# Benefits of Mild Cleansing: Synthetic Surfactant-Based (Syndet) Bars for Patients With Atopic Dermatitis

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*Atopic dermatitis (AD) is a recurring inflammatory skin disease, characterized by marked pruritus, which usually develops in early childhood. AD is associated with a wide array of symptoms, including itching, dryness, erythema, crusted lesions, and superficial inflammation. Topical steroid cream or ointment with proper washing is a primary treatment approach for AD. Nonsoap-based personal washing or syndet bars containing synthetic detergents or surfactants are milder than soaps; thus, they are widely used by patients with a variety of skin conditions, including AD. The primary goals of this study were to determine the compatibility of syndet bar use with the therapy of AD and the potential benefits of syndet bars compared with subjects' usual cleansing products, mostly soap bars. In this evaluation, 50 subjects (14 subjects were aged ≤15 years) with mild AD on a stable treatment regimen were recruited and asked to use 1 of 2 syndet bars as part of their normal shower routine for 28 days. The severity of eczematous lesions, skin condition (dryness, erythema, texture), and hydration were evaluated at baseline and after 28 days of syndet application by investigators and subjects. Syndet bar use reduced the severity of eczematous lesions, improved skin condition, and maintained hydration. Overall, the results of this study indicate that syndet formulations are compatible with the therapy of AD.*

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Atopic dermatitis (AD) is a recurring inflammatory skin disease characterized by marked pruritus that usually develops in early childhood.[1-4] The prevalence of AD, also referred to as eczema, is estimated to affect up to 20% of the general population.[5,6] Eczematous lesions disrupt the natural moisture barrier of the stratum corneum (SC), predisposing the skin to dryness or xerosis.[7] Xerosis, another common feature of AD, generally is caused by environmental factors (eg, temperature, wind, humidity, sun exposure) or contact with detergents but, with AD, often accompanies active inflammatory lesions of the skin.[8,9] Eczematous lesions and xerosis are among a cluster of concurrent conditions associated with AD.

Gentle cleansing, a key component of AD management, may relieve skin inflammation but also may expose the skin to irritating surfactants.[10,11] AD patients demonstrate increased sensitivity to irritation[12] and, thus, should consider the irritancy potential of personal wash products. Irritancy potential is related to the type and amount of surfactant used in the product's formulation.[13,14] Soap is a relatively harsh and drying surfactant. Soap-based wash products often dry and irritate the skin, leading to

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erythema and itchiness, which together often exacerbate the inflammation and dryness of AD.

A number of studies have shown that synthetic detergent (syndet) cleansing bars are generally milder than soap-based products and help maintain the structural integrity and moisture of the SC.[13] The major ingredient commonly found in syndet bars is sodium cocoyl isethionate, a mild synthetic detergent (surfactant).[13] Other ingredients include high levels of free fatty acids, esters, and waxes.[14] The formulation of syndet bars provides mild cleansing combined with moisture retention and clinically has been shown to be less irritating to skin than soap-based formulations.[14] Our 28-day study evaluated the effects of syndet bar use on the severity of eczematous lesions, hydration, and overall appearance, among other skin attributes, in a group of AD subjects.

## Materials and Methods

Two syndet bars (Syndet 1 and Syndet 2) were evaluated for compatibility with eczematous lesions of the skin in subjects with mild AD, which was defined as mild erythematous lesions and mild papulation involving a small area. Both syndet bars underwent testing to confirm market standard of quality and stability and had similar compositions—including the same surfactant sodium cocoyl isethionate—with different emollient mixtures in their 25% cream blends (Table 1).

*Subjects*—Fifty subjects (14 subjects were aged ≤15 years) with mild AD were enrolled by referral from the Divisions of Dermatology and Clinical Pharmacology at Robert Wood Johnson Medical School in New Brunswick, New Jersey. After providing informed consent, subjects were divided into 2 groups of 25 and further subdivided by age (≥16 years or ≤15 years)(Table 2).

*Design*—This was a double-blind parallel group evaluation conducted from August 2000 to January 2001 and was approved by the local Institutional Review Board under Code of Federal Regulations, Title 21, Parts 50 (protection of human subjects) and 56 (institutional review boards). Product assignment was balanced within 2 groups of 25 subjects.

