

Evaluation of a Barrier Repair Cream Containing Pseudo-Ceramide for Practical Use by Hairdressers with Hand Skin Disorders Due to Daily Exposure to Chemical Irritants

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ABSTRACT

Hairdressers are exposed to numerous skin-damaging factors, such as wet work, skin irritants, and thermal changes. Skin protection is a very important factor for the prevention of occupational skin disorders. Therefore, we evaluated a hand cream that was specially formulated for highly stressed skin with regard to its capability to reduce dry, rough, and scaly skin. The objective of this study was to conduct a controlled use test of a barrier repair cream containing pseudo-ceramide and demonstrate its efficacy for hairdressers with dry, sensitive hands and/or occupational skin disorders. A total of 30 hairdressers (29 females and 1 male, aged 20 - 67) participated in the study. All subjects suffered from dry hands. Subjects applied the test cream on their hands for 28 days (four weeks). For each subject, the skin surface topography of the hands was measured by the Surface Evaluation of Living Skin (SELS) system at day 14 (week 2) and day 28 (week 4). Dryness, scaling, cracking, redness, and itchiness were evaluated and graded by experts at week 2 and week 4, and then compared to baselines. All 30 subjects completed the study. A comparison of the changes from baseline to endpoint revealed a statistically significant reduction in skin roughness, scaling, and volume measured according to SELS. These data were confirmed by photographic documentation. The results were further supported by the expert evaluation. For the symptoms dryness and scaling, improvement could be observed in almost all regions of the hands. In addition, according to subjective assessments of overall hand skin condition and the hand cream, subjects reported clear improvement over time (p value below 0.001) and good efficacy of the product. In this study, the test hand cream showed excellent skin compatibility. Therefore, the hand cream may be effective for hairdressers with dry, sensitive hands and/or occupational skin disorders.

Keywords: Occupational Skin Disorder; Hairdresser; Dermatological Controlled Use Test; Pseudo-Ceramide; Barrier Cream; Topical Hand Care

1. Introduction

It is well known that excessive cleansing with detergents is one of the causes of skin dryness and roughness. Consequently, many hairdressers who are exposed to chemical irritants, such as those contained in shampoos and hair dyes, on a daily basis suffer from occupational skin disorders [1,2]. Exogenous occupational irritants that deteriorate the skin barrier are considered one of the

causes of occupational skin disorders. It is known that stratum corneum intercellular lipids, especially ceramides, play an important role in the maintenance of the skin barrier [3-6], but stratum corneum intercellular lipids are washed away by surfactants [7]. As a result, they lower the skin barrier, leading to skin disorders.

For this reason, barrier cream containing ceramide has been developed in recent years, and its efficacy in occupational skin disorders has been evaluated [8].

Although some researchers have reported on the effi-

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cacy of ceramide barrier cream in dry, scaly skin induced artificially by detergents [9,10], no clinical studies have been conducted on a barrier cream containing ceramide for hairdressers who are exposed to chemicals on a daily basis. Therefore, improvement of hand skin symptoms in hairdressers has not been clinically observed.

We developed a skin barrier cream containing synthesized pseudo-ceramide and allantoin, and carried out a controlled use test in hairdressers who had symptoms of dry, sensitive skin on their hands.

2. Materials and Methods

2.1. Test Product

A test hand cream formulation, containing pseudo-ceramide (**Figure 1**) and allantoin, was prepared for this study. INCI declaration: Water (Aqua), Cyclopentasiloxane, Glycerin, Cetyl-PG Hydroxyethyl Palmitamide (Pseudo-ceramide), Hydrogenated Polyisobutene, Neopentyl Glycol Ether, Cetyl Dimethicone, Cholesteryl Iso-stearate, Eucalyptus Globulus Leaf Extract, Magnesium Sulfate, Allantoin, Methylparaben, Succinic Acid, PEG-10 Hydrogenated Castor Oil, Sodium Hydroxide, Tocopheryl Acetate, Bis-Methoxypropylamide Isodocosane. Pseudo-ceramide was synthesized following the procedures in a previous report [11].

2.2. Selection of Test Subjects

Thirty healthy hairdressers (29 females and 1 male) aged between 20 and 67 years of age (40.5 ± 12.6 years) who suffered from dry, sensitive skin on their hands and were able to visit the University of Witten-Herdecke in Germany were selected as test subjects for the study (**Table 1**).

