

**Tradename:** AC ExoTone

**Code:** 60194

**CAS #:** 7732-18-5 & 85251-63-4 & 123465-35-0 (or) 8002-43-5

**Test Request Form #:** 10114

**Lot #:** N230530A

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

**Study Director:** *Maureen Drumwright*

**Principal Investigator:** *Kayla Patterson*

**Test Performed:**

Cellular Renewal Study

**Introduction**

As the largest human organ, the skin's integrity is critical to properly function as a physical barrier and maintenance of a healthy appearance for aesthetics. The epidermis constantly undergoes major self-renewal as the superlayer of cells are lost by desquamation and replaced by cells in the basal layers. The constant replacement of cells mitigates the negative long-term effects of ultraviolet light damage and harmful agents (chemicals, pollutants, etc.) on the skin. Aiding in the processes of cellular renewal can improve the skin's physical appearance as well as function as a protective barrier.

Accordingly, a cellular renewal study was conducted to evaluate the ability of **AC ExoTone** to accelerate skin cell replacement by assessing changes in pigmentation.

**Study Principle**

Dermal Dye Max™ (active ingredient: dihydroxyacetone (DHA) / glycerone) is applied to the skin and creates artificially high pigmented skin. The controls and test materials are applied to the artificially pigmented areas and pigmentation is measured overtime. The artificially pigmented areas provide a model to assess cellular renewal by measuring pigmentation with decreases in pigmentation representing cellular renewal.

**Materials**

- A. Equipment:** DermaLab Skin Combo (Skin Color Probe); Digital Camera
- B. Products:** Dermal Dye Max™ (Alpine Valley Naturals); Base Lotion (Cetaphil® Moisturizing Cream for All Skin Types); Glycolic Acid (positive control)

## Methods

10 volunteers between the ages of 22 and 45, who were known to be free of any skin pathologies with Fitzpatrick skin types I to IV, participated in this study (Table 1).

**Table 1.** The Fitzpatrick Classification of Skin Types Chart<sup>1</sup>

| 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

Five test sites were identified on the volar forearm of participants. The first test site was identified as the Comparative Skin Site, and no dye nor treatment were applied to this site to demonstrate normal pigmentation readings. Dermal Dye Max™ was applied to the remaining four test sites and allowed to develop for 24 hours prior to baseline readings. After dye development and prior to initial treatment application, baseline DermaLab pigmentation index readings were taken for all five identified sites. The skin test site conditions and treatments are described below (Table 2). The Untreated Dye Control received Dermal Dye Max™ but no treatment to demonstrate normal cellular renewal.

All lotion formulations and the Base Lotion were adjusted to a direct pH of 5.0 – 5.5 (Table 2). The Base Lotion utilized in this study was Cetaphil® Moisturizing Cream for All Skin Types. Approximately 0.2 g of each treatment was applied to three 2 cm x 2 cm respective locations on the volar forearm. Pigmentation readings and images were taken every 24 hours until the active test site returned to baseline. After each daily reading, treatment of each respective test site was performed following the same parameters listed above.

**Table 2.** Descriptions of the Conditions and Treatments for each Skin Test Site

| Skin Test Site | Condition             | Dermal Dye Max™ Application? | Treatment / Test Material Application Description | Lotion pH |
|----------------|-----------------------|------------------------------|---|-----------|
| 1              | Comparative Skin Site | No                           | None  | N/A       |
| 2              | Untreated Dye Control | Yes                          | None  | N/A       |
| 3              | Base Lotion           | Yes                          | Base Lotion                                       | 5.36      |
| 4              | 5.0% Glycolic Acid    | Yes                          | 5.0% Glycolic Acid in Base Lotion                 | 5.32      |
| 5              | 5.0% AC ExoTone       | Yes                          | 5.0% AC ExoTone in Base Lotion                    | 5.30      |

The percent change of Pigmentation values was calculated for each test site at every timepoint relative to Baseline values, using the following equation:

$$\text{Percent Change (\%)} = \frac{\text{Pigmentation Index}_{\text{Day}} - \text{Pigmentation Index}_{\text{Baseline}}}{\text{Pigmentation Index}_{\text{Baseline}}} \times 100$$

