Anti-Erythema Study

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Tradename: AC ExoCalm

Code: 60192

CAS #: 7732-18-5 & 84775-66-6 & 123465-35-0 (or) 8002-43-5

Test Request Form #: 11990

Lot #: 9400822

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

Test Performed:
Anti-Erythema Study

Introduction

Skin erythema refers to the redness of skin and is a result of dilation and irritation of superficial capillaries. The appearance of a red hue on the skin is due to the augmented flow of blood through capillaries. Often, hyperpigmentation of the skin is undesirable as it is vibrant in color and can appear visually like a rash. Reducing skin redness and irritation is vital to the appearance of healthy skin.

Accordingly, an Anti-Erythema Study was conducted to evaluate the immediate and short-term redness and irritation reducing properties of **AC ExoCalm**.

Study Principle

Surgical tape is applied to the skin to induce irritation and redness on the skin. After tape removal, erythema measurements are made by placing a probe on the skin of preidentified test sites. The control and test material were applied to the skin test sites once skin redness was induced, and after a given amount of time erythema measurements were recorded again. Additionally, participants quantified the perceived redness on their skin.

Materials

A. **Equipment:** DermaLab Skin Combo (Colori Probe)
B. **Products:** Base Lotion (Cetaphil® Moisturizing Cream for All Skin Types); 3M™ Medipore™ H Soft Cloth Surgical Tape
C. **Software:** Excel Analysis ToolPak (Microsoft)

Methods

14 volunteers between the ages of 23 and 40, who were known to be free of any skin pathologies with Fitzpatrick skin types I to III, participated in this study (Table 1).

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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	

Three assigned test sites were identified on the volar forearm of participants. The surgical tape was applied to the test sites for two minutes before being removed to induce skin redness. Immediately after the surgical tape removal, erythema measurements were recorded, and the test materials were applied. The skin test site conditions and treatments are described below (Table 2). After 15 minutes of product application, erythema measurements were recorded again, and participants were asked to evaluate the visual reduction in redness of each test site compared to immediately after tape removal on a scale from 1 (no change in redness) to 10 (no redness present) (Figure 3). The Base Lotion utilized in this study was Cetaphil® Moisturizing Cream for All Skin Types.

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 ExoCalm**	2.0% **AC ExoCalm** in Base Lotion
3	5.0% **AC ExoCalm**	5.0% **AC ExoCalm** in Base Lotion

An average of three consecutive erythema measurements per condition at each time point was recorded. Data is displayed as averages from all participants and was analyzed using T-tests with statistical significance accepted at $p \leq 0.05$. The percent change in erythema was calculated for each test site at every timepoint relative to Baseline values, using the following equation:

$$Percent\ Change\ (\%) = \frac{Skin\ Erythema_{15\ Minutes\ After\ Application} - Skin\ Eryhtema_{Immediately\ After\ Tape\ Removal}}{Skin\ Erythema_{Immediately\ After\ Tape\ Removal}} \times 100$$

Pearson's Correlation Coefficient (r) measures the strength and direction of the relationship between two variables. The Pearson Correlation Coefficient includes a range of values from +1.0 to -1.0, where a value of 0.0 indicates no association between the two variables. The stronger the relationship between two variables, the closer Pearson's Correlation Coefficient will be to +1.0 or-1.0, depending on the positive or negative nature of the relationship (Table 3). Pearson's Correlation Coefficient was utilized to determine the relationship between percent change in Skin Erythema and Consumer Perceived Redness Reduction (Figures 4, 5).

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Table 3. Interpretation of the Pearson's Correlation Coefficients (r)[2]

Correlation Coefficient	Strength of Relationship
+1.0 -1.0	Perfect
+0.9 -0.9 +0.8 -0.8 +0.7 -0.7	Strong
+0.6 -0.6 +0.5 -0.5 +0.4 -0.4	Moderate
+0.3 -0.3 +0.2 -0.2 +0.1 -0.1	Weak
0 0	Zero

Results

The data obtained from this study met criteria for a valid study as the Base Lotion performed as anticipated. Application of 2.0% and 5.0% **AC ExoCalm** demonstrated effective short-term redness reducing properties.

