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International Journal of Clinical Dermatology & Research (IJCDR)
ISSN 2332-2977

An Alkyl Ether Carboxylate and Alkyl Carboxylate Formulated Cleanser Decreases Facial Sebum and Inflammatory Acne Without Inducing Dry Xerotic Skin in Thai Females

Case Study

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Abstract

Many Thai females feel that their facial skin is oily and suffer from acne. Previously we have confirmed that a facial cleanser formulated with alkyl ether carboxylate (AEC) and alkyl carboxylate (AC) effectively removed sebum and decreased acne prompt without inducing dry skin on Japanese male subjects. In this study, we evaluated the efficacy of this formulated facial cleanser on Thai female subjects with moderate or mild grade acne in Bangkok, Thailand.

We designed a controlled clinical trial. Sixteen female subjects used AEC/AC formulated cleanser twice a day after discontinuing their currently using facial cleansers. Assessment of the efficacy was conducted prior to the start of the study, and at the end of weeks 2 and 4. Following usage of this cleanser for 4 weeks, sebum secretion levels on the forehead skin significantly decreased. Corresponding to decrease in facial sebum, 10 subjects had decrease in non-inflammatory acne. Furthermore eight subjects decreased in inflammatory acne, and the decreases in the number of inflammatory acne within 4 weeks were statistically significant. These decreases in sebum and acne prompt were recognized by subjects. Despite the sebum were cleansed well, the cutaneous capacitance increased significantly within 4 weeks, and there were no complaints of dryness or irritation of the skin during the study.

From these results, we conclude that washing the face with cleanser formulated with AEC and AC is effective for acne care in Thai females.

Keywords: Acne; Facial Cleanser; Sebum; Alkyl Ether Carboxylate; Alkyl Carboxylate; Thailand.

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Received: May 20, 2015
Accepted: June 18, 2015
Published: June 22, 2015

Citation: Takagi Y, et al., (2015) An Alkyl Ether Carboxylate and Alkyl Carboxylate Formulated Cleanser Decreases Facial Sebum and Inflammatory Acne Without Inducing Dry Xerotic Skin In Thai Females. *Int J Clin Dermatol Res.* 3(3), 60-64. **doi: http://dx.doi.org/10.19070/2332-2977-1500016**

Introduction

Acne is a common chronic inflammatory skin disease, which develops in sebaceous glands of trousseau areas including the face, neck, back and chest [1]. Facial washing has been recommended for acne care [2-4]. However cleansers with high detergent performance may penetrate the stratum corneum and extract natural moisturizing factors [5] and intercellular lipids [6], which results in the induction of dry xerotic skin or irritation. Berson recommended the usage of moisturizer following washing face with mild cleanser on American Academy of Dermatology's Summer Academy Meeting in 2013 [4].

Recently it was reported that even mild acne has an extremely large effect on the quality of life of Thai people [7]. Thai females have habit to wash their face with facial cleanser daily, but inappropriate selection of facial cleanser and/or inappropriate method of washing face may worsen acne and also induce xerotic skin or irritation. Many new detergents that have both high cleansing abilities and mildness for the skin have been developed [8-12]. Additionally various formulations, such as combinations of two or more different anionic surfactants, anionic surfactants with cationic surfactants, anionic surfactants with nonionic surfactants, and anionic surfactants with amphoteric surfactants, have been reported to work as mild detergents [13-16]. Recently, we developed a cleanser based on sodium alkyl ether carboxylate (AEC) and alkyl carboxylates (AC), which has suitable foam and effectively remove sebum without penetrating into the stratum corneum [17, 18]. Using a colored artificial sebum mixture, it was demonstrated that the AEC/AC solution removes sebum 1.8 times more efficiently than the AC solution alone [18]. We confirmed that AEC/

AC formulated cleanser was effective in Japanese male subjects with moderate or mild acne [19] and having little effect on the induction of dry skin [20]. However there are large difference in Thai female and Japanese male, such as gender, ethnic, environment and lifestyle and so on. The confirmation of the efficacy of this formulated cleanser on Thai female was desired. Therefore in the present study, we evaluated the efficacy of the AEC/AC formulated facial cleanser on sebum care of Thai female subjects with moderate or mild grade acne.

Materials and Methods

We designed a controlled clinical trial conducted from March to May in 2012 in Bangkok, Thailand. The present study adhered to the tenets of the Declaration of Helsinki, and was reviewed and approved by the Institutional Review Board of the Kao Corporation (#366-20120201). A formal informed consent was obtained from each subject before the study.

