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Original Article

# A study on the traceability and uncertainty of skin hydration measurement on the sole of the foot

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**Objectives:** In order to accurately measure skin moisture and accumulate normal skin moisture data, analyzing the uncertainty of the skin moisture measurement and establishing standard reference data is essential. It helps to evaluate the skin's condition and has great significance in diagnosis and treatment. In this study, the traceability of the equipment and the uncertainty of the results were analyzed for their potential use in the field of Korean medicine. The data was collected measuring skin moisture on the sole of the foot.
**Methods:** One professional measured the moisture of the adult male's foot 10 times following a determined protocol. The standard uncertainty of repeated measurements was calculated from the mean value of 10 repeated measurements. Ten trainee participants also measured the adult male's foot following a determined protocol. The standard uncertainty by tester was calculated from the value of repeated measurements.
**Results:** As a result of analyzing the difference between the mean and standard uncertainties in both the expert and trainees, it was confirmed that the variance in this study did not satisfy the normal distribution. In addition, the Mann-Whitney U-test was carried out, and it was found that there was no significant difference in the measured values of the two groups. The authorized uncertainty of measurements and traceability of all the equipment was not confirmed.
**Conclusions:** This paper establishes the basis for later measurement-equipment research to provide the objective indicators to approach the dryness of plantar skin from dehydration, the Korean medicine perspective.

***Key Words*** : Traceability, Uncertainty, Skin hydration (SH), Transepidermal water loss (TEWL)

## Introduction

In the treatment of spondylosis and degenerative lumbar spinal stenosis patients, it was clinically observed that the dryness of the sole was improved depending on the region. *Donguibogam*, the representative classic book of Korean Medicine, states that 乾勁皴揭 皆屬於燥(Rough, dry, rigid and sore things arc all due to dryness.) suggests that 燥因血少(diseases of dryness are formed due to lack of blood)[1)]

The epidermis has keratinocyte and intercellular lipids, which play a key role in preventing the loss of body fluids and protecting the body from harmful factors[2, 3)]. The sole does not have a sebaceous gland but has many eccrine glands, which produce a hypotonic solution. The hypotonic solution evaporates on the body's surface, regulating the body temperature[2)].

We tried to find research data on the dryness and moisture of soles, but a major current focus is to

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measure skin hydration for cosmetics or moisturizers [3,4]. There is no skin moisture measurement research on the specific site including the sole. In Korean medicine, skin moisture measurement equipment has been tried to evaluate the skin condition of various parts of the human body[5,6]. However, no study has been reported on the moisture of a specific area, including the sole.

In addition, there were many types of measurement equipment that could be used for non-invasive research, but the traceability and uncertainty of these types of measurement equipment were not mentioned. Therefore, it is essential to analyze the traceability and uncertainty and develop standard references in order to utilize the data from all the measurement equipment, including equipment that can measure the skin condition for diagnosis and treatment[5].

We aim to evaluate the traceability and uncertainty as baseline data for the later development of the standard reference data. The professional equipment types used in this study were as follows: the Gpskin Barrier®, which is an easy-to-use instrument for measuring the skin moisture of the sole, CM-825 (Corneometer®), and TM-300 (Tewameter®).

## Subject and Method

### 1. Subject of Study

Twelve male and female participants aged between 20 and 40 without acute or chronic diseases were recruited through an advertisement at the Pusan National University School of Korean Medicine. After receiving the explanation of the research, the participants signed the written consent form. The information gathering and examination of the participants were carried out at the Department of Acupuncture & Moxibustion, Pusan National University Korean Medicine Hospital. This study was approved by the Institutional Review Board of Pusan National University Korean Medicine Hospital (PNUKHIRB-2017006).

The participants were split into two groups: One measurement subject and 11 measurement participants. The professional researcher was in the measurement participants' group. The subject was randomly assigned as a lottery method among the 11 trainees on the day of measurement.

### 2 Measurement Environment and Body Site

Because air flow and temperature and humidity changes may affect the result, the measurement was carried out in the constant temperature and humidity room without air movement or direct sunlight. The room temperature was maintained at 25 ± 5 ℃, and the humidity was maintained at 40 ± 10%.

The moisture of the sole was measured in this study. The sole does not have a sebaceous gland but has many eccrine glands, which produce a hypotonic solution[2]. The hypotonic solution evaporates on the body's surface, regulating the body temperature.