2.3. Study Design

This was a monadic study without any control group. After a three-day regression period (during which subjects were not allowed to use hand care products on their hands), the test subjects applied the test product on their hands, instead of their own hand cream products, at least three times per day over a period of four weeks (28 days). Expert evaluation, instrument measurement, digital photography, and a questionnaire were performed on day 0 (baseline), day 14 (week 2), and day 28 (week 4). The study was realized from April to May 2012.

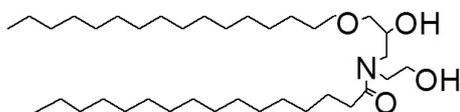


Figure 1. Chemical structure of pseudo-ceramide (Cetyl-PG Hydroxyethyl Palmitamide).

2.4. Skin Physiological Parameters

The skin surface topography was measured with the Visioscan[®] VC98 (Courage & Khazaka Electronics GmbH, Germany). All subjects were required to undergo a thirty-minute acclimation period (22°C, 40% relative humidity). The values recorded were means of three measurements.

The Surface Evaluation of Living Skin (SELS) [12] measuring device consists of a measuring head (Visio-Scan C, Courage & Khazaka, Cologne) containing two special metal-halogenide lights arranged on opposite sides that uniformly illuminate a 15 × 17 mm measuring area of the skin. The spectrum of the lamps as well as their intensity and location had been chosen in such a way that only the skin surface, without reflections of deeper layers, was monitored. Furthermore, unlike with formerly applied procedures with diagonal illumination, with SELS, a distinct representation of the wrinkling is avoided. A CCD-camera, built into the measuring head, takes an image of the skin, which is then transferred as a gray-value bitmap-file by means of the software Skinvisiometer (Courage & Khazaka, Cologne). The color value for each pixel corresponds to quantification with eight bits, which allows a differentiation into 256 grey values. The value “0” corresponds to the color “black”, and the value “255” corresponds to the color “white”. By means of the additional software, the SELS skin specific parameters (roughness, scaling, wrinkles, and volume) are then calculated.

2.5. Expert Evaluation

To determine skin dryness, scaling, cracking, redness, and itchiness of the hands, a subjective visual evaluation of each test subject was conducted by an expert according to the following four grade scales: 0 = none, 1 = slight symptoms, 2 = mild symptoms, and 3 = moderate symptoms. Dryness, scaling, cracking, redness, and itchiness were recorded for the palm side (palm, fingers, fingertips) and back side (back, fingers, fingertips).

2.6. Subjective Evaluation

For the subjective assessment of the test product, cosmetic acceptance and satisfaction of hand skin condition were evaluated. The subjects assessed the cosmetic acceptance and rated the product as “very bad”, “bad”, “neither good nor bad”, “good”, or “very good”. The subjects’ satisfaction with their hand skin condition at baseline, week 2, and week 4 were rated as “not satisfied”, “not so satisfied”, “somewhat satisfied”, “satisfied”, and “extremely satisfied”.

2.7. Digital Photography

To objectively measure the responsiveness to the treat-

Table 1. Hand skin condition at baseline visit.

Symptom	Grading	Front side			Back side		
		Hand	Finger	Finger tip	Hand	Finger	Finger tip
Dryness	0:None	15	13	14	0	0	3
	1:Slight	8	7	9	6	7	4
	2:Mild	4	7	5	14	15	17
	3:Moderate	3	3	2	10	8	6
	Average	0.83	1	0.83	2.13	2.03	1.87
Scaling	0:None	24	20	24	11	12	16
	1:Slight	3	8	3	9	12	9
	2:Mild	1	71	2	7	6	1
	3:Moderate	2	1	1	3	0	4
	Average	0.37	0.43	0.33	1.07	0.8	0.77
Cracking	0:None	30	30	27	26	28	25
	1:Slight	0	0	2	2	0	2
	2:Mild	0	0	0	1	2	2
	3:Moderate	0	0	1	1	0	1
	Average	0	0	0.17	0.23	0.13	0.3
Redness	0:None	30	30	30	12	17	27
	1:Slight	0	0	0	10	8	2
	2:Mild	0	0	0	7	5	1
	3:Moderate	0	0	0	1	0	0
	Average	0	0	0	0.9	0.6	0.13
Itchiness	0:None	26	28	29	13	16	26
	1:Slight	4	1	0	7	9	2
	2:Mild	0	1	1	8	5	2
	3:Moderate	0	0	0	2	0	0
	Average	0.13	0.1	0.07	0.97	0.63	0.2

ment of the highly stressed skin on the hands, photographic documentation was performed (Fotofinder Systems GmbH, Bad Birnbach, Bavaria, Germany).

