Treatments of Superficial Venous Disease: Endovenous Laser Ablation

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Disclosures

Speaker/Trainer/Advisory Board:

- Abbott Vascular
- BARD
- BSCI
- Cardinal Health/Cordis
- Cook Medical
- CSI
- Endologix
- Gore
- Lake Region Medical
- Medtronic
- Penumbra
- Phillips/Volcano
- Spectranetics
- Terumo/Bolton
Prevalence of Varicose Veins

• Vein problems are the most common chronic condition in North America

• 40% of Americans have varicose veins
  • Up to 56% men; up to 60% women

• More people lose work time from vein disorders than from arterial disease

• More than 20 million people in the United States suffer from varicose veins or spider veins

1 Vascular Medicine, Weinberg, May 2010
2 Phlebology, Robertson, 2008
3 Vascular Disease Foundation Newsletter, Spring 2005; Vol. 5, N2
What Causes Varicose Veins?

- Inherited genetic predisposition
- Normal aging process
- Hormonal changes that relax vein walls, which put women at a greater risk than men
- Conditions that put excess pressure on leg veins – including standing for long periods of time, obesity and pregnancy
- History of blood clots and conditions that increase pressure in the abdomen, such as tumors, constipation and tight garments
- Previous venous surgery
- Exposure to ultraviolet rays
The prevalence of venous disease is highest in western, industrialized societies

- 32.1% of English women cotton workers had varicose veins compared with 5.8% of Egyptian women workers
- Various studies documented VV prevalences:
  8% in Singapore
  1.2% in India
  6.1% in Tanzania,
  2-16% in Cook Islands, etc.
Heredity affects incidence of Chronic Venous Disease

- 134 families examined, including 67 patients and 67 controls and their parents
- Risk of developing VVs 90% if both parents affected
- 47% (25% for males and 62% for females) if one parent affected
- 20% if neither parent affected

Pregnancy confers an independent risk: More pregnancies ➔ more varicose veins

• Framingham 2yr incidence:
  P0-1: 45.7/1000
  P2-3: 53.2/1000
  P>3: 59.2/1000

• 405 women with VVs
  13% had 1 pregnancy
  30% had 2 pregnancies
  57% had 3 or more
(Mullane DJ, Am J OB Gyn, 1952,63:620)
Work may be hazardous to your venous health

• Most studies show that prolonged standing or sitting increases the prevalence and severity of venous disease
• 2854 factory workers, in those with varicose veins:
  65.5% stood
  29.2% sat
  6.3% walked

Santler R, Hautarzt 1956;10:460
Conservative Care

- Compression Stockings

Compression therapy is frequently the first and most conservative step in the management of varicose veins. In fact, insurers often require that patients undergo conservative compression therapy prior to becoming eligible for reimbursement for the EVLT or other more aggressive varicose vein treatments. Compression stockings are also often used following those same treatments to promote healing by lessening pain, swelling and bruising.

It is important to recognize that compression stockings can alleviate some symptoms of varicose veins but they cannot treat their underlying cause, failed valves (also called venous reflux). Even with faithful use of compression stockings, the disease may progress to the point that more advanced treatment is necessary.
Minimally Invasive Options

- Endovenous Laser Treatments (EVLT)
- Radiofrequency Ablation (RFA)
- Phlebectomy
- Sclerotherapy
- Stripping & Ligation
Endovenous Laser Treatment (EVLT) is a 30 – 45 minute, in-office procedure requiring only local anesthetic and enables patients to return to normal activity immediately – with little or no pain.
Endovenous Laser Treatment (EVLT)

- EVLT for the elimination of varicose veins is quickly becoming the gold-standard in the treatment of varicose veins.

- EVLT uses laser energy, which is simply a highly concentrated beam of light. Medical lasers work by delivering this light energy to the targeted tissue with extreme precision, so as not to affect the surrounding tissue. Lasers have proven their safety and effectiveness through years of use in all types of medical procedures, from eye surgery to dermatology. In the hands of a skilled physician, lasers offer far less risk for complications than conventional surgery.

- In EVLT, a thin fiber is inserted into the damaged vein through a very small entry point in the skin. A laser light is emitted through the fiber, as the fiber is pulled back through the vein, it delivers just the right amount of energy. The targeted tissue reacts with the light energy, causing the vein to close and seal shut.

- The veins that are closed are superficial veins that handle less than five percent of the body's blood flow. The blood is automatically routed to other, healthy veins.
The EVLT Procedure

Under local anesthesia, a catheter is placed in the vein through a needle.

The laser is passed through the catheter to the top of the vein.

