



Vascular and Endovascular Issues Techniques and Horizons

**Update On All Trial Results With CGuard And CGuard Prime MicroMesh Covered Stents (InspireMD): Are They Making A Difference And Limitations With Transfemoral/ Transradial CAS: Evidence Summary And Long-Term Outcomes**


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## Disclosure

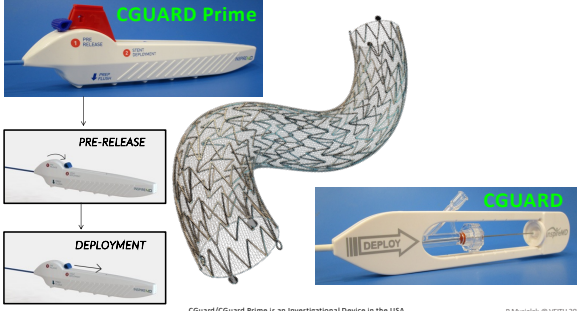
Speaker name: Piotr Musialek  
I have the following potential conflicts of interest to report:

- Consulting/Proctoring: Abbott Vascular, Balton, Gore, InspireMD, Medtronic, Penumbra
- Employment in industry
- Stockholder in a healthcare company
- Owner of a healthcare company
- Others: ESC Stroke Council Scientific Documents Task Force  
Polish Cardiac Society Board Representative for Stroke and Vascular Interventions  
**CGUARDIANS FDA IDE Co-PI**

### The MicroNET-Covered Anti-Embolic Stent



**CGuard**



**CGuard Prime**

PRE-RELEASE


DEPLOYMENT

**CGuard**

DEPLOY

CGuard/CGuard Prime is an Investigational Device in the USA

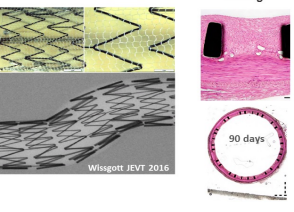
The **MOST 'open'** amongst open-cell stents (metallic FRAME) & the **MOST 'close'** amongst close-cell stents (MicroNet mesh)



UNIQUE mechanical properties

RESPECT of anatomy

FULL apposition



NORMAL healing

90 days

Wissgott JEVT 2016

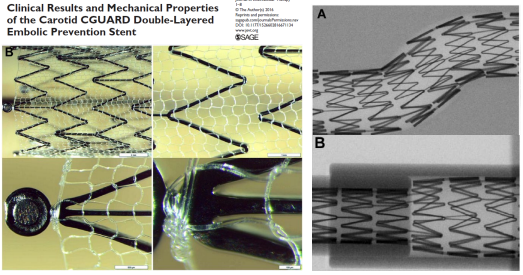
CGuard MicroNET – covered 2nd generation carotid stent

CGuard/CGuard Prime is an Investigational Device in the USA

ENDOASCULAR RESEARCH STUDY

Clinical Investigator: [Name]

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



A

B

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

CGuard/CGuard Prime is an Investigational Device in the USA

### CGuard MicroNet-Covered Stent Expanding Clinical Evidence

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

### CGuard MicroNet-Covered Stent Expanding Clinical Evidence

and...

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

**~ 5000 Patients**

RCT

### Randomized Controlled Trial The CREST Study stent

Human carotid artery treated using a conventional stent; OCT

OCT Images in: P Musialek, G deDonato. *Cardiovascular Route for Carotid Interventions: Practical Guide 2022*

### Randomized Controlled Trial The CREST Study stent

Human carotid artery treated using a conventional stent; OCT

### Level-1 Evidence

Human 3D OCT, symptomatic lesion

CGuard

OCT Images in: P Musialek, G deDonato. *Cardiovascular Route for Carotid Interventions: Practical Guide 2022*

### Neuro-Protective Carotid Stent System

### Randomized Controlled Trial

DW-MRI Embolism raw data

Individual lesion volume (mm<sup>3</sup>)

Lesion number

• Acculink  
• CGuard

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 14, NO. 21, 2022  
NOVEMBER 8, 2022:2573-2587

### Level 1 Evidence

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

MicroNet-Covered Stent - CGuard

Per Lesion

Per Ipsil Hemisphere

Average lesion volume (mm<sup>3</sup>)

Average total volume of embolic protrusions (mm<sup>3</sup>)

