Overview of Newer Stent Devices for Aneurysm Treatment

Randall C. Edgell, M.D.
Associate Professor
Vascular and Interventional Neurology
Saint Louis University
Disclosure

• Outcome adjudication for THERAPY, Penumbra
FDA Pathways

• Premarket Notification (510[K]): may allow device to go to market if “substantially equivalent” to previously marketed devices

• Pre-market Approval (PMA): Efficacy trial required
  – Investigational Device Exemption (IDE): allows use in clinical trials

• Humanitarian Device Exemption (HDE): Only for rare diseases (<4,000 cases per year). Only requires demonstration of safety. Local IRB approval and monitoring required.
WARNING

• Most devises presented are investigational.
• Seeking HDE or PMA approval.
• Some slides/images graciously provided by industry
Flow Diverting Stents
Pipeline™ Embolization Device (Covidien)

- 30-35% surface coverage at nominal diameter
- 48-strand braided mesh
- 75% cobalt chromium/25% platinum tungsten
- Scaffolding for endothelial repavement
- Branch vessels preserved
Pipeline™ Embolization Device (Covidien)
Pipeline™ Flex Embolization Device (Covidien)

- Improved delivery system
- New distal wire
- Resheathable
- No protective coil
Surpass™ Flow Diverter (Stryker)

- High pore density (72-wire & 96-wire braids)
- Long lengths (15mm to 50mm)
- 3mm, 4mm, 5mm diameters
Surpass™ Flow Diverter (Stryker)
<table>
<thead>
<tr>
<th>Description</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of Pts/Aneurysms Successfully Treated</strong></td>
<td>161/186</td>
</tr>
<tr>
<td>Average Number of Devices/Aneurysm</td>
<td>1.05</td>
</tr>
<tr>
<td>Aneurysm Location</td>
<td></td>
</tr>
<tr>
<td>Anterior (ICA) = 63.4% (118/186)</td>
<td></td>
</tr>
<tr>
<td>Anterior (Distal to Willis) = 22.0% (41/186)</td>
<td></td>
</tr>
<tr>
<td>Posterior Circulation = 14.5% (27/186)</td>
<td></td>
</tr>
<tr>
<td><strong>Number of Pts Available for Safety/Clinical Follow-up (at 6Mo)</strong></td>
<td>150 (Anterior = 123; Posterior = 27)</td>
</tr>
<tr>
<td>Primary Endpoint (any stroke and neurologic death)</td>
<td>12.0% (18/150)</td>
</tr>
<tr>
<td>Anterior Circulation</td>
<td>5.7% (7/123)</td>
</tr>
<tr>
<td>Posterior Circulation</td>
<td>14.8% (4/27)</td>
</tr>
<tr>
<td>Permanent Morbidity</td>
<td>6.0% (9/150)</td>
</tr>
<tr>
<td>Procedure-Related Mortality</td>
<td>2.7% (4/150)</td>
</tr>
<tr>
<td>Anterior Circulation</td>
<td>1.6% (2/123)</td>
</tr>
<tr>
<td>Posterior Circulation</td>
<td>7.4% (2/27)</td>
</tr>
<tr>
<td>Patients with Perforator Occlusion</td>
<td>0.7% (1/150)</td>
</tr>
<tr>
<td><strong>Aneurysms Available for DSA Follow-up (at 6Mo)</strong></td>
<td>84.9% (158/186)</td>
</tr>
<tr>
<td>Compete Occlusion</td>
<td>74.7% (118/158)</td>
</tr>
<tr>
<td>Anterior Circulation (ICA); Anterior Circulation (Distal to Willis)</td>
<td>78.6% (77/98); 65.8% (25/38)</td>
</tr>
<tr>
<td>Posterior Circulation</td>
<td>72.7% (16/22)</td>
</tr>
<tr>
<td>Near Complete Occlusion (&gt;95%) or Complete Occlusion</td>
<td>80.4% (127/158)</td>
</tr>
</tbody>
</table>

*Surpass Flow Diverter in the Treatment of Intracranial Aneurysms: A Prospective Multicenter Study.*
Surpass™ Flow Diverter (Stryker)

SCENT Trial

The Surpass IntraCranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms

• Multi-center (23 US sites)
• Single-arm
• Prospective
• Non-randomized
• PMA trial

