Micromesh technology for carotid stents

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TERUMO
CGUARD
GORE

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Disclosure

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

I have the following potential conflicts of interest to report:

☒ Consulting: Terumo, Boston Scientific, GE, Cordis Johnson&Johnson
☐ 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

No stent or EPS protects against late embolization

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>1.2%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Precise</td>
<td>4.1%</td>
<td>3.1%</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>3.7%</td>
<td>7.7%</td>
</tr>
<tr>
<td>Exponent</td>
<td>11.8%</td>
<td>5.9%</td>
<td>9.1%</td>
</tr>
<tr>
<td>Total</td>
<td>3179</td>
<td>2.83%</td>
<td>3.6%</td>
</tr>
</tbody>
</table>

Cas neuro events are POST-procedural

(stroke, TIA)

Eur J Vasc Endovasc Surg Vol 33, Feb 2007
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

- Ideal:
  - One stent fits all!
  - Flexibility, conformability, radial force, plaque penetration
Advantages of technology:

- Flexible structure
- Does not promote thrombosis
- Minimal foreign body reaction
- Does not alter procedure
- Optimal pore size

The MicroNet™ is a bio-stable mesh woven from a single strand of 20μm Polyethylene Terephthalate (PET). The MicroNet™ is sutured to both the distal and proximal crowns of the stent platform.
Conventional Stent v CGuard

Conventional Carotid Stent

plaque prolaps through stent meshes

fine meshwork prevents plaque prolaps
Evaluation of PET Mesh Covered Stent in Patients with Carotid Artery Disease

The CARENET-Trial
(CARotid Embolic protection using microNET)

Joachim Schofer (PI)
Piotr Musialek (Co-PI)
On behalf of the CARENET Investigators

Joachim Schofer, MD, PhD, Hamburg University Cardiovascular Center, Hamburg, Germany
Piotr Musialek, MD, PhD, Jagiellonian University Medical College at John Paul II Hospital, Krakow, Poland,
Ralf Kolvenbach, MD, PhD, Augusta Hospital, Dusseldorf, Germany,
Horst Sievert, MD, PhD, Cardiovascular Center Frankfurt, Frankfurt, Germany
# CARENET I - Clinical Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Post Procedure</th>
<th>Discharge</th>
<th>30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device success</td>
<td>100%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>MACE</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Death</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>MI</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

- Compared to published DW-MRI data of non-mesh covered carotid stents, the incidence of new ischemic lesions was reduced by almost 50% and the average lesion volume per patient 10 times smaller.
CGuard Case Study

Thrombus-containing
34 days post Stroke with Lytic Tx

Pre-dilatation required!

CGuard™ 8.0x30mm, postdilated φ4.5mm/18atm

http://diako.de
GORE® Carotid Stent (GCS)
GORE® Carotid Stent

Attributes

Stent:
- Open Cell NiTi Frame
- Closed Cell 500 µ
  lattice on outside of NiTi Frame
- Bound CBAS Heparin

Delivery System:
- 135 cm
- Single handed delivery
- 5F and 6Fr
- Hypotube Design
# GORE® Carotid Stent - Plaque Stabilization

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>W.L. Gore and Associates*</th>
<th>Abbott Laboratories</th>
<th>Abbott Laboratories</th>
<th>Boston Scientific Corporation</th>
<th>ev3 Inc./Covidien</th>
<th>Cordis Corporation</th>
<th>Medtronic, Inc./Invatec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device</td>
<td>GORE® Carotid Stent</td>
<td>ACCULINK® RX DEVICE</td>
<td>XACT® DEVICE</td>
<td>WALLSTENT® MONORAIL® DEVICE</td>
<td>PROTÉGÉ RX® DEVICE</td>
<td>PRECISE® DEVICE</td>
<td>CRISTALLO IDEALE DEVICE</td>
</tr>
<tr>
<td>Stent Type</td>
<td>Straight, Hybrid Design</td>
<td>Tapered, Open Cell</td>
<td>Tapered, Closed Cell</td>
<td>Straight, Closed Cell</td>
<td>Tapered, Open Cell*</td>
<td>Straight, Open Cell</td>
<td>Tapered, Combination</td>
</tr>
<tr>
<td>Stent Size (mm)</td>
<td>10 - 10 x 40</td>
<td>7 - 10 x 30</td>
<td>8 - 10 x 30</td>
<td>10 x 24</td>
<td>7 - 10 x 30</td>
<td>9 x 30</td>
<td>7 - 10 x 30</td>
</tr>
<tr>
<td>Cell Size (mm)$^2$</td>
<td>0.28</td>
<td>16.60</td>
<td>4.00</td>
<td>1.36</td>
<td>10.40</td>
<td>9.00</td>
<td>3.30 (center) 13.50 (ends)</td>
</tr>
<tr>
<td>Max Fitted-in Circle Diameter (mm)</td>
<td>0.50</td>
<td>1.30</td>
<td>1.25</td>
<td>1.06</td>
<td>1.70</td>
<td>1.25</td>
<td>1.20 (center) 1.90 (ends)</td>
</tr>
<tr>
<td>Max Number of Fitted-in Circles per cell</td>
<td>1</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>1 (center) 3 (ends)</td>
</tr>
</tbody>
</table>

*Though sometimes listed as a closed cell stent, Protégé IFU describes the design as an “open lattice”.

