Sustained embolic protection – Shifting paradigms in CAS?

The concept of Roadsaver carotid micromesh stent

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

ACADEMIC HOSPITALS Flensburg
of UNIVERSITY HOSPITALS Schleswig-Holstein
Ev.-Luth. Diakonissenanstalt zu Flensburg
Knuthstraße 1, 24939 FLENSBURG

Dept. of Diagnostic and Interventional Radiology / Neuroradiology
Sustained embolic protection – Shifting paradigms in CAS?

The concept of Roadsaver carotid micromesh stent

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

ACADEMIC HOSPITALS Flensburg
of UNIVERSITYHOSPITALS Schleswig-Holstein
Ev.-Luth. Diakonissenanstalt zu Flensburg
Knuthstraße 1, 24939 FLENSBURG

Dept. of Diagnostic and Interventional Radiology / Neuroradiology
Disclosure

Speaker name:

.....Stefan Müller-Hülsbeck..........................................................

I have the following potential conflicts of interest to report:

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

☐ I do not have any potential conflict of interest
Optimizing Outcomes = sustained embolic protection

- Recognizing what to expect for outcomes based on lesion location and characteristics

- Matching the right technology to each disease state = lesion specific CAS
Patient selection for CAS: Indications and Contraindications

- Clinical indications
- Anatomic criteria
- Operators experience

(NASCET=(1-md/C)x100% and ECST=(1-md/B)x100%)
Patient selection – anatomic criteria
stenosis morphology

- Other factors for risk of stroke:
  - Increasing stenosis (in the 70-99% range)
  - Plaque surface irregularity
  - Plaque composition

- Issue:
  - Late embolization
Flow chart on prospective stent design decision depending on carotid bifurcation anatomy

Clinical outcome and complications

101 pts.

<table>
<thead>
<tr>
<th>Complications</th>
<th>during procedure</th>
<th>at 30 days</th>
<th>follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Major stroke</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hyperperfusion syndrome</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TIA</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

stroke rate 2.9%
Overall death & stroke stroke rate 1% @ 30 days

$hopf-jensen et al. Int J Angiol 2014;accepted$
Carotid Stents – Free Cell Area

Roadsaver Free Cell Area 0.15 mm²
RoadSaver Carotid Stent

- double layer micromesh scaffold
- enabling sustained embolic protection by very tight plaque coverage
- embolic protection starts with implantation of the stent into the lesion and continues throughout the process of neointimalization
- up to 50% deployment full re-sheathable and repositionable
Sustained Embolic Protection

- Smallest stent cell size - preventing emboli release
  Tacks down/contains plaque, acting like a metallic covered stent

- Plaque coverage
  Characterizes how tight the stent cells cover the plaque material, protecting it from dislodging, prolapsing/embolizing
Lesion specific scaffolding

• Wall apposition
  The way how stent struts conform to the vessel morphology, in combination with the radial force

(e.g. eccentric plaque: struts should not leave any dead-water zones between vessel wall and stent struts ⇒ increased thrombogenicity)
RoadSaver Carotid Stent

- **5Fr Rapid Exchange delivery system**
  Low profile enhances the crossability for primary stenting

- **Push-Pull Stent Delivery System**
  For re-sheathing, a push-pull handle is necessary

- **No tapered version needed**
  Due to the braided mesh double layer design in Nitinol, the stent nicely tapers according to the anatomy, without overstretching the vessel wall
Case 1 – m, 80yrs, symptomatic CAS
RoadSaver 7x30
Case 1 – m, 80yrs, symptomatic CAS
RoadSaver 7x30

✓ Plaque coverage
✓ scaffolding

Goal: sustained embolic protection by preventing emboli release
Case 2 – m, 53 yrs, acute stroke
RoadSaver 7x25

- Absolute contraindications
  Occluded ICA
  Visible thrombus
Case 2 – m, 53 yrs, acute stroke
Roadsaver 7x25
Case 2 – m, 53 yrs, acute stroke
Stentretriever
Case 3 – m, 74 yrs, symptomatic CAS
Roadsaver 6x30
Case 3 – m, 74 yrs, symptomatic CAS
Roadsaver 6x30
## Competitive data