Female subjects with moderate or mild acne (the Hayashi acne grades) [21] were prescreened by a board-certificated dermatologist. Subjects having any serious cutaneous pathology or progressive disease(s) which may interfere with the study were excluded from this study. All subjects were provided with the same mild facial cleanser, formulated with AEC and AC, which does not contain any specific anti-bacterial or anti-acne materials (ingredients are indicated in the Table). Subjects were instructed on how to wash their face with the cleanser twice a day for 4 weeks. The use of any other kind of facial skin care products or cleansers was prohibited during this period.

Assessment of the efficacy was conducted prior to the start of the study (day 0), and at the end of weeks 2 (days 14) and 4 (days 28). Subjects were instructed to wash their face till at least 10 hour prior to their assessment visits and not to wash their face nor to apply any product to their face until their assessment visits. Prior to washing the face, sebum levels on the forehead, the upper cheek, the lower cheek, side of the nose and the jaw regions were analyzed with a Sebumeter® (Courage+Khazaka electronic GmbH, Cologne, Germany). Immediately after washing their face with their cleanser, secreted sebum levels for 30 minutes on the forehead and the upper cheek were analyzed using a Sebutape® (CuDerm Corp, Dallas, TX, USA) at 25 ± 2°C, 50 ± 10% humidity. Referring to the standard scale paper from Cuderm Corp, each sebum level was visually graded on a scale from 1 (least) to 5 (richest) [22]. Following this acclimatization for 30 minutes, cutaneous capacitance and transepidermal water loss (TEWL) on the upper cheek were analyzed with a Corneometer® (Courage+Khazaka electronic GmbH, Cologne, Germany) and a Tewameter TM300® (Courage+Khazaka electronic GmbH, Cologne, Germany), respectively. The numbers of non-inflammatory acne and inflammatory acne were counted by dermatologists on the whole face. On counting the number of acne, facial part was roughly divided into 4 parts, forehead, upper cheek, lower cheek and nose, and we figured improved of acne as decreased more than 4 of acne on whole face and worsened acne as increase more than 4 acne on whole face.

Consumer's self-perception data were obtained with a questionnaire on day 28. Concerns about cleansing ability of the cleanser, improving their oily face, greasy face, and pimples/acne, and induction of dryness of skin were obtained as agree, agree somewhat, neither agree nor disagree, disagree somewhat or disagree. Changes over time of the measured data were determined statistically with an ANOVA-test. Changes over time of the scored data were determined with the Wilcoxon signed rank test.

Table. Ingredient of AEC/AC formulated cleanser.

Water	Sorbitol	Laureth-6 carboxylic acid
Myristic acid	Lauryl hydroxysultaine	Potassium hydroxide
Lauric acid	Ethylhexylglycerin	Acrylates/C10-30 Alky acrylate crosspolymer
Palmitic acid	Fragrance	Disodium EDTA
Polyquaternium-39	PEG-6	PEG-45M
Glycerin	Pentyleneglycol	PEG-40 hydrogenated castor oil
Trideceth - 9	Oryza Sativa Bran extract	Nonfat dry milk
Oryza Sativa germ oil	Phenoxyethanol	Cl 77891

Results

Skin surface sebum levels

Eighteen Thai females aged 20 to 34 years old (24.4 ± 4.8, mean ± S.D.) participated in this study. One subject could not attend the observation on days 14 and 28 due to personal reasons, and one other subject had used AEC/AC formulated cleanser prior to this test. Thus, 16 subjects were involved in the analysis. Prior to this evaluation, 6 subjects used alkyl carboxylates based cleansers (soaps), 5 subjects used cleansers with anionic surfactants not involving soaps, 2 subjects used a cleanser with non-ionic surfactants and 3 subjects used unidentified surfactant because of clinical preparation. During this trial, no adverse event or induction of inflammation was observed.

Sebum levels measured prior to face-washing showed no significant difference between weeks 0 and 4 at any area, 76 ± 59μg/cm^2 vs. 88 ± 82μg/cm^2 on the forehead, 48 ± 20μg/cm^2 vs. 40 ± 41μg/cm^2 on the upper cheek, 35 ±18μg/cm^2 vs. 39 ± 41μg/cm^2 on the lower cheek, 92 ± 58μg/cm^2 vs. 82 ± 62μg/cm^2 on the side of the nose and 78 ± 47μg/cm^2 vs. 57 ± 41μg/cm^2 on the jaw.

