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Feasibility and Safety of Using Combined Light-Emitting Diodes Versus Intense Pulsed Light Technology for the Improvement of Facial Hypervascularization in Adult Patients

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Abstract

Background: Superficial facial vascular lesions can be an aesthetic problem and a symptom of different skin diseases.
Objective: It was to compare the efficacy and safety profiles of Dermalux® Tri-Wave MD, based on three combined light-emitting diodes (LEDs) technology and intense pulsed light (IPL) for reducing the excess of facial vascularization due to superficial cutaneous vascular lesions.
Materials and methods: The study had a single-center, proof-of-concept, open-label, and prospective design. Two groups of adult patients were treated for facial hypervascularization, LED-Group with an LED device combining 633 and 830 nm and IPL-Group with an IPL (555–950 and 530–750 nm). Variables assessed were hemoglobin hyperconcentration (HH), hemoglobin-affected area (HAA) through Antera 3D®, and pain using the Numeric Pain Rating Scale.
Results: Twenty subjects were included, 10 by group (50% female). LED-Group: Mean age 32.1 years (range, 21–46). IPL-Group: Mean age 34.5 years (range, 25–49). HH: LED-Group 100% had a moderate improvement; in the IPL-Group, 10% was moderate, and 90% was marked. HAA: LED-Group 10% had a slight improvement, 70% moderate, and 20% marked; in the IPL-Group, 100%, the improvement was marked. Seventy percent of LED-Group patients reported no pain, 30% mild; in the IPL-Group, 100% of patients reported severe pain.
Conclusions: Treatment with combined red and near-infrared LEDs effectively reduced the excess of facial vascularization with moderate outcomes compared with IPL, but without secondary effects and no pain. This treatment could represent an effective, safe, and well-tolerated approach for facial vascular lesions.

Keywords: low-level laser therapy, light-emitting diode, intense pulsed light, vascular lesions, hemoglobin hyperconcentration, hemoglobin-affected area

Introduction

Superficial facial vascular lesions can represent an aesthetic problem and be a symptom of different skin diseases.[1,2] Predisposing risk factors include skin phototypes I through III,[3] significant sun exposure history, and long-standing rosacea.[4] It has also been associated with increasing age, male sex, smoking (similar in men and women), and mainly outdoor occupations.[5] Their distribution is usually focal, with single lesions; multiple lesions may be related to systemic diseases.[4]

The choice of an effective treatment device for these lesions should consider the wavelength at which the vascular chromophore has the most significant absorption.[6,7] These devices should focus on oxyhemoglobin (HbO2), the primary target chromophore for selective photothermolysis of

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vascular malformations,[8] with a primary absorption spectrum with three-wavelength absorption peaks, 418, 542, and 577 nm,[9] and a secondary ranging from 800 to 1100 nm.[10]

Laser technology using light sources with visible (500–800 nm) and near-infrared (800–1300 nm) wavelengths is an effective treatment modality for these superficial vascular lesions.[1] Based on a selective photothermolysis design, several lasers have been developed to treat congenital and acquired vascular lesions.[11] The most commonly used for these treatments are the 532 nm potassium titanyl phosphate, 595 nm pulsed dye laser, the 755 nm alexandrite laser, intense pulsed light (IPL), and the 1064 nm neodymium yttrium–aluminum–garnet laser (Nd:YAG).[12] Although side effects of IPL are usually rare and of minimal severity, the most common include pain and erythema.

Other reported side effects are edema, blistering, hematoma, crusting, hyper-/hypopigmentation, leukotrichia, scarring, keloid formation, and infection.[13] For the past few years, light-emitting diodes (LEDs) have been demonstrated as an emerging and safe tool with fewer side effects and good results and good results for treating many skin conditions,[14–18] for example, facial vascular lesions.[19] This is why we decided to test it to treat facial hypervascularization. The light from the LEDs interacts directly with its target chromophore (depending on the wavelengths used) to generate photomodulation at a vascular level, reducing the caliber of these small vessels and, therefore, the reddish appearance of the skin.

