A Comparison of Two Pressure-Relieving Devices on the Prevention of Heel Pressure Ulcers

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Abstract *The effectiveness of hospital pillows versus a commercial heel elevation device (the Foot Waffle [EHOB Incorporated]) in preventing heel pressure ulcers was examined using an experimental balanced factorial design with repeated measures on 52 patients (ages 27 to 90) in randomized groups. Heel interface pressures were taken with patients in supine and right lateral tilt positions. Logistic regression demonstrated a statistically significant difference between interface pressures on left and right heels (p = .004) and a trend toward significance between the pillow and Foot Waffle (p = .069). The Generalized Estimating Equations (GEE) method revealed the Foot Waffle was four times more likely not to suspend the heel off the bed than the pillow, and the left heel was four-and-a-half times more likely to have higher interface pressures than the right. There was no significant difference between groups in incidence of lower-extremity pressure ulcers, but patients using the Foot Waffle developed pressure ulcers significantly sooner (10 days versus 13 days for the pillow). Heels require additional protection beyond the use of specialty beds and mattress overlays. In order to provide continuous heel suspension, clinicians must consider proper fit, turning schedules, patient position, patient activity, and presence of additional equipment when selecting heel protection products. This study illustrates how difficult it is to control for all these factors when doing clinical research.*

Note: This study was done with a Foot Waffle model that has since been redesigned. No research is available on the new model.

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The Agency for Health Care Policy and Research's (AHCPR's) guideline, *Pressure Ulcers in Adults: Prediction and Prevention*,[1] recommends using pressure-relieving devices on immobile patients' heels. The guideline lists pillows as a method to achieve this goal; however, patients' movements may disrupt the proper placement of their legs on pillows, making continuous heel suspension difficult. Diligent nursing care is required to maintain proper alignment of the legs on the pillows. Until recently, few heel products were available that met the criteria of reducing pressure, providing comfort, reducing friction and shear, maintaining heel elevation, separating ankles, allowing for leg repositioning without causing pressure in other areas, preventing foot drop, and saving nursing time.[2] The purpose of this study was to examine the effectiveness of hospital pillows versus a commercial heel elevation device, the Foot Waffle (EHOB Incorporated), in preventing heel pressure ulcers.

Prolonged, localized pressure over bony prominences causes tissue ischemia and leads to tissue necrosis. When the body is recumbent, its weight is distributed unevenly across the bony prominences. Because heels have a small surface area, they are a prime site for pressure ulcer development.

Until recently, few research studies described the pressure-reducing properties of specialized heel devices. Existing studies have examined heel wraps, pillows, water-filled gloves, and specialty heel products.

Kosiak[3] studied the effectiveness of a self-adhering polyether urethane foam heel wrap applied to 154 patients admitted with fractures of the pelvis or extremities. Thirty-six patients (23%) developed 54 heel ulcers. Heel ulcers occurred only among the patients who had fractured hips—most often bilaterally (48%) or on the involved side (40%), and less often on the uninvolved side (12%).[3] Pain from the fractured hip may have contributed to the patient's reluctance to move the affected leg, thus resulting in prolonged pressure to the heel.[3] This study was helpful in targeting patients with a fractured hip as high risk for heel ulcer development and identifying the limited effectiveness of this heel wrap.

Cheneworth and colleagues[4] examined a foot wrap made of 4×4 gauze pads, an absorbent pad, and a gauze roll. The wrap was compared with a laminated foam boot

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(Lunax Boot by Bio-Sonics). Patients in intensive care who had heel redness (n = 25) were assigned to one of the two heel-protection methods. Of the 11 patients using the heel wrap, five had unchanging heel erythema and five experienced worsening erythema (one patient died). Heel skin condition improved in 13 (93%) of the 14 patients wearing the foam boot.[4] Although the study had a small sample and lacked aspects of statistical analyses, it highlighted the importance of examining "familiar" practices.

Using water-filled examination gloves under the heels also has been suggested as an inexpensive method to decrease heel interface pressure. With a convenience sample of 40 adults, Williams[5] examined heel interface pressures on a mattress and on a latex glove filled with 260 ml of water. In all patients, heel interface pressure increased on the water-filled latex glove (M = 144.6 mm Hg) compared to the heel resting directly on the mattress (M = 126.5 mm Hg). When asked about the efficacy of the water-filled gloves, nurses expressed various opinions, but 79.4% used them.[5] This study stimulated nurses to question their practice for heel protection.

