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Study of Adjuvant Sensitive-Skin Cleansing and Moisturizing Regimen in Plaque Psoriasis

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ABSTRACT

Background: Epidermal barrier dysfunction is a key feature of plaque psoriasis. Skincare improves epidermal barrier function and is an increasingly recommended part of psoriasis management.

Methods: This multicenter, blinded study of adults (N=46) with psoriasis evaluated the use of a gentle skincare regimen (cleanser, moisturizer, and optional moisturizer with SPF 35) as an adjunct to medical therapy during an 8-week period. Efficacy was assessed via clinical grading of body surface area (BSA), target lesion severity score (TLSS), physician global assessment (PGA), and bioinstrumentation for skin hydration and texture. Standard safety and tolerability assessments were performed, and subjects completed satisfaction and the Dermatology Life Quality Index (DLQI) questionnaires.

Results: There was a statistically significant decrease in BSA by week 8 from 9.3 to 5.1 ($P<0.05$). Significant improvements in TLSS (10.9 to 3.5, $P<0.05$) and PGA (2.7 to 1.4, $P<0.05$) occurred by week 8, with improvements noted at each study time point ($P<0.05$ vs baseline). Bioinstrumentation showed reduced scaling and improved skin smoothness ($P<0.05$ at all timepoints vs baseline). DLQI results improved from 9.2 at baseline (a moderate effect of disease) to 2.9 at week 8 (small effect, $P<0.05$). There was a significant reduction in dryness, itching, and burning/stinging throughout the study ($P<0.05$ at all timepoints). Four adverse events occurred in 4 subjects (itching and burning/stinging) and resolved by the end of the study.

Conclusions: This study highlighted the benefit of skincare in conjunction with prescription products for plaque psoriasis. The skincare regimen supported the skin barrier and improved patient outcomes.

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INTRODUCTION

Psoriasis is a chronic inflammatory skin disease with a clinical presentation of scaly, erythematous plaques, which have a compromised epidermal barrier.[1] Despite that epidermal skin barrier dysfunction is a key aspect of psoriasis, the role of skincare in this disease is not commonly addressed in the medical literature.[1] However, intelligent utilization of skincare products can have a marked impact on psoriasis. When used along with medical therapy, a good skincare regimen can improve symptomatic relief and provide therapeutic benefits associated with epidermal barrier repair.[1]

According to Alexis et al, moisturizing psoriatic skin may "help normalize hyperproliferation, differentiation, and apoptosis" in the epidermis and may also have anti-inflammatory actions.[1] These products effectively reduce scaling and itching, help heal skin cracks, and can facilitate penetration of topical medications.[1] It has been reported that abnormal ceramide composition in psoriasis lesions is a factor in epidermal barrier dysfunction, along with increased transepidermal water loss (TEWL).[2,3] Studies have shown that regular use of a moisturizer and moisturizer plus gentle cleanser improve skin hydration and appearance in up to 75.8% of patients and relieve symptoms for 84.8% of patients.[4,5] Similarly, Li et al conducted a randomized controlled study (N=178) of moisturizer as adjunct to topical corticosteroids and then as maintenance after medical therapy resulted in continuous improvements of body surface area (BSA) involvement, investigators' assessment, and patient quality of life.[6] In 2022, Alexis et al discussed evolving options in psoriasis and based on a review of the literature, recommended the use of pH-balanced, gentle cleansers and ceramide-containing moisturizers to reduce xerosis and pruritus in patients with psoriasis.

Although literature on the benefits of skincare in psoriasis remains limited, existing evidence on its role in supporting the epidermal barrier suggests that integrating skincare regimens into psoriasis management may be beneficial for both clinicians and patients. The objective of this study was to assess the efficacy and tolerability of a skincare regimen (Cetaphil®

Gentle Skin Cleanser [GSC], Cetaphil® Moisturizing Cream [MC], plus an optional Cetaphil® Daily Moisturizer with SPF 35 [SPF35], Galderma Laboratories, LP, Dallas, TX) when used in conjunction with prescription treatments for plaque psoriasis.

MATERIALS AND METHODS

In this multi-center, blinded, 8-week in-use study, adult subjects with psoriasis utilized a skincare regimen (Cetaphil Gentle Skin Cleanser [GSC], Cetaphil Moisturizing Cream [MC], and optional Cetaphil Daily Facial Moisturizer SPF 35, Galderma Laboratories, LP, Dallas, Texas) as adjuncts to prescription therapy. Subjects were instructed to apply GSC and MC twice daily to areas on the body or face experiencing psoriasis. The study conformed to Good Clinical Practice, and all subjects provided written informed consent to participate. Ethics approval was provided by the Sterling Institutional Review Board (IRB ID 11729, clinicaltrials.gov number: NCT06357221).

