

Effects of a Sheer 100% Mineral Sunscreen Moisturizer on Facial Photodamage Across Fitzpatrick Skin Types

Joel L. Cohen MD FAAD FACMS,^{a,b} Morgann Young MS,^c Tatiana Kononov MBA,^c Alisar S. Zahr PhD^c

^aAboutSkin Dermatology, Greenwood Village, CO

^bAboutSkin Research, Greenwood Village, CO

^cRevision Skincare®, Irving, TX

ABSTRACT

Background: All skin tones need to be protected from the damaging effects of solar radiation. Although mineral sunscreens offer protection, they can have a thick, greasy feel and leave a white cast, particularly on darker skin tones. Tints offset white cast and provide visible light protection; however, patients may prefer a sheer option. Therefore, a multifunctional, sheer, 100% mineral sunscreen moisturizer (MSM) with broad-spectrum SPF 50 was developed to have positive aesthetics and deliver anti-aging and skin health benefits to all skin tones.

Methods: An IRB-approved, 12-week, open-label clinical study was conducted to investigate the efficacy and tolerability of the MSM. Thirty-nine (39) females aged 35 to 60 years with moderate-severe overall facial photodamage and representing all Fitzpatrick skin types (FST) were recruited. Participants applied the MSM to the face and neck in the morning and reapplied per US Food and Drug Administration requirements. Efficacy and tolerability grading, photography, ultrasound imaging, corneometer measurements, and questionnaires were completed at baseline and weeks 4, 8, and 12.

Results: Statistically significant progressive improvements were demonstrated from baseline to week 12. At week 12, 23.4% and 26.5% mean improvements in overall photodamage were seen for FST I-III and FST IV-VI, respectively. Favorable tolerability was shown for both the face and neck. Photography corroborated clinical grading, and ultrasound imaging indicated a trend in skin density improvement. The MSM was well-perceived.

Conclusion: The MSM is an efficacious and well-tolerated product for patients of all skin tones who desire a sheer, 100% mineral sunscreen moisturizer with anti-aging and skin health benefits.

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INTRODUCTION

Daily sunscreen usage is an important step to mitigate photodamage so that skin can age well and stay healthy. Photodamage results from exposure to solar radiation and clinically manifests as fine lines and wrinkles, skin tone unevenness, and loss of firmness and elasticity. Solar radiation is composed of 3 components: ultraviolet, visible, and infrared radiation. Ultraviolet (UV) radiation causes the production of free radicals, damages DNA, and changes the balance of harmful matrix metalloproteinase (MMP) cascades in the skin.¹ In comparison, visible light can induce immediate erythema in lighter skin tones and long-term hyperpigmentation in darker skin tones.² Lastly, infrared light (IFRL) increases MMPs that damage collagen and elastin.³

Various ingredients can be used to protect skin from solar radiation. Sunscreen actives — either chemical or mineral (physical) — target harmful ultraviolet rays. While both types of actives protect the skin by converting UV rays into heat within

the skin, mineral actives also reflect rays off the skin. To address high energy visible light (HEVL) and IFRL, typically iron oxides and boron nitride are used, respectively.⁴

Among certain consumers, mineral sunscreen actives are favored over chemical sunscreen actives due to less irritation and perceived safety concerns with mineral sunscreens over their chemical counterparts.⁵ Despite preferences for mineral sunscreens, these sunscreens can have major aesthetic drawbacks. A thick and greasy feel and a white cast after application are common issues that can hinder usage compliance, particularly for those with darker skin types. Furthermore, many consumers look for products that offer numerous benefits in one formulation.

Therefore, a multi-functional, sheer, 100% mineral sunscreen moisturizer (MSM) with broad-spectrum SPF 50 was formulated to meet these consumer preferences. The sunscreen actives

