Carotid artery revascularization using CGuard™ MicroNet-Covered Embolic Prevention Stent System: A Change in the Game

Piotr Musialek, MD DPhil FESC

Jagiellonian University Dept. of Cardiac & Vascular Diseases
John Paul II Hospital, Krakow, Poland
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CGuard™ embolic prevention stent
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Disclosure

Speaker name: Piotr Musialek

I have the following potential conflicts of interest to report:

☑ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest

NB. The PARADIGM study has been Investigator-Initiated and Investigator-Executed (no industry support)
AC, man 63 yo

LICA chronic occlusion

LICA previously occluded
AC, man 63 yo

LICA previously occluded

LICA chronic occlusion

RICA

Case #018
(Krakow)
AC, man 63 yo

LICA previously occluded

LICA chronic occlusion

RICA
Thrombus-containing / acutely symptomatic STROKE-in-evolution

LICA previously occluded

LICA chronic occlusion

RICA

Case # 018 (Krakow)
Thrombus-containing lesion acutely symptomatic patient

DW-MRI on admission
Fresh ischemic lesion in the L hemisphere
[ ‘haemodynamic’ lesion, resulting from cross-flow ]
‘old’ ischemic lesion in the R hemisphere
(no diffusion limitation in the R)

M. Urbanczyk, RP. Banys, Dept. Radiology, JP2 Hospital, Krakow
How would YOU treat?

acutely symptomatic / thrombus-containing
Carotid artery revascularization using CGuard™ MicroNet-Covered Embolic Prevention Stent System: A Change in the Game

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RESULTS The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 48 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction). Protection devices were used in all procedures. Procedure success was 100%, with 0% procedural complications. The 30-day major adverse cardiac or cerebrovascular events rate was 0%. New ipsilateral ischemic lesions at 48 h occurred in 37.0% of patients and the average lesion volume was 0.039 ± 0.08 cm³. The 30-day diffusion-weighted magnetic resonance imaging showed complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm³) lesion in relation to the 48-h scan.
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The CGuard CARENET Trial
(Carotid Embolic Protection Using MicroNet)

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Prior to CAS 24h after 30 d after CAS

Rec.Symptomatic LICA

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

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PARADIGM & PARADIGM-EXTEND STUDIES
PARADIGM & PARADIGM-EXTEND

Mandatory DW-MRI

CARENET 03-007, PJ (Krakow)

Prior to CAS  24h after  30 d after CAS

Rec.Symptomatic LICA

Mandatory DW-MRI

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent (Carotid Embolic Protection Using MicroNet)

The CGuard CARENET Trial

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PARADIGM & PARADIGM-EXTEND

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**PARADIGM & PARADIGM-EXTEND**


**RTN CLINICAL PRACTICE 2016**
CAS (and CEA) are—and will remain—emboli-generating procedures.

Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.
CAS (and CEA) are—and will remain—emboli-generating procedures

**Figure 1.** Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.
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Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.
Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS

Mean total lesion area

Schofer J et al, JACC Cardiovasc interv 2008
Does Free Cell Area Influence the Outcome in Carotid Artery Stenting?

M. Bosiers,1* G. de Donato,2 K. Deloose,1 J. Verbist,3 P. Peeters,3
F. Castriota,4 A. Cremonesi4 and C. Setacci4

Overview of event rates related to the different stents

<table>
<thead>
<tr>
<th>Stent name</th>
<th>Total population</th>
<th>Symptomatic population</th>
<th>Asymptomatic population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients</td>
<td>All events</td>
<td>Post-procedural events</td>
</tr>
<tr>
<td>X-act</td>
<td>1.9%</td>
<td>1.9%</td>
<td></td>
</tr>
<tr>
<td>Nexstent</td>
<td>3.3%</td>
<td>3.3%</td>
<td></td>
</tr>
<tr>
<td>Wallstent</td>
<td>2.3%</td>
<td>1.2%</td>
<td></td>
</tr>
<tr>
<td>Precise</td>
<td>4.1%</td>
<td>3.1%</td>
<td></td>
</tr>
<tr>
<td>Protégé</td>
<td>3.0%</td>
<td>3.0%</td>
<td></td>
</tr>
<tr>
<td>Acculink</td>
<td>4.2%</td>
<td>3.7%</td>
<td></td>
</tr>
<tr>
<td>Exponent</td>
<td>11.8%</td>
<td>5.9%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>3179</td>
<td>2.83%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

2/3 CAS neuro events (stroke, TIA) are POST-procedural

Eur J Vasc Endovasc Surg Vol 33, February 2007
**FREE CELL AREA** drives CAS neurologic adverse events (and majority occur *post-procedure*).