Patient Population

To be eligible, subjects in good general health had to be older than 18 years of age with mild-to-severe plaque psoriasis, and to be currently on or starting a prescription treatment for plaque psoriasis, such as biologics, oral, topical, or ultraviolet (UV) therapy. Subjects could be of all genders, races, and ethnicities and have any Fitzpatrick skin phototype. Subjects had active target lesion plaques with a minimum area of 2 cm x 2 cm, and a cumulative Target Lesion Severity Score (TLSS) ≥6, and at least 3% of the total body surface area (BSA). Subjects also had to agree to stop using current topical skincare products during the study period.

Assessments

Efficacy assessments included clinical grading of BSA (assessed by handprint approximation), TLSS (scoring erythema, induration, and scaling each on a scale of 0-8 for a maximum score of 24), and Physician Global Assessment (PGA; 0=clear to 5=very severe) by investigator. In addition, there was standardized photography of target lesions using digital cameras. Bioinstrumentation was used for lesion imaging analysis, including MoistureMap MM 200 (Courage + Khazaka electronic GmbH, Koln, Germany) to quantitatively assess hydration distribution via image pixelation and Visioscan® VC 20plus (Courage + Khazaka electronic GmbH, Koln, Germany) to quantitatively assess skin smoothness and scaliness. Finally, subjects completed the Dermatology Life Quality Index (DLQI) and self-assessment questionnaires. Safety assessments included monitoring of adverse events and cutaneous tolerability grading by investigator (dryness) and subjects (itching, burning, and stinging).

Statistical Analysis

All endpoints were summarized descriptively for the observed value as well as the change from baseline. Categorical endpoints were presented in frequency tables, and all statistical tests were performed at a significance level of 5% with two-sided *P*-values. One-sample t-test was used to analyze parameters, with a Wilcoxon signed-rank test performed if normality failed. Questionnaire responses were tabulated, and the frequency and percentage of all response options were reported. A binomial test was used to test the favorable responses of the subjects' perception of the study treatment.

RESULTS

Forty-six (46) adult subjects with a mean age of 57.2 years were enrolled in the study, and 41 completed the study. Table 1 presents patient characteristics. Active lesions were present in multiple body areas, including chest, legs, arms, hands, knees, face, ears, and elbows.

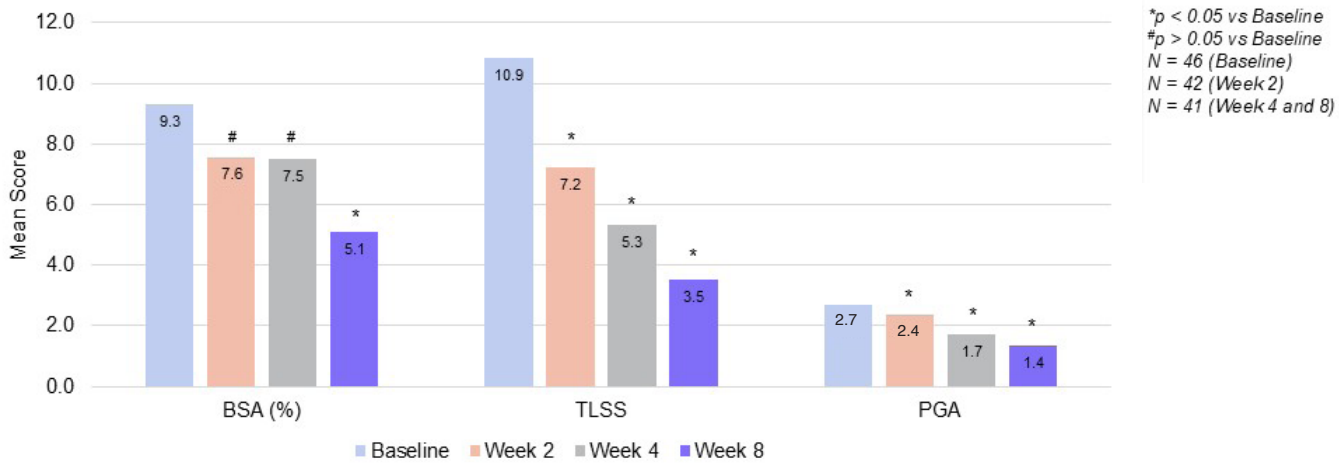
Prescription Therapy

Topical therapies were the most common prescriptions and were primarily topical corticosteroids, either alone or in combination medications. However, subjects were also prescribed non-steroidal topicals including calcipotriene, tapinarof, roflumilast, and calcineurin inhibitors. Twelve (12) subjects were prescribed injectable medications, 6 had oral medications, and 1 had spray medication.

