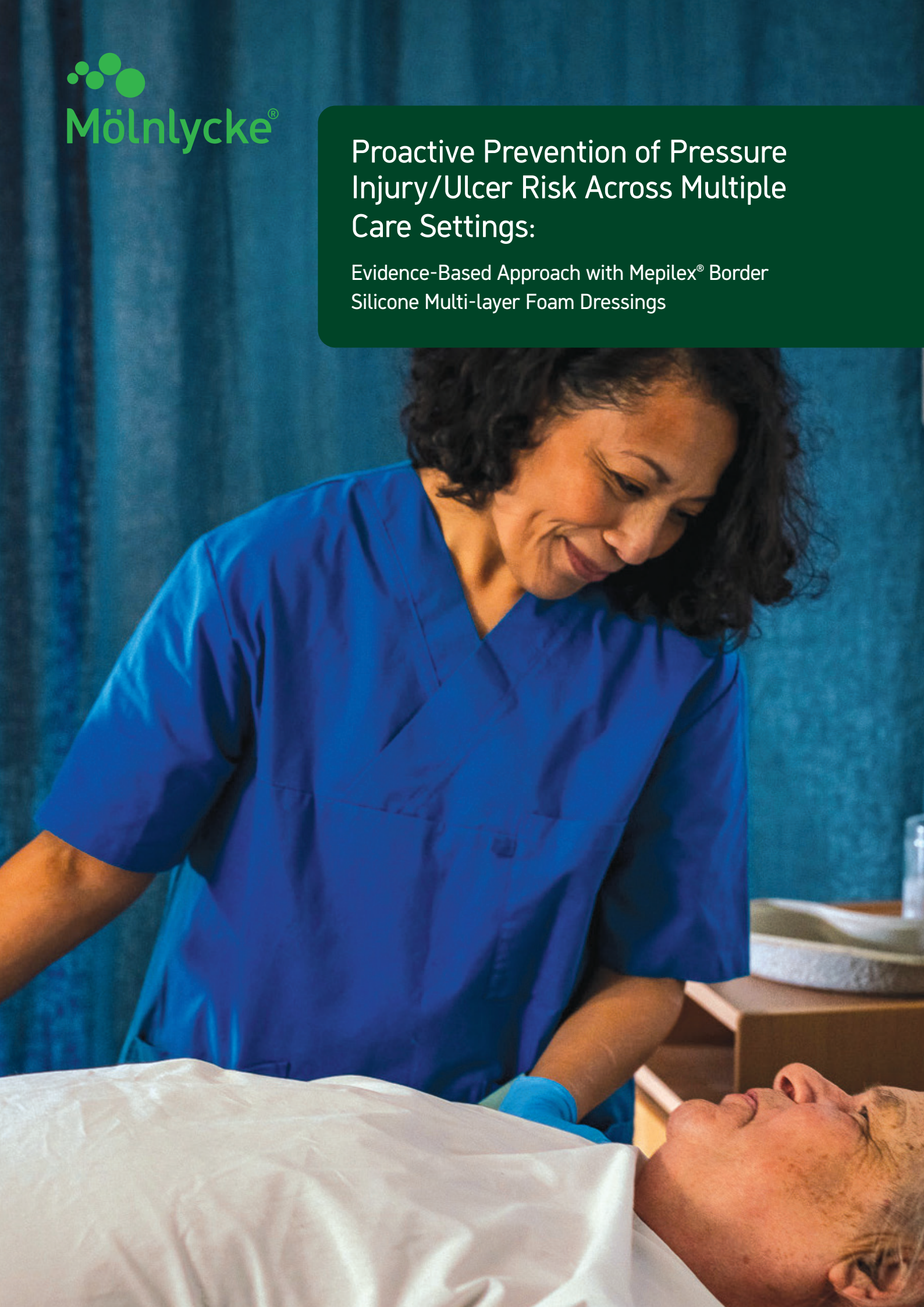
Mölnlycke®

Proactive Prevention of Pressure Injury/Ulcer Risk Across Multiple Care Settings:

Evidence-Based Approach with Mepilex® Border Silicone Multi-layer Foam Dressings



Foreword

First, Do No Harm. This principle from the Hippocratic Oath is central to healthcare. The 1999 report "To Err is Human" revealed that medical errors caused 44,000 to 98,000 deaths annually in the 1990s in the US [1]. This report highlighted the need for trust in healthcare, which had been damaged by issues like staffing shortages and budget cuts and continues to be a global healthcare issue.

The follow-up report, "Crossing the Quality Chasm," emphasizes the need for systematic changes to improve patient safety. This led to innovations like checklists, inspired by airline safety, to ensure consistent and safe practices. For example, surgical safety checklists and simplified infection prevention protocols have significantly reduced hospital-acquired conditions (HACs) [2].

Pressure injuries/ulcers (PI/PUs) are a major HAC with high occurrence rates, affecting over 2.5 million patients annually and causing more than 60,000 deaths in the US at a cost of over $26.8 billion each year [3]. Global burden is high with the cost of treating pressure injuries in the UK estimated to be GBP £1.4-2.1 billion and other countries reporting prevalence as high as 12.7% of the population[4,5]. Despite prevention efforts, these injuries remain a significant global problem.

In response, the National Pressure Injury Advisory Panel (NPIAP), European Pressure Ulcer Advisory Panel and the Pan-Pacific Pressure Injury Alliance developed comprehensive guidelines for PI/PU prevention.[6] These guidelines have been updated multiple times and are used worldwide. However, the 2019 guidelines' length and complexity make them challenging to implement quickly in clinical settings. The 2025 guidelines are streamlined and will be more easily implemented in clinical care settings.

The field of PI/PU prevention has made two major advancements since developing clinical practice guidelines. First, the NPIAP created a Standardized Pressure Injury Prevention Protocol (SPIPP) Checklist with 34 items to make guidelines easy to follow.[7] Second, health technology has greatly improved, with advanced dressings, smart beds, sensors, and diagnostic tools that help prevent pressure injuries and identify high-risk patients efficiently.

These advancements are backed by extensive research and evidence. The SPIPP Checklist and related technologies are supported by clinical trials and studies that ensure their safety, efficacy, and effectiveness. This PI/PU Prevention Evidence Compendium highlights the tested technologies and emphasizes the importance of using evidence-based products.

Value for money is also crucial. Quality includes safety, efficacy, effectiveness, and time-efficiency. Decision-makers should consider both upfront costs and long-term savings when choosing new technologies. Strategic thinking leads to better performance and safety.

Ultimately, "**First, Do No Harm**" means providing patients with clinically proven, beneficial treatments. This compendium helps you understand PI/PU prevention technologies such as the Mölnlycke® family of multi-layer foam dressings with Safetac® which are evidence-based and how to apply them to improve patient care, outcomes, and healthcare economics.

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Aims

The aims of this compendium are to review the scientific, clinical, and health economic evidence for pressure injury prevention to improve patient outcomes, provide sustainable care options, and to provide information that enables caregivers and HCPs to make informed decisions regarding patient care.

Background

Pressure injuries (PI) are localised damage to the skin and underlying tissues, typically over bony areas such as the sacrum, heel, elbows, and hips [8]. They result from prolonged pressure or a combination of pressure and shear forces [6,8]. Prolonged pressure deforms and compresses the skin, fat and muscle, while friction against support surfaces may enhance shear forces and compress blood vessels. One way to mitigate the effects of these extrinsic forces is the utilization of Mepilex® Border multi-layer foam dressings. (**Figure 1**) [9]. The microclimate (moisture levels and temperatures at the skin/surface interface), may increase shear forces and increase the possibility of tissue damage [10].

Figure 1: Diagrammatic representation of a multi-layer foam dressing with Safetac (Mepilex® Border Sacrum)

Medical device-related pressure injuries (MDRPI) may form quickly due to poor device positioning, alterations in the microclimate, or ill-fitting devices.[6,10] MDRPI may comprise between 61-81% of hospital acquired pressure injuries (HAPIs).[6,9]

PIs are classified by severity and depth of tissue damage (**Table 1**). PI staging guides treatment decisions and monitoring of healing outcomes.[11] The prevalence and incidence of PI vary across different patient populations and care settings.

