

# Role of multi-layer foam dressings with Safetac in the prevention of pressure ulcers:

a review of the clinical and scientific data

An educational supplement in association with



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<b>Foreword</b>	<b>S3</b>
<b>Abstract</b>	<b>S4</b>
<b>Aims</b>	<b>S5</b>
<b>Introduction</b>	<b>S6</b>
Classification of pressure ulcers	S6
Aetiology of pressure ulcers	S6
Epidemiology of pressure ulcers	S6
Multi-layer foam dressings with Safetac	S8
Guidelines on the use of prophylactic dressings	S9
<b>Method</b>	<b>S10</b>
<b>Results</b>	<b>S10</b>
Clinical effectiveness	S11
Sacral pressure ulcers	S11
Heel pressure ulcers	S12
Medical device-related pressure ulcers	S12
Systematic reviews	S18
Cost-effectiveness	S18
Mode of action	S19
<b>Conclusion</b>	<b>S20</b>
<b>References</b>	<b>S20</b>
<b>Appendix</b>	<b>S22</b>

## Declaration of interest

This supplement was written by Phil Davies, who is an employee of Mölnlycke Health Care. It has been subject to double-blind peer review.

## About the author

Phil Davies has more than 25 years of experience of working in health-care-related industries. During that time, he has authored and contributed to numerous peer-reviewed journal articles and conference presentations (oral and poster) relating to wound care and other areas of health care. Phil was awarded a BSc (Hons) Medical Cell Biology and Biochemistry by the University of Liverpool (United Kingdom) in 1989.

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## A paradigm shift: changing the perception of unavailability

I have seen much technology come and go over the years, with each episode being heralded by someone saying 'this is the greatest invention ever'. While I was sceptical each time, some of these advances, such as moist wound healing and negative pressure wound therapy, really did change the course of wound care. The use of prophylactic dressings as a component of pressure ulcer (PU) prevention is one such advance.

Pressure ulcers in critically ill patients have often been described as unavoidable. However, the findings of studies on a bordered sacral foam dressing, when used prophylactically as part of a PU prevention strategy, have changed the paradigm of unavailability in these patients. Before 1990, the PU incidence in this patient group averaged 33%, with the ulcers often perceived as inevitable or unavoidable. Even with the advent of better support surfaces in the next decade, the incidence did not change much, ranging between 8% and 40%.<sup>1</sup> In the past decade, incidence has been reported more often by the type of patient, but surgical patients in intensive care unit (ICU) still have an incidence of 6.2% to 23.9%.<sup>2</sup> Randomised controlled trials (RCTs) conducted in the ICU by Santamaria et al.<sup>3,4</sup> have changed that paradigm of unavailability. Their combined data show that the 371 critically ill patients who received customary care with the bordered sacral foam dressing *in situ* had PU rates of 0–3.1%, compared with 3.8–13.1% for the control groups. A variety of less well-controlled studies involving more than 1000 patients provide supporting data. These reductions in PU rates really challenge the perception of unavailability in critically ill patients.

Traditionally, PUs occurring in the operating room (OR) were also perceived to be unavoidable. There are fewer studies on the use of the bordered sacral foam dressing in the OR setting. However, Santamaria et al.'s study started in the emergency department (ED), where randomisation took place. Other studies, which are less powered or had historical controls, also reported reduced numbers of ulcers acquired during surgery. The OR may be a new frontier for PU prevention. I would encourage you to work with your OR staff to identify high-risk patients before surgery and to place the dressings on the areas subjected to pressure before the case begins.

Pressure ulcers from medical devices may not be easily preventable because the device may not be removable. Again, I would encourage you to examine the published work and consider placing thin foam or transfer dressings when the device is placed on the patient. This will require collaboration with the ED and OR staff, as well as respiratory therapists.

Where will you meet resistance from others? Pressure ulcer prevention has classically been grouped into interventions that reduce the magnitude of pressure, such as support surfaces, and those that reduce the duration of pressure, such as turning. So, one question you will hear is: 'How can a dressing do all of that?' Laboratory studies of the bordered sacral foam have showed that: the foam component redistributes pressure from at-risk tissue to the surrounding tissue; the adhesive Safetac and layered structure allow the shear forces to be 'absorbed' by the dressing rather than the skin and soft tissue; the outer surface reduces friction; and the middle layers absorb and transfer sweat to manage microclimate. When comparing potential prophylactic dressings, therefore, look at the design of the dressing because its components work in concert to reduce all aspects of PU development. Foam by itself can reduce pressure but, when the patient is positioned with the head of the bed elevated, it will be unable to reduce shear forces at the sacrum.<sup>5</sup>

A second question you will hear is: 'How can we justify the cost?' To determine the cost benefit, you will need to know the number of current PUs and their usual costs. You will need to address cost avoidance, which may be a challenge to explain. However, if you know the number of beds in your hospital, the number of yearly admissions and the rate of hospital-acquired PUs, you can estimate some savings. For example, in a 300-bed hospital with 15 000 annual admissions and a 3.5% PU rate, you would expect to see 525 patients a year with PUs. Assuming a treatment cost of \$10 700 per patient, the total cost of treating PUs would be: \$5 617 500 a year. Reducing the incidence by 1% would save \$1 605 000. Using those data, you can subtract the price of the dressings to your hospital and determine the cost avoidance. Santamaria et al.'s data, which provide a similar example of cost savings, offer a method of estimating cost avoidance in larger health-care systems.

The evidence base referred to above is summarised in this document. This thorough review provides a firm foundation of work, which we can use to change our practice in PU prevention.



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- 1 Cuddigan, J. Critical care. In Cuddigan, J. Pressure Ulcers in America: Prevalence, Incidence, and Implications for the Future. NPUAP 2000
- 2 Cuddigan, J. Critical care. In: Pieper B, National Pressure Ulcer Advisory Panel, editors. Pressure Ulcers: Prevalence, Incidence, and Implications for the Future. NPUAP, 2012
- 3 Santamaria, N., Gerdtz, M., Sage, S. et al. 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. *Int Wound J* 2015; 12: 3, 302–308
- 4 Santamaria, N., Gerdtz, M., Liu, W. et al. Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial. *J Wound Care* 2015; 24: 8, 340–345
- 5 Call, E., Pedersen, J., Bill, B. et al. Enhancing pressure ulcer prevention using wound dressings: what are the modes of action? *Int Wound J* 2015; 12: 4, 408–413

## Background

Despite the implementation of prevention strategies, pressure ulcers (PUs) continue to be a challenging health problem for patients (and their carers), clinicians and health-care providers. One area of growing interest is the use of prophylactic dressings (which were originally designed for the treatment of PUs and other wound types) as a component of standard prevention measures. Over the past few years, a large amount of scientific and clinical data relating to this subject has been published in peer-reviewed journals and presented at international meetings and conferences. A substantial proportion of these data relate to one group of dressings: multi-layer foam dressings with Safetac, which are manufactured by Mölnlycke Health Care (Gothenburg, Sweden). This evidence pool has influenced the experts involved in updating the Clinical Practice Guideline, produced by the National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance, on the prevention and treatment of PUs. The updated Guideline, published in 2014, recommends that, as part of their PU prevention regimens, clinicians should consider applying prophylactic dressings to bony prominences in anatomical areas that are frequently subjected to friction and shear.

## Aims

A literature review was undertaken to identify clinical data from the entire evidence hierarchy, as well as scientific data from laboratory studies, on the use of multi-layer foam dressings with Safetac in the prevention of pressure ulceration.

## Method

The MEDLINE (National Library of Medicine, Bethesda, US) and EMBASE (Elsevier BV, Amsterdam, Netherlands) bibliographic databases were searched. In addition, abstract books and proceedings documents relating to national and international conferences were scanned in order to identify presentations (i.e. oral, e-posters and posters) of relevance to the review.

## Results

Clinical and health economic experts have undertaken numerous studies, including randomised controlled trials, to assess the efficacy and cost-effectiveness of using multi-layer foam dressings with Safetac as a component of standard PU prevention strategies. The results of these studies indicate that the application of multi-layer foam dressings containing Safetac can reduce the occurrence of PUs on anatomical locations such as the sacrum and the heel, and underneath medical devices. Scientists have also developed and used laboratory methods to gain a better understanding of how prophylactic dressings work. The results of these studies indicate that the composition of foam dressings containing Safetac (i.e. their multi-layer structure) sets them apart from other dressings due to their ability to mediate the effects of physical forces (i.e. pressure, friction and shear) and control microclimate, all of which contribute to pressure ulceration.

## Conclusion

The evidence pool clearly indicates that the prophylactic use of multi-layer foam dressings with Safetac as a component of standard prevention measures is beneficial to the clinician, the health-care provider and the patient. It should be noted that the findings outlined in this review may not be transferable to other products as their makeup and components are likely to differ significantly from those of multi-layer foam dressings with Safetac. As the importance of evidence-based practice and the need for cost-effective care continues to grow, clinicians and provider should carefully consider this point when selecting prophylactic dressings for PU prevention.

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**Keywords:** pressure ulcer ■ prevention ■ multi-layer foam dressings with Safetac

When making decisions about clinical interventions, it is common practice to consider the relative weight of the available data according to the type and quality of studies from which they originate. In this so-called hierarchy of clinical evidence (Figure 1), randomised controlled trials (RCTs) and systematic reviews are generally considered to be the 'gold standards' for judging the benefits of interventions.<sup>1,2</sup>

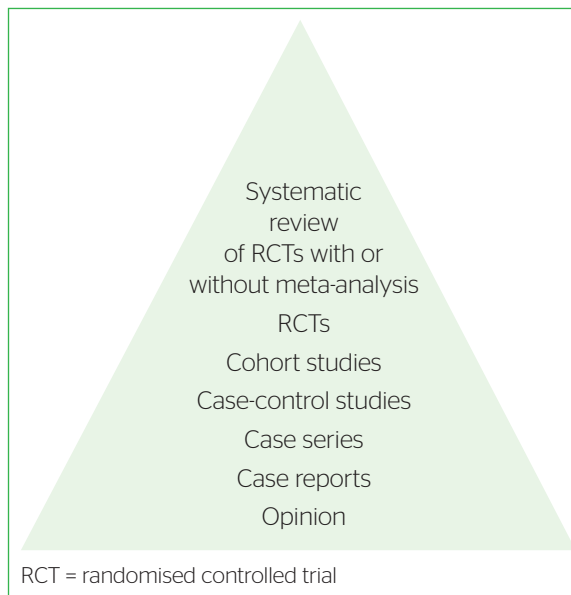
However, some experts have begun to question the true value of the evidence hierarchy and the over-reliance on RCTs in decision-making, focusing on their limitations and the practical difficulties in undertaking them.<sup>3</sup> Concerns have also been raised that evidence from RCTs does not easily inform day-to-day clinical decision-making relating to individual patient needs.<sup>4,5</sup> In relation to wound care, it has been suggested that the extended definition of evidence-based medicine by Sackett et al.<sup>6</sup>

*'Evidence-based medicine is not restricted to randomised trials and meta-analyses, but involves exploration of all types of the best available evidence with which to answer our clinical question'*<sup>6</sup>

may be more appropriate.<sup>7</sup> While this does not indicate that all research data are equally valid, it does mean that all the available evidence should legitimately be considered and evaluated on its own merits.

With this in mind, this review considers clinical data from the entire evidence hierarchy, as well as scientific data from laboratory studies, on the use of multi-layer foam dressings with Safetac in the prevention of pressure ulceration. It is not a systematic review but instead aims to summarise the available evidence in one place and draw conclusions from it.

