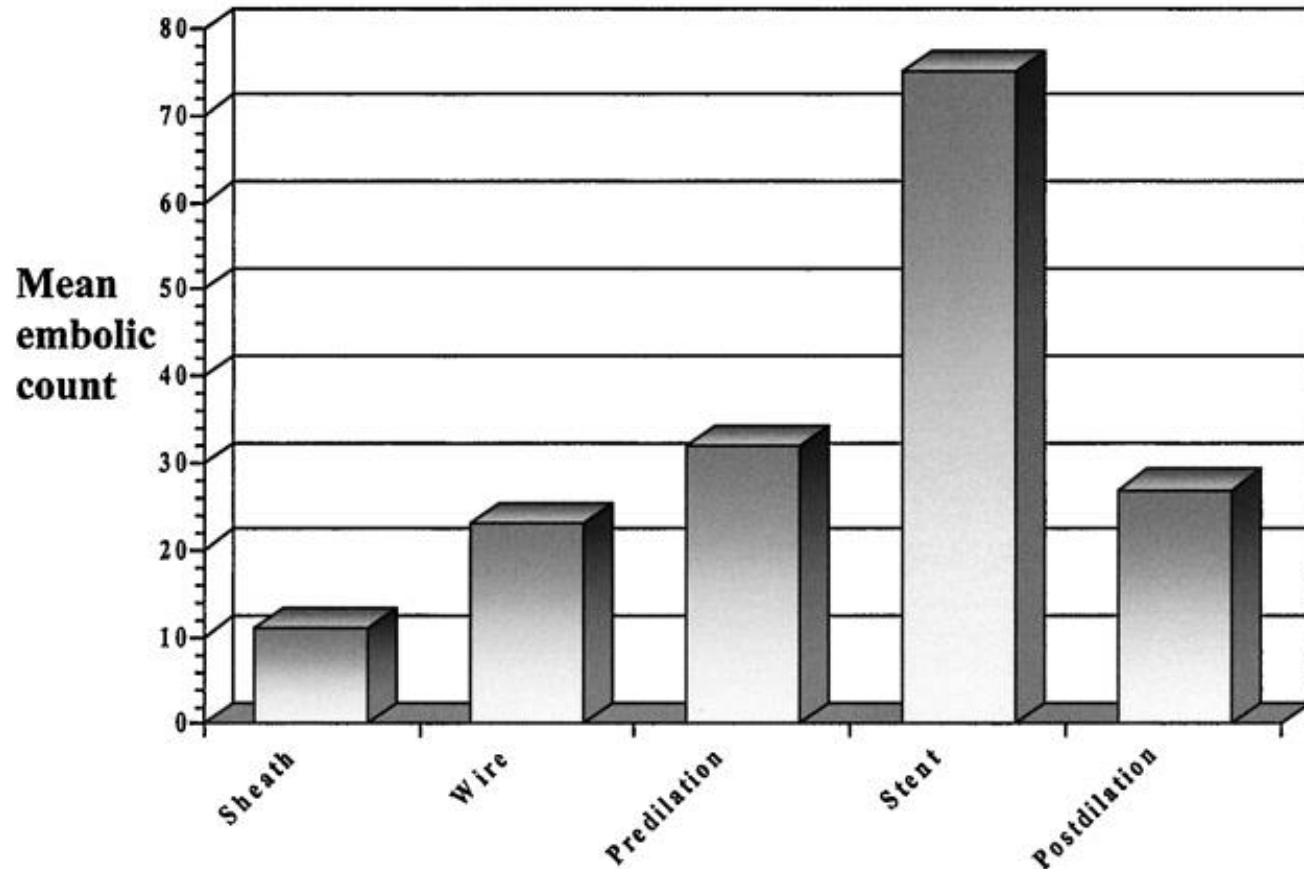


Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

CAROTID ARTERY STENTING

AS AN ENDOVASCULAR ORIENTED VASCULAR SURGEON
I BELIEVE IN THE RENAISSANCE OF CAS



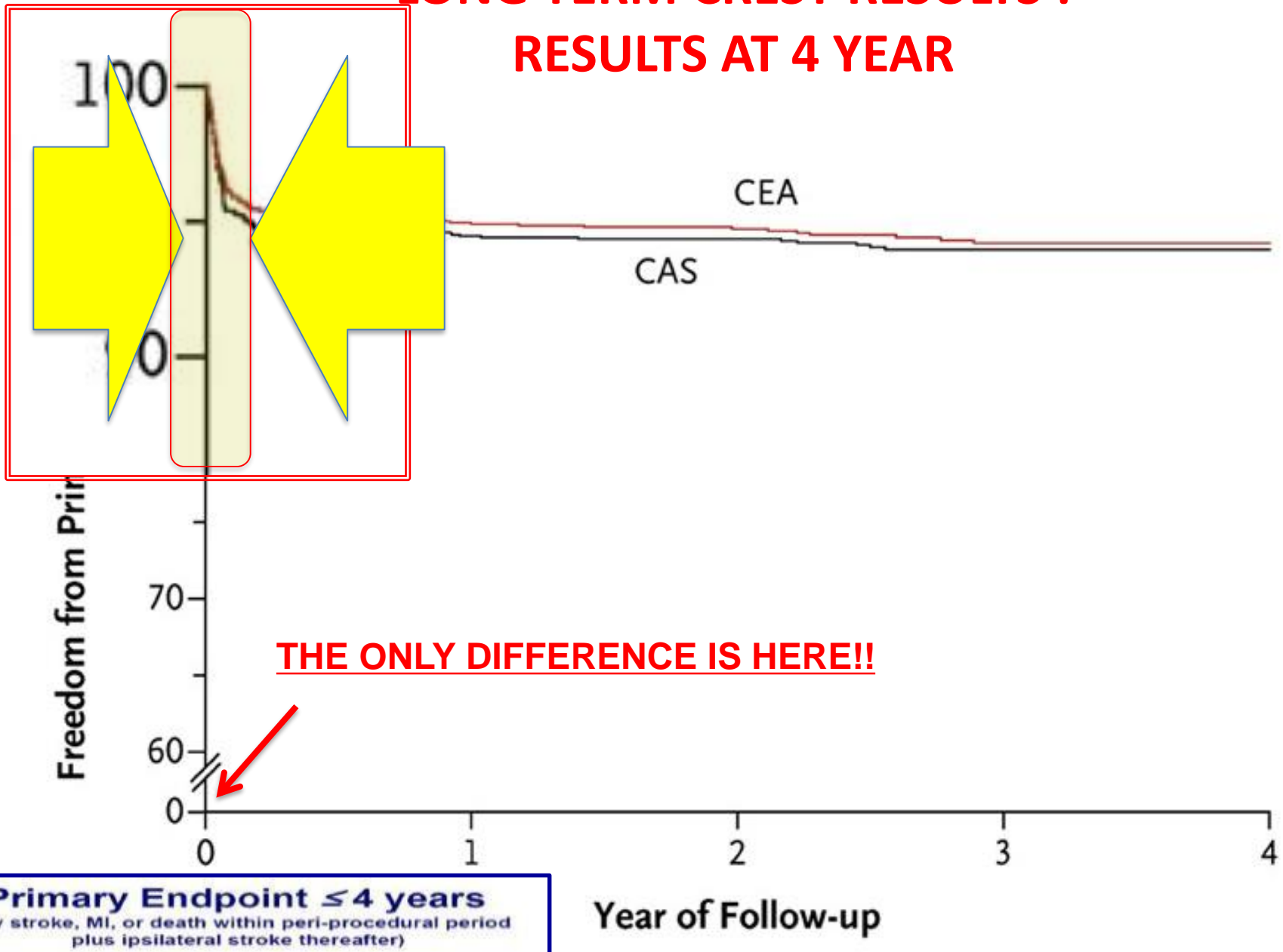
J Cardiovasc Med (Hagerstown). 2016 Dec;17(12):855-856.

Carotid artery stenting renaissance: can tips, tricks and new devices fill the gap?


Setacci C¹, de Donato G.