2.8. Ethics

The study protocol was approved by the ethical committee of the University of Witten-Herdecke. All participating test subjects were informed about the objectives and scope of the study and provided written informed consent prior to the study. The study was carried out in accordance with the GCP-Guideline.

2.9. Statistical Analysis

A two-sided Wilcoxon signed rank sum test was used for statistical analysis of the SELS and questionnaire data.

The statistical analysis of the visual evaluation by experts was performed by Steel's multiple comparison test to investigate differences in distributions in comparison to baselines.

P-values of less than 0.05 were considered as statistically significant.

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3. Results

All thirty enrolled test subjects completed the study. All participants had used their own hand care products on their hands prior to the study, and had dry hand skin at the baseline visit.

The SELS parameters roughness, scaling, wrinkles, and skin volume were evaluated. Skin roughness parameter decreased by 29.7% ($p = 0.0002$) after two weeks and by 32.1% ($P = 0.0003$) after four weeks of treatment with the test product compared to baseline (**Figure 2**). Scaling parameter decreased by 51.4% ($p < 0.0001$) after two weeks and by 49.7% ($p < 0.0001$) after four weeks of treatment with the test product compared to baseline (**Figure 3**). Skin wrinkle parameter decreased

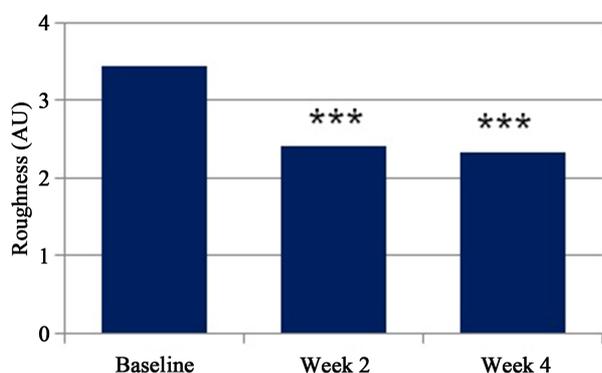


Figure 2. Skin roughness: At baseline and after 2 and 4 weeks of hand cream treatment the skin roughness was assessed. Statistical differences in skin roughness between baseline and after 2 weeks' and 4 weeks' treatment are indicated ($*p < 0.05$, $**p < 0.01$, $***p < 0.001$ Wilcoxon signed-rank test). The bars indicate SD of means for 30 test subjects.

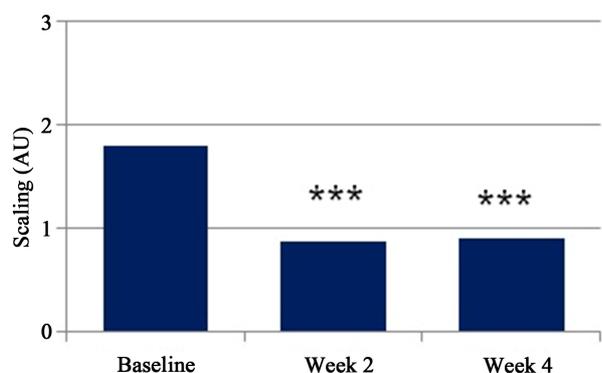


Figure 3. Skin scaling: At baseline and after 2 and 4 weeks of hand cream treatment skin scaling was assessed. Statistical differences in skin scaling between baseline and after 2 weeks' and 4 weeks' treatment are indicated ($*p < 0.05$, $**p < 0.01$, $***p < 0.001$ Wilcoxon signed-rank test). The bars indicate SD of means for 30 test subjects.

by about 3% after two weeks and after 4 weeks of treatment with the test product. Thus, there were no statistical significances between skin wrinkles after two weeks ($p = 0.217$) and four weeks ($p = 0.109$) compared to baseline (**Figure 4**). The parameter volume is the virtual amount of liquid which is required to fill the depth. Thus, the smoother the skin, the less virtual liquid is needed to fill the depth. The skin volume significantly decreased by 16.1% ($p = 0.002$) after two weeks and by 15.75% ($p = 0.0239$) after four weeks of supplementation (**Figure 5**).

In addition to the SELS analysis, improvements of the skin were assessed by comparing observations of the dryness, scaling, cracking, redness, and itchiness of the skin by experts at different time intervals.