- 1 Barton, S. Which clinical studies provide the best evidence? The best RCT still trumps the best observational study. *BMJ* 2000; 321: 7256, 255-256.
- 2 Akobeng, A.K. Community child health, public health, and epidemiology. *Arch Dis Child* 2005; 90: 8, 837-840.
- 3 Kaplan, B.J., Giesbrecht, G., Shannon, S., McLeod, K. Evaluating treatments in health care: the instability of a one-legged stool. *BMC Med Res Methodol* 2011; 11: 65. Available at: <http://biomedcentral.com/content/pdf/1471-2288-11-65.pdf> (accessed December 2015).
- 4 White, R., Jeffery, S. The evidence debate in wound care: is patient welfare an issue? *Wounds UK* 2010; 6: 3, 10.
- 5 White, R., Maylor, M., Iversen, C. Evidence is 'in', ignorance is 'out': a dilemma for advanced wound care products. *Wounds UK* 2010; 6: 3, 114-116.
- 6 Sackett, D.L., Rosenberg, W.M.C., Gray, J.A.M. et al. Evidence based medicine: what is and what isn't. *BMJ* 1996; 312: 71.
- 7 Gottrup, F. Evidence controversy in wound care. *BMJ* 2007; 335: 244.



**Figure 1. Hierarchy of clinical evidence (adapted from Akobeng, 2005)<sup>2</sup>**

#### Key points:

- Evidence-based practice should explore all types of available evidence
- This document aims to summarise all of the evidence (generated from clinical and laboratory studies) relating to the use of multi-layer foam dressings with Safetac as a component of standard measures for the prevention of pressure ulceration

### Classification of pressure ulcers

A pressure ulcer (PU) is a localised injury to the skin and/or underlying tissue (usually over a bony prominence) resulting from pressure, or pressure in combination with shear. The international system referred to by the National Pressure Ulcer Advisory Panel (NPUAP), the European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA) is widely used to categorise PUs based on depth and complexity.<sup>1</sup> (Table 1)

#### Key points:

- All health-care professionals are likely to encounter people vulnerable to, or with, pressure ulcers
- Pressure ulcers are classified according to the depth of tissue damage and the exposure of bone, tendon and muscle

### Aetiology of pressure ulcers

The primary cause of pressure ulceration is a sustained mechanical load that is applied to tissues, generally in the vicinity of a bony prominence. Both a high load for a short period of time and a low load for a prolonged period of time can lead to tissue damage.<sup>1</sup> Load that is distributed in a non-uniform or localised manner is potentially far more damaging to tissues than that distributed in a uniform manner.<sup>2</sup>

A number of aetiological mechanisms are known to contribute to pressure ulceration; these include ischaemia, reperfusion injury, impaired lymphatic drainage and sustained cell deformation.<sup>3,4,5</sup>

Risk factors for pressure ulceration are generally categorised as intrinsic (Figure 2) or extrinsic (Figure 3). The latter include the direct application of pressure and three

other elements – friction, shear and microclimate (humidity/moisture and temperature) – that can potentiate the effects of pressure and are cross-linked to each other.<sup>6</sup>

#### Key points:

- Risk factors for pressure ulcers are numerous
- The impact of friction, shear and microclimate can potentiate the effects of pressure and are cross-linked to each other

### Epidemiology of pressure ulcers

Historically, the number of people with PUs has been reported primarily using measures of prevalence (i.e. the number of people with a PU at a defined moment or period in time) or incidence (i.e. the number of people developing PUs over a defined time period within a specified population).

It has been reported that the prevalence of PUs in health-care settings around the world ranges from 0% to 72.5%<sup>1</sup>, with large variations observed between different geographical regions and clinical settings (Table 2).

Data on PU occurrence rates outside of acute care are relatively lacking. Hence, simply counting people with PUs in hospital settings may considerably underestimate the total number affected.

PUs can occur at any body site where skin and soft tissue loading is prolonged or excessively high (Figure 4). However, the sacrum and heel are reported as the first and second most common locations, respectively.<sup>7,8</sup> In children and neonates, occipital and other head (including facial) PUs are common.<sup>1</sup> Medical device-related PUs are a growing concern, particularly in paediatric populations.<sup>9</sup>

Despite the implementation of prevention strategies, PUs continue to be a challenging health problem for patients ►<sup>PS</sup>

**Table 1. Classification of pressure ulcers (adapted from NPUAP, EPUAP and PPPIA, 2014)<sup>1</sup>**

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

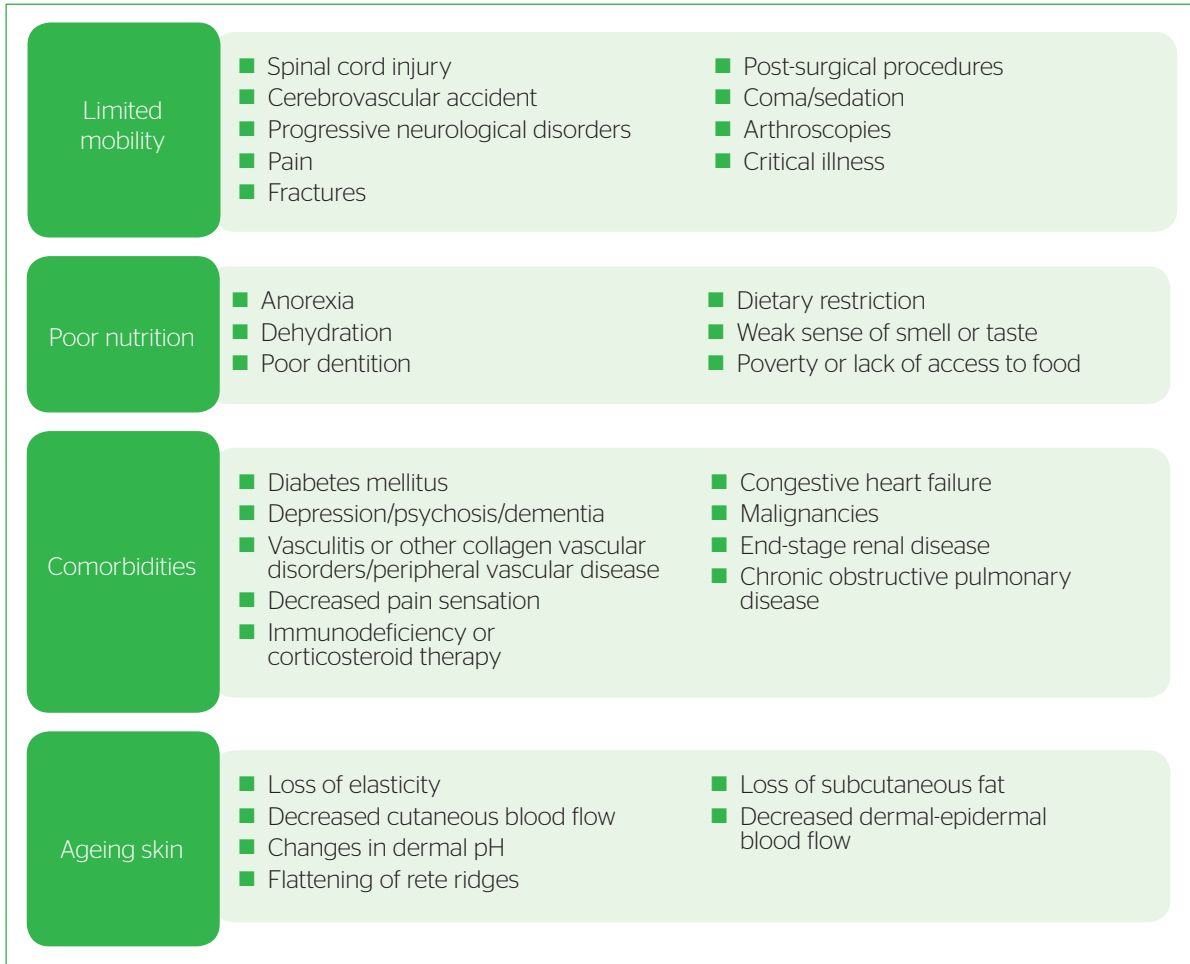


Figure 2. Intrinsic risk factors for pressure ulceration (NPUAP, EPUAP and PPIIA, 2014)<sup>1</sup>

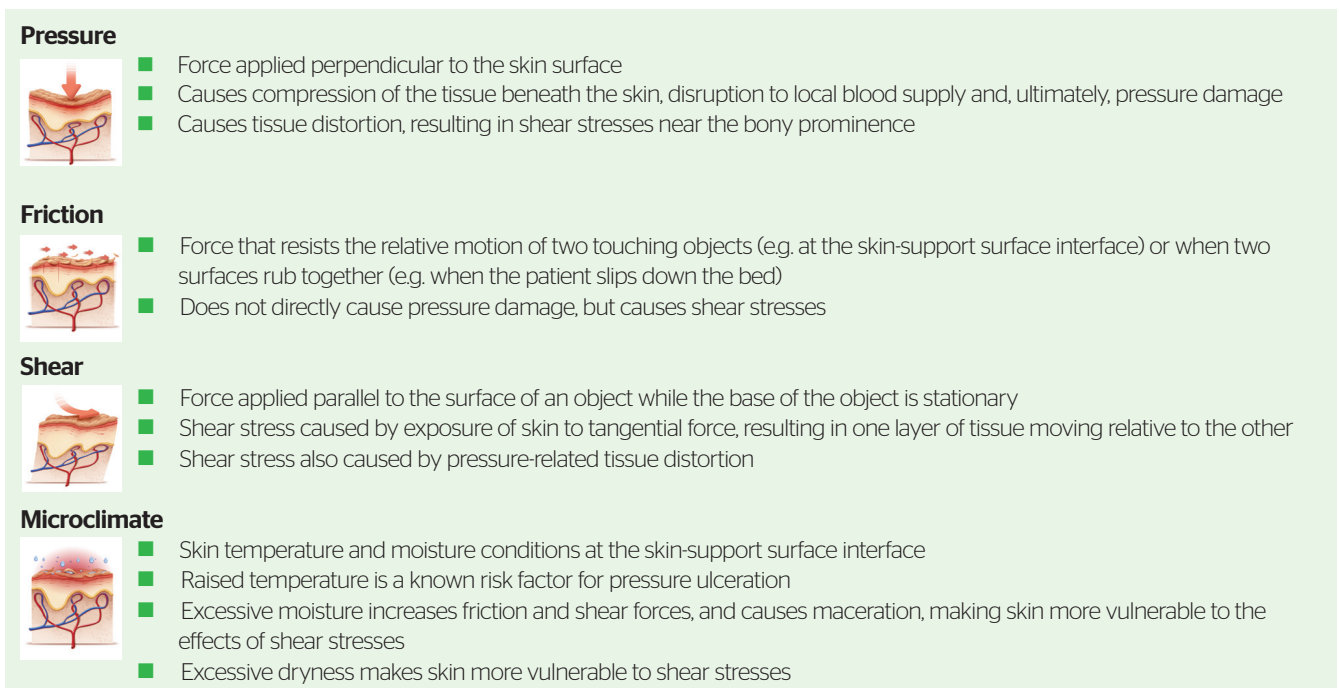
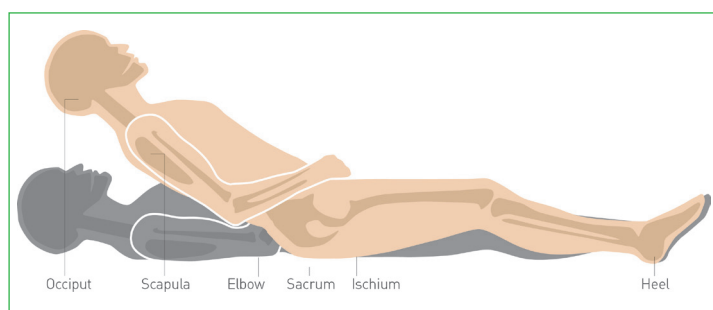


Figure 3. Extrinsic risk factors for pressure ulceration

**Table 2. Pressure ulcer prevalence and incidence (adapted from NPUAP, EPUAP and PPIA, 2014)<sup>1</sup>**

Setting / population	Prevalence rates	Incidence and facility-acquired rates
Acute care	0-46%	0-12%
Critical care	13.1-45.5%	3.3-53.4%
Aged care	4.1-32.2%	1.9-59%
Paediatric care	0.47-72.5%	0.25-27%
Operating room setting	–	5-53.4%



**Figure 4. Areas at risk of pressure ulceration**

**Box 1. Characteristics of an ideal dressing or dressing system (adapted from Thomas, 2003)<sup>42</sup>**

- Creates an ideal microclimate for rapid and effective healing
- Prevents dehydration
- Permeable to oxygen
- Provides good absorption of blood and exudate
- Protects against secondary infection
- Has sufficient mechanical protection to wound
- Is non-adherent
- Is non-toxic
- Is non-allergenic or non-sensitising
- Is non-flammable
- Does not shed loose material into the wound
- Conforms to anatomical contours
- Resists tearing
- Its properties remain constant in a range of temperatures and humidities
- Has a long shelf life
- Has small bulk (avoids storage problems)
- Accepts and releases medicaments
- Is cost-effective

► (and their carers), clinicians and health-care providers. This has led clinicians and scientists to undertake research in the hope of discovering innovative ways to further reduce the risk of pressure ulceration. One area of growing interest to researchers is the use of prophylactic dressings as a component of standard prevention measures.