The study's objective was to assess the efficacy and safety profiles of Dermalux® Tri-Wave MD, a device based on delivering combined LED technology, compared with those of an IPL device for reducing the appearance of excess facial vascularization due to superficial cutaneous vascular lesions.

Materials and Methods

Study design

The study was conducted in a single-center Elite Laser Clinic (Madrid, Spain) as a proof-of-concept, open-label, and prospective treatment of adult patients with facial hypervascularization. Participants were divided into two groups, one experimental group treated with Dermalux Tri-Wave MD LED System (Aesthetic Technology Ltd, Warrington, Cheshire, United Kingdom; LED-Group), and a control group treated with Nordlys IPL System (Ellipse A/S, Hørsholm, Denmark; IPL-Group).

The study was conducted following the principles outlined in the current revised version of the Declaration of Helsinki, the Good Clinical Practice, and in compliance with all applicable laws and regulatory requirements relevant to the use of devices in Spain.

Data were collected to assess the study end-points and compared offline. The participants and the investigator evaluated the outcomes.

Primary objective. Evaluate the use of combination LEDs to reduce the appearance of excess facial vascularization.

Secondary objectives. Compare the reduction of excess facial vascularization between two different technologies, LEDs versus IPL, and collect adverse events associated with the therapy.

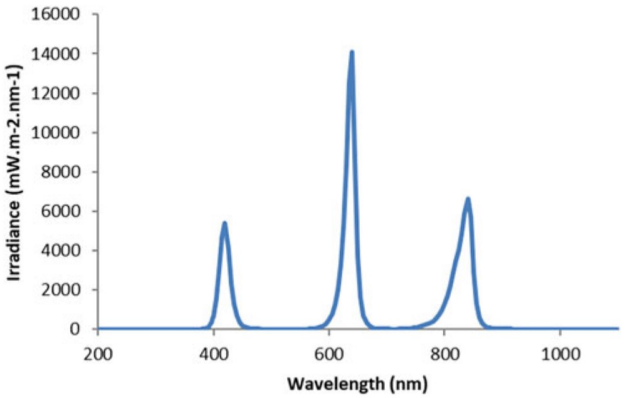

FIG. 1. Diagram of the photonic measurements of the LEDs. LEDs, light-emitting diodes.

Subjects

The study period was estimated at 5 months, from the first enrollment to the completion of the last study subject. The patients had to be diagnosed with excessive facial vascularization and met the following requirements.

Inclusion criteria. (1) Male or female, 30–60 years old, in good health conditions; and (2) subjects diagnosed with excessive facial vascularization desired to correct it and were willing to comply with all the protocol requirements.

Exclusion criteria. (1) Pregnancy or lactation; (2) known sensitivity to light treatments; (3) physical or chemical aesthetic treatment in the facial area to treat within 6 months or before the study enrollment; (4) current anticoagulant therapy; and (5) current skin infection in the area intended to treat.

Primary outcome measures

Primary outcome measures were changes in vascular appearance captured by Antera 3D® (Miravex, Dublin, Ireland), a noninvasive tool for analyzing and measuring diverse skin conditions, such as wrinkles, texture, and pigmentation redness. Antera 3D has a proprietary algorithm that precisely matches the selection on the baseline image across all follow-up images. The images quantified using Antera 3D were taken at baseline and the follow-up visit 1 month after the last treatment session.

