Clinical study of lip balm containing propolis extract and lip applying LED device

Ji-Sun Moon
Professor, Dept. of Medical Beauty Care Jungwon University,

프로폴리스 추출물이 함유된 립밤과 LED 기기를 적용한 입술 임상 연구

문지선
중원대학교 의료뷰티케어학과 교수

Abstract The purpose of this study is to provide clinical information and quantitative data through clinical research on lip balm containing propolis extract and lip application with LED device. Participants in this study were selected as test products for women aged 19 to 50 in Seoul and Gyeonggi Province, and to investigate the effects of LED devices and lip creams on the lips to improve lip elasticity, lip moisture, lip keratin, and lip moisture lasting for 12 hours. Before using the product, immediately after use, after 6 hours of use, after 12 hours of use, and after 2 weeks of use, the use test items are measured and the safety, efficacy, and preference survey of the product is analyzed. The results derived through a series of research procedures are as follows. It has been shown to help lip elasticity, lip moisture, lip keratin improvement, and lip moisture lasting for 12 hours when used once or 2 weeks.

Key Words : Propolis, Lip Balm, Lip, Beauty Device, Near Infrared

요 약 본 연구의 목적은 프로폴리스 추출물이 함유된 립밤 제품과 LED 기기를 적용한 입술 임상 연구를 하여 임상정보와 양적자료로 도움이되고자 한다. 본 연구의 참여자는 서울·경기 소재 만 19~50세 여성을 대상으로 시험제품 선정 후 입술의 LED 기기와 립 크림의 입술 탄력, 입술 보습, 입술 각질 개선 및 12시간 입술 보습 지속효과를 알아보기 위하여 제품 사용 전, 사용 직후, 사용 6시간 후, 사용 12시간 후 사용 2주 후에 사용 시험항목을 측정 후 제품의 안전성, 유효성, 기호도 설문조사를 분석하고자 한다. 일련의 연구절차를 통하여 도출된 결과는 다음과 같다. 1회 또는 2주 사용으로 입술 탄력, 입술 보습, 입술 각질 개선 및 12시간 입술 보습 지속력에 도움을 주는 것으로 나타났다.

주제어 : 프로폴리스, 립밤, 입술, 미용기기, 근적외선

1. Introduction

Recently, with social and economic growth, the demand for skin care is showing a tendency to diversify and continuously increase. In addition, interest and demand for skin care devices are increasing due to the development of internet shopping and home shopping in the domestic skin care market[1]. Skin care devices are used for the purpose of cleaning and beautifying the human body and maintaining or

promoting health[2]. Various products focusing on technology that are relatively easy to miniaturize using laser, high frequency, LED, as well as far-infrared, ultrasonic, and galvanic ions are being released[3]. Among the devices, in the case of devices to which LLLT (Low Level Light Therapy), which is a low-power light therapy, is applied, active research and development is being carried out because of the safety of a light source with a low output and a care effect on the skin only by irradiation of light[4-8].

A light emitting diode (LED) is a device that converts an omniscient current into light having a narrow wavelength, and the wavelength range includes ultraviolet (UV) to near infrared (NIR) [9]. Since the light source has a narrow wavelength line width and emits a light source of a specific wavelength, harmful ultraviolet or unnecessary infrared light is not emitted, so there are few side effects. It is also recognized by the U.S. Food and Drug Administration (FDA)[10].

In the treatment using LED, it has been reported that there is an effect on skin defects or wound healing using mice [11,12], and a study on a facial skin treatment device using LED [13], according to the LED irradiation energy and wavelength Experimental studies on the effects on skin cells have revealed effective wavelengths for improving skin conditions and problems [14]. As described above, LDE light has been used in the medical field because its efficacy in treating inflammation has already been verified, and in recent years, it has been used for skin aging, acne, and regeneration purposes in the skin care field.

