

# Double-mesh stents – background and rationale

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# DISCLOSURE STATEMENT OF FINANCIAL INTEREST

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below

## **AFFILIATION/FINANCIAL RELATIONSHIP**

- Consulting Fees/Honoraria

## **COMPANY**

- Medtronic
- Boston Scientific
- Inspire MD

# BACKGROUND

procedure related events can be caused by lesion crossing, pre- and post dilatation...

but

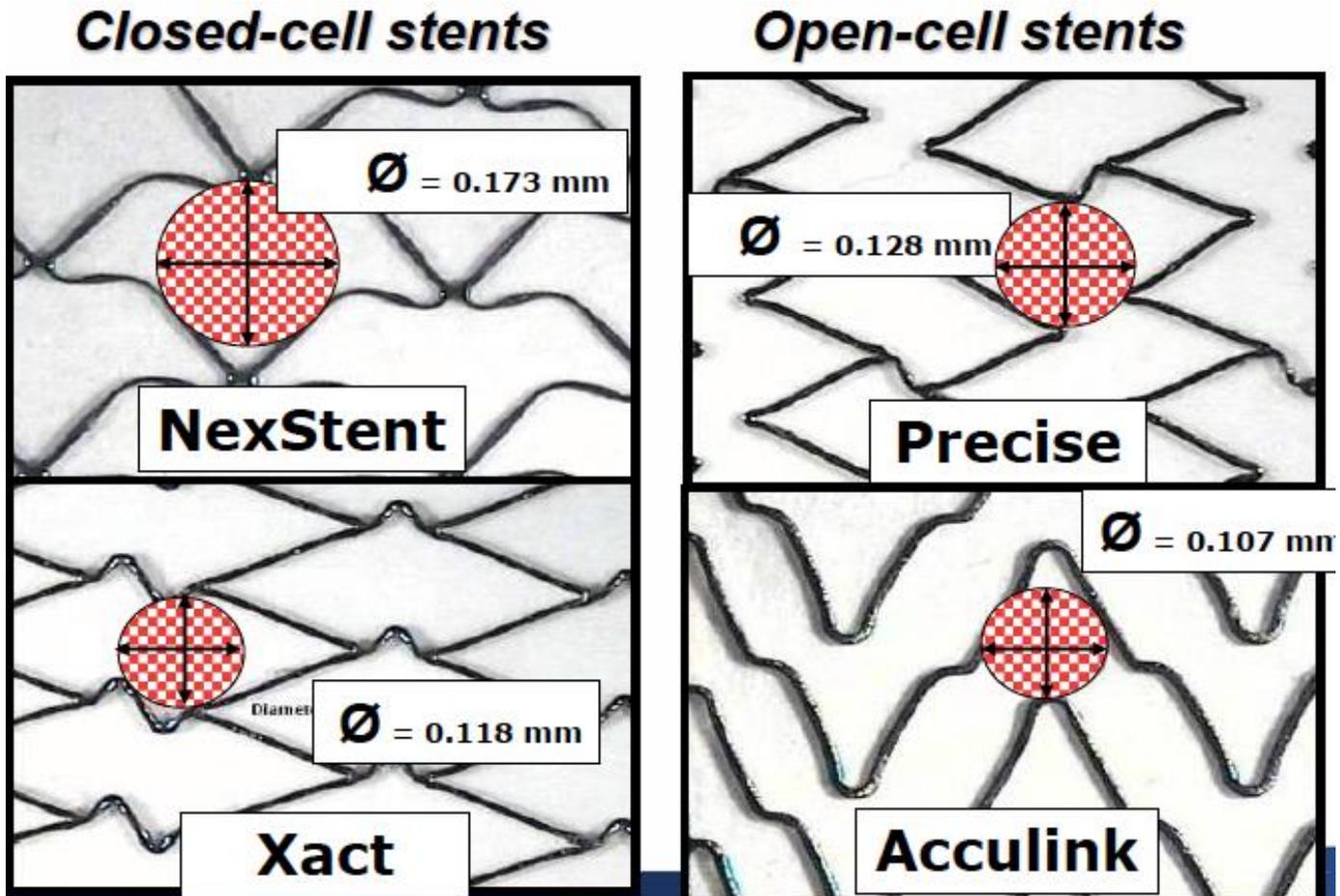
particular attention is focused on the stent design, because post-procedural DW-MRI lesion were significantly more present in patients treated with an open-cell stent vs. treated with a closed-cell stent<sup>1,2</sup>

