

Clinical Evaluation of a Thiamidol-containing Regimen Compared With Photoprotection for the Visual Management of Facial Hyperpigmentation

Susan Taylor¹, Pearl E. Grimes²

¹Department of Dermatology, University of Pennsylvania, Philadelphia, PA ²The Grimes Center for Medical and Aesthetic Dermatology, Vitiligo and Pigmentation Institute of Southern California, Los Angeles, CA

Abstract

Objective: Pigmentary disorders, including melasma, post-inflammatory hyperpigmentation, and solar lentigines, are among the most common skin disorders. Uneven skin tone as a result of hyperpigmentation affects how patients see themselves, and how they are perceived by others, resulting in an impact on patients' quality of life. Photoprotection in the form of broad-spectrum ultraviolet sunscreen is the cornerstone of most standard management protocols to reduce hyperpigmentation exacerbation. Hyperpigmentation is mediated by overactivity of a multi-step synthesis process resulting in the overproduction of melanin from tyrosine via tyrosinase activity. Recently, isobutylamido thiazolyl resorcinol (Thiamidol) has been identified as the most effective human tyrosinase inhibitor out of >50,000 screened compounds, making it an attractive ingredient for anti-hyperpigmentation formulations. The objective of this study was to evaluate the efficacy of a Thiamidol-containing regimen (Day Lotion with SPF 30, Serum, and Night Cream) compared with a standard SPF 30 lotion for visible management of hyperpigmentation.

Materials and Methods: A randomized study was performed (N=95; n=47, Thiamidol regimen; n=48, standard SPF 30 lotion) with subjects aged 18-65 and Fitzpatrick Skin Types I-VI clinically presenting with facial hyperpigmentation (measured by colorimeter and individual typology angle [ITA°]) to assess the efficacy of the Thiamidol-containing regimen (Day Lotion with SPF 30 and Serum applied in the morning, Night Cream and Serum applied in the evening) compared with a standard SPF 30 lotion (applied 1-4 times daily as needed) for 12 weeks, followed by a 6-week regression phase.

Results: Facial hyperpigmentation, measured by skin lightness, ITA° values, radiance and shine, was significantly reduced relative to baseline for both groups as early as Week 2, and significantly reduced for patients receiving the Thiamidol-containing regimen vs the standard SPF 30 lotion at Weeks 8 and 12. Additionally, both groups maintained significant reductions in hyperpigmentation compared to baseline after a 6-week regression phase.

Discussion: This study demonstrates that while SPF alone can reduce the visible signs of hyperpigmentation, the addition of Thiamidol to a daily skin care regimen can confer additional benefit with regard to skin lightness, radiance, and shine. This data supports the integration of Thiamidol-containing formulations into existing skin care regimens for individuals with facial hyperpigmentation.

Materials and Methods

Clinical Study Design

A randomized, clinical trial was conducted in a study center (Dermico, Broomall, PA). In the 12-week treatment phase, the subjects returned at Week 2, Week 4, Week 8, and Week 12, and after a 6-week regression phase (Week 18) for assessments. The study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and followed International Conference on Harmonization Good Clinical Practice (ICH E6 (R2) GCP) guidelines. The protocol was reviewed and approved by the Sterling Investigational Review Board.

Study Population and Treatment

Healthy male and female subjects, aged 18-65 years, with Fitzpatrick Skin Types I-VI demonstrating facial hyperpigmentation as measured by colorimeter and individual typology angle (ITA°) (Thiamidol regimen, n=47; standard SPF lotion, n=48) willing and capable of following the study rules were enrolled in the trial. Individuals with ITA° ranging from +65° to -31° and an ITA° difference of >5 ITA units on their facial skin were included.

