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Randomized controlled trial of conventional versus MicroNet-covered stent use in percutaneous neuroprotected carotid artery revascularization:

Peri-procedural and 30-day diffusion-weighted magnetic resonance imaging and clinical outcomes

The SIBERIA trial

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Potential conflicts of interest

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☑ I do not have any potential conflict of interest to declare

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Why this study?

- In relation to surgery, carotid artery stenting (CAS) using conventional stents is associated with an excess of strokes that are mostly minor; embolism through plaque/thrombus prolapse via the stent struts is an important contributor.
- A new-generation, MicroNet-covered, carotid stent designed to prevent plaque prolapse (**CGuard**) was introduced in 2014 (CE Mark) and has become available for routine use.
- Several single-arm studies have indicated that the MicroNet-covered stent use may (i) reduce peri-procedural, and (ii) eliminate post-procedural plaque-prolapse related cerebral embolism.
- Level 1 evidence has been lacking.

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What did we study?

- We evaluated peri-procedural and 30-day **silent brain infarcts** associated with the use of the MicroNet-covered (open-cell nitinol frame) stent (**CGuard**) versus a conventional (workhorse) open-cell nitinol stent (**Acculink**)
- A head-to-head randomized controlled clinical trial was designed and executed to obtain level 1 data.
- Peri-procedural and post-procedural cerebral embolism resulting in silent brain infarcts (an important measure of the procedure-related clinical stroke risk; *Eur Stroke J* 2019;4:127-143) was determined using diffusion-weighted cerebral MRI (DW-MRI endpoints of ipsilateral ischemic lesion incidence, lesion mean volume, and the total volume).

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How was the study executed?

SIBERIA trial

Carotid revascularization referrals (n= 614)

Enrollment period 21 months

Indication confirmed (n= 522)

CEA increased risk criteria* ***present***

absent → CEA (n=363)

n= 46 not meeting inclusion criteria:
- atrial fibrillation (n=14)
- severe renal failure (n=12)
- restenotic lesion (n=9)
- MRI contraindication (n=11)

Considered for SIBERIA (n=159)

n= 13 declined randomized treatment allocation

Randomized (n= 100)

allocation

allocated to **Acculink** (n= 50)
baseline MRI performed (n=50)
received allocated intervention** (n= 50)

allocated to **CGuard** (n= 50)
baseline MRI performed (n=50)
received allocated intervention** (n= 50)

procedure

Post-procedural MRI performed n=50

Post-procedural MRI performed n=50

monitorized acute and 30d clinical outcomes

Analyzed for primary endpoint (n=50)

Analyzed for primary endpoint (n=50)

30d follow-up

Vital status (n=50)
Full clinical FU (n= 47)
MRI FU (n= 47)
[2 patients declined full clinical follow-up due to travel distance, MRI scanner not functional in 1 – the patient decined to visit]

Vital status (n=50)
Full clinical FU (n= 50)
MRI FU (n= 50)

External Corelab blinded analysis of DW-MRI scans

** All CAS with EmboShield NAV6 as per the Centre routine

* age ≥75y, clinical congestive heart failure, LVEF =< 35%, severe chronic lung disease, CAD requiring revascularization, uncontrolled diabetes, contralateral carotid artery occlusion, prior head/neck surgery or irradiation

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What are the essential study population and index lesion data?

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	variable	Acculink (n=50)	CGuard (n=50)	p
	age	67 [62;72]	65 [61;69]	0.27
	gender (male)	35 (70 %)	38 (76 %)	0.65
risk factors and comorbidities	coronary heart disease	42 (88 %)	39 (78 %)	0.61
	previous PCI	19 (38 %)	16 (32 %)	0.67
	previous CABG	6 (12 %)	6 (12 %)	1
	congestive heart failure	42 (84 %)	44 (88 %)	1
	diabetes mellitus	8 (16 %)	10 (20 %)	0.79
	arterial hypertension	49 (98 %)	48 (96 %)	1
	current smoking	20 (40 %)	17 (34 %)	0.67
	peripheral artery disease			
	ipsilateral stroke stroke ≤ 6m	6 (12%)	11 (22%)	0.18
	ipsilateral TIA ≤ 6m	3 (6 %)	5 (10 %)	0.46
	contralateral carotid artery stenosis	9 (18%)	18 (36%)	0.75
	contralateral carotid artery occlusion	3 (6%)	8 (16%)	0.11
index lesion characteristics	degree of stenosis (QCA, %)	76 [70;80]	75 [72;79]	0.72
	affected side right	27 (54 %)	30 (60%)	0.77

