A Prospective, Observational Study of High-Specification Foam Immersion Surfaces Used in Populations at High Risk for Pressure Ulcers

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Abstract

There are insufficient clinical outcomes data to select pressure redistribution support surfaces for vulnerable populations at risk for skin breakdown. A prospective, descriptive case series study with historical controls was conducted to examine clinical outcomes and user feedback when nonpowered, ergonomically designed, high-specification foam (HSF) devices were added to either a medical grade portable recliner or standard hospital bed used in the care of persons at high risk for pressure ulcers (PU). The study was conducted in a hospice agency and a VA rehabilitation and long-term-care unit. Eligible participants were mobility and/or activity impaired; had at least one comorbidity; received standardized skin hygiene, incontinence, and repositioning protocols; and/or had previously documented negative outcomes (eg, pain or discomfort associated with sitting or lying surfaces, falls from equipment, nonhealing PU, and posturing problems such as leaning, sliding, or slumping) on currently used support surfaces. Patients/caregivers ranked pretrial and trial surface performance for overall comfort, control of downward migration, overall immersion, support while sitting without bottoming-out or hammocking, and heel offloading as evidenced by suspension or total immersion of the foot and ankle. Follow-up variables, including changes in pain, discomfort, PU status (if present), and skin integrity, were obtained every 7 to 21 days. Forty-four (44) persons (24 men, 20 women; average age 79, range 47–98 years) participated in the mattress study for an average of 53 (range 3–120) days); and 33 (eight men, 25 women; average age 82, range 63 to 97 years) participated in the recliner support system evaluation, for an average of 39 days (range 13–66 days). Compared to prestudy surfaces, perceived comfort, migration, immersion, and heel offloading ratings were significantly higher for the mattress and recliner surface (P <0.05). No falls occurred, and 17 of 35 preexisting PU in the mattress and 17 of 20 PU in the seating surface group healed. Two of 26 hospice patients developed a new end-of-life, Stage II PU after day 48 of the mattress trial. No new PU developed in the seating trial. These results suggest randomized comparative studies comparing these nonpowered HSF chair and bed surfaces to other commonly used support surfaces are warranted.

Keywords: clinical study, geriatrics, hospice, mattresses, seating, pressure ulcer

Index: *Ostomy Wound Management* 2014;60(8):30–39

Potential Conflicts of Interest: Ms. Girolami is a clinical consultant to the iheal Company (Cincinnati, OH), which supplied mattress and seating products for the study and is eligible for royalties from portions of iheal Company product sales.

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Ostomy Wound Management 2014;60(8):30–39

Key Points

- There is no strong evidence on support surface material, structure, or style as it relates to patient comfort, safety, and pressure ulcer treatment and prevention.
- The author prospectively evaluated the use of nonpowered, high-specification foam (HSF) chair (n = 33 patients) and bed (n = 44 patients) surfaces.
- Patients/caregivers rated the HSF products higher than previously used surfaces for all variables evaluated, no falls occurred, and the majority of preexisting pressure ulcers healed.
- The study outcomes in this vulnerable population are encouraging, and controlled clinical studies to determine the efficacy of these surfaces are warranted.

The Association for the Advancement of Wound Care's *Guideline of Pressure Ulcer Guidelines*[1] validates that pressure ulcer (PU) vulnerability is associated with decreased mobility and activity, altered nutrition, impaired sensory perception, aging, and declining general health status related to numerous comorbidities that impair tissue metabolism and create posture alterations. Additionally, the Guideline recommendations include the use of support surfaces on the bed and chair when individuals exhibit risk factors that may impair tissue tolerance, induce sustained tissue loads, and/or create excessive tissue stress and load. The Association for the Advancement of Wound Care Guideline Task Force reviewed 12 PU guidelines to establish 368 PU recommendations with strength of evidence ratings based on best available evidence and a content validity index based on a content-validation survey completed by multidisciplinary clinicians. A search of the literature[2] failed to provide any strong evidence on support surface material, structure, or style as it relates to patient comfort, safety, and PU treatment and prevention. Subsequently, studies such as Gefen et al's[3] literature review on the development, detection, and prevention of deep tissue injury (DTI) can alert clinicians that such injury can precede and exceed visual skin changes, reinforcing the importance of early onset pressure redistribution. Gefen's[4] bioengineering perspective of underlying biological, physical, biomechanical, and biochemical mechanisms seen in DTI further clarifies tissue injury sequela that occurs relative to stress load. Using animal experiments to predict DTI, Linder-Ganz et al[5] established pressure- and shear-related tissue injury is associated with internal strains and stresses in muscle, fat, and vascular structures subsequent to deformation created by external forces overlying skeletal prominences. In another study[6] using magnetic resonance imaging, a dimensional buttock model, and comparative pressures over the ischial tuberosity of six healthy and six paraplegic seated individuals, gluteal strains were measured to reflect not only more intense tissue load with sitting versus lying position, but also more intense tissue load in the paraplegic individual than in healthy persons. An overview of the literature on spine ergonomics by Pope et al[7] reveals musculoskeletal injuries and soft tissue stress and deformation occur in healthy persons subjected to fixed postures and prolonged sitting related to static loading, muscle fatigue, and accumulation of metabolites. Naqvi et al's[8] prospective study on chair types and seating comfort among 18 individuals >64 years of age yielding 170 observations, Horton et al's[9] prospective study of 30 healthy male participants demonstrating the craniocervical angle is optimized when seat back angle is 100° and a lumbar support is employed, and Batchelor et al's[10] prospective evaluation of hemiplegic patients in 25 hospitals in the UK identifying that seat shape and back contour are critical to comfort and support demonstrate balanced upright posture, centered torso, spinal alignment, and back and lower extremity positioning are ergonomic principles important to comfort, reduction of static load, and musculoskeletal health when seated.

