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Why Care About Skin Care When Managing Acne?

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Bridging the Gap: Optimizing Skin Care in Acne Treatment

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To optimize the treatment of dermatologic diseases, one must recognize the interplay between maintaining the function of the skin barrier and utilizing topical medications which often disrupt the former. Many skin diseases cause a dysfunctional epidermis further establishing the need for treatments that promote and repair overall skin health. Acne vulgaris (AV) is an inflammatory skin disease for which attention to overall skin health is necessary; treatment must include a skin care regimen that supports epidermal barrier function while contributing to the overall improvement in AV.

Acne can cause scarring and permanent disfigurement which consequently results in social isolation, depression, and anxiety. Not only does AV lead to significant emotional sequelae, it also is one of the most common skin conditions treated by dermatologists. Acne often has a prolonged course and is a chronic disease which may present past adolescence. When managing acne, many of the recommended therapies result in a disruption of the structure and function of the epidermal barrier, which paradoxically has been found to be associated with the pathogenesis of AV.[1] In particular, decreased stratum corneum thickness and increased transepidermal water loss can result from the use of medications to treat AV such as benzoyl peroxide.[3] Thus, formulating a skin care regimen that balances the efficacy of medical treatment while maintaining the integrity of the epidermal barrier becomes imperative. Additionally, patients with AV may be more likely to adhere to a treatment regimen that limits the resulting irritation from disruption of the epidermal barrier. It is important to recognize that the use of an optimized skin care regimen to enhance the treatment of AV is often overlooked.

The current guidelines for the management of acne include a variety of treatment modalities, from topical and oral medications to lifestyle modification.[2] As a dermatologist, offering a prescription treatment regimen for each patient becomes only part of the solution to disease clearance. Educating patients and providing guidance on how to create an optimal skin care routine is a vital aspect of treating AV. With a significant increase in subscription-based skin care services, the options to curate a skin care regimen have only increased and may become overwhelming to patients. Recommendations from a dermatologist can help patients navigate this process with confidence, stay adherent to their chosen skin care regimen, and has even been found to lead to reduced signs of and symptoms of irritation.[3]

This study illustrates the efficacy, tolerability, and cosmetic acceptability of a unique Cetaphil skin care regimen including an acne cleanser and moisturizer. The adjunctive skin care regimen is a critical aspect of acne management as it may enhance the therapeutic benefit while reducing tolerability reactions associated with prescription treatment. As the author emphasizes, the data support the use of a combined skin care regimen as a comprehensive approach to the treatment of acne.

DISCLOSURES

Dr. Farberg is an Advisor for Galderma, Johnson & Johnson Consumer, Novartis, Orthodermatologics, and Sun Pharmaceuticals. Dr. Sharma has no conflicts of interest to declare.

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ORIGINAL ARTICLE

Journal of Drugs in Dermatology

Optimizing Skin Care in Acne Treatment
Evaluation of a Designated Cleanser and Moisturizer Regimen With Improvement in Clinical Outcomes

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INTRODUCTION

Acne vulgaris (AV) is one of the most common skin disorders encountered in outpatient dermatology practice worldwide, commonly affecting adolescents, but also pre-teens and post-adolescent adults of any race, ethnicity, and skin color.[1] The adverse effects of AV, beyond what is visible on the skin, include several negative psychosocial sequelae, including frustration, fear of rejection, poor self-esteem, social withdrawal, anxiety, and depression.[2] A wide variety of effective therapeutic options are available for the treatment of AV, including topical agents, systemic therapies, and physical modalities, with selection of treatment primarily dependent on the severity of AV and also other patient-specific factors.[3] Regardless of the severity of AV and the treatment used, adjunctive skin care is an integral component of AV management.[4,5] Patients with AV appreciate professional guidance from their dermatologist or their designated staff in selecting skincare products, such as a cleanser and moisturizer, in order to avoid the confusion of trying to select what they should use among the plethora of available skincare choices on the market. They also are more confident that a regimen recommended by their dermatologist is more likely to achieve optimal outcomes and avoid complications such as signs and/or symptoms of skin irritation. Ultimately, an ideal skincare regimen for patients with AV helps to support epidermal barrier function, contributes to an overall improvement in AV, and is well-liked by the patients who use the regimen.

