CGUARD™EPS System – My experience in treatment of carotid lesions: Mechanical behavior and clinical results

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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%

2/3 MACCE events occur post-procedure

No stent or current EPS protects against late embolization

Bosiers et al. *Eur J Vasc Endovasc Surg* 2007;33

Background

- procedure related events can be caused by lesion crossing, pre- and post dilatation, but
- particular attention is focussed 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[1,2]

- **Purpose:** Evaluation of clinical implantation procedure and in vitro investigation of mechanical properties of the novel double-layer stent for the carotid artery.

1. *Park et al. J Neurosurg* 2013; 119: 642-647
2. *Nikas et al. J Cardiovasc Surg* 2011; 52: 779-793

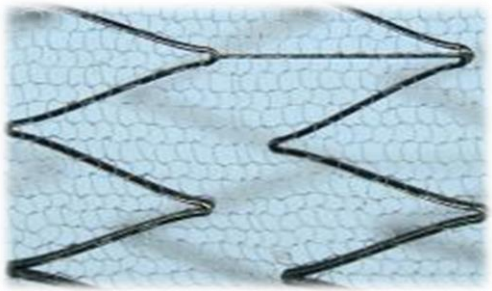
Material & Methods

CGUARD, Inspire MD, Penumbra

Design

- Nitinol stent platform
- 6F self-expanding system
- 4 radiopaque markers
- Smart Fit™ Technology
- Open cell stent platform
- Dual layer design with MicroNet™

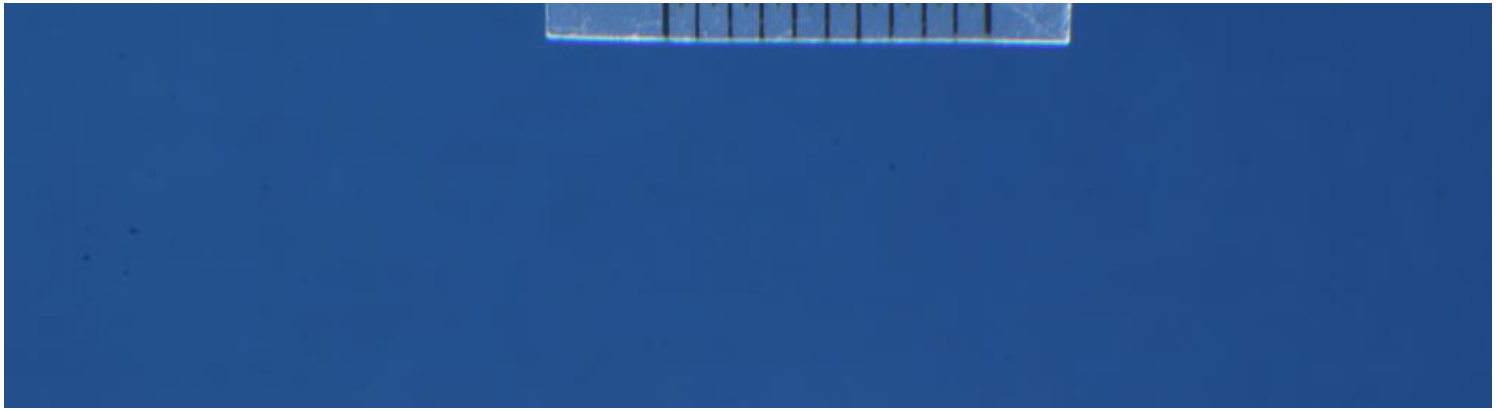
Advantages

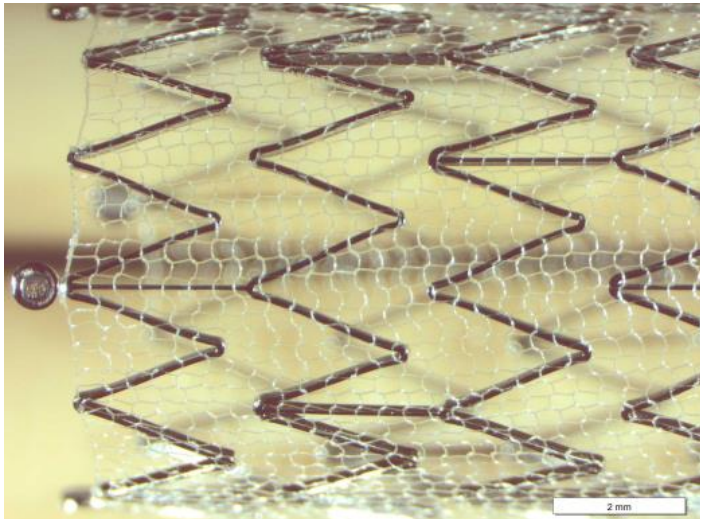


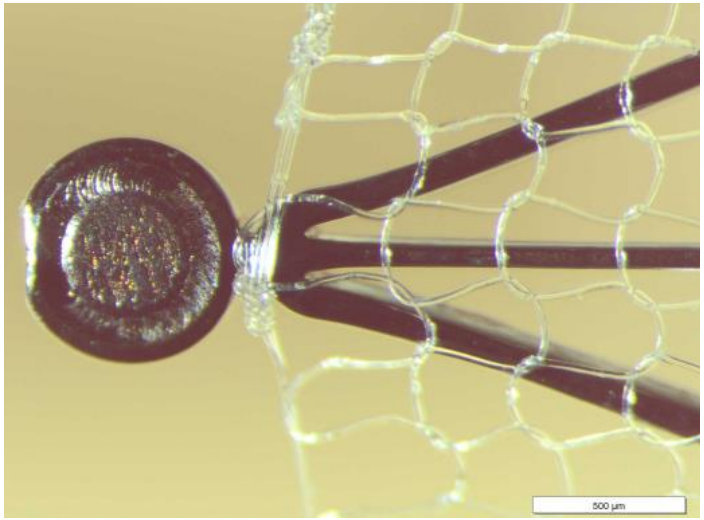
- Prevents embolization during placement and post-dilation, offers greater confidence during post dilation
- Prevents plaque prolapse and late embolization
- Flexible without compromising plaque scaffolding
- Conformable, reconstructs to natural anatomy
- Extremely precise placement
- Great visibility under all imaging modalities
- Allows for natural endothelialization
- Does not inhibit flow to branch vessels
- MicroNet™ encapsulates struts mitigating fish scaling

