A Clinical Study to Assess the Efficacy of LifeVantage® TrueScience® TrueRenew Daily Firming Complex on Facial Appearance Over 6 Weeks

PRINCIPAL INVESTIGATOR:
Dermatology Consulting Services, PLLC

OBJECTIVE:
To evaluate the efficacy of TrueScience® TrueRenew Daily Firming Complex on facial appearance

IRB:
The study was approved by Allendale Institutional Review Board (AIRB)
30 Neck Road, Old Lyme, CT 06371 (Study Number DCA-44-23)

REFERENCE:
LifeVantage® Report, September 2, 2023

Abstract

A total of 45 subjects were recruited for the trial. The subjects were informed to apply TrueScience® TrueRenew Daily Firming Complex to the face after cleansing every morning and evening for 6 weeks. Facial skin appearance was measured at baseline, week 3, and week 6 by self-assessment. Tolerability of the cream was also investigated.

Study participants' self-assessment scores after 3- and 6-week intervals showed significant ($p<0.05$) improvements in 11 categories of facial skin appearance (firmness: 14% and 31%; lift: 18% and 26%; tightness: 22% and 37%; smoothness: 25% and 35%; skin tone: 22% and 35%; lines and wrinkles: 20% and 32%; complexion: 17% and 31%; hydration: 20% and 30%; bounce: 19% and 33%; plumpness: 19% and 36%; radiance 23% and 38% at 3 and 6 weeks, respectively. These results were further supported via standardized colour photographs taken via Visia. Melomental folds (known as marionette lines) around the mouth, jawline contour, complexion, and fine lines and wrinkles around eyes improved over time.
There were no tolerability issues such as dryness, peeling, erythema, or oedema reported at any time throughout the study period.

Introduction

Facial aging is an important consumer concern. Many different ingredients and mechanisms of action have been purported to improve the appearance of the aging face. This research examined the benefits of a facial cream on aging face appearance, specifically on 11 key visible signs of aging: firmness, lift, tightness, smoothness, tone, lines, complexion, hydration, bounce, plumpness, and radiance.

Material and Method

A total of 45 healthy subjects, male and female aged 35–65 years old with a Fitzpatrick skin type I-VI and mild to moderate facial photoaging participated in this study. Subjects participating in the study were asked to apply the study treatment following their own unchanged, self-selected cleansing regimen every morning and evening throughout the 6-week study. Any self-selected skin-care products used by the subject were used 30 days before study start to make sure there were no difficulties. If desired, a self-selected sunscreen could be applied in the morning after the study treatment had dried on the face for 15 minutes. Subjects were also asked to complete a compliance diary documenting product application. No topical medications were allowed on the face and no facial skin-care products other than the treatment product were allowed throughout the study.

A skin examination was performed to ensure all subjects met inclusion/exclusion criteria. Only subjects who met the requirements signed an informed consent prior to performing any study procedures. No study-related procedures or activities were performed until each subject was fully informed and the consent form was signed and dated.

All subjects performed a self-assessment using a 5-point ordinal scale (0=None; 1=Minimal; 2=Mild; 3=Moderate; 4=Severe) at baseline, week 3, and week 6 for skin parameter efficacy (facial firmness, lift, tightness, smoothness, even skin tone, reduction of fine lines and wrinkles, complexion, hydration, bounce, plumpness, radiance) and tolerability parameters (dryness, peeling, oedema, erythema).

Colour photographs were taken of all subjects at baseline, week 3, and week 6 with the Visia CR 4.3 using standard lighting 1 of the central, right, and left face. All subjects were sent a compliance reminder mobile text prior to each visit.

Along with descriptive statistics (means, standard deviations, and percentages), investigator ordinal nonparametric results were analysed using Wilcoxon signed rank test for paired comparison at different time points. The non-invasive data were analysed using a Student’s t-test. Changes were considered significant at the two-sided alpha-level 0.05 (α-level 0.05).

