

Tradename: ACB Modified Pomegranate Enzyme PF

Code: 20440PF

CAS #: 84961-57-9 & 1686112-10-6 (or) 84775-94-0 (or) 9015-54-7

Test Request Form #: 12495

Lot #: 9409855

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

Study Director: Daniel Shill

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Test Performed:

In vivo VISIA Analysis: Texture

Introduction

Skin may feel uneven, dry, or coarse as we age. As skin ages, the process of shedding dead skin cells rapidly declines, resulting in skin cell buildup that appears dry and clumpy. Additionally, collagen and elastin are responsible for providing smoothness and resiliency on the skin. With increased sun exposure, collagen and elastin begin to breakdown thus resulting in more visible and tangible skin Texture. To prevent uneven skin Texture, it is important to include exfoliation in a skincare regimen.

Accordingly, an *in vivo* study was conducted over a period of four weeks to evaluate the ability of **ACB Modified Pomegranate Enzyme PF** to improve Texture 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 during the four-week study period. Photographs of participant faces were obtained using the VISIA Complexion Analysis System and analyzed for Texture. Skin Texture is an analysis of skin smoothness by identifying gradations in color from the surrounding skin tone as well as variations in the surface topography of the skin. Reducing Skin Texture is indicative of smoother skin.

Materials

- A. Equipment:** VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA)
- B. Base Lotion:** Cetaphil® Moisturizing Cream for All Skin Types, Simple® Cleansing Facial Wipes
- C. Software:** Excel Analysis ToolPak (Microsoft)

Methods

Ten volunteers between the ages of 18 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 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 Cetaphil® Moisturizing Cream for All Skin Types. 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 | 1.0% ACB Modified Pomegranate Enzyme PF | 1.0% ACB Modified Pomegranate Enzyme PF 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 light.

Images were analyzed for Texture Feature Count, which indicates the number of discrete instances of Texture, without regard to the size or intensity, within the analyzed region. Skin Texture is an analysis of skin smoothness by identifying gradations in color from the surrounding skin tone as well as variations in the surface topography on the skin. Therefore, skin with lower Texture Counts indicate smoother skin and a more youthful appearance. To further demonstrate the impact of reducing Texture Count 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 Texture 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:

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

Results

The data obtained met criteria for a valid study and the Base Lotion performed as anticipated. Application of 1.0% **ACB Modified Pomegranate Enzyme PF** twice a day for four weeks demonstrated a reduction in the amount of Texture every week throughout the four-week treatment period.