<table>
<thead>
<tr>
<th>Free cell area</th>
<th>Total population</th>
<th>Symptomatic population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Post-procedural events</td>
</tr>
<tr>
<td>&lt;2.5 vs [2.5, 5]</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&lt;2.5 vs [5, 7.5]</td>
<td>0.054</td>
<td>0.072</td>
</tr>
<tr>
<td>&lt;2.5 vs &gt;7.5</td>
<td>0.27</td>
<td>0.006</td>
</tr>
</tbody>
</table>

Eur J Vasc Endovasc Surg Vol 33, February 2007
Conventional Carotid Stent

Plaque protrusion may lead to early and late distal embolization

K. Mathias 2013
Conventional Carotid Stent

Human Carotid OCT Image  Courtesy  Dr Juan Rigla, MD PhD
Perceptual Imaging Lab, Univeristy of Barcelona

P. Musialek @ LINC 2016
ANY data on the incidence of PLAQUE PROLAPSE in conventional carotid stents?
Post-procedural **PLAQUE PROLAPSE** through **conventional stent struts**

Suzuki M et al. ESC 2014 Presentation
www.escardio.org

**30.7%**

1/3 stents = **Precise**
2/3 stents = **Carotid Wallstent**

81 y.o. Female, Symptomatic

Images: Dr M. Suzuki
ESC 2014
www.escardio.org

Post-procedural **PLAQUE PROLAPSE** through conventional stent struts


<table>
<thead>
<tr>
<th></th>
<th>Closed cell (n = 17)</th>
<th>Open cell (n = 13)</th>
<th>Hybrid cell (n = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque prolapse²</td>
<td>17.6%, (3)</td>
<td>61.5%, (8)</td>
<td>30%, (3)</td>
</tr>
</tbody>
</table>

² At least 10 appreciable tissue prolapses between the stent struts per patient.
Conventional Carotid Stent
Plaque protrusion may lead to early and late distal embolization.
CGuard™ embolic prevention system
# CGuard™–Carotid Embolic Prevention System

## System specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
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<tr>
<td>Stent type</td>
<td>Nitinol – self expanding</td>
</tr>
<tr>
<td>Micronet aperture size</td>
<td>150-180 μm</td>
</tr>
<tr>
<td>Guidewire</td>
<td>0.014”</td>
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<tr>
<td>Sizes</td>
<td></td>
</tr>
<tr>
<td>- Diameter</td>
<td>6-10mm</td>
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<td>- Length</td>
<td>20-60mm</td>
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NB. CGuard™ EPS is not yet available in the US

CE Mark – March 2014

Specific, carotid-dedicated design

P. Musialek @ LINC 2016
## CGuard™—Carotid Embolic Prevention System

### System specifications

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CE Mark – March 2014

Specific, carotid-dedicated design

NB. CGuard™ EPS is not yet available in the US
Pore Size

CGUARD™

ROADSAVER=CASPER

GORE

* 150–180µm
Port Size

CGUARD™

ROADSAVER=CASPER

GORE

* 150–180µm

165µm

375µm

500µm

1050µm

Closed cell stent

1900µm

Open cell stent

P. Musialek @ LINC 2016
CGUARD™

ROADSAVER=CASPER

GORE

* 150–180µm
CARENET – Study Design

Prospective, multi-center, all-comer

Objectives:
To evaluate the periprocedural safety and efficacy of the CGuard stent in the treatment of carotid lesions in thirty consecutive patients with symptomatic and asymptomatic carotid artery stenosis, suitable for CAS

Sites:
- Joachim Schofer (PI), Hamburg University Cardiovascular Center
- Piotr Musialek (Co-PI), Jagiellonian University Medical College
- Ralf Kolvenbach, Augusta Hospital
- Horst Sievert, Cardiovascular Center Frankfurt

Endpoints:
- Acute /30-day Cerebral Embolization by DWI (incidence, volume)
- 30 day MACCE (death, stroke, MI)

J. Schofer, P. Musialek et al. JACC Intv 2015;8:1229-34
Evaluation of PET Mesh Covered Stent in Patients with Carotid Artery Disease

The CARENET-Trial
(CARotid Embolic protection using microNET)

Joachim Schofer (PI)
Piotr Musialek (Co-PI)
On behalf of the CARENET Investigators

Joachim Schofer, MD, PhD, Hamburg University Cardiovascular Center, Hamburg, Germany
Piotr Musialek, MD, PhD, Jagiellonian University Medical College at John Paul II Hospital, Krakow, Poland,
Ralf Kolvenbach, MD, PhD, Augusta Hospital, Dusseldorf, Germany,
Horst Sievert, MD, PhD, Cardiovascular Center Frankfurt, Frankfurt, Germany
A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial
(Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPHIL,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡ Mariusz Trystula, MD,† Zbigniew Siudak, MD,§ Horst Sievert, MD‖

ABSTRACT

OBJECTIVES This study sought to evaluate the feasibility of the CGuard Carotid Embolic Protective Stent system—a novel thin strut nitinol stent combined with a polyethylene terephthalate mesh covering designed to prevent embolic events from the target lesion in the treatment of carotid artery lesions in consecutive patients suitable for carotid artery stenting.

BACKGROUND The risk of cerebral embolization persists throughout the carotid artery stenting procedure and remains during the stent healing period.

