

EVALUATION OF IMPROVEMENTS IN SKIN SYMPTOMS WITH APPLICATION OF A LOTION CONTAINING GOLD LEAF

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Abstract

We investigated the effects of topical application of a lotion containing gold leaf on skin symptoms in 11 Japanese women between the ages of 20 and 59 (mean, 47.5 ± 4.6 years) with concerns about skin dryness and sagging. This was an open-label controlled study comparing the effects of a lotion with (test article) and without gold leaf (control), with application of each lotion on different sides of the face in the morning and at night for four consecutive weeks. The results showed that the test article significantly improved cutaneous water content, which reflected moisture retention in the skin, and cutaneous elasticity (return rate), suggesting that the gold leaf in the lotion improved moisture retention and elasticity of the skin. These effects were considered to be due to coating effects and the relaxing effects of gold leaf. We anticipate that the use of gold leaf-containing lotion will be a valuable approach in the cosmetology field.

Key words: gold, lotion, cutaneous moisture retention, cutaneous elasticity, coating effect, cosmetological effect

Introduction

Gold (chemical symbol: Au) possesses a metallic luster, and is a precious metal that has been known since ancient times. It is a metal element that belongs to Group 11 and 1B in the periodic table, and it is one of the elements in the copper group (also known as coinage metals)¹⁾. One of the reasons why gold has been highly prized since ancient times is its unchanging appearance over time, which is a property of gold. Gold does not readily react, and it is able to maintain its luster indefinitely because its surface does not easily oxidize. Prior to the arrival of Europeans, the natives of Central America thought of the radiance of gold as the sun, and gold was also regarded with great importance and was a symbol in their religious belief and worldview²⁾. Gold, similarly to platinum, has been used as a “medicine” for a very long time. Approximately 60 types of “Chinese medicine” that are 1200 years old have been preserved at Shosoin Temple in Nara, Japan, and 37% of these are called “stone medicine” that use minerals (inorganic compounds) as raw materials and elements such as gold, silver, copper, iron, tin, lead and arsenic have been detected in these medicines. Moreover, elements such as iron, copper, mercury, lead, antimony and arsenic were used as oral medications to treat diseases in medieval Europe³⁾. From the medical and scientific perspective, although a number of these minerals are known to be toxic, several pharmaceutical products that contain precious metals such as gold and platinum have been

developed in the late 20th century. Notable examples include cisplatin, an anti-cancer drug that contains a platinum ion; auranofin, an anti-rheumatic agent that is an organogold compound; sucralfate, an anti-ulcer drug that contains aluminum; and polaprezinc, an anti-ulcer drug that contains zinc³⁾. Gold is also used in perfume and cosmetic products; however, its cosmetological effects remain unknown.

Therefore, we conducted an open-label controlled study to investigate the effects of topical application of a lotion containing gold leaf on skin symptoms. A lotion that did not contain gold leaf was used as a control, and each lotion was applied to either the left or right side of the face, twice a day (morning and night) for four consecutive weeks. This study involved 11 Japanese women between the ages of 20 and 59 (mean, 47.5 ± 4.6 years) with skin concerns such as dryness and sagging.

I . Subjects and Methods

1. Subjects

1) Eligibility

Twenty individuals who met the inclusion and exclusion criteria listed below were selected from a database of volunteers who were registered with SOUKEN Co., Ltd. Of these 20 individuals, 11 who volunteered to apply the test article and who were determined to have relatively low cutaneous water content and cutaneous elasticity (return rate) on both cheeks were selected as subjects for this study.

