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**The effects of incontinence pad application on loaded skin with reference to biophysical and biochemical parameters: an exploratory cohort study using a repeated measure design**

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**ABSTRACT**

**Purpose**: The purpose of this study was to evaluate temporal changes in skin responses following exposure to moisture alone or moisture in combination with mechanical loading.

**Design**: Exploratory cohort study to evaluate the effects of incontinence pad application using a repeated measure design on individuals of two different age groups

**Subjects and Settings**: The sample comprised 12 healthy volunteers. Participants were purposely sampled from two different age groups; 50% were 32 to 39 years and 50% were from 50 to 62 years old. Participants identified as white, black or mixed; 83% (n= 10); 8 (67%) were female.

**Methods**: Four sites at the sacrum were challenged with application of specimens taken from two absorbent products; the pad specimens were applied dry or saturated with synthetic urine (SU, pH=8); a further site from the sacral skin was also selected and used as a control. Skin assessments were performed at different points in time: 1.) 60 minutes after exposure to dry or SU saturated pad specimens, 2.) 60 minutes after exposure to pads and mechanical loading (application of pressure in the form of 45⁰C high sitting), and 3.) 30 minutes after removal of all pads (recovery period). Outcome measures were Transepidermal water loss (TEWL), Stratum Corneum (SC) hydration, erythema, pH and skin inflammatory biomarkers measured at each of the time points described above.

**Results**: The control site and those exposed to dry pads showed minimal time-dependent changes irrespective of the parameter investigated. By contrast, significant increases in TEWL (p=0.0000007) and SC hydration responses (p= 0.0000007) were detected at the sites under absorbent pads specimens after saturation with SU (exposure to moisture). In some participants, TEWL and SC hydration parameters were significantly higher during pressure application. Skin pH remained in the mildly acidic range throughout the test session and no consistent trends were observed with erythema. Skin inflammatory biomarkers also exhibited considerable variability across participants with none of the analysed biomarkers presenting significant temporal or spatial changes (p> 0.05).

**Conclusion**: We evaluated an array of parameters to identify changes following skin exposure to two absorbent pads in the presence and absence of synthetic urine and mechanical loading. Analysis revealed changes in skin barrier properties in the presence of moisture and/or pressure. Statistical significant differences (p=0.02) were also detected following the exposure of moisture in combination with pressure.This observation suggests a need for frequent pad changing as well as periods of skin offloading to protect the skin health of individuals with incontinence.

**Keywords**: Incontinence associated dermatitis (IAD), Continence pads, Moisture, Mechanical loading, Skin biomarkers, skin health

# INTRODUCTION

There are multiple scenarios where prolonged exposure to moisture can influence the barrier properties of the skin. For example, exposure to urine and/or fecal matter can lead to development of incontinence-associated dermatitis (IAD), a form of irritant contact dermatitis that exerts negative physical and psychosocial effects on patients and challenges care providers striving to maintain skin health in individuals with urinary or fecal incontinence.1,2  Clinical manifestation of IAD range from mild erythema to more extreme tissue loss and skin breakdown. The perineal, perianal, inner thighs and convex areas of the buttocks are most commonly affected.3 Individuals with IAD also experience significant distress due to pain, burning and itching in the affected areas, resulting in reduced health related quality of life, including loss of independence, depression and sleep disturbance.4,5

Prolonged exposure to urine overhydrates the skin and decreases tissue tolerance to friction and pressure.6,7 . In addition, alkaline urine activates digestive enzymes present in stool, disrupts the skin’s acid mantle, alters the normal microbiome with increased colonization with coliform bacterial species, diminishes stratum corneum cohesion, and compromises the skin’s barrier function.8  In addition, prolonged skin contact with urine induces changes in the local microclimate, where heat, humidity and moisture and decrease the protective function of the skin.9

Current interventions for the prevention and treatment of IAD are designed to minimize skin exposure to urine and/or stool through the management of incontinence and a structured skincare regimen. This typically comprises prompt cleansing of the skin to remove irritants, use of leave on skin protectants, and restoration of skin moisture. However, studies have demonstrated that incontinence pads can contribute to IAD when left in-situ for prolonged periods of time.1,10 Indeed, it has been asserted that prolonged contact between a patient and incontinence pad induces occlusion of the skin and alters the microclimate leading to increase temperature and humidity11, higher transepidermal water loss (TEWL), and disruption of the skin-ambient fluid exchange mechanisms.12

