Next-Generation Carotid Artery Stents: Are Mesh/Membrane Stents Game Changers?

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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</thead>
<tbody>
<tr>
<td>Research Study Sponsorship</td>
<td>Medtronic, Gore, Cordis (non-compensated)</td>
</tr>
<tr>
<td>Royalty Income (modest)</td>
<td>Cook Medical</td>
</tr>
<tr>
<td>Ownership/Founder</td>
<td>Intact Vascular</td>
</tr>
</tbody>
</table>

All faculty disclosures are available on the CRF Events App and online at www.crf.org/tct
An amazing array of configurations

Vulnerable plaque with hemorrhage

Array of images showing different plaque configurations:
- Fibrous cap
- NC
- Fibrin
- NC
- Ulcerated plaque

Images of various sections and perspectives of the plaque.
Why Do We Need Mesh-covered Stents?

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
## Delayed Neurologic Events 1-30d
Especially with Open Cell Stents

<table>
<thead>
<tr>
<th></th>
<th>Total population</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients</td>
<td>All events</td>
<td>Post-procedural events</td>
</tr>
<tr>
<td>Open cell</td>
<td>937</td>
<td>39</td>
<td>32</td>
</tr>
<tr>
<td>Closed cell</td>
<td>2242</td>
<td>51</td>
<td>29</td>
</tr>
<tr>
<td>Total</td>
<td>3179</td>
<td>90</td>
<td>61</td>
</tr>
</tbody>
</table>

2/3 of neuro events were delayed (1-30d)

### Cell type

<table>
<thead>
<tr>
<th></th>
<th>Patients</th>
<th>All events</th>
<th>Post-procedural events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open cell</td>
<td>4.2%</td>
<td>3.4%</td>
<td></td>
</tr>
<tr>
<td>Closed cell</td>
<td>2.3%</td>
<td>1.3%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2.83%</td>
<td>1.9%</td>
<td></td>
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</tbody>
</table>

Failure of the stent!
Increased Neurologic Events With Open Cell Stents

SPACE Trial

Olav J et al. Stroke 2009;40:841

<table>
<thead>
<tr>
<th>Stent</th>
<th>Wallstent</th>
<th>Acculink</th>
<th>Precise</th>
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</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>436</td>
<td>92</td>
<td>35</td>
</tr>
<tr>
<td>Pat. with OE</td>
<td>24</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>OE rate (95% CI)</td>
<td>5.5% (3.6–8.1%)</td>
<td>9.8% (4.6–17.8%)</td>
<td>14.3% (4.8–30.3%)</td>
</tr>
</tbody>
</table>

Combined OE rate: 11.0% (6.2–17.8%)

Closed  Open
New Brain Lesions After Carotid Stenting Versus Carotid Endarterectomy: A Systematic Review of the Literature

Increased DW-MRI Hits With Open Cell Stents
Carotid Stent Design

Figure 1

Carotid Stent Design
Open Cell In Tortuous Bifurcation
Mesh-Covered Stents

**GORE Carotid Stent**

- Open Cell Nitinol Frame
- Closed Cell 500 µ lattice on outside of Frame
- Permanently Bound CBAS Heparin on all device surfaces

**CAUTION**: Investigational Device.
Limited by United States Law to Investigational Use only. Not available in US. Not approved by FDA.
Mesh-Covered Stents
CBAS®-Heparin Evaluation

• Modified Chandler Loop - recirculating blood model
  – CBAS®-treated devices thrombus-free after a one hour exposure to human blood,
  – Untreated control device contained adherent thrombus.

• Coagulation biomarker prothrombin fragment 1 and 2 (F1+2) revealed significantly lower levels associated with CBAS®-treated GCS compared to uncoated control devices
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® Stent
Carotid WALLSTENT™
Mesh-Covered Stents

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.

CAUTION: Investigational Device.

Limited by United States Law to Investigational Use only. Not available in US. Not approved by FDA.
Mesh-Covered Stents

SCAFFOLD Trial

Courtesy: C. Schonholtz

Courtesy of R. Dave

Courtesy of C. Metzger
Mesh-Covered Stents

Casper

Mesh coverage for sustained embolic prevention
Retrievable and repositionable
5Fr delivery
Closed cell, woven stent

Microvention/Terumo
Mesh-Covered Stents

CGuard Prime EPS

Polyethylene Terephthalate (PET) 20µ wide fiber
Attached to nitinol stent
CARANET Study - 30 patient trial, recently completed, to be presented TCT

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Mesh-Covered Stents
CGuard Prime EPS

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Mesh-Covered Carotid Stents

Conclusion

• Goal: decrease neurologic events, especially delayed embolization through the cells of the stent.
• Future: clinically useful stent design will likely include mesh coverage.
• Balance between material type, positioning, and cell size.