In 2005, the results of a study involving the use of an *in vitro* porcine model to measure pressure and shear forces on the skin and subcutaneous tissue were published. The findings revealed that shear forces on both layers of tissue decreased when various dressings were applied to the skin.<sup>10</sup>

Over the past few years, a large amount of scientific and clinical data on this subject has been published in peer-reviewed journals and presented at international meetings and conferences. A substantial proportion of these data relate to one particular group of dressings: multi-layer foam dressings with Safetac, which are manufactured by Mölnlycke Health Care (Gothenburg, Sweden).

**Key points:**

- The sacrum and the heel are the most common locations for pressure ulcers (PUs). Medical device-related pressure ulcers are a growing concern
- The prevalence of PUs in health-care settings around the world ranges from 0% to 72.5%, with large variations between different geographical regions and clinical settings
- Despite the implementation of prevention strategies, PUs continue to be a challenging health problem for patients (and their carers), clinicians and health-care providers

**Multi-layer foam dressings with Safetac**

Ever since a possible mechanism for re-epithelialisation under occlusion in the presence or absence of eschar was identified,<sup>11</sup> the concept of moist wound healing has shaped the development and use of modern wound-care products. The ability to provide a moist wound environment that is conducive to healing is just one of many characteristics that an 'ideal' wound dressing should possess (*Box 1*).

In 1990, Mölnlycke Health Care launched the first of its innovative wound dressings utilising patented Safetac technology. Currently, the Safetac range includes wound contact layers (with and without antimicrobial agents), film dressings (with and without antimicrobial agents), multi-layer absorbent foam dressings (with and without antimicrobial agents), scar treatments and sealants which, collectively, go a long way in providing clinicians with products that fulfil the characteristics listed in *Box 1*.

Safetac technology involves the use of soft silicone. This material readily adheres to intact dry skin, and will remain *in situ* on the surface of a moist wound or damaged surrounding skin without adhering to these fragile tissues.<sup>12</sup> Consequently, dressings with Safetac can be applied and reapplied without damaging the wound or stripping epidermis in the peri-wound region,<sup>13</sup> while also minimising pain and psychological stress at dressing removal.<sup>14,15</sup> The gentle but effective seal that forms between the intact skin and a dressing with Safetac inhibits the movement of exudate onto the surrounding skin,<sup>16</sup> thereby helping to prevent moisture-related damage (e.g. maceration) to the peri-wound region.<sup>17</sup>

Although dressings with Safetac were originally developed for a variety of wound types, multi-layer foam dressings with Safetac (predominantly Mepilex Border Sacrum (*Figure 5*) and Mepilex Border Heel) are increasingly being used prophylactically to help reduce the occurrence of pressure ulceration in at-risk patients (*Box 2*).



**Key points:**

- Dressings with Safetac were originally developed for use in the treatment of wounds
- Results of clinical studies demonstrate that dressings with Safetac prevent tissue trauma and minimise dressing-related pain on removal
- Dressings with Safetac are increasingly being used prophylactically as a means of reducing the occurrence of PUs

**Guidelines on the use of prophylactic dressings**

In 2009, as a result of collaboration between the NPUAP and the EPUAP, the first edition of the Clinical Practice Guideline on the prevention and treatment of PUs was published.<sup>18</sup> More recently, the PPIA has worked with the NPUAP and the EPUAP to produce a second edition of the Guideline,<sup>1</sup> which includes updated recommendations and research summaries, plus a number of new sections on emerging fields of interest.

One such new section, entitled Prophylactic Dressings, includes the following recommendation:

*‘Consider applying a polyurethane foam dressing to bony prominences (e.g. heels, sacrum) for the prevention of pressure ulcers in anatomical areas frequently subjected to friction and shear’<sup>1</sup>*

The results of four clinical studies are cited in support of this recommendation; three investigated the efficacy of multi-layer foam dressings with Safetac.<sup>19,20,21</sup> A similar recommendation has been added to the updated section, entitled Medical Device Related Pressure Ulcers.<sup>1</sup>

*‘Consider using a prophylactic dressing for preventing medical device related pressure ulcers’*

Importantly, the Guideline also recommends that clinicians:

*‘Continue to use all other preventive measures necessary when using prophylactic dressings’*

Further information about the recommendations is given in the Appendix at the back of this document.

In 2014, the recommendations of a consensus panel on the use of dressings as an adjunct to PU prevention strategies were published.<sup>22</sup> Following an extensive literature review process, the panel identified 28 eligible publications, which formed the basis of the discussions. The consensus statements (Box 3) that emanated from the discussions were graded according to the strength of the supporting evidence:

- Level A: derived from high-quality RCTs
- Level B: derived from other evidence, such as well-designed, non-randomised clinical trials, clinical cohort studies and case-control studies with a non-biased selection of study participants and consistent findings

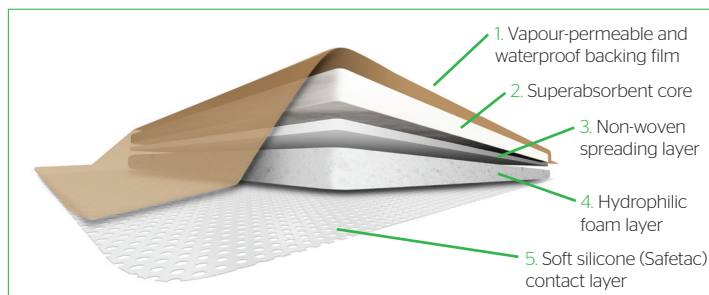
**Box 2. Multi-layer absorbent foam dressings with Safetac that have been used prophylactically in the prevention of pressure ulcers**

Dressing	Description
Mepilex	Absorbent, polyurethane foam dressing with a vapour-permeable film backing and a Safetac wound contact layer
Mepilex Heel	Specifically shaped version of Mepilex to fit the heel
Mepilex Lite	Thinner and less absorbent version of Mepilex
Mepilex Border	All-in-one island dressing consisting of a Safetac wound contact layer, a three-layered flexible and absorbent pad (polyurethane foam, non-woven spreading layer, and a layer with superabsorbent polyacrylate fibres) to wick and absorb exudate, and an outer film that is vapour-permeable and waterproof
Mepilex Border Heel	Specifically shaped version of Mepilex Border to fit the heel
Mepilex Border Sacrum	Specifically shaped version of Mepilex Border to fit the sacral area
Mepilex Ag	Absorbent, polyurethane foam dressing containing silver sulphate and activated charcoal, with a vapour-permeable backing and a Safetac wound contact layer

- Level C: derived from expert opinion and can include data from other sources.

The consensus panel concluded that there is adequate evidence to recommend the use of multi-layer foam dressings with Safetac (Mepilex Border Sacrum and Mepilex Heel) for PU prevention on the sacrum, buttocks, and heels in high-risk patients in the emergency department (ED), intensive care unit (ICU) or operating room (OR). However, the panel stressed that dressings should be considered as a component of (and not a replacement for) standard PU prevention practices:

- Turning and repositioning to reduce the duration of pressure



**Figure 5. Diagrammatic representation of a multi-layer foam dressing with Safetac (Mepilex Border Sacrum)**

**Box 3. International consensus panel's statements on the use of prophylactic dressings<sup>22</sup>**

- Consider using a five-layer soft-silicone bordered foam dressing to enhance, but not replace, PU prevention strategies for the sacrum, buttock and heel (SOE=A)
- Before selecting a dressing, consider the status of the skin and the ease of dressing removal, in order to prevent mechanical stripping (SOE=B)
- Apply the dressing to dry, intact skin. Do not use emollients or other barriers as they will prevent the dressing from adhering to the skin (SOE=C)
- Choose a dressing that exceeds the area of tissue on the sacrum, buttocks or heel needing protection from pressure and shear (SOE=C)
- Inspect the skin beneath the dressing on a regular basis in accordance with standards of care and/or institutional policy (SOE=C)
- Dressings should be changed in accordance with institutional policy and the manufacturers' recommendations, or as clinically indicated (SOE=C)
- Consider discontinuing the dressing as the patient's risk of pressure ulceration decreases, as indicated by clinical assessment (SOE=C)
- Consider placing a five-layer soft-silicone bordered foam dressing onto the buttocks and sacrum before prolonged procedures or anticipated events when the patient cannot move or be moved from the supine position (SOE=B)
- Consider placing soft-silicone dressings onto the buttocks and sacrum when the head of the bed must be continuously elevated (SOE=B)
- Consider placing multi-layer soft-silicone foam dressings on the heels before prolonged procedures or anticipated events when the patient's leg(s) cannot move or be moved from the supine position (SOE=A)
- Consider placing multi-layer soft-silicone foam dressings to the heels of patients at risk of shear injury (SOE=B)

Pressure ulcer - pressure ulcer; SOE - strength of supporting evidence

- Using therapeutic support surfaces to reduce the magnitude of pressure
- Keeping the head of the bed at or below 30° elevation in order to reduce the risk of shear
- Keeping the skin clean and dry in order to control the microclimate
- Providing nutrition and hydration to maintain tissue tolerance for pressure.<sup>22</sup>

**Method**

An extensive literature review was undertaken to identify published articles describing the use of multi-layer foam dressings with Safetac as a component of standard PU prevention practices.

Electronic bibliographic databases – MEDLINE (National Library of Medicine, Bethesda, US) and EMBASE (Elsevier BV, Amsterdam, Netherlands) – were searched using the following search term strategy: 'silicone or Safetac' AND 'dressing' AND 'prevent\$' AND ('pressure ulcer' OR 'pressure injury' OR 'pressure sore' OR 'decubitus').

Abstract books and proceedings documents relating to national and international conferences (EPUAP meeting, Magnet Research Day, NPUAP Congress, Symposium on Advanced Wound Care (Spring and Fall), World Council of Enterostomal Therapists conference, World Union of Wound Healing Societies congress, Wound, Ostomy and Continence Nurses Society conference) held since 2010 were also scanned to identify presentations (oral, e-poster and poster) of relevance to the review.

Research data from all levels of the clinical evidence hierarchy (*Figure 1*) and from pre-clinical studies were included in the review. Due to the large number of items identified by the literature search, there was not enough space to critically evaluate every piece of research in this

**Key points:**

- An international clinical guideline,<sup>1</sup> developed by highly-regarded professional associations, recommends that consideration should be given to applying foam dressings to bony prominences (in conjunction with other prevention measures) to prevent pressure ulceration in anatomical areas that are frequently subjected to friction and shear
- Most of the research findings cited in support of this statement emanate from clinical studies on multi-layer dressings with Safetac
- The same guideline also recommends that prophylactic dressings should be considered for preventing medical device-related pressure ulcers

review, hence the key findings are summarised in one place and broad conclusions drawn from them.

**Results**

The literature search identified relevant research from RCTs (n=3, *Table 3*), non-randomised trials with concurrent or contemporaneous controls (n=6, *Table 4*), non-randomised trials with historical controls (n=17, *Table 5*), case series with no controls (n=4, *Table 6*) and review articles (n=10, *Table 7*). In addition, a number of evidence pieces were identified that refer to reductions in the occurrence of PUs following the introduction of new prevention regimes, one component of which was the use of multi-layer foam dressings with Safetac (n=10, *Table 8*). The search also identified two articles describing the findings of relevant economic studies and three research articles describing relevant pre-clinical data. The key findings of the identified evidence pieces are summarised in the following sections.

