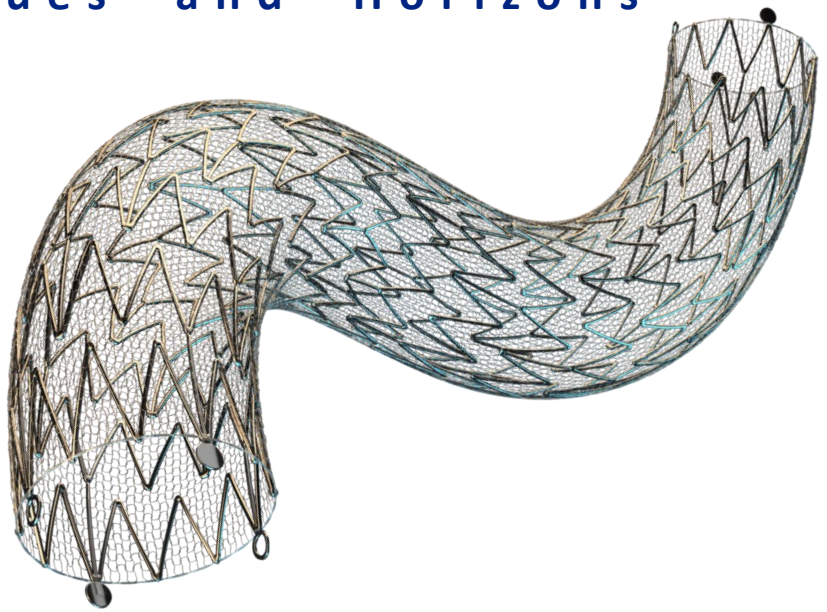
VEITH 2024
Connecting The Vascular Community



Update On All Trial Results With CGuard And CGuard Prime MicroMesh Covered Stents (InspireMD):

Are They Making A Difference And Limitations With Transfemoral/ Transradial CAS: Evidence Summary And Long-Term Outcomes

Piotr Musialek

Jagiellonian University Dept. of Cardiac & Vascular Diseases
St. John Paul II Hospital, Kraków, Poland

Disclosure

Speaker name: Piotr Musialek
I have the following potential conflicts of interest to report:

☑ Consulting/Proctoring: Abbott Vascular, Balton, Gore, InspireMD, Medtronic, Penumbra

☐ Employment in industry

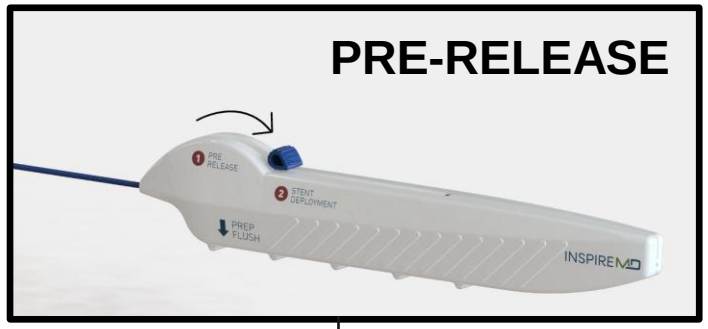
☐ Stockholder in a healthcare company

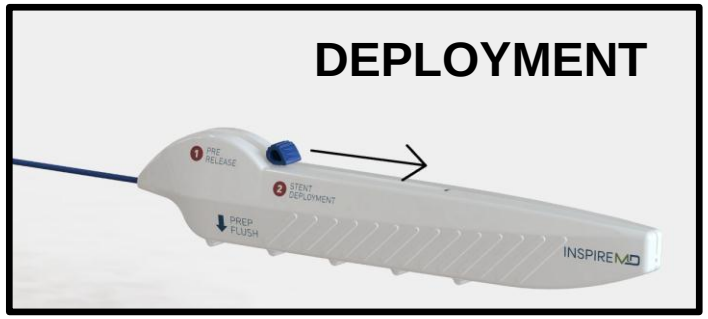
☐ Owner of a healthcare company

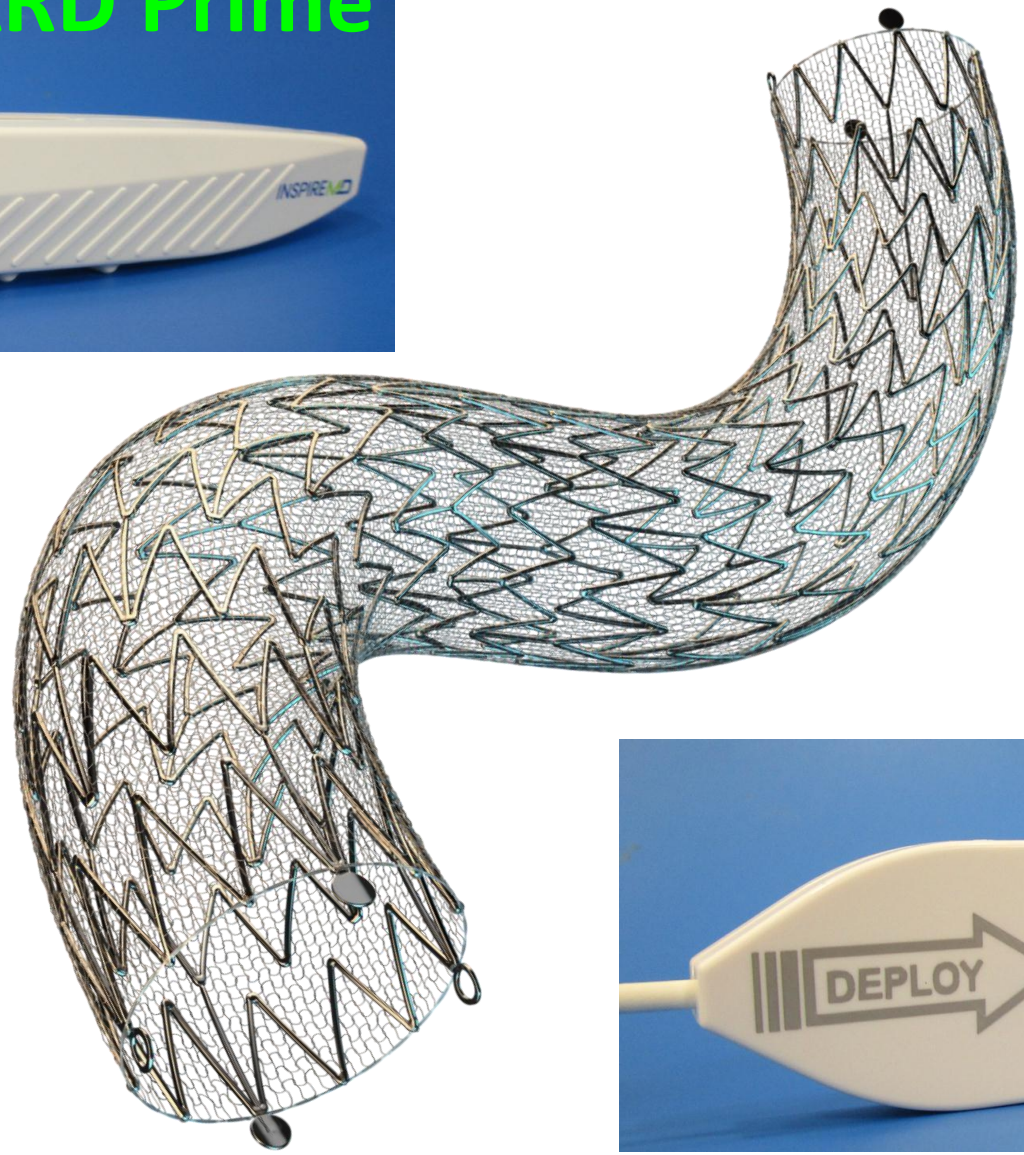
☑ Others: ESC Stroke Council Scientific Documents Task Force
Polish Cardiac Society Board Representative for Stroke and Vascular Interventions
CGUARDIANS FDA IDE Co-PI

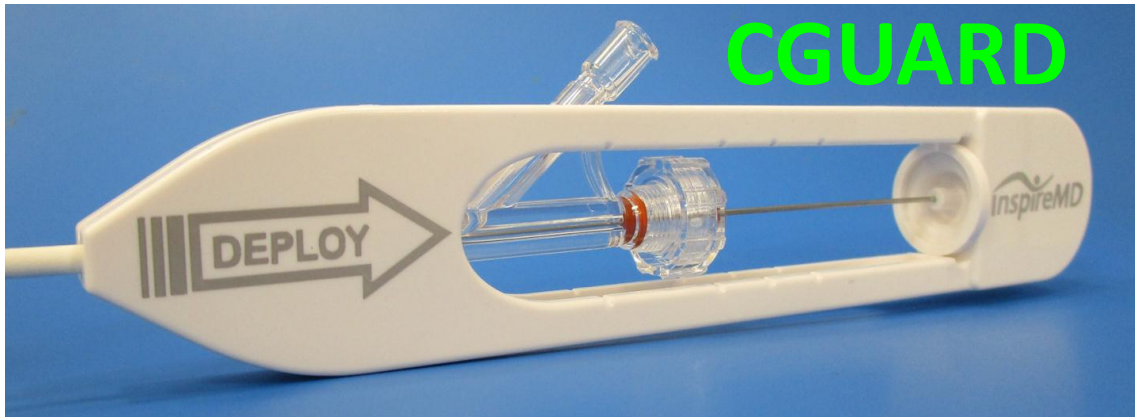
The MicroNET-Covered Anti-Embolic Stent

CGuard









CGuard/CGuard Prime is an Investigational Device in the USA

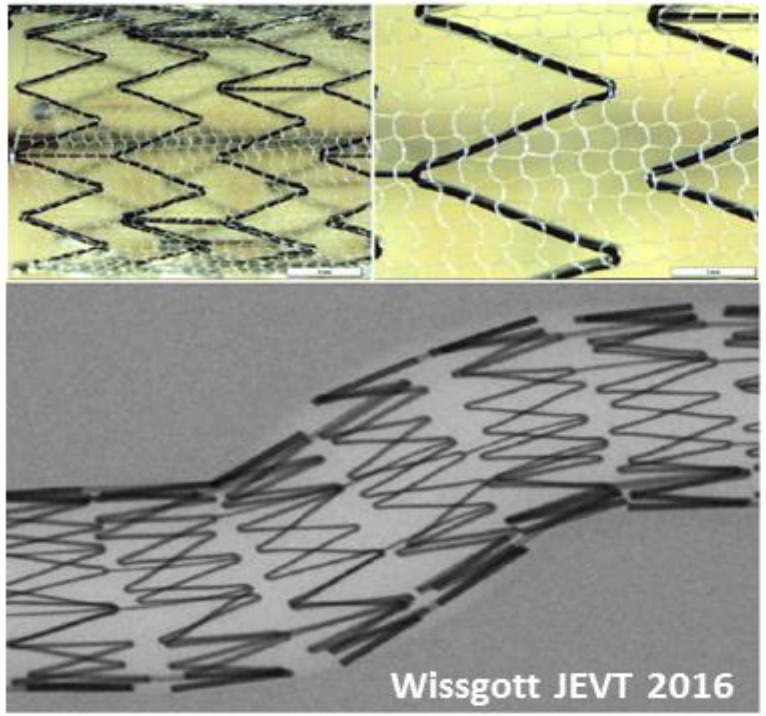
The **MOST 'open'** amongst open-cell stents (metallic FRAME) & the **MOST 'close'** amongst close-cell stents (MicroNet mesh)

CGuard MicroNET – covered
2nd generation carotid stent

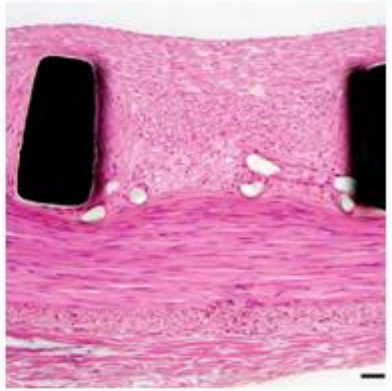
UNIQUE mechanical properties

RESPECT of anatomy

FULL apposition



NORMAL healing



CGuard/CGuard Prime is an Investigational Device in the USA

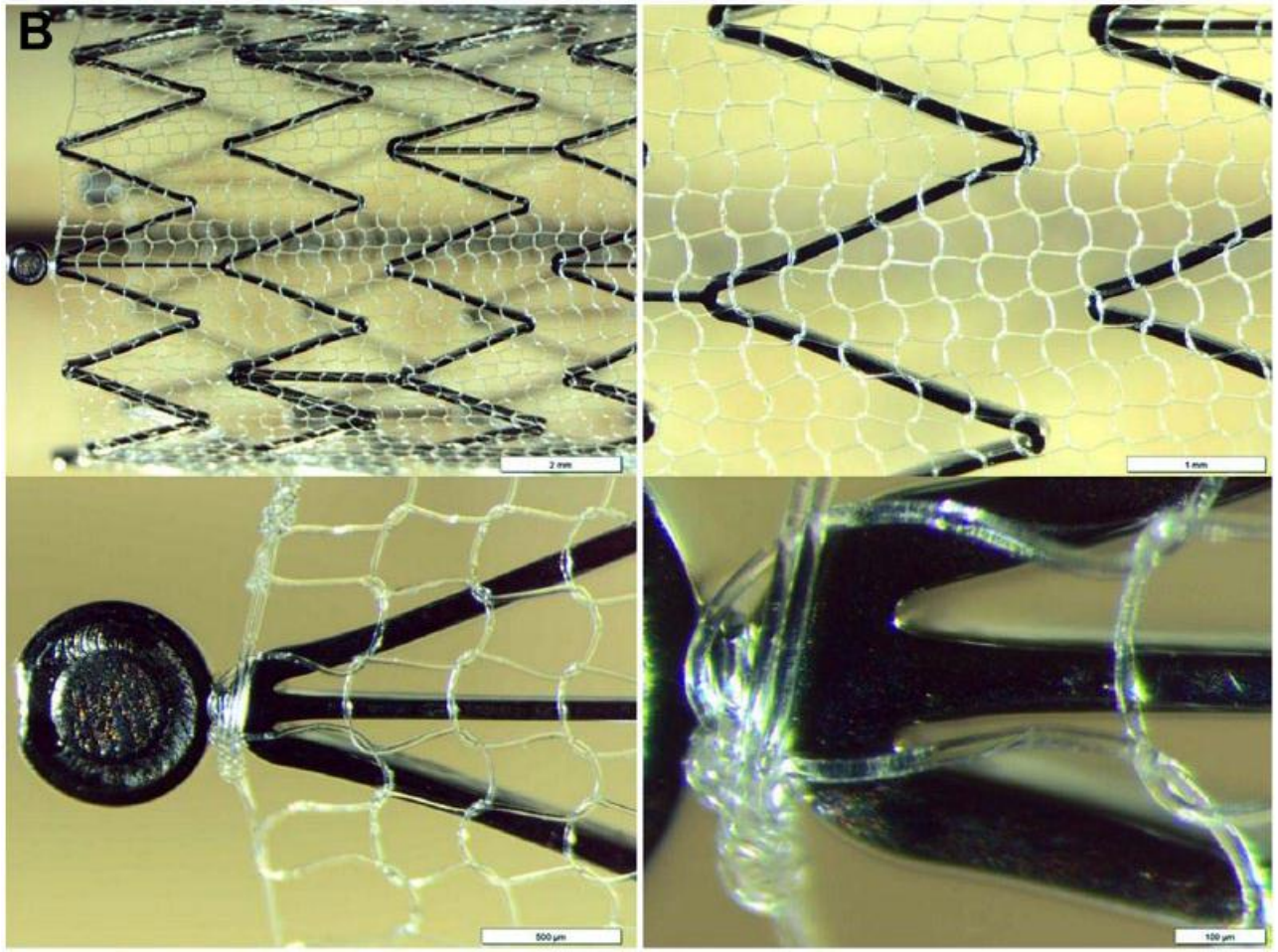
Clinical Investigation

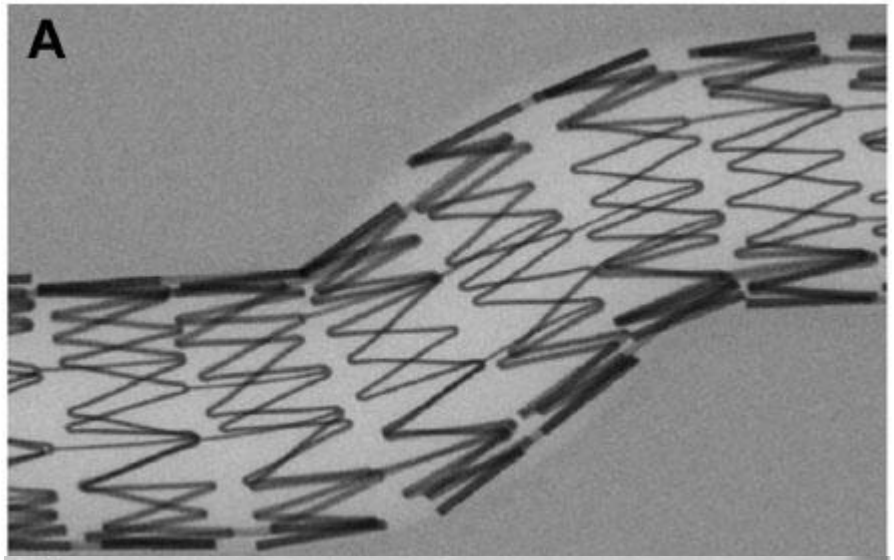
JOURNAL OF ENDOVASCULAR THERAPY

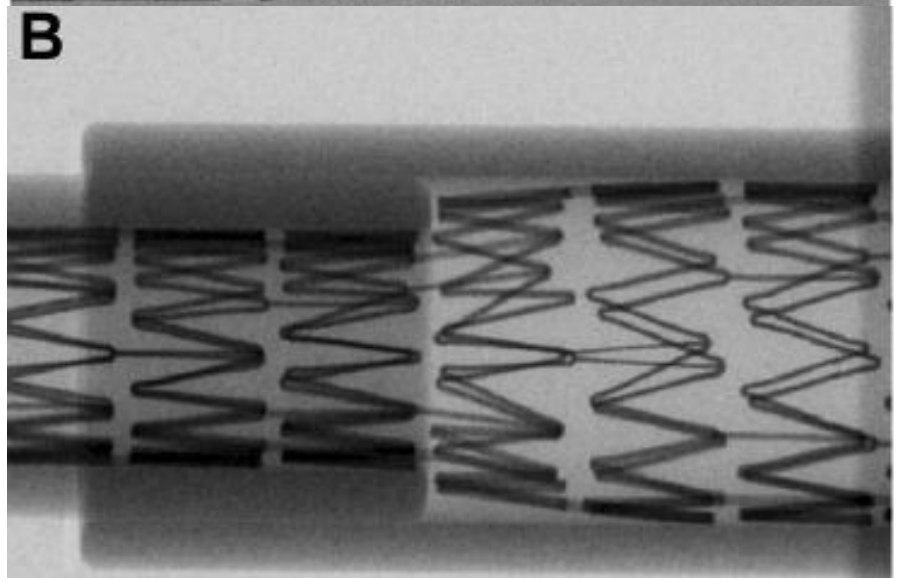
Journal of Endovascular Therapy
1–8

DOI: 10.1177/1526602816671134
www.jevt.org
SAGE

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







In the USA CGuard/CGuard Prime are Investigational Devices not yet marketed; The FDA-IDE Trial (CGUARDIANS) has been recently completed for its Primay Endpoint (2024)