Science supports the theory tissue load and stress can be decreased through ergonomic positioning and pressure redistribution surfaces. Although experts agree support surfaces are a critical component of any PU prevention plan of care for control of external forces, tissue stress, and skeletal strain, evidence is scant regarding individual clinical outcomes among the myriad of support surfaces. Black et al[11] identify multiple pressure redistribution support surface (PRSS) research opportunities in the AAWC PU guideline analysis of content validity and strength of evidence relevant to function and effectiveness of support surfaces, offloading equipment recommendations, effective seating systems and cushions, use of effective PRSS for treatment of multiple wounds and greater than Stage II wounds, and use of static support surfaces in PU treatment that prevent bottoming-out. In five separate systematic reviews and meta-analyses,[12-16] at least one systematic review revealed evidence supporting implementation of high-specification foam (HSF) for preventing and treating PU and some limited evidence for similar effects of air-fluidized beds, but little discussion of differences between various types of PRSS on either beds or chairs. However, a randomized, controlled study[16] comparing HSF and standard mattresses demonstrated HSF designs are more effective than standard foam in pressure redistribution; additionally, these high-specification mattresses offered a more economical choice than air products for PU healing and prevention.

Purpose

To obtain outcomes data regarding patient comfort, sliding and immersion perceptions, fall incidence, skin integrity, and PU healing when adding new HSF support surfaces to standardized PU prevention and treatment regimens for vulnerable, debilitated individuals, a prospective descriptive case

series study with historical controls was conducted. In light of the lack of definitive detailed manufacturing standards for any PRSS surface category and inconsistent testing specifications for PRSS efficacy, clinical outcome data may provide useful information to clinicians faced with selecting offloading equipment for highly vulnerable patients at risk of PU development.

This study included two new HSF devices with strategically designed foam segments and select indentation force deflection engineered to optimize body alignment, contact area, and pressure redistribution; both were in premarket status. One product is a mattress sized to accommodate a standard hospital bed frame; it measures 82 inches length (L) x 36 inches width (W) x 6 inches height (H) and features variable back, pelvic, and lower extremity immersion surfaces, a defined outer edge, sloped heel zone, and bidirectional stretch cover. The other device is a seating support surface sized to fit a standard medical grade portable recliner inclusive of back, seat, arms, and footrest. The portable recliner support surface has side attachments that overhang both chair arms, a contoured back (20-inch L x 19-inch W x 1- to 2-inch variable depth), a seat cushion (19-inch W x 20-inch L x 3-inch H) with attached sloped lower extremity support (15-inch L x 19-inch W x 2- to 3-inch H), and a bidirectional stretch cover.

Methods

Ethical considerations. A proposal for the study of a premarket HSF mattress that accommodates a standard hospital-sized bed frame and a premarket HSF support surface that fits a standard medical grade portable recliner was approved by the Ethics Committee of a large nonprofit hospice agency. This Ethics Committee approval also was provided to the VA rehabilitation unit that participated in the study. All study participants and/or their caregivers were informed regarding their rights of participation and provided signed consent.

Study participants: settings and protocols. Both the hospice and rehabilitation agencies had PU prevention and treatment protocols that included individualized repositioning schedules, support surfaces, skin hygiene, incontinence barriers, routine skin inspections, and weekly measurements of any existing wounds. End-of-life hospice programs endorse palliative care goals that do not include nutritional programs, rehabilitation, or aggressive wound care; thus, the majority of study participants were on supportive care only. The patients from rehabilitation units received nutritional programs, disease management, and physical therapy programs to optimize their health status.

The hospice agency already used a HSF mattress as the primary support surface on both inpatient and outpatient beds prestudy but had occasional product performance concerns. With no reliable support surface for individuals confined to portable recliner seating, the facility was interested in an alternative PRSS that had potential for improving comfort, migration, and PU incidence in their vulnerable patient population. The VA rehabilitation unit was seeking alternative foam mattresses for their inpatient skilled care facility that provided safe, reliable pressure redistribution, and as such included the trial mattress and chair cushion in their evaluation process.

Procedure. Study participants were requested to participate for a 30-day evaluation period unless a request for termination was made or a change in participant condition resulted in discharge or death. Participants could remain in the study from the time of inclusion through the end of the study period if they voiced interest in continuing to provide feedback to the investigators. Inclusion in the study outcome reporting required a minimum of 3 days on the trial product. Individuals were selected to participate over a 6-month period from April 1, 2012 through September 1, 2012. The study was concluded in the seventh month.