Proper selection of a skincare regimen, including a cleanser and moisturizer, is very important in AV management. Although there are limited data on epidermal barrier dysfunctions in AV, it has been shown that active AV exhibits changes associated with structural and functional epidermal barrier impairment that can correlate with the severity of inflammation associated with AV.[6,7] Additionally, certain topical active ingredients for AV, and/or their vehicle formulations, can produce cutaneous changes that promote skin tolerability reactions and symptoms of stinging and burning. The selection of a skincare regimen that can reduce the risk of adverse skin barrier effects and limit cutaneous irritation contributes markedly to the achievement of favorable results. Importantly, a skincare regimen that contains ingredients that also inherently decrease AV lesions further adds to overall clinical improvement.

In this manuscript, a specific skincare regimen incorporating both a designated cleanser and moisturizer is reviewed with study results reported from 44 adult patients with AV. The designated cleanser is Cetaphil Gentle Clear Clarifying Acne Cream Cleanser (CGCAC; Galderma) and the designated moisturizer is Cetaphil Gentle Clear Mattifying Acne Moisturizer (CGCAM; Galderma). A multicenter, in-use, 12-week study was completed to assess the efficacy, tolerability, and cosmetic acceptability of the above products used in a stepwise approach twice daily in adult patients with mild facial AV. In a separate study, evaluations of both corneometry and transepidermal water loss (TEWL) were completed to assess the epidermal hydration and permeability barrier properties of the CGCAM.

STUDY OBJECTIVES, METHODS, AND DESIGN

This study was completed at 2 study centers using an open-label in-use approach that did not incorporate a control group. The primary objective of the study was to assess the efficacy, tolerability, and cosmetic acceptability of a specified skincare regimen in patients with mild facial AV.

TABLE 1.

IGA Acne Vulgaris Grade	
0	Clear skin with no inflammatory or noninflammatory lesions
1	Almost clear; rare noninflammatory lesions with no more than one small inflammatory lesion (one papule/pustule)
2	Mild severity; greater than Grade 1; some noninflammatory lesions with no more than a few inflammatory lesions (papules/pustules only, no nodular lesions)
3	Moderate severity; greater than Grade 2; up to many noninflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion
4	Severe; greater than Grade 3; up to many noninflammatory and inflammatory lesions, but no more than a few nodular lesions

The clinical appearance of AV was assessed at baseline and over the 12-week study period using an Investigator Global Assessment (IGA) Scale (Table 1). To enroll into the study, the participant needed to be ≥age 18 years and exhibit a baseline IGA for facial AV of 1 or 2. Standard inclusion and exclusion criteria for AV studies were utilized and participants needed to fully complete Informed Consent after appropriate education on the study protocol and after having all their questions answered. Females who were pregnant, nursing, or who stated they are planning to become pregnant were excluded as were patients with allergy or hypersensitivity to AV treatments or dermatologic and/or medical disorders that the investigator felt made the patient unsuitable for enrollment. Standard washout periods for AV study inclusion were used for systemic therapies, topical therapies, and facial procedures. Participants were discontinued from the study if a new study exclusion, significant intercurrent illness, or a major adverse event (AE) occurred, or if the participant chose to voluntarily withdraw. Every reasonable attempt was made to ascertain the reason(s) for participant withdrawal.The study was completed following recognized industry standards and good clinical practice.

Test Articles and Application Instructions

The ingredient lists for CGCAC AND CGCAM are depicted in Table 2. Both formulations contain salicylic acid. Participants were instructed to use the test articles according to the following instructions:

Step 1: Cleanser: Every morning and evening (before bedtime), apply to dampened skin and gently massage, avoiding the eye area. Rinse thoroughly and pat dry.

Step 2: Moisturizer: Every morning and evening after using the cleanser, apply moisturizer as a thin layer over the entire face.

Step 3 (Optional): Photoprotection. Use of Cetaphil Daily Facial Moisturizer SPF 35 (Galderma) as needed whenever sun exposure was anticipated, especially more prolonged exposure.

TABLE 2.

