Moisturizing Cream Ameliorates Dryness and Desquamation in Participants Not Receiving Topical Psoriasis Treatment

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Psoriasis is a disorder characterized by faster than normal skin growth, resulting in a buildup of thickened areas with a scaly appearance. Common sites of involvement include the scalp, elbows, knees, and back. Moisturization of these areas may provide relief by increasing hydration. Accordingly, the use of a moisturizing cream (Cetaphil® Moisturizing Cream) was studied in participants with mild to moderate plaque psoriasis (5%–10% body surface area) who either were not being treated or had discontinued the use of all topical psoriasis medications and all other moisturizers and remained off of them for the entire study. The condition of the participants' skin was objectively monitored for skin barrier function through transepidermal water loss (TEWL), skin hydration through corneometry, and desquamation through the use of sticky tape corneocyte counts (D-SQUAME®). Thirty participants were enrolled. The results of this 4-week study indicate there was no further damage to the skin barrier, as no significant change in TEWL was seen. Furthermore, skin hydration increased over the course of the study. Desquamation measurements showed a significant percentage of participants with skin improvements from very dry to dry or normal (P<.0001 for all time points). All of these effects were noted despite the absence of topical psoriasis treatment. The investigator assessed that this moisturizer was well-tolerated and appropriate for use on the damaged skin of participants with psoriasis.

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Psoriasis is a disease of abnormal epidermal proliferation characterized by demarcated erythematic lesions with silvery scales. The disease typically occurs in genetically predisposed individuals following exposure to one or more triggering factors such as stress, certain drugs, climate change, infection, skin injury, smoking, and alcohol consumption.[1] Common sites of involvement include the scalp, elbows, knees, and back, but lesions or plaques may appear anywhere on the body.

Psoriasis has a substantial impact on the quality of life of affected individuals, which includes approximately 2% of the worldwide population and nearly 5% of the US population.[2] It is a chronic disease. Although effective treatments providing relief are available, it often may be short-term, highlighting the need for continued research into enhancing therapeutic regimens to further aid this patient population.[2-4]

Many dermatologists subscribe to the benefits of a cleansing and moisturizing routine in conjunction with therapy for many dermatologic conditions. Accordingly, they generally have samples from a variety of skin care companies claiming to have cleansers and moisturizers that increase hydration and therefore help ameliorate the symptoms associated with many dermatologic conditions. It is of interest that these products typically are tested

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on the skin of healthy volunteers and not on skin affected by the condition for which the products are being recommended. Therefore, a study was conducted to test a moisturizing cream on the affected skin of participants with plaque psoriasis in the absence of topical psoriasis treatment. Skin barrier function, skin hydration, and desquamation each were objectively measured, and a tolerability analysis was carried out. The participants also were monitored for adverse events. A survey also was conducted to capture each participant's perspective on the use of this moisturizer.

Materials and Methods

The objective of this study was to evaluate the use of a moisturizing cream (Cetaphil® Moisturizing Cream)(containing purified water, polyglycerylmethacrylate and propylene glycol, petrolatum, dicaprylyl ether, PEG [polyethylene glycol]-5 glyceryl stearate, glycerin, dimethicone and dimethiconol, cetyl alcohol, prunus amygdalus dulcis [sweet almond] oil, acrylates/C10-30 alkyl acrylate crosspolymer, tocopheryl acetate, phenoxyethanol, benzyl alcohol, disodium EDTA, sodium hydroxide, lactic acid) on the compromised skin of participants with plaque psoriasis covering 5% to 10% of the body. Assessments included an analysis of skin barrier function, skin hydration, and desquamation, as well as the participants' perspective and regimen compliance.

The study design called for 30 participants aged 18 to 70 years with plaque psoriasis defined as slight plaque thickening with definite elevation, fine scales partially or mostly covering lesions, and any erythema up to a moderate rating (definite red coloration). Pregnant women were excluded from enrollment. Eligible participants included those who either were not being treated or had discontinued the use of all topical psoriasis medications and all other moisturizers and remained off of them for the entire study. They were instructed to use the moisturizing cream twice daily (once in the morning and once in the evening). Assessments were performed at baseline and weeks 1, 2, and 4, as described below.

