VISIA Results – Undereye Study

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Tradename: AC ExoVitalize

Code: 60193

CAS #: 7732-18-5 & 8016-20-4 & 90244-99-8 & 123465-35-0 (or) 8002-43-5

Test Request Form #: 10118

Lot #: N230612B

Sponsor: *Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092*
Study Director: *Maureen Drumwright*
Principle Investigator: *Kayla Patterson*

Test Performed:
In-vivo VISIA Analysis
Pigmentation Study

Introduction

Skin pigmentation is determined by the amount of melanin present, which is produced by melanocytes in the bottom layer of the epidermis. Skin pigmentation can lighten, darken, or change color as a result of sun exposure, skin damage, genetics, and hormones. Dark circles and discoloration, which can be caused by factors such as stress, lack of sleep, or dehydration, can influence the appearance of aging and fatigue under the eye. Undereye discoloration is a result of deoxygenated blood pooling in the vessels that lie close to the skin, which is what gives dark circles the appearance of blue and purple hues. Lightening skin pigmentation, improving dark circles, and reducing discoloration under the eye leads to a healthier and more youthful undereye appearance.

Accordingly, an *in-vivo* study was conducted over a period of six weeks to evaluate the effect of **AC ExoVitalize** on skin pigmentation under the eye. To determine if **AC ExoVitalize** is capable of decreasing the appearance of dark circles and undereye discoloration, a VISIA image analysis and pigmentation study were conducted on the undereye area.

Study Principle

Participants applied specific products to particular undereye areas twice a day for four weeks. Measurements were collected once a week during the four-week use period and for two weeks after application ceased for a total of six weeks. Photographs of participant faces were obtained using the VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA) and analyzed using ImageJ software (NIH) to determine color intensity of the undereye region. Pigmentation measurements were obtained via the DermaLab Combo handheld probe to assess undereye melanin levels.

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Materials

A. Equipment: DermaLab Skin Combo (Pigmentation Probe); VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA); Simple® Cleansing Facial Wipes

B. Base Lotion: Simple® Hydrating Light Moisturizer

Methods

This study was conducted using 8 M/F participants between the ages of 23-54 with Fitzpatrick skin types I to IV (Table 1). Each participant was provided two products and were instructed to apply 0.2 g of product to the specified undereye area 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. One product was the control base lotion (Simple® Hydrating Light Moisturizer) and the other consisted of 5.0% **AC ExoVitalize** in the base lotion. This was a blind study and eye specification was randomly chosen for each participant. Baseline measurements were taken prior to starting the lotion regimen. Measurements were collected once a week during the four-week use period and for two weeks after application ceased for a total of six weeks. Participants were instructed not to wear makeup or SPF products for the measurement sessions.

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 the image was obtained. The photographic images were captured with standard, cross-polarized, parallel polarized, and ultraviolet light. Images taken by the VISIA System were exported and analyzed using ImageJ software (NIH) to assess color intensity of the undereye region. Specifically, histogram analysis was performed on the acquired images in specific regions of interest to evaluate the red, green, and blue (R+G+B) color distribution. The R+G+B color spectrum ranges from 0 (left) to 255 (right), where the left side of each histogram reflects exclusively red pixels, and the ride side of each histogram reflects exclusively blue pixels. A shift towards the right side of the histogram indicates a darker color.

Pigmentation levels, measured as melanin, were obtained via the DermaLab Combo handheld probe. Three consecutive measurements were recorded and averaged for each test site. A control area, located on the outer region of the eye (cheek bone), was measured in addition to the undereye region. Percent change is calculated by the following formula:

$$Percent\ Change\ (\%) = \frac{Pigmentation\ \ Value_{Weeks\ of\ Application} - Pigmentation\ Value_{Baseline}}{Pigmentation\ Value_{Baseline}}\ x\ 100$$

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	

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Results

The data obtained from this study met criteria for a valid assay as the color intensity of the control area, located on the outer region of the eye (cheek bone), did not change throughout the study duration. Applying 5.0% **AC ExoVitalize** to the undereye area reduced melanin values and the undereye color intensity during the four-week application period and continued to exhibit positive results during the two-week regression period.

