A prospective, multicentre study on the safety and efficacy of a novel mesh-covered carotid stent in patients with symptomatic and asymptomatic carotid artery stenosis: the CGuard CARotid embolic protection using microNET trial (CARENET)

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On behalf of the CARENET Investigators

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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	Company
• Grant/Research Support	• InspireMD

Late Embolization – The Unmet Need

		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

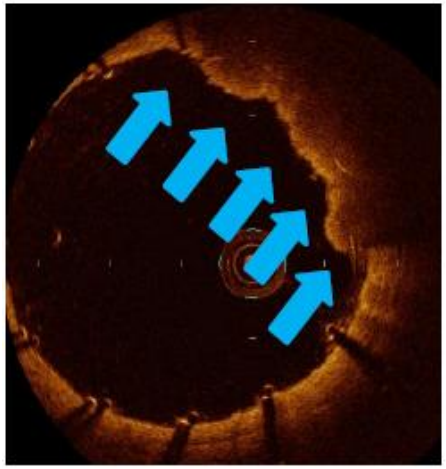
Bosiers et al. *Eur J Vasc Endovasc Surg* 2007;33

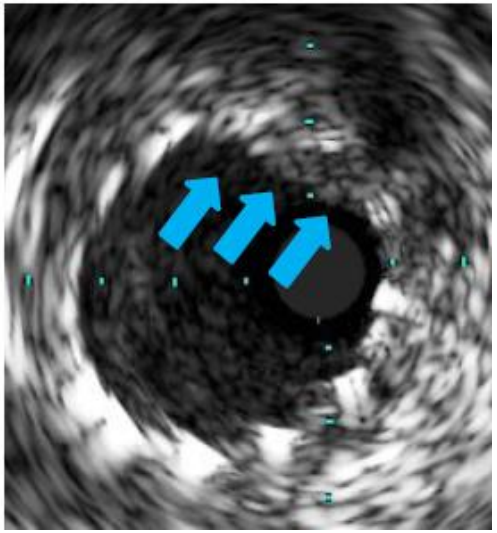
Post Procedural Plaque Prolapse Through Conventional Stent Struts

30.7%

1/3 stents = Precise
2/3 stents = Carotid Wallstent

81 y.o. Female, Symptomatic



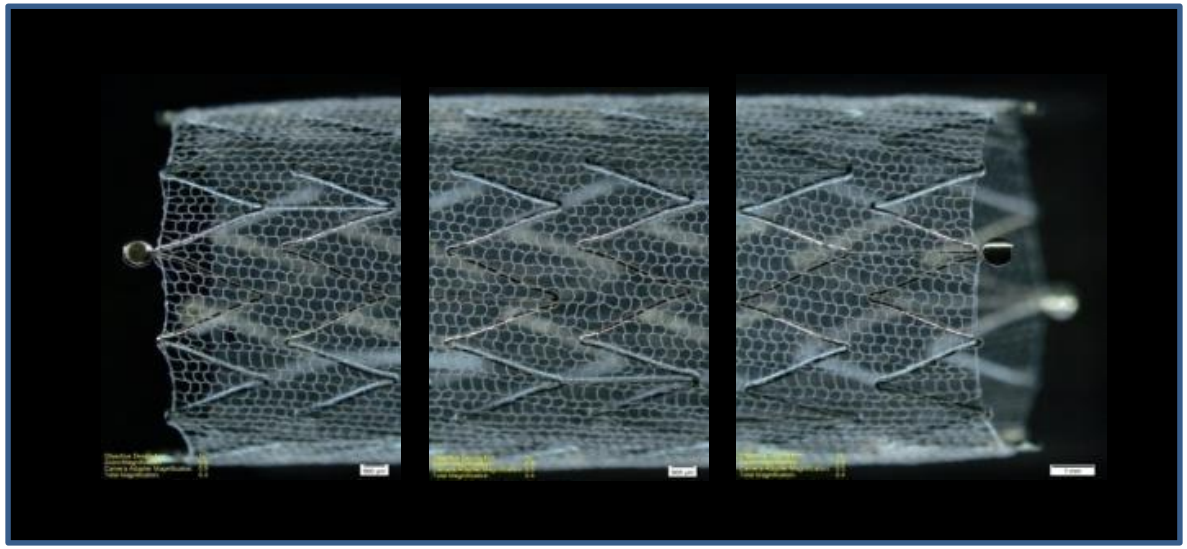


No current stent protects against late embolization

Suzuki M et al. ESC 2014 *Eur Heart J.* 2014;35(Abstr Suppl):178

CGuard™ Carotid Embolic Prevention System Specifications

Device Features	
Stent type	Nitinol Self-Expanding open cell
MicroNet Aperture Size	150-180µ
Guidewire	0.014”
Foreshortening	<10%
Sizes	Diameter(6mm-10mm) x Length (20mm – 60mm)
Delivery System (OD)	6F (2.1mm)



