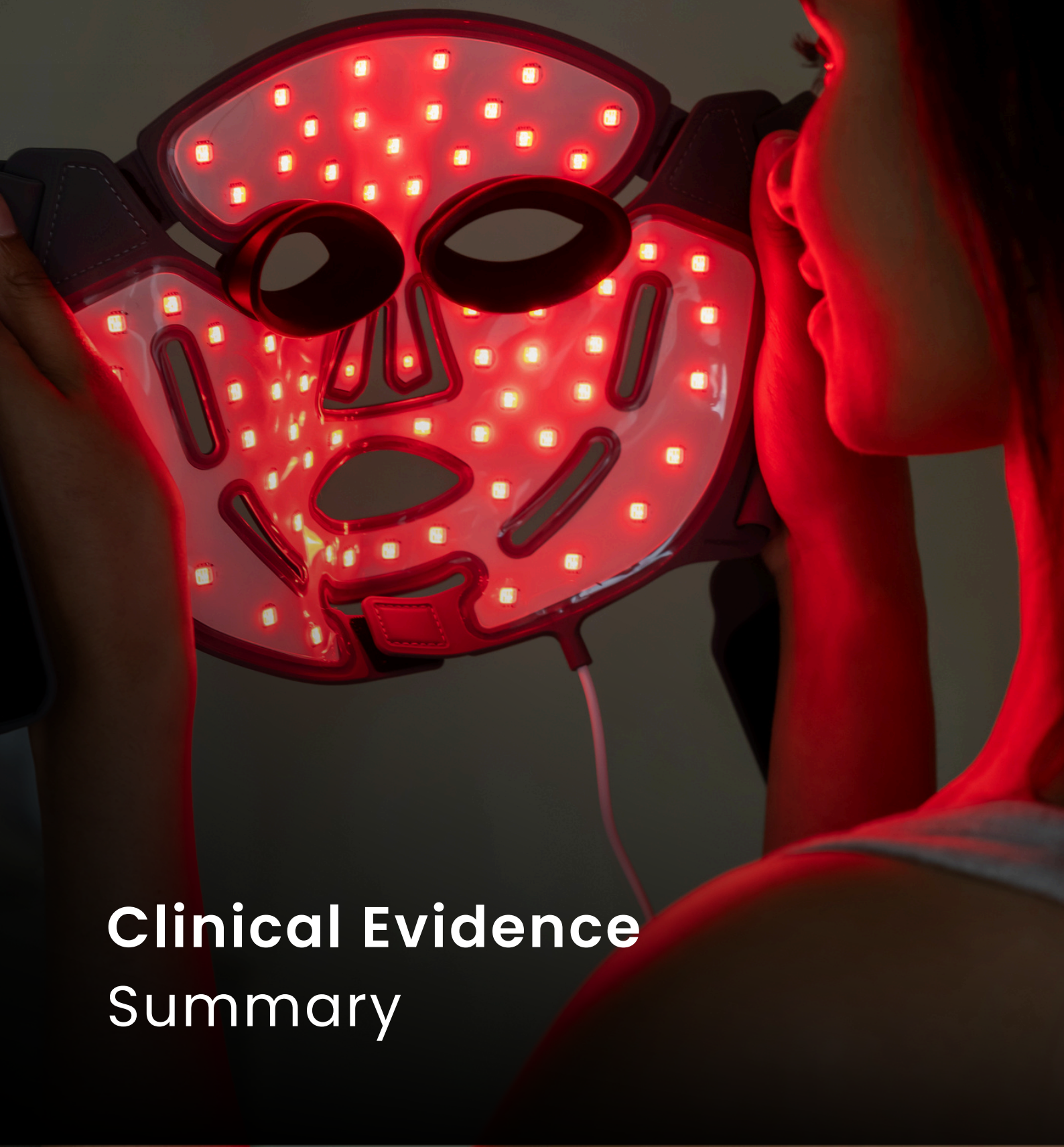


faceLITE

PRO



**Clinical Evidence
Summary**

Clinical Evidence Summary

faceLITE PRO LED Facial Mask

A single-site, open-label clinical study conducted in the United States in accordance with Good Clinical Practices, evaluated the effectiveness of a 5-wavelength red and near-infrared (NIR) LED facial mask for improving multiple visible signs of facial ageing and under-eye dark circles.

