VISIA Results – Reduction in Surface Spots

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Tradename: AC LumiVitis

Code: 21032

CAS #: 8013-01-2 & 85594-37-2 (or) 84929-27-1 & 68333-16-4 (or) 1686112-36-6 (or) 9015-54-7

Test Request Form #: 13665

Lot #: 9418748

Sponsor: *Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092*
Study Director: *Daniel Shill*
Principal Investigator: *Kayla Goodson*

Test Performed:

In-vivo VISIA Analysis: Surface Spots

Introduction

Spots are typically brown or red skin lesions, including hyperpigmentation, freckles, and acne scars. Spots are distinguishable by their color as they vary in shape and size. Reducing spots allows the skin to look more youthful in appearance which is an increasing desire in the cosmetic world. In addition, blue light exposure has been reported to promote pro-inflammatory responses through modulation of cytokine signaling pathways, potentially contributing to increased skin redness, uneven tone, and compromised clarity. Prolonged or unregulated exposure to blue light may exacerbate oxidative stress and inflammation, thereby negatively impacting overall skin appearance. Excessive blue light exposure may undermine efforts to maintain a balanced and even complexion, despite a daily skincare routine.

Accordingly, an *in-vivo* study was conducted over a period of four weeks to evaluate the ability of **AC LumiVitis** to reduce Surface Spots on the face.

Study Principle

Participants applied specific products to designated halves of their face twice a day for four weeks. Measurements were collected once a week, and blue light exposure was monitored via weekly screen time, during the four-week study period. Photographs of participant faces were obtained using the VISIA Complexion Analysis System and analyzed for Surface Spots. Surface Spots are brown or red skin lesions distinguished by their distinct color and contrast from the background skin tone. Surface spots are photographed with standard lighting and are outlined in blue within the masked area.

Materials

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

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Methods

10 volunteers between the ages of 24 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[1]

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 Equate™ Beauty Oil-Free Facial Moisturizer. Baseline photographs were captured after participants were acclimated in a temperature-controlled room for five minutes to ensure measurements were not skewed and reflective of real-world conditions. 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	Base Lotion
2	2.0% **AC LumiVitis**	2.0% **AC LumiVitis** in Base Lotion

Participant blue light exposure was monitored throughout the study period. Weekly screen time was tracked directly through each participant's mobile device to objectively quantify blue light exposure under real-world conditions. To qualify for inclusion in the study, participants were required to have an average daily screen time of at least 2 hours and 30 minutes, ensuring sufficient baseline exposure to blue light. Over the course of the study, the average weekly blue light exposure recorded via participants' mobile devices was 4 hours and 5 minutes.

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.

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Images were analyzed for Surface Spot Feature Count. The Surface Spot Feature Count indicates the number of discrete instances of Surface Spots, without regard to the size or intensity, within the analyzed region. Surface Spots can represent a variety of red or brown skin lesions such as freckles, acne scars, or hyperpigmentation and are photographed with standard lighting. Therefore, skin with lower Surface Spot Counts indicates a more youthful appearance. To further demonstrate the impact of reducing Surface 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 Surface 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:

$$Percent\ Change\ (\%) = \frac{Surface\ Spot\ Count_{Week\ of\ Application} - Surface\ Spot\ Count_{Baseline}}{Surface\ Spot\ Count_{Baseline}}$$