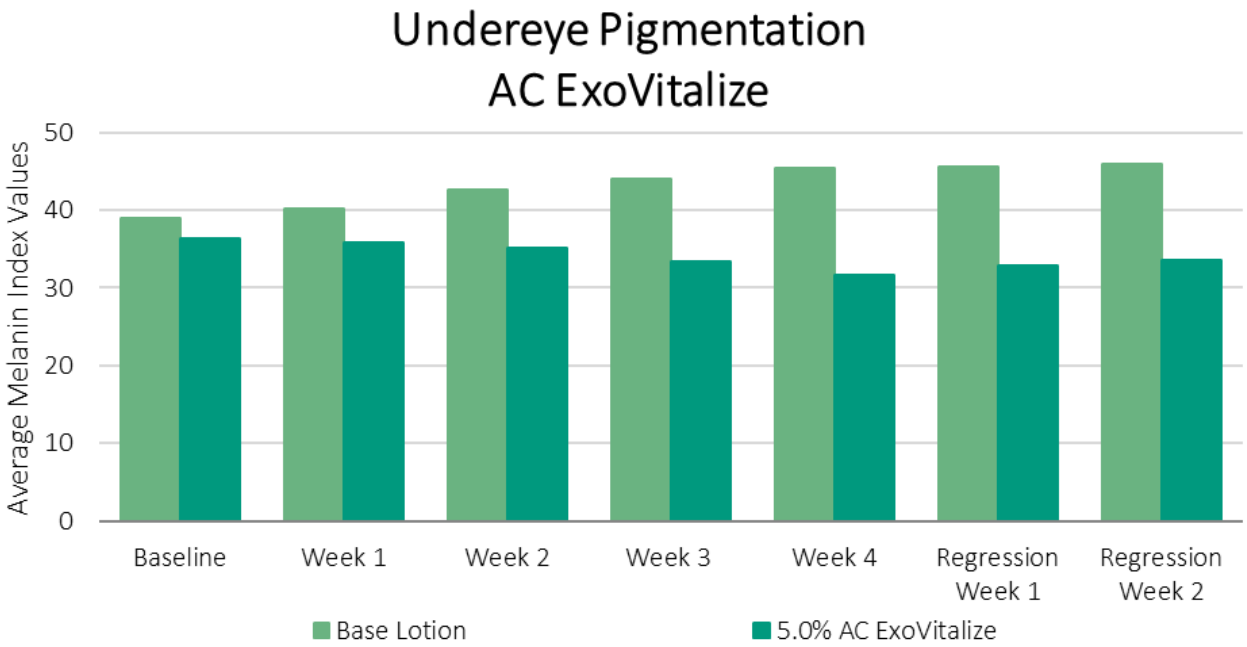

Figure 1. Average Melanin Levels throughout the Six-Week Study Protocol

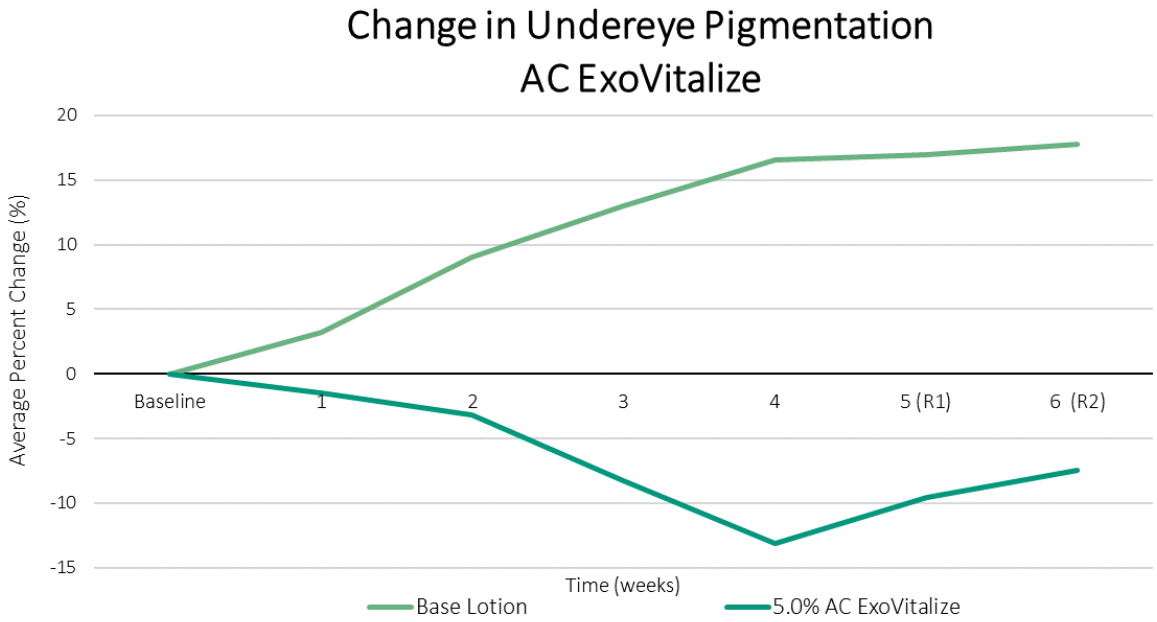

Figure 2. Average Percent Change in