



# Prophylactic Dressing Application to Reduce Pressure Ulcer Formation in Cardiac Surgery Patients

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**PURPOSE:** The study was designed to determine if application of a self-adherent silicone border foam dressing would reduce pressure ulcer incidence when compared to standard preventive interventions among patients managed in a cardiac surgery intensive care unit (CSICU).

SUBJECTS AND SETTING: One hundred consecutive patients in the CSICU at Virginia Commonwealth University Medical Center in Richmond participated in the study. Fifteen were subsequently excluded due to incomplete data or failure to remain in the CSICU for at least 48 hours. Of the 100 subjects consecutively enrolled, 56 subjects were assigned to the intervention group with attrition of 6 subjects (6/56), and 39 were assigned to the standard care comparison group with attrition of 4 subjects (4/39). Five study forms were lost and the group assignment of those subjects is unknown.

**METHODS:** Patients admitted to the CSICU were assigned to either standard treatment or an intervention group consisting of standard preventive care plus application of the silicone border foam dressing. The assignment of subjects to these groups was done in a nonrandom manner, via prestudy room designation (7 intervention rooms/7 standard practice rooms) and room availability on call from the operating room. The charge nurse and bed management staff were unaware of room designation, and staff did not know which group the subjects were assigned to until they admitted the patient and opened the bedside chart that indicated group assignment. Twenty-one covariates were compared between the 2 groups. A Cox proportional hazards model was computed to compare the hazard (risk per unit time) of developing a pressure ulcer between these groups. Propensity score covariate adjustment was performed to adjust for any imbalance between the groups.

**RESULTS:** Nine pressure ulcers developed during the course of the study. Eight pressure ulcers developed in 4 out of 35 patients who received standard preventive care; 5 were classified as suspected deep tissue injuries and 3 were classified as stage II pressure ulcers. One pressure ulcer developed in 1 out of 50 patients in the intervention group; it was classified as suspected deep tissue injury. No statistically significant difference in any covariate was found between the groups (all P > .058). The

group that received standard care had a hazard ratio of 3.6 in relation to the intervention group, but this difference was not statistically significant (P = .3).

**CONCLUSION:** Pressure ulcer incidence was lower than anticipated over the study period for both groups. No statistically significant difference in pressure ulcer incidence between the intervention and control groups was found. A randomized controlled trial based on a power analysis is needed to more precisely determine the efficacy of a silicone border foam dressing for prevention of pressure ulcers in the intensive care unit.

# Introduction

Pressure ulcers (PU) occur as a result of unrelieved pressure to any part of the body; they are most commonly found over bony prominences such as the sacrum, elbows, knees, occiput, ischium, coccyx, and ankles.<sup>1</sup> While prolonged pressure is considered an etiologic factor, other factors also contribute to risk. For example, shear deformation, moisture, temperature, age, incontinence, underlying comorbidities, prolonged surgical procedures, immobility, spinal cord injury, low body weight, and medications are hypothesized to act as possible contributing factors.<sup>2,3</sup> Hospital-acquired PU may be prevented or their progression may be arrested if they are identified in the early stages. If not, they can have a significant effect on the patient's quality of life and may under certain circumstances prove fatal.<sup>4</sup>

Because of their comparatively high-risk profiles, intensive care unit (ICU) patients require aggressive and

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The authors declare no conflict of interest.

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targeted prevention strategies.<sup>5-9</sup> Further, cardiac surgery patients are considered one of the most at-risk patient populations, with incidence rates reported as high as 29.5%.10 The high level of risk associated with critically ill cardiac surgery patients is attributed both to the underlying comorbid conditions of these patients and to factors associated with their surgical procedure. The risk of intraoperative PU formation has been reported as varying from 12% to 66%.<sup>11,12</sup> Common locations for intraoperative PU include the heels and sacrum, but the location of highest risk varies by individual, depending on surgical position.<sup>13</sup> The surgical suite poses multiple challenges to skin integrity including hypothermia, anesthetic agents, hemodynamic changes, position, time, shear, and moisture.14-18 For cardiac surgery patients, these risk factors are intensified by the use of extracorporeal circulation for the process of cooling and rewarming, use of underlying water-filled warming pads to help regulate temperature, and delayed return to normothermia during the immediate postoperative period.<sup>19,20</sup> Unfortunately, despite the existence of multiple validated PU risk assessment tools, none has been validated for assessment of intraoperative risk.<sup>21</sup> As a result, all patients entering the cardiothoracic surgical suite are considered at risk for pressure ulceration.<sup>22</sup>

