

Efficacy of the combined use of a mild foaming cleanser and moisturizer for the care of infant skin

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Objective: Despite the application of skin care treatments, many infants have skin problems such as dryness and erythema. We proposed a new combination skin care for infants which consisted of a foaming cleanser with lower surfactant activity and moisturizers that contained pseudo-ceramide.

Subjects and methods: A total of 50 infants (age: 3–24 months) with insignificant levels of dry skin were enrolled in this usage trial. The parents washed the infants with the test cleanser while bathing and then applied the moisturizer (lotion or cream) containing pseudo-ceramide. Prior to and following the 4-week usage period, visual evaluation of the skin condition was conducted by a dermatologist, in addition to instrumental analysis.

Results: Erythema and papule, accompanied by dryness, were commonly observed at week 0. However, by week 4, these symptoms significantly improved; the condition of none of the subjects deteriorated. The number of infants with lower cutaneous barrier function and higher skin pH decreased. The parents of the infants recognized improvements in the skin symptoms and were appreciative of the test materials.

Conclusion: The combined usage of the foaming cleanser with lower surfactant activity and a moisturizer containing pseudo-ceramide may be effective in maintaining healthy infant skin and ameliorating the skin symptoms.

Keywords: infant, cleanser, lotion, cream, dryness

Introduction

Infant skin is thinner and produces less sebum than adult skin.^{1,2} Thus, it is fragile and has a decreased ability to defend against environmental factors, which can easily lead to skin symptoms such as dry skin and erythema.^{3,4} Recently, skin care from the neonatal stage was proposed to prevent the induction of skin symptoms and atopic dermatitis.^{5–7} In Japan, almost 100% of infants were washed with cleansers during a daily bath, and a moisturizer was applied for most of them (60% in the winter and 30% in the summer). However, most of the infants experienced a skin rash at least once a year.^{8,9} These results suggested that many cleansers and moisturizers may be insufficient for infant skin care.

Skin cleansing is a major factor for the induction of skin dryness or irritation.¹⁰ Infant skin has a fragile stratum corneum and less sebum; thus, a general cleanser, which has less effect on adult skin, may induce skin symptoms. Excessive rubbing during cleansing also induces skin eruption and dryness. Washing with fine foam can reduce friction against the skin and surfactant penetration into the skin.¹¹ It is hard to produce a fine foam without the use of a sponge or towel, but the use of these can

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naturally harm fragile infant skin because of excessive rubbing. The benefits of a weakly acidic base for cleansers have been also reported.^{12,13} We have therefore designed a mild acidic cleanser with less surfactant, which could be used as a fine-textured foam through a dispenser.

Generally, glycerin and petrolatum are used as moisturizers, but they are easily lost from the skin surface. Ceramide is a major component of intercellular lipids and crucial for cutaneous water-holding capacity and barrier function. Imokawa et al¹⁴ designed pseudo-ceramide to compensate for natural ceramide and reported the efficacy of topical application of this pseudo-ceramide against atopic dermatitis skin or sensitive skin.¹⁵ Thus, we used pseudo-ceramide in our moisturizer for infant skin care. We prepared two formulations, a lotion (oil-in-water [O/W] type) and a cream (water-in-oil [W/O] type), to assess the potential differences in utility and effects on infant skin of those formulations.

In the current study, we evaluated the efficacy of the combination skin care, which consisted of a high-foam, mildly acidic body cleanser with a lower detergent activity and a moisturizer (lotion or cream) that contained pseudo-ceramide, on infant skin.

Subjects and methods

Subjects

The subjects comprised Japanese infants whose family had enrolled as research participants with a research company (DRC Co., Ltd., Osaka, Japan), aged 3–24 months, with mild dry skin. The infants were screened by well-trained specialists, and those requiring medical treatments with pharmaceutical preparation were excluded. This study adhered to the tenets of the Declaration of Helsinki. This controlled usage trial was reviewed and approved by the ethics committee of the Kao Corporation (#632-20150127). Trial registration number: UMIN000026877. A formal written informed consent to participate in this study was obtained from their parents.

Test materials

Body cleanser: the cleanser (pH 6.0) was based on the surfactant sodium cocoyl glutamate at a lower concentration compared with general cleansers; consequently, it had a lower cleansing ability (65–75% of the sebum cleansing ability of general body cleansers, analyzed by using artificial sebum [data not shown]). For usage, the cleanser was supplied as a fine foam in a dispenser.

Moisturizer (lotion): this O/W lotion (pH 4.8) contained synthetic pseudo-ceramide and glycerin.

Moisturizer (cream): this W/O cream (aqueous phase; pH 4.0) contained synthetic pseudo-ceramide and glycerin.

All test materials were provided by the Kao Corporation (Tokyo, Japan). All skin care materials were colorant free and fragrance free. Full ingredients of the materials are listed in Table 1.

