Micromesh Technology in Carotid Stents: Soft vs. Hard Landing

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## Disclosures

<table>
<thead>
<tr>
<th>Physician name</th>
<th>Company</th>
<th>Relationship</th>
</tr>
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<tbody>
<tr>
<td>Horst Sievert</td>
<td>4tech Cardio, Abbott, Ablative Solutions, Ancora Heart, Bavaria Medizin Technologie GmbH, Bioventrix, Boston Scientific, Carag, Cardiac Dimensions, Celonova, Cibiem, CGuard, Comed B.V., Contego, CVRx, Edwards, Endologix, Hemoteq, InspireMD, Lifetech, Maquet Getinge Group, Medtronic, Mitralign, Nuomao Medtech, Occlutech, pfm Medical, Recor, Renal Guard, Rox Medical, Terumo, Vascular Dynamics, Vivasure Medical, Venus, Veryan</td>
<td>Consulting fees, Travel expenses, Study honoraria</td>
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Stroke/TIA Following Carotid Stenting

- Up to two-thirds of carotid stenting-associated strokes/TIAs occurred after the procedure.\(^1\)
- Plaque prolapse through the stent struts occurs in 23% to 65% of cases.\(^2\)
- The degree of prolapse depends on the free stent cell area.\(^2\)
- This explains why embolic protection devices have limited effectiveness in abolishing carotid stenting-associated strokes.\(^3\)
- Prevention of plaque protrusion through the struts may result in reduced embolization.\(^4,5,6\)

\(^1\) Annals of Surgery Volume 246, Issue 4, October 2007, Pages 551-556
\(^3\) J Am Coll Cardiol 2012 Apr 10. 59:1383-9. 10.1016/j.jacc.2011.11.035
Post-procedural embolization following carotid stenting is frequent

Post-intervention showing successful opening of the occluded carotid artery with conventional stenting and an MRI showing multiple micro-infarcts (obstructions) post-procedure due to liberation of embolic particles.
Mesh Stents are Designed to Prevent Distal Embolization

- Ultrathin mesh inside or outside of the stent struts
- This “safety net” offers a greater vessel area coverage
- It prevents large plaque protrusion through the scaffold into the vessel lumen
- Mesh-Stents have identical deliverability as other stents
- They provide equivalent revascularization to conventional devices
- Designed to trap and seal thrombus and plaque against the vessel wall, preventing embolization
Best of both worlds

• Open cell stent design with large cell area
  - for better flexibility

• Smaller pore size
  - for better plaque coverage
Pore Size

- CGUARD™
- TERUMO
- GORE

Closed cell stent

- *165µ
- 375µ
- 500µ

1050µ

Open cell stent

1900µ

* Average in lesion at expanded state
<table>
<thead>
<tr>
<th>Name</th>
<th>RoadSaver aka Casper</th>
<th>Gore® Carotid Stent</th>
<th>CGuard™ Embolic Prevention Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent frame</td>
<td>closed-cell Nitinol</td>
<td>open-cell Nitinol</td>
<td>open-cell Nitinol</td>
</tr>
<tr>
<td>Mesh position in relation to frame</td>
<td>inside</td>
<td>outside</td>
<td>outside</td>
</tr>
<tr>
<td>Mesh material</td>
<td>Nitinol</td>
<td>PTFE</td>
<td>PET</td>
</tr>
<tr>
<td>Mesh structure</td>
<td>braided</td>
<td>inter-woven</td>
<td>single-fiber knitted</td>
</tr>
<tr>
<td>Pore size</td>
<td>375 μm</td>
<td>500 μm</td>
<td>150 - 180 μm</td>
</tr>
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</table>
Dual-layer stent comparison

RoadSaver®
Casper

Gore®
Carotid Stent

CGuard™ Embolic Prevention System
RoadSaver (Terumo) = Casper (MicroVena)

Images by Terumo / used with permission
RoadSaver: Push-Pull Stent Delivery System

re-sheathable up to 50% stent length release

CE Mark – January 2014
GORE® Carotid Stent

- Open Cell Nitinol Frame
- Closed Cell 500 µm PTFE lattice on outside of Nitinol Frame
- Permanently Bound Heparin on all device surfaces
The Gore Stent Delivery System

Attributes
- Single handed delivery
- 5Fr or 6Fr
- Hypotube Design
  - Allows for complete closure of hemostatic valve
- 135 cm Working Length
- 30 cm Rx
CGUARD MicroNet™ Technology

