Carotid Anti-Embolic (’Mesh’) Stent:
Optimal Endovascular Therapy

Piotr Musialek

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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

☐ Employment in industry

☐ Stockholder in a healthcare company

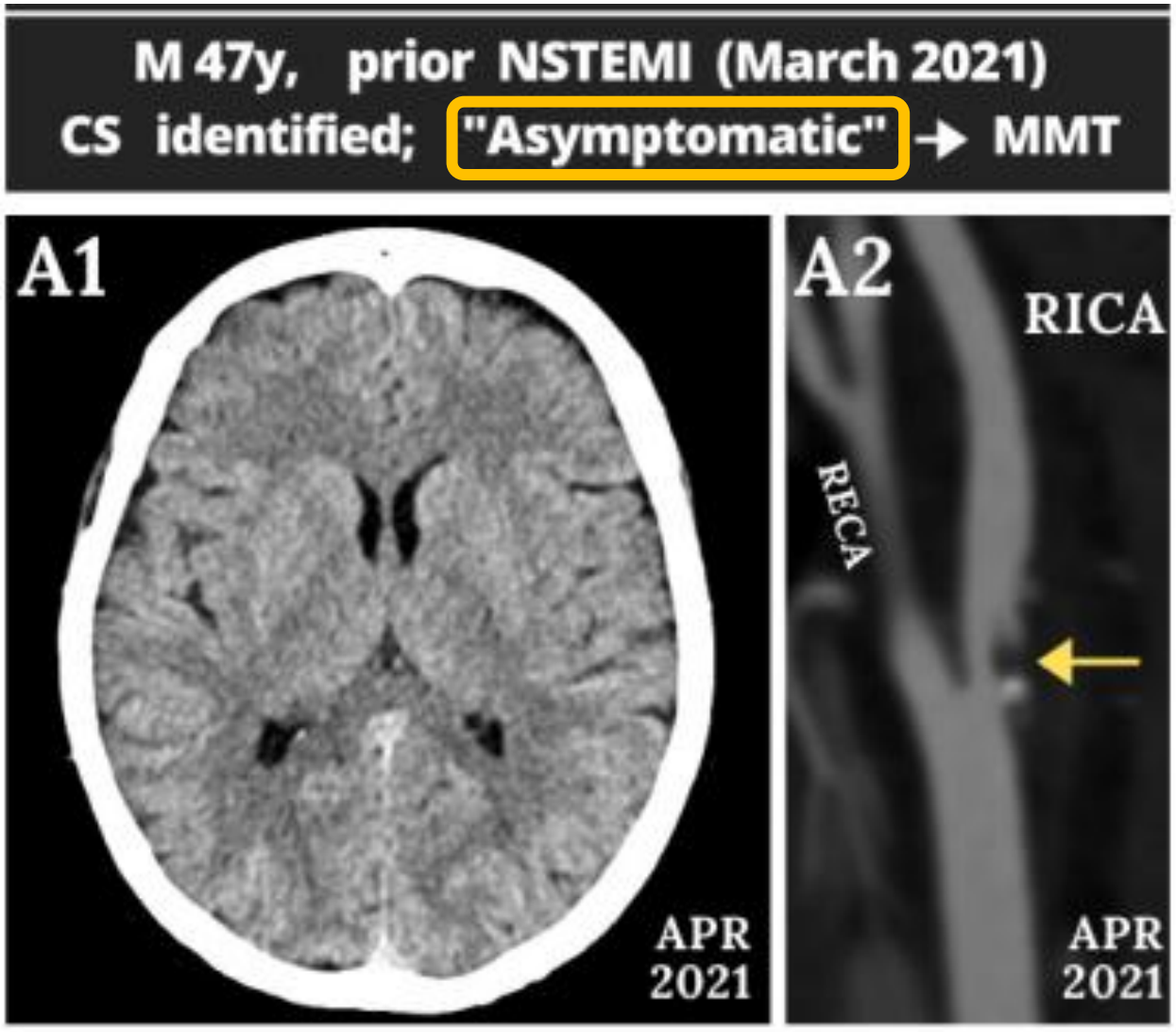
☐ Owner of a healthcare company

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

Thromb Haemost. 2022 Sep 28. doi: 10.1055/a-1952-1159. Online ahead of print.

Carotid Stenosis and Stroke: Medicines, Stents, Surgery - "Wait-and-See" or Protect?

Piotr Musialek [1], Kenneth Rosenfield [2], Adnan Siddiqui [3], Iris Q Grunwald [4]



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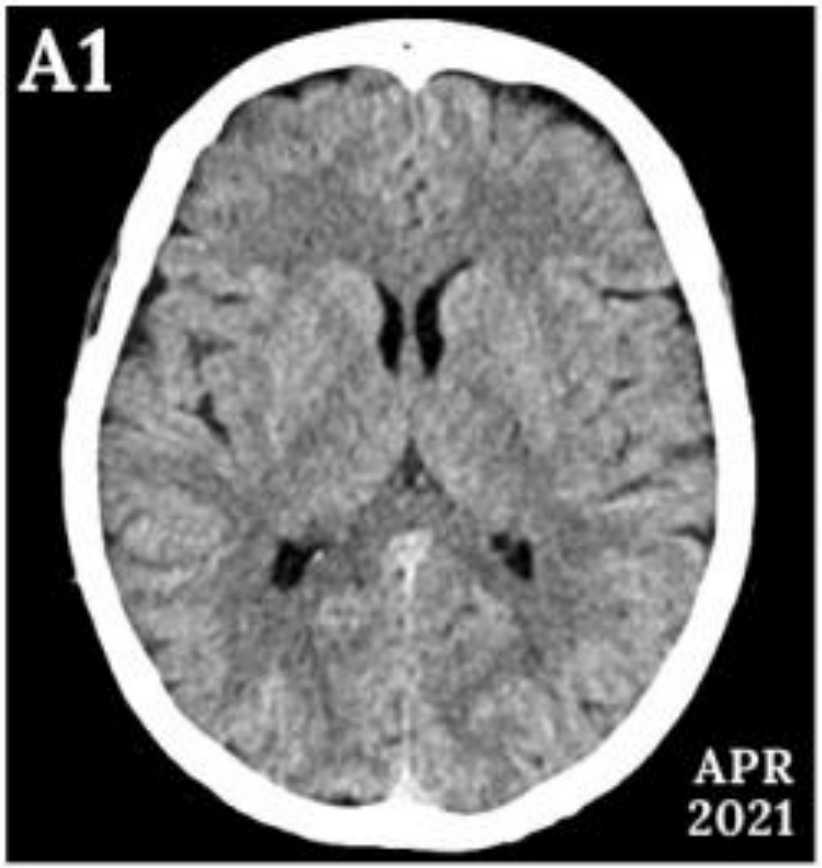
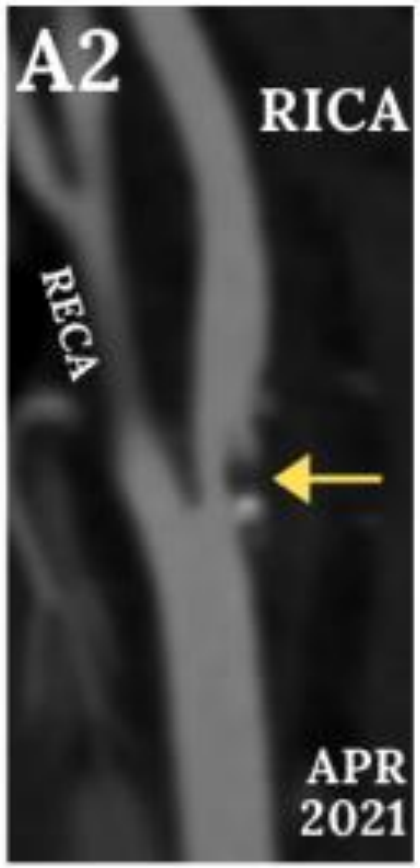
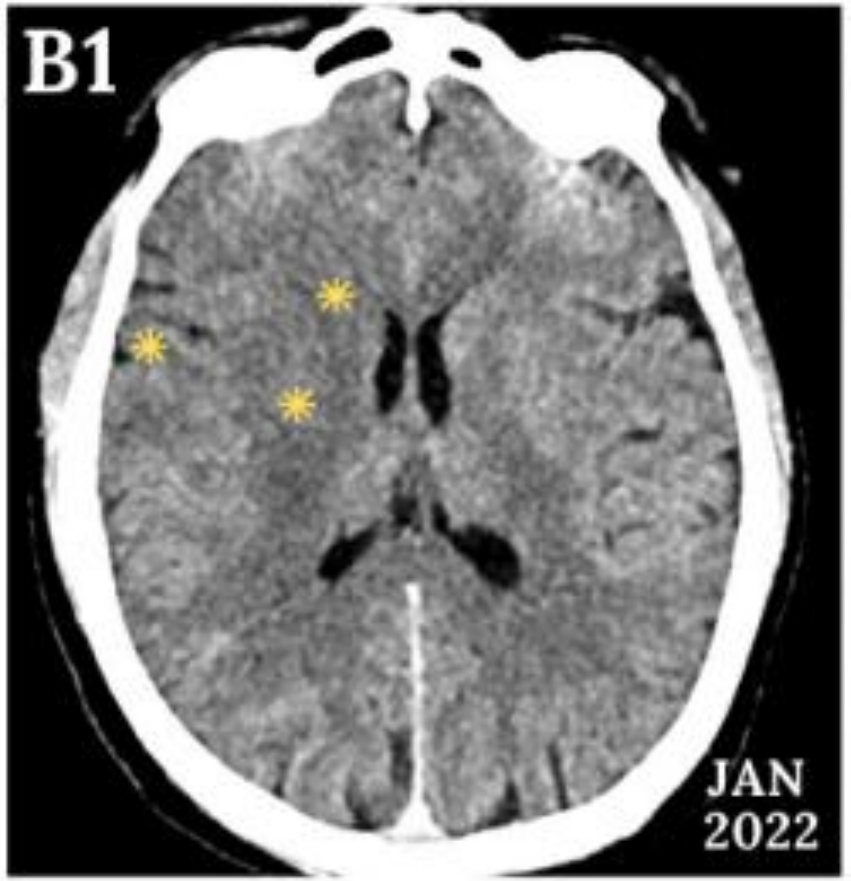
2024 Vilnius Vascular Symposium

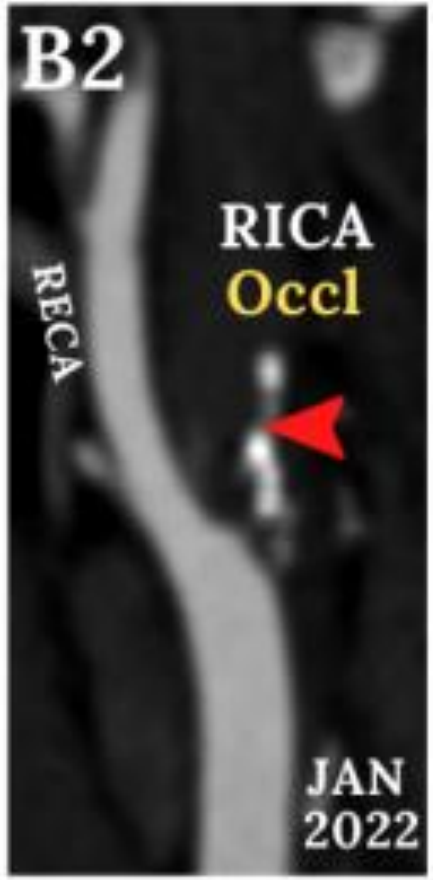
M 47y, prior NSTEMI (March 2021)
CS identified; "Asymptomatic" → MMT

SYMPTOMATIC









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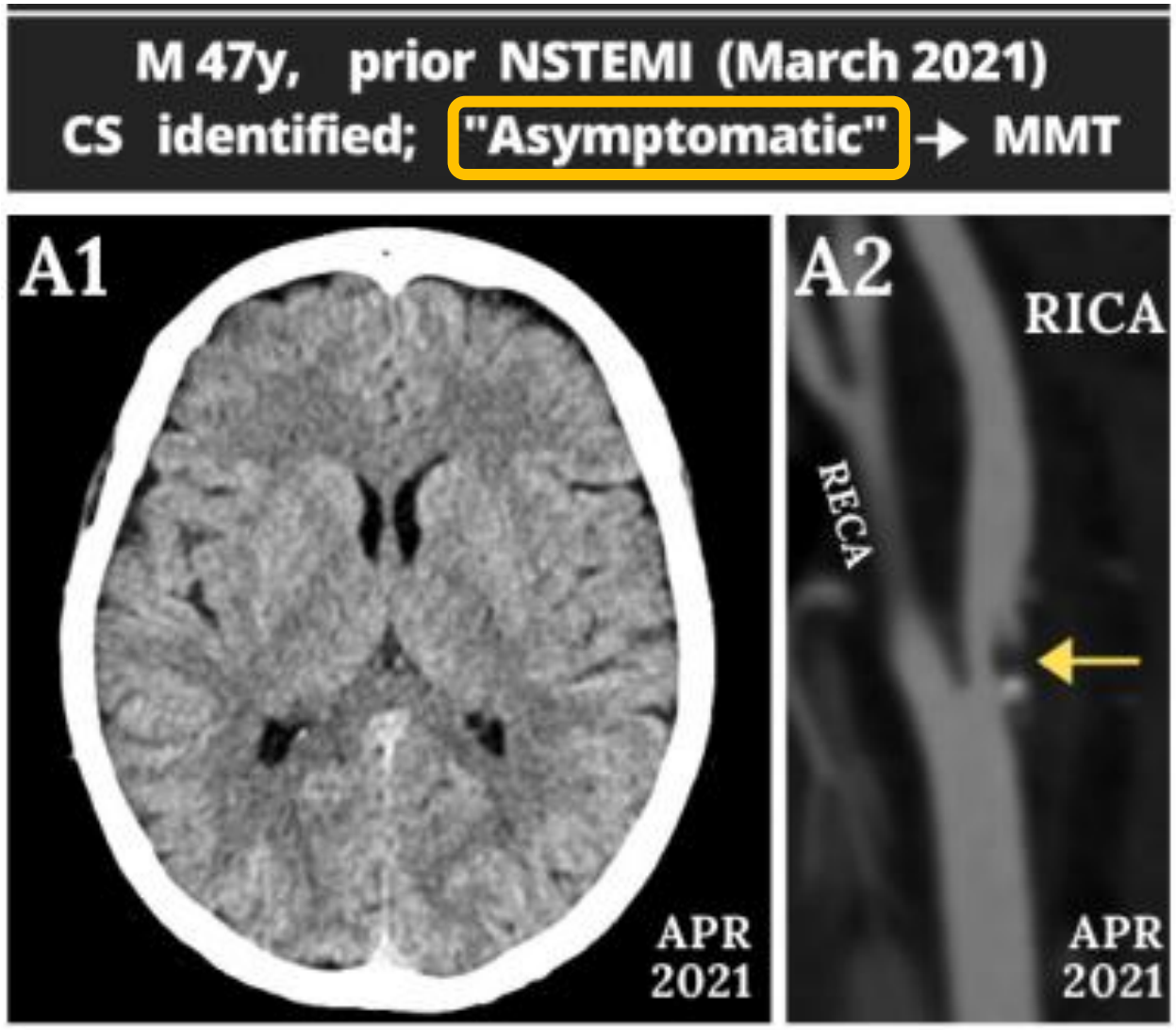


NOT a "benign" condition...

2024 Vilnius Vascular Symposium

Carotid-Related STROKES

Should be Prevented

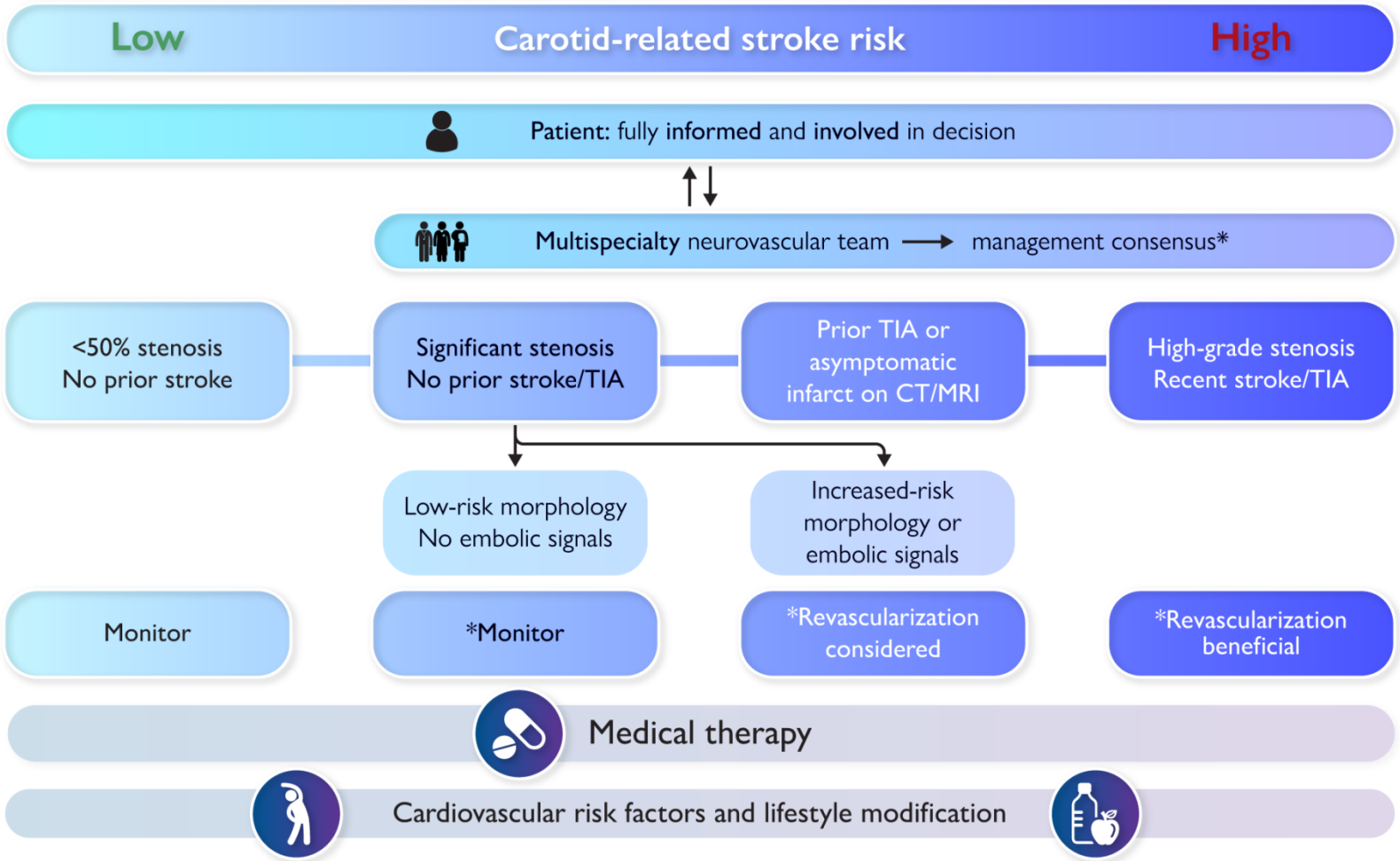
(**rather than experienced…**)

Cardiovasc Res. 2023 Aug 25:cvad135. doi: 10.1093/cvr/cvad135. Online ahead of print.