LONG TERM CREST RESULTS : RESULTS AT 4 YEAR



CREST 10 YEARS RESULTS NEJM 2016



The NEW ENGLAND
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ORIGINAL ARTICLE

Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis

Thomas G. Brott, M.D., George Howard, Dr.P.H., Gary S. Roubin, M.D., Ph.D., James F. Meschia, M.D., Ariane Mackey, M.D., William Brooks, M.D., Wesley S. Moore, M.D., Michael D. Hill, M.D., Vito A. Mantese, M.D., Wayne M. Clark, M.D., Carlos H. Timaran, M.D., Donald Heck, M.D., Pierre P. Leimgruber, M.D., Alice J. Sheffet, Ph.D., Virginia J. Howard, Ph.D., Seemant Chaturvedi, M.D., Brajesh K. Lal, M.D., Jenifer H. Voeks, Ph.D., and Robert W. Hobson, II, M.D., for the CREST Investigators†

February 18, 2016 | DOI: 10.1056/NEJMoa1505215



In conclusion, the long-term follow-up results of **CREST did not show significant differences between carotid-artery stenting and carotid endarterectomy** with respect to the primary composite end point of periprocedural stroke, myocardial infarction, or death and postprocedural ipsilateral stroke over a time period that was appropriate for elderly asymptomatic patients and symptomatic patients with severe carotid artery disease.

ACT 1 RESULTS NEJM 2016



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ARTICLES & MULTIMEDIA ▾

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CME >

ORIGINAL ARTICLE

Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis

Kenneth Rosenfield, M.D., M.H.C.D.S., Jon S. Matsumura, M.D., Seemant Chaturvedi, M.D., Tom Riles, M.D., Gary M. Ansel, M.D., D. Chris Metzger, M.D., Lawrence Wechsler, M.D., Michael R. Jaff, D.O., and William Gray, M.D., for the ACT I Investigators*

February 17, 2016 | DOI: 10.1056/NEJMoa1515706

In conclusion, in this multicenter trial involving patients 79 years of age or younger with asymptomatic severe carotid stenosis, carotid-artery stenting was noninferior to carotid endarterectomy at 1 year with regard to the primary composite end point of death, stroke, and myocardial infarction within 30 days or ipsilateral stroke within 365 days after the procedure. The rates of stroke and survival after the procedure did not differ significantly between the two study groups over a period of 5 years.

Should we protect the brain?

An old, yet unsettled issue

30 day analysis	Combined stroke/death rate (%)	Death rate (%)	Major stroke (%)	Minor stroke (%)
Without Distal Protection (n=2357, 26 studies)	5.5	0.8	1.1	3.7
	>0.001	=0.6	0.05	<0.001
	1.8	0.8	0.3	0.5
With Distal Protection (n=839, 11 studies)				

Kastrup A. *Stroke* 2003;34:813

w/o vs. w DP: ~ 3-fold increase risk of any stroke/death
 > 6-fold increase risk of minor stroke

Should we protect the brain?

ESC/AHA Guidelines for diagnosis and treatment of PAD

ESC

Recommendation	Class ^a	Level ^b
The use of embolic protection devices <u>should be considered</u> in patients undergoing carotid artery stenting.	IIa	C

AHA

1. Embolic protection device (EPD) deployment during CAS can be beneficial to reduce the risk of stroke when the risk of vascular injury is low.^{66,67} (*Level of Evidence: C*)

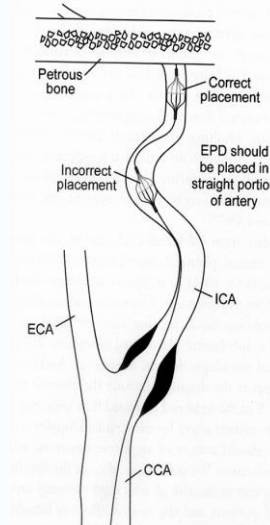
IIa, C

LOE C: consensus of opinion of the experts and/or small studies, retrospective studies, registries

Cerebral distal protection with filters

Strengths & Weaknesses

- Intuitive approach
- Easy to use (in easy case)
- Preserve ICA flow
- Angiographic lesion control during the entire procedure
- Do not significantly prolong procedural time (in easy case and in experienced hands)



- Wire/filter crossing of the stenosis is unprotected
- Lack of capture of particles smaller than filter pores (<80-100 mic.'s)
- Filter suboptimal wall apposition (due to tortuous anatomy) may lead to particles passage between the filter basket and the vessel wall
- "Squeezing" of the captured material during filter withdrawal

Currently used in 80-85% of CAS procedures

Cerebral proximal protection

Strengths & Weaknesses

- Complete brain protection all the time
- Tight, soft plaques, tortuous ICA (no landing zone required)
- Any 0.014" guidewire may be used to cross the lesion

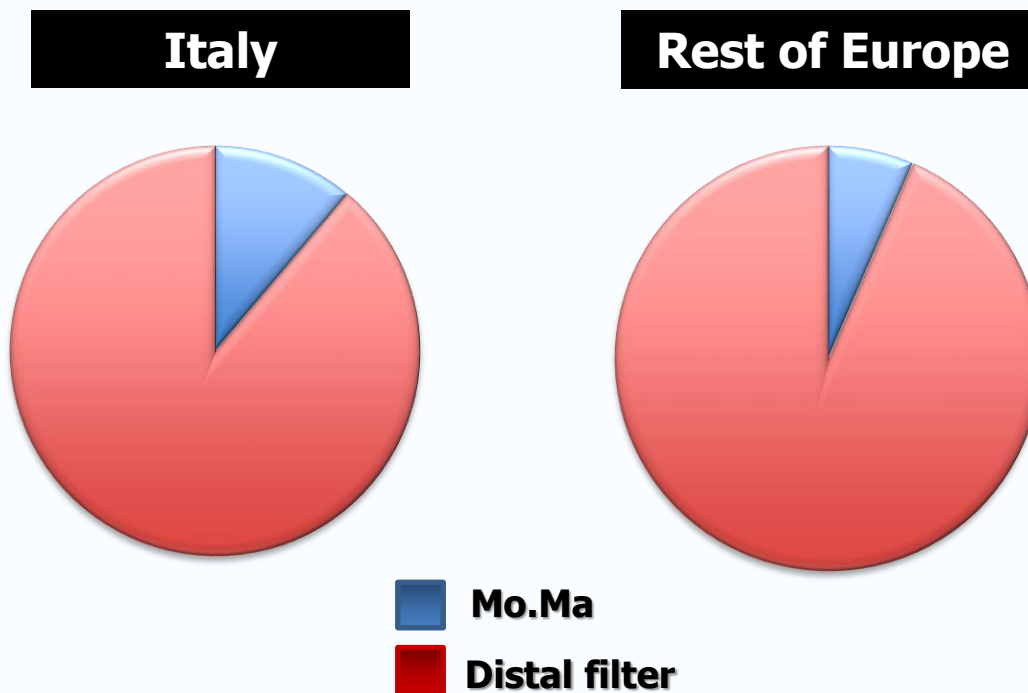


- Blood flow interruption
→ *True intolerance rare: 0.3%-0.6%*
- No angio guidance
→ *Use landmarks (bones, teeth, etc)*
- Potential ECA/CCA spasm/dissection
→ *Do not overinflated the balloons*
- Contraindicated in CCA+ICA or ECA+ICA lesion
→ *CCA+ICA: Mind the distance between lesions. Avoid true bifurcation lesion*
ECA+ICA: if wire crosses, then OK.
- May be difficult to position in complex anatomy
→ *Choose an alternative vascular approach*
Modify the technique (NO.MA technique)
- Large introducer size (8-9F)
→ *Use the 8F with 5F compatible stents*

Currently used in 15-20% of CAS procedures

Proximal protection devices in CAS

Type of cerebral embolic protection in Europe: 2016/2-2017/3



Only prospective studies including a population cohort larger than 100 patients.