Table 1 Test article ingredients**Article: Lotion with gold leaf**

Water, BG, betaine, glycosyl trehalose, hydrogenated starch hydrolysates, hydrolyzed collagen, sodium hyaluronate, gold, platinum, hydrolyzed yeast extract, fermented soybean extract, aloe vera leaf extract, Pueraria root extract, chlorella extract, arginine, carbomer, phenoxyethanol, polysorbate 80

Article: Lotion without gold leaf

Water, BG, betaine, glycosyl trehalose, hydrogenated starch hydrolysates, hydrolyzed collagen, sodium hyaluronate, platinum, hydrolyzed yeast extract, fermented soybean extract, aloe vera leaf extract, Pueraria root extract, chlorella extract, arginine, carbomer, phenoxyethanol, polysorbate 80

2) Inclusion criteria

- i . Japanese women between the ages of 20–59 years (inclusive) at the time of obtaining informed consent
 - ii . Those who feel dryness of the skin
 - iii . Those who feel skin sagging
- 3) Exclusion criteria
- i . Women who are pregnant or may be pregnant, or lactating mothers
 - ii . Those who are taking or applying medications (such as drugs that possess skin-beautifying effects) that might affect the test results
 - iii . Those who regularly consume health foods (such as supplements that claim to have skin-beautifying effects) that might affect the test results
 - iv . Those with a risk of developing skin allergy symptoms or those with cutaneous hypersensitivity
 - v . Those with a risk of developing allergic symptoms to ingredients in the test article
 - vi . Those who regularly visited a dermatologist at the time of the study
 - vii . Those who are participating in another clinical study

4) Subject consent

Approval was obtained from Shiba Palace Clinic Ethical Review Board prior to commencement of the study, and the study content and procedure was thoroughly explained to the subjects. Written consent was obtained from the subjects, and the study adhered to the principles of the Declaration of Helsinki.

2. Test article

The test article was a lotion that contained gold leaf and the control article was a lotion that did not contain gold leaf. The ingredients in each lotion are shown in **Table 1**. Both the test and control articles were provided by Hakuichi Co., Ltd.

3. Study procedure, study duration, testing and measurement methods, subject selection, and subject assignment

1) Study procedure

This was an open-label controlled study in which approximately 2 mL of the test article and control were each applied on one side of the face twice a day (morning

and night after cleansing) for 4 weeks.

2) Study Duration

The study was conducted for 4 weeks between August 28 and October 8, 2013. The test article was applied on one side of the face and the control was applied on the opposite side continuously for 4 weeks. There were three time points for assessments: pre-application, after 2 weeks, and after 4 weeks. In addition, subjects were instructed to refrain from shaving and depilation at the measurement site (cheeks) during the study.

3) Testing and measurement methods

At the three assessment time points, subjects cleansed their faces and rested for 20 minutes in a room maintained at a temperature 22 ± 2 °C and humidity of $50 \pm 10\%$ (RH) to acclimatize the skin. Subsequently, the skin conditions of the face were measured using the appropriate equipment.

i . Cutaneous water content

Using Corneometer CM825 (Courage + Khazaka Electronic GmbH) measurements were made at three sites (5 mm apart) along each cheekbone. The mean of the measured values were recorded as the cutaneous water content of the cheek area.

ii . Cutaneous water loss

Using VapoMeter SWL-4360 (Delfin Technologies, Ltd.), measurements were made 3 cm from the base of the earlobe on the line that connects the base of the earlobe and the corner of the mouth on both sides of the subject's face. Measured values were recorded as cutaneous water loss of the cheek area.

iii . Cutaneous elasticity

Using Cutometer MPA 580 (Courage + Khazaka Electronic GmbH) three measurements were made 4 cm from the base of the earlobe on the line that connects the base of the earlobe and the corner of the mouth on both sides of the subject's face. The differences in the median values of the maximum and minimum amplitudes and the ratio of maximum:minimum amplitudes (return rate) were recorded as the cutaneous elasticity of the cheek area.

iv . Subjective symptom questionnaire

Subjects were given a questionnaire on subjective symptoms and were asked to subjectively assess the skin at each time point. The questionnaire asked the subjects

Table 2 Age of subjects

Items	Women
Number of people	11
Age (years)	47.5 ± 4.6

Mean ± standard deviation

Table 3 Changes in cutaneous water content

Measurement	Units	Group	n	Pre-application	P-value between groups	After 2 weeks	P-value between time points	P-value between groups	After 4 weeks	P-value between time points	P-value between groups
Cutaneous water content	—	With gold leaf	11	47.4 ± 6.4	<i>P</i> = 0.793	51.8 ± 6.3	<i>P</i> = 0.002 **	<i>P</i> = 0.018 *	51.8 ± 7.8	<i>P</i> = 0.002 **	<i>P</i> = 0.006 **
		Without gold leaf	11	47.1 ± 7.7		47.4 ± 6.9			<i>P</i> = 0.927		