The face occupies a large part in the image, and among them, the lips are an important part for determining beauty standards compared to other organs such as the eyes, nose, and mouth [16]. Cosmetics are for infants and toddlers, body cleaning, eye makeup, basic makeup, hair, and color makeup, and lip cosmetics are lipsticks, lip liners, lip glosses, lip balms, etc. A lip balm[16] is a cosmetic used for the purpose of protecting the lips by providing nutrition and moisture to the lips. It protects the skin and prevents chapped lips. It is important to protect the lips by applying lip balm frequently, and to supply nutrients and moisture. It was reported that the cosmetics market size in 2017 was 27,777.6 billion won, an increase of about 200.9% over the past five years compared to 13,828.2 billion won in 2013. According to Euromonitor research, the basic cosmetics market grew by 0.7% in 2018 compared to the previous year, while the color cosmetics market grew by 4.3%. The growth of color cosmetics was remarkable. According to the survey on the safety status of cosmetics for lips, as the age group exposed to cosmetics is gradually decreasing due to the influence of mass media such as one-person broadcasts, the proportion of elementary, middle, and high school students who wear makeup every day reaches 30.5%. In particular, it was found that adolescents use 'tint' applied to the lips the most. However, cosmetics for lips can cause side effects to skin diseases such as epiphysis and keratin, and can be consumed due to the nature of the product, so it is necessary to manage harmful substances more thoroughly. Recall for detection of lead (604 ppm) in lipstick products made in China (Germany, June 2017) Disposal due to detection of arsenic (1.35 ppm) and lead (9.48 ppm) in lipstick products (Ireland, February 2018), antimony standard in lip liner products Cases of heavy metal detection in lip cosmetics have been continuously reported at home and abroad, such as taking voluntary recall measures with thatch detection (Korea, 2018, 3).In addition, 9 types of tar pigments, which

are controversial for safety, are permitted as food additives in some foods, while 82 types of tar pigments are allowed in cosmetics. A re-examination is necessary. In the United States, the use of Red No. 2 and No. 102 in food and cosmetics is prohibited for safety reasons, but the use of products for infants and children under the age of 13 is prohibited according to domestic cosmetic standards. Therefore, we intend to contribute to the importance of lip cleansing and to secure consumer safety of lip balm among lip cosmetics. There are no clinical studies on lipsticks and lip balms related to lip cosmetics. Therefore, in this study, a lip balm to which propolis extract is applied and a lip clinical study using an LED device can be used as basic data to understand the clinical data of lip balm used on the lips.

2. Research method

2.1 Study participants

Participants in this study were adults who met the selection criteria and did not meet the exclusion criteria. The number of subjects was 30 based on the test method of the Regulations on the Review of Functional Cosmetics (Ministry of Food and Drug Safety Notice No. 2017-42). The above were selected and implemented. Female office workers located in Seoul and Gyeonggi Province were selected as the population. The survey period was 2 weeks, the clinical trial was conducted at the clinical center, and the survey method was conducted by the researcher and pre-trained research assistant visiting the direct research subjects. However, in the face of an increased risk perception of domestic coronavirus infection-19 (COVID-19), non-face-to-face surveys were also conducted if the study subjects did not want to conduct face-to-face surveys. The

non-face-to-face survey method was conducted using a questionnaire using the portal site Google and an email method.

Specifically, looking at the characteristics of the study participants, 8 people in their 20s (36.4%) and 8 people in their 30 s (36.4%) showed the highest response frequency. frequency is indicated.

2.2 Selection conditions

(1) Adults between 20 and 50 years of age
(2) Those who do not have acute or chronic diseases including skin diseases
(3) Those who voluntarily signed the consent form after hearing the explanation about the purpose and content of the test
(4) Those who can be followed up during the test period

2.3 Exclusion conditions

(1) Pregnant, lactating women
(2) If it is difficult to evaluate the evaluation site due to trauma such as erythema, crusting, abrasions, tattoos, scars, etc.
(3) If you have an infectious skin disease
(4) If there is a medical history or drug treatment related to skin reaction
(5) In case of severe irritation or allergy to cosmetics, pharmaceuticals, or daily exposure to light
(6) In case of participating in other human application tests
(7) If 3 months have not passed since participating in the same human application test

2.4 Application area and product application method

After washing your face and using skin care products, apply it thickly on your lips. Gently bite the silicone-covered lip LED device fixing bar and put it on the front of the lips for 3

minutes after wearing. The test product was stored at room temperature in a sealed state, and used for 2 weeks (once a day). In addition, the use of cosmetics containing active ingredients that may affect the test results during the human application test period was prohibited. It was applied to a flat area on the back of the test subject except for the spine without any pigmentation or skin damage. Photographs of the test site were taken and the subject's skin condition was pre-examined.

2.5 Application of primary stimulation test products

20 ㎕ was loaded into the IQ Ultimate chamber, adhered to the skin, and fixed with 3 M Micropore Tape. The IQ Ultimate chamber to which the test substance was applied was applied to the test site for 24 hours, and the IQ Ultimate chamber was removed after 24 hours. After 1 hour, the photograph of the test substance application site and the degree of skin reaction by the researcher were evaluated. At 24 hours after removal of the Q Ultimate chamber, pictures of the test substance application site were taken and the degree of skin reaction by the researcher was evaluated.