The CLEAR-ROAD study: evaluation of a new dual layer micromesh stent system for the carotid artery



Marc Boniers^{1*}, MD; Koen Deloosse¹, MD; Giovanni Torsello², MD; Diark Scheinart³, MD; Lieven Maana⁴, MD; Patrick Peeters¹, MD; Stefan Müller-Hilsbeck⁴, MD, PhD; Horst Sievert², MD; Ralf Langhoff², MD; Michel Boniers², MD; Carlo Setacci², MD

Carotid artery stenting with a new-generation double-mesh stent in three high-volume Italian centres: clinical results of a multidisciplinary approach



Roberto Nerla^{1*}, MD; Fausto Castriota¹, MD; Antonio Micari¹, MD, PhD; Paolo Sbarzaglia¹, MD; Gioel Gabrio Secco², MD; Maria Antonella Ruffino³, MD; Gianmarco de Donato⁴, MD; Carlo Setacci⁴, MD; Alberto Cremonesi¹, MD

Thirty-day results from prospective multi-specialty evaluation of carotid artery stenting using the CGuard MicroNet-covered Embolic Prevention System in real-world multicentre clinical practice: the IRON-Guard study



Francesco Speciale¹, MD; Laura Capoccia^{1*}, MD; Pasqualino Sirignano¹, MD; Wassim Mansour¹, MD; Chiara Pranteda¹, MD; Renato Casana², MD; Carlo Setacci³, MD; Federico Accrocca⁴, MD; Domenico Alberti⁵, MD; Gianmarco de Donato⁶, MD; Michelangelo Ferri⁷, MD; Andrea Gaggiano¹, MD; Giuseppe Galzerano⁸, MD; Arnaldo Ippoliti⁹, MD; Nicola Mangialardi¹⁰, MD; Giovanni Pratesi¹¹, MD; Sonia Ronchey¹², MD; Maria Antonella Ruffino¹³, MD; Andrea Siani¹⁴, MD; Angelo Spinazzola¹¹, MD; Massimo Sponza¹², MD

Novel PARADIGM in carotid revascularisation: Prospective evaluation of All-corer perCutaneous cArotid revascularisation in symptomatic and Increased-risk asymptomatic carotid artery stenosis using CGuard™ MicroNet-covered embolic prevention stent system



Piotr Musialek^{1*}, MD, DPhil; Adam Mazurek¹, MD; Mariusz Trystula², MD, PhD; Anna Boratynska³, MD, PhD; Agata Lesniak-Sobelga¹, MD, PhD; Małgorzata Urbanczyk⁴, MD; R. Pawel Banys⁴, MSc; Andrzej Brzychczy², MD, PhD; Wojciech Zajdel⁵, MD, PhD; Lukasz Partyka⁶, MD, PhD; Krzysztof Zmudka³, MD, PhD; Piotr Podolec¹, MD, PhD

Carotid artery stenting with a new generation double-mesh stent in 3 high-volume Italian centres: 12-month follow-up results

Roberto Nerla; Antonio Micari; Fausto Castriota; Eligio Micciché; Maria Antonella Ruffino; Gianmarco de Donato; **Carlo Setacci**; Alberto Cremonesi;

EuroIntervention. 2018 Sep 4. pii: EIJ-D-18-00513. doi: 10.4244/EIJ-D-18-00513. [Epub ahead of print]



The CLEAR-ROAD study: Evaluation of a new dual layer micromesh stent system for the carotid artery: 12-month results

Marc Bosiers; Koen Deloose; Giovanni Torsello; Dierk Scheinert; Lieven Maene; Patrick Peeters; Stefan Müller-Hülsbeck; Horst Sievert; Ralf Langhoff; Joren Callaert; **Carlo Setacci**; Jeroen Wauters

EuroIntervention. 2018 Aug 7. pii: EIJ-D-18-00230. doi: 10.4244/EIJ-D-18-00230. [Epub ahead of print]



Use of Dual Layered stents in endovascular treatment of extracranial stenosis of the internal carotid artery. Results of a patient-based meta-analysis of 4 clinical studies

Eugenio Stabile, MD ¹, PhD, Gianmarco De Donato, MD, PhD ², Piotr Musialek, MD, PhD ³, Koen De loose, MD⁴, Roberto Nerla, MD⁵, Pasqualino Sirignano, MD⁶, Salvatore Chianese, MD ¹, Adam Mazurek MD³, Tullio Tesorio, MD⁷, Marc Bosiers, MD⁴, Carlo Setacci, MD², Francesco Speziale, , MD⁶, Antonio Micari, MD⁴, Giovanni Esposito, MD, PhD¹.

A total 556 patients, who underwent CAS stenting with the use of DLS, Roadsaver[®] (Terumo Corp, Tokyo, Japan) or CGuard[®] (InspireMD, Boston, USA), where included in the study.



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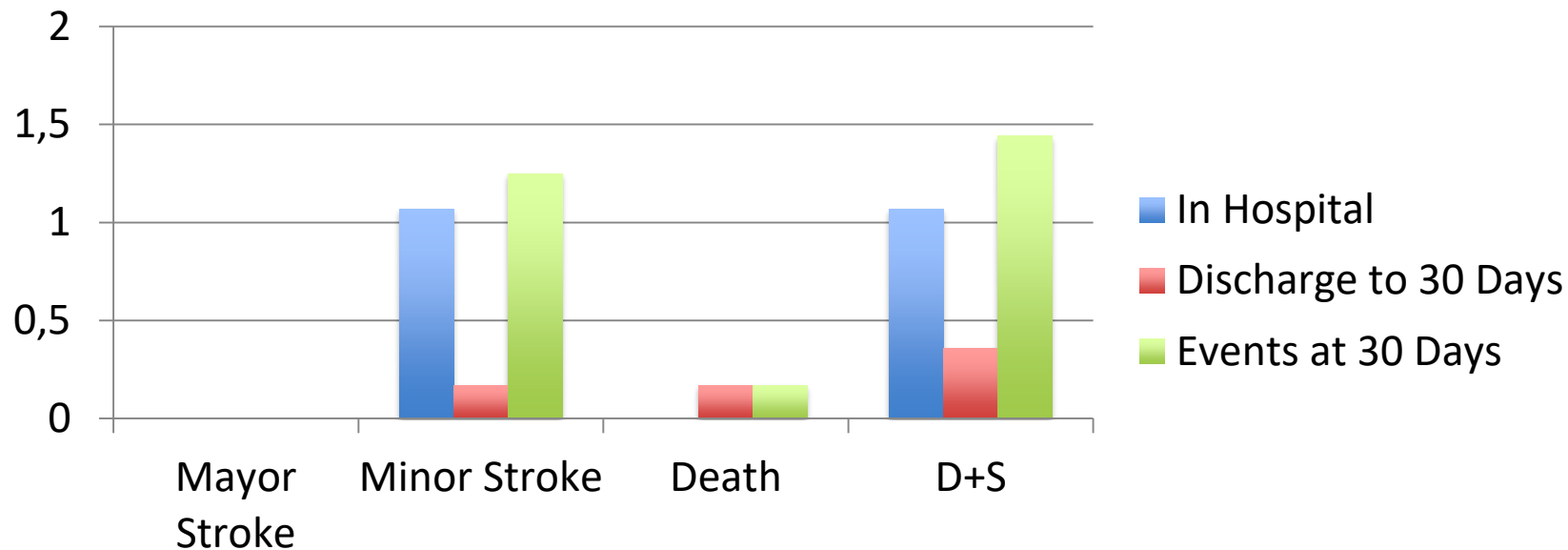


SAPIENZA
UNIVERSITÀ DI ROMA



GVM
CARE & RESEARCH

Incidence of adverse events at 30 days (%)



	Peri-procedural (In Hospital;%/N)	Discharge-30 days (%/N)	Total 30 days (%/N)
Minor Stroke	1,07%(6)	0,17%(1)	1,25%(7)
Major Stroke	0% (0)	0% (0)	0% (0)
Death	0% (0)	0,17%(1)	0,17%(1)
Any Stroke and Death	1,07%(6)	0,36%(2)	1,44%(8)

