Roadsaver
– the optimal solution for all carotid lesions?

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Disclosures

Speaker name:
Univ. Prof. Dr. med. G. Torsello

I have the following potential conflicts of interest to report:

- [x] 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
Known facts in CAS

• 66% of strokes occur after removal of cerebral protection
• This occurs in spite of optimal medical therapy
• Reason: plaque prolapse through stent struts
• Suggestive data of apparent superiority of closed cell over open cell design stents
Problem of plaque protrusion in uncovered areas with resulting delayed stroke

Picture by Makaroun, Pittsburgh; Balzer Mülheim
“Stent design”-based analysis

<table>
<thead>
<tr>
<th>ALL EVENTS</th>
<th>Total population</th>
<th>Symptomatic</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N %</td>
<td>n/N %</td>
<td>n/N %</td>
</tr>
<tr>
<td>Closed</td>
<td>51/2242 2.3%</td>
<td>21/934 2.2%</td>
<td>30/1308 2.3%</td>
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<tr>
<td>Open</td>
<td>39/937 4.2%</td>
<td>27/383 7.0%</td>
<td>12/554 2.2%</td>
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<tr>
<td>TOTAL</td>
<td>90/3179 2.8%</td>
<td>48/1317 3.6%</td>
<td>42/1862 2.6%</td>
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</table>

Bosiers, Setacci, Castriota, 2007
SPACE Results: Closed cell superior to open Cell
### The Dilemma

<table>
<thead>
<tr>
<th>Open cell design</th>
<th>Closed cell design</th>
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<tbody>
<tr>
<td>Suboptimal plaque coverage</td>
<td>Good plaque coverage</td>
</tr>
<tr>
<td>Conforms to vessel anatomy</td>
<td>Suboptimally conforms to vessel anatomy</td>
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<table>
<thead>
<tr>
<th>Double layer micromesh design</th>
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</thead>
<tbody>
<tr>
<td>Optimal plaque coverage</td>
</tr>
<tr>
<td>Conforms to vessel anatomy</td>
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</tbody>
</table>
Kinking of distal ICA after CAS

Technique of carotid angioplasty with stenting, Vitek J.J., New York Heart and Vascular Institute at Lenox Hill Hospital
Vessel Adaptability

- The Nitinol double braided material exhibits a flexibility of an open cell stent, while offering the benefits of a closed cell stent.

73yo male, high grade right carotid lesion
First clinical cases
14 Patients with high grade carotid lesions
Details of procedure

- DAPT before: All, statin before 10
- 2 symptomatic, 12 asymptomatic
- 8 Men, 5 Women. From 56 y to 78 y
- Sedation: none
- Femoral Approach: All
- Protection: All: Filters 11, MOMA: 3
- Atropine before inflation: All
- Direct Stenting: 5
- Post-Dilatation: All
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<tr>
<th>N</th>
<th>Access</th>
<th>Shuttle: I</th>
<th>MOMA: M</th>
<th>Protection System</th>
<th>Pre-dilatation</th>
<th>Post –Stent Dilatation</th>
<th>Stent Size</th>
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Details of procedure

Morphology of access vessels:
- 43% (N = 6) Type I Arch
- 14% (N = 2) Type II Arch
- 36% (N = 5) Type III Arch

Morphology of lesions:
all mild to moderate calcified 70 – 98%
2 symptomatic, 12 asymptomatic
2 after previous CEA
Extreme flexibility of distal tip

- Trackability through complex aortic arches
- Reduced dislodgement risk of access sheath or catheter

- 68yo female, high grade lesion right ICA, Type III Arch
73yo female, high grade lesion right ICA
Stent delivery system tracking through type III arch
73yo male, high grade right carotid lesion (cont.)
Early results (48h)

- No significant local complications requiring surgery
- No clinical neurological events, no findings in post-interventional neurological examination by independent neurologist
- All 14 patients discharged home 24-30h after Roadsaver CAS
Conclusion

- The dual layer stent has proven **good deliverability, wall adaptation** and can be used with proximal and distal protection **in challenging anatomies** and lesions.

- No experience in severely calcified lesions (in Münster) **circumferential calcium** remains an indication for **CEA**.

- Preliminary clinical results are promising, however - evaluation in **larger trials** is **needed** to examine the safety, efficacy and durability of CAS performed with the Roadsaver stent.
Thank you very much!
73yo female, high grade lesion right ICA
Thank you for your attention

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http://www.gefaesschirurgie-muenster.de/
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