used were titanium dioxide and zinc oxide, and no hidden chemical ingredients with SPF-boosting properties were added to the formulation. A main example of such an ingredient is butyloctyl salicylate (BOS), which is structurally similar to ethylhexyl salicylate (octisalate) and often used in sunscreens labeled as fully mineral. Iron oxide was included to protect skin from visible light,² while its unique minimal coloring reduces white cast. Micronized silica provides a soft, creamy feel with moderate oil absorption benefits. In addition, a comprehensive antioxidant blend containing the stable and effective tetrahexyldecyl (THD) ascorbate,⁶⁻⁸ coenzyme Q10,⁹ and epigallocatechin gallate¹⁰ was included. The formulation also contains blue-green plankton for DNA repair and protection,¹¹ microbiome technologies to support the native skin microbiome, and reparative bioavailable peptides. Lastly, a novel *Bacillus Lysate* derived from a microorganism that gained resistance to solar radiation outside the International Space Station was incorporated to provide pre- and postbiotic microbiome benefits and protect skin from broad-spectrum UV, HEVL, and IFRL.¹²

To demonstrate the efficacy and tolerability of the MSM, a 12-week open-label clinical study was conducted involving healthy females aged 35 to 60 years with moderate-to-severe overall facial photodamage and representing all Fitzpatrick skin types (FST). It was hypothesized that daily application of the MSM would significantly improve photodamage in these participants with favorable tolerability.

MATERIALS AND METHODS

Study Design

The MSM was tested in an IRB-approved, 12-week, prospective, single-cell, single-center, open-label study. The study ran from November to February near Philadelphia, PA. Thirty-nine (39) participants were recruited for the study.

Participants

Inclusion criteria included healthy female participants aged 35

to 60 years with FST I-VI and moderate-to-severe (score of 4-9 out of a 10-point Modified Griffiths scale) overall photodamage (Table 1). Areas of photodamage could include the forehead, cheeks, perioral area, chin, and nose. Participants needed to be willing to replace all topical facial products with the provided test products and withhold all facial treatments during the study. Exclusion criteria included participants who had used prescription retinoids within 3 months, prescription skin-lightening products within 4 months, or any other product known to affect skin aging or dyschromia (eg, products containing alpha/beta/poly-hydroxy acids, hydroquinone, retinoids, or vitamin C) within 2 weeks. In addition, excluded participants were those who were nursing, pregnant, or planning a pregnancy as well as those with allergies to facial skincare products or hypersensitivity to any ingredient(s) in the study products.

Ethical Considerations

The study protocol met the Declaration of Helsinki (1975) ethical principles and was conducted according to good clinical practice standards. Participants read and signed an IRB-approved informed consent form after any questions were answered by study staff and before enrollment in the study. IRB approval was obtained through Advarra, Inc., MD.

Study Treatment

Eligible participants completed a 3-day washout period between the screening and baseline visits using a provided Gentle Foaming Cleanser (Revision Skincare®, TX) and basic facial moisturizer (Goodier Cosmetics Inc., TX) in the morning and evening. The cleanser was for use on the face, and the facial moisturizer was applied to the face and neck. At baseline, participants were given the MSM to replace the facial moisturizer in the morning. Specifically, a nickel-size amount of the MSM was to be evenly applied to the face and neck and reapplied per U.S. Food and Drug Administration requirements. Products were weighed and participants completed daily dairies to ensure compliance with product applications throughout the study.

TABLE 1.

Modified Griffiths Scale Used for Clinical Efficacy Grading

Parameter	0 =	9 =
"Skin Tone Evenness (Uniformity of Skin Color)"	No blotchy skin, even skin tone	Severe uneven, blotchy skin, tone/redness apparent
"Skin Roughness (Tactile) "	No palpable superficial skin roughness. Skin that is soft.	Severely palpable superficial skin roughness. Skin that is coarse.
"Fine Lines (Global Face)"	None	"Numerous, long, fine lines (< 1 mm deep)"
"Global Hyperpigmentation (Mottled & Discrete)"	Even skin color, no hyperpigmentation	Pronounced hyperpigmentation
Overall Photodamage	No evidence of photodamaged skin (uneven pigmentation, lines, wrinkles, and skin laxity)	Severely photodamaged skin

Live Clinical Efficacy Grading

At baseline and weeks 4, 8, and 12, a board-certified dermatologist completed live clinical efficacy grading of 8 parameters based on a 10-point scale (Table 1). Clinical grading was performed on cleansed skin. For this evaluation, an improvement is a decrease in value.

