Endovenous 980-nm laser treatment of saphenous veins in a series of 500 patients

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Background: In recent years, endovenous laser treatment (ELT) has been proposed to treat incompetent great saphenous veins (GSV). This study reports the long-term outcome of ELT in a series of 500 patients.

Methods: Incompetent GSV segments in 500 patients (436 women, 64 men) with a mean age of 52.6 years (range, 19 to 83 years) were treated with intraluminal ELT using a 980-nm diode laser (Pharaon, Osyris, France). The GSV diameter was measured by Duplex examination in an upright position in different GSV segments (1.5 cm below the saphenofemoral junction, crural segment, condylar segment, and sural segment). These measurements were used to determine the optimal linear endovenous energy density (LEED) for each segment. During treatment, patients were maintained in the Trendelenburg position. Patients were evaluated clinically and by duplex scanning at 1 and 8 days, 1 and 6 months, and at 1, 2, 3, and 4 years to assess treatment efficacy and adverse reactions.

Results: A total of 511 GSVs were treated. The mean diameter was 7.5 mm (range, 2.4 to 15.0). The LEED was tuned as a function of the initial GSV diameter measured in the orthostatic position, from 50 J/cm (3 mm) up to 120 J/cm (15 mm). At the 1-week follow-up, 9.3% of the patients reported moderate pain. In the immediate postoperative period, the closure rate was 98.0% and remained constant during the 4-year follow-up to reach 97.1%. After 1 year, a complete disappearance of the GSV or minimal residual fibrous cord was noted. Major complications have not been detected; in particular, no deep venous thrombosis. Ecchymoses were seen in 60%, transitory paresthesia was observed in 7%. There was no dyschromia, superficial burns, thrombophlebitis, or palpable indurations. Complementary phlebectomy was done in 98% of patients. Failures occurred only in large veins (saphenofemoral junction diameter >1.1 cm or for GSV truncular diameter >0.8 cm)

Conclusion: ELT of the incompetent GSV with a 980-nm diode laser appears to be an extremely safe technique, particularly when the energy applied is calculated as a function of the GSV diameter. It is associated with only minor effects. Currently, ELT has become the method of choice for treating superficial veins and has almost replaced the treatment of traditional ligation and stripping. (J Vasc Surg 2007;46:1242-7.)

Lower-extremity venous insufficiency is a common medical condition afflicting 25% of women and 15% of men in the United States and in Europe. Great saphenous vein (GSV) reflux is the most common underlying cause of significant varicose veins. Traditional treatment of GSV reflux has been surgical removal of the GSV,1 however, recurrence in 30% to 60% of cases is reported,2 and it is also associated with significant perioperative morbidity.

Less-invasive surgical treatments, including high ligation of the GSV at the saphenofemoral junction (SFJ), have been attempted in the hope that gravitational reflux would be controlled while the vein is preserved for possible use as a bypass graft. Unfortunately, ligation of the GSV alone usually results in recurrent varicose veins. Recurrence has been the rule even when high ligation has been combined with phlebectomy of varicose tributaries or retrograde sclerotherapy. Therefore, when it is determined that GSV reflux is the principal underlying problem, treatment should involve eliminating this source of reflux with ablation of any associated incompetent venous segments.3

Although inadequate surgery of the saphenofemoral junction and progression of disease are mechanisms that explain some cases of recurrence, another important mechanism is neovascularization of the junction area after venous surgery. Histologic evidence has clearly shown that neovascularization is the principle cause of recurrence.4

Minimally invasive techniques have been developed within the last few years as alternatives to surgery in an attempt to reduce morbidity and improve recovery time. Endovenous laser treatment (ELT) is one of the most promising of these new techniques, and numerous studies have since demonstrated that it is safe and efficacious.

Several wavelengths have been proposed, respectively 810, 940, 980, 1064, and 1320 nm,5-9 with 810, 940 and 980 nm the most commonly used. At these wavelengths, power is usually set between 10 and 15 W. The energy is administered endovenously, either in a pulsed fashion (pulse duration, 1 to 3 seconds) with fiber pullback in 3- to 5-mm increments every 2 seconds or continuously with a constant pullback of the laser fiber at a velocity of 1 to 3 mm/s. At these settings, the average linear endovenous energy density (LEED) that is commonly used to report the dose administered to the vein is 20 J/cm to 140 J/cm.10,11 These doses induce heating of the vein wall, which is necessary to cause collagen contraction and de-
struction of endothelium. This stimulates vein wall thickening, leading to luminal contraction, venous thrombosis, and vein fibrosis.12

Tumescent anesthesia is always delivered, so patients feel no pain during ELT ablation at the suggested or commonly used laser settings. This tumescent anesthesia has the two functions of compressing and reducing the diameter of the veins as well as acting as a protective barrier, minimizing the risk of heat-related damage to adjacent tissues.13,14 The discomfort felt by patients occurs 5 to 8 min after the procedure and is related to the inflammation resulting from successful endovenous ablation (ie, wall thickening).15 It is not related to the presence or degree of ecchymosis nor is it the result of nontarget laser damage to periveneous tissue.

This study reports the effectiveness and safety of ELT of the GSV from a large number of patients from S.E.L. Angéio-Phlébo Interventionnelle, Lomme, France with long-term follow-up results.

MATERIALS AND METHODS

Patient selection. Directed history and physical examination, including an evaluation by duplex ultrasound imaging of the superficial venous system, was performed on limbs of subjects with GSV. Study inclusion criteria included varicose veins caused by SFJ incompetence with GSV reflux as demonstrated by duplex ultrasound imaging, age at least 18 years, and ability to return for scheduled follow-up examinations for 12, 24, 36, and 48 months after endovenous laser treatment. Exclusion criteria included nonpalpable pedal pulses, cardiovascular disease, inability to ambulate, deep venous thrombosis (DVT), general poor health; pregnancy, nursing, or plans to become pregnant to ambulate, deep venous thrombosis (DVT), general poor health; pregnancy, nursing, or plans to become pregnant; inability to continue their normal daily activities with vigorous work-outs. All patients received the nonsteroidal anti-inflammatory drug piroxicam (Feldene, Pfizer, New York, NY) for 5 days.

Follow-up examinations. Patients were re-examined at day 1 after the procedure, at 1 week, at 1 and 6 months, and at 1, 2, 3, and 4 years. Patients received duplex scanning and were re-evaluated functionally and clinically. Treatment-related side effects and complications were recorded. Symptoms of interest were the presence of ecchy-
mosis, palpable induration, phlebitic reaction, and pain. The duration of all symptoms was recorded.

**Statistical analysis.** Univariate Kaplan-Meier life-table analysis was used to calculate failure rate, and the 95% confidence interval of the survival rate was also computed. Statistical analysis was performed using SAS 9.1 software (SAS Institute Inc, Cary, NC).

**RESULTS**

Of the 500 patients who underwent ELT of the GSV, 436 were women and 64 were men, and their median age was 52.6 years (range, 19 to 83 years). A total of 511 limbs were treated, and according to the CEAP classification of venous disorders, 388 were C2EpAS2 (GSV above the knee) and 123 were C2EpAS3 (GSV below the knee).

The mean GSV diameter, measured in the orthostatic position, was 5.88 ± 2.23 mm (range, 2.4 to 15.0 mm). The mean length of GSV treated was 32.2 ± 14.4 cm (range, 15 to 86 cm). In the immediate postoperative period, successful occlusion, defined as vein occlusion with absence of flow, was noted in 501 GSVs (98%). This initial success rate remained almost constant during the follow-up period to reach 97.1% at 4 years (Table I, Fig). A total disappearance of the GSV or minimal residual cord was noted in 40% of patients at the 6-month follow-up, mainly in younger patients. At 1 year, a complete disappearance of the GSV or minimal residual fibrous cord was noted for all patients.

The analysis of failures (Table II) shows that the first group of patients with early failures (2- and 4-year follow-up) may have been due to inadequate initial treatments; however, most recurrences were seen at 6 months. In this series, failures occurred only in large veins (SFJ diameter >1.1 cm in diameter for GSV truncular diameter >0.8 cm in diameter). In three patients who had early failure, closure was noted at the 1-month follow-up. For these three patients, SFJ diameter was 9 mm and GSV truncular diameter was 6.5 mm.

Major complications have not been detected; in particular, no DVT. Ecchymoses were seen in 60%, with a median duration of 2 weeks. Transitory paresthesia was observed in 7% of treated legs, with a median duration of 2 weeks (maximum duration, ≤4 weeks). At 1-week follow-up, moderate pain was reported in 9.8% of the patients, and they received analgesics for 1 more week. No dyschromia, superficial burns, thrombophlebitis, or palpable indurations were observed.

The compliance rate for class 3 compression was 100% at 1 week and 70% at 3 weeks. This rate was assessed using a patient questionnaire at the 1-month follow-up.

**DISCUSSION**

Valvular incompetence of the GSV is the most common contributor to primary varicose veins. ELT of the GSV has been widely accepted, and numerous studies have been published. Studies with >400 patients and with a 4-year follow-up are very limited, however:

- In 2003, Min et al published results on 499 GSV in 423 subjects with varicose veins treated during a 3-year period with an 810-nm diode laser. Successful occlusion of the GSV, defined as absence of flow on color Doppler imaging, was noted in 490 of 499 GSVs (98.2%) after initial treatment, and 113 of 121 limbs (93.4%) followed up for 2 years have remained closed, with the treated portions of the GSVs not visible on duplex imaging. Forty subjects have been followed up for 3 years and no new recurrences were seen at 2 or 3 years that were not present at the 1-year follow-up.3

- In 2005, Duran presented a study including 517 GSV in 426 patients with a 24-month follow-up. Among 112 GSV followed up at least 24 months, 98% remained closed or reabsorbed.17

- In 2006, the Italian Endovenous-laser Working Group18 reported a cooperative multicenter clinical study in 1050 patients (1076 limbs) during a 6-year period but with only a 3-year follow up for all the centers using duplex scanning. Thus far, the total occlusion rate has been 97%.

- In 2007, Sadick and Wasser19 reported their 4-year experience with ELT plus ambulatory phlebectomy for

<table>
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<tr>
<th>Follow-up period</th>
<th>GSVs, No.</th>
<th>Successful treatment, %</th>
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<tr>
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GSV, Great saphenous vein.

Table I. Clinical results during 4 years of follow-up

Fig. Success rates. The numbers along the axis represent the numbers of veins available for analysis at intervals through the study. The dotted lines represent 95% confidence intervals. GSV, Great saphenous vein.
the treatment of superficial venous incompetence. The recurrence rate was, respectively 5.9%, 3.6%, 3.4%, and 0% at 1, 2, 3, and 4 years of follow-up. In this study, however, only 90 patients (94 limbs) were treated, and results are reported for only three patients at 4 years.19 Thus, the present study is one of the largest studies performed in a single center with a 4-year follow-up. The experience gained by our group through years has shown that the energy applied during treatment was the main determinant of success; hence, although not perfect, LEED remains our choice when comparing energy. We adapted LEED as a function of GSV diameter measured in upright position. Because thermal damage of the inner vein wall (tunica intima) is required to achieve the tissue alterations necessary to lead the vein to permanent occlusion, mathematic modeling of ELT has confirmed that LEED should be chosen as a function of the GSV diameter.20,21

In contrast to the mode of action of radiofrequency ablation as used in the VNUS closure system (VNUS Medical Technologies, Inc, San Jose, Calif), where a significant shrinkage of the vessel wall is observed, Proebstle et al22 has clearly demonstrated that when performing ELT, permanent occlusion, reported at ≥3 months, can only be obtained by thermal damage of the tunica intima inner vein wall. This observation was confirmed by the histologic study performed by Corcos et al23 after ELT with an 810-nm diode laser. They showed that when permanent occlusion was observed, the endothelium and intima were always damaged. The adventitia and the externa appeared to be involved in only a few of the specimens. They concluded that that success was independent of the vessel wall thickness.23

The role of blood during the ELT must be considered. Because the presence of blood could reduce the light transmitted to the vein wall, it is usually recommended to reduce the amount of blood by emptying the vein lumen using leg elevation by Trendelenburg positioning, perisaphenous subcutaneous tumescent saline solution infiltration, and manual compression. If the laser light energy is entirely absorbed by the blood, the initial success rate is mainly due to a thrombotic effect, but the thrombus dissolution leads to a recanalization.11

The proper tumescent anesthetic technique is essential for this procedure to be safe and painless. With ultrasound guidance, only 300 to 400 mL of fluid is required. The procedure is painless, and a surrounding fascial envelope of the tumescent solution provides a margin of safety so heat damage to surrounding structures does not occur.24

The principal finding in this study is that ELT with a 980-nm diode laser system, when performed under tumescent local anesthesia, is a clinically feasible and well-tolerated technique. Because vein access is with a 21-gauge needle, it is truly minimal procedure that leaves a nearly invisible scar on the patient’s skin.

The efficacy of ELT in obtaining early occlusion of the GSV is very satisfactory, with a 98.4% closure rate at the 1-month follow-up. These results are very similar to those reported by other teams. A 97% closure rate was obtained by Proebstle et al5 with a similar follow-up. Min et al3 reported a 97% closure rate 1 week after initial treatment.

Table II. Patients with immediate and late failures

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GSV, Great saphenous vein; SFJ, saphenofemoral junction.
At 2-year follow-up, the closure rate was 97.8% in our series and 93.4% in the Min et al series. Repeated treatments were sometimes performed, however, which is not the case in our study, where patients were only treated once. Sadick et al obtained a closure rate of 96.4%. Duran obtained a 24-month follow-up on 112 GSV (611 initially), among which 98% have remained closed. Disselhoff et al reported that the treated GSV was not identifiable with duplex ultrasound in 89% and 90% of limbs at the 1- and 2-year follow-up, respectively. A complete disappearance of the GSV or minimal residual fibrous cord was noted in our study.

At 3-year follow-up, the total occlusion rate of GSV was 99.3%. This is similar to the 96.7% rate reported by Agus et al and the 96.6% rate of Sadick et al after 36 months. At 4 years, the closure rate was 97.1%. Sadick et al have obtained 100% occlusion, but with a follow-up on three patients only.

In our series, recanalizations were only observed when SFJ diameter was >1.1 cm or for GSV troncular diameters >0.8 cm. This observation is in agreement with mathematical modeling demonstrating that higher energy should be necessary to treat a larger GSV diameter. Several authors have proposed to use higher LEED to improve the closure rate. Proebstle et al observed that nonocclusion and early reopening of the GSV is energy-dependent.

Timperman et al compared patients treated with an average energy delivered of 63.4 J/cm (range, 20.5 to 137.8 J/cm) and a second group treated with 46.6 J/cm (range, 25.7 to 78 J/cm). They showed that failures were mostly associated with the lower LEED. However, treatment failures were also identified in patients who received doses of ≥80 J/cm or more. Energy delivery for the failures was 120, 80, 110, 98, and 80 J/cm (mean J/cm [SD], 98 [18]), respectively.

That failures were always observed when SFJ diameter was >1.1 cm or for GSV troncular diameter >0.8 cm, where the content of blood is very important even in the Trendelenburg position, confirms that laser irradiation was not sufficient to heat the vessel wall. One can hypothesize that blood remaining inside the lumen could absorb the laser light energy, limiting consequently the light transmitted to the vessel wall.

Side effects are also energy-dependent. Superficial burns and palpable indurations are sometimes associated with LEED >100 J/cm. In our study, LEED was chosen to obtain maximum efficiency but also to limit the treatment-related side effects and complications. No dysthromia, superficial burns, thrombophlebitis, or palpable indurations were reported in our study. These results confirm that our decision to adapt the LEED to the GSV diameter has led to a high rate of GSV closure while minimizing the side effects. The ecchymosis rate in our study was 60%, which is similar to the 61.7% rate reported by Sadick et al. It also compares favorably with the ecchymosis rates observed by Proebstle et al of 73.2% (940 nm, 15W, 1 second, pulsed), 78.2% (940 nm, 15W, continuous wave) and 81.2% (940 nm, 20W, continuous wave).

Most clinical studies published on ELT have not considered postprocedural pain. The difficulty with studies that evaluate pain is the significant variation in pain tolerance among patients. What may seem like “being sore” to one patient might be considered severe pain to another. Even objective measures such as carefully recording usage of pain medication can vary because patients have different pain tolerances. For example, Gibson et al reported pain in 97% of treated patients, and in the series reported by Proebstle et al, 72% of patients complained of pain. In their series, pain was treated with analgesics twice daily, and the median duration of pain and the demand for analgesics lasted usually 1 week (maximum duration, 2 weeks). In our series, analgesics were systematically given to the patients for 5 days, and at the 1-week follow-up, only 9.3% reported moderate pain.

Transitory paresthesia was observed in 7% of treated legs, with a median duration of 2 weeks. Huang et al noted paresthesia in 7.2% of patients. In another study, Proebstle et al reported an 11% incidence of paresthesia for 3 to 8 weeks after treatment, despite all patients being treated with low-molecular weight heparin and postoperative graduated compression for 8 days.

CONCLUSION

ELT of the incompetent GSV with a 980 nm diode laser appears to be an extremely safe technique, particularly when the energy applied is calculated as a function of the GSV diameter. It is associated with only minor effects. Currently, ELT has become the method of choice for treating superficial veins and has almost replaced the traditional treatment of ligation and stripping.

We acknowledge the contribution of Patrick Devos, PhD, Department of Biostatistics, University Hospital, Lille, France, for statistical analysis.

AUTHOR CONTRIBUTIONS

Conception and design: JD, CG, SM
Data analysis and interpretation: JD, BW, SM
Writing the article: SM
Critical revision of the article: JD
Statistical analysis: SM, BW
Obtained funding: no funding
Overall responsibility: JD, CG

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Mathematical modeling of endovenous laser treatment (ELT)

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Abstract

Background and objectives: Endovenous laser treatment (ELT) has been recently proposed as an alternative in the treatment of reflux of the Great Saphenous Vein (GSV) and Small Saphenous Vein (SSV). Successful ELT depends on the selection of optimal parameters required to achieve an optimal vein damage while avoiding side effects. Mathematical modeling of ELT could provide a better understanding of the ELT process and could determine the optimal dosage as a function of vein diameter.

Study design/materials and methods: The model is based on calculations describing the light distribution using the diffusion approximation of the transport theory, the temperature rise using the bioheat equation and the laser-induced injury using the Arrhenius damage model. The geometry to simulate ELT was based on a 2D model consisting of a cylindrically symmetric blood vessel including a vessel wall and surrounded by an infinite homogenous tissue. The mathematical model was implemented using the Macsyma-Pdease2D software (Macsyma Inc., Arlington, MA, USA). Damage to the vein wall for CW and single shot energy was calculated for 3 and 5 mm vein diameters. In pulsed mode, the pullback distance (3, 5 and 7 mm) was considered. For CW mode simulation, the pullback speed (1, 2, 3 mm/s) was the variable. The total dose was expressed as joules per centimeter in order to perform comparison to results already reported in clinical studies.

Results: In pulsed mode, for a 3 mm vein diameter, irrespective of the pullback distance (2, 5 or 7 mm), a minimum fluence of 15 J/cm is required to obtain a permanent damage of the intima. For a 5 mm vein diameter, 50 J/cm (15W-2s) is required. In continuous mode, for a 3 mm and 5 mm vein diameter, respectively 65 J/cm and 100 J/cm are required to obtain a permanent damage of the vessel wall. Finally, the use of different wavelengths (810 nm or 980 nm) played only a minor influence on these results.

Discussion and conclusion: The parameters determined by mathematical modeling are in agreement with those used in clinical practice. They confirm that thermal damage of the inner vein wall (tunica intima) is required to achieve the tissue alterations necessary in order to lead the vein to permanent occlusion. However, in order to obtain a high rate of success without adverse events, the knowledge of the vein diameter after tumescent anesthesia is recommended in order to use the optimal energy. As clearly demonstrated by our calculations, both pulsed and continuous mode operations of the laser can be efficient. An interesting observation in our model is that less amount of energy is required in pulsed mode than in continuous mode. Damaging the vein sequentially along its entire length may lead to permanent occlusion. However, the pulsed mode requires a very precise positioning of the fiber after each pullback and the duration of the treatment is much longer. For these reasons, continuous irradiation seems to be preferred by most clinicians. This model should serve as a useful tool to simulate and better understand the mechanism of action of the ELT.
Introduction

Lower-extremity venous insufficiency is a common medical condition afflicting 25% of women and 15% of men in the United States and in Europe. Great saphenous vein (GSV) reflux is the most common underlying cause of significant varicose veins. Traditional treatment of GSV reflux has been surgical removal of the GSV. Although surgical ligation and stripping of the GSV has been the most durable treatment, it is associated with significant perioperative morbidity. Less-invasive surgical treatments including high ligation of the GSV at the saphenofemoral junction (SFJ) have been attempted in the hope that gravitational reflux would be controlled while the vein is preserved for possible use as a bypass graft. Unfortunately, ligation of the GSV alone usually results in recurrent varicose veins. Even when high ligation has been combined with phlebectomy of varicose tributaries or retrograde sclerotherapy, recurrence has been the rule. Therefore, when it is determined that GSV reflux is the principal underlying problem, treatment should involve eliminating this source of reflux with ablation of any associated incompetent venous segments [1].

In an attempt to reduce morbidity and improve recovery time, several minimally invasive techniques have been developed as alternatives to surgery in the last few years. Endovenous laser treatment (ELT) is one of the most promising of these new techniques [2-4]. In 1999, Boné first reported the delivery of endoluminal laser energy [5]. Numerous studies have since demonstrated that this technique is both safe and efficacious. Several wavelengths have been proposed, respectively 810, 940, 980, 1064 and 1320 nm [6-10] with 810, 940 and 980 the most commonly used. At these wavelengths, power is usually set between 10 and 15 W. The energy is administered endovascularly, either in a pulsed fashion (pulse duration: 1 to 3 s with fiber pull back in 3 to 5 mm increments every 2 seconds) or continuously with a constant pullback of the laser fiber (pullback velocity ranging from 1 to 3 mm). At these parameters, doses applied range from 20 J/cm to 140 J/cm [11,12]. These doses induce an heating of the vein wall which is necessary to cause collagen contraction and destruction of endothelium. This stimulates vein wall thickening leading to luminal contraction, venous thrombosis and vein fibrosis [13]. Since tumescent anesthesia is always delivered, patients feel no pain during endovenous laser ablation at the suggested or commonly used laser parameters. The pain that patients feel occurs 5–8 days following the procedure and is related to the inflammation resulting from a successful endovenous ablation (i.e. wall thickening). It is not related to the presence or degree of ecchymosis nor is it the result of non-target laser damage to perivenous tissue. However, if greater doses of energy are delivered, the treatment is becoming painful.
perivenous tissues. Using another experimental model, Weiss showed that 100% of the laser (810 nm, 12 W, 1s-pulse duration) treated veins showed perforations.

Mathematical modeling of ELT may provide a better understanding of the ELT process and help determine optimal dosage as a function of vein diameter. Although many other models address the laser treatments of blood vessels (Port Wine Stains for example) or Interstitial laser therapy, the mathematical modeling of ELT is yet to be proposed [15-19].

The aim of this paper is to present a mathematical model using dynamic tissue changes based upon the Arrhenius damage model. Numerical simulations are compared to data previously reported in the literature. Optimal parameters emerging from these calculations can be taken in account for improving ELT clinical application.

**Materials and methods**

**Mathematical modeling**

An opto-thermal model of ELT consists of calculations of light distribution, temperature rise and the extent of thermal damage. The following sections describe the manner in which each stage has been implemented in our calculations.

**Geometrical description of the model**

The geometry used to simulate ELT was based on a 2D model consisting of a cylindrical blood vessel (radius: R) including a vessel wall (Thickness: T) and surrounded by infinite and homogenous tissue. Calculations were performed for different vein diameters (3, 5 mm) and at different distances from the center of the vein: in the tunica intima, in the tunica externa and at 1, 2 and 3 mm from the tunica externa.

