# Reduction in Cellulite

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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 #:** 11692

**Lot #:** N240509A

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

**Test Performed:**
*In vivo* DermaLab Analysis: Cellulite

## Introduction

Cellulite is a dermatological condition often appearing as depressions or dimples on the skin. Cellulite typically occurs in areas of the skin like the thighs or buttocks due to greater fat storage in those areas. The skin surface appears uneven and is often referred to as having similar appearance to "cottage cheese" or "orange peels". As people age, collagen fibers often stretch and eventually begin to break down. As a result, cellulite appears on the skin in areas where collagen degradation has occurred. It is important to monitor the visual manifestations of skin damage, such as cellulite, because limiting skin damage provides a healthier and more youthful skin appearance.

Accordingly, an *in vivo* study was conducted over a period of four weeks to evaluate the ability of **AC WonderShroom** to improve the appearance of cellulite on thighs as well as Collagen Fiber Density, Dermal Collagen Thickness, and Skin Elasticity.

## Study Principle

Participants applied specific products to the back of their thighs twice a day for four weeks. Ultrasound and Elasticity measurements were collected once a week during the four-week use period. Photographs of participant thighs were obtained at baseline and after four weeks of product application. Ultrasound skin imaging is based on measuring reflections of an emitted acoustic pulse transmitted into the skin. After processing the reflected signals, a cross-sectional image is generated based on the intensity of the reflected signals (Diagram 1). The Elasticity Probe is based on a suction cup method, which measures the elevation of the skin, as a function of a predefined negative pressure setting. Photographs of cellulite were utilized for qualitative purposes.

## Materials

A. **Equipment:** DermaLab Skin Combo (High Resolution Skin Imaging Probe and Elasticity Probe); Canon EOZ Rebel T3 Digital Camera
B. **Products:** CelluBlue
C. **Software:** ImageJ (National Institutes of Health (NIH)); Excel Analysis ToolPak (Microsoft)

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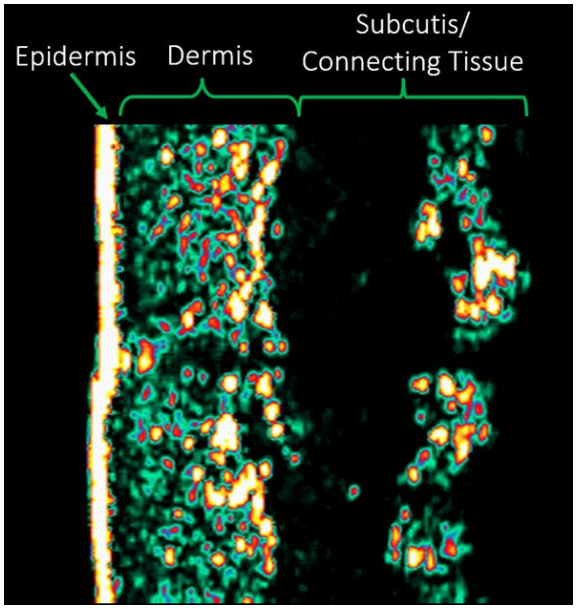


**Diagram 1.** Representative Ultrasound Image with Measurement Areas

## Methods

Ten 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).

**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 were selected by a visual grading criteria to ensure the presence of cellulite on their thighs was distinguishable for this study (Stage 2 or Stage 3) (Table 3). Two randomly assigned test sites were identified on each thigh of participants and Baseline images, Ultrasound, and Elasticity measurements were recorded prior to any product application. Following Baseline measurements, participants were instructed to apply 0.2 g of each treatment to each of their thighs twice a day for a four-week period. Participants were instructed to continue their everyday skin care routine and to apply the lotion once their routine was finished. Participants were instructed not to wear any cosmetic products or lotion on their thighs for each weekly measurement session. The skin test site conditions and treatments are described below (Table 2). All lotion formulations were adjusted to a direct pH of 5.0 – 5.5 (Table 2). The Base Lotion utilized in this study was CelluBlue, given its demonstrated cellulite reducing properties, to illustrate the additive effect of **AC WonderShroom** as a personal care ingredient to a final formulation.

