Multi-Center Study of the MicroNET-Covered Stent in Consecutive Patients with Acute Carotid-Related Stroke:

SAFEGUARD-STROKE

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Disclosure of Relevant Financial Relationships

Investigator-Initiated Study

Supported by Jagiellonian University Medical College
(Grant K/ZDS/007819)
NOT Funded by Industry

Faculty disclosure information can be found on the app

20-30% ischemic strokes

are associated with atherosclerotic carotid stenosis

Musialek P, Bonati LH, Bulbulia R, Halliday A, Bock B, Capoccia L, Eckstein HH, Grunwald IQ, Lip PL, Monteiro A, Paraskevas KI, Podlasek A, Rantner B, Rosenfield K, Siddiqui AH, Sillesen H, Van Herzeele I, Guzik TJ, Mazzolai L, Aboyans V, Lip GYH. **Stroke risk management in carotid atherosclerotic disease: A Clinical Consensus Statement**. *Cardiovasc Res.* 2023

Dzierwa K, Capoccia L, Knapik M, et al. **Saving the brain in carotid-related stroke: patient pathways, treatment strategies**. *J Cardiovasc Surg* 2024

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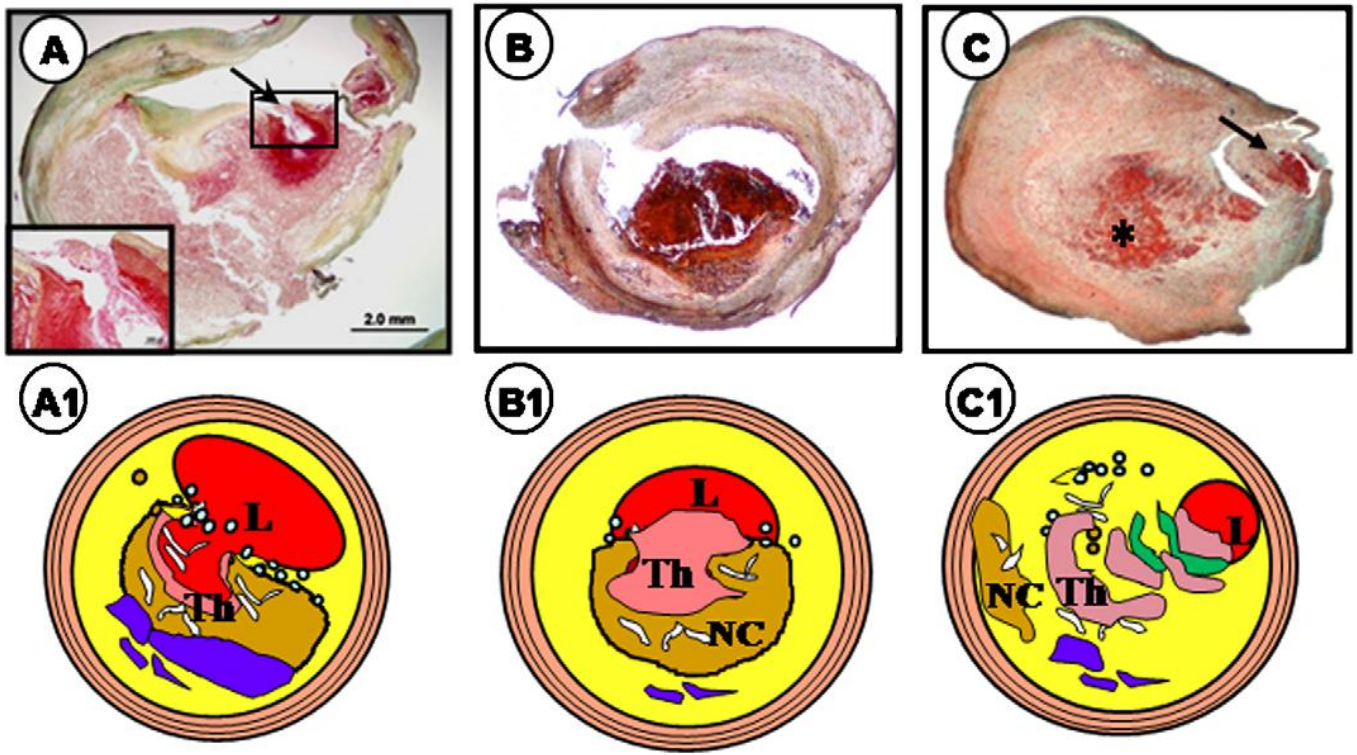

A. Mauriello et al. / Atherosclerosis 2010; 208: 572–580

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Challenges of Acute Carotid-Related Stroke Intervention using Conventional Techniques & Devices

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Challenges of Acute Carotid-Related Stroke Intervention using Conventional Techniques & Devices

- Distal **embolism**
- Stent **thrombosis**

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Challenges of Acute Carotid-Related Stroke Intervention using Conventional Techniques & Devices

- **Distal embolism** up to **20-30%** cases
- **Stent thrombosis** up to **30%** cases

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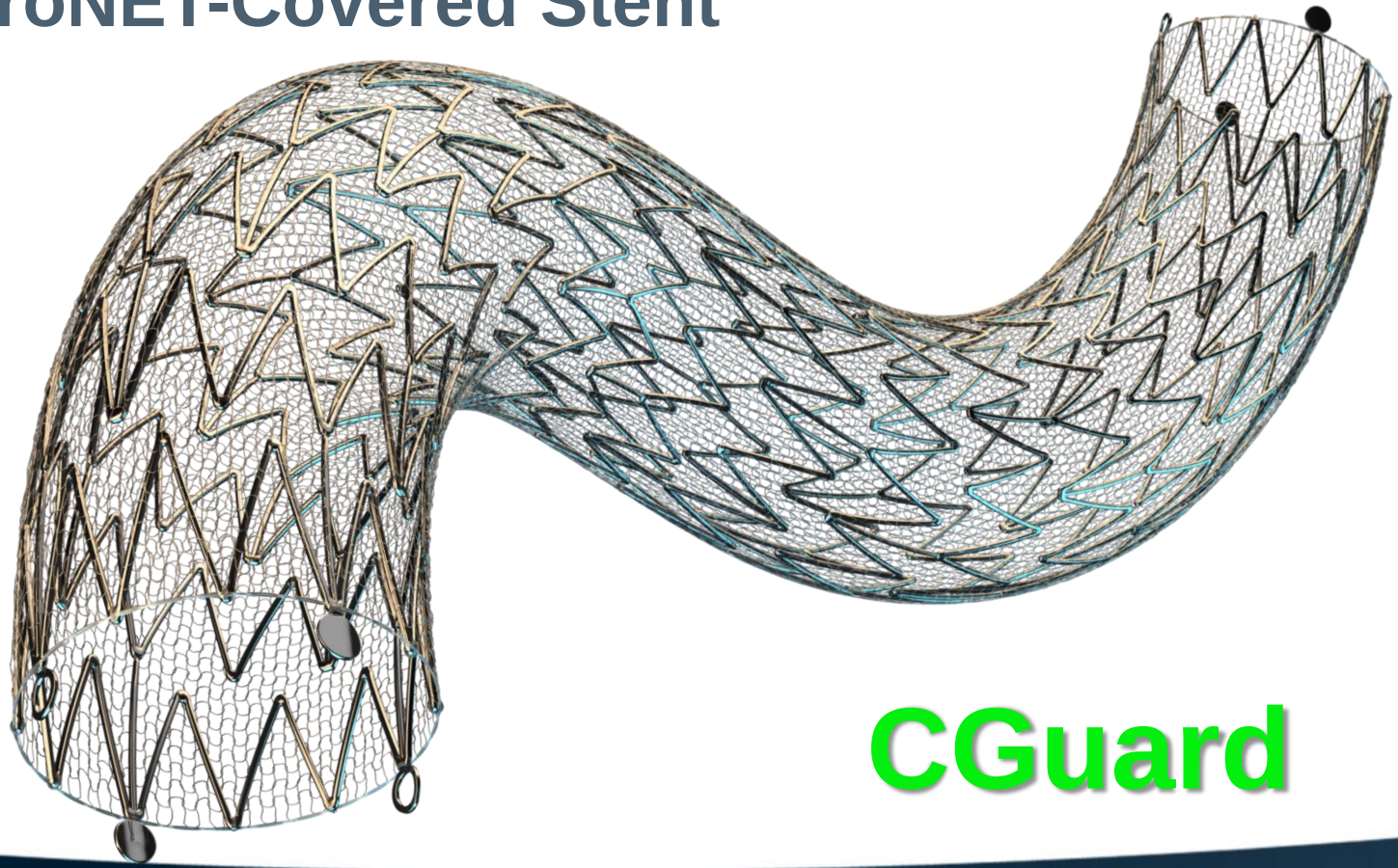
The MicroNET-Covered Stent



