VISIA Results – Undereye Study

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Tradename: AC WonderShroom

Code: 21029

CAS #: 84650-60-2 & 999999-99-4 (or) 68917-13-5 & 999999-99-4 (or) 68917-13-5 & N/A (or) 9057-02-7

Test Request Form #: 11684

Lot #: N240509A

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

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* VISIA Analysis and Pigmentation Study was conducted over a period of four weeks to evaluate the effect of **AC WonderShroom** on undereye skin pigmentation, discoloration, and the appearance of dark circles after long-term product application.

Study Principle

Participants applied specific products to designated undereye areas twice a day for four weeks. Measurements were collected once a week during the four-week use period. 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.

Materials

A. Equipment: DermaLab Skin Combo (Pigmentation Probe); VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA)
B. Materials: Simple® Cleansing Facial Wipes
C. Software: Excel Analysis ToolPak (Microsoft); ImageJ Analysis Software (National Institutes of Health)

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Methods

Ten volunteers between the ages of 24 and 45, 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 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	

Participants had both undereye areas randomly assigned to a specific condition and treatment (Table 2). Following baseline measurements, participants were provided the test material and were instructed to apply 0.2 g of product to the specified undereye area twice a day for the four-week study period. Participants were instructed to continue their usual skin care routine and to apply the product after their everyday skin care routine is finished. Baseline measurements were taken prior to starting test material application. 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 WonderShroom**	2.0% **AC WonderShroom** 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. 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 black and white color distribution. The color spectrum ranges from 0 (left) to 255 (right), where the left side of each histogram reflects exclusively black pixels, and the right side of each histogram reflects exclusively white pixels. A shift towards the left side of the histogram indicates a darker color, whereas a shift to the right side of the histogram indicates a lighter 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. All 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:

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$$Percent\ Change\ (\%) = \frac{Measurement_{Week\ of\ Application} - Measurement_{Baseline}}{Measurement_{Baseline}}\ x\ 100$$

Results

The data obtained met criteria for a valid study as color intensity of the control area, located on the outer region of the eye (cheek bone), did not change throughout the study duration. The Base Lotion performed as anticipated with undereye melanin values and color intensity remaining consistent throughout the study duration. However, 2.0% **AC WonderShroom** application twice a day for four weeks demonstrated a reduction in melanin values as well as the intensity of undereye dark circles every week throughout the four-week treatment period.

