

## ACTIVE CONCEPTS LLC

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Tradename: ABS White Willow Bark Extract Powder

<u>Code:</u> 10229

CAS #: 84082-82-6

Test Request Form #: 528

Lot #: 28788

Sponsor: Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092 Study Director: Erica Segura Principal Investigator: Meghan Darley

#### Test Performed:

High Resolution Ultrasound Skin-Imaging Study

### Introduction

Collagen is the most abundant protein found in the skin and other areas of the body. Collagen connects other tissues to bone, muscles, tendons, cartilage, and skin. Within the skin, collagen aids in the youthful appearance by providing an anchor point. With age, collagen naturally decreases and results in sagging, wrinkles, and fine lines, which can be accelerated by excessive sun exposure. Collagen encourages the top layer of skin to regenerate which in return keeps skin looking healthy and youthful.

Accordingly, a High-Resolution Ultrasound Skin Imaging Study was conducted to assess the ability of **ABS White Willow Bark Extract Powder** to improve Collagen Fiber Density.

#### **Study Principle**

Participants applied specific products to designated areas on their forearms twice a day for four weeks. Ultrasound measurements were collected once a week during the four-week study period. Ultrasound skin imaging is based on measuring reflections of an emitted acoustic pulse that are transmitted into the skin. After processing the reflected signals, a cross-sectional image is generated based on the intensity of the reflected signals (Figure 1).

The signal intensity is converted to a color scale with dark colors representing areas of low reflection. This means that there are no changes or very small changes in density between the structures in the skin. Bright colors represent areas with strong reflections, indicating substantial changes in density between structures. The epidermis is characterized by a high intensity white/yellow color while the dermis is a mixture of colors at varying intensities.



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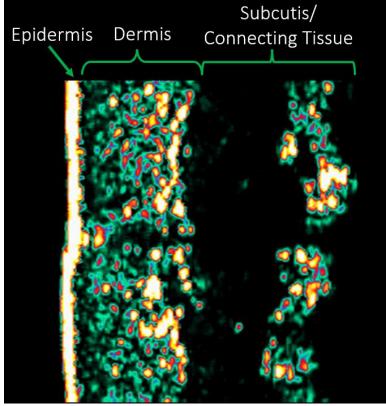


Figure 1. Representative Ultrasound Image with Measurement Areas

## **Materials**

- A. Equipment: DermaLab Skin Combo (Ultrasound Probe)
- B. Products: Base Lotion (Cetaphil® Moisturizing Cream for All Skin Types)
- C. Software: Excel Analysis ToolPak (Microsoft)

#### **Methods**

10 volunteers between the ages of 23 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).

Fitzpatrick Skin Type Descriptions*		
Skin Type	Skin Type Description	
I	I Always burns, never tans	
	Burns easily, tans minimally	
III	Burns moderately, tans to light brown	
IV	IV Burns minimally, tans to moderate brown	
V	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		

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



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Three randomly assigned test sites were identified on the volar forearm of participants and baseline measurements were recorded. Following baseline measurements, participants applied 0.2 g of each test material on their volar forearms twice a day for four weeks. Measurements were recorded once a week for four weeks. The skin test site conditions and treatments are described below (Table 2). The Base Lotion utilized in this study was Cetaphil<sup>®</sup> 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	Untreated Control	None
2	Base Lotion	Base Lotion
3	2.0% ABS White Willow Bark Extract Powder	2.0% ABS White Willow Bark Extract Powder in Base Lotion

An average of three consecutive measurements for Intensity (average) were recorded per condition at each time point. The percent change for Collagen Fiber Density (Intensity) measurements were calculated for each test site at every timepoint relative to baseline values, using the following equation:

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

## <u>Results</u>

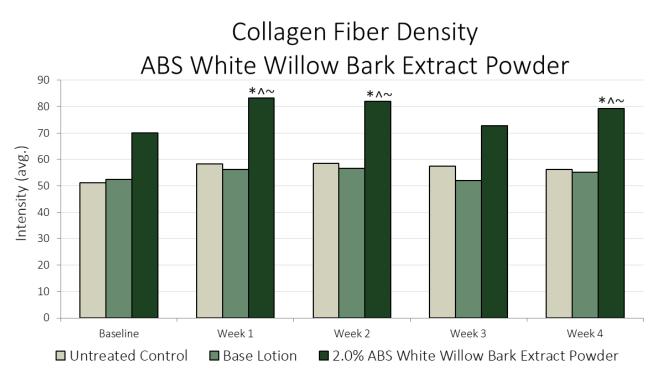
The data obtained from this study met criteria for a valid study as the Untreated Control and Base Lotion performed as anticipated. Application of 2.0% **ABS White Willow Bark Extract Powder** twice a day for four weeks demonstrated effective improvements in Intensity throughout the study duration compared to the Base Lotion.

