

FEBRUARY 25-26, 2024 TEL AVIV, ISRAEL

2nd Generation (Anti-Embolic Stent) CAS vs CEA

Piotr Musialek, MD DPhil



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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) Collaboration Initiator ESC Stroke Council Scientific Documents Task Force



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> 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 Musialek¹, Kenneth Rosenfield², Adnan Siddiqui³, Iris Q Grunwald⁴

- significant medical and societal problem
- pharmacotherapy fails to universally guard against carotid stroke



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- significant medical and societal problem
- pharmacotherapy fails to universally guard against carotid stroke

Carotid-related strokes should be PREVENTED rather than experienced by the stroke-affected Individuals and their Families



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- **1.** ESC Carotid Consensus Document: Patient-Centred MDT Recommendations
- **2.** 2nd Gen Carotid Stents: Answer to the Problem of 1st Gen Stents' CAS



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2. 2nd Gen Carotid Stents: Answer to the Problem of 1st Gen Stents' CAS

3. 1st vs 2nd Gen Stent CAS: RCT Evidence **+** Meta-Analytic Integration of Data



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4. 2nd Gen Stent CAS vs Contemporary CEA: Meta-Analysis



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5. Most Recent Evidence: CGUARDIANS FDA-IDE CAS vs. ACST-2 CEA



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6. Contemporary (vs. Historical) Data in Today's Clinical Decisions: EBM



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- 6. Contemporary (vs. Historical) Data in Today's Clinical Decisions: EBM



EBRUARY 25-26, 2024 TEL AVIV, ISRAEL



Piotr Musialek (1)¹*[†], Leo H. Bonati^{2,3†}, Richard Bulbulia^{4,5}*[†], Alison Halliday^{5†}, Birgit Bock⁶, Laura Capoccia⁷, Hans-Henning Eckstein⁸, Iris Q. Grunwald^{9,10}, Peck Lin Lip¹¹, Andre Monteiro¹², Kosmas I. Paraskevas¹³, Anna Podlasek^{10,14}, Barbara Rantner¹⁵, Kenneth Rosenfield¹⁶, Adnan H. Siddiqui^{17,18}, Henrik Sillesen^{19,20}, Isabelle Van Herzeele²¹, Tomasz J. Guzik^{22,23}, Lucia Mazzolai (1)²⁴, Victor Aboyans (1)²⁵, and Gregory Y.H. Lip²⁴

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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

This consensus document provides a harmonized multi-specialty approach to multi-morbidity prevention in carotid stenosis patients, based on comprehensive knowledge review, pinpointing research gaps in an evidence-based medicine approach. It aims to be a foundational tool for inter-disciplinary collaboration and prioritized patient-centric decision-making.

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The 2023 CONSENSUS Document

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ESC

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Low	Carotid-related stroke risk	High
•	Patient: fully informed and involved in decision	

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Low	(Carotid-related stroke risk High			
	Patient: fully informed and involved in decision				
↑↓					
	n r	Multispecialty neurovascular team> manageme	nt consensus*		

Cardi

Medical therapy

Cardiovascular risk factors and lifestyle modification

*Taking into consideration patient-specific factors such as:

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

The 2023 CONSENSUS Document

2024 MEETING CARDIOVASCULAR INTERVENTIONS

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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MEETING CARDIOVASCULAR INTERVENTIONS

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MEETING CARDIOVASCULAR INTERVENTIONS

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Decision-Making in Carotid Stenosis

Podlasek, Grunwald, Musiałek 2021

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ODECT 4			Periprocedural Period	N Engl J Med 2	010;363:11-23.
CRESI-1	CAS (N=1262)	CEA (N=1240)	Absolute Treatment Effect of CAS vs. CEA (95% CI)	Hazard Ratio for CAS vs. CEA (95% CI)	PValue
	no. of patie	nts (% ±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

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2024

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CRESI-1	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
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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
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2024

The Problem of <u>Conventional</u> (Single-layer) Carotid Stents

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

The **<u>TIMING</u>** 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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The **TIMING** of Stroke by 30-days with CAS in CREST

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

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Timing of neuro-embolic events after CAS

<u>Post-procedural</u> Embolization with conventional carotid stents DW-MRI post CAS

Mean total lesion area

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)

2024 MEETING

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

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2024

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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

2024

Carotid 'mesh' stents

INNOVATION IN CARDIOVASCULAR INTERVENTIONS

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

FEBRUARY 25-26, 2024 TEL AVIV, ISRAEL

Carotid 'mesh' stents

2024 MEETING

INNOVATION IN CARDIOVASCULAR INTERVENTIONS

Name	RoadSaver <i>aka</i> 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 2024

MEETIN

INNOVATION IN CARDIOVASCULAR INTERVENTIONS

JOURNAL OF ENDOVASCULAR ENDOVASCULAR CONTRACTOR SOCIETY THERAPY.

INNOVATION IN CARDIOVASCULAR INTERVENTIONS

Mechanical Behavior of a New Double-Layer Carotid Stent

Journal of Endovascular Therapy 2015, Vol. 22(4) 634–639 © The Author(s) 2015 Reprints and permissions: sagepub.com/journalsPermissions.nav DOI: 10.1177/1526602815593490 www.jevt.org

Christian Wissgott, MD¹, Wolfram Schmidt, BSE², Christoph Brandt, BSE², Peter Behrens, BSE², and Reimer Andresen, MD¹

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

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100 jun

Journal of Endovascular Therapy I-8 © The Author(s) 2016 Reprints and permissions: sagepub.com/journals/Permissions.nav DOI: 10.1177/1526602816671134 www.jevLorg **SAGE**

100 μ

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

UNIQUE mechanical properties

RESPECT of anatomy

FULL apposition

Wissgott JEVT 2016

NORMAL healing

CGuard MicroNET – covered 2nd generation carotid stent

- 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.