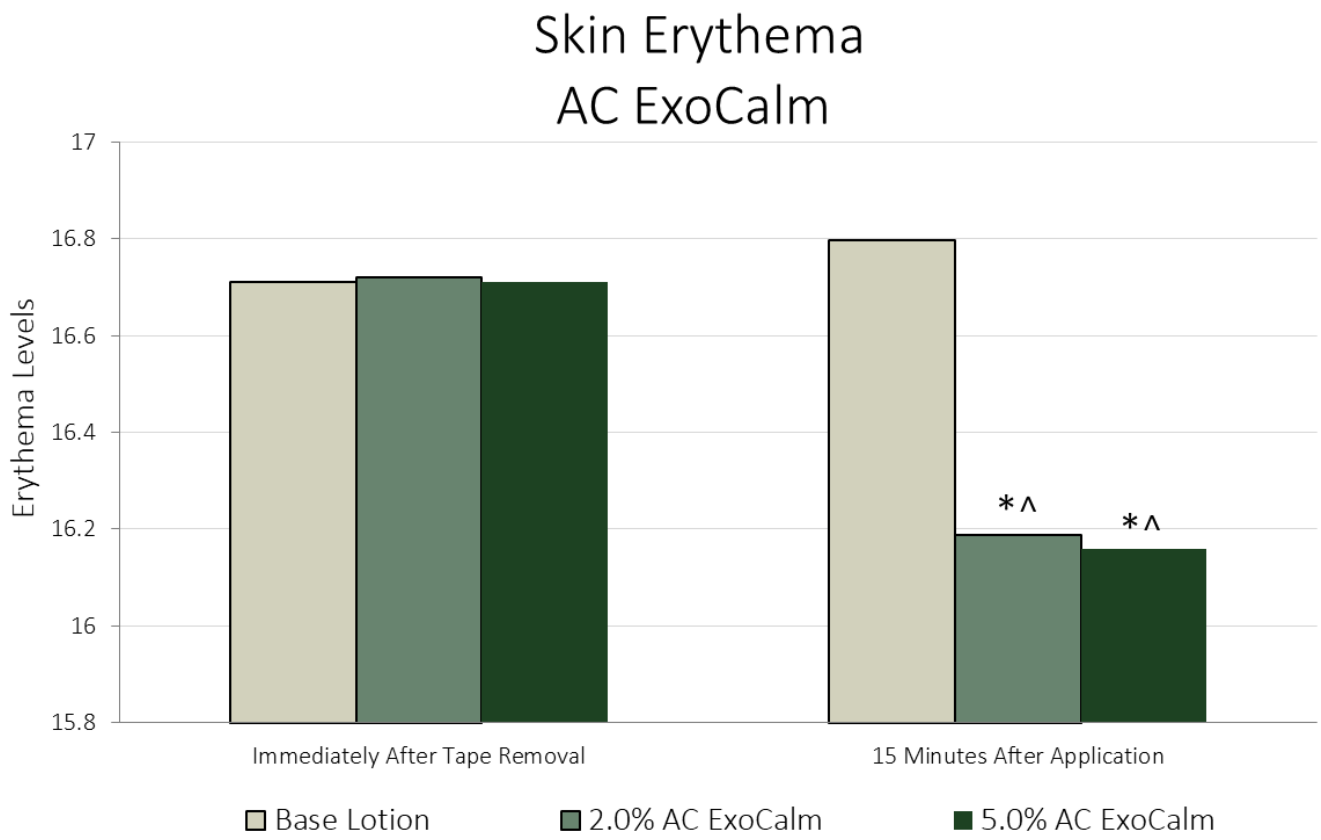

Figure 1. Skin Erythema Before and After Product Application. * indicates significance between timepoints within conditions ($p \leq 0.05$). ^ indicates significance between conditions at given timepoint ($p \leq 0.05$).

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Table 4. Results from T-test Analysis of Skin Erythema Levels. * indicates significance between timepoints within conditions ($p \leq 0.05$). ^ indicates significance between conditions at given timepoint ($p \leq 0.05$).