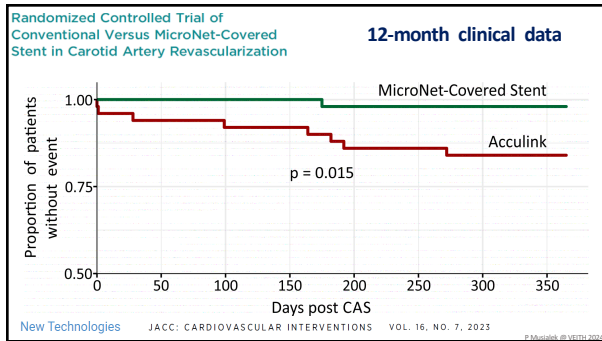
Acculink CGuard

Acculink CGuard

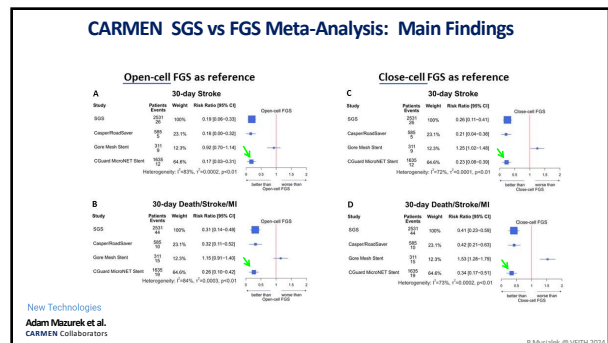
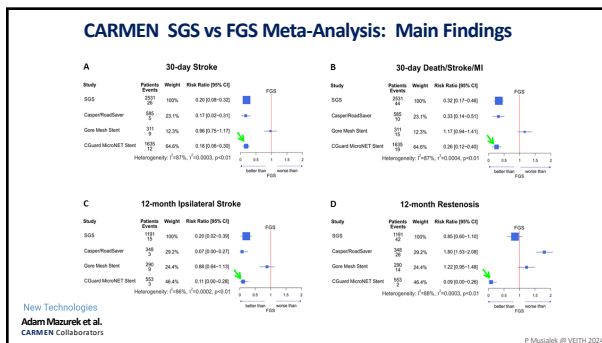
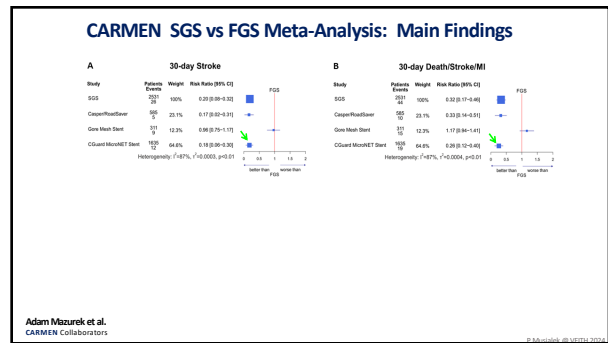
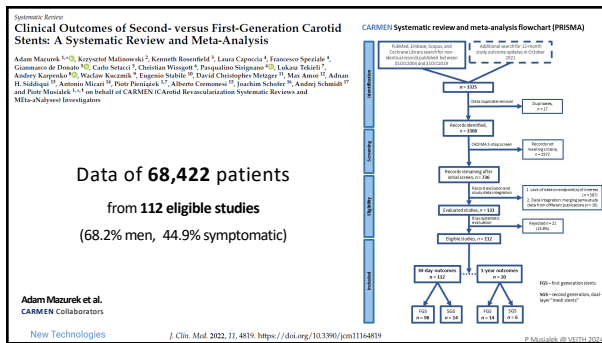
Statistical Comparison: independent samples

**CGuard**  
MicroNET-Covered Stent

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*Meta-Analyses*



*Systematic Review*

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

Adam Mazurek <sup>1,\*</sup>, Krzysztof Malinowski <sup>2</sup>, Kenneth Rosenfield <sup>3</sup>, Laura Capocchia <sup>4</sup>, Francesco Speziale <sup>4</sup>, Gianmarco de Donato <sup>5</sup>, Carlo Setacci <sup>5</sup>, Christian Wissgott <sup>6</sup>, Pasqualino Sirignano <sup>4</sup>, Lukasz Tekieli <sup>7</sup>, Andrey Karpenko <sup>8</sup>, Wacław Kuczmik <sup>9</sup>, Eugenio Stabile <sup>10</sup>, David Christopher Metzger <sup>11</sup>, Max Amor <sup>12</sup>, Adnan H. Siddiqui <sup>13</sup>, Antonio Micari <sup>14</sup>, Piotr Pieniżek <sup>17</sup>, Alberto Cremonesi <sup>15</sup>, Joachim Schofer <sup>16</sup>, Andrej Schmidt <sup>17</sup> and Piotr Musialek <sup>1,4,\*</sup> 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