For 12 weeks, the subjects allocated to the Thiamidol regimen group applied the serum and day lotion in the morning followed by the serum and the night cream at night. Both groups were allowed to apply a standard SPF lotion as needed up to 4 times daily. The first application of the study products was performed at baseline in the study center under the supervision of the study monitor. Three days prior to the start of the study, subjects had to stop the use of all topical products on their face. Subjects were asked to refrain from activities that increase body temperature and avoid extended sun exposure greater than 15 minutes. If longer exposure was needed, subjects were asked to wear a hat or have access to shade (umbrella, etc.).

Assessments

Assessments of skin lightness (L*), ITA° value, radiance, and shine were conducted at baseline, Weeks 2, 4, 8, 12, and 18. Briefly, visible, cross-polarized (X-Pol), parallel-polarized (P-Pol) and UV fluorescence clinical images were acquired for each time point using a Visia-CR skin analysis imaging system (Canfield Scientific, Parsippany, NJ). X-Pol and P-Pol images were used to

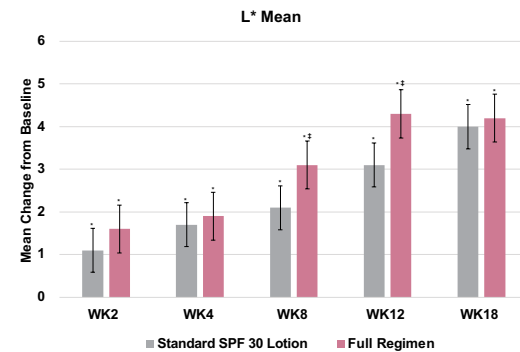
quantify skin tone, shine, and radiance. A standardized region of interest from each facial image was translated pixel by pixel from the native RGB values into the L*a*b* color space, then analyzed in terms of their image histogram parameters. Individual Topology Angle (ITA°) was calculated from L* and b* values using the equation $ITA^\circ = [\arctan(L^*-50/b^*)] * 180/\pi$. The mean of the L* value and ITA° value were used to represent skin lightening, while a partial least squares regression model was employed to quantify perceived shine and radiance as a balance of skin surface and subsurface reflection components.

Statistical Analysis

Statistical analyses of efficacy variables were based on the full analysis set (FAS) consisting of all randomized subjects having completed the study without any major protocol deviation. Statistical significance amongst and between groups was determined using the Wilcoxon signed-rank test using the Statistical Analysis System (SAS Institute, North Carolina) software package.

Results

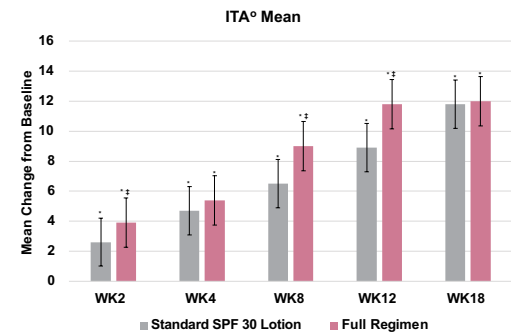
FIGURE 1. L* Mean (Skin Lightness) Following Treatment with Thiamidol Formulated Full Product Regimen (Serum, Day Lotion, and Night Cream) or Standard SPF 30 Lotion Compared to Baseline at All Time Points Assessed. Significant difference between treatment groups and baseline as indicated (*p < 0.05). Significant difference between full regimen and standard SPF 30 lotion as indicated (†p < 0.05).



*Significant improvement compared to baseline, p < 0.05.

†Significant improvement compared to standard SPF 30 lotion, p < 0.05.

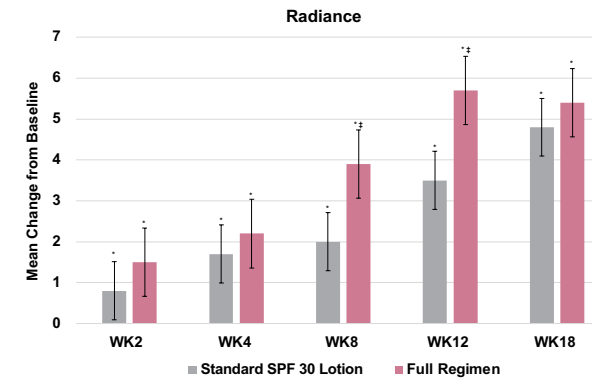
FIGURE 2. Mean Individual Typology Angle (ITA°) Following Treatment with Thiamidol Formulated Full Product Regimen (Serum, Day Lotion, and Night Cream) or Standard SPF 30 Lotion Compared to Baseline at All Time Points Assessed. Significant difference between treatment groups and baseline as indicated (*p < 0.05). Significant difference between full regimen and standard SPF 30 lotion as indicated (†p < 0.05).