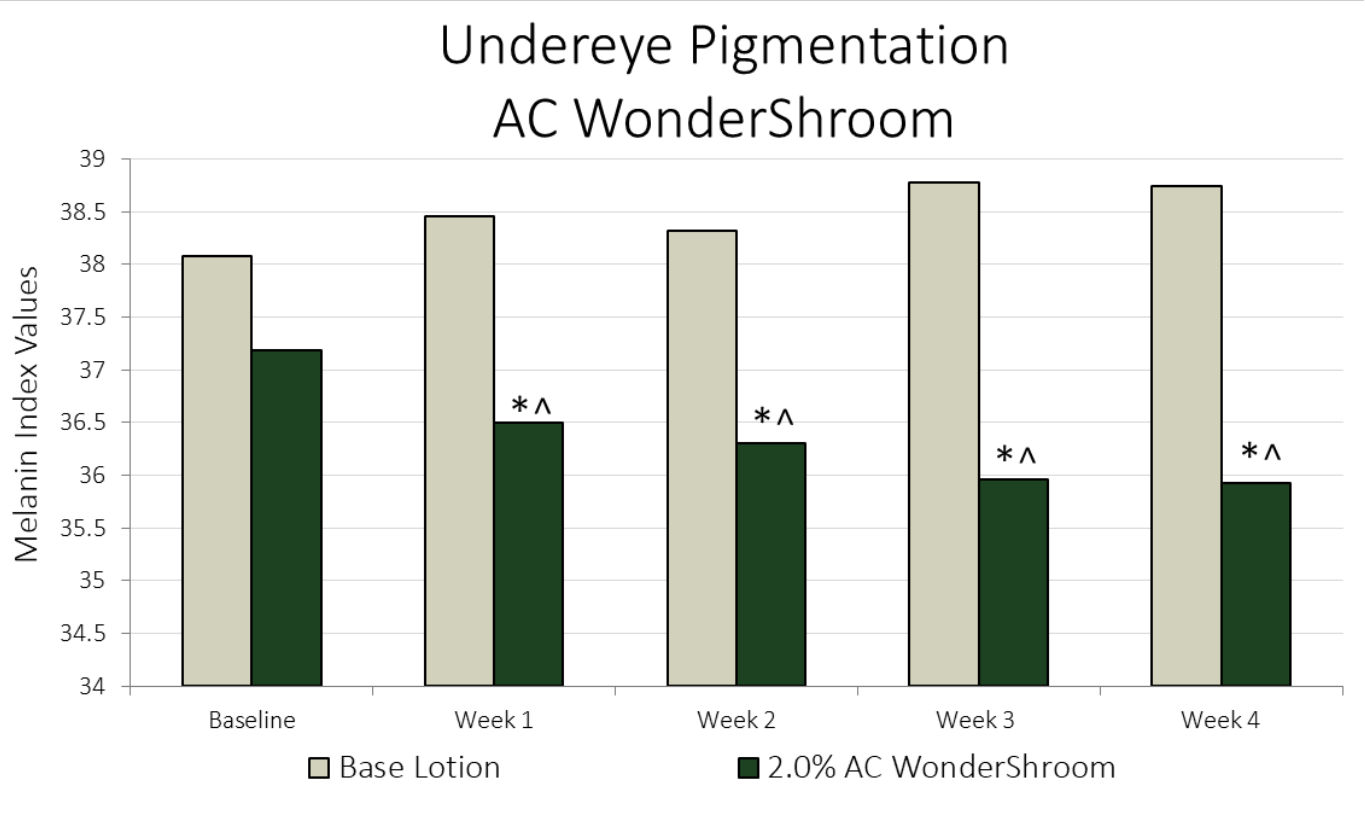

Figure 1. Average Melanin Levels throughout the Four-Week Study Protocol. * indicates significance ($p \leq 0.05$) compared to Baseline. ^ indicates significance ($p \leq 0.05$) between conditions within each timepoint.

Table 3. P-values from t-test Analyses of Melanin 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	0.627
2.0% **AC WonderShroom**	0.009*

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Table 4. T-test Analyses of Melanin between Base Lotion and 2.0% **AC WonderShroom** Throughout 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^	0.034^	0.005^

