Poster number 50811

Demonstrating the Clinical Effectiveness of Mineral Sunscreens in Protecting the Skin Against Ultraviolet A (UVA) Radiation-Induced Pigmentation

Thomas Shyr, Frank Sun Ph.D., Joshua D. Williams Ph.D.

Johnson & Johnson Consumer Inc., part of Kenvue, Skillman, NJ USA

Disclosures: This work was sponsored by Johnson & Johnson Consumer Inc.
Author Disclosures: All authors are employees of Johnson & Johnson Consumer Inc.

Presented at the American Academy of Dermatology Annual Meeting, 8-12 March 2024

Introduction, Objectives, and Methods

Introduction

- Sun Protection Factor (SPF) is widely recognized as an index of the protection against Ultraviolet B (UVB). However, SPF rating does not provide explicit information on the magnitude of protection against Ultraviolet A (UVA), which penetrates deeper into the skin and causes pigmentary, photoaging, photocarcinogenic, and immunomodulatory effects.
- Mineral sunscreens, even those providing broad spectrum protection, may offer different levels of UVA Protection. Sunscreens with higher levels of Zinc Oxide (ZnO) generally have superior in vitro UVA absorbance, but the clinical relevance in terms of UVA induced pigmentation is not well understood.

Objectives

- Clinically validate in vitro UVA protection with in vivo clinical results per ISO24442:2011[1], and imaging.
- Evaluate UVA protection as a function of ZnO level within mineral sunscreen formulas.