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Randomized Controlled Trial The CREST Study stent

Human carotid artery treated using a conventional stent; OCT

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**

Human 3D OCT, symptomatic lesion

INNOVATION IN

CARDIOVASCULAR

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)

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JACC: CARDIOVASCULAR INTERVENTIONS

JACC: CARDIOVASCULAR INTERVENTIONS

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

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Embolic Load to the Brain

Acculink (CREST study device) MicroNet-Covered Stent - CGuard

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

Karpenko.... Musialek JACC Intv 2022

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

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

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

Data of **68,422** patients

from 112 eligible studies

(68.2% men, 44.9% symptomatic)

were meta-analyzed

INNOVATION IN CARDIOVASCULAR INTERVENTIONS

Mazurek... Musiałek J Clin Med. 2022

INNOVATION IN CARDIOVASCULAR INTERVENTIONS

Mazurek... Musiałek J Clin Med. 2022

INNOVATION IN AR ERVENTIONS

Open-cell FGS as reference

В 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]
ŀ	leterogene	ity: 1 ² =84	%, τ ² =0.0003, p<0.01

better than

Open-cell FGS

worse than

Close-cell FGS as reference

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]	0
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]	
ŀ	leterogene	eity: I ² =73	%, t ² =0.0002, p<0.01	

Lack of SGS "class effect"

FEBRUARY 25-26, 2024 TEL AVIV, ISRAEL

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

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30-day Stroke

CARMEN Collaborators *J Cardiovasc Surg* 2023

30-day Death/Stroke/MI

CARMEN Collaborators *J Cardiovasc Surg* 2023

12-month Ipsilateral Stroke

CARMEN Collaborators J Cardiovasc Surg 2023

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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.

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LATEST TECHNIQUES FOR CAROTID REVASCULARIZATION

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

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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

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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.

This may inform clinical practice in anticipation of large-scale randomized trials powered for low clinical event rates. (PROSPERO-CRD42022339789)

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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

¹Department of Cardiac and Vascular Diseases, Jagiellonian University, Krakow, Poland; ²St. John Paul II Hospital, Stroke Thrombectomy-Capable Center, Krakow, Poland; ³Department of Angiology, Sankt-Gertrauden Hospital, Academic Teaching Hospital of Charité University, Berlin, Germany; ⁴Department of Radiology and Interventional Radiology, Casilino Hospital, Rome, Italy; ⁵Main Line Health, Wynnewood, PA, USA; ⁶Sidney Kimmel School of Medicine, Thomas Jefferson University, Philadelphia, PA, USA; ⁷Lankenau Heart Institute, Wynnewood, PA, USA

*Corresponding author: Piotr Musialek, Department of Cardiac and Vascular Diseases, Jagiellonian University, St. John Paul II Hospital, ul. Pradnicka 80, 31-202 Krakow, Poland. E-mail: pmusialek@szpitaljp2.krakow.pl

<u>Historic data</u> (such as those obtained using prior-generation devices that were unable to effectively isolate the atherosclerotic lesion material) have, today, a mostly <u>historical value</u>.

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FDA-IDE Clinical Trial:

CGUARDIANS NCT 04900844

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

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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%
2024 MEETING INNOVATION IN STREETING INTERVENTIONS FEBRUARY 25-26, 20 TEL AVIV, ISRAEL	24 P Musialek @ ICI 2

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

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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* D Chris Metzge	er @ VIVA 2023 0.63% (2)

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

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

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CGUARDIANS FDA-IDE CAS vs. ACST-2 CEA

Comparison of the Micronet-covered stent outcomes in C-GUARDIANS FDA-IDE with asymptomatic-patient CEA in ACST-2 suggests, despite a clear population characteristics bias against C-GUARDIANS (25% symptomatic patients and 41.2% diabetics in C-GUARDIANS vs. 0% symptomatic patients and 30% diabetics in ACST- 2), **a** <u>reduction by half</u> in the 30-day stroke rate and a <u>reduction by ¾</u> in the 30-day

composite endpoint of *death/stroke/myocardial infarction*

for transfemoral CAS using the Micronet-covered stent

0.95% vs. 2.4% and 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.

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Decision-Making in Carotid Stenosis

Podlasek, Grunwald, Musiałek 2021

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Sackett DL

Systematic reviews and meta-analyses

Randomized controlled double blind studies

Cohort studies

Case control studies

Case series

Case reports

MEETING CARDIOVASCULAR INTERVENTIONS

Ideas, editorials, opinion

Animal research

In vitro research

Anti-Embolic Carotid Stent has reached Meta-Analytic Evidence Level

FEBRUARY 25-26, 2024

TEL AVIV, ISRAEL

MicroNet-Covered Stent System

EuroIntervention 2024;20:e1-e3 published online e-edition DOI: 10.4244/EIJ-E-24-00012

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

Piotr Musialek^{1,2*}, MD, DPhil; Kosmas I. Paraskevas³, MD, PhD; Gary S. Roubin⁴, MD, PhD

There are no scientific reasons today to claim that the carotid artery should remain the last artery in the body "reserved" for preferential open surgery.

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