	Base Lotion: Immediately After Tape Removal vs 15 Minutes After Application	2.0% **AC ExoCalm**: Immediately After Tape Removal vs 15 Minutes After Application	5.0% **AC ExoCalm**: Immediately After Tape Removal vs 15 Minutes After Application	15 Minutes After Application: Base Lotion vs 2.0% **AC ExoCalm**	15 Minutes After Application: Base Lotion vs 5.0% **AC ExoCalm**
P-value	0.846	< 0.001*	< 0.001*	< 0.001^	< 0.001^

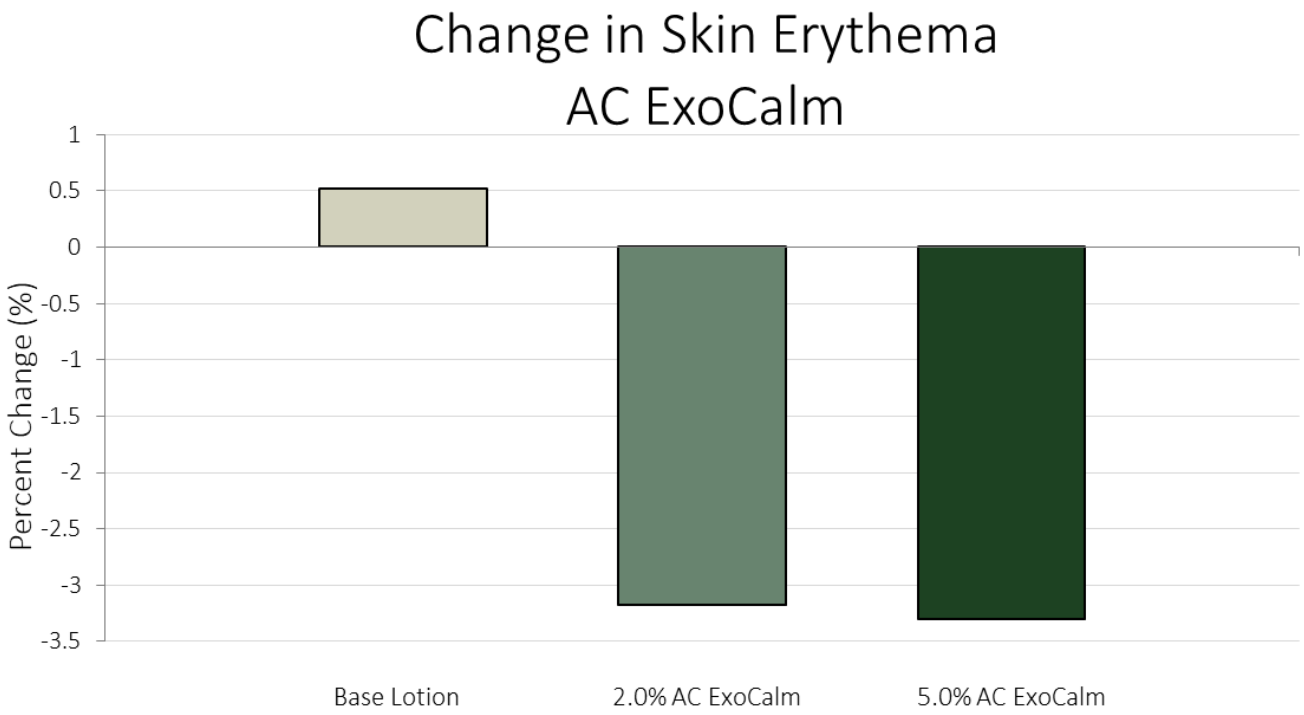

Figure 2. Percent Change in Skin Erythema After Product Application.