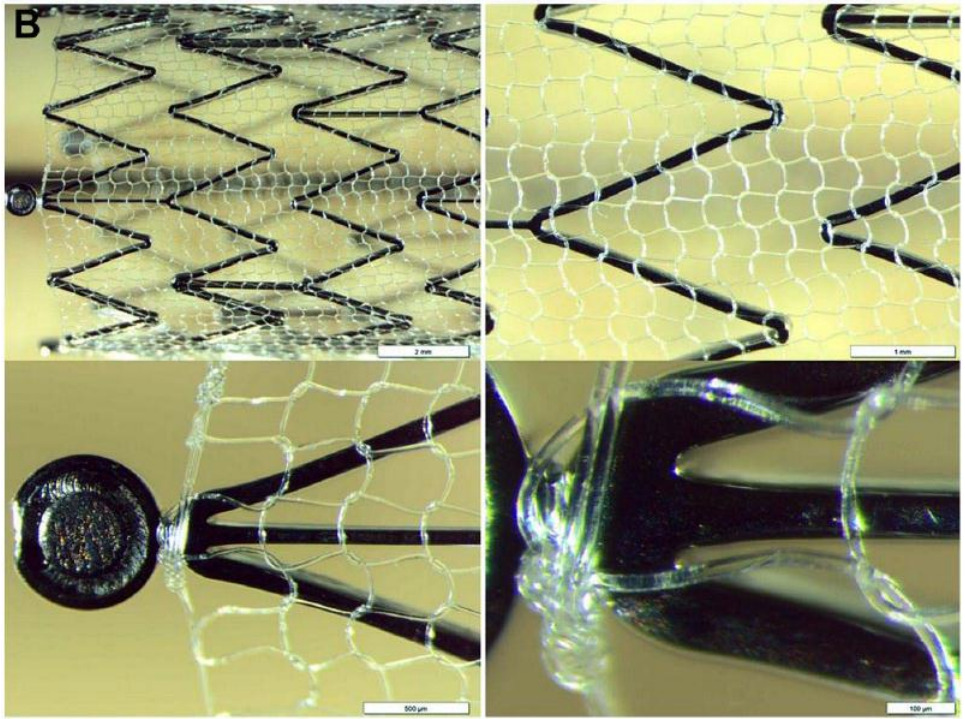
CGuard

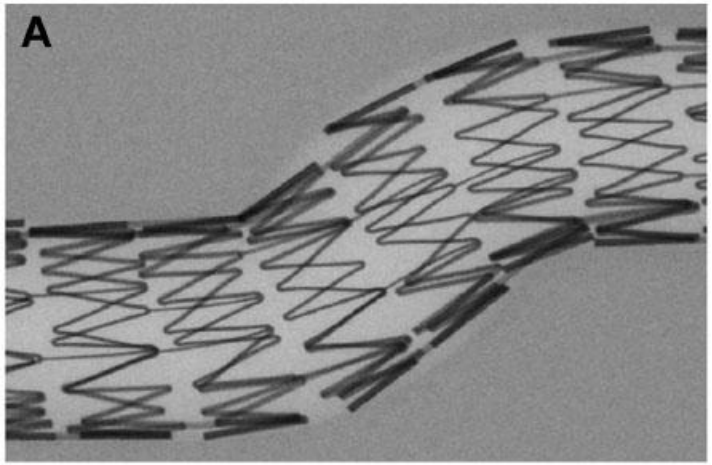
The MicroNET-Covered Stent

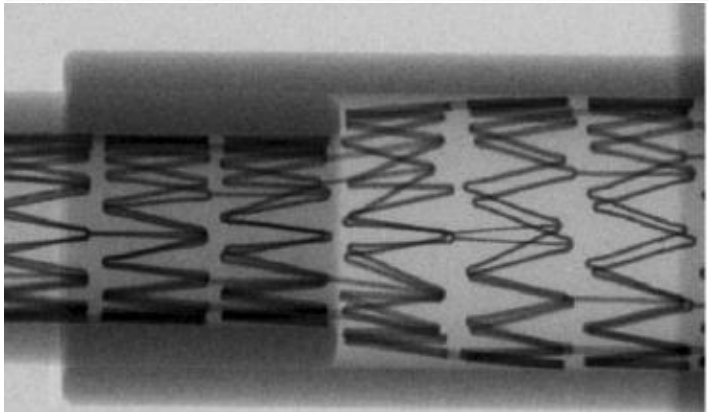
Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent

Journal of Endovascular Therapy
1–8

DOI: 10.1177/1526602816671134
www.jevt.org
SAGE







The CGuard MicroNET-Covered Stent is **not yet available commercially** in the USA.
FDA-IDE Trial (CGUARDIANS NCT04900844): recently COMPLETED for its Primary Endpoint.

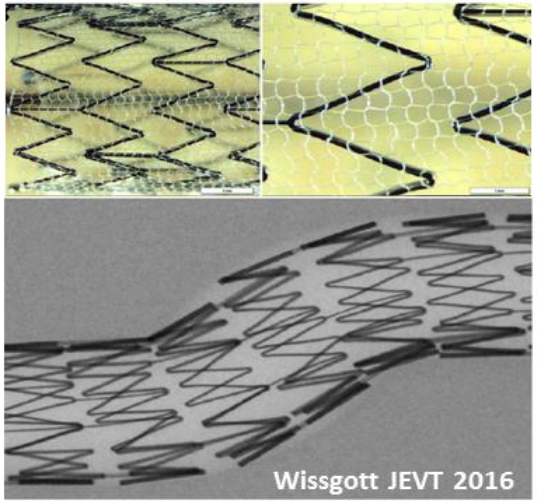
The MOST 'open' amongst open-cell stents (metallic FRAME) & the MOST 'close' amongst close-cell stents (MicroNet mesh)

CGuard MicroNET – covered 2nd generation carotid stent

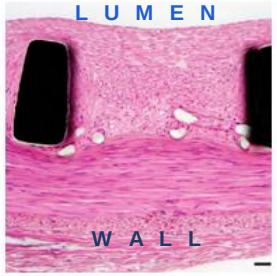
UNIQUE mechanical properties

RESPECT of anatomy

FULL apposition



NORMAL healing

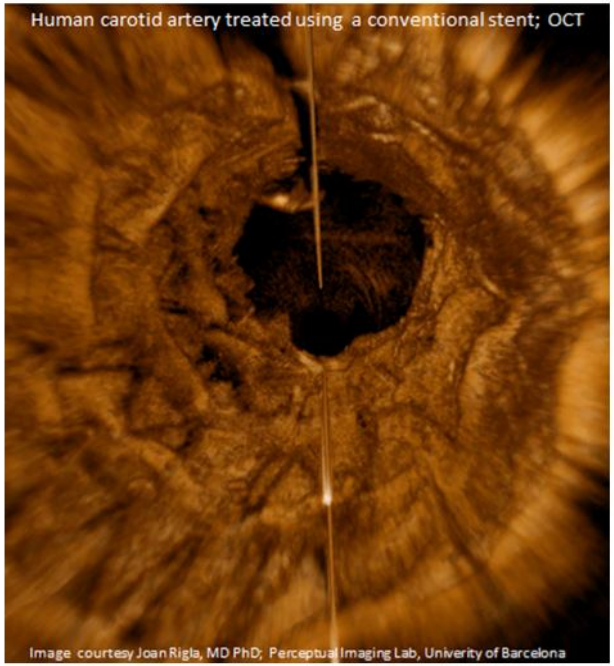


CGuard

Randomized Controlled Trial

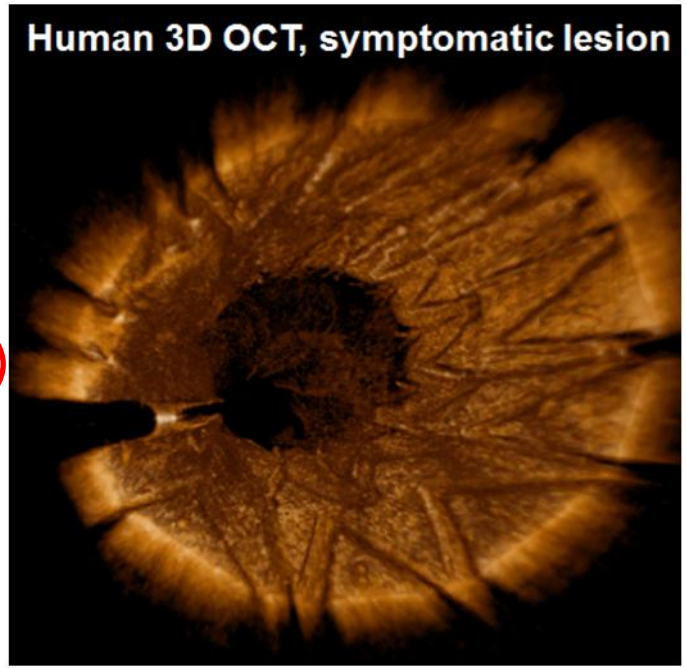
Randomized Controlled Trial

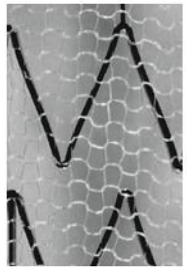
The CREST Study stent



VS.

MicroNet-Covered Stent



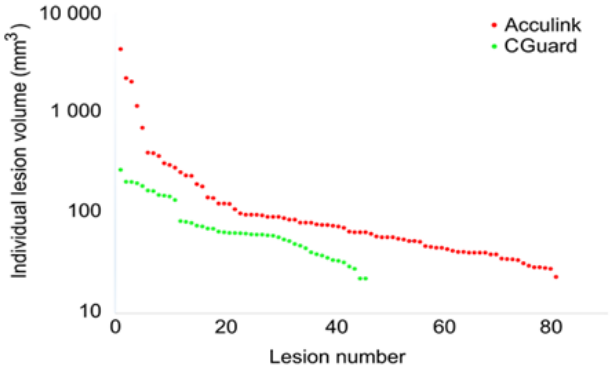


OCT Images: P Musialek, G deDonato. Carotid Artery Revascularization Using the Endovascular Route. In: Carotid Interventions - Practical Guide Minerva Medica 2022

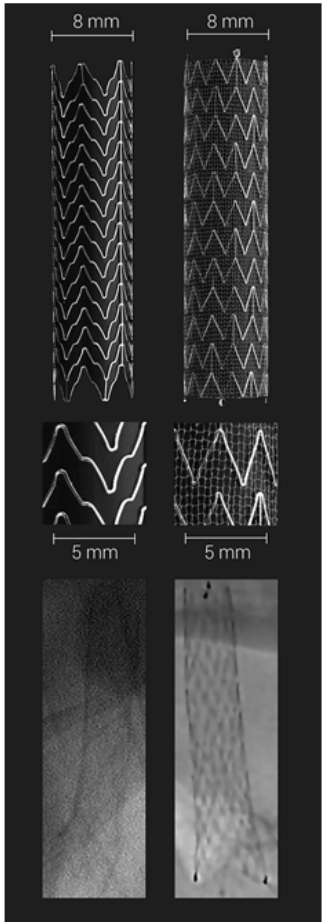
Neuro-Protective
Carotid Stent System

Randomized Controlled Trial

DW-MRI Embolism
raw data



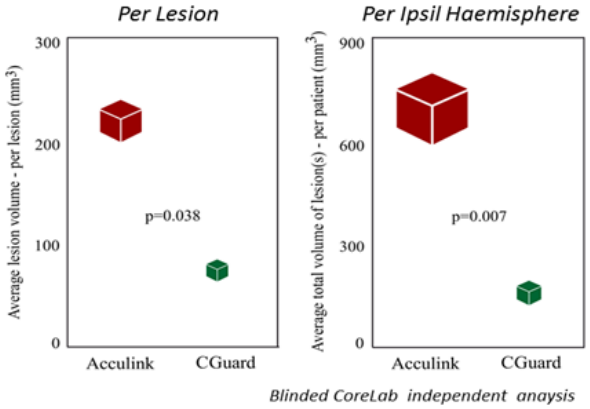
JACC: CARDIOVASCULAR INTERVENTIONS VOL. 14, NO. 21, 2021
NOVEMBER 8, 2021:2377–2387



Level 1 Evidence

Embolic Load to the Brain
PROFOUND REDUCTION
Acculink (CREST study device)

MicroNet-Covered Stent - CGuard



Blinded CoreLab independent anaysis

CGuard
MicroNET-Covered Stent

Systematic Review

Clinical Outcomes of Second- versus First-Generation Carotid Stents: A Systematic Review and Meta-Analysis

Adam Mazurek [1,*], Krzysztof Malinowski [2], Kenneth Rosenfield [3], Laura Capoccia [4], Francesco Speziale [4], Gianmarco de Donato [5], Carlo Setacci [5], Christian Wissgott [6], Pasqualino Sirignano [4], Lukasz Tekieli [7], Andrey Karpenko [8], Waclaw Kuczmik [9], Eugenio Stabile [10], David Christopher Metzger [11], Max Amor [12], Adnan H. Siddiqui [13], Antonio Micari [14], Piotr Pieniążek [1,7], Alberto Cremonesi [15], Joachim Schofer [16], Andrej Schmidt [17] and Piotr Musialek [1,*,†] on behalf of CARMEN (CArotid Revascularization Systematic Reviews and MEta-aNalyses) Investigators

