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Image-based continuous p-value evaluation: A novel approach to detect and visualize integral efficacy of skin care treatments

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Introduction

We recently established a continuous facial color mapping technology enabling the visualization of cutaneous characteristics like skin hydration, transepidermal water loss and skin surface pH [1]. These parameters are displayed as color gradients and by time lapse imaging their evolution over time can be demonstrated, e.g. before and after a skin care treatment. Based on this technology an image-based approach was developed to continuously map statistical significance levels (p-values) for each pixel on a stack of images and visualize these p-values by a color gradient. We here relate this new approach to skin tone analysis using software based L*a*b* calculation measuring the efficacy of a skin care application comprising of the dipeptide diaminobutyroyl benzylamide diacetate previously shown to have anti-aging benefits.

Methodology

Study

54 Asian female subjects (age 41-55 (mean 47.5 ± 1) years old) participated in this full face, placebo controlled, parallel groups study. The study took place in Bangkok from September 22nd to October 22nd, 2015. The subjects (27 subjects per group) applied either the placebo or the active formulation (Table 1) twice daily for 28 days. The volunteers had an average ITA° over the whole face of 0 [2]. Guidelines of the Declaration of Helsinki were applied.

Table 1: Composition of test formulations

Component (INCI)	Active [% w/w]	Placebo [% w/w]
Base Formulation (emulsion)	96	100
Dipeptide Diaminobutyroyl Benzylamide Diacetate, Glycerin, Aqua	4	0

Image preprocessing

The volunteers were photographed with cross polarized light using a Visia CR® device (Canfield, Parsippany, US). Images from both facial sides at 45° angle were taken. A color consistency analysis was performed using a color chart to correct the slight color variations that can appear onto the skin due to ambient light variations. All images were spatially registered to each other to compensate differences of positioning and morphology, and mean faces were generated (Figure 1).

Skin tone analysis

Skin tone was analyzed using a dedicated algorithm to calculate L*a*b* values (CIELAB color space) for each pixel of the deformed images. Using this technique, several maps are obtained such as mean faces and standard deviation faces at each time stamps but also differences maps between the two time stamps (day 0 and day 28). For each pixel, average and standard deviation values consisted of 27 (number of volunteers) measurement points.

P-value mapping

We then created “color-signed” p-value maps using all measurement points per pixel to show significant changes of skin tone between the two time stamps using a paired Student’s T-test for each pixel (Figure 2). P-value maps are so called “color-signed” because they also demonstrate in which direction the treatment affects the skin e.g. increasing or decreasing a given parameter. P-values are displayed as color gradients, e.g. p<0.01 is light red / blue, p<0.05 is dark red / blue (Figure 2).

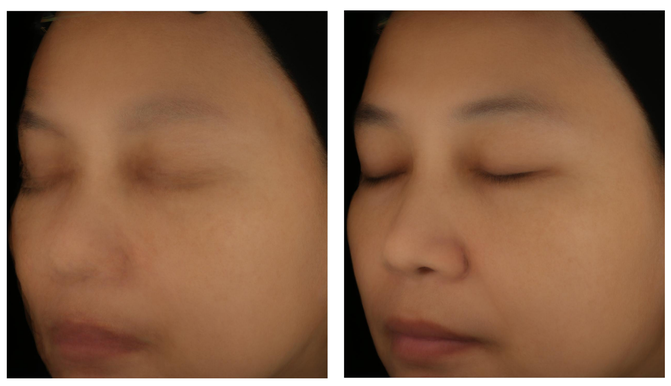

Figure 1: Mean face automatic generation without (left) and with (right) spatial registration using fiducial point detection. While the left image without spatial registration looks blurred, the right image using spatial registration appears in focus.

Results

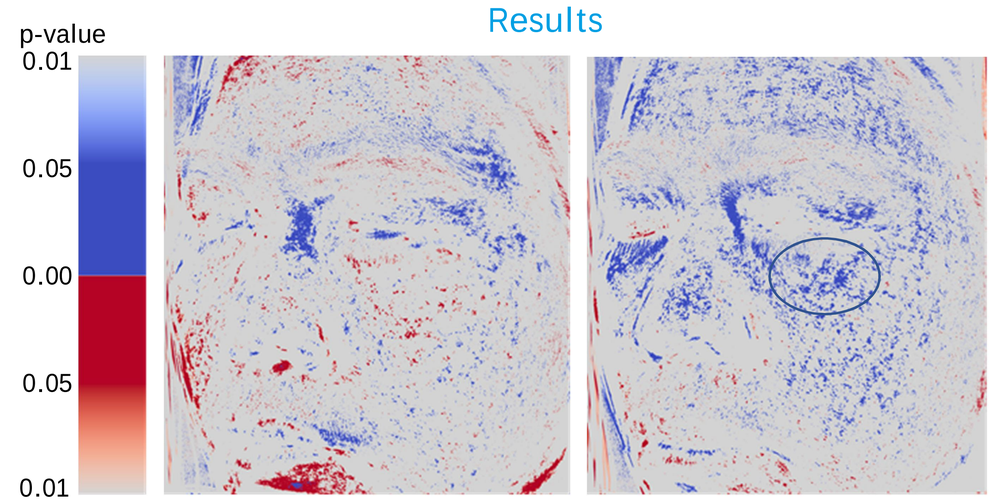

Figure 2A: p-value maps for L* (black to white color space). Red means a decrease in L* (darkening), blue means an increase in L* (lightening). The p-value map for the Active (right image) revealed significance levels for an increase of L* on a greater facial area particularly below the eyes (blue circle). This was not seen for the Placebo (left image) where even a change in the other direction was found. Other promising areas with skin lightening were the forehead and the cheek.