At baseline, all subjects had skin dryness on the backs of their hands and fingers. Severities of dryness, scaling, cracking, redness, and itchiness on the backs of their hands were worse than those of the palms. The mean

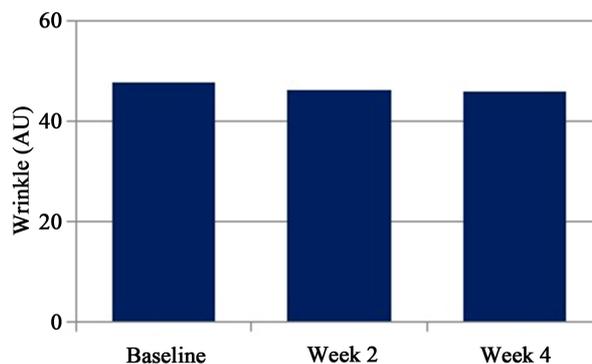


Figure 4. Skin wrinkles: At baseline and after 2 and 4 weeks of hand cream treatment skin wrinkles were assessed. Statistical differences in skin wrinkles between baseline and after 2 weeks' and 4 weeks' treatment are indicated ($*p < 0.05$, $**p < 0.01$, $***p < 0.001$ Wilcoxon signed-rank test). The bars indicate SD of means for 30 test subjects.

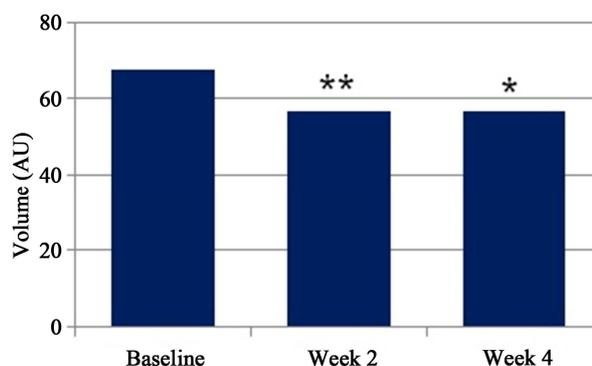


Figure 5. Skin volume: At baseline and after 2 and 4 weeks of hand cream treatment skin volume was assessed. Statistical differences in skin volume between baseline and after 2 weeks' and 4 weeks' treatment are indicated ($*p < 0.05$, $**p < 0.01$, $***p < 0.001$ Wilcoxon signed-rank test). The bars indicate SD of means for 30 test subjects.

grade of dryness on the backs of hands went from 2.13 at baseline down to 1.00 at week 2, and then further down to 0.20 at week 4. Along with the improvement of hand

skin dryness, the mean grades of scaling, redness, and itchiness also decreased (**Figure 6**).

