UPDATE ON VENOUS STENTS

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Disclosure

Speaker name: Michael Lichtenberg

I have the following potential conflicts of interest to report:
- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)
- [ ] I do not have any potential conflict of interest
Venous Stent Options (US)

- Boston Wallstent
- Optimed sinus Venous
- Bentley Beyound
- Cook Zilver Vena
- Veniti Vici
- Optimed sinus-XL flex
- Optmed Sinus obliquus
- BD Venovo
- Optimed Sinus-XL
- Medtronic ABRE
- Plus medica Blueflow
- Vesper
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!
...there is not a perfect venous stent for the whole system.
Aspect ratio of 2 impacts patency rate
Kabnick L, Lichtenberg M, Endovascular Today 11/18, Lumen Shape: A New Measurement to Consider in Treatment of Iliofemoral Venous Outflow Obstruction
<table>
<thead>
<tr>
<th>Study</th>
<th>Stented length 134.3mm</th>
<th>Stented length 100.6 ± 49.1mm</th>
<th>Stented length 149.8 ± 55.7mm</th>
<th>MLL 98.6±69.8mm</th>
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<tbody>
<tr>
<td>ABRE</td>
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<tr>
<td>Vernacular</td>
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<tr>
<td>VIRTUS</td>
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<tr>
<td>ZILVER US</td>
<td></td>
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</tr>
<tr>
<td>Primary Patency</td>
<td>88%</td>
<td>88.3%</td>
<td>84%</td>
<td>89.9%</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>N</td>
<td>Inclusion criteria</td>
<td>Primary Endpoint</td>
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<tr>
<td>ABRE</td>
<td>Multi-center, single arm</td>
<td>200</td>
<td>Acute and chronic outflow obstructions</td>
<td>12M Primary patency: *Freedom from Clinically-driven TLR, Occlusion In-stent restenosis &gt;50%</td>
</tr>
<tr>
<td>Vernacular</td>
<td>Multi-center, single arm</td>
<td>170</td>
<td>Acute and chronic outflow obstructions</td>
<td>12M Primary patency: *Freedom from: Reintervention, Occlusion, thrombosis, In-stent restenosis &gt;50%</td>
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<tr>
<td>VIRTUS</td>
<td>Multi-center, single arm</td>
<td>170</td>
<td>chronic non-malignant obstruction</td>
<td>12M Primary patency: *Freedom from Reintervention, Occlusion, thrombosis, In-stent restenosis &gt;50%</td>
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<tr>
<td>ZILVER US</td>
<td>Multi-center, single arm</td>
<td>243</td>
<td>Acute and chronic outflow obstructions</td>
<td>12-month primary patency: MLD was &gt;50% of the immediate post-procedure MLD</td>
</tr>
<tr>
<td>ZILVER EU</td>
<td>Multi-center, single arm</td>
<td>35</td>
<td>Acute and chronic outflow obstructions</td>
<td>12-Month Freedom from Occlusion</td>
</tr>
<tr>
<td>VIVID</td>
<td>Multi-center, single arm</td>
<td>175</td>
<td>Acute and chronic outflow obstructions</td>
<td>Freedom from ≥50% stenosis or occlusion within the stented segment(s) via DUS and confirmed by diagnostic IVUS</td>
</tr>
</tbody>
</table>
Real world long-term data

Visibility

Flexibility

Positioning

Radial force

Head to head comparison

Below the ligament outcome

e nsuring predictable landing zone and minimal foreshortening

Costs
Two Year Outcome After Chronic Iliac Vein Occlusion Recanalisation Using the Vici Venous Stent®

Stephen Black 9, Adam Gwozdz 9, Narayan Karunanithy 6, Justinas Silickas 9, Karen Breen 6, Beverley Hunt 6, Alberto Smith 6, Ander Cohen 5, Prakash Saha 3
- 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
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

Michael Lichtenberg, Frank Breuckmann, Wilhelm Friedrich Stahlhoff, Peter Naglön, and Rick de Graaf