Results

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

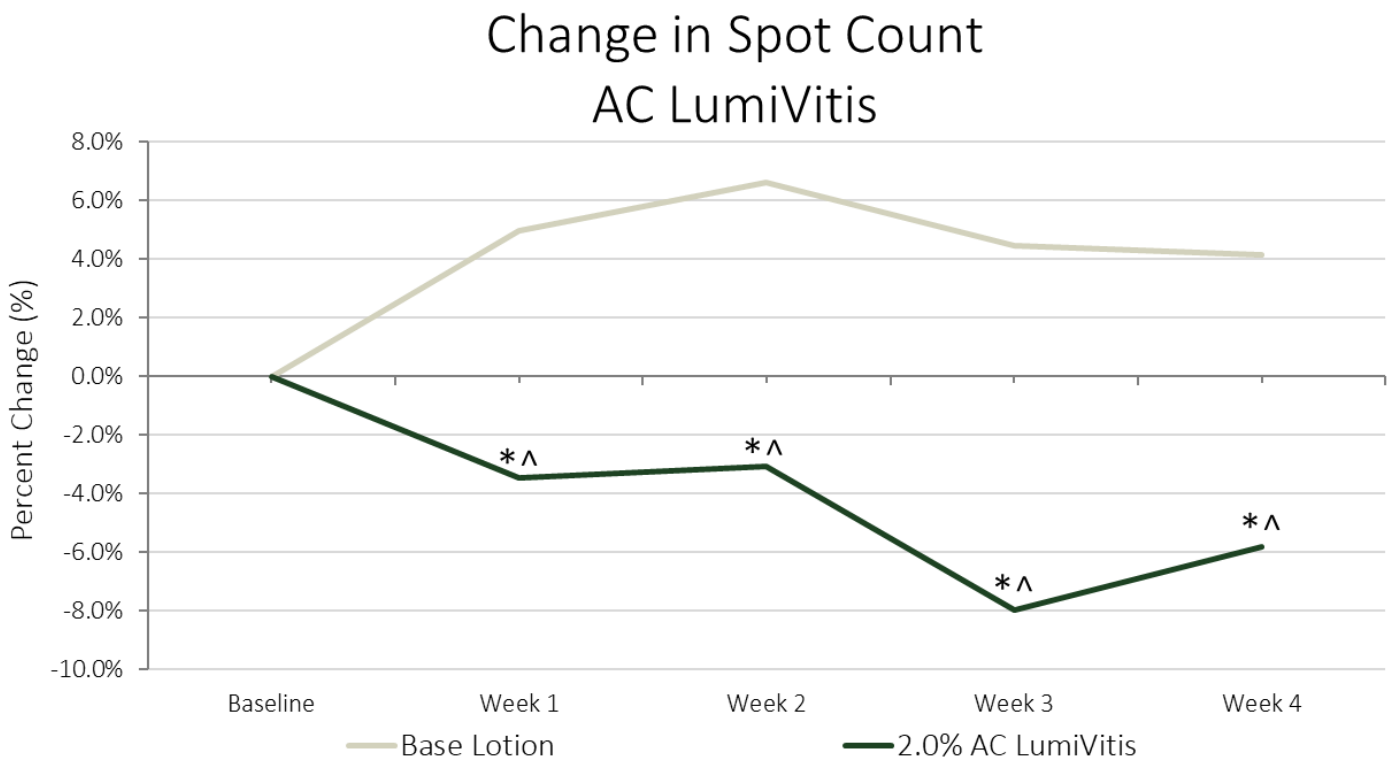

Figure 1. Change in Surface Spot Count from Baseline. * indicates significance ($p \leq 0.05$) compared to Baseline values. ^ indicates significance ($p \leq 0.05$) compared to Base Lotion within the same timepoint.

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Table 3. P-values from t-test Analyses of Change in Surface 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	0.222
2.0% **AC LumiVitis**	0.013*

Table 4. T-test Analyses of Change in Surface Spot Count between Base Lotion and 2.0% **AC LumiVitis** 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	< 0.001^	< 0.001^	< 0.001^	< 0.001^

