Clinical and Economic Evaluation of Zero Pressure Mattress System for Pressure Ulcer Prevention in the Intensive Care Unit

By Rodney Snow, MD and Greg Bearden, MD

Background Prevention of pressure ulcers is a challenge in critically ill patients because of the
use of mechanical ventilation and vasopressors, multiple comorbid conditions, immobility and
hemodynamic instability.
Objective Conduct a clinical and economic evaluation of the Zero Pressure Mattress (ZPM) for pressure ulcer prevention in the ICU compared to current practice at an acute care community hospital. A secondary aim was to conduct a clinical and economic evaluation of the ZPM's optional disposable component for fecal incontinence management in the ICU.
Methods This randomized controlled trial (RCT) used a sample of patients admitted to the surgical and medical ICU's in a 301 bed community hospital. Patients were randomized to either the control group (n= 335) or the study group (n= 238). The control group received usual pressure ulcer preventive care as follows: low air loss or alternating pressure mattresses, mattress overlays, sacrum foam dressing and heel foam dressing. The study group also received usual pressure ulcer preventive care, except the low air loss or alternating pressure mattresses and mattress overlays were replaced with the ZPM.
Results The incidence of hospital acquired pressure ulcers (HAPU's) was 0% for both the study group (ZPM) and the control group.
Conclusion Use of the ZPM yielded a clinically and economic significant benefit in the prevention of HAPU's in the ICU. Additionally, the ZPM's optional disposable component for incontinence management demonstrated merit as a cost-effective alternative to traditional incontinence management products. Finally, the study's hypothesis was confirmed - the ZPM would virtually eliminate HAPU's in the ICU.

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Introduction

According to published data provided by the 2009 and 2015 International Pressure Ulcer Prevalence Surveys, it is estimated the mean incidence of HAPU for U.S. Surgical/Medical ICU's is about 5.5% - 6.0% for year 2017.[1,2] The Agency for Healthcare Research and Quality reported the overall prevalence of PU's of about 0.8% in the general population in 2011 with the estimated cost for treating at about $11.6 billion. In a more recent study, the overall pressure ulcer cost may be as high as $21 billion.[3] Therefore, preventing PU's development can lead to significant healthcare savings.

According to the National Pressure Ulcer Advisory Panel (NPUAP), a pressure ulcer is defined as follows: a pressure ulcer is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear. Thus, in accordance to this definition, if there is no pressure (capillaries remain open), there is no pressure ulcer, regardless of the existence of any of the various significant risk factors.

The objective of current advanced support surface is to reduce pressure over the bony prominences by redistributing a portion of the force/pressure to areas of the human anatomy less vulnerable to the occurrence of pressure ulcers. Today, despite widespread use of many different advanced support surfaces there still occur an estimated mean incidence of HAPU for U.S. Surgical/Medical ICU's of about 5.5%-6.0% for year 2017.[1,2]

To date, there have been extensive literature on various methods and devices on preventing PU's, but today routine repositioning of patients ever 2-4 hours depending on their clinical condition remains a major part of clinical care especially in ICU's. However, a recent study evaluated pressure injury prevention practices in the ICU using a wearable electronic sensor that could evaluate and recorded each patient position ever 10 seconds and give real time feedback to the nurses.[4] There were 555 patients monitored with a control group where nurses received no feedback and the study group, where nurses did receive real time feedback.[4] The study found the overall compliance with turning was 54%.[4] The parameters including turn frequency, turn magnitude, depressurization time and position distribution were all suboptimal along with a bias against men and higher BMI's.[4] Therefore, continued improvement in PU prevention is needed today.