Gentle Clear Product Ingredient Lists	
Gentle Clear Acne Cream Cleanser	Active Ingredient: Salicylic Acid 2.0%
	Inactive Ingredients: Water, Cocamidopropyl Betaine, Distearyl Phthalic Acid Amide, Sodium Methyl Cocoyl Taurate, Sodium Chloride, Cetyl Alcohol, Stearyl Alcohol, PEG-120 Methyl Glucose Dioleate, Phenoxyethanol, Sodium Hydoxide, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Gltcol, Disodium EDTA, Isopropyl Alcohol, Aloe Barbadensis Leaf Juice, Butylene Glycol, Camellia Sinensis Leaf Extract
Gentle Clear Mattifying Acne Moisturizer	Active Ingredient: Salicylic Acid 0.5%
	Inactive Ingredients: Water, Butylene Glycol, Cetearyl Alcohol, Dimethicone, Sodium Polyacrylate, Glycerin, Ceteareth-20, Polysorbate 60, Hydrogenated Polydecene Ethylhexyl Palmitate, Aluminum Starch Octenylsuccinate, PPG-2 Myristyl Ether Propionate, Phenoxyethanol, Alpha-Glucan, Oligosaccharide, Squalane, Caprylic/Capric Triglyceride, Caprylyl Glycol, Zinc Gluconate, C12-15 Alkyl Benzoate, Morus Alba Root Extract, Ethylhexylglycerin, Hexylene Glycol, Bisabolol, Safflower Oil/Palm Oil Aminopropanediol Esters, PPG-5-Laureth-5, Sodium Hydroxide, Kojic Acid, Hydroxypropyl Cyclodextrin, Sophora Angustifolia Root Extract, Disodium EDTA, Polyquaternium-11, Arctostaphylos Uva-Ursi Leaf Extract, Glycyrrjiza Glabra (licorice) Root Extract, Scutellaria Baicalensis Root Extract, Socium Hyaluronate, Allantoin

Clinical Assessments. Clinical grading by visual assessment was completed by a qualified investigator. Lesions counts using a protocol-designated quadrant diagram were completed at baseline and weeks 4, 8, and 12, including inflammatory lesions (papules and pustules), non-inflammatory lesions (open and closed comedones), and total AV lesions (inflammatory lesions + noninflammatory lesions). IGA was completed at baseline and at weeks 4, 8, and 12 using the aforementioned 5-point scale (0 = none, 4 = severe) (Table 1).

Clinical Photography. High-resolution facial images were captured with consent at baseline and weeks 4, 8, and 12 using the Visia-CR (Canfield) or Mark-Vu (All States MED) systems.

Tolerability Assessments. Objective assessment by the investigator of erythema, edema, dryness, and peeling was completed at baseline and weeks 4, and 12 using a 4-point scale (0 = none, 3 = severe).

Subjective assessment by the participants of burning, stinging, and itching was completed at baseline and at weeks 4, 8, and 12 using a 4-point scale (0 = none, 3 = severe) (Figure 1).

Subject Self-Perception Questionnaires (SPQ). Product attributes and efficacy were evaluated by participants at weeks 1, 4, 8, and 12 using a 5-point scale (1 = strongly agree, 5 = strongly disagree). Additional participant comments on product recommendations, purchase intent, and testimonials were captured at end of study (Figure 1).

STUDY DEMOGRAPHICS

The participant distribution and demographics are depicted in Table 3. Of the 45 adult participants that were enrolled, 44 completed the study, with a mean age of 38.2 years. Enrollment was purposefully designed to achieve at least 80% female participants and to be inclusive of all Fitzpatrick skin types, races, and ethnicities.

TABLE 3.

Participant Distribution and Demographics		
Subject	N	%
Enrolled	45	--
Completed	44	--
Age		
Mean	38.2	--
Minimum	18	--
Maximum	62	--
Gender		
Female	40	88.9
Male	5	11.1
Race		
White/Caucasian	25	55.6
Black/African American	14	31.1
Asian	4	8.9
Mixed	1	2.2
Native American Pacific Islander	1	2.2
Ethnicity		
Hispanic/Latino	7	15.6
Non-Hispanic/Latino	38	84.4
Fitzpatrick		
II	13	28.9
III	9	20.0
IV	10	22.2
V	11	24.4
VI	2	4.4

FIGURE 1. Tolerance Assessments were performed by the dermatologist investigator at baseline and weeks 4, 8, and 12 using the photos captured at each visit. The dermatologist investigator was blinded to previous evaluation visit grades. Scoring was completed on the global face for all subjects using the following scale.

