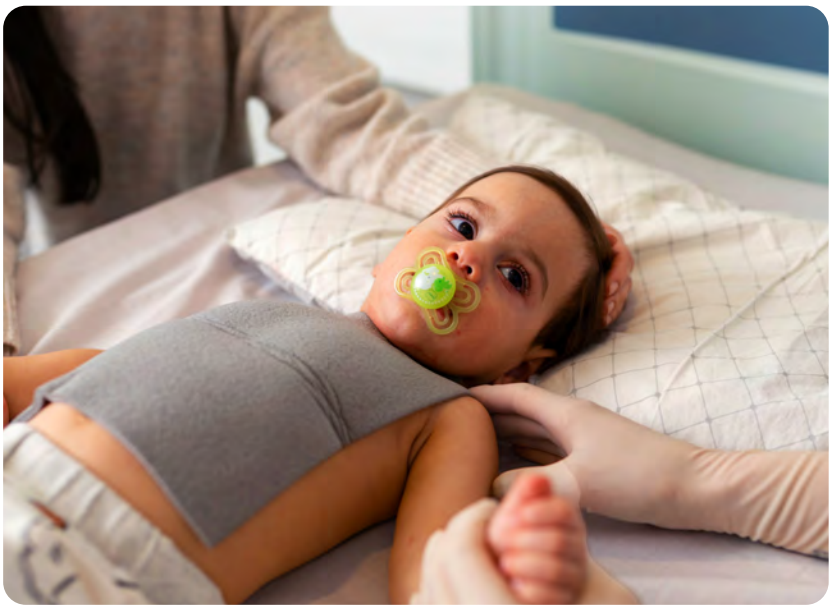
Dressings with Safetac® technology:

revolutionising wound care for patients, health care professionals and payers



Clinical and scientific research data

Mölnlycke®

Contents

foreword

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It is an honour to introduce this remarkable document tracing the history and impressive body of evidence supporting Safetac technology. As I complete my 45th year as a wound care clinician, I have witnessed firsthand the evolution of wound management—from the early 1980s shift away from wet-to-dry dressings toward the moist-healing principles pioneered by Dr. George Winter in the 1960s.

As products emerged to help us create and maintain a moist wound environment, we embraced concepts such as autolytic debridement and saw the reduction in pain that comes when a wound bed remains moist. Healing outcomes improved before our eyes. Yet we still struggled with tapes and dressings that either failed to stay in place or caused pain and epidermal trauma when removed. Then Safetac arrived—transforming wound management and, most importantly, improving the patient experience.

I was proud to present at the first sales meeting when Mölnlycke Health Care first launched dressings with Safetac in the United States of America. We even held a session just to learn how to pronounce the company's name! That moment began what is now a 30-plus-year journey as a consultant and speaker for Mölnlycke. Over the years I have worked with innovations such as Mepitel®, Mepitel® One, Mepilex®, Mepilex® Ag, Mepilex® Transfer, Mepilex® Border, the highly absorbent Mepilex® Border Flex, and most recently the unique Mepilex® Up. Still, I had little appreciation for the sheer volume of research, publications, posters, and case series that document this technology's impact.

Oscar Wilde once said, "**Imitation is the sincerest form of flattery,**" and that is evident in the many silicone products on the market today—proof of how Tomas Fabo's early work revolutionised wound care.

Congratulations to the Medical Affairs team at Mölnlycke for compiling this outstanding historical compendium.

Abstract

The management of different wound types, each presenting with unique clinical and economic challenges, is something that must be undertaken by carers and healthcare professionals (HCPs) working in a variety of care settings. With a focus on clinical and scientific research data and expert opinion in the public domain, this review demonstrates how dressings with Safetac® (soft silicone adhesive technology) can be used effectively (from the perspectives of patients, HCPs and payers) to address the challenges posed by a diverse range of wound types and skin injuries across the age spectrum (from neonates to adults). The presented data and opinion highlight the ability of dressings with Safetac to prevent certain wound types (e.g. pressure injuries) and to promote wound environments that are conducive to healing, as well as addressing patient-centred outcomes such as the avoidance of dressing change-related tissue damage and the minimisation of associated pain and distress.

Disclaimer

Research frequently explores innovative applications, mechanisms, or therapeutic contexts for medical products that may extend beyond their approved or intended use. While such studies can provide valuable scientific insights, reference to such research in this document should not be interpreted as an endorsement by the manufacturer for using its products in ways not specified in its approved labelling. Clinicians are advised to use medical products strictly in accordance with the instructions for use (IFU) provided by the manufacturer. Any deviation from the IFU should be based on sound clinical judgment, carefully weighing the potential clinical benefits against the possible risks to patient safety. Adhering to these principles helps ensure effective intervention and high standards of patient care.

Dressings with Safetac featured:

Mepilex®, Mepilex® Ag, Mepilex® Border, Mepilex® Border Ag,
Mepilex® Border Flex (Comfort), Mepilex® Border Heel,
Mepilex® Border Lite, Mepilex® Border Post-Op, Mepilex® Border Post-Op Ag,
Mepilex® Border Sacrum, Mepilex® Heel, Mepilex® Heel Ag,
Mepilex® Lite, Mepilex® Transfer, Mepilex® Transfer Ag, Mepilex® Up,
Mepilex® XT, Mepitel®, Mepitel® Ag, Mepitel® Film, Mepitel® One,
Mepiform®, Mepitac®, Avance® Solo Adapt Film, Avance® Solo Border

Take home messages:

- Safetac (soft silicone) adhesive technology is incorporated into the design of various dressing types manufactured by Mölnlycke Health Care including wound contact layers*, absorbent foam dressings (with and without self-adhesive borders)*, exudate transfer dressings*, post-operative dressings*, scar management dressings, dressings for use in conjunction with negative pressure wound therapy (NPWT) systems, and fixation tapes. *Silver-containing variants also available
- More than 750 peer-reviewed articles, 40 published conference abstracts and 200 conference posters describing studies across the entire evidence hierarchy support the use of dressings with Safetac, including over 60 randomised controlled trials (RCTs).
- Dressings with Safetac have been demonstrated to minimise dressing-related trauma and pain when used in the management of a diverse range of wound types.

Once upon a time in a kitchen in Sweden....

The **Safetac** story goes all the way back to the mid-1980s when Tomas Fabo, a young product developer, was working in the Research and Development Department at Mölnlycke Health Care. While spending time at healthcare facilities, he observed patients receiving wound care. Among the many observations he made, one thing that struck and never truly left him was the way patients suffered during dressing changes. He was haunted by the sight of adults and children having to be sedated – all because of pain.

This gave Tomas a true sense of urgency and purpose in his research, during which he came upon some test tubes with an interesting sticky substance in them which turned out to be silicone. He started to experiment with this substance. The story goes that he did a lot of early explorative work in his own kitchen – dipping scraps of his daughter's stockings in melted silicone and curing the material in his own oven. A period of extensive laboratory research into the adhesive properties of silicones eventually led to the development of Safetac, a soft silicone-based material that can adhere to intact dry skin and remain in place on moist wounds or damaged surrounding skin without adhering to these fragile tissues (Cutting, 2008).

The first **Safetac**-coated wound dressing (**Mepitel**) was developed and launched in 1989.

The message was wonderfully simple – **Mepitel would not stick to the wound or damage the skin, and, because of this, it would not hurt when removed.**

The rest is history....

To watch a video of Tomas Fabo talking about the development of **Safetac**, please scan the QR code

Role of dressings in wound care

Dressings play a vital role in wound management. Ever since a possible mechanism for re-epithelialisation under occlusion in the presence or absence of eschar was identified way back in the 1960s (Winter, 1962), the concept of healing in a moist environment has shaped the development and use of modern wound care products. However, the ability to provide a moist environment that is conducive to healing is just one of many ways in which modern dressings contribute to wound management. Dressings typically provide a physical barrier to pathogens, thus reducing the risk of wound infection (Eriksson et al, 2022). Some dressing types are designed to protect wounds from further injury, and even prevent them from occurring, e.g. by reducing the impact of mechanical forces that are associated with the development of pressure injury (PI) (Beeckman et al, 2021).

By effectively managing excess exudate, a dressing can minimise the risk of moisture-related damage to the wound and surrounding skin (e.g. maceration) and leakage which would otherwise have a negative impact on the quality of life (QoL) of patients (Weir & Davies, 2023). Some dressing types (e.g. those with silicone-based wound contact surfaces) minimise the trauma and pain that has historically caused so much distress and anxiety to patients during dressing changes (White, 2008). The availability of modern dressings that are designed to stay in place for longer than some of the traditional dressings used historically can reduce the frequency of dressing changes, which can also impact positively on the well-being of patients and reduce treatment costs (Brindle & Farmer, 2019).

A variety of different dressing types are commonly used in wound care, including those based on alginate, foam, fibre, hydrogel, hydrocolloid and superabsorbent polymer technologies. It would be impossible for one dressing, or indeed one dressing type, to have the properties to optimally deliver all the outcomes described above, so it is vitally important for clinicians to understand what each dressing type can offer as part of their dressing selection process. For example, the International Wound Dressing Technology Expert Panel (IWDTEP), a multidisciplinary panel of clinical and scientific experts, reached consensus on the basic performance requirements that a foam dressing must fulfil to most effectively promote wound healing (**Figure 1**) (Santamaria et al, 2023; Gefen et a, 2024).

Fluid handling	Fluid absorption and retention	Should absorb and retain exudate effectively and consistently in terms of volume and mass over the clinically relevant time course, across the reported range of possible human fluid viscosities, without the occurrence of spillovers or pooling
	Conformability / compatibility	Should absorb and retain exudate effectively and consistently across all the possible positions of the body and wound with respect to gravity (e.g. as when used on a leg ulcer), or when subjected to sustained or repeated bodyweight forces (e.g. non-off-loaded wound) Should not be significantly affected by external compressive forces (e.g. application of compression devices for venous leg ulcer management)
	Fluid evaporation	Should constantly and consistently release the retained fluid to the environment, via evaporation, for the ranges of clinically relevant temperatures and humidity values representing the ambient conditions at the geographical regions of use
Mechanical	Stiffness	Stiffness should not substantially exceed that of the skin and sub-cutaneous tissue relevant to the location, aetiology and severity of the wound (to avoid indentation damage)
	Strength	Should be durable to the expected compressive, tensile and shear forces associated with the bodyweight, including any potential body movements against surfaces, and to the mechanical forces when removed
	Adhesiveness	Border should provide consistent adhesiveness throughout the intended period of use (i.e. should stay in place under the influence of bodyweight and external forces, and under the influence of skin moisture conditions) Border should not require excessive peeling forces during removal (to avoid peri-wound skin stripping damage and pain to the patient) Wound pad should never adhere to the wound bed
Biological	Permeability to pathogens	Should prevent penetration or release of particulates of sizes representative of bacterial, viral and fungal pathogens, through the external surface

Figure 1. International expert consensus on the basic performance requirements from a foam dressing
(reproduced from Gefen et al, 2024 with permission)

Healthcare is arguably facing its biggest challenge to date. As the gap between demand and resources continues to grow, healthcare providers are increasingly looking at ways to reduce funding and curtail expenditure. This has created a higher emphasis on the cost of care provision and the need to provide robust models for the delivery of care. Increasingly, clinicians are faced with having to justify decision making to non-clinical personnel such as finance directors and procurement managers. The need to use wound care interventions that are proven to be cost-effective, as well as clinically effective, is therefore of paramount importance to healthcare providers.

Wound-related trauma and pain

Since the 1990s, there has been an increasing awareness of the need for clinicians to consider patients' experiences of wound-related trauma and pain. This has been reflected in the publication of a number of statements and guidelines relating to the management of wound pain, resulting from international initiatives involving clinicians, researchers, patients and industry experts (European Wound Management Association (EWMA), 2002; World Union of Wound Healing Societies (WUWHS), 2004; WUWHS, 2007; EWMA, 2024).

The removal of dressings that have adhered to the wound bed is a common cause of trauma, as is the epidermal stripping of the skin surrounding wounds that can result from the repeated application and removal of adhesive dressings (**Figure 2**) (Rippon et al, 2012; Cutting, 2008). Adhesive-induced **epidermal stripping** may lead to inflammatory skin reactions, oedema and soreness, which can have a detrimental effect on the skin barrier function (Dykes et al, 2001).

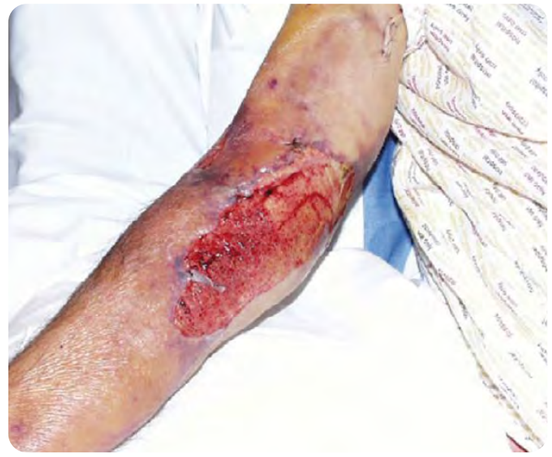


Figure 2. Skin trauma because of the application and removal of an adherent dressing
(photograph courtesy of Pauline Beldon, Epsom and St Helier University Hospital NHS Trust, Carshalton, United Kingdom)

If dressings inadequately manage wound exudate and fail to control moisture balance at the wound-dressing interface, the result may be excoriation, irritant dermatitis and maceration of the peri-wound skin (Weir & Davies, 2023; Cutting & White, 2002). Wound-related trauma can increase the size of wounds, exacerbate wound pain and delay healing, all of which can have cost implications for healthcare providers, and adversely affect the QoL of patients (Weir & Davies, 2023; Rippon et al, 2007).

A study conducted in the United Kingdom (UK) in 2014 identified skin reactions, adherence to the wound, skin stripping, maceration, drying and plugging of the wound as the main types of dressing-related trauma. It was estimated that the mean costs (in Great British Pounds) for the complete management of each occurrence of the trauma types ranged from £56-175 (Charlesworth et al, 2014), equivalent to £76-237 in 2025 according to the Bank of England's inflation calculator (Bank of England, 2025) (**Figure 3**).

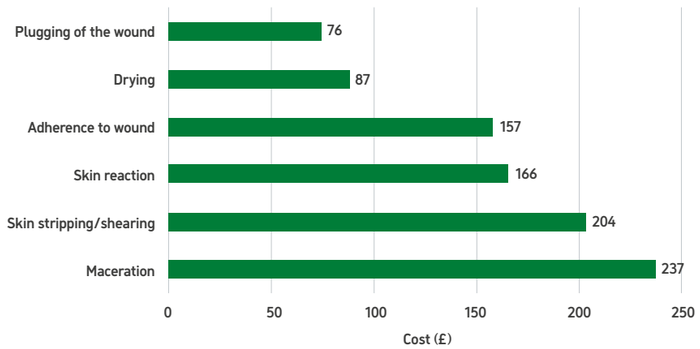
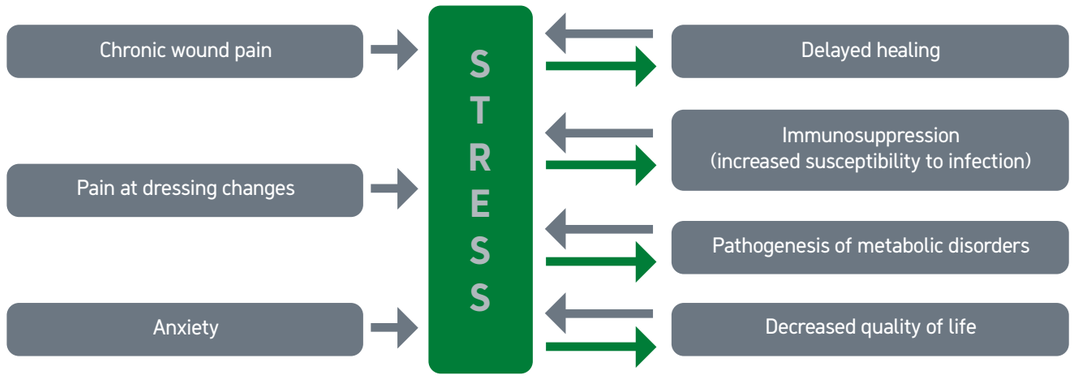


Figure 3. Estimated mean total costs for the complete management of each single occurrence of dressing-related trauma in 2025 (based on an inflation calculation of data published in 2014 (Charlesworth et al, 2014; Bank of England, 2025))

Pain is a significant problem with most wound types, contributing to considerable levels of suffering, distress and reduced QoL (EWMA, 2024). Wound-related pain can also cause psychological stress which may, in turn, delay healing (**Box 1**).

Box 1. Impact of pain-induced stress on wound healing and patient quality of life

- Pain plays an integral role in the physiological and psychological elements of the body's response to traumatic events, such as acute or chronic tissue damage (Soon & Acton, 2006)
- Wound-related pain, either as a direct result of pathological processes or interventions (e.g. dressing changes) causes stress (Woo et al, 2024)
- Stress can cause several unwanted effects, all of which may escalate stress levels. These include:
  - Adverse effects on physical health and physiological processes (O'Connor et al, 2021)
  - Delayed healing of acute wounds which may also be true for chronic wounds (Solowiej & Upton, 2010; Basu et al, 2024)
  - Immunosuppressive effect (Woo et al, 2024), resulting in increased infection rates (Godbout & Glaser, 2006), especially in burns (Tengvall et al, 2006)
  - Possible role in the pathology of metabolic disorders relating to chronic wounds, e.g. diabetes (Hackett & Steptoe, 2017) and cardiovascular disease (Kivimaki & Steptoe, 2018)
  - Negative impact on the quality of life of patients, especially those with chronic wounds (Woo et al, 2024; Yan et al, 2021)



Wound-related pain is multidimensional, integrating the persistent pain usually associated with underlying pathologies with cyclic acute pain (i.e. the periodic pain induced by repeated interventions, e.g. dressing changes) and non-cyclic acute pain (i.e. single episodic pain arising from procedures such as sharp debridement) (Woo, 2024). Factors other than direct tissue damage that can contribute to wound-related pain include infection (EWMA, 2024), especially in burns (Tengvall et al, 2006), and cellulitis (Carter et al, 2007).

The removal of dressings (especially those with particularly aggressive adhesive systems) and wound cleansing have been reported to be the most painful interventions for patients with wounds (Hollinworth & Collier, 2000; Kammerlander & Eberlein, 2002). This was highlighted by the findings of a cross-sectional, international survey involving over 2000 patients from 15 countries. When asked how frequently they experienced pain at dressing change, over 50% indicated either 'quite often', 'most of the time' or 'all of the time'. Over 40% of those surveyed revealed that the pain they experienced at dressing changes was the worst aspect of living with a wound; over 58% of participants expressed concerns about the long-term side effects of medication. Of particular concern was that over 36% of patients felt that the clinicians in charge of their case could do nothing to help with their dressing change-related pain (Price et al, 2008). In a more recent study, undertaken in the United States of America (USA), 74% of patients reported that dressing changes caused moderate to severe pain, nearly half of whom experienced severe pain rated as 8-10 on a 10-point numeric rating scale (Gardner et al, 2014). These research findings exemplify that the management of wound-related pain is key to successful clinical and economic outcomes.

Although modern wound dressings go a long way to meeting many of the requirements discussed above, it is important to note that alginate, film, foam, hydrocolloid and hydrogel dressings have all been reported to cause trauma and pain during dressing changes (Hollinworth & Collier, 2000). The following section of this review demonstrates how the use of dressings that have been demonstrated to be atraumatic on removal (specifically those incorporating Safetac adhesive technology) can play a key role in minimising unnecessary pain experienced by patients receiving wound care.

Introducing the Mölnlycke range of dressings with **Safetac**

Subsequent to the successful introduction of the wound contact layer, Mepitel, Mölnlycke has developed numerous other dressings incorporating Safetac technology. These include other wound contact layers, absorbent foam dressings (with and without self-adhesive borders), exudate transfer dressings, post-operative dressings, scar management dressings, dressings for use in conjunction with negative pressure wound therapy (NPWT) systems, and fixation tapes (**Figure 4**). Details of the classification, composition, intended uses and key supporting evidence can be found at the end of the section.

1989

Mepitel (wound contact layer coated on both sides with **Safetac**) launched

1998

Publication of RCT: Mepitel associated with faster healing of paediatric scald burns, less pain and lower treatment costs than silver sulphadiazine (Gotschall et al, 1998)

Mepiform (scar management dressing) launched

1999

Mepilex (non-bordered foam dressing) launched

2001

Mepilex Border Ag (silver-containing foam dressing with self-adhesive border) launched

2002

Publication of European Wound Management Association Pain at Wound Dressing Changes document: Highlights the importance of dressings that minimise trauma and pain on removal (EWMA, 2002)

Mepitac (adhesive tape) and Mepilex Transfer (exudate transfer dressing) launched

2004

Publication of World Union of Wound Healing Societies Minimising Pain at Wound Dressing-Related Procedures: Implementation of Pain Relieving Strategies document: Highlights the importance of using dressings that are atraumatic on removal, e.g. soft silicones (WUWHS, 2004)

Mepilex Lite (thinner and less absorbent version of Mepilex) launched

2005

Mepilex Border Lite (thinner and less absorbent version of Mepilex Border) launched

2006

Mepilex Heel (anatomically shaped non-bordered foam dressing for use on the heel) launched

2007

Publication of World Union of Wound Healing Societies Minimising Pain at Wound Dressing-Related Procedures document: Refers to research showing dressings with soft silicone adhesive technology (e.g. Safetac) to be less painful before/during/after dressing changes than ones with traditional adhesives (WUWHS, 2007)

Mepilex Border Sacrum (anatomically shaped foam dressing with self-adhesive border for use on the sacrum) and Mepilex Ag (silver-containing non-bordered foam dressing) launched

2009

Mepitel One (wound contact layer with Safetac coating on wound surface only) launched

2011

Publication of RCT: Mepilex Ag associated with shorter hospital stay, less pain and lower burn treatment costs than silver sulphadiazine (Silverstein et al, 2011)

2012

Mepitel Film (transparent film dressing) launched

2013

Mepilex Border Post-Op (post-operative dressing with self-adhesive border), Mepilex Border Heel (anatomically shaped foam dressing with self-adhesive border for use on heels), and Mepilex Transfer Ag (silver-containing exudate transfer dressing) launched

2014

Mepitel Ag (silver-containing wound contact layer) launched
Mepilex XT (non-bordered foam dressing) launched

2015

Publication of RCT: Prophylactic use of Mepilex Border Sacrum and Mepilex Heel in addition to standard preventive care reduced sacrum/heel PI incidence (Santamaria et al, 2015b)

2017

Publication of RCT: Mepitel One associated with faster healing of acute wounds and less pain than a lipidocolloid wound contact layer (David et al, 2017)

2018

Mepilex Border Flex (foam dressing with self-adhesive border and Flex technology for extra conformability) launched

2021

Avance Solo single-use NPWT systems launched, incorporating dressings with Safetac - Avance Solo Border and Avance Solo Adapt Film
Mepilex Border Flex Lite (thinner and less absorbent version of Mepilex Border Flex) launched

2024

Mepilex Up (dimpled, non-bordered foam dressing) launched

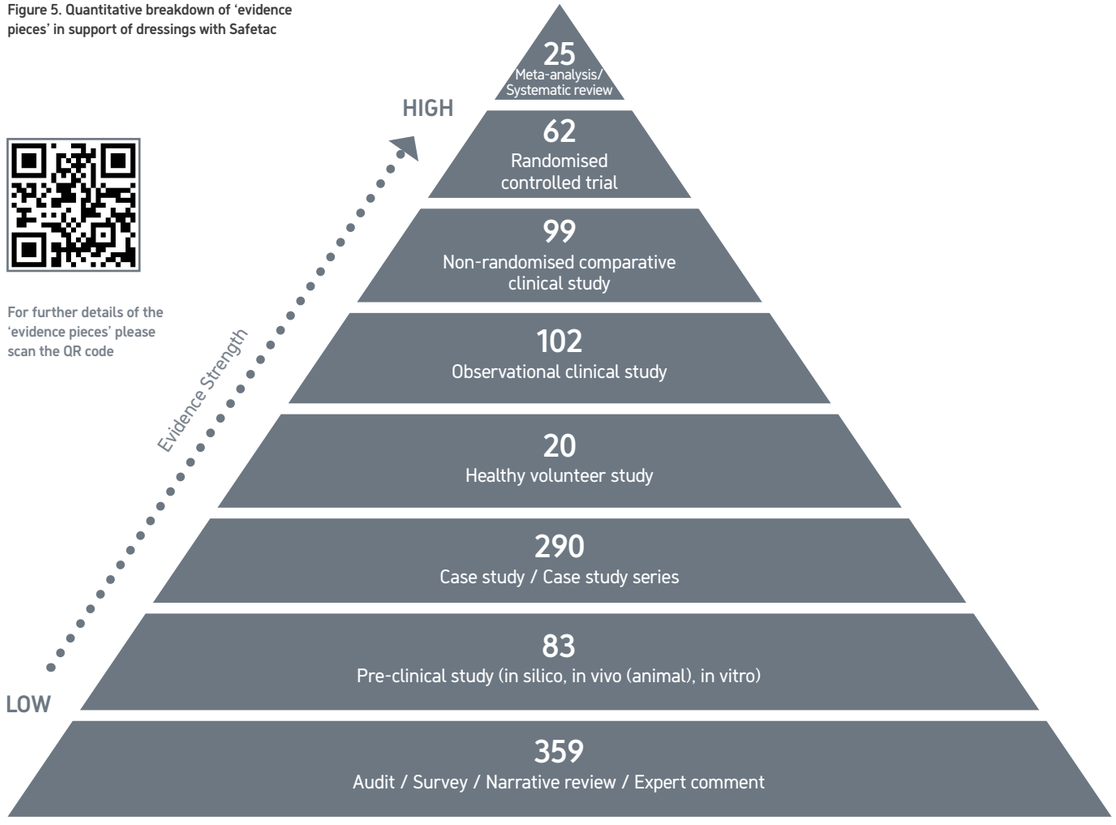
Figure 4. Key milestones in the development and utilisation of dressings with Safetac (any products referred to in this document should be used according to the instructions for use supplied with them. Product availability and intended uses can vary across regions. Please consult your local Mölnlycke representative for guidance). Abbreviation: RCT = randomised controlled trial

Evidence for dressings with **Safetac**

In line with the continued expansion of the range of dressings with Safetac and exploration of their utilisation beyond that originally intended, e.g. for the prevention of PI and the management of radiotherapy-induced skin damage (RISD), research into their efficacy, safety, and mechanisms of action has continued at pace.

An in-depth search of bibliographic databases – MEDLINE (National Library of Medicine, Bethesda, USA) and EMBASE (Elsevier BV, Amsterdam, Netherlands) – identified over 750 peer-reviewed articles and over 40 published conference abstracts in support of dressings with Safetac, as of August 2025. In addition, a search of the Mölnlycke archives revealed over 200 supportive conference posters. Collectively, the identified 'evidence pieces' describe research that encompasses the entire evidence hierarchy (**Figure 5**).

Figure 5. Quantitative breakdown of 'evidence pieces' in support of dressings with Safetac



For further details of the 'evidence pieces' please scan the QR code

When making clinical decisions, it is common practice to consider the relative weight of the available data according to the type of studies from which they emanate. In the hierarchy of clinical evidence, the randomised controlled trial (RCT), in addition to systematic reviews and meta-analyses of data obtained from multiple RCTs, are generally considered to be the 'gold standards' for judging the merits of interventions (Ahuja et al, 2019), yet concerns have been expressed about the over-reliance of RCTs in decision-making. For example, RCTs, with their focus on inter-cohort comparisons and standardised interventions, may not capture the nuances and complexity of real-world wound care, where patients may elicit unique responses to the same interventions (Carter et al, 2009; Bull et al, 2023).

It has been suggested that, regarding wound care, evidence-based medicine should not be restricted to RCTs and meta-analyses, and instead involve the exploration of all available evidence to answer clinical questions (Wounds UK, 2023). This review takes into consideration the full evidence hierarchy in summarising the published research data relating to dressings with Safetac. It is not a systematic review and to critically evaluate every single evidence piece cited in **Figure 5** would make it an extremely large document. Instead, the review aims to present the key evidence in one place and help readers to draw their own conclusions from it.

The evidence in support of dressings with Safetac 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. This should be carefully considered by clinicians when selecting dressings

Preventing dressing-related trauma

There is a predisposition for some modern dressings with traditional adhesive systems to inflict damage on delicate wound tissue or frail peri-wound skin (Charlesworth et al, 2014; Matsumura et al, 2014). A challenge for the clinician, therefore, is to identify dressings that minimise or even negate dressing-related trauma. Safetac technology is based on soft silicone, a material that readily adheres to intact dry skin and remains in place on the surface of a moist wound or damaged surrounding skin without adhering to these fragile tissues. Consequently, dressings with Safetac technology can be repeatedly applied and re-applied without causing damage to the wound or stripping the epidermis of the surrounding skin (Cutting, 2008). The gentle but effective seal that forms between the intact skin and a dressing with Safetac technology inhibits the movement of exudate from the wound into the surrounding area, thereby helping to prevent moisture-related damage (e.g. maceration) of the peri-wound region (White, 2005).

Numerous studies involving healthy volunteers (Dykes et al, 2001; Dykes, 2007; Waring et al, 2008; Waring et al, 2011) and patients with chronic wounds (Zillmer et al, 2006) have confirmed the ability of dressings with Safetac to be less traumatic on removal than dressings with other adhesive systems (**Table 1**).

Table 1. Dressing-related trauma – key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Zillmer et al, 2006 RCT (intra-patient) Denmark	**Subjects:** 29 (adults) **Wounds:** Peri-wound skin of open/healed VLUs (dressings also applied to normal forearm skin) **Setting:** Dermatology clinic	**Safetac:** Mepilex Border **Comparators:** Biatain Adhesive and Duoderm Extra Thin (hydrocolloid-based adhesives); Tielle (polyurethane-based adhesive)	Skin barrier function (TEWL) and stratum corneum hydration (EC) measured after 14 days of applications (dressings changed every 2 days)	No statistically significant difference in TEWL and EC detected between Mepilex Border, polyurethane-based adhesive dressing and non-dressed adjacent area. TEWL and EC of peri-wound skin in contact with hydrocolloid-based adhesive dressings was significantly ($p \leq 0.05$) higher than that of adjacent non-dressed area (**Figure 8**). Similar relative effects were observed for normal forearm skin.
Waring et al, 2011 Healthy volunteer study (randomised dressing application) United Kingdom	**Subjects:** 22 (adults) Dressings applied to lower back (skin pre-stained with dye) **Setting:** Dermatology clinic	**Safetac:** Mepilex Border **Comparators:** Allevyn Adhesive (acrylic adhesives); Biatain, Comfeel Plus and Versiva XC (hydrocolloid-based adhesive); Urgotul Trio (hydrocolloid/ petrolatum-based adhesive)	Skin barrier function (TEWL) Stained skin removal (chromameter), i.e. colour change Skin attached to removed dressings (electron microscopy) Parameters listed above measured at dressing changes (every 2-3 days) over a 15 day period	TEWL of the untreated test area and the skin in contact with Urgotul Trio remained relatively unchanged; for the skin in contact with Mepilex Border, a slight decrease in TEWL ($1 g/m^2/hour$) was observed; increases were recorded in areas in contact with Allevyn Adhesive ($5 g/m^2/hour$), Versiva XC ($14 g/m^2/hour$), Comfeel Plus ($22 g/m^2/hour$) and Biatain ($28 g/m^2/hour$). At study end, only the untreated area (mean 43% dye remaining), Mepilex Border (76%) and Urgotul Trio (34%) areas had visible dye remaining. All dressings showed evidence of stratum corneum attached to the adhesive, except Mepilex Border, which appeared to be free of any attached stratum corneum.
Waring et al, 2008 Healthy volunteer study United Kingdom	**Subjects:** 22 (adults) Dressings applied to forearm **Setting:** Dermatology clinic	**Safetac:** Mepilex Border **Comparators:** Allevyn Adhesive (acrylic adhesive)	Peel force required to remove dressing – measured after 24, 48 and 72 hours of application Cell adhesion to dressing on removal (electron microscopy and protein analysis)	No difference between the dressings in terms of peel force required for removal. Less cellular material and protein deposits attached to Mepilex Border dressings on removal (**Figure 7**).

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Dykes, 2007 Healthy volunteer study (randomised dressing application) United Kingdom	**Subjects:** 30 (adults) Dressings applied to lower back **Setting:** Dermatology clinic	**Safetac:** Mepilex Border Lite **Comparators:** Allevyn Adhesive (acrylic adhesive); Comfeel Plus Transparent and Duoderm Extra Thin (hydrocolloid-based adhesive); Tielle Plus (polyurethane-based adhesive)	CIS (summation of erythema scores at days 3, 5, 8, 10, 12 and 13) Skin barrier function (TEWL)	CIS for Mepilex Border Lite was lower than that for Biatain Adhesive, Comfeel Plus Transparent and Duoderm Extra Thin ($p<0.05$). Skin that had Mepilex Border Lite applied was associated with lower TEWL values than where Biatain Adhesive, Comfeel Plus Transparent and Duoderm Extra Thin had been applied ($p<0.05$). Values for Mepilex Border Lite treated areas were not significantly different to those for non-treated skin.
Dykes et al, 2001 Healthy volunteer study (randomised dressing application) United Kingdom	**Study part 1** **Subjects:** 12 (adults) Dressings applied to forearm (skin pre-stained with dye) **Setting:** Dermatology clinic	**Safetac:** Mepiform **Comparators:** Duoderm Extra Thin (hydrocolloid-based adhesive); Tielle (polyurethane-based adhesive)	Amount of dye left on skin after dressing removal (sampled using skin surface biopsy; measured by spectrophotometry). Measured after 1x24 hour application and 3x24 hour applications of dressings	Higher level of dye on the skin that had Mepiform applied, compared to the skin that had the other dressings applied ($p<0.05$) – indicative of less damage with Mepiform.
	Study part 2 **Subjects:** 20 (adults) Dressings applied to back (skin pre-stained with dye) **Setting:** Dermatology	**Safetac:** Mepilex Border **Comparators:** Allevyn Adhesive (acrylic adhesive); Biatain Adhesive and Duoderm Extra Thin (hydrocolloid-based adhesives); Tielle (polyurethane- based adhesive)	Peel force required to remove dressing – 3 consecutive 24-hour applications – measured after 24, 48 and 72 hours Amount of dye left on skin after dressing removal (skin surface biopsy; spectrophotometry). Measured after 1x24-hour application and 3x24-hour applications of dressings	Rank order (from greatest to least peel force): Allevyn Adhesive > Tielle > Duoderm Extra Thin > Mepilex Border > Biatain Adhesive (**Figure 6a**). Rank order (from most to least damaging): Biatain Adhesive > Duoderm Extra Thin > Allevyn Adhesive > Mepilex Border (**Figure 6b**).

Abbreviations: CIS = cutaneous irritancy score; EC = electrical conductance; RCT = randomised controlled trial; TEWL = transepidermal water loss; VLU = venous leg ulcer

In one healthy volunteer study, measurements of the peel force required to remove dressings and the amount of pre-dyed skin removed at dressing changes (i.e. the more dye left on the skin after dressing removal, the less damage incurred) were undertaken to compare dressings with traditional adhesive systems (acrylic, hydrocolloid and polyurethane) and dressings with Safetac (Mepiform and Mepilex Border), with the traditional dressings showing much greater tendency to cause damage on removal. In terms of peel forces required to remove dressings, Mepilex Border had one of the lowest scores **(Figure 6)** (Dykes et al, 2001). In another healthy volunteer study which set out to compare two adhesive dressings, the surfaces of removed dressings were subjected to electron microscopy and protein analysis. Less cellular materials and protein deposits were attached to Mepilex Border than the dressing with acrylic adhesive **(Figure 7)** (Waring et al, 2008).

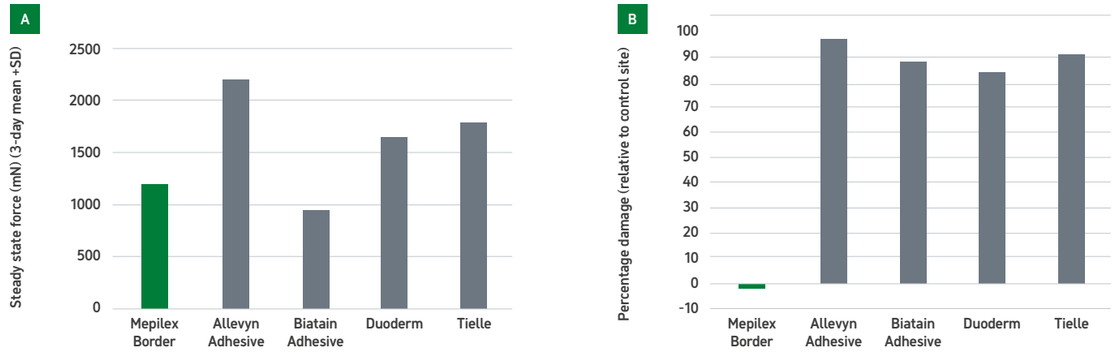


Figure 6. Comparison of adhesive borders of dressings in terms of (a) peel forces required to remove them and (b) removal of pre-dyed skin from backs of healthy volunteers (Dykes et al, 2001)

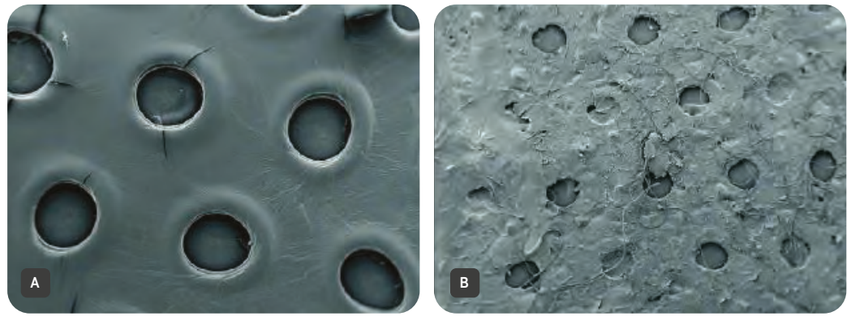


Figure 7. Scanning electron micrographs of: (a) Mepilex Border with Safetac technology after removal; and (b) dressing with acrylic adhesive after removal. Note the lack of epidermal cells on the surface of the dressing with Safetac compared to the large number of cells on the surface of the acrylic adhesive-based dressing

The effect of repeated removal of adhesive dressings on the peri-wound skin of patients with open or healed **venous leg ulcers** was evaluated in an RCT. Patches of adhesive dressings were applied over 14 days (changed every two days). Skin barrier function (assessed by transepidermal water loss (TEWL) measurement) and stratum corneum hydration (assessed by electrical conductance (EC) measurement) were monitored. The peri-wound skin on which dressings with Safetac (Mepilex Border) had been applied had TEWL and EC similar to those of adjacent non-dressing-applied skin, whereas the peri-wound skin on which dressings with hydrocolloid-based adhesive systems had been applied were found to have significantly higher TEWL and EC **(Figure 8)**. Similar results were observed for the normal forearm skin (Zillmer et al, 2008).

A dressing property that is often overlooked in the context of dressing-related trauma is conformability. A conformable dressing should follow the contours of the surface of the wound and surrounding skin. This will generally contribute to patient comfort and minimise the likelihood of dressing-related complications such as blistering and maceration (caused by leaking exudate). More conformable dressings are likely to be more versatile in their applications, as they can be applied to some of the more difficult-to-dress anatomical locations and are more likely to stay in place during wear. In an investigation into six dressings (Biatain Soft, Biatain Silver, Biatain Non-Adhesive, Allevyn Gentle, Mepilex and Mepilex Ag) utilising laboratory methods to distort dressings under pressure, the dressings with Safetac were shown to be the most conformable to a small radius and at lower pressure. As part of the same investigation, a healthy volunteer study was undertaken to compare Mepilex Border with Allevyn Gentle in terms of conformability and comfort during wear. Mepilex Border outscored the comparator dressing in terms of both parameters (Waring & Butcher, 2011).

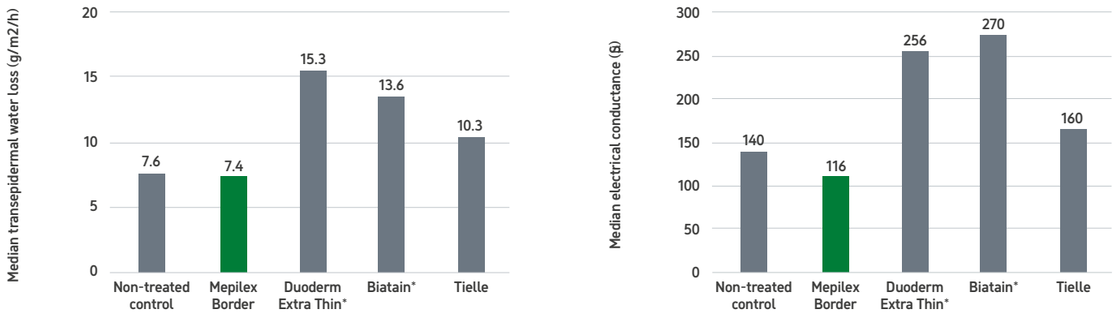


Figure 8. Comparison of adhesive borders of dressings in terms of transepidermal water loss (TEWL) and electrical conductance (EC) associated with repeated application and removal from peri-wound skin of patients with venous leg ulcers (Zillmer et al, 2008). Asterisks indicate statistically significant difference compared to adjacent non-treated skin (p≤0.05).

Negative pressure wound therapy (NPWT) can be described in simple terms as a closed, sealed system that applies negative pressure to the wound. To achieve this, the wound is covered or filled (depending on its depth) with a dressing (usually foam or gauze) and sealed (by means of an adhesive dressing or occlusive drape) before negative pressure is applied by connecting tubes from the dressing to a pump and fluid collector. Widely used in the management of a diverse range of acute and chronic wound types, NPWT increases perfusion and promotes the formation of healthy granulation tissue, whilst removing excess fluid and bacteria from the wound. Numerous articles describe the use of **Mepitel** as an interface between the wound and the dressings supplied with the traditional NPWT systems to minimise trauma and pain at dressing changes, prevent in-growth of tissue into the NPWT dressing and protect delicate deep structures (Banwell, 1999; Dunbar et al, 2005; Muller & de Jongh, 2008; Poulakidas & Kowal-Vern, 2008; Singh et al, 2008; Chadwick et al, 2010; Koehler et al, 2014; Halama et al, 2019; Frear et al, 2020; Lumsden et al, 2023).

Compared to the traditional systems, the recently introduced single-use NPWT systems are generally smaller and lighter, do not require a mains electricity supply (instead, they are powered mechanically or by batteries), require less or no maintenance, are simpler to operate and consume less clinicians' time. Their portability also facilitates patient mobility. In addition to the above, the **Avance Solo NPWT System** is supplied with dressings that have wound contact surfaces coated with Safetac. Clinical studies have observed minimal dressing-related trauma with the absorbent (**Avance Solo Border**) and film (**Avance Solo Adapt Film**) dressings supplied with Avance Solo (Rose et al, 2024; Beele et al, 2025a; Beele et al, 2025b).

Post-operative blistering

The post-operative development of blisters around surgical incision sites is an unwanted complication that can cause pain, discomfort, persistent wound leakage and increase the risk of infection (Eastburn et al, 2016). The incidence of post-operative blistering varies according to surgical specialty, with particularly high rates reported following orthopaedic surgeries, i.e. hip and knee operations (Ousey et al, 2011). For example, incidence rates ranging from 13-35% have been reported on orthopaedic wards (Wright, 1994). Although skin changes in older patients and the presence of soft tissue oedema following surgery have been reported to contribute to post-operative blistering, dressing-related factors are generally regarded as the main contributor.

Presently, the majority of closed surgical incision sites continue to be managed with conventional dressings or, in the case of patients who have intrinsic risk factors for surgical site complications or who have undergone procedures associated with a particularly high incidence of such complications, closed incision negative pressure wound therapy (ciNPWT) (Davies, 2022). However, blistering has been reported to be a problem with some NPWT systems (Howell et al, 2011), and certain dressing types, e.g. those that incorporate the traditional adhesives described earlier that are known to inflict trauma (e.g. skin stripping) on removal (Ousey et al, 2011; Ravenscroft et al, 2006). It has also been suggested that, if a dressing is placed over a joint and left in place for a relatively long period of time, joint movement could cause friction between the skin and the dressing, leading to the creation of shear forces that, in turn, cause separation of the epidermal and dermal layers of the skin (i.e. blisters) (Ravenscroft et al, 2006).

Commenting on the prevention of post-operative blistering, Ousey et al state: "A wound dressing should maintain a warm, moist healing environment and should not damage the peri-wound area, which could lead to blister formation. Protection of the peri-wound area is vital and can be achieved by choosing a dressing that does not adhere to surrounding skin, is easy to apply, easy to remove and flexible. Flexibility of the wound dressing is essential, especially for orthopaedic wounds that are prone to swelling and have an increased risk of friction between the wound and the dressing" (Ousey et al, 2011).

In four prospectively undertaken clinical trials (two of which were RCTs) involving in excess of 500 patients, no blistering or skin damage was reported on patients who had **Mepilex Border Post-Op** applied to their wounds (Beele et al, 2020; Bredow et al, 2018; Zarghooni et al, 2015; Yang et al, 2025). Furthermore, minimal dressing-related trauma associated with NPWT dressings incorporating Safetac wound/skin contact surfaces has also been observed (Rose et al, 2024).

Minimising dressing-related pain

By preventing trauma to the wound and peri-wound region on removal, dressings with Safetac minimise pain at dressing changes. **Table 2** provides a summary of the key research findings relating to dressings with Safetac and their ability to minimise dressing-related pain.

Table 2: Dressing-related trauma and pain – key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
David et al, 2018 RCT France	**Subjects:** 121 (age range 18-95 years) **Wounds:** Benign burns, traumatic wounds **Setting:** Outpatient wound care centres	**Safetac:** Mepitel One (n=59) **Comparator:** UrgoTul (n=62)	Pain severity (measured using VAS 0-100)	Higher proportion of patients experienced non-painful dressing removal (defined as pain rating <30) in the Mepitel One group, compared to the comparator group (p=0.02): - Mepitel One: 89.8% - UrgoTul: 73.6%
Tang et al, 2015 RCT China	**Subjects:** 153 (age range 5-65 years) **Wounds:** Deep partial thickness thermal burns <36 hours post injury (TBSA 2.5-25%) **Setting:** Burn care centre	**Safetac:** Mepilex Ag (n=71) **Comparator:** SSD cream (n=82)	Pain severity (measured using VAS 0-100) before, during and after dressing removal	Lower mean pain severity scores in Mepilex Ag group than in comparator group (**Figure 9**): Week 1: - Before: 11.7 vs. 23.9 (p<0.0001) - During: 19.4 vs. 40.1 (p<0.0001) - After: 17.3 vs. 34.3 (p<0.0001) Week 4: - Before: 6.8 vs. 11.0 (p=0.0081) - During: 9.2 vs. 19.1 (p=0.0050) - After: 9.4 vs. 15.8 (p=0.0013)
Woo et al, 2009 RCT (cross-over design) Canada	**Subjects:** 26 (mean age 63.7 years) **Wounds:** Venous leg ulcers (90.6%), pyoderma gangrenosum (6.3%), vasculitis (3.1%) **Setting:** Outpatient wound care centres	**Safetac:** Mepilex Border (n=26) **Comparator:** Allevyn Adhesive (acrylic adhesive) (n=26)	Pain severity (measured using VAS ranging from 0-10) before and during dressing changes	Lower mean pain severity in Mepilex Border group than in comparator group: Follow-up 1: - Before: 1.8 vs. 3.0 (p=0.007) - During: 2.0 vs. 3.4 (p=0.0089) Follow-up 2: - Before: 2.1 vs. 3.0 (p=0.0009) - During: 2.2 vs. 3.3 (p=0.0024)
Upton & Solowiej, 2012 Non-randomised comparative clinical study United Kingdom	**Subjects:** 49 (age range 38-95 years) **Wounds:** Foot ulcers, leg ulcers **Setting:** Wound care centres	**Safetac:** Mepilex (n=10) **Comparators:** Variety of dressings with traditional and advanced adhesives (n=39)	Physiological (numerical ratings, heart rate, blood pressure, respiratory rate, GSR, salivary cortisol) and psychological (PSS, STAI) assessments of pain and stress at dressing changes	Significantly lower numerical pain and stress ratings and GSR in Mepilex group (p<0.05). Mean heart rate, blood pressure and salivary cortisol levels were lower in the Mepilex group. PSS and STA scores were similar in both groups. See **Table 3** for further details.
White, 2008 Survey (patients) 20 countries (Europe, Asia-Pacific, Americas)	**Subjects:** 3024 (age not specified) **Wounds:** Burns, foot ulcers, leg ulcers, pressure injuries, skin tears **Setting:** Not specified	**Safetac:** Mepilex, Mepilex Lite, Mepilex Border, Mepilex Border Lite, Mepitel **Comparators:** Variety of dressings (e.g. foam and hydrocolloids) with traditional adhesives	Trauma (subjective rating) Pain severity (measured using VAS 0-10) before, during and after dressing changes	Less severe trauma levels with Safetac dressings: - Safetac: high 1%; moderate 11%, very slight 35-37%; none 50% - Comparators: high 10%; moderate 28-39%; very slight 31-35%; none 18-29% Significantly lower pain severity scores with Safetac dressings at all assessments (p=0.01): - Safetac: 1.7-1.8, 2.1-2.2 and 1.6-1.7 before, during and after dressing changes - Comparators: 2.4-3.2, 4.6-5.2 and 2.9-3.9 before, during and after dressing changes >90% of respondents stated a preference for dressings with Safetac to traditional adhesive dressings.

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Dykes & Heggie, 2003 Healthy volunteer study (randomised dressing application) United Kingdom	**Subjects:** 24 (age range 18-65 years) Dressings applied to lower back **Setting:** Dermatology	**Safetac:** Mepilex Border **Comparators:** Allevyn Adhesive (acrylic adhesive); Biatain, Duoderm Extra Thin and Versiva (hydrocolloid-based adhesive); Tielle (polyurethane-based adhesive)	Peel force required to remove dressings Discomfort on dressing removal (measured using VAS)	Mepilex Border associated with significantly lower peel force measurements than Tielle ($p<0.01$) and Allevyn Adhesive ($p<0.05$). Mepilex Border associated with significantly lower discomfort scores than other dressings ($p\leq0.01$).

Abbreviations: GSR = galvanic skin response; PSS = Perceived Stress Scale; RCT = randomised controlled trial; SSD = silver sulphadiazine; STAI = State Trait Anxiety Inventory; TBSA = total body surface area; VAS 0-10 = visual analogue scale ranging from 0 (no pain) to 10 (worst pain imaginable); VAS 0-100 = visual analogue scale ranging from 0 (no pain) to 100 (worst pain imaginable)

One of the first studies to determine the level of pain experienced on removal of dressings involved healthy volunteers. It investigated the causal relationship between the peel force of dressings with a variety of different adhesives and the discomfort experienced upon their removal, measured using a visual analogue scale (VAS). The dressing with Safetac (Mepilex Border) was associated with significantly lower discomfort scores on removal than dressings with traditional adhesives ($p\leq0.01$). Interestingly, there was poor correlation between the discomfort scores and the peel force measurements, suggesting that aspects of skin-surface adhesion interactions other than peel force influence the level of pain experienced on dressing removal (Dykes & Heggie, 2003).

In a more recent healthy volunteer study, the energy (Newton, N) required to remove dressings from the skin was determined for different dressing types – acrylate, hydrocolloid, polyurethane and silicone, including Mepilex, Mepilex Border and Mepilex Lite. The median values obtained were 2.25N for hydrocolloid, 1.14N for acrylate, 0.9N for polyurethane and 0.7N for silicone dressings. In the same study, the pain intensity (measured using a VAS scale ranging from 0 (no pain) to 10 (worst pain imaginable)) was 6.8 for hydrocolloid, 4.9 for acrylate, 3.1 for polyurethane and 2.5 for silicone dressings. A statistically significant correlation between the adhesion and pain intensity was determined (correlation coefficient 0.806; $p=0.01$) (Klode et al, 2011).

Several RCTs observed significantly lower pain severity scores in patients managed with Safetac dressings relative to the comparator dressings. For example, in an RCT which compared Mepilex Ag and silver sulphadiazine (SSD) cream in the management of **deep partial thickness** burns in China, significant differences (in favour of Mepilex Ag) in pain severity scores prior to, during and after dressing removal at various time points were observed ($p\leq0.0081$). Data obtained at weeks 1 and 4 of the study are presented in **Figure 9** (Tang et al, 2015).

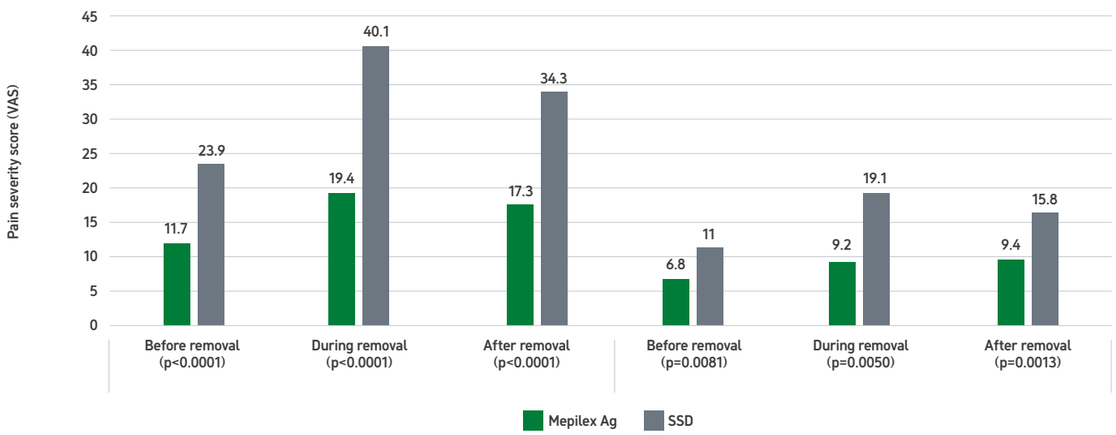


Figure 9. Comparison of pain severity scores between Mepilex Ag and silver sulphadiazine (SSD) cream in patients with partial thickness thermal burns, measured using a visual analogue scale ranging from 0 to 100 (Tang et al, 2015)

Another RCT undertaken in the USA observed significantly lower pain severity at dressing application ($p=0.0018$) and during wear ($p=0.048$) with Mepilex Ag, compared to SSD in the management of **partial thickness thermal burns**. The trend in pain reduction at dressing change was associated with a significant difference in the average weekly costs of pain medication ($p=0.031$). Background pain analgesia was also lower in the Mepilex Ag group (Silverstein et al, 2011). In a later RCT undertaken in Australia involving paediatric patients with **partial thickness burns**, 25% lower VAS pain scores were recorded after dressing removal in patients receiving Mepilex Ag, compared to the group managed with nanocrystalline silver-containing dressings ($p=0.04$). In the same study, FLACC (Face, Legs, Activity, Cry, Consolability) pain scores were 32% lower at dressing removal ($p=0.01$) and 37% lower at new dressing application ($p=0.04$) in the Mepilex Ag group, relative to the group managed with nanocrystalline silver-containing dressings (Gee Kee et al, 2015).

An open, randomised, cross-over, multicentre study was undertaken to compare Mepilex Border with an acrylic adhesive-base dressing in terms of the pain experienced by patients with chronic ulcers (**VLUs, pyoderma gangrenosum** and **vasculitis**). The pain severity scores, measured using a VAS before and during dressing removal were significantly ($p\leq0.001$) lower in patients in the Mepilex Border group than in the comparator group (**Figure 10**). The authors refer to Mepilex Border minimising skin irritation from corrosive exudate, suggesting that this may explain why patients experienced less pain with the Safetac dressing (Woo et al, 2009).

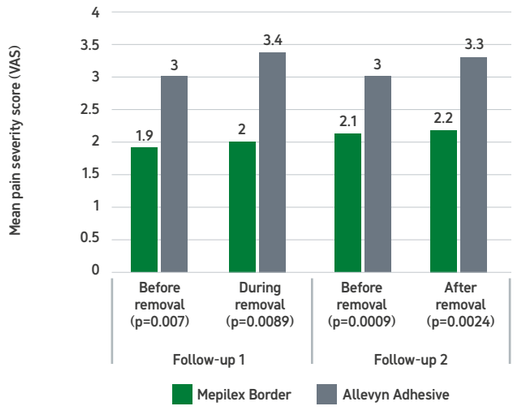


Figure 10. Comparison of pain severity scores between Mepilex Border and an acrylic adhesive-based dressing in patients with chronic wounds, measured using a visual analogue scale ranging from 0 to 10 (Woo et al, 2009)

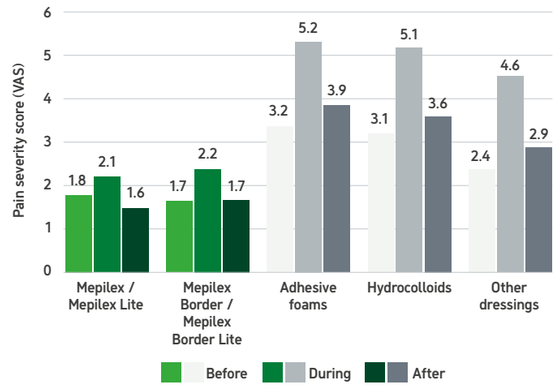


Figure 11. Pain severity scores (based on a visual analogue scale ranging from 0-10) recorded before, during and after removal of dressings with different adhesive technologies (White, 2008).

The wound contact layer, Mepitel One, was also associated with less pain at dressing change than the comparator dressing (lipidocolloid-impregnated wound contact layer) in an RCT involving patients with acute wounds (**traumatic wounds** and **minor burns**). At the first dressing removal, 89.8% of patients in the Mepitel One group experienced non-painful dressing changes (defined as a pain rating of <30 on a VAS ranging from 0 to 100), compared with 73.6% of patients in the comparator group ($p=0.017$) (David et al, 2018). Also of interest are the findings of an observational study involving 36 paediatric patients with a variety of wound types (**burns, surgical wounds** and **traumatic wounds**). Using a VAS-based pain assessment tool and the Wong-Baker faces scale, pain severity levels reported at baseline (i.e. associated with a variety of previously used dressing types) were compared with those after the introduction of Mepilex Border Lite. Mean pain severity scores were significantly lower after the introduction of the dressing with Safetac (Morris et al, 2009).

A multinational survey of over 3000 patients, presenting with a variety of wound types (including **diabetes-related foot ulcers, leg ulcers** (arterial, venous or mixed aetiologies), **pressure injuries (PIs), burns** and **skin tears**), was undertaken to gauge the impact of introducing dressings with Safetac (Mepilex, Mepilex Border, Mepilex Border Lite, Mepilex Lite) on the intensity of wound-related trauma and pain, in comparison to previously used regimes involving dressings with traditional adhesives (e.g. alginates, films, foams, hydrocolloids). The dressings with Safetac were associated with reduced trauma to the wound and peri-wound skin and significantly ($p=0.01$) lower pain severity scores (measured by means of a VAS) before, during and after dressing change, compared to the dressings with traditional adhesives (**Figure 11**). When asked about dressing preference, more than 90% indicated that they preferred the dressings with Safetac to their previous dressing regimes (White, 2008).

Health psychology experts undertook a clinical study to compare the pain and stress experienced by patients with chronic wounds (foot ulcers and leg ulcers) at dressing changes. Of the 49 patients recruited, 10 had their wounds dressing with Mepilex and 39 with conventional dressings. Patients in the Mepilex group reported significantly lower numerical pain and stress ratings and significantly lower galvanic skin response at dressing changes. Heart rate, blood pressure and salivary cortisol levels were also lower in the Mepilex group, compared to the conventional dressings group (**Table 3**) (Upton & Solowiej, 2012).

Table 3. Comparison of Mepilex and conventional dressings in terms of psychological and physiological pain and stress scores (mean) in patients with chronic wounds (Upton & Solowiej, 2012)

Pain/stress parameter	Mepilex	Conventional dressings
Numerical pain	1.43*	3.66*
Numerical stress	2.00*	3.63*
Blood pressure (systolic)	125.70	137.82
Blood pressure (diastolic)	64.22	69.13
Heart rate	69.11	75.62
Respiratory rate	16.86	16.09
Salivary cortisol	0.13	0.17
Galvanic skin response	19.76*	33.15*
Perceived Stress Scale score	24.60	22.72
State Trait Anxiety Index score	38.40	33.31

* difference between groups statistically significant ($p<0.05$)

Dressings with Safetac: composition, intended uses and key evidence

Table 4 provides comprehensive details of the classification, composition and intended uses of the many dressings with Safetac, as well as listing the key supporting evidence.

Table 4. Classification and description of dressings with Safetac (any products referred to in this document should be used according to the instructions for use supplied with them. Product availability and intended uses can vary across regions. Please consult your local Mölnlycke representative for guidance)

Absorbent foam dressings with self-adhesive borders

Mepilex Border

Composition: Safetac wound contact layer with a film carrier; a flexible absorbent pad consisting of three layers (polyurethane foam, non-woven spreading layer, and layer with superabsorbent fibres) and a vapour-permeable backing film (polyurethane).

Uses: Self-adhesive dressing for use as part of a prophylactic regime to help prevent skin damage, e.g. pressure injury (PI), and reduce post-operative bleeding. Also used on a wide range of exuding wound types to absorb excess exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound).

Key evidence

Foot ulcers: White, 2008; Miscavige, 2005; Vowden & D'Arcy, 2008

Leg ulcers: Woo et al, 2009; Zillmer et al, 2006; White, 2008; Mwipatayi et al, 2016; Neal, 2004

Pressure injuries: Sullivan, 2013; Meaume et al, 2003; White, 2008; Barrows, 2009; Webb, 2008

Pressure injury prevention: Beeckman et al, 2021; Oe et al, 2020; Yoshimura et al, 2024; Yang & Shin, 2020; Park, 2014

Surgical wounds: Johansson et al, 2012; Pukki et al, 2010; Joncas et al, 2010

Traumatic wounds: Wood et al, 2019. White, 2008; Dunbar et al, 2006

Mepilex Border Ag

Composition: Safetac wound contact layer; a flexible absorbent pad consisting of three layers (polyurethane foam containing silver sulphate and coloured with activated carbon; non-woven spreading layer, and layer with superabsorbent fibres) and a vapour-permeable backing film (polyurethane).

Uses: Self-adhesive, silver-containing dressing for use on a wide range of medium-to-highly exuding wound types when topical antimicrobial therapy is indicated. The dressing is designed to absorb excess exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. In the presence of exudate, silver ions are released, inactivating wound-related pathogens. By reducing the number of microorganisms, the dressing may also reduce malodour. It can be left in place for up to 7 days (depending on the nature and condition of the wound)."

Key evidence

Burns: McCarty et al, 2013

Foot ulcers: McCarty et al, 2013; Davis, 2012

Leg ulcers: McCarty et al, 2013; Philbin, 2012

Malignant wounds: McCarty et al, 2013

Pressure injuries: McCarty et al, 2013; Krasner & McKinney, 2012; Philbin, 2012

Surgical wounds: Kles et al, 2015; Meek & Downs, 2012; Zurcher et al, 2013

Traumatic wounds: McCarty et al, 2013; Krasner & McKinney, 2012; Philbin 2012

Mepilex Border Lite

Composition: Safetac wound contact layer with a film carrier; a flexible absorbent pad consisting of two layers (polyurethane foam and non-woven spreading layer) and a vapour-permeable backing film (polyurethane).

Uses: Self-adhesive dressing for use on a wide range of non-to-moderately exuding wound types to absorb excess exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound). Can also be used to protect compromised/fragile skin.

Key evidence

Foot ulcers: White, 2008; Meuleneire, 2008a

Leg ulcers: White, 2008; Mansouri et al 2014

Pressure injuries: White, 2008; Ramos-Torrecillas et al, 2013

Surgical wounds: Morris et al, 2009; Meuleneire, 2009; De Meyst & Meuleneire, 2010

Traumatic wounds: Morris et al, 2009; Meuleneire, 2009; White, 2008; Montmaneix et al, 2012

Protection of fragile/compromised skin, e.g.

- epidermolysis bullosa: Denyer et al, 2017
- ostomy complication prevention: Kaufman, 2008

Mepilex Border Flex (sold as Mepilex Border Comfort in the United Kingdom)

Composition: Safetac wound contact layer with a film carrier; a flexible absorbent pad consisting of three layers (polyurethane foam, non-woven spreading layer, and layer with superabsorbent fibres) and a vapour-permeable backing film (polyurethane). The absorbent pad is partly perforated with Flex cut technology (y-shaped cuts) that evenly distribute forces to the dressing's borders which, in turn, supports adherence and conformability while allowing the dressing to stretch (particularly beneficial when applying to joints and other highly mobile areas). The outermost backing film layer includes a pattern of dots that allow the spread of exudate to be tracked without disturbing the wound.

Uses: Highly conformable, self-adhesive dressing for use on a wide range of exuding wound types to absorb excess exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for up to 7 days (depending on the nature and condition of the wound). Also used as part of a prophylactic regime to help prevent skin damage, e.g. pressure injury, and reduce post-operative bleeding.

Key evidence

Foot ulcers: Alvarez et al, 2021; Boixados et al, 2019; Nelson, 2019; Haycocks et al, 2018; Haycocks et al, 2021

Leg ulcers: Alvarez et al, 2021; Roldan Valenzuela et al, 2025; Tyson, 2019; Boixados et al, 2019; Nelson, 2019

Pressure injuries: Roldan Valenzuela et al, 2025; Tyson, 2019; Boixados et al, 2019; Nelson, 2019; Rook et al, 2019

Pressure injury prevention: Bates-Jensen et al, 2024; Peko et al, 2020

Surgical wounds: Boixados et al, 2019; Rook et al, 2019; Conde Montero et al, 2019

Traumatic wounds: Le Blanc & Woo, 2021; Nelson, 2018; Boixados et al, 2019; Nelson, 2019; Rook et al, 2019

Mepilex Border Flex Lite (sold as Mepilex Border Comfort Lite in the United Kingdom)

Composition: Safetac wound contact layer with a film carrier; a flexible absorbent pad consisting of two layers (polyurethane foam and non-woven spreading layer); and a vapour-permeable film (polyurethane) backing. Like Mepilex Border Flex, the absorbent pad is partly perforated with Flex cut technology and the outermost backing film layer includes a pattern of dots for exudate tracking.

Uses: Highly conformable, self-adhesive dressing for use on a wide range of non-to-moderately exuding wound types to absorb excess exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound). Can also be used to protect compromised/fragile skin.

Mepilex Border Heel

Anatomically shaped version of Mepilex Border designed for application to the heels. Composition and Uses: as for Mepilex Border.

Key evidence

Pressure injuries: Sullivan, 2013; Bateman, 2013; Bateman, 2014

Pressure injury prevention: Eberhardt et al, 2021; Hahnel et al, 2020; El Genedy et al, 2020; Santamaria et al, 2015a

Mepilex Border Sacrum

Anatomically shaped version of Mepilex Border designed for application to the sacrum. Composition and Uses: as for Mepilex Border.

Key evidence

Pressure injuries: Brindle et al, 2011

Pressure injury prevention: Beeckman et al, 2021; Hahnel et al, 2020; El Genedy et al, 2020; Santamaria et al, 2018; Kalowes et al, 2016; Santamaria et al, 2015b; Santamaria et al, 2015c; Latimer et al, 2024

Mepilex Border Sacrum Ag

Anatomically shaped version of Mepilex Border Ag designed for application to the sacrum. Composition and Uses: as for Mepilex Border Ag.

Absorbent foam dressings without self-adhesive borders

Mepilex

Composition: Safetac wound contact layer; a flexible absorbent pad (polyurethane foam); and a vapour-permeable backing film (polyurethane).

Uses: Highly conformable dressing for use on a wide range of exuding wound types to absorb excess exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound). Can also be used to protect compromised/fragile skin. May also be used as part of a prophylactic regime to help prevent skin damage, e.g. pressure injury.

Key evidence

Foot ulcers: Upton & Solowiej, 2012; White, 2008; Eytier et al, 2013; Eager, 2001; McCardle et al, 2009

Leg ulcers: Upton & Solowiej, 2012; White, 2008; Eytier et al, 2013; Eager, 2001; Yilmaz et al, 2015

Pressure injuries: White, 2008; Eytier et al, 2013; Ruggeri et al, 2016; Eager, 2001

Pressure injury prevention: Tsao et al, 2013; Acorda, 2015; Hsu et al, 2011; Shearer et al, 2021

Traumatic wounds: Tsai et al, 2019; Xiao et al, 2021; White, 2008; Eager, 2001

Protection of fragile/compromised skin, e.g. epidermolysis bullosa: Tadini et al, 2015; Snelson & Downe, 2023; Schumann et al, 2005; Denyer et al, 2017

Mepilex Ag

Composition: Safetac wound contact layer; a flexible absorbent pad (polyurethane foam) containing silver sulphate and coloured with activated carbon; and a vapour-permeable backing film (polyurethane).

Uses: Highly conformable silver-containing dressing for use on a wide range of low-to-moderately exuding wound types when topical antimicrobial therapy is indicated. The dressing is designed to absorb excess exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. In the presence of exudate, silver ions are released, inactivating wound-related pathogens. By reducing the number of microorganisms, the dressing may also reduce malodour. It can be left in place for up to 7 days (depending on the nature and condition of the wound).

Key evidence

Burns: Gee Kee et al, 2017; Gee Kee et al, 2015; Silverstein et al, 2011; Aggarwala et al, 2021; Karlsson et al, 2019; Tang et al, 2015

Foot ulcers: Truchetet et al, 2012; Durante, 2008; Meuleneire, 2008b; Schumann et al, 2007; Richards & Chadwick, 2011

Leg ulcers: Truchetet et al, 2012; Kota et al, 2014; Durante, 2008; Meuleneire, 2008b; Schumann et al, 2007

Pressure injuries: Ruggeri et al, 2016; Truchetet et al, 2012; Meuleneire, 2008b; Cuvelier, 2009

Mepilex Heel

Anatomically shaped version of Mepilex designed for application to the heels. Composition and Uses: as for Mepilex.

Key evidence

Foot ulcers: Meuleneire, 2008a

Pressure injuries: Meuleneire & Fostier, 2008

Pressure injury prevention: Santamaria et al, 2015b; Santamaria et al 2015c; Santamaria et al, 2018; Padula et al, 2019

Mepilex Heel Ag

Anatomically shaped version of Mepilex Ag designed for application to the heels. Composition and Uses: as for Mepilex Ag.

Mepilex Lite

Composition: Safetac wound contact layer; a thin, flexible absorbent pad (polyurethane foam) and a vapour-permeable backing film (polyurethane).

Uses: Highly conformable dressing for use on a wide range of non-to-low exuding wound types to absorb excess exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound). Can also be used to protect compromised/fragile skin and to prevent skin damaged under medical devices.

Key evidence

Burns: Himdani et al, 2016

Epidermolysis bullosa: Miura & Nakagomi, 2021; Denyer et al, 2017

Foot ulcers: Zhang & Xing, 2014; White, 2008; Khramilin, 2006; O'Neill, 2004

Leg ulcers: White, 2008

Pressure injuries: White, 2008

Radiotherapy-induced skin damage: Zhong et al, 2013; Paterson et al, 2012; Perez et al, 2011; Diggelmann et al, 2010; MacBride et al, 2008

Protection of fragile/compromised skin, e.g.

- pressure injury prevention: Boesch et al, 2012; Cohen et al, 2019; Orlov & Gefen, 2023; Krupova et al, 2024; Smith, 2006
- epidermolysis bullosa: Yuen et al, 2013; Van Vuuren et al, 2017

Mepilex Up

Composition: Safetac wound contact layer; a dimpled, flexible absorbent pad (compressed polyurethane foam) which helps to spread exudate across its structure in all directions, even working against gravitational forces by means of its capillary action, and a vapour-permeable backing film (polyurethane).

Uses: Highly conformable dressing for use on a wide range of low-to-highly exuding wound types to absorb excess exudate of both low and high viscosity (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound).

Key evidence

Foot ulcers: Lev-Tov et al, 2025

Leg ulcers: Lev-Tov et al, 2025

Mepilex XT

Composition: Safetac wound contact layer; a flexible absorbent pad (polyurethane foam) and a vapour-permeable backing film (polyurethane).

Uses: Highly conformable dressing with integrated exudate channels for use on a wide range of exuding wound types to absorb excess exudate of both low and high viscosity (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound).

Key evidence

Leg ulcers: Koerner & Adams, 2016; Villette et al, 2016

Exudate transfer dressings

Mepilex Transfer

Composition: Safetac wound contact layer; a flexible absorbent pad (polyurethane foam).

Uses: Highly conformable dressing for use on a wide range of exuding wound types to transfer exudate to secondary absorbent dressings (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound). Can also be used to protect compromised/fragile skin.

Key evidence

Burns: De Coster & Meuleneire, 2010

Surgical wounds: Lemarechal et al, 2009; Renauld, 2009

Traumatic wounds: Maeda et al, 2015

Protection of fragile/compromised skin, e.g.

- pressure injury prevention: Kim & Mullins, 2016
- radiotherapy-induced skin damage: Lemos et al, 2016
- epidermolysis bullosa: Yuen et al, 2013; Komori et al, 2018; Ly & Su, 2008; Hon et al, 2007

Mepilex Transfer Ag

Composition: Safetac wound contact layer; a flexible absorbent pad (polyurethane foam) containing silver sulphate and coloured with activated carbon.

Uses: Highly conformable silver-containing dressing for use on a wide range of low-to-highly exuding wound types when topical antimicrobial therapy is indicated. It can be left in place for up to 14 days (depending on the nature and condition of the wound). The dressing is designed to transfer exudate to secondary absorbent dressings (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. In the presence of exudate, silver ions are released, inactivating wound-related pathogens. By reducing the number of microorganisms, the dressing may also reduce malodour.

Key evidence

Burns: Schweiger et al, 2013; Lindford et al, 2021
Donor sites: Glat et al, 2017; Arnold-Long, 2015
Foot ulcers: Dhatariya et al, 2016
Leg ulcers: Arnold-Long, 2015
Malignant wounds: Marshall-Hanson, 2015

Wound contact layers

Mepitel

Composition: Transparent and flexible polyamide net coated on both sides with Safetac.

Uses: Wound contact layer for use on a wide range of exuding wounds. It can be left in place for up to 14 days (depending on the nature and condition of the wound), during which its open mesh structure allows exudate to pass into secondary absorbent dressings that can be changed as required, thereby minimising disturbance to the wound. The open structure also enables topical preparations to be delivered to the wound with Mepitel in place.

Key evidence

Burns: Bugmann et al, 1998; Gotschall et al, 1998; Platt et al, 1996; Vloemans & Kreis, 1994
Foot ulcers: Rando, 2009; Stansby et al, 2010; Young, 2002; Yoon & Song, 2024
Leg ulcers: Mwipatayi et al, 2016; Marconi et al, 2009;
Traumatic wounds: O'Donovan et al, 1999; Kennedy-Evans, 2004; Burton, 2004; Moradian & Klapper, 2016; Meuleneire, 2002
Protection of fragile/compromised skin, e.g.
- epidermolysis bullosa: Zhou et al, 2020; Denyer et al, 2017; Van Vuuren et al, 2017
- radiotherapy-induced skin damage: Adamietz et al, 1995

Mepitel One

Composition: Transparent and flexible polyamide net coated on only one side (wound contact surface) with Safetac.

Uses: As for Mepitel.

Key evidence

Burns: David et al, 2018; Patton et al, 2013 ; Edwards & Mason, 2013; Yanagisawa & Yuzuriha, 2018; Barrett, 2012
Foot ulcers: Sanches-Pinto et al, 2023; Atkin et al, 2017; Whalley, 2010
Leg ulcers: Sanches-Pinto et al, 2023; Atkin et al, 2017; Cooper et al, 2010
Traumatic wounds: David et al, 2018; Le Blanc & Woo, 2021; Barrett, 2012; Cooper et al, 2010

Mepitel Ag

Composition: Polyamide net, containing silver sulphate and cellulose compound, and coated on both sides with Safetac.

Uses: Wound contact layer for use on a wide range of exuding wounds when topical antimicrobial therapy is indicated. It can be left in place for up to 8 days (depending on the nature and condition of the wound), during which its open mesh structure allows exudate to pass into secondary absorbent dressings that can be changed as required, thereby minimising disturbance to the wound. In the presence of exudate, silver ions are released, inactivating wound-related pathogens. By reducing the number of microorganisms, the dressing may also reduce malodour.

Key evidence

Burns: Howard et al, 2017; Silverstein et al, 2014; Glat et al, 2017; Alemante et al, 2017; Schuh et al, 2024 ; Larson et al, 2020
Surgical wounds: Berard & Lau, 2022; Chaffin et al, 2021

Post-operative dressings

Mepilex Border Post-Op

Composition: Safetac wound contact layer; a flexible absorbent pad consisting of two layers (non-woven spreading layer and layer with superabsorbent fibres); and a vapour-permeable film (polyurethane) backing.

Uses: Self-adhesive, absorbent surgical dressing for use on exuding acute wounds (e.g. surgical wounds) to absorb blood and exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. Can be left in place for up to 14 days to minimise disturbance to wound healing and risk of contamination.

Key evidence

Beele et al, 2020; Bredow et al, 2018; Srivastava et al, 2025; Van Overschelde et al, 2024; Zarghooni et al, 2015; Yang et al, 2025; Peghetti, 2018

Mepilex Border Post-Op Ag

Composition: Safetac wound contact layer; a flexible absorbent polyurethane foam pad containing silver sulphate and coloured with activated carbon, a layer with superabsorbent polyacrylate fibres, a non-woven layer, and a vapour-permeable backing film (polyurethane).

Uses: Self-adhesive, absorbent surgical dressing for use on exuding acute wounds (e.g. surgical and traumatic wounds) when topical antimicrobial therapy is indicated. It is designed to absorb blood and exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for up to 7 days (depending on the nature and condition of the wound).

Key evidence

Goodman et al, 2022; Korby & Myerthall, 2017; Erickson, 2018; Underhill et al, 2018

Film dressings

Mepitel Film

Composition: Polyurethane film coated with a Safetac wound contact layer.

Uses: Film dressing for the protection of fragile and sensitive skin. Can also be used as a secondary dressing for fixating dressings or as a landing zone for aggressive adhesive tapes to secure devices to the skin. Also used as a protective dressing over intravenous devices secured with adhesive tapes or sutures.

Key evidence

Radiotherapy-induced skin damage: Valcarenghi et al, 2025; Lee et al, 2024; Behroozian et al, 2023; Yan et al, 2020; Moller et al, 2018; Wooding et al, 2018; Herst et al, 2014

Scar management dressings

Mepiform

Composition: Safetac wound contact layer; a vapour-permeable laminate (polyurethane film and viscose non-woven).

Uses: Highly conformable dressing for use in the management of both old and new hypertrophic and keloid scars. Can also be used prophylactically on closed surgical incision sites to help prevent scarring.

Key evidence

Majan, 2006; Nor et al, 2017; Cain et al, 2001

Dressings for use in conjunction with negative pressure wound therapy (NPWT) systems

Avance Solo Border

Composition: Absorbent dressing with Safetac wound contact layer and transfer port (for connecting tubing to the NPWT pump).

Uses: Self-adhesive dressing for use with the Avance Solo NPWT System for use on open wounds and closed surgical incision sites to remove low-to-moderate levels of exudate.

