2023 euroPCR

CAS: State-of-the-Art

Piotr Musialek, MD DPhil

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

PCR

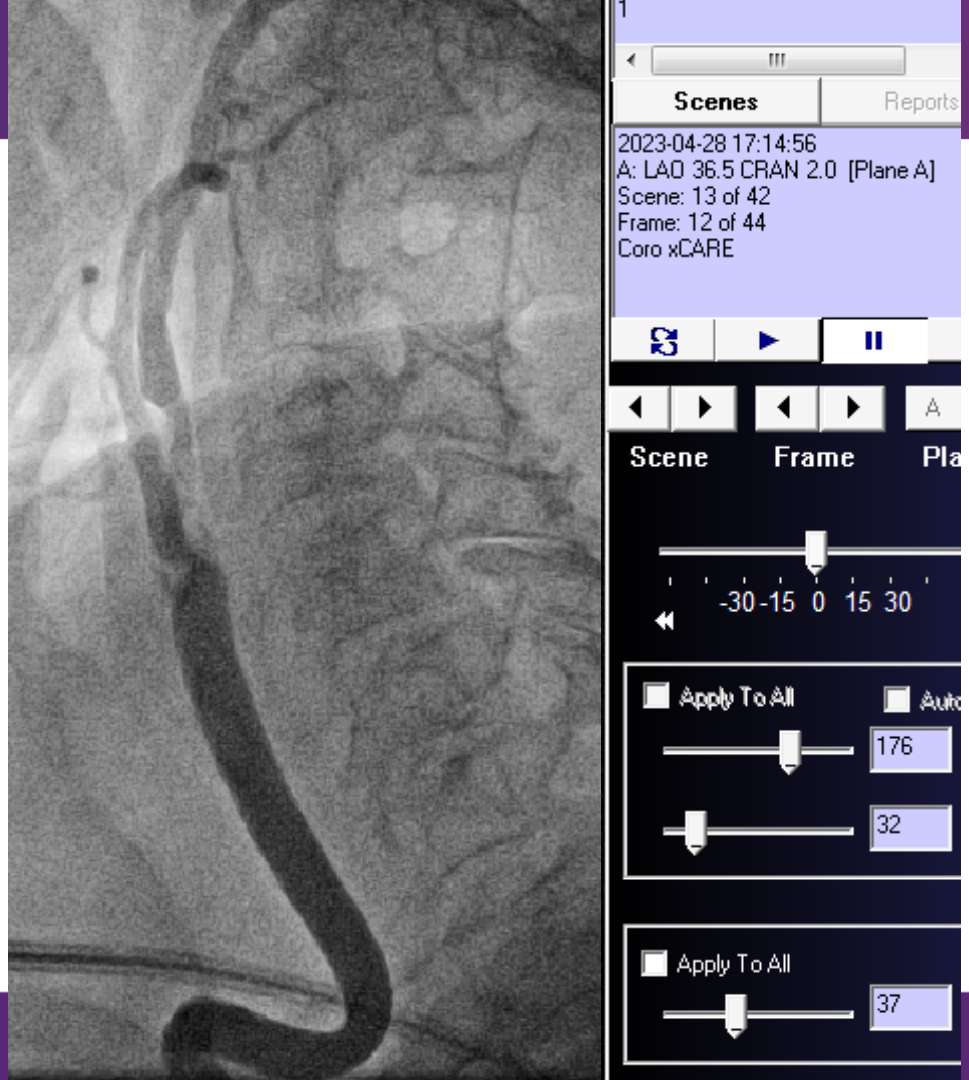
EAPCI
European Society of Cardiology

Potential conflicts of interest

Speaker's name : Piotr Musialek

Proctoring/Consulting: Abbott Vascular, InspireMD, Medtronic

FDA IDE Co-PI: CGUARDIANS Trial

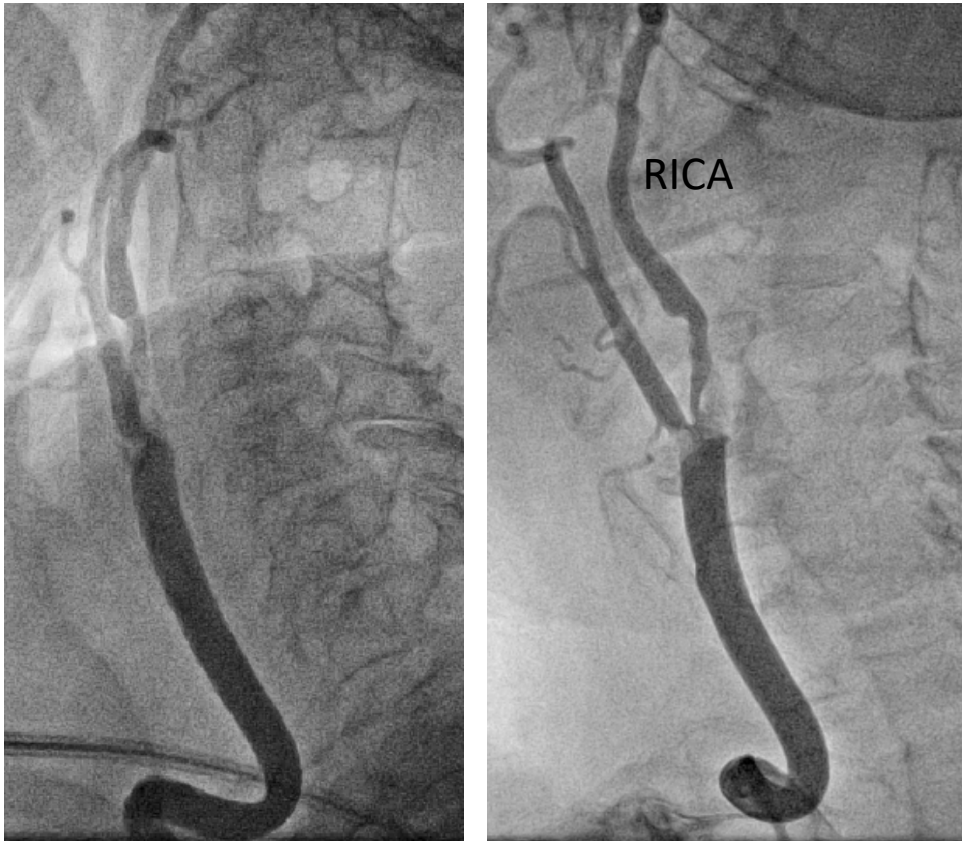


Patient

- Lady, 59 y
- Hypertension
- No **clinical symptoms** of CarAD
- Diabetes
- Family history **+ve** for Stroke
- Children suggested ”carotid scan”
- Received Duplex ultrasound

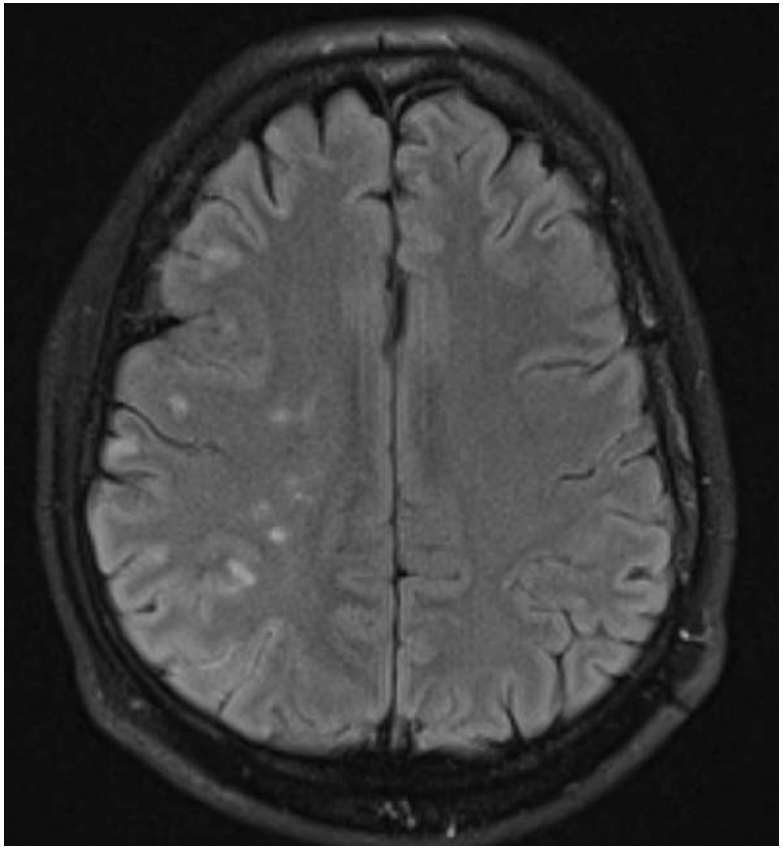
  (3.6/1.4 m/s ”mixed plaque”)

  ”thrombus likely”


RICA

Any thoughts?

Cerebral Scan (preferably MRI)



3 fundamental Qs:

- Does this Patient **NEED** Intervention?
- (if so) **what TYPE** of Intervention?
- **HOW** to do it? (… safe?

…effective?

”can I do it”?

… equipment?)

3 fundamental Qs:

- Does this Patient **NEED** Intervention? **YES** √
- (if so) **what TYPE** of Intervention?
- **HOW** to do it? (… safe?
  …effective?
  … equipment?)

3 fundamental Qs:

- Does this Patient **NEED** Intervention? **YES** √
- (if so) **what TYPE** of Intervention? **?**
- **HOW** to do it? (… safe?
  …effective?
  … equipment?)

Carotid Revascularization in the last >20 years…

”CEA” *”or”* **”CAS”** ?

Carotid Revascularization in 2023

"CEA"

↓

WHAT

CEA

?

~~***"or"***~~

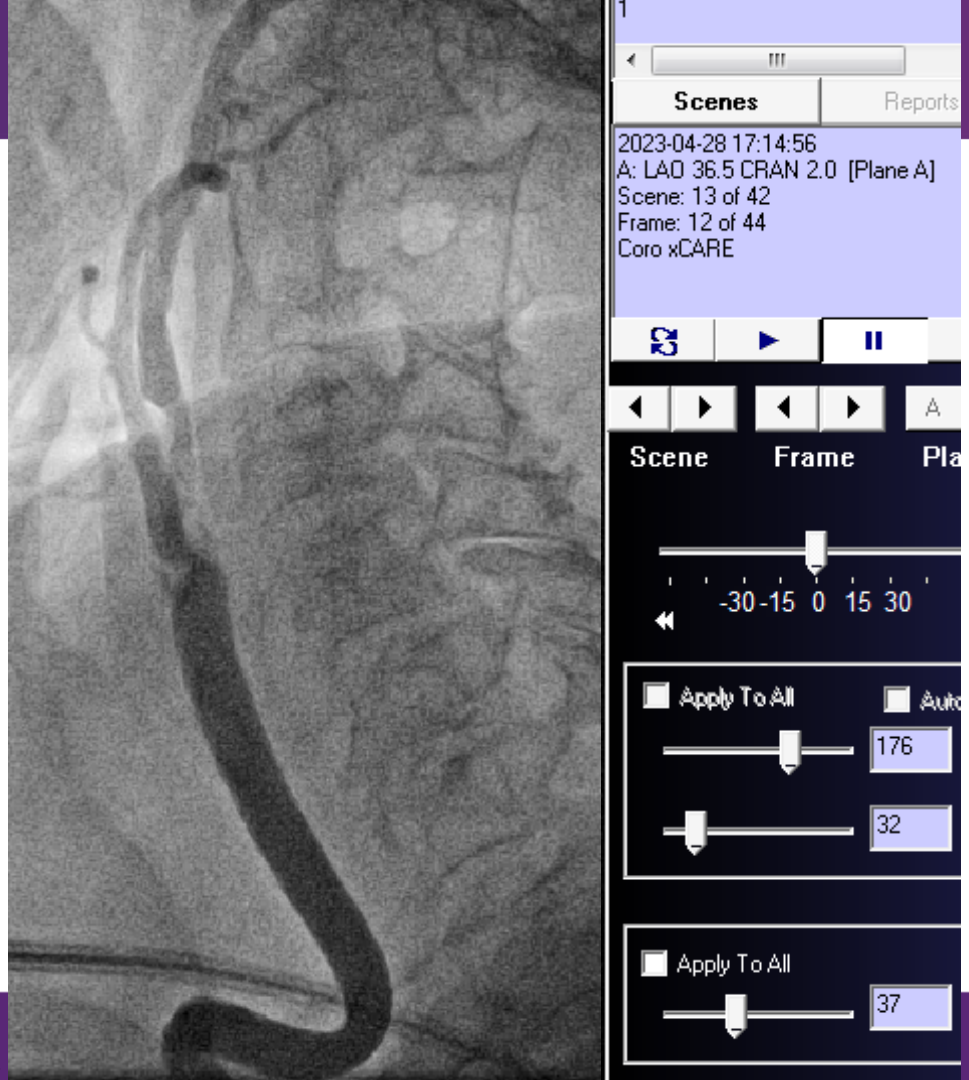
"CAS"

↓

WHAT

CAS

?



