



High Resolution Ultrasound Skin Imaging Assay

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Tradename: AC CytoPure PF

Code: 20757PF

CAS #: 999999-99-4

Test Request Form #: 1286

Lot #: NC 130424-B

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

Study Director: Maureen Danaher

Principle Investigator: Jennifer Goodman

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 **AC CytoPure PF**. Ten 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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Ten 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% **AC CytoPure 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

AC CytoPure 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.

Ultrasound		T = 0	T = 1 Week	T = 2 Weeks	T = 3 Weeks	T = 4 Weeks
Panelist 1	Experimental	62	66	68	70	73
	Base Lotion	59	66	63	65	67
	Untreated	52	55	53	58	60
Panelist 2	Experimental	41	49	52	56	65
	Base Lotion	39	41	36	39	42
	Untreated	35	36	38	41	45
Panelist 3	Experimental	53	58	66	70	71
	Base Lotion	52	55	56	58	59
	Untreated	42	45	48	51	55
Panelist 4	Experimental	55	63	65	68	72
	Base Lotion	52	59	68	69	72
	Untreated	48	51	55	56	60
Panelist 5	Experimental	63	66	69	70	73
	Base Lotion	56	57	59	63	65
	Untreated	38	42	45	47	44
Panelist 6	Experimental	46	52	58	59	61
	Base Lotion	56	68	69	71	73
	Untreated	45	48	49	51	52
Panelist 7	Experimental	55	52	57	63	65
	Base Lotion	68	59	57	58	63
	Untreated	71	64	73	57	67
Panelist 8	Experimental	36	45	46	47	50
	Base Lotion	35	36	42	45	45
	Untreated	32	33	41	45	34
Panelist 9	Experimental	64	63	65	65	65
	Base Lotion	43	45	63	65	67
	Untreated	35	36	32	38	41
Panelist 10	Experimental	55	57	58	61	63
	Base Lotion	51	52	55	53	54
	Untreated	50	56	60	65	62
Number of Panelists		10	10	10	10	10

Chart 1: Individual Raw Data

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Averages	T = 0	T = 1 Week	T = 2 Weeks	T = 3 Weeks	T = 4 Weeks
Experimental (2.0% AC CytoPure PF + Base Lotion)	53.0	57.1	60.4	62.9	65.8
Base Lotion	51.1	53.8	56.8	58.6	60.7
Untreated	44.8	46.6	49.4	50.9	52.0

Chart 2: Average Increase in Skin Density per Individual Test Site

Percent (%) Change	T = 0	T = 1 Week	T = 2 Weeks	T = 3 Weeks	T = 4 Weeks
Base Lotion vs. Untreated	14.06%	15.45%	14.98%	15.13%	16.73%
Experimental (2.0% AC CytoPure PF + Base Lotion) vs. Untreated	18.30%	22.53%	22.27%	23.58%	26.54%
Experimental (2.0% AC CytoPure PF + Base Lotion) vs. Base Lotion	3.72%	6.13%	6.34%	7.34%	8.40%

Chart 3: Comparison of Skin Density Changes between Two Test Sites

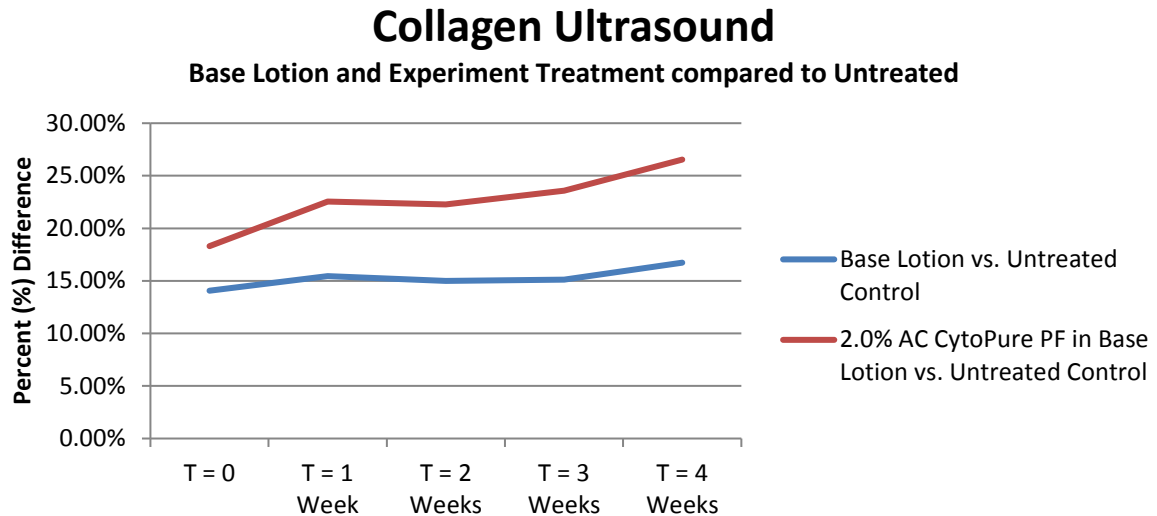


Figure 1. Ultrasound Results Comparing Test Sites to Untreated Control

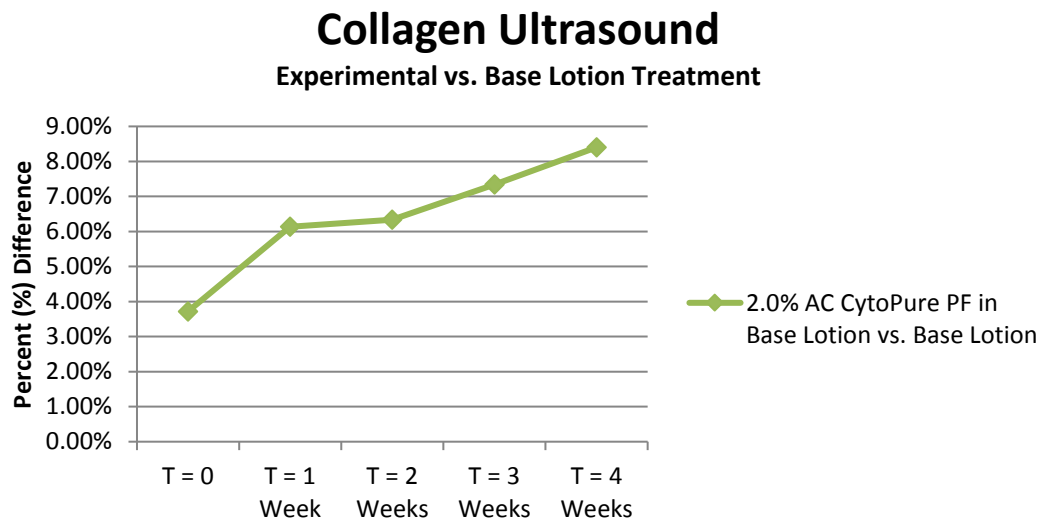


Figure 2. Ultrasound Results Comparing the Difference between the Test Site and the Control Site



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Discussion

As evidenced in a 4 week efficacy study of **AC CytoPure PF** on skin, skin density was improved by 22.53% after 24 hours and by 26.54% after 4 weeks when compared to the untreated control. When compared to the base cream **AC CytoPure PF** improved skin density by 6.34% after two weeks and after 4 weeks **AC CytoPure PF** improved density by 8.40%. Results indicate that **AC CytoPure PF** is capable of improving skin density when compared to both the untreated control as well as the base lotion.

AC CytoPure PF has a positive effect on skin's density when used at recommended use levels.