CONFIDENTIAL

FINAL REPORT

Study Title:

Jevie Lotion
Anti-wrinkle Function Evaluation Study

[Guideline on Evaluating Anti-wrinkle Product for Obtaining Novel Indication Approval]

TEST FACILITY

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I, the undersigned, hereby declare that this report is an accurate description of the outcomes of the study performed based on the protocol under approval by the Institutional Review Board of Kirei Testing Labo, which conforms to the principles of the World Medical Association's Declaration of Helsinki, and the Ethical Principles for Medical Research Involving Human Subjects.

June-9, 2023

Study Director Ichiro Iwai, PhD

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Summary

To the lateral canthus, as a site of interest, of each subject having wrinkles assessed as wrinkle grades 1 to 3,

the investigational product 'Jevie Lotion'

was applied in a continuous-use test.
The wrinkle grade was visually assessed and the wrinkles were measured by using a replica to determine

how effective the investigational product was on the wrinkled lateral canthus skin. The results show:

- The relative value in the value assessed between before and after the test using the wrinkle grade standard was significantly lower in the investigational product application group than in the non-application group.

- The wrinkle area percentage determined by replica analysis was significantly lower in the investigational product application group than in the non-application group.

- The wrinkle count determined by replica analysis, the difference calculated by subtracting the wrinkle count before the test from the wrinkle count after the test, and the relative change between the wrinkle counts were significantly lower in the investigational product application group than in the non-application group.

According to the above results and the “criteria of anti-wrinkle product evaluation guideline to obtain new indication approval” defined by the Expert Committee on Anti-Aging Functional Evaluations (Cosmetic Products Functional Evaluations Investigation Committee) in Japanese Cosmetic Science Society

the investigational product 'Jevie Lotion'

was determined to exert the effects of “making inconspicuous minor wrinkles caused by dryness”.

1. Experimental design

Study title	Investigational Product 'Jevie Lotion' Anti-wrinkle Function Evaluation Study
Investigational product name	Jevie Lotion
Study objective	The investigational product is applied to the lateral canthus, as a site of interest, of each subject having wrinkles assessed as having a wrinkle grade of 1 to 3.The wrinkle grade is then visually assessed and the wrinkles are measured by using a replica to determine how effective the investigational product is on the wrinkled lateral canthus skin.
Study design	Single-blind, 4 week continuous use, comparison with the non-application site in the same subject
The number of subjects	24 persons
How to select subjects	The wrinkles were visually assessed, based on the wrinkle grade standard (with 8 grades of 0 to 7), and 24 subjects were elected for this clinical study.
Usage period	28 days
Observation period	Before the start of application and after the end of 28-day application period
Observation frequency	Twice: before and after the application test.
How to apply and how much	The prescribed application amount was applied to the face (without make-up) of each subject by themselves, namely, the lateral canthus, a site of interest, and the surrounding of either half of the face.
Evaluation items	The following protocols were used to evaluate a change in wrinkles on the application site. 1. Visual assessment using a wrinkle grade standard. 2. Wrinkle analysis using a replica device having silicone as a base material as prepared from the site of interest.
How to analyze efficacy	Compliance with the test procedure was checked and efficacy analysis was conducted in a group of subjects, excluding those who had violated the exclusion criteria. It was judged that there was an efficacy when a significant difference ($P < 0.05$) in the change in the visually assessed wrinkle value or a significant difference ($P < 0.05$) in the change in each wrinkle analysis parameter measured using a replica was observed with respect to the investigational product application group while compared to the non-application group.

2. Preface

To label any functional cosmetic with an indication of "making inconspicuous minor wrinkles caused by dryness", the manufacturer must conduct a test in accordance with the approved evaluation method and prove that the product exerts its efficacy. Also, this efficacy has to be disclosed, based on actually verified data, to consumers.
This has been specified in the notice of "About Amendment on Scope of Indication for Cosmetics" (PFSB/ELD Notification and PFSB/CND Notification No. 0721-1, on July 21, 2011 [1)]) by Pharmaceutical and Food Safety Bureau of Ministry of Health, Labor and Welfare in Japan. Then, the evaluation procedure is in accordance with the "Cosmetic Function Evaluation Test Guideline" by Japanese Cosmetic Science Society (prepared by Japanese Cosmetic Science Society in December 2006) [2)].