Subjects were asked to use their assigned product at home for 4 weeks during routine showering. Subjects could continue their stable AD regimen but were not to use new medications while participating in the trial. They were asked to discontinue using any cleansers for the whole body but could continue using their usual facial cleansers, moisturizers, and cosmetics except on the assessment days. Subjects were able to continue their usual bathing practices; as a result, bathing practices among subjects were

Table 1.

**Principal Ingredients of Syndet Bars Tested***

| Syndet 1 |
|---|
| Sodium cocoyl isethionate |
| Stearic acid |
| Polyethylene glycol |
| Sodium stearate |
| Sodium isethionate |
| Coconut fatty acid |
| Sodium chloride |
| Titanium dioxide |
| Tetrasodium EHDP |
| Tetrasodium EDTA |
| **Syndet 2** |
| CNO fatty acid isethionate (sodium cocoyl isethionate) |
| Stearic acid |
| Sodium isethionate |
| Coconut fatty acid |
| Sodium stearate |
| Sodium chloride |
| Titanium dioxide |
| EHDP |
| Tetrasodium EDTA |

*EHDP indicates ethane-1-hydroxy-1,1-diphosphonate; EDTA, ethylenediaminetetraacetic acid; CNO, coconut oil.

Table 2.

**Patient and Product Assignment (N=50)***

| Subjects | Group 1 | Group 2 |
|---|---|---|
| ≥16 years old | 17 | 19 |
| ≤15 years old | 8 | 6 |

*Subjects in group 1 used Syndet 1 and subjects in group 2 used Syndet 2.

Table 3.

**Physician's Clinical Assessment Scales for Erythema, Dryness, and Texture***

| Erythema |
|---|
| 0=no redness |
| 1=slight redness, spotty and diffuse |
| 2=moderate and uniform redness |
| 3=intense redness |
| 4=fiery red, with edema |
| **Dryness** |
| 0=no signs of dryness |
| 1=slightly dry |
| 2=moderately dry |
| 3=extremely dry |
| 4=severe dryness with cracks and fissures |
| **Texture** |
| 0=very smooth to the touch |
| 1=slightly rough |
| 2=moderately rough |
| 3=extremely rough |

*Total score is a sum of erythema, dryness, and texture grades.

Table 4.

**Product Satisfaction Questionnaire (N=50)**

| |
|---|
| Overall, how much do you like or dislike the test product?* |
| The test product is a high-quality product.† |
| The test product does not irritate your skin.† |
| The test product leaves your skin feeling clean and fresh.† |
| The test product leaves your skin feeling soothed.† |
| The test product rinses off quickly and easily.† |
| The test product has a rich creamy lather.† |
| The test product makes your skin feel healthy.† |
| Which product (old product vs test product) do you like best?‡ |
| Which product (old product vs test product) would you prefer to use in the future?‡ |

*1=dislike it very much, 5=like it very much.
†1=disagree completely, 5=agree completely.
‡1=old product, 2=test product.

not uniform during the course of this study, except for their use of Syndet bars 1 and 2 instead of their usual cleansing bar.

*Outcome Measures*—Subjects' eczematous lesions (whole body) and unaffected skin (forearm and calf) were evaluated at baseline and day 28 using the Eczema Area Severity Index (EASI) performed by a blinded physician,[15] skin clinical assessment, and a measure of skin moisture. There also was a telephone interview at week 2 to assess adherence and inquire about adverse events.

*Physician's Clinical Assessment*—Dermatologists evaluated the skin of the unaffected area on the right inner proximal forearm and lateral aspect of the right lower leg (sites with no eczematous lesions) for erythema, dryness, and texture at baseline and day 28 using the grading scales shown in Table 3. An average value for both sites was assigned, representing the unaffected skin value for that day.

*Skin Hydration Evaluation*—SC hydration was measured using Moisture Checker MY-707S, which compares the unique dielectric constant of water to that of other tissues in the SC. A probe was placed on the inner proximal aspect of the right forearm (free of eczematous lesions) at constant pressure. The final value representing skin hydration of the forearm of each patient was an average of 3 readings obtained at baseline and day 28.

