

INTRODUCTION

An in-vivo study was conducted over a period of four weeks to evaluate the effects of 2.0% AC Melatonin Liposome SF in a base lotion on wrinkle parameters compared to the base lotion alone. AC Melatonin Liposome SF in base lotion demonstrated the ability to reduce the average feature count of wrinkles after one week by 9.30%, compared to the baseline. After four weeks of treatment, AC Melatonin Liposome SF in base lotion demonstrated the ability to reduce the average feature count of wrinkles by 12.58%, compared to the baseline. AC Melatonin Liposome SF consistently decreased the wrinkle feature count over a four week period compared to the control.

MATERIALS AND METHODS

This study was conducted using 10 M/F participants between the ages of 24 - 60. Each participant was instructed to apply 2.0 mg of lotion to their entire face twice a day 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. Half of the participant population used 2.0% AC Melatonin Liposome SF in a Cetaphil Daily Facial Moisturizer for all skin types, while the other half used the Cetaphil Daily Facial Moisturizer alone as a control.

Baseline photos were taken prior to starting the lotion regimen. Photos were taken once a week for 4 weeks. Participants were instructed to not wear makeup during the testing period. Photographic assessments were performed using the VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA). The VISIA System, with a configurable head support, ensured consistent positioning of each subject's head. The subjects cleaned their skin with a gentle facial wipe (Daily Facial Towelettes – Paraben Free Formula by Kirkland Signature) before the image was obtained. The photographic images were captured with standard, cross-polarized, parallel polarized, and ultraviolet light. Images were taken for each subject to quantify the feature counts for wrinkles.

Feature counts provide a count of the number of discrete instances of the feature being evaluated. Skin with a lower feature count was considered to be more youthful in appearance. In the present study, scores were used to more objectively assess changes in skin condition. The average scores for the overall face were calculated, and the differences between time points were recorded and compared. For statistical analysis a two-sample t-test, assuming unequal variance, was performed to compare data. The significance threshold was set at 0.05.



Code Number: 61012

INCI Name: Water & Phospholipids &

Melatonin

INCI Status: Conforms

CAS Number: 7732-18-5 & 123465-35-0 &

73-31-4

EINECS Number: 231-791-2 & N/A &

200-797-7

TRF#: 6089

Lot Number(s): N200114B

Suggested Use Levels: 1.0 - 10.0%

Use Level for Assay: 2.0%

Sponsor:

Active Concepts, LLC 107 Technology Drive Lincolnton, North Carolina 28092

Study Director: Maureen Danaher Principle Investigator: Kara Rivera

Suggested Applications:

Antioxidant, Anti-Inflammatory, Reduces Wrinkles

Benefits of AC Melatonin Liposome SF:

- 'Inflammaging' Defense
- Reduces the Appearance of Wrinkles



RESULTS

Reduction in wrinkles were determined throughout the four week treatment period. Figure 1 illustrates the reduction in wrinkles throughout the study and depicts the percent change, in feature counts, between the experimental time points and the baseline measurement as well as the percent change of the control time points compared to the control baseline. Statistical analysis performed compares the percent change of the experimental and control feature counts throughout the study. Figure 2 displays the p-values for wrinkle feature counts highlighted in yellow. The resulting p-values are less than 0.05. Figure 3 details the average feature counts for wrinkles during the study for experimental and control participants as well as the percent change. The VISIA Complexion Analysis System provides photographic assessments with image enhancements to provide higher visualization of feature changes. Figures 4 through 8 provide visualizations of wrinkle feature changes throughout the study period on participants using **AC Melatonin Liposome SF**. Selected time periods, in Figures 4-8, are shown with both natural photographs and VISIA enhanced images of the same participant. Wrinkle feature counts were collected for experimental and control groups during the study. The averages were calculated as well as the percent change between each time point and the baseline point of the study, (T=0), for both experimental and control values. The result of the t-Test, in terms of p-value, was 0.002 and 0.004, respectively.

Average Feature Counts for Wrinkles

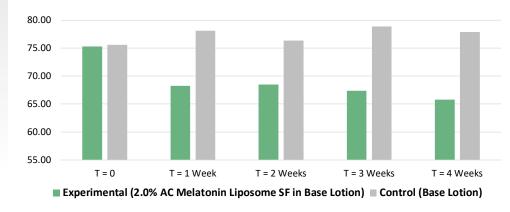


Figure 1. Average feature counts comparing experimental and control values at each time point.

Wrinkles Statistical Analysis

| t-Test: Two-Sample Assuming Unequal Variances | | | | | |
|---|-------------|-------------|--|--|--|
| | Variable 1 | Variable 2 | | | |
| Mean | 30.7868 | 18.59452 | | | |
| Variance | 27.60473974 | 4.573272852 | | | |
| Observations | 5 | 5 | | | |
| Hypothesized Mean | | | | | |
| Difference | 0 | | | | |
| df | 5 | | | | |
| t Stat | 4.806072538 | | | | |
| P(T<=t) one-tail | 0.002428797 | | | | |
| t Critical one-tail | 2.015048373 | | | | |
| P(T<=t) two-tail | 0.004857594 | | | | |
| t Critical two-tail | 2.570581836 | | | | |

Figure 2. Statistical analysis on overall face feature count averages comparing the percent change of experimental and control values throughout treatment to their respective baselines.

