The safety and effectiveness of carotid revascularization with the Acculink stent and the CGuard stent. Independent randomized study

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Disclosure

Speaker name:

Bugurov Savr

I have the following potential conflicts of interest to report:

☐ Consulting

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☒ I do not have any potential conflict of interest

Objectives

The main objective of this randomized study was to compare the clinical outcomes and neuroprotection of conventional carotid stent versus the new MicroNet stent CGuard™

Hypothesis

The study hypothesis was a significant reduction of the number of procedural and postprocedural new DW-MRI lesions after CAS with the novel CGuard™ mesh covered stent compared with the Acculink™ reference stent.

Study design

- The SIBERIA trial was an Independent Investigator Initiated Study.
- It was a single center, open label, randomized comparison of two interventional arms.
- The study was externally monitored and imaging data were evaluated by independent core laboratory
- 100 consecutive patients were enrolled with 1y clinical FU
- DW-MRI scan at baseline, at 24-48 hour after the procedure, and at the 30-days follow-up.
- *The study used the anti-embolic device **Emboshield NAV**, the pore diameter of the device is equal to the diameter of the cells of the Cguard stent (pore size 165 µm)

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ENDPOINTS

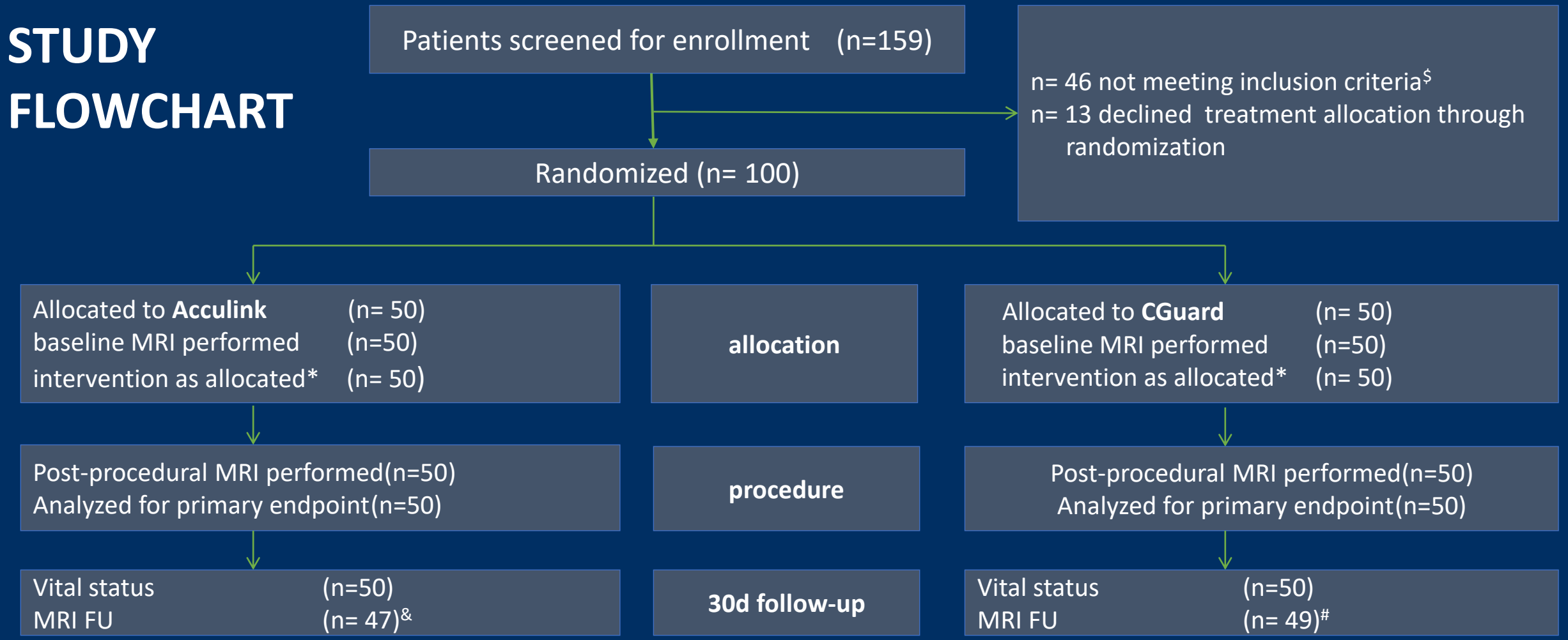
Primary endpoint:

New ischemic brain lesions after the procedure of carotid stenting identified by MRI within 24-48 hours and 30 days.

Secondary endpoints:

Technical success, major neurovascular adverse events (death, stroke, myocardial infarction) developed during the procedure and within 30 days.