Evaluation of Objective Tolerance. Signs of irritation including erythema, edema, dryness, and peeling were assessed on the face according to the following scale:

Erythema	Edema	Dryness	Peeling
0 = None	0 = None	0 = None	0 = None
1 = Mild	1 = Mild	1 = Mild	1 = Mild
2 = Moderate	2 = Moderate	2 = Moderate	2 = Moderate
3 = Severe	3 = Severe	3 = Severe	3 = Severe

Evaluation of Subjective Tolerance. Instances of subjective tolerance to the test article were assessed by the subjects at Visit 1 and after 4, 8, and 12 weeks of use according to the following scale. Subjects were asked if they had experienced any of the following tolerance issues:

Stinging	Burning	Itching
0 = None	0 = None	0 = None
1 = Mild	1 = Mild	1 = Mild
2 = Moderate	2 = Moderate	2 = Moderate
3 = Severe	3 = Severe	3 = Severe

If a subject had a worsening score from baseline for any of the tolerability signs (Objective or Subjective), the score was classified as an Adverse Reaction and it was recorded as an Adverse Event.

STATISTICAL ANALYSIS AND METHODOLOGY

All statistical tests of the hypothesis utilized a level of significance of 0.05, and no adjustments were made for the number of tests performed. With lesion counts, analyses were conducted for each lesion type and for totals of lesions. Analyses of lesion counts, IGA, objective (investigator) tolerability, and subjective (participant) tolerability used descriptive statistics that included mean and standard deviation; change-from-baseline analyses used the Wilcoxon signed-rank test, mean percent improvement from baseline, and percent of participants improving. Statistical analysis of the subjective self-perception questionnaire included frequency distributions of scores and analyzed within treatment using top box analysis.

STUDY OUTCOMES

Efficacy Assessment

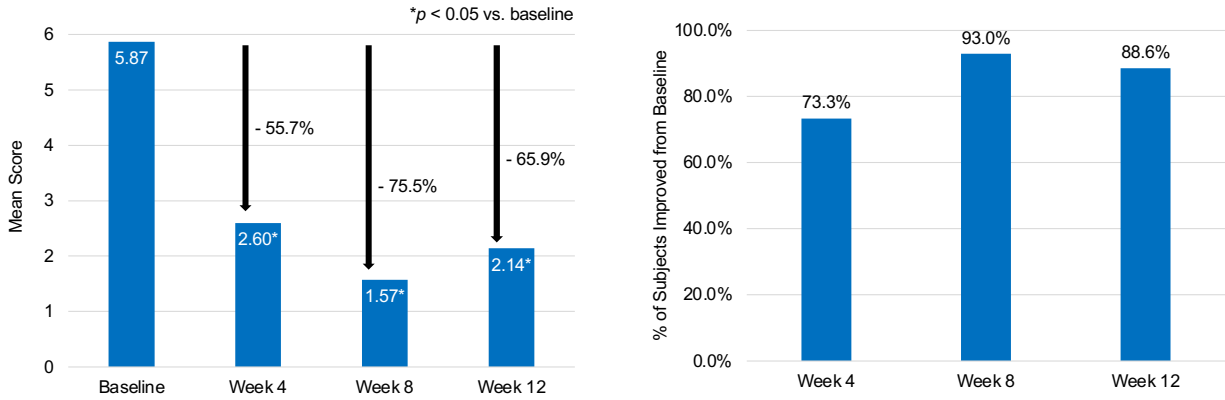
Lesion count reductions of inflammatory lesions, non-inflammatory lesions, and total AV lesions demonstrated significant improvement in mean lesion count scores across all time points compared to baseline. The percentage of participants who improved from baseline are also depicted in Figure 2A-C. With IGA study assessments over time, changes in mean score and the percentage of participants improved from baseline are depicted in Figure 3. Multiple photographic examples are also shown demonstrating individual case results at baseline and weeks 4, 8, and 12 (Figure 4).

