Evaluation of PET Mesh Covered Stent in Patients with Carotid Artery Disease

The CARENET-Trial

(CARotid Embolic protection using microNET)

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Disclosure Statement of Financial Interest

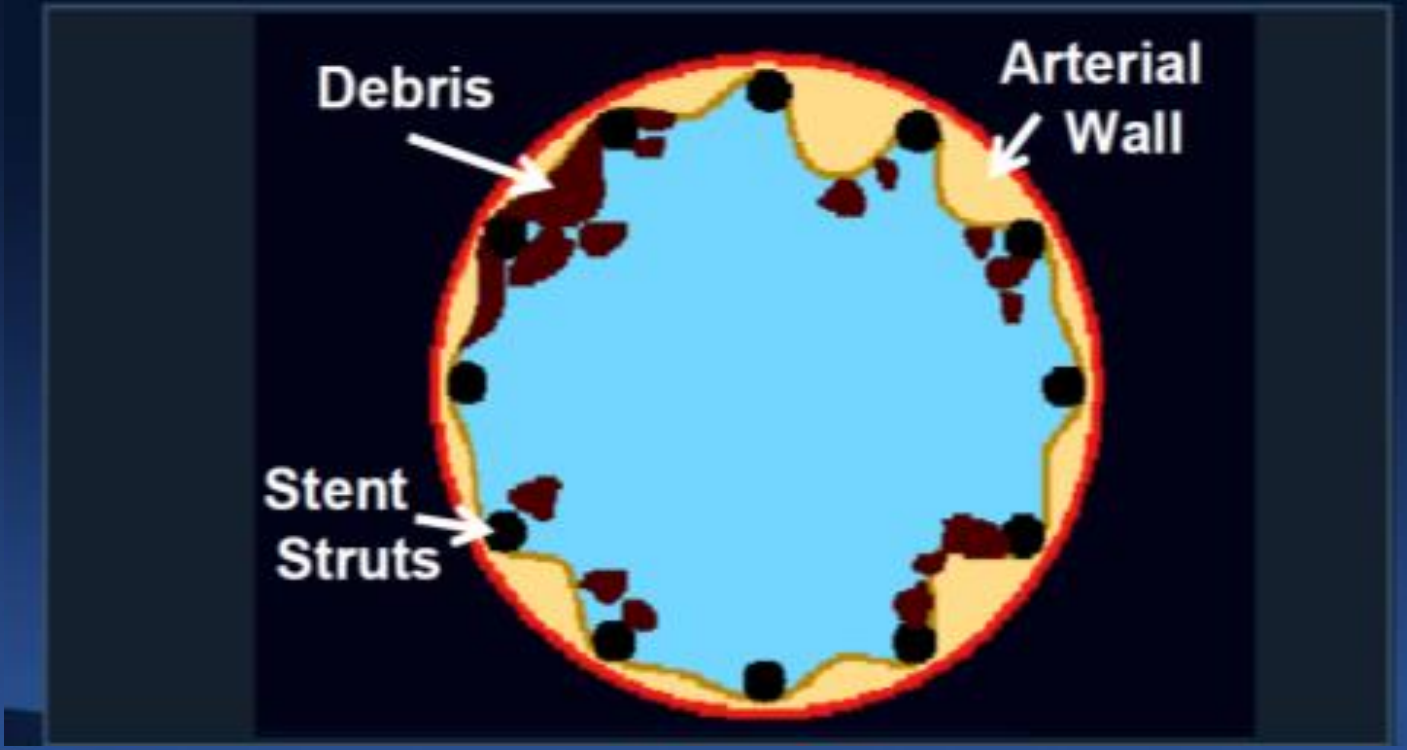
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• InspireMD