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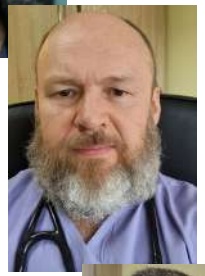
  (3.6/1.4 m/s ”mixed plaque”)

Ideas?

Hospital

Ideas?

M. Knapik



A. Klecha

T. Kowalczyk

Podhalanski Multispecialty Hospital Nowy Targ, Poland

CAS

Protected?/Unprotected?

Filter?

Stent? ANY stent?

CAS –and CEA– are (and will remain) Emboli-generating

Effect of the Distal-Balloon Protection System on Microembolization During Carotid Stenting

Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD

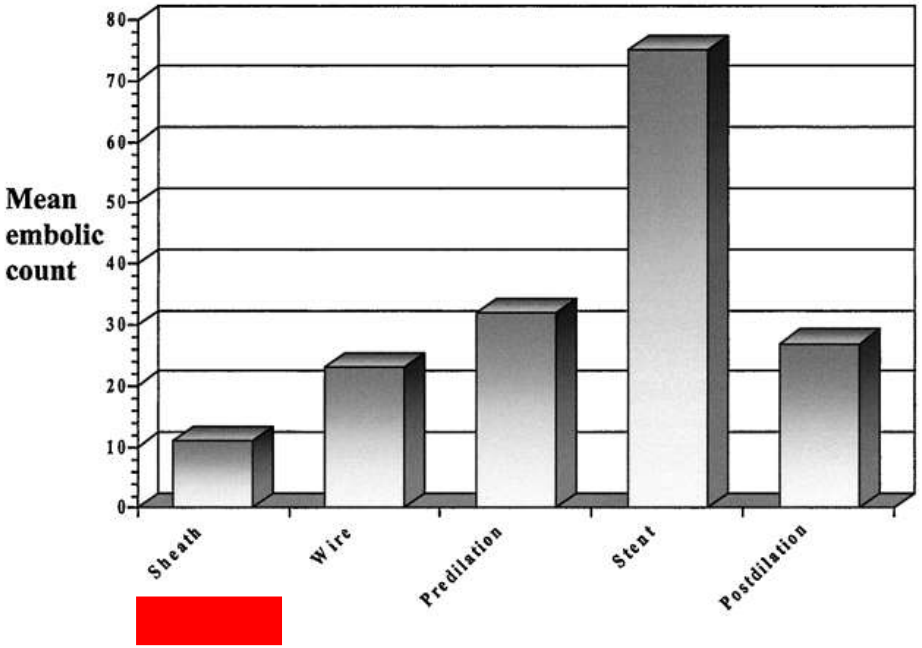


Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

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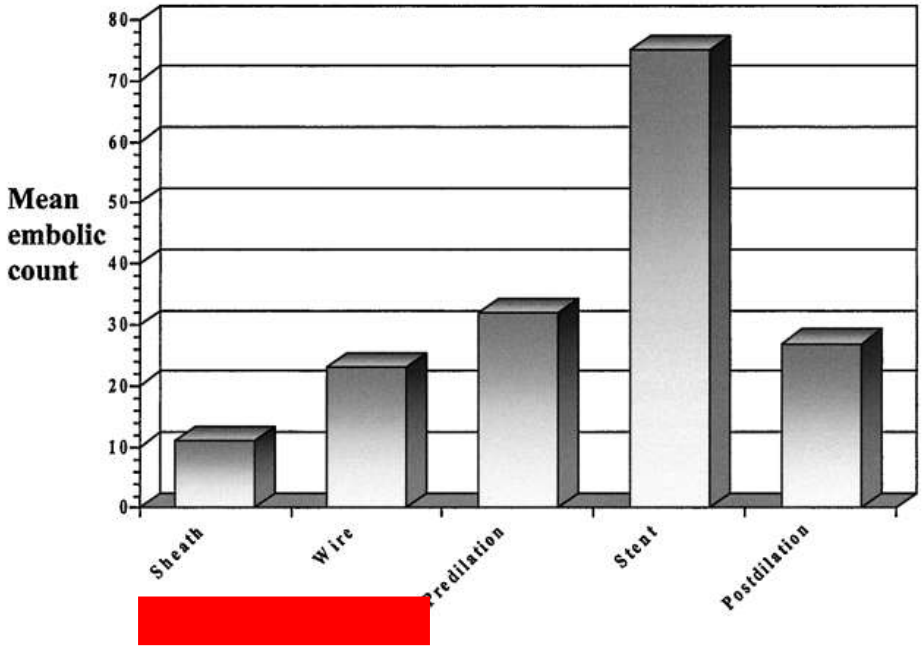

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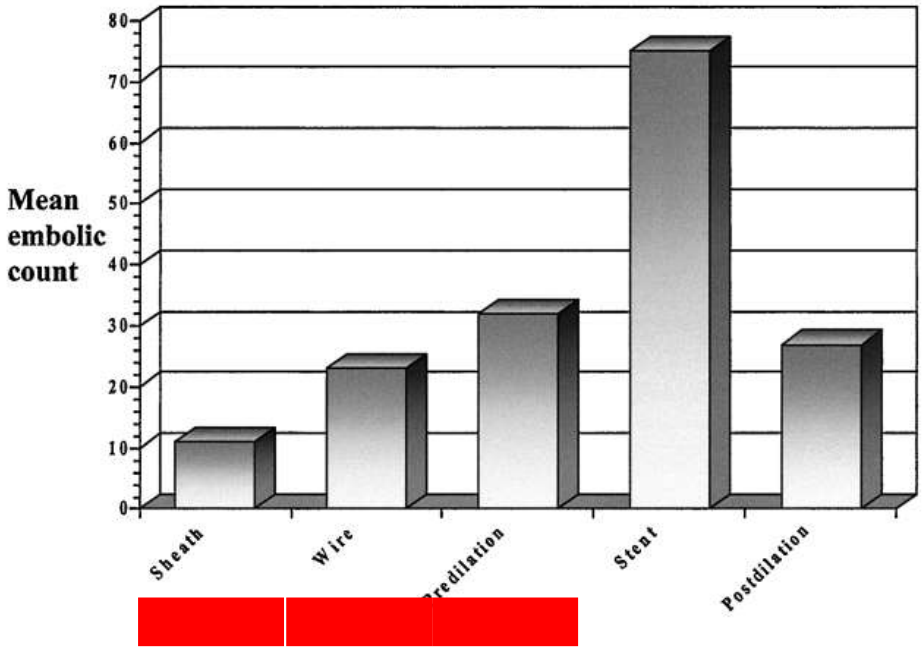

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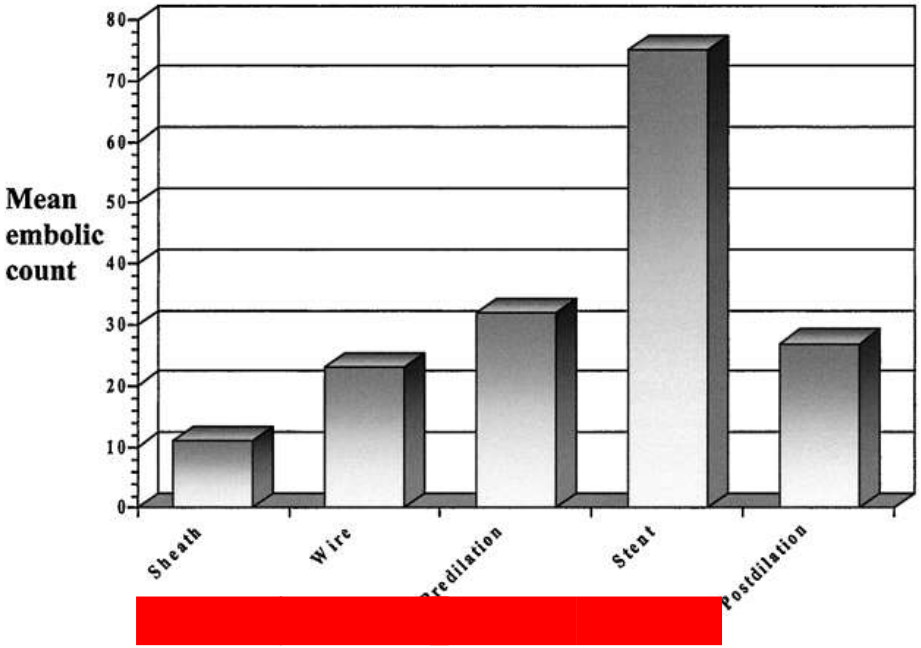

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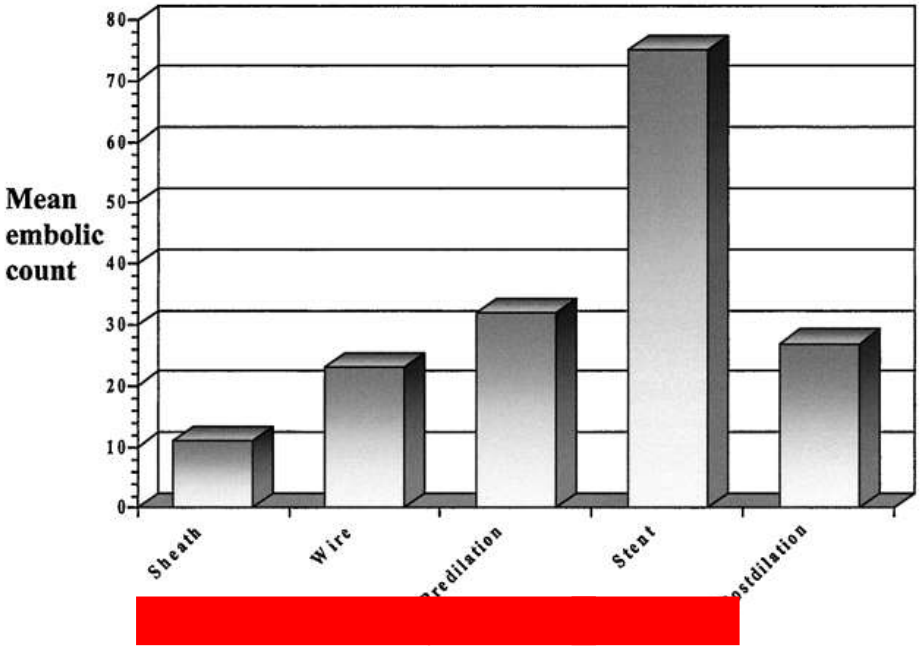

