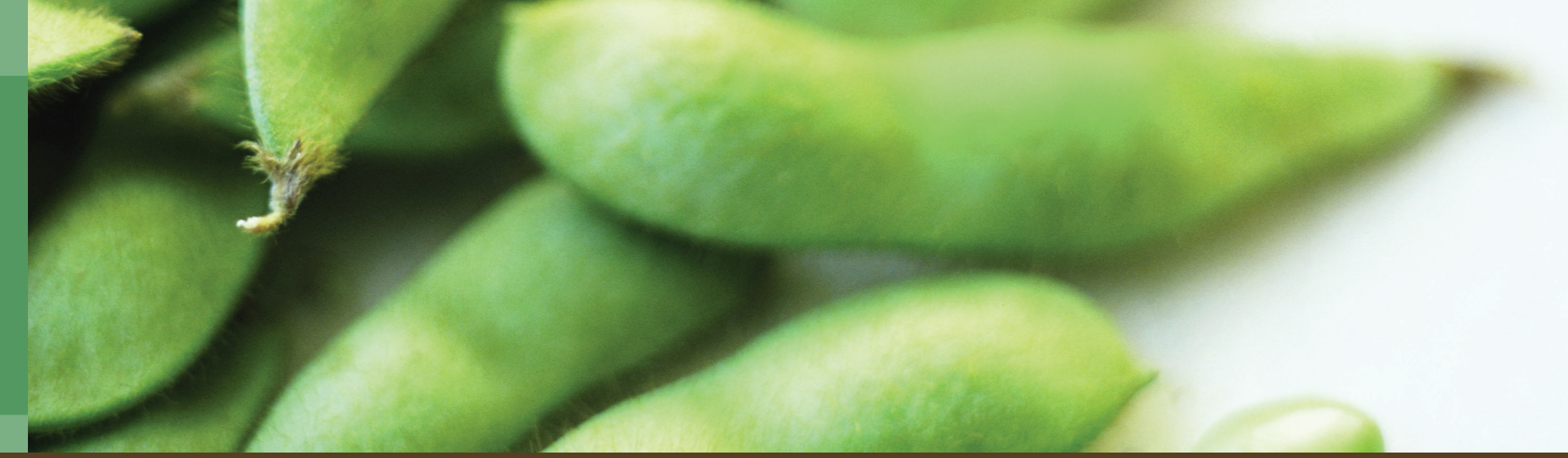


Clinical Improvements in Skin Tone and Texture Using A Facial Moisturizer With A Combination of Total Soy Complex and SPF 30 UVA/UVB Protection

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ABSTRACT

Clinical research has demonstrated that total soy complex preparations can deliver benefits to facial skin, when applied topically. Total soy complex contains small soy proteins and lipids that moisturize and provide textural benefits to skin.

It is important to recommend a daily facial moisturizer that provides broad spectrum UVA and UVB sun protection. More dermatologists are now recommending the use of daily moisturizers containing sunscreens with higher SPF values, such as SPF 30, especially to those patients who currently exhibit photodamage and various types of skin dyschromias. A daily moisturizer containing both total soy complex and broad spectrum SPF 30 could be highly beneficial for this population. The total soy complex addresses the uneven skin pigmentation and textural problems exhibited by photodamaged skin, while the broad spectrum SPF 30 provides adequate sun protection and protects the skin from further photodamage.

A double-blind, placebo-controlled clinical study was performed to determine the benefits of using a daily total soy complex facial preparation with broad spectrum SPF 30 in improving various skin tone and textural parameters. Sixty-three patients, between the ages of 30 and 55 exhibiting moderate levels of skin roughness, blotchiness and mottled hyperpigmentation, were enrolled into the 12-week study. Dermatologist evaluations, self-assessments and instrumental analysis were completed at various time points during the 12-week study.

Dermatologist evaluations demonstrated significant improvements ($p < 0.05$) in skin roughness, clarity and mottled hyperpigmentation after 2 weeks of use of the total soy complex facial preparation containing SPF 30. Significant improvements ($p < 0.05$) in mottled hyperpigmentation, blotchiness, appearance of fine lines and overall skin tone and texture were observed versus the placebo control group after only 2 weeks of use. Digital photography further verified improvements in skin tone parameters. This clinical study clearly showed that daily use of this facial total soy complex preparation containing SPF 30 was effective in improving a number of skin tone and textural parameters as observed by dermatologist evaluations, self-assessments and instrumental analysis.