Change in Texture Count ACB Modified Pomegranate Enzyme PF

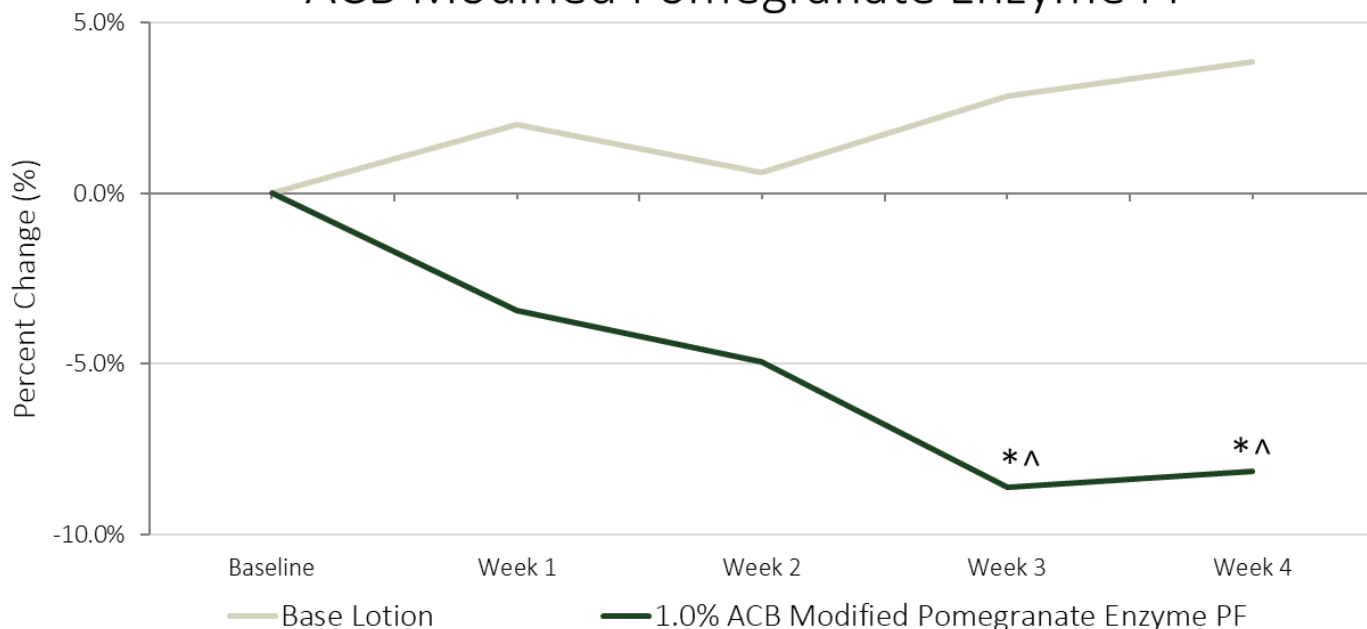


Figure 1. Change in Texture Count from Baseline. * indicates significance ($p \leq 0.05$) compared to Baseline values. ^ indicates significance ($p \leq 0.05$) compared to Base Lotion within the same timepoint. Reducing Skin Texture is indicative of smoother skin.

Table 3. P-values from t-test Analyses of Change in Texture 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 | 0.202 |
| 1.0% ACB Modified Pomegranate Enzyme PF | 0.004* |

Table 4. T-test Analyses of Change in Texture Count between Base Lotion and 1.0% **ACB Modified Pomegranate Enzyme PF** 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 | 0.094 | 0.087 | 0.041^ | 0.048^ |

