

Tradename: AC Retinol Liposome OS

Code: 60184

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Test Request Form #: 10055

Lot #: 9392040

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

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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 and an increase in development as a result to 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.

An in-vivo study was conducted over a period of six weeks to evaluate the effects of 3.0% **AC Retinol Liposome OS** on wrinkles compared to a base lotion.

Materials & Methods

This study was conducted using 10 M/F participants between the ages of 23 – 60 with Fitzpatrick skin types of I to III (Table 1). 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 3.0% **AC Retinol Liposome OS** in a Simple® Hydrating Light Moisturizer for all skin types, while the other half used the Simple® Hydrating Light Moisturizer alone as a control.

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.

Images were analyzed for Wrinkles Score. The Wrinkle Score Feature 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. Wrinkle Scores were used to more objectively assess changes in the skin condition. The average 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. A two-sample t-test, assuming an unequal variance, was performed to compare data. The significance threshold was set at 0.05.

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

Results

The data obtained from this study met criteria for a valid assay and the controls performed as anticipated. **AC Retinol Liposome OS** at a concentration of 3.0% 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.

9 out of 10 participants were included in the analysis. One participant that used 3.0% **AC Retinol Liposome OS**, was excused from the study after week 2 due to skin irritation.

Absolute Wrinkles Score AC Retinol Liposome OS

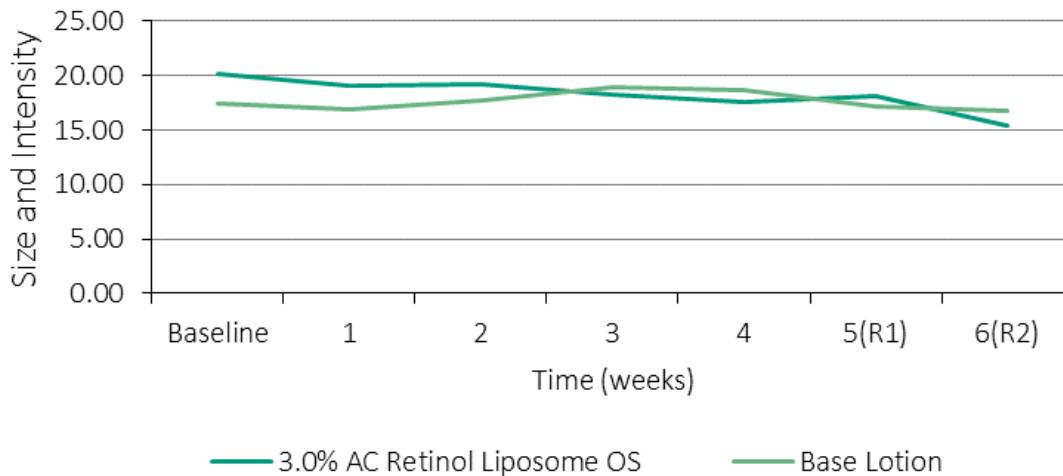


Figure 1. Average Wrinkle Score over Time. R1 and R2 indicate regression weeks with no application.

Table 2. Average Wrinkle Score Count Over Time with Regression.

Averages	T = 0	T = 1 Week	T = 2 Weeks	T = 3 Weeks	T = 4 Weeks	T = - 1 Week	T = -2 Weeks
Experimental (3.0% AC Retinol Liposome OS + Base Lotion)	20.19	19.06	19.21	18.28	17.53	18.09	15.37
Base Lotion	17.49	16.88	17.69	18.99	18.60	17.12	16.79