Study protocol

This trial was performed from March to April in 2015 in Kanagawa, Japan. The infants were assigned to two groups that were approximately equal in age (in months), sex, and skin condition by well-trained specialist. One group (lotion group) used the test cleanser and the test lotion, and the other group (cream group) used the test cleanser and the test cream. The parents washed their infant's body with the test cleanser instead of their preferred cleansers while bathing every day, which was followed by the topical application of the test moisturizer (either lotion or cream) on at least three areas of the body (the face, buttocks, and the flexor of the arm) instead of their commonly used moisturizers. The parents were allowed to apply the test moisturizer to any other areas of the body, at any time in addition to bathing time, if needed. The usage of other skin care materials was prohibited on any part of the body. The parents recorded the usage of the materials and the skin condition of the infants every day in a diary log. Simultaneously, the satisfaction of the parents

Table 1 Full ingredient list of the test materials

Foaming body wash

Water, glycerin, propylene glycol, PEG-150, sodium cocoyl glutamate, lauryl hydroxysultaine, laureth-21, disodium EDTA, laureth-6 carboxylic acid, sodium hydroxide, malic acid, sodium benzoate

O/W lotion including synthetic pseudo-ceramide

Water, glycerin, cetyl-PG-hydroxyethyl palmitamide, squalane, neopentyl glycol dicaprinate, dimethicone, polysorbate 60, cholesterol, sorbitan stearate, xanthan gum, sodium methyl stearyl taurate, succinic acid, sodium benzoate, cetyl alcohol, stearyl alcohol, methylparaben

W/O cream including synthetic pseudo-ceramide

Water, glycerin, cyclopentasiloxane, cetyl-PG hydroxyethyl palmitamide, squalane, isostearyl glyceryl ether, polyglyceryl-2 diisostearate, cholesteryl isostearate, dimethicone, PEG-5 hydrogenated castor oil, magnesium sulfate, succinic acid, PEG-12 dimethicone, dextrin palmitate, sodium hydroxide, methylparaben

Abbreviations: EDTA, ethylenediaminetetraacetic acid; O/W, oil-in-water; W/O, water-in-oil.

of each infant was determined by a questionnaire at week 4. Parents were advised to discontinue use of the test materials if they found any difficulties in using them, for sickness or other reasons, and to resume use after recovery.

Evaluation

The visual and instrumental evaluations were performed prior to the start of the trial (week 0) and after 4 weeks of usage (week 4). All infants were bathed 1 day prior to the initial evaluation. After that bath, the application of any moisturizer was prohibited until all skin assessments and instrumental evaluations were completed. Prior to the evaluation, the infants were undressed and acclimatized to the room conditions ($24.5 \pm 0.5^\circ\text{C}$ and $45 \pm 5\%$ relative humidity) for approximately 10 min.

Visual skin assessments

The skin condition of the entire body was visually evaluated by a dermatologist. Dryness, desquamation, erythema, papules, macerations, scratch marks, crust, erosions, and pigmentation were graded in a five-step grading scale, based on severity and size, as follows: none = 0, slight = 1, mild = 2, moderate = 3, and severe = 4. Photo images of the skin symptoms were recorded using a digital camera (Nikon 600D; Nikon Corporation, Tokyo, Japan). The efficacy of this combination skin care was assessed by visual evaluation on the face, flexor of the arm, and buttocks.

Judgment of safety, overall improvement, and usefulness

At the end of week 4, a dermatologist judged the safety, overall improvement rate, and usefulness of this skin care. The safety was comprehensively judged according to the presence or absence of an adverse event on the whole body according to the diary of each parent and by an inquiry on each examination day. Safety was judged as safe, suspicious, not safe, or undetermined. Overall improvement rates were comprehensively judged based on the changes in skin symptoms on three designated areas of the body as markedly improved, improved, slightly improved, unchanged, or aggravated. The usefulness was comprehensively judged, based on the overall improvement and the safety at 4 weeks, as very useful, useful, slightly useful, useless, and harmful.

Instrumental measurements

Transepidermal water loss (TEWL), cutaneous capacitance, and skin surface pH at the three designated areas were analyzed using a Vapometer® (Delfin Technologies, Kuopio,

Finland), a Corneometer® (Courage + Khazaka Electronic GmbH, Cologne, Germany), and a pH meter (Horiba, Kyoto, Japan), respectively. These measurements were conducted avoiding any lesions except skin dryness and scaling. The average values of three measurements were used for analysis.

Statistical analysis

Changes over time of the scored data and measured data were determined by the Wilcoxon signed-rank test.

