

Non-invasive bioengineering methods in an intervention study in 1020 male metal workers: results and implications for occupational dermatology

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Background: Measurements of transepidermal water loss (TEWL) as an indicator of skin barrier function and colorimetry for quantifying erythema have been recommended for monitoring persons at risk of occupational hand dermatitis.

Objective: This study examines the practicability and usefulness of biophysical measurements at the workplace.

Patients/Material/Methods: A sample of 1020 male metal workers was enrolled; 800 participants were followed up for 1 year. TEWL results and colorimetry (a^* value), respectively, were used as effectiveness outcomes, comparing the findings in the four study arms (skin care, skin protection, both combined, and control group).

Results: At 1 year follow-up, the TEWL was slightly but significantly lower in the group of participants randomized for application of barrier cream alone, indicating a protective effect. However, addressing both the individual absolute change of a^* value and the differences of TEWL (delta-TEWL) of the dominant hand over the study period, no significant difference was found between the four groups.

Conclusions: Dermatological examinations at the workplace cannot be replaced by bioengineering techniques. The supplementary benefit is apparently low, possibly because of difficulties in achieving standardized measurement conditions and other technical reasons.

Key words: bioengineering; chromametry; hand eczema; occupational screening; TEWL; workplace.
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Occupational skin disease represents approximately 40% of occupational illness on an international level; differences in percentages from one country to another are associated with the extent and the type of industrialization (1). In particular, irritant hand dermatitis is a considerable problem in wet work occupations (2), including the metal industry. Funke et al. (3) reported a 1-year cumulative incidence of hand eczema of 9.2% (95% CI: 7.8–10.7%) in a sample of 1110 apprentices employed as metal workers in the automobile industry.

With the aim of yielding ‘objective’ measurements of skin irritation and epidermal barrier impairment, non-invasive bioengineering methods are widely used (4–8). Biophysical techniques are used (i) to assess treatments of dermatological disorders (9), (ii) to evaluate the clinical severity of either distinct skin diseases (10–12) or a single symptom such as dryness (13), (iii) to quantify experimentally induced irritation (7, 14, 15), and finally (iv) to assess the efficacy of skin protective means (e.g. gloves and moisturizers) (16–20). Moreover, the

measurement of transepidermal water loss (TEWL) as an indicator of skin barrier function and colorimetry for quantifying erythema has been recommended for monitoring persons at risk of irritant occupational hand dermatitis. In this context, most studies were performed in air-conditioned laboratories to avoid the interference of environmental factors (2, 8, 21, 22). However, the feasibility of these methods in 'real life' occupational settings – often lacking facilities for ensuring standardized climatic conditions – has not yet been evaluated in a large sample.

This study had the following objectives:

- (1) To examine the practicability of measurements in mostly non-standardized environments at the workplace in a sample of 1020 male white metal workers (23).
- (2) To analyse effectiveness in a prospective intervention study with four arms (skin care, skin protection, both combined, and control group, i.e. no particular measure) using TEWL and colorimetry, respectively, as outcomes. Post-exposure skin care with moisturizers is usually applied after work for enhancing epidermal barrier regeneration, whereas barrier creams (skin protection) are recommended for use before or (repeatedly) during work to prevent skin damage resulting from contact with irritants.
- (3) To compare bioengineering results with clinical findings of the hands.

Material and Methods

Study population

The metal workers were employed in 19 German factories, mainly of small or medium size. Inclusion criteria as recently described by Kütting et al. (23) comprised: (i) male sex, (ii) age ≥ 18 years, (iii) regular exposure to cutting fluids as indicator for wet work, (iv) a working contract for one further year at minimum, (v) fit for work at randomization, and (vi) willing to comply with the randomization result for a 12-month period. All participants provided their written informed consent to take part. Age of the participants ranged from 18 to 62 years (median: 42 years, mean: 40.6 years). The study design was approved by the local ethics committee of the University of Erlangen-Nuremberg. The study duration was 15 months, from winter 2006/2007 to spring 2008, in order to follow up each subject for 12 months.

