

Evaluation of the Efficacy and Tolerability of a Dermocosmetic Repair Balm Containing Vitamin B5, Madecassoside, and a Prebiotic Complex When Used Post-Microneedling in Japanese Individuals

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Abstract

Objective: To assess the ability of a dermocosmetic containing vitamin B5, madecassoside, and a prebiotic complex (DC) to shorten the downtime after a cosmetic procedure. **Methods:** A randomized, evaluator-blinded, split-face study was performed using white petrolatum as the comparator product (CP). After microneedling treatment with a Dermapen® 4, each study product were applied to one half of the face twice daily (morning and night) for 14 days. Observations and evaluations were performed on days 0, 2, 3, 5, 7, 14, and 28 following the Dermapen 4 procedure. **Results:** Twenty-nine participants (27 female, 2 male) with a mean age of 40.7 ± 11.9 years (range 19 - 58) completed the study and had results available for evaluation. Improvement in erythema, a key contributor to downtime, tended to be more rapid on the DC side than on the CP side. The mean time needed for the erythema score to decrease to 2 was 2.63 days for DC and 3.68 days for CP, representing a difference of approximately 1 day. From the patient perspective, the DC was rated higher for usability, willingness to continue use, and overall improvement in skin condition. **Conclusion:** The DC containing vitamin B5, madecassoside, and a prebiotic complex demonstrated potential in terms of reducing post-microneedling downtime, suggesting a value in post-procedure care. Trial Registration: Japan

Registry of Clinical Trials (jRCTs031230421; registered on October 23, 2023).

Keywords

Madecassoside, Prebiotic Complex, Microneedling, Erythema, Downtime

1. Introduction

Cosmetic medical treatments for photoaging, which include blemishes and wrinkles, are widely performed in clinical practice. Such procedures may involve the use of laser devices, phototherapy devices, and microneedling [1] [2] and can be broadly classified as either ablative, which involves wounding of the skin, or non-ablative, which does not. Ablative skin rejuvenation may cause erythema, edema/swelling, bleeding, crusting, dryness/scaling, and pain at the site of the procedure, the time to recovery from which is known as “downtime”. Downtime has a negative impact on a patient’s quality of life, and alleviating symptoms that cause it and reducing its duration are important clinical issues. Current methods for reducing downtime generally include protection from external stimuli, moisturizing, and sun protection.

A dermocosmetic repair balm containing vitamin B5, madecassoside, and a prebiotic complex (DC) (Cicaplast Baume B5+; La Roche-Posay Laboratoire Dermatologique International, Levallois-Perret, France) has been shown to alleviate clinical signs, symptoms, and downtime after ablative and non-ablative procedures [3]-[5]. This balm is formulated with madecassoside and panthenol (vitamin B5), which have anti-inflammatory and soothing properties and stimulate re-epithelialization of the skin [6] [7], shea butter, which protects and moisturizes the skin, and La Roche-Posay thermal spring water. It also contains two active prebiotic ingredients, namely, *Aqua posae filiformis*, which is a heat-inactivated lysate of *Vitreoscilla filiformis* biomass grown in selenium-rich La Roche-Posay thermal water, and Tribioma™, a patented prebiotic complex designed to support a balanced skin microbiome, which includes inactivated *Lactobacillus* spp., sugars and plant extracts. Several randomized clinical studies have confirmed the ability of this combination of active ingredients in a dermocosmetic repair balm to promote post-procedure wound healing [3]-[5] [8] [9]. Wound healing involves the interaction of several types of skin, immune, and vascular cells, growth factors, and cytokines, and the microbiome can play an important role in this process [10].

In this study, we investigated the effects of DC on erythema, edema/swelling, bleeding, crusting, dryness/scaling, pain, and pruritus following treatment with a microneedling device (Dermapen® 4; DermapenWorld, Sydney, NSW, Australia) [11]-[13].

2. Methods

The study protocol was approved by the Certified Review Board of the NPO

Health Institute Research of Skin (CRB No. CRB3210001) and conducted according to the ethical principles of the Declaration of Helsinki and the provisions of the Clinical Trials Act, its enforcement regulations, and other relevant notifications. All study participants provided written informed consent. The study was registered with the Japan Registry of Clinical Trials (jRCTs031230421 on October 23, 2023).