For patients that have a single targeted intracranial aneurysm that:
• Is located in the internal carotid artery (ICA) distribution **up to the terminus**
• Has a neck >4 mm or no discernible neck and an aneurysm size >10 mm (including saccular, fusiform and dissecting configuration)
Aneurysm Scaffold Devices
Current Aneurysm Stents Embody 12 Year Old HDE Technology

Enterprise - Closed Cell Design

Neuroform - Semi-open Cell Design

Stroke. 2009; 40: e305-e312
Common Goals

- Improved wall apposition
- Increased surface area coverage
- Resheathable
- Deliverable through standard coiling catheters
- PMA not HDE approval pathway
Liberty™ Stent System
(Penumbra)
Liberty™ Stent System
(Penumbra)
<table>
<thead>
<tr>
<th>Stent</th>
<th>Approximate Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuroform, Enterprise</td>
<td>6%</td>
</tr>
<tr>
<td>Liberty</td>
<td>15%</td>
</tr>
<tr>
<td>Pipeline, Silk</td>
<td>30%</td>
</tr>
</tbody>
</table>
Liberty Clinical Trial Pathway

• Premarket Approval Pathway
• Single Arm Trial, 120 patients
• ICA Aneurysms only (per FDA guidance)
• Primary Endpoint: Complete occlusion (Raymond Scale 1) at 6 months without rupture, retreatment or parent artery compromise.
LVIS® Device Key Features (Microvention)

- Braided design
- Increased visibility
- Deliverable through Scepter Balloon
- LVIS®
- LVIS Jr. ®
- PMA trial ongoing
## LVIS vs. LVIS Jr. Device Comparison

<table>
<thead>
<tr>
<th>Attribute</th>
<th>LVIS</th>
<th>LVIS Jr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of wires</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>Implant Material</td>
<td>Nitinol</td>
<td>Nitinol</td>
</tr>
<tr>
<td>RO Material</td>
<td>Tantalum</td>
<td>Tantalum</td>
</tr>
<tr>
<td>Headway MC Compatibility</td>
<td>21</td>
<td>17</td>
</tr>
<tr>
<td>No. of Flared Ends</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>No. of Helical RO Wires</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Implant Wire OD</td>
<td>.0023-.0025”</td>
<td>0.0023 -.0025”</td>
</tr>
<tr>
<td>Retrievability up to</td>
<td>~80%</td>
<td>~75%</td>
</tr>
<tr>
<td>Foreshortening</td>
<td>30% max</td>
<td>22% max</td>
</tr>
<tr>
<td>Metal Surface Area (%)</td>
<td>22% max</td>
<td>18% max</td>
</tr>
<tr>
<td>Cell Size (mm)</td>
<td>~1.0mm</td>
<td>~1.5mm</td>
</tr>
<tr>
<td>Pusher Material</td>
<td>Nitinol</td>
<td>Stainless Steel</td>
</tr>
</tbody>
</table>
Competitive Neck Coverage Analysis

Average % Metal Coverage in vessels from 3.0 to 4.0 mm

- LVIS® Jr: 20%
- LVIS®*: 17%
- NeuroForm™*: 11%
- Enterprise™*: 10%
Visibility Comparison

Laser-Cut Stents: Visible only at ends

NeuroForm™ Enterprise™

The LVIS® & LVIS® Jr. Devices: Visible throughout the entire body, not just the ends

LVIS®
- Distal 4 markers
- Body 2 strands
- Proximal 2 grouped markers

LVIS® Jr
- Distal 3 markers
- Body 3 strands
- Proximal 3 markers
LVIS® Jr. Delivery Through Scepter Balloons

1 - Balloon assisted embolization

2 - After balloon deflation, if a coil prolapses into the parent vessel

3 – Deliver LVIS® Jr. device through the Scepter C® or Scepter XC® Balloon

4 – Deploy the stent

5 – The stent is placed in the parent vessel, trapping the coil in the aneurysm
PulseRider
(Pulsar Vascular/Codman Neuro)
PulseRider
(Pulsar Vascular/Codman Neuro)

- In conjunction with detachable coils
- Self-expanding, Nitinol, neck scaffold
- Fully retrievable
- IDE approval, study ongoing
- Seeking HDE approval for treatment of basilar tip aneurysms
Intra-aneurysmal Flow Diversion
Anatomy of Luna™ AES Implant (Covidien)

- Double layer, Nitinol Wire 0.001”
- Mesh basket
- Proximal & distal radiopaque markers (Platinum)
- 9 Sizes: 4.5 – 8.5 mm
Woven Endobridge (WEB) (Sequent Medical)

- Retrievable
- Nitinol