A Randomized, Controlled Study to Assess the Effect of Silk-like Textiles and High-absorbency Adult Incontinence Briefs on Pressure Ulcer Prevention

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Abstract
Pressure ulcer prevention is an important aspect of nursing home care. A 20-week, unblinded, randomized, controlled trial was conducted to compare the rate of nursing home-acquired pressure ulcers and adverse events between residents managed using: 1) a silk-like textile for bedding paired with high-absorbency adult incontinence briefs or 2) usual-care, plain-weave cotton/polyester bed sheets and adult incontinence briefs. All residents with an expected length of stay of 30 days or more who agreed to participate were enrolled in the study and assessed daily. A total of 46 residents (all men) was enrolled; 26 (median age 72.7 years, range 54 to 95 years) in the intervention group and 20 (median age 69.5 years, range 51 to 91 years) in the usual care group. At baseline, there were no significant differences in resident demographic variables, including Braden Scale risk scores. Fewer pressure ulcers developed in the intervention (six; average follow up 75.6 days/person) than in the standard care group (20; average follow up 95.6 days/person) (hazard ratio = 0.31, 95% confidence interval 0.12, 0.78) and the number of new non-Stage I ulcers was significantly lower in the intervention group (HR = .23, 95% CI .078, .69, P = 0.0084). The number of adverse events did not differ significantly between the two groups. Additional research is warranted on use of products with the silk-like fabric, alone or in combination with high-absorbency briefs, in larger groups and different populations.

Keywords: clinical study, pressure ulcer, prevention, nursing homes, textiles

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According to the federally sponsored Healthcare Cost and Utilization Project,1 pressure ulcers harm patients and cost Medicare, Medicaid, private insurance, and their patients more than $10 billion per year. Literature reviews of research involving support surfaces intended to prevent pressure ulcers, as well as research characterizing the impact of patient-turning intervals in combination with different support surfaces on pressure-ulcer formation,2-4 illustrate that pressure ulcers result from a combination of pressure, shearing force, friction, and moisture, which cause injury to the skin and underlying tissue. These literature reviews also indicate that most interventions to prevent pressure ulcers have focused on reduction of pressure.

Few studies explore combined interventions to reduce friction and moisture to prevent pressure ulcers or the relationship of various adult incontinence briefs to pressure...
ulcer development. Two Cochrane reviews1,4 examined comparative effectiveness among 14 different incontinence brief designs; the reviews identified three studies with a total of 270 participants. The studies failed to find a difference in skin health between the interventions. It should be noted that high-absorbency incontinence pads were not specifically included in the Cochrane review, and dermatitis and pressure ulcers were not clearly differentiated under skin health. High-absorbency incontinence pads and briefs are defined as briefs and pads having a fluid retention capacity (the measure of an incontinence product’s capacity to hold fluid without leaking) of ≥350 g; technically, fluid retention capacity quantifies an incontinence product’s ability to hold liquid or moisture and prevent it from rewetting the skin.7

Data involving use of the high-absorbency adult incontinence briefs are limited. A cross-over study8 of 25 elderly institutionalized participants who acted as their own controls measured transepidermal water loss (TEWL) — ie, the quantity of water that passes from inside the body through the epidermal layer to the surrounding atmosphere. TEWL averaged 265.82 g/m² in the usual care group versus 100 g/m² in participants using a high-absorbency adult incontinence brief before and after wearing high-absorbency adult incontinence briefs. Lower TEWL levels found in the intervention group indicated that high-absorbency adult incontinence briefs enhance the reduction of residual moisture against the skin that is not absorbed by the brief.8

A randomized study9 where the intervention location was matched against a control on the opposite side of the body compared the use of a special dressing over the right or left greater trochanter to reduce friction and moisture among 37 geriatric patients with a Braden score <15 in a hospital setting. Results showed erythema over 29.7% of the greater trochanters in the control group and 5.4% on the side with the dressing (relative risk [RR] 0.18, 95% confidence interval [CI] 0.05–0.73). The dressing was noted to reduce the incidence of erythema, and no new pressure ulcers occurred in either the usual care or intervention group.

A cohort study10 conducted on an orthopedic ward in a hospital evaluated a combination of low-friction garments, bed sheets, and pads for high-risk patients as determined by their Waterlow score (113 in usual care group and 77 in the intervention cohort). Among patients with no pressure ulcers on admission, pressure ulcer development was 16% lower (P = 0.029) in the intervention group. No statistically significant difference was found in pressure ulcer formation among the patients with pressure ulcers on admission, but a trend toward improvement was observed (difference 9%, P = 0.184). Additional studies where the intervention aimed to reduce moisture and friction with the intent of reducing pressure ulcer incidence were not found.

