

# The Use of Moisturizers as an Integral Component of Topical Therapy for Rosacea: Clinical Results Based on the Assessment of Skin Characteristics Study

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*Skin care regimens have been recommended in conjunction with topical medications for the treatment of rosacea. Specifically, a mild cleanser and a moisturizer can help relieve symptoms and maintain skin barrier integrity. The Assessment of Skin Characteristics Study, a multicenter open-label study (N=102), compared the use of a specified skin care regimen with or without the moisturizer component. Participants used a facial cleanser immediately before application of azelaic acid (AzA) gel 15% twice daily to both sides of the face and then applied the provided moisturizer to the right side of the face only. Scores for severity and duration of stinging, burning, tingling, and itching were recorded in the morning and evening for 7 days. Cumulative symptom scores (CSSs) decreased on the right side of the face with facial moisturizer applied.*

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**B**oth clinical experience and recent research have supported the importance of an appropriate skin care regimen in mitigating signs and

symptoms of rosacea.<sup>1-7</sup> Several studies have demonstrated the effectiveness of properly chosen skin cleansers, proper cleansing technique, and moisturizer use in minimizing signs and symptoms of rosacea such as erythema, dryness, scaling, stinging, burning, and pruritus.<sup>1,5,6,8</sup> Additionally, the use of a gentle synthetic detergent (syndet) skin cleanser was shown to improve signs and symptoms of rosacea as compared to a soap-based cleanser in participants maintained on topical metronidazole.<sup>4</sup>

Dryness of skin and scaling are not infrequent in patients with rosacea, and the utility of moisturizers in these patients is relevant.<sup>7</sup> However, there is evidence that moisturizer use could play an integral adjunctive role in the topical management of rosacea. In one controlled study, use of a niacinamide-containing moisturizer not only improved facial skin hydration in participants with rosacea, as measured by transepidermal water loss, corneometry, and chemical probe measurements, but also was associated with reductions in erythema and inflammatory lesions as well as dryness and scaling.<sup>8</sup>

The hyperirritability of facial skin in rosacea; its susceptibility to external stimuli, including skin care products; and the presence of subjective symptoms such as stinging, burning, tingling, and itching are indicative of inherent sensitive skin.<sup>9</sup> Skin sensitivity correlates with impaired epidermal barrier function.<sup>10</sup> Increased transepidermal water loss, reflective of epidermal barrier dysfunction, has been demonstrated predominantly in the central facial region of patients with both erythematotelangiectatic rosacea (subtype 1) and papulopustular rosacea (subtype 2).<sup>11</sup>

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### **What is the Assessment of Skin Characteristics Study?**

The Assessment of Skin Characteristics Study was a multicenter open-label study of participants with mild to moderate papulopustular rosacea (subtype 2) who used a specified skin care regimen including a designated facial cleanser and moisturizer in conjunction with a topical medication, azelaic acid (AzA) gel 15%, twice daily. The aim of the study was to assess the effect of this regimen on symptoms of stinging, burning, tingling, and itching in rosacea, particularly to see if the regular application of a facial moisturizer provided any measurable improvement in symptom relief as compared to the same regimen without moisturizer. Preliminary findings based on the first 24 participants were previously outlined.<sup>1</sup> The final results (N=102) are discussed here.

### **What methods were used in the evaluation of skin characteristics?**

The target number for recruitment into the study was approximately 100 individuals who could participate with minimal disruption to their usual routine and regular visits to their dermatologist (study investigator). Participants were provided with the designated topical prescription medication and specific skin care products as well as instructions on the proper method of skin cleansing and application of the topical medication and facial moisturizer.

A split-face design was employed. After washing the entire face with the designated facial cleanser provided by the investigator, participants applied AzA gel 15% to both sides of the face and then applied the provided moisturizer to the right side of the face only. Participants recorded scores for severity and occurrence of stinging, burning, tingling, and itching on each side of the face.

Participants were recruited by 4 dermatologists at different ambulatory dermatology practices in the United States. The study included participants 18 years of age and older with mild to moderate papulopustular rosacea (subtype 2) and facial erythema as determined by the investigators. Exclusion criteria included treatment with topical agents in the preceding 2 weeks, oral agents (antibiotics, anti-inflammatory dose doxycycline) in the preceding 4 weeks, or isotretinoin in the preceding 6 months; pregnancy; breastfeeding; concomitant skin conditions; underlying medical conditions; or treatments that the investigator determined might interfere with study results.

