ARTICLES

Healing of Advanced Pressure Ulcers by a Generic Total Contact Seat: 2 Randomized Comparisons With Low Air Loss Bed Treatments

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ABSTRACT. Rosenthal MJ, Felton RM, Nastasi AE, Naliboff BD, Harker J, Navach JH. Healing of advanced pressure ulcers by a generic total contact seat: 2 randomized comparisons with low air loss bed treatments. Arch Phys Med Rehabil 2003;84:1733-42.

Objective: To compare a therapeutic seat with low air loss bed treatment for healing rates of stage III and IV pressure ulcers.

Design: Randomized prospective cohort study.

Setting: Long-term care facilities.

Participants: Two hundred seven subjects with stage III or IV pressure ulcers.

Intervention: Two separate randomized control studies of advanced pressure ulcers that compared wound healing on 3 different support surfaces. Subjects were allocated to low air loss bed, upgraded bed overlay (only in study 1), or 4h/d sitting on an experimental generic total contact seat. The seat was designed using prosthetics principles aimed at distributing pressure off bony prominences onto less pressure-sensitive areas. Subjects were followed for 6 months or until they were totally healed.

Main Outcome Measures: Number of subjects who totally healed, time to total healing, and pressure ulcer status score after 4 weeks of treatment. Interface pressures and functional capacity were also measured at 4 weeks.

Results: In study 1, 3 subjects worsened on the bed overlay condition and were withdrawn from the study. None worsened on low air loss or generic total contact seat. At 4 weeks in both studies, pressure ulcer status score was lowest for the generic total contact seat ($P<.0001$), compared with the other surfaces. Subject populations were similar, so to analyze total healing, results from both studies were combined. Total healing of pressure ulcers occurred as early as 4 weeks in some subjects using the generic total contact seat. Even at 8 weeks, total healing was primarily seen with use of that seat, on which interface pressures, function, and seating tolerance were best.

Conclusions: Faster healing and better function indicate that treatment using the generic total contact seat is superior to low air loss bed therapy, which is standard care for advanced pressure ulcers.

Key Words: Beds; Pressure; Pressure ulcers; Rehabilitation.

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PRESSURE ULCERS DEVELOP in seated or bed-bound patients when, over time, local pressure on soft tissues overlying bony prominences exceeds capillary filling pressure.[1,2] Pressure ulcers are common in patients with spinal cord injury[3] (SCI) and in debilitated geriatric patients.[4] The annual cost of treatment in the United States exceeds $10 billion.[5] More than 40% of stage III and IV ulcers fail to heal within 6 months.[6]

Interface pressures between tissue and a support surface are much higher in seated patients than in patients who are supine. Hence, standard care for advanced pressure ulcers is bedrest with frequent turning and local wound care. To prevent deconditioning caused by prolonged bedrest, we sought to treat advanced pressure ulcers using a seated position.

Previous studies[7-9] have addressed pressure ulcer treatment results from bed therapies. The generic total contact seat distributes pressure across the seat contact area onto anatomic areas that can better handle pressure without damage by sequentially and alternately inflating and deflating air bladders that are localized under bony prominences. The purpose of this study was to compare the rate of healing when patients were treated with low air loss bed, pressure-relieving bed overlays, and generic total contact seat surface.

Our hypotheses were that the healing rates of stage III and IV pressure ulcers for subjects on the generic total contact seat would be at least as good as the rates for patients on low air loss bed surface, and that subjects using the generic total contact seat would be more functional than those lying on a low air loss bed surface.

METHODS

Study Population

Sample size was calculated using α at .05 and β at .20 (power=80%) based on preliminary data. Sample size was increased to adjust for anticipated dropouts over time. For study 2, sample size was based on the results from study 1 and was increased to permit further analysis of possible predictors of healing. Over 1 separate 18-month period, subjects with pressure ulcers were recruited by contacting staff from long-term care facilities at UCLA, community nursing homes, and the Greater Los Angeles (Sepulveda Campus) Veterans Administration Medical Center (VAMC). All subjects were alert, had been able to sit in the 6 months before the study, and could still sit up with assistance. Patients with a stage III or IV ulcer[10] on the coccyx, trochanter, or ischial tuberosities were studied. We excluded sacral pressure ulcers from the study because the sacral area is suspended above the generic total contact seat and hence is not in contact with the seat (figs 1, 2). If clinically