Undereye Melanin Levels from Baseline. R1 and R2 indicate regression weeks with no application.

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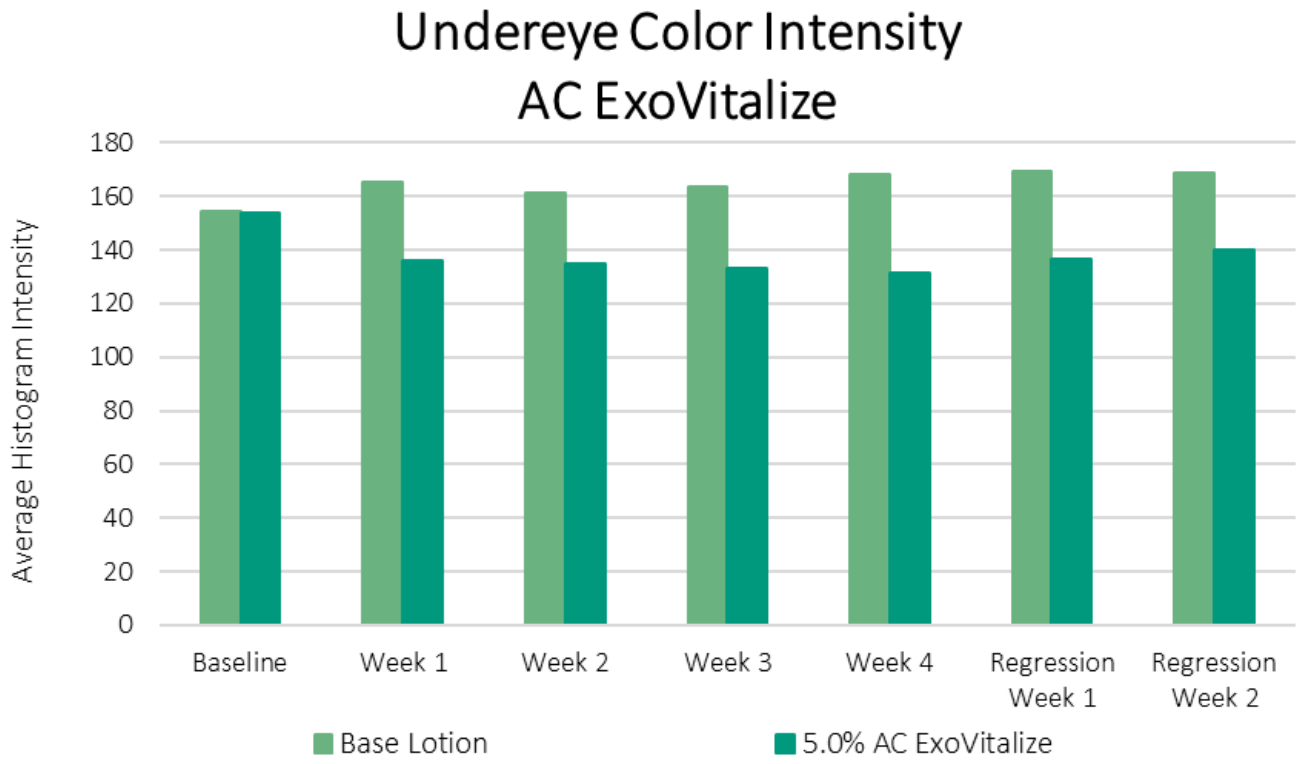

