New Technologies

Anti-embolic stent CAS vs single-layer stent CAS vs CEA

Piotr Musialek, MD DPhil

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St. John Paul II Hospital, Kraków, Poland

Conflicts of Interest Piotr Musialek, MD DPhil

Recipient of public grants for basic and clinical research in atherosclerisis and cardiovascular regeneration

Proctor and/or consultant/advisory board member for Abbott Vascular, Balton, Gore, InspireMD, and Medtronic

Initiator/PI in Investigator-Run Clinical Studies in cardiovascular interventional medicine

Global Co-PI in CGUARDIANS FDA IDE Clinical Trial

Polish Cardiac Society Board Representative for Stroke and Vascular Interventions

CARMEN (CArotid Revascularization systematic reviews and MEta-aNalyses) Colllaboration

ESC Stroke Council Scientific Documents Task Force

Decision-Making in Carotid Stenosis

Podlasek , Grunwald, Musiałek 2021

Decision-Making in Carotid Stenosis

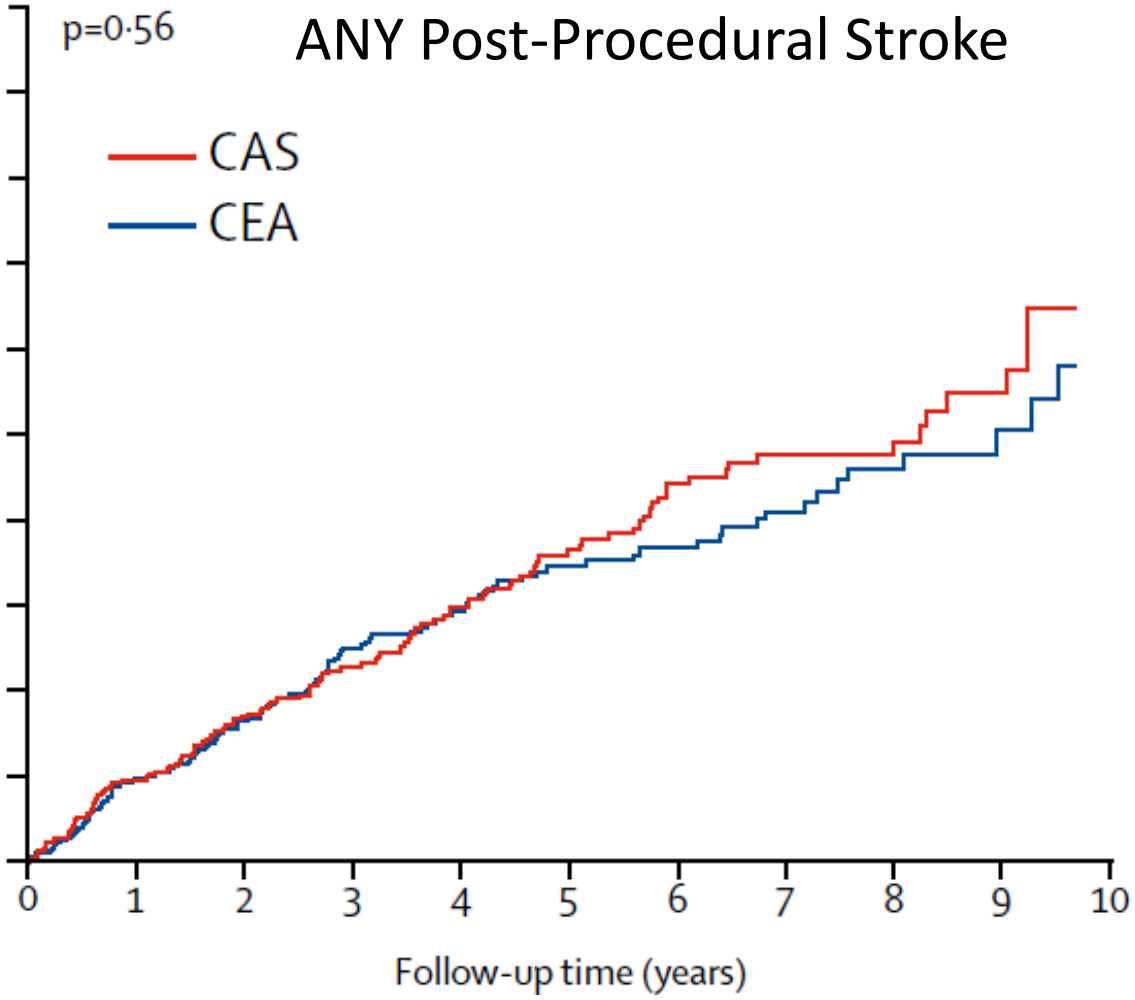
TYPE OF INTERVENTION

(CAS, TCAR, CEA)

Podlasek , Grunwald, Musiałek 2021

Long-term outcomes of stenting and endarterectomy for symptomatic carotid stenosis: a preplanned pooled analysis of individual patient data

Thomas G Brott, David Calvet*, George Howard, John Gregson, Ale Algra, Jean-Pierre Becquemin, Gert J de Borst, Richard Bulbulia, Hans-Henning Eckstein, Gustav Fraedrich, Jacoba P Greving, Alison Halliday, Jeroen Hendrikse, Olav Jansen, Jenifer H Voeks, Peter A Ringleb†, Jean-Louis Mas†, Martin M Brown†, Leo H Bonati†, on behalf of the Carotid Stenosis Trialists' Collaboration*



Fundamental (historical) determinants of the CAS – CEA relationship

Fundamental (historical) determinants of the CAS – CEA relationship

- The CREST Trial

Fundamental (historical) determinants of the CAS – CEA relationship

- The CREST Trial
- Replacing ”who” with ”how”

Fundamental (historical) determinants of the CAS – CEA relationship

- The CREST Trial

- ”**How**” (carotid revasc. should be done)

as a replacement for

”**Who**” (”can”…. ”should” do it)

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

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

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Myocardial infarction	4 (0.3±0.2)	9 (0.7±0.3)	–0.4 (–1.0 to 0.2)	0.45 (0.14 to 1.44)	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
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WHERE exactly was the problem?

International Symposium CHARING CROSS

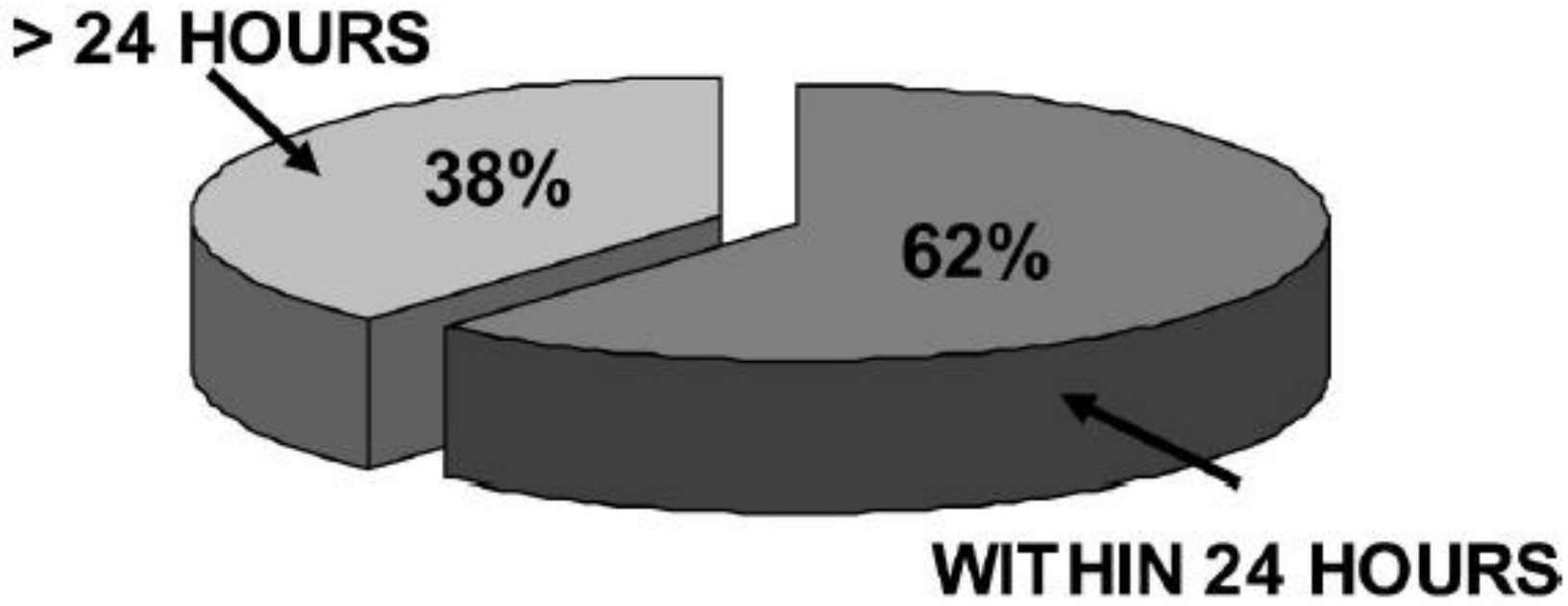
The TIMING of Stroke by 30-days with CAS in CREST

- 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.

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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	4 (0.3±0.2)	10 (0.8±0.3)	–0.5 (–1.2 to 0.1)	0.40 (0.13 to 1.24)	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
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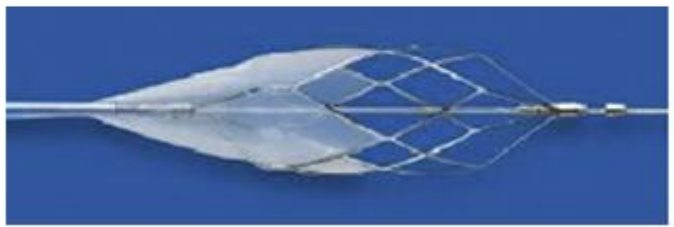
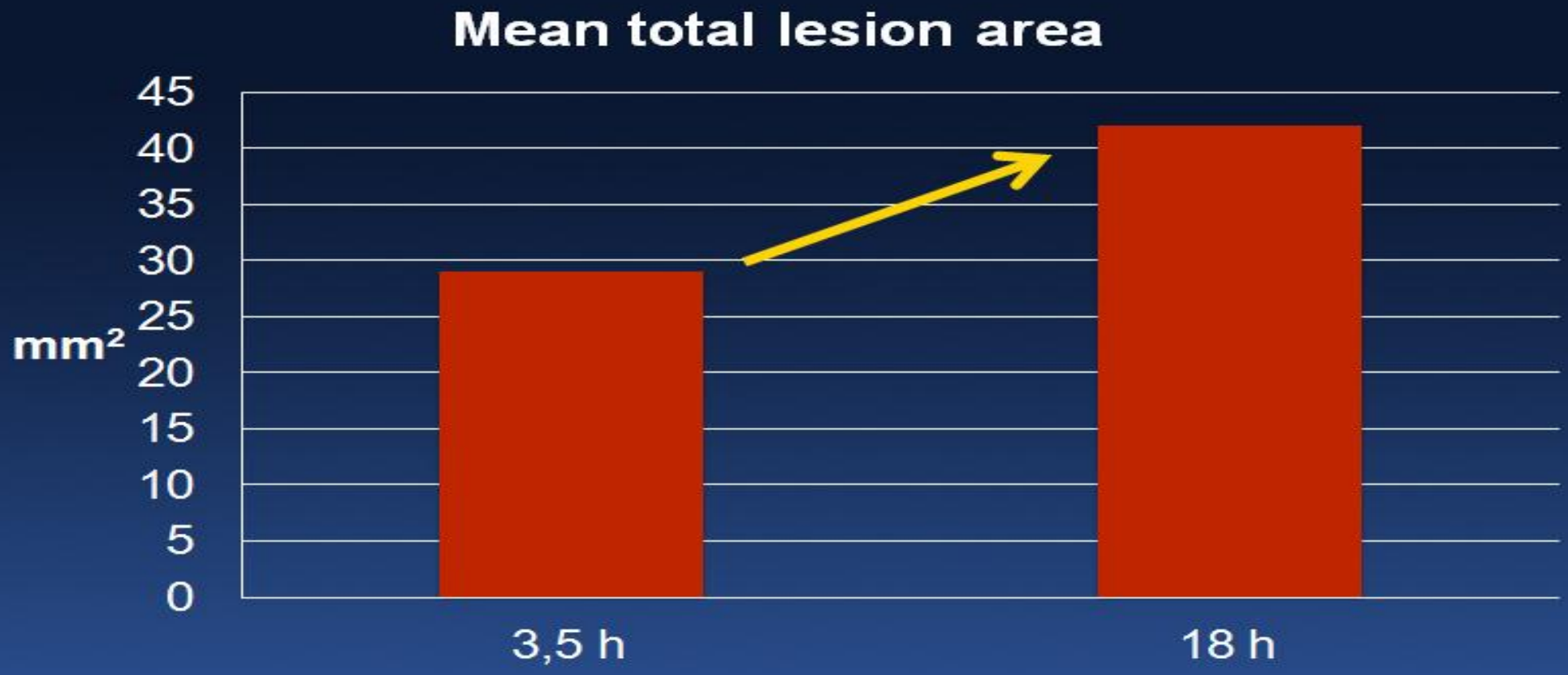