*Self-Assessment Questionnaire*—A self-assessment questionnaire containing 9 items (itching, tightness, irritation, tingling, overall dryness, shiny complexion, smoothness, softness, overall appearance) provided subjects an opportunity to rate their skin condition on the evaluation days. Each item was scored on a 10-point scale ranging from 0 (least) to 9 (most). The responses were experience based, and visual guides were not used.

Table 5.

## Eczema Area Severity Index Scores for Syndet 1 and Syndet 2*†

| | Syndet 1 | | | | Syndet 2 | | | |
|---|---|---|---|---|---|---|---|---|
| | Baseline | Day 28 | Change | *P* value | Baseline | Day 28 | Change | *P* value |
| Overall Mean EASI | 2.20 | 1.58 | -0.62 | .02 | 2.09 | 1.31 | -0.78 | .004 |
| Subjects Aged ≤15 Years Mean EASI | 1.63 | 1.06 | -0.57 | .17 | 3.32 | 1.33 | -1.99 | .02 |
| Subjects Aged ≥16 Years Mean EASI | 2.49 | 1.8 | -0.69 | .06 | 1.68 | 1.31 | -0.37 | .08 |

*EASI indicates Eczema Area Severity Index. These are the average endpoint EASI values.
†*P* values indicate the level of significance of the mean change from baseline to day 28.

Table 6.

## Physician's Clinical Assessment Scores for Syndet 1 and Syndet 2*†

| | Syndet 1 | | | | Syndet 2 | | | |
|---|---|---|---|---|---|---|---|---|
| | Baseline | Day 28 | Change | *P* value | Baseline | Day 28 | Change | *P* value |
| Overall Mean | 2.88 | 1.92 | -0.96 | .01 | 2.90 | 2.19 | -0.71 | .03 |
| Subjects Aged ≤15 Years Mean | 2.31 | 1.63 | -0.68 | .25 | 2.58 | 1.83 | -0.75 | .26 |
| Subjects Aged ≥16 Years Mean | 3.16 | 2.06 | -1.10 | .02 | 3.00 | 2.31 | -0.69 | .06 |

*The average endpoint value of the sum of skin surface erythema, dryness, and texture.
†*P* values indicate the level of significance of the mean change from baseline to day 28.

*Product Satisfaction Questionnaire*—A product satisfaction questionnaire was administered to subjects at day 14 and day 28. The scale and its content are shown in Table 4.

*Statistical Analysis*—Paired *t* tests were conducted to determine whether differences existed between the mean evaluation values before and after syndet application. All statistical calculations were performed using the Stata® statistical software package, and the level of significance for statistical tests was $P \leq .05$.

## Results

*Prior Cleansing Products and AD Medications*—Prior to the study, 35 subjects (70%) used soap as their routine body wash product, 5 subjects (10%) used liquid body wash, and 10 subjects (20%) used a variety of other body wash products. Twenty-one subjects (42%)

