Safety and efficacy of the combined use of a facial cleanser and moisturizers containing pseudo-ceramide and a eucalyptus extract for Thai oily sensitive skin

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ABSTRACT:

TONGCHALAEM P*, TONGPAEN T*, SEKI T**, TAKAGI Y**, HANAZAWA H*, UZU A*, ISHIDA K**, OPHASWONGSE S***. SAFETY AND EFFICACY OF THE COMBINED USE OF A FACIAL CLEANSER AND MOISTURIZERS CONTAINING PSEUDO-CERAMIDE AND A EUCALYPTUS EXTRACT FOR THAI OILY SENSITIVE SKIN. THAI J DERMATOL 2019; 35: 157-170.

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Background: In Thailand, many people recognize their skin as being sensitive. Sebum is the major factor that induces skin sensitivity and acne, and mild cleansing to remove sebum is recommended for skin care.

Objective: To confirm the safety and the efficacy of a combination facial skincare regimen with a weakly acidic foaming facial skin cleanser and moisturizers (lotion and gel) containing pseudo-ceramide and a eucalyptus extract on reducing skin symptoms of Thai oily sensitive facial skin.

Methods: We performed a 4-week clinical trial of facial care on 27 Thai females who have oily sensitive skin selected by a lactic acid stinging test. Each subject washed her face with a weakly acidic foaming cleanser and applied an aqueous lotion with a eucalyptus extract and a moisturizing gel containing pseudo-ceramide and a eucalyptus extract twice a day. Prior to and following 4 weeks of usage, the skin conditions of each subject were evaluated.

Results: After 4 weeks of the combination care, redness and acne were significantly improved, although there were no changes in the sebum secretion rate. Accompanying those improvements, both the water holding capacity and the cutaneous barrier function of the stratum corneum were significantly enhanced and skin sensitivity, indicated by a lactic acid stinging test, decreased significantly. No adverse events due to the test samples were observed and the subjects recognized the changes in their skin conditions.

Conclusion: The combination usage of a weakly acidic foaming cleanser and an aqueous lotion and moisturizing gel containing pseudo-ceramide and a eucalyptus extract is safe and may be effective for the care of oily sensitive skin in Thai subjects.

Key words: lactic acid stinging test, barrier function, ceramide, sensitive skin, Thailand

Introduction

In Thailand, many people recognize their skin as sensitive because they feel irritation or itching due to their sweat and UV. Decreased water holding capacity and low cutaneous barrier function are major factors of sensitive skin[1-3], because many stimuli, such as sweat and sebum, may penetrate skin and induce skin irritation easily. Ceramides are

major components of intercellular lipids and are crucial for cutaneous barrier function and water holding capacity[4,5]. Topically applied pseudo-ceramide, synthesized to compensate for natural ceramides, has been shown to enhance stratum corneum functions[6-8]. Additionally, Ishikawa et al. found that a topically applied eucalyptus extract increases ceramide levels in the epidermis accompanied by improvements of stratum corneum function[9]. Nojiri et al confirmed the efficacy of a topically applied pseudo-ceramide and eucalyptus on improving sensitive skin in China[2]. Consensus guidelines for the management of atopic dermatitis in the Asia–Pacific area were published recently[10], which recommend that the use of a moisturizer not only depends on the skin type and degree of dryness, but also on the humidity of the climate.

Excess sebum and metabolites of sebum also cause skin symptoms such as irritation, acne, seborrheic dermatitis and sensitive skin[11,12], but sebum also works as the natural skin humectants[13]. Thus, a combination skincare regimen with mild cleansing followed by intensive moisturizing may be effective for the care of oily sensitive skin. The washing excess sebum and metabolites of sebum with a cleanser is effective to prevent these skin symptoms[14,15]. However, intensive washing has the risk of inducing skin irritation and dryness, and therefore the selection of cleansers is important. Seki et al. have previously shown that the combined use of a weakly mild facial cleanser with high sebum cleansing ability based sodium acyl glutamate and moisturizers containing pseudo-ceramide and a eucalyptus extract is effective for the care of mild acne patients with oily and sensitive skin in Japan[16] and mild acne patients with non-only and sensitive skin in Thailand[17]. In the present study, we evaluated the safety and the efficacy of a combination skincare regimen consisting of a mild facial skin cleanser and a moisturizer on reducing skin symptoms of Thai females with oily sensitive skin.