Results

Participants

Initially, 53 infants attended this evaluation. However, during the study, one infant in each group was withdrawn because of their skin condition. Based on interviews with the parents of the two withdrawn infants, the dermatologist judged that these skin problems were not related to the study treatment. In addition, for the evaluation at week 4, the skin condition of one subject in the cream group could not be evaluated. Therefore, a total of 50 subjects were involved in the analysis: 25 in the lotion group and 25 in the cream group.

At the week 0 evaluation, all infants had some skin symptoms. Dryness and/or desquamation were observed in 44 and 37 of the 50 infants, respectively. Erythema and papules were also commonly observed symptoms (Table 2). Although most infants had skin symptoms, most of the symptoms had a score of 1, and no symptoms were given a score of 4 (data not shown). As a result of diagnosis by dermatologist, nine infants had mild atopic dermatitis but required no medical treatment with pharmaceutical preparation.

Usage

All infants had their body washed, except for the face and the head. Three infants in the lotion group and two infants in the cream group did not have their face washed with the test cleanser. All infants in the lotion group and 24 infants in the cream group received an application of the test moisturizer in the three designated areas; in one infant in the cream group, the moisturizer was applied on the face and buttocks, but not on the flexor of the arm. Thus, the efficacy of combination skin care on each designated area was obtained from the infants who used both cleanser and moisturizer on each area: (face: lotion group = 22, cream group = 23; flexor of the arm: lotion group = 24, cream group = 25; buttocks: lotion group = 25, cream group = 25).

Meanwhile, many infants received applications of the test moisturizer on the chest and abdomen, the back, and the extensor of the arm almost every day in both groups.

Visual assessment

In week 4, the number of infants with skin symptoms in the three designated areas decreased. The number of infants with skin symptoms on the face decreased from 21 to 16 in the

lotion group (n=22) and from 22 to 11 in the cream group (n=23). Dryness, desquamation, erythema, and papules improved significantly in both groups (Figure 1). A case demonstrating the marked response in face symptoms is

Table 2 Prevalence of each skin symptom at week 0 based on visual skin assessment by dermatologist (number of infants)

	Dryness	Desquamation	Erythema	Papules	Maceration	Scratching	Crust	Erosion	Pigmentation	Total
Face	38	28	38	25	0	12	4	2	0	48
Flexor of arms	9	10	24	8	9	2	0	0	0	31
Buttock	13	12	8	7	0	2	0	0	0	18
Head	3	4	3	2	0	1	0	0	0	7
Neck	19	16	20	15	4	5	0	1	0	35
Chest and abdomen	16	11	16	22	0	5	1	1	0	36
Back	27	17	21	28	0	9	0	0	0	42
Extensor of arms	21	14	18	12	0	4	0	0	0	31
Hand and wrist	7	2	6	8	0	2	0	0	0	14
Extensor of legs	18	10	18	10	3	6	2	0	2	32
Flexor of legs	18	10	11	13	1	8	2	0	0	29
Foot and ankle	14	8	8	10	0	4	2	0	1	22
Total	44	37	48	46	13	23	8	2	2	50

