REPORT

A PROSPECTIVE EVALUATION OF THE SAFETY AND EFFECTIVENESS OF THE LMNT DEVICE IN THE TREATMENT OF FACIAL AGING

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SUMMARY

Background

Facial skin aging is a common concern by patients. A LED based home used device was recently developed to offer aesthetic improvement without any associated downtime.

Objective

To evaluate the efficacy and safety of the LMNT device for facial rejuvenation.

Patients and Methods

Subjects with mild to moderate facial rhytids were enrolled and underwent 3 weekly treatments with a novel device (LMNT) using visible and infrared light. Efficacy outcomes were evaluated 4 and 8 weeks after initiating treatment. Safety data was recorded as well.

Results

Ten female patients, of mean age 41.6 participated in this evaluation. Fitzpatrick skin types I-IV were included. For Fitzpatrick Wrinkle Classification System (FWCS), the mean baseline score was 3.3. There was a mean 2.7 and 2.0 points of improvement at the overall facial appearance in a quartile scale of improvement (0- exacerbation, 4- 76-100% improvement) at 1 and 2-months from the beginning of treatment, respectively. None of the patients experienced any adverse effects or downtime during or following treatment.

Conclusion

The novel LMNT device using LED light is safe and effective for facial rejuvenation in young females with mild to moderate facial wrinkles.

Introduction

Aging is a natural unavoidable process; However, battling the visible signs of aging is in increasingly high demand. Many therapeutic options are available for that matter, including Energy based devices (lasers and intense pulsed light, radiofrequency, ultrasounds), various injectables and surgical procedures. During the recent decades a shift toward noninvasive techniques has been made. These require minimal to no downtime and are associated with minimal side effects.

Most of these techniques are performed in a clinic as they are operator dependent and require the expertise of a well-trained physician.

The search for an effective home device operated by laymen and associated with no side effects and downtime constantly continues.

Non-thermal, non-ablative light emitting diodes (LED) present a safe and moderately effective option for skin rejuvenation and has been successfully used in the past with various wavelengths. Its rejuvenating impact is generally thought to be driven by a photomodulatory effects, such as stimulation of fibroblast proliferation, synthesis of procollagen, extracellular matrix and fibroblastic growth factors, and acceleration of fibroblast-myoblast transformation and mast cell degranulation. Integrating several wavelengths, enables maximizing the favorable effects of each, to achieve an optimal balance of superficial and deep-layer responses.

Several studies evaluating the combination of the 633 nm and 830 nm wavelengths have demonstrated improvement at various skin indices.

LED low-level light therapy has been shown to be safe and effective in rejuvenating the aging skin. Synergistic effects have been observed when integrating multiple wavelengths in treatment regimens. The enhanced outcomes achieved with combination protocols are attributed to the multifaceted impacts they have on cells of the epidermal and dermal layers, as well as on blood flow.

Objectives

To evaluate the efficacy and safety of the LMNT device for facial rejuvenation.

Patients and Methods

Device

The LMNT device is a small, lightweight, portable, battery operated home used device which emits light in the visible (633nm) and infrared (830nm) spectrum with micro-pulses. The device has a heated outer metal plate with a built-in skin surface gauge which ensure temperature will remain at 42 °C.

Patients and procedure

Ten healthy females with mild to moderate facial rhytids were enrolled. To be included, subjects had to be 35-50 years old.
Patients were excluded if they had a facial cosmetic procedure in the past 12 months; facial treatments with laser, light, and energy-based devices, chemical peels, or neurotoxins in the past 12 months; injectable fillers in the face in the past 12 months; visible scars over the area; active cut, infection, or inflammation in the area; history of skin malignancy; history of immunosuppression, autoimmune disease, collagen or vascular disease, bleeding disease, keloid formation, use of oral retinoids in the past 6 months; use of oral steroids;, were currently pregnant, or have given birth less than 3 months ago or planning to become pregnant.
Each patient performed 3 weekly facial treatments (16 minutes each) using the LMNT device, at the comfort of her own home.
Baseline rhytids were graded using the Fitzpatrick Wrinkle Classification System (FWCS) at baseline. A quartile scale of improvement graded as 0 (exacerbation) 1 (1-25% improvement), 2 (26-50% improvement), 3 (51-75% improvement) or 4 (76-100% improvement)] was used to asses improvement in facial appearance 1 and 2 months after initiation of treatment, based on high resolution photographs captured with the VISIA system (CANFIELD SCIENTIFIC, INC., USA). Photos were captures both immediately after treatment (at 4 weeks) and approximately one day after treatment (8 weeks).
Patients' satisfaction was assessed as well at 2 months after initiation of treatment (Graded on a score of 1- 5; 1 being not satisfied and 5 being very satisfied).
Side effects were evaluated throughout treatment as well.

