Dual layer stents for CAS:
All you need to know to avoid acute occlusion

S. Müller-Hülsbeck, MD, EBIR, FCIRSE, FICA, FSIR

ACADEMIC HOSPITALS Flensburg
of Kiel University – Faculty of Medicine
Ev.-Luth. Diakonissenanstalt zu Flensburg
Knuthstraße 1, 24939 FLENSBURG

Dept. of Diagnostic and Interventional Radiology / Neuroradiology

http://www.diako.de
Disclosure

I have the following potential conflicts of interest to report:

☑ Consulting – Boston Scientific, Terumo, Eurocor Tech
Smaller Pore Size – More Material: Enhanced Thrombogenicity?

- CGUARD
- Roadsaver
- GORE

*165µ 375 500 1050
Closed cell stent

*1900
Open cell stent

* Average in lesion at expanded state
## Dual Layer Stent Designs: Early Reports

### CARENET: 30 pts, EPDs were used in all procedures

- Procedure success: 100%
- Procedural complications: 0%
- 30-day MAE cardiac or cerebrovascular: 0%


### Clear-Road: 100 pts, multi-center, prospective

- Procedure success: 100%
- Procedural complications: 0%
- 30-day MAE cardiac or cerebrovascular: 2.1%


### Scaffold-Trial: 312 pts, multi-center, prospective

- Procedure success: 100%
- Procedural complications: 0%

*Presented at Veith 2017*
Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency Treatment of Tandem Lesions

<table>
<thead>
<tr>
<th></th>
<th>2011 - 2016</th>
<th>acute occlusion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dual-layer stents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CASPER-RX™</td>
<td>n=20</td>
<td>45</td>
</tr>
<tr>
<td>ROADSAVER™</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-layer stents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wallstent™ VIVEXX™</td>
<td>n=25</td>
<td>3.7</td>
</tr>
<tr>
<td></td>
<td>n=2</td>
<td></td>
</tr>
</tbody>
</table>

\[ P = 0.001 \]


Dual-Layer Carotid Stents:

45% ACUTE OCCLUSION!?
Dual Layer CAS: The Homburg Experience

- Potential explanation for acute occlusion in dual layer stent group by the authors:
  - increase of thrombogenic material
  - insufficient preparation with antiplatelet medication
  - higher platelet counts
  - smaller stent diameters
  - not administered IV r-tPA (Bridging)
  - All patients received 500 mg acetylsalicylic acid per-interventionally, but the decision when to start the clopidogrel administration was made on an individual case basis!

Dual Layer CAS: The Homburg Experience

- What is a small stent diameter?
- Post-dilatation at what diameter?
- What about stent apposition?
- Correct stent deployment?
- ACT-adjusted heparinization?

# Flensburg Dual-Layer Carotid Stents Experience 2014 – 2018 ongoing

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>total stroke rate (%) @30 days</th>
<th>ISR after 12 months based on US (asymptomatic)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>n=11</td>
<td>n=30</td>
<td>n=30</td>
<td>n=23</td>
<td>n=28</td>
<td>n=122</td>
<td>2/139</td>
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<tr>
<td><strong>Symptomatic/asymp.</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.4%</td>
<td>5/139</td>
</tr>
<tr>
<td>n=11</td>
<td>11/0</td>
<td>26/4</td>
<td>23/7</td>
<td>17/14</td>
<td>25/12</td>
<td>102/37</td>
<td>1.4%/0%</td>
</tr>
<tr>
<td>n=8 Roadsaver™</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>n=9 CGuard™</td>
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<tr>
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<tr>
<td>n=8 Roadsaver™</td>
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<td></td>
</tr>
<tr>
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<td></td>
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<tr>
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<tr>
<td>n=1 CGuard™</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Symptomatic (acute stroke) Tandem lesion</strong></td>
<td>n=3</td>
<td>n=17</td>
<td>n=11</td>
<td>n=8</td>
<td>n=10</td>
<td>n=53</td>
<td>1/53 asymptomatic occlusion 1.9%</td>
</tr>
<tr>
<td>n=1 Roadsaver™</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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</tr>
</tbody>
</table>
### Flensburg Dual-Layer Carotid Stents Experience 2014 – 2018 ongoing

**DUAL-LAYER CAROTID STENTS: NO ACUTE OCCLUSION!!**

<table>
<thead>
<tr>
<th>Total Subjects</th>
<th>Symptomatic (acute stroke)</th>
<th>Asymptomatic (acute occlusion)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=11</td>
<td>11/0</td>
<td>n/a</td>
</tr>
<tr>
<td>n=30</td>
<td>26/4</td>
<td>1.4%/0%</td>
</tr>
<tr>
<td>n=30</td>
<td>23/7</td>
<td>1.4%/2.2%</td>
</tr>
<tr>
<td>n=23</td>
<td>2/139</td>
<td>1.4%</td>
</tr>
<tr>
<td>n=8</td>
<td>17/14</td>
<td>3.6%</td>
</tr>
<tr>
<td>n=28</td>
<td>25/12</td>
<td>1.4%/0%</td>
</tr>
<tr>
<td>n=17</td>
<td>102/37</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

No acute occlusion!!