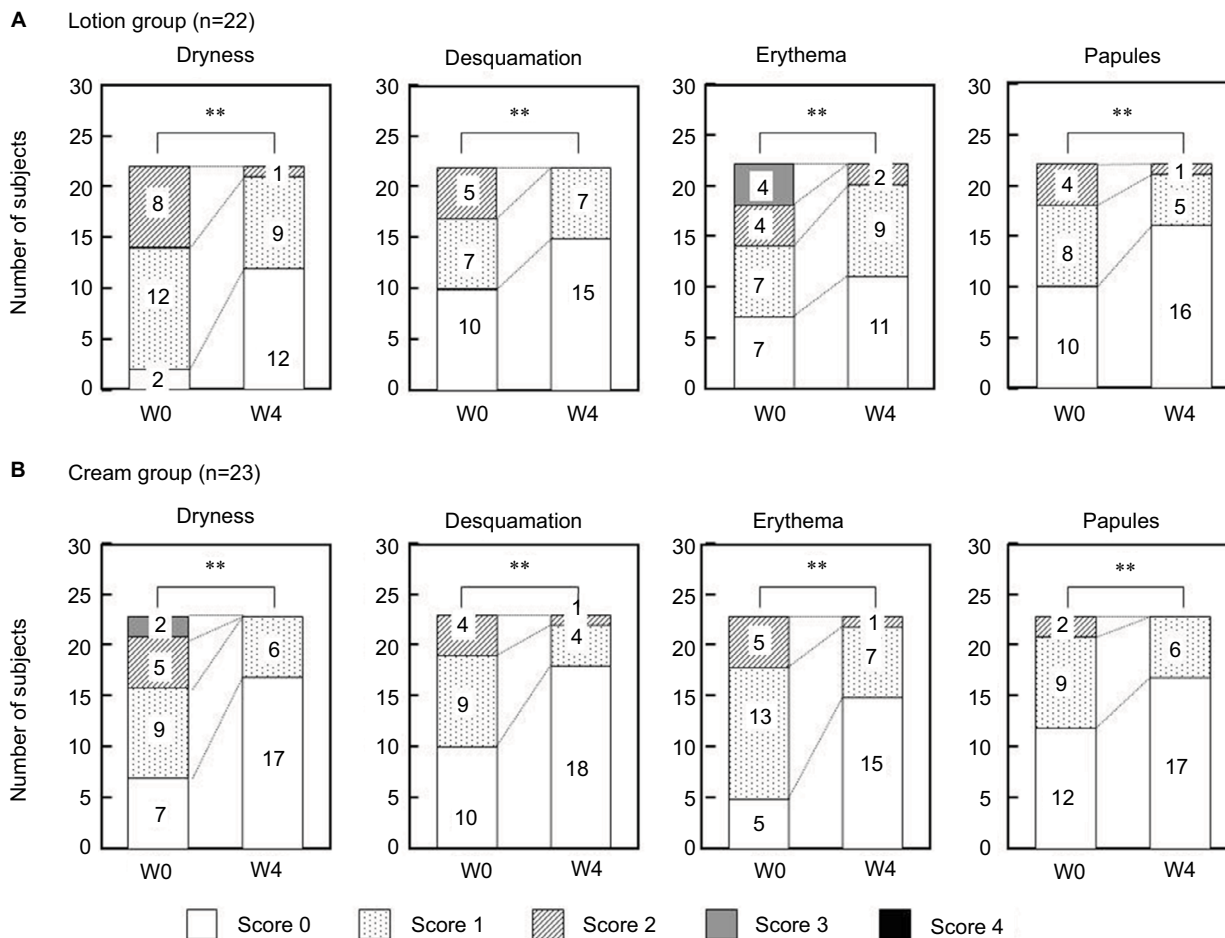


Figure 1 Evaluation of dryness, desquamation, erythema, and papules following the usage of the cleanser and moisturizer on the face. **Notes:** The numeric values in the columns show the number of subjects. ******p < 0.01 as a significant improvement from week 0 (W0) to week 4 (W4) by the Wilcoxon signed-rank test. **(A)** Lotion group (n=22), **(B)** cream group (n=23).

shown in Figure 2. The subject, a female infant in the lotion group, was 8 months old at week 0 and was not diagnosed with atopic dermatitis.

The number of infants with skin symptoms on the flexor of the arm decreased from 15 to 5 in the lotion group (n=24) and from 15 to 5 in the cream group (n=25). The skin symptoms were less severe than for the face but dryness, desquamation, erythema, and papules improved in both groups (Figure 3). Maceration, which was typically observed on

week 0 (lotion group: 2, cream group: 6), was also diminished in week 4 in both groups.

The skin symptoms on the buttocks were the mildest of the three designated areas in week 0. These skin symptoms improved and almost disappeared on week 4 (Figure 4).

Instrumental analysis

Following the 4-week trial, TEWL decreased in the three designated areas in both groups (Figure 5A and B). Although there were no significant differences in the TEWL of the face (cheek), the number of infants with a TEWL greater than 25 g/m²h decreased from 9 to 4 in the lotion group and from 9 to 5 in the cream group. The number of infants with a TEWL higher than 20 g/m²h decreased: for flexor of the arm, the number decreased from 6 to 3 in the lotion group and from 7 to 4 in the cream group, and for buttocks, the number decreased from 10 to 4 in the lotion group and from 10 to 2 in the cream group.

The capacitance measurements did not show any significant changes in any area of the body in either treatment group.

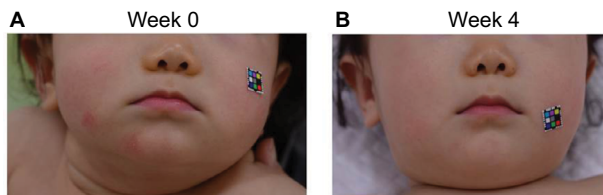


Figure 2 Typical clinical features of facial skin in an 8-month-old female infant. **Notes:** The infant had dryness (score 1), desquamation (score 3), erythema (score 3), and papules (score 1) at week 0, but improvements were observed at week 4: dryness (score 0), desquamation (score 1), erythema (score 1), and papules (score 0). (A) Week 0, (B) week 4.

