Effect of perforator ablation using the 400 μm optical fiber on venous healing and quality of life (SeCure trial)

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VEITH meeting 2018

Quality Of Life After SeCure PERFect

Dr. Gibson is a consultant for Medtronic, Vascular Insights, Vesper, and BTG and receives current research support from Medtronic, AngioDynamics, Bayer, and Vascular Insights. She is in the speaker’s bureau for Pfizer/Bristol Myers Squibb.

Disclosures

When to Treat? Current Guidelines

SVS/AVF recommendations for treatment of perforator veins in patients at risk for ulcer (C4b), healed ulcer (C5) or open ulcer (C6):

- Definition: Pathologic incompetent perforating veins
  1. Outward flow of ≥500 msec
  2. Diameter of ≥3.5 mm
  3. Located beneath a healed or open venous ulceration

- Suggest ablation of the incompetent superficial veins to prevent ulcer development or recurrence
- Perforator ablation can be performed simultaneously or staged if still incompetent on re-evaluation
- Grade 2C


Incompetent Perforator Veins (IPV) and Ulcer healing

- Homans et al. correlated the incompetent perforating veins to development of venous ulcers.
- Endovascular ablation has demonstrated good technical success and low complication rate.
- Most studies have focused on successful ablation of the vein rather than venous ulcer healing.
- Very few studies have investigated the effectiveness of perforator ablation in patients with venous ulcers.

C5/C6
C4

SeCure Study

A Prospective Clinical Study Evaluating the Safety and Effectiveness of the VenaCure Endovenous Laser Treatment (EVLT) 400 µm Fiber Kit for Ablation of Incompetent Perforator Veins

Primary Objective:
- The primary objective of this study is to compare the VenaCure EVLT primary ablation success rate to a performance goal (PG) of 70% of IPV demonstrating treatment success.

Secondary Endpoint:
- 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 (VCSS), quality of life from Baseline (VEINES) and pain measurements (VAS).
- Ulcer Healing:
- Incidence of procedure related adverse events (AEs).

Secondary Endpoint:
- 21 gauge Needle
- .018” x 40cm guidewire
- 4Fr x 10cm sheath with “stiff” dilator
- 400µm optical fiber with compression clamp

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 to Class 6 attributable to the IPV.
  - Saphenous trunks either normal, or previously treated.
  - Only one limb treated. Multiple IPVs within the study limb treated.

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Results: Demographics

- **Gender:** Female - 44.1% and Male - 55.9%
- **Race:** American Indian or Alaska Native 1.1%; Asian 2.2% Black or African American 9.7%; White 87.1%
- **Ethnicity:** Hispanic or Latino 6.5%; Not Hispanic or Latino: 99.2%
  Unknown: 4.3%
- **Weight (Kg):** 93.9 ± 19
  **Height (cm):** 175.9 ± 9
  **BMI (Kg/m²):** 30.3 ± 5
- **Mean diameter (mm):** 4.7 ± 1
- **Limb treated:** Left - 57%; Right - 43%

Results: rVCSS, VEINES QOL, VAS

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>rVCSS score</th>
<th>VEINES QOL</th>
<th>VAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>12.4 (4)</td>
<td>45.2 (10)</td>
<td>23.4 (26)</td>
</tr>
<tr>
<td>1 Month</td>
<td>9.9 (4)</td>
<td>50.8 (9)</td>
<td>14.5 (21)</td>
</tr>
<tr>
<td>3 Month</td>
<td>9.2 (4)</td>
<td>50.7 (10)</td>
<td>14.5 (21)</td>
</tr>
<tr>
<td>6 Month</td>
<td>8.7 (4)</td>
<td>52.7 (9)</td>
<td>10.6 (19)</td>
</tr>
<tr>
<td>9 Month</td>
<td>8.9 (4)</td>
<td>51.7 (9)</td>
<td>12 (19)</td>
</tr>
<tr>
<td>12 Month</td>
<td>8.7 (4)</td>
<td>51 (10)</td>
<td>14.7 (25)*</td>
</tr>
</tbody>
</table>

- Results are expressed as mean (Standard deviation).
- rVCSS, VEINES QOL and VAS scores are all on different scales.
- In all follow-up periods, rVCSS, VEINES and VAS scores improved from screening (p < 0.001)
- * Not statistically significant from screening.

Results: Ulcer healing

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Ulcer present</th>
<th>Total wound Surface (cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>22.9%</td>
<td>3.80(0.01, 38.5)</td>
</tr>
<tr>
<td>1 Month</td>
<td>14.1%</td>
<td>3.40(0.04, 10.5)</td>
</tr>
<tr>
<td>3 Month</td>
<td>13.7%</td>
<td>2.90, (72)</td>
</tr>
<tr>
<td>6 Month</td>
<td>8.5%</td>
<td>210.01, 20</td>
</tr>
<tr>
<td>9 Month</td>
<td>13%</td>
<td>2.703.35, 2.60(0.04, 29.25)</td>
</tr>
<tr>
<td>12 Month</td>
<td>12.8%</td>
<td>2.9, (29)</td>
</tr>
</tbody>
</table>

Total wound surface area is expressed as Mean (Standard deviation) and Median (min, max)

Results: Adverse Events

Following device/procedure related adverse events were reported during the clinical study up through the 3-month follow-up period. They include the following:

- Deep vein thrombosis (2)
- Vein thrombosis (1)
- Thrombophlebitis superficial (1)
- Skin ulcer (4)
- Entry site Wound(1)
- Procedural pain (1)

Summary/Conclusions

- Venous ulcers are most commonly associated with IPVs.
- SVS/AVF guidelines recommend treatment for C5/6 disease, consider for C4b.
- SeCure trial showed 400 µm optical fiber with the 1470 nm laser to be a safe and effective treatment modality for treating IPVs with improved quality of life.
- Trial led to FDA clearance of 400 µm optical fiber for the treatment of IPVs.