The effectiveness of traditional advanced support surfaces with respect to the prevention of HAPU's is limited because these support surfaces only "reduce" pressure over the bony prominences. Obviously, with respect to the prevention of pressure ulcers it is preferable to eliminate pressure over the bony prominences compared to the "reduction"

of pressure. The Zero Pressure Mattress® (Capstone Medical Products Group, Inc.) is the only support surface in the market that eliminates pressure over the bony prominences in the buttocks area based on various product pressure mapping data. Independent pressure mapping (with an industry standard XSensor™ pressure mapping system) shows that the pressure within the cavity where the sacrum, coccyx and ischia are located to be zero (Fig. 1). Therefore, when the buttocks area is within the cavity and with zero pressure there is no requirement to turn patients to prevent PU's.

In addition, independent pressure mapping with XSensor™ shows that interface pressures provided by the ZPM® in the buttock area outside the sacrum, coccyx and ischia are comparable to other advanced support surfaces. The pressures at the edges of the cavity are less than 18 mmHg (Fig. 1). This is due to pressure reduction resulting from increased mattress immersion and envelopment induced by the increased forces experienced in this area due to the ZPM®'s cavity. Furthermore, by eliminating pressure, the Zero Pressure Mattress® (ZPM®) also eliminates shear and friction over the bony prominences in the buttocks area. This is accomplished by suspending the sacrum, coccyx and ischium over air due to the existence of a 28 cm long x 15.5 cm wide x 20.5 cm deep mattress cavity. Additionally, the ZPM® off loads most heels because as a patient's buttocks lower into the mattress cavity the heels elevate slightly off the mattress surface (Fig. 1). To date, there has not been a comparative study to compare all the various support surfaces on the market to one another by pressure mapping.

Prior to this study, nine (9) Direct Comparison Case Studies were conducted involving the ZPM® .[5] These Case Studies involved initially placing the patient onto an advanced surface mattress. Thereafter, the patient was immediately placed onto the ZPM® . Each of the 9 patients had either stage 3 or stage 4 pressure ulcers located in the buttock/sacral area. The results for all 9 patients showed increased healing rates with decrease in area and volume comparing the ZPM® to the other advanced surface mattresses.[5] These results with the ZPM® occurred despite none of the 9 patients were being turned when on the ZPM® during these case studies.[5] By comparison, all the patients on the other advance surface mattresses were turned every 2-4 hours according to their clinical condition.[5] Therefore, with those improvements in healing and results of pressure mapping evaluation, along with years of experience in treating PU's, we felt that the current study would be of value.

The ICU seemed to be somewhat of a more controlled location in an Acute Care Community Care Hospital (ACCH) to do the study. Previous studies have shown significant risk factors and predictors for HAPU's for ICU patients include mechanical ventilation (with head elevation required increase pressure and shear over sacrum), norepinephrine administration (number of hours of infusion), length of ICU stay, cardiovascular disease, and a score of 2 or less on Braden subscale for mobility.[6,7,8]

HAPU's significantly increase healthcare costs. The increased acute care costs are primarily due to prolonged hospitalizations. Studies have shown that the development of a pressure ulcer independently increases the length of a patient's hospital stay by 4-10 days.[9] The cost of treating a pressure ulcer depends on its severity, with estimates generally ranging from $2000-$20,000 per ulcer.[9]

HAPU's have important legal implications; lawsuits filed over pressure ulcers are more common and with more than 17,000 pressure ulcer related lawsuits are filed annually (Agency for Healthcare Research and Quality) with the average settlement (87% settled favoring plaintiffs) of $250,000 being awarded.[9]
A small reduction in pressure ulcer incidence can have a dramatic cost savings effect. For example, consider an ACCH 300-bed hospital with about 15,000 admissions per year, a HAPU rate of 3.5%, and an estimated incremental average treatment acute care costs of about $10,700 per ulcer. If the hospital were able to decrease their incidence of HAPU's by only one percentage point (3.5% to 2.5%), they could save about $1,605,000 annually. Beyond the financial implications, PU's are a source of significant morbidity and mortality for patients each year, with about 60,000 patients dying as a direct result of their PU.[9]

Two studies involving a total of 653 ICU patients determined that 91% of HAPU's were located in the sacral or buttocks region (57% sacrum and 34% buttocks) with most of the remaining HAPU's located at the heels.[6,7] In accordance to the definition, it has been assessed the main etiology for a skin injury located in the buttocks area outside the sacrum, not over the ischium or coccyx, or not due to a device (i.e. tubing), is likely not typical pressure.[10] Furthermore, given an adult sacrum is about 11.4 cm. long x 10.2 cm. wide, it appears likely some of the PU's reported as occurring on the buttocks area are actually sacral PU's.