1.Park et al. *J Neurosurg* 2013; 119: 642-647

2.Nikas et al. *J Cardiovasc Surg* 2011; 52: 779-793



# The concept of plaque scaffolding by stents



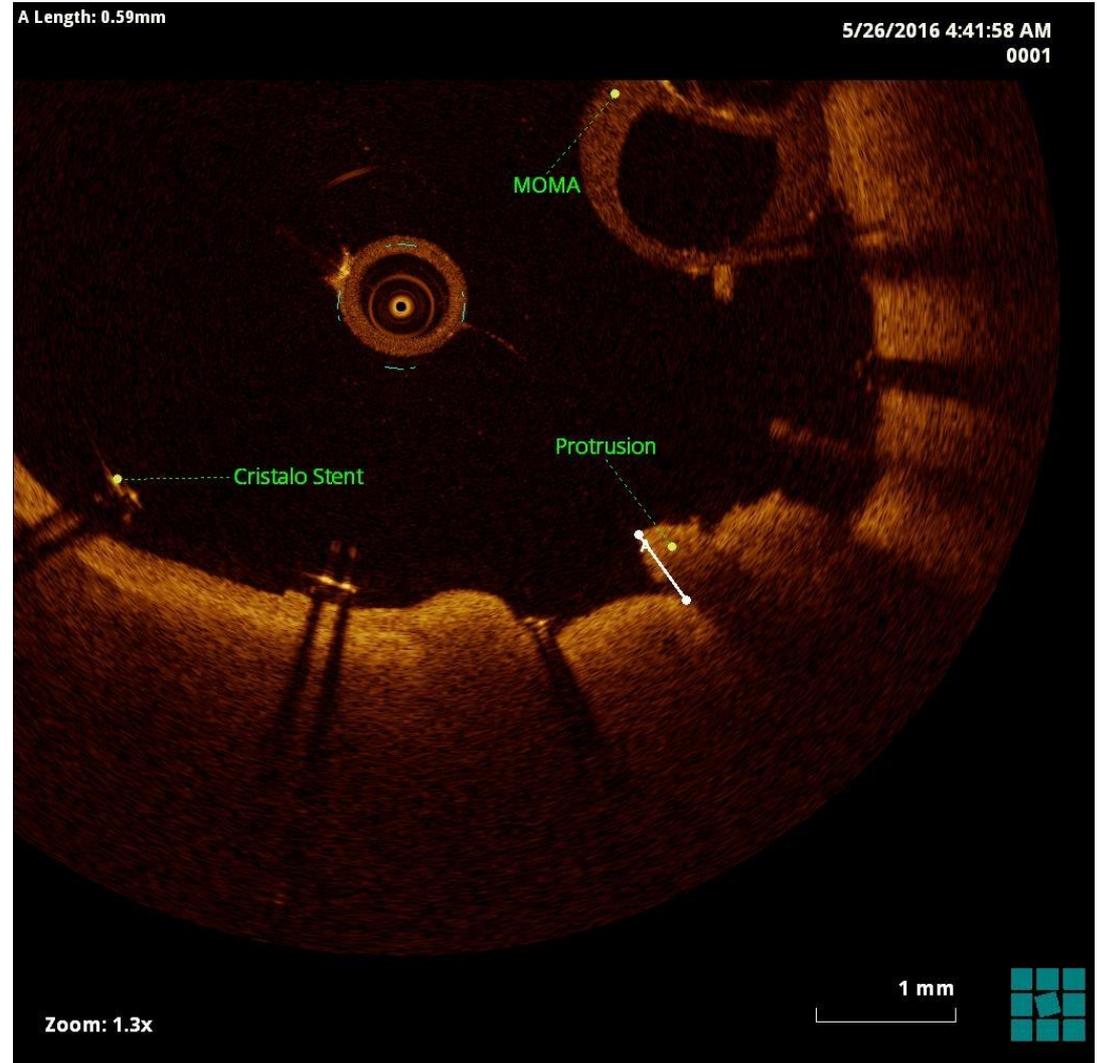
# BACKGROUND



		All events	Post-procedural events	
Stent name				
X-act		1.9%	1.9%	
Nexstent		3.3%	3.3%	