Skin barrier function was objectively determined through transepidermal water loss (TEWL) using the DermaLab® TEWL probe. This technique works by using a probe containing 2 humidity meters at a known distance from the skin. As the water vapor passes by the 2 humidity meters, the level is measured and the difference between the water content at the 2 different time points is determined. This difference is, in effect, the TEWL. Increased TEWL is expected when the skin barrier is damaged and water flows from the moist skin to the

Participant Demographics

Characteristic	Participants (N=30)
Sex, n (%)	
Male	14 (47)
Female	16 (53)
Age, y[a]	
Mean	53
Median	59
Range	24–81
Race, n (%)	
White	29 (97)
Hispanic	1 (3)
Fitzpatrick skin type, n (%)	
I	2 (7)
II	21 (70)
III	5 (17)
IV	2 (7)
Body coverage, %	
Mean	7.6
Median	8.0
Range	5.0–10.0
Duration of disease, y	
Mean	9.5
Median	8.5
Range	1.0–30.0
Discontinued, n (%)	
For medical reason	0 (0)
Participant request	1 (3)
Lost to follow-up	1 (3)

[a]Two participants, aged 71 and 81 years, exceeded the age requirement but were granted exceptions by the investigator and enrolled in the study.

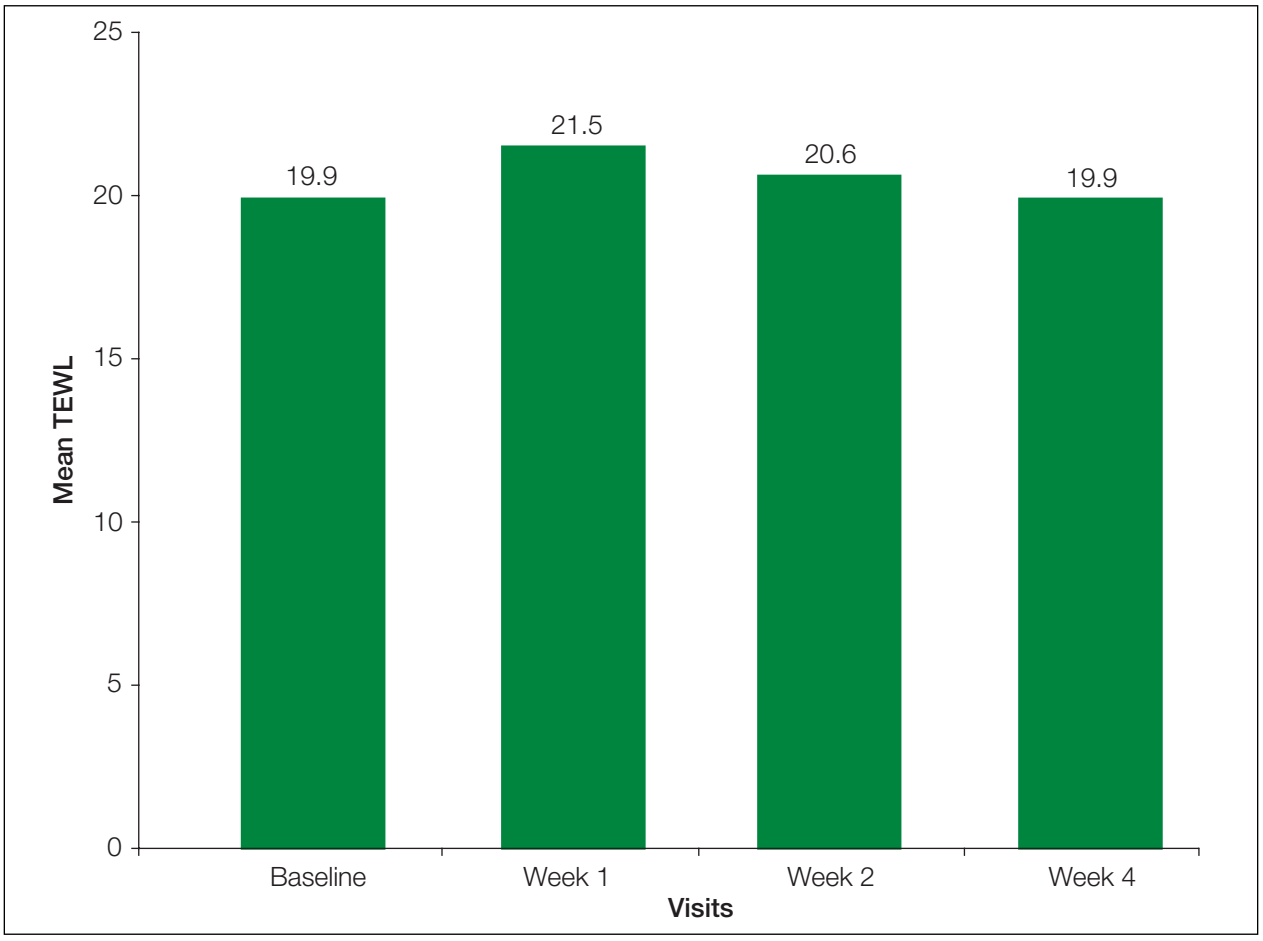

Figure 1. Mean value from 2 independent readings for transepidermal water loss (TEWL) from the psoriasis lesion objectively determined using the DermaLab® TEWL probe. No significant change was seen at weeks 1, 2, or 4 compared with baseline.

lower-humidity air. A decrease in TEWL would be indicative of improved barrier function, and no change would be indicative of preserved barrier function. A linear mixed-effects analysis of variance was used to compare mean TEWL at each week with baseline (α=.05). The analysis controlled for sex, age, and race, and was not adjusted for multiple comparisons.

