The SECURE Trial: Update on Perforator Ablation (Safety and Effectiveness Study: VenaCure Endovenous Laser Treatment (EVLT))

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Disclosures

• Research support provided by Angiodynamics

Primary Objective

• Primary Ablation performance goal (PG) of 70% of IPV

Secondary Endpoints

• Procedural technical success rate (successful access and entry into the IPV to be ablated and the ability to deliver the intended laser energy).
• 1, 3, 6, 9, and 12 Month primary ablation closure rates.
• Changes in Venous Clinical Severity Score (rVCSS), CEAP symptoms, quality of life from Baseline of procedure related adverse events (AEs)

Study design/Methods

• Design: Single-arm, prospective, multi-center (7 investigational sites) non-blinded clinical trial.
• Intent to treat population: 83 patients (125 perforators).
• Follow-up completion: December 2018
• Patients included: CEAP Class 4b, 5, 6 attributable to the IPV.
• Saphenous trunks either normal or previously treated.
• Only one limb treated. Multiple IPV within the study limb treated.

Incompetent Perforator Veins (IPV)

• Approx. 2/3 of limbs with skin changes have IPV as well as superficial or deep reflux.
• 63% of recurrent varicose veins are associated with IPV.
• SVS and AVF recommend treatment of perforating veins with reflux >500 ms and a vein diameter >3.5 mm for C2,6 (4b).
400 um Laser Fiber Kit

Kit Components:
- 21 gauge Needle
- .018” x 40cm guidewire
- 4Fr x 10cm sheath with "stiff" dilator
- 400µm optical fiber with Compression clamp

Photograph, courtesy of Angiodynamics
Results - Primary outcome & retreatment

<table>
<thead>
<tr>
<th>Performance Goal</th>
<th>Study result</th>
<th>p value</th>
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<tbody>
<tr>
<td>Initial/technical success</td>
<td>75%</td>
<td>95.2%</td>
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<tr>
<td>Closure rate 10 days</td>
<td>70% (Ref. literature)</td>
<td>76.8%</td>
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<tr>
<td>1 month</td>
<td>75.7%</td>
<td>N/A (0/0)</td>
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<tr>
<td>3 months</td>
<td>70%</td>
<td>0% (0/0)</td>
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<tr>
<td>6 months</td>
<td>64.4%</td>
<td>80% (6/8)</td>
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<tr>
<td>9 months</td>
<td>72.8%</td>
<td>82.5% (3/4)</td>
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<tr>
<td>12 months</td>
<td>76.5%</td>
<td>N/A (0/0)</td>
</tr>
</tbody>
</table>

Number of patients: 83 and Number of IPVs: 125

Secondary Reintervention:
- Direct ligation (1)
- Foam Sclerotherapy (1)
- Laser retreatment (12)

Adverse Events at 3 Months (93 patients)
- Deep vein thrombosis (2)
- Vein thrombosis [EHIT-ish] (1)
- Thrombophlebitis superficial (1)
- Skin ulcer (4)
- Entry site wound (1)
- Procedural pain (1)

Summary/Conclusions
- CHALLENGING PROCEDURE
- SVS/AVF guidelines recommend treatment for C5/6 disease, consider for C4b.
- SECURE trial showed 400 μm optical fiber with the 1470 nm laser had a superior closure rate.
- Trial led to FDA clearance of 400 μm optical fiber for the treatment of IPVs.
SeCure Study Status

✓ FDA clearance for the VenaCure Endovenous Laser Treatment
  400 µm Fiber Kit received in July 2018.
✓ Participant follow-up continues per the protocol until 12-month visit
  □ Last participant last visit in early December 2018
  □ Study Closure in February 2019
  □ Publication to be submitted 2019

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SeCure STUDY
PROSPECTIVE SAFETY AND EFFECTIVENESS STUDY

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