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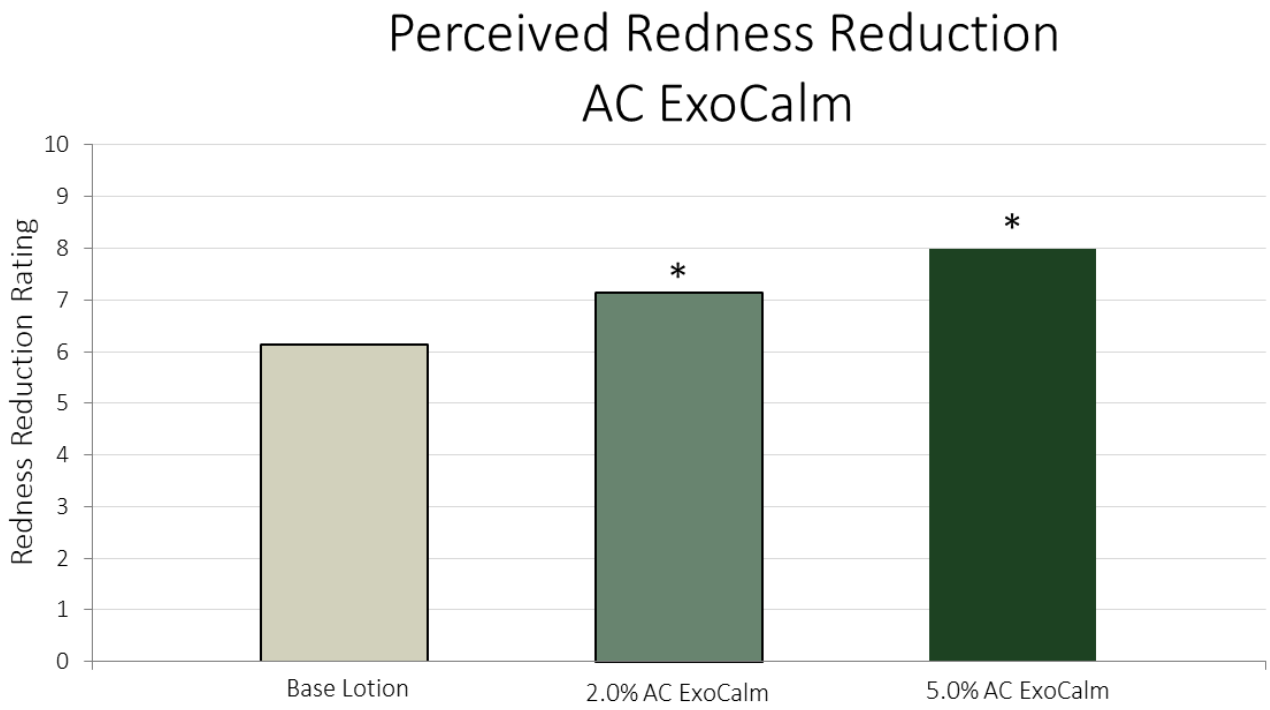

Figure 3. Participant Ratings for Redness Reduction on a Scale of 1 (no change in redness) – 10 (no redness present). * indicates significance compared to Base Lotion ($p \leq 0.05$).

Table 5. Results from T-test Analysis of Participant Redness Reduction Ratings. * indicates significance compared to Base Lotion ($p \leq 0.05$).

	Base Lotion vs 2.0% **AC ExoCalm**	Base Lotion vs 5.0% **AC ExoCalm**
P-value	0.004*	< 0.001*

