

Photo Visualization of Skintone Compatibility of an SPF 35 Sunscreen

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ABSTRACT

Background: Visual casts and discoloration are common barriers to sunscreen use in melanin-rich populations. However, photoprotective measures are essential for individuals with all skin types, including darker skin.

Methods: Single-center, 7-day, open-label study of healthy adult females with Fitzpatrick Skin Types (FST) IV to VI and sensitive skin treated with once-daily daily facial moisturizer sun protection factor 35 (DFM SPF35). Subjects completed a cosmetic acceptability questionnaire at days 1 and 7. Photography using VISIA® CR was performed at day 7. Adverse events were monitored throughout the study.

Results: Thirty-two (32) subjects participated; 31.3% had FST IV, 53.1% V, and 15.6% VI skin. DFM SPF35 was viewed as cosmetically elegant. At day 1, 96.7% of subjects agreed product was easy to apply; 90.0% reported soft skin after product use; 86.7% said it had a lightweight, non-greasy feel and hydrated the skin. At day 7, 93.7% reported no visible white residue on their skin and said the product applied easily/absorbed well. The majority (90.6%) would continue using and would recommend the product; and 87.5% reported the product blended seamlessly into their skin, which agreed with clinical photography. Responses were consistent among subjects with normal, oily, or combination skin. No adverse events were reported.

Conclusions: DFM SPF35 blended well into the skin and was perceived favorably among subjects with SOC after 1 and 7 days of use. Subjects felt it had good cosmetic acceptability without unacceptable white residues or a greasy feeling. Dermatologists need to be versed in products that can be used on a variety of skin types.

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INTRODUCTION

All skin phototypes can be damaged by sun exposure; however, many individuals with darker skin perceive their need for the use of sunscreen to be low.¹ People with skin of color (SOC) can be burned by sun exposure although identifying a sunburn in darker skin can be more challenging than in lighter skin. The difficulty in seeing a sunburn is likely one reason why darker individuals tend to underestimate photosensitivity.¹ A lack of education about cumulative photodamage and its impact on aging, as well as the use of photoprotection for preventing and minimizing pigmentary problems is also a likely reason.² Finally, many dark-skinned individuals report finding sunscreens to be greasy feeling and to leave a cosmetically unacceptable white residue on their skin.²

It is important for both patients and healthcare providers to be aware that skin cancer rates have been rising in the United States (US) for the past 25 years and skin cancer is currently the most common malignancy in the US.³ Although the incidence of skin cancer in individuals with darker skin is lower than in those with lighter skin, skin cancer in SOC often is diagnosed at an advanced stage and has a less favorable prognosis compared to lighter skin tones.³ SOC has more epidermal melanin, which is capable of filtering somewhat more ultraviolet (UV)

radiation than fairer skin.⁴ Minimizing UV radiation exposure is the most preventable environmental risk factor for skin cancers, since UV light damages DNA and indirectly damages cells via reactive oxygen species.⁴ In addition to increasing the risk for skin cancer, UV exposure can also induce and exacerbate photosensitive disorders such as melasma and postinflammatory hyperpigmentation (PIH).⁵

Unfortunately, a 2015 US National Health and Interview Survey reported that just 10.9% of non-Hispanic Blacks and 24.7% of Hispanic individuals used sunscreen with SPF ≥ 15 always or most of the time.⁶ Most individuals with SOC choose to wear sun protective clothing or seek shade instead of using sunscreen.² Lower use of sunscreen in those with SOC may be due to underestimation of the risk and preventability of skin cancer.² In 2012, Buster et al conducted a survey and reported that both Black and Hispanic individuals were less likely than White participants to understand that skin cancer can be prevented.⁷ Further, less than half of Asian/Pacific Islanders (36.1%) and Hispanic (43.4%) individuals in a later survey reported using sunscreens to prevent signs of skin aging such as wrinkles.⁸ However, studies involving people with SOC have shown that prevention of skin darkening is a strong motivator for implementing photoprotective behaviors.⁸⁻¹⁰

Use of sunscreen has been significantly ($P<0.05$) associated with a lower risk of skin cancer.¹¹ But perhaps even more importantly for those with SOC, Fatima et al reviewed the medical literature regarding the relationship of sunscreen use with melasma and PIH.⁵ They found evidence that the use of sunscreens that block UV and visible light have an adjuvant role for these disorders by stabilizing and improving the results of other therapies.^{5,12} In a Japanese study, sunscreen use was also associated with improvements in signs of photoaging such as an uneven skin tone.¹³