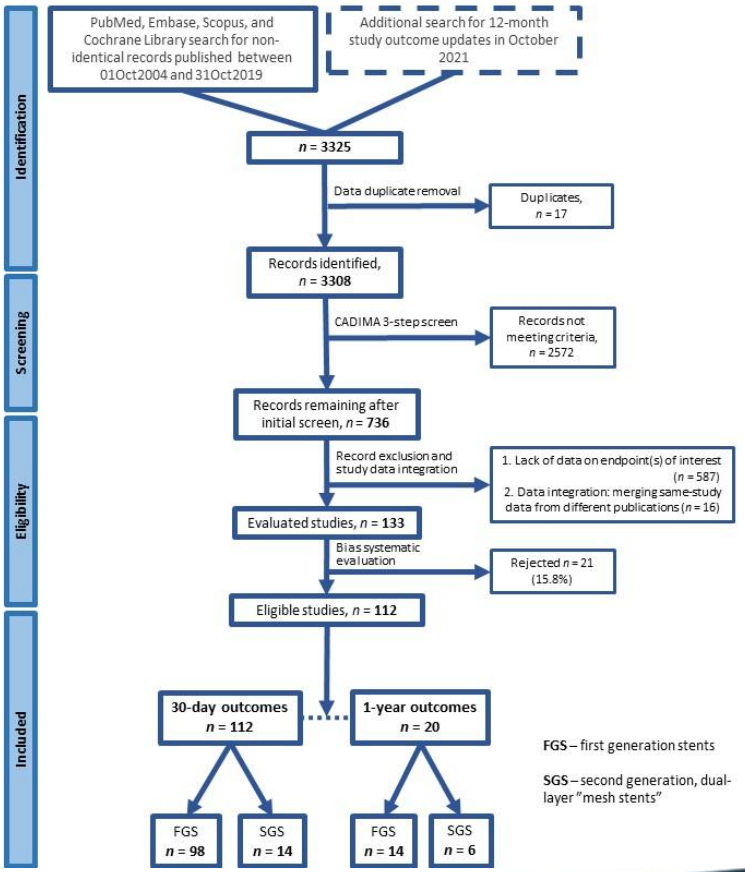
68,422 patients

from 112 eligible studies

44.9% symptomatic

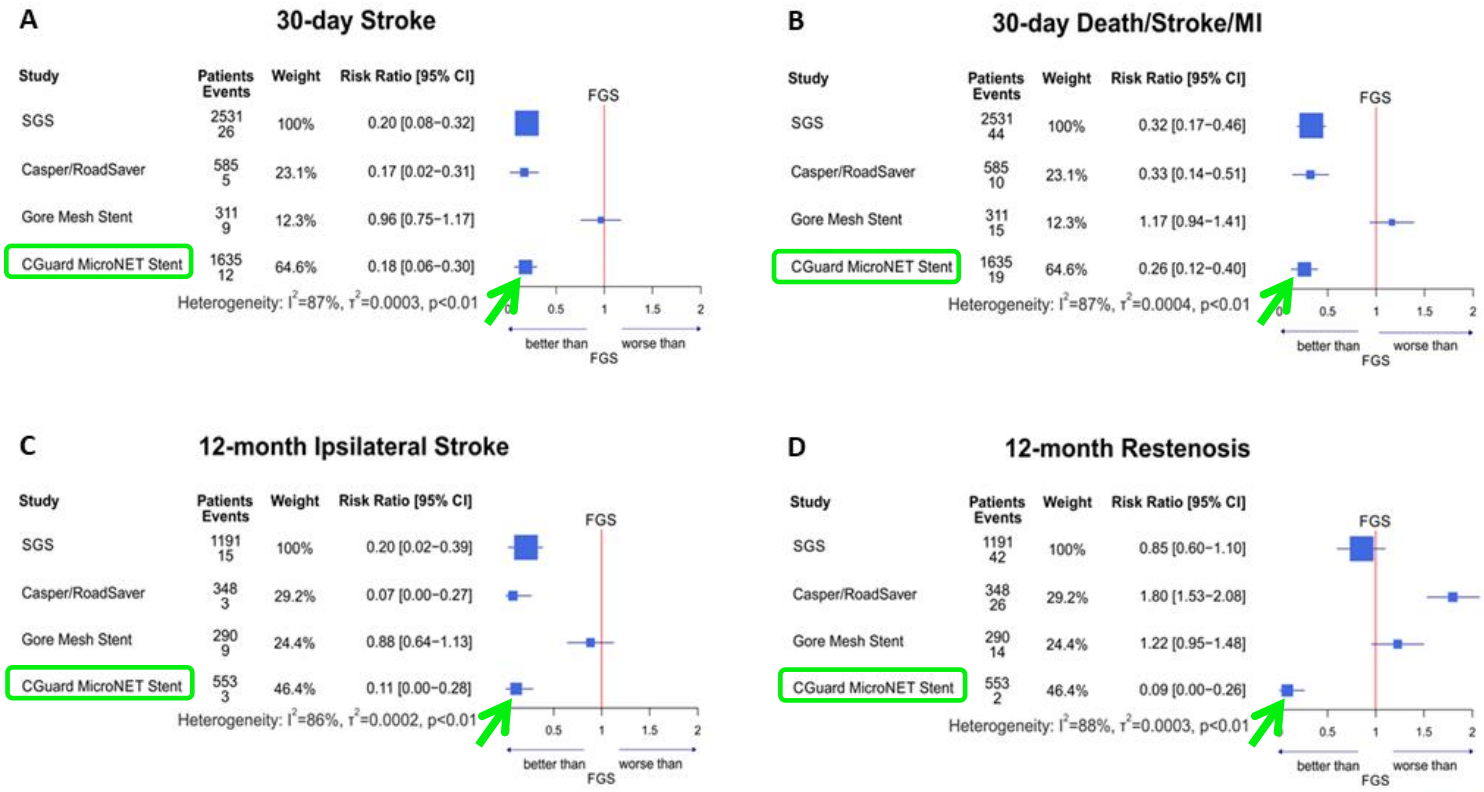
CARMEN
Collaborators

CARMEN Systematic review and meta-analysis flowchart (PRISMA)



J. Clin. Med. **2022**, *11*, 4819. https://doi.org/10.3390/jcm11164819

’DLS’ vs FGS Meta-Analysis: Main Findings



CARMEN
Collaborators

CRF TCT

ABSENCE of any ’DLS Class’ EFFECT

2024

SAFEGUARD-STROKE:

Aim

To evaluate, in a multi-center multi-specialty investigator-initiated study, outcomes of MicroNET-covered (cell area ≈0.02-0.03mm^2)

Anti-Embolic Carotid Stent (CGuard, InspireMD)

in consecutive carotid-related stroke (CRS) patients

eligible for emergency recanalization.

Methods

- Multi-center, Multi-specialty investigator-initiated study (IIS)
- **7 interventional stroke centers in 6 countries**
- Consecutive, ”all-comer” CRS patients eligible for emergency recanalization
- MicroNET-covered carotid stent (CGuard, InspireMD) in all stented CRS
- **Treatment other than study device use according to center/operator routine**

Clinical characteristics

Age, years	67 (61-74)
range	40 - 89
Female gender	21 (28.0)
ASPECTS on admission	9 (8-10)
range	6 - 10
NIHSS on admission	14 (12-19)
range	6-27
mRS prior to index stroke onset	0 (0-1)
range	0-3
Time from symptom onset to presentation, h	5 (3-11)
range	1-38
IVT	29 (38.7)
Hypertension	67 (89.3)
Coronary artery disease	26 (34.4)
Atrial fibrillation	10 (13.3)
TIA preceding index stroke	14 (18.7)
Stroke in history	7 (9.3)
Symptomatic PAD	8 (10.7)

Diabetes	
Type 1	1 (1.3)
Type 2	19 (25.3)
Smoker	41 (54.7)
Hypercholesterolemia or hypolipidemic therapy prior to stroke	62 (82.7)
History of neck/chest radiotherapy	3 (4.0)
Type of stroke (clinical)	
Hyperacute	65 (86.7)
Stroke-in-evolution or crescendo TIA	6 (8.0)
Stuttering/aggravating	4 (5.3)
Stroke side, left	39 (52.0)
Lesion/occlusion level(s)	
Tandem (extra- plus intracranial)	39 (52.0)
Isolated extracranial	36 (48.0)
ICA lesion type	
Atherosclerosis	67 (89.3)
Dissection	5 (6.6)
Thrombo-embolic load from prox circulation*	2 (2.3)
ICA thrombus†	47 (62.7)
ICA higly calcific stenosis‡	11 (14.7)

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Procedural data

Access site	
femoral	67 (89.3)
radial	5 (6.7)
transcarotid±	3 (4.0)
Anaesthesia	
general	41 (54.7)
conscious sedation	34 (45.3)
Cerebral protection device	34 (45.3)
Proximal	29 (38.7)
MoMa system	19 (25.3)
Mono-balloon catheter	8 (10.7)
TCAR	2 (2.7)
Distal (filter)	3 (4.0)
Double (Mono-balloon catheter + filter)	2 (2.7)
No protection device	41 (54.7)
Thrombus extraction*	
In n=47 extracranial thrombotic lesions	45 (95.7)
Aspiration-only	42 (89.4)
Large-bore ST (under aspiration)	3 (6.4)
In n=39 intracranial LVOs	37 (94.9)
Aspiration-only	19 (48.7)
Aspiration followed by ST	15 (38.4)
ST as primary strategy	3 (7.7)

Intracranial MT (n=37)	
ICA	2 (5.4)
ACA	1 (2.7)
M1	21 (56.8)
M2	5 (13.5)
Multisite intracranial	8 (21.6)
Number of passages in intracranial MT	2 (1-4)
	1-9
Primary ('direct') stenting	29 (38.7)
Extracranial lesion predilatation	46 (61.3)
Predilation balloon diameter, mm	3.5 (3.0-3.5)
Range	1.0-5.0
Carotid stent strategy in tandem lesions	
Antegrade	12 (30.8)
Retrograde*	27 (69.2)
Total number of study stents used	78
Non-study stent use	0

SAFEGUARD-STROKE

NCT05195658

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Procedural data, cont'd

Stent size, diameter (mm) x length (mm)	
6 x 40	2 (2.6)
7 x 30	5 (6.4)
7 x 40	5 (6.4)
8 x 30	9 (11.5)
8 x 40	7 (9.0)
9 x 30	12 (15.3)
9 x 40	16 (20.5)
10 x 30	6 (7.7)
10 x 40	10 (12.8)
10 x 60	4 (5.1)
>1 stent implantation, n (% culprit ICA)	3 (4.0)
Second stent reason	
dissection	0
thrombus	0
lesion length[#]	3 (4.0)
Post-dilatation performed	72 (96)
Postdilation balloon peak diameter, mm	5.0 (5.0-5.5)
range	4.0-8.0
Postdilation balloon peak pressure, mmHg	18 (12-20)
range	8-24

New cerebral embolism with stent delivery/implantation[†]	1 (1.3)
Final mTICI, n (%)	
0/1	3 (4.0)
2a	5 (6.7)
2b/c	17 (22.7)
3	50 (66.7)
Procedure duration (min)	70 (45-97)
range	33-170
Intraprocedural heparin use	75 (100)
Intraprocedural heparin regiment	
Catheter(s) flush only	6 (8.0)
Additional dose(s)	69 (92.0)
1500 – 3000 IU	11 (14.7)
3000 – 5000 IU	21 (28.0)
ACT-adjusted dosing with ≥250s target	37 (49.3)

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NCT05195658

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Procedural data, cont'd.