Inclusion criteria. Inclusion criteria required impaired activity/mobility status as determined by the need for assistance with ambulation or position changes; a minimum of one comorbidity; and care regimens employing standardized skin hygiene, incontinence, and repositioning protocols. Individuals were identified for participation in the study by their individual nurse managers based on risk for PU development related to impaired mobility/activity and/or clinician observed negative outcomes on existing PRSS such as pain or discomfort associated with sitting or lying surfaces, falls from equipment, nonhealing PU, and posture problems such as leaning, sliding, or slumping; these observations were verbally communicated by nurse managers but not all were part of the patient record. Study participants and/or their caregivers were informed of the study by the nurse manager and enrolled after inclusion criteria were satisfied, all questions were answered, and signed consent was obtained. Patients residing in a facility setting were seen daily by a nurse manager; patients residing at home were seen at least weekly by a nurse manager to ensure continuing PRSS satisfaction.

Survey tool. The survey tool, developed for this study and not validated, contained a demographic record, a note section to record preexisting conditions including pain and wound details, and a series of open-ended questions asked at each visit regarding comfort ranking, migration ranking, immersion ranking, heel offloading ranking, new pain or PU descriptions, transfer problems or fall occurrence, status of existing pain, and PU status since last visit. Integumentary status was noted as *intact* (absence of open wounds, color or texture changes, or pain over bony prominences) or *altered* (presence of an open wound, color or texture change, or pain over bony prominence, detailed in the patient record regarding appearance, size, and stage) on all patients at the initial investigator interview and at each subsequent interview during the trial period.

Study investigators recorded feedback after verbal prompting on each question category and obtained the following information on the initial patient visit: participant's

age, gender, preexisting conditions, height, weight, current integumentary status, prestudy equipment used, fall history associated with prestudy equipment, presence of pain associated with prestudy equipment, and perceptions of previous PRSS regarding comfort, migration, immersion, and heel offloading. The patient and/or caregiver ranked perceptions of comfort when positioned on equipment, control of migration downward when positioned on equipment, immersion of their body into the equipment surface without hammocking or bottoming-out, and heel offloading through either suspension or immersion of foot and ankle contours using three categories: good/well (coded as 3), fair/average (coded as 2), and poor/substandard (coded as 1). Patient rankings were logged when participants could provide reliable feedback; if patients were unsure of how to rank certain factors or if they were unable to provide feedback, the caregiver was asked to perform the ranking.

Patients who entered the study with preexisting PU or developed a PU during the course of the study had their ulcer stage and location noted on the survey tool; wound progress also was documented on the survey tool on each subsequent interview, recording the ulcer condition as *worse*, *improved*, or *unchanged* using data from the patient record as reported by the nurse manager or direct caregiver. The nurse assigned to each patient documented wound measurement and wound surface description. PU improvement included reduction of slough, necrosis, or ulcer length/width/depth (size); unchanged status included ulcers that remained the same in appearance and size; and worsened ulcer status included increased nonviable tissue or size. Wounds that completely closed through reepithelialization during the trial were recorded as healed. New and existing pressure injuries were staged using the National Pressure Ulcer Advisory Panel (NPUAP) staging criteria[1]; DTI was evidenced by purpuric skin changes or a blood-filled blister; Stage I: unblanchable erythema of the skin, pain, or altered tissue consistency/temperature; Stage II: epidermal erosion without devitalized tissue component; Stage III: full-thickness tissue erosion involving the subcutaneous area with or without devitalized tissue components; Stage IV: full-thickness tissue erosion extending to muscle/tendon/bone with or without devitalized tissue components; and unstageable: dense eschar/necrosis/slough obscuring visual observation of wound depth. Participants with preexisting PU were of particular interest because they had been selected for study inclusion by their healthcare professional due to either nonhealing status or new onset injuries on prestudy support surfaces. This followed PU best practice guideline[1] recommendations for the selection of an alternate support surface for improved pressure redistribution if PU healing expectations were not met. The healthcare professionals expected wounds to remain stable and free of complications on the hospice participants, while progress toward wound closure was the expected outcome for rehabilitation participants. Wound care procedures included dressings that manage drainage and support moist wound healing and autolytic or enzymatic debridement; prevention of skin perimeter trauma; spray wound cleansers; and use of topical antimicrobials as needed.

Study parameters and procedures. Feedback was obtained from nurse managers, study participants, and caregivers by one of the four study investigators via phone or inperson interview every 7 to 21 days for the duration of their participation in the study up to 120 days to log data on the study survey tool. The same trial equipment-related questions as those asked at baseline were asked each visit and responses recorded. Repeat inquiries were done to establish a clear opinion on ranking of their new equipment over time to minimize potential Hawthorne effect responses after first receiving a new device. Patients who entered the study with complaints of discomfort were asked at each interview to quantify their general perception of pain as it related to implementation of the trial equipment as either worse, improved, or unchanged when positioned on the trial mattress or seating system. No pain rating scale was employed other than the inquiry categories of worse, improved, or unchanged; responses from caregivers were included if the patient was unable to voice a response. Facial grimacing, moaning, or calling out was observable and interpreted as an expression of discomfort.

Falls. The incidence of falls (patient safety) was included during each interview and recorded as either absence of or fall occurrence associated with transferring from or falling off the chair or mattress PRSS. Fall data were obtained from the patient when possible or abstracted from the patient record as reported by the nurse manager or by the direct caregivers. Cessation of sliding down, improved posture, and alignment information, as well as comments regarding the perception of stability on the sides of the mattress to aid in standing (affecting security from falls), were recorded in the comments section.