TABLE 1. DERMALUX TRI-WAVE TECHNICAL SPECIFICATIONS

Technical specifications	
Classification	Class IIa medical device
Wavelengths (±2 nm)	415, 633, 830 nm
Treatment time (min)	1–20
Dose range (J)	8–240
Intensity (mW)	7–200
Light beam spot	633 nm = 68 J/cm^2 830 nm = 66 J/cm^2

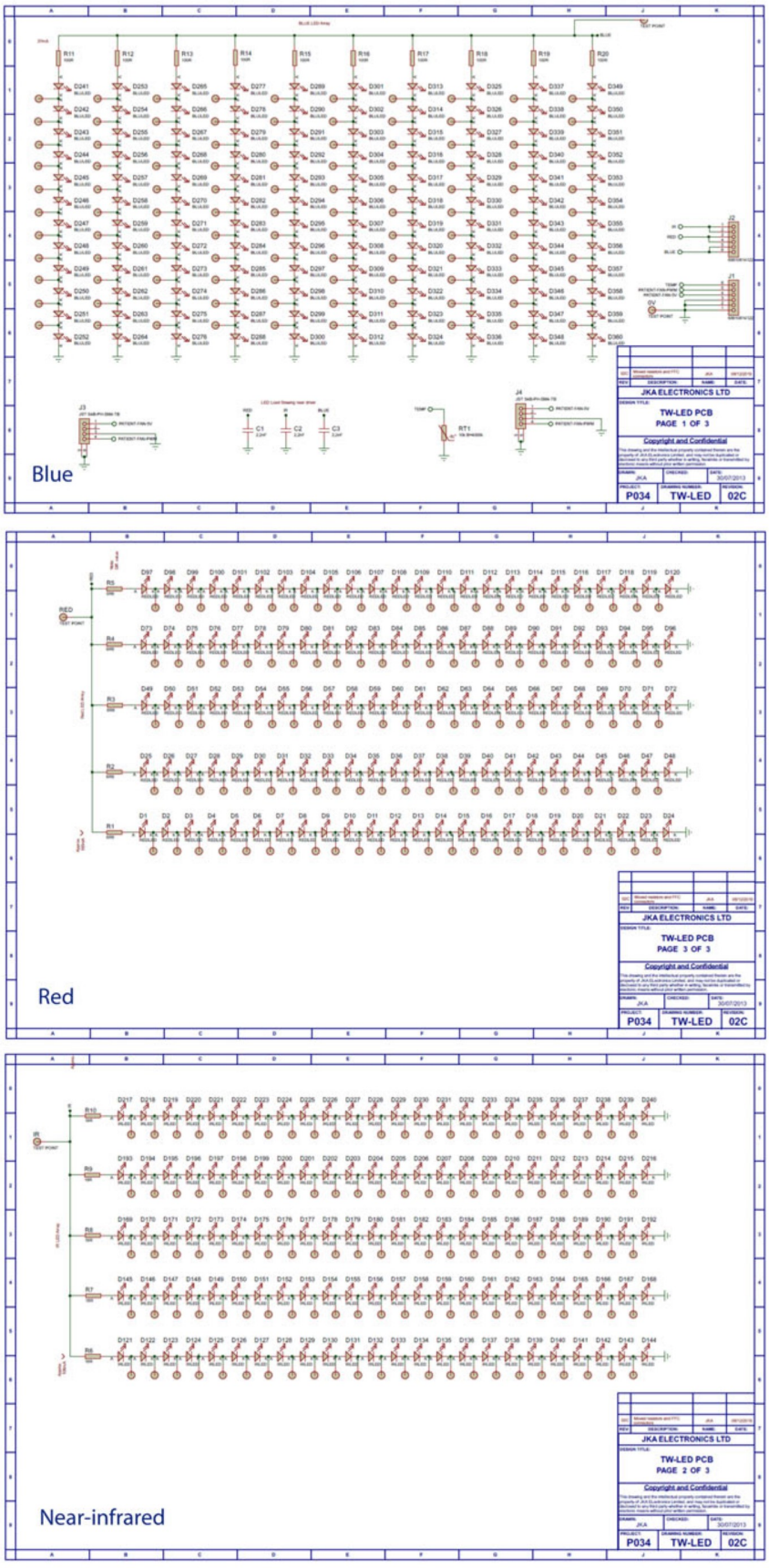

FIG. 2. LEDs, blue (415 nm), red (633 nm), and near-infrared (830 nm), board schematic.

