

Tradename: AC ExoEternal

Code: 60200

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Test Request Form #: 13057

Lot #: N2507010

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

Study Director: *Daniel Shill*

Principal Investigator: *Kayla Patterson*

Test Performed:

In vivo VISIA Analysis: UV Spots

Introduction

UV spots occur when melanin accumulates beneath the surface of the skin as a result of cumulative sun exposure. These spots may not be visible to the naked eye under normal lighting conditions; however, they become apparent under ultraviolet illumination. In mature skin, years of repeated UV exposure combined with slower cellular turnover and altered melanocyte regulation can lead to greater accumulation and persistence of UV spots. Although they may not be immediately visible, UV spots indicate underlying photodamage that compromises skin health and accelerates the development of visible signs of aging, including uneven tone, texture changes, and loss of luminosity.

Accordingly, an *in vivo* study was conducted over a period of six weeks to evaluate the ability of **AC ExoEternal** to reduce UV Spots on the face of mature skin.

Study Principle

Participants applied specific products to designated halves of their face twice a day for four weeks. Measurements were collected once a week during the four-week study period and two weeks after application ceased. Photographs of participant faces were obtained using the VISIA Complexion Analysis System and analyzed for UV Spots. UV Spots are the absorption of UV light by epidermal melanin just below the skin surface.

Materials

- A. Equipment:** VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA)
- B. Products:** Simple® Hydrating Light Moisturizer, Simple® Cleansing Facial Wipes
- C. Software:** Excel Analysis ToolPak (Microsoft)

Methods

Ten volunteers between the ages of 59 and 71, who were known to be free of any skin pathologies with Fitzpatrick skin types of I to IV, participated in this study (Table 1).

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

Each half of a participant's face was randomly assigned to a specific condition and treatment (Table 2). The Base Lotion utilized in this study was Simple® Hydrating Light Moisturizer. Following Baseline measurements, participants were provided both conditions and were instructed to apply 0.2 g of product to the specified half of their face twice daily 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. Baseline measurements were taken prior to starting the lotion regimen. Measurements were collected once a week during the four-week use period and two weeks after application ceased. Participants were instructed not to wear makeup or SPF products for the measurement sessions.

Table 2. Descriptions of the Conditions and Treatments for each Skin Test Site

Skin Test Site	Condition	Treatment / Test Article Application Description
1	Base Lotion Control	Base Lotion
2	2.0% AC ExoEternal	2.0% AC ExoEternal in Base Lotion

Photographic assessments were performed using the VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA). The VISIA System ensured consistent positioning of each participant's head and each participant cleaned their face with a gentle facial wipe (Simple® Cleansing Facial Wipes) before images were obtained. The photographic images were captured with standard, cross-polarized, parallel polarized, and ultraviolet light.

Images were analyzed for UV Spot Feature Count. The UV Spot Feature Count indicates the number of discrete instances of UV Spots, without regard to the size or intensity, within the analyzed region. UV Spots are the absorption of UV light by epidermal melanin just below the skin surface. Therefore, skin with lower UV Spot Counts indicates a more youthful appearance. To further demonstrate the impact of reducing UV Spot Counts on skin appearance, the TruSkin Age™ for each condition was included. TruSkin Age™ is a calculated number performed by VISIA to represent the participant's age of their skin. TruSkin Age™ is calculated by comparing the percentile scores for UV Spots to others of the same age group, skin type, and gender. The data are displayed as averages and t-test analyses were performed with statistical significance accepted at $p \leq 0.05$. Percent change is expressed relative to Baseline values and calculated by the following equation:

$$\text{Percent Change (\%)} = \frac{UV\ Spot\ Count_{Week\ of\ Application} - UV\ Spot\ Count_{Baseline}}{UV\ Spot\ Count_{Baseline}} \times 100$$

Results

The data obtained met criteria for a valid study and the Base Lotion performed as anticipated. Application of 2.0% AC ExoEternal twice a day for four weeks demonstrated a reduction in the number of UV Spots every week throughout the four-week treatment period.