2.1. Participants

The study included adults aged 18 - 64 years who underwent Dermapen 4 treatment to improve their facial skin symptoms. The following exclusion criteria were applied: a skin condition likely to affect the study outcome; use of a medicinal product (oral or topical), quasi-medicinal product (cosmetic product for medicinal use), or cosmetic product for skin-whitening or anti-wrinkle purposes within 1 month before the start of the study; a cosmetic procedure, such as laser therapy, phototherapy, or radiofrequency therapy, performed within 1 month before the start of the study; use of a cosmetic product containing an ingredient with a peeling effect; facial surgery or facial injection of Botulinum toxin or hyaluronic acid within 6 months before the start of the study; and judged by the investigator to be unsuitable for participation in the study.

2.2. Study Design and Treatment

The study had a randomized, evaluator-blinded, split-face (left vs. right) design. The test product was the DC, all ingredients of which conform to European Union regulation number 1223/200 for cosmetic products. The comparator product (CP) was white petrolatum (Propeto®; Daiichi Sankyo Healthcare, Tokyo, Japan), which conforms to the standards of the Japanese Pharmacopoeia.

After securing written consent, instrumental measurements were obtained at the study site for screening purposes. Dermapen 4 treatment was administered to the entire face by any of five dermatologists at their respective clinics within 7 days of obtaining these measurements. The device was set to a needle penetration depth of 1.5 - 1.75 mm and a needle speed of 120 revolutions per second, a depth chosen in accordance with the manufacturer's recommendations for facial rejuvenation and to induce a reproducible, clinically meaningful level of erythema while remaining within the established safety range for microneedling. The participants were transferred to the study site within 2 h following the procedure, where the day 0 evaluation was carried out by a dermatologist. Participants were randomly assigned to receive DC on the left side of the face and the CP on the right side or vice versa using a randomization table that was generated using a random number generation program, ensuring an equal distribution of participants to each treatment group. The treatment consisted of application of the study product and the comparator product to the allocated sides of the face twice daily (morning and night) for 14 days. The amount of DC per application was 2 finger-tip units (1 g). The CP was applied in a thin layer to the allocated side of the face. The dermatologist assessing the treatment outcomes was blinded to which product was applied

to which side of the face.

The participants attended the study site for evaluation at baseline and on days 2, 3, 5, 7, 14, and 28 post-procedure. Participants were instructed not to perform facial cleansing on the day of Dermapen 4 treatment and to use light makeup that could be removed with a facial cleanser for 3 days following treatment, with regular makeup allowed from day 4 onwards. The participants used only an approved facial wash (Toleriane Purifying Foaming Cleanser; La Roche Posay) and sunscreen (Uvidea XL; La Roche Posay) and were instructed not to use skin care products other than skin lotions which they usually use.

2.3. Clinical Evaluation

Erythema, edema/swelling, bleeding, crusting, and dryness/scaling were evaluated on a 5-point scale (0, none; 1, slight; 2, mild; 3, moderate; 4, severe), and the overall clinical evaluation was based on the total score for these variables. Post-inflammatory erythema and post-inflammatory hyperpigmentation were evaluated on day 28.

2.4. Instrumental Measurements

All instrumental measurements were obtained after face washing followed by acclimatization for at least 20 min in a room at constant temperature ($20 \pm 2^\circ\text{C}$) and humidity ($50 \pm 5\%$). The sites for measurement were the fixed left and right cheeks. The water content of the stratum corneum was determined by measuring conductance of high-frequency current (μS) using a Skicon-200EX (Yayoi Co., Ltd, Tokyo, Japan). Five measurements were taken at each site, the highest and the lowest were discarded, and the mean of the remaining three measurements was calculated. Sebum content was determined by measuring once on each cheek using the Sebumeter SM 810 and transepidermal water loss was measured using the Tewameter TM300 (both from Courage + Khazaka Electronic GmbH, Cologne, Germany). Three measurements were taken at each site, and the mean value was calculated.