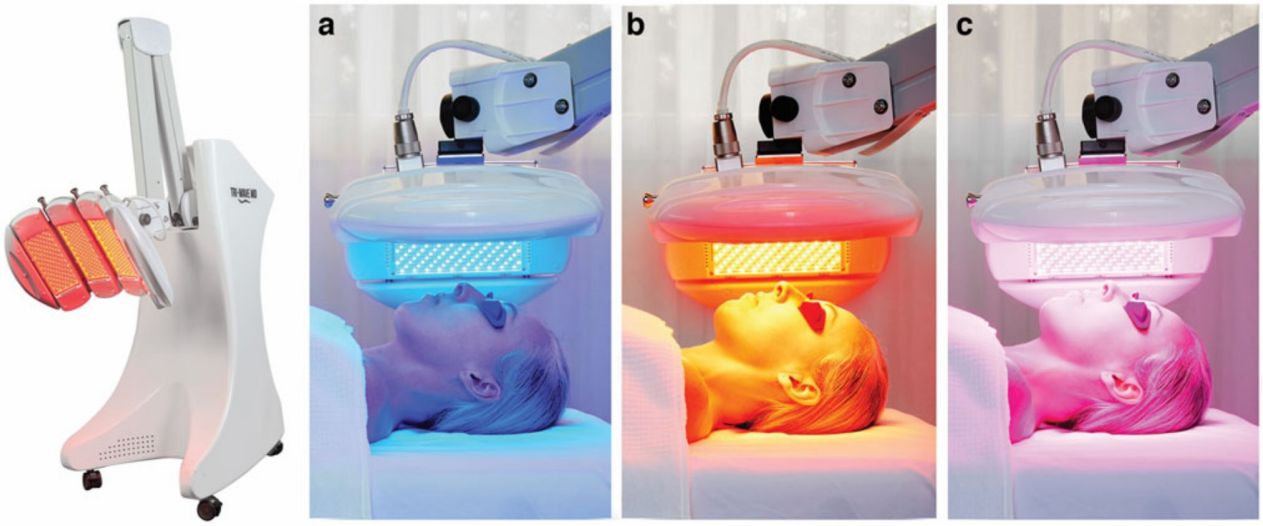

FIG. 3. Tri-Wave MD LED System device and each of the three LEDs in use, **(a)** blue, **(b)** red, and **(c)** near-infrared.

The imaging parameters analyzed were hemoglobin hyperconcentration (HH) and the hemoglobin-affected area (HAA). Based on the percentage of change of HH and HAA in the treated area, the results were divided into four categories: no outcomes (0%), a slight improvement (1–40%), a moderate improvement (40–70%), and a marked improvement (70–100%).

Devices and treatment procedures

For the LED-Group, the device used was the Dermalux Tri-Wave MD LED System (Aesthetic Technology Ltd, Warrington, England), and the delivered light spectrum from the array was blue (415 nm), red (633 nm), and near-infrared (830 nm) (Fig. 1). For the study, the wavelengths used were red and near-infrared. The device's technical specifications are detailed in Table 1, and the LED board schematic is in Fig. 2.

For the IPL-Group, the device used was the Nordlys IPL System, a multi-application and multi-technology platform for IPL, Nd:YAG, and nonablative fractional laser equipment used for skin remodeling. Ellipse's Selective Waveband Technology (SWT®) uses a double filter in all its IPL applicators to emit only the wavelengths effective for the desired treatment, which in this study were 555–950 and 530–750 nm.

LEDs procedure. The patients received 12 treatment sessions, one per week. The device was used in redness mode, where the manufacturer has pre-established wavelengths, power, and time. Red 633 nm (34.2 J) and near-infrared 830 nm (37.2 J) were the wavelengths used. The treatment started with near-infrared (830 nm) alone for 10 min, followed by 10 min with red (633 nm) and near-infrared (830 nm) together. A complete session lasted 20 min, with a total of 71.4 J. Optical radiation was emitted from a focused LED (30°), which has been uniquely designed to deliver the most uniform optical power across the array at 2.5 cm from the source LED. The 30° lens of the LED and the distance from the source when in use were the optimum for maximum uniform energy delivery (Fig. 3).