Key evidence

Closed surgical incision sites: Rose et al, 2024
Open wounds: Beele et al, 2025a

Avance Solo Adapt Film

Composition: Film dressing with Safetac wound contact layer.

Uses: Self-adhesive dressing for use with the Avance Solo Adapt NPWT System for use on pressure injuries to remove low-to-moderate levels of exudate. The film dressing is used over a foam filler to secure a seal.

Key evidence

Pressure injuries: Beele et al, 2025b

Fixation tape

Mepitac

Composition: Safetac wound contact layer; a conformable knitted fabric; and a vapour-permeable film (polyurethane) backing.

Uses: Conformable adhesive tape used for the fixation of medical devices (e.g. drains, tubes, probes, electrodes, cannula and dressings), while minimising trauma and pain on removal.

Key evidence

Yuen et al, 2013; Denyer et al, 2017; Denyer, 2006; Azizkhan et al, 2007

References

Acorda, D.E. (2015) Nursing and respiratory collaboration prevents BiPAP-related pressure ulcers. Journal of Pediatric Nursing 30(4):620-623.

Adamietz, I.A., Mose, S., Haberl, A., Saran, F.H., Thilmann, C., Bottcher, H.D. (1995) Effect of self-adhesive, silicone-coated polyamide net dressing on irradiated human skin. Radiation Oncology Investigations 2(6):277-282.

Aggarwala, S., Harish, V., Roberts, S. Brady, M., Lajevardi, S., Doherty, J., D'Souza, M., Haertsch, P., Matiz, P.K.M., Issler-Fisher, A.C. (2021) Treatment of partial thickness burns: a prospective, randomised controlled trial comparing four routinely used burns dressings in an ambulatory care setting Journal of Burn Care and Research 42(5):934-943.

Ahuja, A.S. (2019) Should RCTs be used as the gold standard for evidence based medicine? Integrative Medical Research 8(1):31-32.

Alemante, Y., Johnson, M., Garner, W., Gillenwater, J. (2017) Silver soft silicone layer in extremity burns: our experience. Poster presentation at the 39th Annual John A Boswick Burn and Wound Care Symposium, Maui, Hawaii, United States of America.

Alvarez, O.M., Granick, M.S., Reyzelman, A., Serena, T. (2021) A prospective, randomized, controlled, crossover study comparing three multilayered foam dressings for the management of chronic wounds. Journal of Comparative Effectiveness Research 10(6):481-493.

Arnold-Long, M. (2015) Initial patient outcomes with use of an absorbent antimicrobial soft silicone exudate transfer foam dressing: a case series. Poster presentation at 47th Annual Conference of the Wound Ostomy and Continence Nurses' Society, San Antonio, Texas, United States of America.

Atkin, L., Fletcher, J., Tickle, J. (2017) Managing patients with large, shallow, complex wounds: a case series. Wounds UK, EWMA Special: 42-46.

Atkinson, A. (1999) Managing split skin donor sites in the community. Journal of Community Nursing 13(5):18-24.

Azizkhan, R.G., Denyer, J.E., Mellerio, J.E., Gonzalez, R., Bacigalupo, M., Kantor, A., Passalacqua, G., Palisson, F., Lucky, A.W. (2007) Surgical management of epidermolysis bullosa: Proceedings of the 2nd International Symposium of Epidermolysis Bullosa, Santiago, Chile, 2005. International Journal of Dermatology 46(8):801-808.

Bank of England. Inflation calculator. Accessible at: https://www.bankofengland.co.uk/monetary-policy/inflation/inflation-calculator [last accessed 30 June 2025].

Banwell, P.E. (1999) Topical negative pressure therapy in wound care. Journal of Wound Care 8(2):79-84.

Barrett, S. (2012) Mepitel One: a wound contact layer with Safetac technology. British Journal of Nursing 21(21):1271-1277.

Barrows, C. (2009) Enhancing patient outcomes-reducing the bottom line: the use of antimicrobial soft silicone foam dressing in home health. Home Healthcare Nurse 27(5):279-284.

Basu, S., Goswami, A.G., David, L.E., Mudge, E. (2024) Psychological stress on wound healing: a silent player in a complex background. International Journal of Lower Extremity Wounds 23(3):365-371.

Bateman, S. (2013) Patient care and management: reduced skin integrity of the foot. British Journal of Nursing 22(20 Supplement):S30-S37.

Bateman, S. (2014) Principles of preventative foot care. British Journal of Community Nursing March (Supplement):S32-S38.

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

Beeckman, D., Fourie, A., Raepsaet, C., Van Damme, B., Manderlier, B., De Meyer, D., Beele, H., Smet, S., Demarre, L., Vossaert, R., de Graaf, A., Verhaeghe, L., Vanderghеynst, N., Hendrickx, B., Hanssens, V., Keymeulen, H., Vanderwee, K., Van De Woestjne, J., Verhaeghe, S., Van Hecke, A., Savoye, I., Harrison, J., Vrijens, F., Hulstaert, F. (2021) Silicone adhesive multilayer foam dressings as adjuvant prophylactic therapy to prevent hospital-acquired pressure ulcers: a pragmatic non-commercial multicentre randomised open label parallel group medical device trial. British Journal of Dermatology 185(1):52-61.

Beele, H., Van Overschelde, P., Olivecrona, C., Smet, S. (2020) A prospective randomized controlled clinical investigation comparing two post-operative wound dressings used after elective hip and knee replacement; Mepilex Border Post-Op versus Aquacel surgical. International Journal of Orthopaedic and Trauma Nursing 38:100772.

Beele, H., Amann, B., Carnali, M., Danneels, M., Gibello, L., Goueffic, Y., Piffaretti. G., Timmons, J. (2025a) Evaluation of a novel, canister-based, portable negative pressure wound therapy system in the management of low-to-moderately exuding acute and subacute wounds. Poster presentation at European Wound Management Association Conference, Barcelona, Spain.

Beele, H., Danneels, M., Nou Howaldt, M., Loschi, D., Lorenzo, G., Amann, B., Kusch, K., Stucker, M., Gomez, C.F., Nuna, V., Alves, P., Colgan, M.P., Castro, J., Andersen, J.A., Timmons, J. (2025b) Evaluation of a novel, canister-based, portable negative pressure wound therapy system in the management of pressure injuries. Poster presentation at European Wound Management Association Conference, Barcelona, Spain.

Behroozian, T., Milton, L., Karam, I., Zhang, L., Ding, K., Lou, J., Gallant, F., Rakovitch, E., Tran, W., Soliman, H., Leung, E., Vesprini, D., Szumacher, E., Chen, H., Donovan, E., Lam, J., Spadafora, S., Wronski, M., Lavoie, C., Walde, N., Lam, E., Wong, G., McKenzie, E., Ariello, K., Kennedy, S., Shariati, S., Carothers, K., Gonzales, G., Kagan, Y., Chow, E. (2023) Mepitel Film for the prevention of acute radiation dermatitis in breast cancer: a randomized multicenter open-label phase III trial. Journal of Clinical Oncology 41(6):1250-1264.

Berard, M.B., Lau, F.H. (2022) Pilot study of minimally adherent silver dressings for acute surgical wounds. Health Science Reports 5(6):e865.

Boesch, R.P., Myers, C., Garrett, T., Nie, A.M., Thomas, N., Chima, A., McPhail, G.L., Ednick, M., Rutter, M.J., Dressman, K. (2012) Prevention of tracheostomy-related pressure ulcers in children. Pediatrics 129(3):e792-e797.

Boixados, D., Allaert, F.A., Drareni, W. (2019) Efficacy of a five-layer silicone foam dressing with 360-degree flex technology for chronic and acute wound management in home care settings E-poster presentation at European Wound Management Association Conference, Gothenburg, Sweden.

Bredow, J., Hoffmann, K., Oppermann, J., Hellmich, M., Eysel, P., Zarghooni, K. (2018) Evaluation of absorbent versus conventional wound dressing - a randomised controlled study in orthopedic surgery. Deutsches Arzteblatt International 115(3):213-219.

Brindle, C.T., Creehan, S., Beavers, S. (2011) Deep tissue injury "imposters": resolution without evolution. Poster presentation at 43rd Wound Ostomy and Continence Nurse Annual Conference, New Orleans, Louisiana, United States of America.

Brindle, T., Farmer, P. (2019) Understanding wound healing: a narrative review of the literature and clinical considerations. Wounds International 10(2):40-48.

Bugmann, P., Taylor, S., Gyger, D. (1998) A silicone-coated nylon dressing reduces healing time in burned paediatric patients in comparison with standard sulfadiazine treatment: a prospective randomized trial. Burns 24(7):609-612.

Bull, R.H., Clements, D., Collarte, A.J., Harding, K.G. (2023) A novel randomized trial protocol for evaluating wound healing interventions. Advances in Wound Care 12(12):671-679.

Burton, F. (2004) An evaluation of non-adherent wound-contact layers for acute traumatic and surgical wounds. Journal of Wound Care 13(9):371-373.

Butcher, M., Swales, B. (2012) Reducing trauma associated with burns care using Safetac technology. Nursing Standard 27(2):57-62.

Cain, V., McMahon, L., O'Donnell, F., Rowland, S.M., Costa, B.A., Moore, M.I., Engrav, L.H., Heimbach, D.M., Gibran, N.S. (2001) Effectiveness of a silicone adherent dressing on post-burn and other traumatic scars. Journal of Burn Care and Rehabilitation 22(Supplement 2):S45-S45.

Carter, L., Kilburn, S., Featherstone, P. (2007) Cellulitis and treatment: a qualitative study of experiences. British Journal of Nursing 16(6):S22-S28.

Carter, M.J., Fife, C.E., Walker, D., Thomson, B. (2009) Estimating the applicability of wound care randomized controlled trials to generate wound-care populations by estimating the percentage of individuals excluded from a typical wound-care population in such trials. Advances in Skin and Wound Care 22(7):316-324.

Chadwick, P., Harrison, M., Morris, C., Bamford, A., Stansby, G. (2010) Avance Negative Pressure Wound Therapy system: a clinical focus. Wounds UK 6(4):114-122.

Chaffin, A.E., Dowling, S.G., Kosyk, M.S., Bosque, B.A. (2021) Surgical reconstruction of pilonidal sinus disease with concomitant extracellular matrix graft placement: a case series. Journal of Wound Care 30(Supplement 7):S228-S234.

Charlesworth, B., Pilling, C., Chadwick, P., Butcher, M. (2014) Dressing-related trauma: clinical sequelae and resource utilization in a UK setting. ClinicoEconomics and Outcomes Research 28(6):227-239.

Conde Montero, E., Perez Jeronimo, L., Peral Vazquez, A., Recarte Marin, L., de la Cueva Dobao, P. (2019) Punch grafting to promote epithelialisation of post-surgical scalp wounds. Poster presentation at Journees Plaies et Cicactrisations, Paris, France.

Cohen, L.P., Ovadia-Blechman, Z., Hoffer, O., Gefen, A. (2019) Dressings cut to shape alleviate facial tissue loads while using an oxygen mask. International Wound Journal 16(3):813-826.

Cooper, P., Gray, D., Russell, F., Stringfellow, S. (2010) Case study using Mepitel One wound contact dressing with Safetac. Wounds International 1-11.

Cutting, K.F. (2008) Impact of adhesive surgical tape and wound dressings on the skin, with particular reference to skin stripping. Journal of Wound Care 17(4):157-162.

Cutting, K.F., White, R. (2002) Maceration of the skin 1: the nature and causes of skin maceration. Journal of Wound Care 11(7):275-278.

Cuvelier, K. (2009) Prise en charge et evolution de plaies chroniques traitées par un pansement hydrocellulaire imprégné d'argent. Poster presentation at 13ème Conferénce Nationale des Plies et Cicatrisations, Paris, France.

David, F., Wutze, J-L., Breton, N., Bisch, O., Gazeu, P., Kerihuel, J-C., Guibon, O. (2018) A randomised, controlled, non-inferiority trial comparing the performance of a soft silicone-coated wound contact layer (Mepitel One) with a lipidocolloid wound contact layer (UrgoTul) in the treatment of acute wounds. International Wound Journal 15(1):159-169. [Epub 2017 Dec 5]

Davies, P. (2022) Closed incision negative pressure wound therapy: a literature review and an introduction to Avance Solo. Wounds International, London, United Kingdom.

Davis, D. (2012) Use of an antimicrobial soft silicone bordered foam dressing as an adjunctive treatment with a single layer bioengineered dermal tissue. Poster presentation at the Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Atlanta, Georgia, United States of America.

De Coster, L. Meuleniere, F. (2010) Case report: second degree burns treated with soft silicone-coated dressings. Poster presentation at the European Wound Management Association Conference, Geneva, Switzerland.

De Meyst, G., Meuleneire, F. (2010) A case study series evaluation of a silicone coated foam dressing in the treatment of patients undergoing orthopaedic surgery. Poster presentation at the European Wound Management Association Conference, Geneva, Switzerland.

Denyer, J. (2006) The use of atraumatic wound dressings in epidermolysis bullosa. Poster presentation at the European Wound Management Association Conference, Prague, Czech Republic.

Denyer, J., Pillay, E., Clapham, J. (2017) Best practice guidelines for skin and wound care in epidermolysis bullosa. Wounds International, London, United Kingdom.

Dhatariya, K., Gooday, C., Franke, B., Pilling, T., Flanagan, A., Zeidan, L. (2016) An open, non-comparative, multi-centre evaluation of performance and safety using an antimicrobial exudate transfer dressing on diabetic foot ulcers: a case series. Journal of Wound Care 25(5):256-265.

Diggelmann, K.V., Zytkovicz, A.E., Tuaine, J.M., Bennett, N.C., Kelly, L.E., Herst, P.M. (2010) Mepilex Lite dressings for the management of radiation-induced erythema: a systematic inpatient controlled clinical trial. British Journal of Radiology 83(995):971-978.

Dunbar, A., Bowers, D.M., Holderness, H. (2005) Silicone net dressing as an adjunct with negative pressure wound therapy. Ostomy Wound Management 51(4):18-20.

Dunbar, A., Rayburn, S., Workman, C. (2006) Road rash: a 'best practice' solution to a painful problem. Poster presentation at the 38th Annual Conference of the Wound Ostomy and Continence Nurses Society, Minneapolis, United States of America.

Durante, CM. (2008) Chronic wounds and local malpractice: an antimicrobial silver soft silicone foam can help in solving the problem. Poster presentation at the 3rd Congress of the World Union of Wound Healing Societies, Toronto, Canada.

Dykes, P.J. (2007) The effect of adhesive dressing edges on cutaneous irritancy and barrier function. Journal of Wound Care 16(3):97-100.

Dykes, P.J., Heggie, R. (2003) The link between the peel force of adhesive dressings and subjective discomfort in volunteer subjects. Journal of Wound Care 12(7): 260-262.

Dykes, P.J., Heggie, R., Hill, S.A. (2001) Effects of adhesive dressings on the stratum corneum of skin. Journal of Wound Care 10(2):7-10.

Eager, C.A. (2001) Comparison of two foams through the measurement of healing time, frequency of dressing changes and peri wound status. Poster presentation at the 14th Annual Symposium on Advanced Wound Care and Medical Research Forum on Wound Repair, Orlando, Florida, United States of America.

Eastburn, S., Ousey, K., Rippon, M. (2016) A review of blisters caused by wound dressing components: can they impede post-operative rehabilitation and discharge? International Journal of Orthopaedic and Trauma Nursing 21:3-10.

Eberhardt, T.D., de Lima, S.B.S., de Avila Soares, R.S., Silveira, L.B.T.D., Pozzebon, B.R., Reis, C.R., dos Santos, K.P.P., Alves, P.J.P. (2021) Prevention of pressure injury in the operating room: Heels operating room pressure injury trial. International Wound Journal 18(3):359-366.

Edwards, J., Mason, S. (2013) Hand burn management: minimising pain and trauma at dressing change. British Journal of Nursing 22(20):S46-S50.

El Genedy, M., Hahnel, E., Tomova-Simitchieva, T., Padula, W.V., Hauss, A., Lober, N., Blume-Peytavi, U., Kottner, J. (2020) Cost-effectiveness of multi-layered silicone foam dressings for prevention of sacral and heel pressure ulcers in high-risk intensive care unit patients: an economic analysis of a randomised controlled trial. International Wound Journal 17(5):1291-1299.

Erickson, M. (2018) Embracing action to achieve a significant reduction in C-section surgical site infection rates and reducing facility costs by implementing antimicrobial soft silicone foam dressing and closing surgical trays. Poster presentation at Association of periOperative Registered Nurses Global Surgical Conference & Expo, New Orleans, Louisiana, United States of America.

Eriksson, E., Liu, P.Y., Schultz, G.S., Martins-Green, M.M., Tanaka, R., Weir, D., Gould, L.J., Armstrong, D.G., Gibbons, G.W., Wolcott, R., Olutoye, O.O., Kirsner, R.S. (2022) Chronic wounds: treatment consensus. Wound Repair and Regeneration 30(2):156-171.

European Wound Management Association. (2024) Holistic management of wound-related pain: an overview of the evidence and recommendations for clinical practice. EWMA, Frederiksberg, Denmark.

European Wound Management Association. (2002) Position Document. Pain at wound dressing changes. Medical Education Partnership, London, United Kingdom.

Eytier, C., Gazeau, E., Beneteau, G., Verfaillie, G. (2013) Praticite et tolerance de l'association d'un pansement hydrocellulaire avec enduction de siliconeet d'un bandage tubulaire extensibile dans les deux sens sur la prise en charge locale des plaies. Une etude observationnelle realisee aupres de 304 infirmiers(eres) diplome(e)s d'etat (IDE) et portant sur 2401 patients. Resultats de l'etude TeMpO. Journal des Plaies et Cicatrisations 18(88):38-44.

Frear, C.C., Cuttlr, L., McPhail, S.M., Chatfield, M.D., Kimble, R.M., Griffin, B.R. (2020) Randomized clinical trial of negative pressure wound therapy as an adjunctive treatment for small-area thermal burns in children. British Journal of Surgery 107(13):1741-1750.

Gardner, S.E., Blodgett, N.P., Hillis, S.L., Borhart, E., Malloy, L., Abbott, L., Pezzella, P., Jensen, M., Sommer, T., Sluka, K.A., Rakel, B.A. (2014) HI-TENS reduces moderate-to-severe pain associated with most wound care procedures: a pilot study. Biological Research for Nursing 16(3):310-319.

Gee Kee, E.L., Kimble, R.M., Cuttle, L., Khan, A., Stockton, K.A. (2015) Randomized controlled trial of three burns dressings for partial thickness burns in children. Burns 41(5):946-955.

Gee Kee, E., Stockton, K., Kimble, R.M., Cuttle, L., McPhail, S.M. (2017) Cost-effectiveness of silver dressings for paediatric partial thickness burns: An economic evaluation from a randomized controlled trial. Burns 43(4):724-732.

Gefen, A., Alves, P., Beeckman, D., Cullen, B., Lazaro-Martinez, J.L., Lev-Tov, H., Najafi, B., Santamaria, N., Sharpe, A., Swanson, T., Woo, K. (2024) How should clinical wound care and management translate to effective engineering standard testing requirements from foam dressings? Mapping the existing gaps and needs. Advances in Wound Care 13(1):34-52.

Glat, P., Smith, D., Foster, K.N., Karlnoski, R. (2017) Clinical investigation of the performance and safety of a soft silicone wound contact layer containing silver in the treatment of skin grafts and a soft silicone transfer dressing containing silver in the treatment of donor sites in surgical burn patients. Poster presentation at Symposium on Advanced Wound Care (Spring), San Diego, California, United States of America.

Godbout, J.P., Glaser, R. (2006) Stress-induced immune dysregulation: implications in bacterial infection during cutaneous wound healing. Journal of Neuroimmune Pharmacology 1(4):421-427.

Goodman, J.R., Durazo-Arvizu, R., Nashif, S., McAlarnen, L.A., Wagner, S.A., Lal, A.K. (2022) Preventing caesarean section wound complications: use of a silver-impregnated antimicrobial occlusive dressing. Journal of Wound Care 31(7 North American Supplement):S5- S14.

Gotschall, C.S., Morrison, M.I., Eichelberger, M.R. (1998) Prospective, randomized study of the efficacy of Mepitel on children with partial-thickness scalds. Journal of Burn Care and Rehabilitation 19(4):279-283.

Hackett, R.A., Steptoe, A. (2017) Type 2 diabetes mellitus and psychological stress – a modifiable risk factor. Nature Reviews: Endocrinology 13(9):547-560.

Hahnel, E., El Genedy, M., Tomova-Simitchieva, T., Hauss, A., Stroux, A., Lechner, A., Richter, C., Akdeniz, M., Blume-Peytavi, U., Löber, N., Kottner, J. (2020) The effectiveness of two silicone dressings for sacral and heel pressure ulcer prevention in high risk intensive care unit patients compared to no dressings: a randomized controlled parallel-group trial. British Journal of Dermatology 183(2):256-264.

Halama, D., Dreilich, R., Lethaus, B., Bartella, A., Pausch, N.C. (2019) Donor-site morbidity after harvesting of radial forearm free flaps—comparison of vacuum-assisted closure with conventional wound care: A randomized controlled trial. Journal of Cranio-Maxillofacial Surgery 47(12):1980-1985.

Haycocks, S., Allen, M., Chadwick, P. (2021) Case series: Mepilex Border Comfort under total contact casting in the treatment of exuding diabetic foot ulcers. Diabetic Foot Journal 24(2):42-51.

Haycocks, S., Chadwick, P., Davies, P. (2018) Case series: Mepilex Border Comfort in the treatment of diabetic foot ulcers with exudate. The Diabetic Foot Journal 21(4):265-271.

Herst, P.M., Bennett, N.C., Sutherland, A.E., Peszynski, R.I., Paterson, D.B., Jasperse, M.L. (2014) Prophylactic use of Mepitel Film prevents radiation-induced moist desquamation in an intra-patient randomised controlled clinical trial of 78 breast cancer patients. Radiotherapy and Oncology 110(1): 137-143.

Himdani, S.Al., Javed, M.U., Hughes, J., Hemington-Gorse, S., Nguyen, D., Falconer, O., Bidder. C. (2016) Home remedy or hazard? Management and costs of paediatric steam inhalation therapy burn injuries. British Journal of General Practice 66(644):e193-e199.

Hollinworth, H., Collier, M. (2000) Nurses' views about pain and trauma at dressing changes. Journal of Wound Care 9(8):369-373.

Hon, K-L.E., Burd, A., Choi, P.C-L., Luk, N-M.T. (2007) Epidermolysis bullosa in three Chinese neonates. Journal of Dermatological Treatment 18;306-311.

Howard, R., Evans, J., Woodhouse, B., Mansfield, J., Lesher, A. (2017) Partial thickness burn injuries in pediatric burn patients. Poster presentation at the 39th Annual John A Boswick Burn and Wound Care Symposium, Maui, Hawaii, United States of America.

Howell, R.D., Hadley, S., Strauss, E., Pelham, F.R. (2011) Blister formation with negative pressure dressings after total knee arthroplasty. Current Orthopaedic Practice 22(2):176-179.

Hsu, M-Y., Chung, H-C., Tang, M.T., Hsiu, S-R., Tai, C-H. (2011) Avoiding pressure damage when using ventilators. Wounds International 1(5).

Johansson, C., Hjalmarsson, T., Bergentz, M., Melin, M., Sandstedt, P., Johansson, C. (2012) Preventing post-operative blisters following hip and knee arthroplasty. Wounds International 3(2):1-6.

Joncas, V., Prado, R., Ritchie, C.P., Kaufman, M., Schober-Flores, C., Arbuckle, H.A. (2010) The closure of a large chronic abdominal wound in a neonate utilizing a biologic dressing. Advances in Skin and Wound Care 23(9):404-405.

Karlsson, M., Elmasry, M., Steinvall, I., Sjöberg, F., Olofsson, P., Thorfinn, J. (2019) Superiority of silver-foam over porcine xenograft dressings for treatment of scalds in children: A prospective randomised controlled trial. Burns 45(6):1401-1409.

Kaufman, L.M. (2008) When small stomas are a big deal: the use of a soft silicone pouching system on the neonatal ostomate complicated by a peristomal wound. Poster presentation at the 40th Annual Conference of the Wound Ostomy and Continence Nurses Society, Orlando, Florida, United States of America.

Kalowes, P., Messina, V., Li, M. (2016) Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit. American Journal of Critical Care 25(6):e108-e119.

Kammerlander, G., Eberlein, T. (2002) Nurses' views about pain and trauma at dressing changes: a central European perspective. Journal of Wound Care 11(2):76-79.

Kennedy-Evans, K. (2004) An innovative solution for skin tears: a case study. Ostomy Wound Management 50(2): 9-10.

Khramilin, V. (2006) Mepilex Lite in the treatment of diabetic foot ulcer. Open non-randomised case study. Poster presentation at the European Wound Management Association Conference, Prague, Czech Republic.

Kim, R.S., Mullins, K. (2016) Preventing facial pressure ulcers in acute respiratory distress syndrome (ARDS). Journal of Wound Ostomy and Continence Nursing 43(4):427-429.

Kivimaki, M., Steptoe, A. (2018) Effects or stress on the development and progression of cardiovascular disease. Nature Reviews: Cardiology 15(4):215-229.

Kles C.L., Murrah, C.P., Smith, K., Baugus-Wellmeier, E., Hurry, T., Morris, C.D. (2015) Achieving and sustaining zero. Preventing surgical site infections after isolated coronary artery bypass with saphenous vein harvest through implementation of a staff-driven quality improvement process. Dimensions of Critical Care Nursing 34(5):265-272.

Klode, J., Schottler, L., Stoffels, I., Korber, A., Schadendorf, D., Dissemond, J. (2011) Investigation of adhesion of modern wound dressings: a comparative analysis of 56 different wound dressings. Journal of the European Academy of Dermatology and Venereology 25(8):933-939.

Koehler, S., Jinbo, A., Johnson, S., Puapong, D., de los Reyes, C., Woo, R. (2014) Negative pressure dressing assisted healing in pediatric burn patients. Journal of Pediatric Surgery 49:1142-1145.

Koerner, S., Adams, D. (2016) Use of a new foam dressing technology with unique exudate channels (UEC) under compression to handle copious thick, viscous exudate. Poster presentation at Wound Ostomy and Continence Nurses Society and Canadian Association for Enterostomal Therapy, Montreal, Canada.

Komori, T., Dainichi, T., Masuno, Y., Otsuka, A., Nakano, H., Sawamura, D., Ishida-Yamamoto, A. Kabasima, K. (2018) p.Glu477Lys mutation in keratin 5 is not necessarily mortal in generalized severe epidermolysis bullosa. Journal of Dermatology 45(8):e209-e210.

Korby, K., Myerthall, S. (2017) Evidence-based practice: clinical evaluation of a new silver soft silicone postoperative dressing in total knee and hip arthroplasty. Poster presentation at the 18th Annual Physician Assistants in Orthopaedic Surgery Conference, Baltimore, Maryland, United States of America.

Kota, A.A., Selvaraj, A.D., Premkumar, P., Ponraj, S., Agarwal, S. (2014) Four layer dressing in the management of chronic venous ulcers in the outpatient setting of a tertiary hospital in India. Wound Medicine 5:21-24.

Krasner, D.L., McKinney, W. (2012) Acute and chronic wound applications in the long term care setting for a soft silicone foam border dressing with silver: a clinical case series demonstrating VALUE. Poster presentation at the Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Atlanta, Georgia, United States of America.

Krupova, L., Hovorkova, J., Pokorna, A. (2024) Innovative approaches to preventing medical device-related pressure ulcers on the head. Poster presentation at European Pressure Ulcer Advisory Panel Annual Meeting, Lausanne, Switzerland.

Larson, K.W., Austin, C.L., Thompson, S.J. (2020) Treatment of a full-thickness burn injury with NovoSorb biodegradable temporizing matric and RECELL autologous skin cell suspension: a case series. Journal of Burn Care and Research 41(1):216-219.

Latimer, S., Chaboyer, W., Walker, R.M., Thalib, L., Deakin, J.L., Gillespie, B.M. (2024) Prophylactic dressings for preventing sacral pressure injuries in adult intensive care unit patients: a randomised feasibility trial. Australian Critical Care 38(2):101133.

Le Blanc, K., Woo, K. (2022) A pragmatic randomised controlled clinical study to evaluate the use of silicone dressings for the treatment of skin tears. International Wound Journal 19(1):125-134.

Lee, S.F., Yip, P.L., Spencer, S., Ho, H., Subramanian, B.., Ding, W., Lapuz, C., Foroudi, F., Kai, C., Chao, M. (2024) StrataXRT and Mepitel Film for preventing postmastecomy acute radiation dermatitis in breast cancer: an intrapatient noninferiority randomized clinical trial. International Journal of Radiation Oncology Biology Physics doi:10.1016/j.jrobp.2024.11.076.

Lemarechal, P., Savard, V., François, D. (2009) Mepilex Transfer dans les suites opératoires de la chirurgie de la main. Poster presentation at 13ème Conferénce Nationale des Plies et Cicatrisations, Paris, France.

Lemos, P., Araujo, J., Chicone, G. (2016) Case study: use of soft silicone foam with Safetac technology to treat radiotherapy-induced moist desquamation. Poster presentation at the World Union of Wound Healing Societies Congress, Florence, Italy.

Lev-Tov, H., Serena, T., Sigal, F., Nygren, E. (2025) Bench to bedside evaluation of an innovative, non-bordered foam dressing for use in exudating chronic wounds. International Wound Journal 22(S1):e70414.

Lumsden, E., Kimble, R., Griffin, B., McMillan, C. (2023) Wound contact layers: the unsung heroes of burn care when utilising negative pressure wound therapy. Burns 7(2):23-25.

Ly, L., Su, J.C. (2008) Dressings used in epidermolysis bullosa blister wounds: a review. Journal of Wound Care 17(11):482-492.

MacBride, S.K., Wells, M.E., Hornsby, C., Sharp, L., Finnila, K., Downie, L. (2008) A case study to evaluate a new soft silicone dressing, Mepilex Lite, for patients with radiation skin reactions. Cancer Nursing 31(1):E8-E14.

Maeda, T., Oyama, A., Funayama, E., Furukawa, H. (2015) Successful conservative management of a large congenital scalp and skull defect. Journal of Craniofacial Surgery 26(3):e275-e277.

Mansouri, Y., Kaur, M.R., Paul, M., Muc, R. (2014) Solitary ulcerative lichen planus on the lower leg, a diagnostic challenge. Journal of the American Academy of Dermatology 70(5 Supplement):AB55.

Maján, J.I. (2006) Evaluation of a self-adherent soft silicone dressing for the treatment of hypertrophic postoperative scars. Journal of Wound Care 15(5):193-196.

Marconi, R., Laverda, F., Trevisan, G. (2009) A case study evaluation of a soft silicone primary wound contact dressing in the prevention of wound pain and tissue trauma. Poster presentation at the European Wound Management Association Conference, Helsinki, Finland.

Marshall-Hanson, C. (2015) Use of an absorbent soft silicone antimicrobial exudate transfer foam to treat widespread bullous lesions and erythroderma reaction in a neutropenic patient. Poster presentation at Symposium on Advanced Wound Care (Spring), San Antonio, Texas, United States of America.

Matsumura, H., Imai, R., Ahmatjan, N., Ida, Y., Gondo, M., Shibata, D., Wanatabe, K. (2014) Removal of adhesive wound dressing and its effects on the stratum corneum of the skin: comparison of eight different adhesive wound dressings. International Wound Journal 11(1):50-54.

McCardle, J., Brewin, E., Young, M. (2009) Use of a synthetic extracellular matrix protein in non-healing diabetic foot wounds. The Diabetic Foot Journal 12(1):27-32.

McCarty, S., Davies, P., Rippon, M. (2013) Mepilex Border Ag: an in-market evaluation. Poster presentation at the Wounds UK Conference, Harrogate, United Kingdom.

Meaume, S., Van De Looverbosch, D., Heyman, H., Romanelli, M., Ciangherotti, A., Charpin, S. (2003) A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers. Ostomy Wound Management 49 (9): 44-51.

Meek, K., Downs, B. (2012) Post operative complication process improvement in the orthopedic population. Poster presentation at the Association of Perioperative Registered Nurses 59th Annual Congress, New Orleans, Louisiana, United States of America.

Meuleneire, F. (2002) Using a soft silicone-coated net dressing to manage skin tears. Journal of Wound Care 11(10):365-369.

Meuleneire, F. (2008a) Management of diabetic foot ulcers using dressings with Safetac: a review of case studies. Wounds UK 4(4):16-30.

Meuleneire, F. (2008b) An observational study of the use of a soft silicone silver dressing on a variety of wound types. Journal of Wound Care 17(12):535-539.

Meuleneire, F. (2009) Case study evaluation of Safetac dressings used for paediatric wounds. Wounds UK 5(2): 12-18.

Meuleneire, F., Fostier, A. (2008) Local treatment of heel pressure ulcers with a silicone foam dressing. Poster presentation at the 3rd Congress of the World Union of Wound Healing Societies, Toronto, Canada.

Miscavige, M. (2005) Considering patient priorities when choosing a dressing. Ostomy Wound Management 51(11A Supplement):23-24.

Miura, Y., Nakagomi, S. (2021) Management of cutaneous manifestations of genetic epidermolysis bullosa. Journal of Wound Ostomy and Continence Nursing 48(5):453-459.

Møller, P.K., Olling, K., Berg, M., Habæk, I., Haislund, B., Iversen, A-M., Ewertz, M., Lorenzen, E.L., Brink, C. (2018) Breast cancer patients report reduced sensitivity and pain using a barrier film during radiotherapy – A Danish intra-patient randomized multicentre study. Technical Innovations and Patient Support in Radiation Oncology 7:20-25.

Montmaneix, N., Eddi, D., Odier, F., Faubert, S., Stephan, J-L., Piguet, C., Deplanque, P., Guibon, O., Demeocq, E., Merlin, E. (2012) Comparison of a device comprising a silicone hydrocellular dressing (Mepilex Border Lite) plus a polyacrylic adhesive (Mefix) and a reference device comprising an acrylic adhesive (Cicaplaie) and a transparent polyurethane adhesive (Tegaderm) in order to keep central catheters positioned in children and adolescents at Clermont-Ferrand, Limoges and St Etienne hospitals. Journal de Plaies et Cicatrisations 83(17):38-43.

Moradian, S., Klapper, A.M. (2016) A novel way to treat skin tears. International Wound Journal 13(2): 283-286.

Morris, C., Emsley, P., Marland, E., Meuleneire, F., White, R. (2009) An observational study of dressing with soft silicone adhesive technology to manage the wounds of paediatric patients. Paediatric Nursing 21(3):38-43.

Muller, S.O.L., De Jongh, G.J. (2008) Craniofacial necrotizing fasciitis: reconstruction after radical surgery. European Journal of Plastic Surgery 31(2):75-80.

Mwipatayi, B.P., Western, C.E., Wong, J., Angel, D. (2016) Atypical leg ulcers after sclerotherapy for treatment of varicose veins: Case reports and literature review. International Journal of Surgery Case Reports 25:161-164.

Neal, S. (2004) Finding an end to the pain – one patient's experience. Ostomy Wound Management 50(3):12-13.

Nelson, D. (2018) Better outcomes for skin tears with new 5 layer bordered foam dressings. Poster presentation at 50th Annual Conference of the Wound Ostomy and Continence Nurses' Society, Philadelphia, Pennsylvania, United States of America.

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

Nor, N.M., Ismail, R., Jamil, A., Shah, S.A., Imran, F.H. (2017) A randomized, single-blind trial of clobetasol propionate 0.05% cream under silicone dressing occlusion versus intra-lesional triamcinolone for treatment of keloid. Clinical Drug Investigation 37(3):295-301.

O'Connor, D.B., Thayer, J.F., Vedhara, K. (2021) Stress and health: a review of psychobiological processes. Annual Review of Psychology 72:663-688.

O'Donovan, D.A., Mehdi, S.Y., Eadie, P.A. (1999) The role of Mepitel silicone net dressings in the management of fingertip injuries in children. Journal of Hand Surg (Edinburgh, Scotland) 24(6):727-730.

O'Neill, C. (2004) Managing foot ulceration in diabetic patients helping to meet the objectives of treatment. Poster presentation at the Wounds UK Conference, Harrogate, United Kingdom.

Oe, M., Sasaki, S., Shimura, T., Takaki, Y., Sanada, H. (2020) Effects of multilayer silicone foam dressings for the prevention of pressure ulcers in high-risk patients: a randomized clinical trial. Advances in Wound Care 9(12):649-656.

Orlov, A., Gefen, A. (2023) Differences in prophylactic performance across wound dressing types used to protect from device-related pressure ulcers caused by a continuous positive airway pressure mask. International Wound Journal 20(4):942-960.

Ousey, K., Gillibrand, W., Stephenson, J. (2011) Understanding and preventing wound blistering. Wounds UK 7(4):50-56.

Padula, W.V., Chen, Y.H., Santamaria, N. (2019) Five-layer border dressings as part of a quality improvement bundle to prevent pressure injuries in US skilled nursing facilities and Australian nursing homes: A cost-effectiveness analysis. International Wound Journal 16(6):1263-1272.

Park, K.H. (2014) The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence associated dermatitis in intensive care unit patients. Journal of Wound Ostomy and Continence Nursing 41(5):424-429.

Paterson, D.B., Poonam, P., Bennett, N.C., Peszynski, R.I., Van Bekhuizen, M.J., Jasperse, M.L., Herst, P.M. (2012) Randomized intra-patient controlled trial of Mepilex Lite dressings versus aqueous cream in managing radiation-induced skin reactions post-mastectomy. Journal of Cancer Science & Therapy 4(11):347-356.

Patton, M.L., Mullins, R.F., Smith, D., Korentager, R. (2013) An open, prospective, randomized pilot investigation evaluating pain with the use of a soft silicone wound contact layer vs bridal veil and staples on split thickness skin grafts as a primary dressing. Journal of Burn Care and Research 34(6):674-681.

Peghetti, A. (2018) Prevention of post-operative surgical site complications: a quality improvement project. Poster presentation at European Wound Management Association Conference, Krakow, Poland.

Peko, L., Barakat-Johnson, M., Gefen, A. (2020) Protecting prone positioned patients from facial pressure ulcers using prophylactic dressings a timely biomechanical analysis in the context of the COVID-19 pandemic. International Wound Journal 17(5):1595-1606.

Perez, Y.P., Carmona, J.A., Perez, I.L., Garcia, C.M. (2011) Prevention and treatment of radiodermatitis using a non-adhesive foam dressing. Journal of Wound Care 20(3):130-135.

Philbin, S. (2012) Simple solutions for complex wounds of multiple types. Poster presentation at the Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Atlanta, Georgia, United States of America.

Poulakidas, S., Kowal-Vern, A. (2008) Facilitating residual wound closure after partial graft loss with vacuum assisted closure therapy. Journal of Burn Care and Research 29(4):663-665.

Platt, A.J., Phipps, A., Judkins, K. (1996) A comparative study of silicone net dressing and paraffin gauze dressing in skin-grafted sites. Burns;22(7):543-545.

Price, P.E., Fagervik-Morton, H., Mudge, E.J., Beele, H., Ruiz, J.C., Nystrom, T.H., Lindholm, C., Meaume, S., Melby-Ostergaard, B., Peter, Y., Romanelli, M., Seppanen, S., Serena, T.E., Sibbald, G., Soriano, J.V., White, W., Wollina, U., Woo, K.Y., Wyndham-White, C., Harding K.G. (2008) Dressing-related pain in patients with chronic wounds: an international patient perspective. International Wound Journal 5(2):159-171.

Pukki, T., Tikkanen, M., Halonen, S. (2010) Assessing Mepilex Border in post-operative wound care. Wounds UK 6(1):30-40.

Ramos-Torrecillas, J., De Luna-Bertos, E., García-Martínez, O., Díaz-Rodríguez, L., Ruiz, C. (2013) Use of platelet-rich plasma to treat pressure ulcers: a case study. Journal of Wound Ostomy, and Continence Nursing 40(2):198-202.

Rando, T. (2009) Use of a biological extracellular matrix wound therapy to heal complex, chronic wounds. Journal of Wound Care 18(2):70-74.

Ravenscroft, M.J., Harker, J., Buch, K.A. (2006) A prospective, randomised, controlled trial comparing wound dressings used in hip and knee surgery: Aquacel and Tegaderm versus Cutiplast. Annals of the Royal College of Surgeons of England 88:18-22.

Renauld, V. (2009) Utilisation d'un pansement hydromousse de contact extra souple au décours de la diminution mammaire. Poster presentation at 13ème Conférence Nationale des Plaies et Cicatrisations, Paris, France.

Richards, K., Chadwick, P. (2011) Addressing local wound infection with a silver-containing, soft-silicone foam dressing: a case series. The Diabetic Foot Journal 14(2):90-95.

Rippon, M., Davies, P., White, R. (2012) Taking the trauma out of wound care: the importance of undisturbed wound healing. Journal of Wound Care 21(8):359-368.

Rippon, M., White, R., Davies, P. (2007) Skin adhesives and their role in wound dressings. Wounds UK 3(4):76-86.

Rook, S., Davies, P., Frenthoff, E., Wurfel, T (2019). Mepilex Border Flex – results of an observational study in German specialist wound care centres. Wounds International 10(1):40-43.

Rose, V., Hachah Haram, N., Gallala, S. (2024) A new portable negative pressure wound therapy device: a prospective study investigating clinical outcomes. Journal of Wound Care 33(11):833-840.

Roldan Valenzuela, A., Galindo Cantillo, V., de Borja Lopez Casanova, F., Ordonez Ferrer, S.M., Hernandez Palanco, L.F., Berjano Rodriguez, A., Cabrera Aguera, M.J., Illanes Valenzuela, J.M., Lopez Moraleda, I., Prieto Torrado, O., Castillo Aparicio, G. (2025) A wound dressing shows its value: clinical and economic effects of a dressing regime change for primary and home care chronic wound management. Poster presentation at European Wound Management Association Conference, Barcelona, Spain.

Ruggeri, E., Martotoni, A.A., Malavasi, I., Agostini, F., Piccinelli, E., Mazzetti, M., Tenace, A., Campullu, L., Boin, B., Pannuti, F. (2016) The treatment of pressure ulcers in advanced cancer patient: the importance of a dedicated team. Acta Vulnologica 14(2):65-77.

Sanches-Pinto, D.C., Eriksson, E., Gomez, D.S., Nunes, M.P.T., Gemperli, R., Soriano, F.G. (2023) Minced skin grafts for chronic wounds compared to conventional mesh grafts. Health Science Report 6(6):e1353.

Santamaria, N., Gerdtz, M., Liu, W., Rakis, S., Sage, S., Ng, A.W., Tudor, H., McCann, J., Vassiliou, T., Morrow, F., Smith, K., Knott, J., Liew, D. (2015a) Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial. Journal of Wound Care 24(8):340-345.

Santamaria, N., Gerdtz, M., Sage, S., McCann, J., Freeman, A., Vassiliou, T., De Vincentis, S., Ng, A.W., Manias, E., Liu, W., Knott, J. (2015b) 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. International Wound Journal 12(3):302-308.

Santamaria, N., Gerdtz, M., Sage, S., McCann, J., Freeman, A., Vassiliou, T., De Vincentis, S., Ng, A.W., Manias, E., Liu, W., Knott, J., Liew, D. (2015c) 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. International Wound Journal 12(3):344-350.

Santamaria, N., Gerdtz, M., Kapp, S., Wilson, L., Gefen, A. (2018) A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial. International Wound Journal 15(3):482-490.

Santamaria, N., Woo, K., Beeckman, D., Alves, P., Cullen, B., Gefen, A., Lazaro-Martinez, J.L., Lev-Tov, H., Najafi, B., Sharpe, A., Swanson, T. (2023) Clinical performance characteristics for bordered foam dressings in the treatment of complex wounds: an international wound dressing technology expert panel review. International Wound Journal 20(9):3467-3473.

Schuh, J.M., Linzell, L.L., Abebrese, E.L., Flynn-O'Brien, K.T. (2024) Caregivers and clinic providers view soft casts for pediatric hand burns as acceptable and feasible: a mixed methods survey. Journal of Burn Care and Research 45(6):1413-1422.

Schumann, H., Beljan, G., Hoping, D., Bruckner-Tuderman, L. (2005) Atraumatic dressings in fragile skin conditions: use of the soft silicone dressing (Mepilex) in hereditary and acquired bullous skin disease. Poster presentation at the European Wound Management Association Conference, Stuttgart, Germany.

Schumann, H., Apelqvist, J., Schmidtchen, A., Hansson, C. (2007) Open, non-comparative, multicentre investigation exploring the tolerance of an absorbent foam dressing containing silver used in chronic wounds. Poster presentation at the European Wound Management Association Conference, Glasgow, United Kingdom.

Schweiger, H., Smith, D., Cruse, C.W., Brown, B. (2013) An open, non-controlled, single-centre, clinical investigation to evaluate efficacy when using a soft silicone wound contact layer containing silver. Poster presentation at the 15th European Burns Association Congress, Vienna, Austria.

Shearer, S.C., Parsa, K.M., Newark, A., Peesay, T., Walsh, A.R., Fernandez, S., Gao, W.Z., Pierce, M.L. (2021) Facial pressure injuries from prone positioning in the COVID-19 era. Laryngoscope 131:E2139-E2142.

Silverstein, P., Heimbach, D., Meites, H., Latenser, B., Mozingo, D., Mullins, F., Garner, W., Turkowski, J., Shupp, J., Glat, P., Purdue, G. (2011) 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. Journal of Burn Care and Research 32(6):617-626.

Silverstein, P., Gibran, N., Glat, P., Sood, R., Foster, K., Smith, H. (2014) Open, non-controlled multicentre clinical investigation evaluating the efficacy and safety of a soft silicone-containing wound contact layer - Mepitel Ag - on partial thickness (superficial, deep, and mixed) second-degree burns. Poster presentation at the 17th Congress of the International Society for Burn Injuries, Sydney, Australia.

Singh, S., Mackey, S., Soldin, M. (2008) VAC it - Some techniques on the application of VAC dressings. Annals of the Royal College of Surgeons of England 90(2):161-162.

Smith, Z.K. (2006) Addressing the pain: adapting a soft silicone dressing to enhance infant outcomes. Ostomy Wound Management 52(4):30-32.

Snelson, K., Downe, A. (2023) Use of topical morphine gel in epidermolysis bullosa wounds - a series of case studies. International Wound Journal 20(6):1954-1959.

Soon, K., Acton, C. (2006) Pain-induced stress: a barrier to wound healing. Wounds UK 2(4):92-101.

Solowiej, K., Upton, D. (2010) Managing stress and pain to prevent discomfort, distress and delayed wound healing. Nursing Times 106(16)21-23.

Srivastava, N., Manisha, G.A., Goyal, M., Kumar, M., Kumar, M. (2025) Comparative efficacy of advanced and traditional wound dressings in post-operative orthopaedic care for hip and knee surgeries: a randomized controlled trial. Journal of Clinical Orthopaedics and Trauma 63:102933.

Stansby, G., Wealleans, V., Wilson, L., Morrow, D., Gooday, C., Dhatariya, K. (2010) Clinical experience of a new NPWT system in diabetic foot ulcers and post-amputation wounds. Journal of Wound Care 19(11):496-502.

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

Tadini, G., Guez, S., Pezzani, L., Marconi, M., Greppi, N., Manzoni, F., Rebulla, P., Esposito, S. (2015) Preliminary evaluation of cord blood platelet gel for the treatment of skin lesions in children with dystrophic epidermolysis bullosa. Blood Transfusion 13(1):153-158.

Tang, H., Lv, G., Fu, J., Niu, X., Li, Y., Zhang, M., Zhang, G., Hu, D., Chen, X., Lei, J., Qi, H., Xia, Z. (2015) An open, parallel, randomized, comparative, multicenter investigation evaluating the efficacy and tolerability of Mepilex Ag versus silver sulphadiazine in the treatment of deep partial-thickness burn injuries. Journal of Trauma and Acute Care Surgery 78(5):1000-1007.

Tengvall, D.M., Bjornhagen, V.C., Lindholm, C., Jonsson, C.E., Wengstrom, Y. (2006) Differences in pain patterns for infected and noninfected patients with burn injuries. Pain management Nursing 7(4):176-182.

Truchetet, F., Guibon, O., Meaume, S. (2012) Clinicians' rationale for using a sliver dressing: the French OMAg+E observational study. Journal of Wound Care 21(12): 620-625.

Tsai, H-C., Shu, H-C., Huang, L-C., Chen, C-M. (2019) A randomized clinical trial comparing a collagen-based composite dressing versus topical antibiotic ointment on healing full-thickness skin wounds to promote epithelialization. Formosan Journal of Surgery 52(2):52-56.

Tsao, W-Y., Lo, S-F., Harmod, T., Lee, R-P. (2013) [A comparison of the efficacy of different wound dressing management techniques in preventing pressure ulcers]. Journal of Nursing (China) 60(4):65-78.

Tyson, L. (2019) Study first: driving the case for improving hospital wound care. Poster presentation at Symposium on Advanced Wound Care (Spring), San Antonio, Texas, United States of America.

Underhill, J., Johnson, C., Rhodes, K. (2018) Decreasing Cesarean section surgical site infection rates by changing post op care: an interdisciplinary approach. Poster presentation at Association of periOperative Registered Nurses Global Surgical Conference & Expo, New Orleans, Louisiana, United States of America.

Upton, D., Solowiej, K. (2012) The impact of atraumatic vs conventional dressings on pain and stress. Journal of Wound Care 21(5):209-216.

Valcarenghi, D., Tolotti, A., Vees, H., Torri, V., Liptrott, S., Presta, G., Puliatti, A., Moser, L., P., Sari, D., Valli, M. (2025) Mepitel Film vs standard care for the prevention of skin toxicity in breast cancer patients treated with adjuvant radiotherapy: a randomized controlled trial. Clinical and Translational Radiation Oncology 52:100936.

Van Overschelde, P., Sinnaeve, F., Lapierre, C., Pauwels, A., Alam, K., Sandy-Hodgetts, K. (2024) A single centre RetrospeCtive sTudy Investigating patient-reported outcomeS of extended dressing wear time for incisional healing following orthopaedic surgery: the ARCTIS study. Journal of Wound Care 33(Supplement 8):S17-S26.

Van Vuuren, A.J., Roy, B., Padilla, M., Melamdowitz, M., Shah, D., Butha, T. (2017) Management of neonatal epidermolysis bullosa (EB) in a special care nursery. Journal of Paediatrics and Child Health (Supplement 2)(53):85.

Villette, A., Dubos, C., Sellem, M. (2016) Une innovation technique pour une absorption rapide et optimale. Poster presentation at 20eme Conference National des Plies et Cicatrisations, Paris, France.

Vloemans, A.F., Kreis, R.W. (1994) Fixation of skin grafts with a new silicone rubber dressing (Mepitel). Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery 28(1):75-76.

Vowden, K., D'Arcy, A. (2008) Treatment of hard-to-heal diabetic and neuropathic foot ulcers with amelogenin, an extracellular matrix protein. Poster presentation at the 3rd Congress of the World Union of Wound Healing Societies, Toronto, Canada.

Waring, M., Butcher, M. (2011) An investigation into the conformability of wound dressings. Wounds UK 7(3):14-24.

Waring, M., Rippon, M. Biefeldt, S., Brandt, M. (2008) Cell attachment to adhesive dressings: qualitative and quantitative analysis. Wounds UK 4(3):35-47.

Waring, M., Biefeldt, S., Matzold, K.P., Butcher, M. (2011) An evaluation of the skin stripping of wound dressing adhesives. Journal of Wound Care 20(9):412-422.

Webb, M. (2008) Use of soft silicone dressings to meet the unique wound care needs of residents in one county long term care facility. Poster presentation at the 40th Annual Conference of the Wound Ostomy and Continence Nurses Society, Orlando, Florida, United States of America.

Weir, D., Davies, P. (2023) The impact of venous leg ulcers on a patient's quality of life: considerations for dressing selection. Wounds International 14(1):36-41.

Whalley, A. (2010) Case study evaluations of Mepitel One in the management of wounds of patients with diabetes. Poster presentation at Wounds UK Conference, Harrogate, United Kingdom.

White, R. (2005) Evidence for atraumatic soft silicone wound dressing use. Wounds UK 1(3):104-109.

White, R. (2008) A multinational survey of the assessment of pain when removing dressings. Wounds UK 4(1):14-22.

Winter, G. (1962) Formation of a scab and the rate of epithelialisation of superficial wounds in the skin of the young domestic pig. Nature 193:293-294.

Woo, K., (2024) The chronic wound-related pain model: holistic assessment and person-centred treatment. Clinics in Geriatric Medicine 40(3):501-514.

Woo, K.Y., Coutts, P.M., Price, P., Harding, K., Sibbald, R.G. (2009) A randomized crossover investigation of pain at dressing change comparing 2 foam dressings. Advances in Skin and Wound Care 22(7):304-310.

Woo, K., Gonzales, C.V.S., Amdie, F.Z., de Gouveia Santos, V.L.C. (2024) Exploring the effect of wound related pain on psychological stress, inflammatory response, and wound healing. International Wound Journal 21(7):e14942.

Wood, M.D., Powers, J., Rechter, J.L. (2019) Comparative evaluation of chest tube insertion site dressings: a randomized controlled trial. American Journal of Critical Care 28(6):415-423.

Wooding, H., Yan, J., Yuan, L., Chyou, T-Y., Gao, S., Ward, I., Herst, P.M. (2018) The effect of Mepitel film on acute radiation-induced skin reactions in head and neck cancer patients: a feasibility study. British Journal of Radiology 91(1081):20170298.

World Union of Wound Healing Societies. (2004) Principles of best practice: minimising pain at wound dressing-related procedures. A Consensus Document. Medical Education Partnership, London, United Kingdom.

World Union of Wound Healing Societies. (2007) Principles of best practice: minimising pain at wound dressing-related procedures: implementation of pain relieving strategies. WoundPedia Inc, Toronto, Canada.

Wounds UK. (2023) Best Practice Statement: Development of a wound care formulary using clinical evidence and ensuring effective change management. Wounds UK, London, United Kingdom.

Wright, M. (1994) Hip blisters. Nursing Times 90:86-88.

Xiao, W., Huang, X, Lin, C., Liu, Y., Chen, S., Wu, R. (2021) Panniculitis caused by progesterone injection can be treated by physical therapy. Dermatologic Therapy 34(1):e14501.

Yan, J., Yuan, L., Wang, J., Li, S., Yao, M., Wang, K., Herst, P.M. (2020) Mepitel Film is superior to Biafine cream in managing acute radiation-induced skin reactions in head and neck cancer patients: a randomised intra-patient controlled clinical trial. Journal of Medical Radiation Sciences 67(3):208-216.

Yan, R., Yu, F., Strandlund, K., Han, J., Lei, N., Song, Y. (2021) Analyzing factors affecting quality of life in patients hospitalized with chronic wound. Wound Repair and Regeneration;29(1):70-78.

Yanagisawa, D., Yuzuriha, S. (2018) Stapling technique through transparent dressing to fix skin grafts. Burns Open 2(1):71-75.

Yang, T-Y., Shin, S.H. (2020) Effect of soft silicone foam dressings on intraoperatively acquired pressure injuries: a randomized study in patients undergoing spinal surgery. Wound Management and Prevention 66(11):22-29.

Yang, T.Y., Park, J.E., Kim, J.B., Lee, N.H. (2025) Incidence and characteristics of medical adhesive-related skin injuries in patients following spinal surgery: a prospective observational study. International Wound Journal 22:e70457.

Yilmaz, S., Aksoy, E., Doganci, S., Yalcinkaya, A., Diken, A., Cagli, K. (2015) Autologous platelet-rich plasma in treatment of chronic venous leg ulcers: a prospective case series. Vascular 23(6):580-585.

Yoon, H.M., Song, W.J. (2024) Using 3D bioprinted autologous minimally manipulated homologous adipose tissue for limb salvage in treating diabetic foot ulcer. Archives of Plastic Surgery 51(3):332-336.

Yoshimura, M., Kohno, M., Okamoto, Y., Tsuchiya, S., Ogawa, K., Fukuma, A., Kurihara, C., Miyama, M., Matsumura, H. (2024) The incidence of intraoperatively acquired pressure injuries in the park-bench position was reduced by applying soft silicone multilayer foam dressings. International Wound Journal 21(2):e14407.

Young, M.J. (2002) Management of the diabetic foot: a guide to the assessment and management of diabetic foot ulcers. Diabetic Foot 5(3 Supplement):S1-S7.

Yuen, W.Y., Huizinga, J., Jonkman, M.F. (2013) Punch grafting of chronic ulcers in patients with laminin-332-deficient, non-Herlitz junctional epidermolysis bullosa. Journal of the American Academy of Dermatology 68(1):93-97.

Zarghooni, K., Bredow, J., Siewe, J., Deutloff, N., Meyer, H.S., Lohmann C. (2015) Is the use of modern versus conventional wound dressings warranted after primary knee and hip arthroplasty? Acta Orthopaedica Belgica 81(4):768-775.

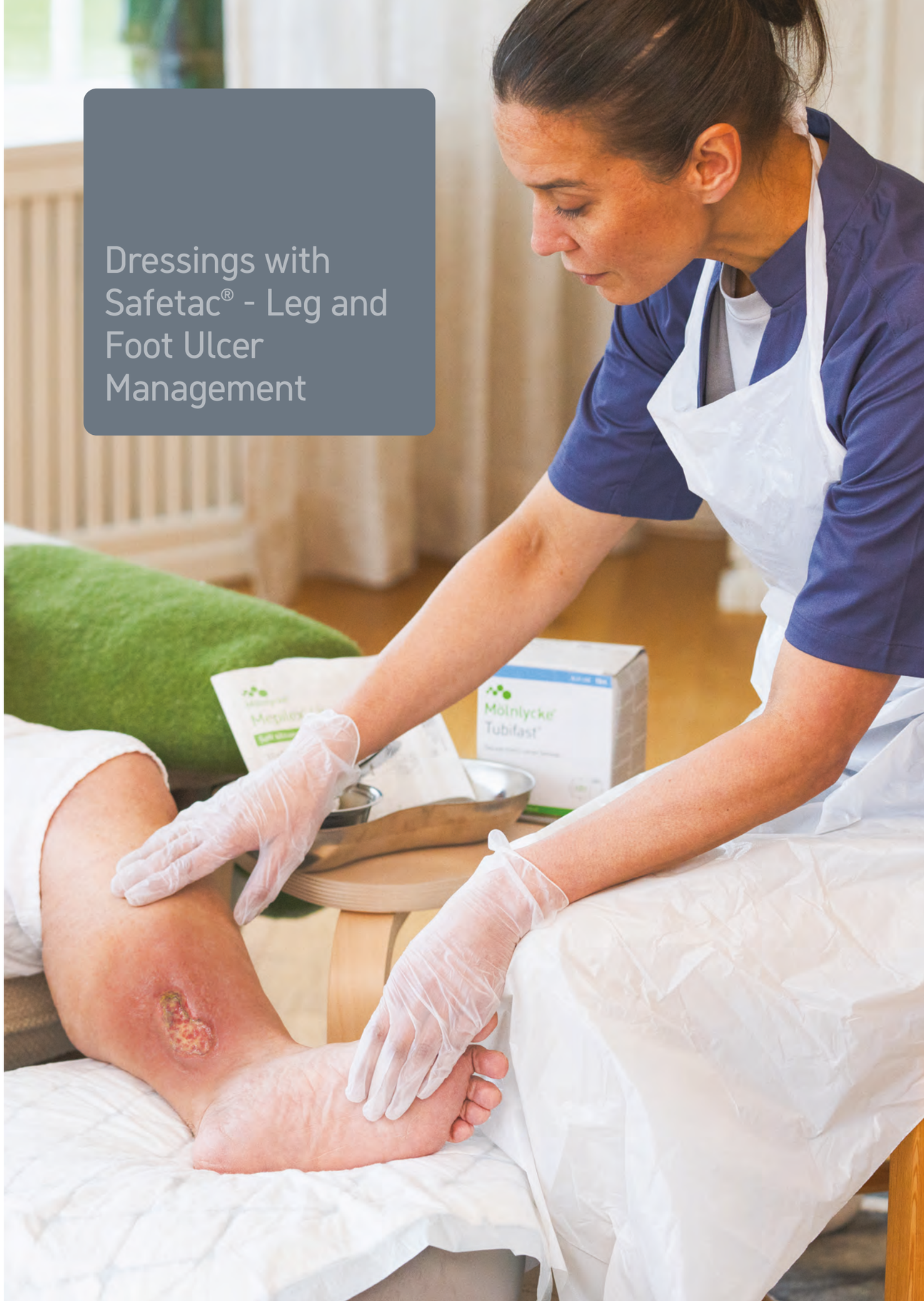
Zhang, Y., Xing, S.Z. (2014) Treatment of diabetic foot ulcers using Mepilex Lite dressings: a pilot study. Experimental and Clinical Endocrinology and Diabetes 122(4):227-230.

Zhong, W-H., Tang, Q-F., Hu, L-Y., Feng, H-X. (2013) Mepilex Lite dressings for managing acute radiation dermatitis in nasopharyngeal carcinoma patients: a systematic controlled clinical trial. Medical Oncology 30(4):761.

Zhou, X., Zhang, Y., Zhao, M., Jian, Y., Huang, J., Luo, X., Yang, J., Sun, D. (2020) Surgical management of hand deformities in patients with recessive dystrophic epidermolysis bullosa. Journal of Plastic Surgery and Hand Surgery 54(1):33-39.

Zillmer, R., Agren, M.S., Gottrup, F., Karlsmark, T. (2006) Biophysical effects of repetitive removal of adhesive dressings on peri-ulcer skin. Journal of Wound Care 15(5):187-191.

Zurcher, S., Krapfl, L., Burds, A. (2013) Reducing postoperative surgical site infections in coronary artery bypass graft patients. Poster presentation at the 45th Annual Conference of the Wound Ostomy and Continence Nurses Society, Seattle, Washington, United States of America.



Dressings with Safetac® - Leg and Foot Ulcer Management

Dressings with Safetac featured:

Mepilex®, Mepilex® Ag, Mepilex® Border, Mepilex® Border Ag, Mepilex® Border Flex (Comfort), Mepilex® Border Lite, Mepilex® Heel, Mepilex® Lite, Mepilex® Transfer, Mepilex® Transfer Ag, Mepilex® Up, Mepilex® XT, Mepitel®, Mepitel® One

Take home messages:

- Lower extremity chronic ulcers typically present with high exudation which can have a negative effect on the quality of life of patients due to leakage (leading to maceration of the peri-wound skin) and odour. High exudation usually requires frequent dressing changes which can be stressful to patients, particularly if they are associated with pain and discomfort.
- Dressings play an important role alongside the key supportive care for lower extremity chronic ulcers, e.g. compression therapy for venous leg ulcers and offloading for diabetes-related foot ulcers.
- Numerous studies have demonstrated the ability of dressings with Safetac to manage excess exudation, thereby minimising the risk of moisture-related damage (e.g. maceration). For example, Mepilex Border Flex (bordered foam) and Mepilex Up (non-bordered foam) effectively absorb and transfer excess exudate away from the wound, even under compression bandaging and offloading devices.
- Also evident is the ability of dressings with Safetac to minimise trauma and pain during dressing changes.
- The available research data indicate that dressings with Safetac can be used effectively alongside other interventions employed in the management of lower limb chronic ulcers, such as compression therapy, offloading, negative pressure wound therapy and skin grafting.

Introduction to leg and foot ulcers

Wounds that fail to progress through an orderly sequence of repair in a timely manner are often referred to as being 'chronic', 'non-healing', 'hard-to-heal' or 'complex'. Many factors contribute to these problematic wounds. Systematic factors include comorbidities (e.g. cardiovascular disease, diabetes, obesity, hypoxia, cancer), ageing, malnutrition, and lifestyle (e.g. smoking, stress). Local factors include vascular disease (venous and arterial), neuropathy, exposure to pressure, infection, malignancy, and the presence of devitalised tissue (Matsuzaki & Upton, 2013; Morton & Phillips, 2016). Inappropriate management and misdiagnosis are also contributory factors (Ahmajarvi, 2022). Most **leg ulcers** are associated with venous (**venous leg ulcer, VLU**), arterial (**arterial leg ulcer, ALU**) or a combination of both venous and arterial aetiologies (**mixed-aetiology leg ulcer, MLU**) (Alagha et al, 2024).

The underlying cause of **VLUs** is chronic venous insufficiency arising from damage to the venous 'non-return' valves which, when healthy, prevent retrograde blood flow back into the legs. The subsequent pooling of blood and raised blood pressure levels cause damage to the walls of the veins, thus allowing fluid and proteins to leak into the surrounding tissues which, in turn, results in oedema. In addition, waste metabolites accumulate in the tissues, such as haemosiderin which stimulates melanin production and, consequently, results in skin hyperpigmentation. Varicose eczema generally develops in the affected area (typically in the medial gator region of the leg) which is at risk for infection and ulceration (Mayrovitz et al, 2023).

Peripheral vascular disease affecting the lower extremity arteries is generally regarded as the most common aetiological factor in the development of **ALUs**. This condition reduces the supply of oxygen and nutrients to the lower leg. As a consequence of this limited perfusion, the tissues are at risk of ulceration (Fierro et al, 2024).

Most foot ulcers are linked to diabetes. There are three generally recognised types of **diabetes-related foot ulcer (DFU)** – neuropathic, ischaemic and neuroischaemic. A neuropathic ulcer results from nerve damage caused by disease (peripheral neuropathy) and associated sensory loss. The altered or loss of feeling in the foot (and/or leg) may result in the patient being unaware of subsequent trauma, increasing the risk of skin loss, blistering and ulceration. An ischaemic ulcer results from peripheral artery disease (PAD) which restricts blood flow to the legs and feet, causing ischaemia and ulceration. A neuroischaemic ulcer is one that has a causal relationship to peripheral neuropathy and PAD (McDermott et al, 2023).

Challenges

As well as imposing a huge financial burden on healthcare systems (Diaz-Herrera et al, 2025), chronic wounds present numerous clinical challenges (due to their morbidity and associated complications) and also impose a psychological and social burden on patients, reducing their quality of life (QoL) across numerous dimensions, e.g. physical function, well-being, autonomy and social participation (Palomer-Albert et al, 2025).

Most chronic wounds are associated with excessive exudation, with VLUs often presenting with particularly high levels of exudate (Grey et al, 2006). If not managed properly, exudate can leak onto the peri-wound region causing maceration which, in turn, can lead to protracted healing, increased risk of wound infection and additional demands on clinical resources and costs (**Figure 1**) (Mervis, 2025). From the patients' perspective, the leakage of exudate and its associated malodour impacts negatively on their wellbeing (e.g. feelings of disgust, self-loathing, low self-esteem and embarrassment (Jones et al, 2006; Jones et al 2008). High exudation is likely to result in the need for frequent dressing changes, which can be stressful to patients, particularly if dressing changes are associated with pain and discomfort (Upton & Solowiej, 2012).

Pain is a common occurrence in patients with chronic wounds (European Wound Management Association, 2024) and has been described as one of the most devastating aspects of living with such

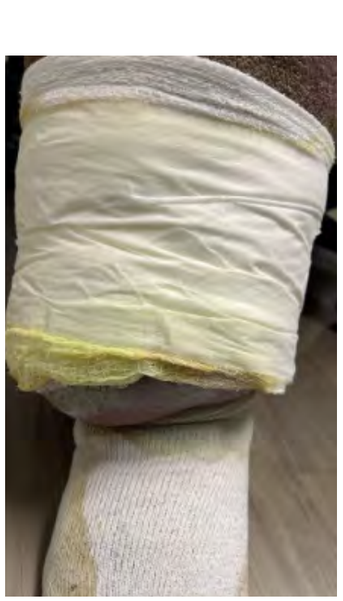


Figure 1. Exudate leakage can lead to peri-wound damage (maceration), delayed wound healing, heightened risk of infection and increased treatment costs. (photograph courtesy of Dot Weir, Saratoga Hospital Center for Wound Healing and Hyperbaric Medicine, Saratoga Springs, New York, United States of America)

wounds (Price et al, 2008). In addition, chronological ageing has cumulative and intrinsic effects that are intimately linked to dynamic changes in the skin such as appearance, structure, mechanical properties and barrier function; these changes may be concomitant with increased skin fragility over time (Cutting, 2008; Waller & Maibach, 2006).

Role of dressings in leg and foot ulcer management

Compression therapy, mostly administered in the form of bandaging around the leg, is the cornerstone of the management of VLUs and aims to counteract gravitational forces and promote the normal flow of venous blood up the leg. It also improves venous and lymph return, thus reducing oedema (Fletcher et al, 2013). Compression therapy is contra-indicated for patients with significant arterial insufficiency (Montero & Isoherranen, 2023); instead, surgical interventions (e.g. angioplasty) are undertaken to help restore circulation in the management of ALUs (Grey et al, 2006). The mainstay of DFU management is the use of offloading devices (e.g. total contact casts and boots) which redistribute pressure away from the wound site, thus reducing trauma and promoting healing (Jones et al, 2023).

The topical management of chronic wounds plays an important role alongside compression therapy and offloading. Modern dressings, for example, are key to the effective management of excess exudate while, at the same time, they help to maintain a moist environment conducive to healing. Dressings can also provide a physical barrier to pathogens, thus reducing the risk of wound infection (Eriksson et al, 2022). To combat the clinical challenges mentioned above, dressings should be able to absorb and retain a wide range of exudate amounts and consistencies (without being adversely affected by the mechanical forces imparted on them by compression therapy and offloading devices). They should also be capable of gently adhering to the wound and surrounding skin while being easy to remove without inflicting damage on delicate tissues. These factors are key to the durability ('wear time') of dressings. An atraumatic dressing with an extended wear time can decrease costs associated with nursing time, materials and pain medication (Alvarez et al, 2021).

Evidence for dressings with Safetac

Many of the studies that have evaluated the use of dressings with Safetac in chronic wound management involved multiple lower limb ulcer types, although some focused on specific ulcer types. The key studies are summarised in **Tables 1** (non-silver containing dressings) and **2** (silver-containing dressings).

Table 1. Mixed lower limb ulcer types - non-silver-containing dressings - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Alvarez et al, 2021 RCT (cross-over design) United States of America	**Subjects:** 38 (age range 35-83 years) **Wounds:** Foot ulcers (n=21), leg ulcers (n=17) **Setting:** Specialist wound care centres (out-patient)	**Safetac:** Mepilex Border Flex **Comparator:** Allevyn Life Optifoam Gentle EX [Patients received one dressing for 2 weeks then crossed-over to second dressing for 2 weeks]	Dressing durability, i.e. time to dressing strike-through (loss of edge seal/adherence, exudate leakage, dislodgement and/or need for dressing change)	<u>Mepilex Border Flex vs. Allevyn Life</u> Fewer patients requiring dressing change after 3 days in Safetac group (p<0.05): - Mepilex Border Flex: 47.1% - Allevyn Life: 72.2% Higher proportion of intact dressings after 1 week in Safetac group (p<0.05): - Mepilex Border Flex: 35.3% - Allevyn Life: 5.6% <u>Mepilex Border Flex vs. Optifoam Gentle EX</u> Fewer patients requiring dressing change after 3 days in Safetac group (p=0.01): - Mepilex Border Flex: 37.5% - Optifoam Gentle EX: 81.3% Higher proportion of intact dressings after 1 week in Safetac group (p=0.01): - Mepilex Border Flex: 43.8% - Optifoam Gentle EX: 12.5%

Woo et al, 2009
 	
RCT (cross-over design)
 	
Canada
	Subjects: 26 (mean age 63.7 years)
	
	Wounds: Leg ulcers (90.6%), pyoderma gangrenosum (6.3%), vasculitis (3.1%)
	
	Setting: Specialist wound care centres (out-patient)
		Safetac:
		Mepilex Border
		
		Comparator:
		Allevyn Adhesive
		
		[Patients had two dressing changes with first assigned dressing, then crossed-over for two dressing changes with second dressing]
			Pain severity before and during dressing changes (measured using VAS 0-10)
			
			Dressing usage
				Lower mean pain severity scores before and during dressing removal in Safetac group:
				- First dressing change:
				  - Before: Safetac 1.8 vs. comparator 3.0 (p=0.007)
				  - During: Safetac 2.0 vs. comparator 3.4 (p=0.0089)
				- Second dressing change:
				  - Before: Safetac 2.1 vs. comparator 3.0 (p=0.0009)
				  - During: Safetac 2.2 vs. comparator 3.3 (p=0.0024)
				
				Patients and investigators preferred Mepilex Border for overall performance and conformability (p<0.05).
				
				Investigators preferred Mepilex Border for fluid handling capacity (p<0.001).

Zhang & Xing, 2014 RCT United States of America	**Subjects:** 46 (age range 53-67 years) **Wounds:** Foot ulcers **Setting:** Endocrinology department	**Safetac:** Mepilex Lite (n=24) **Comparator:** Gauze (n=26) [Patients followed for up to 12 weeks]	Time to healing Pain severity (MPQ/VAS)	Shorter median time to healing in Safetac group (p=0.038): - Mepilex Lite: 49.9 days - Gauze: 65.5 days More patients reported zero pain in Safetac group: - Mepilex Lite: 75% - Gauze: 58%
Zillmer et al, 2006 RCT (intra-patient) Denmark	**Subjects:** 29 (adults) **Wounds:** Peri-wound skin of open/healed VLUs (dressings also applied to normal forearm skin) **Setting:** Dermatology clinic	**Safetac:** Mepilex Border **Comparators:** [Biatain Adhesive and Duoderm Extra Thin (hydrocolloid-based adhesives); Tielle (polyurethane-based adhesive)	Skin barrier function (TEWL) and stratum corneum hydration (EC) measured after 14 days of applications (dressings changed every 2 days)	No statistically significant difference in TEWL and EC detected between Mepilex Border, polyurethane-based adhesive dressing and non-dressed adjacent area. TEWL and EC of peri-wound skin in contact with hydrocolloid-based adhesive dressings was significantly (p≤0.05) higher than that of adjacent non-dressed area. Similar relative effects were observed for normal forearm skin.

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Lev-Tov et al, 2025 Observational prospective clinical study United States of America	**Subjects:** 72 (age range 35-90 years) **Wounds:** Foot ulcers (n=36); leg ulcers (n=36) **Setting:** Specialist wound care centres (out-patient)	**Safetac:** Mepilex Up [Patients followed for up to 6 weeks]	Wound status (i.e. progression to healing) Wound size Dressing usage	Wounds improved or healed at 71.4% of all study assessments (n=367). Wound healing rates of 0.12 and 0.07 cm/day at first and final visits, respectively. 63.1% decrease in median wound area and 92.2% decrease in median foot ulcer volume, relative to baseline. Mean dressing wear time: 5 days (range 1-14); dressings not saturated at 71.9% of changes. Dressing rated highly by clinicians and patients; improvement in patient QoL.
White, 2008 Survey (patients) 20 countries (Europe, Asia-Pacific, Americas)	**Subjects:** 3024 **Wounds:** Foot ulcers, leg ulcers (plus burns, pressure injuries and skin tears) **Setting:** Not specified	**Safetac:** Mepilex, Mepilex Lite, Mepilex Border, Mepilex Border Lite, Mepitel **Comparator:** Variety of dressings (e.g. foam and hydrocolloids) with traditional adhesives	Trauma (subjective rating) Pain before, during and after dressing changes (VAS ranging from 0 (no pain) to 10 (worst pain imaginable)	Less severe trauma levels with Safetac dressings: - Safetac: high 1%; moderate 11%, very slight 35-37%; none 50% - Comparators: high 10%; moderate 28-39%; very slight 31-35%; none 18-29% Significantly lower pain severity scores with Safetac dressings at all assessments (p=0.01): - Safetac: 1.7-1.8, 2.1-2.2 and 1.6-1.7 before, during and after dressing changes - Comparators: 2.4-3.2, 4.6-5.2 and 2.9-3.9 before, during and after dressing changes >90% of respondents stated a preference for dressings with Safetac to traditional adhesive dressings.

Abbreviations: EC = electrical conductance; MPQ = McGill Pain Questionnaire; QoL = quality of life; RCT = randomised controlled trial; TEWL = transepidermal water loss; VAS 0-10 = visual analogue scale ranging from 0 (no pain) to 10 (worst possible pain)

Wound healing

In a randomised controlled trial (RCT) undertaken in the United States of America (USA) involving 46 patients, **DFUs** dressed with Mepilex Lite (thin non-bordered foam) had a significantly shorter median time to healing than those dressed with gauze (49.9 vs. 65.5 days; p=0.038) (Zhang & Xing, 2014). Many of the non-comparative studies summarised in **Tables 1** and **2** refer to good healing responses in leg ulcers and foot ulcers that had dressings with Safetac applied (Lev-Tov et al, 2025; Truchetet et al, 2012; McCarty et al, 2013; Durante, 2008; Meuleneire, 2008a; Schumann et al, 2007; Kota et al, 2014; Dhatariya et al, 2016).

Successful healing of long-standing **VLUs** with regimens including Mepilex Border (bordered foam) have been reported in several case studies (Webb, 2008; Mwipatayi et al, 2016). Furthermore, case studies have been described in which combinations of dressings with Safetac were used successfully in the management of **VLUs**. In the first case, an ulcer with a particularly fragile peri-wound skin was initially managed with Mepilex (non-bordered foam) then, after three weeks once exudation had decreased, with Mepilex Lite (thin, non-bordered foam). Four weeks after commencing dressings with Safetac, the wound had completely re-epithelialised. The dressings effectively managed exudate, maintained the integrity of the peri-wound skin and did not cause pain on removal (Varon et al, 2008).

In the second case, involving an 89-year-old patient with a VLU, Mepitel (wound contact layer) was used initially then, after 10 days once re-epithelialisation had commenced, Mepilex was applied. The dressings with Safetac were not associated with any pain on removal. The ulcer took six weeks to heal (Teixeira & Hermo, 2008).

Mwipatayi et al reported on two **leg ulcer** patients who presented to an outpatient clinic after foam sclerotherapy (an intervention for the management of varicose veins). In one case, after debridement, the wound was dressed with Mepitel, which resulted in a smooth wound surface with healthy granulation tissue present. In the second case, the ulcer was dressed with Mepilex Border and healed after five months (Mwipatayi et al, 2016). Mansouri et al described the use of Mepilex Border Lite (thin bordered foam) dressings in conjunction with topically applied steroid therapy on an ulcer associated with lichen planus on the lower leg. A marked improvement was observed within five weeks of commencing the regime (Mansouri et al, 2014).

Positive outcomes associated with the use of dressings with Safetac in the management of **DFUs** have been observed in numerous case studies and case study series. For example, in a case study series undertaken in Belgium, Mepilex, Mepilex Border Lite, Mepilex Heel (heel-shaped non-bordered foam), Mepilex Lite, Mepilex Ag (silver-containing non-bordered foam), Mepilex Transfer (exudate transfer dressing) or Mepitel were selected according to the different requirements of each ulcer. In each case, the dressings with Safetac helped to overcome the clinical challenges of the complex wounds and assisted in their healing (Meuleneire, 2008b). Mepilex and Mepilex Border have also been used in conjunction with extracellular matrix protein therapies to successfully heal long-standing **DFUs** (McCardle et al, 2009; Rando et al, 2009; Vowden & D'Arcy, 2008).

Mepilex Lite was also evaluated in a 10-patient case study series for the management of non-exuding or low-exuding **DFUs**. Mean wound size decreased from 3.6 cm^2 to 0.85 cm^2 over the five-week study period with complete healing achieved in three patients. The dressing with Safetac was atraumatic to the peri-wound skin and was rated as 'good' or 'very good' by the patients and the investigator (Khramilin, 2006).