## Clinical effectiveness

### Sacral pressure ulcers

In 2010, Brindle reported on the results of a 3-month PU prevention initiative undertaken in a surgical trauma ICU. The initiative included the creation of intervention bundles, a novel tool for identifying patients at highest risk of pressure ulceration, and the prophylactic use of Mepilex Border Sacrum. The decision to use Mepilex Border Sacrum was based on its atraumatic adhesion technology and shape, which allows coverage of the sacrum and separation of the gluteal folds (thereby potentially reducing friction, decreasing shear between the gluteal skin folds and during patient repositioning, absorbing moisture on intact skin and resisting skin damage from minor faecal incontinence). Following application, dressings were peeled back and subsequently resealed on a daily basis to enable skin assessment. Dressing changes were performed every 3 days.

Of 93 patients screened, 41 were identified as at high risk and the prophylactic dressing was applied to their sacral regions. None of these patients developed PUs.

However, 6% (3/52) of the people who did not receive the dressing (i.e. those not deemed at high-risk) developed sacral PUs. Interestingly, three high-risk patients who had worn the prophylactic dressing developed PUs after it was discontinued (because they were discharged from the unit or the trial period had ended).<sup>23</sup>

In the same year, Qiuli and Qiongyu reported on the results of a RCT on the efficacy of multi-layer foam dressings with Safetac in the prevention of PUs in long-term bedridden patients. Some 52 patients were randomly assigned to the intervention group (standard PU prevention measures plus the application of a prophylactic dressing) or the control group (standard PU prevention alone). In the intervention group, Mepilex dressings were applied to the sacrococcygeal region, the hip and the heel (in cases of lower limb paralysis). In situations where Mepilex dressings could not closely adhere to the ankles, Mepilex Border dressings were used. Three new cases of PU were observed in the control group, compared with none in the intervention group.<sup>24</sup>

**Table 3. Randomised controlled trials**

Reference	Setting	Anatomical location(s) reported	Intervention group	Control group	Main results
Santamaria et al. <sup>21</sup> (2015)	ED/ICU	Sacrum/heel	Mepilex Border Sacrum or Mepilex Heel plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Fewer patients with PUs in intervention group (p=0.001):               <ul style="list-style-type: none"> <li>■ Intervention: 5/161 (3.1%)</li> <li>■ Control: 20/152 (13.1%)</li> </ul> </li> <li>■ NNT: 10 to prevent 1 PU</li> <li>■ Fewer PUs in intervention group:               <ul style="list-style-type: none"> <li>■ Overall: 7/161 (4.3%) vs 27/152 (17.8%) (p=0.002)</li> <li>■ Sacral: 2/161 (1.2%) vs 8/152 (5.2%) (p=0.05)</li> <li>■ Heel: 5/161 (3.1%) vs 19/152 (12.5%) (p=0.002)</li> </ul> </li> <li>■ Classification of PUs: not stated</li> </ul>
Kalowes et al. <sup>26</sup> (2012)	ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Fewer patients with PUs in intervention group (p=0.001):               <ul style="list-style-type: none"> <li>■ Intervention: 1/184 (0.5%)</li> <li>■ Control: 7/183 (3.8%)</li> </ul> </li> <li>■ Classification of PUs:               <ul style="list-style-type: none"> <li>■ Intervention: SDTI (n=1)</li> <li>■ Control: category/stage II (n=4), unstageable (n=2); SDTI (n=1)</li> </ul> </li> </ul>
Qiuli and Qiongyu <sup>24</sup> (2010)	AC	Sacrum/hip/heel	Mepilex or Mepilex Border plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Fewer patients with PUs in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 0/26 (0%)</li> <li>■ Control: 3/26 (11.5%)</li> </ul> </li> <li>■ Classification of PUs:               <ul style="list-style-type: none"> <li>■ Intervention: none</li> <li>■ Control: category/stage II (n=3)</li> </ul> </li> </ul>

Key: AC - acute care; ED - emergency department; ICU - intensive care unit; NNT - number needed to treat; PU - pressure ulcer; SDTI - suspected deep tissue injury

In a study of high-risk ICU patients, only one out of 50 subjects (2%) who received a multi-layer foam dressing with Safetac (Mepilex Border Sacrum) as an adjunct to standard care developed a PU, compared with four out of 35 subjects (11.4%) who received just standard care.

While these results were not statistically significant, the findings show a trend suggesting that this dressing type has a prophylactic effect. Commenting on the results, the researchers point out that PU incidence was lower than expected in both treatment groups.<sup>19</sup>

Chaiken conducted a clinical investigation involving 293 patients primarily admitted to an ICU with neurological, cardiac, infectious or respiratory problems. Baseline PU incidence was determined over a 35-month period, after which the effect of application of Mepilex Border Sacrum was assessed over a 6-month period. Baseline PU incidence reduced from 13.6% (during the 35-month observation period) to 1.8% (during the 6-month period when Mepilex Border Sacrum was applied). During the study, the sacral areas were examined twice daily and dressing changes were undertaken twice weekly or more frequently if required.<sup>25</sup>

In another clinical study involving Mepilex Border Sacrum, in which the dressing was changed every 3 days in a sample of 62 patients admitted to an ICU, a PU incidence rate of 7% was observed, compared with 12.5% in the period before the prophylactic dressing was used.<sup>20</sup>

More recently, Santamaria et al.<sup>21</sup> conducted a RCT (the 'Border Trial') in which 440 patients admitted to ICU were randomised in the ED to either an intervention group that received a multi-layer foam dressing with Safetac applied to the sacrum (Mepilex Border Sacrum) or heels (Mepilex Heel) as an adjunct to standard PU prevention or to a control group receiving just standard PU prevention. After transfer to the ICU, skin assessments were performed every 2 to 4 hours. Dressings were changed every 3 days or earlier if dislodged or soiled. There were significantly fewer patients with PUs in the intervention group compared with the control group (5 versus 20,  $p=0.001$ ), representing a substantial difference in incidence between the groups (3.1% versus 13.1%) and a number needed to treat (NNT) of 10 patients to prevent one PU. Fewer sacral PUs (2 versus 8,  $p=0.05$ ), heel PUs (5 versus 19,  $p=0.002$ ) and pressure injuries overall (7 versus 27,  $p=0.002$ ) were observed in the intervention group.<sup>21</sup>

In a similar RCT undertaken by Kalowes et al., ICU patients were randomised to either an intervention group that received Mepilex Border Sacrum on the sacral region as an adjunct to standard PU prevention or a control group receiving just standard PU prevention. Skin assessments were performed every 2 to 4 hours. Dressings were changed every 3 days or as needed. The dressing was found to be effective in reducing the incidence of PU (1/184 in the intervention group versus 7/183 in the control group ( $p=0.001$ )). The investigators reported that the Mepilex Border Sacrum dressing was easy to apply, remained *in situ*, was atraumatic to skin and impermeable to faeces and urine. An absence of fungal infection and dermatitis was also observed.<sup>26</sup>

While incontinence-associated dermatitis (IAD) has a different aetiology to that of pressure ulceration, the two conditions often coexist.<sup>27</sup> A non-randomised comparative cohort study was undertaken to assess the effect of Mepilex Border on the development of PUs and IAD in the sacral and coccygeal areas of patients in an intensive care setting. Some 52 patients were assigned to the intervention group (standard PU prevention measures plus application of Mepilex Border dressing) and 50 subjects to the control group (standard PU prevention alone). The incidence of pressure ulceration and IAD severity (as measured using the Incontinence Associated Dermatitis and its Severity (IADS) instrument) was significantly lower in the intervention group, compared with the control group: PU occurrence: 3/52 [6%] vs 23/50 [46%]  $p<0.001$ ; IADS scores:  $0.54 \pm 0.73$  vs.  $0.98 \pm 1.25$ ,  $p<0.033$ . A logistical regression analysis revealed that PU development was related to IADS score ( $p=0.003$ ), with the risk of developing a PU increasing 1.9-fold for every one point increase in IADS score.<sup>28</sup>

Details of other studies on the prevention of sacral PUs are provided in *Tables 3-8*.

### Heel pressure ulcers

The results of a number of studies described in the previous section of this report (Sacral Pressure Ulcers) demonstrate the potential for multi-layer foam dressings with Safetac to reduce the occurrence of PUs on different locations, including the heel.<sup>21,24</sup>

In addition to these, Santamaria et al. reported on the findings of a prospective cohort study to evaluate the effectiveness of Mepilex Border Heel dressings for the prevention of PUs in trauma and critically ill patients. A cohort of 191 critically ill patients was enrolled into the trial. A Mepilex Border Heel dressing was applied to each heel of each patient on admission to the ED. The dressings were retained with a tubular bandage for the duration of the patients' stay in the ICU. The skin under the dressings was examined daily and the dressings were replaced every 3 days. The comparator for the cohort study was the control group from the 'Border Trial' described earlier. Some 150 patients were included in the final analysis. There was no difference in key demographic or physiological variables between the cohorts, apart from a longer ICU length of stay in the cohort receiving prophylactic dressings. No PUs developed in any of the intervention cohort patients, whereas 14 patients in the control cohort developed a total of 19 heel PUs ( $p<0.001$ ).<sup>29</sup>

Details of other studies that focused on the prevention of heel PUs are provided in *Tables 3-8*.

### Medical device-related pressure ulcers

Medical device-related PUs are defined as pressure injuries associated with the use of devices applied for diagnostic or therapeutic purposes, wherein the PU that develops has the same configuration as the device. Pressure ulceration has been associated with a wide range of medical devices, including cervical neck collars, endotracheal tubes, immobilisers/halo casts, nasogastric tubes, non-invasive positive pressure ventilation devices, oxygen tubing,



**Table 4. Non-randomised trials with concurrent or contemporaneous controls**

Reference	Setting	Anatomical location(s) reported	Intervention group	Control group	Main results
Thul et al. <sup>43</sup> (2015)	ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group : <ul style="list-style-type: none"> <li>■ Intervention: 1/39 (2.6%)</li> <li>■ Control: 19/83 (22.9%)</li> </ul> </li> <li>■ Classification of PUs: not stated</li> </ul>
Park <sup>28</sup> (2014)	ICU	Sacrum	Mepilex Border plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group (p&lt;0.001): <ul style="list-style-type: none"> <li>■ Intervention: 3/52 (6%)</li> <li>■ Control: 23/50 (46%)</li> </ul> </li> <li>■ Classification of PUs: <ul style="list-style-type: none"> <li>■ Intervention: category/stage I (n=1), category/stage II (n=1), SDTI (n=1)</li> <li>■ Control: category/stage I (n=17), category/stage II (n=6)</li> </ul> </li> <li>■ Lower IADS scores in intervention group (p&lt;0.033): <ul style="list-style-type: none"> <li>■ Intervention: 0.54 ± 0.73</li> <li>■ Control: 0.98 ± 1.25</li> </ul> </li> </ul>
Brindle and Wegelin <sup>19</sup> (2012)	OR/ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Fewer patients with PUs in intervention group (NS): <ul style="list-style-type: none"> <li>■ Intervention: 1/50 (2%)</li> <li>■ Control: 4/35 (11.4%)</li> </ul> </li> <li>■ Fewer PUs in intervention group (NS): <ul style="list-style-type: none"> <li>■ Intervention: SDTI (n=1)</li> <li>■ Control: category/stage II (n=2), category/stage III (n=3), SDTI (n=3)</li> </ul> </li> </ul>
Cubit et al. <sup>44</sup> (2012)	AM	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group (NS): <ul style="list-style-type: none"> <li>■ Intervention: 1/51 (2%)</li> <li>■ Control: 6/58 (10.3%)</li> </ul> </li> <li>■ Classification of PUs: <ul style="list-style-type: none"> <li>■ Intervention: category/stage II (n=1)</li> <li>■ Control: category/stage I-II (n=6)</li> </ul> </li> </ul>
Brindle <sup>23</sup> (2010)	ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group: <ul style="list-style-type: none"> <li>■ Intervention: 0/41 (0%)</li> <li>■ Control: 3/52 (6%)</li> </ul> </li> <li>■ [Patients grouped as at either high or low risk of PU development. High-risk patients had dressings applied as part of their PU prevention]</li> <li>■ Classification of PUs: <ul style="list-style-type: none"> <li>■ Intervention: none</li> <li>■ Control: unstageable/SDTI (n=3)</li> </ul> </li> </ul>
Castelino et al. <sup>45</sup> (2012)*	ICU	Thorax	Mepilex Border plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group (p=0.0319) <ul style="list-style-type: none"> <li>■ Intervention: 0/104 (0%)</li> <li>■ Control: 12/114 (10.5%)</li> </ul> </li> <li>■ Classification of PUs: not stated</li> </ul>

\*Two studies described in reference. For details of other study, see Table 5.