The Problem of Conventional (Single-layer) Carotid Stents

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

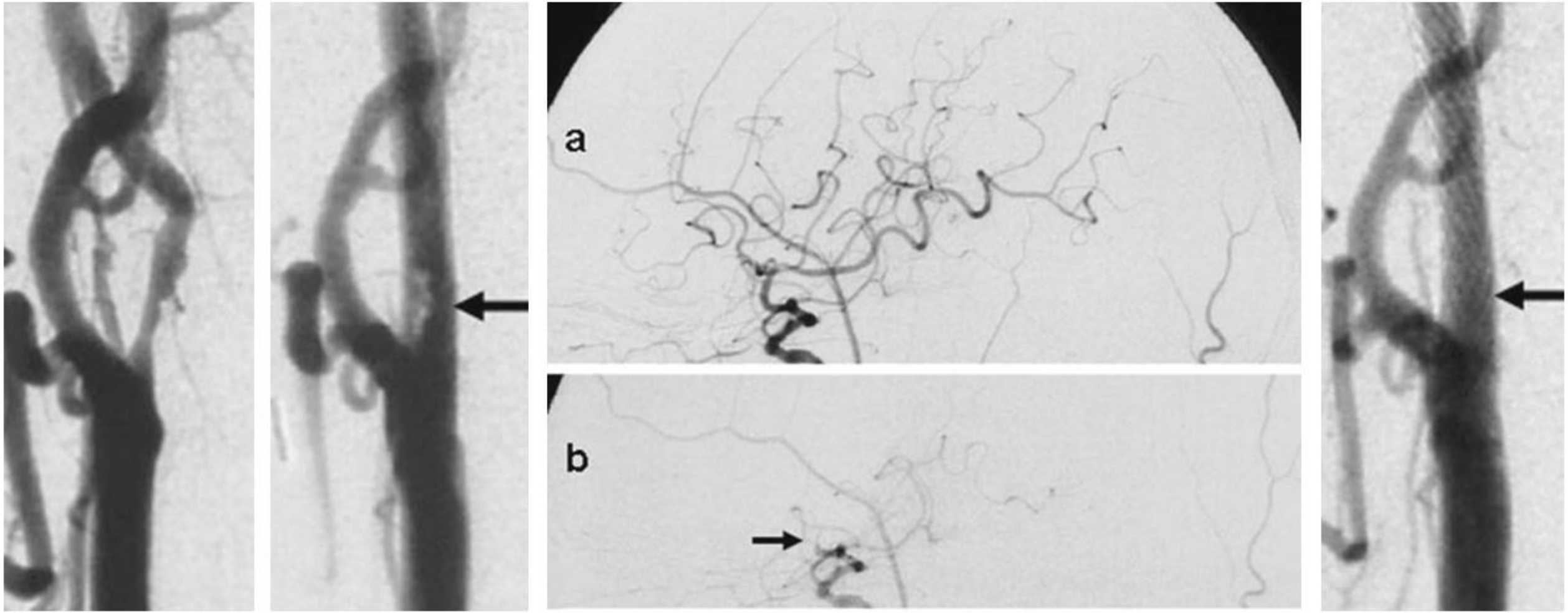
Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS



Schofer J et al, JACC Cardiovasc interv 2008

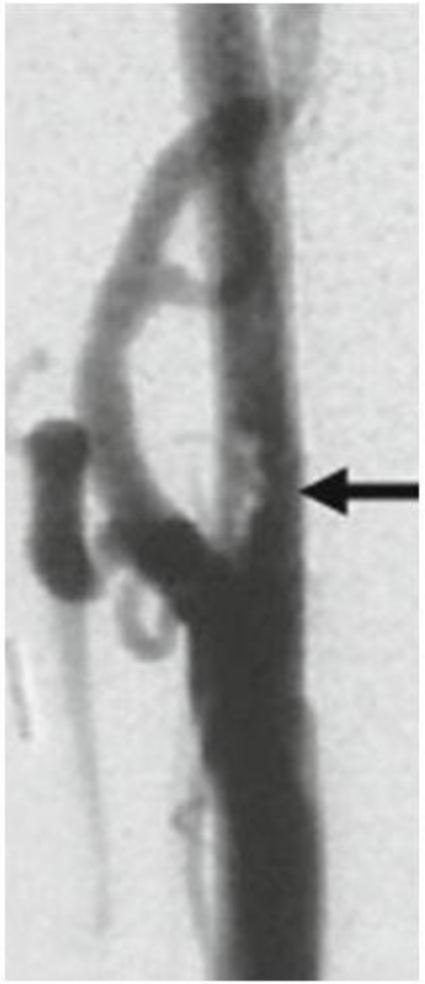
PLAQUE PROLAPSE with 1st Gen. Carotid Stents (Open-cell and Closed-cell)

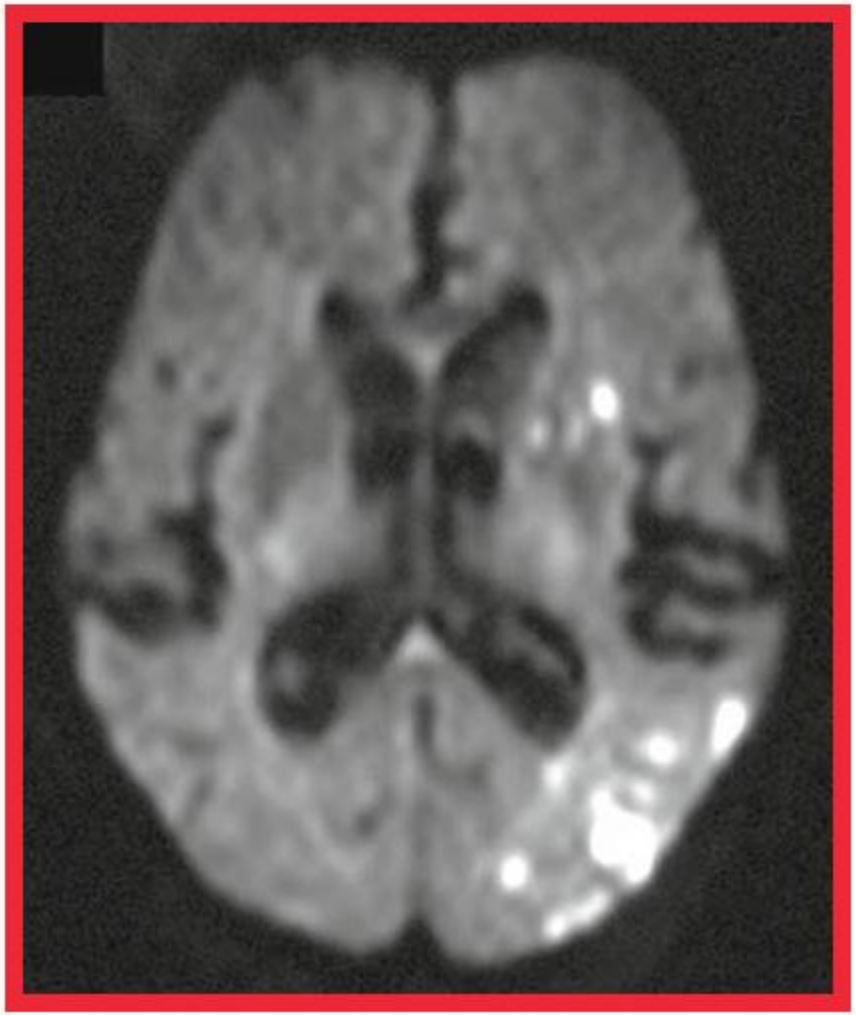


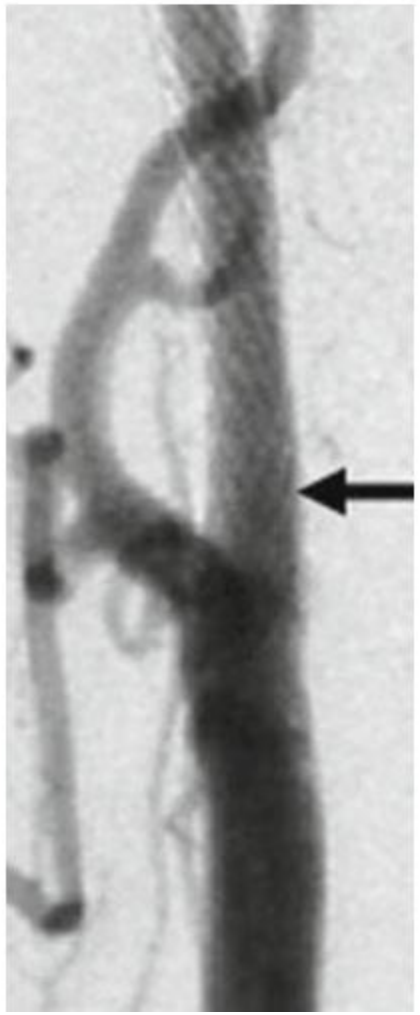
CAUSES STROKE

Aikawa et al. Radiat Med 2008;26:318–323

PLAQUE PROLAPSE with 1st Gen. Carotid Stents (Open-cell and Closed-cell)