CGuard/CGuard Prime is an Investigational Device in the USA

CGuard MicroNet-Covered Stent

Expanding Clinical Evidence

CGUARDIANS	**FDA-IDE**	NCT04900844
OPTIMA	**Intravascular Evaluation of Sympt. plaque exclusion**	NCT04234854
PARADIGM 1000	**High-Risk All-comers with indication, No exclusions**	NCT04271033
SIMGUARD	**Greatest-Risk Patients: SIMULTANEOUS Urgent Cardiac Surgery+CGuard**	NCT04973579
FLOWGUARD	**MicroNET stent in high-risk lesions beyond carotid bif.**	NCT04461717
C-HEAL	**Flow-Diverter: Aneursym exclusion-and-healing**	NCT04434456
SAFEGUARD-STROKE	**CGuard in Carotid-Related Acute Stroke**	NCT05195658
TOPGUARD	**CGuard in Transcervical Flow Reversal CAS**	NCT04547387

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CGuard MicroNet-Covered Stent

Expanding Clinical Evidence

and…

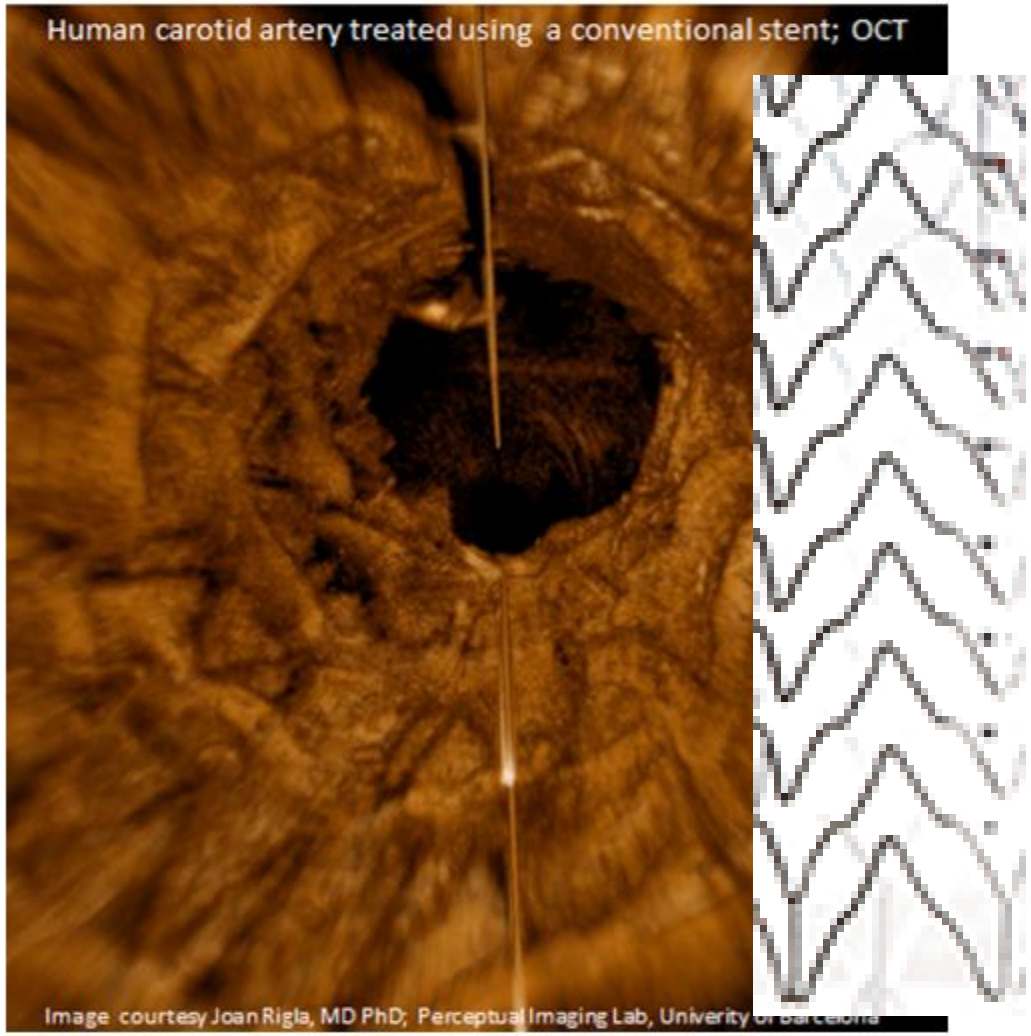
- CGuard vs. Acculink (POWERED, DWI) **RCT**
- IRONGUARD 1
- IRONGUARD 2
- POLGUARD
- CGUARD ”ONE-FITS-ALL” (and others…)

~ 5000 Patients

RCT

Randomized Controlled Trial

The CREST Study stent

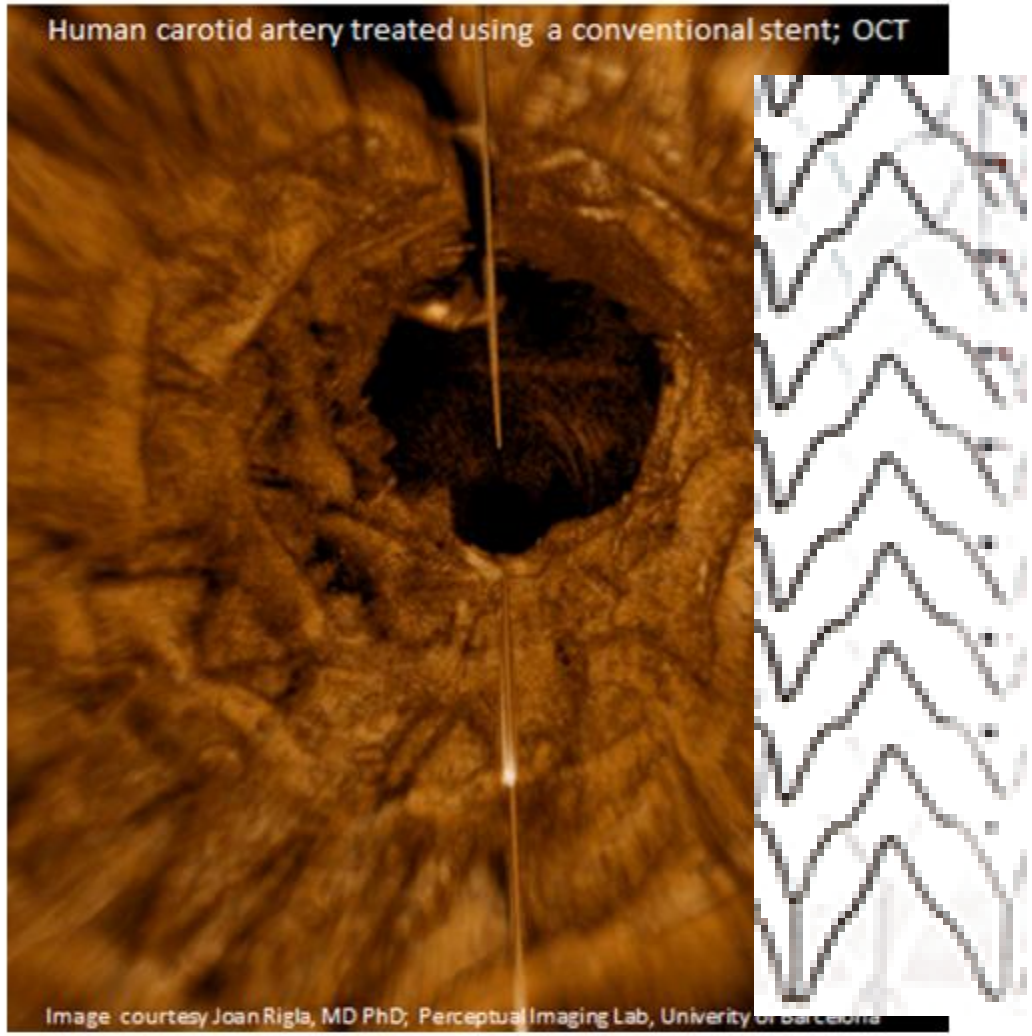


OCT Images in: P Musialek, G deDonato
Carotid Artery Revascularization Using the Endovascular Route
In: **Carotid Interventions - Practical Guide 2022**

JACC Cardiovasc Interv. 2021;14:2377-2387.

Randomized Controlled Trial

The CREST Study stent

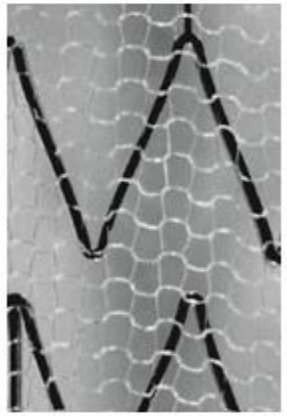


OCT Images in: P Musialek, G deDonato
Carotid Artery Revascularization Using the Endovascular Route
In: **Carotid Interventions - Practical Guide 2022**

Level-1 Evidence

JACC Cardiovasc Interv. 2021;14:2377-2387.

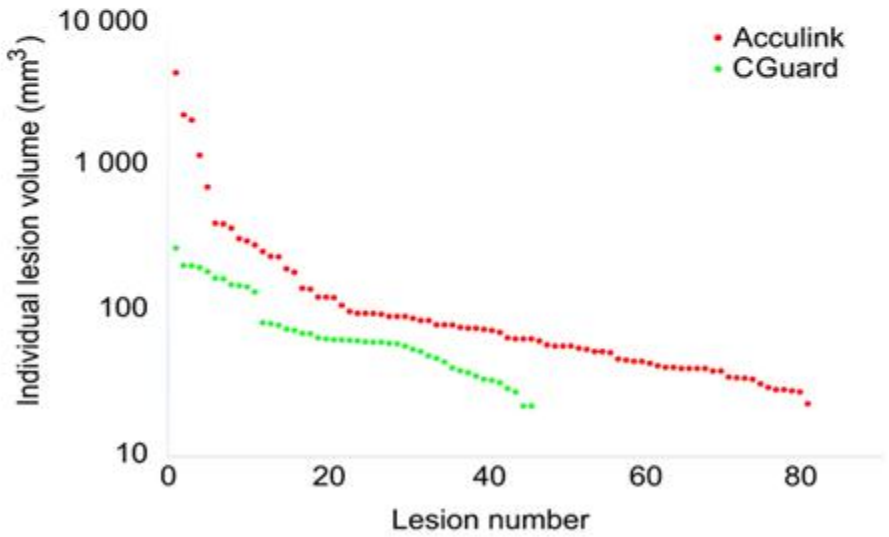
CGuard



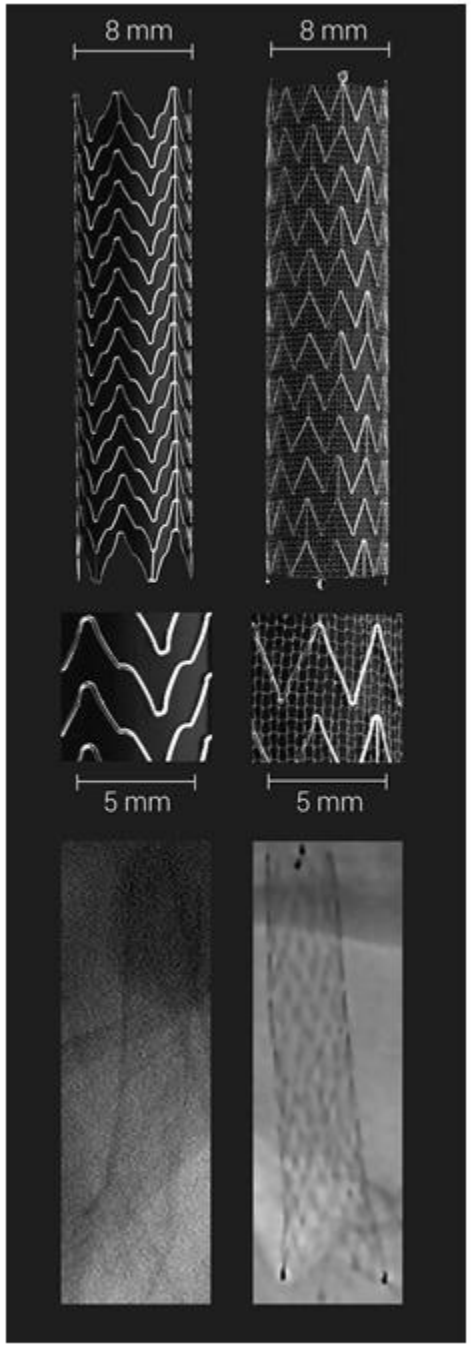
Neuro-Protective
Carotid Stent System

Randomized Controlled Trial

DW-MRI Embolism
raw data



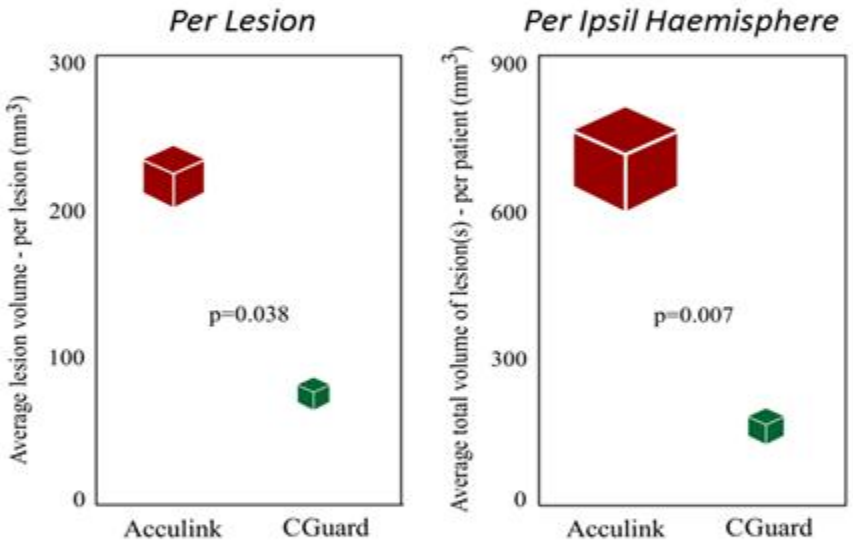
JACC: CARDIOVASCULAR INTERVENTIONS VOL. 14, NO. 21, 2021
NOVEMBER 8, 2021:2377–2387



Level 1 Evidence

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

MicroNet-Covered Stent - CGuard

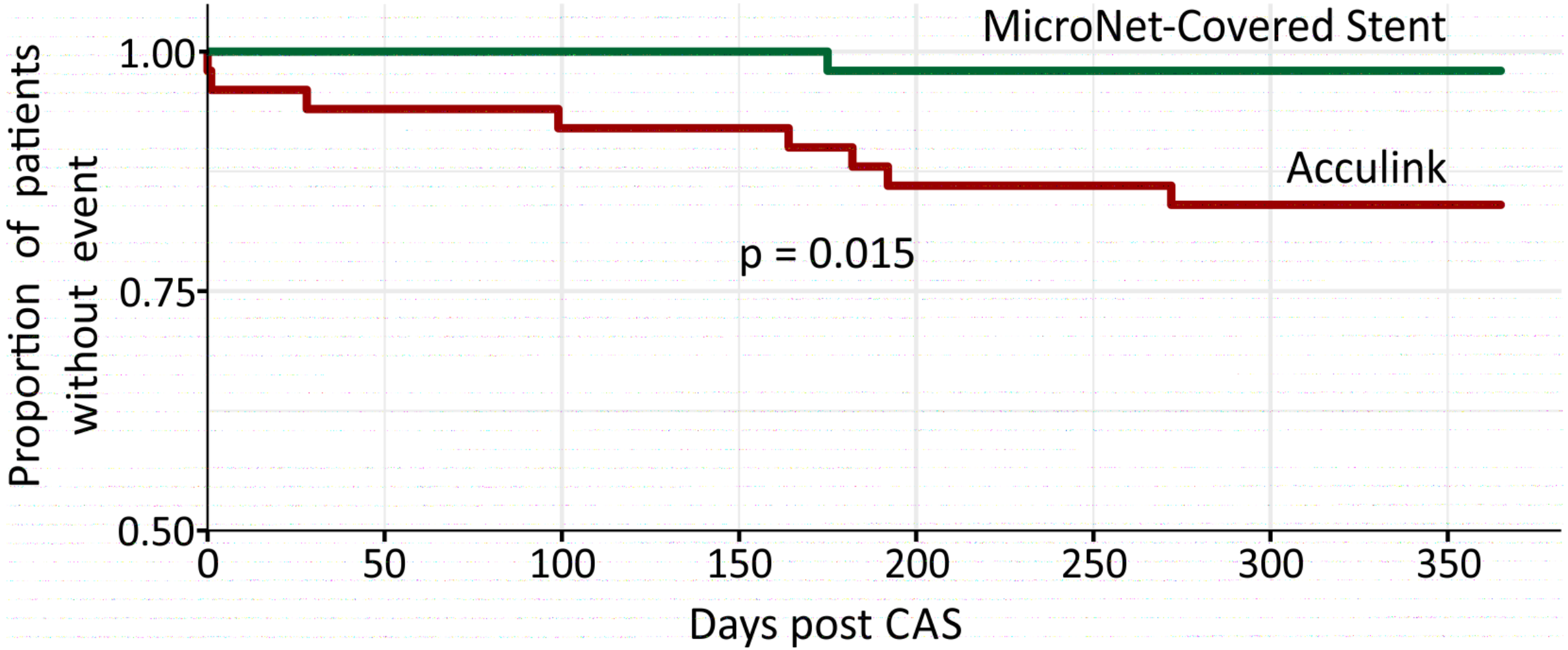


Blinded CoreLab independent anaysis

CGuard
MicroNET-Covered Stent

Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization

12-month clinical data



Meta-Analyses

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

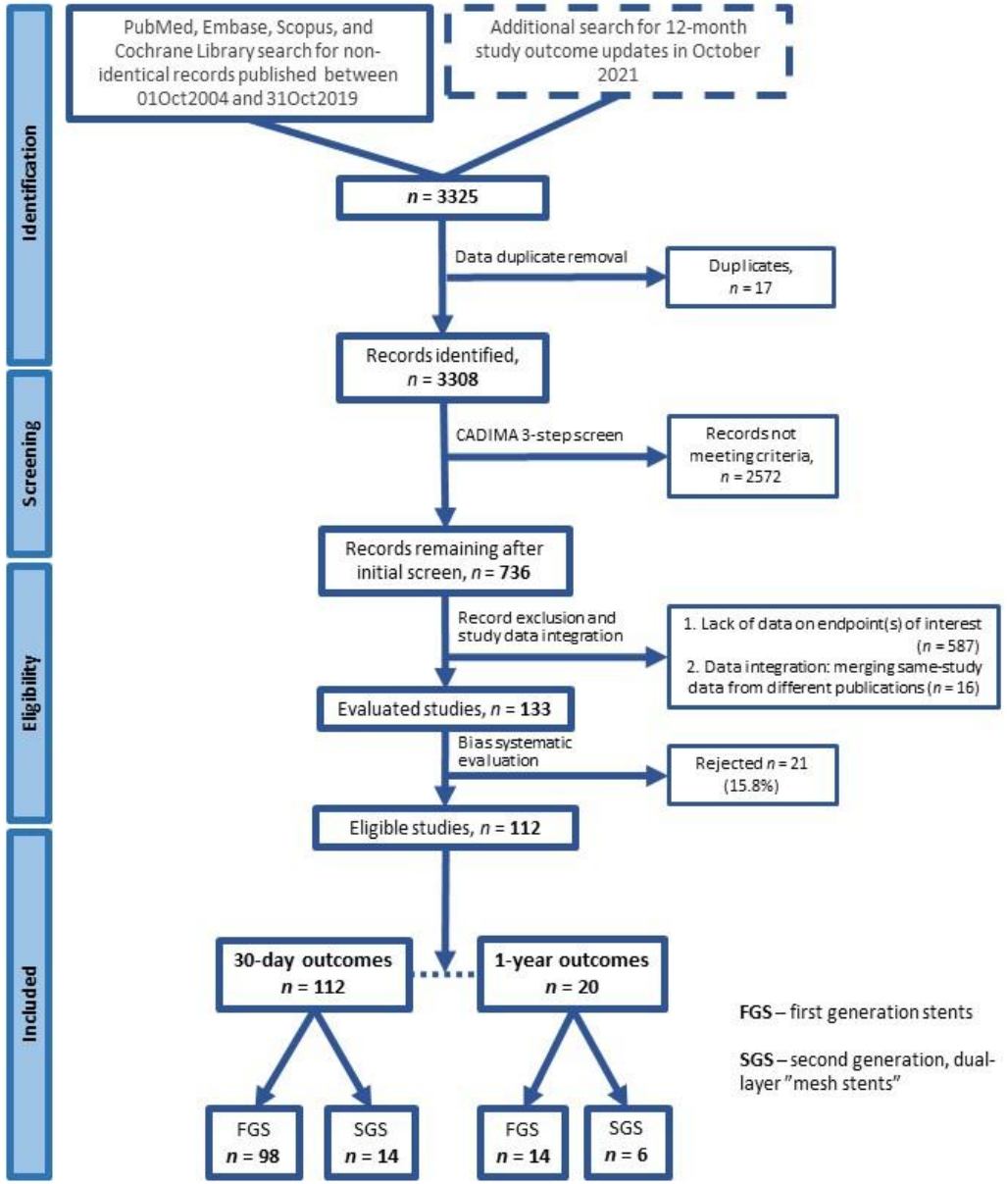
Data of **68,422** patients

from **112 eligible studies**

(68.2% men, 44.9% symptomatic)