Key: AM - acute medical; ICU - intensive care unit; NS - not statistically significant; OR - operating room; PU - pressure ulcer; SDTI - suspected deep tissue injury

**Table 5. Non-randomised trials with historical controls**

Reference	Setting	Anatomical location(s) reported	Intervention group	Control group	Main results
Johnstone and McGown <sup>38</sup> (2013)	CCU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 0/75 (0%)</li> <li>■ Historical comparison: 3/20 (15%) – 9/20 (45%) over a 3-month period (no. of PUs not reported)</li> </ul> </li> </ul>
Lientz <sup>37</sup> (2013)	CCU/ ICU/ OR	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ PU incidence in intervention group: 0/56 (0%)</li> <li>■ PU rate in historical control group: 5/year (no. of PUs not reported)</li> </ul>
Castelino et al. <sup>45</sup> (2012)*	ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 0/71 (0%)</li> <li>■ Historical comparison: 16.7% (no. of patients and PUs not reported)</li> </ul> </li> </ul>
Chaiken <sup>25</sup> (2012)	ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ PU incidence in intervention group: 5/275 (1.8%)</li> <li>■ PU prevalence in historical control group: 13.6% (no. of patients and PUs not reported)</li> <li>■ Classification of PUs:               <ul style="list-style-type: none"> <li>■ Intervention: category/stage II (n=2), SDTI (n=3)</li> <li>■ Historical comparison: not reported</li> </ul> </li> </ul>
Kiely <sup>46</sup> (2012)	ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ PU incidence in intervention group: 0% (no. of patients not reported)</li> <li>■ PU rate in historical comparison: 5/month (no. of patients and PUs not reported)</li> </ul>
Walsh et al. <sup>20</sup> (2012)	ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 3/62 (4.8%)</li> <li>■ Historical comparison: 12.5% (no. of patients and PUs not recorded)</li> </ul> </li> <li>■ Classification of PUs:               <ul style="list-style-type: none"> <li>■ Intervention: category/stage II (n=1), SDTI (n=2)</li> <li>■ Historical comparison: not reported</li> </ul> </li> </ul>
Cano et al. <sup>47</sup> (2011)	ICU/ CCU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 1/166 (0.60%)</li> <li>■ Historical comparison: 6.2% (ICU) and 8.8% (CCU) (no. of patients and PUs not reported)</li> </ul> </li> </ul>
Koerner et al. <sup>48</sup> (2011)	ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 0% (no. of patients not reported)</li> <li>■ Historical comparison: 20% (surgical) and 40% (medical/cardiac ICU) (no. of patients and PUs not reported)</li> </ul> </li> </ul>
Gentry and Wright <sup>49</sup> (2010)	CCU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 0/31 (0%)</li> <li>■ Historical comparison: 33% (no. of patients and PUs not reported)</li> </ul> </li> </ul>
Muldoon et al. <sup>50</sup> (2010)	ICU	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 1%</li> <li>■ Historical comparison: 6% (no. of patients and PUs not reported)</li> </ul> </li> </ul>

Table 5 (continued)

Baker et al. <sup>51</sup> (2014)	OR/ICU	Sacrum/heel	Mepilex Border Sacrum or Mepilex Border Heel plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ PU incidence in intervention group: 0/110 (0%)</li> <li>■ PU rate in historical comparison: 22/year (no. of PUs not recorded)</li> </ul>
Santamaria et al. <sup>29</sup> (2015)	ICU	Heel	Mepilex Border Heel plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Fewer patients with PUs in intervention group (<math>p&lt;0.001</math>):               <ul style="list-style-type: none"> <li>■ Intervention: 0/150 (0%)</li> <li>■ Historical comparison: 14/152 (9.2%)</li> </ul> </li> <li>■ Classification of PUs:               <ul style="list-style-type: none"> <li>■ Intervention: none</li> <li>■ Historical comparison: category/stage I (n=15), category/stage II (n=2), category/stage IV (n=2)</li> </ul> </li> </ul>
Haisley et al. <sup>52</sup> (2015)	CCU/ICU	Heel	Mepilex Border Heel plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Fewer patients with PUs (over 3-month period) in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 0/31 (0%)</li> <li>■ Historical comparison: 3 (no. of patients and PUs not reported)</li> </ul> </li> </ul>
Hsu et al. <sup>32</sup> (2010)	Not stated	Nose	Mepilex plus standard PU prevention measures	Hydrocolloids plus standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 0.9% (no. of patients and PUs not reported)</li> <li>■ Historical comparison: 47/797 (5.9%).</li> </ul> </li> <li>■ Classification of PUs:               <ul style="list-style-type: none"> <li>■ Intervention: not reported</li> <li>■ Historical comparison: category/stage I (n=51), category/stage II (n=33), category/stage III (n=2)</li> </ul> </li> </ul>
Van Capellen and Haggemacher <sup>53</sup> (2011)	ICU	Nose	Mepilex or Mepilex Lite plus standard PU prevention measures†	Hydrocolloid dressings plus standard PU prevention measures	<ul style="list-style-type: none"> <li>■ PU rate in intervention group lower than in historical comparison (no. of patients and PUs not reported)</li> <li>■ Dressings with Safetac associated with better patient comfort and less nursing time required for application and removal</li> </ul>
Kuo et al. <sup>54</sup> (2014)	PC	Tracheostomy site	Mepilex Ag plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence underneath tracheostomy tubes and ties in the intervention group (<math>p=0.02</math>):               <ul style="list-style-type: none"> <li>■ Intervention: 0/41 (0%)</li> <li>■ Historical comparison: 11/93 (11.8%)</li> </ul> </li> <li>■ Classification of PUs:               <ul style="list-style-type: none"> <li>■ Intervention: none</li> <li>■ Historical comparison: category/stage I (n=9), category/stage II (n=2)</li> </ul> </li> </ul>
Boesch et al. <sup>30</sup> (2012)	ICU	Tracheostomy site	Mepilex Lite plus standard PU prevention measures	Standard PU prevention measures	<ul style="list-style-type: none"> <li>■ Lower PU incidence in intervention group:               <ul style="list-style-type: none"> <li>■ Intervention: 0.3% (no. of patients and PUs not reported)</li> <li>■ Historical comparison: 11/136 (8.1%)</li> </ul> </li> <li>■ Classification of PUs: not possible to determine</li> </ul>

\*Two studies described in reference. For details of other study, see Table 4. †Mepitac with Safetac (fixation tape) also used as part of dressing regimen

Key: CCU - critical care unit; ICU - intensive care unit; OR - operating room; PC - paediatric care; PU - pressure ulcer; SDTI - suspected deep tissue injury

**Table 6. Case series with no controls**

Reference	Setting	Anatomical location(s) reported	Intervention group	Main results
Bateman and Roberts <sup>55</sup> (2013)	AWCS	Sacrum	Mepilex Border Sacrum plus standard PU prevention measures*	No further deterioration of existing PUs or development of new PUs (20 patients)
Bateman <sup>56</sup> (2014)	O-P	Heel	Mepilex Border Heel plus standard PU prevention measures	No deterioration of intact tissue (5 patients)
Edwards and Lynch <sup>57</sup> (2014)	ICU	Heel	Mepilex Border Heel plus standard PU prevention measures	PU incidence: 4/102 (3.9%) Classification of PUs: not stated
Haggard et al. <sup>58</sup> (2014)	OR	Chin/thorax	Mepilex Border plus standard PU prevention measures	PU incidence: 0/28 (0%)

\*Used as a component of a moisture lesion management regimen. Key: AWCS - acute wound care service; ICU - intensive care unit; O-P - outpatients; OR - operating room; PU - pressure ulcer

**Table 7. Review articles**

Reference	Key observations
Black et al. <sup>22</sup> (2015)	A consensus panel concludes that there is adequate evidence to recommend the use of multi-layer foam dressings with Safetac (Mepilex Border Sacrum and Mepilex Heel) to prevent PUs on the sacrum, buttocks and heels in high-risk patients in the ED, ICU or OR
Black et al. <sup>59</sup> (2014)	The use of multi-layer soft silicone foam dressings (e.g. Mepilex Border Sacrum) on vulnerable anatomical locations is listed as one of a number of interventions that can reduce the number of OR-acquired PUs in surgical patients
Clark et al. <sup>34</sup> (2014)	A systematic review concludes that the introduction of a dressing as part of PU prevention may help to reduce PU incidence, especially in immobile ICU patients. While there is no firm evidence (at the time of publication) to suggest that one dressing type is more effective than others, high-quality evidence exists for just multi-layer foam dressings with Safetac
Brindle et al. <sup>60</sup> (2013)	The use of Mepilex Border Sacrum as an adjunct to standard PU prevention measures is briefly mentioned
Fletcher <sup>6</sup> (2013)	The use of multi-layer foam dressings with Safetac appears to offer significant benefits as part of an holistic PU strategy (i.e. reduction in risk of PUs, ease of removal and reapplication facilitates skin examination without causing pain and trauma)
Moore and Webster <sup>33</sup> (2013)	A systematic review shows that use of prophylactic dressings over bony prominences can reduce PU incidence (RR 0.21 [95% CI 0.09 to 0.51]; p=0.0006), although the quality of the RCTs (available at the time of publication) is questioned. Further well-designed trials addressing important clinical, quality-of-life and economic outcomes based on the incidence of the problem and the high costs associated with PU management need to be undertaken
Miner et al. <sup>61</sup> (2011)	The use of a pictorial educational tool on the prophylactic use of Mepilex Border dressings has the potential to reduce the incidence of medical device-related PUs (e.g. CPAP/BiPAP masks, tracheostomy plates/ties, nasal cannulae, gastrostomy tubes, casts and braces) in a paediatric care setting
Butcher and Thompson <sup>62</sup> (2010)	There is a body of evidence to support the use of dressings to prevent PUs. The results of a clinical investigation, in which Mepilex Border Sacrum, used as an adjunct to standard prevention measures, reduced the incidence of sacral PUs are described in detail <sup>60</sup>
Butcher and Thompson <sup>63</sup> (2009)	The use of multi-layer foam dressings such as Mepilex Border Sacrum is described as an economic and practical means of reducing PU incidence
Smith <sup>31</sup> (2006)	The application of cut-to-size Mepilex Lite dressings around the nose or across the upper lip can prevent pressure injury to neonatal skin associated with CPAP equipment

Key: BiPAP-bilevel positive airway pressure; CPAP-continuous positive airway pressure; ER-emergency department; ICU-intensive care unit; OR-operating room; PU-pressure ulcer; RR-relative risk



**Table 8. Evaluations of pressure ulcer prevention regimens incorporating the use of multi-layer foam dressings with Safetac**

N.B. The evidence listed below reports on reductions in the occurrence of PUs following the introduction of new PU prevention regimens, one component of which was the use of multi-layer foam dressings with Safetac. Based on the data presented in Tables 3-7, it seems reasonable to assume that the prophylactic dressings contributed to the success of the regimens but it is obviously impossible to determine the extent of the contribution

