



Omnilux Contour™ FACE LED Mask

Clinical Study Summary

Introduction

Light emitting diode (LED) technology is a well-established modality in the treatment of the visible signs of facial skin aging and several other skin conditions. The popularity of the technology has grown over the last two decades and is commonly used by dermatologists and aestheticians as a standalone in-office treatment or in combination with other aesthetic technologies such as microneedling and chemical peels because of its ability to promote skin recovery and healing.

LED phototherapy is *the use of photons of light to alter biological activity* and works through two key mechanisms:

1) Photobiomodulation (PBM) is the effect of light on the cell to alter cellular activity. Light photons of specific wavelengths, typically red at 633nm and near infra-red (NIR) at 830nm are absorbed by cell components, particularly the mitochondria, triggering a cascade of biochemical reactions that leads to increases in cell proliferation, triggering of collagen and elastin production, increases in blood flow and tissue oxygenation and stimulation of cellular energy production (adenosine triphosphate or ATP) within the cell. This typically manifests as smoothing of the skin surfaces, reduction in wrinkles, higher skin moisture retention, evening of skin tone and reduction in pigmentation.

2) Photodynamic therapy (PDT) is the activation of naturally occurring light-sensitive structures within the cell. PDT comprises the use of a topical photodynamic cream or gel that is activated by LED light. PDT has many applications, including the medical treatment of acne vulgaris, non-melanoma skin cancers and pre-cancerous lesions such as actinic keratosis. A recently launched cosmetic version of photodynamic gel (Glycoala®) is used to improve the appearance of pore size, fine lines and wrinkles and other visible signs of sun damage.

In the past several years the home use market for LED light therapy devices has blossomed with companies offering small hand held LED devices for acne blemish "zapping" to full face masks containing several wavelengths (colors) of light that offer treatments for global skin aging, full face wrinkles, acne vulgaris and generally boosting skin health.

Here we summarize a recent consumer trial on the use of the Omnilux Contour™ FACE LED mask (GlobalMed Technologies, Napa, CA) in the treatment of wrinkles and the visible signs of skin aging.

LED System Description

Omnilux Contour FACE is a home use wearable LED phototherapy mask for the treatment of full-face wrinkles.

The Omnilux Contour FACE mask consists of a flexible soft silicone mask that contains light emitting diodes (LEDs) that emit light in the red (633nm) and near infrared (830nm) range. The mask is worn on the face and is held in place by an adjustable Velcro strap. The mask is controlled by a rechargeable controller that switches the LEDs ON/OFF and controls power to the mask. Because the device is powered by a rechargeable battery, the user can wear the mask and move around their environment while undergoing a treatment. Each treatment is 10 minutes and a typical treatment course is 3 treatments per week for 4 weeks.

Study Methodology

The study took place between April through August 2018. Twenty-eight eligible subjects (26 female and 2 males) aged between 30 and 65 with a mean age of 49 years were recruited. 25 completed the study. Skin types of the 25 subjects were 3 skin type 2, 20 skin type 3 and 2 skin type 4. Subjects utilized the Omnilux Contour FACE LED mask along with a special hydrogel mask that allows light to penetrate in order to maximize the absorption of skincare products during the treatment and improve the receptiveness of the targeted skin cells.

(see table I for subject demographics).

Parameter	Number
Number of subjects	25
Male : Female	2:23
Mean age	49
Age range	30 to 65
Fitzpatrick skin types	%
I	0
II	3 (12)%
III	20 (80%)
IV	2 (8%)

Table I – Subject baseline demographics

Subjects completed a basic consent form and general health questionnaire. All subjects conducted a photosensitivity patch test before commencing the study.

Evaluation method included:

- a. Investigator assessment of photodamage using Larnier (1994) wrinkle grading scale.
- b. Blinded investigator assessment of photodamage and texture.
- c. Digital photography using VISIA system.
- d. Mechanical evaluation of elasticity (Cutometer) skin hydration (Corneometer) and pigmentation (Mexameter) MC1000.
- e. Surface roughness and texture parameters Visioscan.
- f. Subject self-assessment questionnaires of treatment response and side effects.
- g. Fitzpatrick skin type.