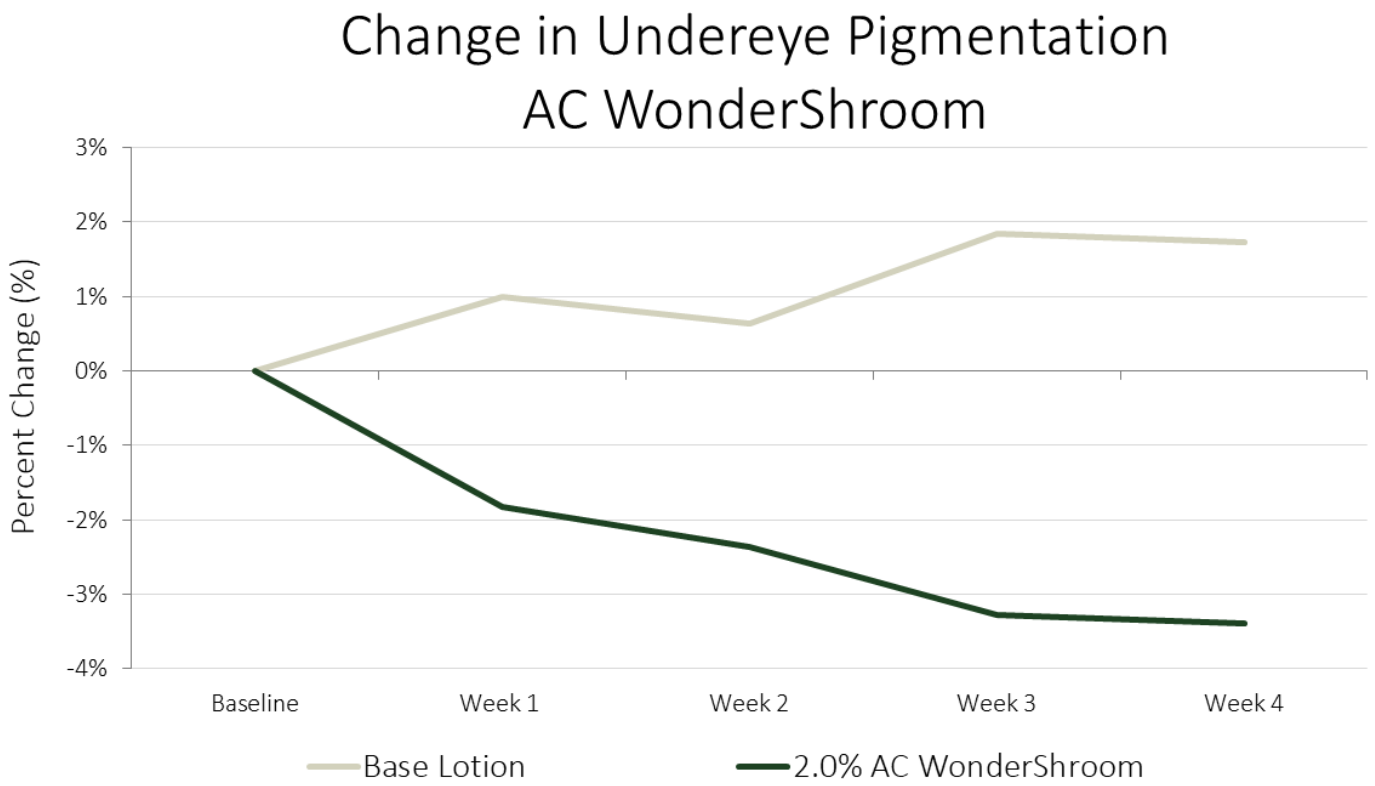

Figure 2. Average Percent Change in Undereye Melanin Levels from Baseline.

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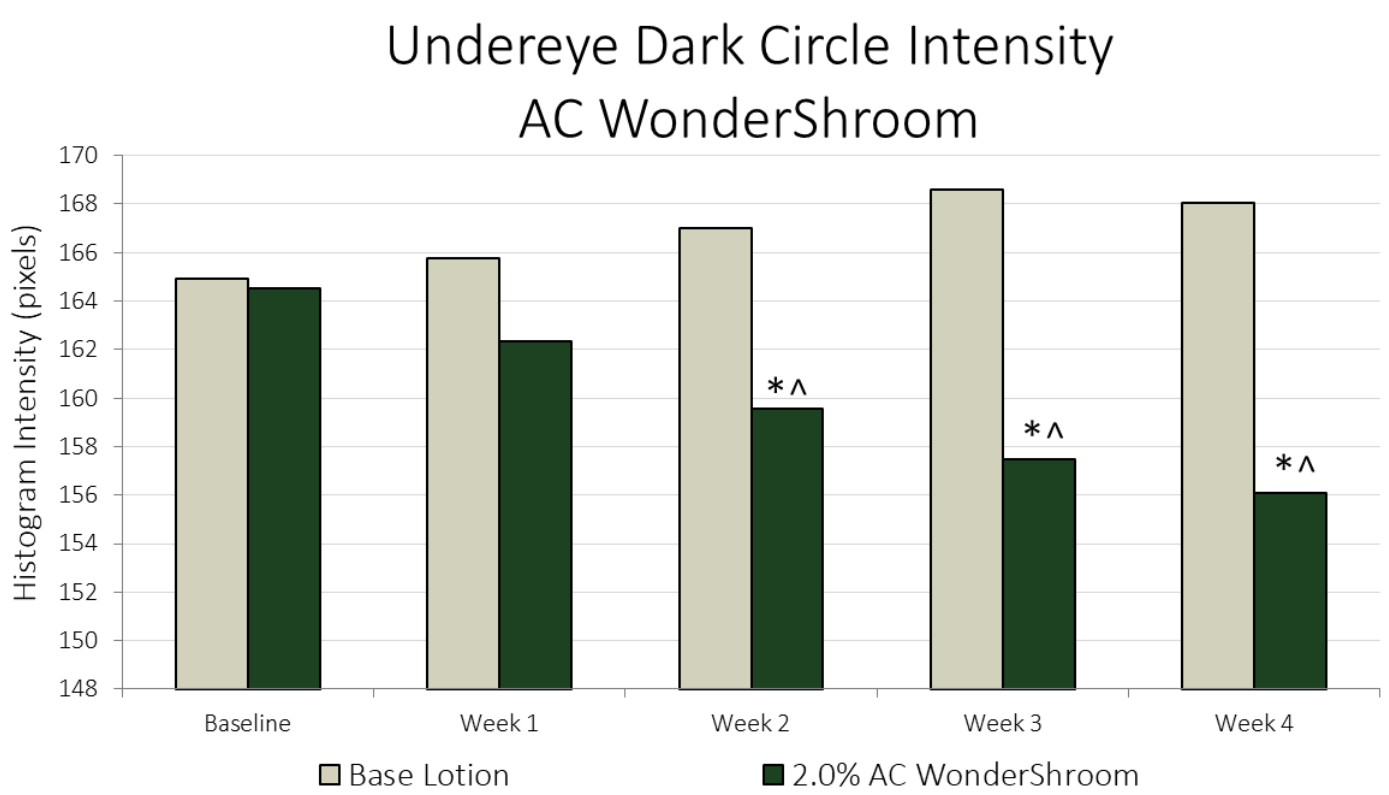