2.5. Image Evaluation

Erythema and pigmentation were evaluated on photographs using the VISIA Evolution 2 system (Canfield Scientific, Parsippany, NJ, USA).

To ensure the homogeneity and consistency of the clinical evaluations, two dermatologists who were not otherwise involved in treatment or the initial skin assessments evaluated each study participant's skin, using photographs taken with the VISIA system. The evaluating dermatologists were blinded to treatment allocation and the initial assessments made by the treating physicians.

2.6. Patient-Reported Outcomes

NRS scores for pain and pruritus

Participants evaluated their pain and pruritus using a numerical rating scale

(NRS). Pain was evaluated for each cheek on an 11-point scale, with 0 being no pain and 10 being the worst pain imaginable. Pruritus was evaluated for each cheek on an 11-point scale, with 0 being no itching and 10 being the worst pruritus imaginable.

Responses to a questionnaire

The participants evaluated whether their skin was better on the left or right side of the face at each visit to the study site between days 2 and 14. The usability of each study product was evaluated by rating of the ease of application to the skin, ease of blending into the skin, absence of irritation, and overall smoothness of application on a 5-point scale (good, somewhat good, neutral, somewhat bad, bad). Willingness to use the product was evaluated by surveying which product the participant preferred, whether the participant would like to use the product after the next cosmetic procedure, and whether the participant would like to continue using the product as part of their daily skin care routine. The product evaluation questionnaire was administered on day 14. The results for product usability, willingness to use the product, and evaluation of skin condition were analyzed and are presented as percentages.

2.7. Safety

Safety was evaluated from the time at which consent was obtained until the end of the observation period. Any symptoms detected were recorded as adverse events. The type and severity of adverse events, number of cases, and number of occurrences were recorded and analyzed.

2.8. Statistical Analysis

The full analysis set comprised all participants who were enrolled in the study and commenced treatment with the study products. The safety analysis set comprised all participants but excluded any who did not use the study products at any time following enrollment or for whom no safety data were obtained. The statistical analysis was performed using JMP statistical software (version 17; JMP Statistical Discovery LLC, Cary, NC, USA). Where data from after the start of the study were missing, they were treated as missing data and excluded from the parameters for calculation without imputation. For the analysis, the mean and standard deviation of the DC side and that of the CP side were calculated for each observation period. The two sides were compared using the paired *t*-test.

The number of days until the erythema score decreased to 2 (the level at which it was considered that erythema would have no effect on day-to-day living) was compared between the treatment groups using the Kaplan-Meier method. Changes in the distribution of erythema and bleeding severity scores over time were analyzed. This included examining the percentage of participants with each severity score (from 0 to 4) at the different time points (*i.e.*, days 0, 2, 3, 5, 7, 14 and 28) and comparing these percentages between the two treatment groups. The time course of resolution of erythema was investigated in participants judged to

have severe erythema (score 4) on day 0.

3. Results

3.1. Baseline Characteristics

Thirty-three subjects (30 female, 3 male) were enrolled. Three subjects discontinued before allocation to treatment (one did not meet the selection criteria, one did not attend the clinic on the day of Dermapen 4 treatment, and one experienced an unrelated adverse event). A further subject withdrew consent. The remaining 29 subjects (27 female, 2 male) were included in the analysis. The study population had a mean age of 40.7 ± 11.9 years. On day 0, the mean erythema score was 3.2 ± 0.7 for both the DC side and the CP side, and the mean NRS scores were 2.4 ± 2.0 for pain and 0.6 ± 1.2 for pruritus on both sides.

3.2. Clinical Evaluations

The score for erythema was lower on the DC side than on the CP side on day 2 (1.9 ± 0.7 vs 2.1 ± 0.8), day 3 (1.3 ± 0.7 vs 1.4 ± 0.9), and day 14 (0.1 ± 0.3 vs 0.2 ± 0.5). The score for bleeding was lower on the DC side on day 2 (1.3 ± 0.9 vs 1.4 ± 1.1). The dryness/scaling score was slightly higher on the DC side on days 3 and 5. The overall clinical evaluation score was slightly lower on the DC side on day 2. No significant difference in edema/swelling or crusting was observed between the sides throughout the observation period.