Prior to commencing the study, subjects were instructed on how to use the device including cleansing the skin prior to treatment, applications of the hydrogel mask, the treatment course and general device maintenance. Subjects completed their first treatment in the presence of study personnel. Subjects were instructed to treat their skin 3 times per week for 4 weeks (each treatment time was 10 minutes).

Results

Of the 28 enrolled subjects, 25 subjects completed the full treatment course and were assessed at the final follow up. There were no recorded photosensitive reactions nor adverse incidents.

Investigator Assessment

Surface Evaluation of Living Skin (SELS)

Significant improvements in skin smoothness, number and width of wrinkles, and scaliness were seen 1 week after the final treatment. See table below for SELS results summary.

Surface Evaluation of Living Skin		Before	After	% Decrease showing level of average improvement
Sesm	Smoothness (proportional to the width and format of wrinkles)	163	100	38.7%
Sew	Number and width of wrinkles. A reduction demonstrates a global improvement in wrinkles measured by the horizontal and vertical lines.	146.6	91.5	37.6%
Sesc	Scaling calculated as a portion of light pixels (grey level) higher than established threshold. A lower score demonstrates improvements in scaliness.	0.63	0.5	20.6%

MC1000 Results - Hydration, skin pigmentation and elasticity:

An average 21.4% improvement in skin elasticity and a 18.9% improvement in hydration were seen immediately following the first treatment. Further improvement was observed after the final treatment (week 5): 29.3% improvement in elasticity and 19.4% improvement in hydration. No significant improvement in pigmentation was observed at either time point. Results are summarized below:

Immediately after treatment 1			
Parameter	Mean Baseline	Mean Post treatment	Percentage Change (one treatment)
Elasticity	54.6	66.3	21.4%
Hydration	63.2	75.2	18.9%
Pigmentation	198	195	no significance
Week 5			
Parameter	Mean Baseline	Mean Post treatment	Percentage Change (one treatment)
Elasticity	54.6	70.6	29.3%
Hydration	63.2	75.5	19.4%
Pigmentation	198	189	no significance

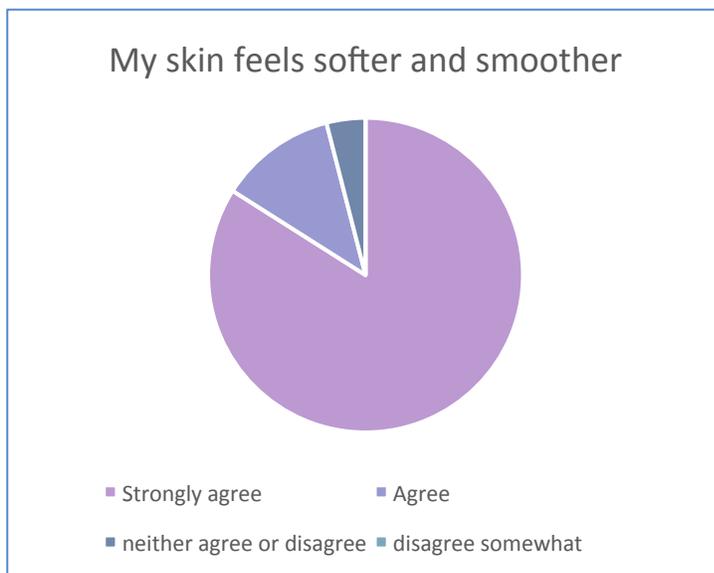
Investigator Assessment of Visia Photography:

The average scores were over 2, indicating a moderate improvement in wrinkle grading.

Subject Self-Assessment and Subjective Responses

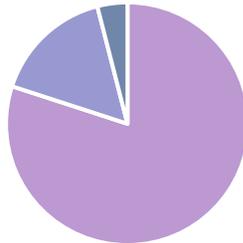
Immediately following the initial treatment, all 28 subjects completed a questionnaire relating to the treatment acceptance and their satisfaction, 26 of 28 (93%) agreed that their skin felt softer and smoother, brighter and refreshed after one treatment. They claimed that they generally looked more “alive”.