Wallstent		2.3%	1.2%	
Precise		4.1%	3.1%	
Protégé		3.0%	3.0%	
Acculink		4.2%	3.7%	
Exponent		11.8%	5.9%	
Total	3179	2.83%	1.9%	

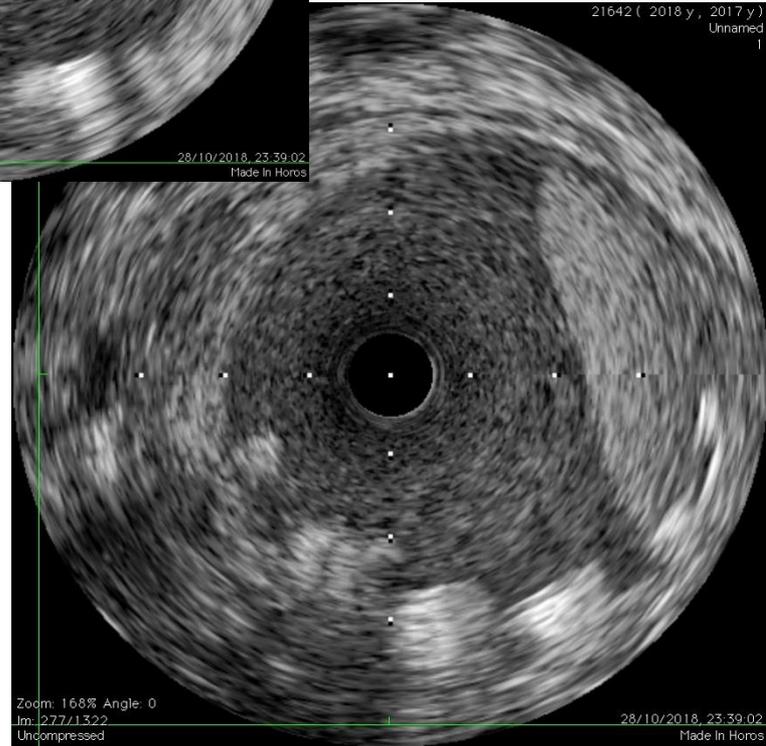
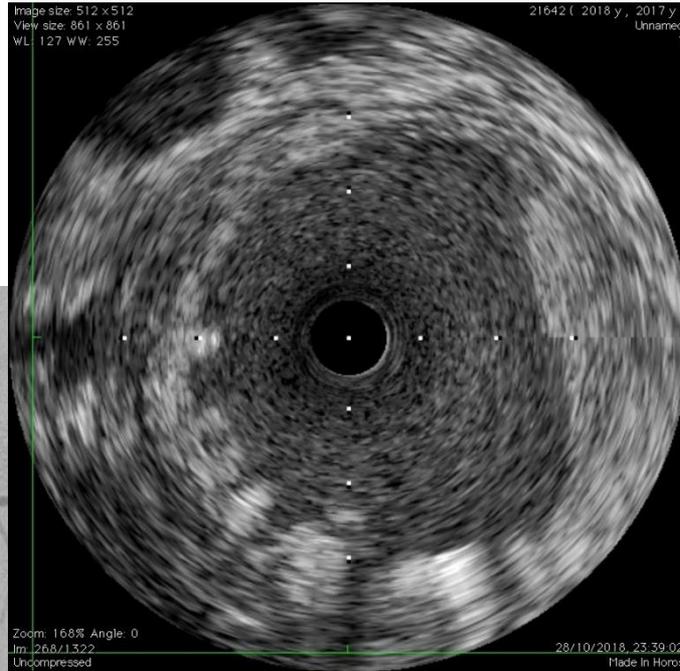
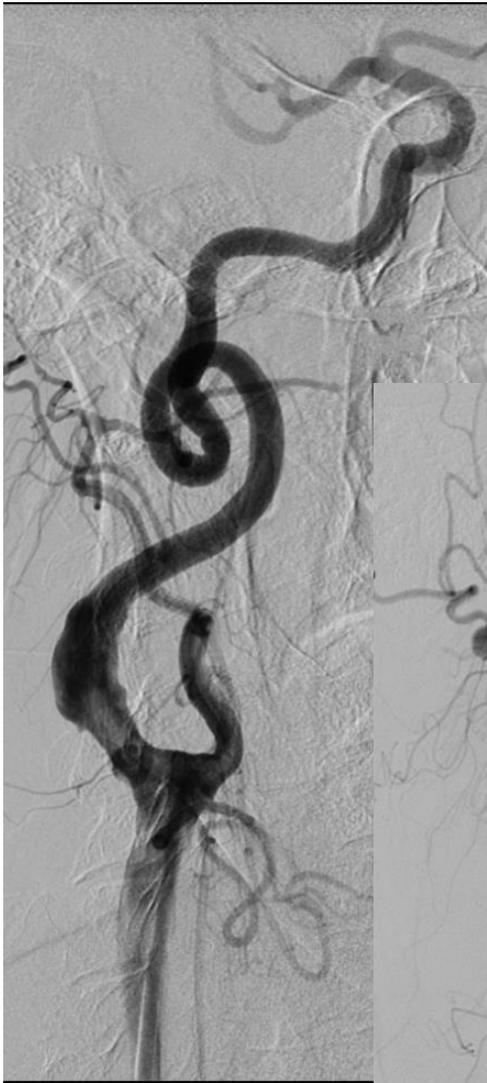
**No stent or current EPS protects against late embolization**