Venous Centre, Klinikum Arnberg GmbH, Arnberg, Germany

Summary: Background: To evaluate the performance of a closed-cell designed venous stent for the treatment of chronic ilio-femoral venous outflow obstruction (VVO) in the short term. Methods: Safety, stent patency, and clinical outcome after placement of the VICI Venous Stent® in patients with chronic ilio-femoral venous obstruction were assessed retrospectively. Stent patency was evaluated by duplex ultrasound scanning, and clinical outcome was determined using the revised Venous Clinical Severity Score (VCSS) at 6 months. Results: 70 patients (54% female, median age 67 years, 82 limbs) with symptomatic significant VVO had stents placed in the ilio-femoral vein. Lower limb venous skin changes including ulcers (C-class in CEAP C 4–5) were found in 31 patients (41%). Nonthrombotic ilio-femoral lesions (NIVLs) and post-thrombotic obstruction (PTO) were found in 40 and 23 limbs, respectively. There were no safety issues. Cumulative primary, assisted-primary, and secondary stent patency in the entire cohort at 12 months was 84%, 94% and 96%, respectively. Four limbs presented with stent occlusion. Two limbs had no intervention, 2 limbs required patent after reintervention. Clinical improvement (decrease) of VCSS points was observed in 91%, 81% and 77% of patients at 1 month, 6 months, and 12 months, respectively. There was a marked drop in the frequency of more marked pain and swelling (VCSS ≥ 2) from 65% to 5% and 93% to 19%, respectively. Four limbs had venous ulcers, three healed during the follow-up. Cumulative primary stent patency at 12 months was 100% and 87% in patients with NIVLs and PTO, respectively (p = 0.033). There was no statistical difference in clinical outcome between these subgroups. Conclusions: The VICI Venous Stent® placed in the ilio-femoral vein segment in patients with symptomatic VVO revealed no safety issues, had excellent primary patency, and substantial symptomatic improvement. Long-term studies are needed to evaluate the durability of this stenting procedure.

Keywords: Chronic venous disease, stent, venous stenting, chronic obstruction, post-thrombotic syndrome, May-Thurner Syndrome

First report on our cohort of 90 patients for the VICI Venous stent in 2018
ONLY 5 patients with loss of patency during follow up

No loss of patency after 6 months

Means and Medians for Survival Time

<table>
<thead>
<tr>
<th></th>
<th>Estimate</th>
<th>Std. Error</th>
<th>95% Confidence Interval</th>
<th>Median</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
<td>1692.386</td>
<td>51.499</td>
<td>1591.448</td>
<td>1793.323</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>.</td>
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</table>

a. Estimation is limited to the largest survival time if it is censored.
Venovo venous stent for treatment of non-thrombotic or post-thrombotic iliac vein lesions – long-term efficacy and safety results from the Arnsberg venous registry

Michael K. W. Lichtenberg¹, Wilhelm F. Stahlhoff¹, Stefan Stahlhoff¹, Ahmet Özkapi¹, Frank Breuckmann², and Rick de Graaf³

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³ Radiology Department, Klinikum Friedrichshafen, Friedrichshafen, Germany

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2-year primary patency

Overall: 95.5% (95%CI 86.5 to 98.5)
NIVL: 95.5% (95%CI 82.5 to 98.8)
PTO: 96.0% (95%CI 72.7 to 99.4)
Log-rank p = 0.83

N=3 events:
Pat. #86 – 34 days (complete)
Pat. #19 – 59 days
Pat. #45 – 156 days
The story below the ligament: Stent Fracture and compression

• Fractures reported with many dedicated venous stents

• HYPOTHESIS: pseudointima growth holds strut rings in place, maintaining patency of stent

• Secondary intervention is angioplasty and/or re-lining with second stent
• Hand braided meshed stent made of two 0.22mm electropolished Nitinol wires.
• Braiding technique with two wires enables closed loop design.
• Each wire loops back when it reaches the stent tip, thus creating 14 radial force stable end loops.
• Two wires are welded together at two points in the center of the stent.
• Welds are only 5mm long and placed inside of the mesh to avoid any vessel contact.
Woven or laser-cut self-expanding common femoral vein stents for the treatment of the post-thrombotic syndrome

Data from the Arnsberg – Zürich Venous Registry
M. Lichtenberg, Tim Sebastian, Laura Moeri, Nils Kucher

Analysis of one-year patency rates of 150 PTS patients with stents placed into the common femoral vein. Patency rates were compared between patients in whom either laser-cut (n=101) or woven nitinol stents (n=49) were used to cross the inguinal ligament.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Laser-cut Overall (n=150)</th>
<th>Laser-cut Nitinol Stent (n=101)</th>
<th>Woven Nitinol Stent (n=49)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>44.3±16.4</td>
<td>43.3±16.6</td>
<td>46.4±15.9</td>
<td>0.270</td>
</tr>
<tr>
<td>Women</td>
<td>71 (48)</td>
<td>46 (46)</td>
<td>25 (52)</td>
<td>0.455</td>
</tr>
</tbody>
</table>
Kaplan Meier curve estimates for the assisted primary patency rate in PTS patients with stents extending into the common femoral vein
Kaplan Meier curve estimates for the secondary patency rate in PTS patients and stents extending into the common femoral vein.
Different venous stents for different locations

less options –
Low evidence