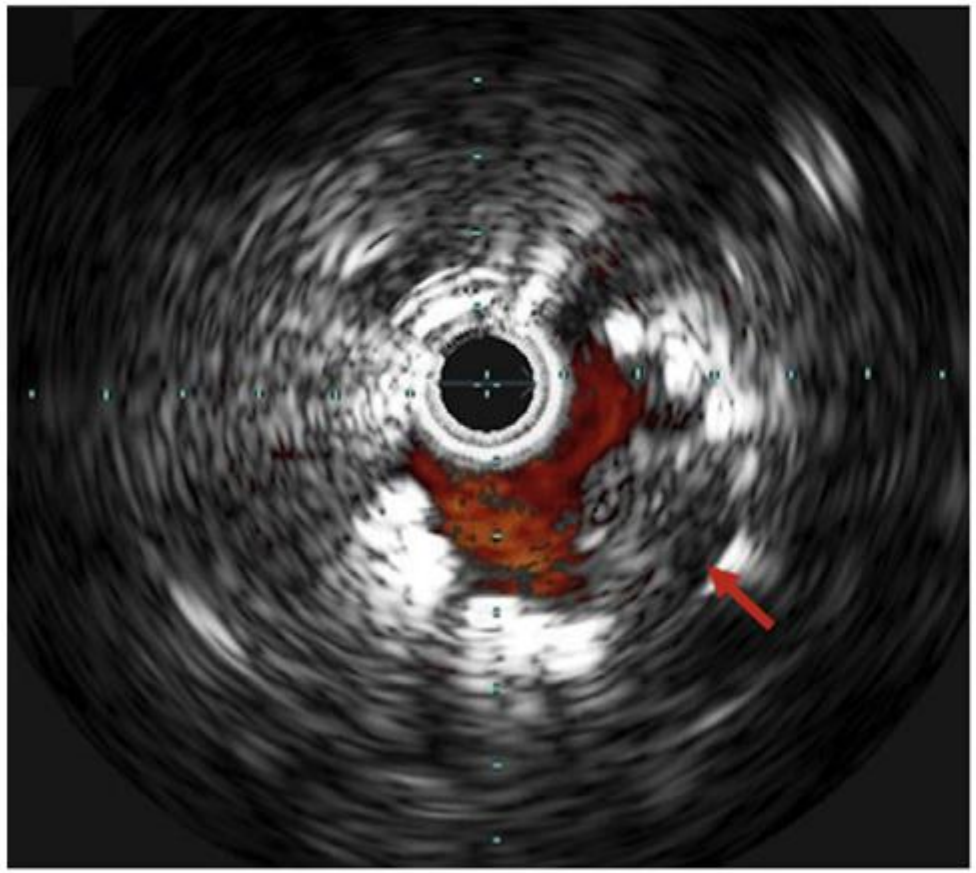


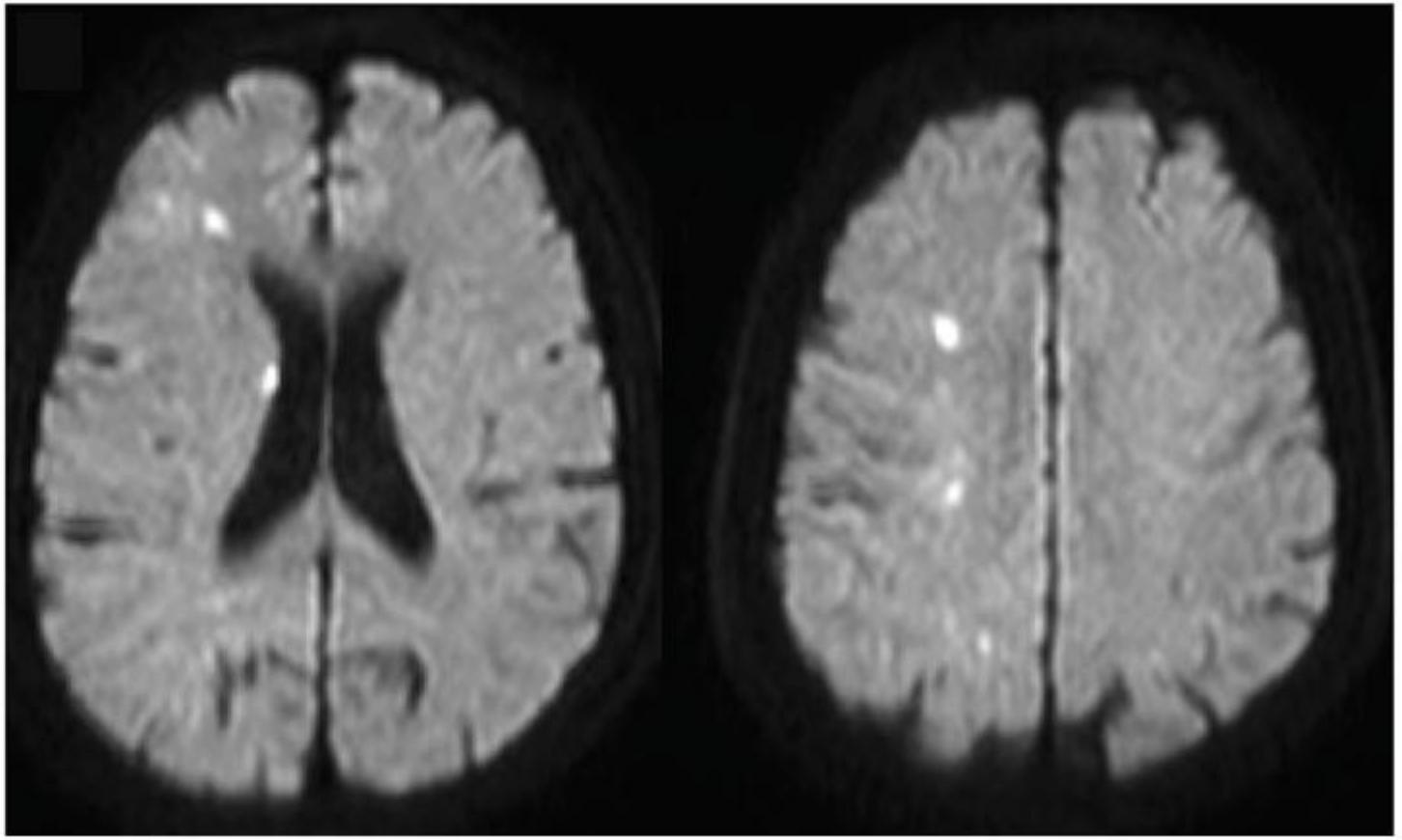
CAUSES STROKE

Aikawa et al. Radiat Med 2008;26:318–323

Failure to Eliminate the Plaque

with 1st Gen. Carotid Stents (Open-cell and Closed-cell)



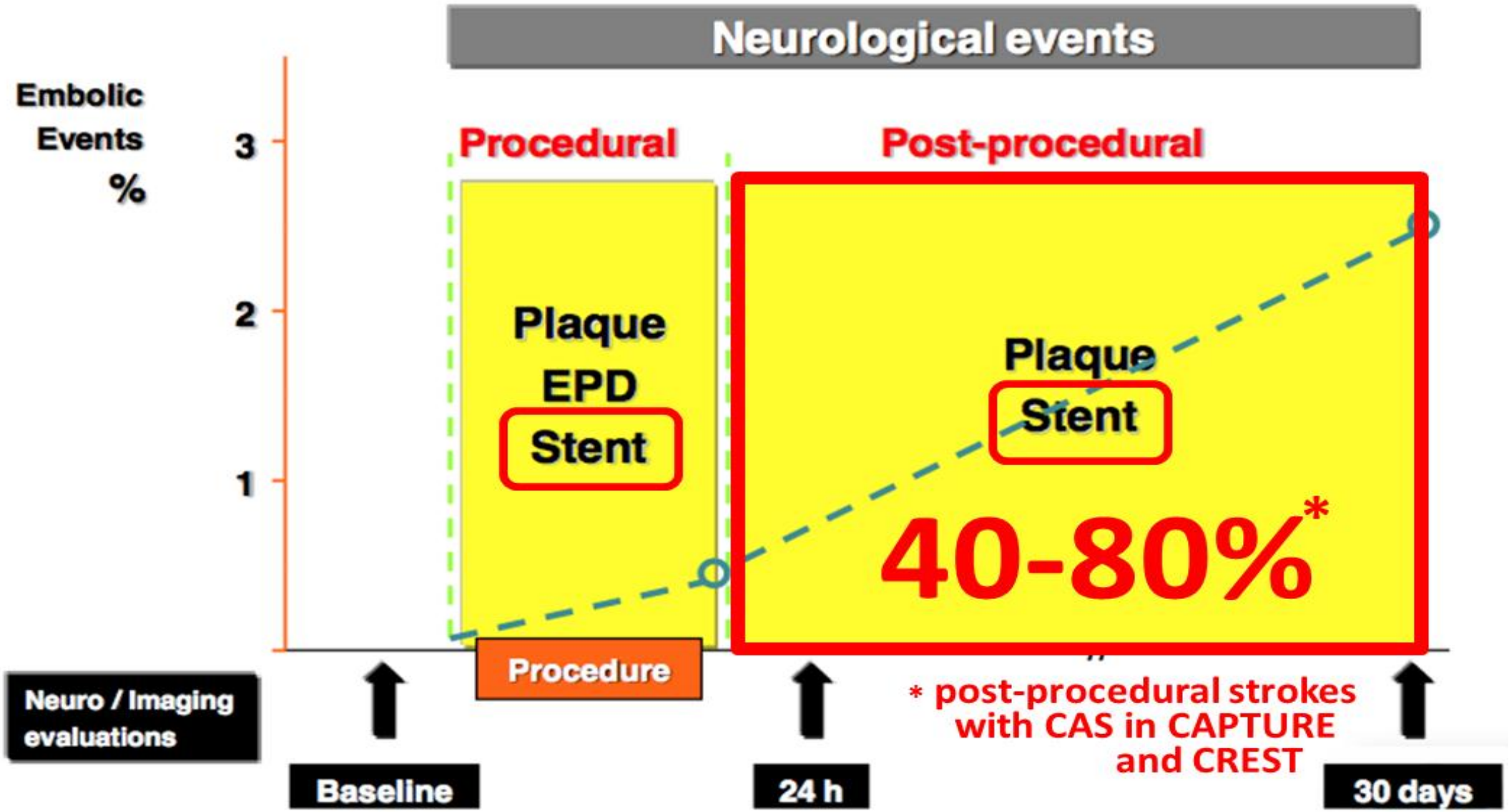


Plaque prolapse was strongly associated with ischemic stroke by 30 days

328 consecutive patients / 354 arteries

Kotsugi et al. JACC Intv 2017;10:824-31

Timing of neuro-embolic events after CAS



D. McCormick TCT 2012, modified

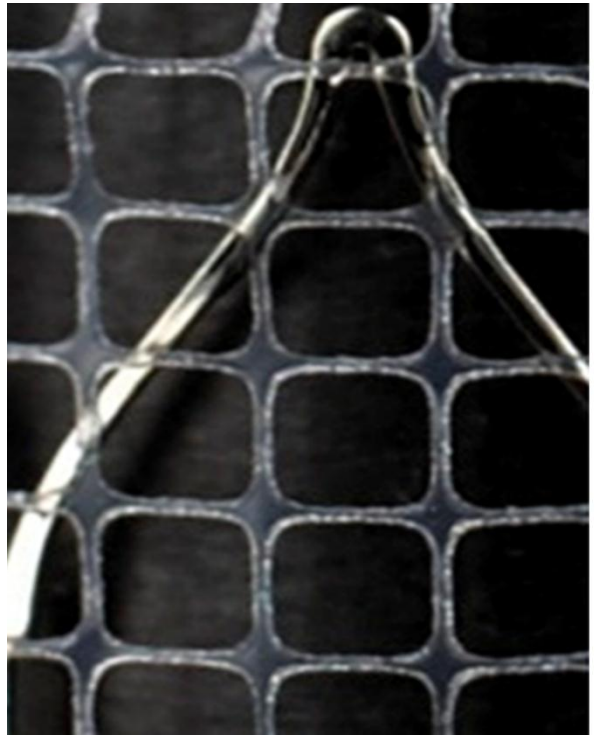
Mechanisms to explain the poor results of carotid artery stenting (CAS) in symptomatic patients to date and options to improve CAS outcomes

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*

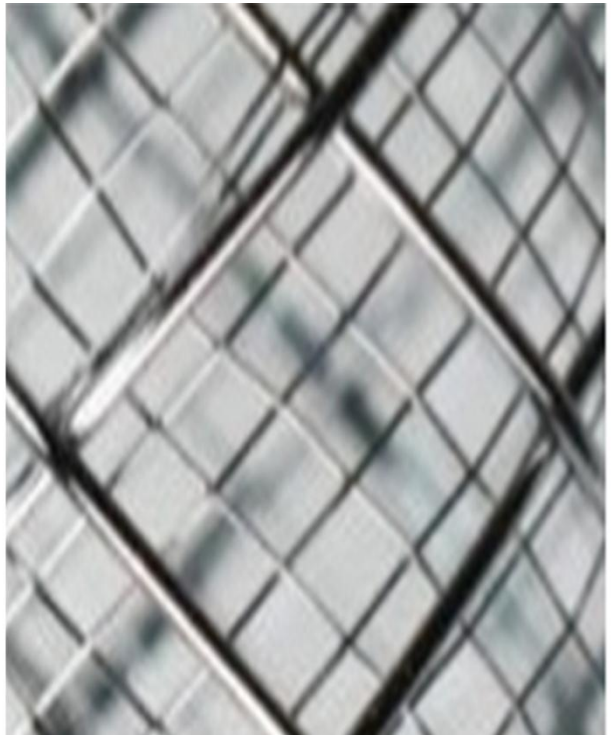
Background: Carotid artery stenting (CAS) is considered by many as an alternative to carotid endarterectomy (CEA) for the management of carotid artery stenosis. However, recent trials demonstrated inferior results for CAS in symptomatic patients compared with CEA. We reviewed the literature to evaluate 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



