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8-Week Trial Study of the Skincare Product ROZATROL® in Japanese Rosacea Patients:

The Role of Skin Care in Improving Quality of Life of Patients with Rosacea

Hiroaki HAYASHI [1] / Ikumi KURIMURA [2] / Haruyo YAMAMOTO [3]

● Abstract

BACKGROUND / OBJECTIVES: Rosacea is a chronic inflammatory disease characterized by persistent dark red erythema primarily on the cheeks and nose. While skincare is known to be important for treatment and maintenance therapy, evidence in Japan is scarce. This study evaluated the safety and efficacy of the skincare cosmetic "ROZATROL ® "with Japanese rosacea patients.

PARTICIPANTS / METHODS: 8-week clinical study was conducted in 30 patients with erythema who had an Investigator's Global Assessment (IGA) score of less than 3 at baseline. The single application dose was approximately 0.75g, applied twice daily in the morning and evening. Evaluations included visual assessment by board certified dermatologists, imaging with diagnostic equipment, and measurements of skin color, stratum corneum moisture content, trans epidermal water loss, and sebum levels. Self-assessments using the Dermatology Life Quality Index (DLQI) and Visual Analogue Scale (VAS) were also performed.

RESULTS: The subjects included in the statistical analysis were 26 patients (all female, mean age 41.3 years [range: 24–62 years]). 8 weeks after the start of the study, the IGA score improved from 2.2 ± 0.41 to 1.3 ± 0.47 （$p < 0.001$） , and the a* value (redness) in skin color measurement significantly decreased from 17.65 ± 1.98 to 16.88 ± 1.96 (p=0.004). Stratum corneum water content significantly increased from 70.33 ± 8.74 AU to 73.05 ± 8.48 AU (p=0.008). VAS confirmed subjective improvement in skin condition across items including redness, oiliness, dryness, and skin texture. DLQI score, an indicator of QOL, also showed significant improvement.

CONCLUSION: ROZATROL ® contributes to alleviating skin symptoms during the remission phase of rosacea and preventing flare-ups. It is expected to contribute to improving the quality of life for rosacea patients. It becomes one of the skincare product options available for Japanese patients with rosacea and facial redness.

Keywords: rosacea, facial redness, skin care cosmetic product, Rozatrol®, use test, stratum corneum water content, transepidermal water loss, sebum level, QOL assessment

1. Introduction

Rosacea is a chronic inflammatory disease characterized by erythema and telangiectasia in the central face, and is particularly common in women. Many exacerbating triggers have been identified, including temperature changes, ultraviolet exposure, diet, medications, and skin care, and the impact on patients' QOL is substantial. Although topical medications became covered by health insurance in 2022 and the number of patients seeking medical care has increased, few therapeutic agents can adequately address the diverse manifestations of rosacea.

Skin care guidance for rosacea is important as part of treatment and maintenance therapy, and guidelines[1] also recommend appropriate sun protection and the use of low-irritation cleansers and moisturizers. However, clinical trials of skin care products in patients with rosacea are limited both in Japan and overseas, and the evidence cannot be considered sufficient[2]. In other countries, meanwhile, the importance of skin care is widely recognized, as reflected in initiatives such as certification systems for skin care products, mainly led by the National Rosacea Society in the United States (NRS[3]) .

[1]Hayashi Dermatology Clinic, Kenmeikai Medical Corporation [2] ZO Skin Health GK [3] Department of Dermatology, Kindai University Faculty of Medicine

Against this background, to evaluate the usefulness of skin care in patients with rosacea in Japan, we conducted an 8-week continuous-use study using Rozatrol®, a skin care cosmetic product developed for patients with rosacea, and evaluated its effects on reducing skin redness, stratum corneum water content, skin barrier function, patient QOL, and safety in Japanese patients with rosacea. Here, we report the results.

2. Methods

This study was conducted after approval by the Brain Care Clinic Institutional Review Board (IRB No. 16000189 in the Ministry of Health, Labour and Welfare Research Ethics Review Committee Reporting System) at an external testing institution equipped with a temperature- and humidity-controlled environmental testing room for skin measurements, after written informed consent had been obtained.

2.1. Overview of the Study Product

Rozatrol® (Photo 1), a patented [4] skin care cosmetic product developed in the United States for the purpose of improving rosacea or related symptoms, was used as the study product. All ingredients contained in the product are shown in Table 1.

The study product contains, as its main ingredients, a complex component consisting of lactose, milk protein, and broccoli extract as anti-inflammatory ingredients that suppress skin redness; botanical components consisting of edelweiss extract meristem cell culture and horehound meristem cell culture; palmitoyl glycine as an ingredient that suppresses telangiectasia; and hydrolyzed arginine, which reduces skin hypersensitivity reactions. In Japan, it is a skin care formulation that complies with cosmetic standards.

2.2. Clinical Use Study

2.2.1. Subjects

24 women who had been diagnosed with rosacea and whose skin symptoms had subsequently stabilized through outpatient treatment, together with 6 men and women recruited through an external organization who were troubled by rosacea or facial redness, were included. A total of 30 participants with an Investigator's Global Assessment (IGA) score of less than 3 (moderate) on the 5-point erythema severity scale at the start of the study were enrolled.

Before the start of the study, the purpose and methods of the study were fully explained, and written consent to participate was obtained from each subject of their own free will.

2.2.2. Use Study

The study was conducted from February 6 to April 3, 2025. The study product was used for 8 weeks. During the study period, participants used the study product continuously twice daily, in the morning and evening after washing their face. The approximate amount of the study product used per application was 0.75 g, and this approximate amount was applied to the entire face. Participants used their usual facial cleanser. When going outdoors, they used a commercially available sunscreen with an SPF of 30 or higher.

During the study period, participants who reported that their skin became dry when using only the study product were permitted to use the skin care products they normally used, such as lotion or cream.

