Midterm Results With a Micromesh Stent for CAS (The Roadsaver™ stent from Terumo). What are the differences between the 3 available Mesh Covered Stents

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Veith November 2015 NYC

Potential conflicts of interest
Speaker’s name: Max Amor
☐ I do not have any potential conflict of interest

More than 70% of events after CAS occur after the procedure

From M. Bosiers, and others

No stent or EPS protects against late embolization

Causes of Late Embolization

Are we able to provide delayed embolic protection Without loosing the long term benefit of Carotid Nitinol Stent?
THE THREE MICROMESH CAROTID STENTS

GORE CAROTID STENT

ROADSAVER

Tentative Summary of the main characteristics of the 3 Micromesh Stents

<table>
<thead>
<tr>
<th></th>
<th>Roadsafer</th>
<th>CGuard™</th>
<th>GORE Carotid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>Microvention / Terumo</td>
<td>Inspire MD</td>
<td>WL Gore</td>
</tr>
<tr>
<td>Material</td>
<td>Nitinol / Nitinol</td>
<td>Nitinol / PET</td>
<td>Nitinol / PTFE / CBAS Coating</td>
</tr>
<tr>
<td>Size of delivery</td>
<td>5F</td>
<td>6F</td>
<td>6F</td>
</tr>
<tr>
<td>Size of Pores µ</td>
<td>375-500</td>
<td>150-180</td>
<td>500</td>
</tr>
<tr>
<td>Flared tips</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Retrievable / Re-Posit</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Accuracy</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
<td>Conformability</td>
<td>+++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Crossability</td>
<td>+++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>ECA preservation</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>EPD compatibility</td>
<td>All</td>
<td>All</td>
<td>All</td>
</tr>
</tbody>
</table>

A Novel Design : ROADSAVER™

- Closed cell structure
- Flexible weave
- Nitinol Dual layer design for sustained embolic prevention
- retrievable and repositionable

Roadsaver Primary Attributes

- plaque coverage
  - The micromesh
  - Small stent cell size, ¼ area compared to smallest on market ~ 375 – 500 µ
  - Preventing embolic release
- In-vessel flexibility
  - Double braided
  - A flexibility of an open cell stent
  - Benefits of a closed cell stent.
- Wall apposition
  - The two Nitinol mesh layers
  - Flexible scaffold
  - Conforms to every morphology

First clinical cases
33 Patients with high risk carotid artery lesions
Midterm results

Single center experience
Clinique Louis Pasteur Essey Les Nancy France

Details of procedure

- DAPT before : All
- 24 Men, 9 Women. From 49 y to 88 y (Mean 72±10y)
- 8 Symptomatic 25 Asymptomatic
- Sedation : Midazolam: All
- Femoral Approach : All
- Protection : 32 : Filters 28, MOMA 4
- Atropine before inflation : All
- Direct Stenting : 8
- Post-Dilatation: All
### Patient and Carotid Lesion Characteristics

<table>
<thead>
<tr>
<th>Patient &amp; Lesion N &amp; initials</th>
<th>Sex &amp; Age</th>
<th>Symptom</th>
<th>Side &amp; Severity</th>
<th>Including Indications</th>
<th>Calcified</th>
<th>Irregular &amp; or Ulcerated</th>
<th>Echogenicity</th>
<th>Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 V.G M80y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Mixed</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>2 R.H M65y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Mixed</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>3 S.H M83y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Mixed</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>4 H.Y M85y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Mixed</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>5 C.P M75y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Mixed</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>6 T.R M80y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Hypo</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>7 A.M M65y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Mixed</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>8 T.G M80y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Hypo</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>9 T.J M80y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Mixed</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>10 R.C M80y</td>
<td>No</td>
<td>Right 80%</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Hypo</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

### Procedure & 48h Embolic Events & 30th day & months

<table>
<thead>
<tr>
<th>Procedure &amp; 48h Embolic Events &amp; 30th day &amp; months</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
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<td>7</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>10</td>
</tr>
</tbody>
</table>

### Complications after 48 h before discharge and 30th day

- No significant local complications requiring surgery
- No clinical neurological events
- No new silent defects or anomalies at the 24h CT scan
Protocol of Follow-up of RoadSaver Patient

- **Medical therapy:**
  - Clopidogrel & Aspirin during one month
  - Clopidogrel or Aspirin thereafter
  - Statins

- **2D Echo & Doppler:**
  - One Month
  - 6 month

- **Physician, cardiologist following the patient, and the patient**
  - 1 month
  - 6 month
  - One year

Follow-up for 35 patients with high risk carotid lesions treated by Micromesh Carotid RoadSaver Stent

- **Mean Follow up period:** 16.7±6.6 months (23 to 6 months)
  - 1 Male pt lost for FU: 76 y asymptomatic Pt
  - 1 Women 86 y died 7 months after procedure (6m Echo: Nil)
  - 1 Male 76y died one year after procedure (Heart Failure)

