



High Resolution Ultrasound Skin Imaging Assay

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Tradename: ABS Pomegranate Sterols

Code: 10247

CAS #: 949109-75-5

Test Request Form #: 526

Lot #: 27174

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 **ABS Pomegranate Sterols**. 10 M/F subjects between the ages of 23-45 participated in the study. Results 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.

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. Baseline elasticity readings were taken on day one of the study.

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Following initial measurements, all subjects were asked to apply 2 mg of each test material on their volar forearms. Measurements were taken immediately after application of test materials and then weekly for 4 weeks. The test material consisted of 2.0% **ABS Pomegranate Sterols** 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

ABS Pomegranate Sterols showed improvements in skin density at a 2.0% concentration. Please note, each value is an average of three consecutive readings per test site.

Individual Raw Data:

	t=24	1 week	2 weeks	3 weeks	4 weeks
Subject 1-Test Untreated Control Base Lotion Control	47	66	67	50	61
	53	54	50	42	45
	47	44	45	42	41
Subject 2-Test Untreated Control Base Lotion Control	97	65	100	100	77
	51	60	65	65	68
	65	69	89	86	75
Subject 3-Test Untreated Control Base Lotion Control	100	99	86	97	0
	71	67	68	64	0
	70	59	62	79	0
Subject 4-Test Untreated Control Base Lotion Control	86	78	92	95	92
	72	59	54	62	60
	50	70	74	52	67
Subject 5-Test Untreated Control Base Lotion Control	71	86	85	88	84
	46	53	43	50	58
	47	53	42	59	59

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	t = 24	1 week	2 weeks	3 weeks	4 weeks
Subject 6-Test	59	77	81	82	0
Untreated Control	40	46	56	38	0
Base Lotion Control	44	59	46	43	0
Subject 7-Test	61	64	64	72	60
Untreated Control	60	60	58	49	45
Base Lotion Control	63	51	58	65	61
Subject 8-Test	0	78	85	81	86
Untreated Control	0	51	50	52	42
Base Lotion Control	0	58	48	45	47
Subject 9-Test	72	72	75	59	67
Untreated Control	55	43	49	29	40
Base Lotion Control	54	50	55	34	52
Subject 10-Test	84	96	86	80	93
Untreated Control	76	69	74	68	72
Base Lotion Control	72	70	66	69	67
# of Subjects	9	10	10	10	8

Results of Group:

	t = 24	1 week	2 week	3 week	4 week
Experimental (2.0% ABS Pomegranate Sterols in Base Lotion)	75.2	78.1	82.1	80.4	77.5
Untreated	58.2	56.2	56.7	51.9	53.8
Base Lotion Control	56.9	58.3	58.5	57.4	58.6
	t = 24	1 week	2 week	3 week	4 week
Experimental vs. Untreated Control	29.20%	38.97%	44.80%	54.91%	44.19%
Base Lotion vs. Untreated Control	-2.29%	3.74%	3.17%	10.60%	9.07%
Experimental vs. Base Lotion	32.23%	33.96%	40.34%	40.07%	32.20%

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Comparative Difference in Skin Density

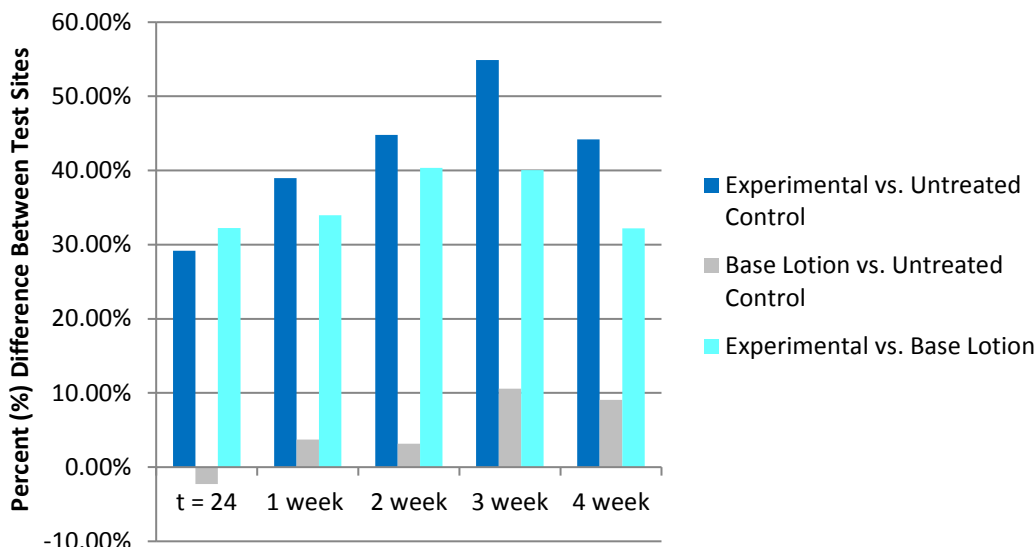


Figure 1: High Resolution Ultrasound Skin Imaging Results

Discussion

As evidenced in a 4 week efficacy study of **ABS Pomegranate Sterols** on skin, skin density was improved by 29.20% after 24 hours and by 44.19% after 4 weeks when compared to the untreated control. When compared to the base cream **ABS Pomegranate Sterols** improved skin density by 32.23% after 24 hours and after 4 weeks **ABS Pomegranate Sterols** improved density by 32.20%. Results indicate that **ABS Pomegranate Sterols** is capable of improving skin density when compared to both the untreated control as well as the base lotion.

ABS Pomegranate Sterols has a strong positive effect on skin's density when used at recommended use levels.