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

Elizabeth T. Makino, BS CCRA MBA; Priscilla Tan, BA; Rahul C. Mehta, PhD
Research & Development SkinMedica, an Allergan Company; Irvine, CA, USA

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

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<0.01; Wilcoxon signed-rank test; week 2: n=19, week 4: n=17, week 8: n=19, 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 compared to baseline. (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.

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 meet the ICMJE authorship criteria. All authors are employees of Allergan.

Figure 1: Investigator Efficacy Assessments

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)

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

Elizabeth T. Makino, BS CCRA MBA; Priscilla Tan, BA; Rahul C. Mehta, PhD
Research & Development SkinMedica, an Allergan Company; Irvine, CA, USA

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

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<0.01; Wilcoxon signed-rank test; week 2: n=19, week 4: n=17, week 8: n=19, 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 compared to baseline. (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.

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 meet the ICMJE authorship criteria. All authors are employees of Allergan.