TABLE 1.

Subject Demographics and Characteristics	
	Subjects (N=46)
Age (y), mean (range)	57.2 (25-80)
Sex	
Female	24 (52.2%)
Male	22 (47.8%)
Race	
White/Caucasian	24 (52.2%)
Black/African American	16 (34.8%)
Southeast Asian	1 (2.2%)
Other	5 (10.9%)
Ethnicity	
Hispanic	5 (10.9%)
Non-Hispanic	41 (89.1%)
Fitzpatrick skin type	
I	13 (28.3%)
II	12 (26.1%)
III	3 (6.5%)
IV	4 (8.7%)
V	7 (15.2%)
VI	7 (15.2%)

FIGURE 1. Improvements in clinical grading parameters.



Efficacy

There was a statistically significant decrease in BSA by week 8 (P<0.05), and improvements in TLSS and PGA at each time point (P<0.05) compared to baseline (Figure 1). As shown, BSA was 9.3 at baseline and 5.1 at week 8 (P<0.05), TLSS was 10.9 at baseline and just 3.5 at week 8 (P<0.05), and PGA improved from 2.7 to 1.4 (P<0.05).

MoistureMap assessment showed there was also a significant increase in moisture distribution at target lesions at each time point compared to baseline (Figure 2). In both analyses of grey index and permittivity, skin moisture steadily increased throughout the study (P<0.05 at each study visit).

In addition, there was a significant improvement in the texture of the lesions at all timepoints compared to baseline, as shown by VisioScan assessment (Figure 3).

Clinical photography showed visible improvement of psoriatic areas over time (Figure 4) that accompanied reductions in BSA, TLLS, and PGA scoring.

Patient's life quality as indicated by mean DLQI scores significantly improved and showed the disease had a moderate effect at baseline (9.2), which improved to a small effect (2.8, P<0.05) at week 8. Results of the self-assessment questionnaire showed subjects had a favorable perception of the regimen.

FIGURE 2. MoistureMap results. Left: Grey index was a rated index in which dark pixels are rated stronger than bright pixels, and an increasing index indicated higher moisture distribution. Right: Permittivity index corresponds to the dielectric constant of a material, and higher scoring translates to increased moisture content.

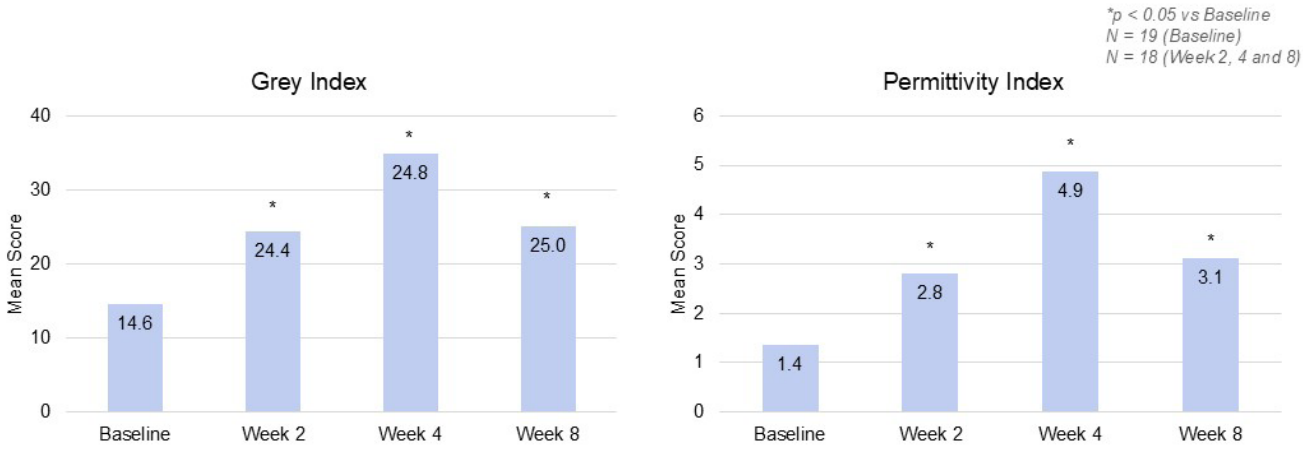


FIGURE 3. VisioScan results. Lower scaliness values indicate less desquamation of the stratum corneum, while lower smoothness values indicate improvements in skin roughness (smoothness).

