# Clinical Evaluation of Thiamidol-containing Formulations for the Visual Management of Facial Hyperpigmentation

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## Abstract

**Objective:** Skin hyperpigmentation, which includes melasma, post-inflammatory hyperpigmentation, and solar lentigines, significantly impacts patients' quality of life. The overproduction of melanin occurs via a complex mechanism and is mediated by activation of the human skin enzyme tyrosinase through conversion of L-Dopa to the end product melanin with subsequent deposition in skin. Thiamidol (isobutylamido thiazolyl resorcinol) formulations have been previously shown to be effective in reducing the visible factors associated with this human skin enzyme. The objective of this research was to investigate the clinical efficacy of a novel cosmetic Thiamidol-containing serum and Thiamidol-containing regimen (Day Lotion with SPF 30, Serum, and Night Cream) for the visible management of facial hyperpigmentation.

**Materials and Methods:** A randomized study was performed with 90 subjects (representative of Fitzpatrick Skin Types I-VI) clinically presenting with facial hyperpigmentation as measured by colorimeter and individual typology angle (ITA°) (Thiamidol serum n=43; Thiamidol regimen n=47), to assess the efficacy of a Thiamidol-based serum (2x daily application; morning/night) or a Thiamidol-based regimen (Day lotion with SPF 30 + Serum in morning; Night cream + Serum at night) for 12 weeks with a 6-week regression period. Assessments of skin lightness (L*), ITA° value, radiance, and shine were conducted at baseline, Weeks 2, 4, 8, 12, and 18.

**Results:** A significant visible reduction in facial hyperpigmentation, assessed by increases in L* and ITA° values, along with an increase in skin radiance and shine, were observed as early as Week 2, with continued improvement through Week 12 in both the Serum and Regimen groups relative to baseline. At Week 12, changes in radiance and shine were trending toward enhancement in the regimen group compared to the serum group.

**Discussion:** This study demonstrates the clinical effectiveness of Thiamidol-containing formulations in the visible improvement of facial hyperpigmentation and in overall skin radiance and shine. These data support the use of Thiamidol-containing formulations as part of the overall management strategy for individuals affected by 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 formulated serum, n=43; Thiamidol formulated regimen, n=47) 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 serum group applied the serum twice daily (morning and evening). 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° = [arctan(L*-50)/b*)] *180/π. 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 Serum or Thiamidol Formulated Full Product Regimen (Serum, Day Lotion, and Night Cream) Compared to Baseline at All Time Points Assessed.** Significant difference between treatment groups and baseline as indicated (*p < 0.05).

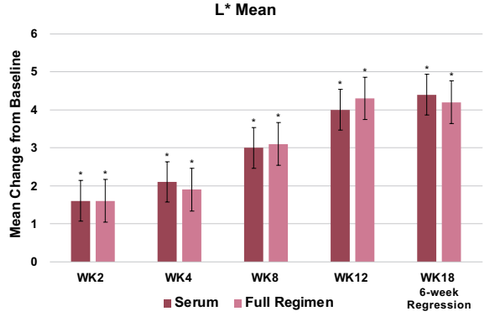



**FIGURE 2. Mean Individual Typology Angle (ITA°) Following Treatment with Thiamidol Formulated Serum or Thiamidol Formulated Full Product Regimen (Serum, Day Lotion, and Night Cream) Compared to Baseline at All Time Points Assessed.** Significant difference between treatment groups and baseline as indicated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

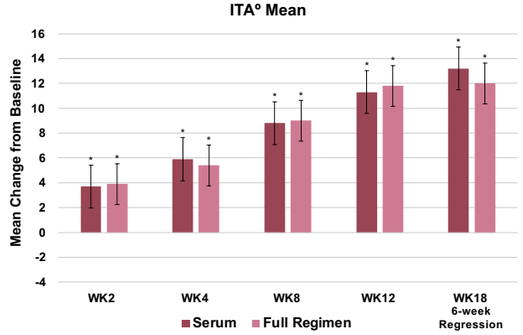



**FIGURE 3. Mean Radiance Measured Following Treatment with Thiamidol Formulated Serum or Thiamidol Formulated Full Product Regimen (Serum, Day Lotion, and Night Cream) Compared to Baseline at All Time Points Assessed.** Significant difference between treatment groups and baseline as indicated (*p <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

