Assessing the feasibility of subepidermal moisture to predict erythema and stage 1 pressure ulcers in persons with spinal cord injury: A pilot study

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Background: Persons with spinal cord injury (SCI) are at high risk for pressure ulcers (PrUs) throughout their lifetime due to decreased mobility, lack of sensation, and other physiological changes. The high prevalence and recurrence rates, and costs associated with PrUs in veterans with SCI indicate the need for a reliable and practical method of detecting early PrUs.

Objective: To assess the feasibility of obtaining biophysical measures of sub-epidermal moisture (SEM) using a handheld dermal phase meter to predict PrUs.

Design/methods: Prospective observational design. Thirty-four veterans at two VA SCI centers (Hines, Long Beach) received daily ($n = 12$) or weekly ($n = 22$) SEM and concurrent visual skin assessment (VSA) across nine anatomic locations for up to 6 weeks.

Outcome measures: SEM, visual skin assessment (VSA), and stage I PrUs.

Findings/results: SEM was lowest for normal skin (39.3 dermal phase units (DPU), SD = 12.6) and higher for erythema/stage 1 PrUs (40.8 DPU, SD = 10.4) across all anatomic sites. Buttocks SEM were different between normal skin (40.5 DPU, SD = 10.3) and erythema/stage1 PrUs (43.8, SD = 9.5). SEM taken at heels were lower across all skin conditions (normal skin 28.2 DPU; erythema/stage 1 PrUs 34.7 DPU). SEM was taken when generalized edema present was lower than without generalized edema.

Conclusions: Preliminary results of using SEM to detect early PrU damage may translate from nursing home (NH) residents to persons with SCI. This study provides a foundation for a larger study to implement and assess SEM use as a method of prevention of PrUs.

Keywords: Spinal cord injuries, Pressure ulcer, Staging, Prevention, Prevalence, Outcomes, Health care costs, Physical examination, Rehabilitation, Physical, Wound care

Background

Persons with spinal cord injury (SCI) are at high risk for pressure ulcers (PrUs) throughout their lifetime due to decreased mobility and sensation coupled with other physiologic changes.¹⁻⁵ This lifelong risk and the scope of this problem is evidenced by reported PrU prevalence rates as high as 40% during acute rehabilitation, 15% at the first annual examination, and 32% at 20 years post-discharge.^{1,4} Health care utilization and costs of caring for veterans with SCI who experience the complication of a severe stage III or IV PrU are high (in excess of

\$100k annually).⁶ Garber *et al.* evaluated health care utilization, costs, and outcomes in outpatients with SCI over a 3-year period.⁷ They report PrU prevalence over the 3 years at 39%, with most ulcers in this study occurring over the pelvic area (sacrum, ischium, and trochanters) and at stage IV PrU severity (e.g., full thickness involving muscle, bone). The high prevalence and recurrence rates, and costs associated with PrUs in persons with SCI indicates a need for reliable and practical methods of detecting early PrUs. Improving detection of early PrUs could impact rehabilitation, health outcomes, costs, and quality of life for individuals with SCI.

Clinical practice guidelines on PrU prevention for persons with SCI specifically recommend daily visual

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inspection with a mirror if necessary and palpation of bony prominences to detect erythema and stage I PrUs, with subsequent follow-up with a health care provider for all PrUs detected.⁸ However, daily skin assessment is often challenging as the most common sites for ulcer development are in anatomic locations that are difficult to see such as the heels, ischium, and sacrum.

