Update on performance of venous stents for PTS patients

Michael K. W. Lichtenberg MD, FESC
Conflict of Interest - Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>1. Honoraria for lectures: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan</td>
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<tr>
<td>2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific</td>
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<td>3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow, Terumo</td>
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<tr>
<td>4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica</td>
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Venous Stent Options (CE)

- Boston Wallstent
- Cook Zilver Vena
- Medtronic ABRE

Stent Options:
- Wallstent
- Optimed
- VIVO (EU) Trial presented
- Veniti Vici
- SINUS obliquus
- VIRTUS Trial LINC 2019

Clinical Trials:
- Sinus Obliquus-01-NIS ongoing/Presented
- ABRE Clinical Study ongoing
- VERNACULAR Trial Presented
- Blueflow IP medical
- PMS ongoing
Conflicting Design Attributes = Trade-offs

- Self-expanding with sufficient chronic outward force
- Crush resistant across length of stent
- Sufficient wall coverage
- Predictable, consistent deployment
- Minimal foreshortening on deployment and balloon dilation
- Flexibility sufficient to resist kink at physiological angles
- Durability allowing repeated shortening, twisting, and bending at the groin

For venous obstruction, Crush Resistance is absolute!
Lichtenberg M, Endovascular Today 11/18, *Lumen Shape: A New Measurement to Consider in Treatment of Iliofemoral Venous Outflow Obstruction*

**Area and Flow vs. Aspect Ratio**

- Area Factor
- Flow Factor
- Pressure (mmHg)

Pressure vs. Aspect Ratio (1L/min, 100 mm)
14mm diameter vein, perimeter held constant
VIRTUS IDE Study (L. Kabnick, 2018)

$r = -0.50$

$p = 0.008$
ASPECT RATIO CORRELATES WITH PATENCY

Placement of closed-cell designed venous stents in a mixed cohort of patients with chronic venous outflow obstructions - short-term safety, patency, and clinical outcomes.
Lichtenberg M, Breuckmann F, Stahlhoff WF, Neglén P, Rick G.

Aspect ratio 1.2

Aspect ratio 1.8
...there is not a perfect venous stent for the whole system..
Different venous stents for different locations

High radial force

Radial force plus flexibility

Flexibility, kink resistance, low fracture rate
Wrong stent design for May-Thurner syndrome
Physical Properties of Venous Stents: An Experimental Comparison

Darius Dabir¹ · Andreas Feisst¹ · Daniel Thomas¹ · Julian A. Luetkens¹ · Carsten Meyer¹ · Ana Kardulovic² · Matthias Menne² · Ulrich Steinseifer² · Hans H. Schild¹ · Daniel L. R. Kuetting¹
VERNACULAR trial 12-month data show successful use of Venovo stent in obstructive lesions

- 12 month primary patency rate 88.3%
- VCCS improved by -1.7 in mean (p<0.0001)
- CIVIQ-20 score improved by -15.7 in mean (p<0.0001)
- Freedom from TLR: 92.6%
- No stent fractures reported by Yale Core lab

<table>
<thead>
<tr>
<th></th>
<th>ITT</th>
<th>PTS (N=93)</th>
<th>NIVL (N=77)</th>
<th>Total (N=170)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from TLR &amp; TVR, % (n/N)</td>
<td>87.6 (78/89)</td>
<td>98.6 (73/74)</td>
<td>92.6 (151/163)</td>
<td></td>
</tr>
<tr>
<td>Stent Fractures¹, % (n/N)</td>
<td>0% (0/72)</td>
<td>0% (0/65)</td>
<td>0% (0/137)</td>
<td></td>
</tr>
</tbody>
</table>
Venovo venous stent in the treatment of non-thrombotic or post-thrombotic iliac vein lesions - short-term results from the Arnsberg venous registry.

Lichtenberg MKW, de Graaf R, Stahlhoff WF, Özkapi A, Rassaf T, Breuckmann F.