INTRODUCTION

Numerous clinical studies have demonstrated the benefits of total soy complex facial formulations in improving skin tone and texture, visibly reducing fine lines while providing superior moisturization to soften and smooth facial skin.^{1,2} Total soy complex is an ingredient that must be processed carefully to help maintain the integrity of the components in the final form to ensure that benefits are delivered to the skin. The total soy complex that is delivered to the skin is a mixture of nutrient rich, non-denatured components.³ It has been shown that total soy complex can improve the hyperpigmentation

and blotchiness of facial skin. It is important to incorporate optimum sun protection, especially in the UVA range, into daily facial moisturizers to protect patients from further dyschromias, sun damage and photoaging that can be caused by incidental daily sun exposure. Patients would benefit from a total soy complex facial moisturizer with an SPF 30 as the soy would improve the hyperpigmentation, blotchiness and fine lines of photoaged skin while SPF 30 with sufficient protection in the UVA range will help protect the skin from future photoaging and reduce problems with mottled hyperpigmentation.

STUDY DESIGN

This was a 12-week, double-blind, placebo-controlled clinical study to evaluate the effects of a total soy complex and SPF 30 moisturizer in improving facial skin tone, texture and clarity. Benefits were measured by dermatologist evaluations, self-assessments, instrumental methods and digital photography.

Population

Sixty-three healthy female subjects between the ages of 30 and 55 years completed the study. Upon enrollment, all patients exhibited moderate levels of roughness, mottled hyperpigmentation, lentiginos, blotchiness and/or skin dullness.

Treatments

Subjects were randomized into either one of the following groups. The total soy complex moisturizer or placebo was applied to the subjects' entire face twice a day.

- Facial moisturizer with total soy complex and SPF 30: n=31
- Placebo moisturizer and SPF 30 (no total soy complex): n=32

RESULTS

Figure 1. Dermatologist Assessments – Week 4 Percent of Improvement in Facial Parameters Total Soy Complex and SPF 30 Facial Moisturizer versus Placebo