Bioengineering

Bioengineering measurements were performed twice: at the beginning of the study (in winter

2006/2007) in a sample of 1020 subjects and at the second (final) follow-up 12 months later in 800 subjects then available, and on both hands. To exclude confounding by seasonal variation (e.g. tan in the summer, xerosis in winter, different climatic factors that may influence skin colour or TEWL), the bioengineering measurements were performed in the same season in the two successive years. The dominant hand was considered in all analyses, presumably being strained most. Of all, 91.8% of the subjects were right-handed, 6.5% left-handed, and the remainder ambidextrous. In this latter group, the mean value of both sides was used for analysis. The measurement of the TEWL (expressed as $\text{g/m}^2 \text{ h}$) was performed on the dorsal area of both hands, whenever possible. In 986 individuals (96.6%), at least one dorsal hand was measured at baseline, and after 12 months this was possible in 90.2%, with measurements failing in the remaining subjects. In contrast, colorimetry could be performed in all subjects.

The Tewameter and Corneometer TC 350 (Courage & Khazaka electronic, Cologne, Germany) was used only for TEWL measurement. Skin surface temperature, following the guidelines by Pinnagoda et al. (24), was measured using IR No Touch Technique (IR-350, VOLTCRAFT®, Germany) (25), particularly because ambient air room temperature often deviated from the standard range ($20\text{--}22^\circ\text{C}$). Measurements of erythema were performed using a portable tristimulus Chromameter CR 400 (Konica-Minolta®, Europe GMBH, Langenhagen, Germany) with a flexible hand-held probe. The measured area is 8 mm in diameter; however, the design of the probe requires a flat and even contact area of 40-mm diameter. Three consecutive readings were taken at the same site and the mean value calculated and recorded. The instrument was calibrated with a calibration plate before each measurement. The colour coordinates are expressed in the $L^*a^*b^*$ three-dimensional colorimetric system as recommended by the Commission Internationale de l'Eclairage (CIE). The L^* value (luminescence) gives the relative lightness, ranging from total black ($L^* = 0$) to total white ($L^* = 100$), and is likely to be influenced by both pigmentation and erythema. The b^* value, representing the balance between yellow (positive value) and blue (negative value), is a good indicator of the tanning level. The a^* value represents the balance between red (positive value) and green (negative value), and shows a significant linear correlation with the dermatologist's perception of erythema. For this reason, we restricted our analysis on the a^* values, again using the dominant hand for analysis.

Clinical examination

We used a scoring system for the clinical examination of initial hand eczema of both hands (23). In brief, the scoring system comprised all morphological criteria and physiological abnormalities (e.g. dryness) characteristic of hand eczema. As one part of this scoring system, erythema intensity was separately measured. To arrive at an operational definition of occupational hand eczema, for evaluation of the predictive value of bioengineering measurements at baseline, the skin score at final follow-up was categorized into 'none/subclinical' (score lower than the first quartile of skin score), 'slight' (score between the first and the third quartiles), and 'moderate/severe' (score above the third quartile).

Results

Environmental conditions

Room temperature at baseline examination ranged from 17°C to 27.7°C (median: 22.6°C; mean: 22.5°C). The mean skin surface temperature at the back of the right hand was on average 0.68°C higher than that of the left hand ($P < 0.0001$, Wilcoxon signed rank test). On the dominant hand, the mean skin surface temperature was 33.8°C (median: 34.0°C; range: 21–39°C). Similarly, relative humidity in the air of the measuring chamber was higher when measuring the right hand (by 1.5% on average, $P < 0.0001$, Wilcoxon signed rank test). The value of relative humidity of the dominant hand was 64.9% (range: 28.6–88.4%, median: 64.5%). At the visit after 12 months (winter 2007/2008), room temperature ranged from 14.4°C to 27.6°C (median: 22.4°C; mean: 22.4°C). The mean skin surface temperature at the back of the dominant hand was 34.6°C (median: 35.0°C; range: 24–39°C). Relative humidity was 61.2% on average (range: 27.8–85.3%, median: 60.6%). Considering these factors, environmental conditions at baseline and after 12 months were similar.