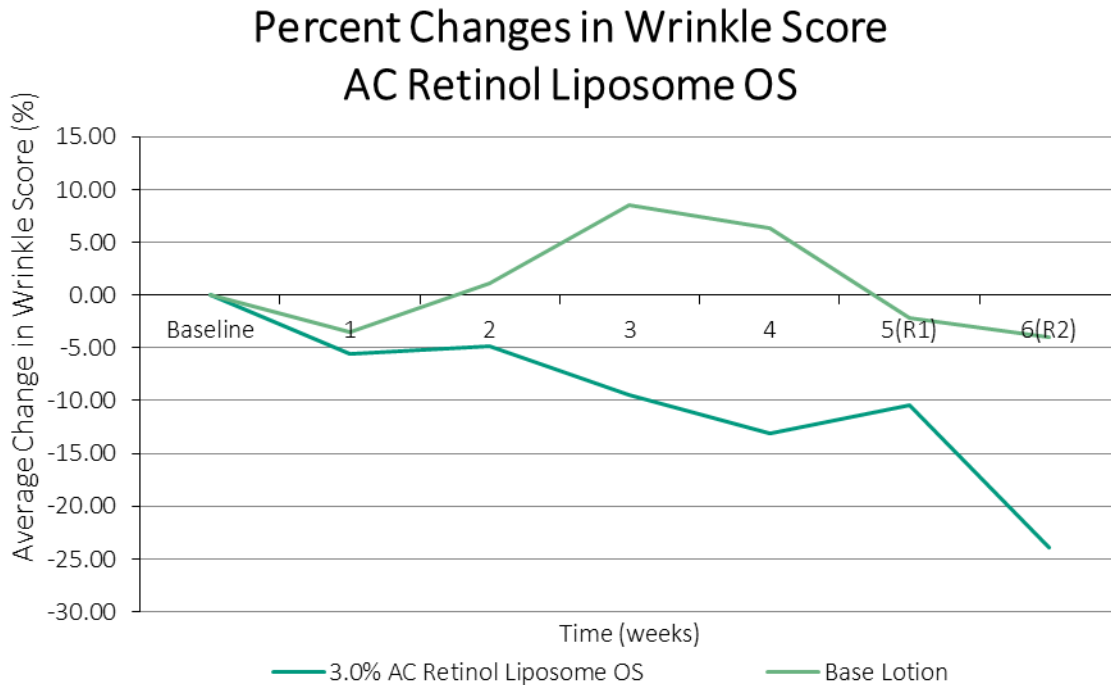


Figure 2. Average Percent Change of Wrinkle Score from baseline. R1 and R2 indicate regression weeks with no application.

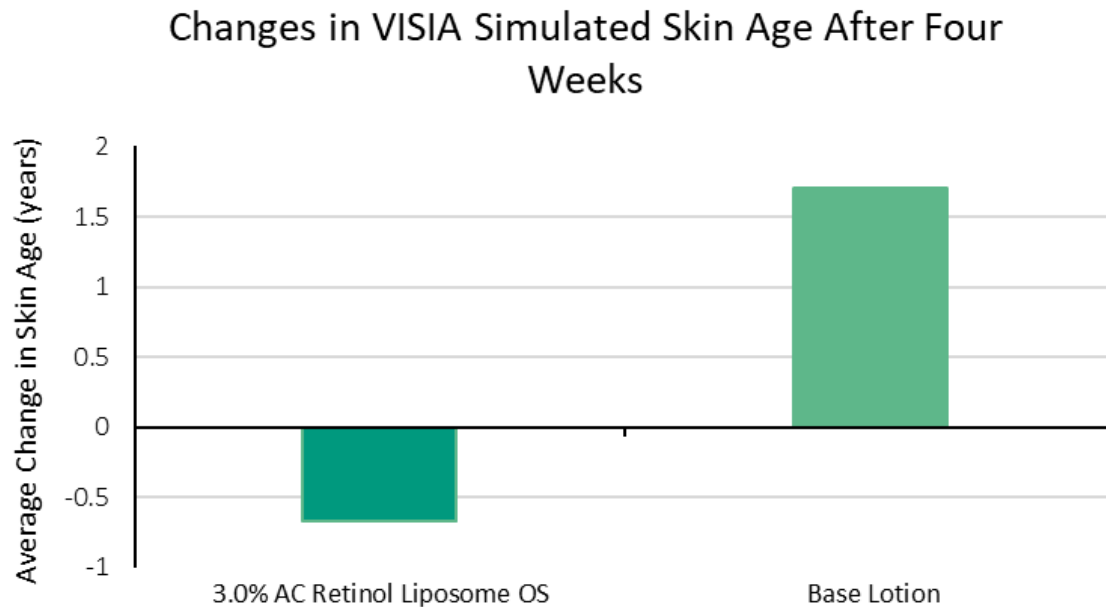


Figure 3. Changes in VISIA Simulated Skin Age of Participants After Four Weeks of 3.0% AC Retinol Liposome OS and Base Lotion Application.