Smith[6] examined heel interface pressures of 35 elderly, preoperative patients admitted with a fractured femur. Interface pressure readings were taken on the affected leg without a heel protection device and with the heel protected by the Ripple mattress, full-length synthetic sheepskin (Seton), synthetic sheepskin heel pads, Parapads (Seton), or a pillow. Heel interface pressures without heel protection ranged from 0 to 160 mm Hg.[6] Heel interface pressures with the various products generally were within the same range. Only the use of pillows effectively reduced heel interface pressure to zero for all patients.

Flemister[7] examined heel interface pressures under a foam or polyester heel protector in seven patients assessed at moderate to high risk for pressure ulcer development. The patients were in a semi-Fowler's position when the measurements were taken. The foam heel protector marginally reduced heel interface pressures (from M = 29.7 mm Hg to M = 28.4 mm Hg), and the polyester heel protector significantly increased interface pressures. Thus, heel interface pressures varied with the product.

Guin and colleagues[8] examined the efficacy of six heel pressure-reducing devices on 40 healthy volunteers. All products were tested with participants in the supine and 30° semi-Fowler's position. A significant interaction was found between the device and position. For patients in the elevated position, the L'Nard Multi-Podus splint yielded the lowest interface pressure—22.9 mm Hg. For supine patients, the Lunax Boot yielded the lowest pressure—24.6 mm Hg. All other products resulted in interface pressures above 32 mm Hg, the pressure at which vessels become occluded, leading to tissue ischemia. Interestingly, a positive correlation was found between foot width and heel pressure. The wider the foot, the higher the pressure on the heel.

Pinzur and colleagues[9] compared the effects of five heel protection products on interface pressures of five men with paraplegia and five healthy men. The authors concluded that devices that lift the heel and prevent contact with a surface were the most effective. Simple cushioned heel protectors did not effectively dissipate pressure off bony prominences.

De Keyser and colleagues[10] examined the pressure-reducing effects of 13 heel protecting devices on 40 hospitalized geriatric patients. Heel interface pressures ranged from 42.2 mm Hg to 147.8 mm Hg. The most effective pressure reduction occurred using the standard hospital head pillow.

In summary, research over the years has indicated that pressure-reducing mattress overlays and pressure-relieving mattresses are more effective than standard hospital mattresses for decreasing interface pressure on the sacrum and trochanter but do not effectively reduce pressures on the heels.[11-16] For patients at risk for developing pressure ulcers on their heels, some form of heel-specific pressure-reducing device is required, as well as mattress overlays or pressure-relieving mattresses.[12]

This study explored whether using pillows or a commercial heel protector made a difference in:

- right and left heel interface pressures with patients in the supine and right lateral tilt positions
- the development of heel pressure ulcers
- the length of time for a pressure ulcer to occur.

Methodology

This study used an experimental, balanced factorial design with repeated measures (heel elevation product [pillow/Foot Waffle]; position [supine/right lateral tilt]; order of position [supine first/right lateral tilt first]; the heel [left/right]); and all two-way interactions. Patients were randomly assigned to either the pillow group or the Foot Waffle group. This study was approved by a Human Rights Committee Institutional Review Board. Inclusion criteria were based on patients' Braden Risk Assessment Scale scores and degree of skin integrity.

The Braden Scale, a tool for predicting pressure ulcer risk, assesses sensory perception, moisture, activity level, mobility, nutritional level, and friction and shearing factors. The score is obtained by adding the points across the six

factors. A score of 16 points or less (out of a possible 23) indicates a patient at risk for pressure ulcer development. The Braden Scale has an established reliability ($r = .93$, $p < .01$) and a validity demonstrating high sensitivity (83% to 100%) and specificity (64% to 90%) of accuracy in predicting pressure ulcer risk with the cutoff score of 16.[17]

Pressure ulcer stages as defined in the AHCPR guideline[1] were used. For this study, blanchable erythema and intact skin (no erythema) also were recorded. When blanchability of erythema was questionable, the skin was rated as non-blanchable.

Subjects were patients admitted to selected nursing units at a large urban hospital. They had a Braden Scale score ≤16 points, had intact skin on the lower extremities, and were able to sign informed consent (or had next of kin available to sign the consent).

A demographic form included the patient's admission date, transfer date, discharge date, diagnosis, age, race, sex, height, weight, and initial Braden Scale score. The lower-extremity assessment consisted of inspecting the skin from the knee to the toes and palpating skin surface areas for edema, warmth, and pedal pulses.