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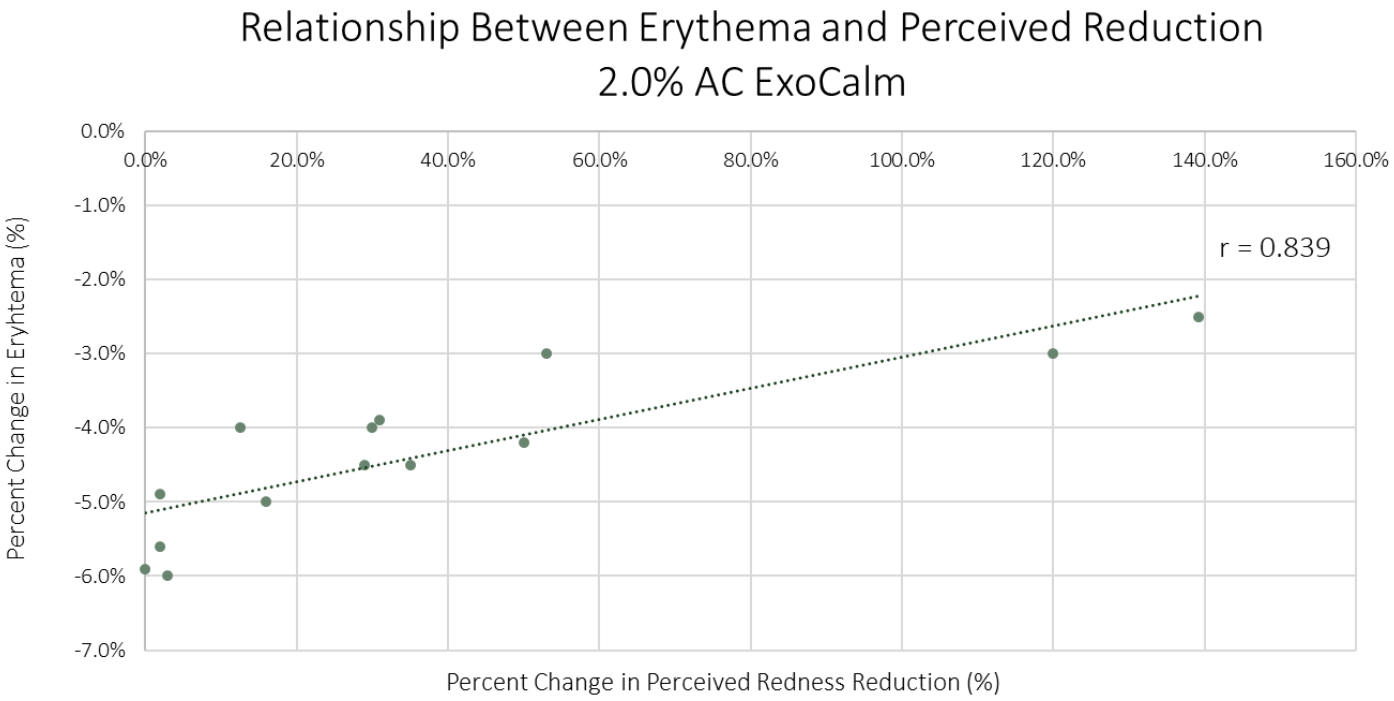

Figure 4. Relationship Between Percent Change in Skin Erythema and Participant Perceived Redness Reduction after Application of 2.0% **AC ExoCalm**. The Pearson Correlation Coefficient indicates a strong relationship between two variables when r ≥ 0.70.

