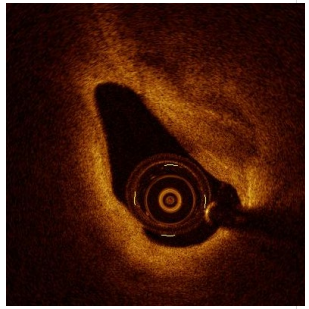
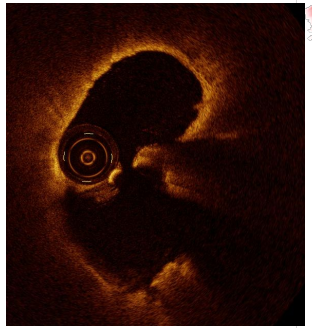
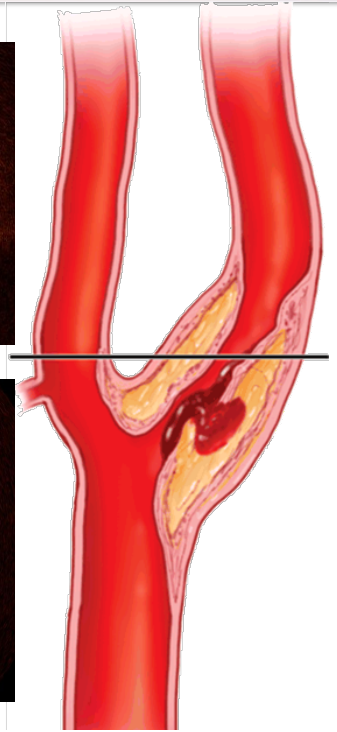
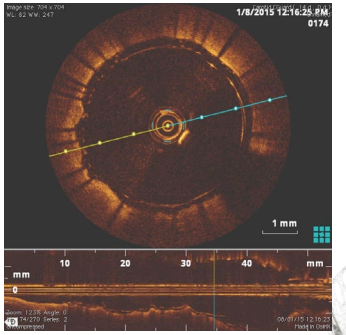
June 8th, 2023

OCT Analysis of CAS Cases – The Benefits of MicroNet™









Gianmarco de Donato
Full Professor of Vascular Surgery
University of Siena
Italy

Disclosure

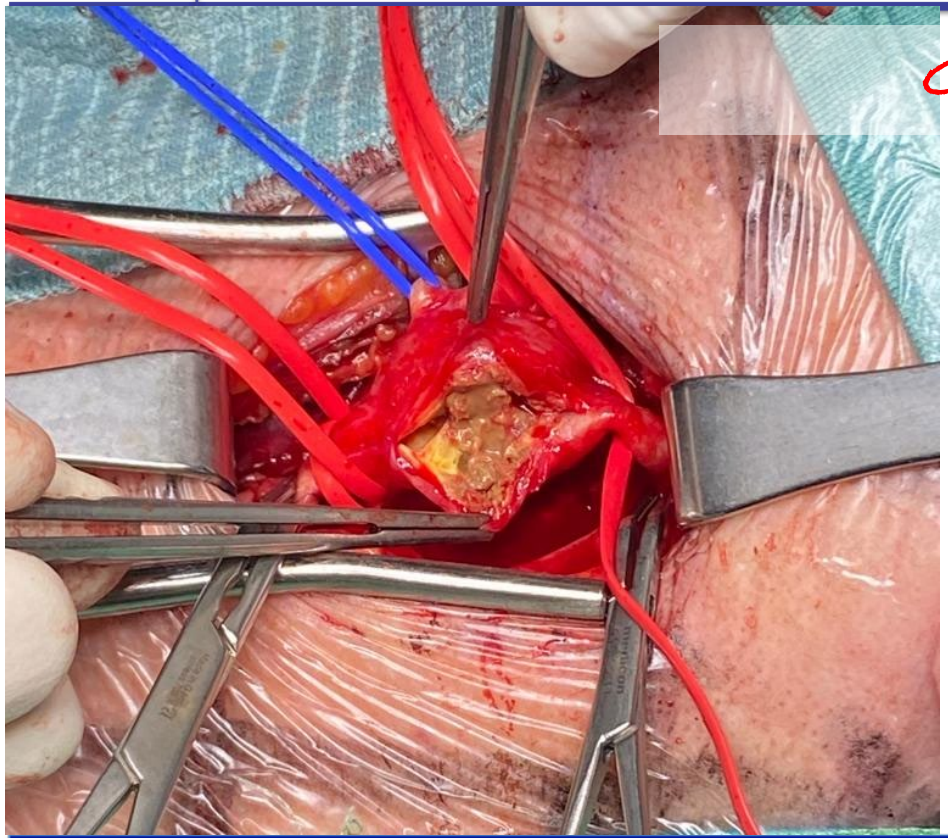
Speaker's name: Gianmarco de Donato

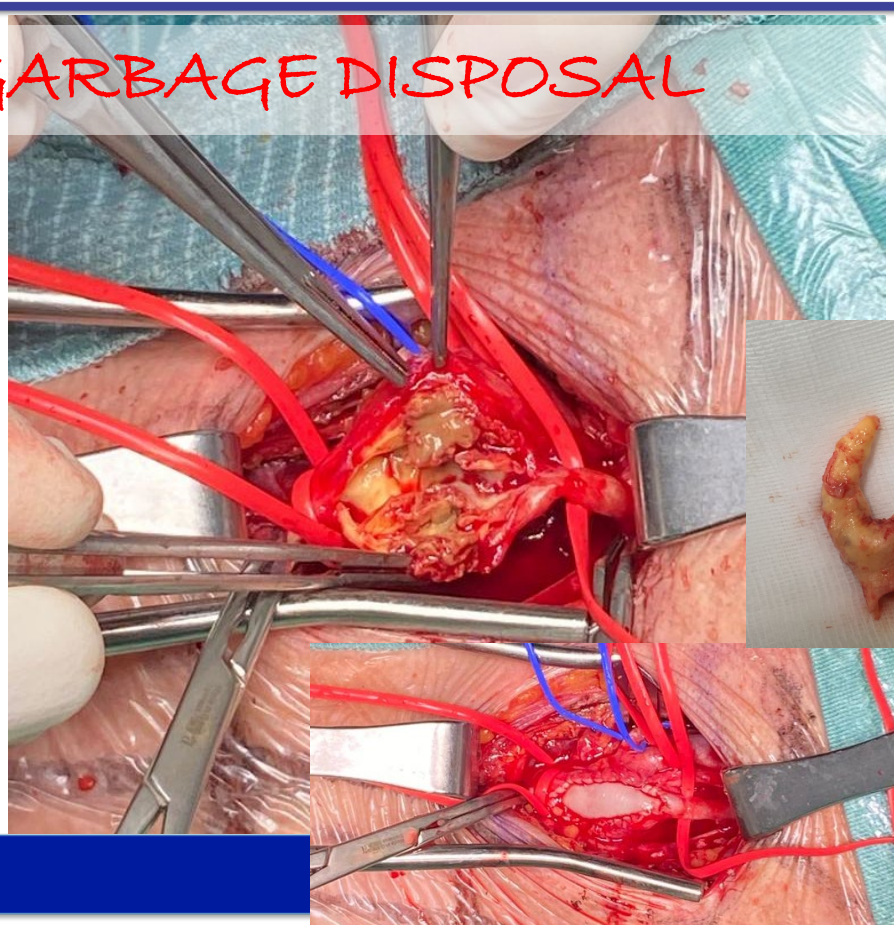
x **I have the following** potential conflicts of interest to report:

- ☐ Research contracts
- x Travel & educational grants (Boston Scientific, Terumo, Inspire, Endologix, Gore, Penumbra)
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ **I do not have any potential conflict of interest**

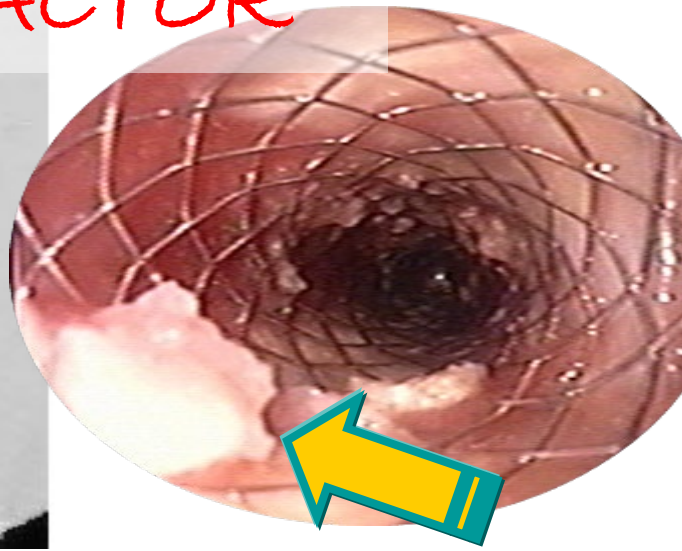
Treatment options





Treatment options

- **ENDOVASCULAR** → Plaque containment!