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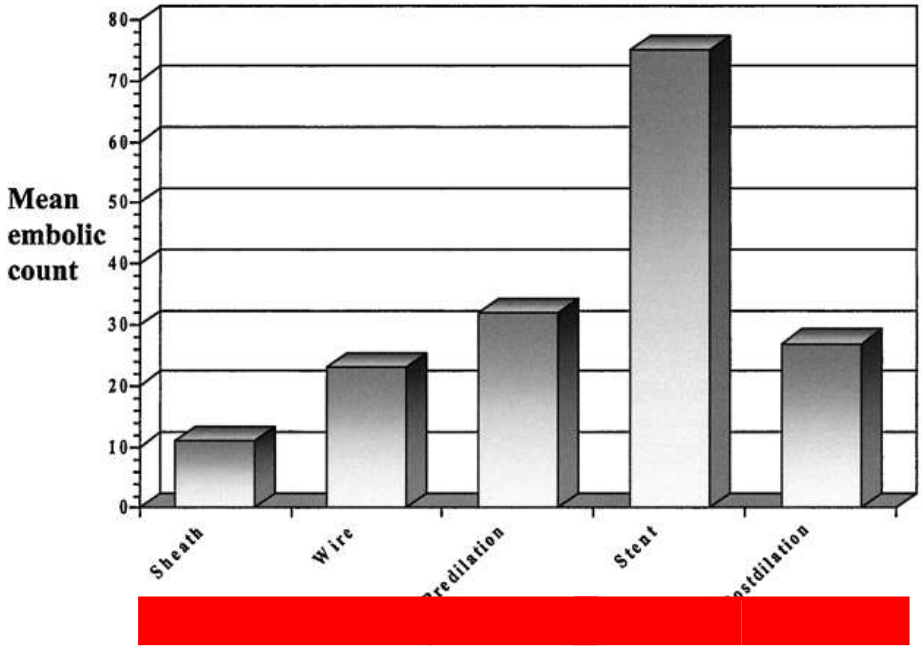

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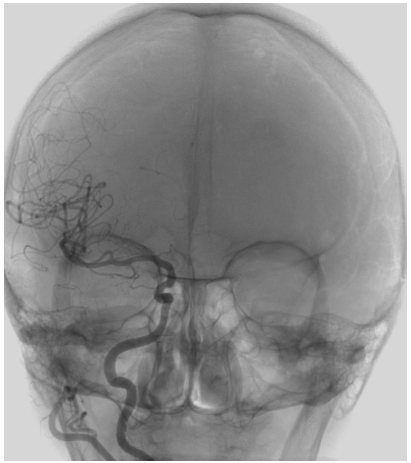
Competent CAS



- (always) Neuro-protected

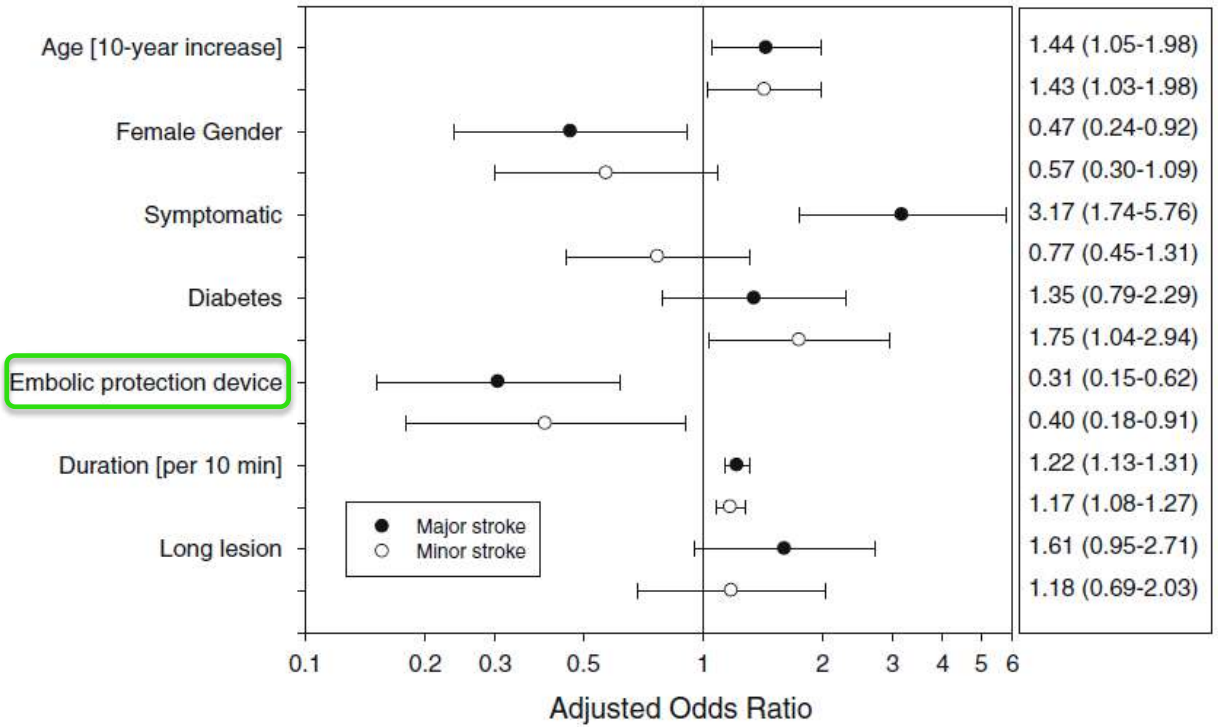
Clin Res Cardiol (2014) 103:345–351
DOI 10.1007/s00392-013-0657-z

ORIGINAL PAPER

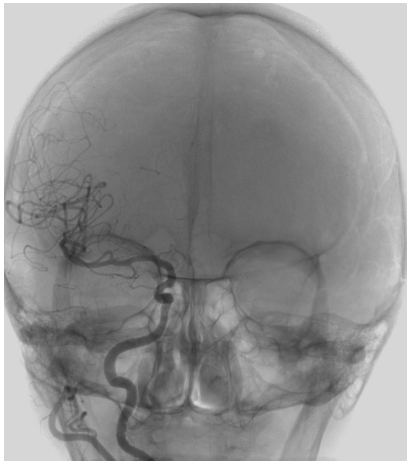
Predictors of minor versus major stroke during carotid artery stenting: results from the carotid artery stenting (CAS) registry of the Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte (ALKK)

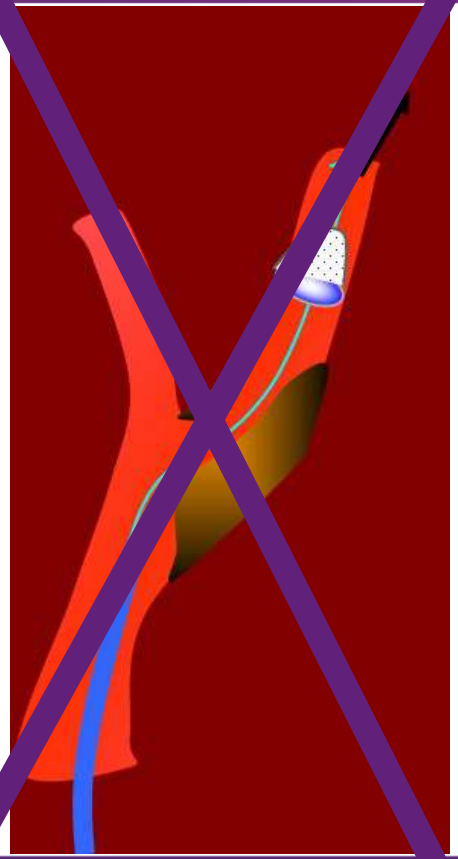
Stephan Staubach · Ralph Hein-Rothweiler · Matthias Hochadel · Manuela Segerer · Ralf Zahn · Jens Jung · Gotthard Rieß · Hubert Seggewiß · Andre Schneider · Thomas Fürste · Christian Gottkehaskamp · Harald Mudra

n=5,709 CAS

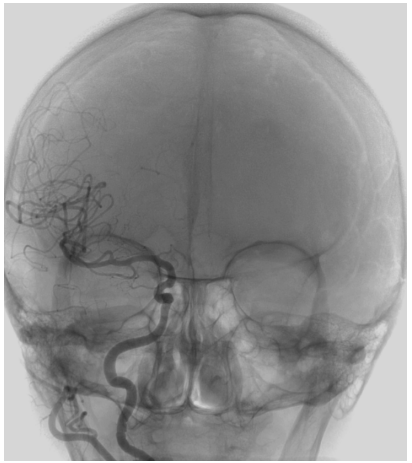


Competent CAS





Competent CAS



- (always) Neuro-protected
- NO Filter (in lesion as here)

Proximal neuroprotection (Flow casessation/reversal)

The PROFI Study (Prevention of Cerebral Embolization by Proximal Balloon Occlusion Compared to Filter Protection During Carotid Artery Stenting)

A Prospective Randomized Trial

Klaudija Bijuklic, MD, Andreas Wandler, MD, Fadia Hazizi, MD, Joachim Schofer, MD, PhD
Hamburg, Germany

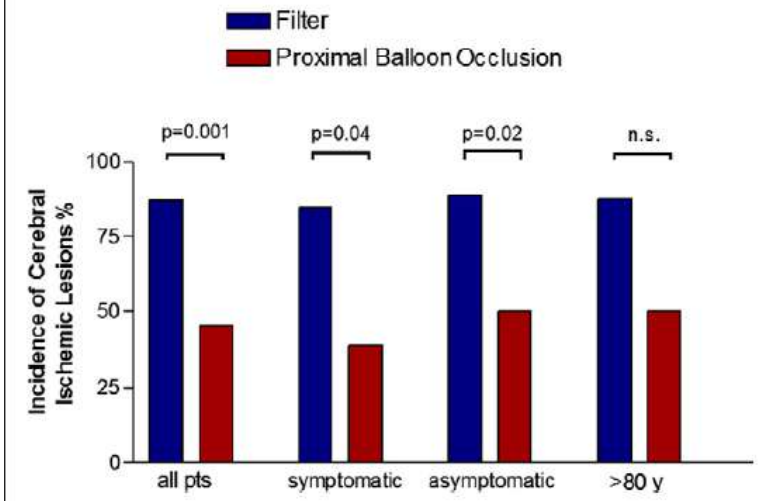
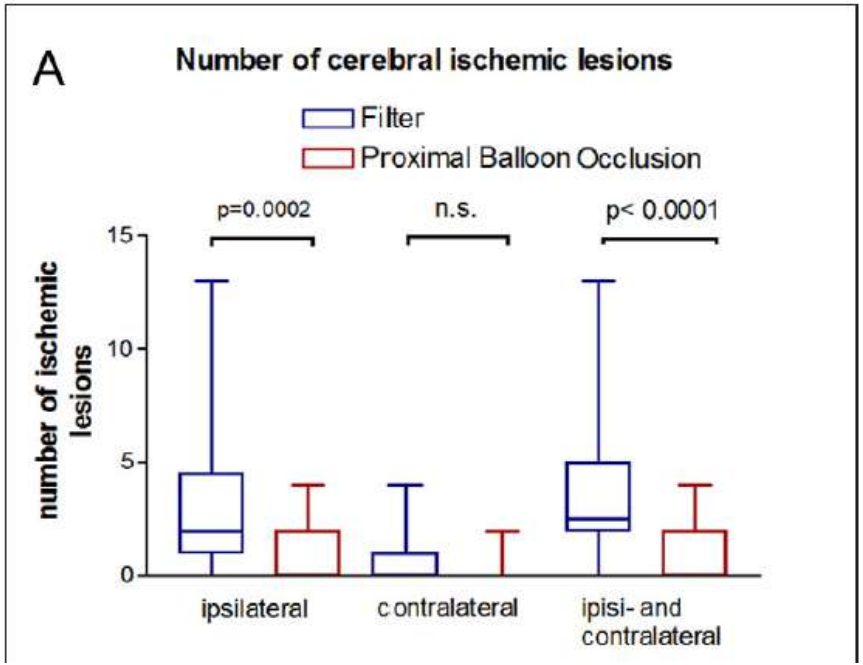
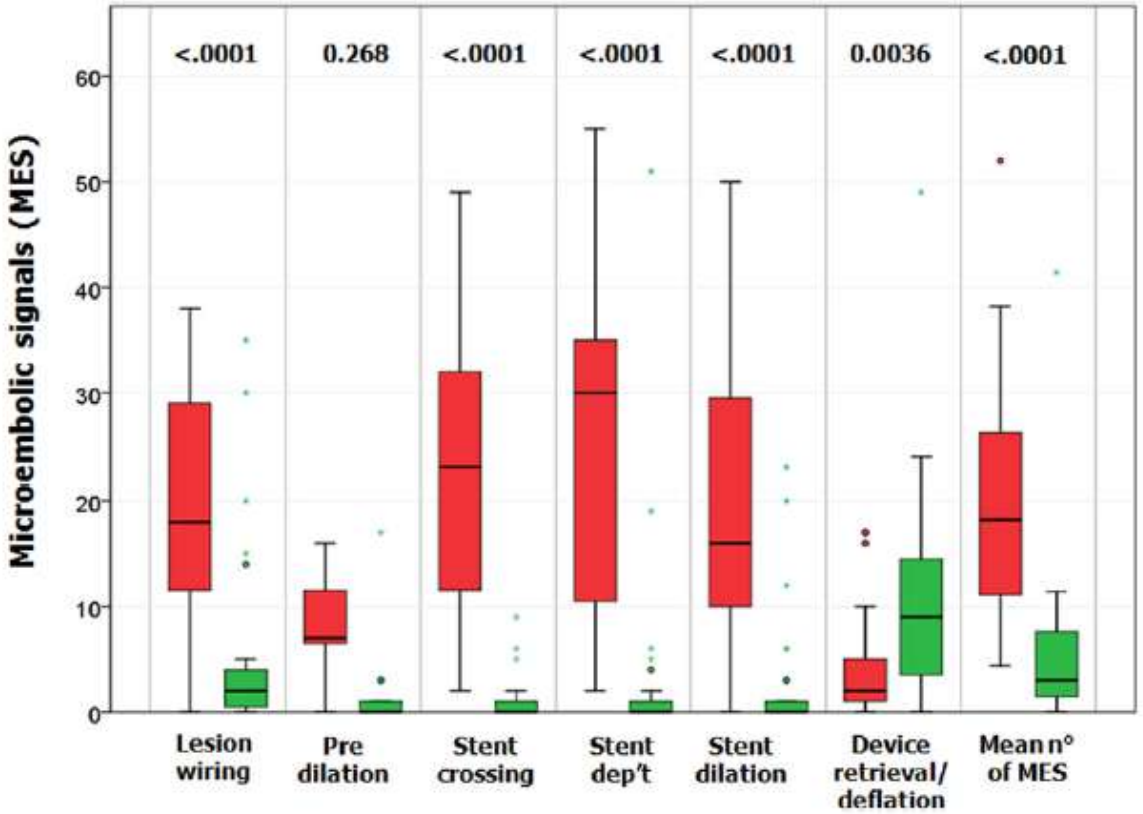