Figure 3. Average Undereye Dark Circle Intensity throughout the Four-Week Study Protocol. * indicates significance ($p \leq 0.05$) compared to Baseline. ^ indicates significance ($p \leq 0.05$) between conditions within each timepoint.

Table 5. P-values from t-test Analyses of Change in Melanin 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	0.615
2.0% **AC WonderShroom**	0.041*

Table 6. T-test Analyses of Change in Intensity between Base Lotion and 2.0% **AC WonderShroom** 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	0.426	0.044^	0.046^	0.040^

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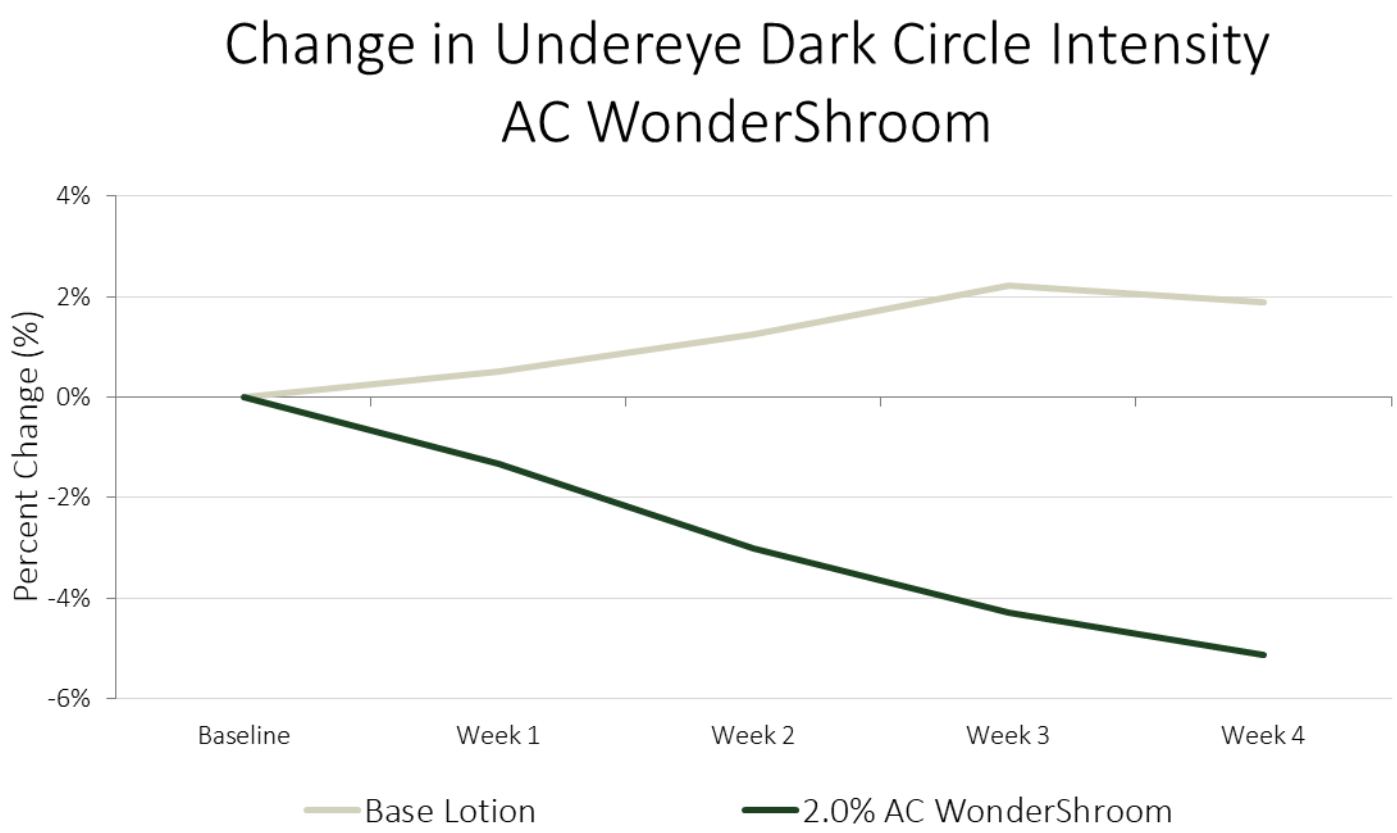