Based on the above information, the current study seemed justified.

Study Purpose

The aim of this prospective, unblinded randomized controlled trial (RCT) was to conduct a clinical and economic evaluation of a new mattress, ZPM®, for PU prevention in the ACCH ICU.

Methods and Procedures

The study was approved by the Human Research Review Board and Facility Research Committee of the [blinded] and was carried out within the ethical standards set forth in the Helsinki Declaration of 1975. The study was granted exemption from the need to obtain consent from participants from the Human Research Review Board.

This prospective unblinded RCT used a convenience sample of all patients admitted to the surgical and medical ICU's in a 301-bed ACCH from July 17, 2017 to October 9, 2017 (13 weeks). Patients less than 19 years old and weighing greater than 375 lbs. (6 individuals) were excluded from the study.

Patients were randomized to either the control group (n= 335) or the study group (n= 238) by the shift ICU charge nurse. The control group received usual PU preventive care with routine repositioning of patients ever 2-4 hours depending their clinical condition. This care for the control group included the use of the following: low air loss (Hill-Rom Services, Inc.) or alternating pressure mattresses (Hill-Rom Services, Inc.). In addition, a waffle mattress overlay (EHOB, Inc.) was used in an estimated 75% of the control group patients, but the exact number was not available. Also, as part of usual PU preventative care, all in the controlled group received Mepilex Border Sacrum® foam dressing (Molnlycke Health Care) and Mepilex Heel® foam dressing (Molnlycke Health Care).

The study patients also received usual PU preventive care except routine repositioning of patients ever 2-4 hours was not consistently applied for the study patients (precise numbers not turned is not known). For the Study patients, the low air loss or alternating pressure mattresses or mattress overlays (waffle mattress) were replaced with the ZPM®. There is evidence, the Mepilex Border Sacrum® foam dressing and Mepilex Heel® foam dressing were not consistently used with the ZPM® (study group) but the exact number of incidences were not available. Furthermore, since the sacrum is suspended over air with the ZPM®, it is likely no additional benefit was provided by the Mepilex Border Sacrum® dressing in the ZPM®

Both the 12 bed Surgical ICU and the 12 bed Medical ICU's at the study hospital are generally 100% occupied. Therefore, randomization was controlled by the next available bed with its included mattress. Mattresses were not moved from one bed to the another. If the next available bed was the ZPM® (study group) the patient was placed onto the ZPM®. Likewise, if the next available bed was a control group mattress, the patient was placed onto a control group mattress.

Patients with preexisting PU's were included in the randomization but no attempt was made to evaluate healing, improvement or deterioration in either the control or study group.

Six ZPM®'s were in the 12 bed Surgical ICU, along with 6 ZPM®'s in each of the 12 bed Medical ICU (12 ZPM®'s total). Six control group mattresses were also used in both the Surgical and Medical ICU's (12 control group mattresses total).

All patients in the study received skin assessments in accordance to the hospital's normal protocol with the ICU nurses conducting skin assessments each 12-hour shift per day. If a skin injury was observed by the ICU nurse, the WOCN staff would be notified, resulting in the WOCN staff evaluating the skin injury to determine if it was a HAPU. Photographs were also taken of the skin injuries, which were evaluated by the study's investigators to further confirm the occurrence of a HAPU. PU's on admission were recorded but no evaluation was done as part of this study.

The study period was from July 17, 2017 to October 9, 2017 (13 weeks). Patients remained in the study while in the ICU, and when they transferred out of the unit, no further skin assessments were completed as part of this study. There were 335 control group patients and 238 study group patients. The 97-patient difference was primarily the result of a greater length of stay (LOS) in the study group compared to the control group (4.3 days vs. 3.5 days).