Photo 1 Rozatrol® (study product)

Table 1: Full Ingredient List of the Study Product

Water, Glycerin, Cetyl Alcohol, Sunflower Seed Oil, C12-15 Alkyl Benzoate, Palmitoyl Glycine, Neopentyl Glycol Diethylhexanoate, Dimethicone, Panthenol, Glyceryl Stearate, PEG-100 Stearate, Potassium Cetyl Phosphate, Laminaria Digitata Extract, Opuntia Ficus-indica Stem Extract, Galactoarabinan, Maltodextrin, β-Glucan, Lactose, PEG-12 Glyceryl Laurate, PEG-35 Castor Oil, Phenoxyethanol, Magnesium Aluminum Silicate, Xanthan Gum, Broccoli Extract, Aminomethyl Propanol, Farnesyl Acetate, Panthenyl Triacetate, Milk Protein, Farnesol, Caprylyl Glycol, Chlorphenesin, Hydrolyzed Algin, Neopentyl Glycol Diisostearate, Edelweiss Meristem Cell Culture, Horehound Meristem Cell Culture, Lactic acid, Carbomer/Papain Crosspolymer, Disodium EDTA, 1,2-Hexanediol, Sodium Alginate, Citric Acid, Lecithin, Fragrance

As a general rule, medications that had been used before the start of the study were continued, and changes in medications during the use study period were prohibited.

On the study start date and after 4 and 8 weeks, interviews and visual assessments by two board-certified dermatologists, imaging using an imaging diagnostic device, and instrumental skin measurements were performed. In addition, participant self-assessments were conducted.

2.2.3. Skin Measurement Environment

Interviews and assessments by two board-certified dermatologists, imaging using an imaging diagnostic device, and instrumental skin measurements were performed in an environmental testing room, a room controlled at a temperature of 21 ± 1°C and humidity of 50 ± 5%. Each measurement was performed after participants had washed their face using the specified facial cleanser and had acclimated in the environmental testing room for at least 20 minutes.

2.2.4. Visual Assessment — Evaluation of Skin Condition

On the study start date and after 4 and 8 weeks, interviews were conducted by two board-certified dermatologists, and the severity of erythema in the participants was assessed
using the following 5-point scale.

Erythema Severity Evaluation Criteria

0 No symptoms: no erythema

1 Minimal: extremely faint erythema

2 Mild: faint erythema

3 Moderate: distinct erythema

4 Severe: severe erythema

On the study start date, the physician designated the skin measurement sites corresponding to the lesional and non-lesional areas for each participant, as well as the left or right side of the face to be photographed using the imaging diagnostic device. In addition, after 4 and 8 weeks, the physician confirmed the occurrence of any adverse events.

2.2.5. Spectrophotometric Colorimeter Measurement — L*, a*, and b* Values

Skin color was measured at two sites, the lesional and non-lesional areas, on either the left or right cheek, using a CM-2600d spectrophotometric colorimeter (Konica Minolta, Inc.) with an 8-mm measurement diameter, and L*, a*, and b* values were obtained.

2.2.6. Imaging Diagnostic Device Photography

Frontal images of the face and images of either the left or right half of the face, as designated by the physician on the start date, were captured using VISIA Evolution (Canfield Scientific Inc.) [5), 6)]. Standard light images, polarized light images, and UV light images were obtained. The analysis items were spots, wrinkles, pores, uneven skin tone, porphyrins, melanin index, and hemoglobin index.

2.2.7. Measurement of Stratum Corneum Water Content and Transepidermal Water Loss

Transepidermal water loss was measured at two sites, the lesional and non-lesional areas, on either the left or right cheek. Stratum corneum water content was measured using a Corneometer CM825 (Courage + Khazaka Electronic GmbH), and transepidermal water loss was measured using a VAPO SCAN AS-VT100RS (Asahi Biomed Co., Ltd.).

2.2.8. Sebum Level

Sebum level was measured at two sites, the lesional and non-lesional areas, on either the left or right cheek, using a Sebumeter SM815 (Courage & Khazaka Electronic GmbH). For sebum level, considering the time required for the skin's sebum status to return to baseline after face washing, measurement was performed after acclimation in the environmental testing room for at least 50 minutes.

2.2.9. Participant Self-Assessment

2.2.9.1. Dermatology Life Quality Index (DLQI)

As an index for evaluating the impact of skin disease on patients' QOL, the Dermatology Life Quality Index (DLQI), which is used in routine clinical practice regardless of the type of skin disease, was used. [7)] Participants performed self-assessments on the study start date and after 8 weeks.

2.2.9.2. Visual Analog Scale (VAS) and Evaluation of Product Use

A questionnaire using a Visual Analog Scale (VAS) was administered on the study start date and after 4 and 8 weeks for 10 items related to the participants' own skin condition. A questionnaire using a Visual Analog Scale (VAS) was administered on the study start date and after 4 and 8 weeks for 10 items related to the participants' own skin condition. In addition to the VAS, a questionnaire survey using a 5-point scale was conducted to assess the feel of the study product during use and participants' preferences regarding the product.

2.2.10. Statistical Analysis

Of the 30 participants, 3 discontinued the study: 2 discontinued clinic visits, and 1 discontinued because of allergic contact dermatitis. One participant was excluded from the analysis: a man with an IGA score of 0 at the initial evaluation. Thus, the final statistical analysis set consisted of 26 participants [24 from Hayashi Dermatology Clinic and 2 from external medical institutions]. All subjects were female; mean age, 41.3 years (range: 24–62 years)]. For each evaluation item, measured values on the study start date and after 4 and 8 weeks were compared within the group. For statistical testing, p-values were calculated using the Wilcoxon signed-rank test for erythema severity, DLQI, and VAS scores, and using the paired t-test for the other items. All tests were two-sided, and the significance level was set at “5% / total number of tests” using the Bonferroni method to account for multiplicity. Statistical analysis was performed using the Excel statistical analysis software ystat 2018 (Igakutosho Shuppan Ltd.).

