

European Multi-Center Study: PhotoDerm® VascuLight™ for the Treatment of Varicose Reticular Veins and Leg Telangiectasias, as well as Other Vascular Lesions

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INTRODUCTION

Varicose and spider veins occur in an estimated 60% of the adult populations of North America and Europe. Women have a greater tendency than men to develop cosmetically disfiguring leg veins; approximately one-third of these women notice the development of these veins during pregnancy. Family history and the use of progestational agents are associated with the development of these veins. Though reports show up to 53% of patients having associated symptoms with the veins, patients primarily seek treatment because the veins are a cosmetic concern.¹ Therefore, it is important that the treatment method results in significant cosmetic improvement without adverse sequelae.

Existing treatment options are all inherent with limiting factors. Short wavelength laser treatment has been successful for the treatment of superficial leg telangiectasias, but not deeper vessels, thus limiting treatment for a number of women and men.¹⁻³ Furthermore, current laser treatment does not address possible defects in the underlying large reticular veins that are usually the source of leg telangiectasias.

Ultrasound examinations have revealed that 88% of patients with thigh telangiectasias have incompetent reticular veins associated with telangiectasias.^{4,5} Sclerotherapy is another widespread method, but the results are dependent on the skill of the physician, since an exact pin-point technique is required. Inadequate concentration of sclerosing solution, poor technique and failure to recognize and treat underlying problematic vein networks can lead to veins that appear to be “resistant” or rapidly recur after treatment.⁶ Moreover, adverse side effects reported with these treatment options, such as disfiguring pigmentation and hypertrophic scarring (laser) and pigmentation and telangiectatic matting (sclerotherapy) can impair cosmetic results.^{1,2,7}

A new treatment modality, the VascuLight system, offers a non-invasive approach to treating the full range of leg veins, as well as a wide variety of other vascular lesions. The system combines the intense pulsed light (IPL) technology of the PhotoDerm device (ESC Medical Systems) with a pulsed 1,064 nm laser. The IPL component, which incorporates a broad spectrum wavelength range from 515 nm to



Fig. 1: Patient with reticular veins and telangiectasias (upper thigh) before and 3 months after VascuLight treatment.

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1200 nm with a fluence range of 3 to 90 J/cm², is ideal for the treatment of vessels up to 1 mm in depth and up to 1 mm in diameter. The pulsed 1,064 nm laser with high fluences (up to 150 J/cm²) enables treatment of deeper (up to 5 mm) and larger (up to 5 mm) vessels. Moreover, multiple pulsing capability (single, double and triple pulsing) with long pulses (2-16 msec per pulse) allows for differential heating and cooling of the various sized vessels, located at different depths. The combination of epidermal cooling with longer wavelengths, where melanin absorption of the light energy is minimal, results in minimal thermal damage to the surrounding tissue, so that even dark skin patients can be safely treated.

A multi-center study was conducted to test the efficacy of VascuLight to close leg telangiectasias and reticular veins up to 5 mm in diameter. A second study was conducted to assess the percent clearance achieved with VascuLight treatment of larger diameter reticular veins and secondary telangiectasias.

METHOD

Study 1

Patients were treated in 3 centers with the VascuLight device. Two centers are located in Switzerland (Geneva & Arlesheim) and one center in Germany.

Forty-two women, aged 22 to 69 years, and 1 man, aged 58 years, were treated for reticular veins and/or leg telangiectasias. Patients were skin types I-IV. Leg veins were assessed with ultrasound (German clinic) or through a visual estimation with a ruler (Swiss clinics) and vein diameters were determined. Patients were divided into three groups according to the vessel diameter (*Table 1*): group 1; < 1.0 mm (49 veins), group 2; 1-2 mm (40 veins) and group 3; 2-5 mm (15 veins). A total of 104 veins were treated with one to four veins per patient. Patients were evaluated at follow-up sessions, one to two months after treatment. Treatment clinical endpoint was closure of the vessel, which was achieved, generally after one session in larger vessels and after two sessions in vessels smaller than 1-mm diameter.

Vessels were treated with fluences from 140-148 J/cm², double or triple pulses with pulse duration of 3.2-5 msec/pulse, and delay time of 15-20 msec. In both Swiss clinics, the “oblique method” was used. The hand piece was placed along the vein, at a 20° angle to the skin, for better absorption in small vessels. In another clinic (Germany), the “V technique” was used to treat larger vessels. The



Fig. 2: 48 year old female (skin type II) with leg telangiectasias before and 2 months after VascuLight treatment.