While many PU risk factors are modifiable, others exist that are beyond the control of the ICU nurse or physician. Recently, experts have reached consensus that not all PU are avoidable.<sup>23,24</sup> Whether they can be modified or not, compressive stress through pressure loading forces exerted on the patient's skin, deformation strain from shear forces, and moisture are the most common and potentially deleterious factors found in the ICU population. Friction and moisture are known to cause damage to the superficial skin layers, but they do not result in PU formation in the absence of pressure or shearing forces.<sup>25</sup> Nevertheless, friction may develop between skin folds, between the patient and the support surface, or as an adjunct to shear injury, resulting in further skin damage.

Application of a prophylactic dressing has been suggested for the ICU population.<sup>26</sup> Several in vitro studies have shown the potential for reducing PU risk, and a small number of quality improvements have also been published suggesting a possible benefit in humans.<sup>27-36</sup> Further, unpublished laboratory testing of a sacral dressing found a reduction in shear, friction, and pressure forces, while managing microclimate in an independent evaluation.37 These findings suggest that friction (the force that imparts shear) is displaced to the outer layer of the dressing. The dressing may also reduce shear forces caused by tissue distortion due to compressive loading, which is referred to as incidental shear (E. Call, written personal communication, July 11, 2011). A sacral dressing also has the potential to absorb moisture within the gluteal cleft created by perspiration and insensible fluid loss, reduce friction within the gluteal cleft by separating skin folds, and alleviate local shear forces by creating an interface between the patient's skin and bed surface. This interface may diminish the shear created by repositioning or elevation of the head of bed by angles greater than 30°. The dressing also may reduce shear forces during transfers, or those created when the patient remains recumbent on an operating table with a 2-inch foam mattress.

Prevention is particularly important in our ICU population and patients undergoing surgical procedures, because they account for 55% to 85% of all hospital-acquired PU occurring within the Virginia Commonwealth University Health System based on 4 years of past prevalence and incidence data.<sup>38</sup> The cost of treating a PU varies from \$37,000 to \$70,000.<sup>2,39</sup> The University Healthcare Consortium states that a PU may add 11 days to the hospital length of stay and approximately \$30,000 in additional costs.<sup>40</sup> The Centers for Medicare & Medicaid Services denies payment of the higher diagnostic category when a PU occurs as a secondary diagnosis in acute care.<sup>41</sup>

We hypothesized that the application of a silicone border foam dressing applied to the sacral area would reduce the incidence of PU formation in the ICU. The aim of the current study was to determine whether routine application of such a dressing to the sacrum, in comparison with standard care, would decrease the hazard (risk per unit time) of developing a PU among high-risk patients such as those cared for in our cardiothoracic ICU. Since the groups studied might possess inherent differences, a secondary aim was (*a*) to tabulate clinically relevant covariates and (*b*) to account for differences in these covariates in the assessment of any difference in hazard between the groups.

## Methods

Institutional review board (IRB) approval was achieved via expedited review from the Virginia Commonwealth University IRB. All patients admitted to the cardiac surgery intensive care unit (CSICU) between July 7, 2010, and September 20, 2010, were screened according to the inclusion and exclusion criteria enumerated in Figure 1. The 14 beds dedicated to cardiac surgery ICU were assigned by location alternately to standard care (7 beds) and standard care plus silicone foam dressing (7 beds, the intervention group). Patients were not randomly allocated to groups; rather, group assignment was based on room number and determined prior to subject enrollment. The charge nurse and bed management nurse assigned patients to beds according to occupancy and availability as report was called from the operating room. Neither the charge nurse nor the bed management nurse was aware of the predetermined room assignments. Clinical diagnosis and surgical procedure were not considered when determining study group assignment. Additionally, no clinical personnel on the ward were aware of the study group assignment until after a patient had been placed in a bed and the chart had been opened.