Mean ± standard deviation

For each group, Dunnett's test was used to compare between pre-application and after 2 weeks, and between pre-application and after 4 weeks. *: *P* < 0.05 **: *P* < 0.01 ***: *P* < 0.001

For each time point, paired t-test was used to compare the group using the lotion with gold leaf with the group using the lotion without gold leaf. *: *P* < 0.05 **: *P* < 0.01 ***: *P* < 0.001

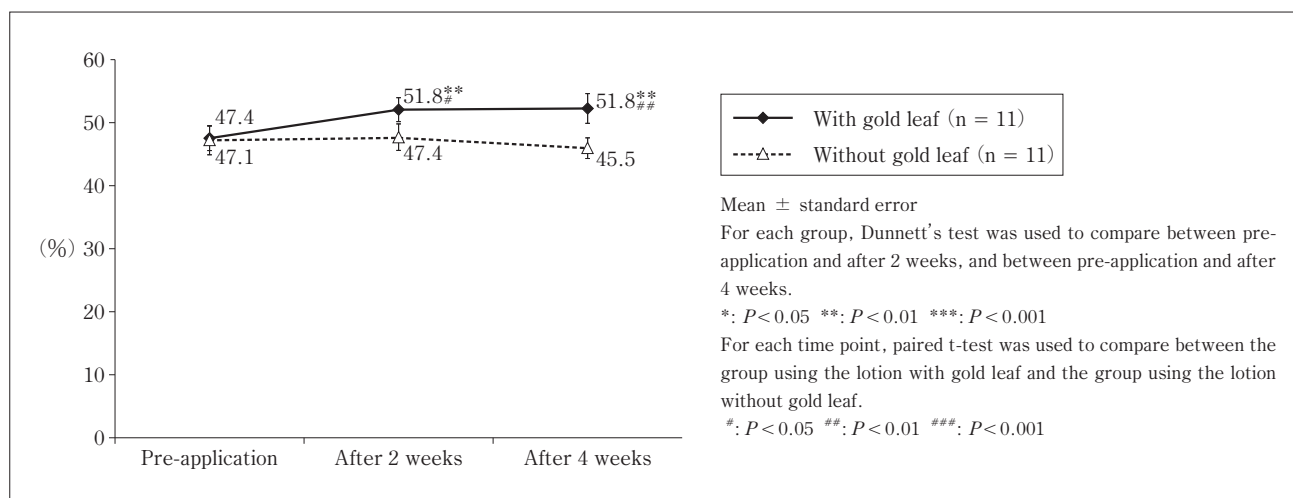


Fig. 1 Changes in cutaneous water content

to assess the following ten facial skin conditions on a five-point scale (1, extremely concerned; 2, a little concerned; 3, neither concerned nor unconcerned; 4, not very concerned; 5, not concerned at all): “sagging”, “makeup not looking smooth”, “dull skin on the whole face and poor complexion”, “dryness on the whole face”, “dryness around the eyes and mouth”, “fine lines”, “tightness after cleansing”, “dark circles under eyes”, “skin texture and open pores”, and “firmness and elasticity of skin”.

4) Selection of subjects

Subjects were screened using the following procedures. First, “cutaneous water content” and “cutaneous elasticity (return rate)” were measured on both the left and right cheeks of 20 individuals, and those who met the inclusion criteria were ranked “1, 2, 3...” according to the measured values. These ranks were used as the score for each type of measurement. Eleven individuals with low total scores were selected to participate in this study. In the event that individuals had the same total score, those with lower “cutaneous water content” took precedence.

5) Application site

The side of the faces for application of the test article and control were randomly selected to achieve similar mean screening values of cutaneous water content and cutaneous elasticity (return rate) as much as possible.

4. Statistical analysis

Measurements are expressed as mean ± standard deviation in the manuscript and tables, and as mean ± standard error in the figures. Dr. SPSS II (SPSS Inc.) was used for statistical analysis.