2.6 Material

The lip balm product containing propolis extract was provided by J Co., Ltd. and used. IQ Ultimate chamber(Chemotechnique Diagnostics, Sweden), 3M Micropore Tape, Marking Pen, Micropipette,

Multi Probe-Adaptor MPA5, MPA5 Data recorder, Sebumeter SM815, Corneometer probe CM825, Skin-pH meter probePH905, Skin-Thermometer probe ST500, Mexameter MX18, Sensor for Room Condition RHT100, Delfin VapoMeter, Skin Visiometer SV600, Skin Visiometer VC98,Skin Visiometer VD300, Skin Visiometer data recorder, Visoface Quick, Chromameter CR400, Multiport Solar Simulator 601-300W, Xenon Lamp Power Supply, Adjustable Multiport Column, Radio meter PMA2100, UVA Detector PMA2113, SUVDetector PMA2103, Micropipette, Chemical Balance, Timer, Whirl pool Folliscope 4.0, Digital Camera

2.7 Test standard

This test was conducted according to the following test standards. Test guidelines for assessment of skin compatibility of cosmetic finished products in man., Task Force of COLIPA, the European Federation of national Cosmetic, Toiletry and Perfumery Associations, Walker AP, Basketter DA, Baverel M, Diembeck W, Matties W, Mougin D, Paye M, Rothlisverger R, Dupuis, J. Food Chem Toxicol., 1996 34(7): 651-60.

2.8 Primary stimulus assessment method

The preliminary survey of the test subjects was conducted with the test subject questionnaire, and it was divided into skin condition and skin condition. Skin conditions were divided into dry, medium dry, neutral, oily, oily, and problem skin, and skin diseases, itchiness, stinging, erythema, cosmetic side effects, drug side effects, light sensitivity, and pato experience were classified as skin conditions.

2.8.1 Evaluation items

As an evaluation item, the degree of skin irritation that appears on the site where the test substance is applied is judged by the investigator's visual evaluation Fig. 1.
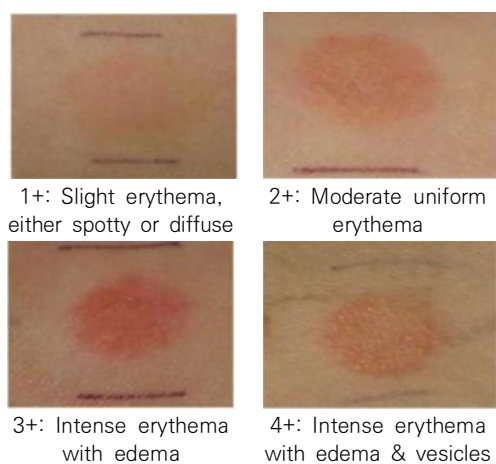
1+: Slight erythema, either spotty or diffuse

2+: Moderate uniform erythema

3+: Intense erythema with edema

4+: Intense erythema with edema & vesicles

Fig. 1. Clinical standard photographs of visual assessment for human patch test

Table 1. Recording of skin reactions

Symbol	Grade	Criteria for determination
+	1	Slight erythema, either spotty or diffuse
++	2	Moderate uniform erythema
+++	3	Intense erythema with edema
++++	4	Intense erythema with edema & vesicles

Table 2. Skin irritation index table

Skin irritation index	Sortation
0.00 - 0.25	non-irritating
0.26 - 1.00	mild irritability
1.01 - 2.50	moderate irritability
2.51 - 4.00	strong irritability

2.8.2 How to evaluate the degree of skin irritation

In this study, the researcher's visual evaluation was based on the Frosch & Kligman, CTFA guideline, the skin reactivity was read Table 1, and the skin irritation index was calculated using the skin irritation index Table 2 generated by applying the Draize method. With reference, the skin irritation level of the test substance was classified.

(1) The skin reactivity was obtained according to the following formula.

Skin reactivity = (Σ evaluation value 35i = 135 (number of subjects))1h + (Σ evaluation value 35i = 135 (number of subjects)) 24h

(i: number of subjects who completed the trial)

(2) The skin irritation index of the test substance was calculated according to the following formula.

Skin irritation index = skin reactivity n (n: number of evaluations)

(3) The level of skin irritation of the test substance was determined by referring to the skin irritation index Table 2.