Current risk assessment methods are unable to adequately assess risk and it is easy over time for patients and staff to become complacent. The extreme diligence necessary to maintain recommended behaviors, especially when combined with the inherent lack of feedback from employing such behaviors, makes sustained behavior change difficult. Another key preventive behavior for persons with SCI requires that they seek out health care on a timely basis when an area of pressure damage is initially detected. Garber *et al.*⁹ demonstrated that community-dwelling persons with SCI who self-identify ulcers as less severe than those identified by health care providers. Individuals taking immediate action when an ulcer was detected also reported performing more preventive actions.⁹ However, the available evidence on PrU development, recurrence, and outcomes among persons with SCI indicates that current methods of early detection are not very effective. In part, this is because PrU risk also varies from person to person over time. Studies suggest that current methods of early PrU detection are poor triggers for preventive care because they rest on information that is not always acted on immediately by patients and/or providers. The difficulty in detecting reliable early signs of skin damage could lead to persons with SCI presenting to the health care system with more severe PrUs. As part of their initial rehabilitation, persons with SCI are taught to inspect their skin daily for impending PrUs visually with a mirror or by touch. There are several barriers to early detection by inspection: patient non-adherence due to limitations and difficulties of using mirrors, difficulty of detecting erythema in those with darkly pigmented skin, and the limitations of surface characteristics in detecting deep tissue injury.^{10,11} Visual assessment of tissue damage may be further hampered because tissue injury in darker pigmented persons may actually appear darker than the normal skin tone. Due to the inherent limitations of visual assessment, skin damage may become more advanced by the time it is detected.¹² In addition, anecdotal data indicate that what initially appears to be a stage I ulcer may conceal a deep tissue injury or may progress to a stage IV ulcer almost overnight, underscoring that the pathophysiology of ulcer development occurs below the skin surface and is often not visible to trained providers.

Previous research has shown that pressure results in tissue ischemia, resulting in inflammatory changes including edema. The cellular swelling and increase in interstitial fluids associated with pre-stage I pressure damage are evidenced as early as 3–10 days prior to visible skin damage in PrU development.^{13–17}

Despite the more comprehensive definition of stage I PrUs and documented concerns about reliability and validity of existing wound assessment instruments, researchers and clinicians continue to depend on visual skin assessment (VSA) as the ‘gold standard’ for detecting early skin damage and/or PrUs. No empirical evidence consistently supports previously suggested alternative non-visual methods of detecting stage I PrUs. From a theoretical viewpoint, skin temperature appears to be a non-visual characteristic with the potential to demonstrate success in detection of stage I PrUs, but it has only been evaluated in very small samples,¹⁸ for short time periods,¹⁶ with conflicting results.^{16,19}

A non-invasive, practical method of detecting early stage PrUs has not yet been evaluated in the SCI population, although a device that measures skin and tissue water or sub-epidermal moisture (SEM) has been tested in a population of frail elderly nursing home (NH) residents.²⁰ However, it has been determined that the differences between NH residents and persons with SCI requires further investigation before applying these methods (e.g., predominantly female NH residents, prevalence of urinary incontinence, differences in skin’s response to ischemia and over scar tissue, etc.). Thus, findings from this study provided an opportunity to explore whether there might be a relationship between SEM measures and visible skin damage in persons with SCI. We expected that obtaining a better understanding of this phenomenon in persons with SCI would allow further investigation of whether a biophysical measure of SEM could be useful in early detection and/or preventing PrUs in this population. Efforts to improve detection of early PrUs in persons with SCI would have immediate and important clinical applications and could increase early and effective treatment and impact rehabilitation, health outcomes and costs, and quality of life.

Previous work

A pilot study conducted in frail elderly NH residents who are vulnerable to PrUs provided support for obtaining pilot data in persons with SCI.⁸ This descriptive cohort study involved 35 residents in 2 NHs. VSAs and SEM readings were obtained at the sacrum, right and left trochanters, buttocks, and ischium weekly for 52 weeks. SEM was measured with a handheld dermal

phase meter (DPM). Higher readings show greater SEM (range: 0–999; NOVA Technology Corp., Portsmouth, NH, USA). VSA was rated as normal, blanchable erythema (a precursor to stage I PrUs), stage I PrU, or stage II+ PrU. Mean SEM was 107 (SD 134) for normal skin, 183 (SD 176) for blanchable erythema, 299 (SD 263) for stage I PrUs, and 554 (SD 324) for stage 2+ PrUs across all anatomic locations ($P < 0.001$); *post-hoc* analysis showed significant pairwise differences between all groups. SEM was modeled as a predictor of VSA of erythema and PrUs 1 week later (controlling for within-patient clustering), with concurrent SEM, Braden Scale risk score,²¹ anatomic site, and ethnicity as covariates. Increase in SEM predicted increased presence of stage I PrU the next week (OR = 1.24 for every 100 units increase in SEM, $P = 0.04$) with similar findings when data were analyzed at quarterly intervals. If replicated in persons with SCI, early intervention to treat and/or prevent more serious PrUs could be developed.

