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A Randomized Control Trial to Evaluate Pressure-Reducing Seat Cushions for Elderly Wheelchair Users

[Features: Original Investigation]

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ABSTRACT

OBJECTIVE: To determine if the use of pressure-reducing wheelchair cushions for elderly nursing home resident wheelchair users who are at high risk for developing sitting-acquired pressure ulcers would result in a lower incidence rate of pressure ulcers, a greater number of days until ulceration, and lower peak interface pressures compared with the use of convoluted foam cushions over a 12-month period. To determine the feasibility of conducting a subsequent full-scale definitive trial to evaluate the use of pressure-reducing seat cushions for elderly nursing home resident wheelchair users.

DESIGN: Randomized control trial

SETTING: 2 200-bed skilled nursing facilities (1 suburban and 1 urban academic medical center)

PATIENTS: 32 male and female at-risk nursing home residents who were wheelchair users >=65 years of age. Participants had Braden Scale scores <=18, Braden Activity and Mobility subscale scores <=5, no sitting surface pressure ulcers, and a daily wheelchair sitting tolerance of more than 6 hours. All met criteria for using the ETAC Twin wheelchair.

INTERVENTIONS: Seating evaluation with pressure-mapping and subsequent seating prescription. Subjects were assigned to either a foam (n=17) or pressure-reducing cushion (n=15) group and weekly assessments of skin and pressure ulcer risk were made.

MAIN OUTCOME MEASURES: Incidence of pressure ulcers, days to ulceration, and peak interface pressure.

MAIN RESULTS: At a 95% confidence interval, a 2-tailed analysis showed no differences between the FOAM and pressure-reducing cushion groups for pressure ulcer incidence, total days to pressure ulcer, or initial peak interface pressure. Pressure-reducing cushions were more effective in preventing sitting-acquired (ischial) pressure ulcers ($P < .005$). Higher interface pressures were associated with a higher incidence of pressure ulcers ($P < .001$).

CONCLUSIONS: A definitive randomized control multicenter cushion trial is feasible with a sample size of 50 to 100 per study group. In the definitive trial, the definition of sitting-acquired pressure ulcers should be limited to lesions occurring over the ischial tuberosities.

PURPOSE: To offer an educational experience that will help to improve the participant's understanding of how pressure-reducing wheelchair cushions for elderly nursing home residents were evaluated in a randomized control trial.

TARGET AUDIENCE: This CME/CE activity is intended for physicians and nurses with an interest in the management of elderly wheelchair users who are at high risk for developing sitting-acquired pressure ulcers.

LEARNING OBJECTIVES: At the conclusion of this course, participants should be able to:

1. Identify the risk for development of sitting-acquired pressure ulcers among elderly nursing home wheelchair users.
2. Describe the use of the Braden Scale in identifying those nursing home residents at high risk for pressure ulcer development.
3. Summarize the issues related to seat cushion research and sitting-acquired pressure ulcers among elderly wheelchair users.

Sitting-acquired pressure ulcers (PUs) are a significant problem for the elderly nursing home population. From a literature review of PUs in the elderly, Zacharkow [1] reported that 36% to 50% of PUs were attributed to sitting in a wheelchair. Shaw [2,3] quantified the scope of the problem in 6 Memphis nursing homes during the early 1990s. He reported that as many as one third of nursing home wheelchair users experienced sitting discomfort and more than half had high sitting interface pressures.[2,3] His research supports previous investigations which demonstrated that many wheelchairs do not fit their elderly users.[4-6] Such inadequacy contributes to the development of PUs.[1,7] In addition, Shaw [8] found that 34% had severe seating or mobility problems and up to 80% had either a seating or a mobility problem. Individuals with mobility impairments that prevent independent repositioning and individuals who are bedridden or chair bound tend to be at the greatest risk for PU development.[9]

Despite this evidence and federal regulations directed at preventing the development and progression of PUs, the US population of elderly wheelchair users (approximately 600,000 and growing) is not routinely evaluated for seating and positioning needs.[3] The lack of seating and positioning services and products for this population is directly related to inadequate funding, which may be attributed to many factors.