Material & Methods

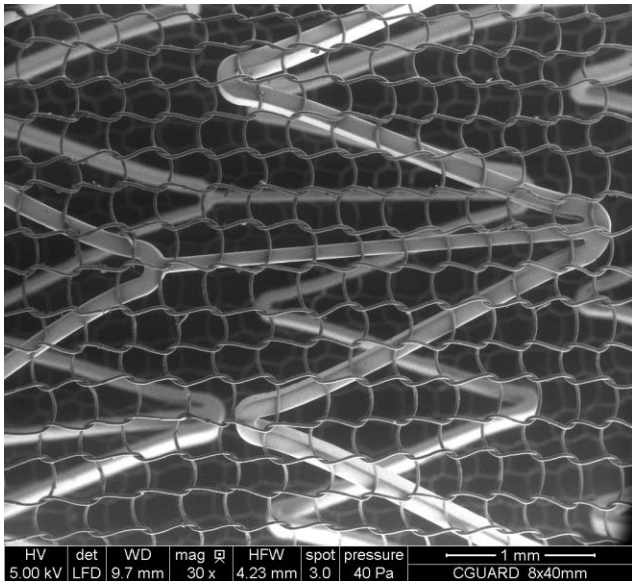
- CGUARD, Inspire MD, Penumbra

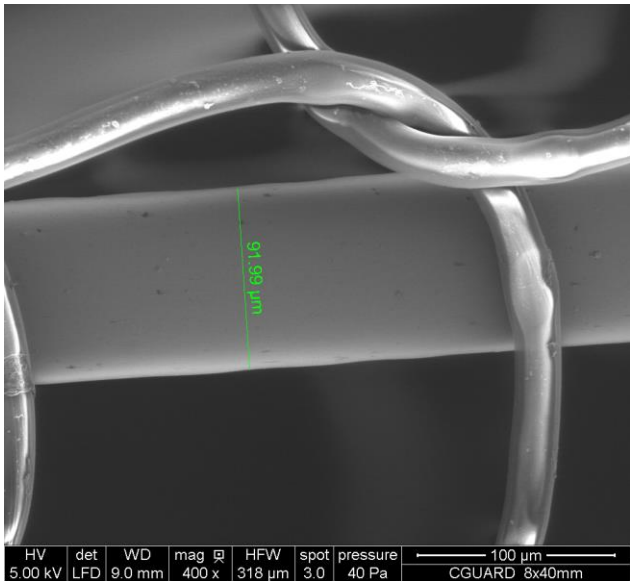


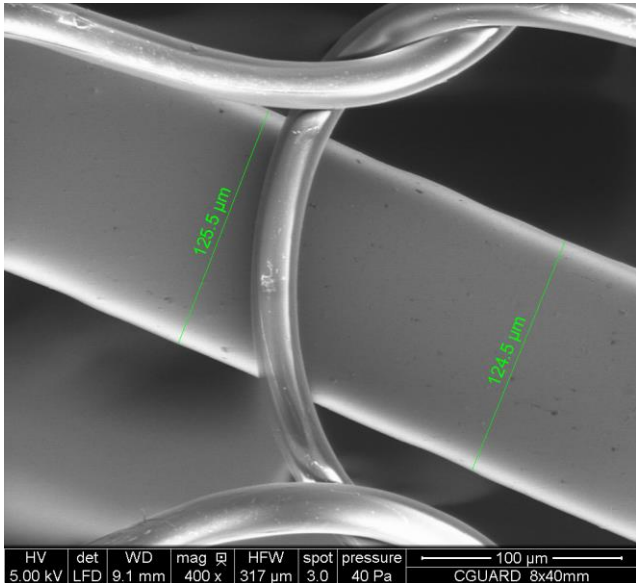




Material & Methods



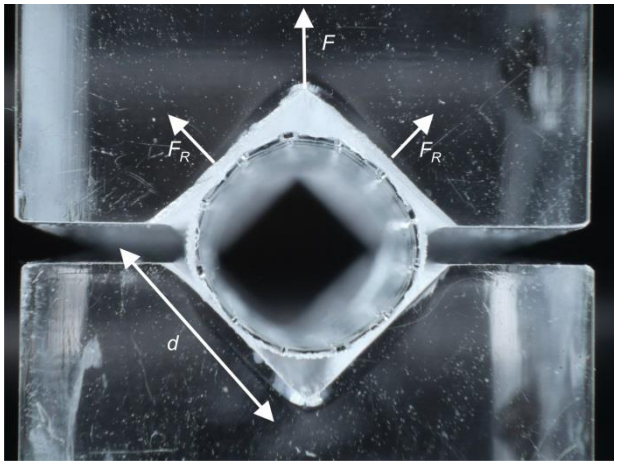


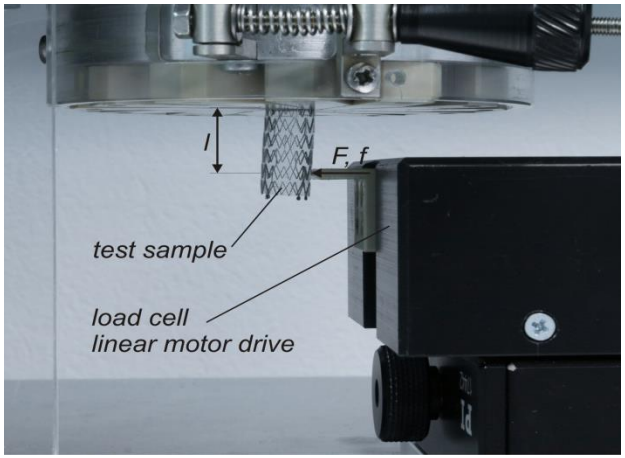


Inside: open-cell Nitinol-Stent (Struts 92 and 125µm)
Outside: closed-cell PET (25 µm)
Cell-size: ca. 165 µm