- **2D Echo Examination for all patients after 6 months**
  - 32 pts explored by echo
  - All External carotid artery patent
  - 4 External ostial carotid stenosed (2 new lesions)
  - No Stented Carotid restenosis at 6 months
  - No new neurological event during FU

Roadsaver Carotid Stent. Mid-term Results (33 Pts)

<table>
<thead>
<tr>
<th>Events</th>
<th>30th days</th>
<th>6months</th>
<th>1year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delayed embolisation</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Neurological events</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Anatomical</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External Carotid Occlusion</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Restenosis</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Stent Geometry</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Migration</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Compression</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Deformation</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Fracture</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
</tbody>
</table>
N6  85 y male Very Symptomatic RICA

Harmonious deployment
Conclusions

- From this first 33 cases, we conclude that Roadsaver micromesh stent represents a true and important progress in carotid stenting.
- It is very easy to place and to deploy (Resheathable and Repositionable, 5F compatible).
- Compatible with all systems of carotid protection.
- Easy to recross and to visualize.
- Does not occlude external carotid.
- Contains plaque or debris against the arterial wall following stent deployment.
- Superior to other stents on the market in preventing immediate and delayed embolization.

- It is premature to prefer one micromesh stent to the other.
Reasons for carotid stenting in our series

- Age
- Symptomatic
- Presence of coronary insufficiency
- Bilaterality
- Before surgery
- Worsening during F/U
- Cranial nerve paralysis post contra-lateral CEA
- Patient and referral physician preference

System Sizes

System Compatibility

- Chronic Embolic Protection
  - Double-layer micromesh design
  - Smallest stent cell size, ¼ area compared to smallest on market ~ 375 – 500 µ
  - Tacks down/contains plaque, acting like a metallic covered stent
- Lesion Specific scaffolding
  - Extremely high plaque coverage
  - Superior in-vessel flexibility (compared to other braided mesh and closed cell lasercut stents)
  - Excellent wall apposition
- Low Profile Delivery System
  - UF: Rapid Exchange for all sizes
  - Up to 50% deployment full re-sheathable and re-positionable
Excellent Healing Despite Multiple Overlapping Stents

83 y, male, Right internal asymptomatic carotid stenosis

Patient n 2, 8F Guiding catheter

Patient n 2, Post dilatation 5x20mm balloon
Retrieval of buddy wire & easy Filter

62y Male, bilateral severe carotid stenoses & Throat cancer with

Step 1: LICA Roadsaver Stent under protection covering an ulcerated lesion

Step 2: RICA Roadsaver Stent under protection covering an ulcerated lesion

Bilateral carotid stenting with double layer micro-mesh stents

OCT of Carotid Lesions
CAGUARD

CARENET I – All Comer CAS Trial

50% reduction in incidence of new lesions
10-fold reduction in average volume of new lesions
100% of lesions disappeared by 30 days post procedure

Prof. Dr. Joachim Schofer, TCT 2014

Ideal Pore Size

50% reduction in incidence of new lesions
10-fold reduction in average volume of new lesions
100% of lesions disappeared by 30 days post procedure

Prof. Dr. Joachim Schofer, TCT 2014
Conventional Stent vs CGuard

Gore Carotid Stent (GCS)

Stent Frame + Stent Lattice

CBAS Coating

Stent Frame
- Laser cut frame from a solid tube of nitinol
- Open cell design (high degree of flexibility and conformability to the native anatomy)
- Helical body with the end rows being of a closed cell construction in order to balance strain within the frame

Stent Lattice
- High strength expanded polytetrafluoroethylene
- High degree of plaque scaffolding that reduce plaque prolapse.
- Reduce amount of emboli released during and after stent deployment
- Stabilize the stent frame by resisting elongation as well as the “fish-scaling”

CBAS Coating
- The stent frame and lattice, once combined, are coated on all surfaces with the Carmeda Bioactive Surface (CBAS®)
- Action is limited only to the device surface and has no systemic anticoagulant effects
**Potential Risk for Plaque Protrusion and Embolization**

*CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.

**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

**GORE® Carotid Stent System Sizing Summary**

**Study Overview**

**Design**
- Multicenter, single-arm, prospective study comparing the GORE® Carotid Stent to a performance goal developed from carotid endarterectomy (CEA) outcomes

**Objective**
- Evaluate the safety and efficacy of the GORE® Carotid Stent for the treatment of carotid artery disease in patients at increased risk for adverse events from carotid endarterectomy

*CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.

**Study Design**

- **Number of Sites**
  - Up to 50 sites in the US, Europe, and Japan

- **Number of Subjects**
  - 312 subjects (max 40 at each site)

- **General Population**
  - Patients at least 18 years of age who have either a single de novo atherosclerotic or post-endarterectomy restenotic lesion in the internal carotid artery or the carotid bifurcation with either:
    - ≥ 50% (by angiography) stenosis if symptomatic (stroke, TIA, TMB within 180 days of procedure), OR
    - ≥ 80% (by angiography) stenosis if asymptomatic
  - Patients must have either anatomic or medical co-morbidities that place them at high perioperative risk for CEA