Figure 2 Incidence of New Ischemic Lesions in Patients With Filter Protection Versus Proximal Balloon Occlusion

JACC Vol. 59, No. 15, 2012
April 10, 2012:1383–9



Proximal neuroprotection (Flow casessation/reversal)



Montorsi P et al. JACC 2011

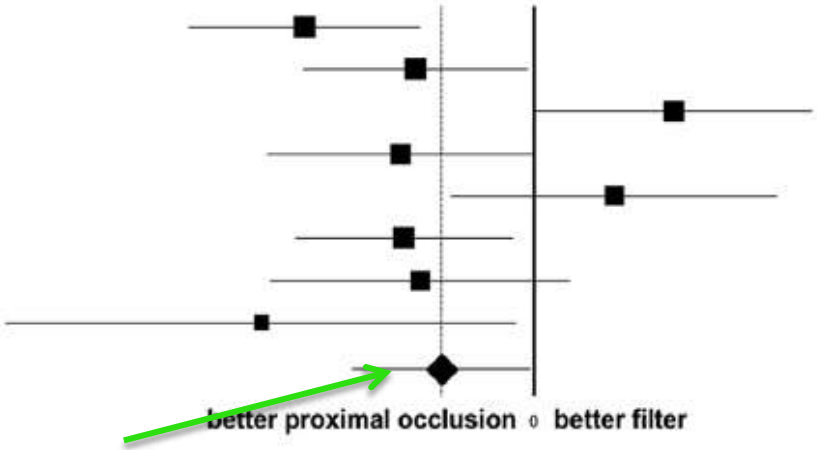
Proximal neuroprotection (Flow casessation/reversal)

Cerebral Embolic Lesions Detected With Diffusion-Weighted Magnetic Resonance Imaging Following Carotid Artery Stenting

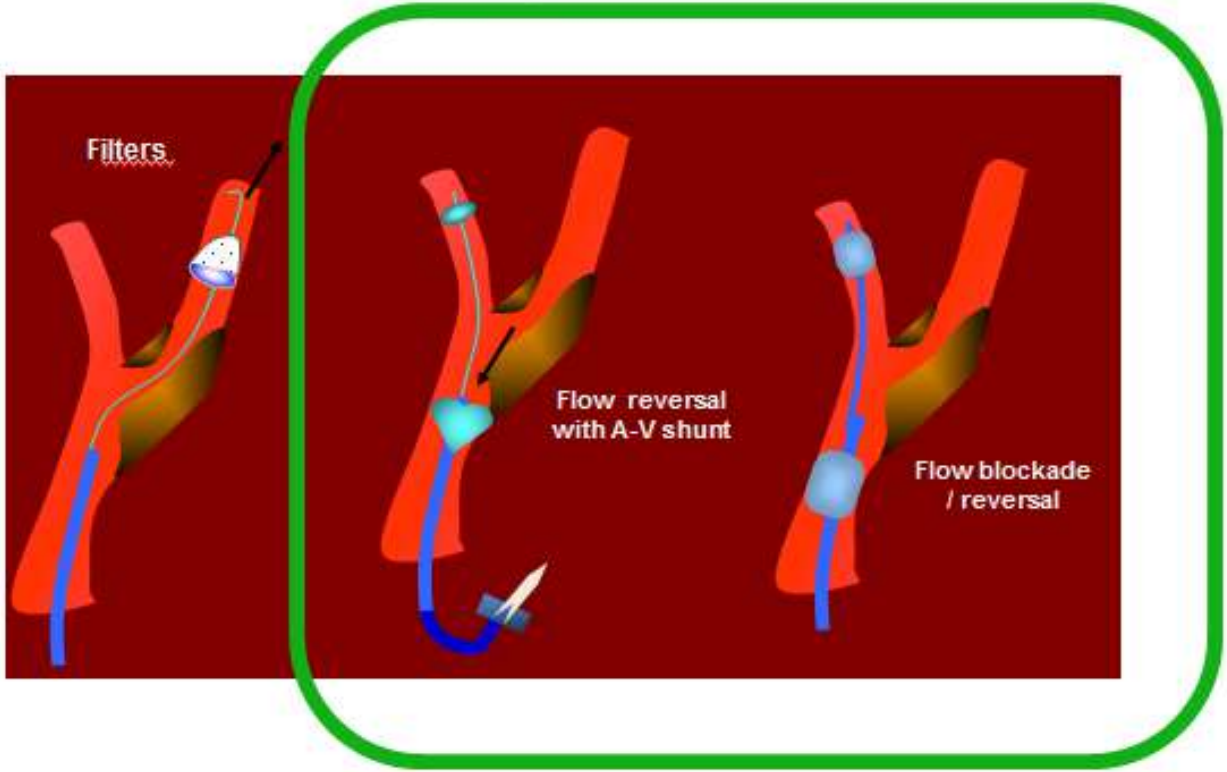
A Meta-Analysis of 8 Studies Comparing Filter Cerebral Protection and Proximal Balloon Occlusion

Eugenio Stabile, MD, PhD, Anna Sannino, MD, Gabriele Giacomo Schiattarella, MD, Giuseppe Gargiulo, MD, Evelina Toscano, MD, Linda Brevetti, MD, Fernando Scudiero, MD, Giuseppe Giugliano, MD, Cinzia Perrino, MD, PhD, Bruno Trimarco, MD, Giovanni Esposito, MD, PhD

Study ID	ES	95% CI	N
Bijuklic K. et al. 2012	-1.05	-1.58 , -0.52	62
Cano N.M. et al. 2013	-0.54	-1.06 , -0.03	60
Castro-Afonso LH. et al. 2013	0.64	0.00 , 1.28	40
El-Koussy M. et al. 2007	-0.61	-1.22 , -0.00	44
Flach Z.H. et al. 2007	0.37	-0.38 , 1.11	33
Leal I. et al. 2012	-0.60	-1.10 , -0.10	64
Montorsi P. et al. 2011	-0.52	-1.21 , 0.17	35
Taha M.M. et al. 2009	-1.25	-2.42 , -0.08	19
Overall (random-effects model)	-0.43	-0.84 , -0.02	357



Cerebral Protection in transfemoral/transradial CAS

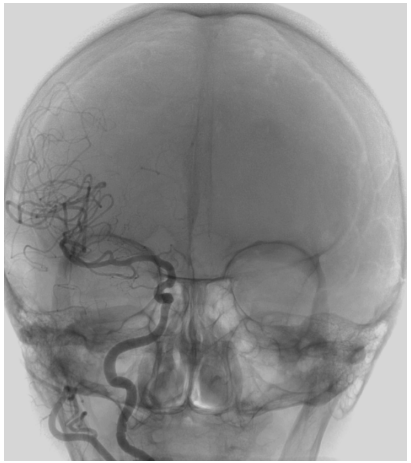


Flow reversed PRIOR to lesion crossing (”no touch”)

√

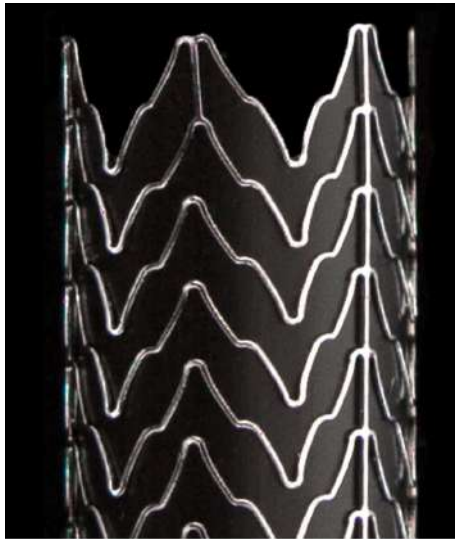
What stent type in 2023?