Study duration. Length of the study participant observation was noted as number of days from the point of entry to the point of withdrawal from the study. Patients who remained in the study 3 or more days were included in the outcome data because strong opinions on improved comfort were voiced by several end-of-life individuals.

Data entry and analysis. All survey tool patient identification data were coded to maintain patient privacy and entered into an EXCEL© (Microsoft, Redmond, WA) spreadsheet for analysis. Prestudy mattress surfaces were grouped and coded as follows: Category A — standard surfaces such as spring style mattresses, recliners, and standard foam mattresses; Category B — similar high-specification mattresses; and Category C — air-replacement mattresses, including powered air flotation mattresses and foam/air combination replacement mattresses. Seating surfaces were categorized as: Category A — gel/foam hybrid cushion; Category B — miscellaneous foam or no additional support; and Category C — wheelchair, including standard or reclining wheelchairs with miscellaneous cushions or orthotic devices.

A comparative analysis of pretrial versus trial PRSS rankings for both mattress and seating system was conducted to determine statistically significant differences between the study variables for all participants who provided pretrial product feedback. A ranking of each factor on the pretrial PRSS provided on the initial visit was compared with the average trial PRSS ranking, which was determined by adding responses on each factor collected over the duration of the patient observation period and dividing by the number of responses. For example, a patient may have ranked his/her pretrial PRSS comfort as 3 and the trial product comfort at level 3 the first week but changed trial product ranking to 2 the second week, and 3 the remaining 3 weeks, resulting in an average trial score of 2.8. Pretrial product scores were compared to the average trial score to determine statistical differences. The pretrial score of 3 in the example would be compared to the trial score of 2.8. Although trial PRSS rankings were obtained from all participants at each interview, only persons who were able to rank their pretrial equipment were included in the statistical analysis. Participants who could not remember the pretrial PRSS or who refrained from providing a ranking on a pretrial PRSS were excluded from the statistical analysis and were included in descriptive trial product response reporting only. Statistical calculations were performed using R© software (R Core Team 2013. R: A language and environment for statistical computing, Vienna, Austria). Because data were ordinal, Wilcoxon signed rank tests and some rapid approximate statistical procedures were used to examine differences between pre- and postranking scores. The Wilcoxon test function was used for comparisons of median pre- and postscores. In cases where the sample size was not large enough to assume a normal distribution for the Wilcoxon W, the Wilcoxon matched-pairs signed-ranks test was used based on probability tables published when this test is used for small samples. For all analyses, two-tailed tests were performed, with a statistical significance criterion of $P = 0.05$ for the probability of incorrectly rejecting the null hypothesis of equal pretrial and trial rankings. (Note: The referenced sample sizes, N, for Wilcoxon tests indicate the number of nonzero differences, not the typical notation for degrees of freedom calculations, N – 1).

Descriptive statistics. The ranking responses inclusive of all participants in each product trial regarding perception of trial product comfort, migration, immersion, and heel offloading were tabulated as the number of respondents whose average ranking of each factor was 2.5 or above (for good/well), 1.8 to 2.4 (for fair/average), and 1.7 and below (for poor/substandard) for the mattress or seating support surface. The number of participants who voiced presence of pain associated with being positioned on a PRSS at the onset of the each product study was calculated, then the number of these participants who reported their pain improved versus those that remained unchanged or became worse on the trial mattress and/or seating product were recorded. Safety event incidence was calculated as the number of patients who had falls related to the pretrial equipment versus the number who had falls associated with the trial mattress or seating support surface. Finally, all PU wounds were categorized according to stage; then the number in each stage that subsequently healed, improved, remained unchanged, or deteriorated, as well as any new onset ulcers that occurred in that stage category during the trial on either the trial mattress or seating system, were calculated and the overall number of healed, improved, or deteriorated wounds was determined.

Results

Hospice patients comprised the majority of the study group the first 4 months; a combination of hospice and rehab participants evolved over the final two solicitation months. The forty-four (44) patients (24 men, 20 women) who participated in the mattress evaluation had an average age of 79 (range 47 to 98) years, average height of 66 (range 48 to 75) inches, and an average weight of 154 (range 85 to 270) lb. The mattress evaluation initially comprised 45 individuals; one person withdrew from the study on day 2 due to transition to alternate care. Of the 44 patients, 32 were from the hospice program and 12 from the rehabilitation facility. All 44 participants exhibited impaired mobility and/or activity: 16 were bedbound and 28 were chair-bed confined. All participants had at least one comorbidity, including cardiovascular disease, stroke, chronic obstructive pulmonary disease, dementia, chronic renal insufficiency, malignant carcinoma, arthritis, peripheral vascular disease, PU, amputation, severe contractures, incontinence, malnutrition, and/or impaired hydration that effected overall health status; 16 had one to two comorbidities, and 28 had more than three conditions. The average period for mattress observation was 53 (range 3–120) days. Most (33) patients were followed for more than 30 days; the remaining 11 individuals were discharged or died but provided relevant contributing data (see Table 1).

Thirty-three (33) patients (eight men, 25 women) who participated in the portable recliner support system evaluation were an average age of 82 (range 63–97) years, an average height of 65 (range 59–75) inches, and an average weight of 146 (range 90–245) lb. The participants for the chair support system included 32 hospice program patients and one rehabilitation program patient. All participants exhibited impaired mobility and/or activity: 32 were chair-bed confined, and one was ambulatory with assistance. All participants had one or more of the previously mentioned comorbidities that affected their overall health status; 19 had one to two comorbidities, and 13 had three or more conditions. The average period for gerichair support system observation was 39 (range 13–66) days, 27 were followed for more than 30 days, and the remaining six were discharged or died but provided relevant contributing data (see Table 1).