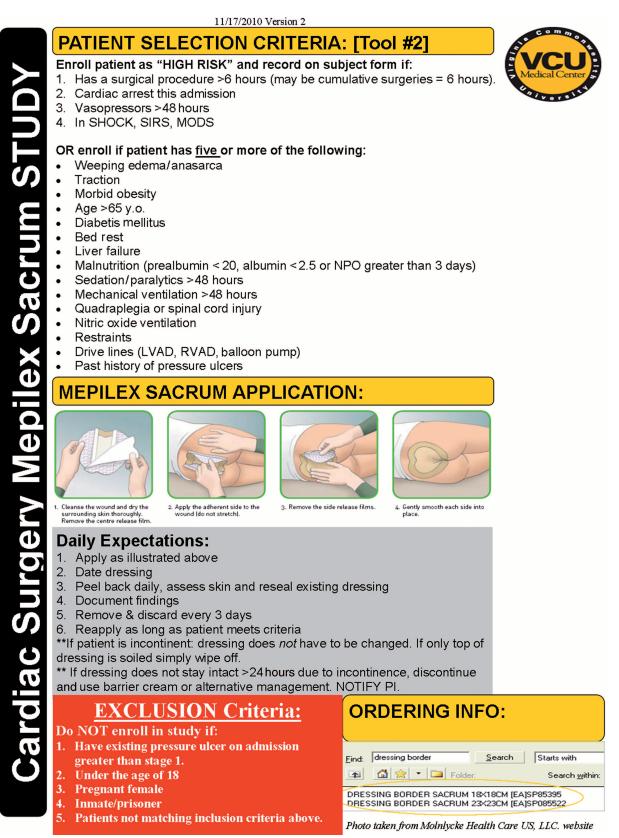


FIGURE 1. Inclusion/exclusion criteria. Photos used with permission from Molnlycke Health Care, LLC.

Cardiothoracic ICU Mepilex Sacrum Study [Tool #3] 11/17/2010					
Subject 1	Number;		Room Number:		
Date of A	Admission to Cardiac Su	irgery ICU;	Date of Discharge:		
Inclusion	a Criteria: (Circle all tha	at apply)			
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FIGURE 2. Intensive care unit tracking tool.

Upon arrival, patients were assessed by the staff nurse to determine if they met criteria for study inclusion. Those who satisfied inclusion criteria were assigned to the group identified in the bedside chart (Figure 2). Group assignment remained constant even when a patient was subsequently moved to another room. Staff members from all shifts were provided education by the principal investigator (T.B.) for 3 weeks prior to study initiation regarding inclusion/exclusion criteria, study design, dressing application, standard interventions for prevention, and data collection procedures. The principal investigator also created an educational PowerPoint bulletin board, highlighting the essential requirements of participation, and was available by pager for questions 24 hours a day, 7 days a week for the duration of the study.

#### Intervention and Standard Preventive Care

Standard preventive care included placement on a low air loss bed (SPORT Low Air Loss or Total Care Bariatric Low Air Loss + Pulmonary bed, Hill-Rom, Bakersville, Indiana). Additional components of standard preventive care are summarized in Figure 3. Turning and repositioning were documented on all patients. Due to previous success with implementation of a prophylactic dressing in other areas of the facility, all patients underwent preoperative placement of the silicone border foam dressing, which remained in place during their surgical procedures. Thus, all patients with the silicone border foam dressing applied were admitted to our cardiothoracic ICU.

The intervention dressing (Mepilex Border Sacrum, Molnlycke Healthcare, Norcross, Georgia) was applied to subjects in the intervention group in accordance with manufacturer recommendations for application. The dressing was applied in a 3-panel fashion with the dressing first applied to central aspect of the sacrum to the proximal pole of the gluteal cleft, and then the 2 lateral sides pulled over the sacrum and buttocks bilaterally. Application of the dressing was primarily focused on covering the sacrum. But the coccyx and proximal gluteal cleft were also covered when possible. According to body habitus, 2 different sizes of the intervention dressing  $(18 \times 18 \text{ cm and } 23 \times 23 \text{ cm})$  were made available.

Patients receiving standard treatment underwent removal of the silicone border foam dressing and staff applied a zinc-based skin protectant (Calmoseptine, Huntington Beach, California) twice daily and as needed