STUDY FLOWCHART



* - all CAS with EmboShield NAV6 as per the Centre routine

$ - atrial fibrillation (n=14)
- severe renal failure (n=12)
- restenotic lesion (n=9)
- MRI contraindication (n=11)

& 2 patients declined full clinical follow-up due to travel distance, MRI scanner not functional in 1 – the patient declined to visit

\# 1 MRI scan Corelab-defined inevaluable due multiple artifacts

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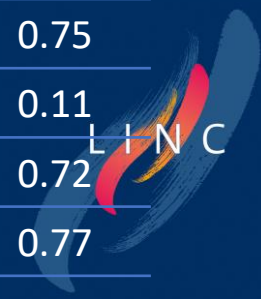
CLINICAL AND LESION CHARACTERISTICS

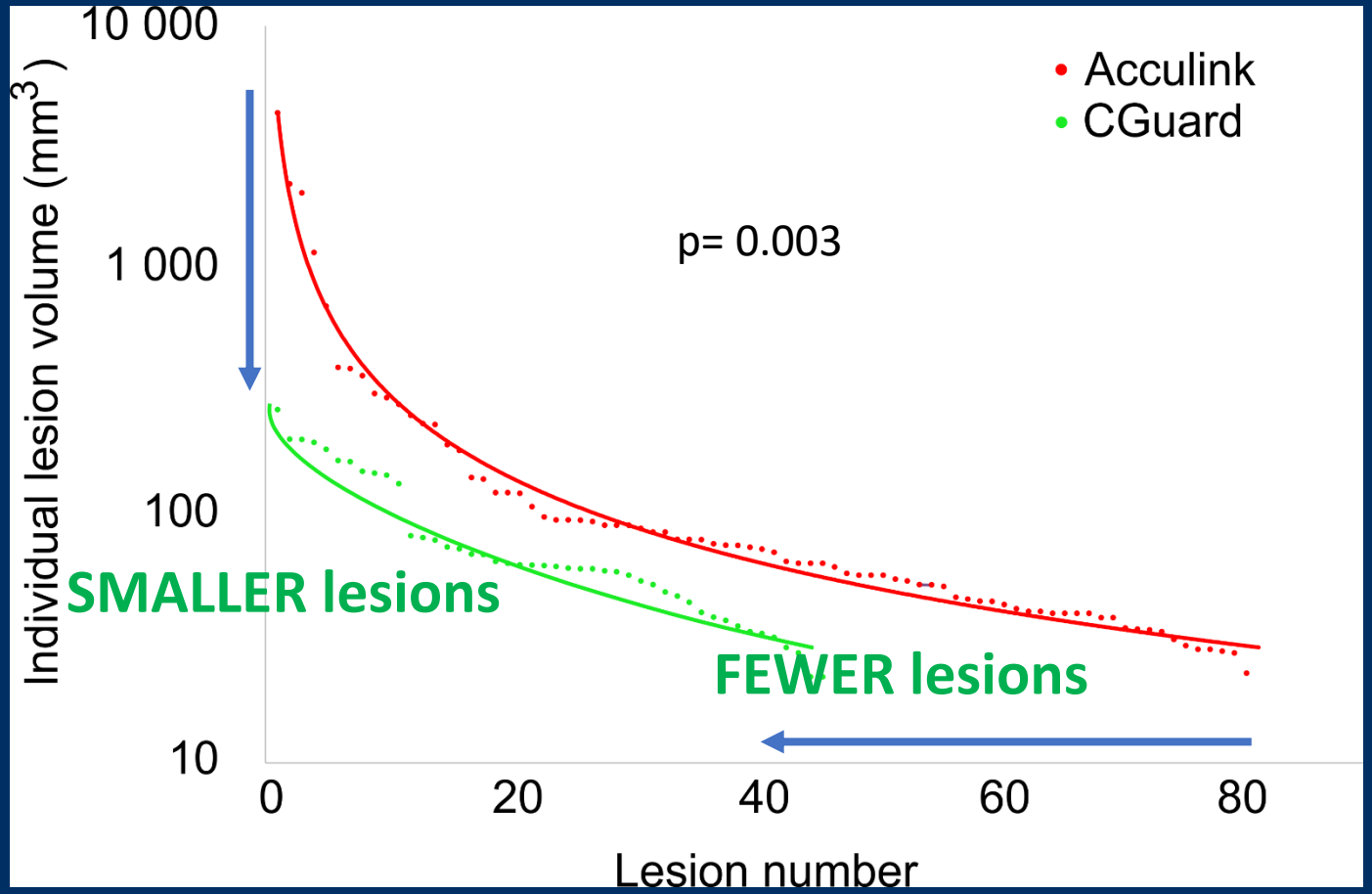
	ACCULINK n=50	CGUARD n=50	P
Age, years [range]	67 [62;72]	65 [61;69]	0.27
Gender, (male) n (%)	35 (70 %)	38 (76%)	0.65
Coronary heart disease, n (%)	42 (88 %)	39 (78 %)	0.61
Previous coronary revascularization (CABG or PCI), n (%)	25 (50 %)	22 (32 %)	0.69
Chronic heart failure, n (%)	44 (88 %)	45 (90 %)	1
Diabetes mellitus treatment, n (%)	8 (16 %)	10 (20 %)	0.79
Arterial hypertension, n (%)	49 (98 %)	48 (96 %)	1
Current smoking, n (%)	20 (40 %)	17 (34%)	0.67
Peripheral arterial disease, n (%)	17 (34%)	15 (30%)	0.83
Ipsilateral stroke ≤ 6m, n (%)	6 (12%)	11 (22%)	0.18
Ipsilateral TIA ≤ 6m, n (%)	3 (6.0 %)	5 (10 %)	0.46
Contralateral carotid artery stenosis ≥50%; n (%)	9 (18%)	18 (36%)	0.75
Contralateral carotid artery occlusion; n (%)	3 (6.0%)	8 (16%)	0.11
Degree of stenosis (QCA, % [range])	76 [67;88]	75 [72;89]	0.72
Affected side right, n (%)	27 (54 %)	30 (60%)	0.77