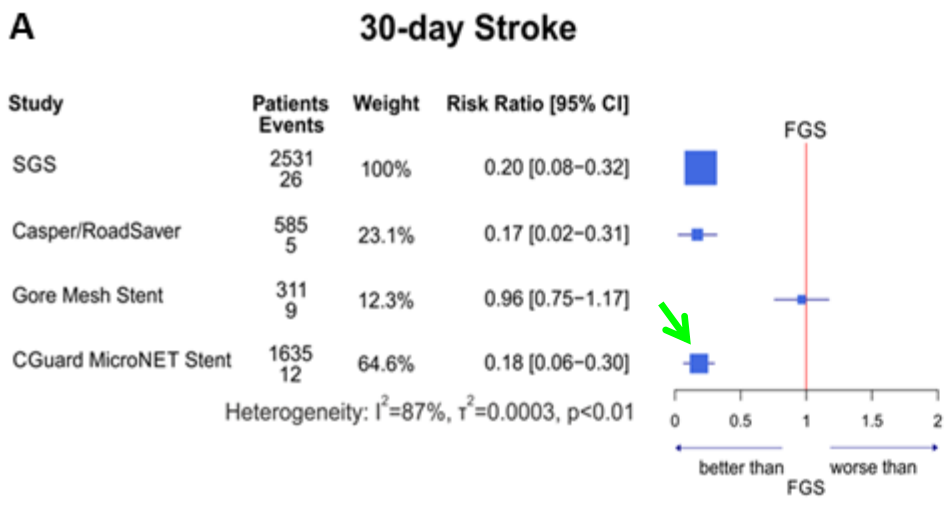
Adam Mazurek et al.
CARMEN Collaborators

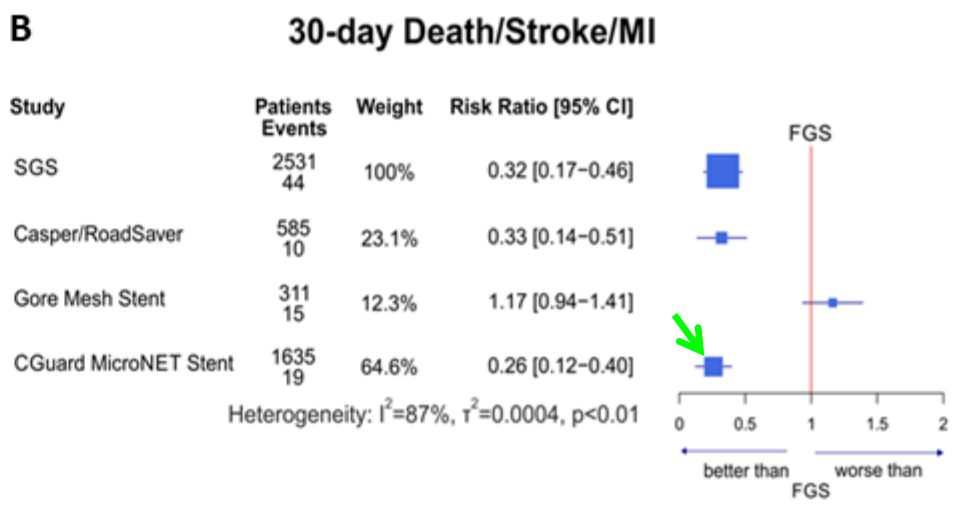
CARMEN Systematic review and meta-analysis flowchart (PRISMA)



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

CARMEN SGS vs FGS Meta-Analysis: Main Findings





Adam Mazurek et al.
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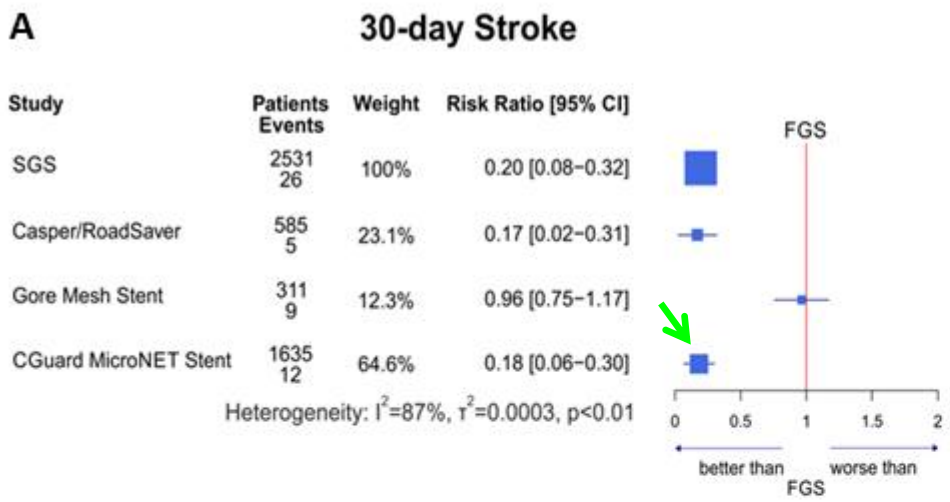
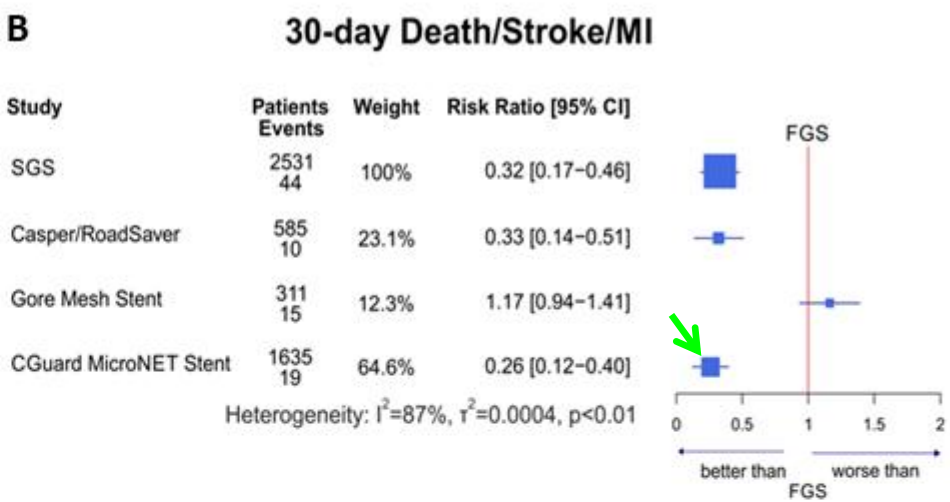
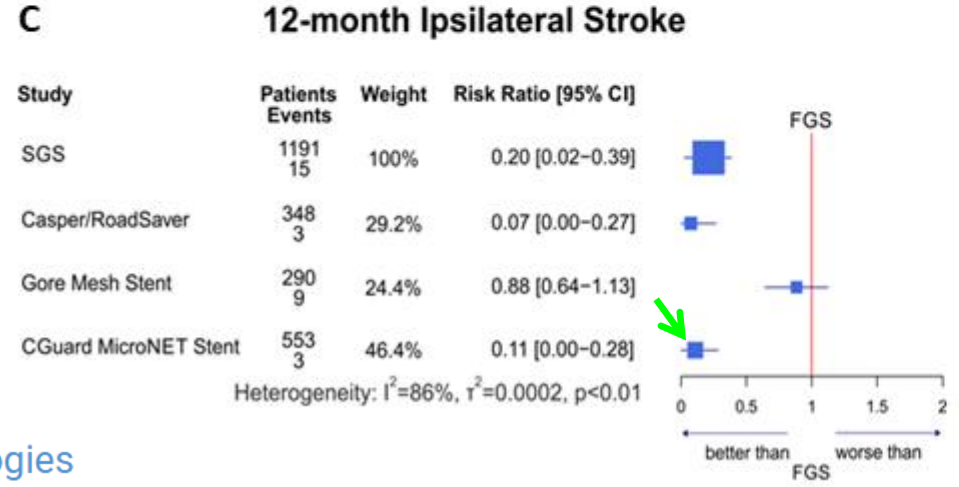
CARMEN SGS vs FGS Meta-Analysis: Main Findings







New Technologies

Adam Mazurek et al.
CARMEN Collaborators

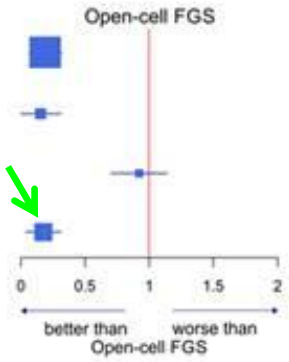
CARMEN SGS vs FGS Meta-Analysis: Main Findings

Open-cell FGS as reference

A 30-day Stroke

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.19 [0.06–0.33]
Casper/RoadSaver	585 5	23.1%	0.16 [0.00–0.32]
Gore Mesh Stent	311 9	12.3%	0.92 [0.70–1.14]
CGuard MicroNET Stent	1635 12	64.6%	0.17 [0.03–0.31]

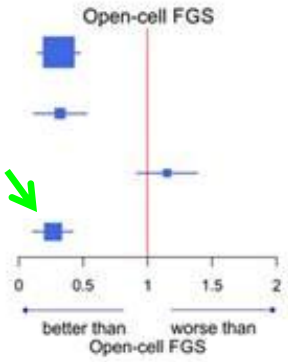
Heterogeneity: I^2=83%, τ^2=0.0002, p<0.01



B 30-day Death/Stroke/MI

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.31 [0.14–0.48]
Casper/RoadSaver	585 10	23.1%	0.32 [0.11–0.52]
Gore Mesh Stent	311 15	12.3%	1.15 [0.91–1.40]
CGuard MicroNET Stent	1635 19	64.6%	0.26 [0.10–0.42]

Heterogeneity: I^2=84%, τ^2=0.0003, p<0.01

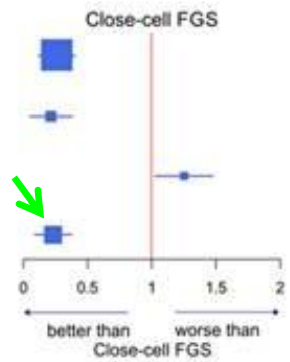


Close-cell FGS as reference

C 30-day Stroke

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.26 [0.11–0.41]
Casper/RoadSaver	585 5	23.1%	0.21 [0.04–0.38]
Gore Mesh Stent	311 9	12.3%	1.25 [1.02–1.48]
CGuard MicroNET Stent	1635 12	64.6%	0.23 [0.08–0.39]

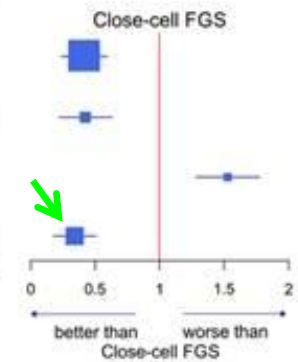
Heterogeneity: I^2=72%, τ^2=0.0001, p<0.01



D 30-day Death/Stroke/MI

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.41 [0.23–0.59]
Casper/RoadSaver	585 10	23.1%	0.42 [0.21–0.63]
Gore Mesh Stent	311 15	12.3%	1.53 [1.28–1.79]
CGuard MicroNET Stent	1635 19	64.6%	0.34 [0.17–0.51]

Heterogeneity: I^2=73%, τ^2=0.0002, p<0.01



New Technologies

Adam Mazurek et al.
CARMEN Collaborators

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

Conclusions: Pooled SGS use was associated with improved short- and long-term clinical results of CAS. Individual SGS types, however, differed significantly in their outcomes, indicating a lack of a "mesh stent" class effect. **Findings from this meta-analysis may provide clinically relevant information** (…).

Adam Mazurek et al.
CARMEN Collaborators

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

103,642 Patients

The Journal of Cardiovascular Surgery 2023 December;64(6):570-82
DOI: 10.23736/S0021-9509.24.12933-3

LATEST TECHNIQUES FOR CAROTID REVASCULARIZATION

Carotid artery revascularization using second generation stents *versus* surgery: a meta-analysis of clinical outcomes

Adam MAZUREK [1, 2] *, Krzysztof MALINOWSKI [3, 4], Pasqualino SIRIGNANO [5], Ralf KOLVENBACH [6], Laura CAPOCCIA [7], Gianmarco DE DONATO [8], Isabelle VAN HERZEELE [9], Adnan H. SIDDIQUI [10, 11], Tomaso CASTRUCCI [12], Lukasz TEKIELI [1, 2, 13], Matteo STEFANINI [14], Christian WISSGOTT [15], Kenneth ROSENFIELD [16], D. Christopher METZGER [17], Kenneth SNYDER [18], Andrey KARPENKO [19], Waclaw KUCZMIK [20], Eugenio STABILE [21], Magdalena KNAPIK [22], Renato CASANA [23], Piotr PIENIAZEK [1, 13], Anna PODLASEK [24, 25], Maurizio TAURINO [5], Joachim SCHOFER [26], Alberto CREMONESI [27, 28], Horst SIEVERT [29], Andrej SCHMIDT [30], Iris Q. GRUNWALD [24, 31], Francesco SPEZIALE [7], Carlo SETACCI [8], Piotr MUSIALEK [1, 2], CArotid Revascularization systematic reviews and MEta-aNalyses (CARMEN) Collaborators

Adam Mazurek et al.
CARMEN Collaborators

(PROSPERO-CRD42022339789)

SGS vs CEA meta-analysis

Major
RCTs
Involving CEA

1. CEA pooled data

SAPPHIRE
EVA 3S
SPACE-1
ICSS
CREST
ACST-1
ACT-1
Manhaim
SPACE-2

Adam Mazurek et al.
CARMEN Collaborators
J Cardiovasc Surg 2023

SGS vs CEA meta-analysis

Major
RCTs
Involving CEA

1. CEA pooled data

SAPPHIRE
EVA 3S
SPACE-1
ICSS
CREST
ACST-1
ACT-1
Manhaim
SPACE-2

CEA in
Contemporary
Clinical Practice

2. CEA in Vascular Quality Initiative (VQI) database*

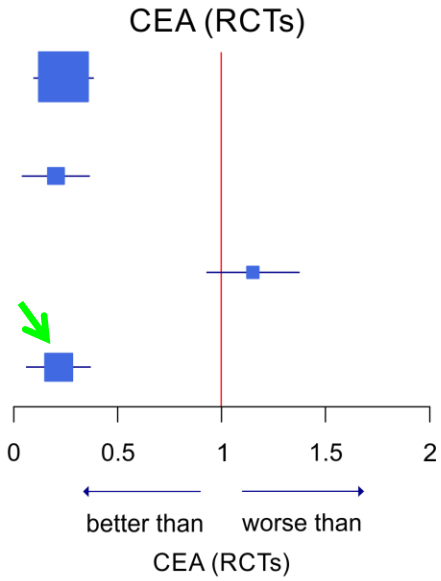
* Dakour-Aridi H, et al. *Ann Vasc Surg.* 2020;65:1-9
Columbo JA, et al. *J Vasc Surg.* 2019;69:104-109

CARMEN Collaborators
J Cardiovasc Surg 2023

30-day Stroke

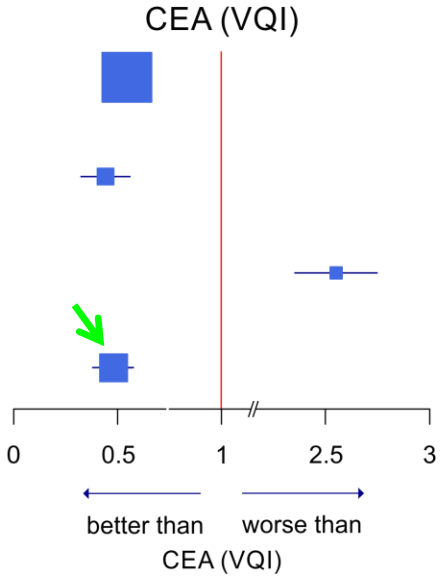
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.24 [0.10−0.38]
Casper/RoadSaver	585 5	23.1%	0.20 [0.04−0.36]
Gore Mesh Stent	311 9	12.3%	1.15 [0.92−1.37]
CGuard MicroNET Stent	1635 12	64.6%	0.22 [0.07−0.36]

Heterogeneity: I^2=71%, τ^2<0.0001, p<0.01



Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.53 [0.44−0.62]
Casper/RoadSaver	585 5	23.1%	0.44 [0.32−0.56]
Gore Mesh Stent	311 9	12.3%	2.55 [2.35−2.75]
CGuard MicroNET Stent	1635 12	64.6%	0.48 [0.39−0.57]