Changes in epidermal function due to prolonged exposure to moisture, with or incontinence products, have been the subject of various studies that have evaluated the biophysical pathways underpinning the loss of skin integrity.11,13,14 In addition, we found one study that indicated that a significant increase in transepidermal water loss (TEWL) occurred when skin was challenged by moist incontinence pads in combination with mechanical loads.15  However, investigators achieved loading of the sacrum via custom-made cylindrical weights, which are not reflective of the real loading scenarios in acute and long-term care facilities. Another study demonstrated a significant increase in mean skin surface water loss when irritated skin was exposed to synthetic urine.16 Another study found that variations in a more alkaline cutaneous pH lead to dryness and decreased antibacterial defenses of the skin’s barrier function.17 Biochemical markers of local inflammation post moisture exposure have recently been explored; researchers reported a significant increase in pro-inflammatory interleukin 1 alpha (IL-1α) following exposure to saturated incontinence pads and mechanical loads.15 However, there is still limited understanding of the exact role of biomarkers, hydration, pH, and mechanical loading in the development of skin damage. Therefore, the aim of this study was to investigate temporal changes in sacral skin health parameters following exposure to dry and moist continence pads, with and without the addition of postural mechanical loads. To explore the effects of age, exposure to continence pads and loads will be conducted on younger and older groups of health individuals. Outcome measures will include skin barrier function (TEWL, erythema, cutaneous pH, cutaneous hydration), inflammatory biomarkers sampled in sebum and secondary analysis of pH within incontinence product specimins pre- and post-application.

# MATERIALS AND METHODS

An exploratory repeated measures study was designed to interrogate the effects of incontinence pad application both in dry and moistened states on individuals of different age groups.Study participants were able-bodied volunteers from the local community; they were recruited through poster advertisements and local recruitment strategies. Exclusion criteria were 1.) back pain limiting the time spent in the supine position, 2.) active skin diseases on one of the test sites, 3.) diabetes mellitus, 4.) use of non-steroidal anti-inflammatory drugs in the last 7 days. Study procedures were reviewed and approved by the University of Southampton Ethics Committee (Approval #: FOHS-ERGOII 25851.A1). Written, signed and dated consent was received from each participant prior to commencing the test session. Participants received a £25 voucher (approximately $31.45 USD) as compensation for the time spent participating in the study.

**Absorbent Products**

The study included two different absorbent incontinence pads, referred to as products M and T (both were provided by Essity AB, Gothenburg, Sweden and currently not commercially available). These products were similar in design and specification apart from the central absorbant material (core). Direct comparison between products was not made due to their similar design and material interface. Both products were prepared in the form of circular-shaped specimens with a diameter of 40 mm and prefabricated to include the following sections: 1.) a top sheet of non-woven polypropylene (PP), 2.) an absorbent core of cellulose fibers and a superabsorbent polymer (SAP) particles, and 3.) a back-sheet of polyethylene (PE) and non-woven laminate. The two products differ from each other in terms of the acquisition material component, which consisted of a curly fire layer for product M and non-woven fabric for product T. Both pads are designed to allow transport of urine through the top sheet, subsequent transport through the acquisition layer and storage in the core layer.

Synthetic was kept refrigerated at 4⁰C and allowed to acclimatize to room temperature prior to each test session. The pH of the synthetic urine was monitored at each session using a pH meter (pH 213 Microprocessor pH Meter, HANNA Instruments, UK) to ensure consistency. Approximately 15 ml of SU (pH = 8.0) was dispensed into the pads via serological pipettes until saturation was achieved, as observed by a small leakage of fluid from the pad samples. Each sample was then left to equilibrate for 15 minutes to ensure equal distribution of the liquid within the product.

Two saturated incontinence products were exposed to the ambient environment and attached to the skin to examine urine loss over a 90-minute period. Subsequent gravimetric tests revealed that both products lost less than 1.5% of the respective saturated weight due to evaporation. This increased to approximately 3% following a combination of evaporation and diffusion.