2.9 Skin measurement and survey

After explaining the clinical trial, demographic survey, selection, exclusion criteria review, and medical history were conducted for the test subjects who agreed to participate in the trial and signed the consent form. Lip elasticity, lip moisture, and lip dead skin improvement were measured before and after using the test product. After 2 weeks of using the test product, lip elasticity, lip moisture, lip keratin measurements and skin symptoms were evaluated. After the end of the test, an efficacy evaluation questionnaire and a product preference questionnaire were conducted.

2.9.1 Evaluation site and measurement method

For the evaluation of clinical instruments, the test subject was allowed to adjust the skin surface temperature and humidity to the environment of the measurement space by resting for 30 minutes in a waiting room under constant temperature and humidity conditions with an indoor temperature of 20 to 25° C and a humidity of 40 to 60%. Water intake was limited while intoxicated. For objective measurement, one researcher measured, and the same area was measured for each measurement.

2.9.2 Lip elasticity measurement

For lip elasticity, the same lip area was measured before, immediately after, and 2 weeks after using the test product using a ballistometer (DIA STRON, U K), which measures the characteristics of the skin returning to its original shape. During the measurement, the ballistometer probe was contacted with the skin and performed three times, and the average value was used as the evaluation data for skin elasticity. Ballistometer is a device that can measure the elasticity of the skin surface through the reciprocating motion trajectory (change in depth of depression) and energy reduction characteristics of the stylus when a preset energy is applied to the skin with a specially designed stylus at the tip of the probe. For skin elasticity, the CoR (Coefficient of Restitution) value, a parameter, was used as an evaluation data, and it means that the lip elasticity improves as the CoR value increases.

2.9.3 Moisturizing lips, measuring lip moisture retention for 12 hours

In this study, the same lip areas were measured before, immediately after, 6 hours, 12 hours, and 2 weeks after use of the test product using Corneometer CM825 for lip moisturizing and 12 hour lip moisturizing lasting power. During the measurement, the corneometer probe was contacted with the skin and conducted three times through the sensor, and the average value was used as the water content evaluation data. Corneometer is a device that sees the skin as a non-conductor and conducts electricity better as it contains more moisture. It measures the capacitance where the probe is in contact. Therefore, the water content before the process is proportional to each other, and it can be seen that the higher the measured value, the higher the water content. The unit is an arbitrary unit (A.U.) which is a unit constant.

2.9.4 Lip keratin measurement

For measurement of lip keratin, Visioscan VC98 (Courage-Khazaka eletronic GmbH, Germany) was used to measure the same lip area before, immediately after, and 2 weeks after using the test product. For measurement, keratin from the lip area is collected using a special film (D-squame), an image is taken and analyzed with Visioscan VC98, and the measured value D.I (Desquamation Index) is used as the evaluation data for lip keratin, and the unit is %.

$$D.I = \frac{2A + \sum_{n=1}^{5} T_n^* (n-1)}{6}$$

D.I : The Desquamation Index (%)
A : The percent area covered by corneocytes
Tn : The percentage of corneocytes in relation to thickness
n : The thickness level (1-5)

2.9.5 Validity Survey(Global Assessment of Efficacy)

After using the test product, they were asked to directly answer the questionnaire in five steps: very good (4), good (3), average (2), bad (1), and very bad (0). The researcher determined the efficacy of the test product by obtaining the percentage of the number of test subjects for each answer.

2.9.6 Product Preference Survey Evaluation

After using the test product, the test subjects were asked to directly answer the questionnaire about the feeling of using the product. The evaluation items were evaluated on a 5-level scale of very good (4), good (3), normal (2), bad (1), and very bad (0) for skin moisture,

smoothness, spreadability, absorbability, fragrance, and overall feeling of use. did..

2.9.7 Safety assessment

For the safety of the test product, the adverse reaction incidence rate was calculated by synthesizing all adverse reactions identified for all test subjects who used the test product and all adverse reactions reported during the test period, and used as data for product safety evaluation.

2.9.8 Adverse reaction evaluation

For abnormal skin symptoms that occurred during the use of the test product in this study, the occurrence and severity of symptoms were checked through a survey during the test period. If the test subject felt any abnormal symptoms, it was instructed to immediately report it to the person in charge of the test. When an adverse reaction is reported, the person in charge of the study notifies the adverse reaction, judges the severity of the symptom and whether it is related to the test product, and decides whether to take appropriate action for the symptom and participate in the test.

2.10 Statistical processing

SPSS 19.0, a statistical analysis program, was used to check whether the measured values were significant compared to before using the test product. Significance was confirmed when the significance probability was $p < 0.05$ in the 95% confidence interval, and the significance probability was rounded to the third decimal place.

