

**Pressure ulcer therapy.**

# **Clinical evidence summary**

**From proven prevention to effective treatment,**  
a comprehensive solution to your pressure ulcer needs



# 1. Prevention of sacral and heel pressure ulcers in trauma and critical ill patients – RCT

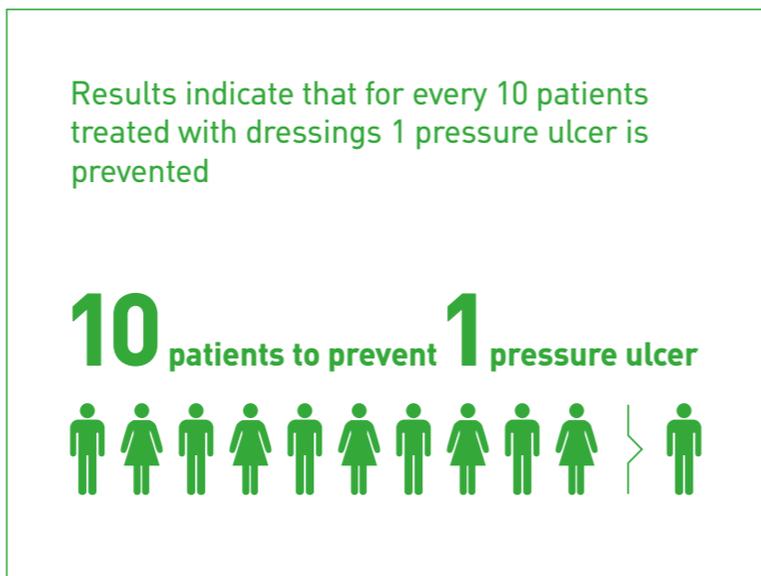
Santamaria N, Gerdtz M, Sage S, McCann J, Freeman A, Vassiliou T, DeVincentis S, Ng AW, Manias E, Liu W, Knott J. A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressing in prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial. Int Wound J 2013; doi: 10.1111/iwj.12101

This was a prospective open labelled study of 440 trauma and critically ill patients admitted to the emergency department.

Patients were randomised into the control group (221) receiving normal standard pressure ulcer reducing strategies and the intervention group (219) receiving the standard pressure ulcer reducing strategies and the multi-layer foam dressing Mepilex® Border Sacrum to their sacrum and Mepilex® Heel to their heels. All patients were examined every 24 hours and the patients in the sacrum and heel group had their dressing changed every 3 days. Both groups were comparable in relation to the major physiological and demographic presentations.

## Results

- 7 patients had pressure ulcer in the intervention group versus 27 in the control group
- The intervention group had a pressure ulcer incidence rate of 3.1%
- The control group had a pressure ulcer incidence rate of 13.1%
- Absolute risk of reduction was 10% for patients in the intervention group



# 2. Prevention of pressure ulcer in intensive care – RCT

Kalowes, P., Messina, V., Li, M. Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit. American Journal of Critical Care, November 2016, Volume 25, No.6

This was a prospective randomised controlled trial in the US. The study set out to compare the pressure ulcer incidence rates of sacral health care acquired pressure ulcers (HAPU) in 2 groups of critically ill patients. Both groups would receive standard care via the SKIN bundle and in addition the treatment group would have Mepilex® Border Sacrum applied to their sacrum within 24 hours of admission. The authors also studied potential causal relationships between co-morbidities and HAPU development and examined the cost savings associated with this intervention.

## Results

- Of the 366 patients in the study there were 2559 patient days at risk, this represents a calculated incidence rate ratio of 3.1%.
- Patients in the intervention group had an 88% reduced risk of developing pressure ulcers compared with the control group.

