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Development, validation and application of an all-in-one dynamic wrinkles evaluation system on keratin material in the cosmetic industries

Submission date
23/07/2025

Recruitment status
No longer recruiting

Registration date
01/08/2025

Overall study status
Completed

Last Edited
31/07/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
As we age, our skin naturally forms wrinkles. This happens because important parts of the skin—like collagen, elastic fibers, and hyaluronic acid—break down over time. Some wrinkles appear even when the face is at rest, while others, like crow's feet or frown lines, show up when we smile or frown. These are called expression lines. Over time, temporary expression lines can become permanent wrinkles. This study tested a new way to measure these expression lines and looked at whether a special anti-wrinkle cream could help reduce both static (resting) and dynamic (expression) wrinkles over 8 weeks.

Who can participate?
Healthy Chinese adults aged 20 to 45 years could take part. All skin types were welcome, and about half of the participants had sensitive skin or concerns like rough texture or loss of firmness. Participants needed to have certain levels of wrinkles, confirmed by a dermatologist. People were not allowed to join if they had serious skin conditions, were undergoing emergency treatment, had allergies to skincare products, or had recently had cosmetic procedures.

What does the study involve?
The study lasted 10 weeks in total. First, there was a 2-week period where participants used only basic skincare products (cleanser, moisturizer, and sunscreen). Then, for 8 weeks, they used the test cream and cleanser twice a day, and sunscreen once a day. They weren't allowed to use other skincare or makeup products, except for lip and eyebrow makeup. Participants visited the clinic five times for skin checks, photos, and questionnaires. A dermatologist with over 30 years of experience assessed their skin each time.

What are the possible benefits and risks of participating?
Participants might see improvements in wrinkles, skin firmness, and elasticity. However, there is a small risk of skin discomfort or irritation from the products.

Where is the study run from?
L'Oréal China Research and Innovation Center (China)

When is the study starting and how long is it expected to run for?
November 2021 to January 2022

Who is funding the study?
L'Oréal China Research and Innovation Center (China)

Who is the main contact?
Jing Li, amy.li@loreal.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Development, validation and application of an all-in-one dynamic wrinkles evaluation system on keratin material in the cosmetic industries

Study objectives
Observe and compare the anti-aging effect of the facial test product during 8 weeks of repeated use.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/11/2021, Shanghai Ethics Committee for Clinical Research (Building A, 380 Fenglin Road (Fenglin International Centre), Shanghai, 200032, China; +86 21-33676001; seccr@scrcnet.org), ref: SECCR/2021/146/02

Primary study design
Interventional

Study design

Single-center interventional study

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Anti-aging

Interventions
This study is a single-arm clinical trial comprising a 2-week washout period followed by an 8-week treatment phase. During the washout phase, eligible participants were permitted to use one set of standard auxiliary products (standard cleanser, moisturizer, and sunscreen) consistently. During the 8-week treatment period, participants applied the investigational product (anti-wrinkle cream) and a standard cleanser twice daily, in the morning and evening. Standard sunscreen was used only once daily, in the morning. For all products, a coin-sized amount was applied evenly to the face, chin, and neck, and the product was massaged until absorbed; the product was kept away the eyes. No other skin care or facial makeup products were permitted except for lip and eyebrow makeup during the entire study period. Follow-up visits were scheduled at five time points: baseline, Timm (15 min after product application), and at week 3, 4, and 8.

Intervention Type
Other

Primary outcome(s)
1. Static lines are measured using the Skin Aging Atlas (Flament 2010) at baseline, Timm (15 minutes after product application), and at weeks 3, 4, and 8
2. Skin firmness is measured using the 10-point Griffiths scale at baseline, Timm, and at weeks 3, 4, and 8
3. Skin elasticity is measured using the 10-point Griffiths scale at baseline, Timm, and at weeks 3, 4, and 8
4. Global fine lines are measured using the 10-point Griffiths scale at baseline, Timm, and at weeks 3, 4, and 8
5. Dynamic wrinkles are measured using photographic grading with the Skin Aging Atlas at Timm, and at weeks 4 and 8
6. Gross elasticity (R5) is measured using the Cutometer Dual Skin Elasticity Meter MPA580 at Timm, and at weeks 4 and 8
7. Net elasticity (R2) is measured using the Cutometer Dual Skin Elasticity Meter MPA580 at Timm, and at weeks 4 and 8
8. Biological elasticity (R7) is measured using the Cutometer Dual Skin Elasticity Meter MPA580 at Timm, and at weeks 4 and 8
9. Participant self-assessed outcomes are measured using self-assessment questionnaires at baseline, Timm, and at weeks 3, 4, and 8
10. Safety is assessed at week 4

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/01/2022

Eligibility

Key inclusion criteria
1. Chinese women, 20–45 years old
2. All skin types
3. Usually have rich expression, love to laugh, often raise eyebrows and frown
4. Presenting obvious dynamic lines while making following facial expression adjusted by Dermatologist:
4.1. Smile expression:
4.1.1. Underneath eye wrinkles: 3 < grade ≤ 9 (L'Oréal Atlas Page 46–47)
4.1.2. Crow's feet wrinkle: 3 < grade ≤ 6 (L'Oréal Atlas Page 40–41)
4.1.3. Nasolabial folds: 1 < grade ≤ 7 (L'Oréal Atlas Page 54–55)
4.2. Raise eyebrow expression:
4.2.1. Forehead wrinkles: 3 < grade ≤ 8 (L'Oréal Atlas Page 32–33)
4.3. Frown expression:
4.3.1. Glabellar wrinkles: 2 < grade ≤ 6 (L'Oréal Atlas Page 36–37)
5. Did not participate in any clinical test or cosmetic product test on skin within 3 months
6. No disagreement of dermatologist because of other reasons that exclude the participation of the volunteer
7. In general, good health at the time of the study
8. Willing and able to participate as evidenced by signing of informed consent and photo release
9. Must be willing to comply with all study protocol requirements

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Upper age limit
45 Years

Sex
Female

Total final enrolment
66

Key exclusion criteria
1. Pregnant or breast-feeding woman or woman planning pregnancy during the study
2. Subject deprived of rights by a court or administrative order
3. Major subject to a guardianship order
4. Subject residing in a health or social care establishment
5. Patient in an emergency setting

6. Volunteer with a skin disease in the test areas as well as skin allergy (particularly e.g., acne, rosacea, eczema)
7. Volunteer presenting a stable or progressive serious disease (per investigator's assessment)
8. Immuno-compromised subject
9. Subject with history of allergy to cosmetic or personal care products or ingredients
10. Subject presenting excessive exposure to sunlight or UV radiation (investigator's assessment)
11. Subjects regularly practicing aquatic or nautical sports
12. Subjects regularly attending a sauna

Date of first enrolment
17/11/2021

Date of final enrolment
21/11/2021

Locations

Countries of recruitment
China

Study participating centre
Shanghai China-Norm Quality Technical Service Co., Ltd.
Building #8, No.697, Lingshi Road, Health Work, Jing'an District
Shanghai
China
20000

Sponsor information

Organisation
L’oreal China Research and Innovation Center

Funder(s)

Funder type
Industry

Funder Name
L’oreal China Research and Innovation Center

Results and Publications

Individual participant data (IPD) sharing plan
Data is not shared in accordance with corporate data management requirements

IPD sharing plan summary
Not expected to be made available