The MicroNet™
• Woven mesh of one single 20μm strand of Polyethylene Terephthalate (PET)
• Is sutured to both distal and proximal crowns of the stent platform

MicroNet™ technology supported by 6+ years of MGuard™ coronary data
CGuard™ Embolic Prevention Stent System
Trial results
Rodsaver – CLEAR-ROAD Study

- N = 100
- 8 EU centers
- Primary endpoint:
  - 30 day MAE (death, stroke, MI)
- Secondary endpoints
  - Technical success
  - MAE by subgroup symptomatic/asymptomatic
  - Late ipsilateral stroke (day 31-365)
  - TLR

Bosiers et al
Roadsaver – 30 day results

- One MI, patient died on day 4
- One ipsilateral stroke on day 12 (Afib?)

<table>
<thead>
<tr>
<th>Per Protocol</th>
<th>MAE’s</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Death, Stroke, or MI</td>
<td>2.00%</td>
</tr>
<tr>
<td>Death</td>
<td>1.00%</td>
</tr>
<tr>
<td>Any Stroke</td>
<td>1.00%</td>
</tr>
<tr>
<td>- Major Stroke</td>
<td>0.00%</td>
</tr>
<tr>
<td>- Minor Stroke</td>
<td>1.00%</td>
</tr>
<tr>
<td>MI</td>
<td>0.00%</td>
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Bosiers et al
Gore Scaffold Trial

- 312 patients
- 30 US sites
- PI William Gray, Peter Schneider
### SCAFFOLD Procedural Data: Technical Success

<table>
<thead>
<tr>
<th>Number of subjects</th>
<th>312</th>
</tr>
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<tbody>
<tr>
<td>Gore carotid stent successfully implanted</td>
<td>100% (312/312)</td>
</tr>
<tr>
<td>Gore embolic filter successfully deployed</td>
<td>94.6% (295/312)</td>
</tr>
<tr>
<td>Additional EPD used</td>
<td>4.5% (14/312)</td>
</tr>
</tbody>
</table>

William A. Gray, LINC 2018
### SCAFFOLD Primary Endpoints

<table>
<thead>
<tr>
<th></th>
<th>Intention to treat (n=311)</th>
<th>Per protocol (n=264)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>30 day endpoints</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAE</td>
<td>4.8 %</td>
<td>3 %</td>
</tr>
<tr>
<td>Death</td>
<td>0.6 %</td>
<td>0.4 %</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1.3 %</td>
<td>1.5 %</td>
</tr>
<tr>
<td>Stroke</td>
<td>2.9 %</td>
<td>1.1 %</td>
</tr>
<tr>
<td><strong>1 year endpoint</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ipsilateral stroke day 31-365</td>
<td>1.7 %</td>
<td>1.2 %</td>
</tr>
</tbody>
</table>
Clinically-driven 1-year Target Lesion Revascularization (TLR): ITT

1yr Clinically Driven TLR: 1.4%
1yr Restenosis (≥80%): 1.0%
1yr ECA Patency: 99.6%
CGUARD CARENET

• N = 30
• 4 centers in Germany and Poland
• Primary endpoints
  - Technical success
  - New ipsilateral lesions on MRI at 48 hours and 30 days
• Secondary endpoint: 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction)
• Procedural success: 100%
• Procedural complications: 0
• 30-day MACE: 0
• New ipsilateral ischemic lesions at 48 h: 37%
  - Complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm(3)) lesion in relation to the 48-h scan
Incidence of new ipsilateral lesions at 48 hours was reduced by almost half compared to published data, and volume was reduced almost 10-fold.

All but one lesion had resolved completely by 30 days.
CGUARD - PARADIGM

- 101 patients
  - 51-86 years
  - 55 symptomatic, evolving stroke in nine
- 106 CAS
- Embolic protection device mandatory
- Results
  - Technical success: 106 (100%)
  - Periprocedural death/major stroke/MI rate: 0
  - Minor stroke (no sequela): 1 (0.9%)
  - New events by 30 days: 0

Musialek P et al
Summary and Conclusions

- Mesh Carotid stents are open cell stents with an additional layer with very small pores
- They are designed to prevent periprocedural embolic events
- Prospective clinical trials have shown promising results
  - Very low periprocedural stroke rate
  - No increased risk of re-stenosis
- Imagine we could have used these stents in CREST and other trials
Thank you!