During the measurement, the subject's posture was maintained, as shown in Figure 1-A. Because the Tewameter® should be used with the measurement site kept horizontal to the ground, the subject lay flat and held his knee flexed with his sole facing up, keeping the probe horizontal to the ground.

Fig. 1-A. Measurement Posture

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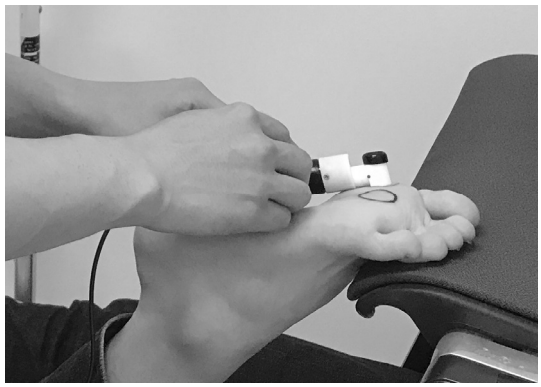

**Fig. 1-B.** Measurement Site(KI01)

The subject washed his feet and dried for 30 minutes. A circle was marked on the sole with a surgical marker to represent the measurement site (KI01) (Figure 1-B).

## 3. Measurement

1) Skin Hydration (SH) measurement

The spring-loaded probe in the head of the Corneometer® CM-825 (Courage - Khazaka Electronic, Germany, Figure 2-②) was gently stuck to the skin's surface to measure the site on the sole. The unit of measurement was expressed by an arbitrary unit (A.U.) given by the equipment. The higher the measured value, the higher the moisture content of the skin's surface.


**Fig. 2.** The Measurement Equipment ①Tewameter® TM-300 (Courage-Khazaka Electronic, Germany), ②Corneometer® CM-825(Courage-Khazaka Electronic, Germany), ③ Gpskin barrier®(G power, Korea)

The Gpskin barrier® (G Power, Korea, Figure 2-③) is an all-in-one measuring instrument capable of measuring Transepidermal Water Loss(TEWL) and Skin Hydration(SH) simultaneously. The measurement unit was not provided.

2) ransepidermal Water Loss (TEWL) measurement

The measurement unit of the Tewameter® TM-300 (Courage - Khazaka Electronic, Germany, Figure 2-①) is g / ㎡ / h. The Tewameter® is generally used as an open-chamber system, but it was covered with a cap as a closed-chamber system in this study[7] because the Gpskin barrier®, the comparative device, is a closed-chamber system. In the measurement process, the measurer generally holds the probe by hand, or the probe is attached to the skin with a sticker. The sticker attachment method was used in this study in order to reduce uncertainty.

The Gpskin barrier® (G Power, Korea) is an all-in-one measuring instrument capable of measuring TEWL and SH simultaneously. The measurement unit was not provided.

3) Uncertainty Calculation

The professional repeatedly measured the sole of the adult male's foot 10 times following a determined protocol. The standard uncertainty of repeated measurement was calculated from the mean value of 10 repeated measurements. Ten trainees also measured the sole of the adult male's foot following a determined protocol. The standard uncertainty by tester was calculated from the value of repeated measurements.