Twenty-four adults (23 females, 1 male) completed the **12-week protocol**.

The average subject age was 48 years (range 30-65). All Fitzpatrick skin types were represented. Seventeen (n=17) subjects identified as Caucasian (white), two (n=2) as Black/African American, two (n=2) as Asian, two (n=2) as Asian/Indian, and one (n=1) as Native American Indian/Alaskan native. Five subjects identified as of Hispanic ethnicity.

Purpose Of Study

The purpose of this study was to investigate a combination of **five multi-layer wavelengths** (Red: 610nm $\pm$ 10nm, 630nm $\pm$ 10nm, 660nm $\pm$ 10nm; NIR: 850nm $\pm$ 10nm, 1070nm $\pm$ 10nm) with emphasis on the treatment of the **visible effects of photo damage** and chronological aging, namely **wrinkles, pigmentation** and **erythema**. Furthermore, the study evaluated the effect of these wavelengths on intra orbital (eye socket) **dark circles**.

Red light (610nm, 630nm, 660nm): Promotes collagen production, reduces wrinkles and fine lines, and accelerates wound healing. It is also known for reducing inflammation and improving circulation.

Near-infrared light (850nm and 1070nm): These wavelengths are known to support collagen production, circulation and penetrate deeper into the skin, making them effective for reducing pain, inflammation, and improving overall healing.

Purpose Of Study

Participants self-administered 10-minute facial treatments, five times weekly, for 12 weeks using the LED mask.

- The LEDs produce red and near infra-red (NIR) light in the visible spectrum (Red: 610nm, 630nm, 660nm; NIR: 850nm, 1070nm).
- A **10-minute** treatment delivered **52 mW/cm**. irradiance and used a non-thermal photobiomodulation mechanism.

Assessments

Clinical evaluations occurred at baseline, Week 9, and Week 14, including:

- Physician-rated wrinkle severity (SASSQ)
- Photo-numeric dark circle scale
- Pigmentation and erythema scoring
- Standardized photography
- Blinded review of randomized before/after images
- Participant self-reported outcomes

Key Clinical Results

- **Facial Wrinkles:** Mean wrinkle grade improved by **0.7 of a grade** from baseline. **79%** of subjects saw **at least a 1 grade** improvement.
- **Under-Eye Dark Circles:** Average dark circle scores improved from 5.9 at baseline (moderate to pronounced) down to 3.9 at Week 14 (mild to moderate). **71%** showed an improvement in under eye dark circles. **All subjects** showed visible improvement by the end of the study.
- **Pigmentation:** Average/mean pigmentation severity improved by one grade over the treatment period, with **87.5%** of subjects demonstrating at least a one-grade improvement.
- **Erythema:** Average/mean erythema scores decreased from 1.8 at baseline to 1.0 at Week 14, with **two-thirds** of subjects showing visible improvement of at least one grade.