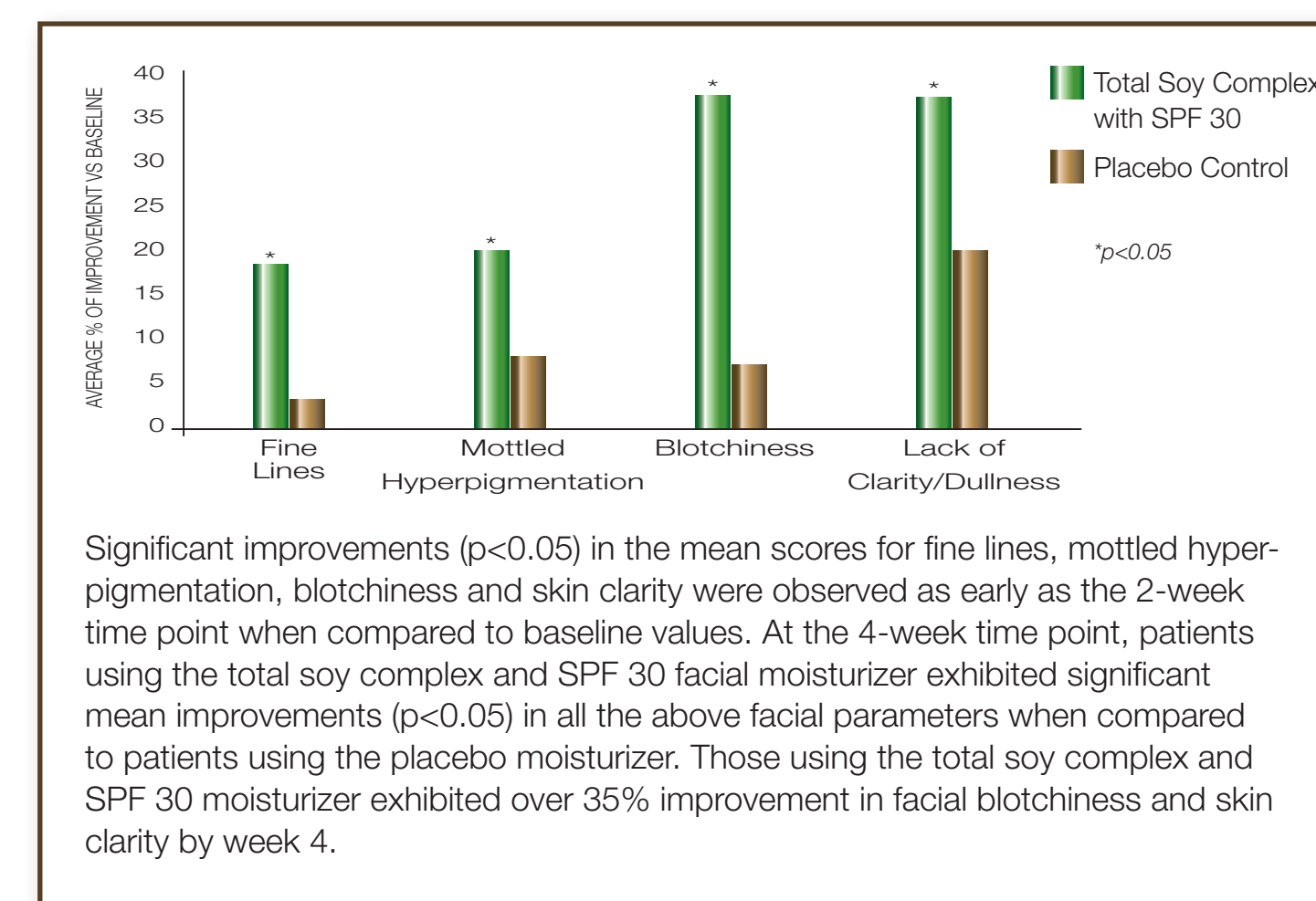


Figure 2. Dermatologist Assessments – Percent of Improvement in Facial Parameters Total Soy Complex and SPF 30 Moisturizer