## 4. Statistical Analysis

The standard uncertainty of this study is the type

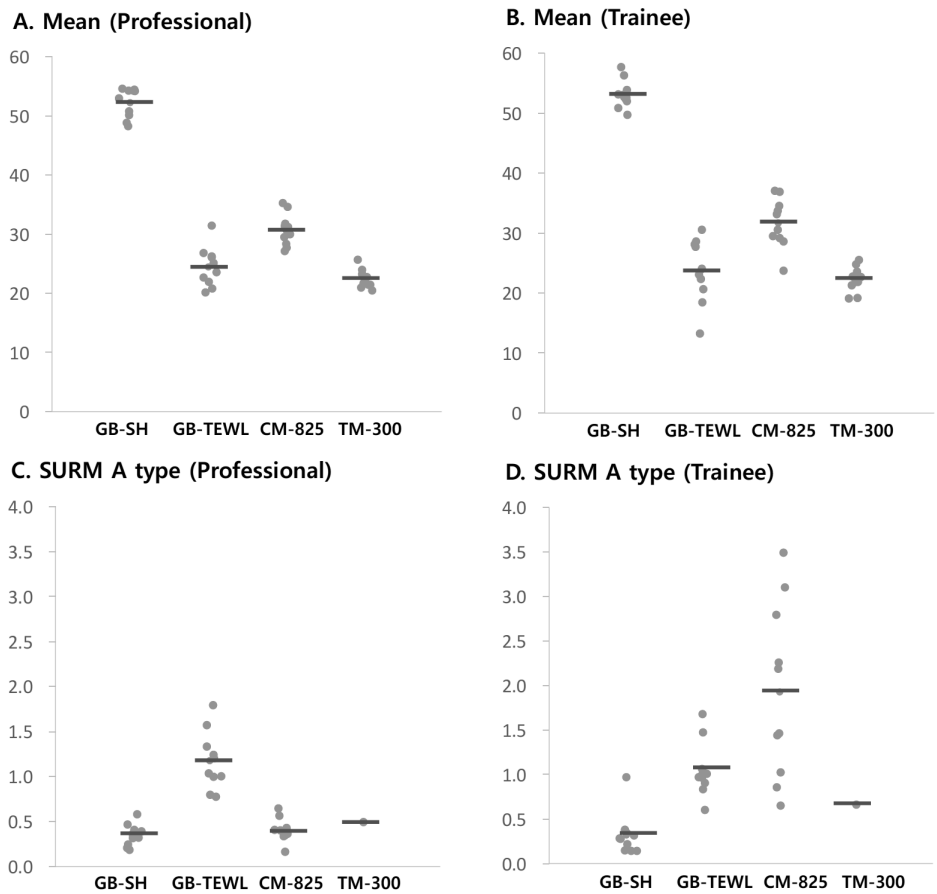


Fig. 3. Mean value and Standard uncertainty of repeated measurement (SURM) with GB-SH (Skin Hydration), GB-TEWL (Transepidermal water loss), CM-825(Skin Hydration) and TM-300((Transepidermal water loss) measures

A evaluation of standard uncertainty, which determines the standard uncertainty of repeated measurements, such as repeated measured values of a sample or pipette use, etc. In this study, SH and TEWL of the same site on the sole were measured 10 times by using three different apparatuses, GB(Gpskin barrier), CM-825, and TM-300, respectively. Four types of data were collected and are as follows: GB-SH, GB-TEWL, CM-825 (skin hydration), and TM-300 (trans-epidermal water loss). The mean value of each type of data is the average value of the type. The standard uncertainty was calculated by dividing the standard deviation of the 10 measurement values by the square root of 10, the number of trials.

The difference between the professional and the trainees was analyzed. The Kolmogorov-Smirnov test was used to check that the data followed the normal distribution, and the Mann-Whitney U-test was used to analyze the difference of the average values obtained by the two groups.

## Result

### 1. Traceability

In order to confirm the traceability data[8], calibration

certificates were obtained from the manufacturers of the Corneometer® CM-825 and Tewameter® TM-300 and were reviewed. However, there was no authorized standard reference of traceability or measurement uncertainty. In the case of the Gpskin barrier®, the test report on the human body in comparison with the Corneometer® CM-825 was obtained, but the manufacturer of the Gpskin barrier® did not have a calibration certificate. Therefore, the authorized traceability and measurement uncertainty of all the equipment was not identified in this study.

### 2. Subject Characteristic and Result Value

The subject was a 35-year-old male. Three males (mean age of 22.7) and seven females (mean age of 22.8) participated in the measurements.

As mentioned earlier, four types of data were collected using three different types of equipment. The professional measured 10 times per set, and a total of 10 sets were carried out. The 10 trainees each measured 10 times. The standard uncertainty and average value of each measurement are described in Figure 3. The results showed that, in the case of CM-825, the variance and mean value obtained by the trainees (0.61 ± 0.31) were higher than the values obtained by the professional (0.41 ± 0.13).

An analysis of the differences of the mean values and the standard uncertainty of the values measured by the professional and trainees was carried out (Table 1.) and confirmed that the variance in this study did not satisfy the normal distribution. The Mann-Whitney U-test was used to analyze the differences between the two groups, and there was no significant difference in the measured values.

## Discussion

In the treatment of patients with spondylosis and degenerative lumbar spinal stenosis accompanied by extensor hallucis longus muscle weakness, amyotrophy, and hypoactive deep tendon reflex[9], it was observed that dryness of the sole was improved depending on the region.