IPL procedure. Patients received three treatment sessions, one session every 4 weeks. In each session, a horizontal pass was first made with the VL+ handpiece (555–950 nm) and 9 J/cm^2, followed immediately by a vertical pass with the PR+ handpiece (530–750 nm) and 7 J/cm^2. The treatment time was 30 min (Fig. 4).

FIG. 4. IPL device. IPL, intense pulsed light.

Table 2. Results of Hemoglobin Hyperconcentration and the Hemoglobin-Affected Area by Patients of the Light-Emitting Diode Group and the Intense Pulsed Light Group

	Hemoglobin hyperconcentration			*Hemoglobin-affected Area (mm^2)*			
	Pre-T	*Post-T*	*Reduction (%)*	*Pre-T*	*Post-T*	*Reduction (%)*	p
LED-G							
Median	52.0	23.0	53.5	567.6	258.5	58.8	0.8159
SD	41.7	16.5		374.6	236.7		
IPL-G							
Median	53.8	12.7	75.0	674.6	133.9	81.4	0.7355
SD	32.2	6.8		318.4	78.0		

LED-G, group treated with light-emitting diodes; IPL-G, group treated with intense pulsed light; Pre-T, pretreatment; Post-T, post-treatment; SD, standard deviation.

The procedures did not require anesthesia, and subjects were evaluated at baseline and 1 month after the last treatment session.

Safety measures

During and after therapy, the patients were asked to rate the perceived pain on a scale of 0 (''no pain'') to 10 (''worst possible pain''). The Numeric Pain Rating Scale (NRS) assessed treatment patient pain levels ranging from 0 to 10. Results interpretation: 0 no pain, 1–3 mild, 4–6 moderate, and 7–10 severe.

A clinical evaluation of transient erythema and post-treatment edema was carried out by a dermatologist and identified as absent, mild, or intense. Adverse events were collected during the treatment course and the follow-up period.

Sample size and statistical analysis

The number of participants was established in 20 subjects, 10 for the LED-Group and 10 for the IPL-Group. Statistical analyzes included appropriate measures for statistical significance through the Student's paired two-sample *t*-test, using the standard cutoff for the significance of $p < 0.05$. Quantitative variables were described as the mean and standard deviation (SD), whereas categorical variables were described as frequency or percentage. Efficacy outcomes were assessed as the corresponding variable changed from baseline to 3 months after the last session.

Results

Subject characteristics

The study included 20 subjects, 10 in each study group. In the LED-Group the mean age was 32.1 years (range, 21–46 years), and in the IPL-Group the mean age was 34.5 years (range, 25–49 years). In both groups, 50% were female.

Efficacy outcomes

All participants showed an improvement in HH. In the LED-Group, all subjects (100%) showed a moderate improvement in the HH; regarding the HAA, one (10%) subject had a slight improvement, seven (70%) showed a moderate improvement, and two (20%) had a marked improvement. In the IPL-Group, HH improvement was moderate in one (10%) subject and marked in nine (90%) subjects; regarding HAA, all participants (100%) showed a marked improvement. Table 2 outlines the global percentages of HH and HAA reduction by device and the respective significance level. Figures 5 and 6 show the percentages of reduction in HH and the HAA per patient and device, respectively. Figure 7 shows the clinical outcomes of two