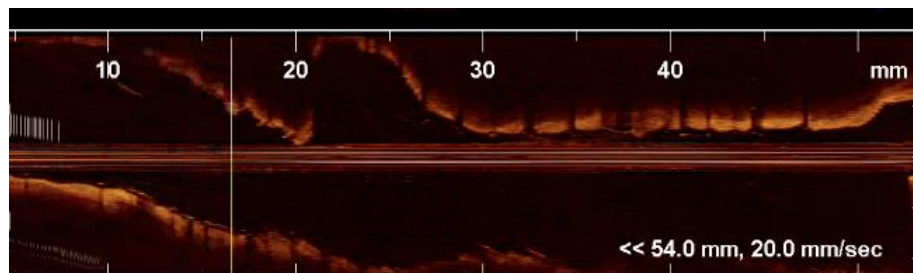
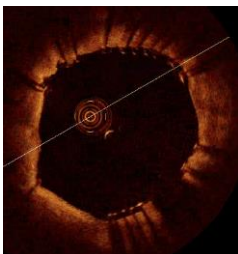
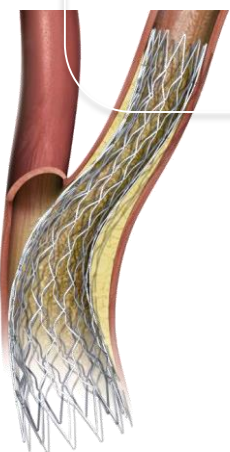
Stabile et al. *JACC Cardiovasc Int* 2018

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

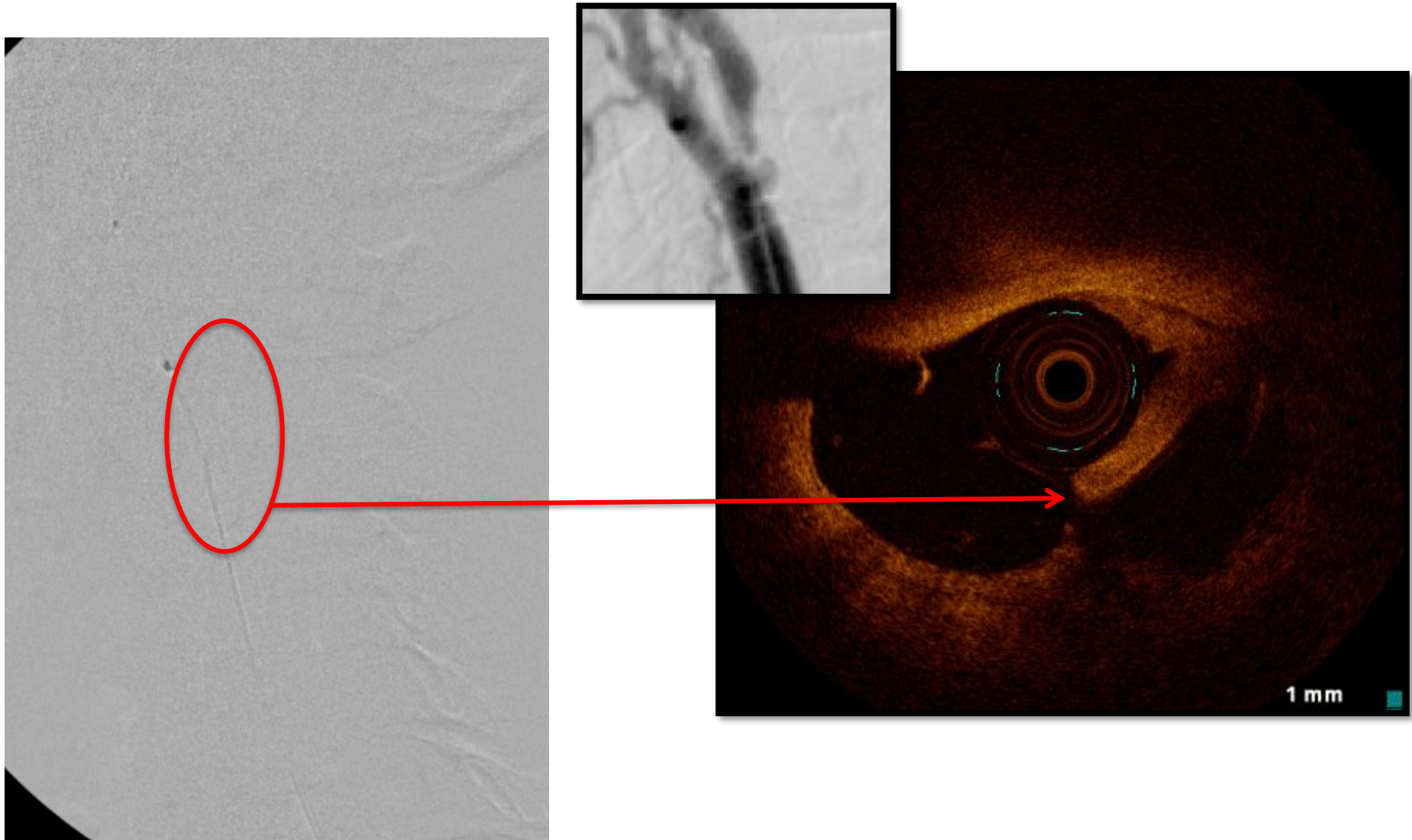
Carlo Setacci, MD; Gianmarco de Donato, MD; Francesco Setacci, MD; Giuseppe Galzerano, MD; Pasqualino Sirignano, MD; Alessandro Cappelli, MD; and Giancarlo Palasciano, MD

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

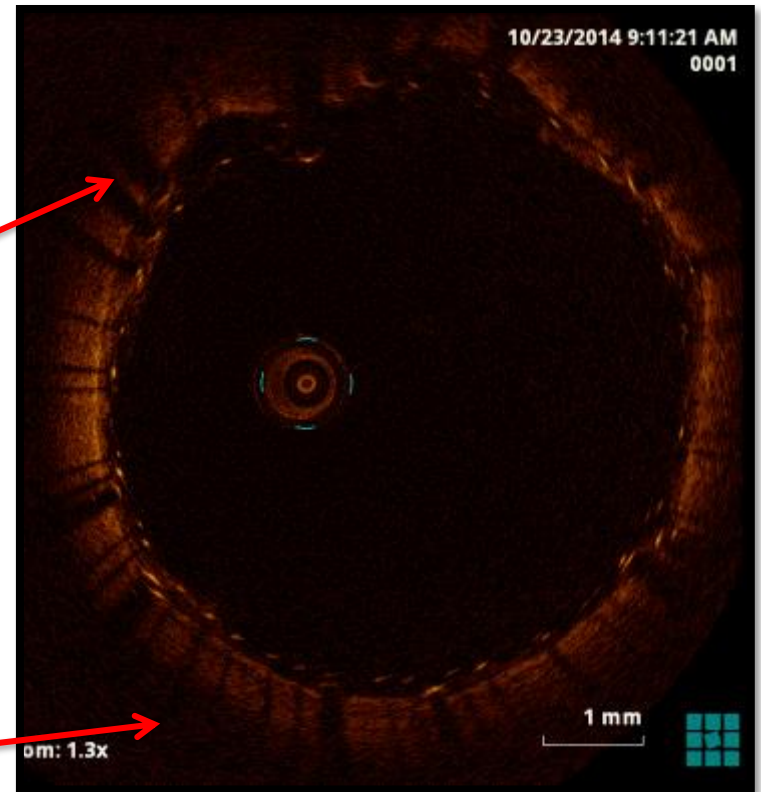
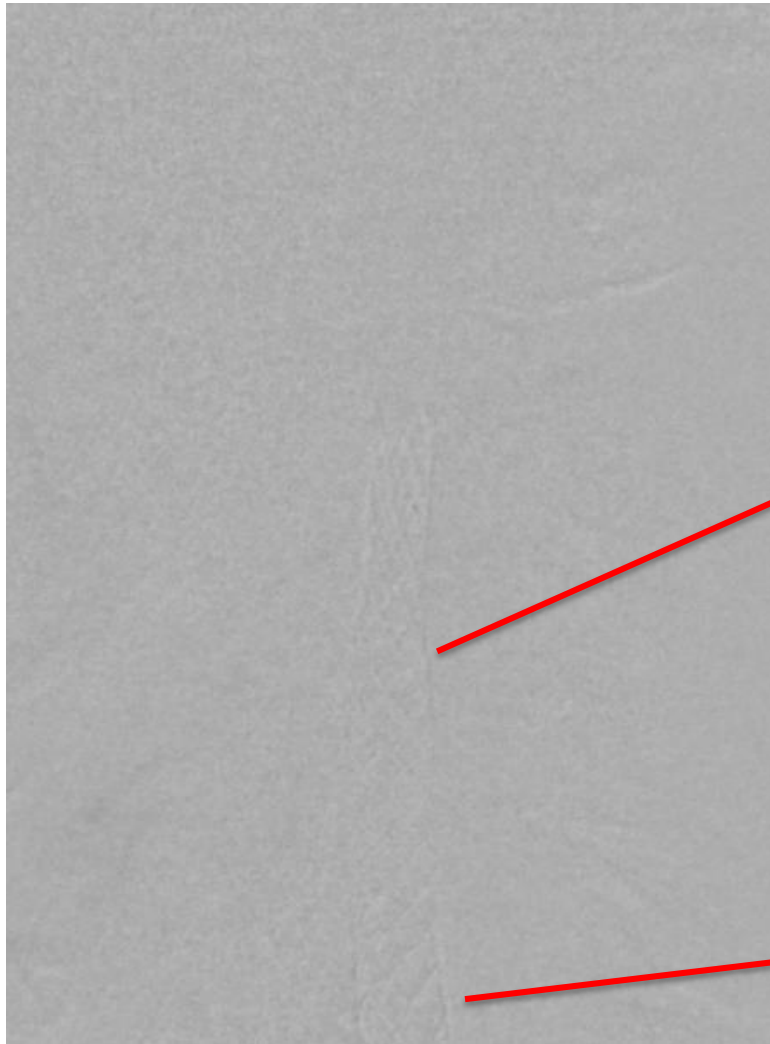
Conclusions: Intravascular OCT during a nonocclusive flush appears to be feasible and safe in carotid arteries.