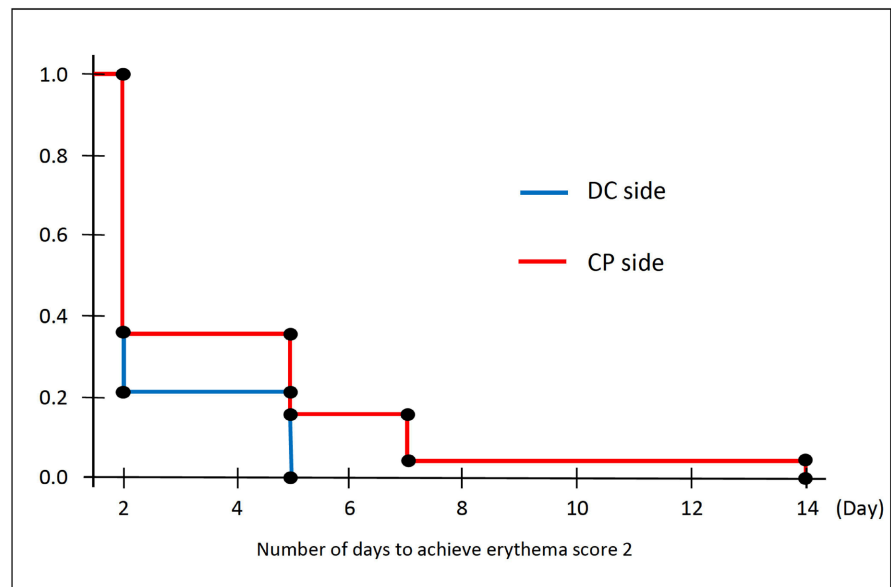


Figure 1. Number of days until erythema score reduced to 2. Average number of days (mean \pm SD); DC side: 2.63 ± 0.25 , CP side: 3.68 ± 0.57 , $p = 0.0687$, Log-rank.

The mean number of days until the erythema score decreased to 2 was 2.63 ± 0.25 for the DC side and 3.68 ± 0.57 for the CP side ($p = 0.0687$, log-rank test) (Figure 1). The percentage change in the erythema severity score (moderate +

severe) was 82.8% on the DC side and 86.2% on the CP side on day 0, 17.2% and 31.0%, respectively, on day 2, and 3.7% and 11.1% on day 3 (Figure 2). The percentage change in the bleeding severity score (moderate + severe) was 58.6% on the DC side and 65.5% on the CP side on day 0, 10.3% and 20.7%, respectively, on day 2, and 0% and 0% on day 3 (Figure 3). The time course in cases with severe erythema (score 4) on day 0 is shown in Figure 4(A) and that for bleeding in Figure 4(B). The erythema scores were lower on the DC side than on the CP side until day 5. The bleeding scores were lower on the DC side on day 2. Scores for dryness/scaling were higher on the DC side on days 2, 3, and 5. Photographs of a typical case are shown in Figure 5.

