

Tradename: AC Melatonin Liposome PF

Code: 61012

CAS #: 7732-18-5 & 123465-35-0 & 73-31-4

Test Request Form #: 6089

Lot #: N200114B

Sponsor: *Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092*

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Test Performed:

In vivo VISIA Analysis: Wrinkles

Introduction

Wrinkles are furrows, folds, or creases in the skin that are associated with a decrease in skin elasticity and an increase in development as a result of sun exposure. As skin ages, cell production slows resulting in the dermis becoming thinner and allowing depressions to form on the skin's surface. Aging skin is often slower to retain moisture and heal wounds and with the formation of wrinkles, the appearance of the skin often looks unappealing. It is important to monitor the development of skin damage, such as fine lines and wrinkles, because limiting skin damage provides a healthier and more youthful appearance.

Accordingly, an *in vivo* study was conducted over a period of four weeks to evaluate the ability of **AC Melatonin Liposome SF** to reduce wrinkles on the face.

Study Principle

Participants applied specific products to designated halves of their face twice a day for four weeks. Measurements were collected once a week during the four-week study period. Photographs of participant faces were obtained using the VISIA Complexion Analysis System and analyzed for Wrinkles. The most pronounced wrinkles are represented by dark green lines whereas light green lines represent finer wrinkles in the analyzed region.

Materials

- A. Equipment:** VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA)
- B. Products:** Base Lotion (Cetaphil® Moisturizing Cream for All Skin Types); Kirkland Signature Daily Facial Towelettes
- C. Software:** Excel Analysis ToolPak (Microsoft)

Methods

Ten volunteers between the ages of 24 and 60, who were known to be free of any skin pathologies with Fitzpatrick skin types I to IV, participated in this study (Table 1).

Table 1. The Fitzpatrick Classification of Skin Types Chart¹

Fitzpatrick Skin Type Descriptions*	
Skin Type	Description
I	Always burns, never tans
II	Burns easily, tans minimally
III	Burns moderately, tans to light brown
IV	Burns minimally, tans to moderate brown
V	Rarely burns, tans to dark
VI	Never burns, least sensitive to changes

*Adapted from The Surgeon General's Call to Action to Prevent Skin Cancer

Each half of a participant's face was randomly assigned to a specific condition and treatment (Table 2). The Base Lotion utilized in this study was Cetaphil® Moisturizing Cream for All Skin Types. Following Baseline measurements, participants were provided both conditions and were instructed to apply 0.2 g of product to the specified half of their face twice daily for a four-week period. Participants were instructed to continue their usual skin care routine and to apply the lotion once their everyday skin care routine is finished. Baseline measurements were taken prior to starting the lotion regimen. Measurements were collected once a week during the four-week use period. Participants were instructed not to wear makeup or SPF products for the measurement sessions.

Table 2. Descriptions of the Conditions and Treatments for each Skin Test Site

Skin Test Site	Condition	Treatment / Test Article Application Description
1	Base Lotion Control	Base Lotion
2	2.0% AC Melatonin Liposome SF	2.0% AC Melatonin Liposome SF in Base Lotion

Photographic assessments were performed using the VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA). The VISIA System ensured consistent positioning of each participant's head and each participant cleaned their face with a gentle facial wipe (Kirkland Signature Daily Facial Towelettes) before images were obtained. The photographic images were captured with standard, cross-polarized, parallel polarized, and ultraviolet light.

Images were analyzed for Wrinkle Feature Count. The Wrinkle Feature Count indicates the number of discrete instances of Wrinkles, without regard to the size or intensity, within the analyzed region. Wrinkles are furrows, folds, or creases in the skin, identified by their characteristic long, narrow shape and are photographed with standard lighting. Therefore, skin with lower Wrinkle Counts indicates a more youthful appearance. The data are displayed as averages and t-test analyses were performed with statistical significance accepted at $p \leq 0.05$. Percent change is expressed relative to Baseline values and calculated by the following equation:

$$\text{Percent Change (\%)} = \frac{\text{Wrinkle Count}_{\text{Week of Application}} - \text{Wrinkle Count}_{\text{Baseline}}}{\text{Wrinkle Count}_{\text{Baseline}}} \times 100$$

Results

The data obtained met criteria for a valid study and the Base Lotion performed as anticipated. Application of 2.0% AC Melatonin Liposome SF twice a day for four weeks demonstrated a reduction in the number of Wrinkles throughout the four-week treatment period.