No side effects (adverse reactions) were observed

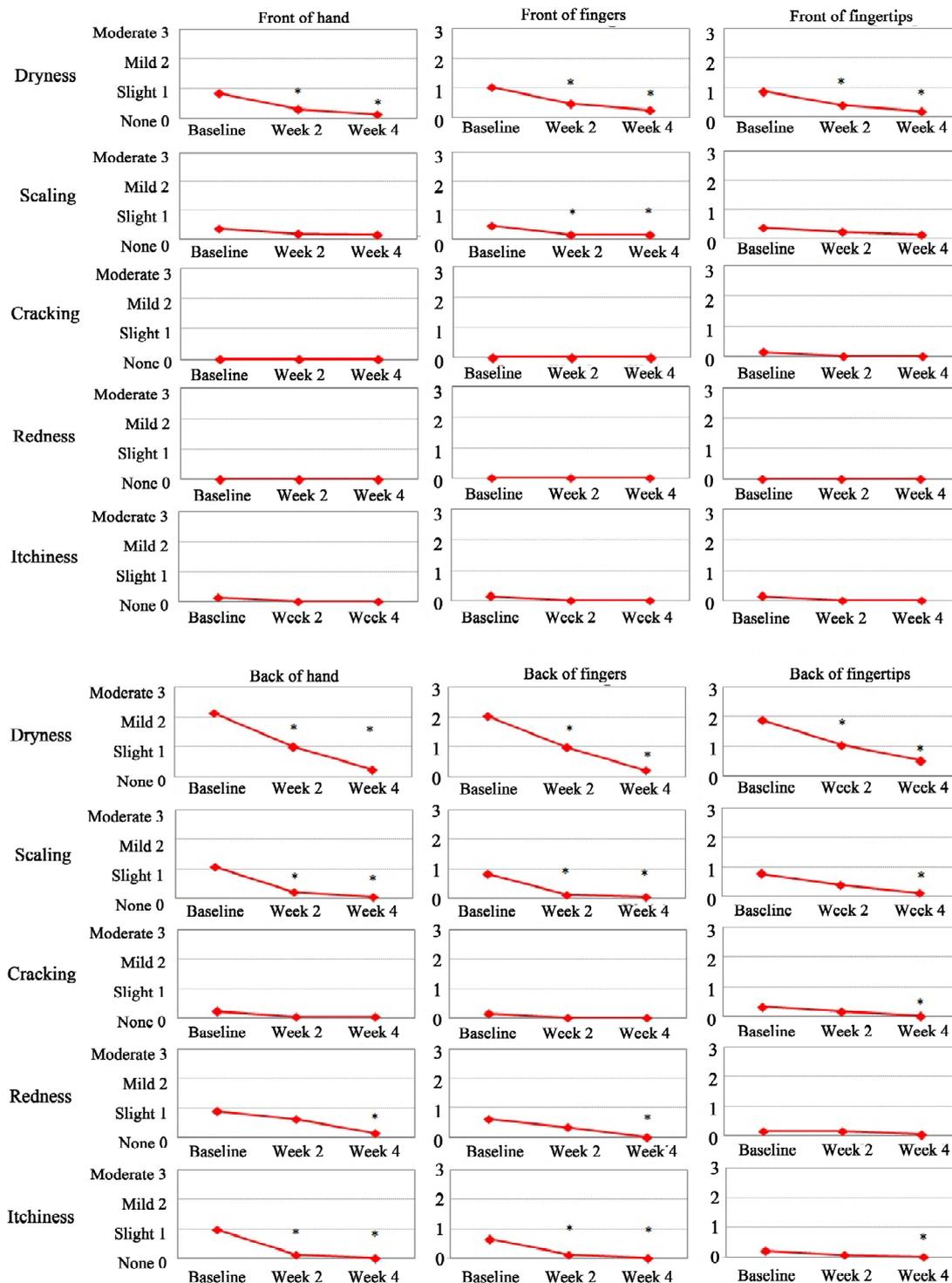


Figure 6. Expert gradings: At baseline and after 2 and 4 weeks of hand cream treatment, experts graded 6 regions of the hands. Statistical differences in expert gradings between baseline and after 2 weeks' and 4 weeks' treatment are indicated (* $p < 0.05$ Steel's multiple comparison test).

throughout the study period for all test subjects. In regards to skin compatibility of the test product, 70.0% [21] of the test subjects were very satisfied and 30.0% [9] were satisfied. Therefore, all test subjects were pleased with skin compatibility, indicating that the test product was very good in terms of skin compatibility (**Table 2**).

According to subjective assessments of overall hand skin condition, subjects reported improvement throughout the test period (**Figure 7**). In terms of cosmetic acceptance, 93.3% of test subjects rated the test product as “very good” or “good” at week 4 (**Table 3**).

The positive effects on the skin of the hands shown by skin physiological parameters measured by the SELS method and by expert evaluation, as well as the noted subjective assessments, were confirmed by digital photographic documentation. A selection of representative digital photographs is shown in **Figure 8**. Before the

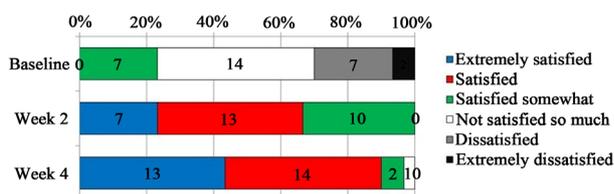


Figure 7. Changes in subjective assessment of satisfaction of hand skin condition: After daily applications of test hand cream, subjects' satisfaction of their hand skin condition improved significantly (Week 2 versus Baseline: $p < 0.001$, Week 4 versus Baseline: $p < 0.001$ Wilcoxon signed-rank test).

Table 2. Skin compatibility.

	Number	%
Very good	21	70
Good	9	30
Fair	0	0
Satisfactory	0	0
Unsatisfactory	0	0
Insufficient	0	0

Table 3. Subjects' assessment of the clinical acceptance of the test hand cream.