First, the magnitude of the problem is difficult to ascertain. As with all PUs, valid estimates of the prevalence and incidence of sitting-acquired PUs in the elderly nursing home population are elusive. Estimates are generally flawed due to inconsistencies in defining PU stages and the fact that Stage I PUs are unreliably assessed, especially in individuals with darkly pigmented skin. However, the best estimates to date report the prevalence of PUs among nursing home residents to be 7% to 28%.[9-13] The most common sites for PUs in this population are the sacrum or coccyx (36%), over the trochanter (17%), over the ischial tuberosities (15%), heels (12%), ankles (7%), and other sites (13%).[10] If the majority of PUs over the ischial tuberosities and a small percentage of sacrococcygeal PUs are considered to have incurred from excessive pressure while sitting, then pressure-reducing seating interventions have the potential to prevent a minimum of 15% of PUs in this population. Healthy People 2010 includes the measurable prevention objective of decreasing PU prevalence 50% by the year 2010.[14] This makes the need for valid estimates of prevalence and incidence of PU sites more urgent because the targeting of future interventions by site will aid in achieving this goal.

Second, relatively few seating studies of the elderly exist. The majority of previous research has been targeted toward those with the highest risk for PU development and for whom third-party funding is available (ie, individuals with spinal cord injury, multiple sclerosis, or spina bifida).[15,16]

Third, the few existing studies of elderly wheelchair users that used comfort and interface pressure as indicators of the pressure-reducing capabilities of seat cushions have not clearly demonstrated the relationship between interface pressure magnitudes and the incidence of PUs.[2,17-19] The primary factors implicated in this lack of evidence are related to characteristics of the different pressure-mapping devices, lack of methodologic standardization, small sample sizes, and inadequate control. For example, although interface pressure is a convenient and, under certain conditions, valid indicator of soft tissue stress and strain, it is not necessarily the most immediate or reliable indicator of potentially damaging loading conditions and has considerable limitations.[20-22] However, despite its limitations, interface pressure is the most common parameter used to assess support surface performance. In addition, lack of standard methodology has hampered the interpretation of study results of interface pressure and PU incidence. There is no widely accepted standard tool or technique for pressure measurement; however, a consensus regarding approximate pressure ranges for seating surfaces has evolved.[3] Conine [23] found that geriatric patients who had interface pressure measurements higher than 60 mm Hg (Scimedics Pressure Evaluator; Next Generation Company, Temecula, CA) had a significantly higher incidence of PUs. Shaw [24] recommends avoiding sitting pressures in excess of 80 to 100 mm Hg (Oxford Pressure Monitor 2; Oxford Pressure Monitor, Oxford, England). Because previous research has not revealed any one cushion that consistently provides the lowest readings for all subjects,[24-26] the need for individual pressure assessment prior to cushion prescription is warranted to assist in determining PU risk.

Lastly, contradictions exist in the literature regarding the clinical benefits of commercial cushions designed to reduce the risk of sitting-acquired PUs. Studies comparing polyurethane foam slabs to custom-contoured foam cushions failed to demonstrate significant differences in the incidence of PUs.[7,27] Conversely, a subsequent study by Conine [23] comparing a polyurethane foam slab with the Jay cushion (Jay Wheelchair Cushions, Boulder, CO) showed a significantly lower incidence of PUs in the Jay group (25%) compared with the foam group (41%). It is important to note that Conine's study included the provision of a seating evaluation and appropriate modifications to the wheelchair. A higher level of internal validity was attained than in previous studies, where the effects of the cushion were confounded by those of the chair. The results of Conine's study are limited, however, because a planar foam cushion was compared with only 1 type of the many available commercial cushions.