Stroke risk management in carotid atherosclerotic disease: A Clinical Consensus Statement of the ESC Council on Stroke and the ESC Working Group on Aorta and Peripheral Vascular Diseases

Piotr Musialek [1], Leo H Bonati [2], Richard Bulbulia [3 4], Alison Halliday [4], Birgit Bock [5], Laura Capoccia [6], Hans-Henning Eckstein [7], Iris Q Grunwald [8 9], Peck Lin Lip [10], Andre Monteiro [11], Kosmas I Paraskevas [12], Anna Podlasek [9 13], Barbara Rantner [14], Kenneth Rosenfield [15], Adnan H Siddiqui [16 17], Henrik Sillesen [18], Isabelle Van Herzeele [19], Tomasz J Guzik [20 21], Lucia Mazzolai [22], Victor Aboyans [23], Gregory Y H Lip [22]

ESC Stroke Council CONSENSUS Document



*Taking into consideration patient-specific factors such as:
life expectancy, co-morbidities and patient-specific stroke risk modifiers (e.g. family history of stroke, diabetes)

Decision-Making in Carotid Stenosis

PHARMACOTHERAPY
+ INTERVENTION

ISOLATED
PHARMACOTHERAPY

Podlasek , Grunwald, Musiałek 2021

Decision-Making in Carotid Stenosis

Podlasek , Grunwald, Musiałek 2021

You can also **CAUSE Stroke**

while treating the carotid…

Decision-Making in Carotid Stenosis

TYPE OF INTERVENTION

(CAS, TCAR, CEA)

Podlasek , Grunwald, Musiałek 2021

Cardiovasc Res. 2023 Aug 25:cvad135. doi: 10.1093/cvr/cvad135. Online ahead of print.

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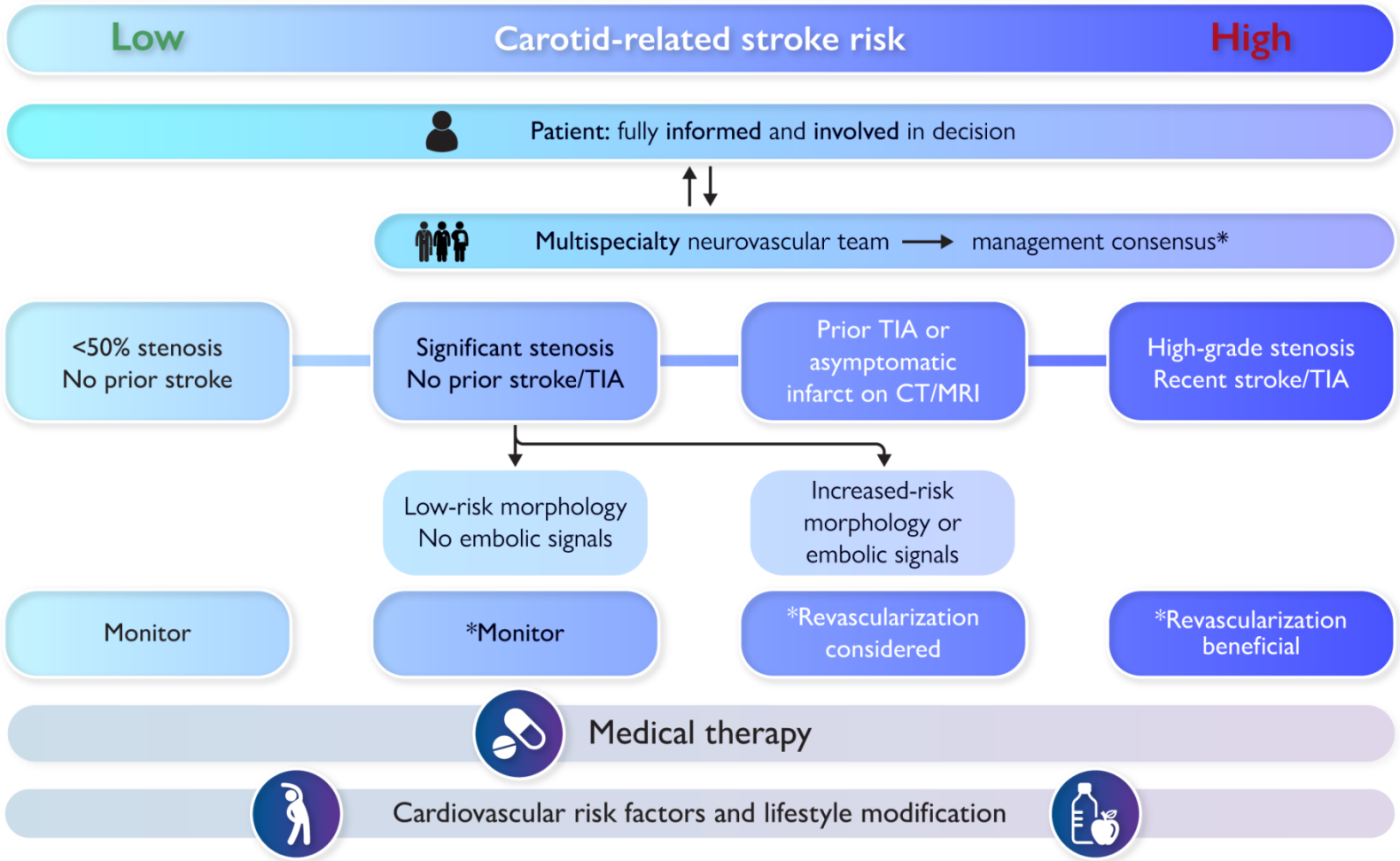

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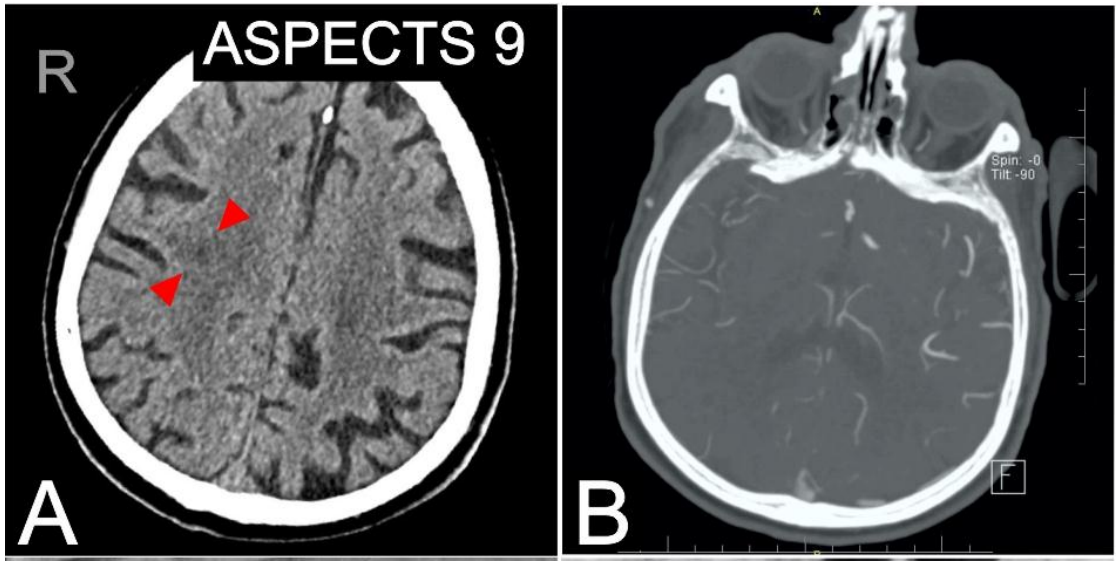
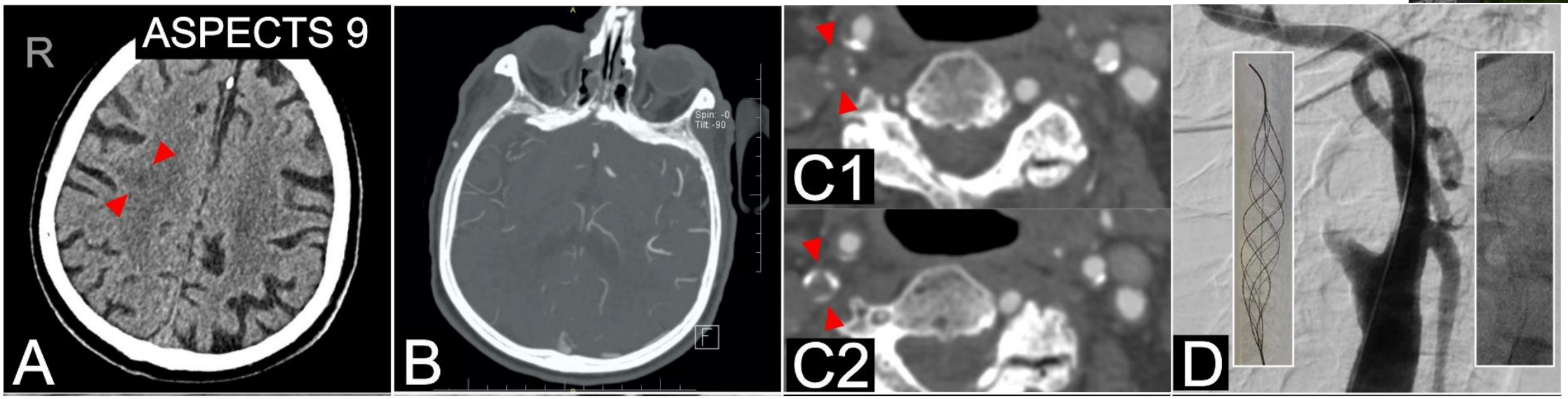
MicroNET-Covered Stent in Acute Carotid Stroke



L. Tekieli, et al. *J Cardiovasc Surg* 2024

MicroNET-Covered Stent in Acute Carotid Stroke



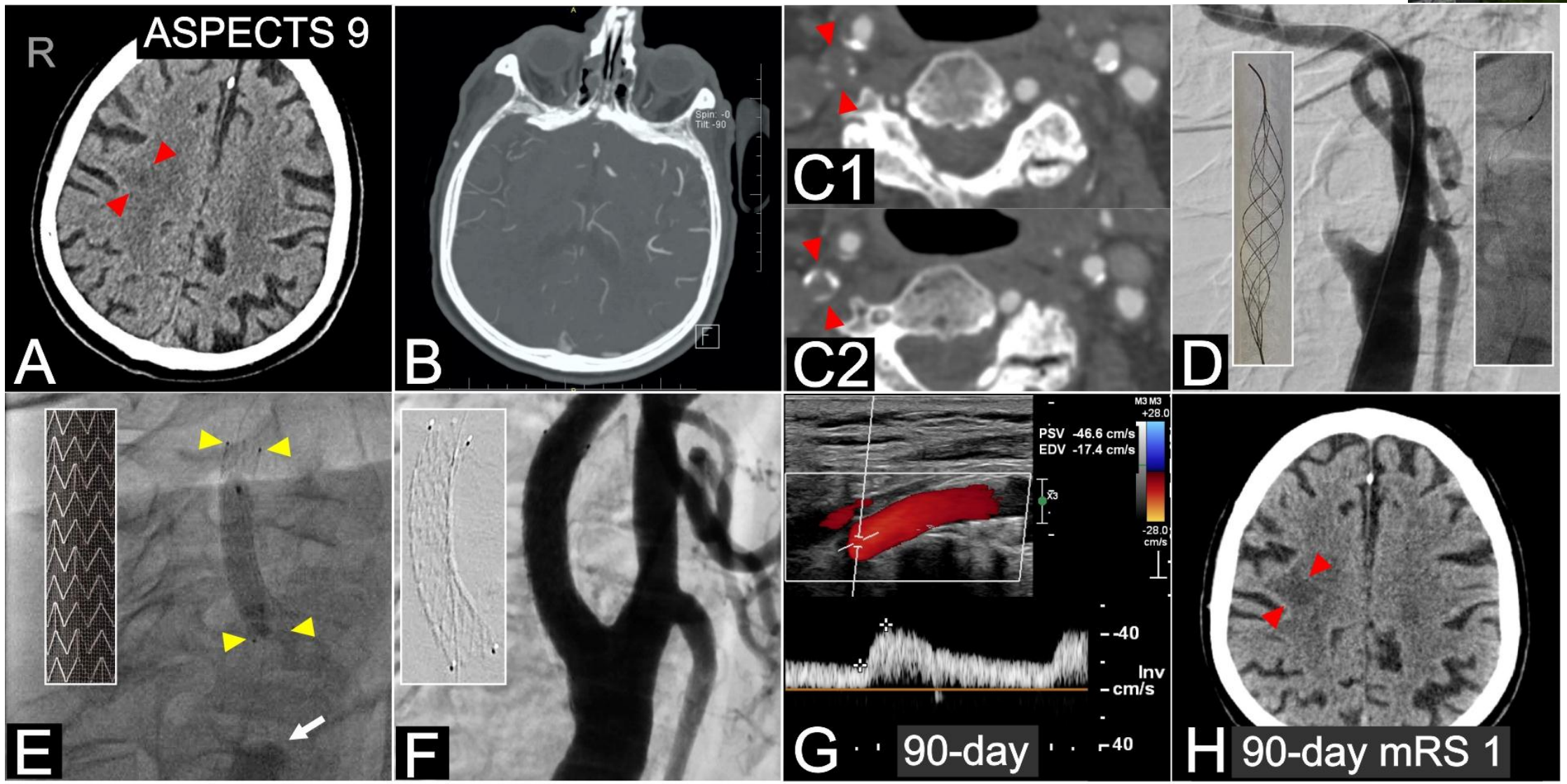
L. Tekieli, et al. *J Cardiovasc Surg* 2024

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

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

Ter Schiphorst A, et al. Endovascular treatment of ischemic stroke due to isolated internal carotid artery occlusion: ETIS registry data analysis. J Neurol. 2022;269:4383-4395
Allard J et al. 24-Hour Carotid Stent Patency and Outcomes After Endovascular Therapy: A Multicenter Study. Stroke. 2023;54:124-131.
Renú A, et al. Carotid stent occlusion after emergent stenting in acute ischemic stroke: Incidence, predictors and clinical relevance. Atherosclerosis. 2020:313:8-13.

MicroNET-Covered Stent in Acute Carotid Stroke



L. Tekieli, et al. *J Cardiovasc Surg* 2024

CREST-1

(The Primary Sin of…)

CREST-1

CREST-1

N Engl J Med 2010;363:11-23.

			Periprocedural Period		
	CAS (N=1262)	CEA (N=1240)	Absolute Treatment Effect of CAS vs. CEA (95% CI)	Hazard Ratio for CAS vs. CEA (95% CI)	P Value
	no. of patients (% ±SE)		*percentage points*		
Death	9 (0.7±0.2)	4 (0.3±0.2)	0.4 (–0.2 to 1.0)	2.25 (0.69 to 7.30)†	0.18†
Stroke					
Any	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major ipsilateral	11 (0.9±0.3)	4 (0.3±0.2)	0.5 (–0.1 to 1.2)	2.67 (0.85 to 8.40)	0.09
Major nonipsilateral‡	0	4 (0.3±0.2)	NA	NA	NA
Minor ipsilateral	37 (2.9±0.5)	17 (1.4±0.3)	1.6 (0.4 to 2.7)	2.16 (1.22 to 3.83)	0.009
Minor nonipsilateral	4 (0.3±0.2)	4 (0.3±0.2)	0.0 (–0.4 to 0.4)	1.02 (0.25 to 4.07)	0.98†
Myocardial infarction	14 (1.1±0.3)	28 (2.3±0.4)	–1.1 (–2.2 to –0.1)	0.50 (0.26 to 0.94)	0.03
Any periprocedural stroke or postprocedural ipsilateral stroke	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major stroke	11 (0.9±0.3)	8 (0.6±0.2)	0.2 (–0.5 to 0.9)	1.35 (0.54 to 3.36)	0.52
Minor stroke	41 (3.2±0.5)	21 (1.7±0.4)	1.6 (0.3 to 2.8)	1.95 (1.15 to 3.30)	0.01
Any periprocedural stroke or death or post-procedural ipsilateral stroke	55 (4.4±0.6)	29 (2.3±0.4)	2.0 (0.6 to 3.4)	1.90 (1.21 to 2.98)	0.005
Primary end point (any periprocedural stroke, myocardial infarction, or death or postprocedural ipsilateral stroke)	66 (5.2±0.6)	56 (4.5±0.6)	0.7 (–1.0 to 2.4)	1.18 (0.82 to 1.68)	0.38

CREST-1

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Myocardial infarction	4 (0.3±0.2)	2 (0.2±0.1)	0.1 (–0.2 to 0.5)	2.00 (0.36 to 11.04)	1.03
Any periprocedural stroke or postprocedural ipsilateral stroke	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
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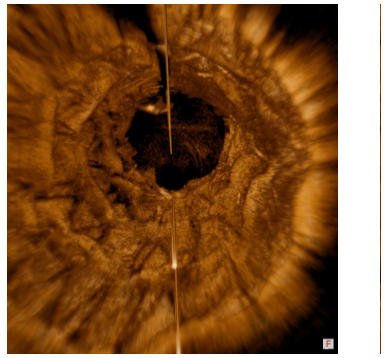
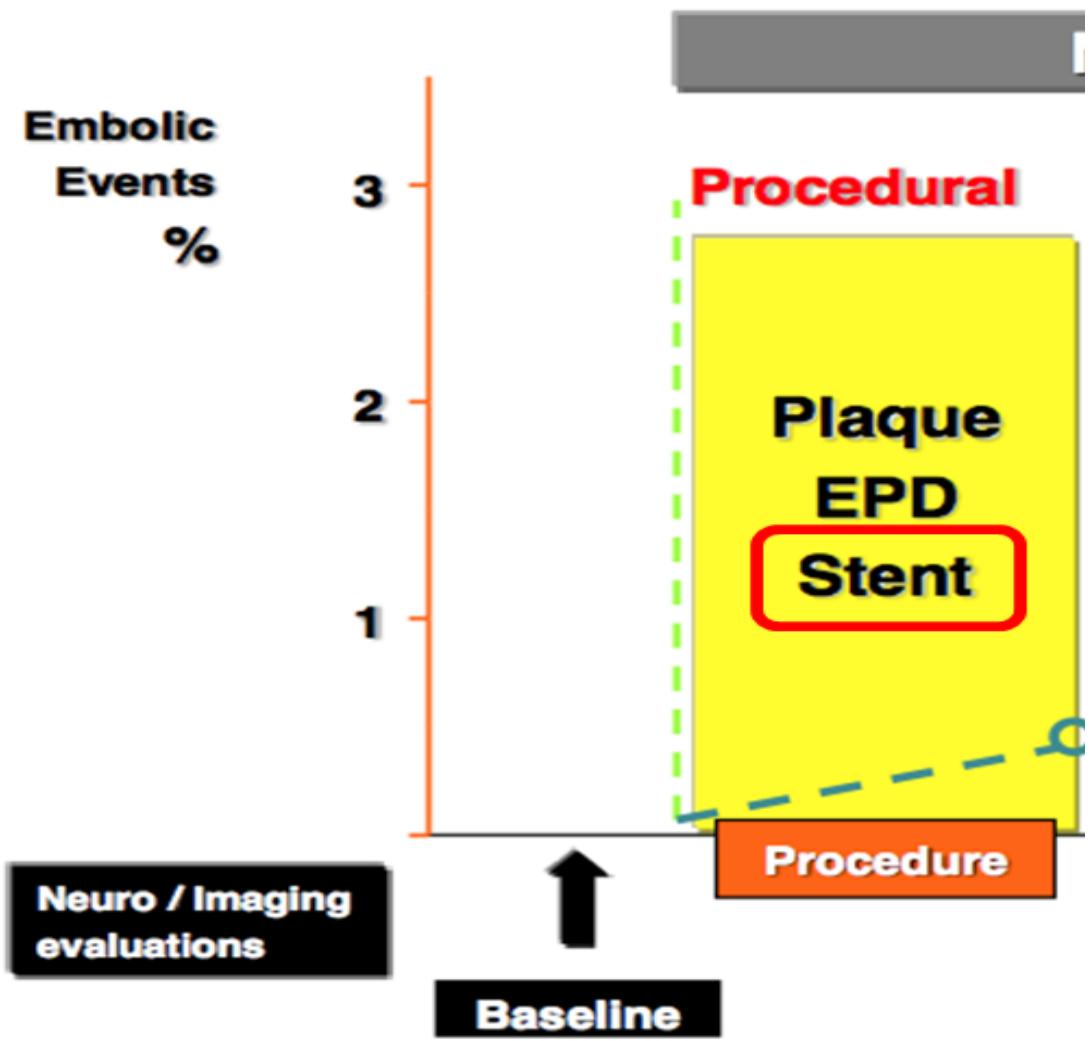
WHERE exactly was the problem?