METHODS A total of 30 consecutive patients (age 71.6 ± 7.6 years, 63% male) meeting the conventional carotid artery stenting inclusion criteria were enrolled in 4 centers in Germany and Poland.
DW-MRI: the unforgiving testimony of what you’ve done to the TARGET ORGAN...
The Power of DW-MRI...

48h after LICA-CAS

M. Urbanczyk, P. Banys, Dept. Radiology, JP2 Hospital, Krakow, Poland
CARENET DW-MRI analysis

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<tr>
<td>Average lesion volume (cm³)</td>
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<td>Maximum lesion volume (cm³)</td>
<td>0.445</td>
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see patient fluxogram

*External Core Lab analysis (US)*

† bilateral lesions

J. Schofer, P. Musialek et al. *JACC Intv* 2015;8:1229-34
# CARENET DW-MRI analysis

## DW-MRI analysis @ 48 hours

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<tr>
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<th>CARENET (n=27)</th>
<th>PROFI (all) (n=62)</th>
<th>ICSS† (n=56)</th>
</tr>
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<tbody>
<tr>
<td>Incidence of new ipsilateral lesions</td>
<td>37.0%</td>
<td>66.2%</td>
<td>68.0%</td>
</tr>
<tr>
<td>Average lesion volume (cm³)</td>
<td>0.039 ± 0.08</td>
<td>0.375</td>
<td>-</td>
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≈50% reduction in new ipsilateral lesion incidence

---

*External Core Lab analysis (US)*


† bilateral lesions

J. Schofer, P. Musialek et al. *JACC Intv* 2015;8:1229-34

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see patient fluxogram
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<td>0.375</td>
<td>-</td>
</tr>
<tr>
<td>Maximum lesion volume (cm³)</td>
<td>0.415</td>
<td></td>
<td></td>
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</table>

>10-fold reduction in cerebral lesion volume

*External Core Lab analysis (US)*


† bilateral lesions

J. Schofer, P. Musialek et al. *JACC Intv* 2015;8:1229-34
Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis

**DW-MRI analysis @ 48 hours**

- INCIDENCE
- new ipsilateral lesions (%)

<table>
<thead>
<tr>
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<th>Conventional Carotid stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>p &lt; 0.005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=27</td>
<td>34.6</td>
<td>87.1</td>
</tr>
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</table>

*see patient fluxogram

Bjuklic et al. JACC, 2012; 59

J. Schofer, P. Musialek et al. JACC Intv 2015; 8:1229-34
Bjuklic et al. (manuscript in preparation)
Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis

DW-MRI analysis @ 48 hours

* see patient fluxogram
Bijuklic et al, JACC 2012;59

J. Schofer, P. Musialek et al, JACC Intv 2015;8:1229-34
Bijuklic et al (manuscript in preparation)
CARENET DW-MRI analysis

All but one peri-procedural ipsilateral lesions

RESOLVED

<table>
<thead>
<tr>
<th>DW-MRI analysis @ 30 days*</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of new ipsilateral lesions</td>
<td>1</td>
</tr>
<tr>
<td>Average lesion volume (cm$^3$)</td>
<td>0.08 ± 0.00</td>
</tr>
<tr>
<td>Permanent lesions at 30 days</td>
<td>1</td>
</tr>
</tbody>
</table>

*External Core Lab analysis (US)

J. Schofer, P. Musialek et al. *JACC Interv* 2015;8:1229-34
Anti-Embolic Carotid Stent

Plaque protrusion may lead to early and late distal embolization

Debris
Arterial Wall

Stent Struts

K. Mathias 2013

J. Schofer, P. Musialek et al. TCT 2014
Anti-Embolic Carotid Stent

CGuard Embolic-Prevention Stent OCT Image (human, iv vivo)
Courtesy Dr Juan Rigla, MD PhD
Perceptual Imaging Lab, University of Barcelona
A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

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RESULTS The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 48 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction). Protection devices were used in all procedures. Procedure success was 100%, with 0% procedural complications. The 30-day major adverse cardiac or cerebrovascular events rate was 0%. New ipsilateral ischemic lesions at 48 h occurred in 37.0% of patients and the average lesion volume was 0.039 ± 0.08 cm³. The 30-day diffusion-weighted magnetic resonance imaging showed complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm³) lesion in relation to the 48-h scan.