A prospective, cohort study11 followed 307 participants in an acute care medical renal unit for 24 weeks to compare use of a silk-like textile for bed sheets, bed pads, pillowcases, and hospital gowns (intervention) with their standard cotton-blend counterparts (control). The incidence of new hospital-acquired pressure ulcers was 4.6% in the intervention group and 12.3% in the control group (P = 0.01). It was hypothesized that the reduction of moisture and friction when using silk-like bed textiles reduced the incidence of pressure ulcers in this patient population.11

Because many nursing home residents are at risk for developing pressure ulcers, a randomized, controlled, clinical study was conducted to: 1) compare the incidence of facility-acquired pressure ulcers in residents using bed sheets, reusable bed pads, and pillowcases made with a plain-weave cotton/polyester textile fabric and, when indicated, incontinence briefs (usual care/control) to the use of bed sheets, reusable bed pads, and pillowcases all made with a silk-like synthetic textile; and, when indicated, high-absorbency adult incontinence briefs constructed using a high-absorbency polymer; and 2) evaluate the safety of the synthetic textile bed sheets, bed pads, and pillowcases and high-absorbency adult incontinence brief in a nursing home setting.

Methods

Design. A single-site, unblinded, randomized controlled study was conducted over 20 weeks. Study participants were randomized using a list of random numbers provided by the principle investigator to the study staff; odd-numbered patients were assigned to the intervention and those with even numbers were assigned to the usual care group. The study staff enrolled the participant into the study and after the enrollment assigned the next random number to consecutive enrollees. The first day for study entrance was January 5, 2011. The last participant enrolled in the study on May 5, 2011, and the study closed on May 27, 2011. The study ended on a predetermined date based upon the original power calculation.
Participants and setting. Study participants were residents of the Durham VA Medical Center nursing home care unit, the Community Living Center (CLC). All new and existing CLC residents with expected stays of 30 days or more were eligible for the study. CLC residents with expected stays <30 days were excluded from the study. Investigational Review Board (IRB) approval was obtained from the Durham VAMC IRB and the Duke University School of Medicine IRB. The study participants’ capacity to provide consent was determined by the Short Portable Mental Status Questionnaire (SPMSQ).\textsuperscript{12} Study participants who consented to enroll in the study and scored 6 or higher on the SPMSQ were enrolled in the study. Eligible study participants who scored <6 on the SPMSQ but who wanted to participate in the study required consent from the Healthcare Power of Attorney to participate. Study participants were enrolled continuously during the study with the goal to have 60 study participants at any given time.

Participant characteristics. Data collected on admission from the medical record and the Minimum Data Set (MDS), included participants’ date of birth, gender, weight (lb), body mass index (BMI), comorbidities, and study entrance date. The study nurses tracked the number of days enrolled in the study, colonization with multidrug resistant organisms, bed type, Braden score,\textsuperscript{13} MDS bed mobility score,\textsuperscript{14} presence of pain and agitation, and skin assessment.

Intervention. The intervention consisted of silk-like textile bed sheets, reusable bed pads, and pillowcases (Derma Therapy®, Precision Fabrics Group, Inc, Greensboro, NC), and a high-absorbency adult incontinence brief (Principle Business Enterprises Inc, Dunbridge, OH) if the participant had nighttime incontinence and was managed with incontinence briefs before the study was initiated. Adult incontinence briefs were the usual care for managing overnight incontinence in this nursing home.

Intervention group study participants in special beds — ie, dynamic beds or dynamic overlay mattresses — used custom-made sheets manufactured using the silk-like textile. The study textiles were a plain-weave construction of 100% continuous-filament yarns, where 100% nylon yarns are woven in one direction of the fabric and >99% polyester yarns in the other (perpendicular) direction. The silk-like textile is woven of 84 yarns per inch in the length direction and 96 yarns per inch in the width direction, producing a fabric that was 2.36 oz per square yard. The polyester yarns have a nonround fiber cross-section to create micro-channels. The usual care textiles were a plain-weave textile fabric in a construction of 120 yarns per inch in the length direction and 74 yarns per inch in the width direction, producing a fabric that was 4.12 oz per square yard. The yarns in the usual-care bedding were produced from a blend of approximately of 50% cotton and 50% polyester.\textsuperscript{11}

The high-absorbency adult incontinence product was a four-layer incontinence brief consisting of a soft, thin non-woven fabric attached to a thicker porous acquisition layer; a layer of a nonhomogeneous blend of cellulose fiber and an absorbent polymer; an absorbent core composed of a higher-absorbency polymer in a thin layer of cellulose fiber; and a nonporous plastic backing sheet. The usual care adult incontinence brief differed slightly from the intervention briefs in terms of polymers used (polymer information is proprietary and not available).\textsuperscript{9} Study participants that normally would have used the standard adult incontinence briefs instead were provided the intervention incontinence brief. Study participants that did not wear the high-absorbency adult incontinence brief wore their own undergarments.