Results

Ten female patients, of mean age 41.6 (range 36-49) participated in this evaluation.
Fitzpatrick skin types II-IV were included.
Baseline mean FWCS was 3.3.

Efficacy

There was a mean 2.7 and 2.0 points of improvement at the overall facial appearance in a quartile scale of improvement at 1 and 2-months after the initiation of treatment, respectively. Patient's satisfaction was high with a mean grade of 4 out of 5 regarding their satisfaction from the improvement of their facial appearance.

Patients were also highly satisfied with the treatment experience with most of them ranking it as 5 out of 5 (with a mean of 4.625).

Safety

None of the patients experienced any adverse effects or downtime during or following treatment.

Discussion

Recently, low level LED light has gained increasing popularity as a treatment modality in the aesthetic field. This evaluated LMNT device works via a mechanism of dermal remodeling; Photo-biomodulation stimulates and supports neocollagenesis and neoelastogenesis. Clinically it translates into improvement of skin texture, fine lines and wrinkles.

This evaluation demonstrates that this device can improve the appearance of the aging facial skin in a safe and effective manner (representative patients are displayed in figures 1-3).

Both objective investigators' evaluation and patients' satisfaction were high in terms of efficacy. As it is light weighted and very easy to use the high satisfaction from the improved outcome is enhanced by the positive treatment experience.

Another important aspect of this novel device is its high level of safety; none of the patients had any adverse events related to the treatment and none experienced any downtime.

This device is part of the growing trend of procedures associated with minimal downtime and its efficiency and safety will undoubtably strengthen this trend.

Conclusion

This prospective evaluation of a novel LED-based home-used device demonstrated moderate improved facial appearance. This device is safe, well-tolerated, effective and well-liked by patients.