CONCLUSIONS The use of the CGuard system in patients undergoing carotid artery stenting is feasible. In addition, the benefit of using CGuard may extend throughout the stent healing period. (J Am Coll Cardiol Intv 2015;8:1229-34)
Prospective evaluation of All-comer percutaneous cArotiD revascularization in symptomatic and increased risk asymptomatic carotid artery stenosis using CGuard™ Micronet covered embolic prevention stent system:

The PARADIGM Study
Objective

- to evaluate feasibility and outcome of routine anti-embolic stent system use in unselected, consecutive patients referred for carotid revascularization (‘all-comer’ study)
**Methods: The CAS Procedure**

- **EPD** use mandatory; EPD selection according to the ‘Tailored CAS’ algorithm*

- **Liberal postdilatation** accepted in order to maximize potential for ‘endovascular full reconstruction’ (minimizing residual stenosis)

**NB.**
1. DWI evidence of effective MicroNet prevention against cerebral embolization (CARENET/PROFI)
2. Residual stenosis after CAS as independent predictor of in-stent restenosis

Cosottini M et al. *Stroke Res* 2010  
Musialek P et al. *J Endovasc Ther* 2010  
Wasser K et al. *J Neurol* 2012

Endpoints:

- feasibility of endovascular Tx in unselected referrals using the study device in otherwise routine practice
- **device success** (able to deliver + implant + <30% DS)
- **procedure success** (device success w/o clinical compl.) (external neurologist, external non-invasive cardiologist)
- clinical efficacy: **MACNE** (death/stroke/MI)
- in-stent velocities (Duplex)

PARADIGM

• **ASYMPTOMATIC** patients treated interventionally only if at **stroke risk**

• established lesion-level increased-risk criteria used:
  
  – thrombus-containing
  – tight, near-occlusive
  – documented progressive
  – irregular and/or ulcerated
  – contralateral ICA occlusion/stroke
  – asymptomatic ipsilateral brain infarct

Methods (cont’d)

PARADIGM: investigator – independent

- external study data verification
- external angiographic analysis
- external statistical analysis
97 carotid stenosis patient referrals* (external >> internal)

Neuro-Vascular Team

for carotid revascularization 73 patients

Neurologist
Interventional Angiologist
Vascular Surgeon
Cardiologist

NOT for carotid revascularization 24 patients

n=19: lesion increased risk and/or severity criteria not met
n=2: ICA totally occluded on verification
n=2: ICA functionally occluded + h/o prior ipsil. large infarct with hemorrhagic transformation
n=1: severe haemodynamic instability (ICA stenosis sympt.)
Study Flow Chart (2)

73 Patients for carotid revascularization

(92%)

CAS in n=67 Patients (bilateral in 3)

(1%)

CAS + CEA in n=1 Patient

(LICA-CEA and RICA-CAS) hybrid management

(7%)

CEA in n=5 Patients

n = 1 eGFR 14 => no contrast
n = 1 extreme access tortuosity
n = 1 severe aortic valve disease + calcific LICA (AVR + CEA)

n = 1 floating thrombus in CCA
n = 1 ICA diameter <2.0 mm + contralateral occlusion

71 ICAs treated endovascularly in 68 patients


P. Musialek @ LINC 2016
acutely symptomatic / thrombus-containing
Thrombus-containing / acutely symptomatic
Thrombus-containing / acutely symptomatic
Thrombus-containing / acutely symptomatic

Case # 018
(Krakow)
Thrombus-containing
Acutely symptomatic

NIH-SS immediate
4-point improvement

P Musialek @ LINC 2016
Thrombus-containing lesion acutely symptomatic patient

**DW-MRI on admission**

- Fresh ischemic lesion in the L hemisphere
  - [‘haemodynamic’ lesion, resulting from cross-flow.] ‘old’ ischemic lesion in the R hemisphere
  - (no diffusion limitation in the R)

**Images:**

- **DWI:**
  - Fresh ischemic lesion
  - ADC = proof of diffusion absence in the DWI focus

- **Flair:**
  - Old ischemic lesion

**Results:**

- **24h after CAS:**
  - No new lesions

- **30 days after CAS:**
  - No new lesions

**Case # 018 (Krakow)**

- NIH-SS 4-point improvement
- NIH-SS further 2-point improvement

M. Urbanczyk, RP. Banys, Dept. Radiology, JP2 Hospital, Krakow

P. Musialek @ LINC 2016
CGuard™ embolic prevention stent
<table>
<thead>
<tr>
<th>Clinical characteristics of study patients (n=68)</th>
</tr>
</thead>
<tbody>
<tr>
<td>age, mean±SD (min–max)</td>
</tr>
<tr>
<td>male, % (n)</td>
</tr>
<tr>
<td>symptomatic, % (n)</td>
</tr>
<tr>
<td>symptomatic ≤ 14 days, % (n)</td>
</tr>
<tr>
<td>acutely symptomatic (emergent CAS), % (n)</td>
</tr>
<tr>
<td>index lesion (CAS), % (n)</td>
</tr>
<tr>
<td>RICA</td>
</tr>
<tr>
<td>LICA</td>
</tr>
<tr>
<td>RICA+LICA</td>
</tr>
<tr>
<td>CAD, % (n)</td>
</tr>
<tr>
<td>h/of MI, % (n)</td>
</tr>
<tr>
<td>CABG or PCI in the past, % (n)</td>
</tr>
<tr>
<td>PCI as bridge to CAS, % (n)</td>
</tr>
<tr>
<td>AFib (h/o or chronic), % (n)</td>
</tr>
<tr>
<td>diabetes, % (n)</td>
</tr>
<tr>
<td>h/o neck or chest radiotherapy, % (n)</td>
</tr>
</tbody>
</table>
PARADIGM: Results (1)

