Endovenous interventions for varicose vein disease – current status

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• Current
  – Medtronic – Consultant/ Speaker
  – Bard – Data Safety Committee
  – Cook – Consultant
  – Volcano – Consultant
  – Boston Scientific – Consultant/ Speaker
Endothermal techniques

- Laser -
  - Hemoglobin-specific laser wavelengths (HSLW)
    - 810, 940, 980, and 1064nm
  - Water-specific laser wavelengths (WSLW)
    - 1320, 1470 and 1510nm
  - 11 participating centers in the United States and Europe
    - 1020 limbs treated using a 980 nm bare-tip laser.
    - Life-table analyses revealed failure rates of 7.7% at 1 year, 5.4% at 2 years, and no additional reported cases of treatment failures at 3 years
  - WSLW better than HSLW lasers for post op pain an discomfort

Phlebology 2014, Vol. 29(1S) 55–60
Endothermal techniques

- RFA

*BJS 2015; 102: 212–218*
Non – Thermal (Non- Tumescent) Technologies

- Mechanical Occlusion Chemically Assisted (MOCA)
- Cyanoacrylate Embolization (CAE)
- Polidocanol Endovenous Microfoam (PEM)
- V Block Assisted Sclerotherapy (VBAS)
Inject 0.10 cc adhesive into the vein pull back 1 cm

Pull back 3 cm, compress for 30 secs

Inject 0.10, pull back 3 cm, compress 3 minutes

Repeat process throughout vein
Clinical Studies With CAE

**Feasibility Study**
- 38 Patients, enrollment completed Aug. 2011
- 1, 3, 6, 12, 24 and 36 month follow-ups
- Primary endpoint: Safety: rate of serious adverse events, Efficacy: vein closure during follow-up

**eSCOPE (European multicenter study)**
- 70 patients, enrollment completed Sept. 2012
- 2 day, 1, 3, 6, 12, 24 and 36 month follow-ups
- Primary endpoint: closure w/o use of sedation, tumescent anesthesia or compression stockings

**VeCLOSE (U.S. pivotal trial)**
- 242 patients, enrollment completed Sept. 2013
- 3 day, 1, 3, 6, 12 months & 2, 3 year follow-ups
- Primary endpoint: non-inferior to RFA in GSV closure
- Secondary endpoint: superiority in reduction of post-procedural pain and bruising
CAE eScope: European Multicenter Study

- 70 GSV – No tumescence – No compression
- 7 Centers
- 92.9% occlusion at 12 months
- VCSS – 4.3 to 1.3

# VeCLOSE Results
## 6 Month Closure Rate

<table>
<thead>
<tr>
<th>6 Month Visit (Site data)</th>
<th>Number with Non-closure (&gt;5cm)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFA (n=108)</td>
<td>6</td>
<td>94.3%</td>
</tr>
<tr>
<td>VenaSeal™ System (n=104)</td>
<td>1</td>
<td>98.9%</td>
</tr>
</tbody>
</table>

P<.0001
VeCLOSE Results

VCSS Mean & (SD) by Visit and Treatment

![Graph showing VCSS mean by visit and treatment over time. The graph compares VSCS and RFA treatments across Baseline, Month 1, Month 3, and Month 6 follow-up periods. The VSCS treatment shows a steady decrease in VCSS mean, while the RFA treatment shows a slight increase initially followed by a decrease.]
Mechanical Occlusion Chemically Assisted (MOCA): ClariVein™
MOCA: Wire
### MOCA – Peer-Reviewed Data