For the analysis between pre-application values and values at each time point, Dunnett's multiple comparison test was used to compare cutaneous water content, cutaneous water loss, and cutaneous elasticity, and Wilcoxon signed-rank test (with Bonferroni correction) was used to compare subjective symptoms.

For the comparison between the test article group and control group at different time points, paired t-test was used to compare cutaneous water content, cutaneous water loss, and cutaneous elasticity, and Wilcoxon signed-rank test was used to compare subjective symptoms.

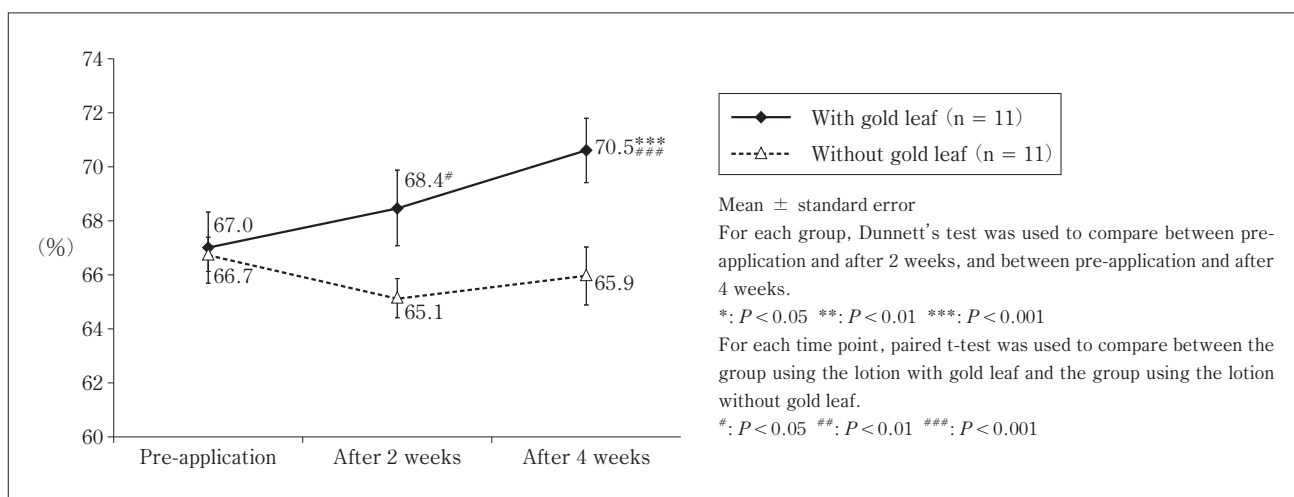
Table 4 Changes in cutaneous elasticity

Measurement	Units	Group	n	Pre-application	P-value between groups	After 2 weeks	P-value between time points	P-value between groups	After 4 weeks	P-value between time points	P-value between groups
Cutaneous elasticity (maximum amplitude)	mm	With gold leaf	11	0.249 ± 0.038	$P = 0.364$	0.273 ± 0.022	$P = 0.073$	$P = 0.556$	0.287 ± 0.045	$P = 0.005^{**}$	$P = 0.279$
		Without gold leaf	11	0.260 ± 0.044		0.265 ± 0.035	$P = 0.937$		0.270 ± 0.047	$P = 0.751$	
Cutaneous elasticity (minimum amplitude)	mm	With gold leaf	11	0.082 ± 0.018	$P = 0.555$	0.087 ± 0.018	$P = 0.527$	$P = 0.417$	0.085 ± 0.016	$P = 0.837$	$P = 0.277$
		Without gold leaf	11	0.087 ± 0.015		0.092 ± 0.013	$P = 0.504$		0.092 ± 0.015	$P = 0.594$	
Cutaneous elasticity (return rate)	%	With gold leaf	11	67.0 ± 4.4	$P = 0.846$	68.4 ± 4.6	$P = 0.099$	$P = 0.044^{*}$	70.5 ± 3.9	$P < 0.001^{***}$	$P < 0.001^{***}$
		Without gold leaf	11	66.7 ± 2.1		65.1 ± 2.4	$P = 0.120$		65.9 ± 3.6	$P = 0.508$	