For three or more repeated measures, repeated measures ANOVA was used as a parametric method after normality test, and post-test was performed by the Bonferroni method.

The Friedman test was used as a non-parametric method, pairwise comparison was performed with the Wilcoxon signed rank test, and the significance level was corrected by the Bonferroni method, followed by post-mortem testing. For comparison between groups, the ratio of change in contrast was used before use, and the non-parametric Mann-Whitney U test was used after the normality test.

3. Research results and considerations

3.1 Test subject skin condition and characteristics

For each test subject, no subjects corresponded to the questionnaire about skin disease, itchiness, stinging, erythema, cosmetic side effects, drug side effects, photosensitivity, and atopic disease experience, and there were no subjects who had experience with other items Table 3.

Table 3. Results of the test subjects survey

	The number of people	%
A skin disease	–	0.000
Itchiness	–	0.000
A stinging	–	0.000
The erythema	–	0.000
Side effects of cosmetics	–	0.000
Side effects of medication	–	0.000
Light sensitivity	–	0.000
Experience of Atopy Disease	–	0.000

3.2 Compliance with the exam

Compliance with product use was calculated as a percentage of the number of times used to the number of times used during the test period. The overall compliance of 30 or more patients who completed the trial was 92.5%, the maximum compliance was 100%, and the minimum compliance was 85.1%. Since no test subject showed less than 80% compliance in this trial, data from all test subjects was used for the analysis of the results Table 4.

Table 4. Test Product Compliance

	Compliance(%)
Final Conformity	92.5%

3.3 Lip elasticity measurement result

As a result of confirming the change in lip elasticity due to use of the test product, there was a significant increase ($p < 0.05$) immediately after use and 2 weeks after use compared to before use of the test product Table 5.

Table 5. Lip elasticity measurement results,(CoR)

		(Mean±SD)
	Sortation	CoR
	Before use	0.531 ± 0.106
	Immediately after use	0.590 ± 0.089
	2 weeks after use	0.561 ± 0.098
an in-group comparison	Probability of significance	Intra-object Effect Test 0.000*
		Before and after use 0.000*
		Before use, 2 weeks after use 0.000*

* : $p < 0.05$, ** : $p < 0.01$, * : $p < 0.001$ by repeated measures ANOVA, post hoc Bonferroni correction

3.4 Lip moisture measurement result

As a result of confirming the change in lip moisture due to use of the test product, there was a significant increase ($p < 0.05$) immediately after use and after 2 weeks of use compared to before use of the test product Table 6.

Table 6. Lip moisturizing measurement results, A.U

		(Mean±SD)
	Sortation	A.U
	Before use	70.286 ± 13.377
	Immediately after use	86.836 ± 11.836
	2 weeks after use	76.939 ± 13.603
an in-group comparison	Probability of significance	Intra-object Effect Test 0.000*
		Before and after use 0.000*
		Before use, 2 weeks after use 0.000*

* : $p < 0.05$, ** : $p < 0.01$, * : $p < 0.001$ by repeated measures ANOVA, post hoc Bonferroni correction

3.5 Lip keratin measurement result

As a result of confirming the change of lip keratin due to use in the test product, it was significantly decreased ($p < 0.05$) before, immediately after, and after 2 weeks of use compared to before use of the test product Table 7.

Table 7. Lip exfoliation measurement results, (%)

		(Mean±SD)
	Sortation	%
	Before use	10.745 ± 4.264
	Immediately after use	3.769 ± 1.968
	2 weeks after use	7.500 ± 3.254
an in-group comparison	Probability of significance	Intra-object Effect Test 0.000*
		Before and after use 0.000*
		Before use, 2 weeks after use 0.000*

* : $p < 0.05$, ** : $p < 0.01$, * : $p < 0.001$ by repeated measures ANOVA, post hoc Bonferroni correction

3.6 Results of 12-hour lip moisturizing and long-lasting measurement

As a result of checking the lip moisture retention for 12 hours after using a lip balm containing propolis extract, the test product group significantly increased ($p < 0.017$) immediately after use, 6 hours after use, and 12 hours after use, compared to before use, and the non-applied group showed a significant increase ($p < 0.017$). There was no significant change compared to before use. In addition, the group using the test product showed a significant difference ($p < 0.05$) immediately after use, 6 hours after use, and 12 hours after use compared to the non-applied group Table 8.

