

**Tradename:** AC Retinol Liposome OS

**Code:** 60184

**CAS #:** 65381-09-1 & 123465-35-0 & 68-26-8

**Test Request Form #:** 10055

**Lot #:** 9392040

**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

Brown spots are lesions that produce an uneven appearance on and deeper within the skin such as freckles, hyperpigmentation, and melasma. Brown spots occur from an excess of melanin which is produced by melanocytes in the bottom layer of the epidermis. Reducing brown spots allows the skin to look more youthful in appearance which is an increasing desire in the cosmetic world.

Accordingly, an *in-vivo* study was conducted over a period of six weeks to evaluate the effects of 3.0% **AC Retinol Liposome OS** in a base lotion on brown spots compared to the base lotion alone.

## Materials & Methods

This study was conducted using 10 M/F participants between the ages of 25 – 63 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 Brown Spot Feature Counts and assigned a Brown Spot Score. The Brown Spot Feature Counts indicate the number of discrete instances of brown spots within the analyzed region. Skin with lower feature counts are considered to be more youthful in appearance. The Brown Spot Score Feature computes the impact that brown spots have on the overall complexion of the skin by factoring in the total size, area, and intensity of detected instances within the analyzed region. Brown Spot Scores were used to more objectively assess changes in 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 determined 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  $p < 0.05$ .

**Table 1.** The Fitzpatrick Classification of Skin Types Chart<sup>1</sup>

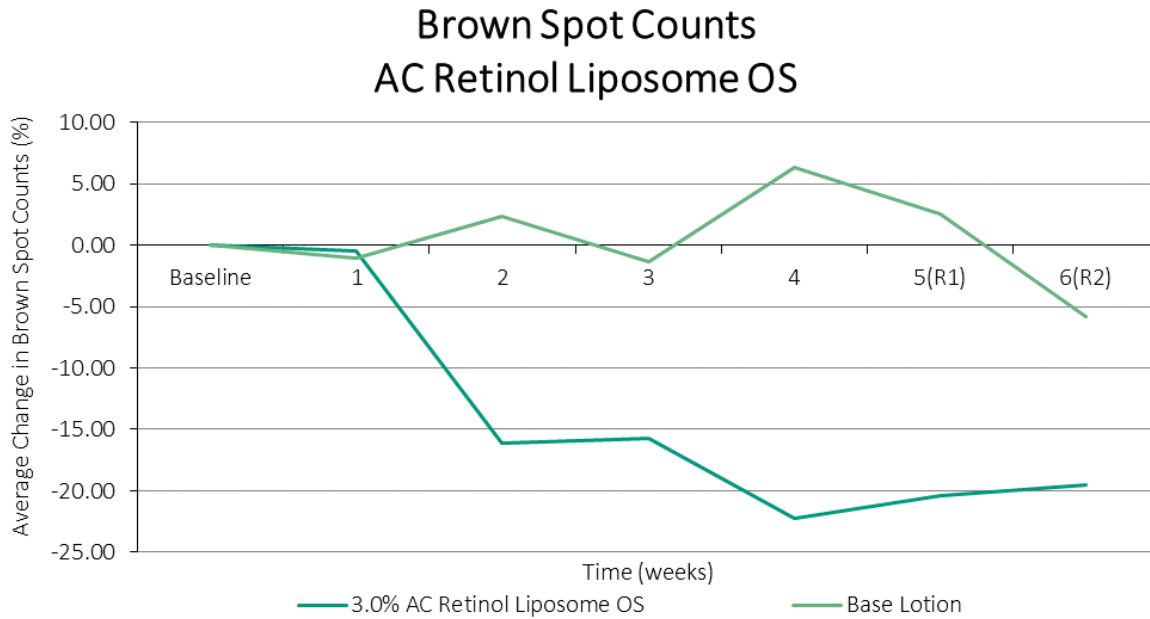
Fitzpatrick Skin Type Descriptions*	
Skin Type	Description
I	Always burns, never tans
II	Burns easily, tans minimally
III	Burns moderately, tans to light brown
IV	Burns minimally, tans to moderate brown
V	Rarely burns, tans to dark
VI	Never burns, least sensitive to changes