Sunscreens and other photoprotective measures are recommended for all individuals, including those with richly pigmented skin.^{12,14} Daily sunscreen use provides protection against UV light, decreases the risk of skin cancer, helps prevent premature cutaneous aging and sunburn, and helps maintain an even complexion while universally accommodating all skin tones. In addition to the problems with sunscreens cited above, persons with SOC have noted that it can be challenging to find a sunscreen that can accommodate their skin tone. There is a need in the market for a universal sunscreen that is compatible with all skin tones, especially skin of color. This publication presents the results of an open-label study of sunscreen use specifically in subjects with SOC and sensitive skin.

MATERIALS AND METHODS

This was a single-center, 7-day, open-label study of healthy adult females (18 to 65 years) with Fitzpatrick Skin Types (FST) IV-VI and self-perceived sensitive skin treated with once-daily daily facial moisturizer sun protection factor 35 (DFM SPF35, Cetaphil® Daily Moisturizer SPF 35, Galderma Laboratories, LP, Dallas, TX). Subjects were excluded if they had a skin condition that could interfere with study evaluations, were pregnant or planning pregnancy, had psoriasis or atopic dermatitis/eczema on the face, or had excessive facial dryness/redness. Subjects taking medications that could interfere with test results agreed to the following washout periods: anti-inflammatories and antihistamines, 1 week; acne treatments, corticosteroids, 2 weeks; immunosuppressive drugs, 4 weeks; any topical drug or cosmetic product day of visit; oral retinoids, 6 months; and 1 month for oral corticosteroids or antibiotics. Participants were instructed to apply the product liberally to the entire face at least once a day after cleansing and to reapply as needed throughout the day. The study was conducted in accordance with good clinical practice and all participants provided written informed consent.

A self-assessment questionnaire administered on day 1 and day 7 asked participants to rate product attributes and efficacy based on a 5-point scale (1 = strongly agree, 5 = strongly disagree). VISIA® CR photography (Canfield Scientific, Parsippany, NJ) photography was performed using standard and ultraviolet (UV) filters before and after product application at day 7. Safety was monitored by a collection of adverse events.

Statistical analysis was applied to the results of the questionnaire. The significance of the questionnaire responses was determined using a binomial test with an a priori 50/50 distribution assumption. The responses were chosen from the following selections: strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree. The responses were pooled into two categories: the first two responses (subjects who agreed with the product attribute) were pooled into one category (success); the last two responses (subjects who did not agree with the product attribute) were pooled into another category (failure). Additionally, subject responses that neither agree nor disagree were divided evenly among the positive and negative categories (ie, half of the neutral responses were placed in the success category and half in the failure category). If there was an uneven distribution of neutral responses, the negative (failure) category received the extra neutral response. Questionnaire data was analyzed with the confidence level set at 95% ($P<0.05$). Percentage of positive responders were reported (the percentage of the population that agreed with each question). Descriptive statistics were used to summarize demographic characteristics.

RESULTS

The demographic characteristics of the study population ($n=32$) are shown in Table 1; all subjects were female, and the mean age of the group was 44 years.