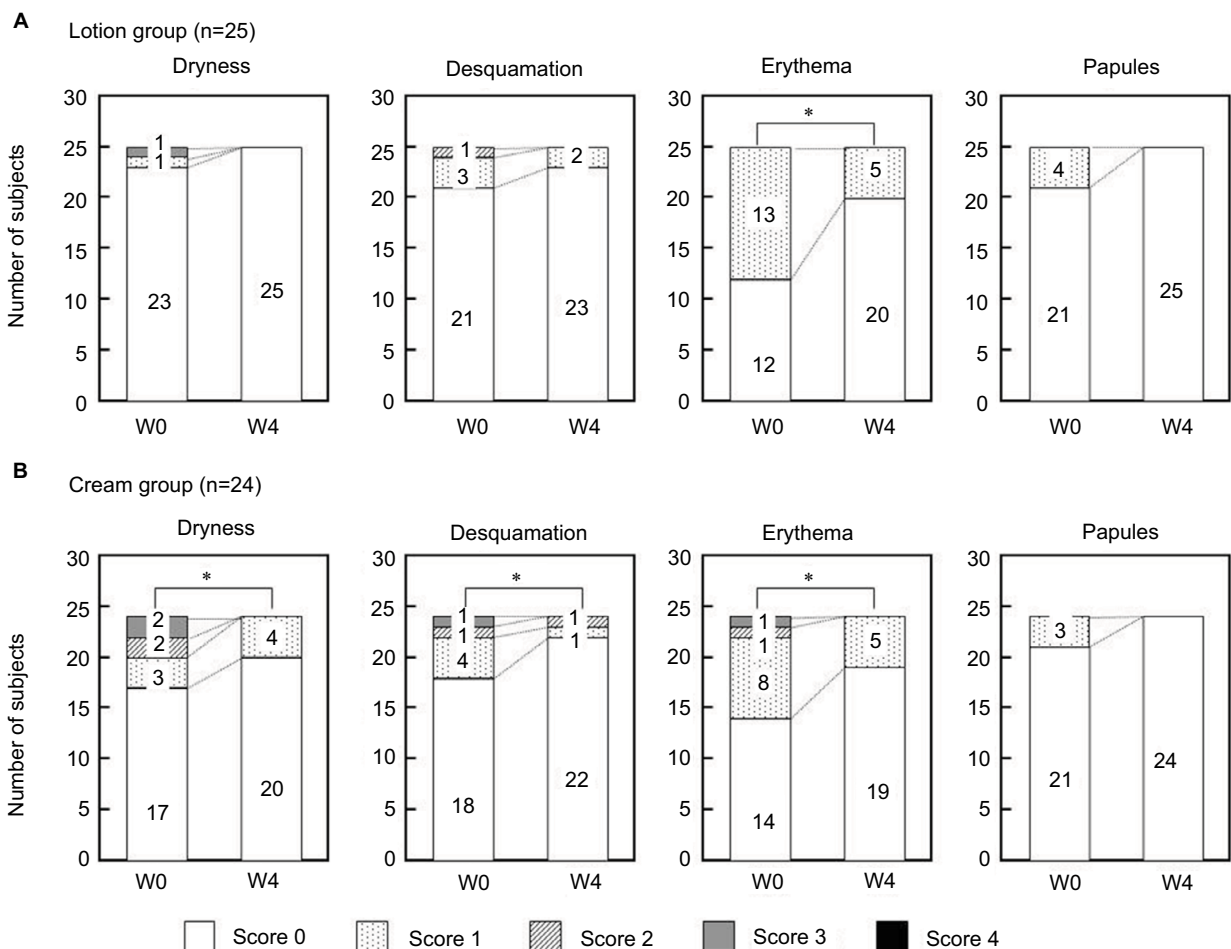


Figure 3 Evaluation of dryness, desquamation, erythema, and papules following the usage of the cleanser and moisturizer on the buttocks. **Notes:** The numeric values in the columns show the number of subjects. *p < 0.05 as a significant improvement from week 0 (W0) to week 4 (W4) by the Wilcoxon signed-rank test. (A) Lotion group (n=25), (B) cream group (n=24).