Figure 3. Average Undereye Histogram Intensity throughout the Six-Week Study Protocol

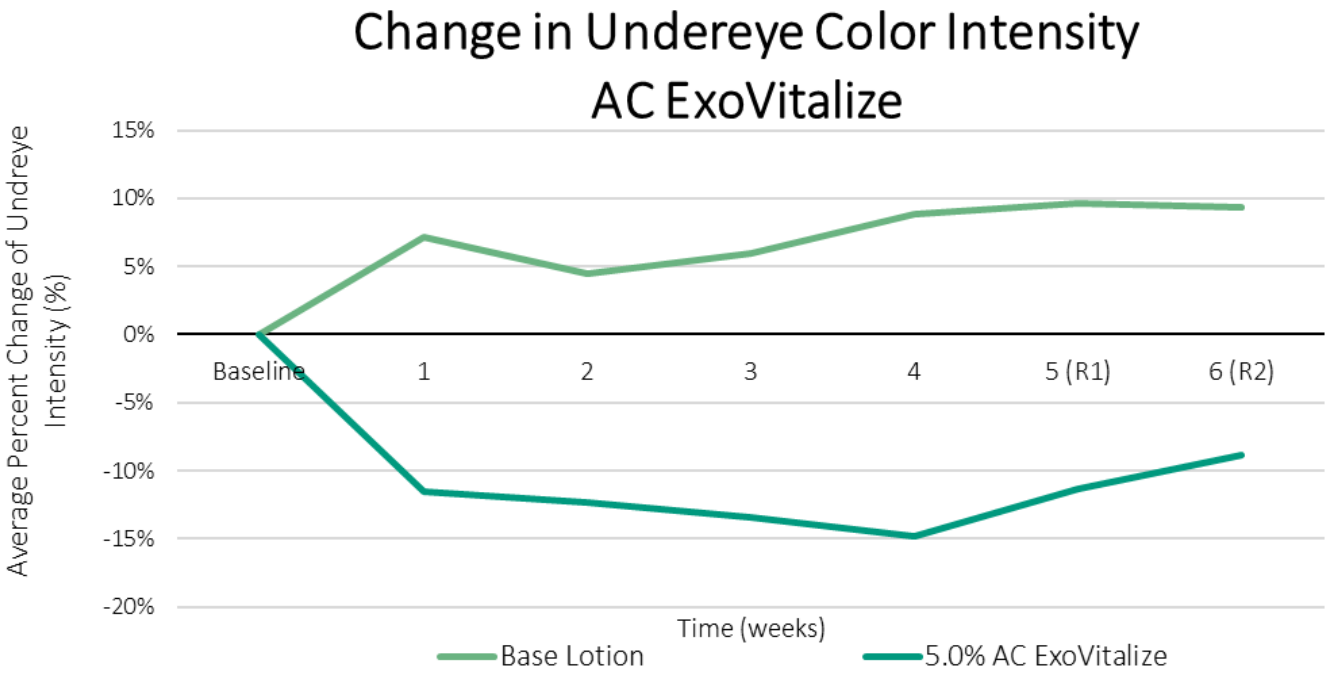

Figure 4. Average Percent Change in Undereye Histogram Intensity from Baseline. R1 and R2 indicate regression weeks with no application.

