New Technologies in Superficial Vein Treatment

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Ariel Soffer, MD, FACC – Bio


- Professor at Florida International University School of Medicine. Published the first article on the importance of venous insufficiency in the cardiovascular practice, Endovascular Today, 2007.

- Founder of "Soffer Vein & Vascular" (Cardiovascular-Based Multi-Specialty private practice with 8 offices throughout South Florida), and the Vein Experts Training Academy (www.vetavein.com)

- Co-Founder of AppwoRx™ - Patented clinical photography applications used heavily in the venous space.
PAID CONSULTANT FOR ALMA LASERS

PAID CONSULTANT FOR SIGVARIS

PRINCIPAL INVESTIGATOR FOR BTG’S VARISOLVE TRIAL
New technology has far reaching effects
What is Old, What is New and What may be the Future

Old

- 6th century BC
- Basic Stripping
- Compression
- Low Life Expectancy
Venous Insufficiency
What does VI typically look like?

**International Consensus CEAP**

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Clinical signs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>C₀S</strong></td>
<td>6</td>
</tr>
<tr>
<td>Heavy legs, pains in the legs, pruritus... But no clinical or palpable signs of venous disease</td>
<td>Telangiectasia or reticular veins</td>
</tr>
<tr>
<td>C₀S</td>
<td>C₁</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Venous oedema (without trophic changes)</td>
<td>Trophic changes of venous origin: atrofie blanche, pigmented purpuric dermatitis, varicose eczema</td>
</tr>
<tr>
<td>C₂</td>
<td>C₃</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Presence of one or more active venous leg ulcers, often accompanied by trophic changes</td>
<td><strong>C₅</strong></td>
</tr>
<tr>
<td>10</td>
<td>11</td>
</tr>
</tbody>
</table>

C₀ - C₆: description of the progression of the disease on the basis of the clinical signs present

C: clinical signs E: etiological classification A: anatomical distribution P: pathophysiological dysfunction
Did you know?

Most patients seek treatment to relieve symptoms rather than cosmetic concerns.
Multi-Disciplinary Care Diagnosis

Detection is very cost effective and treatment is relatively inexpensive.

H&P is simple and focuses on any leg discomfort and early vein appearance, skin changes or swelling.
Multi-Disciplinary Care Considerations

If undetected it can be mistaken for many ailments such as

- Restless Leg Syndrome
- Skin Diseases
- Non-Healing Wounds
- CHF (Bilateral Leg Edema) (Figure 1)
The intersection of VI (venous insufficiency) and CHF (congestive heart failure) with Edema represents an important and challenging area of differentiation.

The large areas of Edema with VI alone (without any CHF) represent areas of medicine that have potentially easily curable Edema and should not be mistaken for the less curable CHF that is treated completely differently.
Last Decade

New(ish) Therapies
- Radiofrequency Ablation
- Endovenous Laser Therapy
- Adjunctive Phlebectomy
- Advanced Sclerotherapy
RadioFrequency Ablation
RadioFrequency Advancement:
Stylet helpful with smaller vessels
Laser Advancement

HEATS THE VEIN WALL TO ABLATION TEMPERATURE FASTER FASTER

+ 1470nm wavelength is absorbed by water NOT hemoglobin - delivers faster ablation of the vein wall, with less energy thus reduced collateral damage such as bruising, burning, etc.
# Laser Therapy with Radial emission Vs. straight shooting fiber

<table>
<thead>
<tr>
<th>Strait shooting</th>
<th>Radial Emission</th>
<th>Perforation Risk</th>
<th>Safety</th>
<th>400 Micron Fiber</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>no</td>
<td>Perforation Risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>High</td>
<td>Safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>no</td>
<td>yes</td>
<td></td>
<td></td>
<td>400 Micron Fiber</td>
</tr>
</tbody>
</table>

- Low power density - Safe
- High Power Density – Risk of Perforation
Robotic Pullback Solution

*Robotic Pullback not FDA cleared in US
Polidocanol injectable foam - 1% Properties

- FDA approved
- Manufactured drug/device under
- Low density, sterile, cohesive microfoam has a mechanism of action which
  - Displaces blood from vein to be treated
  - Chemically ablates endothelial layer

