



High Resolution Ultrasound Skin Imaging Assay

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Tradename: Revital-Eyes

Code: 16671

CAS #: 7732-18-5 & 68333-16-4 & 84650-60-2 & 84961-57-9 & 1686112-36-6 (or)
68333-16-4 & 58-08-2

Test Request Form #: 42

Lot #: SN130813-2

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 **Revital-Eyes**. 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

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

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% **Revital-Eyes** 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

Revital-Eyes 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	52	53	65	72	81
	Base Lotion	57	58	62	67	78
	Untreated	75	65	64	71	69
Panelist 2	Experimental	66	87	86	84	89
	Base Lotion	83	83	82	81	85
	Untreated	70	75	62	65	74
Panelist 3	Experimental	48	54	54	65	69
	Base Lotion	27	41	51	60	53
	Untreated	71	72	59	64	65
Panelist 4	Experimental	73	75	81	94	89
	Base Lotion	68	72	74	79	75
	Untreated	52	61	70	68	66
Panelist 5	Experimental	67	82	62	65	82
	Base Lotion	62	65	60	65	78
	Untreated	62	66	54	69	65
Panelist 6	Experimental	52	52	51	64	58
	Base Lotion	57	61	51	61	69
	Untreated	63	77	81	75	69
Panelist 7	Experimental	70	83	93	80	90
	Base Lotion	92	86	80	79	72
	Untreated	50	54	45	63	52
Panelist 8	Experimental	45	31	33	48	36
	Base Lotion	44	52	40	49	55
	Untreated	52	53	57	69	57
Panelist 9	Experimental	85	66	55	50	62
	Base Lotion	81	75	81	75	73
	Untreated	70	72	71	75	69
Panelist 10	Experimental	65	70	72	77	79
	Base Lotion	57	69	61	72	75
	Untreated	51	39	49	65	55
Number of Panelists		10	10	10	10	10

Figure 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% Revital-Eyes in Base Lotion)	62.3	65.3	65.2	69.9	73.5
Base Lotion	62.8	66.2	64.2	68.8	71.3
Untreated	61.6	63.4	61.2	68.4	64.1

Figure 2: Average values

Percent (%) Change	T = 0	T = 1 Week	T = 2 Weeks	T = 3 Weeks	T = 4 Weeks
Base Lotion vs. Untreated	1.95%	4.42%	4.90%	0.58%	11.23%
Experimental (2.0% Revital-Eyes + Base Lotion) vs. Untreated	1.14%	3.00%	6.54%	2.19%	14.66%
Experimental (2.0% AC Revital-Eyes in Base Lotion) vs. Base Lotion	-0.80%	-1.36%	1.56%	1.60%	3.09%

Figure 3: Percent change

Collagen Ultrasound Comparative Analysis of Skin Density

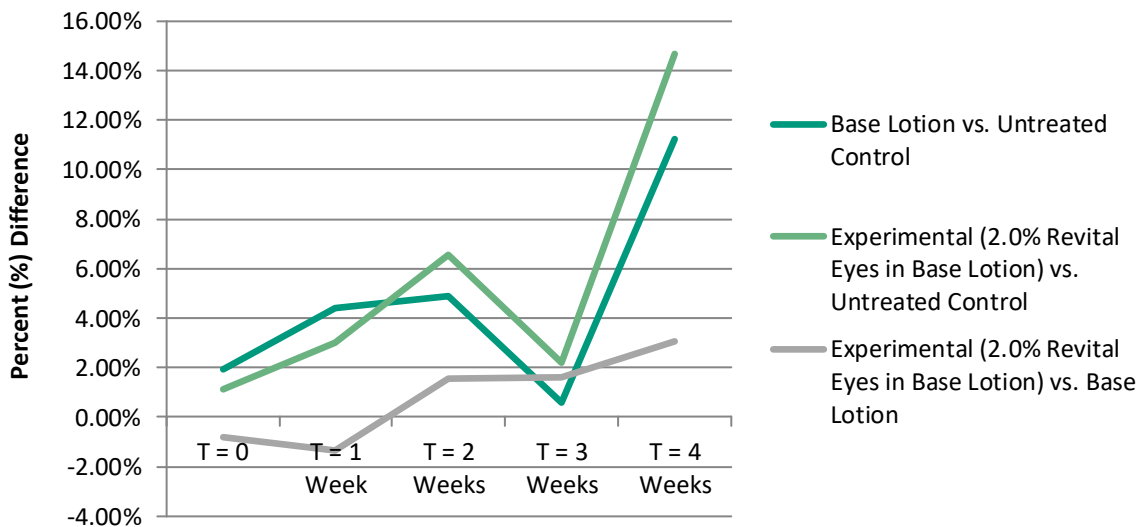


Figure 4: Percent difference in skin density recordings between test materials.

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Discussion

As evidenced in a 4 week efficacy study of **Revital-Eyes** on skin, skin density was improved by 3.00% after one week and by 14.66% after 4 weeks when compared to the untreated control. When compared to the base cream **Revital-Eyes** improved skin density by 3.09% better than the base lotion after four weeks. Results indicate that **Revital-Eyes** is capable of improving skin density when compared to both the untreated control as well as the base lotion. **Revital-Eyes** has a strong positive effect on skin's density when used at recommended use levels.

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