

Tradename: AC OleaShield

Code: 12006

CAS #: 68333-16-4 (or) 92128-79-5 & 8001-25-0 & 68333-16-4 (or) 1686112-36-6 (or) 9015-54-7

Test Request Form #: 10070

Lot #: N230417D

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

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Principle Investigator: *Kayla Patterson*

Test Performed:

In-vivo VISIA Analysis

Introduction

Wrinkles are furrows, folds, or creases in the skin that are associated with a decrease in skin elasticity as a result of sun exposure. 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 six weeks to evaluate the effects of 5.0% **AC OleaShield** on wrinkles compared to a base lotion alone.

Assay Principle

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 (Simple® Cleansing Facial Wipes) before the image was obtained. The photographic images were captured with standard, cross-polarized, parallel polarized, and ultraviolet light. Baseline photos were taken prior to starting the lotion regimen. Photos were taken once a week during the four-week use period and for two weeks after application ceased for a total of six weeks. Female participants were instructed to not wear makeup during the testing period.

Materials

- | | |
|------------------------|---|
| A. Equipment: | VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA) |
| B. Base Lotion: | Generic Cream (Table 1) |

Table 1. Ingredient List (INCI Names) of Generic Cream.

Generic Cream
DI Water
Glycerin
Carbopol Ultrez 10
Tealan (TEA)
Cetearyl Alcohol
Stearic Acid
Glyceryl Stearate
Isopropyl Myristate
Mineral Oil
Leucidal SF Max

Methods

This study was conducted using eight M/F participants between the ages of 23 – 63 with Fitzpatrick skin types of I to IV (Table 2). 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 5.0% **AC OleaShield** in Generic Cream, while the other half used Generic Cream alone as a control.

Images were analyzed for Wrinkle Feature Count and Score. The Wrinkle Feature Count indicates the number of discrete instances of wrinkles within the analyzed region. Skin with lower counts is considered to be more youthful in appearance. The Wrinkle Score computes the impact that wrinkles have on the overall complexion of the skin by factoring in the total size, area, and intensity of detected instances within the analyzed region. The average counts and scores for the analyzed region were calculated, and the differences between time points were recorded.

For added perspective, skin age was assessed using the VISIA Complexion Analysis System.

Table 2. 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	

Results

The data obtained from this study met criteria for a valid assay and the controls performed as anticipated. **AC OleaShield** at a concentration of 5.0% was able to decrease the appearance of wrinkles and fine lines on the face during the four-week treatment period and the two-week regression period.