After injection of additional anesthesia along the length of the vein, the laser is fired, and the catheter is withdrawn back out of small puncture site.
Endovenous Laser Treatment (EVLTT) Procedure
VEIN MAPPING
What Is VenaCure EVLT Treatment?

VenaCure EVLT laser treatment eliminates unsightly varicose veins with:
- No hospital stay
- Minimal-to-no scarring
- No lengthy recovery
- Minimal-to-no side effects

The VenaCure EVLT system uses targeted laser energy to seal the vein shut and help patients look and feel better fast.
Patient prepped for the procedure
Venous Access
Venous Access

Ultrasound-guided Access

Microintroducer
Guidewire Placement
Laser Fiber Placement
# Laser Fiber Placement

<table>
<thead>
<tr>
<th>Guidewire and Laser Fiber Placement</th>
<th>Guidewire and Laser Fiber Placement</th>
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</thead>
</table>

- **Skin:**
- **Guide wire**
- **65V**

![Image of Laser Fiber Placement](image)
Tumescent Fluid Infiltration
Tumescent Infiltration
Endovenous Laser Treatment

Laser in sheath

Laser On

Laser Energy → Heats Blood → Collapses Vein
Endovenous Laser Treatment

- **Safe procedure**
  - Complications are minor and self-limiting
- **Less painful**
  - The majority of patients experienced mild discomfort (1.5, range 0-5) in the early post-operative period
- **Less limiting**
  - Resumes work after 1.2 days
- **Relatively easy procedure (30 – 45 min)**
  - Local anesthesia
    - Treatment of varicose veins under local anesthesia is safe and yields satisfactory clinical and duplex outcome
    - Treatment of varicose veins can be performed safely with comparable results to general anesthesia in selected patients
EVLTT Evidence for Wound Healing
MORE THAN 20 NEW STUDIES SINCE 2010

KEY EVIDENCE

**NICE 2015 Guidelines: Most Effective Cost Coverage with Laser**

**Trial-based Cost-effectiveness Analysis**

**At 6 Months...**
- Foam had highest probability of being considered cost-effective at a ceiling willingness-to-pay ratio of £20,000 per QALY
- EVLA found to cost £26,107 per QALY gained versus foam, and was less costly and generated slightly more QALYs than surgery

**At 5 Years...**
- EVLA had the highest probability (≈ 79%) of being cost-effective at conventional thresholds, followed by foam (≈ 17%) and surgery (≈ 5%)

**Secondary Outcomes**
- Health gains at 6 weeks (p < 0.005) were greater for EVLA than for foam (EQ-5D, p = 0.004)

**Conclusions**
- EVLA should be considered as the treatment of choice for suitable patients

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**SUCCESS RATES AT 3 YEARS...**

"Endovenous Laser Therapy was significantly more effective compared with stripping, foam therapy, and radiofrequency ablation"^{1}

<table>
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<tr>
<th>Treatment</th>
<th>Success Rate</th>
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<tbody>
<tr>
<td>Foam Sclerotherapy</td>
<td>77%</td>
</tr>
<tr>
<td>Stripping</td>
<td>78%</td>
</tr>
<tr>
<td>Radiofrequency</td>
<td>84%</td>
</tr>
<tr>
<td>Endovenous Laser Treatment</td>
<td>94%</td>
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</tbody>
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Endovenous Laser Therapy in the Treatment of Lower-limb Venous Ulcers

Teo TK, et al.

Ulcer healing occurred as early as 1 week after the procedure in some patients.

Cumulative healing rates at 1, 3, 6, and 12 months were 82.1%, 92.5%, 92.5%, and 97.4%, respectively.

No ulcer had recurred at 1 year.
Role of Endovenous Laser Treatment in the Management of Chronic Venous Insufficiency

Sharif MA, et al.

EVLT was used to treat 23 limbs in 20 patients C5 or greater on the CEAP classification.

The cumulative 3- and 12-month healing rates were 87% (20/23) and 100% (23/23).

“These results demonstrate that EVLT, carried out in an outpatient setting, is effective in the treatment and prevention of chronic venous ulcers, with good patient satisfaction and no major complication.”
SUMMARY

OVER 20 KEY EVLT STUDIES have been published IN THE LAST 5 YEARS

EVLT is CONSISTENTLY CONCLUDED AS BEING MOST EFFECTIVE in the treatment and prevention of chronic venous ulcers

EVLT has NO MAJOR COMPLICATIONS

EVLT has GOOD PATIENT SATISFACTION
THANK YOU!
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Vein Forum