Tolerability Assessment

Analysis of mean objective (investigator) tolerability scores showed a slight decrease in erythema at week 4, a slight increase at week 8, and a slight decrease at week 12. None of these changes were statistically significant. There was no edema observed at any time point and mean dryness scores showed a slight decrease over 12 weeks (not statistically significant). Mean scores for peeling remained stable throughout the study. Overall, no significant increase in scores for worsening in erythema, edema, dryness, and peeling were noted indicating favorable tolerability with the skincare regimen.

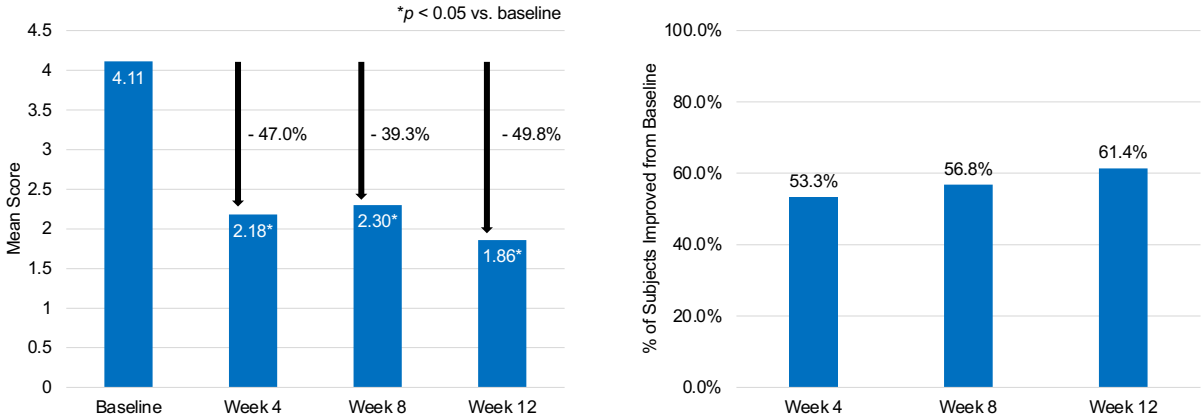
Analysis of subjective (participant) tolerance scores for itching, burning, and stinging showed no statistically significant changes from baseline for all timepoints. There were individual instances of mild subjective tolerability issues noted: four participants reported itching at the week-4 timepoint (all mild) only and 1 participant reported itching at weeks 8 and 12. Burning and stinging were not reported by any participants at any timepoints. These data support

FIGURE 2A. Inflammatory lesion counts from baseline through week 12.



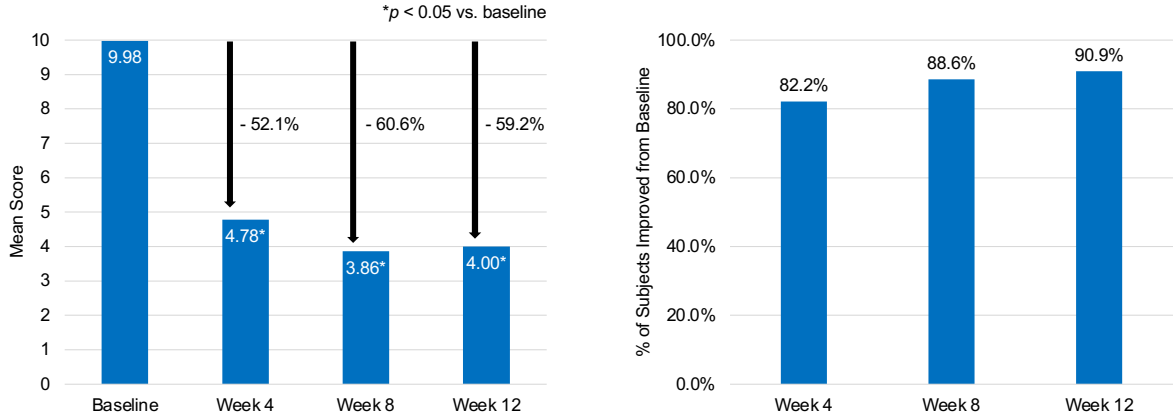
→ Significant improvement in inflamed acne lesions across all timepoints compared to baseline.