Tolerability

Tolerability was also assessed at baseline and weeks 4, 8, and 12. Using a 4-point scale (0 = none, 3 = severe) and assessing the face and neck, a board-certified dermatologist graded erythema, edema, and scaling/peeling, and participants graded burning/stinging, itching, and tightness/dryness. Adverse events were monitored during the study to evaluate the safety of the skincare regimen.

Clinical Photography

Standard digital photographs were captured at baseline and weeks 4, 8, and 12 using VISIA® (Canfield Imaging Systems, NJ). Images of the left, right, and center views of the face were taken under visible and cross-polarized lighting.

Ultrasound Imaging

Ultrasound imaging of the left cheek (for which studies in North America show more sun damage and skin cancer rates due to driving exposure) was completed at baseline and weeks 4, 8, and 12. A DermaScan C ultrasound (Cortex Technology, Hadsund, Denmark) was used, and a water-compatible ultrasound gel was utilized as the skin contact medium (Dane Gel, cyberDERM, Inc.).

In addition to being used to capture images, ultrasound echography was utilized to measure skin density and thickness. For both parameters, an improvement is an increase in value. Dermico, LLC analyzed the ultrasound images.

Corneometer

Corneometer (Courage & Khazaka CM825, Köln, Germany) measurements of the center of each participant's left cheek were performed at baseline and weeks 4, 8, and 12 to evaluate the hydration content of the skin. The average of triplicate measurements at each time point was used for statistical analysis. With this device, an improvement is indicated by an increase in value.

Self-Assessment Questionnaire

Participants answered a questionnaire with statements on product effectiveness and aesthetics at baseline and weeks 4, 8, and 12. A 5-point scale was used to rate statements ranging from "Completely Disagree" to "Completely Agree."

Additionally, using the same questionnaire described above, an in-use study involving a panel of 10 cosmetic dermatologists and one cosmetic plastic surgeon was conducted to gain insight

into the performance and elegance of the MSM from a medical professional perspective. Physicians were instructed to apply the MSM to the full face after cleansing and moisturizing.

Statistical Analysis

Data from participants who completed the study were analyzed. Mean percent improvements from baseline were calculated for all post-baseline time points and between FST I-III and FST IV-VI data. The Student's *t*-test with a 95% confidence interval ($*P < 0.05$) was used for statistical analysis.

For the questionnaire, "Slightly Agree" and "Completely Agree" were considered favorable agreements.

RESULTS**Study Participants**

A total of 34 participants with a mean age of 50.9 years and FST I-VI completed the study (Table 2). Two participants failed the screening, and 1 participant was dropped due to non-compliance before baseline. Two participants withdrew during the study due to adverse events.

TABLE 2.**Demographics of Completed Subjects**

Number of Subjects Completed	n = 34 (100%)
Gender	
Female	34 (100%)
Race	
White	26 (76.5%)
Black or African American	6 (17.7%)
Asian	1 (2.9%)
Other	1 (2.9%)
Ethnicity	
Hispanic or Latino	0 (0%)
Not Hispanic or Latino	34 (100%)
Fitzpatrick Skin Type	
Type I	5 (14.7%)
Type II	8 (23.5%)
Type III	9 (26.5%)
Type IV	5 (14.7%)
Type V	3 (8.8%)
Type VI	4 (11.8%)
Age (years)	
Mean	50.9
Standard Deviation	6.3
Median	52
Min	38
Max	60

Live Clinical Efficacy Grading

Across all participants, progressive improvements in skin tone evenness, fine lines, hyperpigmentation, and overall photodamage were observed throughout the study with highly statistically significant ($***P < 0.001$) mean improvements of 25.0%, 25.5%, 26.1%, and 24.5% at week 12 compared to baseline, respectively.¹³ Furthermore, skin roughness progressively improved from baseline to week 12, leading to a highly statistically significant 35.9% mean improvement at week 12.