Four study participants utilized both devices during the trial; all others used either the mattress or the gerichair support

Table 1. Patient demographics

Patient characteristic	Mattress trial participants	Mattress standard deviation	Seating system trial participants	Seating standard deviation
Age (average: range)	79: 47–98 years	13.26408498	82: 63–97 years	10.05750226
Gender (number of each)	Male 24, female 20		Male 8, female 25	
Height (average: range)	66: 48–75”	5.134383	65: 59–75”	3.71112664
Weight (average: range)	154: 85–270 lb	50.32232825	146: 90–245 lb	36.38014085
Preexisting conditions				
• 1–2 comorbidities (N)	16 patients		19 patients	
• >2 comorbidities (N)	28 patients		13 patients	
Trial period (average: range)	53: 3–120 days	34.3923341	39: 13–66 days	11.92015062

Table 2. Mattress and seating surface prestudy and study rankings

Parameter	Mattress value[a]	Mattress scores			Seating value	Seating scores		
		2.5–3	2.4–1.8	1.7–1		2.5–3	2.4–1.8	1.7–1
Comfort	P=0.0008 (P <0.001)	Post: 39	2	3	P=0.00	Post: 33	0	0
		Pre: 16	20	7		Pre[a]: 0	9	19
Migration	P=0.00466 (P <0.01)	Post: 28	13	3	P=0.0003	33	0	0
		Pre: 17	17	9		Pre[a]: 4	3	21
Immersion	P=0.00544 (P <0.01)	Post: 40	1	2	P=0.00	33	0	0
		Pre: 29	9	5		Pre[a]: 6	13	9
Heel offloading	P=0.00 (P <0.001)	Post: 40	1	2	P=0.00014	31	2	0
		Pre: 11	15	16		Pre[a]: 2	2	18

[a] Scores compared only where pretrial data were provided; scale: 3=good, 2=fair, 1=poor; offloading was not applicable for six participants

surface. None of the participants (total 77) was independently ambulatory, 16 were totally bedbound, and the remaining patients were considered chair-bound status with either no ambulation ability or limited assisted ambulation.

Mattress results. Pretrial sleeping surfaces included 14 home or standard foam mattress (with or without overlay), 16 HSF mattresses similar to the study device, 12 air mattresses, and one recliner chair. The 44 participants predominantly ranked comfort, migration, immersion, and heel offloading on the trial product 2.5 or greater (good) (see Table 2). The poor (<1.8) ranking scores (3) for mattress comfort and (2) for immersion were associated with reports of excess back firmness and/or deep pelvic submersion in the severely contracted or obese individual. One participant was unsure of the pretrial device because he/she was too ill to recall prior experiences, and for another individual heel offloading was not applicable due to bilateral above-the-knee amputation. Otherwise, pretrial mattress rankings for comfort included 16 good, 20 fair, and seven poor. Comparatively for the trial mattress, 39 participants ranked comfort as good, two ranked it fair, and three ranked it poor. Migration control ranking of the pretrial mattress included 17 good, 17 fair, and nine poor, compared to the trial mattress that received rankings of 28 good, 13 fair, and three poor. For immersion into the mattress without bottoming-out on the pretrial mattress, 29 ranked it good, nine ranked it fair, and five ranked it poor, as compared to the trial mattress where 40 ranked it good, one ranked it fair, and two ranked it poor. Heel offloading through shared contact of the lower extremity and elimination of intense strike zones on the bony prominences of the heel/ankle region for the pretrial surface was ranked by 11 as good, 15 as fair, and 16 as poor, while the trial surface was ranked by 40 as good, one as fair, and one as poor.

Among the results for the three categories of pretrial versus trial product, mattresses in Category A included 15 nonpowered pretrial units that were compared to the trial unit. Pretrial standard device category comfort rankings were five good, six fair, and four poor; trial mattress comfort in this category was ranked as 13 good and two poor. Migration control on the pretrial product was ranked as eight good, five

Table 3. Wilcoxon signed rank test calculations for overall mattress performance rankings pre- and posttrial

	N	W value	Mean difference	Sum + rank	Sum - rank	Z	*P* value	Mean W	Standard deviation W
Comfort	29	62.5	-1.17	62.5	372.5	-3.35	0.0008	217.5	46.25
Migration	29	86.5	-1.21	86.5	348.5	-2.83	0.00466	217.5	46.25
Immersion	30	97.5	-0.07	97.5	367.5	-2.78	0.00544	232.5	48.62
Heel offloading	30	0.00	-1.55	0	465.00	-4.78	0.00	232.5	48.62

Table 4. Wilcoxon signed rank test comparing pretrial mattress performance ranking with trial mattress ranking (G=2.5-3, F=1.8-2.4, P=1-1.7) using pretrial product categories