RESULTS

DW-MRI embolism at 48h

(raw data, external CoreLab, blinded analysis)



RESULTS

DW-MRI embolism at 48h

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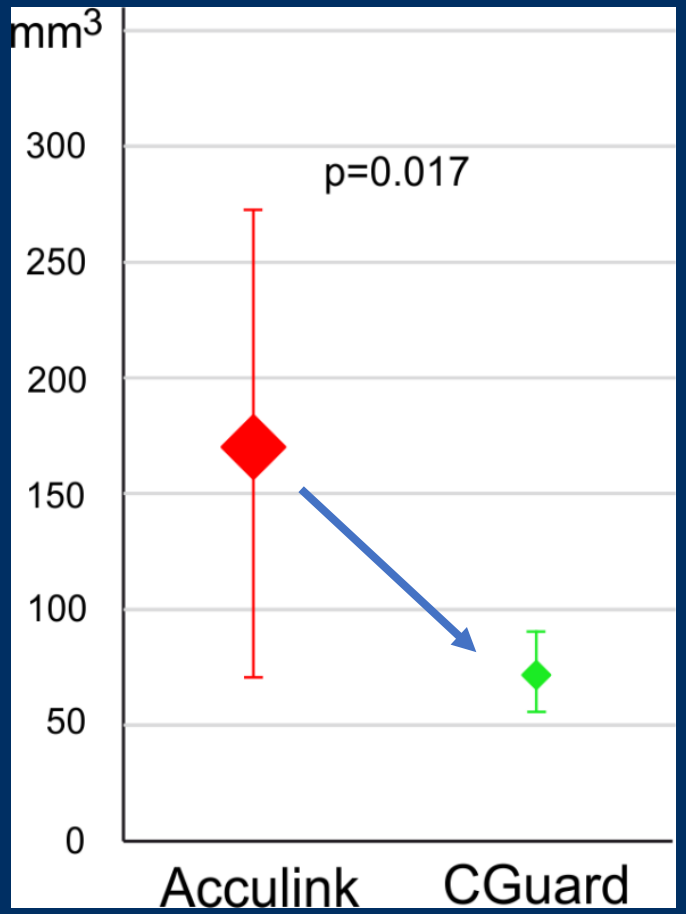
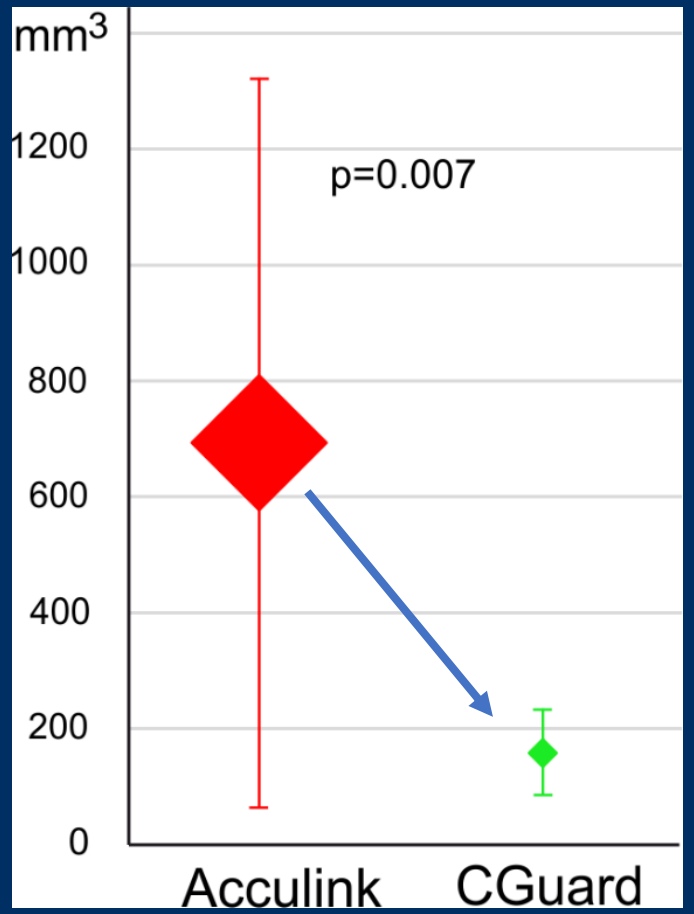
PRIMARY ENDPOINT