Table 1. Classification of pressure ulcers (adapted from NPUAP, EPUAP and PPPIA, 2025)[6]

Category/stage	Depth	Details
I	Non-blanching erythema	Intact skin with non-blanching redness, usually over a bony prominence. While darkly pigmented skin may not have visible blanching, its colour may differ from the surrounding skin
II	Partial-thickness skin loss	Partial-thickness loss of dermis presenting as a shallow open ulcer with a red-pink wound bed, without slough. Can also present as an intact or open/ruptured serum-filled blister
III	Full-thickness skin loss	Full-thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. Can include undermining and tunnelling
IV	Full-thickness tissue loss	Full-thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunnelling
Unstageable	Depth unknown	Full-thickness tissue loss in which the wound bed is covered with slough (yellow, tan, grey, green or brown) and/or eschar (tan, brown or black)
Suspected deep tissue injury	Depth unknown	Purple or maroon localised area of discoloured, intact skin or blood-filled blister caused by damage to the underlying soft tissue by pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler, when compared with adjacent tissue

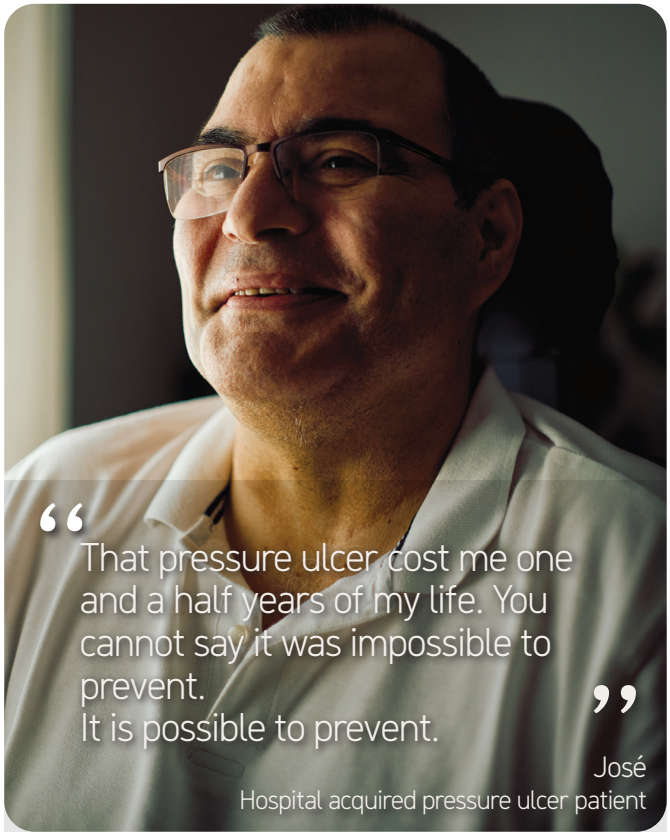
The patients most vulnerable to PI development include intensive care unit (ICU) patients, neonates and paediatric patients, and perioperative patients. **(Table 2)** ICU patients in Australia are four times more likely to develop a PI than patients in general wards [12]. Risk factors include prolonged immobility, sedation, analgesics, use of vasopressors, and reduced tissue perfusion [12,13]. PI incidence increases if patients cannot respond to body signals to self-reposition, or are not repositioned frequently by nursing staff. Increased use of medical devices in the ICU further increases PI risk. Neonates and paediatric patients are vulnerable due to thinner, more fragile skin with less subcutaneous fat and reduced sebum production.[10] Paediatric skin also matures over time and therefore requires dynamic PI prevention strategies. Paediatric patients may be unable to reposition themselves or verbally express discomfort. Additionally, the number of medical devices in use in the paediatric ICU is high [10]. Perioperative patients are at increased risk of PI due to anaesthesia, prolonged immobilisation, and the inability to express pain or discomfort [13,14]. 45% of all HAPIs occur in perioperative patients [15].

Table 2. Pressure injury prevalence and incidence (adapted from NPUAP, EPUAP and PPPIA, 2025)[6]

Setting/Population	Prevalence rates	Incidence and facility-acquired rates
Acute care	6.0 - 18.5%	0.0 - 12.0%
Critical care	10.0 - 25.9%	16.9 - 23.8%
Aged care	4.1 - 32.2%	1.9 - 59.0%
Paediatric care	0.47 - 32.8%	0.25 - 27.7%
Operating room setting	-	5.0 - 53.4%

Bearing the Burden of PI: Patient and Caregiver

The prevention of PI remains a significant challenge for patients, caregivers, and healthcare professionals (HCP) despite PI prevention protocols, advanced prophylactic dressings and increased scrutiny from the quality outcomes perspective. For patients, the pain of living with a PI has been described as a central part of the experience. Constancy of pain is debilitating and can lead to reduced mobility and a loss of autonomy, exacerbated by a lack of control over their body and care decisions. Patients depend on support from family, care workers, or community services, causing a loss of privacy and dignity which contributes to their social isolation, and can lead to feelings of being 'a burden' [16]. Patients find that withdrawal from hobbies or preferred activities, due to social discomfort, in turn reduces self-confidence and may lead to avoidance behaviours. Many patients find themselves unable to work [16,17]. The emotional and psychological impacts of living with a PI are among the most significant challenges for patients. Patients often feel sad, helpless, frustrated, or angry - emotions linked to long healing times, painful exudating wounds, or around a sense of injustice around a preventable injury [16,17]. Prevention strategies can restore a sense of control and self-determination, with support facilitated by family members and nursing professionals being essential [16].



Challenges for caregivers include the emotional stresses of managing PIs at home, guilt over the development of a PI during a period of home care, and a sense of responsibility for the patient. Carers may feel underprepared to manage complex wound care and may lack knowledge of prevention strategies. Financial challenges may be incredibly stressful with additional costs of appropriate dressings, wound care equipment, and healthcare consultations from household budgets [16].

The challenges for HCP around clinical decision-making include identifying patients at high risk of developing a PI, resource allocation for treatment, and strategies for the implementation of evidence-based prevention strategies [3,16].

PI prevention strategies include repositioning, foam support surfaces, optimisation of nutrition and hydration, and the use of prophylactic dressings such as Mepilex® Border foam products **(Figure 1)** on high-risk areas [8–10,18–20]. The mechanism of action of prophylactic dressings is shown in **Figure 2**. Comprehensive clinical guidelines detail strategies for the prevention and management of PI and were issued by the European Pressure Ulcer Advisory Panel (EPUAP), the National Pressure Injury Advisory Panel (NPIAP) and the Pan Pacific Pressure Injury Alliance (PPPIA) in 2019, with an update to living on-line guidelines expected in 2025 [6].

Multiple Cochrane reviews have been conducted around PI treatment and prevention. These have highlighted the need for high-quality multicentre trials that are powered appropriately to fully assess the role of dressings in PI prevention [21–24]. Heterogeneity of terminology, PI classification, and outcome reporting has been highlighted as an issue in published studies [4,25].

Meanwhile, the Mepilex® border foam dressings have shown substantial growth in the evidence supporting these products Since 2010.

Please scan to see and hear Jose's story.

Mechanisms of Action (MOA) of Prophylactic Dressings

Prophylactic dressings help prevent pressure injuries by addressing four extrinsic factors:

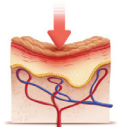
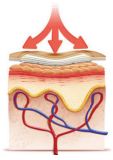
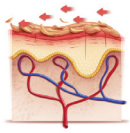
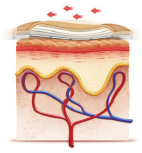
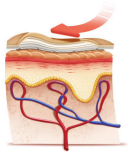
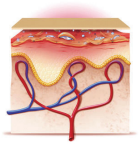
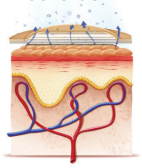
Functional property	Without dressing	With Mepilex® multi-layer foam dressing with Safetac®
Pressure Redistribution: Dressings redistribute pressure away from bony prominences and vulnerable areas to surrounding tissues. Multi-layer foam dressings with a structured design reduce tissue deformation and the concentration of stress on a single point.		
Friction Reduction: : The outermost layer of dressings, designed to be smooth and low-friction, minimises resistance between the skin and surfaces (e.g., bedding, clothing). A low friction will minimise the drag, shear forces, in the skin.		
Shear Force Absorption: Prophylactic dressings absorb and redistribute shear forces that occur when a person is repositioned or sliding down in bed. The layered design and material properties will dictate the ability to mitigates shear stresses.		
Microclimate Management: Dressings manage microclimates by controlling and removing moisture from the skin-dressing interface. Layers absorb and wick away excess moisture (from sweat or incontinence) to avoid an increase in humidity.	Multi-layer foam dressing without Safetac® 	Multi-layer foam dressing with Safetac® 

