The concept of the Roadsaver carotid micromesh stent – initial clinical experience

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Historic and available Carotid implants

SMART®, Cordis

Xact®, Abbott Vascular Devices

Protege®, ev3

Acculink®, Guidant

Exponent®, Medtronic

Carotid WALLSTENT
Boston Scientific

Precise®, Cordis

Cristallo, Invatec

Sinus Carotid® RX, Optimed
Open versus closed cell design – What do we know?

Wallstent (BSCI)
NexStent (BSCI)
Precise (Cordis)
Acculink (Guidant)

Closed cell
Open cell

Houdart, Cirse 2005.
Open versus closed cell design

What do we know?

- Closed cell
- Open cell

FREE CELL AREA (mm²)

Roadsaver 0.38
Known facts in CAS

• 66% of strokes occur after removal of cerebral protection
• This occurs in-spite of Optimal Medical Therapy
• Plaque Prolapse through stent struts
• Suggestive data of apparent superiority of closed cell over open cell design stents

Max Amor @ LINC 2014
Problem of plaque protrusion in uncovered areas with resulting delayed stroke

Bilder von Makaroun, Pittsburg; 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>%</td>
<td>n/N</td>
</tr>
<tr>
<td>Closed</td>
<td>51/2242</td>
<td>2.3%</td>
<td>21/934</td>
</tr>
<tr>
<td>Open</td>
<td>39/937</td>
<td>4.2%</td>
<td>27/383</td>
</tr>
<tr>
<td>TOTAL</td>
<td>90/3179</td>
<td>2.8%</td>
<td>48/1317</td>
</tr>
</tbody>
</table>

Bosiers, Setacci, Castriota, 2007
SPACE Results: Closed cell superior to open Cell
What can be novel in a self-expanding Carotid Stent?

- Dual layer micromesh design for sustained embolic prevention
- Flexible weave completely made of Nitinol
- Extreme flexible delivery system
- Retrievable and repositionable
Plaque coverage ⇒ Sustained Embolic Protection

- Smallest stent cell size - preventing emboli release
  - Tacks down/contains plaque, acting like a metallic covered stent
  - 16 micromesh cells will fit into one macromesh cell!

<table>
<thead>
<tr>
<th></th>
<th>Abbott Vascular RX Acculink</th>
<th>Abbott Vascular Xact</th>
<th>Boston Scientific Carotid Wallstent</th>
<th>Cordis Precise Pro RX</th>
<th>Covidien/ ev3 Protégé RX</th>
<th>Medtronic/ Invatec Cristallo Ideale</th>
<th>Terumo Roadsaver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pore Diameter (mm)</td>
<td>2.7686</td>
<td>2.413</td>
<td>2.1336</td>
<td>2.7686</td>
<td>3.9878</td>
<td>3.2258</td>
<td>1.1176</td>
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<tr>
<td>Pore Area (mm²)</td>
<td>2.3622</td>
<td>1.8034</td>
<td>1.397</td>
<td>2.3622</td>
<td>4.9276</td>
<td>3.2258</td>
<td>0.381</td>
</tr>
</tbody>
</table>
Instent flexibility

- 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, CAS with Wallstent left ICA
Scaffolding – various stent designs

- Open Cell Design
- Closed Cell Design
- Hybrid Cell Design
- Micromesh Double Braided Design

Plaque Coverage
Adaptability
In Vessel Flexibility

Courtesy of F. Castriota, A. Cremonesi, Cotignola, Italy
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
Stent delivery system tracking through type III arch
67 year old female, left hemispheric minor stroke 2/15
Tandem lesion left CCA and ICA, vmax 380cm/sec
hostile neck - neck dissection and radiatio 2008 for esophagus cancer
67 year old female, left hemispheric minor stroke 2/15
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67 year old female, left hemispheric minor stroke 2/15
Tandem lesion left CCA and ICA, vmax 380cm/sec
early clinical experience: 36 Patients with high grade carotid lesions
Details of procedure

- DAPT before: All
- 24 Men, 12 Women. From 56 y to 83 y
- Sedation: none
- Femoral Approach: All
- Protection: All: Filters 26, MOMA: 8
- Atropine before inflation: All
- Direct Stenting: 17
- Post-Dilatation: All
- Type 3 Arch 38% (n = 14)
- Symptomatic 16% (n = 6)
Complications after 48h

- No significant local complications requiring surgery
- 1 minor stroke 5 minutes after removal of protection device, symptoms resolved within 24h
- Post-interventional neurological examination by independent neurologist showed no sequelae (preop. crescendo TIA, patient unfit for surgery)
- 34 patients discharged home 24-30h after Roadsaver CAS
Case example 1
73yo female, high grade lesion right ICA
73yo female, high grade lesion right ICA
73yo male, high grade right carotid lesion, CAS with Wallstent left ICA
Importance of wall adaptability of carotid implants in kinked vessel anatomy
73yo male, high grade right carotid lesion, CAS with Wallstent contralateral (left) ICA
Symptomatic high grade stenosis left ICA

Operators: A. Schwindt, N. Abu-Bakr

Clinical data:
- high grade left ICA stenosis, CTA 90% vmax 320cm
- arterial hypertension
- hyperlipedemia
- thyreoidectomie 1990
- hysterectomy 1990

Symptoms: asymptomatic
Case 70 – MUN 07: female 72 years (B.E.)

Symptomatic high grade stenosis
left ICA
Case 70 – MUN 07: female 72 years (B.E.)

Symptomatic high grade stenosis left ICA

Procedural steps:

- Right femoral approach 5F 10 cm sheath (Terumo)
- Cannulation left CCA with telescope technique (Cook)
  6F 90cm Shuttle sheath + 5.6F VTEK smoothcath
- Cannulation ICA stenosis with Epifilter (Boston Scientific)
- Implantation 7x30mm Roadsaver Stent (Terumo)
- Postdilation with 5mm Sterling rx balloon (Boston Scientific)
For surgeons performing both CEA and CAS the techniques are complementary and not competing. Patient and lesion based selection will lead to best results in both treatment modalities. The Terumo Roadsaver brings the concept of small cell areas to a complete new level. The dual layer stent has already proven good deliverability, wall adaptation and can be used with a variety of protection devices even in challenging anatomies and lesions. Preliminary clinical results are promising but evaluation in larger registries or trials is mandatory to proof the safety, efficacy and durability of CAS performed with the Roadsaver stent.
Thank you for your attention
1. Case – 73yo female patient
Disclosure

Speaker name: ..................................................................................

I have the following potential conflicts of interest to report:

☒ Consulting: Avinger, Biotronik, Covidien, Cordis, Jotec, Terumo,

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

☐ I do not have any potential conflict of interest