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# Validation of a novel smartphone application-enabled, patient-operated skin barrier device

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## Abstract

**Background:** Transepidermal water loss (TEWL) and surface capacitance measure skin barrier permeability and stratum corneum (SC) hydration, respectively, and are frequently utilized in atopic dermatitis clinical trials. Many barrier devices are costly and often used only in the academic setting. GPSkin is a low-cost, patient-operated device that measures both TEWL and SC hydration. This study aimed to test the reliability of GPSkin and assess its correlation with current industry standards.

**Materials and Methods:** GPSkin was compared to the Biox AquaFlux (TEWL) and Courage-Khazaka Corneometer (SC hydration). Participants with healthy skin (n = 50) collected measurements with GPSkin in Trial 1 without any device education and in Trial 2 with additional instruction. In Trial 2, the investigator also performed measurements with GPSkin. Spearman's coefficients ($r_s$) were performed to assess device correlation. Intraclass correlation coefficients (ICC) were calculated to determine reliability.

**Results:** Overall, GPSkin was moderately correlated with current industry device measurements for TEWL (Trial 1 $r_s$:0.48; Trial 2 $r_s$:0.40 participant, 0.34 investigator) and SC hydration (Trial 1 $r_s$:0.63; Trial 2 $r_s$:0.45). GPSkin demonstrated "good" test-retest reliability for both TEWL (ICC: 0.89) and SC hydration (ICC: 0.85) measurements when participants were provided with some device education. There was no difference in reliability between participants provided with device education and investigators.

**Conclusion:** Based on these findings, we concluded that GPSkin provides reasonably precise and reliable measurements of SC hydration and TEWL as compared to current devices.

KEYWORDS

atopic dermatitis, barrier, capacitance, device, hydration, transepidermal water loss

## 1 | INTRODUCTION

The ability to measure skin barrier properties such as transepidermal water loss (TEWL) and surface capacitance provides objective information to investigators and clinicians regarding skin barrier function.[1,2] TEWL is a validated measure of epidermal permeability,[2] whereas measuring surface capacitance provides information about epidermal hydration. Clinical trials utilize both TEWL and SC hydration to monitor disease activity (eg, atopic dermatitis) and/or response to interventions.[3-5]

Conventional devices that measure TEWL and SC hydration can be costly, bulky, and require delicate calibration before each

use. For these reasons, the availability of barrier devices is often limited to tertiary care and research facilities, restricting patient populations that may participate in studies of skin barrier function. GPSkin is a low-cost, non-invasive skin barrier device marketed as patient-operable. It is compact and functions via Bluetooth to a smartphone application. GPSkin potentially allows for skin barrier monitoring by patients in their home; however, the performance characteristics of the GPSkin device have not been well described. The objective of this study was to validate GPSkin by assessing its reliability and its correlation with current industry devices.

## 2 | MATERIALS AND METHODS

### 2.1 | Study design

This prospective cross-sectional validation study was conducted at a single institution. Participants 18 years of age and older with healthy skin, without any active inflammatory skin conditions, participated in the study at the Oregon Health & Science University Dermatology Department (Oregon, USA). The Institutional Review Board approved this study, and informed consent was obtained for all participants.

Measurements were collected on the volar forearm as it is easily accessible, has been a standard anatomical site of previous barrier studies, and demonstrates similar reactivity and baseline measurements to many other body regions.[6] Device probes were held perpendicular to the skin surface for duration of measurement collection with enough pressure to create an adequate seal.

The GPower GPSkin device (TEWL and SC hydration) was compared against current industry devices widely used: the Biox AquaFlux (TEWL) and Courage-Khazaka Corneometer (SC hydration; Figure 1). This study involved two trials (Table 1). In each (n = 50), participants collected their own measurements with GPSkin; AquaFlux and Corneometer measurements were investigator-collected. Participants were provided with minimal device instruction for Trial 1. Additional device education was provided prior to Trial 2. Additionally, investigator-performed GPSkin measurements were collected in Trial 2.