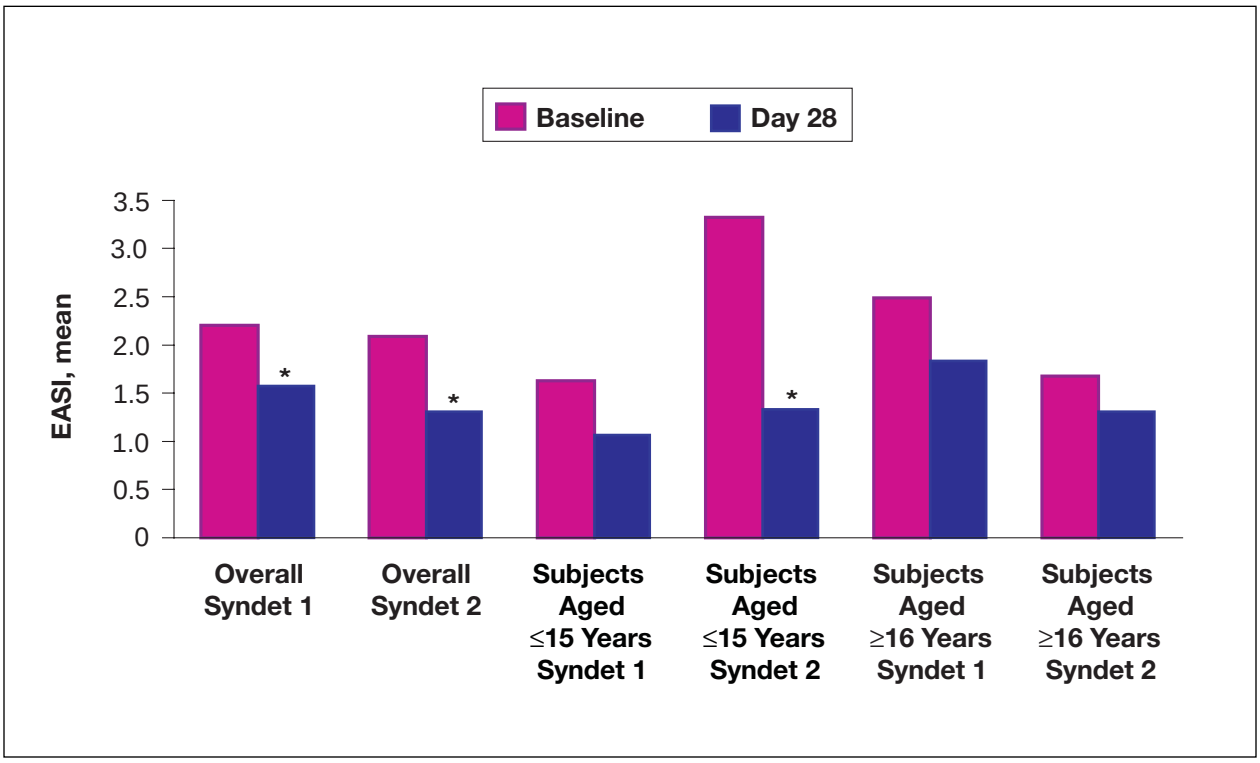


**Figure 1.** Eczema Area Severity Index (EASI) data including the overall means and means for subjects aged ≤15 years and ≥16 years. Asterisk indicates significant decrease from baseline to day 28 (*P*=.02, overall Syndet 1 and subjects aged ≤15 years Syndet 2; *P*=.004, overall Syndet 2).

