

A Comprehensive Facial Skin Brightening Regimen Uses a Multi-Mechanistic Approach to Delivering Pigment Evening Benefits in an Ethnically Diverse Population

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INTRODUCTION

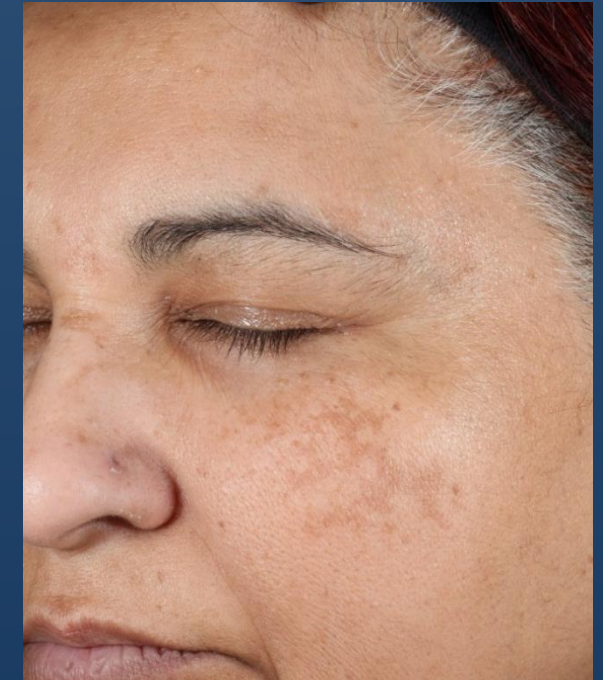
All skin types are affected by pigmentation irregularities making skin brightening a global need. A high-strength skincare regimen, including a cleanser, serum, day cream SPF 25, and night lotion was formulated to target multiple pigmentation pathways. All products contain N-acetyl glucosamine for its known ability to exfoliate¹, reduce tyrosinase activity and provide pigment evening² benefits. The regimen also contains tetrahydrodiferuloylmethane (turmeric), butyl resorcinol, niacinamide, retinol, licorice extract, vitamin C and antioxidants to provide comprehensive skin brightening.³⁻⁶ The safety and effectiveness of the daily regimen were evaluated in an ethnically diverse population.

CLINICAL PHOTOGRAPHY

Improvements in Overall Pigmentation and Lines
Nose, Cheek, Under Eye Lines, Crow's Feet



Week 0



Week 16

STUDY METHODOLOGY

Study Design

- Single-group, prospective skincare regimen use study with direct comparisons to baseline with visits at Weeks 0, 4, 8 & 16

Population/Inclusion Criteria

- Women, 30-60 years old, Fitzpatrick skin types I-IV with a diverse ethnic representation, with distinct areas of mild to moderate facial pigmentation (3-6 on a modified Griffiths' scale {0 =none to 9 =severe}), confirmed to be epidermal in nature with a Wood's lamp

Evaluation Tools

Objective

- Visual grading by a trained clinical grader for pigmentation, clarity/brightness, skin smoothness, fine lines, wrinkles, laxity and overall appearance were assessed on the face
- Chromameter
- Digital photography with image analysis of skin brightness

Subjective - Self-assessment questionnaires

Statistics

- Visual grading change from baseline comparisons using Wilcoxon signed-rank at $p < 0.05$
- Chromameter and Image analysis of digital photographs using paired t-tests at $p < 0.05$
- Tabulation of self-assessment scores

Safety – Observed and reported adverse events

TEST PRODUCTS

The high strength skincare regimen targets multiple pigmentation pathways. Cleanser and Serum were used twice daily, followed by Day Cream SPF 25 for morning and Night Lotion for evening. A marketed SPF 45 was provided for prolonged sun exposure.