The different vein diameters were chosen since Ultra Sound images recorded after tumescent anesthesia have clearly showed that vein diameters can reach up to 5 mm (figure 1).

Since, a cylindrical blood vessel is going to be symmetrical from its axis, a 2D section along this axis was considered sufficient for the purposes of calculation (figure 2).

**Light distribution in tissue**

The light emitted from the fiber inserted in the vein was modeled as an isotropically radiating point source. As previously proposed by Lizuka et al, spatial distribution has been considered to be dominated by scattering processes [20]. The light irradiance rate (W.mm⁻²) of an isotropic point source emitting \( P_{\text{Laser}} \) (W) within an infinite homogeneous medium can be expressed as

\[
\phi(r) = \frac{P_{\text{Laser}} \exp(-\mu_{\text{eff}} r)}{4\pi Dr} \tag{1}
\]

where: \( P_{\text{Laser}} \) : power of the light source

\( \mu_{\text{eff}} \) (mm⁻¹) : effective attenuation coefficient

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![Figure 3](image1.png)

**Figure 3**

Light distribution inside and outside a 3 mm vein when using a 600 µm fiber. The line illustrates where 10% of the initial light irradiance rate is obtained.

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![Figure 4](image2.png)

**Figure 4**

Damage obtained for two different wavelengths (800 nm and 980 nm) power: 12 W, CW, pullback speed : 1.5 mm/s, Energy: 80 J/cm, vein diameter: 3 mm.
$r$ (mm) : radial distance from the source

$D$ (mm): optical diffusion distance

$\mu_{\text{eff}}$ is determined by the following equation

$$\mu_{\text{eff}} = \sqrt{3\mu_a \left( \mu_a + \mu_s' \right)}$$ (2)

where $\mu_a$ (mm$^{-1}$) : absorption coefficient in tissue

$\mu_s'$ (mm$^{-1}$) : reduced scattering coefficient: $\mu_s' = \mu_s(1 - g)$

$\mu_s$ (mm$^{-1}$) : scattering coefficient

$g$ : anisotropy factor incorporating the effects of directionally dependent scattering.

$D$ (mm) is determined by the following equation:

$$D = \frac{1}{3(\mu_a + \mu_s')} = \frac{\mu_a}{\mu_{\text{eff}}}^2$$ (3)

$r$ is defined by the following equation

$$r = \sqrt{x^2 + z^2}$$

Where: $x$ (mm): transverse dimension

$z$ (mm): longitudinal dimension

The absorbed power density (W.mm$^{-3}$) is expressed as follows (Welch 1984):

$$P_{\text{abs}} = \mu_a \phi(r)$$ (4)

The first laser pulse is always applied at coordinates $(0,0)$ in figure 1. When using several pulses, the relative position of the fiber inside the vein is given by:

$$z' = z - z_{\text{inc}}$$

Where: $z_{\text{inc}}$ (mm) is the absolute position of the fiber inside the vein. This position is calculated for each pulse by taking into account the pull-back distance.

When simulating a continuous irradiation performed with a progressive pull-back of the fiber, the relative position of each irradiation is obtained by taking into account the pull-back speed:

$$z_{\text{inc}} = t \times v$$

where : $v$ (mm.s$^{-1}$) is the pull back speed.

**Calculation of temperature rise**

Absorption of light in tissue causes a local elevation in temperature. Tissue heat transfer due to the deposited light is described by the bioheat transfer equation as proposed by Zhang et al [21].

$$\nabla \cdot k \cdot \nabla T(r,t) + P_{\text{abs}} = C_p \frac{\partial T(r,t)}{\partial t}$$ (5)

Where

$T(r,t)$: temperature (°K)

$\rho$ : density of tissue (g mm$^{-3}$)

$C$ : specific heat of tissue (J. g$^{-1}$.°K$^{-1}$)

**Figure 5**

Damage as a function of power, pulse duration and pull back distance for a 3 mm vein diameter (delay between pulses: 2s, $\lambda = 980$ nm).

**Figure 6**

Damage as a function of power, pulse duration and pull back distance for a 5 mm vein diameter (delay between pulses: 2s, $\lambda = 980$ nm).
C_p = C · ρ: heat capacity (J.mm⁻³.°K⁻¹)
k = thermal conductivity of tissue (W. mm⁻¹.°K⁻¹)
r = radial distance (mm)
t = time (s)

Values used for calculation are reported in Table 1

**Phase transition of blood**

In our analysis, we considered that the maximum temperature of blood would not exceed 100°C for all laser parameters. Water being the main constituent of blood, the latent heat of water was included in the calculations. It takes 4.18 J to raise the temperature of one gram of water by one degree C. When considering a 50 mm³ cylinder (diameter: 4 mm, length: 4 mm), the energy required to reach 100°C is 13 J. The latent heat of vaporization of water is 2260 kJ/kg at 100°C. The relationship between pressure and temperature is given by the phase transition diagram of water. At normal pressure: 1.10⁵ Pa and body temperature 37°C, water is in a liquid state. When the temperature increases, two phenomena can be observed: 1) pressure increases and the water stays in its liquid state, 2) pressure remains constant and water reaches its gaseous state, (steam or vapor) [22] To reach the gaseous state of this 50 mm³ cylinder, (steam or vapor) 119 J will be required. It is therefore unlikely that the blood will boil during ELT.

If we consider the vessel to be a closed but deformable container, water evaporation will not occur, and consequently, water will return to its initial liquid state as soon as the temperature drops back to below 100°C. In conclusion, the assumption is that blood temperature stays around 100°C during laser irradiation is both valid and confirmed by previous studies [23].

**Damage function**

Thermal damage in cells and tissue can be described mathematically by a first-order thermal-chemical rate equation, in which temperature history determines damage. Damage is considered to be a unimolecular process, where native molecules transform into a denatured/coagulated state through an activated state leading to cell death. Damage is quantified using a single parameter Ω, which ranges on the entire positive real axis and is calculated from the Arrhenius law [24]. Damage Ω is dimensionless, exponentially dependent on temperature, and linearly dependent on time of exposure.

$$\log(\Omega) = \log(A) + \log(\int_{0}^{\infty} \exp\left(-\frac{E_{a}}{RT(r,t)}\right)dt)$$

where A (s⁻¹) is the frequency factor,

$$E_{a} \text{ (J. mole}^{-1}\text{)}$$ is the activation energy,

$$R \text{ (J. mole}^{-1}.°K^{-1}\text{)}$$ is the universal gas constant,
The activation energy $E_a$ and the frequency factor $A$ are derived from thermodynamic variables. They describe the denaturation process of proteins and other cellular constituents. $A$ ranges from $10^{40}\text{s}^{-1}$ to $10^{105}\text{s}^{-1}$, and $E_a$ from $10^5\text{J/mole}$ to $10^6\text{J/mole}$ [25]. Values used for calculations are reported in Table 1.

$$T (\text{°K})$$ is the temperature.

$\Omega$ can be determined by the following equation

$$\Omega = -\ln \frac{C(t)}{C_0} \quad (7)$$

where: $C_0$ is the concentration of the undamaged molecules at the beginning

$C(t)$ is the concentration of the undamaged molecules at time $\tau$.

The equation indicates that the measure of damage describes the probability of tissue being destroyed. It is the logarithm of the ratio of the initial concentration of undamaged tissue to the concentration once damage has accumulated, for the time interval $t = 0$ to $t = \tau$. Therefore, $\Omega = 1$ corresponds to an irreversible damage of 100% of the affected cells.

### Numerical implementation

The mathematical model was implemented using the Macsyma-Pdease2D software (Macsyma Inc., Arlington, MA, USA). This Finite Element CAD Software needs to specify the Partial Differential Equations, variables, geometry, and boundary conditions; PDEase2D creates both numerical output tables and plots. PDEase2D generates and refines the element grid, adaptively selects time steps, and iterates until it attains convergence in nonlinear problems. And because PDEase2D does automatic error analysis, you do not need to make several runs with different meshes to verify convergence. You can choose whether or not to override the automatic defaults.

For numerical simulations, parameters commonly used for ELT were used. A 600 $\mu\text{m}$ laser fiber was considered. Two different vessel diameters were evaluated: 3 mm and 5 mm. Laser power (10 & 15 W), pulse duration (1, 2, 3 s), delay (or off-phase) between pulses (2, 3 and 4 s) and pullback distances (3, 5 and 7 mm) were the variables. In this case, thermal energy is applied along the length of the vein by withdrawing the laser fiber in 3, 5 or 7 mm increments.

For CW mode simulation, laser power (10, 15 W) and pullback speed (1,2 and 3 mm/s) were the variables.

An irregular $10 \times 60$ finite element grid was used. The time steps were 0.1 s. The tolerances used to converge the solution were $10^{-3}$. The vein wall thickness was considered to

![Figure 9](image_url)  
**Figure 9** Isodamage distribution inside tissues power: 15 W, pulse: 2s, delay: 2s, pull-back distance: 5 mm; vein diameter: 3 mm, $\lambda = 980$ nm.

![Figure 10](image_url)  
**Figure 10** Isodamage distribution inside tissues power: 15 W, pulse: 2s, delay: 2s, pull-back distance: 5 mm; vein diameter: 3 mm, $\lambda = 980$ nm.
be 0.4 mm. The initial temperature was set at 37°C. The listing of physical parameters used for numerical simulation is reported in Table 1.

The product of pullback rate and power yields the total dose of energy delivered to a vein during treatment. Several studies have suggested that this parameter is a major determinant of treatment outcome [26-28]. In order to compare the results obtained through mathematical modeling, the energy per centimeter (J/cm) was calculated.

Results

Light distribution
Figure 3 illustrates how the light is distributed inside and outside a 3 mm vein when using a 600 μm fiber. The line illustrates where 10% of the initial light irradiance rate is obtained.

Wavelength
The role of the laser wavelength was investigated. Figure 4 presents the results of mathematical modeling for 810 and 980 nm, using the same energy of 80 J/cm. Due to its greater absorption in blood, 980 nm leads to slightly greater damage of the tunica intima.

Pulsed mode
Figure 5 (3 mm vein diameter) and Figure 6 (5 mm vein diameter) summarize the results of mathematical modeling for the different set of parameters. For a 3 mm vein diameter, irrespective of the pullback distance (2, 5 or 7 mm), at least 15 J/cm is required to achieve permanent damage of the tunica intima. For a 5 mm vein diameter, permanent damage of the tunica intima is achieved at 15 W and when using a 3 mm pullback distance. A power level of 15 W delivered for 2 s (50 J/cm) or 3 s (90 J/cm) is efficacious. A power level of 10 W is too low to lead to permanent damage of the intima.

Figure 7 shows that the delay between pulses has a very limited effect on wall damage since heat convection play a minor role on heat transport. For a 3 mm diameter vein, energy between 30 J/cm up to 50 J/cm seems to be optimal to provide selective damage to the vessel wall.

Figures 8, 9 and 10 display some examples of damage distribution at different sets of parameters. These figures clearly show that pull-back distance plays a major role when determining the energy applied per centimeter.

When using 3 mm increments, the vein is damaged homogenously along its length. When using 5 mm increments, damage is less homogeneous even though the tunica intima is always damaged. Finally, for 7 mm increments, it is evident that the vein is damaged sequentially along the entire length and consequently the energy applied is lower. Cinépak movies of real time isodamage distribution are also provided for figures 8, 9 and 10 (see additional files 1, 2 and 3).

CW mode
Figure 11 displays the results obtained for several set of parameters for a 3 mm vein diameter. Simulations show that for 10 W and 2 mm/s pull-back speed, the tunica

\[
p = \text{power} \quad \text{J/cm} \\
\]  
\[
p = \text{power} \quad \text{J/cm} \\
\]
intima is damaged (50 J/cm). A minimum of 100 J/cm is required to obtain a permanent damage of the vessel wall.

Figure 12 displays the results obtained for several set of parameters for a 5 mm vein diameter. Simulations show that for 15 W and 2 mm/s pull-back speed, the tunica intima remains undamaged. A minimum of 100 J/cm is required to obtain a permanent damage of the intima and 150 J/cm to damage the vessel wall.

Figure 13 display one example of damage distribution for CW (Power: 15 W, pullback speed: 1.5 mm/s, Vein diameter: 3 mm). This figure shows that the vein is damaged homogenously along its length.Cinepak movie of real time isodamage distribution is also provided for figure 13 (see additional file 4).

Discussion
To date, mathematical modeling of ELT has never been proposed. This task was performed to assist in providing a better understanding of the ELT process and possibly to determine the optimal dosage as a function of vein diameter. Our model remains a mathematical model, implying that errors may appear owing to the considerations and simplifications required to realize it. Generally, such errors appear because of inaccuracy of the optical, thermal, and damage properties that are critical points in the model’s set of equations. In fact, these properties play a key role in the accuracy of the results achieved. Many methods have been presented to calculate these properties but still we see differences in the values presented by the different groups, which reflect the difficulty of measuring these properties. The problem is increased by the reliance of the properties on different variables (temperature, damage) over time. This makes the deviation neither linear nor regular [24].

Before attempting to compare the parameters used for simulation to those usually reported in the literature, the following comments must be made:

1) One of the main problems remains the knowledge of the vein diameters during ELT treatment. Since the vein diameter is considerably reduced after tumescent anesthesia, it should be systematically measured. A recent study by Desmyttere et al have demonstrated that after tumescent anesthesia, the vein diameter was usually reduced down to 5 mm or less [27].

2) In contrast to the mode of action of VNUS closure (radiofrequency) where a significant shrinkage of the vessel wall is observed, Proebstle has clearly demonstrated that, when performing ELT, permanent occlusion, reported at 3 months or later, can be obtained by thermal damage of the tunica intima inner vein wall only [29]. This observation is confirmed by the histological study performed by Corcos et al. They showed that when permanent occlusion was observed, the endothelium and intima were always damaged and that success was independent of the vessel wall thickness [30].

The results of mathematical modeling for 810 and 980 nm shows 980 nm leads to a slightly greater damage of the tunica intima when compared to 810 nm. This is owed to

![Figure 13](image)

Isodamage distribution inside tissues : power: 15 W, pull-back speed: 1.5 mm/s, vein diameter: 3 mm, $\lambda = 980$ nm.

<table>
<thead>
<tr>
<th>Physical Parameters</th>
<th>Blood</th>
<th>Vessel wall</th>
<th>Perivenous tissue</th>
<th>References</th>
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</thead>
<tbody>
<tr>
<td>$\mu_a$ (mm$^{-1}$)</td>
<td>0.20 (810 nm)</td>
<td>0.28 (980 nm)</td>
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<td>1.05.10$^3$</td>
<td>[33,34]</td>
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<tr>
<td>k (W.mm$^{-1}$.K$^{-1}$)</td>
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<td>5.6.10$^4$</td>
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</tr>
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<td>[34,35]</td>
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<td>5.6.10$^{63}$</td>
<td>5.6.10$^{63}$</td>
<td>[34,35]</td>
</tr>
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</table>
its better absorption by blood at 980 nm. However, because of the inaccuracy on vein diameter, one can consider that the choice of the wavelength between 810 and 980 nm has no influence on the results. This is confirmed by the literature where 810, 940, 980 nm were used for ELT with similar parameters [7,9,10]. Proebstle et al performed an in vitro study to evaluate the role of intravascular blood for the effective transfer of thermal damage to the vein wall through absorption of laser energy with 810, 940 and 980 nm. Similar results were obtained with 810 nm, 940 nm and 980 nm [29].

When using the continuous mode (810 nm, 14 W), Timperman, has treated 100 veins with an average energy of 95 J/cm (range, 57–145 J/cm; SD: 16 J/cm). Follow-up and success at 1 week was 100%, 96% at 3 month follow-up and finally 95% at 9 month follow-up [31]. Using 58 J/cm, in another series, Timperman reported only a 76% complete vein ablation rate. Similarly, Theivacumar has confirmed that, of all parameters, energy per cm was the main determinant of successful LSV ablation by ELT [26]. The parameters used by Timperman are very similar to those determined by our simulations. In continuous mode, for a 3 mm vein diameter, 50 J/cm are required to damage the vessel wall. For a 5 mm diameter, 100 J/cm are required.

In pulsed mode, it is often difficult to obtain details concerning parameters used for ELT. If power and pulse duration are usually reported, information concerning speed of fiber withdrawal is usually missing. Results reported in the literature are highly variable and tend to prove that this parameter is not well controlled by the operator. In a study performed in 476 limbs (810 nm, 12 W, 1s and a pull back distance varying from 2 mm to 2.8 mm giving respectively 61 J/cm and 43 J/cm), Theivacumar et al observed that occlusion rates were significantly greater at higher energy levels [26]. Using 50 J/cm, in a series of 56 limbs in 41 patients, Mozes et al reported complete resolution at 3-month follow up [11]. Finally, Proebstle et al on a series of 77 patients, performed ELT with a median energy delivery of 23.4 J/cm (range of 11.8 to 35.5) Using these parameters, at 3 months post ELT, 10% of GSVs were found open by color Doppler examination [12]. These results are similar to our calculations in that it was determined that 15 J/cm is required to obtain a permanent damage of a 3 mm vein diameter and 50 J/cm for a 5 mm vein diameter.

An interesting observation is that less energy is required in pulsed mode than in continuous mode because the vein is not heated along its entire length. However, as illustrated in figures 9 and 10, damaging the vein sequentially along its entire length may lead to permanent occlusion. At last, if steam formation during ELT has already been reported, the interpretation given by the authors is inappropriate [6]. Steam bubbles originating from boiling blood cannot be the pathophysiological mechanism of action of ELT. The steam produced by absorption of laser energy by the blood is a tiny fraction of the energy necessary to damage the vein wall and cannot be the primary mechanism of injury to the vein with endovenous laser. The carbonization and tract within the vein walls seen by histology following endovenous laser can only be the result of direct contact between the laser fiber tip and the vein wall. Venous caliber reduction is maybe due to collagen shrinking by simple heating, but media contraction is only obtained by selective 810–980 nm irradiation.

Consequently, the parameters determined through calculation in our model, especially the ones concerning the different outcome in relation with the different diameters, seem to confirm and explain the observations emerged by the clinical practice

**Conclusion**

The parameters determined by mathematical modeling are in agreement with those used in clinical practice. They confirm that thermal damage of the inner vein wall (tunica intima) is required to achieve the tissue alterations necessary in order to lead the vein to permanent occlusion. However, in order to obtain a high rate of success without adverse events, the knowledge of the vein diameter after tumescent anesthesia is recommended in order to use the optimal energy. As clearly demonstrated by our calculations, both pulsed and continuous mode operations of the laser can be efficient. An interesting observation in our model is that less amount of energy is required in pulsed mode than in continuous mode. Damaging the vein sequentially along its entire length may lead to permanent occlusion. However, the pulsed mode requires a very precise positioning of the fiber after each pullback and the duration of the treatment is much longer. For these reasons, continuous irradiation seems to be preferred by most clinicians.

This model should serve as a useful tool to simulate and better understand the mechanism of action of the ELT

**Additional material**

**Additional File 1**

The movie shows the isodamage distribution inside tissues using the following parameters: power: 15 W, pulse: 2s, delay: 2s, pull-back distance: 3 mm ; vein diameter: 3 mm; λ = 980 nm. The movie belongs to Figure 8. The file can be played using the internet browser.

Click here for file [http://www.biomedcentral.com/content-supplementary/1475-925X-5-26-S1.avi]
Additional File 2
The movie shows the isodamage distribution inside tissues using the following parameters: power: 15 W, pulse: 2s, delay: 2s, pull-back distance: 5 mm; vein diameter: 3 mm; λ = 980 nm. The movie belongs to Figure 9. The file can be played using the internet browser. Click here for file [http://www.biomedcentral.com/content/supplementary/1475-925X-5-26-S2.avi]

Additional File 3
The movie shows the isodamage distribution inside tissues using the following parameters: power: 15 W, pulse: 2s, delay: 2s, pull-back distance: 7 mm; vein diameter: 3 mm; λ = 980 nm. The movie belongs to Figure 9. The file can be played using the internet browser. Click here for file [http://www.biomedcentral.com/content/supplementary/1475-925X-5-26-S3.avi]

Additional File 4
The movie shows the isodamage distribution inside tissues using the following parameters: power: 15 W, pull-back speed: 1.5 mm/s, vein diameter: 3 mm, λ = 980 nm. The movie belongs to Figure 13. The file can be played using the internet browser. Click here for file [http://www.biomedcentral.com/content/supplementary/1475-925X-5-26-S4.avi]

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A 2 years follow-up study of endovenous 980 nm laser treatment of the great saphenous vein: Role of the blood content in the GSV

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Abstract

Background: In recent years, the endovenous laser treatment (EVLT) has been proposed to treat the incompetent greater saphenous veins (GSV). The frequency of recanalization of the GSV after EVLT is highly fluence dependent but other factors such as the presence of blood in the vein could play also a major role. This study aims to evaluate the role of blood during EVLT in two groups of patients: one group maintained in the horizontal position during EVLT and one group maintained in the Trendelenburg’s position in order to treat GSV emptied of blood.

Methods: 126 patients (102 females and 24 males, mean age: 52.6 years, range: 19–83) underwent EVLT of incompetent GSV segments with 980-nm diode laser (Pharaon, Osyris, France) energy delivered intraluminally. The patients were randomly divided into two groups: group #1: 63 patients maintained in the horizontal position during the laser irradiation, group #2: 63 maintained in the Trendelenburg’s position. For each group, the laser irradiation was performed with a 600 μm fiber. The power was tuned at 10 W, but the pulse duration was calculated as a function of the GSV diameter using a dedicated software (Horus, http://horuslog.free.fr). Patients were evaluated clinically and with US imaging at 1 day, 8 days, 1 month, 6 months, 1 year and 2 years thereafter to assess treatment efficacy and adverse reactions.

Results: The demographic, the clinical data and the laser parameters used for EVLT were comparable for both groups. At 6 months, 82% of the patients in the group #1 demonstrated a complete closure of the GSV versus 92.8% in group #2 (p < 0.001), at 1 year 78.9% vs 94.2% (p < 0.001) and finally at 2 years 73.9% vs 94.5% (p < 0.001). No complications were noted. At 2 years, US imaging demonstrated a complete GSV disappearance in 73% of the patients in group#1 vs 94.5% in group #2 (p < 0.001).

Conclusion: EVLT of the incompetent GSV with a 980 nm diode laser appears to be an extremely safe technique, particularly when the energy applied is calculated as a function of the GSV diameter. It is associated with only minor effects. The results are statistically superior when the patient was maintained in the Trendelenburg’s position. Consequently, the position of the patient during the laser procedure should be considered in order to increase the efficacy.

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Keywords: Great saphenous vein; Endovenous laser; Blood; Trendelenburg’s position
Introduction

Lower-extremity venous insufficiency is a common medical condition afflicting 25% of women and 15% of men in the United States and in Europe. Great saphenous vein (GSV) reflux is the most common underlying cause of significant varicose veins. Traditional treatment of GSV reflux has been surgical removal of the GSV. Although surgical ligation and stripping of the GSV has been the most durable treatment, it is associated with significant perioperative morbidity. Less-invasive surgical treatments including high ligation of the GSV at the saphenofemoral junction (SFJ) have been attempted with the hope that gravitational reflux would be controlled while the vein is preserved for possible use as a bypass graft. Unfortunately, ligation of the GSV alone usually results in recurrent varicose veins. Even when high ligation has been combined with phlebectomy of varicose tributaries or retrograde sclerotherapy, recurrence has been the rule. Therefore, when it is determined that GSV reflux is the principal underlying problem, treatment should involve eliminating this source of reflux with ablation of any associated incompetent venous segments.