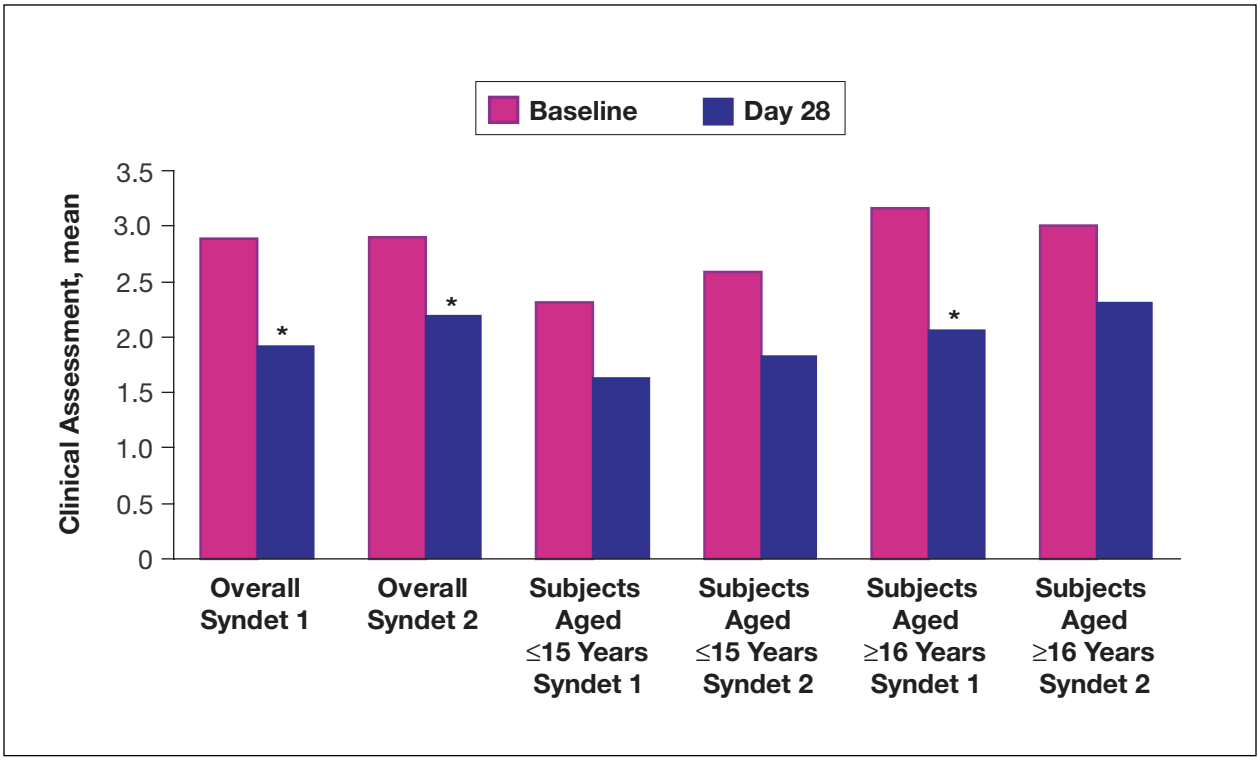


**Figure 2.** Physician's clinical assessment including overall means and means for subjects aged ≤15 years and ≥16 years. Asterisk indicates significant decrease from baseline to day 28 (*P*=.01, overall Syndet 1; *P*=.03, overall Syndet 2; *P*=.02, subjects aged ≥16 years Syndet 1).

Table 7.

## Skin Hydration Scores for Syndet 1 and Syndet 2*†

| | Syndet 1 | | | | Syndet 2 | | | |
|---|---|---|---|---|---|---|---|---|
| | Baseline | Day 28 | Change | *P* value | Baseline | Day 28 | Change | *P* value |
| Overall Mean | 32.1 | 32.5 | 0.4 | .61 | 31.0 | 30.5 | -0.5 | .42 |
| Subjects Aged ≤15 Years Mean | 32.4 | 32.9 | 0.5 | .70 | 28.9 | 30.6 | 1.7 | .32 |
| Subjects Aged ≥16 Years Mean | 32.0 | 32.3 | 0.3 | .75 | 31.7 | 30.5 | -1.2 | .08 |

*The average endpoint value of skin moisture.
†*P* values indicate the level of significance of the mean change from baseline to day 28.