Materials and Methods

Subjects

Thai female volunteers with self-diagnosed sensitive skin were recruited. The subjects with any kinds of skin diseases which might needs medical treatment such as severe acne and atopic dermatitis were excluded. The subjects with sensitive skin and higher sebum secretion level were screened with Sebutape® (CuDerm Corporation, Dallas, TX, USA) analysis and a lactic acid stinging test (LAST) as detailed below. Sebutape® attached to the forehead and the cheek for 30 minutes immediately after facial washing with a facial cleanser[18,19]. Referring to the standard scale paper from the CuDerm Corporation, sebum levels were visually graded on a scale from 1 (least) to 5 (most).

Twenty-seven subjects aged 20 to 39 years old

(28.4 ± 6.9, mean ± SD) were selected and enrolled in the present study. Sebum secretion rate evaluated using Sebutape® ranged from 3 (medium) to 5 (most) both on the forehead and on the cheek (average 3.3 on the forehead and 3.2 on the cheek). The LAST score, which indicate the skin sensitivity, was from 3 to 11 (average 7.2) on cheek.

This study adhered to the tenets of the Declaration of Helsinki. A formal informed consent was obtained from each subject before the study.

Test materials

All test materials used in this study, including the facial skin cleanser, the aqueous lotion and the moisturizing gel were provided by the Kao Corporation (Tokyo, Japan).

The foaming facial skin cleanser (pH 6.2) was based on sodium acyl glutamate[20,21] (Curél Sebum Care Foaming Wash (Kao Corporation, Tokyo, Japan), the full ingredients list is shown in Table 1a). The fine foam was obtained using the dispenser and there was no need to generate foam manually. The aqueous lotion (pH 4.5) contained a eucalyptus extract and the moisturizing gel (pH 4.8) contained synthetic pseudo-ceramide and a eucalyptus extract (Curél Sebum Care Lotion (Kao Corporation, Tokyo, Japan) and Curél Sebum Care Moisture Gel (Kao Corporation, Tokyo, Japan), ingredients are listed in Tables 1b and 1c, respectively). Each subject washed her face with the test facial skin cleanser followed by the use of the aqueous lotion and the moisturizing gel twice a day for 4 weeks after discontinuing their current skin cleanser and moisturizer. The amounts applied for all test materials were instructed prior to the start of usage as follows, foaming facial skin cleanser: 2mL controlled by the pumping containers, aqueous lotion: approximately 0.5mL, and moisturizing cream: approximately 0.5g. The steps of the combination skin care were performed as follows; 1st: facial wash with the foaming facial skin cleanser, 2nd: applying the aqueous lotion, and 3rd: applying the moisturizing gel. No specific instructions for use of the test materials were given except for information about the sequential use of the facial skin cleanser and moisturizers. Changing the current facial skincare products and cosmetics except for the test materials was prohibited during the study. All subjects recorded their usage of samples, their skin symptoms and health conditions daily in their diary.

Observation and trial period

Assessment of efficacy was conducted prior to the start of the study (week 0) and at the end of week 4 (week 4). The investigation was performed in Bangkok, Thailand from December, 2011 to January, 2012. All instrumental measurements and visual assessments were performed following washing the face with the weakly acidic facial skin cleanser and acclimatization in the room at 21 ± 1 °C, 45 ± 5% relative humidity for 15 minutes.