IMPACT OF NEW STENT DESIGN



IMPACT OF NEW STENT DESIGN



Why do I use OCT in carotids?

UTILITY - results

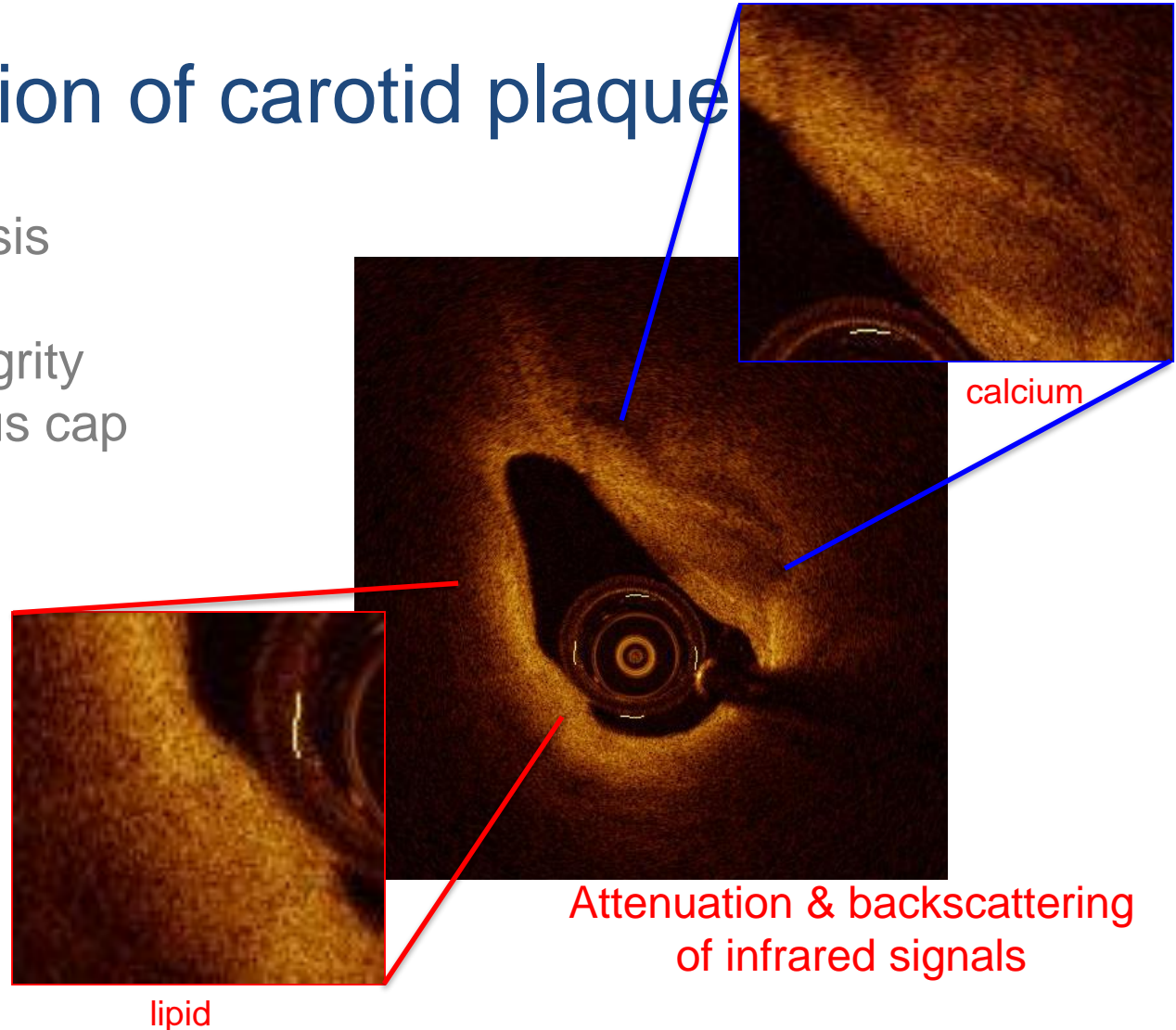
1. High definition of carotid plaque
 2. Interaction between plaque & stent
- 

OCT in carotids – new frontiers

1. High definition of carotid plaque

- **Plaque type**

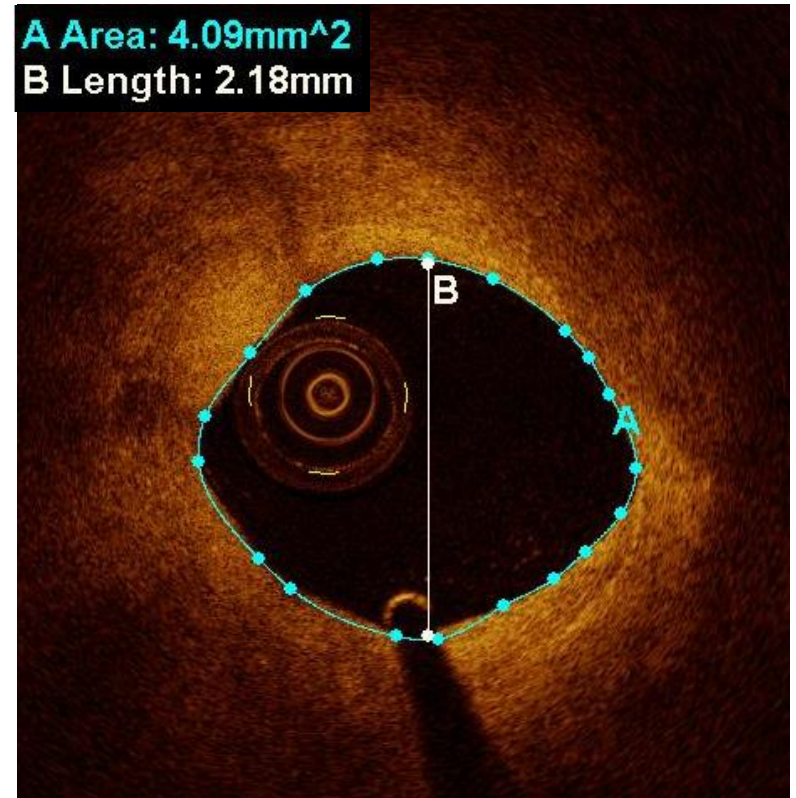
- Degree of stenosis
- Area of stenosis
- Fibrous cap integrity
- Rupture of fibrous cap
- Ulceration