**Instruments and Outcome Measures**

To investigate the skin’s epithelial (moisture) barrier function, we measured multiple outcome variables that were attained using non-invasive biophysical techniques. The outcome variables were transepidermal water loss (TEWL), stratum corneum (SC) hydration, skin pH, and erythema. We measured TEWL using an open-chamber method (Tewameter TM 300, Courage & Khazaka, Germany), which was placed in gentle contact with the skin for 60 seconds. The skin’s TEWL was operationally defined as the mean loss of grams of water per square meter of skin per hour (g/m2/hr) from the last 10 measurements recorded after a period of equilibrium had been achieved. Stratum corneum hydration was determined using a Corneometer (CM 825, Courage & Khazaka, Germany). This variable was estimated by averaging 5 repeated values and was expressed in arbitrary units (AUs). In addition, pH and erythema were measured using a pH meter (PH 905, Courage & Khazaka, Germany) and a Mexameter (MX18, Courage & Khazaka, Germany), respectively. The measurement principle of Mexameter MX18 is based on the absorption and reflection of three specific light wavelengths emitted by the device when in contact with the skin. The melanin content of the individual measured can impact the reflection of these lights, as such influencing its output values. The outputs from both devices were obtained with each probe in gentle contact with the skin. For both parameters, a mean of repeated measures was estimated in AUs.

Inflammatory biomarkers were measured in a biofluid (sebum) that is released from the surface of the skin; it was collected using a commercial adhesive tape, Sebutape patch (CuDerm, Dallas, TX, USA), according to a standardized protocol describe in a previous publication.19 The adhesive tapes were attached to the skin, using surgical pick-ups and gloved hands, and held in place for 2 minutes. The tapes were subsequently removed, placed in appropriately labelled containers, and stored at -80⁰C until biochemical analysis.

The extraction of inflammatory biomarkers was performed using a modified protocol, enhanced by introduction of chemical and mechanical stimuli to improve the extraction efficiency.19 Specifically, containers with individual adhesive tapes were thawed to room temperature, and a 0.85 mL solution of PBS (Sigma-Aldrich Co, St. Louis, Missouri, USA) and 0.1% dodecylmaltoside (DDM) (Thermo Fisher Scientific, UK) was added to each container. After 1 hour of shaking vigorously and immersion in the solution, the containers were sonicated for 5 minutes. The adhesive tapes were then discarded and 0.5 mL of the extraction buffer was transferred into vials for centrifugation. Subsequently, the vials were centrifuged at 4⁰C for 10 minutes at 15000g. The supernatants were discarded and the pellets vortexed vigorously for 10 seconds. An ELISA immunoassay conducted using U-Plex assay kits (Meso Scale Diagnostics, USA) was performed on samples from the sacral three sites covered by saturated incontinence product specimens to quantify concentrations of inflammatory biomarkers IL-1α, IL-1RA, TNF-α, INF-gamma, IL-6 and IL-8.

**Study Procedures**

All tests were performed in a laboratory maintained at a room temperature of 22.5 ± 0.7 ⁰C (72.5 ⁰F) and relative humidity of 42 ± 6%. Participants were allowed to acclimatize to this environment for 15 minutes prior to data collection. Demographic data (gender, ethnicity, and BMI) were recorded during this period of acclimatization.

Five sites (A, B, C, D, and E) on the sacrum and lower lumbar spine of each participant, separated by an area of 40mm x 60mm, were marked using a non-permanent marker (Figure 1a). Sites A and B were exposed to the dry samples M and T, respectively, while sites C and D were exposed to the corresponding 100% saturated samples. Site E represented the negative control skin site, which remained unchallenged (not covered by any product or secondary dressing) throughout the test period. The samples were held in place with the use of strips of an impermeable adhesive dressing (3M™ Tegaderm™, Minneapolis MN, USA) to minimize leakage and cross-contamination between test sites.

A standardized protocol was used to challenge the skin with each test condition (Figure 1a). After 15 minutes of acclimatization, the baseline values for each variable used to evaluate the skin’s barrier function were recorded at each test site. In addition, pH values of the surface and core of the saturated samples were taken using a pH meter (pH 905 Courage & Khazaka, Germany). Subsequently, the five sacral sites were each exposed to their respective test condition in an unloaded state (with participant lying in a prone position) for 60 minutes. At the end of this period, the incontinence product specimens were removed for a brief period for an intermediate skin assessment. This was followed by an additional 60 minutes of exposure to a mechanical load, which was applied by participants adopting a semi-Fowler’s position using a commercially available hospital bed frame and visco-elastic foam mattress (Virtuoso, Wissner-Bosserhoff, Germany). In this posture, participants were positioned on their back with the head and trunk raised to a 45 degrees bed angle, with the knees raised to flex the legs. At the end of this test phase, after 120 minutes of exposure to study interventions (Figure 1b), the absorbent brief specimens were removed, and the skin was blotted with a soft, dry cloth to remove any excess fluid. Outcome variables were then re-assessed at each site. In addition, the pH values of the saturated pads were recorded. Participants were allowed a further 30 minutes of recovery period, prior to a final skin assessment at 150 minutes.

