Technical Aspects And Results With The Gore Scaffold Mesh Covered Stent For CAS: Are Any Of These Mesh Covered Stents Ready For Prime Time?

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VEITH Meeting
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Disclosures
• None of these devices are FDA approved and none are available in the US
• Royalties (modest): Cook
• Entered patients into some trials being discussed
• Chief Medical Officer: Intact Vascular
• Scientific Advisory Board: Abbott, Medtronic, Cardinal (No financial relationship)

Carotid Stent Design

We are asking much of carotid stents.
• Scaffolding
• Lesion containment
• Conformability
• Fatigue resistance
• Minimal fish-scaling for ease of re-crossing
• Visibility
• Ease of use
• Low profile

Plaque Prolapse Causes Events

<table>
<thead>
<tr>
<th></th>
<th>Open Cell</th>
<th>Closed Cell</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque Prolapse</td>
<td>61.5%</td>
<td>17.6%</td>
</tr>
</tbody>
</table>

CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.
Increased DW-MRI Hits with Open Cell Stents

Prospective RCT: Closed versus Open Cell Stents

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

Park et al. J Neurosurg 2013;116

Schnaudigel et al. Stroke 2008;39:911

Neurologic Events with Open Cell Stents

<table>
<thead>
<tr>
<th>Table 4. Influence of Different Stent Types on OE Rate</th>
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</thead>
<tbody>
<tr>
<td>Stent</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>No. of patients</td>
</tr>
<tr>
<td>OE rate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients</th>
<th>All events</th>
<th>Post-procedural events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell type</td>
<td>Open cell</td>
<td>Closed cell</td>
</tr>
<tr>
<td>----------</td>
<td>------------</td>
<td>--------------</td>
</tr>
<tr>
<td></td>
<td>4.2%</td>
<td>3.4%</td>
</tr>
<tr>
<td></td>
<td>2.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Total</td>
<td>3.83%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

Belgian-Italian Registry/Endeavor et al. Eur J Vasc Endovasc Surg 2007;33:135

Mesh-Covered Stents

GORE Carotid Stent

Mesh-Covered Stents

GORE Carotid Stent Preclinical Studies

- Canine artery model
- Biologically acceptable tissue response
  - All sidebranches and devices patent through 56 days
  - Full device endothelialization at 30 days
  - Comparatively less medial compression

GORE Mesh-Covered Carotid Stent

Cases from the SCAFFOLD Trial

- 180 patients entered so far

SCAFFOLD Trial

Design-Prospective study comparing the GORE® Carotid Stent to a performance goal developed from carotid endarterectomy outcomes

50 sites, 312 subjects,
Co-PIs-Bill Gray and Peter Schneider
Objective-Evaluate safety and efficacy of GORE® Carotid Stent 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.

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Mesh-Covered Stents

Roadsaver

Nitinol mesh, repositionable, 5Fr delivery
Roadsaver Italian Registry
150 patients enrolled, MRI subset
3 Italian centers, C Setacci
Clear Road Trial
Enrolling 100 patients (59 patients enrolled)
12 European centers, M Bosiers

CGuard Prime

Polyethylene Terephthalate (PET) 20µ micronet
Attached proximal and distal crowns of the stent
CARANET Study-30 patient trial
No stroke or death at 30 days
50% reduction in DW-MRI lesions, J Schoefer
IRON-Guard: Multicenter Italian Registry
100 patients enrolled, C Setacci

Mesh Covered Stent Designs

<table>
<thead>
<tr>
<th>Design</th>
<th>Gore</th>
<th>Terumo Roadsaver</th>
<th>InspireMD CGuard™</th>
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<tbody>
<tr>
<td>Aperture Size</td>
<td>500µ</td>
<td>300µ</td>
<td>180µ</td>
</tr>
<tr>
<td>Materials</td>
<td>PTFE mesh (Heparin coated) on nitinol stent</td>
<td>nitinol on nitinol</td>
<td>PET MicroNet™ on nitinol stent</td>
</tr>
<tr>
<td>CE Mark</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Conclusion

Mesh-Covered Stent and SCAFFOLD Trial

- SCAFFOLD Trial will study the next development in carotid stent design.
  - Open cell stent frame with PTFE mesh and heparin coating
- Make the first 30 days safer
  - Cell size matters
  - More events, More delayed events
- Future stent design likely to include some type of coverage