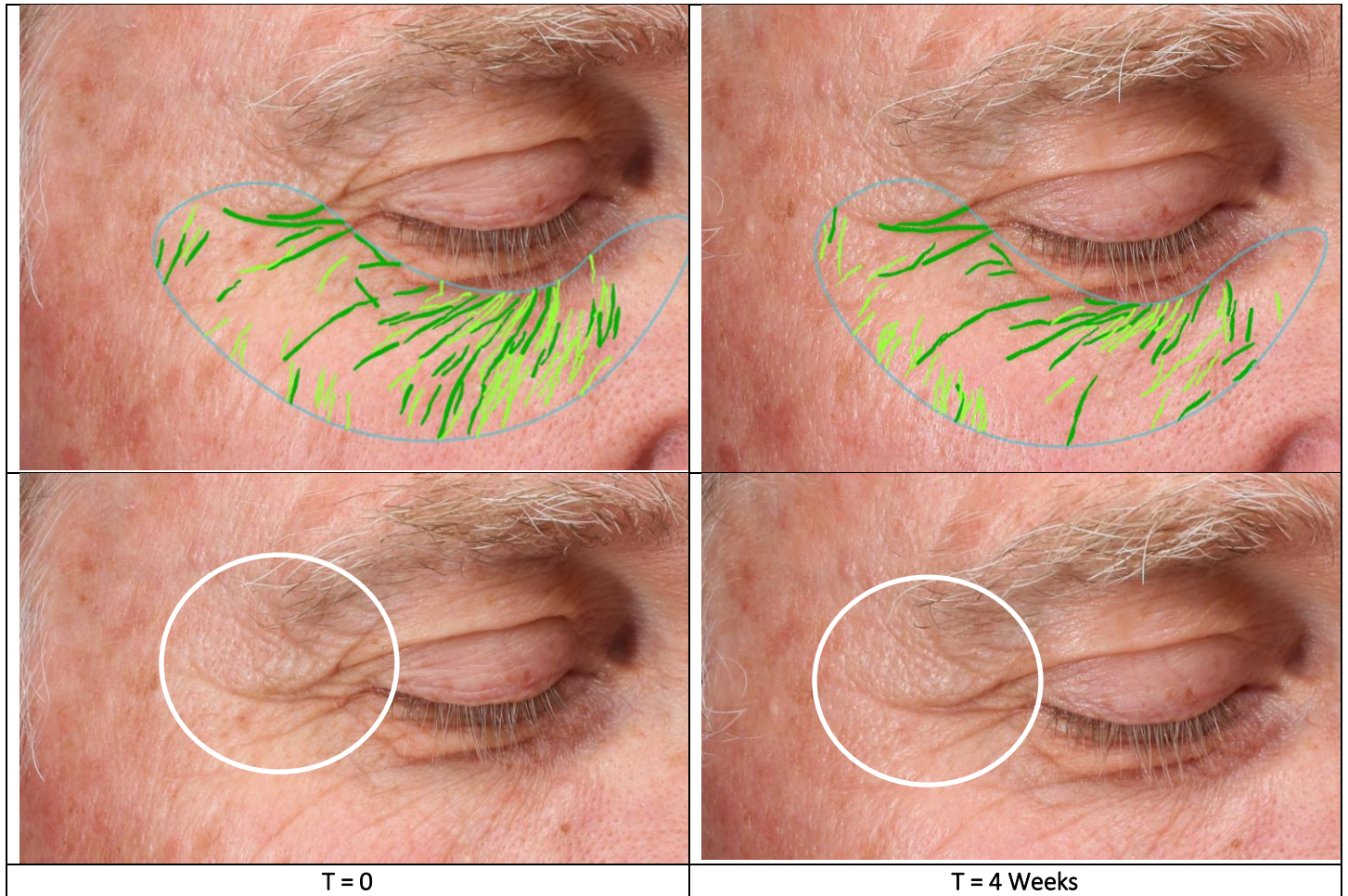


Figure 3. Images of Participant Treated with 3.0% AC Retinol Liposome OS. VISIA Image Enhancement (top) and natural photos (bottom) before and after four weeks.