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

EuroIntervention

Carotid angioplasty and stenting: lesion related treatment strategies

Alberto Cremonesi[1]*; Carlo Setacci[2]; Raffaella Manetti[1]; Gianmarco de Donato[2]; Francesco Setacci[2]; Guido Balestra[1]; Ignazio Borghesi[3]; Paolo Bianchi[1]; Fausto Castriota[1]

1. Interventional Cardio-Angiology Unit, Villa Maria Cecilia Hospital, Cotignola (RA), Italy
2. Department of Vascular and Endovascular Surgery, University of Siena, Siena, Italy
3. Neuro-surgical Department, Villa Maria Cecilia Hospital, Cotignola (RA), Italy

EuroInterv.2005;1:289-295

Table 3. Stent technical characteristics

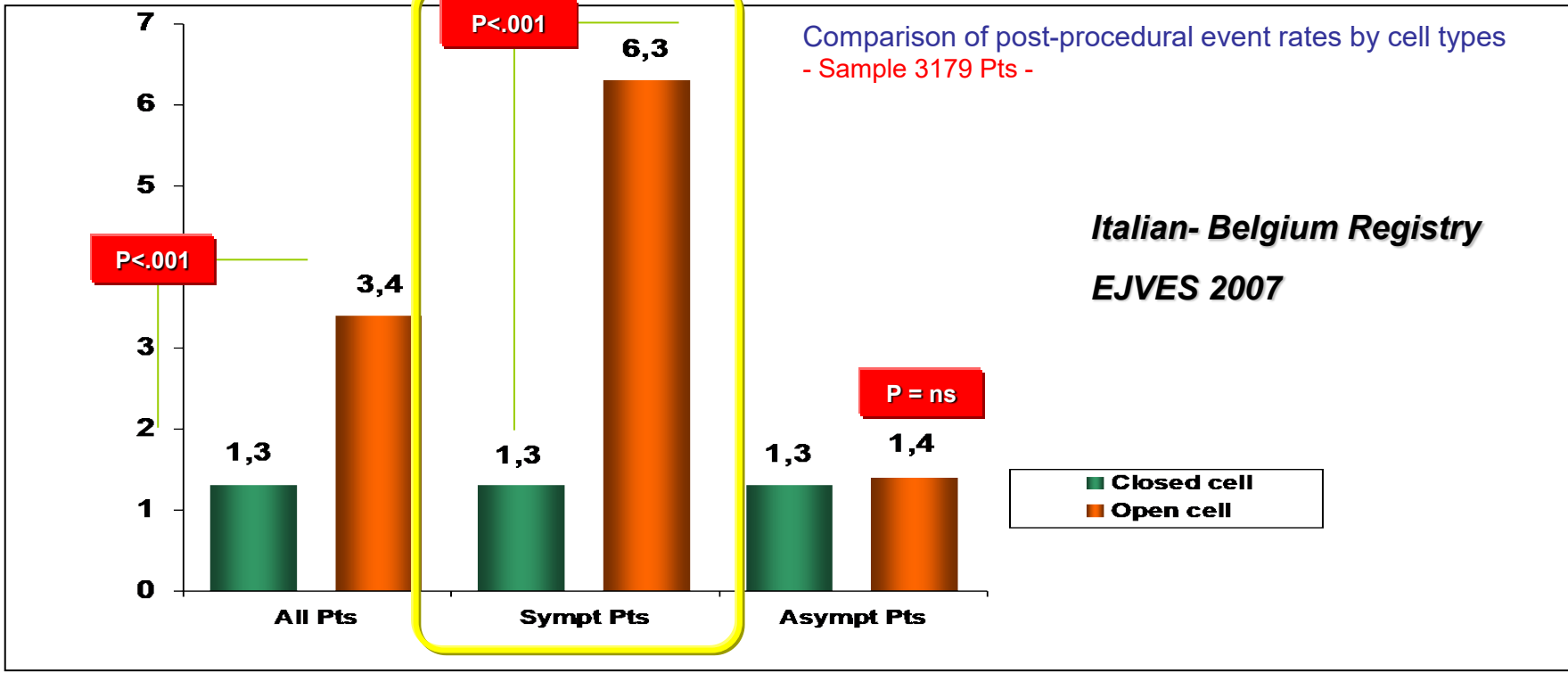
Stent technical features	Cobalt-alloy	Nitinol OCD*	Nitinol CCD**
Foreshortening	TS	TI	TI
Conformability / flexibility	+	++	–
Vessel wall adaptability	+	++	+
Scaffolding	++	+	++
Radial strength	+	++	++
Radial stiffness	+	+	+
Lesion covering	++	–	++

Legend:

Table 4. Specific carotid lesions and bifurcation anatomy

Carotid lesion / bifurcation issue	Type of stent
1. medium to long lesions (15 to > 25 mm)	Cobalt-alloy braided thread stent
2. soft-dishomogeneous lesions	
3. straight carotid bifurcation	
4. carotid bifurcation lesions with ICA/CCA diameter mismatching	Nitinol open cell stents
5. angled carotid bifurcation	
6. short lesions (<15 mm)	
7. highly calcified lesions	Nitinol closed cell stents
8. straight carotid bifurcation	

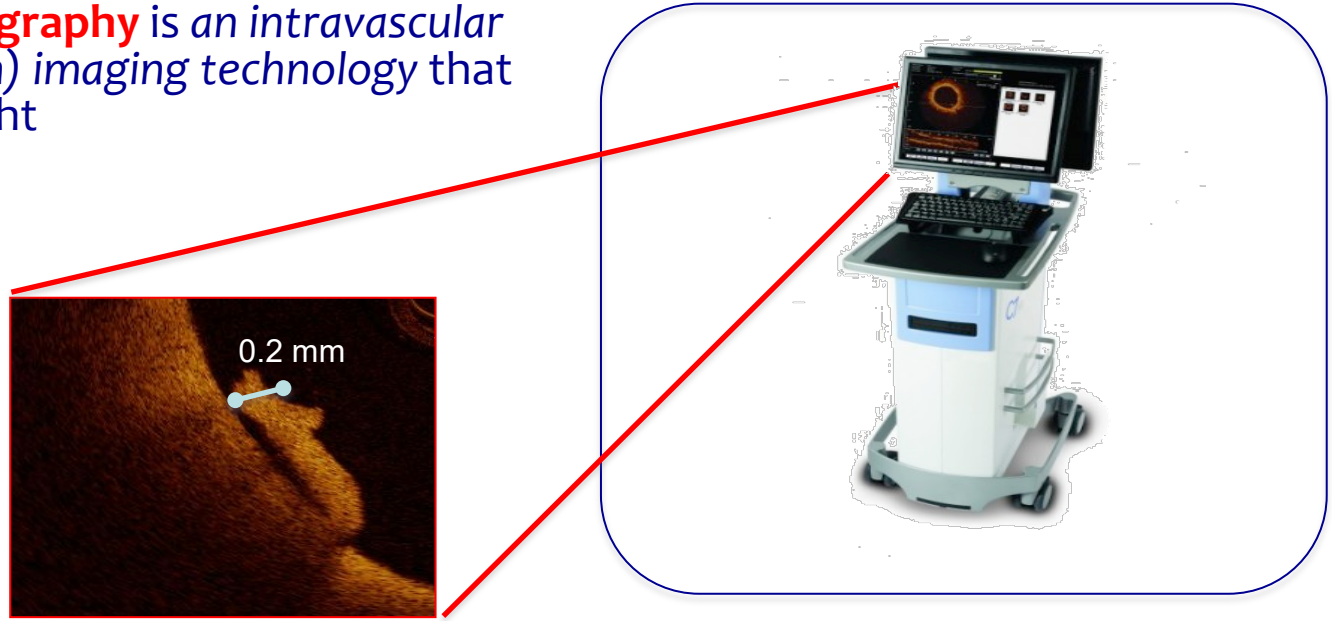
Influence of carotid stent design (closed vs open) & cell area



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.*

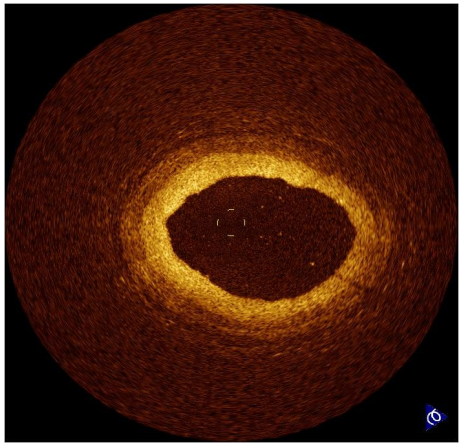
OCT for Stent Selection

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

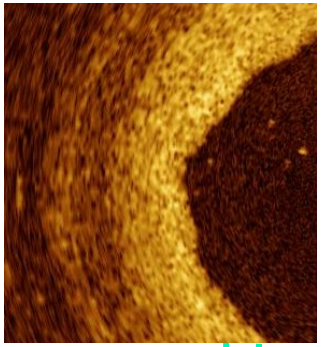


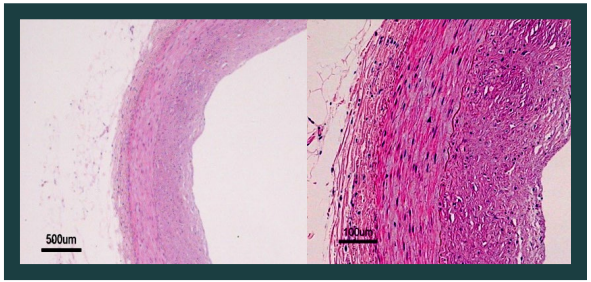
What is OCT?

