Time of Onset to Changes in Skin Condition During Exposure to Synthetic Urine

A Prospective Study

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ABSTRACT

PURPOSE: The purpose of this study was to evaluate the impact of incontinence on epithelial-moisture barrier function and the subsequent risk for incontinence-associated dermatitis by exposing healthy volunteers to a premium incontinence pad wet with synthetic urine.

DESIGN: Prospective, single-group study.

PARTICIPANTS AND SETTING: Thirty women 65 years or older participated in the study. Participants had healthy skin of the buttocks, perineal, and perigenital areas and were not incontinent of urine or stool. The study was conducted at a contracted clinical research facility in Southeastern United States.

METHODS: Four hundred milliliters of synthetic urine was distributed across the width of a premium incontinence pad with wicking technology containing a superabsorbent polymer core. Participants laid supine for a total of 4 hours, with the wet pad under the buttocks. Skin assessments were conducted at baseline prior to contact with the wet pad, at 15 minutes, 30 minutes, and 1, 2, and 4 hours after exposure to the synthetic urine. Outcome measures were skin moisture content, cutaneous pH, transepidermal water loss (TEWL), mean coefficient of friction values (static and dynamic), and tolerability evaluations (expert clinical grader–assessed erythema and participant-assessed discomfort).

RESULTS: Mean moisture content of the skin increased from 46.19 ± 22.1 to 1845.28 ± 542.7 micro-Siemens (μS) after just 15 minutes of exposure and was significantly increased at all time points compared to baseline (P < .001). Cutaneous pH increased from 5.67 ± 0.5 to 6.25 ± 0.1 after 15 minutes; pH was higher at all time points compared to baseline (P < .001). Passive transfer of water through the stratum corneum (TEWL) showed an increase from 9.02 ± 2.2 g/m²/h at baseline to 16.83 ± 5.2 g/m²/h at 4 hours (P < .001). There was a significant increase from baseline to 4 hours in mean coefficient of static friction (0.32 ± 0.01 vs 0.47 ± 0.03; P < .0001) as well as mean coefficient of dynamic friction (0.29 ± 0.01 vs 0.42 ± 0.02; P < .0001). There was a significant increase in erythema and an increase in participant-assessed discomfort at all time points (P < .005).

CONCLUSIONS: Our findings suggest that impairment of the skin’s epithelial-moisture barrier function associated with inflammation and development of incontinence-associated dermatitis begins rapidly after an incontinence event, even with the use of a premium pad with wicking technology. Study findings also suggest that prompt attention to incontinence events is needed to prevent moisture-associated skin damage (incontinence-associated dermatitis) even when absorbent pads are used.

KEY WORDS: Epithelial barrier, Incontinence, Incontinence-associated dermatitis, Incontinence management, Incontinence pads, Moisture-associated skin damage, Moisture barrier, Skin health, Synthetic urine.

INTRODUCTION

The prevalence of urinary and/or fecal incontinence has been shown to be above 50% in the hospital environment.1 Exposure of the skin to fecal and urinary effluent may lead to incontinence-associated dermatitis (IAD), defined as erythema and edema of the surface of the skin, sometimes accompanied by bullae with serous exudate, erosion, or secondary infection.2

The prevalence of IAD varies widely from 5% to 50% in the acute care setting and has been recognized as a risk factor for even more serious skin damage such as full-thickness pressure injury (PI).3,4

Incontinence management strategies in the acute and critical care settings include toileting strategies, use of incontinence products such as pads or briefs, and use of indwelling catheter and fecal management systems in highly selected cases.5 Because of the risk of catheter-associated urinary tract infection associated with indwelling catheter use, many patients undergo early catheter withdrawal, resulting in urinary incontinence and an increased risk of IAD.6 There is a perception that incontinence pads with wicking technology are dry to the touch after an incontinence event, but even with these high-performance pads, patients remain at risk for development of IAD due to exposure to moisture. Limited evidence suggests that exposure to moisture may lead to IAD in as little as 4 days in critically ill patients.6
Research on the cause, pathophysiology, prevention, and treatment of IAD is expanding. It is understood that some of the components of urine and stool contribute to skin damage; it has been suggested that duration of exposure is the major causative factor associated with the development of IAD. The difficulty in establishing time to IAD onset is due to not knowing the precise time that an incontinence event has occurred and not being able to control for repeated exposure to urine and/or feces in the hospital environment. As a result of these limitations, detailed data on the duration of exposure to wet incontinence pads that can likely lead to moisture-associated skin damage have not been quantified.

