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"A Novel Efficacy Evaluation Method for Lip Treatment Products in Improving Lip Hydration in Human Subjects with Dry Lips"

Syifa Athia Zainun Faqiha[1], Dinda Meutiah[1], Nita Sapitri[1], Nisrina Nazhifah[1], Wardah Annajiah[1], Cho Young Kwan[1], Kim Ki Baek[1], Park Sae Rom[2] and Cheong Min Kyoung[1]

[1] Research and Innovation, Cosmax Indonesia, Jakarta, Indonesia
[2] Research and Innovation Center, Cosmax Inc, Seoul, South Korea

1. Introduction

The lips represent a unique and critical region of the face, both in terms of function and aesthetic appeal. The anatomical structure of the lips is distinct from other areas of the skin, as they are characterized by a thinner stratum corneum (SC), limited sebaceous and sweat glands, and a low melanin content, all of which contribute to their heightened susceptibility to environmental stressors [1, 2]. Due to these characteristics, the lips have a compromised barrier function and reduced capacity to retain moisture, making them prone to conditions such as dryness, chapping, and peeling, particularly in response to external factors like cold weather, air pollution, and ultraviolet (UV) radiation exposure [5]. Moreover, prolonged exposure to ultraviolet (UV) radiation often led to lip conditions including dryness, chapping, inflammation, and desquamation [5].

Over the past decade, there has been increasing interest in the development of specialized lip care products aimed at improving hydration, restoring barrier function, and preventing the adverse effects of environmental damage [3]. Despite the growing market for such products, the assessment of their efficacy remains inconsistent and often lacks standardized protocols. Current evaluation methods primarily rely on subjective assessments or general dermatological metrics, which may not accurately capture the unique biophysical properties of lip skin [4]. This lack of a reliable, reproducible testing method limits the ability of both researchers and consumers to effectively compare and assess the performance of different lip care formulations.

To address this gap, the present study aims to develop a robust and standardized method for evaluating the efficacy of lip products, specifically by focusing on two critical parameters: hydration level and the desquamation index. Hydration level, measured as the water content

within the stratum corneum, is a primary indicator of skin health and barrier function. Given the lips' vulnerability to dehydration, tracking this parameter offers direct insight into the effectiveness of a product in maintaining or restoring moisture balance [2]. The desquamation index, which quantifies the rate and severity of corneocyte turnover and shedding, provides an additional marker of lip skin condition, particularly in relation to scaling and the integrity of the epidermal barrier [2].

Integrating these two parameters into a comprehensive test protocol offers the potential for more objective and scientifically grounded assessments of lip product performance. By utilizing these biophysical measures, this method aims to facilitate the development of more effective formulations and provide a clearer, evidence-based understanding of how different products impact lip hydration and barrier recovery.

This research builds on previous studies that have investigated lip skin biophysics and the effects of lip care treatments. For instance, Park et al. (2021) and Yun et al. (2022) demonstrated the efficacy of multifunctional lip moisturizers in enhancing hydration and barrier function. Furthermore, Kim et al. (2023) introduced the concept of the corneocyte unevenness ratio as a novel parameter to quantify lip desquamation, which has the potential to be incorporated into this new test method. The proposed approach aims to address the limitations of existing assessments by providing more reliable and precise metrics, ultimately enhancing both clinical and commercial outcomes in lip care.

2. Materials and Methods

Study Population

The study was conducted with 16 healthy Indonesian female and male subjects, aged between 20 and 30 years (25.56 ± 2.53) who met the inclusion createria. All subjects were selected from an open volunteer recruitment process, and the criteria were assessed based on their self-assessment of the lip condition, combined with visual assessment by the research team. Only subjects with dry, chapped, cracked, and/or peeling lips were included in this study. Participants were excluded from this study if they were pregnant, breastfeeding, had a health issue, were under medication treatment, and/or had any specific condition that could affect the study result.

