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### ORIGINAL RESEARCH

# The Efficacy of Organic Filter-Based Sunscreens in Alleviating Symptoms and Enhancing the Condition of Sensitive Skin

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Background: Sensitive skin causes discomfort from irritants, impacting quality of life. While hypoallergenic moisturizers help prevent moisture loss, some ingredients can still cause irritation. Treatments like steroids and calcineurin inhibitors have side effects, and chemical sunscreens can cause irritation in sensitive skin.

Objective: In this study, we performed a patch test by applying Bariderm Shield Cream MD in patients with facial dermatitis or sensitive skin with weakened skin barrier function and investigated whether it had an effect in relieving clinical symptoms and improving skin barrier function. We also want to find out the safety of whether new dermatitis will not occur.

**Methods:** 15 pruritus patients (average age  $33.07 \pm 11.57$ ) applied this twice daily for 8 weeks. Effectiveness was evaluated using SS-10 (Sensitive scale-10), severity by area, TEWL (transepidermal water loss), and SCH (skin corneum hydration). We performed repeated measures ANOVA and post hoc analysis using Python statistics.

**Results:** Fifteen pruritus patients (average age  $33.07 \pm 11.57$ ) applied this twice daily for 8 weeks. Effectiveness was evaluated using SS-10 (Sensitive scale-10), severity by area, TEWL (transepidermal water loss), and SCH (skin corneum hydration). SS-10 showed a significant difference at week 8. TEWL decreased after 8 weeks, while moisture increased after 4 weeks of application. Severity scores for erythema, scales, papules, and pustules on both cheeks notably decreased compared to baseline at week 4 and 8 after application.

Conclusion: This study shows that Barriederm Shield Cream MD® is safe for patients with sensitive skin. It suggests that it is suitable for sensitive skin, with the result of improving the skin barrier, and addresses safety and efficacy issues.

Keywords: organic sunscreen, sensitive skin, sensitive scale-10, skin corneum hydration

### Introduction

Sensitive skin is defined by the presence of a variety of subjective sensory abnormalities, including burning, tingling, pain, and itching.<sup>1,2</sup> It can also be caused by a defective skin barrier.<sup>3</sup> Sensitive skin has a negative impact on the quality of life of many people, with a reported prevalence of about 39% in Europe and 57% in Korea.<sup>4</sup> Treatment for sensitive skin has not yet been established, and to date, it is common to consistently use topical preparations composed of mild ingredients with minimal irritation.<sup>5</sup>

The prevalence of sensitive skin increases in summer, and exposure to ultraviolet rays is expected to contribute to the development of sensitive skin symptoms.<sup>6</sup> For patients with sensitive skin, applying appropriate moisturizers as well as sunscreen is important to control symptoms. Individuals with sensitive skin are more susceptible to irritation from UV rays, underscoring the importance of sunscreen application.<sup>7</sup> Paradoxically, these patients often encounter challenges in

selecting an appropriate sunscreen, as they may experience irritation or allergies related to blocking agents in sunscreens, unlike regular moisturizers.<sup>7</sup> While it is widely recognized that physical UV-blocking filters, such as inorganic filters like zinc oxide, are beneficial for individuals with sensitive skin, sunscreens containing 100% inorganic filters may be perceived as heavy, sticky, or leave a white residue.<sup>8</sup> This can deter patients from consistent sunscreen use, creating a vicious cycle of sensitive symptoms.

Our study introduces a novel organic sunscreen formula containing bis-ethylhexyloxyphenolmethoxyphenyltriazine, diethylaminohydroxybenzoylhexylbenzo ate, and ethylhexyltriazone, which have passed extensive safety evaluations by the European SCCS for phototoxicity and irritation,<sup>9</sup> and are known for their anti-inflammatory properties.<sup>10</sup> These ingredients offer broad-spectrum UV protection without the common drawbacks of conventional sunscreens, aiming to improve adherence and patient satisfaction among those with sensitive skin. This research not only evaluates the product's safety and efficacy but also includes patch testing to examine its potential allergenicity, addressing a significant gap in care for individuals with sensitive skin.