Competent CAS



- (always) Neuro-protected
- NO Filter (in lesion as here)
- ONLY plaque-sequestrating stent (permanent protection)

The Problem of conventional (single-layer) carotid stents



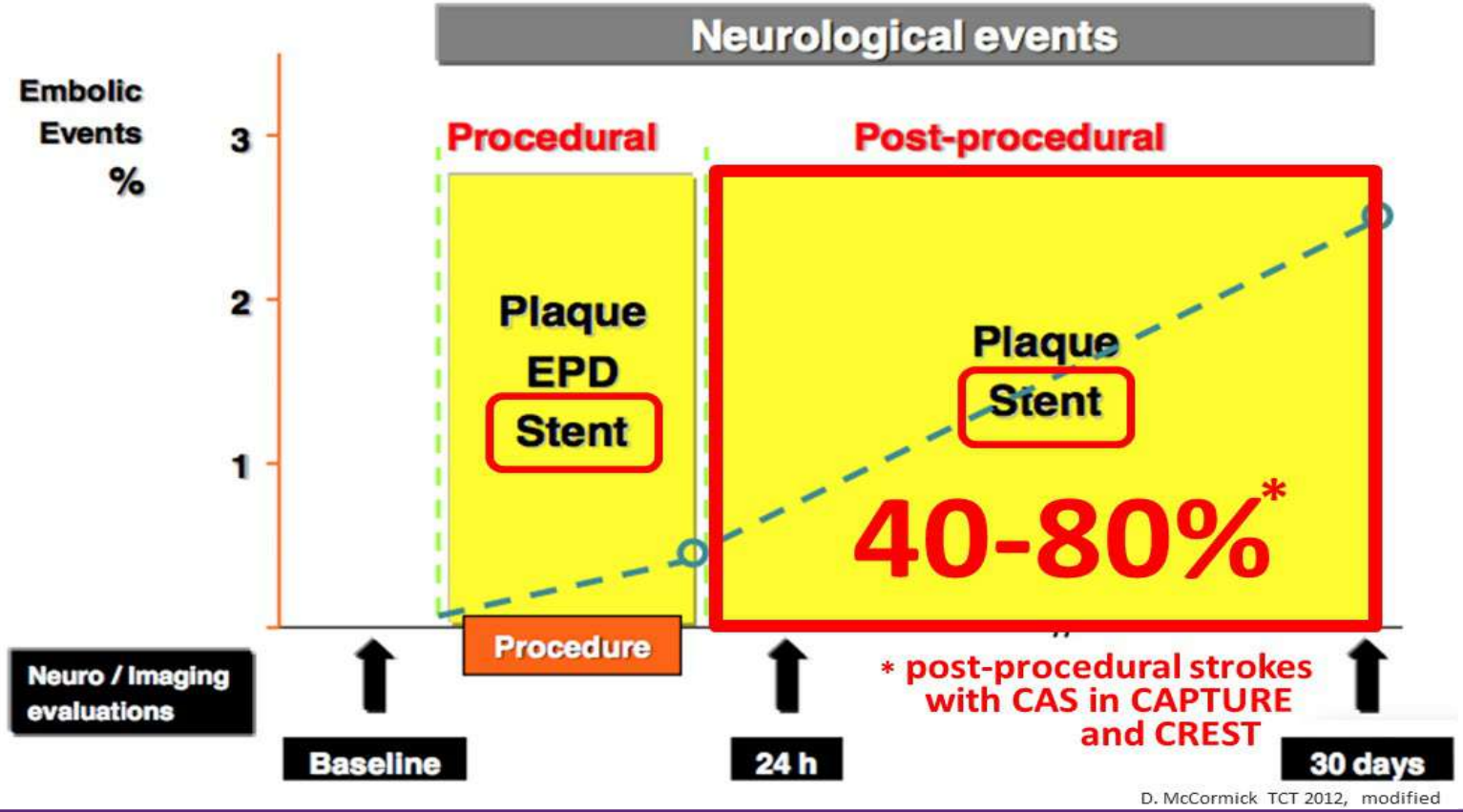
P Musialek, G deDonato
Carotid Artery Revascularization Using the Endovascular Route
In: **Peripheral Arterial Interventions - A Practical Guide 2023**
(in press)

Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS

Schofer J et al, JACC Cardiovasc interv 2008

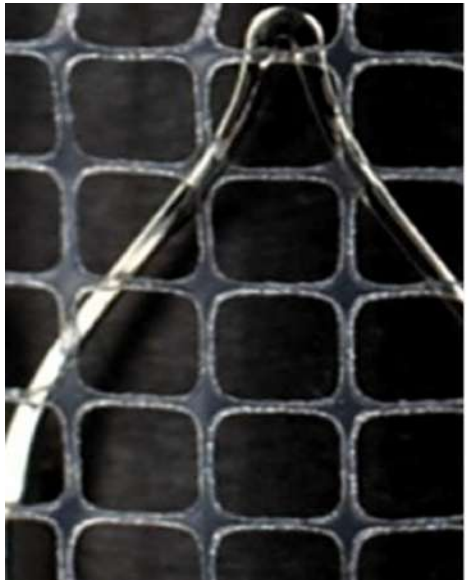
Timing of Neuro-Embolic Events in CAS



D. McCormick TCT 2012, modified

Carotid ”mesh” stents

Gore Hybrid Stent



Casper/RoadSaver

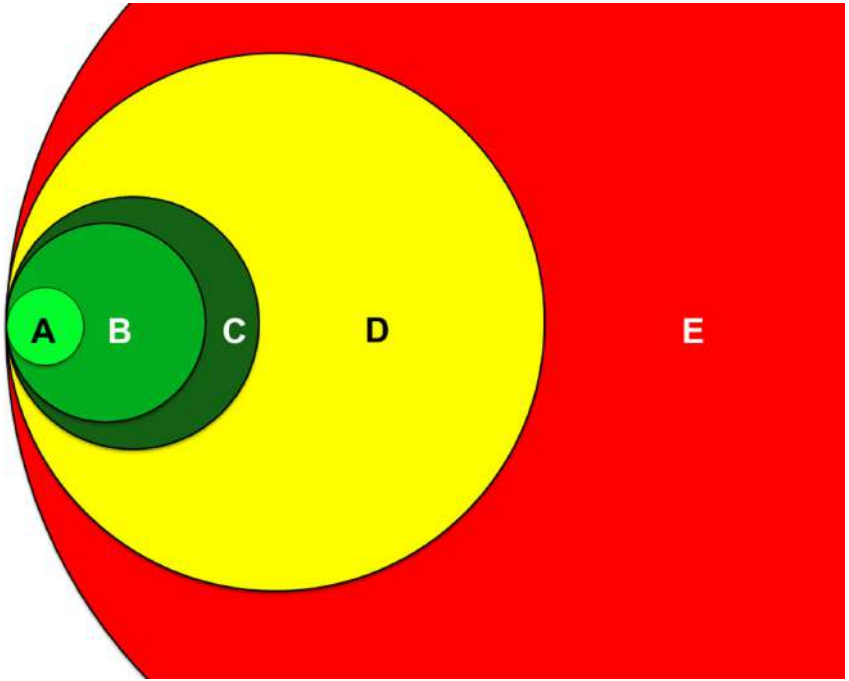
CGuard

P Musialek, G deDonato
Carotid Artery Revascularization Using the Endovascular Route
In: **Peripheral Arterial Interventions - A 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

Carotid ”mesh” stents vs. 1st Gen Stents: The pore size



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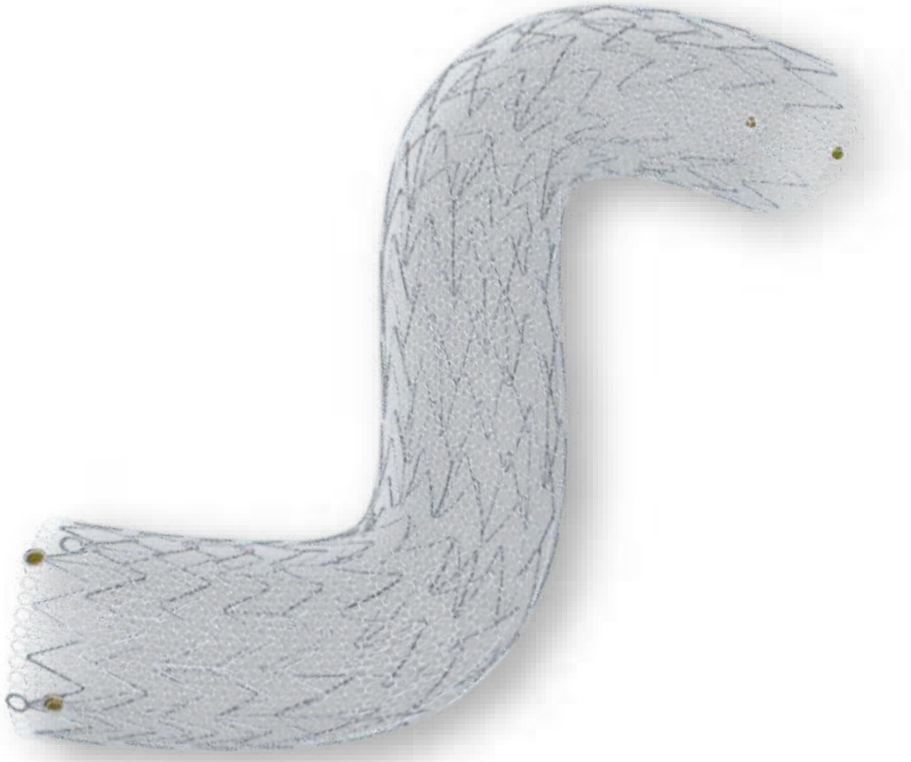
MicroNet-Covered Stent