OCT is a high-resolution imaging technology



OCT





Histology

J ENDOVASC THER
2012;19:303–311

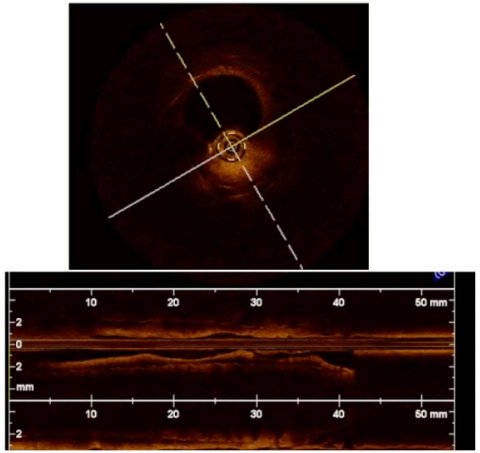
◆ CLINICAL INVESTIGATION ◆

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.

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

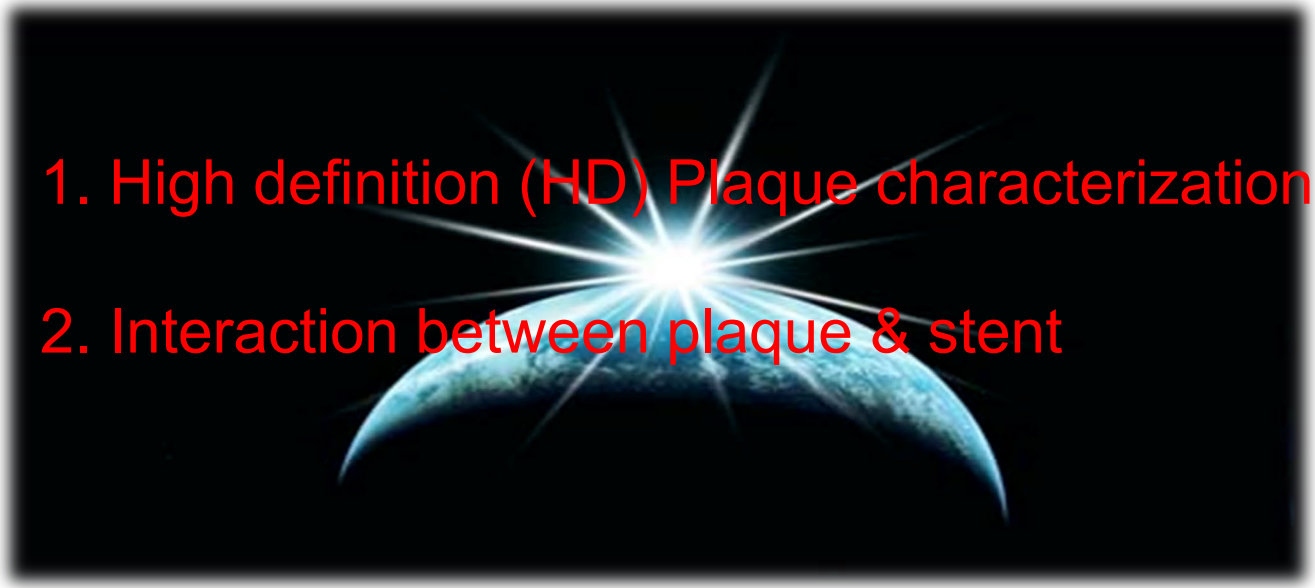


Mechanical injection of 20 ml 50% diluited contrast at 6ml/sec (to replace blood from the artery)

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

Why do I use OCT in carotids?

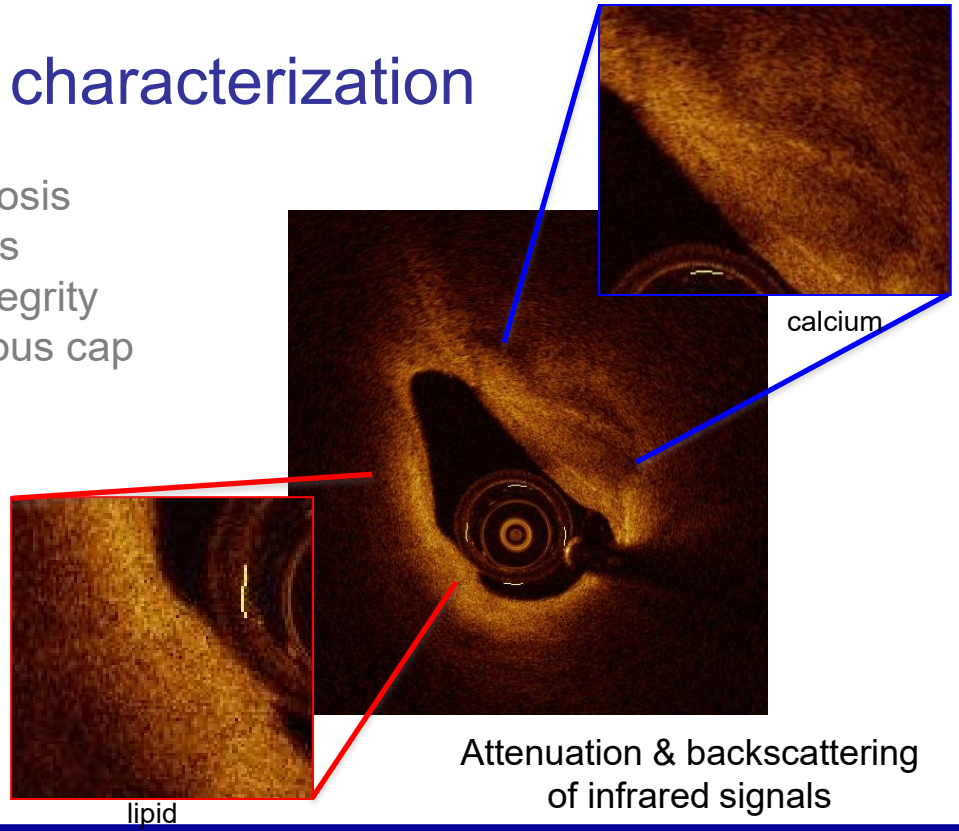
UTILITY - results



OCT in carotids – new frontiers

1. HD Plaque characterization

- **Plaque type**
- Degree of stenosis
- Area of stenosis
- Fibrous cap integrity
- Rupture of fibrous cap
- Ulceration



Attenuation & backscattering of infrared signals

OCT in carotids – new frontiers

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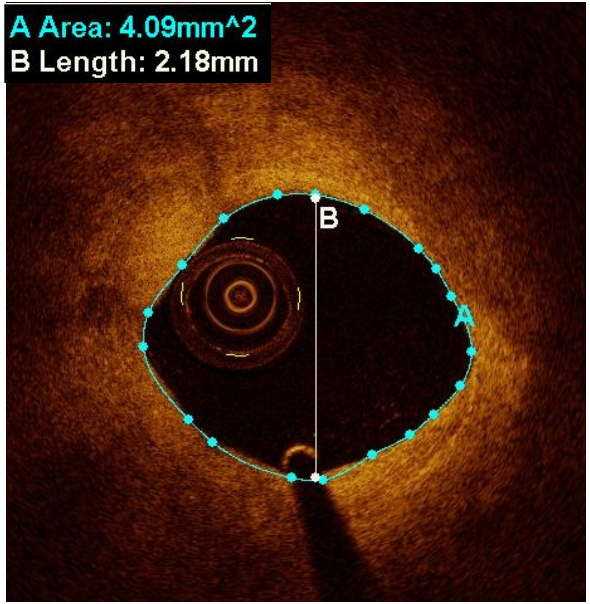

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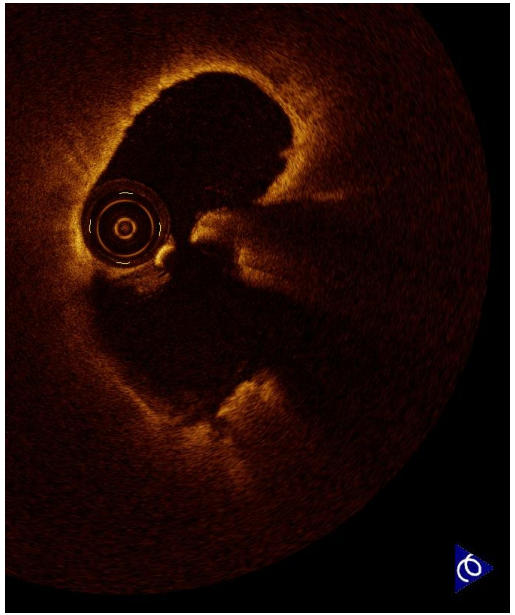
- Thrombus



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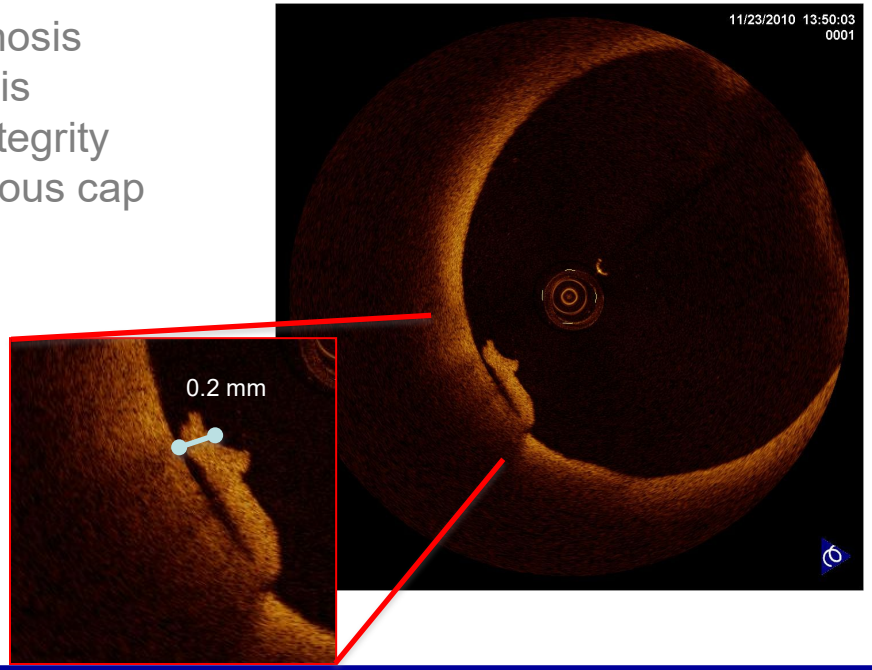

Why do I use OCT in carotids?