Within the last few years, minimally invasive techniques have been developed as alternatives to surgery in an attempt to reduce morbidity and improve recovery time. Endovenous laser treatment (EVLT) is one of the most promising of these new techniques [1–3]. In 1999, Bone first reported on delivery of endoluminal laser energy [4]. Nonthrombotic vein occlusion is accomplished by heating the vein wall with laser energy delivered via a 600 μm laser fiber. Since then, several studies have demonstrated that this technique was safe and efficient. Several wavelengths have been proposed, respectively 810, 940, 980, 1064 and 1320 nm [5–9].

It was demonstrated that greater doses of energy delivered are associated with successful EVLT, particularly when doses of more than 80 J/cm are delivered [10]. Sufficient heating of the vein wall is necessary to cause collagen contraction and denudation of endothelium. This stimulates vein wall thickening, eventual luminal contraction, and fibrosis of the vein. However, when using high dosages, the treatment is painful. Skin injuries are also reported [11]. For example, Chang et al. have reported ecchymosis and dyschromia in 58 legs (23.0%), superficial burn injury in 12 legs (4.8%), superficial phlebitis in four legs (1.6%), and localized hematoma in two legs (0.8%) at 3 weeks postoperatively. Excessive and nonspecific thermal damage has led to 67% of patients complaining of pain along the treated vein for 1 week in one study using the 940-nm intravascular laser [12].

New wavelengths have been proposed in an attempt to improve safety and efficacy. One recent approach has been to use a 1320-nm laser. This wavelength is a water-specific, and a nonvascular specific wavelength and requires lower fluences. Short-term follow-up has showed a high degree of success with minimal side effects. However, the EVLT technique is based on the use of an “optimal set” of parameters which is supposed to treat GVS of different diameters. Min et al. have reported that pretreatment GSV diameter, measured in the upright position approximately 2 cm below the SFJ, ranged from 4.4 to 29 mm (mean, 11 mm; SD, 4.2 mm) [13]. If tumescent anesthesia can reduce the diameter of the vein, it is evident that higher fluences should be required for larger veins. Proebstle et al. have confirmed that nonocclusion and early reopening of the GSV after EVLT was fluence dependent [14]. In order to adapt the laser parameters to the diameter of the GSV, we have developed a new approach consisting in calculating the optimal dosage for a given diameter and then determining the optimal set of parameters using a dedicated software based on the measurement of the vein diameter in different locations (1.5 cm below the SFJ, crural segment, condylar segment and leg segment). At last, the fact that blood present in the vein which is usually the case when the patient is in horizontal position could considerably influence the efficacy of the EVLT technique. Consequently, the aim of the EVLT technique is to obtain the highest rate of GSV closure and minimizing the side effects.

The purpose of this study is to report on the long-term follow-up results of endovenous 980 nm laser treatment for GSV reflux using calculated laser parameters in order to use an optimal energy for each GSV diameter. The study aims to compare two groups of patients in order to evaluate the possible role of the presence of blood on the closure rate and consequently the position of the patient during the procedure: horizontal position or Trendelenburg’s position.

Materials and methods

Patient selection

Directed history and physical examination, including ultrasound imaging evaluation of the superficial venous system, was performed on limbs of subjects with GSV. Study inclusion criteria included varicose veins caused by SFJ incompetence with GSV reflux as demonstrated by duplex US imaging, age of at least 18 years, and ability to return for scheduled follow-up examinations for 12 months and 24 months after EVLT. Exclusion criteria included nonpalpable pedal pulses; cardiovalvular disesase inability to ambulate; deep vein thrombosis; general poor health; pregnancy, nursing, or plans to become pregnant during the course of participation in the investigation; and extremely
tortuous GSVs that would not allow endovenous catheterization and passage of the laser fiber as identified on pretreatment venous duplex US mapping. After initial consultation and evaluation, subjects meeting the appropriate criteria were offered surgery versus EVLT. Nearly all subjects chose endovenous laser over surgical ligation and stripping. The study protocol was approved by our local ethical committee. All patients gave written informed consent before treatment.

Protocol

This prospective, randomized, study included 126 patients (102 females and 24 males, mean age: 52.6 years, range: 19–83) who underwent EVLT of incompetent GSV segments with 980-nm diode laser energy delivered intraluminally. The patients were randomly divided into two groups: group #1: patients maintained in the horizontal position during EVLT, group #2: patients maintained in the Trendelenburg’s position; position in which the patient is on an elevated and inclined plane, at 20 degrees, with the head down and legs and feet over the edge of the table.

Procedure

Duplex US (Aloka 3500, Decines, France) was performed in the upright position to map incompetent sources of venous reflux and then to mark the skin overlying the incompetent portion of the GSV starting at the SFJ. In an outpatient special procedure room in hospital, the patient was placed in the supine position for treatment of the GSV. The target extremity was steriley prepped and draped. Under ultrasound guidance through a sterile ultrasound probe cover, the GSV was visualized at the knee level. The saphenous vein was percutaneously punctured with a 21-G needle under ultrasound guidance. A 5-F micro-introducer guidewire was threaded through the needle followed by the introducer. A 0.035-inch guidewire was passed under ultrasound guidance up to the SFJ; a 5-F introducer was placed over the guidewire. A 600-μm optical fiber (Osyfibre: PH-980-15-600-3, Osyris, Hellemes, France) connected to a 980 nm diode laser (Pharaon, Osyris, Hellemes, France) was passed through the introducer to the SFJ. The laser fiber and catheter were slowly withdrawn in 3 mm increments using a graduated scale. The parameters were as follows: 10 W in continuous mode with bursts of laser energy. Using the Horus software (http://horuslog.free.fr), the delivered volumic energy depended on the GSV diameter measured in the orthostatic position, before tumescent local anesthesia at different locations: (i) 1.5 cm below the SFJ, (ii) crural segment, (iii) condylar segment and (iv) leg segment. For GSV diameters between 1 and 4.5 mm, the energy applied was 0.8 J/mm³. The energy was increased up to 0.9 J/mm³ for 4.8–8 mm GSV diameters, and up to 1 J/mm³ for larger diameters. Consequently, the pulse duration was adjusted for each individual GSV segment from 1.2 s (2 mm) up to 4.5 s (4.5 mm) which was the maximum GSV diameter obtained after tumescent anesthesia.

The last shot was controlled by duplex US in order to avoid any skin burn and delayed healing. 95% of the patients in this series underwent concomitant ambulatory phlebectomy. At the end of the surgical procedure, venous compression was applied during 24 h by irremovable compression bandage. In addition, the patients were asked to wear full thigh class 3 compression stockings only during the day for 3 weeks. Patients were instructed to walk immediately following the procedure and to continue their normal daily activities with the vigorous workouts. All patients received for 5 days NSAID (Piroxicam, Feldene, Pfizer).

Duplex US were performed at 24 h, 1 week, at 1 month, 6 months, 1 year and 2 years after the initial treatment.

Statistical analysis

Differences between the two groups were evaluated using χ² test to highlight the differences between the two groups.

Results

The two groups (group #1: horizontal position; group #2: Trendelenburg’s position) of patients were comparable in terms of population, sex and GSV caliber. Demographic data and clinical data are given in Table 1. 63 patients (52 females, 11 males, mean age: 50.3: pp. 19–79) were included in group #1. 63 patients (49 females, 14 males, mean age: 54: pp. 21–81) were included in group #2.

The GSV diameters in each group were also comparable (Table 1). In group #1: GSV diameters measured 1.5 mm below the SFJ, varied from 3 to 15 mm (mean: 6.5 mm – SD: 2.5 mm). In group #2; GSV diameters measured 1.5 mm below the SFJ, varied from 3 to 14 mm (mean: 6.4 mm – SD: 2.3 mm).
Pain, vessel closure, vessel complete disappearance were evaluated 1 day, 8 days, 1 month, 6 months, 1 year and 2 years after the initial treatment for the two groups of patients. Results were reported as percentage (Tables 2 and 3). The 1 month follow-up was performed on 55 patients in group #1 and 58 patients in group #2; 6 month follow-up on 52 patients in group #1 and 55 patients in group #2; the 1 year follow-up on 47 patients in group #1 and 49 patients in group #2 and finally the 2 year follow-up on 34 patients in group #1 and 32 patients in group #2.

80% ecchymosis, 5% temporary paresthesia, no dyschromia, no superficial burn injury and no superficial phlebitis were observed.

Table 1. Demographic and clinical data for the 126 patients

<table>
<thead>
<tr>
<th></th>
<th>Group #1 Horizontal position</th>
<th>Group #2 Trendelenburg’s position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>63</td>
<td>63</td>
</tr>
<tr>
<td>Male–female</td>
<td>52 females, 11 males</td>
<td>49 females, 14 males</td>
</tr>
<tr>
<td>Mean age</td>
<td>50.4</td>
<td>54</td>
</tr>
<tr>
<td>Range</td>
<td>19–79</td>
<td>21–81</td>
</tr>
<tr>
<td>Pathology</td>
<td>4: Truncular reflux with incompetence sapheno femoral junction 3: Truncular reflux with incompetence thigh perforator 7: Truncular reflux with origine reflux before the junction 9: Truncular reflux with incompetence pelvic collector</td>
<td>4: Truncular reflux with incompetence sapheno femoral junction 6: Truncular reflux with incompetence thigh perforator 5: Truncular reflux with origine reflux before the junction 12: Truncular reflux with incompetence pelvic collector</td>
</tr>
</tbody>
</table>

Table 2. Group #1 follow-up

Group #1: Horizontal position

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>1 day</th>
<th>1 week</th>
<th>1 month</th>
<th>6 months</th>
<th>1 year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nb patient</td>
<td>63</td>
<td>63</td>
<td>55</td>
<td>52</td>
<td>47</td>
<td>34</td>
</tr>
<tr>
<td>Pain</td>
<td>8/63 (12.6%)</td>
<td>8/63 (12.6%)</td>
<td>5/55 (9%)</td>
<td>2/52 (3.8%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Complete closure</td>
<td>63/63 (100%)</td>
<td>61/63 (96%)</td>
<td>51/55 (92.7%)</td>
<td>47/57 (82%)</td>
<td>45/57 (78.9%)</td>
<td>34/46 (73.9%)</td>
</tr>
<tr>
<td>Complete disappearance</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>26/52 (50%)</td>
<td>36/52 (70%)</td>
<td>38/52 (73%)</td>
</tr>
</tbody>
</table>

Table 3. Group #2 follow-up

Group #2: Trendelenburg’s position

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>1 day</th>
<th>1 week</th>
<th>1 month</th>
<th>6 months</th>
<th>1 year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nb patient</td>
<td>63</td>
<td>63</td>
<td>58</td>
<td>55</td>
<td>49</td>
<td>32</td>
</tr>
<tr>
<td>Pain</td>
<td>3/63 (4.7%)</td>
<td>5/63 (7.9%)</td>
<td>2/58 (3.4%)</td>
<td>1/55 (1.8%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Complete closure</td>
<td>63/63 (100%)</td>
<td>63/63 (100%)</td>
<td>57/58 (98.2%)</td>
<td>53/56 (92.8%)</td>
<td>49/52 (94.2%)</td>
<td>32/35 (91.4%)</td>
</tr>
<tr>
<td>Complete disappearance</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>39/55 (70.9%)</td>
<td>51/55 (92.7%)</td>
<td>52/55 (94.5%)</td>
</tr>
</tbody>
</table>
Discussion

The principal finding in this study is that EVLT with a 980 nm diode laser system, when performed under tumescent local anesthesia, is a clinically feasible and well-tolerated technique. Because of vein access via a 21-gauge needle, it is truly minimal procedure, leaving virtually invisible scar on the patient’s skin.

Most clinical studies published on EVLT did not consider the pain. Only Chang et al. have reported on this parameter. At 3 weeks, 36.5% were complaining of pain. At 6 months, this percentage was 2.8% [6]. In our study, this percentage is very low 9% at 1 month in group #1 and 3.4% in group #2. At 6 month follow-up, it reaches 3.8% in group #1 versus 1.8% in group #2.

The efficacy of EVLT in obtaining early occlusion of the GSV is very satisfactory. At 1 month follow-up the closure rate is 93% in group #1 and 100% in group #2. These results are very similar to those reported by other teams. With a similar follow-up, a 97% closure rate was obtained by Proebstle et al. [5]. Navarro et al. observed a 100% rate of closure [15]. Min et al. have reported a 97% closure rate 1 week after initial treatment. Sonographic evaluation demonstrated 73% reduction in GSV diameter at 6 months and 81% reduction in GSV diameter at 9 months after EVLT [9].

At 2 years follow-up, in our series, the closure rate is 73.9% in group #1 and 91.74% in group #2. Min et al. have obtained a 93.4% recurrence rate at 2 years [13]. However, repeated treatments were sometimes performed which is not the case in our study where patients were only treated once.

Since our results demonstrate that the efficacy of the EVLT technique is improved when there is no (or at least less blood) in the GSV, the presence of intravascular blood seems to be determinant [16]. Since the final result is highly dependent on the thermal damage of the vessel wall, it seems that the absence of blood in the vein could considerably improve the light distribution and consequently the vessel wall damage. This observation is in accordance with those of Goldman et al. who have observed clinical results in veins emptied of blood [7]. They have recently reported that 1320 nm wavelength (wavelength mainly absorbed by water in the vessel wall) was efficient in treating GSV. To them, it is not necessary to use laser wavelength that interacts with hemoglobin in red blood cells. Conversely, the variability in the amount of blood within the vein leads to inconstant results. Moreover, the absorption of laser light by blood can generate steam bubbles and leads to pulmonary reaction seen in some patients. The formation of these steam bubbles has been confirmed by Proebstle et al. who have observed that steam bubbles were generated in hemolytic blood by 810, 940 and 980 nm diode lasers, while no bubbles were produced in normal saline or plasma [16].

The fact that failures were always observed when SFJ diameter was superior to 1 cm or for GSV troncular diameter superior to 8 mm, where the content of blood is very important even in the Trendelenburg’s position, confirms that laser irradiation was not sufficient to heat...
up the vessel wall. In these cases, the laser light energy was entirely absorbed by the blood, and the initial success rate was mainly due to a thrombotic effect as already stated by Proebstle et al. [5]. However, the thrombus dissolution leads to a recanalization of those large GSV.

At last, this study seems to confirm that 980 nm wavelength is more absorbable in water and oxyhemoglobin and penetrable into the vein wall that 810, 940 and 1064 nm wavelengths as already observed by Oh et al. [8].

**Conclusion**

EVLT of the incompetent GSV with a 980 nm diode laser appears to be an extremely safe technique, particularly when the energy applied is calculated as a function of the GSV diameter. It is associated with only minor effects. The results are statistically superior when the GSV is emptied of its blood, or at least when the amount of blood is considerably reduced. Consequently, the position of the patient during the laser procedure should be considered in order to increase the efficacy.

**Zusammenfassung**

Zwei Jahre follow-up nach endovenöser 980 nm Laserbehandlung der V. saphena magna: Einfluss der Blutfüllung der VSM

**Background:** In den letzten Jahren wurde die endoluminale Lasertherapie (EVLT) zur Behandlung der insuffizienten V. saphena magna entwickelt. Die angewandte Fluence hat dabei einen Einfluss auf die Rezidivrate (Rekanalisation), aber auch andere Faktoren, wie die Anwesenheit von Blut innerhalb der Vene, könnten eine wesentliche Rolle spielen. Diese Studie untersucht den Einfluss der venösen Blutfüllung während EVLT anhand zwei Patientengruppen: Während der Behandlung wurde die eine Gruppe in horizontaler Position gelagert, die andere in Trendelenburg-Lagerung, um eine Blutleere zu erreichen.


**Ergebnisse:** Demografische und klinische Daten und Laserparameter der EVLT waren in beiden Gruppen vergleichbar. Nach 6 Monaten bestand bei 82% der Gruppe #1 ein kompletter Verschluss der V. saph.m. gegenüber 92,8% in Gruppe #2 (p < 0.001), nach einem Jahr 78,9% vs. 94,2% (p < 0.001) und letztlich nach 2 Jahren 73,9% vs. 94,5% (p < 0.001). Es wurden keine Komplikationen beobachtet. Eine Ultraschalluntersuchung nach zwei Jahren zeigte den Verschluss der V. saph.m. in 73% der Patienten in Gruppe #1 und in 94,5% der Patienten in Gruppe #2 (p < 0.001).

**Schlussfolgerung:** Die EVLT zum Verschluss der inkompetenten V. saph.m. mit einem 980 nm Diodenlaser ist ein sicheres Verfahren, besonders wenn der Energieeintrag dem Gefäßdurchmesser angepasst erfolgt. Dabei ist die Belastung des Patienten durch den Eingriff gering. Die Ergebnisse sind statistisch signifikant besser, wenn die Behandlung in Trendelenburg-Lagerung durchgeführt wird. Eine entsprechende Lagerung während der EVLT sollte beachtet werden, um die Effizienz des Verfahrens zu verbessern.

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**Schlüsselwörter:** Varikosis; Vena saphena magna; Endoluminale Lasertherapie; Blut; Trendelenburg-Lagerung

**References**


Endovenous 980nm laser treatment of saphenous veins in a series of 500 patients

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Abstract

Background: In recent years, the endovenous laser treatment (ELT) has been proposed to treat the incompetent greater saphenous veins (GSV). This study aims to report a long-term outcome of ELT in a series of 511 patients.

Methods: 500 patients (436 females and 64 males, mean age: 52.6 years, range: 19-83) underwent ELT of incompetent GSV segments with 980-nm diode laser (Pharaon, Osyris, France) energy delivered intraluminally. During treatment, patients were maintained in the Trendelenburg's position. Patients were evaluated clinically and with US imaging at 1 day, 8 days, 1 month, 6 months, 1 year, 2 years, 3 years and 4 years thereafter to assess treatment efficacy and adverse reactions. Complementary phlebectomy was performed in almost all patients.

Results: 511 GSV were treated. The mean diameter was 7.5 mm (2.4 – 15.0). The LEED was tuned as a function of initial GSV diameter, from 50J/cm (3 mm) up to 90 J/cm (15 mm). At 1-week follow-up, Moderate pain was reported in 9.3% of the patients. In the immediate postoperative period, the closure rate was 98.0% and remained constant during the 4-year follow-up to reach 97.1%. Major complications have not been detected: in particular no deep venous thrombosis (DVT). Ecchymoses were seen in 60%, transitory paresthesia was observed in 7%, no dyschromia, no superficial burn, no thrombophlebitis, no palpable indurations. 98% of patients have had complementary phlebectomy. Recanalizations were always observed when SFJ diameter was superior to 1 cm or for GSV troncular diameter superior to 8 mm.

Conclusion: ELT of the incompetent GSV with a 980 nm diode laser appears to be extremely safe technique, particularly when the energy applied is calculated as a function of the GSV diameter. It is associated with only minor effects. Failures were always observed when SFJ diameter was superior to 1 cm or for GSV troncular diameter superior to 8 mm, where the content of blood is very important even in the Trendelenburg's position. This observation confirms that laser irradiation is not sufficient to heat up the vessel wall in those large GSV.

Key words: great saphenous vein, endovenous laser, blood, Trendelenburg's position.
The first 1,000 cases of Italian Endovenous-laser Working Group (IEWG). Rationale, and long-term outcomes for the 1999-2003 period

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Aim. The innovations for disease management need to be thoroughly evaluated so that their benefits and potential downsides can be compared with the already existing approaches. Endovascular laser (EVL) treatment for varicose veins offers today several advantages over surgical standard stripping. The Italian Endovenous-laser Working Group (IEWG) is a homogeneous group of surgeons and phlebologists who have been using EVL since 1999 and has undertaken to examine EVL in a multicenter study starting from a well defined rationale, with the benefit of a single protocol to use.

Methods. In a cooperative, multicenter, clinical study, 1,076 limbs in 1,050 patients, mean age of 54.5 years, 241 males and 809 females affected by chronic venous insufficiency (CVI) were considered eligible for surgery and stratified by CEAP classification in a four-year period (January 1999 – December 2003). Inclusion criteria were insufficiency of the great and/or small saphenous vein at various levels, beyond those accessory saphenous trunks with incompetence in the saphenofemoral junction. In all cases truncular reflux appeared upon duplex scan examination, with or without associated varicosities. All the patients underwent a surgery on the basis of the clinical assessment. All the centres involved performed treatment in conformity with the Food and Drug Administration (FDA) validated procedure, using an endo-laser venous system kit with a 810-980 nm diode. Duplex scan was performed in all patients after 36 months with very few lost to follow-up cases.

Results. In the immediate postoperative period the results have been impressive, with a very effective closure of incompetent great saphenous vein and the other treated varicose veins (the early occlusion rate has been 99%). Major complications have not been detected: in particular, no deep venous thrombosis (DVT) evaluated duplex ultrasound. The patients' acceptability and satisfaction regarding the procedure, have been measured by means of a questionnaire on the quality of life, and the result was 96.7%. After 36 months, the total occlusion rate of saphenous trunks has been 97%.

Conclusion. The first important Italian experience with EVL based on preoperative, perioperative and postoperative duplex control and which is also based on the patients' satisfaction at mid/long-term has indicated some advantages over the standard treatment with the stripping method. In terms of reduced postoperative pain, shorter sick leave, a faster resumption of the normal activities, and, in particular, the total absence of DVT, we can conclude that EVL is a good solution for all patients with anatomic and hemodynamic patterns for saphenous vein surgery.

Key words: Endovascular surgical procedures - Laser - Varicose veins - Veins, surgery.

The early Italian experience of endovascular laser (EVL) treatment for varicose veins dates back to the late 1980s. Nevertheless, the first attempts were conditioned by a poor and undedicated technical support, little know-how regarding treatments of truncular reflux without saphenofemoral junction (SFJ) ligation. In contrast, starting from 1999, one member of our group (G. M.) started the clinical practice with diode laser following a standard procedure that later on, in 2001 and 2002, received the approval by Food and Drug Administration (FDA) in the USA.

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Received December 21, 2005; accepted for publication May 25, 2006.
Endovascular treatment for varicose veins offers today several advantages over surgical standard stripping. It is less invasive and it is associated with minimal discomfort and complications, with a quick recovery after treatment. However, the durability of endovascular options, EVL, radiofrequency (RF) or sclerofoam, in the saphenous segment are not the same as the ones shown in the results of the long-term follow-up of stripping. Recurrent recanalization rates have been reported as low as 2-12% after 1-3 years from the endovascular treatment while the rates for recurrent varicose vein that have been reported 35 years after the stripping procedure, can vary widely from 10% to 60%. This wide range made more uncertain the generalized recommendations for the stripping method. It is more likely that differences in the results of varicose vein surgery are related to differences in the patterns of lesions of the chronic venous insufficiency (CVI) that are treated. Few studies have considered the role of extensive dissection of SFJ in association with stripping. It is obvious that the new methods need to be thoroughly evaluated so that their benefits and potential downsides can be compared with the existing approaches.

EVL has been criticized for its applying several different laser types and equipment with multiple devices, but without having a single well-defined protocol. This is in contrast to RF that uses a single type of device and technique. As matter of fact only a single technique, that uses the endolaser vein system (ELVeS) with a single type of device manufactured and which is distributed by a single company with a unique procedure FDA-approved.

The Italian Endovenous-laser Working Group (IEWG) which is a group of surgeons and phlebologists who use the ELVeS investigated the value of EVL in a multicenter study based on a well defined rationale (www.IEWG.org). Duplex ultrasound scanning was used to determine the hemodynamic patterns, which served as the primary outcome measure together with the patient’s satisfaction.