If third-party funding for elderly wheelchair users is to be obtained, more clinical trials must be conducted. Use of commercial cushions, which are available at a retail cost ranging from $150 to $1000, must be justified. Funding is available for specialty beds, mattresses, and mattress overlays that have been designed to provide pressure reduction for bedridden individuals at risk for PUs because clinical trials have demonstrated the effectiveness of pressure- and moisture-controlling support surfaces in reducing PU risk.[28-35] In addition, guidelines have been proposed to standardize methods of evaluating support surfaces [36] in order to improve the design and control of clinical studies of these surfaces. Comparable studies of seating surfaces have not been performed that would justify the funding for seating interventions for all populations at risk for PU development.

The goals of this study were as follows:

(1) to test the hypotheses that for elderly nursing home resident wheelchair users at risk for developing sitting-acquired PUs, the use of pressure-reducing wheelchair cushions over a 12-month period would result in a lower incidence rate of ulceration compared with the use of convoluted foam cushions; a greater number of days until ulceration compared with the use of convoluted foam cushions; and lower initial peak interface pressures compared with the use of convoluted foam cushions

(2) to determine the sitting-acquired PU incidence rate for this population

(3) to compare the interface pressure data with PU incidence

(4) to use the incidence rates found for the control and intervention groups in this pilot study to more accurately estimate the size of the sample needed for a definitive, multicenter clinical trial

(5) to develop and test a protocol for a randomized, multicenter clinical trial investigating the efficacy of pressure-reducing seat

cushions in preventing PUs in this population.

METHODS

Participants

Male and female elderly nursing home residents were cumulatively recruited from 2 local skilled nursing facilities over a 1-year period from June 1998 to June 1999. To be included in the study, residents had to be 65 years or older and have (1) a Braden Scale score of less than or equal to 18, (2) a combined Braden Activity and Mobility subscale score of less than or equal to 5, (3) an absence of sitting-surface PUs, (4) a tolerance for total daily wheelchair sitting time equal to or greater than 6 hours, and (5) sitting needs that could be accommodated by the ETAC Twin wheelchair (ETAC USA, Waukesha, WI), including a body weight of less than 250 lbs.

Potential subjects were identified by either a charge nurse or supervisor from each nursing unit or by the facility's physical therapy and occupational therapy supervisors. After obtaining the subject's consent, an initial screening of the subject's medical records was completed by the research staff. If a subject met the initial eligibility criteria, he or she was asked to participate in the study. After informed consent was obtained, a final eligibility screening was performed by a member of the research team, consisting of validation of the inclusion criteria and a skin inspection to confirm absence of sitting-surface PUs.

Assignment

Subjects were classified according to their initial Braden Scale score as either high risk (Braden Scale score of 8 to 13) or low risk (Braden Scale score of 14 to 18) for later use in testing equivalence between the groups. Patients were then randomly assigned by the 2 risk strata to either a foam (FOAM) or pressure-reducing cushion (PRC) treatment group. Random treatment assignments with a 1-to-1 scheme were generated prior to the start of the study by a separate research team member who was not involved in executing the trial. Sequentially numbered sealed envelopes containing the treatment assignment were prepared to be opened in order as a resident was determined eligible and consented to participate in the study.

Blinding

Although the study could not be completely blinded, the nursing staff members performing the outcome measurements were blinded to the treatment group. This was accomplished by removing all identifying labels from the incontinence covers and seat cushions. In addition, the data analyses were performed by research staff members not involved in the intervention.

Protocol

The Braden Scale was used for prediction of risk for the development of a PU as recommended by the Agency for Healthcare Research and Quality (formerly the Agency for Health Care Policy and Research).[37] The scale appears to have good reliability, includes 2 subscales for activity and mobility, and has been tested for predictive validity in a nursing home population, where it was found to have the greatest sensitivity and specificity with a cutoff score of 18.[38] Risk prediction is based on mobility, functional activity, level of consciousness, incontinence, nutrition, friction, and shear.

In this pilot study, the required wheelchair sitting time was determined to be a minimum of 6 hours per day. The sitting time was not continuous, but a cumulative total. Confidentiality policies at both facilities prohibited the use of time cards or logs attached to the wheelchairs or posted in the resident's rooms. Sitting time was verified weekly through verbal interviews with the nursing assistants assigned to the residents and through review of the nursing notes and nursing assistant logs. Exceptions to the required 6-hour daily sitting time were documented weekly.

