A Dedicated Venous Self-expanding Oblique Hybrid Nitinol Stent
(Sinus-Obliquus® Stent)

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Patency of iliofemoral vein stents

Primary patency

Secondary patency

--- Nonthrombotic
- - - Chronic postthrombotic
- - - Acute thrombosis

Mahmood K. Razavi et al. Circ Cardiovasc Interv. 2015;8:e002772
Patency of iliofemoral vein stents

<table>
<thead>
<tr>
<th>Etiology</th>
<th>Anatomic</th>
<th>Technical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-thrombotic venous obstruction</td>
<td>Adequacy of lower extremity venous inflow</td>
<td>Stent characteristics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diameter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Resistance to compression</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stent extension into IVC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Complete stenting of all disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wall apposition</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Routine use of IVUS</td>
</tr>
</tbody>
</table>

IVC, inferior vena cava; IVUS, intravascular ultrasound
Contralateral iliac vein thrombosis after May Thurner stenting using conventional stents placed into IVC

→ is it an issue or not?
Contralateral iliac vein thrombosis

• The rate of contralateral iliac vein thrombosis after conventional May-Thurner stenting with proximal position in the IVC is unclear because almost no study looked at long term data in patients with stopped anticoagulation therapy post stenting
  – After 5 years up to 10% with contralateral DVT with Wallstent

Murphy et al, J Vasc Surg Venous Lymphat Disord 2017;5:8-17
Iliac vein anatomy: Lateral view 90° hip flexion

90° kinking CIV

Challenge for Stents: Strength and Flexibility

Baekgaard et al, Phlebology 2013

Courtesy of Prof N. Kucher
Dedicated May-Thurner Stent: sinus-Obliquus® stent

Proximal closed cell design:
• Provides high radial force at compression site
• Oblique design (35°) prevents jailing off the contralateral iliac vein
• 4 markers for correct rotational positioning

Distal open cell design:
• Provides flexibility and less radial force for accommodating the curved anatomy of iliac veins during hip flexion
Dedicated May-Thurner Stent: sinus-Obliquus® stent

Visualized from behind
sinus-Obliquus® stent implantation
Objective

• We investigated venous patency rates and clinical outcomes of patients with iliac vein compression treated with this novel venous self-expanding oblique hybrid nitinol stent (sinus-Obliquus®, Optimed, Germany)
Bern Venous Stent Registry

• The Bern Venous Stent Registry is a prospective registry including all patients receiving venous stents at the University Clinic of Angiology in Bern, Switzerland.

• For this analysis, patients treated with sinus-Obliquus® Stent and minimal follow-up of 6 months were analyzed.
Results

• Study population
  – 24 patients: 20 women, mean age 39 ± 18 years
    • 10 with acute ilio-femoral DVT after catheter-directed thrombolysis
    • 10 with post-thrombotic syndrome (PTS)
    • 4 with non-thrombotic iliac vein compression
  – Mean Follow up was 10 months (range 6-18 months)
  – Mean time range between most recent DVT and intervention:
    • 10.3 years in patients with PTS
    • 7 days in patients with acute DVT

• Interventional details
  – 23 (96%) patients with stent implantation in left common iliac vein
  – 12 (50%) with distal stent extension in CFV (sinux-XL Flex)
Results: patency rates

- Primary patency estimates by Kaplan-Meier analysis were 92% at 6 months [95% CI 71-98%]
- Secondary patency was 100%.

Results: reinterventions

- Three symptomatic patients underwent reintervention for early and late stent thromboses and the third for in-stent restenosis.
- No stent fractures
- No contralateral DVTs
Results: clinical outcomes

- In 10 patients with PTS:
  - Villalta score decreased by 6 ± 6 points (P=0.02)
  - Revised Venous Clinical Severity score (rVCSS) decreased by 3 ± 1 points (P= .05)

- In 10 patients with acute DVT
  - all patients were free from the PTS at the latest follow-up
Conclusion

• Patency rates and clinical outcomes at 6 months in patients with common iliac vein compression treated with the sinus-Obliquus stents were excellent

• Further studies need to investigate the efficacy and safety of sinus-Obliquus stenting in a long-term perspective.
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