Heterogeneity: I^2=40%, τ^2<0.0001, p=0.06



New Technologies

A. Mazurek et al.

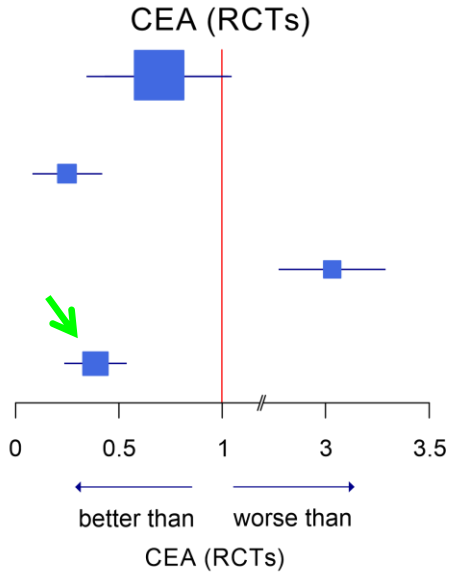
CARMEN Collaborators

J Cardiovasc Surg 2023

12-month Ipsilateral Stroke

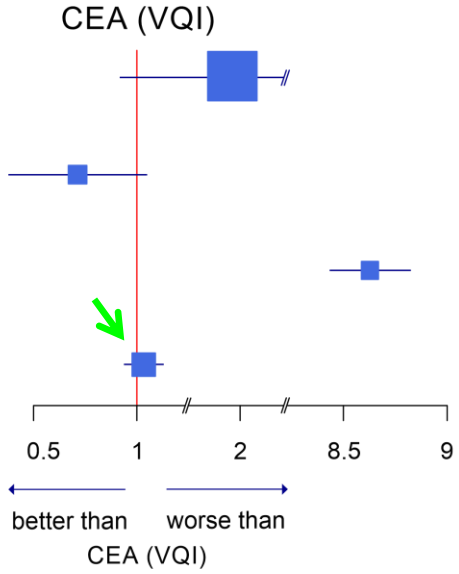
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 15	100%	0.69 [0.34−1.05]
Casper/RoadSaver	348 3	29.2%	0.25 [0.08−0.42]
Gore Mesh Stent	290 9	24.4%	3.07 [2.85−3.29]
CGuard MicroNET Stent	553 3	46.4%	0.38 [0.23−0.53]

Heterogeneity: I^2=59%, τ^2<0.0001, p<0.01



Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 15	100%	1.96 [0.93−2.99]
Casper/RoadSaver	348 3	29.2%	0.71 [0.37−1.05]
Gore Mesh Stent	290 9	24.4%	8.63 [8.43−8.83]
CGuard MicroNET Stent	553 3	46.4%	1.06 [0.96−1.16]

Heterogeneity: I^2=58%, τ^2<0.0001, p=0.08



New Technologies

A. Mazurek et al.

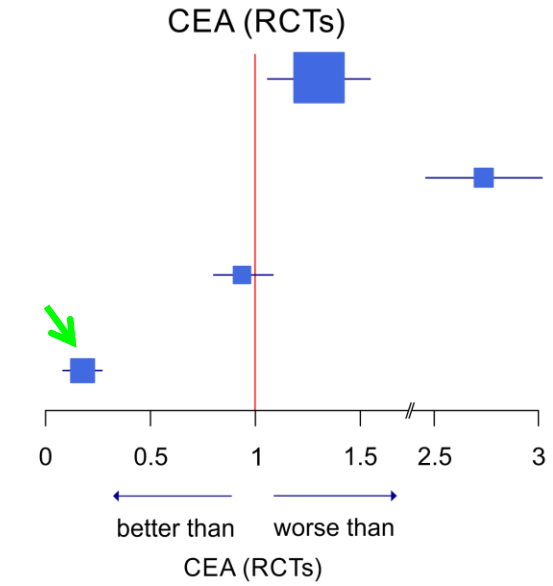
CARMEN Collaborators

J Cardiovasc Surg 2023

12-month Restenosis

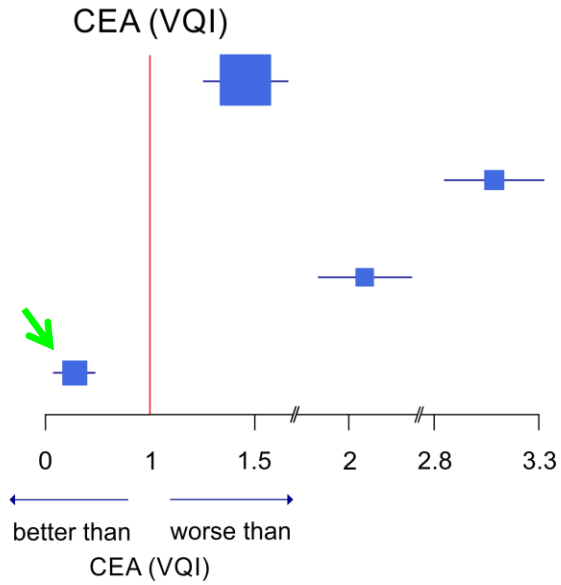
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 42	100%	1.30 [1.05−1.55]
Casper/RoadSaver	348 26	29.2%	2.75 [2.48−3.02]
Gore Mesh Stent	290 14	24.4%	0.94 [0.80−1.08]
CGuard MicroNET Stent	553 2	46.4%	0.16 [0.08−0.24]

Heterogeneity: I^2=84%, τ^2=0.0002, p<0.01



Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 42	100%	1.45 [1.25−1.65]
Casper/RoadSaver	348 26	29.2%	3.08 [2.84−3.32]
Gore Mesh Stent	290 14	24.4%	2.08 [1.85−2.31]
CGuard MicroNET Stent	553 2	46.4%	0.14 [0.04−0.24]

Heterogeneity: I^2=93%, τ^2=0.0002, p<0.01



New Technologies

A. Mazurek et al.

CARMEN Collaborators

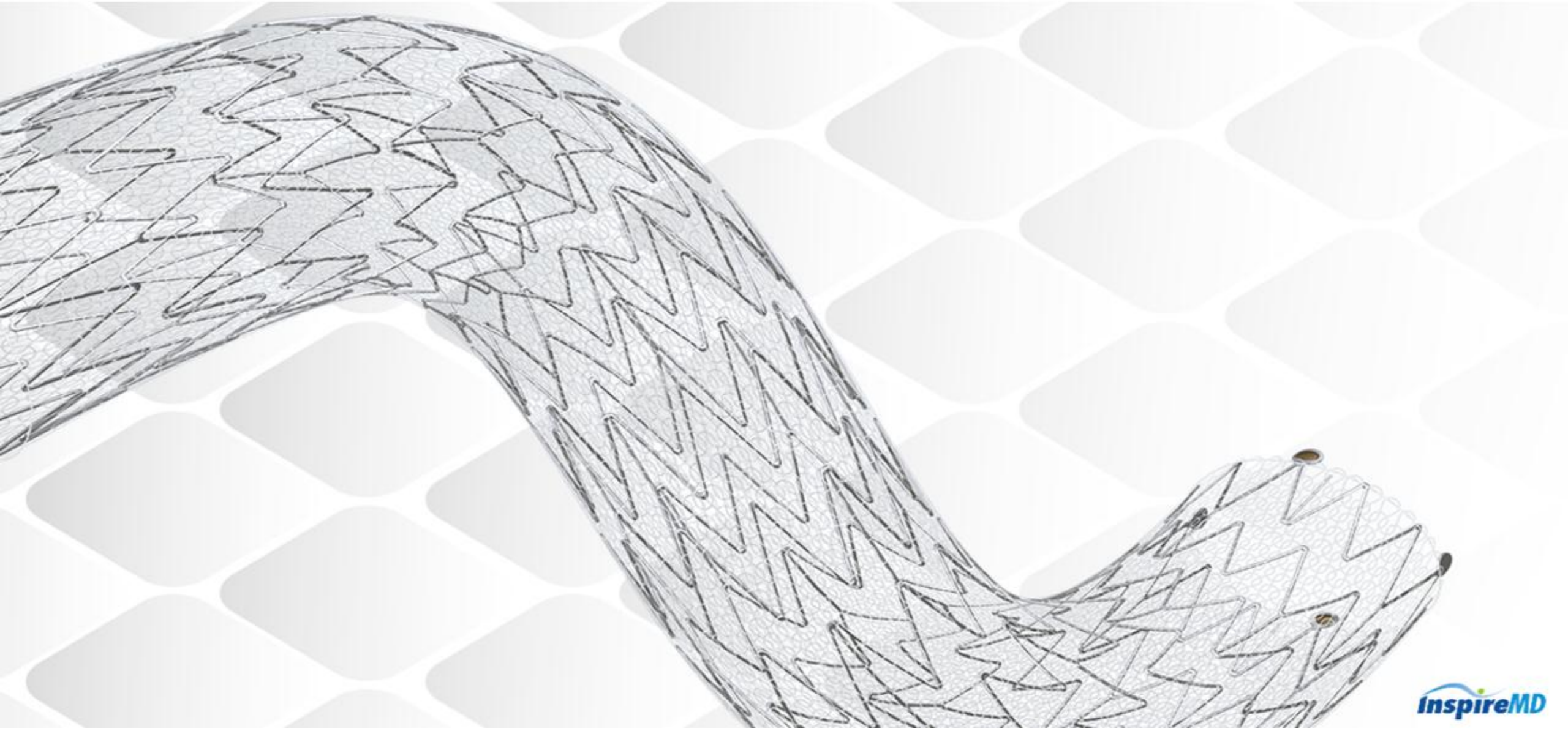
J Cardiovasc Surg 2023

FDA-IDE

FDA-IDE Clinical Trial:

CGUARDIANS

NCT 04900844



InspireMD

C-GUARDIANS Study Design	Prospective, multicenter, single- armed IDE Pivotal trial
Sample size/ Sites	316 Patients; 25 US and European Sites
Primary Endpoint	***Composite of death, stroke, MI (DSMI) at 30 days*** or ipsilateral stroke at 1 year
Sponsor	INSPIRE MD
Principal Investigator **Co- Principal Investigator**	D. Chris Metzger, MD Piotr Musialek, MD
Study Enrollment Period	July, 2021 to June, 2023 (23 months)
Monitor/ CRO	Hart Clinical Consultants

Patient Demographics

Characteristic	ITT (N = 316)
Age (mean ± SD)	69.0 ± 6.6
% Symptomatic	24.3%
% Male	63.9%
Diabetes Mellitus	41.8%
Hypertension	92.6%
Dyslipidemia	90%
CAD	52.1%
COPD	23.8%
Current Smoker	26.4%
PVD	28.6%

D Chris Metzger @ VIVA 2023

Embolic Protection Utilized

Emboshield NAV 6 Distal embolic protection	**261**
MoMA Proximal embolic protection	78
Both (Nav6 and MoMa)	24
None	1

D Chris Metzger @ VIVA 2023

C-GUARDIANS 30-day Results

ITT Analysis (N = 316)	Event rate in % (n)
Death, Stroke or MI*	0.95%(3)
Death#	0.32% (1)
Any stroke#	0.95% (3)
Major Stroke#	0.63% (2)
Minor Stroke#	0.32% (1)
MI	0.0% (0)
Death or any stroke*	0.95% (3)
Death or major stroke*	0.63% (2)

D Chris Metzger @ VIVA 2023

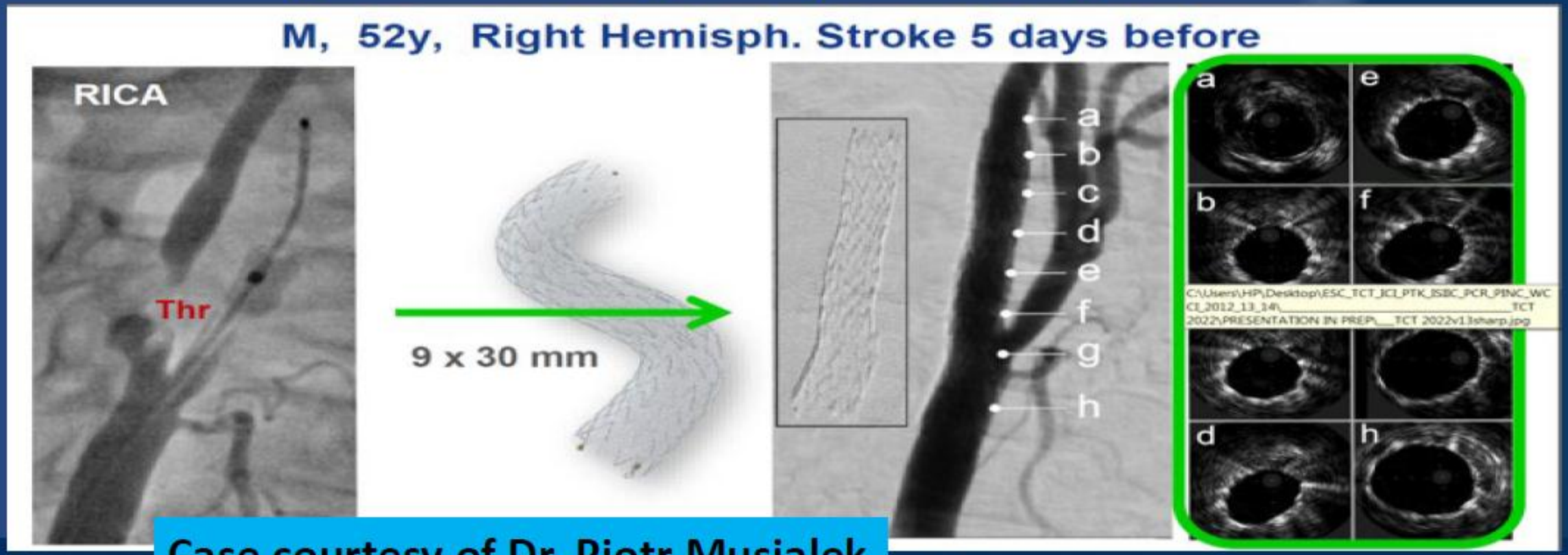
* Hierarchical: patient count (each patient first occurrence of the most serious event).

Non-hierarchical: event count (multiple events in each patient are counted individually).

New Technologies

P Musialek @ VEITH 2024

The CGuard Stent Combines the Conformability of Open Cell Design with the High Plaque Coverage of MicroNet™



Case courtesy of Dr. Piotr Musialek

IVUS

Designed to minimize plaque protrusion *during and after* the procedure

C-GUARDIANS Trial 1-Year Primary Endpoint Results

Event*	ITT	Per Protocol**
30-day DSMI + Ipsilateral stroke between 31 and 365 days	1.95 % (6) <2%	1.70% (5)
30-day DSMI	0.95% (3)	0.63% (2)
Ipsilateral stroke between 31 and 365 days	1.00% (3)	1.04% (3)
TLR	0.98% <1%	1.01% (3)

** Kaplan-Meier estimate for all 1-year endpoints*

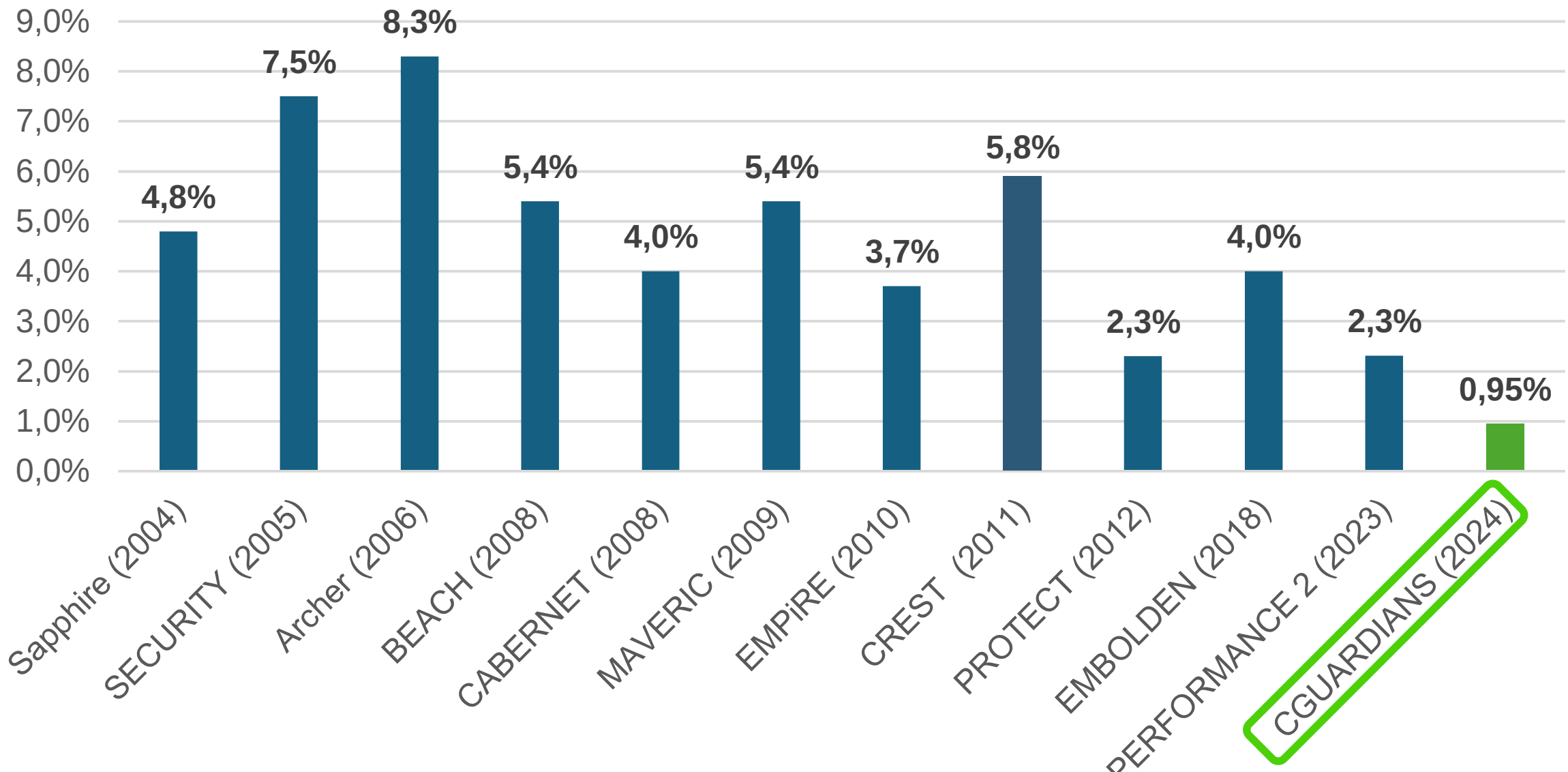
*** Per Protocol Analysis excludes 15 patients with Major Protocol Deviations*

The CEC independently adjudicated all neurological, cardiac events:

- *1 minor stroke (retinal) on POD 189.*
- *1 major stroke on POD 280: Prostatectomy (Antiplatelet therapy stopped).*
- *1 major stroke on POD 307: Stent patent; A Fib discovered.*