Change in UV Spot Count AC ExoEternal

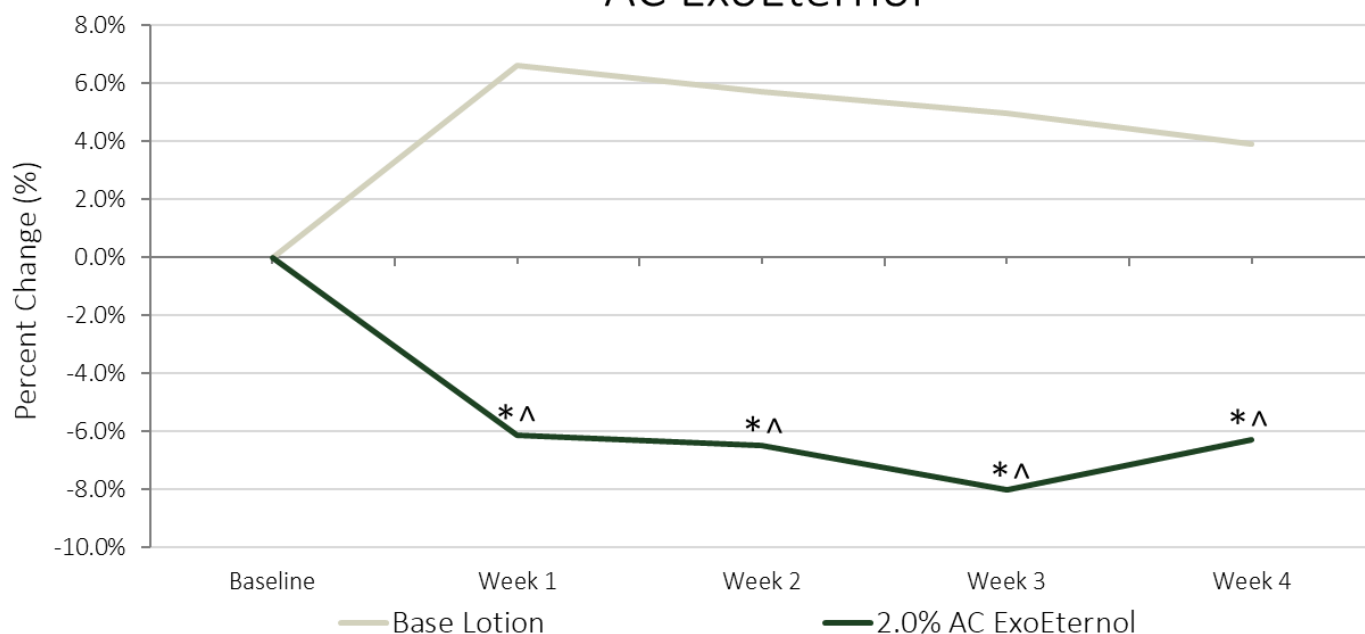


Figure 1. Change in UV Spot Count from Baseline. R1 and R2 indicate One and Two Weeks with no application. * indicates significance ($p \leq 0.05$) compared to Baseline values. ^ indicates significance ($p \leq 0.05$) compared to Base Lotion within the same timepoint.

Table 3. P-values from t-test Analyses of Change in UV Spot Count from Baseline to After Four Weeks of Application.

* indicates significance ($p \leq 0.05$) compared to Baseline values.

	Baseline vs After Four Weeks of Application
Base Lotion	0.220
2.0% AC ExoEternal	0.004*

Table 4. T-test Analyses of Change in UV Spot Count between Base Lotion and 2.0% AC ExoEternal After Four Weeks of Application. ^ indicates significance ($p \leq 0.05$) compared to Base Lotion within the same timepoint.

	After One Week of Application	After Two Weeks of Application	After Three Weeks of Application	After Four Weeks of Application
P-value	0.045^	0.048^	0.040^	0.021^