3. Experimental design overview

To evaluate the anti-wrinkle effect of the investigational product, which is a functional cosmetic, on the lateral canthus skin, the investigational product is applied to the lateral canthus, as a site of interest, of each subject having wrinkles of wrinkle grades 1 to 3. Then, the wrinkles were assessed visually, photographed, and measured using a replica (device) to determine its efficacy. The lateral canthus refers to the outer canthus region, and a lateral canthus wrinkle means a skin groove line running from the outer canthus.

4. Subjects

4.1 Pooled subjects

Those who were listed as subject candidates by an outside subject resource organization were asked to fill in a questionnaire about recruitment.Those who met the following inclusion criteria by self-assessment and did not violate the exclusion criteria were visually assessed (4.2) using the wrinkle grade standard. In this way, screening was conducted. Then, 24 persons who passed the inclusion criteria (4.3) and the exclusion criteria (4.4) were elected as subjects in this clinical study.

4.2 Screening

Screening items: Visually assessed wrinkle grade

4.3 Inclusion criteria

1) Japanese healthy female subjects between 20 years and 59 years old (inclusive) at the time of consent.
2) Subjects whose wrinkles on the lateral canthus on each of both the left and right sides primarily have a wrinkle grade of 1 to 3.
3) Subjects whose skin characteristics fall under the skin type III or IV (according to the Fitzpatrick classification).

4.4 Exclusion criteria

1) Subjects whose wrinkle grade score markedly differs between the left lateral canthus and the right lateral canthus (subjects in which the score difference between the left and the right is ± 1.0 or more.
2) Subjects with any factor (e.g., disease such as atopic dermatitis or urticaria, inflammation, eczema, trauma, contusions, pimples, warts, spots, or traces thereof) that might affect the outcome of the study on the skin at the assessment site.
3) Subjects under continuous use, on the assessment site, of skin care products, cosmetics, quasi-drugs, or health supplements that advocate or emphasize the same or related efficacy (of making inconspicuous minor wrinkles caused by dryness) as the investigational product being evaluated in this study.
4) Subjects who underwent, or planed to undergo, during the test period, cosmetic medical treatment, for instance, at the assessment site.
5) Subjects who changed or newly started health foods and/or basic cosmetics or sunscreens used at the assessment site within the past 4 weeks.
6) Subjects who were exposed to ultraviolet radiation beyond the scope of daily life, such as prolonged outdoor work, exercise, swimming, or leisure activities within the past four weeks, or planned to do so during the test period.
7) Subjects who participated in another clinical trial (any clinical trial for cosmetics, foods, pharmaceuticals, quasi‐drugs, or medical devices in human subjects) on the lateral canthus and the surrounding in human subjects within the past four weeks.Subjects who planed to participate in another human clinical trial on the lateral canthus and the surrounding within the scheduled period of this clinical study.
8) Subjects who, at the time of acquisition of consent, were undergoing treatment (e.g., hormone replacement therapy, drug therapy, exercise therapy, diet therapy) at medical institutions for treatment or prevention of disease, or who were judged to be in need of treatment.
9) Subjects who were undergoing dermatological treatment.
10) Subjects with a history of serious diseases in the glucose metabolism or lipid metabolism, or liver, renal, cardiac, circulatory, respiratory, endocrine, immune, or neurological system, or a history of psychiatric disorders.
11) Subjects who work night and day/night shifts.
12) Subjects with a history of alcohol and drug dependence.
13) Subjects who take alcohol, vitamin B12, melatonin, etc., for sleep.
14) Subjects at a risk of developing allergies to cosmetics and foods (including those who developed a rash or other skin abnormalities to cosmetic products within the past year).
15) Subjects who were pregnant or lactating at the time of obtaining consent or who wished to become pregnant during the test period.
16) Subjects who use mezaik, eye tape, or other double eyelid prosthesis and are unable to remove it for testing purposes.
17) Subjects who wear eyelash extensions and must avoid having solvent on their eyelashes when a replica is collected.