The sebum secretion levels for 30 minutes after face-washing on the forehead and the upper cheek were evaluated by a Sebutape®. During this period, the secreted sebum level on the forehead significantly decreased. The number of subjects with rich sebum secretion on the forehead (more than score 4) decreased from 8 on day 0 to 3 on day 28. On the upper cheek, there were no statistically significant difference but the number of subjects with rich sebum secretion decreased from 6 on day 0 to 3 on day 28 (Figure 1).

Figure 1. Secreted sebum levels for 30 minutes following facial washing. According to the reference scale of the CuDerm Corp., the sebum levels were rated on a scale from 1 to 5 (1 is the least and 5 is the richest level of sebum). A: Forehead, and B: Cheek. Asterisks indicate p<0.05 as a significant difference. Open columns: 1, dotted columns: 2, striped columns: 3, gray columns: 4, and closed columns: 5.

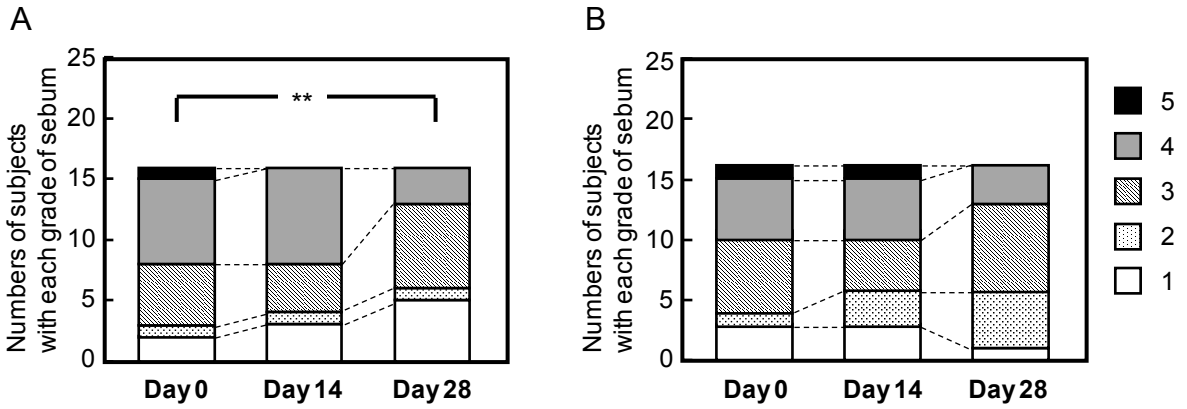
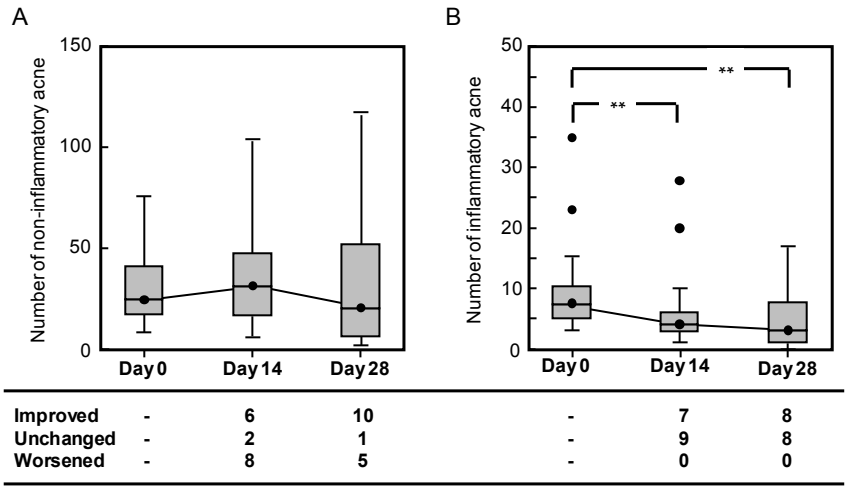


Figure 2. Clinical course of the severity of facial acne lesions. Data are shown as box and whisker plots (median, upper/lower quartile, largest/smallest). A: Non-inflammatory acne, B: Inflammatory acne. ** indicates p<0.01 as a significant difference from day 0. The numbers in the table indicate the number of subjects who improved (decreased more than 4 acne compared to day 0), unchanged (the changes of acne number compared to day 0 was no more than 3), or worsened (increased more than 4 acne compared to day 0).