The ETAC Twin wheelchair was selected for use in this pilot study because it is a highly adjustable manual wheelchair (Table 1). In addition, the wheelchairs were equipped with adjustable upholstered backs that allow the contour of the backrest to be changed to conform to orthopedic deformities and to provide an increased functional seat depth from 18 inches to 20 inches. Other than positioning belts, no other optional equipment was used. Individuals exceeding the weight limit or requiring optional equipment were excluded from the study. By providing a seating system that was individualized, wheelchair effects were eliminated as confounding variables. All subjects assumed ownership of the wheelchairs (approximate $1500 retail value) upon attaining 1 of the study end points. Study end points were defined as the first incidence of a PU, discharge from the facility, voluntary withdrawal from the study, death, or the study end date.

Feature	Height	Depth	Angle	Other
Backrest	15¾"–17¾"	Adjustable	0 – +6°	Adjustable tension
Wheels	22"–24"		2° camber	Fixed or pop-off hub
Seat				
Front	22" wheel: 15¾"–17¾" 24" wheel: 17¾"–19¾"	18"–20"		Seat widths: 16"–20"; maximum weight = 250 lb
Rear	4 axle positions	18"–20"		Adjustable center of balance
Armrest	7½"–12½"			2 positions, at ⅜"
Leg rest	10"		Angle adjusted	2 types, detach/lock with calf support
Footrest	Adjustable	Adjustable	Adjustable	

Table 1. ETAC WHEELCHAIR FEATURES

Treatment began with a seating assessment performed by a physical therapy specialist, who performed ongoing reassessments and made modifications as needed to the seating system throughout the study. Seating needs for the subjects were determined according to procedures described by Engstrom and Waugh.[39,40] As part of the seating assessment, interface pressure measurements were recorded for all subjects while on their seat cushions using a Force Sensing Array pressure-mapping device (Vista Medical, Winnipeg, Manitoba, Canada).

Each patient assigned to the FOAM group received a generic 3-inch convoluted foam (eggerate) cushion (Bioclinic Standard #CE3408; Sunrise Medical, Stevens Point, WI), a fitted incontinence cover, and a solid seat insert. This cushion was chosen based on research conducted by Shaw [3] in which this type of convoluted foam cushion excelled in providing pressure relief and comfort for elderly nursing home residents. In addition, it was representative of the economical cushion frequently used in nursing homes.[3]

Each patient assigned to the PRC group received a commercial cushion selected from a group of cushions designed specifically to improve tissue tolerance in sitting by providing more surface area and/or reducing peak pressure near the ischial tuberosities, sacrum, and coccygeal areas. These patients also received a fitted incontinence cover.

The guidelines proposed by the Health Industry Manufacturer's Association for classification of wheelchair cushions were used to identify cushions for use in this pilot study. Cushions satisfying the functional characteristics of cushion groups 5, 6, or 7 were used (Table 2). If the commercial cushion did not include a solid seat insert or incontinence cover, they were provided. A particular cushion from 1 of these groups was selected for each subject based on the subject's clinical status, including interface pressure measurements.

Seat Support	Description
Group 5	Skin protection and pressure reduction; minimum of 2" thickness; supports or reduces deformities
Group 6	Ability to immerse greater than or equal to 2"; a high level of skin protection by reducing loads on the tissues under the weight-bearing bony prominences, utilizing any of the following: • reduced surface tension designs • active load distribution • isolation of bony prominences.
Group 7	Ability to immerse greater than or equal to 2"; a high level of skin protection by reducing loads on the tissues under the weight-bearing bony prominences, utilizing any of the following: • reduced surface tension designs • active load distribution • isolation of bony prominences. Reduction or accommodation of deformity; capable of contouring to a minimum depth of 2" without bottoming out the seat support