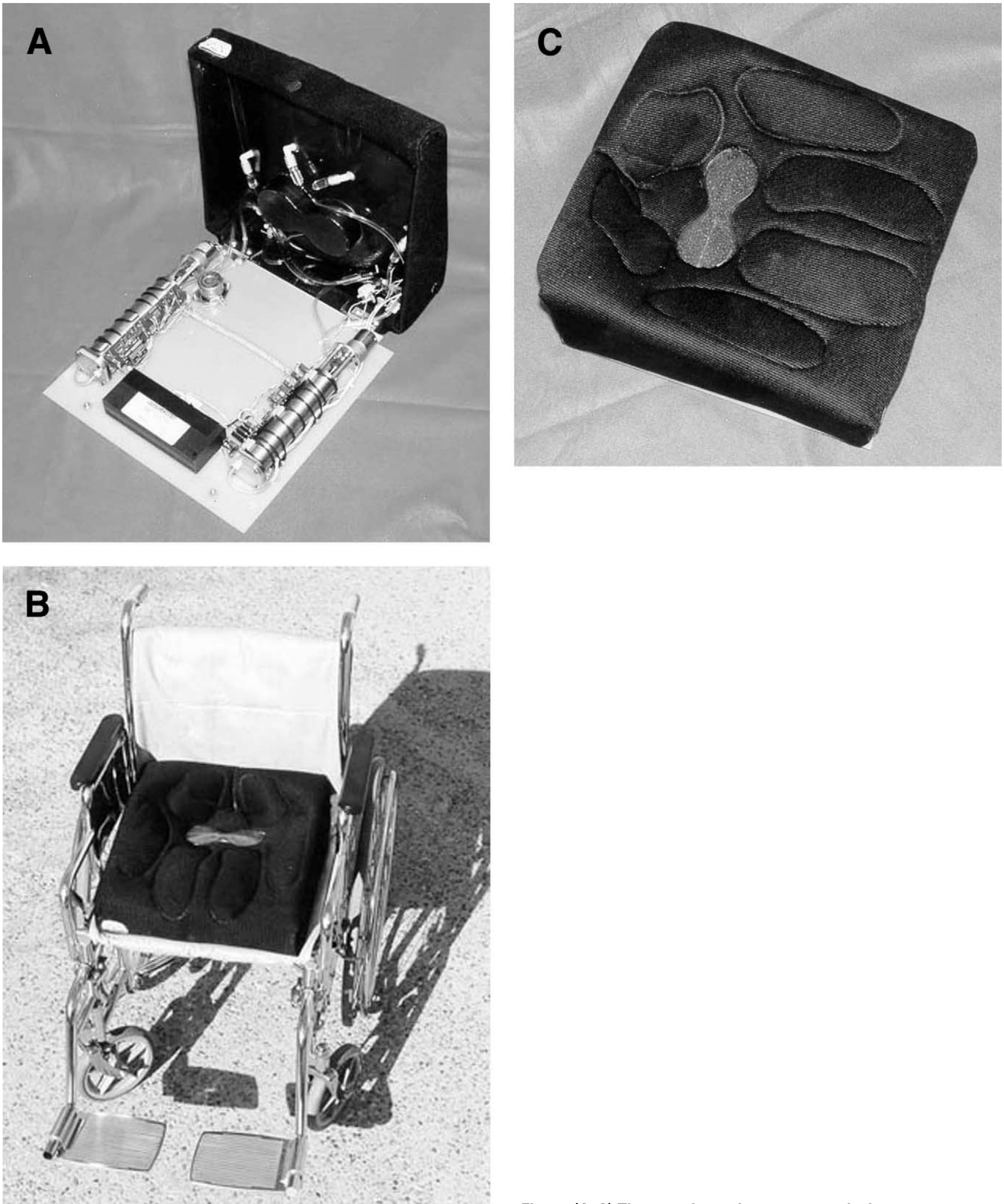
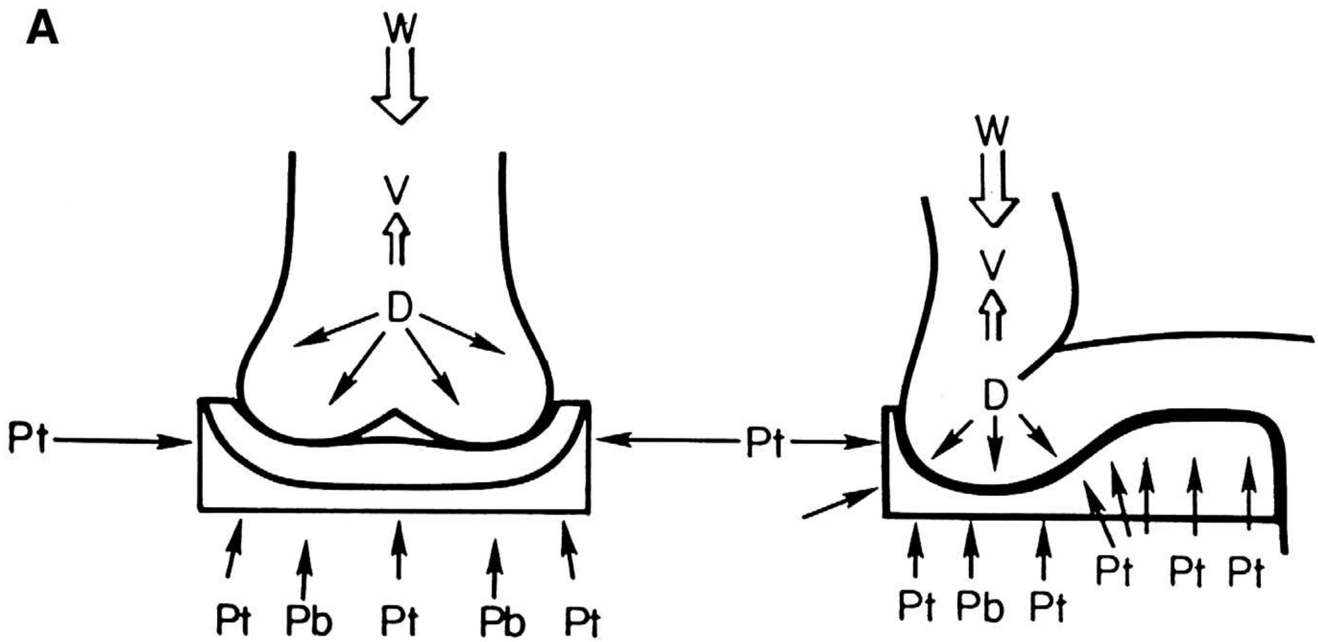


Fig 1. (A–C) The generic total contact seat device.



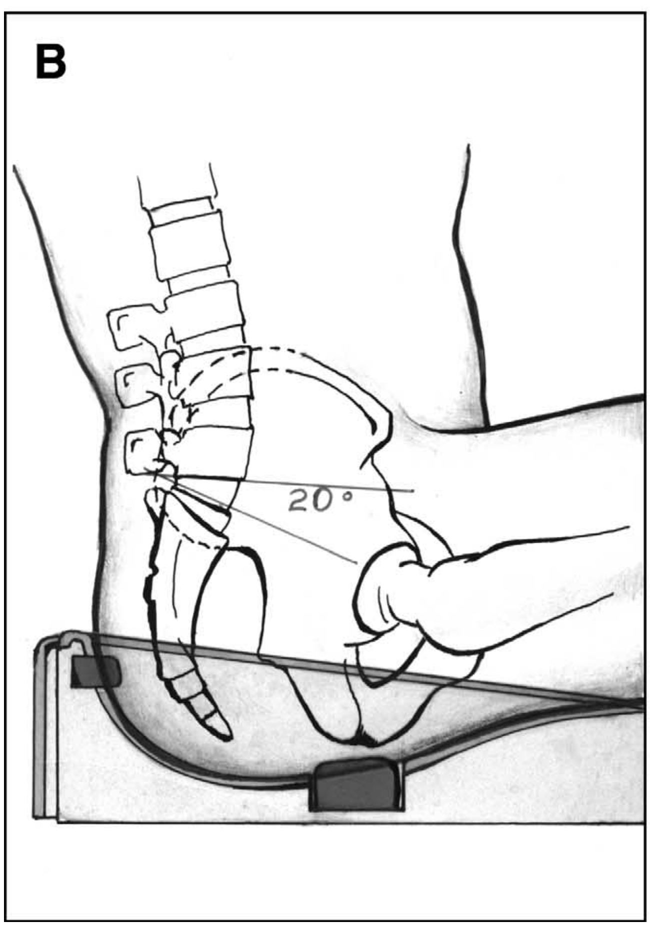


Fig 2. (A) The prosthetic fitting concept for total contact pressure distribution; (B) the lumbosacral angle. Abbreviations: D, displacement-horizontal vector=internal shear; Pb, pressure under bony prominence; Pt, pressure under soft tissue; V, vertical counter shear vector, W, weight-downward force vector.