Material & Methods

- Carotid Embolic Prevention System CGUARD™ were investigated in the dimension 8x40 mm:
  - Radial force
  - Bending stiffness
  - Foreshortening
  - Collapse pressure
  - Vessel wall adaption





Material & Methods

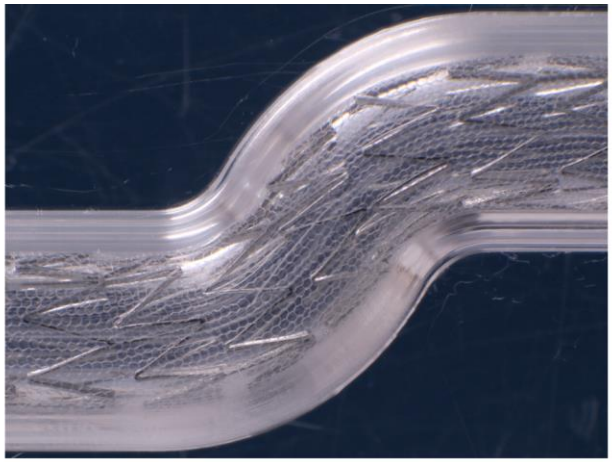
Age, mean	73.1 ± 6.3
Gender, m/f	21m / 9 f
Risc factors	
Art. Hypertension	50 %
Diabetes mellitus	35 %
Hyperlipidemia	45 %
Smoking	50 %
Mean Stenosis %	84.1 ± 7.9
Symptomatic (%)	25 (83)
TIA	21 (70)
Amaurosis fugax	4 (13)
Asymptomatic (%)	5 (17)
Lesion length, mm	16.6 ± 2.1
Stents, n	
7/40 mm	1
8/30 mm	9
8/40 mm	14
9/30 mm	3
9/40 mm	3

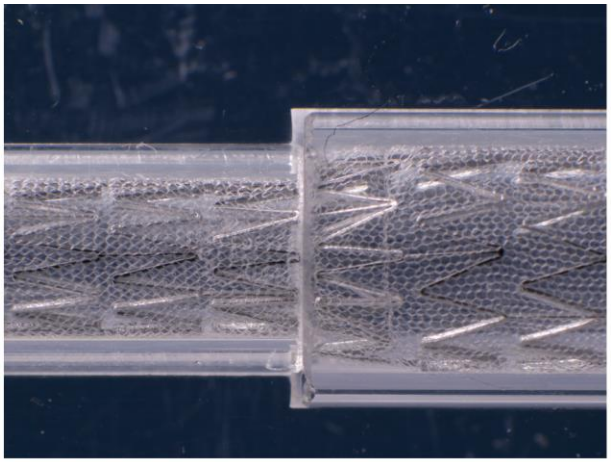
Wissgott et al. J Endovasc Ther 2016, in press

Results

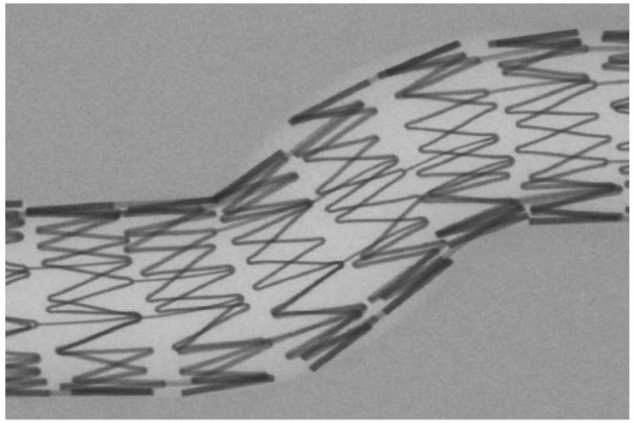
	RX	
Mean profile	8.412 mm	Expanded stent
	8.354 mm	Proximal stent end
	8.458 mm	Distal stent end
Radial force	2.28 N	Expanded to 7 mm
	4.28 N	Compressed to 7 mm
Bending stiffness	530.18 Nmm²	Stent on delivery catheter
	59.88 Nmm²	Fully expanded stent
Stent length	42.5 mm	Mounted on delivery catheter
	41.8 mm	Expanded to 7 mm
Foreshortening	0.7 mm/1.8 %	Expanded to 7 mm
Collapse pressure	0.18 bar	

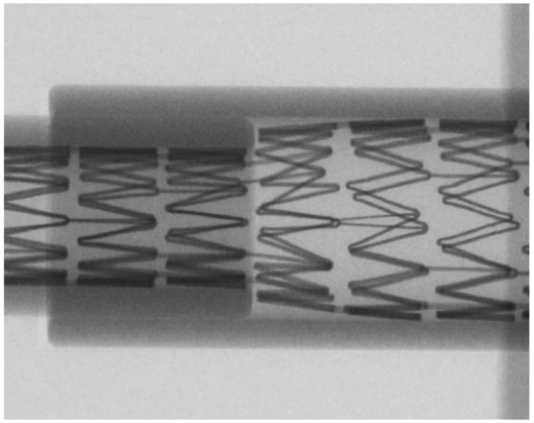
Results





Stent adaption in a straight vessel model with an inner diameter step from 7 to 5 mm for InspireMD CGUARD (macrophotography)

