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Clinical trial of foam cushions in the prevention of decubitis ulcers in elderly patients

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Abstract—Polyurethane foam cushions in a slab form or a customized contoured form are commonly used in wheelchairs to prevent the development of decubitus ulcers (DU) in elderly chronically ill persons. Sixty-two consenting subjects, 60 years or older, were randomly assigned to sit on one of the two types of cushions for 3 or more hours daily for 5 months. A total of 72 DU developed in the 52 subjects who completed the study. These were mostly in the areas of ischial tuberosities, buttocks, and thighs; were of persistent erythema level in severity; and took an average of 6 to 8 weeks to heal. No statistically significant differences were found in the incidence, location, severity, or healing time of the sores that developed in the subjects who used the slab (N = 26) and those who used the contoured (N = 26) cushions. But, more severe sores did develop among the slab cushion group in the area of ischial tuberosities. It appears that foam customization for elderly persons could be justified only if DU have been a particular problem in this region. Incontinence as a contributory factor to DU formation should receive careful attention with respect to prevention. The trials described are being continued, using a larger number of subjects.

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INTRODUCTION

Decubitis ulcers are localized areas of cellular necrosis that generally occur over bony areas that receive excessive and prolonged pressure, as in sitting or lying (16,18). The geriatric residents of institutions who suffer chronic illness or disability are at risk to develop decubitus ulcers (DU). These ulcers can limit their functional ability, interfere with rehabilitation, increase their health care costs, and can contribute to morbidity and death (1,2,5,16).

A combination of intrinsic and extrinsic factors can predispose the individual to DU. The intrinsic factors include advanced age (60 years or older), immobility, sensory or motor loss, being underweight or overweight, poor nutrition (protein deficiency), anemia, edema, heavy perspiration, the presence of tissue fragility (e.g., history of previous skin breakdowns), and friction caused by spasticity (1,7,13,16,18,20,21,23,28,30). Among the most critical extrinsic factors are probably the features of supporting seating surfaces (e.g., the seat cushion and its cover) with respect to pressure distribution, pressure redistribution, pressure relief, postural support, shear forces, and temperature and humidity (3,5,23,28).

A wide variety of cushions, available in the market, are believed to be effective in reducing pressure and preventing the occurrence of DU (3,11,14,28). A number of studies which have attempted to examine these supporting surfaces have

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been inconclusive with regard to clinical applications due to factors such as lack of controls, use of an artificial setting, small samples, or single episode testing in standardized sitting (3,9,11,12,14,17,22,27-29). In the absence of clinical data, extrapolation from these observations to elderly patients would warrant caution (2). There is also a lack of practical and reliable measurement techniques for examining *in situ,* and over time, the factors of shear forces, humidity, temperature, and pressure (23,26). Although devices are available to test the short-term mechanical qualities of the support surfaces, none has a reported predictive validity with respect to DU development. Thus, the present state of the art limits the measurement of preventive qualities of seat cushions to their indirect, but clinically more significant, evidence of skin breakdown.

Despite weaknesses in research design and instrumentation, some investigators and clinicians have concluded that no cushion is universally superior to others in minimizing the causative factors of DU (3,22,27,29). However, the polyurethane foam cushion has been recommended to be clinically the most practical and suitable therapeutic choice for initial or long-term pressure relief (10,23,24). Polyurethane cushions are commonly used for wheelchairs in geriatric and long-term health care settings, either as a slab or in a contoured (carved) form, to provide customized relief of pressure (12,22,24).

The purpose of this study was to assess slab and contoured polyurethane cushions in a randomized, controlled trial involving elderly institutionalized patients. It was hypothesized that no significant differences would be found in the preventive qualities of these cushions in terms of the incidence, location, severity, or healing time of DU in the patients using the cushions.

METHOD

Subjects

The subjects were 62 consenting residents of an extended-care facility in Vancouver, Canada. They were selected if they were: 1) 60 years or older; 2) free of any DU for at least 2 weeks prior to the study; 3) considered to be at "high risk" for developing DU, based on the Norton's Scale (5); and, 4) using a wheelchair for 3 or more hours daily. Subjects were excluded if they had a progressive disease that could confine them to bed or if they became confined to bed for more than 120 consecutive hours due to reasons other than DU.

