Interim Results of the Randomized Study in Carotid Artery Revascularization:

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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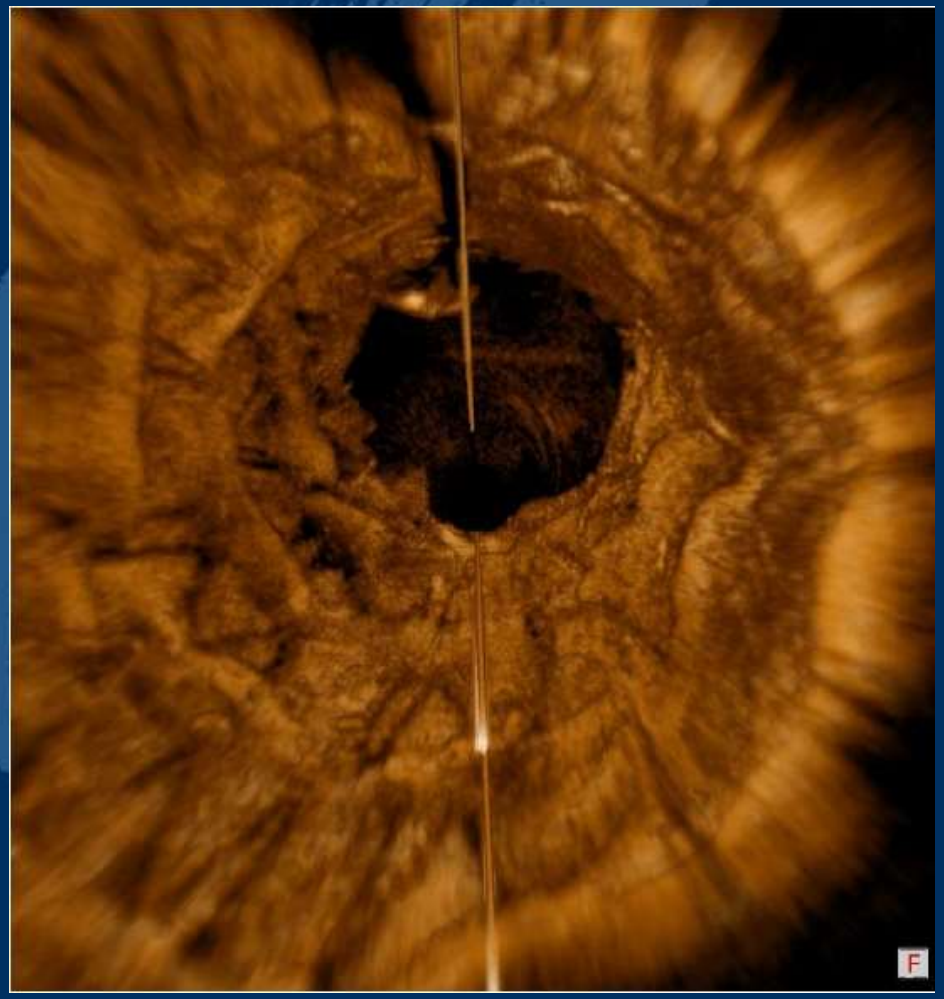
CAS Current Limitations



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).

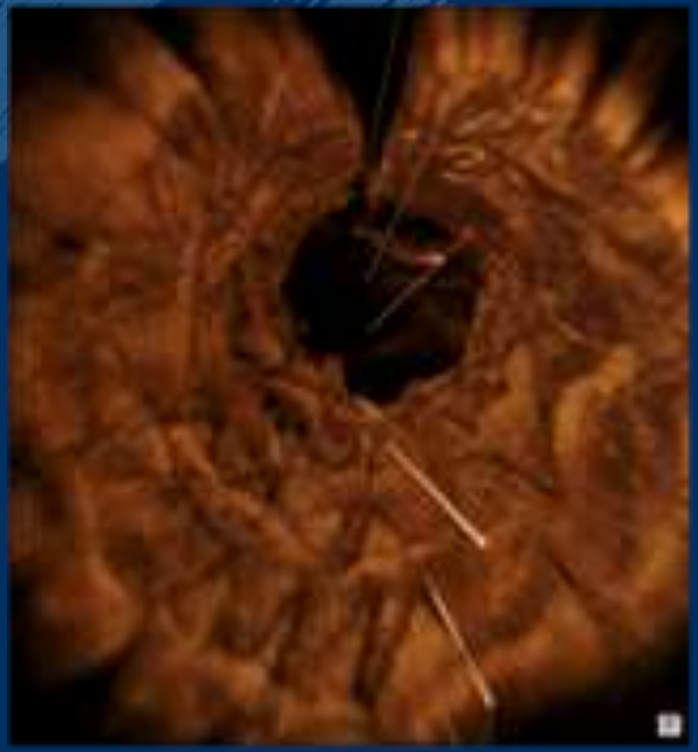
This plaque prolapse is a risk factor for cerebral embolism, not only during carotid artery stenting, but also weeks after the procedure.

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

Study Objective

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

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

↓

30th day
DW-MRI and NIHSS&Rankin scale

↓

1 year
NIHSS&Rankin scale

The **SIBERIA** Trial

Endpoints

Primary endpoint

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

Secondary endpoints

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

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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Stent Characteristics

n=50

Variable	CGuard N=25	Acculink N=25	p
Predilation 3.5–4 mm	9 (36 %)	10 (40%)	1
Postdialation 5-6 mm	25 (100%)	25 (100%)	1
Diameter of stents	**8 [8;8]**	**7 [7;7]**	**0,01**
Stent length	40 [40;40]	40 [40;40]	1,00

Clinical Results

Interim DW-MRI results on the first 50 patients

Intermediate Results	Group CGuard (n = 25)	Group Acculink (n = 25)	p
New DW Lesions 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 24-48	**16%**	44%	**p ≤ 0.05**

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

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Clinical Results

Interim MACE results on 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=NS**

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Device Related MACE*
Interim Results

- Periprocedural minor ischemic stroke
- NSTEMI AMI within 24 hours (+troponin)
- Stroke with clinical sequelae at 30 days

*All the device related MACE events occurred in the Acculink group

All Cause MACE*

Interim Results for the first 50 patients

- Periprocedural minor ischemic stroke
- NSTEMI AMI at 24 hours (+troponin)
- Stroke with clinical sequelae at 30 days

- Death at 6 months post acute occlusion of the superior mesenteric artery
- Death at 7 month due to myocardila infarction
- Death at 7 month dues to congestive heart failure

*All MACE events occurred in the Acculink group

Conclusions

Interim analysis of the first 50 patients

- CGuard EPS trended to lower DW-MRI lesions overall and showed significantly lower incidence of multiple lesions at 24-48h when compared to the Acculink group
- CGuard EPS did not have any MACCE events compared with the Acculink group that had three device related MACE events
- Enrollment in the SIBERIA trial goes on