Peri-procedural antiplatelet administered (at least 1)	69 (92.0)
iv ASA	7 (9.3)
oral/naso-gastric tube ASA	59 (78.7)
IIb/IIIa inhibitor	16 (21.3)
ia bolus only	4 (5.3)
ia bolus + iv infusion	12 (16.0)
cangrelor	3 (4.3%)
Post-procedural antiplatelet(s)	75 (100)
one (ASA *or* clopidogrel)	4 (5.3)
two (ASA *plus* clopidogrel)	71 (94.7)
Timing of second antiplatelet administration (n=71)	
≤24h	38 (53.5)
>24h	22 (46.5)
delay, h	28 (26-31)
delay, range	24-48
Recommended DAPT duration, months	3 (3-3)
range	1-12

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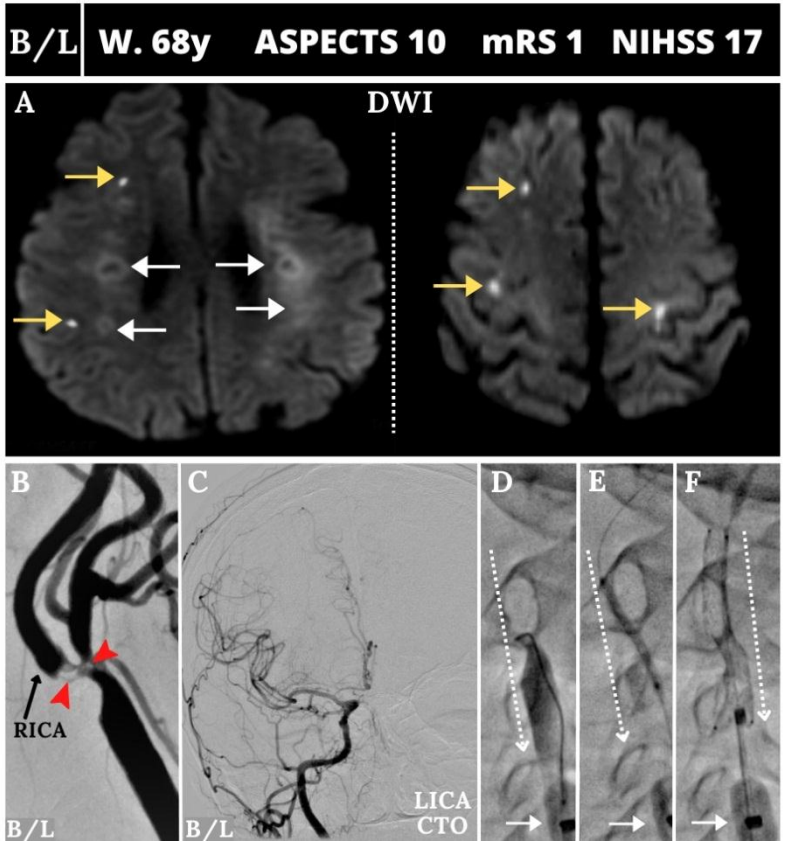
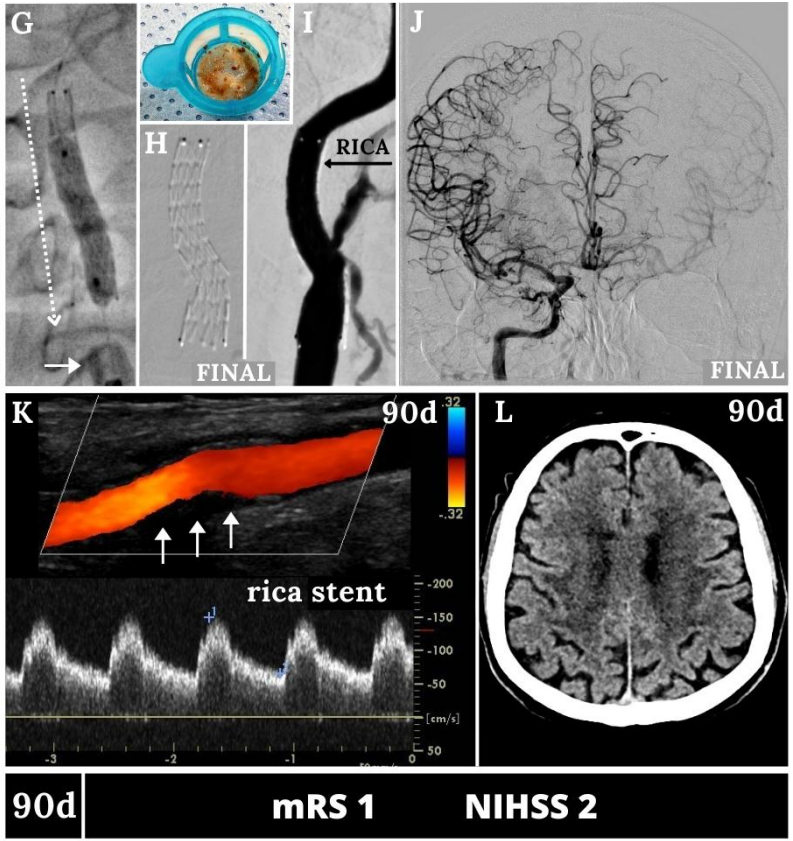
SAFEGUARD-STROKE Case Example 1

- non-tandem
- atherothrombotic





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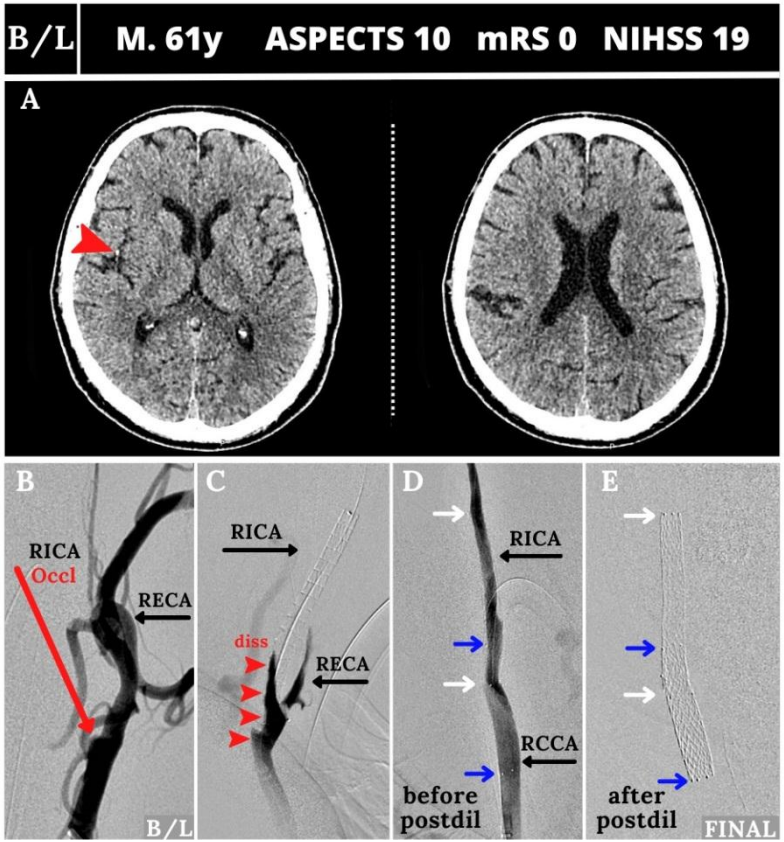
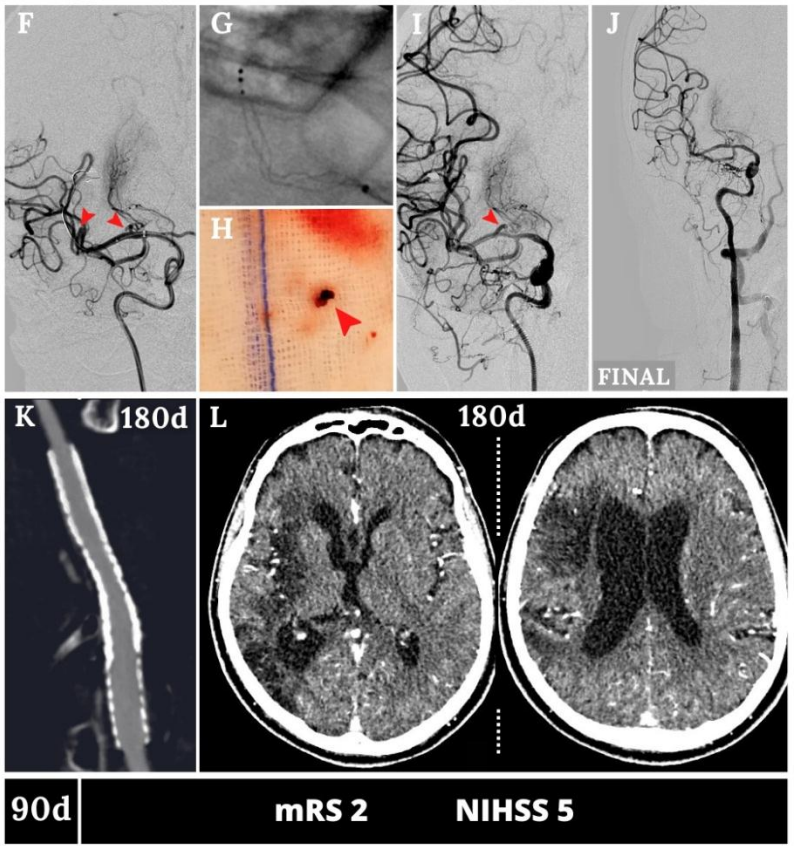


Case Example 2

- thrombotic dissection
- tandem



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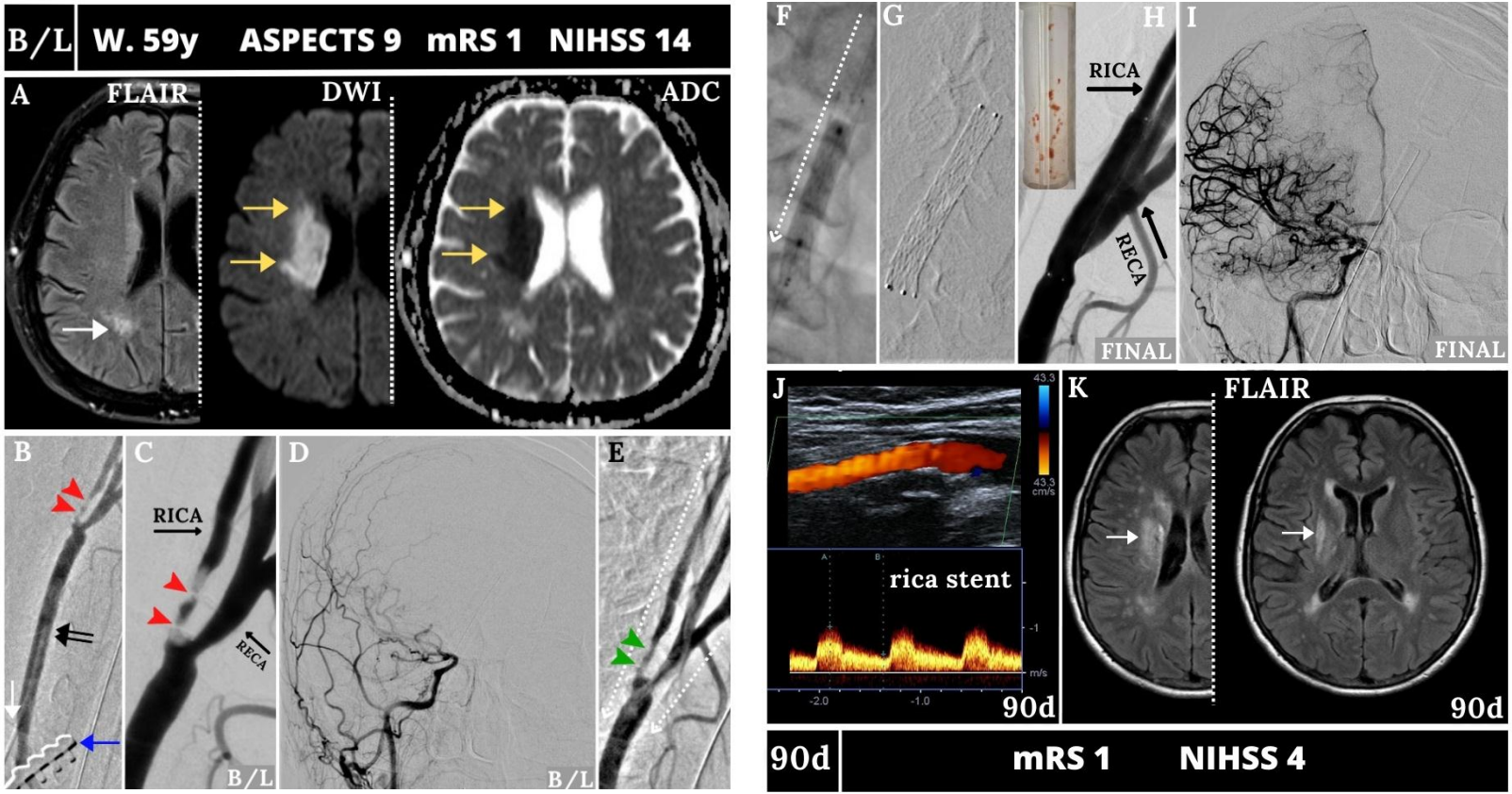
SAFEGUARD-STROKE Case Example 3

