The Dynamics of Venous Stent Design

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Design Constraints

- Design inputs have real world constraints
- Requirements and constraints often compete
- The ideal design is unachievable
Engineering Requirements

- Crush Resistance
- Flexibility
- Radial Strength
- Deployment
- Scaffolding (Coverage)
- Diameters & Lengths

“The ideal stent would be flexible with moderate radial force, no foreshortening, and allow for very precise and accurate placement.” - Brooke Spencer, MD, FSIR

Some desirable features are common to all stents, not just venous devices, and include precise deployment, good visibility, and flexibility of both a low profile delivery catheter and the deployed stent. However, certain attributes are more suited for venous applications, such as larger diameters (≥14 mm) and appropriate levels of radial force and crush resistance.” - Mahmood K. Razavi, MD, FSIR

“The ideal stent has to be reasonably long and flexible, yet provide adequate radial strength to withstand opposing forces at the choke points.” - Seshadri Raju, MD, FACS

Venous Stenting: Expectations and Reservations; Raju S, Razavi MK, Spencer B, Williams DM, Endovascular Today, July 2013
Key Stent Features

**Chronic Outward Force:**
How much the stent pushes outward. Changes with diameter expansion. Often called Radial Force.

**Crush Resistance:**
How much the stent can resist a single load.

**Radial Resistive Force:**
How much circumferential load a stent can resist.
Radial Resistive Force

16mm Stent Radial Strength

Radial Resistive Force: How much circumferential load the stent can take
Crush Resistance

Closed Cell

- Stent Force (N) vs. Extension (mm)
  - Closed Cell - midpoint
  - Closed Cell - endpoint

Open Cell

- Stent Force (N) vs. Extension (mm)
  - Open Cell - midpoint
  - Open Cell - endpoint

Hybrid

- Stent Force (N) vs. Extension (mm)
  - Hybrid - midpoint
  - Hybrid - endpoint

Braided

- Stent Force (N) vs. Extension (mm)
  - Braided - midpoint
  - Braided - endpoint
It is principally about Radius

Suppose the original flowrate is 100 cm³/sec. The effect of changes in the parameters is as follows:

- Double length → 50 cm³/sec
- Double viscosity → 50 cm³/sec
- Double pressure → 200 cm³/sec
- Double radius → 1600 cm³/sec

\[ R = \frac{8\eta L}{\pi r^4} \text{ where } \eta = \text{viscosity} \]

\[ \frac{\text{Volume Flowrate}}{\text{Flowrate}} = \frac{P_1 - P_2}{R} = \frac{\pi(\text{Pressure difference})(\text{radius})^4}{8(\text{viscosity})(\text{length})} \]

A 19% increase in radius will double the volume flowrate!
Three Key Points

• May Thurner compression
• Confluence of the EIV and CIV in the pelvis
• Ligament and CFV

Secondary considerations
– Contralateral limb coverage
– IIV coverage

All these require different stent properties
## Competitive Designs

<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>Radial Strength</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>Scaffolding</td>
<td>++</td>
<td>-</td>
<td>--</td>
<td>+</td>
</tr>
<tr>
<td>Diameters &amp; Lengths</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
Not ‘Strong’ Enough

Arterial stent

Expanded with Venous Stent
Oblique Design
Contralateral Limb
<table>
<thead>
<tr>
<th></th>
<th>Acute iliofemoral DVT</th>
<th>Chronic post-thrombotic patients</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td></td>
<td></td>
<td>168</td>
</tr>
<tr>
<td>Males</td>
<td>66 (44%)</td>
<td>102 (43%)</td>
<td>168</td>
</tr>
<tr>
<td>Median age (yrs)</td>
<td>44</td>
<td>39</td>
<td>73</td>
</tr>
<tr>
<td>Left sided symptoms</td>
<td>52 (79%)</td>
<td>78 (76%)</td>
<td>130</td>
</tr>
<tr>
<td>Bilateral symptoms</td>
<td>8 (12%)</td>
<td>14 (14%)</td>
<td>22</td>
</tr>
<tr>
<td>Thrombolophilia</td>
<td>13 (20%)</td>
<td>36 (35%)</td>
<td>49</td>
</tr>
<tr>
<td>Pre-operative Venous Disability Score (0-3, median)</td>
<td>3</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>C-class 3</td>
<td>-</td>
<td>25 (25%)</td>
<td>-</td>
</tr>
<tr>
<td>C-class 4</td>
<td>-</td>
<td>57 (56%)</td>
<td>-</td>
</tr>
<tr>
<td>C-class 5</td>
<td>-</td>
<td>6 (6%)</td>
<td>-</td>
</tr>
<tr>
<td>C-class 6</td>
<td>-</td>
<td>14 (14%)</td>
<td>-</td>
</tr>
<tr>
<td>Pre-operative Villalta Score (non-ulcer)</td>
<td>-</td>
<td>15</td>
<td>-</td>
</tr>
<tr>
<td>Pre-operative pain</td>
<td>-</td>
<td>87 (85%)</td>
<td>-</td>
</tr>
<tr>
<td>Pre-operative swelling</td>
<td>-</td>
<td>88 (86%)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Local anaesthetic</strong></td>
<td></td>
<td></td>
<td>74</td>
</tr>
<tr>
<td>Total number of stents deployed</td>
<td>152</td>
<td>284</td>
<td>436</td>
</tr>
<tr>
<td>Median number of stents deployed</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Cook Zilver Vena (no of patients)</td>
<td>44 (67%)</td>
<td>28 (27%)</td>
<td>72</td>
</tr>
<tr>
<td>Veniti Vici (no of patients)</td>
<td>15 (23%)</td>
<td>54 (53%)</td>
<td>69</td>
</tr>
<tr>
<td>Wallstent (no of patients)</td>
<td>6 (9%)</td>
<td>14 (14%)</td>
<td>20</td>
</tr>
<tr>
<td>Other stent - Sinus XL, Sinus venous, Sinus-Obliquus (no of patients)</td>
<td>1 (2%)</td>
<td>6 (6%)</td>
<td>7</td>
</tr>
<tr>
<td>Stent crossing the inguinal ligament</td>
<td>25 (38%)</td>
<td>75 (74%)</td>
<td>100</td>
</tr>
<tr>
<td>EndoPhlebectomy (no of patients)</td>
<td>0</td>
<td>6 (6%)</td>
<td>6</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>17 (26%)</td>
<td>48 (47%)</td>
<td>65</td>
</tr>
</tbody>
</table>
What have we seen

- Stent compression at the May Thurner
- Fractures at the ligament
- No issues at the EIV/CIV confluence
- No IIV thrombosis
- No contralateral limb thrombosis
Conclusions

• The stent alone is not the panacea
• Know each device and technical issues
• Be honest in feedback and know this is just the beginning
• We need long term patient outcome data to support use
• We do not have data yet to know if this is durable
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