Study Design

The design used in the study was an open-label clinical trial. Subjects were randomly devided into two groups: the treated group and untreated group, with 8 subjects in each group. Subjects in the treated group were asked to use the lip treatment prepared by Cosmax Indonesia, which contained of 60% glycerin and 5% D-Panthenol as a hydrating agent in the formulation. They were instructed to apply the sample gently and evenly on their cleaned lips twice a day (morning and night) for a period of 28 days and were not allowed to use any other lip products or undergo lip treatment during the period. Meanwhile, the untreated group was instructed not

to use any kind of lip products during the test period. The lip conditions of all subjects were evaluated on the day before the study started and after the 28-day of study period.

Measurement

All measurements were performed on the lower lip, which have been cleansed using a specific micellar water and acclimated for 20 minutes in an air-conditioned room (temperature: 22 ± 2°C; relative humidity: 60 ± 10%). Improvement in lip hydration was evaluated by measuring hydration level and desquamation index. Hydration level was measured using a capacitance-based Corneometer® CM 825 (C + K electronic GmbH, Köln, Germany) and expressed as arbitrary units (a.u.). A higher hydration level respresent a more hydrated lip area.

Skin corneocytes produced during the desquamation process were collected by stripping the surface of the lips with Corneofix® F 20 (C + K electronic GmbH, Köln, Germany) and assessed using the Visioscan® VC 20plus (C + K electronic GmbH, Köln, Germany). The collected corneocytes were captured using Visioscan® VC 20plus, camera features a high-resolution black-and-white video sensor and a LED UV-A light source with circular diffusor for uniform illumination of the skin. The resulting image was a greyscale image that emphasized the skin flakes and was processed into different colors depending on the ultraviolet light absorption due to the thickness of the skin flakes (Figure 1a-b). The skin flakes were classified

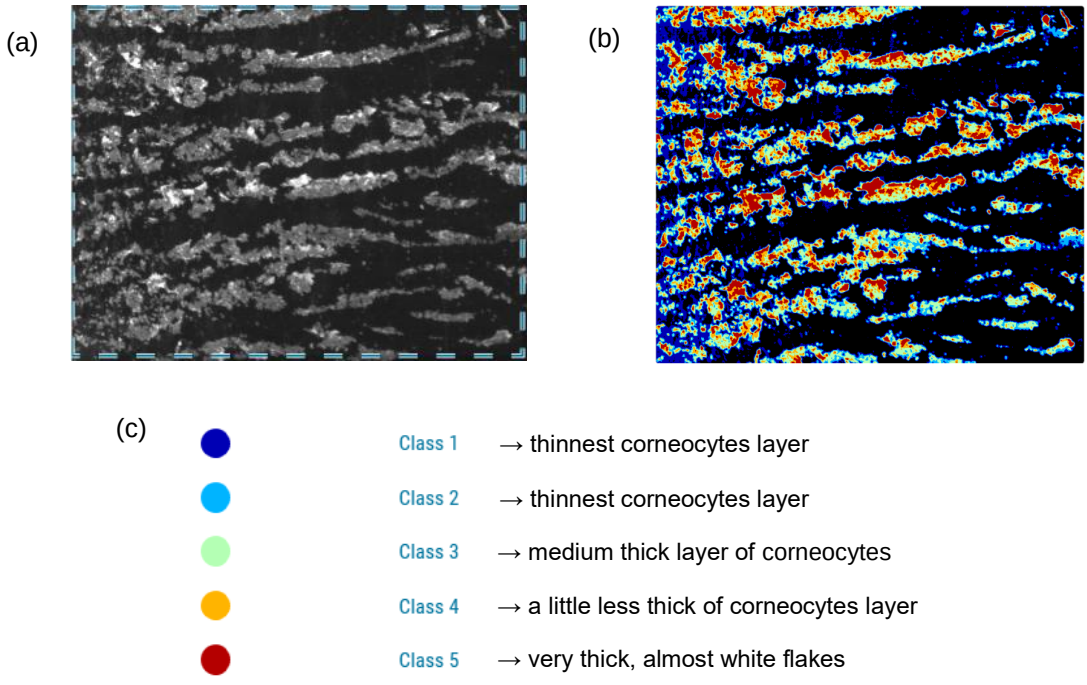


Figure 1. Analysis of corneocyte-related parametes. (a) Images of tape-stripped corneocytes from the lip skin using the Visioscan® VC 20plus. (b) Processed images of tape-stripped corneocytes from the lip skin using the Visioscan® VC 20plus. (c) Classification and color assignment into five categories according to the thickness of lip skin flakes.