Table 1: Underlying Medical Conditions of Study Subjects

	Study 1 (%)	Study 2 (%)
Debilitated geriatric patients	13.5	17.7
Catabolic disease	17.1	20.8
Neuromuscular disease	13.5	10.4
Vascular disease	11.7	21.9
Amputee	19.8	7.3
SCI	24.3	21.3

indicated, pressure ulcers were débrided by staff members before patients were randomized. Each subject's largest ulcer was evaluated. Standard orders were provided with attention given to appropriate nutrition and infection control. No other inclusion criteria were specified. Studies were approved by the human subjects committees at the VAMC and UCLA.

The underlying disabilities and medical conditions of the subjects studied included (1) debilitation in geriatric patients; (2) catabolic diseases (eg, cancer, multiple sclerosis, Parkinson's disease, senile dementias, olivopontine cerebellar degeneration); (3) neuromuscular diseases, including postpoliomyelitis syndrome, Guillain-Barré syndrome, and amyotrophic lateral sclerosis; (4) vascular diseases (eg, cerebral vascular accident, peripheral vascular disease, arteriosclerotic heart disease); (5) amputees (secondary to vascular disease, diabetes, trauma); and (6) patients with SCI.

Before randomizing, subjects were excluded if (1) they were previously in a trial to treat their current pressure ulcer; (2) they were already on low air loss, or transfer to low air loss was planned; (3) skin grafting was planned within 1 week; (4) they had an active sinus tract or fistula; (5) nutrition was poor, as indicated by albumin levels below 3.0g/dL; (6) antibiotics were required to treat methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant enterococci, or active skin infection; (7) osteomyelitis was diagnosed by radiography or bone scan performed whenever it was suspected by clinical indicators; (8) body weight was below 60kg, because such subjects were too small to fit the seating frame; and (9) patients were unable to flex both hip and knee at least 90°, because such patients tend to slide out of the seat.

Eligible subjects were randomized to 1 of 3 test surfaces as experimental conditions (3 surfaces in study 1, 2 surfaces in study 2). Randomization was performed by placing a number corresponding to each experimental condition into a sealed envelope with an equal number of envelopes per condition. A research assistant with no clinical experience drew envelopes by lot as eligible subjects were identified.

Clinical Characteristics

Clinical characteristics of the treatment groups for both studies are listed in tables 1 and 2. Analysis of covariance (ANCOVA) results comparing clinical parameters are shown in table 2. Serum albumin levels were not significantly different across the treatment groups.[11] Pressure ulcer sites included the trochanter, ischial tuberosity, and coccyx. There were no differences in pressure ulcer sites in the treatment conditions in either study. Because nearly all patients were incontinent, continence was not specifically related to pressure ulcer healing.

In study 1, treatment groups did not differ significantly on any parameter, except on the Cumulative Illness Rating Scale (CIRS) ($F_{2,110}=3.38$, $P=.38$). The overlay group had a slightly higher CIRS score (10.97) than did the generic total contact seat group (10.19) and the low air loss bed group (10.18). However, the observed mean differences of less than 0.8 in a scale with a possible range of 0 to 52 points were not thought to be clinically meaningful.

Test Surfaces

Generic total contact seat. The generic total contact seat was developed and tested by Sandia National Laboratories.[a] The static design was previously studied by our group as the total contact seat[12] and was shown in that study to allow interface pressures under the ischial tuberosities to be sustained below the capillary perfusion pressure. The seat frame was designed using the prosthetics principle of total contact pressure distribution. This design redistributes the weight from the

Table 2: Group Characteristics

	GTCS	LAL Bed	Overlay	*P*
Study 1				
Age (y)	70.4±4.5	69.0±4.1	68.6±3.0	.14
Body weight (lb)	170.3±14.5	170.0±9.9	171.3±6.1	.87
Hemoglobin (g/L)	14.5±0.9	14.5±0.8	14.5±1.0	.94
Albumin (g/dL)	3.70±0.38	3.73±0.32	3.75±0.43	.89
Lymphocyte (count/L)	2000±135	1945±126	1971±146	.17
CIRS (comorbidity)	10.2±1.3	10.2±1.6	11.0±1.6	.04
SCI (%)	24.3	23.6	28.9	χ^2=.85
Study 2				
Age (y)	68.0±3.8	68.7±3.9		.41
Body weight (lb)	171.4±6.8	171.0±6.5		.82
Hemoglobin (g/L)	14.3±0.8	14.2±0.7		.93
Albumin (g/dL)	3.7±0.4	3.8±0.3		.79
Lymphocyte (count/L)	1983±122	1970±125		.59
CIRS (comorbidity)	9.6±2.0	9.9±1.8		.43
SCI (%)	21.3	23.4		χ^2=.80

NOTE. Values are mean ± standard deviation (SD).
Abbreviations: GTCS, generic total contact seat; LAL, low air loss.

pressure-sensitive ischial tuberosities and the coccyx onto the thighs and lateral pelvis (figs 1A, 2A). By cradling the pelvis and controlling the lumbosacral angle, the cantilever effect shifts downward pressure forward onto the posterior and lateral thighs. The generic total contact seat is individually fitted to each subject's anatomy to achieve these design goals.