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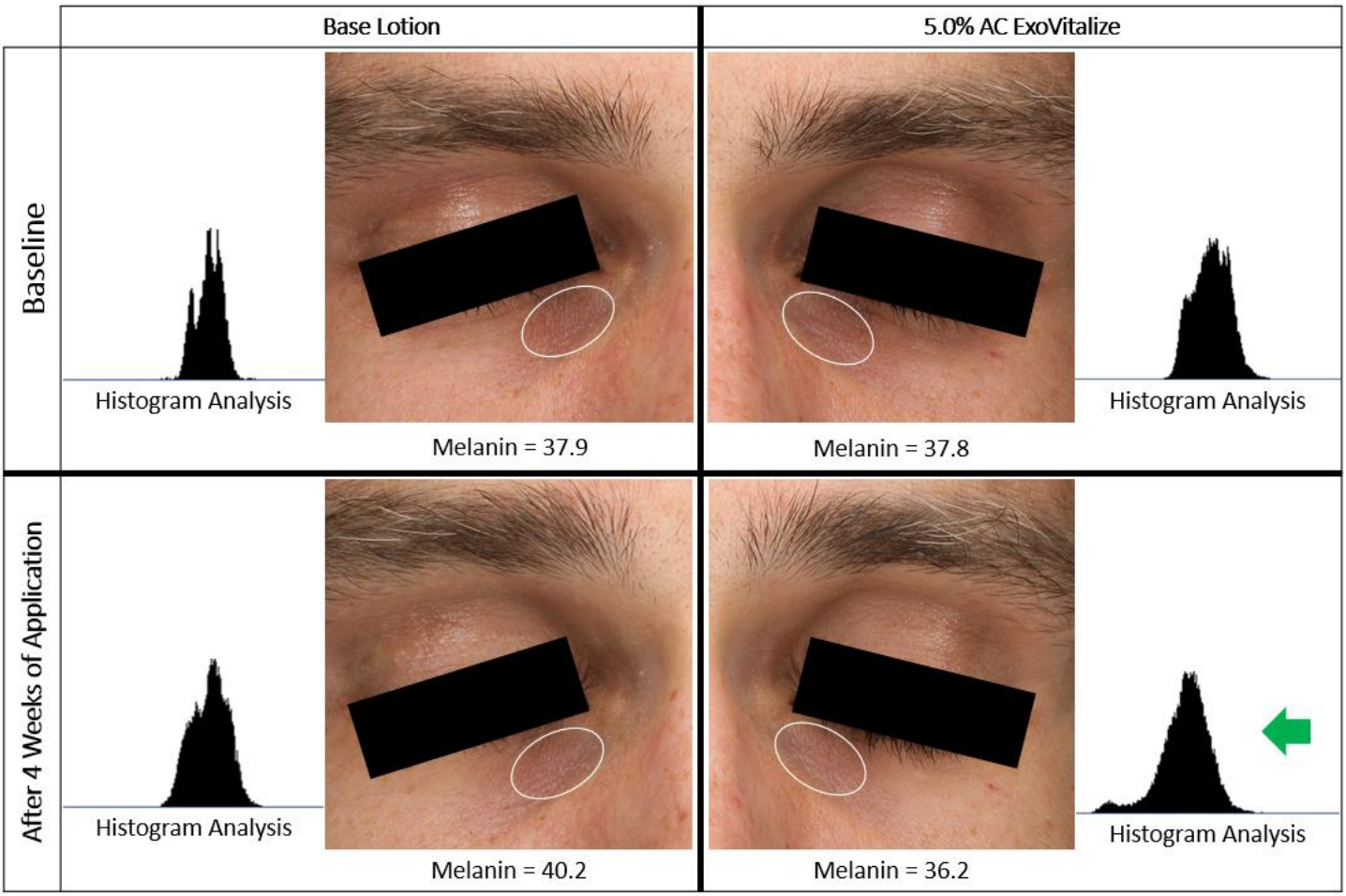