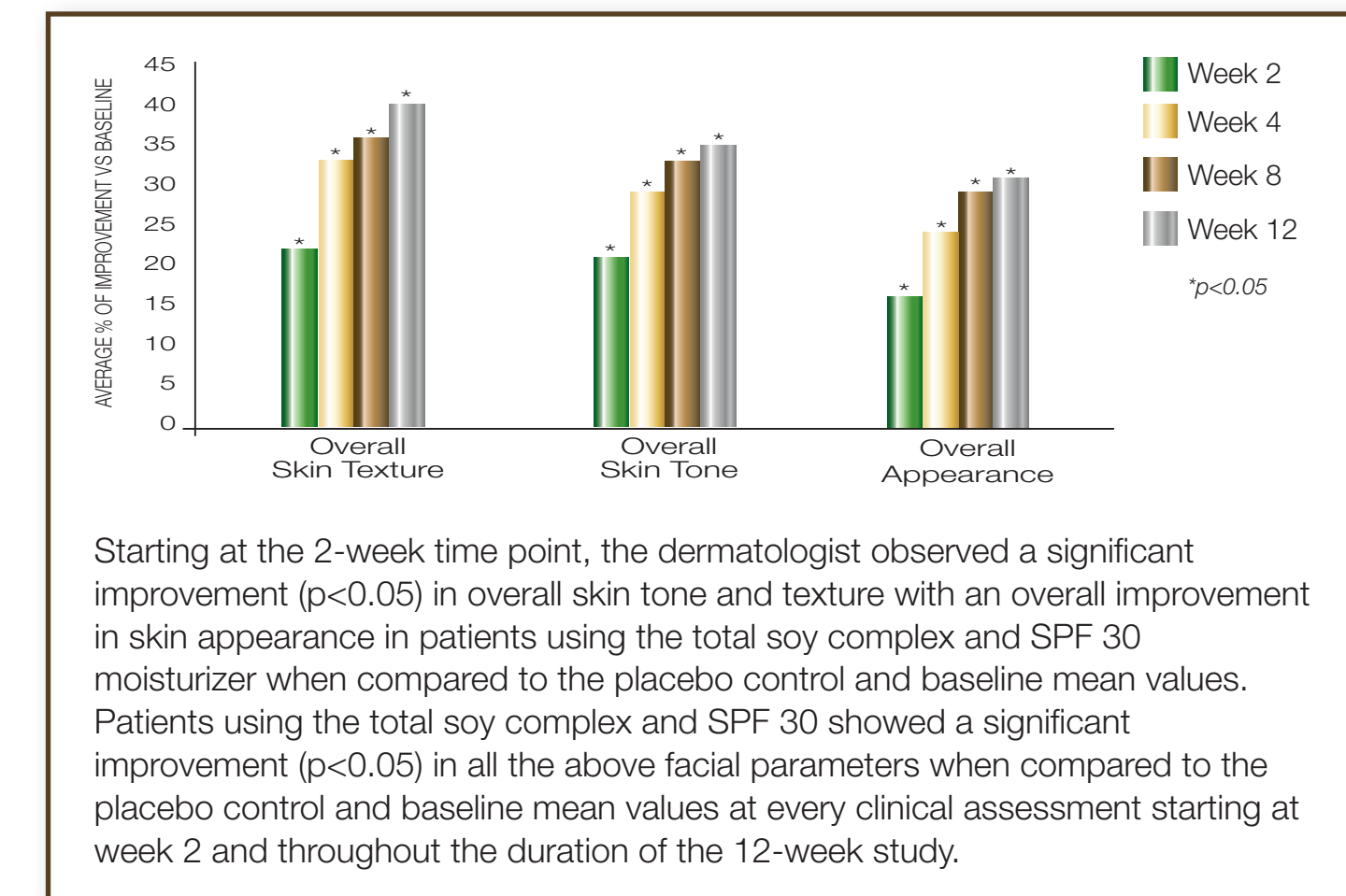


Figure 3. Dermatologist Assessments – Week 8 Percent of Improvement in Facial Parameters Total Soy Complex and SPF 30 Facial Moisturizer