### 2.2 | The devices

#### 2.2.1 | Biox AquaFlux

The Biox AquaFlux AF 200 Evaporimeter utilizes a closed chamber condenser system to measure TEWL. The purpose of the condenser is to create an area of low humidity in the chamber relative to the specimen being measured. Moisture from the chamber atmosphere is sequestered onto the condenser and crystallized into ice, leaving an area of lower humidity in the main chamber region. The probe contacts the moisture-rich skin and water vapor passively diffuses from high to low humidity, toward the Biox AquaFlux chamber sensor.[7]

#### 2.2.2 | Courage-Khazaka Corneometer

The Courage-Khazaka Corneometer CM 825 provides a marker of skin hydration via a high frequency (0.9-1.2 MHz) capacitance measurement of a dielectric skin medium. Utilizing the dielectric medium in the skin, the Corneometer measures a dielectric constant, which is reported in arbitrary Corneometer units of 0-120. This dielectric constant is sensitive to changes is moisture and is what allows capacitance measurements to function as a surrogate for skin hydration.[8,9]

#### 2.2.3 | GPower GPSkin

The GPower GPSkin measures both TEWL and skin capacitance. The GPSkin capacitance measurement is collected from two sensors on the outer edge of the probe and follows the same technological principles as the Corneometer.

GPSkin utilizes a pseudo-closed chamber system for TEWL measurement. The pseudo-closed chamber model is similar to a closed chamber system but provides a degree of chamber ventilation to decrease chamber humidity and pressure. Further specifics on probe configuration remain proprietary at this time.

Both TEWL and SC hydration are transmitted via Bluetooth to a smartphone application where data may be accessed and analyzed.[10] GPSkin is currently being used for investigative purposes only and is not yet FDA approved.

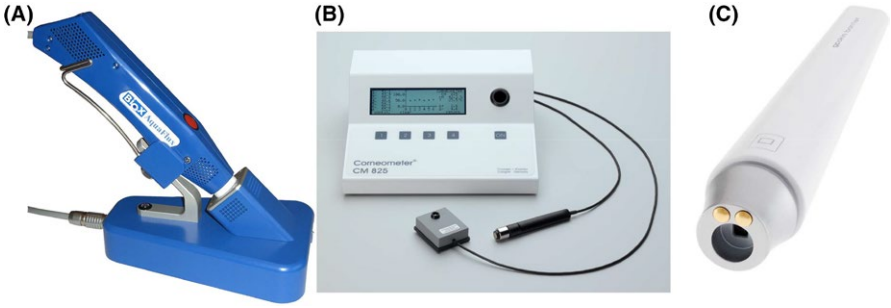


**FIGURE 1** Study devices. A, Biox AquaFlux AF200, capable of measuring TEWL, (B) Courage-Khazaka Corneometer CM 825, capable of measuring skin capacitance, and (C) GPower GPSkin, capable of measuring both TEWL and skin capacitance

**TABLE 1** Data collection schematic

| Device | Measure | Trial 1 (n = 50) | Trial 2 (n = 50) |
|---|---|---|---|
| GPSkin | TEWL + hydration | Participant | Participant + investigator |
| AquaFlux | TEWL | Investigator | Investigator |
| Corneometer | Hydration | Investigator | Investigator |