The sample consisted of 23 females (44%) and 29 males (56%); 32 patients were African-American (61%), one was Asian (2%), and 19 were Caucasian (37%). Participants ranged in age from 27 to 90 years ($M = 66.6$, $SD = 16.5$). The mean height of participants was 166.9 cm ($SD = 9.6$); mean weight, 68.1 kg ($SD = 15.9$). The average Braden score on admission to the study was 11.8. The most common admitting diagnostic categories were respiratory ($n = 21$), cancer ($n = 6$), and stroke ($n = 5$).

The sample size needed for a t-test with a two-tailed alpha of 0.05 and power of 0.8 was 52.[18] A moderate effect (0.5) for the difference of interface pressures between the pillow and Foot Waffle was chosen as being clinically significant. If the mean difference between the two devices was small, there would not be a rational reason to prefer one product over the other. If one device was moderately more effective than the other, one reasonably could favor that device.

Patients who met the study's criteria and gave informed consent were assigned using a block randomized list to either the pillow group or the Foot Waffle group. The patient's position order (supine then right lateral tilt—or right lateral tilt then supine) was determined by a coin toss. The right lateral tilt was obtained using a 30° foam positioning wedge. All patients were lying on a Prism Pressure Reduction Integrated Systems Mattress (DermaGard) with or without a Sof Care (Gaymar) mattress overlay, depending upon the unit's standard of practice.

Tissue interface pressures were measured with the Gaymar electropneumatic pressure transducer, whose reliability has been reported ($r = .89$, $p = .0001$, $SD = \pm 11.92$ mm Hg).[19] This device consists of a 1-inch square inflatable plastic bladder attached to a pump inflation system and an aneroid pressure gauge. A T-piece connector (developed by biomedical engineers at the Harper Hospital vascular laboratory, Detroit) was attached to the pressure transducer and a manometer to obtain readings in millimeters of mercury.

Once patients were in the assigned position, the Gaymar sensor was applied to the most dependent position of the left and right heels. Three consecutive readings were taken, and the highest reading was recorded for statistical analyses. Pressure readings were taken with the patient:

- supine without heel elevation
- supine with the heel elevation product in position
- in a right lateral tilt without heel elevation
- in a right lateral tilt with the heel elevation product in position.

The use of plastic sequential compression devices (SCDs) as a standard of care was not altered during the study; however, interface pressures were taken on the heels with the SCDs removed. Interface pressure measurements were done once, at the beginning of the study.

Patients in the pillow group had one pillow positioned under both legs from below the knee to the Achilles tendon region, leaving the heels suspended above the bed. In this hospital, the standard pillow is a 20-ounce (±2 ounces) polyfiber-filled pillow (part number 4884-089-2000) manufactured by Careline. Patients in the Foot Waffle group had a Foot Waffle placed on each leg. The Foot Waffle is an FDA-approved non-abrasive medical-grade vinyl boot with a built-in foot cradle. Its pre-inflated single air chamber uses a static air design. The Foot Waffle is available in three sizes (small, medium, and large); calf size is used to maximize proper fit. The Foot Waffle surrounds the lower extremity and is secured by three straps with adjustable Velcro fasteners. An adjustable heel flap allows the heel to rest directly on an air cushion or to be elevated. The manufacturer claims that the interface pressures exerted by the Foot Waffle are 18 mm Hg over the calf; 12 mm Hg over the shin; 8 mm Hg over the ankle, Achilles tendon, and foot; and 0 mm Hg on the heel with the flap secured back (4 mm Hg with the heel covered). The Foot Waffle has a non-woven lining for comfort and adjustable straps that permit it to fit around an SCD. For this study, interface measurements were taken with the heel flap secured back against the calf so that the heel was elevated.

The patients were followed during their hospitalization to any nursing unit to which they were transferred until they met one of these completion criteria:

- Braden score >16
- voluntary withdrawal
- discharge or transfer to another facility
- 14 days elapsed since entry into the research project
- pressure ulcer development.

Results

Each heel elevation device could result in total heel suspension (0 mm Hg) or incomplete heel suspension (>0 mm Hg), so results were analyzed with the logistic regression method. Because there were repeated measures per patient, the Generalized Estimation Equations (GEE) method was used to compare the two heel elevation methods. In the initial model, statistically significant differences existed between the left and right heels ($p = .004$), and there was a trend toward significance between the pillow and Foot Waffle ($p = .069$). (See Table 1.)