Bioinstrumentation readings that measure skin surface pH or barrier function of the skin can objectively evaluate IAD and PI-related skin injury through assessments made at the skin surface (stratum corneum) before and after exposure to a potential irritant. It is well established that overhydration of the stratum corneum and pH changes disrupt the skin’s protective epithelial layer, allowing irritants to penetrate more easily and facilitate the growth of pathogenic bacteria, making the skin more susceptible to irritation and injury from friction.

Due to the difficulty in establishing the precise time of incontinence events in a hospital setting, an investigation in a laboratory setting using bioinstrumentation methods was designed to gain information related to short-term exposure to synthetic urine. The purpose of this study was to evaluate the influence of incontinence on skin health by exposing healthy volunteers 65 years or older to a premium incontinence pad with licking technology containing a superabsorbent polymer core wet with synthetic urine. A time series study was conducted to answer the following research questions: Does a single exposure change (1) moisture content of the stratum corneum and (2) skin surface pH, (3) skin barrier properties, (4) skin’s susceptibility to static and dynamic friction, and (5) objective and subjective tolerability assessments including discomfort.

METHODS

The study was designed as a single 4-hour exposure to synthetic urine in healthy participants. This trial was conducted at a contract clinical research facility in Southeastern United States. Study procedures were reviewed and approved by IntegReview institutional review board (IRB) (unique approval number not provided), All participants provided informed consent prior to data collection.

Potential participants were recruited by telephone using an IRB-approved script. Inclusion criteria were (1) women 65 years or older; (2) healthy skin in the buttocks, perineal, and perigenital areas; and (3) free of urinary or fecal incontinence. Prospective participants completed an eligibility and health questionnaire and were screened by the investigator or designee for inclusion criteria.

No power analysis for optimal sample size was conducted.

Study Procedures

All study procedures were conducted over the course of a single visit. Participants were advised to not apply any cream or lotion to the test areas (hip and buttocks regions) for at least 24 hours and to avoid showering or bathing the evening prior to and the day of the data collection visit. After informed consent was obtained, participants acclimated to ambient conditions for at least 15 minutes in a standing position to minimize the effect of seat lines on baseline irritation assessments of the test areas. Study rooms were maintained at a temperature of 68°F to 75°F and relative humidity of 35% to 65% per protocol (PP)-defined ranges. These ranges were within the optimal ranges for operation of all study bioinstrumentation measurements per the clinical research facility’s standard operating procedures.

Four hundred milliliters of synthetic urine was distributed across the width of a premium incontinence pad with licking technology containing a superabsorbent polymer core. The pad type was chosen because it is commonly used as an incontinence management strategy in the hospital environment. This amount of synthetic urine was chosen because it was within the normal range of volume of urine voided, and it provided moisture exposure across the entire test site. Synthetic urine was prepared according to a published formula: 1 L of synthetic urine contained 25 g of urea, 9 g of sodium chloride, 3 g of ammonium chloride, 3 g of sodium sulfate, 2.5 g of anhydrous disodium hydrogen orthophosphate, and 2 g of creatinine dissolved in approximately 1000 g of distilled water. The pH of urine varies from 4.8 to 8.0. Since this was a single-exposure study, the upper limit of pH was chosen, and the pH of the synthetic urine solution was adjusted using 10% ammonium hydroxide to achieve an alkaline pH of 8.0. Participants laid supine on standard hospital mattresses and frames for a total of 4 hours, with the wet pad under the buttocks such that the skin was in contact with the area of the pad containing the synthetic urine. Participants were permitted a single 10-minute break that was not included in the cumulative time that participants’ skin was in full contact with the wet incontinence pad. Assessments were conducted at baseline (prior to contact with the wet pad), at 15 minutes, 30 minutes, and 1, 2, and 4 hours after exposure.