The introduction of Mepilex and Mepitel was also successful in the management of two **DFUs**, a deep ulcer showing little evidence of granulation and an inflamed and infected ulcer. Mepitel helped to protect the new epithelial tissue from trauma at dressing changes (Young, 2002). A case study series evaluated the use of Mepitel One (wound contact layer) in the management of **DFUs**. Of the four ulcers dressed with the wound contact layer, one completely healed and two improved significantly. The dressing was observed to conform well to the contours of the wounds and exhibited good flexibility (Whalley, 2010).

Minimising dressing-related trauma and pain

The effect of repeated removal of adhesive dressings on the peri-wound skin of patients with open or healed **VLUs** was evaluated in an RCT. Patches of adhesive dressings were applied over 14 days (changed every two days). Skin barrier function (assessed by transepidermal water loss (TEWL) measurement) and stratum corneum hydration (assessed by electrical conductance (EC) measurement) were monitored. The peri-wound skin on which dressings with Safetac (Mepilex Border) had been applied had TEWL and EC that were similar to those of adjacent non-dressing-treated skin, whereas the peri-wound skin on which dressings with hydrocolloid-based adhesive systems had been applied were found to have significantly higher TEWL and EC. (Zillmer et al, 2008).

In an open, randomised, cross-over, multicentre study undertaken to compare Mepilex Border with an acrylic adhesive dressing in the management of patients with chronic ulcers (**VLUs, pyoderma gangrenosum, vasculitis**), the pain experienced by patients before, during and after dressing changes was recorded. The pain severity scores, measured using a visual analogue scale (VAS) before and during dressing removal, was significantly (p≤0.001) lower in patients in the Mepilex Border group than in the comparator group (**Figure 2**) (Woo et al, 2009). These findings are consistent with other studies that have demonstrated Mepilex Border Flex (Boixados et al, 2019), Mepilex Up (Lev-Tov et al, 2025), the Mepilex range of non-bordered foam dressings (Eytier et al, 2013) and Mepilex Ag (Schumann et al, 2007; Meuleneire, 2008b) to be associated with minimal pain at dressing changes.

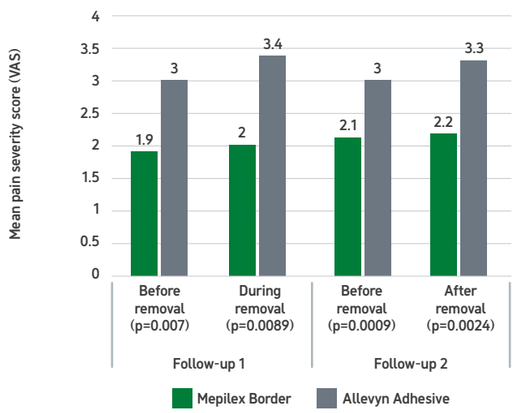


Figure 2. Comparison of pain severity scores between Mepilex Border and an acrylic adhesive-based dressing in patients with chronic wounds, measured using a visual analogue scale ranging from 0 to 10 (Woo et al, 2009)

The benefits of using dressings with Safetac are also highlighted by the findings of a clinical study in which Mepilex Lite was applied to the **foot ulcers** of 77 patients, 64 of whom had diabetes. The healing state of the ulcers, the condition of the surrounding skin and the opinions of both investigators and patients were captured. Treatment objectives were met in 81% of cases, with 88% of patients and 96% of investigators stating that they would be happy to use Mepilex Lite again. The high patient acceptance of the dressing with Safetac was attributed to numerous factors including its ease of application, comfort during wear, and its pain-free removal. The dressing was also observed to be less bulky for footwear than other dressings (O'Neill, 2004). Barrows reported on a patient with a **VLU** who rated dressing change-related pain as two (on a scale from 0 to 10) after the introduction of Mepilex Border Ag (silver-containing bordered foam) dressings, compared to a rating of 10 with a previous dressing regime (Barrows, 2009). Similar reductions in pain were observed in a case study series involving patients with a variety of wound types including **ALUs** dressed with Mepilex Border Ag (Philbin, 2012).

A multinational survey of over 3000 patients, presenting with a variety of wound types including **DFUs, VLUS, ALUs** and **MLUs** (also pressure injuries and acute wounds), was undertaken to gauge the impact of introducing dressings with Safetac (Mepilex, Mepilex Border, Mepilex Border Lite, Mepilex Lite) on the intensity of wound-related trauma and pain, in comparison to previously used regimes involving dressings with traditional adhesives (e.g. alginates, films, foams, hydrocolloids). The dressings with Safetac were associated with demonstrably reduced trauma to the wound and peri-wound skin and significantly (p=0.01) lower pain severity scores (measured by means of a VAS) before, during and after dressing change, compared to the dressings with traditional adhesives. More than 90% of respondents indicated that they preferred the dressings with Safetac to their previous dressing regimes (White, 2008).

Health psychology experts undertook a clinical study to compare the pain and stress experienced by patients with chronic wounds (**foot and leg ulcers**) at dressing changes. Of the 49 patients recruited, 10 had their wounds dressed with Mepilex and 39 with conventional dressings. Patients in the Mepilex group reported significantly lower numerical pain and stress ratings and significantly lower galvanic skin response at dressing changes. Heart rate, blood pressure and salivary cortisol levels were also lower in the Mepilex group, compared to the conventional dressings group (Upton & Solowiej, 2012). Reductions in pain severity were also reported in a study in which Mepilex dressings were used in combination with intralesional injections of autologous platelet-rich plasma in the management of **VLUs** (Yilmaz et al, 2015).

Neal described, from a patient's perspective, a 30-year-long struggle to find a pain-free dressing for **VLUs**. The article refers to various treatment regimes that were unsuccessful in addressing her pain. However, when her ulcer was dressed with Mepilex Border for a period greater than three months, she experienced no pain or difficulty when changing the dressing and found it soothing and comfortable to wear (Neal, 2004). In a two-patient case study series, the introduction of Mepilex Border to the management of painful **DFUs** coincided with a decrease in pain, no trauma to the skin, and reduced frequency of difficult-to-negotiate dressing changes (Miscavige, 2005).

Mepitel One, in conjunction with secondary dressings, was evaluated in five patients with **leg ulcers**. A reduction in the time required to prepare and apply the dressing and decreased patient discomfort while the dressing was in place, relative to previously used dressing regimes, were observed (Atkin et al, 2017). Similar observations were made in an earlier case study (Cooper et al, 2010).

Negative pressure wound therapy (NPWT) involves the wound being covered or filled (depending on its depth) with a dressing (usually foam or gauze) and sealed (by means of an adhesive dressing or occlusive drape) before negative pressure is applied by connecting tubes from the dressing to a pump and fluid collector. Widely used in the management of a diverse range of acute and chronic wound types, NPWT increases perfusion and promotes the formation of healthy granulation tissue, whilst removing excess fluid and bacteria from the wound. In a study undertaken to evaluate a traditional NPWT system in the management of **DFUs and post-amputation wounds** associated with diabetes, investigators had the option of using Mepitel between the wound bed and the wound filler to minimise trauma and pain at dressing changes, and prevent the in-growth of tissue into the NPWT dressing. The vast majority of patients reported no pain at the times of dressing application, activation/deactivation of negative pressure and dressing removal (Stansby et al, 2010).

Exudate management

Mepilex Border Flex is a bordered foam dressing consisting of five layers: Safetac wound contact layer, foam layer, spreading layer, retention layer with superabsorbent fibres and a highly breathable backing film. The dressing design incorporates Flex Technology (y-shaped cuts) which evenly distributes forces to the dressing's borders. This property contributes to adherence and conformability, while allowing the dressing the stretch, which is especially beneficial for applications to joints and other highly mobile areas (Serena et al, 2019) (**Figures 3-4**).

The durability of Mepilex Border Flex was compared to that of two other bordered foam dressings (Allevyn Life and Optifoam Gentle EX) in the management of exuding chronic **VLUs** and **DFUs** in a multi-centre RCT using a 2 x 2 crossover design. In this study, undertaken in the USA, patients were assigned to a Mepilex Border Flex versus Allevyn Life group (Group 1) or a Mepilex Border Flex versus Optifoam Gentle EX group (Group 2). Patients received one dressing for two weeks, then a comparator dressing for the following two weeks. Wounds were assessed at weekly dressing changes. The primary endpoint of the study was dressing durability, defined as the time to dressing strikethrough (i.e. complete saturation, loss of edge seal/adherence, leakage and/or dislodgement) and the need for dressing change. There was a statistically significant higher proportion of intact Mepilex Border Flex dressings (35.3%) than Allevyn Life dressings (5.6%) after one week in Group 1 ($p<0.05$), and a higher proportion of intact Mepilex Border Flex dressings (43.8%) than Optifoam Gentle EX dressings (12.5%) after one week in Group 2 ($p=0.01$) (**Figure 5**). Investigator-judged subjective parameters that were significantly in favour of Mepilex Border Flex over Allevyn Life were exudate absorption ($p=0.017$), conformability ($p=0.007$), ability to stay in place ($p=0.014$) and ease of removal ($p=0.017$). These findings indicate that Mepilex Border Flex has greater durability during the first critical week of care (Alvarez et al, 2021).

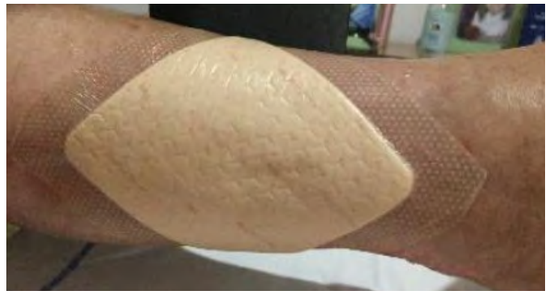


Figure 3. Mepilex Border Flex applied to a mixed aetiology ulcer on lateral medial leg. (photograph courtesy of Juan Jose Suarez Sanchez, University of La Laguna, Las Palmas College of Nursing, Ingenio, Gram Canaria, Spain).

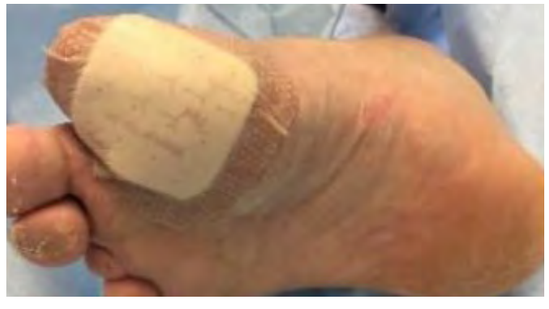


Figure 4. Mepilex Border Flex applied to a foot ulcer on the hallux. (photograph courtesy of Jose Luis Lazaro-Martinez, Complutense University of Madrid, Spain).

Other studies have also demonstrated the ability of Mepilex Border Flex to manage exudate effectively. For example, in an observational study undertaken across 62 nursing practices in France, the dressing performed well in terms of exudate and surrounding skin management of both **chronic** and **acute wounds**. Nurses rated the dressing highly in terms of ease of handling and application, conformability, flexibility, ability to stay in place, and ability to absorb and retain exudate (Boixados et al, 2019).

As mentioned earlier, Woo and colleagues compared Mepilex Border with an acrylic adhesive dressing in the management of **chronic ulcers**, both patients and investigators preferred the dressing with Safetac to the comparator dressings for overall performance and conformability to the wound and peri-wound region ($p<0.05$). Investigators were also more satisfied with Mepilex Border for its exudate handling capacity ($p<0.001$) and ease of removal ($p<0.01$). Wounds that were dressed with the acrylic adhesive-based dressings were more likely to develop maceration and blistering of the peri-wound skin than those managed with the dressing with Safetac (**Figure 6**). The authors also refer to Mepilex Border minimising skin irritation from corrosive exudate, suggesting that this may explain why patients experienced less pain with the Safetac dressing (Woo et al, 2009).

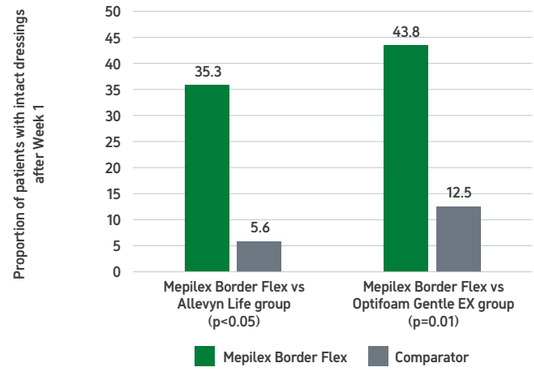


Figure 5. Comparison of Mepilex Border Flex and other bordered foam dressings in terms of durability after one week (Alvarez et al, 2021).

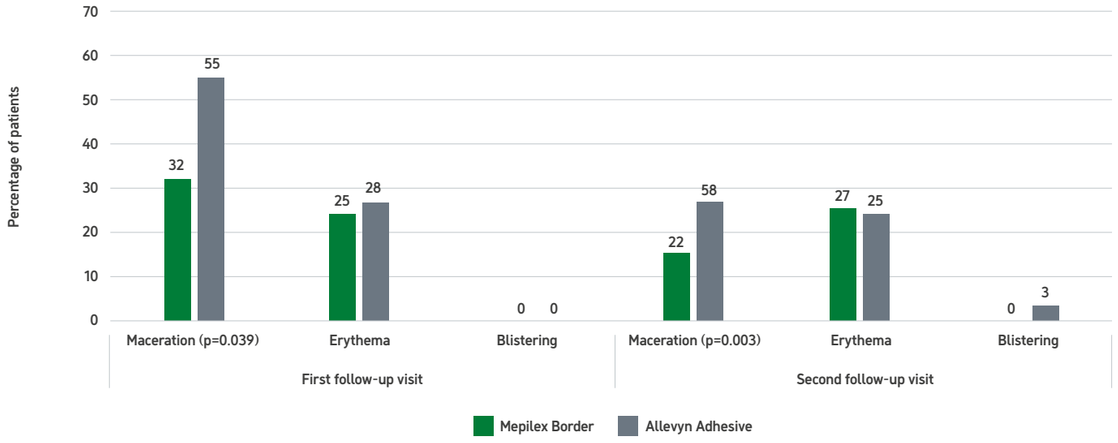


Figure 6. Comparison of peri-wound issues between Mepilex Border and an acrylic adhesive-based dressing in patients with chronic wounds (Woo et al, 2009)

The exudate handling properties of non-bordered foams with Safetac have also been evaluated in clinical studies. For example, a retrospective review of data collected on patients seen at an out-patient clinic in the USA was undertaken to compare, amongst other things, peri-wound issues of wounds dressed with either Mepilex or a hydrophilic polyurethane (Allevyn) dressing. Wound types included **VLUs, ALUs, MLUs** and **DFUs** (also pressure injuries, surgical wounds and traumatic wounds). Eighty-seven wounds were dressed with Mepilex and 86 with the hydrophilic polyurethane dressing. Cases of dermatitis were fewer in the Mepilex-dressed group, i.e. 6 compared to 11 in the comparator group (Eager, 2001).

In a multi-centre observational study undertaken in France, the Mepilex range of non-bordered dressings was evaluated across a variety of acute and chronic wound types in 2401 patients, of whom 890 presented with **leg ulcers** and 165 with **DFUs**. In 97.4% of cases, the study nurses rated the overall performance of the dressings as 'good' to 'very good', with ratings for flexibility and conformability (98.6%), non-adherence to the wound (98.4%), impact on the peri-wound skin (95.3%) and exudate absorption (94.2%) particularly high (Eytier et al, 2013).

More recently, a multi-centre clinical study undertaken in the USA evaluated the use of Mepilex Up (**Figure 7**) in the management of moderately-to-highly exuding chronic wounds (**DFU**, n=36; **VLU**, n=36). At 71.4% of all study assessments, the wound had either improved or healed at the final visit (up to six weeks), with nine (13.2%) wounds healed (**Figure 8**). Relative to baseline, a 63.1% decrease in median wound area and a 92.2% reduction in median foot ulcer volume were recorded. The mean dressing wear time was five days (range 1-14 days). Dressings were not saturated at 71.9% of dressing changes. Alongside the clinical study results, the authors describe the findings of clinically relevant fluid handling tests that were carried out to compare Mepilex Up with other commercially available non-bordered foam dressings. Mepilex Up significantly outperformed the other dressings in fluid dispersion ability and performed well in terms of fluid handling, including under compression (Lev-Tov et al, 2025).

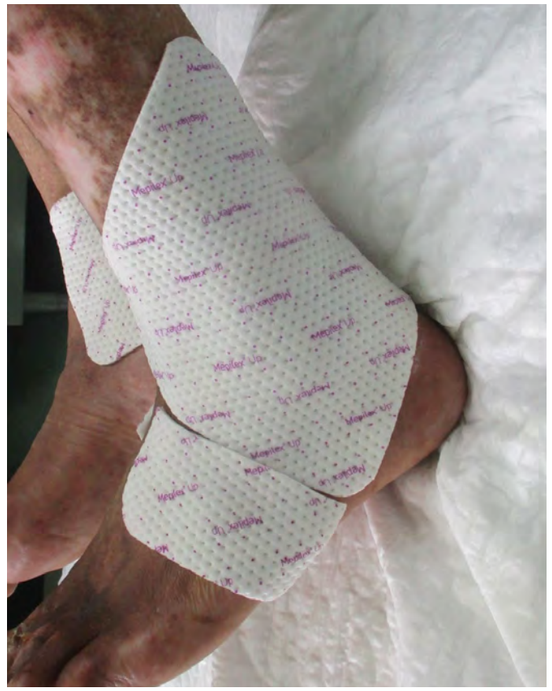


Figure 7. Mepilex Up applied to a venous leg ulcer. Mepilex Up is an innovative non-bordered foam dressing with Safetac. Its foam structure creates a dimpled surface which improves the dressing's capillary action. It is effective at managing low-to-high exudation (low-to-high viscosity), even when working against gravitational forces (Lev-Tov et al, 2025). (photograph courtesy of Paulo Alexandre Silva Ramos, ULS Póvoa de Varzim, Vila do Conde, USF Corino de Andrade, Portugal).

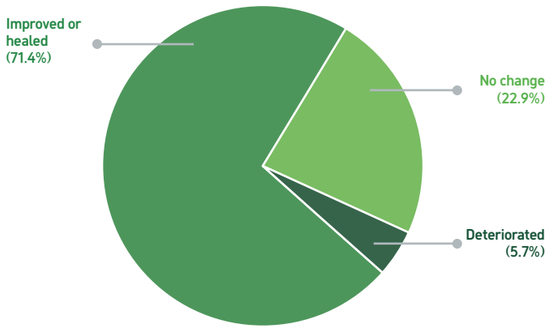


Figure 8. Progression toward healing of chronic wounds dressed with Mepilex Up at study assessments (n=367) (Lev Tov et al, 2025)

Ulceration on the heel generally requires highly conformable or specially shaped dressings that can mould to the shape of the heel. A case study of one such dressing (Mepilex Heel) observed the dressing to be easy to apply to an awkwardly positioned **DFU** on the heel, effectively managed exudate, provided good protection of neo-granulation tissue, and did not cause any skin stripping on removal (Meuleneire 2008b)

Viscous (thick) exudate presents clinical challenges due to its complex composition and impact on wound healing. Compared to serous (thin) exudate, viscous exudate typically contains high levels of proteins, white blood cells, bacteria and cellular debris. It is also more difficult to absorb, leading to increased risk of dressing leakage, peri-wound maceration and infection. It can also hinder dressing removal, causing potential trauma to the wound bed and pain. Effective management requires careful selection of dressings with high absorptive capacity and retention (Vowden et al, 2015). In a case study series undertaken to evaluate the performance of Mepilex XT in the management of **VLUs**, high-volume thick exudate was effectively absorbed and well-managed by the dressing, allowing the peri-wound skin to heal and remain intact, without evidence of maceration or inflammation. There was no evidence of trauma to the wound bed on dressing removal, no bleeding or tearing of re-epithelialisation. No signs of sensitisation to the dressings were observable in any of the patients' skin (Koerner & Adams, 2016). A high proportion (80 to 90%) of caregivers who took part in a survey in France rated Mepilex XT as 'very good' or 'good' across a range of criteria, with exudate absorption singled out as a particularly strong dressing property (Villette et al, 2016).

Dressing change frequency

To investigate potential benefits of change in dressing regime, supported by an educational programme for clinical staff, for chronic wound management in primary and home care settings in Spain, patients (n=37) with wounds that had not reduced in size by greater than 40% to 50% in the preceding four weeks were recruited (seven of whom had **VLUs**). Historical data were collated on the use of the bordered foam dressings being utilised at the time in the seven days preceding the baseline visit. Dressings were switched to Mepilex Border Flex for a minimum of four weeks, while maintaining the same standard of wound care. Usage of the dressing with Safetac in the seven days preceding the final visit was evaluated. The median number of dressing changes in the seven-day period prior to the dressing switch was three, compared to one at the final visit (after dressing switch). This equated to a cost (Euros) saving of €5.38 per week. A 50% reduction in wound area in four weeks in 75% of patients was demonstrated. Pain severity scores (measured on a scale from 0 to 10) before and during dressing change were 3.1 and 3.3 at baseline, reducing to 1.1 and 0.5 at the final visit. These findings highlight the potential benefit of dressing regime improvements in delivering value-based wound care (Roldan Valenzuela et al, 2025).

A study involving 13 patients with a total of 25 wounds (including 15 **chronic wounds**) was undertaken in the USA to evaluate the clinical outcomes, dressing performance and impact on the patient of implementing Mepilex Border Flex dressings and to determine if a change in routine dressing change policy from every 3 to every 7 days affected the number of dressings used and dressing costs.

The average reduction in wound volume was 77% over 13.2 days. No wounds enlarged and four healed. For the chronic wounds, the average reduction in volume was 80.9% over 12.3 days. The dressing was assessed as fully intact without leaking or lifting for 28/29 wound care nurse dressing changes, i.e. a 97% rate of adhesive integrity. A total of 60 dressing changes occurred for the 13 patients. The average wear time of the dressing was 5.5 days. The number of formulary dressings used across the entire facility was reduced by 8.11% and the amount of facility spend on the formulary dressing was reduced by 12.6% when compared to full facility dressing utilisation with the previously used bordered foam dressing (Nelson, et al, 2019).

A quality improvement project (QIP) was undertaken at a community hospital in the USA to address issues (i.e. poor absorption, peri-wound maceration, aggressive adhesion, tissue stripping and frequent painful dressing changes) associated with the silicone bordered foam dressing (Optifoam Gentle Border SA) on formulary at the time. After the wound care team had recommended a switch to Mepilex Border Flex, data were collected from 18 patients (39 wounds) managed with the formulary dressing, and from 14 patients (40 wounds) managed with Mepilex Border Flex. For **VLUs**, a 44.6% reduction (average 3 days) in wound area or volume was observed in the Mepilex Border Flex group, compared to a 12.8% reduction (average 7 days) in the formulary dressing group. There were no episodes of the dressing not adhering / coming off in the Mepilex Border Flex group, compared to 19 in the formulary dressing group. There were no episodes of leaking exudate / peri-wound maceration / epidermal stripping with Mepilex Border Flex compared to 18 episodes of leakage, 14 episodes of peri-wound maceration and 4 episodes of epidermal stripping with the formulary dressing. There were no observations of silicone residues with Mepilex Border Flex, compared to moderate-to-large deposits observed with the formulary dressing. The patients with wounds managed with the formulary dressing experienced 331 dressing changes (average of 8.5 dressings per wound and 18.4 dressings per patient). In contrast, the patients in the Mepilex Border Flex group received 73 dressing changes (average of 1.8 dressings per wound and 5.2 dressings per patient). This equated to 258 fewer dressing changes and 78% fewer dressings being used in the Mepilex Border Flex group. When cost in use (as opposed to unit price) was calculated, Mepilex Border Flex cost 74.2% less than the formulary dressing for the 32 patients, equating to a cost (US Dollars) saving of $695 (Tyson, 2019).

Use with total contact casting

Total contact casts (TCCs) or equivalent are recognised as the 'gold standard' method of offloading for patients with DFUs (Hochlenert & Fischer, 2022). The identification of dressings that work effectively under TCCs is therefore important. After completing a small number of case studies in which Mepilex Border Flex was observed to effectively manage exudate, adhere well to the foot, be comfortable to wear and atraumatic on removal on patients with **DFUs** (Haycocks et al, 2018), a podiatry team in the United Kingdom investigated the use of the dressing under TCCs. In a 10-patient case study series, the use of Mepilex Border Flex was associated with good **DFU** healing progression and healthy peri-wound skin. The performance of the dressing allowed the TCCs to be left in place for the desired length of time (up to seven days), thus promoting patient compliance with treatment and facilitating undisturbed wound healing (Haycocks et al, 2021).

Table 2. Mixed lower limb ulcer types - silver-containing dressings - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Truchetet et al, 2012 Observational prospective clinical study France	**Subjects:** 794 (age range 37-86 years) **Wounds:** Leg ulcers (n=534), foot ulcers (n=14), plus pressure injuries, oncology wounds, burns, traumatic wounds and surgical wounds **Setting:** Community care	**Safetac:** Mepilex Ag [Patients followed for median 19 days]	Wound status Peri-wound status Local signs of infection	Good wound healing response: - All wounds: 17% healed; 73% improved - VLUs: 9.8% healed; 77% improved Reduction in frequency of erythema: 74% at baseline; 52% at final visit. Reduction in mean number of local signs of infection (p<0.001): - All wounds: 2.3 - VLUs: 2.2 (Baseline: 3.7)

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
McCarty et al, 2013 Observational prospective clinical study Multiple countries (n=9)	**Subjects:** 307 (age range 5-108 years) **Wounds:** Leg ulcers (n=160), foot ulcers (n=11) and other chronic and acute wound types **Setting:** Not specified	**Safetac:** Mepilex Border Ag [Patients followed for median 22 days]	Local signs of infection Wound size Pain severity (measured using VAS 0-10) Dressing-related trauma	Reduction in number of wounds with local signs of infection from baseline to final visit. 28.5% and 35% reduction in wound area and volume respectively ($p<0.05$): - Area (cm^2): baseline 36.05 vs. 25.87 final visit - Depth (mm): baseline 4.71 vs. final visit 3.06 Reduction in mean pain severity from baseline to final visit ($p<0.0001$): - During wear: baseline 2.19 vs. final visit 0.88 - During removal: baseline 2.22 vs. 0.86 - After removal: baseline 1.66 vs. final visit 0.63 Increase in percentage of wounds / peri-wound regions without trauma from baseline to final visit: - Wound: baseline 86.99% vs. final visit 92.81% - Peri-wound: baseline 83.56% vs. 89.04%
Durante, 2008 Observational prospective clinical study Italy	**Subjects:** 24 (age range 58-99 years) **Wounds:** Foot ulcers (n=3), leg ulcers (n=14), pressure injuries (n=2), other (n=5) **Setting:** Military hospital	**Safetac:** Mepilex Ag [Patients followed for up to 4 weeks]	Wound size Pain severity Wound bioburden (microbiological swabs)	Mean reduction in wound size of 50% from baseline to final assessment (approximately 30 days). Reduction in pain severity from baseline to final visit; 20.8% and 62.5% of patients with high and moderate pain at baseline vs. 0% and 31.8% at final visit. Reduced bacterial burden from baseline to final visit.
Meuleneire, 2008a Observational prospective clinical study Belgium	**Subjects:** 30 (age range 29-91 years) **Wounds:** Foot ulcers, leg ulcers (plus pressure injuries, burns, surgical wounds, traumatic wounds) **Setting:** Outpatient wound care centre	**Safetac:** Mepilex Ag [Patients followed for up to 4 weeks]	Local signs of infection Wound status Pain severity before and during change (measured using VAS 0-10)	Eradication of local signs of infection in 90% of wounds. Proportion of wounds healed or almost healed at end of study period (4 weeks) was 53% and 27%, respectively. Pain severity (median) before and during dressing change was lower at the first and final dressing change compared to baseline ($p<0.0001$): - Before dressing change: Baseline: 6.5 First dressing change: 4 Final dressing change: 0 - During dressing change: Baseline: 6 First dressing change: 3 Final dressing change: 0
Schumann et al, 2007 Observational prospective clinical study Germany / Sweden	**Subjects:** 18 (ages not specified) **Wounds:** Leg ulcers **Setting:** Specialist wound care centres (in- and out-patients)	**Safetac:** Mepilex Ag [Patients followed for up to 4 weeks]	Local signs of infection Wound status Pain severity (measured using VAS 0-100)	Reduction in number of wounds exhibiting inflammation: - Baseline: 16.7% - Final visit: 0% 29.6% reduction in wound size: - Baseline: 6.3 cm^2 - Final visit: 2.9 cm^2 Pain severity during and after dressing changes was low throughout study (mean values at all visits ≤2).

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Kota et al, 2014 Observational retrospective clinical study India	**Subjects:** 170 (adults) **Wounds:** Leg ulcers **Setting:** Vascular surgery facility (out-patient)	**Safetac:** Mepilex Ag [Patients followed for up to 12 weeks]	Time to healing Patient compliance with regimen	Healing response at 4 weeks: - Complete: 24.7% (n=42) - Partial: 62.9% (n=107) 90% compliance rate.
Dhatariya et al, 2015 Observational prospective clinical study United Kingdom	**Subjects:** 24 (age range 38-82 years) **Wounds:** Infected DFUs **Setting:** Diabetes care centres (in- and out-patient)	**Safetac:** Mepilex Transfer Ag Evaluation duration: up to 4 weeks (with additional 12-week follow-up)	Local signs of infection Wound size Peri-wound condition Pain severity (measured using VAS ranging from 0 to 100)	Reduction in signs of infection: - Baseline: >95% of ulcers with 3-5 signs of infection (63.4% of them regarded as moderate to severe) - Follow-up*: >95% of ulcers improved (no signs of infection in 16.7% and only 1 sign of infection in 54.2%) 44% reduction in mean wound size: - Baseline: 3.06 cm^2 - Follow-up*: 1.72 cm^2 Proportion of patients with healthy peri-wound: - Baseline: 25% - Follow-up*: 71% Reduction in mean pain score: - Baseline: 15.8 - Follow-up*: 4.6 * up to 4 weeks

Abbreviations: VAS 0-10 = visual analogue scale ranging from 0 (no pain) to 10 (worst possible pain); VAS 0-100 = visual analogue scale ranging from 0 (no pain) to 100 (worst possible pain)

Topical antimicrobial therapy

Silver-containing dressings are commonly used in the management of leg and foot ulcers, when topical antimicrobial therapy is indicated. A prospectively undertaken observational study in France examined the use of Mepilex Ag on patients (n=794) with a wide array of chronic and acute wound types managed in the community setting; 534 of the wounds were **VLUs**. At the baseline visit, the mean number of local signs of infection was 3.5. At the end of the study period, the number had decreased by 2.3 across all wound types (2.2 for VLUs) ($p<0.001$). Good wound healing progression was observed with 90% of wounds healed or improved (87% for VLUs) (Truchetet et al, 2012).

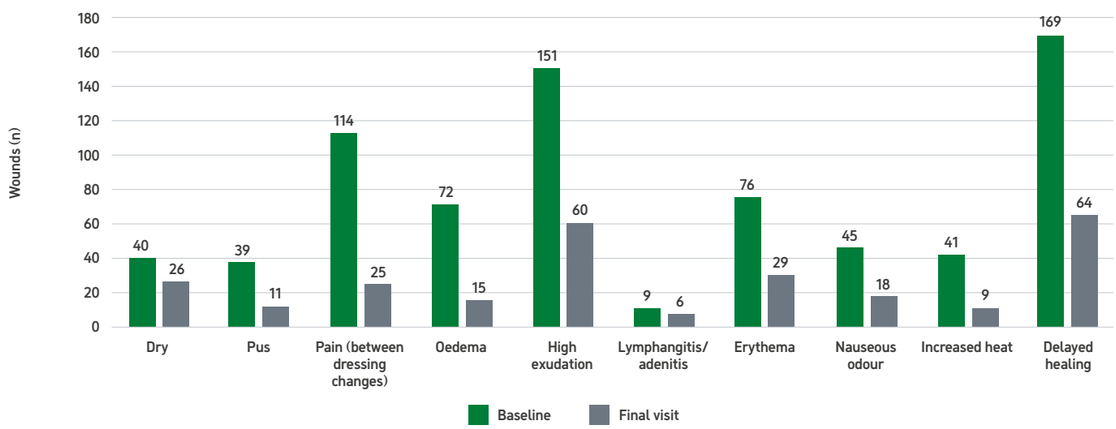


Figure 9. Number of local signs of infection at baseline and final visit in wounds dressed with Mepilex Border Ag (McCarty et al, 2013)

McCarty et al reported on an observational study conducted prospectively across nine countries to evaluate the performance of Mepilex Border Ag. In total, the wounds of 307 patients were evaluated, including 160 **leg ulcers** and 11 **foot ulcers**. Compared to the baseline assessment, the number of wounds exhibiting local signs of infection were reduced at the final visit (**Figure 9**). Statistically significant decreases in wound area (28.5%) and depth (35.0%) between baseline and final visit were recorded ($p<0.05$). Pain severity during dressing wear, at removal and after removal was also significantly lower at the final visit, relative to baseline ($p<0.0001$), with a concomitant increase in the proportion of trauma-free wounds and peri-wound regions (McCarty et al, 2013).

In an observational study undertaken at a wound care centre in Belgium, 30 patients with acute and chronic wounds (including **leg ulcers** and **foot ulcers**) exhibiting clinical signs of localised infection received Mepilex Ag dressings for up to four weeks. At the end of the study period, the clinical signs of infection had been eradicated in 90% of the wounds, while 53% of the wounds had healed and 27% almost healed. The dressings were rated as 'excellent' or 'very good' in 77% of the investigators' evaluations and in 82% of the patients' evaluations (Meuleneire, 2008a). The 90% compliance rate with the Mepilex Ag dressing regimen in a study undertaken in India (Kota et al, 2014) is another strong indicator of a high level of patient satisfaction with the silver-containing foam dressing.

The use of a dressing regime involving the use of Mepilex Ag over a four-week period in the management of 24 patients with infected, chronic wounds (**VLUs, ALUs, MLUs, DFUs** and pressure injuries) was evaluated in an observational study undertaken in Italy. Dressings were changed twice weekly, with more frequent changes undertaken for highly exuding wounds. Wounds were swabbed at the first visit, and after 15 days and 30 days. At the end of the study period, two wounds had completely healed with another eight showing signs of improvement. The mean reduction in wound size from baseline to day 30 was 50%. A reduction in the number of patients experiencing pain was also observed (50% of patients had low levels of pain or no pain at the end of the study period). Microbiological analysis of the swab cultures indicated a reduction in the levels of common wound pathogens (Durante, 2008).

In a multi-centre study undertaken across centres in Germany and Sweden, the use of Mepilex Ag on 18 patients (in- and out-patients) with **VLUs** (n=11), **MLUs** (n=4) and **DFUs** (n=3) was examined. The ulcers were deemed to need antimicrobial therapy and had low-to-moderate levels of exudate. Dressing changes were undertaken weekly over a four-week period. The number of healthy wounds increased from baseline (n=5) to the final visit (n=9). There was also a reduction in wound size from baseline to final visit of approximately 30%. The proportion of viable wound tissue increased from baseline (75%) to final visit (80%), and the number of patients with highly exuding wounds decreased. A reduction in the number of wounds exhibiting signs of inflammation was also observed. The degree of pain reported was low throughout the study period (Schumann et al, 2007).

Davoudi et al reported on the successful management of a **VLU** involving the use of Mepilex Ag, in conjunction with compression therapy, for a period of four weeks. Dressing changes were undertaken approximately twice weekly. The ulcer showed a positive healing response. The level of bacterial contamination within the dressings was less at the end of the study period than at baseline (Davoudi et al, 2007).

In a non-comparative, observational study evaluating the efficacy and safety of Mepilex Ag in the management of **DFUs** and the post-operative management of diabetes-related foot osteomyelitis in Spain, the silver-containing dressing with Safetac was found to be easy to use, malleable, adaptable and suitable for applying anywhere on the foot. A favourable healing response was reported in 10 of the 12 wounds (mean healing time of 57.4 days) and no adverse events were reported. The authors discuss the importance of selecting a dressing that maintains a moist wound environment, allows control of exudate to avoid maceration of the peri-wound region, allows the exchange of gases, isolates the wound, provides comfort for the patient, minimises pain, can be easily removed without damaging granulation tissue and peri-lesional skin, and is cost-effective. Based on their clinical experiences, the authors state that Mepilex Ag meets all these requirements (Quintana Marrero, & Aragon Sanchez, 2011). The same dressing was found to simultaneously resolve local signs of infection and address the issues of trauma and pain in the management of **DFUs** in a case study series. In total, 15 DFUs had the silver-containing dressing applied for up to four weeks. Reductions in pain, erythema, oedema, heat, exudation, and wound size were observed (Richards & Chadwick, 2011).

Exudate transfer dressings are designed to move excess exudation away from the wound into a secondary absorbent layer, thereby minimising the risk of moisture-related damage to the wound and surrounding skin, whilst maintaining a moist wound environment (Arnold-Long, 2015). Their ability to separate absorption from retention allows clinicians to tailor dressing combinations to the specific needs of the wound. For example, Mepilex Transfer Ag was used as part of a dressing regimen for a **leg ulcer**. The patient's pain severity score was rated as 10 (on a scale of 0 to 10) prior to use of the silver-containing exudate transfer dressing and reduced to five after its initiation. The author states that the dressing likely decreased the bacterial load (Arnold-Long, 2015).

Skin graft management

Skin grafting is a commonly used surgical intervention which involves the placement of skin or a skin substitute over a wound to replace and regenerate the damaged tissue (Serra et al, 2016). There are several reports of dressings with Safetac being used on patients with chronic leg ulcers to hold skin grafts in place.

In a study involving 15 patients which set out to monitor the healing of ulcers (mostly **VLUs**) that had either a skin substitute or an autograft applied, Mepitel was placed on top of the grafts and beyond their edges to prevent slippage by shear forces. All ulcers healed within three to five weeks, with no reports of pain (Kuhn & Angehrn, 2009).

Pinch grafting is a technique that involves the harvesting of small discs of skin and applying them evenly across an epithelial defect to enable epithelialisation from the wound edges and the discs. In an article describing the use of a trigger-fired harvester, Mepitel is described as a suitable dressing for holding pinch grafts applied to **VLUs** securely in place (Greenwood et al, 1997).

Marconi et al reported on a case in which Mepitel was used to secure skin grafts applied to a **pyoderma gangrenosum-related ulcer**. The wound contact layer with Safetac was associated with atraumatic and pain-free application and removal, held the skin graft in position and remained in place until the graft was established (Marconi et al, 2009).

In a study undertaken in Brazil to compare micrografting with conventional mesh grafting for chronic wounds, including **VLUs** and **DFUs**, Mepitel One was applied (in both treatment groups) over the grafted area and left in place for 14 days before replacing, allowing the secondary dressing (hydrogel plus foam Mepilex) to be changed as needed without disturbing the grafted area (Sanches-Pinto et al, 2023).

References

Ahmajarvi, K., Isoherranen, K., Venermo, M. (2022) Cohort study of diagnostic delay in the clinical pathway of patients with chronic wounds in the primary care setting. British Medical Journal Open 12:e062673.

Alagha, M., Alfatih, A., Westby, D., Walsh, S.R. (2024) Review of mixed arterial venous leg ulcers (MAVLU) disease in contemporary practice. Vascular and Endovascular Surgery 58(7):747-751.

Alvarez, O.M., Granick, M.S., Reyzelman, A., Serena, T. (2021) A prospective, randomized, controlled, crossover study comparing three multilayered foam dressings for the management of chronic wounds. Journal of Comparative Effectiveness Research 10(6):481-493.

Arnold-Long, M. (2015) Initial patient outcomes with use of an absorbent antimicrobial soft silicone exudate transfer foam dressing: a case series. Poster presentation at 47th Annual Conference of the Wound Ostomy and Continence Nurses' Society, San Antonio, Texas, United States of America.

Atkin, L., Fletcher, J., Tickle, J. (2017) Managing patients with large, shallow, complex wounds: a case series. Wounds UK, EWMA Special: 42-46.

Barrows, C. (2009) Enhancing patient outcomes-reducing the bottom line: the use of antimicrobial soft silicone foam dressing in home health. Home Healthcare Nurse 27(5):279-284.

Boixados, D., Allaert, F.A., Drareni, W. (2019) Efficacy of a five-layer silicone foam dressing with 360-degree flex technology for chronic and acute wound management in home care settings E-poster presentation at European Wound Management Association Conference, Gothenburg, Sweden.

Cooper, P., Gray, D., Russell, F., Stringfellow, S. (2010) Case study using Mepitel One wound contact dressing with Safetac. Wounds International 1-11.

Cunningham, D. (2004) Treating venous insufficiency ulcers with a soft silicone dressing. Ostomy Wound Management 50(10):8-10.

Cutting, K.F. (2008) Impact of adhesive surgical tape and wound dressings on the skin, with particular reference to skin stripping. Journal of Wound Care 17(4):157-162.

Davoudi, M., Werthen, M., Blom, K., Morgelin, M., Schmidtchen, A. (2007) Multiple actions of Mepilex Ag, a new antimicrobial wound dressing. Poster presentation at the European Wound Management Association conference, Glasgow, United Kingdom.

Dhatariya, K., Gooday, C., Franke, B., Pilling, T., Flanagan, A., Zeidan, L. (2016) An open, non-comparative, multi-centre evaluation of performance and safety using an antimicrobial exudate transfer dressing on diabetic foot ulcers: a case series. Journal of Wound Care 25(5):256-265.

Diaz-Herrera, M.A., Gonzalez-Duran, M., Rodriguez-Martinez, F.J., Tujillo-Flores, G., Tuset-Mateu, N., Verdu-Soriana, J., Gea-Caballero, V., Sanllarente-Melenchon, A., Almeda-Ortega, J., Cunillera-Puertalas, O., Acedo-Anta, M., Martinez-Riera, J.R. (2025) The financial burden of chronic wounds in primary care: a real-world data analysis on cost and prevalence. International Journal of Nursing Studies Advances 8:100313.

Durante, CM. (2008) Chronic wounds and local malpractice: an antimicrobial silver soft silicone foam can help in solving the problem. Poster presentation at the 3rd Congress of the World Union of Wound Healing Societies, Toronto, Canada.

Eager, C.A. Comparison of two foams through the measurement of healing time, frequency of dressing changes and peri wound status. Poster presentation at the 14th Annual Symposium on Advanced Wound Care and Medical Research Forum on Wound Repair, Orlando, Florida, United States of America, 2001.

Eriksson, E., Liu, P.Y., Schultz, G.S., Martins-Green, M.M., Tanaka, R., Weir, D., Gould, L.J., Armstrong, D.G., Gibbons, G.W., Wolcott, R., Olutoye, O.O., Kirsner, R.S. (2022) Chronic wounds: treatment consensus. Wound Repair and Regeneration 30(2):156-171.

European Wound Management Association. (2024) Holistic management of wound-related pain: an overview of the evidence and recommendations for clinical practice. EWMA, Frederiksberg, Denmark.

Fierro, A.L., Abeshouse, M., Lagziel, T., Lantis, J.C. (2024) Arterial leg ulcers in the octogenarian. Clinics in Geriatric Medicine 40(3):397-411.

Eytier, C., Gazeau, E., Beneteau, G., Verfaillie, G. (2013) Praticite et tolerance de l'association d'un pansement hydrocellulaire avec enduction de siliconeet d'un bandage tubulaire extensibile dans les deux sens sur la prise en charge locale des plaies. Une etude observationnelle realisee aupres de 304 infirmiers(eres) diplome(e)s d'etat (IDE) et portant sur 2401 patients. Resultats de l'etude TeMpO. Journal des Plaies et Cicatrisations 18(88):38-44.

Fletcher, J., Moffatt, C., Partsch, H., Vowden, K., Vowden, P. (2013) Principles of compression in venous disease: a practitioner's guide to treatment and prevention. Wounds International, London, United Kingdom.

Greenwood, J.E., Parry, A.D., Williams, R.M., McCollum, C.N. (1997) Trigger-fired pinch-graft harvester for use in chronic venous ulcers. British Journal of Surgery 84(3):397-398.

Grey, J.E., Harding, K.G., Enoch, S. (2006) Venous and arterial leg ulcers. British Medical Journal 332(7537):347-350.

Haycocks, S., Allen, M., Chadwick, P. (2021) Case series: Mepilex Border Comfort under total contact casting in the treatment of exuding diabetic foot ulcers. Diabetic Foot Journal 24(2):42-51.

Haycocks, S., Chadwick, P., Davies, P. (2018) Case series: Mepilex Border Comfort in the treatment of diabetic foot ulcers with exudate. The Diabetic Foot Journal 21(4):265-271.

Hochlenert, D., Fischer, C (2022) Ventral windowed total contact casts safely offload diabetic feet and allow access to the foot. Journal of Diabetes Science and Technology 16(1):137-143.

Jones, J., Barr, W., Robinson, J., Carlisle, C. (2006) Depression in patients with chronic venous ulceration. British Journal of Nursing 15(11):S17-S23.

Jones, J., Robinson, J., Barr, W., Carlisle, C. (2008) Impact of exudate and odour from chronic venous leg ulceration. Nursing Standard 22(45):53-54.

Jones, K., Backhouse, M.R., Bruce, J. (2023) Rehabilitation for people wearing offloading devices for diabetes-related foot ulcers: a systematic review and meta-analyses. Journal of Foot and Ankle Surgery 16:16.

Khramilin, V. (2006) Mepilex Lite in the treatment of diabetic foot ulcer. Open non-randomised case study. Poster presentation at the European Wound Management Association Conference, Prague, Czech Republic.

Koerner, S., Adams, D. (2016) Use of a new foam dressing technology with unique exudate channels (UEC) under compression to handle copious thick, viscous exudate. Poster presentation at Wound Ostomy and Continence Nurses Society and Canadian Association for Enterostomal Therapy, Montreal, Canada.

Kota, A.A., Selvaraj, A.D., Premkumar, P., Ponraj, S., Agarwal, S. (2014) Four layer dressing in the management of chronic venous ulcers in the outpatient setting of a tertiary hospital in India. Wound Medicine 5:21-24.

Kuhn, C., Angehrn, F. (2009) Use of high-resolution ultrasound to monitor the healing of leg ulcers: a prospective single-center study. Skin Research and Technology 15(2):161-167.

Lev-Tov, H., Serena, T., Sigal, F., Nygren, E. (2025) Bench to bedside evaluation of an innovative, non-bordered foam dressing for use in exudating chronic wounds. International Wound Journal 22(S1):e70414.

Mansouri, Y., Kaur, M.R., Paul, M., Muc, R. (2014) Solitary ulcerative lichen planus on the lower leg, a diagnostic challenge. Journal of the American Academy of Dermatology 70(5 Supplement):AB55.

Marconi, R., Laverda, F., Trevisan, G. (2009) A case study evaluation of a soft silicone primary wound contact dressing in the prevention of wound pain and tissue trauma. Poster presentation at the European Wound Management Association Conference, Helsinki, Finland.

Matsuzaki, K., Upton, D. (2013) Wound treatment and pain management: a stressful time. International Wound Journal 1096):638-644.

Mayrovitz, H.N., Wong, S., Mancuso, C (2023). Venous, arterial, and neuropathic leg ulcers with emphasis on the geriatric population. Cureus 15(4):e38123.

McCardle, J., Brewin, E., Young, M. (2009) Use of a synthetic extracellular matrix protein in non-healing diabetic foot wounds. The Diabetic Foot Journal 12(1):27-32.

McCarty, S., Davies, P., Rippon, M. (2013) Mepilex Border Ag: an in-market evaluation. Poster presentation at the Wounds UK Conference, Harrogate, United Kingdom.

McDermott, K., Fang, M., Boulton, A.J.M., Selvin, E., Hicks, C.W. (2023) Etiology, epidemiology, and disparities in the burden of diabetic foot ulcers. Diabetes Care 4691):209-221.

Mervis, J. (2025) The impact of chronic wound exudate on the patient, clinician and payer: addressing the challenges with foam dressings. International Wound Journal 22(Supplement 1):e70369.

Meuleneire, F. (2008a) An observational study of the use of a soft silicone silver dressing on a variety of wound types. Journal of Wound Care 17(12):535-539.

Meuleneire, F. (2008b) Management of diabetic foot ulcers using dressings with Safetac: a review of case studies. Wounds UK 4(4):16-30.

Miscavige, M. (2005) Considering patient priorities when choosing a dressing. Ostomy Wound Management 51(11A Supplement):23-24.

Montero, E.C., Isoherranen, K. (2023) Compression therapy beyond venous leg ulcers. Journal of Wound Management 24(3):76.

Morton, L.M., Phillips, T.J. (2016) Wound healing and treating wounds: differential diagnosis and evaluation of chronic wounds. Journal of the American Academy of Dermatology 74(4):589-625.

Mwipatayi, B.P., Western, C.E., Wong, J., Angel, D. (2016) Atypical leg ulcers after sclerotherapy for treatment of varicose veins: Case reports and literature review. International Journal of Surgery Case Reports 25:161-164.

Neal, S. (2004) Finding an end to the pain – one patient's experience. Ostomy Wound Management 50(3):12-13.

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

O'Neill, C. (2004) Managing foot ulceration in diabetic patients helping to meet the objectives of treatment. Poster presentation at the Wounds UK Conference, Harrogate, United Kingdom.

Palomar-Albert, D., Zamora-Ortiz, J., Palomar-Llatas, F., Escudero-Martinez, M., Naranjo-Cuellar, A., Pastor-Orduna, M.I. 2025) Longitudinal observational study on quality of life in patients with chronic wounds using DLQI and EQ-5D. Medicina (Kaunas) 61(5):907.

Philbin, S. (2012) Simple solutions for complex wounds of multiple types. Poster presentation at the Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Atlanta, Georgia, United States of America.

Price, P.E., Fagervik-Morton, H., Mudge, E.J., Beele, H., Ruiz, J.C., Nystrom, T.H., Lindholm, C., Meaume, S., Melby-Ostergaard, B., Peter, Y., Romanelli, M., Seppanen, S., Serena, T.E., Sibbald, G., Soriano, J.V., White, W., Wollina, U., Woo, K.Y., Wyndham-White, C., Harding K.G. (2008) Dressing-related pain in patients with chronic wounds: an international patient perspective. International Wound Journal 5(2):159-171.

Quintana Marrero, Y., Aragon Sanchez, J. Experience regarding a silver absorbent foam dressing for a complicated diabetic foot. Metas de Enfermeria 2011;14(1):18-25.

Rando, T. (2009) Use of a biological extracellular matrix wound therapy to heal complex, chronic wounds. Journal of Wound Care 18(2):70-74.

Richards, K., Chadwick, P. (2011) Addressing local wound infection with a silver-containing, soft-silicone foam dressing: a case series. The Diabetic Foot Journal 14(2):90-95.

Roldan Valenzuela, A., Galindo Cantillo, V., de Borja Lopez Casanova, F., Ordonez Ferrer, S.M., Hernandez Palanco, L.F., Berjano Rodriguez, A., Cabrera Aguera, M.J., Illanes Valenzuela, J.M., Lopez Moraleda, I., Prieto Torrado, O., Castillo Aparicio, G. (2025) A wound dressing shows its value: clinical and economic effects of a dressing regime change for primary and home care chronic wound management. Poster presentation at European Wound Management Association Conference, Barcelona, Spain.

Sanches-Pinto, D.C., Eriksson, E., Gomez, D.S., Nunes, M.P.T., Gemperli, R., Soriano, F.G. (2023) Minced skin grafts for chronic wounds compared to conventional mesh grafts. Health Science Report 6(6):e1353.

Schumann, H., Apelqvist, J., Schmidtchen, A., Hansson, C. (2007) Open, non-comparative, multicentre investigation exploring the tolerance of an absorbent foam dressing containing silver used in chronic wounds. Poster presentation at the European Wound Management Association Conference, Glasgow, United Kingdom.

Serena, T., Chadwick, P., Davies, P., Johansson, C., Karlsson, C., Edenro, G., Skold, E., Wellner, E., Greener, M., Lazaro-Martinez, J.L., Conde Montero, E., Suarez Sanchez, J.J. (2019) Multifunctional and patient-focused. Mepilex Border Flex: an exploration of its holistic clinical benefits. Journal of Wound Care 28(6 Supplement 2):S1-S31.

Serra, R., Rizzuto, A., Rossi, A., Perri, P., Barbetta, A., Abdalla, K., Caroleo, S., Longo, C., Amantea, B., Sammarco, G., de Franciscis, (2016) S. Skin grafting for the treatment of chronic leg ulcers – a systematic review in evidence-based medicine. International Wound Journal 14(1):149-157.

Stansby, G., Wealleans, V., Wilson, L., Morrow, D., Gooday, C., Dhatariya, K. (2010) Clinical experience of a new NPWT system in diabetic foot ulcers and post-amputation wounds. Journal of Wound Care 19(11):496-502.

Teixeira, J.R., Hermo, M.C. (2008) Tratamiento de lesiones utilizando apositos de suave silicona; cura humeda, minimizando el traumatismo y el dolor. Poster presentation at VII Simposio Nacional Úlceras por Presión y Heridas Crónicas, Tarragona, Spain.

Truchetet, F., Guibon, O., Meaume, S. (2012) Clinicians' rationale for using a sliver dressing: the French OMAg+E observational study. Journal of Wound Care 21(12): 620-625.

Tyson, L. (2019) Study first: driving the case for improving hospital wound care. Poster presentation at Symposium on Advanced Wound Care (Spring), San Antonio, Texas, United States of America.

Upton, D., Solowiej, K. (2012) The impact of atraumatic vs conventional dressings on pain and stress. Journal of Wound Care 21(5):209-216.

Varon, M.J.M., Sanchez, J.C., Orta, E.M.F. (2008) Tratamiento de dehiscencias y necrosis postquirurgicas gracias a los apositis con tecnologia de suave silicona. Poster presentation at VII Simposio Nacional Úlceras por Presión y Heridas Crónicas, Tarragona, Spain.

Villette, A., Dubos, C., Sellem, M. (2016) Une innovation technique pour une absorption rapide et optimale. Poster presentation at 20eme Conference National des Plies et Cicatrisations, Paris, France.

Vowden, P., Bond, E., Meuleneire, F. (2015) Managing high viscosity exudate. Wounds UK 11(1):56-60.

Vowden, K., D'Arcy, A. (2008) Treatment of hard-to-heal diabetic and neuropathic foot ulcers with amelogenin, an extracellular matrix protein. Poster presentation at the 3rd Congress of the World Union of Wound Healing Societies, Toronto, Canada.

Waller, J.M., Maibach, H.I. (2006) Age and skin structure and function, a quantitative approach (II): protein, glycosaminoglycan, water, and lipid content and structure. Skin Research and Technology 12(3):145-154.

Webb, M. (2008) Use of soft silicone dressings to meet the unique wound care needs of residents in one county long term care facility. Poster presentation at the 40th Annual Conference of the Wound Ostomy and Continence Nurses Society, Orlando, Florida, United States of America.

Whalley, A. (2010) Case study evaluations of Mepitel One in the management of wounds of patients with diabetes. Poster presentation at Wounds UK Conference, Harrogate, United Kingdom.

White, R. (2008) A multinational survey of the assessment of pain when removing dressings. Wounds UK 4(1):14-22.

Woo, K.Y., Coutts, P.M., Price, P., Harding, K., Sibbald, R.G. (2009) A randomized crossover investigation of pain at dressing change comparing 2 foam dressings. Advances in Skin and Wound Care 22(7):304-310.

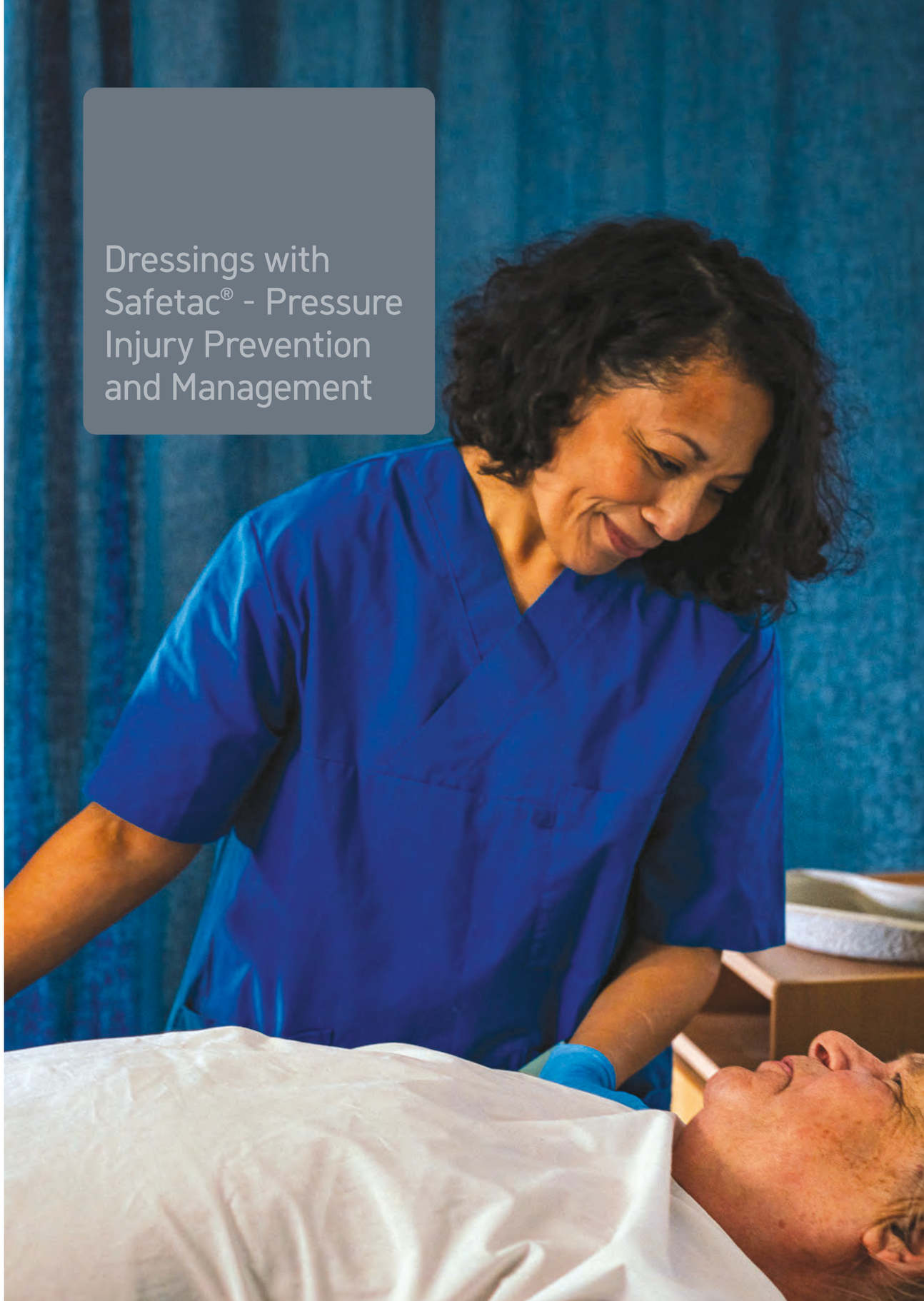
Yilmaz, S., Aksoy, E., Doganci, S., Yalcinkaya, A., Diken, A., Cagli, K. (2015) Autologous platelet-rich plasma in treatment of chronic venous leg ulcers: a prospective case series. Vascular 23(6):580-585.

Young, M.J. (2002) Management of the diabetic foot: a guide to the assessment and management of diabetic foot ulcers. Diabetic Foot 5(3 Supplement):S1-S7.

Zhang, Y., Xing, S.Z. (2014) Treatment of diabetic foot ulcers using Mepilex Lite dressings: a pilot study. Experimental and Clinical Endocrinology and Diabetes 122(4):227-230.

Zillmer, R., Agren, M.S., Gottrup, F., Karlsmark, T. (2006) Biophysical effects of repetitive removal of adhesive dressings on peri-ulcer skin. Journal of Wound Care 15(5):187-191.

Dressings with Safetac® - Pressure Injury Prevention and Management



Dressings with Safetac featured:

Mepilex®, Mepilex® Ag, Mepilex® Border, Mepilex® Border Ag, Mepilex® Border Flex (Comfort), Mepilex® Border Heel, Mepilex® Border Lite, Mepilex® Border Sacrum, Mepilex® Heel, Mepilex® Lite, Mepilex® Transfer, Mepitel®, Avance® Solo Adapt Film

Take home messages:

- Pressure injury (PI) is typically associated with protracted healing, excessive exudation (leading to malodour and increased risk of moisture-related damage), pain, risk of infection and hospitalisation, all of which can escalate healthcare costs and impact negatively on patients.
- Numerous randomised controlled trials (RCTs) and other studies have observed lower PI incidence in patients receiving multi-layer foam dressings with Safetac (applied to 'at risk' anatomical locations, e.g. sacrum and heels) in conjunction with standard preventive measures, compared to standard preventive measures alone (i.e. no dressings), in a variety of settings (e.g. intensive care, emergency department, operating room and residential aged care facilities).
- Heath economic studies, based on RCT-generated data, have demonstrated the cost-effectiveness of multi-layer foam dressings with Safetac in the prevention of PI.
- Multi-layer foam dressings with Safetac can be lifted (to enable skin inspection) and reapplied without inflicting trauma and pain.
- There is a growing body of evidence demonstrating the ability of multi-layer foam dressings with Safetac to reduce the risk of medical device-related PI.
- Numerous studies have demonstrated the ability of dressings with Safetac to effectively manage excess exudation in PIs, thereby minimising the risk of moisture-related damage (e.g. maceration). Also evident is the ability of dressings with Safetac to minimise trauma and pain during dressing changes.

Introduction to pressure injuries

A pressure injury (PI) is defined as localised damage to the skin and underlying soft tissue, generally associated with mechanical forces (pressure, shear and friction) impacting on the skin and sub-cutaneous tissue and increased skin temperature and humidity (adverse microclimate) (World Union of Wound Healing Societies (WUWHS), 2016).

PI can occur at any anatomical location where skin and soft tissue loading is prolonged or excessively high but is most likely to develop at sites that overlay a bony prominence. In adults, the most common locations for PI are the sacral and heel regions (Li et al, 2020), whereas the skin over the occiput is a common location for PI in children and neonates (European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Injury Advisory Board (NPIAP) and Pan Pacific Pressure Injury Alliance (PPPIA), 2019). PI is also associated with devices (e.g. nasogastric tubes, ventilation masks, splints) which are in contact with the skin (Edsberg et al, 2016). Rigid materials incorporated into devices may cause skin abrasion, exert excessive pressure on soft tissues or lead to moisture retention at the skin surface (WUWHS, 2016).

PIs are classified according to their physical appearance and the extent of tissue loss (**Table 1**).

Table 1. Pressure injury classification (European Wound Management Association (EWMA), National Pressure Injury Advisory Board (NPIAP) and Pan Pacific Pressure Injury Alliance (PPPIA), 2019)

Category / stage	Depth	Appearance
I	Non-blanchable erythema	Intact skin with non-blanchable redness of localised area (usually over bony prominence). Darkly pigmented skin may not have visible blanching (colour may differ from surrounding skin). May be painful, firm, soft, warmer or cooler than adjacent tissue.
II	Partial thickness skin loss	Shallow open ulcer with red-pink wound bed; no slough. May also present as intact or open/ruptured serum-filled blister (shiny/dry shallow ulcer without slough or bruising).
III	Full thickness skin loss[a]	Subcutaneous fat may be visible (bone, tendon or muscle not exposed). Slough may be present (depth of tissue loss not obscured). May include undermining and tunnelling.
IV	Full thickness tissue loss[a,b]	Exposed bone, tendon or muscle. Slough or eschar may be present on wound bed. Often include undermining and tunnelling.
Unstageable	Depth unknown	Full thickness tissue loss in which ulcer base is covered by slough and/or eschar which, until removed, prevents ulcer depth from being determined.
Suspected deep tissue injury (DTI)	Depth unknown	Purple/maroon localised area of discoloured intact skin or blood-filled blister due to underlying soft tissue damage from pressure and/or shear. Area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler than adjacent tissue. May be difficult to detect in an individual with dark skin tones (evolution may include thin blister over dark wound bed and thin eschar coverage).

a. Depth varies by location, e.g. (i) bridge of nose, ear, occiput and malleolus do not have subcutaneous tissue and PI can be shallow; (ii) areas of significant adiposity can develop extremely deep PI.

b. Category/stage IV ulcers can extend into muscle and/or supporting structures making osteomyelitis possible.

Tissue damage preceding PI is primarily attributed to ischaemia and mechanical deformation (**Table 2**). The 'superficial' PIs (Category/Stage I and II) often result from friction, shear forces, and external skin insults such as irritant contact dermatitis. These superficial injuries may extend into deeper tissues if unrelieved. In contrast, 'deep' PIs (Category/Stage III and IV, including deep tissue injury [DTI]) are predominantly caused by sustained pressure and shear-induced deformation of deeper structures. Injury typically initiates at the muscle–bone interface, with overlying skin breakdown manifesting at a later stage (Alderden et al, 2021).

Table 2. Pressure injury classification (European Wound Management Association (EWMA), National Pressure Injury Advisory Board (NPIAP) and Pan Pacific Pressure Injury Alliance (PPPIA), 2019)

Category / stage	Description
Ischaemia	Impeded blood flow to tissues caused by compression or distortion of blood vessels by pressure and/or shear; results in tissue hypoxia, accumulation of metabolic waste and tissue damage.
Tissue deformation	Direct tissue damage and cell death caused by compression and large degrees of tissue deformation (develops much quicker than hypoxia).

There are many risk factors for PI including, but not limited to, immobility, reduced perfusion, malnutrition, sensory loss, diabetes, cerebrovascular or cardiovascular disease, recent lower extremity fracture, incontinence and age-related skin changes (Mervis et al, 2019; Jaul et al, 2018; Pender & Frazier, 2005, Wensley et al, 2018; Chiari et al, 2017; Lachenbruch et al, 2016). As these factors are particularly prevalent among high-dependence patients, the relatively high PI prevalence and incidence rates reported in healthcare settings such as intensive (critical) care and aged care are unsurprising (EPUAP, NPIAP and PPPIA, 2019).

Challenges

The adage "prevention is better than cure" suggests that taking proactive measures to avoid problems is more beneficial than addressing them after they have occurred. Taking this into consideration, it could be argued that the most important challenge relating to PI that healthcare professionals (HCPs) must tackle is to prevent it from occurring in the first place.

If a PI occurs, then it is likely to present a number of challenges typically associated with chronic wounds, i.e. protracted healing, excessive exudation (associated with malodour and increased risk of moisture-related damage to the surrounding skin), pain (and associated distress for patients), risk of infection and (prolonged) hospitalisation (Li et al, 2020; Kunimitsu et al, 2023; Williams et al, 2024). These all lead to heightened morbidity and mortality and an escalation of healthcare costs and, in doing so, impact negatively on patients, HCPs and healthcare providers (Li et al, 2020; Padula & Delarmente, 2019).

Role of dressings in pressure injury prevention and management

Prevention

Key to successful preventive strategies is an understanding of the biomechanics of PI development. Mechanical forces (**pressure, friction** and **shear**) and **adverse microclimate** are the most influential extrinsic risk factors in PI development (EPUAP, NPIAP and PPPIA, 2019). As previously mentioned, friction and shear forces are believed to be the main contributors to the development of 'superficial' (i.e. category I and II) PI, whereas pressure and shear are understood to be the main causes of the tissue deformation associated with 'deep' (i.e. category III and IV, DTI) PI (WUWHS, 2016).

Historically, the prevention of PI has focused on patient risk assessment, regular skin and tissue assessment, skin care, nutrition management, repositioning and mobilisation of patients, and the use of specialised support surfaces (EPUAP, NPIAP and PPPIA, 2019). Most of these interventions impact on the extrinsic risk factors in PI development. From around 2010 onwards, substantial research has been undertaken to evaluate the ability of **dressings** placed on 'at risk' anatomical locations to also influence these risk factors and to further reduce the risk of PI when used as an adjunct (as opposed to an alternative) to standard preventive interventions.

Scientists have developed and used a variety of laboratory methods to gain a better understanding of the mechanisms by which the prophylactic application of dressings can reduce PI occurrence. This research has demonstrated that a variety of dressing materials can, to varying degrees, redistribute pressure in vulnerable areas, reduce frictional forces transmitted to the skin, redistribute shear forces, and reduce humidity at the skin-dressing interface (**Figure 1**) (Call et al ,2013; WUWHS, 2016; Avsar et al, 2021).

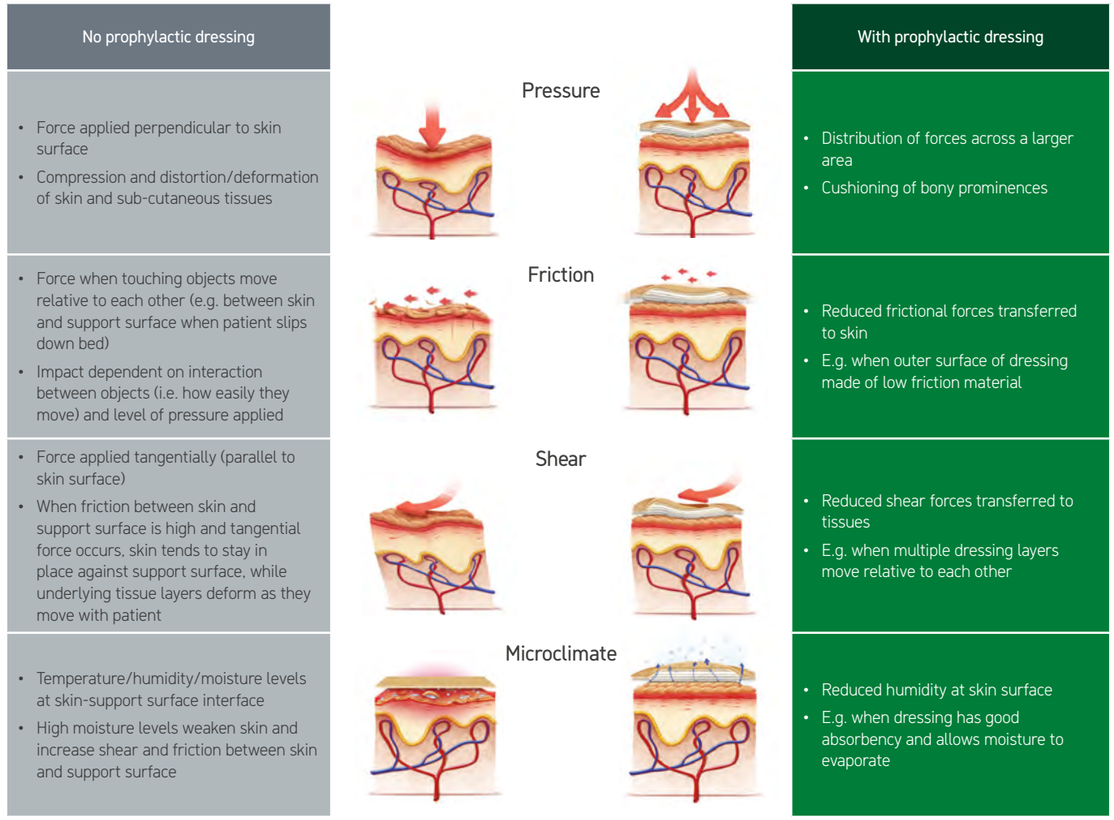


Figure 1. Mechanisms of action of prophylactic dressings for pressure injury prevention

In a series of laboratory studies, Call and colleagues examined the prophylactic characteristics of various dressings. They identified that dressing construction, including the presence of multi-layers within their structure (as used in foam dressings with Safetac) and the type of adhesion (i.e. silicone adhesive (e.g. Safetac) which has elastic properties) play important roles in reducing shear and friction forces at the point of application (**Figure 2**). They also found that the proper sizing of the dressing is important in ensuring the adequate displacement of forces from skin at risk of PI (Call et al, 2015).

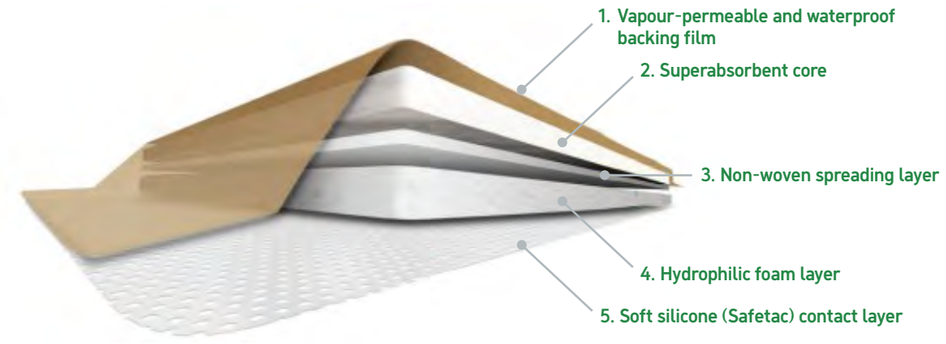


Figure 2. Diagrammatic representation of a multi-layer foam dressing with Safetac (Mepilex Border Sacrum)

It is recommended that the skin under a prophylactic dressing is assessed at least daily to evaluate the effectiveness of the preventive care regimen (EPUAP, NPIAP and PPPIA, 2019).

Management

Regular repositioning of patients and the use of specialised support surfaces (e.g. pressure-relieving mattresses and cushions) to offload pressure, nutritional support, infection control and pain management are key components of PI management. In addition, the topical management of PI plays an important role in providing quality care (EPUAP, NPIAP and PPPIA, 2019). Modern dressings, for example, are key to the effective management of excess exudate while, at the same time, they help to maintain a moist environment conducive to healing. Dressings can also provide a physical barrier to pathogens, thus reducing the risk of wound infection (Eriksson et al, 2022). To combat the clinical challenges mentioned above, dressings should be able to absorb and retain a wide range of exudate amounts and consistencies (without being adversely affected by the mechanical forces imparted on them by offloading devices). They should also be capable of gently adhering to the wound and surrounding skin (while being easy to remove without inflicting damage on delicate tissues). These factors are key to the durability ('wear time') of dressings.

Evidence for dressings with Safetac

Prevention of pressure injury over bony prominences

This section summarises the scientific, clinical and economic evidence in support of the use of multi-layer foam dressings with Safetac in the prevention of PI. According to a clinical expert on PI, the evidence presented "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" (Fletcher, 2013). Other experts have offered similar guidance in the literature (Gefen et al, 2018; Gefen et al, 2019a).

The findings of numerous systematic reviews and meta-analyses are supportive of the prophylactic use of dressings alongside other standard PI preventive interventions (Clark et al, 2014; Huang et al, 2015; Tayyib & Coyer, 2016; Fulbrook et al, 2019; Gaspar et al, 2019; Lovegrove et al, 2020; Sillmon et al, 2021: Rahman-Synthia et al, 2023; Sugrue et al, 2023; Taghiloo et al, 2023). Of note is that most of the data included in these reviews and analyses emanate from clinical studies undertaken to evaluate the efficacy of multi-layer foam dressings with Safetac.

As the skin underneath a prophylactic dressing should be assessed at least daily (EPUAP, NPIAP and PPPIA, 2019), the selection of dressings (e.g. multi-layer foam dressings with Safetac) that can be easily lifted and reapplied without inflicting trauma and pain is an important consideration (Fletcher, 2013).

Dressings versus no dressings

Patients in intensive care units (ICUs) are at particularly high risk of developing PI for multiple reasons including immobility, haemodynamic instability, and poor tissue perfusion (Labeau et al, 2021). In 2010, Brindle reported on the results of a three-month PI prevention initiative undertaken in a **surgical trauma ICU** in the United States of America (USA). The initiative included the creation of intervention bundles, a novel tool for identifying patients at highest risk of PI, and the prophylactic use of Mepilex Border Sacrum (**Figure 3**). The decision to use the dressing with Safetac 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 daily to enable skin assessment. Dressing changes were performed every three 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 PI. However, 6% (3/52) of the people who did not receive the dressing (i.e. those not deemed at high-risk) developed sacral PI. Interestingly, three high-risk patients who had worn the prophylactic dressing developed PI after it was discontinued (because they were discharged from the unit or the trial period had ended) (Brindle, 2010).

In the years that followed, numerous RCTs and non-randomised clinical trials were undertaken to investigate the ability of multi-layer foam dressings with Safetac in conjunction with standard preventive measures to reduce PI occurrence, in comparison to standard preventive measures alone (i.e. no dressings). Undertaken in different countries (Australia, China, Germany, Japan, Republic of Korea, United Kingdom, USA) and involving patients in a variety of settings (e.g. **ICU, emergency department (ED), operating room (OR)**, other **acute care units** and **residential aged care facilities**), the studies consistently revealed lower PI incidence rates in those patients that had multi-layer foam dressings with Safetac applied to various 'at risk' anatomical locations (**sacrum, heels, chest**, and **iliac crest**) (**Tables 3-5**).

Figure 3. Application of Mepilex Border Sacrum, a multi-layer foam dressing with Safetac

Patients in the ED are exposed to sustained tissue deformations, because of bodyweight or body interaction with medical devices (Santamaria et al, 2019). In an RCT (the 'Border Trial') undertaken in Australia, 440 patients 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 PI prevention or to a control group receiving just standard PI prevention. After transfer to the **ICU**, skin assessments were performed every 2 to 4 hours. Dressings were changed every three days or earlier if dislodged or soiled. There were significantly fewer patients with PI 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 PI. Fewer sacral PI (2 versus 8, p=0.05), heel PI (5 versus 19, p=0.002) and PI overall (7 versus 27, p=0.002) were observed in the intervention group (Santamaria et al, 2015a).

A prospective cohort study, also undertaken in Australia, evaluated the effectiveness of Mepilex Border Heel dressings (**Figure 4**) for the prevention of PI in trauma and critically ill patients (n=150). A Mepilex Border Heel dressing was applied to each **heel** 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 above. 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 PI developed in any of the intervention cohort patients, whereas 14 patients in the control cohort developed a total of 19 heel PI (p<0.001) (Santamaria et al, 2015b).

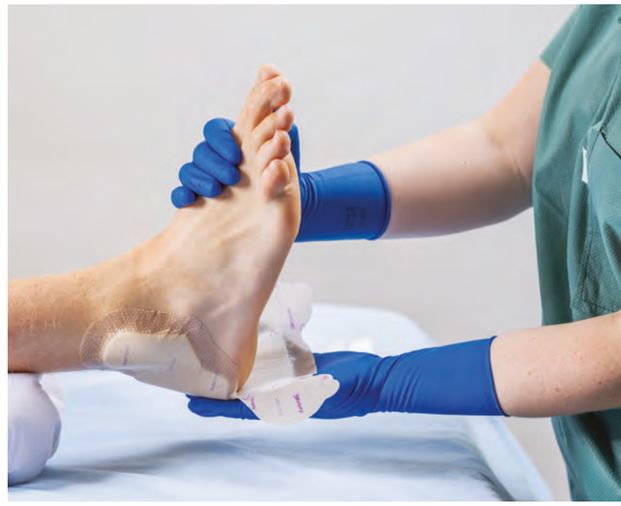


Figure 4. Application of Mepilex Border Heel, a multi-layer foam dressing with Safetac

Undertaken in the USA, a similar RCT involved the randomisation of **ICU** patients to either an intervention group that had Mepilex Border Sacrum applied to the **sacral region** as an adjunct to standard PI prevention or a control group receiving just standard PI prevention. Skin assessments were performed every 2-4 hours. Dressings were changed every three days or as needed. The dressing with Safetac was found to be effective in reducing the incidence of PI (1/184 in the intervention group versus 7/183 in the control group; p=0.001). The investigators reported that the dressing was easy to apply, remained in place, was atraumatic to skin and impermeable to faeces and urine. An absence of fungal infection and dermatitis was also observed (Kalowes et al, 2016).