<table>
<thead>
<tr>
<th></th>
<th>Abbot Vascular RX Acculink</th>
<th>Abbott Vascular Xact</th>
<th>BSX Carotid Wallstent</th>
<th>Cordis Precise Pro</th>
<th>ev3 Protégé RX</th>
<th>MDT/Invatec Cristallo Ideale</th>
<th>MicroVention Roadsaver</th>
<th>stent wall thickness Roadsaver vs Cristallo</th>
<th>stent wall thickness Roadsaver vs Xact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Material</strong></td>
<td>Nitinol</td>
<td>Nitinol</td>
<td>Elgiloy</td>
<td>Nitinol</td>
<td>Nitinol</td>
<td>Nitinol</td>
<td>Nitinol</td>
<td>Nitinol</td>
<td>Nitinol</td>
</tr>
<tr>
<td><strong>Markers</strong></td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>Tantalum</td>
<td>Tantalum</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Labeled Stent Diameter (mm)</strong></td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>9</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td><strong>Labeled Stent Length (mm)</strong></td>
<td>40</td>
<td>30</td>
<td>36</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td><strong>Pre-Deployment Length (mm)</strong></td>
<td>42</td>
<td>Unknown</td>
<td>80</td>
<td>65</td>
<td>41</td>
<td>42</td>
<td>42</td>
<td>95.77</td>
<td></td>
</tr>
<tr>
<td><strong>Post Deployment Unconstrained Overall Length (mm)</strong></td>
<td>42</td>
<td>28</td>
<td>39</td>
<td>42</td>
<td>42</td>
<td>41</td>
<td>42</td>
<td>42</td>
<td>48.2</td>
</tr>
<tr>
<td><strong>Free ID (mm)</strong></td>
<td>8</td>
<td>6.9</td>
<td>7.6</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8.6</td>
<td>7.5</td>
<td></td>
</tr>
<tr>
<td><strong>Free OD (mm)</strong></td>
<td>8.2</td>
<td>7.5</td>
<td>7.8</td>
<td>8.4</td>
<td>8.4</td>
<td>8.5</td>
<td>9.2</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td><strong>Strut Width (µm)</strong></td>
<td>76.2</td>
<td>66.04</td>
<td>91.44</td>
<td>86.4-94.0</td>
<td>76.2-101.6</td>
<td>149.86</td>
<td>93.98</td>
<td>177.8 outer layer; 40.64 inner layer</td>
<td>1.9</td>
</tr>
<tr>
<td><strong>Stent Wall Thickness (µm)</strong></td>
<td>152.4</td>
<td>203.2</td>
<td>190.5</td>
<td>190.5</td>
<td>190.5</td>
<td>241.3</td>
<td>185.42</td>
<td>431.8</td>
<td>2.3</td>
</tr>
<tr>
<td><strong>Cell Type</strong></td>
<td>Open</td>
<td>Closed</td>
<td>Closed</td>
<td>Open</td>
<td>Open</td>
<td>Open</td>
<td>Open/Closed</td>
<td>Closed</td>
<td></td>
</tr>
<tr>
<td><strong>Pore Diameter (mm)</strong></td>
<td>2.7686</td>
<td>2.413</td>
<td>2.1336</td>
<td>2.7686</td>
<td>2.7686</td>
<td>3.9878</td>
<td>3.2258</td>
<td>1.1176</td>
<td></td>
</tr>
<tr>
<td><strong>Pore Area (mm²)</strong></td>
<td>2.3622</td>
<td>1.8034</td>
<td>1.397</td>
<td>2.3622</td>
<td>2.3622</td>
<td>4.9276</td>
<td>3.2258</td>
<td>0.15</td>
<td></td>
</tr>
<tr>
<td><strong>Radial Force (gf)</strong></td>
<td>See Graph</td>
<td>See Graph</td>
<td>See Graph</td>
<td>See Graph</td>
<td>See Graph</td>
<td>See Graph</td>
<td>See Graph</td>
<td>See Graph</td>
<td></td>
</tr>
</tbody>
</table>
Case 4 – m, 73 yrs, symptomatic CAS
Roadsaver 8x30
Data from the bench

Radial Force MV vs. Competitors (Expansion)
Unmatched clinical needs?

Case 1 – m, 80yrs, symptomatic CAS
RoadSaver 7x30
Unmatched clinical needs?

- The ECA remains patent @ 6months !
"We know that with CAS, there are two critical ways to avoid stroke: patient selection and operator experience."

Mark Wholey: J Endovasc Ther 2007; 14: 687-688
Sustained embolic protection

THANKS FOR YOUR ATTENTION!
Sustained embolic protection – Shifting paradigms in CAS?

The concept of Roadsaver carotid micromesh stent

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

ACADEMIC HOSPITALS Flensburg
of UNIVERSITY HOSPITALS Schleswig-Holstein
Ev.-Luth. Diakonissenanstalt zu Flensburg
Knuthstraße 1, 24939 FLENSBURG

Dept. of Diagnostic and Interventional Radiology / Neuroradiology