# Cristallo-Ideale

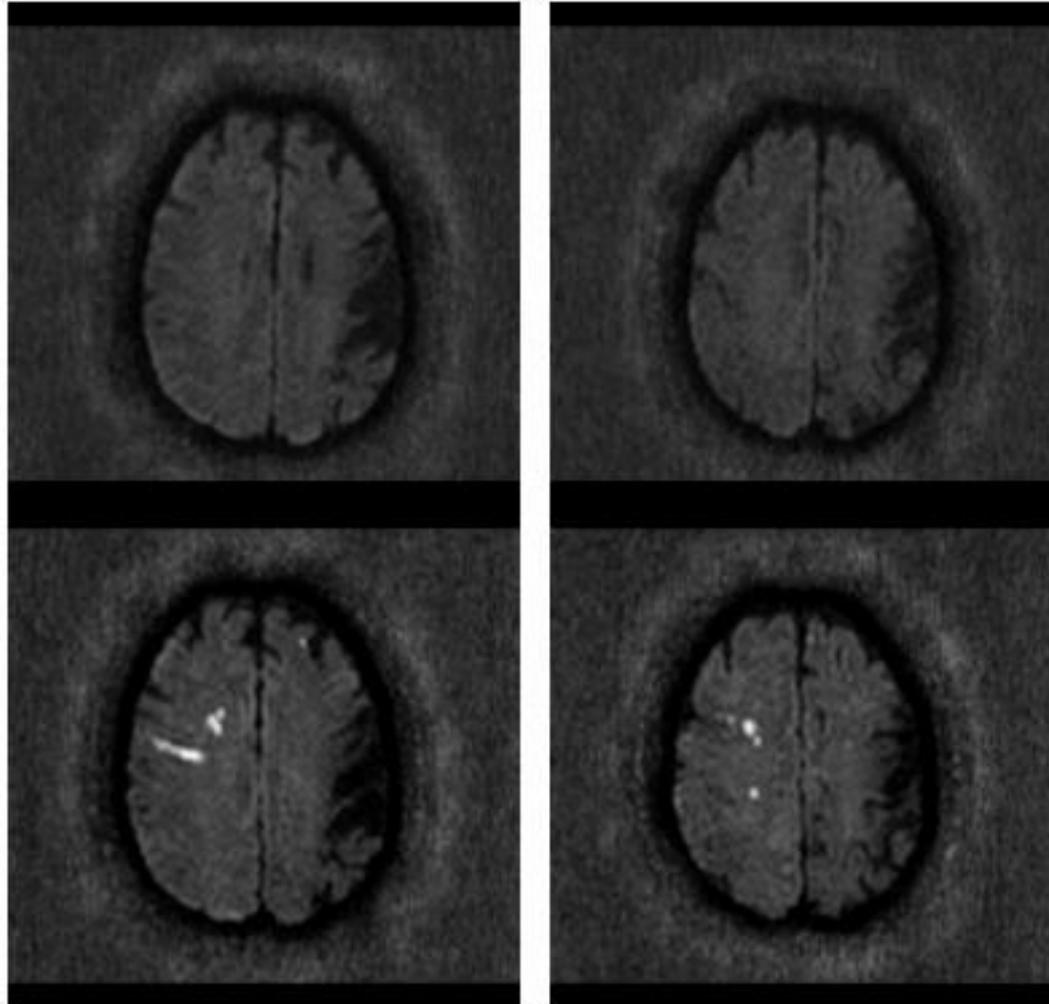


# Precise

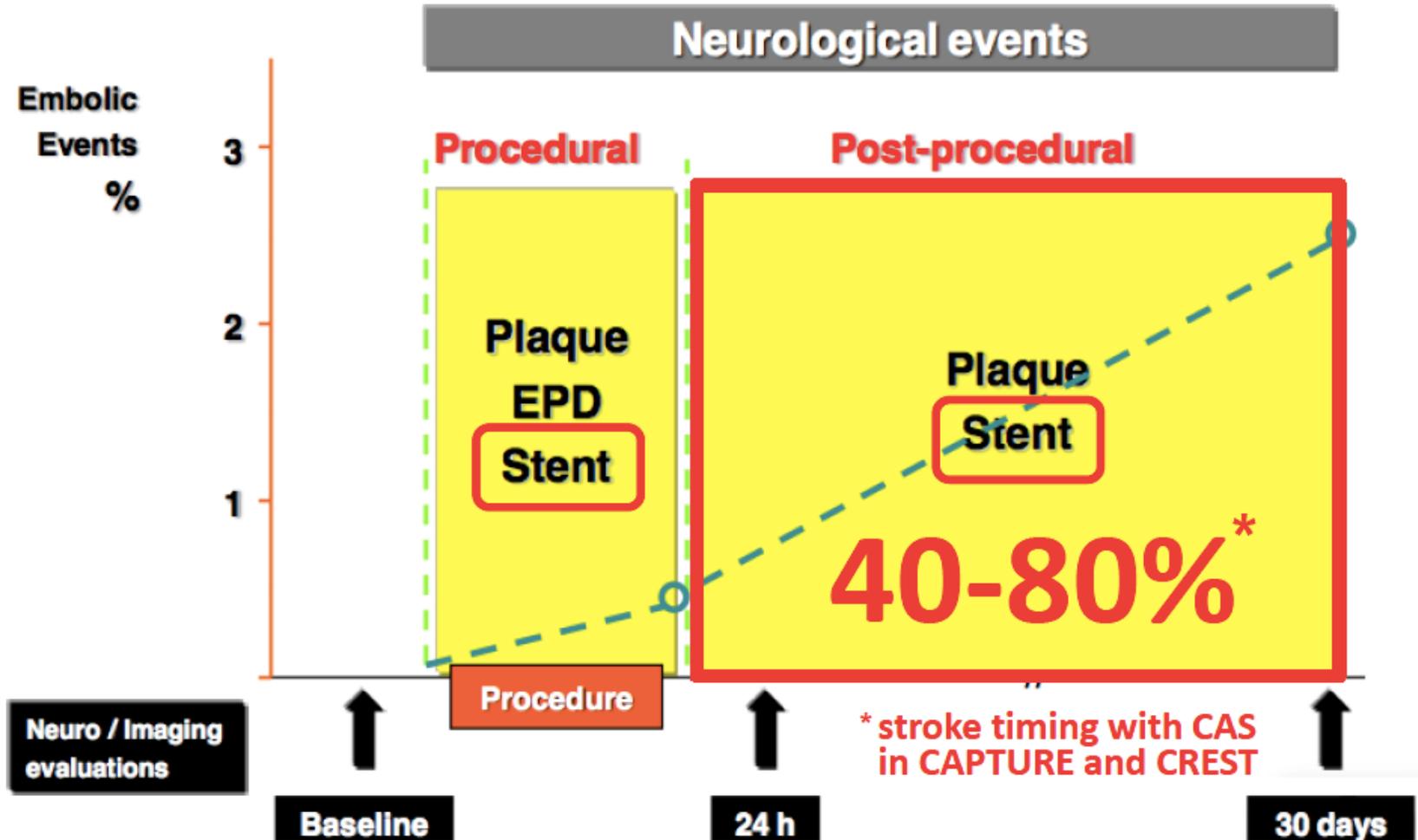
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DW MRI before and  
5 days after CAS