The lumbosacral angle (fig 2B) is formed by a line drawn along the inferior surface of the body of the L5 vertebra and a line drawn along the superior surface of the base of the sacrum through the acetabulum and down the center of the head and neck of the femur. The 2 lines meet at a point adjacent to the posterior surface of the intervertebral disk separating the L5 vertebra from the sacrum. Ideally, this angle in the seated individual should be as small as possible, the center of gravity moving posteriorly with an increase in the angle. In preliminary testing, the investigators showed that this lumbosacral angle was lowest for subjects seated on the generic total contact seat compared with other seating systems.[12] The lumbosacral angle is controlled at the optimal 20° to 24° position to provide a cantilever effect to reduce downward pressure.[13]

The generic total contact seat differs from the static total contact seat system through the addition of 4 pairs of adjustable air bladders strategically placed directly under specific pressure-sensitive bony prominences—for example, ischial tuberosities, gluteal region, or trochanters. Bladders are inflated and deflated sequentially by a piston-drive module to attain the lowest pressures and shear. Maximum air pressure inflation in the gluteal, ischial, and trochanteric bladders did not exceed capillary pressure of .73psi, and in the lateral and posterior thigh bladders was more than 2psi.

Shear. Before we began the studies, the generic total contact seat was fine tuned for each individual, to minimize tissue shear. For any subject whose pressure could not be corrected by a tilt, the hip angle was adjusted to accommodate. A preliminary seating trial was conducted for people assigned to the generic seat condition. Then, pressures on this seat were recorded on the computer-generated Force Management System[b] for 5 minutes. Force Management System results of pressure, friction, and shear were used to fine tune the seating. Pressure measures were repeated 5 minutes after each 15° seat lift from horizontal. The rate of pressure increase over time was measured for each critical area. If the rate of increase was more than 5mmHg/min, the vertical shear was too high for satisfactory seating and the entire seat was adapted by a tilt-in-space maneuver that simultaneously reclined the seat back and tilted the seat bottom up in such a way that the hip angle remained constant. Priority of these measurements was selected to give the lowest pressure in the areas with a current ulcer. Optimum tilt-in-space was determined by restricting pressures below 20 to 50mmHg (with pressure thresholds for tissue damage dependent on the anatomic location listed earlier) and then adjusting so that the subject was seated in the most upright position. If this maneuver was not sufficient to keep pressure changes at less than 5mmHg/min, pressure in the air bladders was increased or decreased, depending on the location of high pressure points. This also corrected for difficulties resulting from an abnormal seating posture.

Friction. Friction factors were calculated as the difference in pressure from the highest sensor reading to the 3 sensors immediately adjacent in the distal direction from the sensor with the highest reading. The subtraction was performed from pressure data for the 6 seat bottom areas. The location of the initial highest sensor in each anatomic zone was automatically determined by the Force Management System. The rate of change of friction over time was determined by measurements taken every minute for 5 minutes. To ensure that the settling rate remained below 5mmHg/min, dwell times were shortened on the sequence of air bladder inflation. Pressure, shear, and friction were measured for 5 minutes. Seat friction measures were used to adjust seating. Ideally, the coefficient of friction would approach zero. If friction persisted, the tilt-in-space angle was altered until values were lowest and pressure and shear were within stated limits. Once pressure, shear, and friction were minimized, subjects were again placed onto the generic total contact seat and the experimental studies were commenced.

Doppler studies performed at UCLA of the anterior and posterior compartments of the femoral-gluteal region showed that local blood supply on the generic total contact seat was equivalent to the low air loss bed.[13] The generic seat can be adapted to fit any wheelchair that is routinely used by experimental subjects. Unpublished preliminary studies showed that reduction of pressure in the pressure ulcer–prone areas not only tends to reduce pressure-induced damage but also enhances healing of previous pressure-induced ulcers. This was achieved by reducing pressures under bony prominences and reducing pressure gradients (shear).

Considering the importance of lower pressures, interface pressure, friction, and shear were calculated by the Force Management System before the longitudinal studies were started. Measurements of seated subjects, using fit factor calculations, were used to select the best seat size,[12] so that bladders were located under sites of frequent ulceration. If a subject did not fit a standard seat because of atrophy or deformity, bladders were added to compensate. Tissue shear tolerance is both age and health dependent. Shifting side to side increases rotatory torque on the disks as well as vertical shear under the ischial tuberosities. Spinal alignment must be maintained during pelvic instability by front to back shifting that moves the center of gravity forward and backward, thus increasing torque on the spinal disks as well as the ischial tuberosities.

Low air loss bed. The low air loss suspension bed[c] is the TheraPulse bed. A rack of inflatable fabric pillows was attached to a modified bed frame to provide pulsating air support that was intended to increase capillary blood flow and to lower interface pressure. These beds were covered with the manufacturer's Gore-Tex fabric surface to reduce friction. When indicated by wound severity, this was standard treatment at all study locations.

Bed overlay. For study 1 only, the bed overlay was a pressure-reducing advanced medium density open-cell polyurethane foam overlay[d] that was contour cut from 8.89-cm (3.5-in) solid foam. Each Geo-Matt cell was meant to respond individually to the weight put on it, thereby customizing support to minimize pressure and shear.

Experimental Design

Generic total contact seat. Subjects were placed on the generic total contact seat for 1 session a day for as long as tolerated, but never for more than 4 hours. After each session, subjects were returned to their hospital beds and were turned every 2 hours.

Bed overlay. Subjects were placed on an overlay atop a standard hospital bed and were turned every 2 hours.

Low air loss bed. Subjects in this group were placed on a low air loss bed preset for body weight, height, girth, and optimum air flow. Bed settings were calculated according to the manufacturer's specifications. Subjects assigned to low air loss do not need to be turned, but in practice for this study, subjects were turned every 2 hours because that was standard nursing procedure where the subjects were housed.

