WHAT IS THE IDEAL VENOUS STENT

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Disclosures

• NOT AN ENGINEER

• Consultant: Veniti
• Options: Veniti

Venous Stenting is Not New...

• Significant body of clinical work
  • Existing stents (off label)...Wallstent
  • Good success treating venous outflow obstruction (peer review publications)
• Current generation of stents in USA IDE trials and available OUS
  • VIVO Trial – Zilver Vena (Cook Medical) 10/16
  • VIRTUS Trial – VICI VENOUS STENT (VENITI, Inc.) 11/16
  • Vernacular Trial – Venovo (Bard) started
  • Sinus Venous (Optimed) – No trial
  • Wallstent (BSC) – No trial
  • ??? Medtronic

Safety and efficacy of current designs

The “Perfect Venous Stent”

• Necessary “chronic outward force”
• Sufficient “radial resistive force” across length of stent
• Self-expandable
• Minimal foreshortening on deployment and balloon dilation

Competing Design Attributes ...
Trade-offs are inevitable...

• Sufficient flexibility not to kink at physiological angles
• Allow repeated shortening, twisting, and/or bending at the groin
• Longer stents to avoid overlapping of multiple stents

Stent Strength

Chronic Outward Force: How much the stent pushes outward. Changes in diameter expansion.
Crush Resistance: How much the stent can resist a single load
Radial Resistive Force: How much circumferential load a stent can resist

Radial Resitve Force

Stents were compressed radially.
Radial strength was measured during loading/compression (radial resistive force) and
unchanged post deployment (chronic outward force).
Radial Resistive Force:
How much circumferential load the stent can take (PT).

Crush resistance:
Each stent was crushed 50% of its diameter between a plate and silicone tube (simulated vein).
The force exerted by the stent was measured at the stent midpoint and endpoint.

Crush Resistance

- Wall Thickness (WT) vs Strut Width (SW) – high wall-to-strut aspect ratio results in high Crush Resistance of the stent.

Coverage

<table>
<thead>
<tr>
<th>Description</th>
<th>Material</th>
<th>Gap size (mm)</th>
<th>MCUSA (sq mm)</th>
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<tbody>
<tr>
<td>Coverage</td>
<td>Closed Cell</td>
<td>1.02</td>
<td>0.8</td>
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<td>Open Cell</td>
<td>2.36</td>
<td>4.5</td>
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<tr>
<td></td>
<td>Hybrid</td>
<td>2.54</td>
<td>5.1</td>
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<td>Braided</td>
<td>1.88</td>
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*Low MCUSA = better coverage

Uniform Strength and Shape

Consistent coverage, strength, and deployment.
**Sufficient Flexibility for Physiology**

- Braided stainless steel stent
- Hybrid design
- Venous Stent — closed cell structure

**Deployment**

Want…
+ Accuracy
+ Control
+ Ease of Use

Don’t want…
- “Jumping”
- Gapping
- Wrapping
- Excessive Foreshortening

**Design Features**

- High crush resistance
- End-to-end radial strength
- Consistent deployment
- Flexibility via alternating circumferential bridges
- Self-expanding nitinol

**Competitive Designs**

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<tr>
<th>Crush Resistance</th>
<th>Closed Cell</th>
<th>Open Cell</th>
<th>Hybrid</th>
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<th>Radial Strength</th>
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**Conclusion**

- Clinical requirements for a venous stent result in numerous engineering requirements
- Optimization of the ideal venous stent design is challenging because of competing requirements

**Finally**

- Arterial stents are not venous stents
- Venous anatomy and disease = trade-offs in stent design
### Conclusion

- Arterial stents are not venous stents
- Venous anatomy and disease = trade-offs in stent design
- Need to look at stent attributes holistically, not individually