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

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Disclosures
• Angiodynamics
• Off label use

IPV contribution to ambulatory venous hypertension
- 70% of the IPV have hemodynamic significance
- 45% of perforators remain intact after saphenous ablation

DUTCH SEPS TRIAL*
- 200 limbs
- 97 SEPS
- 103 Compression
- FU: 27 months
- 72% ulcer free period
- 53%

Statistically significant:
SEPS > compression
*JVS 2006;44:563
ESCHAR TRIAL*  
Compression Alone vs Compression & Surgery  

500 Randomized  
68% Class VI  
32% Class V  

Pop Vein Reflux  
37%  
38%  

Compression  

% Healed  
(6 months)  

114/189  
76%  
128/156  
82%  
73/214  
34%  
32/214  
15%  

P< .001  

Pop Vein Reflux  

Ular Recurrence  
(14 months)  
(Median Fu)  

75/214  
34%  
32/214  
15%  

Review of IPV Ablation  

<table>
<thead>
<tr>
<th>Study Year</th>
<th>Time of Assessment</th>
<th>No. of IPV's</th>
<th>Occluded</th>
<th>Success Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacon</td>
<td>5 years</td>
<td>125</td>
<td>101</td>
<td>80.80%</td>
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<tr>
<td>Dumantepe</td>
<td>12 months</td>
<td>23</td>
<td>20</td>
<td>86.96%</td>
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<tr>
<td>Gabriel</td>
<td>Initial (time of ablation)</td>
<td>22</td>
<td>13</td>
<td>59.09%</td>
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<tr>
<td>Harlander-Locke</td>
<td>Initial (technical success)</td>
<td>9</td>
<td>6</td>
<td>66.67%</td>
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<tr>
<td>Harlander-Locke</td>
<td>Initial (technical success)</td>
<td>66</td>
<td>54</td>
<td>81.29%</td>
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<tr>
<td>Harlander-Locke</td>
<td>Initial (technical success)</td>
<td>66</td>
<td>50</td>
<td>76.94%</td>
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<tr>
<td>Harlander-Locke</td>
<td>1 year FU</td>
<td>124</td>
<td>101</td>
<td>81.45%</td>
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<tr>
<td>Harlander-Locke</td>
<td>3 months</td>
<td>18</td>
<td>9</td>
<td>64.96%</td>
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<td>18</td>
<td>9</td>
<td>64.96%</td>
</tr>
<tr>
<td>Harlander-Locke</td>
<td>1 week</td>
<td>25</td>
<td>23</td>
<td>92.00%</td>
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<tr>
<td>Harlander-Locke</td>
<td>12 months</td>
<td>82</td>
<td>70</td>
<td>82.68%</td>
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<tr>
<td>Harlander-Locke</td>
<td>1 month</td>
<td>68</td>
<td>42</td>
<td>67.60%</td>
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<tr>
<td>Harlander-Locke</td>
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<td>108</td>
<td>72</td>
<td>64.40%</td>
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Guidelines 4.20.0. of the American Venous Forum on Management of Incompetent Perforating Veins with Open and Endoscopic Surgery  

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<tr>
<th>Guideline</th>
<th>Grade of Evidence</th>
<th>Grade of Recommendation</th>
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<td>A</td>
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<td>4.20.2</td>
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<td>4.20.3</td>
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Guidelines 4.21.0 of the American Venous Forum on Percutaneous Ablation of Perforators  

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<th>Grade of Evidence</th>
<th>Grade of Recommendation</th>
</tr>
</thead>
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<td>4.21.1</td>
<td>C</td>
<td>2</td>
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We recommend percutaneous ablation of perforators (PAPS) using ultrasound guided sclerotherapy or thermal ablation as an outpatient procedure, performed in local anesthesia. It is repeatable with minimal morbidity.
SVS Guidelines

• Recommended against selective treatment of perforating vein in patients with simple varicose veins (C2) GRADE 1B
• Recommended treatment of Pathologic Perforating Veins (reflux >500 ms, vein diameter >3.5 mm, located underneath healed or active ulcers, C5-C6) GRADE 2B.

Lawrence P, et al.

• Endovenous ablation of incompetent perforating veins is effective treatment for recalcitrant venous ulcers
  • 75 ulcers
  • 90% healed when at least one perforator was closed;
  • no ulcer healed without at least one perforator being closed.

SEPS

What is the Best Method?

• Open subfascial ligation (Linton Procedure)
• Open suprafascial ligation
• Shearing devices
• Stripping and phlebectomy
• Endoscopic surgery (SEPS)
• Duplex Guided Sclerotherapy
• Duplex Guided RF Ablation

Suprafascial Ablation of Perforator Surgery

Linton—Annals of Surgery 1938

THE COMMUNICATING VEINS OF THE LOWER LEG AND THE OPERATIVE TECHNIC FOR THEIR LIGATION
Homer R. Linton, M.D.
Boston, Mass.

DUPLEX GUIDED RF ABLATION

SAPS

Open subfascial ligation (Linton Procedure)
Open suprafascial ligation
Shearing devices
Stripping and phlebectomy
Endoscopic surgery (SEPS)
Duplex Guided Sclerotherapy
Duplex Guided RF Ablation

Suprafascial Ablation of Perforator Surgery

SEPS

DUPLEX GUIDED RF ABLATION
RF procedure and data

- One-year outcomes of radiofrequency ablation of incompetent perforator veins using the radiofrequency stylet device. Phlebology April 2010 25: 79-84
- 124 IPV's
- 14 month FU
- 82% closed
- 50% clinically improved

IPV Laser Ablation

- 67 IPV's in 60 limbs
- Occlusion rate at day 1: 100%

Duplex Guided Laser vs. RF Ablation

- Murphy - ACP Annual Meeting, 2006
- 100 IPV's in each group
- Occlusion rate at 6 months
  - Laser: 100%
  - RF: <90%

400 µm Laser Fiber Kit

- Kit Components:
  - 21 gauge Needle
  - 0.018" x 40cm guidewire
  - 4Fr x 10cm sheath with "Stiff" dilator
  - 400µm optical fiber with Compression clamp
FDA - Clearance vs Approval

FDA Does Not Approve Devices

FDA Clears Companies to Market and Sell Products For The Indicated Use

Example of a Laser Indication:

Fiber Procedure Kits are intended for use in the treatment of varicose veins and varicosities associated with superficial vein reflux of the Great Saphenous vein, and with veins in the lower limbs with superficial reflux.

Does this Include Perforators in your opinion?

- Not in the eyes of the FDA

FDA - Clearance vs Approval

- FDA Does Not Approve Devices
- FDA Clears Companies to Market and Sell Products For The Indicated Use:
  - Laser Indication
    - "treatment of varicose veins and varicosities associated with superficial vein reflux of the Great Saphenous vein, and with veins in the lower limbs with superficial reflux"
  - NOT IPv4s
SeCure Safety 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.

• Multicenter study; a maximum of 7 investigational sites in the
• 86 Patients – 119-182 veins
• Primary Objective-IPV ablation at 10 days
• 3 month follow-up (CEAP, rVCSS, VeinsQoL, VAS)
• 12 months followup for publication

CEAP Class 4b to Class 6 attributable to the IPV

• ENROLLING NOW

VEITH 2016

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