Because all linens are mixed in a central VA laundry offsite from the Durham VAMC, it would not have been feasible to re-identify the intervention linens. Therefore, the intervention linens were laundered separately at a facility outside the VA, and the usual care linens were laundered at a central VA laundry. The cleaning chemicals used in the two laundry facilities were the same chemical formula; only the chemical manufacturers were different. The only other difference was the use of bleach when stain removal was required at the laundry; a chlorine-based bleach was used in laundering the control items, and a peroxide-based bleach was used in laundering the intervention items.

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<tr>
<th>Table 1. Participant characteristics (N = 46)</th>
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<tr>
<td><strong>Usual care</strong></td>
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<td>(n = 20)</td>
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<tr>
<td>Bed days of care: mean (SD)</td>
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<tr>
<td>Age in years: mean (SD)</td>
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<tr>
<td>Caucasian race (%)</td>
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<tr>
<td>Body mass index: kg/m(^2) — mean (SD)</td>
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<tr>
<td>MDS Bed Mobility Score (%)</td>
</tr>
<tr>
<td>0–1 Independent to supervision</td>
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<tr>
<td>2 Verbal cues plus manual guidance</td>
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<tr>
<td>3–4 Partial to complete physical assistance</td>
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<tr>
<td>Adult incontinence brief use (%)</td>
</tr>
<tr>
<td>Bed type (%)</td>
</tr>
<tr>
<td>Foam gel composite mattress</td>
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<td>Low-air-loss bed</td>
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<td>Mean Braden Scale score (SD)</td>
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Outcome measurements. The primary outcome was the development of new pressure ulcers. All study participants were included in the data analysis. For participants that withdrew from the study, data were included until the date they withdrew from the study.

Two study nurses who had training in skin assessment monitored study participants’ skin on a weekly basis. The skin assessment evaluated for the presence of pressure ulcers and measured pressure ulcer size if present. All areas of skin over bony prominences (occiput, ears, scapulas, spinous processes, shoulders, elbows, iliac crests, sacrum, coccyx, ischial tuberosities, trochanteric areas, knees, malleoli, heels, and toes) were visualized. If a pressure ulcer was present, the ulcer was: 1) inspected for the type and color of tissue present in the wound; 2) measured with a disposable ruler from top to bottom and from side to side; 3) measured for depth by placing a cotton-tipped applicator in the deepest part of the wound and then recording this measurement; 4) assessed for the presence and amount of exudate using the Pressure Ulcer Scale for Healing (PUSH) scoring (none, light, medium, heavy); 5) assessed for odor, warmth, and pain (on a scale of 0 to 10); and 6) checked for undermining and tunneling using a cotton-tipped applicator. The pressure ulcer was staged according to the National Pressure Ulcer Advisory Panel guidelines,16 including Stage I through Stage IV, unstageable ulcers, and suspected deep tissue injury ulcers. The variables length multiplied times width, exudate amount, and tissue type were used to calculate and record PUSH scores.

Adverse events. Adverse events, determined using the Food and Drug Administration17 definition, were captured by: 1) daily review of CLC census to hospitalizations or discharge; 2) participant interview, which included open-ended questions about how the participant was feeling and any unusual health occurrence or incident since the resident was last seen; and 3) medical record review. All adverse events were confirmed with the resident’s nurse practitioners and physician. Adverse event data were organized based upon Coding Symbols for a Thesaurus of Adverse Reaction Terms18 (COSTART), a tool developed by the United States Food and Drug Administration for the coding, filing, and retrieving post-market adverse reaction reports.

Because the intervention fabric was noticeably smoother than the usual care fabric, the authors hypothesized a potential increase in falls from bed among the group receiving the treatment. For this reason, the study nurses assessed falls from bed among the two groups.

Data collection. All study participant data were collected using paper records and later transferred to an Access database (Microsoft Corp, Northeast, WA) where data were stored on a protected hard-drive. All participant data were aggregated in an Excel spreadsheet (Microsoft Corp, Northeast, WA). The paper forms were stored in the individual participant’s research folder in a locked cabinet in a locked room.