The charts below show subjective responses of 25 subjects that completed the full 4 week course of Omnilux Contour FACE treatments. Overall, subject responses were very positive. They felt their skin felt softer and plumper, with a more brightened tone. Their skin appeared more even and less blotchy, with a visible reduction in skin redness. All subjects indicated that their skin was more hydrated or felt more moisturized after the treatment period. This feedback supported the objective measurements and the subjective responses.



- 84% Strongly agree
- 12% Agree
- 4% neither Agree nor disagree
- 0% disagree somewhat

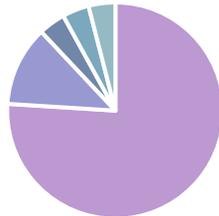
My skin feels plumper and more hydrated



■ Strongly agree ■ Agree ■ Agree somewhat ■

- 80% strongly agree
- 16% agree
- 4% agree somewhat

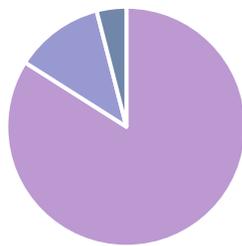
My skin feels firmer or tighter



■ Strongly agree ■ Agree
■ Neither agree or disagree ■ Disagree somewhat
■ Disagree somewhat

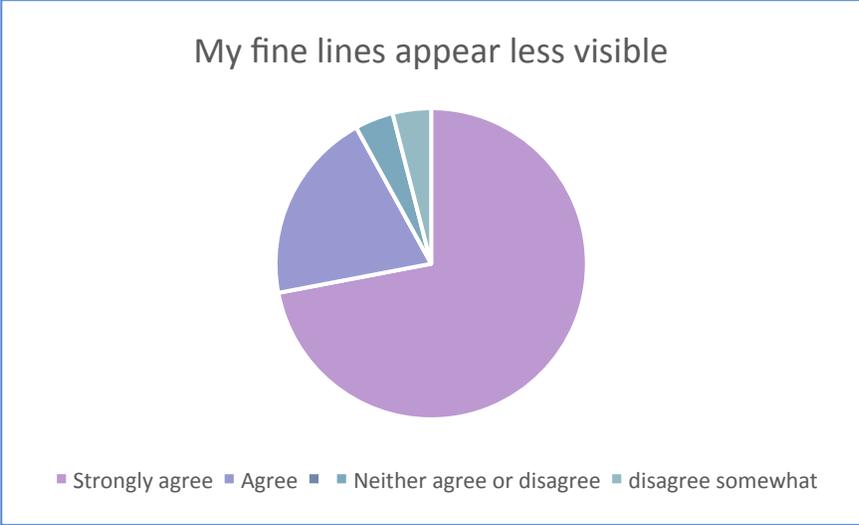
- 76% strongly agree
- 12% agree
- 4% neither disagree of agree
- 4% disagree somewhat
- 4% disagree

My skin looks brighter and more refreshed



■ Strongly agree ■ Agree ■ neither agree nor disagree ■

- 84% strongly agree,
- 12% agree
- 4% neither agree nor disagree



- 72% strongly agree
- 20% agree
- 4% neither agree nor disagree
- 4% disagree

Discussion

Low level LED phototherapy is becoming a popular stand-alone home use treatment and is also being used to support and augment in-clinic professional LED treatments. Here we have reported on a small study using the home use Omnilux Contour FACE LED mask.

The results show that a course of just three 10-minute treatments per week for 4 weeks visibly improves the signs of skin aging. Subjective responses were extremely positive, with all subjects reporting positive improvements in ageing sequelae. No subject's skin worsened.