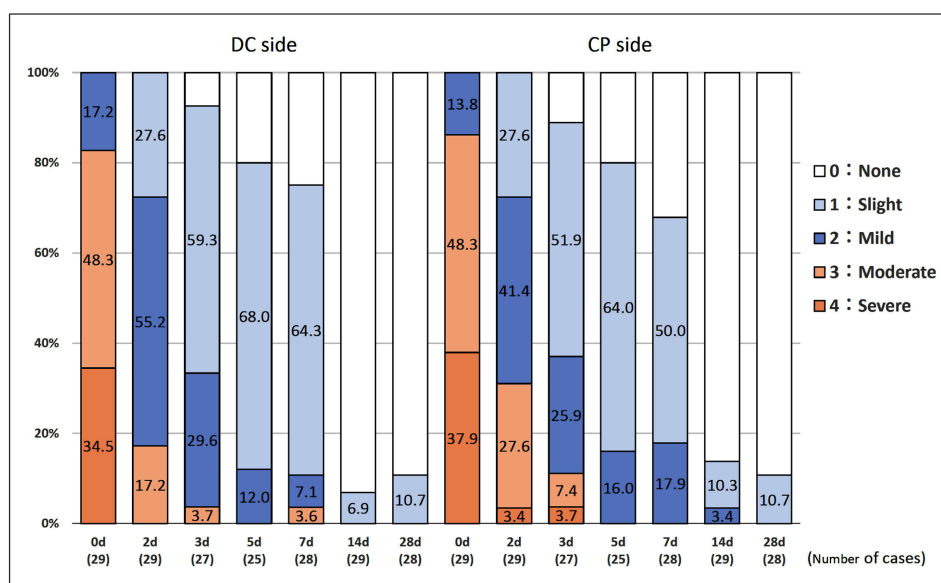


Figure 2. Percentage by erythema severity score.

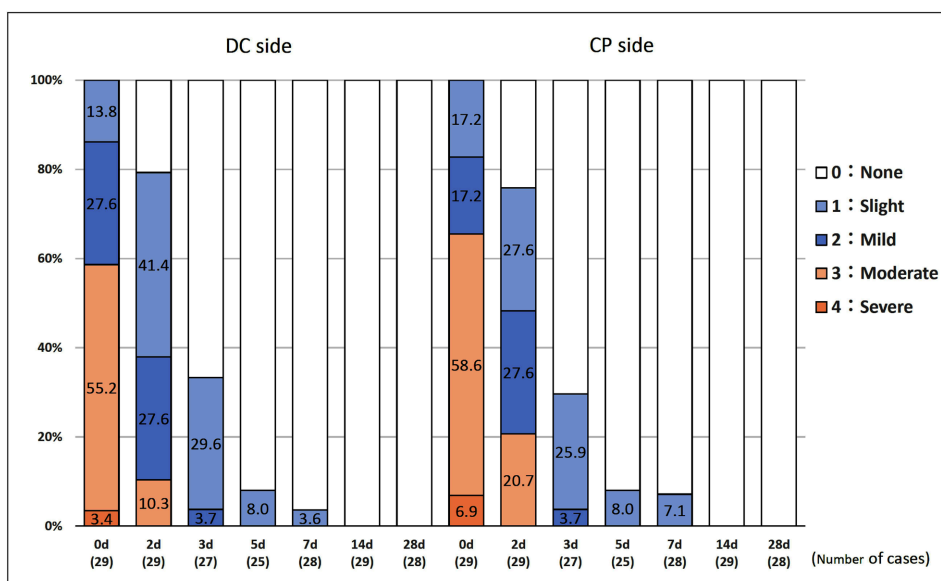


Figure 3. Percentage by bleeding severity score.