Skin hydration was objectively measured through corneometry using DermaLab technology. In this study, the corneometry was measured using a pin probe. The probe is activated by depressing the pins, which produces a low-level electric current that is conducted through the skin by the water contained within the skin. The sensing pins determine how much electric current has been received. This measure of skin electric conductivity is an indirect measure of skin water content. Thus, higher corneometry values are indicative of improved skin hydration. A linear mixed-effects analysis of variance was used to compare mean corneometry at each week with baseline (α=.05). The analysis controlled for sex, age, and race, and was not adjusted for multiple comparisons.

Desquamation was objectively measured through sticky tape corneocyte counts using D-SQUAME® skin sampling discs. In this study, the adhesive discs were applied under standardized pressure onto the surface of the skin, harvesting the cells from the most superficial layers of the skin. The discs then were placed on a black background support and homogeneously illuminated. Determination of the number of dead cells adhering to the disc was analyzed by a trained evaluator using a standardized scale (scored from 1–3). The scale was translated into 3 skin categories: very dry, dry, normal. A generalized estimating equation model for ordinal data was used to compare scores at each week with baseline (α=.05). The model controlled for sex, age, and race. The analysis was not adjusted for multiple comparisons.

Participants were asked to rate 4 attributes of the moisturizer on a scale of 1 to 10, with 10 representing the best/most positive rating for the attribute and 1 the worst/least positive rating. The 4 queried attributes were ease of use, perceived effectiveness,