### **Patients and Methods**

### Study Participants and Materials

The study included adult patients aged 18 and above who had sought medical attention for the primary complaint of unpleasant sensations lasting for more than six weeks on their faces at Kangnam Sacred Heart Hospital, Hallym University, Seoul, Korea, between December 2022 and July 2023 and who provided written informed consent. Patients whose symptoms could be entirely explained by specific conditions (eg, atopic dermatitis, seborrheic dermatitis, contact dermatitis, rosacea, etc) were excluded. Participants were adults over 18, experiencing facial discomfort for over six weeks, excluding those with conditions like atopic dermatitis or using certain medications. Following Helsinki Declaration guidelines, we secured written consent and ethical approval (IRB no. 2022–12-012). The study used a specially formulated, slightly acidic SPF43 and PA+++ sunscreen, Cell Fusion C Expert Barriederm Shield Cream MD®, containing organic UV filters and free from fragrances, suitable for sensitive skin.

### Clinical Trial Design

After verifying participants' eligibility and securing informed consent, we distributed the sunscreen for twice-daily application. Assessments were made at baseline, 4, and 8 weeks, evaluating skin conditions and gathering patient feedback using the Sensitive Scale-10 (SS-10).<sup>11</sup> The SS-10 scale is primarily utilized for assessing skin sensitivity. Typically presented in the form of a questionnaire, this scale is employed to evaluate skin irritation and discomfort.

### Classification of Sensitive Skin Types and Clinical Photography

Patients defined as sensitive skin are classified into Allergic, Rosacea, Acne, and Stinging Types as classification of sensitive skin by Baumann. Clinical photos and medical records were collected for these patients.<sup>12</sup> Collect clinical photos and medical records. Facial images were captured using the Janus-I standardized photographic system, employing a Canon EOS 100 D digital camera (Canon Inc.Japan) with three light sources.

### Severity of Sensitive Skin and Biophysical Skin Parameters

Participants documented their symptoms at the start of the clinical trial (Visit 1) and on subsequent visits (Visit 2 and Visit 3). Transepidermal water loss (TEWL) is a technique utilized to quantify the amount of water lost from the skin. This parameter was assessed using a Tewameter® TM300 probe (Courage & Khazaka GmbH, Cologne, Germany). Stratum corneum hydration (SCH) is a technique employed to assess the hydration status of the skin. Measurements were conducted using a Corneometer® CM825 probe (Courage & Khazaka GmbH, Cologne, Germany) during each visit. Any adverse reactions, including new dermatitis, were noted by the investigator during Visits 2 and 3. Patient satisfaction regarding the product's use, irritation levels, and willingness to reuse the product was rated on a satisfaction scale. For analysis, only frontal facial photos were used, adjusted for brightness and white balance. These images were then

# Digital Image Analysis of Facial Erythema

Digital images were obtained using Janus-III,<sup>13</sup> manufactured by PIE Inc, which employs a high-resolution digital camera to capture the entire face. We adopted the machine learning-based face mesh detection module of Google MediaPipe<sup>14</sup> to mask the relevant face area. The severity of erythema was measured using the method proposed in<sup>15</sup> which decomposes the skin area image into the hemoglobin and melanin components in the log color space. We obtained the average face by averaging the face meshes of the face images, warping the face images according to the average face mesh, and then blending the warped images.

# Allergy Patch Test on Patients with Sensitive Skin

The manufacturer verified the formula's success in primary irritation tests on healthy individuals. An allergy patch test was conducted using the Korean Standard Series and the sunscreen product, applying a sealed patch on the back with the IQ chamber system. The patch was removed after 48 hours for assessments at 20 minutes and then again 48 hours later, with standardized photos evaluated by two dermatologists. Reaction criteria were based on the International Contact Dermatitis Research Group's standards, ranging from negative (-) to extreme positive (3+), including doubtful (?+) and various grades of positive reactions (1+ to 2+), along with different types of irritant reactions (IR), marked by symptoms like fine wrinkling to necrosis with minimal infiltration.<sup>16,17</sup>

### Statistical Analysis

Data were analyzed using IBM SPSS Statistics 27.0 software (IBM, Armonk, NY, USA) with descriptive statistics for baseline information and repeated measures ANOVA for evaluating changes over time. The significance of correlations between variables was determined using Spearman rank correlation, with a significance threshold set at p < 0.05.

# Results

### Patient Population and Baseline Characteristics

The study included 15 patients (2 male, 13 female), with an average age of  $33.07 \pm 11.57$  years, comprising 2 men and 13 women. Baseline measurements before applying Barriederm Shield Cream MD® showed an average TEWL of  $12.33 \pm 4.10$ , skin moisture of  $69.40 \pm 28.25$ , and an SS-10 score of  $33.30 \pm 24.54$ . No correlation was found between age and initial TEWL, SCH, or SS-10 scores. Erythema, papules, pustules, and scales were primarily noted on the cheeks (17.46  $\pm$  5.26), forehead (10.60  $\pm$  5.81), central face (16.33  $\pm$  7.59), and chin (12.4  $\pm$  7.46). The subjects' sensitive skin was classified into 5 Rosacea, 6 Stinging, 2 Acne, and 2 Allergic types Table 1.

