

**Tradename:** AC ExoEternal

**Code:** 60200

**CAS #:** 7732-18-5 & 68333-16-4 (or) 92128-79-5 & 90082-61-4 (or) 68132-21-8 & 123465-35-07

**Test Request Form #:** 13057

**Lot #:** N2507010

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

**Study Director:** Daniel Shill

**Principal Investigator:** Kayla Goodson

## **Test Performed:**

*In vivo* VISIA Analysis: Brown Spots

## **Introduction**

Brown Spots are lesions that contribute to an uneven appearance on and within the skin, including freckles, hyperpigmentation, and melasma. These spots result from excess melanin production by melanocytes located in the basal layer of the epidermis. In mature skin, age-related changes such as cumulative ultraviolet exposure, decreased epidermal turnover, and altered melanocyte regulation can lead to increased formation, persistence, and visibility of Brown Spots. Reducing the appearance of Brown Spots is therefore especially important for aging skin, as improved tone uniformity is closely associated with a more youthful and healthier appearance.

Accordingly, an *in vivo* study was conducted over a period of four weeks to evaluate the ability of **AC ExoEternal** to reduce Brown 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. Photographs of participant faces were obtained using the VISIA Complexion Analysis System and analyzed for Brown Spots.

## **Materials**

- A. Equipment:** VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA)
- B. Base Lotion:** 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 III, participated in this study (Table 1).

**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

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. 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 cross-polarized imaging.

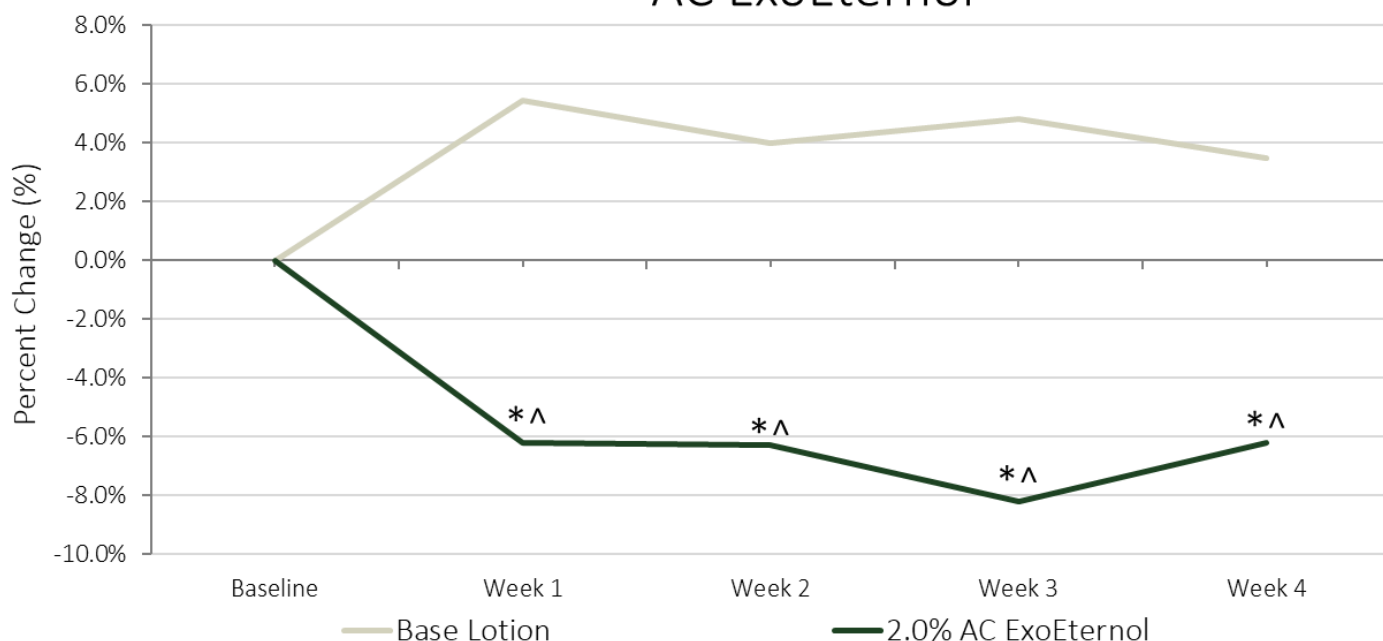
Images were analyzed for Brown Spot Feature Count, which indicates the number of discrete instances of Brown Spots, without regard to the size or intensity, within the analyzed region. Brown Spots are lesions on and deeper within the skin that produce an uneven skin appearance due to excess melanin production. Therefore, skin with lower Brown Spot counts indicate a more youthful appearance. To further demonstrate the impact of reducing Brown 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 Brown 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:

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

## 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 Brown Spots every week throughout the four-week treatment period.

