

Prospective study on combination diode laser and radiofrequency energies (ELOSTM) for the treatment of leg veins

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OBJECTIVE: To evaluate the Polaris LV, electro-optical synergy (ELOS) technology, which combines diode laser (915 nm) and radiofrequency (RF) (1 MHz) energies, for the treatment of leg veins.

METHODS: A total of 25 patients (Fitzpatrick I–IV) with a total of 35 sites (0.3–5.0 mm vessel diameters) were treated with up to three sessions at 4- to 10-week intervals. Polaris LV settings included: 80–140 J/cm² of laser light, 80–100 J/cm³ of conducted RF, and pulses of 100–300 ms. Vessel clearance was

graded by both the treating and an independent physician.

RESULTS: At 1 and 6 months after the final treatment, approximately 77% of treatment sites exhibited 75–100% vessel clearance, and 90% had 50–100% vessel clearance. No treatment sites had less than 25% vessel clearance. Transient dyschromic side effects were common.

CONCLUSIONS: The Polaris LV ELOS system is effective and safe in treating leg veins, including telangiectases, venulectases, and reticular veins. *J Cosmet Laser Ther* 2004; 6: 86–90

Introduction

Lasers and light sources have been used for more than two decades in the treatment of vascular lesions. Traditionally, the use of lasers and light sources for the removal of leg veins has been more difficult than that of facial vessels and superficial hemangiomas.¹ This is related in part to the differential anatomy and physiology of leg veins. Increased hydrostatic pressure on the lower extremities may result in less effective thermal destruction of targeted blood vessels. In addition, lower extremity veins are often larger in diameter, have thicker vessel walls, and are located deeper in the skin than most facial vessels. Variations in skin pigmentation and sensitivity to thermal damage also present difficult challenges for the laser surgeon.

In recent years, significant progress in laser technology, including the development of pulsed lasers with hemoglobin-specific absorption, longer wavelengths, higher fluences, and cooling techniques, has improved the effectiveness of treating larger and deeper venulectases and reticular veins, while considerably reducing the risk of scarring and hypopigmentation.^{2,3} Evidence has shown that longer near-infrared wavelength light energy is needed to penetrate deeper into the skin. For larger blood vessels, longer pulse durations are needed in order to slowly photocoagulate the entire vessel, minimizing the risk of purpura and sparing surrounding structures. Larger beam diameters are needed to penetrate deeper into tissue and optimize fluence delivery to the target vessel. With these advances, lasers and light sources have been gaining popularity for the treatment of leg veins.

A recently introduced technology called electro-optical synergy (ELOSTM) combines pulsed optical energy with

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conducted radiofrequency (RF) energy, utilizing the principle of selective thermolysis. Selective thermolysis stipulates that selective damage to a target tissue can be achieved using energy that is preferentially absorbed by the target to a sufficient degree to create thermal damage of the target.⁴ The premise of ELOS is based on a synergistic activity between the two forms of energy, where the parameters of the laser and RF energies, including spectrum, duration of exposure, and energy density, are set optimally to cause thermal heating of the blood followed by irreversible injury to the target vessel. With this combination, lower levels of both energies can be used, potentially reducing the risk of side effects associated with either optical or RF treatments alone.

The mechanism of vessel destruction with ELOS technology (combination optical and RF energies) is described as follows. Optical energy penetrates the dermis and is absorbed by intravascular hemoglobin, where it is then converted into heat. Blood vessel temperature subsequently rises. RF energy is absorbed as a result of differences between the electrical properties of the blood vessel and surrounding tissue.⁵ Blood has very high electrical conductivity, whereas bone and dry skin are resistant to electrical current. Tissue conductivity is also correlated with tissue temperature, such that higher tissue temperatures further increase conductivity and selective heating by the RF current.⁶ The increase in electrical current therefore creates spatially confined heat, adding to the selective vascular damage. The RF energy conducts through the vessel wall with greater resistance than through hemoglobin. This added resistance generates greater heat than the transfer of heat created intravascularly. Through the heat created by the synergistic activities of the optical laser and RF current, the blood vessel is able to reach a sufficient temperature level that causes permanent injury to the adventitia and endothelium, resulting in vessel shrinkage or disappearance.

The purpose of the present study is to investigate this new method of treatment, using the Polaris LVTM (Syneron Medical Ltd), which combines diode laser energy (915 nm) with conducted RF energy (1 MHz), for the treatment of telangiectases, venulectases, and reticular leg veins. The Polaris LV device consists of a handpiece with a 5 × 8 mm sapphire light guide and lateral bipolar electrodes that are positioned against the skin, perpendicular to the target vessel during treatment. The handpiece integrates contact cooling to 5°C to enhance selectivity and protect the epidermis. To the author's knowledge, this is the first study to describe the effectiveness of combined diode laser energy and conducted RF energy for the treatment of leg veins.