Data was also analyzed by skin type. For both FST I-III and FST IV-VI participants, progressive improvements were seen for these same parameters. Statistically significant mean improvements in skin tone evenness, skin roughness, fine lines, hyperpigmentation, and overall photodamage were found at week 12 compared to baseline (Figure 1A, B). Additional analyses showed there were no statistically significant

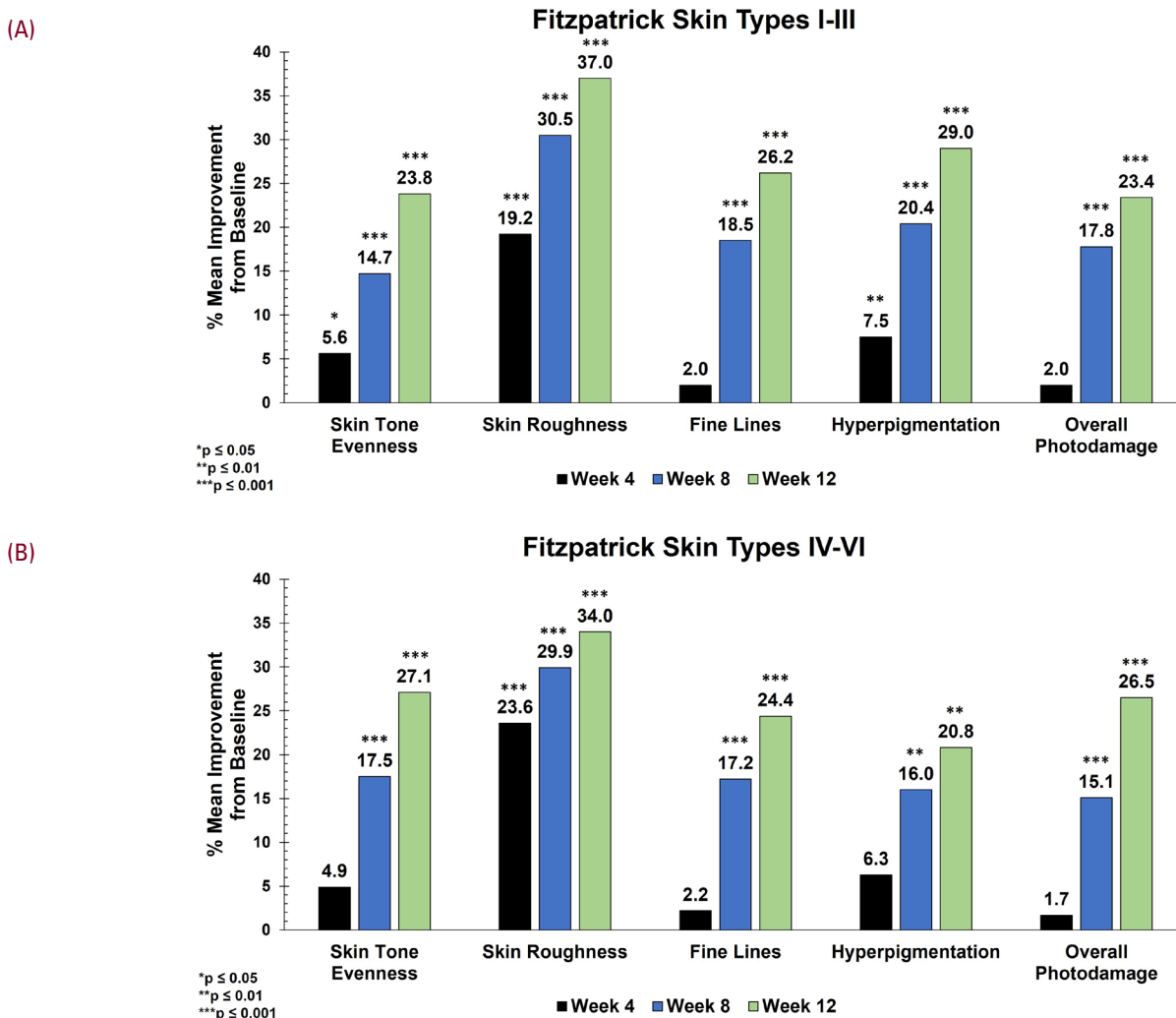
differences between the 2 groups. Furthermore, 86% and 92% of participants with FST I-III and FST IV-VI improved in overall photodamage at week 12 compared to baseline, respectively.

Tolerability

Overall, the skincare regimen was well-tolerated. Scaling/peeling (investigator) and tightness/dryness (participant) occurred post-baseline, mainly at weeks 8 and 12. The majority of cases were mild and may be connected to the study timeframe (fall to winter).