Rationale of Technology

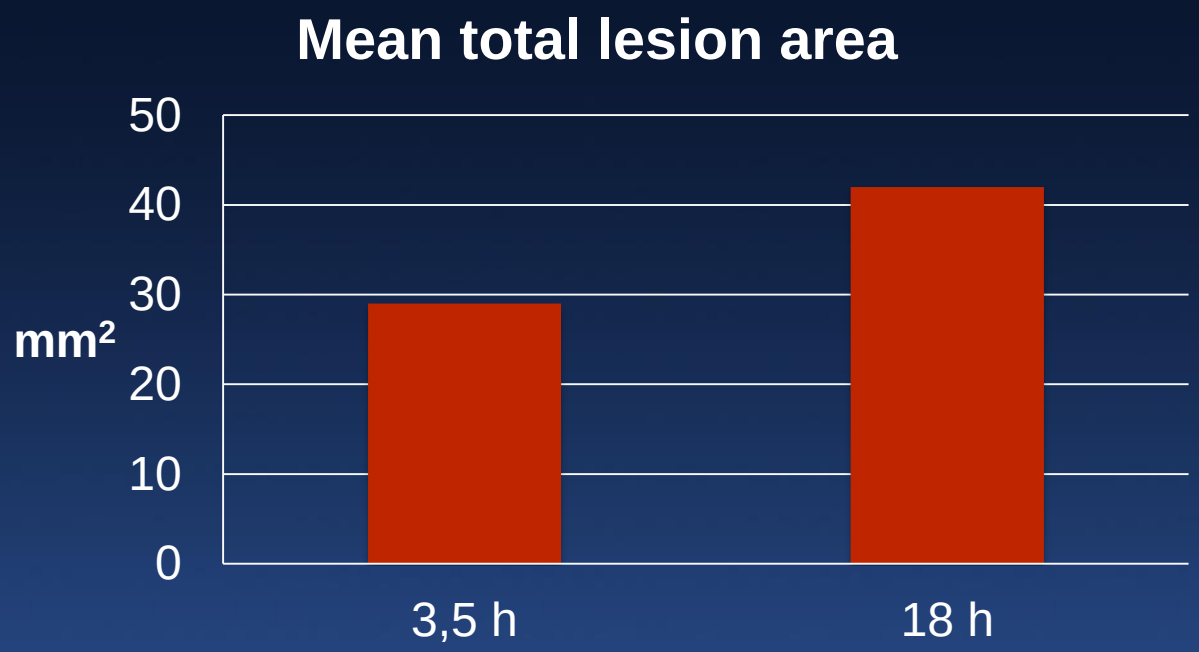
Conventional Carotid Stent

Plaque protrusion may lead to early and late distal embolization



Late Embolization

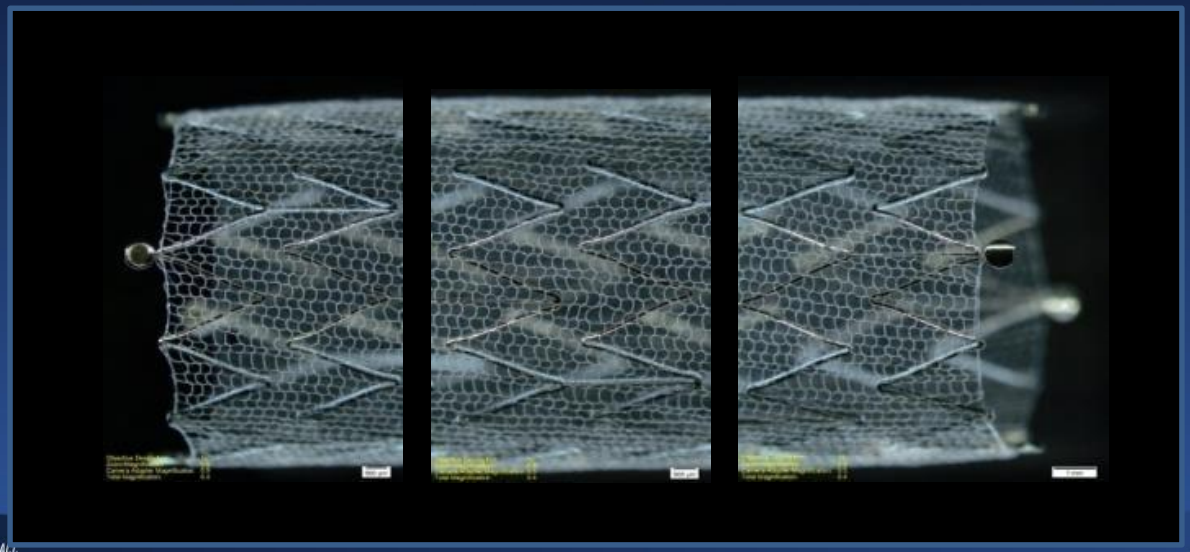
DW-MRI post CAS



Schofer J et al, JACC Cardiovasc interv 2008

CGuard™ Carotid Embolic Prevention System Specifications

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



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

- **Study Design:**
  - **Prospective, multi-center, multi-specialty, international, 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