Table 2. MINIMAL FUNCTIONAL EXPECTATIONS OF HEALTH INDUSTRY MANUFACTURERS ASSOCIATION GROUPS 5, 6, AND 7 SEAT SUPPORTS

For all subjects, interface pressure measurement data were used to monitor the effects of adjustments made to the chair and, in the case of the PRC group, to additionally compare the pressure responses to specific cushions or modifications to cushions. In all

cases, the same procedure was used to obtain the data. Two successive readings were taken, between which the subject stood or was lifted and reseated, according to procedures described by Shaw.[24] Attempts were made to obtain the lowest peak pressure possible and to distribute pressure evenly. A minimum of 2 readings were taken after each adjustment to the seating system. Pressure mapping was performed at the initial assessment and after reassessment at 1 week (plus or minus 1 day) and as needed, following modification of any wheelchair.

Weekly skin and risk assessments were performed by research staff members simultaneously with the completion of the Braden Scale from the time of enrollment to the study until occurrence of 1 of the study end points. The operational definition of a PU was crucial to the primary outcomes of incidence and days to a PU.

The National Pressure Ulcer Advisory Panel (NPUAP) definition of a pressure ulcer was used. This definition describes a PU as "any lesion caused by unrelieved pressure resulting in damage of underlying tissue." The definition states, "Pressure ulcers are *usually* located over bony prominences and are graded or staged to classify the degree of tissue damage observed."[37] In this pilot study, skin reactions were classified according to the NPUAP staging system. In some cases, depending on the subject's anatomy or sitting surface, peak pressures occurred over other bony landmarks of the pelvis in addition to the ischial tuberosities.[24] Garber and Krouskop [41] have documented peak pressures in *nonbony* areas for heavier subjects. In this pilot study, a broad definition for sitting-acquired PUs was used. Lesions occurring on any aspect of the sitting surface, not just over bony prominences, were documented as sitting-acquired PUs.

The analyses of interface pressure measurements were a secondary objective of this pilot study. The analyses of ratio of days at risk for development of a PU to total days and other subsets of factors were performed to determine equivalence between the groups and to aid in refining the selection of the target sample size for the subsequent full-scale trial.

Because specific incidence rates were not found in the literature for this population, an estimate of incidence rate for sitting-acquired PUs of 10% was made based on the available literature.[9,10,17] For this pilot study, recruitment of 40 subjects (20 per group) was deemed feasible, although it was recognized that this number made it unlikely to have sufficient statistical power to definitely test the efficacy of pressure-reducing seat cushions. The difference that could be detected as statistically significant was calculated with 0.9 power for a 2-tailed test at alpha equaling 0.05. With 40 subjects, a difference between true underlying rates of PUs of 10% in the PRC group and 54% in the control group could be detected. Such a large difference was not anticipated; however, it was believed that a smaller difference would be clinically meaningful.

The outcome variables were the incidence of PUs, the number of days until ulceration, and the initial peak interface pressure. Differences in the incidence of PUs between treatment groups were compared using the chi-square test of independence. Differences in the mean number of days until ulceration and initial peak interface pressures were compared using the independent *t* test. These main comparative analyses were completed on an intent-to-treat basis. Confounding variables, which may have affected ulcer formation, were collected for all subjects and were compared using the independent *t* test or chi-square test of independence, as appropriate, to determine equivalence between the groups. Interface pressure was compared between PU and non-PU groups using the independent *t* test. Power analyses (0.9) were completed post hoc for the pilot study and to estimate the sample size needed for the subsequent full-scale trial. All statistical tests were performed at an alpha level of 0.05.

RESULTS

Of the 32 subjects who were eligible for the study, 17 were randomized to foam cushions and 15 were randomized to PRCs. One subject from each group died during the course of the study. Two subjects in the FOAM group were not available for follow-up due to discharge or transfer from the facility. Three subjects in the PRC group were dropped from the study for the same reasons. Excluding death, discharge, and transfer, there were 14 subjects in the FOAM group and 11 subjects in the PRC group who reached the study end points of either a PU or the study end date (Table 3).