MicroNet-Covered Stent

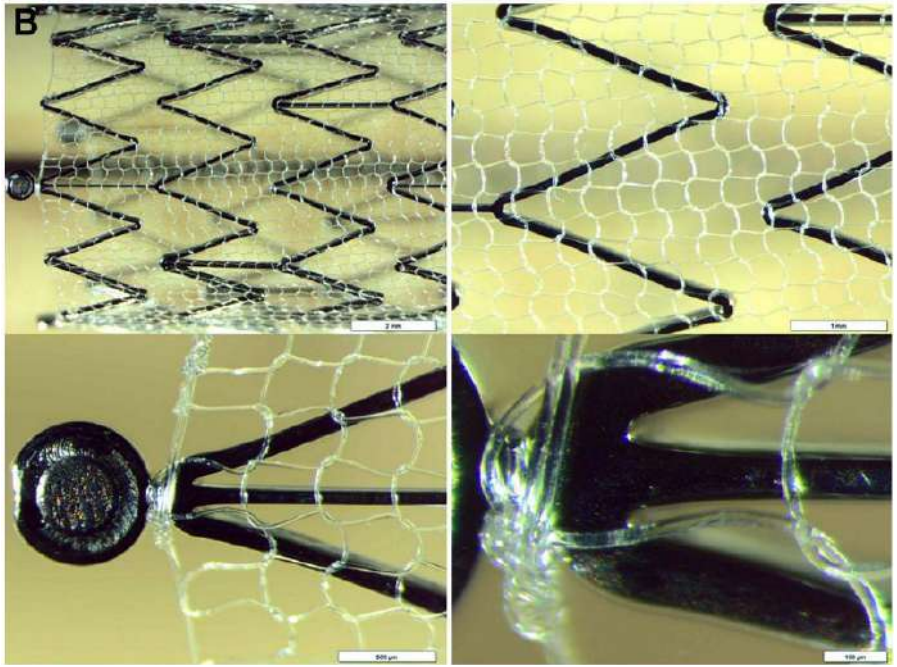
Clinical Investigation

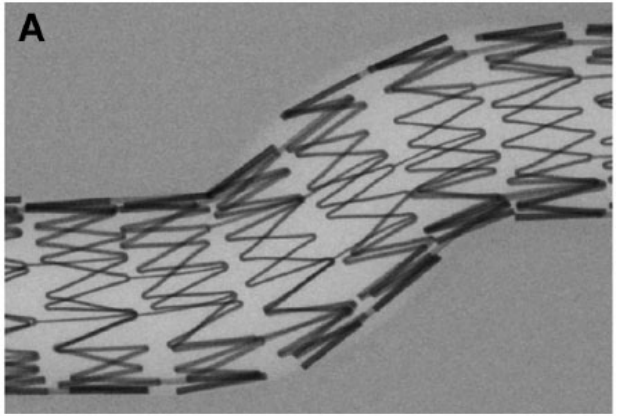
JOURNAL OF ENDOVASCULAR THERAPY

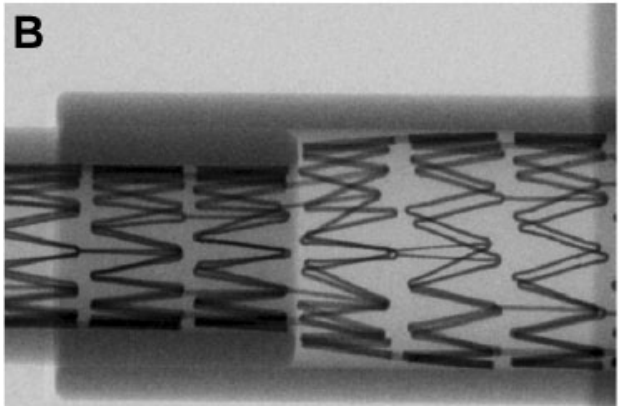
Journal of Endovascular Therapy
1–8

DOI: 10.1177/1526602816671134
www.jevt.org
SAGE

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

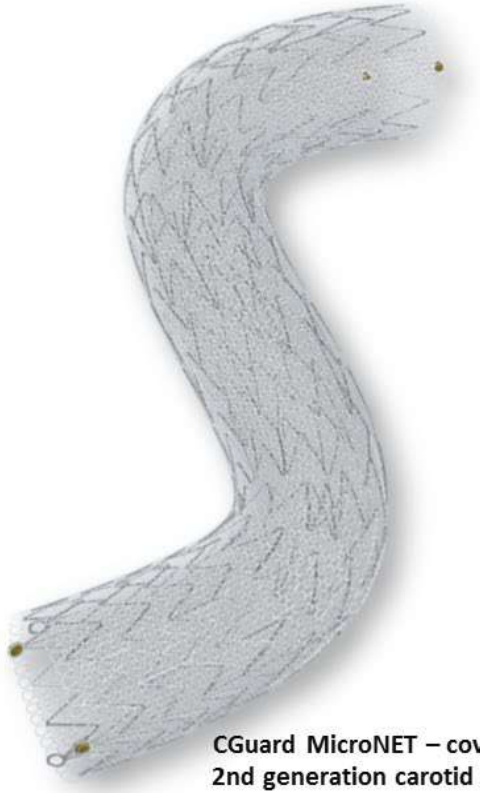






MicroNet-Covered Stent

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

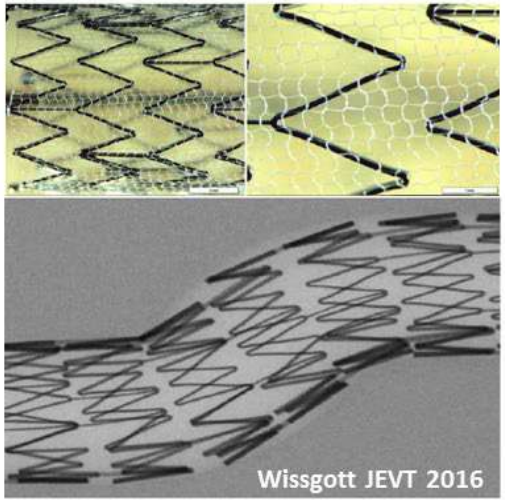


CGuard MicroNET – covered
2nd generation carotid stent

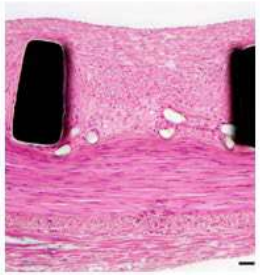
UNIQUE
mechanical
properties

RESPECT
of anatomy

FULL
apposition



NORMAL
healing



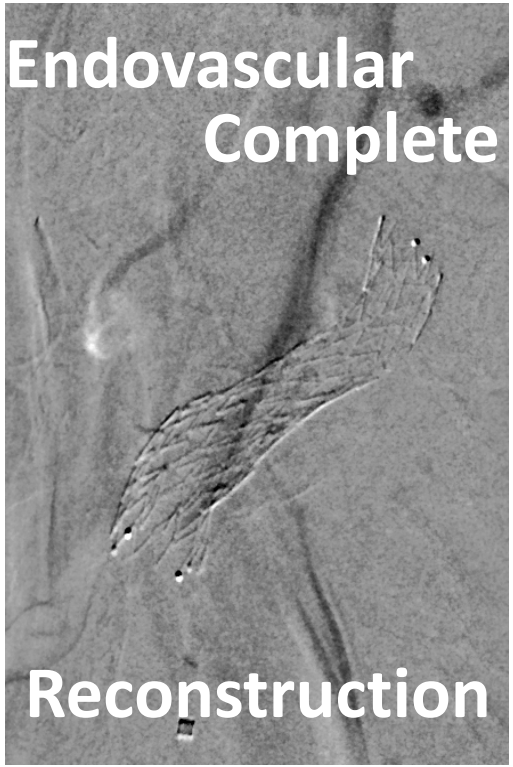
EAPCI
European Society of Cardiology

”Coronary-like” Optimization of CAS

Reconstructing

Normal

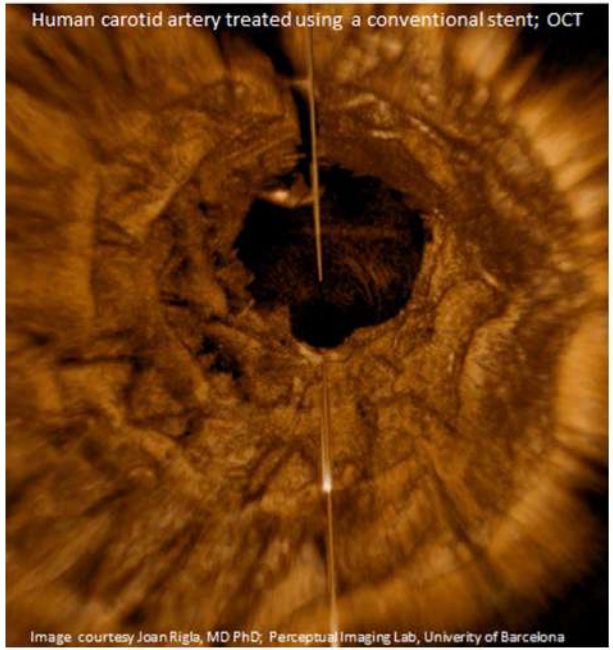
Anatomy



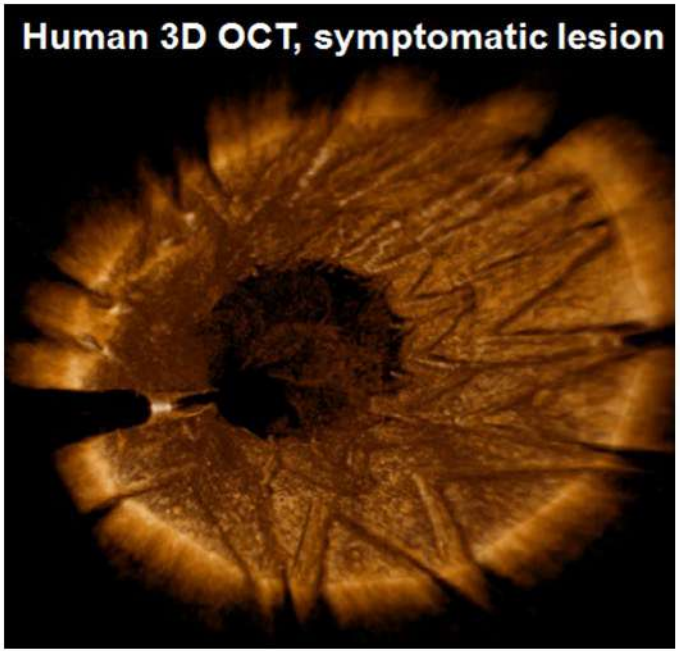
MicroNet Embolic Prevention

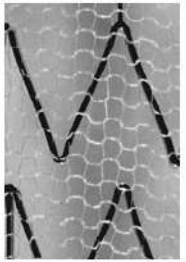
RCT: Conventional vs. Micronet-Covered Stent

The CREST Study stent



MicroNet-Covered Stent

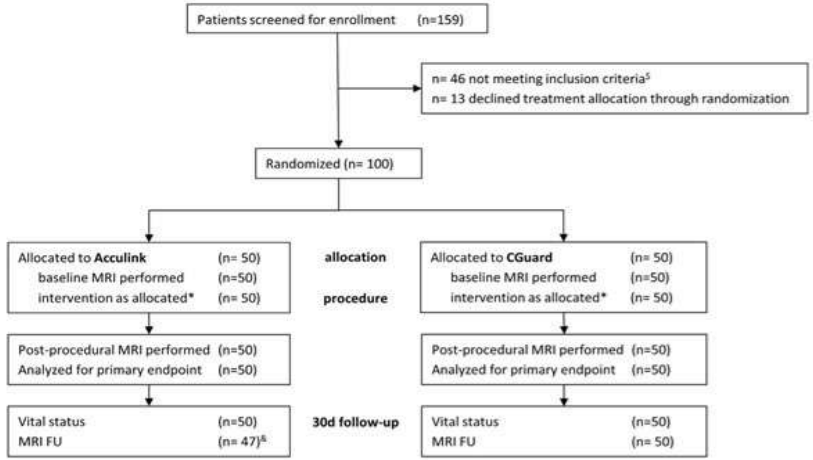




RCT: Conventional vs. Micronet-Covered Stent

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

Andrey Karpenko, MD, PhD,[a] Savr Bugurov, MD,[a] Pavel Ignatenko, MD, PhD,[a] Vladimir Starodubtsev, MD, PhD,[a] Irina Popova, MD, PhD,[a] Krzysztof Malinowski, MSc,[b] Piotr Musialek, MD, DPhil[c]

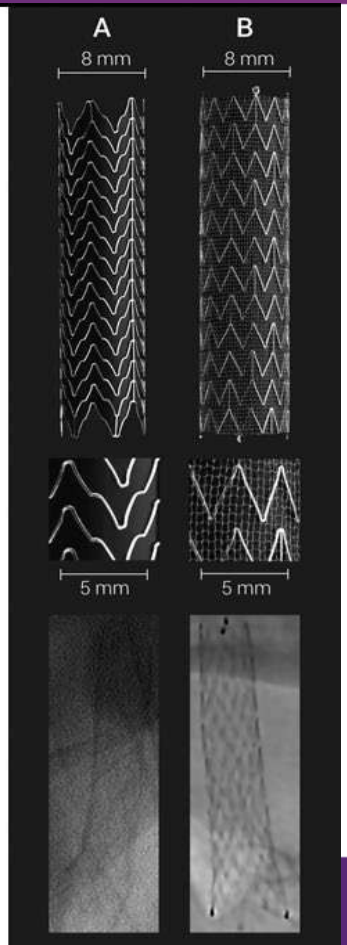


* All CAS with EmboShield NAV6 as per the Centre routine

$ Reasons for not meeting inclusion criteria were: atrial fibrillation (n=14), severe renal failure (n=12), restenotic lesion (n=9), and unsuitability for MRI examination (n=11)

& 2 patients declined on-site follow-up due to travel distance, at the follow up visit the MRI scanner was not functional in 1 (the patient declined re-visit)

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 14, NO. 21, 2021



PCR EAPCI European Society of Cardiology

RCT: Conventional vs. Micronet-Covered Stent

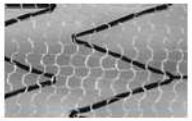
Randomized Controlled Trial of conventional versus Micronet-covered stent use in percutaneous neuroprotected carotid artery revascularization:

Peri-procedural and 30-day **diffusion-weighted magnetic resonance (DWI) imaging** and clinical outcomes

HEAD-TO-HEAD 100 consecutive increased-risk patients (25% symptomatic) **RANDOMIZED 1 : 1**

Distal EPD (Emboshield) in all

MicroNET-Covered
open-cell nitinol frame
2nd generation stent



vs.