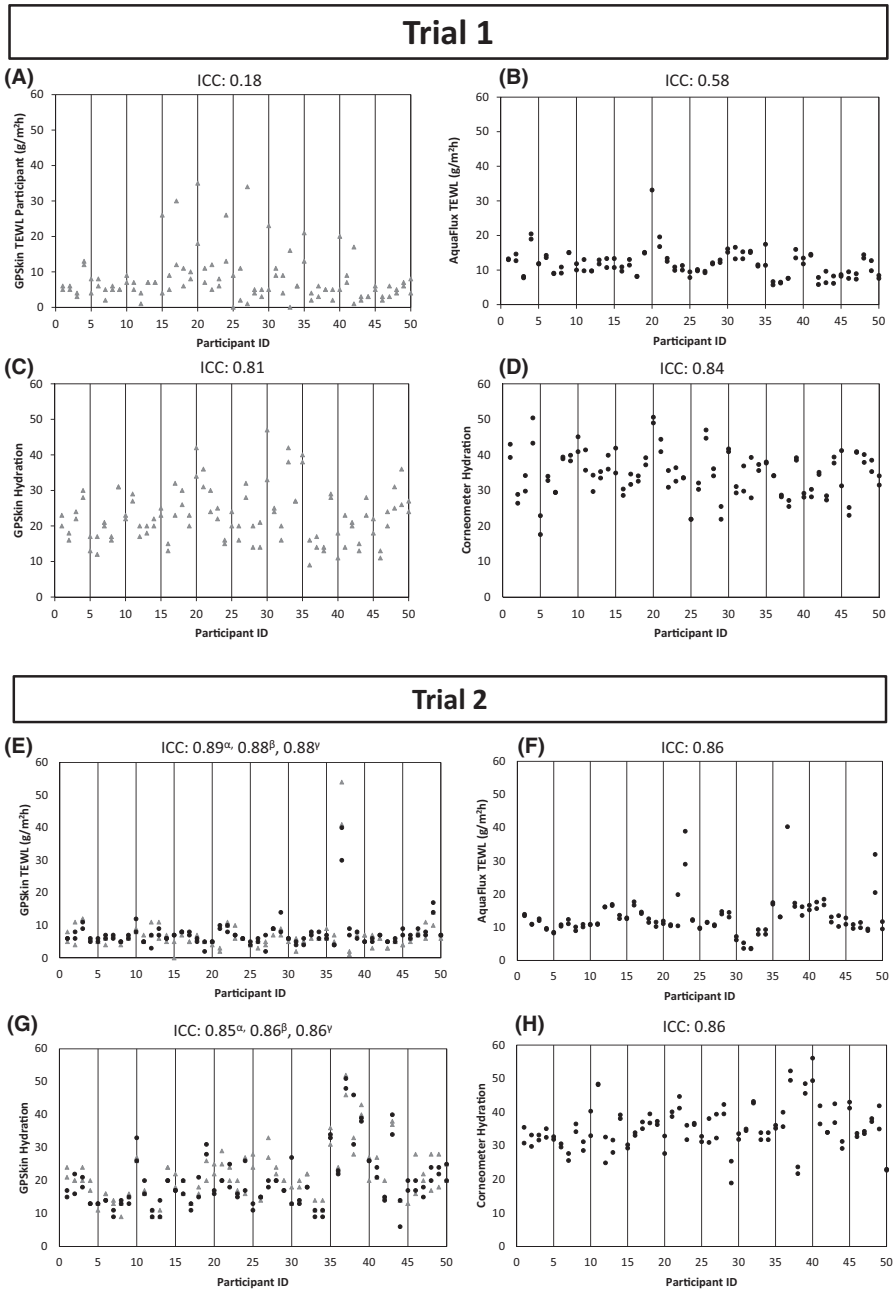


**FIGURE 2** Intraclass correlation coefficients (ICCs) to Assess Device Test-Retest Reliability. ICCs were calculated for both TEWL (A,B,E,F) and hydration (C,D,G,H) measurements collected by participants (triangles) and investigators (circles) for GPSkin (A,C,E,G), the AquaFlux (B,F) and the Corneometer (D,H). Data consisted of two outliers not contained within the above graphs (B,F). TEWL ICCs improved from Trial 1 to 2: GPSkin improved from 0.18 (A) to 0.89 in Trial 2 (E) when comparing participant-collected measurements and the AquaFlux improved from 0.58 (B) to 0.86 (F). ICCs reliability is interpreted as follows: <0.5, poor; 0.5-0.75, moderate; 0.75-0.9, good; and > 0.9 excellent.[12] $^{\alpha}$ICC for participant vs participant, $^{\beta}$ICC for participant vs investigator, $^{\gamma}$ICC for investigator vs investigator

