New Dedicated Venous Stents: Design Attributes and Patient Outcomes

Lowell S. Kabnick, MD, RPhS, FACS, FACPh
I have the following potential conflicts of interest to report:

- Consultant: Bard, Veniti
- Stock: Veniti
- Speaker B: Boston Scientific
With the emergence of dedicated venous stents:

understanding the role of individual design elements (cell architecture, radial strength, flexibility) in performance of the stent

how this therapy improves patient outcomes is critical in continuing the treatment pathway
Why Stent Design Matters

Area is important, but...

For a Given Perimeter:

- Lumen shape impacts area
- Lumen shape impacts flow and pressure
- Aspect Ratio is a better predictor of stent performance and patient outcomes
Stent Strength

CHRONIC OUTWARD FORCE
Force stents exerts on vessel during expansion

CRUSH RESISTANCE FORCE
stent exerts as it resists external, focal or distributed loads

RADIAL RESISTIVE FORCE (RRF)
Force stent exerts as it resists constriction
Calculating Area of Shapes with Same Perimeter

Circle
\[ A = \pi R^2 \]

Ellipse
\[ A = \pi Ra \cdot Rb \]

R = Radius
P = Perimeter
AR = Aspect Ratio
A = Area

R = 7 mm, P = 44 mm, AR = 1
\[ A = 154 \text{ sq mm} \]

Ra = 9 mm, Rb = 4.5, P = 43 mm, AR = 2
\[ A = 127 \text{ sq mm} \]

Ra = 10 mm, Rb = 2.5, P = 43 mm, AR = 4
\[ A = 79 \text{ sq mm} \]

*Area Decreases as Shape becomes Flatter*
Relationship of Area and Shape, Pressure and Flow

- Large changes in flow are related to small systemic pressure changes
- Decreasing transmural pressure impacts both area and flow
- As shape becomes flatter, flow decreases, and pressure and turbulence increase
- Round vessels have less resistance and better flow

Poiseuille’s Law: Applies to a Perfect Circle

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

where \( \eta \) = viscosity

Suppose the original flowrate is 100 cm\(^3\)/sec. The effect of changes in the parameters is as follows:

- Double length \( \Rightarrow \) 50 cm\(^3\)/sec
- Double viscosity \( \Rightarrow \) 50 cm\(^3\)/sec
- Double pressure \( \Rightarrow \) 200 cm\(^3\)/sec
- Double radius \( \Rightarrow \) 1600 cm\(^3\)/sec

* With other parameters held at original values

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

Changing Shape, i.e. Aspect Ratio, Significantly Impacts Area and Volume Flowrate
How do we measure Aspect Ratio?
The Degree of Roundness

Aspect Ratio = Max Diameter to Min Diameter
Changes in Aspect Ratio: Impact on Area, Flow and Pressure (Holding Perimeter Constant)

Round = more area and less drag thus better flow

Pressure increases peripherally

Increasing flatness = less area and more drag thus less flow
2015 Publication Demonstrates that:
Better Patency Associated with Rounder Lumen

- 48 patients with iliac compression and acute DVT followed for avg. of 20 months
- Follow-up was performed with CT venography
- Stent compression considered significant if lumen compression was greater than 50%. (Aspect Ratio 1:2)
- Significant stent compression was inversely correlated with stent patency ($p < 0.001$).
Does Shape Result in Better Patient Outcomes?

- Healthy veins are highly compliant and change shape dynamically when pressure and flow change.

- VIRTUS Study – Feasibility and Pivotal Cohorts – Provides a rich database of patient imaging studies and outcomes.

- Is change in post-stenting vessel shape a predictor of patient outcomes?
VIRTUS IDE Study: Feasibility Cohort

<table>
<thead>
<tr>
<th>Patient demographics, n = 30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Female</strong></td>
</tr>
<tr>
<td><strong>Age</strong></td>
</tr>
<tr>
<td><strong>Baseline CEAP</strong></td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td><strong>Limb</strong></td>
</tr>
<tr>
<td>Left</td>
</tr>
<tr>
<td>Right</td>
</tr>
<tr>
<td><strong>Etiology</strong></td>
</tr>
<tr>
<td>NIVL</td>
</tr>
<tr>
<td>PTS</td>
</tr>
</tbody>
</table>
Deeper Dive into the VIRTUS Feasibility Cohort: Early Look at Lumen Shape and 12-month Patient Outcomes