Measures and procedures

"High" risk was defined as a score of 14 or less on the Norton's Scale (5). This scale is based on the consideration of a number of predisposing intrinsic factors and has been reported to show a high linear relationship with the incidence of DU (4). Patients with a total Norton's score of 14 or less have been found to have a 32 percent chance of developing DU, and those with a score lower than 12 are at very high risk with a 48 percent chance to develop sores in 2 weeks (4). In this study, the Norton's score was taken by an occupational therapist who was experienced with tissue trauma, geriatric rehabilitation, and the use of the scale. Qualified consenting subjects were randomly assigned to one of the two cushions for a period of 5 months.

The incidence, location, severity, and healing time of DU were determined weekly by another occupational therapist, a research assistant, who was from outside of the facility and was not knowledgeable of the Norton's score of the subjects. The "incidence" and "severity" (skin condition) of DU during the trial were measured according to the Exton-Smith Scale (6), which yields a score of 0 = none, 1 = persistent erythema, 2 = localized blister, 3 = superficial score, 4 = deep sore, and 5 = extensive gangrenous sore. Thus, scores of 1 or above were counted as incidences of DU when first observed, with the possibility of more than one count per subject if new DU developed. The maximum score reached by each DU during the healing period provided the "severity" indication for data analysis.

These data were collected weekly, one-half hour after the subjects returned to bed (side lying or prone) so as not to confuse blanching or reactive hyperthermia with persistent erythema. At this time, the skin condition was checked over the buttocks and the bony prominences: sacrum, coccyx, ischial tuberosities, and greater trochanters. DU observations were reported to the ward staff to follow up with the standard nursing and rehabilitation practices of the facility.

Evidence of the reliability and validity of the Exton-Smith scale was not found in the literature.