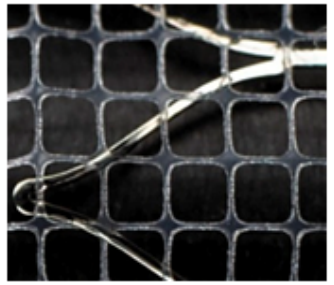
Casper/RoadSaver



CGuard

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

Carotid ’mesh’ stents

			
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

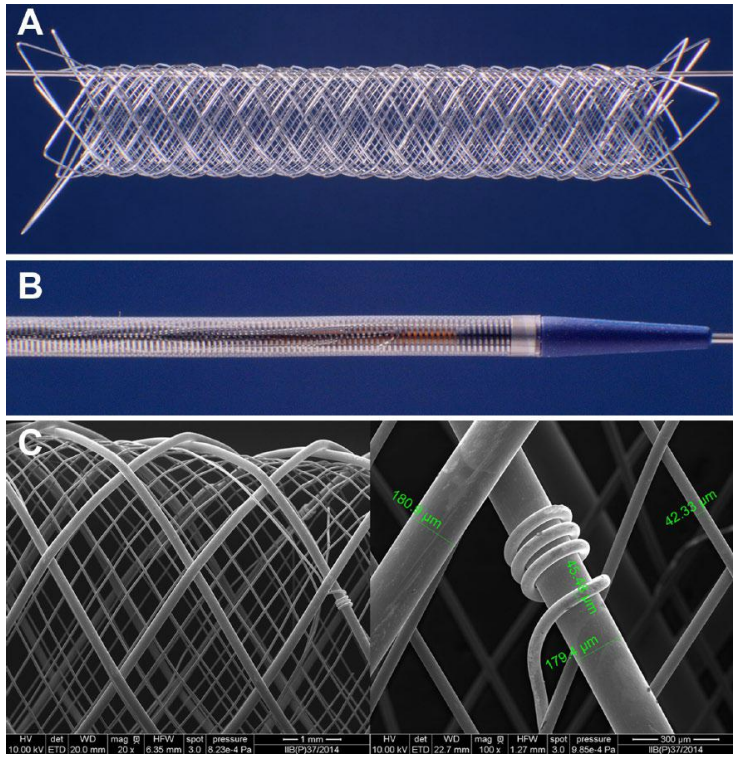
JOURNAL OF ENDOVASCULAR THERAPY

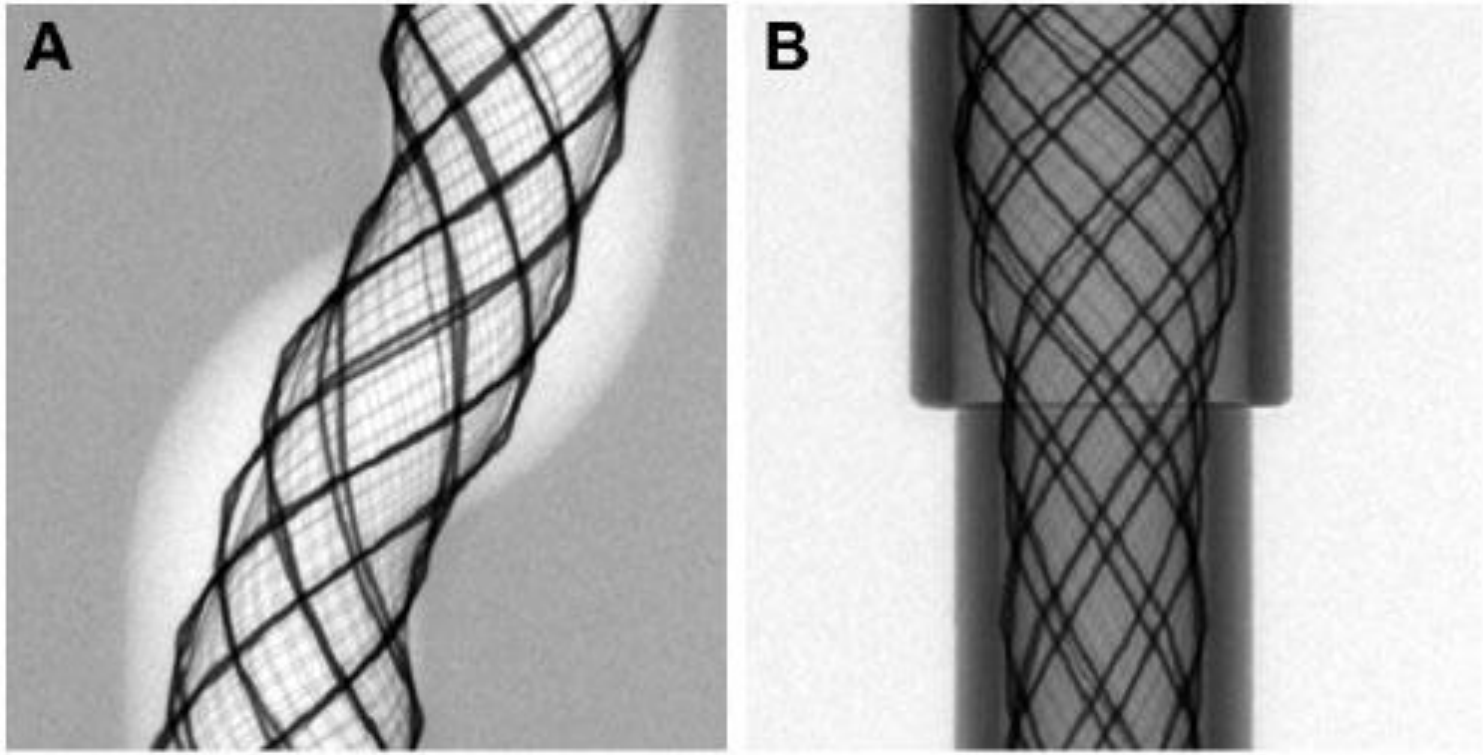
Journal of Endovascular Therapy
2015, Vol. 22(4) 634–639

DOI: 10.1177/1526602815593490
www.jevt.org
SAGE

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]





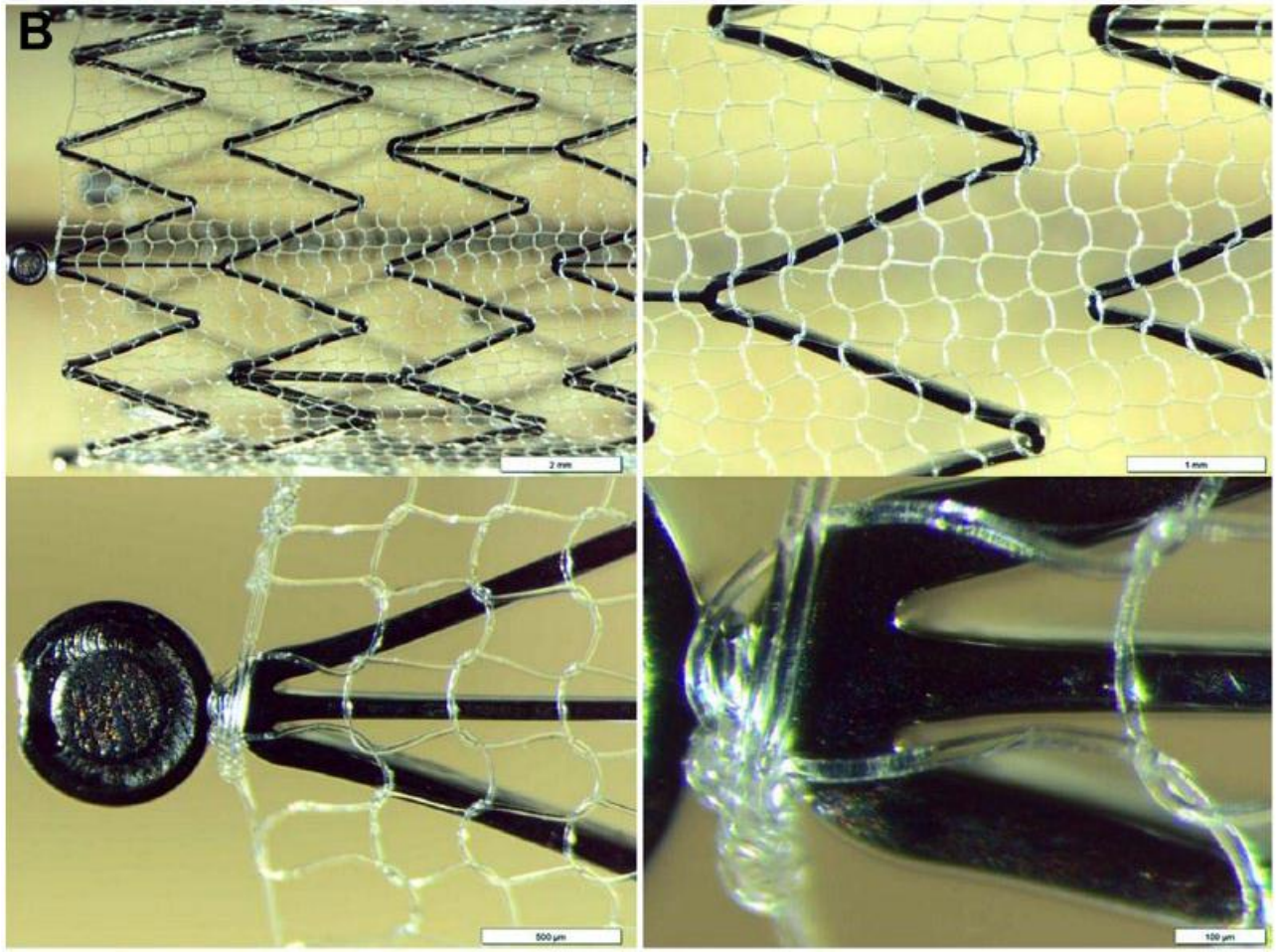
Clinical Investigation

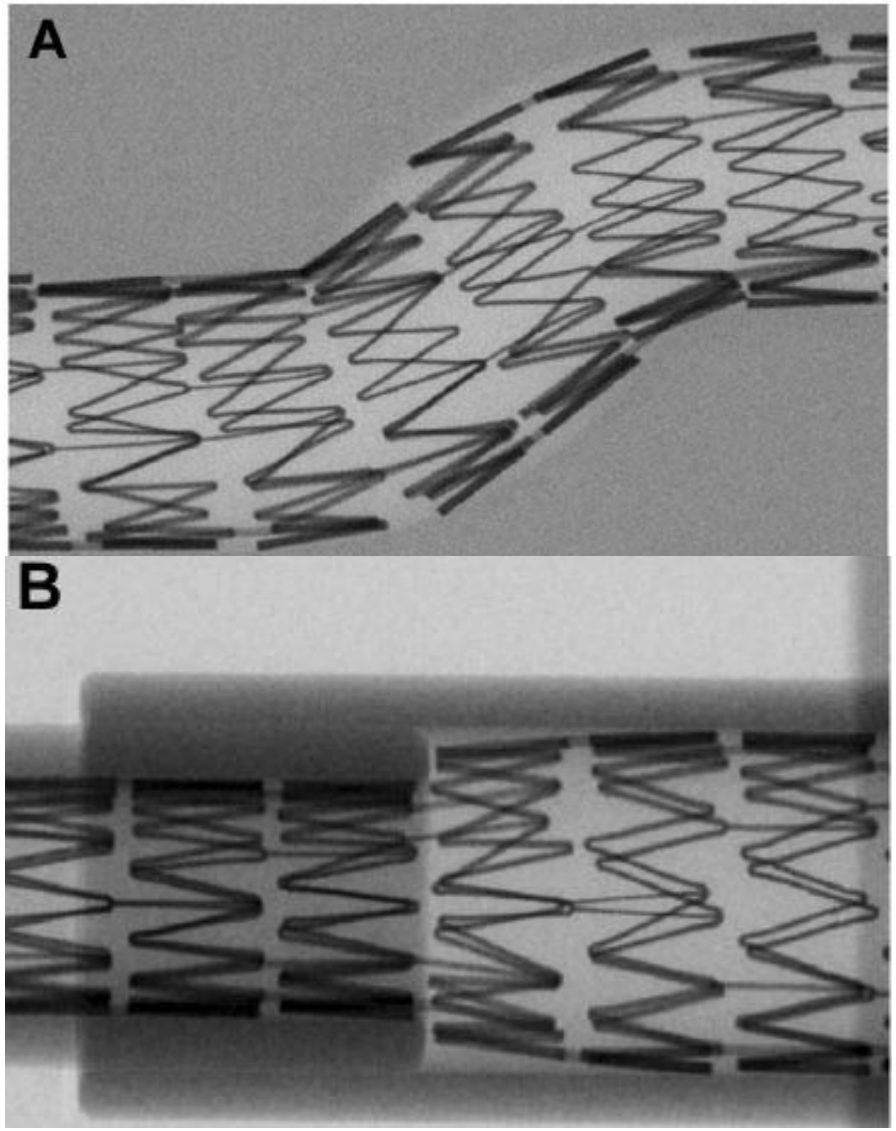
JOURNAL OF ENDOVASCULAR THERAPY
A SAGE Publication
An Official Publication of the International Society of Endovascular Specialists

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





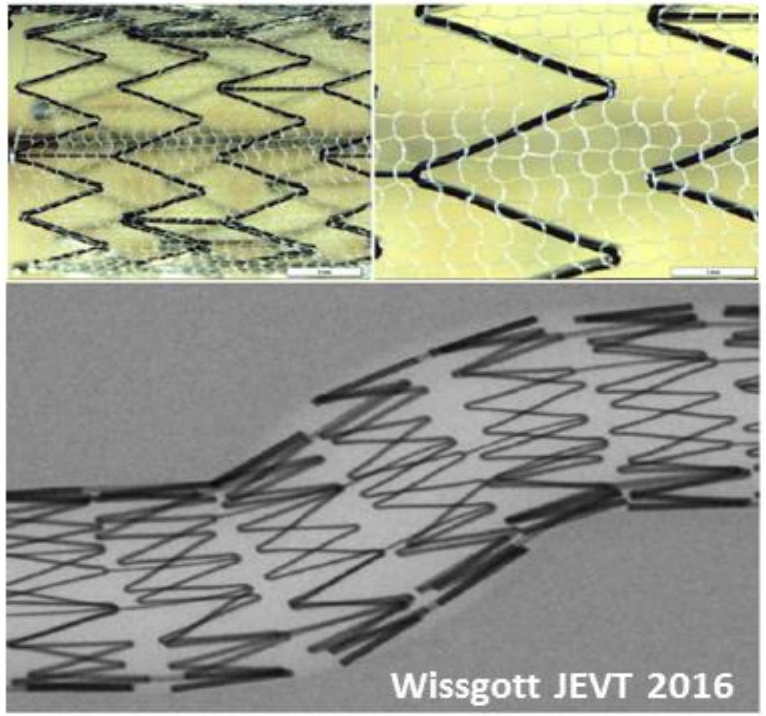
The **MOST 'open'** amongst open-cell stents (metallic FRAME)
& the **MOST 'close'** amongst close-cell stents (MicroNet mesh)