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**Table 2**. Descriptions of the Conditions and Treatments for Each Thigh Test Site

| Thigh Test Site | Condition | Treatment / Test Article Application Description | Lotion PH |
|---|---|---|---|
| 1 | CelluBlue | CelluBlue | 5.3 |
| 2 | 2.0% **AC WonderShroom** | 2.0% **AC WonderShroom** in CelluBlue | 5.2 |

**Table 3**. Nurnberger-Muller Cellulite Scale[2]

| Stage | Criteria |
|---|---|
| 0 | No dimpling or apparent visible alterations to the skin surface upon standing or lying down or upon pinching the skin |
| 1 | No dimpling or apparent visible alterations to the skin surface upon standing or lying down. Dimpling appears with the pinch test or muscular contraction |
| 2 | Dimpling appears spontaneously when standing but not when lying down. The orange peel appearance of the skin is evident to the naked eye, without manipulation |
| 3 | Dimpling is spontaneously present when both standing and lying down, evident to the naked eye without need for manipulation. Orange peel skin surface appearance with raised areas and nodules |

The DermaLab Skin Combo Ultrasound Probe analyzes two distinct parameters Skin Thickness and Intensity. Skin Thickness (Dermal Collagen Thickness) measures the area behind the epidermis to the back of the dermis, with lower values correlating with age and less collagen. Intensity (Collagen Fiber Density) is an indicator of the amount of collagen within the dermis, with greater intensities correlating with higher levels of collagen.

An average of three consecutive measurements for Skin Thickness (µm), Intensity (average), and Youngs Elasticity Modulus (MPa) were recorded per condition at each time point. Data are displayed as averages from all volunteers and analyzed using t-tests with statistical significance accepted at $p \leq 0.05$. The percent change for Dermal Collagen Thickness (Skin Thickness), Collagen Fiber Density (Intensity), and Skin Elasticity (MPa) measurements were calculated for each test site at every timepoint relative to baseline values, using the following equation:

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

## Results

The data obtained met criteria for a valid study as CelluBlue performed as anticipated. Application of 2.0% **AC WonderShroom** twice a day for four weeks demonstrated an increase in thigh Collagen Fiber Density, Collagen Thickness, Skin Elasticity, and reduced visual cellulite throughout the four-week treatment period.

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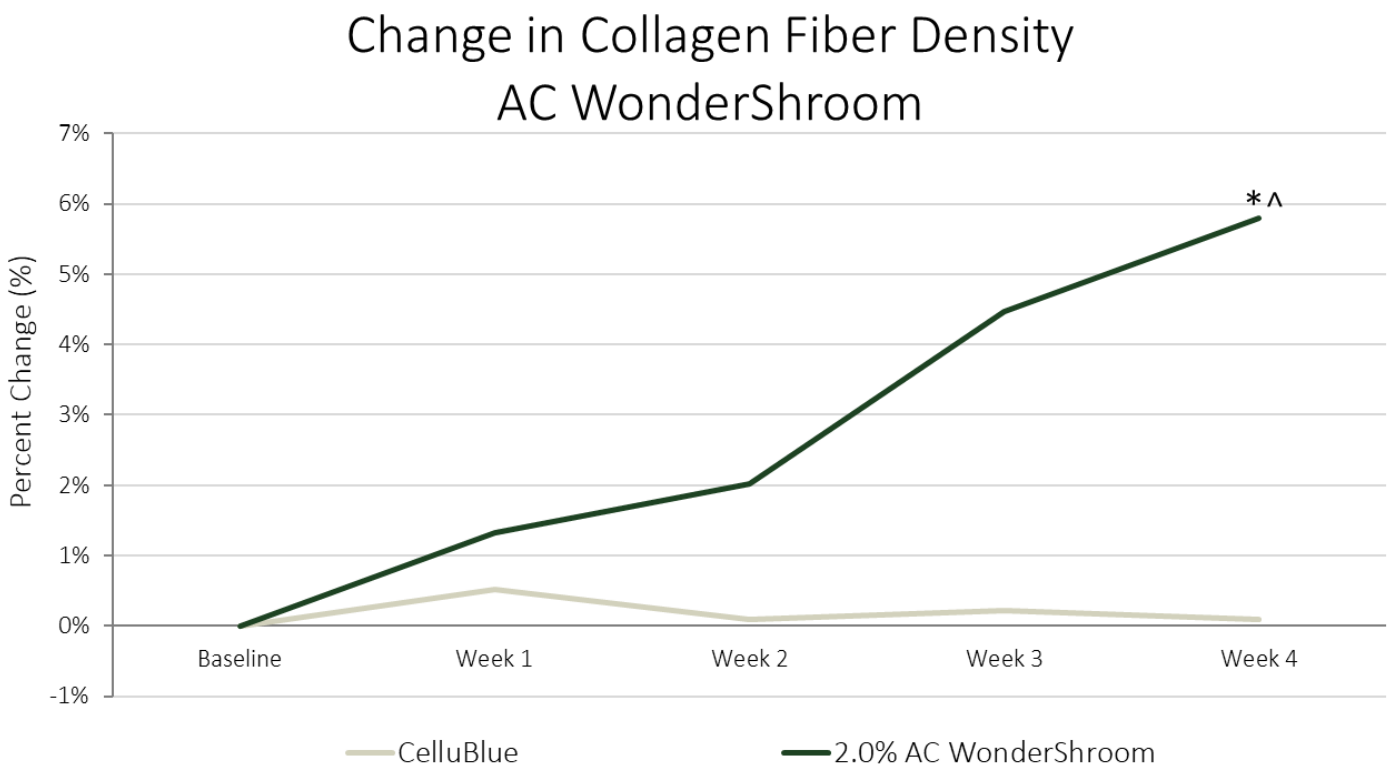


**Figure 1.** Collagen Fiber Density Overtime. * indicates significance ($p \leq 0.05$) compared to Baseline values within the same condition. ^ indicates significance ($p \leq 0.05$) compared to CelluBlue within the same timepoint.