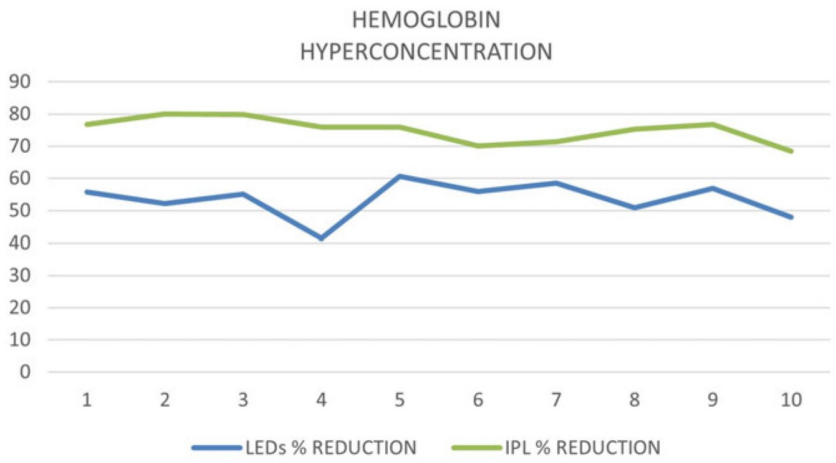

FIG. 5. The overall percentage of HH reduction by patient and device. HH, hemoglobin hyperconcentration.

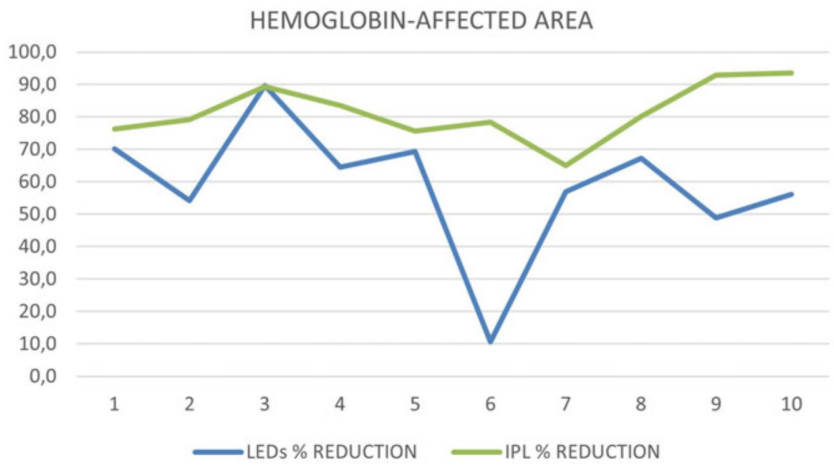

FIG. 6. The overall percentage of HAA reduction by patient and device. HAA, hemoglobin-affected area.

subjects, one of each study group, through the pictures taken with the Antera 3D system at baseline, before the treatment, and 3 months after the last session.

In both groups, pre- and post-treatment results had significant differences in HH and HAA (Table 3), but there were no significant differences between study groups (Table 4).

Safety findings

All patients tolerated the treatment well. In the LED-Group the pain average was 0.8, whereas in the IPL Group it was 7.9. In the LED-Group, 70% of subjects reported no pain and 30% reported mild pain. No patient presented moderate or severe pain. In the IPL-Group, 100% of patients reported severe pain that lasted a few minutes during and after the treatment.

No patients underwent topical anesthesia, systemic antibiotics, or corticosteroid therapy, and there were no side effects. In the immediate post-treatment period, slight transient erythema and edema were reported in all patients of the IPL-Group with a mean duration of 48 h (range, 24–72 h).

Discussion

LED phototherapy has been recently introduced as an alternative to more traditional therapies for treating skin conditions and is clinically advantageous due to its excellent efficacy, safety, nonionizing wavelengths, low cost, availability for home use, and portability.[15] Study results showed that phototherapy based on combined LEDs effectively reduced the appearance of the superficial facial vascular lesions, with statistically significant results after the treatment.