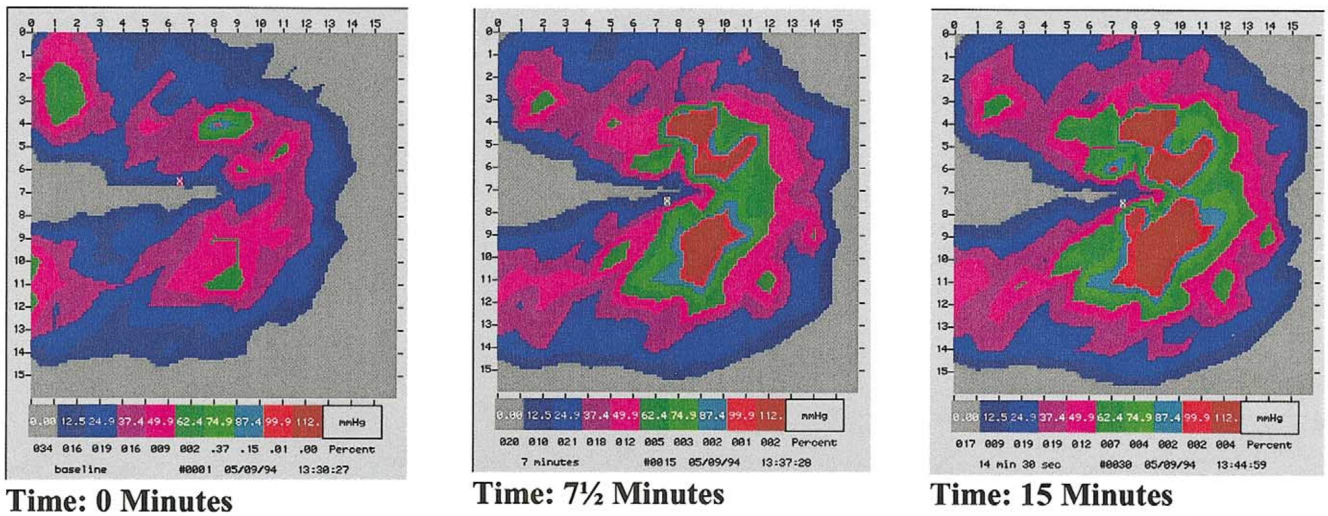


Fig 3. Force Management System pressure map over time (min). The isobaric pictures were done with the single seat mat Force Management System of a person sitting in a cushioned chair. The colors represent different ranges of pressures, with dark blue representing lower pressures and red representing very high pressures. As time passes, there are dramatic increases in localized pressures because of skeletal settling. Over the course of just 15 minutes, the maximum pressure (seen under the ischials) rises from roughly 75mmHg (time 0) in a very small area of 1 ischial, to well over 112mmHg (time 15) in major areas of both ischials. Information like this helps clinicians and therapists determine the most appropriate and effective product for a given patient.

Subjects were randomly assigned to 1 of the 3 treatment conditions, were examined weekly as in previous studies,[7] and were followed until the index ulcer healed, until the ulcer worsened, or for a total of 6 months.

No subject spent any time in standard wheelchairs because they all had full thickness skin loss and could not shift their weight every 15 minutes, as is recommended by National Pressure Ulcer Advisory Panel (NPUAP) guidelines to treat such pressure ulcers on wheelchairs.[10] No subject was ambulatory during the study. Therefore, subjects were on total bedrest except for those who were on the generic total contact seat. Dressings were changed routinely, according to NPUAP guidelines. If a wound worsened or surgery was needed, the patient was withdrawn from study.

In study 1, subjects from UCLA and community nursing homes were randomly treated on 1 of the 3 surfaces listed earlier (n=38 per group). No new wounds occurred but some wounds worsened for subjects on the overlay. Study 2 was performed to confirm findings of study 1 on an entirely new group of subjects recruited from VA, UCLA, or community nursing homes. Only low air loss bed and generic total contact seat were compared (n=47 per group) in study 2, because these treatments showed favorable results in study 1.

Outcome Measures

The primary outcome measures were (1) Pressure Sore Status Score (PSSS) at 4 weeks treatment, (2) number of subjects who totally healed, and (3) length of time for total healing. Secondary outcome measures were (1) interface pressures and (2) functional outcome as measured by the seating tolerance and Katz ADL score[14] extracted from nursing records.

Pressure Sore Status Score

Consistent with suggested best measures,[8] the PSSS was used to evaluate depth, size, and indications of healing. Surface area was determined by tracing epithelial borders of the ulcers on plastic transparencies and measuring the dimensions with a ruler. Two of the investigators separately evaluated ulcers by using a multidimensional PSSS (adjusted range: 0, healed to 120, worst wound), which was modified from the Pressure Sore Status Tool developed by Bates-Jensen,[15,16] the content validity of which has been reported.[15] Pressure ulcers were scored at entry and weekly for 6 months or until total healing. When investigators used the PSSS during the first 4 months of treatment, the consistency of scoring between the investigators, that is, the interrater reliability or Pearson *r*, was .93 for study 1 and .94 for study 2 (both $P<.01$). Intrarater reliability was not tested.

Functional capacity. Activities of daily living (ADLs) were assessed by the 12-point Katz ADL index,[14] which was used in practice at the sites where this study was done, and these data were extracted from the nursing records. At 4 weeks, "seating tolerance" was recorded by nursing staff for 5 consecutive days, once a day, as the maximum time (h/d) each subject could sit on the assigned support surfaces. Patients sat on low air loss bed or bed overlay supported by bolsters with the back of the bed elevated to 75°. When patients decided they were too fatigued to sit up, they were returned to their flat bed condition. The CIRS was used to score comorbidity of medical conditions.[17]

Pressure measurement. The interface pressure measurement system incorporates a 15×15 grid of 1^2-in sensors to measure seating pressure and a 20×48 grid to measure bed pressures. Point-by-point measurements over time were collected by a flexible body–conforming pad into which pressure transducers were incorporated to minimize hammocking. Correction for any hysterises is built into the software. The sensors emit electric signals in proportion to the pressure exerted on them. Signals are transferred to a multiplexer for alignment, are relayed to a computer, and are immediately analyzed to yield quantitative pressure values.[12] An isobar display of color-coded pressure rings indicates pressure values (fig 3). Because skin capillaries close at .73psi, the measuring device is capable of a 0.2 to 0.3psi sensitivity. This system was clinically validated in preliminary studies on patients with pressure ulcers.[12] Considering that validation, the system we used in the 2 studies reported here is preferable to other currently available systems. In our studies, measures were taken continuously at the left ischial tuberosity, which was anatomically determined by digital palpation while the subject was being placed onto the pressure mat. Pressures were compared for data collected at specified times after placement; measurements were collected for analysis immediately after the subjects were placed. Testing was repeated after 30 minutes without moving the subjects.

Statistical Analysis

Analyses were performed by using SPSS, version 10.0.[e] Descriptive statistics (mean, standard deviation [SD], frequencies) were obtained to describe clinical characteristics and outcome variables for patients in each treatment condition. Data are listed ± SD ($P<.05$ used throughout). One-way analysis of variances (ANOVAs) with post hoc Tukey comparisons (study 1) or paired *t* tests (study 2) compared treatment groups at baseline on these characteristics. ANCOVA was used to compare treatment conditions on the PSSS at 4 weeks, adjusting for the baseline PSSS. Study 1 had 3 treatment conditions. Thus, planned comparisons were made to contrast the generic total contact seat with the low air loss bed and with the bed overlay. Study 2 compared 2 treatment conditions (generic total contact seat vs low air loss bed) and the between-group effect in the ANCOVA provided this comparison directly. Distributions of the PSSS were checked for normality and outliers; assumptions of ANCOVA were checked. Time to total healing for the 207 patients in both studies was analyzed by using Kaplan-Meier survival analysis techniques[18] to compare the total healing curves for each treatment condition up to 6 months after the study began.

