

Assessment of the Efficacy and Safety for Wrinkle Reduction and photoaging improvement using a novel Home-Use Device with Diode Arrays and dermal Heating

Handheld Home-use light therapy device for skin rejuvenation and skin texture

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ABSTRACT

Background: The effects of light therapy in the red and infrared part of the spectrum have been proven to be beneficial for skin wrinkles and overall skin texture. The use of Light-Emitting Diodes (LED) delivering a low dose energy to the skin has been described for office and home use.

Summary: In this study, a handheld home-use device, named Telosin, combines red LED and infrared LED with mild contact heating. Thirty subjects aged 18-60 presenting with fine lines, wrinkles, large pores and brown pigmentation received 12 tri-weekly treatments for 4 weeks. Skin condition was evaluated before and after 8 weeks. Grading of outcome was done according to an independent blinded evaluator and patient satisfaction. Results: Facial skin improvement of wrinkling and skin texture were apparent immediately and scored clinically 8 weeks as excellent and considerable by >90% of patients. Pigmentation improvement was less apparent. Overall facial skin improvement was noted by 77% of patients. In conclusion, the combination of red LED, infrared LED and mild contact heating, using an at home portable device, proved to be safe and effective method to improve the quality of photo aged skin.

Keywords: Telosin, Light Therapy, LED, wrinkles, pore reduction, Anti-Aging

1. Introduction

Skin changes inflicted by chronological aging are intensified by environmental photoaging, which occurs as a result of prolonged exposure to UV radiation from the sun

[1]. The most prominent changes are the appearance of uneven pigmentation and dark spots, as well as the reduced number of collagen and elastic fibers causing lax, sagging skin, fine wrinkles, and pronounced expression lines on the face [2].

Although skin aging cannot be prevented, some measures may help slow down and minimize the process. Ablative measures such as dermabrasion, excision, chemical peeling and laser resurfacing are effective, but with a high degree of adverse events and a long down time [3,4]. Non-ablative lasers and Intense Pulsed Light (IPL) technologies, based on selective photothermolysis [5] are more selective, but also presented burn hazards with consequent hyper pigmentation and scarring [6]. The nonablative, non-thermal modality of Light-Emitting Diodes (LED) presents a mild but effective therapy of photoaged skin and has been successfully used by one or combination of diode wavelengths [7,8].

The mechanism of action of low level LED is based on bio-stimulation [9]. At the red wavelength spectrum it has been shown to involve photomodulation of cell activity via dermal receptors that activate collagen synthesis along with inhibiting collagen degrading enzymes [10]. The wound healing process has also been reported to be stimulated by LED [11,12]. The mild and safe nature of the low dose LED treatment made it possible to use at home, after 8 bi-weekly sessions [13].

In the present study, contact heating has been added to fractional LED red light of the Telosin device in order to intensify the facial

anti aging effect and have it visible after a short time. The aim of this study was to assess the safety and efficacy of a low level LED emission home-use device and to record the clinical outcome of facial skin rejuvenation following 8 bi-weekly treatments.

2. Materials and Methods:

2.1 Device Specifications

The Telosin home-use device is a small, battery-operated, lightweight, portable, affordable LED system (Figure 1). The device has a heated metal plate with a built in skin surface gauge which ensures temperature will remain at 42oC and in any condition no will not raise over 45oC.

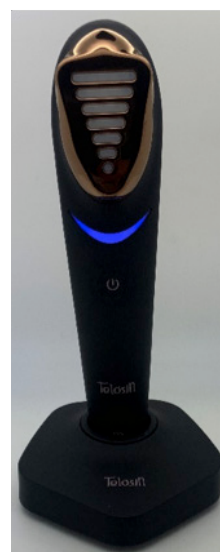


Figure 1. Telosin facial skin rejuvenation device and Docking station

2.2 Study Participants

The subject selection goal was to secure a random population that was representative of the actual “intended users” of the device, with a random demographic mix and varied education level as described in the Demographic Distribution Chart (Table 1). The “intended users” of the Telosin device have been identified persons who have Facial wrinkles and/or enlarged pores and/or brown pigmentation. 30 healthy patients, mostly females, with an age range of 18–60+ years were selected for study.

All participants used the Telosin on their faces for treatment of at least one lesion type, as inclusion criteria.

They were: facial fine lines and wrinkles with Fitzpatrick classification of wrinkling. Exclusion criteria included known sensitivity to laser treatment, any other cosmetic topical, injectable or oral treatment, as well as ablative and non-ablative laser/IPL/RF modality within the last 6 months. The ads were designed for a 6th grade or lower reading level and all of the participants that responded to the ads were able to read English. Informed consents to the treatment were obtained from all study participants prior to study commence.

Demographic Distribution Chart (Rounded up)		
Percent	Number	Gender
13%	4	Male
87%	26	Female
Race		
57%	17	Caucasian
10%	3	Hispanic/Latino
3%	2	African American
--		Native American/Alaskan Indian
30%	9	Asian/Pacific Islander
--		Other
Education Level		
--		Less than HS
17%	5	HS
33%	10	Some College
50%	15	College Graduate
Age		
33%	10	18-24
33%	10	25-44
33%	10	45-60+
Fitzpatrick Wrinkle Scale		
7%	2	0
30%	9	0.5
23%	7	1
20%	6	1.5
17%	5	2
3%	1	2.5
--	0	3

Table 1. Subject Demographic Distribution Chart

2.3 Treatment Technique and Protocol

Patients were guided how to use the equipment and treated themselves under the guidance of a qualified person in the study site. Facial treatment zones were perioral and periorbital zones, as well as the cheeks and forehead. Each zone was treated in a constant circular move until the desired skin surface cut-off temperature was achieved, which took about 3-6 minutes per zone. Treatments were performed three times a week for 8 weeks.