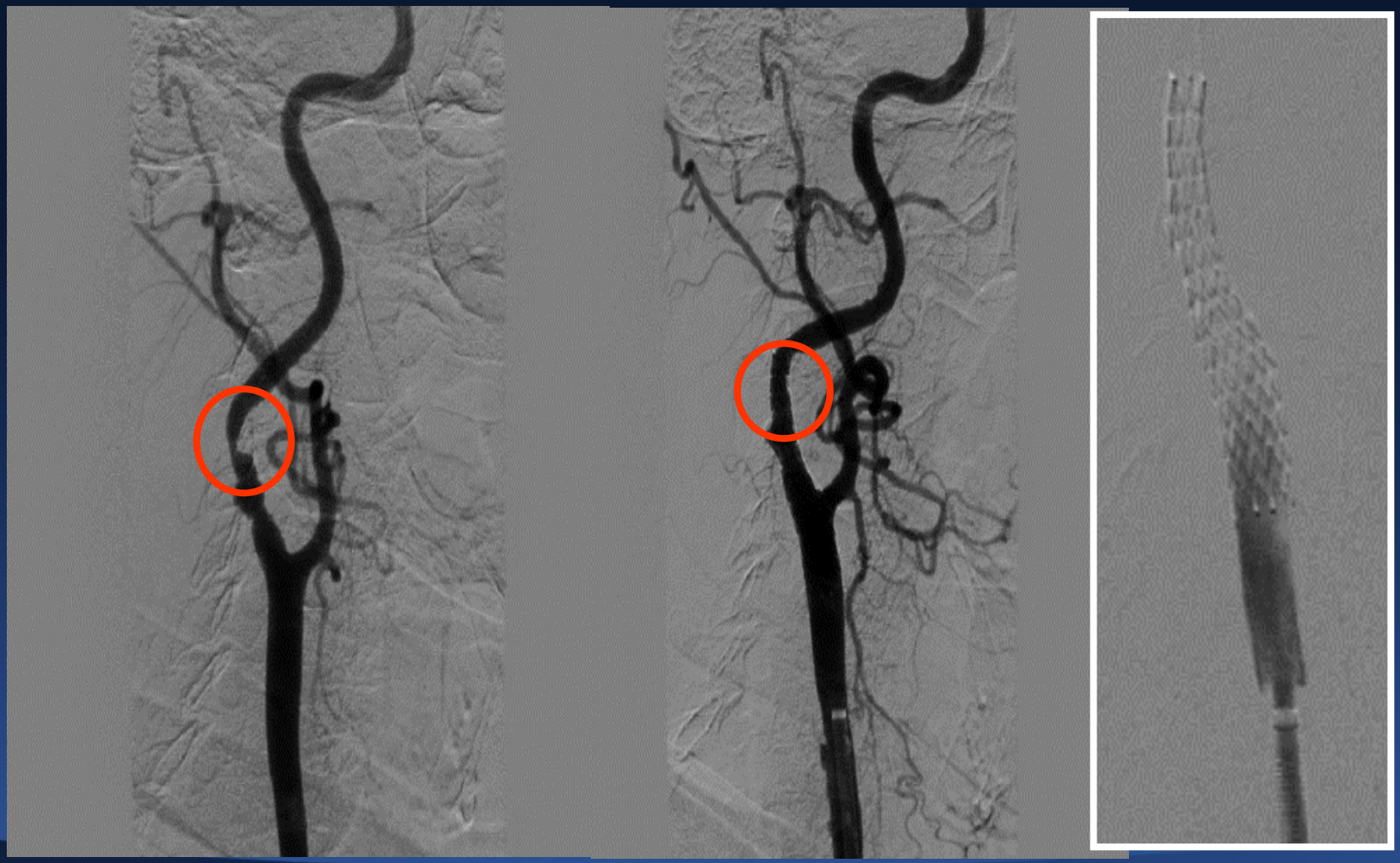
Baseline Characteristics
(n=30)

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)

Procedure Results

Femoral access	100% (30)
Target vessel Left ICA Right ICA	 33.3% (10) 66.6% (20)
Protection used Distal protection Proximal protection	100% 96.6% (29) 3.4% (1)
Pre dilatation	70.9% (22)
Post dilatation	77.4% (24)
Post dilatation Pressure (ATM)	13.6 ±4.5
Device success	100% (30)
Stent deployed	100% (30)
Stent diameter (Mean)	8.23mm ± 0.8
Stent length (Mean)	34.8 mm ± 5.0
Second stent used	3.33% (1)

Pre & Post Procedure Carotid Angiogram in Patient with right ICA Stenosis



Clinical Outcomes

	Post Procedure	Discharge	30 days
Device success	100%	NA	NA
MACE	0%	0%	0%
Death	0%	0%	0%
MI	0%	0%	0%
Stroke	0%	0%	0%

Angiographic Assessment

	Baseline	Final
Lesion location (internal)	100%	NA
Lesion length (mm)	16.94±4.7	NA
RVD (mm)	6.18	5.89
MLD (mm)	1.25	4.82
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%

CARENET with Distal Protection DW-MRI @ 24-48 hrs

	CARENET CGuard with only Distal EPD (N=26*)
Incidence of New Lesions	46%
Lesions (per patient)	1.62 ±2.68
Volume (per patient)	0.061 ±0.11 cm^3

- **3 pts unable to undergo MRI (1 = pacemaker; 2 = claustrophobia)*
- *1 pt with proximal protection had 78 new lesions. New ischemic lesions had no clinical or neurological impact, all lesions been resolved at 30 days.*

CARENET Comparison
DW-MRI @ 24-48 hrs

	CARENET (Filter group) N=26	PROFI[1] (Filter group) N=31	ICSS[2] (Filter group) N=37
Incidence of New Lesions	48%	87%	73%
Avg Lesion Volume	0.06 cm^3	0.59 cm^3	NA

[1] *JACC, April 2012*

[2] *Lancet, March 2010*

Conclusions

- CARENET trial demonstrated the safety of the CGuard™ Technology with zero MACCE at 30 days
- The procedural success was 100%
- Compared to published DW-MRI data of non-mesh covered carotid stents, the incidence of new ischemic lesions was reduced by almost 50% and the average lesion volume per patient 10 times smaller
- These initial clinical results suggest that the MicroNet™ covered CGuard™ offers unique clinical benefits for patients undergoing CAS