Improved	-	6	10	-	7	8
Unchanged	-	2	1	-	9	8
Worsened	-	8	5	-	0	0

Figure 3. Changes in cutaneous capacitance and TEWL on the cheek of the tested subjects at weeks 0, 2 and 4. Data are shown as mean ± S.D.. A: Cutaneous capacitance, B: TEWL. * indicates p<0.05 and ** indicates p<0.01 as a significant difference from day 0.

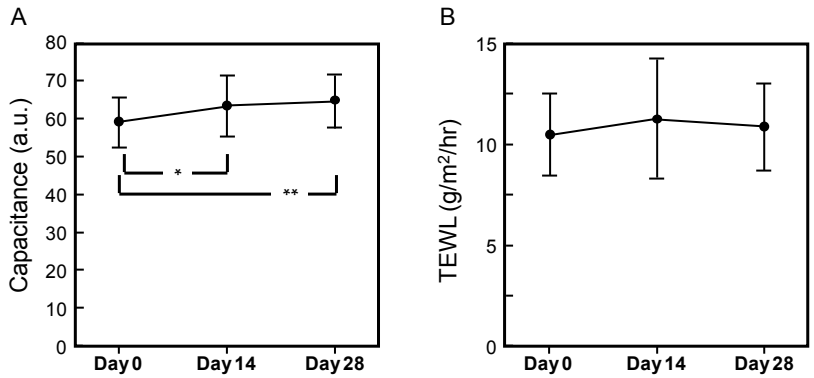
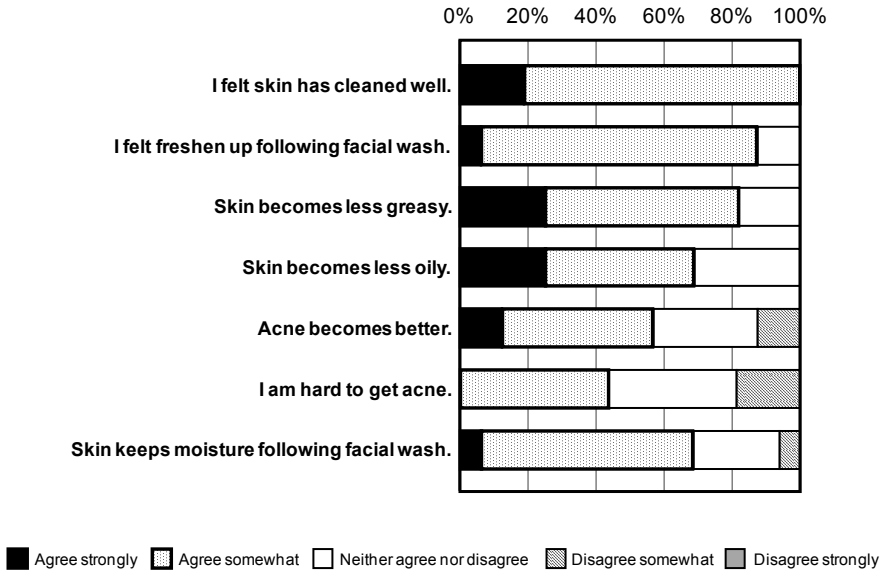


Figure 4. Subjects' self-perception data obtained from the questionnaire on day 28. Closed columns: agree strongly, dotted columns: agree somewhat, open columns: neither agree nor disagree, striped columns: disagree somewhat, and gray columns: disagree strongly.



Visual assessment

The severity was assessed by counting the non-inflammatory acne and inflammatory acne on the whole face. The numbers of non-inflammatory acne did not make statistically significant change, but within 16 subjects 10 subjects improved (decreased more than 4) their non-inflammatory acne and 5 subjects worsened (increased more than 4) their non-inflammatory acne following 4 weeks usage (the median value on day 0 was 24 and that on day 28 was 20, Figure 2A). Furthermore 8 subjects improved (decreased more than 4) their inflammatory acne and no subjects worsened (increased more than 4) inflammatory acne following 4 weeks usage of the cleanser. The number of inflammatory acne decreased significantly (the median value on day 0 was 8 and that on day 28 was 3, $p<0.01$, Figure 2B).