Variables		Total (n=15)
Age, Mean±SD	33.07±11.57	
Sex, n (%)	Male	2 (13.33%)
	Female	13 (86.67%)
Sensitive skin type	Rosacea	5 (33.33%)
	Stinging	6 (40.00%)
	Acne	2 (13.33%)
	Allergic	2 (13.33%)

(Continued)

Variables		Total (n=15)
Baseline TEWL, Mean±SD (g/m2/h)	16.70±5.58	
Baseline moisture, Mean±SD (AU)	69.40±28.25	
Baseline SS-10, Mean±SD (AU)	33.30±24.54	
Baseline Severity of Erythema, Papules, Pustules, and Scales, Mean $\pm$ SD (AU)	Cheeks	17.46±5.26
	Forehead	10.60±5.81
	Central facial area	16.33±7.59
	Chin	12.4±7.46

#### Table I (Continued).

### **Clinical Assessments**

The SS-10 severity score demonstrated a reduction from an initial average of  $33.33 \pm 24.54$  to  $25.33 \pm 17.65$  over 8 weeks, indicating an improvement post-application. Despite a significant overall trend in SS-10 scores reduction as per repeated measures ANOVA, pairwise comparisons lacked statistical significance after Bonferroni adjustment, with a near-significant trend noted between 4 and 8 weeks (p=0.0344). Notably, specific questions on skin irritation and flushing showed significant decreases (Figure 1).

Erythema, scales, papules, and pustules assessment over time highlighted significant improvements on the cheek and forehead at 8 weeks (cheek  $p = 3.89 \times 10^{-5}$ , forehead p = 0.000686) (Figure 2). Arbitrary units (AU) measured the severity of erythema changes in patients' erythema severity over 8 weeks (Figure 3A). The severity of erythema decreased significantly compared to the baseline 4 weeks after application (p < 0.05). As a result of generating the digital average face of 15 patients' facial photographs taken at 0, 4, and 8 weeks, erythema in the center of the face, including both cheeks and nose, gradually decreased (Figure 3B). It allowed us to observe a reduction in redness on the cheeks over time. This was indicated with dotted lines. Upon further analysis of facial regions, both the overall face and regions 1–5 demonstrated a statistically significant decrease in average values between 0–4 weeks. However, for regions 6 and 7, no observed significance was found. It is highly likely that these areas originally had minimal redness. Both the overall face and the remaining regions showed statistical significance during the 0–4 weeks interval. Conversely, the differences observed during the 4–8 weeks interval were not statistically significant (Supplement 1).



Figure 1 (A) Changes in SS-10 scores 4 weeks (V2) and 8 weeks (V3). Data are expressed as mean ± standard deviation. (B) Visualization of (A) data in a radar chart.



Figure 2 Severity of erythema, scales, papules, and pustules by area. Changes in severity scores 4 weeks (V2) and 8 weeks (V3) after application. Data are expressed as mean ± standard deviation. \*\*\*: p< 0.001.



Figure 3 Facial image analysis (A) Facial image analysis results indicate changes in patients' erythema severity over 8 weeks, measured in arbitrary units (AU), with statistically significant differences denoted by \* p < 0.05. (B) Average face of 15 individuals.

### **Biophysical Skin Parameters**

The average TEWL value of the test site before application was  $16.70 \pm 5.58$ , but it tended to decrease over time from  $14.28 \pm 5.554$  weeks after application to  $12.33 \pm 4.108$  weeks after application. And it was not statistically significant (Figure 4A). In addition, the SCH results also improved from an average of  $69.40 \pm 28.25$  in the test area before



Figure 4 Changes in (A) transepidermal water loss (TEWL) and (B) skin corneum hydration (SCH) after 4 weeks (V2) and 8 weeks (V3) of application. Data are presented as mean ± standard deviation.

application to  $77.06 \pm 28.05$  4 weeks after application and  $79.55 \pm 17.91$ . 8 weeks after application, but this was not statistically significant (Figure 4B).