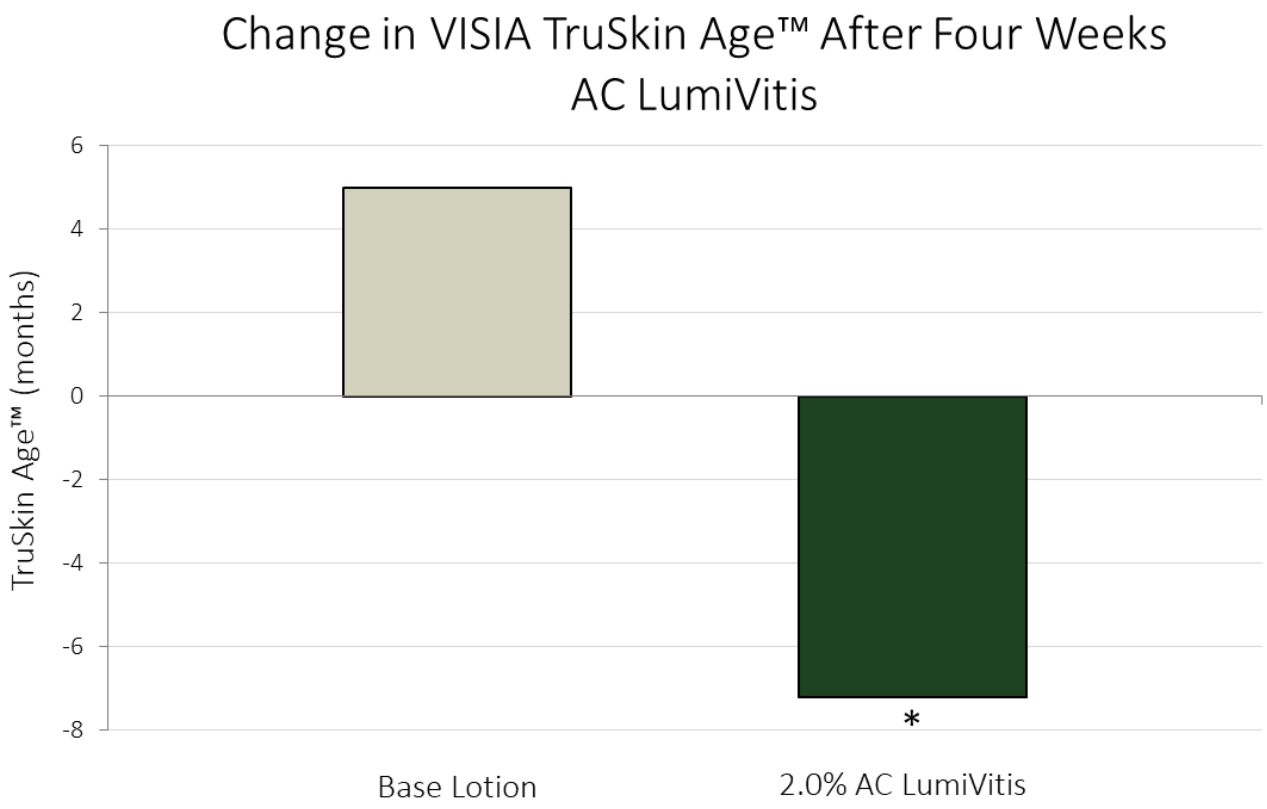

Figure 2. Changes in VISIA TruSkin Age™ of Participants After Four Weeks of 2.0% **AC LumiVitis** and Base Lotion Application. * indicates significance ($p \leq 0.05$) between conditions.

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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 LumiVitis**
P-value	0.018*