CGuard MicroNET – covered
2nd generation carotid stent

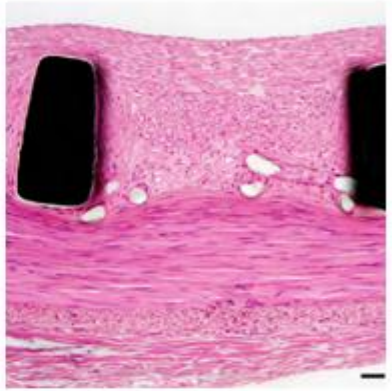
UNIQUE
mechanical
properties

RESPECT
of anatomy

FULL
apposition

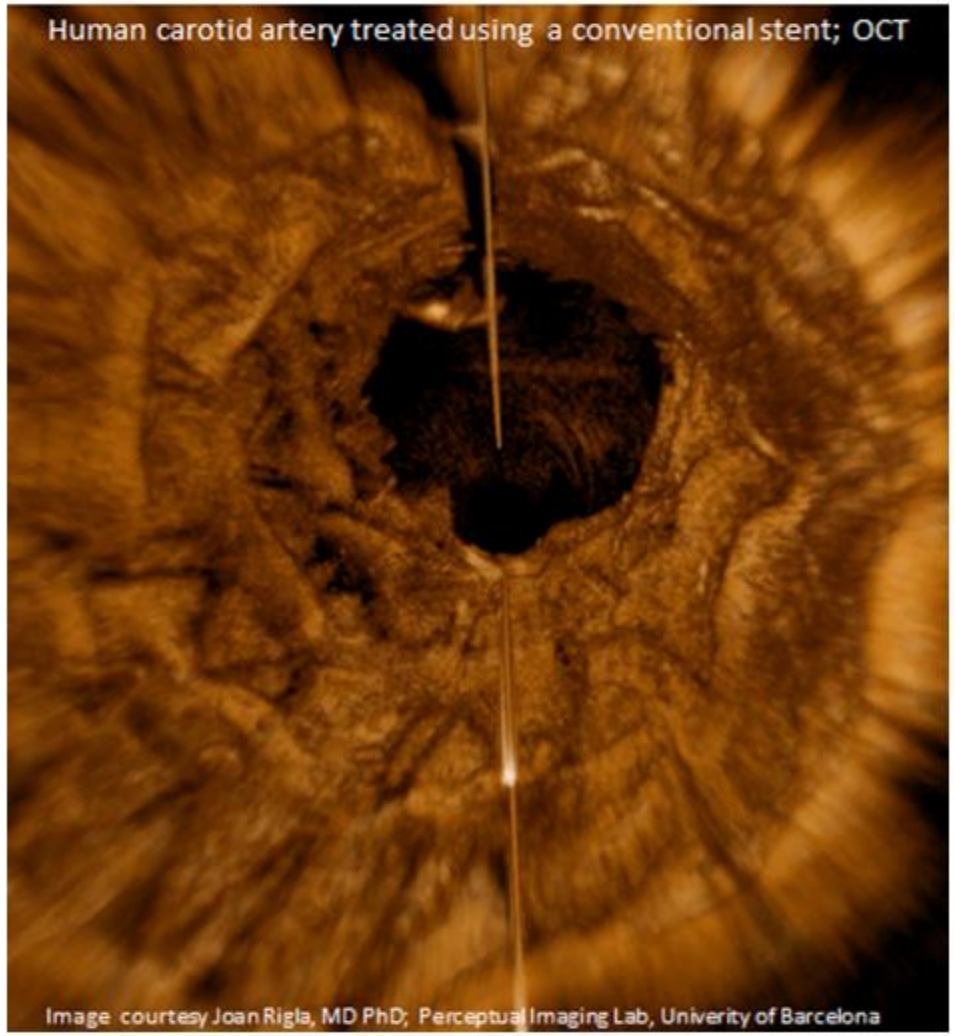


NORMAL
healing



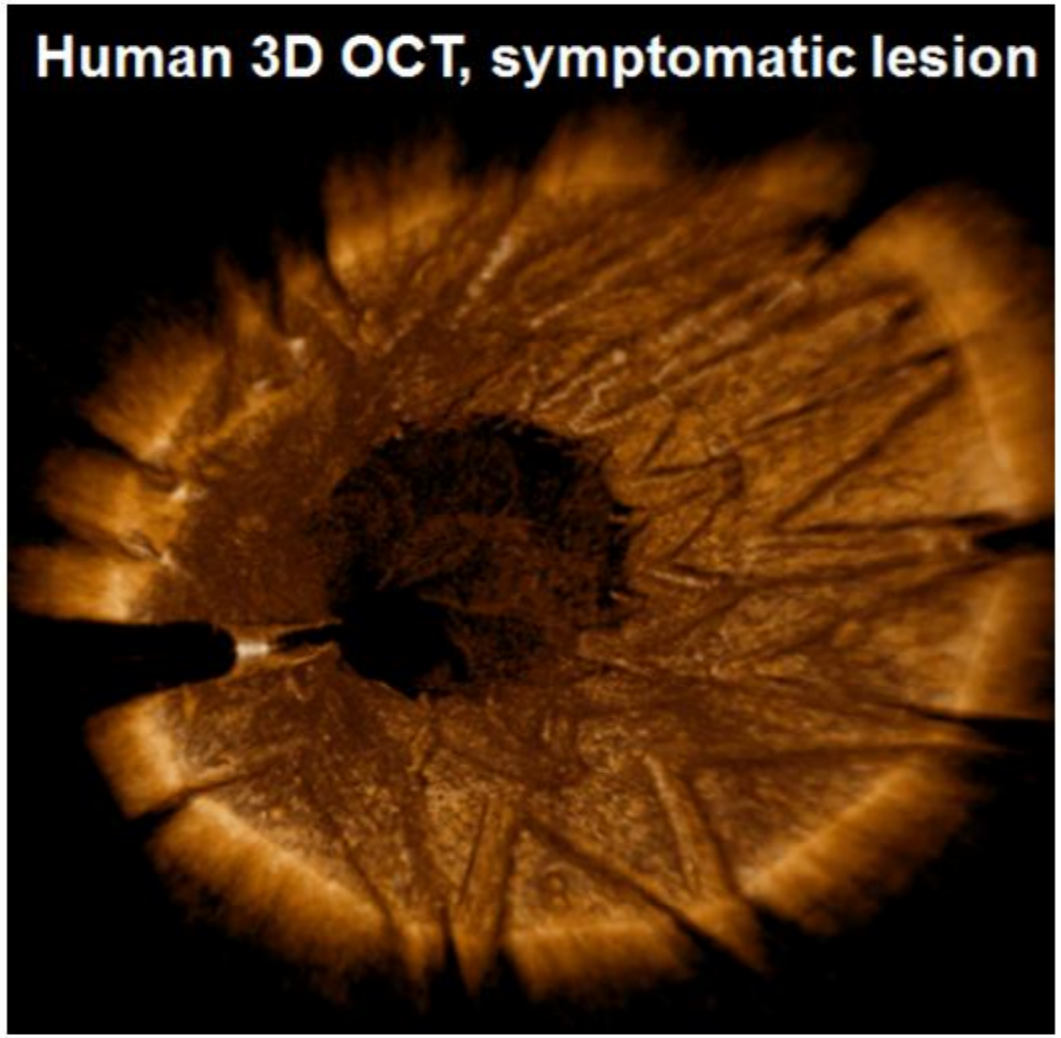
Randomized Controlled Trial

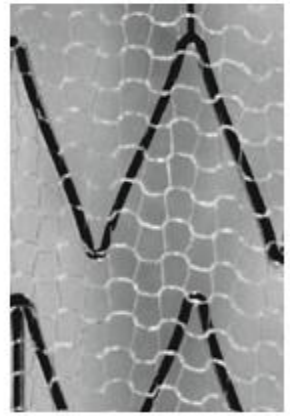
The CREST Study stent



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

MicroNet-Covered Stent

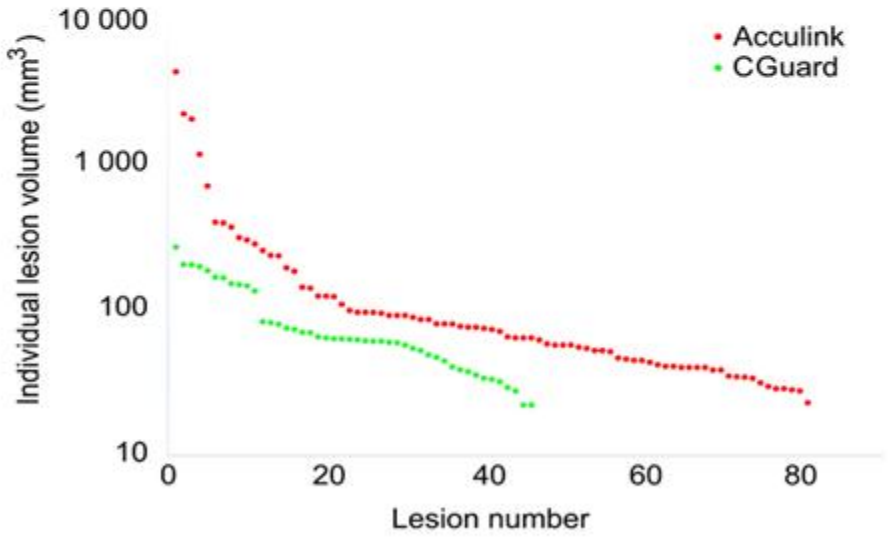




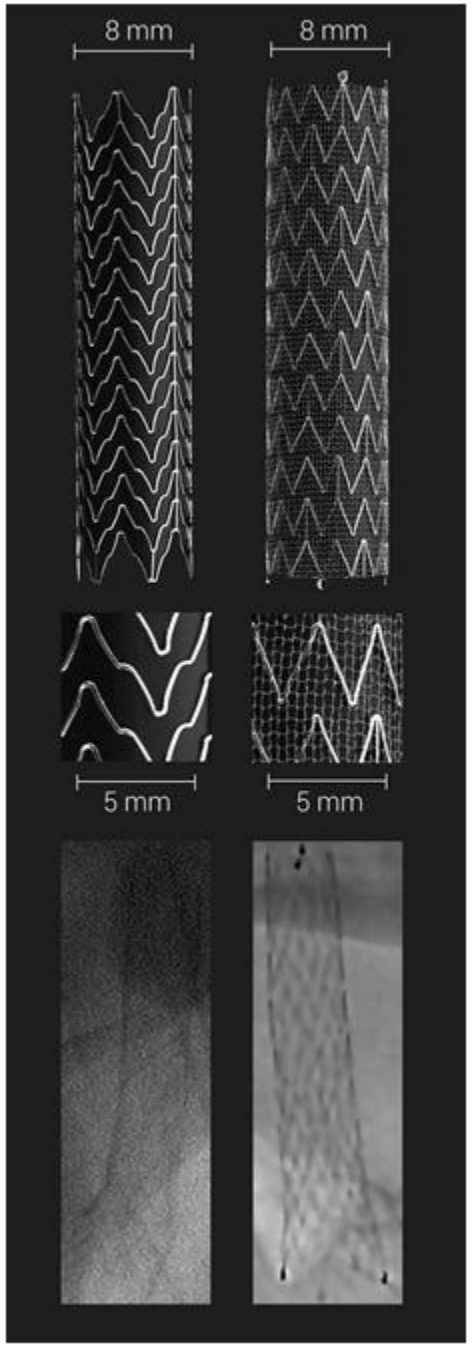
Neuro-Protective
Carotid Stent System

Randomized Controlled Trial

DW-MRI Embolism
raw data



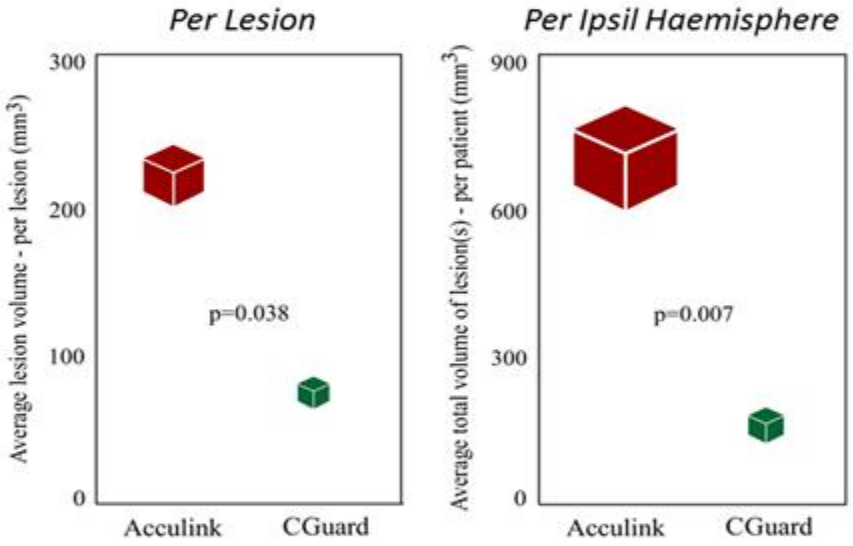
JACC: CARDIOVASCULAR INTERVENTIONS VOL. 14, NO. 21, 2021
NOVEMBER 8, 2021:2377-2387