Outcome	Cushion Groups		Statistical Test
	FOAM (n = 17)	PRC (n = 15)	
Pressure ulcer incidence			
Ulcer	10	6	
No ulcer	7	9	χ^2 test
Total days to end point			
Mean	76.3	99.9	*t* test
Standard deviation	68.6	87.9	
Initial peak pressure			
Mean	101.1	90.4	*t* test
Standard deviation	41.2	37.6	
Study end points			
Pressure ulcer	10	6	
Death	1	1	
Discharge/transfer	2	3	
Study end	4	5	

Table 3. SUBJECT OUTCOMES

Analysis

The descriptive characteristics of the FOAM and PRC groups did not differ significantly for any selected factor including age, gender, or Braden Scale score for initial risk of PU development. The primary diagnoses of the subjects were orthopedic, psychological, neurologic, neuromuscular, cardiac, diabetes, and vascular (Table 4). No significant difference was found between the groups for PU incidence, initial peak interface pressure, or for total days to end point (with or without including subjects who were dropped from the study; Table 3). In addition, no differences were found between the groups for the ratio of total number of days that subjects were rated at risk for PU development to total number of study days (Table 5).

Characteristic	Cushion Groups		Statistical Test
	FOAM (n = 17)	PRC (n = 15)	
Age			
Mean	84.1	85.2	*t* test
Standard deviation	8.3	6.4	
Initial Braden Scale score			
Mean	13.4	12.5	*t* test
Standard deviation	2.3	1.2	
Gender			
Male	1.0	1.0	χ^2 test
Female	16.0	14.0	χ^2 test
Primary diagnostic categories*			
Cardiac	0	1.0	
Diabetes	1.0	0	
Neurologic	3.0	1.0	
Neuromuscular	0	3.0	
Orthopedic	8.0	4.0	
Psychological	4.0	6.0	
Vascular	1.0		

*The diagnostic categories include the following:
Cardiac: myocardial infarction, coronary artery bypass graft, atrial fibrillation, congenital heart disease
Diabetes: type 1 and type 2
Neurologic: cerebrovascular accident, cerebrovascular insufficiency
Neuromuscular: multiple sclerosis, Parkinson's disease, peripheral neuropathy
Orthopedic: fractures, open reduction with internal fixation, total hip arthroplasty, total knee arthroplasty, degenerative joint disease, amputation, fixed deformities, osteoporosis
Psychological: dementia, depression, anxiety, schizophrenia
Vascular: peripheral vascular disease

Table 4. SUBJECT BASELINE CHARACTERISTICS

Variable	Cushion Groups	
	FOAM (n = 17)	PRC (n = 15)
Days at risk/total days		
Mean	0.94	0.95
Standard deviation	0.19	0.20
Sitting time complied/total days		
Mean	0.83	0.95*
Standard deviation	0.24	0.90

*P <.05, 1-tailed

Table 5. *T* TESTS FOR GROUP EQUIVALENCE: FOAM VS PRESSURE-REDUCING CUSHIONS

Significant differences were found between the groups for sitting-time variances ($P < .05$; Table 5). The FOAM group failed to meet the required minimum sitting time of 6 hours per day more frequently than the PRC group. The clinical determination of postural asymmetries ($P < .001$) and peak interface pressure measurement ($P < .05$) were significantly more predictive of PU site for the FOAM group than for the PRC group (Table 6). In addition, a significant difference existed between the groups in terms of PU location ($P < .005$). No ischial PUs occurred in the PRC group (Table 6).

