CHROMAMETRY, MEASURING PRECISION OF DIURNAL AND LOCAL VARIATION OF HUMAN FOREARM SKIN COLOUR

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Introduction

Chromameters are compact portable instruments used for the assessment of surface colour based on the tristimulus analysis of a reflected xenon light pulse, and have been used for the quantification of erythema in the study of irritant dermatitis, and corticosteroid-induced skin blanching in the vasoconstriction assay [1]. The variability and the reproducibility of chromameter results were investigated since it is known that the location and application force of the measuring head on the skin [2, 5] and the orthostatic maneuver of the arms [4] influence the colour measurement. Furthermore the diurnal variation and the homogeneity of forearm skin colour were investigated.

Materials and Methods

A Minolta CR-300 chromameter (Minolta Ltd., Switzerland) was used and calibrated with a white calibration plate before each set of measurements. Skin colours were recorded in the CIE 1976 (L*a*b) colour system [3].

(1) Experience with the chromameter had lead us to believe that self manipulation of the measurement head by the test subject would produce results with greater precision than those generated from investigator manipulation of the device. To test the influence of the operator on the measurement variability and precision, three sites on the flexor aspect of the forearm were outlined and ten independent chromameter readings of each site were taken by both the subject and an investigator.

(2) Skin colour measurements were taken every 2 hours over a 24-hour period, at four adjacent sites demarcated in a straight line between the wrist and the antecubital fossa of both forearms of two volunteers. At each reading time, 4 independent chromameter readings were taken. The experiment was repeated with the same subjects one year later.

(3) To determine the diurnal variation and the homogeneity of forearm skin colour the raw data from two bioequivalence studies with the same study population were re-analysed. The mean colour co-ordinates of the four unmedicated control sites were calculated for each forearm of each volunteer at each reading time. The period of lowest and highest L, a and b co-ordinate values were recorded. The baseline values gained prior to application of formulations were used to analyse the homogeneity of forearm skin colour.

Tab. 1: Variability of chromameter data [Averaged s.d. of 3 sites (n=10 at each site) and range of s.d. (3 sites), averaged rel. s.d. and max. rel. dev. of stray point].

Scale	Self assessment	Assisted assessment
L	± 0.33 (0.17-0.47) ±0.5 % max. dev. 1.2 %	± 0.45 (0.35-0.56) ±0.7 % max. dev. 2.2 %
a	± 0.28 (0.17-0.42) ±3.0 % max. dev. 9.5 %	± 0.30 (0.19-0.43) ± 1.6 % max. dev. 11.7 %
b	± 0.18 (0.13-0.24) ± 1.2 % max. dev. 2.6 %	± 0.23 (0.21-0.25) ± 3.5 % max. dev. 3.5 %

Results

(1) The variability described by the standard deviation of 10 measurements for each site was in the same range (0.1-0.6 units) for all scales (Tab. 1). The variability of the average skin colour measured by the two operators (measuring precision) was of the same order of magnitude but was slightly larger for the investigator assessments than for the self-assessment data.

(2) Diurnal fluctuations in recorded skin colour were detected for the L, a and b colour co-ordinates. The fluctuations were similar for all sites on both arms of the subjects (Fig. 1) but different between the subjects and within the same subject after one year.

(3) Fig. 2 depicts the magnitude of the circadian rhythm of human forearm skin colour. A more distinct rhythm was detected for L- and b-scale (b-scale is very similar to the L-scale; graph not shown) with maximal and minimal values at 8am

and 4pm, respectively. The a-scale showed a maximum at 4pm and a minimum at 8 am. To assess the anatomical homogeneity of forearm skin colour, the differences between the lowest and highest co-ordinate values from each arm were calculated and averaged. The intervals were 3.77±1.96 (range: 1.12 - 7.78) units for the L-, 2.42±0.6 (1.58 - 4.31) units for a- and 3.48±1.39 (1.23 - 9.07) units for b-scale. In general, the outer side showed lower L- and higher a-values compared to the inner side. Dependent on the subject, no to marked and significant differences were observed (see Fig. 3).