**Materials and methods**

In a multicenter study 1050 patients with mean age of 54.5 years (range: 21-80), among which 241 were males and 809 females affected by CVI were considered eligible for surgery and stratified by CEAP classification, in a four-year period (January 1999 – December 2003). Inclusion criteria were the insufficiency of the greater and/or shorter saphenous vein at various levels, beyond the accessory saphenous trunks with SFJ incompetence: in all cases there was a truncular reflux visible upon colour-flow duplex scan examination, with or without associated varicosities. All the patients underwent surgery on the basis of clinical assessments and duplex scan control. The same venous diagnostic protocol was preoperatively used in all centers until 7 days after the surgical procedure according the step-by-step shared procedure (Table I), with standard method previously described.

The study design was a retrospective review of a prospectively maintained database in Milan. Advanced CVI defined as stage C4 to C6 was present in only 8% of the patients, for a total of 84 patients. The largest class of patients was stratified in C2 to C3 with 861 patients (82%) in C2, and 105 (10%) in C4 respectively. In 36% (378 patients) we observed simultaneous clinical stages of CVI, with association C2-C3 in 270 patients (25.7%), C2-C4 in 25 (2.3%) and C2-C6 in 73 (6.9%). Eleven patients (1.04%) showed venous ulcers without significant varicosities.

To assess the symptoms and the generic quality of life a Italian version of MOS SF-36 has been administered before the clinical and duplex examination. Patients completed alone the questionnaire, often helped by nurses when required.

Exclusion criteria were deep venous thrombosis (DVT), superficial venous thrombosis (SVT) and complete obstruction of deep veins. Deep venous insufficiency was not part of the exclusion criteria.

Treatment was performed in 12 centres in the whole Italian territory, north, centre and south, as shown in Table II. All the patients underwent an EVL treatment, instead of standard ligation and stripping.

All the centres involved performed the treatment in conformity with the FDA validated procedure, using endolaser venous system kit with 810-980 nm diode laser (ELVeS, Biolitec AG, Germany). The kit is composed by the following material: 1) “J” Guide-wire 0.035".
The instrumentation that was employed consisted of a diode laser, with an operative frequency between 810 and 980 nm in 31% and 69% procedures respectively. It should be emphasized that only 4 centres made use of the 810 nm diode laser, and only in the early phase of their experience, until October 2002. However, 1 centre used exclusively the aforesaid equipment. On average, the laser-power used was at 12.5 W. For the sake of...
uniformity a step-by-step protocol has been adopt-
ed and was followed by every centre as shown in
Table I.

All the patients underwent a preoperative colour-
flow duplex and have been grouped in 4 surgically
oriented and, hemodynamic patterns, as shown
in Figure 1. All 4 models were considered suitable
for EVL treatment.

Results

The hemodynamic patterns determined by
duplex scanning have been subdivided in the fol-
lowing groups:

1) Patterns 1 and 2 (incompetence of great
saphenous vein, GSV): 1 052 (97.7%).

2) Pattern 3 (incompetence of small saphenous
vein, SSV): 16 (1.6%).

3) Pattern 4 (incompetence of an accessory
saphenic trunk): 8 (0.7%).

In addition, duplex scanning demonstrated that
the lumen diameter of the GSV bore was less than
10 mm in 719 (66.8%) and greater than 10 mm in
the remaining 357 patients (33.2%) with an aver-
age diameter of 10 mm. The distance of the vein
from the skin was less than 5 mm in 463 (50%)
and more than 5 mm in the remaining 50% of the
patients.

During the study, a total of 1 076 procedures
were performed with an average follow-up time
of 36 months. In 526 cases the procedure involved
the right lower limb (48.8%), 543 the left one
(50.4%), while the remaining 5 were bilateral
(0.8%). Mean surgical time of the entire proce-
dure, including those during the learning curve
(5 procedures) was 35 min. In all cases, colour-
flow duplex was used during the operation and
we can firmly assert that the use of this instru-
ment is essential for the correct execution of the
procedure.

Percutaneous access was possible in 422 cases
(39.2%), while a surgical exposure of the saphe-
nous trunk became necessary in 654 (60.8%)
patients. In the majority of these (74.5%) it was
adopted a local anesthesia, while epidural anaes-
thesia, or sometimes other as propofol in the rest
(25.5%).

In 875 cases, complementary surgery was per-
formed such as ablation of varicose tributaries
(794 cases) or ligation of incompetent perforators
(81 cases). An elastic bandage was applied for the
first 24-48 h, while in 463 (43%) patients LMWH
prophylaxis against venous thromboembolism
was administered for 3-7 days in accordance with
each team’s customs because of risk factors such
as age, obesity and previous thrombosis. Subse-
quently, elastic stockings (18 mmHg) had to be
worn in the day-time for a period of 4 weeks.

All the patients were fully ambulant within an
average time of 2 h: in fact, the greater part of the
procedures has been carried out as Day Surgery
(Table III).

The small number of necessary patient hospi-
talization was principally due to the distance
between the treatment site and patient’s home.

In the immediate postoperative period the

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<td>Milan</td>
<td>Institute of Vascular Surgery and Angiology, University of Milan</td>
</tr>
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<td>Siena</td>
<td>Surgical Department, Phlebo-Lymphological Centre, University of Siena</td>
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<td>Verona</td>
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<td>Padua</td>
<td>Multidisciplinary Day Surgery Centre, Busonera Hospital, University of Padua</td>
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Figure 1.—Refluxes: haemodinamic patterns in surgery (accor-
ding to Camilli 12).
results were impressive, with effective closure of incompetent GSV and other treated varicose veins (the early occlusion rate has been of 99%). Major complications have not been detected: in particular, no DVT was detected by the duplex ultrasound, specially if considering the elevated average age of the patients. However, 11 SVT have been observed (1%), more properly to be defined “periphlebitic events”, due to laser-induced heat transmission from the inner vein to the perivenum. Minor complications characterized by rapid clinical resolution are shown in Figure 2.

The patients’ acceptability and satisfaction measured with appropriate forms regarding the quality of life, was 96.7%. Ten patients expressed an insufficient satisfaction probably due to pain suffered during operation (Figure 3).

Currently, we possess over 6 year results in terms of long-term follow-up, but in this study we have decided to consider a 36 months period for all the centres using duplex scanning.

Controls have been carried out by duplex scan, in a total average according to the number of treatments carried out in every centre. The total occlusion rate has been of 97% and only 6% patients required complementary sclerotherapy or phlebectomy of remaining distal varicosities.

**Discussion**

The IEWG has decided to work for an investigation and widespread use of a new treatment for CVI by introducing a Registry. This is the most suitable tool for collecting data as far as such a technologically innovative procedure is concerned. Although Registries produce a lower level of clinical evidence than the randomised clinical trials, they became the most advantageous way to illustrate the reality of the clinical practice. They generate immediate feedback and professional discussion, improve the self-assessment and develop a better decision-making, without long delays or waits for final results. They furthermore enable a larger quantity of data to be collected. Unlike studies on of new drugs and their introduction, which are, furthermore, covered by adequate European legislation, randomised controlled studies are not particularly suitable tools to analyze new surgical practices and biomedical technology. The reasons for this include the learning curve, the rapid evolution of technology even while a study is in progress, the difficult ethics involved in proposing alternative surgical procedures etc. Registries, on the other hand, have proved their worth as valid tools in the field of vascular medicine, starting as far back as 1979, with the first experience of the Cleveland Vascular Society for collecting computerised data on a large scale. Other useful references supporting the decision to introduce the Registry can be found in the EVAR Registry and in the TASC Registry.13, 14

Perrin and Bergan claim the absence of phenomena of neovascularisation, and in particular
at the SFJ following the endoluminal surgery. It is known that this phenomenon, which occurs rather frequently (20-40% at 5 years) after standard surgery plays an important role in the incidence of recurrence. Maintaining the patency of the saphenous termination tributaries can probably play a favourable role, since these tributaries drain physiological (Figure 4), as shown by the duplex ultrasound investigation performed after the GSV endovenous obliteration.6, 9, 10

The mid/long-term results after 3 years were particularly favourable after EVL both in term of vein obliteration and in terms of symptomatological absence and few minor residual varicosities.

Under the economical point of view, the varicose vein surgery involves a cost estimation of the EVL which is definitively cheap for the catheter and favourable in the global cost, as well as for the generator (with respect of the Italian DRG reimbursement).

Finally, possible conflicts of interests are presently a highly topical problem at the international level, aggravated by the development of an increasingly technology-dependent medicine. This, therefore, is unquestionably connected to relations between medical personnel and industry.15 In this context, and mainly for reasons of accountability, the members of the IEWG Board feel that it is extremely important to pursue a working programme in which we are not only investigators but also developers of the technologies and procedure in question. This occurred with our development of a step-by-step protocol for a new treatment possibility of saphenous insufficiency which is less invasive than stripping. Greater and/or shorter varicose vein stripping has proven to be a standard method for treatment of CVI but it is also associated with a significant incidence of recurrence in the groin and of complications and it can result in delayed resumption of normal activity.

Conclusions

Several reports have confirmed the efficacy and safety of EVL. The IEWG presented a large number of scientific contributions in the 15th World Congress of Union International de Phlébologie.16

The first large Italian experience with EVL based on preoperative, perioperative and postoperative duplex control and patients satisfaction at mid/long-term indicated some advantages over standard treatment with stripping method. In terms of reduced postoperative pain, shorter sick leave, faster resumption of the normal activities, and, in particular, the total absence of DVT, we conclude that EVL is a good solution for the patients with standard saphenous vein stripping indication to treat.

Nevertheless, the IEWG would like to recall that innovative Laser treatment of CVI should not let us forget the mainstay of CVI therapy, which for the majority of the patients is not surgery. In these cases, pharmacological and compression therapy must be considered. Similarly, when the indications are appropriate, the IEWG suggests that other options such as ablative surgery and hemodynamic treatment or sclerotherapy should be preferred (www.IEWG.org).17 Patients should be closely followed after the procedure so to ensure a long-term benefit and care.17, 18

References


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Endovenous Laser Treatment for Varicose Veins in Patients with Active Ulcers: Measurement of Intravenous and Perivenous Temperatures during the Procedure

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GLORIA MARIA BRAGA POTÉRIO, MD, PHD,‡ FÁBIO HÜSEMANN MENESES, MD, PHD,‡ AND
GUILHERME VIEIRA MEIRELLES, MD*

BACKGROUND Conventional saphenous vein stripping is difficult to be indicated for the treatment of varicose veins in patients classified as CEAP C4, C5, or C6.

OBJECTIVE This study was developed to evaluate treatment results for varicose veins with active ulcers using endovenous laser (EVL), compared to a group undergoing clinical treatment, during 1 year.

PATIENTS AND METHOD Fifty-two patients presenting with varicose veins with active ulcers for more than 1 year were divided for treatment into two randomized groups: Group 1, clinical treatment, composed of 25 subjects, was submitted to elastic or inelastic compression therapy; Group 2, EVL treatment, composed of 27 subjects, was submitted to great and or small saphenous vein ablation with a 980-nm diode EVL, plus the clinical treatment. Intravenous and perivenous temperatures were measured continuously during the EVL treatment. All patients were followed for 12 months and studied with ultrasound at the beginning and end of the study. The ulcers’ areas were evaluated initially and at every 3 months.

RESULTS In 12 months, 81.5% of the wounds in patients in Group 2 and only 24% in patients in Group 1 had healed. Ulcer recurrence rate was 44.4% in Group 1. The mean wound area in Group 1 decreased from 17.48 to 12.76 cm² at the end of the year. In Group 2, the wound area decreased from 22.26 to 2.7 cm² (p = .0037). Mean intravenous and perivenous temperatures of 79.3 and 43.0°C were recorded.

CONCLUSION The treatment for varicose veins with EVL is safe in patients with active ulcers. Wounds healed faster than in patients undergoing clinical treatment alone during a 1-year period. There was no ulcer recurrence in patients treated with EVL.

The authors have indicated no significant interest with commercial supporters.

Knowledge of varicose veins in the lower limbs is ancient and was engraved on stone in a Greek temple dating back to 3000 B.C.¹ Nevertheless, attempts at treatment only appeared more recently by the end of the 18th century until the present. The best results were obtained with stripping of the dilated veins, using the technique recommended by Babcock in 1907 and is still currently accepted by the medical literature.² Since that time, no major technical advance has been recorded in the area of varicose vein surgery, which is performed essentially with the same technique as it was in the past 100 years.

The concept of provoking heat inside a dilated vein using laser, named endovenous laser (EVL), to produce photothermal sclerosis was formulated by Boné in 1998. The first record dates from 1999.³ Such study allowed the publication of other important articles showing good results and few complications, arousing interest in the medical class for this minimally invasive treatment of varicose veins.⁴⁻¹⁰
In more advanced stages of chronic venous insufficiency with clinical classifications CEAP C4, C5, and C6, the limitations or contraindications to surgical treatment by conventional vein stripping are due to areas of extensive dermatosclerosis, fibrosis, ulcer scarring sequelae, active ulcers, edema, and lymphedema.11

This study was developed to prospectively evaluate treatment results of EVL use for management of varicose vein with active ulcers, compared to another group of varicose vein patients who also had active ulcers and were undergoing clinical treatment during a 1-year period.

**Patients and Methods**

Fifty-two consecutive patients with varicose veins in the lower limbs with active ulcers were selected. Varicose veins were categorized as primary, and patients had been undergoing treatment in the Vascular Surgery Outpatient Facility at the Clinics Hospital of the Universidade Estadual de Campinas (UNICAMP) for more than 1 year.

Exclusion criteria were patients who had previously undergone saphenectomy; those with acute deep venous thrombosis or superficial thrombophlebitis, occlusion of the femoral or iliac vein presenting with postthrombotic syndrome, coagulation disorders, peripheral arterial disease, or degenerative systemic diseases; pregnant women; and those who were unable to ambulate.

For each patient studied, a summary of the general clinical history, ulcerating lesions evolution (duration in years, recurrences, and types of treatments performed), and other comorbidities (diabetes, arterial hypertension, heart, lung, and kidney disease) was recorded. The basic characteristics of patients were similar in both groups and are shown in Table 1.

All patients were evaluated with duplex ultrasound (ATL HDI 3000, Advanced Technology Laboratories, Redmond, WA) with broadband linear array transducer (5–12 MHz) and had important reflux at the great saphenous vein (GSV), small saphenous vein (SSV), or both. In addition, all patients presented a mean of 1.6 incompetent perforators near or in the site of the ulcer and other important branches with reflux.

This study was approved by the Research Ethics Committee of the Medical School of the State University of Campinas (UNICAMP), under No. 039/2005. The patients previously signed an informed consent form and the study protocol conformed to the 1975 Declaration of Helsinki. All patients were offered the clinical treatment. Two groups of patients randomly allocated (case yes/case no) to receive clinical treatment or EVL plus clinical treatment were studied: Group 1, composed of 25 patients with follow-up for clinical treatment; and Group 2, composed of 27 patients treated with EVL plus clinical treatment.

The clinical treatment proposed to the patients consisted in applying dressings at home, followed by the use of an elastic support (hose or an elastic bandage) or an Unna’s boot, according to medical recommendation. No special care or advice was given to any patient in Group 1.

Patients in Group 2 underwent EVL treatment for trunk varicose veins and major branches with reflux, always by the same surgeon. The GSV was treated in 17 cases (63.0%), the SSV in 3 cases (11.1%), and both saphenous veins in 7 cases (25.9%). The Giacomini vein was treated in 3 cases. After 48 hours of compression bandages (20–30 mmHg) all surgical patients continued to apply dressings at home following the routine adopted in the preoperative...
period, in a manner similar to that of the patients in Group 1.

Patient follow-up lasted 1 year. Ultrasound control was performed after 1 week and 30 days and every 3 months until completing 12 months after intervention (Group 2) and in the beginning and at the closing of the study in Group 1. Measurements of ulcer areas were made at the beginning and at 30 days and every 3 months, in both groups. Ulcer areas were measured by placing a plastic transparent sheet over the ulcer and tracing the wound area with a pen. Afterward, a digital photograph of this map was made along a metric scale. The photographs were transferred to a computer where the area was calculated in square centimeters with the aid of computer software (DicomWorks v 1.3.5, Philippe Puech and Loïc Boissel, 2001).

**Technique of EVL Treatment**

The device used was a 980-nm-wavelength diode laser, optic power of 15 W, and pulse-mode operation (Biolitec, Biomedical Technology, Bonn, Germany). Immediately before treatment, the patients were mapped with ultrasound Mode-B, standing up, to determine the diameter of the vein to be treated. Vein diameter was written on the limb at 10 cm intervals starting at the saphenofemoral junction. The amount of energy necessary to obliterate the vein was empirically determined by the authors, based on previous experience, to be 80 J per linear centimeter. To obtain this, the pulse energy was set to 3 J/mm vein diameter and the pulses were repeated in each 1-cm segment to achieve a minimum of 80 J. For example, for an 8-mm GSV, the pulses were set to 24 J and four pulses were applied for each linear centimeter of the vein. All patients received 15 mg midazolam by the oral route, 30 minutes before the procedure.

Vein access for endoluminal placement of the fibers was achieved by means of percutaneous venipuncture under ultrasound guidance, using a 16-gauge needle at the ankle or the knee levels. A 600-μm fiber optic was introduced directly into the vein, placing its tip immediately distal to insertion of the superficial epigastric vein at the groin. When the puncture was made in the knee level, the optic fiber was introduced proximally and distally to treat the entire length of the GSV. Local anesthesia using tumescent infiltration with 50 to 200 mL of 0.2% lidocaine was also performed under ultrasound guidance.

The laser energy, previously calculated for each site, was delivered in pulse mode. The fiber was manually retracted 2- to 5-mm at intervals between pulses. The resting period was gauged to 2 seconds. This cycle was repeated until a distance of 1.0 cm from the puncture site. In all cases, the GSV and/or SSV has been treated from the groin to the ankle. Subsequently, the fiber was removed and the more important collaterals received EVL therapy through multiple punctures. Because there was no means of maintaining a continuous traction on the optic fiber, it was decided to treat all patients by means of pulsed mode laser only. With the completion of laser intervention, patients received a Class II elastic compression (20–30 mmHg) that was applied to the entire extent of their limbs. The patients were instructed to wait in a supine position with their legs elevated until they were in optimal condition to ambulate. Discharge from the post anesthesia recovery room occurred 2 to 3 hours later. An elastic band was used for 2 consecutive days, and routine preoperative therapy was resumed afterward.

In all patients treated with EVL, benzathine penicillin (1,200,000 U intramuscularly in a single dosage) and 500 mg cephalaxin every 6 hours were administered for 1 week. During and after the procedure, the patients were inquired about pain and responded to only three alternatives: no pain, bearable pain, and unbearable pain.

**Measurement of Intravenous and Perivenous Temperature**

During each procedure, intravenous and perivenous temperatures were measured continuously, at the same height of the vein (in real treatment situation)
during traction of the optic fiber, for all times of treatment. The study site chosen for the GSV was the middle thigh or middle leg region. For the SSV, the site chosen was the middle leg region. Measurements were made once for each patient. The introduction of a probe (thermocouple) into the vein, for temperature measurement, was performed by venipuncture with a 14-gauge needle. Another probe was placed perivascularly, 4 mm (SD, 1 mm) near the vein wall. Both punctures were guided by ultrasound.

The probes for temperature readings (intravascular and perivascular) were connected to a digital thermometer (TESTO 175, Testo, Inc., Lenzkirch, Germany) with a serial interface allowing connection to a microcomputer. Using the bundled software, temperature readings were made and recorded every 2.0 seconds in both channels in real time, during all the treatment, allowing the correlation between temperature levels achieved and the amount of energy delivered.

**Statistical Analysis**

The category variables were shown in contingency tables, containing absolute and relative values. The numerical values were analyzed by descriptive statistics. Analysis of differences between both groups was performed with Student's *t*-test for independent samples and chi-square test. Statistical significance was set at *p* < .05.

**Results**

At the end of the third month of treatment, 17 of 27 patients treated with laser had their ulcers completely healed (62.9%), whereas in the clinical treatment group, only 3 (12.0%) of 25 patients had complete wound healing (*p* = .0002). At the end of the first year of study, ulcers healed completely in 81.5% of the patients treated with laser, whereas complete healing occurred in only 24% of those in the clinical treatment group (*p* = .0001; Table 2). The clinical course of the mean ulcer area in both groups is demonstrated in Table 3. Among patients in Group 1, of 9 limbs (36%) that had healed, 4 (44.4%) presented with ulcer recurrence within 30 to 90 days after healing. Of these, only 1 limb (25%) healed again (Table 4).

<table>
<thead>
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<th>TABLE 2. Rate of Ulcers Healed</th>
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<td><strong>Group</strong></td>
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*p* < .05

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<th>TABLE 3. Clinical Course of the Mean Ulcer Area in Both Groups</th>
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<td><strong>Ulcer area (cm²)</strong></td>
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minimum of 61.1°C and maximum of 96.3°C (mean, 79.3°C; SD, 12.44°C). Perivenous temperature oscillated between a minimum of 35.5°C and maximum of 48.4°C (mean, 43.0°C; SD, 5.28°C). In all cases, immediate venous occlusion was a constant factor that did not change during ultrasound controls until the end of the study.

The mean length of treated vein was of 51.7 cm for the GSV and 32.0 cm for the SSV (including the Giacomini vein). The mean amount of laser energy delivered was of 95.17 J/cm in GSV (SD, 19.9 J/cm) and 88.7 J/cm in the SSV (SD, 25.1 J/cm).

**Adverse Effects**

The procedure was performed under local anesthesia using tumescent infiltration and was very well tolerated by the majority of the patients. In 9 limbs treated (33.3%), however, the patients complained of “bearable” pain, which did not prevent or make it difficult to continue the procedure. No case of “unbearable” pain was found. Ecchymoses were observed in 17 limbs (62.9%), in the length of the GSV, and were more extensive along the middle and distal one-third of the thigh, completely disappearing with no sequelae at the end of the 4th week. Induration of the vein undergoing treatment was observed in 18.5% of cases (5 limbs). There were no cases of phlebitis, deep vein thrombosis, or pulmonary embolism. In 1 limb (3.7%), hyperpigmentation occurred in the length of the GSV. Transient paresthesia was observed in 6 limbs (22.2%), located in the medial surface of the middle and distal one-third of the leg and medial and/or lateral inframalleolar region. All cases had complete spontaneous remission at the end of the 6th month, without need of any further treatment. No case of infection related to the procedure was found. In 1 limb (3.7%), there was a skin burn in the medial surface of the middle one-third of the leg, forming a bleb and ulcer, which resolved completely by the end of the 3rd month, resulting in small scarring sequelae. There was also one case (3.7%) of lipoid necrosis in the medial surface of the upper one-third of the leg in which ultrasound-guided aspiration became necessary in the 10th day, with complete resolution at the end of the first month and no sequelae. In two cases (7.4%), thrombus extended 2 or 3 mm from the internal saphenous vein to the common femoral vein, without progression; no deep vein thrombosis or pulmonary embolism was observed and complete spontaneous resolution occurred by the end of the 1st month. All patients were satisfied with the decision to undergo EVL treatment and the subsequent results.

**Discussion**

The protocol employed in this study was modified and adapted from the studies by Navarro and colleagues among others. The performance of conventional varicose vein surgery for patients with varicose ulcers may not always be indicated due to risks from infection and unsuitability of the skin overlying the region to be treated. Furthermore, anesthesia is required and these patients who have common comorbid conditions (obesity, diabetes, and advanced age) are bedridden for a certain period of time after surgery causing serious inconvenience. If the region to be treated has infected wounds and fibrosis, the surgeon is unable to remove the veins adequately, especially in the distal leg region.
The correction of venous reflux as proposed by EVL use, with immediate permission to ambulate, seems to be the most adequate course of action. All effort should be made to reestablish normal hemodynamic conditions in the limb and the social life of each patient.