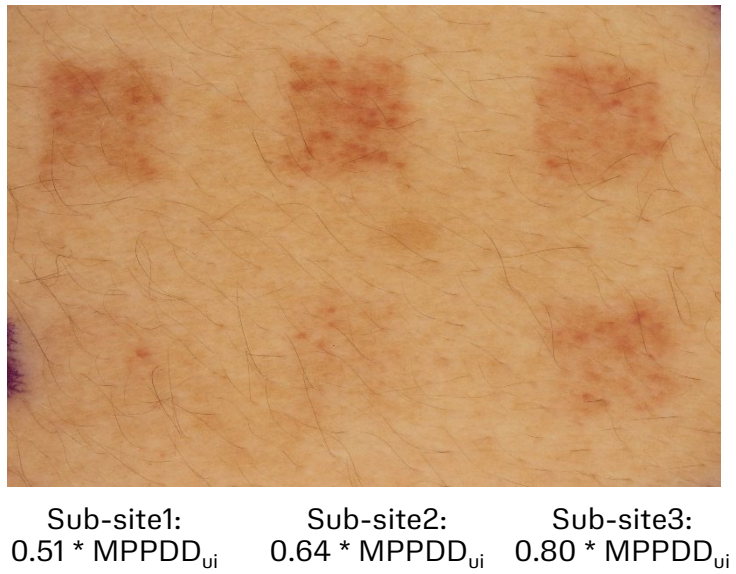
Methods

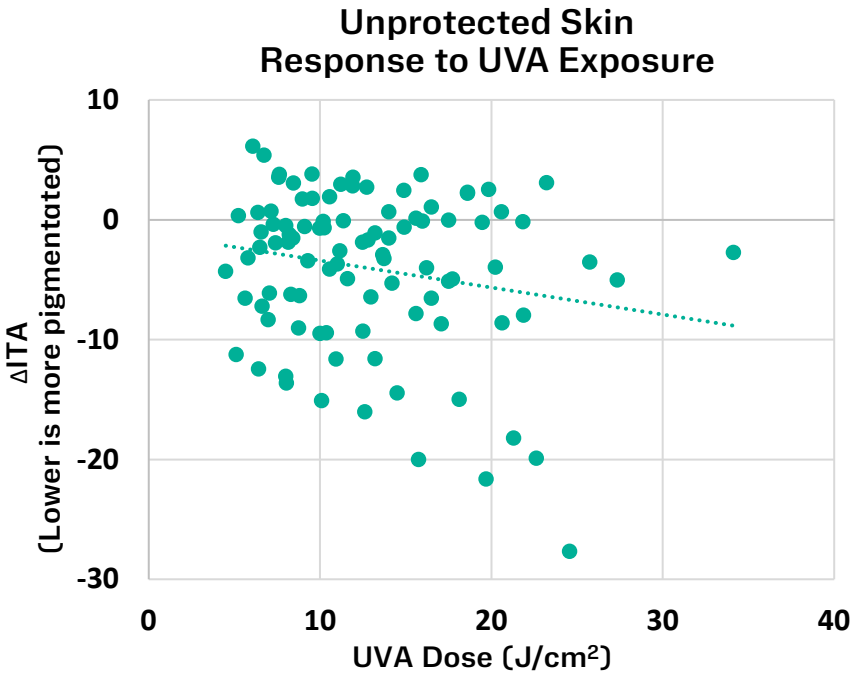
- A single center, randomized, evaluator-blind, self-controlled clinical study was conducted to evaluate the UVA Protection Factor (UVAPF) per the method (ISO24442:2011) described by the International Organization for Standardization (ISO) for evaluating the UVAPF of sunscreen products using the persistent pigmentation darkening (PPD) response of skin.
- Healthy male and female subjects, 18 to 70 years old, with skin Fitzpatrick type II to IV were enrolled.
- Per ISO24442:2011, a sufficient number of subjects will be enrolled to finish with at least 10 valid test results for each investigational product (IP).
- Cross-polarized images were taken at each test site before and after UV irradiation, and individual topology angle (ITA) was calculated for each irradiated sub-sites within the test site.
- Eight broad spectrum mineral sunscreens between 0% and 21.6% ZnO were evaluated.

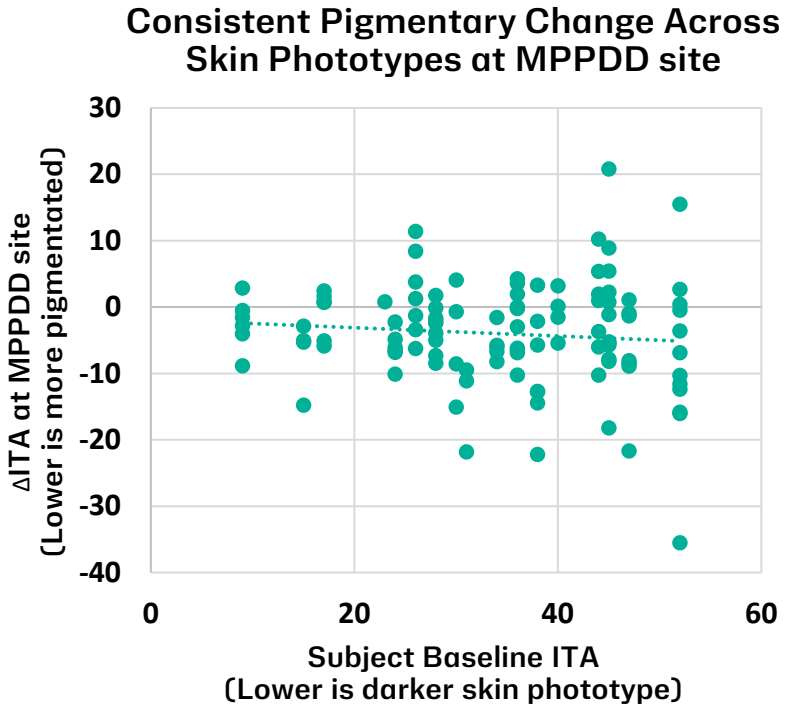
References:
1. International Standard, ISO 24442:2011, Cosmetics – Sun protection test methods – in vivo determination of sunscreen UVA protection, published by International Organization for Standardization (ISO), December 2011.

Results – UVA Induced Skin Pigmentation Is Proportional to Exposure With Consistent Pigmentation Across Skin Types at the Minimal Persistent Pigmentation Darkening Dose Site