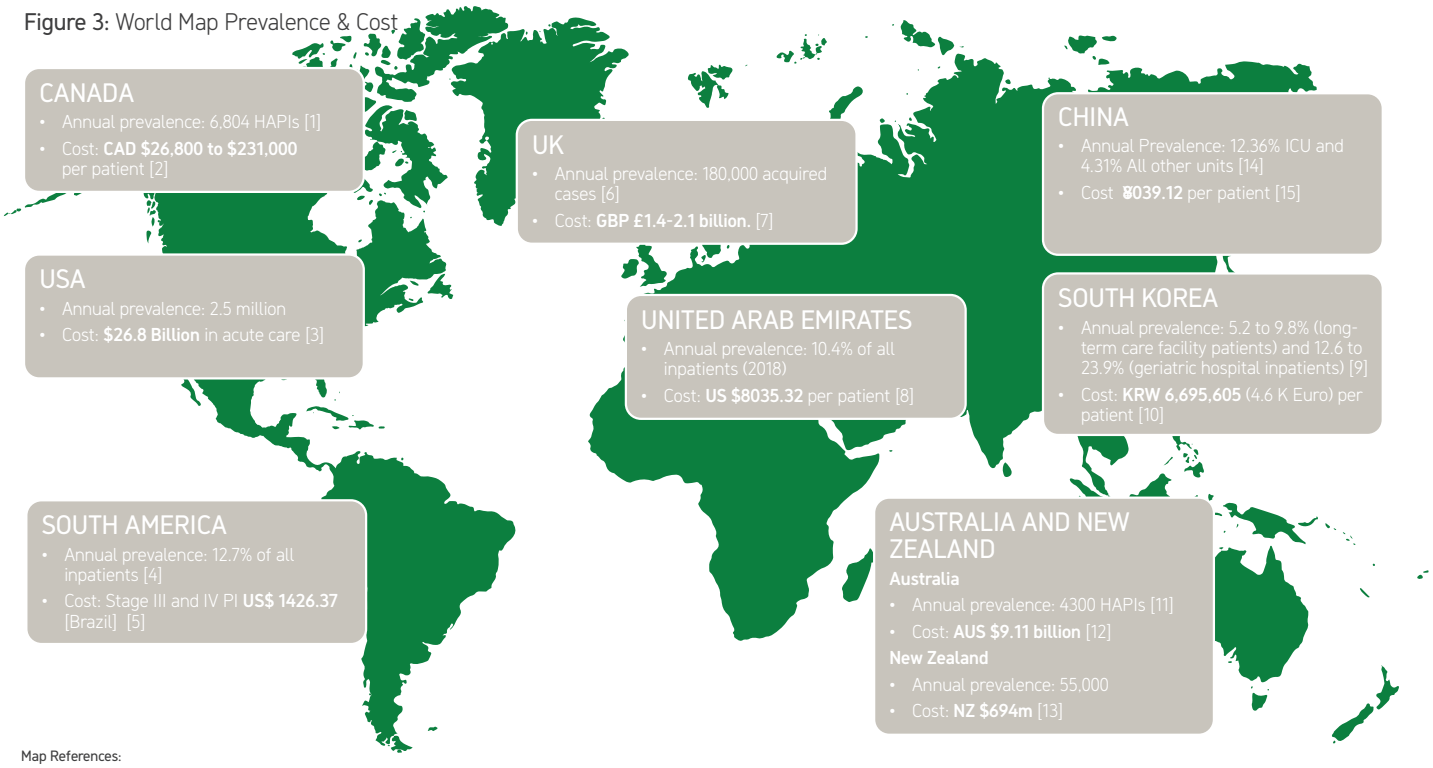
Figure 2: PIs and the mechanism of action of prophylactic dressings

Mölnlycke has been the industry leader in evidence generation for the utilization of silicone interface dressings in PI prevention over the past 15 years.

Why are pressure injuries still a global problem?

PI remain a global problem due to factors including failure to adopt evidence based PIP strategies, an aging population, limited global healthcare funding, a lack of prevention education for both clinical staff and caregivers, flaws in risk assessment procedures, and increased use of medical devices [6,10,17]. The consistent application of clinical guidelines in resource strapped settings where clinical staff are under time and economic constraints may be challenging [17,26]. Despite the implementation of a range of prevention strategies, global health organisations continue to report high rates of HAPIs (**Figure 3**).

Figure 3: World Map Prevalence & Cost



Map References:
1. Canadian Institute for Health Information. Hospital Harm Results, 2014–2015 to 2022–2023. Ottawa, ON: CIHI; 2023. **2.** Best Practice Guideline Implementation to Reduce Hospital-Acquired Pressure Injuries. RNAO, Evidence Booster. Spring 2017. Accessed June 10, 2024. https://rnao.ca/sites/rnao-ca/files/FINAL_Evidence_Boosters_-_Spring_2017_HAPU_May_25_17_FINAL.pdf. **3.** Padula WV, Delarmente BA. The national cost of hospital-acquired pressure injuries in the United States. Int Wound J. 2019 Jun;16(3):634-640. doi: 10.1111/iwj.13071. **4.** Li Z, Lin F, Thalib L, Chaboyer W. Global prevalence and incidence of pressure injuries in hospitalised adult patients: A systematic review and meta-analysis. Int J Nurs Stud. 2020 May;105:103546. doi: 10.1016/j.ijnurstu.2020.103546. Epub 2020 Jan 31. PMID: 32113142. **5.** Chacon, J., Blanes, L., Borba, L., Rocha, L., & Ferreira, L. (2017). Direct variable cost of the topical treatment of stages III and IV pressure injuries incurred in a public university hospital.. Journal of tissue viability, 26 2, 108-112. https://doi.org/10.1016/j.jtv.2016.12.003. **6.** https://cks.nice.org.uk/topics/pressure-ulcers/background-information/incidence/. **7.** Bennett, G., Dealey, C., Posnett, J. The cost of pressure ulcers in the UK. Age and Ageing 2004;33(3):230-235. **8.** Tariq G, Hamed J, George B, Cruz S, Jose J. Pressure ulcer prevalence and prevention rates in Abu Dhabi: an update. J Wound Care. 2019 Apr 1;28(Sup4):S4-S11. **9.** Lee SB, Lee HY. Impact of pressure ulcer prevention knowledge and attitude on the care performance of long-term care facility care workers: a cross-sectional multicenter study. BMC Geriatr. 2022 Dec 21;22(1):988. doi: 10.1186/s12877-022-03702-3. **10.** Lee JH. Socioeconomic effects of pressure ulcer. J Korean Med Assoc. 2021 January; 64(1):11-15. **11.** Independent Hospital Pricing Authority (AU). Activity Based Funding Admitted Patient Care 2015–16, acute admitted episodes, excluding same day. https://www.ihacpa.gov.au/health-care/data/data-specifications/data-set-specifications-2015-16. **12.** Nghiem S, Campbell J, Walker RM, Byrnes J, Chaboyer W. Pressure injuries in Australian public hospitals: A cost of illness study. Int J Nurs Stud. 2022 Jun;130:104191. doi: 10.1016/j.ijnurstu.2022.104191. **13.** https://www.hqsc.govt.nz/assets/Our-work/System-safety/Reducing-harm/Pressure-injury/Publications-resources/KPMG-pressure-injury-report-Jan-2016.pdf. **14.** Lin FF, Liu Y, Wu Z, et al. Pressure injury prevalence and risk factors in Chinese adult intensive care units: A multi-centre prospective point prevalence study. Int Wound J. 2021;1-14. https://doi.org/10.1111/iwj.13648. **15.** Jiang Q, Dumville JC, Cullum N, et al Epidemiology and disease burden of complex wounds for inpatients in China: an observational study from Sichuan province BMJ Open 2020;10:e039894. doi: 10.1136/bmjopen-2020-039894

Singh et al [26]. Advocate a 'plan-do-study-act' approach to reduce HAPIs and improve operational efficiency. The plan focused on three pillars: People - develop a specialised wound care team, who deliver PI prevention training to the staff; Products - purchase several products to facilitate PI prevention, including a 'turn and position' system, Mepilex® Border Foam dressings, moisture wicking fabric and adult briefs; Process - standardize procedures across units and update policies. A pressure injury prevention bundle (PIPB) was implemented on patient admission with a simple question: 'Is the patient immobile or non-verbal?' A 'Yes' prompted PIPB implementation. The number and severity of PIs decreased by 90%. Importantly, the bundle fitted into the nurse's workflow and both direct (treatment) and indirect costs (administration) costs were reduced. Implementation of a bundle of interventions, including identification of high-risk patients, is more likely to be successful for driving process change [20,26].