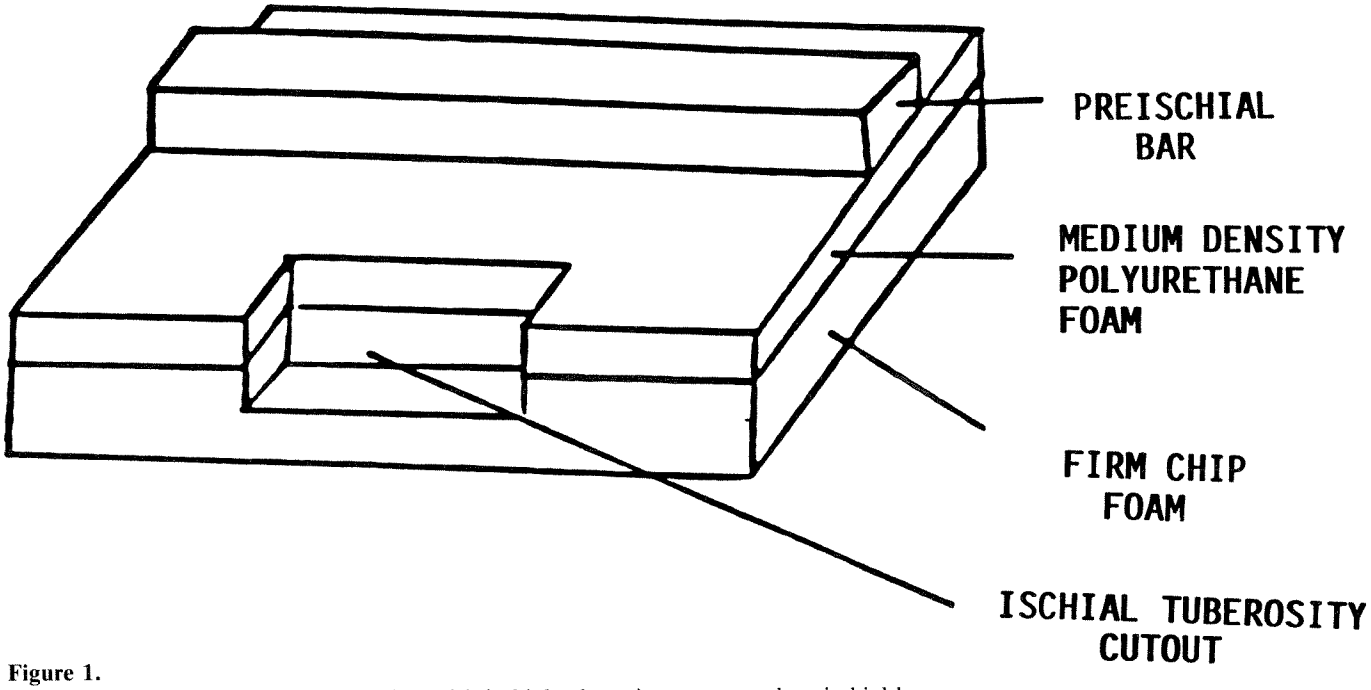

Figure 1.
Customized polyurethane foam cushion with ischial tuberosity cutout and preischial bar.

One of the authors (RL) monitored the research assistant and randomly double-checked 10 percent of the subjects to ensure accuracy of the measures taken. The inter-rater reliability by the Kappa statistic was found to be quite acceptable (0.91).

Subjects in both groups received exactly the same care for the prevention of DU. This consisted of daily bed-baths and pericare, weekly full baths or showers, use of absorbent pads and various topical treatments as normally prescribed, and daily observation by attendants for DU at dressing and undressing time. Dietary care, physical therapy, and occupational therapy were continued as normally programmed. During the study, the same physicians shared ward coverage. All nursing, rehabilitation, and support staff received in-service training about the prevention and care of DU by one of the authors (RS) in a standardized manner. Bimonthly reviews were held with the physicians and staff supervisors to safeguard uniformity of patient care.

Equipment

Foam Slab Cushion. The slab cushion consisted of 2.5 cm medium-density polyurethane foam glued on top of 5 cm firm chipped foam (24) readily available commercially in North America.

Contoured Foam Cushion. The contoured cushion was of material identical to that of the slab cushion. The facility's occupational therapist, experienced in seating problems, contoured the cushion in the posterior aspect according to the method described by Peterson and Adkins (24) for the relief of pressure on the ischial tuberosities. A preischial bar (made of medium-density polyurethane foam, 3.8 cm thick, 36.5 cm by 12.5 cm long) was also glued on top of the cushion, anterior to the ischial cutout (**Figure 1**) to increase pressure on the thighs and offer additional pressure relief to the ischial tuberosities (23,24).

For the cutout, the position of the ischial tuberosities was determined by seating the subject on a 5 cm Tempra-foam cushion, palpating the subject's ischial tuberosities, and making an indent in the foam under the ischial tuberosities. The subject was immediately transferred off the Tempra foam and the position of the ischial tuberosities' indent measured.

Cushion Covers. The slab and contoured cushions were covered with identical snug-fitting covers of

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commercially available knitted-polyester, which was laminated on the inside for protection against spills and incontinence. Knitted-polyester was used because it has two-way-stretch and easily adapts to contours of the body. It also allows water vapor and air to escape, and is sturdy and easily laundered. This type of material has been recommended in the literature (8,9,23).

Cushion Platforms. Both the slab and contoured cushions were mounted on 0.6 cm plywood to eliminate the sling effect of vinyl wheelchair seats (23).

Wheelchairs. Patients were assigned to specific wheelchairs by their staff nurse or occupational therapist. The study's procedures did not interfere with this policy or with the selection of wheelchairs.

The condition of the cushions and covers was examined weekly by one of the authors (RS) for any evidence of deterioration and need for replacement. Also, the use of wheelchairs was monitored weekly to ensure that subjects were using their assigned cushions and wheelchairs and that the appropriate adjustments were maintained for the seat height, backrest height, and foot pedals.

Table 1.
Distribution of the attrition of 10 subjects.