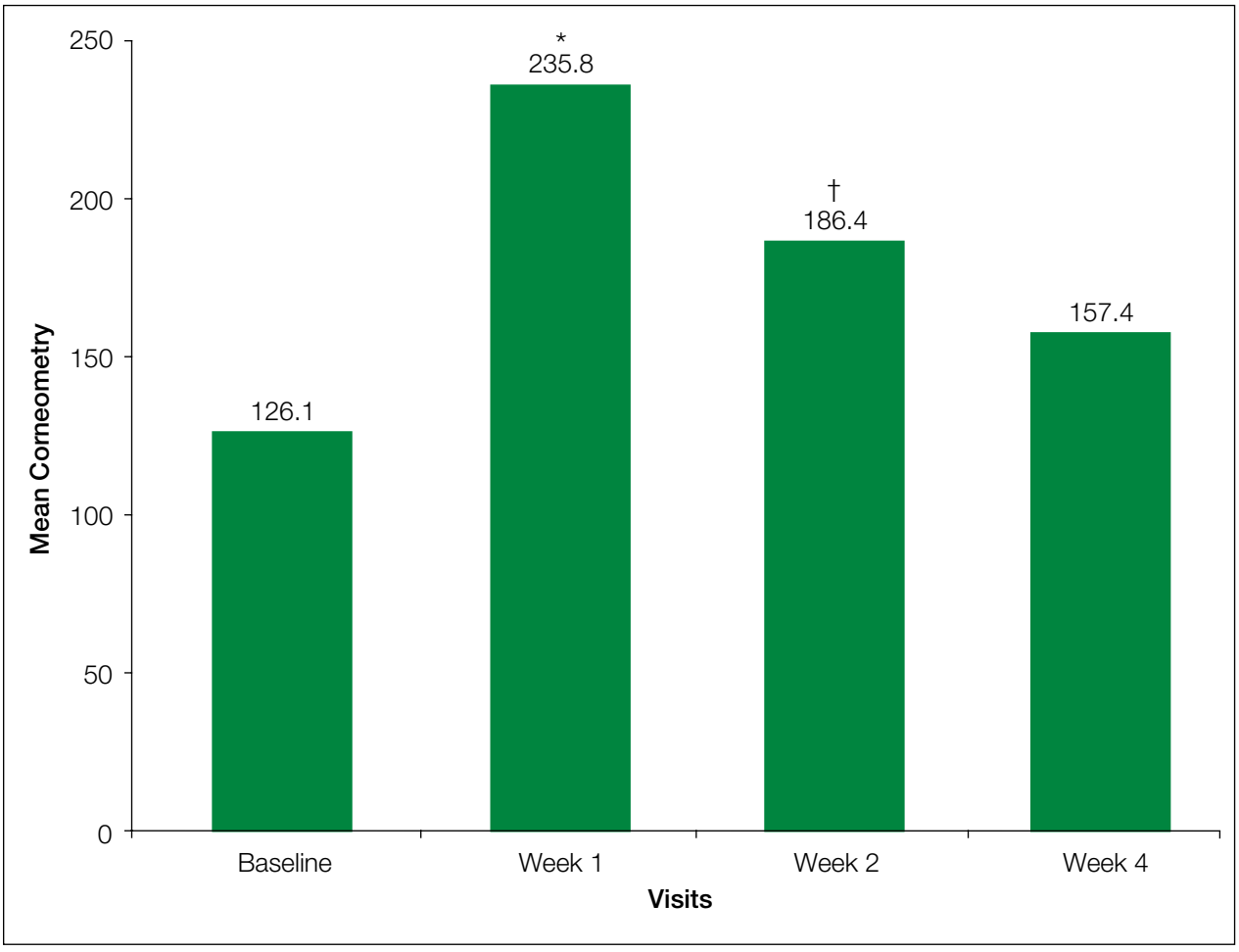

Figure 2. Mean value from 2 independent readings for skin hydration from the psoriasis lesion objectively determined using DermaLab® technology. *P* values represent values measured at weeks 1 and 2 compared with baseline. Asterisk indicates *P*<.0001; dagger, *P*<.05.

satisfaction, and plans for future use. The results of this survey were summarized descriptively.

Results

Thirty participants with plaque psoriasis were enrolled and began moisturizing twice daily with the moisturizing cream. One participant withdrew from the study by request because of absence from visits at weeks 1 and 4, and another participant was lost to follow-up, leaving 28 evaluable participants. There also were 2 protocol violations consisting of 2 participants who exceeded the age requirement. These 2 participants, aged 71 and 81 years, were granted exceptions by the investigator. They were enrolled in the study and included in the analysis. Demographic information on all participants is summarized in the Table. Most participants were female (53%; 16/30), were white (97%; 29/30), and had Fitzpatrick skin type II (70%; 21/30). Participants ranged in age from 24 to 81 years (mean, 53 years). The mean plaque coverage was 7.6% of the body and the mean disease duration was 9.5 years.

