Clinical Efficacy and Tolerability of a Cosmetic Growth Factor Serum for Overall Facial Photodamage

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BACKGROUND

Photodamaged skin is characterized by the presence of fine/coarse lines, mottled pigmentation, among other changes to facial skin. Growth Factors (GF) have been shown to affect different pathways of skin repair and rejuvenation.

OBJECTIVE

To assess and compare the efficacy and tolerability of different facial treatments designed to improve photodamaged facial skin.

STUDY DESIGN

- Single-center, double-blind, randomized, placebo-controlled clinical usage study
- Twelve week study duration with visits at baseline, weeks 2, 4, 8 and 12.

Inclusion Criteria

- Male and female subjects in good general health aged 35-70 years with moderate to severe overall facial photodamage with Fitzpatrick Skin Type (FST) I-VI
- Subjects were required to have a baseline score of 6 to 9 for the Overall Photodamage scale. Subjects were willing to not apply any other topical products (skin lightening, retinoids, alpha/beta/poly-hydroxy acids), undergo facial treatments nor begin new cosmetic facial make-up throughout the duration of the study.

Study Treatments

Four treatment groups:
- TNS Essential Serum (TNS ES; active GF serum)
- Serum A (active cosmetic test formula)
- Serum B (active cosmetic test formula)
- Placebo (basic skincare regimen)

All subjects were provided the placebo regimen, consisting of facial cleanser, moisturizer, and SPF 30 physical sunscreen, to use during the study.

Subjects were randomized to one of the treatment groups. All 3 active treatment groups used their serum twice-daily (once in the morning and night, after cleansing). Facial cleanser and moisturizer were used twice-daily and sunscreen was used once in the morning (and as needed throughout the day).

Clinical Assessments

Investigator gradings were performed at all visits using a modified Griffiths' 10-point grading scale, where 0=none (best possible condition), 1-3=mild, 4-6=moderate, and 7-9=severe (worst condition possible), with half-points allowed as necessary to differentiate degrees of severity for the following efficacy parameters:

- *Overall Photodamage*
- *Fine Lines/Wrinkles (periocular, perioral, forehead and cheeks)*
- *Coarse Lines/Wrinkles (periocular, perioral, forehead and cheeks)*
- *Skin Tone Evenness* (red/brown blotchiness)
- *Tactile Roughness*

Tolerability assessments for erythema and scaling, using a 4-point scale (0=none, 1=mild, 2=moderate, 3=severe) were conducted at all visits. Subjective parameters, including burning/stinging, itching, tightness, and tingling were assessed by the subjects.

Subject Self-Assessment Questionnaires

At all follow-up visits, subjects completed a questionnaire regarding self-perceived efficacy, product texture and product attributes.

Standardized Digital Photography

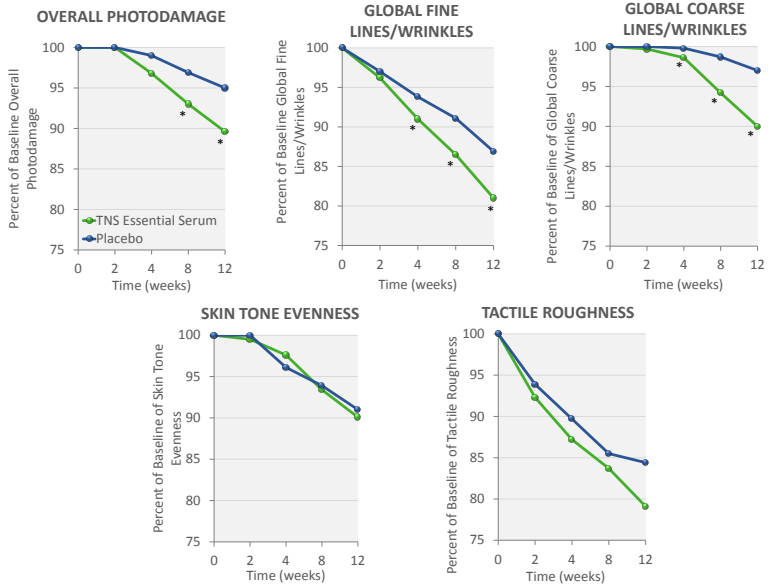
Standardized digital photographs were taken at all visits using the VISIA-CR photo system (Canfield Imaging Systems, Fairfield, New Jersey).

RESULTS

Results herein focus on the comparison between the TNS Essential Serum and placebo treatment groups:

- Thirty-five subjects (TNS ES: n=19, Placebo: n=16), aged 44-69 years with FST I-V who identified as Caucasian (74%), Asian (17%) and African American (9%) completed the study.
  - Subjects in the TNS ES and placebo treatment groups presented with mean scores of 5.55 and 5.72, respectively, for Overall Photodamage.
  - Three subjects in the placebo group voluntarily withdrew from the study, not due to adverse events (AE), and none for TNS ES group.
- Twice-daily use of TNS ES showed early improvements at Week 2 and significant long-term improvements at weeks 4, 8, and 12 compared to baseline in all parameters except for Skin Tone Evenness at weeks 2 and 4. (Figure 1; all P≤0.031; Wilcoxon signed-rank test; week 2: n=19, week 4: n=17, week 8: n=18, week 12: n=19).
- TNS ES was highly-rated by subjects for self-perceived efficacy with a statistically significant proportion of favorable responses observed for all parameters at week 12 (Figure 2; all P≤0.004; Binomial Test; n=19).
- Both treatments were well-tolerated with tolerability scores remaining similar to baseline scores. 6 AEs for the TNS ES group and 4 AEs for the placebo group were reported as unlikely to be related to treatment and resolved by the end of the study.

Figure 1: Investigator Efficacy Assessments



*Significant improvements versus placebo (all P≤0.04 treatment comparisons; Wilcoxon ranked-sum test)

Figure 2: Subject Questionnaire at Week 12

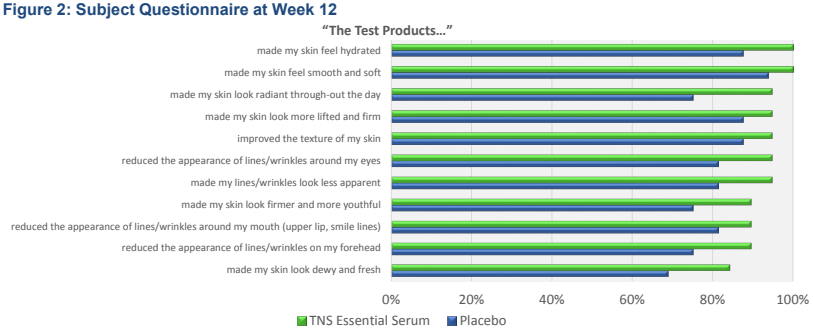


Figure 3: Early Improvements at Week 2 (Female, Age 62, FST II, TNS ES Group)

Figure 4: Long-Term Improvements at Week 12 (Male, Age 62, FST III, TNS ES Group)

Figure 5: Long-Term Improvements at Week 12 (Female, Age 69, FST II, TNS ES Group)

CONCLUSIONS

Results from this study demonstrate that TNS Essential Serum, a cosmeceutical product containing a high concentration of physiologically balanced growth factors reversed signs and symptoms of skin aging significantly more than cleanser, moisturizer, and sunscreen alone.

The addition of TNS Essential Serum to a basic skincare regimen helped improve global fine and coarse lines/wrinkles, facial photodamage, skin tone evenness and tactile roughness.

DISCLOSURES

This study was sponsored by Allergan. All authors met the ICMJE authorship criteria. All authors are employees of Allergan.

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