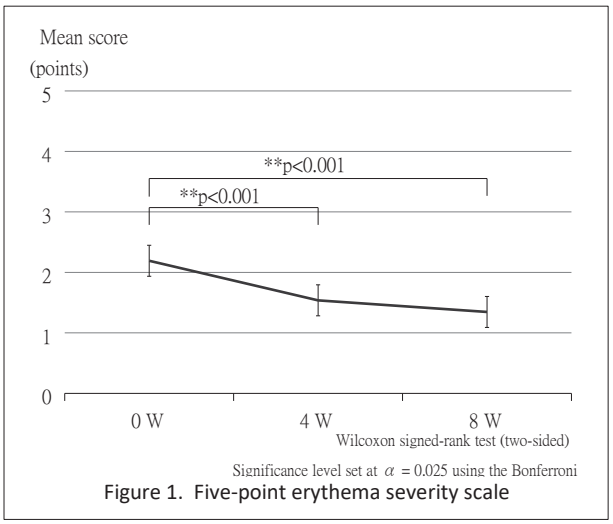


Figure 1. Five-point erythema severity scale

3. Results

3.1. Use Status of the Study Product

Among the 26 participants included in the statistical analysis, the total amount of study product used ranged from 64.7 g to 118.0 g, with a mean of 92.0 g. This was considered to indicate good compliance with product use relative to the specified amount of 84 g, calculated based on the approximate amount to be used per application. Six participants used additional cosmetics, such as lotion or milky lotion, and one participant reported not using sunscreen during the day.

3.2. Visual Assessment — Evaluation of Skin Condition

3.2.1. Erythema Severity

The mean erythema severity score on the 5-point scale, as assessed by two board-certified dermatologists, was 1.5 ± 0.54 after 4 weeks and 1.3 ± 0.47 after 8 weeks.

At both time points, a significant decrease in score was observed compared with the baseline score of 2.2 ± 0.41 (Figure 1). The degree of improvement was also evaluated according to the amount of change in erythema severity. A change in score of 1.5 or more was defined as “improved,” a change of 0.5 to 1 as “slightly improved,” and a change of 0 as “unchanged.”

After 4 weeks, 2 participants were rated as improved, 19 as slightly improved, and 5 as unchanged. After 8 weeks, compared with baseline,

4 participants were rated as improved, 20 as slightly improved, and 2 as unchanged. No cases showed worsening after either 4 or 8 weeks (Table 2).

Table 2. Change in erythema severity evaluation score

Evaluation	Change in score	Number of cases	
		4 W	8 W
Improved	1.5–2	2	4
Mildly improved	0.5–1	19	20
Unchanged	0	5	2

3.2.2. Adverse Events

The only adverse event was one case of allergic contact dermatitis. At the interview after 4 weeks, worsening redness was observed at the study product application site, and use of the study product was discontinued. In this participant, a patch test using the study product was performed, and erythema was observed at the 48-hour and 1-week assessments; the result was therefore judged to be positive.

3.3. Skin Color

In the skin color evaluation using spectrophotometric colorimeter measurements — L*, a*, and b* values — the lesional areas showed significantly stronger redness and significantly lower lightness and yellowness than the non-lesional areas at baseline before the start of the study (Figure 2). These findings were consistent with the visual assessments by the dermatologists. In the lesional areas, lightness (L* value) increased significantly from 61.15 ± 2.30 at baseline to 61.60 ± 2.01 at 8 weeks, and redness (a* value) decreased significantly from 17.65 ± 1.98 at baseline to 16.88 ± 1.96 at 8 weeks (Figure 3). Only one case showed worsening from baseline in redness (a* value). In contrast, no significant change was observed in yellowness (b* value).

3.4. Imaging Diagnostic Device Photography

In the image analysis using VISIA, uneven skin tone on the cheeks significantly improved from 0.088 ± 0.060 at baseline to 0.078 ± 0.057 at 8 weeks, and the spot score also significantly improved from 0.281 ± 0.063 at baseline to 0.264 ± 0.065 at 8 weeks. Although the difference was not significant, the hemoglobin index score decreased over time, from 0.163 ± 0.081 at baseline to 0.154 ± 0.085 at 4 weeks and 0.138 ± 0.074 at 8 weeks (Figure 4). Representative cases are shown below. In Case 1, a 43-year-old woman, after 8 weeks of use, the participant perceived a reduction in redness and a shorter duration of persistent erythema, and decreases in the hemoglobin index score were also observed at 4 and 8 weeks (Figure 5-A). In Case 2, a 49-year-old woman, the participant perceived a reduction in redness relatively early, at 4 weeks, and decreases in the hemoglobin index score were also observed at 4 and 8 weeks (Figure 5-B).