Determination of MPPDD with UVA Dose Series



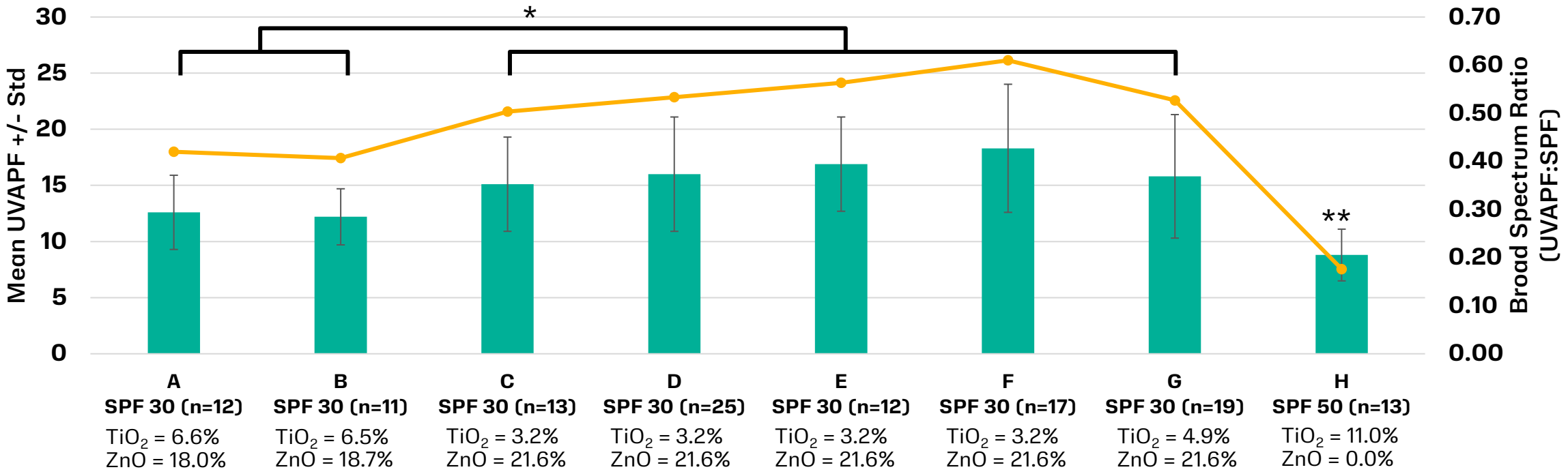




- Minimal Persistent Pigmentation Darkening Dose (MPPDD) was determined for each subject, defined as the smallest UVA dose to induce perceptible unambiguous PPD with defined borders filling more than 50% of the exposure sub-site
- Magnitude of skin pigmentation response (ΔITA) via image analysis is proportional to amount of UVA exposure. Skin becomes more pigmented with greater UVA exposure.
- The UVAPF test method is independent of skin types. Consistent skin pigmentary response (average ΔITA = -4.1) was observed across skin phototypes II to IV at the MPPDD site.

Results – Mineral Sunscreens With ZnO Provides Superior Broad-Spectrum Protection

In vivo UVA Protection Factor and Broad Spectrum Ratio of Mineral Sunscreens



*Products within a bracket had statistically similar UVAPF ($p > 0.05$), but the products had statistically different UVAPF ($p < 0.05$) with majority of products in the other bracket.
**Product H had statistically different UVAPF ($p < 0.05$) from all other products.

- Mineral sunscreen without ZnO (H) has statistically lower UVAPF than all other sunscreens containing ZnO. Higher levels of ZnO provided higher UVA protection by increasing the minimum UVA dose to induce pigmentation by up to 18.3x, which is up to 2.08x higher than without ZnO.
- Not all “broad spectrum” mineral sunscreens have the same broad spectrum protection as indicated by the UVAPF:SPF ratio, which ranged from 0.18 to 0.61. Per EU regulation, to claim broad spectrum the ratio should be at least 0.33.

Conclusions

- The effects of cutaneous exposure to UVA may be visualized through induction of pigmentation across phototypes.
- Consistent pigmentation was induced at the MPPDD site across phototypes, which suggests the UVAPF result is applicable to all phototypes, and everybody needs UVA protection.
- Not all broad spectrum mineral sunscreens provide the same level of UVA protection compared to their SPF (UVAPF:SPF ratio for the SPF 50 product was as low as 0.18).
- Mineral sunscreens formulated with ZnO offered stronger UVA protection against UVA induced pigmentation by increasing the minimum UVA dose to induce pigmentation by up to 18.3x, which is 2.08x greater than the SPF 50 product without ZnO.
- Sunscreens may utilize highly variable levels of ZnO with the potential for significant difference in UVA protection.
- Superior broad spectrum protection in practice does not end with formula efficacy, but it also depends on the formula aesthetics. Further research is needed to optimize the balance between the two.