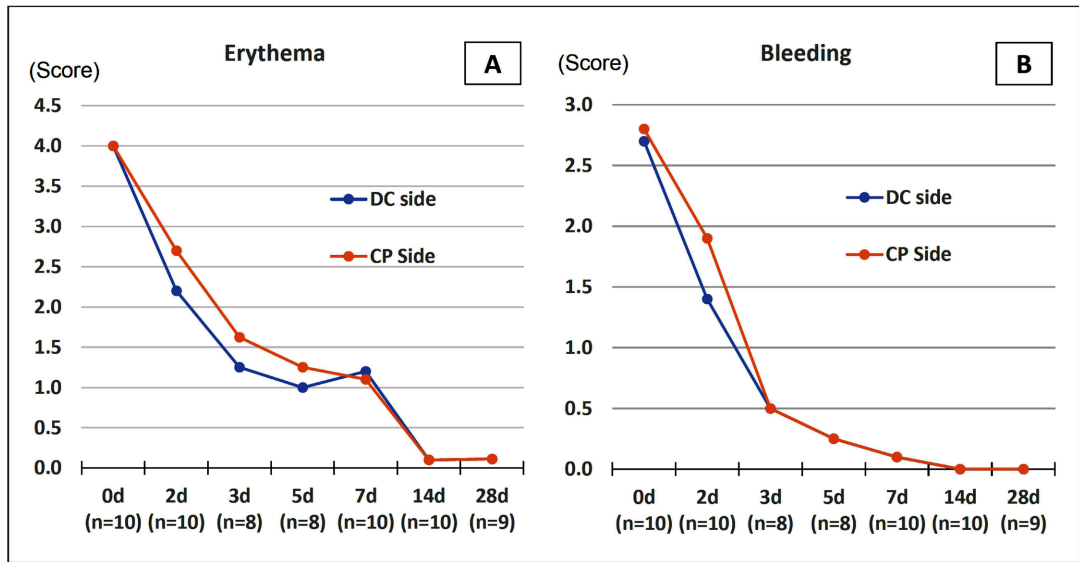


Figure 4. Time course of cases with severe erythema (erythema score 4) at 0 d. (A) Erythema score; (B) bleeding score.



Figure 5. Case photos (VISIA).

Post-inflammatory erythema involving the entire face was observed in 2 cases, on the DC side only in 1 case and on the CP side only in 1 case. There were no cases of post-inflammatory hyperpigmentation on either side.

3.3. Instrumental Measurements

Water content in the stratum corneum was greater on the DC side than on the CP side until day 7 and was significantly higher on day 2 (114.9 μ S vs 98.2 μ S; $p < 0.05$) and day 5 (119.8 μ S vs 103.8 μ S; $p < 0.05$). The sebum content was signifi-

cantly higher on the CP side from day 2 to day 7 ($p < 0.05$). Transepidermal water loss was less on the CP side than on the DC side until day 7 and significantly less on day 2 (5.5 g/[m²·h] vs 4.6 g/[m²·h]; $p < 0.05$) and day 5 (5.9 g/[m²·h] vs 5.2 g/[m²·h]; $p < 0.05$).

3.4. Image Evaluation

No significant differences in changes in erythema or pigmentation were found between the two sides.

There were no noticeable differences between the VISIA photographic evaluation by blinded investigators and the clinical evaluation by the treating physicians.

3.5. NRS Scores for Pain and Pruritus

The NRS scores for pain were lower on the DC side than on the CP side on days 2, 3, and 5 but the differences were not significant. There were no significant differences in the NRS scores for pruritus between the sides.

3.6. Responses to the Questionnaire

The percentages of participants who responded “good” or “somewhat good” to the questionnaire item regarding overall smoothness of application were 75.8% on the DC side and 37.9% on the CP side (**Figure 6**). In response to the question “Which was the best product for shortening downtime?”, 72.4% checked the DC side and 20.7% checked the CP side (**Figure 7(A)**). In response to the question “Would you like to use it for downtime symptoms after your next cosmetic procedure?”, 72.4% checked the DC side and 17.2% checked the CP side (**Figure 7(B)**). In response to the question “Would you like to continue using the product as part of your daily skin care routine?”, 69.0% expressed a desire to continue using the DC (Fig. 7C). In response to the survey question “Which skin condition is better, left or right?”, 37.9%, 37.0%, and 32.0%, considered the DC side to be better and 10.3%, 22.2%, and 4.0% considered the CP side to be better on days 2, 3, and 5 respectively (**Figure 8**).

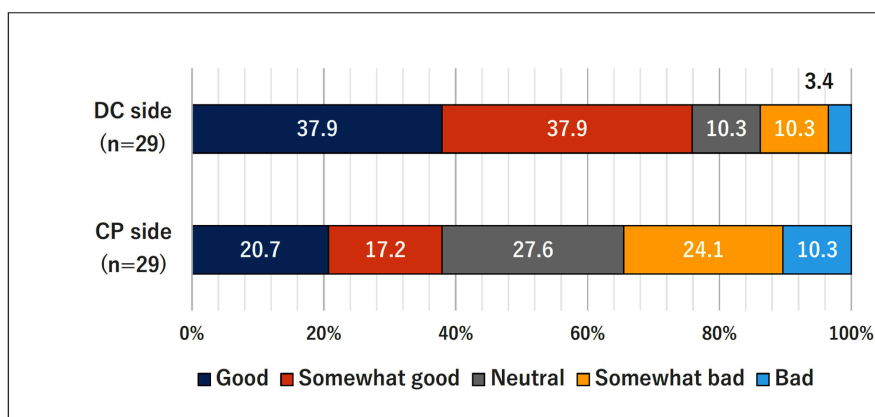


Figure 6. Product survey percentage. Overall smoothness of application.