Visual assessments

Well-trained specialists performed visual assessments of the scaling, redness and acne of skin on the forehead, the cheek and around the mouth throughout this study. For the redness and scaling evaluations, the visual scoring was determined from 1 to 4 based on the severity of scaly skin on the entire face as follows; 1: none, 2: mild, 3: moderate, 4: severe. The maximum score of redness and scaling on the forehead, the cheek and around the mouth was used as the total facial score.

For acne evaluation, the visual scoring was determined from 1 to 4 based on the number of acne lesions on the half face as follows; 1: no acne lesion, 2: 1-5 acne lesions, 3: 6-10 acne lesions, 4: more than 11 acne lesions[16]. Scores of 1 and 2 were comparable to "mild" and scores of 3 and 4 were comparable to "moderate", which is modified the grading criteria for acne severity in the guidelines of the Japanese Dermatological Association[22].

Evaluation of the sebum recovery level, skin hydration and transepidermal water loss (TEWL)

Immediately after acclimatization, sebum recovery levels on the forehead and on the cheek were measured using a Sebumeter® (Courage + Khazaka electronic GmbH, Cologne, Germany). Skin hydration was analyzed as cutaneous conductance on the cheek using a SKICON 200® (IBS Co. Ltd, Shizuoka, Japan) and TEWL on the cheek was analyzed using a Tewameter TM300® (Courage + Khazaka electronic GmbH, Cologne, Germany).

Lactic acid stinging test (LAST)

A filter paper (Φ0.5 cm) soaked with 50 μL of a 10% aqueous solution of lactic acid was put on the cheek. Self-perceived unpleasant sensations (itching, burning, stinging and others) were recorded at 0, 2, 5 and 8 min using a 4-point scale (0 = none, 1 = slight, 2 = moderate, 3 = severe). The sum of each time score was used as the LAST score (0 to 12)[2].

Subjective evaluation by the test subjects

The consumer's self-perception data obtained from the participant's recognition of improvement of skin conditions on week 4 were obtained as follows: agree, no change, and disagree.

Statistical analysis

Changes in data over the time course of the study were determined using the Wilcoxon signed rank test.

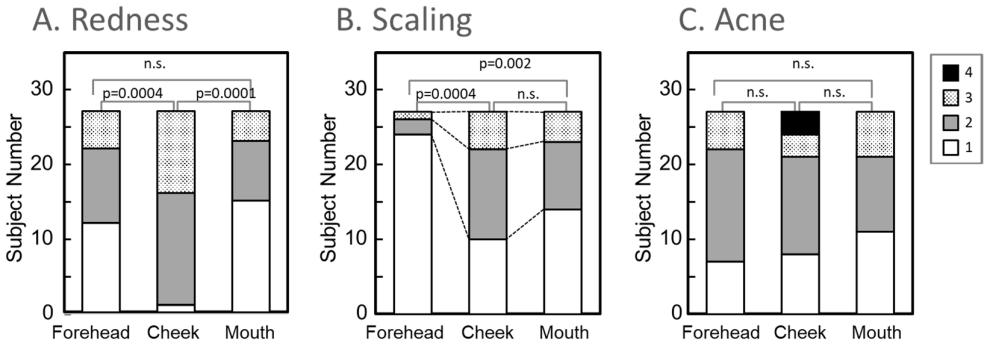

Figure 1 Differences in the severity of skin symptoms (Redness (A), Scaling (B) and Acne (C)) according to facial region. Open columns: none (1), gray columns: mild (2), dotted columns: moderate (3), closed columns: severe (4). P values were calculated using the Wilcoxon signed rank test; n.s. = no significant difference.

Results

Visual evaluation prior to combination skincare

Redness was the major skin symptom of oily sensitive skin Thai subjects and 26 of the 27 subjects had redness on their face (Fig. 1A). The cheek had the most severe redness and all subjects who had redness on their face had redness on the cheek and almost half of them had redness on the forehead and around the mouth. Most of the subjects had mild redness (15 subjects: score 2, 11 subjects: score 3, no subjects: score 4). Scaling was observed on 20 of the 27 subjects, mainly on the cheek and around the mouth: 17 subjects had scaling on the cheek and 13 subjects had scaling around the mouth (Fig. 1B). Only 3 subjects had scaling on the forehead. Twenty-four of the 27 subjects had acne on their face and there were no significant differences between the 3 facial regions but severe acne was observed only on the cheek (score 4, n=4, Fig. 1C).