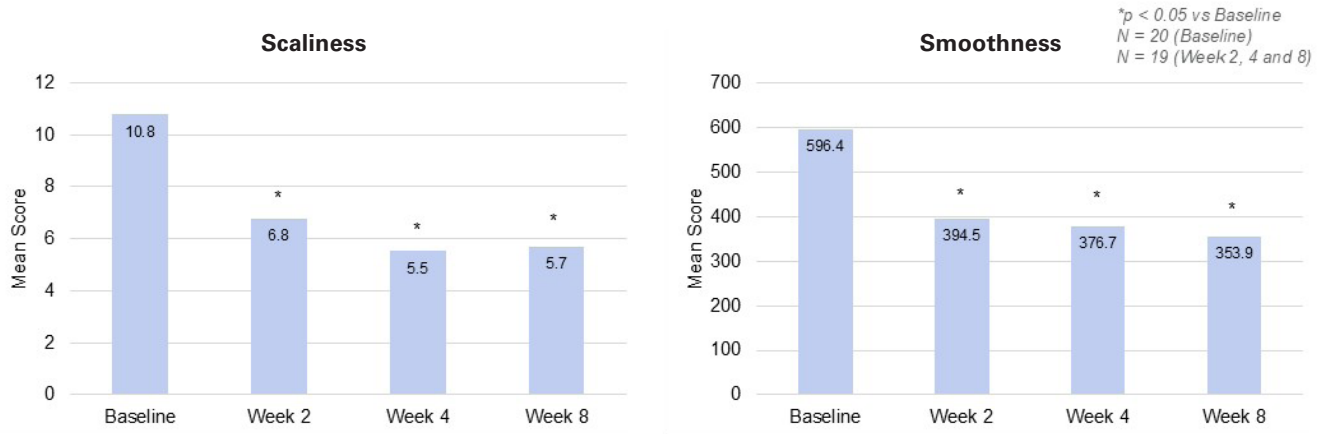
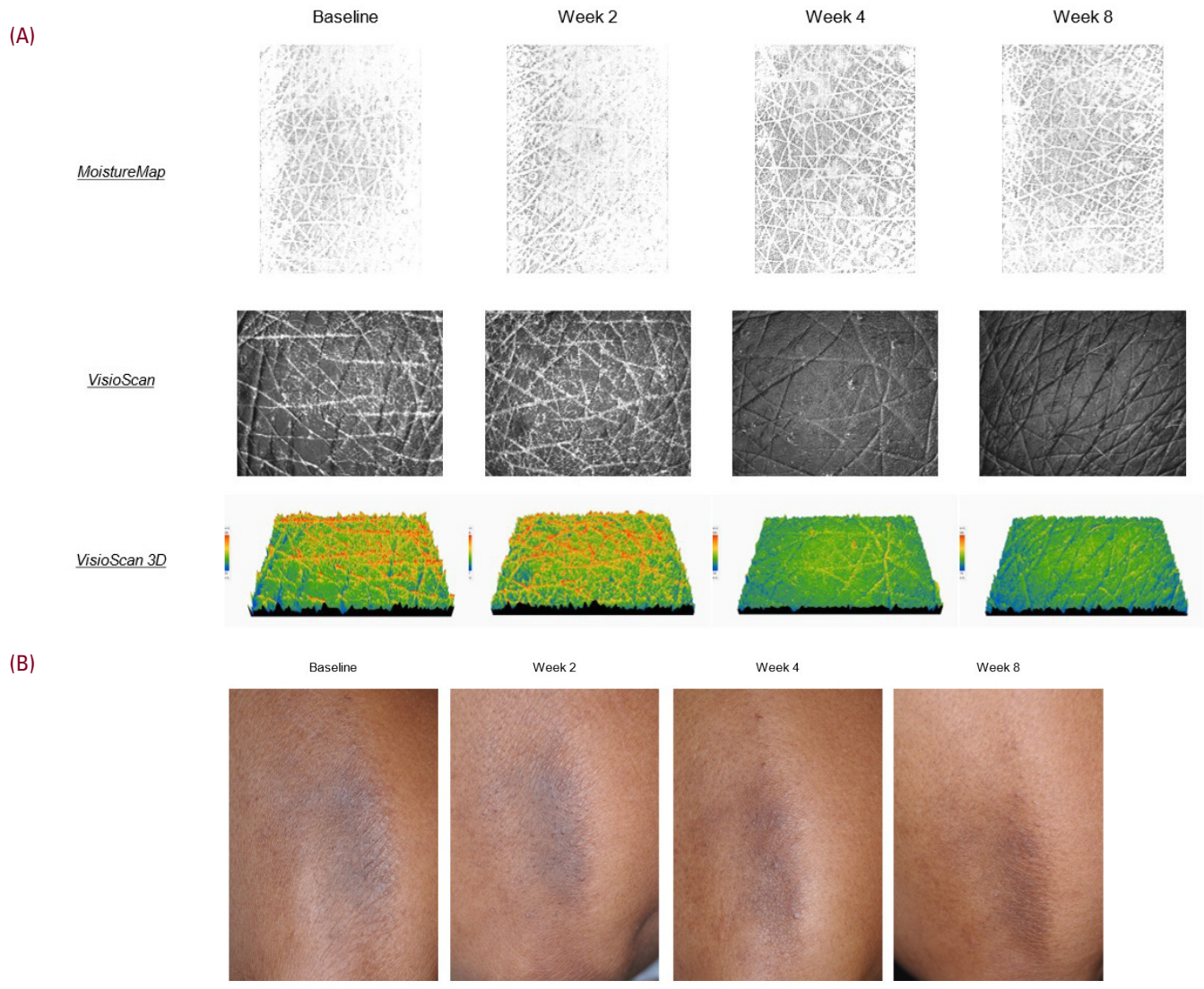