IVUS Measurements utilized (pre and post stent):
- Cross-sectional Area
- Maximum Diameter
- Minimum Diameter

Aspect Ratio = \[
\frac{\text{Maximum Diameter (Major Axis)}}{\text{Minimum Diameter (Minor Axis)}}
\]
Statistical Analysis Design

Pearson correlation coefficients \( (r) \) measured the strength of the relationship between the following pairs of variables:

- Post-stent change in CSA and changes in 12 month VCSS
- Post-stent change in Aspect Ratio and changes in 12 month VCSS

Interpretation of correlation coefficients was per the following thresholds:

* \(-1\) = Perfect negative (i.e., downhill) linear relationship
* \(-0.70\) = Strong negative relationship
* \(-0.50\) = Moderate negative relationship
* \(-0.30\) = Weak negative relationship
* \(0\) = No relationship
* \(0.3\) = Weak positive relationship
* \(0.5\) = Moderate positive relationship
* \(0.7\) = Strong positive relationship
* \(1.0\) = Perfect positive relationship
Anatomic Measurements in Feasibility Cohort Before and After Stenting
(median measurements N=27)

<table>
<thead>
<tr>
<th></th>
<th>Pre Stent</th>
<th>Post Stent</th>
<th>Pre Stent to Post Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area, cm</td>
<td>43 (20-76)</td>
<td>130 (73-286)</td>
<td>74% (18%-448%)</td>
</tr>
<tr>
<td>Aspect Ratio</td>
<td>2.8 (1.2-5.3)</td>
<td>1.3 (1.1-2.2)</td>
<td>-45% (-77%–0.2%)</td>
</tr>
</tbody>
</table>

WE KNOW AREA IS IMPORTANT!

HOWEVER THE QUESTION IS WHETHER ASPECT RATIO IS A BETTER PREDICTOR OF PATIENT OUTCOMES
# VCSS - Our Metric to Assess 12-month Patient Outcome

<table>
<thead>
<tr>
<th>Metric</th>
<th>Score Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-stent VCSS score, n = 30</td>
<td>9 (2-25)</td>
</tr>
<tr>
<td>12-month VCSS score, n = 27*</td>
<td>4 (0-23)</td>
</tr>
<tr>
<td><strong>No. with 50% score improvement</strong></td>
<td>17 (63%)</td>
</tr>
<tr>
<td><strong>No. with symptomatic improvement (≥2 points)</strong></td>
<td>23 (85%)</td>
</tr>
<tr>
<td><strong>No. with any score improvement</strong></td>
<td>25 (93%)</td>
</tr>
<tr>
<td><strong>No. with no score change</strong></td>
<td>0 (0%)</td>
</tr>
<tr>
<td><strong>No. with score worsening</strong></td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Mean VCSS change (Pre-stent to 12 months)</td>
<td>5 (-2 – 14)</td>
</tr>
<tr>
<td>P value</td>
<td>&lt; .001</td>
</tr>
</tbody>
</table>

*Three subjects outside follow-up window 365 +/- 60 days*
Pre-Stent, Post-Stent and 12 month Changes in Aspect Ratio and Area were Performed

<table>
<thead>
<tr>
<th>Aspect Ratio (Max Dia : Min Dia)</th>
<th>Area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-Stent</td>
</tr>
<tr>
<td>2.51</td>
<td>82.68</td>
</tr>
<tr>
<td>1.33</td>
<td></td>
</tr>
<tr>
<td>1.23</td>
<td></td>
</tr>
</tbody>
</table>

Significantly Rounder Shape (1:1 is a Circle)

Increased Area
Relationship between post-stent vessel change and 12-month patient outcome

- One would expect a positive correlation between area change and clinical improvement, but not observed.
- Looking at the graphs - no clear pattern for area change, while change in Aspect Ratio is clearer.
- Moderately positive relationship between decreased ellipticity and clinical improvement.
- Patients with greatest luminal change – oval to round – Most likely to exhibit clinical improvement.
In Conclusion

- Changes to pre-stenting lumen shape may be more important than area
- Rounder post-stent lumen shape has positive correlation to 12-month patient improvement (VCSS)
- Stent design important – High crush resistance
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