Visual evaluation of the efficacy of the combination skincare

Following 4 weeks of the combination skincare regimen, the skin redness was also significantly improved and the number of subjects who had no redness on the face increased from 1 to 8 and the number of subjects with a score of 3 (mild) decreased from 11 to 2 (Fig. 2A). This significant improvement was observed on the cheek and around the mouth. There were no statistically significant differences in redness on the forehead and the number of subjects with a score of 3 (mild) decreased from 3 to 0, which was the maximum score. Scaling was significantly decreased. This decrease was observed on all 3 parts of the face

and scaling on the forehead and on the cheek was diminished (Fig. 2B). Scaling around the mouth was also significantly decreased and only 2 subjects had slight or mild scaling around the mouth at week 4. A significant improvement of acne on the whole face was observed, and this improvement was typically observed on the cheek and around the mouth (Fig. 2C). There were no significant changes in acne on the forehead.

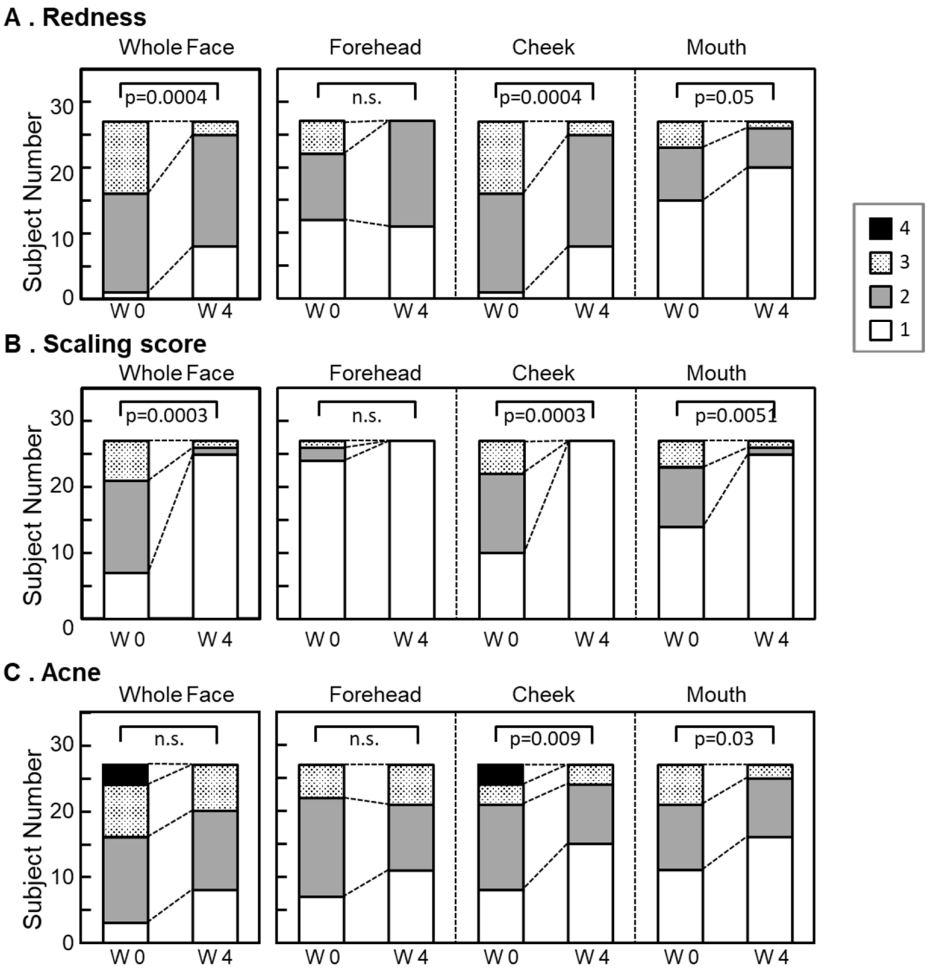

Figure 2 Changes of skin Redness (A), Scaling (B) and Acne (C) before and after usage of the skincare regimen for 4 weeks on the whole face, the forehead, the cheek and around the mouth. Open columns: none (1), gray columns: mild (2), dotted columns: moderate (3), closed columns: severe (4). P values were calculated using the Wilcoxon signed rank test; n.s. = no significant difference.

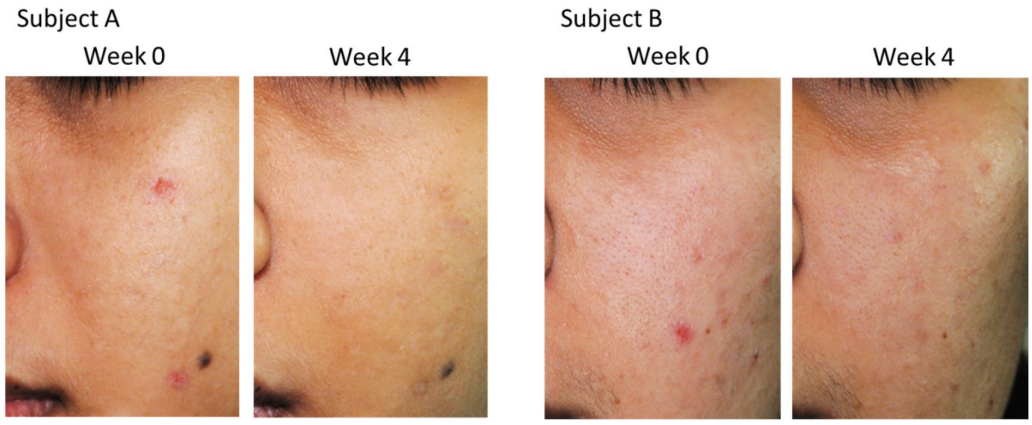

