

# A study to determine the efficacy of a novel handheld light-emitting diode device in the treatment of photoaged skin

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## Summary

The use of visible or near-infrared spectral light alone for the purpose of skin rejuvenation has been previously reported in the literature. These devices use large arrays of diodes to deliver light to the skin. In this study, a novel method of light-emitting diode (LED) photo rejuvenation incorporating a combination of these wavelengths delivered from a small handheld unit is proposed. Twenty-two subjects with facial rhytides received eight light therapy treatments over a course of 4 weeks, using the Omnilux handheld LED system. Assessment of global skin grading was evaluated at weeks 6, 9, and 12 by a dermatologist. Additional outcome measures included assessments of clinical photography and patient satisfaction scores. Seventy-four percent of the subjects reported a visible improvement in fine lines and wrinkles at 8 weeks posttreatment. Combination red and near-infrared LED therapy delivered from a small portable handheld unit represents an effective and acceptable method of photo rejuvenation. Further studies to optimize the parameters of treatment are required.

*Keywords:* aging skin, LED treatment, photoaging

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## Introduction

The clinical features of aged skin are more often than not attributable to photoaging rather than to chronological aging, and such features are especially prominent in facial skin, due to its inherent sun exposure.<sup>1,2</sup>

Incidental and intentional exposure to sunlight and artificial sources containing ultraviolet radiation are known to accelerate the skin's aging process. It is postulated that such exposure results in a reduction in both the amount and biosynthetic capacity of fibroblasts, decreased proliferation of skin-derived cells, and an increased expression of collagen-degrading enzymes.<sup>3</sup>

Such a phenomenon leads to significant and distinctive histological markers, including an overall reduction in quantity of collagen and thickening and degradation of the dermal collagen and elastic fibers.<sup>4,5</sup> Collagen fibers become brittle and are predisposed to fragment.<sup>6</sup> Dermal elastic fibers grow abundant and twisted.<sup>7</sup>

Nonablative procedures have been found to be effective in the treatment of photoaging. These methods have grown increasingly popular because of the prolonged recovery period frequently associated with ablative interventions, such as laser resurfacing and chemical peels.<sup>8-10</sup> Therapy based on light-emitting diode (LED) is one such treatment.

LED therapy is a nonablative, athermal treatment modality, successfully used for a number of dermatological conditions. In the treatment of photodamaged skin, it has been reported to be an effective, nonpainful, safe modality returning high patient satisfaction.<sup>11-15</sup>

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The mechanism of light therapy is based around the absorption of specific wavelengths of light by cellular receptors or photoacceptors.<sup>16</sup>

Near-infrared light (830 nm), absorbed in the cellular membrane, has been shown to enhance cellular recruitment, metabolism, and mitosis and chemotaxis of neutrophils, macrophages, and fibroblasts in the target area, together with accelerated degranulation of mast cells.<sup>17–19</sup>

*In vitro* irradiation of fibroblasts with 633-nm, visible red light increases procollagen synthesis fourfold from baseline, while displaying no effect on the activity of the collagen-regulating proteolytic enzymes collagenase and gelatinase<sup>20</sup>; 633-nm light increases fibroblastic growth factor synthesis from photoactivated macrophages and accelerated mast cell degeneration.<sup>21</sup>

Although the authors are aware that combination 633-nm and 830-nm LED therapy in the treatment of photoaged skin has been demonstrated to be successful using a mixture of optical digital profilometry, histology, transmission electron microscopy, immunohistochemistry, and real-time reverse transcriptase–polymerase chain reaction,<sup>14,22</sup> the purpose of this trial was to clinically assess improvements in signs of sun damage and to assess patient perceptions of treatment success after a course of eight light treatments delivered from a handheld unit by the subject over a period of 4 weeks.

## Materials and methods

### Subjects

Twenty-two healthy volunteers (38% men, 62% women; age range, 38–49 years) were recruited. Subjects displaying wrinkles or crow's feet in the periorbital region and photodamage grade I–III in conformity with the Glogau scale were included.<sup>23</sup>

Subjects who had undergone laser treatment or any other ablative/nonablative cosmetic intervention within the last 6 months, including injectables or fillers, were excluded, as were those with any history of laser treatment or trauma to the test site. Subjects had not used topical, oral, or systemic treatments for 4 weeks and had not received oral retinoids for 6 months prior to the study.