Mean ± standard deviation

For each group, Dunnett's test was used to compare between pre-application and after 2 weeks, and between pre-application and after 4 weeks. *: $P < 0.05$ **: $P < 0.01$ ***: $P < 0.001$

For each time point, the paired t-test was used to compare the group using the lotion with gold leaf with the group using the lotion without gold leaf. *: $P < 0.05$ **: $P < 0.01$ ***: $P < 0.001$

**Fig. 2** Changes in cutaneous elasticity (return rate)

All comparisons were two-tailed tests with significance level at 5%.

II. Study Results

1. Age of subjects

The mean age of the 11 subjects who participated in this study was 47.5 ± 4.6 years (**Table 2**).

2. Changes in cutaneous water content

The changes in cutaneous water content are shown in **Table 3** and **Figure 1**.

Cutaneous water content in the test article (lotion containing gold leaf) group was 47.4 ± 6.4 at pre-application, 51.8 ± 6.3 after 2 weeks, and 51.8 ± 7.8 after 4 weeks, indicating significant elevations in water content after 2 weeks ($P = 0.002$) and after 4 weeks ($P = 0.002$) compared with that at pre-application. In contrast, significant time-dependent changes were not observed in the control (lotion without gold leaf) group. The test article group had significantly higher cutaneous water content compared with the control group after 2 weeks ($P = 0.018$) and after 4 weeks ($P = 0.006$).

3. Changes in cutaneous water loss

Significant changes in cutaneous water loss at different time points were not observed in either group. Significant differences between groups were also not observed.

4. Changes in cutaneous elasticity (return rate)

The changes in cutaneous elasticity (return rate) are

shown in **Table 4** and **Figure 2**.

The return rate in the test article group was $67.0 \pm 4.4\%$ at pre-application, $68.4 \pm 4.6\%$ after 2 weeks, and $70.5 \pm 3.9\%$ after 4 weeks, demonstrating an increase of 1.4 after 2 weeks and a significant increase of 3.5 after 4 weeks ($P < 0.001$). In contrast, significant changes between different time points were not observed in the control group. The test article group had significantly greater cutaneous elasticity compared with the control article group after 2 weeks ($P = 0.044$) and after 4 weeks ($P < 0.001$).

5. Changes in subjective symptoms

The changes in subjective symptoms are shown in **Table 5**.

In both the test article and control groups, the scores of "sagging", "makeup not looking smooth", "dryness around the eyes and mouth", "tightness after cleansing", "skin texture and open pores", and "firmness and elasticity of skin" were significantly higher 2 and 4 weeks after application compared with those at pre-application. In both the test article and control groups, the scores of "dull skin on the whole face" and "poor complexion" were significantly higher 2 weeks after application compared with those at pre-application. In both the test article and control groups, the scores of "dryness on the whole face" and "fine lines" were significantly higher after 4 weeks of application compared with those at pre-