into five categories according to the histogram of the greyscale values. Class 1 and Class 2 are represented in light and dark blue, indicating the thinnest and more even corneocyte layers (dark grey), while Class 3-5 respresented in red, orange, and green, corresponding to very thick, slightly less thick, and the medium-thick corneocyte layers, respectively (Figure 1c). The thicker the flakes, the drier the skin. The area covered by corneocytes in the image, processed by Visioscan® VC 20plus, was shown in mm² and %. The values were calculated to produce desquamation index value, where a higher desquamation index indicates a scalier and drier corresponding skin site.

Data Analysis

Basic data analysis was performed using Microsoft excel, as for the statistical analysis was performed using PAST statistical software (version 4.03). Given the small sample size (n = 16), the normality of the distribution data was tested using the Shapiro-Wilk test, meanwhile for the significance efficacy between two groups was assessed using the student's t-test, with p-values of less than 0.05 considered statistically significant.

3. Results

1.1. Improvement in Hydration

Table 1. Evaluation of Hydration Level in the Lip Area

Group	Hydration Level (a.u)			*p*-value*
	Day 0	Day 28	Difference	
Treated Group	18.37	51.73	33.36	0.000
Untreated Group	25.85	27.85	2.00	0.667

*Probability *p* (Student's t-Test, Significant: $p<0.05$)

Table 1 presents the changes in hydration levels between the treated and untreated groups. A higher hydration level in the lip area indicates better moisturization and improved skin condition. After 28 days of the test period, the treated group showed a significantly greater increase

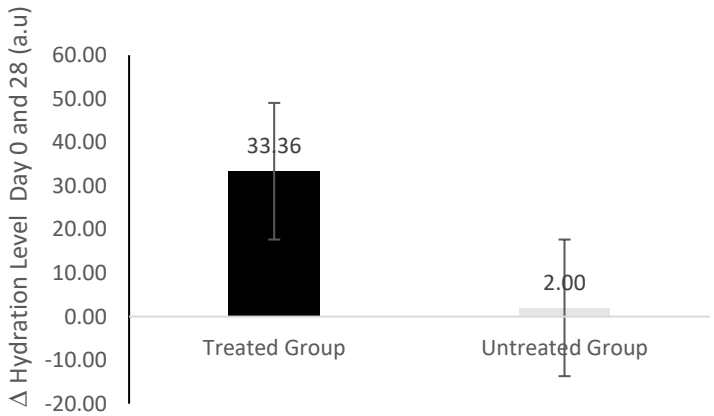


Figure 2. The difference of hydration level improvement in treated and untreated group between Day 0 and Day 28

in hydration level compared to the untreated group (**Figure 2**). In the treated group, hydration levels increased significantly from 18.37 to 51.73, with a mean difference of 33.36 (95% CI: 24.83 to 41.90; $P < 0.05$).

In contrast, the untreated group exhibited only a slight increase in hydration level, which was not statistically significant. This indicates no meaningful improvement in lip hydration over the same period.

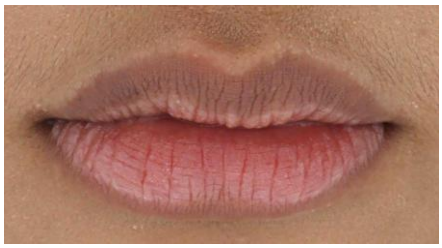
(a)  (b) 

Figure 3. Representative lip condition from treated group at Day 0 (a) and Day 28 (b).

In addition, differences in lip condition after the 28-day test period were observed through visual analysis. As shown in **Figure 3**, the lips of the subject in the treated group appeared smooth, well-hydrated, and showed fewer signs of flaking or cracking after 28 days compared with the initial lip condition before the treatment. In contrast, the lips of the subject in the untreated group appeared dry, flaky, cracked, and showed visible peeling, indicating the lip condition tend to be worsen after 28 days without using any lip products (**Figure 4**).