RESULTS

Data on 1 subject in study 1, who died from unrelated causes 3 weeks after enrollment, was excluded from analysis. All other subjects were tested at 4 weeks. However, in the first study at posttest (after 4wk), 3 patients in the bed overlay condition had worsened and were withdrawn from the study. Their data were not included in the time-to-healing analyses. No new pressure ulcers were found in and no antibiotics were given to any subject in either study.

Table 4: The PSSS Over Time for Treatment Conditions

	GTCS	LAL Bed	Overlay
Study 1			
At start	45.68±9.03	49.41±8.58	44.50±9.54
After 4wk	9.65±7.73	25.39±11.98	36.00±12.15
Study 2			
At start	58.72±7.48	57.47±7.67	
After 4wk	24.17±11.08	39.30±12.19	

NOTE. Values are mean ± SD.

Pressures

Interface pressures were measured over time[12] (fig 3) in study 1 for each of the tested surfaces, and they showed a significant effect of time (table 3). The test for homogeneity of variance across groups was significant (Levene statistic=56.34, $P<.001$), reflecting skewed data. To meet assumptions for normality and homogeneity of variance, the natural log of pressure data was used to normalize the distributions. After transformation, the Levene statistic was .99 ($P>0.3$), reflecting homogenous groups. Group by time interaction for interface pressure changes over time remained significant ($F=56.08$, $P<.001$; table 3). There was a significant effect of time on pressure ($F=580.73$). After 4 weeks of treatment, pressure changes over 0 to 30 minutes of sitting time showed a significant main effect of time ($F=601.6$, $P<.001$) and surface ($F=214.5$, $P<.001$), and a significant interaction of support surface by time ($F=188.2$, $P<.001$). After 4 weeks of treatment, pressures increased with time (in weeks) on the low air loss but not with the generic total contact seat, and this correlated with the wound score (table 4). Post hoc testing showed that pressures were significantly lower on the generic total contact seat than on low air loss ($P<.001$) or overlay ($P<.001$) at time 0 and after 30 minutes ($P<.001$; table 3). Pressures increased significantly from 0 to 30 minutes on all surfaces ($P<.01$). Pressure increase was lowest on the generic total contact seat ($P<.01$). Pressures were higher after 4 weeks than on the first day on low air loss ($P<.02$), but no such

Table 3: Pressure Measurement Data

	Mean	95% CI
Pressure after 30min (mmHg) in study 1		
Overlay	64.7	61–68
LAL bed	35.5	32–39
GTCS	14.3	12–16
Pressure changes over weeks (mmHg)		
Study 1	GTCS	LAL Bed
At start		
Time 0	9.28±0.96	13.72±1.99
Time 30min	15.64±2.47	24.62±1.58
After 4wk		
Time 0	9.83±4.73	21.44±8.26
Time 30min	14.30±5.15	35.53±12.30
Study 2		
After 4wk		
Time 0	16.75±5.67	23.33±8.18
Time 30min	20.10±5.49	46.23±15.75

NOTE. Values are mean ± SD unless otherwise marked.
Abbreviation: CI, confidence interval.

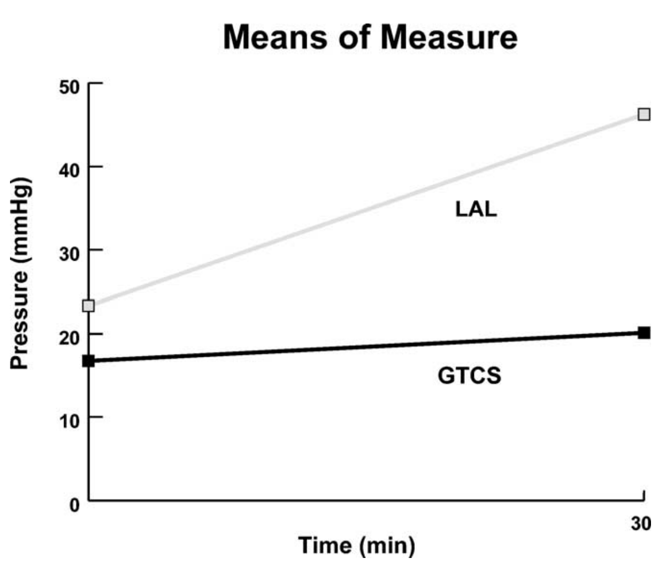


Fig 4. Interface pressures in study 2 at 4 weeks.

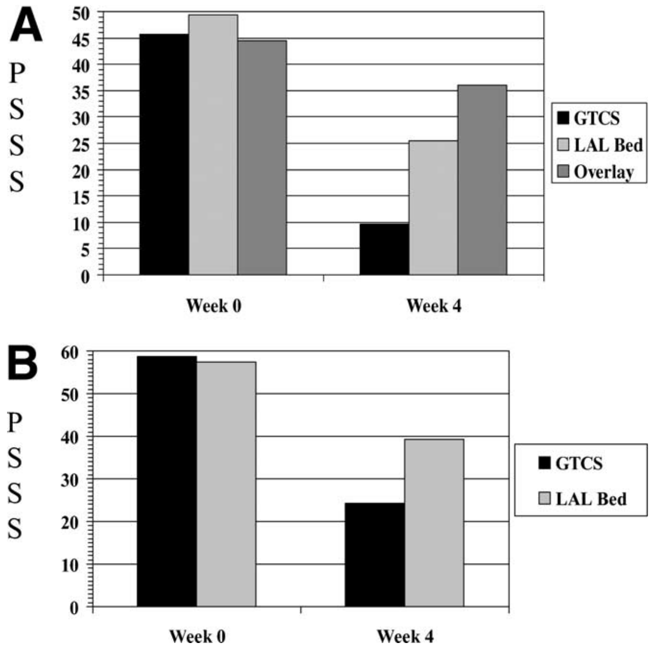


Fig 5. PSSSs at 0 and 4 weeks in (A) study 1 and (B) study 2.

increase occurred on the generic total contact seat ($P<0.3$; table 3B).