## Change in Brown Spot Count AC ExoEternal



**Figure 1.** Change in Brown Spot Count from Baseline. \* 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 Brown Spot Count from Baseline to After Four Weeks of Application.

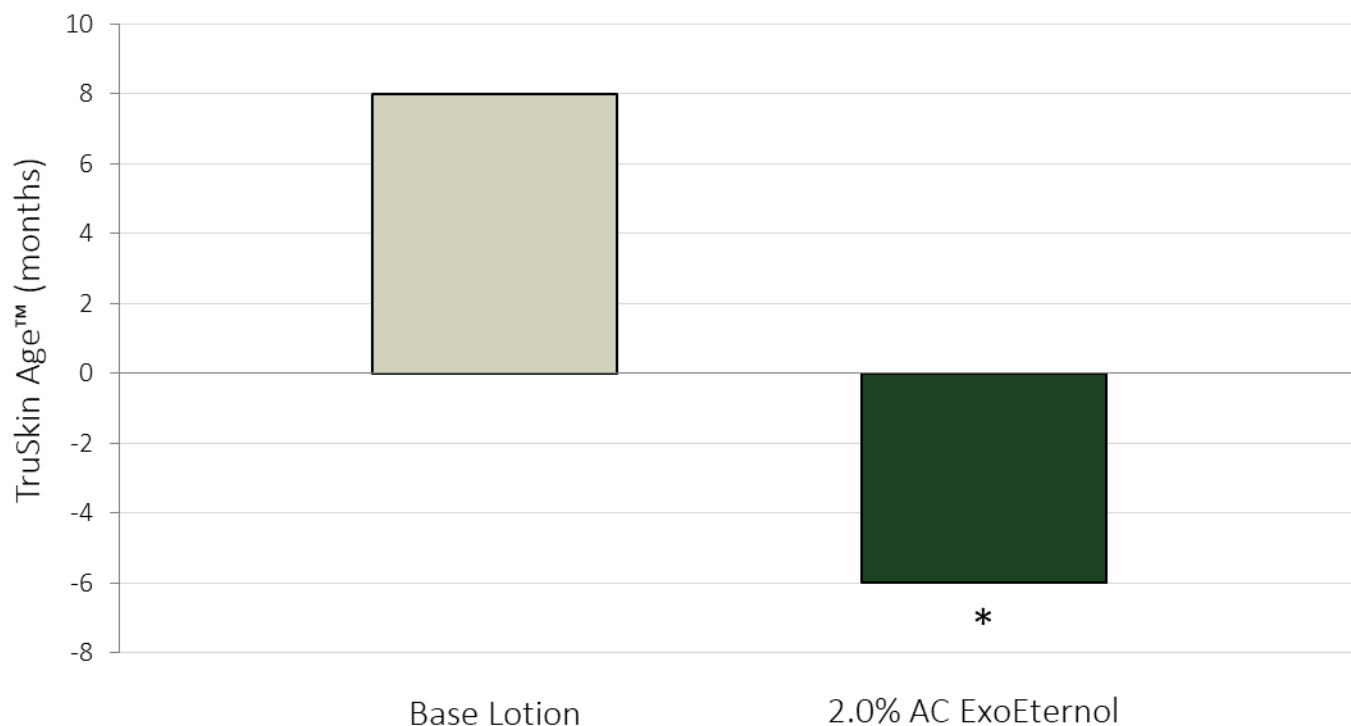
\* indicates significance ( $p \leq 0.05$ ) compared to Baseline values.