- atherothrombotic
- TCAR



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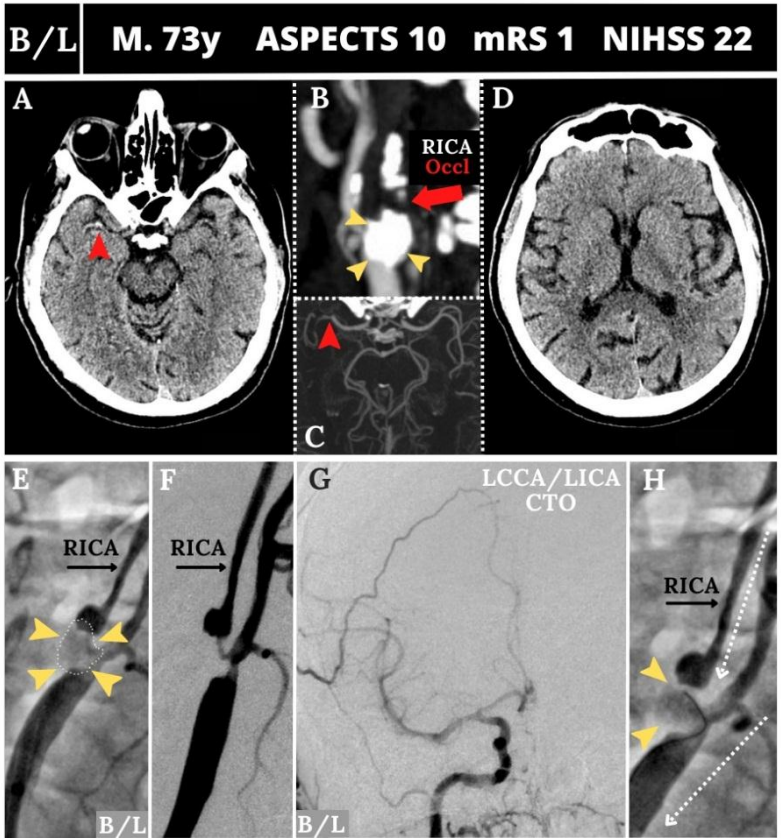
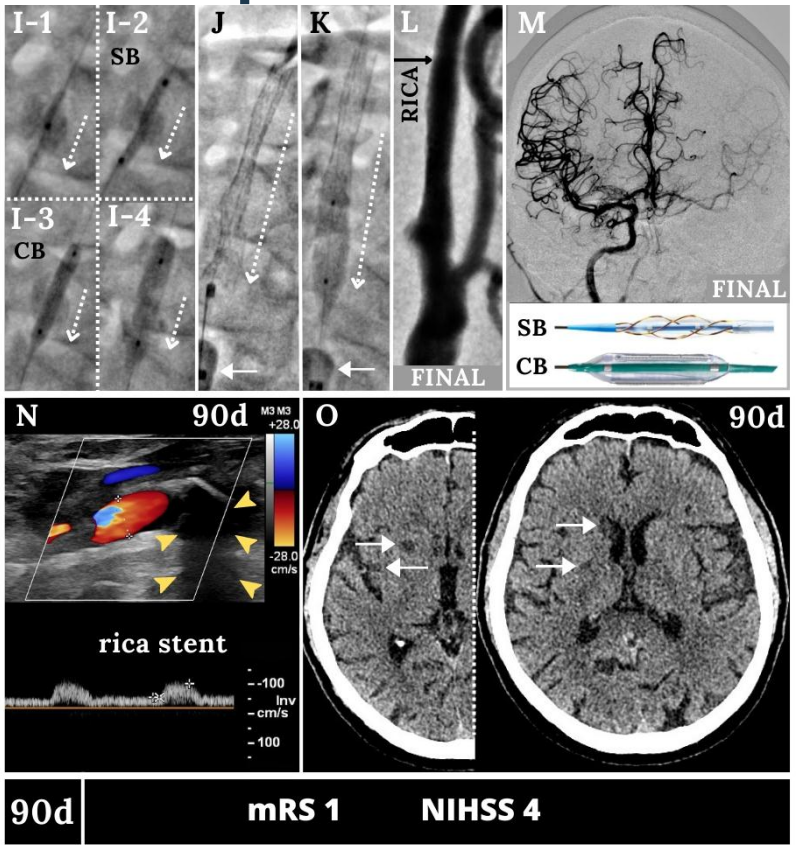
SAFEGUARD-STROKE Case Example 4

- extreme carotid bif. calcium
- tandem, thrombotic





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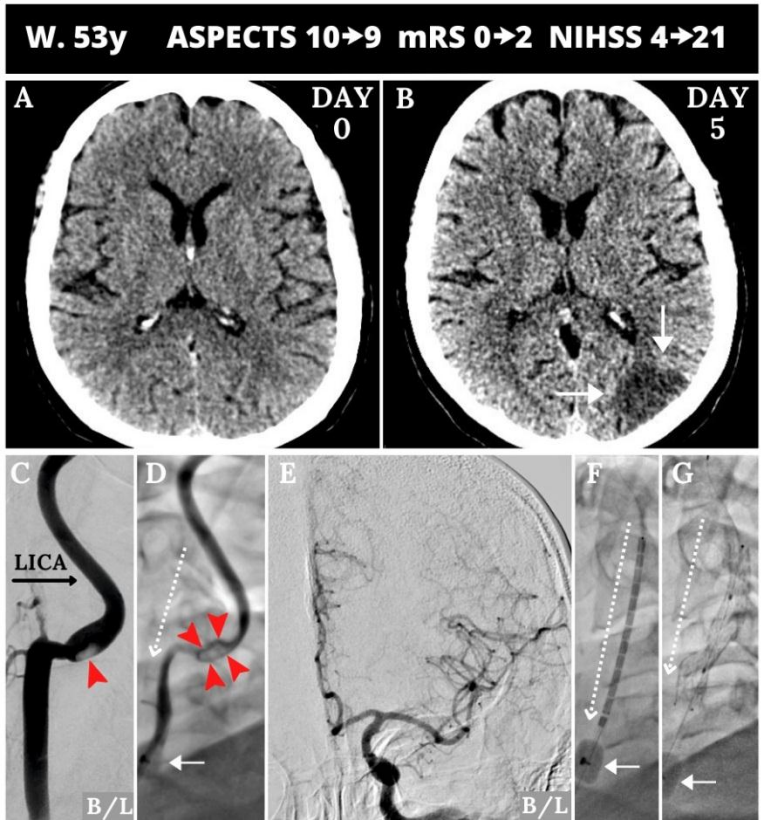
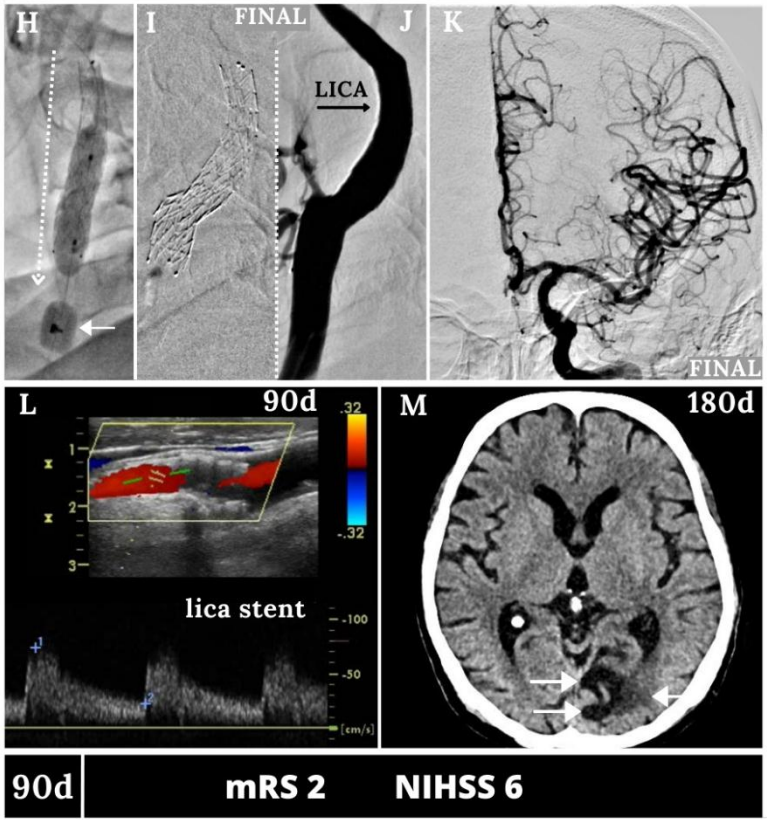
SAFEGUARD-STROKE Case Example 5