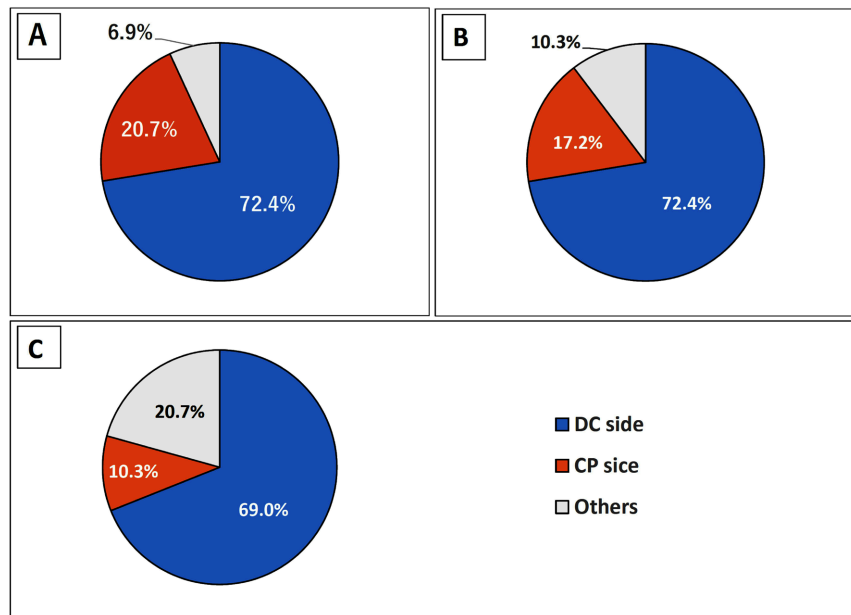


Figure 7. Product survey percentage. (A) Which was the best product to shortening downtime? (B) Would you like to use it for downtime symptoms after your next cosmetic procedure? (C) Would you like to continue using the product as part of your daily skin care routine? n = 29.

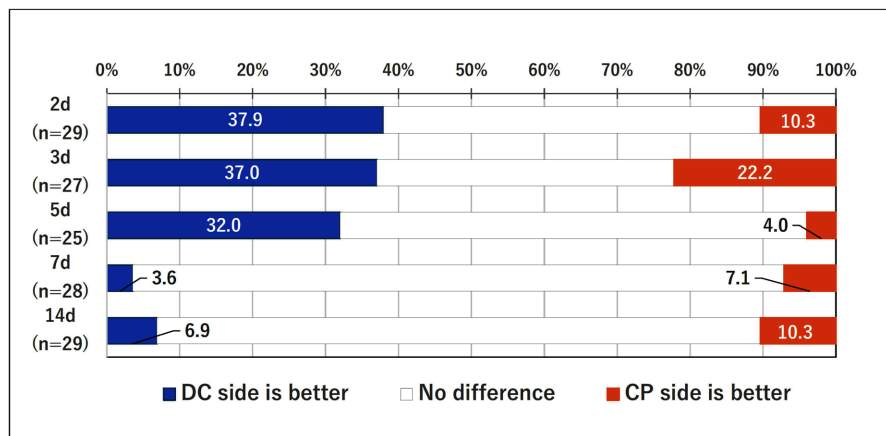


Figure 8. Skin condition survey percentage. Which skin condition is better, left or right?

3.7. Safety Evaluation

Eight adverse events occurred in eight participants during the study period but were not related to either of the study products. The adverse events were fever (five cases, mild, recovered), tinnitus (one case, moderate, recovered), eczema (one case, mild, recovered), and hyperlipidemia (one case, moderate, unresolved).

4. Discussion

This study compared the benefits of a dermocosmetic repair balm (DC) with those of white petrolatum (CP), a widely used moisturizing agent approved in Japan as

a medicinal product, when used in post-microneedling skin care recovery. White petrolatum is commonly used for chronic superficial skin wounds and post-cosmetic procedure care because of its protective and moisture-retaining properties [14]. However, it is an oil-based formulation that results in a sticky texture, potentially reducing patient adherence [15].