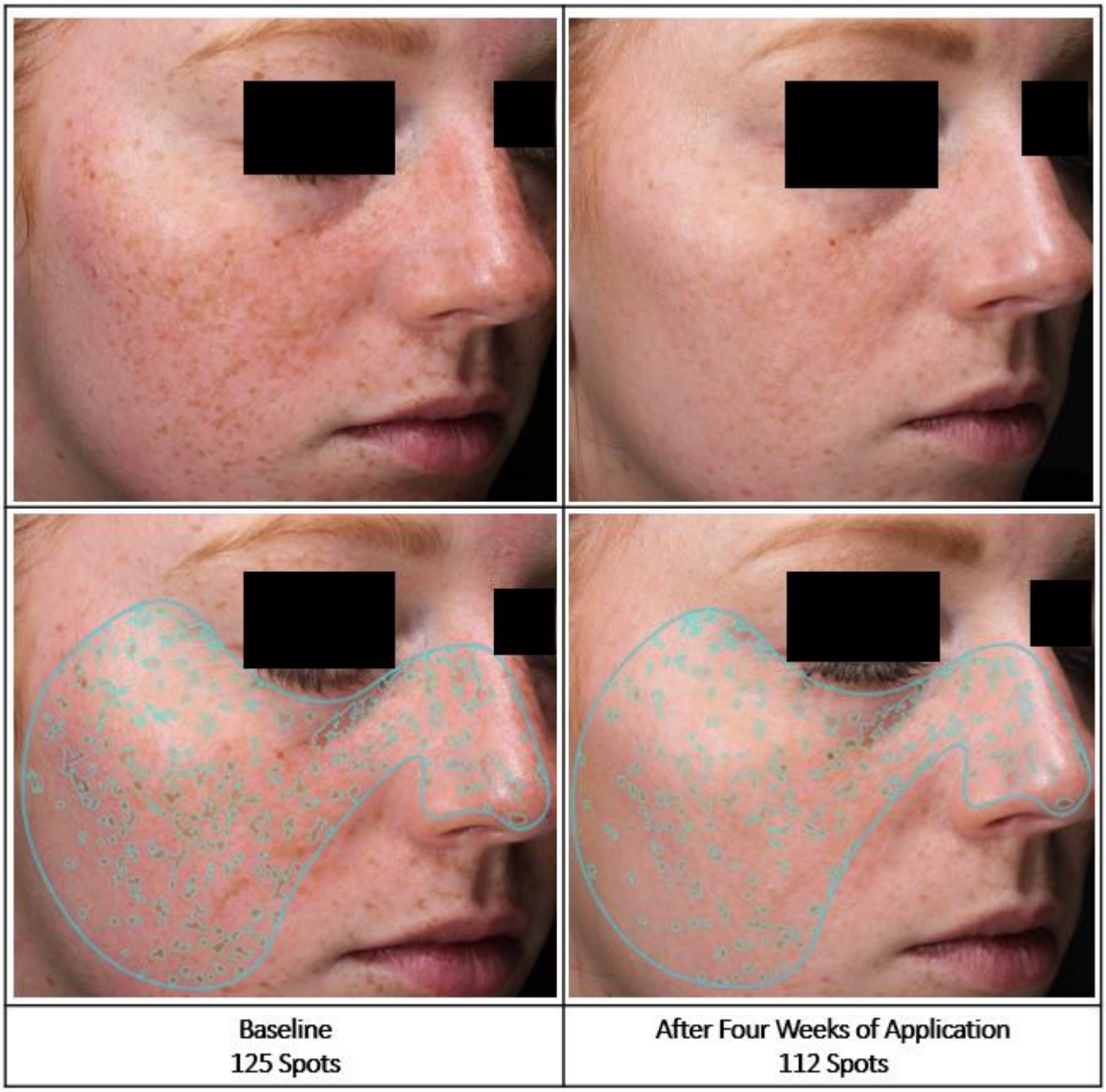

Image 1. Images of Participant Treated with 2.0% **AC LumiVitis**. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks. Surface Spots are denoted by light blue shapes.