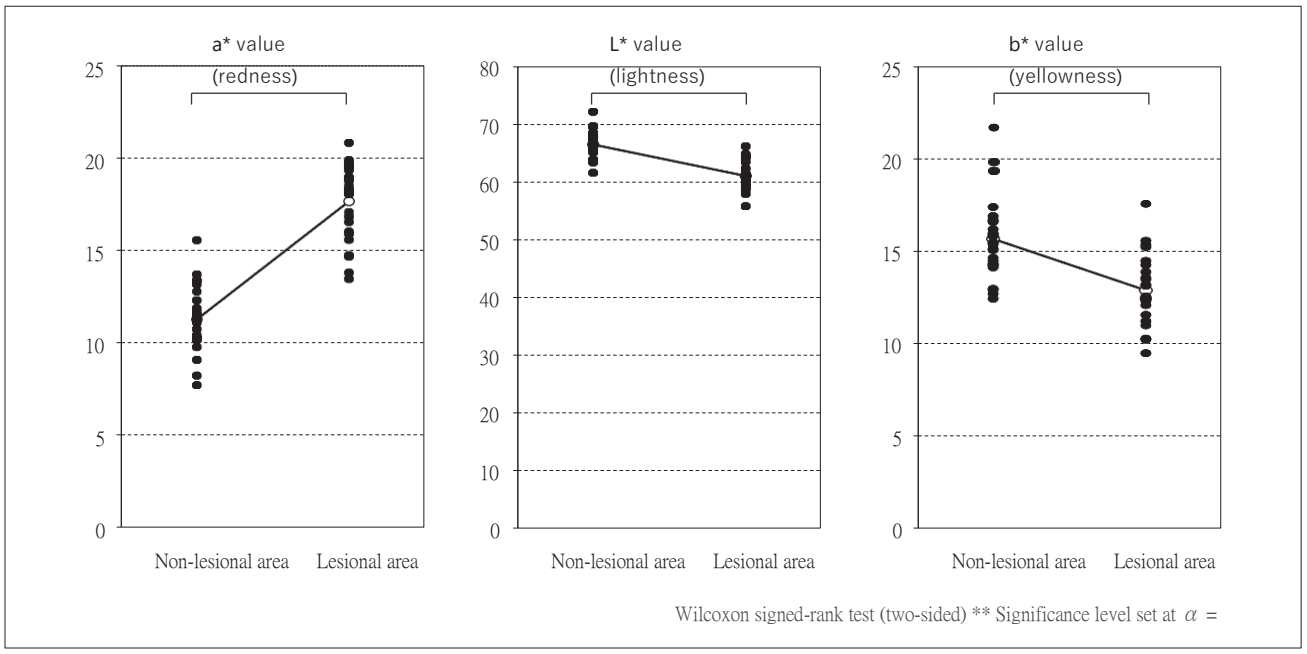


Figure 2. Spectrophotometric colorimeter measurements — L*, a*, and b* values — Skin color evaluation: Comparison of lesional and non-lesional areas at the start of the study

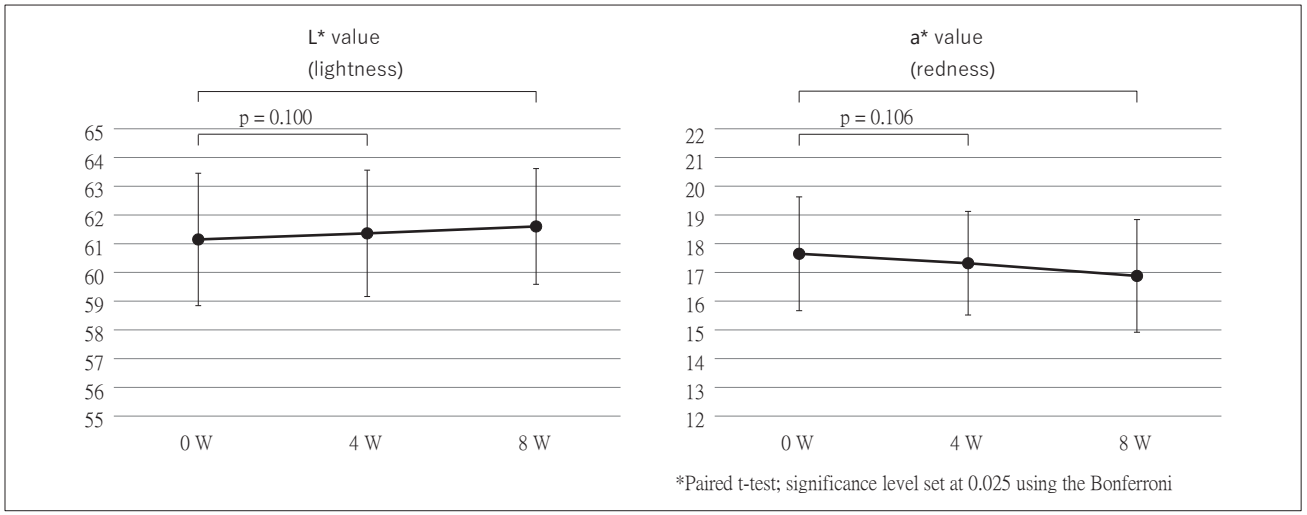


Figure 3. Changes over time in spectrophotometric colorimeter measurements (L* value, a* value)

3.5. Stratum corneum water content

The results for stratum corneum water content are shown in Figure 6. The mean stratum corneum hydration level in all participants increased significantly in the lesional area, from 70.33 ± 8.74 AU at baseline to 73.05 ± 8.48 AU at 8 weeks.

3.6. Transepidermal water loss

The results for transepidermal water loss are shown in Figure 7. The mean transepidermal water loss value for all participants in the lesional area increased from 15.52 ± 4.54 g/m2 •h at the start of the study to 17.30 ± 5.43 g/m 2•h after 4 weeks, but after 8 weeks, it tended to decrease to 15.70 ± 4.93 g/m^2•h, returning to a level similar to that at the start of the study.

3.7. Sebum Level

The results for sebum content in the affected area are shown in Figure 8. The mean sebum content value for all participants tended to decrease from 27.85 ± 30.71 AU at the start of the study to 27.27 ± 28.28 AU after 4 weeks and to 23.27 ± 24.54 AU after 8 weeks. Sebum volume varied widely among individuals, and no significant difference was observed based on whether or not the product was used.