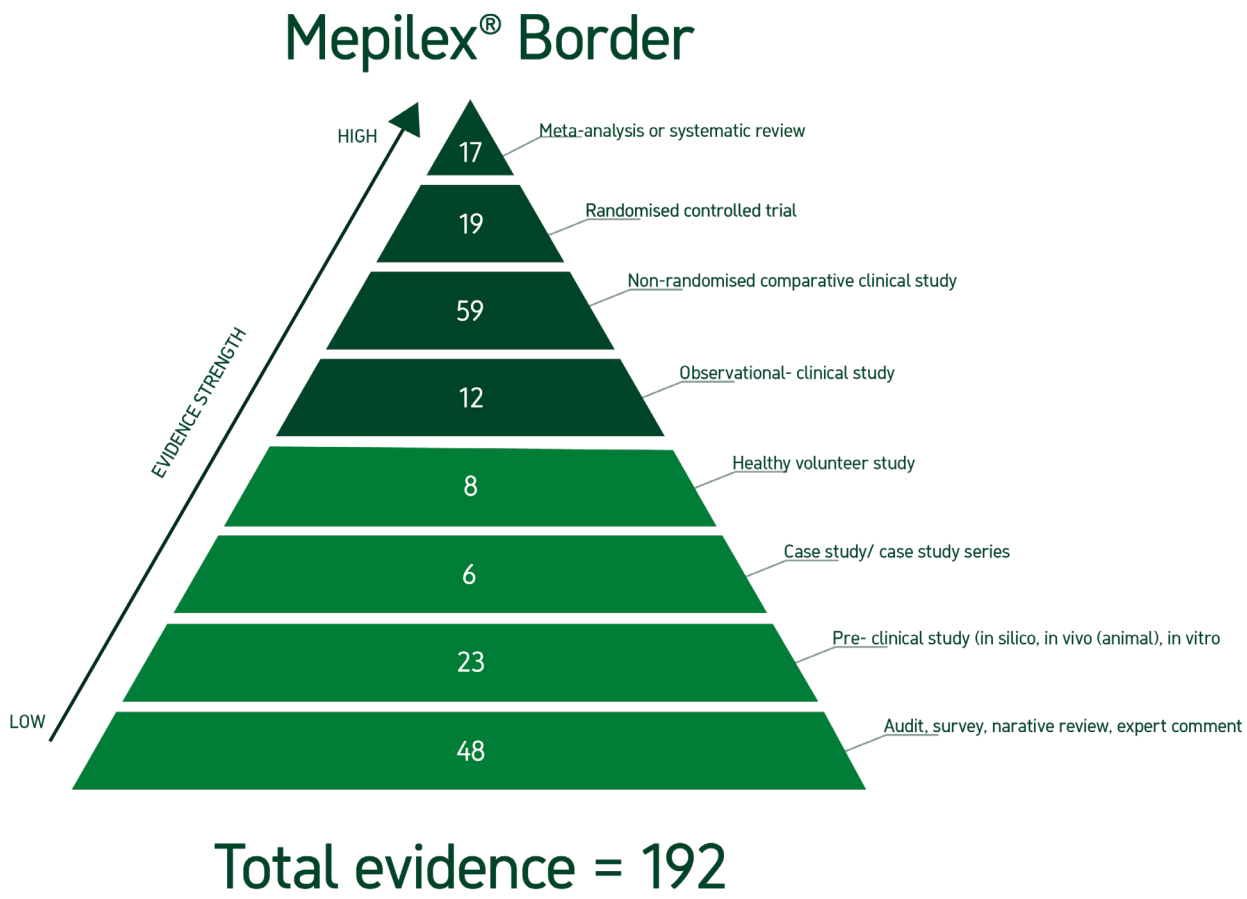
The shift of all modern healthcare is towards a proactive approach to prevention, instead of a focus on reactive care and treatment. There has been continued growth in supportive evidence and clinical practice guidelines in the last ten years, however this has not yet resulted in decreasing rates of PI globally [6,9,19].

Evidence Review and Sites of Patient Care

The growing body of evidence supporting the use of Mepilex® multi-layer bordered form dressings in pressure injury (PI) prevention and the care settings where these studies were conducted are highlighted in **Figures 4 and 5**.

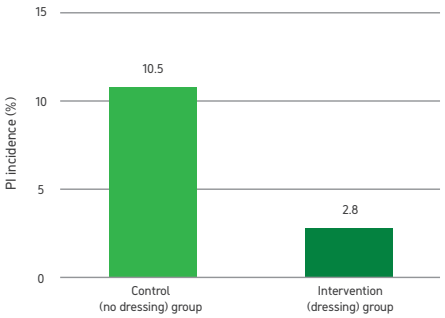
Padula and colleagues (2017) found that sacral foam dressings significantly reduced HAPI incidence rates. Despite an increased investment in prophylactic dressings (from $2.60 to $20/patient), overall spending on PI treatment decreased from $120 to $43 per patient [27]. Further, an RCT by El-Genedy et al. (2020) confirmed the cost-effectiveness of Mepilex® border dressings in ICU patients, with total treatment costs that were 4.2 times lower in the dressing than in the no dressing group [28]. Additionally, a systematic review and meta-analysis by Fulbrook and colleagues in 2019 assessed six global studies and found that sacral protective dressings reduced PI incidence by 70% across care settings[31]. Bates-Jensen et al. (2024) demonstrated that silicone foam dressings significantly reduced PI incidence in patients undergoing prone-position surgery [29]. Finally, Padula and Delarmente reported an average cost of HAPI care in the US of $10,708 per patient, which could reflect a $26.8 billion national PI cost burden - 58% of which could be due to severe stage 3/4 HAPIs. The most cost-effective strategy for the reduction of this economic burden is the implementation of prevention strategies and early treatment interventions [3].

Figure 4: Evidence supporting use of Molnlycke multi-layer border foam dressing for PI prevention.



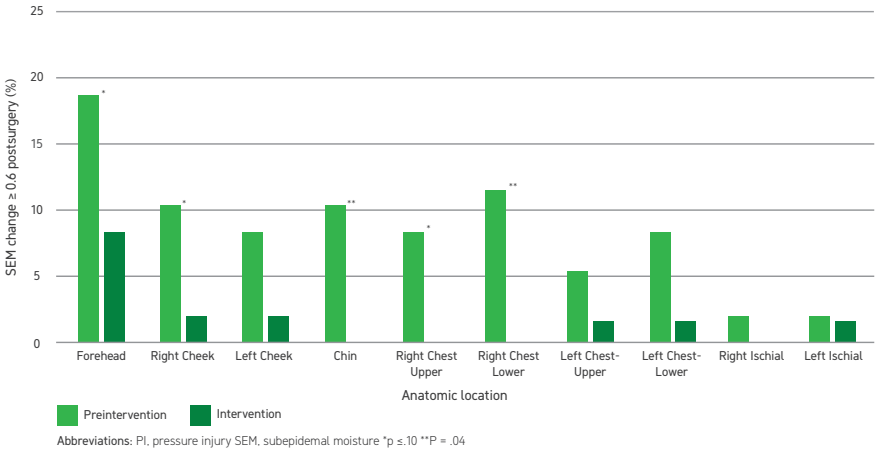
PIP Evidence Across Multiple care Settings

ICU



Hahnel et al, 2020[32]

OR



Bates-Jensen et al, 2024[29]

Figure 5

Conclusions

PIs should no longer be a global issue, given the extensive and compelling evidence available to drive change across healthcare systems. The evidence presented supports the implementation of holistic change and enables healthcare systems to sustain quality improvements and outcomes. The use of dressings in PI prevention strategies is one example of a cost-effective intervention that can positively influence PI incidence rates.

The importance of PI prevention information spans all HCPs, from first-time users seeking to implement a PI prevention plan, to mid-range users aiming to improve care quality and outcomes, and advanced users dedicated to sustaining long-term results and advancing clinical practice. The robust body of research, integrated into international guidelines, reflects a significant evolution in best practices. Once considered a recommendation, prophylactic

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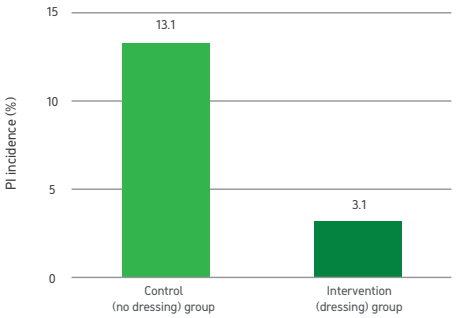
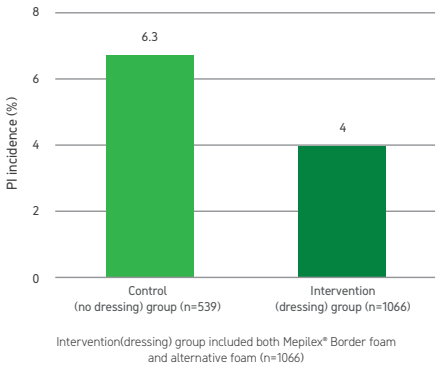


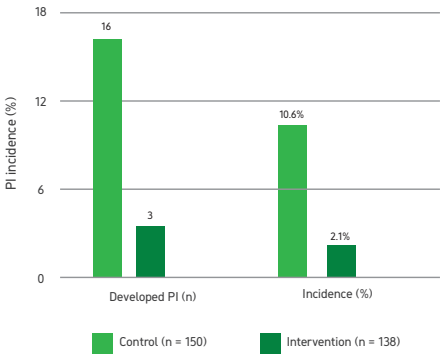
Santamaria et al, 2015[35]

OTHER UNITS



Beeckman et al, 2021[30]

POST ACUTE



Santamaria et al, 2018[36]

dressings for PI prevention are now highly endorsed, reinforcing the critical role of evidence-based strategies in reducing the global burden of PIs. These advancements provide healthcare providers with the tools needed to enhance care, improve patient outcomes, and ensure the sustainability of clinical success.

In the following evidence snapshots, you will find high level evidence supporting the use of the Mepilex® family of prophylactic dressings in surgical, acute care, residential care, and ICU settings. These evidence snapshots are high level clinical trials (RCTs), healthcare economics research, and real-world evidence implementation which have measurable impact on observed outcomes.