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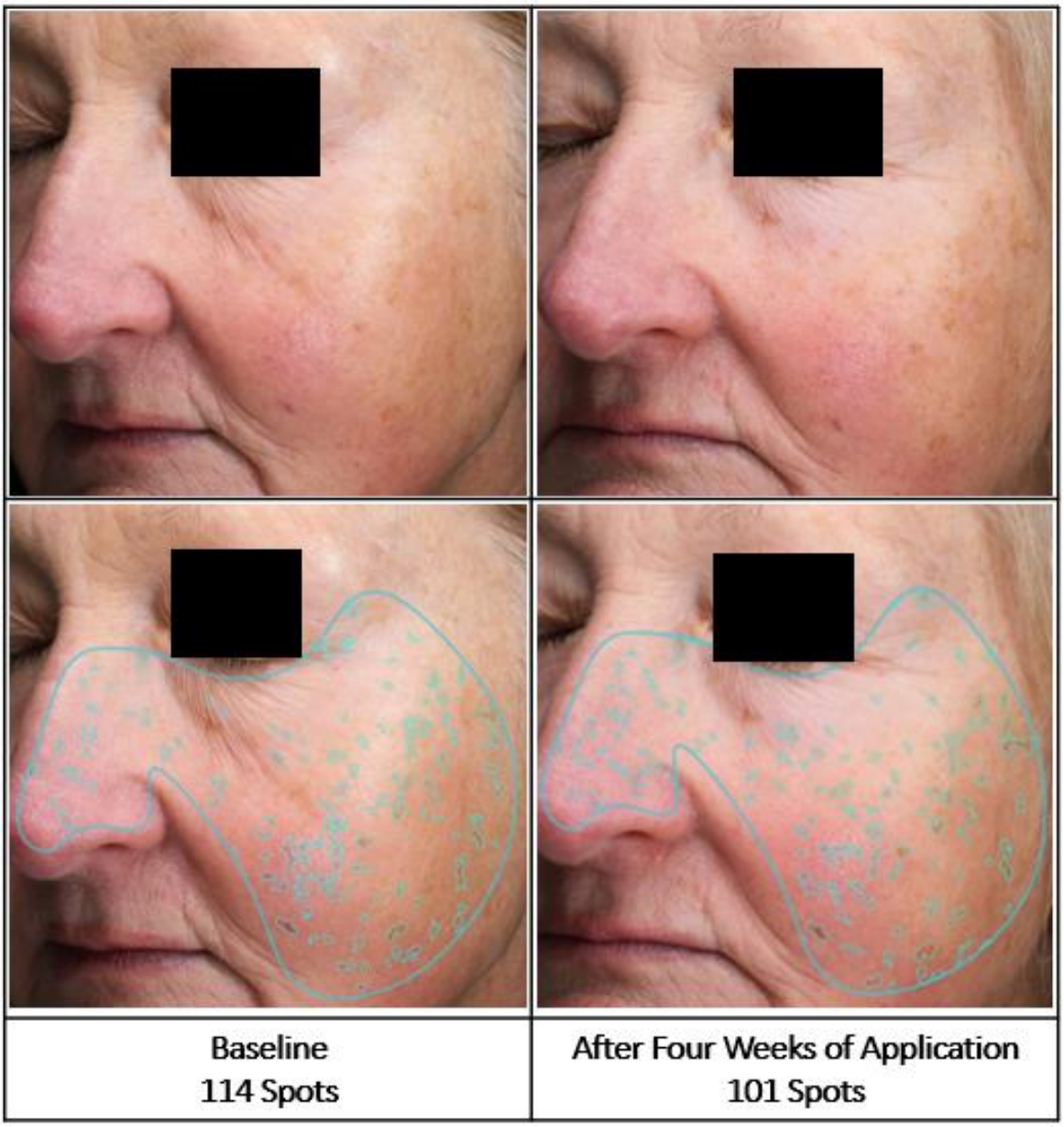

Image 2. Images of Participant Treated with 2.0% **AC LumiVitis**. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks. Surface Spots are denoted by light blue shapes.

Discussion

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

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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 Surface Spots 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 LumiVitis** decreased TruSkin Age™ by 7 months, while the Base Lotion demonstrated an increase of 5 months (Figure 2; Table 5). These results indicate application of 2.0% **AC LumiVitis** for four weeks provides a reduction in VISIA TruSkin Age™ which reduces the visual impacts of normal aging.

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