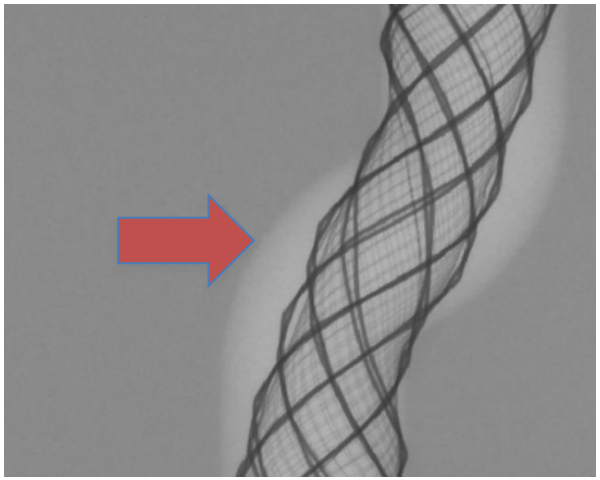




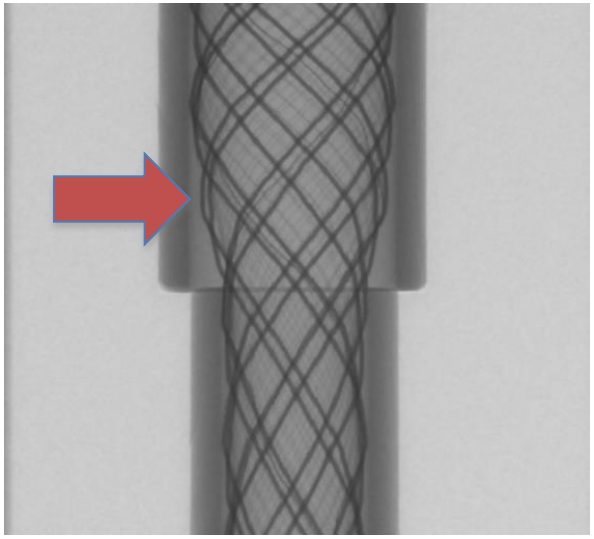
Stent adaption in a straight vessel model with an inner diameter step from 7 to 5 mm for InspireMD CGUARD (micro CT)