57% reduction in lesion (per-patient) **average volume**

TOTAL LESION VOLUME

per-patient



4.5-fold reduction in **total volume** of peri-procedural lesions (per-patient)

(bars are 95%CI)

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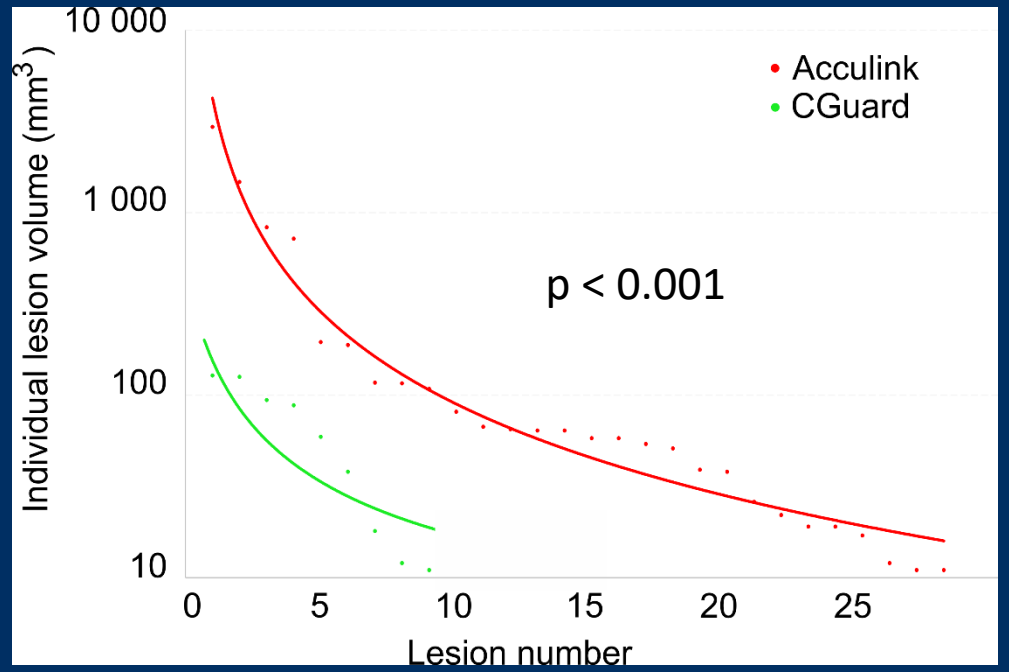
RESULTS
MRI and Clinical outcomes at 30 days

PERSISTENT Cerebral Lesions (FLAIR)



CGuard arm: **No new DW-MRI lesions** at 30 days

	Acculink	CGuard
Number	6	0

p = 0.030

CGuard arm: **No MACNE** at 30 days

	Acculink	CGuard
Stroke	2	0
Myocardial Infarction	1	0

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

CLINICAL OUTCOMES after 1 year

	ACCULINK n=50	CGUARD n=50	P
Restenosis	2 (4%)	0 (0%)	0.49
Vessel occlusion	1 (2%)	0 (0%)	1
Deaths	2 (4%)	1 (2%)	1
TOTAL MACE	10 (20%)	1 (2%)	0.2

CONCLUSION

In a randomized, controlled, externally monitored clinical trial with independent data analysis,

MicroNET-covered carotid stent – in relation to a classic (single-layer) carotid stent:

- **reduced 4.5-fold the magnitude of peri-procedural** silent brain infarcts volume
- **abolished post-procedural silent infarcts** that, in contrast, were on-going with the classic stent

These findings may impact decision-making in carotid revascularization for primary and secondary stroke prevention, including stent type selection