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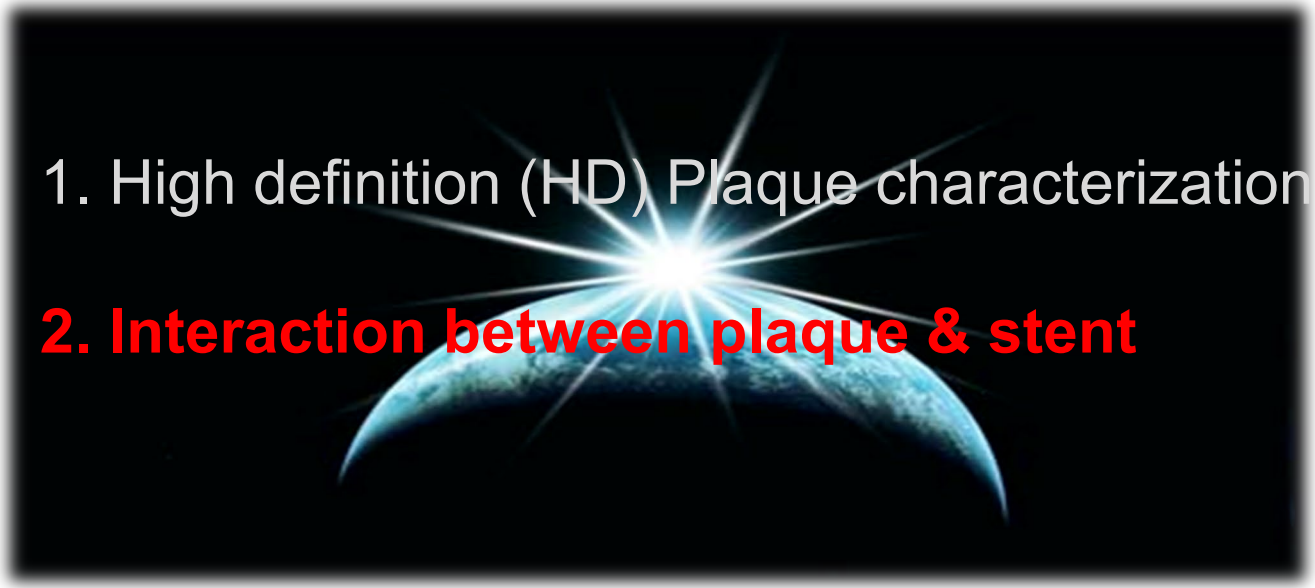


OCT in carotids – new frontiers

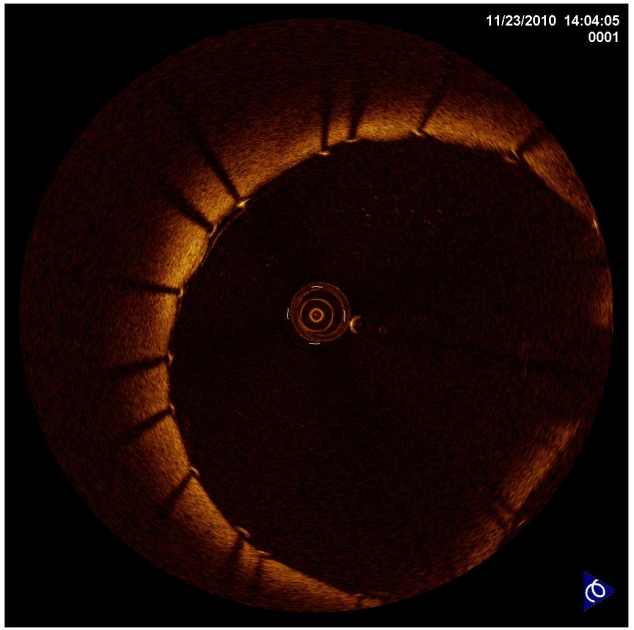
2. Interaction between plaque & stent

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



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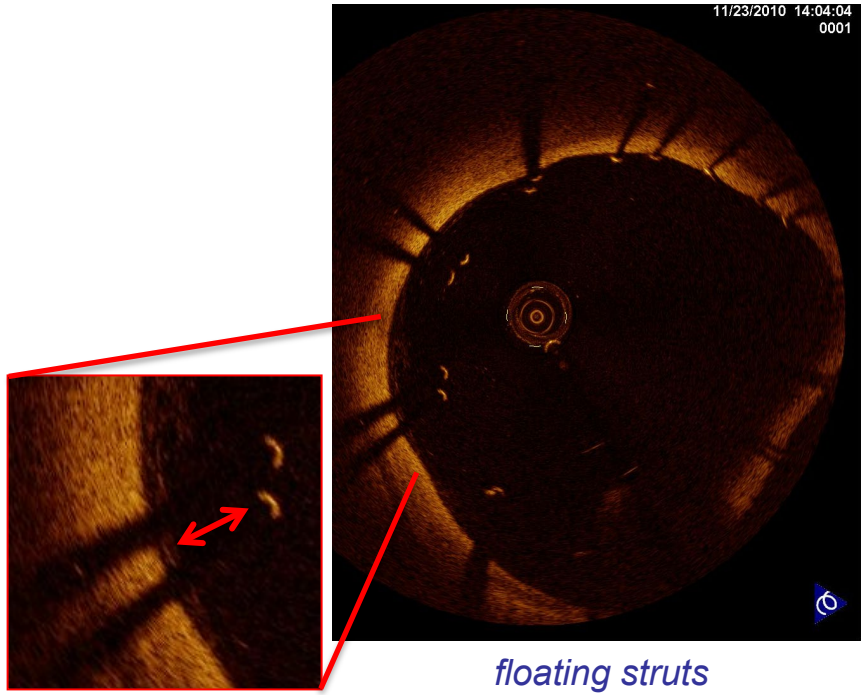

floating struts

2. Interaction between plaque & stent

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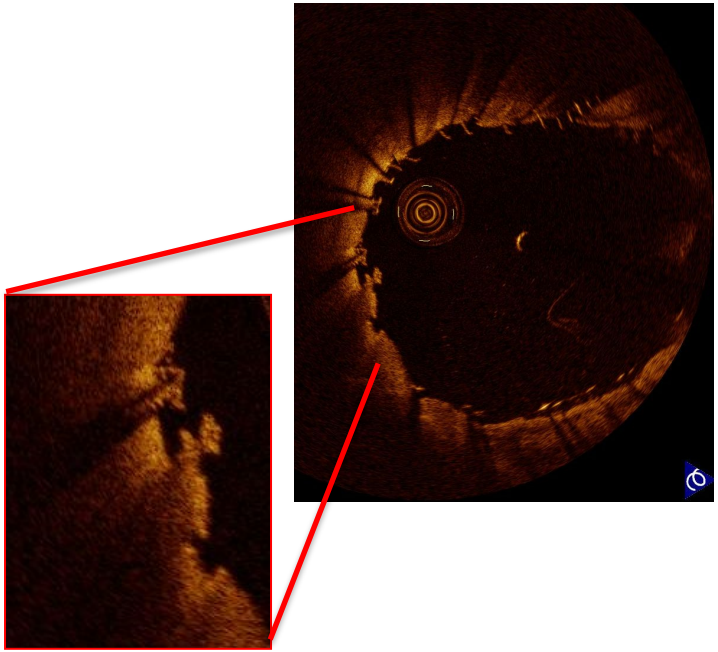

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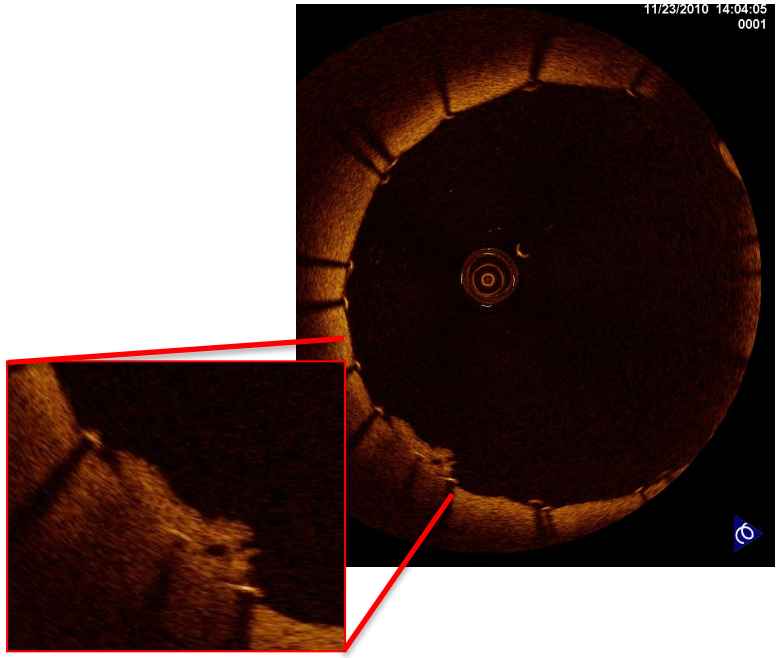