Regarding safety, 3 adverse events (AE) and 1 serious adverse event (SAE) were reported. For AE's, 1 participant experienced a severe irritant reaction to the washout products before baseline, and the second participant experienced moderate conjunctivitis possibly related to the study products before week 4. The third AE and the SAE were not product-related.

FIGURE 1. Clinical efficacy grading results by FST. **A)** FST I-III, **B)** FST IV-VI.



Clinical Photography

Photographs taken pre- and post-application of the MSM demonstrate the aesthetic elegance of the MSM, which provides a sheer, non-oily finish.¹³

Clinical photography also shows the efficacy of the MSM (Figure 2A-H). For example, a participant aged 43 years with FST II saw improved hyperpigmentation on the global face, with the strongest improvements on the lateral cheek, jawline, and neck at week 12 compared to baseline (Figure 2A, B). A participant aged 56 years with FST II shows improved skin tone evenness at week 12 compared to baseline, with a significant reduction in redness on the cheeks. In addition, the intensity and size of hyperpigmented spots on the global face were reduced. The skin also appears brighter and less rough (Figure 2C, D). Furthermore, a participant aged 51 years with FST IV shows a noticeable reduction in global facial hyperpigmented spots and improved skin tone evenness at week 12 compared to baseline (Figure 2E, F). A participant aged 48 years with FST VI demonstrated decreased redness on the global face at week 12 compared to baseline. The skin is also brighter and visibly softer (Figure 2G, H).

Ultrasound Imaging

In addition, ultrasound images were used to visualize and analyze changes in skin structure, density, and thickness throughout the study. Reflection intensity measurements were utilized to measure skin density and thickness.¹⁴⁻¹⁶ Specifically, skin thickness was measured by determining the distance between the highly reflective epidermis and the low reflective subcutaneous tissue.¹⁶

Figure 3 illustrates ultrasound images of 2 participants. A participant aged 48 years with FST II showed a 3.4% improvement in skin density at week 12 versus baseline, which can be visualized by the increase in pixel color and intensity as well as the decreased black areas in the dermis. Additionally, a participant aged 50 years with FST IV showed 34.2% and 7.7% greater skin density and thickness at week 12 versus baseline, respectively. Similar to the previous participant, brighter and intensified colors are evident in the ultrasound images, indicating improved skin density and showing increased skin thickness.

Results demonstrated that across all participants there was a 17.1% mean improvement in skin density ($***P = 0.0003$) at week 12. Skin density significantly improved by mean percentages of 12.2% ($*P = 0.033$) and 26.0% ($*P = 0.003$) for participants with FST I-III and those with FST IV-VI at week 12 compared to baseline, respectively. These findings suggest that the MSM in combination with a gentle cleanser and basic facial moisturizer can improve the structural integrity of the skin, indicating anti-aging benefits.

FIGURE 2. VISIA® clinical photography. Participant aged 43 years, FST II at **A)** Baseline, **B)** Week 12 under standard light. Participant aged 56 years, FST II at **C)** Baseline, **D)** Week 12 under cross-polarized light. Participant aged 51 years, FST IV at **E)** Baseline, **F)** Week 12 under standard light. Participant aged 48 years, FST VI at **G)** Baseline, **H)** Week 12 under standard light.