**Data Analysis**

Data from each outcome variable were imported into Microsoft Excel (Microsoft 365, USA) and normalized to baseline values (i.e. post application value/baseline value). Similar to the proves of normalization used for epithelial (moisture) barrier outcomes, inflammatory biomarker values were also normalized to a baseline value (time point zero) to accommodate individual variability in sebum values, as previously described.15,20 Closer analysis of the data revealed their distribution was non-normal in nature and non-parametric inferential statistical tests were used to analyze study outcomes. The Mann–Whitney U test was used to analyze differences in responses at the different time points of data collection. The Friedman test was employed to investigate whether challenges (application of moisture and tissue load) to the skin were resulted in temporal variations in study outcomes reflecting epithelial barrier function dn inflammation). The rank function test was used to compare the values across the experimental time frame as previously described.15,21 Tests were deemed statistically significant when p < 0.05.

**RESULTS**

Twelve healthy volunteers, four males and eight females with a Body Mass Index (BMI) ranging from 18.5-37.7 kg/m² (mean ± SD = 26.9 ± 5.7 kg/m²) were recruited into the study (Table 1). Participants were purposely sampled from two different age groups (middle-aged adults); 50% ranged in age from 32 to 39 years and 50% ranged from 50 to 62 years old (late middle aged). The mean age ± standard deviation of the middle-aged individuals was 35.5 ± 2.9 years, while the corresponding value for late middle-aged partcicpants was 55.3 ± 4.2 years old. The two different age groups of participants were selected to interrogate whether there could be possible differences in skin responses to moisture and mechanical challenges. Participants identified as white, black or mixed; 83% (n= 10) identified as white. It is of note that the current study did not report on differences between the two products, namely T and M due to their similarity in material and design.

**Transepidermal Water Loss**

The control site (E) had absolute TEWL values ranging from 5.2 – 14.9 g/h/m² throughout the test period. Analysis revealed minimal changes in normalized TEWL at site E at any time point, corresponding to a ratio of approximately 1.0 across all time points (Figure 2). Small, non-significant variations in normalized TEWL were detected at the dry sites (A and B) with ratio changes below 2.0 for all participants with the exception of participants #2, #7 and #9, who exceeded this threshold following the application of pressure when measured at 120 minutes. This finding is reinforced by the total ranks associated with sites A and B, whose maximum values generally corresponded to 120 minutes, following application of mechanical load on the dry pads.

Following the application of saturated pads to the skin, a number of TEWL-related temporal trends were observed (Figure 2). Site C (exposed to 100% saturated M product) revealed ratios ranging from 2.0 to 5.7, analysis indicated these differences represented a significant increase from baseline values after both 60 and 120 minutes (p= 0.0000007). Differences in TEWL values at 60 and 120 minutes values across participant’s were not significant.

Analysis also revealed a significant increase (p=0.00009) in TEWL at site D (subjected to 100% saturated product T)immediately after exposure to saturated samples. However, in contrast to site C, the addition of a mechanical load (120 minutes) demonstrated a significant increase in TEWL (p=0.02). Specifically, 10 out of 12 participants exhibited higher TEWL responses following skin loading, with ratios ranging from 2.5 to 5.7, corresponding to absolute values of 33.3 – 47.7 g/h/m² (Figure 2). Accordingly, the rank sums profiles differed, with the highest values corresponding to 60 and 120 minutes for sites C and D, respectively.

Analysis also revealed that TEWL ratios decreased tending towards basal values across participants for all test sites following the 30-minute recovery period (Figure 2). Nevertheless, that the total rank sums following the recovery period remained higher than corresponding baseline TEWL values.

**Stratum Corneum Hydration**

The temporal profiles of SC hydration values at the five sacral skin sites are presented in Figure 3. Absolute SC hydration values ranging between 5.8 – 86.9 AUs. In addition, no consistent changes in skin hydration were observed at the sites under dry conditions (A and B), with only a few participants (#7, #9, #10) demonstrating small increases post mechanical loading. Nonetheless, the corresponding rank sums of the hydration values revealed the highest ratios observed at 120 minutes (Figure 3).