The primary outcome measured in this clinical trial was the occurrence of a HAPU. Any HAPU occurring during the period of this RCT was staged according to the NPUAP staging system.

Data Collection

All data collected during this study, including all data shown in Table 1, were routinely collected by hospital staff on data collection sheets and were tracked throughout the patient's ICU stay. In addition, the electronic medical record (Epic®) was used in data collection. Patient Braden score was an average over the LOS in the ICU. Parameters analyzed are shown in Table 1.

Results

Table 1 provides the study results. The baseline characteristics of the 573 patients enrolled in this study illustrate the two groups were generally similar statistically. There were 6 patients excluded because their weight being greater than 375 lbs. from the study group. Patients with

preexisting PU's on admission to ICU were not excluded. However, during the study the patients with preexisting PU's were not evaluated in either group for this study. There were 20 preexisting PU patients in the control group and 15 patients in the study group. However, despite 97 more patients in the control group there were more patients in the study group (ZPM®) with mechanical ventilation > 72 hours compared to the control group (34 vs 26). Furthermore, among the group of patients with >72 hours of mechanical ventilation, there were 263 patient/days of mechanical ventilation in the study group vs. 180 patient/days in the control group (not statistically significant).

Additionally, there were 1625 hours of norepinephrine administration in the study group vs. 847 hours in the control group (not statistically significant). Studies have shown mechanical ventilation >72 hours and norepinephrine administration are significantly predictive of HAPU's in ICU's.[4,5]

The characteristics of the 573 patients enrolled in this study were similar to typical ICU patients especially with respect to the following key characteristics: mechanical ventilation and mean ICU LOS.[11]

The incidence of HAPU's was 0% (0/238) for the study group (ZPM®) and 0% (0/335) for the control group.

As stated previously, one study showed 38% (35/91) of ICU patients, all of which were on low air loss mattresses, that received mechanical ventilation for greater than 72 hours developed HAPU's.[5] In our study none of the patients (0/34 for the study group and 0/26 for the control group) that received mechanical ventilation for greater than 72 hours developed HAPU's.

This study also demonstrated that the ZPM®'s cavity significantly stabilized patients, thus consistently keeping them properly positioned within the mattress cavity. In addition, the ZPM® functioned well throughout the study with minimal complaints from staff or patients (personal communications).

Discussion

As discussed in detail on page 2, the ZPM® eliminates pressure, shear and friction in the critical buttock/sacrum region. In addition, most heels are elevated as well. Thus, there is a logical basis supporting this study's 0% HAPU incidence for the ZPM® (study group). HAPU prevention care in the control group included the use of the following: low air loss or alternating pressure mattresses, mattress overlays (waffle mattress), Mepilex Border Sacrum® foam dressing and Mepilex Heel® foam dressing. This combination of products

with other routine ICU nursing care produced a 0% HAPU incidence, which is far below the national ICU average HAPU incidence (5.5%-6.0%) reported on page 2. Therefore, this study's results would indicate the study hospital is among the elite hospitals in the U.S. with respect to an important quality of care measure – pressure ulcer prevention.

However, unlike the ZPM® 's performance, based on the following discussion it is difficult to explain the anomalously low FAPU incidence (0%) for the control group in this study.

- Quoting the referenced Cochrane Review, "For dressings, their relatively small size means that their potential for pressure redistribution is minimal. Dressings will only play a small part in the prevention of pressure ulcers, as the key causative factor is pressure and shear, thus relief of pressure and shear is fundamental to preventing pressure ulcers.