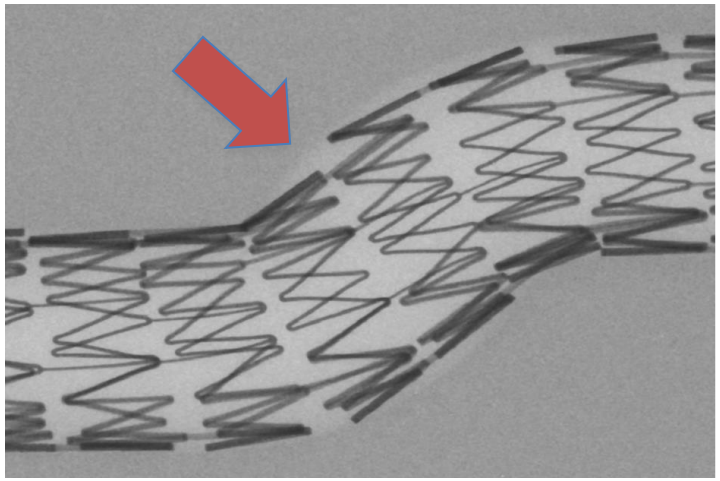
Results

Wall adaption in comparison to Competitor

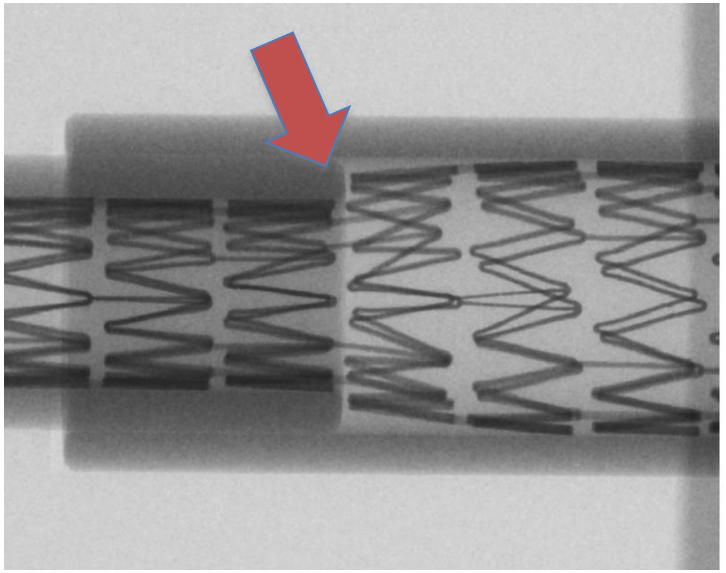


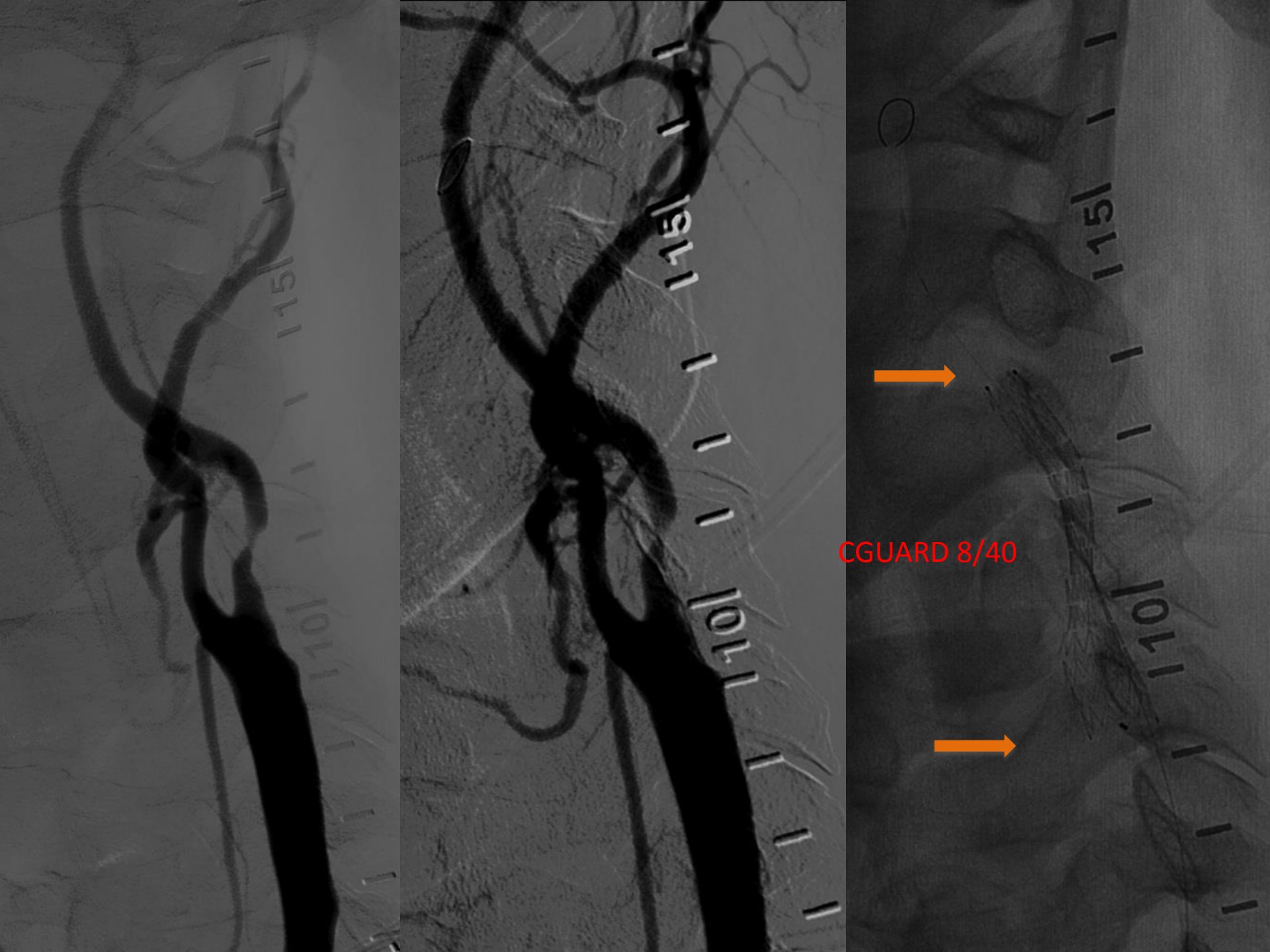
Competitor

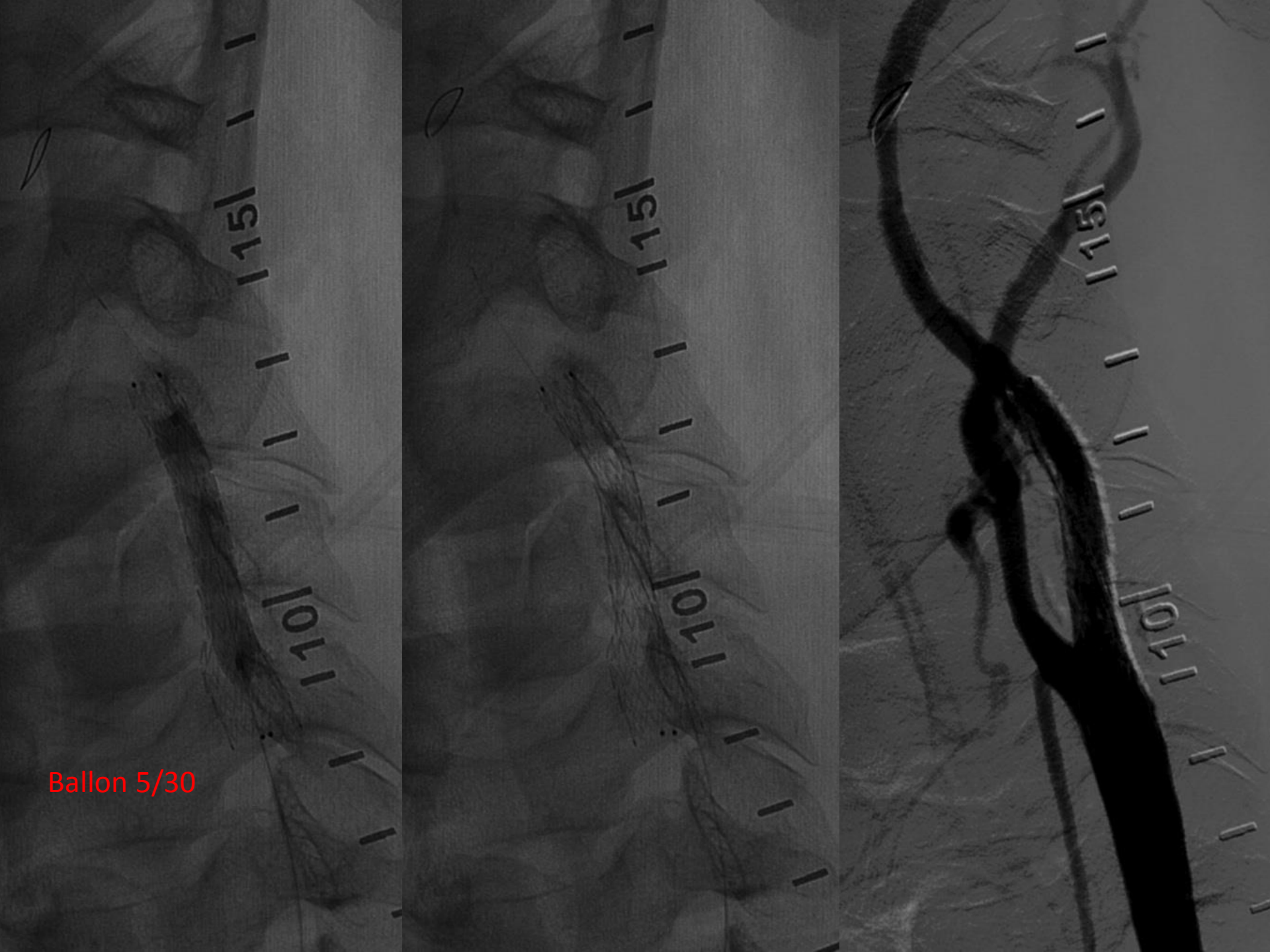


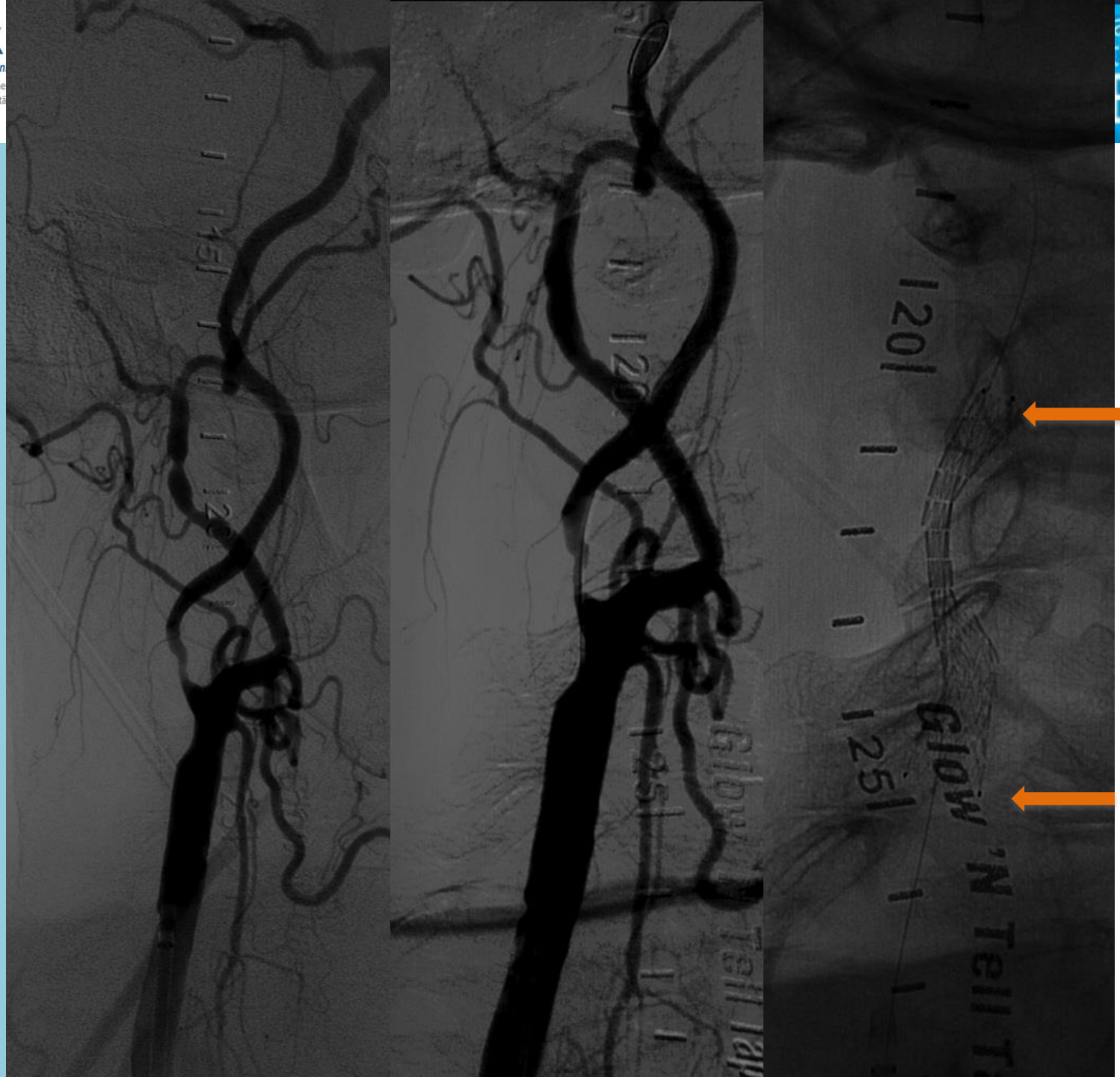


CGUARD

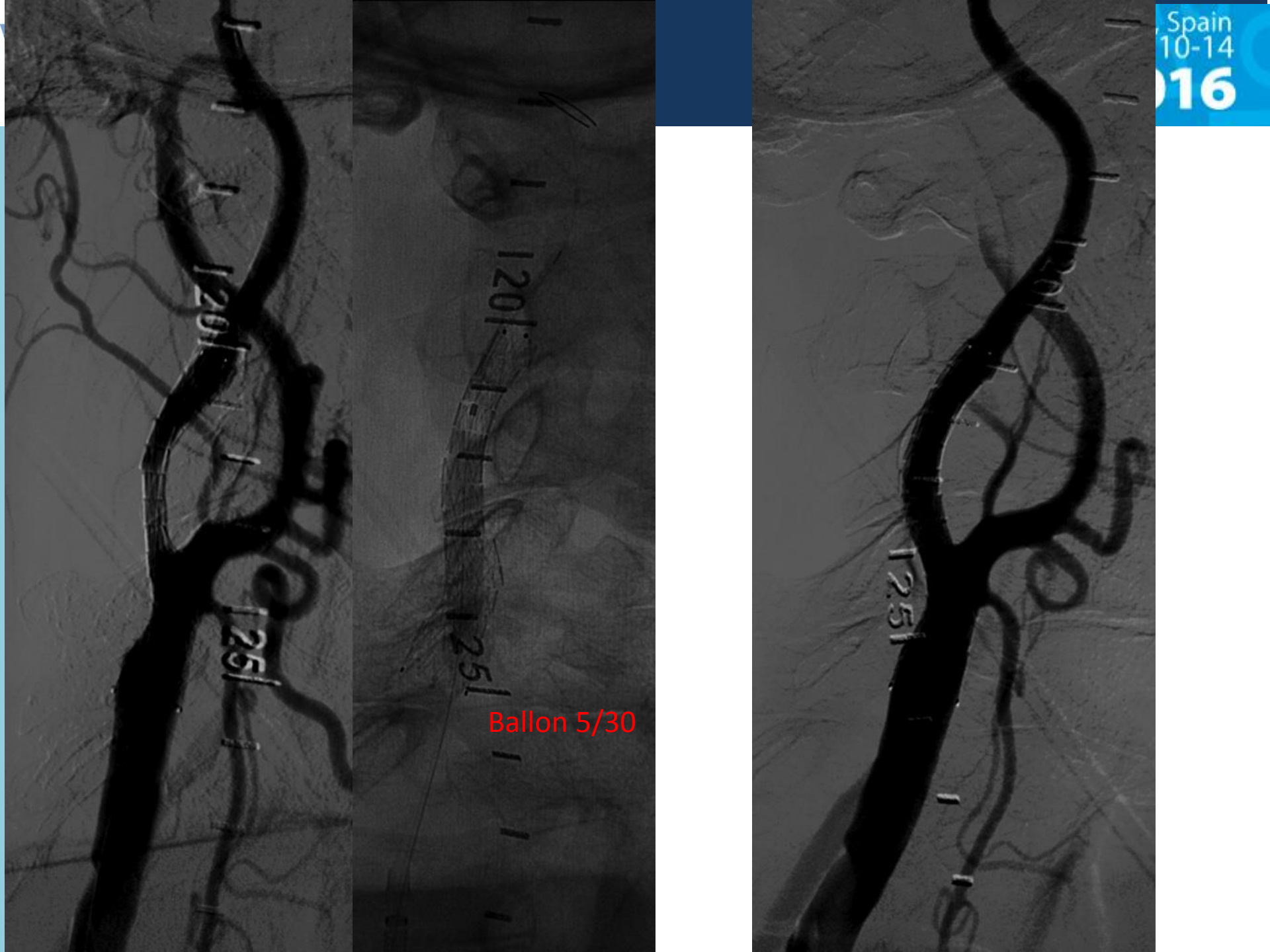



CGUARD 8/40


Ballon 5/30



CGUARD 8/40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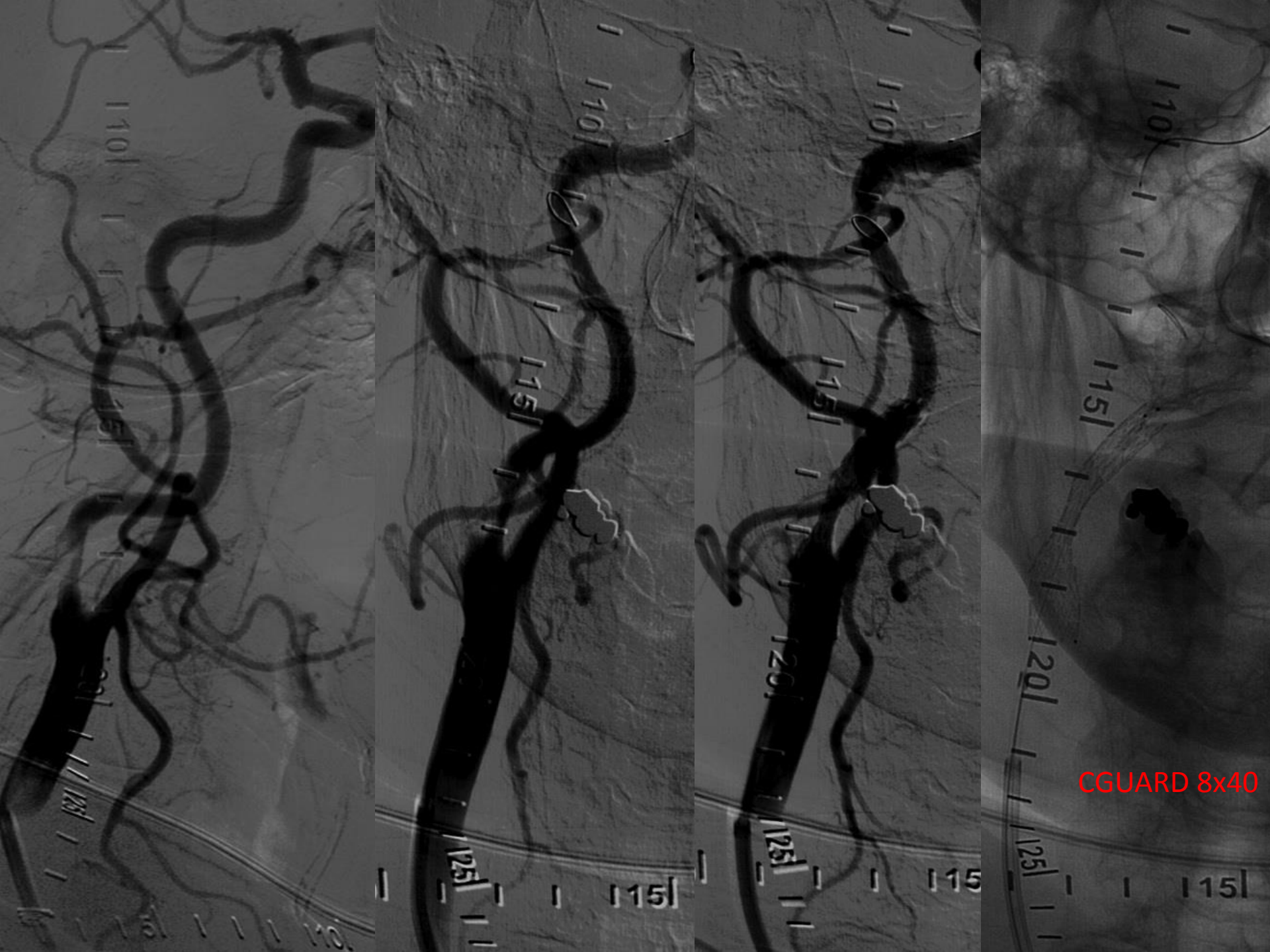
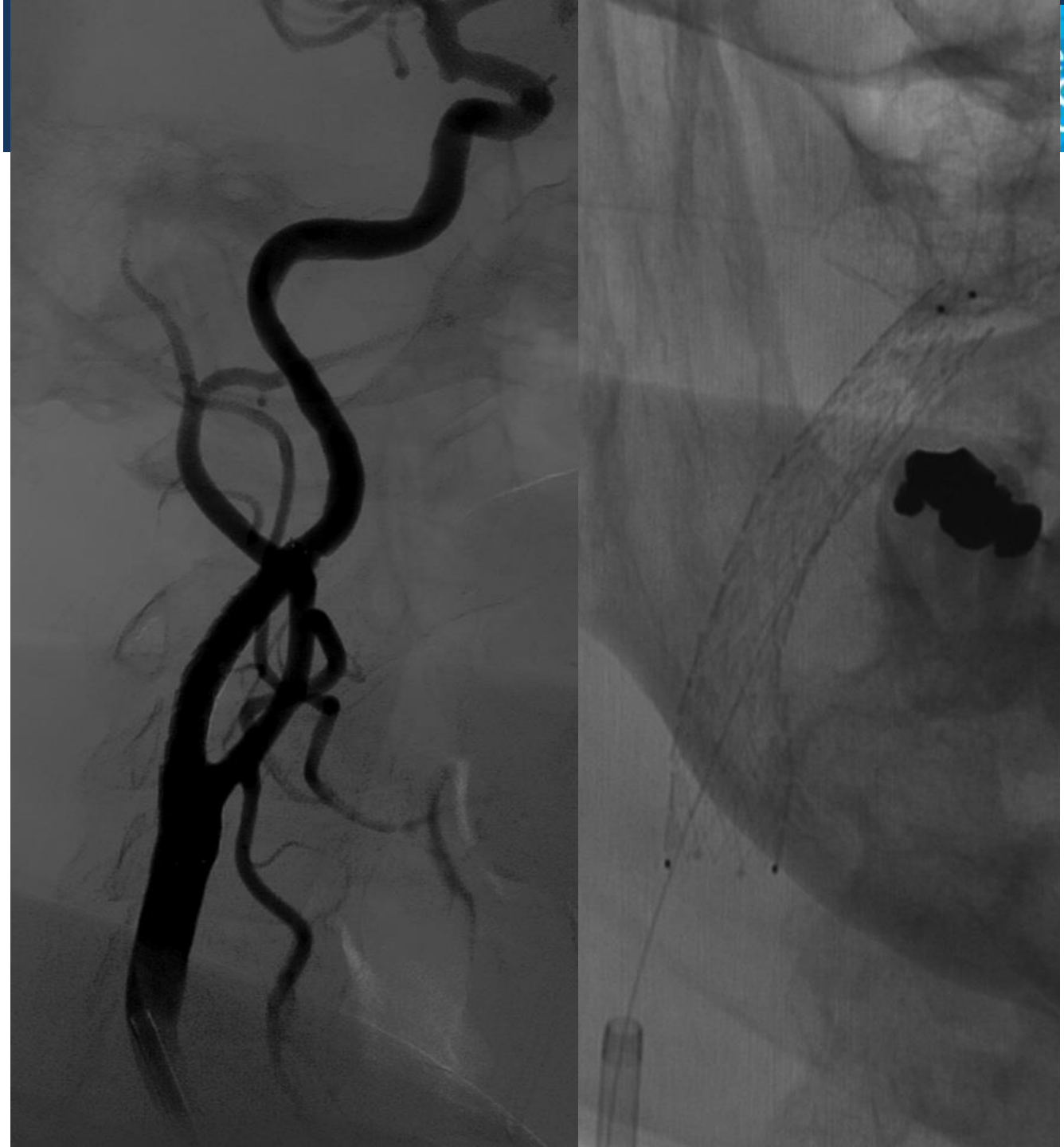

CGUARD 8x40



Final Result

Results