Instruments and Outcome Measures

To better understand the exposure time that results in IAD, gold standard bioinstrumentation measurements were used to assess changes in the skin’s properties including moisture content of the stratum corneum (cutaneous hydrometer), pH of the skin’s surface, skin barrier properties through assessment of transepidermal water loss (TEWL), coefficient of friction values (static and dynamic), and objective and subjective tolerability assessments of the skin exposed to synthetic urine. All bioinstrumentation measurements were performed by trained clinicians at the study site.

Due to the multiplicity of bioinstrumentation methods used during this study, the fleshy region of the left buttocks was divided into 3 distinct regions and individual bioinstrumentation readings were performed in the same region for every time point. All coefficient of friction readings (static and dynamic) were performed on the fleshy part of the right buttocks.

Bioinstrumentation Measures

Skicon (cutaneous hydrometer) is a standard technique to measure the moisture level of the stratum corneum. Triplete Skicon-200EX Skin Surface Hydrometer (IBS Co, Ltd, Hamamatsu, Japan) measurements in micro-Siemens (μS) were taken on the fleshy region of the left buttock using high-frequency conductance methodology.

To assess any changes in the skin’s pH, triplicate Skin-pH Meter PH900 (Courage + Khazaka, Köln, Germany) measurements using a flat glass electrode were taken on the fleshy region of the left buttock. Measurements of pH are taken diurnally and subjective tolerability assessments including discomfort.
aqueous solution excreted by the skin and determined by the concentration of hydrogen ions (H\(^+\)), protons, and hydroxide ions (OH\(^-\)). An increase in pH reflects an impairment of the acidic protective properties of the skin.

A Tewameter measures the passive transfer of water through the stratum cornneum or TEWL. The measurement of this water evaporation is based on the diffusion principle in an open chamber, and the density gradient is measured indirectly by 2 pairs of sensors located inside the hollow cylindrical probe. An increase in TEWL values reflects a compromise in the barrier properties of the skin.\(^{13}\) In the current study, a single Tewameter TM 300 (Courage + Khazaka, Köln, Germany) measurement was taken on the fleshy region of the left buttock for a total of 3 minutes at baseline and for a total of 15 minutes at 4 hours to allow for evaporation of trapped surface water introduced by the incontinence pad from the stratum corneum to the atmosphere. Since this method requires a 15-minute reading period for all post–baseline time points, TEWL measurements were taken at baseline and 4 hours only to avoid drying of the skin due to prolonged exposure to ambient air that could confound other bioinstrumentation readings. The average of the plateau reading at baseline was compared to the average of the plateau reading at 4 hours to provide an indication of skin barrier function. Data were analyzed by a microprocessor and reported in g/m\(^2\)/h. To quantify skin surface water loss (SSWL) as a way to estimate the excess water in the stratum cornneum, the Tewameter measurement area under curve (AUC) at 4 hours was calculated using the method suggested by Fader and colleagues.\(^{14}\) For each participant, the average baseline reading between 0.5 and 2.5 minutes was subtracted from the 4-hour readings between 0.5 and 10.5 minutes and used in the AUC calculation. The unit for SSWL analysis is g/m\(^2\).

Skin friction or the skin’s coefficient of friction (static and dynamic) can be measured with the use of a sled attached to a motorized test stand (Chatillon LTCM 100) capable of measuring force and distance.\(^{15}\) An increase in values indicates an increase in friction, which indicates that the skin is more susceptible to injury. For each study day prior to use, the test system was validated using a standard ground steel friction verification plate. For each participant, a dry incontinence pad from the stratum corneum or TEWL. The measurement of this water evaporation is based on the diffusion principle in an open chamber, and the density gradient is measured indirectly by 2 pairs of sensors located inside the hollow cylindrical probe. An increase in TEWL values reflects a compromise in the barrier properties of the skin.\(^{13}\) In the current study, a single Tewameter TM 300 (Courage + Khazaka, Köln, Germany) measurement was taken on the fleshy region of the left buttock for a total of 3 minutes at baseline and for a total of 15 minutes at 4 hours to allow for evaporation of trapped surface water introduced by the incontinence pad from the stratum corneum to the atmosphere. Since this method requires a 15-minute reading period for all post–baseline time points, TEWL measurements were taken at baseline and 4 hours only to avoid drying of the skin due to prolonged exposure to ambient air that could confound other bioinstrumentation readings. The average of the plateau reading at baseline was compared to the average of the plateau reading at 4 hours to provide an indication of skin barrier function. Data were analyzed by a microprocessor and reported in g/m\(^2\)/h. To quantify skin surface water loss (SSWL) as a way to estimate the excess water in the stratum cornneum, the Tewameter measurement area under curve (AUC) at 4 hours was calculated using the method suggested by Fader and colleagues.\(^{14}\) For each participant, the average baseline reading between 0.5 and 2.5 minutes was subtracted from the 4-hour readings between 0.5 and 10.5 minutes and used in the AUC calculation. The unit for SSWL analysis is g/m\(^2\).