Questionnaire Results

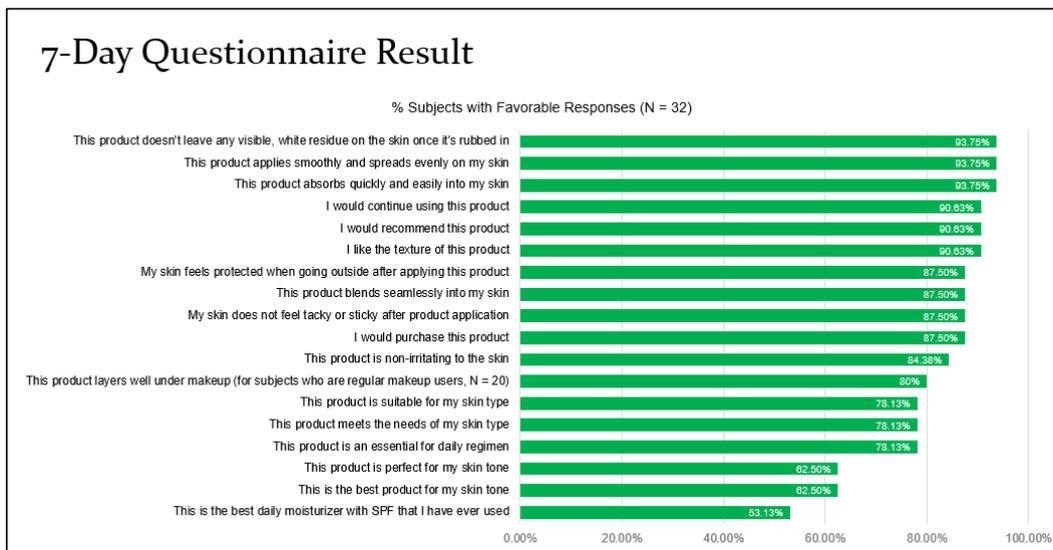
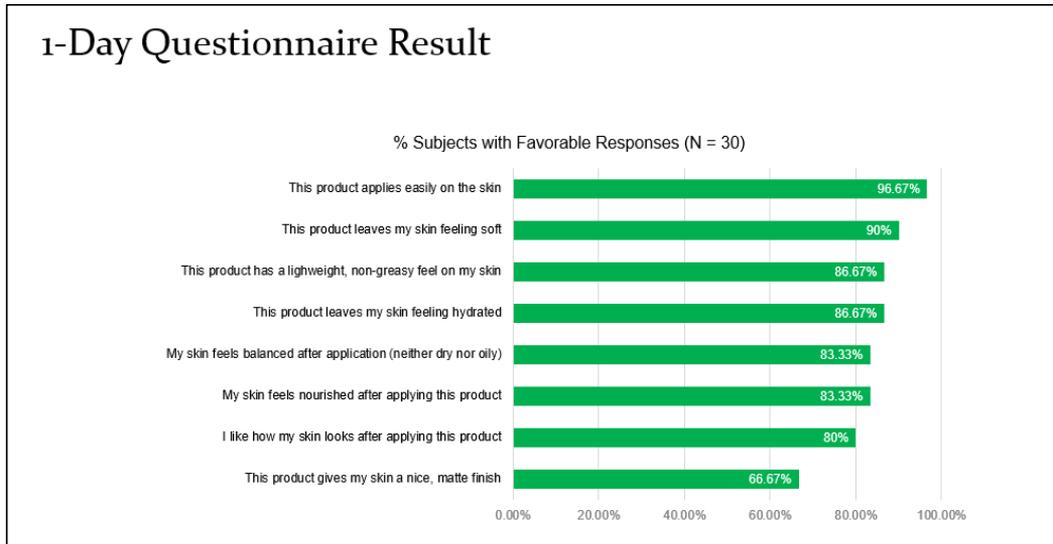
Subjects had favorable responses at day 1 evaluation, with 96.7% indicating the product was easy to apply on the skin. As shown in Figure 1, there were favorable responses to the remaining questions about moisturization, cosmetic acceptability, and skin appearance after application. The results of the day 7 questionnaire were also favorable (Figure 1), with >90% of subjects responding they would recommend and continue to

TABLE 1.

Subject Demographics (n=32)	
Mean age (range), years	44 (20-64)
Race/Ethnic background, n (%)	
Black/African American	25 (78.1%)
Hispanic	5 (15.6%)
Asian/Pacific Islander	1 (3.1%)
Other	1 (3.1%)
Fitzpatrick skin phototype, n (%)	
IV	10 (32.3%)
V	17 (53.1%)
VI	5 (15.6%)
Skin types, n (%)	
Normal to dry	7 (21.9%)
Combination	23 (71.9%)
Oily	2 (6.3%)

FIGURE 1. (A) day 1 and day 7 questionnaire results; (B) proportion of subjects with Fitzpatrick skin types IV-VI who agreed that the test product did not leave any visible residue.