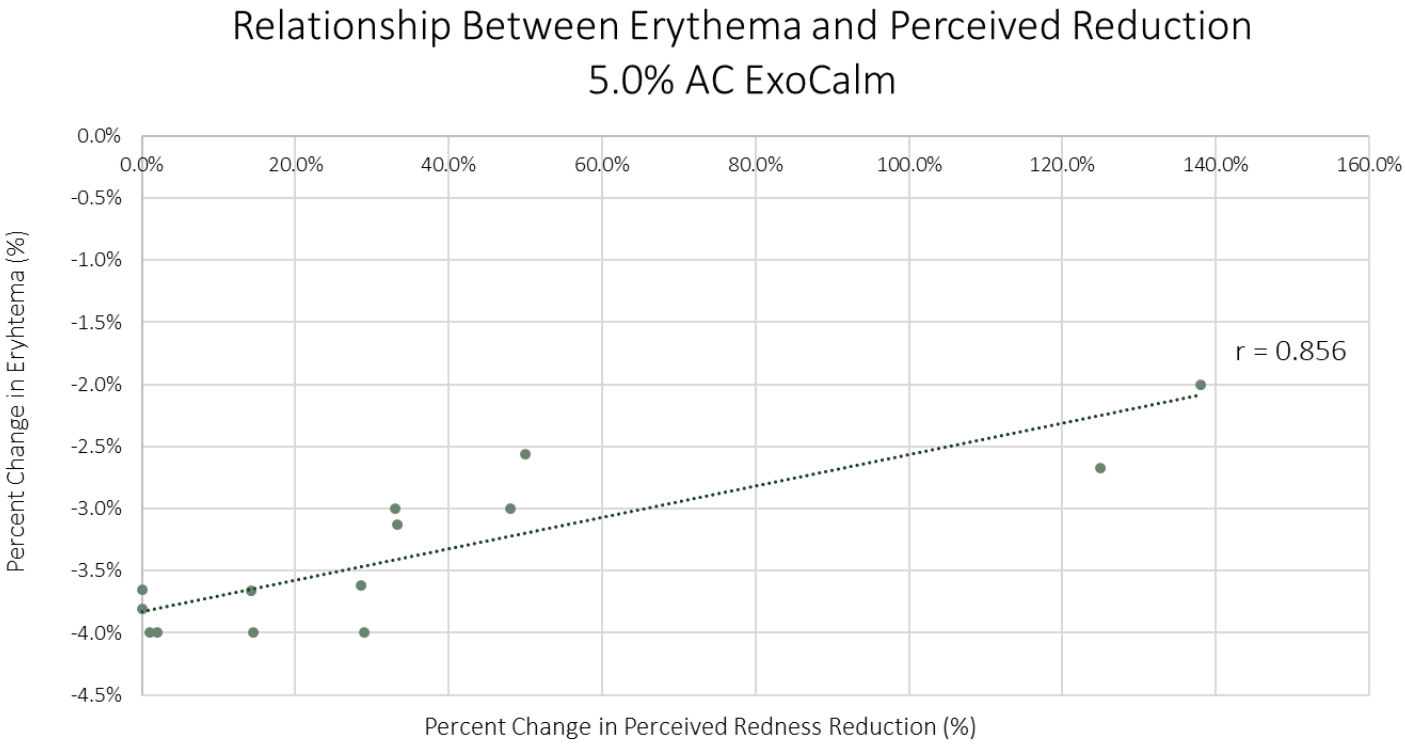

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Figure 5. Relationship Between Percent Change in Skin Erythema and Participant Perceived Redness Reduction after Application of 5.0% **AC ExoCalm**. The Pearson Correlation Coefficient indicates a strong relationship between two variables when $r \geq 0.70$.