2.4 Clinical Assessments

Patients were photographed before the first session to serve as a baseline, as well as after 8 weeks. Standardized front and profile close-up facial photos were taken. Scores were taken by blinded independent physician while comparing the photographs. Fine lines, wrinkles and skin laxity were graded in Fitzpatrick Wrinkle Scale. Improvement from one class to a lower class or within the same class of wrinkling and elastosis were recorded as: none, poor, some, considerable and excellent response. For example, 93% of participants experienced considerable improvement in wrinkling. Improvement was scored according to lesion: wrinkling comprising fine lines and wrinkles, melanin pigmentation, and overall skin texture comprising facial skin pores, elasticity and firmness. Patient satisfaction assessment was recorded for overall improvement of all facial zones and all lesion types according to the same scale.

3. Results

Results were visible after application of the Telosin device, as shown in the face treatment in Figure 2. improved skin texture, reduced periorbital lines and cheek bone lift are noticeable. Records were taken 8 weeks post last treatment. Wrinkling (Figures3 and 4), forehead wrinkling (Figures 5) are presented and show marked improvement.



Figure 2. face showing before (left) and 8 weeks post treatment (right).



Figure 3. Upper lip lines before (left) and 8 weeks post treatment (right).

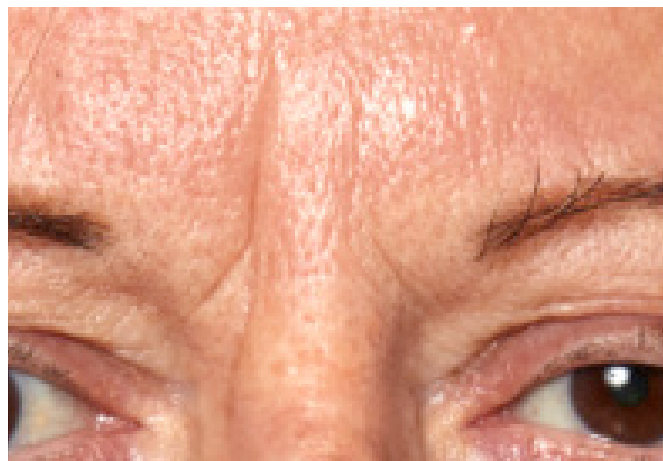


Figure 5. Forehead wrinkle before (left) and 8 weeks post treatment (right).

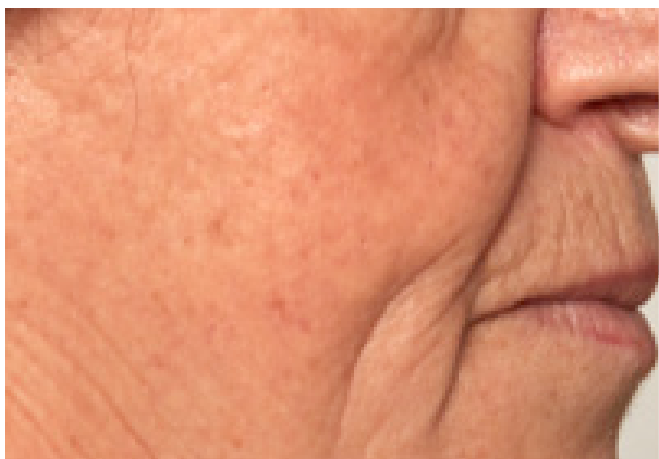


Figure 4. profile wrinkle before (left) and 8 weeks post treatment (right).

Results evaluated by a blind independent physician are summarized in Table 2.

Number of patients	Follow up 8 weeks	Excellent response %	Medium response %	Poor response %	No response %
30	improvement in wrinkling	75	10	15	-
30	Skin Texture	80	10	10	-
30	discoloration	60	10	30	

Table 2 Physician evaluation of response of various facial lesions at follow-up point.

At 8 weeks follow-up, more than 85% of patients were evaluated as having excellent or medium improvement in wrinkling and skin texture, respectively. Improvement of discoloration was less apparent and was recorded after 8 weeks as 70% of patients having excellent or medium improvement. Most patients expressed their degree of satisfaction to the overall improvement of facial skin after 8 weeks follow-up session, as described in Table 3. Patients related to skin texture, to fine line and wrinkles and to discoloration. No one experienced lack of response.

Number of patients	improvement in wrinkling	Excellent response %	Medium response %	Poor response %	No response %
30	Follow up 8 weeks	80	15	5	-

Table 3 Overall patient satisfaction

Overall patient satisfaction at follow-up point. The treatment was very comfortable for all patients who experienced pleasant warmth without any burning sensation. No complications were recorded through the study.

4. Discussion

This study has proven that the Telosin home-use device is clinically safe and effective in improving the appearance and quality of aged and photo-aged facial skin.

Improvement in photoaging is visible as 8 weeks post treatment. In fact immediate results can also be seen. The overall efficacy of the device may be explained by its dual use of energies – LED and contact heating. The low dose optical energy of the non-thermal LED may contribute to bio-stimulation of the dermal fibroblasts, thus increasing the mass of new collagen and elastic fibers concomitantly with inhibiting the degrading enzymes down to the deep dermis. This is manifested as improved wrinkling (fine lines and wrinkles) and

skin texture (skin pores, elasticity and firmness).The optical energy of the LED along with the superficial penetration of heat radiation may heat the epidermis and render the melanin brown spots more fragile. In addition, the contact heating may also help in collagen contracttture of the contact

5. Conclusions

The application of a home-use LED device for facial skin rejuvenation of photoaged skin has been demonstrated in this study. The safe and effective treatment makes it a suitable and valuable modality for home use.

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