Transepidermal Water Loss

Only a minor proportion of the participants (23.5% at baseline and 12.4% at the second examination 12 months later) had skin surface temperatures within the range considered compatible with standardization requirements, i.e. between 28°C and 32°C. Table 1 gives an overview of TEWL measurements [mean, median, minimum, maximum, and interquartile ranges (IQR)] according to the corresponding skin surface temperatures (given in three categories: below the optimum, at optimum, and higher than the optimum range) and the corresponding skin score values. The distribution of these three categories

Table 1. Measurements of TEWL ($\text{g/m}^2 \text{ h}$) in three strata of skin surface temperature at baseline (visit 0) and after 12 months (visit 12), given for the dominant hand

	Skin surface temperature <28°C	Skin surface temperature at the optimum ($\geq 28^\circ\text{C}$ and $\leq 32^\circ\text{C}$) according to guidelines	Skin surface temperature >32°C
Visit 0			
TEWL			
number of subjects	$n = 28$ (2.9%)	$n = 230$ (23.5%)	$n = 720$ (73.6%)
Mean	21.1	27.7	31.1
Median	17.9	25.8	29.1
Range	9.4–42.2	10.1–56.5	11.5–81.0
IQR 1–3 ^a	14.1–26.3	20.2–33.8	23.8–37.6
Skin score			
Mean	11.0	7.8	8.0
Median	8.5	7.0	7.0
Range	1.0–43.0	2.0–25.0	0–41.0
IQR 1–3 ^a	6.0–14.5	5.0–10.0	5.0–10.0
Visit 12			
TEWL			
number of subjects	$n = 14$ (1.9%)	$n = 89$ (12.4%)	$n = 618$ (85.7%)
Mean	18.8	28.6	30.9
Median	18.7	26.8	28.9
Range	11.3–27.1	10.2–63.3	7.6–67.5
IQR 1–3 ^a	15.1–22.0	19.9–36.2	21.9–38.5
Skin score			
Mean	9.3	7.8	7.8
Median	7.0	8.0	7.0
Range	4.0–32.0	0–19.0	0–41.0
IQR 1–3 ^a	5.0–10.0	6.0–10.0	5.0–9.0

IQR: Interquartile range.

^aIQR 1–3 means the range between the first and the third quartiles.

did not differ significantly between the four intervention groups. There was a (very) weak but significant correlation between skin surface temperature and TEWL both at baseline ($r = 0.24$, 95% CI: 0.18–0.30) and at follow-up ($r = 0.16$, 95% CI: 0.09–0.23). Figure 1 illustrates this weak correlation in a scatter plot diagram, the black vertical lines mark all TEWL values obtained under optimal skin surface temperatures (28–32°C). Taking into account only the TEWL values obtained under optimal conditions, no significant correlation could be detected between measurement of TEWL and skin score value of the corresponding hands both at baseline and after 12 months.

Between the four groups, i.e. barrier cream alone (I), moisturizer alone (II), both combined (III), and none (IV), no significant difference between TEWL measurements could be detected both at baseline and at the follow-up visit after 12 months in a per protocol (PP) analysis (defined by actually performed skin protection measure). In contrast, using