Table 8. Results of 12-hour lip moisturizing and long-lasting measurement, (A.U)

		(Mean±SD)
Sortation	a test product	Not a test product
Before use	70.286 ± 13.377	69.889 ± 12.960
Immediately after use	86.836 ± 11.836	69.624 ± 12.908
6 hours after use	81.586 ± 10.670	69.721 ± 12.433
12 hours after use	76.436 ± 10.985	69.702 ± 12.815

(Continued)

Table 8. Results of 12-hour lip moisturizing and long-lasting measurement, (A.U)

			(Mean±SD)	
an in-group comparison	Proba bility of signifi cance	Intra-object Effect Test	0.000#	0.528
		immediately after use	0.000#	/
		after 6 hours of use	0.000#	/
		after 12 hours of use	0.000#	/
an in-group comparison	Proba bility of signifi cance	immediately after use	0.000†	
		after 6 hours of use	0.000†	
		after 12 hours of use	0.000†	

#: $p < 0.017 (=5\%/3)$ by Friedman test, post hoc Wilcoxon signed rank test with Bonferroni correction

* : $p < 0.05$, ** : $p < 0.01$, * : $p < 0.001$ by repeated measures ANOVA, post hoc Bonferroni correction

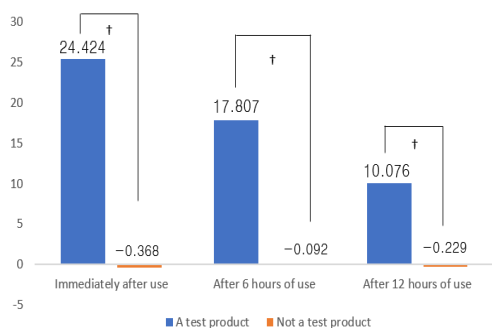† : $p < 0.05$ by Mann-Whitney U test

Fig. 2. 12-hour lip moisturizing duration change rate (intergroup comparison).

† : Statistically significant differences between the two groups($p < 0.05$ by Mann-Whitney U test)

3.7 Validity Assessment Survey Results

The average, standard deviation, and percentage of the number of test subjects were obtained from a survey conducted on lip elasticity, lip moisture, lip keratin improvement and lip moisture retention for 12 hours after using a lip balm containing propolis extract Table 9 . As a result of the survey, 100% of the test subjects rated the lip elasticity, lip moisturizing, and lip keratin improvement items as above average, and 95.5% of the test subjects evaluated the 12 hour lip moisturizing lasting power items as above average.

3.8 Product Preference Survey Results

After using the product, the test subjects' preference for the product was investigated in terms of skin moisture, skin smoothness, spreadability, absorbability, fragrance, ease of operation, appropriate use time, and overall feeling of use. As a result of the survey, it was expressed as a percentage of the number of test subjects for the mean and standard deviation and answers Table 10. As a result of the survey, 100% of test subjects for skin moisturization, skin smoothness, and spreadability items, 95.5% of test subjects for overall feeling of use, 81.8% of test subjects for absorbency items, and fragrance items 59.1% of them rated it as above average.

Table 9. Results of the efficacy evaluation survey for the product

		4*	3*	2*	1*	0*	Average	Standard Deviation
lip elasticity	Number of people	2	12	8	0	0	2.727	0.631
	%	9.091	54.54	36.36	0.000	0.000		
lip moisturizing	Number of people	4	14	4	0	0	3.000	0.617
	%	18.18	63.63	18.18	0.000	0.000		
lip keratin	Number of people	5	10	7	0	0	2.909	0.750
	%	22.72	45.45	31.81	0.000	0.000		
12 hours lip moisture lasting	Number of people	3	13	5	1	0	2.818	0.733
	%	13.63	59.09	22.72	4.545	0.000		

*4: very good, 3: good, 2: commonly, 1:bad, 0:very bad

Table 10. Results of survey on product preference

		4*	3*	2*	1*	0*	Average	Standard Deviation
skin moisturization	Number of people	3	16	3	0	0	3.000	0.535
	%	9.091	54.54	36.36	0.000	0.000		
skin smoothness	Number of people	4	13	5	0	0	2.955	0.653
	%	18.18	63.63	18.18	0.000	0.000		
spreadability	Number of people	4	13	5	0	0	2.955	0.653
	%	22.72	45.45	31.81	0.000	0.000		
absorbency	Number of people	3	6	9	4	0	2.364	0.953
	%	13.63	27.27	40.909	18.18	0.000		
Scent	Number of people	2	4	7	8	1	1.909	1.065
	%	9.091	18.18	31.81	36.36	4.545		
overall feeling	Number of people	3	10	8	1	0	2.682	0.780
	%	13.63	45.45	36.36	4.545	0.000		