- Percutaneous treatment using the intended MicroNet-covered embolic prevention stent system CGuard (i.e., no other stents used during the study period)
  - Device success: 100%
  - Procedure success: 100%
  - Transient Dopamine infusion: 19% (n=14)
  - Debris in EPD: 18% (n=13)
  - Access site complications: 0% (n=0)
  - Vascular plug closure: 45% (n=32)
**PARADIGM: Results (2)**

**Index lesion qualitative characteristics** (n=71 lesions)

<table>
<thead>
<tr>
<th></th>
<th>All (n=71)</th>
<th>Symptomatic (n=37)</th>
<th>Asymptomatic (n=34)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombus, % (n)</td>
<td>15% (11)</td>
<td>24% (9)</td>
<td>6% (2)</td>
<td>0.025</td>
</tr>
<tr>
<td>Near occl./string, % (n)</td>
<td>21% (15)</td>
<td>30% (11)</td>
<td>12% (4)</td>
<td>0.084</td>
</tr>
<tr>
<td>Progressive*, % (n)</td>
<td>27% (19)</td>
<td>11% (4)</td>
<td>44% (15)</td>
<td>0.003</td>
</tr>
<tr>
<td>Ulcerated, % (n)</td>
<td>41% (29)</td>
<td>46% (17)</td>
<td>35% (12)</td>
<td>0.470</td>
</tr>
<tr>
<td>Irregular, % (n)</td>
<td>72% (51)</td>
<td>65% (24)</td>
<td>79% (27)</td>
<td>0.197</td>
</tr>
<tr>
<td>Contralateral occl., % (n)</td>
<td>17% (12)</td>
<td>22% (8)</td>
<td>35% (12)</td>
<td>0.291</td>
</tr>
<tr>
<td>Highly calcific, % (n)</td>
<td>23% (16)</td>
<td>14% (5)</td>
<td>35% (12)</td>
<td>0.050</td>
</tr>
<tr>
<td>Asymptomatic ipsilat. brain embolization/infarct</td>
<td>N/A</td>
<td>N/A</td>
<td>32% (11)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*verified on imaging

**CoreLab-Quantified**

- ICA reference diameter: \(4.99 \pm 0.36\) mm (from 4.27 to 6.02 mm)
- Lesion length: \(19.9 \pm 5.8\) mm (from 8.19 to 30.25 mm)
<table>
<thead>
<tr>
<th></th>
<th>All (n=71 lesions)</th>
<th>Symptomatic n=37</th>
<th>Asymptomatic n=34</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before CAS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSV, m/s</td>
<td>3.8 ± 1.3</td>
<td>3.7 ± 1.1</td>
<td>3.8 ± 1.5</td>
<td>0.862</td>
</tr>
<tr>
<td>EDV, m/s</td>
<td>1.3 ± 0.7</td>
<td>1.4 ± 0.6</td>
<td>1.3 ± 0.8</td>
<td>0.687</td>
</tr>
<tr>
<td>Diameter stenosis % (QA)</td>
<td>82 ± 9</td>
<td>79 ± 9</td>
<td>84 ± 9</td>
<td>0.021</td>
</tr>
<tr>
<td><strong>CAS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EPD type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal*</td>
<td>35% (25)</td>
<td>44% (16)</td>
<td>26% (9)</td>
<td>0.092</td>
</tr>
<tr>
<td>Distal**</td>
<td>65% (46)</td>
<td>56% (21)</td>
<td>74% (25)</td>
<td></td>
</tr>
<tr>
<td>post-dilat balloon#</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>peak pressure, mmHg</td>
<td>18.4 ± 3.4</td>
<td>17.5 ± 3.6</td>
<td>19.2 ± 2.9</td>
<td>0.037</td>
</tr>
<tr>
<td><strong>After CAS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent length (QA)$§$</td>
<td></td>
<td></td>
<td></td>
<td>NA</td>
</tr>
<tr>
<td>Nominal 30 mm (min-max)</td>
<td>29.66 ± 0.30</td>
<td>29.66 ± 0.28</td>
<td>29.65 ± 0.32</td>
<td></td>
</tr>
<tr>
<td>Nominal 40 mm (min-max)</td>
<td>39.73 ± 0.34</td>
<td>39.69 ± 0.41</td>
<td>39.77 ± 0.28</td>
<td></td>
</tr>
<tr>
<td>Residual diam. stenosis</td>
<td>7 ± 4%</td>
<td>5 ± 4%</td>
<td>7 ± 5%</td>
<td>0.257</td>
</tr>
<tr>
<td>in-stent PSV, m/s</td>
<td>0.70 ± 0.28</td>
<td>0.66 ± 0.29</td>
<td>0.74 ± 0.27</td>
<td>0.266</td>
</tr>
<tr>
<td>in-stent EDV, m/s</td>
<td>0.17 ± 0.07</td>
<td>0.17 ± 0.07</td>
<td>0.18 ± 0.07</td>
<td>0.457</td>
</tr>
</tbody>
</table>