Brightening Agent	Known Action	Cleanser <i>(NeoStrata® Enlighten Ultra Brightening Cleanser)</i>	Serum <i>(NeoStrata® Enlighten Illuminating Serum)</i>	Day Cream SPF 25 <i>(NeoStrata® Enlighten Skin Brightener SPF 25)</i>	Night Lotion <i>(NeoStrata® Enlighten Pigment Controller)</i>
N-Acetyl Glucosamine <i>(NeoGlucosamine)</i>	Reduces tyrosinase, exfoliates	4%	6%	8%	6%
Niacinamide B₃	Reduces melanosome transfer, protects skin		✓		
Turmeric Extract	Reduces tyrosinase & melanin			✓	✓
Retinol	Reduces tyrosinase & melanin				0.1%
Butyl Resorcinol	Reduces tyrosinase, melanin & TYRP-1		✓	✓	
Vitamin C	Reduces tyrosinase & melanin		Vitamin C (Tetrahexyldecyl ascorbate)		Vitamin C (Ascorbyl glucoside)
Alpine Plant Extracts <i>(Brightening blend of extracts)</i>	Reduces tyrosinase & melanin	✓			✓
Licorice Extract, Antioxidants	Reduces tyrosinase & free radicals		Licorice Extract	Vitamin E, Grape Seed Extract	Vitamin E

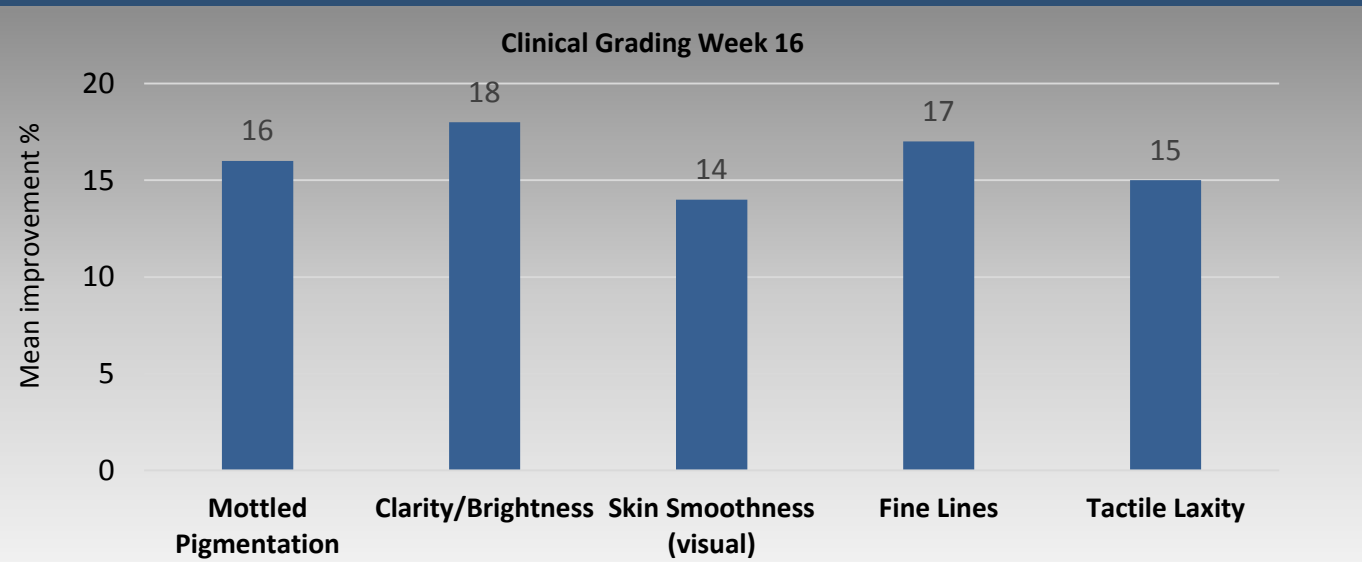


RESULTS

39 ethnically diverse women completed the study; 13% African American, 20% Asian, 26% Hispanic/Latino, and 41% Caucasian

Clinical Grading

- All clinically graded parameters were significantly improved by week 8 and continued through week 16 ($p < 0.05$)