Status of knowledge #3





2024 Vilnius Vascular Symposium

D. McCormick TCT 2012, modified

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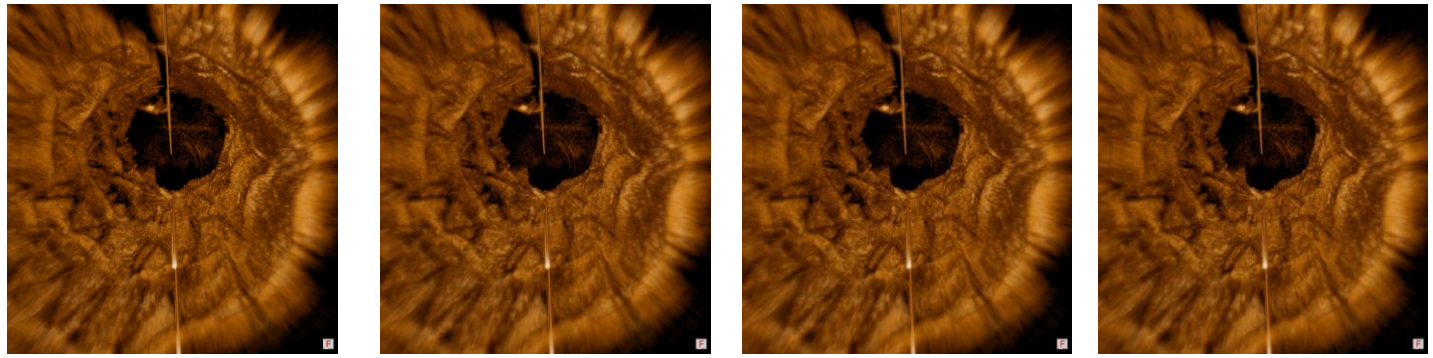
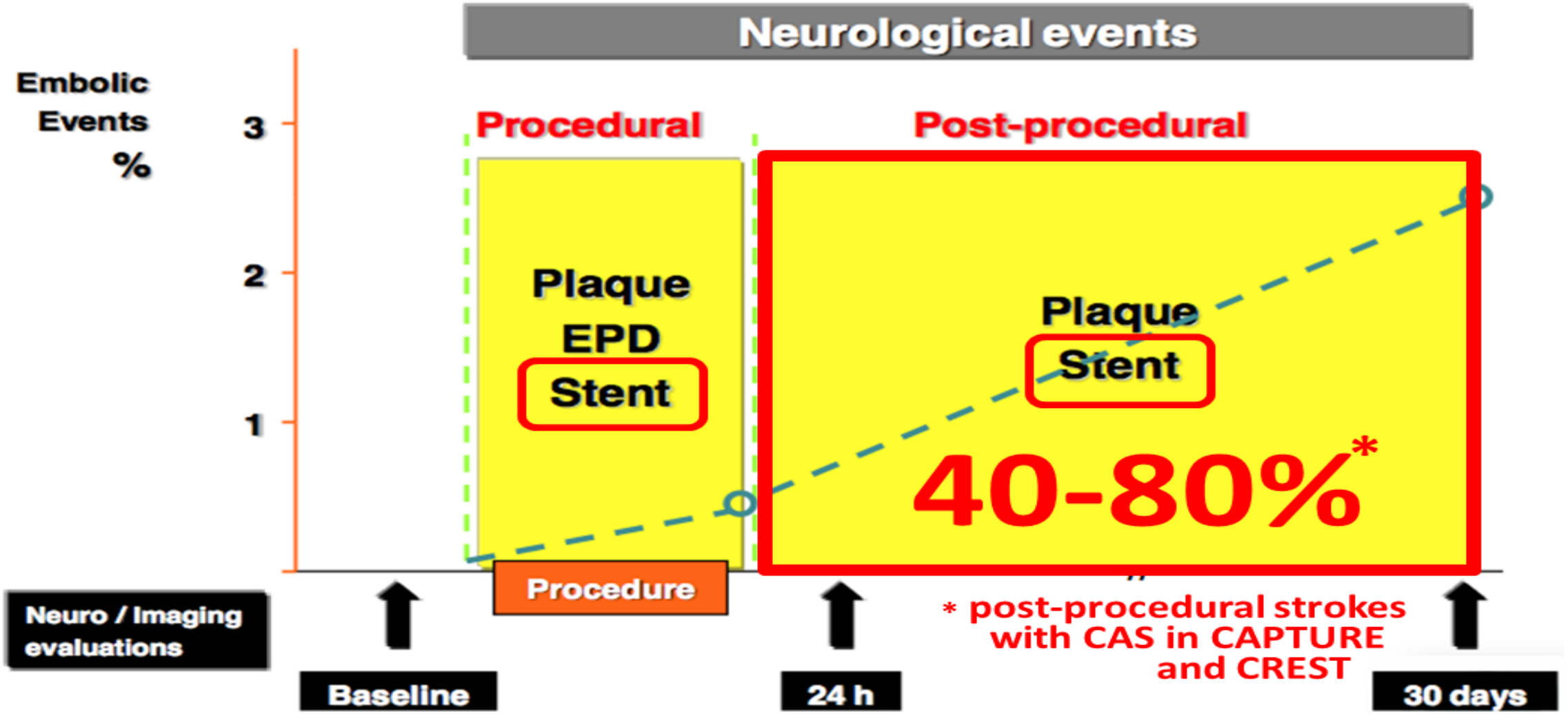
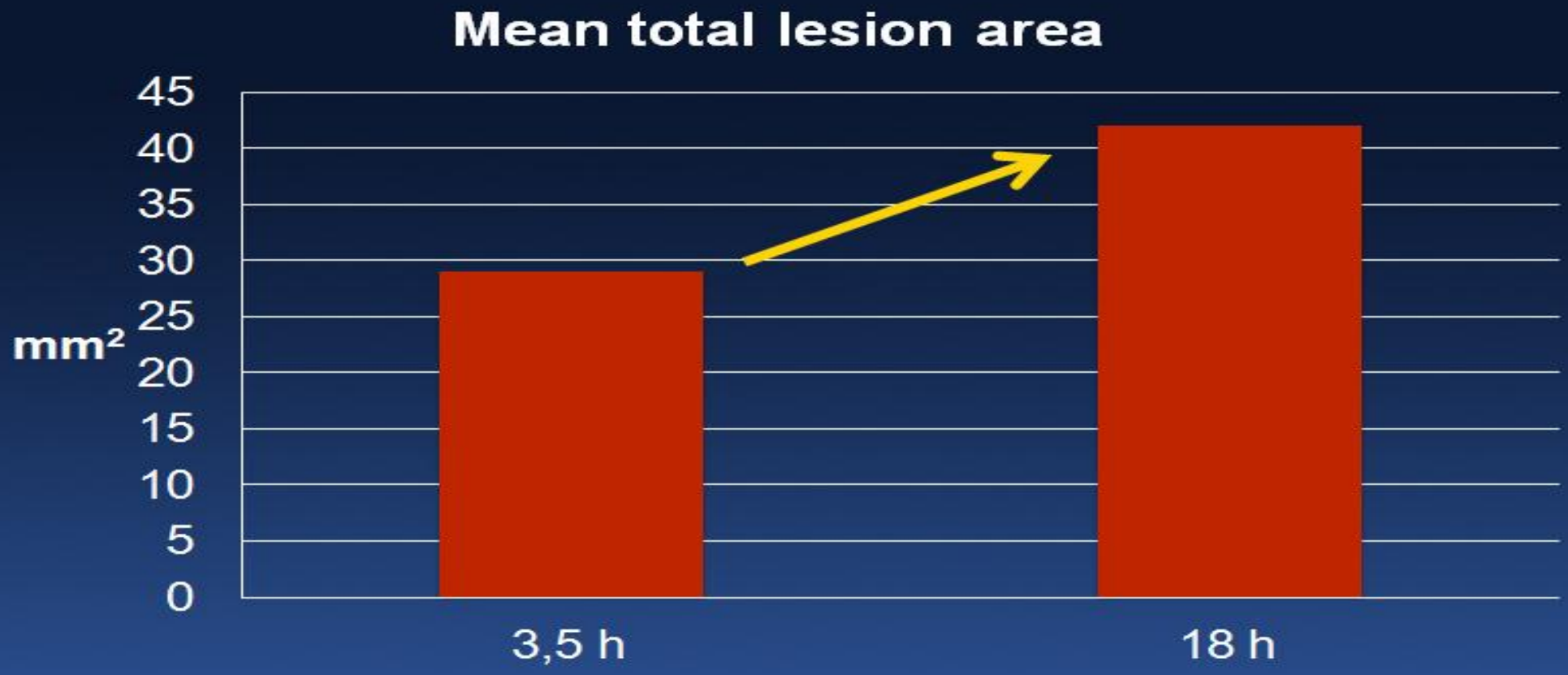




D. McCormick TCT 2012, modified

Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS



Schofer J et al, JACC Cardiovasc interv 2008

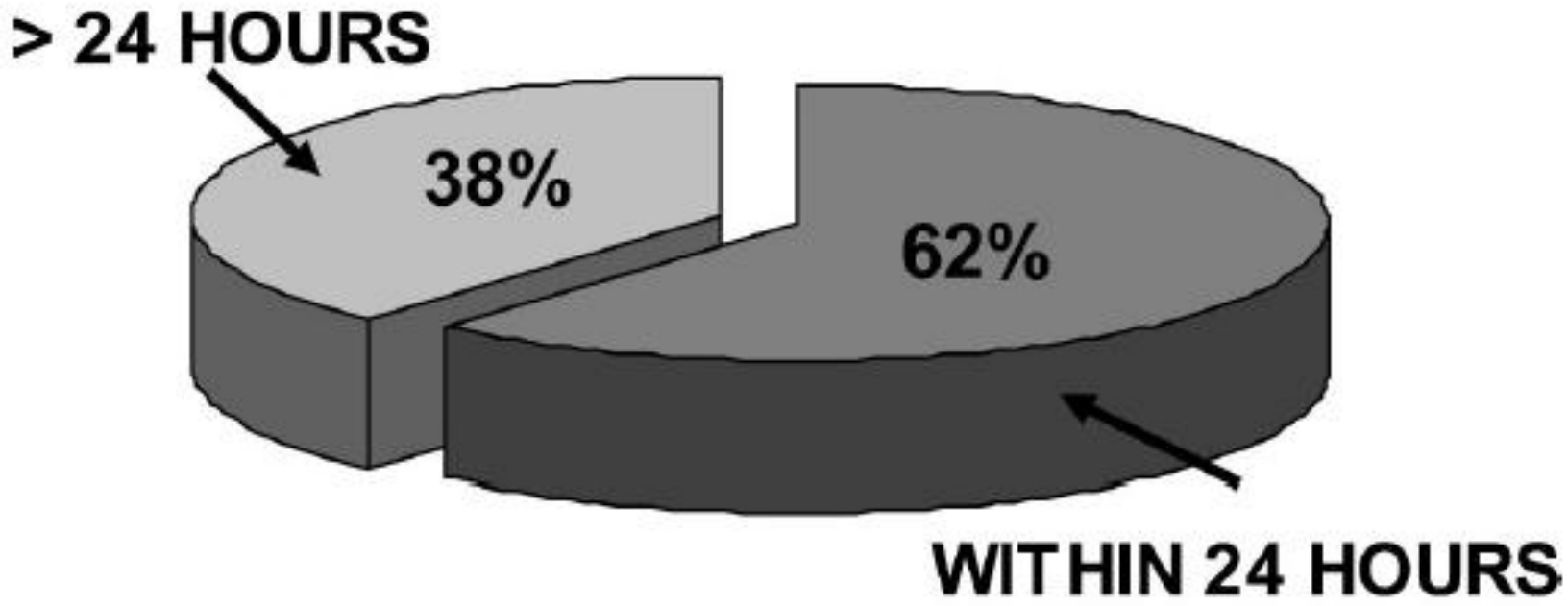
The TIMING of Stroke by 30-days with CAS in CREST

- Day 0 — 29 → **50.0%**
- Day 1-7 — 10 → **17.2%**
- Day 8-30 — 19 → **32.8%**

The DAY AFTER to DAY 30

Hill MD. Circulation. 2012;126:3054–3061.

The TIMING of Stroke by 30-days with CAS in CAPTURE



* n= 168 patients; 2 patients each had two strokes

Fairman R. Ann Surg 2007;246:551–558.

CREST-1

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Myocardial infarction	4 (0.3±0.2)	10 (0.8±0.3)	–0.5 (–1.2 to 0.1)	0.40 (0.12 to 1.34)	0.03
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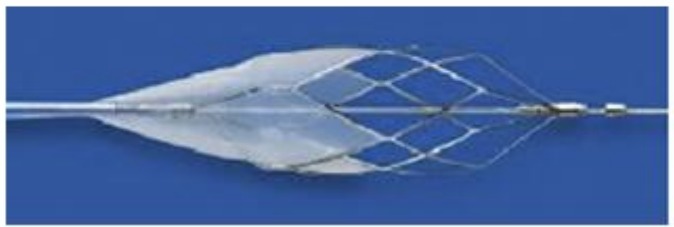


The Problem of Conventional (Single-layer) Carotid Stents

2024 Vilnius Vascular Symposium

P Musialek, G deDonato
Carotid Artery Revascularization Using the Endovascular Route
In: **Carotid Interventions - Practical Guide 2023**

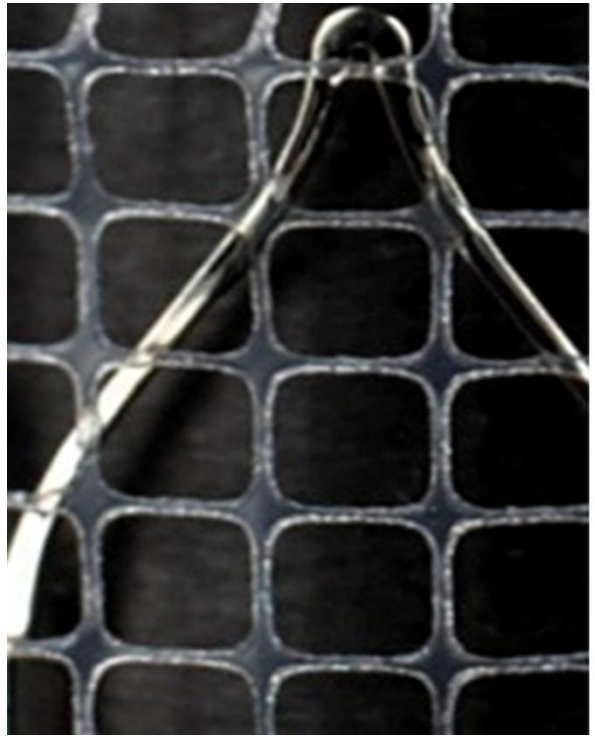
Mechanisms to explain the poor results of carotid artery stenting (CAS) in symptomatic patients to date and options to improve CAS outcomes

Kosmas I. Paraskevas, MD,[a] Dimitri P. Mikhailidis, MD, FFPM, FRCPath, FRCP,[b] and Frank J. Veith, MD, FACS,[c,d] *Athens, Greece; London, United Kingdom; Cleveland, Ohio; and New York, NY*

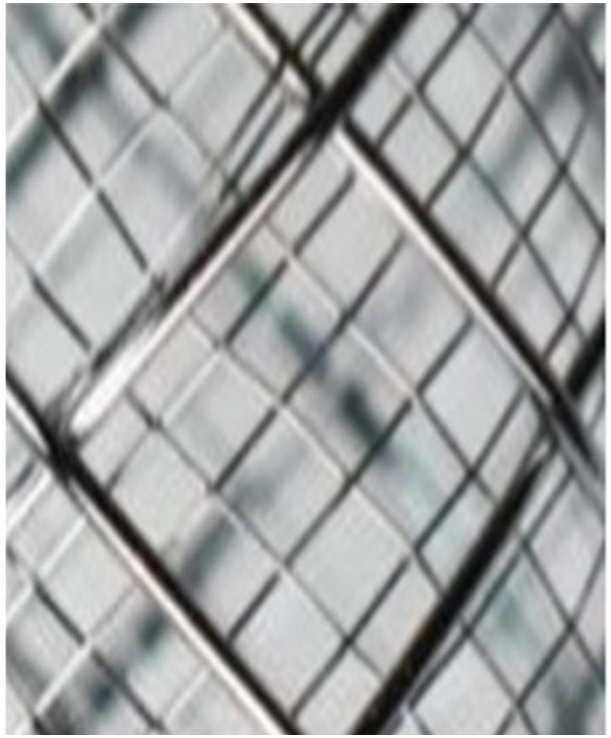
Background: Carotid artery stenting (CAS) is considered by many as an alternative to carotid endarterectomy (CEA) for the management of carotid artery stenosis. However, recent trials demonstrated inferior results for CAS in symptomatic patients compared with CEA. We reviewed the literature to evaluate the appropriateness of CAS for symptomatic carotid artery stenosis and to determine the pathogenetic mechanism(s) associated with stroke following the treatment of such lesions. Based on this, we propose steps to improve the results of CAS for the treatment of symptomatic carotid stenosis.
Methods: PubMed/Medline was searched up to March 25, 2010 for studies investigating the efficacy of CAS for the management of symptomatic carotid stenosis. Search terms used were "carotid artery stenting," "symptomatic carotid artery stenosis," "carotid endarterectomy," "stroke," "recurrent carotid stenosis," and "long-term results" in various combinations.
Results: Current data suggest that CAS is not equivalent to CEA for the treatment of symptomatic carotid stenosis. Differences in carotid plaque morphology and a higher incidence of microemboli and cerebrovascular events during and after CAS compared with CEA may account for these inferior results.
Conclusions: Currently, most symptomatic patients are inappropriate candidates for CAS. Improved CAS technology referable to stent design and embolic protection strategies may alter this conclusion in the future. (J Vasc Surg 2010;52: 1367-75.)