Variable	Cushion Groups	
	FOAM (n = 17)	PRC (n = 15)
Pressure ulcer site predicted by peak pressure		
Yes	7	1*
No	3	5*
Pressure ulcer site predicted by deformities		
Yes	9	0***
No	1	6***
Pressure ulcer site predictor of type of cushion		
Ischial tuberosity	8	0**
Sacrum, coccyx, buttock	2	6**

*P <.05, 1-tailed; **P <.005, 1-tailed; ***P <.001, 1-tailed

Table 6. CHI-SQUARE TESTS FOR GROUP EQUIVALENCE: FOAM VS PRESSURE-REDUCING CUSHIONS

Pressure ulcers developed in 16 of 32 subjects in this study. This rate supports Zacharkow's figures 1 and exceeded recent estimates of sitting-aquired PUs.9,10,13 The incidence of PUs in the FOAM group was 10 of 17 (59%). Table 7 shows the PU incidence rates that can be detected as statistically significant given the recruitment of 100, 200, or 300 subjects in the full-scale trial. If 300 subjects are recruited (150 per group), a difference of 59% versus 40% can be detected with a 0.9 power at alpha equaling 0.05 and a 2-tailed test. This is the approximate sample size that would be needed to obtain statistical significance using the same broad definition of a PU used in this pilot study. However, if more restrictive definitions of sitting-acquired PUs are used, lower incidence rates would be expected. Some restrictive definitions could include the exclusion of all shear injuries or the exclusion of all shear and nonischial lesions. Table 7 includes rates of 30% and 20% to show differences that can be detected for other defined end points with lower incidence rates. Using the most restrictive definition, a sample size of 100 to 200 (50 to 100 per group) may be projected.

Sitting-Acquired Pressure Ulcer Definitions	Cushion Incidence Rates		Projected Total Sample Size
	FOAM	PRC	
Any lesion on the sitting surface	59%	≤28%	100
	59%	≤36%	200
	59%	≤40%	300*
Excluding shear lesions on sitting surface	30%	≤6%	100
	30%	≤12%	200*
	30%	≤14%	300
Excluding shear and nonischial lesions	20%	≤2%	100*
	20%	≤9%	200*
	20%	≤7%	300

*Indicates projection based on pilot study data (to projected sample size) at power of 0.9, α = 0.05, and a 2-tailed test.

Table 7. SAMPLE SIZE PROJECTIONS WITH DIFFERENT PRESSURE ULCER DEFINITIONS AND VARIOUS INCIDENCE RATES

Data analyses of the PU and non-PU groups were also performed. A significant difference was found between the groups for initial peak interface pressure ($P < .001$) (Table 8). No significant group differences ($P > .05$) were demonstrated for initial Braden Scale scores, sitting-time variances, or ratios of days at risk to total days (Table 8).

Variable	Outcome	
	Pressure Ulcer	No Pressure Ulcer
Initial peak pressure		
Mean	114.7	77.5*
Standard deviation	44.6	21.6
Initial Braden Scale score		
Mean	12.9	13.0
Standard deviation	2.3	1.2
Days at risk/total days		
Mean	.98	.90
Standard deviation	.07	.26
Sitting time compiled/total days		
Mean	.84	.94
Standard deviation	.23	.14

*P<.001, 1-tailed

Table 8. *T* TESTS FOR PRESSURE ULCER VS NO PRESSURE ULCER GROUPS

DISCUSSION

In the fall of 1997, a national panel of seating and positioning experts, including clinicians, researchers, and industry representatives, was convened to recommend the appropriate methodology for the pilot study. The recommendations of the panel were incorporated into the protocol whenever financially and logistically possible.

This pilot study constituted the first phase of a long-term aim to demonstrate the effectiveness of commercially available, pressure-reducing seat cushions for elderly persons at risk for developing PUs. The incidence rates found for the FOAM and PRC groups in this study will be used to more accurately estimate the sample size needed for a subsequent randomized, multicenter clinical trial. These results provide the basis for pursuing and obtaining funding for the full-scale trial, for which sufficient statistical power should be attained. The full-scale trial will examine whether pressure-reducing cushions are clinically effective and cost-effective for elderly nursing home residents using wheelchairs.

The sample for this pilot study was drawn from 2 200-bed nursing facilities that maintained approximately 50 to 60 skilled nursing beds. One facility was urban and affiliated with an academic medical center and the other was suburban. The study was performed primarily at 1 clinical site. It is worth noting that during the time the pilot study was conducted, the Balanced Budget Act of 1997 (BBA) was implemented. For skilled nursing facilities, this was a time of dramatic change and the negative effects on patient care may have affected the incidence of PUs in this sample. Accelerated staff turnover, increased reliance on temporary staff, and chronic understaffing or reassignment of staff contributed to a chaotic health care environment, which made it difficult to adhere to standard preventive procedures.