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**

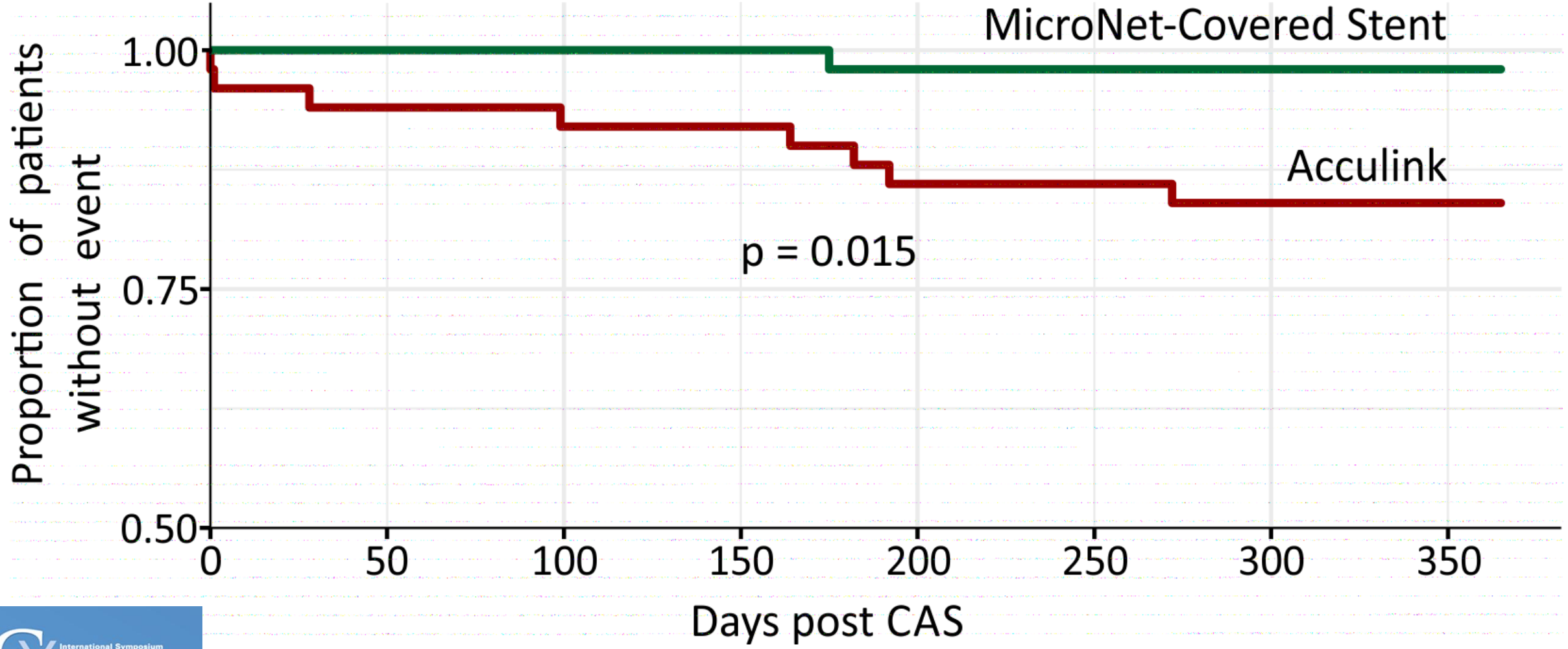
Karpenko A. *JACC Cardiovasc Interv* 2021;14:2377–87.
Nakagawa I. *J Neurointerv Surg* 2023;16:67–72.
Squizzato F. *Stroke* 2023;54:2534–41.

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



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

Systematic Review

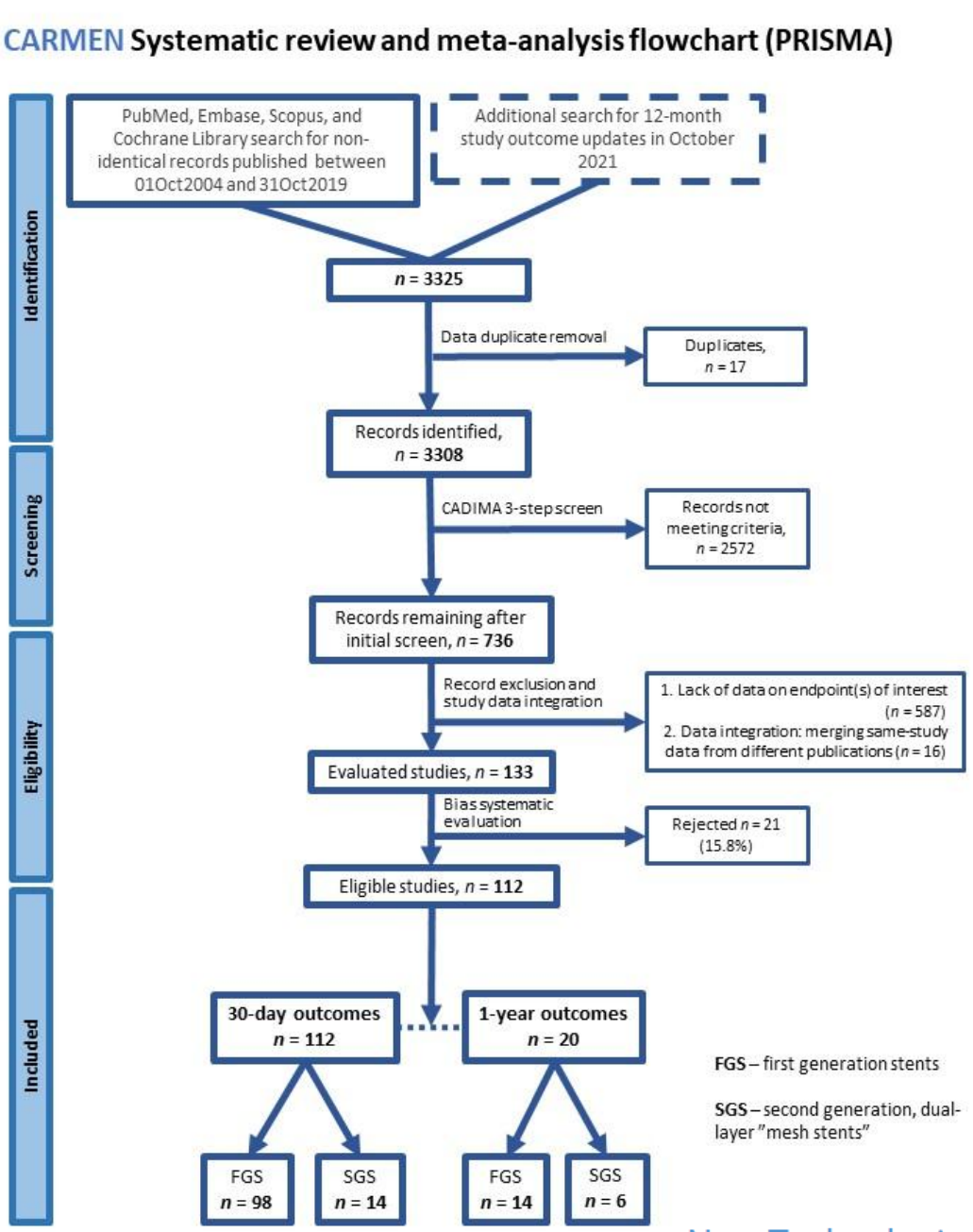
Clinical Outcomes of Second- versus First-Generation Carotid Stents: A Systematic Review and Meta-Analysis

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)



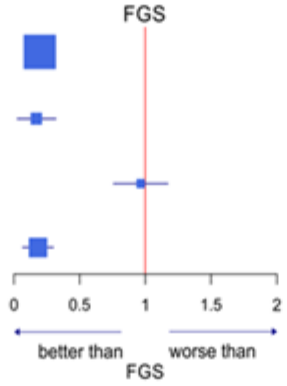
J. Clin. Med. **2022**, *11*, 4819. https://doi.org/10.3390/jcm11164819

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]

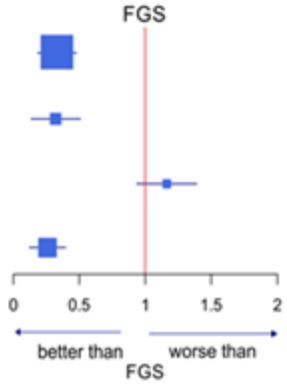
Heterogeneity: I^2=87%, τ^2=0.0003, p<0.01



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



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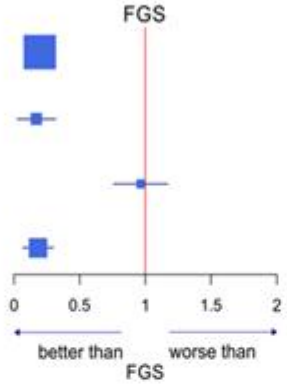

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SGS	2531 44	100%	0.32 [0.17–0.46]
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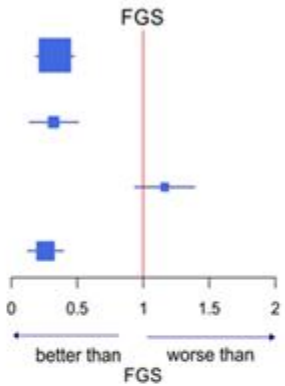
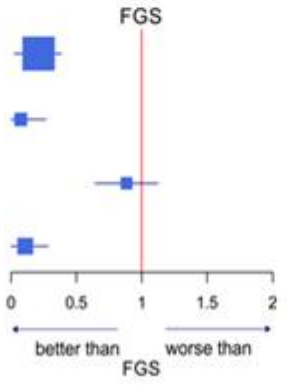


C **12-month Ipsilateral Stroke**

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]

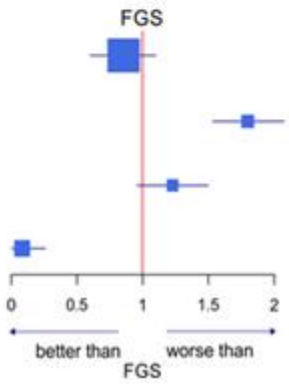
Heterogeneity: I^2=86%, τ^2=0.0002, p<0.01



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



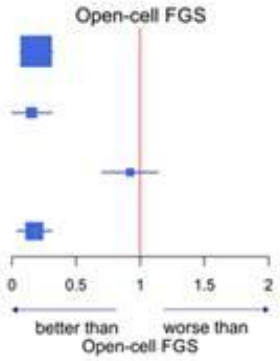
CARMEN SGS vs FGS Meta-Analysis: Main Findings

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]

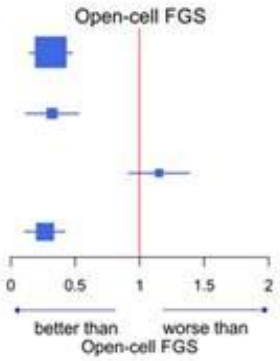
Heterogeneity: I^2=83%, τ^2=0.0002, p<0.01



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

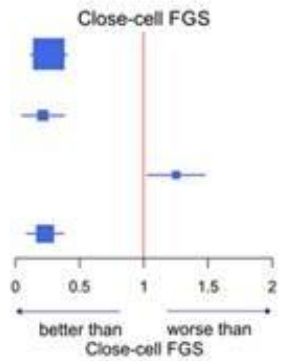


Close-cell FGS as reference

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]

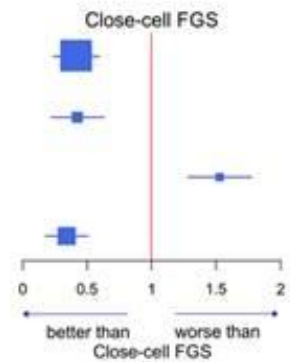
Heterogeneity: I^2=72%, τ^2=0.0001, p<0.01



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



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** (…).