Change in Wrinkle Count AC Melatonin Liposome SF

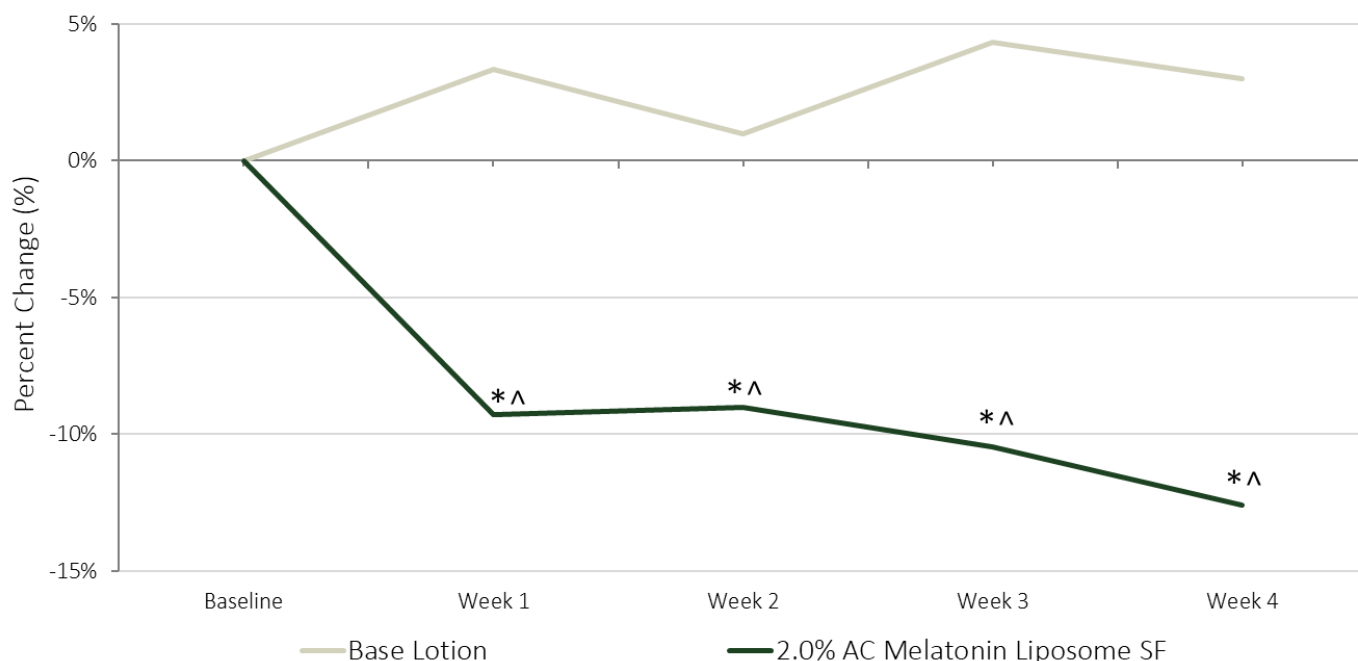


Figure 1. Change in Wrinkle Count from Baseline. * indicates significance ($p \leq 0.05$) compared to Baseline values. ^ indicates significance ($p \leq 0.05$) compared to Base Lotion within the same timepoint.

Table 3. P-values from t-test Analyses of Change in Wrinkle Count from Baseline to After Four Weeks of Application. * indicates significance ($p \leq 0.05$) compared to Baseline values.

	Baseline vs After Four Weeks of Application
Base Lotion	0.235
2.0% AC Melatonin Liposome SF	0.039*

Table 4. T-test Analyses of Change in Wrinkle Count between Base Lotion and 2.0% AC Melatonin Liposome SF After Four Weeks of Application. ^ indicates significance ($p \leq 0.05$) compared to Base Lotion within the same timepoint.