Ultrasound study at 1 week and 30 days after EVL treatment always showed obstruction of the veins treated. There were very few sites of blood pooling and absence of circulation. Complications found within 30 days were hyperpigmentation, fibrosis in the length of the vein, and regional ecchymosis and no case required treatment. There was no case of deep vein thrombosis or symptomatic pulmonary embolism. No case of worsening of ulcer infection was found. In contrast, improvement of local infection and secretions was noted.

All patients treated with EVL showed improvement within 30 days, either by a decrease in the size of the ulcers (Table 3) or by a reduction in the severity of edema in the distal leg region, which patients referred to as “the treated leg being the lighter leg for walking.” In addition, the ulcers became shallower and with less secretions. Changes in wound color from yellowish to reddish and no pain in some cases were observed.

Ulcer closure occurred in 3 months in 62.9% (17 limbs) and in 30 days (44.4%) in 12 cases. Ulcer areas smaller than 5 cm² had the best response in 90 days. Age appeared not to have influence on ulcer healing because one 88-year-old patient recovered quickly after treatment. Patients who delayed in responding with complete healing had complete tibial tarsal ankylosis with atrophic calf muscle. In these cases, gait disturbance could be responsible for maintaining residual edema, although it was milder than before surgery. These patients were advised to wear knee-length elastic stockings on a permanent basis.

No major complication could be attributed to the technique proposed. It could now be considered the optimal treatment for CEAP-C6 patients in the manner proposed. Whether laser can be used for varicose veins without complications and in young patients is debatable, because of the low complication rates currently seen with vein stripping.

Lesion of the saphenous nerve is the most feared complication.17

Figure 1. Intravenous and perivenous temperature during endovenous treatment of varicose veins.
The thermometer used was considered optimal, comfortable, and safe for the patient. It also came bundled with an extremely versatile and reliable program. A temperature study showed that inside the vein the temperature achieved was variable, although the same technique (laser power calculation) and instrument were used. This variation is still the object of ongoing investigation. Mean temperature was 79.3°C, ranging from 61.1 to 96.3°C at the time the fiber reached the thermometer. In all cases, retraction and immediate occlusion of the vein were observed. There was no difference between immediate and late occlusion rates. No treatment failure or vein recanalization occurred during the study period.

Temperature measurements taken in real treatment situation allowed us to observe the efficiency in thermal protection. Protection was provided by perivascular tumescent infiltration that was correctly performed under ultrasound guidance, maintaining mean perivenous temperatures consistently below 45°C. Meanwhile, mean intravenous temperatures were maintained above 75°C. These thermal curve characteristics ensure efficiency in treatment with a low complication rate.18,19

External temperatures were much lower (between 45 and 50°C), lasted a much shorter period, and showed adjustment for power calculation. An important observation was that peak intravenous temperature was of a short duration, but the temperature inside the vessel was maintained above 50°C for more than 2 minutes (ranging from 120 to 240 seconds; Figures 1 and 2) after laser pulse was delivered. This may be a factor determining the definitive thermal lesion in the vessel wall.18,19

Because varicose vein recurrence is always a possibility, these patients should be evaluated annually (duplex Doppler ultrasound). The procedures must be repeated whenever new branches that are considered important appear and venous reflux occurs.

In conclusion, the technique proposed should be used for these cases in the modern medical armamentarium because it is capable of correcting superficial venous reflux in a “minimally invasive” and definitive manner, in the more difficult patients.

Figure 2. Intravenous and perivenous temperature during endovenous laser treatment for varicose veins.
References


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COMMENTARY

This is a very good paper, describing a well-done study on a very important topic. This is the only paper of which I am aware that examines the direct correlation between thermoablation of the incompetent great saphenous vein (GSV) and ulcer healing in C6 patients only, compared to traditional “medical” care. I do have a few comments. First, the rate of paresthesia following laser ablation of the GSV is quite high at 22%, even though it is apparently short-lived. I also noticed that patients complained of “bearable pain” during the procedure. Both of these factors indicate less than adequate perivenous local anesthesia, and as the authors gain experience, the rate of paresthesia should diminish dramatically. Furthermore, either adequate local anesthesia to protect the saphenous nerve or limiting treatment to the portion of GSV above the knee should also improve the paresthesia rate. I suspect that the paresthesia rate for those patients treated along the entire length of the GSV is much higher than for those treated above the knee only. Second, I am unclear from the authors’ description how these patients were randomized to surgical versus medical care and if there may have been any bias introduced at that step. Third, I am curious how close the perivenous temperature probe was to the vein and how this distance was determined and
therefore where these perivenous temperatures were monitored. This measurement could also explain a 22% paresthesia rate if it was more monitored than 1 to 2 mm from the vein. This information is more important to me as a clinician than a description of the exact nature of the temperature-measuring equipment and software that was used. Fourth, the quality of the ultrasound equipment and the sensitivity of the transducer has a direct correlation with the ability to achieve accurate failure rates. These are not specified in the study, and I question a 100% success rate, even at 1 year. Fifth, it appears that the only adjuvant therapy in the surgical patients was laser ablation of some tributary veins. I think with carefully conducted follow-up duplex exams, and ultrasound-guided sclerotherapy directed to the other sources of reflux, such as perforators, in the area of the ulcers, the authors might well have achieved an even higher rate of successful, “permanent” healing of the ulcers. Finally, the medical care that Group 1 received for the venous ulcers, while probably typical in a nonspecialized setting, was abysmal, apparently consisting of bandages, elastic wraps, and the occasional Unna’s boot. Surely a much higher healing rate could have been achieved with inelastic dressings (other than Unna’s boot), compression hose, and careful, knowledgeable follow up. In all fairness, it appears that the patients in Group 2, after 48 hours of compression hose, may have received the same sort of inadequate medical care.

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Endovenous laser ablation

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ABSTRACT

Endovenous laser ablation (EVLA) is a less invasive alternative to vein stripping. Outcomes seem equal to, or better than, those with stripping, with better quality of life scores in the post-operative period. EVLA has been shown to correct or significantly improve hemodynamic abnormality in patients with chronic venous insufficiency (CVI) with superficial venous reflux. Early reports suggest that endovenous ablation techniques, in contrast to surgical stripping, are associated with a low incidence of neovascularization.

A variety of wavelengths are being used to perform EVLA. While the initial chromophore is water or hemoglobin, depending on the wavelength used, carbon appears to be a secondary but key chromophore that is probably independent of wavelength.

The application of the principles of tumescent anesthesia to venous treatments, along with the development of endovenous ablation techniques, offer the possibility of treating the vast majority of patients with varicose veins in-office without general anesthesia or surgical incisions, while at the same time maximizing outcomes and minimizing recurrence.

INTRODUCTION

Saphenous vein reflux is the underlying primary abnormality in the majority of cases of superficial venous insufficiency. Thus, approaches to dealing with saphenofemoral junction and saphenous truncal incompetence have dominated the thinking of phlebologists. Trendelenburg described saphenofemoral junction ligation alone, without stripping of the incompetent saphenous vein, in the 1890s. The advantages of ligation alone over ligation and stripping, which are still extolled today, include preservation of the saphenous trunk for possible future use as a bypass graft and avoidance of saphenous nerve injury. High ligation by itself is less...

Keywords: endovenous laser ablation, EVLA, EVLT, saphenous reflux.
invasive, quicker and simpler to perform, and associated with an easier recovery when compared to vein stripping. While it is true it routinely “spares” the saphenous trunk,¹ the use of a diseased saphenous vein as a conduit has been associated with an increased risk of graft failure.² Most importantly, there is no longer any question that high ligation alone usually results in persistent reflux in the saphenous trunk.³ Varicose recurrence is significantly reduced⁴ and the re-operation rate is 60% to 70% less if the saphenous vein is stripped compared with ligation alone.⁵ Also, after ligation alone, recurrence or residual communication with the junction in the groin was found in 80% of patients, while 34% also had mid-thigh perforator incompetence via the unstripped great saphenous vein (GSV).⁶ As Neglen concluded, stripping of the GSV of the thigh is essential to minimizing recurrence that is caused by redevelopment of incompetent communication with the saphenofemoral confluence, and due to thigh perforator incompetence.⁷ Simply put, the shortcomings of ligation alone outweigh its advantages.

It is important to note that recurrence is common even after ligation and stripping of the saphenous vein. While inadequate surgery of the saphenofemoral junction and progression of disease are mechanisms that explain some cases of recurrence, another important mechanism is neovascularization around the junction after venous surgery.⁸ In fact, neovascularization has been reported as the principle cause of recurrence,⁹ with neovascular channels of variable size, number, and tortuosity accounting for the reflux to recurrent varicosities in the majority of cases.¹⁰ Though some have expressed doubt as to the veracity of true neovascularization, there is clear histological evidence that neovascularization is a cause of recurrent varicose veins.¹¹ Early reports suggest, in contrast, that endovenous ablation techniques are associated with a very low incidence of neovascularization.¹² It may be that the development of neovascularization is largely prevented by avoiding groin dissection and by preserving venous drainage in normal junctional tributaries.¹³,¹⁴

EVLA, like radiofrequency ablation and foam sclerotherapy, is a less invasive alternative to vein stripping. EVLA is indicated in an ambulatory patient with great, small or accessory saphenous vein reflux with surface varices and/or symptoms or complications related to superficial venous insufficiency. EVLA is routinely performed using dilute local anesthesia, with or without supplemental oral anxiolitics, in an office setting. Generally taking 30-60 minutes to perform, procedure times are dependent on the length of segment treated, experience of the operator, and whether ancillary procedures, such as ambulatory phlebectomy, are done. Regardless of how underlying saphenous incompetence is treated, ancillary treatments are typically needed to treat residual varices (Figure 1).

**EFFICACY**

Short- and mid-term studies of EVLA, regardless of wavelength used, seem remarkably consistent, typically reporting ablation of refluxing saphenous veins in 90% or more of cases.¹⁸,²⁰-²³ EVLA of the saphenous vein has been shown to correct or significantly improve the hemodynamic abnormality and clinical symptoms of chronic venous insufficiency (CVI) in Clinical, Etiological, Anatomical, Pathophysiological (CEAP) clinical class 3-6 patients with superficial venous reflux.²⁴-²⁵ Outcomes seem equal to or better than those of stripping, with better quality of life scores in the post-operative period compared to stripping.²⁶,²⁷ High patient satisfaction rates have been reported.¹⁸,²⁸,²⁹ The total cost (cost of the procedure plus societal cost) of endovenous procedures is likely equal to or lower than that of surgery.²⁷

Early data on treatment of the GSV with 810 nm and 940 nm devices suggest treatment failure is uncommon.
in patients treated with >70 J/cm. A withdrawal rate of 2 mm/sec at 14 watts delivers 70 J/cm.

MECHANISM OF ACTION

The following wavelengths are in current use for EVLA: 810, 940, 980, 1064, 1319, 1320, and 2068 nm. It has been postulated that vein wall injury is mediated both by direct effect and indirectly via laser-induced steam generated by heating of small amounts of blood within the vein. Some have suggested that choice of wavelength greatly impacts results.

The main chromophore of 1320 and 2078 nm lasers, at least initially, is water, while other wavelengths used for EVLA primarily target hemoglobin. Obviously it is imperative to thermally damage the vein wall adequately in order to obtain effective ablation. Some heating may occur by direct absorption of photon energy (radiation) by the vein wall as well as by convection from steam bubbles and conduction from heated blood. However, it is unlikely that these latter mechanisms account for the majority of impact on the vein. The maximum temperature of blood is 100°C. Laser treatment has been found to produce carbonization of the vein wall. Carbonization of the laser tip, which occurs at about 300°C, is noted following EVLA, and seems to occur regardless of the wavelength used. Carbonization of the laser fiber tip creates a point heat source and essentially reduces light penetration into tissue to zero. Mordon et al stated “The steam produced by absorption of laser energy by the blood is a tiny fraction of the energy necessary to damage the vein wall and cannot be the primary mechanism of injury to the vein with endovenous laser. The carbonization and tract within the vein walls seen by histology following endovenous laser can only be the result of direct contact between the laser fiber tip and the vein wall.” Dr Rox Anderson, director of The Wellman Center for Photomedicine at Massachusetts General Hospital, reported that carbon appears to be a secondary but key chromophore that is probably independent of wavelength (Figure 2). Note that fiber tip and shape may impact development of carbonization.

TUMESCENT ANESTHESIA

EVLA should be performed under local anesthesia using large volumes of a dilute solution of lidocaine and epinephrine (average volume of 200-400 mL of 0.1% lidocaine with 1:1,000,000 epinephrine) that is buffered with sodium bicarbonate. This solution should be delivered either manually or with an infusion pump under ultrasound guidance so the vein is surrounded with the anesthetic fluid along the entire length of the segment to be treated (Figure 3). The benefits of tumescent anesthesia for endovenous ablation include:

• anesthesia,
• separation of vein to be treated from surrounding structures,
• thermal sink, which reduces peak temperatures in perivenous tissues,
• vein compression, which maximizes the effect of treatment on the vein wall.

Although the maximum safe dosage of lidocaine using the tumescent technique for venous procedures is not
well studied, a dosage of 35 mg/kg is a reasonable estimate.

Using these parameters, tumescent anesthesia in the context of liposuction has been shown to be extraordinarily safe. More information is available at http://www.liposuction.com/pharmacology/drug_interact.php.

**CONTRAINDICATIONS TO EVLA**

Contraindications to EVLA technique are summarized in Table I.

<table>
<thead>
<tr>
<th>Allergy to local anesthetic</th>
<th>Hypercoagulable states</th>
<th>Infection of the leg to be treated</th>
<th>Lymphedema</th>
<th>Nonambulatory patient</th>
<th>Peripheral arterial insufficiency</th>
<th>Poor general health</th>
<th>Pregnancy</th>
<th>Recent/active venous thromboembolism</th>
<th>Thrombus or synechiae in the vein to be treated</th>
<th>Tortuous great saphenous vein (it may be difficult to place the laser fiber)</th>
</tr>
</thead>
</table>

Table I. Contraindications to endovenous laser.

## ADVERSE SEQUELAE

Short-term pain and ecchymoses have been commonly observed after EVLA. Intermittent-pulsed laser fiber pullback has been reported, in a retrospective review, to cause significantly greater levels of post-operative pain and bruising, compared with a continuous pullback protocol. Adding a short-stretch bandage for 3 days following intermittent mode EVLA substantially reduced patient-reported bruising and pain. Employing continuous mode pullback further reduced the severity of pain and bruising to such an extent that levels were similar to those reported by patients treated with radiofrequency ablation (Tables II and III). Preliminary reports suggest there may be some differences in postoperative course depending on wavelength used to perform EVLA, however, this is based on sparse data with short-term follow-up.

## PERIVENOUS THERMAL INJURY

Mean peak intravascular temperatures during EVLA (goat jugular vein, 12 watts, 1-second pulses, 1-second intervals), measured flush with the laser tip, averaged 729°C, while those 4 mm distal to the tip averaged 93°C. However, the risk of collateral thermal injury depends on perivenous tissue heating, not intravascular temperature.

<table>
<thead>
<tr>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulsed: stockings (n=21)</td>
<td>28%</td>
<td>23%</td>
</tr>
<tr>
<td>Pulsed: stockings + short-stretch bandage (n=8)</td>
<td>37%</td>
<td>50%</td>
</tr>
<tr>
<td>Continuous: stockings + short-stretch bandage (n=16)</td>
<td>75%</td>
<td>25%</td>
</tr>
<tr>
<td>Radiofrequency: stockings (n=16)</td>
<td>88%</td>
<td>12%</td>
</tr>
</tbody>
</table>

Table II. Patient-rated post-operative bruising 3-7 days following pulsed endovenous laser ablation (EVLA) with class II stockings, pulsed EVLA with stockings plus short-stretch bandage, continuous mode EVLA with stockings and short-stretch bandage, and radiofrequency ablation with stockings.

<table>
<thead>
<tr>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulsed: stockings (n=21)</td>
<td>38%</td>
<td>39%</td>
</tr>
<tr>
<td>Pulsed: stockings + short-stretch bandage (n=8)</td>
<td>50%</td>
<td>38%</td>
</tr>
<tr>
<td>Continuous: stockings + short-stretch bandage (n=16)</td>
<td>81%</td>
<td>19%</td>
</tr>
<tr>
<td>Radiofrequency: stockings (n=16)</td>
<td>75%</td>
<td>25%</td>
</tr>
</tbody>
</table>

Table III. Patient-rated post-operative pain 3-7 days following pulsed endovenous laser ablation (EVLA) with class II stockings, pulsed EVLA with stockings plus short-stretch bandage, continuous mode EVLA with stockings and short-stretch bandage, and radiofrequency ablation with stockings.
Collagen has been noted to contract at about 50°C, while necrosis occurs between 70°C and 100°C. The extent of thermal injury to tissue is strongly dependent on the amount and duration of heat the tissue is exposed to. Henriques and Moritz investigated the time-temperature response for tissue exposed to up to 70°C. They found that skin could withstand temperature rises for very short exposure times, and that the response appears to be logarithmic as the exposure times become shorter. For example, an increase in body temperature to 58°C will produce cell destruction if the exposure is longer than 10 seconds. Tissues, however, can withstand temperatures up to 70°C if the duration of the exposure is maintained for less than 1 second. Li et al reported that heating endothelial cells to 48°C for 10 minutes did not induce cell death. They also found that osteoblasts, after exposure for 10 minutes or less at 45°C, underwent transient and reversible changes. Another study found reversible tissue damage to the hind limb of mice after submersion in a waterbath at 44°C.

A recent study measured peak temperature at the outer vein wall during EVLA in a live pig ear vein and in exposed hind limb veins. EVLA settings ranged from 8 watts (1-2 second pulse durations), 10 watts (1-1.5 second pulse duration), 12 watts (0.5-1.5 second pulse duration) to 15 watts (0.5-1.0 second pulse duration), with and without tumescent anesthesia. Results demonstrate that peak temperatures ranged from 34.6°C to 49.1°C as a function of joules delivered, with lower peak temperatures obtained when tumescent fluid was present (Figure 4).

Peak temperature measured during EVLA (63 patients, 980 nm, 15 watts, 1.5 sec pulses) at the outer vein wall in humans, 3 cm below the saphenofemoral junction, was 40.9°C and 49.8°C with and without tumescent fluid, respectively. Similar results were reported from another human study during EVLA (12 patients, 810 nm, 12 W, 1 second pulses, 1 second intervals, tumescent technique), with peak temperatures of 43.3°C, 42.0°C, and 36.0°C at 3 mm, 5 mm, and 10 mm from the GSV, respectively.

There appears to be a very rapid fall-off in temperature over short distances during EVLA. This is probably in contrast to radiofrequency energy where microwave heating occurs around the tissue-electrode interface. The animal and human data suggest that peak perivenous temperatures generated during endovenous laser are unlikely to cause permanent damage to perivenous tissue in most situations. The peak temperature generated is reduced with the use of perivenous tumescent fluid. These findings seem to explain the very low reported incidence of nerve injury and skin burns following EVLA. One study, using a 1064 nm Nd: YAG laser, reported a very high incidence of paresthesia in 36.5% and skin burns in 4.8%. It should be noted that the amount of energy delivered was about three times higher than what is typically used and that treatment was done without tumescent anesthesia. Despite the low perivenous temperatures reported with EVLA, it is important to note that special caution is required when considering endovenous intervention in certain cases such as sciatic nerve varices.

**MAJOR COMPLICATIONS**

Major complications following EVLA have been reported rarely. Rates of deep venous thrombosis (DVT), pooled from multiple series, are much lower than 1%. One group reported an incidence of thrombus extension into the femoral vein of 7.7%. However, in that study EVLA was done under general or spinal anesthesia. The fact that patients were not able to ambulate immediately post-operatively may have contributed to the high incidence of thrombus extension. There is a single report of an arteriovenous fistula that developed following EVLA of the short saphenous vein (SSV). One patient developed septic thrombophlebitis following EVLA combined with open ligation of perforators and stab phlebectomy. This resolved with antibiotic treatment and debridement.
**ALTERNATIVE APPROACHES**

EVLA and radiofrequency ablation (RFA)\(^5^4\,^5^5\) both appear to be effective treatments for saphenous incompetence. Advantages of EVLA over RFA include shorter procedure times and lower per treatment cost. Reported occlusion rates of EVLA generally are slightly higher than those obtained with RFA.\(^5^6\) Disadvantages of EVLA may include more bruising and discomfort in the early postoperative period, although this may be technique-dependent. Both techniques continue to undergo refinement, which will improve results. Both procedures, when performed using tumescent anesthesia, are associated with low complication rates.

Another emerging treatment for saphenous reflux is the use of foamed sclerosants delivered under ultrasound control. A gas, such as air or CO\(_2\), can be mixed with liquid detergent sclerosants to create foam, estimated to be about four times more potent than the liquid form of the same agent. Early results suggest this may be a valuable modality, as it is quick and inexpensive to perform with reported short- and mid-term success rates of about 75% to 90%. There are many variables regarding foam (eg, type and amount of gas, technique used to create foam, concentration and type of sclerosant used, volume injected, etc). There may be a higher risk of deep vein thrombosis following foam sclerotherapy compared with standard sclerotherapy. Proper technique is important to minimize the risk of this complication. Other side effects reported following foam sclerotherapy include visual and neurological events. There is a published report of stroke following foam sclerotherapy (20 mL polidocanol foam) in a patient with a 1.8 cm patent foramen ovale.\(^5^7\) Further experience and research with this modality will better delineate its risks as well as long-term efficacy.

**CONCLUSION**

Currently accepted principles of treatment of varicose veins serve to maximize outcomes from a hemodynamic and patient standpoint, while minimizing the risk of recurrence. Appropriate treatment of varicose veins begins with an accurate assessment of the underlying venous pathology and identification of sources of venous hypertension. The aims of treatment include elimination of the incompetent connections between the deep and superficial systems, as well as the obliteration of pathways of venous incompetence and incompetent varicose veins. It is evident that recurrence is reduced if the incompetent segment of the saphenous trunk is ablated.

Endovenous laser ablation is a less invasive alternative to vein stripping. Outcomes seem equal to or better than those of stripping, with better quality of life scores in the post-operative period. EVLA has been shown to correct or significantly improve hemodynamic abnormality in patients with chronic venous insufficiency with superficial venous reflux. Early reports suggest that endovenous ablation techniques, in contrast to surgical stripping, are associated with a low incidence of neovascularization.

The application of the principles of tumescent anesthesia to venous treatments, along with the development of endovenous ablation techniques, offer the possibility of treating the vast majority of patients with superficial venous insufficiency in-office without general anesthesia or surgical incisions, while at the same time maximizing outcomes and minimizing recurrence.

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Endovenous laser ablation

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<th>Reference</th>
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Lower Energy Endovenous Laser Ablation of the Great Saphenous Vein with 980 nm Diode Laser in Continuous Mode

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Abstract

Purpose: To assess clinical outcomes, complication rates, and unit energy applied using 980 nm diode endovenous laser treatment at 11 watts for symptomatic great saphenous vein (GSV) incompetence and reflux disease.

Methods: Thirty-four consecutive ablation therapies with a 980 nm diode endovenous laser at 11 watts were studied. The diagnosis of GSV incompetence with reflux was made by clinical evaluation and duplex Doppler examinations. The treated GSVs had a mean diameter of 1.19 cm (range 0.5–2.2 cm). The patients were followed with clinical evaluation and color flow duplex studies up to 18.5 months (mean 12.19 months ± 4.18). The treated GSVs had a mean length of 33.82 cm (range 15–45 cm). The mean energy applied during the treatment was 1,155.81 joules (J) ± 239.50 (range 545.40–1620 J) for a mean treatment duration of 90.77 sec ± 21.77. The average laser fiber withdrawal speed was 0.35 cm/sec ± 0.054. The mean energy applied per length of GSV was 35.16 J/cm ± 8.43. Energy fluence, calculated separately for each patient, averaged 9.82 J/cm² ± 4.97. At up to 18.5 months follow-up (mean 12.19 months), 0% recanalization was noted; 92% clinical improvement was achieved. There was no major complication. Minor complications included 1 patient with hematoma at the percutaneous venotomy site, 1 patient with thrombophlebitis on superficial tributary varices of the treated GSV, 24% ecchymoses, and 32% self-limiting hypersensitivity/tenderness/”pulling” sensation along the treatment area. One patient developed temporary paresthesia. Four endovenous laser ablation treatments (12%) were followed by adjunctive sclerotherapies for improved cosmetic results.