Evidence Snapshot

ICU

Prophylactic dressings for preventing sacral pressure injuries in adult intensive care unit patients: A randomised feasibility trial

Latimer S, Chaboyer W, Walker R M, et al. Australian Critical Care 2024;3:101133

Study aim

To assess the feasibility of undertaking a larger multi-centre comparative effectiveness trial of two prophylactic sacral dressings in preventing hospital-acquired sacral PI when applied in an ICU setting.

Key points

- Pilot RCT of 66 patients assessed the feasibility of undertaking a larger multi-centre comparative effectiveness trial of two Multilayer foam dressings (Mepilex® Border Sacrum and Allevyn® Life Sacrum) in preventing hospital-acquired PI, when applied to the sacrum of ICU patients.
- Primary Outcome partially met: A larger multi-centre comparative trial is feasible, subject to minor study criteria modifications.
- Secondary Outcomes met: PI incidence and dressing failures reported.

Methodology

- Patients **randomised** to one of 2 groups. All patients checked daily for PI over 14 days:
- **Intervention group 1 (N=34):** patients had Allevyn® Life Sacrum applied
- **Intervention group 2 (N=32):** patients had Mepilex® Border Sacrum applied.

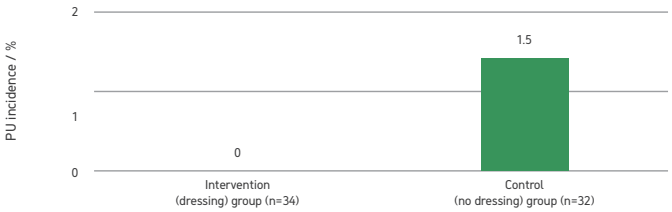
Results

Primary outcome:

Criteria and target	Result	Target achieved
Eligibility: ≥50% screened patients screened eligible for recruitment	77/1069 (7.2%)	No
Recruitment: ≥70% eligible patients recruited	66/77 (85.7%)	Yes
Retention: <10% patients lost to follow-up	6/66 (9.1%)	Yes
Intervention fidelity: ≥95% patients received allocated dressing (baseline)	66/66 (100.0%)	Yes
≥95% patients had allocated dressing present at data collection (daily)	305/334 (91.3%)	No
Missing data: ≤10% missing outcome (sacral photograph for PI assessment) data	65/334 (19.5%)	No

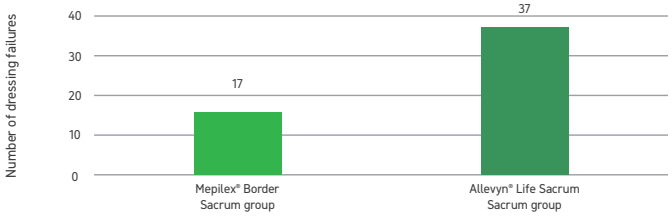
Secondary outcomes:

- The sacral PI incidence rate was 1.5% (1/66).
- One patient in the Allevyn® Life Sacrum group developed an unstageable sacral PI.



Dressing failures

- 109 sacral dressing changes during the study, with (n=54, 49.5%) due to dressing failure (rolled edges n=43, 79.5%; adhesion failure n=11; 20.5%).
- One patient in the Mepilex® Border Sacrum group experienced blistering under the dressing.



Conclusions

- Several prophylactic sacral dressings are available; however, comparative effective evidence between brands relative to performance, benefits and harms is lacking.
- Sacral prophylactic dressing failure and dressing-related harms are care quality and patient safety issues requiring further investigation.

Evidence Snapshot

ICU

Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit

Kalowes P, Messina V, Li M. American Journal of Critical Care 2016;25(6):e108-e119

Study aim

To assess the effectiveness of Mepilex® Border Sacrum in preventing sacral PI when applied in ICUs

Key points

- This RCT of 366 patients assessed the effectiveness of **Mepilex® Border Sacrum** dressings in preventing sacral pressure injury (PI), when applied to the sacrum.
- When used in combination with PI-related prevention strategies, the application of the dressings resulted in a **88% reduced risk of PI development**, compared to standard prevention strategies alone (no dressing).

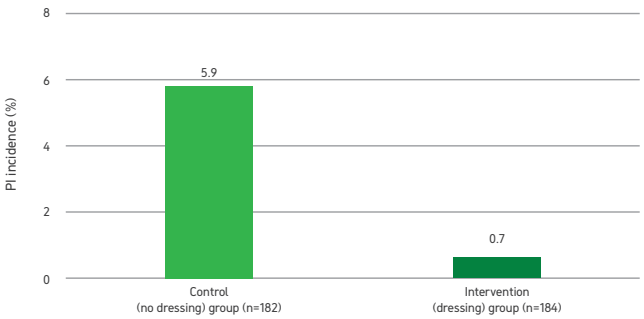
Methodology

Prospective, open-label RCT involving 366 critically ill patients admitted to the cardiac, medical, surgical, and trauma ICUs of a trauma hospital in the **United States of America.**

- Patients **randomised to Intervention group:** patients had Mepilex® Border Sacrum applied to the sacrum within 24 hours of admission to the ICU and maintained throughout stay in the ICU; also received usual PI prevention strategies or **Control group**: patients received usual PI prevention strategies (no dressing).
- All patients examined daily and dressings changed every 3 days, or sooner if they became soiled or dislodged.
- Primary outcome measure: development of a pressure injury.

Results

- **Intervention (dressing) group had significantly less patients who developed a PI than the control (no dressing) group (0.7% vs 5.9%, p = 0.01).**
- The intervention (dressing) group had 88% reduced risk of PI development (hazard ratio, 0.12 [95% CI, 0.02-0.98, p=0.048].
- At baseline, there were no significant differences in demographics or major physiological variables between the intervention and control groups.
- **Algorithm** developed, **mandating use of Mepilex® Border Sacrum:**
- The highest incidence of PI was significantly correlated to patients with sepsis.
- PI also associated with mechanical ventilation, sedation, vasopressors and dialysis.
- Organisational estimates demonstrated that a saving of more than $1 million had been achieved in the 2-year period following dressing purchase



Conclusions

- When used in combination with PI-related prevention strategies, the application of Mepilex® Border Sacrum significantly reduced both the incidence and severity of PI in ICU patients.
- Early identification of patients at risk can aid in preventing development of PI throughout the hospital stay.

Evidence Snapshot

ICU

The effectiveness of two silicone dressings for sacral and heel pressure ulcer prevention compared with no dressings: a randomised controlled parallel-group trial

Hahnel E, El Genedy M, Tomova-Simitchieva T, et al, British Journal of Dermatology 2020;183(2):256-264

Study aim

To assess the effectiveness of Mepilex® Border Sacrum and Mepilex® Border Heel in preventing sacral and heel PI when applied in the ICU

Key points

- This RCT of 475 patients assessed the effectiveness of the two dressings in preventing sacral and heel pressure injury (PI), when applied in the **intensive care unit (ICU)**.
- When used with PI-related prevention strategies, application of the dressings resulted in a **73% relative reduction in PI (category 2 or worse) incidence**, compared to standard prevention strategies alone (no dressing).
- The cumulative PI incidence (category II and above) was significantly lower in the intervention group (2.8%) compared to the control group (10.5%).
- Relative risk reduction in intervention group was 0.26, and absolute risk reduction was 0.08.

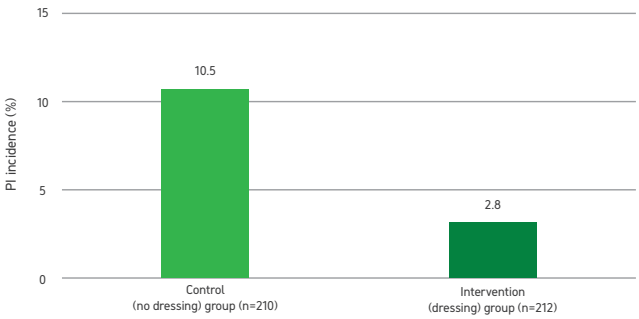
Methodology

- Patients randomised to either: Intervention group: patients had Mepilex® Border Sacrum / Mepilex® Border Heel applied to the sacrum/heels in the ICU; also received usual PI prevention strategies or Control group: patients received usual PI prevention strategies (no dressing).
- All patients examined daily and dressings changed every 3 days, or sooner if needed.
- Patients followed-up@ median 9 (range 1-130) days.
- Primary outcome measure: cumulative incidence of PI (category 2 or worse) at the sacrum/heels.

