Combination of Endovenous Thermal Ablation and Ultrasound Guided Foam Sclerotherapy:
Ariel D. Soffer, MD, FACC
Dr. Ariel David Soffer-Bio
NCVH Vein Forum

• Fellow of the American College of Cardiology since 1998 with training at Cedars-Sinai, Beverly Hills, USC/UCLA, and Harvard Business School.

• 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.veinamein.com)

• Co-Founder of AppwoRx™ - Patented clinical photography applications used heavily in the venous space.
Dr. Soffer’s relevant disclosures

- Consultant for Angiodynamics (2011-13)
- Consultant for Vascular Solutions (2007-10)
- Consultant for Sigvaris (2014-Present)
- Principal Investigator for BTG’s Varisolve Trial (2011-2013)
- Consultant for Alma Lasers (2014-Present)
• Facts
  • Endothermal Ablation (both Laser and RF) had reproducibly shown greater than 95% of the time, long term closure of the intended GSV in the recent literature.
  • Perforators are the most common cause of either failure of primary ablation or recalcitrant symptoms
  • Tumescence, although minimally uncomfortable, remains one of the most uncomfortable portion of the modern endovenous thermal ablative procedure
Innovative Treatment

Laser treatment

FEMORAL ARTERY
FEMORAL VEIN
LASER FIBER
GREAT SEPHENOUS VEIN
How Does Endovenous Laser Ablation (EVLA) Work?

+ During the procedure, light energy is delivered through a small laser handpiece to a targeted vein.
+ The light energy is absorbed by the lining of the blood vessels and the blood within the blood vessels.
+ The heat generated causes a coagulation (clotting) of the blood subsequently absorbed by the body.
### Technique – steps 1-3

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>STEP 2</th>
<th>STEP 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>The GSV is punctured just below the knee and the guide wire is located within the vein lumen</td>
<td>The correct position of the sheath is controlled</td>
<td>Intraoperative US imaging of the vein is of paramount importance</td>
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### Technique – steps 4-5

<table>
<thead>
<tr>
<th>STEP 4</th>
<th>STEP 5</th>
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<tbody>
<tr>
<td>The laser fiber will be introduced, through the sheath, within the vein lumen</td>
<td>The laser fiber is advanced toward the SFJ and the vein course is marked. This maneuver is useful in tumescent administration</td>
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</table>
The 1470 nm wavelength has largely become the endovenous treatment standard by providing the safest most effective, accurate treatment available for the treatment of great and small saphenous veins (GVS, SSV) particularly with a radial emitting diode.

+ Optimal 1470nm diode laser
+ 360° radial fiber deliverance
+ New Robotic pullback may reduce procedure time and maximizes treatment efficiency

*Robotic Pullback not FDA cleared in US
The Different Wavelengths

HEATS THE VEIN WALL TO ABLATION TEMPERATURE FASTER

+ 1470nm superficial penetration depth, absorbed by water NOT hemoglobin - delivers excellent ablation of the vein wall, with less bruising than alternative methods.
Radial Fiber Benefit Vs. Bare Fiber

Radial360
cone: 25-30°
d=1.8mm

Low power density, Safe, very good clinical results

Radial360
cone: 25-30°
d=1.8mm

Bare fibre
cone: 25°
d=0.6mm

Very high power density, perforation high risk
Quick Seal & Heal - the Radial Advantage

(360°) radial fiber delivers 1470 nm laser energy directly into the venous wall ensuring homogenous ablation, immediate sealing of the vein and faster wound healing. Once the diseased vein is sealed off, blood is re-routed to other healthy veins.

For treating different size veins radial emission fibers provides easy access for the even the most difficult veins.
- 400 micron radial emission fiber
- 600 micron radial emission fiber
## Radial emission Vs. straight shooting fiber

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

- **Low power density - Safe**
- **High Power Density – Risk of Perforation**
Conclusion

“We demonstrate that treatment of varicose veins with 1470-nm endovenous laser therapy is safe and effective. Compared with the bare fiber, the radial fiber reduces the energy requirement, adverse side effects, and patient discomfort at a comparable success rate. Thus, for future studies of the long-term outcome of endovenous procedures compared with surgery, the 1470-nm endovenous laser combined with radial fiber appears to be the most promising device.”
Robotic Pullback Solution

*Robotic Pullback not FDA cleared in US
Unique Robotic Pullback Device

+ **Automated control** of the lasing process
+ **Continuous real-time feedback** – with automatic complete feedback to the main unit for monitoring the pullback speed and distance accomplished along the vein
+ **Time-saving preset pull-back speeds** – adjustable for 1, 2, 3, or 4 nm/sec.
+ **Automatic “Pull & cool” model** – new treatment modality allowing for pre-set “cooling” breaks (stop time) at 1 cm intervals
+ **Robust pullback mechanism** – actively overcomes vein locking
+ **Safer Technology** – utilizing 1470nm Laser Energy with Radial Emission Fiber