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

(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

CARMEN Collaborators
J Cardiovasc Surg 2023

SGS vs CEA meta-analysis

Major
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Involving CEA

1. CEA pooled data

SAPPHIRE
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CREST
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ACT-1
Manhaim
SPACE-2

CEA in
Contemporary
Clinical Practice

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

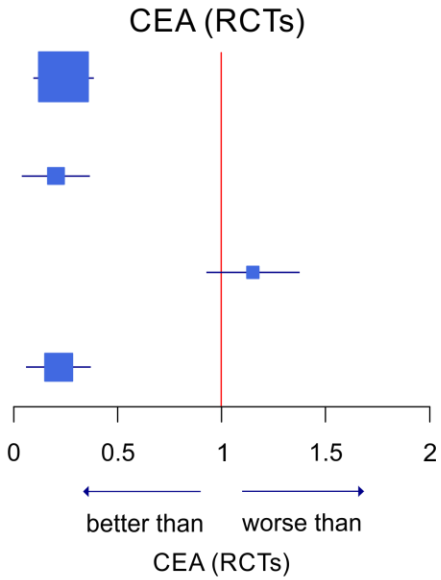
* Dakour-Aridi H, et al. *Ann Vasc Surg.* 2020;65:1-9
Columbo JA, et al. *J Vasc Surg.* 2019;69:104-109

CARMEN Collaborators
J Cardiovasc Surg 2023

30-day Stroke

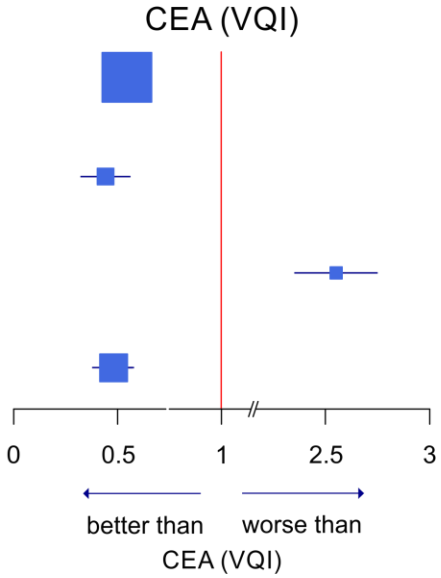
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.24 [0.10−0.38]
Casper/RoadSaver	585 5	23.1%	0.20 [0.04−0.36]
Gore Mesh Stent	311 9	12.3%	1.15 [0.92−1.37]
CGuard MicroNET Stent	1635 12	64.6%	0.22 [0.07−0.36]

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

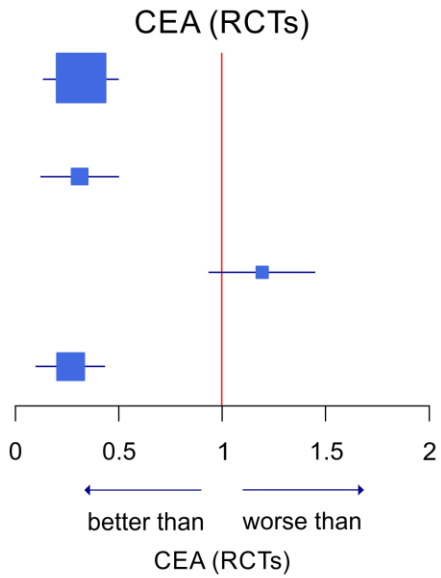


CARMEN Collaborators
J Cardiovasc Surg 2023

30-day Death/Stroke/MI

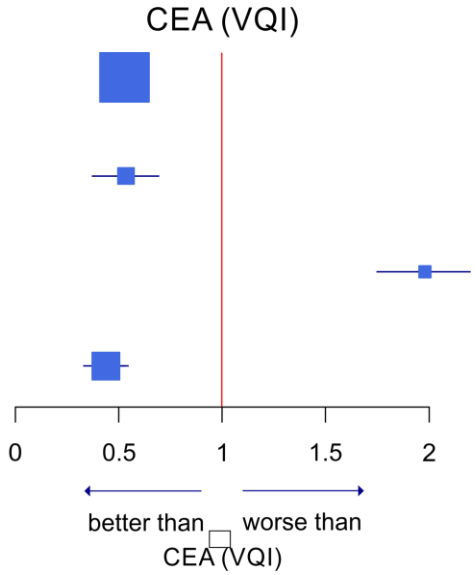
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.32 [0.14−0.50]
Casper/RoadSaver	585 10	23.1%	0.33 [0.12−0.54]
Gore Mesh Stent	311 15	12.3%	1.19 [0.94−1.45]
CGuard MicroNET Stent	1635 19	64.6%	0.27 [0.10−0.44]

Heterogeneity: I^2=81%, τ^2=0.0003, p<0.01



Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.53 [0.41−0.65]
Casper/RoadSaver	585 10	23.1%	0.54 [0.38−0.70]
Gore Mesh Stent	311 15	12.3%	1.98 [1.76−2.20]
CGuard MicroNET Stent	1635 19	64.6%	0.44 [0.33−0.55]

Heterogeneity: I^2=76%, τ^2=0.0001, p<0.01



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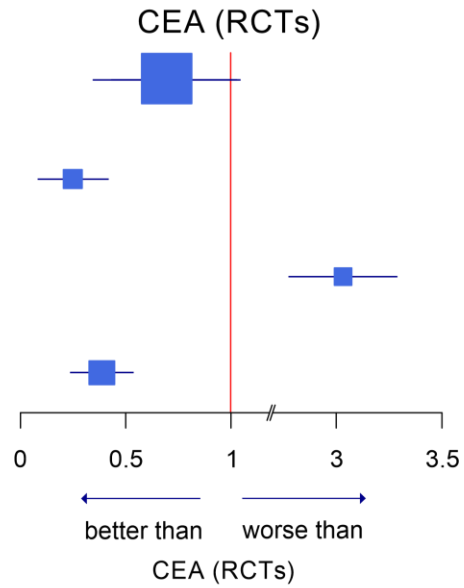
J Cardiovasc Surg 2023

12-month Ipsilateral Stroke

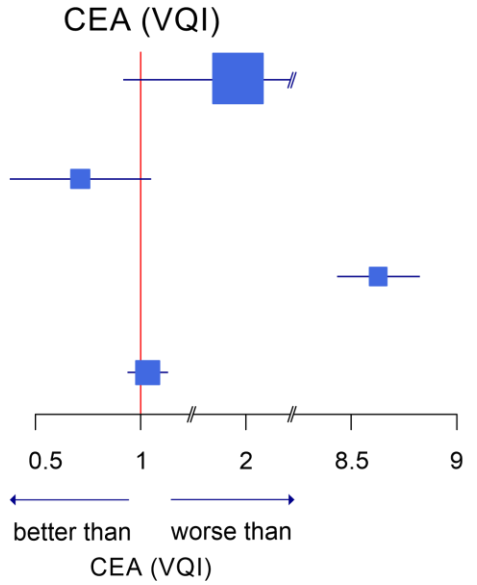
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 15	100%	0.69 [0.34−1.05]
Casper/RoadSaver	348 3	29.2%	0.25 [0.08−0.42]
Gore Mesh Stent	290 9	24.4%	3.07 [2.85−3.29]
CGuard MicroNET Stent	553 3	46.4%	0.38 [0.23−0.53]

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

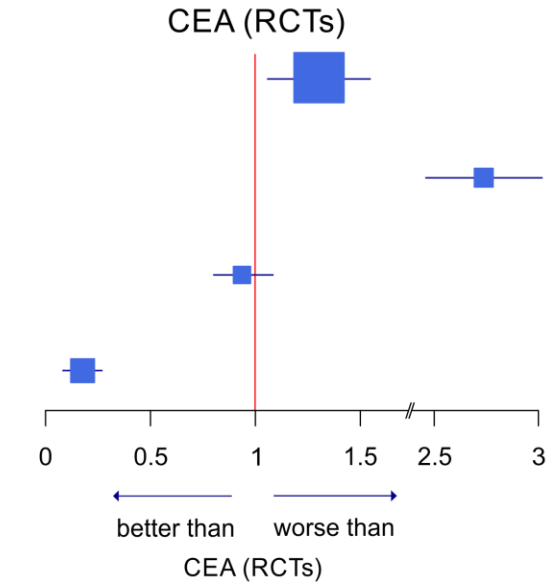


CARMEN Collaborators
J Cardiovasc Surg 2023

12-month Restenosis

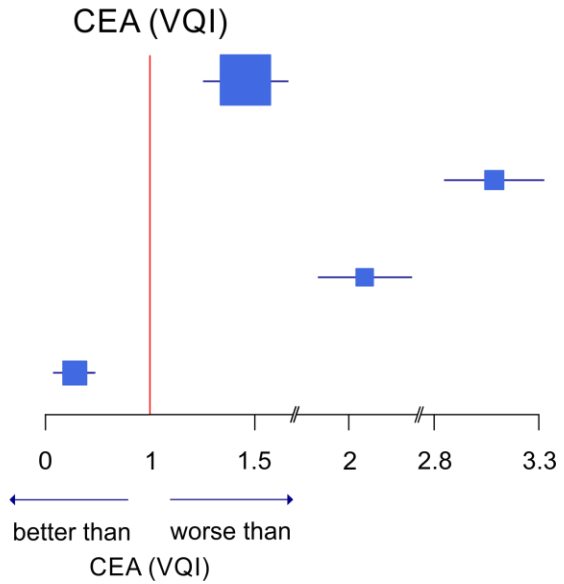
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 42	100%	1.30 [1.05−1.55]
Casper/RoadSaver	348 26	29.2%	2.75 [2.48−3.02]
Gore Mesh Stent	290 14	24.4%	0.94 [0.80−1.08]
CGuard MicroNET Stent	553 2	46.4%	0.16 [0.08−0.24]

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



CARMEN Collaborators
J Cardiovasc Surg 2023

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LATEST TECHNIQUES FOR CAROTID REVASCULARIZATION

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

Meta-analytic integration of available clinical data indicates:

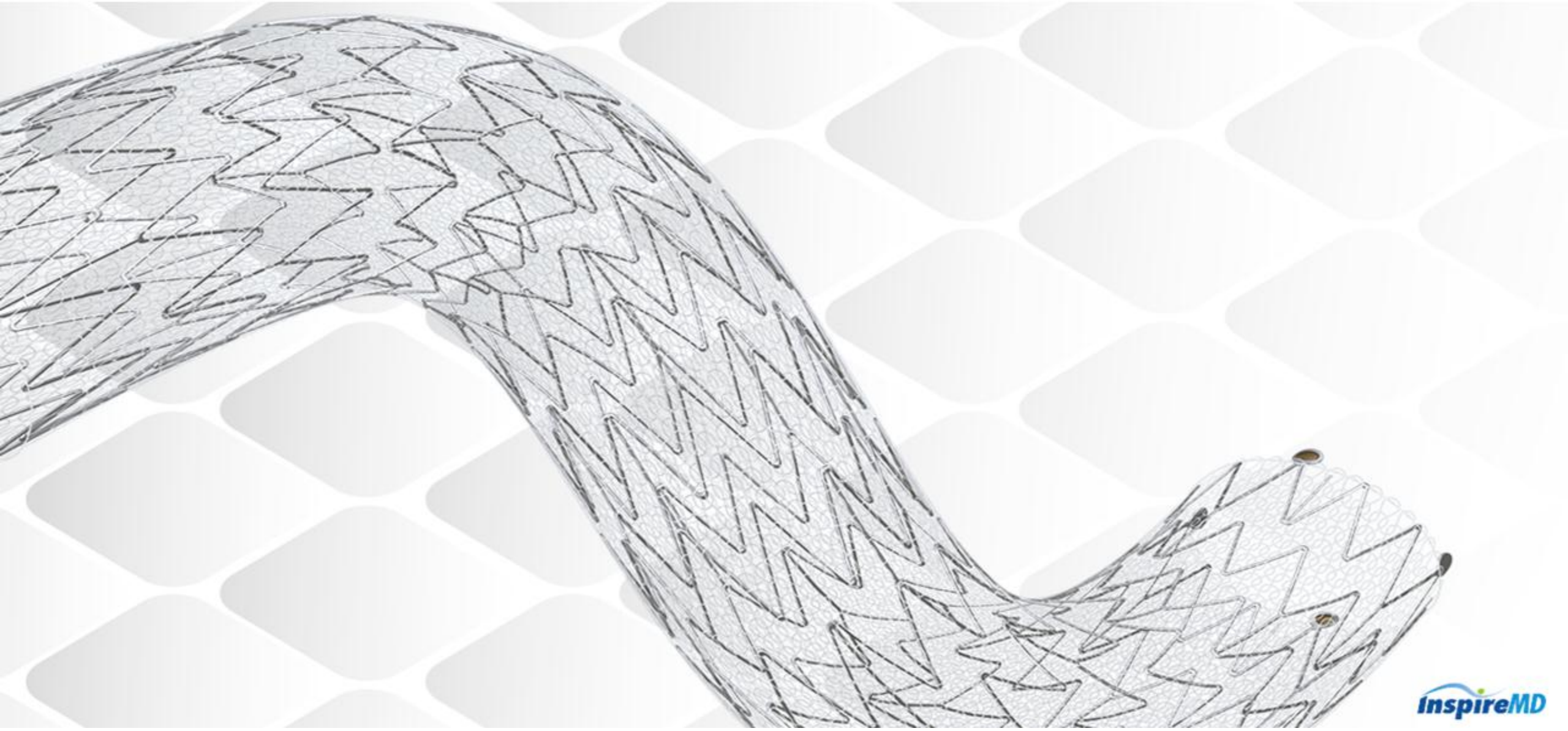
1) reduction in stroke but increased restenosis rate with Casper/Roadsaver,
2) reduction in both stroke and restenosis with CGuard MicroNET-covered stent

against contemporary CEA outcomes at 30 days and 12 months used as reference.

