

Comparing Epionce® Anti-Aging Regimen vs. Prescription Renova® 0.05% + Lactic Acid Moisturizer

Clinical Assessment Results

ABSTRACT

In a six-month double-blind, prospective, controlled clinical study, Epionce Renewal Facial Cream and Lytic Tx produced a statistically significant superior dermal thickening and epidermal glycosaminoglycans compared to gold standard prescription treatment regimen of Renova (0.05% tretinoin + lactic acid moisturizer). This Epionce regimen performed numerically better than the Renova regimen in 5 of 7 epidermal parameters. This Epionce regimen also produced a highly statistically significant lower incidence of irritation. This Epionce regimen provides significantly superior efficacy and safety over the first retinoid approved to treat wrinkles combined with an AHA. Thus, the healthier skin induced by repairing the skin barrier and inhibiting chronic inflammation results in less visible photoaging.

INTRODUCTION

A compromised stratum corneum permeability barrier results in the activation of chronic cutaneous inflammation by releasing and stimulating the 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.^{1,2}

Barrier disruption releases preformed 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.² 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 over time. The moniker of "induce pain to produce gain" in skin rejuvenation is a complete fallacy.

METHOD

Using a split-face, prospective methodology, an Epionce regimen was compared with prescription Renova (prescription 0.05% tretinoin), by board-certified dermatologist investigators (FAAD) in a six-month double-blind, 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 Epionce regimen consisted of Renewal Facial Cream applied twice daily and Lytic Tx applied nightly, 7-15 minutes prior to Renewal Facial Cream. The Renova regimen consisted of applying Renova nightly and Johnson & Johnson Softlotion™ 24 Hour Moisturizer, twice daily (it has a similar consistency to the Epionce Renewal Facial Cream). The 25 panelists cleansed their skin prior to the application of the leave-on products. Most of the middle-aged population

living in the region where the study was conducted, who use Renova, also use a moisturizer twice daily, so these regimens are similar to their preexisting skin care routines and comparable in product consistency.

RESULTS

The clinical results show no statistical difference between the two regimens, although the Epionce regimen performed better than the Renova regimen in 5 of 7 parameters, as shown in Table 1.

Table 1 – Clinical Results

Parameter	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	-100.0	-94.4

Table 2 shows the performance of the Epionce regimen mixed according to the histological parameters. While results show a comparable reduction of epidermal and papillary dermal thickness, the Epionce regimen was statistically superior ($p < 0.05$) at increasing epidermal glycosaminoglycans (13.3% vs. 7.4%) and increasing dermal density (20.8% vs. 10.3%). Renova induced a statistically significant increase of stratum corneum compaction (44.4% vs. 20%). The Epionce regimen induced a highly statistically significant lower incidence of eyelid mild erythema and scaling ($p < 0.001$).

Table 2 – Histologic Results

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

**Statistically significant ($p < 0.05$)

Comparing Epionce Anti-Aging Regimen vs. Prescription Renova 0.05% + Lactic Acid Moisturizer, cont.

DISCUSSION

Epionce is the first non-prescription cosmeceutical product line to directly compare itself to 0.05% Renova, the prescription gold standard to treat visible signs of skin aging. The competitive bar was further raised by adding a lactic acid moisturizer to the retinoid regimen. 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.

Renova was the first retinoid therapy approved by the U.S. Food & Drug Administration (FDA). Retinoids are known to induce exfoliation, contact irritant and photoirritant reactions.^{3,4} The frequency of local skin irritation, desquamation, burning sensation, erythema, pruritus, and dry skin reached up to 59% in panelists using the product. Most reactions were mild, but the incidence of severe reactions was 5% with a 0.05% tretinoin cream.⁵ In a study of people with acne and sensitive skin, 23% withdrew by day 29 of treatment.⁶

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 anti-aging therapies does not preclude combining them. In fact, using Epionce Renewal Facial Cream with Renova and Tazorac® eliminated irritant reactions. Anecdotal observations suggest clinical efficacy is improved by combining Epionce and retinoids. Retinoids were originally developed for teenagers afflicted with acne who have a much higher lipid content

in their skin than more mature patients. It follows that the infusion of Epionce physiologic barrier lipids and regulatory ions combined with specific anti-inflammatory factors that are naturally derived applied to photoaged skin would be expected to maximize retinoid and AHA efficacy and minimize adverse reactions as well.

CONCLUSION

This Epionce regimen and other Renewal products are a significant advance in the pursuit of reversal and prevention of visible aging. They provide a safe and effective over-the-counter (OTC) therapy that results in healthy, optimally functioning, younger-looking skin without irritation. Epionce is the first cosmeceutical to be compared to a prescription anti-aging regimen and was superior in efficacy and safety questioning the exfoliation myth for skin rejuvenation.

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