Statistical analysis. Originally, the study was calculated to need 60 study participants followed for 1 year in order to
have a 90% chance of detecting a 50% difference of occurrence in all stages of pressure ulcers between the intervention and usual care group. A simple t-test was used to evaluate for differences between the usual care and intervention groups for the descriptive characteristics and a P value of 0.05 was used to determine statistical significance.

The difference between the usual care and intervention groups for the rate of pressure ulcers and falls was evaluated using bivariate analyses using Poisson (ie, arm x rate of outcome variables). The Poisson analysis was conducted for two outcome variables: total number of pressure ulcers and number of pressure ulcers non-Stage I (eg, Stage II through Stage IV, unstageable, and deep tissue injury). The time-to-event (survival) analysis was used to explore differences between the groups to the first pressure ulcer (of any stage) to estimate survivor functions. Those survivor functions then were compared between arms using nonparametric product-limit (Kaplan-Meier) estimates. SAS Version 9.2 (SAS Institute, Cary, NC) was utilized to conduct all analyses. Adverse events were analyzed using the nonparametric Wilcoxon Rank-Sum test and SAS v9.3 software.

**Results**

The study involved an all-male cohort; 20 in the usual care group who had a total of 1,912 bed days of care (BDOC) (average 95.6 days/person) and 26 study participants in the intervention group who had a total of 1,939 BDCC (average 75.6 days/person) (see Table 1). The study participants were similar in age (usual care average 69.5 years versus intervention group 72.7 years, P = 0.40), race (usual care 55.0% Caucasian versus 53.9% in the intervention group, P = 0.94), BMI (usual care average 27.5 versus intervention 26.9, P = 0.78), Braden score (average 16.8 in the usual care group and 17.1 in the intervention group, P = 0.71), bed types (usual care 30.0% on low air-loss bed versus intervention 30.8%, P = 0.40), and adult incontinence brief use (70% of usual care group participants using high-absorbency adult incontinence brief versus 57.7% in the intervention group, P = 0.23). The lower MDS mobility scores (45.0 in usual group and 26.9 in the invention group, P = 0.23) indicated more limitations in activities of daily living in the usual care group as compared to the intervention group. None of the measured characteristics that could have affected pressure ulcer development — ie, BMI, Braden score, bed type, use of adult incontinence brief (as a marker for incontinence), or MDS mobility score — were significantly different between the usual care and intervention groups.

All study participants remained in their randomized group and received the assigned treatment. Three of the participants in the usual care group withdrew from the study; all were discharged from the nursing home. Thirteen participants in the intervention group withdrew from the study; eight were discharged from the nursing home, and five chose to withdraw from the study. Four deaths among the usual care group and one death in the intervention group occurred (P = 0.15); the deaths were not related to the study. One of the study participants withdrew from the intervention group occurred after he had fallen from a bed late in the study period.

Pressure ulcers. Table 2 illustrates the distribution of pressure ulcers in the two groups by stage and location. The number of facility-acquired pressure ulcers was significantly lower in the intervention (six) than the usual care group (20) (HR = 0.31, 95% CI 0.12, 0.78, P = 0.0125). The usual care group experienced more non-Stage I pressure ulcers (16) than the intervention group (four), and this difference was statistically significant (HR = 0.23, 95% CI 0.33, 4.58, P = 0.0084). More Stage II pressure ulcers were noted in the usual care group (eight) than in the intervention group (two), which was not statistically significant (P = 0.063). The time to development of the first pressure ulcer was shorter in the usual care group than the intervention group, but the difference was not statistically significant (P = 0.11). Most of the pressure ulcers occurred early in the study and were located in typical locations (see Figure 1).

Adverse events. No significant differences were found between the usual care and intervention groups in any adverse events, number of adverse events per person, any serious adverse events, number of serious adverse events per person, falls from bed, and deaths (see Table 3). The participant who fell did not suffer an injury.

**Discussion**

This study showed no difference in the rate of adverse events between standard care linens and the combination of interventions tested — ie, a silk-like textile for bed sheets, underpads, and pillowcases and a high-absorbency adult incontinence briefs. In this small sample of nursing home residents (n = 46) with limited BDCC (3,851), the number of facility-acquired pressure ulcers was lower in the intervention than in the standard nursing care group. This finding supports the hypothesis that reduction of moisture and friction lowers the risk of a pressure ulcer development.

Bedbound individuals experience friction through skin rubbing against the bed sheets during repeated episodes of sliding down or being pulled up in the bed. As skin moisture increases through sweat, spills, or incontinence, the coefficient of friction increases between the skin and polyester/cotton textile materials, increasing the skin risk for injury and particularly pressure ulcer formation. A component of the intervention, the silk-like textile, manages the friction and moisture between the skin and support surface to reduce the probability for the development of new pressure ulcers. The silk-like textile microfibers form tiny channels that rapidly wick away moisture from the surface. The textile is designed to be smooth and soft. These properties are designed to maximize moisture wicking and drying, while minimizing the frictional properties of hospital bed linens.