	Baseline vs After Four Weeks of Application
Base Lotion	0.174
2.0% AC ExoEternal	0.036*

**Table 4.** T-test Analyses of Change in Brown 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	0.020^	0.024^	0.027^	0.032^

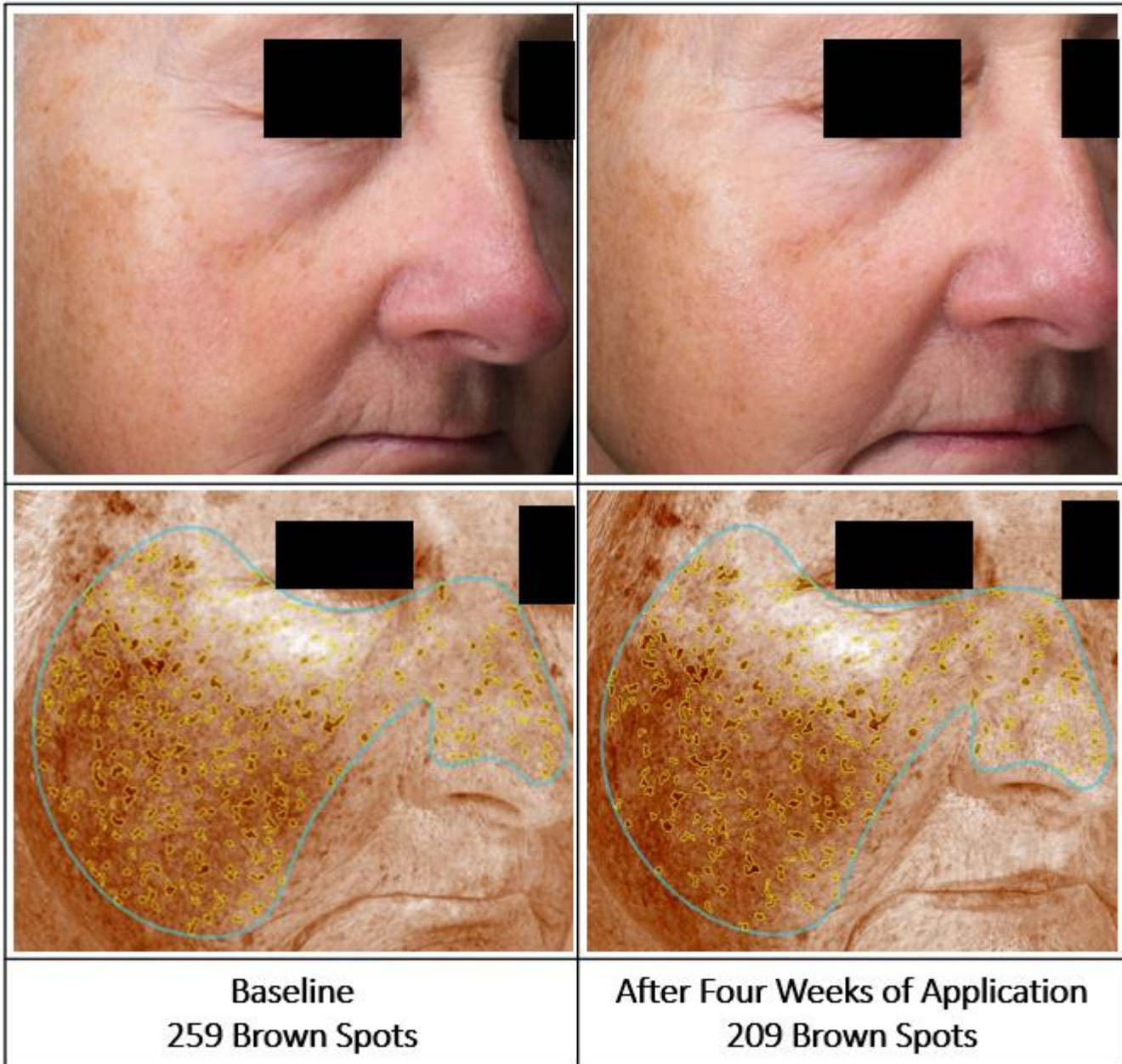
## Change in VISIA TruSkin Age™ After Four Weeks AC ExoEternal



