

Evaluation of the Efficacy and Tolerability of a Topical Facial Serum in Improving Signs of Aging

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INTRODUCTION

Skin is the major reservoir for hyaluronic acid (HA) in the human body. HA is distributed throughout the epidermal and dermal compartments and plays an important role in cutaneous moisture control. Decrease in HA levels, reduction in HA size and loss of HA functionality all directly impact the biomechanical properties of aging skin resulting in loss of elasticity and firmness. Topically applied HA has traditionally been limited to use as a humectant due to lack of skin penetration. A topical product which could affect endogenous HA levels would be highly desirable as a cosmetic treatment. The goal of the present study was to evaluate the ability of a novel topical serum to modify histochemical markers associated with HA and improve visible signs of aging.

METHODS

A 12-week, single center, clinical study was conducted on 59 females, ages 42-60, presenting with mild to moderate facial sagging, loss of firmness, rough skin texture, nasolabial fold wrinkles, marionette wrinkles and presence of fine lines/wrinkles in the crow's feet area, including those with self-perceived sensitive skin. Efficacy and tolerability evaluations were conducted and self-assessment questionnaires were administered at baseline, weeks 4, 8 and 12. Bioinstrumental measurements were taken at baseline and at week 12. Additionally, a subset of the study population (n=20, pre-menopausal women) had 3mm punch biopsies collected from 2 sites of the face at baseline and week 12 based on a computer-generated randomization. 50% of the biopsy samples were used for immunohistochemical staining/analysis and the remaining samples were used for quantitative RT-PCR analysis of CD44, HAS2, HAS1, HYAL1 and Collagen 1a1.

Table 1: Expert evaluator graded skin attributes. All attributes showed statistical significant improvement at weeks 4, 8 and 12 vs. baseline.

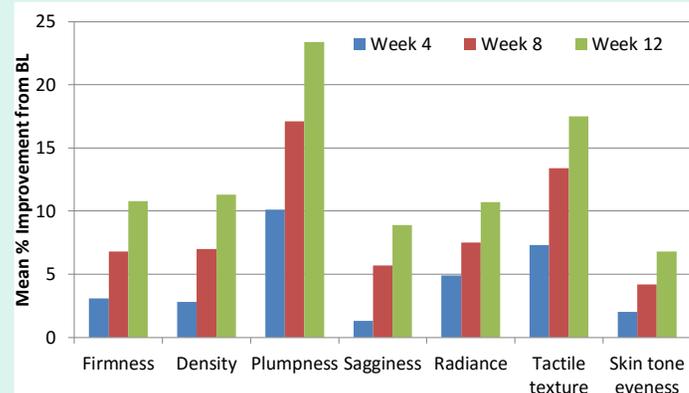
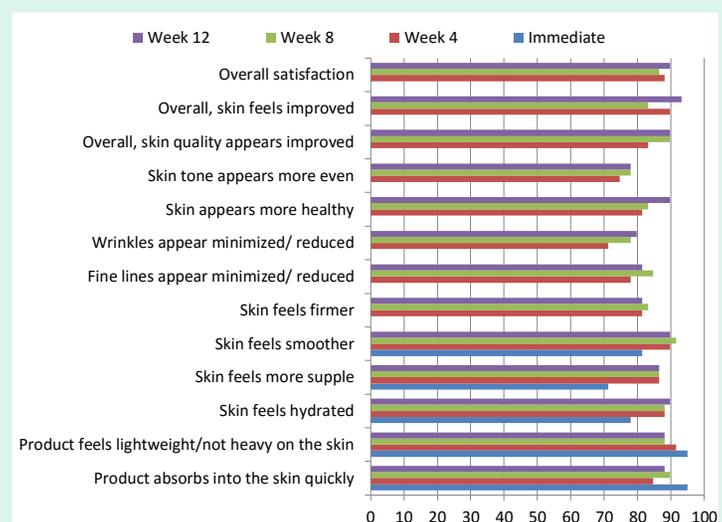


Table 2: Percentages of favorable responses from self-assessment questionnaires.



CONCLUSIONS

This topical formulation may have significant utility for improving signs of aging skin due to a decrease in HA level, reduction in HA size, and loss of HA functionality. In addition to the improvements observed in the clinical skin attributes, the study panel also showed improvements in skin hydration and barrier properties of the stratum corneum, skin density, increased HA content, and an increase in histochemical markers expression associated with HA such as HAS2 and Col1a1.

RESULTS

Results of the expert grading showed statistically significant improvement in firmness, density, plumpness, sagginess, radiance, texture and skin tone evenness at weeks 4, 8 and 12 when compared to baseline (Table 1).

Bioinstrumental measurement analysis showed statistically significant improvement in hydration ($p < 0.001$), barrier properties of the stratum corneum ($p = 0.017$) and skin density ($p = 0.012$) at week 12 when compared to baseline.

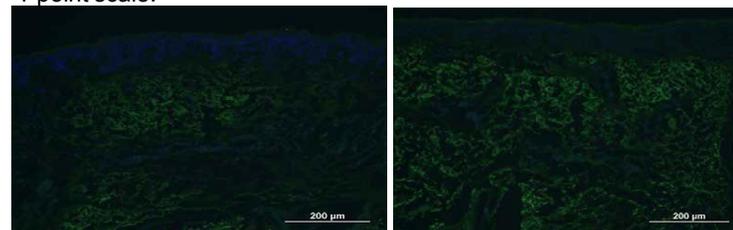
HA staining showed statistical significant increase in HA content after 12 weeks of product treatment ($p = 0.016$) (Figure 1).

RT-PCR analysis showed statistical significant increase in HAS2 and Col1a1 expression after 12 weeks of product use when compared to baseline ($p = 0.0008$ & 0.0245 , respectively).

Results from self-assessment showed favorable responses from the subjects (Table 2).

Tolerability evaluations showed no statistical significant difference in the objective and subjective tolerance scores when compared to baseline.

Figure 1: Green color indicates HA binding protein conjugated to streptavidin and blue color indicates DAPI counterstained cellular nuclei. Fluorescent intensity was semi-quantitatively assessed on a 4-point scale.



Baseline

Week 12