

# Lytic Products Help Visibly Reduce Periorcular Wrinkles

Clinical Assessment Results (Presented at 2006 AAD Annual Meeting Poster Exhibit No. P229)

## ABSTRACT

Two dual action cosmeceutical products tested in a blinded, prospective controlled clinical trial with 23 panelists produced a statistically significant visible reduction in periorcular area wrinkles of 48.3% ( $p=0.036$ ). The panelists used each of the nonprescription products once daily.

## INTRODUCTION

Numerous products to ameliorate the signs of skin aging have entered the market in the last two decades since the introduction of retinoids/retinols and alpha hydroxy acids. The effectiveness of these two classes of compounds has been well documented with numerous clinical trials. However, the newer vitamin, antioxidant, botanical, growth factor and peptide products have few, if any, supporting clinical trials. Most of those few existing trials consist of combinations of at least two of the technologies. Furthermore, few, if any, can document compliance with principles of product development and dermatopharmacokinetics to prove the “active” ingredients are delivered intact to the substratum corneum skin at high enough concentrations to affect physiologic processes and the anatomy of aging skin.

Board certified dermatologists at a nationally prominent contract research organization conducted this double-blind, prospective, controlled clinical study. Both cosmeceutical products tested have two primary mechanisms of action. Both, Epionce Lite Lytic Tx and Lytic Tx, consist of blends of novel botanical extracts with natural and naturally derived keratolytics and inhibitors that prevent the release and activation of proinflammatory factors. These extracts are formulated in an elegant emollient base containing delivery systems to maximize efficacy and minimize adverse affects. Safety and stability data have also been generated with these products.

## PATIENTS

24 Caucasian and Hispanic females and males ages 51-73 with Fitzpatrick photoskin types I-III completed the study after signing the consent form. Individuals afflicted with active dermatitis and papulosquamous diseases were excluded. Panelists must have avoided retinoids and any other “anti-aging” products as well as systemic antibiotics and retinoids for at least four months. High oral nutritional supplementation was not permitted for the month preceding as well as during the test period.

## METHOD

The test period was 8 weeks long. Panelists used Epionce Lite Lytic Tx each morning and Lytic Tx each night. The panelists used no sunscreens or moisturizers. One panelist discontinued within the first week due to intolerance to the test product.

Board certified dermatologist investigators conducted clinical grading of the periorcular wrinkling severity at baseline and at week 8. The wrinkling was graded using a scale where 0 = no wrinkle and 10 = severe wrinkle developing into a furrow. A dime-sized amount of test material was applied over the entire face after gentle cleansing with their preferred non-medicated cleanser. The test products were not applied to the upper eyelids. The mean values for the clinical severity of periorcular wrinkling were statistically compared to mean baseline values using paired t-test at the  $p=0.05$  significance level.

## RESULTS

The mean periorcular wrinkling score for the 23 panelists who completed the trial was decreased by 48.3%, which was statistically significant at  $p=0.036$ .

## DISCUSSION

This is the first prospective controlled clinical study to document significant reduction in visible periorcular wrinkling induced by novel cosmeceuticals. These Epionce products consist of blends of unique botanical extracts that impart keratolytic effects and prevent the release and activation of proinflammatory factors. To date, approximately 18 efficacy studies of cosmeceuticals that modulate signs and symptoms of skin aging have been published in poster exhibits and/or presented at both national and international meetings. Only one of these has focused on periorcular wrinkling.

That study tested coenzyme Q10 0.05% on 20 panelists for 12 weeks, twice daily, on eyelids. A peak of 42.6% decrease in fine wrinkles at 8 weeks was observed.<sup>1</sup> A product containing this technology is sold via mass marketing by a multinational pharmaceutical company. The apparent numerical superiority of Epionce Lite Lytic Tx and Lytic Tx products confirm the efficacy of these test products. Definite superiority of the Epionce products cannot be claimed because the two products have not been studied in the same population in a comparative trial.

The single panelist adverse reaction is 4.5%, which is a low rate compared to the incidence of retinoid irritation of 29% in sensitive skin adults. The eyelid skin of elderly people would be expected to have similar rates of sensitivity due to atrophy.<sup>2</sup>

Other clinical studies using these same Epionce products to reduce the number and severity of lesions of sebaceous hyperplasia and actinic/senile comedones suggest additional mechanisms of action for the novel botanical blends in these products. The suggested functions include phytoestrogenic or antiandrogenic activities. These products do not contain teas, soy, vitamins, retinoids, traditional antioxidants or alpha hydroxy acids.

In conclusion, Epionce Lite Lytic Tx and Lytic Tx appear to be a new addition to the armamentarium for ameliorating the signs and symptoms of skin aging.

## REFERENCES

1. Ghosh DK, Murthy UV. Anti aging benefits of a topical formulation containing coenzyme Q10: Results of two clinical studies. *Cosmet Dermatol.* 2002;15: 55-60.
2. Leyden JJ, Grove GL. Randomized facial tolerability studies comparing gel formulations of retinoids used to treat acne vulgaris. *Cutis.* 2001; 67 (65 supp): 17-27.