OCT in carotids – new frontiers

1. High definition of carotid plaque

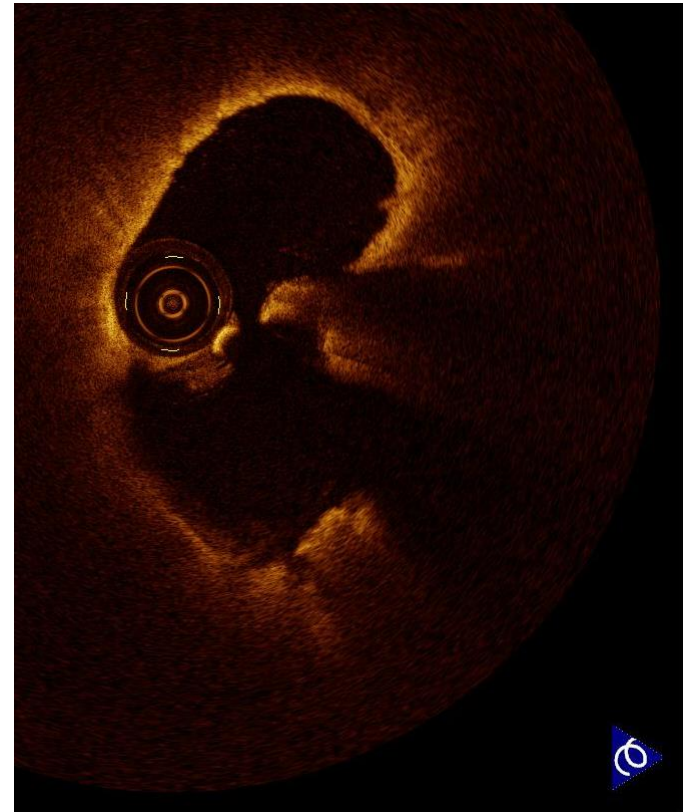
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- Rupture of fibrous cap
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OCT in carotids – new frontiers

1. High definition of carotid plaque

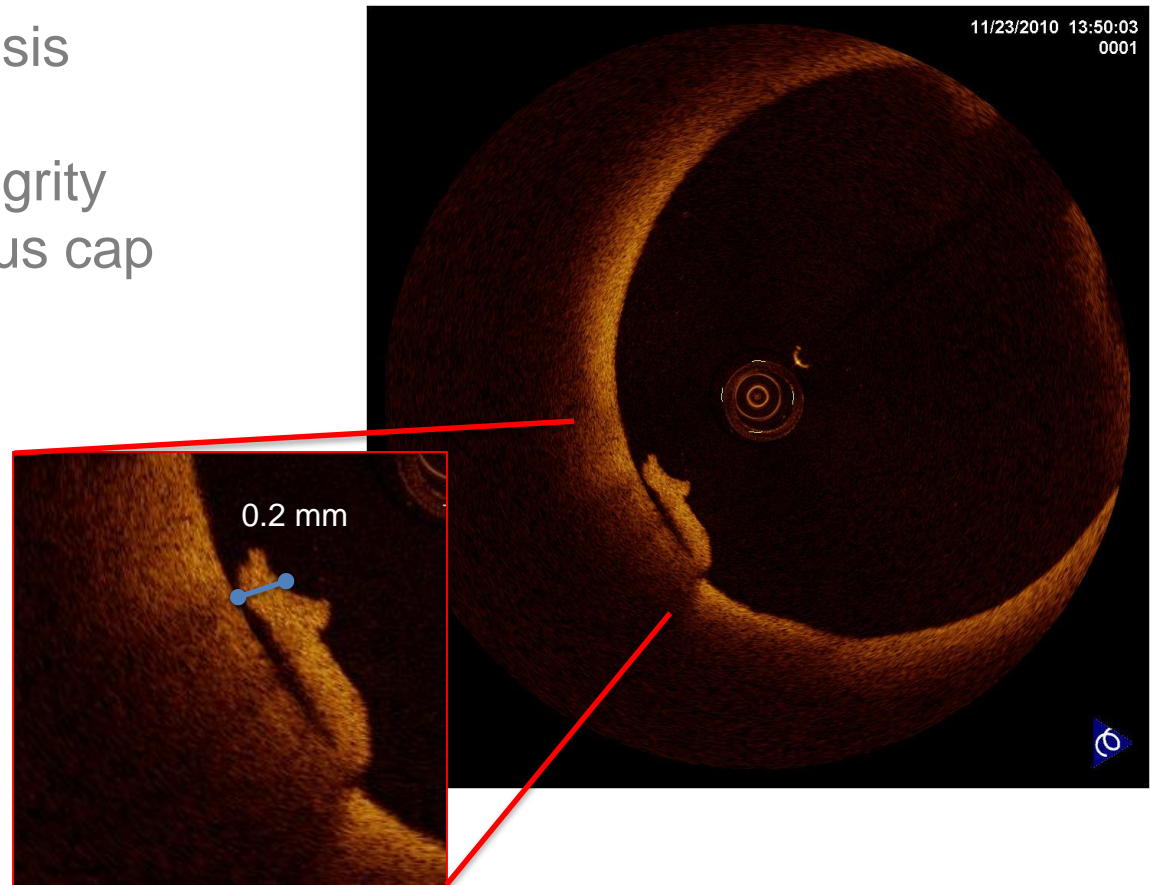
- Plaque type
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- **Ulceration**
- Thrombus



OCT in carotids – new frontiers

1. High definition of carotid plaque

- Plaque type
- Degree of stenosis
- Area of stenosis
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Why do I use OCT in carotids?

UTILITY - results

1. High definition of carotid plaque

2. Interaction between plaque & stent



OCT in carotids – new frontiers

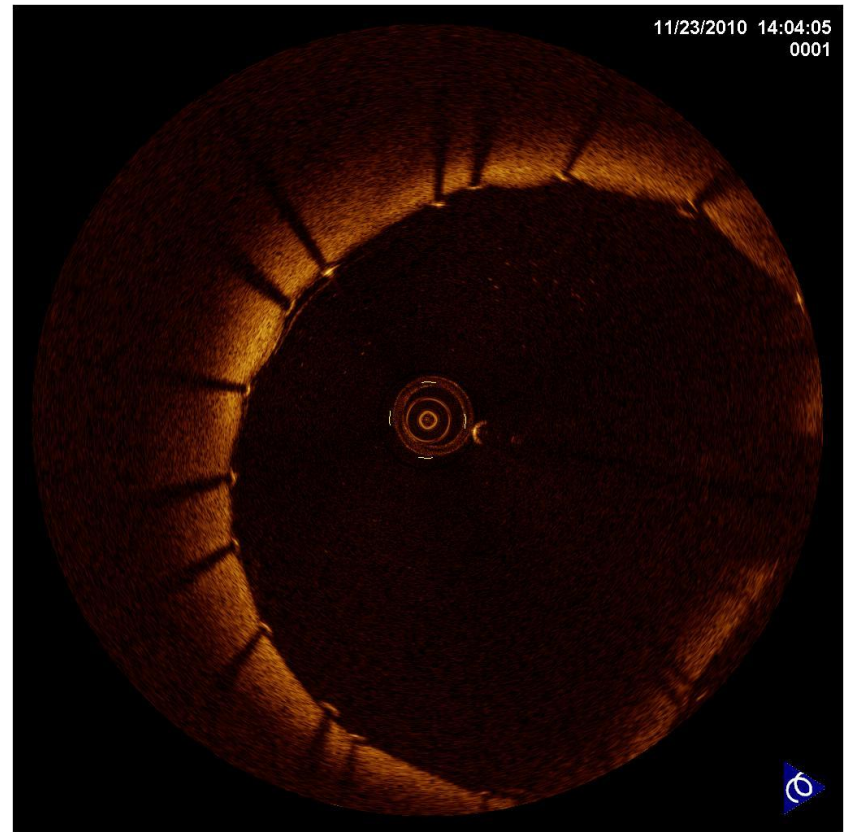
2. Interaction between plaque & stent

Intraop control:

- Residual stenosis
- **Stent apposition**
- Stent malapposition
- Cell area modification
- Fibrous cap rupture
- Plaque micro-prolaps
- Branch side coverage

Follow-up control:

- neointimal thickness
- complete/incomplete
stent struts coverage



OCT in carotids – new frontiers

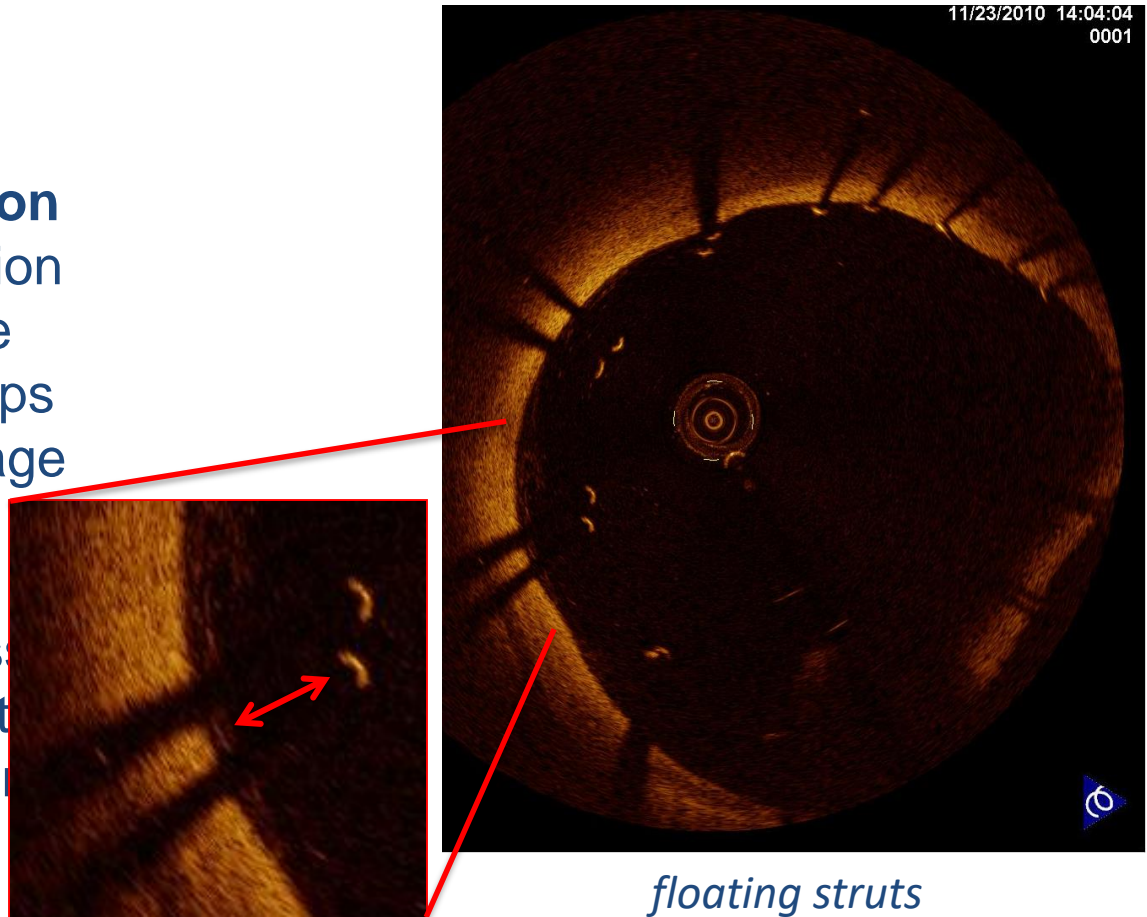
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OCT in carotids – new frontiers

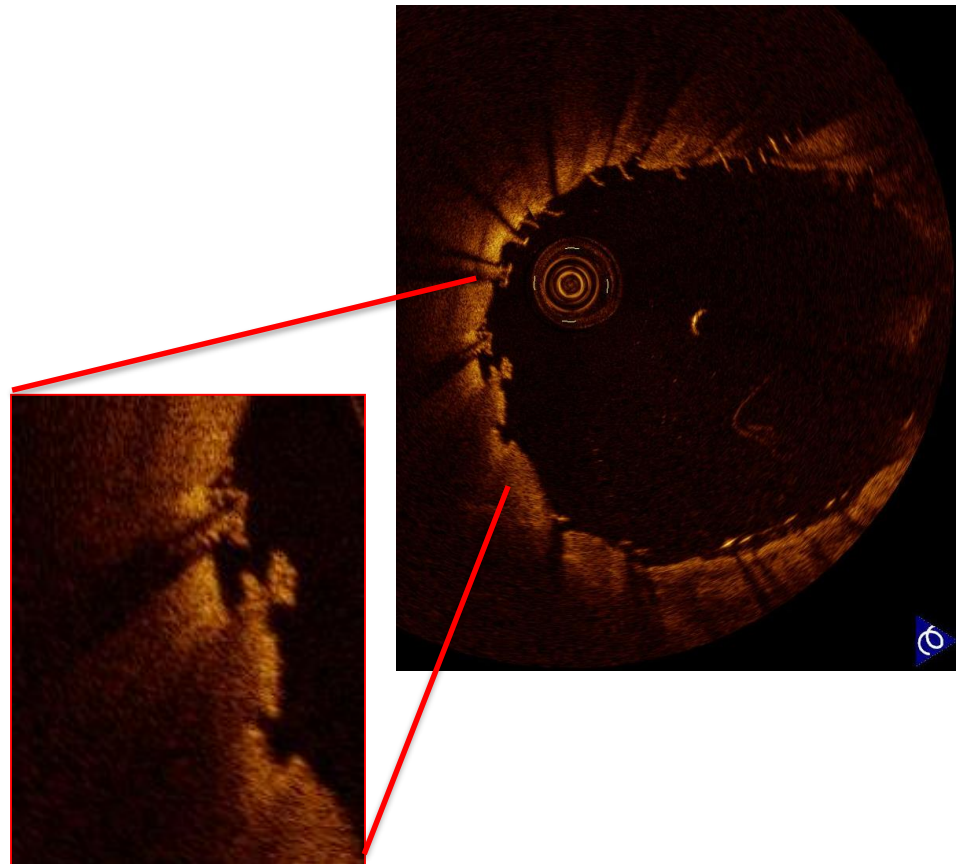
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OCT in carotids – new frontiers

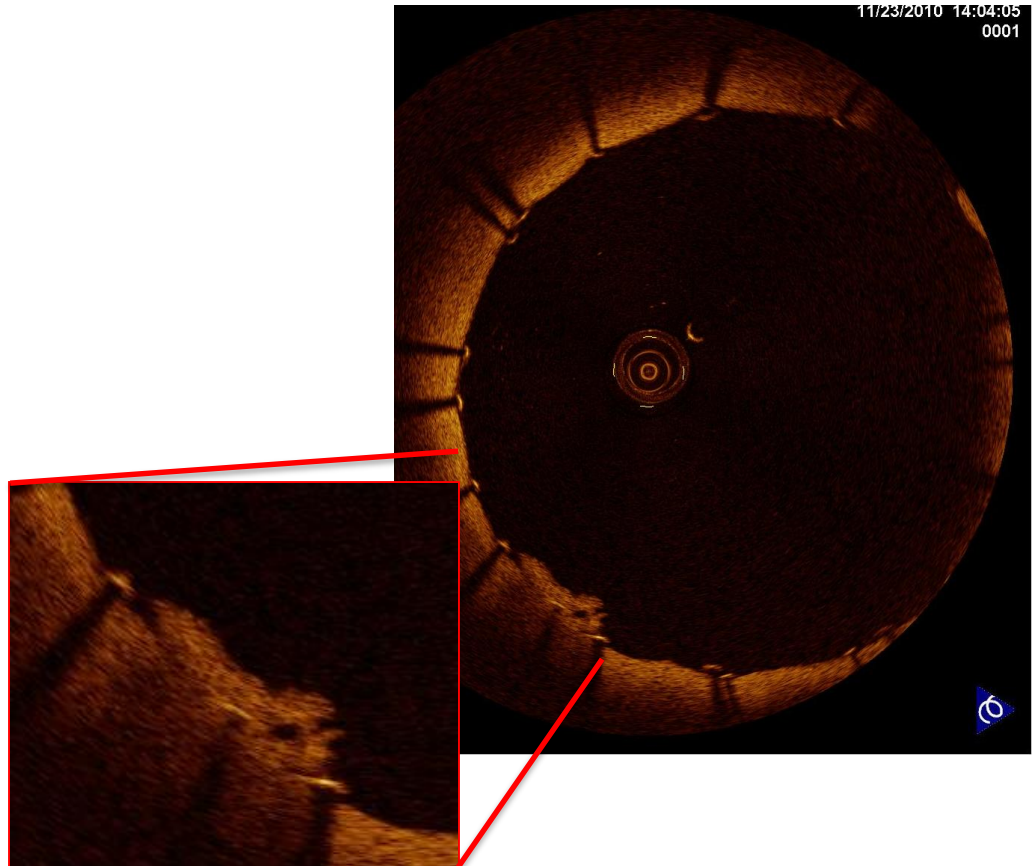
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OCT in carotids – new frontiers

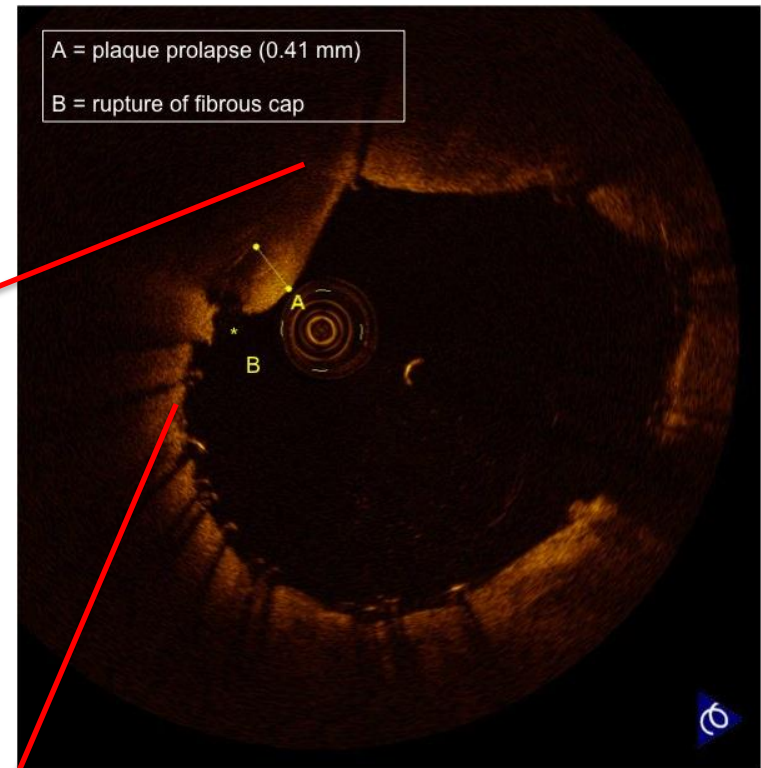
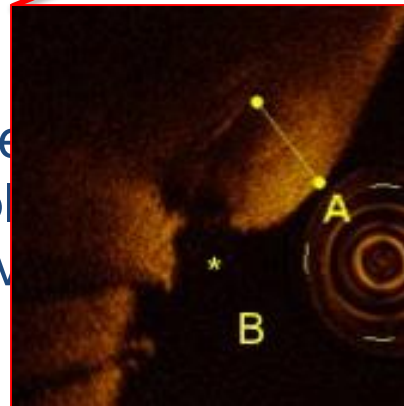
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Intraop control:

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- Stent apposition
- Stent malapposition
- Cell area modification
- **Fibrous cap rupture & Plaque micro-prolaps**
- Branch side coverage

Follow-up control:

- neointimal thickness
- complete/incomplete stent struts coverage



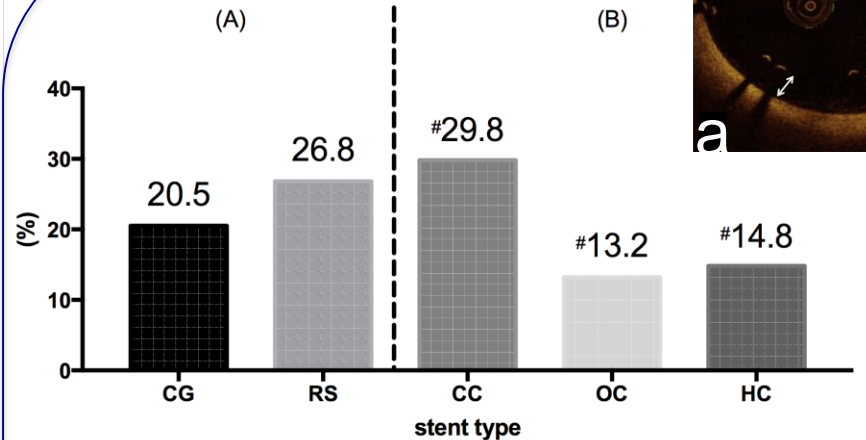
Optical coherence tomography assessment of new-generation mesh-covered stents after carotid stenting.

[Umemoto T, de Donato G, Pacchioni A,
Reimers B, Ferrante G, Isobe M, **Setacci C.**](#)

***EuroIntervention. 2017 Dec 20;13(11):1347-1354.
doi: 10.4244/EIJ-D-16-00866.***



Strut malapposition

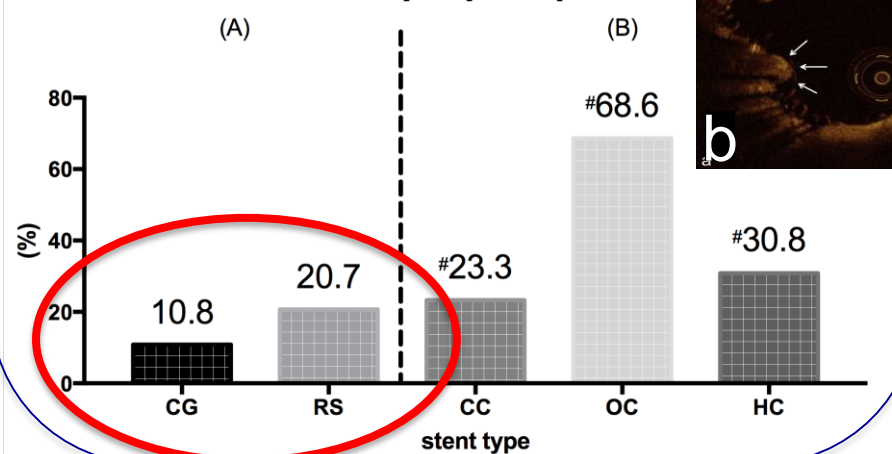


- No procedural neurological complications occurred (TIA/stroke/death 0% at 30 days).

Slice-based analysis

- Compared with conventional stents, the incidence of plaque prolapse was lower

Plaque prolapse



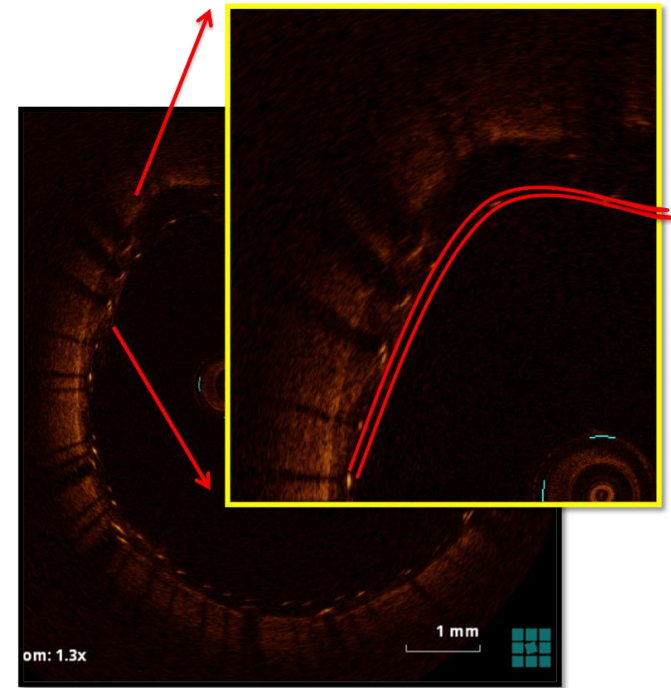
EuroIntervention. 2017 Aug

Conclusions

Why A Reinvigoration Of CAS Is Justified By Better Embolic Protection And Newer Mesh Covered Stents; OCT Proves It

- **Better Embolic Protection**
- **Newer Mesh Covered Stents**

Definitively, OCT Proves It!



Plaque prolapse contained by the mesh component of next gen stents