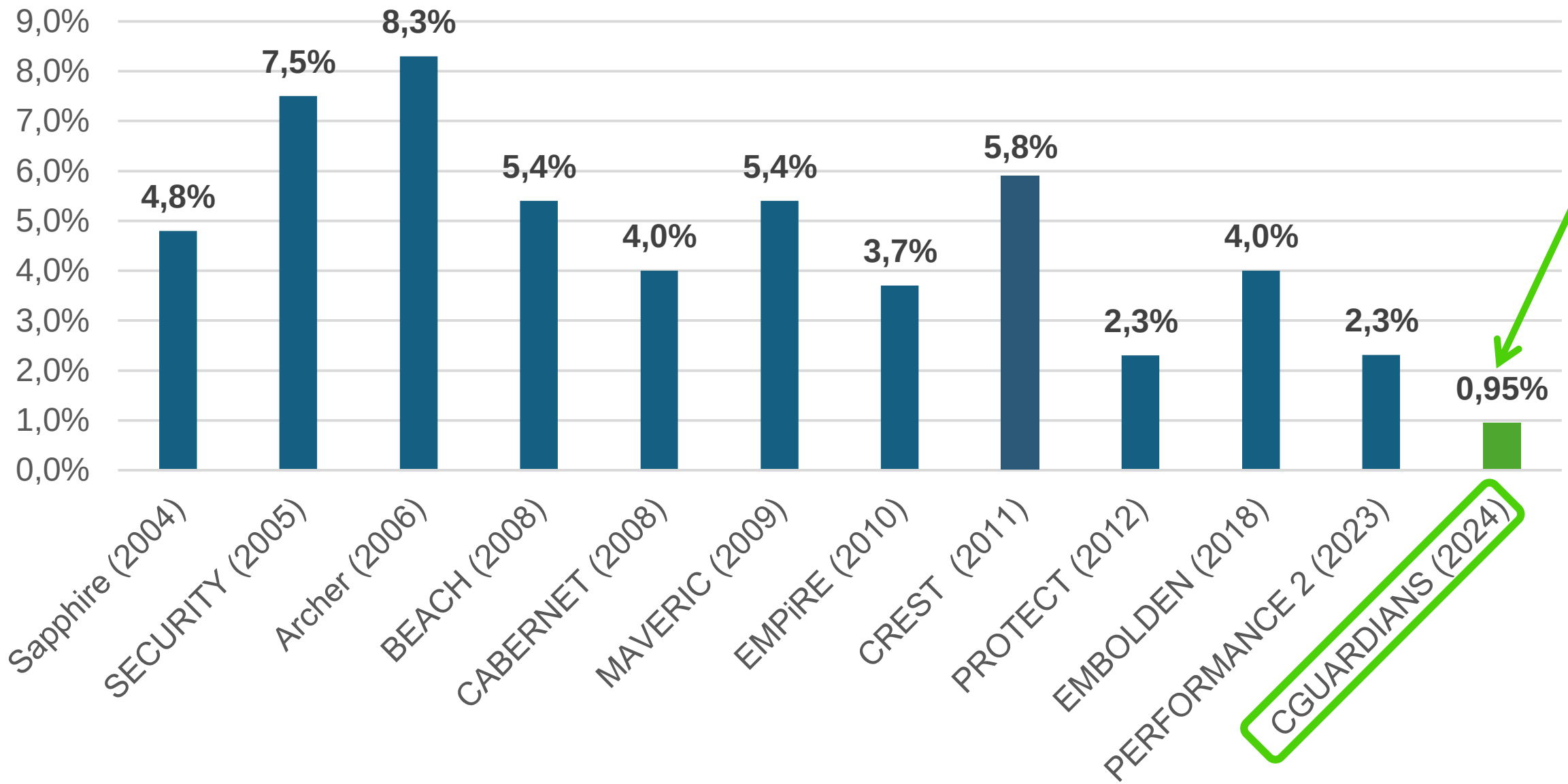
IDE Data in Context

30-day Death/Stroke/MI Rate in **Carotid FDA-IDE Trials**



*PERFORMANCE II Data based on VIVA 2023 Presentation

30-day Death/Stroke/MI Rate in **Carotid FDA-IDE Trials**



BEST Clinical Outcomes EVER !

*PERFORMANCE II Data based on VIVA 2023 Presentation

CGUARDIANS FDA-IDE CAS vs. ACST-2 CEA

30-day STROKE	0.95% vs. 2.4%
30-day Death/Stroke/MI	0.95% vs. 3.2%

p=0.029

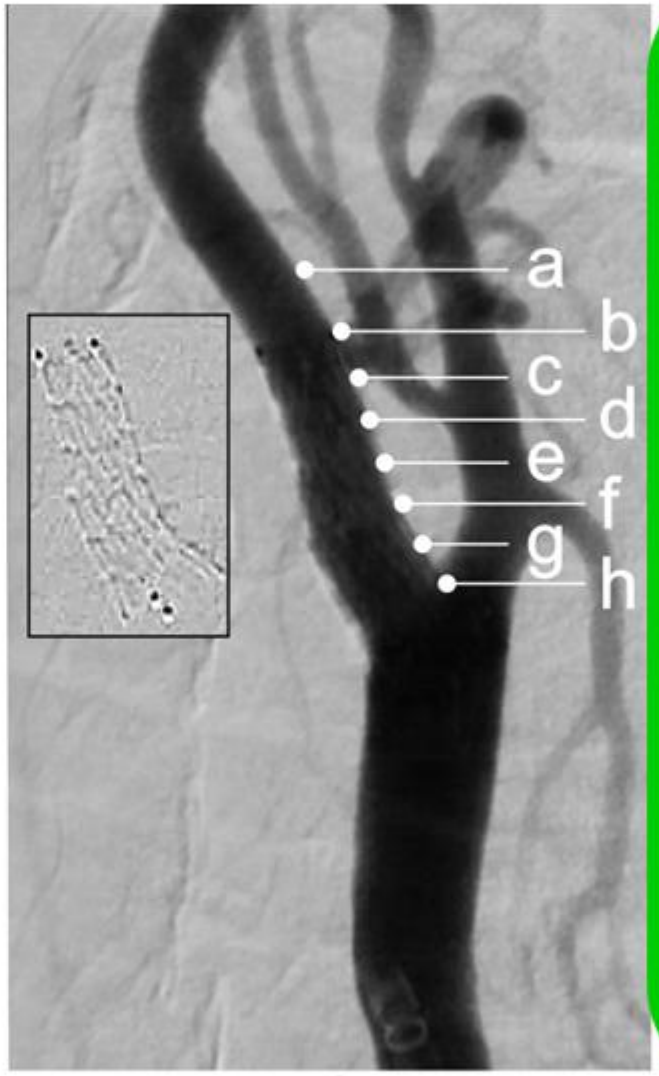
Metzger DC. (on behalf of CGUARDIANSFDA-IDE Trial Investigators). 30-Day Results From the C-Guardians Pivotal Trial of the CGuard Carotid Stent System. https://vivafoundation.org/
Halliday A, et al. Second asymptomatic carotid surgery trial (ACST-2): a randomised comparison of carotid artery stenting versus carotid endarterectomy. Lancet 2021;398:1065–73.

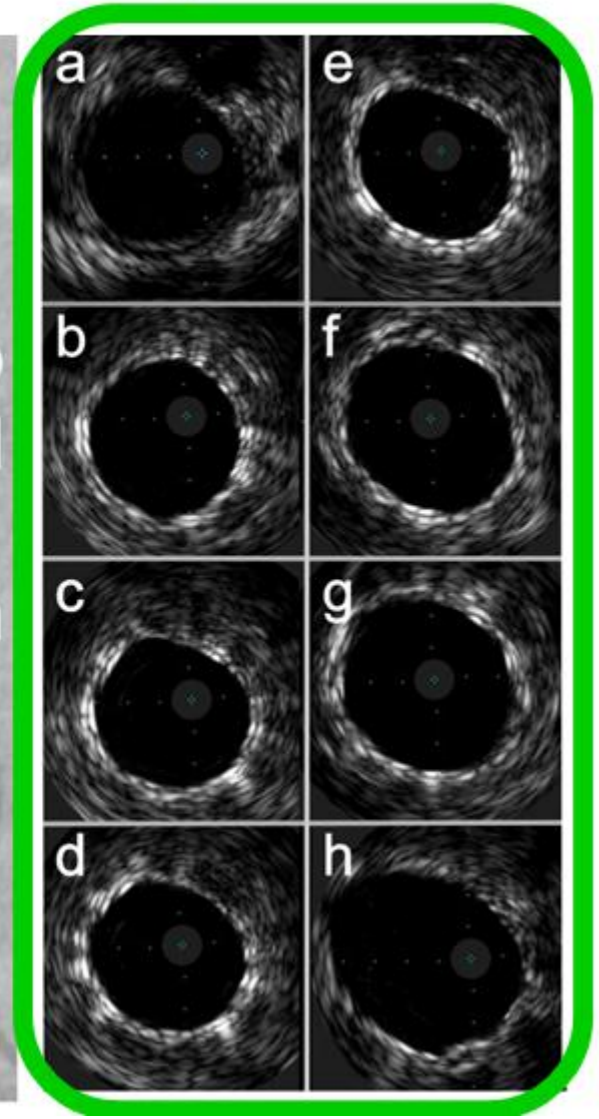
Transradial

Transradial *in* ***CGUARD OPTIMA*** *Trial* (NCT04234854)

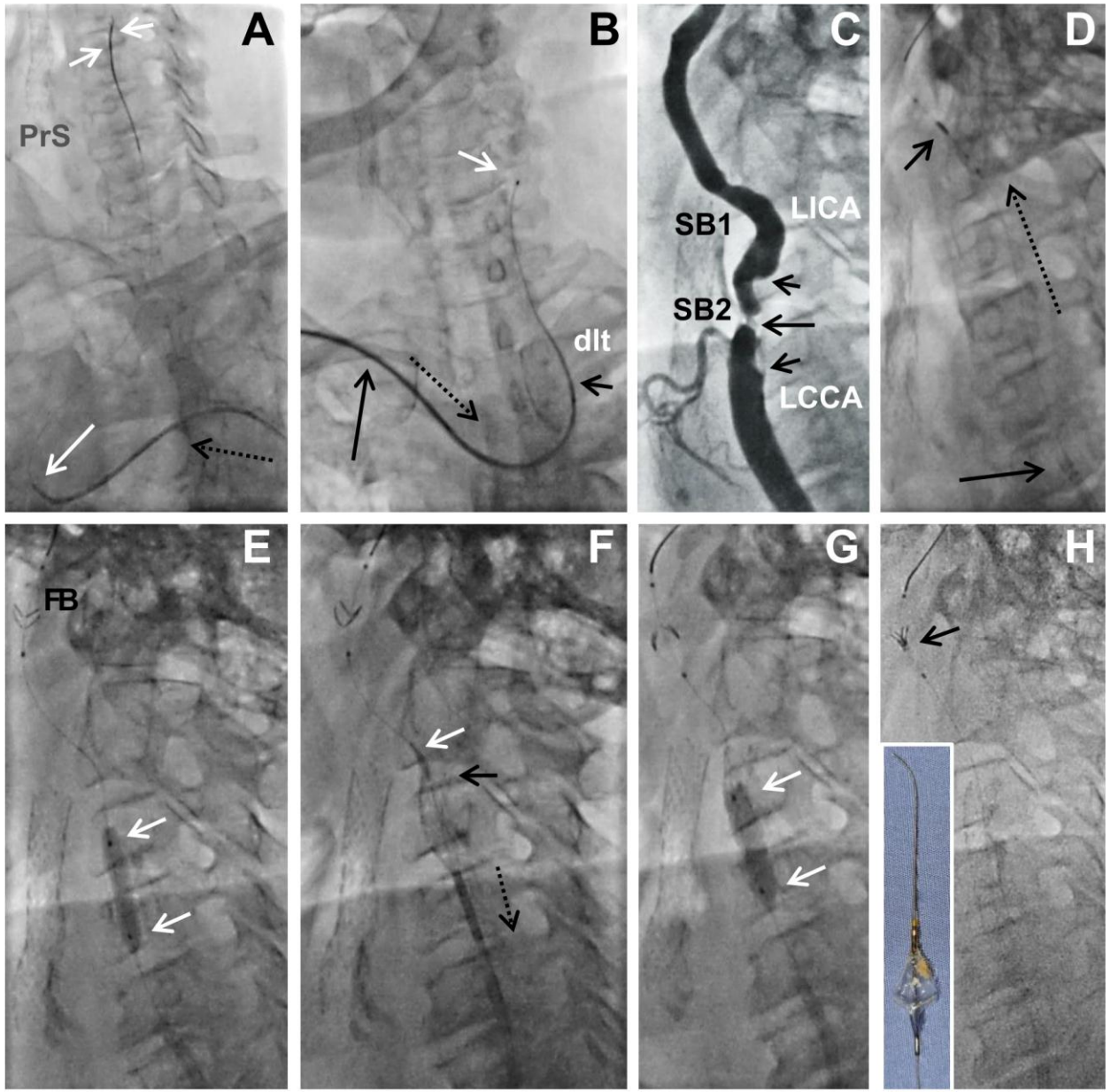
M, 71y, h/o larynx RadioTx, Leriche, 2 recent R hemisp Strokes

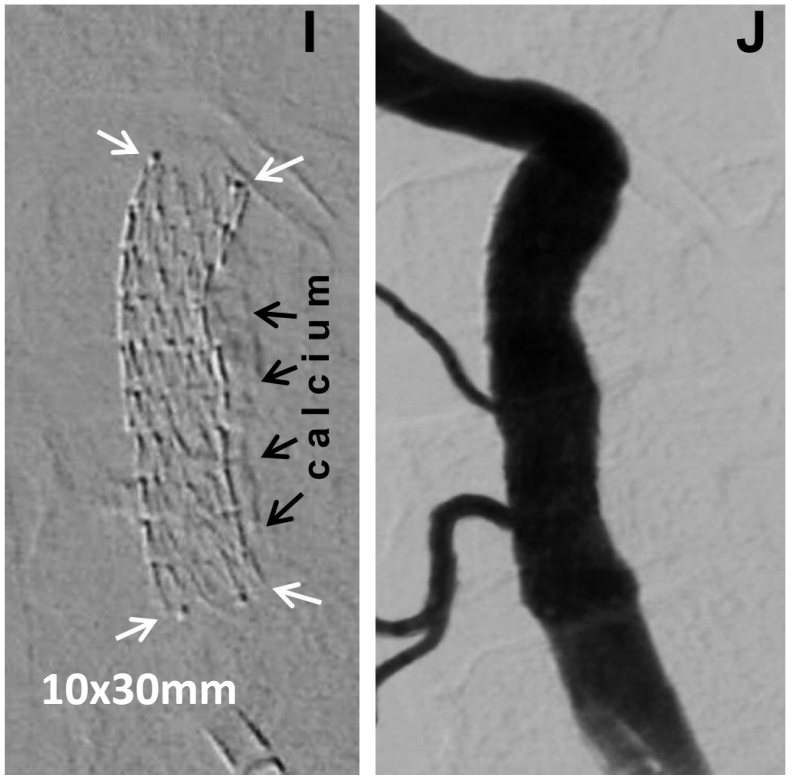
7.0 x 20 mm

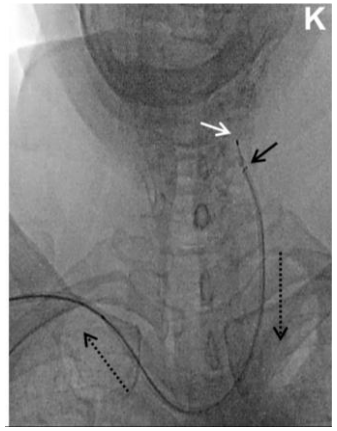




Transradial *in* ***PARADIGM-500*** (NCT04271033)

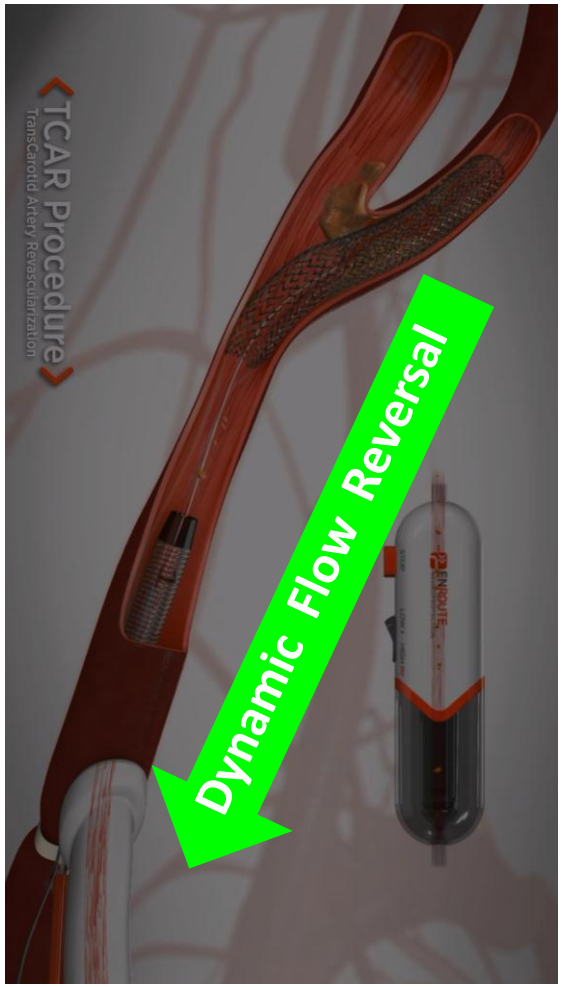






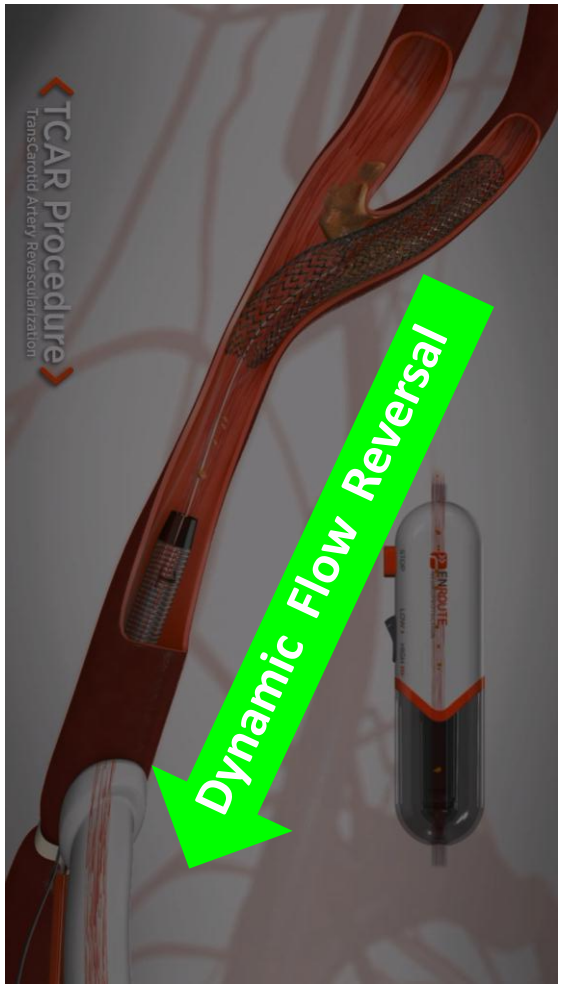
Trans-Carotid

TCAR



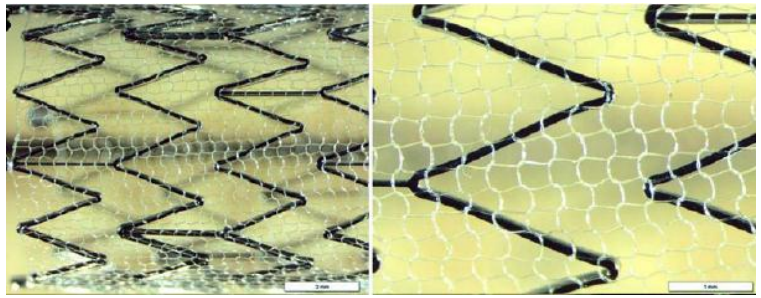
- efficient capture & removal of ***intra***-procedural debris