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hand piece was directed to the skin at a 45° angle on both sides and perpendicular to the vessel, thereby delivering two pulses to the vessel without overlap. This method produced more effective closure from both sides, without damaging the epidermis.

Study 2

Twenty-seven patients were treated (clinic in Spain) for blue reticular veins that were larger than 2 mm in diameter and greater than 1.5 mm in depth. Thirty-two patients were treated for red/blue secondary telangiectasias that were smaller than 2 mm in diameter and 1-1.5 mm in depth. The following treatment parameters were used: one treatment with 1,064 nm wavelength and fluences of 130 to 150 J/cm² (reticular veins) or 120 to 145 J/cm² (telangiectasias). Patients were evaluated for percentage clearance of the vessels at follow-ups, 1-2 months after treatment.

RESULTS

Study 1

Follow-up sessions, conducted at 1 to 2 months after treatment, revealed that all 104 vessels were closed. Closure of the vessels was visually assessed by

pressing on the skin with an ultrasound transducer or by tracing along the vessel with a finger. Vessels that were closed could not be compressed, while alive and open vessels could be compressed, resulting in a change of form in the ultrasound image. Closure of the vessel can be assessed immediately after treatment, however, the process of visible clearance (when the vessel can no longer be seen on the skin) is more prolonged and requires approximately one month for smaller vessels and up to several months for larger vessels. This prolonged process is a direct result of selective photothermolysis, whereby the vessel is heated to the point of destruction (vessel closes), followed by fragmentation of the vessel and removal by the body, and replacement by granulation tissue. Side effects were minimal and transitory. Three cases (2.9% of patients) of blistering were reported, as a result of directing one pulse after the other on the same spot on the skin (not recommended by manufacturers). Ten cases (9.6%) of hemosiderin hyperpigmentation were reported. The IPL component (in Pigmented Lesion mode) of the VascuLight can be used to safely and effectively eliminate these stains.



Fig. 3: 41 year old female (skin type II) with leg telangiectasias before (gel on skin) and 2 months after VascuLight treatment.

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Study 2

Follow-up sessions were conducted at 1-2 months to assess percent clearance of the vessels. The following results were observed (*Table 2*): 62.1% clearance \pm 7.4% (reticular veins) and 79.7% clearance \pm 14.2% (secondary telangiectasias). Closure of the vessel was not assessed after treatment; however, for visual clearance to occur, the vessel does need to close, thus suggesting that in the current study, the treatments did achieve closure of the vessel. Complete clearance of the vessels was not observed; however, since the process of removal of the destroyed vessel by the body (vessel disappears from the skin) takes several months, an increase in the percent clearance would be expected with longer follow-up time.

No side effects were reported after treatment. Some patients reported discomfort with the treatment. Applying ice packs for 1-3 minutes prior to treatment has been successful in alleviating this discomfort.

There were no cases of scarring or of telangiectatic matting, often seen with sclerotherapy.

SUMMARY

In our combined studies at 4 multi-national centers, we have demonstrated that VascuLight is an excellent system for treating both small and large diameter vessels (as demonstrated by the two methods used to assess treatment efficacy: closure of all vessels in Study 1 and percent clearance in Study 2). VascuLight offers many advantages over traditional methods for the treatment of leg veins. The treatment is non-invasive and doesn't require an exact pin-point technique, as in sclerotherapy. The system addresses a wide range of leg veins and achieves superior results even in larger diameter vessels. The optimal parameters for wavelength, timing and fluence can be selected to treat vessels of different sizes and located at various depths, even certain vessels that are resistant to other laser therapy. Most patients can be

VascuLight can treat a wide variety of vascular lesions, such as the thick and deep port-wine stain presented below, in addition to varicose veins.