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Tolerability assessments or the condition of the skin at baseline and after exposure to the synthetic urine were objectively and subjectively assessed on each participant’s entire buttocks (the entire test area region) at all time points. A scale of 0 to 3 was used, with 0 representing no condition and 3 representing severe condition, with half-point scores assigned as necessary to better describe the clinical condition. A single expert clinical grader of skin from the test facility assessed the signs and symptoms of objective irritation parameters: erythema and edema. Subjective irritation was verbally communicated by participants including burning, stinging, itching, and discomfort. Discomfort ratings were recorded on a scale of 0 to 3, with 0 representing no discomfort associated with the treatment area and 3 representing severe discomfort associated with the treatment area.

### Data Analysis

Statistical analyses were performed using SAS software version 9.4 (SAS Statistical Institute, Cary, North Carolina). The PP population, which included all participants who received treatment and completed the study in general accordance with the protocol, was the primary population for all statistical analyses. For continuous variables, descriptive statistics including number of participants (N), mean, median, standard deviation (SD), minimum (MIN), and maximum (MAX) values were calculated. For categorical variables, the frequency and percentage of each category were calculated. Changes in bioinstrumentation data were analyzed using the paired t test. Changes in tolerability measurements were analyzed using the Wilcoxon signed-rank test. All inferential analyses were 2-sided, and P values more than .05 were deemed statistically significant.

### RESULTS

Thirty participants were enrolled and completed the study. Mean age of participants was 69.8 years; 73.3% (n = 22) of participants identified themselves as white, 23.3% (n = 7) as Asian, and 3.3% (n = 1) as black or African American. Data were collected on 6 separate days: 5 participants participated on each day of data collection, and all data for individual participants were collected on a single day. All participants completed study procedures, however, 1 participant was excluded from the Tewameter analysis due to high baseline values. Additionally, one participant’s baseline skin friction measurements were more than 2 SDs greater than the average and were deemed a statistical outlier based on a Tukey’s test. As a result, friction measurements for this participant were excluded from the analysis.

Epidermal water content over time measured by a cutaneous hydrometer is shown in Figure 1. An increase in values indicates increased hydration or overhydration of the skin. We observed a statistically significant rise in mean moisture content from 46.19 ± 22.1 μS at baseline to 1845.28 ± 542.7 μS after 15 minutes of exposure to urine. Change from baseline in epidermal water content was significantly increased at all time points (P < .001). All participants had an increase in epidermal water content at all time points.

The influence of exposure to a pad wet with synthetic urine is illustrated in Figure 2. Similar to epidermal water content, changes in pH were noted after 15 minutes of exposure, with an increase in mean pH from 5.67 ± 0.5 to 6.25 ± 0.1. The

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**Figure 1.** Mean cutaneous hydrometer values. μS is a measure of moisture level.
pH of healthy skin is within the range of 4.0 to 6.0, and the skin’s innate buffering properties work to maintain this range. An increase in pH, especially outside the healthy range, reflects a reduction in the protective properties of the skin. The increase in pH was statistically significant at all time points ($P < .001$). On an individual basis, at 15 minutes, 3 participants (10.0%) had a decrease in pH from baseline; 2 participants (6.7%) had a decrease in pH from baseline at 30 minutes, 1 hour, and 4 hours; and 1 participant (3.3%) had a decrease in pH from baseline at 2 hours.