OCT in carotids – new frontiers

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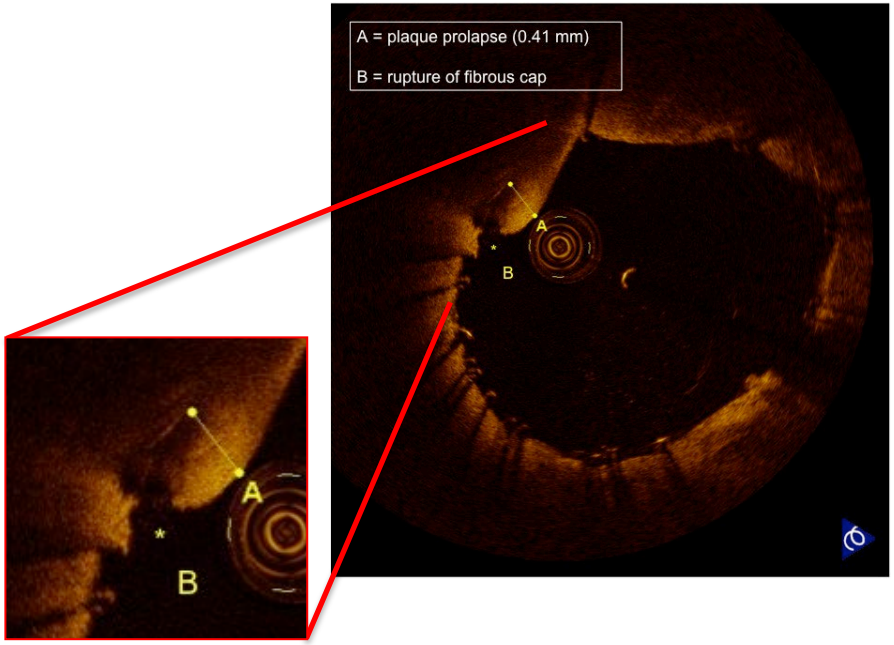


High-resolution makes the difference

Low-resolution image

High-resolution image

OCT & Carotid stent design

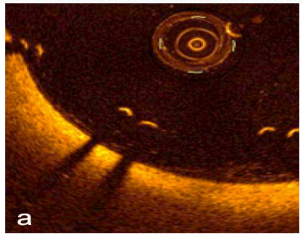
Design

Prospective single center study

Objectives

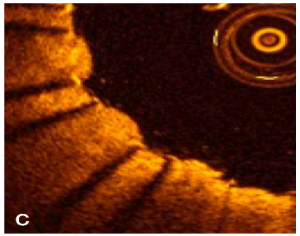
To evaluate the rate of:

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



"Malapposed"

"Well apposed"



"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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To evaluate the rate of:

- stent malapposition
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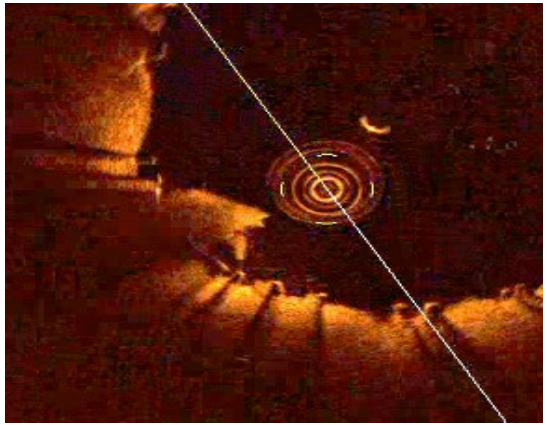

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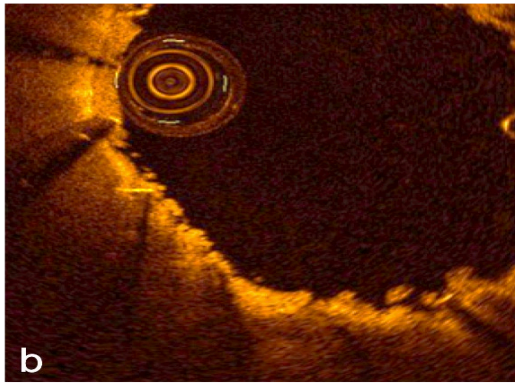

G. de Donato, F. Setacci, P. Sirignano, G. Galzerano, A.Cappelli, C. Setacci.
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OCT & Carotid stent design

Design

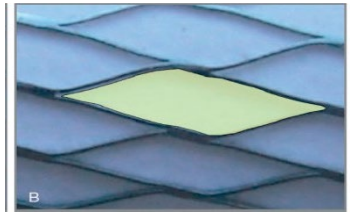
Prospective single center study

Objectives

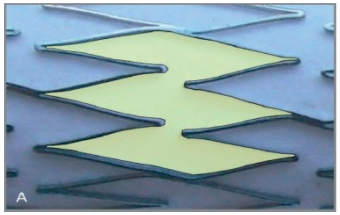
To evaluate the rate of:

- stent malapposition
- plaque prolapse
- fibrous cap rupture

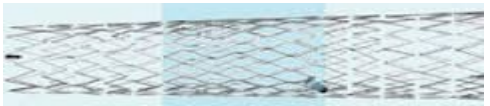
according to carotid stent design



Closed cell (CC)



Open cell (OC)