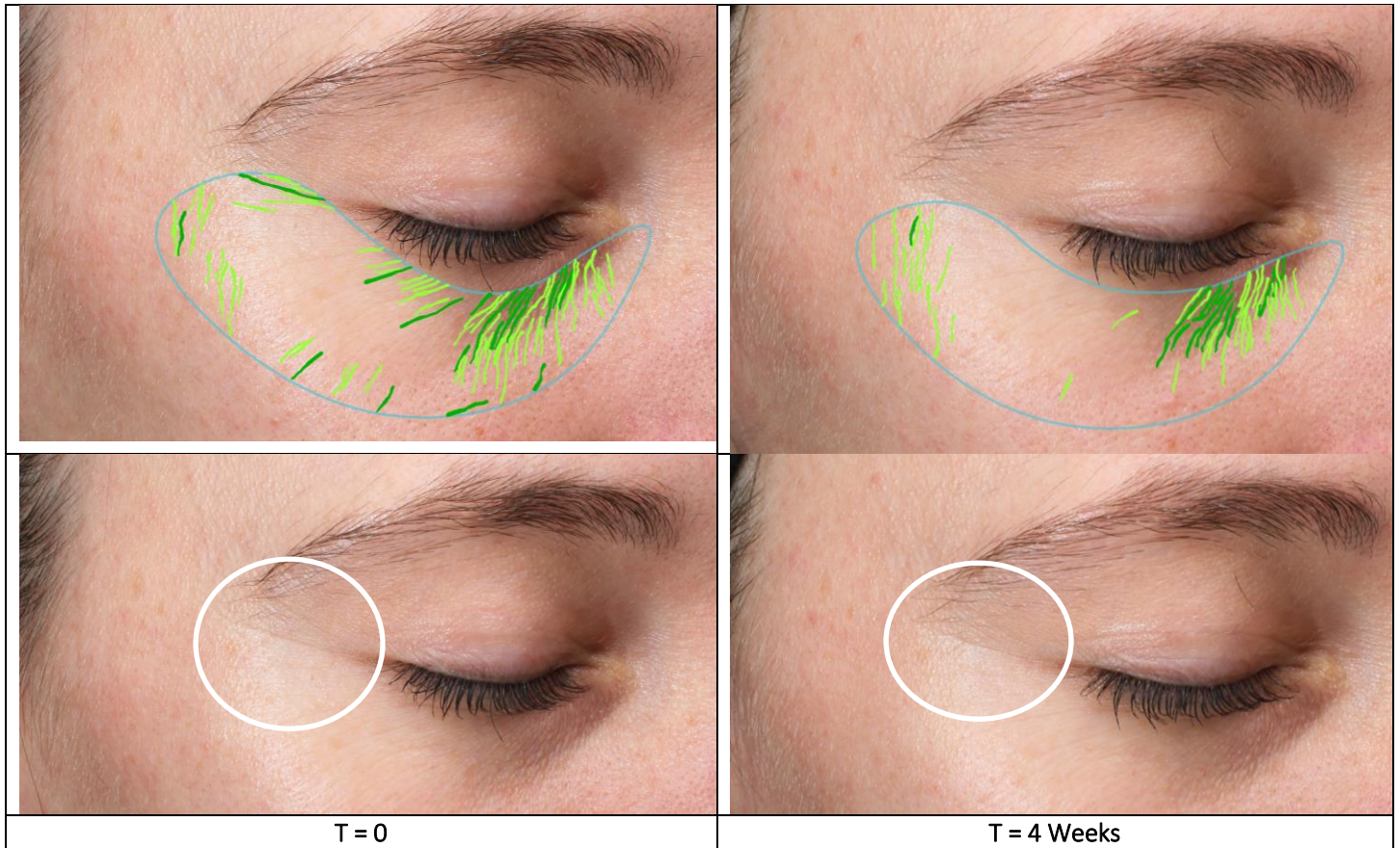


Figure 4. Images of Participant Treated with 3.0% AC Retinol Liposome OS. VISIA Image Enhancement (top) and natural photos (bottom) before and after four weeks.

Table 3. T-test Analysis of the Percent Change (%) in Wrinkle Score from baseline to T=4 between 3.0% AC Retinol Liposome OS and Base Lotion (n=9, $\alpha=0.05$, df=21).

	AC Retinol Liposome OS	Base Lotion
Mean	-0.12	0.088
Variance	0.0056	0.012
t Stat	-3.52	
P(T<=t) two-tail	0.0096	
t Critical two-tail	2.36	

Discussion

As evidenced in this four-week study, **AC Retinol Liposome OS** is capable of reducing the appearance of fine lines on the face. After four weeks, participants applying 3.0% **AC Retinol Liposome OS** demonstrated a 13% decrease in Wrinkle Score, compared to baseline. Conversely, base lotion increased Wrinkle Score by 6% after four weeks. These results indicate that applying 3.0% **AC Retinol Liposome OS** for four weeks provides a reduction in the size and intensity of wrinkle appearance.

After treatment ended, the Wrinkle Score in participants applying 3.0% **AC Retinol Liposome OS** continued to outperform the base lotion alone. After two weeks of regression, the participants that applied 3.0% **AC Retinol Liposome OS** demonstrated a 24% reduction in wrinkle size and intensity, whereas the base lotion decreased Wrinkle Scores by 4%. These results indicate that after treatment ended, participants applying 3.0% **AC Retinol Liposome OS**, continued to see a decrease in the intensity and size of wrinkles.

Additionally, the VISIA software analyzes each image and provides a Simulated Skin Age metric for each participant. After four weeks of application, 3.0% **AC Retinol Liposome OS** decreased the VISIA Simulated Skin Age by 0.67 years, while the base lotion demonstrated an increase of 1.7 years. These results indicate that applying 3.0% **AC Retinol Liposome OS** 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 Retinol Liposome OS** for four weeks reduces the appearance and intensity of visible fine lines and simulated skin age. Utilizing **AC Retinol Liposome OS** 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/>