Dual layer stents for treatment of symptomatic and asymptomatic carotid artery stenosis: 6-year data of a high volume centre - Is reocclusion an issue?

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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
Value: Cell Size Comparison

Micromesh (375-700 µm)

Roadsaver Stent A Stent B

Stent C Stent D Stent E
Smaller Pore Size – More Material: Enhanced Thrombogenicity?

- CGUARD
- Roadsaver
- GORE

*165µm
375
500
1050
Closed cell stent
1900
Open cell stent

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

<table>
<thead>
<tr>
<th>Stent Design</th>
<th>Study Details</th>
<th>Procedure Success</th>
<th>Procedural Complications</th>
<th>30-day MAE cardiac or cerebrovascular</th>
<th>30-day MAE cardiac or cerebrovascular</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARENET</td>
<td>30 pts, EPDs were used in all procedures</td>
<td>- Procedure success: 100%</td>
<td>- Procedural complications: 0%</td>
<td>- 30-day MAE cardiac or cerebrovascular: 0%</td>
<td>- New ipsilateral ischemic lesions at 48 h: 37.0%</td>
</tr>
<tr>
<td>CGUARD</td>
<td>Schofer et al. JACC Cardiovasc Interv. 2015 Aug 17;8(9):1229-34.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clear-Road</td>
<td>100 pts, multi-center, prospective</td>
<td>- Procedure success: 100%</td>
<td>- Procedural complications: 0%</td>
<td>- 30-day MAE cardiac or cerebrovascular: 2.1%</td>
<td></td>
</tr>
<tr>
<td>Scaffold-Trial</td>
<td>312 pts, multi-center, prospective</td>
<td>- Procedure success: 100%</td>
<td>- Procedural complications: 0%</td>
<td>- 30-day MAE cardiac or cerebrovascular: 1.1%</td>
<td></td>
</tr>
<tr>
<td>GORE</td>
<td>VEITH 2017 presentation</td>
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</tbody>
</table>
Dual Layer CAS in acute ischemic stroke (I): The Homburg Experience 2017

Dual-Layer Carotid Stents: 45% Acute Occlusion!

Potential explanation for acute occlusion in dual layer stent group by the authors:

- Increase of thrombogenic material (micromesh)
- Insufficient preparation with antiplatelet medication
- Higher platelet counts
- Smaller stent diameters
- Not administered IV r-tPA (Bridging)
- All patients received 500 mg acetylsalicylic acid peri-interventionally, but the decision when to start the clopidogrel administration was made on an individual case basis

# Dual Layer CAS in acute ischemic stroke (II): The European and Australian Experience 2019

## Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency Treatment of Tandem Lesions significant ICA stenosis

<table>
<thead>
<tr>
<th>Dual-layer stents</th>
<th>acute occlusion (%)</th>
<th>Reference</th>
</tr>
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Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency Treatment of Tandem Lesions significant ICA stenosis

<table>
<thead>
<tr>
<th>Dual-layer stents</th>
<th>April 2014 – November 2018</th>
<th>acute occlusion (%)</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASPER-RX™</td>
<td>n=160</td>
<td>n=12 (7.5) within 72hrs</td>
<td></td>
</tr>
<tr>
<td>ROADSAVER™</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

# Dual Layer CAS: The Flensburg Experience

## Flensburg Dual-Layer Carotid Stents Experience

### 2014 – 2019: ongoing

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>Symptomatic/Asymptomatic</th>
<th>Symptomatic (Acute Stroke) Tandem Lesion</th>
<th>Stroke Rate (%) @30 Days</th>
<th>ISR &amp; Occlusion within 12 Months based on US</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>n=11</td>
<td>11/0</td>
<td>n=3</td>
<td>6/181 3.3%</td>
<td>7/181 3.8% ISR 2/181 1.1% Occl.</td>
</tr>
<tr>
<td>2015</td>
<td>n=30</td>
<td>26/4</td>
<td>n=8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>n=30</td>
<td>23/7</td>
<td>n=9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>n=23</td>
<td>17/14</td>
<td>n=6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>n=28</td>
<td>25/12</td>
<td>n=6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>n=36</td>
<td>39/3</td>
<td>n=23</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>n=158</td>
<td>141/40</td>
<td>n=69</td>
<td>1/69 1.4% acute occlusion - pat. wasn’t on ASA!</td>
<td></td>
</tr>
</tbody>
</table>