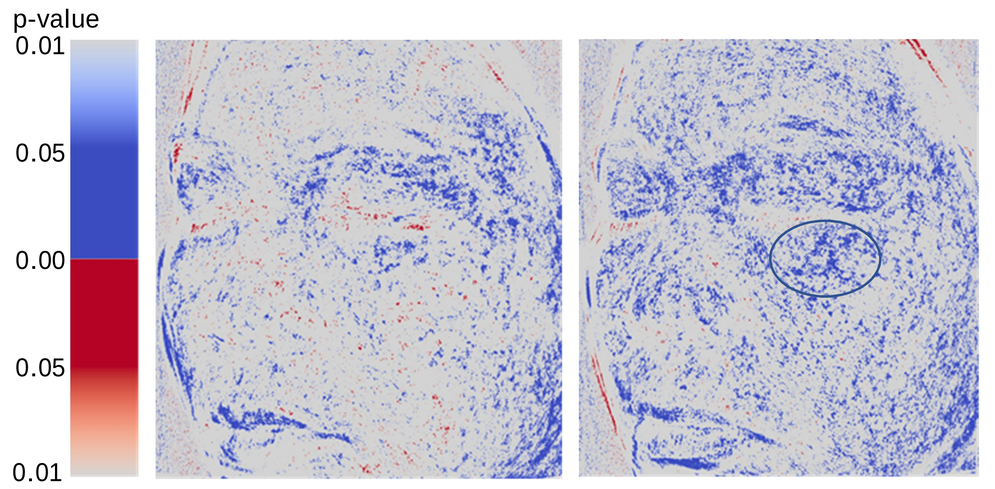

Figure 2B: p-value maps for a* (green to red color space). Red means an increase in a* (reddening), blue means a decrease in a* (less red) The p-value map for the Active (right image) revealed significance levels for a decrease of a* on a greater facial area particularly below the eyes (blue circle). This was not seen for the Placebo (left image) indicating no effect. Other promising areas with less reddening were the forehead, the cheek, and the jawline.

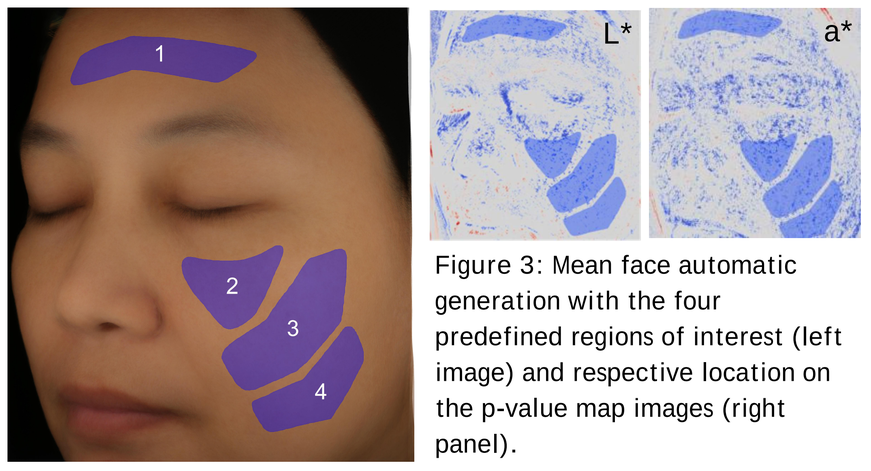

Figure 3: Mean face automatic generation with the four predefined regions of interest (left image) and respective location on the p-value map images (right panel).

Facial area (as displayed in Fig. 3)	ΔL* value (day 0 - day 28)	Significance (p-value)	Δa* value (day 0 - day 28)	Significance (p-value)
Forehead (1)				
Placebo	-0.05	0.705	-0.06	0.443
Active	0.36	0.064	-0.24	0.040
Cheek under eyes (dark circles) (2)				
Placebo	-0.13	0.744	-0.09	0.082
Active	0.36	0.016	-0.35	0.018
Cheek (3)				
Placebo	0.10	0.185	-0.12	0.071
Active	0.29	0.081	-0.26	0.057
Jawline (4)				
Placebo	0.07	0.502	-0.13	0.360
Active	0.09	0.671	-0.29	0.026

Table 2: L* and a* value changes and p-values for four defined areas shown in Figure 3. Bold black numbers = significant. Bold grey numbers = trend.

Conclusion

We show here a novel image-based method with which we can visualize statistically significant changes over time or between groups regarding cutaneous parameters using a color-signed facial map. We call this a p-value map, or a significance map, as it displays p-values representing significance levels.

As an example, we herein use the application of a dipeptide containing test formulation in comparison to its respective placebo. We found a small but significant improvement for skin tone, particularly in the area below the eyes (dark circles) for the L* and the a* parameter, which was not found with the placebo. This novel p-value mapping approach both helps to instantly show areas of significant efficacy of skin care formulations and identifies regions of interest not readily visible for dedicated cosmetic and dermatological claim substantiation and intervention.

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