CGuard™ CARENET (CARotid Embolic protection using microNET) Trial Design

- Study Design:
  - Prospective, multi-center, open label, single arm, non-randomized clinical trial in patients with symptomatic and asymptomatic carotid artery stenosis
- Objectives:
  - To evaluate the periprocedural safety and efficacy of the CGuard™ system in the treatment of carotid lesions in 30 consecutive patients suitable for carotid artery stenting (CAS)
- Sites:
  - Hamburg University CardiovascularCenter, Hamburg Germany, Joachim Schofer
  - Jagiellonian University MedicalCollege at JohnPaul II Hospital, Krakow Poland, Piotr Musialek
  - Cardiovascular Center Frankfurt, Frankfurt Germany, Horst Seivert
  - Augusta Hospital, Dusseldorf Germany, Ralf Kolvenbach

CGuard™ CARENET (CARotid Embolic protection using microNET) Trial Design

- **Study Population**:
  - Symptomatic pts (w/ history of a transient ischemic attack, stroke, or amaurosis fugax within the last 6 mos on the ipsilateral side) w/carotid stenosis ≥ 50%
  - Asymptomatic pts w/ carotid stenosis ≥ 80%

    both as diagnosed by angiography using NASCET methodology
- **Primary Endpoint**:
  - 30 day MACE (death, stroke, MI)
- **Key secondary Endpoints**:
  - Technical success
  - Periprocedural complications (including device-related)
  - Incidence, number and volume of new lesions assessed by DW MRI during pre-procedure, 24-48 hours post-procedure, and at 30 days (+/- 3 days)
  - Peak systolic velocity (PSV) and end diastolic velocity (EDV) assessment by ultrasound examination at 30 days, 6 mos, and 1 year

Baseline Characteristics (n=30)

Age	71.6 ±7.6
Male	63.4%
Symptomatic	33.3% (10)
BMI (kg/m^2)	26.4 ± 3.9
Hypertension	83.3% (25)
Dyslipidemia	90% (27)
Diabetics	23.3% (7)
Smoker: Current Former	 13.4% (4) 36.6% (11)
Prior MI	26.7% (8)
Prior TIA	13.3% (4)

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Procedural Results (n=30)

Femoral access		100% (30)
- Left ICA		33.3% (10)
- Right ICA		66.6% (20)
Protection used		
-Distal filter protection		96.6% (29)
-Proximal balloon protection		3.4% (1)
Pre dilatation		70.9% (22)
Post dilatation		77.4% (24)
Procedure success		100% (30)
Diameter stenosis (%)	79.9%±5.0%	16.9%±6.5% (in stent)
ECA stenosis (%)	18.0%	22.1%
TIMI flow in ECA		
Normal	100.0%	100.0%

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Clinical Events

	30 days (n=30)	6 months (n=28*)
MACCE (MI, stroke, death)	(0) 0.0%	(1) 3.6%
MI	(0) 0.0%	(0) 0.0%
Stroke	(0) 0.0%	(0) 0.0%
Death	(0) 0.0%	(1) 3.6%

- Comparative data from other CAS trials include higher 30 day and 6 month MACCE rates:

	30 days** (14 trials, 5255 patients)	6 months† (3 trials, 1053 patients)
MACCE (MI, stroke, death)	5.72%	8.09%

* 2 patients exited the study

** Trials included in analysis: ARCHeR pooled, ARMOUR, BEACH, CABERNET, CREATE, EMPIRE, EPIC, MAVErIC 1+2, MAVErIC International, PRIAMUS, SAPPHIRE, SECURITY, PROFI, ICSS

† Values extrapolated from event curves

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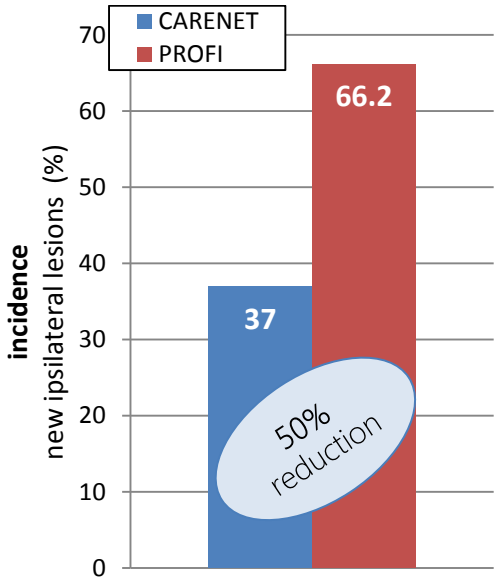
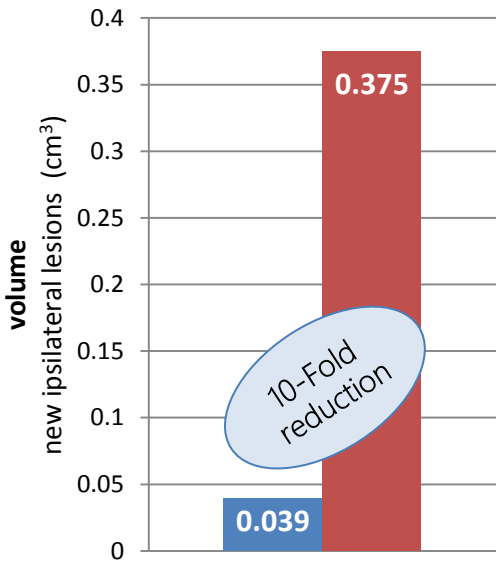
DW-MRI Analysis

