SCAFFOLD Study
Gore PTFE mesh-covered stent
preclinical and clinical data so far

Peter A. Schneider, MD
Kaiser Foundation Hospital
Honolulu, Hawaii
Disclosure

Peter A. Schneider

I have the following potential conflicts of interest to report:

Scientific Advisory Board (non-paid):
- Cardinal, Abbott, Medtronic, BSCI

Royalty (modest): Cook

Co-founder and Chief Medical Officer: Intact, Cagent

Enter patients into studies: NIH, Bard, Gore, Medtronic, BSI,
- Silk Road (no financial relationship).

VIVA Board member (nonprofit)

Selected slides are courtesy of Claudio Schonholtz
Gore Carotid Stent (GCS)

Stent Frame + Stent Lattice

CBAS Coating

Investigational Device. Limited by US Law to Investigational Use only.
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
Amazing array of configurations and morphologies

What About the Stent?
- Scaffolding
- Lesion containment
- Conformability
- Fatigue resistance
- Ease of re-crossing
- Visibility
- Low profile
More Plaque Prolapse with Open Cell Stents

Plaque Prolapse
Open Cell  Closed Cell
61.5%    17.6%

Plaque prolapse between stent struts

deDonato et al. Eur J Vasc Endovasc Surg 2013;45:479

Wholey J Endovasc Ther 2009;16:178
More DW-MRI Lesions with Open Cell Stents

Prospective RCT: MRI Hits Closed versus Open Cell Stents

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

Park et al. J Neurosurg 2013;119:

Schnaudigel et al. Stroke 2008;39:911
### Delayed Neurologic Events (>24 Hours) with CAS

<table>
<thead>
<tr>
<th></th>
<th>Patients</th>
<th>All events</th>
<th>Post-procedural events</th>
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</thead>
<tbody>
<tr>
<td>Total</td>
<td>3179</td>
<td>90</td>
<td>61</td>
</tr>
<tr>
<td>Cell type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open cell</td>
<td></td>
<td>4.2%</td>
<td>3.4%</td>
</tr>
<tr>
<td>Closed cell</td>
<td></td>
<td>2.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Total</td>
<td>3179</td>
<td>2.83%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

Bosiers et al. Eur J Vasc Endovasc Surg 2007;33:135

### CREST-Timing of Stroke After Carotid Stenting

<table>
<thead>
<tr>
<th></th>
<th>0-24 hours</th>
<th>1-30d</th>
<th>% of strokes that occurred after 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>29 events</td>
<td>19 events</td>
<td>40%</td>
<td></td>
</tr>
</tbody>
</table>

Hill et al. Circulation 2012;126:3054
GCS pore size <20% the area of WALLSTENT cell size
SCAFFOLD: 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
**Carotid Stent Delivery System**

**Attributes**
- Single handed delivery
- 5Fr Introducer Sheath Compatible (White Tip)
- 6Fr Introducer Sheath Compatible (Gray Tip)
- Hypotube Design
  - Allows for complete closure of hemostatic valve
- 135 cm Working Length
- 30 cm Rx

**Diagram**
- Stent/Sheath (5Fr or 6Fr)
- Hub
- Handle
- RO Markers
- Hypotube (2.4 Fr)
Gore Carotid Stent
SCAFFOLD Study

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

50 sites, 312 subjects.

Co-PIs—Peter Schneider and Bill Gray

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.

Investigational Device.
Limited by United States Law to Investigational Use only. Not available in US. Not approved by FDA.
SCAFFOLD Study

• Patient Population:
  – >18 years of age
  – De novo atherosclerotic or post-endarterectomy restenotic lesions in the CCA or ICA
  – $\geq 50\%$ (by angiography) stenosis if symptomatic, or
  – $\geq 80\%$ (by angiography) stenosis if asymptomatic
  – High risk for CEA

• 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
SCAFFOLD Status

312/312 patients enrolled

30-day data to be presented at Charing Cross 2017
Gore Mesh-Covered Carotid Stent
Cases from the SCAFFOLD Trial

Courtesy: C. Schonholtz

Courtesy of C. Metzger

Courtesy of R. Dave
SCAFFOLD Patient Selection: STAGE 1

100 patients enrolled and reviewed by FDA

Potential inclusion/exclusion criteria violations

- Stenosis location or severity (inclusion)
- Severely tortuous anatomy (exclusion)
- Severe lesion calcification (exclusion)
Highest Risk Anatomies for CAS

McDonald et al, *Stroke* 2009

1. Type III Arch
2. Vessel tortuosity
3. Heavy calcification
4. Lesion related thrombus

White et al, *Cath Card Int* 2013

1. Vessel tortuosity
2. Severe arch disease
3. Angulated ICA
4. Circumferential calcification
SCAFFOLD Patient Selection: STAGE 2

Additional 212 patients enrolled, subject to a screening committee for eligibility

- Physicians from different disciplines
  - 1 NS, 1 IC, 1 IR, 1 VS
- Review CTA or angiograms for inclusion/exclusion criteria based on protocol
- 2 review each case; if no consensus, 3rd physician included
- Patients either accepted or rejected for enrollment in SCAFFOLD
Patients Rejected by Screening Committee

1. Severe lesion calcification
2. Severely tortuous anatomy
3. \( \geq 50\% \) stenosis of proximal CCA
Mesh-Covered Stent and SCAFFOLD Trial Conclusion

• SCAFFOLD Trial studied next development in carotid stent design. Release Q2 2017.
  – Open cell stent frame, PTFE mesh, heparin coating

• Make the first 30 days safer.
  – Smaller cell size=less plaque prolapse, fewer delayed events
  – Case selection for carotid stenting is key to good clinical results and evaluating device performance

• Future stent design likely to include some type of coverage.
GORE® Carotid Clinical Study for the treatment of carotid Artery stenosis in patients at increased risk for adverse events from carotid endarterectomy.

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