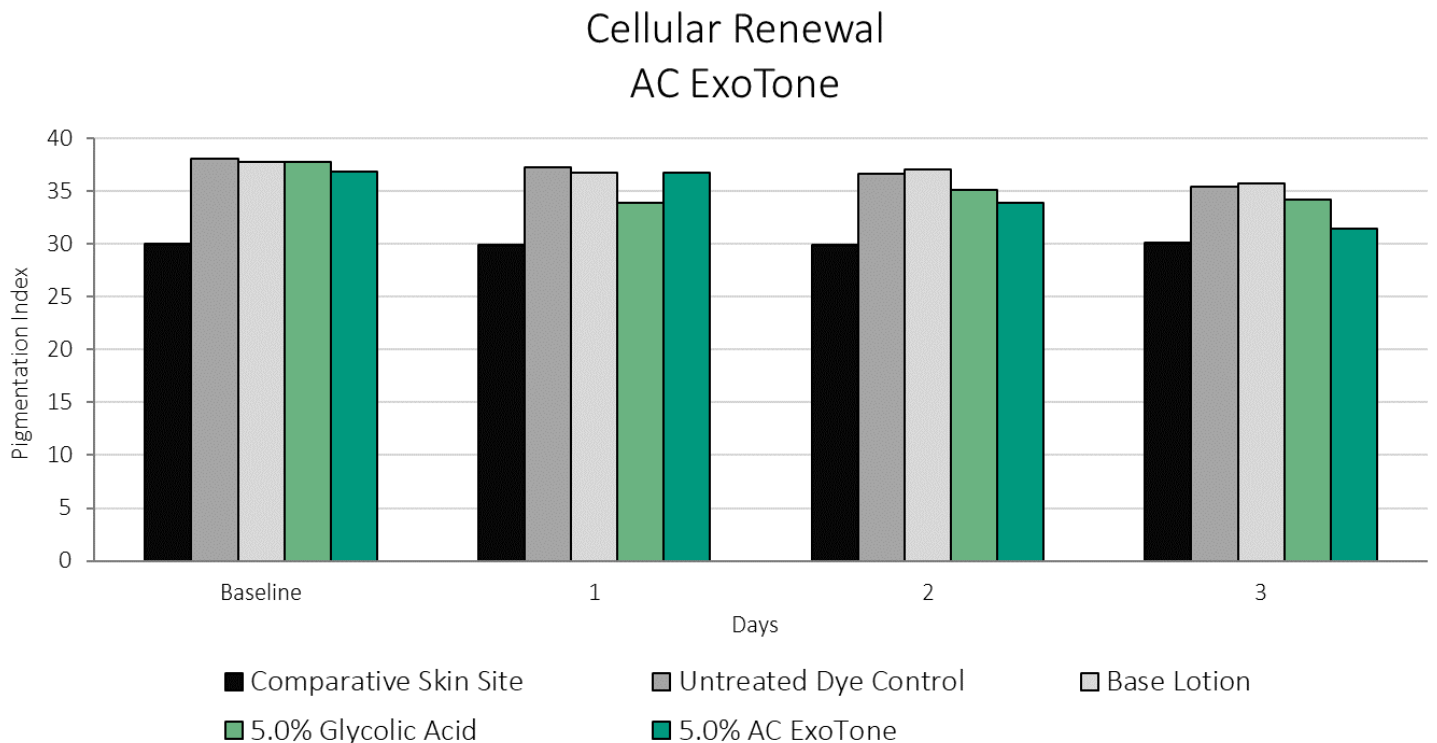
Cumulative Cellular Renewal, represented by the Pigmentation Index values and relative to the Untreated Dye Control, was calculated as area under the curve (AUC) by using the following equation:

$$AUC = \frac{1}{2} \sum_{i=0}^{n-1} (t_{i+1} - t_i) (Pigmentation Index_i + Pigmentation Index_{i+1})$$

