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Illustrating Skin Hydration by Capacitive Contact Imaging after Frequent Hand Disinfection

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(presented in part at the 7th ICPIC Conference, Geneva, Switzerland, 12th -15th September 2023)

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Hand hygiene is essential for preventing healthcare-associated infections. However, hand hygiene compliance is often hindered by a number of factors, one of which is irritant contact dermatitis. Illustrating the benefits of skin friendly hand disinfectants and their effect on skin condition could positively influence hand hygiene compliance.
The aim of this study was to analyse the skin hydrating effect of a hand disinfectant with a comprehensive skin care complex using Capacitive Contact Imaging (CCI) as a method to assess and visualise skin hydration in comparison to conventional corneometry. In addition to established parameters, including pH value, transepidermal water loss (TEWL), and dermatological assessments, the study investigated the dermatological effects of a two-week application of a hand disinfectant foam.
Frequent daily application of the product led to an improvement in skin hydration without causing intolerability. The results from CCI and corneometry were consistently comparable and showed significantly elevated skin hydration after the two-week application period. CCI illustrated the increased skin hydration and it's potential to be used as an additional method to evaluate and demonstrate the effect of hand hygiene products on skin health.

Introduction

Hand hygiene (HH) is generally regarded as the most effective way to stop the spread of healthcare-associated infections. However, hand hygiene compliance (HHC), the correct use of hand hygiene at the right indications, is frequently too low. For example, a 2019 review on hand hygiene compliance in emergency departments revealed, that only 33% of the studies included reported HHC over 50% [1]. Even in neonatal intensive care units, where compliance is often highest, a systematic review found an average compliance rate of only 67.6% [2].

Interventions to improve HHC often attempt to remove hurdles for hand hygiene, for example by introduction of standard operating procedures [3,4] or increasing the numbers of disinfectant dispensers. One of the barriers to HHC as cited by healthcare workers (HCW) is the occurrence of irritant contact dermatitis which is primarily associated with risk factors such as wet work, frequent contact with skin irritants, frequent hand washing with soap or wash-lotions and prolonged use of protective gloves. As a result, skin problems such as dry skin or even hand eczema have long been reported in healthcare workers, which was exacerbated during the COVID-19 pandemic [5]. As damaged and cracked skin is not only more difficult to disinfect, but also more likely to be colonised by microbes [6], healthy skin must be prioritised as a prerequisite for successful hand hygiene in healthcare settings. Studies on the prevention of occupational hand eczema in healthcare settings have shown that interventions such as education on topics like the risks of excessive hand washing and the advantages of hand disinfection compared to hand washing, together with the distribution of appropriate (skin friendly) products, can be effective in preventing occupational hand eczema [7,8]. However, similar to hand hygiene behaviour, HCW's skin care is often inadequate [9].

Studies aimed at improving HCW's behaviour, especially those focusing on hand hygiene compliance, show that self-protection is often the most motivating factor, resulting in higher compliance for hand hygiene adherence after exposure to body fluids or after touching a patient [3,10]. It is therefore important to vividly demonstrate efficacy against pathogens as well as benefits of skin-friendly hand disinfection and skin care to healthcare workers (HCWs). The "My 5 moments of Hand hygiene" model proposed by *Sax et al.* in 2005 [11] combines visualization and text to conceptualise correct hand hygiene at the five moments in which transmission of pathogens can occur. Since its publication, it has been successfully used in numerous studies and interventions worldwide to improve hand hygiene compliance and has been included in international guidelines on hand hygiene [12,13], including the WHO guideline on hand hygiene in healthcare [14]. Another common practice in teaching hand hygiene to HCWs is the use of skin coverage visualization methods as an easy-to-implement and comprehensible method to emphasize the need to use hand disinfectants correctly [15-17].

In this study, we analysed the skin hydrating effect of a hand disinfectant with a skin care complex. In addition to conventional corneometry, Capacitive Contact Imaging (CCI) was used to assess and visualise the hydration of the skin in order to show the benefits of hand disinfection concerning its effect on skin condition.