**Table 4.** T-test Analysis of Collagen Fiber Density from Baseline to After Four Weeks of Application. * indicates significance ($p \leq 0.05$) compared to Baseline.

| | CelluBlue | 2.0% **AC WonderShroom** |
|---|---|---|
| **P-value** | 0.396 | 0.045* |

**Table 5.** T-test Analysis of Collagen Fiber Density After Four Weeks of Application. ^ indicates significance ($p \leq 0.05$) compared to CelluBlue within the same timepoint.

| | CelluBlue vs 2.0% **AC WonderShroom** |
|---|---|
| **P-value** | 0.032^ |

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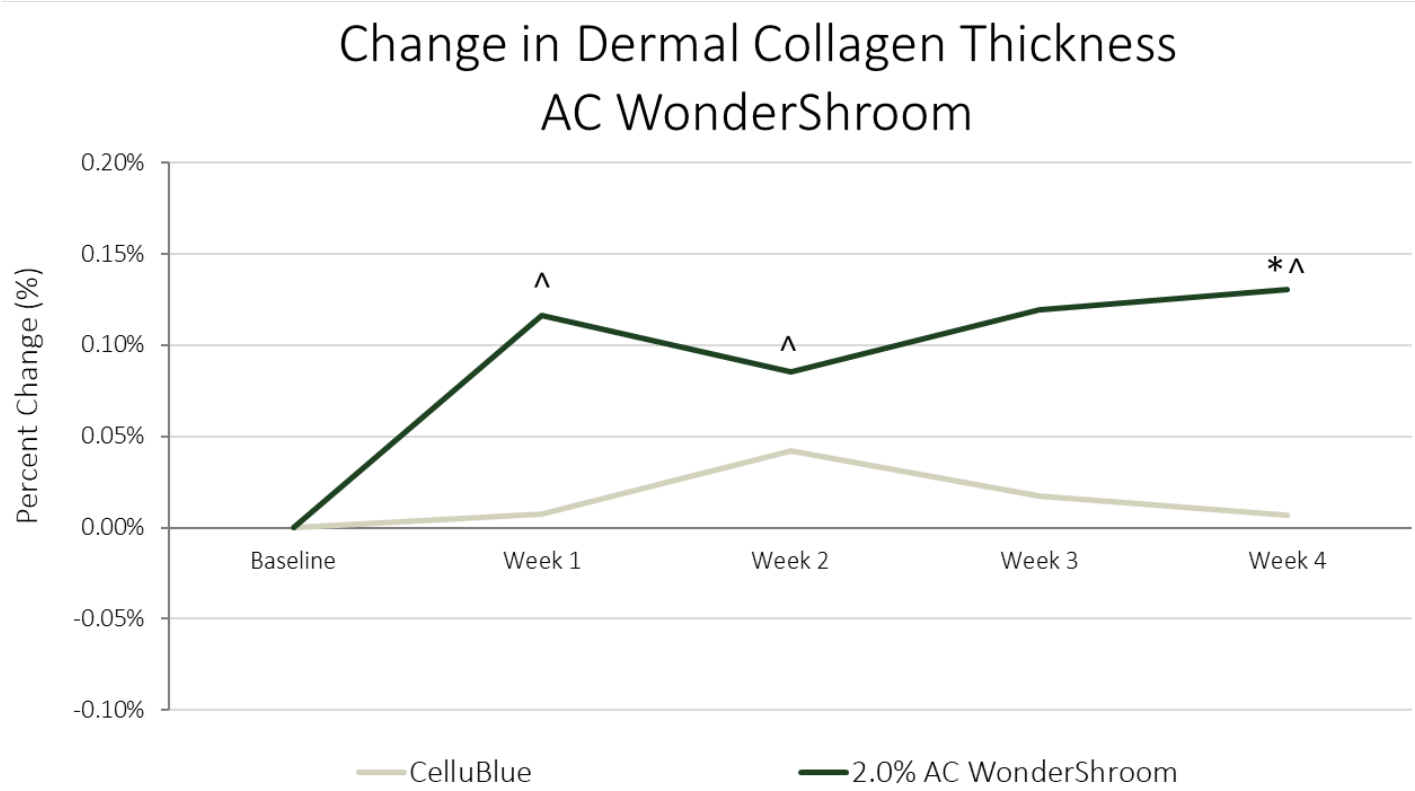


**Figure 2.** Dermal Collagen Thickness Overtime. * indicates significance ($p \leq 0.05$) compared to Baseline values within the same condition. ^ indicates significance ($p \leq 0.05$) compared to CelluBlue within the same timepoint.