* Emboshield (n=7); FilterWire (n=14); Spider (n=25)
** Gore FlowReversal (n=4) or flow reversal with MoMa (n=21)
(NB. mean flow reversal time was 6min 48s, from 5min 18s to 11min 2s)
# ø 4.5mm (n=5); ø 5.0mm (n=36); ø 5.5mm (n=29); ø 6.0mm (n=1);
§ 30mm in 51 lesions; 40mm in 18 lesions (2 other lesions required two stents each)
PARADIGM: Results (4)

- Death/stroke/MI @ 48h 0%
- Death/stroke/MI @ 30d 0%

Evolving L Haemisph stroke

Case # 063 (Krakow)
Case # 063 (Krakow)

NO new brain lesions

M. Urbanczyk, P. Banys, Dept. Radiology, JP2 Hospital, Krakow, Poland
R Haemisph minor stroke 4 d before, now recurrent TIAs

Note self-tapering

Case # 067 (Krakow)
R Haemisph minor stroke 4 d before, now recurrent TIAs

NO new brain lesions

Case # 067 (Krakow)

M. Urbanczyk, P. Banys, Dept. Radiology, JP2 Hospital, Krakow, Poland

P. Musialek @ LINC 2016
L Haemisph minor stroke 5 d before
L Haemisph minor stroke 5 d before

Case # 068 (Krakow)

NO new brain lesions

NO new brain lesions
L Haemisph minor stroke 5 d before

NO new brain lesions

Case # 068 (Krakow)

M. Urbanczyk, RP. Banys, Dept. Radiology, JP2 Hospital, Krakow

P. Musialek @ LINC 2016
Predilatation 3.0x20mm followed by NC 4.5x15/20atm
CGuard™ 9.0x30mm, postdilated ø5.5x20mm/16atm

RICA 6.2/1.5 m/s

Highly-calcific I

A. Mazurek, P. Musialek  ePCR2015: CGuard Micro-Net covered embolic prevention stent in endovascular management of highly calcific lesions
Highly-calcific II

NO brain lesions with CAS

Predilatation 2.0x20 followed by NC 4.0x15, CGuard™ 8.0x40mm, postdilated ø 5.0mm/16 atm

A. Mazurek, P. Musialek  ePCR2015: CGuard Micro-Net covered embolic prevention stent in endovascular management of highly calcific lesions
Highly-calcific III

Predilatation 2.5x15mm followed by 4.0x15, CGuard™ 9.0x30mm, postdilated ø5.0mmx20/24atm

Note self-tapering

A. Mazurek, P. Musialek  ePCR2015: CGuard Micro-Net covered embolic prevention stent in endovascular management of highly calcific lesions
CGuard 5 months follow-up
RCCA & RICA

LICA CGuard
5 months follow-up
PARADIGM – EXTEND

PARADIGM – 101 recruitment completed

24.09.2015

Cardiovascular and Interventional Radiological Society of Europe

PARADIGM – 101

Patient #101 in 'PARADIGM-EXTEND' (a.k.a. 'PARADIGM 101')
A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent
The CGuard CARENET Trial
(Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPhJ,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡ Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD||
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Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD||

• 2 asymptomatic self-withdrawals @ 30 days

30d data
ZERO Stroke/MI/death

12mo data
A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial
(Carotid Embolic Protection Using MicroNet)

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- 2 asymptomatic self-withdrawals @ 30 days
- **100% follow up** of the remaining patients
A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent
The CGuard CARENET Trial
(Carotid Embolic Protection Using MicroNet)

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- 2 asymptomatic self-withdrawals @ 30 days
- **100% follow up** of the remaining patients

**ZERO** Stroke Deaths @ 12mo
**ZERO** Strokes

Per-Protocol independent neurological assessment
A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial
(Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPhIL,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡ Mariusz Trystula, MD,† Zbigniew Siudak, MD,¶ Horst Sievert, MD||

• 2 asymptomatic self-withdrawals @ 30 days
• 100% follow up of the remaining patients

ZERO Stroke Deaths @ 12mo

ZERO Strokes

Per-Protocol independent neurological assessment

• 1 pulmonary embolism death @ 5 mo
• 1 respiratory failure death @ 8 mo
• 1 malignant tumor death @ 9 mo
- NO device-related adverse events
- NO procedure-related events

CARENET Multicenter Trial  12 mo data
CARENET in-stent Peak Systolic Velocities

70% in-stent stenosis threshold*

![Graph](image)

**Peak Systolic Velocity (cm/sec)**

- **30 d**: Various values
- **6 mo**: Various values
- **12 mo**: Various values

**ECA patency**
- **30 d**: 100%
- **6 mo**: 100%
- **12 mo**: 100%

* Setacci et. Al.. Grading Carotid Intrastent Restenosis of 814 CAS patients *Stroke* 2008

P. Musialek @ LINC 2016
CARENET in-stent Peak Systolic Velocities

70% in-stent stenosis threshold*

Peak Systolic Velocity (cm/sec)

