

Renewal Facial Cream Reduces Signs of Photoaging

Clinical Assessment Results (Presented at 2006 & 2008 AAD Annual Meetings - Poster Exhibit Nos. P1128 & P915)

ABSTRACT

This clinical study overview discusses a split-face, double-blind, prospective controlled clinical study of 25 panelists comparing a cosmeceutical with bifunctional mechanisms of action with baseline to panelists' non-medicated moisturizers. The graded photoaging parameters include fine lines, wrinkles, clarity and tactile roughness. Very statistically significant improvements were documented. Tactile roughness improved by 56%, clarity by 53%, fine lines improved by 27% and wrinkles by 19% at 12 weeks. All panelists improved their fine lines, clarity and tactile roughness by week 8. Wrinkles were measurably improved by week 12 in 84% of the panelists.

INTRODUCTION

Visible signs of extrinsic aging primarily result from UV radiation induced oxidation reactions activating chronic inflammation. However, any chronic inflammation triggers the destructive processes. Disruption of the stratum corneum permeability barrier also results in activation of chronic inflammation.¹ Moreover, an incompetent barrier allows increased ingress of other proinflammatory environmental insults such as irritants and pollutants.

The cosmeceutical product tested in this double-blinded prospective controlled clinical study uniquely prevents and reverses release and activation of proinflammatory factors while optimizing stratum corneum barrier function. Other documented and alleged treatments for skin aging lack both of these functions in one product. The most commonly used topical anti-inflammatory agents, corticosteroids, are known to induce epidermal atrophy.

The Epionce Renewal Facial Cream used in this study consists of a blend of novel botanical extracts with physiological lipid precursors and biologic response modifying ions in an emollient base with specific delivery systems to maximize efficacy and minimize the risk of adverse reactions. The technology in this cream does not contain any traditional anti-aging compounds such as retinoids, teas, vitamins, hydroxy acids or traditional antioxidants.

PATIENTS

25 Caucasian, Asian, and Hispanic females and males ages 45-62 signed the informed consent for this double-blind, randomized, split-face 12-week study. No sunscreen was used during the study. Exclusions included active facial dermatitis, use of retinoids systemically in the past year, use of topical retinoids and use of hydroxy acids for the past 4 months.

METHOD

A nationally prominent contract research group conducted the study. At the baseline visit, four extrinsic aging parameters were graded by board certified dermatologist investigators on the scale of 0 = no visible parameter to 10 = very severe visible parameter. The four parameters included fine lines, wrinkles, clarity and tactile roughness. They were graded at weeks 4, 8, and 12. The mean values of the clinical severity scores were compared to baseline. The panelists preferred nonmedicated moisturizer in a split-face design using a paired t-test with $p < 0.05$ significance level.³ After cleansing, a dime-size portion of the test product was applied to half of the face, ipsilateral neck and ear, twice daily. Panelists were also assessed for development of visible inflammatory reactions and symptoms after application.

RESULTS

Epionce Renewal Facial Cream reduced tactile roughness by a mean value of 56%, improved clarity by 53%, and reduced fine lines by 27% and wrinkles by 19% at week 12. These values were all highly statistically significant (in all $p < 0.001$). This high level of significance was also seen in all parameters at weeks 4 and 8, as shown in Table 1.

Table 1 - Mean Clinical Severity % Change from Baseline $p < 0.001$

Clinical Parameter	Week 4	Week 8	Week 12
Tactile Roughness	-21	-46.5	-56
Fine Lines	-11	-19	-27
Wrinkles	-6	-18	-19
Clarity	28	50	53

These mean values were compared with baseline. Statistical superiority against the panelists' moisturizer was seen at all time points of all parameters. The dermatologist investigators determined that all panelists had measurable improvement in fine lines, wrinkles, tactile roughness and clarity by week 8. By week 12, the wrinkle parameter was measurably improved in 84% of the panelists.

DISCUSSION

The results of this combined study are numerically inferior to an unpublished 12-week pilot study of 11 panelists, which included a patient assessment. The data in that study produced a 61.5% reduction in tactile roughness, 34.8% reduction in fine lines, 23.5% decrease in wrinkles and a 94% increase in clarity ($p = 0.0001-0.0006$). A 33.5% decrease in hyperpigmentation and 19% decrease in laxity were also documented.

The panelists' assessment of the Epionce Renewal Facial Cream was all (100%) agreed or strongly agreed the texture of the skin was visibly improved. In addition, 91% agreed or strongly agreed the fine lines were less noticeable and the skin looked and felt healthier. An 8-week study determining optical profilometry parameters in 15 patients supported the pilot study results, as noted in Table 2.

Table 2 - Mean Clinical Severity % Change from Baseline $p < 0.001$

Clinical Parameter	Improvement (p value)
Roughness	0.034 ra/0.0002 cz
Increased space between wrinkle	0.039
Decreased wrinkle breadth	0.025
Decreased shadows	0.05

Continued

Renewal Facial Cream Reduces Signs of Photoaging, cont.

The rates of improvement of extrinsic aging factors by the proprietary, patent-pending technologies in Epionce Renewal Facial Cream are numerically superior to other commonly used “anti-aging” products in most parameters but inferior to others. However, until head-to-head comparative studies are completed, specific conclusions of product superiority cannot be claimed. Table 3 compares published data.²⁻⁴

Table 3 - Comparative data as published at 12 weeks (% improvement)

Parameter	8% GA*	10% PH*	REN*	KIN*	CS*	PIL*
Roughness	-43	-42	-16	-48	-56	-61.5
Fine Lines	-20	-22	-24	-10.5	-27	-33.8
Wrinkles	-13	-10.5	--	--	-19	-23.5
Clarity	30	32	--	--	53	94

*GA (Glycolic Acid); PH (Polyhydroxy Acid); REN (Renova); KIN (Kinerase);
CS (Current Study); unpublished PIL (Pilot Study)

This data confirms the clinical utility of a cosmeceutical product, which is apparently the first marketed product to optimize stratum corneum barrier function and safely prevent the release and activation of proinflammatory factors. Epionce Renewal Facial Cream does not contain any tea, soy, growth factors, peptides, alpha hydroxy acids, retinoids, vitamins or traditional antioxidants.

REFERENCES

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