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

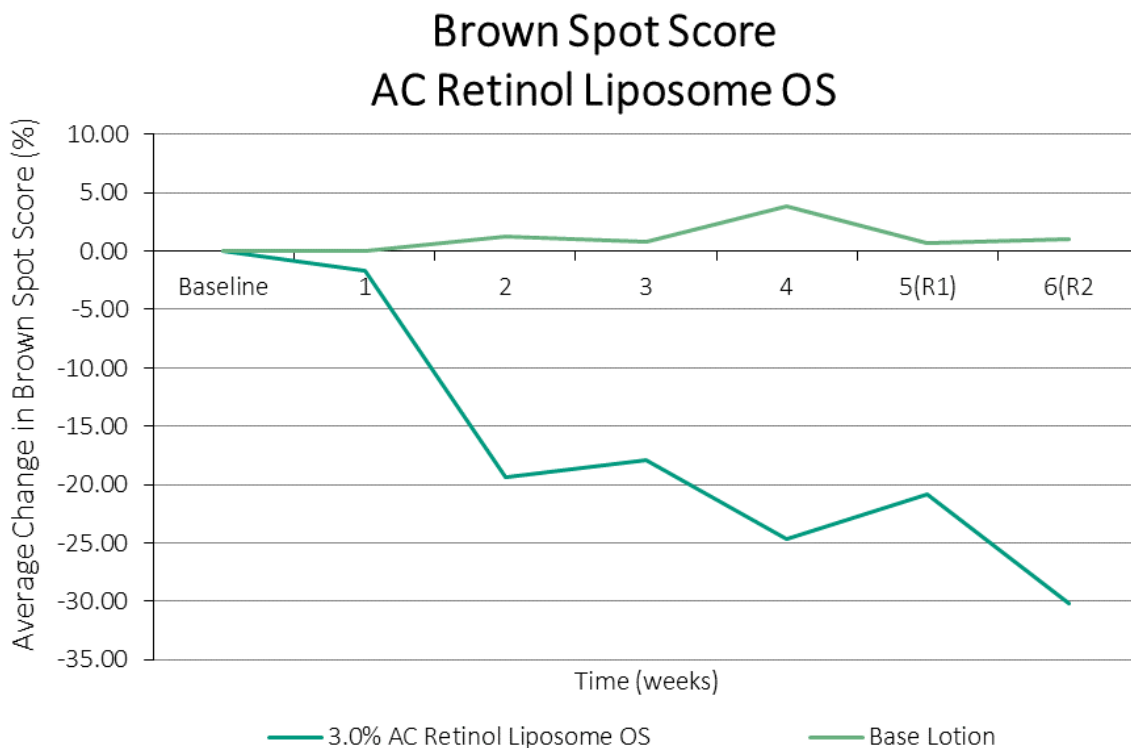
## Results

The data obtained from this study met criteria for a valid assay and the controls performed as anticipated. **AC Retinol Liposome OS** at a 3.0% concentration was able to decrease the appearance of Brown Spot Counts and Scores on the face during the four-week treatment period and during the two-week regression period.