3.8. Participant Self-Assessment

3.8.1. DLQI

In the DLQI-based QOL assessment,

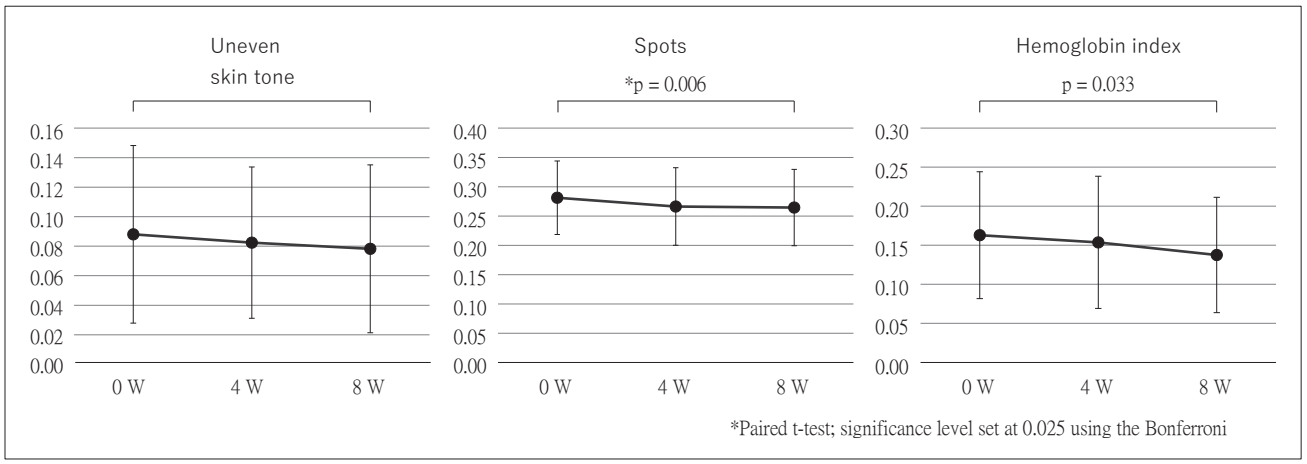


Figure 4. Changes over time in image analysis scores obtained using VISIA

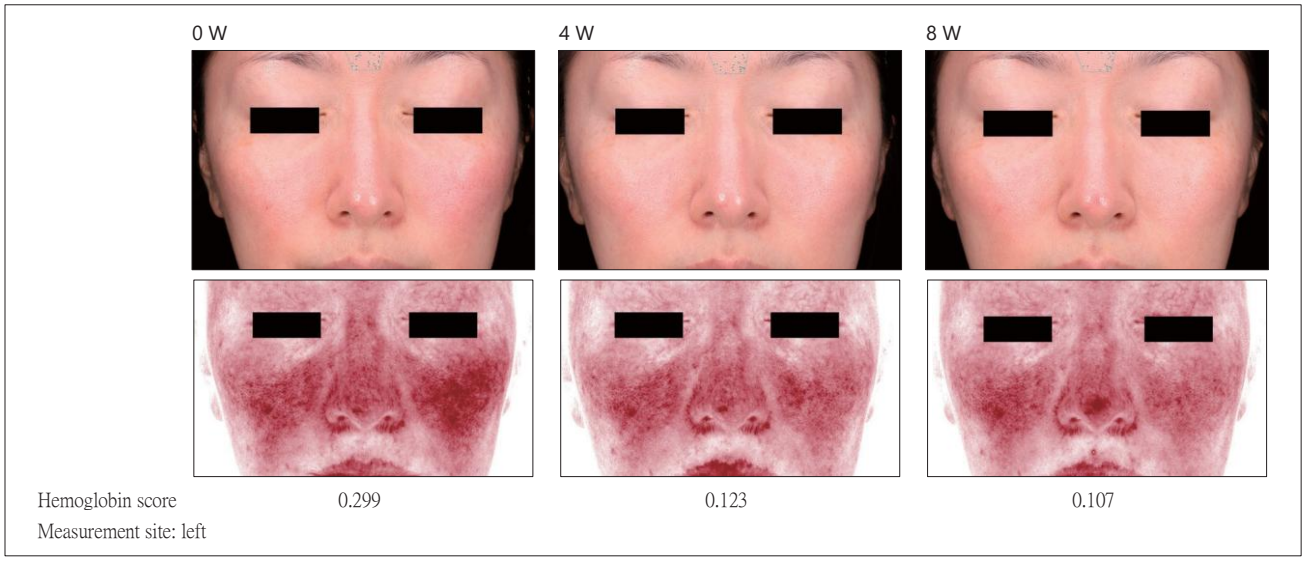


Figure 5-A. Clinical course (VISIA evaluation): Case 1, 43-year-old woman

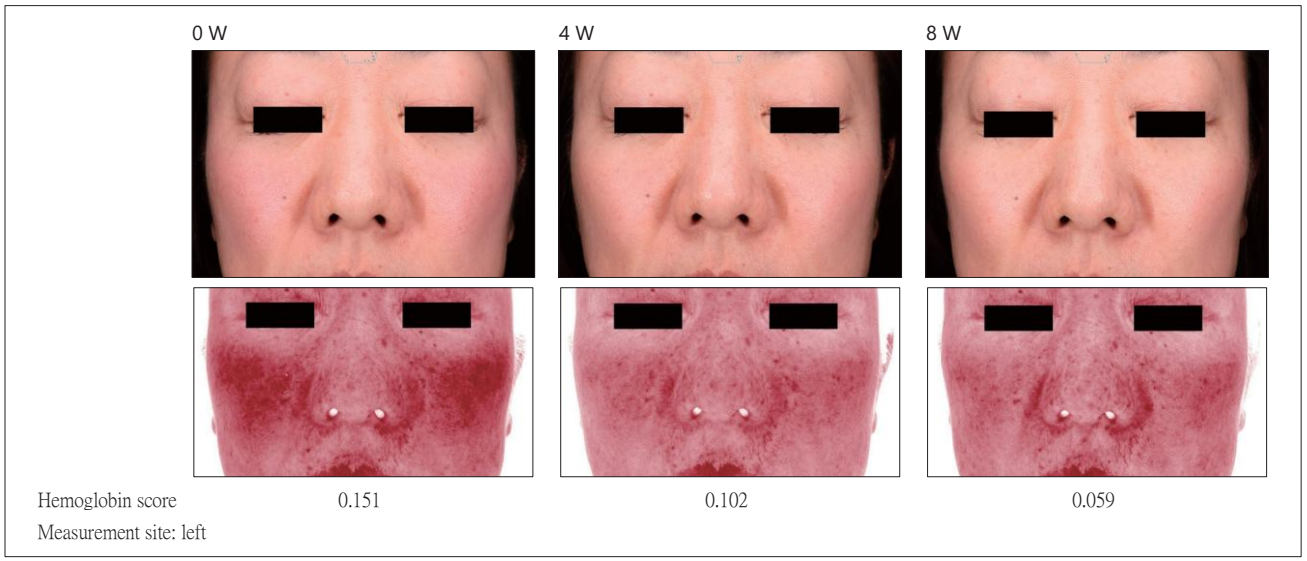


Figure 5-B. Clinical course (VISIA evaluation): Case 2, 49-year-old woman

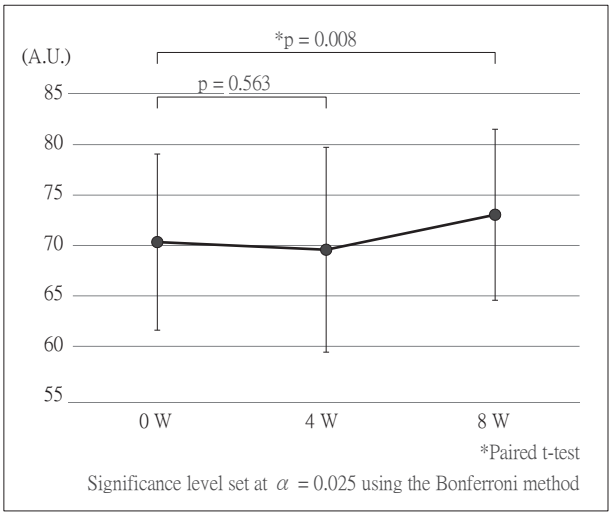


Figure 6. Changes over time in stratum corneum water content (lesional area)

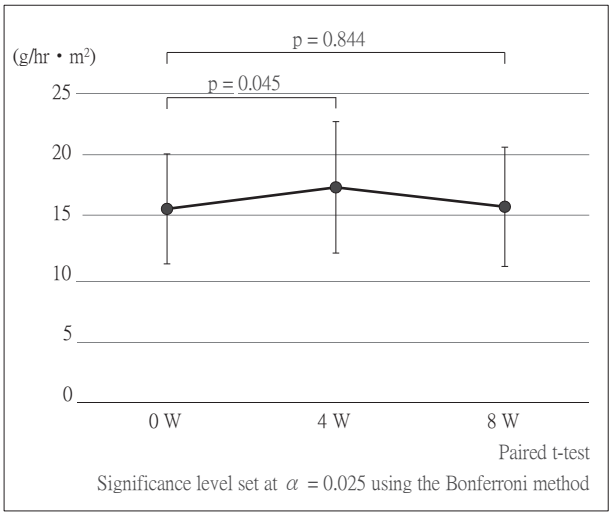


Figure 7. Changes over time in transepidermal water loss (lesional area)

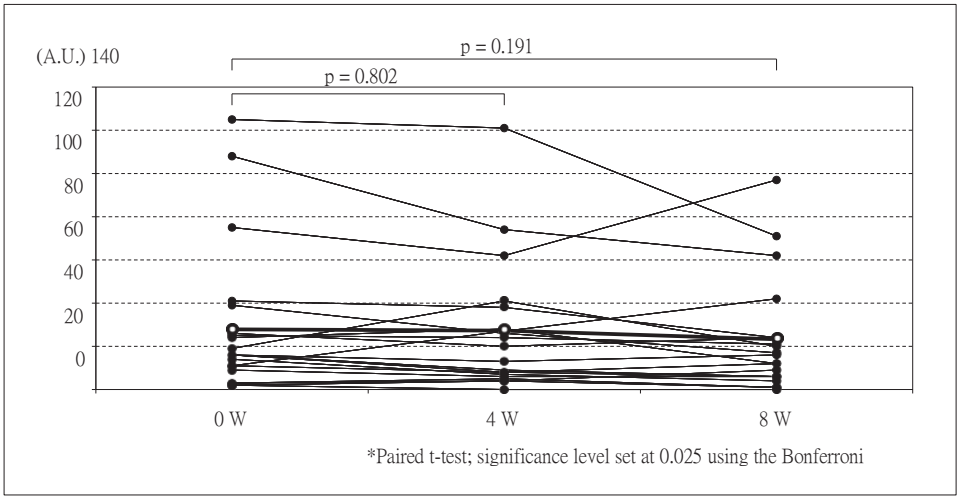


Figure 8. Changes over time in sebum level (lesional area)

scores for items such as skin symptoms, embarrassment, and interpersonal relationships, as well as the total score, improved significantly (Figure 9).

3.8.2. VAS and Product Use Questionnaire

In the self-assessment questionnaire on product use using the VAS — Visual Analog Scale — significant improvements in self-assessment scores were observed at 4 weeks for dullness, redness, oiliness, rough skin texture, dryness, skin feel, pores, skin quality, and skin tone/brightness. At 8 weeks, participants reported subjective improvement in all items (Figure 10).

In the product use questionnaire conducted at the end of the study, 23 participants (88%) responded that they "did not feel irritation after application." Regarding symptoms characteristic of rosacea, 13 participants (50%) responded that "flushing decreased," 13 (50%) that "the duration of skin redness decreased," and 12 (46%) that "the frequency of skin redness decreased", indicating that approximately half of the participants perceived a reduction in the frequency and duration of redness. In contrast, some comments on product use were also noted, such as "dryness is a concern" and "it does not blend well with makeup."

4. Discussion

Since the introduction of metronidazole gel for rosacea treatment, insurance-covered topical medications have gradually become established as standard initial treatment in Japan. However, treatment and management during the maintenance phase, or chronic phase, remain largely exploratory. Rosacea, a chronic inflammatory disease, frequently recurs after treatment is discontinued. Various year-round and seasonal factors are involved in symptom exacerbation, including sunlight, cosmetics, stress,