FIGURE 2B. Noninflammatory lesion counts from baseline through week 12.



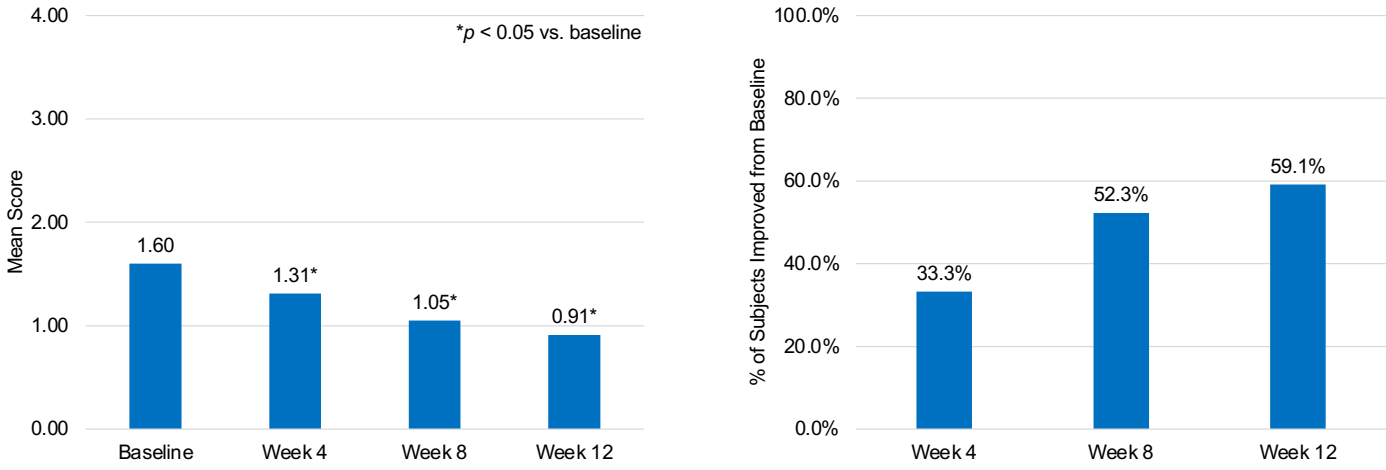
→ Significant improvement in non-inflamed acne lesions across all timepoints compared to baseline.

FIGURE 2C. Total lesion counts from baseline through week 12.



→ Significant improvement in overall acne lesions across all timepoints compared to baseline.

FIGURE 3. Investigator Global Assessments from baseline through week 12.



the results shown with objective tolerability assessments by the investigators supporting favorable tolerability with the skincare regimen.

The objective and subjective tolerability assessments based on mean scores are shown in Figure 5.

Subject Self-Perception Questionnaires (SPQ)

The results of the subject self-perception questionnaires were completed at multiple timepoints. Tables below depict the results at the end of study (12 weeks). As shown in Table 4A-B, the results were highly favorable.

Epidermal Hydration and Barrier Function Evaluation

A prospective study was completed on 20 White females evaluating corneometry and TEWL after a single application of CGCAM to dry forearm skin as compared to an untreated forearm site (control). A corneometer was used to test epidermal hydration at baseline, 1 hour, 8 hours, 24 hours, and 48 hours (Figure 6). Tewameter measurements reflecting TEWL were obtained at baseline, 1 hour, 8 hours, and 24 hours (Figure 7).

The results of the above objective corneometry and TEWL studies support that CGCAM provides long-term significant epidermal hydration and sustains permeability barrier function.

CONCLUSION

Adjunctive skin care is an important component of acne management as it may enhance the therapeutic benefit and reduce the potential for skin tolerability reactions associated with acne therapy. The data reviewed in this manuscript support the use of a combined skincare regimen using a designated cleanser (CGCAC) and moisturizer (CGCAM). This skincare regimen was shown to improve mild acne with improvement in acne lesions and IGA. Skin tolerability was very favorable, and the regimen was well received among subjects.