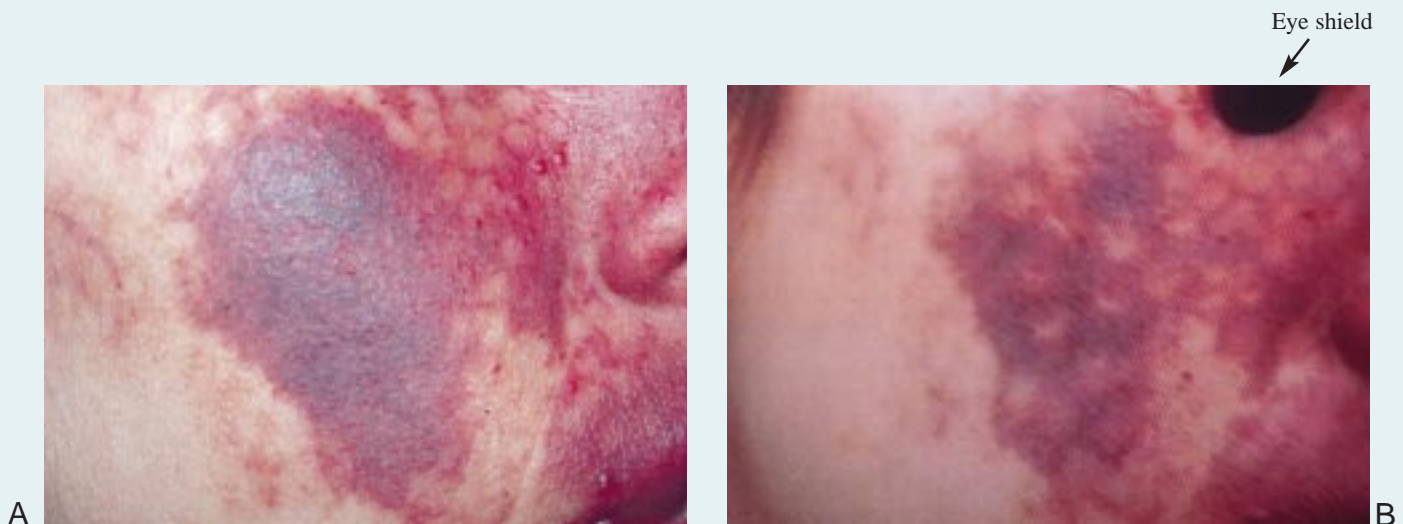


Fig. 4: Female patient with an extensive, purple port-wine stain on the face. Patient had previously undergone 10 treatments with a pulsed dye laser and agreed to a test session with VascuLight. A) Before treatment B) 1 month after test session (90 J/cm², single pulse, 6 msec). The test spots on the cheek demonstrate the effectiveness of VascuLight to penetrate deeper blood vessels. Center of treated areas have returned to a normal skin color (confirmed by colorimetric measurement). Patient was satisfied with test session and is now undergoing treatment.

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safely treated with little risk of adverse effects. The treatment shows fewer complications such as the hyperpigmentation and hypopigmentation reported with the pulsed dye laser treatment or telangiectatic matting seen with sclerotherapy.

Furthermore, the device can be used to treat not only varicose veins, but also a wide variety of benign

vascular and pigmented lesions such as thick and deep port-wine stains that have no other treatment modality (*See Fig. 4, French clinic*). VascuLight incorporates the IPL technology of PhotoDerm, which has been used to safely and effectively treat such lesions as laser-resistant port-wine stains, facial and leg telangiectasias, and angiomas.^{2, 8-10}

TABLE 1 (Study 1)
Number of Vessels per Lesion Type

	Leg Vein Size (diameter)		
	Group 1; < 1.0 mm	Group 2; 1-2 mm	Group 3; 2-5 mm
Swiss clinic (Arlesheim)	16	3	4
Swiss clinic (Geneva)	30	21	0
German clinic	3	16	11
No. vessels treated	49	40	15
No. vessels closed	100%	100%	100%

Vessel closure for all 104 vessels was observed, immediately after treatment and at 1.5 months follow-ups (German clinic) and at 1-2 months follow-up sessions (Swiss clinics).

TABLE 2 (Study 2)
Percentage Clearance of Veins After Treatment

Lesion type	# patients	% clearance
Reticular veins	27	62.1 ± 7.4
Secondary telangiectasias	32	79.7 ± 14.2

Follow-up sessions were at 1-2 months post VascuLight treatment. Overall complete clearance was not noted at follow-up sessions, however, since the time period for visual clearance of larger vessels is often several months, an increase in the percentage clearance would be expected with time.

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