Carotid ’mesh’ stents: 2nd Gen Carotid Stents

Gore Hybrid Stent



Casper/RoadSaver

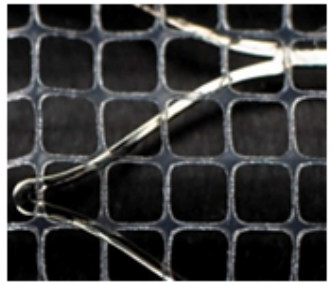


CGuard

P Musialek, G deDonato
Carotid Artery Revascularization Using the Endovascular Route
In: **Carotid Interventions - Practical Guide 2023**

Carotid ’mesh’ stents

New Technologies

			
Name	**RoadSaver *aka* Casper**	**Gore® Carotid Stent**	**CGuard™ Embolic Prevention Stent**
Stent frame	**closed-cell Nitinol**	**open-cell Nitinol**	**open-cell Nitinol**
Mesh position in relation to frame	**inside**	**outside**	**outside**
Mesh material	**Nitinol**	**PTFE**	**PET**
Mesh structure	**braided**	**inter-woven**	**single-fiber knitted**
Pore size	**375 µm**	**500 µm**	**150 - 180 µm**

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

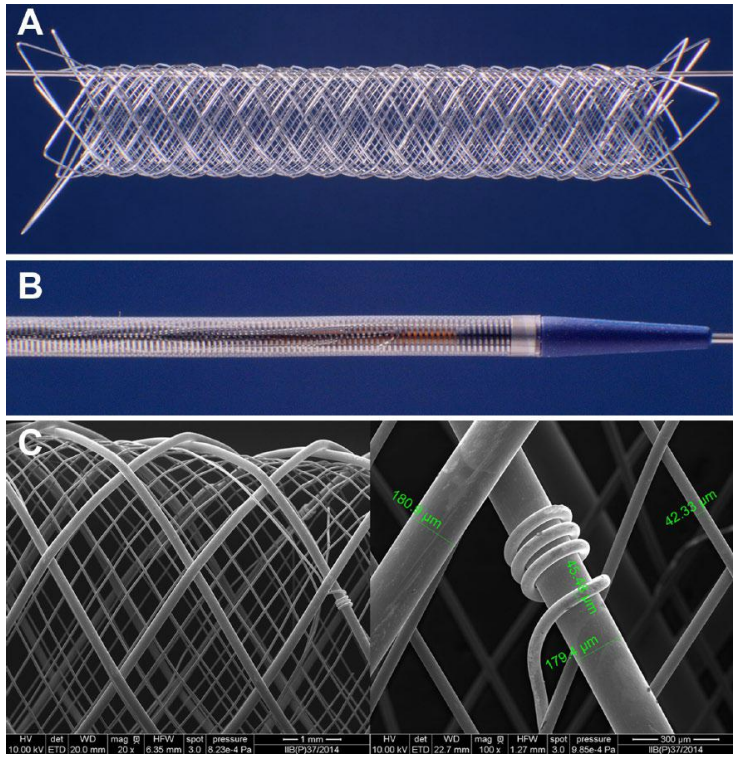
Journal of Endovascular Therapy
2015, Vol. 22(4) 634–639

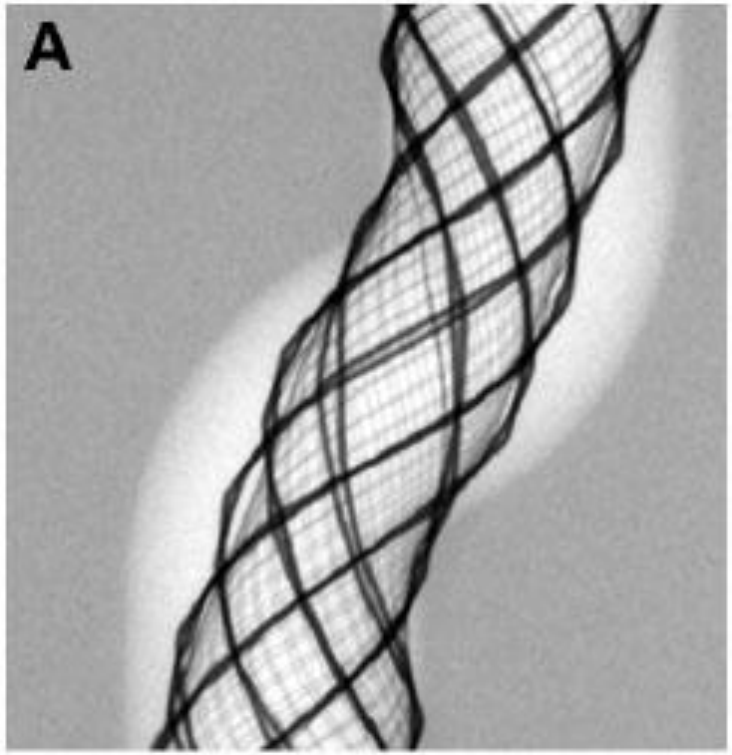
DOI: 10.1177/1526602815593490
www.jevt.org
SAGE

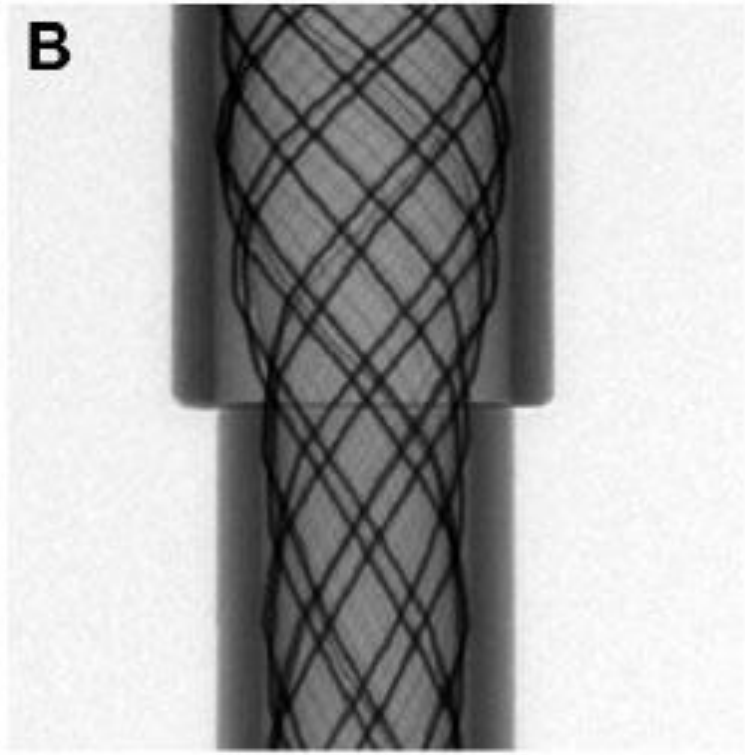
2024 Vilnius Vascular Symposium

Mechanical Behavior of a New Double-Layer Carotid Stent

Christian Wissgott, MD[1], Wolfram Schmidt, BSE[2],
Christoph Brandt, BSE[2], Peter Behrens, BSE[2], and Reimer Andresen, MD[1]







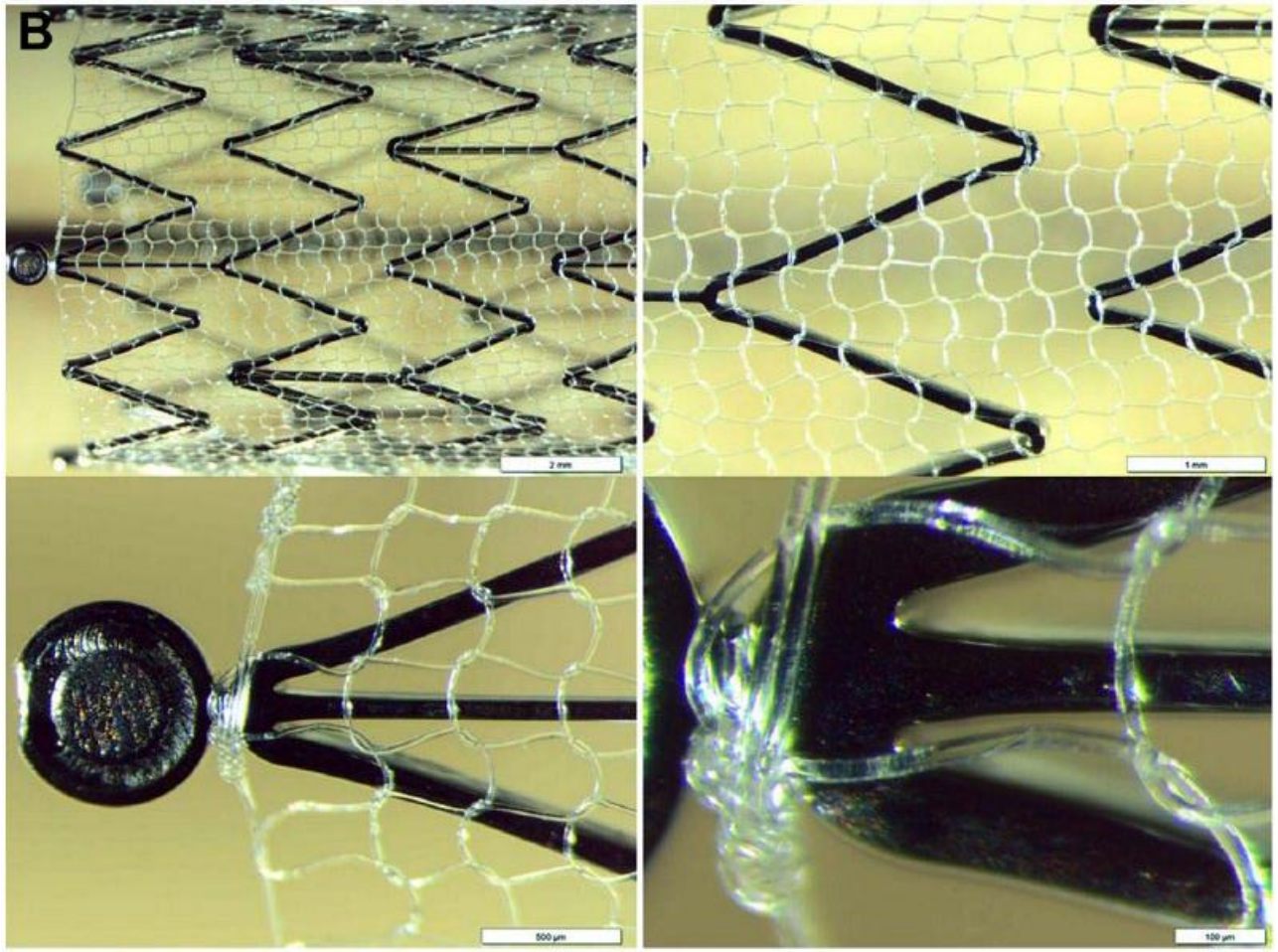
Clinical Investigation

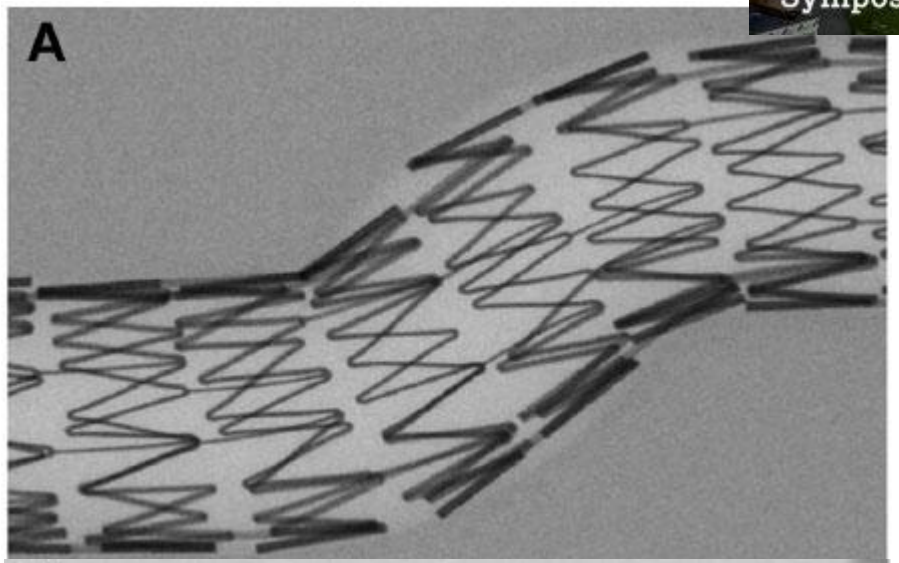
JOURNAL OF ENDOVASCULAR THERAPY

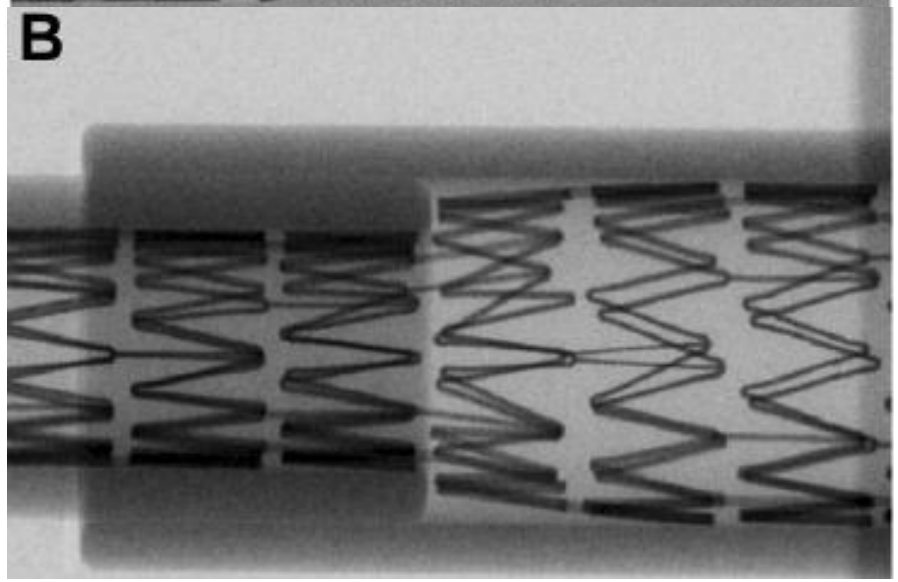
Journal of Endovascular Therapy
1–8

DOI: 10.1177/1526602816671134
www.jevt.org
SAGE

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







2024 Vilnius Vascular Symposium

New Technologies

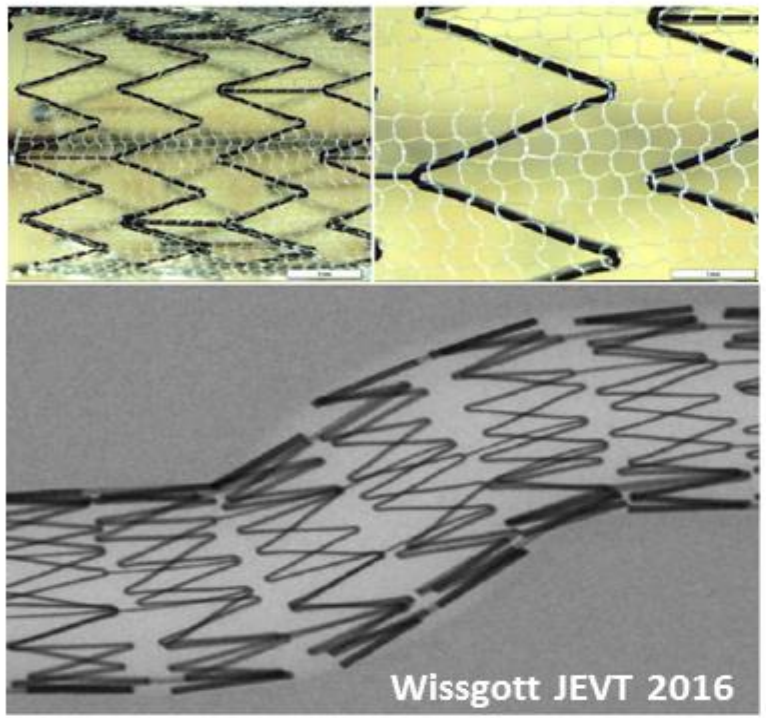
The **MOST 'open'** amongst open-cell stents (metallic FRAME) & the **MOST 'close'** amongst close-cell stents (MicroNet mesh)