## 2.3 | Controlling for variables

TEWL and SC hydration measurements may be affected by external factors, such as emollient use, hygiene habits, and room conditions. These variables were controlled for during measurement collection.[6,11] The study room was maintained at 20-22°C, 30%-50% humidity as thermal sweating is unlikely to occur and skin temperature is unlikely to affect measurements in this range.[6] Participants were required to acclimate to the environment for 10-15 minutes. The microclimate above the skin is sensitive to changes in water vapor, so participants were not allowed to apply emollients or bathe for 6 hours prior to measurements.

### 2.4 | Statistical analysis

Primary outcomes included TEWL and SC hydration measured on healthy skin. Each measurement was collected twice to allow for calculation of means and analysis of device test-retest reliability. Intraclass correlation coefficients (ICCs) were calculated by a two-way mixed effect model, with absolute agreement, and classified as poor (<0.5), moderate (0.5-0.75), good (0.75-0.9), or excellent (>0.9).[12] Spearman's correlation coefficients ($r_s$) were utilized to assess the correlation between related devices (GPower GPSkin and AquaFlux; GPower GPSkin and Corneometer). $r_s$ were categorized as very weak (0.00-0.19), weak (0.20-0.39), moderate (0.40-0.59), strong (0.60-0.79), or very strong (0.80-1.0). Statistical analysis was performed using Stata software (StataCorp, LLC, College Station, TX, USA).[13]

## 3 | RESULTS

### 3.1 | Trial 1

Fifty participants with healthy skin were included in Trial 1. Mean (±SD) TEWL values were 7.89 g/m$^2$h (±5.09) for GPSkin and 12.62 g/m$^2$h (±7.78) for the AquaFlux. Mean SC hydration values were 22.88 AU (±7.27) for GPSkin and 34.57 AU (±6.18) for the Corneometer. GPSkin demonstrated "poor" test-retest reliability (ICC = 0.18, 95% CI: −0.08-0.42) for TEWL, whereas the AquaFlux showed "moderate" reliability (ICC = 0.58, 95% CI: 0.36-0.73) for TEWL (Figure 2A,B). The devices were moderately correlated by Spearman's for TEWL ($r_s$ = 0.48, $P$ = 0.0004; Figure 3A1). Several data points were identified as having a > four-fold difference between values, all within GPSkin TEWL measurements.