Conclusion: Endovenous laser ablation treatment of GSV using a 980 nm diode laser at 11 watts in continuous mode appears safe and effective. Mean energy applied per treated GSV length of 35.16 J/cm or mean laser fluence of 9.82 J/cm² appears adequate, resulting in 0% recanalization and low minor complication rates.

Key words: Diode laser—Great saphenous vein—Laser ablation, endovenous—Valvular incompetence

Valvular incompetence at the saphenofemoral junction with great saphenous vein (GSV) reflux can result in chronic venous stasis disease. Significant clinical symptoms can result from chronic reflux disease, including chronic pain, edema, ulceration, and thrombophlebitis. The various clinical symptoms affect up to 55% of women and 50% of men, with visible varicosities seen in 20–30% of women and 10–15% of men [1], making varicosities of the GSV the most common manifestation of chronic venous disease encountered in clinical practice [2].

The incidence is highest in women between the ages of 40 and 49 years according to the Framingham study [3], with prevalence of varicose veins increasing with age [1, 4]. Given the high prevalence and morbidity of GSV reflux, effective yet low-risk treatment options are needed.

Treatment of GSV reflux has traditionally been surgical. Recently, minimally invasive endovenous laser ablation has shown promising results. This method causes direct thermal injury to endothelium and results in vessel occlusion.

Clinical results with endovenous laser ablation have been reported with 810 nm, 940 nm, and 980 nm diode lasers and with 1064 nm Nd:YAG lasers using 10 to 15 watts (W).
Table 1. Patient demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>% of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>23%</td>
</tr>
<tr>
<td>Female</td>
<td>77%</td>
</tr>
<tr>
<td>Among women</td>
<td></td>
</tr>
<tr>
<td>HRT use</td>
<td>50%</td>
</tr>
<tr>
<td>Parous</td>
<td>54%</td>
</tr>
<tr>
<td>History of:</td>
<td></td>
</tr>
<tr>
<td>Varicose veins in family</td>
<td>74%</td>
</tr>
<tr>
<td>Prior superficial phlebitis or resolved DVT</td>
<td>15%</td>
</tr>
<tr>
<td>Prolonged standing job</td>
<td>76%</td>
</tr>
</tbody>
</table>

DVT, deep venous thrombosis

Although investigators have used various wavelengths and energies [5–12], some studies advocate using higher energy for greater clinical responses [11, 13].

As laser ablation causes direct thermal effects, tendency toward higher energy may translate to greater thermal-related side-effects such as skin burn [12, 14]. The ideal laser energy to achieve permanent vein occlusion without unwanted thermal injury to surrounding structures or complication is currently unknown.

We treated our patients using a 980 nm diode laser at 11 W on the basis of an initial pilot animal study [15] that showed venous occlusion without perivenous hematoma or nerve injury using the laser at that power. The purpose of this study was to report on the clinical efficacy and complication rates in treating GSV reflux disease using the 980 nm diode laser at 11 W in continuous mode, with lower laser energy than in previously published studies.

Materials and Methods

Demographics and History

Thirty-four consecutive leg varicose veins in 26 patients (6 men, 7 women; mean age 54.61 years ± 1.64) were included in the study, and a chart review was conducted.

Thirteen patients (50%) had recurrence of disease after previous surgical or sclerotherapies. Five patients (21%) had prior surgical ligation and stripping, 7 patients (27%) had sclerotherapy with recurrence, and 1 patient (4%) had stab avulsion ambulatory phlebectomy prior to endovenous laser ablation.

The endovenous laser treatment was performed in 17 left legs and 17 right legs. Twenty patients (83%) had unilateral treatment, with 1 being retreated for undiagnosed accessory GSV after the initial treatment. Six patients (23%) had bilateral treatment. One of the 6 was retreated for undiagnosed accessory GSV after a later reevaluation.

Ninety-one percent of the patients had a positive pregnancy history with varicosities worsened during the pregnancy. Seventy-six percent of the patients admitted to having jobs or habits that made them stand for long periods. Thirty-nine percent took pain medicines for their varicosities, and 74% elevated their legs to relieve symptoms. Furthermore, 47% of the patients complained of skin color changes, 15% of venous stasis ulceration, 65% of leg tiredness, 68% of leg pain, and 59% of leg edema (Table 2). The diagnosis of venous incompetence with reflux was made with clinical evaluation and color duplex Doppler studies in 100% of patients.

We performed color duplex studies in cross-sections and longitudinal sections with the patient standing. Maximum and mean diameters of GSV were measured. We tested flow on color duplex images by manual compression-release of the calf to provoke reflux. Reflux was defined as >0.5 sec of reverse flow. The common femoral vein, superficial femoral vein, and popliteal veins were also evaluated by duplex Doppler, and patients with thrombus in deep veins were excluded from endovenous laser ablation therapy. The CEAP classifications of the patients were recorded (Table 3).

Clinical Outcomes and Data Analysis

Postoperative evaluations assessing clinical outcomes and duplex ultrasound of the GSV were performed within 1 week, 1 month, 6 months, 1 year, and then yearly after the endovenous laser treatment. Duplex ultrasound was used as it has shown to be highly sensitive (0.92–0.95) in identifying the competence of saphenofemoral and saphenopopliteal junctions [16].

The endpoint of the study was the measurement of clinical outcomes and complications. Clinical success was defined as occlusion of the GSV by duplex ultrasound and disappearance of clinical symptoms. Clinical failure was defined as patency or recanalization of the treated GSV or any significant residual symptoms. Complications were listed as minor and major. Minor complications were defined as temporary and self-limiting symptoms without any clinical sequelae, and major complications were defined as those involving further intervention, hospitalization, or permanent sequelae. The patients were followed up to 18.5 months (mean 12.19 months ± 4.18).

To assess unit energy delivered during the treatment, GSV diameter and length, total energy delivered, laser pull back speed, and total laser ablation time were recorded. Energy in joules (J) per length of GSV in centimeters and energy fluence of GSV were calculated for each patient and reported as the mean ± SD (Microsoft, Redmond, WA, USA and SPSS, V11, Chicago, IL, USA). The fluence was calculated as joules per surface area of the inner surface of the approximately cylindrical vein, which was approximated as joules/(vein length × vein circumference).
Institutional review board approval was obtained for this study.

**Techniques**

After informed consent was obtained, the patient’s medial lower thigh was prepared and draped in the usual sterile fashion. Conscious sedation was given intravenous midazolam HCl (Abbott Laboratories, Abbott Park, IL, USA) and fentanyl citrate (Abbott Laboratories, Abbott Park, IL, USA). After local anesthesia with 1% xylocaine (Astra Zeneca, Wilmington, DE, USA), the most distal GSV at a knee level was accessed using the Seldinger technique with a 5Fr micropuncture set (Cook, Bloomington, IN, USA) under hand-held ultrasound guidance (Logic Book; GE Medical Systems, Milwaukee, WI, USA). A 5 Fr, 45 cm sheath (Vascular Solution, Maple Grove, MN, USA) was advanced over a 0.035-inch Bentson guidewire (Cook, Bloomington, IN, USA) through the GSV. Tumescent anesthesia was performed over the entire length of the GSV under hand-held ultrasound guidance (Logic Book; GE Medical Systems, Milwaukee, WI, USA) with a 0.035-inch Bentson guidewire (Cook, Bloomington, IN, USA) through the GSV. Tumescent anesthesia was performed over the entire length of the GSV under hand-held ultrasound guidance (Logic Book; GE Medical Systems, Milwaukee, WI, USA). Attention was given to injecting tumescent anesthesia in the perivenous area, around the wall of the GSV, via a 25G needle under real-time sonographic guidance to produce the so-called saphenous eye appearance on ultrasound examination. This was performed to compress the GSV for circumferential displacement of laser energy and to dissect and separate the GSV from perivenous tissue to prevent skin burn or nerve damage [5]. The “heat-sink” effects of the anesthetic also help to reduce perivenous tissue damage from laser heat energy [5]. Tumescent anesthetic was made by mixing 440 ml of 0.9 normal saline, 16 ml of sodium bicarbonate and 60 ml of 1% xylocaine with 1:100,000 epinephrine. Subsequently, a 600 μm bare-tip SMA 905 Fiber Optic Delivery Catheter or laser fiber (Vascular Solution, Maple Grove, MN, USA) was advanced through the sheath, and the laser fiber positioned about 1–2 cm below the saphenofemoral junction, as confirmed by ultrasound or contrast injection under fluoroscopic guidance. Careful was taken to leave 2 cm of the tip of the laser fiber uncovered by the sheath, by retracting the sheath over the fiber. Subsequently, the entire length of GSV was ablated with a 980 nm diode laser (Angiodynamics, Queensbury, NY, USA). For all patients, the power was set at 11 W, and the laser was run in continuous mode. The laser fiber pull-back speed was kept at about 0.3–0.5 cm/sec. Achieving the nearly constant pull-back speed was helped by measurement marks on the 45 cm sheath (Vascular Solution, Maple Grove, MN, USA). Manual compression over the treated site was applied during the laser pull-back to help increase the vessel wall contact with the laser heat.

After the treatment, hemostasis at the venous access site was achieved by manual compression. Constant pressure was applied to the treated leg by immediately wrapping the leg with class II (30–40 mmHg) graduated compression stockings. Patients were kept in recovery for 45 min in accordance with the hospital sedation protocol. After discharge, patients were encouraged to ambulate immediately and kept the treated leg above waist level when sitting or lying. No prescription-strength pain medication was given. The patient kept the class II graduated compression stocking on, except when sleeping and showering, until the follow up visit.

**Results**

Using 980 nm diode continuous endovenous laser ablation, 100% initial technical success was noted. The technical success is measured by feasibility of the endovenous laser ablation technique. The mean diameter of the GSV in our patients was 1.19 cm ± 0.48. The mean length of saphenous vein treated was 33.82 cm ± 7.07. The mean energy applied during the treatment was 1155.81 J ± 239.5 for a mean treatment duration of 90.77 sec ± 21.77. The average laser fiber pull-back speed was 0.35 cm/sec ± 0.054. Mean energy applied per length was 35.16 J/cm ± 8.43. Energy fluency, calculated separately for each patient, averaged 9.82 J/cm² ± 4.97.

At 1 month follow-up, 100% occlusion rate was noted on treated veins by duplex Doppler examination. Two legs had accessory saphenous veins undetected at the initial clinic
visits; these were treated with endovenous laser ablation for clinical improvement. No major complication was observed. No deep venous thrombosis or pulmonary embolism was noted. No skin burn or permanent nerve injury was noted.

The following minor complications were observed. One patient developed hematomata at the percutaneous venotomy site, which was resolved with conservative treatment. This was related to inadequate manual compression and delayed application of the compression stocking. One patient developed thrombophlebitis on superficial tributary varices of the treated GSV, which resolved within a week. Twenty-four percent of patients (8 of 34) developed ecchymoses or skin bruises along the treated GSV, possibly from direct laser ablation or needle punctures for tumescent anesthesia. These were self-limiting during the period of 1 week. Thirty-two percent of patients (11 of 34) developed mild hypersensitivity, tenderness, or “pulling” sensation along the treatment area, which was self-limiting over a 2 week period. An over-the-counter nonsteroidal anti-inflammatory was used when indicated, but no narcotic or prescription analgesic was needed by the patients. One patient developed temporary paresthesia in the treated leg. The symptom was noted as mild numbness in a spot in the calf area, which was self-limiting over 2–4 weeks without intervention. The paresthetic symptom resolved. One patient developed an allergy to the compression thigh stockings, and developed hives and skin irritation to the tapes holding the stocking at the upper thigh. No permanent focal neurologic symptoms or any debilitating symptom was noted. There were no lost work-days.

At follow-up times up to 18.5 months (mean 12.19 months), 0% recanalization was noted. Ninety-two percent of patients improved clinically. Clinical failure in 8% resulted despite the absence of GSV reflux. These patients’ calf cramp/pain may be attributed to previous small vessel thrombosis in the calf, small perforator vein incompetency, or nonvenous causes. Four endovenous treatments (12%) were followed by adjunctive sclerotherapies on remaining spider veins and small residual varicose veins off the treated GSV for improved cosmetic results.

**Discussion**

Zero recurrence rate at up to 18.5 months (mean 12.19 months) follow-up in our patients demonstrates highly the favorable clinical outcome of endovenous laser ablation with a 980 nm diode laser in continuous mode set at 11 W. Our clinical success rate is higher than or comparable to the rates in previously published studies using 810, 940 or 1064 nm lasers with higher power.

Using a mean laser pull-back speed of 0.35 cm/sec, the mean applied total energy of 1155.81 J is less than in previously published studies. Data on applied energy are available for four previously published studies and are listed in Table 4 [5, 11–13]. Chang and Chu reported treatments with a 1064 nm Nd:YAG laser at a mean energy of 15,240 J (range 9200–20,100 J) [12]. Min et al. reported a mean energy of 1727 J (SD 650 J) using an 810 nm laser over a mean GSV treatment length of 35 cm [5].

The mean applied energy in our study of 35.16 J/cm ± 8.43 is less than that in the series reported by Chang et al., Min et al., and Timperman et al. [5, 12, 13]. Timperman et al. suggest using more than 80 J/cm of GSV for successful treatment [13]. Our results, however, show equally promising clinical outcome at lower energy.

The mean laser fluence of 9.82 J/cm² ± 4.97 we used is less than the 11.8 J cm² reported by Proebstle et al. [11], although their median energy of 23.4 J/cm is lower than that in our series. Their study reports a median laser fluence in occluded veins of 13.0 J/cm² and in recanalized veins of 7.6 J/cm², which suggests that a higher laser fluence (J/cm²) reduces the risk of early recanalization [11]. Our results, however, show a comparably favorable clinical outcome with a lower energy delivered per inner surface area of GSV.

With 0% recanalization in our study, we believe that the mean energy per length of 35.16 J/cm, or mean laser fluence of 9.82 J/cm², may be adequate for successful clinical outcome and GSV occlusion.

With the lower laser energy used in our study than previously reported, our patients develop no major complication such as skin burn, permanent nerve injury, or deep venous thrombosis. The complication rates on our patients are lower than or comparable to those in previous reports.

Success rates and complication profiles of our therapy compare favorably with surgical therapy and sclerotherapy for GSV reflux disease.

Surgical high ligation and stripping treats the GSV reflux by mechanical removal to eliminate the source of the reflux and improve venous hemodynamics. However, a clinical
recurrence rate of 40% after 5 years [17] and recurrent incompetent veins in the groin on duplex sonography in 57% of patients after 8 years [17, 18] have been reported, with neovascularization as the cause of the high rate of recurrence [19]. Risks from surgery include paresthesia, bleeding, infection, scar formation, prolonged recovery times, and risks associated with general anesthesia or spinal anesthesia. In particular, neurologic complication has been reported up to 11% of patients [20] and deep venous thrombosis in up to 5.3% [21].

Ultrasound-guided sclerotherapy is a less invasive outpatient procedure which is widely used in practice. This technique causes damage in the endothelial and subendothelial layers by injection of sclerosing agents, which results in fibrotic obliteration. Most complications are minor, including urtication, hyperpigmentation, and superficial phlebitis [22], although rare complications such as visual disturbances, femoral vein thrombosis, and arterial injury have been reported [23, 24]. The utility of sclerotherapy in GSV treatment, however, has not been clearly established, as a recanalization rate of 23.8% by 1 year [25] and detection of incompetent distal veins in 43.8% of patients on follow up [26] have been reported after sclerotherapy.

Endovenous laser ablation causes direct endothelial damage by the laser energy, resulting in collagen contraction, fibrosis, and hyperplasia with subsequent occlusion of the vessel. Common local postoperative complications are ecchymosis or skin bruises, tightness, hypersensitivity along the treated area, or pain and transient paresthesia. The tightness is related to venous occlusion of the GSV, and is thus probably unavoidable. Ecchymosis may be related to multiple subcutaneous injections of tumescent anesthetics, vessel trauma, or direct injury from laser heat. Direct laser thermal effects are likely to contribute to local side-effects, such as ecchymosis, pain, and paresthesia.

The physiologic difference between various laser wavelengths is not entirely understood. The clinical significance of pulse versus continuous mode is unknown. Reported studies have not shown a significant difference in clinical results.

Energy level during the treatment, however, does influence the clinical outcome and can be assessed and controlled. As endovenous laser treatment depends on direct endothelial damage by laser energy, higher applied energy may theoretically result in improved occlusion rates. Our study, however, shows that favorable clinical outcome with high occlusion rates can result from lower energy treatment. Better contact of the laser heat with the endothelial layer by venous spasm during guidewire, sheath, and laser fiber manipulations, vasoconstriction with perivenous tumescent anesthetics, and manual compression during the lower energy laser treatment assist favorable clinical outcome.

Higher energy, however, may risk in directly damaging nerve, artery, and skin. This is suggested by high rates of paresthesia (36.5%) and skin burn (4.8%) following high-energy (mean 15,240 J per GSV) laser treatment using a 1064 nm Nd:YAG laser [12]. Cases of skin burn [14] after 1296 J over 20 cm of laser treatment (64.8 J/cm of GSV treated) and arteriovenous fistula [27] after 970 J over 9 cm of short saphenous vein (107.8 J/cm) have also been reported. These are significantly higher energies than the mean applied energy of 35.16 J/cm in our series. Lower energy can reduce such major complication as well as minor side-effects, such as skin bruises and pain.

Limitations of this study are its retrospective nature with a modest number of patients and the single laser energy-level setting used. It is important to determine the optimal laser energy over the length of the GSV or surface area that will lead to high clinical success with acceptable occlusion rates with the least complication rates. A larger prospective study with randomization to different laser energy levels would help to clarify the ideal laser energy to use.

**Conclusion**

Endovenous laser ablation treatment of GSV using a 980 nm diode laser at 11 W in continuous mode for GSV reflux disease appears safe and effective. The mean energy applied per treated GSV length of 35.16 J/cm, or mean laser fluence of 9.82 J/cm², which are lower than previously reported, appear adequate in our study as they resulted in 0% recanalization in treated GSVs. The optimal laser energy for endovenous ablation to achieve an adequate occlusion rate with minimal complication rates remains to be established.

**References**

Endovenous laser treatment for primary varicose veins


Key words. Varicose veins ; saphenous vein ; laser ablation.

Abstract. Venous insufficiency of the lower extremities is a highly prevalent condition. Successful treatment of superficial venous insufficiency will most often necessitate treatment of the saphenofemoral junction incompetence with correction of saphenous vein reflux. In the majority of patients it concerns a reflux of the greater saphenous vein. The standard procedure consists of ligation and stripping of the greater saphenous vein combined with additional phlebectomies or ligation of insufficient perforant veins if necessary. Although the standard procedure is widely known and accepted, the postoperative morbidity and postoperative limitations of activity are high. In this context minimally invasive percutaneous endovenous techniques were developed to improve the patients comfort and faster resumption of work. Among these, endovenous laser ablation of the greater saphenous vein is a relatively new procedure. Percutaneous introduction of a laser fiber into the incompetent vein and ablation with pulsed laser energy is far less invasive than stripping.

Introduction

Venous insufficiency in the lower extremities is a common medical condition afflicting 25% of women and 15% of men in the United States (1). Gender, pregnancy, hormones, obesity, aging and gravitational forces from prolonged standing or sitting are the most common factors that influence the appearance or worsening of primary varicose veins (2,3).

Untreated venous insufficiency has significant morbidity. The sequelae include chronic pain, edema, ulceration and thrombophlebitis (4).

To realize successful long-term results we must obtain elimination of the highest point of reflux and elimination of the incompetent venous segment. Surgical ligation and stripping has proven to be the most successful treatment method for truncal varicosities when the saphenofemoral junction (SFJ) and the greater saphenous vein are incompetent.

Although crossectomy(saphenofemoral disconnection) and stripping of the greater saphenous vein (GSV) has been well accepted by most vascular surgeons as the standard of care for superficial venous insufficiency, the postoperative morbidity and the activity limitations recommended after surgery are less than ideal. The drawbacks of the traditional surgery also include risks associated with general or spinal anesthesia, prolonged recovery periods and surgical complications such as bruising, hematoma, groin wound infection, cutaneous nerve injuries and scars (3,4). Recurrence is reported in approximately 20% of varicose vein operations done for recurrent veins (5,6).

Due to these drawbacks, alternative minimally invasive techniques such as sclerotherapy, mini-phlebectomy, ultrasound- and transcatheter-guided sclerotherapy, radiofrequency ablation and endovenous laser have been developed. Among these, laser and radiofrequency devices have become increasingly popular over the last few years. Elimination of saphenous vein reflux can be achieved with percutaneous, catheter-based technology using either radiofrequency energy (VNUS®) or laser energy (EVLT) and if necessary combined with extraction of varicose vein clusters.

These new techniques have several advantages compared to classical ligation and stripping procedures: they can be performed under local anesthesia, there is less postoperative haematoma, less pain, less neuralgia, faster resumption of work, less scars and pigmentation and are thus more esthetical.

Indications

Clinical findings

Varicose veins cause often prolonged discomfort and disability, with impairment of quality of life and a major socio-economic impact.

Unfortunately, symptoms of primary venous insufficiency are often not recognized by patients. Characteristic symptoms are leg fatigue, heaviness or restlessness, aching pain and night cramps. Left untreated, near-
edly 50% of patients with significant superficial venous insufficiency will eventually experience chronic venous insufficiency characterized by lower-extremity swelling, eczema, pigmentation, hemorrhage, ulceration and thrombophlebitis. Often are teleangectasias or protuberant varicose veins the reason for consultation (3,4).

**Indications**

Patient selection is important in deciding to use endovenous laser treatment for varicose veins. Indications are symptomatic varicose veins based on insufficiency of the greater saphenous vein, the lesser saphenous vein or accessory veins.

General exclusion criteria include pregnancy or breast-feeding, an inability to ambulate, deep vein thrombosis, aneurismal veins > 2 cm in diameter or too tortuous veins, hypercoagulability, arterial occlusive disease and general poor health.

**Working mechanism**

The underlying mechanism of action in this new technique is still not fully understood. Animal studies showed that endovenous radiofrequency occlusion and laser ablation have completely different modes of action (7). Laser ablation almost completely lacks the collagen shrinkage effect (fibrosis) of the veins and heat-induced venous spasm caused by prolonged exposure to moderate heat (85°C) in radiofrequency occlusion. Instead, laser ablation causes a thrombotic occlusion of the laser-treated vein. Endovenous laser releases thermal energy to the blood and laser-generated steam bubbles transfer a substantial amount of thermal damage to the endothelium of the vessel wall. Steam bubble formation is a local, instantly reversible heating phenomenon that, after collapse of the bubble, poses no risk, such as gas embolism, to the patient. The complete thrombotic occlusion can be detected after one day by means of a Duplex scanning which shows an incompressible, hypoechogenic cord in the lumen of the saphenous vein. Probably the density of the laser-induced damage of the endothelium leads to a more stable thrombus than with spontaneous thrombophlebitis (8-10).