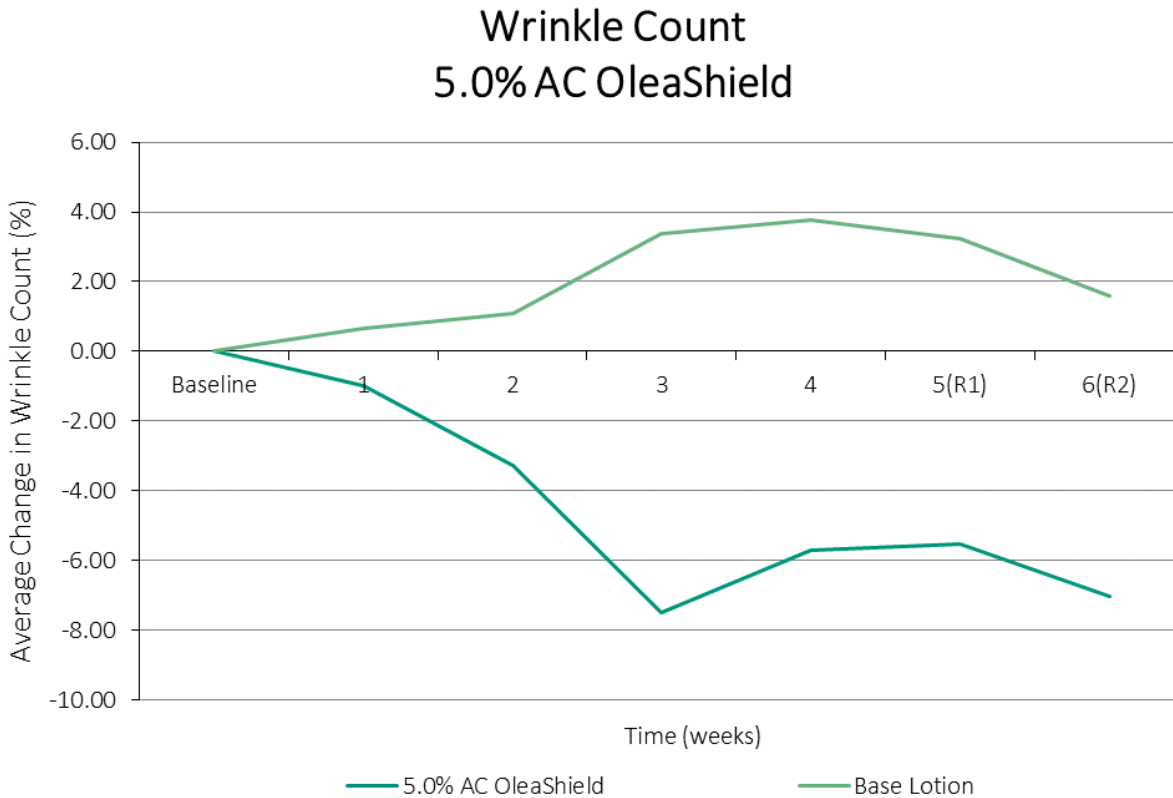


Figure 1. Average Percent Change in Count for Wrinkles from Baseline. R1 and R2 Indicate Regression Weeks with No Application.

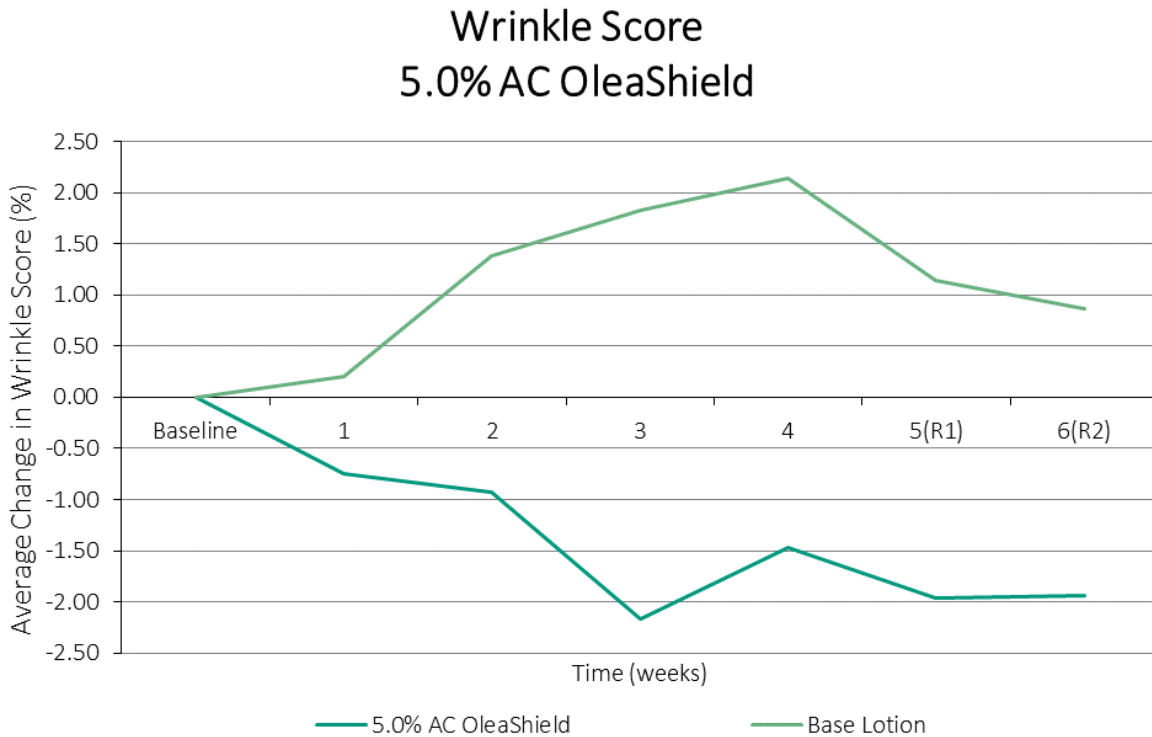


Figure 2. Average Percent Change in Score for Wrinkles from Baseline. R1 and R2 Indicate Regression Weeks with No Application.