One of the adverse events following cosmetic procedures, including microneedling, is erythema, which can have a considerable impact on day-to-day living. In this study, erythema scores were used to assess skin redness. The time it took for the erythema score to decrease to 2 (the level at which erythema can be camouflaged by makeup) was approximately 1 day less for the DC side than for the CP side. However, the log-rank test for the primary endpoint did not reach conventional statistical significance ($p = 0.0687$), and this trend should therefore be interpreted with caution. The lack of significance may be related to the modest sample size and inter-subject variability in baseline erythema and healing dynamics, which can limit the power to detect differences in time-to-event analyses in a split-face design. One day makes a considerable difference in terms of time taken to return to normal everyday life. In the stratified analysis, the changes in scores for erythema and bleeding, which were aggregated by severity, indicated that the DC side recovered more rapidly than the CP side when symptoms were more severe. More rapid improvement was seen on the DC side in participants with more severe erythema at the start of treatment. The greater efficacy of DC in cases of severe erythema may be attributed to its ability to promote wound healing by improving recovery of the skin barrier and reducing inflammation while maintaining a well-balanced skin microbiome.

Our instrumental measurements identified a higher stratum corneum water content on the DC-treated side, with significant differences on days 2 and 5. There was less transepidermal water loss on the CP-treated side than on the DC-treated side. Although white petrolatum appeared to be more effective in improving skin barrier function, this observation may be attributed to residual petrolatum film on the skin during measurements. This finding is consistent with the known occlusive properties of petrolatum, which form a semi-occlusive film that effectively reduces evaporative water loss. Although such occlusion can be beneficial for short-term barrier recovery, prolonged use on facial skin may raise concerns about follicular occlusion and potential comedogenicity in predisposed individuals. In our short-term study, no acneiform eruptions or occlusion-related adverse events occurred, but clinicians should remain mindful of this aspect when selecting post-procedure care, particularly for patients with oily or acne-prone skin. The CP side also had a significantly higher sebum content, potentially because of increased production of sebum or residual petrolatum interfering with measurements. Overall, the instrumental measurements suggest that white petrolatum and the DC have comparable effectiveness.

The questionnaire results showed high ratings for the DC in terms of usability and perceived reduction of downtime. Notably, the overall smoothness of DC ap-

plication was rated as “good” or “somewhat good” by 75.8% of respondents but by only 37.9% for white petrolatum. This finding suggests that DC is easier to apply, which may contribute to better adherence. Furthermore, 72.4% of participants expressed an intention to use the DC for shortening of downtime after cosmetic procedures in the future, whereas only 17.2% indicated a preference to use white petrolatum for further cosmetic procedures. These findings underscore the high acceptability of DC among users. In the post-procedure setting, such superior usability is clinically relevant because products that are pleasant and easy to apply are more likely to be used as recommended, which in turn may improve adherence to the prescribed skin-care regimen and lead to more consistent and satisfactory healing outcomes in real-world practice.

Overall, our findings indicate that the DC is at least as effective as white petrolatum in alleviating symptoms and reducing downtime after a cosmetic procedure. The ability of DC to mitigate erythema, a symptom that significantly impacts daily activities, was comparable at least to that of white petrolatum. The questionnaire responses indicated that DC was superior in terms of ease of application, perceived reduction of downtime, user willingness to continue treatment, and the self-reported condition of the skin. These results suggest that the DC may overcome the adherence concerns associated with white petrolatum, potentially leading to improved treatment outcomes.

5. Conclusion

In this study, recovery from erythema following a cosmetic procedure tended to be more rapid when DC was applied than when white petrolatum was used, particularly in patients with severe skin injury. This result is important because erythema contributes substantially to the burden of downtime. DC was also found to have superior usability, potentially leading to improved adherence. These findings suggest that DC may offer an effective and safe approach for mitigating clinical signs and symptoms while reducing downtime after cosmetic interventions.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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