Change in VISIA TruSkin Age™ After Four Weeks AC ExoEternal

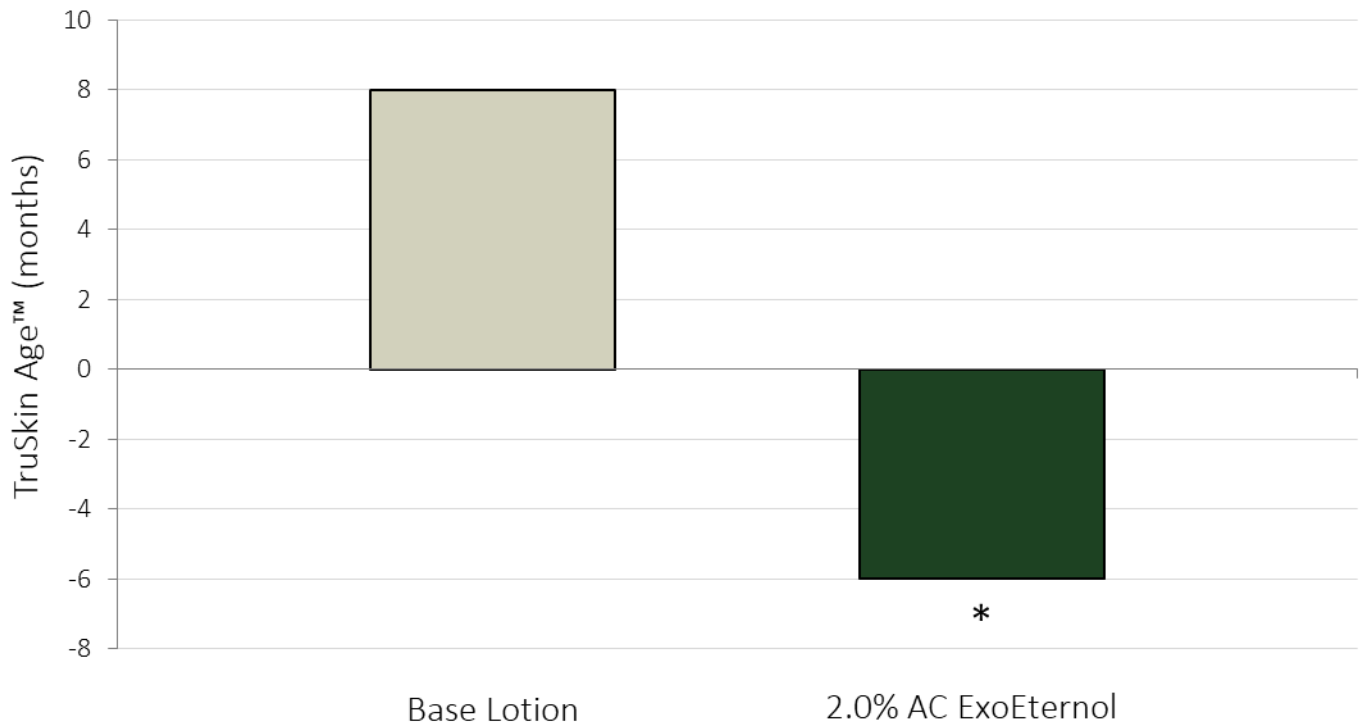


Figure 2. Changes in VISIA TruSkin Age™ of Participants After Four Weeks of 2.0% **AC ExoEternal** and Base Lotion Application. * indicates significance ($p \leq 0.05$) between conditions.

Table 5. T-test Analyses of Change in VISIA TruSkin Age™ in Participants After Four Weeks of Application. * indicates significance ($p \leq 0.05$) between conditions.