Materials and methods

Twenty-five female patients between 37 and 72 years of age (mean age 52 years) with various sizes and depths of leg veins were enrolled into the study. Candidates were excluded if they had a history of prior leg vein treatment. Fitzpatrick skin types included type I ($n=2$), II ($n=17$), III ($n=5$) or IV ($n=1$). Patients with a deep sun tan were

excluded. The protocol was approved by Essex Institutional Review Board, and all participants gave informed consent.

A total of 35 sites with vessel diameters varying from 0.3 to 5.0 mm were treated with the Polaris LV. Typical treatment sites included vessels with a diameter of 1.0–3.0 mm proximally, tapering to less than 1.0 mm distally. Approximately half of the treatment sites included reticular veins of 3.0–5.0 mm in diameter. Energy settings were set relative to skin type and were increased until a vessel reaction was observed. The desired visual endpoints included vessel blanching, vessel darkening, or erythema above the leg vein. A thin layer of transparent gel (Aquasonic clear ultrasound gel; Parker) was applied to the treatment site prior to treatment. The handpiece was applied to the treatment site with light pressure to ensure coupling of the RF electrodes and cooling to the skin surface. Patients were treated with up to three treatment sessions at 4- to 10-week intervals. The decision to retreat was based on clinical assessment by the investigator. No topical anesthetic was utilized. In no instance were dressings, medications, or compression stockings used.

Polaris LV specification

Optical energy. The light source that is utilized in the Polaris LV is a high-power diode laser that emits pulses at a wavelength of 915 nm. Optical energy density can go as high as 140 J/cm² with a pulse duration as long as 300 ms. Optical energy is delivered through a contact 5 × 8 mm sapphire light guide.

Conducted RF energy. The bipolar system of the Polaris LV can generate RF energy as high as 100 J/cm³ with pulse duration as long as 300 ms. The geometry of the RF electrodes is designed to generate an electrical field to a maximum depth of approximately 5.5 mm. The two electrodes of this bipolar system are laterally affixed to opposing sides of the 5 × 8 mm rectangular sapphire light guide.

Thermo-electric cooling (TEC) is utilized to provide a temperature of 5°C at the contact surface of the sapphire and electrodes, before, during, and after energy delivery.

Pulses of energy were delivered along all aspects of the targeted vessel with no more than 20% overlap. The orientation of the RF electrodes to the axis of the treated vessel was varied depending on tissue effect; that is, orientation was changed 90 degrees if the original orientation did not achieve the desired endpoint. The treatments were usually performed starting at the distal aspect of the vessel, advancing pulses to the proximal aspect. Depending on the skin type, the initial optical energy used in this study ranged from 80 to 120 J/cm². Higher energy levels were used in lighter skin types. The RF setting ranged from 80 to 100 J/cm³. Test spots were delivered with a 5- to 10-minute waiting period to allow for observance of a tissue reaction. In the absence of a tissue reaction, optical and RF energies were alternatingly increased by 2–5 J until the desired response was observed with no epidermal injury. Optical or RF energies were

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increased again on subsequent treatments in the absence of side effects.

Standardized photographs were taken at baseline, 1 month and 6 months after the last treatment session. Vessel clearance was graded by the treating physician and a nurse. In addition, vessel clearance was graded, through comparison of pre- and post-treatment photography, by a cosmetic surgeon experienced with treating leg veins with sclerotherapy and long-pulsed 1064 nm lasers. This physician has no relationship with the investigator, and has no proprietary interest in the Polaris LV system. The grading was based on the overall appearance of the treatment site, including the number and size of vessels, according to the following: Grade A, 75–100% vessel clearance; Grade B, 50–74% vessel clearance; Grade C, 25–49% vessel clearance; and Grade D, 0–24% vessel clearance. The degree of vessel clearance was assessed at week 2, then monthly thereafter throughout treatment until 6 months after the last treatment. A patient self-assessment questionnaire was used to assess the patient's experience during the first 2 weeks after the initial treatment. Patients were examined for and inquired about side effects on each follow-up visit. Patients were asked to observe the treated site and to report any side effects noticed in the immediate hours or days following their first treatment session. Patients also were asked to grade the level of discomfort from treatment at the target area on a scale from 1 to 10, with 1 denoting no discomfort and 10 denoting severe discomfort.