Figure 3 Example of clinical features at week 0 and at week 4 in the skincare regimen.

(A) subject A: 20 year old Thai female.

(B) subject B: 22 year old Thai female. Each of left photograph is week 0 and right side photograph is week 4 (right).

Figure 3 shows the remarkable effective example of photographs of the clinical improvement of scaling, redness and acne on the cheek in the present study. A: a 20 year old Thai female at week 0 and at week 4: scaling score (3 to 1), redness score (3 to 2) and acne score (4 to 3), respectively. B: a 22 year old Thai female at week 0 and at week 4: scaling score (2 to 1), redness score (2 to 1) and acne score (3 to 2), respectively.

There were no adverse events noted throughout the study and all subjects attended throughout this evaluation.

Sebum secretion rate, water holding capacity and TEWL

Although a significant improvement of acne was observed on the cheek, the secretion rate of sebum following face washing was not changed on the cheek, which is the same as on the forehead (medium value, forehead: week 0 was 49 a.u and week 4 was 48 a.u., no significant difference; cheek: week 0 was 26 a.u. and week 4 was 22 a.u., no significant difference, Fig. 4A and B respectively).

However accompanying the improvement of scaling and redness, the water holding capacity on the cheek was significantly increased (medium value: 150 $\mu\Omega^{-1}$on week 0 and 260 $\mu\Omega^{-1}$ on week 4 (Fig. 4C) and TEWL on the cheek was significantly decreased (medium value, 13.3 g/m^2/hr on week 0 and 9.0 g/m^2/hr on week 4 (Fig. 4D).

