Venous Stents: What’s New?

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Faculty Disclosures

**Brian Schiro:** Speakers’ Bureau – Penumbra, Inc., Medtronic, Philips Medical, Sirtex; Research Support – Medtronic

*Brand names are included in this presentation for participant clarification purposes only. No product promotion should be inferred.*
Introduction

• Iliac vein stenosis
  – May Thurner
  – Post-thrombotic syndrome
  – Other extrinsic compression
    • Malignant
    • Fibrosis
  – Radiation
  – Iatrogenic

• Pathology should guide stent selection
Meta-Analysis: Venous Stenting

- Non-thrombotic (NT)
  - Iliac vein compression
  - May Thurner
- Acute Thrombosis (AT)
- Chronic Post Thrombotic (CPT)
- Technical success 94-96%
- Complications
  - 0.3% to 1.1% major bleeding
  - 0.2% to 0.9% for pulmonary embolism
  - 0.1% to 0.7% for periprocedural mortality

Chronic lower extremity edema, right > left
MRV shows large GSV varicose veins bilaterally, worse on the right.
Right external iliac artery passes anterior to the right external iliac vein.

Venous phase images show deformity of the right external iliac vein due to compression by the artery.
Off-Label Venous Stents

• Stents v1.0
  – Balloon expandable

• Stents v2.0
  – Wallstents®
  – Z-Stent®

• Stents v2.1
  – Nitinol Stents
    • SMART®
    • Others
    • Zilver®
    • Luminexx®
Right external iliac artery passes anterior to the right external iliac vein.

Venous phase images show deformity of the right external iliac vein due to compression by the artery.
Stent 2.1 – 14mm SMART® Stent
Follow-up

Before stenting

1 mo after stenting. Now here for GSV ablation (residual varicosities)
Stent Designs

• Biomaterial/biocompatibility
  – Stainless steel/cobalt chromium → Balloon-expandable
  – Nickle titanium alloy-Nitinol/Elgiloy® → Self expanding

• Cell design
  – Open Cell
  – Closed Cell

• Biomechanics
  – Chronic Outward Force → ability to expand vessel
    • AKA Radial Force
  – Radial Resistive Force → ability to withstand extrinsic compression
    • AKA Hoop Strength
  – Crush Resistance → ability to withstand axial load
# Cell Design

<table>
<thead>
<tr>
<th></th>
<th>Closed Cell</th>
<th>Open Cell</th>
<th>Hybrid</th>
<th>Braided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crush Resistance</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>++</td>
</tr>
<tr>
<td>Flexibility</td>
<td>-</td>
<td>++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td>Deployment</td>
<td>+</td>
<td>+</td>
<td>--</td>
<td>-</td>
</tr>
<tr>
<td>Radial Resistive Force</td>
<td>+</td>
<td>-</td>
<td>++</td>
<td>+/-</td>
</tr>
</tbody>
</table>

**Closed Cell**

**Braided**

**Open Cell**

**Wholey M. EV Today. 2007.**
Stent Fractures

- Repetitive stress
  - Areas of flexion
  - Twisting
- Elongation or shortening during deployment
- Stent overlap
Wallstent — Braided

**Pros**
- Woven mesh
  - COF when ends fixed
  - Crush resistance
- Elgiloy superalloy
  - Cobalt, chromium, nickel, and other metals
- Reliable – Largest experience in venous stenting
- Can be used in IVC and large veins

**Cons**
- Imprecision during deployment
- Marked shortening
- Weakness at edges
- Central compression results in elongation/foreshortening with dilatation
Z-Stent — Open Cell

**Pros**
- Short length
- Large openings allow for placement across venous confluences
- Large diameters for IVS
- Can be used to ‘anchor’ Wallstents

**Cons**
- Short length
- Rigid
- Large, valve-less sheath
- Potential erosion through veins
  - Barbed with high COF

Non-Venous Nitinol Stents — Open/Closed Cell

Pros
• More precise deployment
• Low-profile system
• Conformable
• Inexpensive

Cons
• Up to 14mm diameter
• Less COF
• Limited data on venous obstruction
The Ideal Stent

- Precise deployment
- Low profile delivery
- Short and long lengths
- Fracture resistant
- Flexible/conformable
- High radial resistive force
- Low chronic outward force
- High durability
Next Generation
Dedicated Nitinol Venous Stents

• Zilver Vena® – FDA Pending

• Venovo®

• Abre® – FDA Pending

• Vici®

## Venous Stent Devices

<table>
<thead>
<tr>
<th></th>
<th>Wallstent</th>
<th>Vici</th>
<th>Zilver Vena</th>
<th>Venovo</th>
<th>Abre</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stent layout</strong></td>
<td>Braided</td>
<td>Closed cell</td>
<td>Open cell</td>
<td>Open cell</td>
<td>Open cell</td>
</tr>
<tr>
<td><strong>Diameter, mm</strong></td>
<td>14, 16, 18, 20, 22, 24*</td>
<td>12, 14, 16</td>
<td>10, 12, 14, 16</td>
<td>10, 12, 14, 16, 18, 20</td>
<td>10, 12, 14, 16, 18, 20</td>
</tr>
<tr>
<td><strong>Stent lengths, mm</strong></td>
<td>60 (14–18), 70 (20, 24), 90 (14–18), 80 (20), 70 (24)†</td>
<td>60, 90, 120‡</td>
<td>40 (10, 12), 60‡, 100‡, 140‡</td>
<td>40, 60, 80, 100, 120, 140, 160‡</td>
<td>40 (10), 60‡, 80‡, 100‡, 120‡, 150‡</td>
</tr>
<tr>
<td><strong>Size, F</strong></td>
<td>10 (14, 16), 11 (18–22), 12 (24)</td>
<td>9</td>
<td>7</td>
<td>8, 9 (14), 10 (16–20)</td>
<td>9</td>
</tr>
<tr>
<td><strong>Delivery</strong></td>
<td>Coaxial</td>
<td>Coaxial</td>
<td>Coaxial</td>
<td>Triaxial dual thumbwheel</td>
<td>Triaxial thumbwheel</td>
</tr>
<tr>
<td><strong>Catheter working length, cm</strong></td>
<td>75*</td>
<td>100</td>
<td>80, 120§</td>
<td>80, 120§</td>
<td>90</td>
</tr>
</tbody>
</table>
Characteristics of Venous Stents