In study 2, there was a significant effect on log-transformed pressure measurements over time ($F=132.78$, $P<.001$), a significant effect of support surface on pressure ($F=89.4$, $P<.001$), and a significant interaction of support surface with time ($F=39.39$, $P<.001$). Pressure went up over time on both surfaces. Pressure on the seat was lower than what it was on the low air loss bed initially (time 0) and after 30 minutes (fig 4). Change in pressure over time on the seat was significantly lower than it was for the low air loss bed. Interface pressure did not exceed the allowable threshold of .73psi on the generic total contact seat.

Pressure Sore Status Score

PSSS was measured at baseline and at 4 weeks, at which time ANCOVA was performed, by using the baseline PSSS as the covariate. All assumptions for ANCOVA were met, including equality of error variances, and linear and parallel regression of the covariate across groups. Because 8 subjects had healed totally within the first 4 weeks, measures of the PSSS were compared at 4 weeks.

In study 1, treatment groups did not differ statistically at baseline ($F_{2,110}=3.5$, $P=.51$); post hoc Tukey comparisons were also not significant. The Levene test for equality of error variances was significant ($F_{2,110}=7.50$, $P=.001$). Treatment groups differed significantly on the PSSS at 4 weeks ($F_{2,109}=79.57$, $P<.001$; fig 5A, table 4). F test analysis showed differences between groups, which were compared by contrast estimates. Planned contrasts showed that PSSS scores on the generic total contact seat were significantly lower than on the bed overlay (contrast $F_{2,109}=27.1$, $P<.001$) or on the low air loss bed (contrast $F_{2,109}=13.4$, $P<.001$). Planned contrasts also showed that the PSSS improvement on the generic seat was significantly greater than that in the other 2 conditions ($P<.001$ for both contrasts).

Of the clinical characteristics listed in table 2 (study 1), only CIRS correlated modestly with the PSSS at 4 weeks (Pearson $r=.199$, $P=.35$). Higher comorbidity was associated with higher PSSS. CIRS was also modestly related to improvement in the PSSS (Pearson $r=-.185$, $P=.05$). Higher CIRS related to less improvement in the PSSS.

In study 2, the PSSS was measured at baseline and at 4 weeks, in a new sample randomized to low air loss bed and generic total contact seat conditions. There were no differences between groups in the baseline PSSS ($P=.42$). No wound worsened over time. Clinical parameters did not significantly differ across conditions. As in study 1, ANCOVA was performed on the PSSS at 4 weeks by using the baseline PSSS as the covariate. The generic total contact seat group had a significantly lower PSSS at 4 weeks (23.8±1.5) than did the group on the low air loss bed (39.7±1.5) ($F_{1,91}=53.11$, $P<.0001$; fig 5B, table 4). Although the PSSS in both groups improved significantly at 4 weeks, the improvement in the generic total contact seat group (34.3±1.5) was greater than in the low air loss group (18.4±1.5) ($P<.0001$).

The relation between CIRS and PSSS observed in study 1 was not replicated in study 2. This was a modest effect in study 1, although it was significant and this merits further investigation. There might be additional variables that affect both CIRS and PSSS improvement, such as nutritional parameters, other than albumin levels. In support of that notion, in study 2—but not in study 1—higher ADL function was associated with a lower PSSS at 4 weeks (Pearson $r=-.467$, $P<.001$) and with greater improvement in the PSSS (Pearson $r=.408$, $P<.001$). The subjects' different responses in the 2 studies may relate to other factors, given the fact that initial and 4-week PSSSs appear to have been higher in study 2 than in study 1 despite the lack of support from CIRS data. This merits additional study.

Time to Total Healing

Except for subjects who worsened in the bed overlay condition and were withdrawn from study, subjects in both studies were maintained on experimental treatments and were followed for 6 months or until their wounds healed. PSSS improvement for the whole sample was a continuous variable at a fixed point in time. At 4 weeks, 8 subjects in the generic total contact seat condition had healed totally. Thereafter, the number of people who totally healed made it sensible to look at total healing and not the PSSS as a primary dependent variable to evaluate wound healing. Time to healing was analyzed in the combined sample from both studies, because both used the same eligibility criteria, had similar clinical profiles, and had little difference for time to total healing of any particular anatomic pressure ulcer locations. There was no significant difference by facility where treatment was delivered: UCLA and community (100.8d for total healing) versus VAMC (106.4d to total healing) ($P=.34$). By using the Kaplan-Meier estimation,[18] the median time to total healing differed between the groups: generic total contact seat was 3.33±0.12 months (95% confidence interval [CI], 3.09–3.58), low air loss bed was 4.38±0.14 (95% CI, 4.1–4.65), and bed overlay was

Table 5: Effects of Anatomic Site on Time to Total Healing in Combined Studies

Site	Months
Ischial tuberosity	3.61±1.26
Trochanter	3.45±1.16
Coccyx	3.19±1.39

NOTE. Values are mean ± SD.

Table 6: Anatomic Site for Each Surface on Time to Total Healing (mo)

	GTCS	LAL Bed
Trochanter	3.02±0.87	3.88±1.27 (*P*<.05)
Ischial tuberosity	3.30±1.1	3.93±1.83 (*P*=0.2)
Coccyx	2.41±0.88	3.93±1.40 (*P*<.05)

NOTE. Values are mean ± SD.

4.55±0.22 months (95% CI, 4.13–4.98). The generic total contact seat led to more rapid total healing than both the low air loss bed (log rank=28.03, $P<.001$) and the bed overlay (log rank=20.64, $P<.001$). The total healing of low air loss and overlay groups did not differ (log rank=.58, $P=0.4$), similar to a previous report.[19] The anatomic sites of pressure ulcers did not affect time to healing (table 5). The effects of support surfaces on time to healing were not affected by wound location except that improved healing on generic total contact seat did not reach significance for wounds on the ischial tuberosity compared with wound healing on the low air loss (table 6).