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).

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.

In conclusion,

The landscape has changed

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]

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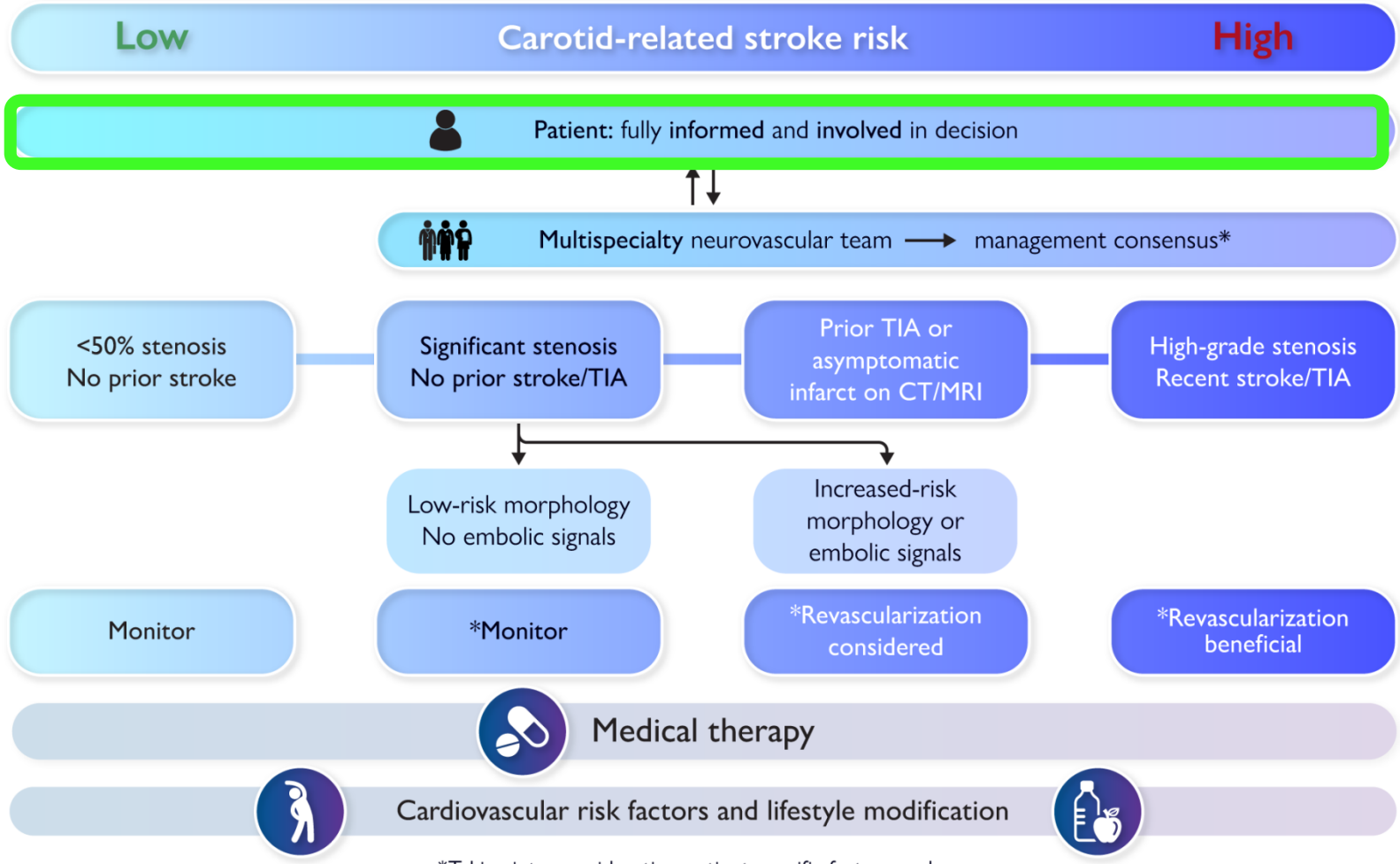

*Taking into consideration patient-specific factors such as:
life expectancy, co-morbidities and patient-specific stroke risk modifiers (e.g. family history of stroke, diabetes)

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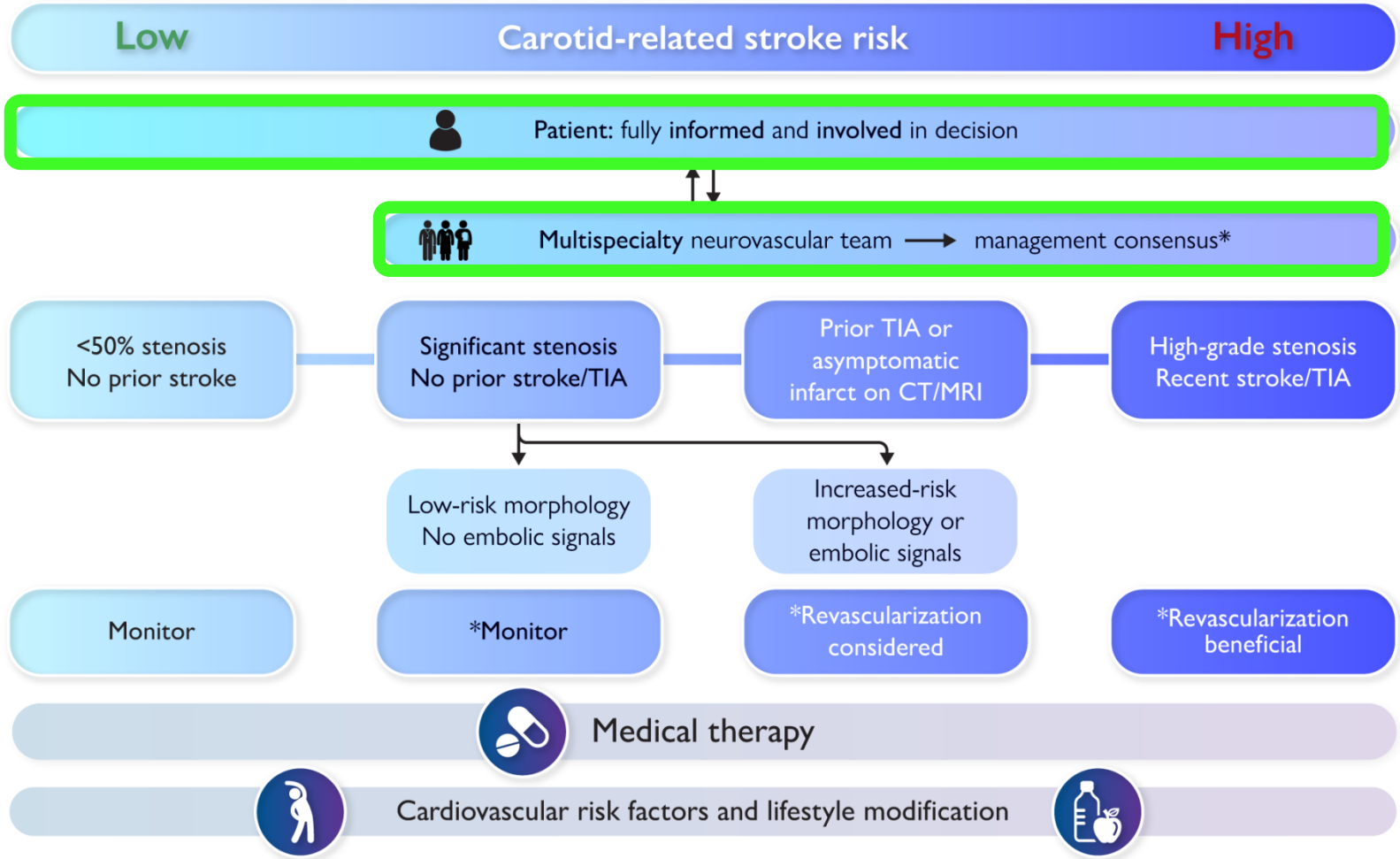

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LATEST TECHNIQUES FOR CAROTID REVASCULARIZATION

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.

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.)

Improving carotid artery stenting to match carotid endarterectomy: a task accomplished

Piotr Musialek[1,2]*, MD, DPhil; Kosmas I. Paraskevas[3], MD, PhD; Gary S. Roubin[4], MD, PhD

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There are no scientific reasons today that the carotid artery should remain the last artery in the body "reserved" for preferential open surgery. Today, physicians, and more importantly patients[2], do have a choice of treatment mode.

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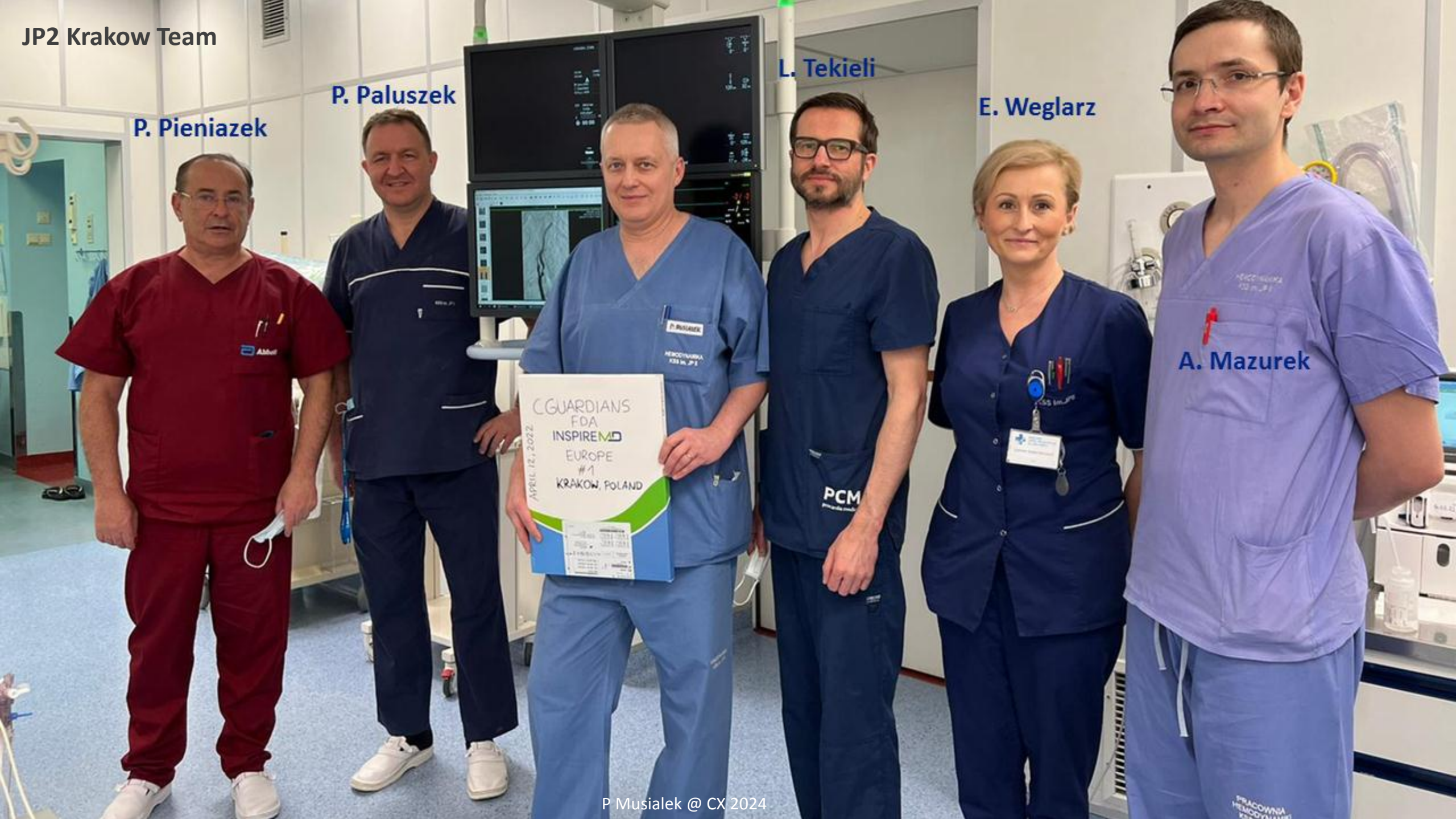
2024;20:e402-e404

JP2 Krakow Team



P Musialek @ CX 2024

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