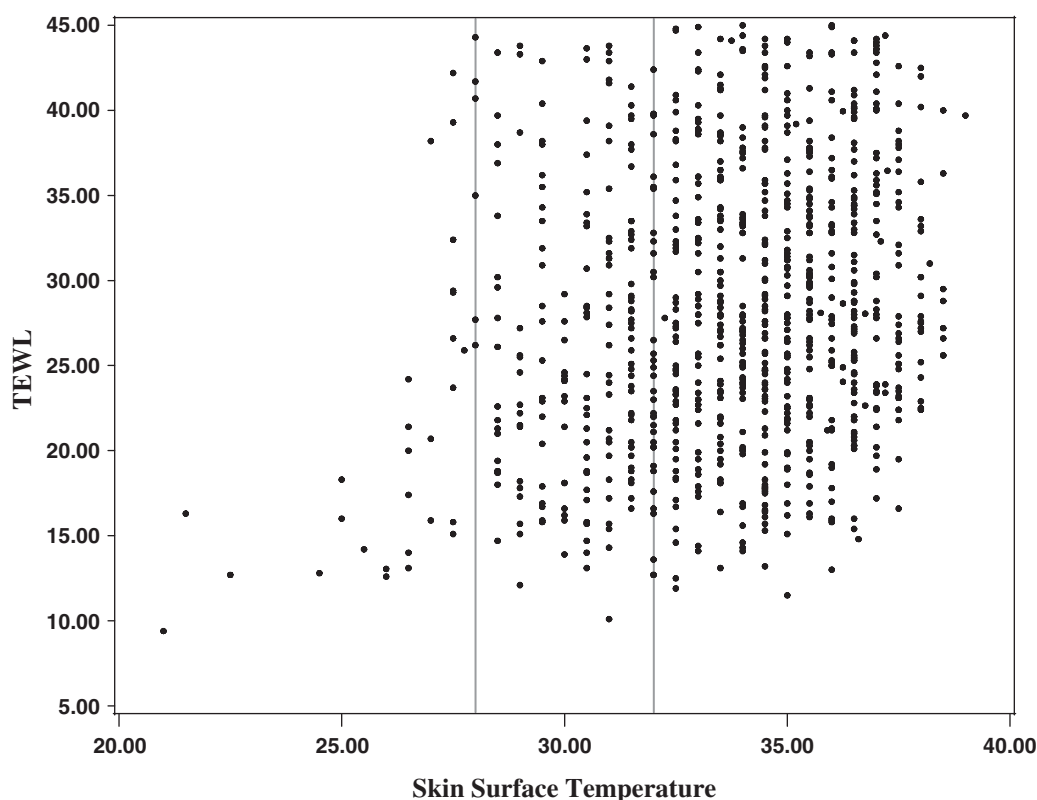


Fig. 1. Weak correlation between skin surface temperature and the corresponding TEWL at baseline examination. The range of optimal skin surface temperature is marked by two vertical lines.

the intention-to-treat (ITT) analysis (defined by randomized measure), the TEWL on the dominant hand was significantly lower in the group of participants randomized for application of barrier cream alone after 12 months, compared with that in all other groups ($P < 0.02$, non-parametric closing test procedure), indicating a protective effect of barrier creams in this analysis (only). However, addressing the development of TEWL (delta-TEWL) between baseline and 1-year follow-up, differences between the groups were non-significant both in the ITT and in the PP analyses.

Moreover, the TEWL at baseline did not differ significantly between the three subgroups of eczema classification after 1 year.

Taking into account only the TEWL values obtained under optimal skin temperature conditions, no significant correlation could be detected between TEWL and global skin score values of the corresponding hands both at baseline and after 12 months.

Chromametry

Measurements of a^* values were obtained from all subjects at baseline ($n = 1020$) and after 1 year ($n = 800$). Table 2 gives an overview of mean, median, and range for a^* value and for the score

Table 2. Measurement of a^* value indicating redness and clinical perception of erythema (score value) at baseline examination ($n = 1020$) and after 1 year ($n = 800$) on the dorsum of the dominant hand

	At baseline		
	Number $n = 1020$	a^* value	Erythema
Mean		11.8	3.0
Median		11.8	2.0
Range		5.2–20.5	0–29
	After 12 months		
	Number $n = 800$	a^* value	Erythema
Mean		11.6	3.1
Median		11.3	3
Range		6.0–22.0	0–26

values for erythema, as one component yielded from the clinical examination aggregated to the 'skin score'. As the a^* value is supposed to indicate redness and should therefore correspond to the clinical perception of erythema (albeit regarding the entire hand), correlation (Spearman Rho) between these two values was analysed. The correlation at baseline was 0.08 (95% CI: 0.02–0.14) and at follow-up was 0.13 (95% CI: 0.06–0.20), i.e. significant but (extremely) weak.

As erythema is one of the most frequent morphological changes in acute hand eczema, a^* values were evaluated as a possible indicator of effectiveness in skin protection. However, analysing our data we did not detect a significant difference in the a^* values of the dominant hand between the four study arms in a PP analysis, both at baseline and at follow-up. Conversely, in the ITT analysis, higher a^* values were observed in subjects following the skin protection regimen correctly (skin care + skin protection) than in all the other groups ($P < 0.045$, non-parametric closing test procedure) on follow-up. Finally, addressing the individual change in a^* values of the dominant hand over the study period (a^* value at baseline – a^* value after 12 months), no significant difference was found between the four groups, both in ITT and PP analyses. Moreover, the chroma value at baseline did not differ significantly between the three subgroups of eczema classification after 1 year.