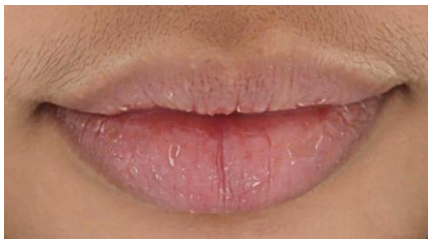
(a)  (b) 

Figure 4. Representative lip condition from untreated group at Day 0 (a) and Day 28 (b).

1.2. Reduction in Desquamation Index

Table 2. Evaluation of Corneocytes in the Lip Area

Group	Desquamation Index (a.u)			*p*-value*
	Day 0	Day 28	Difference	
Treated Group	18.11	12.04	-6.98	0.014
Untreated Group	18.86	23.69	4.83	0.052

*Probability *p* (Student's t-Test, Significant: $p<0.05$)

Table 2 shows the changes in the desquamation index between the treated and untreated groups. A higher desquamation index value indicates a greater presence and thickness of corneocytes collected from the lip surface. Differences in corneocyte distribution between the groups can also be observed visually in **Figure 5**, based on the variation in color representation.

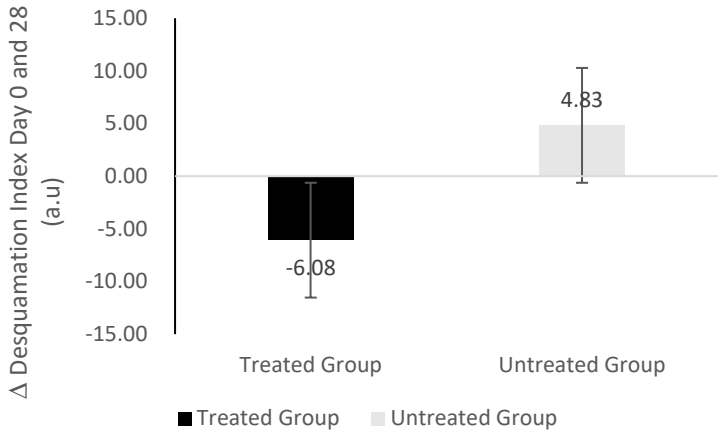


Figure 5. The difference of desquamation index improvement in treated and untreated group between Day 0 and Day 28

In the image, Class 3 to 5—represented by red, orange, and green, respectively—indicate areas with thicker corneocyte layers. In contrast, Class 1 and 2, represented by blue, indicate thinner corneocyte layers. The black areas in the image correspond to the background of the analyzed region and are not part of the lip surface.