- **ISR & Occlusion within 12 Months based on US**
- **Stroke Rate (%) @30 Days**
- **Major Stroke**
- **TIA**
- **3.3%/0%**

**Notes:**
- 1/69 acute occlusion - pat. wasn’t on ASA!
Use of Dual-Layered Stents in Endovascular Treatment of Extracranial Stenosis of the Internal Carotid Artery: Results of a Patient-Based Meta-Analysis of 4 Clinical Studies.

Stabile E¹, de Donato G², Musialek P³, De Loose K⁴, Nerla R⁵, Sirignano P⁶, Chianese S⁷, Mazurek A³, Tesorio T⁷, Bosiers M⁴, Setacci C⁷, Speziale F³, Micari A⁴, Esposito G².

Abstract

OBJECTIVES: The aim of this study was to evaluate the clinical efficacy of dual-layered mesh-covered carotid stent systems (DLS) for carotid artery stenting (CAS).

BACKGROUND: The need to minimize the risk for plaque debris prolapsing between stent struts following CAS has resulted in the development of DLS. Small clinical studies evaluating 2 available devices, [Roadsaver and CGuard], have been recently published; none of these studies is sufficiently powered to test the role of common risk factors on the occurrence of stroke at 30 days post-CAS.

METHODS: A search was performed of multiple electronic databases for studies larger than 100 cases of CAS with DLS. Four single-arm prospective studies were identified, and individual patient data were collected. The primary endpoint was the occurrence of stroke at 30 days; secondary endpoints were technical and procedural success, periprocedural stroke, and in-hospital and 30-day rates of death.

RESULTS: The Roadsaver and CGuard stents were used in similar proportions, and technical success was achieved in all procedures (100% [n = 500]). There were 0 periprocedural strokes (0.00%; all minor). During 30-day follow-up, there was 1 death (0.17%) from myocardial infarction and 1 additional minor stroke (0.17%). The cumulative 30-day mortality rate was 0.17%, and the incidence of stroke at 30 days was 1.25%. No predictors of stroke at 30 days could be identified.

CONCLUSIONS: This meta-analysis suggests that DLS can be safely used for CAS, and their use minimizes the incremental risk related to symptomatic status and other risk factors.
Tips & Tricks (I):
How do I today treat patients with Roadsaver & CGuard

Emergency treatment of tandem lesions:

- 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
Tips & Tricks (I):
How do I today treat patients with Roadsaver & CGuard

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
Tips & Tricks (II):
How do I today treat patients with Roadsaver & CGuard

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

- Stent-deployment
  ✓ Continouus

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

Emergency treatment of tandem lesions

&

Elective treatment
Conclusions

• Acute thrombosis or occlusion of CASPER/ROADSAVER occur less frequently then previously reported – 0.6% to 1.1% in the Flensburg population

• In-stent restenosis doesn’t seem an issue, however reports on that are limitted

• Stent sizing, stent post-dilatation should be adapted to established knowledge from single layer stents

• 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
ROADSAVER study

**Design:**
Prospective, single-arm, multi-center, observational study

**Primary endpoint:**
The rate of Major Adverse Events (MAE) defined as cumulative incidence of any death or stroke up to 30 days after the index procedure.

**Sponsor:**
TERUMO

Clinical follow-up
- 30-day (ongoing)
- 1-year (ongoing)

58 sites selected (13 countries)*
42 sites enrolling (12 countries)*
937 enrolled patients*

*as of 15/11/2019
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