Discussion

Screening tests at the workplace should meet several requirements: be (i) inexpensive, (ii) easy and fast to perform, (iii) non-invasive, causing minimal discomfort in the tested persons, and (iv) highly valid and reproducible. The first three requirements are met by tewametry and chromametry: both biophysical techniques are non-invasive and quickly applied, taking less than 5 min on average for each participant on the dorsum of both hands. Guidelines for measurement of skin colour (chromametry) and TEWL (tewametry) had been published to standardize both techniques, which can be impaired by many environmental and individual factors (24, 26, 27) – a particular problem for the TEWL.

However, in occupational screenings, it is often difficult to follow strictly all recommendations for standardization. For instance, a 15–30 min rest in a room with an ambient air temperature regulated to about 20°C is recommended (28) prior to TEWL measurement. However, climatic chambers or at least air-conditioned units are seldom available on-site. Moreover, this quite time-consuming procedure strongly interferes with the work flow and hampers the acceptability of TEWL measurements during medical check-ups at the workplace. Additionally, skin surface properties are difficult to optimize under working conditions. Restricted hand-washing and omitting topical application of ‘barrier creams’ over a period of 24 hr prior to bioengineering measurements (2, 14, 29) seem hard to achieve at workplaces with a massive skin contamination, for example, because of cutting fluids and oils. Therefore, past controversial findings concerning the predictive value of the TEWL in field studies

might at least partly be a result of the fact that measurements were not performed under completely standardized circumstances. In an epidemiological study performed in the Singapore metal industry, pre-employment measurement of baseline TEWL was considered predictive for the development of contact dermatitis in wet work (30), whereas later studies, under more or less standardized conditions in a sample of machinists (31), hairdressers and nurses (32), or nurses (33) did not confirm these results.

Earlier studies had proposed different formulas to convert TEWL at any given temperature to a standard reference temperature of 30°C (34, 35); however, a generally accepted conversion formula does not exist until now. Therefore, more recent publications (2, 21, 22) emphasize on standardization of surrounding factors (28), instead of correcting measurements by mathematical modelling.

In our sample including many cases with slight irritation or mild hand eczema, at most, chromametry results showed only a very weak correlation with clinically diagnosed erythema. However, the weakness of the correlation is quite easily explained by the fact that all measurements (chromametry and tewametry) were taken in a pre-defined identical area on the back of the hands in all participants, and therefore did not necessarily correspond to pathology elsewhere. For instance, erythema occurred often on the knuckles and interdigitally. Chromametry cannot be performed at these particular anatomical sites for technical reasons: the measuring head requires a flat surface with a diameter of 4 cm. This ‘site mismatch’ regarding erythema versus a^* value may be a partial explanation for the observed lack of a meaningful difference between the four study arms, in contrast to the use of a clinical outcome (23). The practical relevance of measurement of TEWL at workplace was limited by environmental factors in the majority of cases. Thus, the overall benefit of this technique in the workplace setting appears to be low.

Assessing the effectiveness of intervention using the bioengineering outcomes, and also clinical outcomes (23), for that matter, the individual change (delta) over the observation period of 1 year is most appropriate, as the skin condition at baseline is taken into due consideration. Disappointingly, both delta-TEWL and delta- a^* failed to discriminate any intervention effect, in contrast to our results based on the clinical signs (23), which identified the combined application of barrier cream and moisturizer as the best regimen, followed by skin protection alone. Biophysical techniques may fail to detect this clinical difference for the technical reasons mentioned above. Moreover, the bioengineering results obtained at baseline were not predictive

regarding prevalent skin changes at final follow-up, which is in accordance with other studies employing such point measurements without irritant provocation testing (25).

Conclusions

- (1) Dermatological examinations at the workplace cannot be replaced by bioengineering techniques.
- (2) The supplementary benefit of both bioengineering methods is low and can probably not be increased much by establishing standardized conditions for measurement.
- (3) Based on our results, bioengineering as part of occupational screenings cannot be regarded as effective.

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