Change in VISIA TruSkin Age™ After Four Weeks ACB Modified Pomegranate Enzyme PF

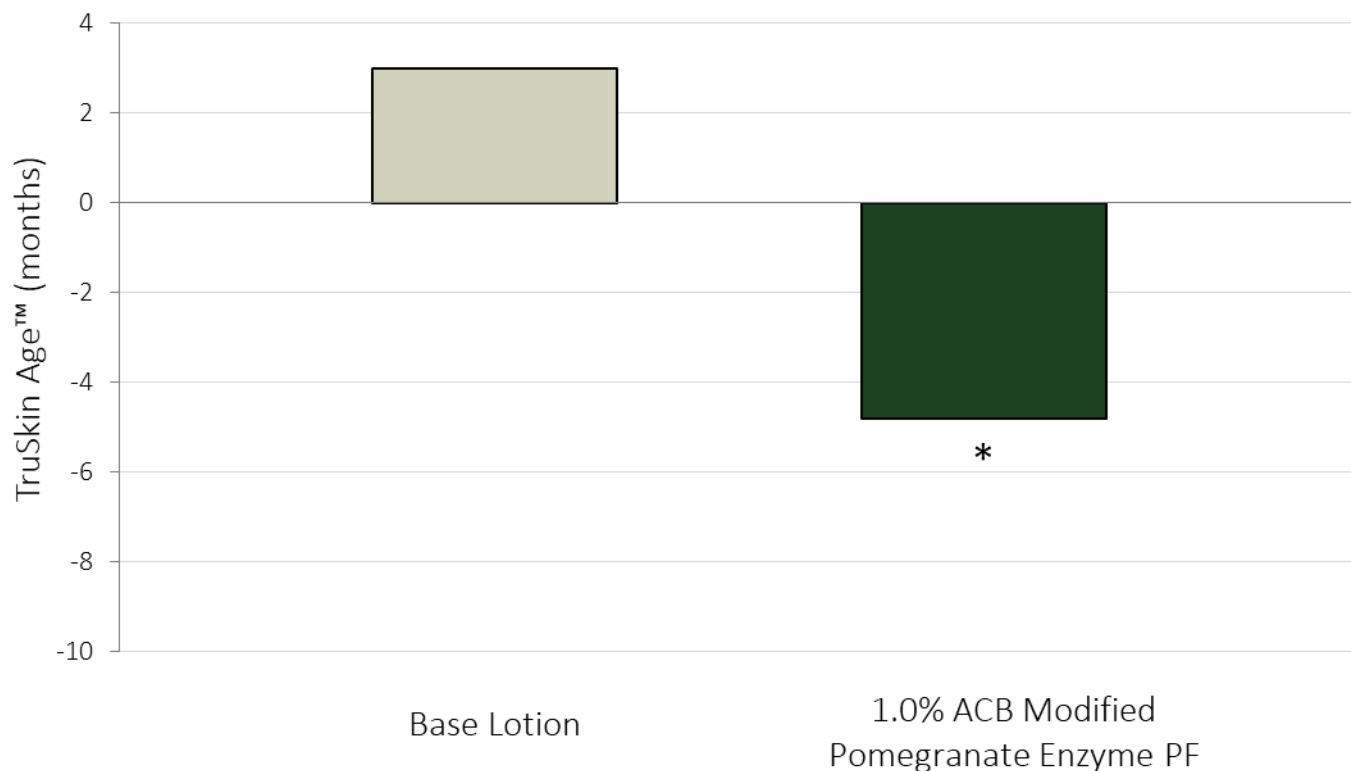


Figure 2. Changes in VISIA TruSkin Age™ of Participants After Four Weeks of 1.0% **ACB Modified Pomegranate Enzyme PF** and Base Lotion Application. * indicates significance ($p \leq 0.05$) between conditions.

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 1.0% ACB Modified Pomegranate Enzyme PF |
|----------------|--|
| P-value | 0.019* |