Skin Dryness

The stratum corneum condition was evaluated by cutaneous capacitance measured with a Corneometer®, which indicates the water holding capacity of the stratum corneum and also by TEWL measured with a Tewameter®, which indicates cutaneous barrier function. Use of the AEC/AC formulated cleanser increased the capacitance significantly ($p<0.05$) from 59.7 ± 6.5 (on day 0) to 65.4 ± 7.0 (on day 28, Figure 3A) but the TEWL did not change during this period (from 10.5 ± 2.1 g/m^2/hr (on day 0) to 10.9 ± 2.2g/m^2/hr (on day 28), (Figure 3B).

Subjects' self-perception

The subjects' self-perception data obtained from the questionnaire on day 28 revealed that the subjects appreciated the cleansing ability of the AEC/AC formulated facial cleanser and the improvement of their greasy skin (Figure 4). All subjects felt their skin cleaned well (100%) and 88% of them felt freshened up following facial wash. Eighty-one% of the subjects felt that their skin became less greasy and 69% of subjects felt their skin became less oily. Accompanied with this recognition, many subjects recognized how their acne had improved (56%) and how it was harder for them to get acne (44%). Moreover they felt their skin kept moisture following facial wash (69%).

Discussion

In 2010 we found that almost three quarters of them worry about their oily skin and more than half of adult females were concerned about acne on their face (age 18-35, n=100, data not shown). Washing the face with cleansers has been recommended for oily skin care and acne care. Thai females have a daily habit to wash their face with cleanser but still many of them worry about their oily skin and acne on their face.

The cleansers with high detergent performance may penetrate the stratum corneum, which results in the induction of dry xerotic skin or irritation of the skin. Furthermore Thai females tend to wash their faces longer and rinse less compared to Japanese (data not shown) and they wash their faces repeatedly when they feel their cleansing is not enough. These face-washing habits tend to induce dry xerotic skin or irritation. Thus the facial cleansers with high sebum cleansing ability without inducing dry skin are desired in Thailand. Previously we confirmed the efficacy of AEC/AC formulated facial cleanser on acne in Japanese male [19]. Moreover this facial cleanser had little effect on the induction of dry skin [20]. Here we have evaluated the efficacy of this AEC/AC formulated facial cleanser on acne prompts of Thai female in Bangkok.

Following usage of the AEC/AC formulated cleanser, the sebum level for 30 min following facial wash decreased on forehead significantly. This cleanser did not contain any materials which control the sebum production or secretion, such as endocrine factors [23-27]. Moreover, Draelos demonstrated that there were no significant changes in secreted sebum levels in his evaluation of cleansers on mild acne [28]. Thus we presume this decrease in sebum might be caused by high sebum cleansing ability of the AEC/AC. This decrease in sebum was realized by subjects. There were no changes of casual sebum level which was analyzed prior to facial wash, because more than 10 hours following last facial

wash might diminish these decreases.

All subjects had kept using facial cleansers even prior to this trial and the facial cleanser had just changed to AEC/AC formulated cleanser on this trial. However nearly two third of subjects had improved their non-inflammatory facial acne. Moreover inflammatory acne had significantly decreased. These improvements were also recognized by subjects. This facial cleanser did not contain any anti-acne materials and these results suggest that the high sebum cleansing ability might improve the acne of Thai females same as Japanese male, as previously reported [19]. Especially the significant decrease in inflammatory acne may suggest that AEC/AC cleanser prevents the non-inflammatory acne from worsening and becoming inflammatory acne.

AEC/AC formulated cleanser did not induce dry skin on Japanese female [20]. On this Thai trial, the cutaneous capacitance was increased significantly. These results may suggest that Thai subject might have low cutaneous capacitance because of their hard face washing habit as well as washing their faces for a long time and repeatedly. However AEC/AC formulated cleanser did not induce dry xerotic skin with high cleansing ability which satisfied Thai subjects.

The present study demonstrates that adequate face washing with a properly chosen mild cleanser is a valuable approach for acne care, which prevents the worsening of acne, without inducing skin irritation or dry xerotic skin. Moreover, washing their face with the AEC/AC formulated cleanser is suitable for acne care and very effective in improving their quality of cleansing manner in Thailand such as washing their faces for a long time and repeatedly.

Acknowledgment

This study was supported financially by Kao Corporation. We thank our colleagues in the Global R&D, Kao Corporation, and the colleagues in Mae FahLuang University Hospital for their kind help during the study.

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