The skin hydration values at sites C and D increased significantly (p=0.0000007 for site C and p= 0.002 for site D) after 60 minutes of exposure to moisture (Figure 3). The relative change following mechanical loading were different with the profiles for the rank sums reached a maximum value at 60 minutes for site C, and it reached a maximum value at 120 minutes for site D. Figure 3 also illustrates that 10 of the 12 participants demonstrated a skin hydration ratio that declined towards baseline values for all test sites following the 30-minute recovery period. Nevertheless, the total rank sums following the recovery period remained higher than baseline values of skin hydration during the recovery period, indicating partial recovery following removal of moisture and tissue load during data collection. The control site (E) presented no temporal changes although a degree of inter-subject variability was evident.

**Erythema**

Erythema did not change over time, nonetheless, with a high degree of inter-subject variability ranging from 6.8 to 457.8 AUs. We found no significant changes in erythema values for any of the five sites over time. The sites exposed to the dry sample pads (sites A and B) demonstrated a small increase in erythema values at 120 minutes after the application of pressure, particularly in two participants (#10 and #11). We also observed that at sites C and D there was a decrease in erythema below basal values for all participants after moisture exposure at 60 minutes (median ratio = 0.7, range 0.1-1.2), followed by an increase after the period of mechanical loading (median ratio = 0.9, range 0.5-2.9). There were isolated cases of time-dependent changes were detected at the control site E. After the recovery period of 150 minutes, erythema values were generally similar to those of the baseline values.

**Skin pH**

We found no significant temporal changes at any of the test sites; absolute pH values ranged from 4.7 to 6.9. All participants maintained a skin pH at a slightly acidic level throughout the test session.

**Inflammatory Biomarkers**

A summary of the post to pre-insult ratios of the six cytokines is presented in Table 2. With respect to sites B and D, no consistent temporal trends across the cohort were observed. However, there were statistically significant temporal differences in Site-B for the low abundance biomarkers, such as IL-6 (p=0.03), TNF-α (p=0.04) and INF-γ (p=0.02). Close examination of the data revealed variable temporal changes in cytokines relative to basal values, as an example, with INF-γ, IL-6 and TNF-α ratios increasing at time points 60 and 120 at site 2 (median ratios of 1.27-1.94). However, IL-1α, IL-8 and IL-1RA displayed no significant changes (p>0.05) over time (median ratios of 0.54-1.10). Moreover, it was observed that at the control site 3 all the cytokines displayed variable changes in the ratio values (median ratios of 0.53 -1.16), with the exception of IL-6. Normalised ratio of pro-inflammatory cytokines to its corresponding anti-inflammatory cytokine, i.e., IL-1α/IL-1RA revealed no significant (p>0.05) changes in all sitees, with the majority of the participants exhibited a ratio value of 1 at Site B and Site D (Figure 4 and Table 6-2).

**Absorbent Product Ph**

The cutaneous pH values at the surface and core of the two different absorbent products were analyzed before and after the two skin challenges at sites C and D. In 11 of 12 participants, the baseline pH values at the surface and core of both types of sample pads were higher than the post test session values; specifically surface pH values ranged from 0.2 to 2.6, and pH values at the absorbent cores ranged from 0.2 to 1.2. Following application of a tissue load, pH values ranged from 5.3 to 6.5 and from 5.7 to 6.5 AUs on the surface and core, respectively. These acidic values persisted up to 150 minutes. Considered collectively, these findings indicate that the products were able to support the maintenance of the skin pH values by reducing the pH of the synthetic urine from alkaline to acidic.

We also evaluated the buffering capacity on the skin underneath the products saturated with SU (sacral skin sites C and D). Baseline cutaneous pH values were in the acidic range at both sites (4.7 – 6.1 AUs). When measured 60 minutes, cutaneous pH values rose to the near neutral pH range (5.8 – 6.9) with a single exception (participant #1). By contrast, at the end of the test session (120 minutes), the pH absolute values of the surface of both products were within a mildly acidic range (5.3 to 6.5 and 5.4 to 6.5 for products M and T, respectively).

**DISCUSSION**

We examine changes in specific parameters reflecting skin health following the application of specimens of absorbent pads for incontinence, either dry or saturated with SU, to a sample of healthy participants aged between 32 to 39 years old (middle-age adults) and from 50 to 62 years old (late middle-aged). We found significant increases in TEWL and SC hydration ratio values at the sites exposed to saturated pad specimens at 60 minutes; these changes were maintained or exacerbated following application of mechanical load created by raising the head of the bed to 45 degrees at 120 minutes. We hypothesize that these findings may be attributed to the combination of prolonged skin interaction with moisture in the presence of occlusion. However, after a 30 minute recovery period, TEWL and SC hydration returned to values comparable to baseline, indicating no evidence of prolonged skin changes.