**Table 6.** T-test Analysis of Dermal Collagen Thickness from Baseline to After Four Weeks of Application. * indicates significance ($p \leq 0.05$) compared to Baseline.

| | CelluBlue | 2.0% AC WonderShroom |
|---|---|---|
| **P-value** | 0.052 | 0.047* |

**Table 7.** T-test Analysis of Dermal Collagen Thickness After Four Weeks of Application. ^ indicates significance ($p \leq 0.05$) compared to CelluBlue within the same timepoint.

| | CelluBlue vs 2.0% AC WonderShroom |
|---|---|
| **P-value** | 0.041^ |

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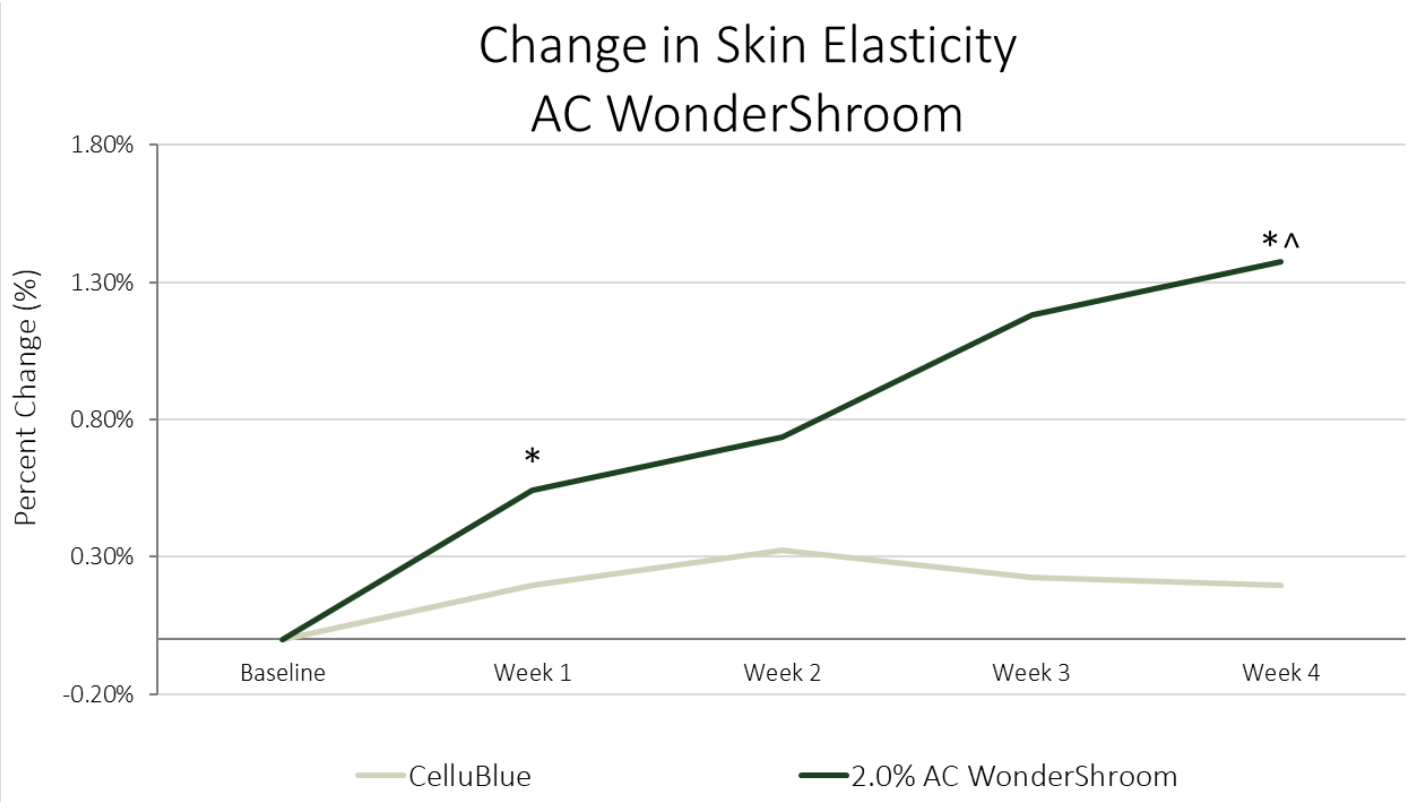


**Figure 3.** Skin Elasticity Overtime. * indicates significance ($p \leq 0.05$) compared to Baseline values within the same condition. ^ indicates significance ($p \leq 0.05$) compared to CelluBlue within the same timepoint.