There is a positive correlation between the length of surgery and the risk of PI development. For example, one study of patients undergoing surgeries for four hours or more revealed that every 30 minutes of surgery beyond four hours increases the risk of PI development by approximately one-third (Schoonhoven et al, 2002). The prone positioning of surgical patients involves the abdomen being supported or raised off the operating table. This technique is associated with various anatomical locations (e.g. forehead, chin, nose, breasts, genitalia and tissues over bony prominences) being subjected to sustained pressure and shear (Gefen et al, 2020). An RCT undertaken in the Republic of Korea evaluated the ability of multi-layer dressings with Safetac to reduce **intraoperatively acquired PI** in prone positioned patients undergoing spinal surgery (n=50). Before surgery, the right or left side **chest** and **iliac crest** areas were randomly assigned to be covered with Mepilex Border or not dressed (control). Immediately after surgery, a significantly lower incidence of PIs was observed in the dressed chest areas, compared to the non-dressed chest areas (4% vs. 28%, p=0.002) and in the dressed iliac crest areas, compared to the non-dressed iliac crest areas (0% vs. 20%, p=0.001). After one week, there were no PIs in the areas that had been covered with the dressing; in contrast, 8 chest and 4 iliac crest area PIs were observed in the not dressed areas. The majority of PIs were classified as stage I, with one evolving into a stage III injury (Yang & Shin, 2020).

In another study involving prone positioned surgical patients, Mepilex Border Flex was applied intraoperatively to the **face**, **chest** and **iliac crests** alongside usual PI prevention strategies, and PI development compared with that observed in a historical control group of patients receiving usual PI prevention strategies alone (no dressing). PI development was assessed by visual skin assessment (VSA; erythema/discolouration of minimal or greater severity post-operatively when no erythema/discolouration detected pre-operatively) and the difference between pre- and post-operative sub-epidermal moisture (SEM) measurement. Significantly fewer patients in the intervention group had SEM >0.5pF across all anatomical locations than did patients in the control (no dressing) group (p=0.04) (**Figure 5**) (Bates-Jensen et al, 2024).

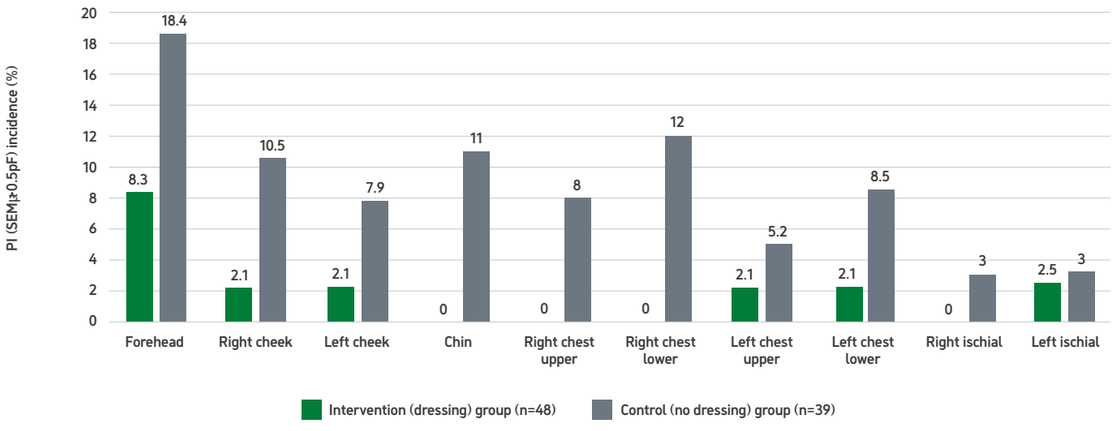


Figure 5. Intraoperative PI occurrence (as assessed by difference in pre- and post-operative sub-epidermal moisture (SEM)measurement >0.5pF) in prone positioned patients receiving dressings with Safetac plus standard prevention strategies (intervention), compared to standard prevention strategies alone (historical control) within an academic medical centre in the USA (Bates-Jensen et al, 2024)

Acute care is not the only setting associated with risk of PI development. For example, residents of nursing homes who are immobile, malnourished, incontinent, and have age-related skin changes, cognitive impairment and multiple comorbidities are highly vulnerable to PI (Santamaria & Gefen, 2018). In an RCT (the 'Border III' trial) undertaken at 40 Australian **nursing homes**, patients were randomised to either multi-layer dressings with Safetac applied to the **sacrum** (Mepilex Border Sacrum) or **heels** (Mepilex Heel) as an adjunct to standard PI prevention (n=138) or to a control group receiving just standard PI prevention (n=150). The number of patients who developed PI in the group that had dressings applied was significantly less than in the no dressings group (3 vs. 16; p=0.004) (Santamaria et al, 2018).

Two other RCTs demonstrated lower incidences of PI when dressings with Safetac were applied prophylactically. In the first of these studies carried out in China, Mepilex or Mepilex Border dressings were applied to the **sacrum**, **hips** and **heels** in conjunction with standard PI preventive measures. No PI occurred in the intervention group (0/26), compared to 3/26 in the control (no dressings) group (Qiuli & Qiongyu, 2010). In the other study undertaken in Japan, Mepilex Border dressings were applied to the **sacrum** and **coccyx** alongside standard PI preventive measures.

The incidence of PI in the dressing group was significantly lower than in the control (no dressings) group (1.7% (n=5) versus 7.3% (n=22); p=0.001), with an NNT of 18 patients to prevent one PI (Oe et al, 2020).

Table 3. Multi-layer foam dressings with Safetac plus standard PI prevention versus standard PI prevention only (no dressings) - randomised controlled trials

Reference / Study type / Country	Setting	Dressings evaluated	Main results
Santamaria et al, 2015a RCT Australia	ED / ICU	**Intervention group:** Mepilex Border Sacrum / Mepilex Heel applied to sacrum / heels in ED and maintained throughout ICU stay plus standard PI prevention measures (n=161) **Control group:** No dressings. Standard PI prevention measures only (n=152)	Lower incidence of PI in intervention group (p=0.001): - Intervention: 3.1% (n=5) - Control: 13.1% (n=20) NNT: 10 patients to prevent 1 PI. PI classification: - Intervention: sacral stage II, n=2; heel stage I, n=4; heel stage II, n=1 - Control: sacral stage I, n=8; heel stage I, n=15; heel stage II, n=2; heel stage IV, n=2
Santamaria et al, 2015b Cost-effectiveness analysis Australia			Intervention cost (estimated) of AU$36.41 per person, offset by lower downstream costs associated with PI treatment of AU$1103.52. Intervention associated with lower average cost of treating PI per episode of care: - Intervention: AU$70.82 - Control: AU$144.56
Hahnel et al, 2020 RCT Germany	ED / ICU	**Intervention group:** Mepilex Border Sacrum / Mepilex Border Heel applied to sacrum / heels, plus standard PI prevention measures (n=212) **Control group:** No dressings. Standard PI prevention measures only (n=210)	Lower incidence of PI (stage II or worse) in intervention group (p=0.001): - Intervention: 2.8% (n=6) - Control: 10.5% (n=22) NNT: 12.3 patients to prevent 1 PI (stage II or worse). PI classification: - Intervention: stage II, n=4; DTI, n=2 - Control: stage II, n=12; stage III, n=1; DTI, n=9
El Genedy et al, 2020 Cost-effectiveness analysis		Cost-effectiveness	4.2 times lower treatment costs in intervention group: - Intervention: €134.88 - Control: €569.49 ICER was €1945.30 per PI avoided (€8144.72 on heels; €701.54 on sacrum) in intervention group.
Kalowes et al, 2016 RCT USA	ED / ICU	**Intervention group:** Mepilex Border Sacrum applied to sacrum plus standard PI prevention measures (n=184) **Control group:** No dressings. Standard PI prevention measures only (n=182)	Lower incidence of PI in intervention group (p=0.01): - Intervention: 0.7% (n=1) - Control: 5.9% (n=7) PI classification: - Intervention: suspected DTI, n=1 - Control: stage II, n=4; unstageable, n=2; suspected DTI, n=1
Yang & Shin, 2020 RCT Republic of Korea	OR	Left or right-side chest and iliac crest areas randomly assigned to Mepilex Border (intervention) plus standard PI prevention measures or no dressing (control) plus standard PI prevention measures (n=50)* *Data from only 13 subjects analysed 1 week after surgery	Lower incidence of intraoperatively acquired PI with intervention immediately following surgery: - Chest: Intervention 4% (n=2/50) vs. Control 28% (n=14/50); p=0.002 - Iliac crest: Intervention 0% vs. Control 20% (n=10/50); p=0.001 Lower incidence of intraoperatively acquired PI with intervention 1 week after surgery: - Chest: Intervention 0% vs. Control 61.5% (n=8/13); p=0.002 - Iliac crest: Intervention 0% vs. Control 30.8% (n=4/13); p=0.096 PI classification: mostly stage I.

Reference / Study type / Country	Setting	Dressings evaluated	Main results
Santamaria et al, 2018 RTC Australia	Residential aged care	**Intervention group:** Mepilex Border Sacrum / Mepilex Heel applied to sacrum / heels plus standard PI prevention measures (n=138) **Control group:** No dressings. Standard PI prevention measures only (n=150)	Lower incidence of PI in intervention group (p=0.004): - Intervention: 2.1% (n=3) - Control: 10.6% (n=16) NNT: 12 patients to prevent 1 PI. PI classification: - Intervention: sacrum stage I, n=1; sacrum stage II, n=1; heel stage I, n=2; heel stage II, n=1 - Control: sacrum stage I, n=5; sacrum stage II, n=6; sacrum stage IV, n=2; heel stage I, n=4; heel stage II, n=1

Abbreviations: AC = acute care; AU$ = Australian dollar; DTI = deep tissue injury; ED = emergency department; ICER = incremental cost-effectiveness ratio; ICU = intensive care unit; NNT = number needed to treat; OR = operating room; PI = pressure injury; RCT = randomised controlled trial; USA = United States of America

Table 4. Multi-layer foam dressings with Safetac plus standard PI prevention versus standard PI prevention only (no dressings) - non-randomised controlled trials with concurrent controls

Reference / Study type / Country	Setting	Dressings evaluated	Main results
Park, 2014 Non-randomised comparative clinical study Republic of Korea	ICU	**Intervention group:** Mepilex Border applied to sacrum plus standard PI prevention measures (n=52) **Control group:** No dressings. Standard PI prevention measures only (n=50)	Lower incidence of PI in intervention group (p<0.001): - Intervention: 6% (n=3) - Control: 46% (n=23) PI classification: - Intervention: stage I, n=1; stage II, n=1; suspected DTI, n=1 - Control: stage I, n=17; stage II, n=6 Lower IAD scores in intervention group p<0.033): - Intervention: 0.54 - Control: 0.98
Brindle, 2010 Non-randomised comparative clinical study USA	ICU	**Intervention group:** Mepilex Border Sacrum applied to sacrum plus standard PI prevention measures (n=41) **Control group:** No dressings. Standard PI prevention measures only (n=52)	Lower incidence of PI in intervention group: - Intervention: 0% - Control: 6% (n=3) PU classification: - Intervention: none - Control: unstageable/suspected DTI (n=3)
Brindle & Wegelin, 2012 Non-randomised comparative clinical study USA	OR / ICU	**Intervention group:** Mepilex Border Sacrum applied to sacrum plus standard PI prevention measures (n=50) **Control group:** No dressings. Standard PI prevention measures only (n=35)	Lower incidence of PI in intervention group (ns): - Intervention: 2% (n=1) - Control: 11.4% (n=4) PI classification: - Intervention: suspected DTI, n=1 - Control: stage II, n=2; stage III, n=3; suspected DTI, n=3
Johnson et al, 2018 Non-randomised comparative clinical study United Kingdom	Orthopaedic surgery unit	**Intervention group:** Mepilex Border Heel applied to heels plus standard PI prevention measures (n=87) **Control group:** No dressings. Standard PI prevention measures only (n=64)	Lower incidence of heel PI in intervention group: - Intervention: 0% - Control: 18.6% (n=12) PI classification: - Intervention: none - Control: stage II, n=12
Cubit et al, 2013 Non-randomised comparative clinical study USA	AC	**Intervention group:** Mepilex Border Sacrum applied to sacrum plus standard PI prevention measures (n=51) **Control group:** No dressings. Standard PI prevention measures only (n=58)	Lower incidence of PI in intervention group (ns): - Intervention: 2% (n=1) - Control: 10.3% (n=6) PI classification: - Intervention: stage II, n=1 - Control: stage I-II, n=6

Abbreviations: AC= acute care; DTI = deep tissue injury; IAD = incontinence-associated dermatitis; ICU = intensive care unit; ns = not statistically significant; OR = operating room; PI = pressure injury; USA = United States of America

Table 5. Multi-layer foam dressings with Safetac plus standard PI prevention versus standard PI prevention only (no dressings) - non-randomised controlled trials with historical controls

Reference / Study type / Country	Setting	Dressings evaluated	Main results
Santamaria et al, 2015c Non-randomised comparative clinical study Australia	ICU	**Intervention group:** Mepilex Border Heel applied to heel plus standard PI prevention measures (n=150) **Control (historical) group:** No dressings. Standard PI prevention measures only (n=152)	Lower incidence of PI in intervention group (p<0.001): - Intervention: 0% - Control: 9.2% (n=14) PI classification: - Intervention: none - Control: stage I, n=15; stage II, n=2; stage IV, n=2
Chaiken, 2012 Non-randomised comparative clinical study USA	ICU	**Intervention group:** Mepilex Border Sacrum applied to sacrum plus standard PI prevention measures (n=275) **Control (historical) group:** No dressings. Standard PI prevention measures only (number of patients not reported)	Fewer patients with PI in intervention group: - Intervention: 1.8% (n=5) - Control: 13.6% (number of patients not reported) PI classification: - Intervention: stage II, n=2; suspected DTI, n=3 - Control: not reported
Walsh et al, 2012 Non-randomised comparative clinical study USA	ICU	**Intervention group:** Mepilex Border Sacrum applied to sacrum plus standard PI prevention measures (n=62) **Control (historical) group:** No dressings. Standard PI prevention measures only (number of patients not reported)	Fewer patients with PI in intervention group: - Intervention: 4.8% (n=3) - Control: 12.5% (number of patients not reported) PI classification: - Intervention: stage II, n=1; suspected DTI, n=2 - Control: not reported
Cano et al, 2011 Non-randomised comparative clinical study USA	ICU / CCU	**Intervention group:** Mepilex Border Sacrum applied to sacrum plus standard PI prevention measures (n=166) **Control (historical) group:** No dressings. Standard PI prevention measures only (number of patients not reported)	Fewer patients with PI in intervention group - Intervention: 0.6% (n=1) - Control: 6.2% (ICU); 8.8% (CCU) (number of patients not reported) PU classification not stated.
Johnstone & McGown, 2013 Non-randomised comparative clinical study United Kingdom	CCU	**Intervention group:** Mepilex Border Sacrum applied to sacrum plus standard PI prevention measures (n=75) **Control (historical) group:** No dressings. Standard PI prevention measures only (n=20)	Fewer patients with PI in intervention group: - Intervention: 0% - Control: ranging from 15% (n=3) to 45% (n=9) over a 3-month period PI classification not stated. Inclusion of Mepilex Border Sacrum dressings resulted in a cost saving of £29.56 per patient per day (average cost saving of £266.04 per patient).
Bates-Jensen et al, 2024 Non-randomised comparative clinical study USA	OR	**Intervention group:** Mepilex Border Flex applied to face, chest and iliac crests during prone position surgery plus standard PI prevention measures (n=48) **Control (historical) group:** No dressings. Standard PI prevention measures only (n=39)	Lower incidence of intraoperative PI, as assessed by VSA, in intervention group (ns): - Intervention 33% vs. Control 29% Lower incidence of intraoperative PI, as assessed by SEM, in intervention group (ns): - Intervention 23% vs. Control 44% Fewer patients in the intervention group had SEM >0.5 pF across all anatomic locations than did patients in control group (p=0.04).

Reference / Study type / Country	Setting	Dressings evaluated	Main results
Strauss et al, 2019 Non-randomised comparative clinical study USA	OR	**Intervention group:** Mepilex Border Sacrum applied to sacrum pre-operatively to patients undergoing cardiac surgery plus standard PI prevention measures (n=224) **Control (historical) group:** No dressings. Standard PI prevention measures only (n=300)	Lower incidence of PI in intervention group (p=0.02): - Intervention: 0% - Control: 2.3% (n=5) PI classification: not stated. Annual cost of treating PIs estimated to be US$1,498,656; expected cost of implementing the intervention (dressings) for all elective cardiac surgery patients was US$62,928, equating to a projected annual cost saving of US$1,435,728.

Abbreviations: CCU = critical care unit; DTI = deep tissue injury; ICU = intensive care unit; ns = not statistically significant; OR = operating room; PI = pressure injury; SEM = sub-epidermal moisture difference (between pre- and post-operative); USA = United States of America; US$ = United States Dollars; VSA = visual skin assessment

Dressing comparisons

Healthy volunteers were recruited to participate in an RCT with an intra-individual comparator design to compare the effects of multi-layer foam dressings on sacral skin. The subjects were asked to remain in the supine position on a standard mattress for 3.5 hours, during which they had periods of having three different dressings (Mepilex® Border Sacrum, Allevyn Life Sacrum and Optifoam Gentle Sacrum) applied to their **sacral skin** and a period of having no dressing (control) applied. The order of assigned treatments was determined by randomisation. After 3.5 hours, skin temperature increases (between 3.0 and 3.8°C) were observed with all three dressings and the control (no dressing) site; differences between the control and the dressings sites were minor. Increases in stratum corneum hydration were observed with all three dressings and the control; Optifoam Gentle Sacrum and the control were associated with the highest increases. No relevant changes in skin roughness were observed, apart from a decrease with Optifoam Gentle Sacrum. Allevyn Life Sacrum and the control were associated with the highest erythema index score, while the highest releases in interleukin 1 alpha were seen with Allevyn Life Sacrum and Optifoam Gentle Sacrum. Changes were minor with the dressing with Safetac. The findings indicate that the application of dressings does not cause additional occlusion to the sacral skin, compared to having no dressing applied, although some differences between the dressings in terms of cutaneous responses during loading were observed (Lechner et al, 2021). These data are consistent with that from similar research undertaken on healthy volunteers which demonstrated that the occlusive effects of dressings with Safetac (Mepilex Border Heel and Mepilex Border Sacrum) are similar or only slightly greater than those observed with loading without dressings (Lichterfeld-Kottner et al, 2021).

A number of RCTs involving patients at risk of PI and evaluating more than one dressing type have been undertaken (**Table 6**). A pilot RCT assessed the feasibility of undertaking a large multi-centre comparative effectiveness trial of two multi-layer foam dressings (Mepilex Border Sacrum and Allevyn Life Sacrum) in preventing hospital-acquired PI, when applied to the **sacrum** of 66 patients in an **ICU** setting. As well as achieving the main goal (i.e. confirming that the proposed larger trial was feasible, subject to minor modifications to study criteria), the RCT revealed some interesting data. Only one sacral PI developed (unstageable PI in the Allevyn Life Sacrum group). In total, 109 dressing changes were undertaken during the study period, 54 of which were due to dressing failure (rolled edges or adhesion failure). Over two thirds of the dressing failures were in the Allevyn Life Sacrum group (68.5%, n=37), with the remainder in the Mepilex Border Sacrum group (31.5%, n=17) (Latimer et al, 2024). When considering these findings, it is important to remember that the pilot study was not designed to specifically compare the two dressings.

A large RCT undertaken in Belgium assessed the effectiveness of multi-layer foam dressings in preventing hospital-acquired PI, when applied to the **sacrum**, **heels**, and **greater trochanter** areas of patients in **ICU** and **non-ICU** settings. Patients were randomised into one of three groups: intervention group 1 (Allevyn Life Sacrum / Allevyn Life Heel / Allevyn Life applied to sacrum / heels / greater trochanter; also received usual PI prevention strategies); intervention group 2 (Mepilex Border Sacrum / Mepilex Border Heel / Mepilex Border applied to sacrum / heels / greater trochanter; also received usual PI prevention strategies) and control group (usual PI prevention strategies without dressings). The data from the two intervention groups were combined for the study analysis; the study was not designed or sufficiently powered to compare their effects on PI incidence. However, it was reported that the number of adverse device events (all non-serious) was lower in the group receiving dressings with Safetac than in the group receiving Allevyn Life dressings (2.2% (n=12) vs. 3.9% (n=21). Device deficiencies were also fewer in the dressings with Safetac group (Mepilex Border variants - 14.5% (n=78); Allevyn Life variants – 31.2% (n=168) (Beeckman et al, 2021).

Two studies, one undertaken to compare Mepilex Border Heel with film dressings (applied to **heels**) and the other carried out to compare Mepilex Border with film dressings (applied to the **chests** of prone positioned patients), both demonstrated significantly lower incidence of **OR**-acquired PI in the groups receiving dressings with Safetac, compared to the groups receiving film dressings (heel PI: 26.7% vs. 46.7%, p=0.001 (Eberhardt et al, 2021); chest PI: 3% vs. 11%, p=0.027 (Yoshimura et al, 2018)). In another RCT undertaken in China, Mepilex was compared to a hydrocolloid dressing when used as adjuncts to standard PI preventive measures. No PIs occurred in the Mepilex group (n=30), four (13.3%) occurred in the hydrocolloid group, and seven (23.3%) occurred in a 'no dressing' (control) group (Tsao et al, 2013).

Table 6. Multi-layer foam dressings with Safetac versus other dressings for PI prevention – key studies

Reference / Study type / Country	Setting	Dressings evaluated	Main results
Latimer et al, 2024 RCT Australia	ICU	**Safetac:** Mepilex Border Sacrum (n=34) **Comparator:** Allevyn Life Sacrum (n=32) Both groups also received standard PI prevention measures	Sacral PI incidence rate: 1.5% (n=1). PI classification: - Mepilex Border Sacrum: none - Comparator: unstageable, n=1 109 dressing changes undertaken, 54 due to dressing failure - rolled edges (n=43) and adhesion failure (n=11). Over two thirds of dressing failures in comparator group: - Mepilex Border Sacrum: 31.5% (17/54) - Comparator: 68.5% (37/54)
Beeckman et al, 2021 RCT Belgium Neyt et al, 2024 Cost-effectiveness analysis Belgium	ICU / non-ICU (acute care)	**Safetac:** Mepilex Border Sacrum / Mepilex Border Heel / Mepilex Border applied to sacrum / heels / trochanter, plus standard PI prevention measures **Comparator:** Allevyn Life Sacrum / Allevyn Life Heel / Allevyn Life applied to sacrum / heels / trochanter, plus standard PI prevention measures Data from Safetac and Comparator groups pooled (Combined Intervention group (n=1066)) **Control:** Standard PI prevention measures (no dressings) only (n=539)	Lower incidence of PI (stage II or worse) in combined intervention group (p=0.04): - Combined intervention: 4% (n=43) - Control: 6.3% (n=34) NNT: 43 patients to prevent 1 PI (stage II or worse). Lower incidence of sacral PI (stage II or worse) in combined intervention group (p=0.04): - Combined intervention: 2.8% (n=30) - Control: 4.8% (n=26) NNT: 50 patients to prevent 1 sacral PI (stage II or worse). No significant difference between combined intervention and control groups in terms of heel (1.4% vs. 1.9%) and trochanter (0.1% vs. 0%) PI incidence. Fewer adverse device events in Mepilex Border dressings group (all non-serious): - Mepilex Border: 2.2% (n=12) - Allevyn Life: 3.9% (n=21) Fewer device deficiencies in Mepilex Border dressings group: - Mepilex Border: 14.5% (n=78) - Allevyn Life group: 31.2% (n=168) Cost consequence analysis confirmed that the intervention was found to be cost neutral in a conservative scenario regarding the prevention of sacral PI.
Eberhardt et al, 2021 RCT (with intra-patient comparator) Brazil	OR	Left or right heels randomly assigned to dressings with Safetac (Mepilex Border Heel) plus standard PI prevention measures or polyurethan film plus standard PI prevention measures (comparator) (n=135)	Lower incidence of heel PI in Safetac group (p=0.001): - Mepilex Border Heel: 26.7% (36/135) - Film: 46.7% (63/135) PI classification: - Mepilex Border Heel: stage I, n=33; stage II, n=1; DTI, n=2 - Film: stage I, n=59; stage II, n=1; DTI, n=3
Yoshimura et al, 2018 Non-randomised comparative clinical study (with intra-patient comparator) Japan	OR	**Safetac:** Mepilex Border applied to left side of chest (n=100) **Comparator:** Polyurethane film dressing applied to right side of chest (n=100) Both groups also received standard PI prevention measures	Fewer patients with intra-operatively acquired PI with Safetac dressings (p=0.027): - Mepilex Border: 3/100 (3%) - Comparator: 11/100 (11%) PI classification: - Intervention: none - Comparator: stage I, n=10; stage II, n=1

Reference / Study type / Country	Setting	Dressings evaluated	Main results
Aloweni et al, 2017 RCT Singapore	AC	**Safetac:** Mepilex Border applied to sacrum plus standard PI prevention measures (n=124) **Comparator:** Fatty acid oil applied to sacrum plus standard PI prevention measures (n=123) **Control:** Standard PI prevention measures (no dressings) only (n=192)	No significant differences in PI incidence between groups: - Mepilex Border: 3.9% (5/124) - Comparator: 5.4% (7/123) - Control: 5% (10/192) Significantly lower incidence of PI in patients with Braden Score ≤12 in Safetac group vs. control (p=0.04) and in comparator group vs. control (p=0.048): - Mepilex Border: 0% - Comparator: 0% - Control: 4.8% (4/83) PI classification: not stated.

Abbreviations: AC = acute care; DTI = deep tissue injury; ICU = intensive care unit; NNT = number needed to treat; OR = operating room; PI = pressure injury; RCT = randomised controlled trial

Cost-effectiveness

Data from the 'Border Trial' RCT described above (Santamaria et al, 2015a) were used to perform a cost-benefit analysis of the use of multi-layer foam dressings with Safetac in the prevention of PI within **ED** and **ICU** settings. The intervention (Mepilex Border Sacrum and Mepilex Heel dressings) cost (Australian Dollars) was estimated to be AU$36.61 per person, but this was offset by lower downstream costs associated with PI treatment (AU$103.52). The average net cost of the intervention was calculated to be lower than that of the control (no dressings) (**Figure 6**), leading the authors to conclude that the use of multi-layer dressings with Safetac for the prevention of **sacral** and **heel** PI in critically ill patients can be expected to result in cost savings in the acute care setting (Santamaria et al, 2015b). Based on an extrapolation of the costing method to the annual acute patient population in Australian hospitals in 2013, a conservative estimate was made of the potential cost saving of introducing multi-layer foam dressings with Safetac for the prevention of hospital-acquired PI in high-risk patients. It was estimated that, within this population, more than 71,000 patients could be expected to develop a PI annually, costing AU$77.8 million, and that the implementation of a national PI prevention initiative based on the use of multi-layer dressings with Safetac for high-risk patients could result in an annual saving of AU$34.8 million (55% cost benefit) (Santamaria & Santamaria, 2014).

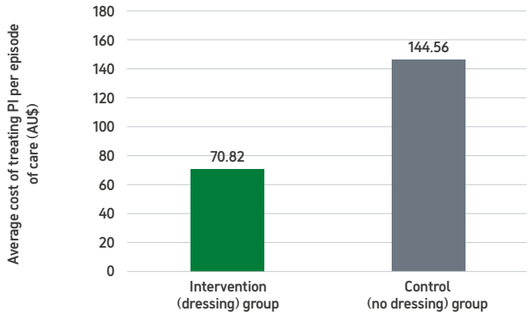


Figure 6. Cost-effectiveness of dressings with Safetac plus standard prevention strategies (intervention), compared to standard prevention strategies alone (control) in ED and ICU patients within an Australian hospital (Santamaria et al, 2015b)

Along similar lines, a cost-effectiveness analysis of preventing facility-acquired PI in Australian and American **long-term care facilities** by means of a quality improvement bundle, including the prophylactic use of Mepilex Border Sacrum and Mepilex Heel dressings, was undertaken. The findings of the Border III trial described earlier (Santamaria et al, 2018) were used to develop models for calibrating outcomes for standard PI measures (no dressing) compared with a dressing-inclusive bundle. Dressing use yielded greater quality-adjusted life years (QALYs) at slightly higher costs from perspectives. The incremental cost-effectiveness ratio (ICER) for Australia was AU$15,898/QALY, while for the USA it was US$36,652/QALY. Both ICERs fell below the willingness-to-pay threshold of $100,000/QALY, meaning that a dressing-inclusive bundle is a cost-effective means of preventing PI in long-term care residents in Australia and the USA (Padula et al, 2019).

An RCT undertaken at a tertiary care hospital in Germany revealed that, when used in conjunction with PI-related prevention strategies, the application of Mepilex Border Sacrum (to **sacrum**) and Mepilex Border Heel (to **heels**) of **ICU** patients resulted in a significant reduction in PI (category/stage II or worse) incidence, compared to standard prevention strategies alone (2.8% (6/212) vs. 10.5% (22/210); p=0.001) (Hahnel et al, 2020). These data were used to determine the cost-effectiveness of the intervention by calculating the incremental cost-effectiveness ratio (ICER). The analysis confirms that the application of dressings to the sacrum is both clinically- and cost-effective for high-risk ICU patients. Due to the low incidence of heel PI in the RCT, the application of dressings to the heel was less cost-effective (**Figure 7**) (El Genedy et al, 2020).

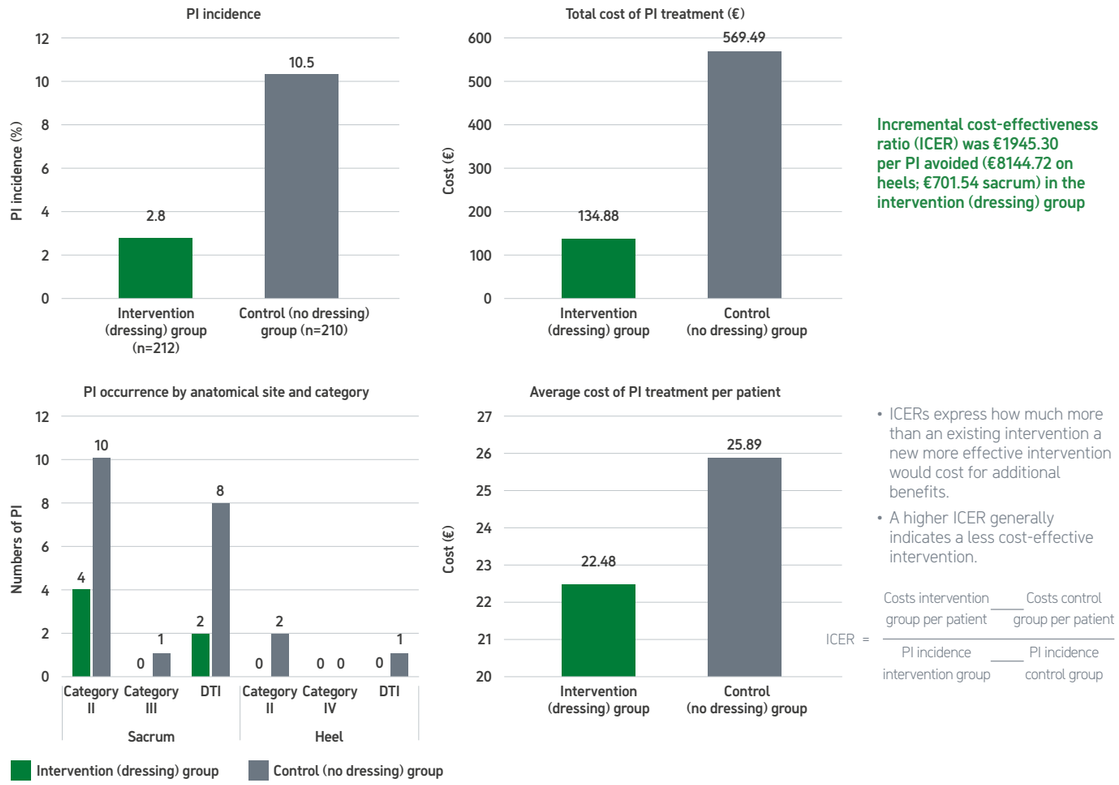


Figure 7. Clinical and cost-effectiveness of dressings with Safetac plus standard prevention strategies (intervention), compared to standard prevention strategies alone (control) in ICU patients within a German tertiary care hospital (Hahnel et al, 2020; El Genedy et al, 2020)

A retrospective observational cohort study, based on data acquired from **acute care** facilities in the USA, was undertaken to assess the effectiveness and value of the prophylactic use of multi-layer foam dressings with Safetac for the prevention of PI. Records of adult patients who were hospitalised for at least five days and had a PI (stage II, stage III or unstageable) were reviewed across 38 hospitals. Data pertaining to the purchase of Mepilex Border Sacrum by hospital quarter between 2010 and 2015 were collated from the same institutions. Analyses were then undertaken to test the longitudinal association between dressing use and PI rates. A statistically significant 0.3 reduction in the average PI occurrence per quarter was revealed in those hospitals where the dressings were available, relative to those facilities where the dressings were unavailable (p=0.0063) (**Figure 8**). Over the five-year observation period, spending on PI decreased by US$77 per patient (**Figure 9**), while the investment in prophylactic dressings increased from US$2.60 to US$20 per patient. The analysis highlighted that hospitals investing in prophylactic dressings at a rate of one dressing per patient made a 100% return on investment in less than one year (not including litigation costs typically in the region of US$250,000) (Padula, 2017).

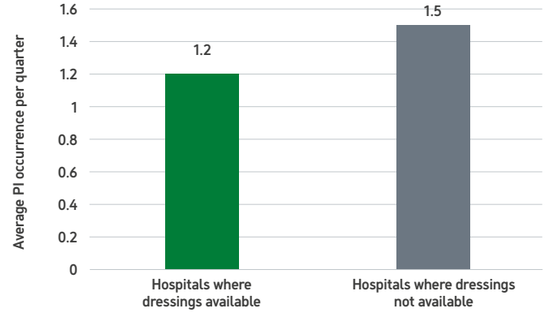


Figure 8. Average pressure injury occurrence per hospital quarter: a comparison of facilities where Mepilex Border Sacrum was available with those where the dressing was unavailable at the time of analysis. The 0.3 difference is statically significant (p=0.0063) (Padula, 2017)

In 2015, a PI 'prevention bundle' was introduced at an acute care facility in the USA in an attempt to reduce the occurrence of **OR-acquired PI**. The bundle incorporated skin and risk assessments, the application of prophylactic dressings, proper positioning aids, enhanced communication, follow-up strategies and education. Regarding prophylactic dressings, Mepilex Border Sacrum was applied to the **sacrum**. Bony prominences in contact with the operating room bed or equipment were padded with multi-layer foam dressings with Safetac, gel pads or fluidised positioners. For surgical procedures lasting in excess of three hours, Mepilex Border Heel was applied to the **heels**. The bundle led to a 50% decrease in perioperative PI within the first year of implementation, and 75% by the end of the second year; the intervention was estimated to have reduced projected treatment costs by 43% (Kimsey, 2019).

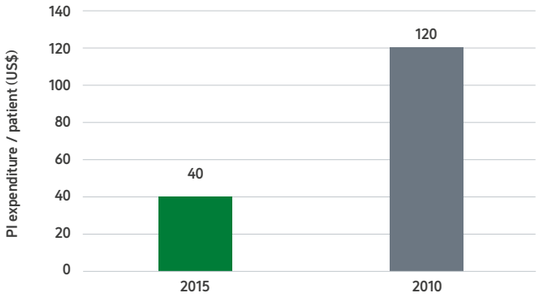


Figure 9. Quarterly pressure injury expenditure before (2010) and after (2015) the introduction of prophylactic Mepilex Border Sacrum dressings (Padula, 2017)

Pre-clinical studies

Computer finite element (FE) modelling has been employed in numerous studies to understand the modes of action of prophylactic dressings, in particular multi-layer foam dressings with Safetac. These studies have identified three design features of these dressings that contribute to the clinical outcomes described above: (i) multi-layer alternating-stiffness structure with embedded anisotropy (Levy et al, 2017; Schwartz & Gefen, 2019); (ii) minimal friction coefficient at the external surface of the dressing (Gefen et al, 2019b), and (iii) low impact of fluid retention on performance (Schwartz et al, 2018).

Mepilex Border Sacrum is anisotropic in its design, i.e. it is stiffer in the longitudinal direction of the spine and less so in the lateral direction of the buttocks. This feature reduces the soft tissue deformations along the spine and over the sacrum (where the highest shear forces associated with friction between the body and support surface act), leading to most deformations spreading to the buttocks. FE modelling was used to mimic the application of different prophylactic sacral dressings - anisotropic dressing (Mepilex Border Sacrum) with directionally dependent stiffness properties; isotropic dressing with same stiffness in all directions; and a completely stiff dressing - to patients lying supine on a standard foam mattress. The anisotropic dressing was associated with the lowest exposures to internal tissue strain energy density (SED) and shear stresses. Compared to the isotropic dressing, the anisotropic Mepilex Border Sacrum dressing was associated with an additional 11% reduction in exposure to SED (Levy & Gefen, 2017). A similar model was used to compare the biomechanical efficacy of Mepilex Border Sacrum and a hypothetical dressing with different mechanical properties under dry and three levels of moist/wet conditions. Effective stresses and maximal shear stresses were calculated from the simulations, and a protective endurance (PE) index was calculated. Compared to the hypothetical dressing, the multi-layer dressing with Safetac was associated with an approximately four times greater PE (80% versus 22%) (Schwartz et al, 2018).

More recently, tissue thickness changes in weight-bearing sacral skin, sub-cutaneous fat and muscle of three healthy volunteers were measured using magnetic resonance imaging. The combination of a prophylactic dressing (Mepilex Border Sacrum), turning and positioning device and a mattress resulted in significantly lower deformation of each of the three tissue layers, compared to when the subjects were lying on a rigid surface (Cohen et al, 2018).

Levy and colleagues reported on laboratory research that set out to evaluate the biomechanical performance of Mepilex Border Heel using FE modelling to mimic the heel when the patient is in the supine position. The researchers 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 (Levy et al, 2015). Further research by the same group observed similar effects of the dressing using FE modelling to mimic the heel of a patient with diabetes lying in the supine position (Levy & Gefen, 2016).

A computational model was also used to investigate how Mepilex Border Flex is likely to interact with the facial tissues of a prone-positioned patient. The findings indicate that, from a biomechanical perspective, the multi-layer dressing with Safetac should be considered as a means of preventing facial PI during prone positioning (Peco et al, 2020).

Prevention of medical device-related pressure injury (MDRPI)

Medical device-related pressure injury (MDRPI) can often be prevented by applying a thin dressing, such as a foam, under the causative device, which can redistribute pressure and absorb moisture from the body area in contact with the device (Black et al, 2015). Studies that have been undertaken to evaluate the use of dressings with Safetac in the prevention of MDRPI are summarised below and in **Table 7**.

A retrospective analysis of the prevalence of MDRPI in the head area across two healthcare facilities in the Czech Republic was undertaken in order to assess the impact of introducing prophylactic Mepilex Lite (**Figure 10**) dressings for at risk patients, such as those receiving non-invasive ventilation, high-flow nasal oxygen, prone positioning and those wearing cervical collars. The analysis revealed reductions in MDRPI incidence from 61% to 32% at one facility, and from 48% to 32% at the other facility, coinciding with the introduction of the prophylactic dressings (Krupova et al, 2024).

Figure 10. Application of Mepilex Lite to prevent medical device-related pressure injury

Prolonged use of **non-invasive ventilation (NIV) masks** for respiratory support exposes facial tissues to sustained deformations caused by tightening of the masks and adverse microclimate. With this in mind, laboratory-based research was undertaken to investigate the effect of placing cuts of Mepilex Lite dressings at the mask-face interface. A force measurement system was used to mimic the local forces that the skin at the bridge of the nose, cheeks and chin is typically exposed to by NIV masks. FE modelling was used to examine the maximal effective stresses in facial tissue with and without the placement of the dressing cuts. The ability of the dressing cuts to substantially alleviate facial tissue deformation and stresses by providing cushioning to the at-risk tissues was evident (Cohen et al, 2019). Subsequent research, again using FE modelling to mimic the application of dressings to facial skin under masks, compared the biomechanical protective performance (protective efficacy index, PEI) of three foam-based dressings (one of which was Mepilex Lite) with a hydrocolloid dressing. The foam-based dressings generally performed considerably better than the hydrocolloid, but varied in terms of their protective performance, for example, in terms of tissue protection across the nasal bridge, cheeks and chin and throughout the tissue depth at each location, Mepilex Lite and one of the other foam-based dressings had similarly high PEIs (approximately 70%), whereas the hydrocolloid and other foam-based dressing had substantially lower PEIs (approximately 20%) (Orlov & Gefen, 2023).

In an article on the potential for nasal continuous positive air pressure therapy (CPAP) equipment (i.e. **masks** and **prongs**) to induce PI and skin stripping of neonatal skin, Smith reported how staff in 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 the dressing with Safetac provides conformability and security and does not interfere with the delivery of air. The ability to lift the edge of the dressing, which enables the area concerned to be inspected with minimal disruption to the infant, was also highlighted (Smith, 2006).

Hsu and colleagues reported 86 occurrences of nasal PI among 47 of 797 (5.9%) patients wearing face masks over a one-year period, even though hydrocolloid dressings had been 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 Mepilex. The incidence of face mask-related PI subsequently reduced to 0.9% (Hsu et al, 2011). The adjuvant use of Mepilex Border alongside standard preventive measures has also been reported to be associated with a lower occurrence of PI associated with **biphasic positive airway pressure (BiPAP)** and **continuous positive airway pressure (CPAP) masks**, with zero PI occurrence in the group receiving dressings compared to 5 PI per 1000 ventilator days in the historical (no dressings) group (Clay et al, 2018). The implementation of a new preventive regime (including a switch from hydrocolloid to Mepilex) in Q3 2012 coincided with a reduction in the occurrence of **BiPAP mask**-related PI. The number of mask-related PIs in 2011, 2012, 2013 and 2014 were 5, 12, 5 and 1, respectively (Acorda, 2015).

In a small clinical study carried out in the USA, it was observed that the incidence of PI 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** (Boesch et al, 2012). These findings are consistent with those from another small study in which Mepilex Ag plus standard PI prevention measures was associated with fewer PI at **tracheostomy sites** than standard PI prevention (no dressing) alone (Kuo et al, 2013).

An article published in 2016 summarises the experiences of four patients with acute respiratory distress syndrome (ARDS). Two did not receive PI preventive measures and subsequently developed multiple necrotic facial PIs related to prone positioning. The other two patients had Mepilex Transfer applied between their skin and the **endotracheal tube fastener**; neither of these patients developed facial PI during pronation therapy (Kim & Mullins, 2016). In a narrative review focusing on the prevention of facial PI among prone positioned patients during the COVID-19 pandemic, reference is made to the placement of a Mepilex dressing between the skin and the endotracheal tube fastener adhesive tube as being standard preventive practice within the ICU of a hospital in the USA (Shearer et al, 2021).

In a study undertaken in Australia, the ability of prophylactic dressings (foam dressings with Safetac (Mepilex Lite, Mepilex Border Lite) or hydrocolloid dressing) to fit under five different **particulate filter respirators** was assessed. Of the 600 healthcare workers who participated, only two chose to use hydrocolloid dressings, therefore the data analysis focused on dressings with Safetac. Successful fit was achieved by 63% of respirator-dressing combinations, with pass rates ranging from 90.2% down to 25.9%. Most participants reported comfort with the dressings under the respirators (Barakat-Johnson et al, 2022). A later feasibility study, conducted in the USA, observed no PI in the healthcare workers who had Mepilex Lite applied to the nasal bridge underneath respirators, maintaining the mask seal/fit (Holder et al, 2023). More recently, a small RCT was undertaken to evaluate the use of dressings with Safetac (Mepilex Border Lite and Mepilex Lite) for the prevention of **face mask**-related PI in healthcare workers. In one of the interventional groups, the prophylactic dressings were applied to at risk areas on the face (n=20). Adhesive strips in addition to prophylactic dressings were applied to workers in the second interventional group (n=8). Both groups also received standard PI preventive measures as did those assigned to the control (no dressings) group (n=20). Skin injuries developed in 20/20 participants in the no dressing group, compared to 2/20 and 1/8 workers in the two interventional groups. Although the findings of these small studies are encouraging, it is important to stress that larger studies need to be undertaken to determine the true efficacy of these dressings for the prevention of personal protective equipment-related PI and to confirm that the dressings do not impede the performance of the equipment.

Table 7. Multi-layer foam dressings with Safetac for the prevention of medical device-related pressure injuries – key studies

Reference / Study type / Country	Setting	Dressings evaluated	Main results
Clay et al, 2018 Non-randomised comparative clinical study USA	OR	**Safetac:** Mepilex Border applied to face (number of patients not recorded) **Control (historical):** No dressings (number of patients not recorded) Both groups also received standard PI prevention measures	Fewer patients with BiPAP/CPAP face mask-related PI in Safetac group: - Mepilex Border: 0% - Control: 5 PI / 1000 ventilator days PI classification: not stated.
Boesch et al, 2012 Non-randomised comparative clinical study USA	ICU	**Safetac:** Mepilex Lite applied to tracheostomy site (number of patients not reported **Control (historical):** No dressings applied (n=136) Both groups also received standard PI prevention measures	Fewer patients with tracheostomy-related PI in Safetac group: - Mepilex Lite: 0.3% (number of patients not reported) - Control: 8.1% (n=11) PI classification: not stated.
Kuo et al, 2014 Non-randomised comparative clinical study USA	PC	**Safetac:** Mepilex Ag applied to tracheostomy site (n=41) **Control (historical):** No dressings applied (n=93) Both groups also received standard PI prevention measures	Fewer patients with PI underneath tracheostomy tubes and ties in Safetac group (p=0.02): - Mepilex Ag: 0% - Control 11.8% (n=11) PI classification: - Intervention: none - Control: stage I, n=9; stage II, n=2
Hsu et al, 2010 Non-randomised comparative clinical study Taiwan	Not specified	**Safetac:** Mepilex applied to nose (number of patients not reported) **Comparator (historical):** Hydrocolloid dressings applied to the nose (n=797) Both groups also received standard PI prevention measures	Fewer patients with face mask-related PI in Safetac group: - Mepilex: 0.9% (number of patients not reported) - Comparator: 5.9% (n=47) PI classification: - Intervention: not stated - Control: stage I, n=51; stage II, n=33; stage III, n=2

Abbreviations: BiPAP = biphasic positive airway pressure; CPAP = continuous positive airway pressure; ICU = intensive care unit; OR = operating room; PC = paediatric care; PI = pressure injury; USA = United States of America

Management of existing pressure injury

The key studies relating to the use of dressings with Safetac in the management of existing PIs are summarised in **Table 8** (non-silver containing dressings) and **Table 9** (silver-containing dressings).

Wound healing

In a multi-centre RCT involving patients with **stage II PIs** undertaken in France, Mepilex Border was compared with a hydropolymer foam dressing (Tielle) for a treatment period of up to 8 weeks. Of the 18 PIs dressed with Mepilex Border, eight healed and seven improved; of the 20 PIs dressed with Tielle, 10 healed and nine improved (Meaume et al, 2003).

An observational retrospective study was undertaken to increase understanding of the evolution and outcomes of **suspected DTIs** in an acute care facility in the USA. The treatment regimen involved the application of Mepilex Border as either the primary or secondary dressing, depending on clinical goals. Offloading or barrier cream was used in combination with the bordered foam dressings or when dressings could not be maintained. Honey-containing dressings (if infection was suspected) and fibre dressings (if additional exudate management was required) were also used as primary dressings. Data from 77 patients (with a total of 128 suspected DTIs, mostly located on the sacrum or heels) were included in the analysis. At the final assessment, 85 (66.4%) suspected DTIs had completely resolved

or were progressing toward resolution, 31 (24.2%) were unchanged and only 12 (9.3%) had deteriorated to full-thickness tissue loss (Sullivan, 2013).

Webb described a case involving a terminally ill patient who presented with **multiple PIs (stages I to IV)**. The clinical staff decided to manage the ulcers with Mepilex Border dressings, changed every 4-6 days, without disrupting the integrity of the fragile skin. Prior to the death of the patient two months later, all stage II and III ulcers had healed (Webb, 2008).

Mepilex Border Lite was used as part of a dressing regimen alongside platelet-rich plasma therapy for a longstanding **stage III PI**. The PI healed approximately 8 weeks after the new regimen had been introduced (Ramos-Torrecillas et al, 2013).

Minimising dressing-related trauma and pain

In the multi-centre RCT described earlier in which Mepilex Border was compared with a hydropolymer foam dressing (Tielle) in the management of **stage II PIs**, there were significantly fewer reports of dressing-related trauma in the Mepilex Border group (n=2) than in the Tielle group (n=32) ($p<0.05$). Similarly, there were fewer reports of leakage and maceration in the Mepilex Border group (**Figure 11**) (Meaume et al, 2003).

A retrospective, observational study undertaken across 12 specialist wound care centres in Germany evaluated the use of Mepilex Border Flex on 431 patients with a total of 549 wounds, including 124 PIs. Patients were assessed at up to 10 follow-up visits. The mean reduction in wound area (all wound types) from baseline to final visit was 35.9%. The dressing was observed to promote a moist wound environment, while effectively managing exudate. At baseline and at the final visit, most wounds (81.9% and 89.1%, respectively) had no maceration. Dressing wear time ranged from one to seven days (mean 4.5 days). The majority of patients had no pain at dressing changes. For the 47 patients at baseline and the 49 patients at the final visit who reported pain, the mean pain severity scores rated on a visual analogue scale from zero to 10 were 2.95 and 3.29, respectively (Rook et al, 2019). The ability of dressings with Safetac to minimise the risk of maceration was also demonstrated in a case study series involving five patients who presented with **heel PIs** and maceration associated with leaking exudate. These findings are consistent with other studies that have demonstrated Mepilex Border Flex (Boixados et al, 2019) and the Mepilex range of non-bordered foam dressings (Eytier et al, 2013) to be associated with minimal pain at dressing changes.

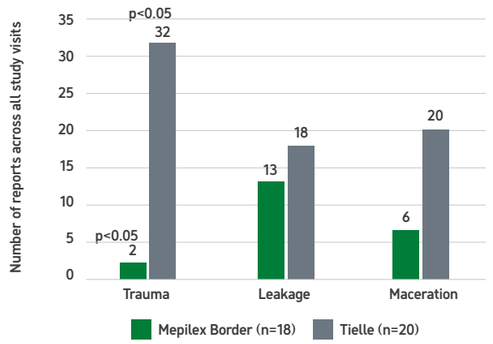


Figure 11. Comparison of Mepilex Border and Tielle dressings in terms of dressing-related trauma, leakage and maceration occurrence (Meaume et al, 2003)

Exudate management

In a case study series undertaken in the United Kingdom, the introduction of Mepilex Border Heel was associated with good exudate management, with three of the five patients' maceration resolved and improvement in the peri-wound skin condition observed in all patients at the second dressing change. Dressing wear time was generally undertaken every five days. Nursing staff found the dressing easy to apply and fit to the heel and ankle (Bateman, 2013; Bateman, 2014).

The exudate handling properties of non-bordered foams with Safetac have also been evaluated in clinical studies. For example, a retrospective review of data collected on patients seen at an out-patient clinic in the USA was undertaken to compare, amongst other things, peri-wound issues of wounds dressed with either Mepilex or a hydrophilic polyurethane (Allevyn) dressing. Wound types included PIs (also foot and leg ulcer, surgical wounds and traumatic wounds). Eighty-seven wounds were dressed with Mepilex and 86 with the hydrophilic polyurethane dressing. Cases of dermatitis were fewer in the Mepilex-dressed group, i.e. 6 compared to 11 in the comparator group (Eager, 2001).

In Belgium, an observational prospective study was undertaken to evaluate the efficacy of Mepilex Heel in the management of **heel PIs** (**Figure 12**). Over the four-week evaluation period, the dressing conformed well to the heels, thereby minimising leakage and maceration. The dressing was easy to apply and remove without any aggressive adhesion to the skin or wound surfaces; hence pain and discomfort experienced by patients during and in between dressing changes was minimal (Meuleneire & Fostier, 2008).

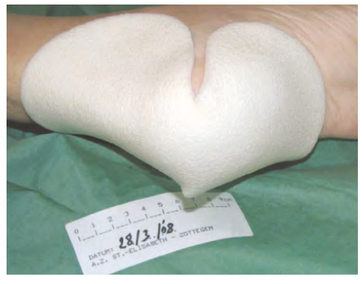


Figure 12. Mepilex Heel applied to a heel pressure injury. (photograph courtesy of Frans Meuleneire, Woundcare Centre, Zottegem, Belgium)

Dressing change frequency

To investigate potential benefits of change in dressing regime (supported by an educational programme for clinical staff) for chronic wound management in primary and home care settings in Spain, patients (n=37) with wounds that had not reduced in size by greater than 40% to 50% in the preceding four weeks were recruited (nine of whom had **stage II PIs**). Historical data were collated on the use of the bordered foam dressings being utilised at the time in the seven days preceding the baseline visit. Dressings were switched to Mepilex Border Flex for a minimum of four weeks, while maintaining the same standard of wound care. Usage of the dressing with Safetac in the seven days preceding the final visit was evaluated. The median number of dressing changes in the seven-day period prior to the dressing switch was three, compared to one at the final visit (after dressing switch). This equated to a cost (Euros) saving of €5.38 (44%) per week. A 50% reduction in wound area in four weeks in 75% of patients was demonstrated. Pain severity scores (measured on a scale from zero to 10) before and during dressing change were 3.1 and 3.3 at baseline, reducing to 1.1 and 0.5 at the final visit. These findings highlight the potential benefit of dressing regimen improvements in delivering value-based wound care (Roldan Valenzuela et al, 2025).

A study involving 13 patients with a total of 25 wounds (including five PIs) was undertaken in the USA to evaluate the clinical outcomes, dressing performance and impact on the patient of implementing Mepilex Border Flex dressings and to determine if a change in routine dressing change policy from every 3 to every 7 days affected the number of dressings used and dressing costs. The average reduction in wound volume was 77% over 13.2 days. No wounds enlarged and four healed (achieved complete re-epithelialisation). For the chronic wounds, the average reduction in volume was 80.9% over 12.3 days. The dressing was assessed as fully intact without leaking or lifting for 28/29 wound care nurse dressing changes, i.e. a 97% rate of adhesive integrity. A total of 60 dressing changes occurred for the 13 patients. The average wear time of the dressing was 5.5 days. The number of formulary dressings used across the entire facility was reduced by 8.11% and the amount of facility spend on the formulary dressing was reduced by 12.6% when compared to full facility dressing utilisation with bordered foam dressings used previously (Nelson, et al, 2019).

A quality improvement project (QIP) was undertaken at a community hospital in the USA to address issues (i.e. poor absorption, peri-wound maceration, aggressive adhesion, tissue stripping and frequent painful dressing changes) associated with the silicone bordered foam dressings (Optifoam Gentle Border SA) on formulary at the time. After the wound care team had recommended a switch to Mepilex Border Flex, data were collected from 18 patients (39 wounds) managed with the formulary dressing, and from 14 patients (40 wounds) managed with Mepilex Border Flex. For PIs, a 57.5% reduction (average 4.6 days) in wound area or volume was observed in the Mepilex Border Flex group, compared to a 0.4% reduction (average 6.5 days) in the formulary dressing group. There were no episodes of the dressing not adhering / coming off in the Mepilex Border Flex group, compared to 19 in the formulary dressing group. There were no episodes of leaking exudate / peri-wound maceration / epidermal stripping with Mepilex Border Flex compared to 18 episodes of leakage, 14 episodes of peri-wound maceration and 4 episodes of epidermal stripping with the formulary dressing. There were no observations of silicone residues with Mepilex Border Flex, compared to moderate-to-large deposits observed with the formulary dressing. The patients with wounds managed with the formulary dressing experienced 331 dressing changes (average of 8.5 dressings per wound and 18.4 dressings per patient). In contrast, the patients in the Mepilex Border Flex group received 73 dressing changes (average of 1.8 dressings per wound and 5.2 dressings per patient). This equated to 258 fewer dressing changes and 78% fewer dressings being used in the Mepilex Border Flex group. When cost in use (as opposed to unit price) was calculated, Mepilex Border Flex cost 74.2% less than the formulary dressing for the 32 patients, equating to a saving of US$695 (Tyson, 2019).

Table 8. Management of pressure injury - non-silver-containing dressings - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Meaume et al, 2003 RCT France	**Subjects:** 38 (age range 66-95 years) **Wounds:** Stage II PI (n=40): sacrum/back, n=14; heel/foot, n=15; other, n=11) **Setting:** Nursing home	**Safetac:** Mepilex Border (n=18) **Comparators:** Tielle (n=20) [Patients followed for up to 8 weeks]	Wound status	Number of wounds healed / improved: - Mepilex Border: 44% (n=8) healed; 39% (n=7) improved - Tielle: 50% (n=10) healed; 45% (n=9) improved
			Dressing-related trauma	Fewer reports of dressing-related trauma in Mepilex Border group (n=2), vs Tielle group (n=32) ($p<0.05$). Fewer occurrences of leakage in Mepilex Border group (n=13), vs. Tielle group (n=18). Fewer occurrences of maceration in Mepilex Border group (n=6) vs. Tielle group (n=20).
			Dressing usage	Fewer reported dressing removal difficulties in Mepilex Border group (1 patient) vs. Tielle group (23 reports across 9 patients).

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Roldan Valenzuela et al, 2025 Observational prospective clinical study Spain	**Subjects:** 37 (age range 30-90 years) **Wounds:** Chronic wounds, including stage II PI (n=9) **Setting:** Primary/home care	**Safetac:** Mepilex Border Flex plus educational programme (n=18) **Comparator (historical control):** Previously used bordered foam dressings prior to switch to dressings with Safetac [Patients followed for up to 4 weeks]	Dressing usage (in final week of assessment period) Wound status Pain severity (measured using VAS 0-10)	Median number of dressings used in last evaluation week: - Mepilex Border Flex: 1 - Control: 3 Cost saving of €5.38 per week (44%). 50% reduction in wound area in 75% of patients. Pain severity scores before / during dressing change: - Mepilex Border Flex: 1.1 / 0.5 - Control: 3.1 / 3.3
Sullivan, 2013 Observational retrospective clinical study USA	**Subjects:** 77 (age range 32-91 years) **Wounds:** Suspected DTI (n=128): sacrum, n=51; heel, n= 37; other, n=40 **Setting:** Acute care	Mepilex Border applied as either primary or secondary dressing, in conjunction with offloading or barrier creams. Other primary dressings used included honey-containing and fibre dressings	Wound progression	Final visit assessments (average follow-up 6 days): - Completely resolved or progressing toward resolution: 66.4% (n=85) - Unchanged: 24.2% (n=31) - Deteriorated: 9.3% (n=12)
White, 2008 Survey (patients) 20 countries (Europe, Asia-Pacific, Americas)	**Subjects:** 3024 **Wounds:** PI (plus burns, foot ulcers, leg ulcers and skin tears) **Setting:** Not specified	**Safetac:** Mepilex, Mepilex Lite, Mepilex Border, Mepilex Border Lite, Mepitel **Comparators:** Variety of dressings (e.g. foam and hydrocolloids) with traditional adhesives	Trauma (subjective rating) Pain before, during and after dressing changes (VAS ranging from 0 (no pain) to 10 (worst pain imaginable))	Less dressing-related trauma with Safetac dressings: Trauma levels with Safetac dressings: high 1%; moderate 11%, very slight 35-37%; none 50% Trauma levels with traditional adhesive dressings: high 10%; moderate 28-39%; very slight 31-35%; none 18-29% Significantly lower pain severity (VAS) scores with Safetac dressings at all assessments (p=0.01): Safetac dressings: 1.7-1.8, 2.1-2.2 and 1.6-1.7 before, during and after dressing changes Traditional adhesive dressings: 2.4-3.2, 4.6-5.2 and 2.9-3.9 before, during and after dressing changes >90% of respondents stated a preference for dressings with Safetac compared to traditional adhesive dressings.

Abbreviations: DTI = deep tissue injury; PI = pressure injury; RCT = randomised controlled trial; USA = United States of America; VAS 0-10 = visual analogue scale ranging from 0 (no pain) to 10 (worst pain imaginable)

Table 9. Management of pressure injury – silver-containing dressings - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Truchetet et al, 2012 Observational prospective clinical study France	**Subjects:** 794 (age range 37-86 years) **Wounds:** PI (n=32), plus leg ulcers, foot ulcers, oncology wounds, burns, traumatic and surgical wounds **Setting:** Community care	**Safetac:** Mepilex Ag [Patients followed for median 19 days)	Wound status Peri-wound status Local signs of infection	Good wound healing response: - All wounds: 17% healed; 73% improved Reduction in frequency of erythema: 74% at baseline; 52% at final visit. Reduction in mean number of local signs of infection (p<0.001): - All wounds: 2.3 (Baseline: 3.7)
McCarty et al, 2013 Observational prospective clinical study Multiple countries (n=9)	**Subjects:** 307 (age range 5-108 years) **Wounds:** PI (n=41) and other chronic and acute wound types **Setting:** Not specified	**Safetac:** Mepilex Border Ag [Patients followed for median 22 days]	Local signs of infection Wound size Pain severity scores (measured using VAS 0-10) Dressing-related trauma	Reduction in number of wounds with local signs of infection from baseline to final visit. 28.5% and 35% reduction in wound area and volume respectively (p<0.05) - Area (cm^2): from 36.05 (baseline) to 25.87 (final visit) - Depth (mm): from 4.71 (baseline) to 3.06 (final visit) Reduction in mean pain severity from baseline to final visit (p<0.0001): - During wear: baseline 2.19 vs. final visit 0.88 - During removal: baseline 2.22 vs. final visit 0.86 - After removal: baseline 1.66 vs. final visit 0.63 Increase in percentage of wounds / peri-wound regions without trauma from baseline to final visit: - Wound: baseline 86.99% vs. final visit 92.81% - Peri-wound: baseline 83.56% vs. final visit 89.04%
Meuleneire, 2008 Observational prospective clinical study Belgium	**Subjects:** 30 (age range 29-91 years) **Wounds:** PI; also foot ulcers, leg ulcers, burns, surgical wounds, traumatic wounds **Setting:** Outpatient wound care centre	**Safetac:** Mepilex Ag [Patients followed for up to 4 weeks]	Local signs of infection Wound status Pain severity before and during dressing changes (measured using VAS ranging from 0-10)	Eradication of local signs of infection in 90% of wounds. Proportion of wounds healed or almost healed at end of study period (4 weeks) was 53% and 27%, respectively. Pain severity (median) before and during dressing changes was lower at the first and final dressing change compared to baseline (p<0.0001): - Before dressing change: Baseline: 6.5 First dressing change: 4 Final dressing change: 0 - During dressing change: Baseline: 6 First dressing change: 3 Final dressing change: 0

Abbreviations: PI = pressure injury; VAS 0-10 = visual analogue scale ranging from 0 (no pain) to 10 (worst pain imaginable)

Topical antimicrobial therapy

McCarty et al reported on an observational study, conducted prospectively across nine countries, to evaluate the performance of Mepilex Border Ag. In total, the wounds of 307 patients were evaluated, including 41 **PIs**. Compared to the baseline assessment, the number of wounds exhibiting local signs of infection were reduced at the final visit (**Figure 13**). Statistically significant decreases in wound area (28.5%) and depth (35.0%) between baseline and final visit were recorded ($p<0.05$). Pain severity during dressing wear, at removal and after removal was also significantly lower at the final visit, relative to baseline ($p<0.0001$), with a concomitant increase in the proportion of trauma-free wounds and peri-wound regions (McCarty et al, 2013).

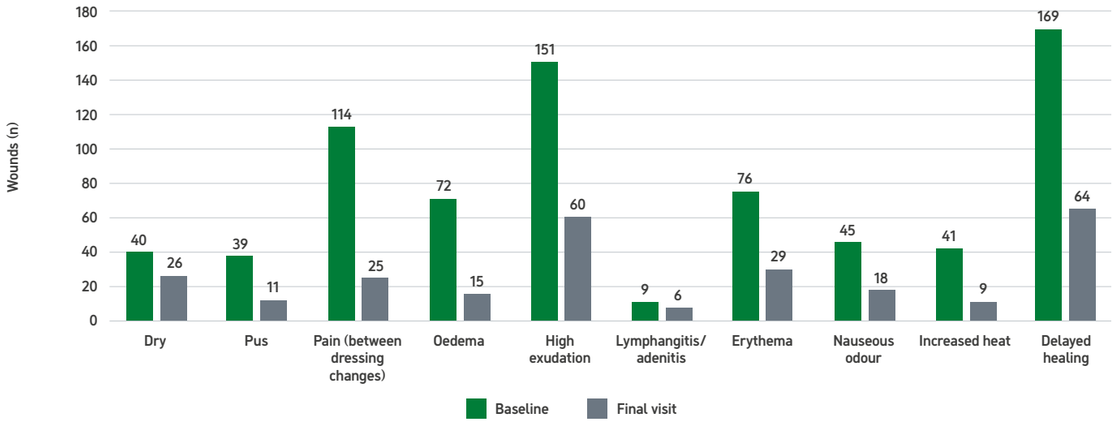


Figure 13. Number of local signs of infection at baseline and final visit in wounds dressed with Mepilex Border Ag (McCarty et al, 2013)

In an observational study undertaken at a wound care centre in Belgium, 30 patients with acute and chronic wounds (including **PIs**) exhibiting clinical signs of localised infection received Mepilex Ag dressings for up to four weeks. At the end of the study period, the clinical signs of infection had been eradicated in 90% of the wounds, while 53% of the wounds had healed and 27% almost healed. The dressings were rated as 'excellent' or 'very good' in 77% of the investigators' evaluations and in 82% of the patients' evaluations (Meuleneire, 2008). A case study series undertaken in France also observed that Mepilex Ag provides good exudate management and infection control, minimises trauma and pain at dressing changes, is easy to use and comfortable to wear (Cuvelier, 2009).

A five-patient case study series was undertaken to evaluate the use of Mepilex Border Ag in a nursing home in the USA. Patients presented with a variety of wound types, including two with **PIs**. The clinicians highlighted their observations from using the dressing with Safetac by referring to the acronym VALUE: Versatility - wide range of applications for topical acute and chronic wounds; Accessibility - over-the-counter, reimbursed; provided by most hospices for palliative wound care; Lifts up - after repositioning; Unequalled - in its ability to reduce pain and trauma; Ease of use - simple for staff to use and easy for resident's families and caregivers to learn to use at home or assisted living (Krasner & McKinney, 2012). Around the same time, the same dressing was evaluated in a 10-patient case study series in a hospital setting. The patients presented with a variety of wound types including PIs. The outcomes were positive in several areas. Wound healing was either accomplished or progressed towards healing. Mepilex Border Ag conformed to the contours of several body locations, stayed in place, managed exudate for several days, was easy to apply, provided comfort for the patient during wear time, decreased pain associated with dressing application and removal, and provided an antimicrobial barrier (Philbin, 2012).

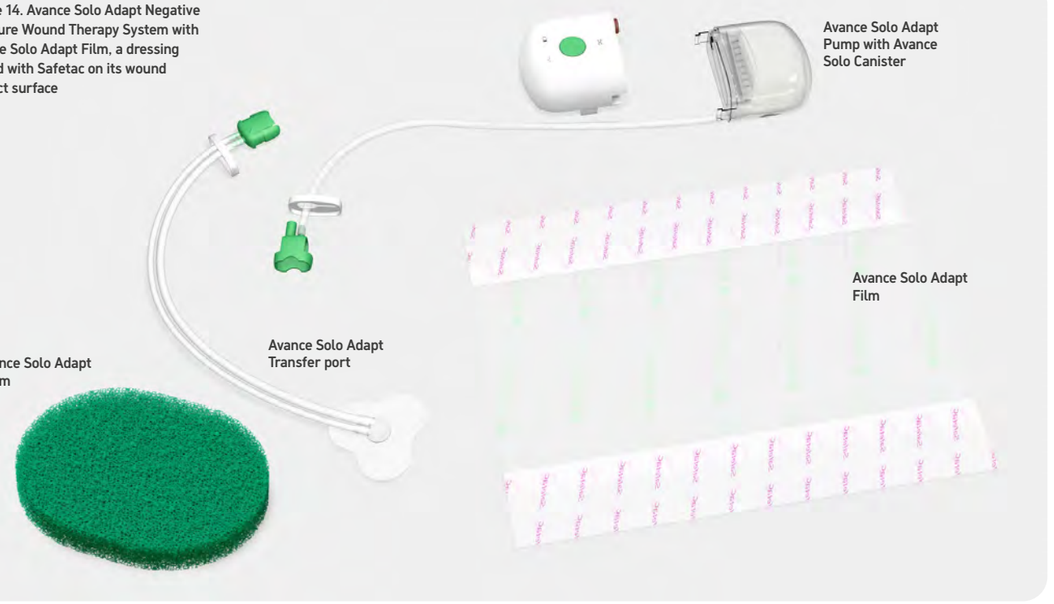
Ruggeri and colleagues described a clinical study that evaluated the impact of a clinical team dedicated to the management of **PI** in advanced cancer patients in Italy. Mepilex is listed as one of the dressings utilised by the team, with Mepilex Ag mentioned as one of the dressings used in the presence of wound infection. Complete healing of the PIs was observed in 23 of 26 patients after just six weeks (Ruggeri et al, 2016).

Barrows reported on a case in which a hospital-acquired **stage III PI** was initially managed with a dressing regimen which included an alginate (primary) dressing and Mepilex Border Ag used as a secondary dressing. The silver-containing dressing was chosen to address suspected candidiasis of the peri-wound region. Prior to the regimen introduction, the patient reported pain severity of 7-9 on a scale from zero to 10. With the new regimen, the patient experienced no pain. The moist weeping peri-wound skin was resolved completely within seven days, enabling a switch to a non-silver-containing secondary dressing (Mepilex Border) (Barrows, 2009).

Negative pressure wound therapy

Avance Solo Adapt is a portable, single-use negative pressure wound therapy (NPWT) system intended for use on PIs. It consists of a fluid collection canister attached to a pump which delivers consistent negative pressure (-125 mmHg) via tubing and a transfer port to a specialised dressing (**Figure 14**). The dressing, Avance Solo Adapt Film, is coated with Safetac on its wound contact surface to minimise trauma and pain on removal. In a clinical study conducted across 14 sites in seven European countries, the system was evaluated in 35 patients with **low-to-moderately exuding** PIs at weekly visits for up to 28 days. Wound progress was noted as improved at 80.6% of follow-up visits, relative to the previous visit. At the final visit, the mean decrease in wound area was 11.2%, compared to baseline. Increases in the proportion of wounds with no necrotic (11.4%) or sloughy tissue (35.7%), and in the proportion of patients with healthy peri-wound skin (18.3%), compared to baseline, were also observed. Pain severity scores at follow-up visits were low, ranging from 0.8 to 1.0 on a numerical ratings scale ranging from zero (no pain) to 10 (worst imaginable pain). The vast majority (97.1%) had no dressing-related trauma to the wound across all visits. With regard the peri-wound region, the proportion of patients with no trauma was 79.4% at the first follow-up visit, increasing to 85.3% at the final visit (Beele et al, 2025).

Figure 14. Avance Solo Adapt Negative Pressure Wound Therapy System with Avance Solo Adapt Film, a dressing coated with Safetac on its wound contact surface



References

Acorda, D.E. (2015) Nursing and respiratory collaboration prevents BiPAP-related pressure ulcers. Journal of Pediatric Nursing 30(4):620-623.

Alderden, J., Amoafo, L., Zhang, Y., Fife, C., Yap, D. Yap, T. (2021) Comparing risk profiles in critical care patients with stage 2 and deep tissue pressure injuries: exploratory retrospective cohort study. Journal of Medical Internet Research Dermatology 4(2):e29757.

Aloweni, F., Lim, M.L., Chua, T.L., Tan, S.B., Lian, S.B., Ang, S.Y. (2017) A randomised controlled trial to evaluate the incremental effectiveness of a prophylactic dressing and fatty acids oil in the prevention of pressure injuries. Wound Practice and Research 25(1):24-34.

Avsar, P., Moore, Z., Patton, D. (2021) Dressings for preventing pressure ulcers: how do they work? Journal of Wound Care 30(1):33-39.

Barakat-Johnson, M., Stephenson, J., Dempsey, K., Innes, L., Jain, S., Leong, T., Schouten, T., Coyer, F., Hallahan, A. (2022) Fit testing and comfort evaluation of prophylactic dressing use for healthcare workers under N95/P2 respirators in one health service district in Australia. Journal of Hospital Infection 123:100-107.

Barrows, C. (2009) Enhancing patient outcomes-reducing the bottom line: the use of antimicrobial soft silicone foam dressing in home health. Home Healthcare Nurse 27(5):279-284.

Bateman, S. (2013) Patient care and management: reduced skin integrity of the foot. British Journal of Nursing 22(20 Supplement):S30-S37.

Bateman, S. (2014) Principles of preventative foot care. British Journal of Community Nursing March (Supplement):S32-S38.

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

Beeckman, D., Fourie, A., Raepsaet, C., Van Damme, B., Manderlier, B., De Meyer, D., Beele, H., Smet, S., Demarre, L., Vossaert, R., de Graaf, A., Verhaeghe, L., Vandergheynst, N., Hendrickx, B., Hanssens, V., Keymeulen, H., Vanderwee, K., Van De Woestjne, J., Verhaeghe, S., Van Hecke, A., Savoye, I., Harrison, J., Vrijens, F., Hulstaert, F. (2021) Silicone adhesive multilayer foam dressings as adjuvant prophylactic therapy to prevent hospital-acquired pressure ulcers: a pragmatic non-commercial multicentre randomised open label parallel group medical device trial. British Journal of Dermatology 185(1):52-61.

Beele, H., Danneels, M., Nou Howaldt, M., Loschi, D., Lorenzo, G., Amann, B., Kusch, K., Stucker, M., Gomez, C.F., Nuna, V., Alves, P., Colgan, M.P., Castro, J., Andersen, J.A., Timmons, J. (2025) Evaluation of a novel, canister-based, portable negative pressure wound therapy system in the management of pressure injuries. Poster presentation at European Wound Management Association Conference, Barcelona, Spain.

Black, J., Alves, P., Brindle, C.T., Dealey, C., Santamaria, N., Call, E., Clark, M. (2015) Use of wound dressings to enhance prevention of pressure ulcers caused by medical devices. International Wound Journal 12(3):322-327.

Boesch, R.P., Myers, C., Garrett, T., Nie, A.M., Thomas, N., Chima, A., McPhail, G.L., Ednick, M., Rutter, M.J., Dressman, K. (2012) Prevention of tracheostomy-related pressure ulcers in children. Pediatrics 129(3):e792-e797.

Boixados, D., Allaert, F.A., Drareni, W. (2019) Efficacy of a five-layer silicone foam dressing with 360-degree flex technology for chronic and acute wound management in home care settings E-poster presentation at European Wound Management Association Conference, Gothenburg, Sweden.

Brindle, C.T. (2010) Outliers to the Braden Scale: identifying high-risk ICU patients and the results of prophylactic dressing use. World Council of Enterostomal Therapists Journal 30(1):11-18.

Brindle, C.T., Wegelin, J.A. (2012) Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients. Journal of Wound Ostomy & Continence Nursing 39(2):133-142.

Call, E., Pedersen, J., Bill, B., Oberg, C., Ferguson-Pell, M. (2013) Microclimate impact of prophylactic dressings using in vitro body analog method. Wounds 25(4):94-103.

Call, E., Pedersen, J., Bill, B., Black, J., Alves, P., Brindle, C.T., Dealey, C., Santamaria, N., Clark, M. (2015) Enhancing pressure ulcer prevention using wound dressings: what are the modes of action? International Wound Journal 2015;12(4):408-413.

Cano, A., Smits, D., Corvino, P. (2011) 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. Journal of Wound, Ostomy and Continence Nursing 38(3S):S73.

Chaiken, N. (2012) Reduction of sacral pressure ulcers in the intensive care unit using a silicone border foam dressing. Journal of Wound Ostomy & Continence Nursing 39(2):143-145.

Chiari, P., Forni, C., Guberti, M., Gazineo, D., Ronzoni, S., D'Allesandro, F. (2017). Predictive factors for pressure ulcers in an older adult population hospitalized for hip fractures: a prognostic cohort study. PLoS One 12(1):e0169909.

Clark, M., Black, J., Alves, P., Brindle, C., Call, E., Dealey, C., Santamaria, N. (2014) Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers. International Wound Journal 11(5):460-471.

Clay, P., Cruz, C., Ayotte, K., Jones, J., Fowler, S.B. (2018) Device related pressure ulcers pre and post identification and intervention. Journal of Pediatric Nursing 41:77-79.

Cohen, L.A., Levy, A., Shabshin, N., Neeman, Z., Gefen, A. (2018) Sacral soft tissue deformations when using a prophylactic multilayer dressing and positioning system. MRI studies. Journal of Wound Ostomy and Continence Nursing 45(5):432-437.

Cohen, L.P., Ovadia-Blechman, Z., Hoffer, O., Gefen, A. (2019) Dressings cut to shape alleviate facial tissue loads while using an oxygen mask. International Wound Journal 16(3):813-826.

Cubit, K., McNally, B. Lopez, V. (2013) 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. International Wound Journal 10(5):579-584.

Cuvelier, K. (2009) Prise en charge et evolution de plaies chroniques traitées par un pansement hydrocellulaire imprégné d'argent. Poster presentation at 13ème Conferénce Nationale des Plies et Cicatrisations, Paris, France.

Eager, C.A. Comparison of two foams through the measurement of healing time, frequency of dressing changes and peri wound status. Poster presentation at the 14th Annual Symposium on Advanced Wound Care and Medical Research Forum on Wound Repair, Orlando, Florida, United States of America, 2001.

Eberhardt, T.D., de Lima, S.B.S., de Avila Soares, R.S., Silveira, L.B.T.D., Pozzebon, B.R., Reis, C.R., dos Santos, K.P.P., Alves, P.J.P. (2021) Prevention of pressure injury in the operating room: Heels operating room pressure injury trial. International Wound Journal 18(3):359-366.

Edsberg, L.E, Black, J.M., Goldberg, M., McNichol, L., Moore, L., Sieggreen, M. (2016) Revised National Pressure Ulcer Advisory Panel pressure injury staging system. Journal of Wound Ostomy and Continence Nursing 45(6):585-597.

El Genedy, M., Hahnel, E., Tomova-Simitchieva, T., Padula, W.V., Hauss, A., Lober, N., Blume-Peytavi, U., Kottner, J. (2020) Cost-effectiveness of multi-layered silicone foam dressings for prevention of sacral and heel pressure ulcers in high-risk intensive care unit patients: an economic analysis of a randomised controlled trial. International Wound Journal 17(5):1291-1299.

Eriksson, E., Liu, P.Y., Schultz, G.S., Martins-Green, M.M., Tanaka, R., Weir, D., Gould, L.J., Armstrong, D.G., Gibbons, G.W., Wolcott, R., Olutoye, O.O., Kirsner, R.S. (2022) Chronic wounds: treatment consensus. Wound Repair and Regeneration 30(2):156-171.

European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Board and Pan Pacific Pressure Injury Alliance. (2019) Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Haesler, E. (Ed.). EPUAP/NPIAP/PPPIA.