TABLE 4A.

Subjective Questionnaire Results at Week 12	
	% of subjects with favorable responses N = 44
I love the lather of this cleanser	90.91%
This cleanser feels more gentle than others that I have tried	90.91%
This cleanser is a game changer for my sensitive skin	88.64%
This cleanser is gentle enough for daily use	95.45%
This cleanser leaves my skin feeling purified without irritation	90.91%
This moisturizer feels luxurious on the skin	93.18%
This moisturizer helps sooth irritation	86.36%
This moisturizer is a game changer for my sensitive skin	86.36%
This moisturizer is gentle enough for daily use	93.18%
This moisturizer hydrates my skin without feeling heavy or greasy	97.73%
I love the lightweight feeling of this moisturizer	97.73%
This regimen helps to control my breakouts	79.55%
This regimen is a game changer for my acne-prone, sensitive skin	81.82%
This regimen clears acne without feeling harsh on my skin	86.36%
These products help correct my overall skin imperfection	88.64%
I love how radiant my skin looks since starting this regimen	86.36%
My pores are much more refined	93.18%
My skin feels the least stressed and irritated	88.64%
I love how smooth my skin feels	90.91%
I wear less make up since I started this regimen	61.36%
This routine provides complete care for my acne-prone, sensitive skin	86.36%
I've finally found a gentle routine for clearer skin	84.09%
I worry less about my acne since starting this regimen	79.55%

TABLE 4B.

Subjective Questionnaire Results at Week 12	
	% of subjects with favorable responses N = 44
I would recommend this regimen for acne-prone, sensitive skin	82.22%
I would purchase this cleanser	82.22%
I would purchase this moisturizer	86.67%
I would purchase this regimen	82.22%
I would switch from my current product to this cleanser	73.33%
I would switch from my current product to this moisturizer	68.89%
I would switch from my current products to this regimen	73.33%

FIGURE 4. The following photographs depict response over the course of the study in individual cases from baseline through 12 weeks.

FIGURE 5. Objective and subjective tolerability assessments from baseline through week 12.

