

Measurement with a New in-vivo Skin Topographical Method of Facial Wrinkle Improvement by Skin Moisturizers Formulated with Anti-aging Ingredients

Kukizo Miyamoto Ph.D.*1, Joe Kaczvinsky Ph.D.*2, Larry Robinson Ph.D., *2, Gang Deng Ph.D.*3

*1: Research and Development Skin Beauty Care, Procter & Gamble Japan K.K., *2: Research and Development Beauty Care, Procter & Gamble Company, *3: Research and Development Skin Care, Procter & Gamble China

INTRODUCTION OBJECTIVE

Three-dimensional topographical information is a critical enabler for quantifying chronological change of facial wrinkles. A new 3D wrinkle method, such as FOITS (Schrader Institute) has been an increasingly popular approach for wrinkle measurement and recommended by Japan Cosmetic Science Society's evolving guidelines for anti-wrinkle product evaluation. 3D wrinkle method methodology allows quantifying the surface topography of the skin and excludes skin color tone and surface reflection artifacts. Anti-aging formulas with well-established and new functional ingredients have clinically demonstrated wrinkle-improving efficacy with 3D wrinkle methodology.

The objectives of this study are

- 1: validate a new 3D wrinkle measurement methodology
- 2: evaluate wrinkle improvement efficacy of moisturizers formulated with anti-aging ingredients using the validated 3D wrinkle method.

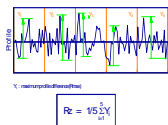
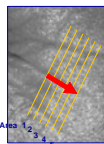
METHODS

3D wrinkle Method Validation

A new, non-contact 3D wrinkle imaging system was designed using a dermTop blue® (EO tech) skin surface topography device. A system superstructure was constructed to position the subject's face so that the 3D imaging device could rotate to capture either the left or right side of the face's crow's feet region. Method validation was done assessing 1: measurement reproducibility by capturing subjects' facial wrinkles 5 times and 2: correlating with visual wrinkle evaluation.



A new 3D wrinkle System



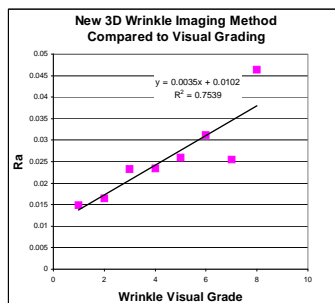
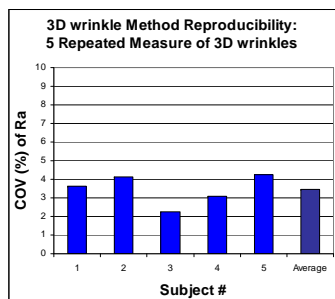
Clinical Assessment with 3D wrinkle methodology

Clinical protocol was designed following FOITS methodology. In short, this was an eight (8) week, split face, round-robin, double blinded control clinical protocol among healthy Caucasians females (total 200, base size = 40/leg) who have moderate to severe wrinkles at the periorbital region on both sides of the face. Skin moisturizers which contained three different anti-aging ingredients of Retinol (0.05%), Retinyl palmitate, (0.13%) and Niacinamide (2%) in addition to 5% glycerin were compared to no treatment and 5% glycerin placebo. Wrinkle topography measurement method was employed at baseline, and subsequent post treatment visits at week 4 and 8. Topographical information such as Ra and Rz at periorbital region were analyzed.

RESULTS

Method Validation

The validation assessment of the new 3D method demonstrated 1: excellent measurement reproducibility *in-vivo* (coefficient of variance = 3.47%), and 2: significant positively correlation with visual evaluation of wrinkles ($R^2=0.754$).

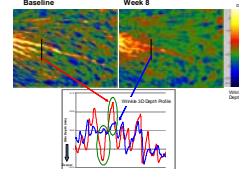
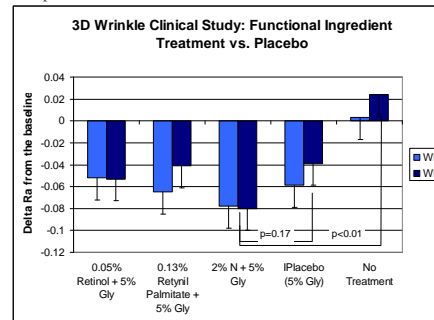


Clinical Assessment

An eight (8) week split face, round-robin, double blinded facial wrinkle study was placed among 120 Caucasians aged 35 to 55, testing moisturizers formulated with anti-aging ingredients compared to 5% glycerin placebo.

	Test products (either left or right side of the face)	Base size
Leg A	0.05% Retinol (5% glycerin)	40
Leg B	0.13% Retinyl palmitate (5% glycerin)	40
Leg C	2% Niacinamide (5% glycerin)	40
Leg D	Placebo - (5% glycerin)	40
Leg E	No-Treatment	40

Among the treatments, the moisturizer with 2% Niacinamide demonstrated the best wrinkle reduction efficacy showing strong trend vs. 5% glycerin placebo ($p=0.17$). 2% Niacinamide, 0.05% Retinol and 0.13% Retinyl palmitate containing moisturizers showed significant wrinkle reduction compared to "no treatment" at week 8.



CONCLUSIONS

A new 3D wrinkle method was successfully validated in a highly reproducible manner. Significant topographical information was captured and analyzed to reveal treatment effects of a moisturizer with Niacinamide versus well-established retinoids and placebo. The clinical trial results provide efficacy demonstration of anti-aging ingredients.

- A new non-contact 3D wrinkle method has been validated for application to human clinical assessment.
- A clinical study indicated efficacy of wrinkle reduction by moisturizers with: 2% Niacinamide \geq 0.05% Retinol \geq 0.13% Retinyl Palmitate \geq Placebo $>$ No Treatment.
- A higher base size may be required to have statistically significant test leg results compared to the placebo in future clinical designs.

References

1. M. Rohr, K. Schrader, Fast Optical in vivo Topometry of Human Skin (FOITS); SOFW Journal 124, (1998), pp. 52-59
2. Jaspers, S., et al; Rapid in vivo measurement of the topography of human skin by active image triangulation using a digital micromirror device. Skin Res. and Tech. (1999); 5, 195-207
3. Schrader K., et al; Comparative studies of skin roughness measurements by image analysis and several in vivo skin testing methods. J. Soc. Cosmet. Chem. (1991) 42, 385-391.
4. Pin-Chi Chiu, MD, et al; The clinical anti-aging effects of topical keratin and niacinamide in Asians; a randomized, double-blind, placebo-controlled, split-face comparative trial; J. Cos. Derm. (2007), 6, 243-249
5. Task force committee for evaluation of anti-aging function, Guideline for Evaluation of Anti-Wrinkle Products, Journal of Japanese Cosmetic Science Society, vol. 30, No.4 pp. 312-315 (2006)