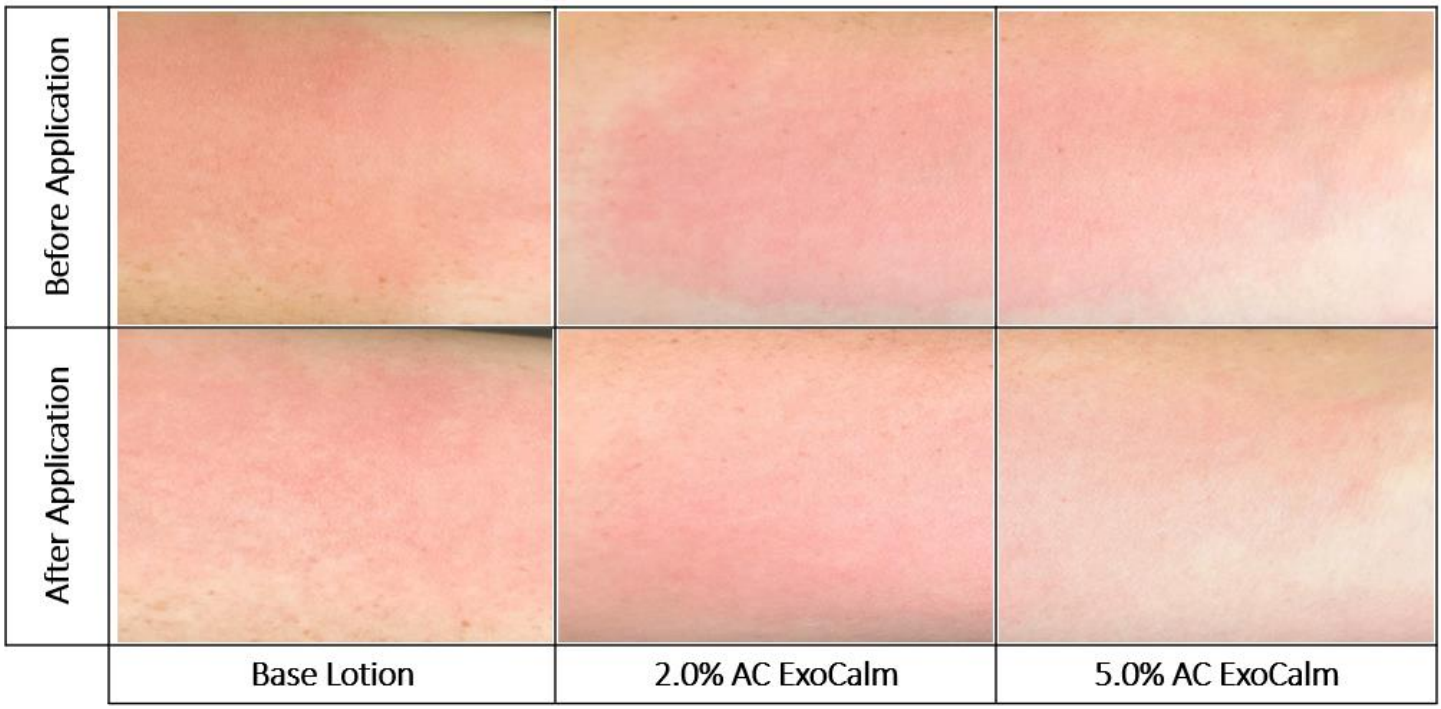

Image 1. Participant Image Before (Top) and After (Bottom) Application of Base Lotion and **AC ExoCalm.**

Discussion

The ability of **AC ExoCalm** to reduce redness and irritation on the skin was assessed via erythema measurements and perceived redness reduction after tape stripping. As shown in Figures 1 and 2, Base Lotion did not alter erythema levels, indicating consistent skin redness and irritation 15 minutes after application (Table 4). Conversely, applying 2.0% and 5.0% **AC ExoCalm** immediately after tape removal significantly reduced skin redness by 3.1% and 3.3%, 15 minutes after application, respectively (Figures 1 & 2; Table 4). This data indicates Base Lotion alone does not reduce skin redness, whereas **AC ExoCalm** exerts significant redness and irritation reducing properties.

Additionally, participants rated the perceived redness of their skin 15 minutes after product application compared to immediately after tape removal. Participants did not perceive a reduction in skin redness with Base Lotion application, indicating the Base Lotion alone does not exert redness reducing properties on the skin (Figure 3; Table 5). Conversely, participants perceived a significant reduction in redness following the application of 2.0% and 5.0% **AC ExoCalm** (Figure 3; Table 4). Furthermore, a strong correlation between the percent change in Erythema and Perceived Redness Reduction, after applying 2.0% and 5.0% **AC ExoCalm**, was determined using Pearson's Correlation Coefficient (Figures 4, 5; Table 3). These results demonstrate **AC ExoCalm** elicits reductions in erythema levels proportional to perceived reductions in skin redness.

Visually, participants experienced a greater reduction in skin redness and irritation when applying 2.0% and 5.0% **AC ExoCalm** compared to Base Lotion application (Image 1). In summary, these results demonstrate **AC ExoCalm** elicits a visual and perceived reduction in skin redness and irritation with just one application.

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Taken together, these results indicate **AC ExoCalm** reduces erythema levels in addition to improving the visual and perceived redness on skin when added to personal care applications at recommended use levels. Collectively, **AC ExoCalm** demonstrates anti-redness and anti-irritation properties which improves the skin's protective barrier function and contributes to the appearance of healthier looking skin.

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/
2. Akoglu H. User's guide to correlation coefficients. Turk J Emerg Med. 2018 Aug 7;18(3):91-93. doi: 10.1016/j.tjem.2018.08.001. PMID: 30191186; PMCID: PMC6107969.