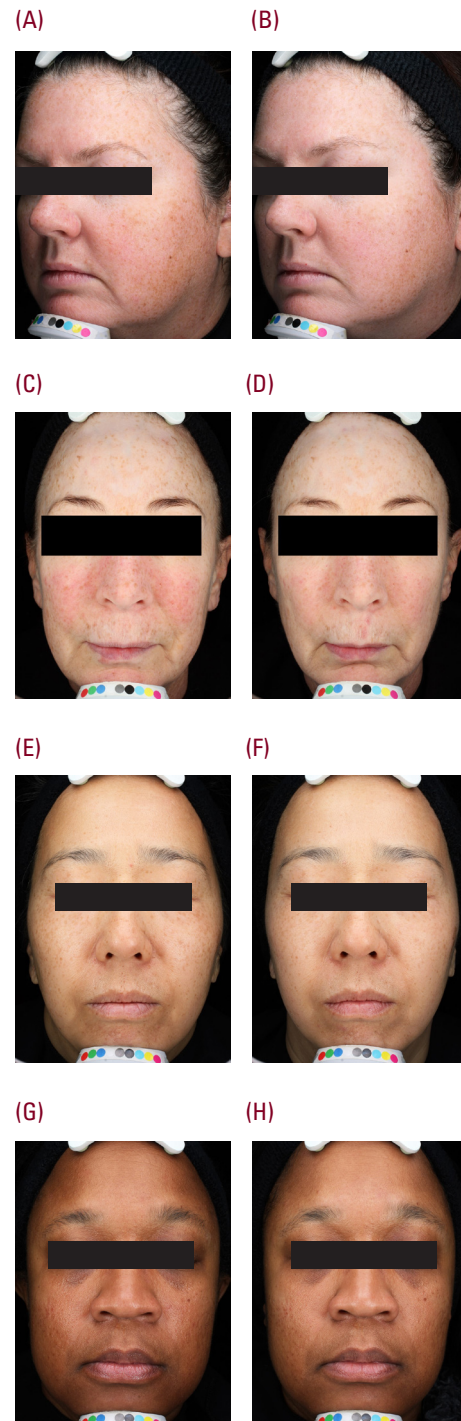
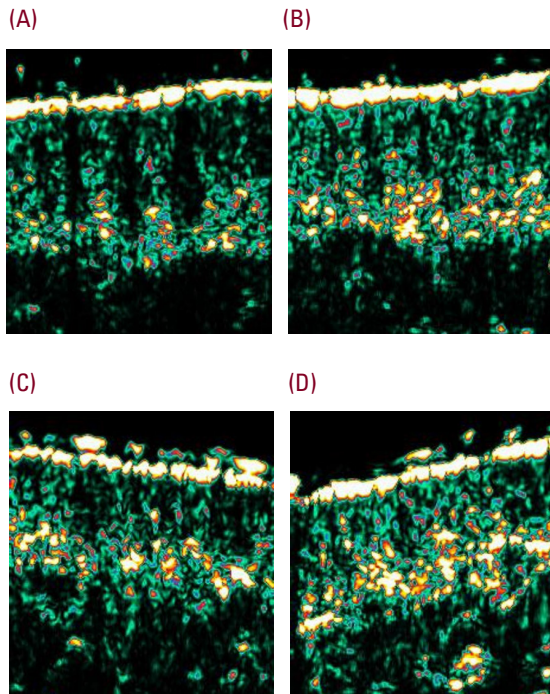


FIGURE 3. Ultrasound imaging. Pixel color indicates density of skin structures. The scale ranges from white (highest density) > yellow > red > green > blue > black (lowest density). Connective tissue structures including collagen and elastin are yellow, red, or green. Fat cells and lymphatic fluid are black. Participant aged 48 years, FST II at **A)** Baseline, **B)** Week 12. Participant aged 50 years, FST IV at **C)** Baseline, **D)** Week 12.



Corneometer

Across all participants, there were statistically significant 118.6% ($***P=0.001$), 59.5% ($***P=0.001$), and 619.9% ($**P=0.005$) mean improvements in skin hydration at weeks 4, 8, and 12 compared to baseline, respectively. The decrease seen at week 8 is potentially attributed to the winter conditions experienced by participants during the study. After 12 weeks, results indicate that MSM can improve the skin barrier by improving skin moisture retention.

Self-Assessment Questionnaire

Overall, the MSM was positively perceived by participants as shown in Table 3. There were similarities between participants

with FST I-III and FST IV-VI, with some differences between participant and physician ratings (Table 3). Notably, 91% of physicians favorably agreed that “My skin feels protected throughout the day,” while 73% of FST I-III participants and 75% of FST IV-VI participants favorably agreed. Furthermore, as shown in Young et al (2023), a majority of participants favorably agreed at week 12 that “The product blends to an invisible finish on my skin.”

DISCUSSION

The MSM is a comprehensive 100% mineral sunscreen moisturizer formulated to effectively address solar radiation, which can induce photodamage and negatively impact all skin tones.¹⁻³ A multi-functional sunscreen moisturizer, particularly one that is mineral-based, provides a high SPF with broad-spectrum protection, and has additional skin protective benefits, can combat the damaging effects of sun exposure.