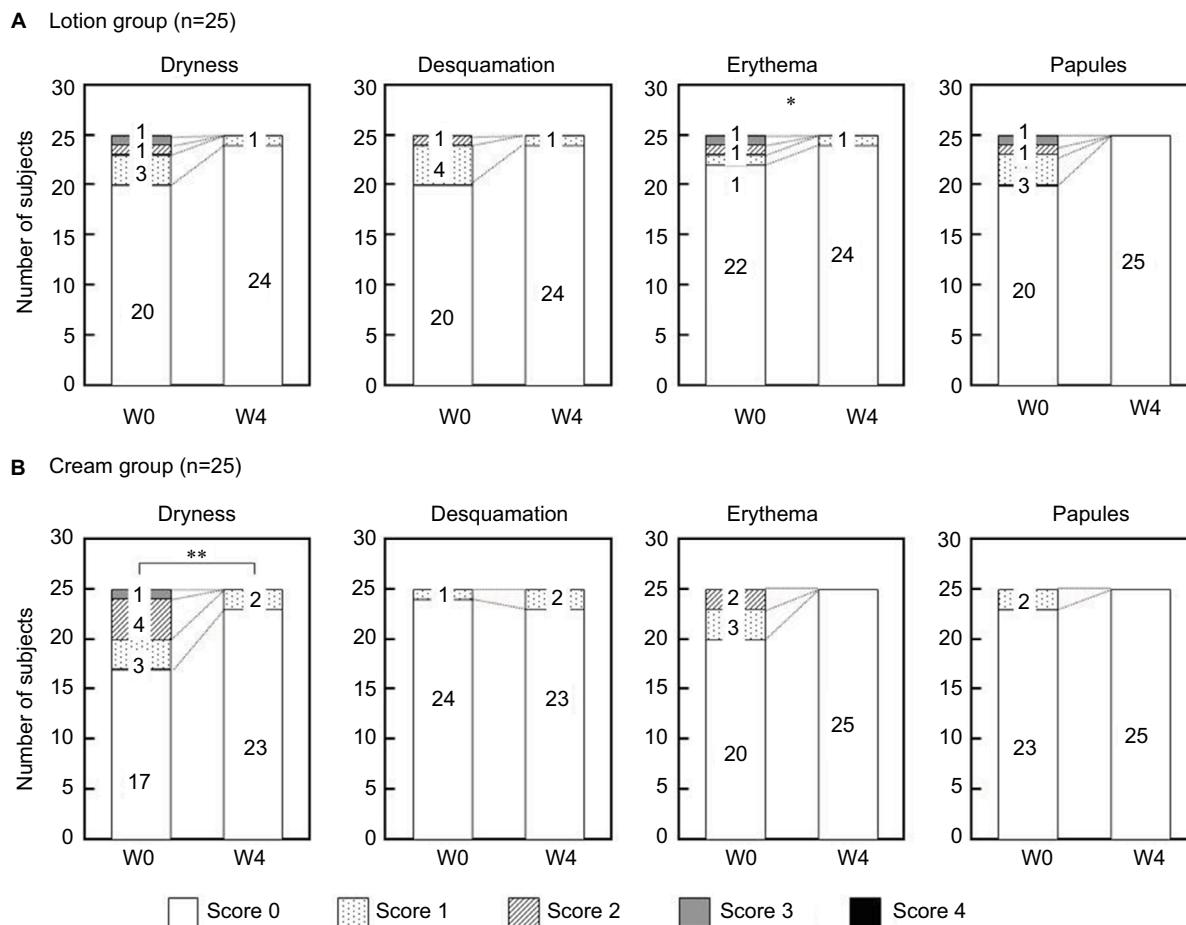


Figure 4 Evaluation of dryness, desquamation, erythema, and papules following the usage of the cleanser and moisturizer on the flexor of the arms.

Notes: The numerical values in the columns show the number of subjects. $**p < 0.01$ as a significant improvement from week 0 (W0) to week 4 (W4) by the Wilcoxon signed-rank test. (A) Lotion group (n=25), (B) cream group (n=25).

The skin surface pH significantly decreased on the buttocks in both groups. Moreover, there were no significant differences in the skin pH for the face and for the flexor of the arm in both groups; the number of infants with a higher skin pH decreased: the number of infants with skin pH higher than pH 6 decreased from 7 to 5 for the face in the lotion group, from 6 to 3 for the face in the cream group, from 1 to 0 for the flexor of the arm in the lotion group, and from 3 to 1 for the flexor of the arm in the cream group (Figure 5C and D).

There was no correlation between the score of skin condition and instrumental measurements.

Safety, overall improvement rate, and usefulness judged by the dermatologist

No adverse events resulting from the investigational materials were identified in the 50 infants, and safety in all infants was judged as safe. The overall improvement rate and usefulness were judged on the infants who were treated with both test

cleanser and test moisturizer on three designated areas (lotion group = 23, cream group = 22). All infants were evaluated as slightly improved or better; none were classified as unchanged or aggravated (Table 3). As all subjects were judged safe, all subjects were judged useful and no subjects were judged as useless or harmful (Table 3).

Parental assessment

The results of the parental assessments from this study are shown in Figure 6. The satisfaction (those who answered good or somewhat good) about the test materials was cleanser = 74%, lotion = 72%, and cream = 77% (Figure 6A). The recognition of the improvement of dryness of the skin of the infants was as follows: lotion group = 76% and cream group = 77% (Figure 6B).