	Base Lotion vs 2.0% AC ExoEternal
P-value	0.001*

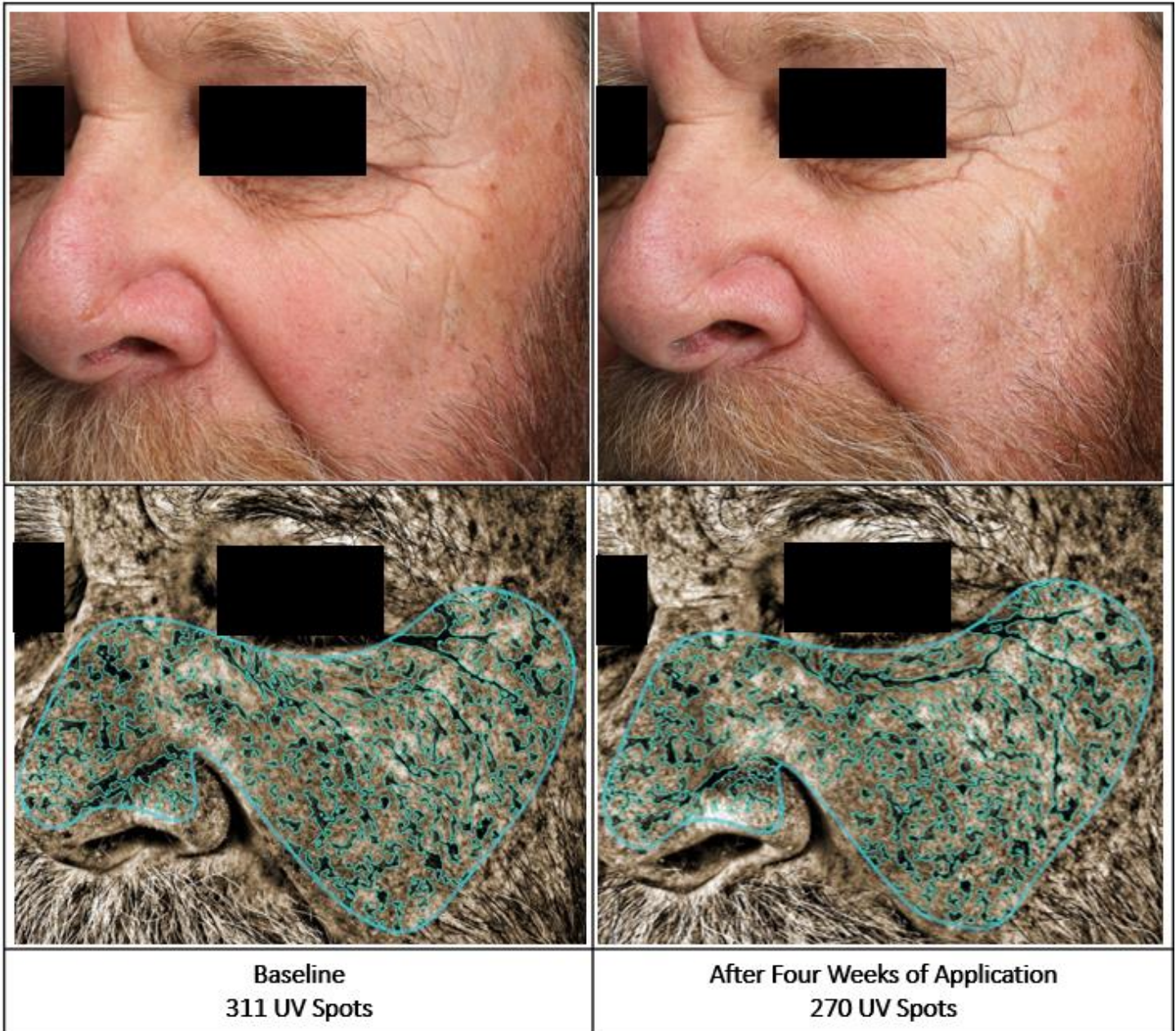


Image 1. Images of Participant Treated with 2.0% AC ExoEternal. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks. UV Spots are the absorption of UV light by epidermal melanin just below the skin surface and denoted by the yellow-outlined shapes.