One distinct major difference compared with classic varicose vein surgery is that endoluminal laser energy solely occludes the GSV without affecting tributaries at the level of the SFJ. This is remarkable, because it is generally accepted that recurrent varicose veins after surgery often have their origin in residual tributaries of the SFJ or in a residual saphenous stump. Surprisingly, the combined experiences with transcatheter endovenous ablation procedures have shown lower recurrence rates than with surgical ligation and stripping. Perhaps minimizing dissection in the groin and preserving venous drainage in normal, competent tributaries while removing only the abnormal refluxing segments does not incite neovascularization (2,3,9,11).

**Technique**

Preoperative a Duplex scanning is performed in the upright standing position to map incompetent sources of venous reflux and then to mark the skin overlying the incompetent portion of the GSV starting at the SFJ. After venous duplex mapping a percutaneous entry point is chosen. This point may be where reflux is no longer seen or where the GSV becomes too small to access (usually just above or below knee level). All treatments are performed under general or spinal anesthesia. First of all the laser fiber is inserted in the 5 Fr catheter in a way that the tip of the laser fiber exceeds approximately 1.5 cm. This position is marked with a locking system. The patient is then set in reverse Trendelenburg position with the use of a tourniquet to facilitate the procedure. With the use of sonographic guidance the GSV is punctured with a 18-gauge needle and a 0.035 guide wire (Kayak™ hydrophilic straight guide wire, Boston Scientific, Miami, USA) is advanced past the SFJ into the femoral vein. Next step is to place a 5 Fr angiocatheter (Beacon Tip Royal Flush Plus straight visceral angiographic 5 F catheter Cook, Pennsylvania, USA) over the wire and, after withdrawal of the guide wire, insertion of the laser fiber (ELVeSTM Endolaser Vein System laser fiber, 600µm core, biolitec AG, Jena, Germany) in the 5 Fr straight angio-sheat-catheter. The laser fiber is marked with a lock that indicated exposition of the distal 1.5 cm of the laser tip. The sheath and fiber are pulled back together, after locking, and positioned at about 1 cm from the SFJ under ultrasound guidance. Position is also confirmed by direct visualization of the red aiming light-beam of the laser fiber through the skin (Fig. 1). This should limit the risk of thrombus extension beyond the SFJ with thrombus protrusion inside the common femoral vein. Now the patient is put in a Trendelenburg position to reduce the blood volume and tumescent infiltration with saline is given under ultrasound guidance.

The tip of the laser fiber is repositioned 1 cm distal to the SFJ under ultrasound guidance and laser energy is delivered with pulsed laser activity. When the laser beam is fired, manual compression is applied over the laser fiber tip to approve vessel wall apposition and collars around the laser-tip. The laser fiber is withdrawn at an average rate of 3 mm per step. The amount of laser energy given with each step depends on the diameter of the vein and its distance to the skin. We normally start at 12W/s laser emission power at the groin and descend discontinuously gradually until 6W/s at knee level, using a 980 nm diode laser (ELVeSTM Endolaser Vein System diode laser Cerálas D25 – biolitec AG, Jena, Germany).
If necessary stab avulsion phlebectomies, using a Muller hook, are performed. Postoperatively compressive stockings, class II (30-40 mm Hg), must be worn for at least one week in order to avoid early recanalisation of the freshly occluded GSV. Patients are instructed to ambulate immediately and resume their normal activities with the exception of vigorous exercise. Patients are staying in a day hospital setting. Posttreatment medication is NSAID for four days and LMWH for ten days. If necessary, paracetamol for pain control is prescribed. Follow-up is scheduled one week postoperatively to remove the bandages and the compressive stockings.

Discussion

The primary aims in the treatment of primary varicose vein should be directed toward the elimination of the highest point of reflux and the ablation of incompetent venous segment. The surgical ligation and stripping have proven to be the most successful treatment method of GSV incompetence with SFJ reflux. Because of the drawbacks and high recurrence rates, alternative minimally invasive techniques were developed. Since the first introduction of endovenous laser surgery by Boné at 1998, several studies have been undertaken. In 2001 Navarro et al reported 100% closure rate of treated GSV segments (12). Min et al confirmed closure in 98% which remained as long as 12 months with the 810 nm wavelength laser. All recurrences were noted before nine months, with the majority seen by 3 months. This may indicate that these were no true recurrences but rather inadequate initial treatment (2). Proebstle reported suc-
cessful GSV occlusion in 97% of limbs treated with the 940 nm laser at 1 month follow-up (8).

Despite the limitation of small number and only short term data, the efficacy of endovenous laser for the treatment of incompetent GSV has been reported to be greater than 95%. (2,8,12-16) To avoid undertreatment of the target vessel, vein diameter, laser power and pull-back speed has to be taken into account. Standardized pullback protocols are awaited (15).

No severe complications (e.g. deep-vein thrombosis and pulmonary embolism) after endovenous laser treatment have been reported.

Commonly observed side-effects with laser obliteration are induration and mild-to-moderate ecchymoses which are present for approximately two weeks. This could be a problem for patients who are expecting a minimally invasive and barely visible treatment for their GSV incompetence (3,8,10,13).

In our centre we use a saline solution without local anesthetics. This subcutaneous tumescence of saline solution along the course of the GSV has two functions: (1) it compresses and reduces the diameter of the veins to provide vein wall apposition around the fiber tip with subsequent circumferential heating of the vein wall and (2) it acts as a protective barrier, minimizing the risk of heat-related damage to adjacent tissues. When using anesthetic tumescence, described in literature, there is the extra anesthetic effect. (2,4,7-10) Question is if its use is necessary when performing endovenous laser obliteration under general or spinal anesthesia.

The more complete the emptying of the vein lumen (by leg elevation, peri-saphenous subcutaneous saline infil-tration and manual compression), the less tissue reaction of local thrombophlebitis will be produced.

In conclusion, reported results indicate that endovenous laser obliteration may offer an advantage over conventional stripping operation in terms of reduced post-operative pain and discomfort, less numbness of the operated leg, shorter sick leaves, and faster return to normal activities. Even with small patient numbers and short-term data, endovenous laser surgery with the 980 nm diode laser appears to be a safe, well-tolerated, effective and cosmetically acceptable procedure, with high patient satisfaction, for incompetent GSV with SFJ reflux.

In a recent study on a Belgian population it was calculated that the mean surgical cost for a laser procedure amounts 850 euro compared to 710 euro for a classical stripping. Even the fact that laser treatment is more expensive for the hospital, it was demonstrated that endovenous laser obliteration offers an interesting financial advantage for society because of the significant faster resumption to work (18).

Randomized controlled trials comparing the outcomes of endovenous laser ablation of the saphenous vein to surgical ligation and stripping should be performed.

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Endovenous Laser Treatment of Saphenous Vein Reflux: Long-Term Results

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PURPOSE: To report long-term follow-up results of endovenous laser treatment for great saphenous vein (GSV) reflux caused by saphenofemoral junction (SFJ) incompetence.

MATERIALS AND METHODS: Four hundred ninety-nine GSVs in 423 subjects with varicose veins were treated over a 3-year period with 810-nm diode laser energy delivered percutaneously into the GSV via a 600-μm fiber. Tumescent anesthesia (100–200 mL of 0.2% lidocaine) was delivered perivenously under ultrasound (US) guidance. Patients were evaluated clinically and with duplex US at 1 week, 1 month, 3 months, 6 months, 1 year, and yearly thereafter to assess treatment efficacy and adverse reactions. Compression sclerotherapy was performed in nearly all patients at follow-up for treatment of associated tributary varicose veins and secondary telangiectasia.

RESULTS: Successful occlusion of the GSV, defined as absence of flow on color Doppler imaging, was noted in 490 of 499 GSVs (98.2%) after initial treatment. One hundred thirteen of 121 limbs (93.4%) followed for 2 years have remained closed, with the treated portions of the GSVs not visible on duplex imaging. Of note, all recurrences have occurred before 9 months, with the majority noted before 3 months. Bruising was noted in 24% of patients and tightness along the course of the treated vein was present in 90% of limbs. There have been no skin burns, paresthesias, or cases of deep vein thrombosis.

CONCLUSIONS: Long-term results available in 499 limbs treated with endovenous laser demonstrate a recurrence rate of less than 7% at 2-year follow-up. These results are comparable or superior to those reported for the other options available for treatment of GSV reflux, including surgery, US-guided sclerotherapy, and radiofrequency ablation. Endovenous laser appears to offer these benefits with lower rates of complication and avoidance of general anesthesia.

Abbreviations: GSV = great saphenous vein, RF = radiofrequency, SFJ = saphenofemoral junction

LOWER-extremity venous insufficiency is a common medical condition affecting 25% of women and 15% of men in the United States (1). Gender, pregnancy, hormones, aging, and gravitational forces from prolonged standing or sitting are the most common factors that influence the appearance or worsening of primary varicose veins (2,3). Although many people seek medical treatment for varicose veins because they find them unsightly, most people with varicose veins do experience symptoms (4,5). Unfortunately, symptoms of primary venous insufficiency are often not recognized by patients or their physicians. Characteristic leg complaints associated with varicose veins include aching pain, night cramps, fatigue, heaviness, or restlessness. Symptoms arise from pressure on somatic nerves by dilated veins and are typically worsened with prolonged standing, during the premenstrual period, or in warm weather (6). Left untreated, nearly 50% of patients with significant superficial venous insufficiency will eventually experience chronic venous insufficiency characterized by lower-extremity swelling, eczema, pigmentation, hemorrhage, and ulceration (7).

Great saphenous vein (GSV) reflux is the most common underlying cause of significant varicose veins. Traditional treatment of GSV reflux has been surgical removal of the GSV. Al-
though surgical ligation and stripping of the GSV has been the most durable treatment, it is associated with significant perioperative morbidity. Less-invasive surgical treatments including high ligation of the GSV at the saphenofemoral junction (SFJ) have been attempted with the hope that gravitational reflux would be controlled while the vein is preserved for possible use as a bypass graft. Unfortunately, ligation of the GSV alone usually results in recurrent varicose veins (8). Even when high ligation has been combined with phlebectomy of varicose tributaries or retrograde sclerotherapy, recurrence has been the rule (9,10). Therefore, when it is determined that GSV reflux is the principal underlying problem, treatment should involve eliminating this source of reflux with ablation of any associated incompetent venous segments.

In 1999, Boné (11) first reported on delivery of endoluminal laser energy. Since then, a method for treating the entire incompetent GSV segment has been described (12,13). Endovenous laser treatment, which received approval from the US Food and Drug Administration in January 2002, allows delivery of laser energy directly into the blood vessel lumen. Nonthrombotic vein occlusion is accomplished by heating the vein wall with 810-nm wavelength laser energy delivered via a 600-μm laser fiber (Diomed, Andover, MA). Sufficient heating of the vein wall is necessary to cause collagen contraction and denudation of the endothelium. This stimulates vein wall thickening, eventual luminal contraction, and fibrosis of the vein. The purpose of this study is to report on the long-term follow-up results of endovenous laser treatment for GSV reflux.

MATERIALS AND METHODS

This prospective, nonrandomized, consecutive-enrollment study included 423 patients who underwent endovenous laser treatment of incompetent GSV segments with 810-nm diode laser energy delivered intraluminally for treatment of primary varicose veins. The study protocol was approved by the Weill Medical College of Cornell University Institutional Review Board. All patients gave written informed consent before treatment.

Patient Selection

Directed history and physical examination, including duplex ultrasound (US) evaluation of the superficial venous system, was performed on limbs of subjects with varicose veins. Study inclusion criteria included varicose veins caused by SFJ incompetence with GSV reflux as demonstrated by duplex US imaging, age of at least 18 years, and ability to return for scheduled follow-up examinations for 12 months after endovenous laser treatment. Exclusion criteria included nonpalpable pedal pulses; inability to ambulate; deep vein thrombosis; general poor health; pregnancy, nursing, or plans to become pregnant during the course of participation in the investigation; and extremely tortuous GSVs that would not allow endovenous catheterization and passage of the laser fiber as identified on pretreatment venous duplex US mapping. After initial consultation and evaluation, subjects meeting the appropriate criteria were offered surgery versus endovenous laser treatment. Nearly all subjects chose endovenous laser over surgical ligation and stripping.

Five hundred four incompetent GSVs were treated with endovenous laser over a 39-month period. Five limbs were lost to follow-up. The remaining 499 limbs in 423 patients comprise the study population. This group consists of 352 women (83%) and 71 men (17%) ranging in age from 23 to 72 years, with a mean age of 42 years.

Follow-up ranged from 1 month to 39 months with a mean follow-up period of 17 months and an SD of 11 months. Aching leg pain was the most common presenting symptom, found in 87% of limbs. Overall, slightly more left legs (n = 263, 53%) were treated, and 76 patients (18%) were treated for bilateral GSV reflux. Pretreatment GSV diameter, measured in the upright position approximately 2 cm below the SFJ, ranged from 4.4 mm to 29 mm (mean, 11 mm; SD, 4.2 mm).

None of the patients in this series underwent concomitant ambulatory phlebectomy. All but seven patients underwent compression sclerotherapy treatment of distal varicose tributaries or associated telangiectasias at follow-up visits.

Description of Technique

Duplex US was performed in the upright position to map incompetent sources of venous reflux and then to mark the skin overlying the incompetent portion of the GSV starting at the SFJ. After venous duplex mapping, a percutaneous entry point was chosen. This point may be where reflux is no longer seen or where the GSV becomes too small to access (usually just above or below knee level). With use of local anesthesia and sonographic guidance, the GSV was punctured. A 5-F introducer sheath was placed into the GSV over a guide wire and advanced past the SFJ into the femoral vein. Intraluminal position within the GSV was confirmed by aspiration of nonpulsatile venous blood and visualization with US.

The sheath was flushed and a 600-μm laser fiber (Diomed) was inserted in the sheath and advanced up to the first site mark, indicating that the distal tip of the laser fiber was flush with the end of the sheath. The sheath was then withdrawn to the second site mark, exposing the distal cm of the bare-tipped laser fiber. The sheath and fiber were pulled back together and positioned at the SFJ under US guidance. Position was confirmed by direct visualization of the red aiming beam of the laser fiber through the skin.

Tumescent local anesthesia consisting of 100–200 mL of 0.2% lidocaine neutralized with sodium bicarbonate, was administered along the perivenous space with use of US guidance. In addition to the anesthetic effects, properly delivered, this fluid serves two important functions: (1) it compresses and reduces the diameter of even the largest veins to provide vein wall apposition around the fiber tip with subsequent circumferential heating of the vein wall and (2) it provides a "heat sink" to minimize the possibility of heat-related damage to adjacent tissues. Figure 1a demonstrates the typical transverse sonographic appearance of the laser fiber and catheter seen centrally within an enlarged GSV located in the saphenous space. Proper and adequate delivery of tumescent anesthesia should result in fluid surrounding a compressed GSV as shown in Figure 1b.

The tip of the laser fiber was repo-
sitioned within the GSV 5–10 mm distal to the SFJ. Tip position was checked by US and direct visualization of the red aiming beam through the skin. Laser energy (810-nm diode laser; Diomed) was delivered at 14 W in continuous mode. The vein was treated from 5–10 mm below the SFJ to approximately 1 cm above the skin entry site. Length of GSV treated with endovenous laser ranged from 10 cm to 55 cm (mean, 35 cm; SD, 10 cm). The laser fiber was withdrawn at an average rate of 3 mm per second (18 cm per minute). Of patients treated with 14-W continuous mode (n = 276, or 55% of limbs), delivery of laser energy ranged from 25 seconds (at 358 J) to 187 seconds (at 2,615 J), with a mean of 123 seconds (SD, 47 sec) or 1,727 J (SD, 650 J).

A class II (30–40 mm Hg) full-thigh graduated support stocking or panty hose was worn for at least 1 week at all times except to sleep or to shower. Patients were instructed to ambulate and resume their normal daily activities immediately. Clinical and duplex US follow-up was obtained at 1 week, 1, 3, 6, 9, and 12 months, and then yearly.

Compression sclerotherapy treatment of distal varicose tributaries was performed with use of sodium tetradecyl sulfate (0.3%–1% concentration). A detailed description of sclerotherapy technique is beyond the scope of this article but the approach used was the “French school” originally advocated by Tournay and more recently popularized in the United States by Goldman and other phlebologists (14). This technique relies on starting from the highest points of reflux and proceeding downward, and treating veins from the largest to the smallest. Compression stockings or panty hose were worn for at least 1 week after sclerotherapy treatments except to sleep or shower. Sclerotherapy treatments were performed at 4-week intervals, starting 1 month after endovenous laser ablation of the GSV.

Study Endpoints and Definitions

Duplex US criteria for successful treatment were the following: at 1-week follow-up, an enlarged noncompressible GSV, minimally decreased in diameter, with echogenic, thickened vein walls, and no flow seen within the occluded vein lumen on color Doppler interrogation; at 3- and 6-month follow-up, an occluded GSV with substantial (>50%) reduction in diameter; and at 1 year and beyond, complete disappearance of the GSV or minimal residual fibrous cord with no flow detectable. It is important to note that the expected appearance 1–2 weeks after endovenous laser is a slightly smaller GSV demonstrating wall thickening with absence of flow within the treated vein segment. The vein lumen is usually obliterated by the thickened wall, which has low-level echoes and is incompressible. This wall thickening should be differentiated from acute GSV thrombosis wherein the vein is also incompressible but the lumen is filled with anechoic acute thrombus. Several weeks after successful endovenous laser treatment, resolution of the acute inflammation in the vein wall should result in reduction in vein diameter. After several months, most of the treated vein segments will fibrose and be difficult to identify. Alternatively, superficial thrombophlebitis with GSV thrombosis would result in recanalization of the vein. A longitudinal view of an enlarged, incompetent GSV is seen in Figure 2a. Figure 2b demonstrates the typical color Doppler appearance of a successfully treated GSV 1 year after endovenous laser treatment.

Clinical evaluation was performed on all subjects at 1 week, 1, 3, 6, 9, and 12 months, and yearly thereafter by the same physician (R.M.) who performed all the endovenous laser procedures. Patients were queried about symptomatic relief at follow-up visits, particularly improvement or resolution of lower-extremity pain believed to be associated with venous insufficiency. Improvement in the appearance of the leg, including reduction in visible varicosities, swelling, pigmentation, or other skin changes secondary to chronic venous insufficiency, were assessed by the patient and with direct comparison with pretreatment photographs obtained from all subjects undergoing treatment. Patients were evaluated for possible adverse reactions caused by endovenous laser treatment at each follow-up visit. Minor complications were defined as those that had no significant clinical sequelae, such as bruising. Major complications were defined as those necessitating an increased level of care, sur-
surgery, hospitalization, or permanent adverse sequelae.

RESULTS

Follow-up results ranging from 1 month to 39 months (mean, 17 months; SD, 11 months) were obtained in 499 of the 504 limbs treated with endovenous laser during the study period. Successful endovenous laser treatment, as defined earlier, was seen in 490 of 499 limbs (98%) at 1-month follow-up. Eight of nine GSVs requiring repeat endovenous laser were successfully closed with a second endovenous laser treatment. Continued closure of the treated GSV segments was noted at longitudinal follow-up at the following rates: 444 of 447 (99.3%) at 3 months, 390 of 396 (98.5%) at 6 months, 351 of 359 (97.8%) at 9 months, 310 of 318 (97.5%) at 1 year, and 113 of 121 (93.4%) at 2 years. Forty subjects have been followed for 3 years and no new recurrences were seen at 2 or 3 years that were not present at 1-year follow-up. In fact, all recurrences were noted before 9 months, with the majority seen by 3 months. This may indicate that these were not true recurrences but rather inadequate initial treatments.

Clinical examination correlated well with duplex US findings. All patients showed improvement in the appearance of the limb with disappearance or reduction in the size and number of visible varicosities. The typical appearance of varicose veins caused by incompetence of the SFJ with GSV reflux is shown in Figure 3a.

One month after endovenous laser treatment, relief of symptoms and significant improvement in the appearance of the varicose veins was noted (Fig 3b). By 6 months after initial treatment, pain was greatly improved or resolved in all treated limbs. Although symptomatic resolution and significant improvement in the appearance of the leg is usually noted after endovenous laser treatment alone, most patients will need additional complementary procedures (ie, sclerotherapy or phlebectomy) to fully realize the restorative benefits of treatment.

Bruising outside the puncture site was noted in 24% of limbs at 1-week follow-up. Bruising resolved in all subjects before 1-month follow-up. Ninety percent of subjects felt a delayed tightness peaking 4–7 days after laser treatment and lasting 3–10 days. This sensation, described as "pulling" along the course of the treated GSV, was not felt in the nine patients in whom initial treatment failed. Five percent of patients developed superficial phlebitis of varicose tributaries after endovenous laser occlusion of the GSV. Most cases required no treatment. Symptomatic patients were treated with graduated compression stockings and over-the-counter antiinflammatory agents. All minor complications listed earlier resolved without sequelae. There have been no skin burns, paresthesias, cases of deep vein thrombosis, or other minor or major complications. The procedure was well-tolerated by all subjects with strictly local anesthesia.

Overall treatment satisfaction was determined by asking subjects if they would recommend the procedure to a friend with similar leg vein problems, and 422 of 423 subjects (99.8%) indicated they would recommend the procedure.

DISCUSSION

Percutaneous methods for treating incompetent GSVs are not new. Duplex-guided sclerotherapy for treatment of GSV reflux has been attempted, but long-term studies have failed to prove durability comparable to surgery (15–19). Initial attempts at damaging vein walls by electrocoagulation involved creation of a thrombus within the vessel lumen, ultimately resulting in recanalization (20–22). Early methods of intraluminal delivery of high-frequency alternating-current radiofrequency (RF) energy to treat GSV reflux were complicated by skin burns, saphenous nerve and peroneal nerve injury, phlebitis, and wound infection (23).

A more modern technique of the use of RF energy to eliminate saphenous vein reflux has been developed by VNUS Medical Technologies (Sunnyvale, CA). Early results reported from a multicenter trial demonstrated a reasonable degree of success with an overall failure rate of 10% at a mean follow-up of 4.7 months (13% in patients treated with RF alone and 3% in patients treated with RF plus high ligation of the GSV). Complications included transient paresthesias (thigh, 9%; leg, 51%), skin burns (3%), deep venous thrombosis (3%), and one pulmonary embolus (24). More recent studies have demonstrated success rates of 73%–90% with follow-up to 24 months in 21 limbs (25–27).

One of the limitations of our study is that it does not provide a blinded, randomized comparison of the various modern percutaneous methods available for treatment of GSV reflux, including RF and wavelengths of laser energy other than 810 nm. However, review of the literature allows some comparisons and raises some interesting areas for future study.

RF current damages tissue by resistive heating of structures in direct cont-
tact with the electrodes. Deeper tissue planes are heated by conduction into normothermic tissue. Because the potential for heating of adjacent perivascular tissue is high, safe treatment with RF depends on proper delivery of adequate tumescent anesthesia. Effective use of tumescent anesthesia appears to have reduced the incidence of heat-related complications. In expert hands, the incidence of paresthesias after RF has occurred in as few as 8.5% of limbs within 1 week of treatment and decreased to 0.7% at 6 months (27). However, with less-experienced physicians, RF still has been complicated with heat-related adverse effects such as paresthesias (10% at 6 months) and skin burns (3.3%) (25).

Published experience with endovenous laser with use of wavelengths other than 810 nm is limited. A recent study by Chang and Chua (28) reported the use of 1,064-nm laser energy delivered endovenously for treatment of GSV reflux. Although this study reported a success rate of 96.8% in 244 legs followed up to 28 months, significant complications were noted, including paresthesias (36.5%) and skin burns (4.8%). In addition to endovenous laser ablation, all patients in their study underwent surgical ligation and division of the proximal and distal ends of the treated GSV. In addition, patients treated with the 1,064-nm wavelength underwent spinal or general anesthesia rather than strictly local tumescent anesthesia (28).