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**103,642 Patients**

The Journal of Cardiovascular Surgery 2023 December;64(6):570-82  
DOI: 10.23756/S0021-9509.24.12933-3

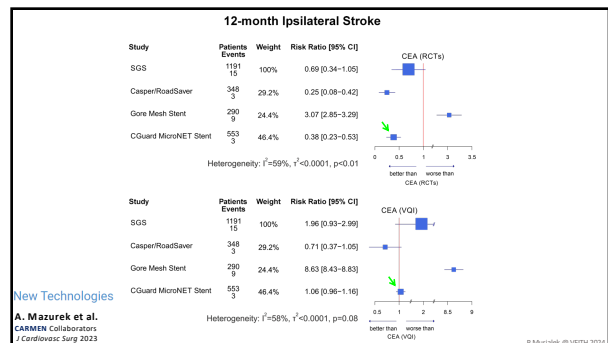
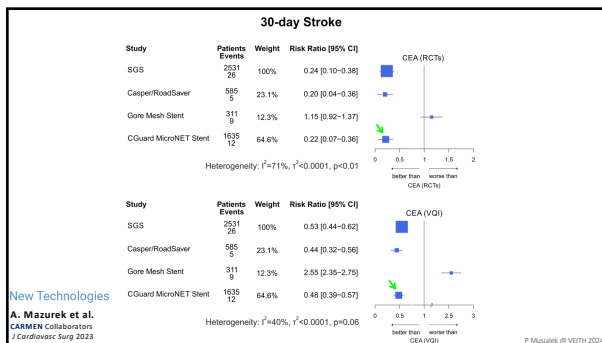
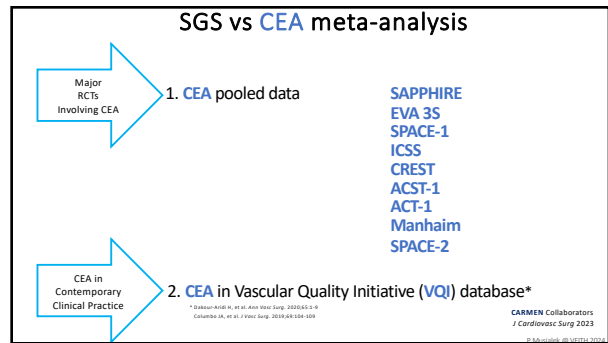
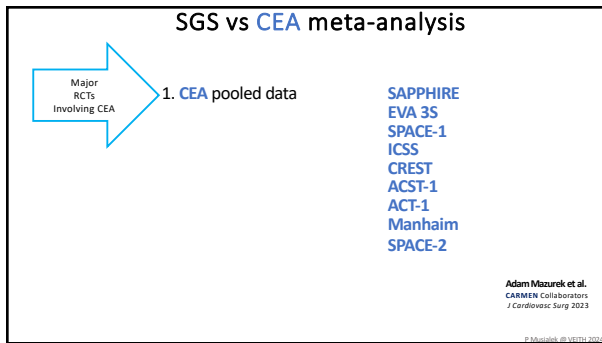
LATEST TECHNIQUES FOR CAROTID REVASCUARIZATION

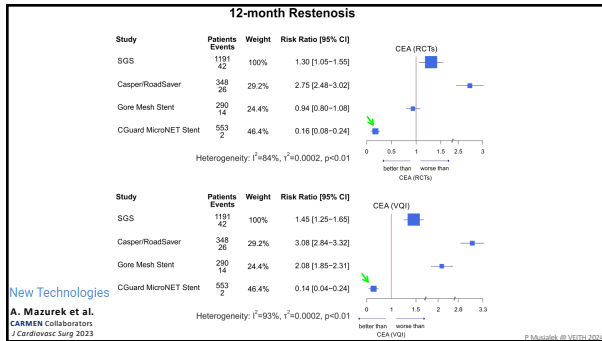
### Carotid artery revascularization using second generation stents versus surgery: a meta-analysis of clinical outcomes

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

Adam Mazurek et al.  
CARMEN Collaborators  
(PROSPERO-CRD42022339789)

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**FDA-IDE**



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

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**Embolic Protection Utilized**