Alongside established parameters (pH value, TEWL, objective and subjective dermatological assessment), the dermatological effect of a two-week application of a hand disinfectant foam was investigated.

Methods

This was an open-label, randomised, two-week exploratory investigation. The study was executed according to the requirements of the Declaration of Helsinki, and according to the main principles of Good Clinical Practice (GCP), with volunteers providing their written informed consent for inclusion. Study approval was granted by the IRB of the test institute for the protocol, protocol amendment(s), and volunteer informed consent forms.

Product: The test product was a proprietary topical leave-on disinfectant alcoholic foam (Sterillium® foam extra care).

Subjects and Study Design: 24 subjects (60% females and 40% males), aged 55.7 ± 9.4 years (mean ± standard deviation), were recruited. Subjects who met the exclusion and inclusion criteria, with healthy or unhealthy skin (at least 30% with atopic predisposition and/or a history of contact allergy and/or self-perceived sensitive skin and/or rosacea) on the hands and forearms were included.

Product Testing: Product was applied 20 times daily at home to both hands and one volar forearm according to **Table 1** and **Figure 1**. On Days 1 (Baseline), 15 and 16, skin pH, skin hydration (corneometry), TEWL, and skin hydration via permittivity (CCI) were measured. All instrumental measurements took place in an air-conditioned room at a temperature of 22 ± 2°C and at 50 ± 7.5% relative humidity. Prior to any measurements, subjects were acclimatised for at least 30 minutes.

Capacitive Contact Imaging (CCI): CCI was measured with an Epsilon E100 (Biox Systems Ltd, London, UK). Epsilon measures skin hydration through visual Capacitive Contact Imaging [18]. The sensor head consists of an array of individual capacitance sensors. The measuring principle is based on changes in the capacitance of each sensor, functioning as a condensator. Between the conductors, an electrical field is built. Its electronics and signal processing algorithms map the sensor's non-linear signals onto a calibrated scale for measuring hydration. The capacitance data of all sensors of the array is translated into pixel brightness and assembled into one image of 12.8 x 15 mm. 1 image was taken per test area (forearm only), at each assessment time.

Skin Hydration Measurement: The measurement of *Stratum corneum* hydration was performed by electrical capacitance using a Corneometer CM825 (Courage & Khazaka, Cologne, Germany), whereby the di-electricity of the upper skin layer is measured. Since the di-electricity varies as a function of the skin's water content, the *stratum corneum* hydration can be measured. 5 measurements per test area (forearm only) were conducted at each assessment time.

Skin pH: The skin pH was determined with a skin pH meter, 900 PC, (Courage & Khazaka, Cologne, Germany). The contact surface of a specific wetted glass electrode was gently placed onto the measurement area of the skin and 2 measurements per test area (forearm only) were taken at each assessment time.

Transepidermal Water Loss: TEWL measurements were conducted with a Tewameter® TM 300 (Courage & Khazaka, Cologne, Germany). The probe was held in place for each measurement for 30 seconds. The values of the last 10 seconds (= 10 values) were averaged as the actual measurement value, with 1 measurement taken per test area (forearm only) at each assessment time.

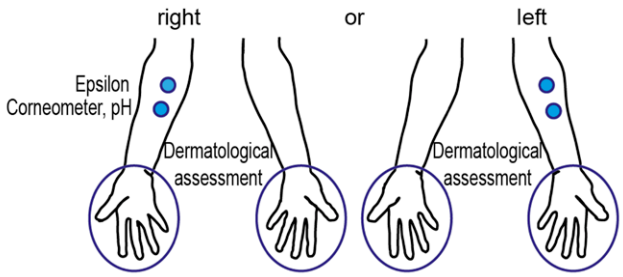

Fig. 1 Measurement areas

	Day 1 (baseline)	Day 2 to 14	Day 15	Day 16
Dermatological evaluation (by a physician and the subjects)	X		X	
pH-Meter	X		X[1]	X[2]
Corneometer	X		X[1]	X[2]
TEWL	X		X[1]	X[2]
Epsilon	X		X[1]	X[2]
Application of test product (by the subjects at study site)	X		X	
Application of test product (by the subjects at home)	X	X		

Table 1: Overview of the test schedule. Tests marked with [1] were done 30 mins and 3 hours after last application, tests marked with [2] were done 24 hours after last application.