Data in [ ] are Q1;Q3

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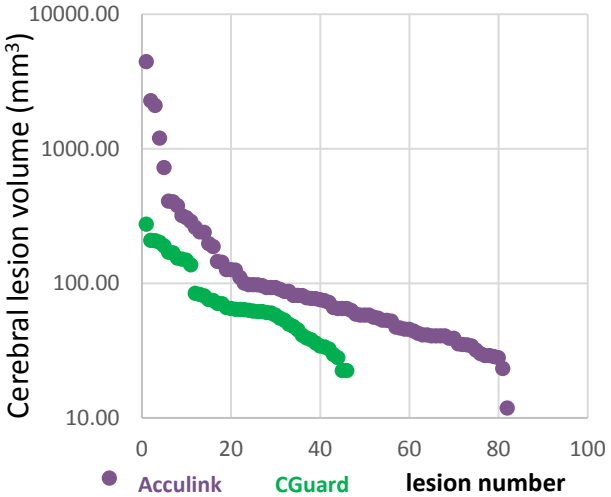
What are the essential results?

1 **CGuard** arm:
Fewer lesions, **smaller** lesions



2 **CGuard** arm: **Smaller** average lesion volume per patient (pp) p=0.007

	Acculink	CGuard
Mean (mm3)	**700**	**157**
95% CI	(79; 1321)	(84; 229)
Median	**138**	**82**
[Q1;Q3]	[97; 574]	[60; 212]

and **smaller** total lesion volume pp p=0.038

	Acculink	CGuard
Mean (mm3)	**222**	**84**
95% CI	(92; 352)	(66; 101)
Median	**73**	**63**
[Q1;Q3]	[42; 125]	[41; 84]

3 **CGuard** arm:
No MACCNE at 30 days

	Acculink	CGuard
Stroke	**2**	**0**
Myocardial Infarction	1	**0**

4 **CGuard** arm:
No new DWI lesions on 30-day scan

	Acculink	CGuard
Number	**6**	**0**

p = 0.030

NB. data are for ipsilateral lesions as per the study protocol main endpoint

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Why is this important?

- CAS safety is critical for a **further growth** of the endovascular route of carotid revascularization – on top of optimized medical therapy – in primary and secondary stroke prevention.
- Our study data provide, for the first time, **Level-1** evidence for a novel role of the MicroNet-covered carotid stent (**stent** as a peri- and post-procedural **cerebral protector**).
- New insights into the **procedure-related vs. device(s)-related** cerebral embolism with CAS with clinically-relevant, practical implications for further procedural improvement considerations and pathways.
- Evidence for a wide adoption of the **new quality in CAS**.

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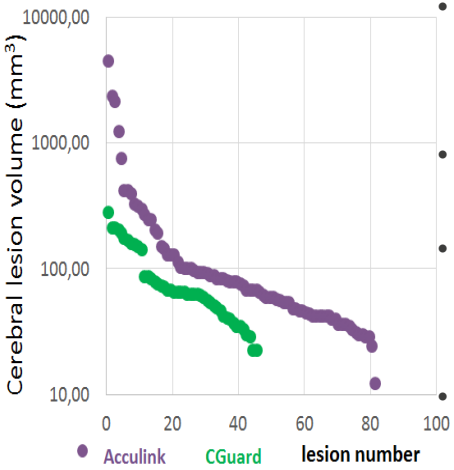
The essentials to remember

The trial raw data: MicroNet-covered stent reduction in silent brain infarcts



- **Why?**
  Level 1 evidence for the MicroNet covered stent efficacy in reduction of peripricedural cerebral embolism and prevention of postprocedural cerebral embolism has not been available.
- **What?**
  We studied the incidence and magnitude of silent brain infarcts occurring peri-procedurally and by 30 days, using a novel (MicroNet-covered) open-cell frame carotid stent system versus a conventional (workhorse) open-cell carotid stent.
- **How?**
  Randomized controlled head2head comparison trial, with external monitoring of the data and external DW-MRI cerebral scan analysis.
- **What are the results?**
  The CGuard MicroNet stent use in consecutive unselected patients subjected to neuroprotected CAS was associated with an over 3-fold reduction in the procedure-generated cerebral lesion mean volume and with a totally abolished post-procedural cerebral embolism.
- **Why is this important?**
  These data will affect clinical practice by providing, for the first time, level 1 evidence for the benefit of a MicroNet-covered stent in reducing cerebral silent infarcts in neuroprotected CAS.

What is the core point for the audience to remember?

In a randomized clinical trial of neuroprotected CAS in asymptomatic and symptomatic patients, the MicroNet-covered carotid stent use was associated with a 3-fold reduction in the magnitude of peri-procedural silent brain infarcts and it abolished post-procedural infarcts – in relation to the workhorse (classic) carotid stent use.

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