Conventional (workhorse)
open-cell nitinol
1st generation stent

JACC Intv 2021

RCT: Conventional vs. Micronet-Covered Stent

JACC: CARDIOVASCULAR INTERVENTIONS

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

Andrey Karpenko, MD, PhD,[a] Savr Bugurov, MD,[a] Pavel Ignatenko, MD, PhD,[a] Vladimir Starodubtsev, MD, PhD, Irina Popova, MD, PhD,[a] Krzysztof Malinowski, MSc,[b] Piotr Musialek, MD, DPhil[c]

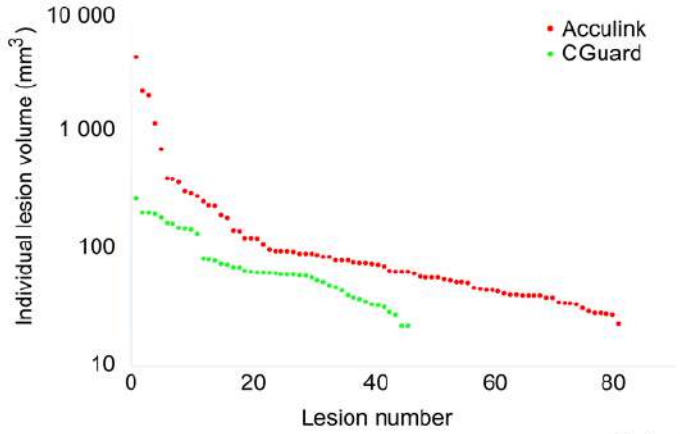
Embolic Load to the Brain

Acculink (CREST study device)

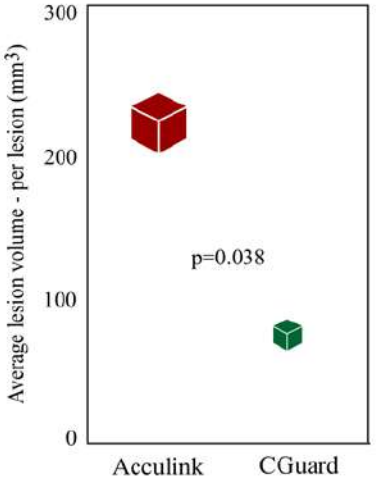
MicroNet-Covered Stent - CGuard

DW-MRI Embolism

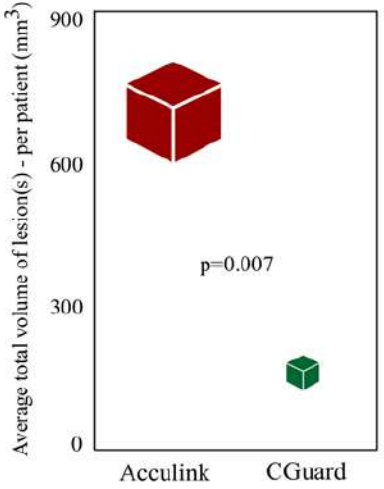
raw data



Per Lesion



Per Ipsil Haemisphere



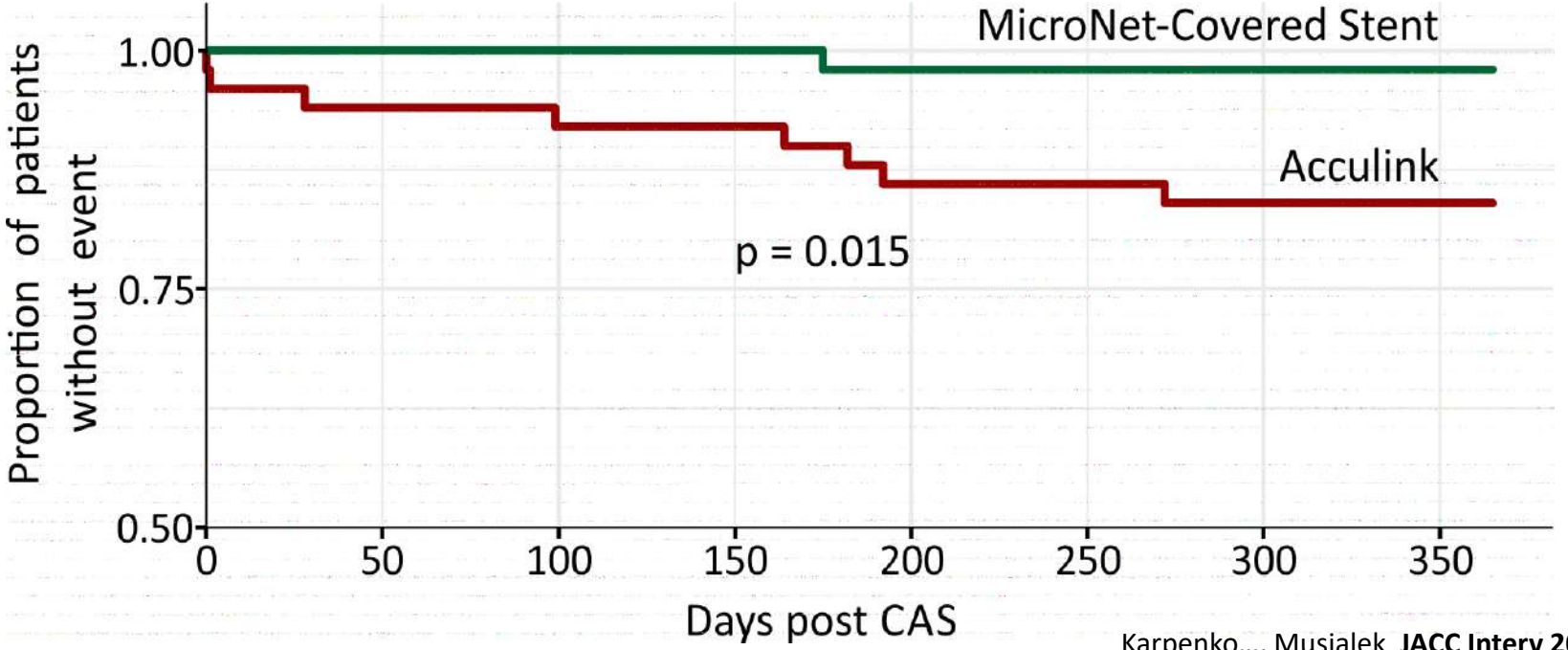
Emboshield NAV in ALL CAS

Blinded CoreLab independent anaysis

RCT: Conventional vs. Micronet-Covered Stent

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

12-month data

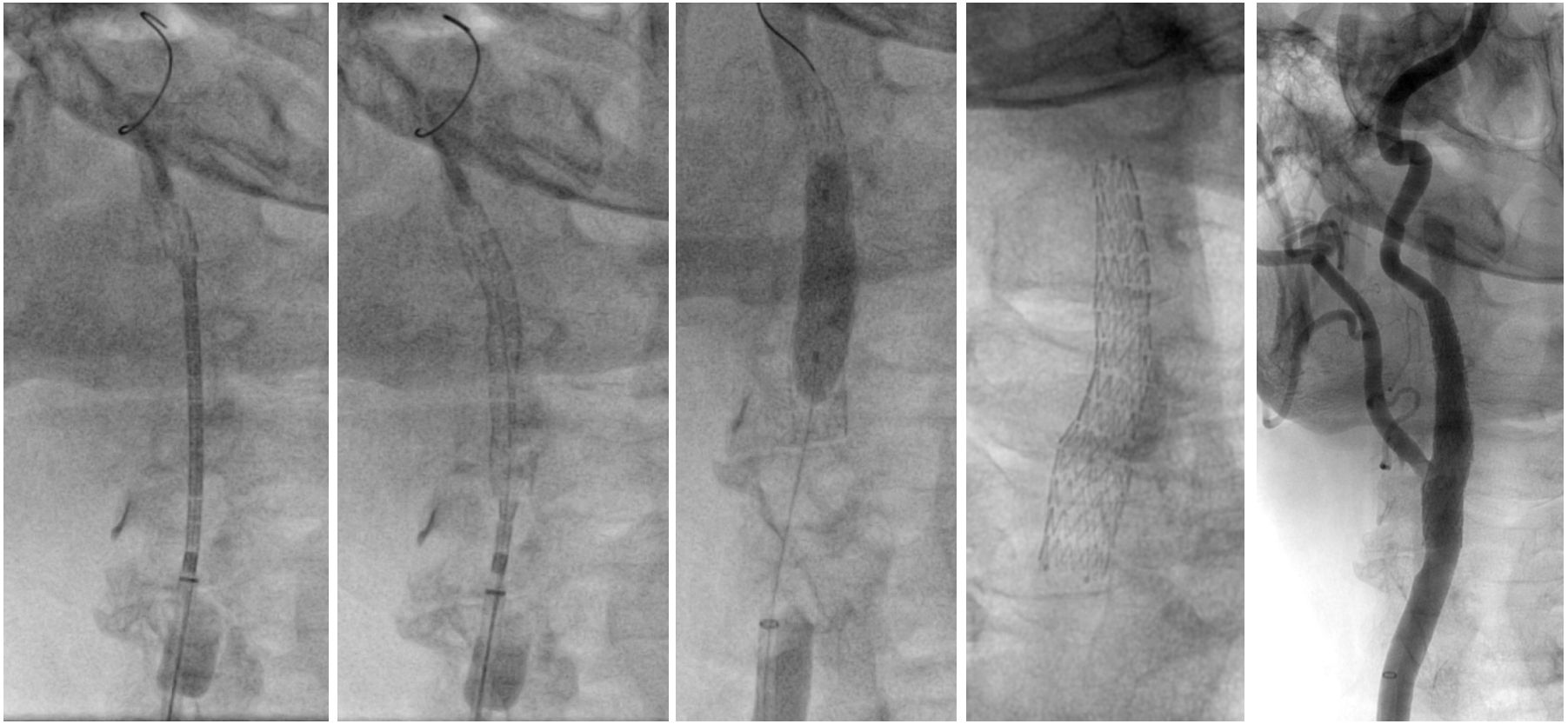


Karpenko…. Musialek **JACC Interv 2023**

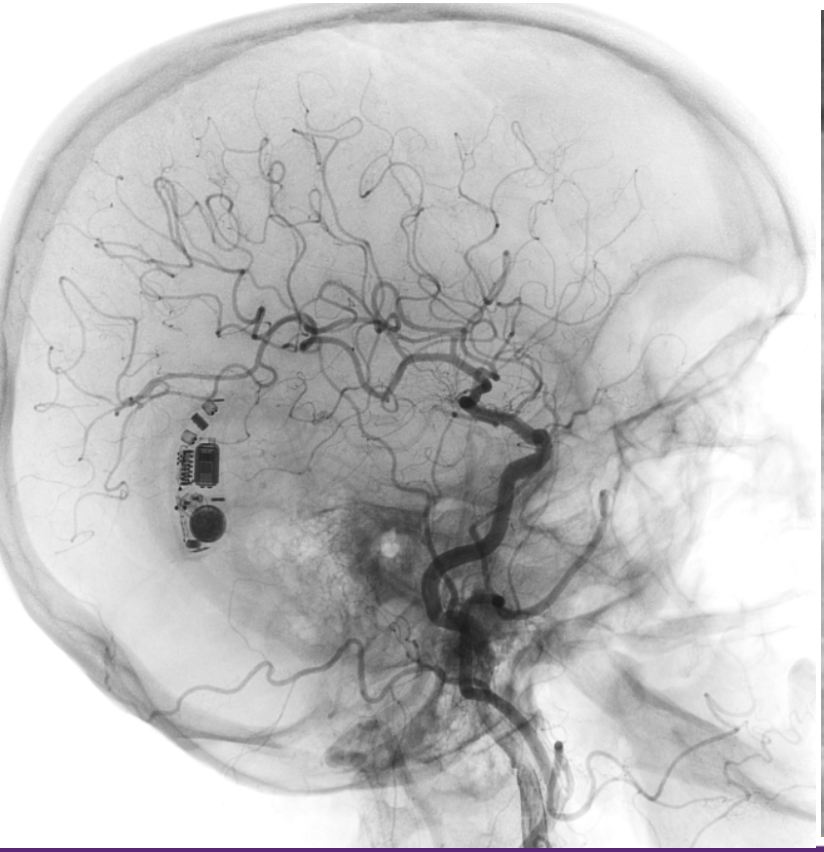
Flow reversed PRIOR to lesion crossing (”no touch”)

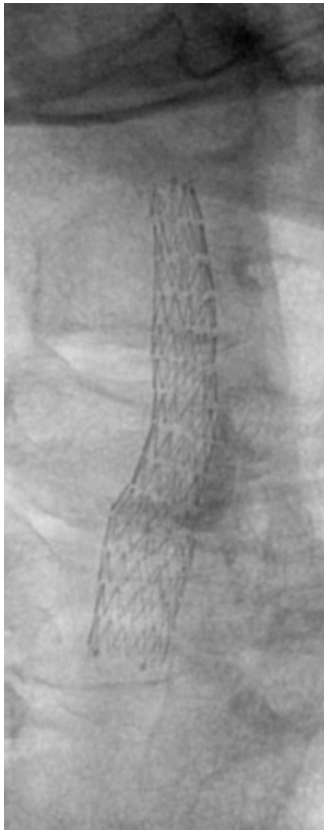
√

Under FR: Predil + MicroNet-Covered stent + Postdil



Final Result of Today's Case (Competent CAS)