<b>Emboshield NAV 6 Distal embolic protection</b>	261
<b>MoMA Proximal embolic protection</b>	78
<b>Both (Nav6 and MoMa)</b>	24
<b>None</b>	1

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### C-GUARDIANS 30-day Results

ITT Analysis (N = 318)	Event rate in % (n)
Death, Stroke or MI <sup>#</sup>	0.95% (3)
Death <sup>#</sup>	0.32% (1)
Any stroke <sup>#</sup>	0.95% (3)
Major Stroke <sup>#</sup>	0.63% (2)
Minor Stroke <sup>#</sup>	0.32% (1)
MI	0.0% (0)
Death or any stroke <sup>#</sup>	0.95% (3)
Death or major stroke <sup>#</sup>	0.63% (2)

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\* Hierarchical: patient count (each patient first occurrence of the most serious event).  
<sup>#</sup> Non-hierarchical: event count (multiple events in each patient are counted individually).

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

M, 52y, Right Hemisph. Stroke 5 days before

Case courtesy of Dr. Piotr Musialek

**IVUS**

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

DC Metzger LINC 2024 CAUTION: The CGuard Stent System is Investigational Use Only and Not for Sale in the USA.

### C-GUARDIANS Trial 1-Year Primary Endpoint Results

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

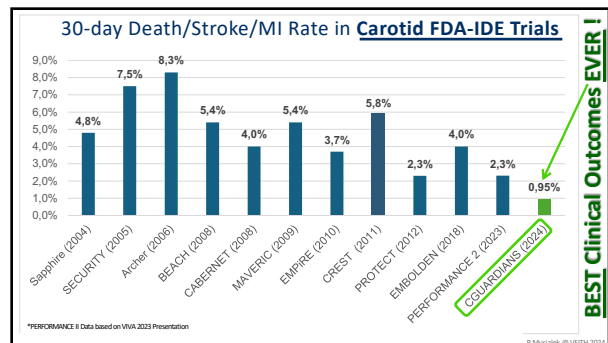
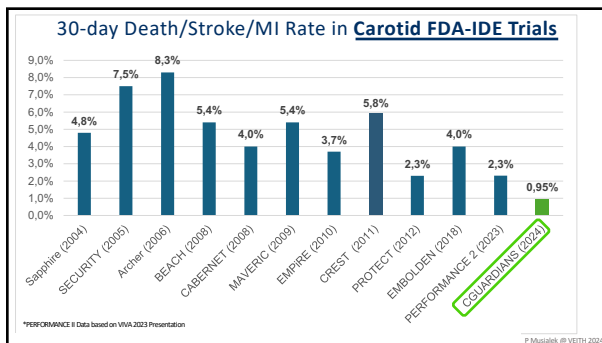
\* Kaplan-Meier estimate for all 1-year endpoints  
\*\* Per Protocol Analysis excludes 15 patients with Major Protocol Deviations

The CEC independently adjudicated all neurological, cardiac events:

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

DC Metzger LINC 2024 CAUTION: The CGuard Stent System is Investigational Use Only and Not for Sale in the USA.

*IDE Data  
in Context*



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**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 CGUARDIAN/FDA-IDE Trial Investigators). 30-Day Results From the C-Guardians Pivotal Trial of the CGuard Carotid Stent System. <https://www.foundation.org/> Halliday A, et al. Second asymptomatic carotid surgery trial (ACST-2): a randomised comparison of carotid artery stenting versus carotid endarterectomy. Lancet. 2021;398:1065-73.

*Transradial*

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

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

RICA

7.0 x 20 mm

a, b, c, d, e, f, g, h, i

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

A, B, C, D, E, F, G, H, I, J

PYS, S81, S82, dtt, RICA, LCCA, FB

10x30mm


*Trans-Carotid*

**TCAR**

Dynamic Flow Reversal

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

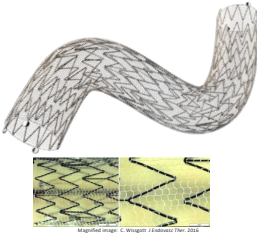
**TCAR**



*Dynamic Flow Reversal*


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

**CGuard**



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

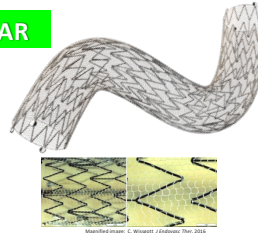
**TCAR**



*Dynamic Flow Reversal*

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

**TOPGUARD**



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

**TCAR + CGUARD = TOPGUARD** (NCT04547387)

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

- 106 increased-risk patients / 3 centers
- 60.4% symptomatic / 49.1% diabetic
- 1 intra-procedural minor stroke (0.9%) (prior to established neuroprotection)
- NO further clinical events by 30-d; NO ST
- 100% stent patency @ 30-days
  - PSV 0.7 (0.62-0.83)m/s
  - EDV 0.2 (0.18-0.21) m/s

Trystula, Kolvenbach, Van Herzele et al. / Cardiovasc Surg 2024;65:181-194.

