

CLINICAL TRIAL TO EVALUATE THE EFFICACY AND TOLERANCE OF AN ANTI-AGING LOTION ON WOMEN WITH PHOTODAMAGED FACIAL SKIN

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INTRODUCTION

The purpose of the study was to evaluate a facial lotion containing tripeptide solution, niacinamide, phycojuvenine and glycerin when used by women with photo damaged facial skin (mild to moderate crow's feet fine lines and wrinkles and presence of dull/matte, sallow, uneven skin tone and rough skin texture), including those with self-perceived sensitive facial skin, over the course of 12 weeks.

METHODS

Fifty-six (56) subjects women, aged 40-55 with mild to moderate fine lines and wrinkles, lack of radiance, sallow and uneven skin tone, and rough skin texture.

Subjects were instructed to apply the test product to the face twice daily after cleansing.

Clinical efficacy was assessed by expert grading for crow's feet fine lines and wrinkles, skin tone clarity, skin tone evenness, radiance/luminosity, pore appearance, skin texture/smoothness, skin softness, lifting, firmness/tightness, elasticity, and overall appearance/healthy look.

Bioinstrumental measurements such as Corneometer® and Tewameter®, digital photography and self-assessment questionnaires at baseline, weeks 4, 8 and 12 were included in the study.

Eleven (11) subjects were randomly selected to have 3mm facial punch biopsies (which include both dermis and epidermis) collected at Week 12 for gene expression analysis (biomarkers).

Objective and subjective tolerance assessments were performed at each study visit.

RESULTS

Clinical Grading:

The results from the 12-week clinical usage study showed that the anti-aging lotion was statistically significant in improving all assessed efficacy parameters: skin tone clarity, skin tone evenness, radiance/luminosity, pore appearance, skin texture/smoothness, skin softness, crow's feet fine lines, crow's feet wrinkles, lifting, firmness/tightness, elasticity, and overall appearance/healthy look after 8 and 12 weeks of test material use, with all parameters but lifting showing a significant improvement in scores after 4 weeks of use when compared with baseline scores (Figure 1, 2).

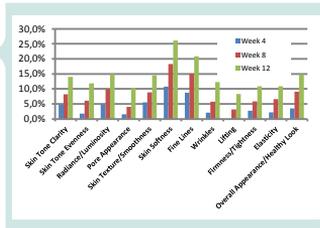


Figure 1: Significant Mean Percent Improvement of Clinical Grading Attributes (p<0.05) at the week 4, week 8 and week 12 time points compared to baseline



Figure 2: Subject showed similar improvement to those of the entire study panel for fine lines, lifting, radiance/luminosity, skin tone evenness and skin texture/smoothness after 12 weeks of daily product use.

Bioinstrumental Measurements:

Use of the anti-aging lotion showed a statistically significant increase (improvement) in moisturization of the stratum corneum at weeks 4, 8 and 12 when compared with baseline values (Figure 3).

Use of the anti-aging lotion showed a statistically significant decrease (improvement) in transepidermal water loss (TEWL) at weeks 4, 8 and 12 when compared with baseline values (Figure 4).

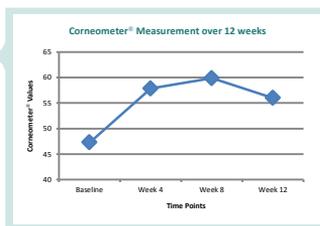


Figure 3: The anti-aging lotion significantly improved hydration level at Weeks 4, 8 and 12 when compared to baseline. Measurements were performed on bare skin at each time point.

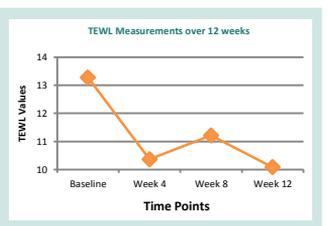


Figure 4: The anti-aging lotion significantly improved TEWL values at Weeks 4, 8 and 12 when compared to baseline. Measurements were performed on bare skin at each time point.

Gene Expression Analysis (Biomarkers):

There was a statistical significant decrease in tyrosinase expression level of more than 1.5 fold.

There was a statistical significant increase in involucrin expression level of more than 1.5 fold.

Questionnaires and Tolerance:

Results from the self-assessment questionnaire analysis indicated the anti-aging lotion was well-perceived by subjects for all product attributes assessed (Figure 5).

The product was well tolerated by the subjects.



Figure 5: Percentage of subjects that had favorable rating for each attribute at week 12

CONCLUSION

The anti-aging lotion showed statistically significant improvement in crow's feet fine lines and wrinkles, skin tone clarity, skin tone evenness, radiance/luminosity, pore appearance, skin texture/smoothness, skin softness, lifting, firmness/tightness, elasticity, and overall appearance/healthy look at all time points when compared to baseline with the exception of skin lifting at week 4.

Global tolerance evaluations showed the facial lotion containing tripeptide solution, niacinamide, phycojuvenine and glycerin was well tolerated by the study panel throughout the twelve week study period.

Corneometer® measurements showed that the lotion was effective in improving skin surface hydration at each time point when compared to baseline.

Tewameter® measurements showed that the lotion was effective in improving skin barrier function at each time point when compared to baseline.

Self-assessment questionnaires indicated positive perception of the anti-aging lotion performance over the course of the study for product attributes assessed, with 88% of subjects showing overall satisfaction with the product at week 12.

Gene expression analysis showed that there was a significant decrease in tyrosinase expression and a significant increase in involucrin expression by more than 1.5 fold at week 12 when compared to baseline, which may indicate an improvement in skin tone evenness and skin barrier function, respectively.

« The authors declare no conflict of interest »