Average Feature Counts for Wrinkles

| | Overall Feature Count | | | | |
|---|-----------------------|------------|-------------|-------------|-------------|
| | T = 0 | T = 1 Week | T = 2 Weeks | T = 3 Weeks | T = 4 Weeks |
| Experimental (2.0% AC Melatonin Liposome SF in Base Lotion) | 75.27 | 68.27 | 68.47 | 67.40 | 65.80 |
| Control (Base Lotion) | 75.60 | 78.13 | 76.33 | 78.87 | 77.87 |
| % Change Compared to T=0 | T = 0 | T = 1 Week | T = 2 Weeks | T = 3 Weeks | T = 4 Weeks |
| Experimental Percent (%) Change | 0% | -9.30% | -9.03% | -10.45% | -12.58% |
| Control Percent (%) Change | 0% | 3.35% | 0.97% | 4.32% | 3.00% |

Figure 3. Feature counts for wrinkles determined using overall face averages of experimental and control groups. Percent change is determined by comparing each time point (T=1 Week, T=2 Weeks, etc.) to T=0 for the respective group.

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Figure 4. Panelist #1 treated with 2.0% AC Melatonin Liposome SF in Base Lotion displays a reduction (21.4%) in feature counts for wrinkles from beginning of treatment (T=0) to T=4 Weeks via VISIA Image Analysis. Images on the left are panelist #1 with image enhancement, through VISIA, which provides higher visualization of feature changes. Images on the right are natural photos of panelist #1.



Figure 5. Panelist #2 treated with 2.0% **AC Melatonin Liposome SF** in Base Lotion displays a reduction (6.62%) in feature counts for wrinkles from beginning of treatment (T=0) to T=4 Weeks via VISIA Image Analysis. Images on the left are panelist #2 with image enhancement, through VISIA, which provides higher visualization of feature changes. Images on the right are natural photos of panelist #2.

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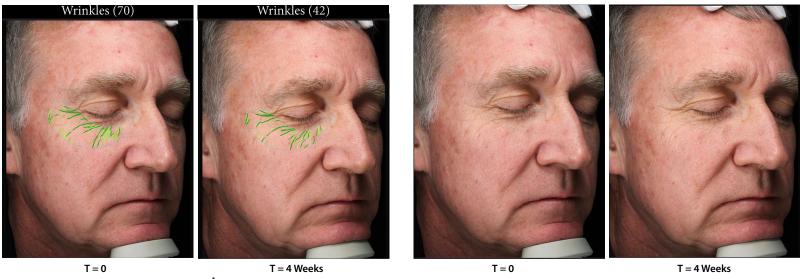


Figure 6. Panelist #3 treated with 2.0% **AC Melatonin Liposome SF** in Base Lotion displays a reduction (40.0%) in feature counts for wrinkles from beginning of treatment (T=0) to T=4 Weeks via VISIA Image Analysis. Images on the left are panelist #3 with image enhancement, through VISIA, which provides higher visualization of feature changes. Images on the right are natural photos of panelist #3.



Figure 7. Panelist #4 treated with 2.0% AC Melatonin Liposome SF in Base Lotion displays a reduction (9.18%) in feature counts for wrinkles from beginning of treatment (T=0) to T=4 Weeks via VISIA Image Analysis. Images on the left are panelist #4 with image enhancement, through VISIA, which provides higher visualization of feature changes. Images on the right are natural photos of panelist #4.

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Figure 8. Panelist #5 treated with 2.0% **AC Melatonin Liposome SF** in Base Lotion displays a reduction (9.58%) in feature counts for wrinkles from beginning of treatment (T=0) to T=4 Weeks via VISIA Image Analysis. Images on the left are panelist #5 with image enhancement, through VISIA, which provides higher visualization of feature changes. Images on the right are natural photos of panelist #5.

DISCUSSION

Digital photographs and facial surface analysis were conducted as objective computer assessments by VISIA Complexion Analysis. Improvements in wrinkles were evaluated by comparing feature counts throughout the course of treatment. 2.0% **AC Melatonin Liposome SF** in base lotion demonstrated the ability to reduce the average feature count of wrinkles after one week by 9.30%, compared to the baseline. After four weeks of treatment, 2.0% **AC Melatonin Liposome SF** in base lotion demonstrated the ability to reduce the average feature count of wrinkles by 12.58%. The active in base lotion demonstrated a statistically significant difference in feature counts for wrinkles over the course of the study, when comparing the percent change of experimental and control groups. P-values were less than or equal to 5% indicating results of the study, regarding wrinkles, were not due to random chance.

Graceful aging trends are now taking center stage. Everyone ages, but we can age gracefully by incorporating products into our skin care routines that reduce visible signs of wrinkles. We can turn back the clock on our skin a few wrinkles at a time. Throughout the treatment period, participants using **AC Melatonin Liposome SF** in base lotion displayed a reduced number of facial wrinkles when compared to the control. **AC Melatonin Liposome SF** may be used to capitalize on the benefits associated with reducing wrinkles in a variety of cosmetic and skin care applications.



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