*Aneurysm Exclusion & Healing*



**43 yo Man, highly-symptomatic**

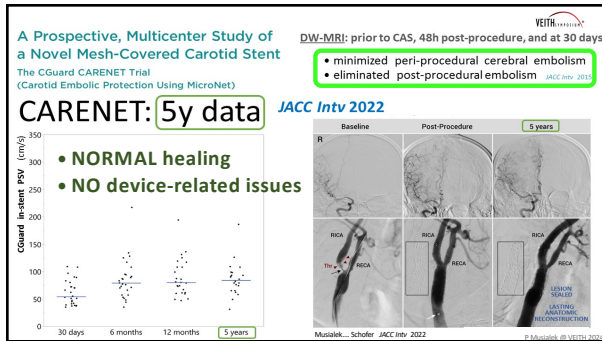


**C-HEAL (NCT04434456)**

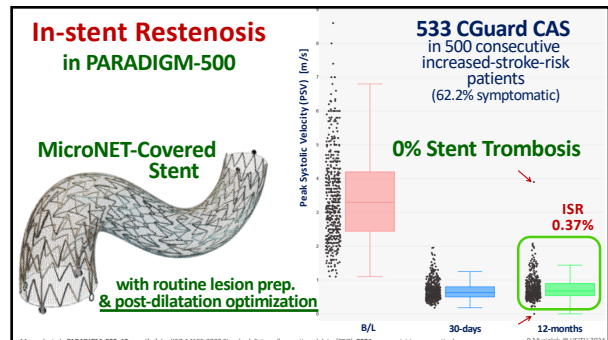
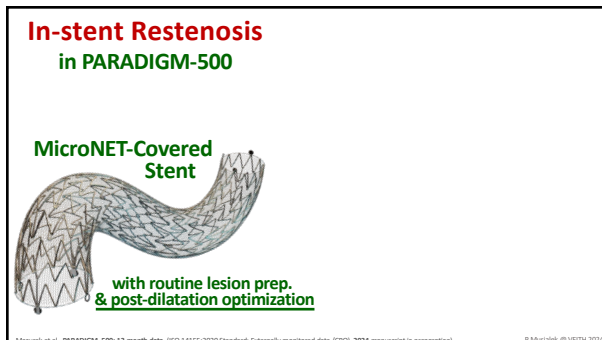








*Optimized Procedures*  
 ("Endovascular Reconstruction")



**Carotid Lesion Management in PARADIGM-500 PREDILATATION**

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

**84.05%**

**Carotid Lesion Management in PARADIGM-500 POSTDILATATION**

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

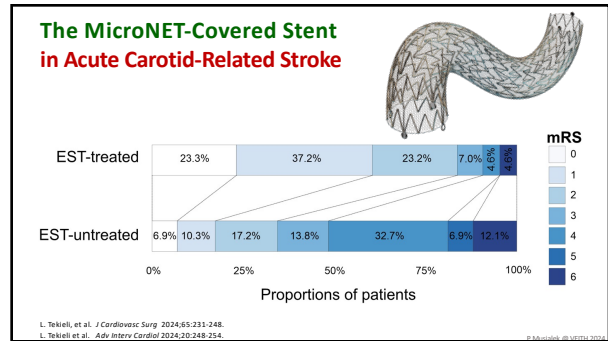
**58.91%**

**STROKE Treatment**

**Predictors of stent patency loss by 90 days**

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

L. Tekieli et al. Adv Interv Cardiol 2024;20:248-254. © KARDIOLOGIA I STROKOW 2024



**LATEST TECHNIQUES FOR CAROTID REVASCUARIZATION**

**Carotid stent as cerebral protector: the arrival of Godot**

Piotr MUSIALEK<sup>1,2\*</sup>, Rafi LANGHOFF<sup>3</sup>, Matteo STEFANINI<sup>4</sup>, William A. GRAY<sup>5,6,7</sup>

\*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@poczta2.krakow.pl

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**.

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