Mechanico-Chemical Ablation
Non-thermal, Non-tumescent Venous Ablation Therapy

Disclaimer

- Descriptions of brand name devices will be used during this presentation but do not imply endorsement of any particular device.
- Descriptions of billing codes are intended for reference only and should not be used for actual clinical use. Please refer to your own billing and collections departments for details.
- You are to be commended if you have stayed through the entire conference and still have the motivation to read this disclaimer all the way to the finish.
What is the problem?

Varicose veins are the result of poorly selecting one's grandparents.

- Sir William Osler, MD

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What is the problem?

C1: Telangiectasia or Reticular Veins

C2: Varicose Veins

C3: Edema

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CEAP Classification for Chronic Venous Disorders

C1: Telangiectasia or Reticular Veins

C2: Varicose Veins

C3: Edema

Images courtesy of Jennifer Heller, M.D.
### CEAP Classification for Chronic Venous Disorders

<table>
<thead>
<tr>
<th>CEAP Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C4a:</td>
<td>Pigmentation or Eczema</td>
</tr>
<tr>
<td>C4b:</td>
<td>Lipodermatosclerosis or Atrophie Blanche</td>
</tr>
<tr>
<td>C5:</td>
<td>Healed Venous Ulcer</td>
</tr>
<tr>
<td>C6:</td>
<td>Active Venous Ulcer</td>
</tr>
</tbody>
</table>

Images courtesy of Gordon Gibbs, M.D. and Jennifer Heller, M.D.

### What are the solutions?

- Conservative Therapies
  - Exercise
  - Leg elevation
  - Compression stockings
  - Unna boot
- Surgical Stripping
  - Phlebectomy
- Thermal Ablation
  - Radiofrequency Ablation
  - Laser Ablation

### Current Treatment Disadvantages

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>- Manually removes the vein segment from the leg</td>
</tr>
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</tr>
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<td>- Scarring</td>
</tr>
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<tr>
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<td>- Hematoma</td>
</tr>
<tr>
<td></td>
<td>- Thrombophlebitis</td>
</tr>
<tr>
<td></td>
<td>- Nerve injury</td>
</tr>
<tr>
<td></td>
<td>- Compression stockings</td>
</tr>
</tbody>
</table>

Complications of Thermal Ablation

<table>
<thead>
<tr>
<th>Complication</th>
<th>1 Week (N=395)</th>
<th>3 Months (N=371)</th>
<th>1 Year (N=350)</th>
<th>5 Years (N=279)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecchymosis</td>
<td>5.8%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Erythema</td>
<td>1.3%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1.0%</td>
<td>0.3%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Infection</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Pain</td>
<td>1.8%</td>
<td>0.0%</td>
<td>0.6%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>1.5%</td>
<td>2.4%</td>
<td>0.3%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

More Recent Treatment Options

- Non-thermal, Non-tumescent
  - Mechnochemical
  - Foam Sclerotherapy
- Non-thermal, Non-tumescent, Non-sclerostant
  - Cyanoacrylate adhesive

Chemical Ablation: Ultrasound Guided Foam Sclerotherapy (UGFS)
Polidocanol Endovenous Microfoam: VANISH 2 Study

Primary Endpoint
- Patient-reported improvement in symptoms, as measured by the change from baseline to week 8 in the 7-day average VVSymQ™ score.

Secondary Endpoints
- Included the improvement in appearance of varicosities from baseline to week 8, as measured by patients (using PA-V) and by a physician review panel (IPR-V).
- Improvement in VCSS, VEINES-QOL and occlusion/reflux were also assessed at week 8 as tertiary endpoints.

Randomized, multicenter
- Patients injected with polidocanol endovenous microfoam (PEM)
- 232 patients were randomized to:
  - PEM 0.125%
  - PEM 0.5%
  - PEM 1.0%

VANISH 2 Study – Results

Duplex ultrasound response at 8 weeks:

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Placebo</th>
<th>PEM 0.125%</th>
<th>PEM 0.5%</th>
<th>PEM 1.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duplex responder</td>
<td>1.1%</td>
<td>59.6%</td>
<td>86.3%</td>
<td>98.2%</td>
</tr>
<tr>
<td>The most commonly reported adverse events in %:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>10.0%</td>
<td>12.5%</td>
<td>7.5%</td>
<td>15.5%</td>
</tr>
<tr>
<td>Retained coagulum</td>
<td>0%</td>
<td>0%</td>
<td>3.5%</td>
<td>0%</td>
</tr>
<tr>
<td>Duplex ultrasound response</td>
<td>0%</td>
<td>0%</td>
<td>3.5%</td>
<td>8.6%</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>0%</td>
<td>0%</td>
<td>3.5%</td>
<td>8.6%</td>
</tr>
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<td>0%</td>
<td>3.5%</td>
<td>8.6%</td>
</tr>
<tr>
<td>CFVTE</td>
<td>0%</td>
<td>0%</td>
<td>1.7%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Pain in extremity</td>
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<td>12.5%</td>
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1 P < 0.001 compared to PEM 0.125%
2 P < 0.05 compared to PEM 0.125%
3 CFVTE – Common Femoral Vein Thrombus Extension. This is non-occlusive thrombi starting in the superficial vein and extending into the common femoral vein (similar to EHIT).