In comparison, in our series of more than 500 limbs treated with 810-nm diode laser energy delivered endovenously, there have been no heat-related complications despite the high temperatures attained at the laser fiber tip. This may be explained by the following: (1) improved delivery and use of sufficient amounts of tumescent fluid in the proper tissue plane providing a protective thermal “sink;” (2) selective, homogeneous, and circumferential heating of the inner vein wall by absorption of 810-nm laser energy by blood lining the vein wall, as noted in a recent study by Proebstle et al (29), rather than deeper penetration of laser energy and less-homogeneous heating from endovenous laser performed with wavelengths such as 1,064 nm, which are absorbed less by blood and more by water; and (3) faster rates of withdrawal and shallower depth of penetration of 810-nm laser energy, resulting in less damage to surrounding nontarget tissue compared with methods that use RF.

It has been suggested that a randomized controlled trial comparing outcomes of endovenous laser ablation of the saphenous vein to surgical ligation and stripping should be performed; however, such a study would be difficult given patients’ overwhelming desire for minimally invasive treatments rather than surgery. Review of the existing surgical literature does provide some insight in assessing treatment durability. Multiple studies have shown that recurrence of varicose veins after GSV stripping occurs early (30), with 73% of limbs destined for recurrent varicosities at 5 years already having them at 1 year (31,32). Our results with endovenous laser have supported this, demonstrating that what is found on duplex imaging early is predictive of what will be seen later, with none of the treated patients developing recanalization of successfully occluded GSVs at 2 or 3 years that was not seen before 9 months.

Performing endovenous ablation of the GSV without dissection of the SFJ violates a cardinal rule in saphenous vein surgery that each of the tributaries must be individually divided. Surprisingly, the combined experiences with transcatheter endovenous ablation procedures have shown lower recurrence rates than with surgical ligation and stripping. Perhaps minimizing dissection in the groin and preserving venous drainage in normal, competent tributaries while removing only the abnormal refluxing segments does not incite neovascularization.

The understanding of venous disorders continues to improve with tremendous strides being made over the past decade. Readily available noninvasive diagnostic tests allow physicians to precisely map out abnormal venous pathways and identify sources of incompetence. Modern percutaneous methods of sealing incompetent veins...
provide patients with alternatives to lig
igation and stripping for treatment of
GSV reflux without the familiar morbid-
ities associated with surgery (33,34).
Given these recent advances, many phy-
sicians, when properly trained, will now
be able to successfully diagnose and
treat the whole spectrum of superficial
venous insufficiency, offering accept-
able options to the millions of people in
the United States alone who have var-
icose veins but are unwilling or unable to
undergo surgery.

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Extension of saphenous thrombus into the femoral vein: A potential complication of new endovenous ablation techniques

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Endovenous techniques such as radiofrequency ablation (RFA) and endovenous laser therapy (ELT) have emerged as percutaneous minimally invasive procedures for ablation of incompetent great saphenous veins in patients with varicosity and venous insufficiency. Early reports showed safety and efficacy of both techniques, with excellent technical success rates and few major complications, such as deep vein thrombosis or pulmonary embolism. During our initial experience with ELT in 56 limbs of 41 patients, 39 underwent postoperative duplex scanning. We encountered three cases (7.7%) with thrombus extension into the common femoral vein. All three patients were anticoagulated, and a temporary inferior vena cava filter was placed in one. All remained asymptomatic. The thrombus resolved by 1 month in all three patients. Review of the literature revealed that the incidence of thrombus extension into the common femoral vein or deep vein thrombosis in published clinical series is 0.3% after ELT and 2.1% after RFA. This possibility warrants routine postoperative duplex scanning, more alertness during these procedures, and patient education on this possible complication. (J Vasc Surg 2005;41:130-5.)

Until recently, high ligation and surgical stripping of the great saphenous vein (GSV), usually from the groin to the knee, has been the treatment of choice for GSV incompetence associated with varicose veins and chronic venous insufficiency. In recent years, percutaneous minimally invasive endovenous techniques such as radiofrequency ablation (RFA) (Closure procedure; VNUS Medical Technologies Inc, San Jose, Calif) and endovenous laser therapy (ELT) have emerged and are used with increasing frequency for ablation of incompetent GSV. Early reports have claimed safety and efficacy of both procedures, with initial technical success in more than 95% of patients. Short-term clinical benefit with sustained occlusion of the GSV and freedom from reflux at 2 years has been reported in 95% to 97% of patients. These procedures have already replaced standard surgical stripping as the therapy of choice for many patients undergoing GSV ablation. Major complications such as deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported to be relatively rare with these techniques.1

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Competition of interest: none.

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**DISCUSSION**

DVT has been rarely reported after surgical treatment of lower extremity varicosity; therefore, DVT prophylaxis routinely has been limited to early mobilization and compressive stockings. Subcutaneous heparin has been used only for high-risk patients. Two, three The surgical technique of GSV stripping includes its flush ligation with the CFV to avoid a cul-de-sac providing a nidus for proximal thrombus propagation. Although flush ligation can easily be accomplished with an open technique, the concept is compromised during endovenous therapy. The potential for thrombus extension is therefore real, because most techniques recommend leaving the upper 1 or 2 cm of the GSV open to avoid occlusion of the groin collaterals and to maintain patency of the SFJ. Only very few investigators suggest flush occlusion of the saphenous vein with the femoral vein during these procedures (R. J. Min, Cornell University, New York, personal communication, 2003).

The immediate fate of the lumen of the GSV after endovenous therapy is unclear. Min et al suggested that swelling of the injured venous wall obliterates the lumen after ELT. Others, however, found that GSV occlusion is a thrombotic process associated with an increase in the level of circulating D-dimer. Explanation for this controversy may be related to the differences in wavelength (940- vs 810-nm diode laser) and the amount of laser energy applied in these studies. Intuitively, acute thrombosis of the GSV could easily predispose for femoral DVT by propagation through the SFJ.

Despite these concerns, Min et al, who reported the largest series on ELT, from Cornell University, encountered no DVT in 499 limbs. Only one DVT was found in the literature among studies reporting on ELT of GSV insufficiency (Table II). When we looked on the Food and Drug Administration Web site for adverse reactions and searched for “Dornier MedTech” and “Diomed,” we were able to find only one case in which a small nonocclu-

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**Table I.** Length of great saphenous vein (GSV) treated with endovenous laser therapy and the amount of energy applied in cases complicated by extension of thrombus into the common femoral vein

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Length of GSV treated (cm)</th>
<th>Laser energy (J/cm)</th>
<th>Laser energy (J/f)</th>
<th>Total laser energy (J)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30</td>
<td>50</td>
<td>17</td>
<td>1500</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
<td>50</td>
<td>17</td>
<td>1500</td>
</tr>
<tr>
<td>3</td>
<td>32</td>
<td>56</td>
<td>19</td>
<td>1800</td>
</tr>
</tbody>
</table>

---

**Fig 1.** A, One week after treatment, thrombus (arrowhead) appears to protrude from the great saphenous vein (GSV) into the common femoral vein (CFV). B, Three months later, the thrombus is no longer visible.
Sive thrombus was observed to be partially in the femoral vein after ELT with the Diomed device (Diomed Inc, Andover, Mass). No reports were found for Dornier (Dornier MedTech America, Kennesaw, Ga). Differences in finding thrombus extension after ELT, in our experiences and those reported by Min et al, can be explained by the technique we used. We prefer to perform ELT under general, spinal, or epidural anesthesia supplemented by tumescent local anesthesia, and we always combine saphenous ablation with stab phlebectomy. The Cornell group uses only tumescent local anesthesia for ELT and applies delayed sclerotherapy during follow-up to eliminate

**Fig 2.** A, Axial scan of the inguinal region showing the common femoral vein (CFV) and common femoral artery (CFA). In the left picture, the vein is partially filled by echogenic material (arrowhead). In the right picture, maximum compression with the probe was not able to produce vein collapse. B, One week later, as shown in the left picture, there was no filling defect in the vein, which collapsed (arrowhead in the right picture) as the probe compressed the inguinal region.

**Table II.** Thromboembolic complications reported in clinical series of endovenous laser therapy

<table>
<thead>
<tr>
<th>First author, year</th>
<th>Wavelength of laser (nm)</th>
<th>No. Limbs/No. Patients</th>
<th>Limbs followed up with DUS</th>
<th>Timing of DUS follow-up</th>
<th>DVT</th>
<th>PE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Navarro, 2001</td>
<td>810</td>
<td>40/33</td>
<td>40</td>
<td>1 and 7 d</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gerard, 2002</td>
<td>980</td>
<td>20/20</td>
<td>20</td>
<td>3 and 8 d</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Chang, 2002</td>
<td>1064</td>
<td>252/149</td>
<td>252</td>
<td>Not reported</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Min, 2003</td>
<td>810</td>
<td>504/423</td>
<td>499</td>
<td>1 wk</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Proebstle, 2003</td>
<td>940</td>
<td>109/85</td>
<td>104</td>
<td>1 and 8 d</td>
<td>0*</td>
<td>0*</td>
</tr>
<tr>
<td>Oh, 2003</td>
<td>980</td>
<td>15/12</td>
<td>15</td>
<td>1 wk</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Perkowski, 2004</td>
<td>940</td>
<td>203/165</td>
<td>203</td>
<td>2 wk</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Timperman, 2004</td>
<td>810-940</td>
<td>111/87</td>
<td>111</td>
<td>1 wk</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Mayo Clinic, 2004</td>
<td>810</td>
<td>56/41</td>
<td>39</td>
<td>1 wk</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

Articles that seemed to report on the same series of patients were excluded. *Patients received prophylactic postoperative low-molecular-weight heparin.
persistent varicosities. Both general anesthesia and concomitant varicectomy can increase the period of immobilization; however, historically they have not resulted in such high rates of DVT after stripping of the GSV. The amount of laser energy delivered and the size and distension of the vein with blood may influence the relative extent of destruction of the vein wall. The number of patients treated in this early phase of our experience is too small to assess all of these variables. It is also difficult to directly correlate our higher thrombus extension rate with a learning curve, because these events were sporadic during our early experience. However, the high rate of DVT in this small series suggests that the exemplary results of pioneers in ELT technology may not be easily reproducible.

Currently, there is no agreement regarding whether the first 1 to 2 cm of the GSV should be treated during endovenous laser ablation. We start GSV ablation at 1 cm distal to the confluence of the inferior epigastric vein and the GSV. Regardless of the distance considered appropriate for the proximal end point of treatment, ultrasonographic visualization of the SFJ can never be compromised. This, in our experience, permits continued patency of the SFJ, and flow from the inferior epigastric vein prevents extension of the saphenous thrombus. In addition, leg elevation during treatment decreases the blood in the saphenous vein and aids in minimizing the thrombus load in the occluded saphenous vein.

The VNUS Closure procedure is associated with a presumably higher incidence of thromboembolic complications (Table III). Twenty-one cases of DVT and 2 of PE have been reported in 11 previous articles. A recent series of 66 patients treated with VNUS Closure reported a 16% incidence of DVT. All but one were described as thrombus extension into the CFV. No association of the DVT episodes with the type of anesthesia, postoperative mobilization, age, sex, or associated vein procedures was found.

Searching the Food and Drug Administration Web site for “VNUS” and “Closure,” we found reports of 24 DVT episodes and 3 PE episodes. Some of these reports, however, may refer to the same patients, thus making it difficult to calculate the absolute number of thrombotic events. In many series of RFA, the postoperative duplex follow-up scanning is incomplete; therefore, the exact incidence of asymptomatic DVT is unknown. With these limitations in mind, we estimate that the cumulative incidence of DVT and PE after the VNUS Closure procedure is 2.1% and 0.2%, respectively (Table III). Expert authors, however, report lower incidences: in a cumulative series from Merchant et al, there were 5 episodes of DVT among 1150 procedures (0.4%), with no PE.

The incidence of DVT after GSV stripping is not well known. Historically, Loefgren et al reported 16 cases of suspected PE among more than 4000 operations for varicose veins at the Mayo Clinic. In a more recent study, 3 (0.6%) symptomatic DVT cases were reported after 544 procedures. Surprisingly, a prospective study with ultrasonography follow-up showed 20 (5.7%) DVT incidents in 377 patients (494 limbs) who underwent varicose vein surgery. Most DVT was asymptomatic (12/20) and lo-
these patients will benefit from drug prophylaxis. Potential factors for increased thromboembolic risk, because procedures. Careful attention should be paid to all potential clinical course of GSV treated for incompetence and merits underlying postoperative thrombosis. It is our opinion (based on the available data) that both RFA and ELT result in an increased risk of CFV thrombosis when compared with the open procedure. For this reason, we recommend that a postoperative duplex examination be performed within 1 week to detect asymptomatic adverse events. The same recommendation came from a recently published consensus conference on laser treatment of varicose veins. The role for pharmacologic prophylaxis remains uncertain. Because the adverse events are so sporadic, only prospective studies specifically addressing the problem can answer the question. Until more evidence is available, we emphasize the importance of early ambulation and compression stockings for patients undergoing endovenous procedures. Careful attention should be paid to all potential factors for increased thromboembolic risk, because these patients will benefit from drug prophylaxis.

In conclusion, the apparent increased risk of early extension of thrombus or DVT after radiofrequency ablation and ELT, according to this series and other recent publications, warrants routine postoperative duplex scanning within a few days, more alertness during these procedures, and patient education on the possibility of such complications. With these precautionary considerations in mind, we continue to offer ELT as an alternative option to patients who are suitable candidates for both laser and open surgical therapy. Prospective randomized studies comparing stripping with new minimally invasive methods are necessary to determine the exact role for ELT and RFA in the armamentarium of the venous surgeon.

### REFERENCES


### Table III. Thromboembolic complications reported in clinical series with radiofrequency ablation of the great saphenous vein (VNUS Closure procedure)

<table>
<thead>
<tr>
<th>First author, year</th>
<th>No. Limbs/No. Patients</th>
<th>Limbs followed up with DUS</th>
<th>Timing of DUS follow-up</th>
<th>DVT</th>
<th>PE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chandler, 15 2000</td>
<td>301/272*</td>
<td>223</td>
<td>Not reported</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Goldman, 16 2002</td>
<td>50/47</td>
<td>41</td>
<td>6 mo</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Komenaka, 17 2002</td>
<td>29</td>
<td>Not reported</td>
<td>Not reported</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Fassiadis, 18, 19 2002</td>
<td>127/79</td>
<td>99</td>
<td>1 wk</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Merchant, 19 2002</td>
<td>318/286</td>
<td>286</td>
<td>1 wk</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Rautio, 20 2002</td>
<td>30/27</td>
<td>30</td>
<td>1 wk</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sybrandy, 21 2002</td>
<td>26/26</td>
<td>26</td>
<td>3 wk</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Weiss, 22 2002</td>
<td>140/120</td>
<td>140</td>
<td>1 wk</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Lurie, 23 2003</td>
<td>44/44</td>
<td>44</td>
<td>3 and 7 d</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Wagner, 24 2004</td>
<td>28/24</td>
<td>28</td>
<td>3 to 5 d</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hingorani, 25 2004</td>
<td>73/66</td>
<td>73</td>
<td>2 to 30 d</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Mayo Clinic, 2004</td>
<td>51/39</td>
<td>18</td>
<td>1 wk</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Including eight small saphenous veins and one accessory saphenous vein.
†Unpublished data.

Articles that seemed to report on the same series of patients were excluded.

*DUS, Duplex ultrasonography; DVT, deep vein thrombosis; PE, pulmonary embolism.

Endovenous Thermal Ablation (EVTA). Standardization of the Energy: Literature Review and ELVeS Users

D. Kontothanassis, R. Di Mitri, S. Ferrari Ruffino, M. Ugliola, N. Labropoulos for the IEWG Group

Endovenous Laser Thermal Ablation (EVTA) is a new, minimally invasive technique for treating the incompetent saphenous veins and their tributaries. Although the safety and efficacy of this technique is well established, there is no standardization of the energy needed to ablate these veins.

In almost all the studies with EVTA the recanalization rate ranges from 2% to 12%. The main parameter influencing vein recanalization seems to be the delivered energy at the vein wall (Joule/cm). Other parameters have also been taken under consideration to explain early and late vein recanalization after endovenous thermal ablation such as vein diameter, different Laser Wavelengths, modality mode to deliver energy at the vein wall (pulsed/continuous mode), quality of the optical fiber, obesity and hemodynamic type of the saphenofemoral junction. Clinical data based on histopathologic specimen analysis after EVTA has shown that the wall damage is total and not reversible. However, there are not enough data to determine a standardization of the energy that can produce such effect limited to the vein wall without other side effects to the perivenous tissues. Regarding energy, a recent prospective study demonstrated that higher dosing of laser energy (30 Watt compared with 15 Watt) shows a 100% immediate success rate and a significantly reduced recanalization rate during a 12 month follow-up (97% vs 82.7%) 1.

Although parameters influencing failure and recanalization rates of EVTA are still to be determined the failure seems to be related to the administration of low laser fluences 3.

Other studies were undertaken to establish the incidence of early recanalization after EVTA and to study the histopathologic features of reperfused and excised GSV. Early recanalization requiring retreatment is observed in less than 10% of GSV after EVTA. The histopathologic pattern mimics recanalization after thrombotic occlusion 7.

Comparison of low rates of delivered energy (around 33 J/cm²) to the vein wall were used to study their success rate and for early retreatment of the failed procedures. There were no significant differences in mean total energy or unit energy applied among successful, failed, and repeat treatments. EVTA with lower energy appeared to be safe and effective. Larger GSV diameter was associated with early treatment failures 8. Further studies sustained the efficacy and good results of EVTA of GSV with low energy, using a 980 nm diode laser at 11 watts in continuous mode. Mean energy applied per treated GSV length of 35.16 J/cm (mean laser fluence of 9.82 J/cm²) appeared adequate, resulting in 0% recanalization and a low number of minor complication rates 9.

In contrast with the previous statements the hypothesis that higher energy dose improves procedural success without increasing complications was prospectively evaluated by per-
forming EVTA at energies greater than 80 J/cm (average energy of 95 J/cm). Ultrasound (US) and clinical follow-up was performed at 1 week, 3, 6, 9, and 12 months. Success was defined as absence of reflux throughout the entire treated segment. Incomplete vein ablation was defined as US evidence of flow in a segment of a treated vein. The success rate at 1 week was 100%. At an average follow-up of 9 months (range, 3-15 months) there were 5 failures and 91 successes for a success rate of 95%. Four of the treatment successes demonstrated segmental patency but no reflux on US for a complete vein ablation rate of 91%. No major complications occurred. The treatment failures occurred at an average energy dose of 98 J/cm. Average body mass index (BMI) was 30 for the successes and 46 for the failures. The author of the paper stated that higher energy GSV EVTA is safe and highly successful but the comparison with low energy vein ablation seems to have worst results 4, 5. Exaggerated high rates of energy of Nd:YAG 1.064 nm laser, delivered with a 600 micron optical fiber were reported. Laser power was set at 10 or 15 W, delivered with pulse duration of 10 seconds. The range of total delivered energy was from 9,200 to 20,100 J. The entire procedure was completed in 95-175 minutes (mean 122.3 minutes) for bilateral procedures, and 65-100 minutes (mean 81.07 minutes) for unilateral procedures. In a mean follow up of 19 months, 96.8% of the patients demonstrated remarkable improvement. Common early complications of EVTA in this study were local paresthesias of the treated area in 36.5%, ecchymosis and discoloration in 23%, superficial burn injury in 4.8%, superficial phlebitis in four limbs 1.6%, and localized hematoma in 0.8% at 3 weeks postoperatively. The final outcome showed no significant morbidity or mortality. All patients recovered completely. It was concluded that EVTA is a simple effective treatment modality for varicose veins and a less invasive method that can minimize the complications of conventional surgery 10.

Recently, experimental models provide evidence that successful EVTA depends on the selection of optimal parameters required to achieve vein damage while avoiding side effects. Mathematical modeling of EVTA provides a better understanding of the ablating process and may determine the optimal dosage as a function of vein diameter. Results demonstrated that in pulsed mode, for a 3 mm vein diameter, irrespective of the pullback distance (2, 5 or 7 mm), a minimum fluence of 15 J/cm² was required to obtain a permanent damage of the intima. For a 5 mm vein diameter, 50 J/cm² (15W-2s) was required. In continuous mode, for a 3 mm and 5 mm vein diameter, respectively 65 J/cm and 100 J/cm were required to obtain a permanent damage of the vessel wall. Finally, the use of different wavelengths (810 nm or 980 nm) had a minor influence on these results. Results of the study confirmed that thermal damage of the intimal layer was required to achieve the tissue alterations necessary in order to lead the vein to permanent occlusion. However, in order to obtain a high rate of success without adverse events, the knowledge of the vein diameter after tumescent anesthesia is recommended in order to use the optimal energy 11.

In our experience which is based on more than 1300 EVTA of GSV and SSV (mean follow up of 36 months) and according to other surgeons current opinion 12-14, is that EVTA is appropriate and the procedure is successful only if the treated portions of the veins are not visible on duplex imaging after 6-12 months of follow up. The success of EVTA is multifactorial. Main importance is given from the author firstly to have a good skill in EVTA and excellent command of US technologies in order to perform a secure and precise technique. Vein diameter, tumescent preoperative anesthesia and standardization of delivered energy are the most important factors in order to achieve a procedure with-
out complications, a permanent occlusion of the treated vein and absence or very low rate of recanalization in the follow up.

A lot of studies sustain that the presence of occluded veins is equivalent of good treatment. Many of these studies have provided evidence that in the follow up a variable number of the post EVTA occluded veins, (2-20%), undergoes recanalization. Usually all recurrences occur before 9 months, with the majority noted immediately or before 3 months 15.

The reason for this is a reversible damage of the vein wall. The delivered energy is enough to determine a thrombotic occlusion but not a pannus damage of the wall with a consecutive necrosis of the vasa vasorum. In these cases, recent studies on neovascularization after vein ablation, demonstrated an arteriovenous fistula between vasa vasorum and the vein lumen 16. Also the different type of Gray Scale analysis of endoluminal thrombus can be a very good prediction for early recanalization. Echolucent endoluminal material is usually the result of a thrombotic occlusion of the vein, designated to early recanalization or to an extremely delayed absorption. Contrary, postoperative findings of echogenic vein occlusion are correlated with duration of occlusion and early absorption of the treated vein. Distribution of Laser energy to the vein wall is the most crucial factor of EVTA success. The optical fiber should be placed always at the centre of the vein lumen in order to have a homogeneous distribution of energy around the vein wall and produce a symmetric damage. Considering the extreme variability of the vein diameter along the treated vein length or between different patients and also the morphological variability of diseased vein walls, the only way to standardize these is by producing a vein spasm that will make the vein to encircle the catheter. Therefore tumescent anesthesia has a very important role. Provides extreme spasm of the vein around the catheter and produces a protection for the perivenous tissues. At this point the authors introduced a simple physical method to exaggerate the vein spasm in order to standardize EVTA and make it reproducible and also avoiding thermal damage on perivenous tissues. We infused high volume of tumescent cold saline (400-500 cc). The energy was delivered either with 12, 13, 14, or 15 Watt using a 980 nm diode Laser with a pulsed mode in order to have an echogenic US assisted occlusion of the vein. The medium energy required for veins with diameter (4-14 mm) was 45-60 Joule/cm. Immediate results were excellent as in the mean follow up (3 years). In our late series we provide a 100% success of vein occlusion in a mean follow up of 3 months while in the rest of our data we obtained a 98,2% success. No skin burns, discoloration, phlebitis, DVT or other adverse effects have been noticed in this last series. Drastic reduction of pain was defined in the last 6 months by using cold saline tumescent anesthesia, probably due to a better distribution of energy into the vein wall and a higher protection from thermal energy of the perivenous tissues.

References