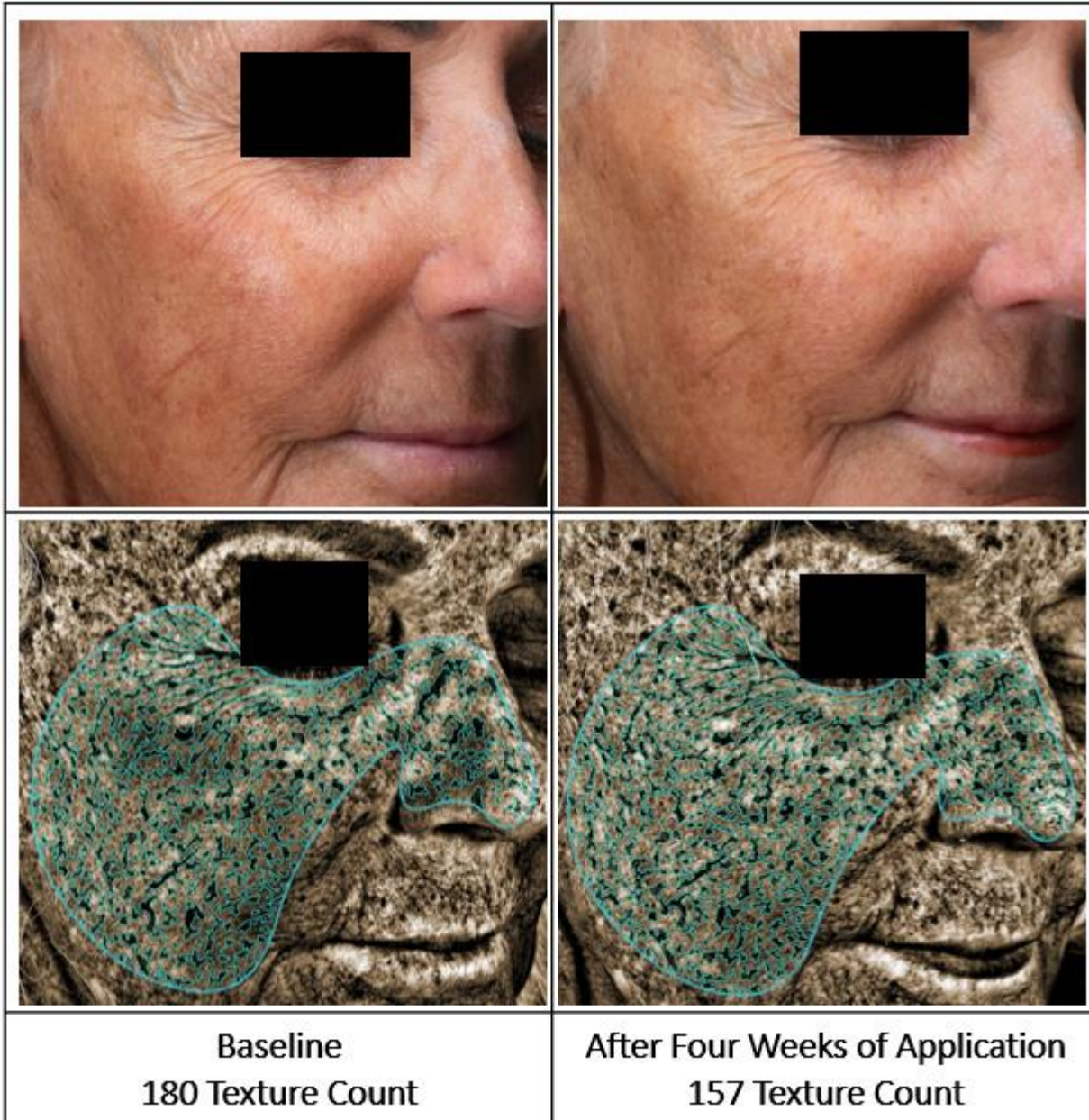


Image 2. Images of Participant Treated with 2.0% AC ExoEternal. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks. UV Spots are the absorption of UV light by epidermal melanin just below the skin surface and denoted by the yellow-outlined shapes.