Eytier, C., Gazeau, E., Beneteau, G., Verfaillie, G. (2013) Praticite et tolerance de l'association d'un pansement hydrocellulaire avec enduction de siliconeet d'un bandage tubulaire extensibile dans les deux sens sur la prise en charge locale des plaies. Une etude observationnelle realisee aupres de 304 infirmiers(eres) diplome(e)s d'etat (IDE) et portant sur 2401 patients. Resultats de l'etude TeMp0. Journal des Plaies et Cicatrisations 18(88):38-44.

Fletcher, J. (2013) The use of dressings in pressure ulcer prevention: unsafe practice or thinking differently? Wounds UK 9(4):67-71.

Fulbrook, P., Mbuzi, V., Miles, S. (2019) Effectiveness of prophylactic sacral protective dressings to prevent pressure injury: a systematic review and meta-analysis. International Journal of Nursing 2019;100:103400.

Gaspar, S., Peralta, M., Marques, A., Budri, A., Gaspar de Matos, M. (2019) Effectiveness on hospital-acquired pressure ulcers prevention: a systematic review. International Wound Journal 6(5):1087-1102.

Gefen, A., Santamaria, N., Creehan, S., Black, J. (2018) Extrapolation of evidence-related to dressings for pressure ulcer prevention may compromise patient safety. Wounds International 9(2):10-17.

Gefen, A., Santamaria, N., Creehan, S., Black, J. (2019a) Patient safety may be compromised if study conclusions are generalized to products that make similar claims but have no equivalent research evidence. Journal of Patient Safety and Risk Management 24(1):39-47.

Gefen, A., Alves, P., Creehan, S., Call, E., Santamaria, N. (2019b) Computer modelling of prophylactic dressings: an indispensable guide for healthcare professionals. Advances in Skin and Wound Care 32(7 Supplement):S4-S13.

Gefen, A., Creehan, S., Black, J. (2020) Critical biomechanical and clinical insights concerning tissue protection when positioning patients in the operating room: a scoping review. International Wound Journal 17(5):1405-1423.

Hahnel, E., El Genedy, M., Tomova-Simitchieva, T., Hauss, A., Stroux, A., Lechner, A., Richter, C., Akdeniz, M., Blume-Peytavi, U., Löber, N., Kottner, J. (2020) The effectiveness of two silicone dressings for sacral and heel pressure ulcer prevention in high risk intensive care unit patients compared to no dressings: a randomized controlled parallel-group trial. British Journal of Dermatology 183(2):256-264.

Holder, H., Aningalan, A.M., Walker, S., Cato, K., Gannon, B.R. (2023) Feasibility of nasal bridge pressure injury prevention using a protective dressing and the Halyard Fluidshield N95 mask in a COVID-positive environment. International Wound Journal 20(2):278-284.

Hsu, M-Y., Chung, H-C., Tang, M.T., Hsiu, S-R., Tai, C-H. (2011) Avoiding pressure damage when using ventilators. Wounds International 1(5).

Huang, L., Woo, K.Y., Liu, L-B., Wen, R-J., Hu, A-L., Shi, C-G. (2015) Dressings for preventing pressure ulcers: a meta-analysis. Advances in Skin and Wound Care 28(6):267-273.

Jaul, E., Barron, J., Rosenzweig, J.P., Menczel, J. (2018) An overview of co-morbidities and the development of pressure ulcers among older adults. BMC Geriatrics 18(1):305.

Johnson, C., Renwick, C., Parkinson, J., Burn, K., Colledge, D. (2018) Prophylactic dressing use to prevent heel ulceration in post-epidural orthopaedic patients. Wounds UK 14(1):84-89.

Johnstone, A., McGown, K. (2013) Innovations in the reduction of pressure ulceration and pain in critical care. Wounds UK 9(3):76-80.

Kalowes, P., Messina, V., Li, M. (2016) Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit. American Journal of Critical Care 25(6):e108-e119.

Kim, R.S., Mullins, K. (2016) Preventing facial pressure ulcers in acute respiratory distress syndrome (ARDS). Journal of Wound Ostomy and Continence Nursing 43(4):427-429.

Kimsey, D.B. (2019) A change in focus: shifting from treatment to prevention of perioperative pressure injuries. Association of periOperative Registered Nurses 110(4):380-393.

Krasner, D.L., McKinney, W. (2012) Acute and chronic wound applications in the long term care setting for a soft silicone foam border dressing with silver: a clinical case series demonstrating VALUE. Poster presentation at the Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Atlanta, Georgia, United States of America.

Krupova, L., Hovorkova, J., Pokorna, A. (2024) Innovative approaches to preventing medical device-related pressure ulcers on the head. Poster presentation at European Pressure Ulcer Advisory Panel Annual Meeting, Lausanne, Switzerland.

Kunimitsu, M., Nakagami, G., Kitanura, A., Minematsu, T., Koudounas, S., Ogai, K., Sugama, J., Takada, C. Yeo, S.A., Sanada, H. (2023) Relationship between healing status and microbial dissimilarity in wound and peri-wound skin in pressure injuries. Journal of Tissue Viability 32(1):144-150.

Kuo, C.Y., Wootton, C.T., Tylor, D.A., Werkhaven, J.A., Huffman, K.F., Goudy, S.L. (2013) Prevention of pressure ulcers after pediatric tracheostomy using a Mepilex Ag dressing. The Laryngoscope 123(12):3201-3205.

Labeau, S.O., Afonso, E., Benbenishty, J., Blackwood, B., Boulanger, C., Brett, S.J., Calvino-Gunther, S., Chaboyer, W., Coyer, F., Deschepper, M., Francois, G., Honore, P.M., Jankovic, R., Khanna, A.K., Llaurado-Serra, M., Lin, F., Rose, L., Rubulotta, F., Saager, L., Williams, G., Blot, S.I. (2021) prevalence, associated factors and outcomes of pressure injuries in adult intensive care unit patients: the DecubICUs study. Intensive Care Medicine 47:160-169.

Lachenbruch, C., Ribble, D., Emmons, K., van Gilder, C. (2016) Pressure ulcer risk in the incontinent patient: analysis of incontinence and hospital-acquired pressure ulcers from the International Pressure Ulcer Prevalence Survey. Journal of Wound Ostomy and Continence Nursing 43(3):235-241.

Latimer, S., Chaboyer, W., Walker, R.M., Thalib, L., Deakin, J.L., Gillespie, B.M. (2024) Prophylactic dressings for preventing sacral pressure injuries in adult intensive care unit patients: a randomised feasibility trial. Australian Critical Care 38(2):101133.

Lechner, A., Rancan, F., Hadam, S., Vogt, A., Blume-Peytavi, U., Kottner, J. (2021) Comparing the effects of three different multilayer dressings for pressure ulcer prevention on sacral skin after prolonged loading: an exploratory crossover trial. Wound Repair and Regeneration 29(2):270-279.

Levy, A., Ben-Or Frank, M., Gefen, A. (2015) The biomechanical efficacy of dressings in preventing heel ulcers. Journal of Tissue Viability 24(1):1-11.

Levy, A., Gefen, A. (2016) Computer modeling studies to assess whether a prophylactic dressing reduces the risk for deep tissue injury in the heels of supine patients with diabetes. Ostomy Wound Management 62(4):42-52.

Levy, A., Gefen, A. (2017) Assessment of the biomechanical effects of prophylactic sacral dressings on tissue loads: a computational modeling analysis. Ostomy Wound Management 63(10):48-55.

Levy, A., Schwartz, D., Gefen, A. (2017)The contribution of a directional preference of stiffness to the efficacy of prophylactic sacral dressings in protecting healthy and diabetic tissues from pressure injury: computational modelling studies. International Wound Journal 14(6):1370-1377.

Lichterfeld-Kottner, A., Vogt, A., Tomova-Simitchieva, T., Blume-Peytavi, U., Kottner, J. (2021) Effects of loading and prophylactic dressings on the sacral and heel skin: an exploratory cross-over trial. International Wound Journal 18(6):909-922.

Li, Z., Lin, F., Thalib, L., Chaboyer, W. (2020) Global prevalence and incidence of pressure injuries in hospitalised adult patients: a systematic review and meta-analysis. International Journal of Nursing Studies 105:103546.

Lovegrove, J., Fulbrook, P., Miles, S. (2020) International consensus on pressure injury preventative interventions by risk level for critically ill patients: a modified Delphi study. International Wound Journal 17:1112-1127.

McCarty, S., Davies, P., Rippon, M. (2013) Mepilex Border Ag: an in-market evaluation. Poster presentation at the Wounds UK Conference, Harrogate, United Kingdom.

Meaume, S., Van De Looverbosch, D., Heyman, H., Romanelli, M., Ciangherotti, A., Charpin, S. (2003) A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers. Ostomy Wound Management 49 (9): 44-51.

Mervis, J.S., Phillips, T.J. (2019) Pressure ulcers: pathophysiology, epidemiology, risk factors, and presentation. Journal of the American Academy of Dermatology 81(4):881-890.

Meuleneire, F. (2008) An observational study of the use of a soft silicone silver dressing on a variety of wound types. Journal of Wound Care 17(12):535-539.

Meuleneire, F., Fostier, A. (2008) Local treatment of heel pressure ulcers with a silicone foam dressing. Poster presentation at the 3rd Congress of the World Union of Wound Healing Societies, Toronto, Canada.

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

Neyt, M., De Meester, C., Devriese, S., Marynen, E., Beeckman, D. (2024) Silicone adhesive multilayer foam dressings to prevent hospital-acquired sacrum pressure ulcers: an economic evaluation based on a publicly funded pragmatic randomised controlled trial linked with real-world data. Journal of Tissue Viability 33(4):772-777.

Oe, M., Sasaki, S., Shimura, T., Takaki, Y., Sanada, H. (2020) Effects of multilayer silicone foam dressings for the prevention of pressure ulcers in high-risk patients: a randomized clinical trial. Advances in Wound Care 9(12):649-656.

Orlov, A., Gefen, A. (2023) Differences in prophylactic performance across wound dressing types used to protect from device-related pressure ulcers caused by a continuous positive airway pressure mask. International Wound Journal 20(4):942-960.

Padula, W.V. (2017) Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals. An observational cohort study. Journal of Wound Ostomy and Continence Nursing 44(5):413-419.

Padula, W.V., Chen, Y.H., Santamaria, N. (2019) Five-layer border dressings as part of a quality improvement bundle to prevent pressure injuries in US skilled nursing facilities and Australian nursing homes: A cost-effectiveness analysis. International Wound Journal 16(6):1263-1272.

Padula, W.V., Delarmente, B.A. (2019) The national cost of hospital-acquired pressure injuries in the United States. International Wound Journal 16(3):634-640.

Park, K.H. (2014) The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence associated dermatitis in intensive care unit patients. Journal of Wound Ostomy and Continence Nursing 41(5):424-429.

Peko, L., Barakat-Johnson, M., Gefen, A. (2020) Protecting prone positioned patients from facial pressure ulcers using prophylactic dressings a timely biomechanical analysis in the context of the COVID-19 pandemic. International Wound Journal 17(5):1595-1606.

Pender, L.R., Frazier, S.K. (2005) The relationship between dermal pressure ulcers, oxygenation and perfusion in mechanically ventilated patients. Intensive and Critical Care Nursing 21(1):29-38.

Philbin, S. (2012) Simple solutions for complex wounds of multiple types. Poster presentation at the Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Atlanta, Georgia, United States of America.

Qiuli, B., Qiongyu, J. (2010) [Observation on effect of Mepilex on the prevention and treatment of pressure sores.] Chinese Journal of Medical Nursing.

Rahman-Synthia, S.S., Kumar, S., Boparai, S., Gupta, S., Mohtashim, A., Ali, D. (2023) Prophylactic use of silicone dressing to minimize pressure injuries: systematic review and meta-analysis. Enfermeria Clinical (English Edition) 33(1):4-13.

Ramos-Torrecillas, J., De Luna-Bertos, E., García-Martínez, O., Díaz-Rodríguez, L., Ruiz, C. (2013) Use of platelet-rich plasma to treat pressure ulcers: a case study. Journal of Wound Ostomy, and Continence Nursing 40(2):198-202.

Roldan Valenzuela, A., Galindo Cantillo, V., de Borja Lopez Casanova, F., Ordonez Ferrer, S.M., Hernandez Palanco, L.F., Berjano Rodriguez, A., Cabrera Aguera, M.J., Illanes Valenzuela, J.M., Lopez Moraleda, I., Prieto Torrado, O., Castillo Aparicio, G. (2025) A wound dressing shows its value: clinical and economic effects of a dressing regime change for primary and home care chronic wound management. Poster presentation at European Wound Management Association Conference, Barcelona, Spain.

Rook, S., Davies, P., Frenthoff, E., Wurfel, T (2019). Mepilex Border Flex – results of an observational study in German specialist wound care centres. Wounds International 10(1):40-43.

Ruggeri, E., Martotoni, A.A., Malavasi, I., Agostini, F., Piccinelli, E., Mazzetti, M., Tenace, A., Campullu, L., Boin, B., Pannuti, F. (2016) The treatment of pressure ulcers in advanced cancer patient: the importance of a dedicated team. Acta Vulnologica 14(2):65-77.

Santamaria, N., Gerdtz, M., Sage, S., McCann, J., Freeman, A., Vassiliou, T., De Vincentis, S., Ng, A.W., Manias, E., Liu, W., Knott, J. (2015a) 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. International Wound Journal 12(3):302-308.

Santamaria, N., Gerdtz, M., Sage, S., McCann, J., Freeman, A., Vassiliou, T., De Vincentis, S., Ng, A.W., Manias, E., Liu, W., Knott, J., Liew, D. (2015b) 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. International Wound Journal 12(3):344-350.

Santamaria, N., Gerdtz, M., Liu, W., Rakis, S., Sage, S., Ng, A.W., Tudor, H., McCann, J., Vassiliou, T., Morrow, F., Smith, K., Knott, J., Liew, D. (2015c) Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial. Journal of Wound Care 24(8):340-345.

Santamaria, N., Santamaria, H. (2014) An estimate of the potential budget impact of using prophylactic dressings to prevent hospital-acquired PUs in Australia. Journal of Wound Care 23(11):583-589.

Santamaria, N., Gefen, A. (2018) Clinical innovations: can dressings help to prevent pressure ulcers in high-risk nursing home residents? Wounds International 9(2):30-34.

Santamaria, N., Gerdtz, M., Kapp, S., Wilson, L., Gefen, A. (2018) A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial. International Wound Journal 15(3):482-490.

Santamaria, N., Creehan, S., Fletcher, J., Alves, P., Gefen, A. (2019) Preventing pressure injuries in the emergency department: current evidence and practice considerations. International Wound Journal 16(3):746-752.

Schoonhoven, L., Defloor, T., van der Tweel, I., Buskens, E., Grypdonck, M.H.F. (2002) Risk indicators for pressure ulcers during surgery. Applied Nursing Research 15(3):163-173.

Schwartz, D., Levy, A., Gefen, A. (2018) A computer modeling study to assess the durability of prophylactic dressings subjected to moisture in biomechanical pressure injury prevention. Ostomy Wound Management 64(7):18-26.

Schwartz, D., Gefen, A. (2019) The biomechanical protective effects of a treatment dressing on the soft tissues surrounding a non-offloaded sacral pressure ulcer. International Wound Journal 16(3):684-695.

Shearer, S.C., Parsa, K.M., Newark, A., Peesay, T., Walsh, A.R., Fernandez, S., Gao, W.Z., Pierce, M.L. (2021) Facial pressure injuries from prone positioning in the COVID-19 era. Laryngoscope 131:E2139-E2142.

Sillmon, K., Moran, C., Shook, L., Lawson, C., Burfield, A.H. (2021) The use of prophylactic foam dressings for prevention of hospital-acquired pressure injuries. Journal of Wound Ostomy and Continence Nursing 48(3):211-218.

Smith, Z.K. (2006) Addressing the pain: adapting a soft silicone dressing to enhance infant outcomes. Ostomy Wound Management 52(4):30-32.

Strauss, R., Preston, A., Zalman, D.C., Rao, A.D. (2019) Silicone foam dressing for prevention of sacral deep tissue injuries among cardiac surgery patients. Advances in Skin and Wound Care 32(3):139-142.

Sugrue, C., Avsar, P., Moore, Z., Patton, D., O'Connor, T., Nugent, L., Budri, A. (2023) The effect of prophylactic silicone dressings on the incidence of pressure injuries on patients in the acute care setting. Journal of Wound Ostomy and Continence Nursing 50(2):115-123.

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

Taghiloo, H., Ebadi, A., Saeid, Y., Jalali Farahni, A., Davoudian, A. (2023) Preventing pressure injury in open-heart surgical patients: a systematic review. Health Science Reports 6(3):e1148.

Tayyib, N., Coyer, F. (2016) Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: a systematic review. Worldviews on Evidence-Based Nursing 13(6):432-444.

Truchetet, F., Guibon, O., Meaume, S. (2012) Clinicians' rationale for using a sliver dressing: the French OMAg+E observational study. Journal of Wound Care 21(12): 620-625.

Tsao, W-Y., Lo, S-F., Harmod, T., Lee, R-P. (2013) [A comparison of the efficacy of different wound dressing management techniques in preventing pressure ulcers]. Journal of Nursing (China) 60(4):65-78.

Tyson, L. (2019) Study first: driving the case for improving hospital wound care. Poster presentation at Symposium on Advanced Wound Care (Spring), San Antonio, Texas, United States of America.

Walsh, N.S., Black, A.W., Smith, L., Cross, M., Andersson, L., Polito, C. (2012) Use of a sacral silicone border foam dressing as one component of a pressure ulcer prevention program in an intensive care unit setting. Journal of Wound Ostomy & Continence Nursing 39(2):146-149.

Webb, M. (2008) Use of soft silicone dressings to meet the unique wound care needs of residents in one county long term care facility. Poster presentation at the 40th Annual Conference of the Wound Ostomy and Continence Nurses Society, Orlando, Florida, United States of America.

Wensley, F., Kerry, C., Rayman, G. (2018) Increased risk of hospital-acquired foot ulcers in people with diabetes: large prospective study and implications for practice. British Medical Journal Open Diabetes Research Care 6(1):e000510.

White, R. (2008) A multinational survey of the assessment of pain when removing dressings. Wounds UK 4(1):14-22.

Williams, A.T., Bates-Jensen, B.M., Hodge, F., Lee, E., Levy-Storms, L. (2024). Pressure injury pain over time among nursing home residents. Geriatric Nursing 59:362-371.

World Union of Wound Healing Societies (2016) Consensus Document. Role of Dressings in Pressure Ulcer Prevention. Wounds International, London, United Kingdom.

Yang, T-Y., Shin, S.H. (2020) Effect of soft silicone foam dressings on intraoperatively acquired pressure injuries: a randomized study in patients undergoing spinal surgery. Wound Management and Prevention 66(11):22-29.

Yoshimura, M., Ohura, N., Tanaka, J., Ichimura, S., Kasuya, Y., Hotta, O., Kagaya, Y., Sekiyama, T., Tannba, M., Suzuki, N. (2018) Soft silicone foam dressing is more effective than polyurethane film dressing for preventing intraoperatively acquired pressure ulcers in spinal surgery patients: the Border Operating room Spinal Surgery (BOSS) trial in Japan. International Wound Journal 15(2):188-197.

Dressings with Safetac® -Surgical Wound Management

Dressings with Safetac featured:

Mepilex®, Mepilex® Ag, Mepilex® Border, Mepilex® Border Ag, Mepilex® Border Flex (Comfort), Mepilex® Border Lite, Mepilex® Border Post-Op, Mepilex® Border Post-Op Ag, Mepilex® Transfer, Mepilex® Transfer Ag, Mepitel®, Mepitel® Ag, Mepitel® One, Avance® Solo Border

Take home messages:

- Closed surgical incision sites are associated with a variety of post-operative complications, e.g. infection, dehiscence, blistering, seroma, haematoma, local skin ischaemia and necrosis, and poor quality/abnormal scarring.
- Dressings are used as physical barriers to protect incision sites until the continuity of the skin is restored, to absorb exudate and to prevent microbial contamination from the external environment.
- Numerous clinical studies have observed very low rates of complications when advanced post-operative dressings with Safetac have been applied to closed surgical incision sites. For example, in four clinical trials involving more than 500 patients, no blistering or skin damage was reported on patients who had Mepilex Border Post-Op applied to their wounds.
- Open surgical wounds are often large and deep, produce high levels of exudate and are at risk of infection.
- A variety of different dressings with Safetac have been used successfully to manage exudate and to minimise trauma and pain during dressing changes for patients with open surgical wounds.

Introduction to surgical wounds

Wounds that result from surgical interventions should, in theory, present less of a clinical challenge than certain other types of wounds, as they are generally 'clean' and formed by pre-determined incidents. However, despite many advances in the technologies and techniques used in the pre-, intra- and post-operative phases of patient care, **surgical site complications** (e.g. infection and dehiscence) continue to be a major cause of delayed healing, morbidity and mortality. They also contribute to a significant economic burden on healthcare providers (Sandy-Hodgetts et al, 2020).

There are two main approaches to wound healing (closure) - primary (where tissue loss is minimal and wound edges can be satisfactorily approximated) and secondary (where wounds are intentionally left open (e.g. because of infection or the inability to approximate the wound edges). Healing by primary intention is applicable to most surgical wounds. When the edges of a surgical incision site have been brought together and retained in place (e.g. with adhesives, staples or sutures) to facilitate primary closure, this is commonly referred to as a **closed surgical incision site** (World Union of Wound Healing Societies (WUWHS), 2016).

Wounds healing by secondary intention are associated with some degree of tissue loss or where there is a wide separation of the wound edges (e.g. those resulting from tumour excision). These wounds heal from the base upwards, by laying down new granulation tissue.

Challenges

Closed surgical incision sites are associated with a variety of post-operative complications, e.g. infection (surgical site infection [SSI]), dehiscence, blistering, seroma, haematoma, local skin ischaemia and necrosis, and poor quality/abnormal scarring (WUWHS, 2016; Beele et al, 2020). For the healthcare provider, these complications can extend patients' hospitalisation, lead to unplanned hospital re-admissions and delay planned interventions, all of which can increase healthcare costs. From the perspective of patients and carers, these complications can impact negatively on quality of life, increase morbidity (e.g. pain and anxiety) and heighten the risk of mortality (WUWHS, 2016).

Open surgical wounds (i.e. those healing by secondary intention) are associated with a range of clinical challenges that complicate management and patient recovery. They are often large and deep, produce high levels of exudate, and are at risk of infection (McCaughan et al, 2020).

Role of dressings in surgical wound management

Closed surgical incision sites

Measures taken to prevent closed surgical incision site complications begin in the pre-operative phase (e.g. with the use of antimicrobial sealants), before continuing into the intra-operative period (e.g. with the use of antimicrobial-impregnated sponges) and then into the post-operative phase (Scalise et al, 2016). A variety of interventions are used in the post-operative phase, including the use of debriding agents, topical antimicrobial agents, dressings, and advanced topically applied therapies (e.g. autologous blood products, growth factors, cultured skin and negative pressure wound therapy (NPWT)) (Scalise et al, 2016; Beele et al, 2020; Norman et al, 2020).

Dressings play a key role in the management of closed surgical incision sites; they are used as physical barriers to protect wounds until the continuity of the skin is restored (typically within 48 hours post-surgery), to absorb exudate and to prevent microbial contamination from the external environment (Toon et al, 2015). Clinicians have a duty to select dressings that are designed and have been demonstrated in clinical studies to have relevant properties, such as those recently identified by a panel of surgeons in Australia (**Box 1**) (Sandy-Hodgetts & Morgan-Jones, 2024).

Box 1. Properties of an 'ideal' post-operative wound dressing (Sandy-Hodgetts & Morgan-Jones, 2024)

- Flexibility and patient comfort (does not impede patient's movement; provides elasticity to avoid pulling or blistering, particularly over joints)
- Well-fixed to dry skin on application and remains adhered even if there is perspiration
- Absorbent of wound exudate (retains/locks in fluid; no exudate leakage from dressing to peri-wound skin should occur)
- Protective of surrounding skin (to reduce risk of blistering or irritation) and provides patient comfort (with minimal discomfort/pain during removal)
- Waterproof to provide a good seal/barrier function and enables the patient to shower
- Where necessary, eliminates 'dead space' between the wound bed and dressing to avoid exudate pooling
- Easy-to-use and remove by patients and care staff (to ensure consistent care)
- Transparent dressing borders to allow for observation of surrounding skin

The majority of closed surgical incision sites continue to be managed with conventional dressings or, in the case of patients who have intrinsic risk factors (**Box 2**) for surgical site complications or who have undergone procedures associated with a particularly high incidence of such complications, closed incision negative pressure wound therapy (ciNPWT) (Davies, 2022). However, blistering has been reported to be a problem with some NPWT systems (Howell et al, 2011) and certain dressing types, e.g. those that incorporate the traditional adhesives that are known to inflict trauma (e.g. skin stripping) on removal (Ousey et al, 2011; Ravenscroft et al, 2006). It has also been suggested that, if a dressing is placed over a joint and left in place for a relatively long period of time, joint movement could cause friction between the skin and the dressing, leading to the creation of shear forces that, in turn, cause separation of the epidermal and dermal layers of the skin (i.e. blisters) (Ravenscroft et al, 2006). Commenting on the prevention of post-operative blistering, Ousey and colleagues state: "A wound dressing should maintain a warm, moist healing environment and should not damage the peri-wound area, which could lead to blister formation. Protection of the peri-wound area is vital and can be achieved by choosing a dressing that does not adhere to surrounding skin, is easy to apply, easy to remove and flexible. Flexibility of the wound dressing is essential, especially for orthopaedic wounds that are prone to swelling and have an increased risk of friction between the wound and the dressing" (Ousey et al, 2011).

Box 2. Factors that may indicate the need for closed incision negative pressure wound therapy (ciNPWT) (WUWHS, 2016)

- Body mass index ≥40 kg/m^2 or ≤18 kg/m^2
- Uncontrolled insulin-dependent diabetes mellitus
- Renal dialysis
- Surgery that has a particularly high incidence and/or high consequence of surgical site complications

Open surgical wounds

Regarding the management of open surgical wounds, the main role of dressings is to support the local wound environment in order to facilitate healing. Providing a protective barrier, maintaining a moist wound environment, managing excess exudate, preventing infection and minimising scarring are key to the efficacy of dressings in the management of open surgical wounds (Holloway & Harding, 2022).

Evidence for dressings with Safetac

Closed surgical incision sites

The performance and safety of dressings with Safetac, when used on closed surgical incision sites, have been evaluated in numerous clinical studies, the majority involving the use of Mepilex Border Post-Op and the silver-containing variant, Mepilex Border Post-Op Ag (**Figure 1**). The key studies are summarised in **Table 1**.

Table 1. Management of closed surgical incision sites - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Srivastava et al, 2025 RCT India	**Subjects:** 314 (age range 42-72 years) **Wound type:** Closed incision site after fracture fixation around hip/knee **Setting:** Orthopaedics	**Safetac:** Mepilex Border Post-Op (n=79) **Comparators:** Aquacel Ag (n=78), Opsite Post-Op (n=79), gauze (n=78) [Patients followed for up to 14 days]	Surgical site complications (erythema, maceration, blistering) Pain levels during dressing changes Dressing usage	Surgical site complications significantly lower in the Safetac group on day 14 (p=0.003): - Mepilex Border Post-Op: 1.2% - Aquacel Ag: 5.4% - Opsite Post-Op: 4.9% - Gauze: 9.8% Safetac group reported the lowest mean pain scores over 14 days (p=0.002): - Mepilex Border Post-Op: 1.2 - Aquacel Ag: 2.5 - Opsite Post-Op: 2.8 - Gauze 3.5 Mepilex Border Post-Op outperformed other dressings in terms of ease of application and removal, with significantly higher ratings given by nurses on Day 3 and Day 14 compared with other dressings.
Beele et al, 2020 RCT Belgium	**Subjects:** 113 (age range 55-88 years) **Wound type:** Closed incision sites after THA / TKA **Setting:** Orthopaedics	**Safetac:** Mepilex Border Post-Op (n=56) **Comparator:** Aquacel Surgical (n=57) [Patients followed for 5 days]	Dressing failure (composite score based on 3 points for dressing change, 2 points for blister occurrence, 1 point if pain ≥30mm, 1 point if skin red under dressing) Pain severity before and during dressing removal (100mm VAS) Dressing usage	No significant difference between groups in terms of dressing failure, e.g. dressing failure score of 0 in 67.9% of Safetac group vs. 64.0% in comparator group; no blisters in the Safetac group vs. 1 blister in the comparator group. Mean pain severity score during dressing removal: - Mepilex Border Post-Op: 6.9 - Comparator: 10.0 (Difference significant in PP (p<0.0129) but not ITT population) Significantly more 'excellent' ratings for Mepilex Border Post-Op than comparator dressing in terms of clinicians' satisfaction with dressing application/ removal, prevention of dressing residuals and ability to absorb blood; and patients' satisfaction with wearing dressing, and overall experience (p<0.05 for all parameters).
Bredow et al, 2018 RCT Germany	**Subjects:** 208 (age range 33-92 years) **Wound type:** Closed incision sites after primary THA / TKA **Setting:** Orthopaedics	**Safetac:** Mepilex Border Post-Op (n=103) **Comparator:** Cosmopor (n=105) [Patients followed for 6 days]	Blister formation Dressing usage	Single case of blistering on post-operative day 6 in Safetac group but patient mistakenly given a comparator dressing. Mepilex Border Post-Op judged more favourably (e.g. proportion of 'excellent' ratings; p<0.001) than comparator dressings with regard to: - Overall patient rating: 50.5% vs. 1.9% - Patient comfort: 53.4% vs. 1.9% - Usability by clinician: 30.9% vs. 1.0% - Dressing removal by clinician: 64.9% vs. 1.0% - Ability to assess wound: 68.0% vs. 1.0% Lower mean number of dressing changes undertaken after the post-operatively applied dressing in Safetac group (p<0.001): - Mepilex Border Post-Op: 0.3 - Comparator: 1.2
Zarghooni et al, 2015 Non-randomised interventional clinical study (contemporaneous control) Germany	**Subjects:** 360 (age range 55-83 years) **Wound type:** Closed incision sites after primary THA / TKA **Setting:** Orthopaedics	**Safetac:** Mepilex Border Post-Op (n=49) **Comparator:** Variety of conventional dressings* (n=11) *Vliwazell, Fixomull, Mepore, Cosmopor [Patients followed for 7 days]	Blister formation Dressing usage Treatment costs	Significant difference between groups in terms of blistering (p<0.001): - Mepilex Border Post-Op: 0 - Comparators: 27.3% (n=3) Significant difference between groups in terms of mean number of dressing changes (p=0.0004): - Mepilex Border Post-Op: 0.66 - Comparators: 2.00 Significant difference between groups in terms of time required for dressing changes (p=0.003): - Mepilex Border Post-Op: 2.54 minutes - Comparators: 4.3 minutes Significant difference between groups in terms of mean cost of dressing changes (p=0.0062): - Mepilex Border Post-Op: €28.00 - Comparators: €43.10

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Yang et al, 2025 Non-randomised interventional clinical study (contemporaneous control) Republic of Korea	**Subjects:** 140 (age range not stated) **Wound type:** Closed incision sites after spinal surgery **Setting:** Orthopaedics	**Safetac:** Mepilex Border Post-Op (n=66) **Comparator:** Hypafix with acrylate-based adhesive (n=74) [Patients followed for up to 10 days]	MARSI occurrence	Significantly lower cumulative incidence of MARSI in Safetac group (p=0.003): - Mepilex Border Post-Op: 31.8% - Comparator: 56.8% 2.55 x higher risk of MARSI in comparator group (p<0.001). Significantly longer mean time to first MARSI in Safetac group (p<0.001): - Mepilex Border Post-Op: 5.90 days - Comparator: 2.67 days Significantly shorter mean duration of MARSI in Safetac group (p=0.025): - Mepilex Border Post-Op: 2.67 days - Comparator: 5.19 days
Van Overschelde et al, 2024 Observational retrospective clinical study Belgium	**Subjects:** 558 (age range 55-75 years) **Wound type:** Closed incision sites after hip/ knee surgery (mostly THA / TKA) **Setting:** Orthopaedics	**Safetac:** Mepilex Border Post-Op (n=49) [Patients followed for up to 29 days]	Dressing usage HRQoL (measured using EQ-5D-5L instrument, HOOS and KOOS questionnaires)	Mean wear time of first and second dressings was 13.6 and 5.3 days, respectively. Proportion of patients who wore the first dressing for 1-7 days, 8-13 days and for >14 days was 17.2%, 13.2% and 69.5%, respectively. Patients had improvements in quality of life over time: - Increase in mean EQ-5D-5L index from 0.64 (post-operative day 8) to 0.79 (day 83) - Increase in mean KOOS score from 45.8 (day 12) to 68.0 (day 83) - Increase in mean HOOS score from 42.3 (day 12) to 75.8 (day 83)

Abbreviations: EQ-5D-5L = EuroQol 5-Dimensional 5-Level; HOOS = Hip Disability and Osteoarthritis Outcomes Survey; HRQoL = health-related quality of life; ITT = intention to treat; KOOS = Knee Injury and Osteoarthritis Outcomes Survey; MARSI = medical adhesive-related skin injury; PP = per protocol; RCT = randomised controlled trial; THA = total hip arthroplasty; TKA = total knee arthroplasty; VAS = visual analogue scale

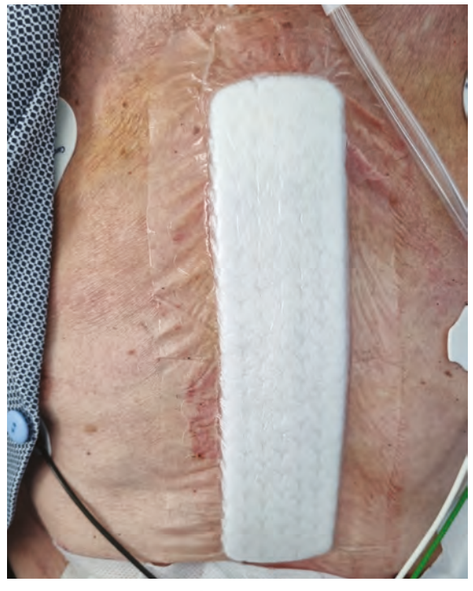


Figure 1. Mepilex Border Post-Op applied to a closed surgical incision site

In a randomised controlled trial (RCT) undertaken in India, the closed surgical incision sites of patients who had undergone **hip or knee surgeries** were randomly assigned to Mepilex Border Post-Op (n=79), Aquacel Ag (n=78), Opsite Post-Op (n=79) or gauze (n=78) dressings. The occurrence of surgical site complications (including erythema, maceration and blistering) was significantly lower in the dressings with Safetac group than in the gauze group (p=0.006 and p=0.003 on post-operative days 3 and 14 respectively). Similarly, mean pain severity scores on dressing removal were significantly lower in the dressings with Safetac group than the gauze dressing group at the same timepoints (p≤0.002) (Srivastava et al, 2025).
Mepilex Border Post-Op was compared with Opsite Post-Op when applied to **simulated closed surgical incision sites** on the hip area of patients with no history of hip surgery in an RCT undertaken in Thailand. The dressing with Safetac was applied to one hip; Opsite Post-Op was applied to the other hip. The dressing with Safetac was associated with significantly less moisture accumulation (Mepilex Border Post Op 13.8% vs. Opsite Post-Op 37.9%; p<0.01), less dressing failures (Mepilex Border Post-Op 20.7% vs. Opsite Post-Op 34.5%; p=0.016) and fewer complications (Mepilex Border Post-Op 17.2% vs. Opsite Plus 37.9%; p=0.012) at the 14-day follow-up (Anusitviwat & Tuenyongviwat, 2025).

Mepilex Border Post-Op dressings were also rated highly by clinicians and patients in an earlier RCT involving patients who had undergone **primary hip or knee endoprostheses or spinal surgery** in Germany. Compared to Cosmopor dressings, the dressings with Safetac were given significantly higher ratings by both clinicians (dressing usability and removal; ability to assess the wound) and patients (overall experience, comfort) when applied to their closed surgical incision sites (p<0.05). Out of the 208 recruited patients, there was a single occurrence of blistering (on post-operative day 6). The patient concerned was assigned to the Safetac group but had a Cosmopor dressing wrongly applied. There was also a significant difference between the groups in terms of the number of dressing changes (i.e. subsequent to the dressing applied intraoperatively), with 0.3 and 1.2 per patient required in the Safetac and comparator groups, respectively (p<0.001) (Bredow et al, 2018). Also in Germany, 60 patients were included in an observational study of patients undergoing **hip or knee joint replacement surgery**. Of 47 participants who had Mepilex Border Post-Op applied to their closed surgical incision sites, none were observed to have blistering. In contrast, 27.7% (n=3) of the comparator (traditional dressings) group developed blisters (p=0.001). Patient comfort and overall satisfaction was rated as very good-excellent in 96.6% of total knee arthroplasty (TKA) patients and 93.6% of total hip arthroplasty (THA) patients, with similarly high clinicians' ratings. Almost all patients rated the application and removal of the dressing with Safetac as painless. Treatment costs in the Safetac group were calculated to be 35% less than those in the comparator group (Zarghooni et al. 2015).

At a university teaching hospital in Italy, a quality improvement project was initiated with the aim of improving the quality of care of patients undergoing **hip or knee arthroplasty**. Following the implementation of a new best practice protocol including a change from the use of traditional dressings (antiseptic, gauze and fixation tape) to Mepilex Border Post-Op dressings (alongside appropriate training), a significant reduction in post-surgical site complications, including SSI, was observed, compared to the historical data (1.5% (n=3/205) vs, 13.7% (n=16/117) respectively (p<0.001)) (Peghetti, 2018).

Advantages of using dressings with Safetac over those with traditional adhesive systems were evident from the results of a study that compared Mepilex Border Post-Op and an acrylate-based adhesive dressing (Hypafix) with regard to the development of medical adhesive-related skin injury (MARSI) in patients who underwent **spinal surgery**. Compared to the group that had dressings with Safetac applied to their closed incision sites, those assigned to the traditional adhesive-based dressing had a higher cumulative incidence of MARSI (56.8% vs. 31.8%; p=0.003), a 2.55 times higher risk of MARSI (p<0.001), shorter mean time to the first MARSI (p<0.001) and longer MARSI duration (p<0.001) (Yang et al, 2025). As MARSIs impair skin barrier function, delay healing and cause pain (Fumarola et al, 2020; Hampton, 2020), clinicians should consider post-operative dressings that reduce the risk of them occurring, thus avoiding unnecessary negative impact on the quality of life of patients.

Mepilex Border Post-Op and Aquacel Surgical were compared in a 113-patient multi-centre RCT undertaken in Belgium when applied to closed surgical incision sites following **elective hip or knee arthroplasty**. Dressing failure rate (a composite measure taking into consideration the need for dressing changes, blister occurrence, pain severity ≥30 mm on a 100 mm visual analogue scale, and skin redness under the dressing), itching under the dressing, pain during dressing removal and the number of patients requiring a dressing change were low in both groups. However, the dressing with Safetac outperformed the comparator dressing in terms of ease of application (p<0.0001) and removal (p<0.0001), ability to handle blood (p<0.0001), prevention of dressing residuals (p=0.0167), patient satisfaction with dressing wear (p=0.0037) and patient overall experience (p=0.0025) (Beele et al, 2020).

In an audit of patients (n=27) who had undergone **total hip replacement surgery** in the United Kingdom, 96% of participants stated that Mepilex Border Post-Op did not restrict movement or pull on the skin, 92% stated that it was comfortable on removal, and 95% stated that the dressing did not need to be changed after showering (average 4.8 showers per patient) (Southern et al, 2023).

A retrospective review of the medical records of 558 patients who had Mepilex Border Post-Op applied following **hip or knee replacement** was undertaken in Belgium, with a focus on dressing wear time. The average wear time of the first dressing was 13.6 days, and 5.3 days for the second dressing. The proportion of patients who wore the first dressing for 1-7 days, 8-13 days and for greater than 14 days was 17.2%, 13.2% and 69.5%, respectively. These findings demonstrate the suitability of the dressing with Safetac for a 14-day wear time (Van Overschelde et al, 2024). Historically, post-operative wound care has involved frequent dressing changes which may be unnecessary. Frequent dressing changes have the potential to disrupt the healing process and increase the chance of incision site and peri-wound contamination (Rippon et al, 2012). Having access to post-operative dressings that can be left in place for up to 14 days enables clinicians to avoid tissue disturbance and contamination from frequent dressing changes, thus following the concept of undisturbed wound healing (Sandy-Hodgetts et al, 2021).

The silver-containing post-operative dressing with Safetac (Mepilex Border Post-Op Ag) is also used in the management of closed surgical incision sites, specifically in cases where the application of a topical antimicrobial is indicated. In a clinical study undertaken within an obstetrics and gynaecology department of a university teaching hospital in the United States of America (USA), women undergoing **primary caesarean sections** were recruited. Those who gave consent to participate (n=185) had Mepilex Border Post-Op Ag applied to their closed surgical incision sites (i.e. the intervention group), whereas those who declined to participate (n=190) had gauze with tape dressings applied (i.e. the control group). The overall SSI incidence was 3.7%; a 50% reduction (not statistically significant) in incidence was observed in the intervention group, relative to the control group (2.7% vs. 4.7%). Commenting on the results, the research team stated that the decrease in infection rates in both groups (in comparison with pre-study rates) may have been influenced by the adoption of a care bundle and awareness of the planned study heightening staff commitment to comply with the bundle (Goodman et al, 2022).

Implementation of a protocol incorporating the use of Mepilex Border Post-Op Ag for seven days post-operatively and the implementation of a closing surgical tray procedure post-**caesarean delivery**, coincided with a 54% reduction in SSI rates, potentially saving a USA-based facility US$244,629 in avoided treatment costs (Erickson, 2018). Similarly, **caesarean section** SSI rates fell from 4.0% (prior to the implementation of a dressing regime including Mepilex Border Post-Op Ag) to 1.2% (after implementation), equating to approximately US$1.3 million avoided costs (Underhill et al, 2018).

In a small study, again undertaken in the USA, the use of Mepilex Border Post-Op Ag on the closed incision sites of 20 patients undergoing **orthopaedic surgery** (TKA, n=9; THA, n=11) was evaluated. Dressing performance and patient experience were evaluated at post-operative days 1, 3 or 4 and 7. None of the 20 patients (all at least 90 days post-surgical procedure) showed signs of infection, maceration, leakage outside of dressing or skin injury caused by the dressing. No patients complained of pain at dressing removal (Korby & Myerthall, 2017).

Other dressings with Safetac have been used successfully in the management of closed surgical incision sites. For example, the efficacy of Mepilex Border was compared to that of three dressing combinations (Zetuvit with Cosmopor E; Zetuvit with Opsite Post-Op Visible; Aquacel Surgical) in an RCT involving 111 patients undergoing **TKA**. No wound complications were observed in the Mepilex Border group, but blisters were recorded in the Aquacel (6.9%) and Opsite (4%) groups. Irritation and erythema were highest in the Cosmopor group (12.9%; p=0.012). Based on a subjective assessment by the patients, the dressing with Safetac received the best scores for pain, freedom of movement and general comfort (Dobbelaere et al, 2015). Similarly, in a clinical study undertaken in Sweden to evaluate the use of Mepilex Border in the management of closed incision sites after **hip or knee arthroplasties**, none of the patients (n=117) developed blisters (Johannson et al, 2012).

A survey of nurses (n=113) from various surgical (gastroenterology, orthopaedics, plastic and reconstructive, vascular) and intensive care departments was undertaken in Finland to assess the usage of Mepilex Border in the management of closed incisions following a diverse range of surgeries (**hip, knee, vascular, cardiovascular, shoulder, caesarean section, laparotomy, back, breast and inguinal hernia**). Ninety one percent of respondents indicated that they had observed a decrease in peri-wound skin reactions (42% considered the decrease to be significant) following the introduction of Mepilex Border, compared to previously used post-operative dressing regimes. The vast majority (97%) of participants rated the overall performance of Mepilex Border as 'better' or 'much better' than previously used dressings; 100% rated the dressing as being 'easy' or 'very easy' to apply; 98% rated it as being 'easy' or 'very easy' to remove; and 100% rated its absorbency as 'good' or 'very good' (Pukki et al, 2010).

In a case study series, nine patients who had undergone **knee or hip replacement surgery** had their surgical incision sites dressed with Mepilex Border Lite (in theatre and at subsequent dressing changes). No dressing-related blistering was observed in any of the cases. The highest pain score recorded was 4 (on a scale ranging from 0 [no pain] to 10 [worst pain imaginable]) and this was transient in one patient shortly after the surgical procedure. The general trend for pain was in the region of 2-3 (reducing to 0-1) as the incision sites healed. The dressings were retained in place, absorbed blood and exudate, and did not cause damage to the surrounding skin (De Meyst & Meuleneire, 2010). These findings are consistent with other studies that have demonstrated Mepilex Border Lite (Morris et al, 2009; Meuleneire, 2009) and Mepilex Border Flex (Boixados et al, 2019; Rook et al, 2019) to be associated with minimal pain at dressing changes when used on various wound types including surgical wounds.

In a case study series undertaken in France, Mepilex Transfer was applied to sutured wounds following **hand surgery**. The thin, flexible exudate transfer dressing conformed well to the shape of the hand, facilitated good finger mobility from the day of the surgery, hardly adhered to the wound and was painless on removal (Lemarechal et al, 2009). Another case study series demonstrated that Mepilex Transfer was easy for patients to apply themselves, without any nursing assistance, following **breast surgery** (Renauld, 2009).

Meek & Downs reported on a quality improvement project (QIP) that set out to reduce the occurrence of SSIs in patients undergoing **orthopaedic surgeries** at an acute care facility in the USA. The project involved the introduction of Mepilex Border Ag dressings alongside an educational tool. Dressings were applied to orthopaedic patients intra-operatively and left in place for up to 3 days. Patients were then provided with a care package that included the educational tool and an additional dressing for use at home. At 7 days post-discharge, the patients changed their dressings. The new dressing was left in place until the 2-week follow-up. The following were observed: reduction in SSIs; excellent dressing conformability providing improved comfort and range of motion for patients; increased patient participation secondary to decrease in pain with dressing application and removal; ease of dressing application; and patient ability to shower without affecting the dressing or the wound (Meek & Downs, 2012).

Subsequently, details of two QIPs aimed at reducing the occurrence of SSIs at acute care facilities in the USA were reported. In the first reported QIP, a standard protocol of care for closed surgical incision sites, including the use of Mepilex Border Ag dressings, was introduced. Prior to the new care protocol being introduced, an SSI incidence rate of 10.9% was reported. After its introduction, the incidence fell to 3.3%, equating to an estimated cost avoidance of US$313,000 per year (Zurcher et al, 2013). The second reported QIP involved many process changes, including the introduction of Mepilex Border Ag dressings applied to the **mid-sternal closed incision site**s. As a result of the changes, the incidence of deep sternal wound infections reduced from 3.74 per 100 procedures to 0.7 and ultimately to zero. Over a period of approximately 30 months, during which 590 surgical procedures were carried out, no patients developed deep sternal wound infections, resulting in cost (US Dollars) savings in excess of $600,000 with 377 excess hospital days avoided (Kles et al, 2015).

The silver-containing wound contact layer, Mepitel Ag, and NPWT was used as part of a dressing regime alongside an extracellular matrix graft placement following surgical reconstruction of **pilonidal sinus disease**. There was minimal erythema, no signs of dehiscence and the patient reported no pain. No complications or recurrence were recorded during the 40-week follow-up period (Chaffin et al 2021).

Avance Solo is a portable, single-use negative pressure wound therapy (NPWT) system intended for use on a variety of open wound types and closed surgical incision sites. It consists of a fluid collection canister attached to a pump which delivers consistent negative pressure (-125 mmHg) via tubing and a transfer port to a specialised dressing (**Figure 2**). The dressing, Avance Solo Border, is coated with Safetac on its wound contact surface to minimise trauma and pain on removal. In a multi-centre clinical study, the system was applied to the closed surgical incision sites of 31 patients who had undergone a variety of surgery types (mostly **cardiovascular**-related). All incision sites remained closed throughout the 28-day follow-up period. The vast majority (87.1%) of patients had healthy peri-wound skin condition at the final visit. There were no reports of trauma to the incision sites throughout the study; trauma to the surrounding skin was noted on two occasions at day seven and on four occasions at the final visit. Patients experienced low levels of pain between and at dressing changes, and reported zero instances of pain that negatively impacted on their quality of life (Rose et al, 2024).

Figure 2. Avance Solo Negative Pressure Wound Therapy System with Avance Solo Border, a dressing coated with Safetac on its wound contact surface

Surgical wound healing by secondary intention

Numerous studies have been undertaken to evaluate dressings with Safetac in the management of various types of surgical wounds healing by secondary intention. The key studies are summarised in **Table 2**.

Table 2. Management of surgical wounds healing by secondary intention - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Campanella et al, 2011 RCT Australia	**Subjects:** 15 (age range 1-18 years) **Wounds:** Donor sites **Setting:** Burn care centres	**Safetac:** Mepitel (n=8) **Comparator:** SurfaSoft (n=7) Donor sites in both groups treated with ECS prior to dressing application	Wound size / epidermal maturation (measured by SEC) Pain severity (measured using four scales (CHIPPS, FLACC, FPS-R, VAS), depending on patient age) Ease of dressing removal (peel-force gauge)	Similar trends in wound size reduction and epidermal maturation in both groups. Greater overall mean difference (reduction) in pain intensity from day 2 to day 8 in the Mepitel group (5.02) versus 1.91 in the comparator group. Mepitel group associated with significantly lower pain levels than comparator group during dressing changes ($p<0.01$). Slightly lower dressing removal peak peel-force (approximately 0.1 kgF) observed in the Mepitel group.
Berard & Lau, 2022 RCT United States of America	**Subjects:** 25 (average age: 45 years) **Wound type:** Acute wounds from surgical excision of skin and/or subcutaneous tissue **Setting;** Plastic and reconstructive surgery department	**Safetac:** Mepitel Ag (n=15) **Comparator:** Gauze (n=10) Evaluation duration (average): 5-7 weeks	Infection Time to wound closure Pain severity	Low infection rates in both groups: - Mepitel Ag: 6.7% (n=1) - Gauze: 10.0% ((n=1) Shorter (not statistically significant) mean time to wound closure in Mepitel Ag group: - Mepitel Ag: 4.4 weeks - Gauze: 6.0 weeks Significantly lower mean pain severity scores in Mepitel Ag group ($p=0.008$): - Mepitel Ag: 1.1 - Gauze: 2.8

Abbreviations: CHIPPS = Children and Infants Postoperative Pain; ECS = epithelial cell suspension; FLACC = Face, Legs, Arms, Crying, Consolability; FPS-R = Faces Pain Scale – Revised; RCT = randomised controlled trial; SEC = surface electrical capacitance; VAS = visual analogue scale

An RCT was undertaken in the plastic and reconstructive surgery department at a university teaching hospital in the USA. Patients with **acute surgical wounds** were randomised to either Mepitel Ag (n=15) or gauze (n=10) dressings. Infection rates were low in both groups (Mepitel Ag 6.7%, gauze 10.0%). There was a non-statistically significant trend toward shorter time to healing in the wounds dressed with the silver-containing wound contact layer (4.4 weeks vs. 6.0 weeks in the gauze group). Patients in the Mepitel Ag group had less severe pain than those in the gauze group (mean scores of 1.1 and 2.8 respectively; $p=0.008$) (Berard & Lau, 2022).

In a case study series undertaken in Spain, 10 post-surgical **scalp wounds** were dressed with Mepilex Border Flex. All wounds healed within 3 weeks. Patients preferred the dressing with Safetac to previously used bulky bandages (Conde Montero, 2019). Joncas et al describe the closure of a large, non-healing abdominal surgical wound in a neonate. After the placement of a dermal substitute in the wound, Mepitel was used to cover it, then a silver-containing dressing followed by a Mepilex Border dressing was applied. Dressings were changed three times per week. The wound proceeded to close by secondary intention, with complete healing within two months (Joncas et al, 2010).

Dehisced wounds

The Avance Solo single-use (NPWT) system, with Avance Solo Border dressings (**Figure 2 and Figure 3**), was evaluated in a multi-centre (n=10) study conducted across four European countries involving in- and out-patients with low-to-moderately exuding acute (traumatic, flap/graft) or sub-acute (e.g. dehisced) wounds. Of the 104 patients recruited, 23 presented with **dehisced wounds**. The wounds were assessed at weekly visits for up to 28 days. Wound progress was noted as improved at 80.7% of follow-up visits, relative to the previous visit (**Figure 4**). At the final visit, the mean decrease in wound area was 43.6%, relative to baseline. Increases in the proportion of wounds with no necrotic (40.5%) or sloughy tissue (36.3%), and in the proportion of patients with healthy peri-wound skin (8.5%), compared to baseline, were also observed. Pain severity scores at dressing changes were low throughout the study, with a mean score of 1.6 on a numerical ratings scale ranging from zero (no pain) to 10 (worst imaginable pain). The vast majority (95%) of patients had no dressing-related trauma to the wound at the final visit; 93% had no dressing-related trauma to the peri-wound skin at the final visit (Beele et al, 2025).

Lower limb amputation in the developed world happens most frequently due to ischaemia or infection, resulting from peripheral vascular disease, diabetes or renal failure (Kozhakhmetov et al, 2024; Seo et al, 2023). Post-amputation wounds are complex, and require dressings that are conformable, can manage exudate even under the compressive forces of shrinker socks and prostheses, and comfortable for the patient to wear. In a case series of three **dehisced transtibial post-amputation wounds**, Mepilex dressings were used as part of a regime to address the dehiscence and allow rehabilitation to continue. Despite the first case presenting with completely dehisced, heavily exudating and extremely painful wounds with the distal ends of both tibia exposed (**Figure 5**), almost complete healing was achieved by week 22. Similar successes were achieved with the other two patients, who were able to continue physiotherapy and mobilisation with the aid of bilateral prostheses even with open wounds (Weaver & Crawford 2007).

Mepitel One was used in the successful management of **toe amputation wounds** that became infected post-operatively. In the first of two cases presented, the wound contact layer was used to retain a topical antimicrobial cream in place on a difficult-to-dress area. The second case involved the use of a silver-containing primary dressing that the patient found uncomfortable and had a tendency to slip off the wound bed when covered with a secondary dressing. The problem was overcome by cutting Mepitel One into strips that were then used to retain the primary dressing securely in place. A non-adhesive absorbent pad was then applied on top of the wound contact layer, secured by a tubular retention bandage and orthopaedic padding (Cooper et al, 2010).

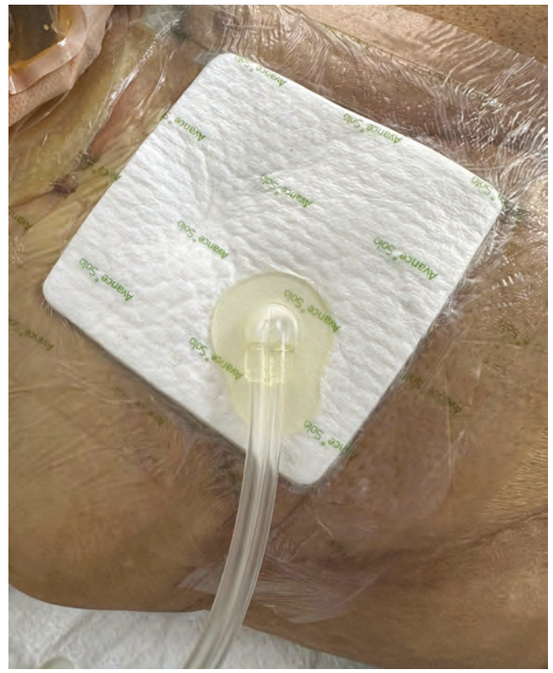


Figure 3. Avance Solo Border dressing applied to a dehisced surgical wound. (photograph courtesy of Chew Khong Yik, Singapore General Hospital, Singapore)

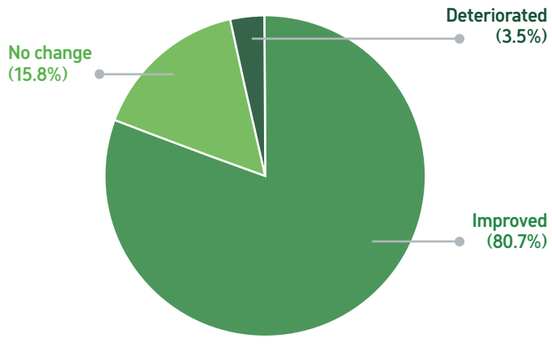


Figure 4. Progression toward healing of acute wounds managed with Avance Solo NPWT System at study assessments (Beele et al, 2015)

Donor sites

In the context of skin grafting, a commonly used intervention in the management of wounds where primary closure is not possible, a donor site refers to the area of the body from which healthy skin is harvested to be transplanted to the wound (the recipient site). The two main types of skin grafts are split-thickness (involving the epidermis and part of the dermis) and full-thickness (involving the epidermis and the entire dermis) (Andreassi et al, 2005). Common donor sites include the thigh, buttocks, back and upper arms for split-thickness grafts; with the groin, postauricular region and supraclavicular area often being the source of full-thickness grafts (Shimizu & Kishi, 2012).

An RCT was undertaken in Australia to examine the effects of Mepitel and a monofilament polyamide woven dressing (SurfaSoft) on the rate of epithelialisation and epidermal maturation, pain, and ease of dressing removal on **paediatric donor sites** treated with epithelial cell suspension (ReCell). Fifteen children (1–15 years) admitted for acute or reconstructive burns procedures were randomly assigned to either the Mepitel group (n=8) or to the SurfaSoft group (n=7). All donor sites were treated with ReCell and covered with the assigned dressing. There was no difference in the rate of epidermal maturation between the two groups. Less pain and force to remove the dressing was shown in the Mepitel group when compared to SurfaSoft. The findings suggest that Mepitel's pliable, self-adhesive and atraumatic properties may improve healing of ReCell-treated donor sites with less pain at dressing changes (Campanella et al, 2011).

Exudate transfer dressings are designed to move excess exudation away from the wound into a secondary absorbent layer, thereby minimising the risk of moisture-related damage to the wound and surrounding skin, whilst maintaining a moist wound environment (Arnold-Long, 2015). Their ability to separate absorption from retention allows clinicians to tailor dressing combinations to the specific needs of the wound. In a multi-centre clinical study undertaken across three specialist centres in the USA, the use of Mepilex Transfer Ag on **donor sites** (≤30% total body surface area) was evaluated. Pain levels experienced by the patients (n=19) were considered to be acceptable for donor site wounds. The exudate transfer dressing efficiently managed the peri-wound, was observed to be flexible, conformable, comfortable to wear, adhered adequately to the donor sites but was easy to remove (Glat et al, 2017). The same dressing was evaluated in a case study series involving patients who presented with leg ulcers and **donor sites**. The use of Mepilex Transfer Ag was associated with a decrease in the frequency of dressing changes by allowing exudate to pass through to a secondary dressing. This resulted in decreased pain and enhanced

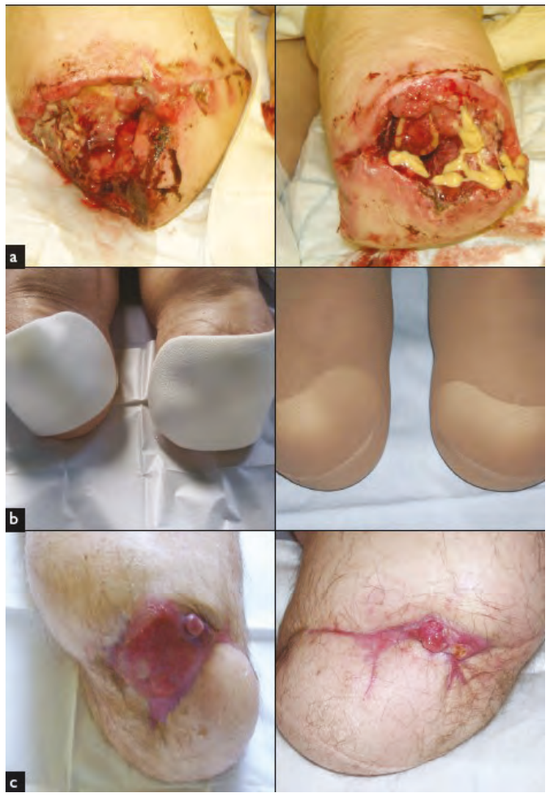


Figure 5. Bilateral transtibial amputation wounds (a) prior to first application of Mepilex dressings; (b) dressings in place; (c) wounds almost healed 5 months after first application of Mepilex. (photographs courtesy of Gill Weaver, Manchester Royal Infirmary, Manchester, United Kingdom)

wound insulation. The antimicrobial effect of the dressing likely decreased bacterial load (Arnold-Long, 2015).

In a retrospective review of burn patients whose split-thickness skin graft **donor sites** had been dressed with either an autograft or Mepilex Ag across two burn centres, the patients who had autografts applied had increased odds of donor site infection (OR=1.08, p=0.002). Analysis also revealed that donor sites dressed with the silver-containing foam dressing had a lower rate of infection compared to those dressed with gauze. However, it is important to note that, due to insufficient supporting data, the use of Mepilex Ag on donor sites is not listed in the manufacturer's instructions for use supplied with the dressing.

References

Andreassi, A., Bilenchi, R., Biagiolo, M., D'Aniello, C. (2005) Classification and pathophysiology of skin grafts. Clinical in Dermatology 23(4):332-337.

Anusitviwat, C., Tuenyongviwat, V. (2025) Comparing silicone-coated self-adhesive absorbent polyurethane films with transparent absorbent films for bilateral hip dressing: a prospective randomised controlled trial. Journal of Orthopaedic Surgery and Research 20:129.

Arnold-Long, M. (2015) Initial patient outcomes with use of an absorbent antimicrobial soft silicone exudate transfer foam dressing: a case series. Poster presentation at 47th Annual Conference of the Wound Ostomy and Continence Nurses' Society, San Antonio, Texas, United States of America.

Beele, H., Van Overschelde, P., Olivecrona, C., Smet, S. (2020) A prospective randomized controlled clinical investigation comparing two post-operative wound dressings used after elective hip and knee replacement: Mepilex Border Post-Op versus Aquacel surgical. International Journal of Orthopaedic and Trauma Nursing 38:100772.

Beele, H., Amann, B.; Carnali, M., Danneels, M., Gibello, L., Goueffic, Y., Piffaretti. G., Timmons, J. (2025) Evaluation of a novel, canister-based, portable negative pressure wound therapy system in the management of low-to-moderately exuding acute and subacute wounds. Poster presentation at European Wound Management Association Conference, Barcelona, Spain.

Berard, M.B., Lau, F.H. (2022) Pilot study of minimally adherent silver dressings for acute surgical wounds. Health Science Reports 5(6):e865.

Boixados, D., Allaert, F.A., Drareni, W. (2019) Efficacy of a five-layer silicone foam dressing with 360-degree flex technology for chronic and acute wound management in home care settings E-poster presentation at European Wound Management Association Conference, Gothenburg, Sweden.

Bredow, J., Hoffmann, K., Oppermann, J., Hellmich, M., Eysel, P., Zarghooni, K. (2018) Evaluation of absorbent versus conventional wound dressing - a randomised controlled study in orthopedic surgery. Deutsches Arzteblatt International 115(3):213-219.

Campanella, S.D., Rapley, P., Ramelet, A.S. (2011) A randomised controlled pilot study comparing Mepitel and SurfaSoft on paediatric donor sites treated with ReCell. Burns 37(8):1334-1342.

Chaffin, A.E., Dowling, S.G., Kosyk, M.S., Bosque, B.A. (2021) Surgical reconstruction of pilonidal sinus disease with concomitant extracellular matrix graft placement: a case series. Journal of Wound Care 30(Supplement 7):S228-S234.

Conde Montero, E., Perez Jeronimo, L., Peral Vazquez, A., Recarte Marin, L., de la Cueva Dobao, P. (2019) Punch grafting to promote epithelialisation of post-surgical scalp wounds. Poster presentation at Journees Plaies et Cicactrisations, Paris, France.

Cooper, P., Gray, D., Russell, F., Stringfellow, S. (2010) Case study using Mepitel One wound contact dressing with Safetac. Wounds International 1-11.

Davies, P. (2022) Closed incision negative pressure wound therapy: a literature review and an introduction to Avance Solo. Wounds International, London, United Kingdom.

De Meyst, G., Meuleneire, F. (2010) A case study series evaluation of a silicone coated foam dressing in the treatment of patients undergoing orthopaedic surgery. Poster presentation at the European Wound Management Association Conference, Geneva, Switzerland.

Dobbelaere, A., Schuermans, N., Smet, S., Van der Straeten, C, Victor, J. (2015) Comparative study of innovative postoperative wound dressings following total knee arthroplasty. Acta Orthopaedica Belgica 81(3):454-461.

Erickson, M. (2018) Embracing action to achieve a significant reduction in C-section surgical site infection rates and reducing facility costs by implementing antimicrobial soft silicone foam dressing and closing surgical trays. Poster presentation at Association of periOperative Registered Nurses Global Surgical Conference & Expo, New Orleans, Louisiana, United States of America.

Fumarola, S., Allaway, R., Callaghan, R., Collier, M., Downie, F., Geraghty, J., Kiernan, S., Spratt, F., Bianchi J., Bethell, E., Downe, A., Griffin, J., Hughes, M., King, B., LeBlanc, K., Savine, L., Stubbs, N., Voegeli, D. (2000) Overlooked and underestimated: medical adhesive-related skin injuries. Journal of Wound care 29(Supplement 3c):S1-S24.

Glat, P., Smith, D., Foster, K.N., Karlnoski, R. (2017) Clinical investigation of the performance and safety of a soft silicone wound contact layer containing silver in the treatment of skin grafts and a soft silicone transfer dressing containing silver in the treatment of donor sites in surgical burn patients. Poster presentation at Symposium on Advanced Wound Care (Spring). San Diego, California, United States of America.

Goodman, J.R., Durazo-Arvizu, R., Nashif, S., McAlarnen, L.A., Wagner, S.A., Lal, A.K. (2022) Preventing caesarean section wound complications: use of a silver-impregnated antimicrobial occlusive dressing. Journal of Wound Care 31(7 North American Supplement):S5- S14.

Hampton, S. (2020) Medical adhesive related skin injury: methods of prevention. Nursing and Residential Care 22(3):148-154.

Holloway, S., Harding, K.G. (2022) Wound dressings. Surgery (Oxford) 40(1):25-32.

Howell, R.D., Hadley, S., Strauss, E., Pelham, F.R. (2011) Blister formation with negative pressure dressings after total knee arthroplasty. Current Orthopaedic Practice 22(2):176-179.

Johansson, C., Hjalmarsson, T., Bergentz, M., Melin, M., Sandstedt, P., Johansson, C. (2012) Preventing post-operative blisters following hip and knee arthroplasty. Wounds International 3(2):1-6.

Joncas, V., Prado, R., Ritchie, C.P., Kaufman, M., Schober-Flores, C., Arbuckle, H.A. (2010) The closure of a large chronic abdominal wound in a neonate utilizing a biologic dressing. Advances in Skin and Wound Care 23(9):404-405.

Kles C.L., Murrah, C.P., Smith, K., Baugus-Wellmeier, E., Hurry, T., Morris, C.D. (2015) Achieving and sustaining zero. Preventing surgical site infections after isolated coronary artery bypass with saphenous vein harvest through implementation of a staff-driven quality improvement process. Dimensions of Critical Care Nursing 34(5):265-272

Korby, K., Myerthall, S. (2017) Evidence-based practice: clinical evaluation of a new silver soft silicone postoperative dressing in total knee and hip arthroplasty. Poster presentation at the 18th Annual Physician Assistants in Orthopaedic Surgery Conference, Baltimore, Maryland, United States of America.

Kozhakhmetov, Z., Sabitov, E., Salmenbaev, Y., Imanbaev, M., Toleutayev, T., Kazymov, Y., Masalov, A. (2024) Improvement of lower limb amputation procedure in patients with critical lower limb ischaemia. Georgian Medical News (356):28-38.

Lemarechal, P., Savard, V., François, D. (2009) Mepilex Transfer dans les suites opératoires de la chirurgie de la main. Poster presentation at 13ème Conferénce Nationale des Plies et Cicatrisations, Paris, France.

McCaughan, D., Sheard, L., Cullum, N., Dunville, J., Chetter, I. (2020) Nurses' and surgeons' views and experiences of surgical wounds by secondary intention: a qualitative study. Journal of Clinical Nursing 29:2557-2571.

Meek, K., Downs, B. (2012) Post operative complication process improvement in the orthopedic population. Poster presentation at the Association of Perioperative Registered Nurses 59th Annual Congress, New Orleans, Louisiana, United States of America.

Meuleneire, F. (2009) Case study evaluation of Safetac dressings used for paediatric wounds. Wounds UK 5(2): 12-18.

Morris, C., Emsley, P., Marland, E., Meuleneire, F., White, R. (2009) An observational study of dressing with soft silicone adhesive technology to manage the wounds of paediatric patients. Paediatric Nursing 21(3):38-43.

Norman, G., Goh, E.L., Dunville, J.C., Chunhu, S., Zhenmi, L., Chiverton, L., Stankiewicz, M., Reid, A. (2020) Negative pressure wound therapy for surgical wounds healing by primary closure. Cochrane Database of Systematic Reviews 15(6):CD009261.

Ousey, K., Gillibrand, W., Stephenson, J. (2011) Understanding and preventing wound blistering. Wounds UK 7(4):50-56.

Peghetti, A. (2018) Prevention of post-operative surgical site complications: a quality improvement project. Poster presentation at European Wound Management Association Conference, Krakow, Poland, 2018

Pukki, T., Tikkanen, M., Halonen, S. (2010) Assessing Mepilex Border in post-operative wound care. Wounds UK 6(1):30-40.

Ravenscroft, M.J., Harker, J., Buch, K.A. (2006) A prospective, randomised, controlled trial comparing wound dressings used in hip and knee surgery: Aquacel and Tegaderm versus Cutiplast. Annals of the Royal College of Surgeons of England 88:18-22.

Renauld, V. (2009) Utilisation d'un pansement hydromousse de contact extra souple au décours de la diminution mammaire. Poster presentation at 13ème Conférence Nationale des Plaies et Cicatrisations, Paris, France.

Rippon, M., Davies, P., White, R. (2012) Taking the trauma out of wound care: the importance of undisturbed healing. Journal of Wound Care 21(8):359-368.

Rook, S., Davies, P., Frenthoff, E., Wurfel, T (2019). Mepilex Border Flex – results of an observational study in German specialist wound care centres. Wounds International 10(1):40-43.

Rose, V., Hachah Haram, N., Gallala, S. (2024) A new portable negative pressure wound therapy device: a prospective study investigating clinical outcomes. Journal of Wound Care 33(11):833-840.

Sandy-Hodgetts, K., Ousey, K., Conway, B., Djohan, R., Nair, H.K.R., Serena, T.E., Tariq, G. (2020) International best practice recommendations for the early identification and prevention of surgical wound complications. Wounds International, London, United Kingdom.

Sandy-Hodgetts, K., Cao, L., Doozhang, C., Hyun, L.S>, Keng, T.B., Koboyashi, J., Nariani, B., Morgan-Jones, R. (2021) Post-surgical incision care across the Asia-Pacific region: current practice and perceptions. Wounds International 12(3):63-69.

Sandy-Hodgetts, K., Morgan-Jones, R. (2024) Incision care and dressing selection in surgical incision wounds. Findings from an international meeting of surgeons from Australia. Wounds International, London, United Kingdom.

Scalise, A., Calamita, R., Tartaglione, C., Pierangeli, M., Bolletta, E., Gioacchini, M., Gesuita, R., Di Benedetto, G. (2016) Improving wound healing and preventing surgical site complications of closed surgical incisions: a possible role of incisional negative pressure wound therapy: a systematic review of the literature. International Wound Journal 13(6):1260-1281.

Seo, M.J., Lee, D.G., Ko, S.Y., Song, G.Y., Lee, G.Y., Kim, S.H., Kang, D.R., Kim, J., Lee, J.Y. (2023) Risk factors for lower extremity amputation in patients with end-stage kidney disease: a nationwide cohort study. Journal of Clinical Medicine 12(17):5641.

Shimizu, R., Kishi, K. (2012) Skin graft. Plastic Surgery International 2012;563493.

Southern, K., Wainwright, T., Middleton, R. (2023) Compliance with the ISWCAP checklist in a THR ERAS pathway - a snapshot audit. Clinical Nutrition ESPEN 57;810.

Srivastava, N., Manisha, G.A., Goyal, M., Kumar, M., Kumar, M. (2025) Comparative efficacy of advanced and traditional wound dressings in post-operative orthopaedic care for hip and knee surgeries: a randomized controlled trial. Journal of Clinical Orthopaedics and Trauma 63:102933.

Toon, C.D., Lusuku, C., Ramamoorthy, R., Davidson, B.R., Gurusamy, K.S. (2015) Early versus delayed dressing removal after primary closure of clean and clean-contaminated surgical wounds. Cochrane Database of Systematic Reviews (9):CD010259

Underhill, J., Johnson, C., Rhodes, K. (2018) Decreasing Cesarean section surgical site infection rates by changing post op care: an interdisciplinary approach. Poster presentation at Association of periOperative Registered Nurses Global Surgical Conference & Expo, New Orleans, Louisiana, United States of America.

Van Overschelde, P., Sinnaeve, F., Lapierre, C., Pauwels, A., Alam, K., Sandy-Hodgetts, K. (2024) A single centre RetrospeCtive sTudy Investigating patient-reported outcomeS of extended dressing wear time for incisional healing following orthopaedic surgery: the ARCTIS study. Journal of Wound Care 33(Supplement 8):S17-S26.

Weaver, G., Crawford, K. (2007) The use of Mepilex on dehisced amputation wounds. Wounds UK 3(1):70-74.

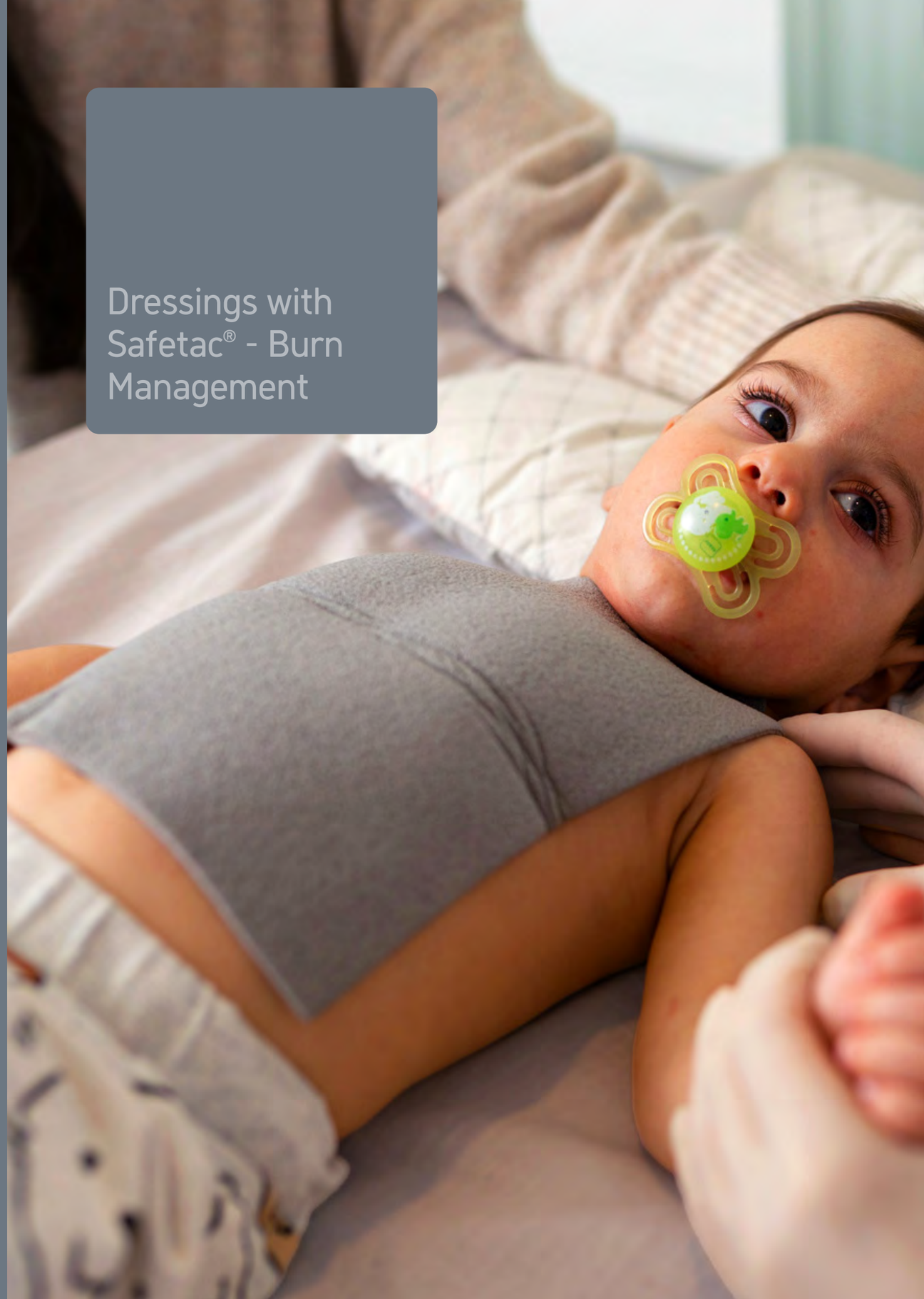
World Union of Wound Healing Societies (WUWHS). (2016) Consensus document. Closed surgical incision management: understanding the role of NPWT. Wounds International, London, United Kingdom.

Yang, T.Y., Park, J.E., Kim, J.B., Lee, N.H. (2025) Incidence and characteristics of medical adhesive-related skin injuries in patients following spinal surgery: a prospective observational study. International Wound Journal 22:e70457.

Zarghooni, K., Bredow, J., Siewe, J., Deutloff, N., Meyer, H.S., Lohmann C. (2015) Is the use of modern versus conventional wound dressings warranted after primary knee and hip arthroplasty? Acta Orthopaedica Belgica 81(4):768-775.

Zurcher, S., Krapfl, L., Burds, A. (2013) Reducing postoperative surgical site infections in coronary artery bypass graft patients. Poster presentation at the 45th Annual Conference of the Wound Ostomy and Continence Nurses Society, Seattle, Washington, United States of America.

Dressings with Safetac® - Burn Management



Dressings with Safetac featured:

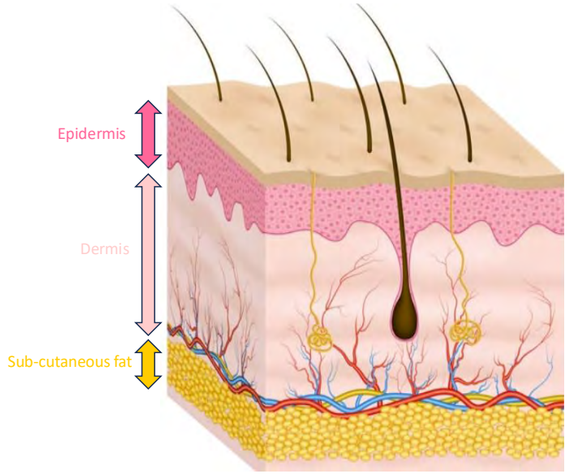
Mepilex® Ag, Mepilex® Border Ag, Mepilex® Border Lite, Mepilex® Transfer, Mepilex® Transfer Ag, Mepitel®, Mepitel® Ag, Mepitel® One

Take home messages:

- Burn wounds are associated with slow healing, predisposition to wound bed trauma, susceptibility to infection, high exudation, desiccation, scarring, pain (particularly at dressing changes), distress and reduced patient quality of life.
- Silver-containing foam dressings with Safetac have been demonstrated in numerous randomised controlled trials (RCTs) to outperform silver sulphadiazine (SSD) and other dressings with regard to burn wound management – i.e. reduced healing times, less dressing-related pain, better scar outcomes, higher satisfaction ratings (clinicians and patients) and greater cost-effectiveness.
- Wound contact layers with Safetac have also been demonstrated in RCTs to outperform SSD and other dressings – reduced healing times, less dressing-related trauma and pain, and reduced treatment costs – in burn wound management.
- Studies have also demonstrated the ability of wound contact layers with Safetac to facilitate skin graft take.