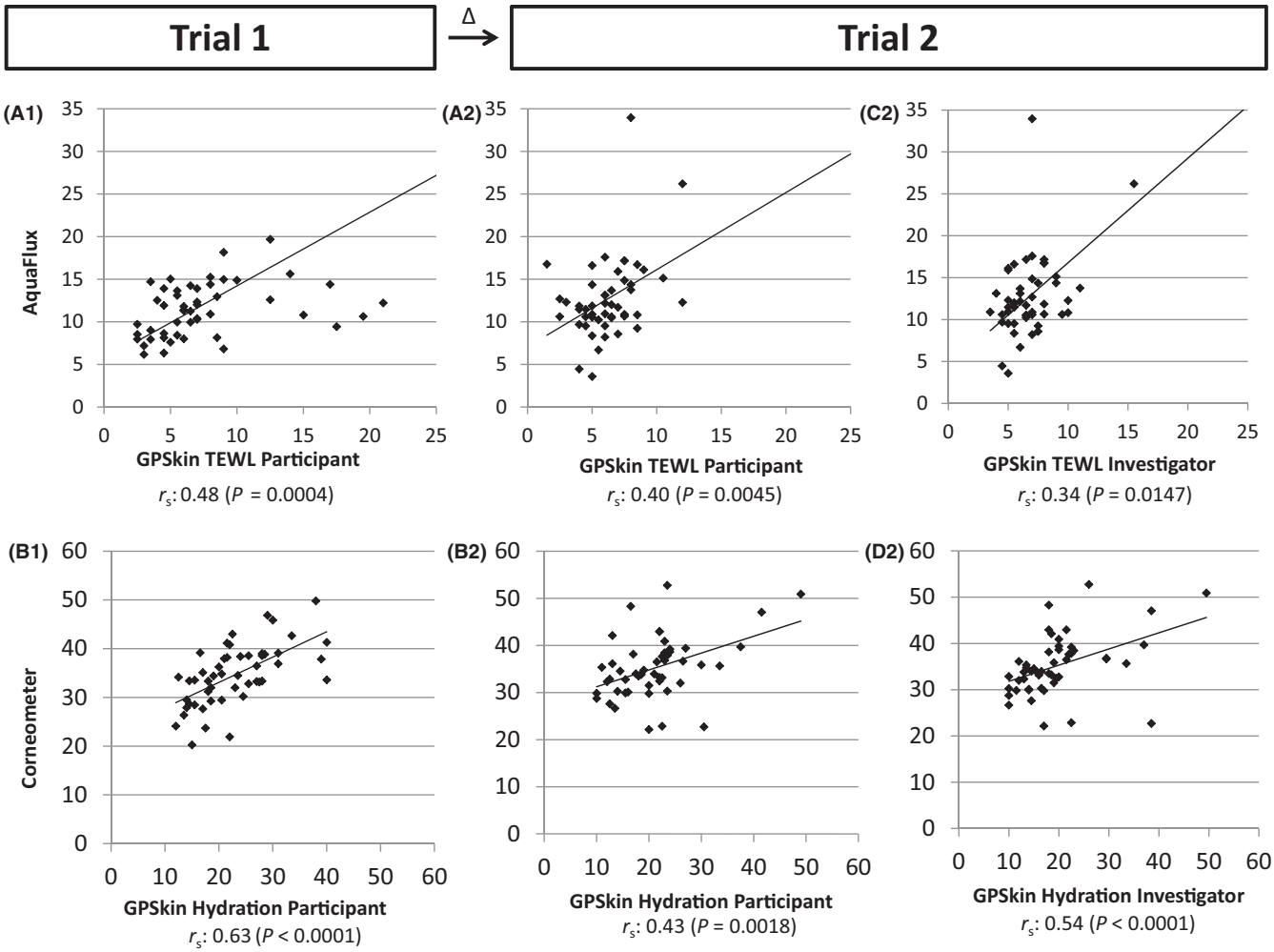


**FIGURE 3** Spearman correlation coefficients ($r_s$) for GPSkin versus standards. GPSkin was tested against the AquaFlux to measure TEWL (top) and the Corneometer to measure hydration (bottom). In Trial 1, only participants collected measurements with GPSkin (A1 and B1). In Trial 2, both participants (A2 and B2) and investigator (C2 and D2) collected measurements with GPSkin. Trial 2 TEWL data consisted of one outlier data point not contained within the above graphs (A2, C2). Δ denotes method modification between trials. $r_s$ is interpreted as follows: 0.00-0.19, very weak; 0.20-0.39, weak; 0.40-0.59, moderate; 0.60-0.79, strong; and 0.80-1.0, very strong[13]

For SC hydration, GPSkin demonstrated "good" reliability (ICC = 0.81, 95% CI: 0.70-0.89) as did the Corneometer (ICC = 0.84, 95% CI: 0.73-0.91; Figure 2G,H), and the two devices showed a moderately strong correlation ($r_s$ = 0.63, $P$ < 0.0001; Figure 3B1).

### 3.2 | Trial 2

Because of the low test-retest reliability in the first trial, methods were modified to include increased participant education on device use prior to the start of Trial 2. Participants (n = 50) were instructed to click start on the device button, immediately stick the device onto their forearm, and hold consistent pressure for the entirety of measurement. Mean TEWL values for GPSkin were 7.04 g/m$^2$h (±6.16) for participant-measured and 7.32 g/m$^2$h (±4.45) for investigator-measured. Mean TEWL value for the AquaFlux was 13.45 g/m$^2$h (±7.09). Mean SC hydration values for GPSkin were 21.1 AU (±7.69) for participant-measured and 19.66 AU (±8.14) for investigator-measured. Mean SC hydration value for the Corneometer was 35.19 AU (±6.41).