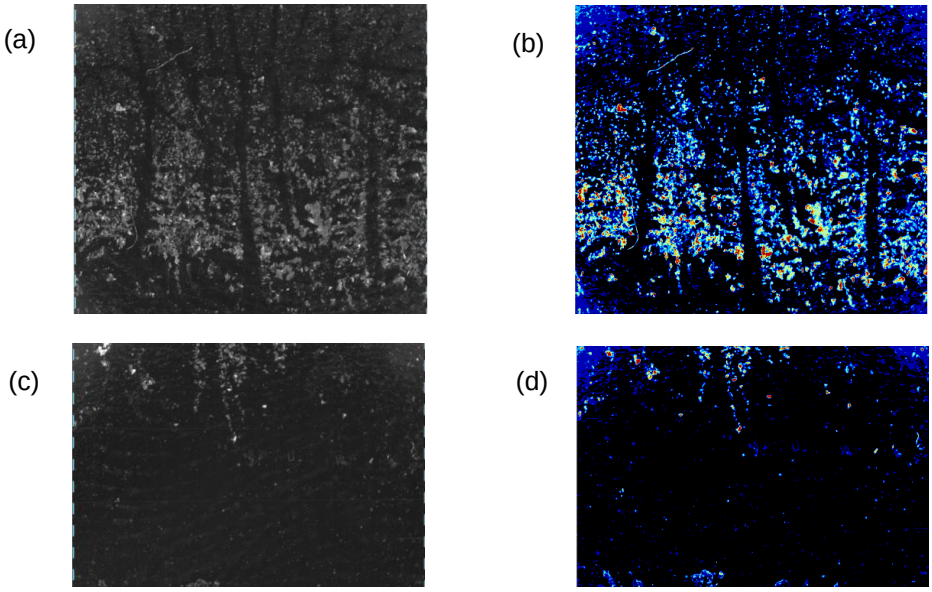


Figure 6. Lip Desquamation from the treated group. (a) Images of tape-stripped corneocytes from the lip skin at Day 0. (b) Processed images of tape-stripped corneocytes from the lip skin at Day 0. (c) Images of tape-stripped corneocytes from the lip skin at Day 28. (d) Processed images of tape-stripped corneocytes from the lip skin at Day 28

According to the results, the desquamation index in the treated group showed a statistically significant decrease after 28 days of product use (difference: –6.08; 95% CI: –10.50 to –1.66; $P < 0.05$), indicating a reduction in lip dryness and flakiness (**Figure 6**).

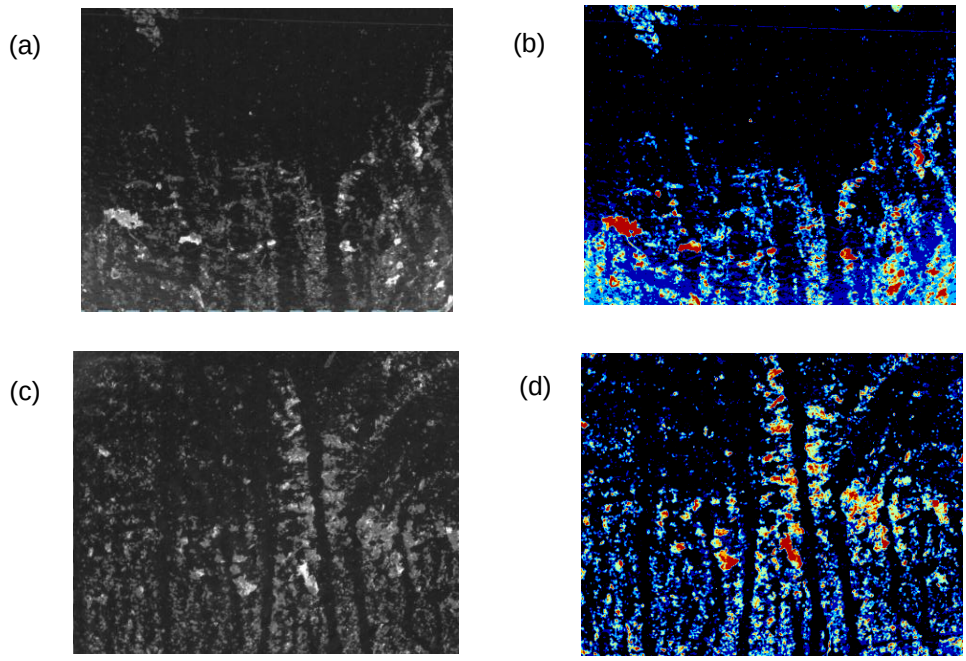


Figure 7. Lip Desquamation from the untreated group. (a) Images of tape-stripped corneocytes from the lip skin at Day 0. (b) Processed images of tape-stripped corneocytes from the lip skin at Day 0. (c) Images of tape-stripped corneocytes from the lip skin at Day 28. (d) Processed images of tape-stripped corneocytes from the lip skin at Day 28

On the other hand, the untreated group showed an increase in the desquamation index by day 28 (**Figure 7**). This suggests a worsening of lip condition, with more visible signs of dryness, flaking, cracking, and peeling due to the absence of any lip care product during the study period.

4. Discussion

The results of this study clearly demonstrate the positive impact of the lip care product on hydration and desquamation, offering strong evidence of its effectiveness in improving lip skin health over a 28-day period. Our findings show a significant improvement in hydration levels and a reduction in desquamation in the treated group, both of which contribute to a healthier, more hydrated lip appearance.