**Table 8.** T-test Analysis of Skin Elasticity from Baseline to After Four Weeks of Application. * indicates significance ($p \leq 0.05$) compared to Baseline.

| | CelluBlue | 2.0% **AC WonderShroom** |
|---|---|---|
| **P-value** | 0.807 | 0.041* |

**Table 9.** T-test Analysis of Skin Elasticity After Four Weeks of Application. ^ indicates significance ($p \leq 0.05$) compared to CelluBlue within the same timepoint.

| | CelluBlue vs 2.0% **AC WonderShroom** |
|---|---|
| **P-value** | 0.047^ |

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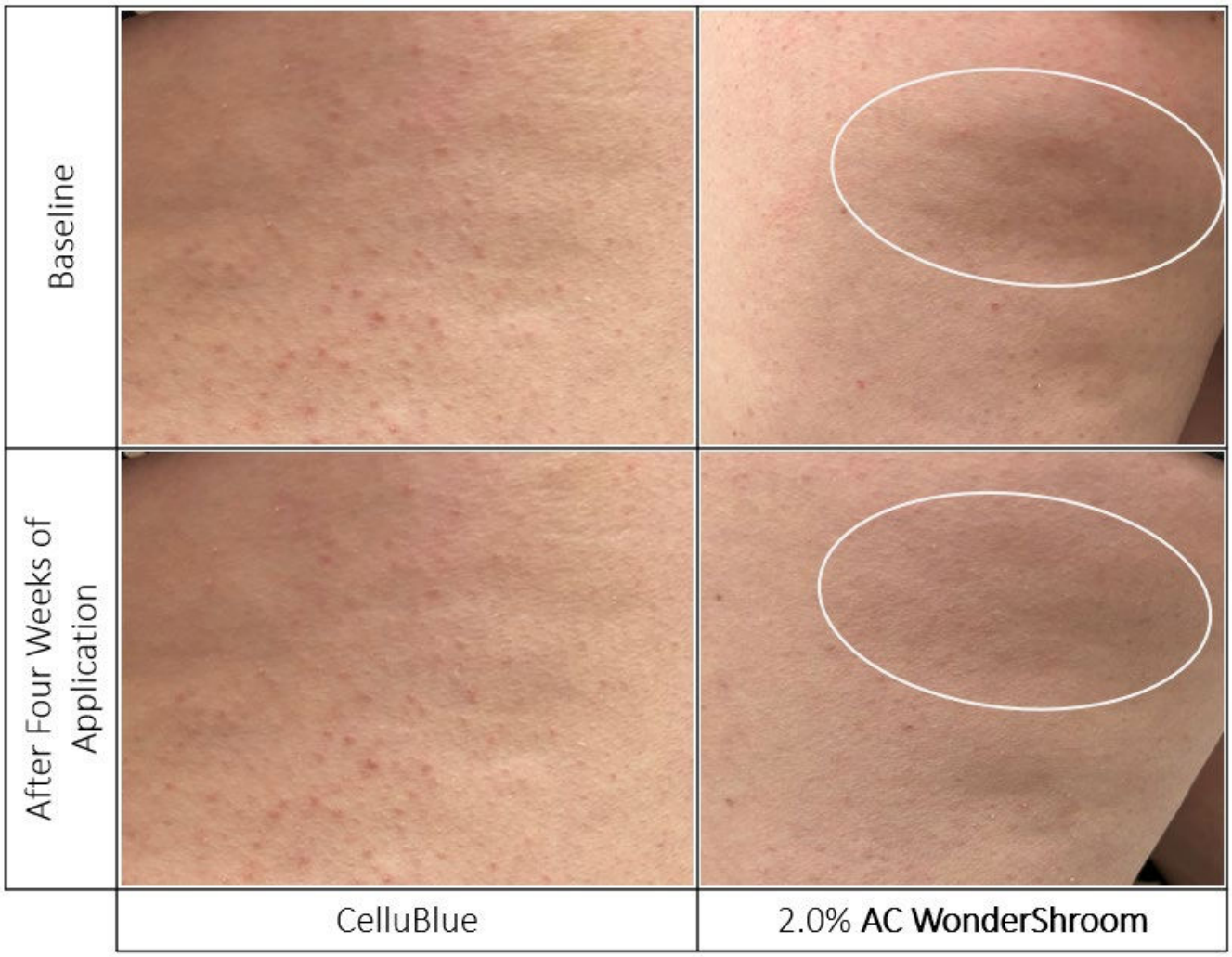