Tolerability Assessment: Tolerability of the foam on the hands (not the forearm), was assessed by a physician on Day 1 and 15, and by subject questionnaire after two-weeks use. Objective visual evaluation of the skin status on both hands, was assessed for erythema, dryness, scaling, fissures, papules, pustules, oedema, vesicles, and weeping, according to the following scale by a physician: 0 = None; 0.5 = Very slight; 1 = Slight; 2 = Moderate; 3 = Strong. Scores were then computerised. On Day 15, subjects filled in a questionnaire evaluating their subjective assessment for: itching, burning, tension, tickling, and feeling of dryness, according to the following scale by the subjects: 0 = None; 0.5 = Very slight; 1 = Slight; 2 = Moderate; 3 = Strong. Scores were then computerised.

Adverse Events: Any adverse events were recorded according to the principles of ICH GCP.

Statistics: A significance level of 0.05 (alpha) was chosen for statistical analysis. Due to the explorative character of the study, no adjustment for multiplicity was done.

For skin tolerability assessments, descriptive statistics (n, mean, standard deviation, median, minimum, and maximum) were calculated for raw data for each parameter and assessment time. For instrumental measurements, a pairwise comparison of assessment times was done by paired t-test on raw data for each parameter. Computation of the statistical data was carried out with commercially available statistics software (SAS for Windows).

Results

Subjects: Of the 24 subjects recruited, there were 3 drop-outs and 1 subject had their data excluded for a protocol deviation. Of the subjects analysed, 25% were self-assessed as sensitive-skinned; 10% had a Type IV allergy; and 5% had atopy. No adverse events occurred during the course of the study.

Capacitive Contact Imaging (CCI): To assess and illustrate skin hydration capacitance in comparison to conventional corneometry, visual skin hydration was measured by CCI. Data showing an increase in dielectric permittivity values, indicates an increased skin hydration. Compared to baseline, a significant 3-fold increase in skin hydration was recorded on Day 15 (30 minutes post-final application), which reduced to 2-fold above baseline (Day 1), on Day 15 (3 hours post-final application) and remained relatively stable to Day 16 **(Figure 2)**. Moreover, CCI images clearly illustrated the hydration effect **(Figure 1)** from baseline (Day 1) to Day 16. Although the degree of hydration was reduced after the final application (Day 15, 30 minutes), it remained elevated compared to Day 1.

Skin Hydration Measurement via Corneometry: Compared to baseline, significantly higher corneometry skin capacitance (hydration) values were obtained at all post-treatment

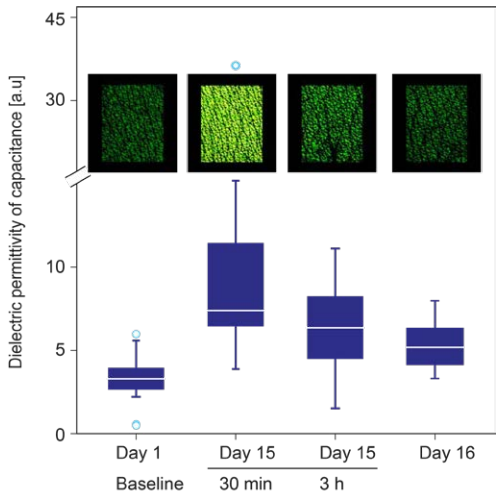

Fig. 2 Results from Capacitive Contact Imaging. Graph depicting boxplots with median values and whiskers with 5–95 percentile and outliers. Above the boxplot, CCI images of one subject over the course of the study.