Surface category	Comfort	Migration	Immersion	Heel offloading
A. Standard surfaces: *P* value	>0.05[a]	0.65	0.084	<0.05[a]
Pretrial rank	G: 5, F:6, P:4	G:8, F:5, P:2	G:9, F:4, P:2	G:3, F:6, P:5, NA:1
Posttrial	G:13, F:0, P:2	G:9, F:5, P:1	G:14, F:0, P:1	G:13, F:0, P:1, NA:1
B. High-specification foam surface: *P* value	0.0034	0.093	0.061	0.0051
Pretrial rank	G:5, F:9, P:2	G:7, F:7, P:1	G:11, F:3, P:1	G:6,F:4, P:6
Posttrial	G:15, F:1, P;0	G:11, F:3, P:2	G:15, F:1, P:0	G:15, F:1, P:0
C. Air surfaces: *P* value	>0.05 [a]	<0.05 [a]	>0.05 [a]	0.0051
Pretrial rank	G:6, F:5, P:1	G:2, F:5, P:5	G:9, F:2, P:1	G:2, F:5, P:5
Posttrial	G:10, F:1 P:1	G:7, F:4, P:1	G:11, F:0, P:1	G:12, F:0, P:0

[a] The sample size is not large enough to calculate an accurate P value. Using the critical-value approach for the W value statistically significance is determined. G=good, F=fair, P-poor

fair, and two poor; trial mattress was ranked as nine good, five fair, and one poor. Immersion on the pretrial products was ranked as nine good, four fair, and two poor; trial mattress immersion was ranked as 14 good and one poor. Heel offloading on the pretrial product was ranked as three good, six fair, and five poor; trial mattresses were ranked as 13 good and one poor. One participant with bilateral lower extremity amputation marked heel offloading as not applicable.

Mattress Category B included 16 nonpowered pretrial products compared to the trial mattress. Comfort on the pretrial HSF category was ranked five good, nine fair, and two poor; on the trial mattress 15 ranked comfort as good and one as fair. Migration control ranking on the pretrial product included seven good, seven fair, and one poor versus 11 good, three fair, and two poor on the trial mattress. Immersion rankings on the pretrial product included 11 good, three fair, and one poor versus 15 good and one fair on the trial product. Heel offloading rankings on the pretrial product included six good, four fair, and six poor versus 15 good and one fair on the trial mattress.

Mattress Category C consisted of 12 powered products compared to the trial product. Comfort rankings on the pretrial air products included six good, five fair, and one poor versus 10 good, one fair, and one poor on the trial mattress. Migration control ranking on the pretrial product included two good, five fair, and five poor versus seven good, four fair, and one poor on the trial product. Immersion ranking on the pretrial product included nine good, two fair, and one poor compared to 11 good and one poor on the trial product. Heel offloading ranking on the pretrial product included two good, five fair, and five poor compared to 12 good on the trial product.

For the 43 participants who ranked their pretrial equipment, overall pretrial and trial rankings were compared to determine statistical significance in comfort, migration, immersion, and heel offloading. The negative sum rank for comfort (372.50) was higher than the positive rank (62.50), which indicates the postscore is higher than the pre-score. The Wilcoxon signed rank revealed significantly greater mattress comfort during the trial ($z = -3.35$, $P < 0.001$). As shown in Table 3, similar statistically significant improvements occurred during the PRSS trial period for migration, immersion, and heel offloading.

Wilcoxon signed rank tests were conducted between pre- and posttrial scores on ratings for comfort, migration, immersion, and heel offloading in each of the pretrial categories as a direct comparison to various product types. When analyzed by categories, sleep surface comparisons show statistically significant and higher posttrial scores for the trial mattress in the following areas: heel offloading for standard

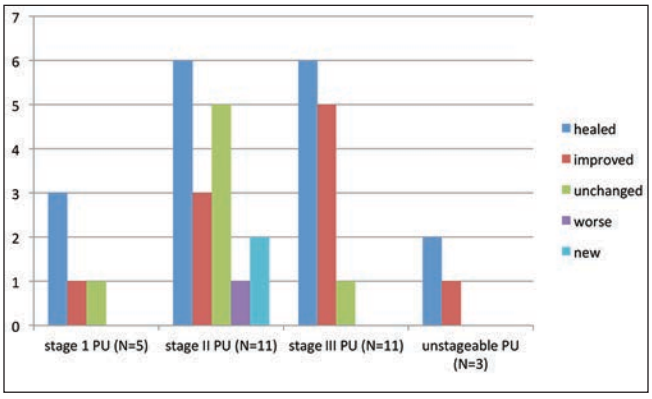

Figure 1. Mattress trial pressure ulcer (PU) outcomes. The number of patients with PU in each stage is represented by N. Five participants had more than one PU of the same stage and four participants had more than one stage wound; thus, the total of N exceeds the actual patient total.

surfaces, comfort and heel offloading for alternative high-specification mattresses, and migration and heel offloading for air mattresses (see Table 4).

Pain. Twenty-seven of the mattress trial participants reported pain associated with their pretrial mattress at the onset of the evaluation; 19 of these individuals reported improvement in their pain status they associated with the trial mattress introduction, eight reported their pain was unchanged, and one reported increased pain after the trial mattress replaced a sleep recliner.

Falls. No falls were associated with transfer or repositioning on the trial mattress. The two participants who had experienced repeated falls from their pretrial mattress ceased having fall issues with the introduction of the trial mattress. Feedback on mattress safety and fall prevention included comments that the mattress does not shift on the bed frame during transfer and the firm wide edge provides stability with sitting and grasping assistance during egress. One bariatric patient reported the mattress center was too soft, making egress difficult.