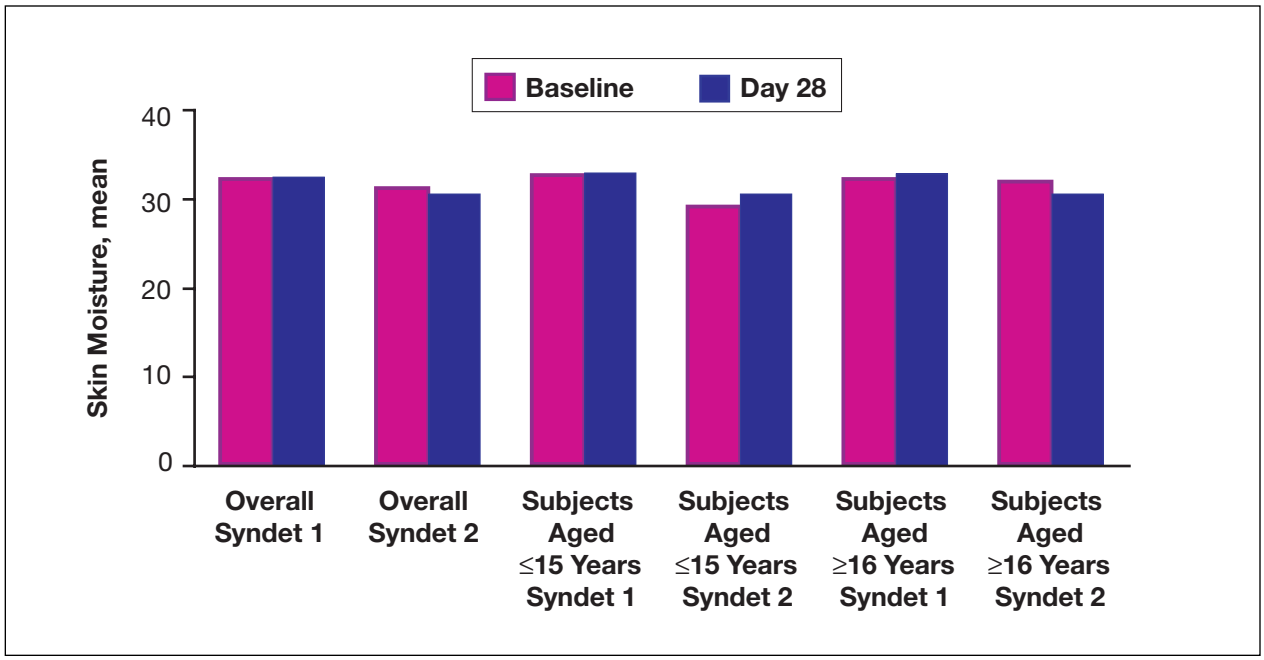


**Figure 3.** Skin hydration evaluation including overall means and means for subjects aged ≤15 years and ≥16 years.

did not use any topical medication for their eczematous lesions and 29 subjects (58%) used corticosteroid creams or ointments for months or years without improvement; therefore, a chronic course was unpredictable.

*Disease Severity*—The EASI evaluation revealed significant decreases in disease severity in the whole group after 28 days of applying Syndet 1 (*P*=.02) and Syndet 2 in the whole group (*P*=.004) and subjects aged ≤15 years (*P*=.02) who used Syndet 2 from baseline to day 28 (Table 5; Figure 1).

*Physician's Clinical Assessment*—There was significant improvement in the clinical assessment in the whole groups for both Syndet 1 (*P*=.01) and Syndet 2 (*P*=.03) and in the adult group using Syndet 1 (*P*=.02)(Table 6; Figure 2).