**Image 1.** Images of Participant 2's Thighs Over Time. Participant was graded as Stage 2 at Baseline.

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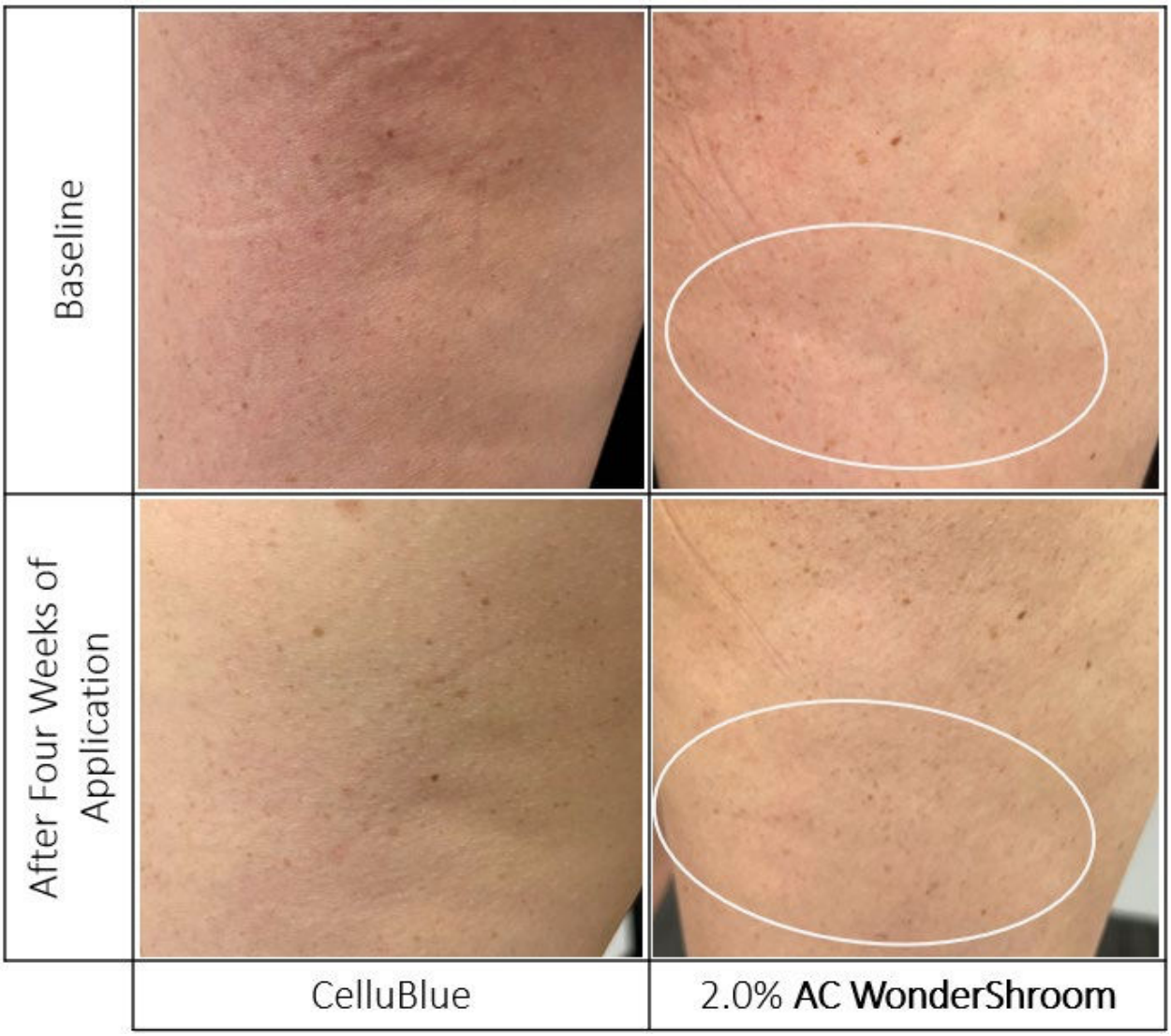