Attrition cause	Cushion		Total
	Contour	Slab	
Death	2	6	8
Refused to continue	1	0	1
Transfer	0	1	1

RESULTS

Sixty-two patients met the criteria and all consented to enter the trial. Ten subjects were lost from the study during the trial due to death, dropout, or transfer, as shown in **Table 1**. The characteristics of the remaining 52 subjects (84 percent) are described in **Table 2**. The comparison of the demographic and intrinsic variables by the independent t-test (for continuous measures) and chi-square (for categorical measures) did not indicate any significant differences between the two groups who were randomly assigned to the slab (N = 26) or contoured cushions (N = 26).

Seventy-two (72) DU developed in the 52 subjects (**Table 3**). Forty-four (60 percent) of the DU were of Level 1 according to the Exton Smith Scale. None of the DU had progressed beyond Level 3 of the scale. Note that the numbers reflect the observed incidence of each new DU, so that those subjects with more than one DU are represented more than once.

There was no significant difference in the number of observed DU (slab = 37, contoured = 35) between the two groups ($X^2 = .06$; d.f. = 1; $p > .05$). When the proportion of subjects developing any DU (no matter how many) was compared, no significant difference was found (slab 19/26 or 73 percent; contoured 18/26 or 69 percent; $z = .01$; $p > .05$).

In both groups, significantly more DU appeared in the area of ischial tuberosities (**Table 3**) as compared to other locations ($X^2 = 19.5$; d.f. = 5; $P < .01$). However, 22 (30 percent) of all DU were in the skin creases and other non-bony parts of the buttocks and inner and upper thighs, and these appeared to be associated with incontinence. A significant difference between the slab and contoured groups was found in the categorical location of severity frequencies ($X^2 = 7.46$; d.f. = 2; $P < .05$). **Table 3** shows that this difference was due to the presence of seven Level-2 measures on the Exton-Smith Scale in the area of ischial tuberosities in the slab cushion group and none for the contour cushion group.

To control for potential confounding variables, the DU data for severity and healing time were first averaged per subject with multiple DU incidence. **Table 4** shows the statistics pertaining to the severity of DU and the duration of healing in each group of subjects. Many DU (more than 50 percent) did not progress beyond Level 1 (persistent erythema) and healed in 7 days or less. However, those with prolonged healing raised the mean duration to about 40 days. The comparisons between groups were made by the independent t-test for severity and duration of healing of DU. They did not yield any significant results with regard to the type of cushion used.

Table 2.
Characteristics of patients assigned to contoured cushion (Group I) or slab cushion (Group II) who completed the trial.

Characteristics		Contour N = 26	Slab N = 26	Total 52
Sex:	Male	6	8	14
	Female	20	18	48
Age:	Mean	83.0	84.6	83.8
	S.D.	7.7	8.2	8.0
	Range	65–103	70–104	
Weight:	Mean	52.0	55.1	53.6
	S.D.	12.7	11.7	12.2
	Normal	9	9	18
	Underweight	14	15	29
	Overweight	3	2	5
Norton's:	Mean	12.3	12.3	12.3
	S.D.	1.4	1.8	1.6
	Range	10–16	9–16	
Primary Diagnoses:				
	MI	10	11	21
	Hip fx	4	3	7
	Alzheimer	2	5	7
	Hypertension	2	2	4
	Arthritis	3	1	4
	Other	2	1	3
	Progressive	0	0	0
	Unknown	3	3	6
Sensory Status:				
	Normal	15	17	32
	Not normal	11	9	20
Friction:	Mild	20	19	39
	Severe	1	0	1
	None	5	7	12
Time in Wheelchair:				
	3 hours	2	1	3
	4–6 hours	21	20	41
	> 6 hours	3	5	8
Mobility:	Immobile	1	0	1
	Very limited	6	8	14
	Slightly limited	19	18	37

Table 3.
Incidence, Exton-Smith grade, and location of decubitus ulcers developed in the subjects using slab (N = 26) or contoured cushions (N = 26).