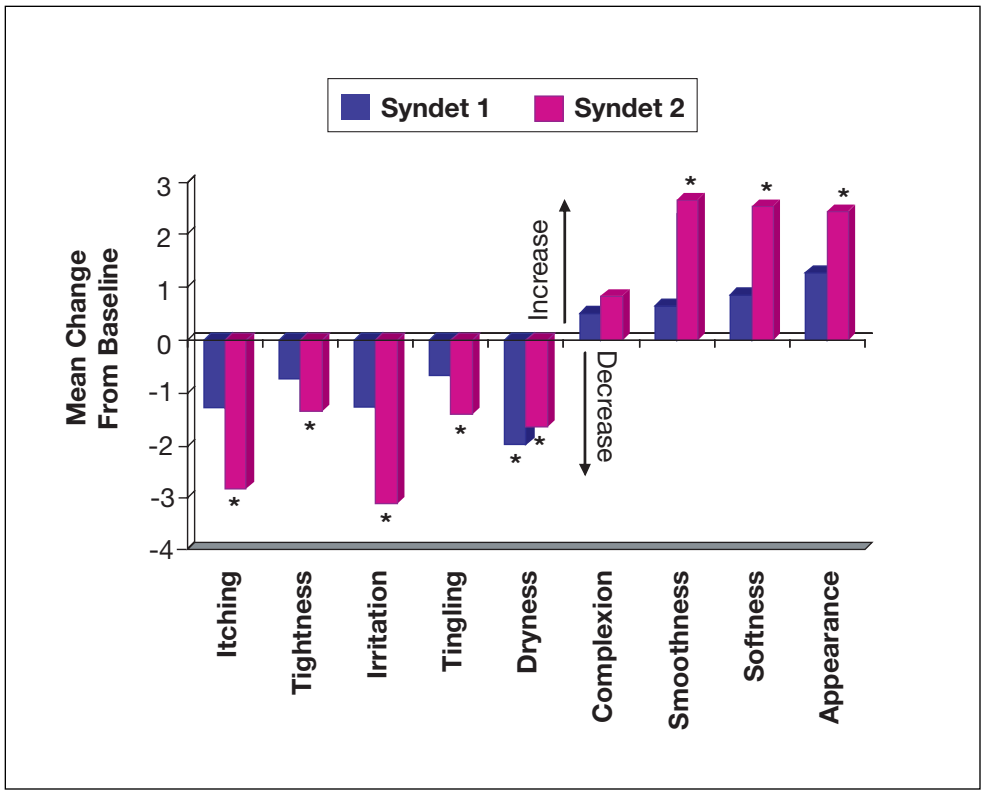


**Figure 4.** Patient self-assessment results. Asterisk indicates significant difference from baseline ($P<.05$).

*Skin Hydration Evaluation*—In general, a comparison of mean scores of skin moisture at baseline was not significantly different at day 28 for either syndet bar (Table 7; Figure 3). Thus, skin moisture was maintained during the course of the evaluation.

*Self-Assessment Questionnaire*—Compared with baseline values, perceptions of skin conditions significantly improved ($P<.05$) in all domains except complexion after 28 days of using Syndet 2, while overall dryness significantly decreased ($P<.05$) after 28 days of using Syndet 1 (Figure 4).

*Product Satisfaction Questionnaire*—Overall, subjects demonstrated a high degree of satisfaction with the syndet products (Table 4). After using Syndet 1, there were marked increases in the mean scores for the categories "is a high-quality product" and "makes your skin feel healthy." After using Syndet 2, there were marked increases in the mean scores for the categories "leaves your skin feeling soothed" and "rinses off quickly and easily." Forty-two subjects (84%) expressed their intent to use these syndet bars in place of their usual products if available on the market.

## Comment

This study showed a clear benefit for AD patients, including subjects aged ≤15 years and ≥16 years, during the 28 days in which they used a syndet cleansing bar as a replacement for their routine daily cleansing product, which was soap in 35 subjects (70%). Uncontrolled AD may lead to erythema and secondary bacterial infections. Mild AD generally improves with simple maintenance measures such as gentle skin cleansing and moisturization, which can greatly reduce persistent symptoms.[3,16]

In the present study, after one month of using syndet products, the severity of eczematous lesions in subjects with AD was reduced and erythema improved. All subjects using Syndet 2 reported the degree of itching, tightness, irritation, tingling, and overall dryness was significantly decreased ($P<.05$), and skin smoothness, softness, and overall appearance significantly increased ($P<.05$) from baseline to day 28. Differences in the responses of subjects aged ≤15 years and ≥16 years were apparent and possibly related to physiological differences based on age.

Skin dryness is a major cause of pruritus in AD; the associated scratching drives the release of proinflammatory mediators that make itching worse and cause skin inflammation.[2] The scratching and inflammation may cause disruptions in the SC. Atopic dry skin demonstrates abnormally high levels of transepidermal water loss, the hallmark sign of a dysfunctional SC barrier.[17,18] The SC barrier consists of highly specialized and protein-rich keratinocytes

(corneocytes) embedded in a continuous matrix of lipids, primarily ceramides, fatty acid, and cholesterol.[19] Studies have demonstrated an abnormal ceramide metabolism in patients with AD, suggesting that the biochemical mechanisms that maintain optimal hydration levels and the ultrastructural integrity of the SC barrier are impaired in AD patients.[20,21] These and other barrier abnormalities highlight the need for cleansers that minimally perturb the SC protein and lipid milieu.

Given the diminished irritant threshold in AD patients, the choice of cleanser is an important component in the overall skin care regimen.[17] Soap-based formulations can dry skin and may cause erythema and transepidermal water loss, further exacerbating the skin dryness and itching of AD.[14] Syndet formulations, by minimally interacting with SC proteins and lipids, help maintain SC hydration and therefore are well suited to counter the dryness and latent secondary skin inflammation associated with eczematous lesions.[2] Importantly, the benefits of syndet use as compared with soap have been demonstrated in a number of studies.[7,18]

## Conclusion

These results indicate that the 2 syndet bar formulations used in this study are effective, mild, nondrying cleansers compatible with mild AD. Given the potential harshness of soap-based surfactants, syndet bars of the type tested here offer a gentler cleansing alternative for patients with skin conditions that increase susceptibility to skin irritation.

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