High Resolution Ultrasound Skin Imaging Assay

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Tradename: ACB Bio-Chelate 5 PF

Code: 20339PF

CAS #: 7732-18-5 & 8013-01-2 & 8013-01-2 & 8013-01-2 & 8013-01-2 & 8013-01-2

Test Request Form #: 532

Lot #: 23671

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

Test Performed:
High Resolution Ultrasound Skin-Imaging Assay

Introduction

An *in-vivo* study was conducted over a period of four weeks to evaluate the effect on skin density of **ACB Bio-Chelate 5 PF.** 10 M/F subjects between the ages of 23-45 participated in the study. Data gathered from the high resolution ultrasound imaging yielded results that indicate that this material is capable of significantly improving skin density compared to the control.

Materials

A. Equipment: DermaLab Skin Combo (Ultrasound Probe)

Methods

High Resolution Ultrasound Skin imaging is based on measuring the acoustic response after an acoustic pulse is sent into the skin. The energy of the acoustic pulse is low and will not affect the skin in any way. When the acoustic pulse is emitted and hits different areas of the skin, part of the pulse will be reflected and part will be transmitted further into the skin. The reflected signal travels back and is picked up by the ultrasound transducer. After processing the signal, a cross-sectional image appears on the screen. This image represents an intensity, or amplitude, analysis of the signals.

The intensity of the signals that are received refer to a color scale. Dark colors represent areas of the skin with 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, signifying substantial changes in density between structures.

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10 volunteers M/F between the ages of 23 and 45 and who were known to be free of any skin pathologies participated in this study. The DermaLab ultrasound probe was used to determine the skin density of the subject's volar forearms.

Following initial measurements, all subjects were asked to apply 2 mg of each test material on their volar forearms. Measurements were taken 24 hours after application of test materials and then weekly for 4 weeks. The test material consisted of 2.0% **ACB Bio-Chelate 5 PF** in a base lotion.

For added perspective, measurements of an untreated test site and a site treated with a base lotion (Cetaphil Moisturizing for All Skin Types) were recorded.

Results

ACB Bio-Chelate 5 PF showed improvements in skin density at a 2.0% concentration. Please note, each value is an average of three consecutive readings per test site.

Raw Data:

	t = 24	1 week	2 week	3 week	4 week
Experimental (2.0% ACB Bio-Chelate 5 PF in Base Lotion)	54.4	59.0	60.9	58.9	66.7
Untreated	58.6	60.9	64.1	67.1	69.1
Base Lotion Control	52.1	62.4	68.1	61.0	69.2
	t = 24	**1 week**	**2 week**	**3 week**	**4 week**
Experimental vs. Untreated	11.02%	13.08%	15.07%	12.25%	13.54%
Base Lotion vs. Untreated	1.01%	2.46%	3.21%	2.25%	1.16%
Experimental vs. Base Lotion	14.48%	15.41%	13.26%	13.46%	13.69%

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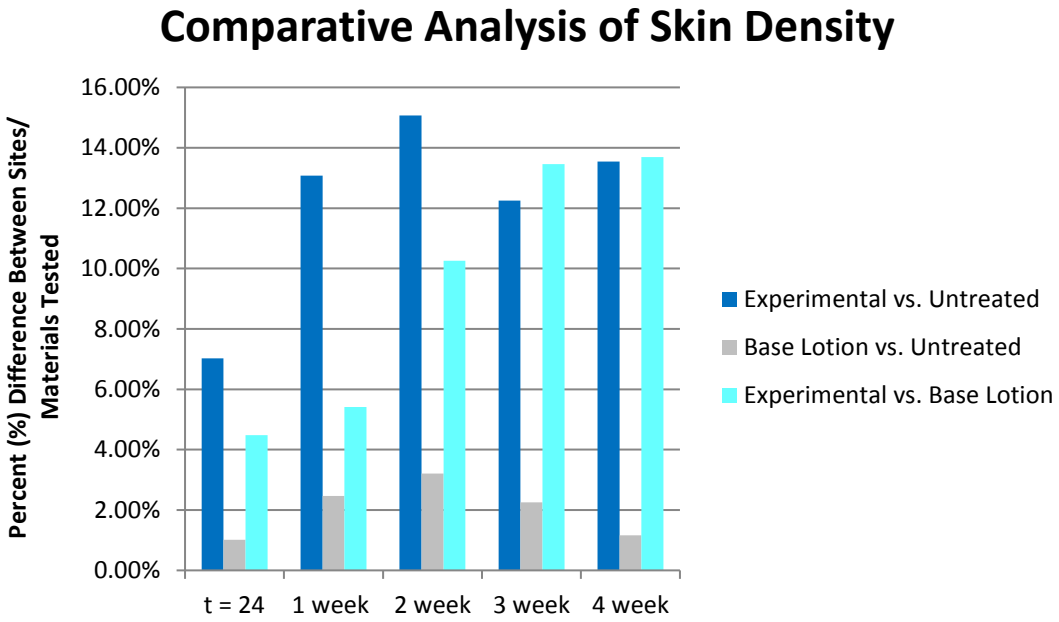

Figure 1: Percent difference in skin density recordings between test materials

Discussion

As evidenced in a 4 week efficacy study of **ACB Bio-Chelate 5 PF** on skin, skin density was improved by 11.02% after 24 hours and by 13.54% after 4 weeks when compared to the untreated control. When compared to the base cream **ACB Bio-Chelate 5 PF** improved skin density by 14.48% after 24 hours and after 4 weeks **ACB Bio-Chelate 5 PF** improved density by 13.69%. Results indicate that **ACB Bio-Chelate 5 PF** is capable of improving skin density when compared to both the untreated control as well as the base lotion.

ACB Bio-Chelate 5 PF has a positive effect on skin's density when used at recommended use levels.