The Treatment of Saphenous Vein Occlusion by Endovenous Laser Ablation (EVLA) with a 1064 nm VSP Nd:YAG Laser

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Abstract
This paper presents a study in which endovenous laser ablation (EVLA) of saphenous veins with a VSP Nd:YAG laser system (Fotona, Ljubljana, Slovenija) was conducted on 525 legs. The study was held at a single clinical site (Avelana vein clinic) over a 2.5 year period. The first 102 legs underwent EVLA at 15W to 18W average power, supplied from Nd:YAG laser. In the remaining 423 legs EVLA was administered at an average power of 25W. After 1 year, 88.2% of the veins in the 15-18W treatment group remained occluded; in the 25W treatment group 98.5% of the veins remained occluded. Side effects were minimal. All patients, even those whose veins were not fully ablated reported satisfaction with the treatment. The results of the study have lead us to conclude that the 1064 nm, VSP Nd:YAG laser is an effective and safe treatment modality for varicose veins.

Introduction
Due to higher patient satisfaction, shorter recovery times, lower cost, and ease of operation Endovenous Laser Ablation (EVLA) of the great and/or short saphenous vein has become the treatment of choice for varicose veins. EVLA shows minimal side effects in comparison with other surgical methods; patients can walk immediately after surgery and recovery times are short [1]. The EVLA procedure can be performed in an outpatient setting and usually, only local anesthesia is required.

The principle mechanism of EVLA therapy is ablation and photocoagulation of the vein interior by laser-induced thermal effects. In brief, EVLA is accomplished by inserting an optical fiber just below the saphenofemoral junction (SFJ) through the great saphenous vein (GSV) and delivering laser energy through the fiber as it is withdrawn down the GSV. During fiber withdrawal the vein wall is irreversibly destroyed and the vein is occluded. A full procedure is presented below in the Surgical Protocol section. A similar procedure can be followed for the small saphenous vein (SSV), in which the tip of the fiber is positioned at the saphenopopliteal junction.

Wavelength Considerations in EVLA
To develop the necessary heat for effective vein wall destruction and occlusion, the target tissue must absorb laser light. Different chromophores in the target tissue absorb laser light with different efficiency at different wavelengths. For successful EVLA treatment, hemoglobin and water in the blood and vein walls must absorb laser light. Water and hemoglobin absorb well across a wide range of wavelengths and many wavelengths have been successfully used in EVLA; 810nm [1], 940nm [2,3], 980nm [1], 1064nm [5,7,9,11], 1320nm [2], and 1470 nm [10]. In the case study presented in this paper a 1064nm wavelength was used for all EVLA treatments.
controlled laser-tissue interaction. This was enabled by
transmission of the fiber. The transmission of the fiber
should remain constant over the course of the
procedure to ensure homogenous energy delivery. We
tentatively attribute this observation to a “cleansing”
effect of the high peak power pulses of the pulsed
VSP Nd:YAG laser.

Laser Power Considerations in EVLA
Delivering a large amount of energy in a very short
time is important to the proper and efficacious
administration of EVLA. In this study, laser power
was the only parameter that changed between
treatment groups. It was increased from 15-18W to
25W. Recent research suggests that using higher laser
powers improves treatment efficacy [8]. Energy
delivery is usually reported in units of joules per
centimeter of the vein. This is referred to as linear
endovenous energy density or LEED.

Pulse Form Considerations in EVLA
In contrast to diode lasers, which operate
continuously, Nd:YAG lasers operate in rapid pulsed
mode. This means that the Nd:YAG lasers fire many
times per second. Each pulse itself has a duration or
period; during that period light, and therefore energy,
is delivered through the optical fiber-end. In some
laser systems the pulse power can vary significantly
during the duration of the pulse, resulting in
suboptimal energy delivery and thus reduced efficacy
in vein destruction and occlusion. In this case study,
the power of each Nd:YAG laser pulse was constant
during the entire pulse duration, enabling well-
controlled laser-tissue interaction. This was enabled by
proprietary, Fotona Variable Square Pulse (VSP)
technology.