ECA patency 100% 100% 100%

30 d 6 mo 12 mo

* Setacci et. Al.. Grading Carotid Intrastent Restenosis of 814 CAS patients Stroke 2008

P. Musialek @ LINC 2016
CARENET in-stent Peak Systolic Velocities

70% in-stent stenosis threshold*

• NO in-stent restenosis concern

Peak Systolic Velocity (cm/sec)

ECA patency

<table>
<thead>
<tr>
<th>Time</th>
<th>30 d</th>
<th>6 mo</th>
<th>12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

* Setacci et. Al.. Grading Carotid Intrastent Restenosis of 814 CAS patients Stroke 2008

P. Musialek @ LINC 2016
CARENET in-stent Peak Systolic Velocities

- NO in-stent restenosis concern
- NO CGuard ECA patency concern

Peak Systolic Velocity (cm/sec)

70% in-stent stenosis threshold*

ECA patency

30 d | 6 mo | 12 mo
--- | --- | ---
100% | 100% | 100%

* Setacci et. Al. Grading Carotid Intrastent Restenosis of 814 CAS patients Stroke 2008
CAS (and CEA) are—and will remain—emboli-generating procedures amenable to elimination with MicroNet.
Endovascular Solution for All-Comers

Endovascular Reconstruction of the Carotid Bifurcation

Prevention of embolism, Optimal radial force, Excellent conformability...

Note self-tapering

P. Musialek @ LINC 2016
CGuard embolic prevention stent system

- Full respect of the carotid bifurcation anatomy
  -> ‘endovascular anatomic reconstruction’

- Optimal performance across all lesion subsets
  (including high calcium/thrombus/string)

‘The most OPEN of open-cell stent designs’
and
‘The most CLOSED of the closed-cell designs’
CGuard embolic prevention stent system

- Full respect of the carotid bifurcation anatomy -> ‘endovascular anatomic reconstruction’

- Optimal performance across all lesion subsets (including high calcium/thrombus/string)

‘The most OPEN of open-cell stent designs’

and

‘The most CLOSED of the closed-cell designs’

DW-MRI Evidence (CARENET) + Clinical Evidence (CARENET, PARADIGM, PARADIGM-EXTEND)
This concept has been desired.
This concept has been desired. And it works.
This concept has been desired.
And it works.

This is the future of Carotid Artery Stenting
This concept has been desired.
And it works.

This is the future of Carotid Artery Stenting
This concept has been desired. And it works.

This is the future of Carotid Artery Stenting revascularization?
Study Flow Chart (2)

73 Patients for carotid revascularization

- CAS in n=67 Patients (bilateral in 3)
- CAS + CEA in n=1 Patient
- CEA in n=5 Patients

71 ICAs treated endovascularly in 68 patients

(LICA-CEA and RICA-CAS) hybrid management

n = 1 eGRF 14 => no contrast
n = 1 extreme access tortuosity
n = 1 severe aortic valve disease + calcific LICA (AVR+CEA)
n = 1 floating thrombus in CCA
n = 1 ICA diameter <2.0 mm + contralateral occlusion

Study Flow Chart (2)

73 Patients for carotid revascularization

(92%)

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(1%)

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(7%)

CEA in n=5 Patients

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n=1 severe aortic valve disease + calcific LICA (AVR+CEA)
n=1 floating thrombus in LCA
n=1 ICA diameter <2.0 mm + contralat. occlusion

71 ICAs treated endovascularly in 68 patients
JZ, man 63 yo symptomatic CAD (NSTEMI, LVEF 25-30%)
JZ, man 63 yo

symptomatic CAD (NSTEMI, LVEF 25-30%)
+bilateral severe carotid disease (L haemisph TIAs)
JZ, man 63 yo
symptomatic CAD (NSTEMI, LVEF 25-30%) + bilateral severe carotid disease (L haemisph TIA)
JZ, man 63 yo 22 Oct 2015
symptomatic CAD (NSTEMI, LVEF 25-30%) + bilateral severe carotid disease (L haemisph TIA's)
JZ, man 63 yo  22 Oct 2015
symptomatic CAD (NSTEMI, LVEF 25-30%)
+ bilateral severe carotid disease (L haemisph TIAs)

*First* truly simultaneous CAS + CABG hybrid in our Institution
(same OT, CAS when Extra-Corporeal Circulation connected and at standby)
JZ, man 63 yo  
22 Oct 2015  
symptomatic CAD (NSTEMI, LVEF 25-30%) + bilateral severe carotid disease (L haemisph TIA)  

Open-chest patient  

First truly simultaneous CAS + CABG hybrid in our Institution (same OT, CAS when ECC hooked up and at standby)  

Spider-protected CAS
JZ, man 63 yo 22 Oct 2015

Symptomatic CAD (NSTEMI, LVEF 25-30%) + bilateral severe carotid disease (L haemisph TIAs)