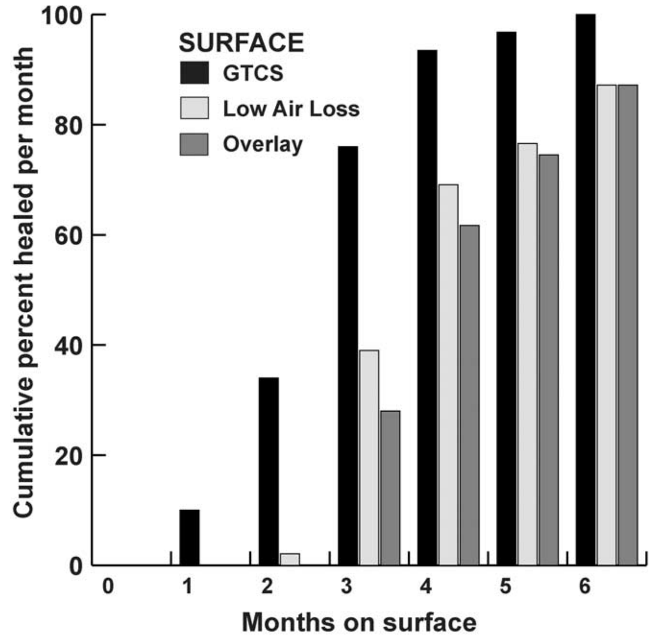


Fig 6. **Percentage of subjects who healed totally by treatment type over time, shown as cumulative percentage healed by month.**

Functional Outcomes

Functional outcomes as measured by the Katz ADL index[14] and seating tolerance are shown in table 7. These secondary outcomes were measured only at 4 weeks, and treatment groups were compared by using 1-way ANOVA. ADL results were similar in studies 1 and 2. ADL function was significantly higher after 4 weeks on the generic total contact seat than on the other surfaces (table 7). Every subject on the generic seat could sit at least 2 hours, some as long as 4 hours. In both studies, seating tolerance was better for subjects on the generic total contact seat than those on the low air loss (study 1, $P<.001$; study 2, $P=.12$; table 7).

DISCUSSION

In study 1, healing of stage III and stage IV pressure ulcers was compared between treatment on the low air loss bed, the bed overlay, and the generic total contact seat surfaces. The finding that the generic total contact seat promoted faster healing than the low air loss bed was unexpected, and some subjects worsened on the bed overlay. Therefore, study 2 compared low air loss and generic total contact seat in an independent sample by using the same method to replicate and confirm the findings of study 1. In study 2, healing was also best at 4 weeks on the generic total contact seat. There was total healing at 4 weeks (fig 6) for 8 subjects in the generic total contact seat condition. No other study of advanced pressure ulcers has examined time to total healing as a primary outcome measure. Our study also found interface pressures in subjects seated on the generic total contact seat to be as low as or lower than the pressures in subjects seated upright on the low air loss bed and pressure increase over time to be lower on the generic total contact seat. By reducing the pressure gradients, it would appear that the metabolic breakdown commonly incurred in sitting for long periods has been reduced. Others (W. Hickerson et al, unpublished manuscript, 2002) have reported similar pressure distinctions, but have yet to evaluate their impact on healing.

Interface pressures under the bony prominences[12] were lower using the generic total contact seat, and the reductions were maintained over time (table 3). Lower interface pressures correlated with lower PSSSs. Alternating inflation and deflation of the bladders within the generic total contact seat may have improved healing by promoting circulation to the soft tissues underlying the bony prominences. Vertical shear or settling into the seat or body tissues prevents wound healing and can lead to new ulcers. Shear is not significantly ameliorated by pillowing. Rapid displacement on a flat surface, such as a bed or foam pad, still occurs. Most significant is the fact that the tissue pressure gradients increase faster than the actual pressures, which indicates that there is displacement of soft tissue beneath the bony prominence. In essence, the bone acts as a snowplow, displacing soft tissue, and tends to produce a coring action through the nondisplaceable soft tissue.

High friction (sliding out of the seat) can create new ulcers and can also prevent healing. This is a lesser problem for stage

Table 7: Functional Outcomes at 4 Weeks

	GTCS	LAL Bed	Overlay
ADL by 12-point Katz score			
Study 1	6.6±1.85	3.1±1.23 (*P*<.001)	1.9±0.62 (*P*<.001)
Study 2	6.7±1.37	4.8±2.06 (*P*<.001)	
Seating tolerance (h) after 4 weeks treatment			
Study 1	5.06±0.63	2.11±0.66 (*P*<.001)	
Study 2	3.69±0.66	2.11±0.63 (*P*=.12)	

NOTE. Values are mean ± SD.

III ulcers because the depth of the wound decreases the forces of friction. Pressure would be affected by changes of shear and friction. Overall, sitting pressure, friction, and shear were individually optimized for subjects in the generic total contact seat condition. As opposed to other testing surfaces, only on the generic seat was the support surface individually modified to minimize the potentially deleterious factors of shear and sliding friction. The generic total contact seat relies on particular placement of air bladders that were inflated to relieve the actual pressure ulcer sites. This differs from previous "alternating" support[9,20-23] and from the accommodation of pressures achieved by low air loss bed surfaces that (1) do not follow an inflating and deflating cycle, (2) are not anatomically particularized, and (3) do not control alignment of bony anatomy. We showed better alignment of bony anatomy on the seat in a previous radiographic study.[12]

The studies reported here addressed effects on healing with subjects spending time in the more physiologically beneficial position of upright sitting, as opposed to being restricted to bed.[24,25] Longer seating capacity and better ADL results indicated enhanced function in feeding and dressing skills through use of the seat (table 7). More improvement in the PSSS was significantly associated with a higher ADL score. Seating tolerance on the generic total contact seat correlated with PSSS improvement ($r=.58$, $P<.0001$ in study 2). Subjects who could sit longest on the seat had the most healing. Further evaluation of this relationship is needed to clarify the mechanism for such findings. It appears that use of the generic total contact seat helped promote healing of old ulcers and the prevention of new ulcers by reducing resting pressure, friction, and shear. Improved sitting tolerance also appears to have permitted independent functional activity, but the effect of better function on healing has yet to be precisely defined.

CONCLUSION

Enhanced postural tone and improved pelvic stability may have been related to seat design.[13] We previously found that prolonged sitting on the generic total contact seat improved capacity for endurance compared with sitting on a flat seat, presumably because less energy is needed for sitting. It is not known whether such factors affect wound healing. Results of these 2 studies may have reflected better nutrition and function in our subjects than in other patients with pressure ulcers. This possibility has yet to be studied. The studies reported here support an alternative to bedrest, which has been the treatment of choice for advanced pressure ulcers.[26]

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