Clinical results and mechanical properties of a novel double-layered carotid stent (CGUARD)

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I have the following potential conflicts of interest to report:

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

X I do not have any potential conflict of interest

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

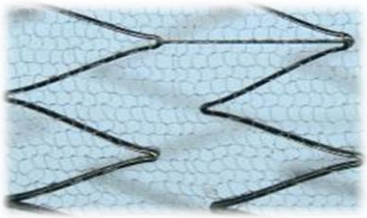
Material & Methods

CGUARD, Inspire MD

DESIGN

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

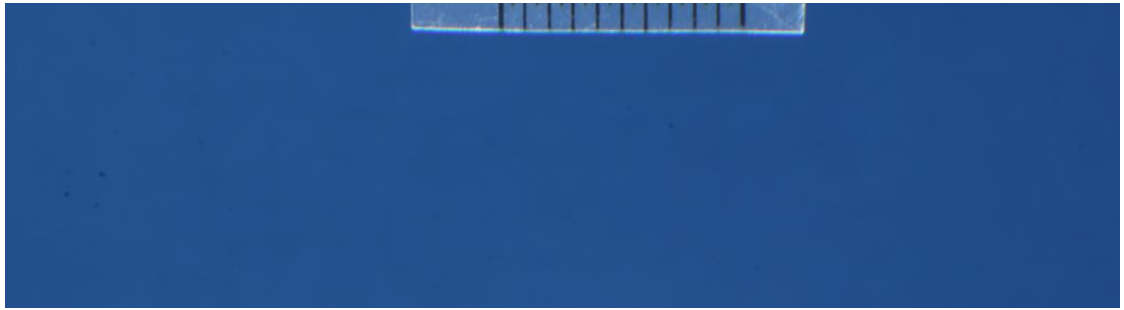
ADVANTAGES

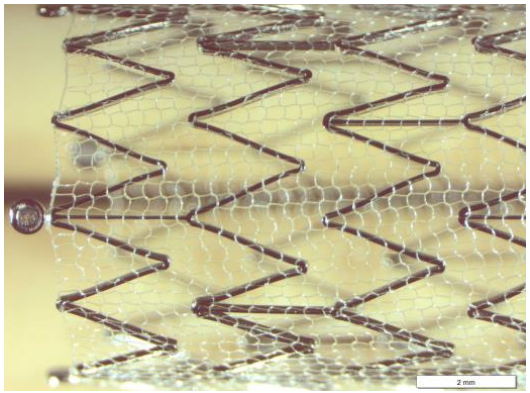


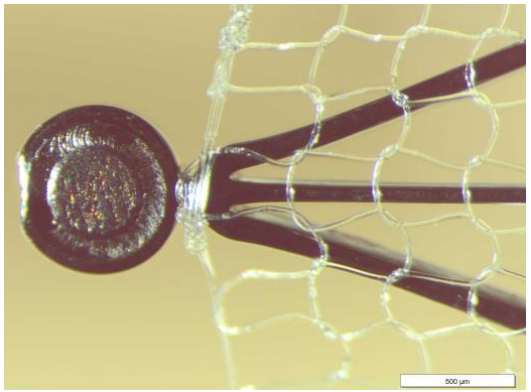
- Prevents embolization during placement and post-dilation, offers greater confidence during post dilation
- Prevents plaque prolapse and late embolization
- Flexible without compromising plaque scaffolding
- Conformable, reconstructs to natural anatomy
- Extremely precise placement
- Great visibility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