Results

All 45 subjects completed the study. The study enrolled 3 males (M) and 42 females (F). All Fitzpatrick skin types were represented with the following ethnicities enrolled: 25 Caucasian (C), 14 African American (AA), 4 Hispanic (H), and 2 Asian (AS). The participants ranged in age 36–64 years. There were no compliance issues.

Any self-selected skin care products used 30 days before start of the study by the volunteers were used without difficulty.

1. Facial skin parameters

Using the self-assessment questionnaires, the subjects experienced statistically significant visible improvements in all assessed parameters (skin firmness, lift, tightness, smoothness, skin tone, reduction in look of fine lines and wrinkles, complexion, hydration, bounce, plumpness, and radiance) at week 3 and week 6 ($p<0.05$). All assessments were made on a 5-point ordinal scale (0=None; 1=Minimal; 2=Mild; 3=Moderate; 4=Severe) (Table 1). Before and after pictures were also taken at the same time points (Figures 1–4).

TABLE 1. STUDY PARTICIPANTS' SELF-ASSESSMENT SCORES

SKIN PARAMETER	% IMPROVEMENT AT 3 WEEKS*	% IMPROVEMENT AT 6 WEEKS*
Firmness	14%	31%
Lift	18%	26%
Tightness	22%	37%
Smoothness	25%	35%
Skin tone	22%	35%
Lines and wrinkles	20%	32%
Complexion	17%	31%
Hydration	20%	30%
Bounce	19%	33%
Plumpness	19%	36%
Radiance	23%	38%

*All scores at week 3 and week 6 were statistically highly significant at $p<0.05$.

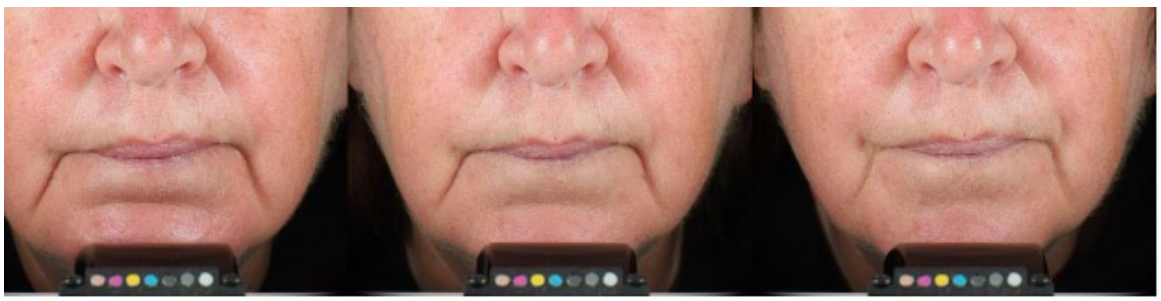

Figure 1. Marionette lines around the mouth improved and softened significantly in appearance over the 6-week study.

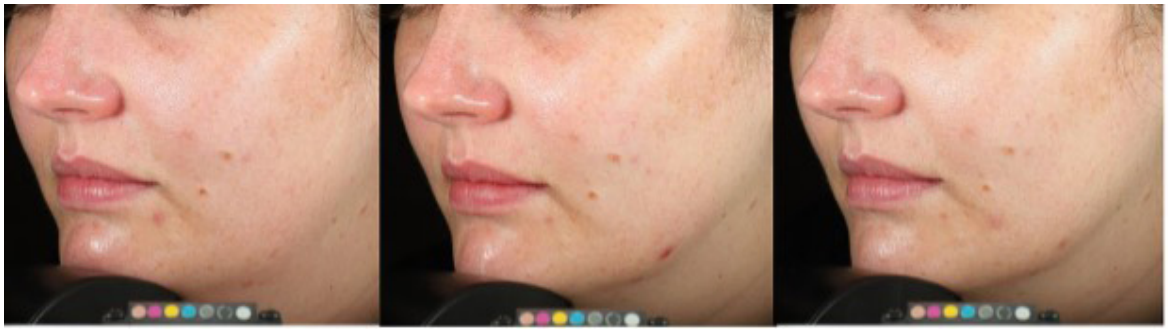

Figure 2. Subject's jawline showed improved visible definition over time.