Reference	Setting	Anatomical location(s) reported	Key observations
Cooper et al. <sup>64</sup> (2015)	ICU/OR	Sacrum/ elbow/face	Implementation of a regimen (including application of Mepilex Border Sacrum dressings to the sacral regions of patients in the OR and during their subsequent stay in ICU, application of Mepilex Border dressings to protect the elbows of cachectic patients, and use of Mepilex Lite dressings to protect against respiratory medical device-related PUs) resulted in a 56% decrease in the rate of PUs and significant cost savings
Kalowes et al. <sup>65</sup> (2014)	ICU	Catheter hub/face/ tracheostomy site	Implementation of a protocol that included application of Mepilex Border and Mepilex Lite dressings was associated with a reduction in the incidence of PUs related to medical devices (tracheostomy equipment, non-invasive ventilation mask, catheter hubs) from 0.06% per 1000 patient days to 0% in paediatric patients (benchmark: 0.0-0.04%) and from 0.28% to 0% in adult patients (benchmark: 0.0-0.09%)
Tamburino et al. <sup>66</sup> (2014)	ICU	Sacrum	The initiation of a protocol that included the prophylactic use of Mepilex Border Sacrum dressings in the care of patients following implantation of VADs was associated with a reduction in the occurrence of sacral PUs from 2/4 patients (50%) to 0/14 (0%)
Pitti et al. <sup>67</sup> (2013)	RT	Face	Implementation of a protocol that included application of Mepilex dressings was associated with a reduction in BiPAP-related PU incidence from 2.54% (no. of patients and PUs not reported) to 1/175 (0.6%) and, ultimately, 0%
Sullivan <sup>68</sup> (2013)	AC	Sacrum/heel/ other*	A 2-year retrospective review identified that a treatment regimen that included the use of multi-layer foam dressings with Safetac is effective in inhibiting SDTI evolution to category/stage III and IV PUs
Nowicki <sup>69</sup> (2012)	AC	Sacrum	Introduction of skin-care protocols that included the prophylactic use of Mepilex Border Sacrum coincided with a 50% reduction in sacral pressure injury in a referral hospital specialising in cardiac and thoracic medicine (no. of patients and PUs not reported)
Byars et al. <sup>70</sup> (2011)	AC	Sacrum	Introduction of a regimen that included the use of Mepilex Border Sacrum dressings for patients on kinetic therapy support surfaces was associated with a reduction in the occurrence rate of PUs, from 100% to 0%, within 4 months of its implementation
Coakley and Downs <sup>71</sup> (2011)	AC	Sacrum	Implementation of a regimen that included application of Mepilex Border Sacrum on patients in an acute care setting was associated with a 42% reduction in the PU rate (no. of patients and PUs not reported)
Cherry and Midyette <sup>72</sup> (2010)	ICU	Sacrum	Implementation of a protocol that included application of Mepilex Border Sacrum dressings for the care of patients in an ICU setting was associated with a reduction in the incidence of sacral PUs, from 19/153 (112.4%) to 0/36 (0%)
Ruben and Armstead <sup>73</sup> (2010)	ICU	Tracheostomy site	Implementation of a regimen that included application of Mepilex Ag between the tracheostomy ties and the skin for postoperative care in an ICU setting was associated with a reduction in the PU occurrence around the tracheostomy site from 5/11 (45%) to 25% (no. of patients and PUs not reported)

\*Other = foot/buttock/spine/leg/ischium/scrotum/peri-anus/hip/back/ankle

Key: AC-acute care; BiPAP-bilevel positive airway pressure; ICU-intensive care unit; OR-operating room; PU-pressure ulcer; RT-respiratory therapy; SDTI-suspected deep tissue injury; VAD-ventricular assist device

- ▶ pulse oximetry monitors, stockings/boots and tracheostomy flanges and ties. Medical device-related PUs can often be prevented by applying a thin dressing, such as a foam, under the device, which can redistribute pressure and absorb moisture from the body area in contact with the device.<sup>9</sup> For example, Boesch et al. observed that the incidence of PUs reduced from 8.1% to 3.4% after the introduction of a new care bundle including education and the application of Mepilex Lite dressings under tracheostomy tube flanges.<sup>30</sup>

In an article on the potential for nasal continuous positive air pressure therapy (CPAP) equipment (i.e. masks and prongs) to induce pressure injuries and skin stripping of neonatal skin, Smith reported how a neonatal ICU overcame these problems by fitting cut-to-size Mepilex Lite dressings around the nose or across the upper lip to protect the fragile skin. The author pointed out that the thinness and flexibility of Mepilex Lite provides conformability and security, and does not interfere with the delivery of air. The ability to lift the end of the dressing, which enables the area concerned to be inspected with minimal disruption to the infant, was also highlighted.<sup>31</sup>

Hsu et al. reported baseline nasal PU incidence data gathered over one year within one facility, where 47 of 797 (5.9%) patients wearing face masks developed 86 PUs, even though hydrocolloid dressings were used to protect the skin. As the skin under the face masks was peeling and the patients were experiencing pain at dressing change, it was decided to replace the hydrocolloid dressings with multi-layer foam dressing with Safetac. The incidence of PUs caused by the face masks subsequently reduced to 0.9%.<sup>32</sup>

Details of other studies on the prevention of medical device-related PUs are provided in Tables 3-8.

### Systematic reviews

Back in 2013, Moore and Webster reported on the findings of a systematic review on the effects of dressings and topical agents in the prevention of PUs in any health-care setting. The review identified four RCTs, the results of which show that the use of prophylactic dressings over bony prominences reduced the incidence of PUs: RR 0.21 (95% CI 0.09 to 0.51);  $p=0.0006$ . However, the reviewers questioned the quality of the RCTs and called for further well-designed trials to address important clinical, quality-of-life and economic outcomes based on the incidence of the problem and the high costs associated with its management.<sup>33</sup>

More recently, the results of a systematic review of the evidence supporting the use of prophylactic dressings in the prevention of PUs were reported by Clark et al.<sup>34</sup> Interestingly, almost half of the papers included in the review relate to the use of multi-layer foam dressings with Safetac. The authors concluded that the available evidence suggests that using a dressing as part of PU prevention may help to reduce incidence, especially in immobile ICU patients. While the article stated that there was no firm clinical evidence (at the time of publication) to suggest that one dressing type is more effective than others, it seems appropriate to highlight that they refer to the existence of high-quality evidence for the use of just one group of dressings (multi-layer foam dressings with Safetac) in PU prevention.<sup>34</sup>

Interestingly, the high-quality evidence referred to by Clark et al.<sup>34</sup> was generated from the RCT undertaken by Santamaria et al.,<sup>21</sup> which is discussed in an earlier section of this review (see Sacral Pressure Ulcers, page S11). It would appear that this research, along with the findings of a subsequent economic analysis of the same RCT data,<sup>35</sup> were not published in time for inclusion in the systematic review by Moore and Webster.<sup>33</sup> However, the high-quality research undertaken by Santamaria et al. clearly goes a long way in addressing the evidence gap identified by Moore and Webster.

According to Fletcher,<sup>6</sup> the evidence outlined above:

*'may not be transferable to other products as the makeup and components vary and it may be specific elements of the product studied that result in the positive patient outcomes'*<sup>6</sup>

### Key points:

- More than 40 evidence pieces (peer-reviewed journal articles and conference presentations (oral/poster)), including three describing the findings of RCTs, have been identified that describe reductions in pressure ulceration associated with the prophylactic use of multi-layer foam dressings with Safetac
- According to an independent systematic review, high-quality evidence exists for just one group of dressings (multi-layer foam dressings with Safetac) in relation to pressure ulcer prevention
- This evidence may not be transferable to other products as their structure and composition vary

### Cost-effectiveness

Subsequent to the completion of the Border Trial<sup>21</sup> described earlier in this review, Santamaria et al. performed a cost-benefit analysis, from an Australian health-care sector perspective, of the use of multi-layer foam dressings with Safetac in the prevention of PUs. In the Border Trial, patients were randomly assigned either to an intervention group (standard PU prevention measures plus the application of Mepilex Border Sacrum/Mepilex Heel in the ED, which was changed every 3 days in the ICU) or to a control group (standard PU prevention measures alone). The results revealed a significant reduction of PU incidence rates in the intervention group ( $p=0.001$ ). The intervention cost was estimated to be AU\$36.61 per person, based on an intention-to-treat analysis, but this was offset by lower downstream costs associated with PU treatment (AU\$1103.52). The average net cost of the intervention was calculated to be lower than that of the control, leading the authors to conclude that the use of multi-layer foam dressings with Safetac for the prevention of sacral and heel PUs in critically ill patients results in cost savings in the acute-care setting.<sup>35</sup>

Based on an extrapolation of the costing method described above to the annual acute patient population in Australian hospitals in 2013, a conservative estimate was made of the potential cost saving to the Australian health-care system of introducing the use of prophylactic multi-layer foam dressings with Safetac to the prevention

of hospital-acquired PUs in high-risk patients (*Box 4*). The estimate indicates that implementation of an initiative based on the use of prophylactic dressings could save the Australian health-care system just under AU\$35 million per annum. Commenting on their findings, the authors point out that, while their work has focused on the economic benefits of using multi-layer foam dressings with Safetac to prevent pressure ulceration,<sup>36</sup>

*'the real value in this emerging approach is in the potential to better safeguard vulnerable patients from an all too common, yet mostly preventable, hospital adverse event'*<sup>36</sup>

Lientz describes the results of a study in which Mepilex Border Sacrum was applied to patients in a number of settings (critical care unit, ICU, cardiovascular ICU and cardiovascular OR). Its use was associated with a reduction in the incidence rate of hospital-acquired PUs and suspected deep tissue injury (DTI) to 0% (reported rate of six per annum prior to the use of the dressing). The author reports that the estimated cost of using prophylactic multi-layer foam dressings with Safetac over a 15-month period was \$21590, nearly half the cost of treating one hospital-acquired PU or suspected DTI.<sup>37</sup> Having applied a cost-benefit analysis to the results of another study in which the application of Mepilex Border Sacrum coincided with a reduction in the incidence of PU, the researchers demonstrated that the inclusion of multi-layer foam dressings with Safetac, as a prophylactic dressing, into a package of care would result in a cost saving of £29.56 per patient per day (average cost saving of £266.04 per patient).<sup>38</sup>

### Key points:

- The use of multi-layer foam dressings with Safetac as a component of standard pressure ulcer (PU) prevention measures can be expected to achieve substantial savings to health-care providers
- The potential benefits of safeguarding patients from mostly preventable PUs should be considered alongside the economic benefits expected of prophylactic dressing use

### Mode of action

The preceding sections of this review focused on the results of research on the clinical and cost-effectiveness of using multi-layer foam dressings with Safetac as a component of standard PU prevention measures.

Scientists have developed and used laboratory methods to gain a better understanding of how prophylactic dressings work. Call et al. reported the results of laboratory studies on the characteristics of prophylactic dressings. They identified that dressing construction, including the presence of multi-layers within the dressing structure (as used in foam dressings with Safetac), and the type of adhesion (e.g. silicone adhesive (Safetac), which has elastic properties) play an important role in reducing shear and friction forces at the point of application. They also found that the proper sizing of the dressing is important in ensuring the adequate displacement of forces from skin at risk of pressure ulceration.<sup>39</sup>

### Box 4. Estimate of the potential financial impact of using prophylactic multi-layer foam dressings with Safetac to prevent hospital-acquired pressure ulcers in Australia<sup>36</sup>

- Within the high-risk population of acute hospitals, more than 71000 patients could be expected to develop a PU annually, costing AU\$77800000
- By implementing a national PU prevention initiative based on the use of prophylactic multi-layer foam dressings with Safetac for high-risk patients, an annual saving of AU\$34800800 could be achieved
- This represents a cost benefit of 55% to the Australian health-care system

PU-pressure ulcer

The same group has also undertaken laboratory research indicating that prophylactic dressings influence the skin microclimate.<sup>40</sup> The researchers found that the construction of dressings significantly influences moisture trapping and humidity close to the skin. The accumulation of moisture at the skin surface decreased the ability of some dressings to transpire. They referred to an 'optimal performance band' for microclimate management. The results of the tests indicate that, due to its properties, multi-layer foam dressings with Safetac can be expected to provide this optimal microclimate management. Although heat at the skin surface increases with the application of prophylactic dressings, heat rise was considered insufficient to place the skin at additional risk of injury.<sup>40</sup> The mechanisms by which dressings with Safetac are thought to redistribute pressure, reduce friction, reduce shear and manage microclimate are summarised in *Figure 6*.

