

ACTIVE CONCEPTS LLC

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Tradename: AC ExoTone

Code: 60194

CAS #: 7732-18-5 & 85251-63-4 & 123465-35-0 (or) 8002-43-5

Test Request Form #: 10115

Lot #: N230530A

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

Study Director: Maureen Drumwright Principle Investigator: Kayla Patterson

Test Performed:

In-vivo VISIA Analysis

Introduction

UV Spots occur when melanin accumulates below the surface of the skin as a result of sun damage. UV Spots may not be visible to the naked eye under normal lighting conditions; however, they are visible with ultraviolent illumination. Although UV Spots may not be visible, their effects are detrimental to skin health and can expedite the process of visible ageing.

An *in-vivo* study was conducted over a period of six weeks to evaluate the effects of 3.0% **AC ExoTone** in a base lotion on UV Spots compared to the 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. UV Spots are outlined by yellow circles.

Materials

A. Equipment: VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA)



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Methods

This study was conducted using 10 M/F participants between the ages of 25-39 with Fitzpatrick skin types of I to IV (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 ExoTone** in a Simple[®] Hydrating Light Moisturizer for all skin types, while the other half used the Simple[®] Hydrating Light Moisturizer alone as a control.

Images were analyzed for UV Spots Feature Count. The UV Spots Feature Count indicates the number of discrete instances of pores within the analyzed region. Skin with lower counts is considered to be more youthful in appearance.

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

Table 1. The Fitzpatrick Classification of Skin Types Chart¹

Fitzpatrick Skin Type Descriptions*	
Skin Type	Description
	Always burns, never tans
	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 ExoTone** at a 3.0% concentration was able to decrease the appearance of UV Spot Counts on the face during the four-week treatment period and during the two-week regression period.



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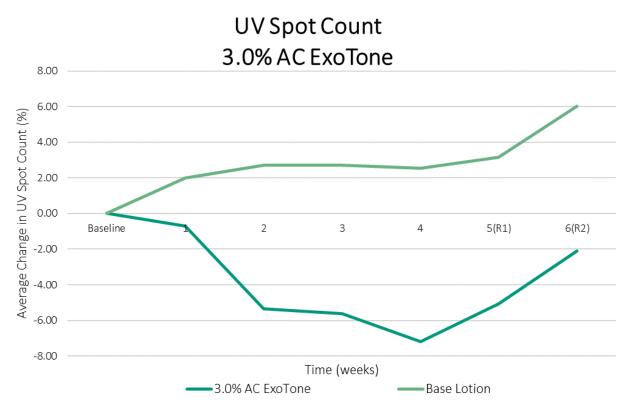


Figure 1. Average Percent Change of UV Spots from Baseline. R1 and R2 indicate regression weeks with no application.

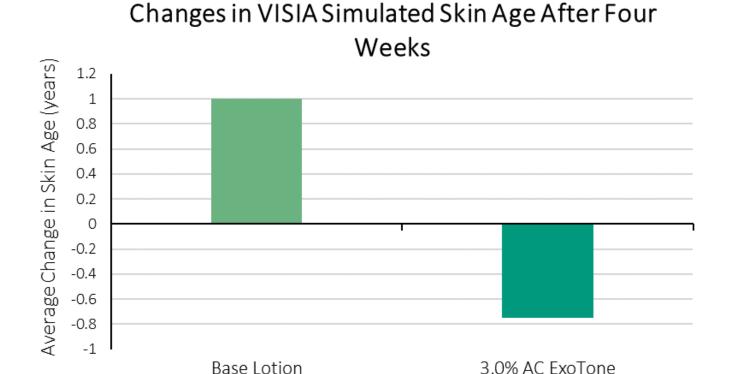


Figure 2. Changes in VISIA Simulated Skin Age of Participants After Four Weeks of 3.0% **AC ExoTone** and Base Lotion Application.