Introduction to burns

Burns are injuries that occur when heat (i.e. scalds (hot liquids), contact burns (hot solids) and flames), radiation, radioactivity, electricity, friction or contact with chemicals causes cellular damage to the skin or other tissues (Zwierello et al, 2023). Burns vary in severity, with a wide range of clinical needs depending on multiple factors, e.g. anatomical location, degree of temperature, duration, surface area and depth (Evans et al, 2010). They are generally classified by depth (**Figure 1**) (Zwierello et al, 2023; Malhotra et al, 2024).



Superficial (first-degree)	• Involves epidermis only • Pink-red, dry (no blisters) appearance • Typical healing time: 5-10 days (without scarring)
Superficial partial thickness (second-degree)	• Extends down to superficial dermis • Red, dry (with blisters) appearance; blanchable erythema • Severe pain • Typical healing time: <3 weeks (with minimal scarring)
Deep partial thickness (second-degree)	• Extends down to deep dermis • Yellow-white, dry appearance; non-blanchable erythema • Minimal pain (due to decreased sensation) • Typical healing time: 3-8 weeks (with scarring)
Full thickness (third-, fourth-, fifth- and sixth-degree)	• Extends down to sub-cutaneous structures • White-black/brown, leathery, dry appearance; non-blanchable (third degree); charred skin and possible exposed bone (fourth degree); charred, white skin and exposed bone (fifth degree); loss of skin and exposed bone (sixth degree) • Minimal pain (due to decreased sensation) • Typical healing time: >8 weeks (heals by contracture) • Requires skin grafting

Figure 1. Classification of burns according to their impact on the skin (Zwierello et al, 2023; Malhotra et al, 2024)

Challenges

While morbidity and mortality rates for severe burns remain high, early removal of devitalised tissue and skin grafting are now common practices that have significantly improved patient outcomes. Despite these advances in burn care, clinicians have to address a number of major challenges such as slow healing, predisposition to wound bed trauma, susceptibility to infection, high exudation, desiccation, scarring, pain (particularly at dressing changes), distress and reduced patient quality of life (Butcher & Swales, 2012; Roy et al, 2024; Wang et al, 2018; Solowiej et al, 2009; Gauffin et al, 2016). Failure to address these challenges can lead to complications such as partial-thickness burns developing into full thickness skin loss requiring costly surgical intervention and increased risk of morbidity and mortality (Atiyeh et al, 2014).

The overall aim of burn care is to minimise the adverse effects caused by the injury, i.e. maintaining range of movement, minimising contracture development and the impact of scarring, promoting functional ability, and maximising psychological wellbeing and social integration (Procter, 2010; Manasyan et al, 2025).

Role of dressings in burn management

Topically applied products play an important role in burn care by promoting wound healing, preventing wound infection and graft loss, and maintaining movement and function of the affected body part (Atiyeh et al, 2014; Booth et al, 2013). Dressings provide a protective barrier until tissue integrity is re-established or, if this is not possible, until reconstruction (e.g. skin grafting) can be undertaken. Following reconstruction, dressings provide further protection and an optimal environment in which stabilisation and healing of the skin graft can take place (Butcher & Swales, 2012). Clinicians have access to a wide array of dressing types for use in burn wound care including, but not limited to, absorbent dressings (e.g. foams) that are used to manage excess exudate, and exudate transfer dressings and wound contact layers that allow exudate to pass through their structures into secondary absorbent dressings that can be changed as required, without inflicting dressing change-related trauma to the wound. Many of the available dressing types include variants containing antimicrobial agents, should topical antimicrobial therapy be indicated.

For many years, silver sulphadiazine (SSD) creams were used as one of the standard treatments for partial thickness burns (Hermans, 2008). However, several side effects of SSD creams (leukopenia, hypersensitivity, allergic reactions, wound bed discolouration, microorganism resistance, and pain during application and removal) have been documented (White & Cooper, 2005). Consequently, an alternative approach to the topical antimicrobial management of partial thickness burns that is at least as effective as SSD but associated with fewer side effects was justified. One such alternative is silver-containing dressings with Safetac technology (Davies et al, 2017).

Evidence for dressings with Safetac

Foam dressings

Numerous randomised controlled trials (RCTs) have been undertaken to investigate the efficacy of Mepilex Ag, a silver-containing foam dressing with Safetac (**Figure 2**), in the management of burn wounds. These are summarised in **Table 1**.

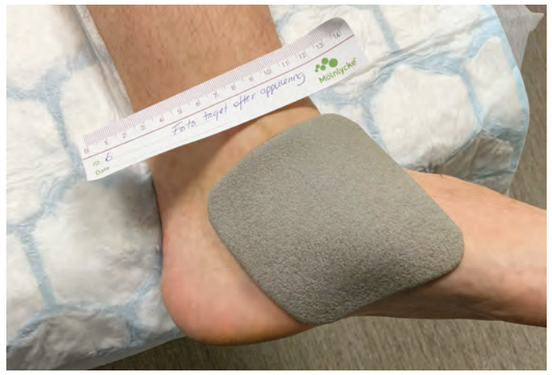


Figure 2. Mepilex Ag applied to a superficial partial thickness burn on the inside of the foot. (photograph courtesy of Matilda Karlsson, Linkoping University Hospital, Sweden)

Table 1. Mepilex Ag – burns - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Aggarwala et al, 2021 RCT Australia	**Subjects:** 119 (age range 18-65 years) **Wounds:** Partial thickness burns <72 hours post injury (TBSA 0.3-6%) **Setting:** Ambulatory care	**Safetac:** Mepilex Ag (n=35) **Comparators:** Acticoat (n=37); Aquacel Ag (n=27); Biobrane (n=32) Dressings changed every 3 days until healing had occurred (apart from Biobrane which was inspected until re-epithelialisation but not changed)	Time to healing (>95% re-epithelialisation) Cost effectiveness	Shorter mean re-epithelialisation time in the Mepilex Ag group (8.9 days), compared to Acticoat (9.6 days), Aquacel Ag (9.6 days) and Biobrane (10.8 days) groups, but differences not statistically significant. 26% greater number of days to re-epithelialisation in Biobrane group compared to Mepilex Ag group (p<0.01 when adjusted for gender, age, smoking status, burn mechanism, TBSA and first aid frequency). 99%, 71% and 53% probability that Mepilex Ag dominated (less expensive and more effective) Biobrane, Acticoat and Aquacel Ag, respectively.
Karlsson et al, 2019 RCT Sweden	**Subjects:** 58 (age range 1-5 years) **Wounds:** Partial thickness scalds <72 hours post injury (TBSA 3-22%) **Setting:** Burn care centre	**Safetac:** Mepilex Ag (n=28) **Comparator:** Porcine xenograft (n=30) Treatment duration: up to 42 days. Dressings changed up to 3 times per week	Time to healing (97% and 100% re-epithelialisation) Dressing usage Pain; infection; length of hospital stay; need for surgery	Shorter 97% re-epithelialisation time (median) in Mepilex Ag group (9 days), compared to xenograft group (15 days) (p=0.004). Shorter 100% re-epithelialisation time (median) in Mepilex Ag group (15 days), compared to xenograft group (20.5 days) (p=0.01). Number of dressing changes and time for dressing changes were lower in the Mepilex Ag group (p=0.03 for both variables), compared to xenograft group. No significant difference between groups in terms of pain, infection, length of hospital stay and need for surgery.
Gee Kee et al, 2015 RCT	**Subjects:** 96 (age range 0-15 years) **Wounds:** Superficial partial to deep partial thickness burns <72 hours post injury (TBSA ≤10%) **Setting:** ED / paediatric burn care centre	**Safetac:** Mepilex Ag (n=33) **Comparators:** Acticoat (n=31); Acticoat with Mepitel (n=32) Treatment duration: up to 14 days. Dressings changed every 3-5 days	Time to healing (≥95% re-epithelialisation) Pain at dressing removal and new application (measured using FLACC and VAS-P scales)	Median healing time (days): - Mepilex Ag group: 7.0 - Acticoat group: 9.5 - Acticoat with Mepitel group: 10.0 After adjusting for burn depth, healing times were 40% and 33% longer in the Acticoat group and Acticoat with Mepitel group respectively, compared to the Mepilex Ag group (p≤0.01). FLACC scores in the Mepilex Ag group were 32% lower at dressing removal (p=0.01) and 37% lower at new dressing application (p=0.04) compared to the Acticoat group; scores in the Acticoat with Mepitel group were 23% lower at dressing removal (p=0.04) and 40% lower at new dressing application (p<0.01), compared to the Acticoat group. VAS-P scores in the Mepilex Ag group were 25% lower at dressing removal (p=0.04) and 34% lower in the Acticoat with Mepitel group (p=0.02) at new dressing application, compared to the Acticoat group.
Gee Kee et al, 2017 Cost-effectiveness analysis (based on RCT) Australia			Cost-effectiveness	Median costs (dressings, analgesics, scar management) were lower in the Mepilex Ag group (AU$94.45) compared to the Acticoat (AU$244.90) and Acticoat with Mepitel (AU$196.66) groups. 99% and 97% probability that Mepilex Ag dominated (less expensive and more effective than) Acticoat and Acticoat with Mepitel, respectively.
Tang et al, 2015 RCT China	**Subjects:** 153 (age range 5-65 years) **Wounds**: Deep partial thickness thermal burns <36 hours post injury (TBSA 2.5-25%) **Setting:** Burn care centre	**Safetac:** Mepilex Ag (n=71) **Comparator:** SSD cream (n=82) Treatment duration: up to 14 days. Dressings changed every 5-7 days	Time to healing (>95% re-epithelialisation) Dressing usage Pain severity scores (measured using VAS)	No significant difference in healing rates between groups: - Mepilex Ag group: n=56 healed (79%); median healing time 15 days - SSD group: n=65 healed (79%); median healing time 16 days Mean total number of dressings used was lower in the Mepilex Ag group (3.06), compared to the SSD group (14.0) (p<0.0001). Mepilex Ag was rated higher than SSD by clinicians in terms of ease of application, lack of dressing adherence, ease of removal and overall experience (p<0.0001). Mepilex Ag was rated higher than SSD by patients in terms of experience of anxiety during dressing change, ease of movement while wearing it, ability to remain in place and lack of stinging/burning while wearing it (p<0.0001). Pain at dressing change (before, during and after removal) was lower in the Mepilex Ag group, compared to the SSD group (p≤0.0254).

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Silverstein et al, 2011 RCT United States of America	**Subjects:** 100 (age range 8-88 years) **Wounds:** Partial thickness burns <36 hours post injury (TBSA 2.5-20%) **Setting:** Burn care centres	**Safetac:** Mepilex Ag (n=49) **Comparator:** SSD cream (n=51) **Treatment duration:** up to 21 days. Dressings changed every 1-7 days	Time to discharge from inpatient hospital care	Mean time to hospital discharge (days) was shorter in the Mepilex Ag group (p=0.034): - Mepilex Ag group: 5.6 - SSD group: 8.3
			Healing time	No significant difference in mean healing times (days) between groups: - Mepilex Ag group: 13.4 - SSD group: 17.1
			Pain severity scores (measured using VAS)	Pain intensity was lower in the Mepilex Ag group at dressing application (p=0.018), during wear (p=0.048) and on removal (p=0.097), compared to the SSD group.
			Dressing usage	Mepilex Ag was rated higher than SSD in terms of ease of use (p=0.0028) and flexibility (p=0.0038).
			Treatment costs	Total cost of treatment per patient: - Mepilex Ag group: US$309 - SSD group: US$514

Abbreviations: AU$ = Australian Dollars; ED = emergency department; FLACC = face, legs, activity, cry, consolability; RCT = randomised controlled trial; SSD = silver sulphadiazine; US$ = United States Dollars; TBSA = total body surface area; VAS = visual analogue scale; VAS-P = Visual Analogue Scale-Pain

Healing

In several of the RCTs summarised in **Table 1**, healing time was found to be significantly shorter in burns dressed with Mepilex Ag, compared to those receiving other interventions. For example, in the earlier of the two RCTs undertaken in Australia, it was observed that **superficial partial to deep partial thickness burns** dressed with Mepilex Ag had the quickest time to re-epithelialisation (median 7.0 days), with a nanocrystalline silver-containing dressing associated with a 40% increase in expected days to full re-epithelialisation (p<0.01) (Gee Kee et al, 2015). **Partial thickness scalds** dressed with Mepilex Ag had a significantly shorter median time to complete healing (15 days) than those that had a xenograft applied (20.5 days) in the RCT conducted in Sweden (p<0.001). The authors postulate that the faster healing time in the silver-containing dressing group was due to the ability of the dressing to control exudate and avoid minor disturbances of the wound bed due to its Safetac wound contact surface (Karlsson et al, 2019).

In another study involving patients (n=20) with **partial thickness burns**, three dressings (Mepilex Ag, a silver-containing gel and a collagen dressing) were applied simultaneously onto randomly selected areas. There was a significantly greater proportion of burn areas with 60-80% re-epithelialisation (at study day 10) that had the silver-containing foam dressing with Safetac applied (80%, versus 50% for both the silver gel and collagen dressings; p=0.042). The burn areas that were dressed with the silver-containing Safetac dressing were associated with the highest rate of complete healing (90%, versus 30% for the silver gel and 20% for the collagen dressing; p=0.032). The need for skin grafting was lowest in the burn areas that had the silver-containing Safetac applied (5%, versus 25% for the silver gel and 15% for the collagen dressing) (Erring et al, 2019).

Steam inhalation is commonly utilised as a home remedy for children with respiratory tract infections but poses a risk of burn injuries. A retrospective review of patients (n=16) admitted to a specialist burn care centre in the United Kingdom with **steam inhalation-related scalds** revealed that most of the burn injuries were dressed with Mepilex Ag or Mepilex Lite (thin foam dressings with Safetac). The average time to healing was 22.9 days and none of the patients had any permanent scarring, with the exception of one patient who underwent skin grafting (Himdani et al, 2016).

McCarty and colleagues reported on an observational study conducted prospectively across nine countries to evaluate the performance of Mepilex Border Ag (silver-containing bordered foam dressing with Safetac). In total, the wounds of 307 patients were evaluated, including 17 burn wounds. Compared to the baseline assessment, the number of wounds exhibiting local signs of infection were reduced at the final visit (**Figure 3**). Statistically significant decreases in wound area (28.5%) and depth (35.0%) between baseline and final visit were recorded (p<0.05) (McCarty et al, 2013).

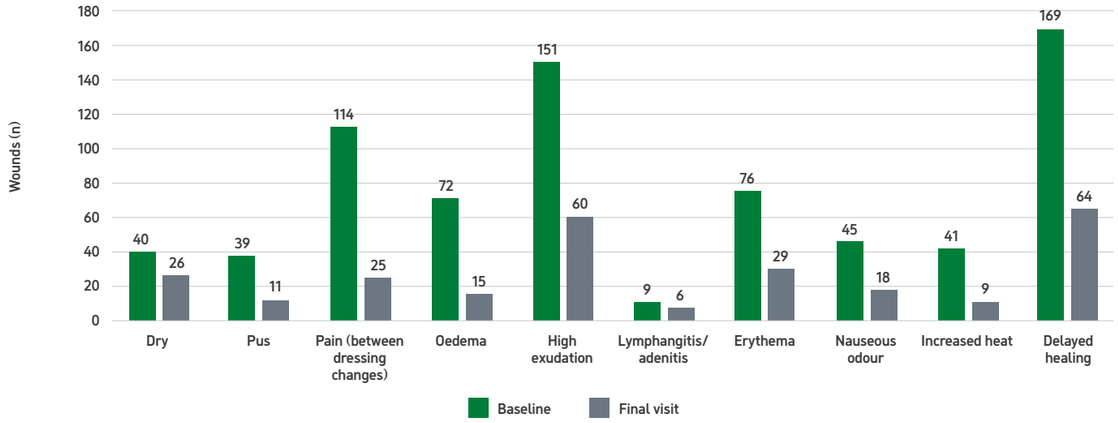


Figure 3. Number of local signs of infection at baseline and final visit in wounds dressed with Mepilex Border Ag (McCarty et al, 2013)

Pain management

Managing the pain of burn wounds is important as a failure to do so can lead to longer recovery times and chronic pain is more likely to develop (Judkins & Clark, 2010). Several RCTs observed significantly lower pain severity scores in burn patients managed with silver-containing dressings with Safetac relative to the comparator dressings. For example, differences in pain intensity, in favour of Mepilex Ag compared to SSD, were noted by Silverstein and colleagues at dressing application (p=0.018), during wear (p=0.048) and on removal (p=0.097) in patients with **partial thickness burns.** The trend in pain reduction at dressing change was associated with a significant difference in the average weekly costs of pain medication (p=0.031). Background pain analgesia was lower in the silver-containing dressing with Safetac group compared to the SSD group (Silverstein et al, 2011).

In an RCT undertaken in China involving patients with **deep partial thickness burns,** Tang and colleagues observed a significant difference in the mean visual analogue scale (VAS) pain score between Mepilex Ag and SSD before (11.7 vs. 23.9), during (19.4 vs. 40.1) and after dressing removal (17.3 vs. 44.3) (p<0.0001) during the first week of the study. The silver-containing dressing with Safetac was also associated with significantly lower mean pain scores than SSD before (6.8 vs. 11.0; p=0.0081), during (9.3 vs. 19.1; p=0.0050) and after dressing removal (9.4 vs. 15.8) at the final study assessment (p=0.0013) (Tang et al, 2015). Gee Kee and colleagues reported 25% lower expected Visual Analog Scale-Pain (VAS-P) scores after dressing removal in the Mepilex Ag group, compared to the group managed with nanocrystalline silver-containing dressings (p=0.04). In the same study, expected FLACC (Face, Legs, Activity, Cry, Consolability) scores were 32% lower at dressing removal (p=0.01) and 37% lower at new dressing application (p=0.04) in the silver-containing dressing with Safetac group, relative to the group managed with nanocrystalline silver-containing dressings (Gee Kee et al, 2015).

In the prospective observational study described earlier which evaluated the performance of Mepilex Border Ag in the management of burns and other wounds, pain severity during dressing wear, at removal and after removal was significantly lower at the final visit, relative to baseline (p<0.0001), with a concomitant increase in the proportion of trauma-free wounds and peri-wound regions (McCarty et al, 2013).

Numerous other studies have also observed low pain severity scores in patients who had Mepilex Ag applied to their burn wounds (Erring et al, 2019; Glat et al, 2015; Budkevich et al, 2010).

Scar quality

In an RCT undertaken in Australia which compared four dressings in the management of **partial thickness burns**, scar quality was determined through telephone follow-up calls with patients. Mepilex Ag was associated with the second lowest mean Vancouver Scar Scale (VSS) score at the three-month follow-up (1.10) and the lowest score at the six-month follow-up (0.63), relative to the three comparator dressings (Acticoat, Aquacel Ag and Biobrane), thus contributing to the best overall scar outcomes (Aggarwala et al, 2021).

Patient and clinician perspectives

In the RCT reported by Aggarwala and colleagues, Mepilex Ag was one of two dressings that the nursing staff found to be significantly easier to apply and remove, and to use overall (Aggarwala et al, 2020). Gee Kee and colleagues observed that the cumulative dressing removal and application time at the first dressing change was significantly shorter in the Mepilex Ag group (5.03 minutes) compared to both comparator groups. Nursing staff generally rated the silver-containing dressing with Safetac as 'very easy' to 'extremely easy' to apply and remove (Gee Kee et al, 2015). In the RCT undertaken by Silverstein and colleagues, clinicians considered Mepilex Ag to be easier to use (95.6% of ratings as 'extremely well' or 'very well') than SSD (78.4%) (p=0.028) and more flexible (97.8%) than SSD (74.6%) (p=0.038 for both variables). The mean number of dressing applications undertaken in the first week following injury was 1.54 in the silver-containing dressing group and 6.82 in the SSD group (Silverstein et al, 2011). Similarly, Karlsson et al reported that the number of dressing changes and time spent by staff on dressing changes were significantly less in the Mepilex Ag group compared to the xenograft group (p=0.03) (Karlsson et al, 2019).

Tang et al reported a mean total number of dressing changes of 3.06 in the Mepilex Ag group compared to 14.0 in the SSD group (p=0.0001). With regard to clinicians' evaluation of the dressings, the 'good' to very good' response rate significantly favoured the silver-containing dressing over SSD in terms of ease of application (96% vs. 76%; p=0.0001), adherence (85% vs. 68%; p=0.0003), and ease of removal (93% vs. 59%; p=0.0001). Patient evaluations were also significantly in favour of the silver-containing dressing over SSD in terms of anxiety during dressing change, ease of movement, dressing remaining in place, and discomfort during dressing wear (p=0.0001 for all parameters) (Tang et al, 2015).

A research team in the USA reported on the implementation of an outpatient short stay programme at a burns centre. The programme was focussed around the introduction of Mepilex Ag for small **paediatric burns** (≤15% total body surface area [TBSA]). Patient data (n=77) were collated over a two-year period prior to implementing the programme and compared with data from patients (n=142) gathered over a similar time period after the implementation. The post-implementation group was associated with shorter in-patient length of stay (2.93 days vs. 5.21 days; p<0.001) and fewer dressing changes (2.32 vs. 4.71; p<0.001). There were no statistically significant differences between groups with regard to readmission rates or the need for grafting. Non-statistically significant trends towards fewer infectious complications and reduced need for reoperations were observed. Not surprisingly, patient and family satisfaction with the programme was high (Zens et al, 2018).

Cost-effectiveness

An economic analysis of the RCT that compared four dressing types for the management of partial thickness burns demonstrated that there was a 99%, 71% and 53% probability that Mepilex Ag dominated Biobrane, Acticoat and Aquacel Ag, respectively (i.e. the silver-containing foam dressing with Safetac was found to be the most cost-effective dressing overall) (Aggarwala et al, 2020).

Gee Kee and colleagues conducted a cost-effectiveness analysis of the data generated from their RCT (Gee Kee et al, 2015). They identified that the costs (in Australian Dollars) of dressings, labour, analgesics and scar management were considerably lower in the Mepilex Ag group (median AU$94.45) compared to the Acticoat (median AU$244.90) and Acticoat with Mepitel (median AU$196.66) dressing regimes. There was a 99% and 97% probability that the silver-containing foam dressing with Safetac dominated (i.e. less expensive and more effective than) Acticoat and Acticoat with Mepitel, respectively. This pattern was consistent across raw cost and effects, after a priori adjustments, and sensitivity analyses (Gee Kee et al, 2017).

In the RCT undertaken by Silverstein and colleagues in the USA, the cost of pain medication in the Mepilex Ag group was substantially less than in the SSD group (**Figure 4**). Furthermore, the mean total cost of wound management per patient was calculated at US$309 for the silver-containing Safetac dressing group and US$514 for the SSD group (p<0.001) (**Figure 5**). The average cost-effectiveness of the dressings per burn healed was US$395 in the silver-containing Safetac dressing group compared with US$776 in the SSD group, i.e. a net saving per burn healed of US$381 with a protocol of care using the silver-containing Safetac dressing instead of SSD. The incremental cost-effectiveness ratio was calculated to be -US$1688 in favour of the silver-containing dressing with Safetac protocol (Silverstein et al, 2011).

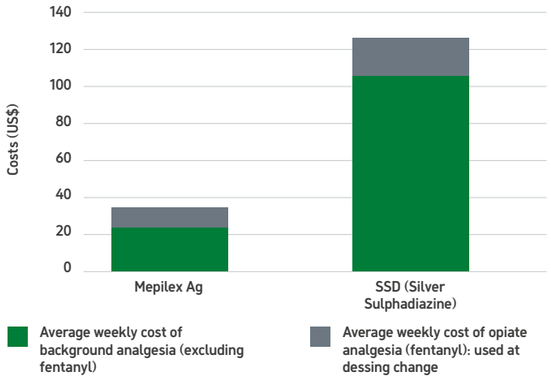


Figure 4. Cost comparison of pain medication for patients with partial thickness burns managed with Mepilex Ag or silver sulphadiazine (Silverstein et al, 2011)

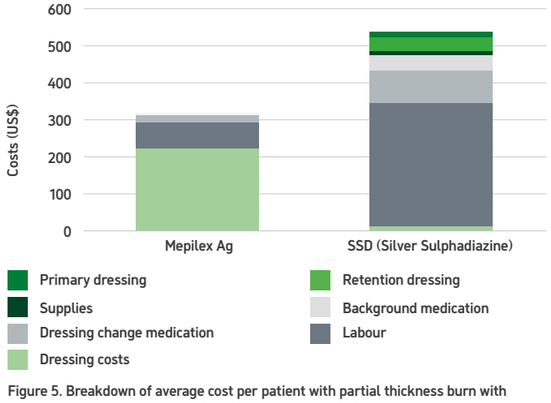


Figure 5. Breakdown of average cost per patient with partial thickness burn with Mepilex Ag or silver sulphadiazine (Silverstein, et al, 2011)

In a decision analysis with an incremental cost-utility ratio, silver-containing dressings (Mepilex Ag and a silver-containing fibre dressing) were compared with SSD in the management of **partial thickness burns** affecting less than 20% of total body surface area (TBSA). A literature review determined clinically relevant health states (healing, infection, and non-infected delayed healing requiring surgery or conservative management). The probabilities of these health states occurring were combined with Centers for Medicare and Medicaid Services' Current Procedural Terminology (United States of America) reimbursement codes (cost) and patient-derived utilities (relative quality of life preference). The incremental cost-utility ratio for silver-containing dressings relative to SSD was approximately US$40,000 per quality adjusted life year (QALY). A one-way sensitivity analysis of complication rates confirmed the robustness of the model. Assuming a maximum willingness to pay of approximately US$50,000/QALY, the complication rate for SSD must be 22% or higher for silver-containing dressings to be cost-effective. By varying complication rates for SSD and silver-containing dressings, the two-way sensitivity analysis demonstrated the cost-effectiveness of using silver-containing dressings at the majority of complication rates for both interventions. These findings led to the conclusion that silver-containing dressings are a cost-effective means of managing partial thickness burns (Sheckter et al, 2014).

Wound contact layers

The wound contact layer, Mepitel, is coated on both sides with Safetac. It provides a good basis for the management of non-complex burns by promoting a moist wound environment that is conducive to healing and is easy and relatively painless to use (Bugmann et al, 1998; Gotschall et al, 1998; Greenwood et al, 2000; Williams et al, 2001; Fowler, 2006). With Mepitel One, clinicians have the option of using a wound contact layer that can be expected to perform as well as Mepitel, but has the Safetac coating on just one side (i.e. the wound contact surface), to make it particularly easy to handle and apply (David et al, 2018; Edwards & Mason, 2013).

Numerous RCTs have been undertaken to investigate the efficacy of Mepitel and Mepitel One in the management of burn wounds. These are summarised in **Table 2**.

Table 2. Burns - Mepitel / Mepitel One - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
David et al, 2018 RCT France	**Subjects:** 121 (age range 18-95 years) **Wounds:** Benign burns (n=21), traumatic wounds (n=100) **Setting:** Outpatient wound care centres	**Safetac:** Mepitel One (n=59) **Comparator:** UrgoTul (n=62)	Pain severity scores (measured using VAS 0-100) Time to wound closure Dressing use	Higher proportion of patients experienced non-painful dressing removal (defined as pain rating <30) in the Mepitel One group (p=0.02): - Mepitel One: 89.8% - UrgoTul: 73.6% Higher proportion of wounds healed at day 21 in the Mepitel One group (p=0.012): - Mepitel One: 66.1% - UrgoTul: 43.5% Mepitel One rated significantly higher than UrgoTul in terms of ability to remain in place (p=0.016).
Bugmann et al, 1998 RCT Switzerland	**Subjects:** 76 (age range 3 months to 15 years) **Wounds:** Superficial partial thickness burns <24 hours post injury **Setting:** Paediatric surgery	**Safetac:** Mepitel (n=41) covered with chlorhexidine-soaked gauze **Comparator:** SSD cream (n=35) covered with gauze	Time to healing Dressing usage	Shorter time to healing in the Mepitel group (p<0.01): - Mepitel: 7.6 days - SSD: 11.3 days Fewer dressings used in the Mepitel group (p<0.05): - Mepitel: 3.64 - SSD: 5.13

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Gotschall et al, 1998 RCT United States of America	**Subjects:** 63 (age < 12 years) **Wounds:** Partial thickness scald burns (TBSA <15%) **Setting:** Paediatric burns centre	**Safetac:** Mepitel (n=33) **Comparator:** SSD (n=30)	Time to healing	Shorter time to healing in the Mepitel group (p<0.001): - Mepitel: 10.5 days - SSD: 27.6 days Less eschar formation (p<0.05) in the Mepitel group.
			Pain on dressing change (measured using OPS)	Lower OPS scores in the Mepitel group (p<0.05): - Mepitel: 3.8 - SSD: 4.6
			Treatment costs	Significantly lower daily hospital costs (US$1937 vs. US$2316, respectively; p=0.025), dressing change-related costs (US$413 vs. US$739, respectively; p<0.02) and analgesia costs (US$52 vs. US$132, respectively; p<0.001) in the Mepitel group.

Abbreviations: AU$ = Australian Dollars; ED = emergency department; FLACC = face, legs, activity, cry, consolability; RCT = randomised controlled trial; SD = standard deviation; SSD = silver sulphadiazine; US$ = United States Dollars; TBSA = total body surface area; VAS = visual analogue scale; VAS-P = Visual Analogue Scale-Pain

Conducted at multiple centres in France, an RCT compared two wound contact layers in outpatients with acute wounds (**benign burns** and traumatic wounds). Patients were randomised to either Mepitel One (benign burns, n=9; traumatic wounds, n=50) or Urgotul, a lipidocolloid-impregnated wound contact layer (benign burns, n=12; traumatic wounds, n=50). On the third study day (first dressing removal), 89.8% of patients in the Safetac wound contact layer group had non-painful (defined as pain rating <30mm on a 100mm visual analogue scale) dressing removal, compared with 73.6% of patients in the comparator group (p=0.017). At study day 21, 66.1% of wounds in the Safetac wound contact layer group were healed, compared with 43.5% in the comparator group (p=0.012) (**Figure 6**). Although both wound contact layers were rated highly in terms of in-use characteristics, the dressing with Safetac was rated significantly higher than the lipidocolloid-impregnated dressing in terms of ability to remain in place (p=0.016) (David et al, 2018). In a case study series undertaken in Spain, two of the patients had **burn injuries** that had Mepitel One applied as part of their management regimen. No patients experienced any untoward reactions to the product. All patients reported low pain scores in association with the dressing. The product was also reported to be 'gentle' on the skin surrounding the wounds, as well as excelling in terms of ease of use (Sanchez, 2010).

In an RCT undertaken in Switzerland, 76 children with previously untreated **partial thickness burns** less than one day old were randomised to management with Mepitel (n=41) or SSD cream (n=35). For those patients assigned to the Safetac group, one or more sheets of the wound contact layer were applied directly to the burn in a single layer and covered with chlorhexidine-soaked gauze. In the comparator group, a thick layer of SSD cream was applied and covered by paraffin gauze followed by a layer of absorbent gauze. Dressings were changed every 2-3 days until complete healing had been achieved. The wounds in the Safetac wound contact layer group were associated with reduced healing time compared to those in the SSD group (7.6 days vs. 11.3

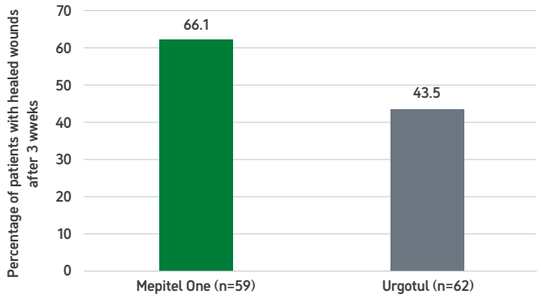


Figure 6. Healing rate comparison of Mepitel and Urgotul in the management of benign burns and traumatic wounds (David et al, 2018)

days, respectively; p<0.01). Moreover, the mean number of dressings used was significantly less in the Safetac wound contact layer group compared to the SSD group (3.64 vs. 5.13, respectively; p<0.05). The Safetac wound contact layer was also reported to be easy to use and atraumatic on removal (Bugmann et al, 1998).

Mepitel was also compared with SSD cream in an RCT undertaken in the USA involving 63 children with **partial thickness scald burns**. Patients were randomised to management with the Safetac wound contact layer (n=33) or SSD cream (n=30); both were covered with gauze. Dressings were changed every second day. The median time for complete healing was significantly shorter in the Safetac wound contact layer group compared to the SSD group (10.5 days vs. 27.6 days, respectively; p<0.05). There was less eschar formation (p<0.05) and less pain at dressing change (p<0.05) in the Safetac wound contact layer group. Burn wounds managed with the Safetac wound contact layer were associated with significantly lower daily hospital costs (US$1937 vs. US$2316, respectively; p=0.025), dressing change-related costs (US$413 vs. US$739, respectively; p<0.02) and analgesia costs (US$52 vs. US$132, respectively; p<0.001) than those managed with SSD cream (**Figure 7**) (Gotschall et al, 2008).

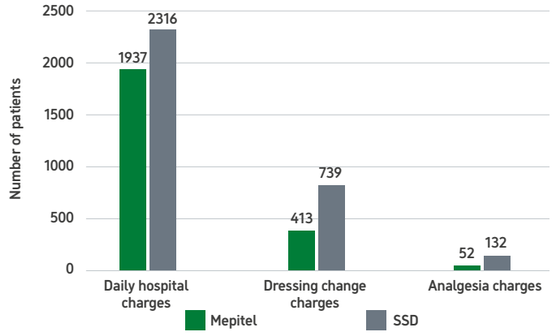


Figure 7. Cost comparison of Mepitel and SSD in the management of partial thickness burns (Gotschall et al, 2008)

The use of Mepitel One in the management of **hand burn injuries** (predominantly deep dermal with some partial thickness and superficial burns) was evaluated in a study undertaken at a specialist burn care centre in the United Kingdom involving 10 adult patients. The wound contact layer coated on one side with Safetac was used as the primary dressing with gauze used as the secondary dressing. The wound contact layer was associated with low pain severity (mean scores of 2 on dressing application, 1.74 with the dressing in place and 2 on dressing removal on a scale of zero to 10 were recorded). Based on a 10-point Likert scale, with zero being poor and 10 being excellent, the wound contact layer scored, on average, 8.23 for ease of application, 8.44 for conformability, 8.36 for durability and 8.95 for ease of removal (Edwards & Mason, 2013). In another case study, Mepitel One was reported to have been more comfortable than previously used dressings, thus helping a patient to maintain mobility and independence (Barrett, 2012).

A multi-centre study undertaken at specialist burn centres in the USA evaluated the use of the silver-containing wound contact layer with Safetac, Mepitel Ag, as the primary dressing in the management of **partial thickness (superficial, deep and mixed depth) second-degree burns** in adults and children. Gauze rolls and, if applicable, compression bandaging were used as secondary dressings. Thirty seven patients were recruited. The proportion of burn wounds that healed was 56.8% after week one, 71.4% after week two and 100% after week three. Pain severity was measured using a 100mm visual analogue scale. Pain before, during and after dressing removal remained low (<10) throughout the study. The dressing was found to be easy to apply and generally adhered well to the wound (Silverstein et al, 2014).

Mepitel Ag was also evaluated for use in the management of **partial thickness burn wounds** at a specialist paediatric burns centre in the USA. Data were gathered prospectively from 30 paediatric patients (average age 5.4 years) who had the silver-containing dressing with Safetac applied to their injuries, and compared to a historical control group of patients (n=235; average age 5.8 years) who had been managed with a synthetic skin substitute. Average time to healing was similar in both groups. No infections occurred in either group. The mean in-patient length of stay was reduced by 2.2 days in the intervention group, 16% more patients in the intervention group were managed exclusively in the out-patient setting, the number of out-patient visits in the intervention group was almost half that in the control group (**Table 3**) (Howard et al, 2017).

Table 3. Comparison of Mepitel Ag and a synthetic skin substitute in the management of partial thickness burn in paediatric patients (Howard et al, 2017)

Parameter	Mepitel Ag (intervention) group (n=30)	Synthetic skin substitute (historical control) group (n=235)
Age (mean)	5.4 years	5.8 years
Percentage total body surface area (mean)	5.7%	6.0%
Length of in-patient stay (mean)	0.4 days	2.6 days
Number of out-patient visits (mean	2.1	3.9
Time taken to heal (mean)	9.4 days	9.0 days
Percentage of patients treated exclusively as out-patient	62%	46%

In an article describing a survey of patient caregivers and providers to assess the acceptability and feasibility of soft casting for **paediatric hand burns**, a custom-made Mepitel Ag 'glove', fashioned and sewn in place in the operating room, is one of a number of described techniques for burn care prior to the introduction of soft casts (Schuh et al, 2024).

Skin graft management

Skin grafting is a surgical procedure that is used to quickly restore skin integrity of wounds that are large and cannot be directly closed (Beldon, 2003). For grafts to adhere to wound beds, they must be held in close proximity and immobilised (Holden, 2015). Historically, this was achieved by suturing (which is relatively time-consuming) and by using clips, skin adhesive or staples, the latter being painful to remove and requiring analgesia and, on occasions, sedation or anaesthesia (Chavez, 2004). Another approach to the fixation of skin grafts is the use of wound dressings. To maximise the potential for grafts to take, dressings should prevent mechanical displacement, allow exudate to drain and topically applied antimicrobials to reach the wound and not adhere to the graft and open areas of the wound (Vloemans & Kreis, 1994).

In a review of the different types of skin grafts that are managed in the community setting, the author reports that Mepitel is commonly used to aid graft take because it allows the free passage of exudate through its open mesh, adheres to the surrounding skin and not to the wound tissue, facilitates atraumatic and pain-free removal, and can be left in place for up to 14 days allowing only the secondary dressing to be changed if necessary (Atkinson, 1999).

Wound contact layers with Safetac have been evaluated for use on skin grafts in numerous clinical studies described below and in **Table 4**. The first of these evaluations was an open, prospective study involving 38 children in which Mepitel was evaluated for the fixation of split skin grafts applied to mainly post-burn wounds. Cotton wool gauze (soaked in an antimicrobial solution), applied as a secondary dressing over the wound contact layer, was changed every one to two days. With the wound contact layer in place, changing the outer absorbent dressing was painless, as was the final removal of the wound contact layer after 5-7 days. The use of the wound contact layer also prevented disturbance of open wound areas at dressing changes. In 42 of 45 cases, graft take was almost (>95%) complete (Vloemans & Kreis, 1994).

Mepitel was also compared with paraffin gauze as the primary wound contact layer applied to 38 **newly grafted burn** wounds in an RCT involving adults and children. Pain severity scores (measured using a VAS) at the first post-operative dressing change were significantly ($p<0.01$) greater in the gauze group. Whereas all patients in the gauze group experienced pain on dressing removal, 53% of patients in the Safetac wound contact layer group experienced no pain. The Safetac wound contact layer was also found to be significantly easier to remove than the gauze ($p<0.001$) (Platt et al, 1996). Further evidence of the usefulness of Mepitel in this indication has been presented in a case report in which the author states that the dressing proved to be ideal, providing the advantage or relatively painless removal, easy and effective graft fixation, and reducing operative time because no staples were needed for graft placement (Chavez, 2004).

In an RCT undertaken in the USA, adult patients with **newly grafted burn wounds** were randomised to either Mepitel One or Bridal Veil (netting-like dressing) plus staples. Although there was no significant difference between the two groups regarding skin graft take (Mepitel One, 99.0%; Bridal Veil plus staples, 93.1%), pain severity during dressing removal was significantly less in the Safetac wound contact layer group ($p=0.0118$). Staffing costs were also lower in the Safetac wound contact layer group ($p=0.0005$); the dressing with Safetac typically took less than a quarter of the time taken to remove the Bridal Veil and staples. The dressing with Safetac was easier to use, more conformable and stayed in place better compared with the other regimen (Patton et al, 2013).

A plastic and reconstructive surgical team in Japan undertook a case study series to evaluate a technique for fixating skin grafts of patients (n=14) with **burn wounds** or other skin defects. The technique involves the application of Mepitel One as the primary dressing on the grafts, stapling the surface of the dressing to fix the grafts, and then applying tie-over dressing or NPWT dressing. The skin grafts took in all cases. After removal of the tie-over / NPWT dressing 5-7 days post-surgery, the graft could be observed due to the transparency of the dressing with Safetac. Between post-operative days 5 and 12, the sutures were removed at the same time as the primary dressing, without any complications observed (Yanagisawa & Yuzuriha, 2018).

Mepitel Ag has also been used successfully in the management of **grafted burns**. In a case study series undertaken in the USA, the silver-containing wound contact layer (in conjunction with a secondary absorbent dressing) was applied to 11 burns, 10 of which demonstrated 95% healing after 10 days. No infections were observed, and the wound contact layer demonstrated good conformability and gentle adherence to the grafted burns (Alemante et al, 2017).

Exudate transfer dressings

In a case study series undertaken in Belgium, dressings with Safetac were evaluated for the management of **second-degree burns** (n=15). Different dressings were chosen depending upon the clinical challenge relating to the level of exudate. Mepilex Ag dressings were mainly used during the inflammatory phase of the healing process when high levels of exudate were present. As the wound healed, Mepilex Transfer (exudate transfer dressing) and

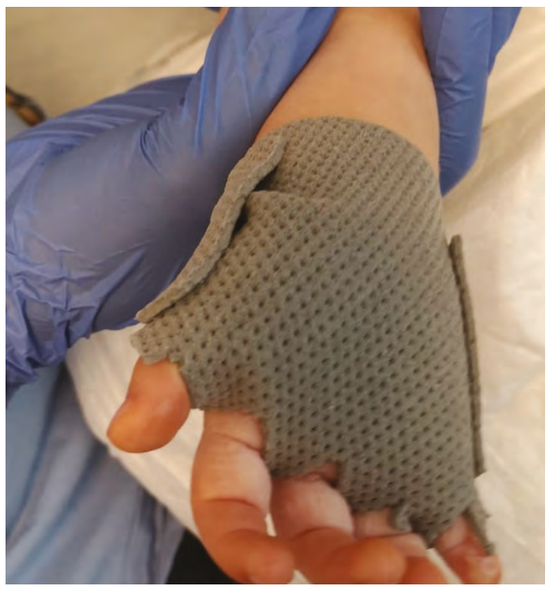


Figure 8. Mepilex Transfer Ag applied to a paediatric second-degree thermal burn. Finger holes were created in the centre of the dressing sheet allowing it to be applied and worn like a glove. (photograph courtesy of Paulo Alves, Universidade Catolica, Porto, Portugal)

Table 4. Post-burn skin grafting - Mepitel / Mepitel One - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Patton et al, 2013 RCT United States of America	**Subjects:** 43 (age range 18-70 years) **Wounds:** Grafted deep partial or full thickness burns (1-25% TBSA) **Setting:** Burn care centres	**Safetac:** Mepitel One (n=21) **Comparator:** Bridal Veil and staples (n=21)	Graft take Pain severity during dressing removal (measured using VAS 0-100) Staffing costs	High graft take in both groups (postoperative day 7): - Mepitel One: 99.0% - Comparator: 93.1% Lower median pain severity at dressing change in Mepitel One group ($p=0.018$): - Mepitel One: 4 - Comparator: 44 Lower staff costs in the Mepitel One group ($p=0.0064$), as reflected in the 75% shorter time required for dressing removal ($p=0.0005$): - Mepitel One: US$4.89 - Comparator: US$10.40
Platt et al, 1996 RCT United Kingdom	**Subjects:** 38 (age range 1-74 years) **Wounds:** Grafted post-burn wounds (TBSA grafted <15%) **Setting:** burn care centre	**Safetac:** Mepitel (n=19) **Comparators:** Paraffin gauze (n=19); Both Mepitel and gauze dressings covered with loose gauze.	Graft take Pain severity on dressing removal (measured using VAS 0-10) Dressing usage	High graft take in both groups: - Mepitel: 95.7% - Paraffin gauze: 94.3% Lower mean pain scores at the first post-operative dressing change in the Mepitel group ($p<0.01$): - Mepitel: 1.4 - Paraffin gauze: 4.4 All patients in the paraffin gauze group experienced pain on dressing removal, whereas 53% of those in the Mepitel group experienced none. Mepitel was easier to remove than paraffin gauze ($p<0.001$).
Vloemans & Kreis, 1994 Observational prospective clinical study Netherlands	**Subjects:** 38 (age range 0.5-13 years) **Wounds:** Grafted post-burn wounds (n=33) and non-burn-related trauma wounds (n=5) Setting: Paediatric burn care centre	**Safetac:** Mepitel covered with cotton gauze (soaked in antimicrobial solution) applied as secondary dressing **Comparator:** None Secondary dressings changed every 1-2 days; Mepitel changed after 5-7 days	Graft take Pain severity on dressing removal	Graft take >95% complete in 42/45 cases. Painless removal of secondary dressings with Mepitel.

Abbreviations: RCT = randomised controlled trial; TBSA = total body surface area; US$ = United States Dollars; VAS 0-10 = visual analogue scale ranging from 0 (no pain) to 10 (worst possible pain); VAS 0-100 = visual analogue scale ranging from 0 (no pain) to 100 (worst possible pain)

Mepilex Border Lite (thin bordered foam dressing) were used. Every patient demonstrated a decrease in pain sensation during wound care. These dressings provided a favourable moist environment resulting in excellent healing. Mepilex Transfer was retained in place throughout the study period and effectively transferred exudate to secondary dressings. No infections were observed in any of the case studies (De Coster & Meuleniere, 2010).

The performance of Mepilex Transfer Ag (silver-containing exudate transfer dressing; **Figure 8**) was evaluated in a 10-patient study. It was applied as the primary dressing on **second-degree partial thickness (superficial, deep, and mixed depth) burns**. Secondary dressings were gauze rolls and compression bandaging. After one week, 70% of burn wounds had healed, with the remainder healing by the second week (median 8.0 days, range 5.0-14.0). Despite a small number of positive microbiological swabs at baseline, infection did not proliferate. The dressing was also reported to have handled exudate effectively (Schweiger et al, 2013). Mepilex Transfer Ag was also reported to have been used successfully on a patient who sustained high voltage **electrical burn injuries**, The wounds healed within three weeks and the patient was able to return to work six weeks after the initial injury (Lindford et al, 2021).

References

Aggarwala, S., Harish, V., Roberts, S. Brady, M., Lajevardi, S., Doherty, J., D'Souza, M., Haertsch, P., Matiz, P.K.M., Issler-Fisher, A.C. (2021) Treatment of partial thickness burns: a prospective, randomised controlled trial comparing four routinely used burns dressings in an ambulatory care setting Journal of Burn Care and Research 42(5):934-943.

Alemante, Y., Johnson, M., Garner, W., Gillenwater, J. (2017) Silver soft silicone layer in extremity burns: our experience. Poster presentation at the 39th Annual John A Boswick Burn and Wound Care Symposium, Maui, Hawaii, United States of America.

Atiyeh, B., Barret, J.P., Dahai, H., Duteille, F., Fowler, A., Enoch, S., Greenfield, E., Magnette, A., Rode, H., Zhao-fan, X. (2014) International Best Practice Guidelines: Effective skin and wound management of non-complex burns. Wounds International, London, United Kingdom.

Atkinson, A. (1999) Managing split skin donor sites in the community. Journal of Community Nursing 13(5):18-24.

Barrett, S. (2012) Mepitel One: a wound contact layer with Safetac technology. British Journal of Nursing 21(21):1271-1277.

Beldon, P. (2003) Skin grafts 2: management of donor site wounds in the community. British Journal of Community Nursing 8(9 Supplement):6-14.

Booth, S., Chadwick, P., Cooper, R., Kingsley, A., Ousey, K., Tickle, J., White, R. (2013) Best Practice Statement: The use of topical antimicrobial agents in wound management (3rd edition). Wounds UK, London, United Kingdom.

Budkevich, L.I., Mirzoyan, G.V., Astamirova, T.S. (2010) [Use of Mepilex Ag silver-containing dressing in the topical treatment of children with thermal injury. Khirurgiia (Mosk) 9:57-60.

Bugmann, P., Taylor, S., Gyger, D. (1998) A silicone-coated nylon dressing reduces healing time in burned paediatric patients in comparison with standard sulfadiazine treatment: a prospective randomized trial. Burns 1998;24(7):609-612.

Butcher, M., Swales, B. (2012) Reducing trauma associated with burns care using Safetac technology. Nursing Standard 27(2):57-62.

Chavez, B. (2004) Making the case for using a silicone dressing in burn wound management. Ostomy Wound Management 50(6):11-12.

David, F., Wutze, J-L., Breton, N., Bisch, O., Gazeu, P., Kerihuel, J-C., Guibon, O. (2018) A randomised, controlled, non-inferiority trial comparing the performance of a soft silicone-coated wound contact layer (Mepitel One) with a lipidocolloid wound contact layer (UrgoTul) in the treatment of acute wounds. International Wound Journal 15(1):159-169.

Davies, P., McCarty, S., Hamberg, K. (2017) Silver-containing foam dressings with Safetac: a review of the scientific and clinical data. Journal of Wound Care 26(6 Supplement):S1-S32.

De Coster, L. Meuleniere, F. (2010) Case report: second degree burns treated with soft silicone-coated dressings. Poster presentation at the European Wound Management Association Conference, Geneva.

Edwards, J., Mason, S. (2013) Hand burn management: minimising pain and trauma at dressing change. British Journal of Nursing 22(20):S46-S50.

Erring, M., Gaba, S., Mohsina, S., Tripathy, S., Sharma, R.K. (2019) Comparison of efficacy of silver-nanoparticle gel, nano-silver foam and collagen dressings in treatment of partial thickness burn wounds. Burns 45:1888-1894.

Evans, L.H., Bhavsar, D., Mailander, P. (2010) The biology of burn injury. Experimental Dermatology 19(9):777-783.

Fowler, A. (2006) Atraumatic dressings for non-complex burns. Practice Nurse 17(4):193-196.

Gauffin, E., Oster, C., Sjoberg, F., Gerdin, B., Ekselius, E. (2016) Health-related quality of life (EQ-5D) early after injury predicts long-term pain after burn. Burns 42(8):1781-1788.

Gee Kee, E.L., Kimble, R.M., Cuttle, L., Khan, A., Stockton, K.A. (2015) Randomized controlled trial of three burns dressings for partial thickness burns in children. Burns 41(5):946-955.

Gee Kee, E., Stockton, K., Kimble, R.M., Cuttle, .L, McPhail, S.M. (2017) Cost-effectiveness of silver dressings for paediatric partial thickness burns: An economic evaluation from a randomized controlled trial. Burns 43(4):724-732.

Glat, P.M., Zhang, S-H., Burkey, B.A., Davis, W.J. (2015) Clinical evaluation of a silver-impregnated foam dressing in paediatric partial-thickness burns. Journal of Wound Care 24(4 Supplement): S4-S10.

Gotschall, C.S., Morrison, M.I., Eichelberger, M.R. (1998) Prospective, randomized study of the efficacy of Mepitel on children with partial-thickness scalds. Journal of Burn Care and Rehabilitation 19(4):279-283.

Greenwood, J.E., Dunn, K.W., Davenport, P.J. (2000) Experience with severe extensive skin blistering disease in a paediatric burns unit. Burns 26(1):82-87.

Hermans, M.H.E. (2008) A survey: silver is still the gold standard in burn care. Journal of Wound Technology 2:56-57.

Himdani, S.A., Javed, M.U., Hughes, J., Hemington-Gorse, S., Nguyen, D., Falconer, O., Bidder. C. (2016) Home remedy or hazard? Management and costs of paediatric steam inhalation therapy burn injuries. British Journal of General Practice 66(644):e193-e199.

Holden, J. (2015) Top tips for skin graft and donor site management. Wounds UK 10(2):7-13.

Howard, R., Evans, J., Woodhouse, B., Mansfield, J., Lesher, A. (2017) Partial thickness burn injuries in pediatric burn patients. Poster presentation at the 39th Annual John A Boswick Burn and Wound Care Symposium, Maui, Hawaii, United States of America.

Judkins, K., Clark, L. (2010) Managing the pain of burn wounds. Wounds UK 6(1):110-118.

Karlsson, M., Elmasry, M., Steinvall, I., Sjöberg, F., Olofsson, P., Thorfinn, J. (2019) Superiority of silver-foam over porcine xenograft dressings for treatment of scalds in children: A prospective randomised controlled trial. Burns 45(6):1401-1409.

Lindford, A., Juteau, S., Jaks, V., Klass, M., Lagus, H., Vuola, J., Kankuri, E. (2021) Case report: unravelling the mysterious Lichtenberg Figure Skin Response in a patient with a high-voltage electrical injury. Frontiers in Medicine 8:663807.

Malhotra, H., Sharma, P., Kamal, M.A., Kaushik, P., Rani, N. (2024) Concise review on scientific approaches to burns and scars. Current Drug Safety 9(2):191-199.

Manasyan, A., Choi, K., Pham, C., Kurakazu, D., Collier, Z., Gillenwater, J. (2025) Occupational therapy improves range of motion and functional independence in patients with hand burns. Journal of Burn Care and Research 46 (Supplement 1):S20.

McCarty, S., Davies, P., Rippon, M. (2013) Mepilex Border Ag: an in-market evaluation. Poster presentation at the Wounds UK Conference, Harrogate, United Kingdom.

Patton, M.L., Mullins, R.F., Smith, D., Korentager, R. (2013) An open, prospective, randomized pilot investigation evaluating pain with the use of a soft silicone wound contact layer vs bridal veil and staples on split thickness skin grafts as a primary dressing. Journal of Burn Care and Research 34(6):674-681.

Platt, A.J., Phipps, A., Judkins, K. (1996) A comparative study of silicone net dressing and paraffin gauze dressing in skin-grafted sites. Burns 22(7):543-545.

Procter, F. (2010) Rehabilitation of the burn patient. Indian Journal of Plastic Surgery 43 (Supplement): S101-S113.

Roy, S., Mukherjee, P., Kundu, S., Majumder, D., Raychaudhuri, V., Choudhury, L. (2024) Microbial infections in burn patients. Acute and Critical Care 39(2):214-225.

Sanchez, F.J.G. (2010) Evaluation; first experiences of a new one-sided self-fixating wound contact layer. Poster presentation at the European Wound Management Association conference, Geneva, Switzerland.

Schuh, J.M., Linzell, L.L., Abebrese, E.L., Flynn-O'Brien, K.T. (2024) Caregivers and clinic providers view soft casts for pediatric hand burns as acceptable and feasible: a mixed methods survey. Journal of Burn Care and Research 45(6):1413-1422.

Schweiger, H., Smith, D., Cruse, C.W., Brown, B. (2013) An open, non-controlled, single-centre, clinical investigation to evaluate efficacy when using a soft silicone wound contact layer containing silver. Poster presentation at the 15th European Burns Association Congress, Vienna, Austria.

Sheckter, C.C., Van Vliet, M.M., Krishnan, N.M., Garner, W.L. (2014) Cost-effectiveness comparison between topical silver sulfadiazine and enclosed silver dressing for partial-thickness burn treatment. Journal of Burn Care and Research 35(4):284-290.

Silverstein, P., Heimbach, D., Meites, H., Latenser, B., Mozingo, D., Mullins, F., Garner, W., Turkowski, J., Shupp, J., Glat, P., Purdue, G. (2011) 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. Journal of Burn Care and Research 32(6):617-626.

Silverstein, P., Gibran, N., Glat, P., Sood, R., Foster, K., Smith, H. (2014) Open, non-controlled multicentre clinical investigation evaluating the efficacy and safety of a soft silicone-containing wound contact layer - Mepitel Ag - on partial thickness (superficial, deep, and mixed) second-degree burns. Poster presentation at the 17th Congress of the International Society for Burn Injuries, Sydney, Australia.

Solowiej, K., Mason, V., Upton, D. (2009) Review of the relationship between stress and wound healing: part 1. Journal of Wound Care 18(9):357-366.

Tang, H., Lv, G., Fu, J., Niu, X., Li, Y., Zhang, M., Zhang, G., Hu, D., Chen, X., Lei, J., Qi, H., Xia, Z. (2015) An open, parallel, randomized, comparative, multicenter investigation evaluating the efficacy and tolerability of Mepilex Ag versus silver sulphadiazine in the treatment of deep partial-thickness burn injuries. Journal of Trauma and Acute Care Surgery 78(5):1000-1007.

Vloemans, A.F., Kreis, R.W. (1994) Fixation of skin grafts with a new silicone rubber dressing. Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery 28(1):75-76.

Wang, Y., Beekman, J., Hew, J., Jackson, S., Issler-Fisher, A.C., Parungao, R., Lajevardi, S.S., Li, Z., Maitz, P.K.M. (2018) Burn injury: challenges and advances in burn wound healing, infection, pain and scarring. Advanced Drug Delivery Reviews 123:3-17.

White, R., Cooper, R. (2005) Silver sulphadiazine: a review of the evidence. Wounds UK 2005;1(2):51-61.

Williams, G., Withey, S., Walker, C.C. (2001) Longstanding pigmentary changes in paediatric scalds dressed with a non-adherent siliconised dressing. Burns 27(2),200-202.

Yanagisawa, D., Yuzuriha, S. (2018) Stapling technique through transparent dressing to fix skin grafts. Burns Open 2(1):71-75.

Zens, T., Yan, A., Lee, C.W., Schmitz, C., Faucher, L., Gibson, A. (2018) A pediatric burn outpatient short stay program decreases patient length of stay with equivalent burn outcomes. Journal of Burn Care and Research 39(3):353-362.

Zwierello, W., Piorun, K., Skorka-Majewicz, M., Maruszewska, A., Antoniewski, J., Gutowska, I. (2023) Burns: classification, pathophysiology, and treatment: a review. International Journal of Molecular Sciences 24:3749.

Dressings with Safetac featured:

Mepilex®, Mepilex® Border, Mepilex® Border Ag, Mepilex® Border Flex (Comfort), Mepilex® Border Lite, Mepilex® Lite, Mepilex® Transfer, Mepitel®, Mepitel® One, Avance® Solo Border

Take home messages:

- Although many traumatic wounds heal within relatively short timeframes and require little intervention, some may require management of infection, exudation, odour and pain.
- Dressings with Safetac (absorbent foam dressings, exudate transfer dressings and wound contact layers) have been used successfully in the management of various traumatic wound types including skin tears, fingertip injuries and road rash.
- Studies have shown that dressings with Safetac can facilitate the healing of traumatic wounds through exudate management and the minimisation of additional trauma and pain at dressing changes.

Introduction to traumatic wounds

Traumatic wounds are generally sudden, unplanned injuries that range from minor skin grazes to something as severe as wounds from explosions or gunshots (Leaper & Harding, 2006). Box 1 describes some of the most common types of traumatic wounds.

Box 1. Traumatic wound types

Abrasions - superficial epithelial wounds caused by mechanical forces (e.g. friction and shear) scraping the skin (Leaper & Harding, 2006)

Lacerations - cuts/tears in the skin and/or underlying tissues caused by blunt trauma (e.g. falls and collisions), incision by a sharp object, or animal/human bites (National Institute for Health and Care Excellence, 2022). Skin tears are a specific type of laceration and involve separation of the skin layers. They are caused by shear, friction and/or blunt force and can be partial thickness (separation of the epidermis from the dermis) or full thickness (separation of both the epidermis and dermis from underlying structures (LeBlanc et al, 2011)

Contusions- bruising caused by severe blunt or blast trauma. Haematomas under the skin/muscle may co-exist (Leaper & Harding, 2006)

Challenges

Depending on their cause and extent, traumatic wounds can range from being life-threatening (e.g. gunshot wounds) to ones that are minor and require relatively little intervention (e.g. minor abrasion). It is important that clinicians understand the nature of a traumatic wound, what caused it and consider the possibility of complications. Although many traumatic wounds heal within relatively short timeframes and require little intervention, some may require management of infection, exudation, odour and pain (Dearden et al, 2001; Burton, 2006).

Role of dressings in traumatic wound management

Regarding the management of traumatic wounds, the main role of dressings is to support the local wound environment in order to facilitate healing. Providing a protective barrier, maintaining a moist wound environment, managing excess exudate, and preventing infection and other complications are the key roles of dressings in the management of traumatic wounds (Burton, 2006).

Evidence for dressings with Safetac

Data from clinical studies indicate that the use of dressings with Safetac can impact positively in the management of different types of traumatic wounds. The key studies are summarised in Table 1.

Table 1. Traumatic wounds - dressings with Safetac - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
LeBlanc & Woo, 2022 RCT Canada	**Subjects:** 126 (age range 45-102 years) **Wounds:** Skin tears **Setting:** Long-term care facilities	**Safetac:** Mepilex Border Flex for exudative skin tears types 2 and 3 (n=55) Mepitel One for less exudative skin tears types 1 and 2 **Comparator:** Non-adhesive absorbent composite dressings	Wound healing at day 21	Proportion of healed skin tears: - Safetac: 96.9% (n=63) - Comparator: 34.4% (n=21) Significant lower mean wound surface area in the Safetac group (p<0.001): - Safetac: 2.9cm^2 - Comparator: 0.6cm^2 Wounds in Safetac group took, on average, 50% less time to heal (p<0.0001): - Safetac: 11 days - Comparator: 22 days

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
David et al, 2018 RCT France	**Subjects:** 121 (age range 18-95 years) **Wounds:** Traumatic wounds, benign burns **Setting:** Outpatient wound care centres	**Safetac:** Mepitel One (n=59) **Comparator:** UrgoTul (n=62)	Pain severity scores (measured using VAS 0-100) Time to wound closure Dressing use	Higher proportion of patients experienced non-painful dressing removal (defined as pain rating <30) in the Mepitel One group (p=0.02): - Mepitel One: 89.8% - UrgoTul: 73.6% Higher proportion of wounds healed at day 21 in the Mepitel One group (p=0.012): - Mepitel One: 66.1% - UrgoTul: 43.5% Mepitel One rated significantly higher than UrgoTul in terms of ability to remain in place (p=0.016).
White, 2008 Survey (patients) 20 countries (Europe, Asia-Pacific, Americas)	**Subjects:** 3024 (ages not specified) **Wounds:** Skin tears (plus burns, foot ulcers, leg ulcers and pressure injuries) **Setting:** Not specified	**Safetac:** Mepilex, Mepilex Lite, Mepilex Border, Mepilex Border Lite, Mepitel **Comparators:** Variety of dressings (e.g. foam and hydrocolloids) with traditional adhesives	Trauma (subjective rating) Pain before, during and after dressing changes (VAS 0-10)	Less severe trauma levels with Safetac dressings: - Safetac: high 1%; moderate 11%; very slight 35-37%; none 50% - Comparators: high 10%; moderate 28-39%; very slight 31-35%; none 18-29% Significantly lower pain severity scores with Safetac dressings at all assessments (p=0.01): - Safetac: 1.7-1.8, 2.1-2.2 and 1.6-1.7 before, during and after dressing changes - Comparators: 2.4-3.2, 4.6-5.2 and 2.9-3.9 before, during and after dressing changes >90% of respondents stated a preference for dressings with Safetac compared to traditional adhesive dressings.

Abbreviations: RCT = randomised controlled trial; VAS 0-10 = visual analogue scale ranging from 0 (no pain) to 10 (worst pain imaginable); VAS 0-100 = visual analogue scale ranging from 0 (no pain) to 100 (worst pain imaginable)

Mepitel compared favourably to other wound contact layers (Atrauman, N-A Ultra, Tegapore, and Urgotul) in a clinical study involving 52 patients with a range of surgical (digit amputation, post-surgical cellulitis, toenail avulsion) and **traumatic wounds (digit crush injury, laceration, skin tear)** with regard to ease of removal and patient comfort during wear (Burton, 2004). McCarty et al reported on an observational study conducted prospectively across nine countries to evaluate the performance of Mepilex Border Ag, a silver-containing bordered foam dressing. In total, the wounds of 307 patients were evaluated, including 25 **traumatic wounds**. Compared to the baseline assessment, the number of wounds exhibiting local signs of infection were reduced at the final visit. Statistically significant decreases in wound area (28.5%) and depth (35.0%) between baseline and final visit were recorded (p<0.05). Pain severity during dressing wear, at removal and after removal was also significantly lower at the final visit, relative to baseline (p<0.0001), with a concomitant increase in the proportion of trauma-free wounds and peri-wound regions (McCarty et al, 2013). These findings are consistent with other studies that have demonstrated Mepilex Border Lite (thin bordered foam dressing) (Meuleneire, 2009) and Mepilex Border Flex (bordered foam dressing) (Boixados et al, 2019; Rook et al, 2019) to be associated with minimal pain at dressing changes when used on various wound types including **traumatic wounds**.

Patients (n=32) with **acute traumatic wounds** referred to a plastic surgery department in Taiwan were recruited into an RCT that compared a dressing regimen (silver-containing wound contact layer followed by a collagen-based dressing and an outer layer of Mepilex) with topical antibiotic ointment. Significantly faster healing rates were observed in the dressings group (p<0.05) (Tsai et al, 2019). A retrospective review of data collected on patients seen at an out-patient clinic in the United States of America (USA) was undertaken to compare, amongst other things, peri-wound issues of wounds dressed with either Mepilex (non-bordered foam dressing) or a hydrophilic polyurethane (Allevyn) dressing. Wound types included **traumatic wounds** (also surgical wounds and chronic wounds). Eighty-seven wounds were dressed with the foam dressing with Safetac and 86 with the hydrophilic polyurethane dressing. Cases of dermatitis were fewer in the Safetac group, i.e. six compared to 11 in the comparator group (Eager, 2001).

The Avance Solo single-use (NPWT) system, with Avance Solo Border dressings (**Figure 1**), was evaluated in a multi-centre (n=10) study conducted across four European countries involving in- and out-patients with low-to-moderately exuding acute (traumatic, flap/graft) or sub-acute (e.g. dehisced) wounds. Of the 104 patients recruited, 29 presented with **traumatic wounds**. The wounds were assessed at weekly visits for up to 28 days. Wound progress was noted as

improved at 80.7% of follow-up visits, relative to the previous visit. At the final visit, the mean decrease in wound area was 43.6%, compared to baseline (**Figure 1**). Increases in the proportion of wounds with no necrotic (40.5%) or sloughy tissue (36.3%), and in the proportion of patients with healthy peri-wound skin (8.5%), relative to baseline, were also observed. Pain severity scores at dressing changes were low throughout the study, with a mean score of 1.6 on a numerical ratings scale ranging from zero (no pain) to 10 (worst imaginable pain). The vast majority (95%) of patients had no dressing-related trauma to the wound at the final visit; 93% had no dressing-related trauma to the peri-wound skin at the final visit (Beele et al, 2025).

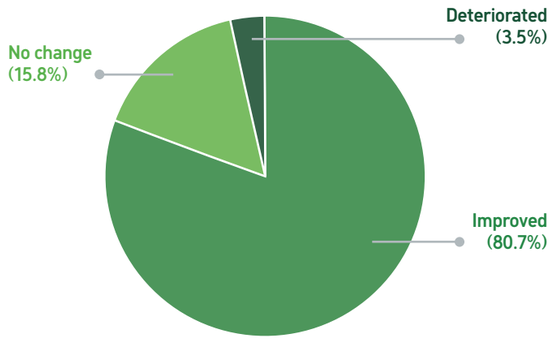


Figure 1. Progression toward healing of acute wounds managed with Avance Solo NPWT System at study assessments (Beele et al, 2015)

Skin tears

Skin tears are a type of traumatic wound seen most frequently in the elderly, in malnourished patients, and in critically ill or injured individuals. They are caused by shear, friction and/or blunt force that causes the separation of the layers of the skin, and are often associated with use of wheelchairs, patient transfer, or falls (Moradian & Klapper, 2016). Prevention of skin tears should be prioritised over treatment to prevent patient suffering and avoid unnecessary care costs. Strategies aimed at preventing skin tears include the regular use of emollients and protective products, patient and carer education and the use of risk assessment tools to identify at risk patients (LeBlanc et al, 2018). When skin tears occur, current best practice includes management with dressings that promote moist wound healing, secure skin flaps, manage exudate, conform to the wound, and provide pain-free and atraumatic dressing application and removal (Kennedy-Evans, 2004; LeBlanc & Baranoski, 2011; Fulbrook et al, 2024). Dressings with Safetac have been shown to fulfil these criteria in a number of clinical evaluations, as described below and in **Table 1**.

The efficacy of dressings with Safetac in the management of **skin tears** has been demonstrated in two RCTs. In the first RCT, undertaken in Canadian long-term care facilities, dressings with Safetac (Mepitel One and Mepilex Border Flex) were compared with non-adhesive composite dressings in terms of wound healing. The proportion of healed skin tears was 96.9% in the dressings with Safetac group and 34.4% in the comparator group. At the final study visit, the wound surface area in the dressings with Safetac group was significantly less (p<0.001), with those wounds taking, on average, 50% less time to heal (p<0.0001), compared to those in the comparator group (LeBlanc and Woo, 2022). The decision to use the absorbent foam dressing on the more exudating skin tears and the wound contact layer on the less exuding wounds in the Canadian RCT is supported by the findings of a pilot RCT which observed better healing rates with the absorbent foam dressing, compared to a wound contact layer, across all skin tear categories (Fulbrook et al, 2023).

Other studies have also demonstrated the successful use of dressings with Safetac in the management of skin tears. The first of these involved the application of Mepitel, in conjunction with a secondary absorbent dressing, to 88 **skin tears** (59 patients). The dressing regimen was associated with a high healing rate (83% of skin tears healed by the eighth study day) and reduced patient discomfort during dressing changes (compared to gauze dressings used previously) (Meuleneire, 2002). **Figure 2** follows the progress of a skin tear managed with Mepitel.

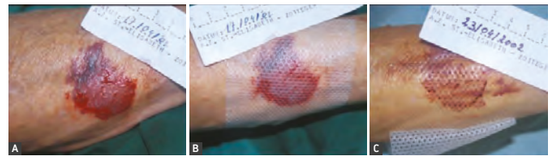


Figure 2. Skin tear management with Mepitel: (a) epidermal flap in its original position; (b) Mepitel in place; (c) after removal of Mepitel, the flap is attached to the dermis. (photographs courtesy of Frans Meuleneire, Woundcare Centre, Zottegem, Belgium)

A multinational survey of over 3000 patients, presenting with a variety of acute and chronic wound types including **skin tears**, was undertaken to gauge the impact of introducing dressings with Safetac (Mepilex, Mepilex Border, Mepilex Border Lite, Mepilex Lite) on the intensity of wound-related trauma and pain, in comparison to previously used regimes involving dressings with traditional adhesives (e.g. alginates, films, foams, hydrocolloids). The dressings with Safetac were associated with demonstrably reduced trauma to the wound and peri-wound skin and significantly (p=0.01) lower pain severity scores, as measured by means of a visual analogue scale (VAS) before, during and after dressing change, compared to the dressings with traditional adhesives. More than 90% of respondents indicated that they preferred the dressings with Safetac to their previous dressing regimes (White, 2008).

A five-patient case study series was undertaken to evaluate the use of Mepilex Border Ag in a nursing home in the United States of America (USA). Patients presented with a variety of wound types, including two with **skin tears**. The clinicians highlighted their observations from using the dressing with Safetac by referring to the acronym VALUE: Versatility - wide range of applications for topical acute and chronic wounds; Accessibility - over-the-counter, reimbursed, provided by most hospices for palliative wound care; Lifts up - after repositioning; Unequalled - in its ability to reduce pain and trauma; Ease of use - simple for staff to use and easy for resident's families and caregivers to learn to use at home or assisted living

(Krasner & McKinney, 2012). Around the same time, the same dressing was evaluated in a 10-patient case study series in a hospital setting. The patients presented with a variety of wound types including **skin tears**. The outcomes were positive in several areas. Wound healing was either accomplished or progressed towards healing. Mepilex Border Ag conformed to the contours of several body locations, stayed in place, managed exudate for several days, was easy to apply, provided comfort for the patient during wear time, decreased pain associated with dressing application and removal, and provided an antimicrobial barrier (Philbin, 2012).

In a case study involving the use of Mepitel for **skin tear** management, Kennedy-Evans described the care of an 81-year-old woman with a complex medical history. A full-thickness skin tear measuring 1 cm x 1.5 cm was cleansed before the wound contact layer with Safetac was applied as a cover dressing and secured with a gauze wrap. The wound fully healed in 15 days (Kennedy-Evans, 2004). Mepitel was also used as part of a quality improvement protocol to manage **skin tears** in a nursing home in the United Kingdom. Adoption of the dressing with Safetac resulted in reduced trauma and pain among residents, with improved skin tear healing (average 37 days). Less frequent dressing changes, resulting in cost-savings of two-thirds, were also reported (Armstrong, 2003). In another report, the introduction of a new dressing regimen for skin tears (Mepitel with an isotonic saline gel [Normlgel, Mölnlycke Health Care]) is discussed. Compared to the previous dressing regimen (antibiotic ointment covered with non-adherent gauze and secured with a gauze wrap), the new regimen was associated with reduced dressing-related trauma and pain to patients, a 33% reduction in healing time, and a 62% reduction in dressing change frequency, all equating to an average cost saving per skin tear of US$872 (Barrows et al, 2007).

Nineteen patients with a total of 42 **skin tears** took part in a study to compare two foam dressings. At baseline, a three-layered foam dressing was applied to all new skin tears. After one day, the three-layered dressing was removed, the wound assessed, and the five-layered dressing (Mepilex Border Flex) applied. Dressings were then changed according to local clinical practice or until discharge, unless there was justification for changing it sooner. The clinicians recorded several instances of exudate leakage, poor border adhesion, dressing adherence to the wound bed and encrusting of the skin flap within the dressing during usage of the three-layered dressing. In contrast, no problems relating to the leaking of exudate, dressing adhesion and dressing adherence to the wound bed were observed with the five-layered dressing. In addition, the clinicians found that the five-layered dressing was easier to use and more comfortable to wear than the three-layered dressing. The average wear time of the five-layered dressing was 6.02 days. Eleven skin tears healed by study day seven, with an average of 78.2% re-epithelialisation during hospitalisation (Nelson, 2018).

In a later study undertaken at the same acute care facility in the USA, 13 patients with a total of 25 wounds (including seven **skin tears**) were followed-up to evaluate the clinical outcomes, dressing performance and impact on the patient of implementing Mepilex Border Flex dressings, and to determine if a change in routine dressing change policy from every 3 to every 7 days affected the number of dressings used and dressing costs. The average reduction in wound volume was 77% over 13.2 days. No wounds enlarged and four healed (achieved complete re-epithelialisation). For the chronic wounds, the average reduction in volume was 80.9% over 12.3 days. The dressing was assessed as fully intact without leaking or lifting for 28/29 wound care nurse dressing changes, i.e. a 97% rate of adhesive integrity. A total of 60 dressing changes occurred for the 13 patients. The average wear time of the dressing was 5.5 days. The number of formulary dressings used across the entire facility was reduced by 8.11% and the amount of facility spend on the formulary dressing was reduced by 12.6% when compared to full facility dressing utilisation with the bordered foam dressing used previously (Nelson, et al, 2019).

Fingertip injuries

Fingertip injuries in paediatric patients are common plastic surgery referrals, with most requiring dressings for several weeks post-injury (O'Donovan et al. 1999). In an RCT involving 45 children with **fingertip injuries** referred to a plastic surgery department from an accident and emergency unit, wound healing, dressing adhesion to the wound, and stress experienced by the child were assessed for two different dressing regimes. Twenty patients had Mepitel dressings applied, and 25 were managed with paraffin gauze dressings. Wound healing rates at study week 6 were similar in both groups, but the Safetac wound contact layer group had significantly lower patient stress scores at week 1, week 2 and week 3 compared to the gauze dressing group ($p<0.01$), (**Figure 3**) corresponding to statistically significant lower mean adhesion scores ($p<0.01$) (**Figures 4**). These study findings indicate that the wound contact layer with Safetac offers a less painful alternative to traditional dressings with equally effective wound healing in a variety of fingertip injuries in children (O'Donovan et al. 1999).

The clinical challenges of traumatic wound healing in children includes both the smaller size of the patient and the need to minimise pain suffered during treatment. Dressings must be highly conformable and flexible to dress digit and limb injuries, in addition to usual requirements for exudate management and barrier functions. A multi-centre observational study of 36 acute paediatric wounds (including n=10 burns, n=11 surgical wounds, n=13 **traumatic wounds**, n= 1 **cannula insertion site** wound and n= 1 post-herpes zoster lesion) aimed to determine the pain during and in-between dressing changes with Mepilex Border Lite. Importantly, over 99.5% of dressing changes were reported to be atraumatic, and more than half of the wounds healed within the six-week study period (Morris et al, 2009). **Figures 5 and 6** follow the progress of traumatic injuries to the hands of children dressed with Mepilex Border Lite.

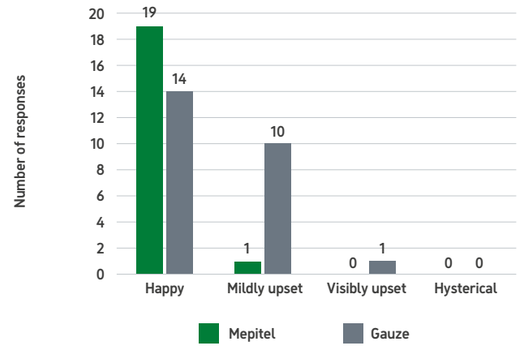


Figure 3. Comparison of Mepitel and gauze in terms of patients' stress at study week three (O'Donovan et al, 1999)

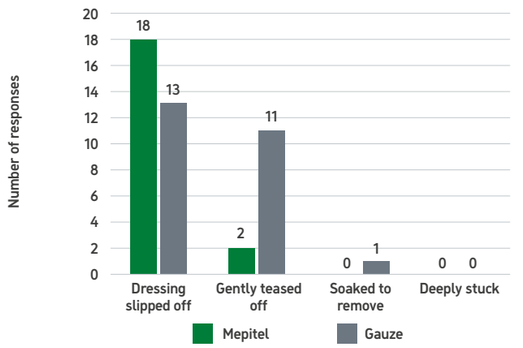


Figure 4. Comparison of Mepitel and gauze in terms of dressing adherence at study week three (O'Donovan et al, 1999)

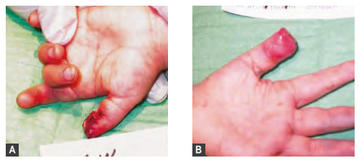


Figure 5. Traumatic injury to the thumb dressed with Mepilex Border Lite at the start (a) and end (b) of treatment. (photographs courtesy of Clare Morris, North Wales NHS Trust (East), Wrexham, United Kingdom)

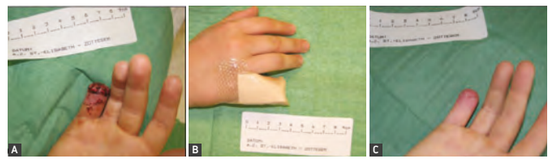


Figure 6. Finger amputation wound of a paediatric patient dressed with Mepilex Border Lite, demonstrating the flexibility and conformability of the dressing and the excellent outcome achieved: at the start (a), mid-point (b) and end (c) of treatment. (photographs courtesy of Frans Meuleneire, Woundcare Centre, Zottegem, Belgium)

Road rash

Road rash is a term used to describe the abrasive (partial thickness) injury that occurs when a casualty comes into contact with, for example, a road surface, resulting from a traffic accident. Road rash is often painful and at high risk of infection due to the presence of embedded foreign matter (Grossman et al, 2023; Collier et al, 2020).