Fig. 1: Mean of left (continuous line) and right (dotted line) forearm skin colour co-ordinates in one volunteer over 24 hours starting at 8 am.

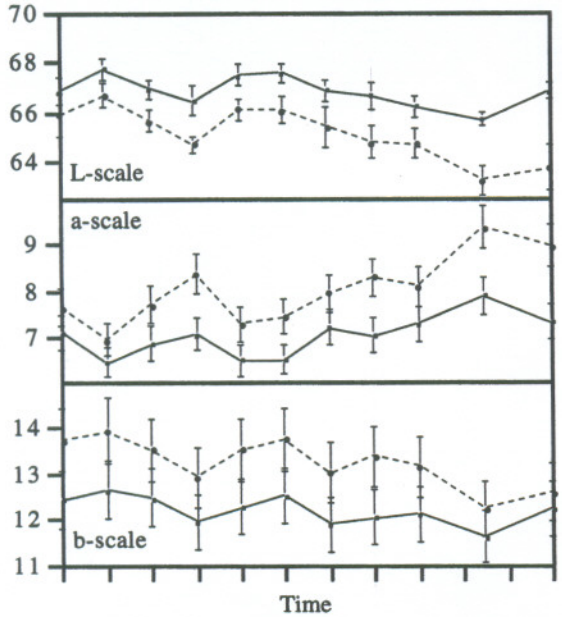


Fig. 2: Number of highest (pos. y-axis) and lowest (neg. y-axis) a-scale and L-scale values against time.

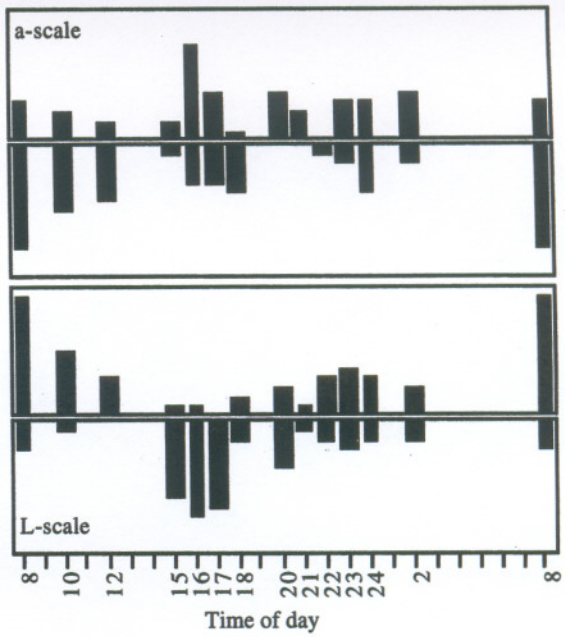
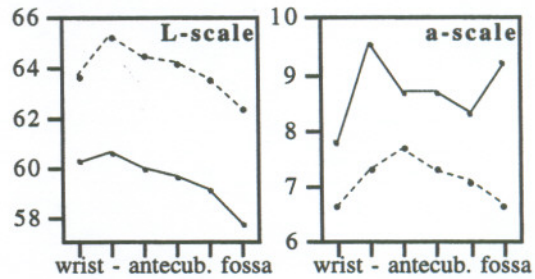


Fig. 3: Example of baseline skin colour in one subject (continuous line=outer side, dotted line=inner side).



Discussion

Good precision (1) was achieved for all data readings, as the deviations of the stray points from the mean of 10 measurements were not greater than the deviation of the two means from the two operators. (2) Skin colour fluctuation follows a circadian rhythm with low intra-subject and moderate inter-subject variability. The larger differences in colour between lateral and dorsal forearm skin observed (3) in a considerable number of volunteers therefore might have some influence on the results of blanching/erythema studies. This artefact is avoided by the visual scoring of the erythema/blanching response as it is compared to the surrounded skin. The FDA recommends [1] an adjustment to baseline values (zero time) and correction for the mean of baseline adjusted untreated control sites on the same arm, however, we were not able to improve the consistency of results using the FDA methodology.

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