Material & Methods

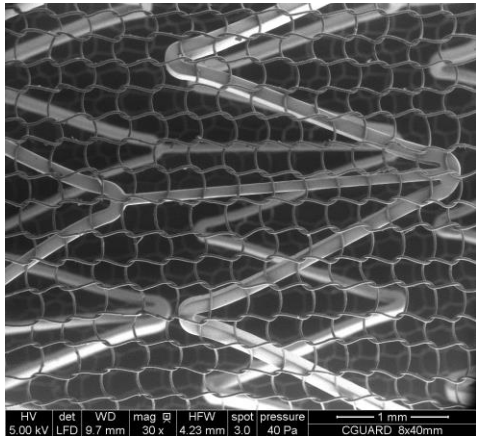
- CGUARD, Inspire MD

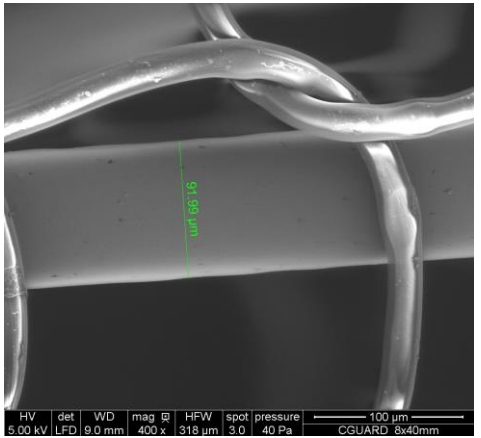


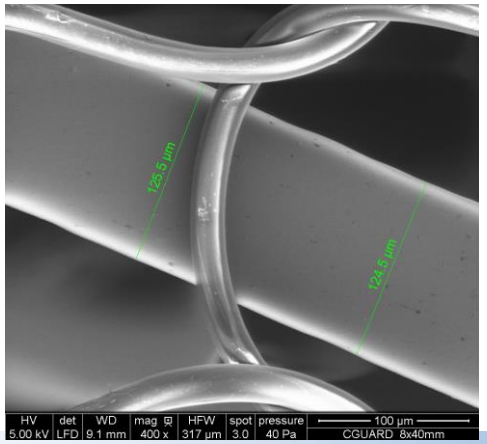




Material & Methods



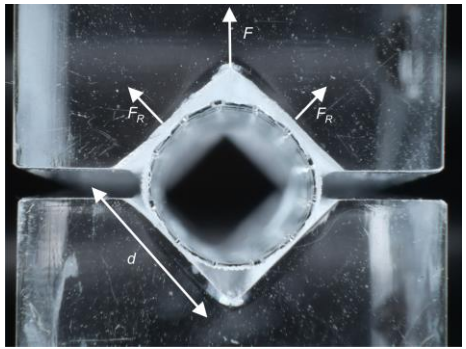


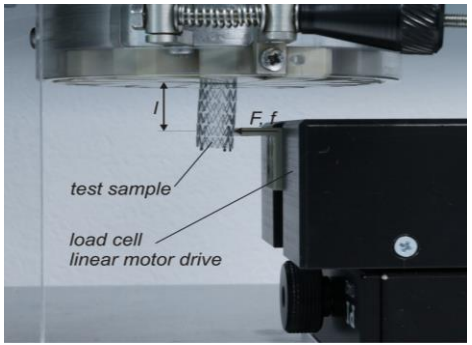


Inside: open-cell Nitinol-Stent (Struts 92 and 125µm)
Outside: closed-cell PET (25 µm)
Cell-size: ca. 165 µm

Material & Methods

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





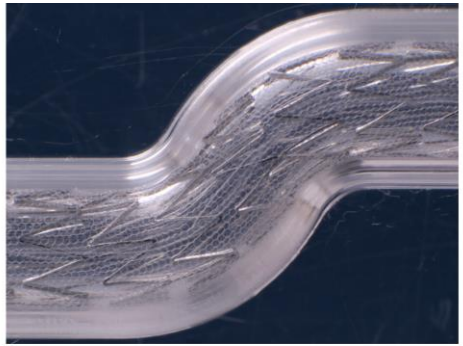
Material & Methods

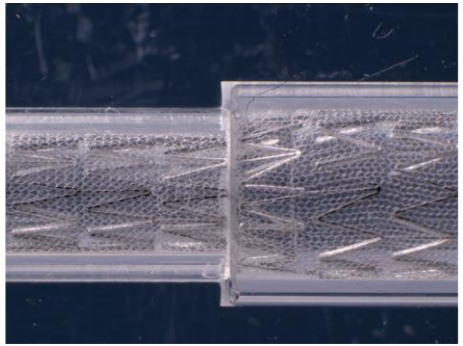
Age, mean	74.5 ± 8.6
Gender, m/f	58m / 12f
Risc factors	
Art. Hypertension	85.7 %
Diabetes mellitus	54.3 %
Hyperlipidemia	60.0 %
Smoking	68.6 %
Rankin Scale	1.32 ± 0.48
Mean Stenosis %	83.9 ± 5.9
Lesion length, mm	18.2 ± 3.9
Stents, n	
7/40 mm	4
8/30 mm	10
8/40 mm	49
9/30 mm	3
9/40 mm	4