- Clinical results:
  - 30 patients were consecutive treated and have completed a 6 months FU
  - Technical success 100 %
  - No perinterventional complications
  - No peri- or postinterventionell Minor- or Majorstrokes
  - Median treatment time was 42.2 min

Results

- Clinical results:
  - The modified Rankin Scale of the symptomatic patients improved from 1.56 ± 0.57 prior to intervention to 0 postinterventionally
  - DUS observed that all stents were fully patent
  - peak systolic velocity (PSV) was 67.4±7.4 after 30d and 71.2±15.1 after 6 months
  - DWI-MRI from 19/30 patients after 30 days and 6 months detected no new ipsilateral lesions

Discussion

CGUARD

- Schofer et al. CARENET Trial
  (JACC Cardiovasc Interv 2015;8:1229-1234)
  - 30 Pat.
  - 100 % techn. success
  - No complications

- Musialek et al. PARADIGM-Study (PCR 2015)
  - 71 Pat.
  - 100 % techn. Success
  - no minor/major stroke

Conclusion

- The novel double-layer stent CGuard with the combination of an open-cell nitinol stent and a micro-mesh coverage leds to prevention of post-procedural embolic events in this moderate series of otherwise routine CAS in consecutive patients.
- The tested stent is easy and save to implant, because it has no foreshortening and a very smooth wall adaption.

Conclusion

- CGUARD stent provides a high radial force and strong support for expanded stenotic vessel sections.
- Its structure adapts well to changes in diameter and direction of tortous vascular anatomies.
- The novel feature for embolic protection, the MicroNet PET mesh, causes no measurable changes of specific mechanical parameters

Thank you for your attention