*4: very good, 3: good, 2: commonly, 1:bad, 0:very bad

Table 11. Results of the preference survey for the device

		4*	3*	2*	1*	0*	Average	Standard Deviation
Device Convenience	Number of people	8	12	2	0	0	3.273	0.631
	%	36.36	54.54	9.091	0.000	0.000		
Appropriate use time	Number of people	4	14	4	0	0	3.000	0.617
	%	18.18	63.63	18.18	0.000	0.000		
overall feeling	Number of people	5	9	7	1	0	2.818	0.853
	%	22.72	40.90	31.81	4.545	0.000		

*4: very good, 3: good, 2: commonly, 1:bad, 0:very bad

3.9 Results of the preference survey for the device

After using the device, the test subjects' preference for the device was investigated for the convenience of operation, the appropriate use time, and the overall feeling of use. As a result of the survey, it was expressed as a percentage of the number of test subjects for the mean and standard deviation and answers Table 11. As a result of the survey, 100% of the test subjects rated the convenience of operation and the appropriate time to use the items, and 95.455% of the test subjects rated it as above average for the overall feeling of use.

3.10 Results of Safety evaluation

The researcher evaluated the results of the researcher's visual evaluation of the site where the test product was used and the test subject's survey Table 12. There were no reports of specific skin adverse reactions during the period in which the test subjects used the test product, and no abnormal findings were observed on physical examination by a dermatologist. As a result of the safety survey of the test subjects, no specific symptoms related to skin adverse reactions were observed Table 13.

Table 12. Results of the researcher's visual evaluation

	Test product
Erythema	–
Edema	–
Keratin production	–

Table 13. Results of the test subjects survey

	Test product
Itchiness	–
Pain	–
A burning sensation	
Stiffness	
Tingling	–

4. Conclusion and Suggestions

4.1 Conclusion

This study measured lip elasticity, lip moisture, lip keratin improvement, and lip moisturizing lasting for 12 hours while using a lip LED device and lip balm care containing propolis extract for 2 weeks on adult females aged 19 to 50 years. After the end of the study, efficacy and preference questionnaires were completed. The conclusions drawn through a series of research procedures are as follows[4].

First, the 22 test subjects who completed this study were all female, and the average age was 33 years old. The selected test subjects did not have any specific skin symptoms and had no history of diseases or medications that could affect the study.

Second, as a result of confirming the change in lip elasticity after using a lip balm containing propolis extract, there was a significant increase ($p<0.05$) immediately after use and 2 weeks after use compared to before use.

Third, as a result of confirming the change in lip moisture after using a lip balm containing propolis extract, there was a significant increase ($p<0.05$) immediately after use and 2 weeks after use, compared to before use.

Fourth, as a result of confirming the change of lip keratin after use of lip balm containing propolis extract, it was significantly decreased ($p<0.05$) immediately after use and after 2 weeks of use, compared to before use.

Fifth, as a result of confirming the change in lip moisture retention for 12 hours after using a lip balm containing propolis extract, there was no significant change in the test product group immediately after use, 6 hours after use, and 12 hours after use, compared to before use. In addition, significant changes were observed immediately after use, after 6 hours of use, and after 12 hours of use, compared with the non-applied group ($p<0.05$).

Sixth, the results of a survey on effectiveness evaluation of lip balm products containing propolis extract, lip elasticity and lip moisture. With respect to the lip keratin improvement item, 100% of the test subjects rated it as above average for the 12 hour lip moisturizing durability item, and 95.45% of the test subjects rated it as above average.

Seventh, there were no reports of any special skin adverse reactions while the test[8] subjects used the lip balm product containing propolis extract, and no abnormal findings were observed on physical examination by a dermatologist[10].

As a result of these results, the lip balm containing propolis extract is judged to be a product that helps lip elasticity, lip moisture, lip keratin improvement and lip lasting power for 12 hours with one use or two weeks of use.

4.2 Suggestion

The follow-up tasks of this study are suggested as follows.

In this study, lip balm containing propolis extract and the use of LED devices were the first to deal with lip-related research in the field of beauty science. In this study, results were derived through lip clinical and questionnaire using lip balm products containing propolis extract and LED devices. Of course, the validity of the measurement tool was implemented in the research method, but it was insufficient to establish a clear concept such as the study period and the number of participants.