- Clinical grading also showed
 - 87% of subjects had improved mottled pigmentation
 - 100% of subjects had improvement in clarity/brightness

Tolerability

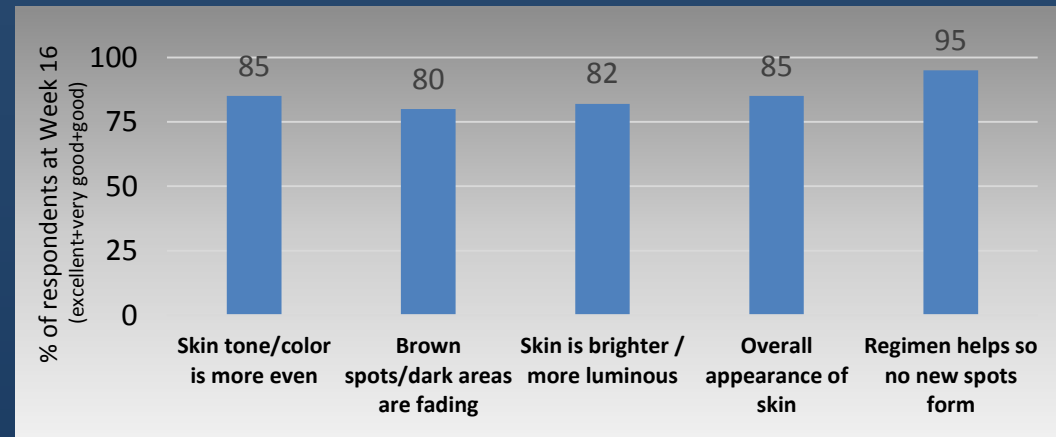
- The high strength regimen was well tolerated with self-assessed irritation of mild or less on average and no significant increases in Chromameter a^* values (redness)
- Three adverse events were reported with mild to moderate dryness, peeling and/or erythema; one subject continued and two subjects discontinued use of the regimen

Chromameter & Image Analysis for Brightness

- Luminance (L^*) showed significant brightening of skin via Chromameter (pigmented area) and Image Analysis of digital photographs (forehead) at Week 16, ($p < 0.05$)
- Chromameter yellow (b^*) values demonstrated significant decreases in sallowness of skin at Week 16, ($p < 0.05$)

Self-Assessment

- Self-assessment demonstrated a perceived lightening effect supporting the clinical grading

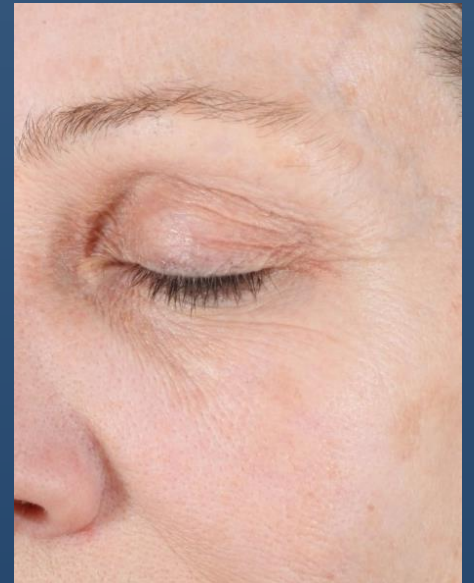


- 100% of subjects thought the regimen started to make their skin brighter and more even toned within 4 weeks

CLINICAL PHOTOGRAPHY Improvement in Overall Pigmentation and Anti-Aging Parameters



Cheek, Forehead



Spots on Cheek



Under Eye Lines, Crow's Feet

All photos are Week 0 and Week 16



CONCLUSION

- **The new, multi-mechanism daily skincare regimen delivers clinically and consumer perceivable benefits for overall skin brightening in an ethnically diverse population**
- **A significant improvement in skin tone brightness, reduced appearance of uneven pigmentation, as well as improvements in overall skin quality such as fine lines was demonstrated through clinical grading, instrumental measurement, image analysis, and self-assessment**
- **The high-strength regimen was well tolerated**

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