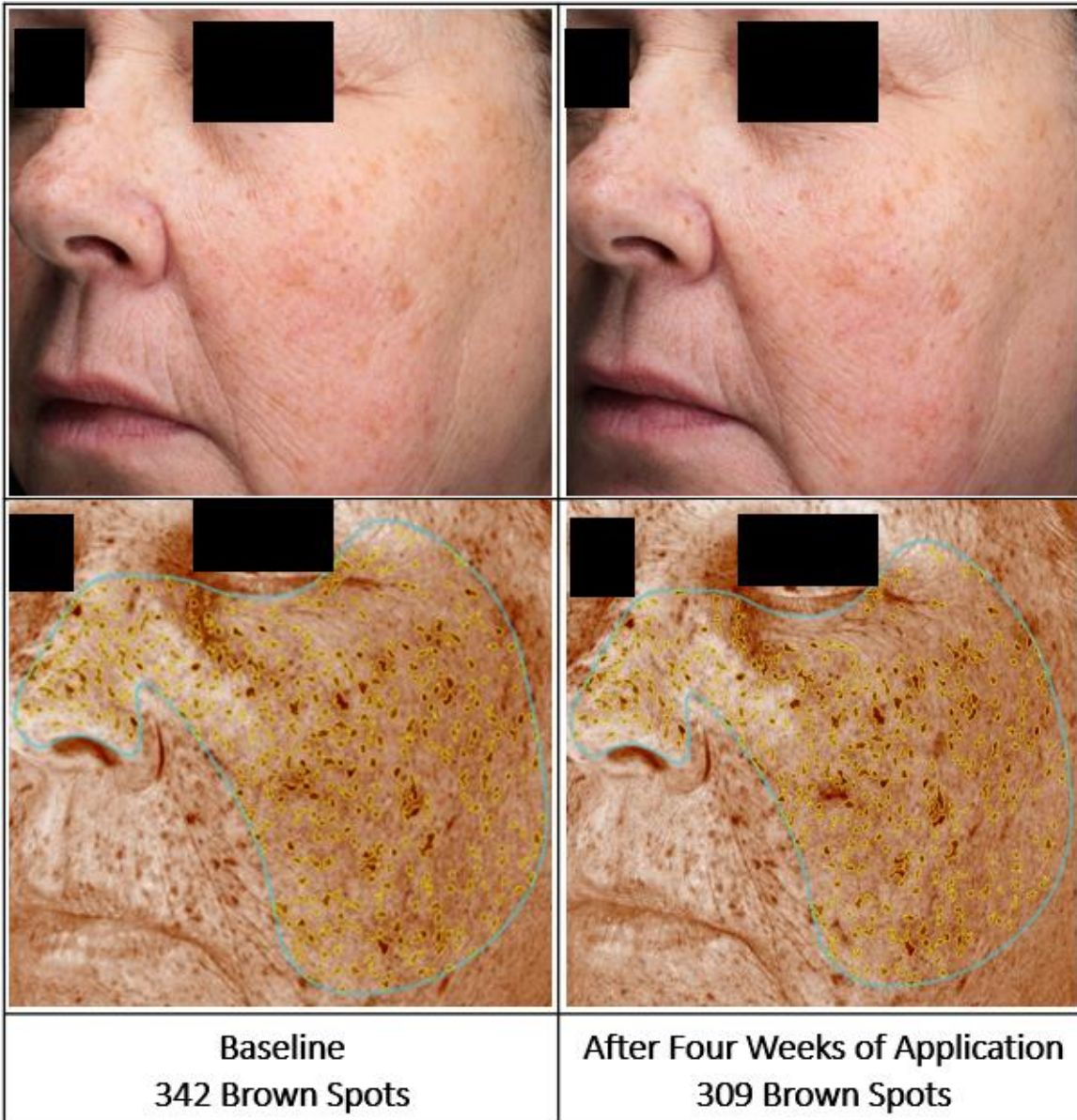
**Figure 2.** Changes in VISIA TruSkin Age™ of Participants After Four Weeks of 2.0% **AC ExoEternal** and Base Lotion Application. \* indicates significance ( $p \leq 0.05$ ) between conditions.

**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% <b>AC ExoEternal</b>
<b>P-value</b>	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. Brown Spots are lesions on and deeper within the skin that produce an uneven skin appearance due to excess melanin production and denoted by 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. Brown Spots are lesions on and deeper within the skin that produce an uneven skin appearance due to excess melanin production and denoted by yellow-outlined shapes.

## Discussion

As evidenced in this four-week study, **AC ExoEternal** reduces the appearance of Brown Spots on the face, in addition to reducing VISIA TruSkin Age™. The amount of Brown Spots present was not significantly altered throughout the study with Base Lotion application, indicating the Base Lotion does not exert significant Brown 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 Brown Spots present, compared to baseline (Figure 1; Table 3). Moreover, applying 2.0% **AC ExoEternal** significantly decreased the amount of Brown 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 Brown Spot appearance on the face resulting in a more youthful skin appearance (Images 1, 2).

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 Brown 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 Brown Spots 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/>