Closurefast radiofrequency ablation for the treatment of GSV: Technique and outcome results

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Disclosure

Speaker name:
Stephen Black

I have the following potential conflicts of interest to report:
- Consulting: Medtronic, Cook, Optimed, Volcano, Veniti
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
System Components: ClosureFast Catheter

- 3 catheter sections:
  - Handle
  - Shaft
Heating Element

Lubricious outer jacket covers heating element and thermocouple
Closurefast™ Treatment Parameter Overview

- 20-second treatment cycles
  - Generator timer counts down from 20 to 0
  - Energy delivery automatically stops at end of cycle

- Device temperature: 120°C

- Maximum power: 40 Watts

- Impedance monitored internally by generator
  - Indicate uniformity of heating along coli
  - User prompted to make adjustments to external compression if necessary
ClosureFast ablation - Method of Action

- Vein wall heated via RF energy delivery to catheter heating element, resulting in:
  - Endothelial denaturation
  - Collagen contraction
  - Fibrotic sealing
ClosureFast segmental ablation procedure
ClosureFast full vessel wall fibrosis induction

Goat saphenous vein 12 wks post-ablation
## EVLA vs. ClosureFast: Continuous Pullback vs. Segmental Ablation

<table>
<thead>
<tr>
<th>Endovenous Laser Ablation</th>
<th>ClosureFast™ Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Continuous Pullback</strong></td>
<td><strong>Segmental Ablation</strong></td>
</tr>
<tr>
<td>- Used by endovenous lasers and some RF ablation systems (F-Care Systems)</td>
<td>- Used by the Venefit™ procedure delivered by the ClosureFast™ catheter</td>
</tr>
<tr>
<td>- Energy source is <strong>on</strong> throughout treatment</td>
<td>- Vein segment treated at one time</td>
</tr>
<tr>
<td>- Energy delivery <strong>varies</strong> by pullback speed as well as other factors</td>
<td>- No energy delivered during catheter pullback</td>
</tr>
<tr>
<td>- Small area treated at any given time</td>
<td>- Energy delivery does not vary by pullback speed</td>
</tr>
</tbody>
</table>

*Image source: Covidien R&D dept.*
RESULTS
500 patients (580 limbs) were randomized. All groups were similar in regards to baseline characteristics.
Kaplan Meier estimates – showing the percent of patients who were free from the following endpoints at 3 yrs *P<.0001 difference across all 4 groups

<table>
<thead>
<tr>
<th></th>
<th>RFA</th>
<th>EVLA</th>
<th>UGFS</th>
<th>Stripping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reflux-free*</td>
<td>93%</td>
<td>93.2%</td>
<td>73.6%</td>
<td>93.5%</td>
</tr>
<tr>
<td>Free of Recurrent Varicose Veins</td>
<td>85.1%</td>
<td>80%</td>
<td>80.9%</td>
<td>79.8%</td>
</tr>
<tr>
<td>Free of Reoperations*</td>
<td>88.9%</td>
<td>87.5%</td>
<td>68.4%</td>
<td>84.5%</td>
</tr>
</tbody>
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CONCLUSIONS
The author concluded that all treatment modalities were efficacious and resulted in a similar improvement in VCSS and QOL. However, more recanalization and reoperations were seen after UGFS
### CEAP at 36 months

<table>
<thead>
<tr>
<th>Overall</th>
<th>74.1% (189 limbs) showed an improvement when compared to pre-treatment (P&lt; .001)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3 &amp; C4</td>
<td>8%, a reduction from 46% at pre-treatment</td>
</tr>
<tr>
<td>C4 (skin changes)</td>
<td>4%, a reduction from 15% at pre-treatment</td>
</tr>
</tbody>
</table>
| C2     | 33.3% an increase from 12.5% at 12 months  
This may be due to the normal course of the disease or related to the study protocol prohibiting the treatment of thigh varicosities |

### VCSS at 60 months

<table>
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<tr>
<th>Pre-treatment</th>
<th>3.9 ± 2.1</th>
</tr>
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<tbody>
<tr>
<td>3-60 months</td>
<td>1.3 ± 1.7; P&lt;0.0001</td>
</tr>
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Conclusion

• Safe and effective treatment
• Straightforward
• Good long term data
• May be challenged by the NTNT techniques
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