During the initial interview, investigators recorded baseline scoring on erythema and inflammatory lesions; baseline severity and frequency

of stinging, burning, tingling, and itching as reported by the participant; and participant age, sex, race, skin type, and the facial cleanser and moisturizer used.

### **What was the procedure used for application of topical medication and skin care products?**

On the first study day, investigators provided participants with AzA gel 15%, a designated facial cleanser (CeraVe™ Hydrating Cleanser or Cetaphil® Gentle Skin Cleanser), and a designated facial moisturizer (CeraVe Moisturizing Cream or Cetaphil Moisturizing Cream), and instructed them to adhere to the following procedure twice daily in the morning and evening for 7 days: (1) Wash the face gently with the provided skin cleanser only. (2) After gently drying the face, evenly apply AzA gel 15% to the entire face. (3) Apply the provided moisturizer to the right side of the face only. (4) Score sensations of stinging, burning, tingling, and itching on the left and right sides of the face for severity (0=none; 1=mild; 2=moderate; 3=severe) and duration (in minutes), and record the information in a participant diary in the AM and PM.

### **How were data reported and analyzed?**

Separate scores for stinging, burning, tingling, and itching were averaged at each measurement point to provide a cumulative symptom score (CSS). Because these sensations are highly subjective and participants might categorize them differently, the CSS served as an overall measure of facial discomfort. To reveal trends in symptom severity, mean CSSs for each side of the face were calculated for AM and PM on all 7 study days for all participants. The statistical analysis, however, was not done on the mean CSS but by pairwise comparison of individual CSSs using a Wilcoxon signed rank test. These comparisons were between (1) baseline (AM of day 1) and end of study (PM of day 7) for each side of the face for each participant, and (2) left and right side of the face for each participant at end of study.

Symptom durations were analyzed both by paired Student *t* test and Wilcoxon signed rank test in case there were extreme outliers. When more than one symptom occurred at the same time on the same side of the face and durations recorded for the different symptoms were different, these durations were averaged.

Mean CSSs and durations were calculated on the basis of all available participant diary entries for each measurement point. Pairwise comparisons were done for all available pairs.

Statistical significance was defined as  $P \leq .05$  (2-tailed test).

### **What were the skin characteristics captured at baseline that were associated with the presence of papulopustular rosacea?**

Baseline characteristics of the participant population are shown in the Table and baseline symptoms are shown in Figure 1.

Overall, 78 of 102 participants enrolled in the study reported regularly experiencing symptoms of stinging, burning, tingling, and/or itching before the study began. Itching was the symptom experienced by the greatest percentage of participants (53% [54/102]) and was described as severe by 13% (7/54) of those participants who experienced it. The symptom that occurred most frequently among those participants who experienced it was burning. Burning was noted as a daily occurrence by 11 of 45 participants (24%) who reported this symptom and was the symptom most often described as either moderate or severe as noted by 42% (19/45) of those participants with this symptom. Tingling was experienced by the fewest participants and also was experienced with the least frequency, with only 5 participants (13%) reporting that they experienced tingling every day. It also was the symptom most often described as mild as noted by 82% (31/38) of those participants who experienced it.

### **What changes in skin characteristics were noted over the course of the evaluation?**

Ten participants did not return diaries after the study and an additional 14 diaries had incomplete or missing data. Mean CSS for the 2 regimens at AM and PM of the 7 study days is shown in Figure 2. Starting with similar scores at baseline, there was a reduction for both regimens over the course of the study. There was a greater overall reduction for the regimen with moisturizer applied to the right side of the face compared to the left side without moisturizer. Comparing end of study values of the CSS to baseline for each treatment, the reduction in CSS proved significant for the regimen with moisturizer ( $P = .008$ ) but not for the regimen without moisturizer. End of study CSSs also were significantly lower with moisturizer versus without moisturizer ( $P = .015$ ).