  When data was combined from the four studies (Han 2011; Kalowes 2012; Nakagmi 2007; Qiuli 2010), they showed that dressings applied over bony prominences reduced the PU incidence, however, due to the high or uncertain risk of bias, firm conclusions cannot be drawn from this analysis. It is unlikely that the reduction in incidence relates to the pressure/shear reduction ability of the dressings, rather may relate to the ability to reduce friction forces."[12] One would not expect a foam dressing to eliminate PU's. There are additional studies going on to better evaluate the role of these various foam dressings in preventing PU's.
- A RCT sponsored by the manufacturer of the Waffle Mattress, showed no statistical difference in the occurrence of HAPU's comparing the Waffle Mattress to a low air loss mattress.[13]
- Despite widespread use of foam dressings and advanced surface mattresses in U.S. ICU's, the estimated the mean incidence of HAPU for U.S. Surgical/Medical ICU's is about 5.5%-6.0% for year 2017.[1,2]

Nonetheless, despite the preceding discussion, a RCT (referenced as Kalowes 2012 above) involving 366 participants showed the use of a soft silicone foam dressing yielded a statistically and clinically significant benefit in reducing HAPU's in intensive care patients.[14] The foam dressing used in this unblinded RCT was identical to the foam dressing used by the control group in this study.

Economics

Aside from the important matter of pressure ulcer prevention, there is another related important matter- the cost of pressure ulcer prevention. The estimated cost for the single patient use Waffle Mattress used by the control group in this study is **$112,000 annually**. This is based on data from the study hospital showing 2500 annual patient admissions for the Surgical and Medical ICU's, along with about 75% of these patients placed onto the Waffle Mattress. The reported cost for the Waffle Mattress is $65/mattress.

The use of the ZPM provides an extremely significant economic benefit compared to using the Waffle Mattress as shown below.

There are 24 beds in the surgical and medical ICU's. The ZPM sells for $575/mattress and is provided with a 5 year warranty. Therefore, total purchase price for 24 ZPM's = $13,800

Return on Investment (ROI) for ZPM = $13,800/$112,000 x 12 months per year = **1.47 months.**

Regarding the preceding economics, it should be noted costs associated with low air loss mattresses and alternating pressure mattresses, also used by the control group in this study, were not included. Inclusion of these costs would further enhance the economics in favor of the ZPM.

Limitations

The control group's anomalously low 0% HAPU incidence made it impossible for our findings to show statistically significant results for the ZPM® with respect to the study's aim. A future study evaluating the performance of the ZPM® with respect to PU prevention at a site represented by typical ICU HAPU incidence is warranted. Additionally, a future RCT is planned at the study site to extend and expand the current data and evaluate possible reasons for the unexpected results in the control group.

Conclusions

Our findings have demonstrated a potential clinical and economic significant benefit for the

ZPM® in the prevention of HAPU's in the ICU. The ZPM® functioned well throughout the study with minimal complaints from staff or patients.

Finally, our findings in this study show that the ZPM® could virtually eliminate HAPU's in the ICU.

More data needs to be collected in ICU's as well as other areas of patient care in hospitals along with other healthcare institutions because of how important prevention of PU's would be for our healthcare system and patients.

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Table 1

Characteristics of Patients in Study

Characteristic Group	Overall	ZPM	Control
	N = 573	N = 238	N= 335
No. and % of patients with HAPU	0(0%)	0(0%)	0(0%)
LOS, mean days	3.9	4.3	3.5
Age, mean, years	63.6	63.4	63.7
Braden score, mean	17.9	18.2	17.6
Significant Risk Factors:			
Mechanical Ventilation No. and % of patients	101(17.6%)	49(20.6%)	52(15.5%)
Mechanical Ventilation > 72 hrs. No. (%) of patients	60(10.5%)	34(14.3%)	26(7.8%)
Total Patient/Days of Mechanical Ventilation for patients with > 72 hours of mechanical ventilation	443	263	180
Norepinephrine			
Total hours of infusion	2472	1625	847
Braden mobility, No. And % of patients with Score 2, or less	104(18.4%)	49(20.7%)	55(16.7%)
Cardiovascular disease, No. and % of patients	210(36.7%)	88(37.0%)	122(36.5%)

Abbreviations: Hospital acquired pressure ulcer (HAPU); Length of stay (LOS)