Per-Protocol Interim Results in a Randomized DW-MRI Controlled Study of Carotid Artery Revascularization using a MicroNet Mesh Stent

CGuard™ Micronet® Covered **S**tent vs. Accul**I**nk: **B**asal, 30d DW MRI and 1y Clinical **E**valuation in 100 **R**andom**I**zed p**A**tients: The **SIBERIA** Trial

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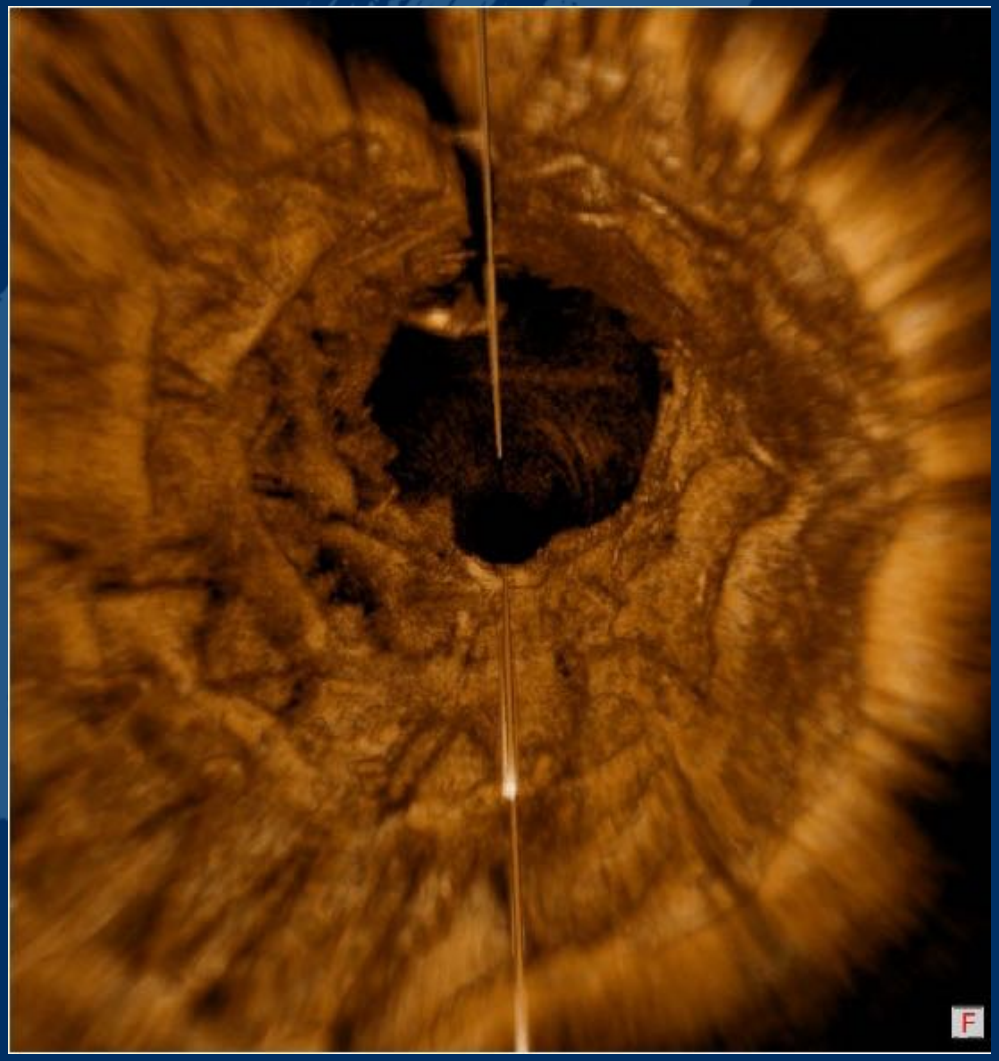
CAS Current Limitations



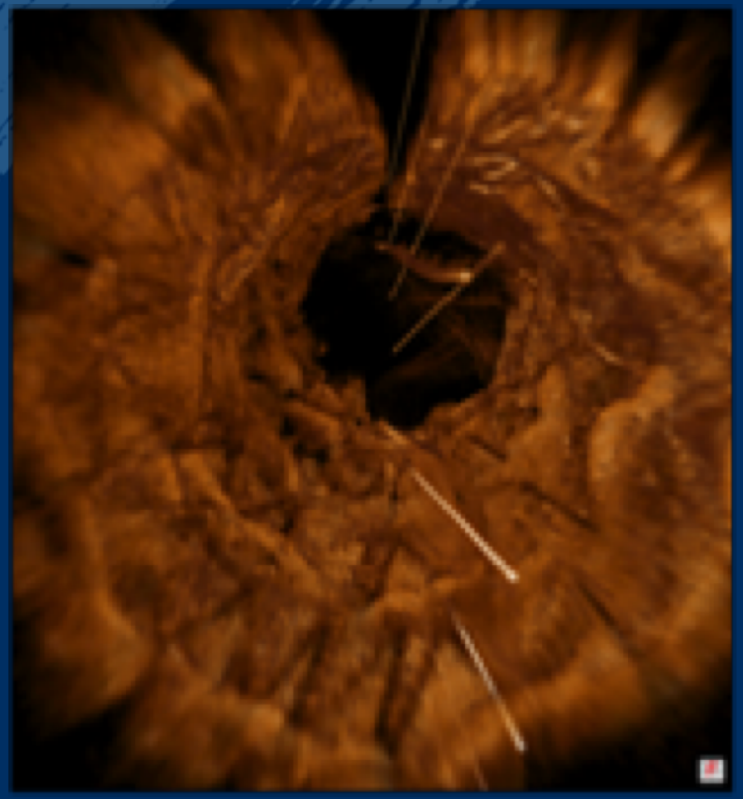
Protrusion of atheromatous plaque through the stent struts is a fundamental problem of carotid artery stenting
(Reimers B.2011; De Donato G.2013; Liu R, Jiang Y.2015).