	After One Week of Application	After Two Weeks of Application	After Three Weeks of Application	After Four Weeks of Application
P-value	0.041^	0.048^	0.037^	0.032^

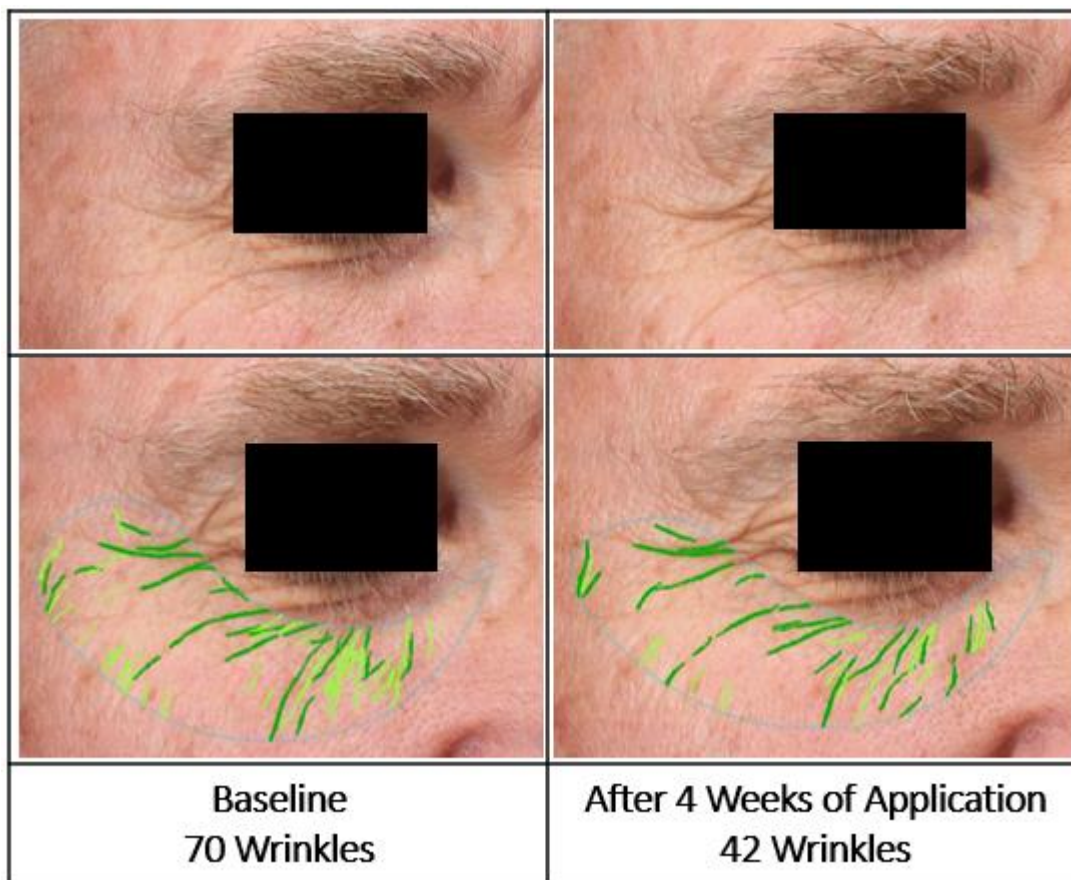


Image 1. Images of Participant Treated with 2.0% AC Melatonin Liposome SF. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks. The most pronounced wrinkles are represented by dark green lines whereas light green lines represent finer wrinkles.