PU. Among the 44 mattress participants, 26 — 23 hospice program participants and three rehab participants — had preexisting PUs. A total of 35 preexisting PUs were followed during the trial; 17 healed, 10 improved, seven remained unchanged, and one coccyxgeal ulcer deteriorated from a Stage II to Stage III in an obese individual who required continual upright positioning in the final weeks of life. Of the 35 preexisting PUs, five were Stage I, 14 Stage II, 13 Stage III, and three were unstageable, eschar-covered ulcers. The number of PUs in each stage that healed or improved included four Stage I, eight Stage II, 12 Stage III, and all three unstageable (see Figure 1). New-onset Stage II PUs occurred in two participants; one hip ulcer developed on day 60 in a severely malnourished individual with a preexisting, unchanged coccyx ulcer, and one intermittent recurring sacrococcygeal ulcer developed on day 48 in a person who was severely contracted who remained in a continual upright sitting position due to gastric reflux. The latter individual had healed preexisting heel and hip ulcers during her observation period.

Portable recliner (seating) PRSS outcomes. Most (31) of the 33 participants ranked the trial seating general comfort, migration control, immersion, and heel offloading as good; scores exceeded 2.5. All 33 participants ranked the trial seating PRSS as good in comfort, migration control, and immersion; 31 ranked heel offloading good and two ranked it fair.

Twenty-eight participants were able to recall pretrial equipment for ranking purposes. Pretrial seating replaced by the trial recliner PRSS seating included 11 gel/foam hybrid seat cushions, eight generic foam seat cushions or recliners with no additional support, and nine miscellaneous seating systems. For overall pretrial device comfort, none ranked it good, nine ranked it fair, and 19 ranked it poor. Migration control on the pretrial device was rated good by four, fair by three, and poor by 21. Immersion rankings were noted as good by six, fair by 13, and poor by nine. Heel offloading was ranked as good by two, fair by two, poor by 18, and not applicable by six individuals who had a pretrial device that did not include heel suspension (see Table 2).

Seating Category A comfort ranking included six good and five fair; all 11 participants ranked the trial PRSS as good. Pretrial product migration control was ranked poor by all 11 respondents; all 11 ranked the trial product as good. Immersion on the pretrial cushion ranking included four good, four fair, and three poor; all 11 ranked trial PRSS immersion as good. Heel offloading on the pretrial product was rated as poor by all 11 participants; 10 rated the trial PRSS good and one rated it fair.

Seating Category B ranking for comfort when no cushion or a standard foam was used was rated poor by seven and fair by one of eight participants; all eight ranked the trial PRSS comfort as good. Migration control ranking on the pretrial seating included five poor, one fair, and one good; all eight rated the trial product as good. Immersion ranking pretrial was rated as three poor, four fair, and one good; all rated the trial PRSS as good. Pretrial heel offloading included six poor, one fair, and one good, versus seven good and one fair on the trial PRSS.

Seating Category C for all four categories on miscellaneous seating systems using the trial PRSS was ranked as good by all nine participants in this group.

For the 28 participants who ranked their pretrial equipment, Wilcoxon signed rank tests were conducted between pre- and postscores on ratings for comfort, migration, immersion, and heel offloading for participants who used a portable recliner with or without support. The results indicate statistically significant differences between pre- and postscores for all ratings. The higher negative sum-ranks indicate a higher postscore (see Table 5).

Wilcoxon signed rank tests were conducted between pre-

Table 5. Wilcoxon signed rank test calculations for overall seating system performance ranking pre-/posttrial

	N	W value	Mean difference	Sum + rank	Sum - rank	Z	*P* value
Comfort	21	0.00	-1.67	0.00	231.00	-4.01	0.00
Migration	17	0.00	-1.94	0.00	153.00	-3.62	0.0003
Immersion	21	0.00	-1.12	0.00	231.00	-4.01	0.00
Heel offloading	19	0.00	-1.89	0.00	190.00	-3.82	0.00014

Table 6. Wilcoxon signed rank test comparing each pretrial surface category performance ranking by patient or care provider

Category	Comfort	Migration	Immersion	Heel offloading
A. Recliner/Gel	0.0034	0.0034	0.0034	0.0034
Pretrial rank	G:6, F:5, P:0	G:0, F:0, P:11	G:4, F:4, P:3	G:0, F:0, P:11
Posttrial	G:11, F:0, P:0	G:11, F:0, P:0	G:11, F:0, P:0	G:10, F:1, P:0
B. Recliner/Basic	<0.05 [a]	0.0038	0.0038	<0.05 [a]
Pretrial rank	G:0, F:1, P:7	G:2, F:1, P:5	G:1, F:4, P:3	G:1, F:1, P:6
Posttrial	G:8, F:0, P:00	G:8, F:0, P:0	G:8, F:0, P:0	G:7, F:1, P:0
C. Wheelchair	<0.05 [a]	<0.05 [a]	<0.05 [a]	<0.05 [a]
Pretrial rank	G:0, F:3, P:6	G:2, F:2, P:5	G:1, F:5, P:3	G:1, F:1, P:1,
Posttrial	G:9, F:0, P:0	G:9, F:0, P:0	G:9, F:0, P:0	G:9, F:0, P:0

[a] *The sample size is not large enough to calculate an accurate P value. However, using the critical value approach for the W value, the result is statistically significant.*

and post-scores on ratings for comfort, migration, immersion, and heel offloading for seating devices in categories A, B, and C. The results indicate statistically significant differences between pre- and postscores for all ratings (see Table 6).