Results

Primary outcome:

- **Intervention (dressing) group had significantly lower cumulative PI (category 2 or worse) incidence than control (no dressing) group (2.8% vs 10.5%, p=0.001).**
- At baseline, there were no significant differences in demographics sample characteristics between the intervention and control groups.
- Compared with the control (no dressing) group, the relative risk in the intervention (dressing group) was 0.26 [95% confidence interval (CI) 0.11 – 0.62].
- Compared with the control (no dressing) group, the absolute risk reduction in the intervention (dressing) group was 0.08 [95% CI 0.03 – 0.13].
- **Number needed to treat (NNT) of 12.3 patients to prevent one PI (category 2 or worse).**



Conclusions

- When used in combination with PI-related prevention strategies, the application of multilayered foam dressings (Mepilex® Border Sacrum and Mepilex ® Border Heel) to high-risk ICU patients is effective in preventing PI at the sacrum and heels.

Evidence Snapshot

ICU

Cost-effectiveness of multi-layered silicone foam dressings for prevention of sacral and heel pressure ulcers in high-risk intensive care unit patients: an economic analysis of a randomised controlled trial

El Genedy M, Hahnel E, Tomova-Simitchieva T, et al. International Wound Journal 2020;17(5):1291-1299

Study aim

To assess the cost-effectiveness of Mepilex® Border Sacrum and Mepilex® Border Heel in preventing sacral and heel PI when applied in the ICU.

Key points

- This study, based on the results of a randomised controlled trial (RCT), assessed the cost-effectiveness of the two dressings in preventing sacral and heel PI, when applied in the intensive care unit (ICU).
- When used in combination with PI-related prevention strategies, **the application of the dressings is cost-effective for the sacral area**, but only marginal for the heels of critically ill patients.

Methodology

- Direct costs for preventive dressings in the intervention group and costs for the treatment of incident PIs in both RCT groups were measured using a bottom-up approach.
- A cost-effectiveness analysis was performed by calculating the incremental cost-effectiveness ratio (ICER).

Results

Costs of PI treatment

- The **total treatment costs** in the intervention (dressing) group was 4.2 lower than in the control (no dressing) group.
- The **average treatment cost per PI** was **€3.41 lower** in the intervention (dressing) group than in the control (no dressing) group.

ICER analysis

- **The ICER was €1945.30 per PU avoided (€8144.72 on heels; €701.54 sacrum) in the intervention (dressing) group.**
- ICERs express how much more than an existing intervention a new more effective intervention would cost for additional benefits.
- A higher ICER generally indicates a less cost-effective intervention.

	Intervention group (dressing) n=6 PI	Control group (no dressing) n=22 PI
Total cost of PI treatment	€134.88 [€106.77 – material €28.11 – labour]	€569.49 [€445.96 – material €123.53 – labour]
Average cost of treatment per PI	€22.48	€25.89

**The effectiveness of two silicone dressings for sacral and heel pressure prevention compared with no dressings: a randomised controlled parallel-group trial.* Hahnel E, El Genedy M, Tomova-Simitchieva T, et al, British Journal of Dermatology 2020;183(2):256-264.

Conclusions

- Applying preventive dressings to the sacrum is both clinically- and cost-effective for high-risk ICU patients.
- Application of preventive dressings to heels was less cost-effective, due to lower incidence in study.
- To maximise cost-effectiveness, preventive dressings should be targeted to high-risk patients.

Evidence Snapshot

ICU

Clinical Effectiveness of a Silicone Foam Dressing For the Prevention of Heel Pressure Ulcers in Critically Ill Patients: Border II trial

Santamaria N, Gerdtz M, Liu W, Rakis S, Sage S, Ng A. W, Tudor H, McCann J, Vassiliou T, Morrow F, Smith K, Knott J and Liew D, Journal of Wound Care 2015;24(8):S26-S31

Study aim

To examine the effectiveness and value of prophylactic 5-layer heel dressings in preventing HAPIs in acute care settings.

Key points

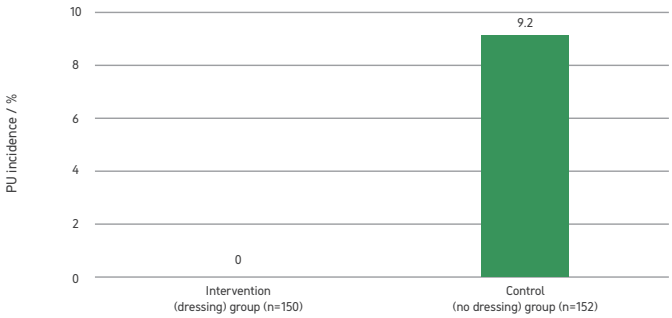
- Cohort study of critically ill patients at Royal Melbourne Hospital.
- Patients received the **silicone foam dressing on both heels upon** ICU admission.
- **No PUs in intervention group, 19 heel PUs developed in 14 patients in the control group.**
- Statistically significant difference between groups **(p<0.001)**.

Methodology

Small scale quality assurance study was conducted involving **150 trauma and critically ill patients** at Royal Melbourne Hospital, Australia.

- Patients allocated to either:
  - Intervention group: multi-layer soft silicone foam heel dressings (Mepilex® Border Heel).
  - Control group: Patients who received standard PU prevention care only.
- Primary outcome measure: incidence of hospital-acquired heel PUs in the ICU.

Results



	Intervention group (n=150)	Control group (no dressing) (n=152
Heel	0	19
Total numbers patiens with PUs	0	14

Conclusions

- Prophylactic multi-layer soft silicone foam dressings are effective in preventing hospital-acquired PUs in critically ill patients.
- High-quality bedside nursing care remains essential for PU prevention.
- Early risk assessment and intervention (application of dressings) are crucial.

Evidence Snapshot

OR

Decreasing Intraoperative Skin Damage in Prone-Position Surgeries.

Bates-Jensen B, Crocker J, Nguyen V, Robertson L, Nourmand D, Chirila E, Laayouni M, Offendel O, Peng K, Romero A. S, Fulgentes G, McCreath H. E, Advances in Skin and Wound Care 2024;37(8):413-421

Study aim

To evaluate the effectiveness of Mepilex® Border Flex dressings in preventing intraoperative acquired pressure injuries (IAPIs) during prone-position surgery.

Key points

- Mepilex® Border Flex dressings applied preoperatively to face, chest, and iliac crests.
- Fewer intervention group participants developed postoperative erythema on the face and chest compared to pre-intervention group and had subepidermal moisture (SEM)-defined IAPIs at all locations compared to pre-intervention group.
- Mepilex® Border Flex dressings mitigated IAPI risk factors like surgery length, skin tone, and BMI.

Methodology

Non-randomised clinical trial involving 187 patients at an academic medical centre in the greater Los Angeles area.

- Patients allocated to either: **Intervention group:** received a Mepilex® Border Flex dressing on face, chest and iliac crest after pre-op assessment and removed post-op. **Control group:** no dressing.
- Skin assessment up to 7 times: pre-op, post-op and daily until day 5 or discharge
- Primary outcome measures: compare visual skin assessment (VSA) vs. SEM-determined IAPI incidence.

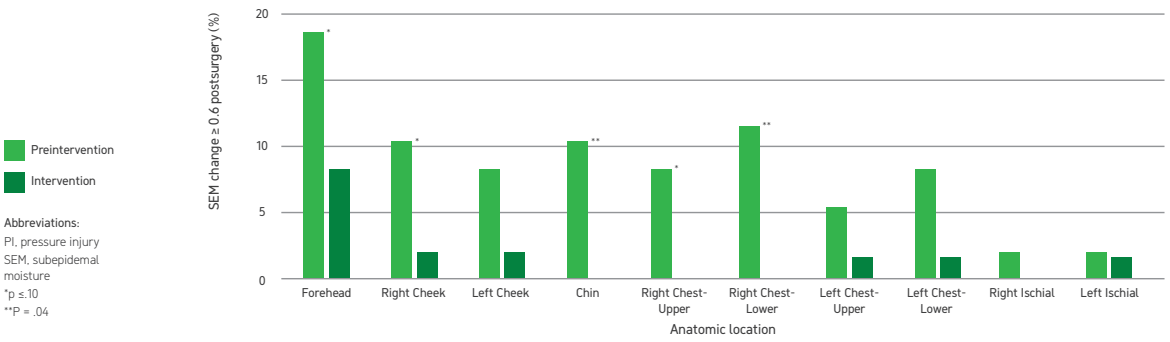
Results

Primary outcome:

- **The incidence rate of PUs was significantly less in patients treated with the foam dressing (intervention) than in the control group (preintervention group).**
- **SEM change / SEM Δ¥**Difference between pre-op and post-op SEM)
- SEM △> 0.5 was considered indicative of IAPI.
- Fewer intervention participants had SEM△ ≥ 0.6 across all anatomic locations than preintervention participants [most significant for the chin and right lower chest (P = 0.04)]

Cost

- Cost of Mepilex® Border Flex dressings and application was $34.81 per patient.



Conclusions

- Mepilex® Border Flex dressings effectively reduced IAPI incidence in prone-position surgery.
- SEM measurements were more sensitive than visual assessment in detecting skin damage.