There were marked differences in mean duration of symptoms for the 2 regimens during the first study day, mostly attributable to a single outlier, which was symptom duration of more than an hour

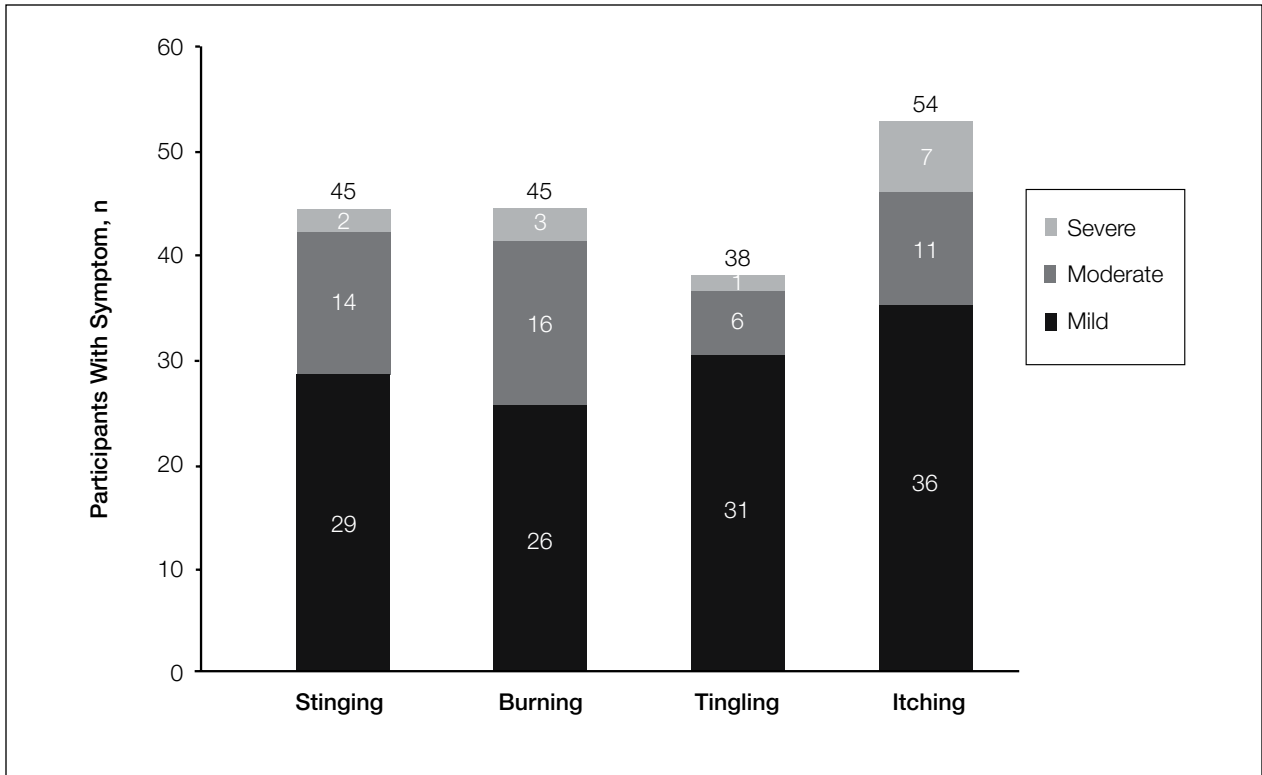
## **Baseline Characteristics (N=102)**

<b>Characteristic</b>	<b>Participants, n</b>
Age, y <sup>a</sup>	
20–39	29
40–59	52
>60	21
Sex	
Female	85
Male	17
Race	
White	92
Black	2
Asian	3
Other	5
Skin type	
Dry	21
Oily	27
Normal	34
Other/combination	20
Erythema	
Light red or pink	32
Red	59
Beet red	10
N/A	1
Inflammatory lesions, n	
1–10	54
11–20	37
>20	10
N/A	1