**Image 2.** Images of Participant 4's Thighs Over Time. Participant was graded as Stage 2 at baseline.

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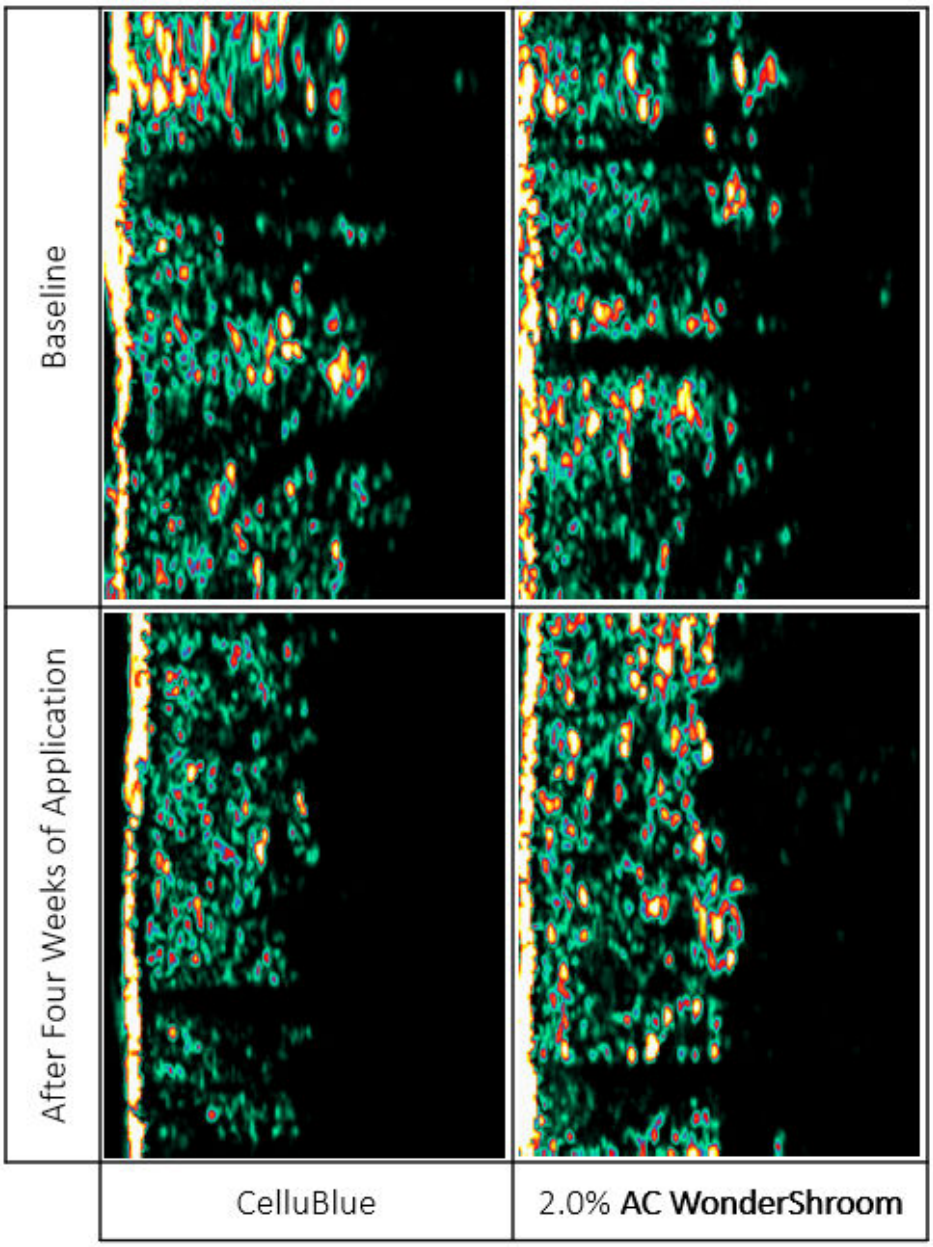


Image 3. Participant Ultrasound Images of Each Test Site at Baseline (Top) and After Four Weeks (bottom) of 2.0% AC WonderShroom application.