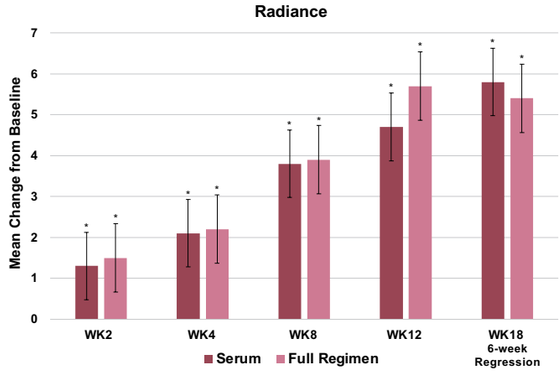
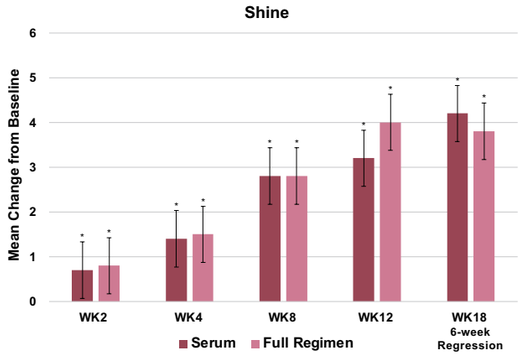


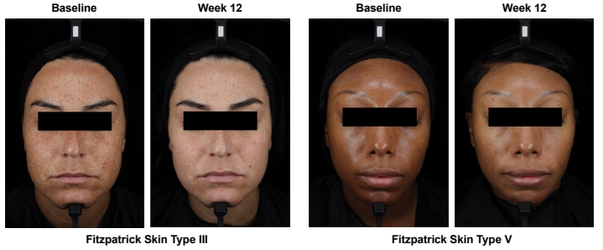

**FIGURE 4. Mean Shine Measured Following Treatment with Thiamidol Formulated Serum or Thiamidol Formulated Full Product Regimen (Serum, Day Lotion, and Night Cream) Compared to Baseline All Time Points Assessed.** Significant difference between treatment groups and baseline as indicated (*p < 0.05).




**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. **4.** Hearing VJ, Jr., Ekel TM, Montague PM, Nicholson JM. *Biochim Biophys Acta.* 1980;611(2):251-268. **5.** Vachiramon V, Kositkuljorn C, Leerunyakul K, Chanprapaph K. *J Cosmet Dermatol.* 2021;20(3):987-992.

**FIGURE 5. Representative Clinical Photography of Subjects. Improvement in Facial Hyperpigmentation Following Treatment with Thiamidol Formulated Serum (12 Weeks)**


**FIGURE 6. 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

- Skin hyperpigmentation, including melasma, post-inflammatory hyperpigmentation, and solar lentigines, has a significant impact on patients' quality of life
- Recently, Thiamidol, isobutylamido thiazolyl resorcinol, has been identified as the strongest inhibitor of human tyrosinase, thus a suitable ingredient for inclusion in over-the-counter anti-pigmentation products
- This single center, randomized clinical trial demonstrated a significant visible reduction in facial hyperpigmentation, assessed by increases in L* and ITA° values, along with an increase in skin radiance and shine observed as early as Week 2, with continued improvement through Week 12 in both the Serum and Regimen groups relative to baseline. At Week 12, changes in radiance and shine were trending toward enhancement in the regimen group compared to the serum group
- This study demonstrates the clinical effectiveness of Thiamidol-containing formulations in the visible improvement of facial hyperpigmentation and in overall skin radiance and shine

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