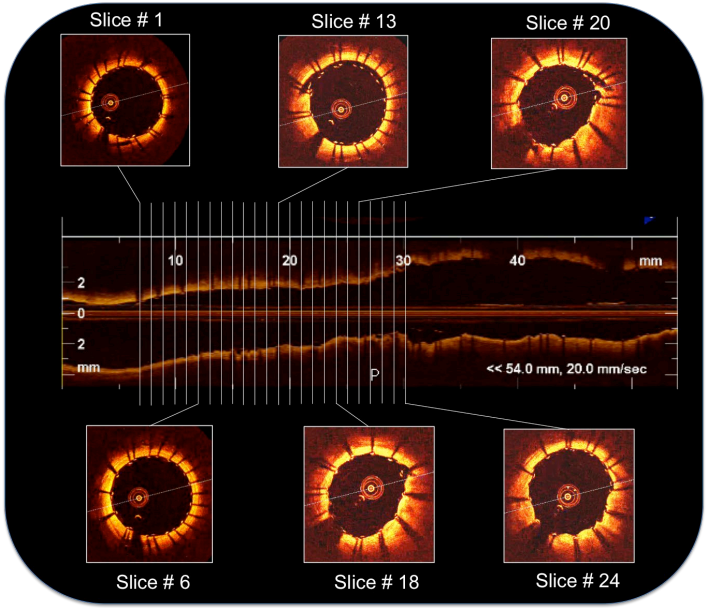


Hyb

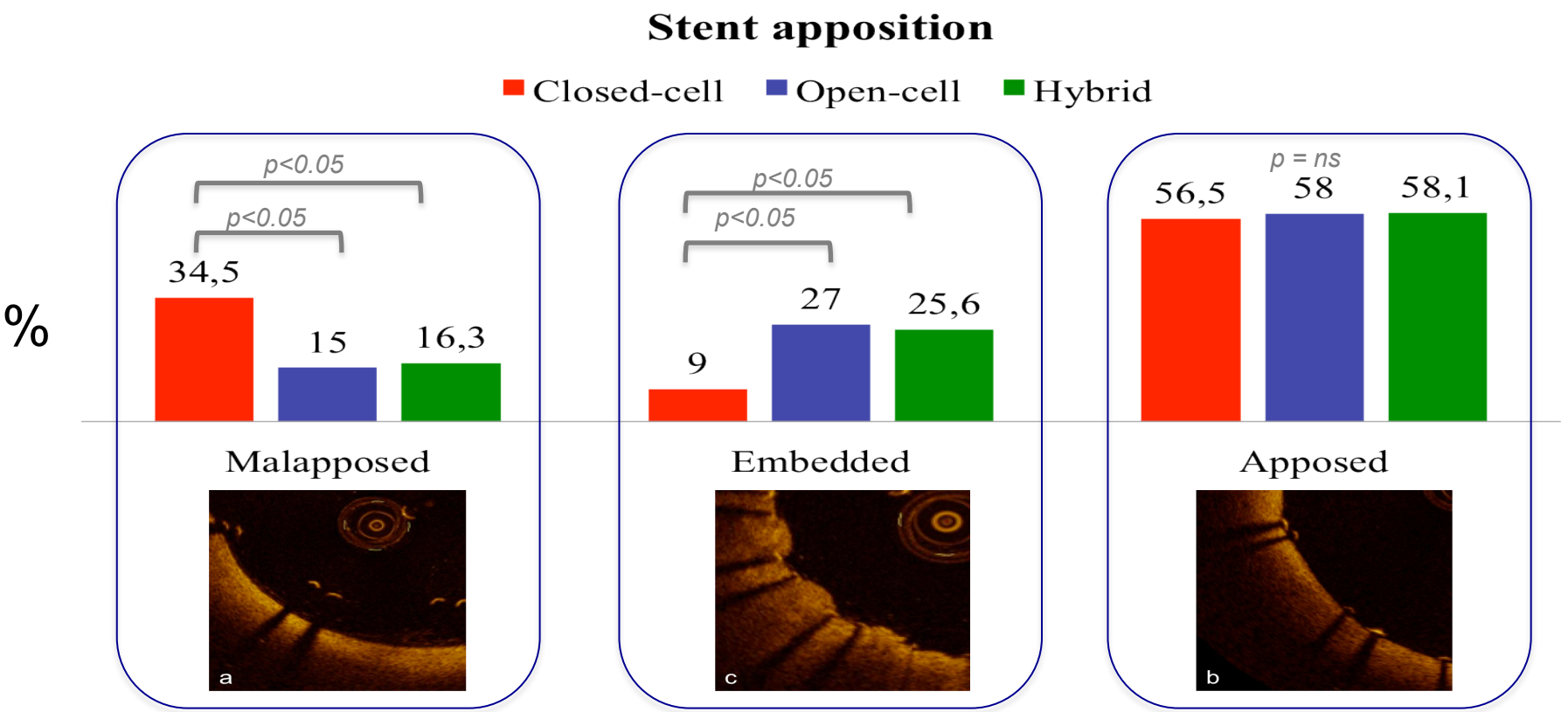
open closed open

Materials and Methods

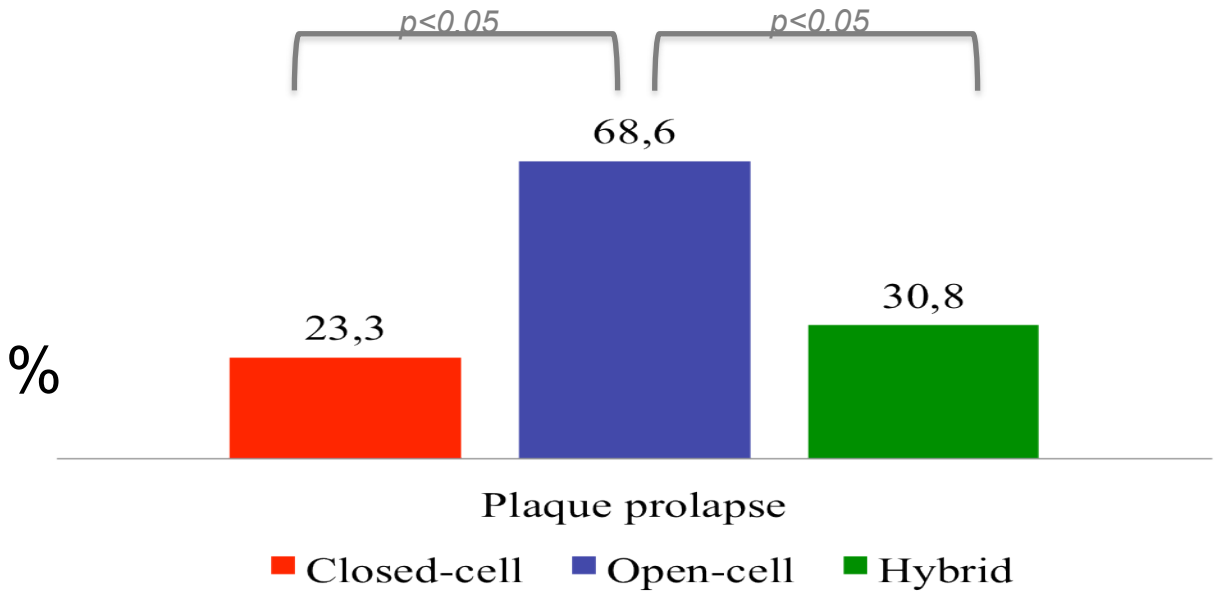
- 40 consecutive patients undergoing protected CAS + OCT
- Off-line analysis of OCT frames (dedicated core laboratory)
- Cross-sectional OCT images within the ICA were evaluated at 1 mm intervals.

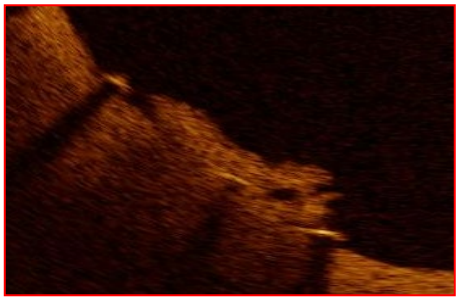


Results:
Stent apposition

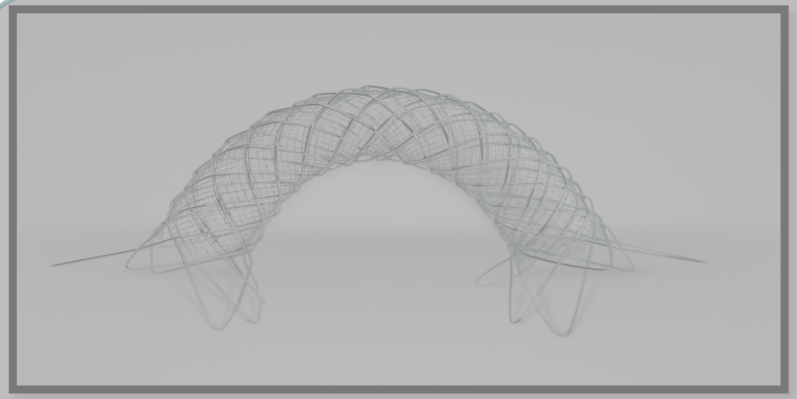


Results:
Plaque prolapse



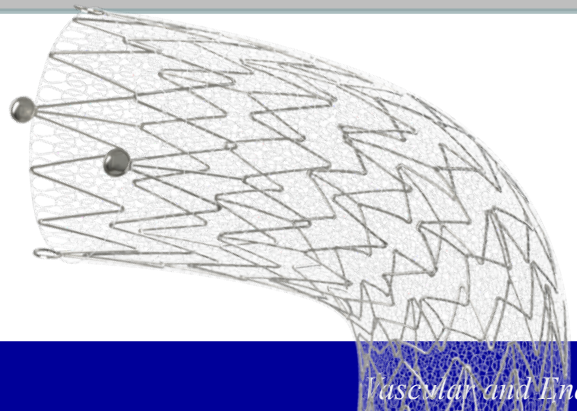


New carotid stent design



Terumo - Roadsaver

Gore – carotid stent



Inspire – C-Guard

Dual layered stents – Meta-Analysis

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.

Stabile E, **de Donato G**, Musialek P, De Loose K, Nerla R, Sirignano P, Chianese S, Mazurek A, Tesorio T, Bosiers M, Setacci C, Speziale F, Micari A, Esposito G.

JACC Cardiovasc Interv. 2018 Dec 10;11(23):2405-2411. doi: 10.1016/j.jcin.2018.06.047.

PMID: 30522670 **Free article.**

	Peri-Procedural (in Hospital)	Discharge to 30 Days	Total 30 Days
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)

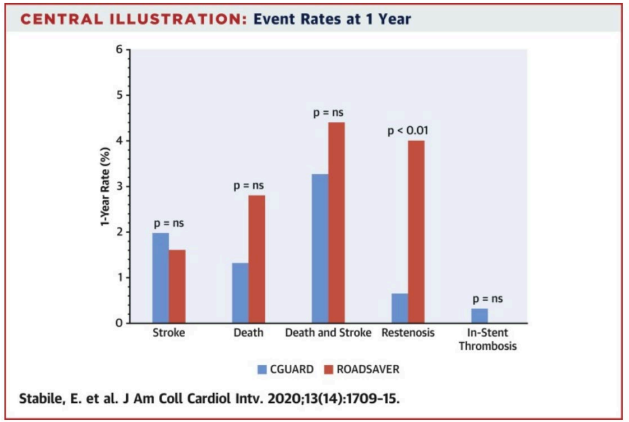
Values are % (n).

Use of Dual-Layered Stents for Carotid Artery Angioplasty: 1-Year Results of a Patient-Based Meta-Analysis.

Stabile E, **de Donato G**, Musialek P, Deloose K, Nerla R, Sirignano P, Mazurek A, Mansour W, Fioretti V, Esposito F, Chianese S, Bosiers M, Setacci C, Speziale F, Micari A, Esposito G.

JACC Cardiovasc Interv. 2020 Jul 27;13(14):1709-1715. doi: 10.1016/j.jcin.2020.03.048.

PMID: 32703595 **Free article.**



Meta-analysis Second- vs. First- generation carotid stents

Review > J Clin Med. 2022 Aug 17;11(16):4819. doi: 10.3390/jcm11164819.