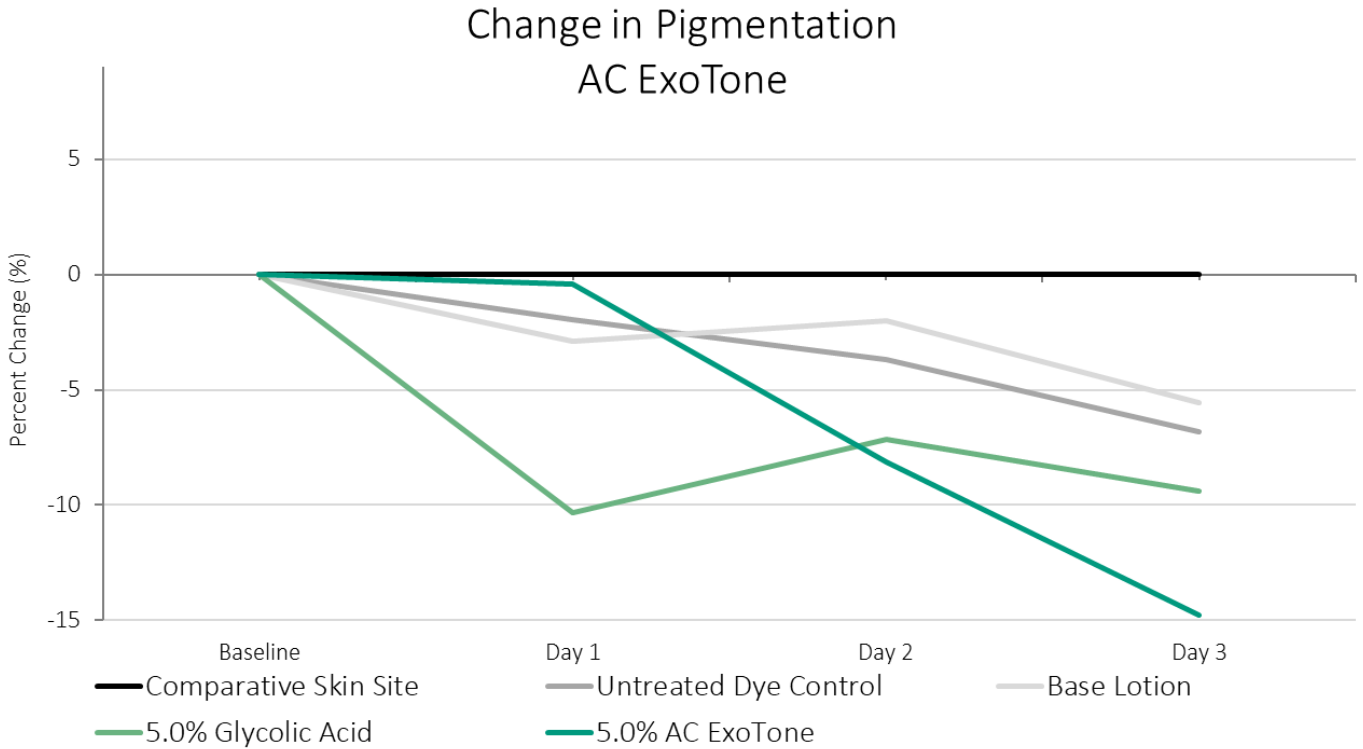
For pigmentation measurements *Pigmentation Index1* and *Pigmentation Index 2* at times *t1* and *t2*, the AUC between those two time points is equivalent to the product of difference in time and the average of the two Pigmentation measurements. Provided Pigmentation Index values decreased over time AUC was calculated as an inverse and presented as a positive value to demonstrate the amount of cellular relative to the Untreated Dye Control.