Spider-protected CAS

CGuard 8.0 x 30mm full endovascular reconstruction

First truly simultaneous CAS + CABG hybrid in our Institution (same OT, CAS when ECC hooked up and at standby)
JZ, man 63 yo  
22 Oct 2015 
symptomatic CAD (NSTEMI, LVEF 25-30%) 
+bilateral severe carotid disease (L haemisph TIAs) 

First truly simultaneous CAS + CABG hybrid in our Institution  
( same OT, CAS when ECC hooked up and at standby )

CABG 
(3 grafts) 
Dr Jacek Piątek 
Dr Piotr Mazur

P. Musialek @ LINC 2016
JZ, man 63 yo
symptomatic CAD (NSTEMI, LVEF 25-30%)
+bilateral severe carotid disease (L haemisph TIAs)

On day 5 the patient – asymptomatic and w/o any deficit – discharged to a rehab centre, 30 day follow-up uneventful; now scheduled for RICA - CAS

*First truly simultaneous CAS + CABG hybrid in our Institution (same OT, CAS when ECC hooked up and at standby)*
Study Flow Chart (2)

73 Patients for carotid revascularization

- CAS in n=67 Patients (bilateral in 3)
- CAS + CEA in n=1 Patient
- CEA in n=5 Patients

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- (92%)
- (1%)
- (7%)

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- n=1 extreme access tortuosity
- n=1 severe aortic valve disease + calcific LICA (AVR + CEA)
- n=1 floating thrombus in LCA
- n=1 ICA diameter <2.0 mm + contralateral occlusion

Hostile access

TW, man 69 yo
critical LICA stenosis post stroke

9 Dec 2015
Hostile access

TW, man 69 yo
critical LICA stenosis
(stroke with haemorrhagic transformation in Feb 2015, now neuro-cleared for carotid revascularization)
Hostile access  TW, man 69 yo  critical LICA stenosis (stroke with haemorrhagic transformation in Feb 2015, now neuro-cleared for carotid revascularization)

endo
routine access
abandoned
after 35 min attempts

P. Musialek @ LINC 2016
TW, man 69 yo
critical LICA stenosis, post-stroke

Surgical Team: M. Trystula, M. Kazubudzki, J. Krzywoń, A. Brzychczy; L. Pinter
Endo: P. Musialek & A. Mazurek

First-in-Poland  direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal
TW, man 69 yo
critical LICA stenosis, post-stroke

12 Jan 2016
TW, man 69 yo
critical LICA stenosis, post-stroke

lesion crossing, predil, CGuard stent implantation and postdil
under En Route (SilkRoad Medical) Flow Reversal
TW, man 69 yo
critical LICA stenosis, post-stroke

CGuard 7.0 x 30mm  full endovascular reconstruction

First-in-Poland  direct carotid access CAS under
En Route (SilkRoad Medical) Flow Reversal
TW, man 69 yo
critical LICA stenosis, post-stroke

CGuard 7.0x30mm  full endovascular reconstruction

*First-in-Poland* direct carotid access CAS under
En Route (SilkRoad Medical) Flow Reversal
TW, man 69 yo
critical LICA stenosis, post-stroke

Z E R O  new DWI lesions

24h prior to CAS

48h after CAS

First-in-Poland direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal + CGuard MicroNet Stent

Brain Imaging: M. Urbanczyk, RP. Banys, Dept. Radiology, JP2 Hospital, Krakow
TW, man 69 yo
critical LICA stenosis, post-stroke

**Z E R O** new DWI lesions

24h prior to CAS

48h after CAS

*First-in-Poland* direct carotid access **CAS under En Route (SilkRoad Medical) Flow Reversal + CGuard MicroNet Stent*
TW, 69 y, L haemispheric stroke with haemorrhagic transformation Feb 2015

En Route plus **CGuard** (Krakow, 12 January 2016)

Profound improvement of L hemispheric viable tissue perfusion

**TTP**
Time-To-Peak Flow

red is prolonged
yellow shows fast

Images: M. Urbanczyk & RP. Banys, Dept. of Radiology, John Paul II Hospital, Krakow
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Mean Transit Time

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WE, woman, 58 y, R haemispheric minor stroke on 22 Dec and 30 Dec 2015
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En Route (SilkRoad Medical) Flow Reversal
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lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal
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Final Result

CGuard 7.0x30 mm full endovascular reconstruction plus NO new lesions on DW-MRI!
WE, woman, 58 y, R haemispheric minor stroke 22 Dec and 30 Dec 2015

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Profound improvement in R hemispheric perfusion

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**Profound improvement in R hemispheric perfusion**

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Improved technology for CAS — better EPDs (flow reversal and proximal occlusion) and better stents (membrane-covered, ultra-closed cell, and biodegradable). Several issues may improve CAS outcomes, such as the introduction of new and better stents. An ex vivo study showed that use of a polyurethane membrane-covered stent resulted in lower cerebral embolization rates.69
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Carotid artery revascularization using CGuard™ MicroNet-Covered Embolic Prevention Stent System: A Change in the Game

Piotr Musialek, MD DPhil FESC

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