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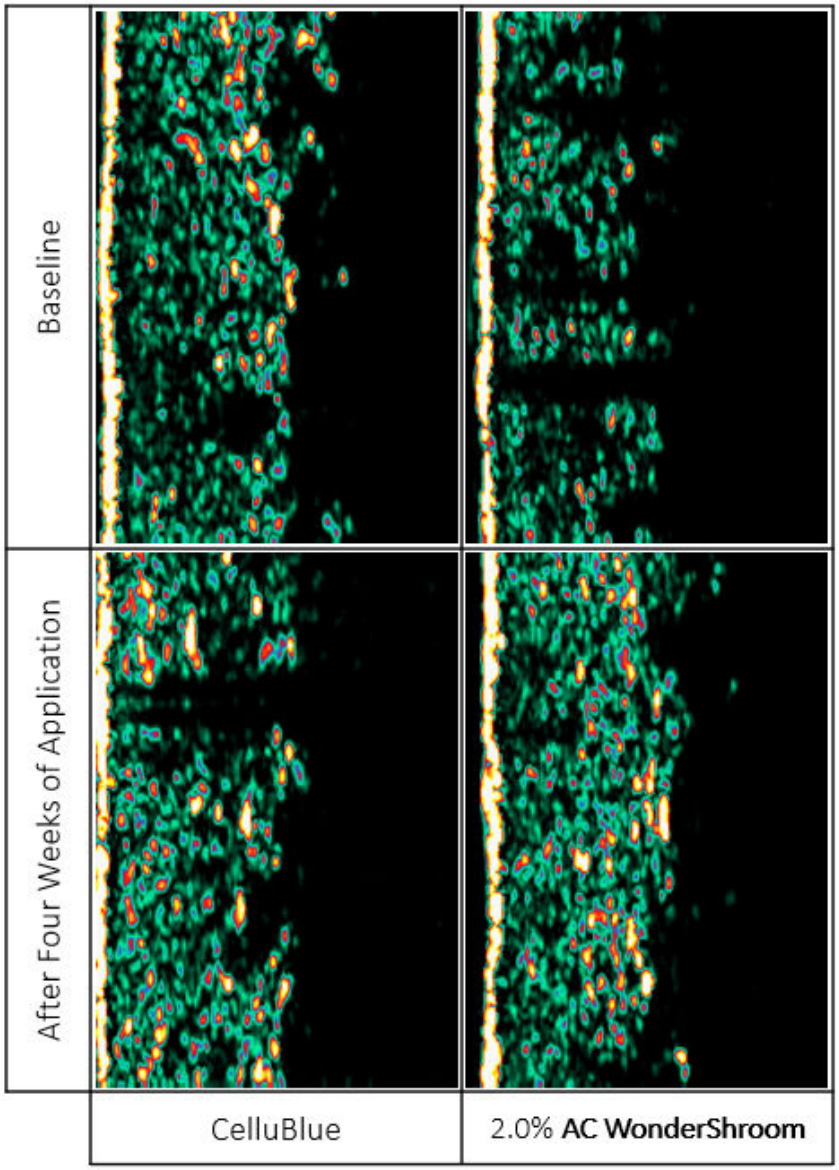


**Image 4.** Participant Ultrasound Images of Each Test Site at Baseline (Top) and After Four Weeks (bottom) of 2.0% **AC WonderShroom** application.

## Discussion

The ability of **AC WonderShroom** to improve the appearance of cellulite on thighs as well as Collagen Fiber Density, Dermal Collagen Thickness, and Skin Elasticity were assessed via ultrasound and elasticity measurements throughout four weeks of twice daily application.

As shown in Figure 1, Collagen Fiber Density was not significantly altered over four weeks with CelluBlue application, indicating consistent collagen density throughout the study (Table 4). Collagen Fiber Density significantly increased by 5.8%, relative to baseline, after four weeks of 2.0% **AC WonderShroom** application (Figure 1; Table 4). Compared to CelluBlue after four weeks of application, 2.0% **AC WonderShroom** demonstrated a significant increase in Collagen Fiber Density (Figure 1; Table 5). These results indicate application of 2.0% **AC WonderShroom** elicits an increase in collagen density, reducing the visual impacts of normal aging on the thighs.

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Similarly, Dermal Collagen Thickness did not significantly change throughout the four-week protocol with CelluBlue application, indicating consistent skin thickness throughout the study (Figure 2; Table 6). Application of 2.0% AC WonderShroom twice daily significantly augmented Dermal Collagen Thickness by 0.13%, relative to baseline, after four weeks of application (Figure 2; Table 6). Cumulatively, applying 2.0% AC WonderShroom twice daily demonstrated a significant increase in Dermal Collagen Thickness compared to the CelluBlue after one, two, and four weeks (Figure 2; Table 7). These results indicate AC WonderShroom augments dermal collagen production resulting in a more youthful thigh appearance.

With respect to Skin Elasticity, CelluBlue did not elicit any significant alterations, indicating consistent skin elasticity throughout the four-week study (Figure 3; Table 8). Skin Elasticity significantly increased by 1.37% after four weeks of 2.0% AC WonderShroom application, relative to baseline (Figure 3; Table 8). Compared to CelluBlue after one and four weeks of twice daily application, 2.0% AC WonderShroom demonstrated a significant increase in Skin Elasticity (Figure 3; Table 9). These results indicate AC WonderShroom improves skin elasticity, improving the visual impacts of normal aging on the thighs.

Visually, participants experienced an improvement in cellulite after four weeks of 2.0% AC WonderShroom application compared to the CelluBlue alone (Images 1, 2, 3, 4). These results indicate AC WonderShroom visually improves the appearance of cellulite present on thighs.

Taken together, these results indicate that AC WonderShroom helps improve the visual appearance of skin on the thighs, supporting increased Collagen Fiber Density, Dermal Collagen Thickness, and Skin Elasticity when incorporated into personal care applications at recommended use levels. Collectively, AC WonderShroom enhances skin texture and elasticity, promoting a smoother, firmer, and more youthful-looking appearance.

## References

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