CGuard MicroNET – covered
2nd generation carotid stent

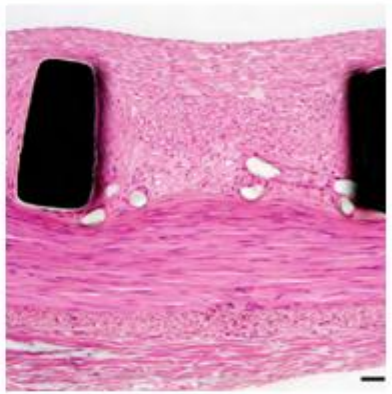
UNIQUE mechanical properties

RESPECT of anatomy

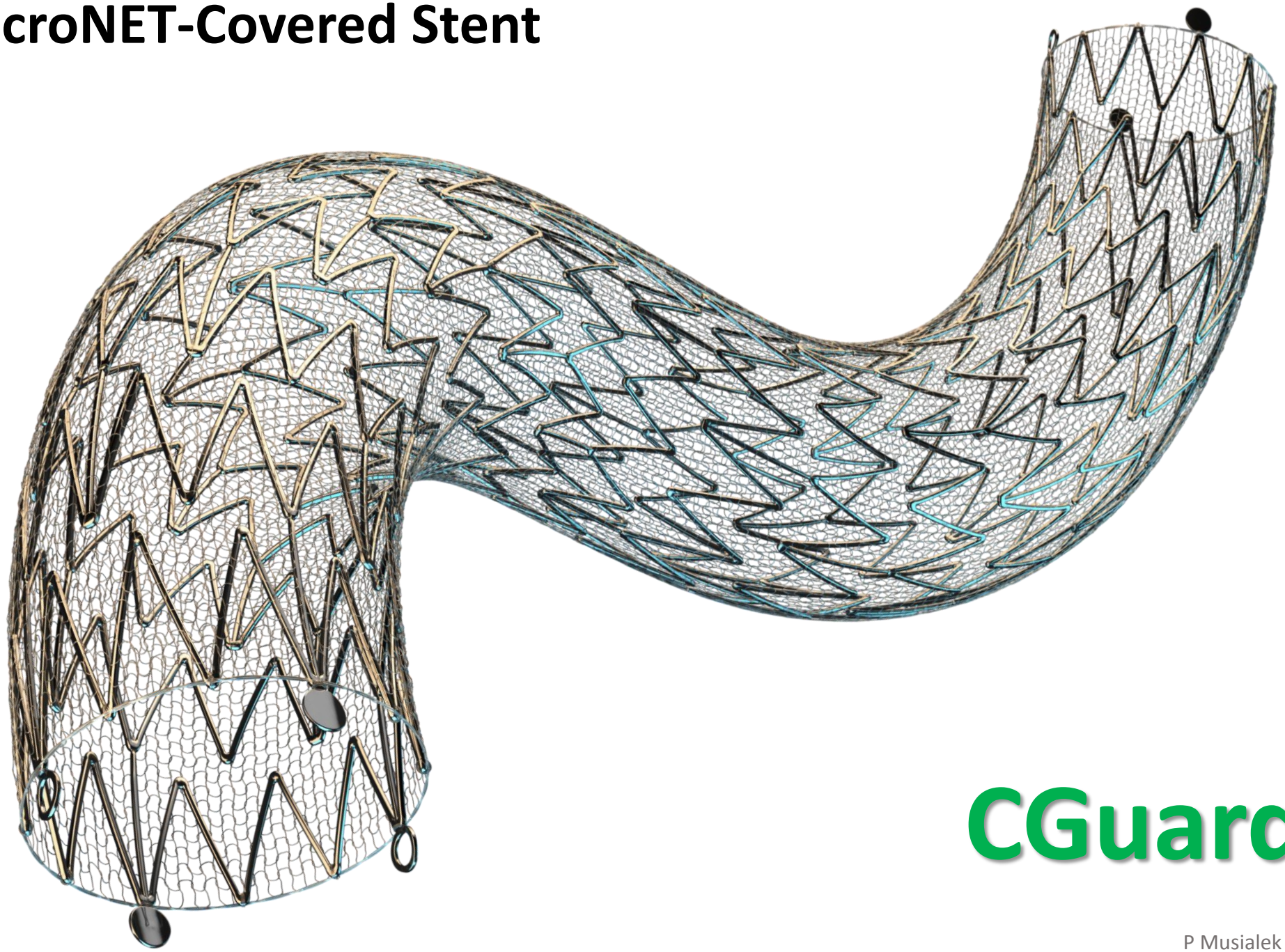
FULL apposition



NORMAL healing



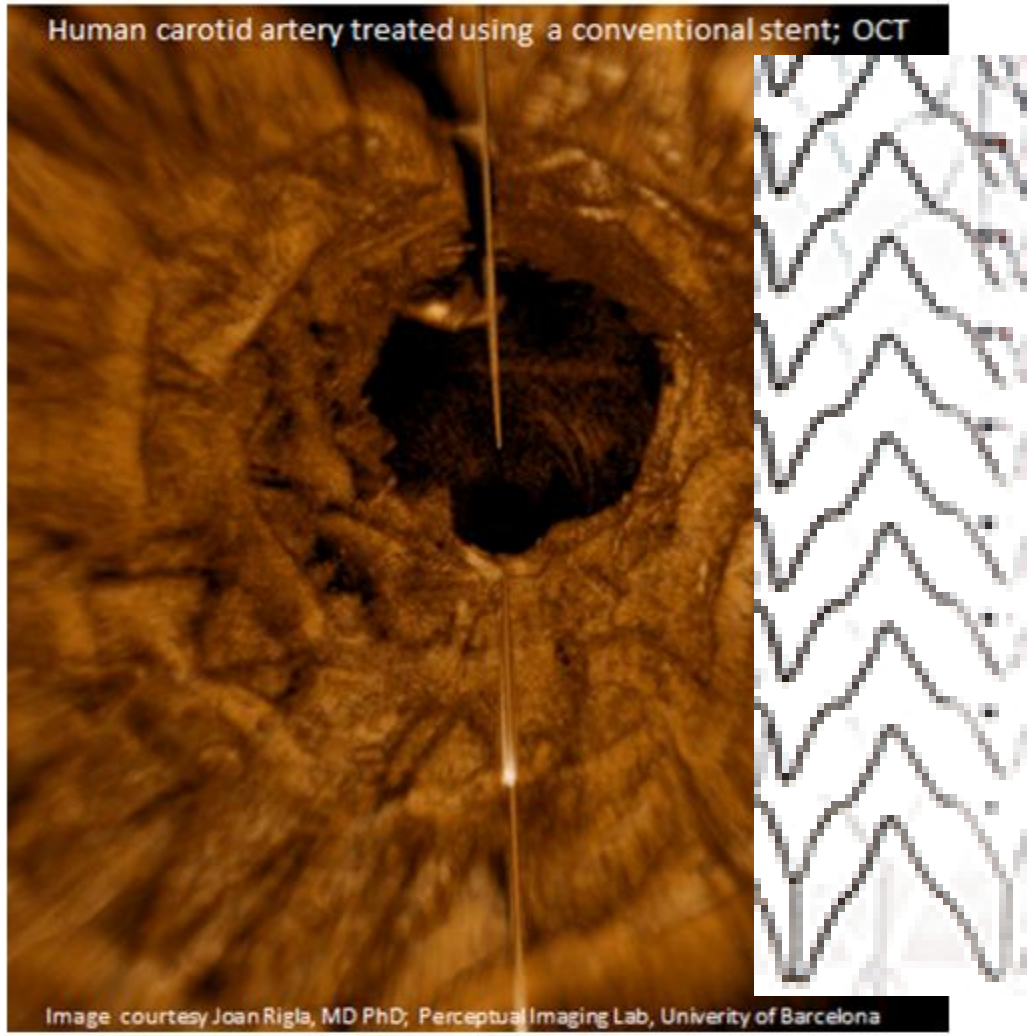
The MicroNET-Covered Stent



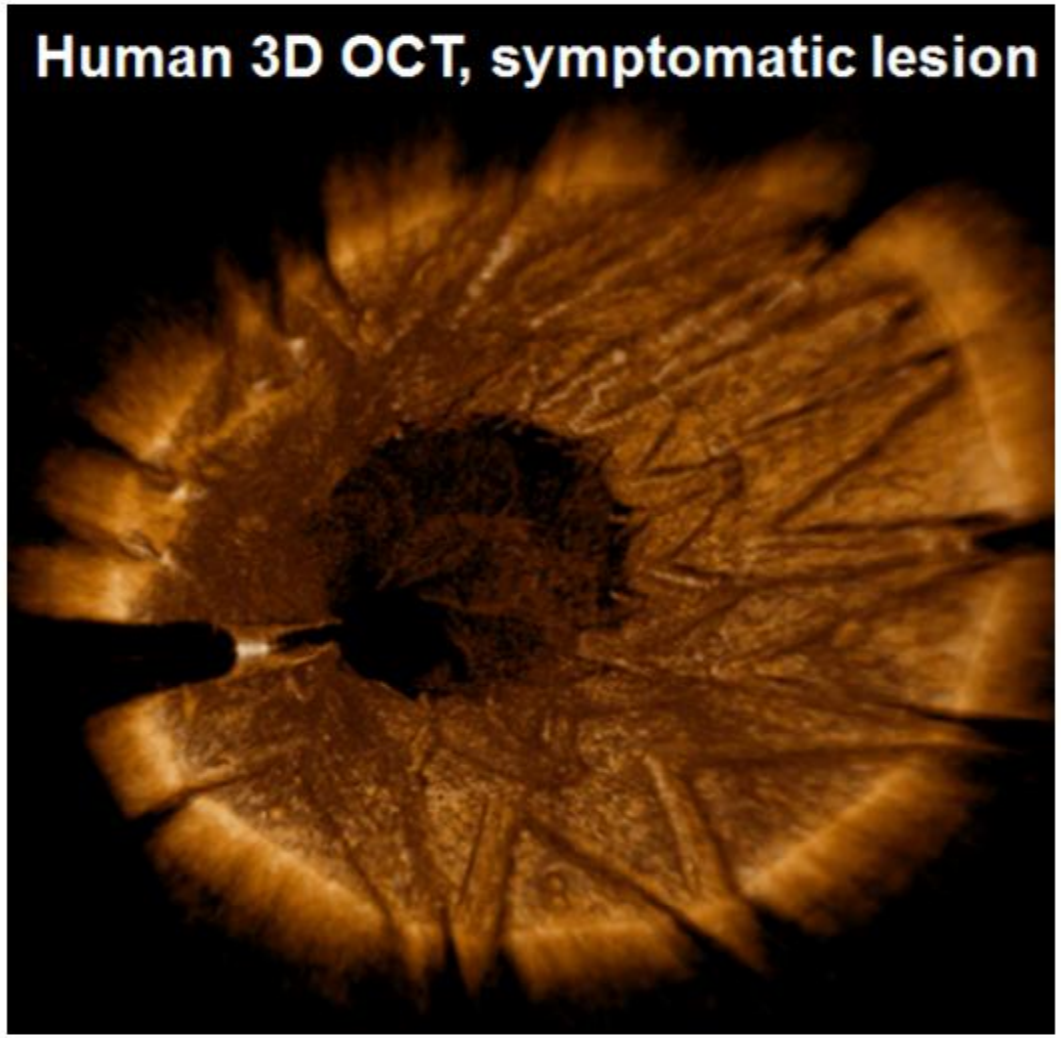
CGuard

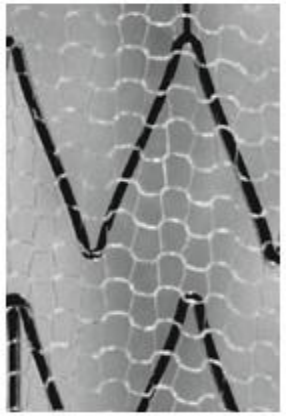
Randomized Controlled Trial

The CREST Study stent



MicroNet-Covered Stent



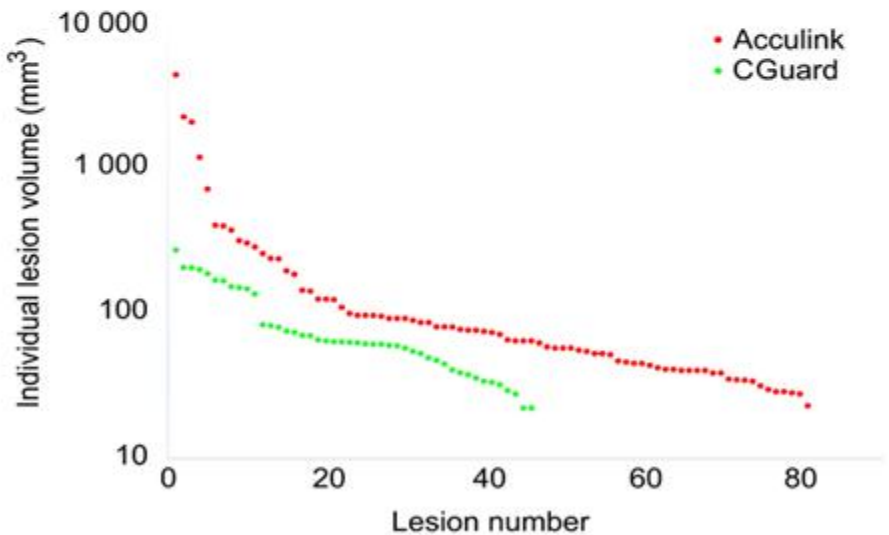


OCT Images in: P Musialek, G deDonato
Carotid Artery Revascularization Using the Endovascular Route
In: **Carotid Interventions - Practical Guide 2022** (in press)

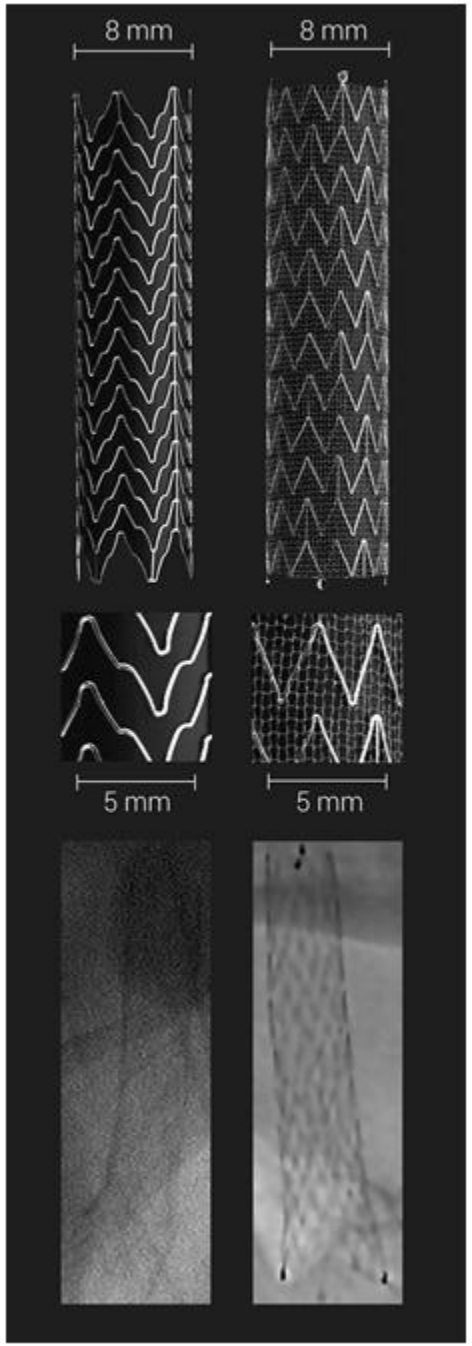
Neuro-Protective
Carotid Stent System

Randomized Controlled Trial

DW-MRI Embolism
raw data



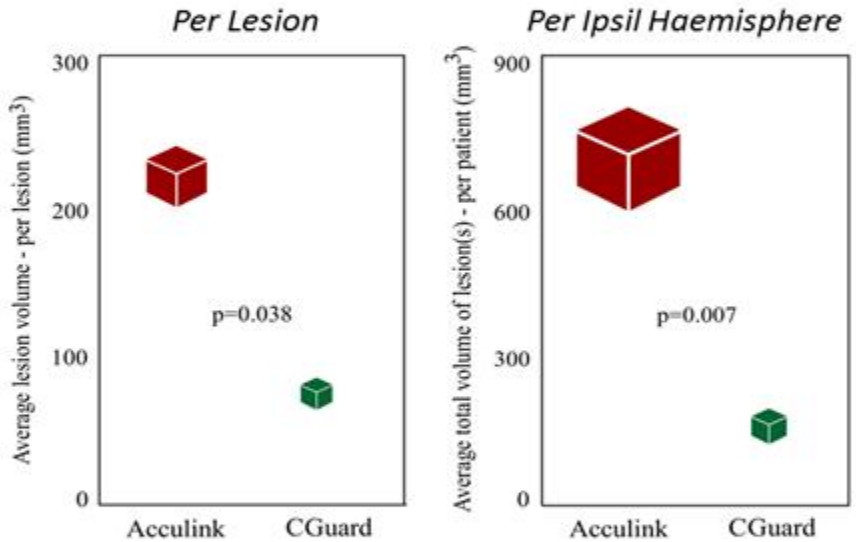
JACC: CARDIOVASCULAR INTERVENTIONS VOL. 14, NO. 21, 2021
NOVEMBER 8, 2021:2377-2387



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

2nd Gen Carotid Stents ('mesh' stents)

- significantly reduce the **incidence** of embolic material in filters
- significantly reduce **filter load**
- profoundly reduce CAS-related **cerebral injury**

New Technologies

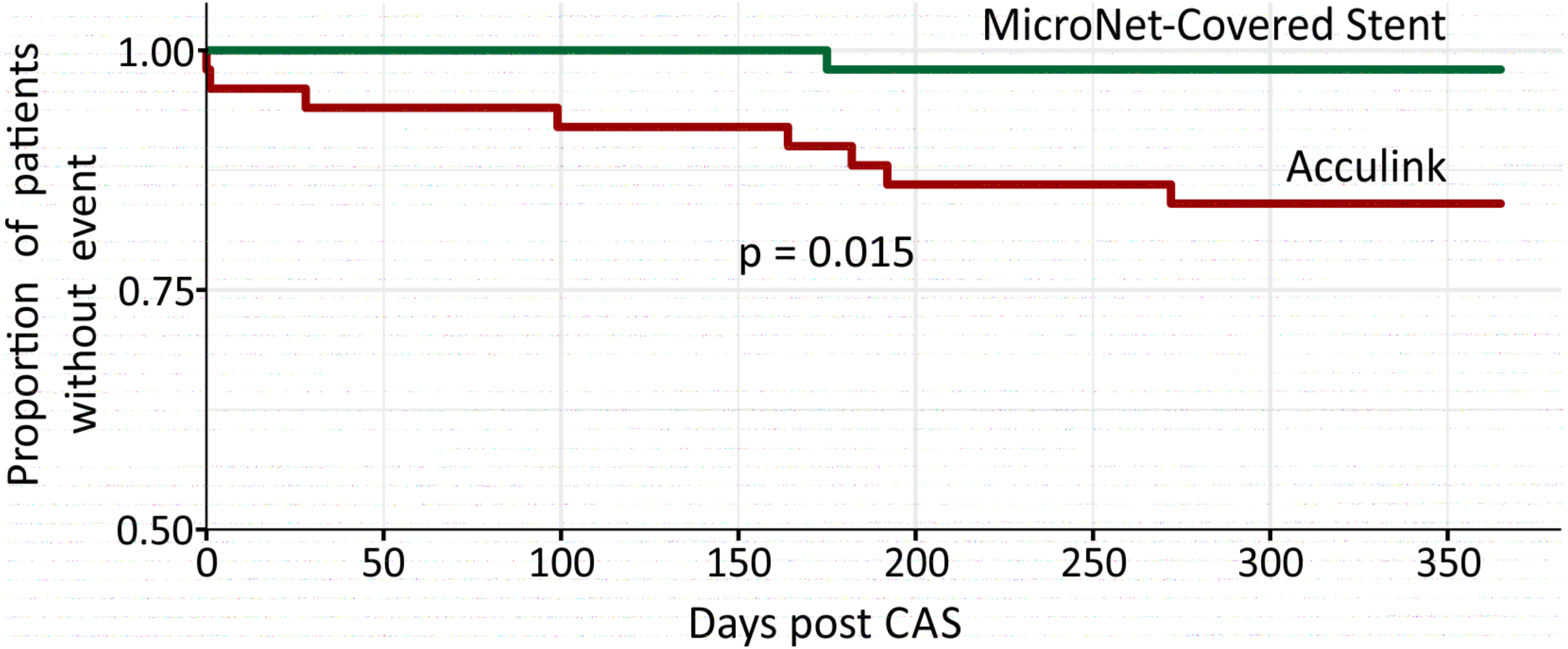
Karpenko A. *JACC Cardiovasc Interv* 2021;14:2377–87.
Nakagawa I. *J Neurointerv Surg* 2023;16:67–72.
Squizzato F. *Stroke* 2023;54:2534–41.