Passive transfer of water through the stratum corneum as measured by the Tewameter (TEWL) showed a statistically significant increase in plateau from 9.02 ± 2.2 g/m²/h at baseline to 16.83 ± 5.2 g/m²/h at 4 hours ($P < .001$). This increase in TEWL indicates a reduction in barrier properties of the skin following 4 hours of exposure. Out of 29 participants, 1 participant (3.4%) had a decrease in TEWL at 4 hours. The AUC analysis showed a mean value of 2.20 g/m² at 4 hours. This calculation quantifies skin surface water loss as a way to estimate excess water trapped in the stratum corneum following 4 hours of exposure.

There was a statistically significant increase from baseline to 4 hours in the mean coefficient of static friction (0.32 ± 0.01 vs 0.47 ± 0.03; $P < .00001$) as well as the coefficient of dynamic friction (0.29 ± 0.01 vs 0.42 ± 0.02; $P < .00001$; Figure 3). Increases in these values are indicative of higher frictional properties of the skin and greater susceptibility to injury. Four participants’ (13.8%) findings did not demonstrate a statistically significant difference in coefficient of static or dynamic friction between baseline and 4 hours.

Study procedures were completed in groups of 5 participants on 6 different study days, and there was an apparent difference between the friction values based on study day that appeared to correlate with differences in ambient relative humidity. Lower average relative humidity (36.6%) was associated with lower average friction values, and higher average relative humidity (50.5%) was associated with higher average friction values. There was also a greater difference between baseline and 4-hour readings in the third through sixth groups of study participants than in the first and second groups. This was due to a longer period of time between the participant lying on the wet pad and the 4-hour friction test in the first and second groups of study participants.

Tolerability assessment scores indicated that there was a significant increase in participant-assessed discomfort and a significant increase in expert clinical grader–assessed erythema at all time points ($P < .005$) (Table). Participants reported mild to severe discomfort associated with the test sites; only 5 participants did not report any change in comfort following exposure to the wet incontinence pad. A total of 22 participants experienced mild to severe erythema in the test sites.

**DISCUSSION**

We investigated 4 skin properties of the buttocks of healthy female volunteers 65 years and older exposed to a synthetic urine–soaked incontinence pad. Skin moisture content (cutaneous hydrometer), cutaneous pH, TEWL, mean coefficient of friction values (static and dynamic) were measured at baseline and at 5 time points during the 4-hour exposure period. Findings showed that statistically significant changes in skin properties occurred after just 15 minutes of exposure to wet incontinence pads. Epidermal water content increased significantly after 15 minutes of exposure, indicating overhydration of the skin within a matter of minutes. The pH of the surface of the skin also increased by 0.58 (notably outside the healthy pH range) after 15 minutes of exposure. These statistically significant increases in epidermal water and pH did not equilibrate; they were sustained throughout the 4-hour study period. There was a corresponding significant increase in erythema, and participants reported discomfort at all time points. After 4 hours of exposure to wet incontinence pads, there was a statistically significant increase in TEWL, signifying a decrease in function and integrity of the stratum corneum.

Skin that is wet gradually loses mechanical strength and is more susceptible to injury at lower force levels. After 4 hours of exposure to wet incontinence pads, there was a statistically significant increase in both the coefficient of static friction and the coefficient of dynamic friction. These results are consistent with previous investigations measuring the skin’s frictional properties in a porcine skin model after exposure to moisture. However, to our knowledge, this is the first study to use 2 measures of coefficient of friction (static and dynamic) on the human buttocks, mimicking a real-world scenario to assess the impact of exposure to wet incontinence pads in the area most likely to develop IAD.

Exposure to urine is an etiologic factor for development of IAD and is associated with an increased likelihood of PI. Evidence further supports IAD as an independent risk factor for PI development, including full-thickness ulcers. Research findings have shown that patients with IAD are over 4 times more likely to develop a facility-acquired sacral PI and are nearly 3 times more likely to develop a partial-thickness stage 2 PI.

**Figure 2.** Mean skin surface pH values.

**Figure 3.** Mean CoF values (static and dynamic). CoF indicates coefficient of friction.
Our findings link exposure to wet incontinence pads with rapid changes in skin health and integrity; additional research of such exposure on the natural history of IAD in patients managed using absorbent pads placed on the bed is needed.