Clinical Outcomes of Second- versus First-Generation Carotid Stents: A Systematic Review and Meta-Analysis

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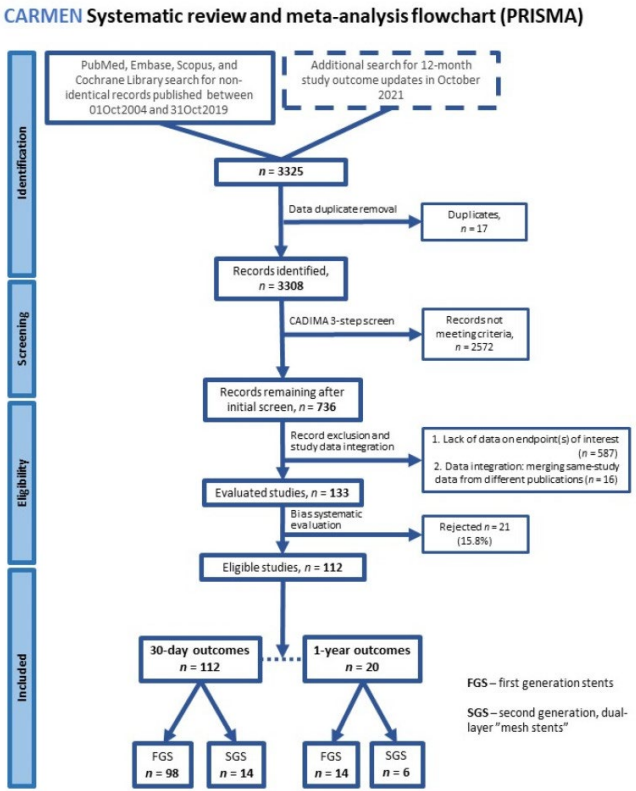

Data of 68,422 patients from 112 eligible studies were meta-analyzed

Meta-analysis Second- vs. First- generation carotid stents

30-day death, stroke, myocardial infarction

First generation	Second generation	
4.1%	1.3%	p<.05

30-day stroke

First generation (closed cell)	Second generation	
2.3%	0.6%	p<.05

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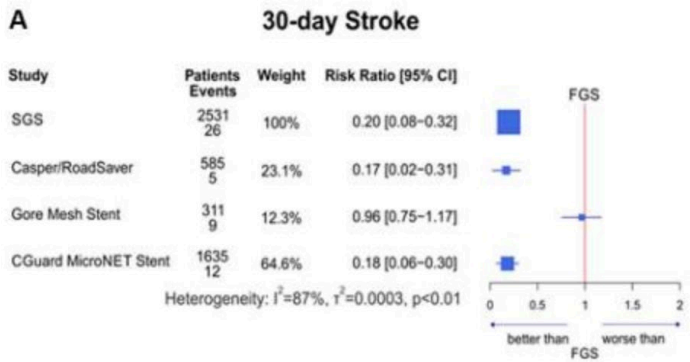
Meta-analysis Second- vs. First- generation carotid stents

At 30 days (in relation to FGS)

- both Casper/Roadsaver and CGuard reduced 30-day DSM (- 2.78 and 3.03% $p < 0.001$)
- the Gore stent was neutral.

At 12 months (in relation to FGS)

- Casper/Roadsaver reduced Ipsil Stroke (−3.25%, $p < 0.05$) but increased ISR (+3.19%, $p = 0.04$),
- CGuard showed a reduction in both Ipsil Stroke and ISR (−3.13%, −3.63%; $p = 0.01$, $p < 0.01$),
- whereas the Gore stent was neutral.



lack of a “mesh stent” class effect

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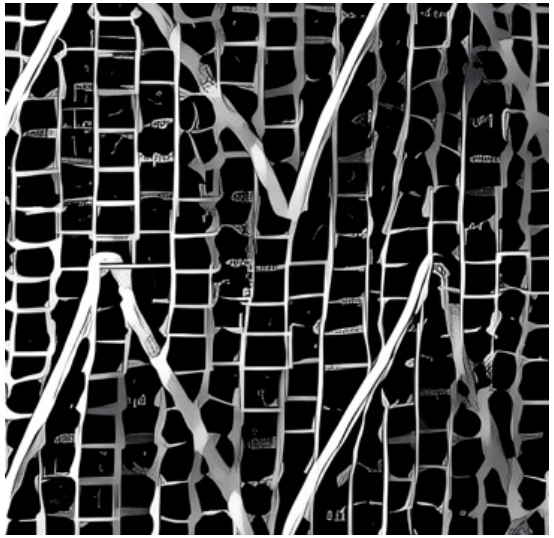
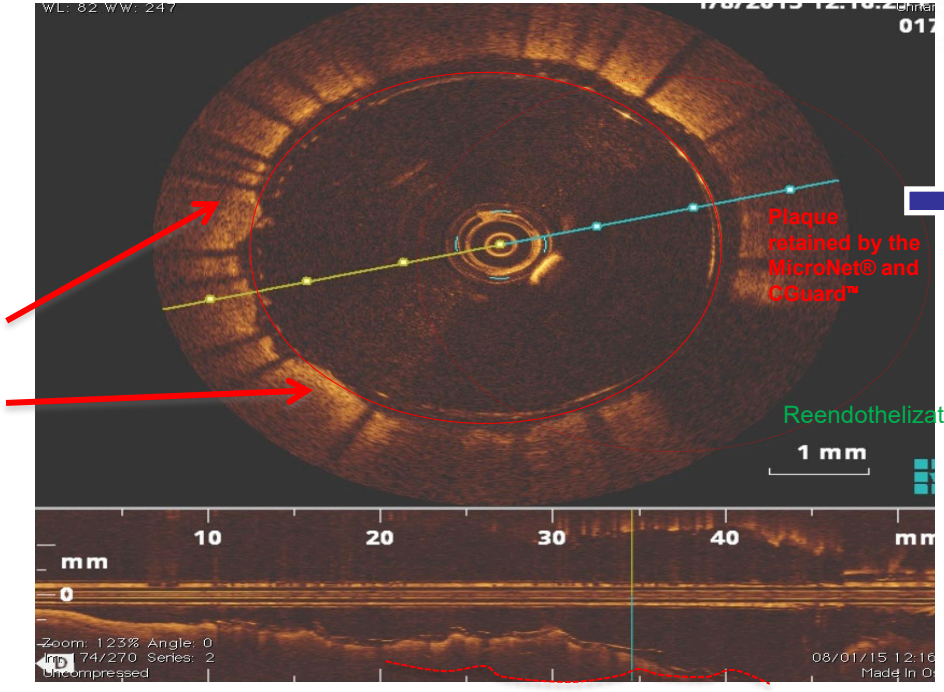
The real mesh stent

Inspire C-Guard



Open-cell nitinol frame
+
Outside PET micronet
Cell size : 150-180 μm



New Generation, Mesh-Covered Stents

EuroIntervention
Official Journal of EuroPCR and the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

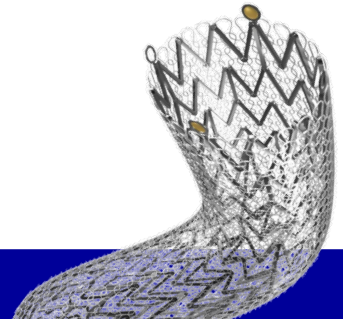
IMPACT FACTOR 5.165
2016 Journal Citation Reports ® Science Edition (Clarivate Analytics, 2017)

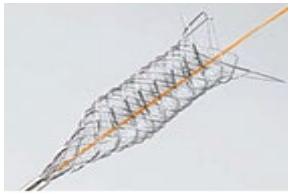
JUST ACCEPTED ARTICLE

EuroIntervention. 2017 Aug 1. pii: EIJ-D-16-00866. doi: 10.4244/EIJ-D-16-00866. [Epub ahead of print]

Optical Coherence Tomography Assessment of New Generation Mesh- Covered Stents after Carotid Stenting.

Umemoto T[1], de Donato G, Pacchioni A, Reimers B, Ferrante G, Isobe M, Setacci C.





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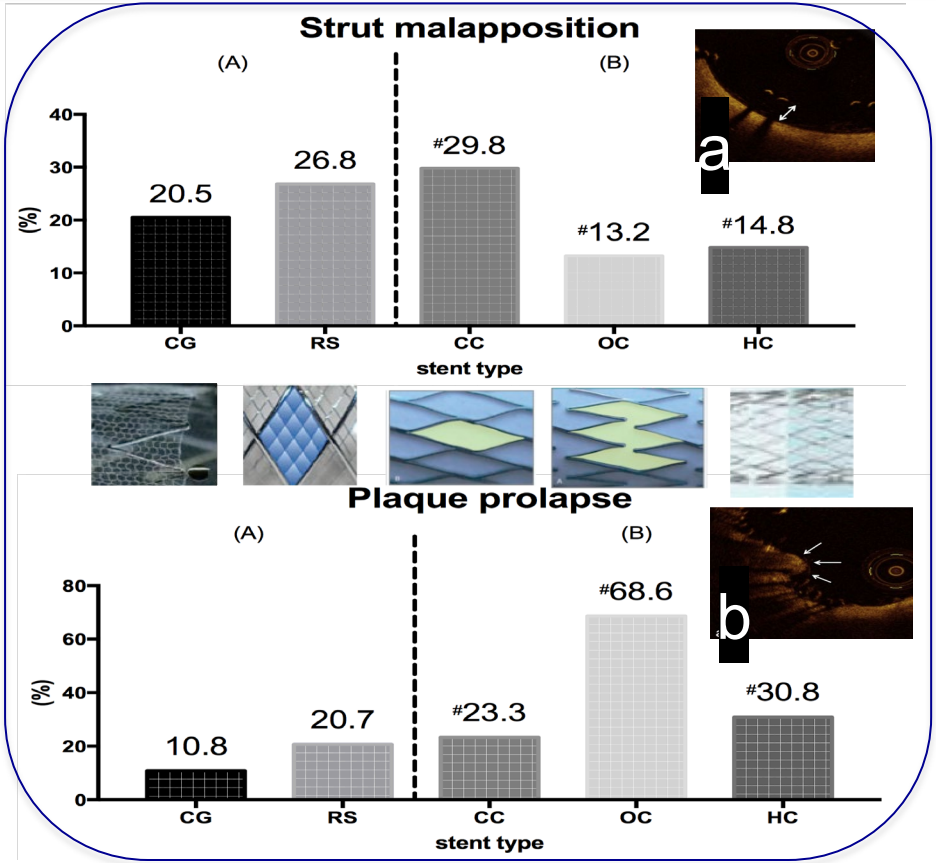
Outcomes



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

Slice-based analysis

- Compared with conventional stents, the incidence of stent malapposition in mesh-covered stents was intermediate between closed cell stents (29.8%) and open and hybrid cell stents (13.2% and 14.8%).

- Plaque prolapse was more frequent in open cell stents (p .04).