VANISH 2 Study – Summary

Percentage of patients treated with the 1.0% polidocanol solution experienced the following mild to moderate adverse events:

- Experienced retained coagulum: 15.5%, 27.6%, 8.6%, 6.9%
- Experienced a DVT: 7.4%, 0%, 3.3%, 1.7%

Duplex ultrasound response at 8 weeks:

- Percentage of patients treated with the 1.0% polidocanol solution experienced the following mild to moderate adverse events:
  - Experienced retained coagulum: 15.5%, 27.6%, 8.6%, 6.9%
  - Experienced a DVT: 7.4%, 0%, 3.3%, 1.7%
How do the VANISH 2 Study Results Compare to RFA?*

| Dietzek Study | VANISH 2 Study
|---------------|----------------|
| Multi-center  | Multi-center
| 326 patients  | 232 patients
| 99.6% occlusion at 6 months | 87.9% occlusion at 8 weeks
| 90.0% occlusion at 5 years | No data at 5 years

*ClosureFast long-term data is shown for perspective only and not meant to imply that the data can be used in a head-to-head comparison with the data from the Vanish 2 study.

Summary: UGFS
- Non tumescent
- Non thermal
- Less effective
- More side effects

Mechanico-Chemical Ablation (MOCA):
- Non-thermal
- Non-tumescent
- MOCA combines mechanical damage to the endothelium of the vein wall with the infusion of a sclerosant. (1)
**MOCA**

- Mechanical damage:
  - Promotes coagulation activation by minimal mechanical damage to the endothelium.
  - Induces vasospasm that reduces the diameter of the vein.
  - Increases the action of sclerosant by an increase in surface.
  - Ensures an even distribution of the sclerosant at the endothelium.

- Chemical Ablation
  - Liquid sclerosant produces irreversible damage to the venous endothelium.
  - Cellular membranes of the endothelium are damaged, creating endofibrosis.
  - This causes venous obliteration and thrombus development.
  - Damage of the endothelium depends on the concentration of sclerosant.

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**How does ClariVein™ work?**

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**ClariVein™**

- When a catheter/laser system, a needle or a plug is positioned within the vein, the surgeon's guidance allows the procedure to be performed accurately. At the same time, a laser or an ablation device is introduced through the lumen of the catheter to the target region, where it creates a scar that occludes the vein and terminates the reflux of blood in the vein.
Mechanochemical Tumescentless Endovenous Ablation (MOCA): Elias Study

- Prospective, single-center
- 30 GSVs in 29 patients
- Treated with Clarivein™ catheter
- Avg. diameter was 8.1mm
- Avg. length of treated segment was 37.5cm
- Avg. total procedure time was 14 minutes
- Follow-ups were 1 week, 1 month, 3 months, and 6 months post-procedure

Primary Endpoints
- Safety (measured through adverse events).
- Closure rate at 6 months.

Secondary Endpoints
- Procedural pain, post-proc pain, pain medication use, and degree of ecchymosis.

Elias and Raines
Mechanochemical Tumescentless Endovenous Ablation: Final Results of the Initial Clinical Trial. Phlebology 2012;27:67-72

*Trademark of its respective owner.

Elias Study – Results

- Closure Rate: 96.70%
- Duration: 260 days

Elias and Raines
Mechanochemical Tumescentless Endovenous Ablation: Final Results of the Initial Clinical Trial. Phlebology 2012;27:67-72
Summary of Clinical Efficacy

<table>
<thead>
<tr>
<th>Procedure</th>
<th>1 Year</th>
<th>5 Years</th>
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<tbody>
<tr>
<td>EVLA</td>
<td>87.3%</td>
<td>87.3%</td>
</tr>
<tr>
<td>MOCA</td>
<td>80.0%</td>
<td>80.0%</td>
</tr>
<tr>
<td>Foam sclerotherapy</td>
<td>94.2%</td>
<td>94.2%</td>
</tr>
<tr>
<td>Surgical stripping</td>
<td>80.0%</td>
<td>80.0%</td>
</tr>
</tbody>
</table>

What is the code for MOCA?

- **36473** Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance, percutaneous.
- **36474** (subsequent visit) Endovenous ablation therapy of first vein treated.

Summary - MOCA

- Non Thermal
- Non Tumescent
- Very few adverse side effects
- Safe and efficacious
- Reimbursement is available
What else is coming out?

Current Treatment Disadvantages

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<td>Nerve injury</td>
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Opportunities for Improvement

Elimination of:
- Tumescent anesthesia
- Post-procedure compression stockings
- Post-procedure pain and bruising
Cyanoacrylate: Venaseal™

- Non-tumescent
- Non-thermal
- Non-sclerosant

Safety of Cyanoacrylate Adhesives

- Widely used medical tissue adhesive.¹
- Antimicrobial effect against gram-positive organisms.²
- Used safely on millions of patients with no reported carcinogenicity in humans (1986 study).²

¹ Lawson et al. 
² Quinn J., Tissue Adhesives in Clinical Medicine, 2nd ed. (2005) p 34-35

Properties of Ideal Cyanoacrylate for Venous Closure

- Ideal viscosity
- Polymerize quickly
- Soft and elastic
- Maintains a strong bond
- Eliminate need for compression stockings*  

*Some patients may benefit from compression stockings post procedure.
How does it work?