Diseases such as spinal stenosis disturb the neurotransmission process by physically compressing the autonomic nervous system, especially the sympathetic nervous system that passes around it[10]. This disturbance of the sympathetic nervous system due to pressure is believed to cause a direct change in perspiration, one of the physiological mechanisms, at the peripheral regions, such as the soles of the feet.

Korean Medicine describes the skin dryness as 燥因血少(Diseases of Dryness Are Formed Due to Lack of Blood), 燥者肺金之病(A Disease of Dryness Is a Disease of Lung Metal). Blood Should Be Nurtured in a Disease of Dryness[1].

The medical text Huangdi Neijing (黃帝內經) instructs that dryness should be moistened, meaning to nurture it with blood. An accumulation of fluid and humor can engender qi. An accumulation of qi engenders fluid and humor. A fine jade paste should be used. Bleeding and pain due to fire melting lung metal causes extreme dryness. If nutrient and defense dry, they should be moistened with a damp medicine [1].

The skin consists of the epidermis, dermis, and subcutaneous fat layer. Nerves, blood vessels, sweat glands, sebaceous glands, apocrine glands, and hair are present in the dermis and subcutaneous fat layer. The epidermis has keratinocyte and intercellular lipids, which play a key role in preventing the loss of body fluids and protecting the body from harmful factors. Therefore, it is essential to maintain a skin barrier for a healthy skin condition[2].

TEWL is known to be one of the main indicators of measuring skin barrier function. The loss of water through the skin occurs in two ways: eccrine sweat and transepidermal diffusion. The transepidermal

diffusion is regulated by ambient temperature, relative humidity, skin temperature, and the integrity of the stratum corneum[11,12]. TEWL is not only the best indicator of the severity of atopic dermatitis[13], but it is also used in many studies as an index to measure recovery after skin barrier damage[14,15].

The difference in TEWL values according to each body part is due to the diversity of skin structures, such as the distribution of the epidermis, the stratum corneum, and the distribution of sweat glands. The distribution of sweat glands plays an important role and is high in the palms and soles[2].

Uncertainty is the parameter that characterizes the dispersion of the quantity that is being attributed to a measure and is based on the information used. The higher the value, the greater the doubt, and the smaller the value, the greater the confidence level[16]. Standard reference refers to materials that are widely or repeatedly used in all areas on a national scale. Standard reference data are established by scientifically analyzing, evaluating, and authorizing the accuracy and reliability of measurement data and information [16]. Traceability is the property of a measurement result whereby the result can be related to a reference through a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty[8].

The four types of data were collected using three different types of equipment in this study. The professional measured 10 times per set, and a total of 10 sets were carried out. The 10 trainees each measured 10 times. The standard uncertainty and average value of CM-825 shown in Figure 3. describe a larger variance and a higher average value in trainees (0.61 ± 0.31) than the professional (0.41 ± 0.13). The average value and standard uncertainty obtained by two groups were analyzed to confirm the statistical significance. The variables do not follow a normal distribution. The Mann-Whitney U-test was used, and there was no significant difference between the two groups. The values of CM_SH were expected to have significant differences, but there was no significance. The statistical significance not being confirmed is possibly due to the large variance.

However, it seems that uncertainty or bias can be induced in the actual test. Because it is hard to maintain constant pressure due to the spring-loaded probe of the CM 825, the pressure on the skin may be different for each measurement. The TM-300 has a small standard deviation between measurers because it is attached to the skin using a sticker to measure the water loss. We reasoned that the uncertainty could be influenced by the proficiency of measurers. Therefore, it is important to use the probe carefully for clinical use.

Since the Gpskin barrier® uses a simple pressure type probe, the standard deviation of the interrater measurement value and the repeated measurement value are not large in the case of moisture. However, in the case of water loss, the standard deviations between repeated measurements and interrater measurements show that large differences representing values can, without caution, vary greatly depending on the proficiency in using the probe. Therefore, future studies should focus on the measurement devices to reduce the uncertainty of the measurement equipment.

This study is expected to establish the basis for later measurement equipment research to provide the objective indicators to approach dryness of plantar skin from 燥(dehydration), the Korean medicine perspective. In order to utilize the measurement method selected in this study as a diagnostic method in clinical practice, further comparative studies on sole hydration measurement are necessary.

In addition, in Korean Medicine research, especially clinical research, the development and standardization of various tests are of great significance to support clinical care, and it is necessary to actively expand the use of clinical equipment accordingly.

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## Conflicts of interest

The authors declare no conflict of interest.

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