Experimental Results

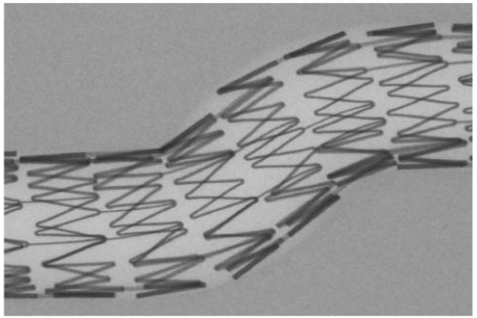
	RX	
Mean profile	8.412 mm	Expanded stent
	8.354 mm	Proximal stent end
	8.458 mm	Distal stent end
Radial force	2.28 N	Expanded to 7 mm
	4.28 N	Compressed to 7 mm
Bending stiffness	530.18 Nmm^2	Stent on delivery catheter
	59.88 Nmm^2	Fully expanded stent
Stent length	42.5 mm	Mounted on delivery catheter
	41.8 mm	Expanded to 7 mm
Foreshortening	0.7 mm/1.8 %	Expanded to 7 mm
Collapse pressure	0.18 bar	

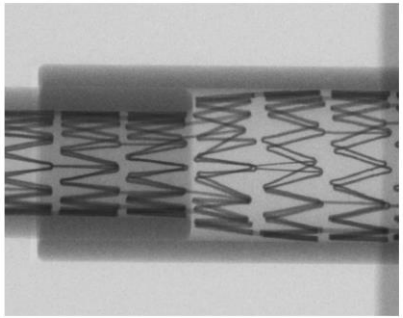
Experimental Results



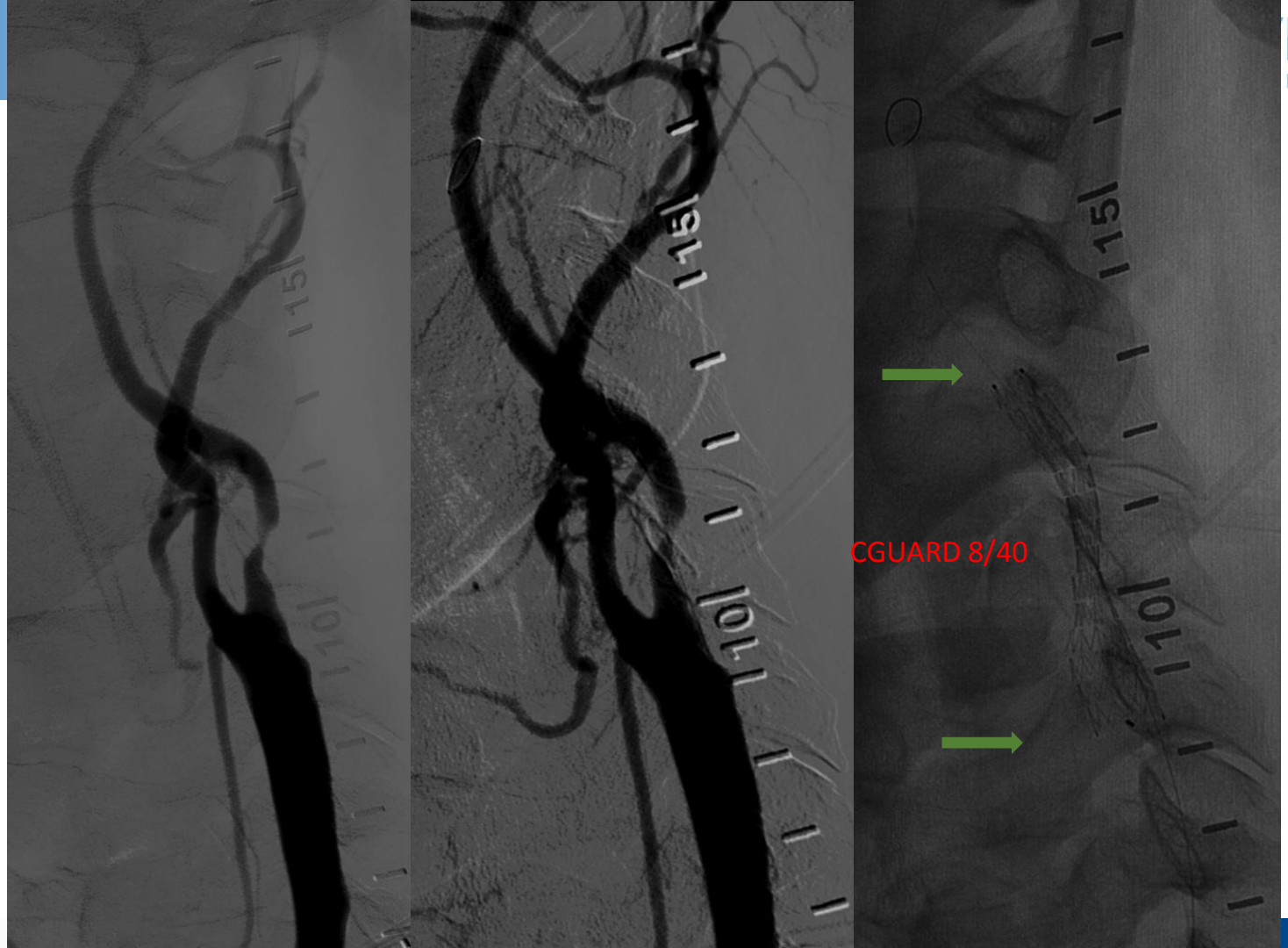


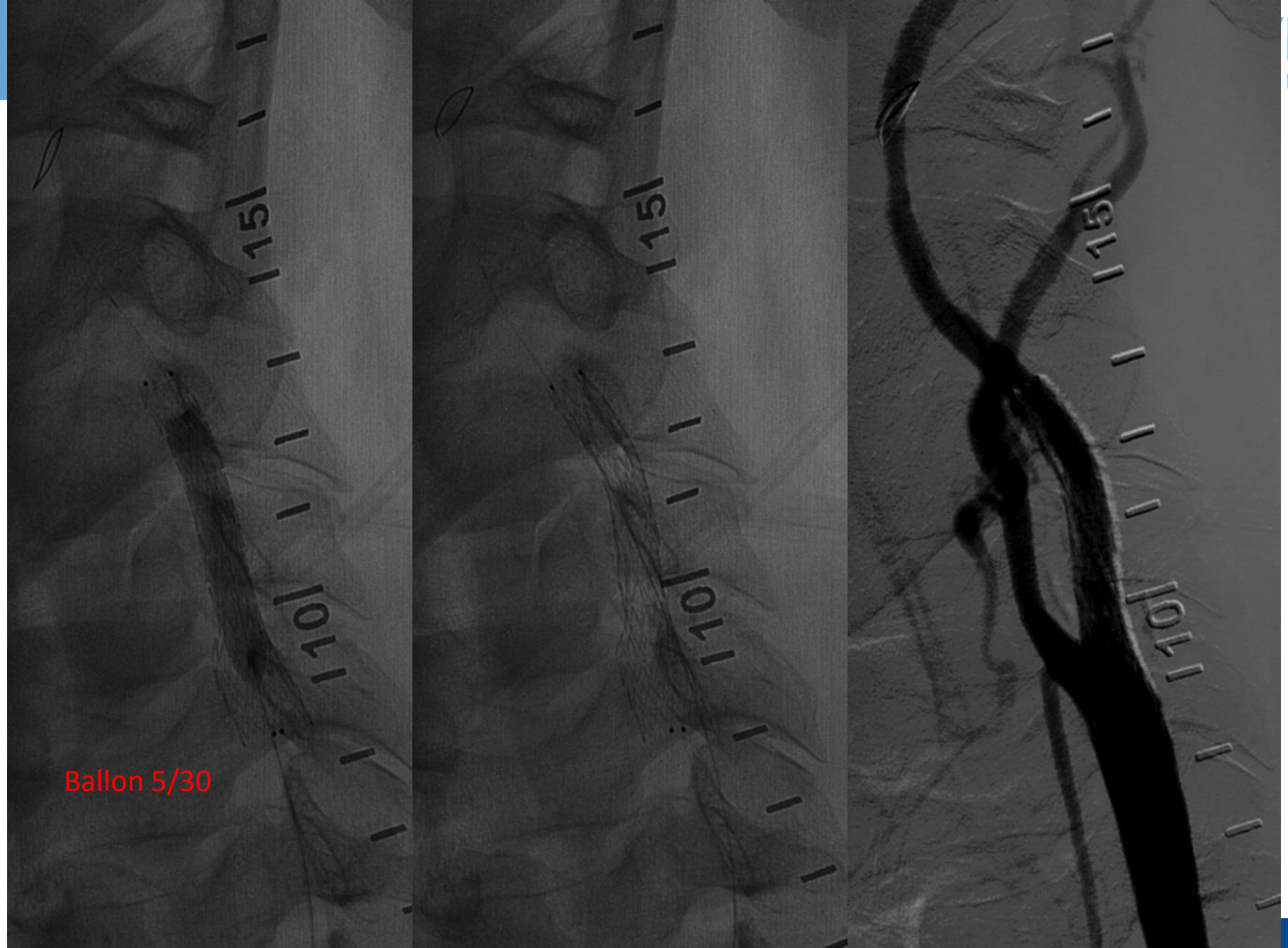
Stent adaption in a curved and in a straight vessel model with an inner diameter step from 7 to 5 mm for InspireMD CGUARD (macrophotography)





