Roadsaver – innovative solutions for CAS

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Disclosure

Speaker name:
S. Müller-Hülsbeck

☐ I have the following potential conflicts of interest to report:
☐ Consulting: Terumo, Boston Scientific, GE, WL Gore
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)
☐ I do not have any potential conflict of interest
Unmet Need In The CAS Market – Sustained Embolic Protection

1. No stent or EPS protects against late embolization
2. Closed cell designs shows lower post-procedural events

Table 4. 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>2.2%</td>
</tr>
<tr>
<td>Nexstent</td>
<td>3.3%</td>
<td>3.3%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Wallstent</td>
<td>2.3%</td>
<td>2.3%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Precise</td>
<td>4.1%</td>
<td>4.1%</td>
<td>6.3%</td>
</tr>
<tr>
<td>Protégé</td>
<td>3.0%</td>
<td>3.0%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Acculink</td>
<td>4.2%</td>
<td>4.2%</td>
<td>7.7%</td>
</tr>
<tr>
<td>Exponent</td>
<td>11.8%</td>
<td>11.8%</td>
<td>9.1%</td>
</tr>
<tr>
<td>Total</td>
<td>3179</td>
<td>2.83%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

CAS neuro events (Stroke, TIA) are post-procedural !!!

Eur J Vasc Endovasc Surg Vol 33, Feb 2007
Optimizing Outcomes = sustained embolic protection

• Recognizing lesion location and characteristics
  
• Matching the right technology to each disease state
  • lesion specific CAS

• Ideal:
  • One stent fits all!
  ➢ Flexibility, conformability, radial force, plaque penetration and ...


Comparisons – **dual layer** vs. **closed cell** / open cell
RoadSaver
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
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
Dual Layer Stent Designs

- double layer micromesh nitinol scaffold, up to 50% deployment full re-sheathable and repositionable; pore size 375µm

6 pts
- Procedure success 100%
- Procedural complications 0%
- 30-day MAE cardiac or cerebrovascular 0%
- 6-months MAE cardiac or cerebrovascular 0%

12 pts
- no ischemia


Dual Layer Stent Designs

- double layer micromesh nitinol scaffold, up to 50% deployment full re-sheathable and repositionable; pore size 375µm

100 pts, multi-center, prospective
- Procedure success 100%
- Procedural complications 0%
- 30-day MAE cardiac or cerebrovascular 2.1%


23 pts, single-center, prospective
- 30-day MAE cardiac or cerebrovascular 0%
- 30-day DWI MRI lesions 0%

Dual Layer Stent Designs

Initial Clinical Experience With the Micromesh RoadSaver Carotid Artery Stent for the Treatment of Patients With Symptomatic Carotid Artery Disease

Silke Hopf-Jensen, MD, Leonardo Marques, MD, Michael Preiß, MD, and Stefan Müller-Hülsbeck, MD, EBIR, PhD

Flensburg RoadSaver™ Experience 2015 – 2016

<table>
<thead>
<tr>
<th></th>
<th>n=62</th>
<th>3.2% TIA @ 30days (n=2*)</th>
<th>ECA patent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special Indication</td>
<td>n=30</td>
<td>*TIA</td>
<td>ECA patent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*Hyperperfusion syndrome</td>
<td></td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>n=8</td>
<td>0% TIA @ 30days</td>
<td>ECA patent</td>
</tr>
</tbody>
</table>

http://www.diako.de
Dual Layer Stent Designs

CGUARD

TERUMO

GORE
Ideal Pore Size

CGUARD

TERUMO

GORE

*165µ 375

Closed cell stent

1900
Open cell stent

500 1050

* Average in lesion at expanded state
Were do we stand?

- CREST: postprocedural ipsilateral stroke over the 10-year follow-up occurred in 6.9%
  - 2502 pts, multi-center, prospective
  - RX Acculink stent and, whenever feasible, RX Accunet device
  - RX Acculink stent and, whenever feasible, the RX Accunet device
  - periprocedural MAE cerebrovascular event 5.2%
  - symptomatic status is of relevance in the context of periprocedural risk

Were do we stand?

- “Currently, most symptomatic patients are inappropriate candidates for CAS. Improved CAS technology referable to stent design and embolic protection strategies may alter this conclusion in the future.”

  - Possible options to improve CAS outcomes:
    1. Modification of vascular risk factors — plaque stabilization
    2. Better patient selection
    3. Improved CAS skills/techniques
    4. **Improved technology for CAS** — better EPDs (flow reversal and proximal occlusion) and better stents (membrane-covered, ultra-closed cell, and biodegradable)

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<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPACE (2008)</td>
<td>2-year follow-up data of the original SPACE study</td>
</tr>
<tr>
<td>Steinbauer et al (2008)</td>
<td>Single-center randomized study comparing the long-term (mean follow-up: 66 ± 14.2 vs 64 ± 12.1 months, respectively) results of CAS (n = 48) with CEA (n = 44)</td>
</tr>
<tr>
<td>CAVATAS (2009)</td>
<td>5-year results of the initial CAVATAS Study</td>
</tr>
<tr>
<td>ICSS (2010)</td>
<td>Randomization of 1710 symptomatic pts to CAS (n = 853) vs CEA (n = 857)</td>
</tr>
<tr>
<td>CREST (2010)</td>
<td>Randomization of 2,502 pts (1321 symptomatic; 1181 asymptomatic) to CAS (n=1262) or CEA (n=1240).</td>
</tr>
</tbody>
</table>
Switching from single to dual layer stent design?
Will mesh **Micromesh Covered And Dual Layer Stent Designs** make a difference?

- Yes?
  Will likely be the default strategy stent for CAS

- And no?
  Clinical outcome differences need to be demonstrated

**Comparative trial data are still pending**!

The role of EPDs needs to be reevaluated!
Anything to add?

- “We know that with CAS, there are two critical ways to avoid stroke: patient selection an operator experience”

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