Table 5 Changes in subjective symptoms

Concerns	Units	Group	n	Pre-application	P-value between groups	After 2 weeks	P-value between time points	P-value between groups	After 4 weeks	P-value between time points	P-value between groups
Skin sagging	—	With gold leaf	11	1.36 ± 0.50	<i>P</i> = 1.000	2.00 ± 0.45	<i>P</i> = 0.008 *	<i>P</i> = 1.000	2.55 ± 1.04	<i>P</i> = 0.006 *	<i>P</i> = 1.000
		Without gold leaf	11	1.36 ± 0.50		2.00 ± 0.45	<i>P</i> = 0.008 *		2.55 ± 1.04	<i>P</i> = 0.006 *	
Makeup not looking smooth	—	With gold leaf	11	2.00 ± 1.00	<i>P</i> = 1.000	3.27 ± 1.01	<i>P</i> = 0.010 *	<i>P</i> = 0.317	3.64 ± 0.81	<i>P</i> = 0.004 **	<i>P</i> = 0.157
		Without gold leaf	11	2.00 ± 1.00		3.09 ± 0.83	<i>P</i> = 0.013 *		3.45 ± 0.82	<i>P</i> = 0.004 **	
Dull skin on the whole face and poor complexion	—	With gold leaf	11	1.91 ± 1.38	<i>P</i> = 1.000	2.82 ± 1.08	<i>P</i> = 0.014 *	<i>P</i> = 1.000	3.00 ± 1.55	<i>P</i> = 0.026	<i>P</i> = 1.000
		Without gold leaf	11	1.91 ± 1.38		2.82 ± 1.08	<i>P</i> = 0.014 *		3.00 ± 1.55	<i>P</i> = 0.026	
Dryness on the whole face	—	With gold leaf	11	2.18 ± 0.87	<i>P</i> = 1.000	3.18 ± 1.17	<i>P</i> = 0.041	<i>P</i> = 1.000	3.55 ± 1.21	<i>P</i> = 0.014 *	<i>P</i> = 1.000
		Without gold leaf	11	2.18 ± 0.87		3.18 ± 1.25	<i>P</i> = 0.035		3.55 ± 1.21	<i>P</i> = 0.014 *	
Dryness around the eyes and mouth	—	With gold leaf	11	2.09 ± 0.94	<i>P</i> = 1.000	3.09 ± 1.04	<i>P</i> = 0.022 *	<i>P</i> = 1.000	3.45 ± 1.13	<i>P</i> = 0.011 *	<i>P</i> = 0.317
		Without gold leaf	11	2.09 ± 0.94		3.09 ± 1.04	<i>P</i> = 0.022 *		3.36 ± 1.29	<i>P</i> = 0.016 *	
Fine lines	—	With gold leaf	11	1.55 ± 1.04	<i>P</i> = 1.000	2.18 ± 0.87	<i>P</i> = 0.080	<i>P</i> = 0.317	2.27 ± 1.01	<i>P</i> = 0.023 *	<i>P</i> = 0.317
		Without gold leaf	11	1.55 ± 1.04		2.09 ± 0.70	<i>P</i> = 0.124		2.36 ± 0.92	<i>P</i> = 0.014 *	
Tightness after cleansing	—	With gold leaf	11	1.82 ± 0.75	<i>P</i> = 1.000	3.09 ± 0.94	<i>P</i> = 0.009 *	<i>P</i> = 0.317	3.36 ± 1.12	<i>P</i> < 0.010 *	<i>P</i> = 0.157
		Without gold leaf	11	1.82 ± 0.75		3.27 ± 0.90	<i>P</i> = 0.004 **		3.18 ± 1.17	<i>P</i> < 0.010 *	
Dark circles under eyes	—	With gold leaf	11	2.09 ± 1.38	<i>P</i> = 1.000	2.64 ± 1.12	<i>P</i> = 0.323	<i>P</i> = 0.317	2.64 ± 1.12	<i>P</i> = 0.250	<i>P</i> = 0.317
		Without gold leaf	11	2.09 ± 1.38		2.55 ± 1.04	<i>P</i> = 0.374		2.73 ± 1.10	<i>P</i> = 0.176	
Skin texture and open pores	—	With gold leaf	11	1.55 ± 0.93	<i>P</i> = 1.000	2.73 ± 1.10	<i>P</i> = 0.010 *	<i>P</i> = 1.000	2.64 ± 1.12	<i>P</i> < 0.010 *	<i>P</i> = 1.000
		Without gold leaf	11	1.55 ± 0.93		2.73 ± 1.10	<i>P</i> = 0.010 *		2.64 ± 1.12	<i>P</i> < 0.010 *	
Firmness and elasticity of skin	—	With gold leaf	11	1.27 ± 0.47	<i>P</i> = 1.000	2.27 ± 0.65	<i>P</i> = 0.005 **	<i>P</i> = 0.317	2.55 ± 1.04	<i>P</i> = 0.006 *	<i>P</i> = 1.000
		Without gold leaf	11	1.27 ± 0.47		2.36 ± 0.67	<i>P</i> = 0.006 *		2.55 ± 1.04	<i>P</i> = 0.006 *	

Mean ± standard deviation

For each group, Wilcoxon signed-rank test (Bonferroni correction for multiple comparisons) was used to compare between pre-application and after 2 weeks, and between pre-application and after 4 weeks.