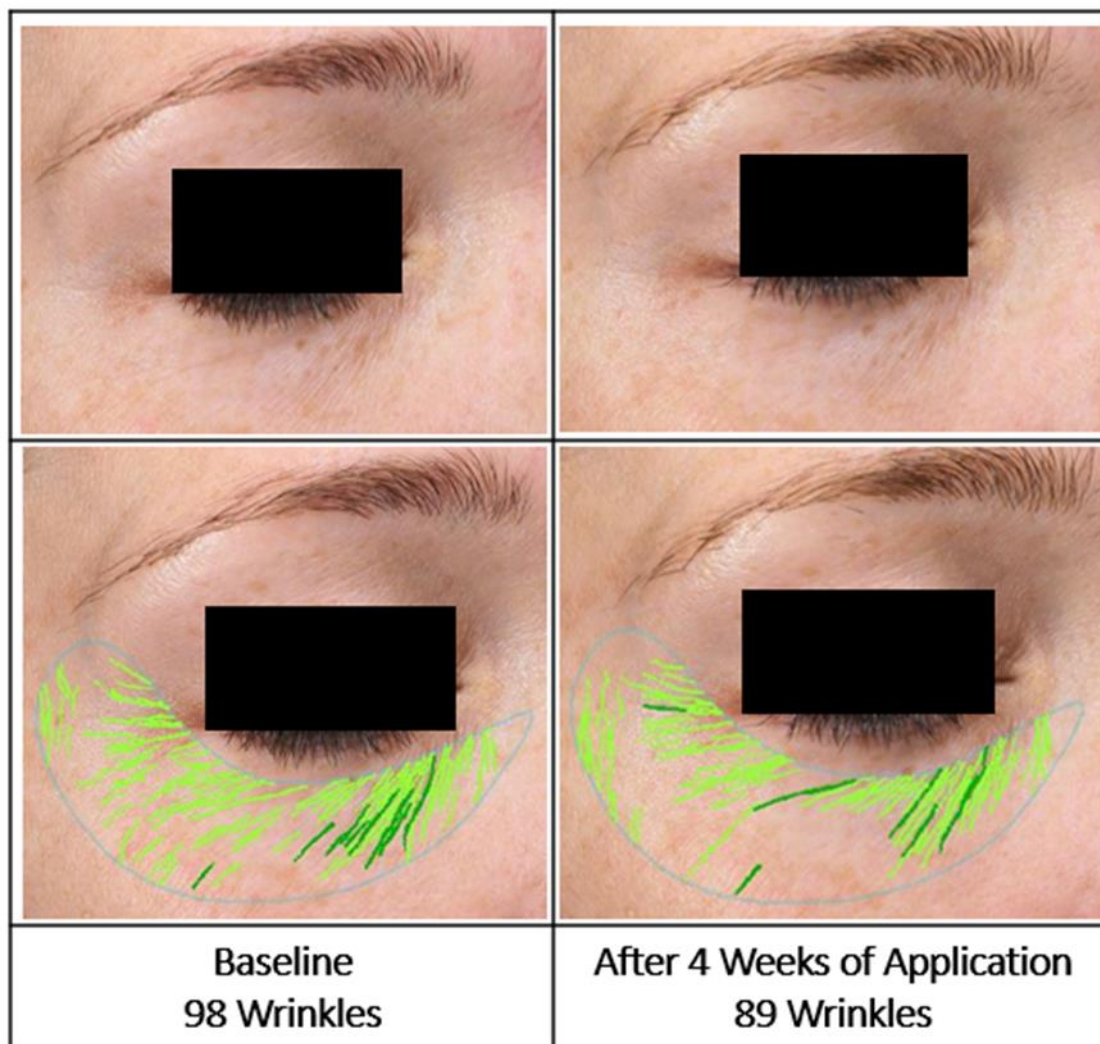


Image 2. Images of Participant Treated with 2.0% AC Melatonin Liposome SF. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks. The most pronounced wrinkles are represented by dark green lines whereas light green lines represent finer wrinkles.

Discussion

As evidenced in this four-week study, **AC Melatonin Liposome SF** reduces the appearance of Wrinkles on the face. The amount of Wrinkles present was not significantly altered throughout the study with Base Lotion application, indicating the Base Lotion does not exert significant Wrinkle reducing properties on the skin (Figure 1; Table 3). Conversely, applying 2.0% **AC Melatonin Liposome SF** for four weeks resulted in a 13% decrease in the overall amount of Wrinkles present, compared to baseline (Figure 1; Table 3). Moreover, applying 2.0% **AC Melatonin Liposome SF** significantly decreased the amount of Wrinkles present compared to the Base Lotion after every week of application (Figure 1; Table 4). These results indicate that applying 2.0% **AC Melatonin Liposome SF** for four weeks provides a reduction of Wrinkles on the face resulting in a more youthful skin appearance (Images 1, 2).

Collectively, these results indicate **AC Melatonin Liposome SF** reduces the appearance of Wrinkles and simulated skin age when added to personal care applications at recommended use levels. Collectively, **AC Melatonin Liposome SF** improves skin health and provides a more youthful appearance by reducing the visual consequences of normal aging.

References

1. Sharma AN, Patel BC. Laser Fitzpatrick Skin Type Recommendations. [Updated 2022 Mar 9]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK557626/>