Transepidermal water loss was objectively measured to determine the effects of twice-daily moisturizing with the moisturizing cream on skin barrier function. Although there were minimal changes in the values reported, there was no significant change in TEWL over the course of the study, indicating that the skin barrier was not further damaged. Maintaining the condition of the skin barrier was particularly unexpected because of the lack of topical psoriasis treatment, which would expectedly help to reverse skin barrier impairment (Figure 1).

Skin hydration was objectively measured to assess the effects of twice-daily moisturizing with the moisturizing cream on the level of hydration in the skin. It was expected that skin hydration levels would decrease over the course of the study, as these participants were not receiving any topical treatment for their psoriasis. On the contrary, skin hydration improved over the course of the study compared with baseline. This improvement was significant at

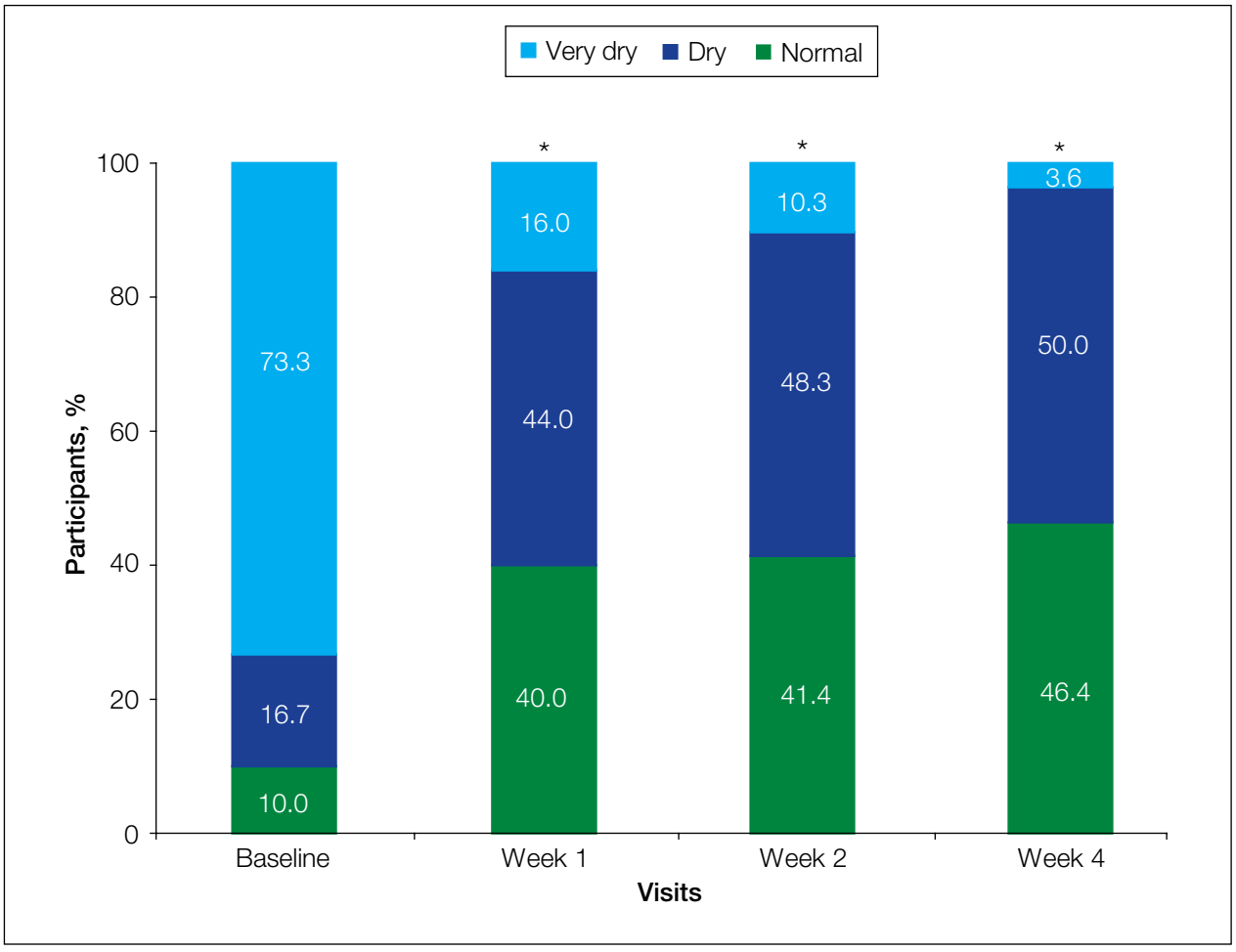

Figure 3. Distribution of participants among 3 skin categories (very dry, dry, normal) describing the severity of desquamation using D-SQUAME® skin sampling discs. *P* values represent comparison with baseline. Asterisk indicates *P*<.0001.