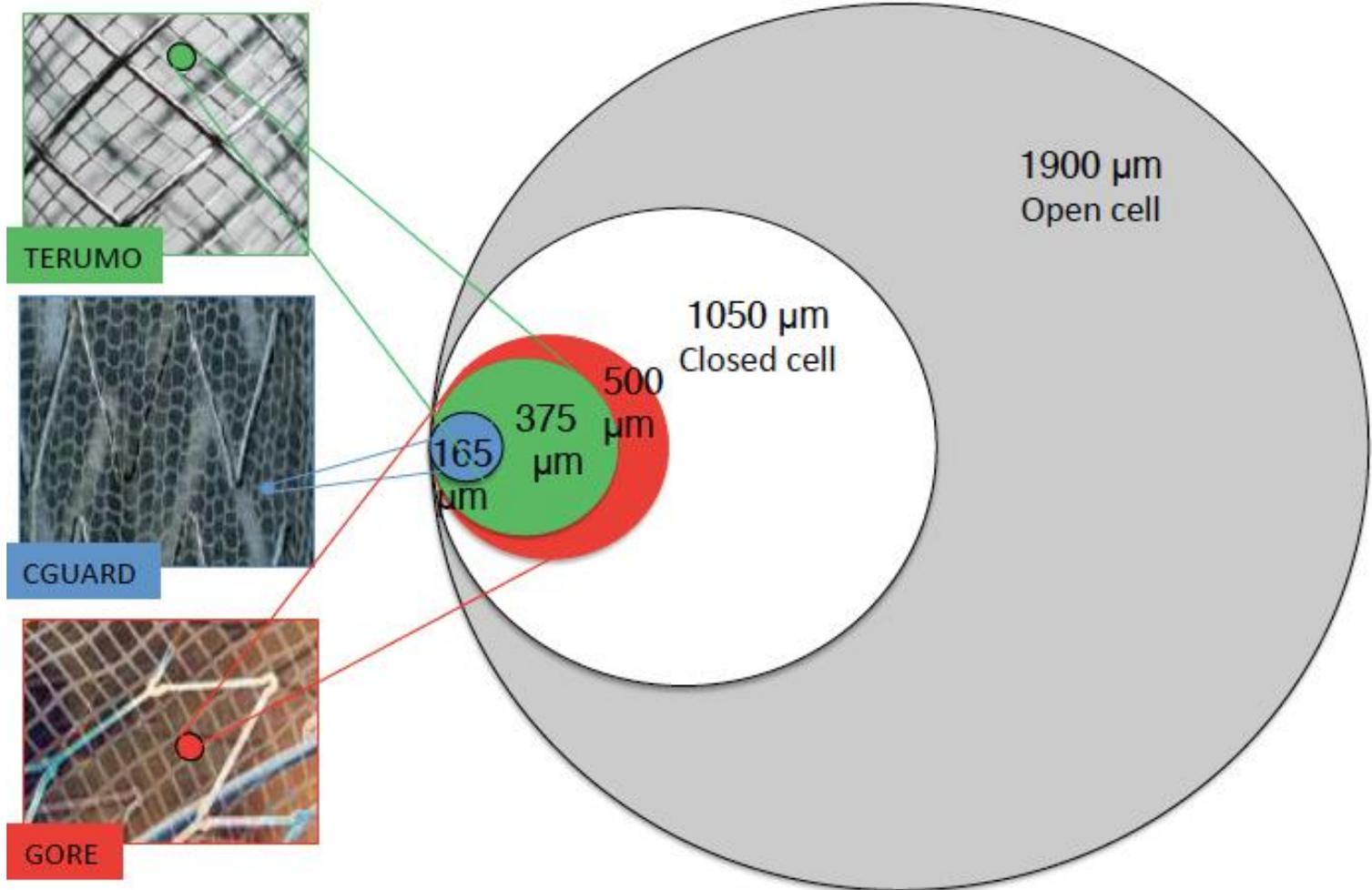
# Timing of neuro-embolic events after CAS





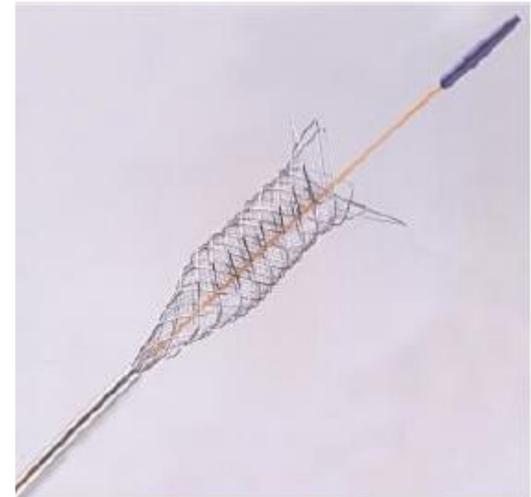
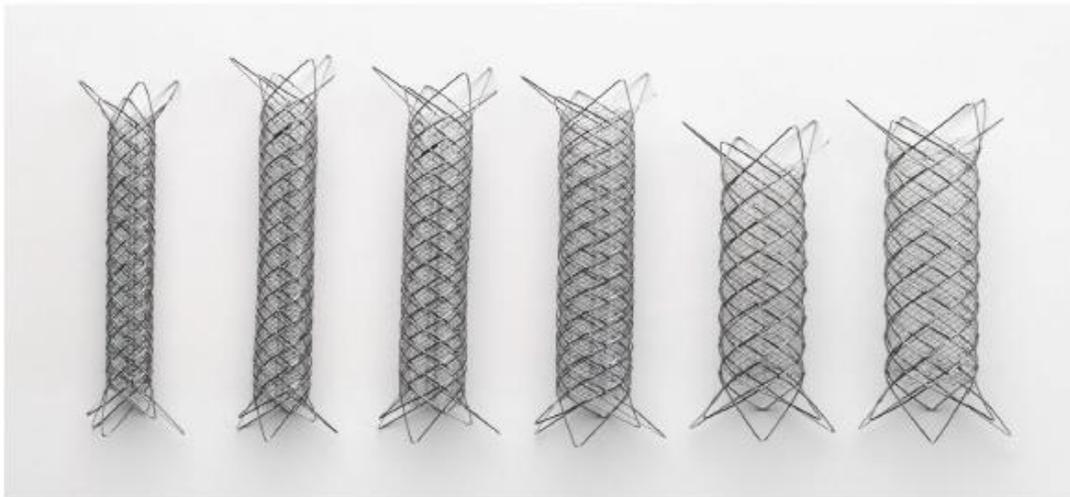
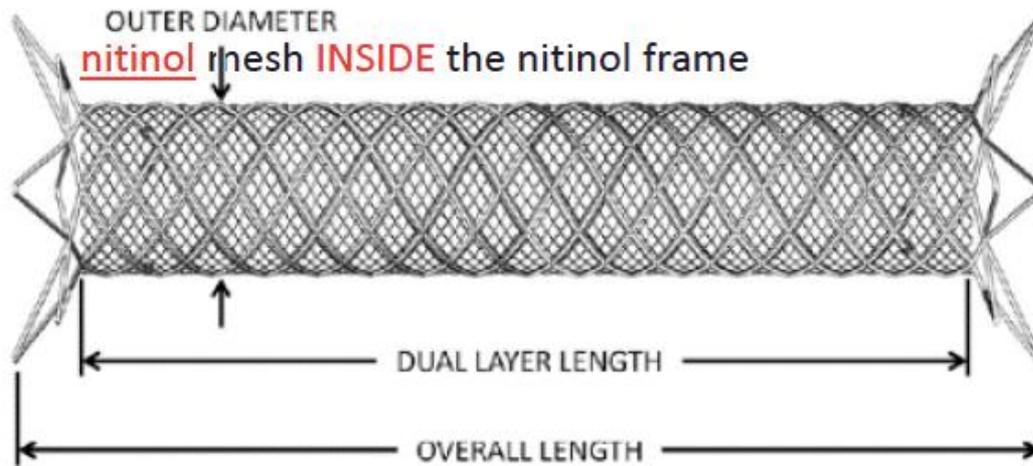
# Double-mesh stents – a new concept for effective CAS