TCAR



- efficient capture & removal of ***intra***-procedural debris

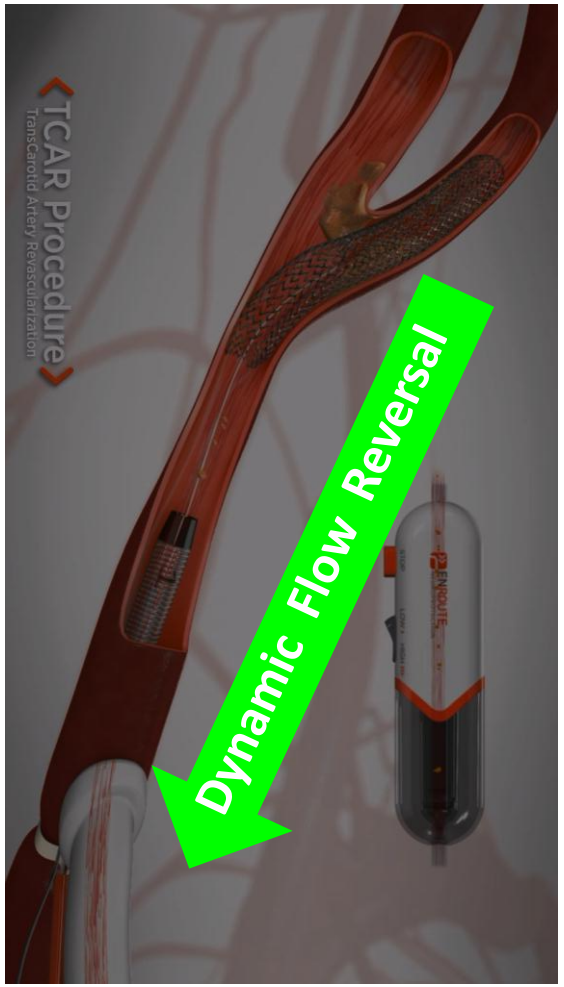
CGuard



Magnified image: C. Wissgott *J Endovasc Ther.* 2016

- less embolic material ***during*** CAS
- sustained anti-embolic ***after*** CAS

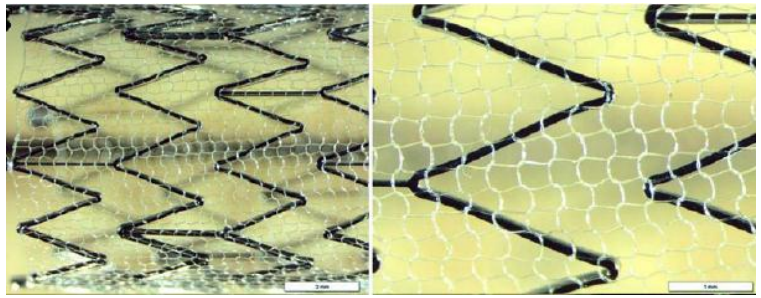
TCAR



- efficient capture & removal of ***intra***-procedural debris

CGuard

TOPGUARD



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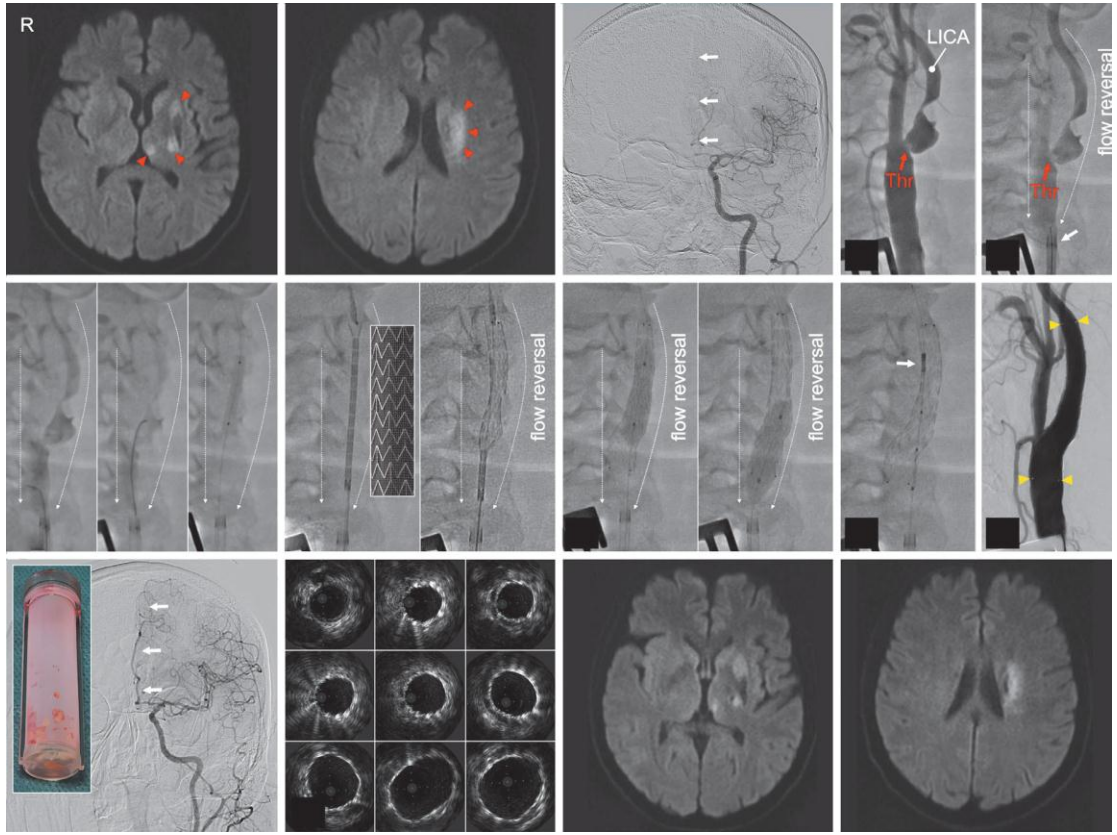
- less embolic material ***during*** CAS
- sustained anti-embolic ***after*** CAS

The Journal of Cardiovascular Surgery 2024 June;65(3):181-94
DOI: 10.23736/S0021-9509.24.13121-7

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

Next-generation transcarotid artery revascularization: TransCarotid flOw Reversal Cerebral Protection And CGUARD MicroNET-Covered Embolic Prevention Stent System To Reduce Strokes – TOPGUARD Study

Mariusz TRYSTULA [1], Isabelle VAN HERZEELE [2], Ralf KOLVENBACH [3], Lukasz TEKIELI [4, 5], Charlotte FONTEYNE [6], Adam MAZUREK [4, 5], Karolina DZIERWA [7], Jakub CHMIEL [4, 5], Julie LINDSAY [8], Tomasz KWIATKOWSKI [1], Adam HYDZIK [1], Maksymilian OPLAWSKI [1], Krzysztof BEDERSKI [9], Piotr MUSIALEK [4, 5] *



TCAR + CGUARD = TOPGUARD

(NCT04547387)

- **106 increased-risk patients / 3 centers**
- **60.4% symptomatic** / 49.1% diabetic

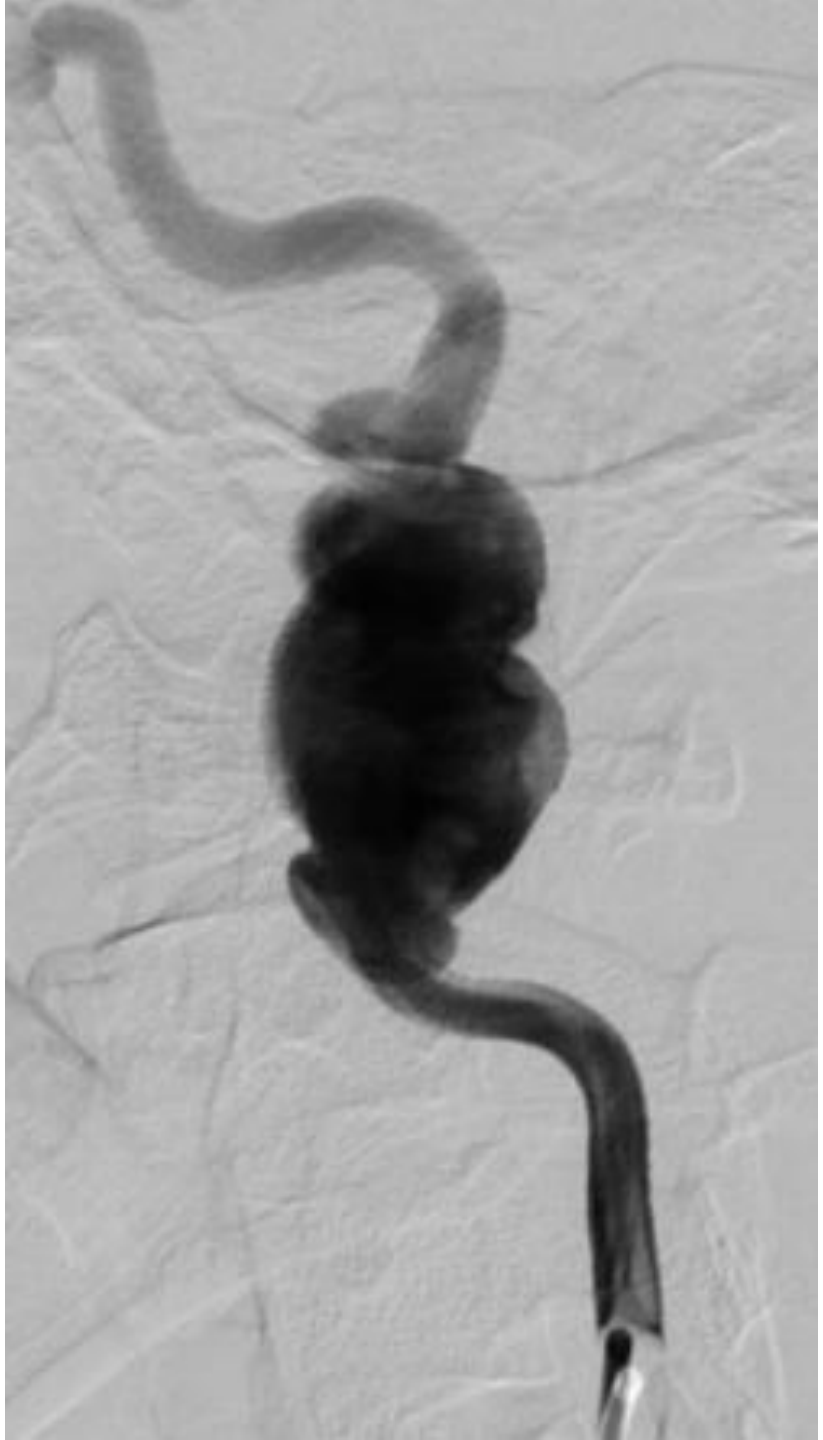
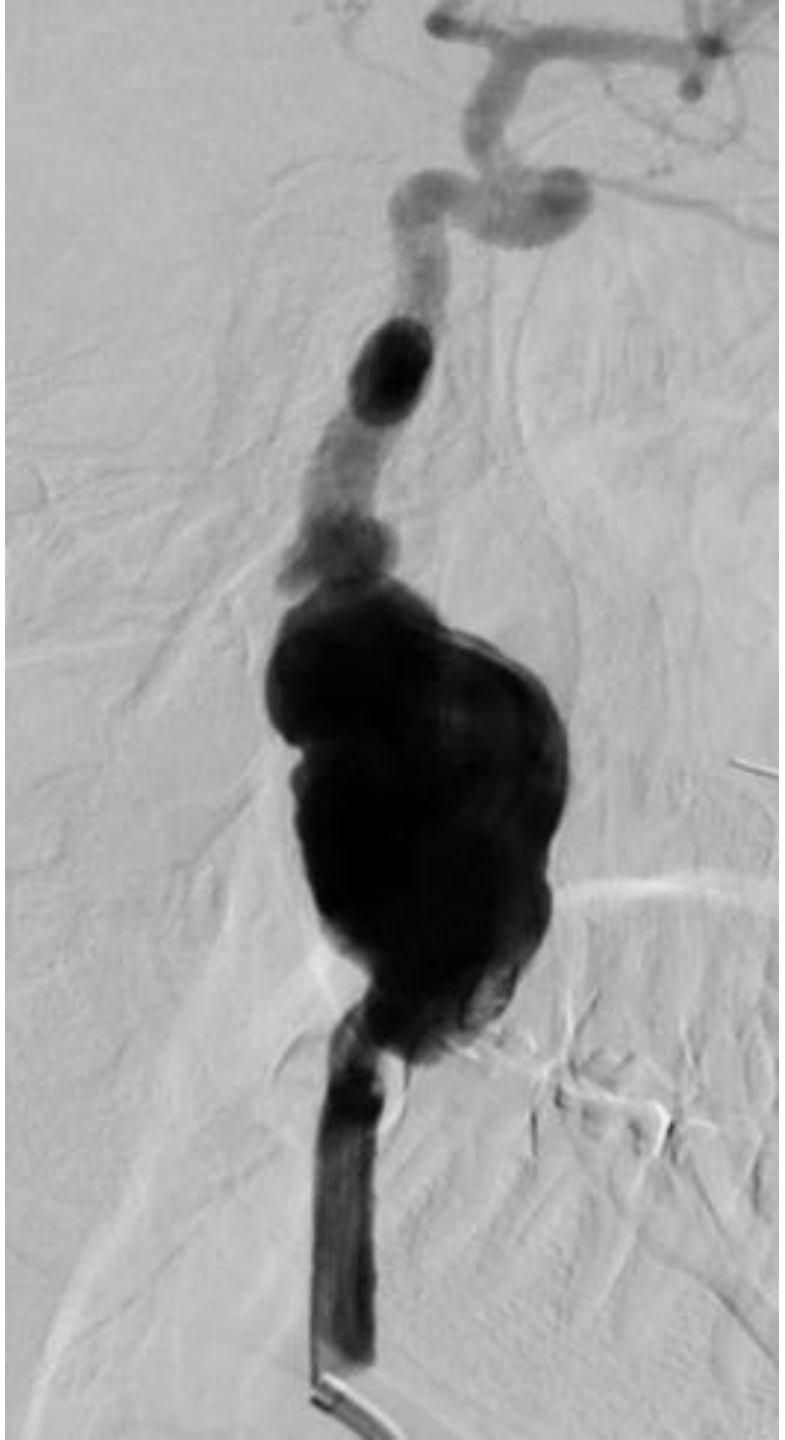
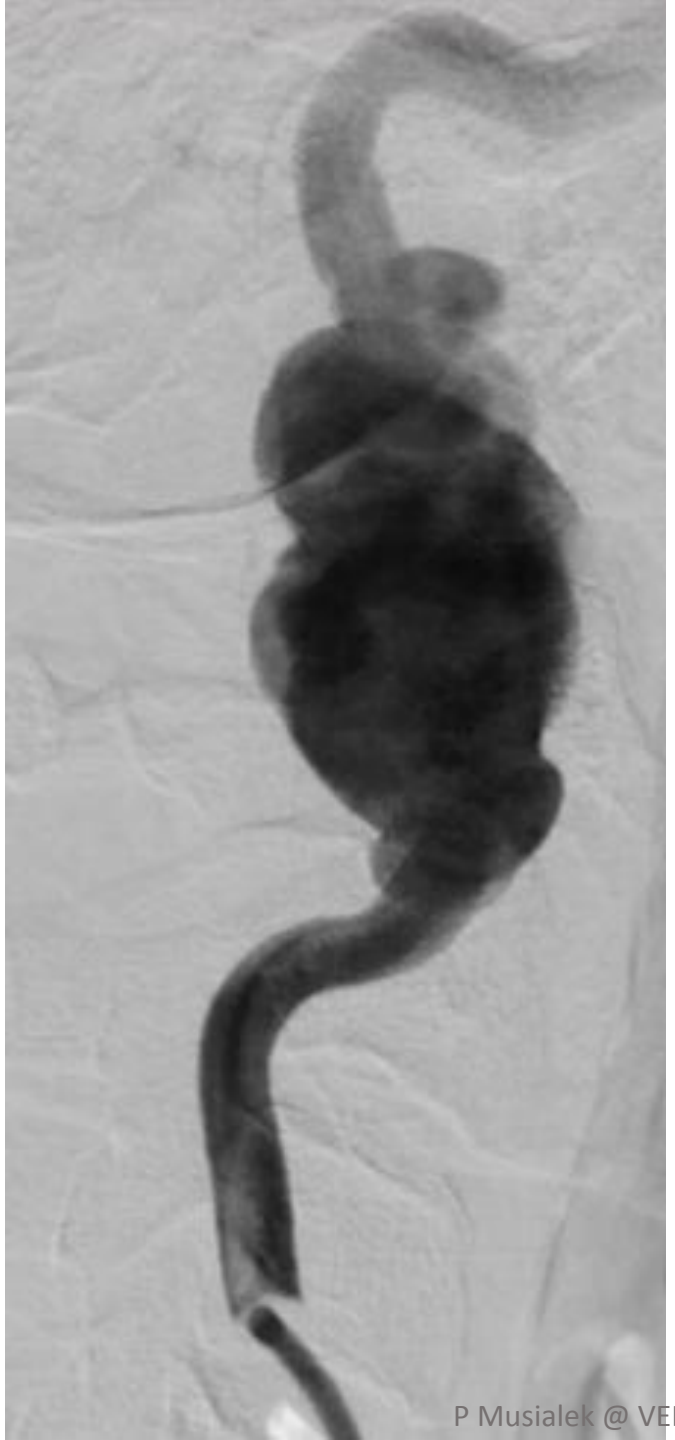
- **1 intra-procedural minor stroke (0.9%)** (prior to establihsed neuroprotection)
- <u>NO further clinical events by 30-d</u>; NO ST
- 100% stent patency @ 30-days
  - PSV 0.7 (0.62-0.83)m/s
  - EDV 0.2 (0.18-0.21) m/s

Trystula, Kolvenbach, Van Herzeele *et al.* *J Cardiovasc Surg* 2024;65:181-194.