Improvement in Hydration

As shown in Table 1 and Figure 2, the treated group experienced a marked increase in hydration levels, with an average improvement of 33.36 (95% CI: 24.83 to 41.90; $P < 0.05$). This significant increase in hydration suggests that the product effectively enhanced the moisture retention of the lips. In contrast, the untreated group showed only a slight and statistically

insignificant improvement, which indicates that without proper treatment, lips do not naturally experience substantial hydration recovery over time. This result is in line with previous studies that highlighted the vulnerability of the lips to dehydration, which is exacerbated by their thinner skin and lack of sebaceous glands [4].

The visual changes observed in Figure 3 further support these findings. The treated group's lips appeared smoother, more hydrated, and free from the visible signs of cracking or flaking, while the untreated group showed significant dryness and peeling. These results are consistent with Park et al. (2021), who demonstrated that lip moisturizers can restore skin moisture balance and significantly improve the condition of the lips, particularly in environments prone to dehydration.

Reduction in Desquamation

Table 2 and Figure 4 present the changes in the desquamation index, which serves as a measure of the outermost skin layers on the lips. The treated group showed a statistically significant reduction in desquamation (mean difference: –6.08; 95% CI: –10.50 to –1.66; $P < 0.05$), which indicates a decrease in visible dryness and flaking. The visual assessment of corneocyte distribution (Figure 4) further corroborated this result, showing less pronounced thick corneocyte layers (Class 3–5) in the treated group, compared to the untreated group, where thicker layers of corneocytes were more prominent. This suggests that the product helped to smooth the lip surface and reduce the peeling process.

This reduction in desquamation is consistent with findings from Ryu et al. (2022), who found that effective lip treatments can improve the cohesion of corneocytes, thus reducing visible skin flaking and peeling. Similarly, Kim et al. (2023) highlighted the importance of corneocyte cohesion in assessing lip health, supporting the desquamation index as a valuable tool for evaluating lip skin condition. The significant improvement in the treated group suggests that the product not only hydrated the lips but also played a crucial role in restoring the integrity of the skin barrier, preventing further damage.

Clinical Implications

The results of this study underscore the importance of using targeted lip care products to improve hydration and skin health. The significant improvements in both hydration and desquamation demonstrate the potential of this product to address common lip issues, such as dryness, cracking, and peeling. As emphasized by Lee et al. (2020), lips, especially in certain populations, are more vulnerable to environmental stressors, and without proper care, they can deteriorate further. The effectiveness of this treatment offers promising clinical implications, particularly for individuals with chronically dry lips or those exposed to harsh environmental conditions.

Moreover, the use of biophysical parameters like hydration levels and desquamation index provides an objective and reliable way to assess lip health. This study highlights the value of

such measures, which offer more precise insights into the skin's condition compared to traditional subjective assessments. Incorporating these metrics into routine product evaluations can help advance the development of more effective lip care products, offering consumers and clinicians evidence-based options for maintaining lip health.

Study Limitations and Future Research

While the findings are promising, this study has a few limitations. The 28-day test period, while adequate for observing short-term effects, may not fully capture the long-term benefits or potential side effects of continuous product use. Additionally, the study population was relatively homogenous, and future research should include a more diverse group of participants to assess the product's effectiveness across different skin types and conditions. Investigating the product's performance in individuals with specific lip conditions, such as those affected by cold sores or chronic lip irritation, would also be beneficial. Further studies should also explore the impact of longer-term usage and evaluate the product's effectiveness in various environmental conditions, such as exposure to UV radiation or extreme temperatures. In addition, the more comprehensive study also needed to assess the correlation between the hydration level and desquamation index related to lip hydration assessment.

5. Conclusion

In summary, this study provides compelling evidence that the tested lip care formulation significantly improves hydration and reduces desquamation, contributing to better overall lip health. By using objective measures like hydration level and desquamation index, this research paves the way for more precise and reliable assessments of lip care products, supporting both scientific understanding and consumer confidence in lip care solutions. Additionally, further studies are recommended to validate long-term benefits across diverse populations and conditions. Moreover, the study related to the correlation among lip hydration parameters are necessary to develop more comprehensive efficacy test method.

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