Results

Of the 35 treatment sites, 22 received three treatment sessions, nine treatment sites received two treatment sessions, and four treatment sites received one treatment session. Sites that were treated only once or twice received fewer treatments due to two factors: (1) incomplete fading of dyschromic side effects from the prior treatment session; and (2) as the dyschromic side effects fully cleared, the vessels were cleared as well, negating the need for additional treatments. All vessels were treated to an endpoint of blanching, darkening, or the appearance of erythema. Within minutes of treatment, the vascular lesion developed an urticarial appearance that persisted for up to 48 hours. At 2 weeks following the first treatment session, no patients evidenced more than 25% vessel clearance. Reticular veins were palpably firm, non-tender, and were blurred in appearance.

The responses are shown in Table 1. At 1 month and 6 months after the final treatment, approximately 77% of treatment sites exhibited Grade A improvement (75–100% vessel clearance), 13% had Grade B improvement (50–74% vessel clearance), and 10% had Grade C improvement (25–49% vessel clearance). There were no treatment sites that demonstrated only a 0–24% vessel clearance (Grade D). Figure 1 shows the baseline and post-study photographs of a 0.5 mm treated vessel. Comparatively, Figure 2 shows the baseline and post-study photographs of a larger reticular vein measuring 3.0 mm.

	No. of treatment sites (%) <i>n</i> = 35			
	Grade A (75–100%)	Grade B (50–74%)	Grade C (25–49%)	Grade D (0–24%)
Investigator	28 (80%)	3 (9%)	4 (11%)	0 (0)
Independent physician	26 (74%)	6 (17%)	3 (9%)	0 (0)
Average	27 (77%)	4.5 (13%)	3.5 (10%)	0 (0)

Table 1

Distribution of the categories of vessel clearance for the 35 treatment sites.

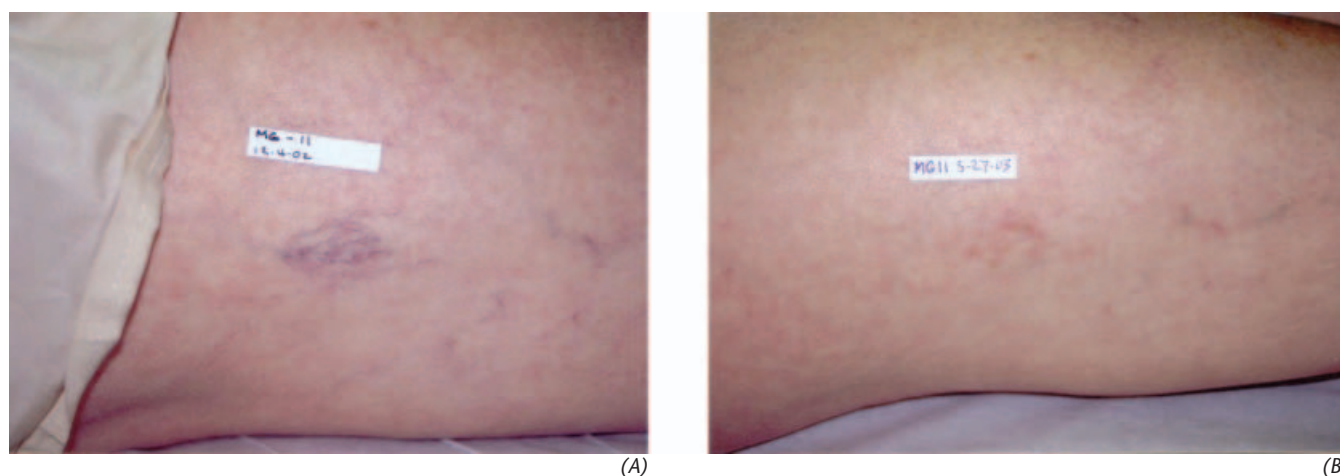


Figure 1

Before (A) and 4 weeks after the last treatment (B) of a 0.5 mm leg vessel, using the Polaris LV system.

Discomfort at the target area was common during treatment with the Polaris LV. The average discomfort rating reported was 7 (based on a scale of 1–10, with 10 being the worst). One treatment site developed dysesthesia, which resolved without treatment after 8 weeks. At three sites on three different patients, eschar formation occurred, but there were no permanent textural or dyschromic sequelae. Although temporary ecchymotic or hyperpigmented side effects were common, there were no permanent dyschromic or textural changes in any patients.