Pain. Seventeen participants said they had pain related to sitting at the onset of the evaluation; all of these individuals reported their pain resolved or improved during the trial period, which they associated with the support surface introduction. Additional undocumented feedback relative to comfort was observed as positive behavioral changes evident in multiple individuals based on perceptions of previous attempts to get out of the chair or continual calling out to be returned to bed; these patients had become quiet and content with implementation of the recliner PRSS.

Safety. Seating surface safety on the trial recliner PRSS was a major concern in all care settings; no falls, leaning over, or migration were reported with the trial device. Users and caregivers reported cessation of sliding down, improved posture, and alignment in all of the study participants. Although no falls had occurred on the prestudy seating products, multiple complaints of fall risk were expressed by caregivers associated with patients sliding down in the chair before the new device was implemented.

PU. Of the 33 study participants, 13 hospice patients had 20 PU; no PU were present on enrollment in the rehabilitation center. No new PU occurred during the seating trial. Preexisting PU included two Stage I, six Stage II, 10 Stage III, and two unstageable, eschar-covered ulcers. Of the total 20 wounds, 17 ulcers healed and three improved; the improved wounds all occurred on a lower extremity (two unstageable and one Stage III) (see Figure 2).

Discussion

Gefen et al's[3] review states tissue injury begins in tissues under stress and deformation; thus, the goal of pressure redistribution is best accomplished by addressing static load and musculoskeletal stress through posturing and immersion for increased contact surfaces. The current study findings showed the majority of participants gave high ratings for comfort, migration control, immersion, and heel offloading of the trial products. The most notable clinical results show 34 out of 55 PU healed and of these healed wounds, 33 healed in individuals who had significant comorbidities and were on hospice programs without aggressive treatment interventions to improve healing rates. The hospice population would be considered one of the most vulnerable for PU development due to their disease states, altered nutrition, and progressive inactivity.[1] General palliative care goals are unique in that impaired states are not aggressively treated; rather, patient-centered goals consist of comfort, safety, and prevention of complications. Achieving healing in this population supports the premise that PRSS selection may be one of the most rel-

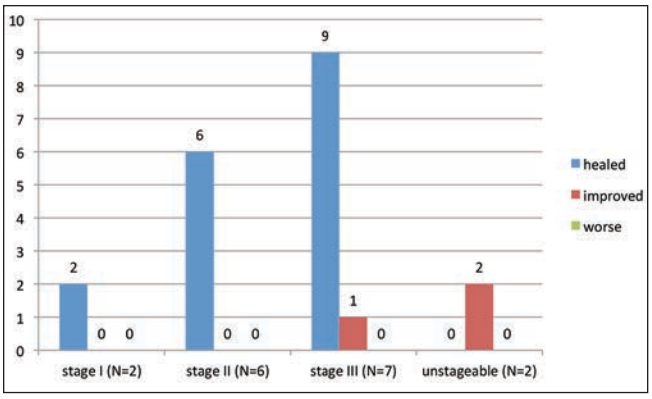

Figure 2. Seating trial preexisting pressure ulcer (PU) outcomes. The number of patients with PU in each stage is represented by N. One participant had more than one PU of the same stage and four participants had more than one stage wound; thus, the total of N exceeds the actual patient total.

evant interventions in PU healing and prevention. This study additionally is consistent with earlier research[16] that identifies HSF designs as more effective in pressure redistribution than standard foam as evidenced by favorable analysis of the trial products in pre- and posttrial rankings on various surfaces inclusive of standard foam. Although ergonomics is not frequently discussed in conjunction with pressure redistribution and comfort in the healthcare world, Pope,[7] Naqvi,[8] Horton,[9] and Batchelor[10] provide reason to consider the critical role of contours and design in preserving musculoskeletal health. The trial product designs incorporate engineering that addressed skeletal contours and weighting; as such, comfort ranking, migration control, improvement in pain, and tissue integrity preservation are relevant findings. Although not included as a study variable, it is noteworthy that caregivers reported improved sitting posture in the vast majority of participants with introduction of the recliner PRSS.

Limitations

Small sample size, convenience sampling, and the lack of a prospective control arm of the study are important limitations. Additionally, the use of a survey tool specifically constructed for this study that lacks validated ranking scales for comfort, pain, migration, immersion, and heel offloading limit comparison of current results to other research findings. Repeat studies utilizing validated scales and randomized controlled studies are needed to establish clinical guidelines for PRSS classification, levels of efficacy, and design requirements.

Conclusion

Clinical outcomes data are needed to select support surfaces for vulnerable populations at risk for skin breakdown. The results of this prospective descriptive case series study with historical controls showed that, in this population, the surfaces were safe and rated highly by patients and/or caregivers for providing comfort, migration control, immersion, heel offloading, less pain, and fewer falls. In addition, PU healing and prevention outcomes were good. Randomized comparative studies to compare patient and wound outcomes as well as safety criteria and user variables are needed to establish evidence-based practice product selection guidelines. ■

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