week 1 (*P*<.0001) and week 2 (*P*<.05) but was not significant at week 4 (Figure 2).

Desquamation was objectively measured using D-SQUAME skin sampling discs. The distribution of participants among 3 skin categories (very dry, dry, normal) significantly improved over the course of the study, with 73.3% (22/30) of participants having very dry skin at baseline, 16.0% (4/25) at week 1, 10.3% (3/29) at week 2, and only 3.6% (1/28) at the end of the study (week 4), with proportionately more participants in the other 2 categories (dry, normal) at each time point after baseline (*P*<.0001 for all time points)(Figure 3). Statistically dichotomized analyses also revealed that significantly fewer participants had very dry skin at each time point compared with baseline (*P*<.001 for each time point) and significantly more participants had normal skin at each time point compared with baseline (week 1, *P*<.05; weeks 2 and 4, *P*<.01)(Figure 3).

Participants were asked to complete a survey grading their thoughts about the moisturizing cream on a scale of 1 (worst) to 10 (best). When asked about ease of use, 79% (23/29) of participants gave the moisturizing cream a score of 10. When asked about perceived improvement, 62% (18/29) of the participants rated the cream 7 or better. More than half (55% [16/29]) of the participants scored their satisfaction with the cream as 8 or better. Finally, 62% (18/29) of participants scored their likeliness of future use as 10. The therapeutic regimen compliance rate for this study was reported as 99.6%. In addition, the investigator assessed the moisturizing cream as well-tolerated for use in participants with psoriasis.

Comment

Psoriasis is a chronic disorder characterized by scaling and inflammation of the skin. Scaling occurs because the cells of the outer skin layer are reproducing faster than normal and thus piling up at the skin's surface. In the most common form, plaque psoriasis (psoriasis vulgaris),[5] the skin lesions have a reddened base

covered by silvery scales. These plaques damage the skin barrier and consequently allow release of moisture from the skin.[6] Although moisturizers cannot be used as treatment for psoriasis, they may provide some relief from the symptoms of skin dryness by increasing skin hydration and restoring the integrity of the stratum corneum of the affected areas.[7-10] To identify an etiologic factor of this extreme dryness, prior studies have extensively examined the hydration and water-retention capacity of the stratum corneum in participants with psoriasis.[11-13] It has been reported that impaired barrier function and increased TEWL corresponded with dry skin conditions. In addition, a decrease in water-binding properties and a reduction in skin surface lipids, specifically levels of ceramides, contributed to the dryness and scaliness symptoms of psoriasis.[6,10] Furthermore, it has been reported that the structural organization of these lipids in the stratum corneum of the affected skin has been altered in comparison to healthy skin.[6] Clinical studies have shown that use of an appropriate moisturizer can alleviate some of these skin deficiencies in participants with healthy skin.[7,10] Thus, this study examined the benefits of a moisturizer on the affected skin of participants with psoriasis.

It was observed that twice-daily application of the moisturizing cream maintained the function of the skin barrier despite the lack of topical treatment in participants with plaque psoriasis in a 4-week period. In addition, twice-daily moisturizing significantly increased skin hydration at weeks 1 and 2 ($P<.0001$ and $P<.05$, respectively). Desquamation, measured by the change in distribution of D-SQUAME scores, also significantly improved with the use of the moisturizing cream during this 4-week study ($P<.0001$ for all time points). Moreover, according to the investigator's assessments, this moisturizer was well-tolerated and appropriate for use on the damaged skin of participants with psoriasis. Collectively, these results may indicate the importance of a moisturizer as a component in a psoriasis skin care regimen to help alleviate skin dryness.

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