The model was further reduced using a stepwise method. Two significant variables remained in the final model—left and right heel and heel elevation method ($p < .01$ and $p = .001$, respectively). Odds ratio were calculated for these variables using the final model. The use of the pillow or Foot Waffle demonstrated an odds ratio of 4.38, with the occurrence of interface pressures >0 mm Hg four times more often with the Foot Waffle than the pillow. An odds ratio of 4.62 existed between the left and right heel, with the occurrence of interface pressures >0 mm Hg four-and-a-half times more frequent on the left heel than the right (see Table 2). When patients were supine, the pillow eliminated pressure (0 mm Hg) in 47% of the right heels and 43% of the left heels, versus 45% and 31%, respectively, for the Foot Waffle. In the right lateral tilt position, the pillow eliminated pressure in 47% of the right heels and 37% of the left; the Foot Waffle eliminated pressure in 39% of the right heels and 22% of the left.

In patients using the Foot Waffle, pressure ulcers occurred over the left lateral malleolus ($n = 1$), the top of the foot ($n = 1$), right first metatarsal ($n = 1$), left first metatarsal ($n = 1$), left fifth metatarsal ($n = 1$), and shin ($n = 1$). Patients using the pillow developed pressure ulcers over the left fifth metatarsal ($n = 1$) and the side of the heel ($n = 1$). A Fisher's exact did not demonstrate a significant difference between the incidence of pressure ulcers and the method of heel elevation; however, the cell size for calculation was small and therefore unreliable. It is clinically significant that three times the number of patients developed pressure ulcers using the Foot Waffle than the pillow, and that patients using the pillow for heel elevation developed pressure ulcers on the heel, and those using the Foot Waffle did not.

Mean survival time was defined as the length of time patients remained in the study until a pressure ulcer occurred. Of the 52 patients, eight developed Stage I pressure ulcers and were removed from the study. The mean length of survival in the group using the pillow was 13 days; two patients were removed because of skin changes. The mean length of survival for the group wearing the Foot Waffle was 10 days; six patients were removed because of skin changes. Survival analysis using Kaplan-Meier estimates demonstrated a significant difference between the pillow group and the Foot Waffle group in length of time for skin breakdown. Patients using the pillow did not develop skin changes as rapidly as patients wearing the Foot Waffle. Additionally, statistically significant differences occurred between the pillow and the Foot Waffle groups using the log-rank tests ($p = .036$).

Interface pressures were taken over the right Achilles tendon while the patient was supine and the heel elevated. With heels suspended using either the pillow or Foot Waffle, pressure was displaced to the adjacent dependent part of the foot, especially the Achilles

TABLE 1
Initial logistic regression between tilt positions, heels, and pressure-relieving devices

Variable	Estimate	Standard error	p
Intercept	−0.14	0.52	0.78
Supine/tilt	0.88	0.56	0.12
Left/right heel	−1.46	0.51	0.004
Pillow/Foot Waffle	−1.48	0.81	0.069
Supine first/tilt first	−0.70	0.43	0.10
Supine/tilt by left/right	−0.18	0.70	0.79
Supine/tilt by pillow/Foot Waffle	−0.17	0.91	0.85
Pillow/Foot Waffle by left/right	−0.13	0.92	0.89

TABLE 2
Final reduced logistic regression between heels and pressure-relieving devices

Variable	Estimate	Standard error	p	Odds ratio
Intercept	−0.06	0.28	0.82	1.06
Left/right	−1.53	0.38	0.00*	4.62
Pillow/Foot Waffle	−1.48	0.44	0.001	4.38

* $p < .01$

tendon, possibly increasing the risk for pressure ulcer development in that area. Mean interface pressure on the Achilles tendon was 14.2 mm Hg (*SD* = 15.6 mm Hg) using a pillow for heel elevation and 31.2 mm Hg (*SD* = 15.6 mm Hg) using the Foot Waffle. An independent *t*-test demonstrated that using the pillow caused significantly lower interface pressures on the Achilles tendon than the Foot Waffle ($p < .01$).

Discussion

Using pillows to suspend heels off the bed surface is a common nursing intervention to prevent pressure ulcers. Pillows are inexpensive, convenient, and readily available. When examining the effectiveness of products designed to suspend heels, clinicians typically use pillows as the standard of comparison. An interface pressure reading >0 mm Hg indicates that the heel elevation product did not successfully suspend the heel. Interface pressures >0 mm Hg occurred four times more frequently with the Foot Waffle than with the pillow, and four-and-a-half times more frequently on the left heel than on the right.