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


CGUARD 8/40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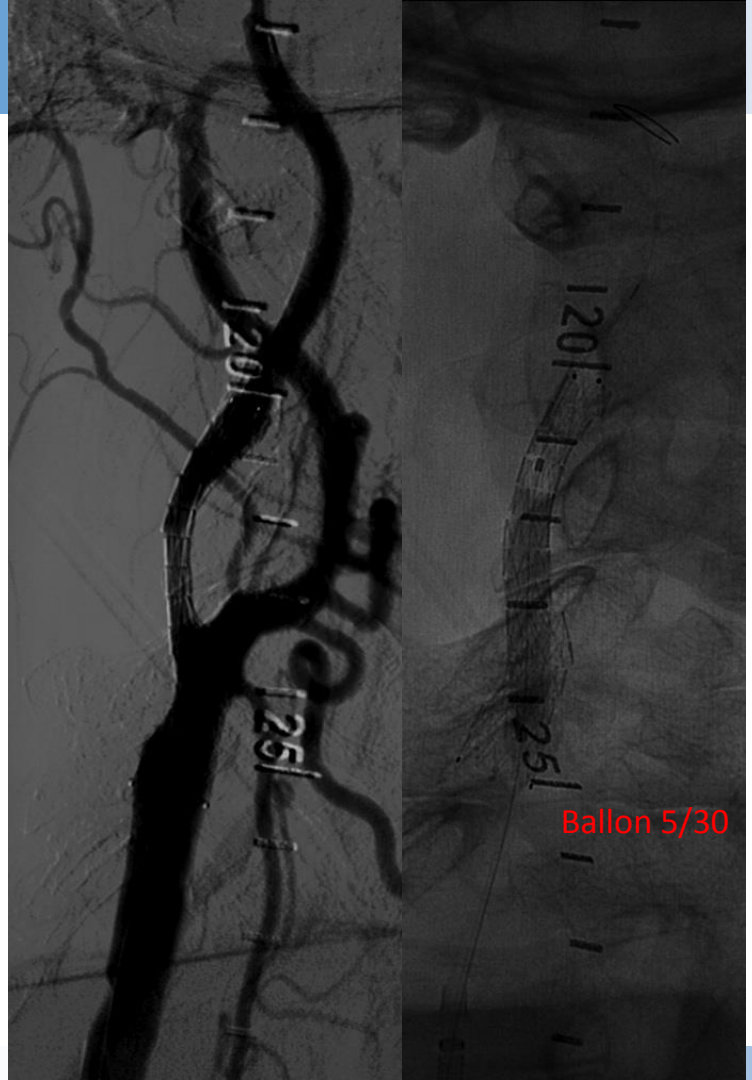
Ballon 5/30

CGUARD 8/40



Ballon 5/30

Clinical Results

- 70 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 38.4 min

Clinical Results

- The modified Rankin Scale of the symptomatic patients improved from 1.32 ± 0.48 prior to intervention to 0 postinterventionally
- DUS observed that all stents were fully patent and all ECA were fully patent
- peak systolic velocity (PSV) was 69.8±8.9 after 30d and 78.9±14.8 after 6 months
- DWI-MRI from 29/70 patients after 30 days and 6 months detected no new ipsilateral lesions

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