More recently, Levy et al. reported the results of laboratory research that set out to evaluate the biomechanical performance of Mepilex Border Heel in the prevention of heel PUs when the patient is in the supine position. Using finite element modelling, the researchers also investigated the states of mechanical loading at the soft tissues of the supported heel and how this is influenced by the dressing. The multi-layer foam dressing with Safetac was shown to effectively reduce exposure of weight-bearing soft tissue to elevated strains and stress on a variety of support surfaces. The researchers concluded that, taken together with the findings of the clinical studies described earlier in this document, their results indicate a great promise in using a prophylactic multi-layer dressing for PU prevention.<sup>41</sup>

### Key points:

- A dressing construction that includes the presence of multi-layers and Safetac adhesive technology plays an important role in reducing shear and friction forces at the point of application and providing optimal microclimate management
- Multi-layer foam dressings with Safetac provide a biomechanical protective effect against heel pressure ulcers (PUs)

Functional property	Without dressing	With multi-layer foam dressing with Safetac
<p><b>Pressure redistribution</b></p> <p>A dressing with adequate thickness will distribute forces over a larger area, thereby reducing the percentage of magnitude of forces applied to the skin</p>		
<p><b>Friction reduction</b></p> <p>The texture of and material used in the construction of the outer layer of the dressing will determine if it increases or reduces friction. If the surface of the dressing is slippery, it will reduce friction. This is important because friction is the source of shear</p>		
<p><b>Shear reduction</b></p> <p>The dressing translates shear force to the skin outside of the area of concern. It is the interface of multiple layers within the dressing that helps absorb the shear. Buckling at the end of the adhesive border of the dressing also absorbs shear. Dressings of a thickness between 3.5 and 4.5mm or thicker appear to be the most effective in reducing shear</p>		
	<b>With basic dressing</b>	
<p><b>Microclimate balance</b></p> <p>Use of a dressing that maintains a relative humidity of between 40% and 80% at the skin surface will maximise the resilience of the skin. Dressings that withdraw too much moisture can predispose skin to stiffness and cracking. This can be identified by obvious signs of maceration or dryness</p>		

Figure 6. Mode of action of prophylactic dressings

**Conclusion**

The evidence detailed in this review indicates that the prophylactic use of multi-layer foam dressings with Safetac as a component of standard PU prevention measures is beneficial to the clinician, the health-care provider and the patient.

The second edition of the Clinical Practice Guideline states:

*‘Prophylactic dressings differ in their qualities; therefore it is important to select a dressing that is appropriate to the individual and the clinical use’*

A substantial proportion of the scientific and clinical evidence supporting the use of prophylactic dressings relates specifically to multi-layer foam dressings with Safetac. This evidence may not be transferable to other products as their makeup and components vary, and it may be specific elements of the multi-layer dressings with Safetac that result in the positive patient outcomes reported in the literature. Given the increasing importance of evidence-based practice and the need for cost-effective care, this point should be carefully considered by clinicians and provider when selecting prophylactic dressings for PU prevention.

With reference to the use of prophylactic dressings, the Clinical Practice Guideline recommends clinicians should:

*‘Assess the skin for signs of pressure ulcer development at each dressing change or at least daily’*

To achieve this, clinicians require dressings that can be easily lifted for routine skin checks without causing trauma (skin stripping) to the skin and unnecessary pain and distress to the patient. As well as providing clinicians with a cost-effective means of reducing the risk of PUs (when used as adjuncts to standard prevention measures), multi-layered foam dressings with Safetac are designed in such a way that they can be easily removed and reapplied for regular skin assessment without causing trauma and pain to the patient.

**References**

- 1 National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Ulcer Injury Alliance. Prevention and treatment of pressure ulcers: clinical practice guideline. In: Haesler E. (ed) Cambridge Media, 2014.
- 2 Linder-Ganz, E., Gefen, A. The effects of pressure and shear on capillary closure in the microstructure of skeletal muscles. *Ann Biomed Eng* 2007; 35: 12, 2095-2107.
- 3 Bluestein, D., Javaheri, A. Pressure ulcers: prevention, evaluation, and

- management. *Am Fam Physician* 2008; 78: 10, 1186-1194.
- 4 Coleman, S., Nixon, J., Keen, J. et al. A new pressure ulcer conceptual framework. *J Adv Nurs* 2014; 70: 10, 2222-2234.
  - 5 Soetens, J., Oomens, C., Bader, D. Mechanical properties and damage etiology of human skin resulting from large amplitude shear deformation. Poster presented at European Pressure Ulcer Advisory Panel meeting, Ghent, Belgium, 2015.
  - 6 Fletcher, J. The use of dressings in pressure ulcer prevention: unsafe practice or thinking differently? *Wounds UK* 2013; 9: 4, 67-71.
  - 7 Moore, Z., Cowman, S. Pressure ulcer prevalence and prevention practices in care of the older person in the Republic of Ireland. *J Clin Nurs* 2012; 21: 3-4, 362-371.
  - 8 Leijon, S., Bergh, I., Terstappen, K. Pressure ulcer prevalence, use of preventive measures, and mortality risk in an acute care population: a quality improvement project. *J Wound Ostomy Continence Nurs* 2013; 40: 5, 469-474.
  - 9 Black, J., Alves, P., Brindle, C.T. et al. Use of wound dressings to enhance prevention of pressure ulcers caused by medical devices. *Int Wound J* 2015; 12: 3, 322-327.
  - 10 Ohura, N., Ichioka, S., Nakatsuka, T., Shibata, M. Evaluating dressing materials for the prevention of shear force in the treatment of pressure ulcers. *J Wound Care* 2005; 14: 9, 401-404.
  - 11 Winter, G.D. Formation of the scab and the rate of epithelialization of superficial wounds in the skin of the young domestic pig. *Nature* 1962; 193: 293-294.
  - 12 Silverstein, P., Heimbach, D., Meites, H. et al. An open, parallel, randomized, comparative, multicenter study to evaluate the cost-effectiveness, performance, tolerance, and safety of a silver-containing soft silicone foam dressing (intervention) vs silver sulfadiazine cream. *J Burn Care Res* 2011; 32: 6, 617-626.
  - 13 Zillmer, R., Ågren, M.S., Gottrup, F., Karlsmark, T. Biophysical effects of repetitive removal of adhesive dressings on peri-ulcer skin. *J Wound Care* 2006; 15: 5, 187-191.
  - 14 Woo, K.Y., Coutts, P.M., Price, P. et al. A randomized crossover investigation of pain at dressing change comparing 2 foam dressings. *Adv Skin Wound Care* 2009; 22: 7, 304-310.
  - 15 Upton, D., Solowiej, K. The impact of atraumatic vs conventional dressings on pain and stress. *J Wound Care* 2012; 21: 5, 209-216.
  - 16 Wiberg, A-B., Feili, F., Daun, E.K. Preventing maceration with a soft silicone dressing: in-vitro evaluations. Poster presented at the 3<sup>rd</sup> Congress of the World Union of Wound Healing Societies, Toronto, Canada, 2008.
  - 17 Meaume, S., Van De Looverbosch, D., Heyman, H. et al. A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers. *Ostomy Wound Manage* 2003; 49: 9, 44-51.
  - 18 National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel. Prevention and treatment of pressure ulcers: Clinical Practice Guideline. National Pressure Ulcer Advisory Panel, 2009.
  - 19 Brindle, C.T., Wegelin, J.A. Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients. *J Wound Ostomy Continence Nurs* 2012; 39: 2, 133-142.
  - 20 Walsh, N.S., Blanck, A.W., Smith, L. et al. Use of a sacral silicone border foam dressing as one component of a pressure ulcer prevention program in an intensive care unit setting. *J Wound Ostomy Continence Nurs* 2012; 39: 2, 146-149.
  - 21 Santamaria, N., Gerdtz, M., Sage, S. et al. 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. *Int Wound J* 2015; 12: 3, 302-308.
  - 22 Black, J., Clark, M., Dealey, C. et al. Dressings as an adjunct to pressure ulcer prevention: consensus panel recommendations. *Int Wound J* 2015; 12: 4, 484-488.
  - 23 Brindle C.T. Outliers to the Braden Scale: identifying high-risk ICU patients and the results of prophylactic dressing use. *World Council of Enterostomal Therapists* 2010; 30: 1, 11-18.
  - 24 Qiuli, B., Qiongyu, J. Observation on effect of Mepilex on the presentation and treatment of pressure sores. *Chinese Journal of Medical Nursing* 2010.
  - 25 Chaiken, N. Reduction of sacral pressure ulcers in the intensive care unit using a silicone border foam dressing. *J Wound Ostomy Continence Nurs* 2012; 39: 2, 143-145.
  - 26 Kalowes, P., Li, M., Carlson, C. et al. Use of a soft silicone, self-adherent, bordered foam dressing to reduce pressure ulcer formation in high risk patients: a randomized clinical trial. Poster presented at the Symposium on Advanced Wound Care (Fall), Baltimore, Maryland, United States of America, 2012.
  - 27 Defloor, T., Schoonhoven, L., Fletcher, J. et al. Statement of the European Pressure Ulcer Advisory Panel-pressure ulcer classification: differentiation between pressure ulcers and moisture lesions. *J Wound, Ostomy Continence Nurs* 2005; 32: 5, 302-306.
  - 28 Park, K.H. The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence-associated dermatitis in intensive care unit patients. *J Wound Ostomy Continence Nurs* 2014; 41: 5, 424-429.
  - 29 Santamaria, N., Gerdtz, M., Liu, W. et al. Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial. *J Wound Care* 2015; 24: 8, 340-345.
  - 30 Boesch, R.P., Myers, C., Garrett, T. et al. Prevention of tracheostomy-related pressure ulcers in children. *Pediatrics* 2012; 129: 3, e792-e797.
  - 31 Smith, Z.K. Adapting a soft silicone dressing to enhance infant outcomes. *Ostomy Wound Manage* 2006; 52: 4, 30-32.
  - 32 Hsu, M-Y., Chung, H-C., Tang, M.T. et al. Avoiding pressure damage when using ventilators. *Wounds International* 2010; 1: 5, 22-24.
  - 33 Moore, Z.E.H., Webster, J. Dressings and topical agents for preventing pressure ulcers. *Cochrane Database Syst Rev* 2013; 18: 8.
  - 34 Clark, M., Black, J., Alves, P. et al. Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers. *Int Wound J* 2014; 11: 5, 460-471.
  - 35 Santamaria, N., Liu, W., Gerdtz, M. The cost-benefit of using soft silicone multi-layered foam dressings to prevent sacral and heel pressure ulcers in trauma and critically ill patients: a within-trial analysis of the Border Trial. *Int Wound J* 2015; 12: 3, 344-350.
  - 36 Santamaria, N., Santamaria, H. An estimate of the potential budget impact of using prophylactic dressings to prevent hospital-acquired PUs in Australia. *J Wound Care* 2014; 23: 11, 583-589.
  - 37 Lientz, J. Dollars and sense: economic value in HAPU/sDTI prevention. Poster presented at National Pressure Ulcer Advisory Panel Biennial Conference, Houston, Texas, United States of America, 2013.
  - 38 Johnstone, A., McGown, K. Innovations in the reduction of pressure ulceration and pain in critical care. *Wounds UK* 2013; 9: 3, 76-80.
  - 39 Call, E., Pedersen, J., Bill, B. et al. Enhancing pressure ulcer prevention using wound dressings: what are the modes of action? *Int Wound J* 2015; 12: 4, 408-413.
  - 40 Call, E., Pedersen, J., Bill, B. et al. Microclimate impact of prophylactic dressings using *in vitro* body analogue method. *Wounds* 2013; 25: 4, 94-103.
  - 41 Levy, A., Frank, M.B., Gefen, A. The biomechanical efficacy of dressings in preventing heel ulcers. *J Tissue Viability* 2015; 24: 1, 1-11.
  - 42 Thomas, S. Atraumatic dressings. *World Wide Wounds* 2003. Available at: <http://www.worldwidewounds.com/2003/january/Thomas/Atraumatic-Dressings.html> (accessed December 2015).
  - 43 Thul, J., Valero, E. Sacral pressure ulcer prevention in trauma patients. Poster presented at Wound, Ostomy and Continence Nurses Society conference, San Antonio, Texas, United States of America, 2015.
  - 44 Cubit, K., McNally, B., Lopez, V. Taking the pressure off in the Emergency Department: evaluation of the prophylactic application of a low shear, soft silicon sacral dressing on high risk medical patients. *Int Wound J* 2012; 10: 5, 579-584.
  - 45 Castelino, L., Mercer, D., Forrest Calland, J. Reducing peri-operative pressure ulcers in thoracic, cardiovascular, and spinal surgery patients: achieving zero incidence is possible! Poster presented at The Symposium on Advanced Wound Care (Spring), Atlanta, Georgia, United States of America, 2012.
  - 46 Kiely, C. Cultural transformation in pressure ulcer prevention and care. *J Wound Ostomy Continence Nurs* 2012; 39: 4, 443-446.
  - 47 Cano, A., Smits, D., Corvino, P. Efficacy of the prophylactic use of silicone foam dressing for the prevention of pressure ulcers in patients: an observational study in a 24 bed cardiovascular and cardiac intensive care unit. *J Wound, Ostomy Continence Nurs* 2011; 38: 3S, S73.
  - 48 Koerner, S., Adams, D. Does the use of an absorbent soft silicone self-adherent bordered foam improve quality of care by decreasing incidence of hospital acquired pressure ulcers? *J Wound Ostomy Continence Nurs* 2011; 38: 3S, S70.
  - 49 Gentry, T., Wright, A. The 'Sacral Heart' Dressing Study: use of an absorbent self-adherent soft silicone sacral foam dressing across acute care settings. Poster presented at the Joint Conference of the Wound, Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, Phoenix, Arizona, United States of America, 2010.
  - 50 Muldoon, C., Grossman, N., Lawrence, P. Initial use absorbent soft silicone self-adherent bordered foam dressing reduces sacral pressure ulcers in the cardiovascular ICU. Poster presented at the Joint Conference of the Wound, Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, Phoenix, Arizona, United States of America, 2010.