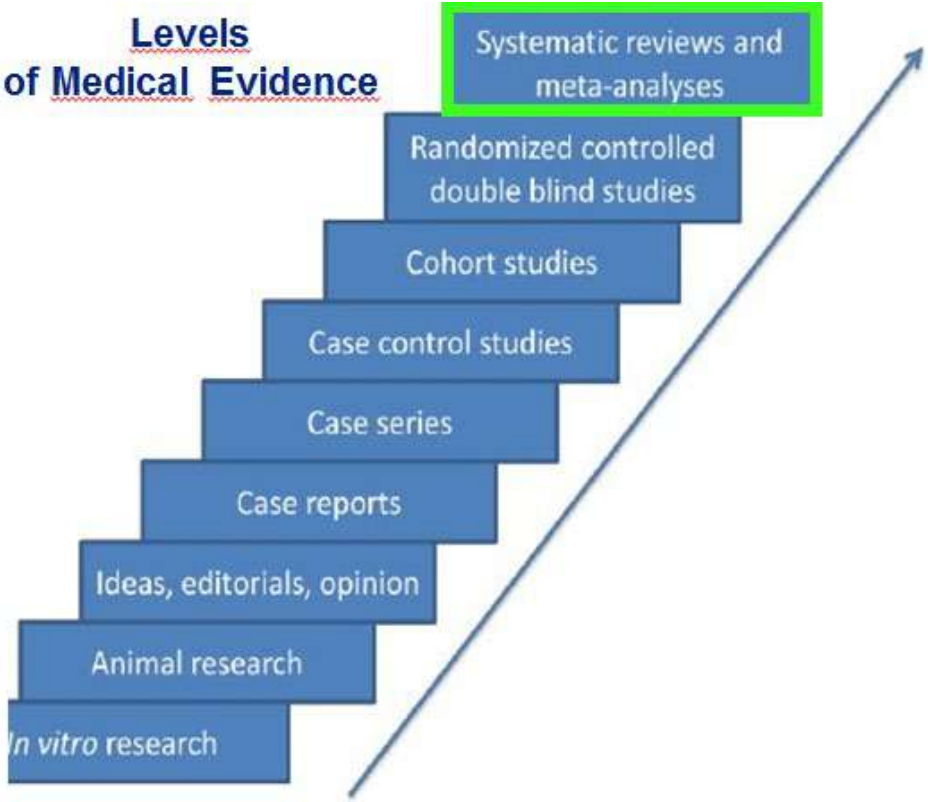




Safe and Effective Procedure

Absence of Residual Stenosis

FULL Anatomic & Functional reconstruction


Levels
of Medical Evidence
Systematic reviews and meta-analyses
Randomized controlled double blind studies
Cohort studies
Case control studies
Case series
Case reports
Ideas, editorials, opinion
Animal research
In vitro research
Sackett DL

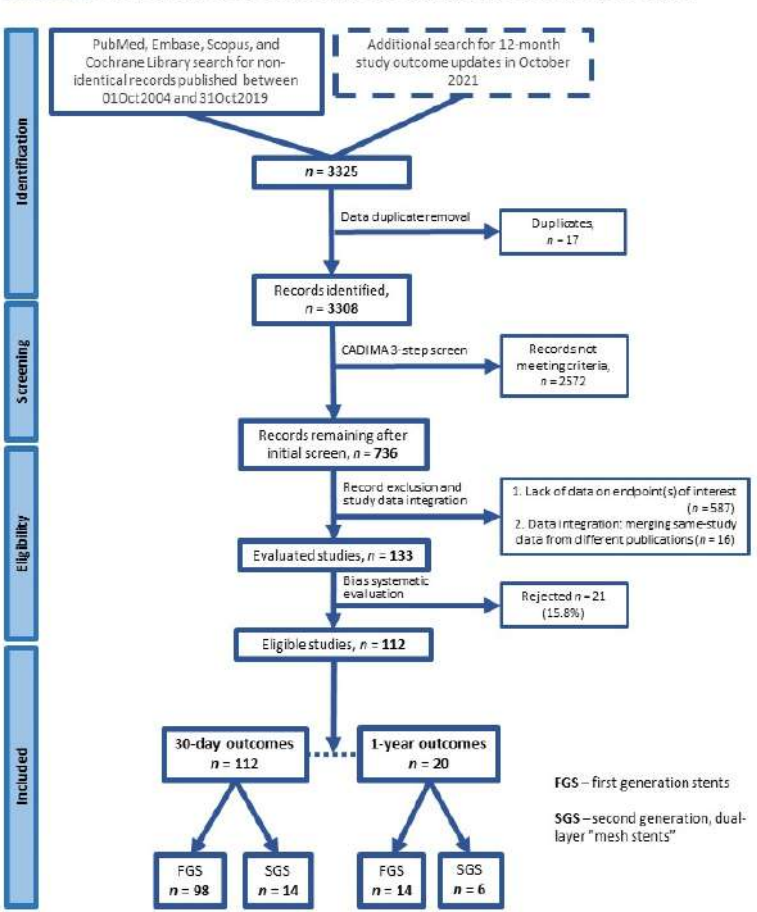

MicroNet-Covered
Stent System

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)



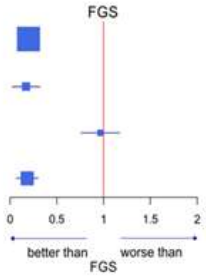
J. Clin. Med. 2022, *11*, 4819. https://doi.org/10.3390/jcm11164819

CARMEN 1st vs. 2nd Generation Carotid Stents Meta-Analysis

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]

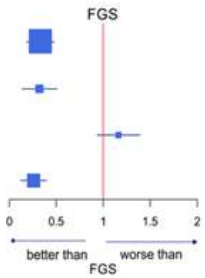
Heterogeneity: I^2=87%, τ^2=0.0003, p<0.01



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]

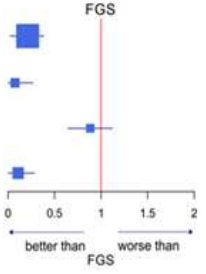
Heterogeneity: I^2=87%, τ^2=0.0004, p<0.01



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]

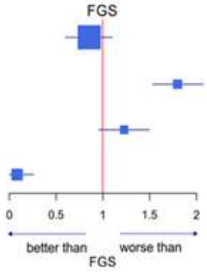
Heterogeneity: I^2=86%, τ^2=0.0002, p<0.01



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



Mazurek… Musiałek **J Clin Med. 2022**

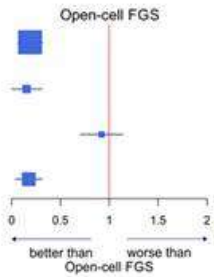
CARMEN 1st vs. 2nd Generation Carotid Stents Meta-Analysis

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]

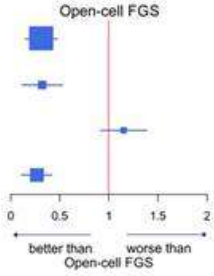
Heterogeneity: I^2=83%, τ^2=0.0002, p<0.01



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

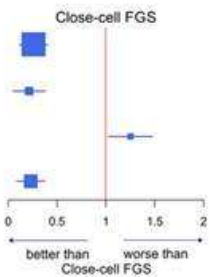


Close-cell FGS as reference

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]

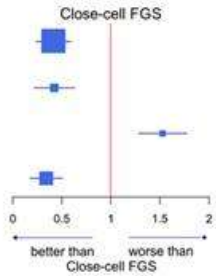
Heterogeneity: I^2=72%, τ^2=0.0001, p<0.01



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



Mazurek… Musiałek **J Clin Med. 2022**

CARMEN 1st vs. 2nd Generation Carotid Stents Meta-Analysis

- Improved short- and long-term clinical results of CAS with pooled 2nd Gen stents

- Individual SGS types, however, differ significantly in their outcomes, indicating

lack of a “mesh stent” class effect

MicroNet-Covered Stent: 5-year data

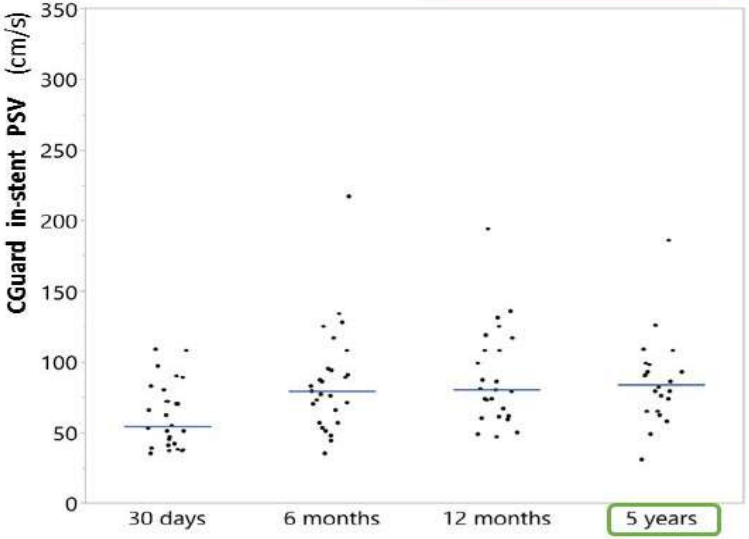
A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial
(Carotid Embolic Protection Using MicroNet)

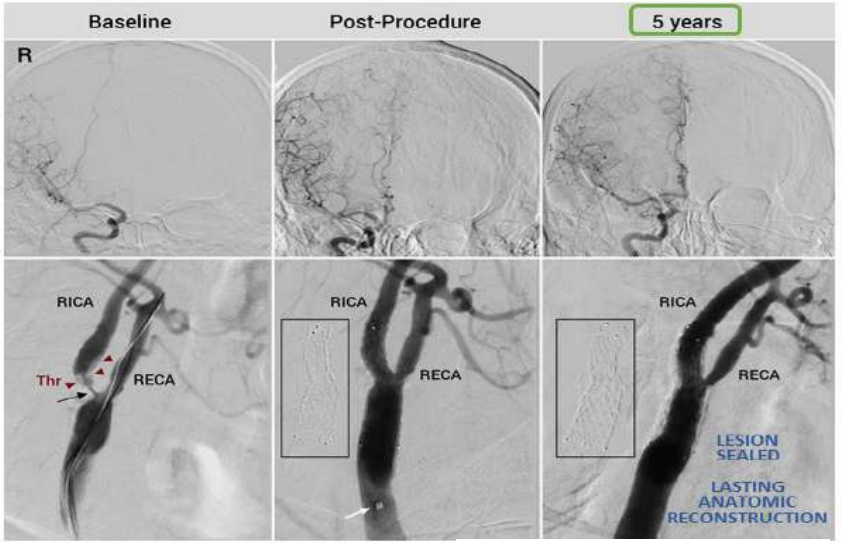
DW-MRI: prior to CAS, 48h post-procedure, and at 30 days

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

CARENET: 5y data



***JACC Intv* 2022**



Musialek…. Schofer *JACC Intv* 2022

Musialek…. Schofer *JACC Intv* 2022

MicroNET-Covered Stent

Contemporary Management of Acute Carotid-Related Stroke

Dr. Lukasz Tekieli, MD PhD

on behalf of **SAFEGUARD-STROKE** Multi-centre, Multi-specialty Investigators

Acute **S**troke of C**A**rotid Artery Bifurcation Origin Treated With Use o**F** the Micron**E**t-covered C**GUARD** Stent

LINC

8 June 2023

(**SAFEGUARD-STROKE**, NCT05195658)

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