All subjects gave informed consent to the treatment and had been prescreened before inclusion in the study. Subjects were allocated to a single treatment group. No control group was used in this study.

### Light source

The unit consisted of an air-cooled, fixed planar array of LEDs, emitting at 830 nm, 55 mW/cm<sup>2</sup> and 633 nm,

70 mW/cm<sup>2</sup>. The active LED area measured 60 mm by 50 mm and was used to illuminate the treatment area (Omnilux New-U, Photo Therapeutics Inc., Carlsbad, CA, USA).

### Treatment

Before the treatment course, subjects were instructed to read the user manual on the use of the equipment and were monitored during the study for their ability to fully understand and operate the equipment. Each subject was given one side of the face to treat.

Each subject received alternate exposures to near-infrared light, 830 nm, 55 mW/cm<sup>2</sup>, 66 J/cm<sup>2</sup>, 20-min duration and red light, 633 nm, 70 mW/cm<sup>2</sup>, 126 J/cm<sup>2</sup>, 30-min duration, twice weekly (2-day interval between red and infrared light treatments) for a period of 4 weeks (total of eight treatments). The unit was operated by the subjects during the treatment period and held in contact with the subject's face for the duration of the treatment.

### Clinical assessments

Clinical grading of wrinkles and photodamage according to the Glogau photodamage classification scale was conducted at baseline. Clinical assessments of skin smoothness using the tactile roughness grading scale and Fitzpatrick scale skin type of all subjects were also recorded. For tactile roughness, 0 indicated that the skin was smooth; 1 indicated that the skin was smooth, with occasional rough areas; 2 indicated mild roughness; 3 indicated moderate roughness; and 4 indicated severe roughness.

At 6, 9, and 12 weeks, the principal investigating physician repeated assessment of Glogau scale in all patients and graded skin roughness using tactile grading score. In addition, response to treatment was graded by the assessor into one of seven categories: "complete response" (complete resolution of photo damage), "almost complete response" (approximately 90% improvement in photodamage), "marked response" (approximately 75% improvement), "moderate response" (approximately 50% improvement), "slight response" (approximately 25% improvement), "no response," and "condition worsened." These assessments were made for the periorbital region only.

Subject's own assessment of treatment success was assessed at 6, 9, and 12 weeks. Subjects were asked whether they perceived the light treatments to have softened wrinkles in the periorbital areas. Furthermore, subjects were asked to grade the effect of treatment in these areas as "no effect," "poor," "moderate," "good," or

**Table 1** Physician assessment all time periods.

	Follow-up point	Marked response (75%) to treatment (%)	Moderate response (50%) to treatment (%)	Slight response (25%) to treatment (%)
Periorbital region	Week 6	0	21	79
	Week 9	16	58	26
	Week 12	21	68	11

“excellent.” All participants were asked to respond to their perception of improved “skin tone,” “skin smoothness,” “skin clarity,” “skin elasticity,” and “skin firmness” as a result of the course of treatment. Finally, all participants were asked to grade the ease of use of the equipment.

Baseline digital photography (Canon EOS 300D, Tokyo, Japan) was performed on all subjects: this was repeated at weeks 6, 9, and 12. Lighting and ambient conditions for photography were standardized throughout the trial. The principal investigator conducted image analysis and photoaging assessment.

Adverse reactions in terms of pain, stinging/burning sensation, erythema, blistering, ulceration, pigmentation, and scarring were scored on a scale of 0 (absent) to 10 (severe).

Details of adverse events and concomitant medications were noted at all treatment appointments.

## Results

Nineteen subjects completed the trial to a 12-week follow-up. Three subjects failed to return after the course of light therapy. These subjects' data were subsequently excluded from analysis. No adverse events were reported during or after the treatment program.

Three subjects reported side effects of the light treatment in the form of mild facial erythema, both occurring after the first light treatment. These events were self-limiting in all cases and resolved within 24 h of the treatment. There appeared to be no link to Fitzpatrick skin type and erythema, and the erythema did not present upon subsequent treatments.