Control group 182 patients	Intervention group 184 patients
<b>Skin bundle</b> <ul style="list-style-type: none"> <li>• Braden Scale score at admission and every shift</li> <li>• Full skin assessment on every shift</li> <li>• Use of ICU specialty beds</li> <li>• Routine repositioning</li> <li>• Heel off-loading</li> <li>• Incontinence skin care</li> </ul>	<b>Skin bundle+</b> <ul style="list-style-type: none"> <li>• Mepilex® Border Sacrum applied within 24 hours of admission to the ICU</li> </ul>

**8 Sacral pressure injuries total**

7 Control group + 1 Intervention group

**88% Reduced risk of HAPU development**  
[hazard ratio, 0.12 [95% CI, 0.02-0.98], P=.048]



### 3. Health economic evidence on effectiveness of sacral dressings to prevent pressure ulcers

**Padula, W.V. Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals: An observational cohort study.**

Journal of Wound, Ostomy, and Continence Nursing, 2017, Volume 44, No.6

A retrospective longitudinal cohort approach was used to examine the data from the UHC database on all patients between 2010 and 2015 who developed a pressure injury. Hospital level data was collected from UHC and 1.03 Million patients with stage 3, stage 4 and unstageable pressure injury were included in this analysis. This data was matched with the sales data of prophylactic bordered sacral dressings used during the time of the study. 38 hospitals of the original 240 were used in the final analysis of the data in order to detect a meaningful and statistically significant reduction in pressure injury.

#### Results

- A robust sample of acute care hospitals experienced significant reduction in the numbers of Stage 3, 4 and unstageable pressure injuries following adoption of a 5 layer foam sacral dressing
- Hospitals using 1–2 dressings per patient admission lasting over 5 days, witnessed 1 case reduction per quarter (4 patients per annum)
- The cost for a pressure injury ranges from \$50,000–\$150,000. This could result in a saving of \$200,000–\$600,000 per year in addition to avoiding CMS penalties for hospital acquired conditions

**64%** Reduction in per-patient treatment costs

Treatment costs fell from \$120 per patient to \$43 per patient. Hospital used 1–2 dressings per 5+ hospital days



Possibly **USD 200,000–600,000** saved/year

in treatment expense per Hospital, in addition to possibly avoiding reimbursement penalties for reportable pressure ulcers



Average reduction was one reportable pressure ulcer per quarter, **saving 4 patients per year** from serious pressure ulcer per facility

**100%** ROI  
Within 1 year

### 4. Reduction in dressing utilization with Mepilex® Border Flex

**Tyson L. Study First: Driving the Case for Improving Hospital Wound Care**

Poster presentation at Symposium on Advanced Wound Care (Spring), San Antonio, Texas, United States of America. 2019

Data was collected on the performance of Medline's Optifoam® Gentle Border SA and Mepilex® Border Flex dressing. Data relating to wounds that did not require a filler were collated over an 18-month period. Visual assessment of wounds at the hospital were conducted at every shift. Routine dressing changes were done generally every 5 days and whenever necessary. For the QIP, dressing changes were done every 3 days (or sooner if required) until patient discharge from the hospital and wound healing progress (percentage change in area or volume) was measured. Incidents of peri-wound maceration, medical adhesive-related skin injury, silicone residue deposited on the skin or wound bed, and patient pain severity at dressing change (rated from 1 = no pain to 5 = severe pain) were documented.

#### Results

- A total of 258 less dressing changes and a 78% reduction in dressing utilization occurred in the Mepilex® Border Flex dressing group
- When cost in use as opposed to unit price is calculated, Mepilex® Border Flex dressing cost 74.2% less than Medline's Optifoam® Gentle Border SA
- The Mepilex® Border Flex dressing group reported 0 instances of dressing not adhering or coming off compared to 19 instances for Medline's Optifoam® Gentle Border SA
- The Mepilex® Border Flex dressing group had no episodes of exudate leakage or wound maceration, compared to 30 reported for Medline's Optifoam® Gentle Border SA



#### On average

✗ Optifoam® Gentle Border SA stayed in place over wounds for **less than one day**

✓ Mepilex® Border Flex Stayed in place for the **3-day wear time** as indicated in the protocol

In the 14-patient group using Mepilex® Border Flex, there was 258 fewer dressing changes, a 78% reduction in dressing utilization.