Discussion

Sodium cocoyl glutamate, an amino acid-based detergent that has been used successfully in cleansers for sensitive

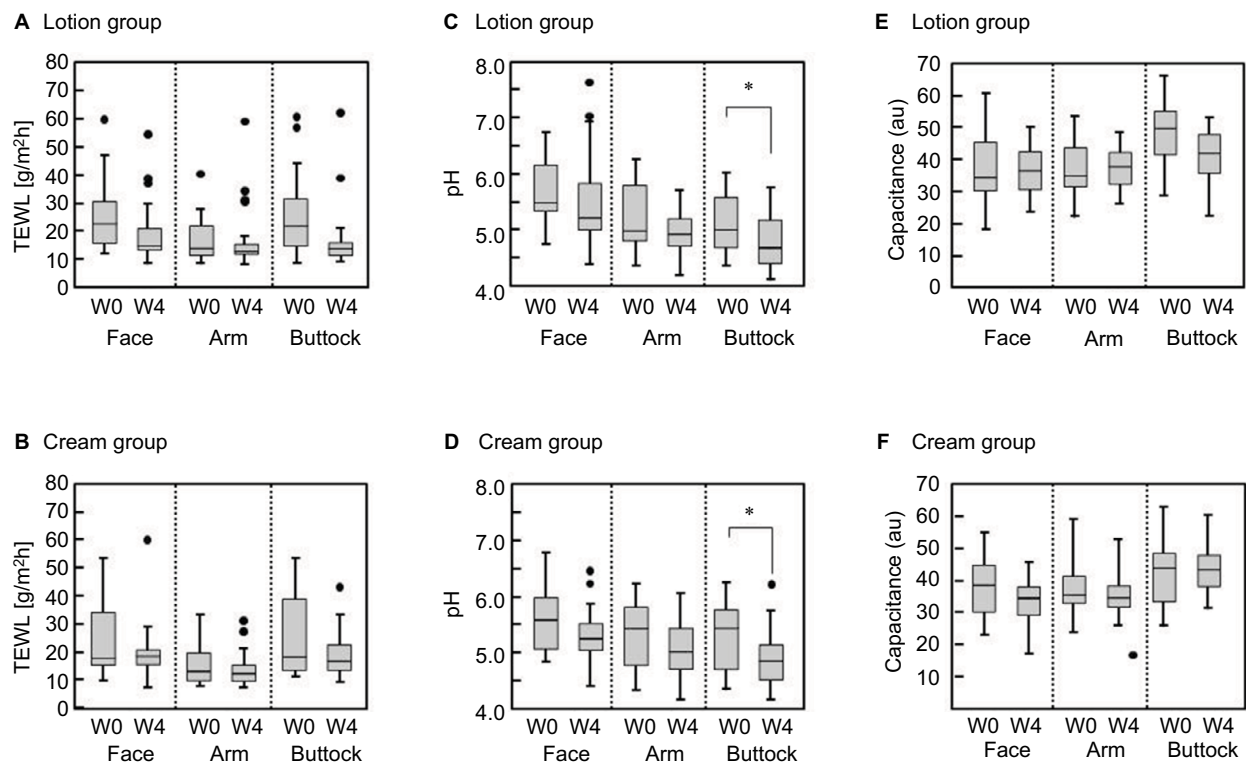


Figure 5 TEWL, pH and capacitance of the face, flexor of the arm, and buttock following the usage of the cleanser and moisturizer.

Notes: (A, B) TEWL. (C, D) pH. (E, F) Capacitance. (A, C, E) Lotion group: face (n=22); flexor of the arm (n=25) and buttock (n=25); (B, D, F) cream group: face (n=23); flexor of the arm (n=24), buttock (n=25). * $p < 0.05$ as a significant improvement from week 0 (W0) to week 4 (W4) by the Wilcoxon signed-rank test.

Abbreviation: TEWL, transepidermal water loss.

Table 3 Overall improvement rate and usefulness judged by dermatologist (number of infants)

	Lotion group (n=23)	Cream group (n=22)
Overall improvement		
Markedly improved	6	4
Improved	11	11
Slightly improved	6	7
Unchanged	0	0
Aggravated	0	0
Usefulness		
Very useful	6	4
Useful	11	11
Slightly useful	6	7
Useless	0	0
Harmful	0	0

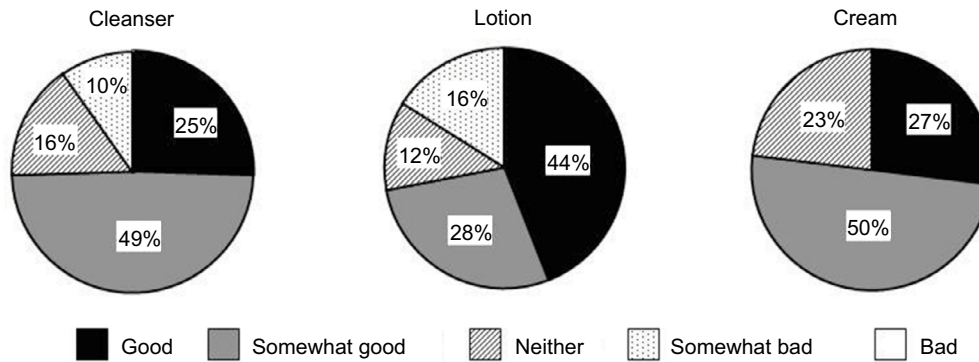
skin, was selected as the main surfactant. Generally, it is difficult to make fine foam with a low surfactant concentration, but by adjusting the balance of surfactants and solvents, we formulated a cleanser with a fine-textured foaming ability. In addition, we used the mechanical force of a pumping foam container to generate a fine foam. Owing to this reduced surfactant content, the cleansing performance is lower than that of common cleansers for adults. However, the parents