*Robotic Pullback not FDA cleared in US*
Robotic Pullback Software
– full visualization and control

Easy tracking & measurement of fiber length and status course along the vein

Set Power

Set Pulling Velocity: ranges between 1-4 mm/sec

Set Pulling Length

Aiming Beam
Brightness Level

*Robotic Pullback not FDA cleared in US
Possibly a safer and more consistent technology

+ 1470nm Laser Energy with Radial Emission Fiber

+ The Robotic Pullback Control with new “Pull & Cool” Mode

“Pull & Cool” Mode - Set Stop Time –

Set on 0 indicates continuous pulling
For maximum safety and treatment control

*Robotic Pullback not FDA cleared in US
Potential for reduced treatment time

Physician can simultaneously track the fiber's course along the vein while treating other smaller varicose veins saving valuable procedure time.

This in turn, substantially shortens procedures - **one-third on average treatment time**- freeing the surgeon from the tedious physical labor required for pull back, to concentrate on treating smaller veins while easily monitoring the pullback process.

*Robotic Pullback not FDA cleared in US
Cost Savings

No need for dedicated introducer – compatible just standard grey 'Venflon accessory

No need for guiding catheters
Facts

- Historical foam data as well as recently presented data suggests that a limitation of sclerosant/gas treatment to truncal vessels might exhibit a long term re-opening rate that is somewhat greater than thermal ablation.
- Historical foam data suggested that deep vein thrombosis might have been seen at a somewhat higher rate. Current data suggests that with adequate junctional compression (along with other reasons) this DVT concern is less of an issue.
- No tumescence is typically used in foam treatment to truncal, branch or perforator vessels. However, foam seems to travel to many of these intended targets with relative frequency and ease of administration.
Combination Therapy: Hypothesis

- By combining the two techniques we may maximize the intended benefits while minimizing the unwanted side effects.
• Adequate, safe closure of the truncal Greater and Saphenous Vein
  • Additionally, as the proximal thermal procedure is done first it might yield the reduction in DVT’s due to immediate spasm of the truncal vessel and less likelihood of significant foam reaching the deep system.
• Reduce the amount of tumescence delivered, thus reducing overall procedural and post procedural pain.
• Reach and disrupt more residual pathologic venous vessels, thus more efficiently and completely treating patients venous insufficiency.
Retrospective review of 2176 patients seen between 2012–2013 (24 months)
Chart review (via our EMR, E-ClinicalwoRx)
NOT meant to be a proper scientific review presentation or publication. Only meant to give further support to our hypothesis that might inspire further properly designed research.
Pre-op Out of 2176 Patients

- 78% were female, 22% male
- Average age was 45.7 years old
- Average size of the GSV was 5.5 cm with over 3 seconds of reflux
- Average size of the SSV was 4.1 cm with over 3 seconds of reflux
- Average objective score (VCSS, CEAP, CIVIQ) was improved by greater than 33%
• Procedural experience
  • Average thermal burn length- 10.7 cm
  • Average thermal energy- 667 J
  • Delivered 73% with 1470nm and 27% with 940nm
  • Tumescence delivered generally under 50 cc of NS/1% lidocaine with Bicarb using power injector
  • Average of 6 cc of 1% polidocinol with 2:1 dilution of CO2 after laser ablations
Post procedural results (at 1 month).

- 98% occlusion rate of Greater Saphenous above the knee
- 95% occlusion rate of Greater Saphenous below the knee
- 99% occlusion rate of Lesser saphenous
- Pain Score was improved by greater than 33%
When compared to either Thermal Ablation alone or Ultrasound Guided Foam Sclerotherapy alone;

- Closure rate was significantly higher than foam alone, and slightly higher than thermal ablation alone.
- Discomfort (Pain Score) was reduced when measured at 1 week. At the 1 month interval Pain Score was not materially different.
- In all cases of foam usage a small but consistent percentage of patients required a Retained Coagulum Release (RCR) procedure. This routinely improved the Pain Score in these patients immediately.
Patients experienced a significantly higher level of overall satisfaction of procedure at the 3 and 6 month interval with the combination procedure.
Based on our non-scientific, retrospective review of one clinic's informal data, we have concluded that our hypothesis of combination therapy with thermal ablation and polidocinal foam is supported and we would hope to proceed with a formal, multi-center, prospective analysis in the future.
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Closing Remarks / Thank You
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