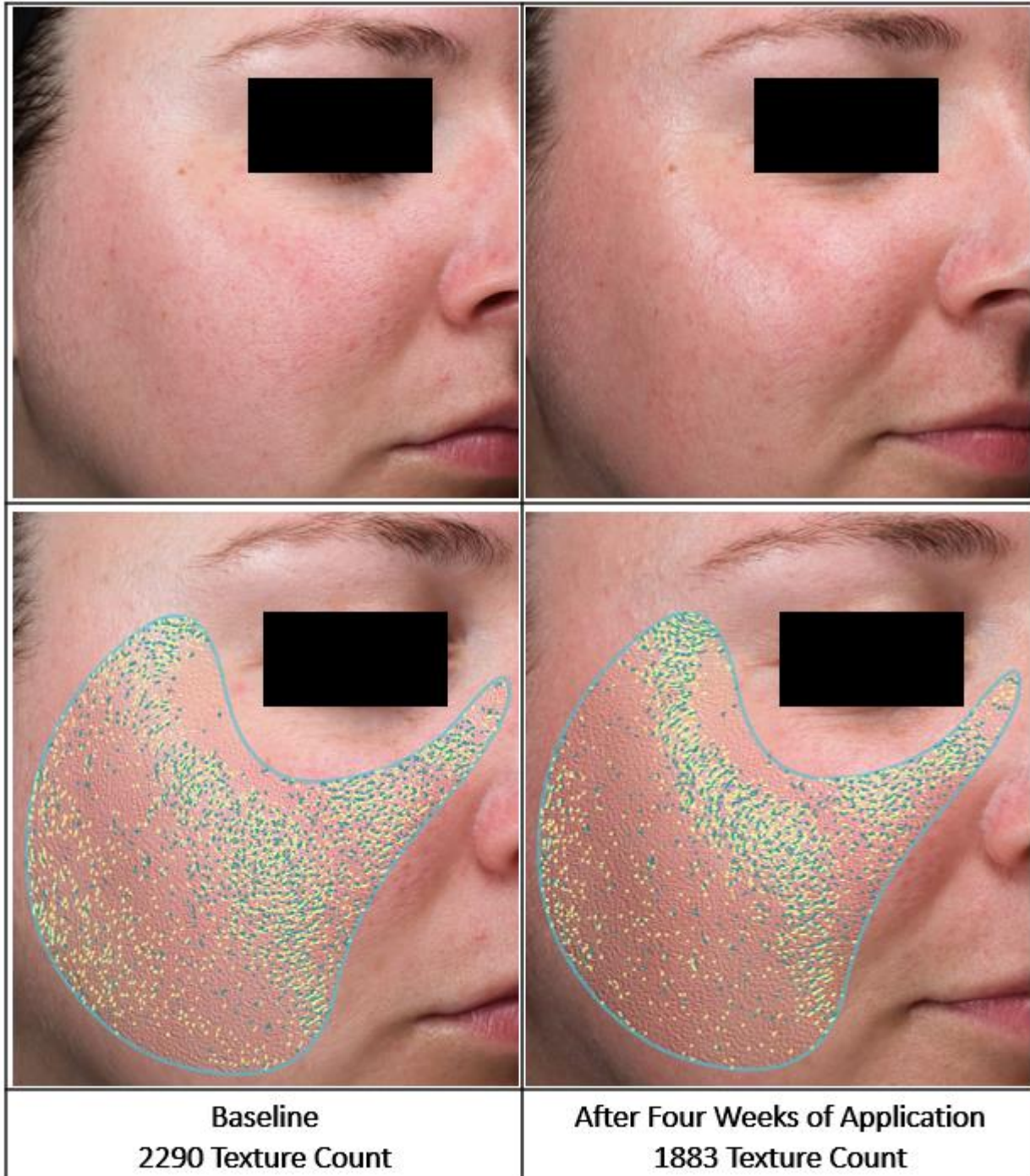


Image 1. Images of Participant Treated with 1.0% ACB Modified Pomegranate Enzyme PF. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four Weeks. Skin Texture is an analysis of skin smoothness by identifying gradations in color from the surrounding skin tone as well as variations in the surface topography on the skin. Yellow indicates raised areas and blue denotes depressions in the skin. Reducing Skin Texture is indicative of smoother skin.