18) Subjects who were judged unsuitable for participation in the study by the study doctor or principal investigator (individuals were excluded from the analysis when the study doctor or principal investigator became aware of the fact that made them ineligible during the course of the study).

5. Subject information and consent

After the following 1) to 10) were explained, the investigator obtained the subject's signed and dated informed consent expressing his or her freewill in participating in the clinical study, before any study-related activities were carried out.

1) Purpose and procedures of this clinical study
2) Description and action of the investigational product, potential risk, discomfort, and inconvenience from participating in this study, and how these matters will be managed
3) The subjects are substantially controlled by the investigator during the study period.
4) Subjects do not suffer a disadvantage even if they disagree with participation in this study.
5) The subjects are free to withdraw from the study at any time after providing consent.
6) The subjects are eligible to receive appropriate intervention and treatment in case of any study-related injury or adverse event.
7) The subject would be promptly informed of any new information obtained that could potentially affect the subject's willingness to continue participation in the study.
8) Information about the subject's rights, information disclosure requirements, and so on.
9) Compliance of subjects
10) Details regarding a help desk where subjects could request further information about their rights regarding participation in the study, or about any study-related adverse event or injury.
11) Regarding compensation for subjects

6. Overview of the investigational product

All ingredients of the investigational product are listed in Annex 1.

6.1 Usage

<Application Amount>

Morning: 1 push /half-face

Night: 1 push /half-face

6.2 Investigational product application method

This test adopted a half-face protocol, which was performed on left and right corresponding sites of the face of each subject.The investigational product was applied on one side of the subject and the other side was free of the investigational product. The subject was instructed to apply the investigational product twice: morning and night possibly during the same time zone every day. The subject was instructed to apply the investigational product in accordance with specified usage during the test period until the day before the end of the test.

The subject was instructed to apply the specified amount of the investigational product after cleansing (after make-up removal and cleansing if the subject had make-up) while the application was conducted on the lateral canthus (application side) of either the left or right half of the face. The subject was instructed not to use, on the lateral canthus on the application side, any skin care product other than the investigational product. The subject was instructed not to apply the investigational product on the lateral canthus on the other side of the face. The subject was allowed to use other regularly used skin care products, such as skin lotion, emulsion, beauty lotion, and gel, on sites other than the lateral canthus and the surrounding. However, neither a change nor addition was permitted during the test period.

7. Test and measurement procedure

The state and response of a test site were photographed, assessed visually, and measured using a device twice: before the start of the investigational product application and after the end of the test.

1. Visual assessment using a wrinkle grade standard.
2. How to photograph a site of interest and the surrounding.
3. Wrinkle analysis using a replica device having silicone as a base material as prepared from the site of interest.

7.1 Photography and visual assessment using a wrinkle grade standard

7.1.1 How to photograph

After cleansing and washing using cleansing lotion and then resting in a room kept at a temperature of 21.0 ± 0.3°C and a relative humidity of 45.0 ± 2.0% for about 20 min to adapt their skin to the test environment, each subject was visually assessed using the wrinkle grade standard and photographed on each of the two examination days.

To reduce a deviation of the angle of the site of interest in the subject during photography, a jaw stand to fix the face was used. The subject was then instructed to lightly close the eyes during the photography. The area from the lightly closed eyes to the temple was photographed.

A digital single-lens reflex camera (D610, Nikon, Japan) equipped with a large-diameter zoom lens (SP 24-70mm F2.8 Di VC USD, TAMRON, Japan) was used for the photography.

7.1.2 How to assess visually

A trained expert(s) skilled at the wrinkle assessment scored, based on the wrinkle grade criteria and the wrinkle grade images (*), wrinkles in eight different grades. If not corresponded to each grade standard image, the half or the 1/4 score point (e.g., 3.5 or 3.25) was given.