Discussion

The present study supports the efficacy and safety of the Polaris LV ELOS system, which combines diode laser energy and conducted RF energy, for the treatment of leg veins. In this study, total energy up to 140 J/cm^2 of laser light and 100 J/cm^3 of conducted RF energy – and pulses in the range of 100–300 ms resulted in substantial clearance of both small and large vessels (0.3–5.0 mm in diameter). By combining the two forms of energy in the Polaris system, lower levels of optical and RF energies can be used to irreparably damage targeted blood vessels; that is, one energy synergistically working with the other. This may potentially reduce the risk of adverse side effects with either technology alone. The major risk associated with laser therapy is epidermal damage from excess absorption by melanin chromophore in the skin. The major risk of RF energy is non-specific thermal injury. Importantly, the two energy forms are differentiated in the way they are absorbed by the target vein. Optical energy absorption is dependent on the light absorption properties of hemoglobin and other chromophores in skin,⁴ whereas RF heating is dependent on the frequency of electrical current, electrical conductivity of tissue elements, and the tissue temperature.⁵

In the Polaris LV system, optical energy is delivered using a high-power diode laser set at a wavelength of 915 nm and with pulse durations up to 300 ms. The major absorption peak of hemoglobin is approximately 550 nm, and the second peak, which has a much lower absorption

coefficient, is at the near infrared wavelength of approximately 920 nm. As a result of higher blood and melanin absorption of light at shorter wavelengths, light penetration into the tissue is limited to approximately 0.5 mm. Therefore, lasers using shorter wavelengths in the vicinity of 400–600 nm are effective for treating superficial vascular lesions but ineffective for the treatment of larger, deeper veins.^{7–10} In contrast, there is lower blood and melanin absorption of light at the longer wavelengths, enabling optical energy to penetrate deeper (approximately 3.0–4.0 mm). Consistent with this effect, the use of lasers with longer wavelengths, such as the alexandrite (755 nm), diode (810 and 940 nm), and Nd:YAG (1064 nm), has been more successful in the treatment of larger and deeper veins.^{11–14}

Conducted RF energy is applied through electrodes in the Polaris LV system applicator and brought into contact with the skin surface. The Polaris LV is a bipolar system, such that the depth of penetration of electrical current is a function of the area between the electrodes and the thermoconductivity of the tissue adjacent to the electrodes. Electrical current in the RF range interacts with tissue according to the impedance values of tissue elements.⁵ The current will always follow the route of lower impedance. The density of electrical current can be controlled by precooling or preheating different parts of tissue. External contact cooling (with the TEC handpiece) increases the impedance in the epidermis, directing the RF current to penetrate deeper where the diode laser has preheated the blood vessel, and creates a temperature gradient between the vessel and surrounding tissue. The RF current creates an intrinsic and extrinsic thermolytic impact to the blood vessel, resulting in vessel wall injury.

The results of this study demonstrated that the Polaris LV ELOS system, which combines diode laser and RF energies, is effective and safe in treating leg veins, including telangiectases, venulectases, and reticular veins. Of the 35 treatment sites, approximately 77% of vessels were improved by at least 75% (Grade A). A total of 90% of vessels were improved by at least 50% (Grade A or B). No treatment sites had less than 25% improvement (Grade D).

Contact cooling with the TEC handpiece protects the epidermis from immediate erythema and edema. Typically,



(A)



(B)

Figure 2
Before (A) and 4 weeks after the last treatment (B) of a 3 mm leg vessel, using the Polaris LV system.

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erythema above the vessel appears as a result of the heat that is dissipating from the vessel and not from direct absorption of the laser light by the epidermis. In the three patients with eschar formation, the side effect developed 2–3 days after treatment, suggesting that it was due to heat that was generated in the vessel and then dissipated to the skin surface. This heat emanating from the treated vessel would be expected to damage the deep epidermis to a greater degree than the superficial epidermis, which receives greater protection from the externally applied contact cooling.

Conclusions

This study describes a new approach based on ELOS for the treatment of telangiectases, venulectases, and larger

reticular leg veins. Results showed that the Polaris LV system, which combined diode laser energy (915 nm) and conducted RF energy, is able to provide a clearance of greater than 75% for nearly 80% of treatment sites with diameters ranging between 0.3 mm and 5 mm. Minimal side effects were observed.

Combining laser and RF energies heats the target blood vessel in two different ways, enabling lower levels of both energy types to be used. Efficacy is related to the ability of the system to selectively target the blood vessel. The two forms of energy act synergistically (i.e. the optical vascular heating facilitates RF conduction, resulting in additional vascular heating). In addition, surface cooling before, during, and after treatment using the contact cooling handpiece enhances selective vascular injury while protecting the epidermis from the laser energy.

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