- atherothrombotic
- stuttering





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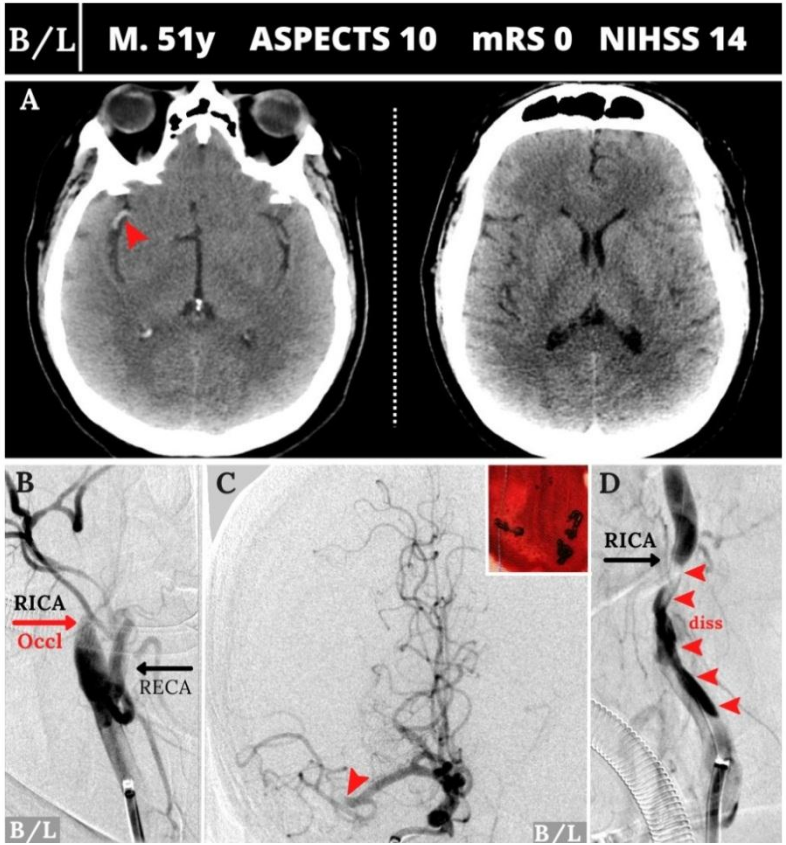
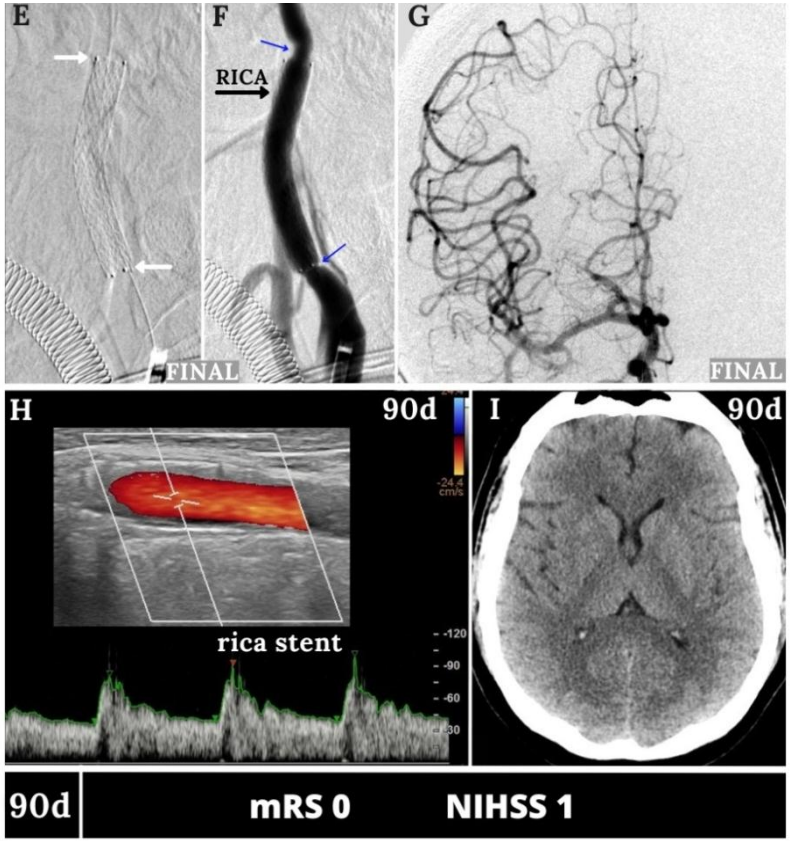
SAFEGUARD-STROKE Case Example 6

- atherothrombotic
- tandem





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Main outcomes of interest

In-hospital/by discharge	n=75
Any intracranial hemorrhage	12 (16)
sICH	4 (5.3)
asICH	8 (10.7)
In-hospital death	7 (9.3)
NIHSS[#] on discharge	4 (2-8)
range	0-23
mRS at discharge	1 (1-3)
range	0-6
Stent patent[#] on discharge	66 (94.3)
DUS in-stent velocities	
PSV, cm/s	69 (53-91)
EDV, cm/s	20 (12-26)
Any in-stent material	0 (0)

90-day outcomes[†]	n=66
New stroke by 90-days, any	2 (3)
ipsilateral	1 (1.5)
contralateral	0
posterior circulation	1 (1.5)
90-day death (total*)	9 (12.0)
NIHSS at 90-days	3 (0-5)
mRS[‡] at 90-days	1 (1-2)
Stent patent[¥] by 90-days	59 (92.2)
Any in-stent material[§]	0 (0)
Stent occluded by 90-days	5 (7.8)
DUS in-stent velocities	
PSV, cm/s	64 (55-84)
EDV, cm/s	24 (21-30)

L. Tekieli et al. *Adv Interv Cardiol* 2024;20:172–193.

Predictors of sICH

Univariate	Mulitvariate
GP IIb/IIIa inhibitor ia. bolus + iv. infusion OR 6.4 (1.8-24.5), p<0.001	GP IIb/IIIa inhibitor ia. bolus + iv. infusion OR 16.9 (4.8-44.3), p<0.001
T-occlusion OR 3.9 (1.9-15.1), p<0.001	
Tandem lesion OR 3.4 (1.3-35.9), p=0.010	
IVT OR 1.9 (1.1-20.6), p<0.001	
Additional dose of heparin[#] OR 1.4 (1.1-18.7), p=0.020	

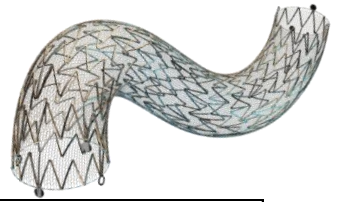
L. Tekieli et al. *Adv Interv Cardiol* 2024;20:172–193.

Predictors of bad clinical outcome (mRS >2) at 90 days

Univariate	Mulitvariate
GP IIb/IIIa inhibitor ia. bolus + iv. infusion OR **23.8** (5.3-94.5), p<0.001	NIHSS > 20 OR **14.7** (2.1-78.2), p=0.006
ASPECT < 8 OR **11.2** (3.2-38.9), p<0.001	GP IIb/IIIa inhibitor ia. bolus + iv. infusion OR **13.9** (5.1-84.5), p<0.001
NIHSS > 20 OR **8.3** (2.4-32.6), p<0.001	ASPECT < 8 OR **12.8** (2.0-81.6), p=0.007
Tandem lesion OR **6.1** (1.8-20.8), p=0.004	
Postdilatation balloon < 5mm or absent* OR **4.6** (1.2-17.6), p=0.020	
Peri-procedural DAPT initiation OR **0.77** (0.41-0.92), p=0.006	
Balloon catheter use for cerebral protection OR **0.68** (0.21-0.89), p=0.003	

L. Tekieli et al. *Adv Interv Cardiol* 2024;20:172–193.

Predictors of patency loss by 90 days



Univariate	Mulitvariate
Heparin limited to flush OR **14.3** (1.5-53.1), p=0.007	Postdilatation balloon < 5mm OR **15.2** (5.7-72.3), p<0.001
mTICI < 2b OR **12.7** (4.9-97.9), p=0.001	mTICI < 2b OR **6.3** (0.98-45.2), p=0.080
Tandem lesion OR **9.2** (1.1-28.4), p=0.030	
Postdilatation balloon < 5mm* OR **7.1** (5.4-57.9), p=0.002	
ASPECT < 8 OR **6.2** (1.3-14.1), p=0.024	

L. Tekieli et al. *Adv Interv Cardiol* 2024;20:172–193.

Conclusions

- The MicroNET-covered stent was beneficial in ICA recanalization and re-establishing cerebral perfusion with minimized iatrogenic cerebral embolism, and was associated with a high rate of functional independence.

- Study stent post-dilatation with a small-diameter balloon –or absence of post-dilatation– independently predicted patency loss.

The CGuard MicroNET-Covered Stent is **not yet available commercially** in the USA.
FDA-IDE Trial (CGUARDIANS NCT04900844): recently COMPLETED for its Primary Endpoint.

Conclusions (Cont'd)

- This mulicenter, multi-speciality sudy demonstrated
  - high acute angiographic success rate,
  - high 90-day patency,
  - favorable clinical outcomes

  despite differences in procedural strategies and pharmaco--therapy, reflecting real-life variability in approaches by different operators/centers.

- Findings from this study may inform management strategy in patients with acute ischemic stroke of carotid artery origin.

Commentary: A multi-center study of the MicroNET-covered stent in consecutive patients with acute carotid-related stroke: SAFEGUARD-STROKE

Jaims Lim[1,2], Vinay Jaikumar[1,2], Tyler A. Scullen[1,2], Adnan H. Siddiqui[1,2,3,4,5]

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[2]Department of Neurosurgery, Gates Vascular Institute at Kaleida Health, Buffalo, New York, USA
[3]Canon Stroke and Vascular Research Center, University at Buffalo, Buffalo, New York, USA
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Adv Interv Cardiol 2024; 20, 3 (77): 245–247
DOI: https://doi.org/10.5114/aic.2024.142327

The future of CGuard EPS in tandem strokes

The CGuard EPS features a dual-layer nitinol mesh, with the self-expandable open-cell stent that exerts a radial outward pressure on the outer MicroNET cover ensuring the thorough apposition of the mesh against the vessel wall [9, 10]. Additionally, the tight MicroNET cover across the stent prevents "cheese-grating" of acute and chronic plaque, thereby reducing the risk of additional emboli and stroke in the intracranial space. Together, these features of the CGuard result in effective containment of the plaque, preventing inadvertent intraprocedural embolization and reducing the risk of tandem conversion. Additionally, they help prevent postprocedural embolization, thereby mitigating the risk of recurrent ipsilateral ischemic strokes

MicroNET-covered stent (CGuard) routine use in acute carotid-related stroke – SAFEGUARD-STROKE Study: response to the Buffalo Group commentary

Lukasz Tekieli[1,2,3], Maciej Mazgaj[4], Zoltan Ruzsa[5], Bogdan Janus[6], Piotr Paluszek[7], Horst Sievert[8], Iris Q. Grunwald[9,10,11], Piotr Musialek[1,2]

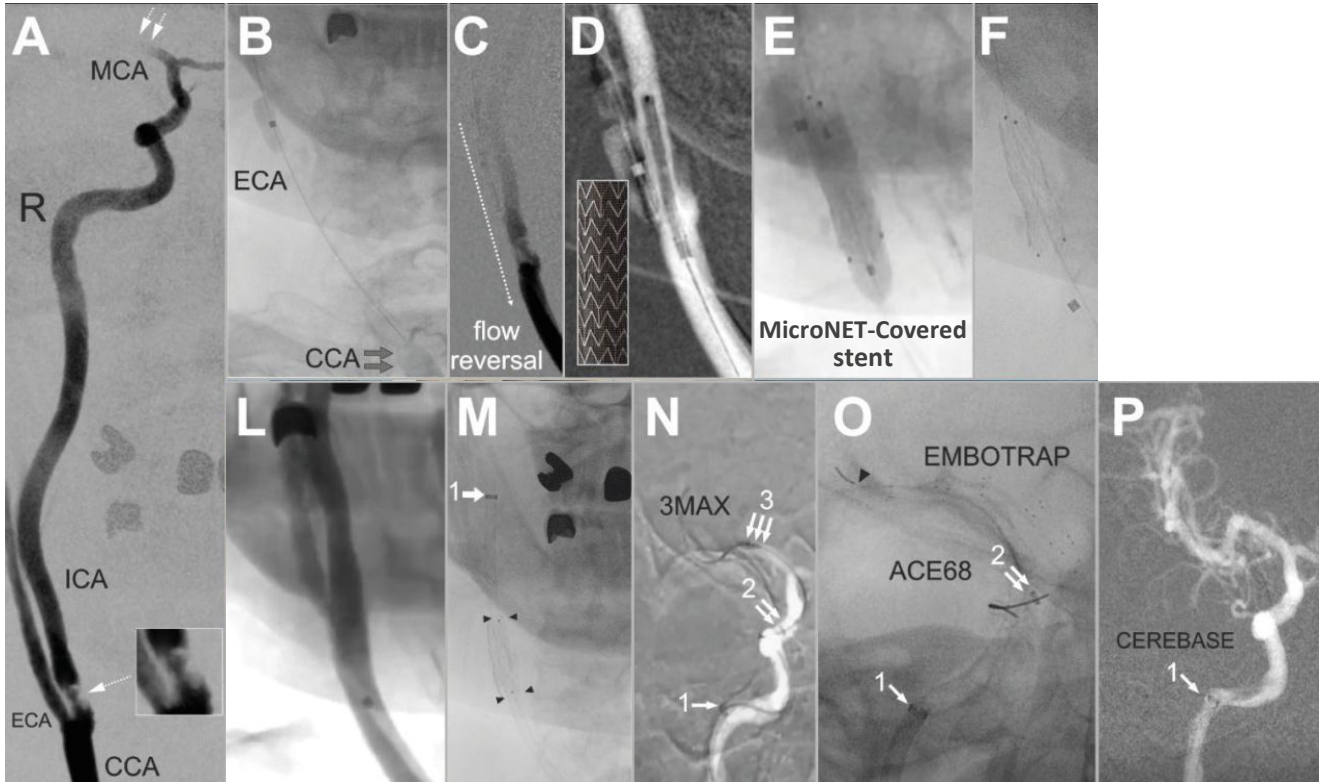
[1]St. John Paul II Hospital in Krakow, Stroke Thrombectomy-Capable Cardiovascular Centre, Krakow, Poland
[2]Department of Cardiac and Vascular Diseases, Jagiellonian University Medical College, Krakow, Poland
[3]Department of Interventional Cardiology, Jagiellonian University Medical College, Krakow, Poland
[4]Department of Diagnostic and Interventional Radiology, Stephan Cardinal Wyszynski Regional Hospital, Lublin, Poland
[5]Invasive Cardiology Division, University of Szeged, Szeged, Hungary
[6]Department of Cardiology, St Lucas Regional Specialist Hospital, Tarnow, Poland
[7]Department of Vascular Surgery and Endovascular Interventions, St. John Paul II Hospital, Krakow, Poland
[8]CardioVascular Center Frankfurt (CVC), Sankt Katharinen Hospital, Frankfurt, Germany
[9]Division of Imaging Science and Technology, School of Medicine, University of Dundee, Dundee, Scotland, United Kingdom
[10]Ninewells Hospital, Department of Radiology, Dundee, Scotland, United Kingdom
[11]University of Dundee, Chair of Neuroradiology

Adv Interv Cardiol 2024; 20, 3 (77): 248–254
DOI: https://doi.org/10.5114/aic.2024.143686

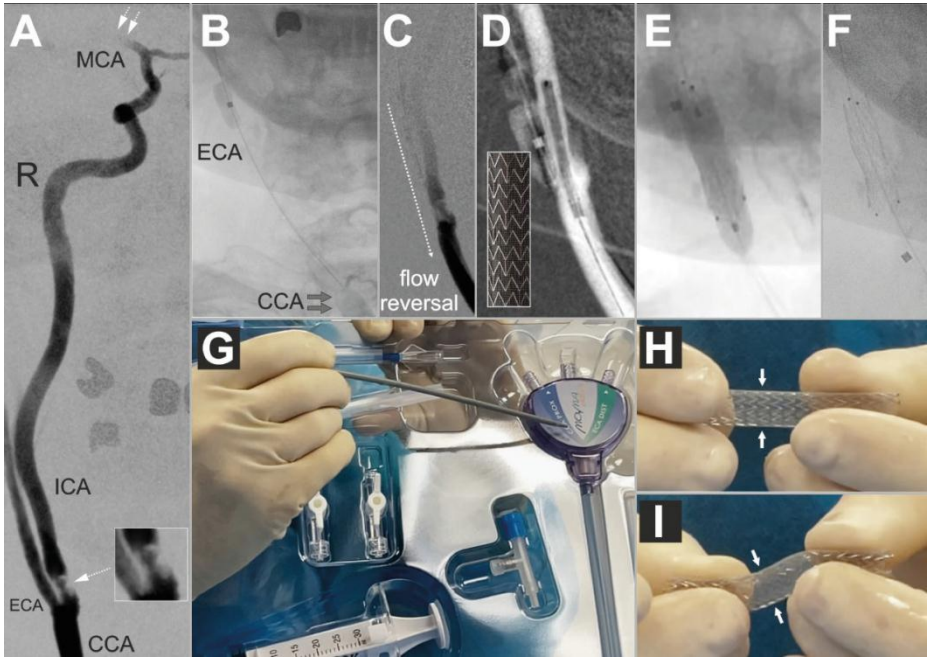
Antegrade vs. Retrograde Strategy in Tandems *and* Importance of Embedment

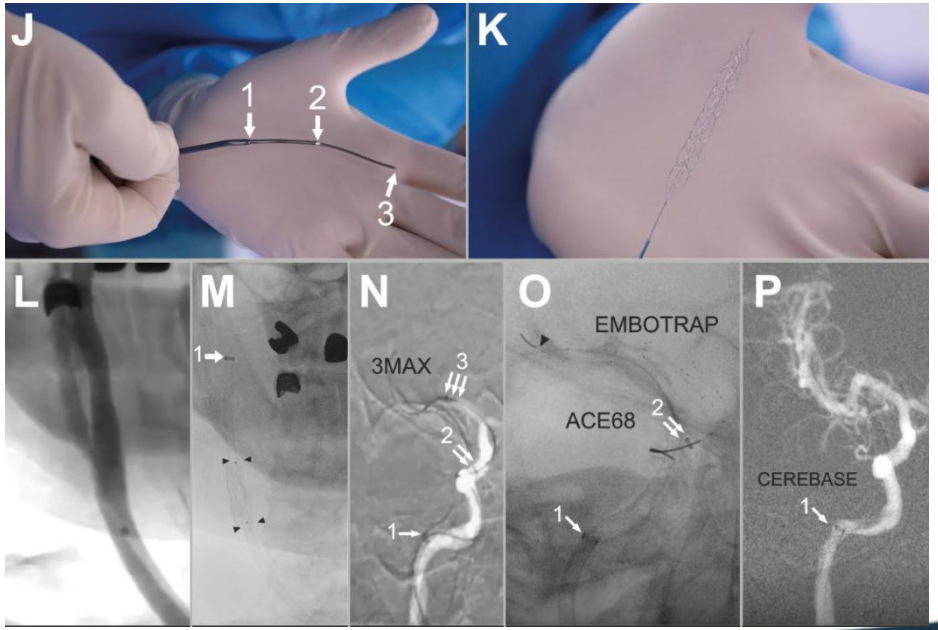
Finally, the use of an antegrade vs. a retrograde strategy in the management of tandem lesion in the SAFEGUARD-STROKE Study is consistent with the multitude of approaches guided by operator preference and patient anatomy in tandem stroke interventions, as raised by the Buffalo group [31]. One fundamental advantage of the MicroNET-covered stent in eCAS is its sequestration of the atherothrombotic plaque, preventing further plaque-related embolism. We fully agree with our Buffalo colleagues that resolving the carotid pathology before intracranial manipulation is an important contribution to a stepwise approach to prevent new distal embolization in carotid-related strokes and to prevent blind maneuvering into the intracranial circulation during revascularization of tandem lesions [31]. One fundamental disadvantage, however, is the need to cross the carotid stent to reach the intracranial lesion. The latter, as shown in the SAFEGUARD-STROKE study is feasible and can be done safely [30]. Importantly, it may require positioning the guiding catheter distal to the ICA/CCA stent for increased catheter support for the intracranial intervention and – if stentrievers are used – to avoid the risk of entanglement of the stentriever with the stent struts during the stentriever removal. Also, in eCAS, stenting often occurs under limited (for some operators/centers – absent) anticoagulation and with suboptimal antiplatelet protection [9]. Thus optimization of stent embedment with appropriate post-dilatation is crucial to reduce the risk of clot formation [30]. Importantly, for training in acute stroke interventions [42], both the antegrade and retrograde strategy (and their variations) can be practised today, including anti-embolic stent use, in a novel human stroke model that can address different clinical scenarios and operator preferences [43].

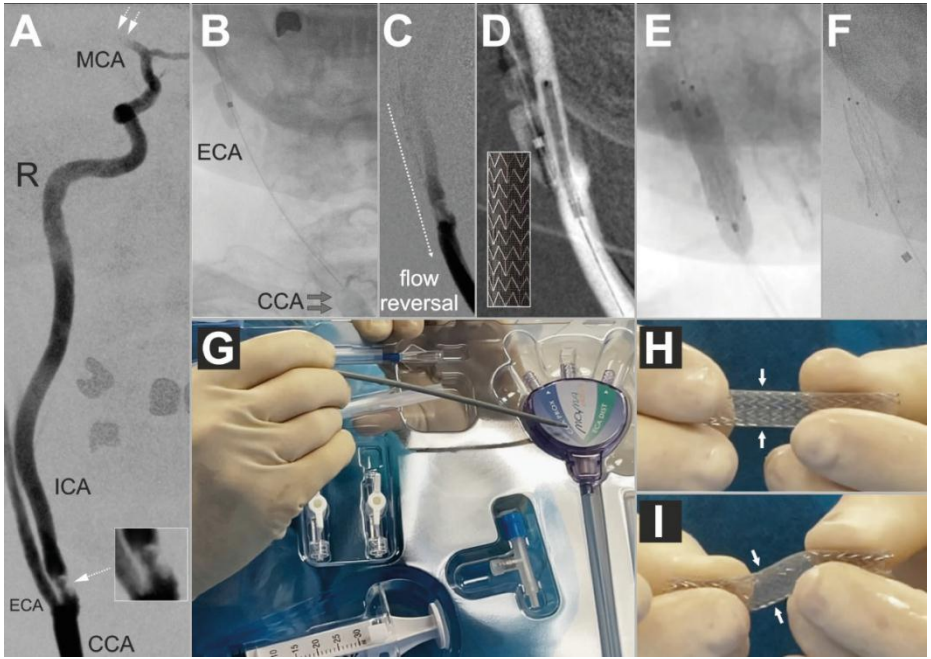
Post Scriptum: Today, antergrade vs. retrograde strategy, in tandem stroke, using this and other devices, can be practiced…



Tandem stroke ’live’ case



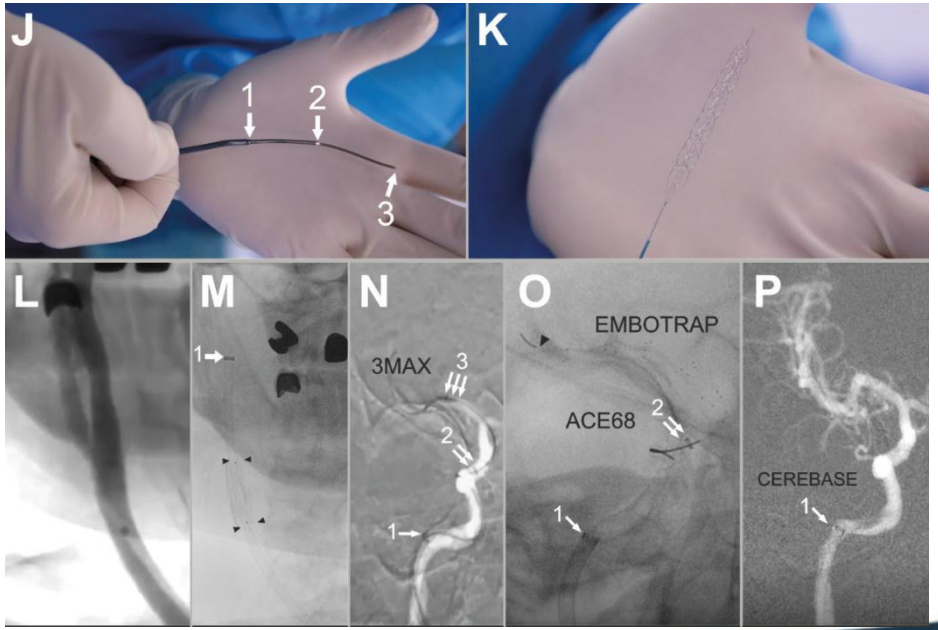


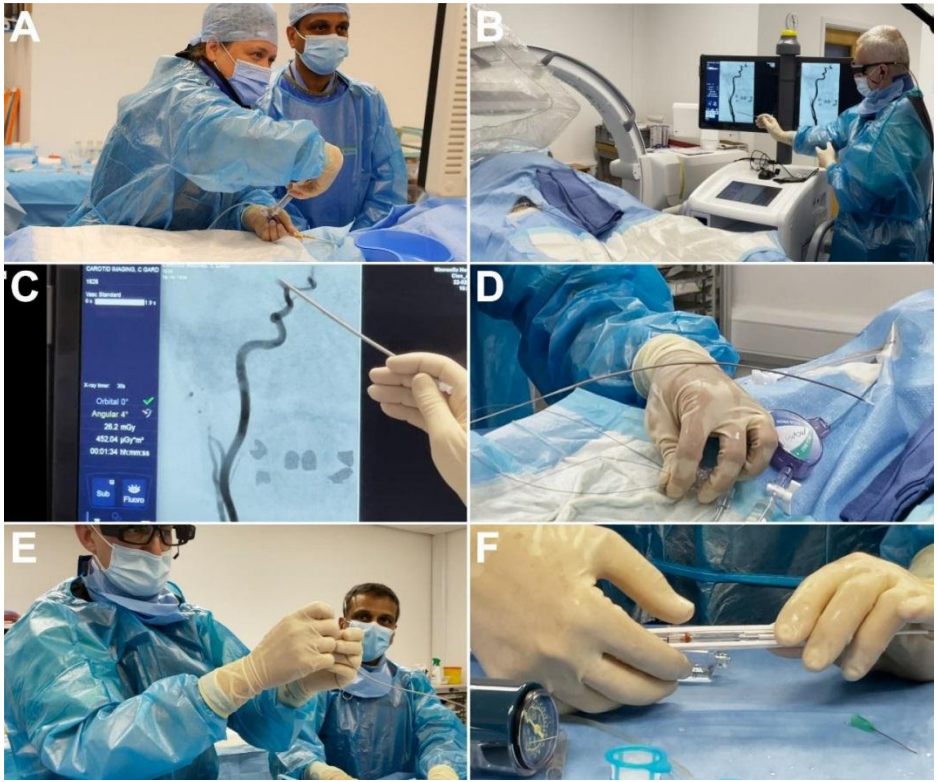


EuroIntervention
2024;20:e1-e4
published online e-edition
DOI: 10.4244/EIJ-D-24-00248

Endovascular treatment of tandem lesions in a novel cadaveric stroke model

Iris Q. Grunwald[1,2*], MD, PhD; Lukasz Tekieli[3,4], MD, PhD; Anna Podlasek[1,2,5], MD, PhD; Helen Donald-Simpson[1,2], PhD; Stephanie Clark[2]; Chloe Voutsas[2]; Sanjay Pillai[2,6], MD, PhD; Graeme Houston[1,2], MD, PhD; Magdalena Knapik[3,7], MD; Leah White[2]; Pamela Barr[2]; Andreas Melzer[8,9], PhD; Piotr Musialek[3], MD, DPhil





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FLASHLIGHT

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This paper also includes supplementary data published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-24-00248

EuroIntervention
2024;20:e1-e4
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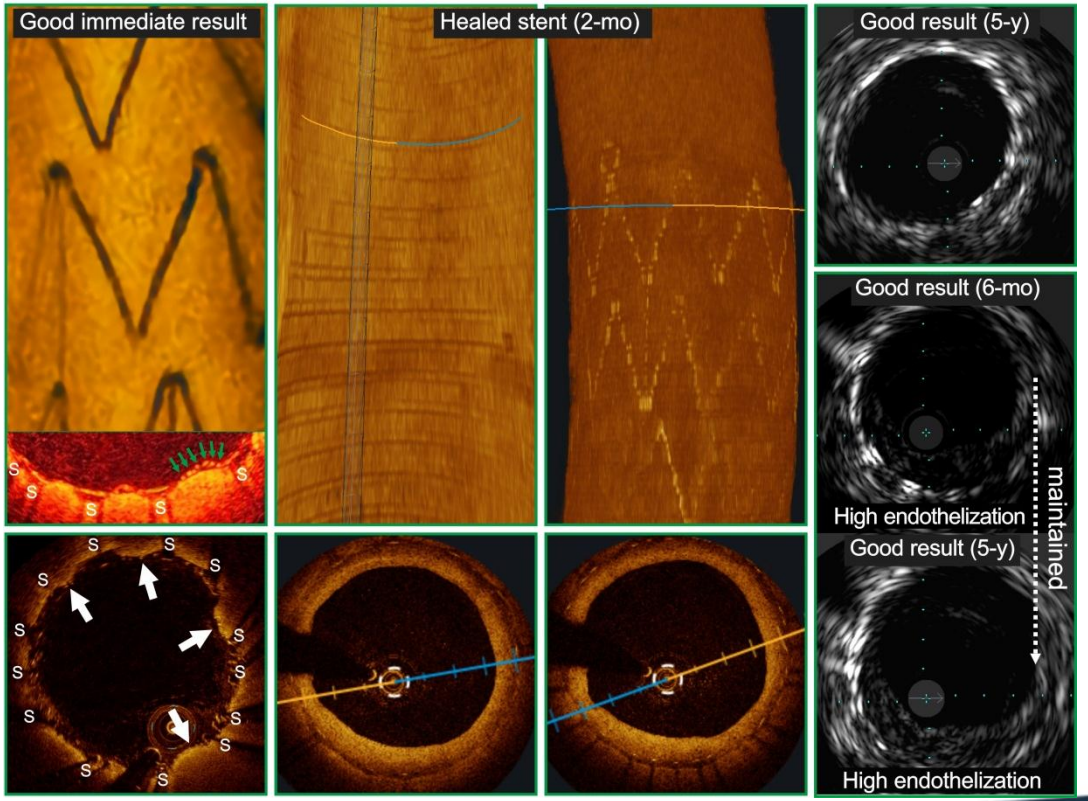
This paper also includes supplementary data published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-24-00248

More Imaging…
(incl. Protected Coverage of Aterothrombotic Material)



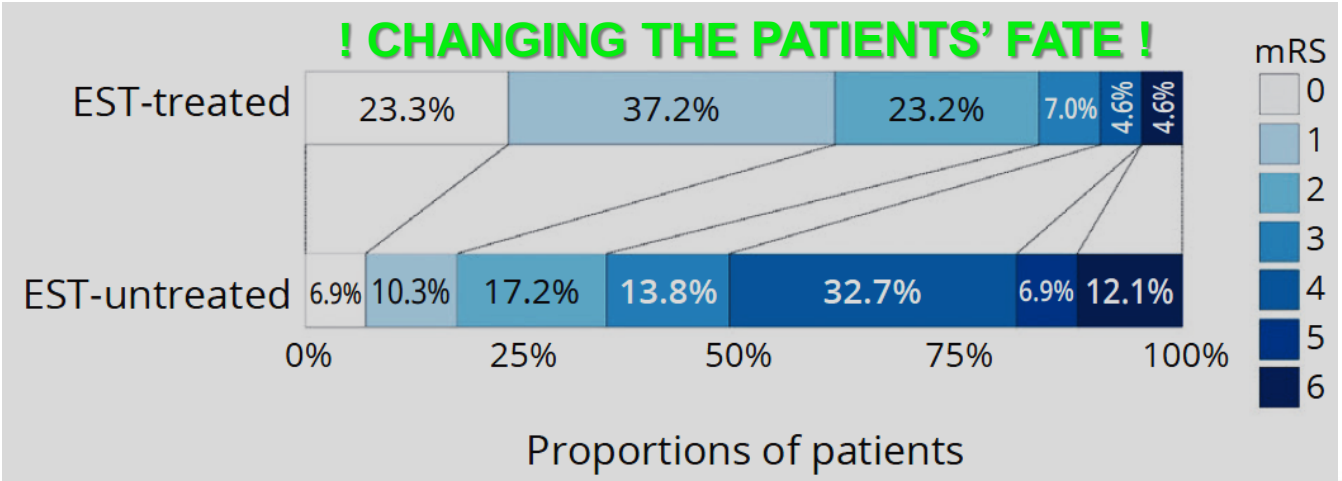
Musialek P, Tekieli L, Umemoto T. ***JSCAI*** 2024 (in press)

Optimized Emergency Treatment = Optimized CRS Patient Outcomes

The Journal of Cardiovascular Surgery 2024 June;65(3):231-48
DOI:10.23736/S0021-9509.24.13093-5

ORIGINAL ARTICLE
NOVEL DATA IN CAROTID-RELATED STROKE TREATMENT AND PREVENTION

Outcomes in acute carotid-related stroke eligible for mechanical reperfusion: SAFEGUARD-STROKE Registry



Multi-Center Study of the MicroNET-Covered Stent in Consecutive Patients with Acute Carotid-Related Stroke:

SAFEGUARD-STROKE

Lukasz Tekieli, Andrey Afanasiev, Maciej Mazgaj, Vladimir Borodetsky, Kolja Sievert, Zoltan Ruzsa, Magdalena Knapik, Audrius Širvinskas, Adam Mazurek, Karolina Dzierwa, Thomas Sanczuk, Valerija Mosenko, Malgorzata Urbanczyk-Zawadzka, Mariusz Trystula, Piotr Paluszek, Lukasz Wiewiorka, Justyna Stefaniak, Piotr Pieniazek, Inga Slautaitė, Tomasz Kwiatkowski, Artūras Mackevičius, Michael Teitcher, Horst Sievert, Iris Q Grunwald, Piotr Musialek

Krakow/**Poland,** Vilnius**/Lithuania,** Jerusalem**/Israel,** Frankfurt**/Germany,** Szeged-Budapest**/Hungary,** Lublin**/Poland,** Dundee**/Scotland UK**