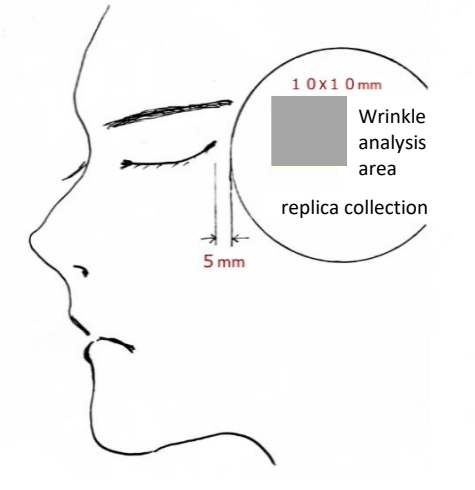
Wrinkle grade standard

Findings	Grade
No wrinkles	0
Inconspicuous shallow wrinkles are slightly detected.	1
Conspicuous shallow wrinkles are slightly detected.	2
Conspicuous shallow wrinkles are detected.	3
Among conspicuous shallow wrinkles, somewhat deep wrinkles are slightly detected.	4
Somewhat deep wrinkles are detected.	5
Conspicuous deep wrinkles are detected.	6
Very deep wrinkles are detected.	7

* According to the “Cosmetic Function Evaluation Test Guideline”.

7.2 Wrinkle measurement by replica analysis.

7.2.1 How to collect a replica and process information



On each of the two examination days, the face of each subject was subjected to cleansing and washing using cleansing lotion, and the skin was adapted to the test environment. SKIN CAST (R.S.I., Japan), a rubber-type precision impression agent (hydrophilic vinyl silicone impression agent), was applied to an area approximately 5 mm away from the edge of the eyes of the subject in a resting state with eyes lightly closed.A skin replica of 10 × 10 mm or larger was prepared on a site of interest within this area.

The replica collected was analyzed using a replica analysis system (ASA-03RXD, Asch Japan Co., Ltd., Japan) to calculate the wrinkle area percentage, the wrinkle volume percentage, the maximum wrinkle depth, the maximum wrinkle width, the average wrinkle depth, and the wrinkle count [3, 4].

7.2.2 To calculate parameters for wrinkle analysis

Wrinkles with a depth of 90 μm were defined as wrinkles in this test. Then, the replica analysis area (10 × 10 mm) was examined for the parameters below.

7.2.2.1 Wrinkle area percentage

The total area of wrinkles was calculated after binarization. Then, the wrinkle area percentage (%), which is their wrinkle percentage with respect to the analysis area, was determined.

7.2.2.2 Wrinkle volume percentage

The total volume of wrinkles was calculated after binarization. Then, the wrinkle volume percentage (%), which is their volume percentage with respect to the analysis volume, was determined.

7.2.2.3 Maximum wrinkle depth

The area and length of the shadow of a projected part of the replica as created by light projection were analyzed as the depth of each wrinkle. Then, the deepest one was determined as the maximum wrinkle depth (μm).

7.2.2.4 Maximum wrinkle width

The broadest portion of the wrinkle width after binarization was calculated as the maximum wrinkle width (μm).

7.2.2.5 Average wrinkle depth

The depths of all the wrinkles in the analysis area were calculated and averaged to give the average wrinkle depth (μm).

7.2.2.6. Wrinkle count

The number of wrinkles with a depth of 90 μm in the analysis area was calculated as the wrinkle count (the number).

8. Overall evaluation on efficacy

In the case where a significant decrease (improvement) ($P < 0.05$) in the score of the visual evaluation or each wrinkle parameter measured by a (replica) device in the group of subjects who had the investigational product applied was detected when compared with the non-application group (side), the effects of “making inconspicuous minor wrinkles caused by dryness” were determined to be exerted.

9. Restrictions

The subjects were instructed to comply with the following regulations unless the subjects needed medical care or their life and physical safety should be protected. In case of occurrence of such events, the subjects are instructed to report the events to the investigator, etc.