Assessments of photoaging at all follow-up points for the periorbital region are displayed in Table 1. None of the subjects in the group were assessed as having “no response” or “negative response” to the treatment. The majority of subjects displayed moderate response to the treatment, with improvements in grading seeming to be linked to follow-up period (Figs 1 and 2).

Subjects' responses to the overall effect of treatment are displayed in Table 2. At 12 weeks, 74% of subjects



12 weeks follow-up



Baseline

**Figure 1** Baseline and 12-week follow-up.

reported visible changes in fine lines and wrinkles, with a total of 73% reporting the outcome of the treatment as either good or excellent. At the 12-week follow-up, improved skin tone was reported by 84% of subjects, improved smoothness and clarity by > 70%, improved firmness by 68%, and improved elasticity by 47% of subjects (Table 3). Again, optimum results for all parameters were seen at the 12-week follow-up. Although not formerly assessed, subjects also reported a visible reduction



12 weeks follow-up



Baseline

**Figure 2** Baseline and 12-week follow-up.

in pore size. Subjects were asked to rate the ease of use of the system after reading and understanding the user guide. Eighty-four percent rated the product very easy or extremely easy to use. Only three subjects (16%) rated the

product as only slightly easy. No subject rated the product as difficult to use.

### Discussion

This study has demonstrated, using clinical and subjective assessment, that LED therapy delivered from a small handheld unit can have a significantly visible effect on the signs of photoaging. Photoaging scores displayed an overall improvement in the visible signs of skin aging, with a trend demonstrating that such improvement is linked to time. This trend was also seen in subjective scoring of skin parameters, with the greatest improvements being seen in skin tone (84%), smoothness (79%), and skin clarity (73%).

Subjective softening of wrinkles was consistently reported, with the highest response at the 12-week follow-up of 74%. From a patient satisfaction viewpoint, subjective responses were encouraging, with over 70% of subjects reporting the effects of the treatment as either good or excellent.

Previous studies have demonstrated significant reductions in fine lines and wrinkles and global skin improvement using athermal LED light of wavelengths of 830 nm and/or 633 nm.<sup>13,14,22</sup>

Such studies have used greater subject numbers, have been more complex in their design and measurement parameters, and have demonstrated statistically significant reductions in fine lines and wrinkles<sup>14,22</sup>; yet, this modest study has displayed improvement patterns similar to those previously cited.

The pattern of improvement seen here and described by other authors describes significant improvements occurring 9–12 weeks from the start of treatment, with

**Table 2** Subjects' responses in wrinkle softening and overall effect of treatment.

	Time point	Softening of wrinkles (%)		Effect of treatment (%)				
		Yes	No	Excellent	Good	Moderate	Poor	No effect
Periorbital area	Week 6	58	32	0	47	42	10	0
	Week 9	63	37	5	53	31	10	0
	Week 12	74	26	10	63	26	0	0

**Table 3** Subjective reports of improvements in skin parameters at all follow-up points.

Follow-up assessment	Tone (%)	Smoothness (%)	Clarity (%)	Elasticity (%)	Firmness (%)
Week 6	47	42	58	26	42
Week 9	79	84	64	47	53
Week 12	84	79	73	47	68

some visible improvement occurring as early as 5–6 weeks. This visible change can no doubt be seen as a direct response to the athermal and atraumatic stimulation of a subclinical “quasi-wound” and the subsequent increase in the amount and thickening of collagen bundles and packing of the collagen network as described by Lee *et al.*<sup>22</sup> Lee *et al.* reported increases in collagen in routine hematoxylin–eosin sections at 6-week follow-up; yet, it is interesting to see that using only visual assessments, these changes do not become apparent until the 9th and 12th weeks, which again is consistent with previously reported studies.<sup>13,14,22</sup>

## Conclusion

This study has successfully demonstrated the use of a handheld LED device for the treatment of photoaged skin. Subjective assessments correlate well with previously published data using more sophisticated measurement techniques and parameters.

The light treatments were well received by subjects, with > 70% reporting the effect of the treatment as either good or excellent. All subjects found the system easy to use.

Further studies are necessary to elucidate the full promise of this handheld system and the potential it promises for other clinical applications, where collagen stimulation and remodeling would offer further advantages.

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