Figure 1

a b

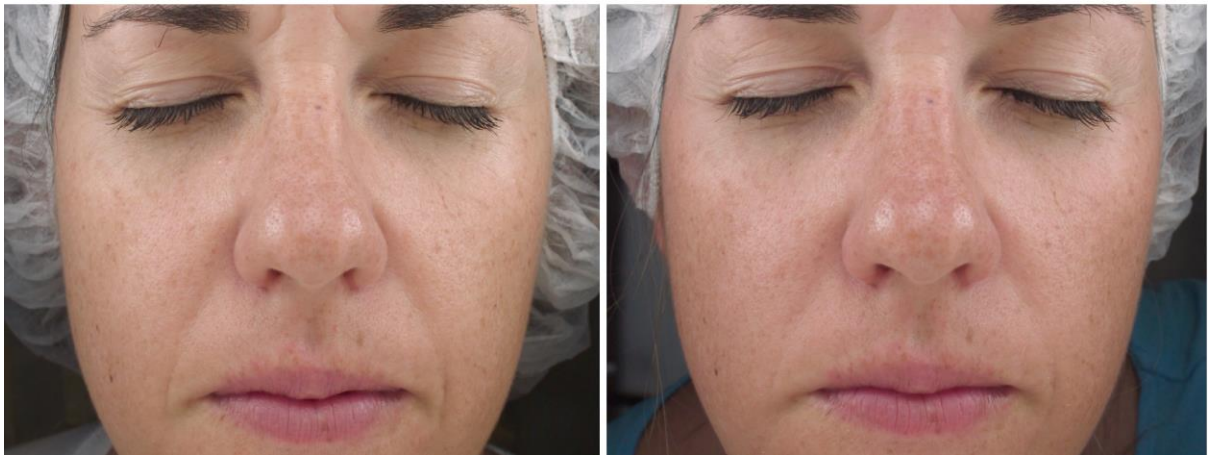

Figure 2

a b

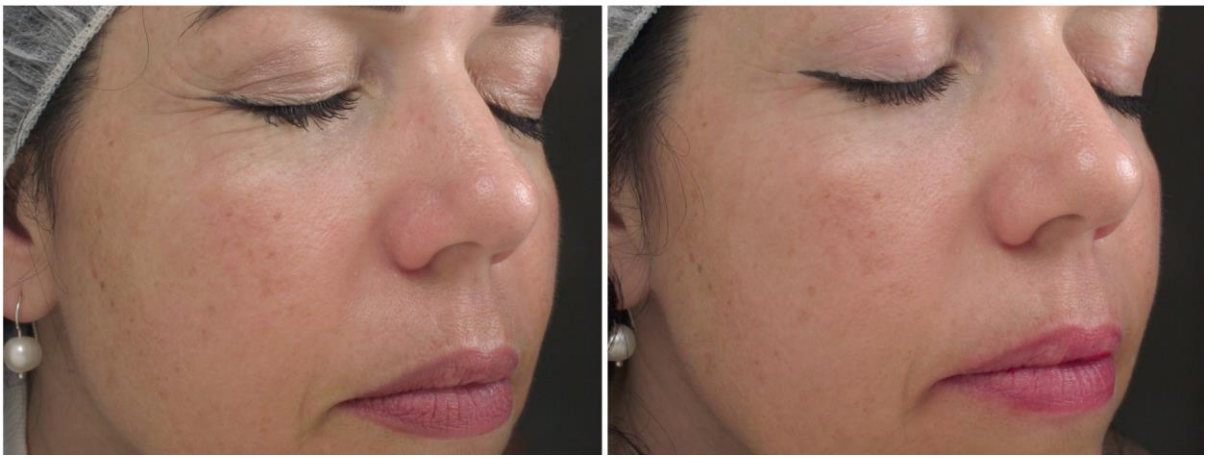

Figure 3

a b

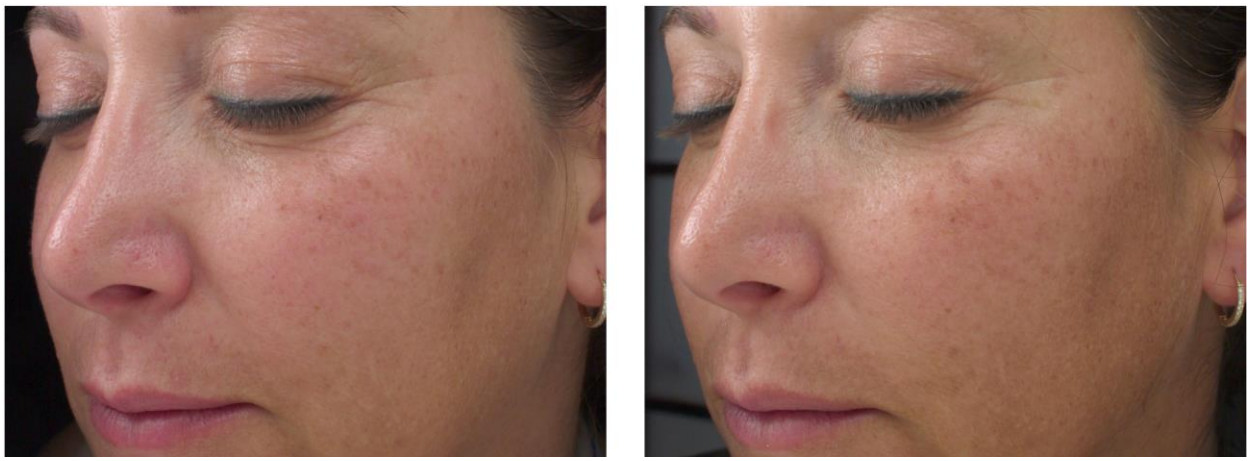

Figure legend

Figure 1

A patient before (a) and 4 weeks after initiation of treatment(b).

Figure 2

A patient before (a) and 4 weeks after initiation of treatment(b).

Figure 3

A patient before (a) and 8 weeks after initiation of treatment(b).

Signatures:

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