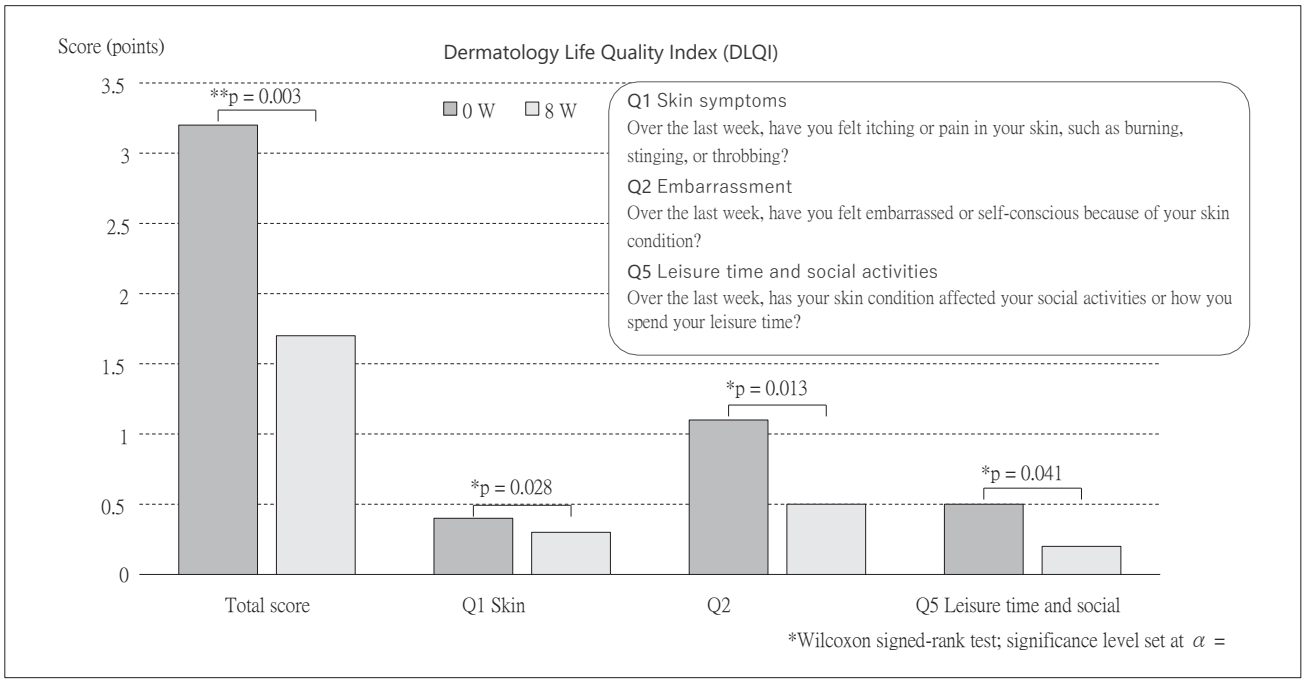
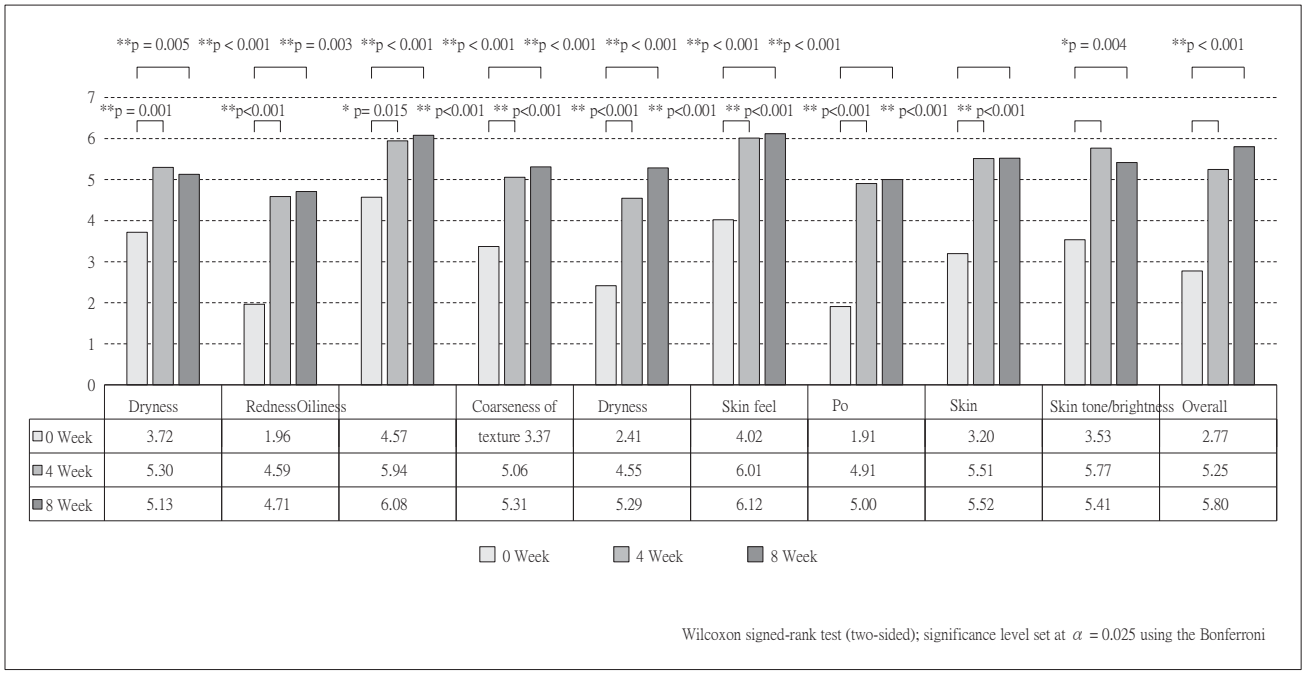


Figure 9. Items showing significant improvement in scores after use of the study product



	Dryness	Redness	Oiliness	Coarseness of texture	Dryness	Skin feel	Po	Skin	Skin tone/brightness	Overall
0 Week	3.72	1.96	4.57	3.37	2.41	4.02	1.91	3.20	3.53	2.77
4 Week	5.30	4.59	5.94	5.06	4.55	6.01	4.91	5.51	5.77	5.25
8 Week	5.13	4.71	6.08	5.31	5.29	6.12	5.00	5.52	5.41	5.80

Figure 10: Changes in self-assessment based on VAS

alcohol consumption, spices, strenuous exercise, high and low atmospheric pressure, and hot foods. These factors are thought to trigger innate immunity, causing various cells to respond and inducing inflammation in the nerves and blood vessels [8]. Because it is difficult to eliminate exacerbating factors that are widely present in daily life, recurrence occurs in a considerable number of cases.