Withdrawal Rate Considerations in EVLA
The withdrawal rate of the optical fiber affects the
amount of energy delivered to the vein wall. The best
treatment results are achieved when the optimal
amount of energy is uniformly distributed along the
length of the vein. The diameter of the vein wall
changes along the vein length, from 10-20mm at the
SFJ to 2-3mm at the entry point, so to deliver constant
energy per vein wall surface area, either the withdrawal
rate or the laser energy must vary. Some
manufacturers promote motorized withdrawal systems
that provide a constant withdrawal rate to perform
EVLA procedures. Yet these solutions cannot
provide uniform energy distribution if the laser power
is also held constant. Therefore most practitioners
prefer to manually control the withdrawal rate while
the laser delivers constant energy; withdrawing the
fiber slowly in wide sections of the vein and faster in
narrow sections. Withdrawal rate was manually
controlled during this study (see the Surgical Protocol
section).

Surgical Protocol
The surgical protocol [7,9] used in this study was
similar to other standard protocols used for the
EVLA of varicose veins [1]. All patients that
participated in this study gave informed consent.

Surgery was performed according to the following
steps. First, the patients were premedicated with a
midazolam (Dormicum, Roche) sedative and 125 mg
diklofenak (Naklofen, Krka) analgesic. Vein
assessment and mapping by color-flow duplex scan
was performed and a decision was made about the
point of vein cannulation. The patient’s leg was
cleaned, draped, and a sterile operating field was
prepared. A layer of gel was applied to the US probe
and the probe was then covered with a watertight
cover.

The patient was placed in the anti-Trendelenburg
position on the table. Local intradermal anesthesia
was infiltrated through a 27G needle at the point of
percutaneous insertion. Care was taken so that the
needle did not touch the vein. The vein was then
punctured under ultrasound (US) control with a 19G
needle at the selected entry point. A 0.035” J tipped
guide wire was introduced into the vein. The guide
wire was slid to the SFJ, aided by duplex monitoring, and
then positioned at the SFJ. A stab incision with a
blade 11 knife was made at the entry point of the
guide wire. A dilator was introduced over the guide
wire.

Before inserting the laser fiber and catheter assembly
into the vein, the optimal laser fiber length was
determined outside of the body. The laser fiber was
introduced into the catheter and positioned so as to
protrude 2.5cm from the distal end of the catheter.
The stopper at the proximal end of the catheter was
firmly tightened onto the fiber. The fiber (with
properly positioned and secured stopper) was
removed from the catheter. This step ensured that the
fiber protrudes correctly from the catheter when the
catheter is in the vein.

The dilator on the guide wire was extracted. The
catheter was passed over the guide wire to the desired
position at the SFJ. Once the catheter was in position the guide wire was removed, leaving the catheter inside the vein. The fiber was introduced into the catheter and locked into its predefined position with the stopper.

Further fine adjustments were made to the catheter and fiber tip position under US control. The laser fiber was then connected to the laser system.

Fig. 2: The proper position of the fiber inside GSV, below SFJ and just below the Epigastric vein

Tumescent anaesthesia was delivered through a syringe or by special pump. When administered by syringe the anaesthetic solution consisted of 20ml of 2% lignocain (Xylocain) diluted in 100ml of saline and a 4ml of 1N solution of sodium bicarbonate. When applying anaesthesia with a special pump the anaesthetic solution consisted of 40ml of 2% lignocain (Xylocain) diluted in 500ml of saline with the addition of 8 ml of 1N solution sodium bicarbonate and 1ml of 0.1% Epinephrine.

Fig. 3: The vein with catheter and fiber in the centre without (a) and with (b) tumescent anesthesia applied around it.

The laser was activated and during lasing the fiber was slowly withdrawn. The first 7 cm of extraction were US controlled. Every 10 cm the amount of delivered energy was checked. Laser energy was administered according to the generally accepted rule that LEED (J/cm) is 10x the vein diameter (mm). For the first 7 cm, energy by 50% in excess of the value indicated by this rule was administered. The delivery of laser light was stopped 2cm from the surgical entry point.