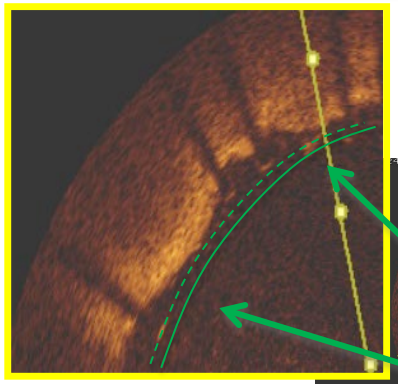
EuroIntervention. 2017 Aug

Micromesh vs. Dual layer – OCT analysis

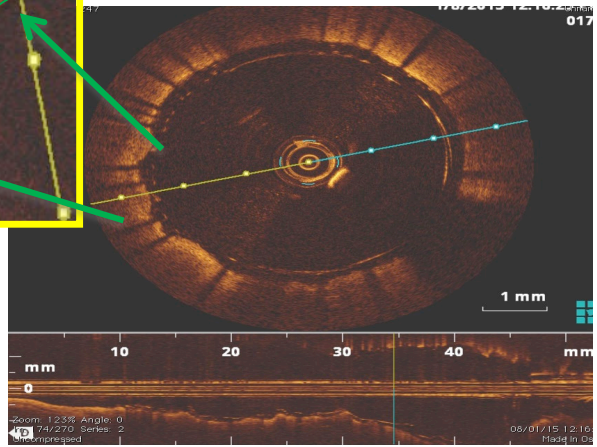
EuroIntervention. 2017 Aug

Stent	CGUARD			ROADSAVER		
Plaque type*	All type	Type 1-3	Type 4	All type	Type 1-3	Type 4
Patient n.	11	6	5	5	5	0
Slice n.	166	96	70	82	82	0
Prolapse ,n	18	9	9	17	17	0
Prolapse, %	10.8	9.3	12.8	20.7	20.7	0

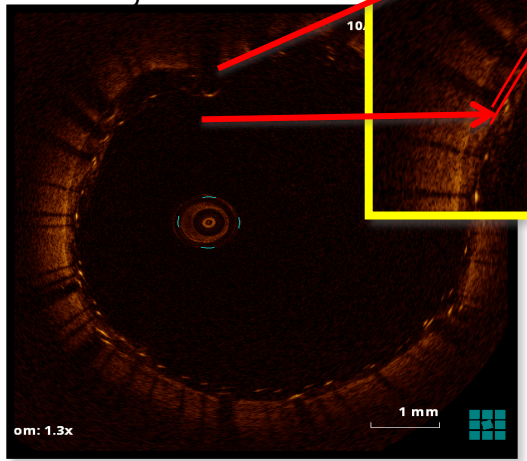
*According to the Gray-Weale classification[2]

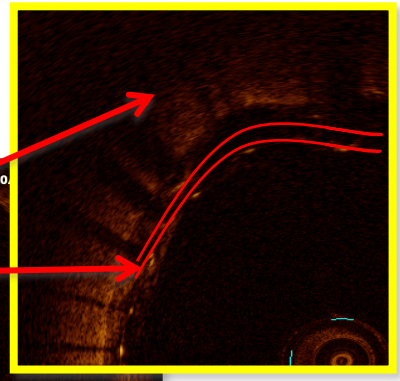


Micromesh



Dual layer

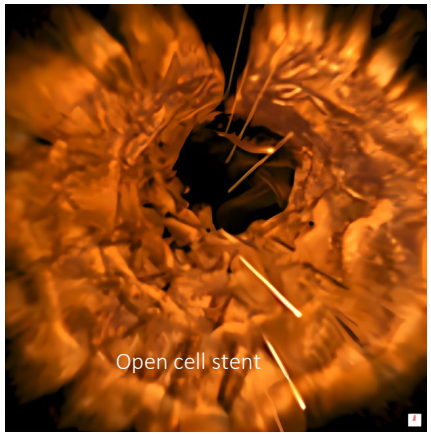




First vs. second generation carotid stents – OCT comparison

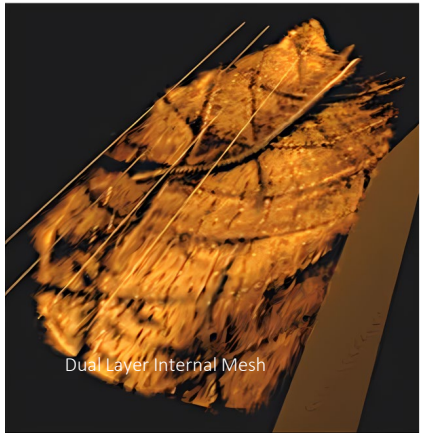
Conventional Carotid Stents

Partial and not uniform plaque coverage, leading to plaque protrusions or prolapse into the vessel lumen



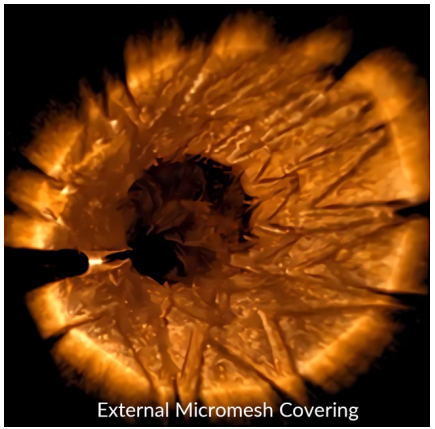
Roadsaver / Casper

Uniform plaque coverage; no plaque protrusions; big support structures are dimed by the big metal amount in the lumen



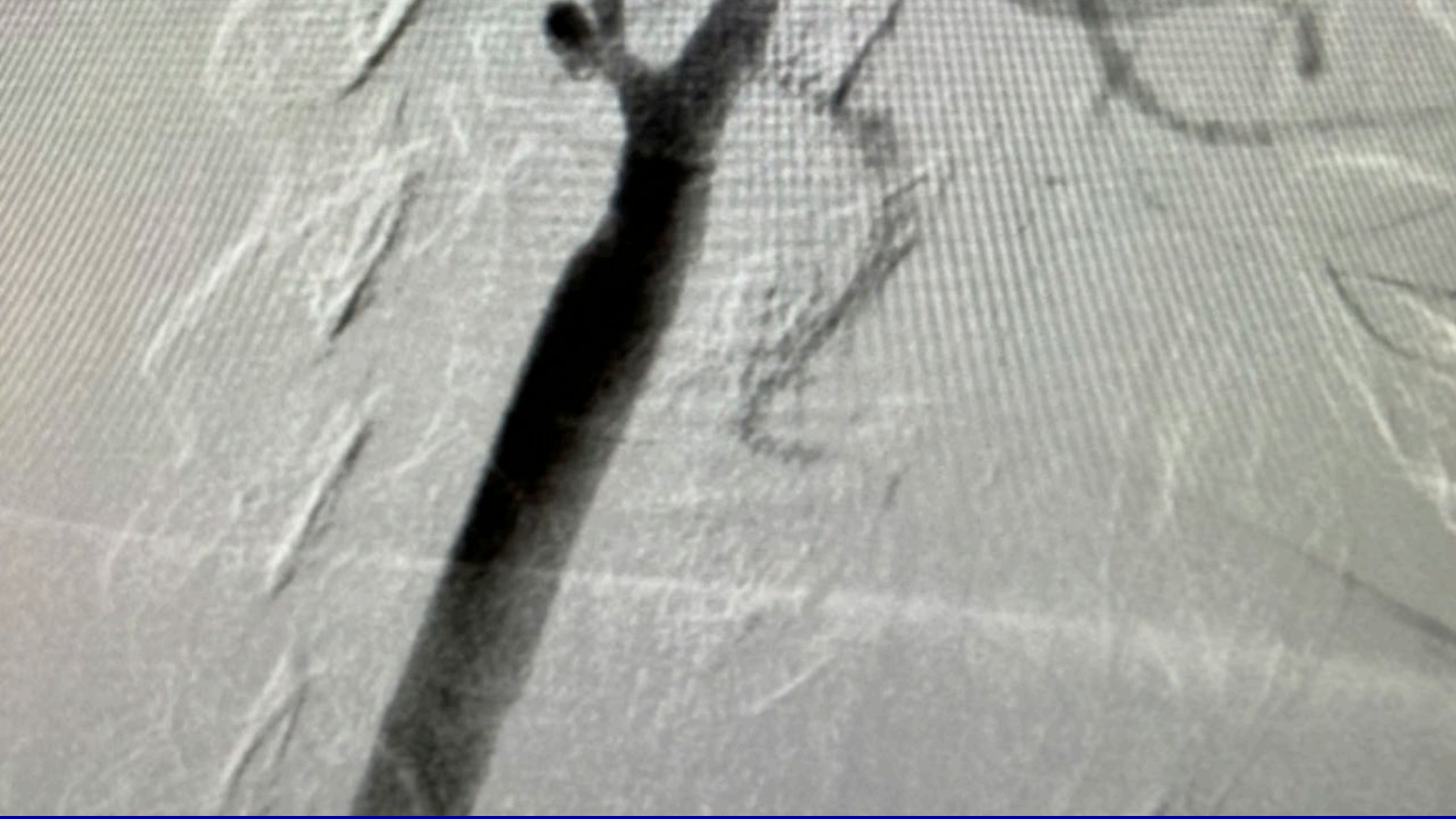
CGuard EPS

The MicroNet™ **permanently covers** the plaque preventing “debris” passage through the mesh



CONCLUSION

From EBM to tailored surgery & precision medicine



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