Figure 4. Average Percent Change in Undereye Histogram Intensity from Baseline.

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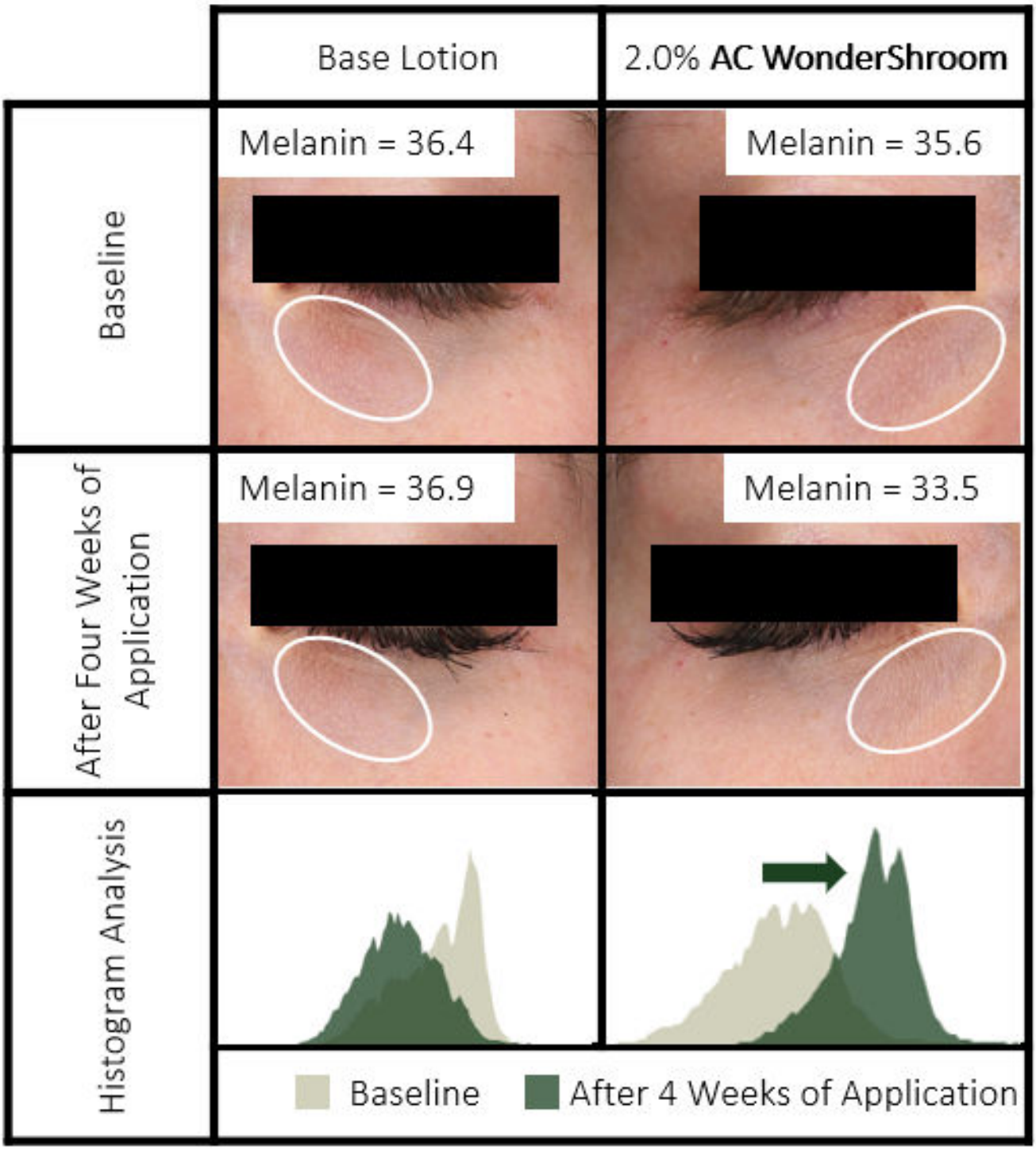