Test-retest reliability of GPSkin TEWL measurements improved to "good" for participant (ICC = 0.89, 95% CI: 0.82-0.94), investigator (ICC = 0.88, 95% CI: 0.79-0.93), and participant-investigator (ICC = 0.88, 95% CI: 0.79-0.93) comparisons (Figure 2E). The AquaFlux also demonstrated "good" reliability for TEWL (ICC = 0.86, 95% CI: 0.76-0.92; Figure 2F). Participant GPSkin TEWL measurements and the AquaFlux were moderately correlated ($r_s$ = 0.40, $P$ = 0.0045; Figure 3A2) while investigator GPSkin TEWL measurements and the AquaFlux were weakly correlated ($r_s$ = 0.34, $P$ = 0.0147, Figure 3C2).

The test-retest reliability of GPSkin SC hydration measurements remained "good" for participant (ICC = 0.85, 95% CI: 0.74-0.91), investigator (ICC = 0.86, 95% CI: 0.77-0.92), and participant-investigator (ICC = 0.86, 95% CI: 0.79-0.93) comparisons (Figure 2G). The Corneometer continued to have "good" reliability (ICC = 0.86, 95% CI: 0.77-0.92; Figure 2H). GPSkin and the Corneometer were moderately correlated for participant ($r_s$ = 0.45, $P$ = 0.0018; Figure 3B2) and investigator ($r_s$ = 0.54, $P$ < 0.0001; Figure 3D2) measurements.

## 4 | DISCUSSION

We found GPSkin to provide reasonably precise and reliable measurements of SC hydration and TEWL, with some limitation in accuracy when compared to current gold standard devices. While GPSkin underestimated both TEWL and SC hydration measurements, these underestimations were consistent and of similar sizes suggesting software changes could adjust for this potential calibration issue. Importantly, GPSkin correlated with established industry devices for TEWL and SC hydration. Additionally, GPSkin demonstrated "good" test-retest reliability for both TEWL and SC hydration measurements when participants were provided with some device education. There was no difference in reliability between participants provided with device education and investigators. This is of particular significance as it suggests participants may be able to self-monitor their skin barrier at home and provide more comprehensive data for future studies with GPSkin.

In many dermatological diseases, barrier measurements correlate with disease activity. Equipping patients with their own barrier devices may help guide patient-directed changes in therapy or improve adherence to emollients.[4,5,14] Additionally, the smartphone era and its application-based technology provide the healthcare industry with a new platform for real-time interaction with patients. Several specialties across medicine are exploring this new communication mode to improve adherence and patient-reported outcomes. Smartphone application use has been associated with an increase in medication adherence,[15,16] enhanced sun protective behaviors,[17] and improved post-operative patient-reported outcomes.[18] GPower's application-based take-home technology could improve adherence by offering patients real-time skin barrier function information.

While barrier devices provide valuable objective information in trials, they can be cost-prohibitive, ranging from $10,000 to $20,000 per device. GPSkin is a lower-cost alternative that may allow for a greater number of clinicians and investigators to participate in skin barrier research or track skin barrier-related outcomes.

This study had some limitations. The AquaFlux and Corneometer were utilized as gold standards for comparison; however, there are no established industry standards for barrier devices. Additionally, while maximal efforts were made to control external variables, data collection occurred over several days with slight variations in climate variables.

### 4.1 | Future directions

GPSkin is currently being explored in patients with atopic dermatitis to validate the device on lesional and non-lesional skin and to measure the discriminative ability of the device between known disease severity states. Future directions will also include real-world longitudinal data collection to inform clinical care.