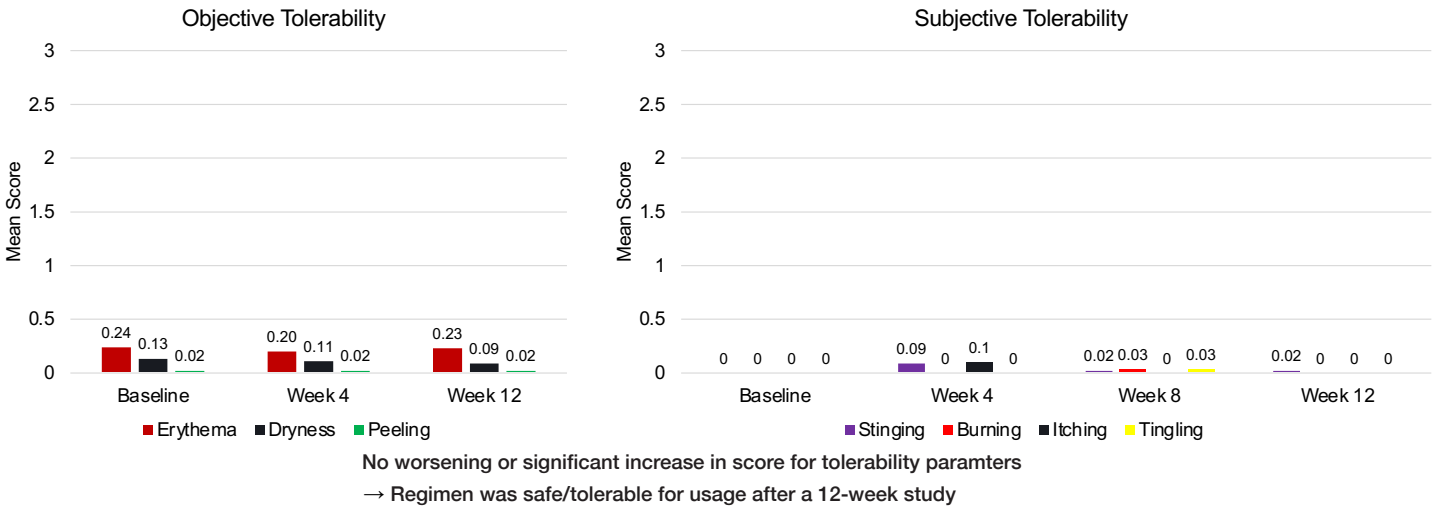


FIGURE 6. Corneometry measurements.

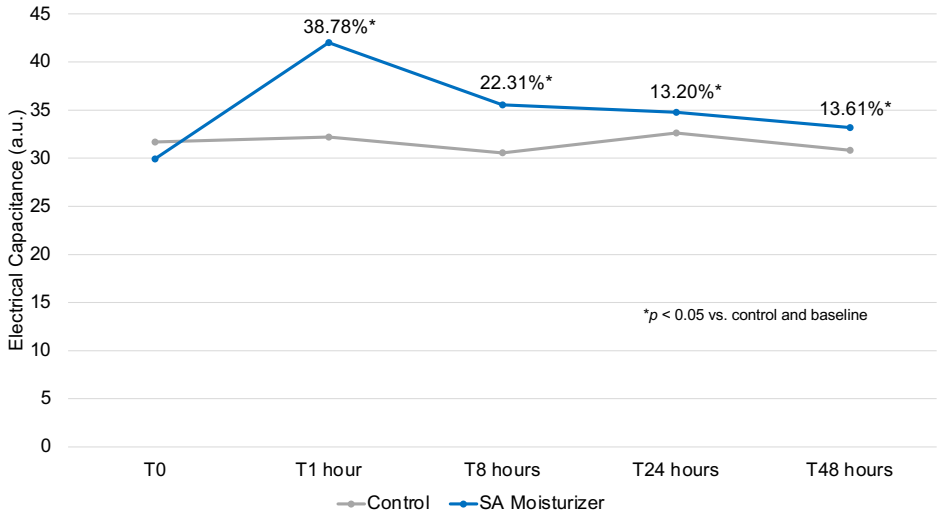
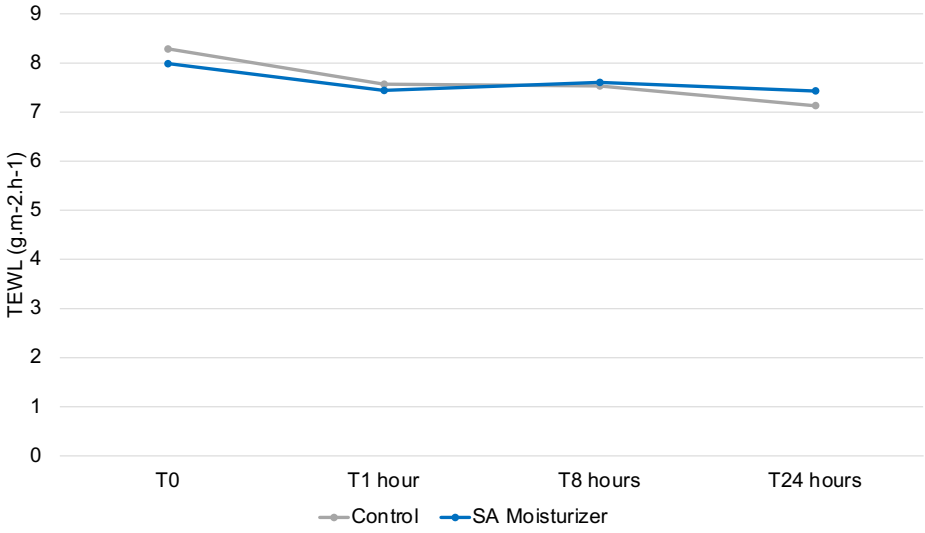


FIGURE 7. Tewameter measurements.



DISCLOSURES

Dr. Del Rosso is a research investigator, consultant, and speaker for Galderma Laboratories.

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