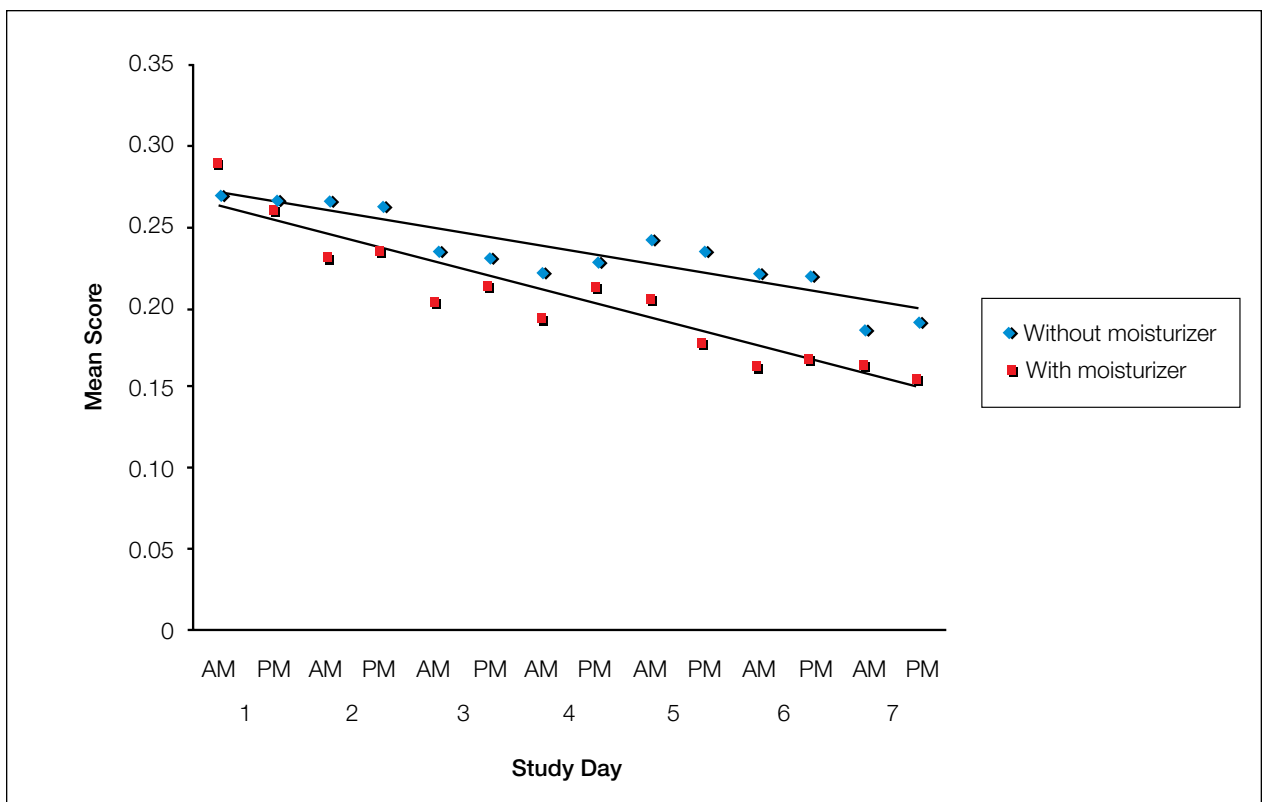
Abbreviation: N/A, not available.

<sup>a</sup>The age range was 20–80 years.

recorded on the left side of the face by 1 participant. These differences were not significant under either parametric or nonparametric testing. From the second study day through the end of the study, mean duration of symptoms were in the range of 7 to 9 minutes for both regimens.



**Figure 1.** Baseline symptoms of stinging, burning, tingling, and itching (N=102). Data are missing for one participant for burning and tingling.



**Figure 2.** Mean cumulative symptom scores recorded over 7 study days at AM and PM for participants treated with azelaic acid gel 15% and a facial cleanser, with or without a moisturizer.

### What can be concluded from the results of this evaluation?

The study appears to confirm that the inclusion of a moisturizer in a skin care regimen used in conjunction with a topical rosacea medication, AzA gel 15%, improves rosacea symptom relief as compared with the same regimen without moisturizer. Starting with equivalent baseline values, CSS in the regimen with moisturizer decreased markedly, while CSS in the regimen without moisturizer did not, and the end of study CSS was significantly lower in the regimen with moisturizer ( $P=.015$ ).

Given the characteristic presence of sensitive skin symptoms in patients with rosacea, which appears to correlate at least partially with impaired epidermal barrier function, and the role of skin hydration in maintaining the integrity of the epidermal barrier, the reduction in subjective signs and symptoms of facial skin irritation observed in this evaluation are attributed to the improvement in stratum corneum integrity after moisturizer use.<sup>10,12</sup>

It can be concluded based on this evaluation and others that the overall level of facial discomfort, characterized as stinging, burning, tingling, and/or itching, is appreciably reduced by the addition of a moisturizer to the topical skin care regimen in patients with rosacea.<sup>1-6,8</sup>

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