**ISR after 12 months based on US (asymptomatic)**

- Total: 3/139 (1.4%)
- Symptomatic: 1/53 (1.9%)
- Asymptomatic: 1/53 (1.9%)

**Roadsaver™**

- n=9
- n=17

**CGuard™**

- n=10
- n=53
How to minimize / avoid stent thrombosis I

Emergency treatment:

- **Bridging**
  - ✓ 0.9mg/kg BW r-tPA

- **antiplatelet medication**
  - *Peri-procedural*
    - ✓ 5000 units Heparine (ACT 250s-300s)
    - ✓ 500mg ASA i.v.
    - ✓ 300mg Clopidogrel after control (conebeam-)CT, usually @ day 1
  - *Post-procedural*
    - ✓ 75mg Clopidogrel for 6 months
    - ✓ 100mg ASA life-long

Rouadsaver

CGUARD
How to minimize / avoid stent thrombosis I

Elective treatment:

- antiplatelet medication

**Pre-procedural**
- 300mg Clopidogrel and 100mg ASA (5 days before or loading dose 300mg Clopidogrel)

**Peri-procedural**
- 5000 units Heparine (ACT 250s-300s)

**Post-procedural**
- 75mg Clopidogrel for 6 months
- 100mg ASA life-long
How to minimize / avoid stent thrombosis II

- **Stent sizing**
  - ✓ 7mm or 8mm diameter
  - ✓ 18mm to 25mm length

- **Stent-deployment**
  - ✓ Continuous, no re-sheath manoeuvre

- **Stent –post-dilatation**
  - ✓ 5mm in all cases!!

Roadsaver

CGUARD
Dual-Layer Carotid Stents: proven concept of safety


Preparation + ongoing antiplatelet medication

http://www.diako.de
Double layered stents for carotid angioplasty: A meta-analysis of available clinical data

Anna Sannino, MD\textsuperscript{1,2*} | Giuseppe Giugliano, MD, PhD\textsuperscript{1,2*} | Evelina Toscano, MD\textsuperscript{1,2} |
Gabriele G. Schiattarella, MD\textsuperscript{1,2} | Anna Franzone, MD, PhD\textsuperscript{1,2} | Tullio Tesorio, MD\textsuperscript{3} |
Bruno Trimarco, MD\textsuperscript{1,2} | Giovanni Esposito, MD, PhD\textsuperscript{1,2} |
Eugenio Stabile, MD, PhD\textsuperscript{1,2}  

Roadsaver subgroup demonstrated very low rates of post procedural AEs at 30-day.
299 patients
Death and Stroke Rate 0.02%

FIGURE 2  30-day mortality and stroke rate. Random effects event rate and 95% confidence interval for 30-day mortality and stroke (A) and relative subgroup analysis (B)
CAS - ROADSNER Study

• **Study Design:** Prospective, single-arm, multi-center, observational study of the Roadsaver™ Carotid Stent

• **Primary Objective:** The purpose of ROADSNER study is to further confirm the safety and efficacy of the Roadsaver™ Carotid Stent device for the treatment of carotid artery stenosis in patients considered eligible for elective stenting procedure.

• **Patient Population:** 2000 patients

• **Enrollment Period:** 2 years + 1 year FU

• **Study Timelines:** First patient enrolled 23-Jan-2018, current >200 patients enrolled

• **Site Locations:** +/- 50 centers across 14 countries in Europe

• **Study Organization:**
  - Independent Clinical Events Committee (CEC)
  - Steering Committee (SC)
  - Sponsored by Terumo Europe
  - European Medical & Clinical Division (EMCD)
Status of dual layer stents for CAS: *Is acute occlusion an issue?*

No, neither in acute nor in elective cases...  
... since you start an immediate preparation with antiplatelet medication!

- **Pre-procedural** (elective treatment)
- **Peri-procedural** (stroke treatment) combined with bridging  
  ✓ 500mg ASA i.v.  
  ✓ 300mg Clopidogrel after control (conebeam-) CT, usually @ day 1
- **Post-procedural**  
  ✓ 75mg Clopidogrel for 6 months  
  ✓ 100mg ASA life-long

**Be aware of adequate**
- Stent-sizing, deployment and post-dilatation !!!
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   75mg Clopidogrel for 6 months
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Be aware of adequate:

• Stent-sizing, deployment and post-dilatation !!!!

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