- When cyanoacrylate (CA) comes in contact with blood or plasma, it begins to polymerize.
- The body encapsulates the polymer as a foreign body.
- CA triggers inflammatory reaction in the vessel wall resulting in occlusion.

Features of the VenaSeal™ Procedure

- Eliminates need for tumescent anesthesia.
- No risk of thermal injury.
- No post treatment compression stockings needed.¹ ²
- Rapid return to normal activities.²

VeClose (U.S. pivotal trial)

- Prospective, randomized 1:1 comparing the VenaSeal™ system (VSCS) to RFA (ClosureFast™ catheter).
- Demonstrate safety and effectiveness of the VenaSeal™ closure system (VSCS) for the treatment of lower extremity truncal reflux by showing non-inferiority at three months to RFA using the ClosureFast™ system.

Closure Rates

<table>
<thead>
<tr>
<th></th>
<th>3-Months:</th>
<th>6-Months:</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFA</td>
<td>94.3%</td>
<td>94.3%</td>
</tr>
<tr>
<td>VSCS</td>
<td>95.0%</td>
<td>94.3%</td>
</tr>
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</table>


2 Gibson, K. A Randomized, controlled study comparing cyanoacrylate adhesive embolization with radiofrequency ablation for treatment of incompetent great saphenous veins (VeClose study). German Society of Phlebology, 2014.

*Some patients may benefit from compression stockings post procedure.
Summary: VenaSeal™

- Non Thermal
- Non Tumescent
- Non Sclerosant
- Non compression stockings
- Safe and effective
- Very few adverse effects
- No distinct coding reimbursement at this time.

Conclusions:

- Thermal ablation is effective but has shortcomings that interfere with complete patient satisfaction.
- Safety and efficacy of ClariVein and VenaSeal is well supported, ultrasound guided foam sclerotherapy is not.
- Reimbursements are evolving to include these new techniques.
- Eliminating heat and the need for tumescent anesthesia and reducing or eliminating the need for compression stockings without compromising procedural success is another promising advance in the treatment of chronic venous disease.

References:

- Todd KL 3rd, et. al. The VANISH-2 study: a randomized, blinded, multicenter study to evaluate the efficacy and safety of polidocanol endovenous microfoam 0.5% and 1.0% compared with placebo for the treatment of incompetence. Phlebology; 2013 July 17.
- Rasmussen et al. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. BJS 2011;98:1079-1087.
Venous Symposium Wrap Up

- Chronic Venous Insufficiency and Varicose Veins are extremely common and remarkably under treated.
- Evaluation of lymphedema, varicose veins, and venous disease in general, relies on listening carefully to the history, examining the extremities, and obtaining a thorough venous duplex ultrasound with reflux testing.
- A multispecialty approach, including conservative therapy, wound care, and procedures, is essential for the successful treatment of chronic venous disease and its complications.
- Deep vein interventions and varicose vein pathology continue to be challenging, and Venous stasis ulcers require a lifelong commitment to maintenance compression therapy.
- Overall, treatment modalities for venous disease have evolved tremendously and continue to improve the patient’s outcomes with less risk and less morbidity.

Summary - Venous Symposium

- Overview
  - Robert Vorhies, MD
- Anatomy and Physiology
  - John Waites, MD
- Ultrasound Evaluations
  - Brent Wilkinson, RDMS
- Conservative Therapies
  - Julie Highfill, PA-C
  - Laura Ross, PA-C
- Lymphedema
  - Jan Weiss, PT, DHS, CLT-LANA
- Deep vein interventions
  - Randy Mullins, MD
- Venous stasis and ulcers
  - John Waites, MD
- pelvic congestion
  - Randy Mullins, MD
- Varicose vein procedures
  - Zak Schmittling, MD
- Mechanico-Chemical Ablation
  - Robert Vorhies, MD

Thank you

- Planning Committee
  - Lisa Boyer
  - Triesa Massey
  - Kristen Richner
  - Bryan Williams
  - Becky Watts
  - Leah Cook
  - Steve Shoemaker
  - Cathy Adams
  - Julie Highfill
  - Laura Ross
- Vascular Ultrasonographers
  - Brent Wilkinson
  - Sarah Hillman
  - Madison Holbein
  - Jaron Schmittling
  - Steve Shoemaker
- Vein Center Nursing Staff
  - Sara Miller
  - Sarah Hillman
  - Cody Johnson
  - Brad Hampton
  - Justin Thacker
  - Tia Johnson
  - Kayla Scantlin
- Vein Center Office Staff
  - Sarah Hillman
  - Laura Chumbley
  - Christa Lawrence
  - Ashley Goss
  - Vein Center Office Nurses
  - Crystal Price
  - Cindy Whitsell
  - Glenda Bostic
  - Cassie Lawrence
  - Lori Davis
See you next year. Tell a friend