After the laser procedure was complete microphlebectomies were performed to remove smaller superficial varicosities. Sutures and steri-strips were applied to the incisions. Class II medical compression stockings were given to the patients to wear for 4 weeks after the treatment.

Follow-up appointments were done 1 week, 4 weeks, 6 months and 1 year after the treatment session.

Results
No problems were reported by any of the patients, except for mild skin irritation and ecchymosis. No deep vein thrombosis was recorded. The microphlebectomies usually showed transient and insignificant bruising. During follow-up appointments patients were checked with US for signs of full or partial vein recanalization. Six months after the surgery, 94% of the veins in the 15-18W treatment group and 99.2% of the veins in the 25W treatment group remained occluded. After 1 year, 88.2% of the veins in the 15-18W and 98.5% in the 25W treatment group remained occluded. All patients, even those whose veins were not fully occluded, reported being satisfied with treatment.

Fig. 4: Occlusion of GSV below SFJ – 9 days post-op (a) and 6 weeks post-op (b). In 6 weeks the vein is fully overgrown by surrounding tissue.

Discussion
The Fotona’s 1064nm, Nd:YAG XP-2 laser at 25W and in QCW mode is a very effective treatment modality for EVLA of the GSV and SSV varicose veins, resulting in 98.5% vein occlusion after one year. This study demonstrates that Fotona’s XP-2 laser system can deliver the necessary power for the successful and safe treatment of varicose veins. After
increasing the power from 18W to 25W, the percentage of occluded veins increased with 5.2% at 6 month check-up and with 10.3% at one year.

The results seen in this clinical study are in-line with results from Proebstle et al [2], who saw statistically significant differences in occlusion rate (9.7% more) between 15W and 30W at a wavelength of 940nm. Yet the same study demonstrated a statistically significant effect on side effects between three cohorts; A (940nm, 15W), B (940nm, 30W) and C (1320nm, 8W). Patients in cohort C showed less ecchymosis and felt less pain than patients in the other cohorts. Because of differences in both wavelength and power, it is difficult to directly apply these findings to treatments at 1064nm and 25W. In our study, using the same 1064nm wavelength in both patient groups, we observed no increase in side effects for procedures administered at 25W versus those at 15-18W.

Low power (15W) data for the 1064nm wavelength was published by Chang et al [5]. In this study EVLA was used to obliterate the varicose veins, although ligation was used to inhibit proximal SFJ reflux. Nevertheless the published long-term data on side effects are relevant to treatment at the 1064nm wavelength. In this retrospective multiple case study Chang et al reported on 149 patients and 252 legs, which were treated over a period of four years at one clinical center. At the six month evaluation stage, 96.8% of patients showed eradication of varices. The most common initial side effects observed in Chang et al.’s study were ecchymosis and dyschromia in 23.0%, superficial burns in 4.8%, superficial phlebitis 1.6%, and localized hematoma in two legs 0.8%. Most of the complications resolved spontaneously with time. At the six month follow-up stage most of these minor side effects had disappeared. Local paresthesia was found in only 2.8% of legs, 0.8% still had persistent hyperpigmentation and 2.4% had minimal scarring from burn injuries. In total, 9.1% of patients still suffered from minor side effects, 6 months after EVLA. At the 28 month follow-up, none of the patients exhibited any side effects.

The data gathered in our study and in previously published studies [2,8] supports increasing the energy dose of the laser treatment to increase the efficacy of EVLA. In agreement with other published studies [5,11], our experiences suggest that side effects are minimal when using the 1064nm wavelength. The data led us to conclude that the 1064 nm Nd:YAG laser is an effective and safe treatment modality for varicose veins.

Fig. 5: Transient bruising as a side effect of microphlebectomies performed in the same session with EVLA at two weeks (a) and two months (b) after the procedure.

Fig. 6: EVLA provides an excellent aesthetic result – typical patient from this study, before (a) and after (b) the procedure.
References:


