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Efficacy and Tolerance of a Polymeric Surfactant Technology-Based Cleanser for Clinically Diagnosed Sensitive Skin

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ABSTRACT

Background: Cleansing is an important hygiene activity, necessary to prevent bacterial, fungal, yeast, and viral infection. However, in the presence of skin disease, cleansing can take on a new challenge: removing the sebum, sweat, externally applied substances, environmental debris, and organisms from the face without damaging the skin barrier. Since cleansers cannot easily distinguish between sebum and the intercellular lipids required to maintain skin integrity, unique cleansing technologies are necessary to provide mild cleansing for the many manifestations of sensitive skin.

Objective: This 4-week clinical study aimed to evaluate the appropriateness of a cosmetic facial foaming gel cleanser with a polymeric surfactant technology in a diverse sensitive skin population.

Method: Eighty-five subjects with sensitive skin due to eczema/atopic dermatitis, rosacea, acne, or cosmetic intolerance syndrome were evaluated via investigator grading, self-assessment questionnaire, noninvasive measurements, and digital photography.

Results: The foaming gel cleanser was well tolerated showing no significant increases in investigator-graded irritation endpoints. Sensitive skin subjects saw considerable reduction ($P<0.05$) in stinging, itching, burning, tightness, and overall sensitivity at 2 and 4 weeks. Improvements in smoothness, softness, clarity, radiance, and overall skin appearance, were observed by both the investigator and patients ($P<0.05$) at 2 and 4 weeks.

Conclusion: The polymeric surfactant technology-based foaming gel cleanser provided a rich, foaming lather that felt gentle and left skin feeling comfortable.

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INTRODUCTION

Cleansing is an important hygienic activity for maintaining skin health; however, cleansers cannot distinguish between the lipids from sebum and environmental dirt and the intercellular lipids necessary for a robust skin barrier. A careful balance must be created when designing a cleanser formulation to remove enough water- and oil-soluble dirt without worsening sensitive skin. The substances that produce cleansing are known as surfactants. A new method to achieve this cleansing balance while respecting the skin barrier is the development of polymeric surfactant cleansing technologies. These technologies can provide premium cleansing and foaming aesthetics while minimizing surfactant penetration into the skin.[1] Surfactant penetration occurs when the skin is exposed to highly alkaline detergents that swell the stratum corneum, enabling penetration. Much of the skin tightness that is experienced post-cleansing is an indication of cleanser penetration through the stratum corneum and the interaction between proteins and lipids in the epidermis[2] resulting in skin tightness, skin dryness, epidermal barrier damage, erythema, irritation, and itching.[3-7]

The key to cleansing is the formation of micelles, which are spheres that have a hydrophobic interior to solubilize oily dirt and a hydrophilic exterior to allow the oily dirt to dissolve in water. The foaming action and mildness of the cleanser are influenced by the surfactant charge and formation of micelles helping to remove lipids from the skin surface.[1,3,8] Hydrophobically modified polymers (HMP), such as potassium acrylate copolymer, physically associate with surfactants, resulting in the formation of polymer-surfactant complexes that are less irritating to the stratum corneum lipid barrier.[1,9,10] HMPs interact with the hydrophobic tails of other surfactants, leading to the formation of larger surfactant structures and a reduction in the surfactant dynamics. HMPs also lower the effective concentration of free surfactant micelles in solution and facilitate foam formation.[10] HMPs can also be combined with the next-generation polymeric cleansing technology,

polymeric surfactants (PS) such as sodium hydrolyzed potato starch dodecenylsuccinate. The combined polymeric cleansing system results in a greater micelle size, even further minimizing surfactant penetration into the skin, while at the same time promoting a higher quality foaming of the cleanser,[11] a desirable consumer-perceived cleansing attribute. Thus, surfactant selection represents a trade-off between functionality, aesthetics, and mildness of the cleanser.

Early soaps consisted of salts of fatty acids and were derived from plant or animal triglycerides in combination with a base, typically lye. Although soaps are effective cleansers, alkaline soaps can increase skin surface pH[12] and can dissolve fat-soluble and water-soluble components of the skin.[13] Due to these properties, alkaline cleansers have greater potential to irritate skin than neutral cleansers[12,14,15] and can adversely affect barrier repair.[16] Liquid detergents enable the creation of liquid surfactant solutions at pHs below 7 and produce less skin damage and drying.

This research examined the tolerance and efficacy of a facial cleanser designed with two polymeric cleansing technologies formulated together, HMP and a PS, in a diverse population with clinically diagnosed sensitive skin due to atopic dermatitis, eczema, rosacea, cosmetic intolerance syndrome, or acne.

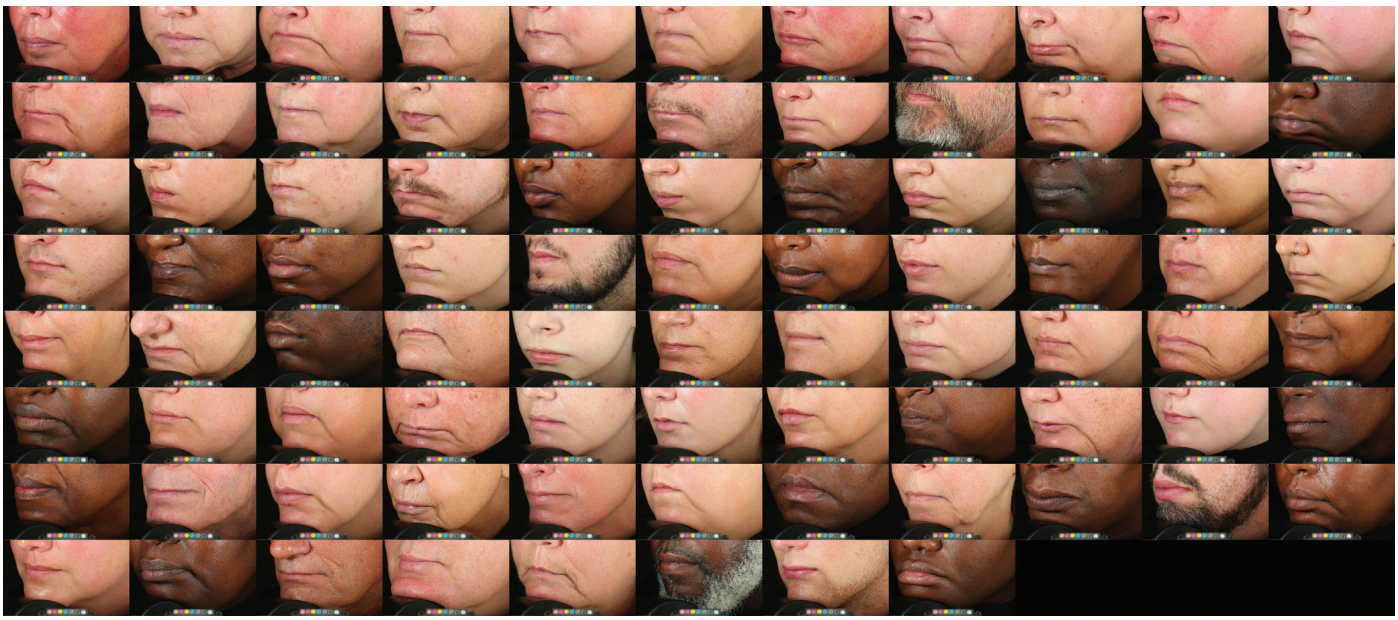
METHODS

Eighty-five male and female subjects 18 to 65 years of age with sensitive skin were enrolled in this single-center (Dermatology Consulting Services, PLLC, High Point, NC), open-label 4-week study (Table 1). The study enrolled a diverse population (Figure 1). Sensitive skin was defined as the presence of eczema/atopic

TABLE 1.

Subject Demographics and Characteristics	
Parameter	**Subjects (N=85)**
Skin Disease	
Eczema/Atopic Dermatitis	22
Rosacea	21
Cosmetic Intolerance Syndrome	21
Acne	21
Gender	
Female	73
Male	12
Race	
White	64
African American/Black	20
Asian	1
Fitzpatrick Skin Type	
I	34
II	26
III	4
IV	1
V	9
VI	11
Ethnicity	
Non-Hispanic	84
Hispanic	1

FIGURE 1. Visual demography of the 85 participating clinical subjects.



dermatitis, rosacea, cosmetic intolerance syndrome, or acne-prone skin. Each of these skin conditions is characterized by a defective skin barrier that can effectively test the mildness of a novel cleanser formulation. Subjects who met all the inclusion criteria and none of the exclusion criteria and signed an institutional review board-approved (Advarra Institutional Review Board, Columbia, MD) consent were enrolled. Subjects were instructed to use the study skin cleanser in place of their normal cleanser twice daily. Subjects were asked to continue using other skin care products, cosmetics, and sunscreens that they had used for 30 days without difficulty for the 4-week duration of the study.

The investigator and subjects assessed tolerability and efficacy on a 5-point ordinal scale at baseline, week 2, and week 4 (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe). Visia CR4.3 (Canfield Scientific, Parsippany, NJ) images were obtained at each visit. Noninvasive assessments consisted of transepidermal water loss (TEWL) (RG1 Evaporimeter, Cyberderm, Broomall, PA), corneometry (Dermalab, Cortex Technology, Hansund, Denmark), and pH (Dermalab, Cortex Technology, Hansund, Denmark). Fifty percent of the subjects underwent d-squame sampling for skin biomarkers and the other 50% underwent facial microbiome swabbing at each visit. Subjects were selected randomly for the extra procedures. Finally, subjects completed a self-assessment questionnaire for product attributes and aesthetics at week 4. Compliance was determined from a subject-completed diary.

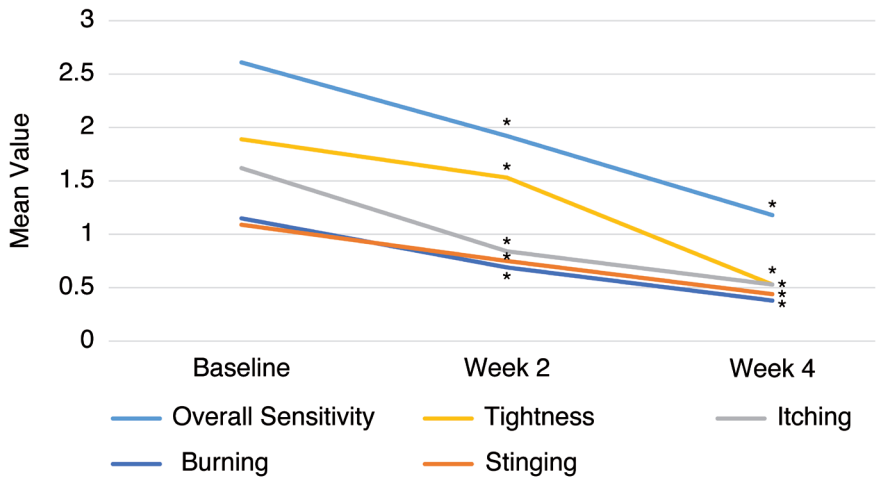
The mean change from baseline was determined at each applicable post-baseline time point. The null hypothesis that the mean change from baseline is zero was tested using a Wilcoxon signed rank test for investigator- and subject-observed tolerability and efficacy parameters. A paired t test was used for TEWL, corneometry, and skin pH measurements.

RESULTS

All 85 subjects successfully completed the study. No adverse events or adverse experiences occurred. The efficacy and safety analyses were based on data from the intent-to-treat (ITT) population comprising all patients who received the investigational product (facial cleanser) and participated in at least one post-baseline evaluation. All enrolled subjects completed study participation; thus, the ITT population is the same as the per-protocol population. Analysis was performed for all subjects combined, separately by skin condition (eczema/atopic dermatitis, rosacea, acne, and cosmetic intolerance syndrome), and separately for eczema/atopic dermatitis, rosacea, and cosmetic intolerance syndrome combined.

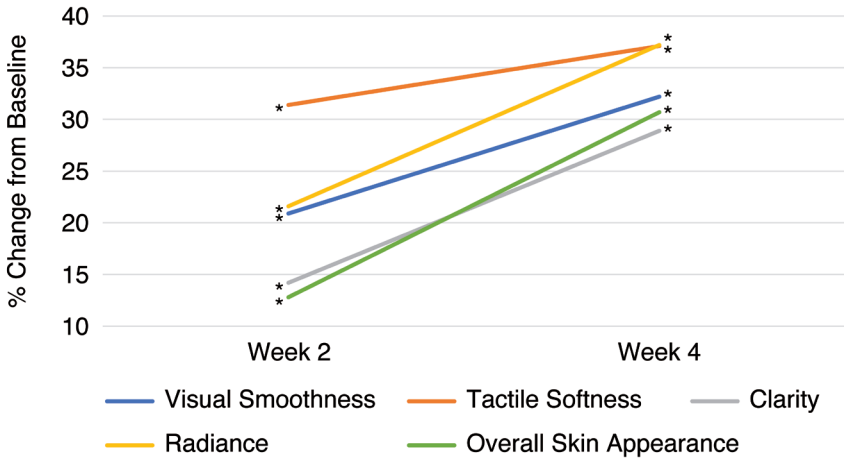
The dermatologist investigator assessed no statistically significant increases in erythema, irritation, peeling, tactile roughness, or dryness at any time point. There were statistically significant improvements in subjective assessments of irritation starting at week 2 in terms of stinging, itching, burning, tightness, and overall sensitivity (Figure 2). The dermatologist investigator observed significant improvement in visual smoothness, tactile softness, clarity, radiance, and overall skin appearance (Figure 3). The subjects also rated significant improvement in the aforementioned parameters. Figure 4 demonstrates the improvement in facial appearance in a subject with rosacea.

FIGURE 2. Subject-assessed sensory attributes.



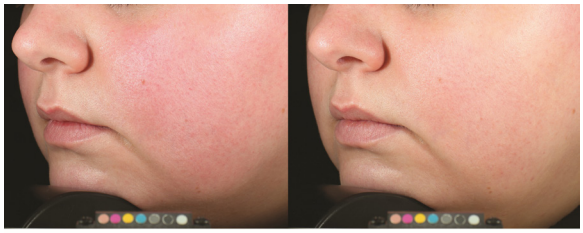
N = 85.*P<0.05 versus baseline.
Five-point ordinal scale, whole points only, 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe. Decrease in values indicates improvement.

FIGURE 3. Investigator-assessed skin attributes.



N=85 *P<0.05 versus baseline.
Increase indicates improvement.

FIGURE 4. Improved erythema in female rosacea subject.



The noninvasive instrumental assessments were consistent with the subject and investigator evaluations. No increases in TEWL scores from baseline were noted, supporting the absence of cleanser-induced barrier damage. The pH also remained unchanged, indicating the absence of barrier damage from an elevated skin pH. Corneometry showed no change, indicating no negative effect on clinically diagnosed subjects with sensitive skin. Finally, the swabs indicated no change in the skin microbiome and the d-squames showed no change in natural moisturizing factor markers (urea, lactate, amino acids) or lipid markers (cholesterol, free fatty acids, ceramides) in subjects with clinically diagnosed sensitive skin. Collectively, these findings demonstrate the ability of the study product to cleanse the skin without inducing any negative changes.

DISCUSSION

This pivotal study was conducted because there is a lack of clinical evidence supporting the use of foaming cleansers in clinically diagnosed sensitive skin. Cleansing is the cornerstone for skin hygiene in dermatological disease states. It is imperative, however, that the cleanser is well tolerated to ensure the disease state does not worsen. This study provided clinical evidence regarding the tolerance and efficacy of a daily foaming cleanser in subjects with clinically diagnosed sensitive skin due to atopic dermatitis, eczema, rosacea, cosmetic intolerance syndrome, or acne. The formulation included humectants such as hyaluronic acid and glycerin, while omitting potential irritants such as alcohol and fragrance. While cleansers traditionally have been designed to induce no skin barrier harm, properly formulated cleansers can provide additional benefits, delivering on superior tolerance and improved skin appearance with excellent aesthetics.

One commonly held consumer belief is that a facial cleanser must foam in order to properly clean the skin. This is not correct. Some surfactants foam better than others, but foaming agents are added to facial cleansers in order to generate foam. As a matter of fact, as soils and sebum are removed from the face, the amount of cleansing foam decreases. Yet, a foaming facial cleanser is a preferred consumer aesthetic that possibly drives compliance in clinically diagnosed persons with sensitive skin. Anionic surfactants, such as sodium lauryl sulfate (SLS), generate excellent foam, but are also known cutaneous irritants. This irritation arises due to stratum corneum swelling induced by the anionic surfactant that subsequently allows penetration of the cleanser into the skin. One way to minimize skin barrier damage is to combine cationic and anionic surfactants or use a surfactant that is amphoteric, with both cationic and anionic ends of the molecule.

This research examined the utility of a foaming facial cleanser in sensitive skin with a unique formulation designed with two polymeric cleansing technologies combined with mild

surfactants. The potassium acrylate copolymer (an HMP) associates with several surfactants in the formulation to create HMP-surfactant complexes.[11] An amophoteric surfactant, cocoamidopropyl hydroxysultaine, and two anionic surfactants, sodium cocoyl isethionate and sodium methyl cocoyl taurate, were combined to create excellent foaming and mild cleansing properties. Sodium hydrolyzed potato starch dodecenylsuccinate (a PS) can also form mixed micelles with the surfactants and surfactant complexes, with the HMP preventing skin penetration through the mechanism of hydrodynamic size exclusion.[11]This unique cleansing concept allows the production of a high-quality foam without surfactant-induced skin irritation, thereby combining excellent aesthetics and skin hygiene with maintenance of the stratum corneum barrier in a sensitive skin population.

The limitation of this research was the inability to design a placebo-controlled study. It is not possible to design a placebo cleanser. Further, it is unethical to prohibit subjects from face washing for the duration of the study. For this reason, the research was designed as a monadic study.

SUMMARY

The research demonstrated the value of a well-tolerated, polymeric cleansing technology-based surfactant foaming cleanser in providing visual skin benefits in clinically diagnosed subjects with sensitive skin across various ages, races, Fitzpatrick skin types, and genders.

DISCLOSURES

Dr Zoe Diana Draelos has received an educational grant from Johnson & Johnson Consumer Inc., a subsidiary of Kenvue Inc., to conduct research detailed in the manuscript. Rabab Hussain, Heather Smith, Thomas Shyr, and Neena K. Tierney are employees of Johnson & Johnson Consumer Inc., a subsidiary of Kenvue Inc., and may own stock or stock options.

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