Aneurysm Exclusion & Healing

43 yo Man, highly- symptomatic

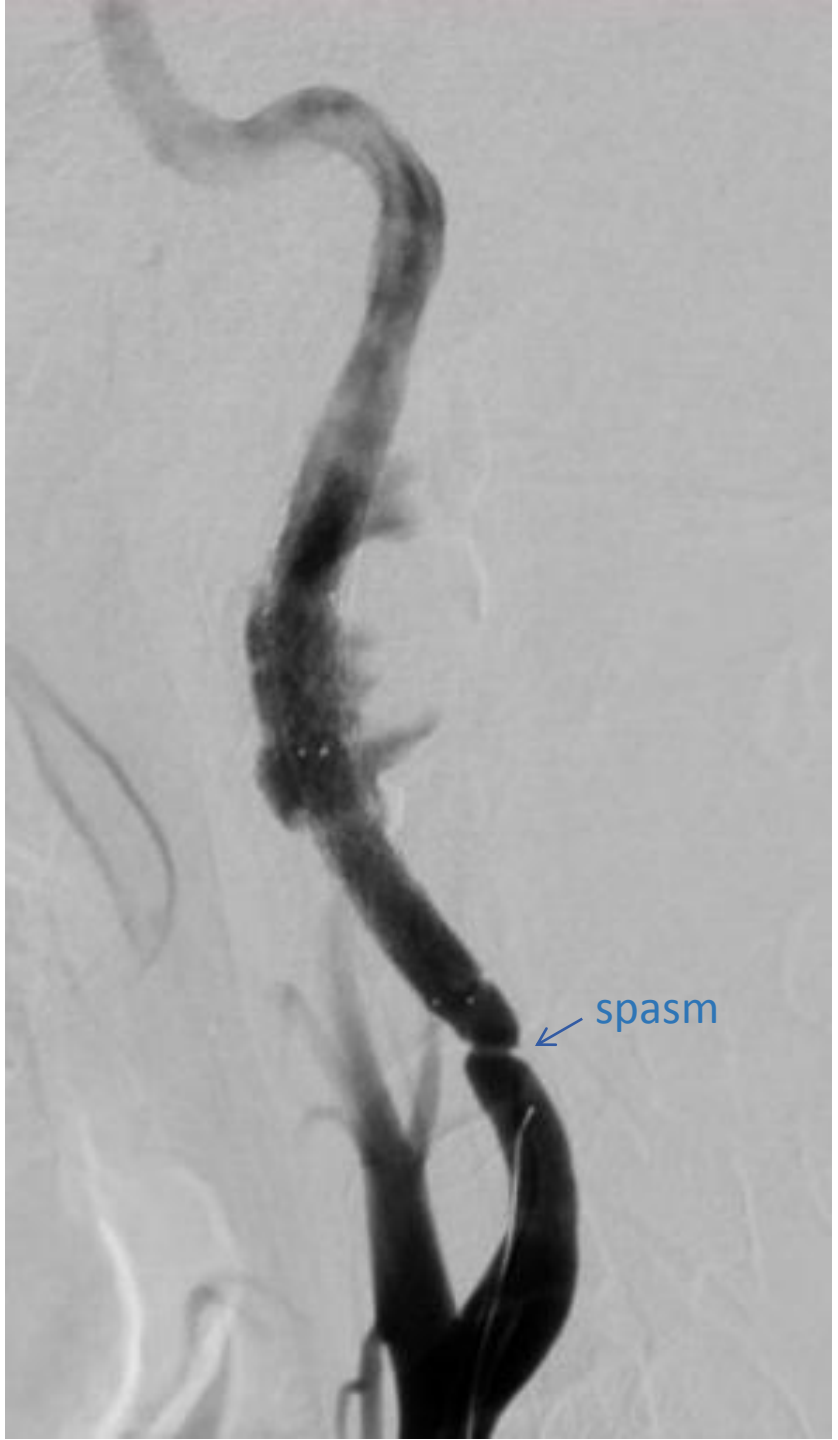
C-HEAL (NCT04434456)

C-HEAL

STUDY

NCT04434456



Immediate result

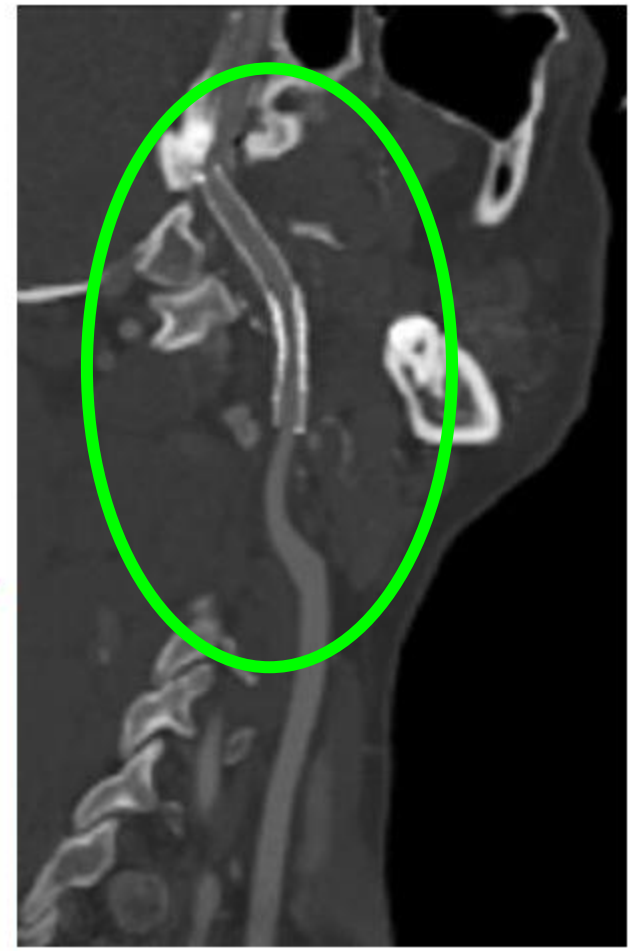
C-HEAL STUDY

VEITH SYMPOSIUM®
Connecting The Vascular Community

ANEURYSM
Total Exclusion
@ 72h

SPONTANEOUS HEALING

Reconstruction of NORMAL ANATOMY



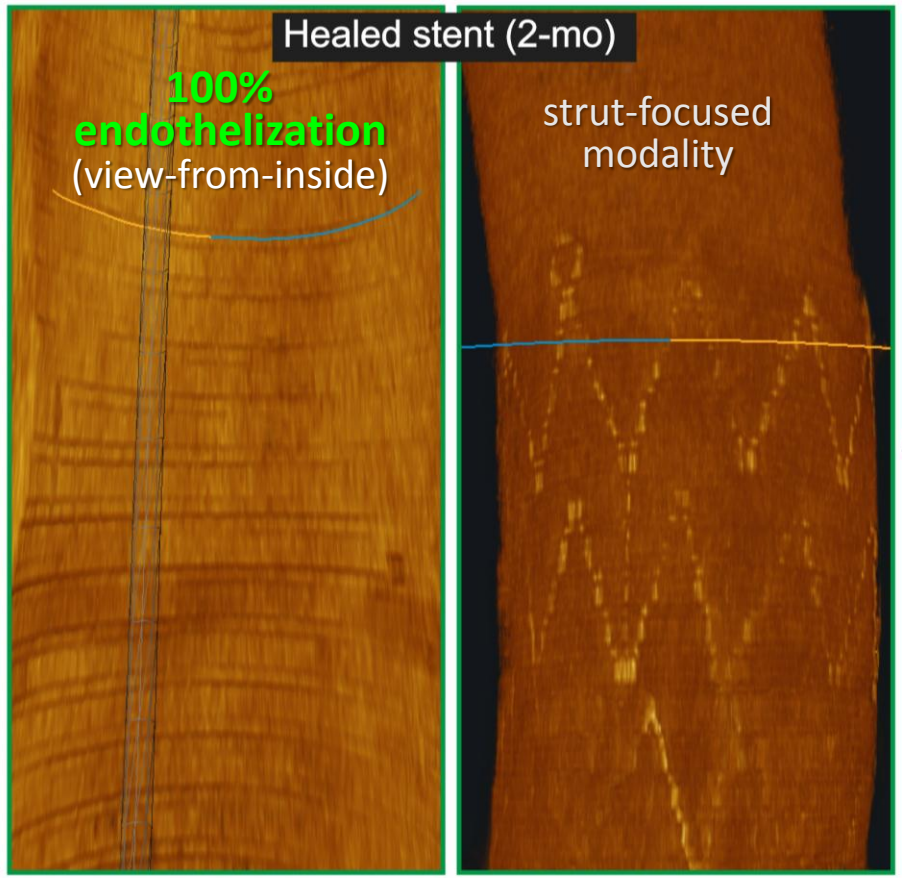
6-mo Follow-up

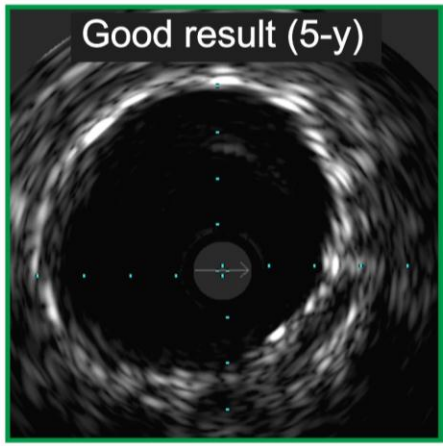
NCT04434456

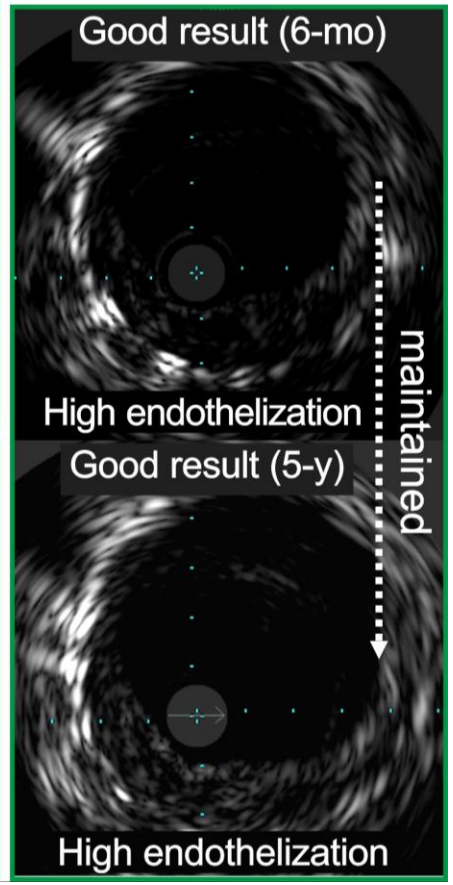
Patient CURED

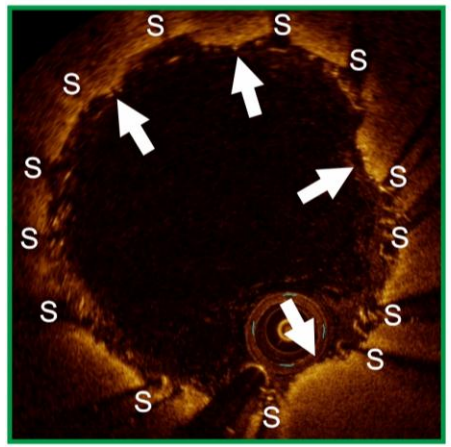
Advanced Imaging

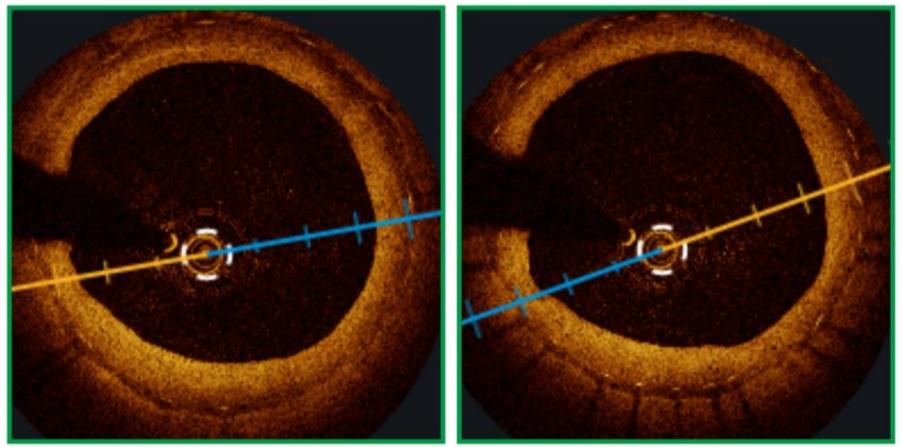
NORMAL healing











VEITH SYMPOSIUM®
Connecting The Vascular Community

Musialek, Tekieli, Umemoto ***JSCAI*** 2024 (in press)

Long-term outcomes

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

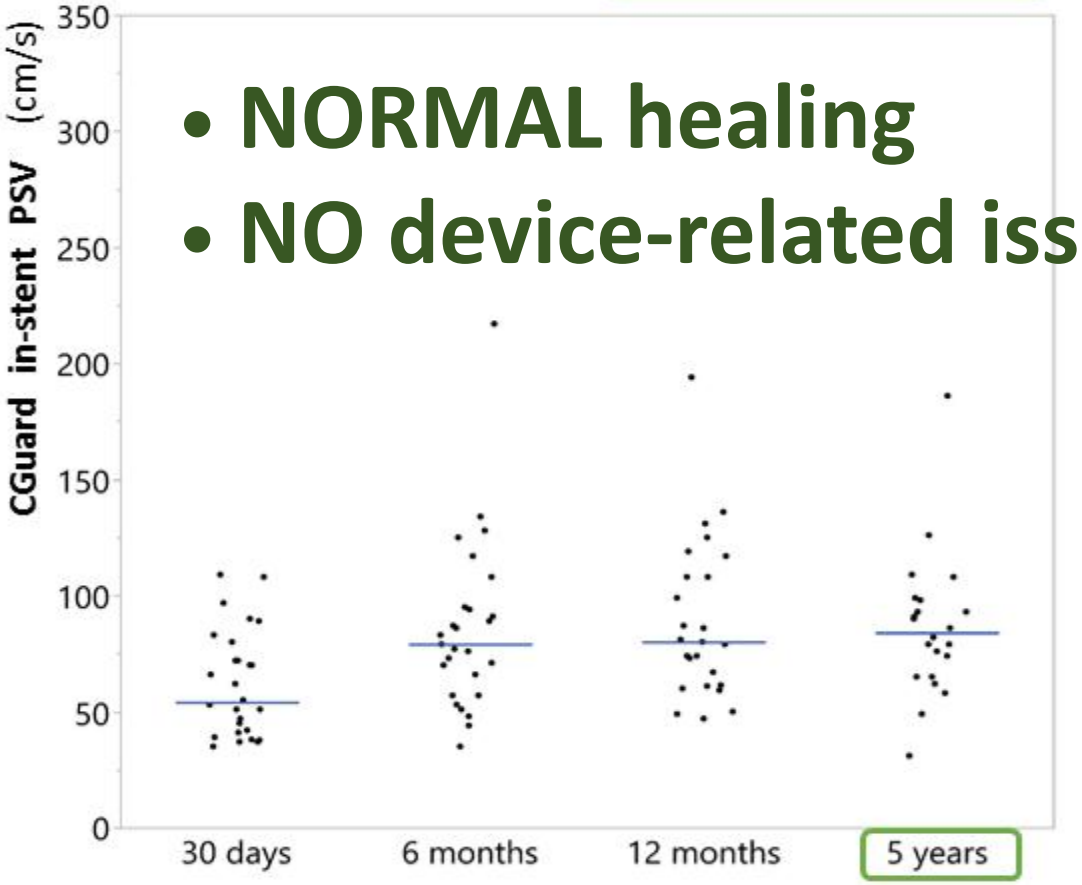
DW-MRI: prior to CAS, 48h post-procedure, and at 30 days

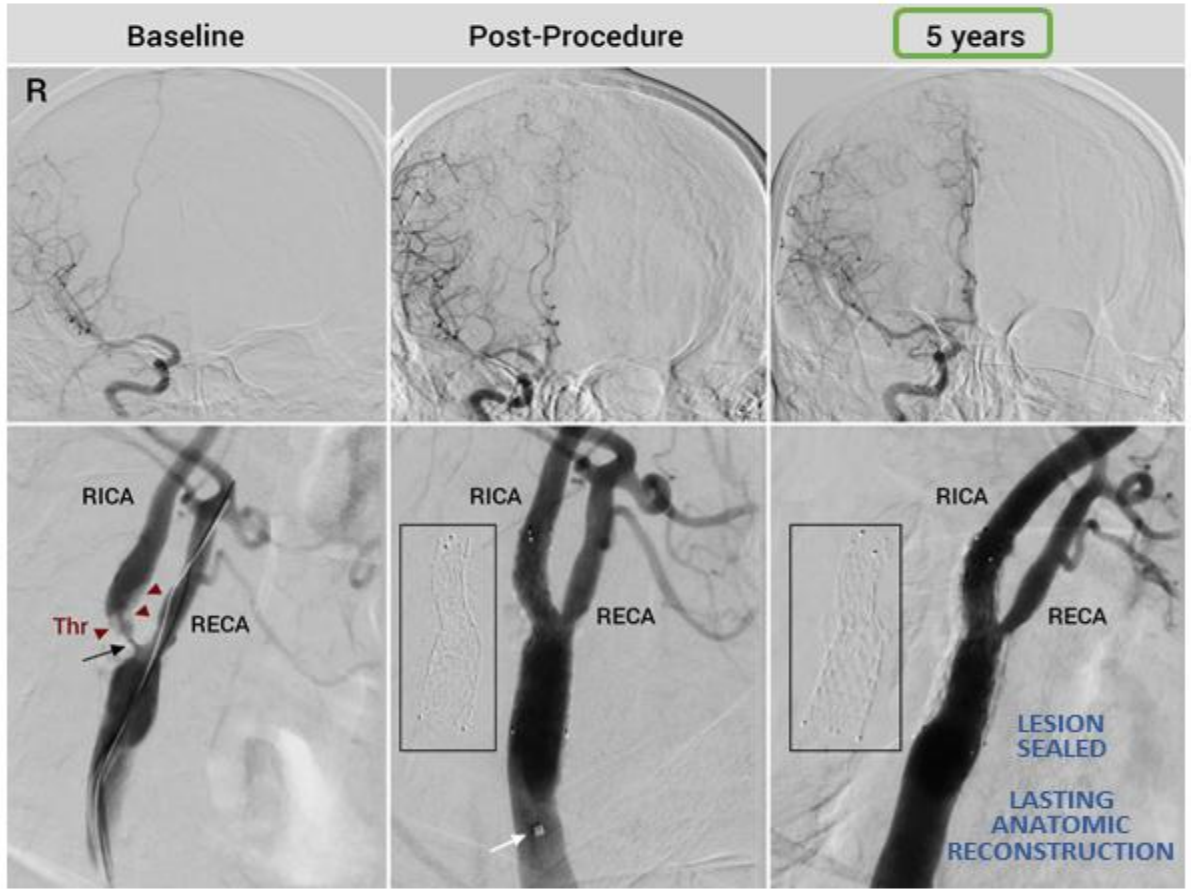
- minimized peri-procedural cerebral embolism
- eliminated post-procedural embolism *JACC Intv* 2015