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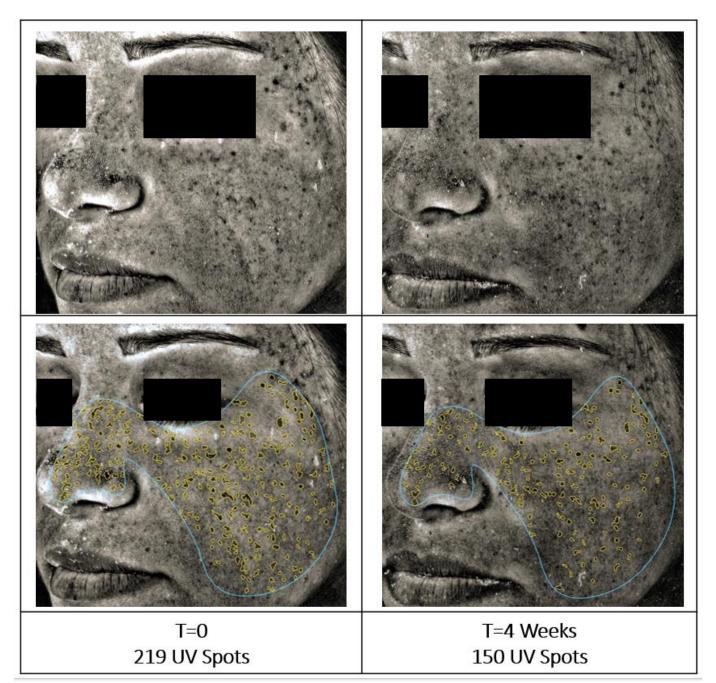


Figure 3. Images of Participant Treated with 3.0% **AC ExoTone**. Natural photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks.

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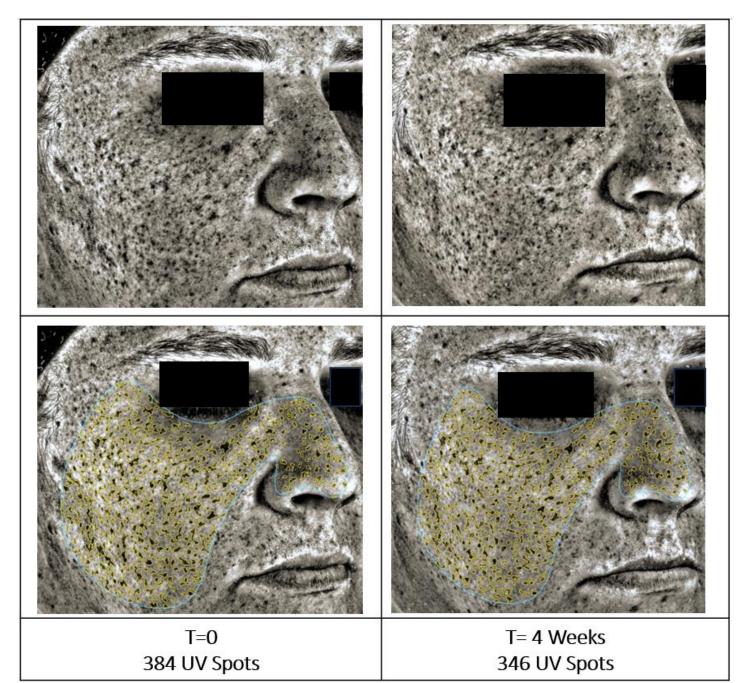


Figure 4. Images of Participant Treated with 3.0% **AC ExoTone**. Natural photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks.



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Discussion

As evidenced in this four-week study, **AC ExoTone** is capable of significantly reducing the appearance of UV Spots on the face. After four weeks, participants applying 3.0% **AC ExoTone** demonstrated a 7% decrease in the overall number of UV Spots, compared to baseline (Figure 1). Conversely, base lotion application increased the total number of UV Spots by 3% in four weeks when compared to baseline (Figure 1). Visually, participants experienced a decrease in UV Spots on the face after four weeks of applying 3.0% **AC ExoTone** (Figures 3, 4). These results indicate that applying 3.0% **AC ExoTone** for four weeks provides a reduction of UV Spot appearance on the face resulting in a more youthful skin appearance.

After treatment ended, the reduction of UV Spots for participants applying 3.0% **AC ExoTone** continued to outperform the base lotion alone. After two weeks of regression, the participants that applied the 3.0% **AC ExoTone** demonstrated a 2% reduction in the total number of UV Spots, while the base lotion produced an increase of 6% (Figure 1). These results indicate that after treatment ended, participants applying 3.0% **AC ExoTone** continued to see a reduction in the number of UV Spots on the face.

Additionally, the VISIA software analyzes each image and provides a Simulated Skin Age metric for each participant. After treatment ended, 3.0% **AC ExoTone** decreased the VISIA Simulated Skin Age by 1 year, while the base lotion demonstrated an increase of 1 year (Figure 2). These results indicate that applying 3.0% **AC ExoTone** for four weeks provides a reduction in VISIA Simulated Skin Age which reduced the visual impacts of normal aging.

Collectively, we provide evidence that applying **AC ExoTone** for four weeks reduces simulated skin age, and the number of UV Spots present on the analyzed region. In conclusion, utilizing **AC ExoTone** at the recommended use levels improves skin health and provides a more youthful appearance by reducing the visual consequences of UV Spots.

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/