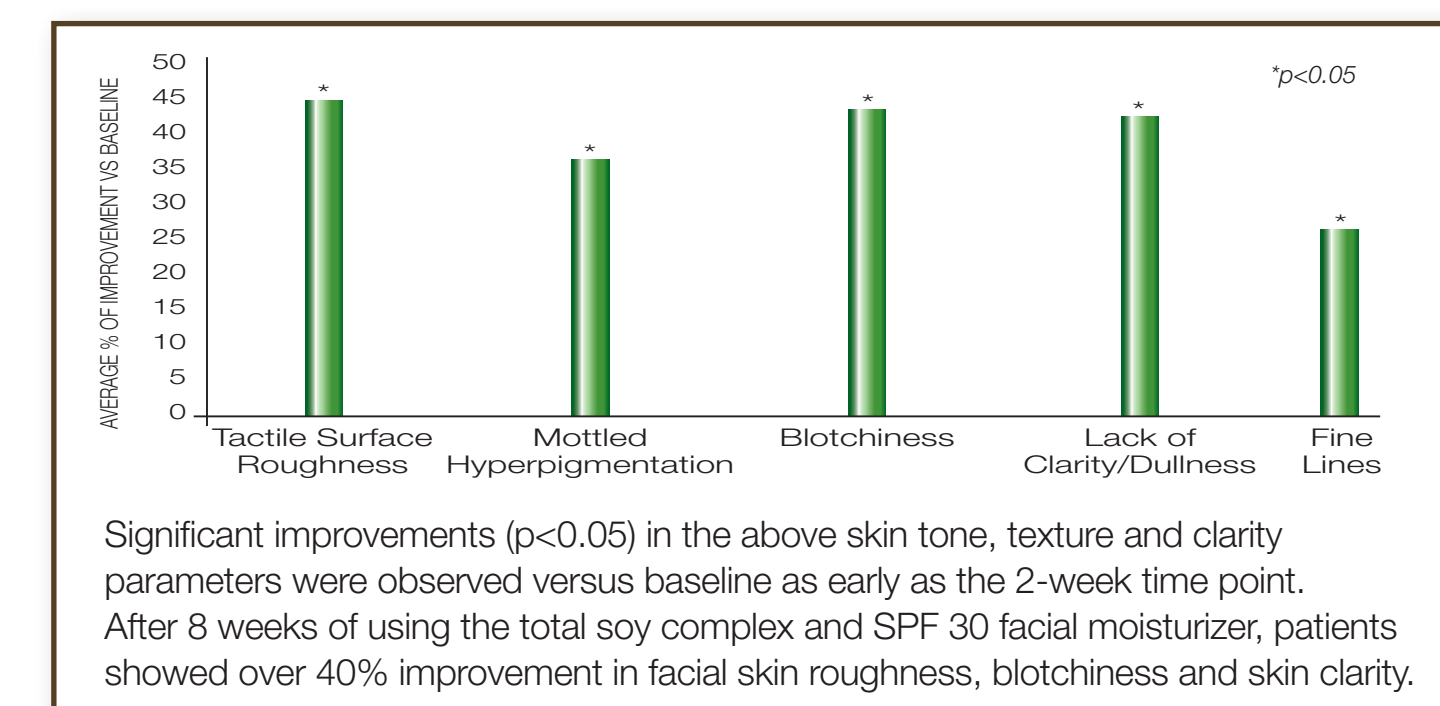


Figure 4. Digital Photography Before and After Use of the Total Soy Complex and SPF 30 Moisturizer



Visible and enhanced images clearly show an improvement in skin tone, texture and clarity after 12 weeks of use of the total soy complex and SPF 30 facial moisturizer.

CONCLUSIONS

This total soy complex and SPF 30 facial moisturizer has been shown to be safe and effective in providing overall improvements in facial skin tone, texture and clarity. It provides adequate daily sun protection and has been shown to deliver multiple skin benefits to patients exhibiting signs of photoaging and hyperpigmented, blotchy skin. This facial moisturizer was well tolerated and there were no serious adverse skin reactions reported during the 12-week study. The effectiveness of this total soy complex SPF 30 moisturizer was demonstrated in this clinical study by the following:

- Dermatologist assessments at the 2-week time point showed significant mean improvements ($p < 0.05$) in overall facial skin tone and texture parameters including improvements in mottled hyperpigmentation, blotchiness and fine lines when compared to the placebo control group and baseline mean values. After 4 weeks of use, there was over a 35% mean improvement in skin blotchiness and clarity of the skin.
- Self-assessments showed that subjects began to perceive significant improvements ($p < 0.05$) in various skin tone, texture and brightness parameters as soon as 1 week of using the total soy complex and SPF 30 facial moisturizer.
- The colorimeter showed a significant increase ($p < 0.05$) in skin luminosity with a significant decrease ($p < 0.05$) in the yellow coordinate correlating to an improvement in skin brightness and overall skin tone.
- Visible and enhanced photography both demonstrate improvements in skin tone, texture and radiance parameters.
- Moisturization measurements showed that the total soy complex and SPF 30 moisturizer significantly improved facial skin hydration ($p < 0.05$) at all measured time points throughout the duration of the study.
- Additional studies showed that this moisturizer was noncomedogenic, gentle to the skin and did not induce dermal sensitization. The sunscreens used in this total soy complex moisturizer have been shown to be photostable based on both clinical and scientific studies.

ACKNOWLEDGEMENTS

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REFERENCES

1. Nebus J, Wallo W, Sher D, et al. Clinical Improvement in Skin Tone, Texture and Radiance with Facial Moisturizers Containing Total Soy Complex. Poster presented at: 20th World Congress of Dermatology; July 1-5, 2002; Paris, France, P 0444.
2. Nebus J, Costes F, Wallo W, et al. Clinical Evaluation of a Concentrated Soy Formulation with Antioxidants in Improving Skin Tone. Poster presented at: American Academy of Dermatology 64th Annual Meeting; March 3-7, 2006; San Francisco, Calif., P 1100.
3. Nebus J, Wallo W. Evaluating the tolerance of an oat-based cream and cleanser in infants and children with atopic dermatitis. *J Am Acad Dermatol.* 2008; 58:AB52.