Mepilex Border and Mepilex Lite compared favourably with previous dressing regimens (semi-occlusive film dressings, normal saline dressings, and silver sulphadiazine cream covered with gauze dressings) when used on **road rash**. The dressings with Safetac demonstrated good absorption characteristics and protected the healing tissue. The dressing regimen change also resulted in decreases in the frequency of dressing changes, supply costs and nursing time (by 50%). Pain severity levels also decreased from an average of eight to three (on a scale of 1-10) and the need for parenteral analgesia was eliminated (Dunbar et al, 2006).

Other traumatic wounds

Barrett reported on a case study involving a patient who presented with a **pretibial wound** associated with cardiac disease, lower limb oedema and diabetes. The author refers to the exudate absorption challenges of such wounds as 'almost insurmountable' for dressings. It was decided to initiate a regime including Mepitel One and an absorbent pad as the primary and secondary dressings, respectively, in conjunction with a light compression system. The regime was effective in reducing the fluid in the lower limb. The dressing with Safetac remained in place when the secondary dressing was changed, thus leaving the wound undisturbed (Barrett, 2012). A similar regime was used to manage a **bruised and blistered area** on the outer aspects of the foot, resulting from a fall. The limb was compromised by oedema. After one week, the Mepitel One dressing had remained in place, the blistering had resolved, sloughy tissue was exposed for debridement, and there was no oedema present in the lower limb. The regime was successful in enabling the clinical team to progress to the next phase of treatment (Cooper et al, 2010).

Maeda et al reported on a neonate born with large **congenital scalp and skull defects**, including exposure of the cranial arachnoid mater. As it was not possible to cover the large defects surgically, a conservative approach was adopted, including the use of Mepilex Transfer. The exudate transfer dressing helped to keep a moist wound environment, provided a cushioning effect to counter the effects of movement-related frictional forces, and was gentle but sufficiently adhesive to the wound surface. Complete healing of the defect was achieved in just over 30 weeks (Maeda et al, 2015).

Progesterone injections are commonly used in assisted reproductive technology. One side effect of this therapy is the development of

inflammation (panniculitis) around the injection sites. A study was undertaken to assess the effectiveness of a regime for addressing progesterone-related **injection site inflammation**. The regime involved the application of a corn peroxide oil-based solution, followed by a sodium chloride-based absorbent dressing and then Mepilex as the outermost layer for protection and exudate absorption. Symptoms and local signs of panniculitis disappeared completely in 15 of the 16 patients (Xiao et al, 2021).

Thoracostomy tubes (chest tubes) are used to drain air or fluid in the pleural cavity. Practices vary with regards to dressing choice and dressing change frequency at the incision site, with limited evidence to guide decision-making. A convenience sample of 127 patients from cardiovascular intensive care units (ICUs), medical ICUs and surgical and trauma ICUs with thoracic or mediastinal chest tubes (placed within 24 hrs) were included in a study, in which **chest tube insertion wounds** were dressed with Mepilex Border or gauze. Overall, 63% of nurses reported that the dressings with Safetac absorbed drainage better than gauze dressing for both mediastinal and pleural chest tubes, and maintained the best skin integrity (Wood et al, 2019).

Central venous catheters are used to deliver pharmacological agents, fluids, nutrition and blood products directly into the venous system and to draw blood for sampling. Dressings are normally used to stop the catheters from becoming dislodged and to provide a barrier against the migration of skin microorganisms at the insertion site into the catheter (Xu et al, 2024). In a study undertaken at an oncology centre in France, 28 children had their **central venous catheter insertion sites** dressed with one of two regimens. During the first study period, a regimen consisting of Mepilex Border Lite plus a polyacrylic adhesive (Mefix, Mölnlycke Health Care) was used. During the second period, a regimen comprised of an acrylic adhesive dressing (Cicaplaie) plus a transparent polyurethane adhesive (Tegaderm) was used. In total, 206 dressing applications were performed. The regimen including the dressing with Safetac was associated with less accidental dislodgement ($p<0.0001$), less skin inflammation ($p<0.05$) and less pain and apprehension at dressing changes, compared to the second regimen (Montmaneix et al, 2012).

References

Armstrong, L. (2003) 'The patients are delighted at how quickly they have healed'. Nursing Times 99(44):36-37.

Barrett, S. (2012) Mepitel One: a wound contact layer with Safetac technology. British Journal of Nursing 21(21):1271-1277.

Barrows, C., McQueeney, M., Lemiska, L. (2007) Repair the tear – value analysis of a skin tear protocol. How CWCNs changed clinical and financial management of wounds for a homecare agency. Poster presentation at the 20th Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Tampa, Florida, United States of America.

Beele, H., Amann, B.; Carnali, M., Danneels, M., Gibello, L., Goueffic, Y., Piffaretti. G., Timmons, J. (2025) Evaluation of a novel, canister-based, portable negative pressure wound therapy system in the management of low-to-moderately exuding acute and subacute wounds. Poster presentation at European Wound Management Association Conference, Barcelona, Spain.

Boixados, D., Allaert, F.A., Drareni, W. (2019) Efficacy of a five-layer silicone foam dressing with 360-degree flex technology for chronic and acute wound management in home care settings E-poster presentation at European Wound Management Association Conference, Gothenburg, Sweden.

Burton, F. (2004) An evaluation of non-adherent wound-contact layers for acute traumatic and surgical wounds. Journal of Wound Care 13(9):371-373.

Burton, F. (2006) Best practice overview: surgical and trauma wounds. Wound Essentials 1:98-107.

Collier, Z.J., Choi, K.J., Pham, C.H., Yenikomshian, H.A., Gillenwater, J. (2020) 536 Road Rash: understanding a challenging form of burn injury. Journal of Burn Care and Research 41(Supplement 1):S106-S107.

Cooper, P., Gray, D., Russell, F., Stringfellow, S. (2010) Case study using Mepitel One wound contact dressing with Safetac. Wounds International 1-11.

Dearden, C., Donnell, J., Donnelly, J., Dunlop, M. (2001) Traumatic wounds: cleansing and dressing. Nursing Times 97928):50-52.

Dunbar, A., Rayburn, S., Workman, C. (2006) Road rash: a 'best practice' solution to a painful problem. Poster presentation at the 38th Annual Conference of the Wound Ostomy and Continence Nurses Society, Minneapolis, United States of America.

Eager, C.A. (2001) Comparison of two foams through the measurement of healing time, frequency of dressing changes and peri wound status. Poster presentation at the 14th Annual Symposium on Advanced Wound Care and Medical Research Forum on Wound Repair, Orlando, Florida, United States of America.

Fulbrook, P., Miles, S.J., Williams, D.M. (2024) Healing rate of hospital-acquired skin tears using adhesive silicone foam versus meshed silicone interface dressings: A prospective, randomized, non-inferiority pilot study. International Journal of Nursing Practice 30(3):e13229.

Grossman, H., Pang, A., Griswold, J. (2023) Treatment of severe road rash with ReCell autologous skin cell suspension. Journal of Burn Care and Research 44(3):731-733.

Kennedy-Evans, K. (2004) An innovative solution for skin tears: a case study. Ostomy Wound Management 50(2): 9-10.

Krasner, D.L., McKinney, W. (2012) Acute and chronic wound applications in the long term care setting for a soft silicone foam border dressing with silver: a clinical case series demonstrating VALUE. Poster presentation at the Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Atlanta, Georgia, United States of America.

Leaper, D.J., Harding, K.G. (2006) ABC of wound healing. Traumatic and surgical wounds. British Medical Journal 332(7540):532-535.

LeBlanc, K., Baranoski, S., Skin Tear Consensus Panel Members (2011). Skin tears: state of the science: consensus statements for the prevention, assessment and treatment of skin tears. Advances in Skin and Wound Care 24(9):2-15.

LeBlanc, K., Campbell, K., Beeckman, D., Dunk, A.M., Harley, C., Hevia, H., Holloway, S., Idensohn, P., Langemo, D., Ousey, K., Romanelli, M., Vuagnat, H., Woo, K. (2018) Best practice recommendations for the prevention and management of skin tears in aged skin. Wounds International, London, United Kingdom.

LeBlanc, K., Woo, K. (2022) A pragmatic randomised controlled clinical study to evaluate the use of silicone dressings for the treatment of skin tears. International Wound Journal 19(1):125-134.

Maeda, T., Oyama, A., Funayama, E., Furukawa, H. (2015) Successful conservative management of a large congenital scalp and skull defect. Journal of Craniofacial Surgery 26(3):e275-e277.

McCarty, S., Davies, P., Rippon, M. (2013) Mepilex Border Ag: an in-market evaluation. Poster presentation at the Wounds UK Conference, Harrogate, United Kingdom.

Meuleneire, F. (2002) Using a soft silicone-coated net dressing to manage skin tears. Journal of Wound Care 11(10):365-369.

Meuleneire, F. (2009) Case study evaluation of Safetac dressings used for paediatric wounds. Wounds UK 5(2): 12-18.

Montmaneix, N., Eddi, D., Odier, F., Faubert, S., Stephan, J-L., Piguet, C., Deplanque, P., Guibon, O., Demeocq, E., Merlin, E. (2012) Comparison of a device comprising a silicone hydrocellular dressing (Mepilex Border Lite) plus a polyacrylic adhesive (Mefix) and a reference device comprising an acrylic adhesive (Cicaplaie) and a transparent polyurethane adhesive (Tegaderm) in order to keep central catheters positioned in children and adolescents at Clermont-Ferrand, Limoges and St Etienne hospitals. Journal de Plaies et Cicatrisations 83(17):38-43.

Moradian, S., Klapper, A.M. (2016) A novel way to treat skin tears. International Wound Journal 13(2):283-286.

Morris, C., Emsley, P., Marland, E., Meuleneire, F., White, R. (2009) Use of wound dressings with soft silicone adhesive technology. Paediatric Nursing 21(3):38-43.

National Institute for Health and Care Excellence (2022). Clinical Knowledge Summaries: Lacerations.

Nelson, D. (2018) Better outcomes for skin tears with new 5 layer bordered foam dressings. Poster presentation at 50th Annual Conference of the Wound Ostomy and Continence Nurses' Society, Philadelphia, Pennsylvania, United States of America.

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

O'Donovan, D., Mehdi, S., Eadie, P. (1999) The role of Mepitel silicone net dressings in the management of fingertip injuries in children. Journal of Hand Surgery 6:727-730.

Philbin, S. (2012) Simple solutions for complex wounds of multiple types. Poster presentation at the Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Atlanta, Georgia, United States of America.

Rook, S., Davies, P., Frenthoff, E., Wurfel, T (2019). Mepilex Border Flex – results of an observational study in German specialist wound care centres. Wounds International 10(1):40-43.

Tsai, H-C., Shu, H-C., Huang, L-C., Chen, C-M. (2019) A randomized clinical trial comparing a collagen-based composite dressing versus topical antibiotic ointment on healing full-thickness skin wounds to promote epithelialization. Formosan Journal of Surgery 52(2):52-56.

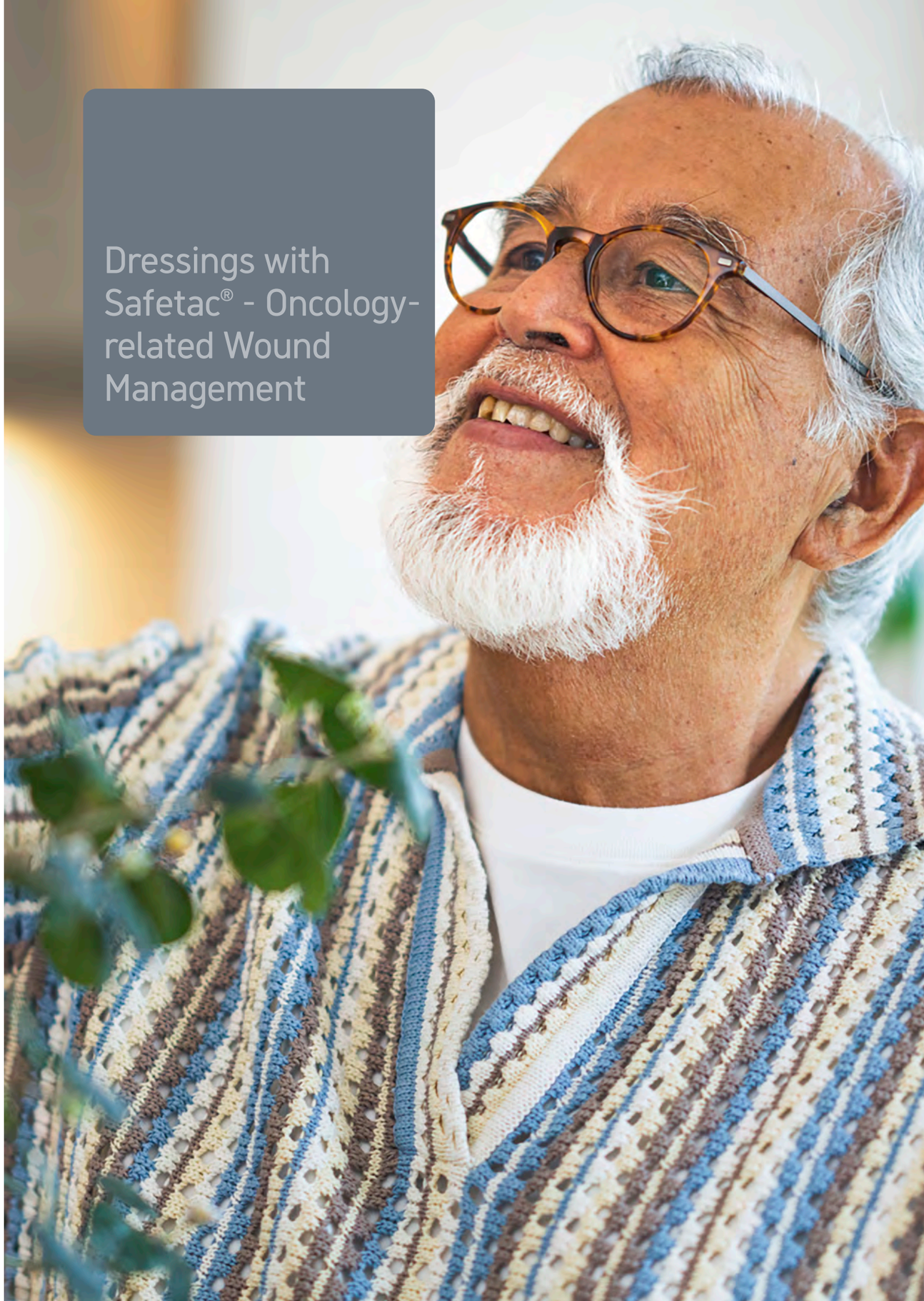
White, R. (2008) A multinational survey of the assessment of pain when removing dressings. Wounds UK 4(1):14-22.

Wood, M., Powers, J, Rechter, J. (2019) Comparative evaluation of chest tube insertion site dressings: a randomized controlled trial. American Journal of Critical Care 28(6):415-423.

Xiao, W., Huang, X, Lin, C., Liu, Y., Chen, S., Wu, R. (2021) Panniculitis caused by progesterone injection can be treated by physical therapy. Dermatologic Therapy 34(1):e14501.

Xu, H., Hyun, A., Mihala, G., Rickard, C.M., Cooke, M.L., Lin, F., Mitchell, M., Ullman, A.J. (2024) The effectiveness of dressings and securement devices to prevent central venous catheter-associated complications: a systematic review and meta-analysis. International Journal of Nursing Studies 149:104620.

Dressings with Safetac® - Oncology-related Wound Management



Dressings with Safetac featured:

Mepilex®, Mepilex® Border Lite, Mepilex® Lite, Mepilex® Transfer, Mepitel®, Mepitel® Ag, Mepitel® Film

Take home messages:

- Malignant fungating wounds (MFWs) can be disfiguring and are frequently associated with malodour, high exudation, pain, bleeding and risk of infection. Dressings with Safetac have been demonstrated to improve the quality of life of patients with MFWs by effectively managing exudate, reducing pain at dressing changes and reducing malodour.
- Dressings with Safetac have been reported to play key roles in the management of wounds following tumour excision, including exudate management, minimisation of trauma and pain at dressing changes and skin graft fixation.
- Radiotherapy-induced skin damage (RISD) can reduce patient quality of life as a result of pain and discomfort, poor cosmesis, loss of sleep, anxiety, and decreased functional and social ability. Moist desquamation is the main cause of patient suffering, leading to pain and discomfort whilst also increasing the risk of infection. Randomised controlled trials have demonstrated the ability of dressings with Safetac to prevent (Mepitel Film) and successfully manage (Mepilex Lite) RISD.

Introduction to oncology-related wounds

Patients with cancer may experience a range of wound types resulting from the disease itself and the interventions (medical and surgical) that are employed to address the disease.

Malignant fungating wounds

One of the most distressing oncology-related wound is the malignant fungating wound (MFW) which occurs when cancerous cells infiltrate the skin and underlying tissue, leading to ulceration, necrosis and often infection (Vardhan et al, 2019; Pramod et al, 2024).

Wounds associated with tumour removal

Tumours are surgically removed for several reasons, primarily to diagnose cancer, determine its stage and to remove cancerous tissue to potentially cure the disease. Surgery can also be used to relieve symptoms caused by tumours, prevent cancer from developing further, or to reconstruct parts of the body affected by cancer (Freise et al, 2006; Meuleneire et al, 2008).

Radiotherapy-induced skin damage

Radiotherapy is the primary treatment for many types of cancer (Wei et al, 2019); high energy X-rays (photons) and other forms of ionising radiation are used. Ionising radiation directly or indirectly damages the structures and chemicals within cells of a target area. Radiotherapy is based on the concept that cells in healthy tissues are much more likely to recover and repopulate than the cancer cells in the tumour (Morgan, 2014). Yet, radiotherapy-induced skin damage (RISD), also termed radiotherapy-induced dermatitis, radiation-induced dermatitis, radiation dermatitis or radiodermatitis, is one of the main adverse events associated with radiotherapy, and it can damage the healthy tissues in both the short and long term (Wei et al, 2019). Manifestations of RISD include erythema, pigmentation and dry desquamation; severe radiodermatitis can cause moist desquamation, pain and decreased quality of life (QoL) (Yee et al, 2021). **Figure 1** provides a simplified schematic of the process leading to RISD.

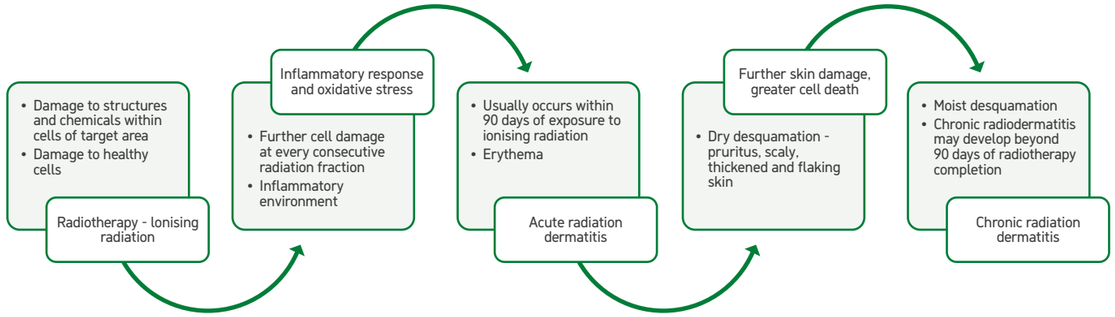


Figure 1. Simplified schematic of the process leading to radiotherapy-induced skin damage

RISD affects approximately 90-95% of patients undergoing radiotherapy (Zasadziński et al, 2022). The severity of the reactions relates to the biological damage done to the dermis and epidermis during radiotherapy (Morgan, 2014). The extent of tissue damage depends on a range of internal (patient-related) and external (e.g. treatment-related) factors (Hegedus et al, 2017; Behroozian et al, 2021; Wei et al, 2019; Yee et al, 2021; Robijns et al, 2023; Finkelstein et al, 2022).

RISD is normally categorised by versions of internationally recognised systems that typically grade the severity of the dermatitis from 0-4 or 0-5, with the higher grades indicative of more severe reactions. The categorisations are part of broader toxicity grading systems, such as one developed by the **Radiation Therapy Oncology Group (RTOG)**, in conjunction with the **European Organization for Research and Treatment of Cancer (EORTC)** (Cox et al, 1995), and another referred to as the **Common Terminology Criteria for Adverse Events (CTCAE)** (Spampinato et al, 2025) (**Table 1**).

Table 1. Comparison of two commonly used systems for the grading of radiotherapy-induced skin damage

Grade	Radiation Therapy Oncology Group (RTOG) / European Organization for Research and Treatment of Cancer (EORTC)	Common Terminology Criteria for Adverse Events (CTCAE)
0	No change over baseline	Not defined
1	Faint erythema / dry desquamation	Faint erythema / dry desquamation
2	Moderate to brisk erythema / patchy moist desquamation, mostly in skin folds and creases / moderate oedema	Moderate to brisk erythema / patchy moist desquamation, mostly in skin folds and creases / moderate oedema
3	Confluent moist desquamation (not limited to skin folds) / pitting oedema	Moist desquamation in areas other than skin folds and creases / bleeding induced by minor trauma or abrasion
4	Skin necrosis or ulceration of full thickness dermis / spontaneous bleeding from involved site	Life-threatening consequences / skin necrosis or ulceration of full thickness dermis / spontaneous bleeding requiring intervention
5	Not defined	Death related to radiation dermatitis (extremely rare)

A third commonly used tool is the **Radiation-Induced Skin Reaction Assessment Scale (RISRAS)**. This was designed to address limitations with the RTOG/EORTC and CTCAE scales by incorporating both clinician-assessed objective signs and patient-reported symptoms. The clinician-assessed parameters are erythema and dry desquamation (using a zero-to-four-point scale) and moist desquamation and necrosis (assessed on a scale having values 0, 2.5, 5.0. 7.5 and 10). The patient-assessed parameters are tenderness and discomfort or pain, itch, burning sensation and the extent to which skin reactions affect daily activities (assessed on a scale of 'not at all', 'a little', 'quite a bit' and 'very much'). The total RISRAS score is determined by the summation of the clinician and patient scores (Noble-Adams, 1999).

Challenges

Malignant fungating wounds

These wounds rarely heal and are typically associated with pain, malodour, bleeding and copious exudate. Their presence can significantly impact a patient's physical, emotional and social well-being, often requiring interdisciplinary care and specialised wound care strategies. Typically occurring in patients with advanced wound care (Dowsett, 2002), MFWs can be disfiguring and are frequently associated with malodour, high exudation, pain, bleeding and risk of infection (Gethin et al, 2025). Realistic care outcomes may be palliative and relate to symptom control, rather than healing (Young, 1999).

Wounds associated with tumour removal

Wounds resulting from the surgical removal of tumours present several clinical challenges, which can significantly impact recovery, QoL and the timing of subsequent medical intervention. These challenges stem from both the nature of the surgery and the effects of cancer and its treatments on the body's healing capacity. For example, chemotherapy and radiotherapy can weaken the immune system, reduce blood supply to tissues and impair cellular repair mechanisms (Deptuta et al, 2018). Infection, haematoma, seroma and wound dehiscence are frequent after tumour resections, especially in complex or deep surgeries (Gerken et al, 2023). Lymphatic leakage and prolonged drainage are common in soft tissue resections, particularly in the lower extremities. These can delay healing and increase the risk of infection (Gerken et al, 2023).

Radiotherapy-induced skin damage

RISD can have a significant patient impact (Wei et al, 2019; Behroozian et al, 2021); these skin reactions can negatively influence patient QoL as a result of pain and discomfort, poor cosmesis, loss of sleep, anxiety, and decreased functional and social ability (Morgan, 2014; Wei et al, 2019; Behroozian et al, 2021). Moist desquamation is the main cause of patient suffering, leading to pain and discomfort whilst also increasing the risk of infection (Wei et al, 2019). Moist desquamation reactions are not only painful but also provide an environment conducive to infection (MacBride et al, 2008). Furthermore, the onset of RISD and associated symptoms may increase the risk of treatment interruptions and non-compliance, and thus progress of cancer treatment, which can in turn increase the likelihood of disease recurrence, increase late radiation-related side effects, and decrease overall survival (Wei et al, 2019; Behroozian et al, 2021; Zasadziński et al, 2022; MacBride et al, 2008; Yee et al, 2021; Finkelstein et al, 2022). **Figure 2** provides a simplistic schematic of the impact that RISD has on the patient.

A Canada-based research group completed a study involving 1093 patients to evaluate the impact of patient-related and treatment-related characteristics, including body mass index (BMI), surgery type, prior chemotherapy, smoking status and radiotherapy skin dose, on the development of RISD. Results highlighted several predictive factors for RISD symptoms including erythema, oedema, desquamation, pain and bleeding. High BMI, high tissue volume irradiated by tangential fields, conventional fractionation (50 Gy/25), and addition of a boost or bolus were all significant factors that enhance skin reaction severity among breast cancer patients. (Behroozian et al, 2021).

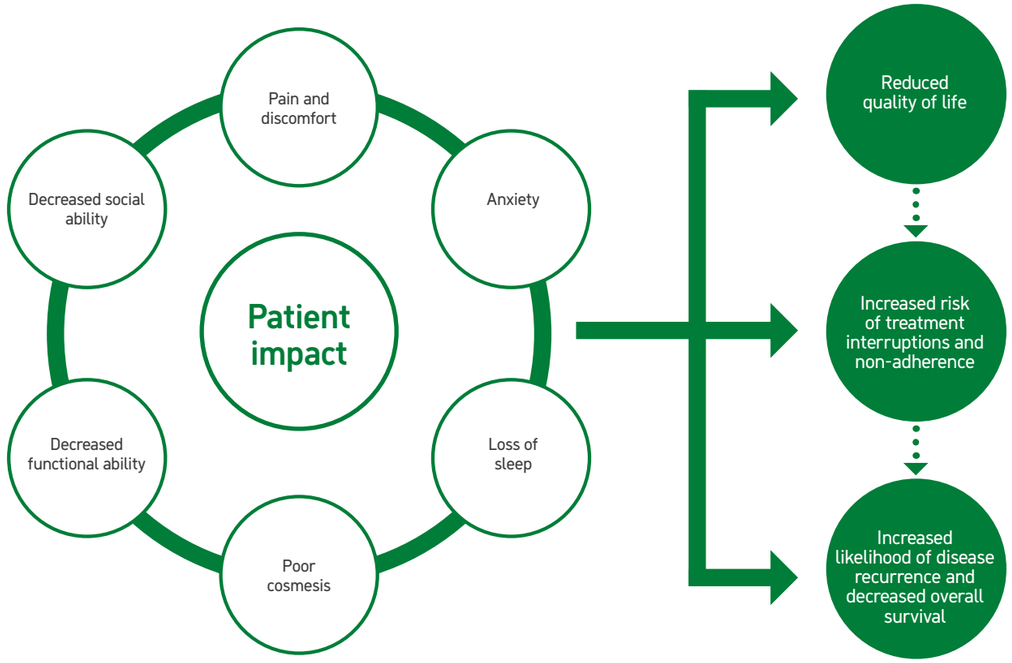


Figure 2. Impact of radiotherapy-induced skin damage on the patient

Role of dressings in oncology-related wound management

Malignant fungating wounds

Symptom control and patient's QoL are typically the main focus of **MFW** management since wound healing is rarely considered to be a realistic objective (Probst et al, 2013). In advanced cancer care, the goal is to enhance comfort and preserve dignity, making dressing selection a critical component of palliative wound care (Niculescu et al, 2024). Management of excess exudate, protection of the peri-wound region from moisture-related skin damage, bleeding control, and malodour control are the main ways in which appropriately selected dressings can address the symptoms of MFWs and contribute positively to the QoL of patients (Ousey et al, 2024).

Wounds associated with tumour removal

Regarding the management of wounds arising from tumour removal, the main role of dressings is typically the same as that for surgical wounds types, i.e. to support the local wound environment in order to facilitate healing by providing a protective barrier, maintaining a moist wound environment, managing excess exudate, preventing infection and minimising scarring (Holloway & Harding, 2022).

Radiotherapy-induced skin damage

Various types of dressings may be used either as RISD prophylaxis (from the beginning of radiation therapy) or as a management method (applied at the onset of signs of skin damage) (Zasadziński et al, 2022). Of note, the application of a protective layer is likely to be more effective when applied from the very beginning of radiotherapy in comparison to applying the dressing once RISD is visible (Herst et al, 2014). Furthermore, application technique must be considered; the dressing must be applied correctly with minimal overlapping and should be applied with the patient in radiotherapy treatment position (Herst et al, 2014). The management of RISD using dressings is also multifaceted and requires considerations such as whether the addition of certain materials (e.g. thick foam dressings) would lead to changes in radiotherapy dose distribution (Zasadziński et al, 2022).

The authors of a 2020 systematic review and meta-analysis concluded that, at the time of their publication, overall research in the area of RISD prevention and management provided low to moderate evidence on interventions. However, the analysis identified that

semipermeable dressings have a moderate protective effect on the development of grade 2 or higher RISD and on the development of moist desquamation. The analysed studies also revealed minimisation of patient-reported symptoms – tenderness, discomfort, pain and pruritus. A beneficial effect was also highlighted in terms of QoL, although clinical significance was deemed likely to be small (Ginex et al, 2020).

There is limited consensus around the management and prevention strategies for RISD. According to an international review panel, the limited consensus can be attributed to a number of factors - limited high-quality data from robust clinical trials, heterogeneity in study design, high variability in outcome measures and variability in interventions used to manage RISDs. The same group reviewed international guidelines published between 2010 and 2021, including those of the Multinational Association for Supportive Care in Cancer (MASCC), British Columbia Cancer Agency (BCCA), Cancer Care Manitoba (CCMB), Oncology Nursing Society (ONS), Society and College of Radiographers (SCoR) and International Society of Nurses in Cancer Care (ISNCC). They noted only moderate concordance of guideline recommendations across the different organisations. However, BCCA, CCMB, SCoR and ISNCC were found to be in agreement regarding the ability of silicone-based dressings to reduce trauma from moist desquamation, although there was limited consensus on the use of other barrier films or dressings. The authors commented that, as new evidence becomes available, new guidelines must be generated and implemented into practice to optimise patient outcomes (Finkelstein et al, 2022).

Film dressings can be applied directly to the skin or wound, providing protection from friction and excess moisture by providing a semi-permeable mechanical barrier between the damaged basal skin layer and any potential additional trauma (Dejonckheere et al, 2023; Herst, 2014). The use of barrier films as a protective layer in patients undergoing radiotherapy of the breast or chest wall are of particular interest given RISD (and especially moist desquamation) have a predilection for areas prone to friction such as the axilla and inframammary fold (Dejonckheere et al, 2023). Of note, patients receiving chest wall radiotherapy and patients with large breasts are especially sensitive to developing more severe skin reactions (Wan et al, 2019). Furthermore, film dressings typically have an insignificant bolus effect and have high patient tolerability and comfort (Yee et al, 2021; Dejonckheere et al, 2023). Indeed, tests have confirmed that Mepitel Film has a negligible bolus effect (Yee et al, 2021).

The selection of dressings that are known to minimise trauma and pain to the patient on removal and allow for infrequent dressing changes is an important consideration for all the oncology-related wound types described above and below (Niculescu et al, 2024).

Evidence for dressings with Safetac

Malignant fungating wounds

In a review article focusing on the assessment and management of **MFWs**, it is stated that dressings with Safetac (Mepilex and Mepitel) cause less pain than conventional dressings on removal, suggesting that when pain is experienced at dressing changes, the type of dressing used should be reviewed (Dowsett, 2002).

Mepitel was used to good effect in the management of a wound related to **mycosis fungoides**, a cutaneous form of lymphoma. The patient presented with deeply ulcerated and necrotic areas on the head, neck and back. The ulcers were associated with severe pain and purulent exudate which, together with their appearance, were having a significant impact on the patient's QoL. Within the first day of introducing Mepitel, the wound-related pain was greatly reduced (Taylor, 1999). This outcome is in line with other reports of the use of Mepitel leading to reductions in wound-related pain and trauma, alongside improvements in the emotional state of patients (Naylor, 2003; Wilson, 2005; Mekrut-Barrows, 2006).

In a conference poster presentation, the application of Mepilex Transfer and topical metronidazole as part of a management regime for three cases of **MFWs** are discussed. The author states that the regime improved the quality of patient care. The exudate transfer dressing effectively pulled exudate away from the wound bed and into a secondary dressing that was changed by the patient as needed, thus maintaining the patient's sense of independence and dignity. It was also reported to have promoted pain-free dressing changes, while also providing exudate management and decreasing odour, improving the QoL of the patients (Barrows, 2007).

McCarty et al reported on an observational study conducted prospectively across nine countries to evaluate the performance of Mepilex Border Ag. In total, the wounds of 307 patients were evaluated, including 3 malignant wounds. Compared to the baseline assessment, the number of wounds exhibiting local signs of infection were reduced at the final visit. Statistically significant decreases in wound area (28.5%) and depth (35.0%) between baseline and final visit were recorded ($p<0.05$). Pain severity during dressing wear, at removal and after removal was also significantly lower at the final visit, relative to baseline ($p<0.0001$), with a concomitant increase in the proportion of trauma-free wounds and peri-wound regions (McCarty et al, 2013).

Wounds associated with tumour excision

A study undertaken at a specialist wound care centre in Belgium, involving patients who had undergone oncology-related reconstructive breast surgery, blistering in the peri-wound region was observed, because of the adhesive component of post-operative dressings causing trauma. Ten patients who had Mepilex Border Lite applied to their closed incision sites did not experience any peri-wound blistering (**Figure 3**). In contrast, prior to the introduction of the dressing with Safetac, more than 80% of patients attending the centre developed post-operative lesions due to poor dressing choice. Patients commented positively about the comfort of the thin bordered foam dressing with Safetac; its removal was not painful and did not cause further trauma (Meuleneire et al, 2008).

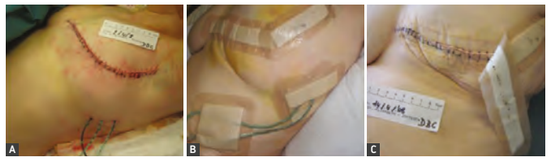


Figure 3. Post-oncologic breast surgery wound dressed with Mepilex Border Lite: (a) immediately after surgery; (b) dressing in place; (c) dressing removed 12 days post-operatively (no blisters evident)

In a study involving 10 patients with **wounds resulting from the removal of skin tumours** or chronic skin disorders, Mepilex was applied during the granulation and epithelialisation phases of healing. The wounds healed completely in a timely manner without any complications, pain was rarely reported and no impairment to the daily lives of the patients was observed (Freise et al, 2006).

Skin grafts are often applied to wounds resulting from the surgical removal of tumours. This helps to restore the skin barrier and promote healing, especially when direct closure or skin flaps are not feasible (Hou et al, 2023). The use of Mepitel as a temporary dressing before delayed split skin grafting of extensive wounds resulting from the local excision of skin tumours was evaluated in a randomised controlled trial (RCT) (Dahlstrom, 1995). Sixty-four patients were randomised to have either the wound contact layer with Safetac (n=32) or paraffin gauze (n=32) applied after the excision of malignant melanomas. In both study groups, the wounds were covered with a saline-soaked absorbent secondary dressing. All dressings were removed on the following day and an unmeshed skin graft applied, which was left exposed. Statistically significant differences were seen between the study groups with the Safetac wound contact layer associated with less wound bed adherence ($p<0.001$), less bleeding ($p<0.02$), less pain ($p<0.001$), and less time required for dressing removal ($p=0.02$). Commenting on their results, the author considered the dressing with Safetac to be "an optimum temporary dressing for delayed split-skin grafting" (Dahlstrom, 1995).

Ninety-six patients who had full thickness skin graft reconstruction following facial skin cancer excision had Mepitel applied to their **graft sites**. Complete graft take was observed in 98% (94) of patients. Partial graft failure was observed in two patients: in the first case, the wound went on to heal and the patient had successful late scar revision surgery; in the second case, the wound was managed conservatively and went on to heal (Armstrong et al, 2022). Another report describes using Mepitel instead of tie down sutures on **skin grafts** applied to wounds resulting from skin tumour removal. The wound contact layer was associated with improved adherence between the grafted skin and the wound bed. The report also refers to the dressing's ability to apply even pressure throughout the entire area (due to its elasticity), reduce the amount of booster bulk required, and reduce the number of sutures required. The authors describe the dressing with Safetac as "an efficient and simple tool for securing skin grafts" (Roh et al, 2008).

Radiotherapy-induced skin damage

Published in 2023, a systematic review with meta-analysis explored the efficacy of barrier films and dressings in preventing RISD and their impact on related symptoms. Data from 25 studies were pooled and analysed, including five RCTs (Herst et al, 2014; Møller et al, 2018; Wooding et al, 2018; Rades et al, 2019; Yan et al, 2020) that assessed Mepitel Film in RISD prevention. Despite identifying some limitations (particularly relating to the quality of evidence available and study heterogeneity), the authors highlighted that the film dressings can be expected to significantly reduce RISD clinical signs in **breast cancer** and **head and neck cancer** patients (Robijns et al, 2023).

Film dressings in the prevention and management of radiotherapy-induced skin damage in breast cancer patients

A systematic review and network meta-analysis of RCTs was undertaken to investigate the effectiveness of barrier films for the prevention of **breast** RISD. Despite limitations with regards to study design, patient populations and resulting interpretability of research findings, the authors were able to identify Mepitel Film and one other film dressing as the only products that have been shown (in studies that allowed pooling of results) to significantly improve clinician-reported outcomes and patient-reported outcomes, compared to standard of care. Commenting on the benefits of using film dressings to prevent severe RISD, the authors believe that such dressings may be cost-effective in settings with the relevant funds and resources, although a formal cost-effectiveness analysis would be required to confirm this (Wong et al, 2024).

Another systematic review and meta-analysis of RCTs, the results of which were published in 2023, concluded that barrier films are an excellent tool for use in the prevention of RISD among patients receiving **whole-breast** or **chest wall** radiotherapy (Dejonckheere et al, 2023). Of the five studies analysed, three involved the use of Mepitel Film (Herst et al, 2014; Møller et al, 2018; Behroozian et al, 2023). Details of these and other relevant studies are summarised below and in **Table 1**.

Table 1. Prevention and management of radiotherapy-induced skin damage - film dressings - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Valcarenghi et al, 2025 RCT Switzerland	**Subjects:** 154 (age range not specified) **Radiotherapy:** Whole breast plus boost irradiation **Setting:** Oncology centres (n=2)	**Safetac:** Mepitel Film (n=75) **Comparator:** Aqueous-urea cream (beginning of radiotherapy); either SSD or SSD with HA (at onset of moist desquamation) (n=79)	Occurrence of moist desquamation (RTOG grade ≥2)	RTOG ≥2 in 9.5% of Mepitel Film group, compared to 13.9% of comparator group (p=0.393). Longer median time to appearance of RTOG >0 in Mepitel Film group (p=0.035): - Mepitel Film: 26 days - Comparator: 21 days Shorter median time to recovery from RTOG >1 in Mepitel Film group (p=0.027): - Mepitel Film: 17 days - Comparator: 32 days
Behroozian et al, 2023 RCT Canada	**Subjects:** 376 (age range 22-90 years) **Radiotherapy:** Breast / chest wall ± regional lymph node irradiation **Setting:** Oncology centres (n=3)	**Safetac:** Mepitel Film (n=251) **Comparators:** Aqueous cream (n=125)	Occurrence of RISD grade 2 or 3 (CTCAE) RISD severity (RISRAS / SSA)	Lower incidence of grade 2 or 3 RISD in Mepitel Film group (p<0.0001): - Mepitel Film: 15.5% (n=39) - Comparator: 45.6% (n=57) Lower mean total RISRAS scores in Mepitel Film group (p<0.001): - Mepitel Film: 4.0 - Comparator: 5.9 Patient-assessed SSA scores: significantly lower for Mepitel Film than comparator regimen for blistering/peeling (p=0.009), erythema (p=0.001), pigmentation (p<0.0001) and oedema (p=0.03) Clinician-assessed SSA scores: significantly lower for Mepitel Film than comparator regimen for pain/soreness (p=0.0009), blistering/peeling (p=0.009), erythema (p<0.0001) and pigmentation (p=0.001).
Møller et al, 2018 RCT (intra-patient) Denmark	**Subjects:** 79 (age range 31-82 years) **Radiotherapy:** Breast / chest wall ± regional lymph node irradiation **Setting:** Oncology centres (n=3)	**Safetac:** Mepitel Film **Comparator:** Skin care regime (daily washing, moisturising lotion and/or lotion with glucocorticoids for itching) Breast / chest wall divided into halves for randomisation to either Mepitel Film or skin care regime	PREMs / PROMs RISD severity (RTOG / EORTC)	Less pain (p<0.001), itching (p=0.005), burning sensation (p=0.005), oedema (p=0.017) and sensitivity (p<0.001) reported by patients in Mepitel Film group, compared to comparator group. 76% of patients stated that they would have preferred Mepitel Film on the entire treatment area (p<0.001) and 85% would have preferred the film dressing as a standard treatment option (p<0.001). Significantly less RISD in Mepitel Film group at last day of radiotherapy among mastectomy patients (p=0.005), although no significant difference between groups 14 days post-radiotherapy.
Yan et al, 2020 RCT (intra-patient) China	**Subjects:** 39 (age range 37-69 years) including 11 Chinese patients from Wooding et al (2018) **Radiotherapy:** Bilateral lymph nodes in neck irradiation **Setting:** Oncology centre	**Safetac:** Mepitel Film **Comparator:** Moisturising cream Neck divided into halves for randomisation to either Mepitel Film or moisturising cream	RISD severity (RISRAS / expanded RTOG) Patient preference	Compared to comparator product, Mepitel Film decreased combined RISRAS score by 30% (p < 0.001). Compared to comparator product, Mepitel Film decreased moist desquamation rates by 41% (p<0.001). 80% of patients preferred Mepitel Film over the comparator product.
Wooding et al, 2018 RCT (intra-patient) New Zealand, China	**Subjects:** 33 (age range not specified) Radiotherapy or radio(chemo)therapy: head and neck irradiation **Setting:** Oncology centres - New Zealand cohort (n=22): 11 complied with management protocol; 11 complied with prevention protocol - China cohort (n=11): all followed prevention protocol	**Safetac:** Mepitel Film **Comparator:** Moisturising cream Neck divided into halves for randomisation to either Mepitel Film or moisturising cream	RISD severity (RISRAS, expanded RTOG) [Data for management and prophylactic protocols pooled]	Compared to comparator product, Mepitel Film decreased overall RISD severity by 29% in the China cohort (p<0.003) and by 27% in the New Zealand cohort (p<0.001). Compared to comparator product, Mepitel Film decreased moist desquamation rates by 37% in the China cohort and by 28% in the New Zealand cohort.
Herst et al, 2014 RCT (intra-patient) New Zealand	**Subjects:** 78 (age range 30-94 years) **Radiotherapy:** Breast / chest wall ± regional lymph node irradiation Setting: Oncology centre	**Safetac:** Mepitel Film **Comparator:** Aqueous cream Breast / chest wall divided into medial and lateral halves for randomisation to either Mepitel Film or aqueous cream	Occurrence of moist desquamation (RTOG) Skin reaction severity (RISRAS)	RTOG grades: - Mepitel Film: 44% of patients had skin reaction, none of which progressed to moist desquamation (grade 1, 36%; grade 2a, 8%). - Comparator: 100% of patients had skin reaction, with 26% progressing to moist desquamation (grade 1, 28%, grade 2a, 46%, grade 2b, 18%, grade 3, 8%) Overall skin reaction severity reduced by 92% in favour of Mepitel Film (p<0.0001).
Lee et al, 2024 RCT (intra-patient) Australia	**Subjects:** 40 (age range 40-90 years) Radiotherapy: Chest wall / reconstructed breast ± regional lymph node irradiation Setting: Oncology centres (n=4)	**Safetac:** Mepitel Film **Comparator:** Silicone-based gel dressing (non-Safetac) Chest area divided into halves for randomisation to either Mepitel Film or gel dressing	Severity and duration of acute RISD (CTCAE) Patient preferences	Mean time-weighted average grade of RISD was 0.19 higher with the gel dressing (p<0.001). 40% of patients preferred Mepitel Film; 37.5% preferred the comparator dressing.

Abbreviations: CTCAE = Common Terminology Criteria for Adverse Events; EORTC = European Organisation for Research and Treatment of Cancer; HA = hyaluronic acid; PREM = patient-reported experience measures; PROM = patient-reported outcome measure; RCT = randomised controlled trial; RISD = radiotherapy-induced skin damage; RISRAS = Radiation-induced Skin Reaction Assessment Scale; RTOG = Radiation Therapy Oncology Group; SSA = Skin Symptom Assessment; SSD = silver sulphadiazine

In New Zealand, Herst and colleagues undertook an RCT to evaluate the effect of Mepitel Film on skin reaction severity and the incidence of moist desquamation when used prophylactically in 78 **breast cancer** patients. Lateral and medial halves of the skin areas to be irradiated were randomised to either the film dressing or aqueous cream. Skin dose was measured using thermoluminescent dosimeters and skin reaction severity was assessed using RISRAS and RTOG scales. The RTOG data revealed that all of the skin areas that had aqueous cream applied developed some form of reaction (which progressed to moist desquamation in 26% patients), whereas reactions occurred in only 44% of the areas that had the film dressing applied (none of which progressed to moist desquamation). Likewise, the RISRAS data demonstrated an overall skin reaction severity reduction of 92% (p<0.0001) in favour of the film dressing (Herst et al, 2014).

The efficacy of Mepitel Film was also investigated in an RCT undertaken across multiple centres in Denmark involving 79 **breast cancer** patients receiving radiotherapy. Lateral and medial halves of the skin areas to be irradiated were randomised to either the film dressing or a regimen in accordance with Danish National Clinical Guidelines (comprising daily washing and the application of moisturising lotion and/or lotion with glucocorticoids for itching). A questionnaire was used to capture patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs). Compared to the comparator regimen, the film dressing was associated with statistically significant reductions in pain severity (p<0.001), itching (p=0.005), burning sensation (p=0.005), oedema (p=0.017) and reduced sensitivity (p<0.001). Furthermore, 76% of patients indicated that they would have preferred to have had the film dressing applied to the entire irradiated area (p<0.001), with 85% of patients stating

that they would have liked to have had the film dressing as a standard treatment option (p<0.001). While a significantly lower severity of RISD was observed in patients after mastectomy in the film dressing group (p=0.005), a blinded evaluation revealed no significant differences between the two groups at follow-up (Møller et al, 2018).

In 2021, a study was undertaken in Canada to assess the feasibility and efficacy of Mepitel Film for the prevention of RISD in 30 patients receiving external beam radiotherapy to the **breast** and **chest wall**. The primary outcome was RISD (graded using the CTCAE assessment tool). Outcomes were compared to previously published data relating to similar patients receiving standard prophylaxis for RISD. Two patients (6.7%) discontinued use of the film dressing before completing radiotherapy. No patients developed grade 3 or higher RISD. Five patients (17.9%) developed grade 2 RISD; three (10.7%) had moist desquamation and two (7.1%) had brisk erythema without moist desquamation. The authors concluded that the film dressing completely prevented grade 3 RISD, with the rates of moist desquamation and grade 2 RISD being lower than previously reported rates associated with aqueous cream (Yee et al, 2021).

However, unlike previous trials, the use of the film dressing did not achieve complete prevention of moist desquamation in the study reported by Yee and colleagues, indicating the need for further research to confirm the efficacy of the film dressing for RISD and to identify those patients likely to benefit the most from the dressing. Consequently, an RCT was undertaken across three oncology centres in Canada in patients who had undergone **lumpectomy (large breasts)** or **mastectomy** (irrespective of breast size). In total, 376 patients were recruited and randomised to receive either Mepitel Film or aqueous cream. In addition to using the CTCAE and RISRAS assessment tools, patients and clinicians rated the same parameters as those in the RISRAS tool using a Skin Symptom Assessment (SSA) scale. During and after radiotherapy, the film dressing group had significantly fewer patients with grade 2 or 3 RISD than those in the comparator group (odds ratio (OR): 0.20; p<0.0001). The total RISRAS scores were significantly lower in the film dressings group (p<0.001), as were the patient-assessed SSA scores for blistering/peeling, erythema, pigmentation and oedema (p≤0.03) and the clinician-assessed SSA scores for pain/soreness, blistering/peeling, erythema and pigmentation (p≤0.001) (Behroozian et al, 2023). As noted by Valcarenghi and colleague, the results of this trial are particularly interesting given that the recruited patients are representative of those at particularly high risk for RISD (Valcarenghi et al, 2025).

An RCT undertaken across two hospitals in Switzerland, involving patients with **breast cancer** compared Mepitel Film (n=75) with a regime comprising an aqueous-urea cream (applied at the beginning of radiotherapy) and either a silver sulphadiazine (SSD) or SSD with hyaluronic acid (HA) cream (applied at the onset of moist desquamation) (n=79). Moist desquamation (RTOG score ≥2) was observed in 9.5% of the film dressing group compared to 13.9% of the comparator group (p=0.393). Although no statistically significant difference was observed between the two groups in relation to the proportion of patients with moist desquamation, the time to appearance of RTOG ≥ 2 was significantly longer (p=0.035) and the skin recovery time was significantly shorter (p=0.027) in the film dressing group. Furthermore, the film dressing with Safetac was well tolerated by patients (Valcarenghi et al, 2025).

Also in 2025, a multicentre, intra-patient, RCT was conducted across 4 hospitals in Australia involving 40 patients undergoing post-mastectomy radiotherapy for **breast cancer**. Patients were randomly assigned to receive either a silicone-based gel dressing (non-Safetac) to one half of the irradiated chest area and Mepitel Film to the alternate half, comparing their efficacy in reducing the severity and duration of acute RISD. Both treatments were applied from the first day of radiotherapy until complete resolution of acute RISD. Patients had weekly assessments of dermatitis severity for a period of 10 weeks, or until complete resolution (whichever occurred sooner). Acute RISD severity was graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (version 4.0). The gel dressing did not meet the non-inferiority threshold compared with the film dressings in relation to the primary outcome. Indeed, statistical significance was found in terms of acute RISD severity between the two dressings (mean time-weighted average RISD grade was 0.19 higher in the gel dressing group, p<0.001); as such, the authors concluded that the gel dressing should be considered inferior, compared to the film dressing (Lee et al, 2025).

Film dressings in the prevention and management of radiotherapy-induced skin damage in head and neck cancer patients

An RCT was conducted to investigate the feasibility of using Mepitel Film (for both prophylaxis and management of RISD) in **head and neck cancer** patients (n=33) undergoing radiotherapy or radio(chemo) therapy (two patient cohorts were included, one from New Zealand and one from China). An area of the neck receiving a homogenous radiation dose of >35 Gy was divided into two equal halves; one half was randomised to film dressings, the other to moisturising creams. Skin reaction severity was measured using RISRAS and expanded RTOG criteria. Results were pooled for prophylactic and management protocols, given similarities found in terms of the protective effect of the film dressing. Skin reaction severity, as measured using the extended RTOG grading system and the combined RISRAS, showed a decrease in skin reaction severity and moist desquamation rates. However, while the film dressing did not affect head movement, it was reported that the dressing did not adhere well to the skin, particularly in males with heavy beard stubble, and caused itchiness, particularly in the Chinese patients (Wooding et al, 2018).

Given the positive results, particularly in the Chinese cohort of patients without heavy stubble, the same research group conducted a second RCT, for which datasets from 28 Chinese patients were added to those of the 11 Chinese patients included in the feasibility study to determine whether or not Mepitel Film is superior to the moisturising creams in managing RISD, including moist desquamation, in **head and neck cancer** patients. Skin reaction severity was measured using RISRAS and expanded RTOG grades. While skin dose underneath the film dressing and the moisturising creams were similar, skin reaction severity (using the combined RISRAS) underneath the film dressings was decreased by 30% (p<0.001) and moist desquamation rates were reduced by 41% (p<0.001). Importantly, 80% of patients preferred the film dressing over the moisturising cream. However, there were some reports of poor adherence and patient discomfort with the film dressing during hot weather and showering, and itching skin underneath it. Overall, the authors concluded that when used prophylactically, the film dressing was superior to the moisturising creams in reducing the severity of acute RISD and incidence of moist desquamation in this patient cohort (Yan et al, 2020).

Foam dressings in the management of RISD

Several studies have explored the role of Mepilex Lite in the management of RISD. These are summarised below and in Table 2.

Table 2. Management of radiotherapy-induced skin damage – foam dressings - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Zhong et al, 2013 RCT China	**Subjects:** 88 (age range not specified) **Radiotherapy:** Head / neck with concurrent chemoradiotherapy **Setting:** Oncology centre	**Safetac:** Mepilex Lite (n=43 patients) **Comparator:** Usual care (n=45 patients)	Time to healing Pain (measured using VAS 0-10) Neck mobility, sleep problems and appearance disturbance (measured using 10-pont Likert scale – higher scores indicative of more distress)	Shorter median time to healing in the Mepilex Lite group (p=0.009): - Mepilex Lite: 16 - Comparator: 23 Lower mean pain scores in the Mepilex Lite group (p=0.02): - Mepilex Lite: 5.31 - Comparator: 6.89 Lower mean sleep problem score in the Mepilex Lite group (p=0.005): - Mepilex Lite: 4.38 - Comparator: 7.23 No statistically significant differences between groups in neck mobility and appearance disturbance.
Paterson et al, 2012 RCT (intra-patient) New Zealand	**Subjects:** 74 (age range 29-84 years) **Radiotherapy:** Chest wall **Setting:** Oncology centres (n=4)	**Safetac:** Mepilex Lite **Comparator:** Aqueous cream Chest area divided into halves for randomisation to either Mepitel Film or aqueous cream	RISD severity (RISRAS) Occurrence of moist desquamation Patient preferences	41% reduction in overall RISD severity with Mepilex Lite, relative to comparator (p<0.001). Moist desquamation incidence: - Mepilex Lite: 15% - Comparator: 19% 49% reduction in average moist desquamation (RISRAS) score (p=0.043): - Mepilex Lite: 0.18 - Comparator: 0.37 28% reduction in length of time of moist desquamation: - Mepilex Lite: 25 weeks - Comparator: 18 weeks Most patients preferred Mepilex Lite (easy to use, comfortable to wear). Dressing out-performed comparator in terms of pain/discomfort, itchiness, burning and effect on daily life.

Abbreviations: RCT = randomised controlled trial; RISD = radiotherapy-induced skin damage; RISRAS = Radiation-induced Skin Reaction Assessment Scale; VAS 0-10 = visual analogue scale from 0 (no pain) to 10 (worst pain imaginable)

In 2012, an intra-patient, multicentre RCT was conducted to evaluate the effect of Mepilex Lite dressings on the overall severity of chest wall RISD, the incidence of moist desquamation, the time to moist desquamation, and time to healing in 74 **post-mastectomy** patients. The intervention started from the time erythema first appeared (generally about 10-14 days after the first fraction). The dressings with Safetac were allocated to either the superior/left or inferior/right areas where erythema was present; the other continued to have aqueous cream applied (control area). Skin reactions were measured using RISRAS. Fewer areas underneath the dressings with Safetac developed moist desquamation than in the areas that had aqueous cream applied (difference not statistically significant). However, compared to the control group, a 41% reduction in overall severity of RISD was achieved in the dressings group (p<0.001). Furthermore, the average moist desquamation score was reduced by 49% (p=0.043). The total number of weeks of moist desquamation in the areas underneath the dressings was found to be 28% lower compared with that of the control areas. Most patients preferred the dressings to the aqueous cream, finding them easy to use and very comfortable to wear. Furthermore, the dressings outperformed aqueous cream with regards to pain/discomfort, itchiness, burning and effect on daily life (Paterson et al, 2012).

Diggelmann and colleagues investigated the efficacy of Mepilex Lite dressing in reducing radiation-induced erythema in 24 women (34 erythematous areas) with **breast cancer**. The areas of erythema were randomly divided into two halves; one half was covered with the dressing and the other half had aqueous cream applied. The extent of erythema was measured using the RISRAS scale. The dressings with Safetac significantly reduced the severity of radiation-induced

erythema when compared with aqueous cream (p=0.001). There were eight instances of skin breakdown reaching dry desquamation in the areas that had aqueous cream applied (24%), compared with five (15%) of the skin areas that had dressings applied. The majority (17/24) of patients preferred the dressings over the cream; patients indicated that the dressings increased comfort levels, decreased the amount of pain experienced and allowed them to wear normal clothing. It was also noted by patients that the dressings were soothing and provided pain relief and relief from friction (Diggelmann et al, 2010).

In a small two-centre study, patient comfort and overall experience when using Mepilex Lite in the management of dry and moist desquamation during radiotherapy were evaluated in 16 patients undergoing radiotherapy to the **head** and **neck** or **breast**, and who had a RTOG score of 3 plus 1 symptom measured via the RISRAS. Most patients found the dressing comfortable to wear and remove, and in many cases it had a positive impact on daily living. Benefits reported included reduction of friction (e.g. from clothes), minimisation of pain during dressing changes, ease of lifting and readjustment without loss of adherent properties, a cooling and soothing effect on the skin, and improved sleep pattern (MacBride et al, 2008).

The effectiveness of Mepilex Lite dressings in the management of RISD (resulting from curative-intent radiotherapy) in **nasopharyngeal carcinoma** patients (n=88) was investigated in an RCT conducted in China. Patients were randomised to either dressings with Safetac (n=43) or the standard care provided at the study centre (n=45). A significantly shorter median time to RISD healing was observed in the dressings group (16 days) than in the standard care group (23 days) (p=0.009). No statistically significant differences were found between the two groups in regards to neck mobility and appearance disturbance. However, a significant improvement in patients' sleep (p=0.005) and a significant reduction in pain (p=0.02) in favour of the dressing group were observed (Zhong et al, 2013).

A case study has been reported in which the exudate transfer dressing, Mepilex Transfer, was used in the management of RISD (**moist desquamation**). When applied to the severe RISD, the dressing provided good skin protection, was easy to use and remove, exhibited good conformability and adaptability on difficult-to-dress areas. The patient also found the dressing to be comfortable to wear and experienced a reduction in pain severity (Lemos et al, 2016).

Wound contact layers in the prevention of radiotherapy-induced skin damage

In a pilot study undertaken in Germany, Mepitel was used on 21 patients receiving radiotherapy, seven with intact portal skin and 14 in whom the portal included an epitheliolysis and a skin ulcer. The portals were located on the **neck, breast, pelvis, groin, thorax, nose, forehead, head, spine** and **thigh**. There were no reactions to the dressing on non-irradiated skin, no additional skin irritation in the irradiated regions, and no injury to new epithelium at dressing changes. The ulcers covered with the wound contact layer re-epithelialised quickly. Furthermore, the tolerance of the wound contact layer was good in all patients (Adamietz et al, 1995).

Chemotherapy-related skin lesions

Dressings with Safetac have been reported to be beneficial when used to prevent or manage trauma-related injuries arising from contact with needles used to deliver chemotherapy. A study undertaken in Italy observed that patients at risk of developing these injuries were generally obese or had a port-a-cath in place. In these cases, Mepitel was placed under the needle, allowing it to be left in place for 21 days. This intervention avoided patients having to change the needles at home, thereby reducing patient stress and anxiety (Milani et al, 1999).

More recently, a case study involving a patient who presented with widespread **bullous lesions** relating to chemotherapy has been described. Large sheets of Mepilex Transfer Ag were used to wrap the entirety of body areas involved. Within 15 days of initiating the dressing regime, and three dressing changes, all of the bullous lesions had completely re-epithelialised and no further wound care was needed. This was accomplished despite acute renal failure and respiratory failure, pancytopenia / acute lymphocytic leukaemia relapse, vasopressor therapy for low blood pressure and coagulopathy that created other challenges in this patient's care (Marshall-Hanson, 2015).

References

Adamietz, I.A., Mose, S., Haberl, A., Saran, F.H., Thilmann, C., Bottcher, H.D. Effect of self-adhesive, silicone-coated polyamide net dressing on irradiated human skin. Radiation Oncology Investigations 1995;2(6):277-282.

Armstrong, D., Van Gijn, D., Newlands, C. (2022) Are tie-over bolster dressings necessary for healing or success of full thickness skin graft reconstruction following facial skin cancer excision? British Journal of Oral and Maxillofacial Surgery 60(7):951-955.

Barrows, C. (2007) Management of fungating tumours. Poster presentation at the 20th Annual Symposium on Advanced Wound Care and the Wound Healing Society Meeting, Tampa, Florida, United States of America.

Behroozian, T., Milton, L., Karam, I., Zhang, L., Ding, K., Lou. J., Gallant, F., Rakovitch, E., Tran, W., Soliman, H., Leung, E., Vesprini, D., Szumacher, E., Chen, H., Donovan, E., Lam, J., Spadafora, S., Wronski, M., Lavoie, C., Walde, N., Lam, E., Wong, G., McKenzie, E., Ariello, K., Kennedy, S., Shariati, S., Carothers, K., Gonzales, G., Kagan, Y., Chow, E. (2023) Mepitel Film for the prevention of acute radiation dermatitis in breast cancer: a randomized multicenter open-label phase III trial. Journal of Clinical Oncology 41(6):1250-1264.

Behroozian, T., Milton, L., Li, N., Zhang, L., Lou, J., Karam, I., Wronski, M., McKenzie, E., Mawdsley, G., Razvi, Y., Chow, E., Ruschin, M. (2021) Predictive factors associated with radiation dermatitis in breast cancer. Cancer Treatment and Research Communications 28:100403

Cox, J.D., Stetz, J., Pajak, T.F. (1995) Toxicity criteria of the Radiation Therapy Oncology Group (RTOG) and the European Organization for Research and Treatment of Cancer (EORTC). International Journal of Radiation Oncology, Biology, Physics 31(5):1341-1346.

Dahlstrøm, K.K. (1995) A new silicone rubber dressing used as a temporary dressing before delayed split skin grafting. A prospective randomised study. Scandinavian Journal of Plastic Reconstructive Surgery and Hand Surgery 29(4):325-327.

Dejonckheere, C.S., Dejonckheere, E., Layer, J.P., Layer, K., Sarria, G.R., Koch, D., Abramian, A., Kaiser, C., Lindner, K., Bachmann, A., Anzbock, A., Rohner, F., Schmeel, F.C., Schmeel, L.C. (2023) Barrier films for the prevention of acute radiation dermatitis in breast cancer: a systematic review and meta-analysis of randomised controlled trials. The Breast 71:31-41.

Deptuta, M., Zielinski, J., Wardowska, A., Pikuta, M. (2018) Wound healing complications in oncological patients: perspectives for cellular therapy. Postepy Dermatologii I Allergologii 42(3):267-275.

Diggelmann, K.V., Zytkovicz, A.E., Tuaine, J.M., Bennett, N.C., Kelly, L.E., Herst, P.M. (2010) Mepilex Lite dressings for the management of radiation-induced erythema: a systematic inpatient controlled clinical trial. British Journal of Radiology 83(995):971-978.

Dowsett, C.(2002) Malignant fungating wounds: assessment and management. British Journal of Community Nursing 7(8):394-400.

Finkelstein, S., Kanee, L., Behroozian, T., Ryan Wolf, J., van den Hurk, C., Chow, E., Bonomo, P. (2022) Comparison of clinical practice guidelines on radiation dermatitis: a narrative review. Supportive Cancer Care 30(6):4663-4674.

Freise, J., Lehnen, M., Korber, A., Grabbe, S., Dissemond, J. (2006) Sekundare Wundheilung postoperativer akuter Wunden unter Therapie mit Silikon-beschichtetem Schaumstoff [Secondary wound-healing in surgical acute wounds by therapy with silicon-coated foam dressing] Zeitschrift fur Wundheilung 11(3):110-115.

Gerken, A.L.H., Jawny, P., Weigl, H., Yang, C., Hardt, J., Menge, F., Hohenberger, P., Weiss, C., Reissfelder, C., Jakob. J. (2023) Postoperative drainage management and wound complications following resection of lower limb soft tissue tumours: a retrospective cohort study. Langenbeck's Archives of Surgery 408:202.

Gethin, G., Kottner, J., Lamza, A., Meaume, S., Megal, C., Conde Montero, E., Rawlinson, F., Ryan, H., Probst, S.(2025) Palliative wound care, Recommendations of wound-related symptoms. Journal of Wound Management 2025/26:(Supplement 1):S1-S40.

Ginex, P.K., Backler, C., Croson, E., Horrell, L.N., Moriarty, K.A., Maloney, C., Vrabel, M., Morgan, RL. (2020) Radiodermatitis in patients with cancer: systematic review and meta-analysis. Oncology Nursing Society 47(6):E225–E236.

Hegedus, F., Mathew, L.M., Schwartz, R.A. (2017) Radiation dermatitis: an overview. International Journal of Dermatology 56(9):909-914.

Herst, P.M., Bennett, N.C., Sutherland, A.E., Peszynski, R.I., Paterson, D.B., Jasperse, M.L. (2014) Prophylactic use of Mepitel Film prevents radiation-induced moist desquamation in an intra-patient randomised controlled clinical trial of 78 breast cancer patients. Radiotherapy and Oncology 110(1): 137-143.

Holloway, S., Harding, K.G. (2022) Wound dressings. Surgery (Oxford) 40(1):25-32.

Hou, C-C., Chou, Y-Y., Chen, S-G., Wang, C-H., Tzeng, Y-S. (2024) Full-thickness skin graft from the submental triangle for facial defect reconstruction. Journal of Clinical Medicine 12(9):3195.

Lee, S.F., Yip, P.L., Spencer, S., Ho, H., Subramanian, B.., Ding, W., Lapuz, C., Foroudi, F., Kai, C., Chao, M. (2024) StrataXRT and Mepitel Film for preventing postmastecomy acute radiation dermatitis in breast cancer: an intrapatient noninferiority randomized clinical trial. International Journal of Radiation Oncology Biology Physics doi:10.1016/j.jrobp.2024.11.076.

Lemos, P., Araujo, J., Chicone, G. (2016) Case study: use of soft silicone foam with Safetec technology to treat radiotherapy-induced moist desquamation. Poster presentation at the World Union of Wound Healing Societies Congress, Florence, Italy.

MacBride, S.K., Wells, M.E., Hornsby, C., Sharp, L., Finnila, K., Downie, L. (2008) A case study to evaluate a new soft silicone dressing, Mepilex Lite, for patients with radiation skin reactions. Cancer Nursing 31(1):E8-E14.

Marshall-Hanson, C. (2015) Use of an absorbent soft silicone antimicrobial exudate transfer foam to treat widespread bullous lesions and erythroderma reaction in a neutropenic patient. Poster presentation at Symposium on Advanced Wound Care (Spring), San Antonio, Texas, United States of America.

McCarty, S., Davies, P., Rippon, M. (2013) Mepilex Border Ag: an in-market evaluation. Poster presentation at the Wounds UK Conference, Harrogate, United Kingdom.

Mekrut-Barrows C. (2006) Softening the pain of cancer-related wounds. Ostomy Wound Management 52(9):12-13.

Meuleneire, F., Mulier, P., Fostier, A., Goossens, K. (2008) Introducing of a new procedure for preventing skin lesions after oncologic breast surgery. Poster presentation at the 3rd Congress of the World Union of Wound Healing Societies, Toronto, Canada.

Milani, A., Lunghi, L., Vernizzi, S., Passoni, C., Sociale, O., Macciola, F., Rawanna, S., Remoli, S., Grimaldi, C., Sciancalapone, M. (1999) Poster abstract. Continuous infusion therapy: for how long can a Huber needle be left in situ without being changed? Use of a non adherent silicone dressing (Mepitel) under the Huber needle in order to prevent sores in obese patients and in patients with a deep port-a-cath. European Journal of Cancer 35(4 Supplement):S18.

Møller, P.K., Olling, K., Berg, M., Habæk, I., Haislund, B., Iversen, A-M., Ewertz, M., Lorenzen, E.L., Brink, C. (2018) Breast cancer patients report reduced sensitivity and pain using a barrier film during radiotherapy – A Danish intra-patient randomized multicentre study. Technical Innovations and Patient Support in Radiation Oncology 7:20-25.

Morgan, K. (2014) Radiotherapy-induced skin reactions: prevention and cure. British Journal of Nursing 23(16):S24-S32.

Naylor, W. (2003) Pain in fungating wounds: another perspective. Ostomy Wound Management 49(11):9-12.

Niculescu, A.G., Georgescu, M., Marinas, I.C., Ustundag, C.B., Bertesteanu, G., Pinteala, M., Maier, S.S., Al-Matarneh, C.M., Angheloiu, M., Chifiriuc, M.C. (2024). Therapeutic management of malignant wounds: an update. Current Treatment Options in Oncology 25:97-126.

Noble-Adams, R. (1999) Radiation0induced skin reactions. 3: evaluating the RISRAS. British Journal of Nursing 8(19):1305-1312.

Ousey, K., Pramod, S., Clark, T., Dhoonmoon, L., Gardner, S., Hodgson, H., Mogford, J., Porter, C., Rando, T., Stringer, J. (2024) Malignant wounds: management in practice. Wounds UK, London, United Kingdom.

Paterson, D.B., Poonam, P., Bennett, N.C., Peszynski, R.I., Van Bekhuizen, M.J., Jasperse, M.L., Herst, P.M. (2012) Randomized intra-patient controlled trial of Mepilex Lite dressings versus aqueous cream in managing radiation-induced skin reactions post-mastectomy. Journal of Cancer Science & Therapy 4(11):347-356.

Pramod, S., Dumville, J., Norman, G., Stringer, J. (2024) A survey of UK nurses about their care of people with malignant fungating wounds. European Journal of Oncology Nursing 70:102609.

Probst, S., Arber, A., Faithfull, S. (2013) Malignant fungating wounds – the meaning of living in an unbounded body. European Journal of Oncology Nursing 17(1):38-45.

Rades, D., Narvaez, C.A., Splettstößer, L., Dömer, C., Setter, C., Idel, C., Ribbat-Idel, J., Perner, S., Bartscht, T., Olbrich, D., Schild, S.E., Carl, J. (2019) A randomized trial (RAREST-01) comparing Mepitel® Film and standard care for prevention of radiation dermatitis in patients irradiated for locally advanced squamous cell carcinoma of the head and-neck (SCCHN). Radiotherapy and Oncology 139:79-82.

Robijns, J., Aquilano, M., Banerjee, S., Caini, S., Wolf, J.R., van den Hurk, C., Beveridge, M., Lam, H., Bonomo, P., Chow, E., Behroozian, T. (2023) Barrier films and dressings for the prevention of acute radiation dermatitis: a systematic review and meta-analysis. Supportive Care in Cancer 31:219.

Roh, M.R., Shin, J.U., Chung, K.Y. (2008) Silicone net bolster dressing for skin grafts. Dermatologic Surgery 34(9):1233-1235.

Rosenthal, A., Israelevich, R., Moy, R. (2019) Management of acute radiation dermatitis: a review of the literature and proposal for treatment algorithm. Journal of the American Academy of Dermatology 81(2):558-567.

Spampinato, S., Tanderup, K., Barcellini, A., Burchardt, E., Eminowicz, G., Segedin, B., Stankiewicz, M., Valgma, M., Kirchheiner, K. (2025). Radiotherapy and Oncology 207:110881.

Taylor, R. (1999) Use of a silicone net dressing in severe mycosis fungoides. Journal of Wound Care 8(9):429-430.

Valcarenghi, D., Tolotti, A., Vees, H., Torri, V., Liptrott, S., Presta, G., Puliatti, A., Moser, L., P., Sari, D., Valli, M. (2025) Mepitel Film vs standard care for the prevention of skin toxicity in breast cancer patients treated with adjuvant radiotherapy: a randomized controlled trial. Clinical and Translational Radiation Oncology 52:100936.

Vardhan, M., Flaminio, Z., Sapru, S., Tilley, C.P., Fu, M.R., Comfort, C., Li, X., Saxena, D. (2019) The microbiome, malignant fungating wounds, and palliative care. Frontiers in Cellular and Infection Microbiology 9:373.

Wan, B.A., Chan, S., Herst, P., Yee, C., Popovic, M., Lee, J., Lam, H., Pon, K., Aljabri, S., Soliman, H., Wronski, M., Chow, E. (2019)Mepitel Film and Mepilex Lite for the prophylaxis and treatment of skin toxicities from breast radiation. Breast 46: 87-89.

Wei, J., Meng, L., Hou, X., Qu, C., Wang, B., Xin, Y., Jiang, X. (2019) Radiation-induced skin reactions: mechanism and treatment. Cancer Management and Research 11:167-177.

Wilson, V. (2005) Assessment and management of fungating wounds: a review. British Journal of Community Nursing 10(3):S28-S34.

Wong, H.C.Y., Lee, S.F., Caini, S., Chan, A.W., Kwan, J.Y.Y., Waddle, M., Sonis, S., Herst, P., Alcorn, S., Bonomo, P., Wong, C., Corbin, K., Choi, J.I., Rembielak, A., Alkhaifi, M., Marta, G.N., Rades, D., van den Hurk, C., Wolf, J.R., Cham, R.J., Schmeel, L.C., Lock, M., Hijal, T., Cao, J., Kim, H., Chow, E. (2024) Barrier films or dressings for the prevention of acute radiation dermatitis in breast cancer: a systematic review and network meta-analysis. Breast Cancer Research and Treatment 207(3):477-496.

Wooding, H., Yan, J., Yuan, L., Chyou, T-Y., Gao, S., Ward, I., Herst, P.M. (2018) The effect of Mepitel film on acute radiation-induced skin reactions in head and neck cancer patients: a feasibility study. British Journal of Radiology 91(1081):20170298.

Yan, J., Yuan, L., Wang, J., Li, S., Yao, M., Wang, K., Herst, P.M. (2020) Mepitel Film is superior to Biafine cream in managing acute radiation-induced skin reactions in head and neck cancer patients: a randomised intra-patient controlled clinical trial. Journal of Medical Radiation Sciences 67(3): 208-216.

Yee, C., Lam, E., Gallant, F., Karam, I., Czarnota, G., Soliman, H., Wong, G., Drost, L., Vesprini, D., Rakovitch, E., Wronski, M., Leung, E., Szumacher, E., Carothers, K., Pon, K., Gonzales, G., Easton, L., Lewis, D., Zhang, L., Chow, E. (2021) A feasibility study of Mepitel Film for the prevention of breast radiation dermatitis in a Canadian center. Practical Radiation Oncology 11(1):e36-e45.

Young, T. (1999) Fungating wounds: their diagnosis and management. Nurse Prescriber (Supplement):S3-S4.

Zasadzinski, K., Spalek, M.J., Rutkowski, P. (2022) Modern dressings in prevention and therapy of acute and chronic radiation dermatitis - a literature review. Pharmaceutics 14(6):1204.

Zhong, W-H., Tang, Q-F., Hu, L-Y., Feng, H-X. (2013) Mepilex Lite dressings for managing acute radiation dermatitis in nasopharyngeal carcinoma patients: a systematic controlled clinical trial. Medical Oncology 30(4):761.

Dressings with Safetac® - Scar Management

Dressings with Safetac featured:

Mepiform®

Take home messages:

- Although they play an important role in maintaining skin integrity, scars are associated with unwanted physical effects (e.g. dryness and itching) and psychological problems (e.g loss of self-esteem and self-satisfaction).
- Numerous studies have observed scar (hypertrophic and keloid) improvement, reduced pain and reduced discomfort with the use of Mepiform.

Introduction to scars

Scars are fibrous tissues that replace skin during the wound healing process. The different scar types are presented in **Table 1**.

Table 1. Scar types (Tredget et al, 1997; Alster et al, 2003; Atiyeh & Ibrahim, 2020; Chapman, 2007; Mustoe et al, 2020)

Type	Description
Immature	• Slightly raised, pink appearance; firm to touch • May be itchy • Begins soon after injury (peaks a few weeks after injury); typically takes a year or longer to mature
Mature	• Flat; no erythema; colour ranges from white to hyperpigmented • Generally, no other symptoms
Atrophic	• Depressed/thinned • Transitions from immature scar (e.g. after radiotherapy)
Hypertrophic	• Elevated, pink/red appearance; stiff to touch • Typically itchy and painful • Can limit motion if it crosses a joint • Evolves from immature scar within weeks; progressive enlargement for months and some late resolution; scar tissue remains within the confines of the wound • Often associated with surgery and burns
Keloid	• Elevated, large, often irregular in shape (frequently seen in multiple locations) • Usually itchy and painful • Evolve months after the initial injury with progression but no resolution; scar tissue extends beyond the borders of the original injury • Strong genetic predisposition; more common in patients with darker skin

= normal; = abnormal

Challenges

Although they play an important role in maintaining skin integrity, scars are associated with unwanted physical effects (e.g. dryness and itching) and psychological problems (e.g loss of self-esteem and self-satisfaction) (Wu et al, 2024).

Role of dressings in scar management

A wide array of interventions aimed at treating existing scars are described in the literature. These include corticosteroid injections, cryotherapy, radiotherapy, laser therapy, 5-fluorouracil injections, stem cell therapy, fat grafting, interferon injections, botulinum toxin injections, and scar revision surgery. Prophylactic measures include tension-free closure of wounds, flavonoids, pressure therapy and the use of topically applied silicone-based gels and dressings (sheets) (Lee & Jang, 2018).

Topically applied silicone gel sheets have been used successfully in the management of hypertrophic and keloid scars for over 30 years (Carney et al, 1994; Musgrove et al, 2002; Majan, 2006; Zurada et al, 2006; Berman & Perez, 2007; Chernoff et al, 2007; Lacarrubba et al, 2008). The therapeutic mechanism by which topical silicone-based dressings exert their beneficial effect has not been fully elucidated, but it has been proposed that they aid in the hydration of damaged tissues (Sawada & Sone, 1992). More recently, it has been suggested that there are two mechanisms of action. Firstly, the dressings limit moisture loss from the skin surface, aiding in hydration. Secondly, their high permeability does not impede the skin surface's access to oxygen, resulting in a localised increase in oxygen tension. In turn, this leads to a down-regulation of signals that stimulate growth near the skin surface, thus preventing/reducing scar formation (Gilman, 2003).

In an article providing an overview of over 300 published references and expert consensus on best practice, it states that silicone gel sheeting should be considered as "first-line prophylaxis" for preventing the development of hypertrophic scars or keloids after surgery or trauma. It also states that silicone gel sheeting and intralesional corticosteroids should have primary roles in the management of a wide variety of abnormal scars (Mustoe et al, 2002).

Evidence for dressings with Safetac

The efficacy and safety of one particular silicone-based scar dressing, Mepiform, have been evaluated in numerous studies described below, with the key data presented in **Table 2**.