Image 1. Representative VISIA images and histogram analysis of Participant 2 at baseline and after four weeks of application of the Base Lotion and **AC WonderShroom**. White circles indicate the area subjected to histogram analysis. The green arrow indicates a shift away from the darker end of the color spectrum.

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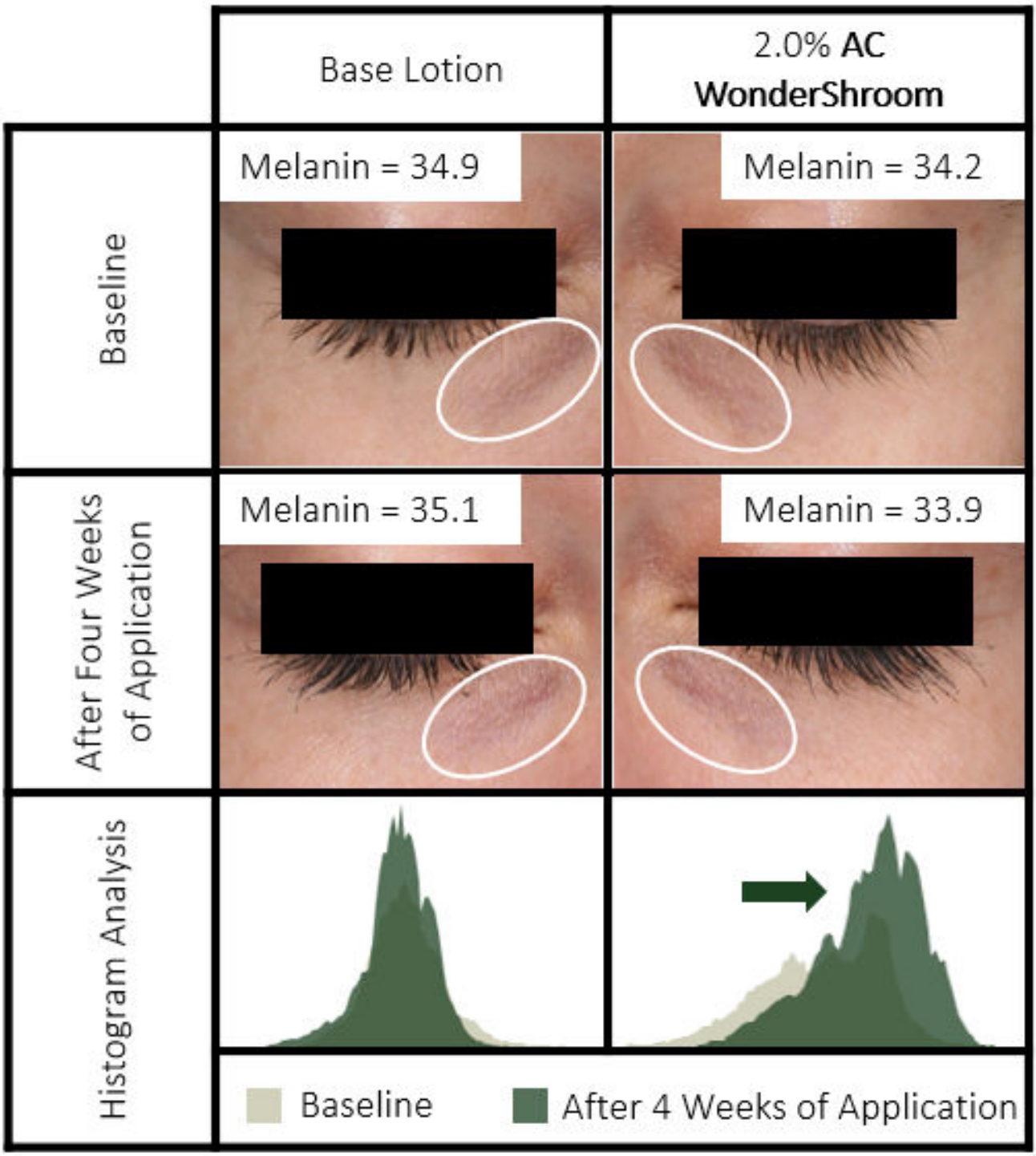