## Ideal Pore Size



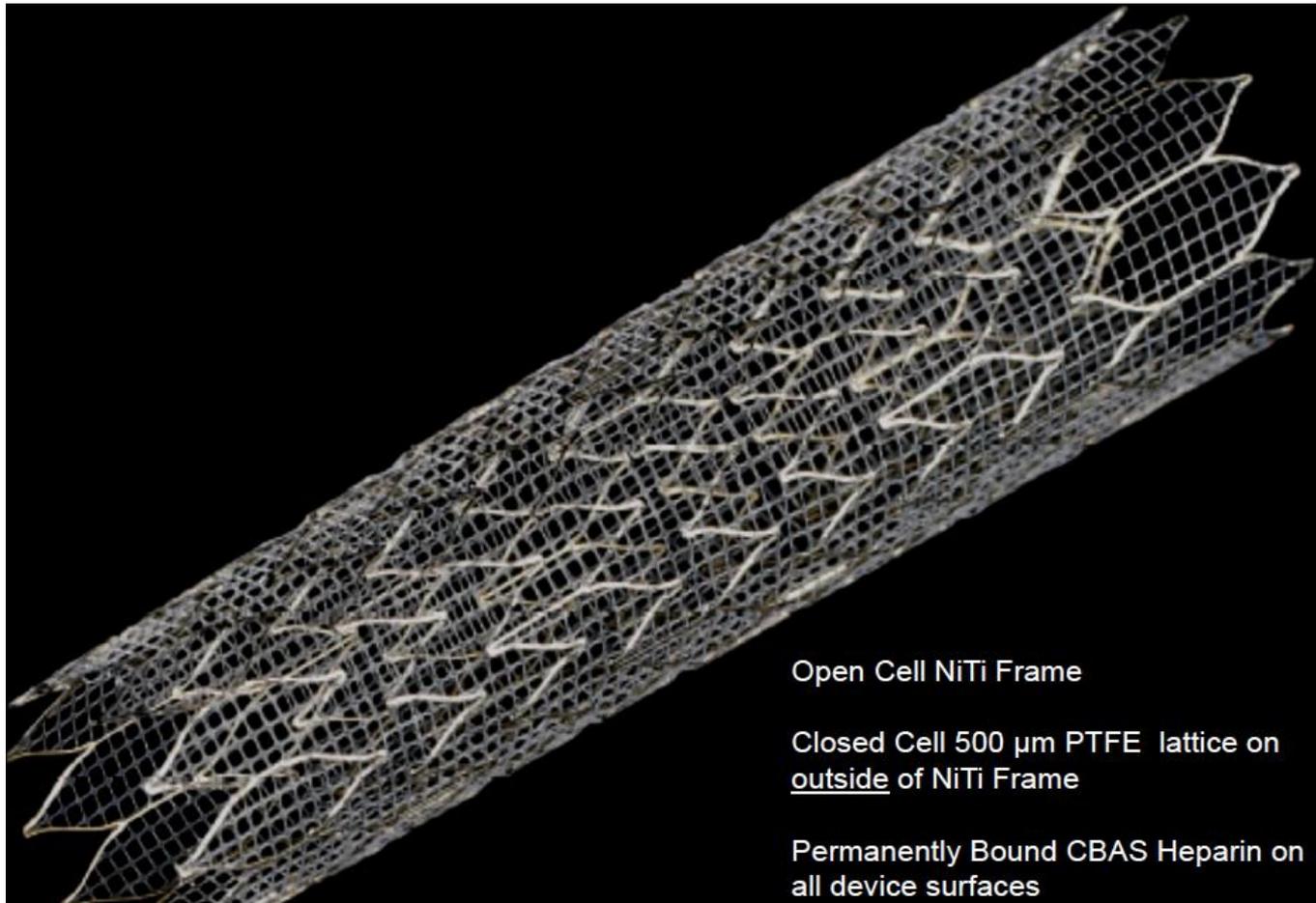
# RoadSaver (Terumo) Casper (MicroVention)

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# GORE Carotid stent (GORE)



Open Cell NiTi Frame

Closed Cell 500  $\mu$ m PTFE lattice on  
outside of NiTi Frame

Permanently Bound CBAS Heparin on  
all device surfaces



# CGuard (InspireMD)



# Evidence

## A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

### The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,\* Piotr Musiałek, MD, DPHIL,† Klaudija Bijuklic, MD,\* Ralf Kolvenbach, MD,‡  
Mariusz Trystula, MD,‡ Zbigniew Siudak, MD,†§ Horst Sievert, MD||

## CARENET DW-MRI analysis\*

DW-MRI analysis @ 48 hours			
	CARENET (n=27)	PROFI (all) (n=62)	ICSS <sup>†</sup> (n=56)
Incidence of new ipsilateral lesions	37.0%	66.2%	68.0%
Average lesion volume (cm <sup>3</sup> )	0.039 ± 0.08	0.375	-
Maximum lesion volume (cm <sup>3</sup> )	0.445		

≈50% reduction  
in new ipsilateral lesion incidence

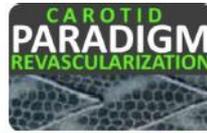
see patient fluxogram

\*External Core Lab analysis (US)

Bijuklic et al. *JACC*, 2012; Bonati et. al, *Lancet Neurol* 2010

† bilateral lesions

# PARADIGM: 30 days



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## Clinical Results (MACNE)