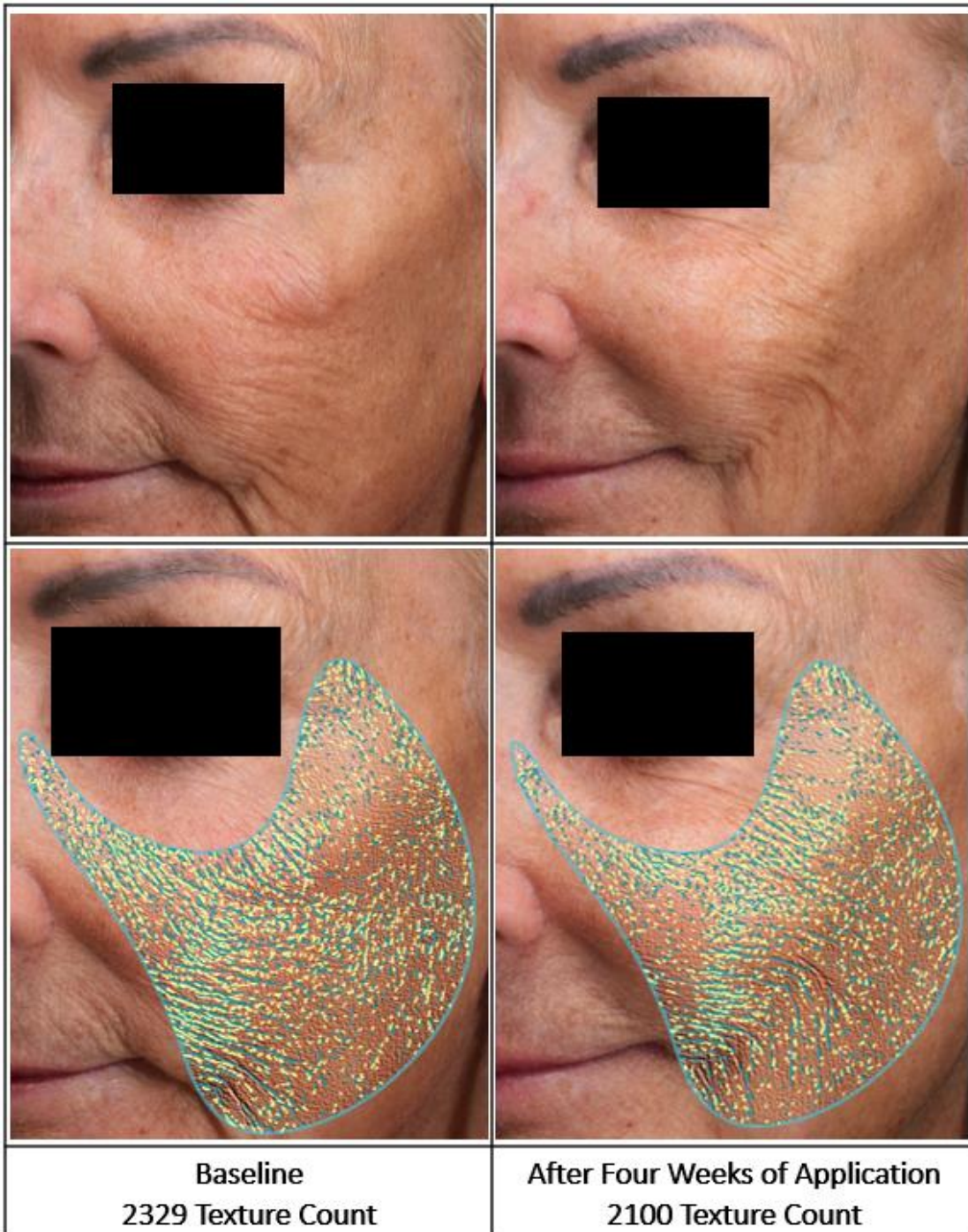


Image 2. Images of Participant Treated with 1.0% ACB Modified Pomegranate Enzyme PF. Natural Photos (top) and VISIA Image Enhancement (bottom) Before and After Four Weeks. Skin Texture is an analysis of skin smoothness by identifying gradations in color from the surrounding skin tone as well as variations in the surface topography on the skin. Yellow indicates raised areas and blue denotes depressions in the skin. Reducing Skin Texture is indicative of smoother skin.

Discussion

As evidenced in this four-week study, **ACB Modified Pomegranate Enzyme PF** reduces the appearance of Texture on the face, in addition to reducing VISIA TruSkin Age™. The amount of Texture present was not significantly altered throughout the study with Base Lotion application, indicating the Base Lotion does not exert significant Texture reducing properties on the skin (Figure 1; Table 3). Conversely, applying 1.0% **ACB Modified Pomegranate Enzyme PF** for four weeks resulted in a 8% decrease in the overall amount of Texture present, compared to baseline (Figure 1; Table 3). Moreover, applying 1.0% **ACB Modified Pomegranate Enzyme PF** significantly decreased the amount of Texture present compared to the Base Lotion after three and four weeks of application (Figure 1; Table 4). These results indicate that applying 1.0% **ACB Modified Pomegranate Enzyme PF** for four weeks provides a reduction in Texture appearance on the face resulting in smoother skin and 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 Texture percentile scores against individuals of the same group, skin type, and gender in the VISIA database. After four weeks of application, 1.0% **ACB Modified Pomegranate Enzyme PF** significantly decreased TruSkin Age™ by 5 months, while the Base Lotion demonstrated an increase of 3 months (Figure 2; Table 5). These results indicate application of 1.0% **ACB Modified Pomegranate Enzyme PF** for four weeks provides a reduction in VISIA TruSkin Age™ which reduces the visual impacts of normal aging.

Taken together, these results indicate **ACB Modified Pomegranate Enzyme PF** reduces Texture and simulated skin age when added to personal care applications at recommended use levels. Collectively, **ACB Modified Pomegranate Enzyme PF** 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/>