CARENET: 5y data

JACC Intv 2022

- **NORMAL healing**
- **NO device-related issues**





Musialek…. Schofer *JACC Intv* 2022

Optimized Procedures

("Endovascular Reconstruction")

In-stent Restenosis

in PARADIGM-500

MicroNET-Covered Stent

with routine lesion prep.
& post-dilatation optimization

Mazurek et al. **PARADIGM–500: 12-month data**. (ISO 14155:2020 Standard; Externally monitored data /CRO) **2024** *manuscript in preparation*)

In-stent Restenosis

in PARADIGM-500

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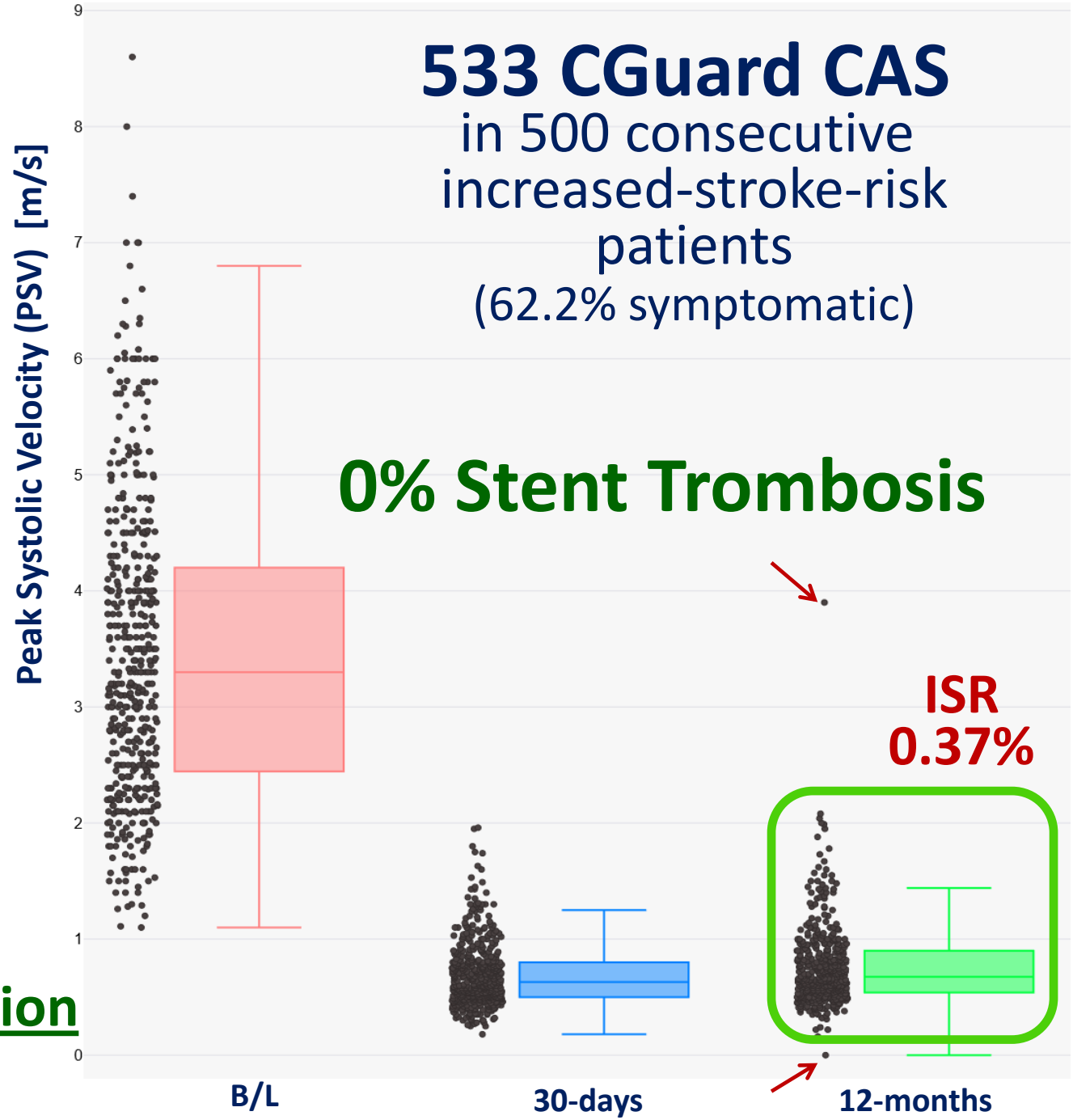


Mazurek et al. **PARADIGM–500: 12-month data**. (ISO 14155:2020 Standard; Externally monitored data /CRO) **2024** *manuscript in preparation*)

P Musialek @ VEITH 2024

Carotid Lesion Management in PARADIGM-500

PREDILATATION

CGuard

Balloon Pre-dilatation performed	N=533	
No (direct)	73	13.70%
Yes	460	86.30%
Balloon Pre-dilatation peak diameter (mm)		
3	0.56%	(3/533)
3.5	39.40%	(210/533)
4	39.77%	(212/533)
4.5	4.88%	(26/533)
5	1.13%	(6/533)
5.5	0.38%	(2/533)
6	0.19%	(1/533)

84.05% (3.5 + 4 + 4.5)

Mazurek et al. **PARADIGM–500: 12-month data**. (ISO 14155:2020 Standard; Externally monitored data /CRO) **2024** *manuscript in preparation*)

Carotid Lesion Management in PARADIGM-500

POSTDILATATION

CGuard

Balloon Post-dilatation performed		N=533	
	No	0	
	Yes	533	
Balloon Post-dilatation diameter (mm)			
	4.5	9.57%	(51/533)
	5	31.52%	(168/533)
	5.5	33.02%	(176/533)
	6	17.45%	(93/533)
58.91%	6.5	3.00%	(16/533)
	7	4.13%	(22/533)
	8	1.31%	(7/533)

Mazurek et al. **PARADIGM–500: 12-month data**. (ISO 14155:2020 Standard; Externally monitored data /CRO) **2024** *manuscript in preparation*)

STROKE Treatment

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

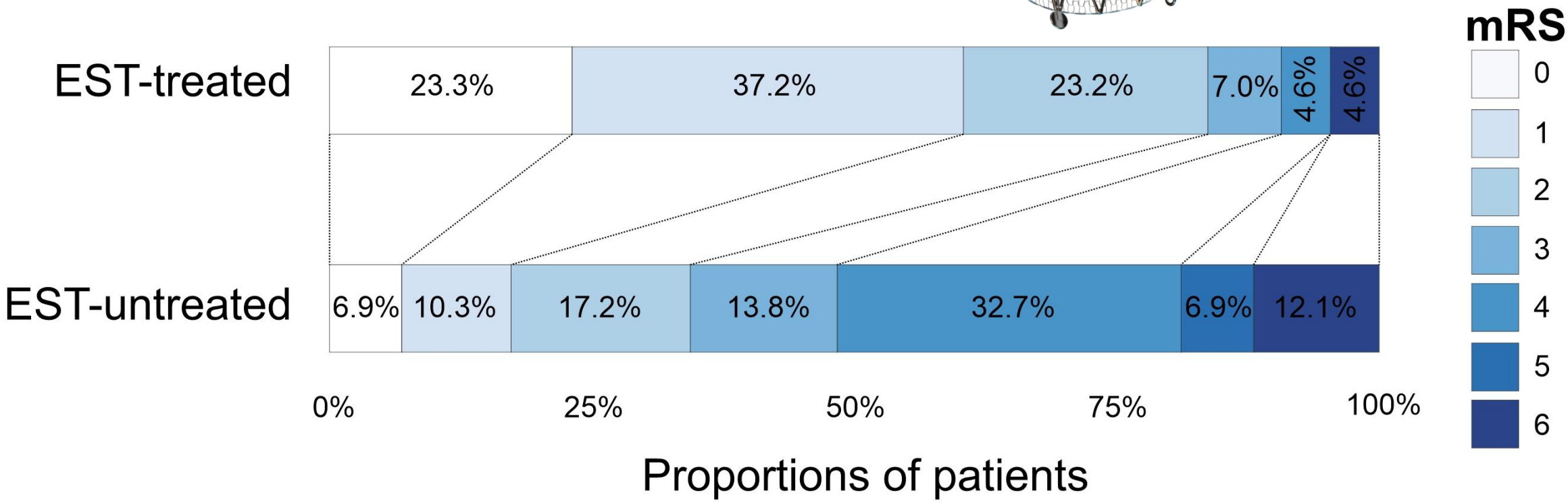
Lukasz Tekieli[#1-5], Andrey Afanasiev[#4], Maciej Mazgaj[#5], Vladimir Borodetsky[6], Kolja Sievert[7], Zoltan Ruzsa,[8] Magdalena Knapik[2,9], Audrius Širvinskas[4], Adam Mazurek[1,2], Karolina Dzierwa[10], Thomas Sanczuk[11], Valerija Mosenko[12], Malgorzata Urbanczyk-Zawadzka[13], Mariusz Trystula[14], Piotr Paluszek[1,14], Lukasz Wiewiorka[15], Justyna Stefaniak[15], Piotr Pieniazek[2,3,16], Inga Slautaitė[16], Tomasz Kwiatkowski[14],

Predictors of stent 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;20:248-254.

The MicroNET-Covered Stent in Acute Carotid-Related Stroke



L. Tekieli, et al. *J Cardiovasc Surg* 2024;65:231-248.
L. Tekieli et al. *Adv Interv Cardiol* 2024;20:248-254.

The Journal of Cardiovascular Surgery 2023 December;64(6):555-60
DOI: 10.23736/S0021-9509.23.12956-9

LATEST TECHNIQUES FOR CAROTID REVASCULARIZATION

Carotid stent as cerebral protector: the arrival of Godot

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With respect to clinical decision-making, it is important to understand that any historic data (such as data obtained using prior-generation devices that were unable to effectively isolate the atherosclerotic lesion material) need to be viewed as having, today, a mostly historical value.

The MicroNET-Covered Self-Expandable Stent

DOCUMENTED ADVANTAGES

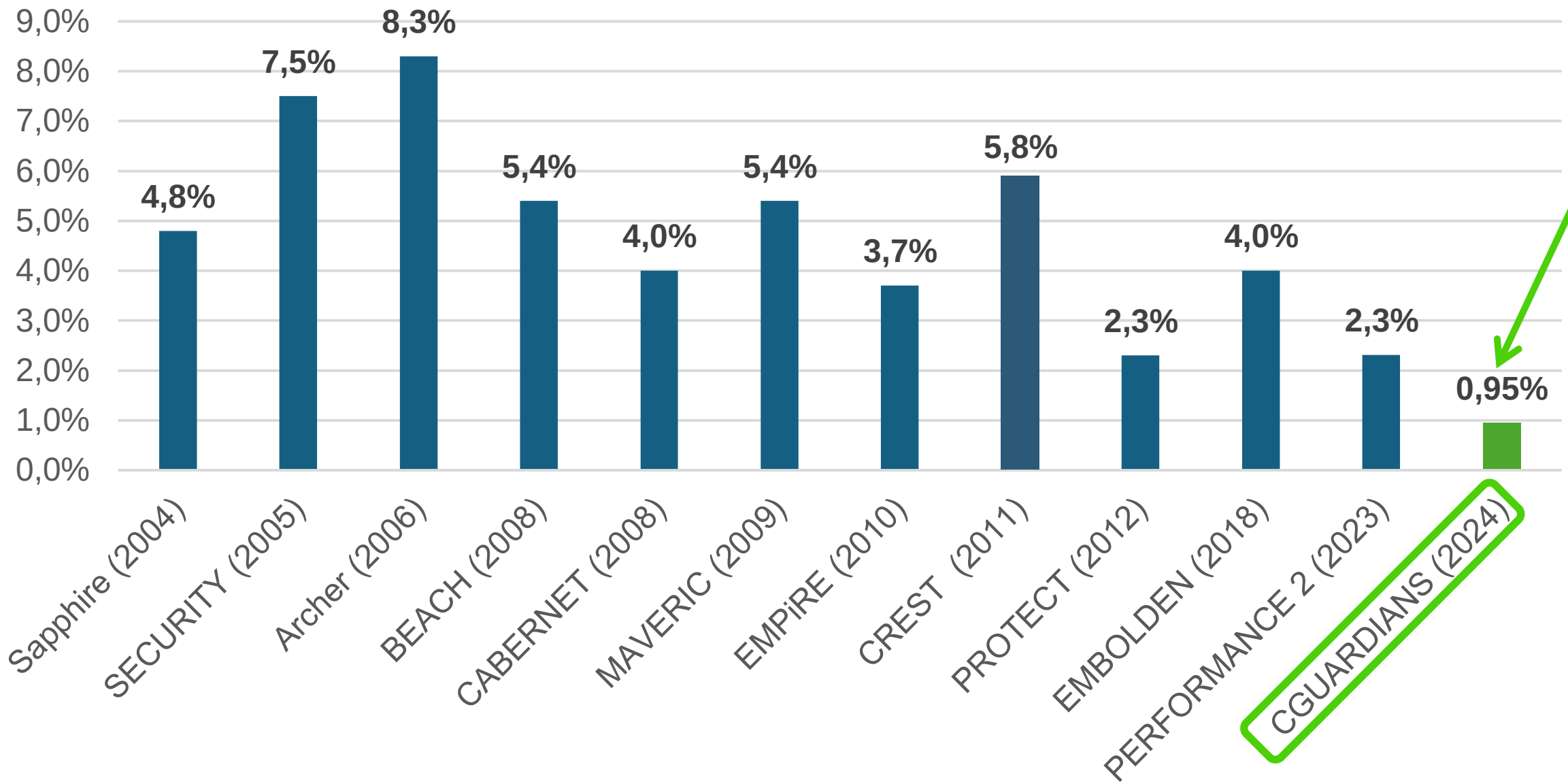
- PLAQUE/THROMBUS CONTROL
- CAN BE OPTIMIZED
- ABSENCE OF FORESHORTENING/ELONGATION
- PLACEMENT PRECISION FEASIBILITY
- SEALING PROPERTIES
- UNPRECEDENTED -AND HIGHLY CONSISTENT!- CLINICAL TRIAL DATA

The MicroNET-Covered Self-Expandable Stent

DOCUMENTED ADVANTAGES

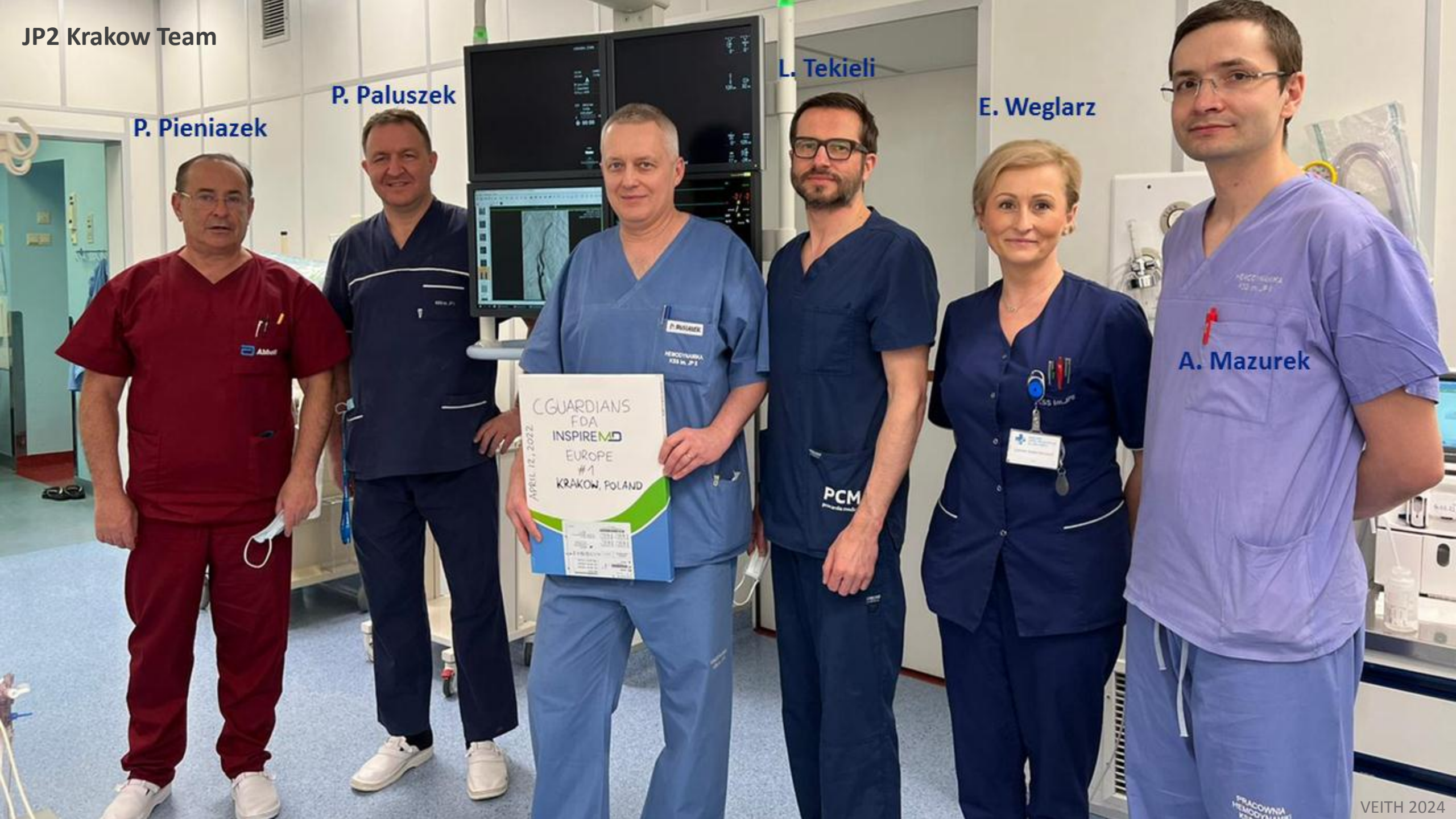
- **PLAQUE/THROMBUS CONTROL** (exclusion from the lumen + **Post-proc Protection**)
- **CAN BE OPTIMIZED** (zero-to-minimal residual stenosis; "**full reconstruction**")
- **ABSENCE OF FORESHORTENING/ELONGATION**
- **PLACEMENT PRECISION FEASIBILITY** (as with balloon-mounted stents)
- **SEALING PROPERTIES** (in absence of ↑ISR seen with fully covered stents)
- **UNPRECEDENTED -AND HIGHLY CONSISTENT!- CLINICAL TRIAL DATA**

30-day Death/Stroke/MI Rate in **Carotid FDA-IDE Trials**



BEST Clinical Outcomes EVER !

*PERFORMANCE II Data based on VIVA 2023 Presentation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CGuard MicroNET-Covered Anti-Embolic Stent

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