Participants in our study were otherwise healthy women, thus representing a best-case scenario when compared to incontinent patients in an acute or critical care setting. Incontinent older patients admitted to the hospital setting with an acute illness often have 1 or more comorbid conditions that increase their vulnerability to moisture-associated skin deterioration and IAD. We tested a single exposure of urine alone, which differs from patients who are at risk for fecal or dual urinary and fecal incontinence and often experience repeat incontinence episodes. Bliss and colleagues found that stool, and stool plus urine, was more likely to cause IAD than urine alone. Our findings indicated that synthetic urine alone can lead to impaired epithelial-moisture barrier function within a short duration of time.

There are gaps in the understanding of time to onset of IAD in the hospital setting due to nature of incontinence management and the difficulty in knowing how long a patient’s skin has been in contact with a wet pad. Routine rounding by the nursing staff is commonly used to monitor incontinence events and change wet pads. Fader and colleagues studied the impact of changing wearable superabsorbent incontinence pads every 4 hours versus every 8 hours in a long-term care facility. They found that although there was a decrease in skin wetness and a trend toward fewer full-thickness PIs in patients with pad changes every 4 hours, there was no difference in the incidence of IAD. Based on the results of our study, we posit that changes in skin properties associated with moisture-associated damage may occur prior to the 4- to 8-hour time period described in their research.

While most research in this area has focused on skin changes and associations with PI, in a group of community-dwelling adults with fecal incontinence and IAD, more than three-fourths of participants experienced pain and discomfort and over one-third of participants reported itching and burning. In the current study, there was a statistically significant increase in patient discomfort that ranged from no reported discomfort to severe discomfort. Study participants may expect some level of inconvenience or discomfort in a test setting, which may be reflected in some of the more modest discomfort levels reported by participants in this study. However, our collective clinical experience suggests that patients in a hospital setting with underlying conditions may be more impacted by sensory changes in the skin due to exposure to moisture, especially after repeat exposure. Additional research in this area is needed.

While not a specific study parameter, it is worth noting that incontinence negatively influences patient dignity and health-related quality of life. Improved incontinence management could improve patient satisfaction while reducing the risk for developing IAD or other moisture-related skin damage as well as decreasing costs of care from prolonged hospitalization and additional treatment.

Not all incontinent patients develop IAD. Risk factors for IAD include poor skin condition due to aging, poor nutritional status, raised body temperature, medications, critical illness, and use of products that occlude the skin. Several participants in the current investigation experienced no changes or no statistically significant changes in skin properties, for example, in pH or friction. This finding warrants further investigation of skin type and other factors such as body mass index, ethnicity, race, or sex that influence susceptibility to IAD or moisture-associated skin damage.

### STRENGTHS AND LIMITATIONS

The main strength of our study was recruitment and use of healthy volunteers 65 years or older rather than younger volunteers, more closely reflecting the influence of alkaline synthetic urine on epithelial-moisture barrier function in older patients. Limitations of our study included data collection in healthy volunteers rather than acutely or critically ill patients, variability in room temperature and humidity over the 6-day data collection period, and limited time frame for data collection.

### CONCLUSION

Study findings show that impaired epithelial-moisture barrier function of the skin begins rapidly after an incontinence event, even when participants were placed on a premium incontinence pad containing a superabsorbent polymer core. Specifically, we found clinically relevant and statistically significant changes in skin condition after 15 minutes of exposure to a wet incontinence pad. Our findings reinforce the importance of adopting incontinence management plans and technology resulting in timely response to incontinence events to minimize exposure and risk.

### ACKNOWLEDGMENTS

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*P < .005.*
REFERENCES


Call for Authors: Continence Care

Original research, case studies and case series addressing, in particular:

- Urinary or fecal stream diversion: indwelling urethral, suprapubic catheters or fecal/bowel management system.
- Pelvic floor muscle rehabilitation protocols for stress, urge and mixed urinary incontinence in men or women.
- Current state of the science presented in systematic reviews and/or meta analyses.
- Evidence based management of incontinence associated dermatitis or moisture associated skin damage.
- Incidence and prevalence of incontinence in understudied populations.
- Quality of life issues associated within continence, care-giving, catheter management, prevention of incontinence.