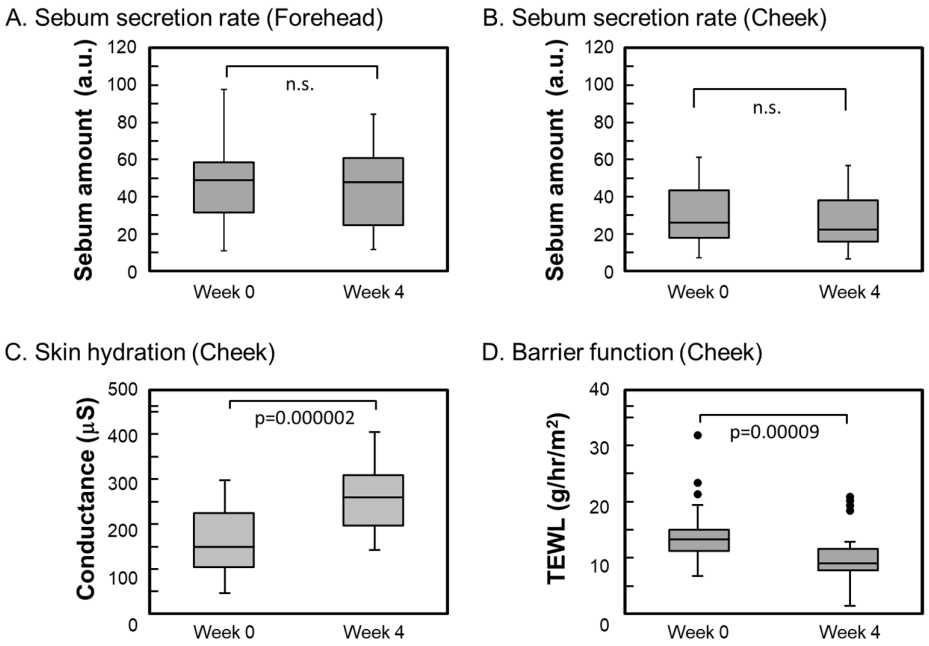

Figure 4 Change in sebum secretion rate on the forehead (A), on the cheek (B), skin hydration on the cheek (C) and TEWL on the cheek (D). P values were calculated using the paired Student's t-test; n.s. = no significant difference..

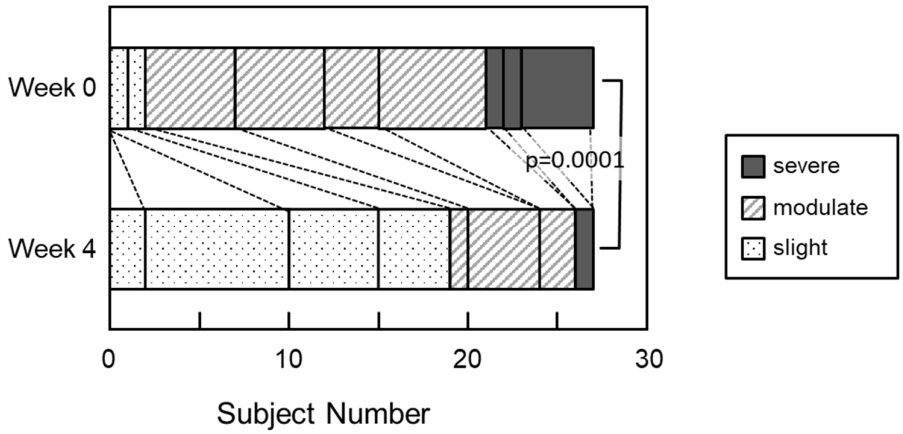

Figure 5 Changes in LAST score (total) on the cheek. Open columns: 0 'none', gray columns: 1 to 4 (mild), dotted columns: 5 to 8 (moderate), and closed columns: 9 to 12 (severe). P value was calculated using the Wilcoxon signed rank test.