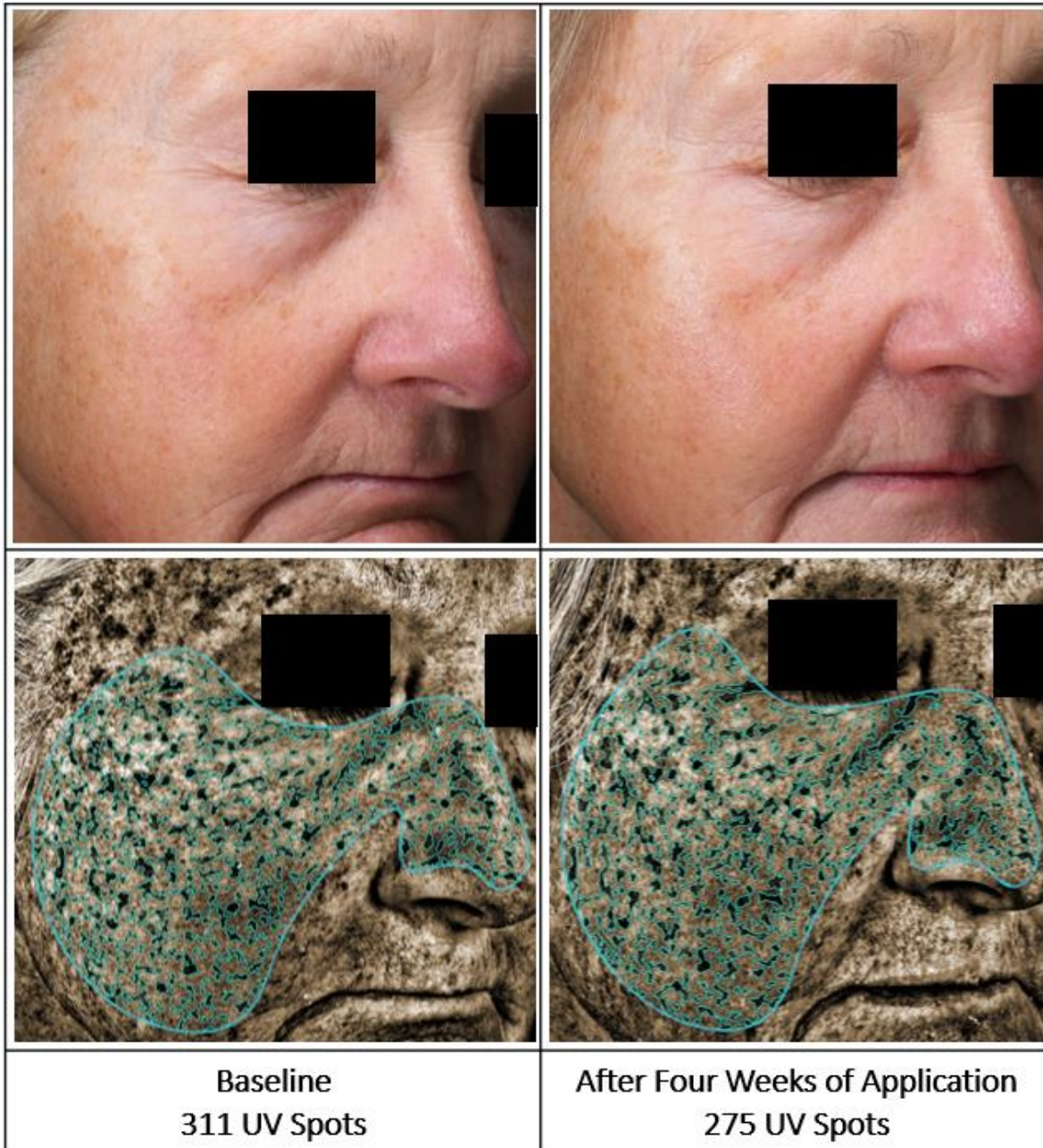


Image 3. Images of Participant Treated with 2.0% AC ExoEternal. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks. UV Spots are the absorption of UV light by epidermal melanin just below the skin surface and denoted by the yellow-outlined shapes.

