Carotid Stenting: closed cell design versus dual layer design - are there any differences in clinical outcome?

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

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

Dept. of Diagnostic and Interventional Radiology / Neuroradiology
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
1. No stent or EPS protects against late embolization
2. Closed cell designs shows lower post-procedural events

Unmet Need In The CAS Market – Sustained Embolic Protection

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></td>
</tr>
<tr>
<td>Nexstent</td>
<td>3.3%</td>
<td>3.3%</td>
<td></td>
</tr>
<tr>
<td>Wallstent</td>
<td>2.3%</td>
<td>1.2%</td>
<td></td>
</tr>
<tr>
<td>Precise</td>
<td>4.1%</td>
<td>3.1%</td>
<td></td>
</tr>
<tr>
<td>Protégé</td>
<td>3.0%</td>
<td>3.0%</td>
<td></td>
</tr>
<tr>
<td>Acculink</td>
<td>4.2%</td>
<td>3.7%</td>
<td></td>
</tr>
<tr>
<td>Exponent</td>
<td>11.8%</td>
<td>5.9%</td>
<td></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 ...


Dual Layer Stent Designs

- CGUARD
- TERUMO
- GORE

* Average in lesion at expanded state
Dual Layer Stent Designs

- **MicroNet™** is a bio-stable mesh woven from a single strand of 20μm Polyethylene Terephthalate (PET): pore size 165μm

CARENET: 30 pts, EPDs were used in all procedures
- Procedure success 100%
- Procedural complications 0%
- 30-day MAE cardiac or cerebrovascular 0%
- New ipsilateral ischemic lesions at 48 h 37.0%
- 30-day DWI MRI showed complete resolution of all but 1 periprocedural lesion and only 1 new minor lesion in relation to the 48-h scan

Dual Layer Stent Designs

- **MicroNet™** is a bio-stable mesh woven from a single strand of 20μm Polyethylene Terephthalate (PET): pore size 165μm

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

*Average in lesion at expanded state*

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%

## Clinical Investigation

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

* Average in lesion.
Dual Layer Stent Designs

- FIM
  GORE® Carotid Stent
  – 6/8x40

Dual Layer Stent Designs

- Open Cell NiTi Frame, closed Cell lattice on outside of NiTi Frame, bound CBAS Heparin: pore size 500µm

GORE® Carotid Stent – Study (SCAFFOLD)
- 50 sites in the US, Europe, and Japan
- 312 subjects (max 40 at each site)

- enrolled nearly 300 patients, and are close to the 312 needed to finish enrollment. There will be a 1 year follow up, so results will not likely be available till early/mid 2018
Ideal Pore Size?

Closed cell stent

Open cell stent

* 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)

Switching from single to dual layer stent?
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

**Competitive trial data are still pending**!

The role of EPDs needs to be reevaluated!
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