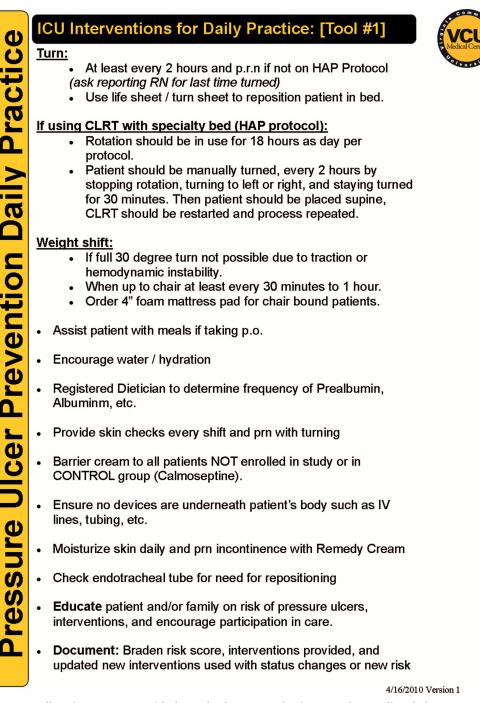


FIGURE 3. All patients were provided standard preventative interventions as listed above. Turning protocol includes (but is not listed) heel floating with pillows or heel offloading device (H.O.L.D) per registered nurse assessment. PRN indicates nothing by mouth; RN, registered nurse.

for incontinence, in addition to the daily skin interventions and low air loss surface described earlier. For patients assigned to the intervention group, the silicone border foam dressing was peeled back, the underlying skin was assessed, and the dressing was reapplied. The silicone border foam dressing was changed every 3 days throughout the duration of their ICU stay. If during daily assessments the patient's intervention dressing was found to be displaced, a new dressing was applied by the assessing RN. Both comparison and intervention groups underwent daily skin assessments, and RN staff recorded the findings on data collection forms. Any suspected skin breakdown occurring around the sacrum, coccyx, or gluteal fold was immediately reported to the principal investigator (T.B.), a CWOCN, or, in the event of the principal investigator's absence, to the WOC Nursing team. Additionally, a member of the unit's Champions of Skin Integrity team, trained by the WOC nurse, was available for assistance with the study. Patients were followed until their discharge from the ICU and a final skin evaluation was performed on the day of discharge. Patients were removed from the study if they expired or were discharged before being cared for in the ICU for 48 hours. Any patients who developed a PU during the study period were provided an individualized treatment plan by the WOC nurse.

## Data Analysis

The incidence of PU, hours in the ICU, and 21 covariates were summarized within the intervention and standard care groups by percent for nominal variables and by mean  $(\pm SD)$ for continuous variables. For each covariate, a P value was computed to assess evidence of a difference between the intervention and standard care groups, by the Fisher exact test for nominal covariates and Mann-Whitney U test for

continuous covariates. A Kaplan-Meier estimate of time until incident (occurrence of a hospital-acquired PU) was computed for each group. This curve estimates the proportion of individuals, among those who have not been discharged, who would remain PU-free.<sup>42</sup>

A Cox proportional hazards regression model was calculated to compare the standard care and intervention groups in terms of their hazard of developing a PU.<sup>43</sup> From this model, a hazard ratio was obtained with associated confidence interval and significance level. To adjust for the effect that any imbalance in the covariates between the 2 groups might have exercised on the hazard ratio, an adjusted Cox proportional hazards model was also completed. Adjustment was performed as follows. First, a multiple logistic regression model was computed in which the binary outcome was assignment to intervention versus standard care. All 21 covariates were included in this model, as all were potentially associated with differences in hazard. Second, this regression model produced a

#### TABLE 1.

Variable	Standard Care (n = 35)	Intervention (n = 50)	Р
Developed pressure ulcer, yes	4 (11%)	1 (2%)	.154
Time at risk (hours in the ICU)	167 (121)	149 (92.9)	.62
Age, y	62.7 (12.7)	61.2 (13.6)	.639
Gender, male	25 (71%)	31 (62%)	.486
Body mass index	27.4 (8.93)	29.3 (6.3)	.0589
Braden Scale risk score	11.3 (2.28)	11.1 (2.03)	.762
Number of surgeries during this hospitalization	1.17 (0.568)	1.14 (0.405)	.538
Hours in OR	7.68 (3.81)	7.82 (2.02)	.986
Malnutrition: prealbumin $<$ 20, albumin $<$ 3.5, NPO greater 3 days	2 (6%)	1 (2%)	.566
Fecal or urinary incontinence	1 (3%)	1 (2%)	1
Restraint use	11 (31%)	15 (30%)	1
Diabetes mellitus	13 (37%)	16 (32%)	.649
Traction device	0 (0%)	2 (4%)	.51
Bed rest	23 (66%)	37 (74%)	.472
Drive lines (LVAD, RVAD, Hearmate 2, IABP, TAH-Syncardia/Jarvic)	8 (23%)	15 (30%)	.621
Generalized edema/anasarca	11 (31%)	10 (20%)	.308
Nitric Oxide Ventilation	6 (17%)	14 (28%)	.304
Continuous sedation/paralyzing medications $>$ 48 h	8 (23%)	15 (30%)	.621
Mechanical ventilation greater than 48 h	11 (31%)	21 (42%)	.369
Use of vasopressive medications > 48 h (norepinephrine bitartrate [Levophed], dopamine, vasopressin, etc)	19 (54%)	30 (60%)	.659
Cardiac arrest (this admission)	1 (3%)	3 (6%)	.64
Shock (septic, hypovolemic, cardiogenic)	4 (11%)	3 (6%)	.439