<table>
<thead>
<tr>
<th>Author/Journal</th>
<th>Title/Objective</th>
<th>Result/Conclusion</th>
</tr>
</thead>
</table>
| Bishawi et al Phlebology, 2013       | Prospective, multicenter study on MOCA in 126 Patients with lower extremity chronic venous disease | • Closure at 3 months = 98%  
• Closure at 6 months = 94%  
• No VTE  
• Significant improvement of VCSS score (p<0.001) |
| Boersma, et al European Journal of Vascular and Endovascular Surgery, 2012 | 1 year results of MOCA in the SSV in 50 patients                               | • Technical Success = 100%  
• Closure at 1 year = 94%  
• No major complications, no nerve injury  
• VCSS decrease from 3 to 1 |
| Van Eekeren, et al Journal of Vascular Surgery, 2013 | Prospective Observational Study 68 patients with GSV incompetence treated with either RFA or MOCA | • MOCA achieved 74% reduction in post operative pain compared to RFA  
• Lower post operative pain scores associated with significant earlier return to normal activity and work resumption |
| Elias, S, Raines JK Phlebology, 2011 | ClariVein system for ablation of the GSV Conducted in 30 legs                | • Mean closure at 260 days = 97.6%  
• Primary closure rate at 6 months is comparable to the best results with other techniques |
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| Sullivan, LP  | To determine the efficacy of MOCA in below the knee GSV in patients with persistent venous ulcers following above the knee GSV ablation | • Mean time to heal was 28 days  
• MOCA is effective in promoting ulcer healing in patients with persistent ulceration following above the knee ablation  
• Risk of nerve damage is reduced in the absence of thermal therapy  
• MOCA can be delivered directly to the veins feeding the ulcer |
| Phlebology    |                                                                               |                                                                                                                                                  |
| 2013          |                                                                               |                                                                                                                                                  |
| Moore, HM     | Retrograde mechanochemical ablation of the small saphenous vein for the treatment of a venous ulcer | • 3 month follow up had no report of pain or inflammation  
• Demonstrated improvement in symptoms  
• Ulcer decreased from 4 cm to 3 mm with granulation tissue at the ulcer base  
• VCSS score decreased from 16 to 12  
• Duplex exam showed an occluded SSV and competent deep system |
| Vascular, 2013|                                                                               |                                                                                                                                                  |
|               |                                                                               |                                                                                                                                                  |

Courtesy – Steve Elias, MD
Varithena® (polidocanol endovenous microfoam (PEM))

Safety evaluated in 1,333 patients in 12 clinical trials
Polidocanol Endovenous Microfoam (PEM) Versus Vehicle for the Treatment of Saphenofemoral Junction (SFJ) Incompetence (VANISH-2)

• n=230 pts
• Primary - improvement in symptoms (VVSymQ score) - 80%
• Tertiary (duplex response, venous clinical severity score (VCSS) and VEINES-QOL questionnaire)
• All endpoints met with all therapeutic PEM concentrations compared to placebo (p < 0.0001).
• % duplex ultrasound success rate -
  – 89% at visit 5/week
  – 73% at 1 year.

V Block: SFJ Occlusion
VBAS: Early Results

- 50 patients

- 4.6 month avg. follow-up (1 yr. results similar)

- 100% occlusion (46 pts.)

Kolvenbach R. VEITH 2014
<table>
<thead>
<tr>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOCA</td>
<td>Need to pullback/inject simultaneously</td>
</tr>
<tr>
<td></td>
<td>Valve tear/ stuck</td>
</tr>
<tr>
<td></td>
<td>Longest learning curve</td>
</tr>
<tr>
<td></td>
<td>Compression 5 days</td>
</tr>
<tr>
<td></td>
<td>No reimbursement codes in the USA</td>
</tr>
<tr>
<td>CAE</td>
<td>Foreign body (Avg ~1.3ml glue) left</td>
</tr>
<tr>
<td></td>
<td>Phlebitic reaction</td>
</tr>
<tr>
<td></td>
<td>Tortuous veins – difficult</td>
</tr>
<tr>
<td></td>
<td>Not reimbursed – Self pay</td>
</tr>
<tr>
<td>PEM</td>
<td>Requires 2 people for procedure</td>
</tr>
<tr>
<td></td>
<td>IFU – 2 weeks compression</td>
</tr>
<tr>
<td></td>
<td>Not indicated for SSV</td>
</tr>
<tr>
<td></td>
<td>No reimbursement codes</td>
</tr>
<tr>
<td>V BAS</td>
<td>Foreign body left</td>
</tr>
<tr>
<td></td>
<td>Shortest follow up</td>
</tr>
<tr>
<td></td>
<td>Smallest number treated</td>
</tr>
<tr>
<td></td>
<td>Tortuous veins - difficult</td>
</tr>
<tr>
<td></td>
<td>Compression 7 days</td>
</tr>
</tbody>
</table>
Current Status Summary

• Thermal ablative therapies are here to stay (for few more yrs at least)
  – Fast
  – Reimbursed
  – Safe

• Non – Thermal techniques are good potential options
  – Tortuous
  – Neovascularized
  – Active patients
  – Personal choice

• Adjunctive treatments – may still be required in advanced disease
Thank you
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