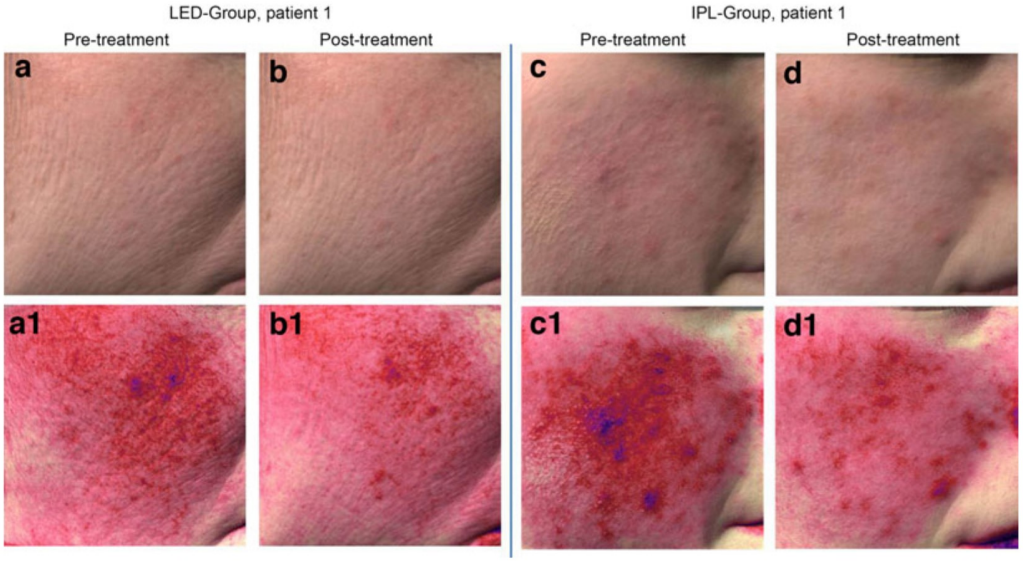

FIG. 7. Comparative quantitative and qualitative assessment of hemoglobin pigmentation with an Antera 3D® diagnostic system of two patients, patient number 1 treated with LEDs and patient number 1 treated with IPL (Table 2). Pretreatment: **(a, a.1, c, c.1)** Post-treatment (12 weeks after the last treatment): **(b, b.1, d, d.1)** Analysis of hemoglobin pigmentation: **(a.1, c.1)** pretreatment; **(b.1, d.1)** 12 weeks after the last treatment. LED-Group patient HH decreased by 55.7%, the affected area decreased by 70.1%, IPL-Group patient HH decreased by 76.8%, and the affected area decreased by 76.3%.

Table 3. The Results in Each Study Group Were Analyzed Before and After Facial Treatment with Light-Emitting Diodes or Intense Pulsed Light

	Pretreatment		*Post-treatment*		
	Mean	*SD*	*Mean*	*SD*	p
LED-G (HH)	52.0	41.7	23.0	16.5	0.0558
LED-G (HAA; mm^2)	567.6	374.6	258.5	236.7	0.0406[a]
IPL-G (HH)	53.8	32.2	12.7	6.8	0.0009[a]
IPL-G (HAA; mm^2)	674.6	318.4	133.9	78.0	0.0001[a]

[a]Statistically significant.
HAA, hemoglobin-affected area; HH, hemoglobin hyperconcentration.

However, the results were moderate compared with patients treated with IPL but without transient side effects and significantly less pain. Measurements were made with Antera 3D, a device based on multi-directional lighting using LEDs of different wavelengths, with more accuracy, specificity, and repeatability than other devices in the qualitative assessment of various dermatological conditions,[20,21] which ensures the reliability of the data obtained.