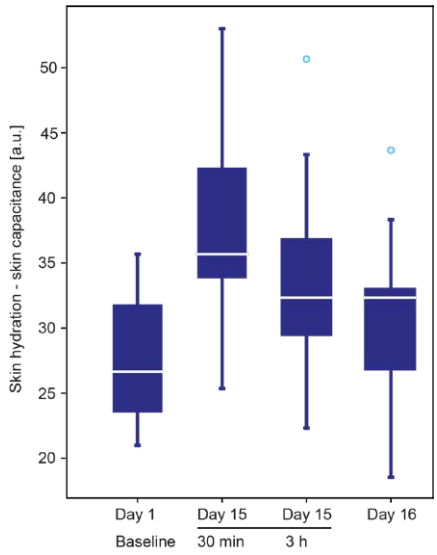

Fig. 3 Results from Corneometry. Graph depicting boxplots with median values and whiskers with 5–95 percentile and outliers.

times. Skin capacitance increased compared to Day 1 (Baseline). Hydration levels (Days 15 and 16), remained stable and slightly above or equal to Day 1 **(Figure 3)**.

Skin pH: In general, skin pH values remained stable over the two-weeks study period.

Compared to Baseline, slightly increased pH values were found on Day 15 at both 30 minutes and 3 hours post treatment. pH levels were lowered returning to within normal parameter on Day 16 **(Figure 4)**.

Transepidermal Water Loss: As expected, compared to Baseline, higher TEWL values were measured on Day 15, however decreasing on Day 16 on **(Figure 5)**. All TEWL values were within the physiological range.

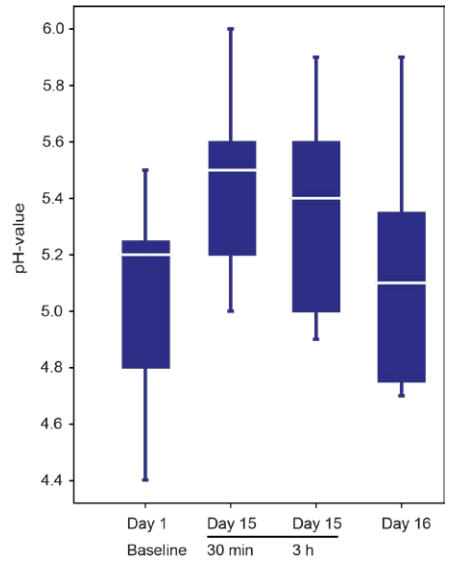

Fig. 4 Results for pH-value over the study. Graph depicting boxplots with median values and whiskers with 5–95 percentile.

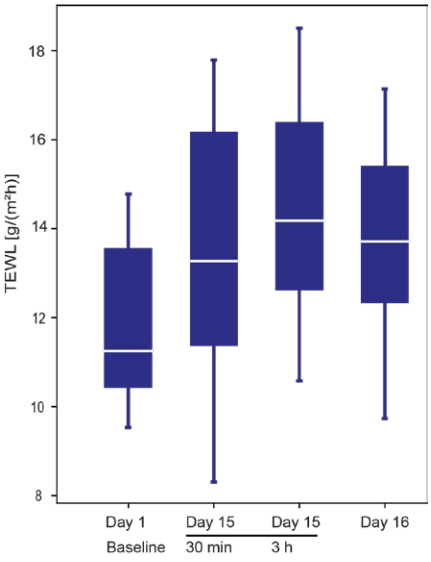

Fig. 5 Results for Transepidermal Water Loss (TEWL) over the study. Graph depicting boxplots with median values and whiskers with 5–95 percentile.

Objective Dermatological Evaluation: The results of the dermatological assessment after two weeks of product usage **(Figure 6)** showed a decrease in the number of findings for all diagnosed parameters: Very slight erythema was recorded in 11 subjects on Day 1 (Baseline), and this number was reduced to 5 subjects on Day 15. Skin dryness (very slight to moderate) was recorded in all subjects on Day 1 (Baseline), and this number was reduced to 17 subjects (very slight to slight), on Day 15. Scaling was recorded in 16 subjects (very slight to slight) on Day 1 (Baseline) and this was reduced to 6 subjects on Day 15, recording very slight scaling. None of the volunteers presented fissuring, papules, pustules, oedema, vesicles or weeping at Day 1 (Baseline) and Day 15.