DW-MRI analysis @ 48 hours, n=27*





DW-MRI analysis @ 30 days, n=25**

Incidence of ipsilateral lesions	4.0% (n=1)
Average lesion volume (cm^3)	0.08 ± 0.00

Bijuklic et al. *JACC*, 2012;59

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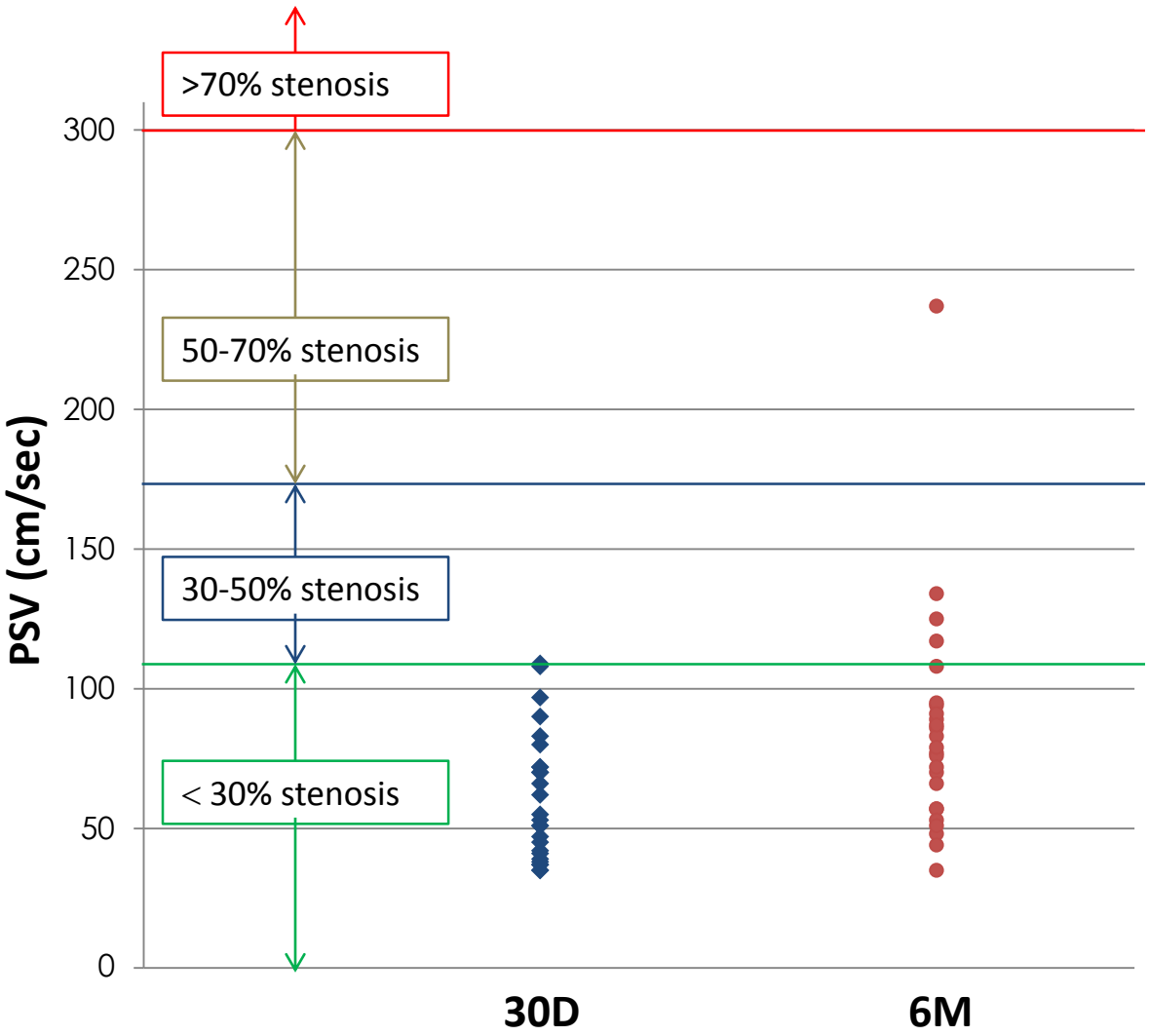
Ultrasound PSV scatter plot



Conclusions

- CARENET trial met primary endpoint of zero MACE (no death, stroke, and MI) at 30 days
- The procedural success was 100%
- Incidence of new ipsilateral lesions at 48 hours was reduced by almost half compared to published data, and volume was reduced almost 10-fold.
- All but one lesion had resolved completely by 30 days.
- 6 month ultrasound analysis is indicative of healthy healing without restenosis concern.
- These initial clinical results suggest that the MicroNet™ covered CGuard™ offers unique clinical benefits for patients undergoing CAS

Thank You