Objectives

The purpose of this study was to assess the feasibility of obtaining biophysical measures of SEM to predict PrUs in persons with SCI in preparation for a larger study to fully examine the use of SEM. The immediate objectives were to: (1) describe the relationship between SEM and stage I PrUs in persons with SCI, (2) assess the sensitivity of various anatomic locations to SEM measures, and (3) test the relationship between SEM measurement intervals (daily, weekly, and bi-weekly) and stage I PrUs. We also identified study participants whose caregivers were willing to discuss issues around satisfaction and the feasibility of collecting the SEM measures.

Methods

Research design

A prospective, single-arm post-test observational design targeted non-ambulatory persons with SCI receiving post-acute rehabilitation or follow-up care in the hospital, outpatient clinics, NHs, and the community.

Population

Patients were enrolled from two VA SCI centers (Hines and Long Beach) and received daily ($n = 10$) or weekly ($n = 22$) concurrent VSA and SEM measurements using a handheld dermal phase meter across nine anatomic locations for 16 weeks.

Study sites

All study participants ($N = 32$) were recruited as inpatients receiving acute rehabilitation or follow-up care at

Long Beach SCI Service and those residing at the VA Hines residential care facility (RCF).

Measures

VSAs and SEM measures of each subjects' sacrum, right and left heels, trochanter, ischium, and buttocks were obtained by research staff daily (VA Hines RCF participants) or weekly (Long Beach SCI Service participants) for 16 weeks. Munsell color tiles were used to objectively assess skin tone during the initial skin assessment. SEM was measured with a DPM (MoistureMeter D, Delfin Technologies, Ltd, Kuopio, Finland) at two penetration depths (0.5 and 1.5 mm). Values range from 1 to 80 dielectric constant (vacuum/air = 1; pure water = 78.5; normal skin approximately 40), with higher DPM readings indicating more water (e.g., edema and inflammation). The DPM measures the dielectric constant in relation to stratum corneum thickness. Readings are generated immediately after 8 seconds of light skin touch and are stable with a coefficient of variation of only 2.8%. Initial inter-rater reliability assessments on the DPM were conducted with 13 healthy volunteers measuring SEM over the hip. Assessments conducted using two pairs of observers resulted in correlation coefficients of $r = 0.92$ and 0.86 . VSA was rated as: 0 = no skin damage present, erythema/stage I PrU or stage II + PrU. Erythema/stage I PrU was determined by visible erythema that was moderate (bright red in lightly pigmented skin and discolored with blue/gray or deepening of normal ethnic skin color in darkly pigmented skin) to severe (dark red in lightly pigmented skin and purple in darkly pigmented skin) and/or non-blanchable. Stage II or greater PrUs were classified using the National Pressure Ulcer Advisory Panel (NPUAPs) 1998 staging classification.

To track behavior changes, research staff interviewed participants on skin health-related behaviors (e.g., activity level, strategies for pressure relief, nutrition) weekly. Medical record review and Salzberg⁷ risk assessment for PrUs were collected monthly by research staff. For those who developed a PrU, we obtained wound assessment data and photos from their electronic medical records.

Data analysis

Descriptive analyses were conducted calculating means, medians, and minimum and maximum values. We compared SEM measures to VSA of skin damage for all anatomic locations and for each anatomic location separately. Additionally, we evaluated SEM values

obtained over scar tissue and the stability of SEM values taken daily. We describe participant/caregiver interview data on device use.

Results

Table 1 presents demographic and medical data for participants in this study. Participants were male with a mean age of 66 years (SD = 11.5), with an average duration of injury of 25 years (13.9 SD), 53% non-Hispanic white and 32% presenting with current stage IV PrUs at the start of the study.

Two research staff at each study site independently rated participants' skin color by comparing the Munsell color tile chart (Chart # 5YR was used in this study) to the skin on the volar surface of the forearm during the baseline VSA. The reliability coefficient for 30 paired observations was $r = 0.93$.