Participant-Reported Outcomes

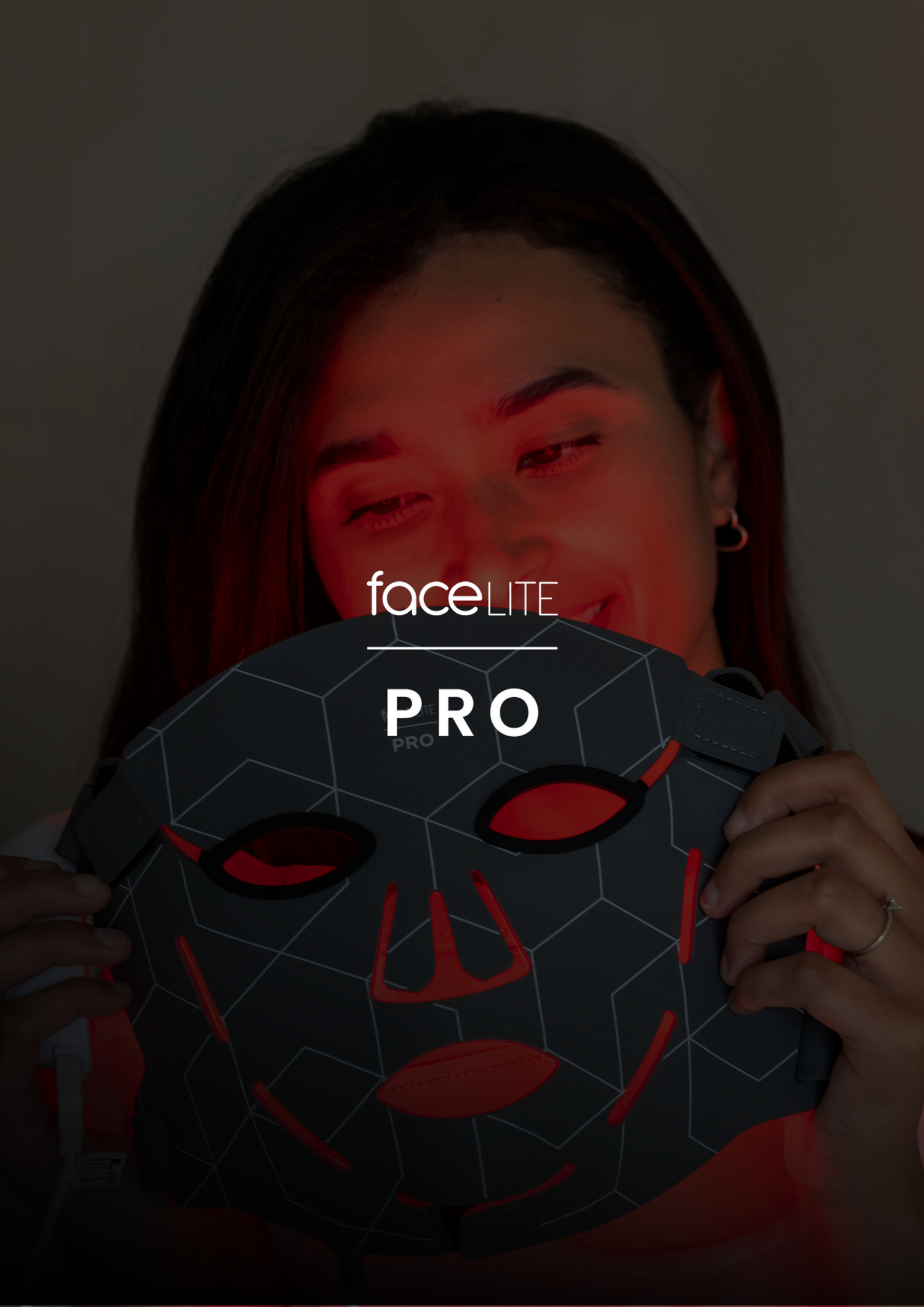
- **100%** reported overall facial improvement
- **83%** perceived a greater than **≥30%** improvement
- **65%** perceived a greater than **≥50%** improvement Reported outcomes aligned closely with physician assessments.

Safety

- No adverse events during or after treatment
- No delayed treatment-related issues at 8-week follow-up

Concise Overall Conclusion

Regular at-home use of faceLITE PRO 5-wavelength red + NIR LED mask over 12 weeks produced consistent, clinically verified improvements in wrinkles, under-eye dark circles, pigmentation and erythema, with excellent safety and high participant satisfaction. The combined wavelengths effectively target both superficial and deeper tissue layers through photobiomodulation, supporting skin rejuvenation without adverse effects.

A woman with long dark hair is smiling and holding a dark grey LED light therapy mask in front of her face. The mask has a white geometric pattern and several red light-emitting diodes. The background is a plain, light-colored wall. The text 'faceLITE' is overlaid on the image, with 'face' in lowercase and 'LITE' in uppercase, followed by a horizontal line and the word 'PRO' in large, bold, uppercase letters.

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