Abbreviations: IABP, intra-aortic balloon pump; ICU, intensive care unit; LVAD, left ventricular access device; NPO, nothing by mouth; OR, operating room; RVAD, right ventricular access device; TAH, total artificial heart (Syncardia Systems Inc., Tuscon, AZ).

<sup>a</sup>Quantitative variables are summarized by mean (standard deviation) and qualitative variables by frequency (percent).

number for each patient, representing the the log odds of the probability that the patient would be assigned to the experimental group, based only on each patient's values for the 21 covariates.<sup>44,45</sup> Third, this propensity score was entered as a covariate into the Cox proportional hazards model.<sup>46</sup>

## Results

One hundred subjects were enrolled in the study; 56 were assigned to the intervention group, and 39 were assigned to the comparison group. Data collection forms of 5 patients were lost and their group assignment is not known Six out of 56 subjects in the intervention group did not complete the study and 4 out of 39 control subjects also failed to complete the study. Analysis was therefore based on 50 subjects in the intervention group and 35 subjects in the comparison group. Subject characteristics are summarized by group in Table 1. No statistically significant difference among demographic characteristics was found between the groups (all P > .058). Over both groups, average age was  $61.8 \pm 13.2$  years (mean  $\pm$  SD), and 65.9% were male; their average Braden Scale risk score was  $11.2 \pm 2.12$ .

Nine PU developed during the course of the study. Four out of 35 subjects (11.7%) in the comparison group developed 8 PU. Five were classified as suspected deep tissue injuries; 3 evolved into stage III PU and 3 evolved into stage II PU. One out of 50 subjects (2.0%) in the intervention group developed a PU; it was classified as suspected deep tissue injuries, but it did not evolve into a PU. No patient developed a PU until at least 6 days after the operative procedure.

Kaplan-Meier curves, showing pressure-ulcer-free survival rates in the ICU by group and time, are displayed in Figure 4. Pressure ulcer developed in patients receiving standard care at 6.7, 9.7, 10.6, and 13.7 days. In contrast, the PU in the intervention group developed in 12 days. The unadjusted hazard ratio obtained from the Cox regression model was 4.4 (95% CI: 0.49 to 39.4, P = .19). After adjustment by propensity score, the hazard ratio of 3.6 would indicate that individuals who receive standard care experience a risk per unit time of developing a PU 3.6 times that of an individual receiving the intervention.

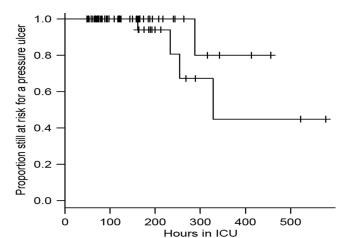


FIGURE 4. Kaplan-Meier estimates of the survival curves for the control (lower curve) and experimental groups. Ticks on the curves represent discharge times of patients from the intensive care unit (ICU) without pressure ulcer whereas drops in the curves represent the times at which patients were discovered to have developed pressure ulcers. After 13 days, the estimated proportion of people who would not have developed a pressure ulcer in the control group drops to 45% whereas in the experimental group this estimate never drops less than 80%.

But the ratio in the current study was not statistically significant. The results of the Cox models are presented in Table 2.

### Discussion

The PU incidence for both groups was lower than those in published reports for this high-risk population, which are as high as 29.5%.<sup>10</sup> Many factors may account for this discrepancy, including the use of low air loss mattresses, aggressive turning practices, and other PU preventive interventions routinely used in this patient population. In the regression model, the inclusion of a propensity score permitted us to adjust for any imbalance in the covariates and risk factors, and thus to obtain an adjusted hazard ratio that more precisely reflects the difference between receiving a silicone border foam dressing versus standard treatment.