Overseas, comparisons have been reported regarding recurrence rates and relapse-free periods after treatment discontinuation according to drug type and degree of improvement. In the extension phase of the ATTRACT study, patients who had achieved an IGA score of 0 or 1 after 16 weeks of treatment discontinued treatment and were followed for 36 weeks.

The recurrence rate was lower with topical ivermectin than with topical metronidazole, and the median relapse-free period was also longer with topical Ivermectin

[9), 10)]. In addition, according to a pooled analysis of four randomized controlled trials (RCTs), the time until 50% of cases relapsed was significantly longer in the “clear” group (252 days) than in the “almost clear” group was significantly longer in the “clear” group (252 days) than in the “almost clear” group (85 days) for inflammatory lesions (P < 0.0001), and the relapse-free rates were 23% and 54%, respectively[11)]. In other words, because rosacea is a chronic disease, recurrence can occur after treatment is discontinued; however, if treatment is continued until “clear” is achieved, the recurrence rate decreases and the relapse-free period is prolonged. In light of these findings, overseas specialists have proposed an approach to long-term maintenance therapy for rosacea in which skin care and treatment are continued in parallel for 9 months after achieving an IGA score of 0 or 1; if no recurrence occurs, skin care alone is continued, whereas if recurrence occurs, treatment is resumed[12)].

In the present study, we conducted an 8-week continuous-use study to examine the usefulness and safety of Rozatrol® in Japanese patients with rosacea. Use of the study product was found to improve the erythema severity (IGA) score and skin color (redness and lightness), and to improve skin condition by increasing stratum corneum water content. The study product has been certified by the U.S. NRS as a product that can be recommended for patients with rosacea, following an ingredient review by an expert panel confirming that the formulation does not contain irritants or allergens, does not impair the skin barrier function, does not induce vasomotor activity that causes facial flushing, and does not promote heightened neurosensory symptoms such as itching or a sensation of heat[3)]. Its main ingredients include multiple anti-inflammatory components consisting of milk protein and botanical ingredients, palmitoyl glycine, an amino acid-derived ingredient that suppresses telangiectasia, and hydrolyzed arginine, which is intended to reduce skin hypersensitivity reactions. These ingredients may have contributed in combination to the improvement in skin redness, particularly in lesional areas, and the appropriate skin care guidance provided during the study period was also considered to have contributed to improvement in the participants' skin condition.

The only adverse event was one case of allergic contact dermatitis, and many participants gave positive evaluations of the feel of the product during use. The product was therefore considered favorable from the perspectives of safety and continued use.

In the QOL evaluation using the DLQI conducted in this study, improvements were observed after use of the study product in item scores for skin symptoms, embarrassment, and interpersonal relationships, as well as in the total score. As has been reported in patients with atopic dermatitis and acne [13)14)], this product was also considered likely to contribute to improved QOL in patients with rosacea.

Pharmacologic treatment is central to the initial treatment of rosacea and treatment during exacerbations. After improvement, however, skin care is important as maintenance therapy, and products that can be used safely by patients with rosacea are needed. The skin care cosmetic product Rozatrol®, which was evaluated in the present study, may contribute to alleviating skin symptoms during remission and preventing relapse in patients with rosacea, is expected to contribute to improved QOL in patients with rosacea, and was suggested to be a possible skin care product option that Japanese patients with rosacea and facial redness can use with confidence, from a role distinct from that of pharmaceuticals.

5. Conflicts of interest

Conflicts of interest are present. The costs required for this study were borne by ZO Skin Health GK.

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8-Week Trial Study of the Skincare Product “ROZATROL ®” in Japanese Rosacea Patients:

The Role of Skincare in Improving Quality of Life for Rosacea Patients

Hiroaki HAYASHI[1)] ／ Ikumi KURIMURA[2)] ／ Haruyo YAMAMOTO[3)]

1）Hayashi Dermatology Clinic 2）ZO
Skin Health LLC
3）Department of Dermatology, Kinki University School of Medicine

Abstract

BACKGROUND / OBJECTIVES: Rosacea is a chronic inflammatory disease characterized by persistent dark red erythema primarily on the cheeks and nose. While skincare is known to be important for treatment and maintenance therapy, evidence in Japan is scarce. This study evaluated the safety and efficacy of the skincare cosmetic “ROZATROL ®”with Japanese rosacea patients.

PARTICIPANTS / METHODS: 8-week clinical study was conducted in 30 patients with erythema who had an Investigator’s Global Assessment (IGA) score of less than 3 at baseline. The single application dose was approximately 0.75g, applied twice daily in the morning and evening. Evaluations included visual assessment by board certified dermatologists, imaging with diagnostic equipment, and measurements of skin color, stratum corneum moisture content, trans epidermal water loss, and sebum levels. Self-assessments using the Dermatology Life Quality Index (DLQI) and Visual Analogue Scale (VAS) were also performed.

RESULTS: The subjects included in the statistical analysis were 26 patients (all female, mean age 41.3 years [range: 24–62 years]). 8 weeks after the start of the study, the IGA score improved from 2.2 ± 0.41 to 1.3 ± 0.47（$p < 0.001$）, and the a* value (redness) in skin color measurement significantly decreased from 17.65 ± 1.98 to 16.88 ± 1.96 ($p=0.004$). Stratum corneum water content significantly increased from 70.33 ± 8.74 AU to 73.05 ± 8.48 AU ($p=0.008$). VAS confirmed subjective improvement in skin condition across items including redness, oiliness, dryness, and skin texture. DLQI score, an indicator of QOL, also showed significant improvement.

CONCLUSION: ROZATROL ® contributes to alleviating skin symptoms during the remission phase of rosacea and preventing flare-ups. It is expected to contribute to improving the quality of life for rosacea patients. It becomes one of the skincare product options available for Japanese patients with rosacea and facial redness.