*: $P < 0.05/2$ **: $P < 0.01/2$ ***: $P < 0.001/2$

For each time point, Wilcoxon signed-rank test was used to compare between the group using the lotion with gold leaf and the group using the lotion without gold leaf, and no significant differences were found.

application.

Significant differences between the test article group and control group were not observed with any of the assessed items.

6. Safety

Adverse events were not observed during the study, and the test article was considered to be safe.

III. Discussion

In the present study, we conducted an open-label controlled study to investigate the effects of a lotion containing gold leaf on skin symptoms. Lotion that did not contain gold leaf was used as a control, and each lotion was applied to either the left or right side of the face, twice a day (morning and night) for four consecutive weeks. A total of 11 Japanese women between the ages 20 and 59 (mean, 47.5 ± 4.6 years) with skin concerns such as dryness and sagging were examined in this study.

Significant improvements in cutaneous water content, which represents moisture retention of the skin, and skin elasticity were observed with the application of lotion containing gold leaf compared with the effect of a lotion that did not contain gold leaf. This suggested that the gold leaf itself improved moisture retention and elasticity of the skin.

People have highly prized gold through the ages²⁾. In the medical field, for example, the effects of the continuous consumption of pure gold on brain activity were investigated using electroencephalography⁴⁾. This study demonstrated that the consumption of gold activates the left brain and induces relaxation effects, suggesting that it reduces stress. However, these effects

may be attributed to its color apart from other physical characteristics of gold. Color is known to have a strong psychological impact on people even without such a fact being verbalized⁵⁾. For example, in a study that asked subjects in their 20s to evaluate the colors projected on a screen on a seven-point scale from “cute” to “not cute”, the authors simultaneously measured several parameters such as heart beat and brainwaves, and found that biological reactions were more active when the subjects viewed colors that they evaluated (acknowledged) as “cute” relative to “not cute” colors⁶⁾. In addition, multiple elements such as color, fragrance and texture of cosmetic products stimulate the central nervous system, and colors with high levels of brightness were shown to increase comfort and the sense of relaxation compared with those with low brightness⁷⁾. The superiority of the lotion containing gold leaf over the lotion that did not contain gold leaf in this study was considered to be attributable, at least partly, to the visual characteristics of gold.

In the present study, both the test article and control contained hydrolyzed collagen and sodium hyaluronate, and the control without gold leaf could also be a product that benefits the skin. Nonetheless, we confirmed that the lotion containing gold leaf significantly improved objective indices such as cutaneous water content and cutaneous elasticity. Oil-based ingredients such as Vaseline (petroleum jelly) form a coating on the stratum corneum and are known to prevent water loss⁸⁾⁻¹⁰⁾, and it was considered that a similar effect may be obtained by applying gold leaf on the skin surface.

Our findings suggest that the test article in the present

study may improve moisture retention and elasticity of the skin through relaxing and coating effects by the gold leaf in the test article.

Conclusion

In the present study, we conducted an open-label controlled study to investigate the effects of a lotion containing gold leaf on skin symptoms. Lotion that did not contain gold leaf was used as a control, and each lotion was applied to either the left or right side of the face, twice a day (morning and night) for four consecutive weeks. A total of 11 Japanese women between the age of 20 and 59, (mean, 47.5 ± 4.6 years) with skin concerns such as dryness and sagging were examined. The study revealed the following results:

1) Cutaneous water content significantly improved after application of a lotion that incorporated gold leaf as an ingredient.

2) Cutaneous elasticity (return rate) significantly improved after application of a lotion that incorporated gold leaf as an ingredient.

3) We suggest that skin symptoms may have improved because of the coating effects and relaxing effects of gold

leaf on people.

4) The above findings indicate that, by applying lotion containing gold leaf twice a day at morning and night after facial cleansing, moisture retention and elasticity of the skin can be improved safely and effectively, and we anticipate that the use of this lotion will be a valuable approach in the cosmetology field.

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