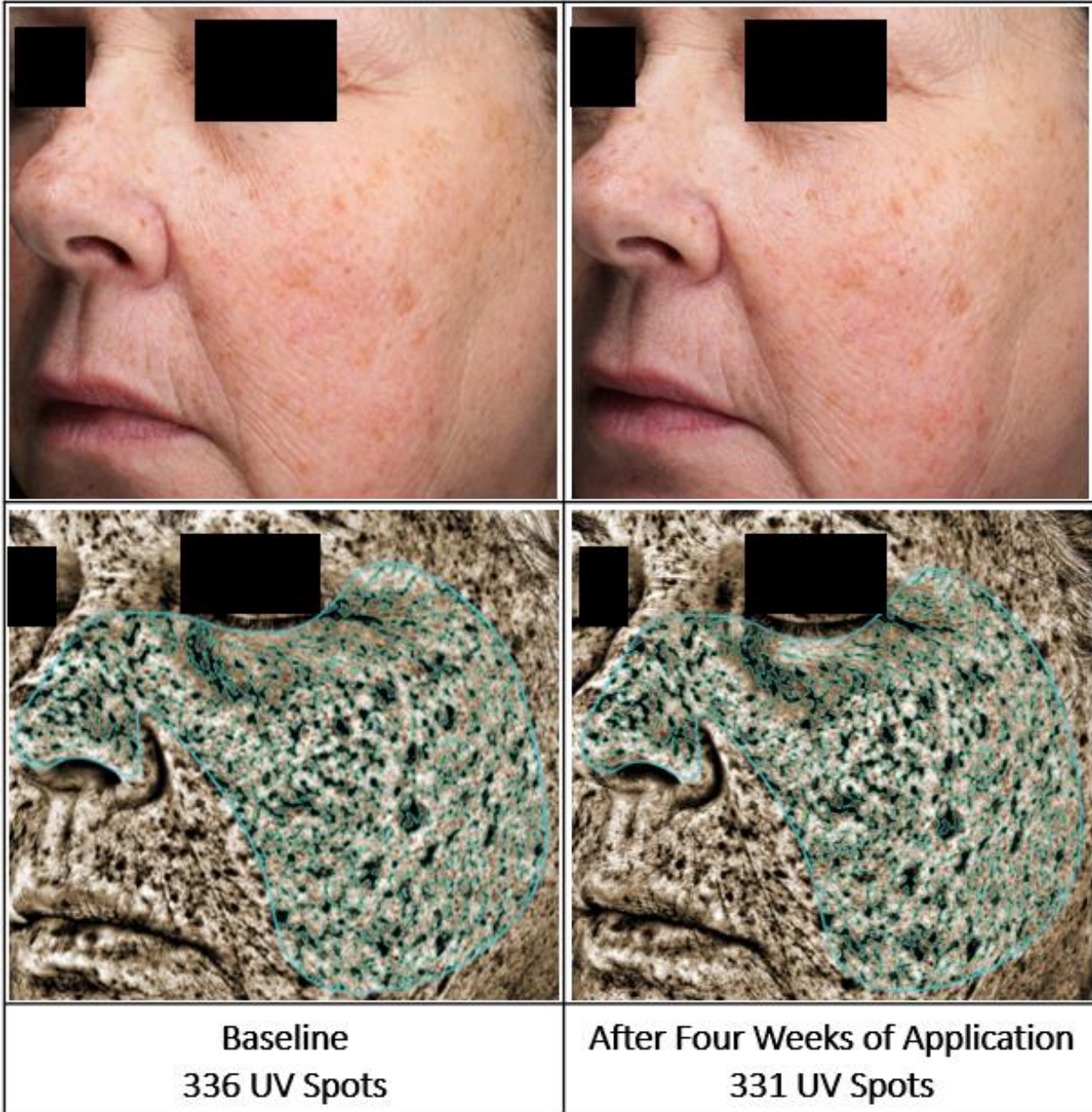


Image 4. Images of Participant Treated with 2.0% AC ExoEternal. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks. UV Spots are the absorption of UV light by epidermal melanin just below the skin surface and denoted by the yellow-outlined shapes.

Discussion

As evidenced in this six-week study, **AC ExoEternal** reduces the appearance of UV Spots on the face, in addition to reducing VISIA TruSkin Age™. The amount of UV Spots present was not significantly altered throughout the study with Base Lotion application, indicating the Base Lotion does not exert significant UV Spot reducing properties on the skin (Figure 1; Table 3). Conversely, applying 2.0% **AC ExoEternal** for four weeks resulted in a 6% decrease in the overall number of UV Spots present, compared to baseline (Figure 1; Table 3). Moreover, applying 2.0% **AC ExoEternal** significantly decreased the amount of UV Spots present compared to the Base Lotion after every week of application (Figure 1; Table 4). These results indicate that applying 2.0% **AC ExoEternal** for four weeks provides a reduction of UV Spot appearance on the face resulting in a more youthful skin appearance (Images 1, 2, 3, 4).

Additionally, the VISIA software analyzes each image and provides a TruSkin Age™ metric for each participant. TruSkin Age™ represents the age of participants' skin by comparing UV Spot percentile scores against individuals of the same age group, skin type, and gender in the VISIA database. After four weeks of application, 2.0% **AC ExoEternal** significantly decreased TruSkin Age™ by 6 months, while the Base Lotion demonstrated an increase of 8 months (Figure 2; Table 5). These results indicate application of 2.0% **AC ExoEternal** for four weeks provides a reduction in VISIA TruSkin Age™ which reduces the visual impacts of normal aging.

Taken together, these results indicate **AC ExoEternal** reduces the appearance of UV Spots and simulated skin age when added to personal care applications at recommended use levels. Collectively, **AC ExoEternal** 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/>