- 0 peri-procedural death/major stroke/MI 0%
  - 1 peri-procedural minor stroke\* 0.9%
  - 0 new clinical events by 30 days 0%
- (100% follow-up, independent neuro evaluation)

\* One patient, with symptomatic RICA stenosis (minor right-hemispheric stroke 2 months prior to CAS), had hypotonia and transient, fluctuating cognitive dysfunction at 24-48h after CAS. The patient had additional neurologic evaluation on discharge (day 7) that showed **no change in NIH-SS [=3] and no change in modified Rankin scale [=1] against 48h (and baseline) evaluation.** CT scan on day 2 showed no new cerebral lesions but day 6 CT indicated **an extension of the prior lesion in the right hemisphere.** The event, in **absence of right haemispheric symptoms and in absence of any clinical sequelae**, was CEC–adjudicated as 'minor stroke in relation to CAS'.

tct2016

EuroIntervention 2016;12:e658-70

TCT 2016 Featured Research

CGUARD™  
Carotid Embolic Prevention System



12month data

## PARADIGM

### 12 months

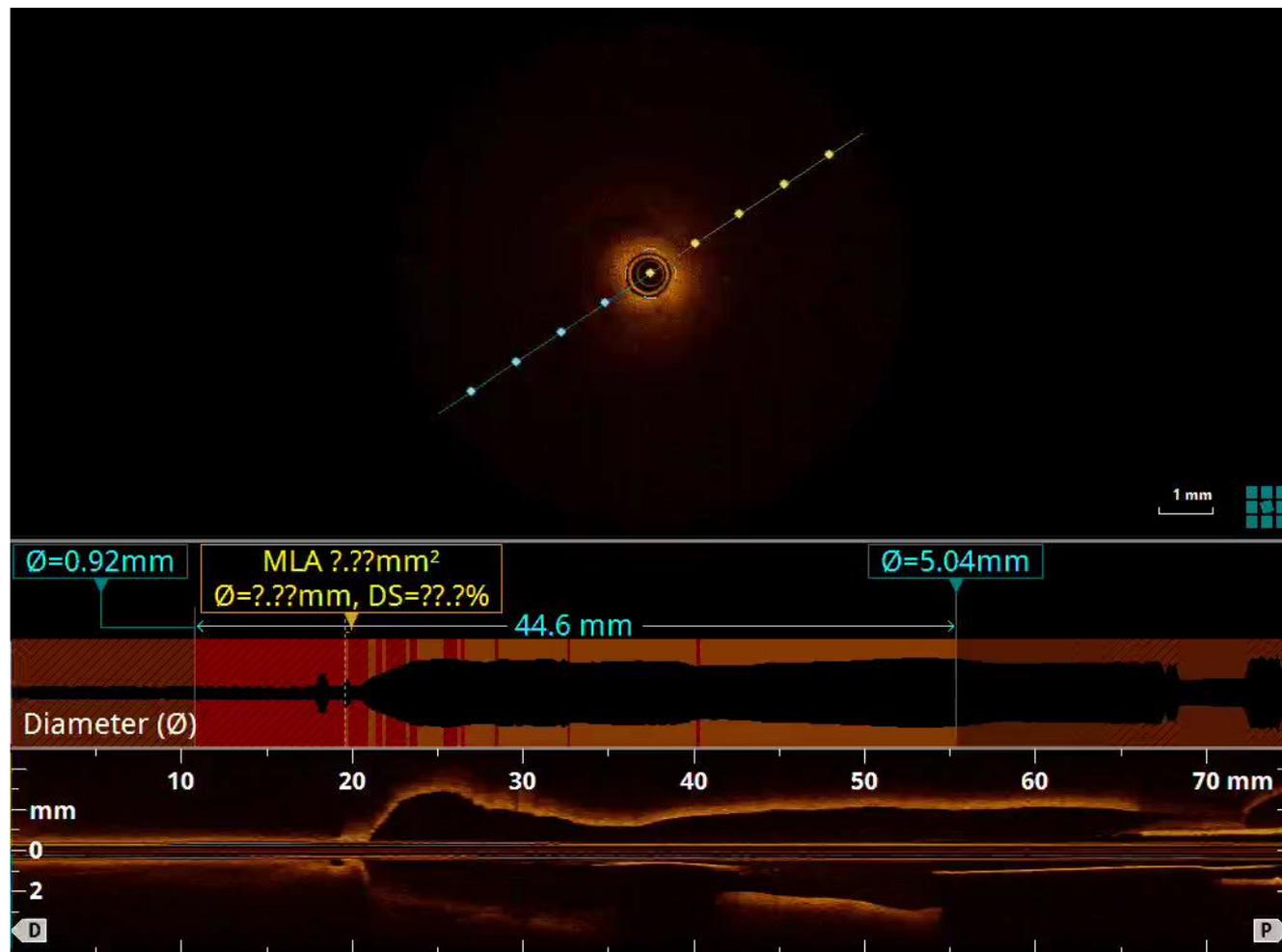
- NO device-related adverse events
- NO procedure-related events