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### CONFLICT OF INTEREST

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### REFERENCES

1. Elias PM, Holleran WM, Feingold KR, Tsai J, Menon GK. The potential of metabolic interventions to enhance transdermal drug delivery. *J Investig Dermatol Symp Proc*. 2002;7(1):79-85.

2. Fluhr JW, Feingold KR, Elias PM. Transepidermal water loss reflects permeability barrier status: validation in human and rodent in vivo and ex vivo models. *Exp Dermatol*. 2006;15(7):483-492.
3. Danby Sg, Chalmers J, Brown K, Williams Hc, Cork Mj. A functional mechanistic study of the effect of emollients on the structure and function of the skin barrier. *Br J Dermatol*. 2016;175(5):1011-1019.
4. Kelleher M, Dunn-Galvin A, Hourihane JO, et al. Skin barrier dysfunction measured by transepidermal water loss at 2 days and 2 months predates and predicts atopic dermatitis at 1 year. *J Allergy Clin Immunol*. 2015;135(4):930-935.e931.
5. Kim D-W, Park J-Y, Na G-Y, Lee S-J, Lee W-J. Correlation of clinical features and skin barrier function in adolescent and adult patients with atopic dermatitis. *Int J Dermatol*. 2006;45(6):698-701.
6. Pinnagoda J, Tupkek Ra, Agner T, Serup J. Guidelines for transepidermal water loss (TEWL) measurement. A report from the Standardization Group of the European Society of Contact Dermatitis. *Contact Dermatitis*. 1990;22(3):164-178.
7. AquaFlux B. Biox AquaFlux Condenser-Chamber TEWL Brochure In: Ltd BS, ed. Biox Systems Ltd. 2013. https://www.biox.biz/Downloads/Brochures/Biox_AquaFlux-AF200_Brochure_07a.pdf2013. Accessed October 30, 2018.
8. Anthonissen M, Daly D, Peeters R, et al. Reliability of repeated measurements on post-burn scars with Corneometer CM 825((R)). *Skin Res Technol*. 2015;21:302-312.
9. Courage-Khazaka. Scientific Devices: Corneometer® CM 825. https://www.courage-khazaka.de/index.php/en/products/scientific/55-corneometer-cm1. Accessed October 31, 2018.
10. GPower. Meeting the gpskin Barrier. https://mygpskin.com/device. Accessed October 31, 2018.
11. Imhof Re, De Jesus M, Xiao P, Ciortea Li, Berg Ep. Closed-chamber transepidermal water loss measurement: microclimate, calibration and performance. *Int J Cosmet Sci*. 2009;31(2):97-118.
12. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. *Journal of chiropractic medicine*. 2016;15(2):155-163.
13. Weir I, Spearman's Rank Correlation. http://www.statstutor.ac.uk/resources/uploaded/spearmans.pdf. Accessed May 5, 2018.
14. Gupta J, Grube E, Ericksen MB, et al. Intrinsically defective skin barrier function in children with atopic dermatitis correlates with disease severity. *J Allergy Clin Immunol*. 2008;121(3):725-730.e722.
15. Morawski K, Ghazinouri R, Krumme A, et al. Association of a smartphone application with medication adherence and blood pressure control: the MedISAFE-BP randomized clinical trial. *JAMA Intern Med*. 2018;178(6):802-809.
16. Labovitz DL, Shafner L, Reyes Gil M, Virmani D, Hanina A. Using artificial intelligence to reduce the risk of nonadherence in patients on anticoagulation therapy. *Stroke*. 2017;48(5):1416-1419.
17. Buller DB, Berwick M, Lantz K, et al. Evaluation of immediate and 12-week effects of a smartphone sun-safety mobile application: a randomized clinical trial. *JAMA Dermatol*. 2015;151(5):505-512.
18. Jaensson M, Dahlberg K, Eriksson M, Nilsson U. Evaluation of postoperative recovery in day surgery patients using a mobile phone application: a multicentre randomized trial. *Br J Anaesth*. 2017;119(5):1030-1038.


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