Figure 8: Manufacturer, name, cell size, and fitted in circle data. Data for the GORE® Carotid Stent is based on nominal manufacturing specifications. Competitive device information from Müller-Hülsbeck S, et al. Images are shown for illustrative purposes only; the stent type shown may not be the same size measured by Müller-Hülsbeck.
GORE® Carotid Stent Clinical Study for the treatment of carotid Artery stenosis in patients at increased risk For adverse events From carOtid enDarterectomy

The Gore SCAFFOLD Clinical Study
GORE® Carotid Stent - Study Design

• Number of Sites
  Up to 50 sites in the US, Europe, and Japan

• Number of Subjects
  312 subjects (max 40 at each site)

• General Population
  Patients at least 18 years of age who have either a single de novo atherosclerotic or post-endarterectomy restenotic lesion in the internal carotid artery or at the carotid bifurcation, with either:
  \( \geq 50\% \) (by angiography) stenosis if symptomatic (stroke, TIA, TMB within 180 days of procedure), OR
  \( \geq 80\% \) (by angiography) stenosis if asymptomatic
  Patients must have either anatomic or medical co-morbidities that place them at high perioperative risk for CEA
Illustrated Features-CASPER/Roadsaver

- **Common Carotid Artery (CCA)**
- **Designed to tack down and contain plaque**
- **Braided Nitinol design** to conform to carotid anatomy and minimize kinking
- **Double layer micromesh design.**
  Inner mesh has a significantly smaller cell size designed to prevent emboli release
# Cell Size Comparisons

<table>
<thead>
<tr>
<th>CASPER/Roadsaver</th>
<th>Wallstent</th>
<th>Precise</th>
<th>Acculink</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="http://diako.de" alt="Image" /></td>
<td><img src="http://diako.de" alt="Image" /></td>
<td><img src="http://diako.de" alt="Image" /></td>
<td><img src="http://diako.de" alt="Image" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>XACT</th>
<th>Protégé</th>
<th>Crystallo (ends)</th>
<th>Crystallo (middle)</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="http://diako.de" alt="Image" /></td>
<td><img src="http://diako.de" alt="Image" /></td>
<td><img src="http://diako.de" alt="Image" /></td>
<td><img src="http://diako.de" alt="Image" /></td>
</tr>
</tbody>
</table>
Case 3 – m, 74 yrs, symptomatic CAS
Roadsaver 6x30

6F Destination .014 Choice PT
Roadsaver PTA 5x30
Case 3 – m, 74 yrs, symptomatic CAS
Roadsaver 6x30

Unmatched clinical needs?

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

- The ECA with CASPER/Roadsaver remains patent @ 6months!
Flensburg RoadSaver Experience 2015

<table>
<thead>
<tr>
<th>Category</th>
<th>n</th>
<th>Event Description</th>
<th>Patent Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic</td>
<td>33</td>
<td>3.5% TIA @ 30days (n=2*)</td>
<td>ECA patent</td>
</tr>
<tr>
<td>Special indication</td>
<td>26</td>
<td>*TIA</td>
<td>ECA patent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*Hyperperfusion s.</td>
<td></td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>4</td>
<td>0% TIA @ 30days</td>
<td>ECA patent</td>
</tr>
</tbody>
</table>

 Publications - CASPER/Roadsaver

* TIA: Transient Ischemic Attack
* Hyperperfusion: Hyperperfusion Syndrome
ECA: External Carotid Artery
## Competition Carotid Stents

<table>
<thead>
<tr>
<th>Brands</th>
<th>Images</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terumo/Microvention</td>
<td><img src="image1" alt="Image" /></td>
<td>0.38 mm², 0.15 mm², 0.44 mm²</td>
</tr>
<tr>
<td>Inspire MD</td>
<td><img src="image2" alt="Image" /></td>
<td>2.36 mm², 1.89 mm², 1.397 mm²</td>
</tr>
<tr>
<td>W.L. Gore</td>
<td><img src="image3" alt="Image" /></td>
<td>4.93 mm², 2.36 mm², 3.23 mm²</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td><img src="image4" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Boston Scientific</td>
<td><img src="image5" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Ev3/Covidien/Medtronic</td>
<td><img src="image6" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Cordis/Cardinal Health</td>
<td><img src="image7" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Invatec/Medtronic</td>
<td><img src="image8" alt="Image" /></td>
<td></td>
</tr>
</tbody>
</table>

**Bench marking by Microvention**

<table>
<thead>
<tr>
<th>Sizes</th>
<th>Sarcomesh</th>
<th>Micromesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>375-500µm</td>
<td>150-180µm</td>
<td>500µm</td>
</tr>
</tbody>
</table>

**Advertising by Inspire MD**

**Micromesh Stents**
Ideal Pore Size

* Average in lesion at expanded state

CGUARD

TERUMO

GORE

*165µ

375

500 1050

Closed cell stent

1900

Open cell stent

* Average in lesion at expanded state
Switching from single to dual layer stent?
Will mesh covered stents make a difference?

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

• And no?
  Clinical outcome differences need to be demonstrated

**Trial data are still pending!**

The role of EPDs needs to be reevaluated!
Micromesh technology for carotid stents

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