Because this was a feasibility study, statistical power was limited. Outcomes were complicated by the broad operational definition of a sitting-acquired PU. It was thought that based on the literature and the lack of specific incidence rates for this population, a broader definition was adequate and would prevent the loss of what might prove to be clinically relevant data. More recently, however, clinicians purport that sacral and ischial PUs are substantially different and warrant different treatment. Ischial PUs are argued to be sitting-induced and sacral ulcers are attributed to excessive loading in bed.[42]

The pilot data indicate that the pressure-reducing cushions were significantly more effective in preventing ischial PUs. No ischial PUs were acquired in the PRC group. If one accepts the argument of Pompeo [42], none of these PUs should be attributed to sitting. The investigators of this pilot study support Pompeo's contention because in the PRC group, every PU occurred following an unusual period of bed rest, sleeping overnight in a gerichair, or sitting with the wheelchair cushion turned backwards in the seat. Three of 6 PUs in the PRC group were actually shear injuries, but were recorded as PUs based on the study definition. In addition, the pressure-mapping data did not demonstrate that in sitting, interface pressures over the coccyx and/or sacrum were equivalent or nearly equivalent to the pressures over the ischial tuberosities. In the pilot study, 6 of 16 PUs (38%) were sacrococcygeal. Because of this, the investigators acknowledge that a small number of coccygeal ulcers may be attributed to sitting. However, coccygeal PUs rarely present without concomitant sacral involvement. This fact makes it difficult to include coccygeal PUs in the operational definition of sitting-acquired PUs without confounding the data. The operational definition for the full-scale trial will be modified to exclude all shear injuries and lesions not located over the ischial tuberosities.

Because this definition will lower the incidence rates, it will have the effect of decreasing the number of subjects required for the full-scale trial. In planning the full-scale trial, these statistical considerations will be balanced with the feasibility of recruitment and cost in order to arrive at a goal for the number of patients to be enrolled.

The fact that peak interface pressure and the clinical evaluation were better predictors of the PU site for the FOAM group illustrates the inability of the foam cushions to support or reduce deformities. In the FOAM group, 8 of 10 PUs were located over the ischial tuberosities, suggesting that they were sitting-acquired. The remaining 2 were coccygeal-related and shear injuries. In addition, the significant failure of the FOAM group to comply with the required sitting time may have extended the time that a number of higher-risk subjects in this group remained PU-free, thereby distorting the days to end point. The documentation of

sitting duration by facility staff was found to be inconsistent. Considering the constraints imposed by the BBA, requesting documentation of sitting time by facility staff in a future study would be impractical. If possible, a timing device will be used to monitor actual sitting time in the full-scale trial.

Because 16 of 32 subjects in the pilot study developed PUs, incidence expectations were exceeded. This supports the belief of many clinicians that risk does not decline with length of stay. Because the inclusion criteria were successful in targeting those individuals at risk for developing PUs, it is recommended that they be used in the full-scale trial.

Higher interface pressures were associated with a higher incidence of PUs in this study ($P < .001$). These results support the use of pressure measurements as an aid in determining PU risk. The pilot study's results confirm the results of a similar study [23] and the popular belief that high interface pressure is a factor in PU development. Although interface pressure as a predictor of PU risk is limited, such limitations do not diminish the clinical significance of this finding because it is common clinical practice to use pressure measurements when comparing seat support surfaces. This finding supports the use of such technology in the selection of support surfaces in clinical practice when risk for PUs is the primary concern. Pressure-mapping may be employed in order to minimize peak pressures and pressure gradients, provide stability, accommodate orthopedic deformities, and provide comfort. Because the analyses of interface pressure measurement in this pilot study were secondary objectives, comprehensive results of these analyses will be published separately.

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