Additionally, we evaluated the Munsell rating by ethnicity/race and found, as expected, non-Hispanic whites scored highest, Hispanics next highest, and African Americans scored lowest on the Munsell color chart as shown in Table 2. However, for all ethnicities/races there was a wide range of values and overlap between ethnic/race groups. For example as shown in Table 2, the lowest value for non-Hispanic whites was 5.3 and the highest value was 8.3 (range 3.0) and the lowest value for African Americans was 3.2 and the highest value was 6.4 (range 3.2).

Most participants had one or more PrUs upon entry into the study and were hospitalized for care of the PrU(s). Eleven of the study participants had 14 PrUs that developed during the study period. Of these ulcers, seven were stage I, three were stage II, two were stage III, and two were stage IV. We also observed 66 cases of visible erythema/stage I PrU developed on 22 participants during the course of the study. The erythema/stage I PrUs developed on the following anatomic locations: sacral (frequency = 7), buttocks ($n = 17$), ischium ($n = 15$), trochanters ($n = 6$), and heels ($n = 21$).

SEM was lowest for normal skin (41 dermal phase units [DPU], SD 10) and higher for erythema/stage I PrUs (42 DPU, SD 11) across all anatomic sites. Ischial and buttocks SEM differentiated between normal skin (mean 41.7–42.5 DPU) and erythema/stage I PrUs (mean 44.9–48 DPU). Fig. 1 presents these data graphically.

New PrUs were least likely to occur on patients' buttocks, trochanters, or ischium. The two locations with more frequent erythema/stage I PrU occurrences, the sacrum and heels, demonstrate a linear relationship with SEM values increasing as skin damage increases as shown in Fig. 2.

Table 1 Demographic and medical data for study participants

Demographics/ characteristics	Mean (SD, Min–Max) frequency (%)
Age ($n = 32$)	65.19 (11.35, 47–83)
Race	
White	18 (56.25%)
African-American	11 (34.38%)
Hispanic	2 (6.25%)
Other	1 (3.13%)
Type of residence	
House	18 (56.25%)
Apartment	3 (9.38%)
NH	1 (3.13%)
RCF	10 (31.25%)
Education	
High school graduate	6 (18.75%)
Some college	9 (28.13%)
College graduate	4 (12.50%)
Graduate school	3 (9.38%)
Unknown	10 (31.25%)
Duration of injury	
Duration of injury in years ($n = 23$)	26.59 (13.94, 0.17–59.47)
Etiology	
Motor vehicle	12 (37.50%)
Fall	2 (6.25%)
Gun shot wound	1 (3.13%)
Other acts of violence	1 (3.13%)
Other	7 (21.88%)
Unknown	9 (28.13%)
Level of injury	
Cervical	22 (68.75%)
Lumbar	1 (3.13%)
Thoracic	7 (21.88%)
Unknown	2 (6.25%)
ASIA	
A	3 (9.38%)
B	1 (3.13%)
C	2 (6.25%)
D	4 (12.50%)
Not available	22 (68.75%)
Regular care assistance	
Spouse care	9 (28.13%)
Paid attendant	17 (53.13%)
Partner/significant other	1 (3.13%)
Other relative	4 (12.50%)
PrU history	
Number of prior ulcers ($n = 29$)	2.14 (2.66, 0–10)
Current ulcers	
No current ulcers	17 (53.13%)
One current ulcer	13 (40.63%)
Two current ulcers	1 (3.13%)
Three current ulcers	1 (3.13%)
Stage of current ulcer	
II	4 (12.50%)
III	1 (3.13%)
IV	9 (28.13%)
Unstaged	1 (3.13%)

SEM taken at heel locations was lower across all skin conditions (normal skin 30 DPU; erythema/stage I PrUs 33 DPU). SEM values taken over scar tissue (previously healed PrUs) were somewhat lower than without scar tissue. These findings are presented in Fig. 3.

Table 2 Mid forearm Munsell color values (SD) and range for participants

Ethnicity/race	Munsell score mean (SD); mode (range)
Non-Hispanic White (<i>n</i> = 19)	7.42 (0.2); 7.2 (5.3–8.3)
Hispanic (<i>n</i> = 2)	6.53 (0.23); 6.3 (6.3–7.2)
African American (<i>n</i> = 9)	4.72 (0.21); 5.3 (3.2–6.1)

Figure 1 Mean SEM values by visual assessment category.