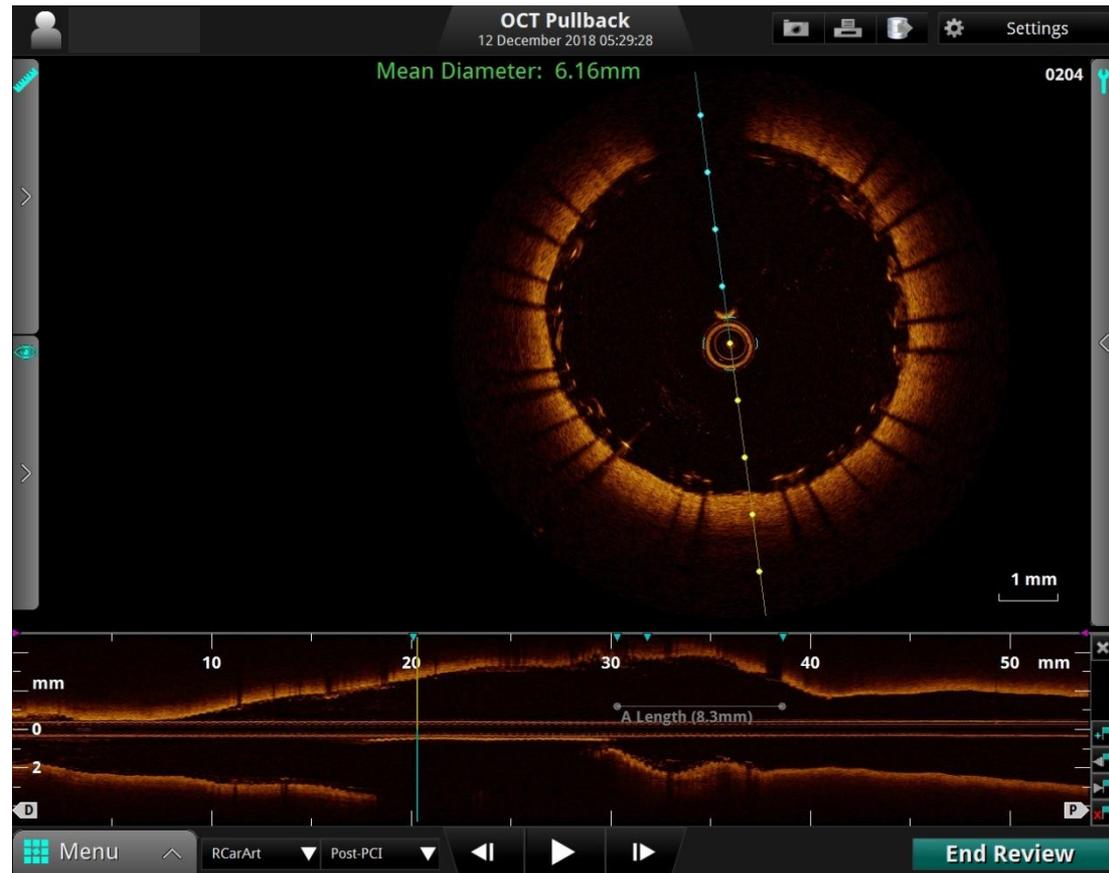


tct2016

TCT 2016 Featured Research

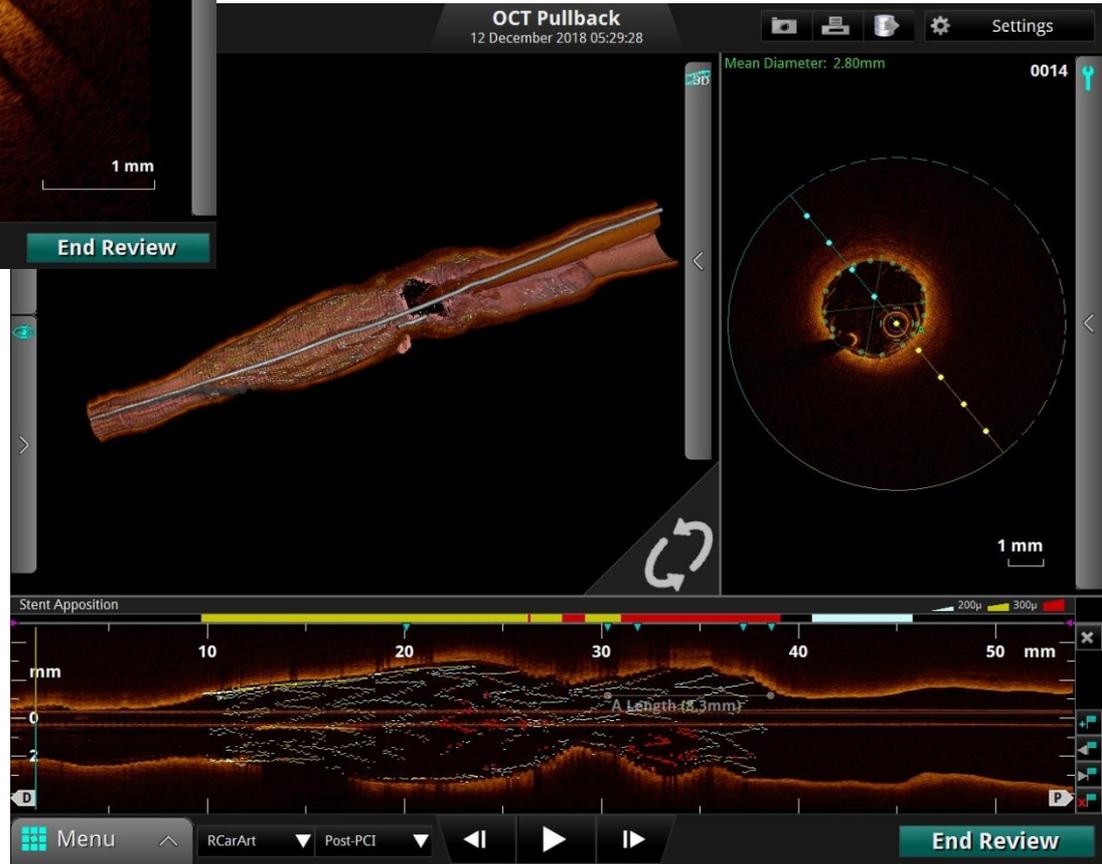
67 y.o. women; episodes of TIA during last 2 weeks







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## Take-home message:

Using a double-mesh stents is more safety and that is why RATIONALE for improve our carotid stenting results!

But we still don't have randomize trials for demonstrate this fact!

Thank you for your attention!

