

Efficacy Evaluation of Anti-wrinkle Products in Japan

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Abstract

Two categories of cosmetic products, cosmetics and quasi-drugs, have been established by the Ministry of Health, Labor and Welfare (MHLW) in Japan. Japanese pharmaceutical law has defined that products categorized as cosmetics do not exhibit any effects on human skin. In fact, cosmetic products are not permitted to claim any efficacy. On the other hand, products in the quasi-drug category can claim several efficacies such as anti-inflammatory effects, whitening/lightning effects, hair growth effects and so on. Unfortunately, the Japanese MHLW has not yet approved the efficacy of anti-aging/anti-wrinkle effects as a claim point. However, the population is aging, and the demand for anti-aging/anti-wrinkle products is increasing year by year.

Japanese cosmetic companies have proposed to the MHLW that anti-aging/anti-wrinkle agents be approved as a claim concept of a quasi-drug. However, unified evaluation methods for anti-aging/anti-wrinkle effects have not been established. Currently, each company evaluates the efficacy of products/materials using their own original methods. Thus, to request approval of the MHLW, the establishment of a unified evaluation method is needed. Consequently, the Japan Cosmetic Industry Association (JCIA) has established a task force to develop guidelines for evaluating anti-wrinkle effects in 1998. In conclusion, the JCIA would like to adopt visual and image analysis scales to evaluate the anti-wrinkle effects objectively.

Generally, wrinkles are roughly classified into three groups as fine wrinkles, linear deep wrinkles and crow's feet. However, academic societies of dermatology or cosmetics have not yet established a definition of wrinkles in Japan. Thus, in advance of setting up an evaluation method, the definition of wrinkles for evaluation must be decided.

Wrinkles are defined by the task force of the JCIA as follows; furrows that people can

recognize visually and that appear on the forehead, the corners of the eyes and the backs of the neck with aging. In addition, furrows are emphasized by exposure to solar light and by dry conditions.

Visual evaluation is the most sensitive method and can be applied to most types of wrinkles. However, visual evaluation is hard to express digitally as results. Besides, in the case of image analysis, comparisons of data obtained from distinct examinations can not be done, because data from image analysis are relative values. Thus, to enhance the reliability of the evaluations, the adoption of an objective scale was required. The principle of the evaluation method is to analyze images taken from silicone replicas of wrinkle areas using several parameters, such as the proportion of the wrinkle area (%), the mean depth of the wrinkles (mm), the mean depth of the deepest wrinkle (mm) and the deepest point on the deepest wrinkle. Lights are shown on the skin replica from an orthogonal direction of the main orientation of the wrinkle, and the resulting shadow images are quantified by the image analysis method. To increase the precision of the data or to allow comparisons of independent examinations, a scale with furrows of several depths, 200, 400, 600, 800, and 1000 μm , is adapted in the evaluation system.

I will explain the guidelines established by the JCIA in the presentation.

EDUCATION

- 1978 University of Osaka Prefecture (Department of Applied Chemistry, Faculty of Engineering)
- 1980 Entered postgraduate course of Kobe University (Department of Chemistry, Faculty of Science)
- 1995 Ph.D. (Pharmacology)

PROFESSIONAL AND RESEARCH EXPERIENCE

- 1996 Senior researcher of Kyoto Pharmaceutical University
- 2001 Visiting assistant professor of Fujita Health University School of Medicine
- 2001 Senior researcher of Kobe University School of Medicine

PUBLICATIONS

Author or co- author of more than 13 publications in international peer reviewed journals.

MEMBERSHIP

- Committee member of: Japanese Cosmetic Industry Association
- Committee member of: Society of Cosmetic Chemistry Japan

Committee member of: Society of Japanese Cosmetic Science Society

Member of: The Japanese Dermatological Association

Member of: The Japanese for Investigative Dermatology

Member of: of The Japanese Society for Photomedicine and Photobiology

Efficacy Evaluation on Anti-wrinkle Products in Japan

Category of Cosmetics and Quasi-drugs in Japan

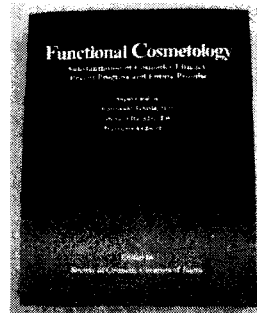
Two categories of cosmetic products, cosmetics and quasi-drugs, have been established by the Ministry of Health, Labor and Welfare (MHLW) in Japan.

- cosmetic products are not permitted to claim any efficacy.**
- Products in quasi-drug category can claim several efficacies such as anti-inflammatory effects, whitening/lightning effects, hair growth effects , anti-acne , etc**

Anti-aging/anti-wrinkle has not been approved as a claim in quasi-drug.

•Japan Cosmetic Industry Association (JCIA) has made a task force to develop guidelines for evaluating anti-wrinkle effect in 1998.

•Society of Cosmetic Chemist Japan (SCCJ) published the book regarding the efficacy of cosmetics.



Definition of Wrinkle

Wrinkle is defined by the task force of JCIA as follows;

•Furrows that people can recognize visually and that appear on the forehead, the corners of the eyes and the backs of the neck with aging.