*Significant improvement compared to baseline, p < 0.05.

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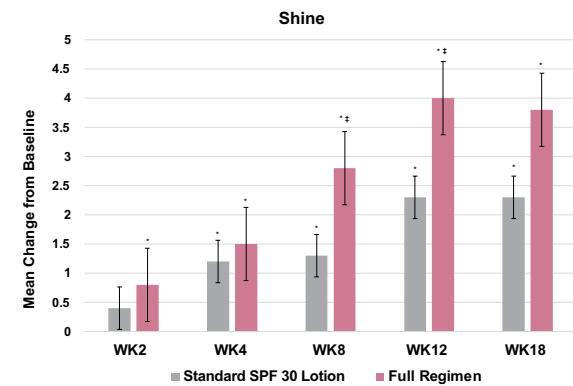
FIGURE 3. Mean Radiance Measured Following Treatment with Thiamidol Formulated Full Product Regimen (Serum, Day Lotion, and Night Cream) or Standard SPF 30 Lotion Compared to Baseline at All Time Points Assessed. Significant difference between treatment groups and baseline as indicated (*p < 0.05). Significant difference between full regimen and standard SPF 30 lotion as indicated (†p < 0.05).



*Significant improvement compared to baseline, p < 0.05.

†Significant improvement compared to standard SPF 30 lotion, p < 0.05.

FIGURE 4. Mean Shine Measured Following Treatment with Thiamidol Formulated Full Product Regimen (Serum, Day Lotion, and Night Cream) or Standard SPF 30 Lotion Compared to Baseline at All Time Points Assessed. Significant difference between treatment groups and baseline as indicated (*p < 0.05). Significant difference between full regimen and standard SPF 30 lotion as indicated (†p < 0.05).



*Significant improvement compared to baseline, p < 0.05.

†Significant improvement compared to standard SPF 30 lotion, p < 0.05.

REFERENCES: 1. Wang RF, Ko D, Friedman BJ, et al. *J Am Acad Dermatol.* 2023;88(2):271-288. 2. Kerob D, Passeron T, Alexis A, et al. *J Am Acad Dermatol.* 2024;91(3):AB73. 3. Mann T, Gerwat W, Batzer J, et al. *J Invest Dermatol.* 2018;138(7):1601-1608.

FIGURE 5. Representative Clinical Photography of Subjects. Improvement in Facial Hyperpigmentation Following Treatment with Thiamidol Formulated Full Regimen (Serum, Day Lotion, and Night Cream; 12 Weeks)



Summary and Conclusions

- Pigmentation disorders including melasma, post-inflammatory hyperpigmentation, and solar lentigines have significant impacts on patients' self-perception and quality of life
- Thiamidol (isobutylamido thiazolyl resorcinol) was recently identified as the strongest inhibitor of human tyrosinase out of >50,000 screened compounds, indicating its potential as an anti-hyperpigmentation ingredient
- In this randomized study of adult subjects with facial hyperpigmentation, the Thiamidol-containing regimen was compared with a standard SPF 30 lotion for 12 weeks, followed by a 6-week regression phase
- While SPF alone can reduce the visible signs of hyperpigmentation, the addition of Thiamidol to a daily skin care regimen can confer additional benefit with regard to skin lightness, radiance, and shine
- This study supports the integration of Thiamidol-containing formulations into existing skin care regimens for individuals with facial hyperpigmentation

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