### Allergy Patch Test Results

The study encompassed 30 patients, comprising five males and 25 females with an average age of  $41.00 \pm 8.65$  years, all diagnosed with sensitive skin. The Stinging type was the most common subtype at 53.33%, followed by Rosacea at 26.67%, Allergic at 13.33%, and Acne at 6.67%. All participants had severe sensitive skin with scores of 50 or above on the Sensitive Skin Scale-10, averaging 55.33  $\pm$  4.59. A vast majority, 96.67% of patients, reacted positively to one or more antigens in patch tests. No subjects showed positive reactions to Barriederm Shield Cream MD®. One subject displayed an irritant reaction to Barriederm Shield Cream MD® at 48 hours, which resolved by 96 hours, yet direct application of the cream did not lead to any symptoms of contact dermatitis.

### Discussion

This investigation aimed to assess the effectiveness and safety of innovative organic sunscreen formulations on individuals with sensitive skin, who often encounter adverse reactions when using traditional sunscreens due to their predisposition to allergic sensitization.<sup>2,17</sup> The study's significance lies in addressing the challenge of providing suitable sun protection for those typically at a higher risk of discomfort from conventional sunscreens,<sup>10,18</sup> emphasizing the necessity for formulations that cater specifically to sensitive skin requirements.<sup>19</sup> Although the improvements in TEWL (transepidermal water loss) and SCH (skin corneum hydration) did not reach statistical significance, a positive trend was observed in the alleviation of subjective symptoms assessed through the SS-10 questionnaire. Most notably, a significant reduction in clinical symptoms like erythema, scaling, roughness, and pustules was recorded, especially in areas like the cheeks. The participants expressed high satisfaction levels with the product, and no significant adverse effects were reported, highlighting the product's potential benefits for sensitive skin management.

Patch test results revealed a high positivity rate (96.67%) for one or more standard antigens among the study participants, indicating a high level of allergic sensitivity within the group. However, the reaction to Barriederm Shield Cream MD® was notably absent, suggesting its suitability for sensitive skin types and its potential to be a preferred choice for those unable to use standard sunscreen products due to exacerbation of symptoms. This observation is particularly relevant given the backdrop of previous studies that have shown a correlation between high sensitivity scores and a propensity for positive reactions to common allergens in cosmetic products.<sup>20</sup>

Barriederm Shield Cream MD® stands out due to its formulation, which includes SPF43 and PA+++ for adequate UV protection and incorporates fragrance-free, hypoallergenic ingredients suitable for sensitive skin types.<sup>10</sup> The product features organic sunscreen components such as Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine,<sup>21</sup> Diethylamino Hydroxybenzoyl Hexyl Benzoate,<sup>22</sup> and Ethylhexyl Triazone,<sup>23</sup> alongside moisturizing agents like ceramides and panthenol.<sup>21–23</sup> Despite the common preference for inorganic sunscreens owing to their minimal absorption and lower allergenic potential, Barriederm Shield Cream MD® offers a compelling alternative by avoiding the typical issues associated with inorganic formulations, such as a sticky texture and white residue.<sup>24–26</sup>

This research underscores the critical need for sun protection options tailored to the unique needs of individuals with sensitive skin. It highlights the potential of Barriederm Shield Cream MD® as a safe, effective, and user-friendly option, contributing to the broader discussion on the environmental and safety implications of sunscreen ingredients, particularly the use of nanoparticles in inorganic filters.<sup>9,27–29</sup> Further studies are encouraged to deepen our understanding of the optimal approaches to sunscreen formulation that balance efficacy, safety, and environmental considerations.

### Conclusion

This pilot study highlights Barriederm Shield Cream MD® as a safe and effective sunscreen for sensitive skin, and is characterized by a well-defined group of participants and thorough evaluation. Despite the positive results, including

improved skin barrier, the limitations, such as the small sample size and lack of a control group, require further studies to clearly establish long-term benefits and safety.

### **Abbreviations**

SS-10, Sensitive scale-10; TEWL, transepidermal water loss; and SCH, skin corneum hydration; UV, ultraviolet; IR, irritation reaction.

## **Ethics Statement**

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to and the appropriate ethical review committee approval has been received.

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### Disclosure

Researchers affiliated with CMSLAB supplied the organic sunscreen formulation for this study and provided safety information on ingredient allergies, photoallergy, and mutagenicity, among other concerns. Beyond this contribution, they had no further involvement in the clinical trial, which was independently carried out by dermatology researchers until its conclusion. The authors have no other conflicts of interest to declare.

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