The significant difference in interface pressures between right and left heels may be explained by physical variations of the foot that contribute to varying pressure points along the ankle and heels. Weight distribution could be disseminated along the long axis of the dependent right leg and malleolar region of the foot, causing the trend for decreased pressures on the right heel. The weight of the left foot as a stabilizing force to keep the body in the tilted position may account for the trend of increased pressures on the left heel.

Other clinical research studies using the Foot Waffle were not available; therefore, comparisons for this study were directed toward similar commercial heel elevation products. Some researchers have found high interface pressures on the heels of patients using a variety of commercial heel elevation products.[5,7-10] Thompson-Bishop and colleagues[10] reported increased interface pressures on heels when patients were in a semi-Fowler's position. Whittemore and colleagues[20] did not cite differences in heel interface pressures between patients in supine or semi-Fowler's positions. Patel and colleagues[21] found increased heel interface pressures in patients in a semi-Fowler's position and high interface pressures during lateral tilt positioning. This study's results showed a decreased success rate for maintaining heel elevation with the patient in a right lateral tilt position. Comparisons of left and right heel interface pressures generally are not found in the literature. These research findings are in agreement with Smith's[9] findings of heel interface pressure of 0 mm Hg versus De Keyser and colleagues'[10] findings of 42 mm Hg while using a pillow for heel elevation.

Heel elevation difficulties were encountered with the pillow and with the Foot Waffle. Continuous heel suspension was not maintained over 24 hours. This study did not control for a patient's degree of restlessness or nursing care activities that may have altered the leg position. Spontaneous leg movement also displaced the feet from the pillow or positioned the Foot Waffle improperly, causing the heel to rest against the bed. After completing patient care activities, nurses and assistive personnel did not consistently reposition the legs with the heel elevation device. As a result, daily spot checks revealed that both heels were effectively elevated off the bed 5.6% to 40% of the time; one heel was effectively elevated off the bed 7.7% to 50% of the time; and neither heel was elevated 40% to 75% of the time.

The Foot Waffle is available in three sizes (small, medium, and large) based on calf diameter; for each size, the length of the boot is in proportion to the size of the calf. This posed a problem for patients with small calf diameters who had long legs. Because the small size would not rest high enough on the leg to properly suspend the heel, the medium-size Foot Waffle was used. As the patient was turned, his or her foot slipped inside the Foot Waffle, causing the heel to lose suspension. As the leg rested in the Foot Waffle, the foot support enveloped the entire metatarsal and phalange area. This created an area of pressure in some patients. Since completion of this study, the Foot Waffle has undergone design changes to improve the product.

The combination of the SCD and the Foot Waffle caused excessive heat and moisture retention on some patients' legs. One patient was dropped from the study after blisters formed on the shins—possibly caused by the SCD, the Foot Waffle, or both. As the patient was turned, the SCD sleeve had to be rotated to prevent the tubing from lying directly under the malleoli or heel. The knee-high SCD sleeve allowed for quick and easy tubing adjustments; the thigh-high sleeve could not be adjusted as easily because when it was rotated, the precut knee hole also rotated, covering the knee and putting it at risk for pressure development. Although looping the SCD tubing on top of the pillow or Foot Waffle adequately displaced the tubing away from bony prominences, it required more nursing vigilance to keep the tubing looped as the patient moved in bed.

Conclusion

The findings of this study support the use of the pillow versus the Foot Waffle to protect the heel, al-

though using pillows is not without problems. Patients who moved spontaneously had to have their pillows repositioned to keep the heel off the bed; patient restlessness made heel elevation difficult if not impossible to maintain. The pillows also must be positioned so that the heels are actually suspended (not just resting on the pillow) and the nurse must decide how many pillows are needed to achieve heel elevation. Using multiple pillows may decrease arterial circulation to the extremities in patients who have peripheral vascular disease, and pillows do not protect against foot drop.

Using the Foot Waffle for heel elevation is subject to the same considerations as using pillows. A restless patient may shift the foot's position in the Foot Waffle. The Foot Waffle must be properly sized, and appropriate skin care continued. The results of this study did not support the use of the previously designed Foot Waffle for continuous heel elevation. Research may be indicated for the newly designed product.

Understanding the nature of pressure ulcer formation, the meaning of pressure reduction, and the use of a heel elevation product is a necessity for nursing personnel. Research error may have occurred in this study during the assessment of erythema and with the measurement of interface pressures. The researcher (AT) also knew the product in use when assessments were done. Continued research in heel protection is needed.

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