Therefore, in future research, research on the development of measurement tools that can be evaluated with the participation of a large number of people and a wide research period in the beauty industry is required.

The cosmetics industry will also be able to provide basic data on consumer motivations in the cosmetics industry related to the lips, such as lipstick, lip gloss, and lip balm. Therefore, in future research, it is considered to be a meaningful research task that needs to be carried out more widely in relation to color cosmetics related to various makeup such as lipstick, lip gloss, and lip balm, and the related study of LED devices.

REFERENCES

[1] B. S. Kim & J. N. Lee. (2018). A Study on The Characteristics of Aesthetic Salon Operation and Job Satisfaction by Important Aspects in Launching Aesthetic Salon Business. *Journal of the Korean Academia-Industrial cooperation Society*, *19(2)*, 318-328.
DOI : 10.5762/KAIS.2018.19.2.318

[2] E. S. Myung. (2015). *Status and Improvement in the use of Home Facial Skin Care Equipments*, ChungAng University, Seoul.

[3] J. H. Park & Y. S. Choi. (2019). *Beauty and medical device technology trends and industry prospects*. KEIT PD Issue Report, *7*, 18-28.

[4] Y. W. Lee. (2012). Medical applycations of LED. *Korean Institute of Information Technology Magazine*, *10(2)*, 87-91.

[5] D. Barolet. (2008). Light-Emitting Diodes (LEDs) in Dermatology. *Seminars in Cutaneous Medicine and Surgery*, *2(4)*, 227-238.

[6] P. Bjerring. (2004). Photorejuvenation – An overview. *Med. Laser Appl.*, *19(4)*, 186-195.
DOI : 10.1078/1615-1615-00142

[7] R. A. Weiss. Margaret A. Weiss, Roy G. Geronemus & D. H. McDaniel. (2004). A novel non-thermal non-ablative full panel LED photomodulation device for reversal of photoaging : Digital microscopic and clinical results in various skin types. *Journal of Drugs in Dermatology, 3(6)*, 605-610.

[8] M. R. Hanblin & T. N. Dermidova. (2006), Mechanisms for Low-Light Therapy. *Proc. SPIE, 6140*, 1-12.
DOI : 10.1117/12.646294

[9] C. Y. Park, J. Y. Park, (2018). An Importance Analysis on the NCS-Based Qualification L2 Level of Education Using AHP in Skin Care Fields, *Journal of the Korea Entertainment Industry Association, 12(6)*, 207-215.

[10] J. T. Kim, S. B. Bae & D. H. Yun, (2010). Medical Treatment Machinery Based on LED Light Source. *Electronics and Telecommunications Trends*, *84*, 171-181.
DOI : 10.22648/ETRI.2010.J.250506

[11] M. W. Cheon, S.-H. Kim & Y. P. Park. (2008). The effect of 470nm LED Irradiation on skin Injury of RAT, *The Korea Institute of Electrical and Electronic Metrial Engineers Fall Conference*, *21*, 416-417.

[12] M. W Cheon, S. H. Kim & Y.-P. Park, T.-G. Kim & S. M. Yu. (2007). The Effect of LED Light Irradiation on Skin Injury Cure of Rat, *The Korea Institute of Electrical and Electronic Metrial Engineers Fall Conference, 20(12)*, 1087-1092.
DOI : 10.4313/JKEM.2007.20.12.1087

[13] J. S. Cha, J. P. Yun, M. S. Park, I.-S. Eo & E.-S. Suh. (2016). Research on Facial Skin Treatment Device using LED, *The Korean Institute of Electrical Engineers., 7*, 86-27.

[14] S. J. Kim & Y. W. Lee. (2016). Experimental Study on LED Irradiating Effects on Human Cell with the Change of the Energy and Wavelengths, *Journal of Advanced Information Technology and Convergence, 14(1)*, 79-84.

[15] O. N. G-jin Cho. (2007). *Beauty,* (Seoul) : Haetham Publishing, 212.

[16] S. K. Lee & J. M. Lee. (2013). A Comparison with Efficacy and Usability of Natural Lip Balm from Plant Extracts., *Joumal of Korean Society Cosmetology, 19(3)*, 493-500.

문 지 선(Ji Sun Moon)   [정회원]

· 2009년 2월 : 건국대학교 생물공학과 (이학석사)
· 2015년 2월 : 건국대학교 생물공학과 (이학박사)
· 2015년 9월 : 중원대학교 의료뷰티케어학과 교수

· 관심분야 : 화장품, 뷰티미용
· E-Mail : mjs@jwu.ac.kr