Roadsaver Carotid Artery Stent for tandem lesions in acute ischemic stroke - The Flensburg Experience

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
Objectives

- Prove of concept for dual layer: CAS examples
- Tandem lesion treatment: when action is required
- Design differences of current dual layer technologies
- Anticoagulation regime
- Current role of dual layer for acute stroke treatment
Disclosure

Speaker name:
.....Stefan Müller-Hülsbeck........................................................

I have the following potential conflicts of interest to report:

☒ Consulting: Terumo, Boston Scientific, Eurocor Tech, Alvimedica
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Male, 80yrs, symptomatic CAS RoadSaver™ 7x30

Male, 80yrs, symptomatic CAS Roadsaver™ 7x30

- Plaque coverage
- Scaffolding

Goal: sustained embolic protection by preventing emboli release
Roadsaver competitor: CGuard™
Tandem lesion treatment: when action is required!

- Complete ICA occlusion
  - Direct ICA stenting
  - Aspiration distally
  - Mechanical Thrombectomy (MT)

- Significantly ICA stenosis
  - Direct ICA stenting, if ICA stenosis potentially interacts with intermediate device(s)
  - Aspiration distally
  - Mechanical Thrombectomy (MT)
Dual Aspiration Technique in Stent-Assisted (or Stent-Based) MT

Potential impact of design differences (I)

- **Roadsaver™**: 375-700 µm
- **CGUARD™**: 165 µm

**Cross Section**
- Braided narrow
- Straight smooth elongated
- Laser-cut Open cell
- Straight smooth # elongated fish scaling
Potential impact of design differences (II)

Crossing Profile

- **Roadsaver™ 7x18**
- **CGUARD™ 7x30**
  - 6F
  - D=2mm
  - $3.14\text{mm}^2$
- **Roadsaver™ 7x18**
  - 5F
  - D=1.67mm
  - $2.19\text{mm}^2$

30% difference!
Intracranial Recanalization
Elongated vessel anatomy?
# Dual Layer CAS: The Flensburg Experience

## Flensburg Dual-Layer Carotid Stents Experience
**2014 – 2020 ongoing**

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>total</th>
<th>stroke rate (%) @30 days</th>
<th>ISR since 2014 based on US + occlusion (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=28</td>
<td>n=22</td>
<td>n=178</td>
<td>1/179 (0.6%)</td>
<td>8/179 +2/179 4.5% +1.1% ISR occl. 5/3 (ISR)</td>
</tr>
<tr>
<td>Symptomatic/ asymptomatic</td>
<td>11/0</td>
<td>26/4</td>
<td>23/7</td>
<td>17/14</td>
<td>25/12</td>
<td>29/3</td>
<td>23/6</td>
<td>154/46</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>symptomatic (acute stroke)</strong></td>
<td>n=3</td>
<td>n=16</td>
<td>n=11</td>
<td>n=8</td>
<td>n=10</td>
<td>n=15</td>
<td>n=6</td>
<td>n=75</td>
<td>1/75 (1.3%) acute occlusion - pat. wasn’t on ASA</td>
<td>1/75 asymptomatic occlusion 1.3%</td>
</tr>
<tr>
<td><strong>Tandem lesion</strong></td>
<td>n=1</td>
<td>n=3</td>
<td>n=1</td>
<td>n=1</td>
<td>n=1</td>
<td>n=1</td>
<td>n=1</td>
<td>n=1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ISR = In-stent Restenosis
Dual Layer CAS: **STROKE**
The Flensburg Experience

![Roadsaver™](image1)

![CGUARD™](image2)

Dual Layer CAS: **STROKE**
The Flensburg Experience

![Roadsaver™](image1)

![CGUARD™](image2)
Tips & Tricks: How do I treat today patients with Roadsaver™ & CGuard™

Emergency treatment (tandem lesions in acute ischemic stroke):

- **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
Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency Treatment of Tandem Lesions

<table>
<thead>
<tr>
<th>April 2014 – November 2018</th>
<th>acute occlusion n=12 (7.5%) within 72hrs</th>
</tr>
</thead>
</table>

- Favorable early neurological outcome was similar in patients with (n=15; 45.5%) and without (n=63; 49.6%) thrombus formation at the CASPER stent.

Acute thrombosis or occlusion of CASPER stents ... were less frequent then previously reported, and showed no impact on early neurological outcome.

Conclusions

• Tandem lesion treatment with CASPER™/ROADSAVER™ is technical efficient and safe
• Acute thrombosis or occlusion of CASPER™/ROADSAVER™, occur less frequent than previously reported (1.3%)
• The ideal antiplatelet and anticoagulation regime is not clearly established and proven
• Future prospective studies should clarify the role of double layer mesh stents in high-risk stroke patients, symptomatic and asymptomatic CAS patients as well as for stroke/tandem lesion treatment