## Results

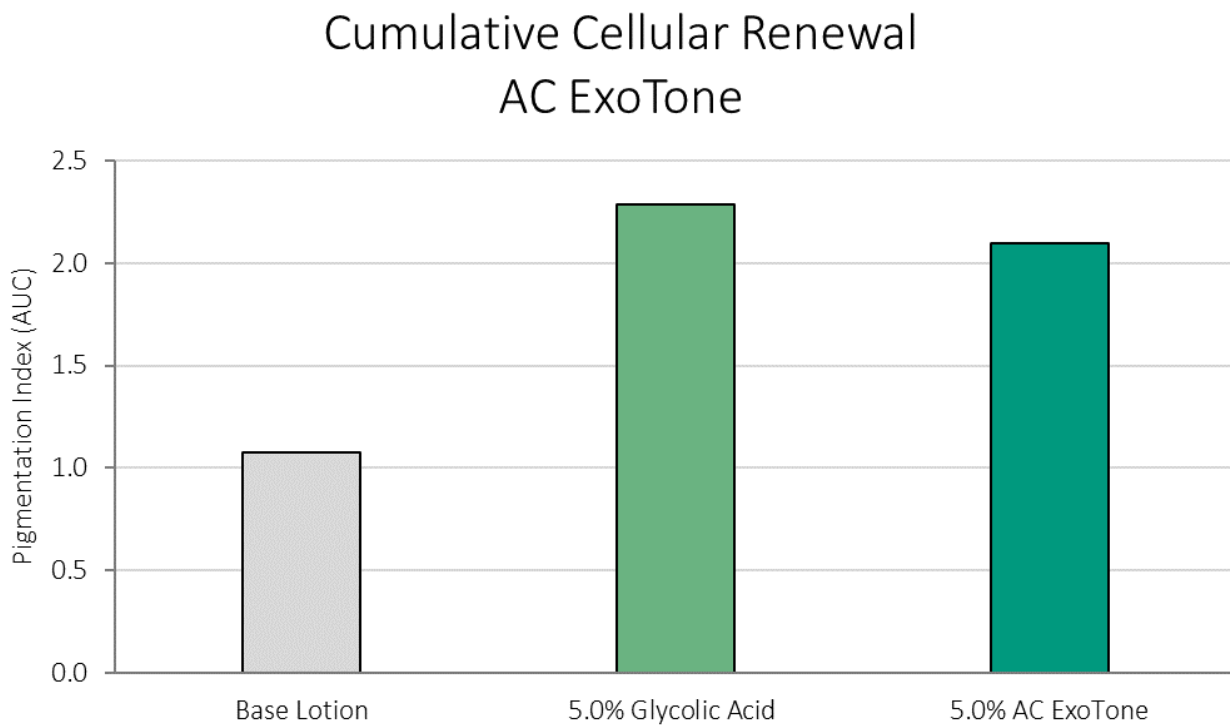
The data obtained from this study met criteria for a valid study as the Comparative Skin Site, Untreated Dye Control, and Glycolic Acid performed as anticipated. Application of 5.0% AC ExoTone accelerated cellular renewal as pigmentation values returned to the baseline levels of the Comparative Skin Site after three days.



**Figure 1.** Cellular Renewal of Pigmentation Index Values Overtime



**Figure 2.** Percent Change in Pigmentation Relative to Baseline Readings



**Figure 3.** Cumulative Cellular Renewal in Pigmentation Relative to the Untreated Dye Control



**Figure 4.** Participant Images of Each Test Patch at Baseline (Top) and After Three Days (Bottom)

### Discussion

The ability of **Ac ExoTone** to accelerate skin cellular renewal was assessed through changes in pigmentation. As shown in Figure 1 and 2, the Dermal Dye Max™ artificially augmented pigmentation values at baseline measurements. After three days, the Untreated Dye Control demonstrated a 7% reduction in pigmentation indicating normal cellular renewal (Figures 1, 2). Similarly, the Base Lotion exhibited a 6% decrease in pigmentation demonstrating normal cellular renewal. After three days of application, 5.0% Glycolic Acid induced a 9% decrease in pigmentation as expected. However, 5.0% **AC ExoTone** elicited a 15% reduction in pigmentation and outperformed the positive control.

Similar results are shown when the data is displayed to illustrate the collective effect of each treatment when the Untreated Dye Control pigmentation values are accounted for. As shown in Figure 3, 5.0% Glycolic Acid and 5.0% **AC ExoTone** produced large changes in cumulative cellular renewal compared to the Base Lotion. Additionally, 5.0% Glycolic Acid and 5.0% **AC ExoTone** elicited similar changes in cumulative cellular renewal, however **AC ExoTone** elicited a larger change compared to baseline. Examining images of the skin test sites at Baseline and after three days of the application, 5.0% **AC ExoTone** visually outperformed the Base Lotion and 5.0% Glycolic Acid in terms of reducing pigmentation.

Taken together, these results indicate **AC ExoTone** enhances cellular renewal when added to personal care applications at recommended use levels. Collectively, **AC ExoTone** accelerates the processes of cellular renewal which can improve the skin's physical appearance as well as function as a protective barrier.

## 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/>