Figure 5. Representative VISIA images and histogram analysis of Participant 1 at baseline and after four weeks of application of the Base Lotion and 5.0% **AC ExoVitalize**. White circles indicate the area subjected to histogram analysis. The green arrow indicates a shift away from the darker end of the color spectrum.

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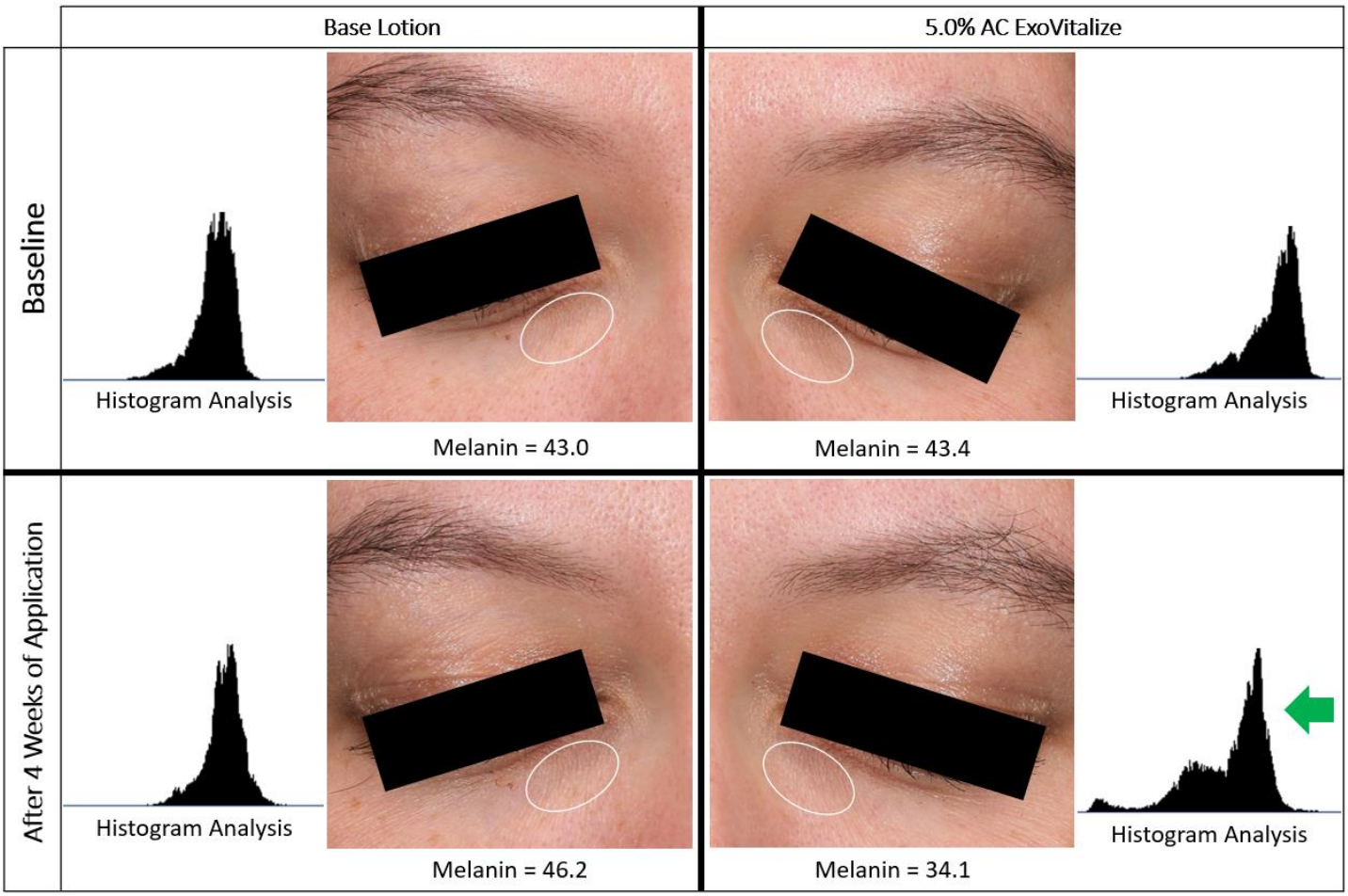