2nd Gen Carotid Stents ('mesh' stents)

Clinical Data

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

12-month clinical data



New Technologies

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 7, 2023

Systematic Review

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

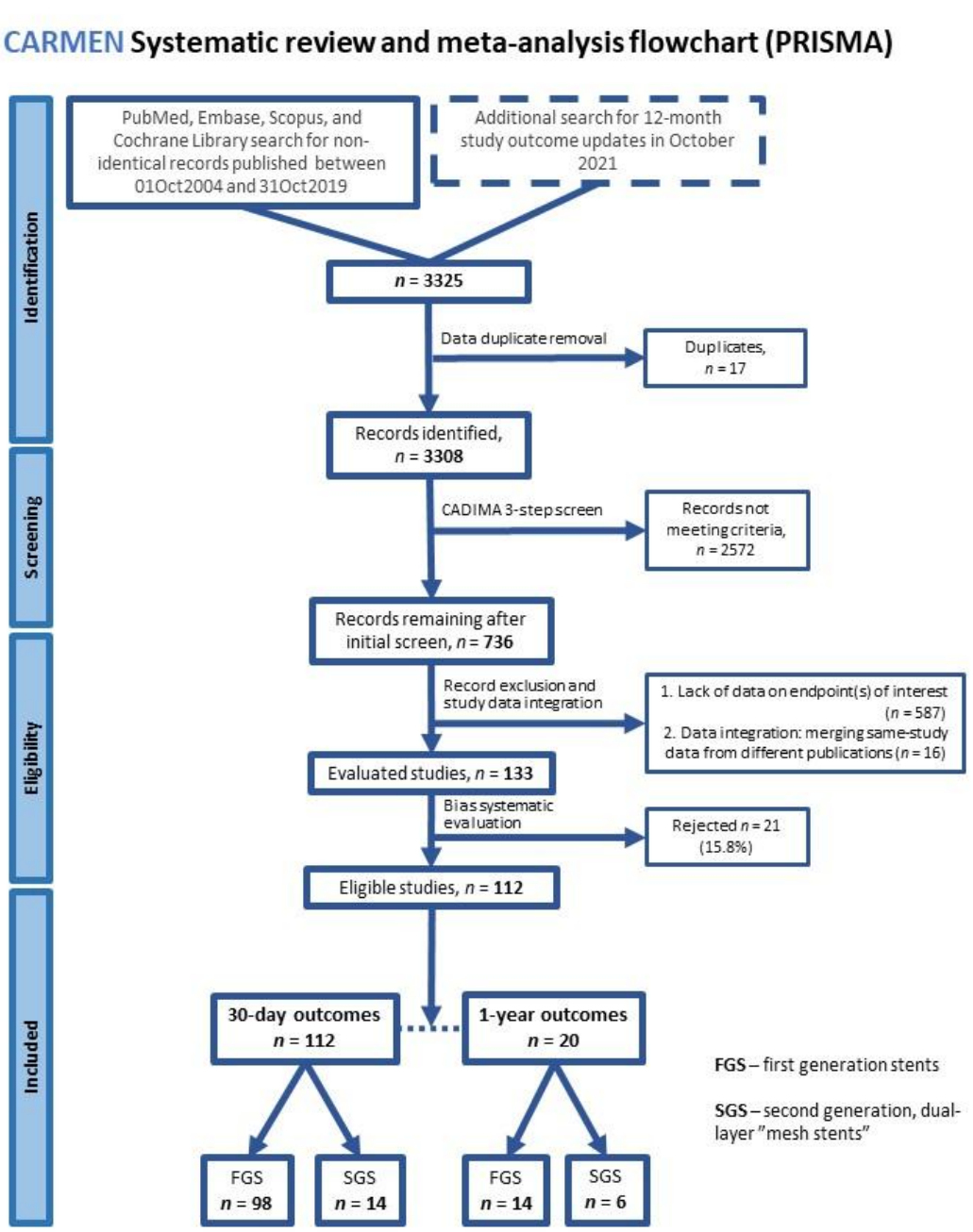
Adam Mazurek [1,*], Krzysztof Malinowski [2], Kenneth Rosenfield [3], Laura Capoccia [4], Francesco Speziale [4], Gianmarco de Donato [5], Carlo Setacci [5], Christian Wissgott [6], Pasqualino Sirignano [4], Lukasz Tekieli [7], Andrey Karpenko [8], Waclaw Kuczmik [9], Eugenio Stabile [10], David Christopher 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**

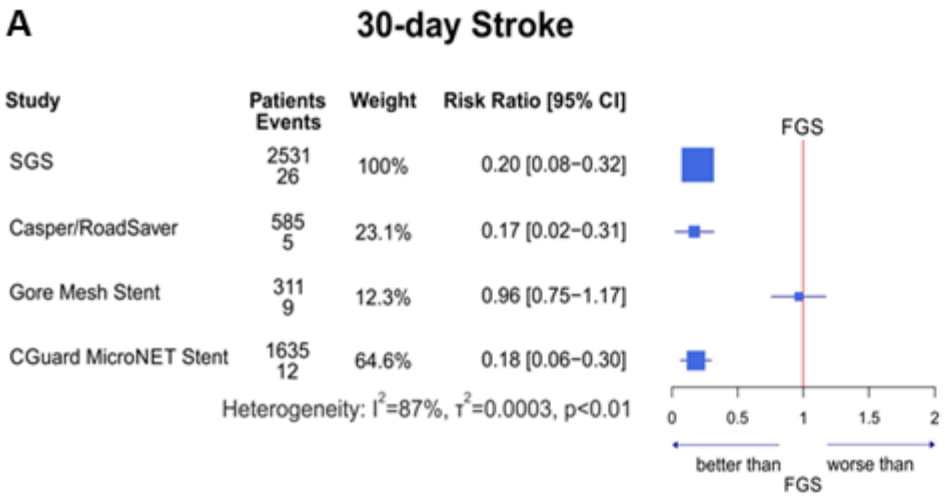
(68.2% men, 44.9% symptomatic)

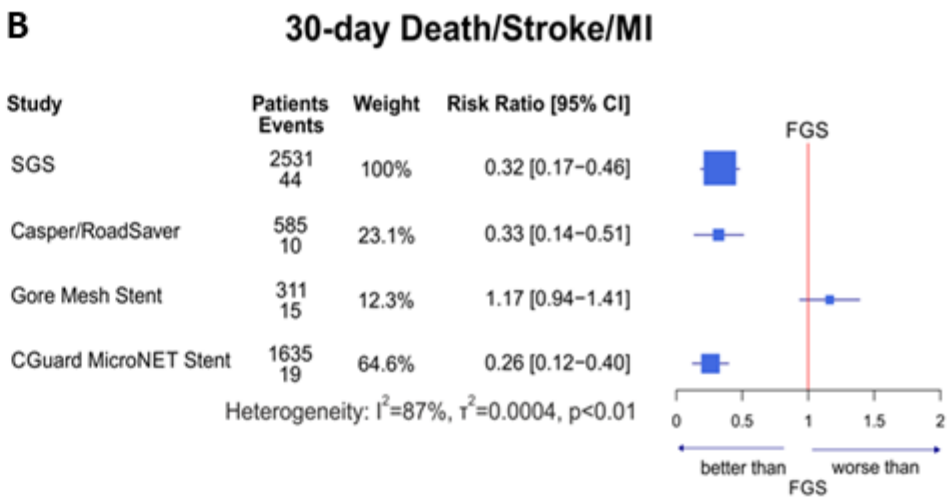
Adam Mazurek et al.
CARMEN Collaborators



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

CARMEN SGS vs FGS Meta-Analysis: Main Findings





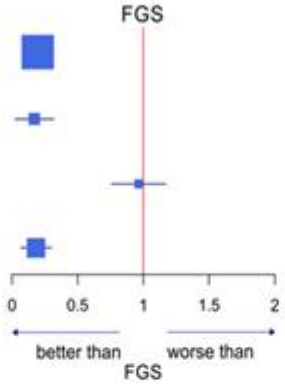
Adam Mazurek et al.
CARMEN Collaborators

CARMEN SGS vs FGS Meta-Analysis: Main Findings

A 30-day Stroke

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.20 [0.08–0.32]
Casper/RoadSaver	585 5	23.1%	0.17 [0.02–0.31]
Gore Mesh Stent	311 9	12.3%	0.96 [0.75–1.17]
CGuard MicroNET Stent	1635 12	64.6%	0.18 [0.06–0.30]

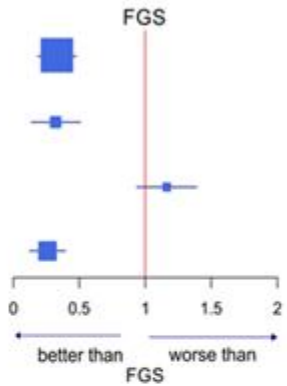
Heterogeneity: I^2=87%, τ^2=0.0003, p<0.01



B 30-day Death/Stroke/MI

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.32 [0.17–0.46]
Casper/RoadSaver	585 10	23.1%	0.33 [0.14–0.51]
Gore Mesh Stent	311 15	12.3%	1.17 [0.94–1.41]
CGuard MicroNET Stent	1635 19	64.6%	0.26 [0.12–0.40]

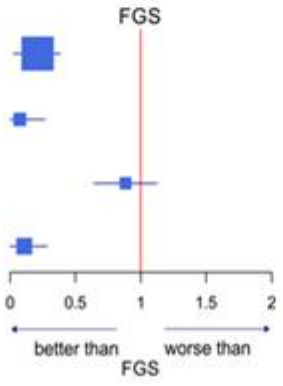
Heterogeneity: I^2=87%, τ^2=0.0004, p<0.01



C 12-month Ipsilateral Stroke

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 15	100%	0.20 [0.02–0.39]
Casper/RoadSaver	348 3	29.2%	0.07 [0.00–0.27]
Gore Mesh Stent	290 9	24.4%	0.88 [0.64–1.13]
CGuard MicroNET Stent	553 3	46.4%	0.11 [0.00–0.28]

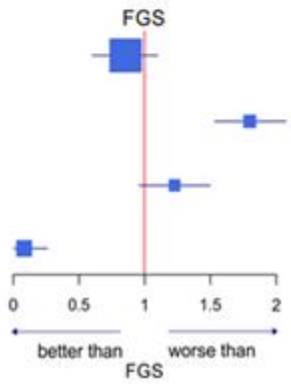
Heterogeneity: I^2=86%, τ^2=0.0002, p<0.01



D 12-month Restenosis

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 42	100%	0.85 [0.60–1.10]
Casper/RoadSaver	348 26	29.2%	1.80 [1.53–2.08]
Gore Mesh Stent	290 14	24.4%	1.22 [0.95–1.48]
CGuard MicroNET Stent	553 2	46.4%	0.09 [0.00–0.26]

Heterogeneity: I^2=88%, τ^2=0.0003, p<0.01



New Technologies

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CARMEN Collaborators

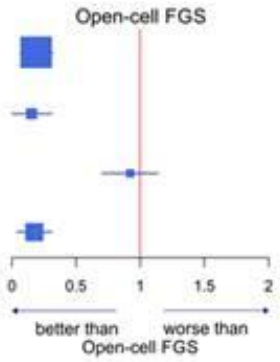
CARMEN SGS vs FGS Meta-Analysis: Main Findings

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]

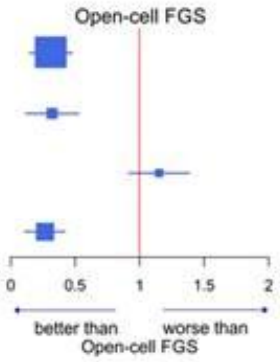
Heterogeneity: I^2=83%, τ^2=0.0002, p<0.01



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

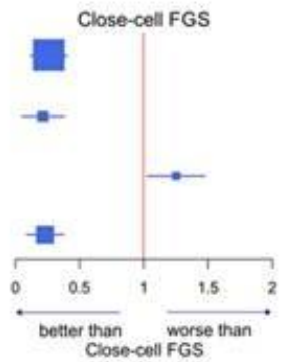


Close-cell FGS as reference

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]

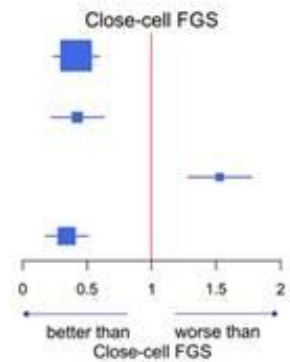
Heterogeneity: I^2=72%, τ^2=0.0001, p<0.01



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)

2024 Vilnius Vascular Symposium

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

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CARMEN Collaborators
J Cardiovasc Surg 2023

2024 Vilnius Vascular Symposium

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*

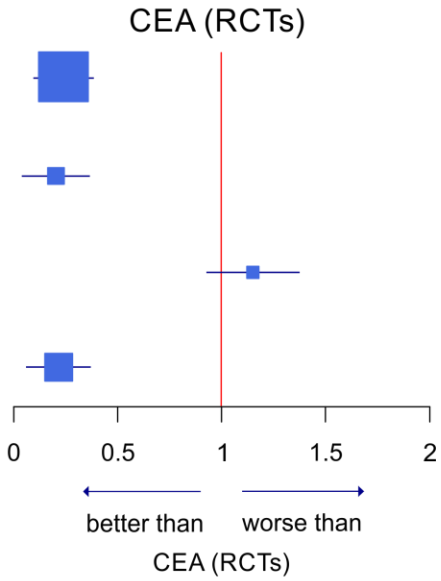
* Dakour-Aridi H, et al. *Ann Vasc Surg.* 2020;65:1-9
Columbo JA, et al. *J Vasc Surg.* 2019;69:104-109

CARMEN Collaborators
J Cardiovasc Surg 2023

30-day Stroke

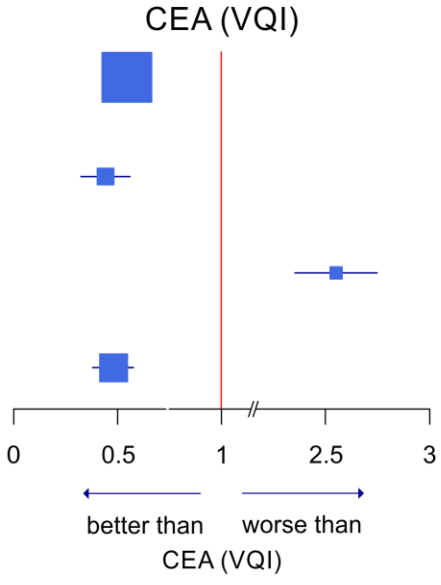
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.24 [0.10−0.38]
Casper/RoadSaver	585 5	23.1%	0.20 [0.04−0.36]
Gore Mesh Stent	311 9	12.3%	1.15 [0.92−1.37]
CGuard MicroNET Stent	1635 12	64.6%	0.22 [0.07−0.36]

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

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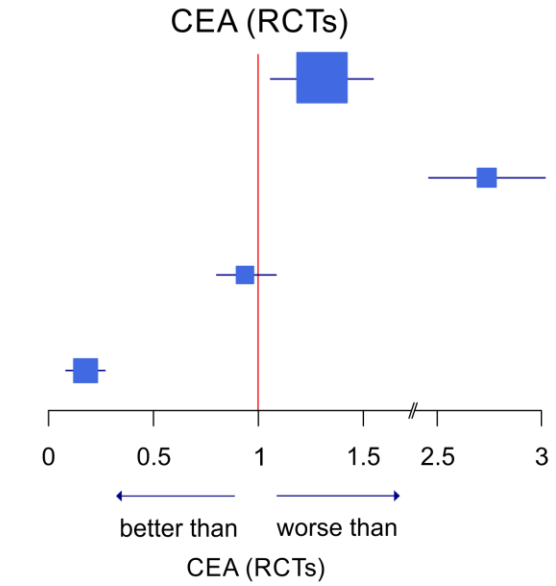
CARMEN Collaborators

J Cardiovasc Surg 2023

12-month Restenosis

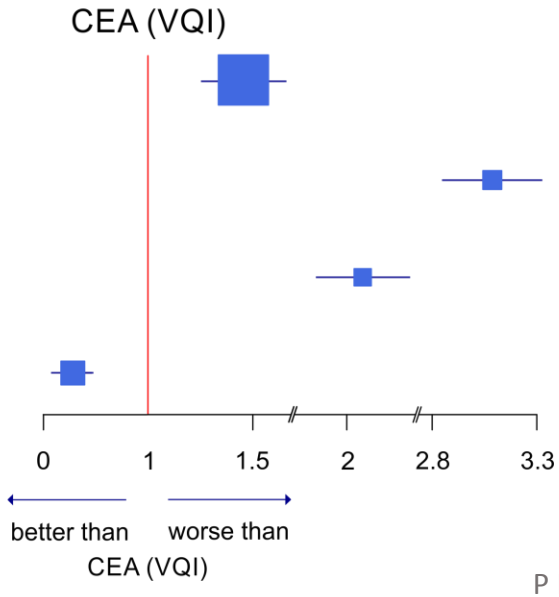
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 42	100%	1.30 [1.05−1.55]
Casper/RoadSaver	348 26	29.2%	2.75 [2.48−3.02]
Gore Mesh Stent	290 14	24.4%	0.94 [0.80−1.08]
CGuard MicroNET Stent	553 2	46.4%	0.16 [0.08−0.24]

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.

