How to Integrate latest Technology to make Carotid Stenting safer?

Stephan Duda
Disclosure

Speaker name: S. Duda

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
Access

MRA/CTA

Type I

Type II

Type III

1-2 diameter of CCA

> 2 diameter of CCA
Radial Access
Cervical Access (TCAR, Silkroad)

Direct Carotid Access
CCA Clamp & Loop Control

Back-bleeding to Clear Debris

TCAR

Flow Reversal
to Clear Debris

TCAR = Transcarotid Artery Revascularization
## TCAR: Clinical Studies

<table>
<thead>
<tr>
<th>Study type</th>
<th>PROOF</th>
<th>TESLA</th>
<th>ROADSTER</th>
<th>TCD CEA v TCAR vs TF-CAS</th>
<th>ROADSTER 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>75</td>
<td>58</td>
<td>208</td>
<td>34</td>
<td>600+</td>
</tr>
<tr>
<td>Profile</td>
<td>All-comers</td>
<td>All-comers</td>
<td>High Surgical Risk: Sx &amp; Asx</td>
<td>CEA vs TCAR vs TF-CAS</td>
<td>High Surgical Risk: Sx &amp; Asx</td>
</tr>
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<td></td>
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</tr>
</tbody>
</table>

**PROOF Study:** 2.7% Hoarseness
Gore Carotid Stent (GCS)

Stent Frame

Stent Lattice

CBAS heparin-bonded coating
Gore SCAFFOLD Lattice Structure: comparison to other CAS

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>W.L. Gore and Associates*</th>
<th>Abbott Laboratories</th>
<th>Abbott Laboratories</th>
<th>Boston Scientific Corporation</th>
<th>ev3 Inc./Covidien</th>
<th>Cordis Corporation</th>
<th>Medtronic, Inc./Invatec</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device</strong></td>
<td>GORE® Carotid Stent</td>
<td>ACCULINK® RX DEVICE</td>
<td>XACT® DEVICE</td>
<td>WALLSTENT® MONORAIL® DEVICE</td>
<td>PROTEGE RX® DEVICE</td>
<td>PRECISE® DEVICE</td>
<td>CRISTALLO IDEALE DEVICE</td>
</tr>
<tr>
<td><strong>Stent Type</strong></td>
<td>Straight, Hybrid Design</td>
<td>Tapered, Open Cell</td>
<td>Tapered, Closed Cell</td>
<td>Straight, Closed Cell</td>
<td>Tapered, Open Cell*</td>
<td>Straight, Open Cell</td>
<td>Tapered, Combination</td>
</tr>
<tr>
<td><strong>Cell Size (mm)$^2$</strong></td>
<td>0.28</td>
<td>16.60</td>
<td>4.00</td>
<td><strong>1.36</strong></td>
<td>10.40</td>
<td>9.00</td>
<td>3.30 (center) 13.50 (ends)</td>
</tr>
</tbody>
</table>

GCS pore size 20% the area of WALLSTENT cell size
## SCAFFOLD:
### Per Protocol Subgroup analysis: n=264

<table>
<thead>
<tr>
<th>All Per-Protocol Subjects (N=264)</th>
<th>N</th>
<th>Death</th>
<th>Stroke</th>
<th>MI</th>
<th>MAE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Evaluable(^1)</td>
<td>263</td>
<td>1 (0.4%)</td>
<td>3 (1.1%)</td>
<td>4 (1.5%)</td>
<td>8 (3.0%)</td>
</tr>
<tr>
<td>Symptomatology (N=263)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic</td>
<td>33 (12.5%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>230 (87.5%)</td>
<td>1 (0.4%)</td>
<td>3 (1.3%)</td>
<td>4 (1.7%)</td>
<td>8 (3.5%)</td>
</tr>
<tr>
<td>High-Risk Subgroup (N=263)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anatomic</td>
<td>79 (30.0%)</td>
<td>0 (0.0%)</td>
<td>1 (1.3%)</td>
<td>1 (1.3%)</td>
<td>2 (2.5%)</td>
</tr>
<tr>
<td>Comorbid</td>
<td>184 (70.0%)</td>
<td>1 (0.5%)</td>
<td>2 (1.1%)</td>
<td>3 (1.6%)</td>
<td>6 (3.3%)</td>
</tr>
<tr>
<td>Comorbid Age Status (N=263)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 75+ years</td>
<td>124 (47.1%)</td>
<td>1 (0.8%)</td>
<td>2 (1.6%)</td>
<td>2 (1.6%)</td>
<td>5 (4.0%)</td>
</tr>
<tr>
<td>Age &lt;75 years</td>
<td>139 (52.9%)</td>
<td>0 (0.0%)</td>
<td>1 (0.7%)</td>
<td>2 (1.4%)</td>
<td>3 (2.2%)</td>
</tr>
<tr>
<td>Octogenarian Status (N=263)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 80+ years</td>
<td>61 (23.2%)</td>
<td>0 (0.0%)</td>
<td>1 (1.6%)</td>
<td>1 (1.6%)</td>
<td>2 (3.3%)</td>
</tr>
<tr>
<td>Age &lt;80 years</td>
<td>202 (76.8%)</td>
<td>1 (0.5%)</td>
<td>2 (1.0%)</td>
<td>3 (1.5%)</td>
<td>6 (3.0%)</td>
</tr>
</tbody>
</table>

\(^1\) Includes those who died, had a stroke, had a MI, or had a major adverse event (MAE) within 30 days of enrollment.
How Do Results Compare?

Risk of Death, Stroke or Myocardial Infarction Within 30 Days of Procedure (%)

- 30d MAE
- 30d Any Stroke
Conformability: Braided Nitinol design allows for in-vivo stent tapering and conformability to ICA-CCA segments.

Flexibility: Closed cell stent with the flexibility of open cell stent, resulting in excellent vessel wall apposition in tortuous anatomy.

Inner layer
- Micro-mesh with very small cell size (375-700 µm) limits plaque prolapse and embolic release.

Outer layer
- Conformability: Braided Nitinol design allows for in-vivo stent tapering and conformability to ICA-CCA segments.
- Flexibility: Closed cell stent with the flexibility of open cell stent, resulting in excellent vessel wall apposition in tortuous anatomy.
Roadsaver (Terumo)

- Fully repositionable with up to 50% deployment.
- 5 Fr sheath compatible system.
Major Stroke Rate: 0.00% at 30 days (K. Deloose, EuroPCR 2017)
2 Coaxial Xact. 0.7mm²
Paladin System (IEP, ContegoMedical)

- Filter Chassis
- Filter Membrane with 40-Micron Pores
- Minimal Balloon to Filter Transition Zone
- Sheathless Design
- Angioplasty Balloon
A Word of Caution
Thank you
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