Figure 6. Representative VISIA images and histogram analysis of Participant 3 at baseline and after four weeks of application of the Base Lotion and 5.0% **AC ExoVitalize**. White circles indicate the area subjected to histogram analysis. The green arrow indicates a shift away from the darker end of the color spectrum.

Table 2. T-test Analysis of the Percent Change (%) Melanin between Baseline and After 4 Weeks of Application of 5.0% **AC ExoVitalize** (n=8, α=0.05, df=11)

	Baseline	After 4 Weeks of Application
Mean	36.35	31.575
Variance	28.69	7.94
t Stat	2.231	
P(T<=t) two-tail	0.0474	
t Critical two-tail	2.200	

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Table 3. T-test Analysis of the Percent Difference (%) in Melanin between 5.0% **AC ExoVitalize** and Base Lotion After 4 Weeks of Application (n=8, α=0.05, df=10)

	AC ExoVitalize	Base Lotion
Mean	32.9	45.47
Variance	5.50	24.49
t Stat	-6.49	
P(T<=t) two-tail	6.952E-05	
t Critical two-tail	2.228	

Discussion

As evidenced in this six-week study, **AC ExoVitalize** significantly reduces skin pigmentation and improves the color of dark circles under the eyes. After four weeks, participants applying 5.0% **AC ExoVitalize** demonstrated a decrease of 13% in skin pigmentation and a decrease of 15% in undereye color intensity when compared to the baseline readings (Figures 1, 2, 3, 4; Table 2). By comparison, base lotion application elicited an increase of 17% in skin pigmentation and an increase of 9% in undereye color intensity after the four-week period (Figures 1, 2, 3, 4; Table 3). Visually, **AC ExoVitalize** effectively reduced undereye skin pigmentation and discoloration than the base lotion after 4 weeks of daily application (Figures 5, 6).

After the four-week application period ended, skin pigmentation and color intensity under the eyes receiving **AC ExoVitalize** continued to outperform the base lotion during the regression period. After two weeks of regression, participants who had applied 5.0% **AC ExoVitalize** still maintained an 8% reduction in skin pigmentation and a 9% reduction in undereye color intensity compared to baseline measurements (Figures 1, 2, 3, 4). Conversely, base lotion treatment sites continued to elicit increased skin pigmentation by 18% and undereye color intensity by 9% compared to baseline measurements (Figures 1, 2, 3, 4). These results indicate that after the four-week treatment period ended, participants who had applied 5.0% **AC ExoVitalize** maintained the benefits of decreased skin pigmentation and undereye discoloration, compared to baseline, suggesting a lasting effect.

Collectively, we demonstrate applying **AC ExoVitalize** for four weeks to the undereye area improves the appearance of dark circles and undereye discoloration through a reduction in skin pigmentation and color intensity. In conclusion, utilizing **AC ExoVitalize** at the recommended use levels provides a more youthful appearance by reducing the visual consequences of undereye dark circles and discoloration.

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/