Tradename: AC Dermal Respiratory Factor PF

Code: 20219PF

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

Test Request Form #: 811

Lot #: NC140218-A

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
Collagen is the most abundant protein that can be found in the skin and other areas of the body. Collagen encourages the top layer of skin to regenerate which in return keeps skin looking healthy and youthful. Collagen naturally decreases with age and can result in sagging, wrinkles, and fine lines.

The High-Resolution Ultrasound Skin Imaging Assay was conducted to assess the ability **AC Dermal Respiratory Factor (DRF) Advanced PF** to enhance skin density.

Assay Principle
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 refers 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. The epidermis is characterized by a high intensity white/yellow color while the dermis is a mixture of colors at varying intensities.

Materials
A. Equipment: DermaLab Skin Combo (Ultrasound Probe)

Methods

10 M/F volunteers 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% **AC Dermal Respiratory Factor Advanced 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 Dermal Respiratory Factor Advanced 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.

Percent change in density is calculated by the following formula:

$$Percent\ (\%)\ Change = \frac{Average\ Density\ Value_{T=24\ hours.etc} - Average\ Baseline\ Value_{T=0}}{Average\ Baseline\ Value_{T=0}}$$

Table 1. Average Collagen Levels at Each Time Point

Averages	T=0	T =1 Week	T =2 Weeks	T =3 Weeks	T =4 weeks
Experimental (2.0% AC Dermal Respiratory Factor Advanced PF + Base Lotion)	68	76	84	82	81
Base Lotion	78	76	77	76	79
Untreated	71	70	74	68	69

Table 2. Collagen Change between Tests Sites at Each Time Point

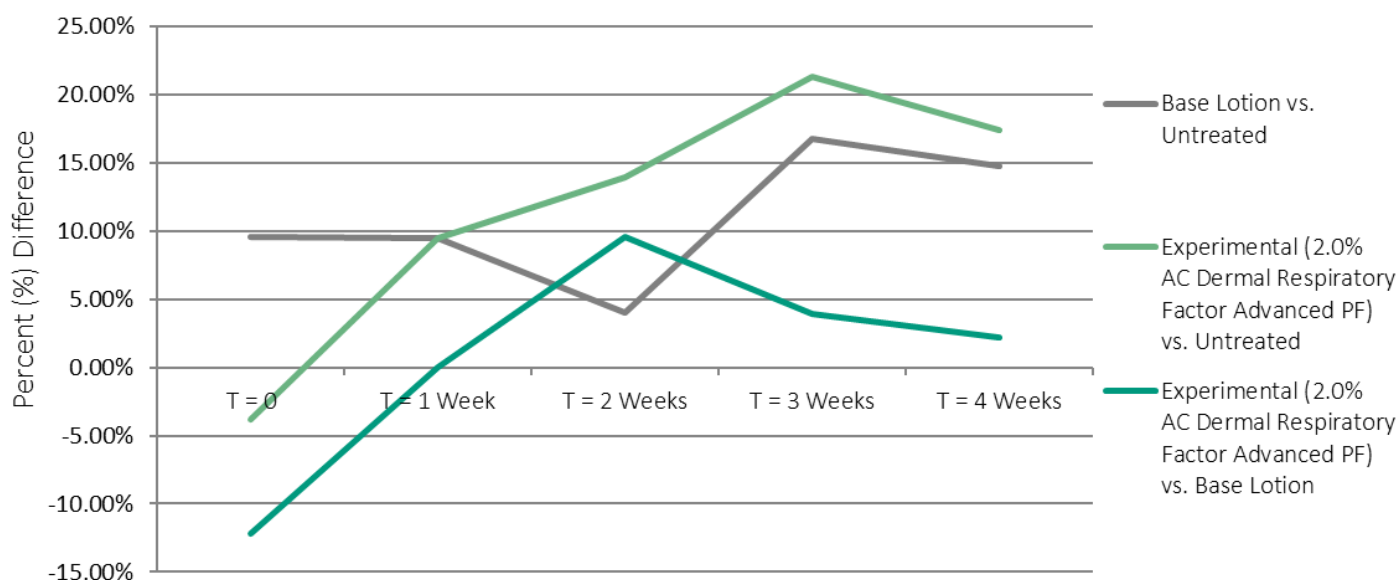| Percent Change (%)	T=0	T =1 Week	T =2 Weeks	T =3 Weeks	T =4 weeks
Experimental (2.0% AC Dermal Respiratory Factor Advanced PF + Base Lotion) vs. Base Lotion	-12%	0%	10%	8%	2%
Experimental (2.0% AC Dermal Respiratory Factor Advanced PF + Base Lotion) vs. Untreated	4%	9%	14%	22%	17%
Base Lotion vs. Untreated	10%	10%	4%	13%	15%

Figure 1. Percent Difference in Skin Density Recordings Between Test Materials

Discussion

As evidenced in a 4-week efficacy study of **AC Dermal Respiratory Factor Advanced PF** on skin, skin density was improved by 17% after four weeks when compared to the untreated control. When compared to the base lotion, 2.0% **AC Dermal Respiratory Factor Advanced PF** improved skin density by 10%. At the end of the four-week study, **AC Dermal Respiratory Factor Advanced PF** improved skin density by 2% more than the base lotion.

Results indicate that **AC Dermal Respiratory Factor Advanced PF** is capable of improving skin density at recommended use levels when added to personal care applications. In conclusion, **AC Dermal Respiratory Factor Advanced PF** is able to increase collagen and promote a healthier skin appearance.