1) During the test period, only the investigational product was used on the lateral canthus on the investigational product application side, and nothing was applied on the lateral canthus on the investigational product non-application side.
   Regularly used skin care products, such as skin lotion, emulsion, beauty lotion, and gels, were optionally used, but their change or addition was prohibited during the test period.
2) During the test period, shaving, depilation, or removal of hair at the measurement sites (near the right and left lateral canthus) was prohibited.
3) Skin care therapy, such as facial beauty therapy, which could affect the test area, was not conducted during the test period and during four weeks prior to the test period.
4) The subjects were advised to avoid excessive UV exposure during the test period.
5) Additional intake of supplements, etc., was prohibited during the test period.
6) On the day of examination after the investigational product application, the subjects were instructed not to use the investigational product on the lateral canthus and the surrounding until the examination on that day was completed.

10. Withdrawal and drop-out criteria

If any of the following events occurred, the study would be ceased based on the physician's medical or ethical discretion or the investigator's decision. Unless otherwise indicated, appropriate medical care is provided to the subjects so as to protect the safety of the subjects.

1) Serious adverse events or subjective and objective symptoms, etc.
2) Difficulty in continuing participation in the study due to comorbidity or complications/worsening of symptoms.
3) Marked difficulty in testing.
4) Found to be pregnant.
5) The entire study discontinued.

11. Compensation for subjects

If a subject experienced any study-related injury during the study period or a subject filed a complaint for damage caused by this study, the investigator would immediately notify the sponsor.
In the case of health-related injury caused by willful harm or negligence of the study site team, the site is responsible for the compensation for damage. However, if health-related injury occurs due to the investigational product, the sponsor is entirely responsible for the compensation. However, this should not apply to a subject making a false report or suffering health-related injury caused by his/her intent.

12. Criteria for exclusion of subjects from analysis (report)

If the following items were applicable, the subjects would be under examination of the case study committee.Unless otherwise indicated, the subjects would be excluded from the test analysis (report).

1) The examination appointment day delayed for one or more weeks.
2) Non-compliance to the regulations during the test period was confirmed.
3) Unreliability of data due to problems in the testing.
4) The number of days where the the investigational product was not properly applied (where the prescribed daily amount was not applied) exceeded 15% of the scheduled days of application.
5) Enrollment criteria were violated and the subjects were thus found to fall under the exclusion criteria.
6) The dropout was obviously appropriate, and others.

13. Test data changes and loss

If there was an unavoidable delay in evaluations or loss of data due to the subject's ill health or at the subject's request, the subject's health and wishes would be prioritized, in compliance with the principles of the Declaration of Helsinki. Meanwhile, if it was impossible to collect part of data due to the above reasons or other unavoidable reasons, the data would be processed as deficient data.

14. Subject's privacy protection

All parties who involved the study were instructed to pay full attention to handling of the personal identification information. Here, each person's name was replaced by the number in the other documents recorded in this clinical study so as to make the person unidentifiable.

15. Compliance and conformity

This study was reviewed and approved as per ethical and social considerations based on the Declaration of Helsinki (revised in 2013 at the General Assembly, Fortaleza, Brazil) by the ethics committee. After the subjects were informed of the history, objective, and protocol of this study, how the personal information obtained in this study would be handled, the rights of the subjects, how to consult and receive compensation in case of adverse events, they, who had each given a written consent, participated in the study of their own free will. Note that real drop-out from the study regimen required approval of the committee.

16. Results and conclusions

24 subjects were initially enrolled in this clinical study. Among them, 23 subjects, who did not fall under the drop-out and subject exclusion criteria, were analyzed.
Annex 2 collectively provides the levels of significant difference observed by comparing at 4 weeks between the investigational product application group and the non-application group. Annex 3 provides information on the subjects and the means and standard deviations of the measured values, the differences, and the relative values as well as the bar graphs of the results. Annex 4 lists the personal data. In addition, digital single-lens reflex camera images of the lateral canthus and the surrounding of each subject were separately dispatched as an electronic file.