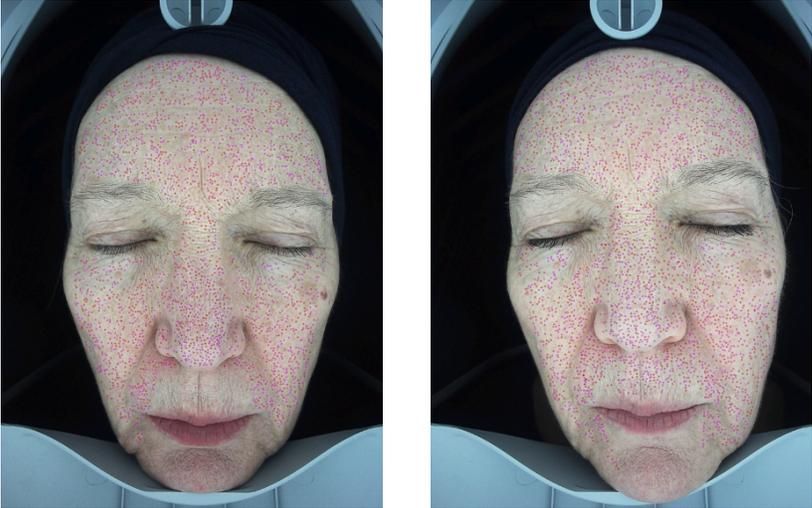


Figure i. Before and 1 week after a course of 3 x 4 weekly treatments. Note the visible reduction in pores.

The before and after images in figures i. – v. were taken using a specialized professional Visia camera for digital skin analysis and illustrate improvements after the full course of treatment.

The use of red and near infrared light at 633nm and 830nm has been well documented in the literature to reduce fine lines and wrinkles, lighten pigmentation and brown spots, reduce pore size and help reduce visible lines and wrinkles. These results reported in this study appear to support these previous findings.

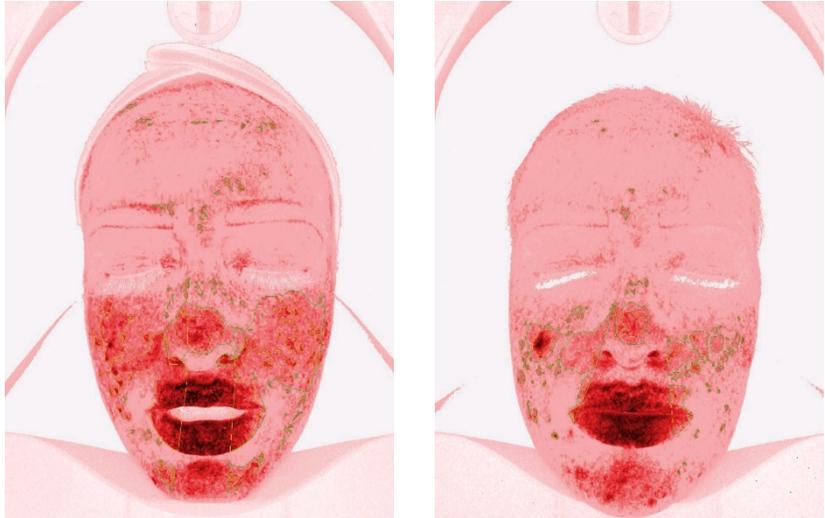


Figure ii. Before and 1 week after a course of 3 x 4 weekly treatments.
Note the visible reduction in skin redness.

633 nm and 830 nm LED phototherapy delivered by way of a flexible silicone mask (Omnilux Contour FACE) is an effective, safe, well-tolerated and painless treatment for treating the signs of skin aging. From a clinical aspect, the non-thermal feature of LED phototherapy is a significant advantage, because it achieves effective rejuvenation of the skin without using heat or inducing any tissue damage, and combined with its low risk profile, it is a safe and effective at home treatment.



Figure iii. Before and 1 week after a course of 3 x 4 weekly treatments.
Note the visible reduction in lines, wrinkles



Figure iv. Before and 1 week after a course of 3 x 4 weekly treatments.
Note the visible reduction in lines, wrinkles and redness

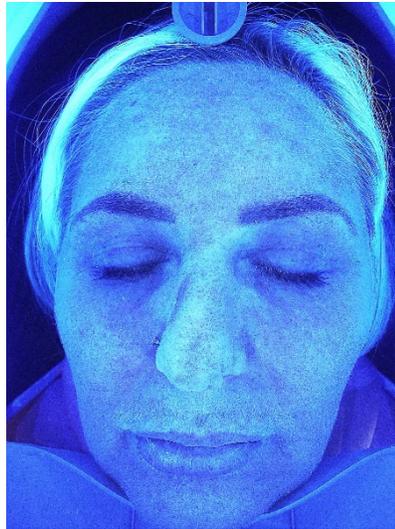


Figure v. Before and 1 week after a course of 3 x 4 weekly treatments.
Note the visible reduction in pigment and sun damage

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