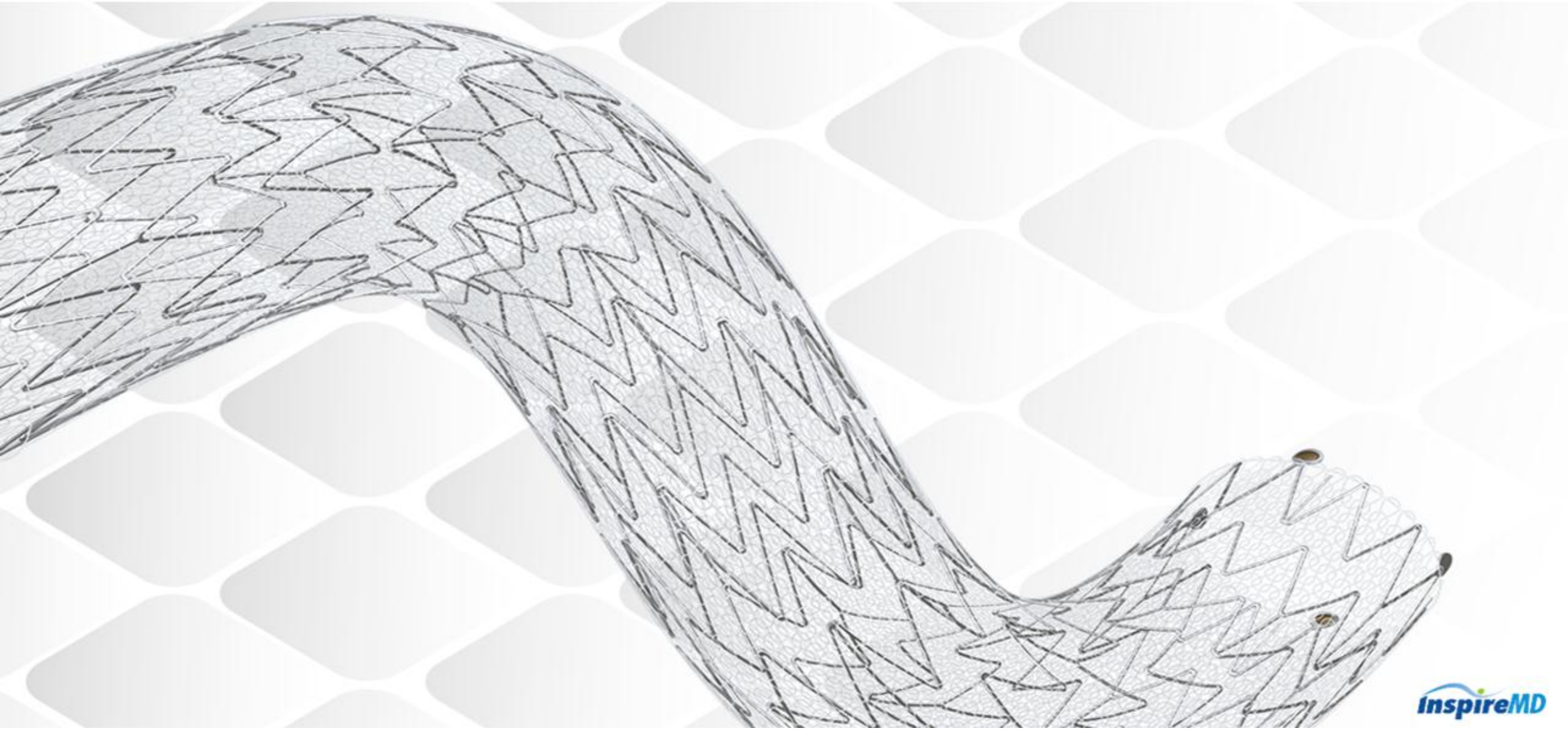
CARMEN Collaborators

J Cardiovasc Surg 2023

FDA-IDE 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

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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)

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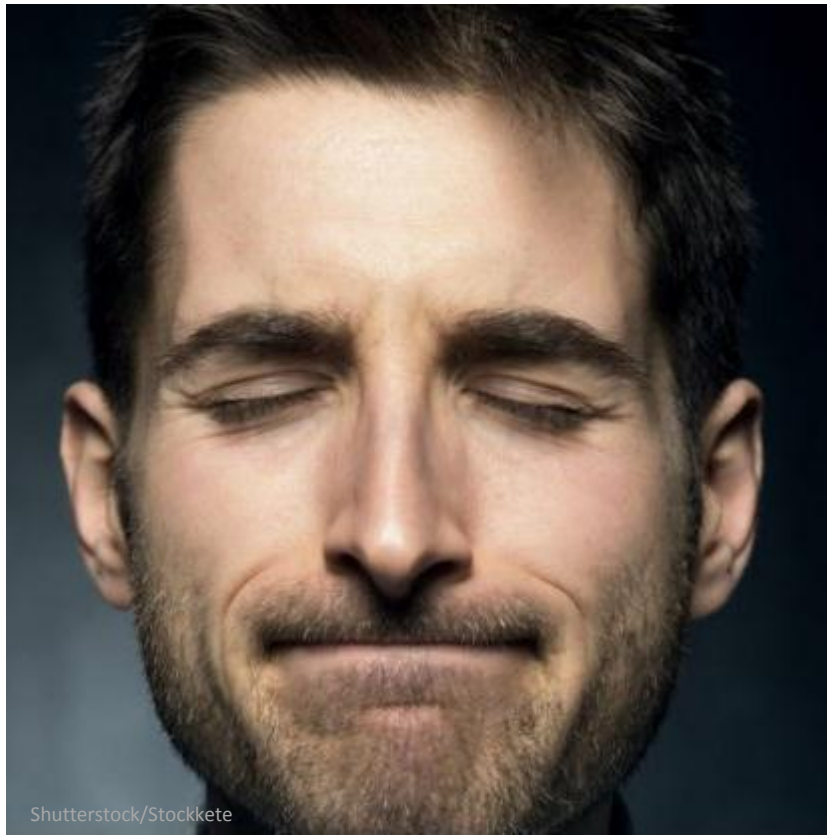
* Hierarchical: patient count (each patient first occurrence of the most serious event).

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



! BEWARE OF INAPPROPRIATE CONTENT !

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.

Summary of C-GUARDIANS 1 Year Outcomes

- **30-Day Outcomes**
  - * DSMI: **ITT 0.95%, PP 0.63%**
  - * No MI, No contralateral stroke

- **1-Year Outcomes**

  Follow up compliance rate at 1-year: 97%

  30-day DSMI or ipsilateral stroke between 31 and 365 days:
  - * **ITT 1.95%, PP 1.7%**
  - * **TLR (any target revascularization up to 365 days): 1% (3)**

Prospective, single-arm, multi-center, **observational study** in one of the **largest CAS cohorts** to date

1967 Patients enrolled*

13 Countries

52 Sites

ROADSAVER study

Analysed: N=1965

Cardiologist/ Angiologists N=717 (36.5%)

Radiologists *(Interventional/Neuro)* N=878 (44.7%)

Surgeons *(Vascular/Neuro)* N=370 (18.8%)

0 — **30d** — **Clinical follow-up** — 1y →

Population:
Patients with **non-occlusive & non-thrombotic** carotid artery stenosis eligible for **elective** CAS treatment as per standard hospital practice

Primary Endpoint:
The rate of **Major Adverse Events (MAE)** defined as cumulative incidence of **any death** or **stroke** up to **30 days** post-procedure

*1965/1967 subjects received the Roadsaver™ carotid stent (for 2 enrolled patients adequate Roadsaver™ stent size was unavailable, and another stent was implanted).
d, days; y, year; ClinicalTrials.gov ID: NCT03504228

European ROADSAVER Study

	Cardiologists/ Angiologists (N=717)	Radiologists (N=878)	Surgeons (N=370)	p-value$
Access				
▪ Femoral	73.1	60.8	87.3	<0.0001
▪ Radial (incl. ulnar)	25.7	37.2	1.4	
▪ Cervical	-	-	10.0	
▪ Brachial	1.3	1.9	1.4	
Embolic protection use	80.8	46.7	71.4	<0.0001
Embolic protection type				
▪ Distal filter	81.9	98.3	81.4	<0.0001
▪ Proximal protection*	18.1	1.2	18.2	
▪ Mix distal & proximal	-	0.5	0.4	
Pre-dilatation	36.4	19.9	18.4	<0.0001
Post-dilatation	98.3	94.1	96.8	<0.0001

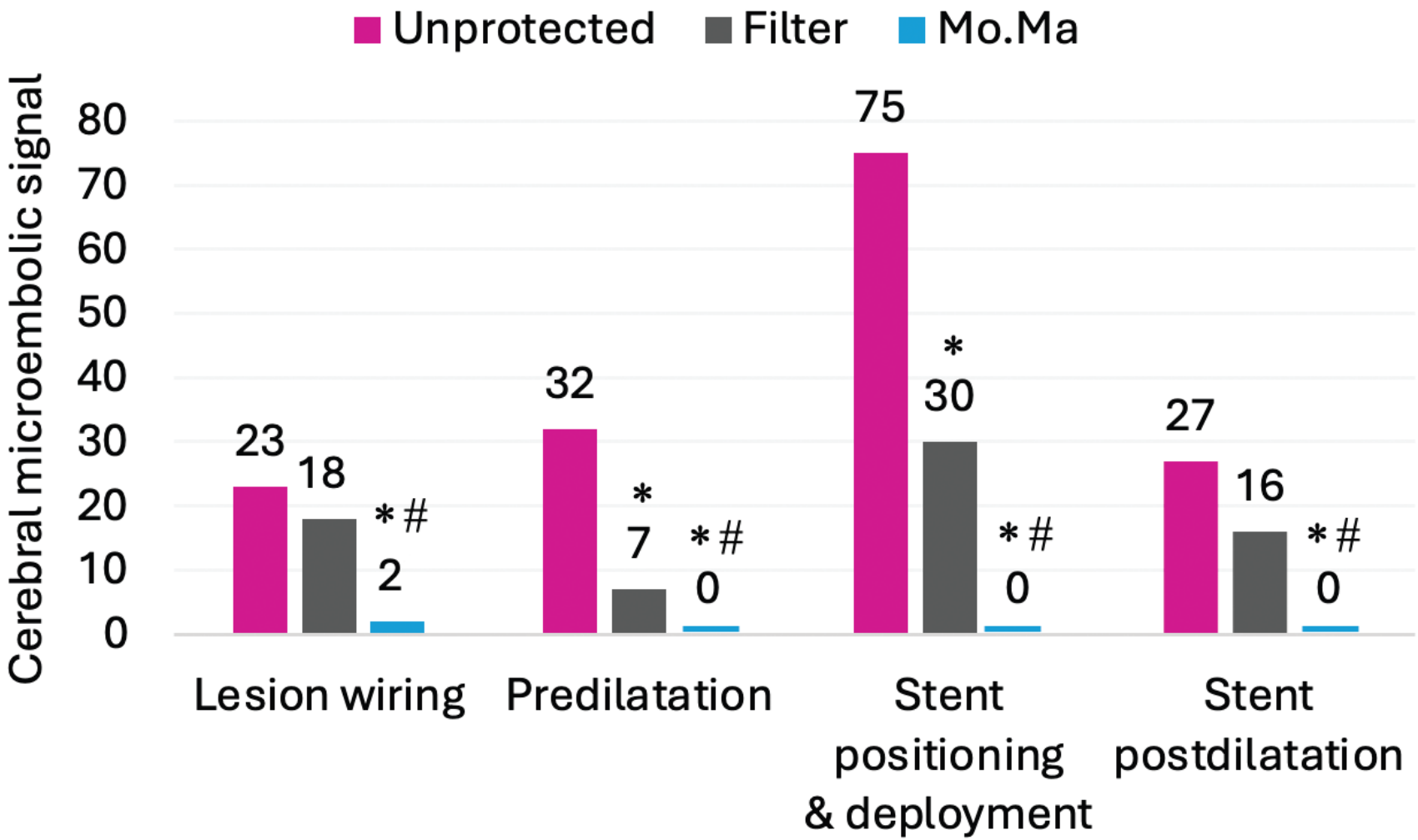
European ROADSAVER Study

30-day **Safety Outcomes**

% (n)	Cardiologists/ Angiologists (N=717)	Radiologists (N=878)	Surgeons (N=370)
❑ **Primary endpoint** MAE (*i.e. any death or stroke*)	2.0 (14)	2.5 (22)	1.9 (7)
▪ **Any death**	1.0 (7)	0.8 (7)	0.3 (1)
○ Stroke-related death	0.4 (3)	0.6 (5)	0.3 (1)
▪ **Any stroke**	1.4 (10)	2.3 (20)	1.9 (7)
○ Minor	0.8 (6)	1.1 (10)	0.8 (3)
○ Major*	0.6 (4)	1.0 (9)	1.4 (5)

All deaths and strokes were adjudicated by an independent Clinical Event Committee (CEC)

Proximal Embolic Protection With the Mo.Ma Ultra™ Device: A "Must Know How" for Competent Carotid Artery Stenting



ENDOVASCULAR TODAY JUNE 2024 VOL. 23, NO. 6

In conclusion,

The landscape has changed

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

Carotid stent as cerebral protector: the arrival of Godot

Piotr MUSIALEK [1, 2] *, Ralf LANGHOFF [3], Matteo STEFANINI [4], William A. GRAY [5, 6, 7]

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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.

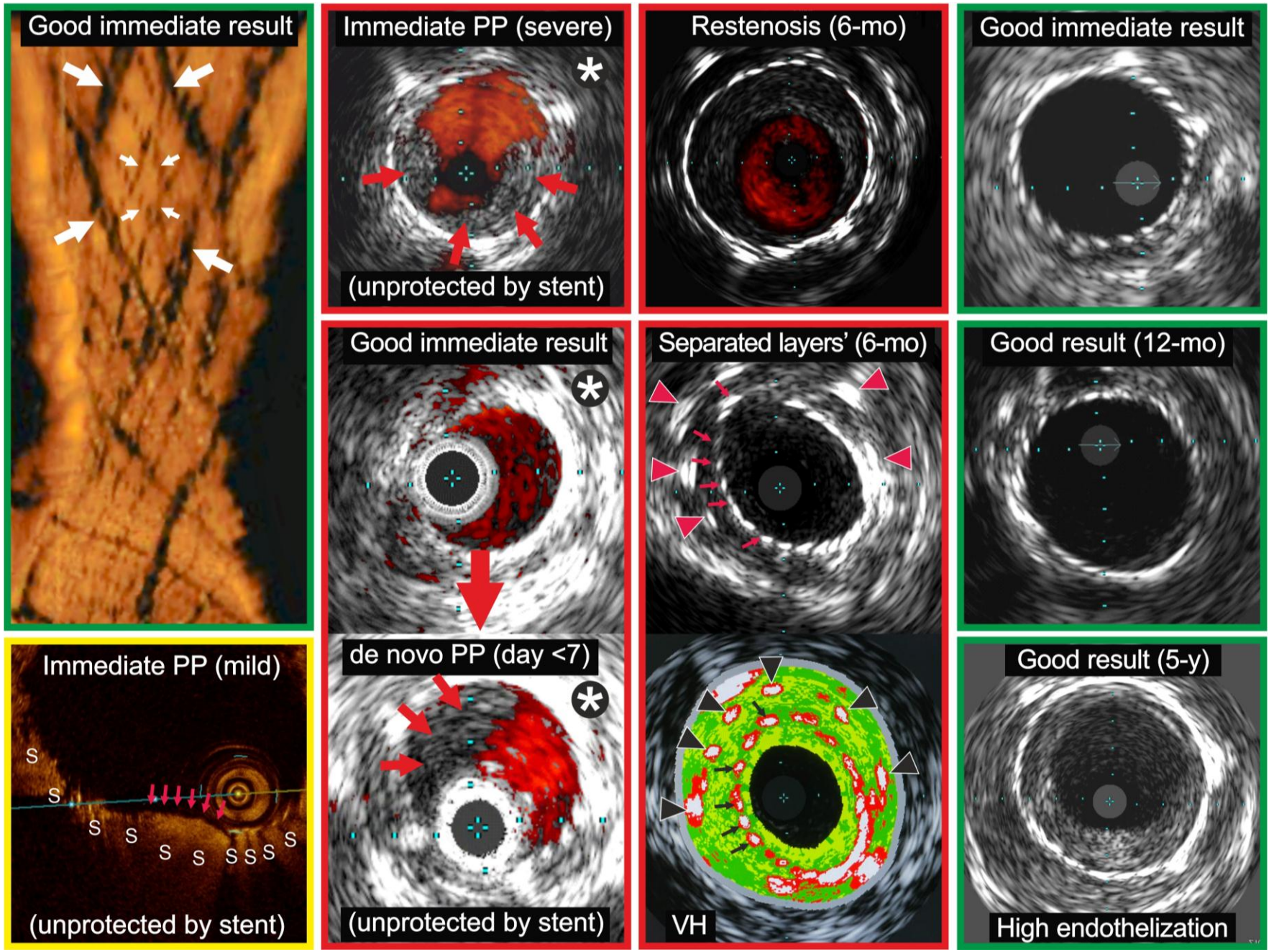
2024 Vilnius Vascular Symposium

Carotid Anti-Embolic (’Mesh’) Stents:

Not Created Equal

Piotr Musialek Lukasz Tekieli Tomoyuki Umemoto

JSCAI 2024 (in press)



2024 Vilnius Vascular Symposium

*Myouchin et al.
JSCAI 2024 (in press)

Piotr Musialek Lukasz Tekieli Tomoyuki Umemoto

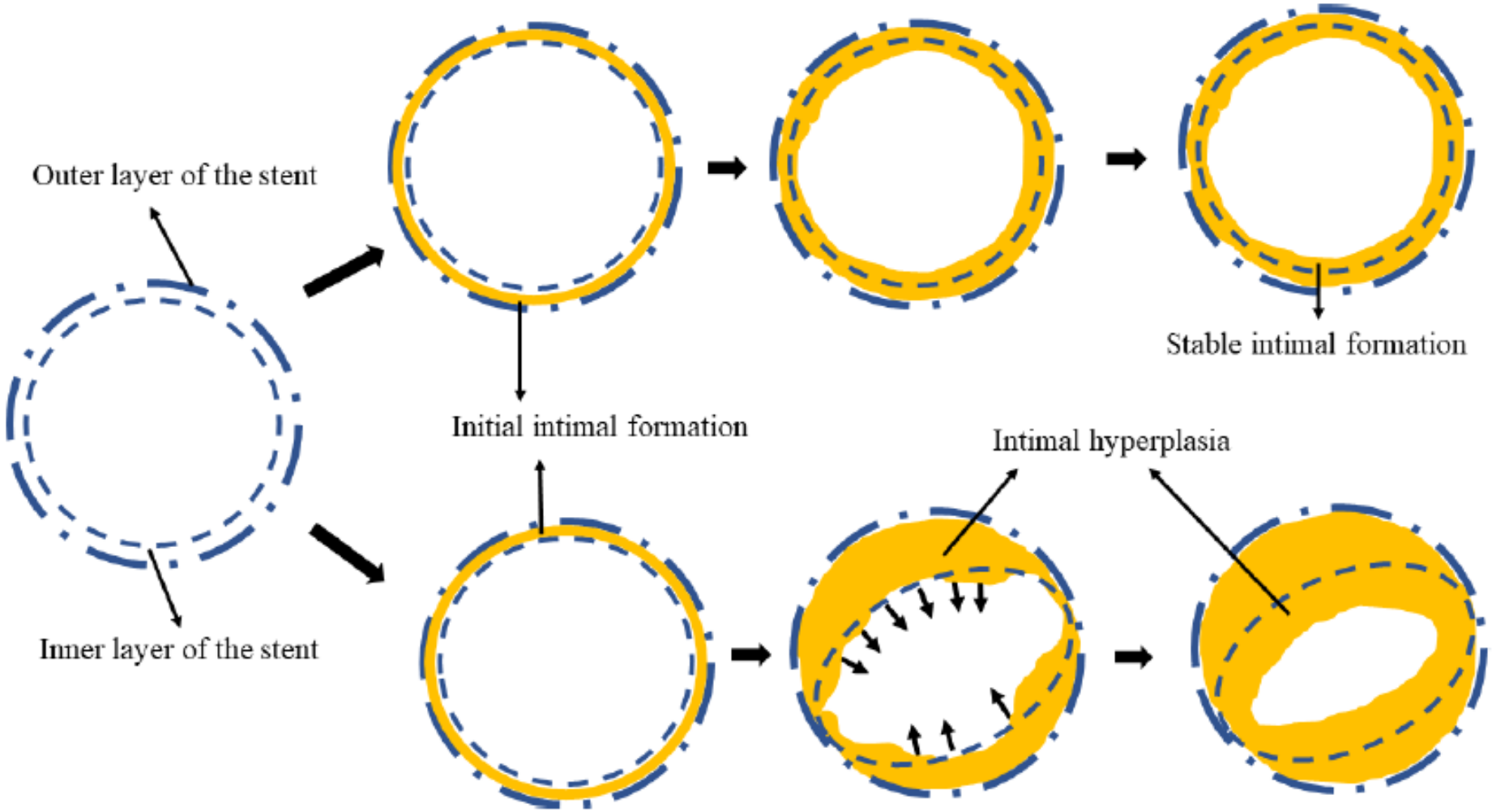
JSCAI 2024 (in press)