51 Baker, G. Nursing driving excellence: preventing pressure ulcers in the high-risk population. Poster presented at the Symposium on Advanced Wound Care (Fall), Las Vegas, Nevada, United States of America, 2014.

52 Haisley, V., Potter, K., Wallace, J. et al. An ounce of prevention: the use of an absorbent soft silicone self-adherent bordered foam heel dressing to decrease the incidence of hospital-acquired heel pressure ulcers in an acute care setting. Poster presented at Wound, Ostomy and Continence Nurses Society conference, San Antonio, Texas, United States of America, 2015.

53 Van Capellen, P., Haggendamacher, C. The use of a silicone dressing in the prevention of pressure ulcer on the nose with children treated with non-invasive ventilation. Poster presented at the 4<sup>th</sup> Paediatric Wound Care Conference, Bristol, United Kingdom.

54 Kuo, C.Y., Wootten, C.T., Tylor, D.A. et al. Prevention of pressure ulcers after pediatric tracheotomy using a Mepilex Ag dressing. *Laryngoscope* 2013; 123: 12, 3201-3205.

55 Bateman, S.D., Roberts, S. Moisture lesions and associated pressure ulcers: getting the dressing regimen right. *Wounds UK* 2013; 9: 2, 97-102.

56 Bateman, S. Principles of preventative foot care. *Br J Community Nurs* 2014; (Suppl. S30), S32-S38.

57 Edwards, M.B., Lynch, J.H. Head over heels for prevention: use of a silicone bordered foam heel dressing in the prevention of pressure ulcers. Poster presented at the Symposium on Advanced Wound Care Fall, Las Vegas, Nevada, United States of America, 2014.

58 Haggard, C., Tiamson, L., Mathews, L., Blair, J. Preventing pressure ulcers in the prone perioperative patient. Poster presented at the 46<sup>th</sup> Annual Conference of the Wound Ostomy and Continence Nurses Association, Nashville, Tennessee, United States of America, 2014.

59 Black, J., Fawcett, D., Scott, S. Ten top tips: preventing pressure ulcers in the surgical patient. *Wounds International* 2014; 5: 4, 14-18.

60 Brindle, C.T., Malhotra, R., O'Rourke, S. et al. Turning and repositioning the critically ill patient with hemodynamic instability: a literature review and consensus recommendations. *J Wound Ostomy Continence Nurs* 2013; 40: 3, 254-267.

61 Miner, K.J., Vassar, C., Bechert, K., McNeil, M. Teacher's PPET: developing a pediatric pictorial education tool to reduce medical device related pressure ulcers. Poster presented at the Joint Conference of the Wound, Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, New Orleans, Louisiana, United States of America, 2011.

62 Butcher, M., Thompson, G. Can the use of dressing materials actually prevent pressure ulcers: presenting the evidence. *Wounds UK* 2010; 6: 1, 119-125.

63 Butcher, M., Thompson, G. Pressure ulcer prevention: can dressings protect from pressure ulcer damage? An advertorial. *Wounds International* 2009; 1: 1.

64 Cooper, D.N., Jones, S.L., Currie, L.A. Against all odds: preventing pressure ulcers in high-risk cardiac surgery patients. *Crit Care Nurse* 2015; 35: 5, 76-82.

65 Kalowes, P., Messina, V., Paige, R. Reducing medical device related pressure ulcers. An interprofessional approach using data & innovation to improve adult & pediatric outcomes. Poster presented at the Symposium on Advanced Wound Care (Fall), Las Vegas, Nevada, United States of America, 2014.

66 Tamburino, J., McGrath, M., Cooper, M. et al. A quality improvement initiative focusing on high risk left ventricular device patients; a combination of people, process, and technology. Poster presented at the 46<sup>th</sup> Annual Conference of the Wound, Ostomy and Continence Nurses Society, Nashville, Tennessee, United States of America, 2014.

67 Pitti, G., Clemente-Skurlusky, C., Garner, B., Gayden, S. Collaborative approach to reduce respiratory medical device related pressure ulcers. Poster presented at the Symposium on Advanced Wound Care (Fall), Las Vegas, Nevada, United States of America, 2013.

68 Sullivan, R. A two-year retrospective review of suspected deep tissue injury evolution in adult acute care patients. *Ostomy Wound Manage* 2013; 59: 9, 30-39.

69 Nowicki, T. Preventing pressure injury in Australia. *Wounds International* 2012; 3: 1, 13-14.

70 Byars, M., Raxter, K., Reed-Chism, R. How to prevent pressure ulcers on a kinetic therapy support surface. Poster presented at the Joint Conference of the Wound, Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, New Orleans, Louisiana, United States of America, 2011.

71 Coakley, K., Downs, B. Take it to zero: a process improvement project for reducing pressure ulcer rates. Poster presented at the 12<sup>th</sup> Biennial National Pressure Ulcer Advisory Panel Congress, Norfolk, Virginia, United States of America, 2011.

72 Cherry, C., Midyette, P. The Pressure Ulcer Prevention Care Bundle: a collaborative approach to preventing hospital-acquired pressure ulcers. Poster presented at Magnet Research Day, Alabama, United States of America, 2010.

73 Ruben, B., Armstead, S. Post operative tracheostomy protocol for obese and low Braden score patients in ICU setting. Poster presented at the Joint Conference of the Wound, Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, Phoenix, Arizona, United States of America, 2010.

Appendix

References to the use of prophylactic dressings for the prevention of pressure ulcers (PUs) in Haesler, E. (ed.) National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Ulcer Injury Alliance (PPPUIA). *Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline*. Cambridge Media: Perth, Australia, 2014

Table 9. Level of studies

Level	Intervention studies
1	Randomised controlled trial(s) with clear-cut results and low risk of error OR systematic literature review or meta-analysis according to the Cochrane methodology or meeting at least nine of the 11 quality criteria according to AMSTAR appraisal tool
2	Randomised controlled trial(s) with uncertain results and moderate to high risk of error
3	Non-randomised trial(s) with concurrent or contemporaneous controls
4	Non-randomised trial(s) with historical controls
5	Case series with no controls. Specify number of subjects



Emerging therapies for prevention of pressure ulcers



Prophylactic dressings (p72-73)

'1. Consider applying a polyurethane foam dressing to bony prominences (e.g. heels, sacrum) for the prevention of pressure ulcers in anatomical areas frequently subjected to friction and shear. (Strength of Evidence = Ⓝ; Strength of Recommendation = Ⓝ).'

'2. When selecting a prophylactic dressing consider: Ability of the dressing to manage microclimate



- Ease of application and removal
- Ability to regularly assess the skin
- Anatomical location where the dressing will be applied
- The correct dressing size (Strength of Evidence = Ⓝ; Strength of Recommendation = Ⓝ).'

'3. Continue to use all other preventive measures necessary when using prophylactic dressings. (Strength of Evidence = ; Strength of Recommendation = ).'

'4. Assess the skin for signs of pressure ulcer development at each dressing change or at least daily, and confirm the appropriateness of the current prophylactic dressing regime. (Strength of Evidence = ; Strength of Recommendation = ).'



'5. Replace the prophylactic dressing if it becomes damaged, displaced, loosened or excessively moist. (Strength of Evidence = ; Strength of Recommendation = ).'

### Medical device-related pressure ulcers Recommendations for prevention of medical device-related pressure ulcers (p120-122)



4. Consider using a prophylactic dressing for preventing medical device-related pressure ulcers. (Strength of Evidence = ; Strength of Recommendation = ).

Caution: Avoid excessive layering of prophylactic dressings that may increase pressure at the skin-device interface.'

4.1. When selecting a prophylactic dressing consider:

- Ability of the dressing to manage moisture and microclimate, especially when used with a medical device that may be in contact with bodily fluids/drainage (e.g. percutaneous endoscopic gastrostomy tube)
- Ease of application and removal
- Ability to regularly assess skin conditions
- Thickness of the dressing under tightly fitting devices
- Anatomical location of the medical device
- Type/purpose of the medical device (Strength of Evidence = ; Strength of Recommendation = ).'




### Special populations: older adults Medical Device-Related Pressure Ulcers (p57)

'3. Consider using a prophylactic dressing for preventing medical device-related pressure ulcers. (Strength of Evidence = ; Strength of Recommendation = ).'






### Explanation of 'strength of evidence' and 'strength of recommendation' used in the guidelines

The evidence pool supporting each recommendation in the guidelines was given a strength of evidence rating based on the level of evidence available (Tables 9-11). A consensus voting process (GRADE) was then used to assign a strength of recommendation, which is an indicator of the confidence that health professionals can have that the recommended practice will improve patient outcomes.

**Table 10. Strength of evidence**

Strengths of evidence	Description
	The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on PUs in humans (or humans at risk of pressure ulcers), providing statistical results that consistently support the recommendation (level 1 studies required)
	The recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on PUs in humans (or humans at risk of PUs) providing statistical results that consistently support the recommendation (level 2, 3, 4 and 5 studies)
	The recommendation is supported by indirect evidence (e.g. studies in healthy humans, humans with other types of chronic wounds, animal models) and/or expert opinion

**Table 11. Strength of the recommendations**

Strengths of recommendation	Description
	Strong positive recommendation: definitely do it
	Weak positive recommendation: probably do it
	No specific recommendation
	Weak negative recommendation: probably don't do it
	Strong negative recommendation: definitely don't do it