16.1 Subject's information

The sex, average age, and age standard deviation of subjects are listed in Table 2.

16.2 Change in the wrinkle grade assessed visually

Table 3 and Figs. 1-1, 1-2, and 1-3 show the value assessed based on the wrinkle grade standard, the difference in the assessed value between before and after the test, and the relative change in the value while the value assessed before the test was set to 100%.

16.3 Change in the wrinkle area percentage determined by replica analysis.

Table 4 and Figs. 2-1, 2-2, and 2-3 show the wrinkle area percentage determined by replica analysis, the difference in the wrinkle area percentage between before and after the test, and the relative change in the wrinkle area percentage while the wrinkle area percentage before the test was set to 100%.

16.4 Change in the wrinkle volume percentage determined by replica analysis.

Table 5 and Figs. 3-1, 3-2, and 3-3 show the wrinkle volume percentage determined by replica analysis, the difference in the wrinkle volume percentage between before and after the test, and the relative change in the wrinkle volume percentage while the wrinkle volume percentage before the test was set to 100%.

16.5 Change in the maximum wrinkle depth determined by replica analysis.

Table 6 and Figs. 4-1, 4-2, and 4-3 show the maximum wrinkle depth determined by replica analysis, the difference in the maximum wrinkle depth between before and after the test, and the relative change in the maximum wrinkle depth while the maximum wrinkle depth before the test was set to 100%.

16.6 Change in the maximum wrinkle width determined by replica analysis.

Table 7 and Figs. 5-1, 5-2, and 5-3 show the maximum wrinkle width determined by replica analysis, the difference in the maximum wrinkle width between before and after the test, and the relative change in the maximum wrinkle width while the maximum wrinkle width before the test was set to 100%.

16.7 Change in the average wrinkle depth determined by replica analysis.

Table 8 and Figs. 6-1, 6-2, and 6-3 show the average wrinkle depth determined by replica analysis, the difference in the average wrinkle depth between before and after the test, and the relative change in the average wrinkle depth while the average wrinkle depth before the test was set to 100%.

16.8. Change in the wrinkle count determined by replica analysis.

Table 9 and Figs. 7-1, 7-2, and 7-3 show the wrinkle count determined by replica analysis, the difference in the wrinkle count between before and after the test, and the relative change in the wrinkle count width while the wrinkle count before the test was set to 100%.

16.9 Digital photography

In addition, an electronic file was separately dispatched.

17. Conclusion

- The relative value in the value assessed between before and after the test using the wrinkle grade standard was significantly lower in the investigational product application group than in the non-application group.

- The wrinkle area percentage determined by replica analysis was significantly lower in the investigational product application group than in the non-application group.

- The wrinkle count determined by replica analysis, the difference calculated by subtracting the wrinkle count before the test from the wrinkle count after the test, and the relative change between the wrinkle counts were significantly lower in the investigational product application group than in the non-application group.

According to the above results and the “criteria of anti-wrinkle product evaluation guideline to obtain new indication approval” defined by the Expert Committee on Anti-Aging Functional Evaluations (Cosmetic Products Functional Evaluations Investigation Committee) in Japanese Cosmetic Science Society,

The investigational product 'Jevie Lotion'

was determined to exert the effects of “making inconspicuous minor wrinkles caused by dryness”.

18. References

1) Notice of “About Amendment on Scope of Indication for Cosmetics” (PFSB/ELD Notification and PFSB/CND Notification No. 0721-1, on July 21, 2011) by Pharmaceutical and Food Safety Bureau of Ministry of Health, Labor and Welfare in Japan.
2) “Cosmetic Function Evaluation Test Guideline” by Japanese Cosmetic Science Society (prepared by Japanese Cosmetic Science Society in December 2006)
3) JIS B 0601, Surface Roughness-Definitions and Terms
4) S. Jaspers., et al., Skin Res. Technol., 5, 195-207, 1999.
5) S. Jaspers., et al., XXIst IFSCC International Congress Proceedings, 430-434, 2000.