FIGURE 4. Before and After Photography. Female, 72 years old, Black/African American with psoriasis lesion on left elbow, receiving Duobrii since the start of the study. (A) Bioinstrumentation images taken at the psoriasis lesion. (B) Clinical photography of the psoriasis lesion.



Typical comments were that the products helped clear skin, and skin felt more hydrated. For example, at week 4, 97% of subjects felt their plaque lesions to be more hydrated, and 95% felt the moisturizer helped smooth skin roughness, while at week 8, 100% reported the moisturizer helped soothe sensitive skin and would recommend the product regimen.

Safety

Four adverse events (itching, stinging/burning) were reported in 4 study subjects that were judged possibly or probably related to the skincare regimen. Three resolved spontaneously, and 1 subject discontinued use of study products. Tolerability assessments of dryness, itching, burning/stinging improved at each post-baseline visit ($P<0.05$), indicating the products were well tolerated.

DISCUSSION

Psoriasis often has a major negative impact on quality of life, and both patients and physicians agree that improvement in quality of life is a key consideration in psoriasis management.[7-9] In addition, psoriasis sufferers frequently feel stigmatized, which can lead to depression and suicidal ideation.[10-12] Further, mental stress and worry can impede the efficacy of treatment.[13] For these reasons, psoriasis severity may be judged as a composite of both physical and psychological factors.[13] Implementing a good skincare regimen has been shown in this study to improve quality of life both for patients on existing long-term medical therapy and for those who have just initiated prescription therapy. As this is a relatively easy measure to implement, it seems like good clinical practice would make skincare a regular part of the psoriasis treatment plan.

This skincare regimen, consisting of a gentle skin cleanser and moisturizers, supports the skin barrier and improves psoriasis patient outcomes. After regular use of the skincare regimen, there were notable improvements in lesion moisture distribution as well as lesion texture. In addition, patients reported that their quality of life was significantly improved.

The skincare products were safe and efficacious when used as an adjunct with a variety of psoriasis prescription products, including corticosteroids in differing strengths as well as biologic treatments.

In conclusion, this study provides more data underscoring the importance of using skincare products in plaque psoriasis, particularly in conjunction with prescription treatments. The benefit of skincare as an adjunct to prescription products in subjects with plaque psoriasis supported the skin barrier and improved patient outcomes in efficacy and tolerability measures.

DISCLOSURES

Dr Draelos and Dr Hougeir have served as investigators for Galderma and received a grant to perform research; Dr Nguyen, Ms Garimella, Dr Emesiani, Dr Qureshi, Dr Mantilla, and Dr Meckfessel are employees of Galderma Laboratories, LP.

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