The LED device used in the study employed a combination of red 633 nm and near-infrared 830 nm wavelengths, similar to the absorption spectra of hemoglobin.[10,22,23] Although HbO2 has been regarded as the primary target chromophore. It has been found that venous lesions can be better treated with wavelengths preferentially absorbed by deoxyhemoglobin (Hb), whose absorption peak is 760 nm.[8] Yamashita et al. showed that the 664 and 830 nm pair is the most optimal for both HbO2 and Hb.[24]

Red light (633 nm) has a penetration capability to reach a depth of up to 2–3 mm, and near-infrared up to 8–10 mm, covering the entire dermis.[25] Red LEDs have the deepest tissue penetration of the visible wavelengths and have been shown to activate fibroblast growth factor, increase procollagen type 1, matrix metalloproteinase-9 (MMP-9), and decrease MMP-1, promoting faster repair and renewal.[26] Near-infrared light (830 nm) stimulates vasodilatation by inducing the release of guanylate cyclase and nitrous oxide from the endothelium, which, in turn, promotes vasodilation and growth factor production, as well as angiogenesis, reduces inflammation, soothes irritation and strengthen the skin, and has been shown to increase cell regeneration.[18,27]

Table 4. Analysis of the Results Between the Study Groups Before and After Facial Treatment with Light-Emitting Diodes or Intense Pulsed Light

	LED-G		*IPL-G*		
	Median	*SD*	*Median*	*SD*	p
Pretreatment (HH)	52.0	41.7	53.8	32.2	0.9152
Post-treatment (HH)	23.0	16.5	12.7	6.8	0.0846
% Reduction	53.5	5.7	75.0	3.9	0.3282
Pretreatment (HAA; mm^2)	567.6	374.6	674.6	318.4	0.5001
Post-treatment (HAA; mm^2)	258.5	236.7	133.9	78.0	0.1313
% Reduction	58.8	20.4	81.4	8.8	0.2820

Several studies have shown that exposing patients to a combination of LED wavelengths is more effective than monotherapy.[28–32] However, we have not found a similar design to compare our results in the literature. Most studies compare IPL with other lasers but not with LEDs.[33,34] IPL wavelength bands used in this study were 530–950 nm, similar to those used by the LED device. Owing to the heat employed and penetration capability, IPL treatments are more effective. Nevertheless, it can result in adverse events such as blisters, dyspigmentation, scar formation, and hyperpigmentation, usually reversible, but hypopigmentation may be permanent because of the thermal destruction of melanocytes.[35] LEDs are nonablative and nonthermal and, when used alone, do not cause damage to the epidermis or dermal tissue.[36] Therefore, there are no adverse events associated with their use, little to no downtime, and patients very well accept it.[37]

IPL devices produce noncoherent polychromatic light (within a wavelength spectrum of ~400–1400 nm) with a wide range of wavelengths. Its fluence, pulse duration (10–12 ms), spot size, and filter type can be adjusted to target specific chromophores.[38] Wavelength can be adjusted using cutoff filters, allowing the targeting of various tissues by selective photothermolysis. IPL can generate a fluence of up to 40 J/cm^2; however, pigmented lesions are typically treated at a lower fluence (16–20 J/cm^2).[39,40] The pulse duration, shorter than its thermal relaxation time, minimizes thermal damage. In contrast, the device studied combining three LEDs and magnetic fields used a wavelength spectrum of 415–830 nm, and fluences were around 67 J/cm^2. Photon interference, characteristic of LEDs, increases photon intensity and penetration below the skin, which results repairing damaged or compromised cells and improving normal cell function.[41]

Study limitations were that it was not a randomized multicenter study without long-term monitoring of the patients. More LED sessions would have been necessary to further assess the efficacy and safety of combined LEDs with red and near-infrared wavelengths to treat facial vascular lesions. The number of patients included is low, so the results are preliminary and do not have statistical robustness. In addition, we did not find published studies to compare our findings.

Conclusions

Treatment with combined red and near-infrared LEDs effectively reduced the appearance of excess facial vascularization with moderate outcomes compared with IPL, but without secondary effects and no pain. The LED treatment could represent an effective, safe, and well-tolerated approach to treating facial vascular lesions.

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Authors' Contributions

Conceptualization, methodology, data curation, supervision, validation, formal analysis, writing original draft, review, and editing (lead) by P.N.G. Conceptualization, methodology, data curation, investigation, validation, original draft, review, and editing (supporting) by R.L.A.

Author Disclosure Statement

No competing financial interests exist.

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