Evidence Snapshot

OR

A change in focus: shifting from treatment to prevention of perioperative pressure injuries

Kimsey DB. AORN Journal 2019;110(4):379-393

Study Aim

To assess the impact of implementing a perioperative PI prevention bundle in an acute care facility

Key points

- Clinical audit at an acute care facility in the US assessed the impact of implementing a perioperative PI prevention bundle that incorporates skin and risk assessments, prophylactic dressings, proper positioning aids, enhanced communication, follow-up strategies and education.
- The prevention bundle successfully reduced the occurrence of perioperative PI and contributed to a two-year record of zero perioperative PI.

Results

Perioperative PI occurrence

2015

- **8 perioperative PI (5 prior to bundle implementation.**

2016

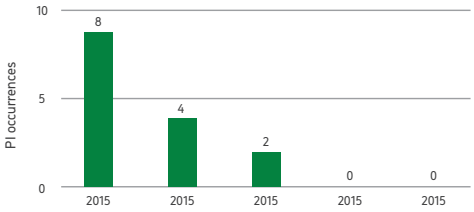
- 4 perioperative PI (all heel); addition of heel prophylactic dressings to bundle.

2017

- 2 perioperative PI (unstageable occipital PI due to donut-shaped foam head device, stage IV sacral PI due to patient refusal of repositioning); addition of fluidised positioner to bundle.

July 2017 - June 2019

- No PI



Methodology

- The evidence-based perioperative PI prevention bundle was developed by a multi-disciplinary team and implemented in 2015. PI rates were monitored through 2019.
- After implementation of the bundle, PI incidence rates were tracked to measure performance improvement.
- Bundle was applied to patients meeting following 4 inclusion criteria: 1.Body mass index ≤19 or ≥35. 2.Braden Scale score <16. 3. Previous PI in body area on which patient will be lying. 4..Procedure ≥3 hours.

Preoperative interventions

- **Assessment, cleaning and treatment of existing skin injury with five-layer soft silicone-bordered foam dressing.**
- **Education of patient on offloading anticipated surgical position.**
- **Application of visual alerts for high-risk patients.**

Care in positioning programme

- **Application of prophylactic five-layer soft silicone-bordered foam dressing to sacrum.**
- Padding of bony prominences that will be contact with operating room bed or equipment with five-layer soft silicone-bordered foam dressing, gel pads, or fluidized positioners.
- Insertion of fluidized positioner under occiput and Gel pad under patient to maintain pressure redistribution for an extended time.
- Application of foam egg-crate heel device for procedures <3 hours or a five-layer soft silicone-bordered foam heel dressing*** for procedures >3 hours.

Postoperative interventions

- **Assessment of need for specialized support surface.**
- **Completion of full-body skin assessment.**
- **Communicating skin and risk assessments**
- **Reinforcement of patient education on offloading surgical position.**
- **Assessment of need for wound care nurse consult.**

Conclusions

- The prevention bundle led to a 50% decrease in perioperative PI within the first year of implementation, and 75% by the end of the second year.
- Implementation of the PI prevention bundle provided an estimated 43% reduction in projected treatment costs.
- The bundle maintained a two-year period with zero instances of perioperative PI.

Evidence Snapshot

ED / ICU

A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial

Santamaria N, Gerdtz M, Sage S, et al. International Wound Journal 2013;12(3):302-308. Epub 2013

Study aim

To assess the effectiveness of Mepilex® Border Sacrum and Mepilex® Heel in preventing sacral and heel PI when applied in the ED and used throughout ICU stay.

Key points

- This RCT of 440 patients assessed the effectiveness of the two dressings in preventing sacral and heel pressure injury (PI), when applied in the **Emergency Department** (ED) and used throughout the stay in the **Intensive Care Unit (ICU)**.
- When used in combination with risk assessment and PI-related prevention strategies, the application of the dressings resulted in a **76% relative reduction in PI incidence**, compared to standard prevention strategies alone (no dressing)

Methodology

- Patients **randomised** to either:
  - **Intervention group**: patients had Mepilex® Border Sacrum / Mepilex® Heel applied to the sacrum and/or heels in the ED and maintained throughout stay in the ICU; also received usual PI prevention strategies.
  - **Control group**: patients received usual PI prevention strategies (no dressing).
- All patients examined daily and dressings changed every 3 days, or sooner if needed.
- Primary outcome measure: incidence rate of hospital acquired PI.

Results

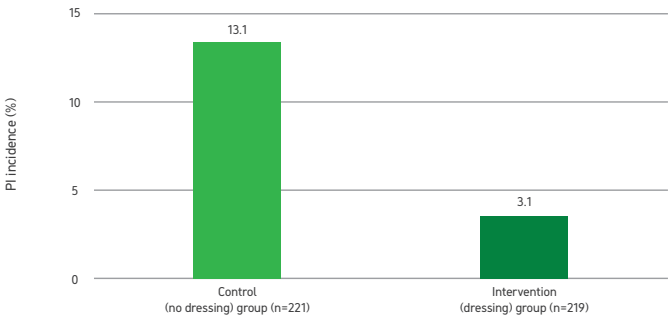
Primary outcome:

- **Intervention (dressing) group had significantly less patients who developed a PI** in ICU (5 vs 20, p=0.001).
- Absolute risk reduction of 10%.
- **Number needed to treat (NNT) of 10 patients to prevent one PI.**

Secondary outcomes:

Number of PI by anatomical site:

	Intervention group (dressing) n=161	Control group (no dressing) n=152	P value
Sacrum	2	8	0.05
Heel	5	19	0/002



Onset of PI:

- A survival analysis confirmed that patients in the intervention (dressing) group developed PI at a significantly slower rate than patients in the control (no dressing) group (HR 0.19, p=0.002).

Conclusions

- The findings demonstrate a statistically and clinically significant benefit for the application of multilayered foam dressings for the prevention of sacrum and heel PI.
- When used in combination with risk assessment and PI-related prevention strategies, the application of multilayered foam dressings (Mepilex® Border Sacrum and Mepilex ® Heel) is effective in preventing PI in critically ill patients when applied in the ED and prior to ICU transfer.

Evidence Snapshot

ICU/OTHER UNITS

Silicone adhesive multilayer foam dressings as adjuvant prophylactic therapy to prevent hospital-acquired pressure ulcers: a pragmatic noncommercial multicentre randomized open-label parallel-group medical device trial.

Beeckman D, Fourie A, Raepsaet C, et al. British Journal of Dermatology 2021;185(1):52-61

Study aim

To assess the effectiveness of MFDs in preventing hospital-acquired PI when applied in ICUs and non-ICUs.

Key points

- This RCT of 1605 patients assessed the effectiveness of MFDs in preventing hospital-acquired PI, when applied to the sacrum, heels and greater trochanter areas of patients in intensive care unit (ICU) and non-ICU settings of eight Belgian hospitals.
- When used in combination with PI-related prevention strategies, the application of the MFDs resulted in a 36% relative reduction in PI (category 2 or worse) development, compared to standard prevention strategies alone (no dressing).

Methodology

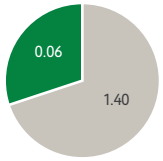
- Patients **randomised** to one of 3 groups:
  - **Intervention group 1:** patients had Allevyn® Life Sacrum / Allevyn® Life Heel / Allevyn® Life applied to sacrum / heels / greater trochanter; also received usual PI prevention strategies.
  - **Intervention group 2:** patients had Mepilex® Border Sacrum / Mepilex® Border Heel / Mepilex® Border applied to / heels, / greater trochanter; also received usual PI prevention strategies.
  - **Control group:** patients received standard PI preventive strategies (no dressing).
- Primary outcome measure: development of PI (category 2 or worse) within 14 days in **combined intervention group** (pooled data from intervention groups 1 and 2).

Results

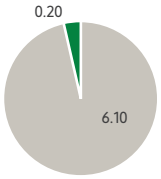
Primary outcome:

- **Combined intervention (dressing) group had significantly less patients who developed a category 2 or worse PI than the control (no dressing) group (4% vs 6.3%, p = 0.04).**
- Combined intervention (dressing) group had 36% reduced risk of PI developing compared to the control (no dressing) group.
- **Number needed to treat (NNT) of 43 patients to prevent one PI for all anatomical locations (category 2 or worse).**
- No major differences in effectiveness between the two dressing brands (study was not powered to detect such differences).

Key Adverse Device Effects:

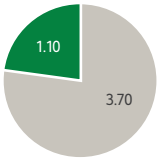


Skin Injury

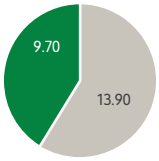


Rolling edges

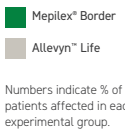
Key Device Deficiencies:



Separation of layers



Poor adhesion/failure



Numbers indicate % of patients affected in each experimental group.

Conclusions

When used in combination with PI-related prevention strategies, **MFDs reduce the incidence of PI (category 2 or worse) in both ICU and non-ICU** settings for all combined anatomical sites and specifically for the sacral area.