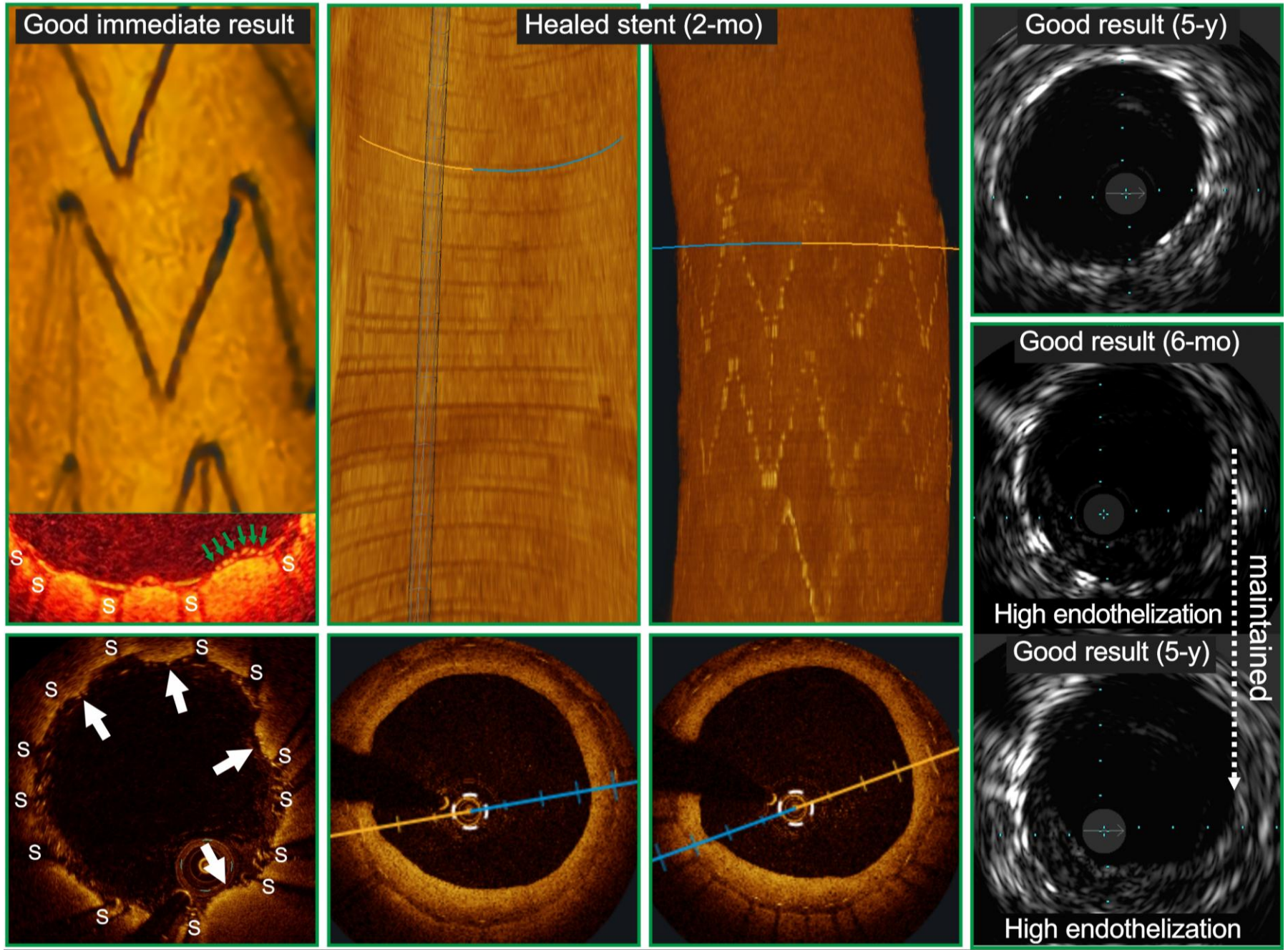
OPEN ACCESS

Original research

Clinical results of 30 consecutive patients of carotid artery stenosis treated with CASPER stent placement: 1-year follow-up and in-stent findings on intravascular ultrasound examination immediately and 6 months after treatment

Hiroyuki Matsumoto, Daisuke Izaw
Kazuhide Maeshima





2024 Vilnius Vascular Symposium

Piotr Musialek Lukasz Tekieli Tomoyuki Umemoto

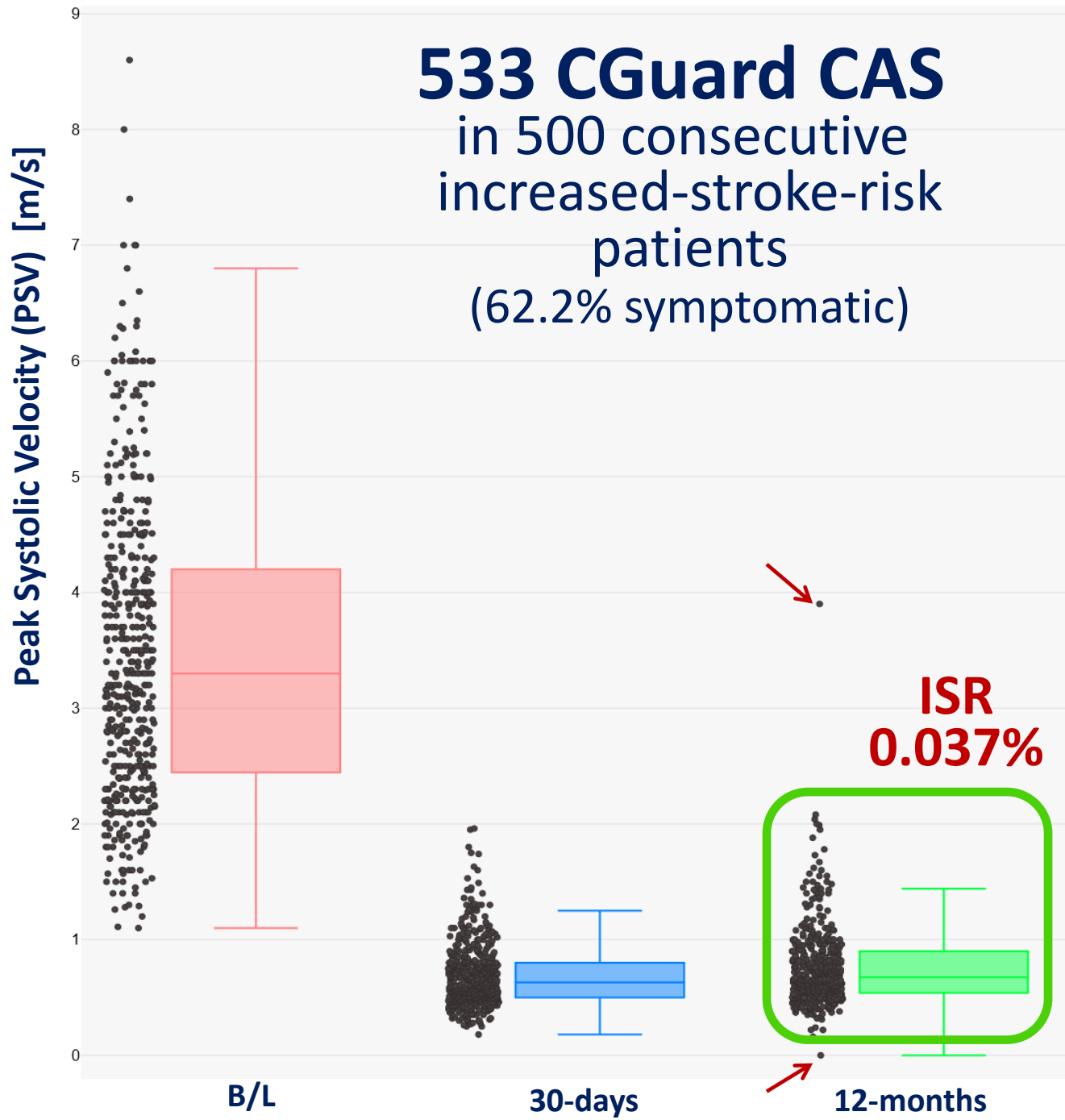
JSCAI 2024 (in press)

Vilnius Vascular Symposium

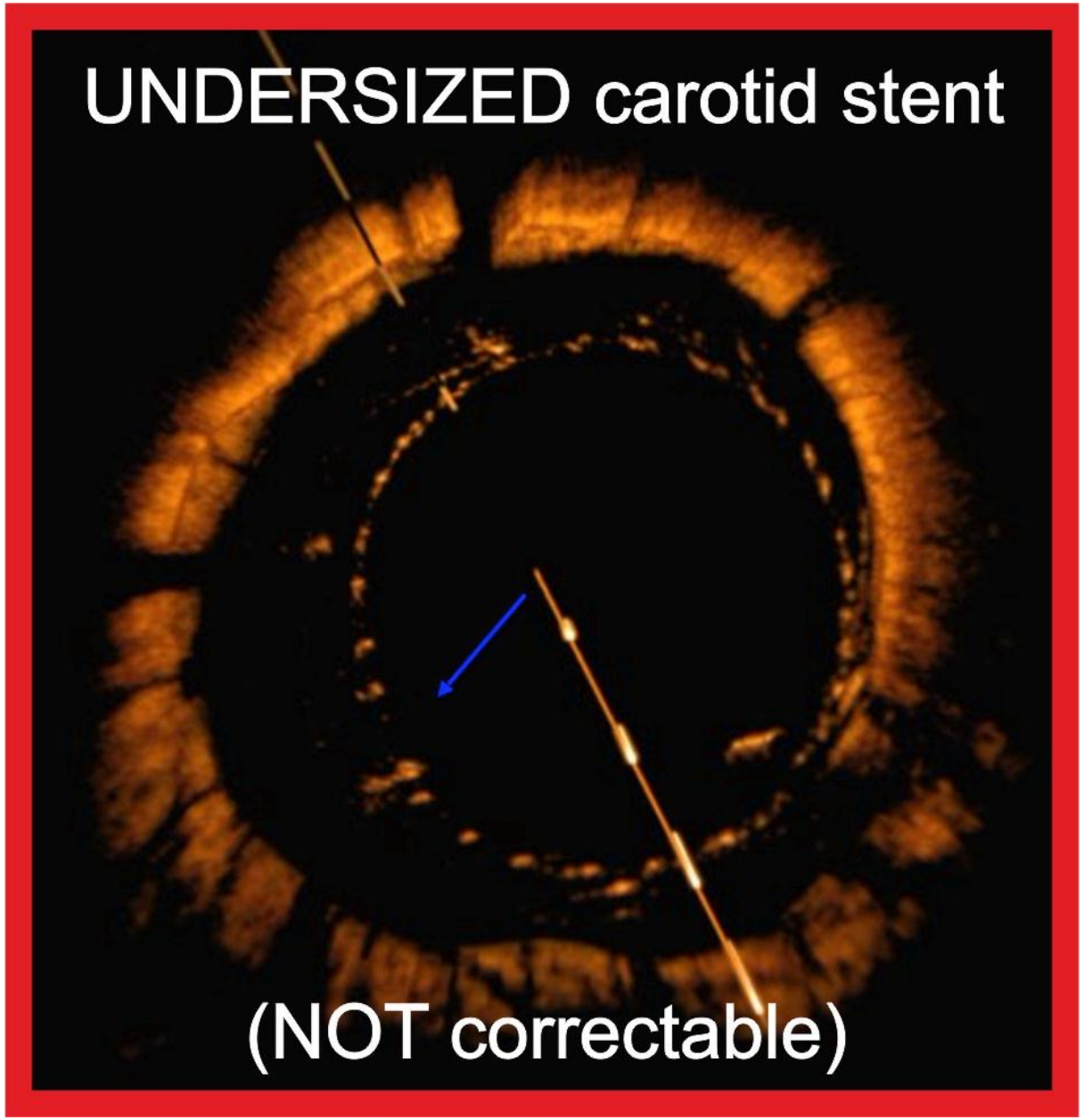
In-stent Restenosis
in PARADIGM-500

MicroNET-Covered Stent

with routine
post-dilatation optimization



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



2024 Vilnius Vascular Symposium

Piotr Musialek Lukasz Tekieli Tomoyuki Umemoto ***JSCAI*** 2024 (in press)

Circulation
Volume 91, Issue 6, 15 March 1995; Pages 1891-1893
https://doi.org/10.1161/01.CIR.91.6.1891

ARTICLE

Who Was Thrombogenic: The Stent or the Doctor?

Patrick W. Serruys and Carlo Di Mario

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],

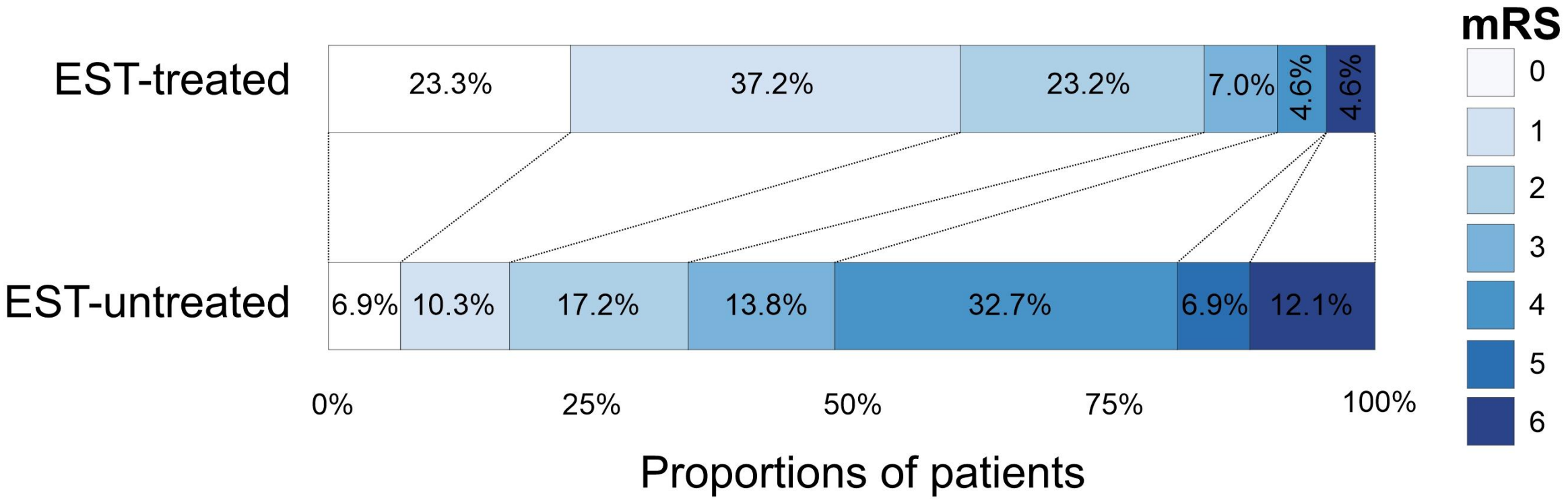
2024 Vilnius Vascular Symposium

Predictors of stent patency loss by 90 days

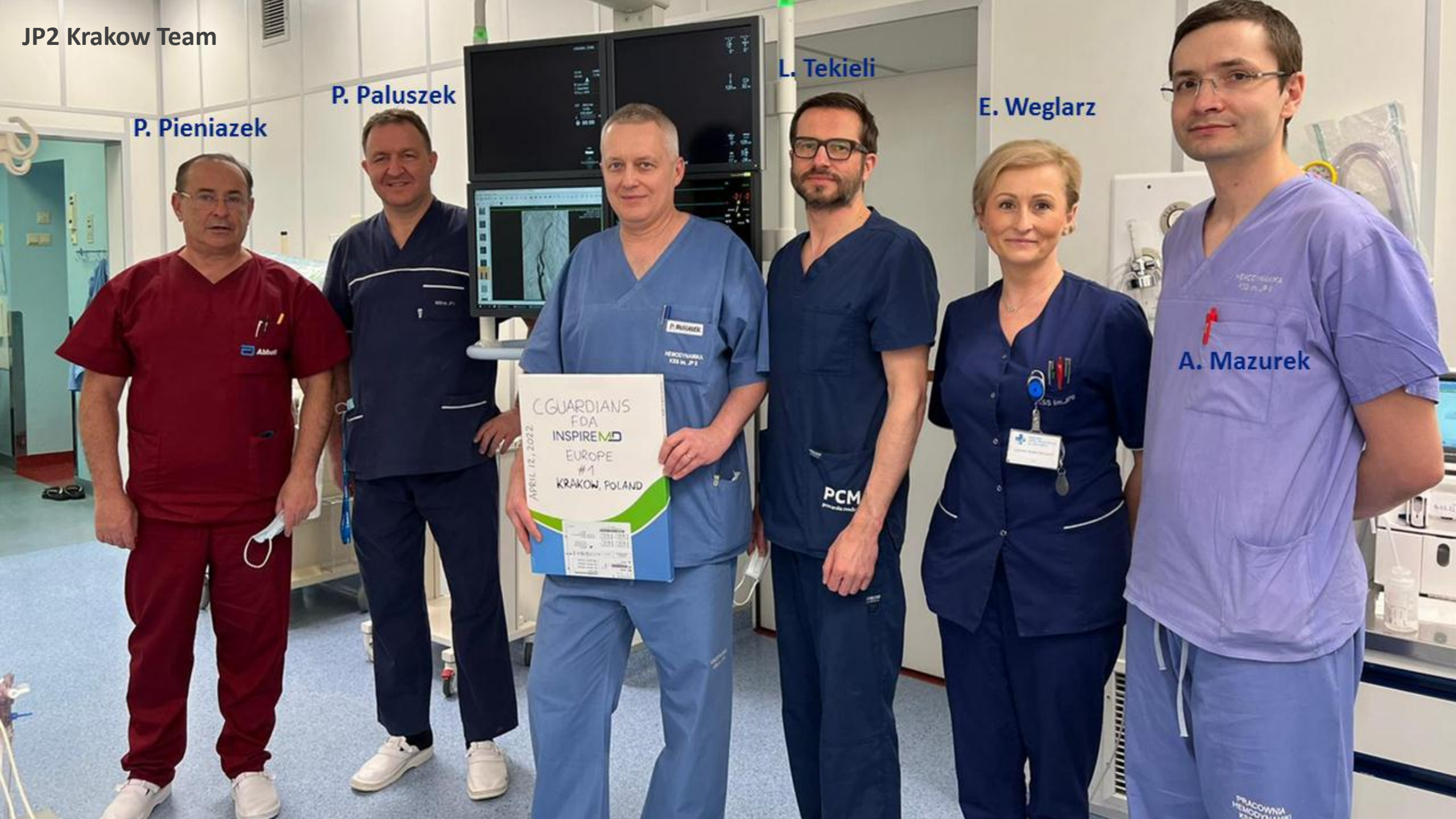
Univariate	Mulitvariate
Heparin limited to flush OR **14.3** (1.5-53.1), p=0.007	Postdilatation balloon < 5mm OR **15.2** (5.7-72.3), p<0.001
mTICI < 2b OR **12.7** (4.9-97.9), p=0.001	mTICI < 2b OR **6.3** (0.98-45.2), p=0.080
Tandem lesion OR **9.2** (1.1-28.4), p=0.030	
Postdilatation balloon < 5mm*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

Adv Interv Cardiol 2024

MicroNET-Covered Stent in Acute Carotid Stroke



L. Tekieli, et al. *J Cardiovasc Surg* 2024;65:231-248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