80 patients all comers registry

Overall primary patency: 98%
Overall sec. patency: 100%
Medical history

45 y, female, BMI 23, no cv risk factors
10/2014: iliofemoral DVT (probably MTS associated)
Complains: persistent swelling, venous claudication (treadmill test 100 m)
Medication: Rivaroxaban 20 mg since 2015
Very compliant with stockings
Patency rates, safety and clinical results of the sinus-Obliquus venous stent in the treatment of chronic ilio-femoral venous outflow obstruction – data from the Arnsberg venous registry

Michael Lichtenberg¹,², Rick de Graaf¹, Wilhelm F. Stahlhoff¹, Ahmet Özkapl¹,², Maria Simon¹, and Frank Breuckmann²
sinus-Obliquus

Right CIA

Left CIV compression

Right CIA

sinus-Obliquus in left CIV
Two Year Outcome After Chronic Iliac Vein Occlusion Recanalisation Using the Vici Venous Stent®

Stephen Black a,*, Adam Gwozdz b, Narayan Karunanithy b, Justinas Silickas a, Karen Breen c, Beverley Hunt c, Alberto Smith a, Ander Cohen c, Prakash Saha a

<table>
<thead>
<tr>
<th>Patient characteristics (n = 88)</th>
<th>n (%) or median (range)</th>
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<tbody>
<tr>
<td>Age (y)</td>
<td>42 (13–83)</td>
</tr>
<tr>
<td>Male</td>
<td>28 (32)</td>
</tr>
<tr>
<td>Post-thrombotic syndrome</td>
<td>88 (100)</td>
</tr>
<tr>
<td>Thrombophilia</td>
<td>29 (33)</td>
</tr>
<tr>
<td>Factor V Leiden</td>
<td>14 (16)</td>
</tr>
<tr>
<td>APS</td>
<td>11 (13)</td>
</tr>
<tr>
<td>Protein S deficiency</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Anti-thrombin III deficiency</td>
<td>1 (1)</td>
</tr>
<tr>
<td>HbSC</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Bilateral treatment</td>
<td>13 (15)</td>
</tr>
<tr>
<td>Left leg only</td>
<td>69 (78)</td>
</tr>
<tr>
<td>Right leg only</td>
<td>6 (7)</td>
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Limb characteristics (n = 101)

<table>
<thead>
<tr>
<th>CEAP C class</th>
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<tbody>
<tr>
<td>C3</td>
<td>10 (10)</td>
</tr>
<tr>
<td>C4a</td>
<td>64 (63)</td>
</tr>
<tr>
<td>C4b</td>
<td>12 (12)</td>
</tr>
<tr>
<td>C5</td>
<td>3 (3)</td>
</tr>
<tr>
<td>C6</td>
<td>12 (12)</td>
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<tr>
<td>Villalta score</td>
<td>14 (5–33)</td>
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<tr>
<td>Vessel involvement</td>
<td></td>
</tr>
<tr>
<td>IVC</td>
<td>31 (31)</td>
</tr>
<tr>
<td>CIV</td>
<td>101 (100)</td>
</tr>
<tr>
<td>EIV</td>
<td>101 (100)</td>
</tr>
<tr>
<td>CFV</td>
<td>63 (62)</td>
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</table>

![Graph showing freedom from loss of stent patency over time with 82%, 73%, and 51% success rates at respective time points.](image)
Placement of closed-cell designed venous stents in a mixed cohort of patients with chronic venous outflow obstructions - short-term safety, patency, and clinical outcomes.

Lichtenberg M, Breuckmann F, Stahlhoff WF, Neglién P, Rick G.

- No clinical outcome difference between infrainguinal and suprainguinal stenting
- No significant patency difference between infrainguinal and suprainguinal stenting
- 5 stent compressions below the ligament
- 3 stent fractures close to/below the ligament
- Resolved by braided stents
Blueflow braided nitinol venous stent below the ligament
Take home message

- Use dedicated venous stents!
- Choose wisely - based on lesion morphology
- Choose wisely – based on stent technology
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