Evidence Snapshot

ICU/OTHER UNITS

Silicone adhesive multilayer foam dressings to prevent hospital-acquired sacrum pressure ulcers; an economic evaluation based on a publicly funded pragmatic randomized controlled trial linked with real-world data

Neyt M, De Meester C, Devriese S, Marynen E, Beeckman D. Journal of Tissue Viability 2024;33(4):772-777

Study aim

Utilize real world data from a publicly funded RCT to determine the healthcare economic value of prophylactic multilayer foam dressings for PI prevention.

Key points

- Application of MBF dressings to the sacrum for a population similar to the previously published RCT population can be supported from both a clinical and economic perspective, when used in combination with PI-related prevention strategies.

Methodology

- An economic evaluation was performed from a health care payer's perspective; with a cost-consequences analysis over a one-year time horizon.
- The evaluation was based on a Belgian publicly funded pragmatic RCT, linked with real-world data from an administrative claims database and an updated Belgian cost analysis.
- Silicone adhesive multilayer foam dressings as an adjuvant prophylactic therapy to prevent hospital-acquired pressure ulcers: a pragmatic noncommercial multicentre randomized open-label parallel-group medical device trial. Beeckman D, Fourie A, et al. British Journal of Dermatology 2021;185(1):52-61.

Results

Relevant data from reference RCT*

- Sacrum PIs (category 2 or worse) were observed in 2.8% (30/1062) of patients in the intervention (dressing) group and 4.8% (26/539) of patients in the control (no dressing) group; relative reduction (RR) of 41% (p=0.04).
- The absolute risk reduction (ARR) of 2.0% coincided with a number needed to treat (NNT) to prevent one new sacrum PI (category 2 or worse) of 50.
- Percentage of category 2 sacrum PIs was 76.7% in the intervention (dressing) group and 65.5% in the control (no dressing) group.
- A mean of 3.0 dressings per patient was used in the intervention group.
- The time taken per dressing change was approximately 2 minutes.

Conclusions

- A pragmatic RCT has shown that the preventive use of MBF dressings on the sacrum reduced the incidence of sacral PIs in hospitalised patients. A subsequent cost-consequences analysis has demonstrated that the intervention provides benefits by avoiding sacrum PI (NNT = 50) while being already cost neutral in a conservative scenario.

Cost consequences analysis

Variable	Value	Comments
Prevention costs: Dressings	€30	Based on average use of 3 dressings per patient
Time for dressing changes (3 x 2 min)	€4.52	Based on hourly nurse cost of €45.16 (health index adjustment of Belgian manual for hospital intervention pricing)
Total investment costs per PI avoided	€1726	Calculation: [Dressing costs (30) + dressing change time costs (4.52)] x NNT (50)
PI category 2 treatment cost	€212	Based on assumption on no increase in LoS
PI category 3 or 4 treatment cost	€4313	Based on assumption of increase in LoS of 5 days and averaging of category 3 and 4 costs (3907 + 4719 / 2).
Total savings	**€1631**	Calculation; [% category 2 PI in RCT (65.4) x category 2 PI treatment cost (212)] + [% category 3 or 4 PI in RCT (34.6) x category 3 or 4 PI treatment costs (4313)]

Evidence Snapshot

OTHER UNITS

Effectiveness of Prophylactic Sacral Protective Dressings to Prevent Pressure Injury: A Systematic Review and Meta-Analysis

Fulbrook P, Mbuzi V and Miles S, International Journal of Nursing Studies, 2019;100:103400

Study Aim

To assess the effectiveness of prophylactic sacral protective dressings to prevent PI.

Key points

- Systematic review and meta-analysis of six randomized controlled trials (RCTs) published between 2008 and 2019 suggests using a prophylactic sacral dressing can significantly reduce PI.
- Significant reduction (70%) in pressure injury (PI) incidence with prophylactic sacral dressings.

Methodology

- Data sources: CINAHL, MEDLINE, Scopus, Web of Science.
- Two reviewers independently extracted data.
- 557 studies initially identified, 6 included in the final review (five in acute care settings, one in a residential aged care setting).
- Sample sizes ranged from 71 to 440 participants.
- Three different sacral dressings were studied:

  Mepilex® Border Sacrum **Allevyn® Life Sacrum** **Allevyn® Gentle Border**

Results

Primary outcome:

- A significant reduction (70%) in pressure injury incidence with prophylactic sacral dressing.
- Subgroup analysis:
  - Intensive care studies: large relative risk reduction (83%).
  - Studies using the same dressing: moderate relative risk reduction (68%).

Author / Year	Intervention	PI Incidence	
		Intervention	Control group
Aloweni et al. 2017	Silicone foam dressing	3.9% (5) n=129	5.4% n=202
Forni et al. 2018	Multi-layer polyurethane foam dressings plus standard care	4.5% (8) n=177	15.4% n=182
Kalowes et al. 2016	5-layered soft silicone foam dressing plus standard care	0.6% (1) n=184	3.8% n=182
Lee et al. 2013	Silicone adhesive dressing	2.8% (1) n=36	25.7% n=35
Santamaria et al. 2013	5-layered soft silicone foam dressing plus standard care	0.9% (2) n=219	3.% n=221
Santamaria et al. 2018	5-layered soft silicone foam dressing plus standard care	1.3% (2) n=150	8.4% n=155

Conclusions

- Prophylactic sacral dressings are effective in reducing pressure injury incidence by ₹0%.
- Intensive care patients benefit most from these dressings.
- More research is needed to identify the optimal dressing type.

Evidence Snapshot

OTHER UNITS

Effectiveness and Value Prophylactic 5-Layer Foam Sacral Dressings to Prevent Hospital-Acquired Pressure Injuries in Acute Care Hospitals: An Observational Cohort Study

Padula, W.V., Journal of Wound, Ostomy, and Continence Nursing, 2017; 44(5):413-419.

Study aim

To examine the effectiveness and value of prophylactic 5-layer sacral dressings in preventing HAPIs in acute care settings.

Key points

- Collected longitudinal data on dressing purchases from 38 acute care hospitals of the University Health Consortium (2010-2015).
- A significant reduction in pressure injury (PI) rates associated with: The use of prophylactic 5-layer foam sacral dressings and changes to Medicare payment

Methodology

- Patients allocated to either: **Intervention group**: received a prophylactic 5-layer foam sacral dressing (Mepilex® Border Sacrum). **Control group**: patients received standard PU prevention care only (no dressing).
- Primary outcome measure: incidence of pressure injuries.
- Secondary outcome: cost.

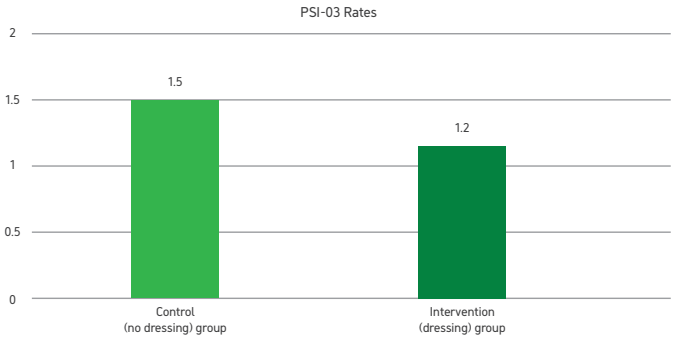
Results

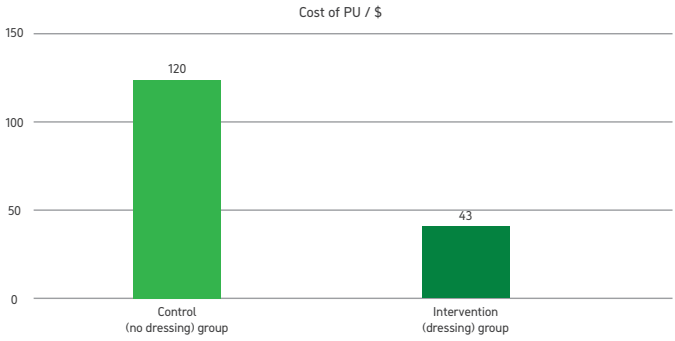
Primary outcome:

- **The incidence rate of PUs was significantly less in patients treated with the foam dressing than in the control group (1.2 vs 1.5, P=0.0063).**
- PSI-03: Patient Safety Indicator #3 for PI rates was reduced and correlated with increased use of prophylactic dressings.

Secondary outcomes:

- Hospitals purchased 2586 units of dressings per quarter (1.5 units/patient).
- Average hospital spent $19,506 per quarter.
- Reduced pressure injury rates led to decreased spending on pressure injury care.
- Spending on pressure injuries decreased from $120/patient to $43/patient.
- Investment in prophylactic dressings increased from $2.60/patient to $20/patient.





Conclusions

- Prophylactic 5-layer foam sacral **dressings are an effective component of pressure injury prevention** protocols.
- Hospitals adopting these technologies can expect **positive outcomes and value** for their investment.
- $77 cost reduction in the per patient treatment cost. from $120 per patient to $43 per patient.

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