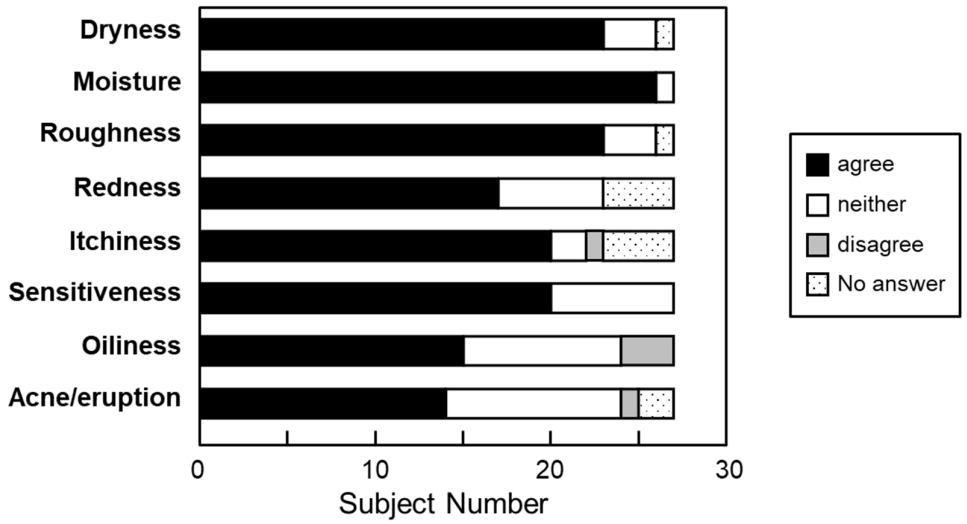

Figure 6 Recognition of improvement of skin conditions by subjective evaluation. Closed columns: agree, open columns: neither agree nor disagree, gray columns: disagree.

Last

Prior to usage of the test products, 2 subjects had a LAST score 1 to 4 (slight), 19 subjects had a score of 5 to 8 (moderate), 6 subjects had a score of 9 to 12 (severe) and none of the subjects had a score from 13 to 16 (Fig. 5). However, at week 4, the LAST score was significantly decreased accompanied by an improvement of cheek skin conditions evaluated visually and by instrumental analysis. Subjects who had a sensitivity score of 9 to 12 were decreased to only 1 (score = 10) at week 4. The number of subjects with a sensitivity score of 5 to 8 at week 4 was also decreased to 7. On the other hand, the number of subjects who had a sensitivity score of 1 to 4 at week 4 increased to 19.

Subjective evaluation

Most subjects recognized that their skin had less dryness and more moisture following usage of the test materials. Furthermore, decreases in redness, sensitivity and itchiness were also recognized by nearly two-thirds of the subjects and only 1 subject claimed an increase in itchiness (Fig. 6). During the interview, these improvements were recognized by decreases in the induction of skin roughness and dryness when in an air conditioned environment and itchy skin induced by sunshine and sweat.

Discussion

Sebum is one of the major factors that induces sensitive skin because oxidized sebum or free fatty acids derived from sebum may irritate the skin and

cause cutaneous problems such as seborrheic dermatitis, acne, and skin sensitivity[11]. In this evaluation, significant improvements of acne were observed accompanied by significant decreases in skin redness, even the subjects had a higher sebum secretion rate and there were no changes in the sebum secretion rate following the 4 weeks of combination skincare. This result may indicate that the sebum level itself has less of an effect on skin conditions.

Improper skin cleansing induces dryness and irritation of the skin. Thai people are concerned that sweat, sebum, and air pollution in Bangkok may induce skin irritation. Thus, they tend to wash their face hard such as using detergent with high detergency, rubbing skin, washing repeatedly twice or more, and so on. But these facial washing habits might be one reason to induce sensitive skin because of removing intercellular lipids and natural moisturizing factors resulting in lower cutaneous barrier function and water holding capacity. Also skin friction during cleansing causes skin irritation. We have confirmed that mild cleansing itself improves skin condition including decreasing acne prompt[23]. Thus for this evaluation, we designed a mild facial cleanser with the following considerations. Sodium cocoyl glutamate is well known as a mild detergent for cleansers[20,21]. The benefits of a weakly acidic base for cleansers have been also pointed out[24,25]. Furthermore, washing with cleansers which are foamed enough can reduce friction against the skin and also the surfactant penetration into the skin[26]. Furthermore, more than half of the subjects recognized that their face become less oily and only 3 subjects felt that their skin became more oily, which indicates that this cleansing ability is sufficient to cleanse oily skin.