•In addition, the furrows are emphasized by exposure to solar light and by dry conditions

Wrinkle Evaluation Methods

Visual examination	Examine an enlarged photograph of replica photograph with the naked eye and give a score for findings. Semi-quantitative	
Image analysis (2-dimensional)	Oblique illumination	Illuminate replica obliquely to accentuate shadows. Photograph with CCD camera and analyse image. Analysis of parts in the shadow of others is difficult.
	Epi-illumination	Illuminate replica uniformly, photograph it with a CCD camera and analyse the brightness distribution of pixels. Difficult to measure depth of wrinkle

Wrinkle Evaluation Methods

Projection methods (3-dimensional)	Laser beam interruption	Illuminate replica with a laser slit beam from a specific angle with respect to baseline, β , and then observe the changes produced in the beam by replica relief from a different angle, γ , in order to obtain the height of a particular point on the replica (x,y) from β and γ .
	Lattice pattern projection	Project a lattice pattern on to the surface to be measured and then observe the result from a different direction from the direction of projection. The lattice pattern will be distorted by the surface being measured and a 3-dimensional picture of the surface relief may be obtained by analysing the distorted lattice image so produced.

Concept of Guideline for Evaluation of Wrinkle Improvement by JCIA

Visual examination

Image analysis
(2-dimensional)

Projection methods
(3-dimensional)

Oblique illumination

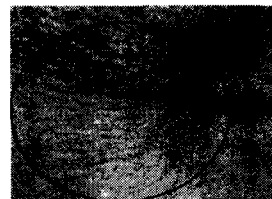
Epi-illumination

Laser beam interruption

Lattice pattern projection

Preparation Method of Skin Replica

Impressioning Agents :
SILFRO (Flexico, England)
EXAFINE (GC)

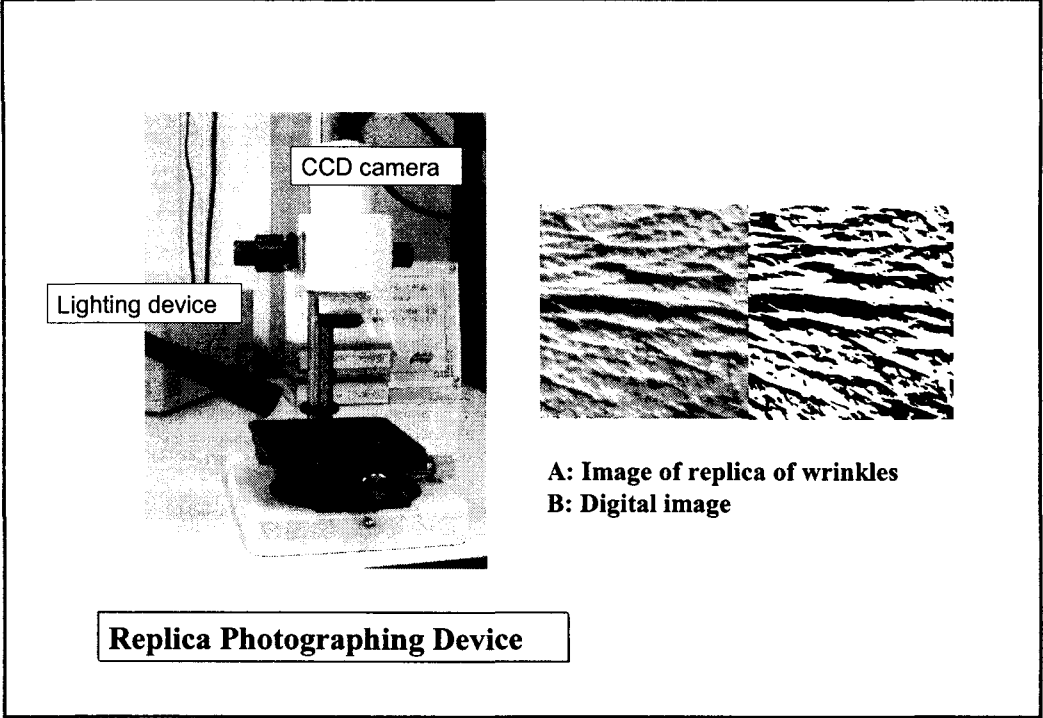


Conditions:

Volunteer is in conditions (temp.; 20-22°C, humidity; 50-60%) for 10 min , when possible. Replica is taken in sitting or lying face up.

Fixing of Replica:

Replica is fixed in flat by adhesion bond to eliminate distortion due to facial structure



Analysis of Parameters on Wrinkle

θ : Light angle

l : Length of Shadow
S : Area of Shadow
d : Depth of Wrinkle

$d = (S/l) \tan \theta$

A Scale for Wrinkle Depth

1000 800 600 400 200 μm

- Proportion of wrinkle area (%) (RWA):
A ratio of Shadow in a area (10 x 10 mm)
- Mean depth of wrinkles (mm) (V_i)
- Mean depth of deepest wrinkle (mm) (V_{max})
- Deepest point of deepest wrinkle (mm) ($V_{\text{max-max}}$)