	Exton-Smith Grade								
	Slab (N = 26)				Contoured (N = 26)				
	Persist. eryth. 1	Local blister 2	Superf. sore 3	Total	Persist. eryth. 1	Local. blister 2	Superf. sore 3	Total	Grand Total
Location	No.	No.	No.	No.	No.	No.	No.	No.	No.
Sacrum	2	0	1	3	4	0	3	7	10
Coccyx	3	0	1	4	2	0	2	4	8
Isch. Tuber.	3	7	4	12	8	0	3	11	25
Great Troch.	1	0	1	4	2	0	3	5	7
Buttocks*	7	0	2	9	4	0	1	5	14
Other*	5	0	0	5	3	0	0	3	8
Total	21	7	9	37	23	0	12	35	72

*Skin surfaces in contact with urine in incontinent subjects.

DISCUSSION

Polyurethane foam cushions are commonly used as an inexpensive and convenient seat surface to offer comfort and to prevent the formation of DU in elderly patients. In this study, the preventive qualities of the slab form of polyurethane cushion were compared with those of the contoured form that requires individualized customization by a specialist in seating for each user. The consenting subjects were carefully selected, randomized, and given standardized care under controlled conditions to the fullest degree possible and consistent with ethical and normal clinical procedures. Although disguising the cushions was impossible, care was taken to control bias by separating the responsibilities for: subject selection and assignment, providing the cushions, taking the measures, and monitoring related activities. Individuals external to the setting, and not informed of the specific questions of this study, were used for some of these functions.

When the results were analyzed, the null hypothesis of no significant difference in the preventive qualities of the two cushions was confirmed. There were no significant differences found in the overall incidence, location, severity or the healing time of

Table 4.
Severity of decubitus ulcers as measured by Exton-Smith Scale and duration of healing in the subjects using slab or contoured cushions.

	Severity			Healing duration (weeks)		
	Mean	Median	SD	Mean	Median	SD
Slab (N = 17)	1.9	1.0	1.1	6.2	1.0	6.9
Contoured (N = 18)	1.7	1.0	0.9	5.4	1.1	6.1
t-test	t = 0.379	d.f. = 33	P > .05	t = 0.382	d.f. = .33	P > .05

DU that developed in the two groups of subjects over the 5-month period. However, it was noted that more sores occurred in the area of ischial tuberosities in both groups. And in this particular location, the DU were more severe in subjects who used the slab cushion than in those who were provided with customized contoured cushions for relief of pressure on the ischial tuberosities. The sores on an average required 6 to 8 weeks to heal, which is comparable to data reported for similar patients in other settings (31).

The design of the study may be criticized for the absence of a no-treatment (no-cushion) control group. However, Pocock (25) has stated that a basic principle of ethics in research is that patients cannot be assigned to a placebo or no-treatment group if there exists a standard therapy. The use of foam cushions for the at-risk elderly patient has been around for so long, and is so common, that it is considered the standard therapy. To have assigned our subjects to a no-cushion control group would have been unethical and unacceptable.

It should be noted that more than 52 subjects would be required to reach a conclusive decision as to which cushion should be offered to elderly patients. Considering the incidence of DU (71 percent) as a primary outcome measure, the sample size needed for each group would be 124 (19). Therefore, the trial described above is being continued with more subjects to: 1) determine if one cushion performs better than, or equal to, the other; 2) test the possible interaction of important variables (e.g., age x cushion x weight); and, 3) conduct a Kaplan-Meier (15) analysis to allow data from all subjects to be studied (given that not everyone develops DU before dropout or at the end of a 5-month trial despite a "high risk" status).

Based on the existing evidence, it may be prudent to provide a customized contoured cushion to the elderly user only if DU in the area of ischial tuberosities has been a repeated and particular problem. However, if the user slides in chair and has poor sitting posture, the cutout for ischial tuberosities in the contoured cushion may accentuate pelvic tilt and result in sacral sitting with DU formation in the sacrococcygeal area. The data also seem to indicate that patient hygiene related to incontinence as a contributing factor to DU formation may deserve greater attention than the literature reflects at present.

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