This translates to a dressing cost savings of **955\$** for those 14 patients, which is 74.2% cost reduction. **This saves 68\$ per patient**

## 5. Improving wear time and wound outcomes with Mepilex® Border Flex

**Nelson D. A new bordered foam dressing technology improves wound outcomes and satisfaction while reducing dressing utilization in acute care**  
Poster presentation at Wound Ostomy and Continence Nurses Society 2019 Conference, Nashville, Tennessee, United States of America

This study was done to determine the impact of a change in routine dressing change policy from every 3 to every 7 days, supporting the benefits of undisturbed wound healing using Mepilex® Border Flex. Clinical outcomes, dressing performance and patient impact were evaluated. Patients with wounds who were seen for a minimum of 2 WOC Nurse consults were included. The dressing was assessed for its ability to stay on and to absorb exudate. The WOC Nurse assessed the wound, the peri-wound and the percent change in wound volume. Each dressing utilized by the WOC Nurse and clinical nurse for QIP patients was counted and the average dressing wear time calculated based of the number of days of observation from the initial to last WOC Nurse assessment. At 1 year following full facility dressing implementation, there was a comparison of dressing utilization over the past 6 months to utilization of dressings over the same period the year prior.

### Results

- 4 wounds completely healed and 15 of 25 wounds were classed as 'chronic' and these wounds reduced in size by an average of 80.9% in an average time of 12.3 days.
- Average wear time was 5.5 days (over twice the published average 2.3–2.6 days)
- Mepilex® Border Flex was assessed as fully intact without leaking or lifting for 28/29 WOC nurse dressing changes, a 97% rate of adhesive integrity

Dressing protocol change: **3 days → 7 days**

**60%**  
of wounds were  
**chronic**  
(15/25)

Those wounds reduced  
in volume an average

**80.9%**

Over the average number of days of  
WOC Nurse care for these patients:  
12.3 (Wound volume measured  
by L x W x D)

**97%** Rate of  
adhesive  
integrity

28/29 dressing changes fully  
intact without leaking or lifting

**5.5** Average  
wear time  
of the  
dressing  
**days**

## 6. Improved outcomes in patients with suspected deep tissue injuries

**Sullivan R. Use of a soft silicone foam to change the trajectory of destruction associated with suspected deep tissue pressure ulcers**  
MEDSURG Nursing, July-August 2015, Vol. 24/No.4

The aim of this study was to explore the evolution of suspected Deep Tissue Injury (sDTI) in order to identify the role of early identification and intervention to alter the trajectory of the sDTI. A 24 month audit (2010–2012) evaluated 77 adult hospitalized subjects with 128 wound care nurse identified sDTI's over the course of 1 day to 14 weeks for 377 encounters analysed sDTI evolution process including site, initial presentation, measurements, tissue consistency and treatment. In response to significant sDTI recovery, a further in depth analysis was carried out to focus on commonalities of improved patient outcomes and to explore the possible link between the use of preventative dressings and sDTI recovery. Patients were given Mepilex® Border Sacrum, Mepilex® Border Heel or Mepilex® Border as primary or secondary dressings as standard of care.

### Results

- 66.4% (85) sDTI's resolved completely by the end of the study period, when using one of the three Mepilex® Border dressings as primary therapy
- In 24.2% (31) sDTI's, further deterioration was prevented
- Of the 12 (9.3%) of ulcers that deteriorated, lapses in compliance with the dressings were observed in 98.4%
- All Mepilex® Border dressings used in the study facilitated sDTI resolution as early as day 4 (mean healing time of 17.8 days)

**66.4%**  
of sDTI's resolved  
completely

Facilitated sDTI  
resolution as early  
as day

**4**

Prevented  
progression of  
**90.6%**  
of sDTI's

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

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