Cleansing face and application of moisturizers are habitual behaviors of Thai women. It is not reasonable to stop using cleansers and moisturizers. Furthermore the alternative skincare materials on wash out period may affect the decision of the efficacy. Thus we have aimed to clarify the efficacy of our combination skincare compared to the subjects' skincare regimen in Thai oily people with sensitive skin on this evaluation similar to previous report[17]. No specific instructions for the use of the test materials were given and all the subjects might have kept performing the facial skincare in their own method. However, following switching the facial skin cleanser and moisturizers, their skin symptoms were improved, which may indicate our skincare regimen is more suitable for Thai people with oily sensitive skin.

On the previous evaluation of skin cleanser consisted of different surfactants in Thailand by Jananya's group, sebum secretion rate on the forehead, which evaluated by Sebutape®, was significantly decreased[27]. However in present evaluation there were no significant changes in sebum secretion level. This sebum secretion level basically depends on the proliferation rate of

sebocytes but the combination skincare materials may not affect the growth of sebocytes. The decrease in sebum secretion level in previous work might be caused because the test cleanser with higher cleansing ability may remove the sebum even from duct of sebaceous gland, but this test cleanser may not have such high cleansing ability.

The sebum secretion level may have less of an effect on worsen skin conditions. However metabolites of sebum may induce skin irritation. Furthermore skin inflammation induces the abnormal proliferation of keratinocytes in the epidermis that results in lower stratum corneum functions. Thus the appropriate washing face to decrease these metabolites may be useful. Furthermore the skin with lower cutaneous barrier function allows penetrating these stimuli into skin. Topical application of a moisturizer containing ceramide or pseudo-ceramide is effective on dry skin[7,8], and might prevent the penetration of the stimuli. Additionally it is reported that moisturizers have the ability to prevent irritation[28], thus this decrease in skin redness may be one of the major factors of the decrease in scaling and the enhancement of cutaneous barrier function.

We have reported the efficacy of a combination skincare regimen with a facial cleanser and a moisturizer containing pseudo-ceramide on oily sensitive skin with acne in Japan[16], and non-oily sensitive skin with acne in Thailand[17]. The environments and/or sebum secretion level was different but the usage of this combination skincare regimen enhanced stratum corneum functions. Accompanied with these improvements, skin sensitivity on the cheek was significantly decreased as indicated by the LAST score. Thus, these data suggest that Thai sensitive skin may be caused by lower cutaneous function as reported in other countries[1-3]. A decreased cutaneous barrier function causes easy penetration of stimuli such as sweat and air pollution and induces skin redness, scaling and irritation. The inducing factor of the decreased stratum corneum function is not clear. However, usage of the mild cleanser might help to improve their sensitive skin although sebum might be one of the factors. The facial washing habits of Thai people might be one reason that induces sensitive skin. Thus, the combination skincare with a mild cleanser and application of pseudo-ceramide with the eucalyptus extract might be effective to improve their stratum corneum function resulting in decreases of skin redness, scaling, irritation, and so on.

Based on these findings, we conclude that the use of a mild foamy cleanser followed by the application of a moisturizer containing pseudo-ceramide and a eucalyptus extract is safe and may be quite effective to improve Thai oily sensitive skin.

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Conflict of Interest

Panomporn Tongchalaem, Tiyachat Tongpaen, Tsuyoshi Seki, Yutaka Takagi, Hideyuki Hanazawa, Atsushi Uzu and Koichi Ishida are employees of Kao Corporation (Tokyo, Japan). These studies were funded in full by Kao Corporation. Suwirakorn Ophaswongse received honoraria for participation in advisory boards for Kao Corporation.

The authors have no other conflicts of interest.

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