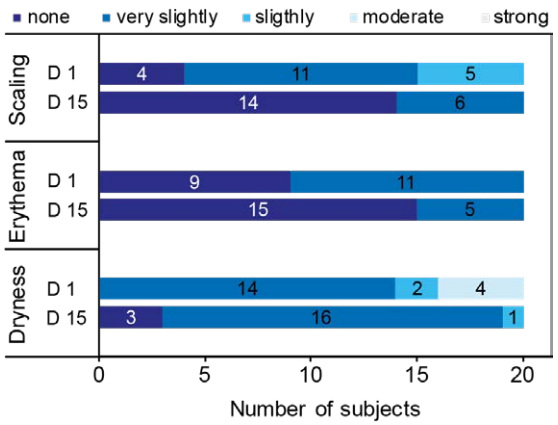

Fig. 6 Objective dermatological assessment

Subjective Dermatological Evaluation: Self-evaluation by subjects **(Figure 7)** recorded the following skin sensations: At Day 1 (Baseline) only 1 subject recorded very slight itching which had resolved by Day 15. A very slight burning sensation was recorded by 1 subject on Day 15 only, with no subjects recording this sensation at Day 1 (Baseline). Skin tension was recorded by 1 subject on Day 15 only. A total of 8 subjects recorded skin dryness (very slight to moderate) at Baseline which had resolved by Day 15, with none of the subjects recording any skin dryness.

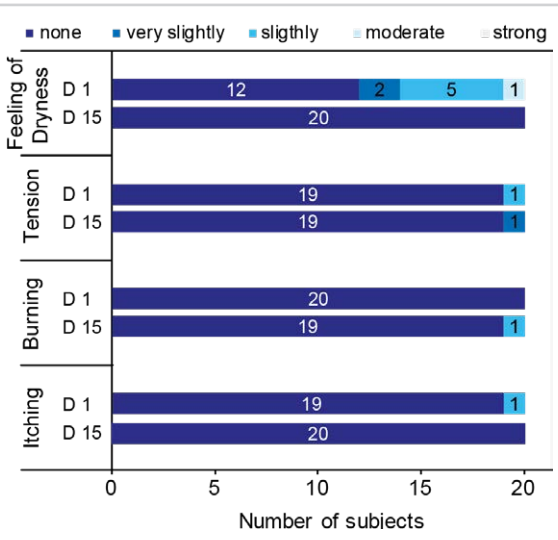

Fig. 7 Subjective dermatological evaluation

Discussion and Conclusions

The purpose of this exploratory study was to establish CCI as a new method to assess and illustrate skin hydration of a hand disinfectant foam, in comparison to conventional corneometry and to evaluate whether CCI could be a means to visualise skin health, as visualisation of the skin hydration effect might be a useful motivator for healthcare workers to comply with hygiene measures such as hand disinfection, provided that skin-friendliness is convincingly demonstrated.

The results on skin hydration from CCI and corneometry show a comparable increase during the application of the disinfectant that slowly decreases after the last use. Data of both methods across all assessment times allows to draw the same conclusions on skin hydration.

Results of the objective and subjective dermatological assessment complete the picture of overall beneficial effects of the two-week disinfectant application among the study population. Increases of pH and TEWL, albeit statistically significant, remained within physiological ranges. Overall, in this study, a positive effect on the skin could be shown for the investigated hand disinfectant foam. Frequent daily application of the product led to an improvement in skin hydration without causing intolerability. The observed slight increase of water permeability of the skin (TEWL) was within the physiological range.

Three conclusions can be drawn from the collected data. Firstly, CCI and corneometry data are consistently comparable. Secondly, the study shows a positive effect on the skin for the hand disinfectant foam tested and thirdly the CCI images convey the skin hydrating properties of the hand disinfectant.

A technology such as CCI could be used not only to demonstrate the caring properties, but also to visualise the effects of different hand hygiene measures on the skin. For example, it could help to change the widespread assumption that hand disinfection is more harmful than hand washing which often originates from a burning sensation felt when using alcohol-based hand disinfectants on already damaged skin [19].

Conflict of interest statement

CM, HG, NN, HN are employees of BODE Chemie GmbH, a company of the HARTMANN GROUP (Hamburg, Germany). Throughout the study, TS was an employee of BODE Chemie GmbH.

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