of the infants were satisfied with the cleansing ability of this cleanser. These results suggested that the formulation of body cleansers with less surfactant, which generate a fine foam and results in less rubbing on the body, was effective as infant body cleansers and for the reduction in skin symptoms.

The topical application of moisturizer is also very important. The efficacy of moisturizer containing pseudo-ceramide on atopic dermatitis and sensitive skin was confirmed.¹⁵ The results of this study show that pseudo-ceramide-containing moisturizers may also be beneficial for dry skin in infants, as indicated by the marked improvement of their skin symptoms.

Although there were significant improvements in skin symptoms on three designated areas, no statistically significant decreases in TEWL were observed. One explanation for this may be that many infants had normal TEWL values, the same as water-holding capacity. Thus, this result may also indicate that many infants had skin symptoms even though cutaneous barrier function and water holding capacity were normal. However, a decrease in the number of infants with higher TEWL indicated that this combination skin care could improve lower cutaneous barrier function. It is important to maintain the infant skin surface at a weakly acidic pH to

A Overall evaluation of the products



B Recognition of improvement of dry skin

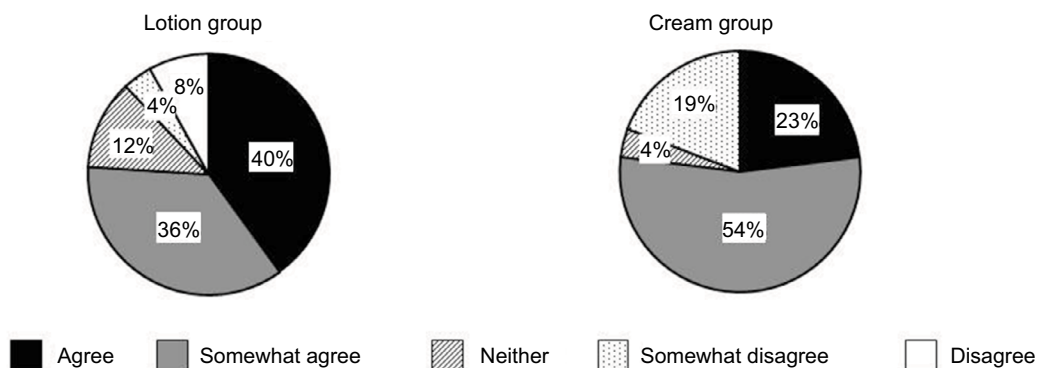


Figure 6 Parental assessments following the usage of the cleanser and moisturizer.

Notes: (A) Overall evaluation of the materials: cleanser (n=50), lotion (n=25), cream (n=25). (B) Recognition of improvement in dry skin: lotion group (n=25), cream group (n=25).

allow the development of skin barrier function,¹⁵ but some reports have indicated that skin pH is transiently raised by cleansing with soap, liquid surfactants, or water.¹³ The skin surface pH on the face, buttocks, and the flexor of the arm was decreased in both the lotion group and in the cream group. The decreased skin surface pH can be interpreted as support of the efficacy of the test materials.

From the ethics viewpoint, there were no comparative data, but we found that skin symptoms after 4-week treatment with combination skin care significantly decreased. Thus, this study demonstrated the effectiveness of the combination skin care for the alleviation of rash symptoms without using pharmaceutical preparation in infants well. These skin care products are expected to contribute to the maintenance of healthy skin in infants.

Conclusion

The combined usage of the foaming cleanser with lower surfactant activity and a moisturizer containing pseudo-ceramide

may be effective in maintaining healthy infant skin and ameliorating the skin symptoms.

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Disclosure

Naoko Okamoto, Kaori Umehara, Junko Sonoda, Hiroki Mizushima, and Yutaka Takagi are employees of Skin Care Products Research Laboratories, Kao Corporation, Tokyo, Japan. Mitsuyuki Hotta is an employee of Biological Science Research Laboratories, Kao Corporation, Tochigi, Japan. Keiko Matsuo is an employee of Kao Corporation, Office of the President, Tokyo, Japan. Naoko Baba is an employee of Department of Dermatology, Kanagawa Children's Medical

Center, Kanagawa, Japan. The authors report no other conflicts of interest in this work.

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