EVA Choices 2015 Update

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Disclosures

• Medtronic/Covidien Inc. – Medical Advisory Board
• Vascular Insights LLC – Medical Advisory Board
• LeMaitre Vascular – Consultant
• VVT Medical - Consultant

EVA Technologies: Categories*

• TT (Thermal, Tumescent)
• NTNT (Non Thermal, Non Tumescent)
• TNT – (Thermal Non Tumescent) – Holmium laser
• NTT – (Nom Thermal Tumescent) – S&L modern


TT and NTNT Technology

**Thermal Tumescent**
- Radiofrequency (RFA)
- Laser (LA)
- Steam (SVS)

**Non Thermal Non Tumescent**
- Mechanical Occlusion
- Chemically Assisted (MOCA)
- Cyanoacrylate Embolization (CAE)
- V Block Assisted Sclerotherapy (VBAS)
- Polidocanol Endovenous Microfoam (PEM)

RF CATHETER

RF: technology change
RF Segmental Ablation: 7 CM (or 3)

**RF GENERATOR/CATHETERS**

- **RF Segmental Ablation**
  - Standard energy delivery
  - Eliminates pullback rate
  - 7cm and 3 cm lengths
  - Simplified procedure
  - PAPS – technical challenge

- **Laser Sheath Introducer**
  - Laser Fiber

**TT: RF and Laser**

**Improved Technique/Technology**

**RF**
- Segmental ablation
- Standard energy delivery
- Eliminates pullback rate
- 7cm and 3 cm lengths
- Simplified procedure
- PAPS – technical challenge

**LASER**
- HSLW now WSLW better
- Fibers – jacketed, radial, tulip, etc
- Lower energy/less pain
- Less bruising – almost like RF
- PAPS – simple, easier

**CAE (Cyanoacrylate Embolization): NTNT**
CAE SYSTEM

CAE: Segmental NTNT Ablation

Clinical Studies with CAE

- **Feasibility Study**
  - 18 Patients, enrollment completed Aug. 2011
  - 1, 3, 6, 12, 24 and 36 month follow-up
  - Primary endpoint: safety, rate of serious adverse events, efficiency venous closure, follow-up

- **eSCOPE (European multicenter study)**
  - 70 patients, enrollment completed Sept. 2012
  - 1, 3, 6, 12, 24 and 36 month follow-up
  - Primary endpoint: closure w/o use of radiation, fluorescent mapping or compression stockings

- **VeClose (U.S. pivotal 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
  - Secondary endpoints: Superiority in reduction of post-procedural pain and bruising, feasibility

- **VeClose (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

CAE: Published Literature


Mechanical Occlusion Chemically Assisted (MOCA): Clarivein™

- **MOCA: Wire Unsheathed**

- **MOCA: Wire Unsheathed**
MOCA – Peer Reviewed Data

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<tr>
<th>Author/Journal</th>
<th>Title/Description</th>
<th>Result/Conclusion</th>
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| Bishawi et al, Phlebology, 2013 | Prospective, multicenter study on MOCA in 126 Patients with lower extremity chronic venous disease | • Closure at 3 months: 88%  
• Closure at 6 months: 96%  
• 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, Holowka, Physical Therapy 2011 | Quillkin system for ablation of the GSV Conducted in 10 legs | • Mean closure at 30th day = 98%  
• Primary closure rate at 4 months is comparable to the best results with other techniques |
| Mueller, RL, Vascular and Endovascular Surgery, 2012 | Literature review of MOCA relative to other ablation techniques | • MOCA addresses deficiencies of thermal ablation; reduced side effects, streamlining procedure and broadening applications |
| Sullivan, LP, Phlebology 2013 | 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 was effective in promoting ulcer healing in patients with persistent ulcers following above the knee GSV ablation  
• Risk of nerve damage is reduced in the absence of thermal therapy  
• MOCA can be delivered directly to the veins feeding the ulcer |
| Moore, HM, Vascular, 2013 | 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 |

Data Summary - 60,000 cases

- Closure -> 90% at 1-3 yr time (SSV/GSV)
- Elias – FIM 96% @ 3 yrs
- DVT < 0.5%
- No Nerve/Skin injury - NTNT

Clinical Trials

- Imperial College London UK RCT  
  Principal Investigator: Alan Davies
- Maastricht NL RCT  
  Principal Investigator: Cees Wittens
- Arnhem NL RCT  
  Principal Investigator: Michel Reijnen
- Histology Guilford UK  
  Principal Investigator: Mark Whitney
V BLOCK ASSISTED SCLEROTHERAPY (VBAS): NTNT

V Block: SFJ Occlusion

VBAS delivery system

VBAS: Technique

VBAS: Early Results
• 50 patients
• 4.6 month avg. follow up (1 yr. results similar)
• 100% occlusion (46 pts.)
• Kolvenbach R. VEITH 2014
NTNT: Special Considerations

- SSV, BK GSV, suprafascial – can go to malleolus
- C5 –C6 – antegrade (ankle) or retrograde tumescence hard to place
- AK GSV or AAGSV – anything works
- Minimal nerve/skin injury

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<tr>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
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<td>MOCA</td>
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| Uses approved liquid sclerosant | Longest learning curve
| Longest follow up on all NTNT | Compression 5 days
| Tumorous veins – angled wire | Perforations – PAPS
| Segmental ablation | Foreign body left
| Pullback rate variable eliminated | Phlebitic reaction
| Second longest follow up | Tortuous veins - difficult
| No post procedure compression | |
| CAE        |               |
| Uses approved liquid or foam sclerosant | Shortest follow up
| Shortest follow up | Compression 3 days
| Pullback rate variable eliminated | |
| No post procedure compression | |
| V BAS      |               |
| Uses approved liquid or foam sclerosant | Requires 2 people for procedure
| Pullback rate variable eliminated | IFU – 2 weeks compression
| Tumorous veins – foam traverses | Not indicated for SSV
| Treater branch varicosities also | |
| Perforations – PAPS | |

TT vs. NTNT (need both)

**TT (10-15%)**
- Big veins
- Good F/U
- Nerve - concern
- Patient comfort – tumescence (learning curve)

**NTNT (85-90%)**
- GSV/SSV/C6/BK GSV
- Shorter F/U but equal
- Nerve – no issue
- Patient comfort: better
- Shorter learning curve?