Scaffold - Gore PTFE Mesh-Covered Stent - Preclinical and Clinical Data

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Hamburg / Germany
I have the following potential conflict of interest to report:

Chairman of the GORE DATA SAFETY AND MONITORING BOARD
Study Design

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 GCS 10-08
Why Hybrid Stent

More DW-MRI Lesions with Open Cell Stents

Prospective RCT:
MRI Hits Closed versus Open Cell Stents*

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Closed cell (n=48)</td>
<td>27.3%</td>
</tr>
<tr>
<td>Open cell (n=48)</td>
<td>51.1%</td>
</tr>
<tr>
<td>P value</td>
<td>0.020</td>
</tr>
</tbody>
</table>

*Park et al. J Neurosurg 2013
Why Hybrid Stent

More Plaque Prolapse with Open Cell Stents*

Open Cell 61.5%
Closed Cell 17.6%

*deDonato et al. Eur J Vasc Endovasc Surg 2013;45:479
Why Hybrid Stent

Hybrid Stent

Plaque Prolaps

No Plaque Prolaps
Hybrid Stent

Gore PTFE mesh-covered stent
Design goals
• Flexibility/conformability
  – Improved device navigation
  – Open cell stent design enables device to conform to difficult anatomy
• High scaffolding potential
  – Closed cell lattice to reduce stroke risk
• Minimize thrombus formation
  – CBAS® Heparin Surface
Hybrid Stent

- Scaffolding
- Lesion containment
- Conformability
- Fatigue resistance
- Ease of re-crossing
- Visibility
- Low profile
## Hybrid Stent

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Device</th>
<th>Cell Size (mm$^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>W.L. Gore and Associates*</td>
<td>GORE® Carotid RX DEVICE</td>
<td>0.28</td>
</tr>
<tr>
<td>Abbott Laboratories</td>
<td>ACCULINK® DEVICE</td>
<td>16.60</td>
</tr>
<tr>
<td>Abbott Laboratories</td>
<td>XACT® DEVICE</td>
<td>4.00</td>
</tr>
<tr>
<td>Boston Scientific Corporation</td>
<td>WALLSTENT® MONORAIL® DEVICE</td>
<td>1.36</td>
</tr>
<tr>
<td>ev3 Inc./ Covidien</td>
<td>PROTÉGÉ RX® DEVICE</td>
<td>10.40</td>
</tr>
<tr>
<td>Cordis Corporation</td>
<td>PRECISE® DEVICE</td>
<td>9.00</td>
</tr>
<tr>
<td>Medtronic, Inc./ Invatec</td>
<td>CRISTALLO IDEALE DEVICE</td>
<td>3.30 (center) 13.50 (ends)</td>
</tr>
</tbody>
</table>

GCS pore size <20% the area of WALLSTENT cell size
Hybrid Stent

Carotid Stent Delivery System

Attributes
• Single handed delivery
• 6Fr Introducer Sheath
• Hypotube Design
  Allows for complete closure of hemostatic valve
• 135 cm Working Length
The device is designed to be flexible, offers plaque retention and along with bound heparin may provide advantages for improved patient outcomes.
Gore Carotid Stent Scaffold Study

Prospective study comparing the GORE® Carotid Stent to a performance goal developed from carotid endarterectomy outcomes.
50 sites, 312 subjects.

Objective-Evaluate safety and efficacy in patients at increased risk for adverse events from carotid endarterectomy. Primary endpoint-Death, stroke, or myocardial infarction through 30 days plus ipsilateral stroke between 31 days and 1 year.
Gore Carotid Stent Scaffold Study

Patient Population:
– >18 years of age
– De novo atherosclerotic or post-endarterectomy restenotic lesions in the CCA or ICA
– ≥50% (by angiography) stenosis if symptomatic
– ≥80% (by angiography) stenosis if asymptomatic
– High risk for CEA
Gore Carotid Stent Scaffold Study

Design:

**Stage 1:** review 6 month data from first 100 patients

**Stage 2:** contingent on Stage 1 review & approval to proceed

Primary Endpoint: 1-Year Major Adverse Events

30-day death/stroke/MI + ipsilateral stroke to 1 year

Enrollment (approved):

- Sites: 50 in US
- Subjects: 312
- FIM: August 6, 2013

Status: IDE Approved December 15, 2012
# Gore Carotid Stent Scaffold Study

**Patients**

<table>
<thead>
<tr>
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<th>100%</th>
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</thead>
<tbody>
<tr>
<td>Hypotension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>During CAS</td>
<td>312</td>
<td>6.2%</td>
</tr>
<tr>
<td>After CAS</td>
<td></td>
<td>1.6%</td>
</tr>
<tr>
<td>Bradycardia</td>
<td></td>
<td>6.2%</td>
</tr>
</tbody>
</table>

- **Cerebrovascular event (TIA)** 0.8%
- **Stroke parietal lobe** 0.8%
- **Dizziness** 0.8%
- **Diplopia** 0.8%
- **Hematoma groin** 1.6%
- **MI day 2** 0.8%
- **Contrast media reaction with renal failure** 0.8%
- **FU Stroke day 123** 0.8%
## Gore Carotid Stent Scaffold Study

<table>
<thead>
<tr>
<th>Patients</th>
<th>312</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success rate</td>
<td>98%</td>
<td></td>
</tr>
<tr>
<td>Major stroke</td>
<td>0.8%</td>
<td></td>
</tr>
<tr>
<td>Minor neurological reactions</td>
<td>2.4%</td>
<td></td>
</tr>
<tr>
<td>Major stroke 4 months after CAS</td>
<td>0.8%</td>
<td></td>
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