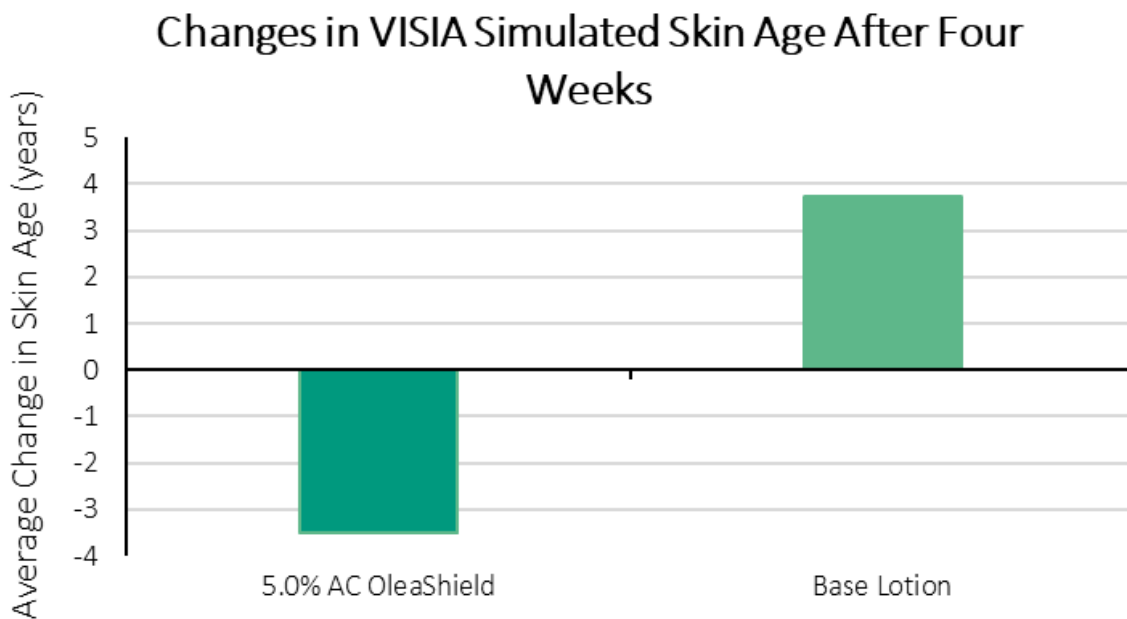


Figure 3. Changes in VISIA Simulated Skin Age of Participants After Four Weeks of 5.0% AC OleaShield and Base Lotion Application.