Image 2. Representative VISIA images and histogram analysis of Participant 5 at baseline and after four weeks of application of the Base Lotion and **AC WonderShroom**. White circles indicate the area subjected to histogram analysis. The green arrow indicates a shift away from the darker end of the color spectrum.

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Discussion

As evidenced in this four-week study, AC WonderShroom significantly reduces undereye skin pigmentation and improves undereye dark circle discoloration.

Undereye melanin levels were not significantly altered with Base Lotion application, indicating the Base Lotion did not impact undereye skin pigmentation throughout the study (Figures 1, 2; Table 3). Conversely, applying AC WonderShroom twice a day for four weeks demonstrated a decrease of 3% in skin pigmentation compared to baseline (Figures 1, 2; Table 3). Similar results are shown when examining the collective effect between each condition. Compared to the Base Lotion, AC WonderShroom elicited significantly lower melanin levels under the eye at every timepoint measured throughout the study (Figures 1, 2; Table 4). Visually, AC WonderShroom effectively reduced undereye skin pigmentation to a greater extent than the Base Lotion throughout the study duration (Images 1, 2). These results indicate applying AC WonderShroom twice a day for four weeks provides a reduction in melanin levels under the eye.

Undereye dark circle color intensity was not significantly altered with Base Lotion application, indicating the Base Lotion did not impact undereye skin discoloration throughout the study (Figures 3, 4; Table 5). Conversely, applying AC WonderShroom twice a day for four weeks demonstrated a reduction of 5% in undereye dark circle color intensity compared to baseline (Figures 3, 4; Table 5). Comparable results are shown when examining the collective effect between each condition. Compared to the Base Lotion, AC WonderShroom significantly lowered undereye dark circle color intensity two, three, and four weeks after application (Figures 3, 4; Table 6). Visually, AC WonderShroom effectively reduced undereye skin discoloration to a greater extent than the Base Lotion throughout the study duration (Images 1, 2). These results indicate applying AC WonderShroom twice a day for four weeks provides a reduction in undereye skin discoloration.

Collectively, we demonstrate applying AC WonderShroom for four weeks to the undereye area improves the appearance of dark circles and undereye discoloration through a reduction in skin pigmentation and dark circle intensity while improving perceived undereye skin benefits. In conclusion, incorporating AC WonderShroom into a normal skin care routine 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/