One of the unique features of the MSM is the inclusion of ingredients that offer visible light absorption and protection yet allow for a sheer formulation. These include a transparent iron oxide as well as Bacillus Lysate. Absorption of visible light is traditionally addressed with iron oxides that have the added benefit of mitigating white cast. Although visible light can cause damage across all skin tones,² the effect of visible light on darker skin tones is a major concern as long-term hyperpigmentation can affect quality of life.¹⁷ In this study, statistically significant improvements in hyperpigmentation in participants with FST IV-VI indicate that the MSM can protect and correct this often-distressing skin parameter. Notably, the MSM provides SPF 50 without ingredients similar in structure to chemical sunscreen actives, for example, BOS. Overall, the MSM offers patients with darker skin tones the benefits of a tinted sunscreen in a high SPF sheer formulation.

In addition to protecting the skin from solar radiation, the MSM was formulated to target aging skin and support younger skin with an antioxidant blend, blue-green plankton for UVB-induced DNA damage,¹¹ microbiome technology, and reparative bioavailable peptides for additional benefits. A blend of squalane, aloe barbadensis leaf juice, and glycerin was included to hydrate and moisturize skin.

TABLE 3.

Self-Assessment Questionnaire Results			
SAQ Statement	Percent of Participants Favorably Agreed at Week 12		Percent of Participants Favorably Agreed After at Least One Use
	FST I-III	FST IV-VI	Physicians
The product feels lightweight on my skin.	64	67	73
My skin feels protected throughout the day.	73	75	91
The product does not leave my skin looking shiny (oily).	82	83	73

Results from live clinical grading and standardized photography showed statistically significant progressive improvements in skin tone unevenness, skin roughness, fine lines, hyperpigmentation, and moderate-to-severe overall photodamage. Notably, there were no statistically significant differences between participants with FST I-III and those with FST IV-VI, suggesting that the MSM is effective for a broad patient population. Furthermore, the highly statistically significant increase in skin density across all participants at week 12 indicates that the MSM supports and enhances the structural strength of the skin and likely does so through various mechanisms of action.¹⁴

The appearance and sensation of dryness-related symptoms were reported post-baseline, however, hydration increased to a statistically significant extent based on corneometer measurements. These findings suggest that the deeper layers of the stratum corneum had improved hydration compared to the most superficial layers. Since the study was conducted during the winter in Philadelphia and the majority of participants and physicians felt the MSM was lightweight, the MSM may need to be used with an additional moisturizer depending on environmental conditions and a patient's skin type. Overall, when connecting clinical efficacy grading to corneometer results, the MSM promotes moisture retention in the skin and therefore long-term skin health.

In terms of product aesthetics, the MSM was positively rated by participants and a panel of physicians, indicating both patient and medical professional acceptance. Product feel and look after application are important features of sunscreen moisturizers, and the favorable opinions for the MSM suggest that the MSM could be used consistently to optimize product benefits.¹⁸

The limitations of the study include a lack of double-blinding, a vehicle control, and randomization.

Future research includes investigating the MSM in a study that addresses the limitations of the current study. In addition, the MSM could be tested in procedural-pairing clinical studies.

CONCLUSION

The MSM provided significant improvements in females aged 35 to 60 years across all Fitzpatrick skin types and with moderate-to-severe overall facial photodamage. The product also provided tolerable protection for both the face and neck. The MSM is a clinically validated, cosmetically elegant option for patients of a wide range of skin tones searching for a multi-functional, sheer, 100% mineral sunscreen moisturizer without hidden chemical SPF-boosting ingredients.

DISCLOSURES

Dr Joel Cohen has performed clinical trials and consulting for a variety of organizations and serves in multiple leadership

capacities. Dr Cohen serves as a consultant and scientific advisory board member for Revision Skincare®. Morgann Young MS and Dr Alisar Zahr analyzed the images and statistical data and drafted the manuscript. Both are employees of Revision Skincare®. Tatiana Kononov designed the clinical trial and assisted in the draft of the manuscript. Ms Kononov is a consultant for Revision Skincare®.

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AUTHOR CORRESPONDENCE

Alisar S. Zahr PhD

E-mail: azahr@revisionskincare.com