Several studies have reported potential harmful effects when the skin is exposed to occlusion plus moisture with or without increased tissue load (interface pressure), including overhydration of the stratum corneum, increases in the dynamic and static friction coefficients of exposed skin, and a greater susceptibility to skin damage.14,22 Our findings are consistent with these studies, which examined the impact of exposure of moisture (water or sodium lauryl sulphate solution) and mechanical loads at a range of skin sites e.g. sacrum, heel, which demonstrated changes to skin barrier function.15,23,24 In contrast, we found significantdifferences in TEWL and skin hydration when skin was occluded under a dry absorbent pad specimen, although a few participants (4/12) displayed small increases in TEWL following exposure to mechanical loads resulting from the high sitting posture (Figure 2). The skin hydration values, however, were only influenced when the pads were saturated with SU (Figure 3). This finding was anticipated the SC hydration method estimates the water gradient and as such, the superimposition of mechanical loads on saturated pads would enhance infiltration of water into the skin, thus altering the flow gradient [25]. In addition, both the TEWL and SC hydration values return to values comparable to baseline measurements following the 30-minute recovery period. This finding supports traditional practice advocated by multiple clinicians who recommend allowing the skin to be dried on a daily basis. Nevertheless, a study detailing the temporal behavior of these parameters is needed to confirm this concept and identify the minimum and optimal recovery period.

No significant or consistent changes were observed in erythema over time. In contrast to anticipated trends in development of erythema, 9 out of 12 participants demonstrated a decrease in erythema below baseline levels following exposure to SU. These values generally returning to baseline after the recovery period. Our findings are consistent with those from other studies which demonstrated no considerable changes in skin redness post exposure to moisture and/or mechanical loading [26, 27]. Nevertheless, study findings also may reflect a lack of ability to detect subtle changes in skin tone due to variability in healthy skin tone, anatomic, location, and environmental factors such as temperature and humidity.27,28 Further, we used an instrument to measure skin tone rather than clinical observation. Though not formally measured and observation during testing revealed no visible redness in the skin surface. Additional research is needed to determine whether visible changes in erythema at the surface of the skin is a reliable indicator of epithelial barrier function of the skin versus some alternative physiologic parameters not currently available in the clinical practice setting.

Findings demonstrated that the skin pH of all participants remained in the acidic range when exposed to both dry pad specimens and those saturated with SU with an alkaline pH of 8.0, irrespective of the incontinence product. These findings are consistent with a study which showed surface pH in the acidic range following the exposure of the skin to incontinence briefs containing spiral-shaped fiber wet with an alkaline solution.29 Contrary to our findings, other studies demonstrated an increase in pH when the skin was exposed to SU.12,16 These differences may be partly attributable to different absorbent product designs used in previous studies.

Inflammatory skin biomarkers varied widely across the study participants (Table 2). Nevertheless, upregulation of both the inflammatory biomarkers we measured occurred in 7 of the 12participants at both dry and SU-saturated test sites (Figure 4). Increased expression of the high abundance proteins IL-1α and IL-1RA following skin exposure to moisture has been previously reported.15,30 Findings from a recent study indicated an increase in IL-1α when skin was in contact with pads moistened with 0.9% saline solution alone; however, no differences in the expression of low abundance proteins (TNF-α, IL-6 and IL-8) were detected.12 These discrepancies in study findings also may attributed to our use of an optimized method of extraction involving both chemical and mechanical stimuli.31

**Limitations**

The study is limited by its small sample size and lack of diversity in persons with darker skin tones. In addition, the two age groups in the cohort were only separated by only 10 years. Also, the study did not recruit individuals over the age of 70 years, who are more representative of users of absorbent incontinence products. Generalizability of study findings are also limited by the exposure time to for condition. Specifically, an exposure time of 120 minutes may not reflect clinical practice, where body worn absorbent products are often worn for more than two hours, and where a 30 minute recovery time is not practicable.33 Furthermore, for ease of data interpretation, interventions were not allocated randomly based on skin site Finally, the use of a this film barrier dressing to reduce the prevent cross-contamination between sites might have influenced changes in skin parameters due to the occlusive nature of this dressing.