This plaque prolapse is a risk factor for cerebral embolism, not only during carotid artery stenting, but also weeks after the procedure.
(De Donato G.2013).

Plaque Coverage in Carotid Stents

Conventional Carotid Stents

No plaque protection - leading to plaque protrusions or prolapse passing into the vessel lumen



Conventional Carotid Stent

CGuard™ EPS

The MicroNet® **permanently covers** plaque and prevents “debris” from passing through the mesh.

CGuard™ EPS

Case reports courtesy Dr. Gianmarco de Donato, Department of Medicine Surgery and Neuroscience Universita degli studi di Siena, Italy.

Hypothesis

CGuard™ EPS MicroNet covered stent will provide protection in CAS, both procedural and postprocedural, from new DW-MRI lesions compared with the Acculink™ reference stent. As a consequence, CGuard may demonstrate a reduction in neuro-embolic events.

Study Objective

To compare cerebral embolism and clinical outcomes with the new CGuard™ EPS MicroNet® stent versus the conventional carotid stent Acculink™ in the standard treatment of carotid artery disease

Endpoints

Primary endpoint

Incidence and volume of new DW-MRI lesions post procedure, within 24-48 hours, and at 30 days

Secondary endpoints

Technical success, periprocedural and 30 days adverse events and 1 year device related events (any homolateral stroke, device related death or restenosis)

Study design

100 patients with lesions of the carotid artery bifurcation.
Screening patients to determine inclusion / exclusion criteria

Basal brain DWI-MRI

↓

Randomization (1:1)

Acculink (n=50) CGuard (n=50)

↓

24-48 hours
DW-MRI and NIHSS&Rankin scale

↓

30 days
DW-MRI and NIHSS&Rankin scale

↓

1y
NIHSS&Rankin scale

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Study Population

n=50

Variable	CGuard N=25	Acculink N=25	p
Age	66 [63;72]	66 [64;69]	0,66
Degree of stenosis	75 [70;81]	75 [70;79]	0,89
Gender			
Male	16 (64 %)	19 (76 %)	
female	9 (36 %)	6 (24 %)	0,53
Concomitant pathology and risk factors			
Ischemic heart disease	19 (76 %)	15 (60 %)	0,36
CHF	22 (88 %)	22 (88 %)	1
Diabetes	3 (12 %)	5 (20 %)	0,70
PTCA	14 (56 %)	8 (32 %)	0,15
PTA	3 (12 %)	5 (20 %)	0,70
Aorto-Femoral Shunt	1 (4 %)	1 (4 %)	1,00
CABG	4 (16 %)	1 (4 %)	0,38
Primary Hypertension	24 (96 %)	24 (96 %)	1
smoking	10 (40 %)	7 (28 %)	0,55
hypercholesterolemia	1 (4 %)	4 (16 %)	0,38

Study Population

n=50

Variable	CGuard N=25	Acculink N=25	p
Asymptomatic patients	15 (60 %)	20 (80 %)	0,21
Symptomatic patients	10 (40 %)	5 (20 %)	0,21
Stroke	7 (28 %)	3 (12 %)	0,13
TIA	3 (12%)	2 (8 %)	0,67
Neurological deficit (paresis, paralysis)	3 (12 %)	2 (8 %)	0,67
Side of the lesion			
On the right ICA	15 (60 %)	13 (52 %)	0,77
On the left ICA	10 (40%)	12 (48%)	0,77
Previous intervention in the contralateral carotid artery:	2 (8%)	4 (16%)	0,40
Current disease in the Contralateral Carotid Artery:	10 (40%)	3 (12%)	0,05

- Higher number of symptomatic patients in the CGuard group.
- Higher number of stroke patients included in the CGuard arm group
- Disease in the contralateral carotid artery was significantly higher in the CGuard group

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Clinical Results

Interim DW-MRI results on the first 50 patients

Intermediate Results	Group CGuard (n = 25)	Group Acculink (n = 25)	p
Any New DW Lesion at 24-48	12 (48%)	14 (56%)	p = NS
Bilateral	2 (8%)	4 (16 %)	p = NS
New DW Lesions at 24-48 > 3 mm	**24%**	**40%**	p = NS
Multiple DW Lesions at 24-48h	**16%**	**44%**	**p ≤ 0.05**

Intermediate Results	Group CGuard (n = 25)	Group Acculink (n = 25)	p
New DW-MRI Lesions at 30d	0	1(4%)	p = NS

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Clinical Results

MACE results in the first 50 patients

Periprocedural (<24h)	CGuard N=25	Acculink N=25	p
Stroke	0	1 (4%)	p = NS
AMI	0	1 (4%)	p = NS
Periprocedural MACE	**0**	**2 (8%)**	p = NS

24h-30 days	CGuard N=25	Acculink N=25	p
Stroke	0	1 (4%)	p = NS
AMI	0	0	p = NS
MACE	**0**	**1 (4%)**	p = NS

Cummulative MACE at 30 days	CGuard N=25	Acculink N=25	p
MACE	**0**	**3 (12%)**	**P = 0.24**

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Conclusions

Per-Protocol interim analysis in the first 50 pts

In this first randomized trial comparing CGuard EPS with a reference carotid stent:

- CGuard EPS demonstrates a significantly lower incidence of multiple new DW-MRI lesions at 24-48h
- The MACCE incidence is numerically lower in the Guard EPS arm, suggesting a clinical benefit.
- Enrollment is continuing to reach the target population of 100 patients

The **SIBERIA** Trial