Active Concepts Tomorrow's vision...Today!\*

# High Resolution Ultrasound Skin Imaging Study

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**Figure 2**. Collagen Fiber Density Overtime. \* indicates significance ( $p \le 0.05$ ) compared to Baseline values within the same condition. ^ indicates significance ( $p \le 0.05$ ) compared to Untreated Control within the same timepoint. ~ indicates significance ( $p \le 0.05$ ) compared to Base Lotion within the same timepoint.

Table 3. T-test Analysis of Collagen Fiber Density from Baseline to After Four Weeks of	Application
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	Untreated Control	Base Lotion	2.0% ABS White Willow Bark Extract Powder
P-value	0.353	0.615	0.031*

**Table 4.** T-test Analysis of Collagen Fiber Density After Four Weeks of Application. ^ indicates significance ( $p \le 0.05$ ) compared to Untreated Control within the same timepoint. ~ indicates significance ( $p \le 0.05$ ) compared to Base Lotion within the same timepoint.

	Untreated Control vs Base Lotion	Untreated Control vs 2.0% ABS White Willow Bark Extract Powder	Base Lotion vs 2.0% ABS White Willow Bark Extract Powder
P-value	0.803	< 0.001^	< 0.001~



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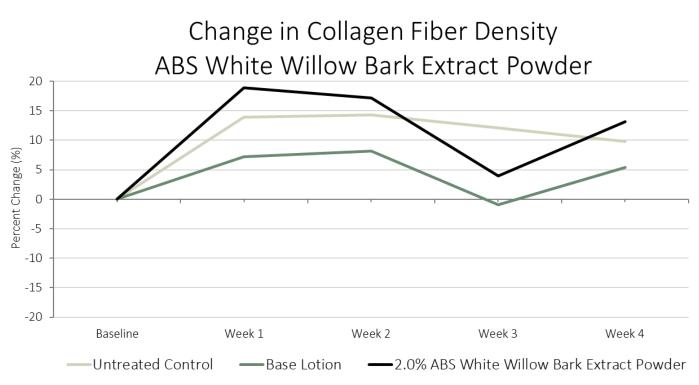


Figure 3. Percent Change in Collagen Fiber Density Relative to Baseline Values

#### **Discussion**

The ability of **ABS White Willow Bark Extract Powder** to improve the Collagen Fiber Density was assessed via ultrasound measurements throughout four weeks of twice daily application.

As shown in Figures 2 and 3, Collagen Fiber Density was not significantly altered throughout the study with the Untreated Test Site, indicating consistent collagen density throughout the study (Table 3). Similarly, Collagen Fiber Density was not significantly altered throughout the study with Base Lotion application, indicating the Base Lotion does not exert significant improvements in Collagen Fiber Density (Figures 2, 3; Table 3). However, Collagen Fiber Density significantly increased by 19% and 13% after one and four weeks of 2.0% **ABS White Willow Bark Extract Powder** application, and to a greater extent than the Base Lotion alone (Figures 2, 3; Table 3).

After four weeks of application, there was no difference in Collagen Fiber Density between the Untreated Control and Base Lotion (Table 4). Conversely, applying 2.0% **ABS White Willow Bark Extract Powder** twice daily demonstrated a significant increase in Collagen Fiber Density compared to the Untreated Control and Base Lotion after four weeks (Figure 3; Table 4). These results indicate application of 2.0% **ABS White Willow Bark Extract Powder** elicits an increase in collagen density, reducing the visual impacts of normal aging.

Taken together, these results indicate **ABS White Willow Bark Extract Powder** improves collagen density when added to personal care applications at recommended use levels. Collectively, **ABS White Willow Bark Extract Powder** improves normal skin aging by augmenting collagen density resulting in a healthier and more youthful skin appearance.



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#### **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: <u>https://www.ncbi.nlm.nih.gov/books/NBK557626/</u>