Chronic Outward Force: Caution Oversizing

Oversizing with Chronic Outward Force

- Chronic outward force of stent imparts Hoop stress on vessel wall
- Vessel wall injury leads to:
  - Stent induced vascular growth and remodeling
  - SMC proliferation and migration
  - Neointimal hyperplasia
  - Restenosis

# IDE Trial Designs

<table>
<thead>
<tr>
<th>Trial</th>
<th>VIRTUS</th>
<th>YIVO</th>
<th>VERNARULAR</th>
<th>ABRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device</td>
<td>Vici</td>
<td>Zilver Vena</td>
<td>Venovo</td>
<td>Abee</td>
</tr>
<tr>
<td>Type</td>
<td>Multicenter, single arm</td>
<td>Multicenter, single arm</td>
<td>Multicenter, single arm</td>
<td>Multicenter, single arm</td>
</tr>
<tr>
<td>Patients (N)</td>
<td>203</td>
<td>243</td>
<td>170</td>
<td>230</td>
</tr>
<tr>
<td>Eligibility</td>
<td>- CEAP &quot;C&quot; ≥ 3 and/or VCSS ≥ 2, AND, ≥ 50% iliofemoral venous outflow obstruction</td>
<td>- CEAP &quot;C&quot; ≥ 3 and/or VCSS ≥ 2, AND, ≥ 50% iliofemoral venous outflow obstruction</td>
<td>- CEAP &quot;C&quot; ≥ 3 and/or VCSS ≥ 2, AND, ≥ 50% iliofemoral venous outflow obstruction</td>
<td>- CEAP &quot;C&quot; ≥ 3, VCSS ≥ 2, and/or acute DVT, AND, ≥ 50% iliofemoral venous outflow obstruction</td>
</tr>
<tr>
<td>Imaging for eligibility</td>
<td>- Diameter reduction on venography</td>
<td>- Diameter reduction on venography</td>
<td>- Diameter reduction on venography</td>
<td>- Diameter reduction on venography/VUS or Area reduction on VUS</td>
</tr>
<tr>
<td>Acute DVT inclusion</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Patient cohorts</td>
<td>- Postthrombotic, Nonthrombotic</td>
<td>- Acute (&lt; 30d symptoms)</td>
<td>- Postthrombotic (including acute DVT), Nonthrombotic</td>
<td>- Acute DVT, Postthrombotic, Nonthrombotic</td>
</tr>
<tr>
<td>Primary effectiveness endpoint</td>
<td>12-mo primary patency Freedom from: - Reintervention - Occlusion, thrombosis - In-stent restenosis &gt; 50% by venography</td>
<td>12-mo primary patency Freedom from: - Reintervention - Occlusion, thrombosis - In-stent restenosis &gt; 50% by venography</td>
<td>12-mo primary patency Freedom from: - Reintervention - Occlusion, thrombosis - In-stent restenosis &gt; 50% by DUS</td>
<td>12-mo primary patency Freedom from: - Reintervention - Occlusion, thrombosis - In-stent restenosis &gt; 50% by DUS (confirmed by venography)</td>
</tr>
<tr>
<td>Safety endpoint</td>
<td>30-day MAE</td>
<td>30-day MAE</td>
<td>30-day MAE</td>
<td>30-day MAE</td>
</tr>
<tr>
<td>CE Mark</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Venovo (BD Bard)

- **VERNACULAR**
  - 88.3% weighted primary patency at 12 months
  - 96.9% patency in non-thrombotic lesions
  - 81.3% patency in post-thrombotic lesions
  - Zero stent fractures at 12 months
  - 100% acute technical success at time of index procedure

- Open cell design

- 3 mm flared stent ends are designed to reduce the risk of stent migration and maximize wall apposition

Vici (Boston Scientific)

• VIRTUS
  – 84% 12-month primary patency
  – 98.8% freedom from MAE through 30 days
  – 4.4 decrease in the VCSS score from baseline out to 12 months
  – Severe VCSS score from almost 66% down to 27%
  – 10/170 asymptomatic stent fractures (9/10 in CFV)

• Closed-cell geometry and high radial strength, without compromising flexibility or deployment accuracy

Zilver Vena (Cook)

- VIVO – Results Pending
- VIVO-EU
  - 87.9% freedom from occlusion
  - 97.8% Technical success
  - 70% improvement in luminal diameter
- Open-cell design

Biomechanics
- COF (+/-)
- RRF (-)
- CR (+/-)
Abre (Medtronic)

- ABRE IDE Trial – Results Pending
- Open-cell design with three connection points between the cells that are intended to enable flexibility and conformability

Biomechanics
- COF ?
- RRF ?
- CR ?
Conclusions

• Iliac vein compression is a common problem
• Guidelines needed for venous stenting
• New venous stents appear to have some improved performance profile over older generations
  – More data required
• Ideal treatments pending...
Thank You!