#### TABLE 2.

Coefficients of the Cox Proportional Hazards Model Comparing Standard Care Group to Intervention Group

Model	Hazard Ratio, Control vs Experimental	95% Confidence Interval	Р
Unadjusted			
Comparison vs intervention	4.4	0.49-39.4	.185
Adjusted			
Propensity score	0.94	0.624-1.42	.77
Comparison vs intervention	3.6	0.32-40.7	.296

Comparison of adjusted and unadjusted cox proportional hazard ratios between groups was not statistically significant. In a study with only 85 participants and 5 events, a hazard ratio of 15 would be necessary to achieve 80% power. Conversely, a hazard ratio of 3.6, as observed in the current study, would require 22 PU to achieve 80% power. Given the PU incidence in our setting, approximately 374 participants would be required to observe 22 PU so as to achieve 80% power. Therefore, it is not possible to determine whether the absence of statistically significant differences between groups reflects a type 2 ( $\beta$ ) error caused by insufficient power to detect a clinically relevant difference.

## Limitations

Limitations of this study began with a delayed response from the IRB, which led to a change in study design and reduction in the sample size. The original study was designed as a multicenter trial comprising 3 academic medical centers of approximately the same size in 3 different states. Withdrawal of 2 sites reduced the sample size by a factor of 3 and consequently reduced the power of the study to detect differences between groups. In addition, the lack of random allocation of subjects to group resulted in unequal subject distribution; this situation was further complicated by the loss of 5 of the study forms. Finally, the overall incidence of PU was less than anticipated, perhaps because the intervention dressing was applied to all patients in the operating room (Table 3).

## Future Research

Future researchers should consider testing the effectiveness of the dressing in the operating theatre as well as in the ICU population, with the control and experimental groups randomized preoperatively. Additionally, it is unknown whether or not a similar dressing from another manufacturer will produce the same results seen in our experiences. Composite dressing designs may vary between manufacturers, and it is not known whether specific dressings might be recommended for clinical practice or whether simply the use of any foam dressing might be recommended.

We acknowledge that subjects in intervention and comparison groups who underwent cardiothoracic procedures had the dressing applied during their surgical procedures. We observed that no PU developed until 6 days following surgical procedure in either group, suggesting that the dressing may have influenced the intraoperative risk of PU development. Additional research is needed to determine whether placement of a silicone border foam dressing reduces the risk for intraoperative pressure ulceration, especially in high-risk patients such as those undergoing cardiothoracic procedures.

## Conclusions

We compared a sacral dressing to standard care for prevention of hospital-acquired sacral PU in an ICU setting; statistical analysis revealed no statistically difference between groups. However, the incidence of hospital-acquired PU during this study was less than anticipated in this highrisk cardiothoracic surgery population and this influenced the power of the study to detect differences. The overall reduction in hospital-acquired PU incidence may have been influenced by the presence of evidence-based, critical care prevention bundle utilized by the RN staff as part of their standard interventions. Further research is needed to evaluate the efficacy of a silicone border foam dressing for reduction of hospital-acquired PU via a study that enrolls a larger sample size with adequate power analysis and uses random allocation to treatment group.

#### TABLE 3.

Surgery Duration: Comparison of Length of Surgery in Study vs Reported Incidence Rates in Literature

	Standard Care Group	Intervention Group	Reported Incidence in Literature Over Time
Number of cases $>$ 4 h in duration	30/35 (85.7%)	46/50 (92%)	3-h surgery: 5.8%47
Number of cases $>$ 8 h in duration	17/35 (49%)	24/50 (48%)	4-5 h: 8.9% 5-6 h: 9.9% ≫7 h: 13.2% <sup>48</sup>
Longest case (hours)	18.49; no pressure ulcer developeda	15.1; no pressure ulcer developed <sup>a</sup>	Schoonhaven and colleagues <sup>49</sup> report that for every 30 min surgery is prolonged over 4 h, risl of developing pressure ulcers is increased by 33%. <sup>49</sup> (95% Cl 13%-56%)

<sup>a</sup>Both control and experimental groups had the soft silicone foam dressing in place during their surgical procedure.

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## **Call for Authors: Wound Care**

- Continuous Quality Improvement projects, research reports, or institutional case studies focusing on innovative approaches to reduction of facility acquired pressure ulcers.
- Original research or literature review on causes and management of refractory wounds.
- Case studies, case series, review articles, or research reports on management of wound-related pain.
- Case studies, case series, review articles, or research reports on matrix dressings, human skin substitutes, growth factors, or other advanced wound therapies.
- Research reports or literature review on pathology, prevention, and management of biofilms.
- Literature review and current guidelines on skin and wound care in neonates and infants.