A cross-over study of eight healthy volunteers, where each subject served in the control and intervention groups,
found a positive linear relationship between skin moisture and the coefficient of friction; the latter was more than two times greater when wet cotton fabric rubbed on skin compared to dry cotton fabric. A prospective cohort study\textsuperscript{11} found a cotton polyester textile’s coefficient of friction was almost two times greater than that of the silk-like textile when wet. An observational study\textsuperscript{21} in a long-term care setting involving a review of de-identified medical records, pressure ulcer prevalence monitoring, and caregiving staff interviews found that if the skin is irritated or inflamed by maceration or incontinence-associated dermatitis, superficial damage due to friction will occur more easily and result in more damage to the skin.

Similar to the silk-like textile, the high-absorbency adult incontinence briefs used in this study reduced TEWL caused by fluid contact with the epidermis as well as tissue maceration as a result of incontinent events by removing moisture away from the skin faster than the usual care product. The observations reported by Milne\textsuperscript{2} in a cross-over study that evaluated 25 elderly incontinent subjects found that high-absorbency adult briefs significantly reduce moisture levels next to the skin and thereby reduce the negative impact of incontinent episodes on the skin’s barrier function.

The number of pressure ulcers found in the current study participants was higher than the incidence noted in the literature among nursing home residents.\textsuperscript{22,23} Pressure ulcer incidence described in the literature is based upon the MDS tool, and reports are based upon 90-day reviews. Pressure ulcer incidence reported in other studies\textsuperscript{2,24} based upon daily or weekly examinations of the nursing home residents is consistent with current observations in the usual care group (31%/month) for all stages of pressure ulcers. The percentage of pressure ulcers found to be suspected deep tissue injuries was also higher than the approximately 9% of pressure ulcers reported previously.\textsuperscript{25}

Explanations could include the very small sample of pressure ulcers or a dearth of information about incidence of deep tissue injuries in the nursing home, particularly among special populations (males, near end of life).

Limitations

The final number of enrolled study participants was smaller than the intended sample size of 60 study participants. The nursing home underwent renovations during the study, which reduced total census and therefore the number of potential study participants. It was not possible to blind the study participants, staff, and study nurses to the intervention because the textile and briefs were very different from the usual care products. The study population was all male, which may limit the generalizability of the study findings to females. The intervention and control group linens were laundered in separate facilities. The laundering chemicals used were the same chemical formula but different brands; however, the silk-like textile, when tested using chlorine or peroxide bleaches, exhibited no difference in softness, surface properties, or wearlife.\textsuperscript{11}

The intervention group experienced a higher withdrawal rate than the control group, which may represent participants’ ability to tolerate the intervention. The number of discharges from the facility was greater in the intervention group, which could indicate an unmeasured difference between the groups not accounted for because of the small number of participants randomized in the study. Finally, although no significant difference in the use of briefs was noted between the groups, the briefs differed slightly in polymer content between the two groups, and, given the small number of observations, this may have been important. A related observation of whether the intervention is most effective in continent or incontinent study participants was not discovered because of the small number of observations in the two groups.

Based upon this study, a larger study is warranted to address the limitations inherent in this study. A large study would be able to examine whether the results were from chance and not related to the intervention, whether the intervention was successful in nursing home residents regardless of continence status, whether effectiveness of the intervention differs between men and women or among all residents or only high-risk residents, and whether bed type and intervention success are related, as well as the cost-benefit of the intervention. Even with these limitations, the positive results suggest that interventions to address moisture and friction could be an effective means to reduce pressure ulcers in the nursing home setting and that nursing home staff using pressure ulcer prevention interventions should be more cognizant of the importance of reducing moisture and friction.

Conclusion

The purpose of the study was to compare the number of adverse events and nursing home acquired-pressure ulcers...
between residents using a silk-like fabric and high-absorbency incontinence briefs and usual care linens (plain-weave cotton/polyester textile fabric). The rate of all new pressure ulcers was lower in intervention group (23%) than in the control group (100%) and significantly lower for non-Stage I ulcers (HR = .23 (95% CI .078, .69) P = 0.0084).

No significant difference was found in the incidence of adverse events between the standard care and intervention groups. Future research should determine the efficacy of these products in a multisite clinical trial with a larger population of nursing home residents that is powered to detect clinically meaningful differences in the incidence of facility-acquired pressure ulcers.

References