	N	%	Cumulative %
Very good	13	43.3	43.3
Good	15	50	93.3
Neither good nor bad	2	6.7	100
Bad	0	0	100
Very bad	0	0	100

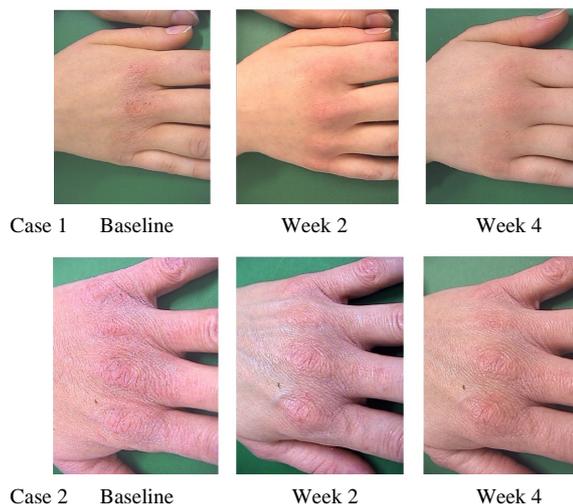


Figure 8. Photographic documentation: At baseline visit, the skin was rough, flaky, and dry. However, after daily applications of the test hand cream, the skin on the hands appeared shiny, smooth, and well maintained.

treatment, the skin was rough and dry. However, after daily application of the test product for four weeks, the skin on the hands appeared shiny, smooth, and well maintained.

4. Discussion

Hairdressers are exposed to numerous skin-damaging factors, such as wet work, chemical irritants, and thermal changes. In fact, 87% of the subjects of this study did not wear gloves while shampooing hair, and 77% of them did not wear gloves while perming hair (**Table 4**). Thus, skin protection by hand care treatment is a very important factor for the prevention of occupational skin disorders.

Ceramide is well known as one of the stratum corneum intercellular lipids that play an important role in the maintenance of skin barrier function [3]. With a decrease in the amount of ceramide and other stratum corneum intercellular lipids, the skin barrier function lowers on atopic dermatitis [4]. Decreased ceramide level is caused by an abnormality in ceramide metabolism in atopic dermatitis [13,14]. It has been reported that application of barrier repair cream containing ceramide improves atopic symptoms along with improvement of the skin barrier function as measured by transepidermal water loss [15,16].

However, detergents are known to cause dry skin problems since they facilitate the flowing out of stratum corneum intercellular lipids [7]. Previous reports have shown the efficacy of treatment with topical creams containing ceramide in cases of dry skin induced by detergents [8,9], but there have been no reports on the

Table 4. Glove use ratio of daily duties.

Duty	N (%)				
	Hair shampoo	Hair coloring	Bleaching	Hair perm (acid)	Hair perm (alkali)
with globe	4 (13.3)	27 (90.0)	22 (73.3)	7 (23.3)	7 (23.3)
without globe	26 (86.7)	3 (10.0)	8 (26.7)	23 (76.7)	23 (76.7)

clinical efficacy of ceramide cream in occupational skin disorders of hairdressers who are exposed to chemical irritants on a daily basis. Therefore, a hand cream that contains pseudo-ceramide and is formulated for highly stressed skin of the hands is evaluated with regard to its capability of reducing dry, rough, and scaly skin.

A comparison of changes from baseline to endpoint revealed a statistically significant reduction in skin roughness, scaling, and volume measured according to SELS. These data were confirmed by photographic documentation.

The results were further supported by expert evaluation. For the symptoms dryness and scaling, improvements could be observed in almost all regions of the hands.

In addition, self-assessment showed that overall hand skin condition clearly improved over time (p value below 0.001), and test subjects reported good efficacy of the test product.

Since problem skin requires special skin care, skin care products have to be mild with excellent skin compatibility, preventing skin irritations and dryness. In this study, the test hand cream showed excellent skin compatibility.

Since this study was a single-test without any controls, we could not definitively declare the efficacy of the test hand cream. However, though all of the subjects continued their daily work tasks, including shampooing and perming hair, throughout the test period and had used commercial hand care products until the study started, the clinical scores and SELS measurements improved significantly. In addition, by self-assessment, subjects reported improved hand skin condition throughout the test period. These results suggest that the test hand cream is effective for dry hand skin problems in hairdressers.

In order to confirm the efficacy for occupational hand skin eczema, we should conduct a double-blind study using placebo as a control and measure skin barrier function to clearly demonstrate that the effects of the test product are due to pseudo-ceramide and its ability to maintain skin barrier function.

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