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

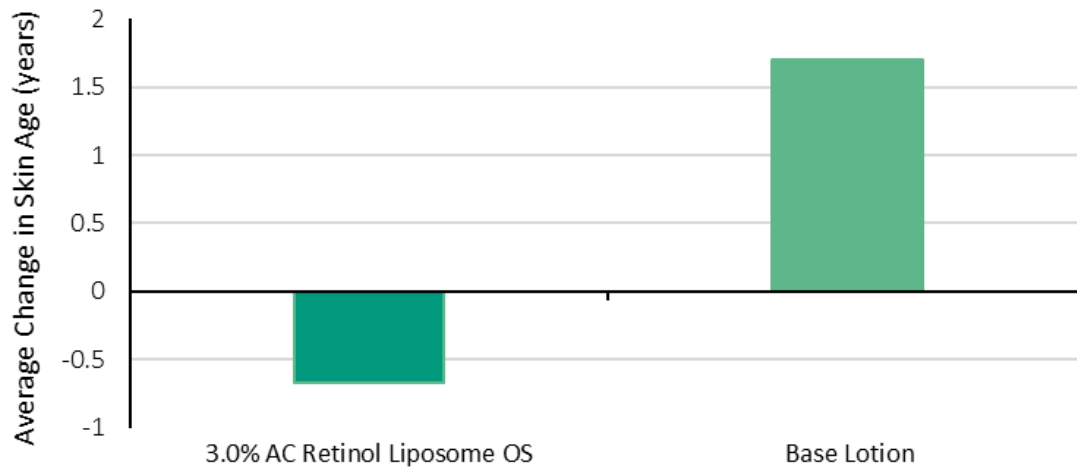


**Figure 1.** Average Percent Change of Brown Spot Counts from baseline. R1 and R2 indicate regression weeks with no application.



**Figure 2.** Average Percent Change of Brown Spot Counts from baseline. R1 and R2 indicate regression weeks with no application.

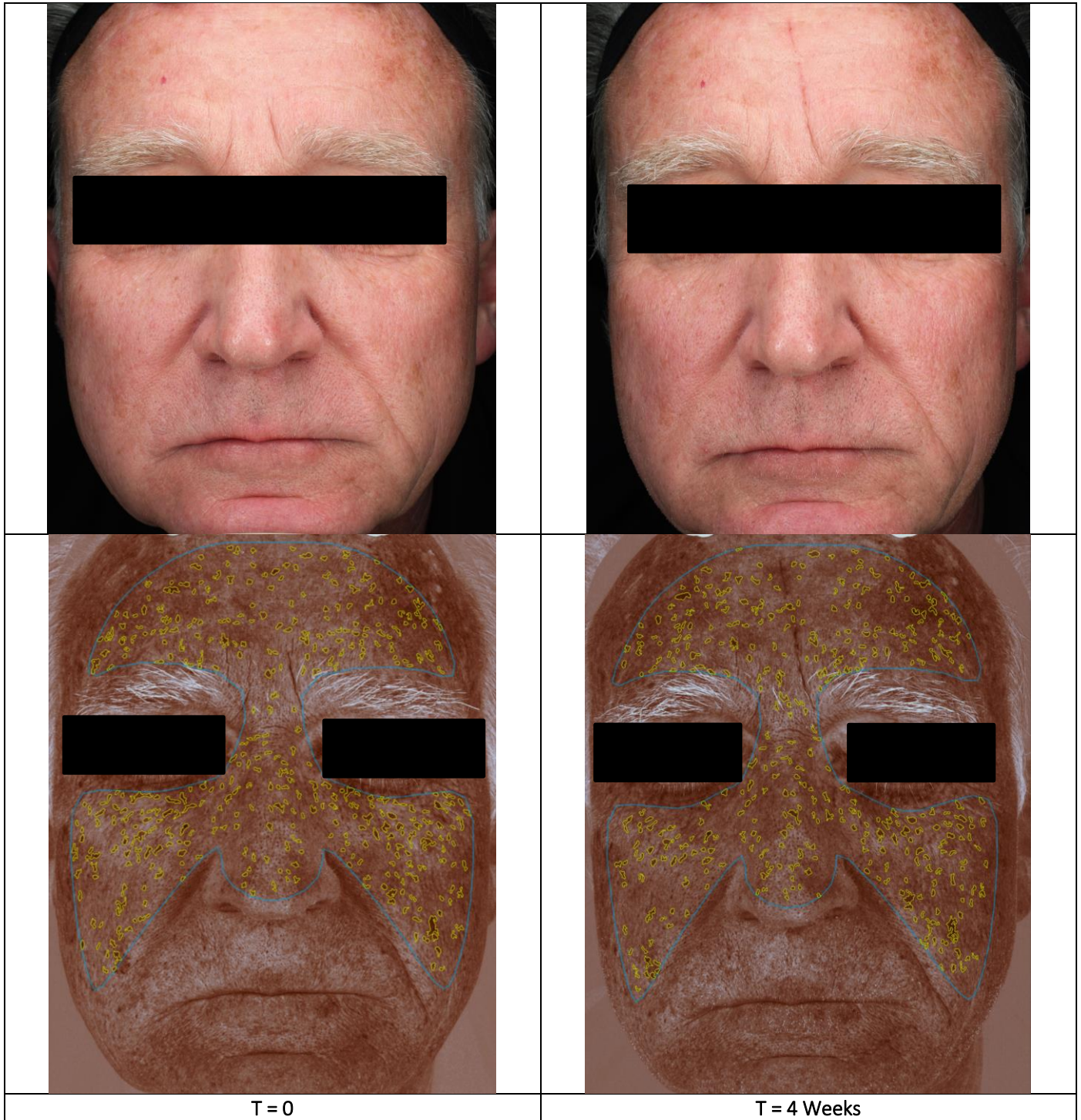
## Changes in VISIA Simulated Skin Age After Four Weeks



