

Clinical Assessment Results Comparing Epionce and Prescription Renova

Introduction

The Epionce product line was developed with the dual objective of optimizing permeability barrier function and reversing/preventing chronic inflammation of the skin. The concept behind the Epionce product line has been validated by the completion of more than twelve double-blind controlled clinical trials, all of which were conducted by independent clinical research organizations. These entities are nationally prominent contract research organizations that perform studies sponsored by a wide range of cosmetic and pharmaceutical companies.

Method

Using a split-face methodology, an Epionce® regimen was compared with prescription Renova® (0.05% cream) in a six-month double-blinded, prospective, controlled clinical trial during the winter and spring months. The study consisted of 25 panelists who used no sunscreen during the study period. The regimen consisted of Epionce Renewal Facial Cream applied twice daily and Epionce Lytic Lotion applied nightly, 7-15 minutes prior to the Renewal Facial Cream application. The Lytic Lotion includes ingredients allowed under the FDA over-the-counter monographs to treat acne, psoriasis and dermatitis due to their keratolytic and anti-inflammatory activity. The Renova regimen consisted of Renova (0.05%) nightly and Johnson & Johnson Softlotion™ 24 Hour Moisture, applied twice daily. The latter has a consistency similar to that of Epionce Renewal Facial Cream. Most of the middle-aged population living in the region where the study was conducted, who use Renova, also uses a moisturizer twice daily (during winter and spring months).

Results

Board-certified dermatologists performed the clinical assessment for both regimens. The clinical results showed no statistical difference between the two regimens, although the Epionce regimen was numerically superior in 5 of 7 parameters, as in Table I. In Table II, the histologic parameters were mixed with comparable results with reduction of epidermal and papillary dermal thickness. The Epionce regimen was statistically significantly superior ($p < 0.05$) to Renova of increasing epidermal glycosaminoglycans 13.3% vs. 7.4% for Renova. Dermal density by ultrasound also was statistically superior ($p < 0.05$) of Epionce increasing dermal density by 20.8% vs 10.3% for Renova. Renova induced a statistically significant increase ($p < 0.05$) of stratum corneum compaction of 44.4% vs 20% for Epionce. The Epionce regimen induced a highly statistically significant ($p < 0.001$) lower incidence of eyelid mild erythema and scaling than Renova. Nonprescription Epionce, with unique mechanisms of action, is the first cosmeceutical with clinical and histologic results comparable to Renova.

Discussion

Epionce appears to be the first nonprescription (cosmeceutical) product line to directly compare itself to Renova, the prescription gold standard to treat visible signs of skin aging. This data clearly thrusts Epionce to the forefront of non-prescription amelioration of extrinsic aging. Most importantly, it validates this new concept for reversing/preventing visible photoaging by optimizing stratum corneum barrier function while safely reversing/preventing activation of chronic inflammatory factors. This breakthrough concept is intuitively based upon increasingly published cutaneous pathobiology discussed in the following paragraphs. A compromised stratum corneum permeability barrier results in the activation of chronic cutaneous inflammation

by releasing and stimulating synthesis of proinflammatory biologic response modifiers. With as many as fifty percent of women having sensitive skin, including individuals exhibiting signs of extrinsic skin aging, a large segment of the population has a documented incompetent permeability barrier with accompanying chronic inflammation.^{2,3}

Barrier disruption releases pre-formed interleukins (IL-1 alpha and beta, IL-8, IL-12), tumor necrosis factor alpha, growth factors (epidermal platelet derived, fibroblast and transforming growth factors and granulocyte colony stimulating factor), substance P, and calcium, among others.³ These biologic response modifiers activate nuclear receptors (activating protein-1 and nuclear factor kappa beta) which encode for gene transcription of other biologically active compounds including adhesion molecules, chemokines, selectins, defensins and proteinases. One group of these end products, matrix metalloproteinases, destroys collagen, elastin and ground substances thereby producing microscars, which progress to the visible fine lines and wrinkles of extrinsic aging. It follows that chronic exfoliation, unlike the reports in lay literature, is actually destructive, producing visible skin aging.

The gold standard for photoaging therapy is prescription retinoids. Renova was the first retinoid therapy approved by the FDA. Retinoids are known to induce exfoliation, contact irritant and photoirritant reactions.^{1,4} The frequency of local skin irritation, desquamation, burning sensation, erythema, pruritis and dry skin reaches up to 59% in patients using the product. Most were mild, but the incidence of severe reactions was 5% with 0.05% tretinoin cream.⁵ In a study of people with acne and sensitive skin, 23% withdrew by day 29 of treatment.⁶ The documented incidence of photoirritation to UVB in humans in the laboratory was 11.4%.¹

The FDA has made cautionary recommendations regarding exfoliating compounds due to concerns of increasing chronic inflammation, inducing tumorigenesis.⁷ Furthermore, the disruption of the permeability barrier allows a significantly increased ingress of environmental insults, including proinflammatory molecules, inducing even more destructive chronic cutaneous inflammation.

The difference in the mechanisms of action for Epionce from traditional antiaging therapies does not preclude combining them. In fact, using Epionce Renewal Facial Cream with Renova and Tazorac® eliminated the irritant reactions (pending publication). Anecdotal observations suggest clinical efficacy is improved by combining Epionce and retinoids. Retinoid delivery appears enhanced after Epionce use because retinoids were developed for teenagers afflicted with acne who have much higher lipid content in their skin than more mature patients. It follows that the infusion of Epionce lipids into photoaged skin would be expected to maximize retinoid efficacy and minimize adverse reactions. Epionce products are a significant advance in the pursuit for reversal and prevention of the visible extrinsic aging. They provide a safe and effective over-the-counter therapy that results in healthy, optimally functioning, younger-looking skin.

References

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(Continued)

Table 1: Clinical Results*

<i>Parameter</i>	Epionce (% Change)	Renova (% Change)
Tactile Roughness	-63.5	-58.0
Fine Lines	-37.9	-35.1
Wrinkles	-32.9	-31.2
Clarity	+59.0	+57.5
Mottled Hyperpigmentation	-33.2	-35.0
Laxity	-20.6	-21.6
Actinic Keratoses	-100	-94.4

Table 1: Histologic Results**

<i>Parameter</i>	Epionce (% Change)	Renova (% Change)
Epidermal GAGs	+13.3**	+7.4
Epidermal Thickness	-19.6	-23.6
Papillary Dermal Thickness	+4.5	+4.3
Stratum Corneum Compaction	+20.0	+44.4**
Dermal Density	+20.8**	+10.3

* Skin was cleansed prior to the application of all four leave-on products

**Statistically Superior (p<0.05)