# CONCLUSION

We measured an array of biophysical and biochemical parameters to characterize the response of sacral skin occluded under an absorbent incontinence product; some skin areas were exposed to a dry absorbent pad specimen while other areas were exposed to a pad specimen exposed to SU and mechanical loading. Study findings suggest the potential beneficial effects of incontinence products when employed in a dry state. However, the presence of sufficient moisture to saturate the absorbent pad, when applied alone or in combination with mechanical loads caused changes in TEWL and SC hydration, which were restored following 30 minutes of recovery period. Analysis of biomarkers indicated subject-specific skin inflammatory responses in both dry and SU saturated pad sites. There is therefore a compelling need to ensure that individuals presenting with incontinence have regular pad changes, as well as periodic intervals of off-loading of pressure from the skin underneath an absorbent product.

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**REFERENCE**

1. Gray, M., et al., Incontinence-associated dermatitis: a comprehensive review and update. Journal of Wound Ostomy & Continence Nursing, 2012. **39**(1): p. 61-74.

2. Cunich, M., et al., The Costs, Health Outcomes and Cost-effectiveness of Interventions for the Prevention and Treatment of Incontinence-Associated Dermatitis: A Systematic Review. International Journal of Nursing Studies, 2022: p. 104216.

3. Beeckman, D., A decade of research on Incontinence-Associated Dermatitis (IAD): Evidence, knowledge gaps and next steps. Journal of Tissue Viability, 2017. **26**(1): p. 47-56.

4. Gray, M. and K.K. Giuliano, Incontinence-Associated Dermatitis, Characteristics and Relationship to Pressure Injury: A Multisite Epidemiologic Analysis. Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society, 2018. **45**(1): p. 63-67.

5. Beeckman, D., et al., Incontinence-associated dermatitis: moving prevention forward. Wounds International, 2015.

6. Lichterfeld-Kottner, A., et al., Maintaining skin integrity in the aged: A systematic review. Int J Nurs Stud, 2020. **103**: p. 103509.

7. Lumbers, M., Moisture-associated skin damage: cause, risk and management. British Journal of Nursing, 2018. **27**(Sup12): p. S6-S14.

8. Fluhr, J.W. and P.M. Elias, Stratum corneum pH: formation and function of the ‘acid mantle’. Exogenous Dermatology, 2002. **1**(4): p. 163-175.

9. Ichikawa-Shigeta, Y., et al., Physiological and appearance characteristics of skin maceration in elderly women with incontinence. Journal of wound care, 2014. **23**(1): p. 18-30.

10. Junkin, J. and J.L. Selekof, Prevalence of incontinence and associated skin injury in the acute care inpatient. J Wound Ostomy Continence Nurs, 2007. **34**(3): p. 260-9.

11. Falloon, S.S., et al., The Impact of Microclimate on Skin Health With Absorbent Incontinence Product Use: An Integrative Review. Journal of Wound Ostomy & Continence Nursing, 2018. **45**(4): p. 341-348.

12. Koudounas, S., S. Abbas, and D. Voegeli, The Effect of Absorbent Pad Design on Skin Wetness, Skin/Pad Microclimate, and Skin Barrier Function: A Quasi-experimental Open Cohort Study. Journal of Wound, Ostomy and Continence Nursing, 2020. **47**(5): p. 497-506.

13. Fujimura, T., et al., The influence of incontinence on the characteristic properties of the skin in bedridden elderly subjects. International journal of dermatology, 2016. **55**(5): p. e234-e240.

14. Phipps, L., M. Gray, and E. Call, Time of Onset to Changes in Skin Condition During Exposure to Synthetic Urine: A Prospective Study. Journal of Wound Ostomy & Continence Nursing, 2019. **46**(4): p. 315-320.

15. Bostan, L.E., et al., The influence of incontinence pads moisture at the loaded skin interface. Journal of tissue viability, 2019. **28**(3): p. 125-132.

16. Koudounas, S., D.L. Bader, and D. Voegeli, Elevated Skin pH Is Associated With an Increased Permeability to Synthetic Urine. Journal of Wound, Ostomy and Continence Nursing, 2021. **48**(1): p. 61-67.

17. Schmid-Wendtner, M.H. and H.C. Korting, The pH of the skin surface and its impact on the barrier function. Skin pharmacology and physiology, 2006. **19**(6): p. 296-302.

18. Mayrovitz, H.N. and N. Sims, Biophysical Effects of Water and Synthetic Urine on Skin. Advances in Skin & Wound Care, 2001. **14**(6): p. 302-308.

19. Perkins, M.A., et al., A noninvasive method to assess skin irritation and compromised skin conditions using simple tape adsorption of molecular markers of inflammation. Skin Research and Technology, 2001. **7**(4): p. 227-237.