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



**Figure 5.** Images of Participant Treated with 3.0% AC Retinol Liposome OS. Natural photos (top) and VISIA Image Enhancement (bottom) before and after four weeks.

**Table 2.** T-test Analysis of the Percent Change (%) in Brown Spots Counts from baseline to T=4 weeks between 3.0% AC Retinol Liposome OS and the base lotion (n=15,  $\alpha=0.05$ , df=22).

	T = 0	T = 4
Mean	190.55	101.933
Variance	7483.78	1369.64
t Stat	3.51	
P(T<=t) two-tail	0.0019	
t Critical two-tail	2.073	

**Table 3.** T-test Analysis of the Percent Change (%) in Brown Spots Score from baseline to T=4 weeks between 3.0% AC Retinol Liposome OS and the base lotion (n=15,  $\alpha=0.05$ , df=22).

	T = 0	T = 4
Mean	20.51	16.02
Variance	28.64	7.97
t Stat	2.70	
P(T<=t) two-tail	0.012	
t Critical two-tail	2.07	

## Discussion

As evidenced in this four-week study, **AC Retinol Liposome OS** is capable of significantly reducing the appearance of brown spots on the face. After four weeks, participants applying 3.0% **AC Retinol Liposome OS** demonstrated a 22% decrease in the overall number of brown spots and a 25% reduction in the size and intensity (score) in those spots, compared to baseline. Conversely, base lotion application increased the total number of brown spots by 6% and augmented the size and intensity (score) of those brown spots by 4% after four weeks (Figures 1, 2, 4, 5; Tables 3, 4). These results indicate that applying **3.0% AC Retinol Liposome OS** for four weeks provides a reduction of brown spot appearance on the face resulting in a more youthful skin appearance.

After treatment ended, the size, intensity, and number of brown spots 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 20% reduction in the total number of brown spots, while the base lotion only produced a decrease of 6%. Similarly, 3.0% **AC Retinol Liposome OS** elicited a 30% decrease in brown spot size and intensity, whereas the base lotion increased brown spot scores by 1% (Figures 1, 2, 4, 5). These results indicate that after treatment ended, participants applying 3.0% **AC Retinol Liposome OS**, continued to see a reduction in size, intensity, and number of brown spots 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, 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 (Figure 3). 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 simulated skin age, and the number, size, and intensity of brown spots. In conclusion, 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.