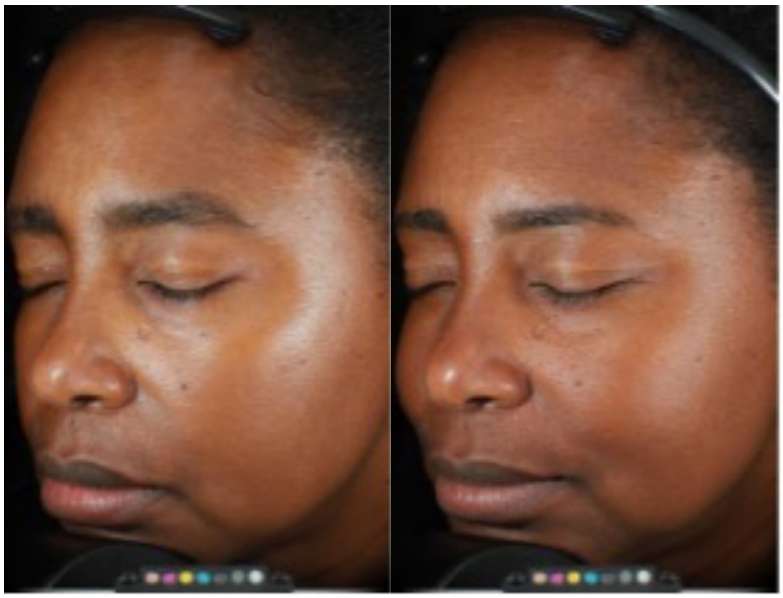

Figure 3. The complexion homogeneity improved significantly after 3 weeks.

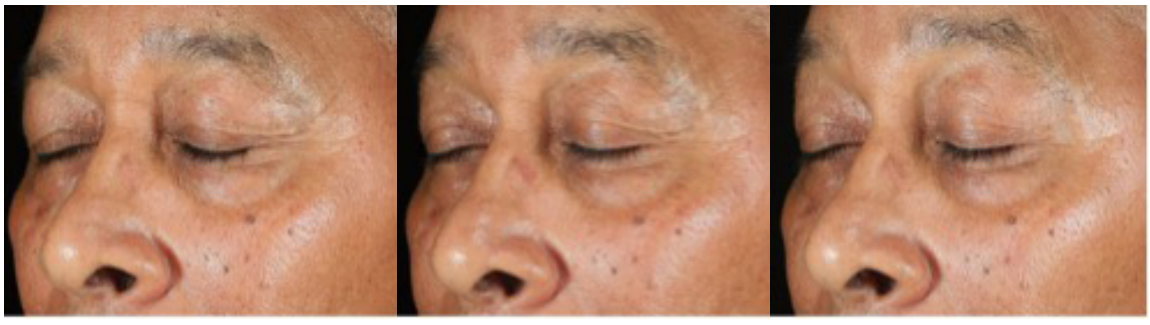

Figure 4. Fine lines and wrinkles around the eyes show a significant improvement over time.

2. Tolerability parameters

No tolerability issues were observed at any timepoint when rated by the dermatologist investigator (Table 2). Three subjects noted worsening of their acne during the study, but it could not be confirmed that it was study product related.

TABLE 2. TOLERABILITY ASSESSMENT BY DERMATOLOGIST USING THE 5-POINT ORDINAL SCALE

SKIN PARAMETER	3 WEEKS	6 WEEKS
Dryness	**0**	**0**
Peeling	**0**	**0**
Erythema	**0**	**0**
Oedema	**0**	**0**

(0=None; 1=Minimal; 2=Mild; 3=Moderate; 4=Severe)

Conclusion

The primary efficacy endpoint showed statistically significant improvement in the self-assessment of overall facial appearance in subjects using the study product for 3 and 6 weeks as compared to baseline. No product irritation occurred in any of the subjects and no product-related serious issues occurred.