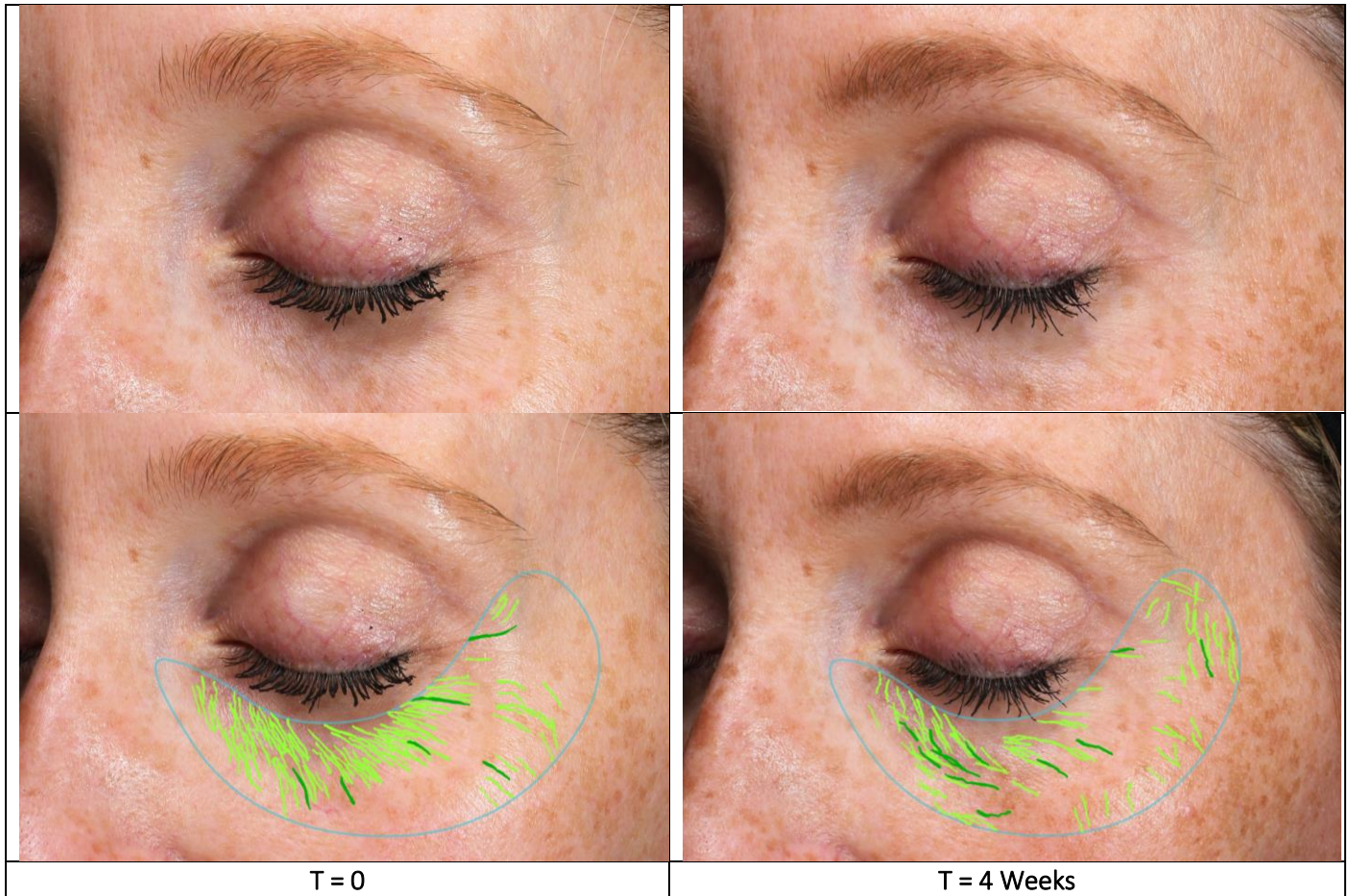


Figure 3. Images of Participant Treated with 5.0% AC OleaShield. Natural photos (top) and VISIA Image Enhancement (bottom) Before and After Four Weeks.



Figure 4. Images of Participant Treated with 5.0% **AC OleaShield**. Natural photos (top) and VISIA Image Enhancement (bottom) Before and After Four Weeks.

Discussion

As evidenced in this four-week study, **AC OleaShield** is capable of reducing the appearance of fine lines on the face. After four weeks, participants applying 5.0% **AC OleaShield** demonstrated a 6% decrease in the overall number of wrinkles and a 2% reduction in the size and intensity (score) of those wrinkles, compared to baseline. Conversely, base lotion application increased the total number of wrinkles by 4% and augmented the size and intensity (score) of those wrinkles by 2% after four weeks (Figures 1, 2, 4, 5). These results indicate that applying 5.0% **AC OleaShield** for four weeks provides a reduction of wrinkle appearance on the face resulting in a more youthful skin appearance.

After treatment ended, the size, intensity, and number of wrinkles in participants applying 5.0% **AC OleaShield** continued to outperform the base lotion alone. After two weeks of regression, the participants that applied 5.0% **AC OleaShield** demonstrated a 7% reduction in the total number of wrinkles, while the base lotion produced an increase of 2%. Similarly, 5.0% **AC OleaShield** elicited a 2% decrease in wrinkle size and intensity, whereas the base lotion increased wrinkle scores by 1% (Figures 1, 2, 4, 5). These results indicate that after treatment ended, participants applying 5.0% **AC OleaShield** continued to see a reduction in size, intensity, and number of wrinkles on the face.

Additionally, the VISIA software analyzes each image and provides a Simulated Skin Age metric for each participant. After four weeks of application, 5.0% **AC OleaShield** decreased the VISIA Simulated Skin Age by 4 years, while the base lotion demonstrated an increase of 4 years (Figure 3). These results indicate that applying 5.0% **AC OleaShield** for four weeks provides a reduction in VISIA Simulated Skin Age which reduces the visual impacts of normal aging.

Collectively, we provide evidence that applying **AC OleaShield** for four weeks reduces the size, appearance, and intensity of visible fine lines and simulated skin age. In conclusion, utilizing **AC OleaShield** at the recommended use levels 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/>