- Proprietary soluble gas mixture
  - Low Nitrogen Content <0.8%
  - 65% O₂ / 35% CO₂
  - 1:7 Liquid to gas ratio by volume

- Small consistent bubble size
  - Median bubble size <100 μm
  - No bubble >500 μm

**Physician compounded foam (PCF)**

- Reported cases of patients with pulmonary embolism and neurologic events (including stroke) following treatment with PCF made with ambient air
- PCF is highly variable in concentration, gas composition, bubble size, stability, sterility, and drug used
Product Description

- Polidocanol injectable foam- 1% is a drug/device combination that generates injectable foam for intravenous injection using ultrasound guidance

- Available injectable foam delivers a 1% polidocanol solution. Each mL of injectable foam contains 1.3 mg of polidocanol

- One canister of PEM yields 45 mL of usable foam for injection when following instructions for use

- Use up to 5 mL per injection and no more than 15 mL per session

- Once activated, the canister of must be used within seven (7) days

- Manufactured in accordance with FDA Current Good Manufacturing Practices (cGMPs)

- Local anesthetic may be administered prior to cannula insertion, but neither tumescent anesthesia nor patient sedation is required
Mechanical Chemical Ablation
Recent Trial

MARADONA Trial (worlds worst acronym) (Mechanicochemical endovenous Ablation verseRADiOfrequeNcy Ablation)

Netherlands study with 460 Patients

Endpoint was comparability to thermal ablation with less discomfort

Showed equal results at 1 year with less procedural and post-procedural pain
Restrospective analysis of patients treated with proximal SFJ 1470nm Laser and distal Polidocinol Microfoam.

Patients experienced a significantly higher level of overall satisfaction of procedure at the 3 and 6 month interval with the combination procedure.
Glue for Veins
Glue for Veins
Cyanoacrylate Polymerization Structure

Proprietary Formulation

Microscopic view of the polymerized adhesive

Proprietary formulation of high grade medical cyanoacrylate-based adhesive designed to coapt the vein wall to treat venous reflex disease
European Multicenter Study eSCOPE

- **Objective:** To evaluate safety, efficacy of the Sapheon™ closure system for the treatment of refluxing great saphenous veins
- **Study Design:** Prospective, multicenter, non-randomized study
- **Subjects:** 70 patients enrolled, N= 70 GSVs treated
- **Follow-up:** 48 hours, 1, 3, 6 , 12 and 36 months
- **Primary Endpoints:** Duplex ultrasound closure without use of sedation, tumescent anesthesia or compression stockings
- **No adjunctive treatments for 3 months**

- **Closure Rates:**
  - 1 Year, 92.9%

Proebstle, T et al., The European Multicenter Cohort Study on Cyanoacrylate Embolization of Refluxing Great Saphenous Veins. JVS: Venous and Lymphatic Disorders 2014; Accepted for publication.
Managing clinical photos is a cumbersome process requiring a great deal of time to accurately catalogue and store.
Patient Engagement: Screenshots 1

Marketing & Education

Reports
Newly patented device provides feature rich clinical photography management on your mobile device, in the cloud, or directly through your EMR.
NCVH Vein Forum & V.E.T.A. Miami

Training Facility
Largest Vascular/Venous Training Facility in the U.S. Relocated in 2014 to New 30 Million Dollar facility near both Ft. Lauderdale and Miami International Airports.

Lodging & Entertainment
Adjacent Corporate Hotel and Entertainment Complex

Operating Theatre
Can comfortably accommodate multiple attendees with fully automated Operating Theater.

Vein Experts
Vascular, Cardiovascular and Interventional Radiology faculty professor/trainers.

CME Accreditation ICAVL accredited labs
Summary

• Superficial Venous Disease diagnosis and treatment may be one of the fastest evolving parts of medicine

• A multi-disciplinary approach is crucial to sustain optimal results and superior technologic advancement

• COME TO THE ANNUAL VEIN FORUM SATURDAY, MAY 30TH AT 8AM-4PM. FOR A POINTED DISCUSSION AND OPEN FORUM WITH EXCELLENT SPEAKERS FROM ALL AROUND THE WORLD.
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