(A)



(B)

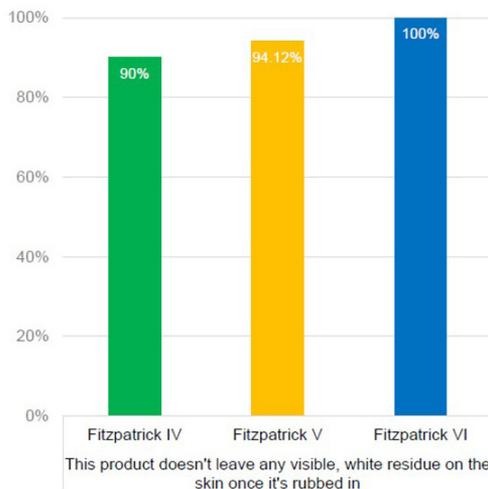
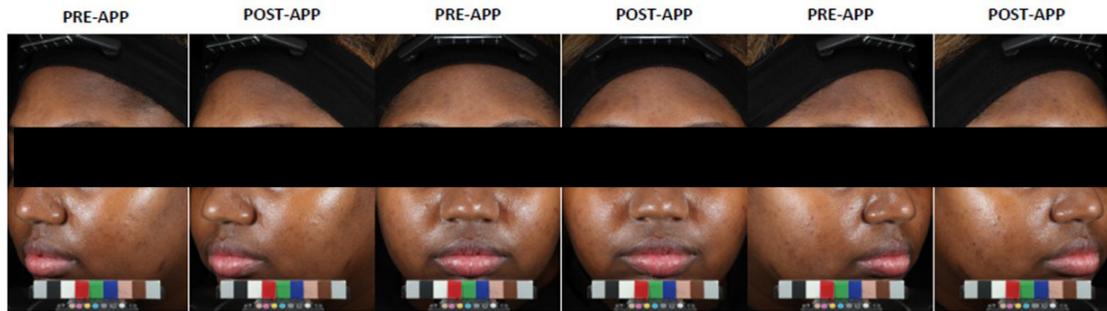


FIGURE 2. Clinical photography with standard lighting comparing half face and full face without DFM 35, and with product applied, showing how well DFM SPF 35 blends into the skin.



use the product. Again, subjects had a high approval rating of cosmetic acceptability and noted it did not leave any visible white residue on the skin after application.

Photography

Clinical photography showed distinct differences under UV filters for skin with DFM SPF 35 applied compared to bare skin (not shown). The photos highlighted areas of the skin missed by sunscreen and the importance of proper application to ensure adequate protection. Additionally, as shown in Figure 2, the product also blended well into the skin. These characteristics were apparent in all Fitzpatrick skin types that were in the study.

Safety

No adverse events were reported during the study.

DISCUSSION

The moisturizing sunscreen DFM SPF 35 was well perceived among the SOC subjects after days 1 and 7 of daily usage. Clinical photography also visually showed how well the product blended into the skin, which is frequently cited as a major concern for individuals with SOC. DFM SPF 35 was specifically formulated to be a lightweight moisturizer that provides immediate, oil-free hydration and protects against both UVA and UVB exposure. The skin remained hydrated for 24 hours and DFM SPF 35 left the skin with a cosmetically appealing matte satin finish. This product contains edelweiss flower and vitamins E, B3, and B5, which are antioxidants that protect against cutaneous free-radical damage.¹² The inclusion of antioxidants and free radical scavengers in sunscreens helps reduce some damaging effects of visible light and may have a protective effect against infrared radiation, which is not directly targeted by current sunscreens.¹² As noted by the study subjects, the formulation absorbs quickly without a greasy residue while being gentle on sensitive skin. As mentioned in the introduction, a greasy feeling is also a significant barrier to the use of sunscreen in SOC populations.

Sunscreen usage has proven to be essential in protecting the skin against the harmful effects of exposure to UV light.² Epidermal melanin in individuals with SOC can attenuate UV damage, but is also susceptible to creating undesirable effects such as post-

inflammatory hyperpigmentation and melasma.² While uptake of sunscreen use has increased in the general population, there exists a disconnect between individuals with SOC and consistent, adequate use of sunscreens which is due to a variety of factors including formulation aesthetics.² Sunscreens with traditional inorganic filters such as titanium dioxide or zinc oxide often have an unfavorable cosmetic appearance in patients with SOC, and such patients avoid using these sunscreens.^{2,12} A well-formulated sunscreen incorporated into a moisturizing product can influence more use and is needed in the SOC community to help prevent skin damage from sun exposure.

DISCLOSURES

Dr Nguyen, Dr Emesiani, and Dr Meckfessel are employees of Galderma Laboratories, LP, Dallas, TX. Dr Davis has no conflicts of interest to disclose.

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