20. Henshaw, F.R., et al., Evaluating the effects of sedentary behaviour on plantar skin health in people with diabetes. Journal of Tissue Viability, 2020. **29**(4): p. 277-283.

21. Jayabal, H., et al., Anatomical variability of sub-epidermal moisture and its clinical implications. Journal of Tissue Viability, 2021.

22. Gerhardt, L.C., et al., Influence of epidermal hydration on the friction of human skin against textiles. Journal of the Royal Society, Interface, 2008. **5**(28): p. 1317-1328.

23. Firooz, A., et al., The effects of water exposure on biophysical properties of normal skin. Skin Research and Technology, 2015. **21**(2): p. 131-136.

24. Tomova‐Simitchieva, T., et al., Comparing the effects of 3 different pressure ulcer prevention support surfaces on the structure and function of heel and sacral skin: An exploratory cross‐over trial. International wound journal, 2018. **15**(3): p. 429-437.

25. Jansen van Rensburg, S., A. Franken, and J. Du Plessis, Measurement of transepidermal water loss, stratum corneum hydration and skin surface pH in occupational settings: A review. Skin Research and Technology, 2019. **25**(5): p. 595-605.

26. Jayabal, H., et al., The identification of biophysical parameters which reflect skin status following mechanical and chemical insults. Clinical Physiology and Functional Imaging, 2021. **41**(4): p. 366-375.

27. Denzinger, M., et al., A quantitative study of hydration level of the skin surface and erythema on conventional and microclimate management capable mattresses and hospital beds. Journal of Tissue Viability, 2020. **29**(1): p. 2-6.

28. Abiakam, N., et al., Biophysical and biochemical changes in skin health of healthcare professionals using respirators during COVID-19 pandemic. Skin Research and Technology. **n/a**(n/a).

29. Bliss, D.Z., et al., Incontinence Briefs Containing Spiral-Shaped Fiber Acidify Skin pH of Older Nursing Home Residents at Risk for Incontinence-Associated Dermatitis. Journal of Wound, Ostomy and Continence Nursing, 2017. **44**(5): p. 475-480.

30. De Jongh, C.M., et al., Differential cytokine expression in skin after single and repeated irritation by sodium lauryl sulphate. Experimental Dermatology, 2007. **16**(12): p. 1032-1040.

31. Jayabal, H., D.L. Bader, and P.R. Worsley, Development of an efficient extraction methodology to analyse potential inflammatory biomarkers from sebum. Skin pharmacology and physiology, 2022: p. Accepted.

32. Rea, I.M., et al., Age and Age-Related Diseases: Role of Inflammation Triggers and Cytokines. Frontiers in Immunology, 2018. **9**.

33. Bliss, D.Z., et al., Incontinence-associated dermatitis in critically ill adults: time to development, severity, and risk factors. J Wound Ostomy Continence Nurs, 2011. **38**(4): p. 433-45.

34. Graham, H.K., et al., Human skin: composition, structure and visualisation methods, in Skin Biophysics. 2019, Springer. p. 1-18.

**Figure Legends**

**Figure 1a**. Test protocol illustrating experimental test sites on the sacral region of each participant

**Figure 1b**. Test protocol illustrating timescale of skin challenge and data collection.

**Figure 2**. Changes in ratio TEWL and rank sum of absolute TEWL values at the five sacral sites of each participant over the test session

**Figure 3**. Changes in skin hydration ratio and rank sum of absolute values at the five sacral sites of each participant over the test session

**Figure 4**. Ratio changes in IL-1alpha and TNF-alpha for each participant at three sacral sites over the test session

**Figure 5**. The influence of age on the absolute concentrations of (a) IL-1alpha and (b) TNF-alpha at site B over the test session

**Table 1. Demographic Characteristics of Participants**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Participant ID | Sex\*  | Age (years) | Ethnicity | BMI kg/m2 |
| #1 | F | 32 | White | 21.9 |
| #2 | M | 36 | White | 32.1 |
| #3 | F | 32 | White | 19.8 |
| #4 | M | 39 | Black | 23.6 |
| #5 | M | 39 | White | 29.4 |
| #6 | F | 35 | Mixed  | 29.8 |
| #7 | F | 59 | White | 24.1 |
| #8 | F | 62 | White | 18.5 |
| #9 | F | 54 | White | 34.7 |
| #10 | M | 51 | White | 25.7 |
| #11 | F | 56 | White | 37.7 |
| #12 | F | 50 | White | 25.1 |

\*Sex = F=female, M = male