Figure 2 Mean SEM values by PrU anatomic location.

Figure 3 Mean SEM value for subjects with/without scar tissue.

Feasibility/satisfaction with use: One participant with SCI and two caregivers participated in using the DPM for 1 week. This was followed by an interview to assess the ease of use and practicality for self-use. After a 1 hour in-person education session with research staff, all three participants completed all daily SEM values from the nine anatomic locations for the 5 days. All three participants indicated the device was easy to use and no difficulties with self-use were encountered.

Discussion

All participants from the weekly site were recruited while hospitalized and followed at home to complete the 16-week study time once discharged (the maximum time any participant was followed at home was 16 weeks). Internal VA quality assessment data indicate that VA SCI units have an extremely low PrU incidence for inpatients (<2% of all PrUs in the SCI population are hospital acquired). However, because most of our participants were hospitalized for much of the time they participated in the study, most of the ulcers we observed were hospital acquired. Because we enrolled all of our study participants as inpatients, the follow-up time period in the home environment (where we would expect to see more skin breakdown) did not enable us to observe enough occurrences of erythema and/or stage I ulcers. The low frequency of occurrence of erythema/stage I or higher PrUs in our sample during the study did not allow for more robust analysis of SEM measures and skin damage. Future work should focus on recruiting and following persons with SCI residing in the community where erythema/stage I PrUs are more likely to occur.

Our findings that SEM values differ over scar tissue when erythema/stage I PrUs are present should be further explored as we had insufficient data to evaluate this more than superficially. Our findings that SEM values on the heels are lower in all cases suggest the need for differing threshold values for this anatomic location.

Limitations

We were unable to address the question of whether or not SEM measures varied on a daily vs. weekly basis due to difficulties in recruiting and retaining subjects for the daily assessments. Daily assessments within the hospital environment were sometimes problematic and the number of occurrences of new skin breakdown among those who were hospitalized was very low, suggesting that the next study should focus on outpatients where the probability of new skin breakdown was higher.

Blanchable erythema and stage 1 ulcers were grouped together due to the small sample size. In fact, blanchable erythema alone has been suggested as a strong predictor of later stage ulcers among NH residents and can be viewed as visible pre-stage I pressure damage.^{22–25} Future studies should consider examining erythema and non-blanching erythema separately.

For our study, blanchable erythema and stage 1 ulcers were grouped together due to the small sample size. To address the reviewer's concerns, we have included this among the study limitations.

Several other issues arose during the study that should be addressed in a larger study. Possible factors that could affect SEM include (but are not limited to), time of day that SEM is measured, body composition, diuretic use, and co-morbid conditions that increase edema (e.g., congestive heart failure, lower extremity edema, or prior deep vein thrombosis).

Conclusion

This pilot study has addressed several questions that are important for a larger study. One question this pilot study sought to address was whether it was possible to recruit persons with SCI to a longitudinal study involving weekly visits. Our results indicate that recruitment for weekly home visits are feasible. Second, we have demonstrated that SEM values can be obtained reliably using the DPM. This is important for a larger study. Third, we have identified anatomical issues (e.g., scar tissue from previously healed ulcer sites and generalized edema) as potentially important differences in the SCI population. More data are needed on SEM values over scar tissue in individuals with SCI to better understand the inflammatory process with scar. Fourth, our results indicate that SEM values from the heels are lower than pelvic locations for all skin conditions, and this will require identification of different thresholds for this location.

While our data suggest a possible relationship between SEM and skin damage, we were unable to examine this definitively. Our results indicate that there is a need for more data from a larger sample over a longer period of time to address the relationship between SEM and skin damage, as well as the sensitivity and specificity of SEM values. The issue of frequency of data collection (daily vs. weekly assessments) remains unanswered and should also be addressed in a larger study.

Some key recommendations for future study can also be derived from our pilot experience. The most important finding is that future studies should focus on recruitment of persons with SCI in the community setting (where there is likely to be more erythema/

stage I damage) and longer study time periods are necessary for observing sufficient rates of erythema/stage I PrU occurrences.

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