Table 2. Scar management – Mepiform – key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Majan, 2006 RCT Spain	**Subjects:** 11 (age range 21-43 years) **Scar:** Hypertrophic post-surgery (breast surgery, n=9; abdominal-glutealplasty, n=2) **Setting:** Plastic Surgery	**Safetac:** Mepiform (n=6) **Comparator:** 'Leave alone' management (n=5) **Treatment duration:** up to 1 year. Dressings changed every 1-7 days	Scar characteristics (VSS) Dressing usage	Patients in the Mepiform group showed greater and more rapid improvements in scars than in the comparator group. Clinicians rated the overall performance of Mepiform as 'very good' or 'good'.
Nor et al, 2017 RCT Malaysia	**Subjects:** 17 (2 scars per patient) (ages not specified) **Scar:** Keloid **Setting:** Dermatology	**Safetac:** Mepiform with clobetasol propionate (CP) cream **Comparator:** Intralesional triamcinolone (ILT) **Treatment duration:** up to 12 weeks	Scar characteristics (POSAS) at 4-weekly intervals Keloid dimension Adverse effects	Significant improvement of POSAS and keloid dimensions at 12 weeks compared to baseline in both groups (p≤0.05). No significant difference in POSAS or keloid dimensions between groups. Significantly lower rate of adverse effects – pain (0 vs. 100%), erythema (17.6 vs. 41.2%), hypopigmentation (23.5 vs. 35.3%), telangiectasia (17.6 vs. 41.2%) and skin atrophy (5.9 vs. 23.5%) in the Mepiform plus CP group compared to the Mepiform plus ILT group.
Dykes et al, 2001 Healthy volunteer study (randomised dressing application) United Kingdom	**Subjects:** 12 (adult) Dressings applied to forearm (skin pre-stained with dye) **Setting:** Dermatology	**Safetac:** Mepiform **Comparators:** Duoderm Extra Thin (hydrocolloid-based adhesive); Tielle (polyurethane-based adhesive)	Amount of dye left on skin after dressing removal (sampled using skin surface biopsy; measured by spectrophotometry). Measured after 1 x 24-hour application and 3 x 24-hour applications of dressings (assumption: the more dye left on the skin, the less the skin damage)	After 1 and 3 dressings applications, higher level of dye was seen on the skin that had Mepiform applied, compared to the skin that had the other dressings applied (p<0.05) – indicative of less damage with Mepiform.

Abbreviations: POSAS = Patient and Observer Scar Assessment Scale; RCT = randomised controlled trial; VSS = Vancouver Scar Scale

In a healthy volunteer study, measurements of the peel force required to remove dressings and the amount of pre-dyed skin removed at dressing changes (i.e. the more dye left on the skin after dressing removal, the less damage incurred) were undertaken to compare dressings with traditional adhesive systems (acrylic, hydrocolloid and polyurethane) and Mepiform, with the latter showing much less tendency to cause damage on removal (Dykes et al, 2001).

The adherence and simplicity of the application of Mepiform appeared to enhance patient compliance, as well as improving scar quality and patient comfort, in an observational study involving 87 patients (adult and paediatric) with **post-burn and other traumatic scars**, (Cain et al, 2001). This was further demonstrated in a case study in which Mepiform was used successfully to prevent scarring of a severe **forehead laceration (Figure 1)** (Meuleneire, 2007).

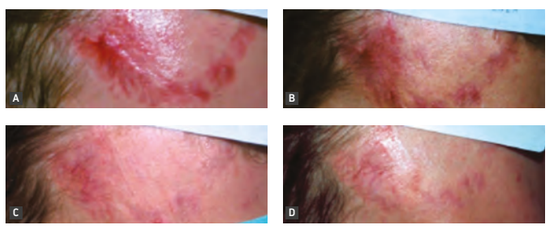


Figure 1. Use of Mepiform for scar management following a severe laceration above the eyebrow: (A) Hypertrophic scar formed 10 days after suture removal; Mepiform applied; (B) After two months, significant improvement in texture and colour noted; (C) After five months, continued improvement in scar appearance was observed; the patient was very happy with the cosmetic results; (D) The application of Mepiform continued for 11 months. The patient was very satisfied with its application and removal. (photographs courtesy of Frans Meuleneire, Woundcare Centre, Zottegem, Belgium)

In a four-patient case study series, Mepiform was used for scar management of **closed surgical incision sites** and **burns**. Throughout the period of use (at least six months for each patient), the dressings maintained a low profile and remained in place under compression garments without edge roll or interfering with joint mobility. The scars, originally hyperpigmented, evolved into a more normal pigmentation with a smoother and more flexible nature (Saulsberry et al, 1999).

A randomised controlled trial (RCT) was undertaken to evaluate the efficacy and safety of soft silicone scar dressings in the management of **post-operative hypertrophic scars**. Eleven patients were randomly allocated to Mepiform dressings or 'left alone' management. As measured using the Vancouver Scar Scale, the patients in the dressings group had greater and faster improvements, compared to the comparator group. Commenting on their results, the author concluded that, as Mepiform is self-adhesive and its use limits damage to the stratum corneum on removal, it gives it an added value compared to non-adhesive silicone gel dressings (Majan, 2006).

The use of Mepiform was also associated with a significant improvement in the colour of **hypertrophic scars** in an observational study involving 12 patients (Middelkoop et al, 2000). Mepiform was also observed to preclude the need for additional fixation and to be painless on removal in the management of a child with a **hypertrophic scar** (Forest-Lalande, 2001). It was also used successfully in the management of a two-year old child with a **post-burn-related hypertrophic scar** that had previously not responded to pressure therapy and massage with silicone gel (Eisendle et al, 2020).

In a more recent RCT, the efficacy and safety of topical corticosteroid cream under occlusion with Mepiform was compared to intralesional injections of triamcinolone in the management of **keloid scars**. Both regimes were associated with significant improvement in scar characteristics and keloid dimensions; however, a significantly lower rate of adverse events (pain, hypopigmentation, erythema, telangiectasia and skin atrophy) was observed in the regime involving the Safetac dressing (Nor et al, 2017).

Good clinical outcomes associated with the use of Mepiform were reported in a three-patient case study series involving post-circumcision **penile keloid scars** (Xie et al, 2013) and in a one-year-old child with a **post-burn-related keloid scar** (Wagner, 2002).

References

Alster, T.S., Tanzi, E.L. (2003) Hypertrophic scars and keloids: etiology and management. American Journal of Clinical Dermatology 4(4):235-243.

Atiyeh, B.S., Ibrahim, A. (2020) Nonsurgical management of hypertrophic scars: evidence-based therapies, standard practices, and emerging methods: an update. Aesthetic Plastic Surgery 44(4):1345-1347.

Berman, B., Perez, O.A. (2007) A review of the biologic effects, clinical efficacy, and safety of silicone elastomer sheeting for hypertrophic and keloid scar treatment and management. Dermatologic Surgery 33(11):129-1302.

Carney, S.A., Cason, C.G., Gowar, J.P., Stevenson, J.H., McNee, J., Groves, A.R., Thomas, S.S., Hart, N.B., Auclair, P. (1994) Cica-Care gel sheeting in the management of hypertrophic scarring. Burns 20(2):164-167.

Chapman, T.T. (2007) Burn scar and contracture management. Journal of Trauma 62(6 Supplement): S8.

Chernoff, W.G., Cramer, H., Su-Huang, S. (2007) The efficacy of topical silicone gel elastomers in the treatment of hypertrophic scars, keloid scars, and post-laser exfoliation erythema. Aesthetic Plastic Surgery 31(5):495-500.

Cain, V., McMahon, L., O'Donnell, F., Rowland, S.M., Costa, B.A., Moore, M.I., Engrav, L.H., Heimbach, D.M., Gibran, N.S. (2001) Effectiveness of a silicone adherent dressing on post-burn and other traumatic scars. Journal of Burn Care and Rehabilitation 22(Supplement 2): S45-S45.

Dykes, P.J., Heggie, R., Hill, S.A. (2001) Effects of adhesive dressings on the stratum corneum of skin. Journal of Wound Care 10(2):7-10.

Eisendle, K., Pichler, M., De Luca, J., Thuile, T. (2020) Use of self-adherent silicone sheets in a pediatric burn patient: A case report and instructions for use. Pediatric Dermatology 37(1):257-260.

Forest-Lalande L. (2001) Hypertrophic scar management: our experience with Mepiform dressing. Poster presentation at the 7th Annual Canadian Association of Wound Care Conference, London, Ontario, Canada.

Gilman, T.H. (2003) Silicone sheet for treatment and prevention of hypertrophic scar: a new proposal for the mechanism of efficacy. Wound Repair and Regeneration 11(3):235-236.

Lacarrubba, F., Patania, L., Perrotta, R., Stracuzzi, G., Nasca, M.R., Micali, G. (2008) An open-label pilot study to evaluate the efficacy and tolerability of a silicone gel in the treatment of hypertrophic scars using clinical and ultrasound assessments. Journal of Dermatological Treatment 19(1):50-53.

Lee, H.J., Jang, Y.J. (2018) Recent understandings of biology, prophylaxis and treatment strategies for hypertrophic scars and keloids. International Journal of Molecular Sciences 19(3):711.

Maján, J.I. (2006) Evaluation of a self-adherent soft silicone dressing for the treatment of hypertrophic postoperative scars. Journal of Wound Care 15(5):193-196.

Meuleneire, F.(2007) Using a soft silicone dressing (Mepiform) to prevent scarring in an acute traumatic wound. Wounds UK 3(4):134-135.

Middelkoop, E., van Uhen, E., Vloemans, J. (2000) The use of Mepiform silicone dressing as treatment for hypertrophic scars. Poster presentation at European Wound Management Association Conference, Stockholm, Sweden.

Musgrove, M.A., Umraw, N., Fish, J.S., Gomez, M., Cartotto, R.C. (2002) The effect of silicone gel sheets on perfusion of hypertrophic burn cars. Journal of Burn Care and Rehabilitation 23(3):208-214.

Mustoe, T.A., Cooter, R.D., Gold, M.H., Hobbs, F.D.R., Ramelet, A.R., Shakespeare, P.G., Stella, M., Teot, L., Wood, F.M., Ziegler, U.E., International Advisory Panel on Scar Management. (2002) International clinical recommendations on scar management. Plastic and Reconstructive Surgery 110(2):560-571.

Mustoe, T.A. (2008) Evolution of silicone therapy and mechanism of action in scar management. Aesthetic Plastic Surgery 32(1):82-92.

Mustoe, T.A (2020) Chapter 9. International Scar Classification in 2019. In: Textbook on Scar Management. Eds. Teot, L., et al. Springer, Cham, Switzerland.

Nor, N.M., Ismail, R., Jamil, A., Shah, S.A., Imran, F.H. (2017) A randomized, single-blind trial of clobetasol propionate 0.05% cream under silicone dressing occlusion versus intra-lesional triamcinolone for treatment of keloid. Clinical Drug Investigation 37(3):295-301.

Saulsberry, C.M., Abney, S.B., Landry, K.N. (1999) An evaluation of a new silicone dressing for the management of hypertrophic scars. Poster presentation at 13th Symposium on Advanced Wound Care and Medical Research Forum in Wound Repair, Anaheim, California, United States of America.

Sawada, Y., Sone, K. (1992) Beneficial effects of silicone cream on grafted skin. British Journal of Plastic Surgery 45(2):105-108.

Tredget, E.E., Nedelec, B., Scott, P.G., Aziz, G. (1997) Hypertrophic scars, keloids, and contractures. Surgical Clinics of North America 77(3):701-730.

Wagner, G. (2002) Treatment of severe keloid formation in childhood by using occlusive dressing. Aktuelle Dermatologie 28(10):359-362.

Wu, J., Zou, J., Yang, Q., Wang, H., Tian, H., Chen, L., Ji, Z., Zheng, D., Li, Z., Xie, Y. (2024) The effects of scar in psychological disorder: a bibliometric analysis from 2003 to 2022. International Wound Journal 21(1):e14373.

Xie, L.H., Li, S.K., Li, Q. (2013) Combined treatment of penile keloid: a troublesome complication after circumcision. Asian Journal of Andrology 15(4):575-576.

Zurada, J.M., Kriegel, D., Davis, I.C. (2006) Topical treatments for hypertrophic scars. Journal of the American Academy of Dermatology 55(6):1024-1031.

Dressings with Safetac® - Protection of Compromised/ Fragile Skin

Dressings with Safetac featured:

Mepilex®, Mepilex® Ag, Mepilex® Border, Mepilex® Border Lite, Mepilex® Lite, Mepilex® Transfer, Mepitel®, Mepitel® Film, Mepitel® One, Mepiform®, Mepitac®

Take home messages:

- Fragile and compromised skin conditions pose significant challenges, e.g. the physical and emotional suffering caused by recurrent blistering and skin loss in patients with epidermolysis bullosa (EB), and the vulnerability of skin grafts to injury.
- Many publications refer to the use of dressings with Safetac as being suitable for the management of EB lesions, due to their ability to be atraumatic and to minimise pain on removal.
- Studies have also demonstrated the ability of wound contact layers with Safetac to facilitate skin graft take.

Introduction to compromised/fragile skin

Fragile and compromised skin conditions pose significant challenges in clinical care, particularly in patients with genetic disorders, cancer or those undergoing intensive therapies. A few examples of conditions and scenarios associated with fragile and compromised skin are described below.

Epidermolysis bullosa (EB) is a term used to describe a rare complex group of genetically determined fragility disorders of the skin and mucous membranes. EB is classified into four categories; the common factor in all EB types is the tendency for skin and mucous membranes to blister or shear away due to friction and trauma (Fine et al, 2014) (**Table 1**).

Table 1. Classification of epidermolysis bullosa (EB) (Fine et al, 2014)

Classification	Location of blister formation in the skin
Epidermolysis bullosa simplex (EBS)	Epidermis or uppermost layer of skin cells (keratinocytes). Most common form of EB
Junctional epidermolysis bullosa (JEB)	Lamina lucida within the basement membrane zone
Dystrophic epidermolysis bullosa (DEB)	Lamina densa and upper dermis
Kindler syndrome (KS)	Variable blister formation – within the epidermis, lamina lucida or beneath the lamina densa. Rarest form of EB

Aplasia cutis congenita (ACC) is another rare condition which may occur as an isolated anomaly or as part of a genetic syndrome. It is characterised by localised or widespread absence of skin at birth (Marneros, 2024).

Skin grafting is a commonly used surgical procedure to quickly restore skin integrity of wounds that are large and cannot be directly closed (Beldon, 2003). It involves the placement of skin or a skin substitute over a wound to replace and regenerate the damaged tissue (Serra et al, 2016). The two main types of skin grafts are split-thickness (involving the epidermis and part of the dermis) and full-thickness (involving the epidermis and the entire dermis) (Andreassi et al, 2005). Skin grafts are fragile because they are separated from their original blood supply during transplantation and rely on the recipient wound bed to re-establish vascular connections, a process that is highly sensitive to disruption. Skin grafts are relatively thin and lack the structured resilience of native skin, making them vulnerable to trauma, desiccation and breakdown (Curtin et al, 2025).

Ostomy care involves the management of a surgically created opening (stoma) on the abdomen for elimination of body waste. Peristomal skin (i.e. that surrounding the stoma) is regarded as being particularly fragile due to contact exposure to moisture, effluence and adhesive materials. It is frequently affected by moist-associated skin damage (MASD), peristomal dermatitis and medical adhesive-related skin injury (MARSI) (LeBlanc et al, 2019).

Challenges

In best practice guidelines for skin and wound care in patients with **EB** published in 2017, it is stated that the common factor in all types of EB is the tendency for skin and mucous membranes to blister or shear away in response to minimal everyday friction and trauma. The guidelines also point out that the severity of **EB** varies from simple blistering affecting the hands and feet to death in early infancy. In addition, people with more severe forms of EB can experience recurrent blistering and skin loss, and there is a tendency for EB lesions to become chronic wounds (Denyer et al, 2017). Patients with EB endure profound physical and emotional suffering due to the extreme fragility of their skin. They typically experience constant cycles of wound formation and healing, leading to chronic pain, infection and scarring that often require intensive daily wound care and hospitalisation (Goldschneider et al, 2014). EB also interferes with basic activities such as walking, dressing and eating, as well as limiting independence and mobility (Salamon et al, 2025). Although EB and **ACC** are distinct in origin, they share several clinical challenges relating to the fragile and compromised nature of the skin (Marneros, 2024).

For **skin grafts** to adhere to wound beds, they must be held in close proximity and immobilised (Holden, 2015). When a skin graft fails to adhere or revascularise, the wound remains open, vulnerable to infection and at risk of delayed healing, all of which can prolong care and require additional surgical interventions (e.g. re-grafting) (Shanmugam et al, 2013; Abdulmughni et al, 2025).

In patients with ostomy sites, the **peristomal skin** (i.e. that surrounding the stoma) is vulnerable to MASD, dermatitis and MARSI, all of which can result in inflammation, erosion and painful lesions (parastomal pyoderma gangrenosum) (Wu & Shen, 2013). Leakage from the stoma exposes the vulnerable skin to enzymatically and chemically irritating effluent that can damage the skin. The repeated application and removal of pouching systems with aggressive adhesives can lead to trauma (e.g. skin stripping) and delayed healing (LeBlanc et al, 2019).

Role of dressings in the protection of fragile/compromised skin

The best practice guidelines for skin and wound care in patients with **EB** recommend that "Atraumatic dressings should be used to prevent further blistering, skin and wound bed damage" (Denyer et al, 2017).

Historically, **skin grafts** were secured in place by suturing (which is relatively time-consuming) and by using clips, skin adhesive or staples, the latter being painful to remove and requiring analgesia and, on occasions, sedation or anaesthesia (Chavez, 2004). Another approach to the fixation of skin grafts is the use of wound dressings. To maximise the potential for grafts to take, dressings should prevent mechanical displacement, allow exudate to drain and topically applied antimicrobials to reach the wound, and not adhere to the graft and open areas of the wound (Vloemans & Kreis, 1994).

Dressings also have an important role in **ostomy care**, protecting the peristomal skin, absorbing fluid and facilitating healing (Liu et al, 2021).

Evidence for dressings with Safetac

Epidermolysis bullosa

The best practice guidelines for skin and wound care in patients with EB incorporate tables which list numerous dressing types that are suitable for use on patients with EB, including several dressings with Safetac (**Table 2**) (Denyer et al, 2017).

Table 2. References to dressings with Safetac in best practice guidelines for skin and wound care in patients with EB (Denyer et al, 2017)

Dressing with Safetac	Indication / function
Mepilex	EBS (localised and generalised) / JEB / DEB / KS / neonates with EB - for protection and exudate management
Mepilex Lite	EBS (localised and generalised) / JEB / DEB / KS / neonates with EB - for protection and exudate management Tracheostomy and stoma site care - for protection
Mepilex Transfer	EBS (localised and generalised) / JEB / DEB / KS / neonates with EB / fungating wounds - for protection and exudate transfer to absorbent dressing
Mepilex Border	EBS (localised and generalised) / DEB (isolated wounds) / KS (isolated wounds) - for protection and blister sites Low-to-moderately exuding wounds - for moisture / exudate management
Mepilex Border Lite	EBS (localised and generalised) / KS (isolated wounds) – for protection and blister sites
Mepitel	EBS (localised and generalised) / DEB / KS (moist and most dry wounds) / neonates with EB Gastrostomy site / tracheostomy care – for use as a wound contact layer
Mepitel One	EBS (localised and generalised) / JEB / DEB – for use as a wound contact layer EB patients in the OR – for avoiding skin damage associated with ECG monitoring electrodes, oxygen saturation monitoring probes and face masks
Mepitel Film	EB patients in the OR – for retention / securing of cannula and equipment to avoid skin damage Tracheostomy care – for use as a wound contact layer
Mepitac	EBS (localised and generalised) – for retention of non-bordered dressings
Mepilex Ag	Infected and critically colonised wounds – for use as primary dressings (short-term use only) Silver products should be used with caution in infants under one year. Also potential risk of raised plasma silver levels / argyria. Restrict use to 14 days and apply to a small area for short-term use only

Abbreviations: DEB = dystrophic epidermolysis bullosa; EB = epidermolysis bullosa; EBS = epidermolysis bullosa simplex; ECG = electrocardiogram; JEB = junctional epidermolysis bullosa; KS = Kindler Syndrome; OR = operating room

In an extensive review of dressing usage in the management of **EB-related blister wounds**, Ly & Su refer to the rarity of **EB** as being a key factor in the paucity of data from large scale clinical studies; hence they relied on their clinical experience and the preference of patients to determine best practice. They suggest using **Mepitel** (wound contact layer) and the **Mepilex** range of absorbent dressings for ulcers when depth, pain, exudate, infection and chronicity are evident. The **Mepilex** range of dressings is also suggested for superficial erosions, intact skin requiring protection, and hypergranulation. When intense pruritus is present, the authors suggest using **Mepitel**. For the prevention of digital webbing, **Mepilex**, **Mepilex Lite** and **Mepilex Transfer** are suggested. **Box 1** includes other guidance provided by the authors on the usage of dressings with Safetac (Ly & Su, 2008). In the same review, **Mepilex Ag** is suggested for ulcers with heavy microbial contamination. However, as stated in the instructions for use supplied with this dressing, clinicians should be aware that there are very limited data on prolonged and repeated use of silver-containing dressings, particularly in children and neonates. With this in mind, clinicians should take this into consideration alongside the guidance given in the best practice guidelines mentioned earlier, i.e., "Silver products should be used with caution in infants under one year. Also potential risk of raised plasma silver levels / argyria. Restrict use to 14 days and apply to a small area for short-term use only" (Denyer et al, 2017).

Box 1. Guide to using dressings with Safetac in the management of epidermolysis bullosa (EB) (Ly & Su, 2008)

"Mepitel allows for visual inspection of the affected areas without disturbing the erosion/ulcer. It also allows for reapplication of ointments/creams etc., without removing the dressing and disturbing the healing process."

"Light to moderate exudate: Mepilex or Mepilex Border (waterproof) or Mepilex Ag (if heavier microbial colonisation)."

"None to minimal exudate: Mepilex Lite (waterproof) or Mepilex Ag (if heavier colonisation)."

"None to light exudate for large (>20 cm) areas, or difficult-to-dress areas, i.e. underarms / groin / digits: Mepilex Transfer."

Another review highlights that, irrespective of the dressing used, the primary contact layer must not adhere to the wound or the peri-wound skin because the removal of adherent dressings can lead to further blistering and skin breakdown. Lara-Corrales and colleagues state that, to optimise the healing of new **blisters or bullae**, their patients are advised to cover them with non-adhesive dressings (preferably silicone-based dressings as these tend not to stick to the wound). They refer to **Mepilex**, **Mepilex Border** and **Mepilex Border Lite** as dressings that can help to provide a cushioning effect and padding for wounds in easily traumatised areas, and **Mepitel** as being ideal for using when topical medications need to be re-applied to wounds and dressing change-related trauma minimised (Lara-Corrales et al, 2010). **Mepitel** has also been used to secure intravenous cannulae (Denyer, 2000).

In an article which summarises various presentations that were given at a symposium relating to the perioperative management of patients with **EB**, reference is made to the use of **Mepiform** as a means of securing precordial stethoscopes to the skin; **Mepiform** and **Mepitac** for securing intravenous lines; and **Mepilex** being applied to facial masks and to the skin of the submandibular, perioral, neck and nasal areas for protection (Azizkhan et al, 2007).

In another report, **Mepilex** use is described as part of a technique to protect the face when using mask ventilation for delivering anaesthesia to patients with **EB**. The dressing is cut to correspond with the mouth and the shape of the mask; the adhesive side is attached to the mask and the foam side to the patient's face. The author suggests that the technique protects patients from developing pressure- and trauma-related injuries (Meola, 2008).

In a more recent review, focussing on the peri-operative anaesthetic management of patients with **EB**, reference is made to the use of **Mepilex** on open wounds to prevent adherence to the sheets or the operating room table, and **Mepitac** to secure intravenous catheters (Brooks Peterson et al, 2022).

After taking into consideration the difficulties of designing statistically valid studies to provide evidence to determine the efficacy and safety of interventions used in the management of EB-related wounds, the 'real world' observations described in the articles and posters referred to above make a relatively strong case for using dressings with Safetac. This is reflected in the best practice guidelines for skin and wound care in patients with EB, published in 2017, in which it is stated that soft silicone dressings are widely used and accepted in the management of EB (Denyer et al, 2017).

Clinical studies and case studies in which dressings with Safetac have been evaluated for use in the management of EB are summarised in **Table 3**.

Table 3. Managing epidermolysis bullosa (EB) - dressings with Safetac - key studies

Reference / Study type / Country	Number of subjects / EB type	Dressings evaluated	Main results
Yuen et al, 2013 Observational prospective clinical study Netherlands	JEB (n=23) Age: not stated	Mepilex / Mepilex Transfer / Mepitac In conjunction with punch grafting	Longstanding ulcers (on average persisted for 6 years prior to study) treated with punch grafting. After grafting, Mepilex was applied to recipient site. For deep ulcers, Mepilex Transfer was applied underneath Mepilex. Donor sites were sutured or had Mepilex (secured with Mepitac) applied. Healing rate was 70% (n=16) with a mean healing time of 2 months; 30% (n=7) of the ulcers improved.
Zhou et al, 2020 Case study series China	DEB (n=11) Age: 4-24 years	Mepitel	Mepitel was used to cover the hands as part of a management regimen post-surgical correction.
Chen et al, 2022 Case study Canada	EBS (n=1) Age: 15 years	Mepilex	Mepilex was used to secure intravenous and arterial lines as part of the anaesthetic management of a patient with EBS. Post-operatively, the patient's skin was reassessed frequently without signs of injury.
Giannoudis et al, 2021 Case study United Kingdom	DEB (n=1) Age: 35 years	Mepitel One	As part of the wound care regime, Mepitel One was applied to all skin areas (except incision sites) prior to surgery (intramedullary nailing) after the patient had sustained a femur fracture. At the time of the surgery, the patient had extensive blistering of most of her skin. At 6 weeks post-operatively, the wounds had healed with no signs of infection.
Miura & Nakagomi, 2021 Case study Japan	DEB (n=1) Age: 5 years	Mepilex Ag / Mepilex Lite	Mepilex Lite and Mepilex Ag were used as part of a dressing regimen for a patient with recessive DEB who experienced skin breakdown covering 2% to 40% of TBSA over a 35-week period.
Komori et al, 2018 Case study Japan	EBS (n=1) Age: not stated (neonate)	Mepilex Transfer	Mepilex Transfer was used as part of a dressing regimen that prevented the patient from developing lethal complications associated with EBS.
Denyer et al, 2017 Case study series United Kingdom	JEB (n=1) Age: 23 years DEB (n=1) Age: 24 years	Mepilex Transfer / Mepitel	JEB case: Mepilex Transfer was used to transfer exudate to a secondary absorbent dressing on a shin wound. The wound almost healed over an 18-month period. DEB case: Mepitel (primary) and Mepilex Transfer (secondary) dressings were applied to head wounds. The improvement of the wounds over a 4-week period was described as 'remarkable'.
Van Vuuren et al, 2017 Case study series Australia	EB (type not stated) (n=2) Age: neonates	Mepitel Mepilex Lite	In two neonates, Mepitel was applied around the individual fingers and toes to avoid digital fusion, with Mepilex Lite used as a secondary dressing to absorb serous discharge.
Atkin et al, 2017 Case study United Kingdom	EB (type not stated) (n=1) Age: not stated	Mepitel One	In one of eight cases presented, reference is made to the use of Mepitel One on EB. No further details are provided.
Downe, 2017 Case study United Kingdom	DEB (n=1) Age: 41 years	Mepitel	Mepitel was applied to the hands, elbows, knees, lower legs and feet. The use of the dressing was associated with reduced pain, increased comfort and enhanced the patient's quality of life.
Muller & Kiritsi, 2017 Case study Germany	EBS (n=1) Age: 10 years	Mepilex Transfer	Mepilex Transfer was used as a secondary dressing to secure a hydrocolloid dressing. The exudate transfer dressing provided good adherence to the intact dry skin but was easily removed without causing blistering.
Denyer & Foster, 2010 Case study series United Kingdom	DEB (n=2) JEB (n=1) Age: not stated (children)	Mepitel One	DEB case 1: Mepitel One was used to delay digital fusion and loss of hand function. The dressing was placed in the web spaces then stretch bandages placed over the top to provide added protection and to increase traction. DEB case 2: Mepitel One was used to cover the face beneath a mask (through which anaesthesia was being delivered to the patient) to prevent skin damage. JEB case: Mepitel One was applied to facial blisters. The dressing was reported to be comfortable, remained in place and, therefore, unlikely to have been removed by a small child. The transparency of the dressing also proved popular and was considered less conspicuous than other dressings.
Motley et al, 2010 Case study United States of America	DEB (n=1) Age: 7 months	Mepilex	Mepilex was applied to the forehead, zygomatic arch, and eyelids prior to ophthalmic surgery. No iatrogenic complications were observed. Improved visual function was evident at 2 years of age.
Dawson, 2008 Case study United States of America	EB (type not stated) (n=1) Age: not stated	Mepitel	A patient with EB who had a peripheral catheter inserted required a dressing for the insertion site that would not adhere to the skin and cause blistering around the catheter. Mepitel, in conjunction with a secondary dressing, was identified as a suitable means of dressing the insertion site. The dressing regime was initially used for 2 weeks without complications. The same regime was then used over many months as the patient had to be re-admitted to hospital with chronic health problems.
Hon et al, 2007 Case study China	DEB (n=3) Age: neonates	Mepilex / Mepilex Transfer / Mepitel	Affected areas were covered with Mepitel, then Mepilex or Mepilex Transfer and fixed in place with a retention bandage. If fingers or toes became sore, then they were dressed individually with Mepitel placed between the digits to avoid fusion.
Denyer, 2006 Case study United Kingdom	DEB (n=1) Age: not stated (neonate)	Mepitel Mepilex Mepilex Transfer Mepitac	Mepitel was used to dress the feet (covered with Mepilex) and hands (covered with Mepilex Transfer). Healing was achieved after 21 days. Reference is also made to the use of Mepitac instead of adhesive tape for cannula fixation.
Rubin et al, 2006 Case study Australia	JEB (n=1) Age: 10 years	Mepilex	The patient presented with blisters and erosions at the urethral meatus which had caused fusion of the meatal opening, To micturate, the patient had to tear apart the fused tissue, resulting in considerable pain. Prevention and re-stenosis were accomplished with the application of Mepilex to the urethral meatus after each micturition, where it remained until the next episode of micturition. No recurrence of the stenosis was observed in the 10-month period after the introduction of Mepilex dressings.
Schumann et al, 2005 Case study series Germany	Fragile skin conditions (n=22) including EB (n=13) Age: 1-91 years	Mepilex	Good wound healing was observed with fast re-epithelialisation in most patients. Mepilex gave excellent protection and did not tear the fragile skin. Minimal pain was experienced during dressing changes. No allergic reactions were reported. Mepilex was easy to handle and enabled some patients to change their dressings without assistance.

Reference / Study type / Country	Number of subjects / EB type	Dressings evaluated	Main results
Hall, 2004 Case study United Kingdom	DEB (n=1) Age: not stated (adult)	Mepitel Mepilex Transfer	Mepitel (covered with Mepilex Transfer) was used to dress various parts of the body. The dressings were reported to be virtually pain-free to apply, comfortable to wear and compatible with the active lifestyle of the patient.
Weiner, 2004 Case study United State of America	JEB (n=1) Age: not stated (infant)	Mepilex Transfer	The infant was suffering from non-healing angry wounds that were worsened by the friction of her diaper. Her parents had used many products to protect the areas without success. After about one weeks' use of Mepilex Transfer, the patient experienced significant healing, along with a decrease in pain and irritability.
Lapioli-Zufelt & Morris, 1998 Case study United States of America	EB (type not stated) (n=1) Age: 3 years	Mepitel	The child had EB lesions affecting her feet, elbows, buttocks, hands, face, neck and chest. The lesions had previously been managed with a multitude of dressings that were painful and had not facilitated healing. Mepitel, however, did not adhere to the moist wound sites but adhered to the surrounding dry skin, therefore its removal was atraumatic. Mepitel was typically changed every 3-4 days (secondary dressings changed daily). The porous structure of Mepitel allowed exudate to pass to an outer absorbent dressing, as well as being permeable to an antibiotic ointment used to manage secondary skin infections. The most dramatic response to Mepitel was the alleviation of dressing change-related pain and anxiety, impacting positively on both the patient and caregivers.
Spitz & Rosslein, 1998 Case study Switzerland	DEB (n=1) Age: 5 years	Mepitel	Mepitel was used to dress the hand. Complete re-epithelialisation occurred within four weeks, and a major part of the patient's hand function was restored. Improvement in the patient's wellbeing and self-esteem were also observed.

Abbreviations: DEB = dystrophic epidermolysis bullosa; EB = epidermolysis bullosa; EBS = epidermolysis bullosa simplex; JEB = junctional epidermolysis bullosa; TBSA = total body surface area

Aplasia cutis congenita and other congenital skin disorders

In a case study involving a premature infant with **ACC**, changing the dressing regime to Mepitel (with a secondary absorbent gauze when required) resulted in fewer dressing changes (compared to previously used dressing regimes) and good clinical progress. Dressing changes were also reported to be atraumatic (Lahiri & Nishikawa, 2006).

Congenital erosive and vesicular dermatosis is a rare condition seen in newborns. It is associated with crusted erosions and vesicles that heal relatively rapidly, forming reticulated scars. A case report describes the use of a dressing regime including Mepitel for a premature baby with this condition. Clinical improvement was reported to be excellent, with complete healing observed within seven weeks of commencing the new regime (De Lange et al, 2010).

Skin graft management

In a review of the different types of **skin grafts** that are managed in the community setting, it is stated that Mepitel is commonly used to aid graft take because it allows the free passage of exudate through its open mesh, adheres to the surrounding skin and not to the wound tissue, facilitates atraumatic and pain-free removal, and can be left in place for up to 14 days allowing only the secondary dressing to be changed if necessary (Atkinson, 1999).

Dressings with Safetac, specifically the wound contact layers Mepitel, Mepitel Ag and Mepitel One, have been evaluated for use on skin grafted wounds in numerous clinical studies described below and in **Table 4**.

Table 4. Skin grafting - dressings with Safetac - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Patton et al, 2013 RCT United States of America	**Subjects:** 43 (age range 18-70 years) **Wounds:** Grafted deep partial or full thickness burns (1-25% TBSA) **Setting:** Burn care centres	**Safetac:** Mepitel One (n=21) **Comparator:** Bridal Veil and staples (n=21)	Graft take Pain severity during dressing removal (measured using VAS 0-100) Staffing costs	High graft take in both groups (postoperative day 7): - Mepitel One: 99.0% - Comparator: 93.1% Lower median pain severity at dressing change in Mepitel One group (p=0.018): - Mepitel One: 4 - Comparator: 44 Lower staff costs in the Mepitel One group (p=0.0064), as reflected in the 75% shorter time required for dressing removal (p=0.0005): - Mepitel One: US$4.89 - Comparator: US$10.40
Platt et al, 1996 RCT United Kingdom	**Subjects:** 38 (age range 1-74 years) **Wounds:** Grafted post-burn wounds (TBSA grafted <15%) **Setting:** Burn care centre	**Safetac:** Mepitel (n=19) **Comparators:** Paraffin gauze (n=19) Both Mepitel and gauze dressings covered with loose gauze. Dressings changed after 3-5 days	Graft take Pain on dressing removal (measured using VAS 0-10) Dressing usage	High graft take in both groups: - Mepitel: 95.7% - Paraffin gauze: 94.3% Lower mean pain scores at the first post-operative dressing change in the Mepitel group (p<0.01): - Mepitel: 1.4 - Paraffin gauze: 4.4 All patients in the paraffin gauze group experienced pain on dressing removal, whereas 53% of those in the Mepitel group experienced none. Mepitel was easier to remove than paraffin gauze (p<0.001).
Vloemans & Kreis, 1994 Observational prospective clinical study Netherlands	**Subjects:** 38 (age range 0.5-13 years) **Wounds:** Grafted post-burn wounds (n=33) and non-burn-related trauma wounds (n=5) **Setting:** Paediatric burn care centre	**Safetac:** Mepitel covered with cotton gauze (soaked in antimicrobial solution) applied as secondary dressing **Comparator:** None	Graft take Pain on dressing removal	Graft take >95% complete in 42/45 cases. Painless removal of secondary dressings with Mepitel in place; painless removal of Mepitel.

Abbreviations: RCT = randomised controlled trial; TBSA = total body surface area; US$ = United States Dollars; VAS 0-10 = visual analogue scale ranging from 0 (no pain) to 10 (worst possible pain): VAS 0-100 = visual analogue scale ranging from 0 (no pain) to 100 (worst possible pain)

Mepitel has been evaluated for use on skin grafted burn wounds in numerous clinical studies. The first of these evaluations was an open, prospective study involving 38 children in which Mepitel was evaluated for the fixation of split skin grafts applied to mainly **post-burn wounds**. Cotton wool gauze (soaked in an antimicrobial solution), applied as a secondary dressing, was changed every one to two days. Changing the outer absorbent dressing was painless, as was the final removal of the wound contact layer after 5-7 days. The use of the dressing with Safetac also prevented disturbance of open wound areas at dressing changes. In 42 of 45 cases, graft take was almost (>95%) complete (Vloemans & Kreis, 1994).

Mepitel was also compared with paraffin gauze as the primary wound contact layer applied to 38 **newly grafted burn wounds** in a randomised controlled trial (RCT) involving adults and children. Pain severity scores (measured using a visual analogue scale) at the first post-operative dressing change were significantly ($p<0.01$) greater in the gauze group. Whereas all patients in the gauze group experienced pain on dressing removal, 53% of patients in the dressing with Safetac group experienced no pain. The wound contact layer was also found to be significantly easier to remove than the gauze ($p<0.001$) (Platt et al, 1996). Further evidence of the usefulness of Mepitel in this indication has been presented in a case report in which the author states that

the dressing proved to be ideal, providing the advantage of relatively painless removal, easy and effective graft fixation, and reducing operative time because no staples were needed for graft placement (Chavez, 2004).

Two studies evaluated the use of Mepitel One on skin **grafted burn wounds**. In an RCT undertaken in the USA, adult patients with newly grated burn wounds were randomised to either Mepitel One or Bridal Veil (netting-like dressing) plus staples. Although there was no significant difference between the two groups regarding skin graft take (Mepitel One, 99.0%; Bridal Veil plus staples, 93.1%), pain severity during dressing removal was significantly less in the dressings with Safetac group (p=0.018). Staffing costs were also lower in the Safetac dressing group (p=0.0005); removal of the dressing with Safetac typically took less than a quarter of the time taken to remove the Bridal Veil and staples. The dressing with Safetac was easier to use, more conformable and stayed in place better compared with the other regime (Patton et al, 2013). More recently, a plastic and reconstructive surgical team in Japan undertook a case study series to evaluate a technique for fixing skin grafts of patients (n=14) with **burn wounds or other skin defects**. The technique involves the application of Mepitel One as the primary dressing on the grafts, stapling the surface of the dressing to fix the grafts, and then applying a tie-over dressing or negative pressure wound therapy (NPWT) dressing. The skin grafts took in all cases. After removal of the tie-over / NPWT dressing 5-7 days post-surgery, the graft could be observed due to the transparency of the dressing with Safetac. Between post-operative days 5 and 12, the sutures were removed at the same time as the primary dressing, without any complications observed (Yanagisawa & Yuzuriha, 2018).

Mepitel Ag has also been used successfully in the management of **skin grafted burn wounds**. In a case study series undertaken in the USA, the silver-containing wound contact layer (in conjunction with a secondary absorbent dressing) was applied to 11 burns, 10 of which demonstrated 95% healing after 10 days. No infections were observed, and the wound contact layer demonstrated good conformability and gentle adherence to the grafted burns (Alemante et al, 2017).

There are several reports of dressings with Safetac being used on patients with chronic leg ulcers to hold skin grafts in place. In a study involving 15 patients which set out to monitor the healing of ulcers (mostly **VLUs**) that had either a skin substitute or an autograft applied, Mepitel was placed on top of the grafts and beyond their edges to prevent slippage by shear forces. All ulcers healed within 3-5 weeks, with no reports of pain (Kuhn & Angehrn, 2009). Pinch grafting is a technique that involves the harvesting of small discs of skin and applying them evenly across an epithelial defect to enable epithelialisation from the wound edges and the discs. In an article describing the use of a trigger-fired harvester, Mepitel is described as a suitable dressing for holding pinch grafts applied to VLUs securely in place (Greenwood et al, 1997).

Marconi et al reported on a case in which Mepitel was used to secure skin grafts applied to a **pyoderma gangrenosum-related ulcer**. The wound contact layer with Safetac was associated with atraumatic and pain-free application and removal, held the skin graft in position and remained in place until the graft was established (Marconi et al, 2009). In a study undertaken in Brazil to compare micrografting with conventional mesh grafting for chronic wounds, including **VLUs** and **DFUs**, Mepitel One was applied (in both treatment groups) over the grafted area and left in place for 14 days before replacing, allowing the secondary dressing (hydrogel plus foam Mepilex) to be changed as needed without disturbing the grafted area (Sanches-Pinto et al, 2023).

The use of Mepitel as a temporary dressing before delayed split skin grafting of extensive wounds resulting from the local excision of skin tumours was evaluated in an RCT (Dahlstrom, 1995). Sixty-four patients were randomised to have either the wound contact layer with Safetac (n=32) or paraffin gauze (n=32) applied after the **excision of malignant melanomas**. In both study groups, the wounds were covered with a saline-soaked absorbent secondary dressing. All dressings were removed on the following day and an unmeshed skin graft applied, which was left exposed. Statistically significant differences were seen between the study groups with the Safetac wound contact layer associated with less wound bed adherence (p<0.001), less bleeding (p<0.02), less pain (p<0.001), and less time required for dressing removal (p=0.02). Commenting on the results, the author considered the wound contact layer to be "an optimum temporary dressing for delayed split-skin grafting" (Dahlstrom, 1995).

Ninety-six patients who had full thickness skin graft reconstruction following **facial skin cancer excision** had Mepitel applied to their graft sites. Complete graft take was observed in 98% (94) of patients. Partial graft failure was observed in two patients: in the first case, the wound went on to heal and the patient had successful late scar revision surgery; in the other case, the wound was managed conservatively and went to heal (Armstrong et al, 2022).

Another report describes the use of Mepitel instead of tie down sutures on skin grafts applied to wounds resulting from **skin tumour removal**. The wound contact layer was associated with improved adherence between the grafted skin and the wound bed. The report also refers to the dressing's ability to apply even pressure throughout the entire area (due to its elasticity), reduce the amount of booster bulk required, and reduce the number of sutures required. The authors describe the Safetac wound contact layer as "an efficient and simple tool for securing skin grafts" (Roh et al, 2008).

Peristomal skin care

In a clinical evaluation involving two patients with peristomal skin breakdown, Mepilex Lite was effectively used as an absorptive cover dressing and as a dry pouching surface, which allowed for pouch adherence and reduction in trauma and pain associated with pouch changes (Rice & Fellows, 2006). Similarly, Mepilex Border and Mepilex Border Lite were found to be effective skin barriers assisting with preservation of skin integrity, protection of fragile wound tissue, and containment of stools (by fixing a pouch to the top of the dressings) in three infants (Kaufman, 2008).

References

Abdulmughni, L.A., Al-Sanabani, J.A., Gilan, W.M., Issa, M.A., Jowah, H.M. (2025) Split-thickness skin graft outcomes and associated risk factors in patients with skin defects at Al-Gumhouri hospital, Sana'a, Yemen: a prospective observational study. BMC Surgery 25:292.

Alemante, Y., Johnson, M., Garner, W., Gillenwater, J. (2017) Silver soft silicone layer in extremity burns: our experience. Poster presentation at the 39th Annual John A Boswick Burn and Wound Care Symposium, Maui, Hawaii, United States of America.

Andreassi, A., Bilenchi, R., Biagiolo, M., D'Aniello, C. (2005) Classification and pathophysiology of skin grafts. Clinical in Dermatology 23(4):332-337.

Armstrong, D., Van Gijn, D., Newlands, C. (2022) Are tie-over bolster dressings necessary for healing or success of full thickness skin graft reconstruction following facial skin cancer excision? British Journal of Oral and Maxillofacial Surgery 60(7):951-955.

Atkin, L., Fletcher, J., Tickle, J. (2017) Managing patients with large, shallow, complex wounds: a case series. Wounds UK; EWMA Special: 42-46.

Atkinson, A. (1999) Managing split skin donor sites in the community. Journal of Community Nursing 13(5):18-24.

Azizkhan, R.G., Denyer, J.E., Mellerio, J.E., Gonzalez, R., Bacigalupo, M., Kantor, A., Passalacqua, G., Palisson, F., Lucky, A.W. (2007) Surgical management of epidermolysis bullosa: Proceedings of the 2nd International Symposium of Epidermolysis Bullosa, Santiago, Chile, 2005. International Journal of Dermatology 46(8):801-808.

Beldon, P. (2003) Skin grafts 2: management of donor site wounds in the community. British Journal of Community Nursing 8(9 Supplement):6-14.

Brooks Peterson, M., Strupp, K.M., Brockel, M.A., Wilder, M.S., Zieg, J., Bruckner, A.L., Kaizere, A.M., Szolnoki, J.M. (2022) Anesthetic management and outcomes of patients with epidermolysis bullosa: experience at a tertiary referral center. Anesthesia and Analgesia 134(4):810-821.

Chavez, B. (2004) Making the case for using a silicone dressing in burn wound management. Ostomy Wound Management 50(6):11-12.

Chen, K., Borschneck, D., Zalan, E.J. (2022) Anesthetic management of a pediatric patient with epidermolysis bullosa simplex undergoing spinal fusion. Journal of Clinical Anesthesia 76:110568.

Curtin, K., Shannon, E., Alison, E., Alba, A., Kelly, B., Carney, B.C., Tejiram, S., Travis, T., Shupp, J., Moffatt, L. (2025) 540 Evaluation of factors contributing to autologous skin graft failure in the outpatient setting. Journal of Burn Care and Research 46(Supplement 1):S131.

Dahlstrøm, K.K. (1995) A new silicone rubber dressing used as a temporary dressing before delayed split skin grafting. A prospective randomised study. Scandinavian Journal of Plastic Reconstructive Surgery and Hand Surgery 29(4):325-327.

Dawson, R.B. (2008) Nursing beyond the process: collegiality and consultation improves outcomes by protecting the tissue integrity of PICC insertion sites. Journal of the Association for Vascular Access 13(1):8-11.

De Lange, A., Bayet, B., Debauche, C., Fraitag, S., Lachapelle, J.M., Marot, L., Vanwijck, R. (2010) Congenital erosive and vesicular dermatosis with reticulated scarring in a newborn: an innovative treatment using a silicone dressing. Pediatric Dermatology 26(6):735-738.

Denyer, J. (2000) Management of severe blistering disorders. Seminars in Neonatology 5(4):321-324.

Denyer, J. (2006) The use of atraumatic wound dressings in epidermolysis bullosa. Poster presentation at the European Wound Management Association Conference, Prague, Czech Republic.

Denyer, J., Foster, L. (2010) Use of a transparent porous dressing coated on the wound contact side with soft silicone (Mepitel One) in the management of children with epidermolysis bullosa. Poster presentation at Wounds UK Conference, Harrogate, United Kingdom.

Denyer, J., Pillay, E., Clapham, J. (2017) Best practice guidelines for skin and wound care in epidermolysis bullosa. Wounds International, London, United Kingdom.

Downe, A. (2017) The effect of current economic cuts to wound dressings and its impact on patients with epidermolysis bullosa: a case study. Wounds UK 13(1):46-53.

Fine, J.D., Bruckner-Tuderman, L., Eady, R.A.J., Bauer, E.A., Bauer, J.W., Has, C., Heagerty, A., Hintner, H., Hovnanian, A., Jonkman, M.F., Leigh, I., Marinkovich, M.P., Martinez, A.E., McGrath, J.A., Mellerio, J.E., Moss, C., Murrell, D.F., Shimizu, H., Uitto, J., Woodley, D., Zambruno, G. (2014) Inherited epidermolysis bullosa: updated recommendations on diagnosis and classification. Journal of the American Academy of Dermatology 70(6):1103-1126.

Giannoudis, V.P., Panteli, M., Aderinto, J., Giannoudis, P.V. (2021) Reverse oblique proximal femoral fracture in dystrophic epidermolysis bullosa; challenges and recommendations. British Medical Journal Case Reports 14:e238483.

Goldschneider, K.R., Good, J., Harrop, E., Liossi, C., Lynch-Jordan, A., Martinez, A.E., Maxwell, L.G., Stanko-Lopp, D. (2014) Pain care for patients with epidermolysis bullosa: best care practice guidelines. BMC Medicine 12:178.

Greenwood, J.E., Parry, A.D., Williams, R.M., McCollum, C.N. (1997) Trigger-fired pinch-graft harvester for use in chronic venous ulcers. British Journal of Surgery 84(3):397-398.

Hall, S. (2004) Life, epidermolysis bullosa and chasing tornadoes. Journal of Wound Care 4;13(10):405-406.

Holden, J. (2015) Top tips for skin graft and donor site management. Wounds UK 10(2):7-13.

Hon, K-L.E., Burd, A., Choi, P.C-L., Luk, N-M.T. (2007) Epidermolysis bullosa in three Chinese neonates. Journal of Dermatological Treatment 18;306-311.

Kaufman, L.M. (2008) When small stomas are a big deal: the use of a soft silicone pouching system on the neonatal ostomate complicated by a peristomal wound. Poster presentation at the 40th Annual Conference of the Wound Ostomy and Continence Nurses Society, Orlando, Florida, United States of America.

Komori, T., Dainichi, T., Masuno, Y., Otsuka, A., Nakano, H., Sawamura, D., Ishida-Yamamoto, A. Kabasima, K. (2018) p.Glu477Lys mutation in keratin 5 is not necessarily mortal in generalized severe epidermolysis bullosa. Journal of Dermatology 45(8):e209-e210.

Kuhn, C., Angehrn, F. (2009) Use of high-resolution ultrasound to monitor the healing of leg ulcers: a prospective single-center study. Skin Research and Technology 15(2):161-167.

Lahiri, A., Nishikawa, H. (2006) A nonadherent dressing for aplasia cutis congenita. Journal of Plastic Reconstructive and Aesthetic Surgery 59(7):781-782.

Lapioli-Zufelt, A., Morris, E.J. (1998) Skin and wound care management for a child with epidermolysis bullosa. Journal of Wound Ostomy and Continence Nursing 25(6): 314-316.

Lara-Corrales I., Arbuckle A., Zarinehbaf, S., Pope, E. (2010) Principles of wound care in patients with epidermolysis bullosa. Pediatric Dermatology 27(3):229-237.

LeBlanc, K., Whitely, I., McNichol, L., Salvadalena, G., Gray, M. (2019) Peristomal medical adhesive-related skin injury. Results of an international consensus meeting. 46(2):125-136.

Liu, L., Gao, O., Cao, G., Pan, C., Fu, Y. (2021) Application and nursing key points of wet dressings on the intestinal flora after enterostomy. American Journal of Translational Research 13(12):13741-13749.

Ly, L., Su, J.C. (2008) Dressings used in epidermolysis bullosa blister wounds: a review. Journal of Wound Care 17(11):482-492.

Marconi, R., Laverda, F., Trevisan, G. (2009) A case study evaluation of a soft silicone primary wound contact dressing in the prevention of wound pain and tissue trauma. Poster presentation at the European Wound Management Association Conference, Helsinki, Finland.

Marneros, A.G. (2024) Aplasia cutis congénita pathomechanisms reveal key regulators of skin and appendage morphogenesis. Journal of Investigative Dermatology 144(11):2399-2405.

Meola, S. (2008) Epidermolysis bullosa: a new technique for mask ventilation. Paediatric Anaesthesia 18(11):1109-1111.

Miura, Y., Nakagomi, S. (2021) Management of cutaneous manifestations of genetic epidermolysis bullosa. Journal of Wound Ostomy and Continence Nursing 48(5):453-459.

Motley W.W., Vanderveen D.K., West C.E. (2010) Surgical management of infantile cataracts in dystrophic epidermolysis bullosa. Journal for the American Association for Paediatric Ophthalmology and Strabismus 14(3):283-284.

Muller, S., Kiritsi, D. (2017) Epidermolysis bullosa simplex complicated by allergic contact dermatitis caused by a hydrocolloid dressing. Contact Dermatitis 76(3):185-186.

Patton, M.L., Mullins, R.F., Smith, D., Korentager, R. (2013) An open, prospective, randomized pilot investigation evaluating pain with the use of a soft silicone wound contact layer vs bridal veil and staples on split thickness skin grafts as a primary dressing. Journal of Burn Care and Research 34(6):674-681.

Platt, A.J., Phipps, A., Judkins, K. (1996) A comparative study of silicone net dressing and paraffin gauze dressing in skin-grafted sites. Burns 22(7):543-545.

Rice, M., Fellows, M. (2006) Case study challenge: use of soft silicone foam in treating peristomal skin breakdown. Journal of Wound Ostomy and Continence Nursing 33(5):542-546.

Roh, M.R., Shin, J.U., Chung, K.Y. (2008) Silicone net bolster dressing for skin grafts. Dermatologic Surgery 34(9):1233-1235.

Rubin, A.I., Moran, K., Fine, J.D., Wargon, O., Murrell, D.F. (2006) Urethral meatal stenosis in junctional epidermolysis bullosa: a rare complication effectively treated with a novel and simple modality. International Journal of Dermatology 46(10):1076-1077.

Salamon, G., Strobl, S., Matschnig, M.S., Diem, A. (2025) The physical, emotional, social, and functional dimensions of epidermolysis bullosa. An interview study on burdens and helpful aspects from a patients' perspective. Orphanet Journal of Rare Diseases 20:3.

Sanches-Pinto, D.C., Eriksson, E., Gomez, D.S., Nunes, M.P.T., Gemperli, R., Soriano, F.G. (2023) Minced skin grafts for chronic wounds compared to conventional mesh grafts. Health Science Report 6(6):e1353.

Schumann, H., Beljan, G., Hoping, D., Bruckner-Tuderman, L. (2005) Atraumatic dressings in fragile skin conditions: use of the soft silicone dressing (Mepilex) in hereditary and acquired bullous skin disease. Poster presentation at the European Wound Management Association Conference, Stuttgart, Germany.

Serra, R., Rizzuto, A., Rossi, A., Perri, P., Barbetta, A., Abdalla, K., Caroleo, S., Longo, C., Amantea, B., Sammarco, G., de Franciscis, (2016) S. Skin grafting for the treatment of chronic leg ulcers – a systematic review in evidence-based medicine. International Wound Journal 14(1):149-157.

Shanmugam, V.K., McNish, S., Duncan, J., Root, B., Tassi, E., Wellstein, A., Kallakury, B., Attinger, C.E. (2013) Late failure of a split-thickness skin graft in the setting of homozygous factor V Leiden mutation: a case report and correlative animal model from the Wound Etiology and Healing (WE-HEAL) study. International Wound Journal 12(5):537-544.

Spitz, C., Rosslein, R. (1998) [Epidermolysis bullosa hereditaria dystrophica mutilans Hallopeau-Siemens; a complex problem] Handchirurgie, Mikrochirurgie Plastiche Chirurgie 30(2):71-81.

Van Vuuren, A.J., Roy, B., Padilla, M., Melamdowitz, M., Shah, D., Butha, T. (2017) Management of neonatal epidermolysis bullosa (EB) in a special care nursery. Journal of Paediatrics and Child Health (Supplement 2)(53):85.

Vloemans, A.F., Kreis, R.W. (1994) Fixation of skin grafts with a new silicone rubber dressing (Mepitel). Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery 28(1):75-76.

Weiner, M.S. (2004) Pain management in epidermolysis bullosa: an intractable problem. Ostomy Wound Management 50(8):13-14.

Wu, X-R., Shen, B. (2013) Diagnosis and management of parastomal pyoderma gangrenosum. Gastroenterology Report (Oxford) 1(1):1-8.

Yanagisawa, D., Yuzuriha, S. (2018) Stapling technique through transparent dressing to fix skin grafts. Burns Open 2(1):71-75.

Yuen, W.Y., Huizinga, J., Jonkman, M.F. (2013) Punch grafting of chronic ulcers in patients with laminin-332-deficient, non-Herlitz junctional epidermolysis bullosa. Journal of the American Academy of Dermatology 68(1):93-97.

Zhou, X., Zhang, Y., Zhao, M., Jian, Y., Huang, J., Luo, X., Yang, J., Sun, D. (2020) Surgical management of hand deformities in patients with recessive dystrophic epidermolysis bullosa. Journal of Plastic Surgery and Hand Surgery 54(1):33-39.

Dressings with Safetac® - Addressing Wound Microbiome

Dressings with Safetac featured:

Mepilex® Ag, Mepilex® Border Ag, Mepilex® Border Post-Op Ag, Mepilex® Heel Ag, Mepilex® Transfer Ag, Mepitel® Ag

Take home messages:

- Topical antimicrobial therapy (e.g. the use of silver-containing dressings) is a widely used intervention alongside systemic antibiotics in the management of wound infection.
- Silver-containing dressings with Safetac have been shown to exert rapid, sustained and broad-spectrum activity against common wound pathogens.
- Clinical studies of silver-containing dressings with Safetac across a range of acute and chronic wounds have observed good healing outcomes, reductions in clinical signs of infection, good exudate management and minimisation of trauma and pain at dressing changes.

Introduction to wound microbiome

Whereas intact skin provides a physical barrier to the ingress of microorganisms, wounds generally provide environments that are favourable to the colonisation of microorganisms (Maheswary et al, 2021). The term wound microbiome is used to describe the microorganisms (bacteria, fungi and viruses) that reside in a wound. Virtually all wounds are contaminated or colonised by microorganisms that are potentially pathogenic, even though they exist as commensals as part of the human body's natural flora (e.g. *Staphylococcus aureus* which is present on skin and in the nasal cavity, *Pseudomonas aeruginosa* which colonises moist sites such as the ears, and *Bacteroides fragilis* which resides in the intestine) (Brown et al, 2012; Bowler et al, 2001).

In most wounds, colonisation does not affect the wound healing process because there is a balance between the ability of the microorganisms to invade the host tissue and the ability of the host to prevent it. The survival and replication of microorganisms depends on their ability to evade the host's immune system and on whether essential physico-chemical requirements are met (Bowler, 2003). Species that are successful in this respect may establish the states of colonisation, critical colonisation or wound infection, as described in the wound infection continuum (Kingsley, 2003).

Planktonic ('free floating', single cell form) bacteria are typically involved in acute infections. These bacteria are generally susceptible to antimicrobial agents (e.g. antibiotics and antiseptics). However, they can transform into a more resilient state by forming **biofilms**, aggregates of sessile microorganisms embedded in an extracellular matrix that are tolerant to both antimicrobials and host defence mechanisms (International Wound Infection Institute (IWII), 2022; World Union of Wound Healing Societies, 2016). Biofilms are more common in chronic wounds, with one study identifying their presence in 60% of chronic wounds and in only 6% of acute wounds (James et al, 2008). Furthermore, a systematic review highlighted a 78% prevalence of biofilm in chronic wounds (Malone et al, 2017).

Challenges

Acute wound infection is characterised by friable granulation tissue (red) with epithelial bridging and pocketing, increased malodour, new or increased pain (or change in sensation), protracted healing, wound breakdown, enlargement, or the formation of peri-wound ulcerations (IWII, 2022). As such, acute wound infection impacts negatively on patients and poses significant clinical and economic challenges to healthcare providers.

As well as impairing wound healing, clinical infection may increase the severity of wound-related pain, directly affecting patient comfort. For example, a multinational, multidisciplinary Delphi study revealed a causal relationship between wound infection and the onset or change in the nature of pain. Fifteen of the respondents (n=21) identified this as an issue in event-related pain, 19 cited this phenomenon in relation to somatic-related pain, and 17 cited that patients with wound infection generally experience more pain than those who were free of infection. Twenty respondents thought that some dressing types caused pain during dressing changes (Cutting et al, 2012). Therefore, when selecting topical antimicrobial products, clinicians should consider the ability of dressings to minimise dressing change-related trauma and pain, as well as their antimicrobial properties.

Role of dressings in addressing microbiome

Systemic antibiotics have been, and continue to be, used as the primary intervention against wound infection. However, their use must be considered within the framework of antimicrobial stewardship, as overuse or inappropriate use of antimicrobial agents can contribute to antimicrobial resistance. Consequently, a wide range of topically applied amorphous products and dressings containing antiseptic agents (e.g. iodine, zinc, honey and silver-based agents) are now used alongside systemic antibiotics to provide adjunctive, antimicrobial therapy for wounds that are clinically infected or, where indicated, at risk of infection (Cooper, 2007; Lansdown et al, 2007; Scepankova et al, 2021; Jiang et al, 2024; Roberts et al, 2017). Antibiotics typically act through a single, specific mechanism, whereas antiseptics generally exert their antimicrobial effects through multiple modes of action. In theory, this makes it easier for bacteria to adapt or develop resistance to antibiotics (Nair et al, 2023).

The antimicrobial properties of silver have been recognised for centuries. The metal itself is inactive, but when ionised in the presence of fluid (e.g. wound exudate), it has broad-spectrum activity against microorganisms. The silver ions interact with the bacterial cell wall and plasma membrane, bacterial DNA and bacterial proteins, including the enzymes involved in cellular processes such as the electron transport chain (Gunasekaran et al, 2012; Mussin & Guisiano, 2022; Morris et al, 2019). Silver ions possess broad-spectrum activity against aerobic and anaerobic bacteria (including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE), fungi and viruses (Gunasekaran et al, 2012), as well as having a low toxicity profile (Walker & Parsons, 2012).

Because of these properties, silver-based compounds are included in a wide array of dressings and other topically applied products for use in wound care. The efficacy and safety of silver-containing

dressings differ and depend on the dressing material, the type of silver compound, its location in the dressing and the total silver content. As a result, not all silver dressings should be expected to perform in exactly the same way (Fletcher et al, 2021).

Silver-containing dressings are used on individuals at increased risk of wound infection, to manage localised infection and, in conjunction with systemic antibiotics, to manage spreading or systemic wound infection (IWII, 2022). Authoritative sources stipulate that the duration of use of topical antiseptics should be individualised and based on regular assessment. These sources also refer to a two-week challenge (i.e. sufficient time for the agent to exert some observable activity to inform an evaluation of the management plan) (Leaper et al, 2012; Fletcher et al, 2021), although a four-week period may be more appropriate where there is biofilm involvement (IWII, 2022).

Silver-containing dressings with Safetac include Mepitel Ag (wound contact layer), Mepilex Ag and Mepilex Heel Ag (non-bordered foam dressings), Mepilex Border Ag (bordered foam dressing), Mepilex Transfer Ag (exudate transfer dressing) and Mepilex Border Post-Op Ag (advanced post-operative dressing).

Evidence for dressings with Safetac

Pre-clinical studies

The antimicrobial properties of silver-containing dressings with Safetac have been evaluated using a variety of test methods described below and in **Table 1**.

Table 1. Laboratory testing of the antimicrobial effects of silver-containing foam dressings with Safetac

Reference	Methodologies	Main results
Halstead et al, 2015	**Biofilm formation assays** Test organisms: *Pseudomonas aeruginosa* and *Acinetobacter baumannii* isolates from burn wounds Test dressings: Mepilex Ag, Aquacel Ag, Aquacel Ag Foam, Aquacel Ag Burn, UrgoTul Silver, Acticoat, PolyMem Silver, Inadine, L-Mesitran Net, L-Mesitran Hydro, Bactigras	Large variation in the ability of dressings to prevent isolates of test organisms forming biofilms, ranging from 33% increases with a honey-containing dressing (Mesitran) to 100% decreases with Mepilex Ag and Acticoat. After 72 hours incubation with Mepilex Ag, all isolates exhibited a 95–100% ($p<0.05$) reduction in biofilm formation compared with the positive control.
Bibic & Hamberg, 2014a	**Modified ISO 20743:2013 Textile: determination of antibacterial activity of textile products** Test organisms: eight species for evaluation of rapid/sustained activity; 15 species for evaluation of spectrum of activity (see Table 2 for details) Test dressing: Mepilex Transfer Ag	**Rapidity of action:** Mepilex Transfer Ag reduced the number of CFUs of *Enterococcous faecalis* (VRE), MRSA, *Acinetobacter baumannii*, *Enterobacter cloacae*, *Pseudomonas aeruginosa*, *Candida albicans* and *Candida guillermondii* by > 4.0 $\log_{10}$ and ESBL-producing *Klebsiella pneumoniae* by 3.6 $\log_{10}$ within 30 minutes (**Figure 2A**). **Longevity of action:** Mepilex Transfer Ag reduced the number of CFUs of *Candida faecalis* (VRE), MRSA, *Acinetobacter baumannii*, *Enterobacter cloacae*, *Pseudomonas aeruginosa*, ESBL-producing *Klebsiella pneumoniae*, *Candida albicans* and *Candida guillermondii* by ≥ 4.0 $\log_{10}$ after 15 days. **Broad-spectrum of action:** Mepilex Transfer Ag reduced the number of CFUs of 15 wound-relevant pathogens by ≥ 4.0 $\log_{10}$ after 24 hours.
Bibic & Hamberg, 2014b	**Logarithmic reduction assays (planktonic species): secondary dressing model** Test organisms: *Pseudomonas aaeruginosa*, *Staphylococcus aureus* and *Candida albicans* Test dressings: Mepilex Transfer Ag, Restore Duo Ag, Therabond 3D, Acticoat 7, Aquacel Ag	**Without secondary dressing:** Only Mepilex Transfer Ag and Acticoat 7 reduced the number of CFUs of all three test organisms by > 4.0 $\log_{10}$. Three other wound contact layers reduced *Staphylococcus aureus* by approximately 2.0 $\log_{10}$, whereas the viable counts of *Pseudomonas aeruginosa* and *Candida albicans* were not reduced at all (**Figure 2A**). **With secondary dressing:** The antimicrobial properties of the tested wound contact layers were not affected (**Figure 2B**). Mepilex Transfer Ag was the only wound contact layer to be associated with test organisms below levels of detection in the secondary dressing. In contrast, the other dressings allowed at least one of the test organisms to pass through to the secondary dressing. (**Figure 2C**).
Hamberg et al, 2012	**Logarithmic reduction assays (planktonic species): two-compartment model** Test organisms: *Pseudomonas aeruginosa* and *Staphylococcus aureus* Test dressings: Mepilex Ag, Mepilex Border Ag, Acticoat 7, Allevyn Gentle Ag, Aquacel Ag, Cellosorb Ag (Urgocell Silver), Contreet (Biatain Ag), Melgisorb Ag	A relationship (positive) between the amount of silver released from the dressings and the antimicrobial effect was observed (**Figure 1A**). Mepilex Border Ag and Mepilex Ag released the highest amount of silver and resulted in the highest $\log_{10}$ reduction of the test organisms (**Figure 1B**). No correlation was observed between the total silver content in the dressings and the release of silver or the antimicrobial effect.
Werthen et al, 2012a	**Logarithmic reduction assays (planktonic cultures): Agar plate method and two-compartment model** **Logarithmic reduction assays (biofilm cultures): 3D-model** **Dressing adhesiveness (to 3D-fibroblast culture)** [NB. Corresponding non-silver-containing dressings were used to prevent cytotoxic effects interfering with test results] Test organism (all assays): *Pseudomonas aeruginosa* Test dressings: Mepilex Ag, Aquacel Ag	**Planktonic assays:** Both Mepilex Ag and Aquacel Ag reduced the number of CFUs of the test organism in the region of 3.0 $\log_{10}$ after 24 hours in the agar plate and two-compartment models. **Biofilm assays:** Mepilex Ag reduced the number of CFUs of the test organism by 3.0 $\log_{10}$ whereas no reduction was observed with Aquacel Ag. **Dressing adhesiveness assays:** Aquacel Ag reduced cell numbers in the culture by around 35% ($p<0.05$), whereas Mepilex Ag showed no reduction compared with the control.
Werthen et al, 2012b	**Logarithmic reduction assays (planktonic cultures): Two-compartment model** **Logarithmic reduction assays (biofilm cultures): 3D-model** Test organism (all assays): *Pseudomonas aeruginosa* Test dressings: Mepilex Ag and Acticoat 7	Both test dressings were associated with similar reductions in the number of CFUs of the test organism (in the region of 3.0 $\log_{10}$) in both planktonic and biofilm cultures.
Chadwick et al, 2009	**Zone of inhibition measured following the addition of dressing eluates / SDS-PAGE and zymography** Test organism: *Pseudomonas aeruginosa* Test dressings: Mepilex Ag, Contreet, Acticoat Moisture Control (MC), Cellosorb Ag, Silvercel Ag, Acticoat 7, Tegaderm Ag **ASTM E2149 Standard test method for determining the antimicrobial activity of antimicrobial agents under dynamic contact conditions** Test organisms: five species for evaluation of rapid/sustained activity; 18 species for evaluation of spectrum of activity (see Table 2 for details) Test dressings: Mepilex Ag	**Growth of *Pseudomonas aeruginosa* without serum:** Mepilex Ag: none (up to 48 hours); Contreet: after 18 hours; Acticoat MC: after 18 hours; Cellosorb Ag: after 10 hours; Silvercel Ag: after 10 hours; Acticoat 7: after 10 hours; Tegaderm Ag: after 6 hours. **Growth of Pseudomonas aeruginosa with serum:** Mepilex Ag: none (up to 48 hours); Contreet: none (up to 48 hours); Acticoat MC: after 24 hours; Cellosorb Ag: after 10 hours; Silvercel Ag: after 10 hours; Acticoat 7: none (up to 48 hours); Tegaderm Ag: after 10 hours. Mepilex Ag and other silver dressings blocked the release of proteases (elastase), protecting from *Pseudomonas aeruginosa*-mediated tissue degradation. **Rapidity of action:** Mepilex Ag reduced the number of CFUs of *Candida albicans* by 3.8 $\log_{10}$ and *Enterococcus faecalis* (VRE), *Pseudomonas aeruginosa*, MRSA and MSSA by > 4.0 $\log_{10}$ within 3 hours. **Longevity of action:** Mepilex Ag reduced the number of CFUs of *Candida albicans*, *Enterococcus faecalis* (VRE), *Pseudomonas aeruginosa*, *Serratia marcescens*, MSSA/MRSA, and *Acinetobacter baumannii* by > 3.0 $\log_{10}$ every 24 hours over a period of seven days. **Broad-spectrum of action:** Mepilex Ag reduced the number of CFUs of 18 wound-relevant pathogens by > 4.0 $\log_{10}$ after 24 hours.

Abbreviations: ASTM = American Society for Testing and Materials; CFU = colony forming unit; ESBL = extended spectrum beta-lactamase; ISO = International Organisation for Standardization; MRSA = methicillin-resistant *Staphylococcus aureus*; MSSA = methicillin-sensitive *Staphylococcus aureus*; SDS-PAGE = sodium dodecyl sulphate polyacrylamide gel electrophoresis; VRE = vancomycin-resistant enterococci

Planktonic microorganisms

In a series of logarithmic reduction assays, Mepilex Ag was found to reduce the number of viable cells (colony forming units, CFUs) of 18 wound-relevant pathogens by more than 4.0 logarithmic units (log_{10}) after 24 hours' incubation (**Table 2**) (Chadwick et al, 2009). Later research demonstrated that Mepilex Transfer Ag reduced the number of viable cells by at least 4.0 log_{10} after 24 hours' incubation in the case of 15 tested microorganisms (**Table 2**) (Bibic & Hamberg, 2014a). A compound may be considered cidal if it reduces the test organism by at least 3.0 log_{10} (Peterson & Shanholtzer, 1992). These findings indicate that silver-containing dressings with Safetac can control a broad range of common wound pathogens (Gram-positive and Gram-negative bacteria, yeasts and antibiotic-resistant strains) *in vitro*.

Table 2. List of microorganisms against which Mepilex Ag and Mepilex Transfer Ag have been shown to have antimicrobial activity *in vitro*

Type	Mepilex Ag (Chadwick et al, 2009)	Mepilex Transfer Ag (Bibic & Hamberg, 2014a)
Gram - positive bacteria	*Bacillus cereus ATCC 14579* *Enterococcus faecalis ATCC 19433* *Enterococcus faecium ATCC 19434* *Enterococcus faecalis (VRE) CCUG 34289* *Enterococcus faecium (VRE) CCUG 36804* *Staphylococcus aureus ATCC 6538* *Staphylococcus aureus (MRSA) ATCC 43300* *Staphylococcus aureus (MRSA) CCUG 35571*	*Enterococcus faecalis (VRE) ATCC 51575* *Staphylococcus aureus ATCC 6538* *Staphylococcus aureus (MRSA) ATCC 43300* *Bacillus cereus ATCC 14579* *Staphylococcus epidermidis ATCC 12228*
Gram -negative bacteria	*Acinetobacter baumannii ATCC 19606* *Aeromonas hydrophilia ATCC 7966* *Enterobacter cloacae ATCC 13047* *Klebsiella pneumonia ATCC 13883* *Proteus vulgaris ATCC 29905* *Pseudomonas aeruginosa ATCC 15442* *Pseudomonas aeruginosa Multiresistant CCUG 37385* *Salmonella enterica ATCC 25928* *Serratia marcescens ATCC 13880*	*Acinetobacter baumannii ATCC 19606* *Enterobacter cloacae ATCC 13047* *Pseudomonas aeruginosa ATCC 9027* *Klebisella pneumonia (ESBL) CCUG 59349* *Escherichia coli ATCC 8739* *Proteus vulgaris ATCC 29905* *Salmonella marcescens ATCC 13880*
Fungi	*Candida albicans ATCC 2091*	*Candida albicans ATCC 10231* *Candida guillermondi ATCC 6260* *Candida lusitaniae ATCC 37495*

Abbreviations: ATCC = American Type Culture Collection; CCUG = Culture Collection University of Gothenburg

A rapid effect of an antimicrobial dressing is clinically important, since bacteria can physically adapt to an antimicrobial agent, which in turn may result in the development of resistance to it (Peterson, 2008). If bacteria are killed quickly, this possibility is substantially decreased. Conversely, dressings that release low levels of antimicrobial agents are likely to be more problematic in terms of selection for resistance, especially if the antimicrobial concentration is sub-lethal.

Logarithmic reduction assays have shown that silver-containing foam dressings with Safetac have rapid antimicrobial effects against common wound-relevant pathogens. Mepilex Ag reduced the number of viable cells of *Candida albicans* by 3.8 log_{10} within three hours; the number of viable cells of four strains of bacteria (*Enterococcus faecalis* [VRE], *Pseudomonas aeruginosa*, methicillin-sensitive *Staphylococcus aureus* [MSSA] and were reduced by more than 4.0 log_{10} within the same time period (Chadwick et al, 2009).

In similar tests, Mepilex Transfer Ag reduced the number of viable cells of two fungal species (*Candida albicans* and *Candida guilliermondii*) and six bacterial species (*Acinetobacter baumannii, Enterobacter cloacae, Enterococcus faecalis* [vancomycin-resistant enterococcus, VRE], *Pseudomonas aeruginosa* by more than 4.0 log_{10} within 30 minutes (Bibic & Hamberg, 2014a). The extended spectrum beta-lactamase-producing *Klebisella pneumoniae* was reduced by 3.6 log_{10} within the same time frame; however, this still remains above the range considered as cidal (Peterson & Shanholtzer, 1992).

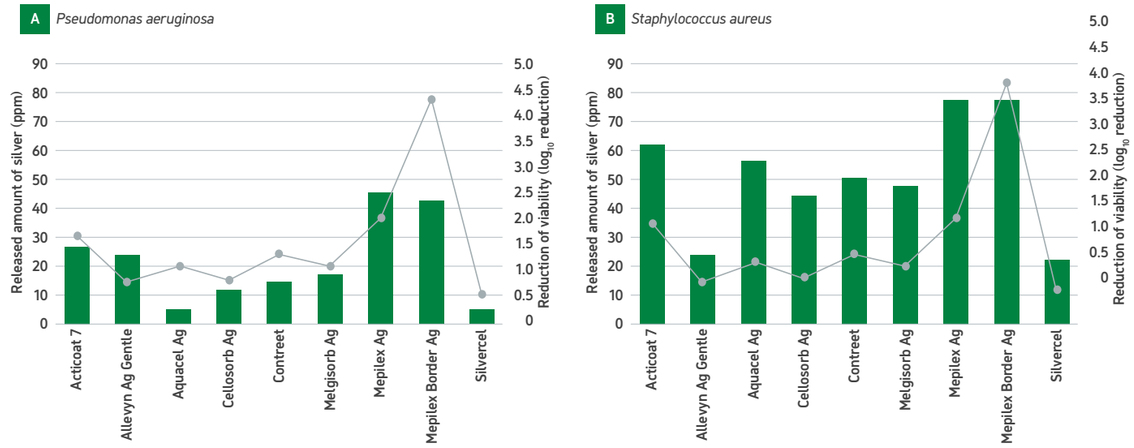
Logarithmic reduction assays have also been used to evaluate the sustained antimicrobial effect of silver-containing foam dressings with Safetac. Mepilex Ag reduced the number of viable cells of seven common wound-related pathogens (*Candida albicans, Acinetobacter baumannii, Enterococcus faecalis* [vancomycin-resistant enterococcus, VRE], *Pseudomonas aeruginosa, Serrata marcescens*) by more than 3.0 log_{10} every 24 hours over a period of seven days (Chadwick et al, 2009). Similarly, Mepilex Transfer Ag, when exposed to microbial challenge at baseline and seven days later, was able to reduce the number of viable cells of eight common wound-related pathogens (*Candida albicans, Candida guilliermondii, Acinetobacter baumannii, Enterobacter cloacae, Enterococcus faecalis* [vancomycin-resistant enterococcus, VRE], *Pseudomonas aeruginosa*) by at least 4.0 log_{10} after 15 days (**Table 2**) (Bibic & Hamberg, 2014a).

A sustained antimicrobial effect makes it possible to avoid frequent and regular dressing changes (subject to other variables such as exudate levels), thus minimising the risk of delayed healing due to wound bed disturbance. If the antimicrobial effects of dressings are maintained over time, this may help to reduce the risk of resistance developing in surviving microorganisms.

Theoretically, a higher release of an antimicrobial will result in greater inactivation of microorganisms. Studies, however, have failed to identify a correlation between the silver content of dressings and its antimicrobial effect (Thomas & McCubbin, 2003) or a correlation between antimicrobial release and effect (Parsons et al, 2005).

However, the research undertaken by Parsons and colleagues did not test both factors in the same system and, because silver release depends on the test medium, this may account for the observed lack of correlation.

The relationship between silver release and the antimicrobial effect of Mepilex Ag, Mepilex Border Ag and seven other commercially available silver-containing dressings was studied in tests involving *Staphylococcus aureus* and *Pseudomonas aeruginosa* (Hamberg et al, 2012). A relationship between silver release and antimicrobial effect was observed when the amount of silver from each dressing was plotted against log_{10} reductions of the test organisms (**Figure 1**). Of the dressings tested, the two silver-containing foam dressings with Safetac released the highest amount of silver and resulted in the highest log_{10} reductions of viable cells of both test organisms.



ppm = parts per million

Figure 1. Silver release (grey line) versus antimicrobial effect at 24 hours (green bars) of different silver-containing dressings (Hamberg et al, 2012)

Silver-containing dressings designed as wound contact layers allow the transfer of exudate into a secondary absorbent dressing. The latter can be changed independently of the wound contact layer, leaving the wound bed undisturbed. The reduction of trauma to the wound and minimisation of dressing-related pain are favourable to the wound healing progress (Rippon et al, 2012). The antimicrobial effect of five silver-containing wound contact layers, alone and in combination with a secondary dressing, to imitate typical dressing usage in the clinical setting has been investigated (Bibic & Hamberg, 2014b). When tested alone, Mepilex Transfer Ag and a silver-coated barrier dressing were found to reduce the viable counts of all three test organisms (*Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans*) by more than 4.0 log_{10} (**Figure 2A**). When tested in combination with a secondary dressing, the antimicrobial properties of the tested wound contact layers were not affected (**Figure 2B**). However, of all the wound contact layers tested, only Mepilex Transfer Ag minimised the passage of all three microorganisms into the secondary dressing; the others allowed at least one of the organisms to pass through (**Figure 2C**). As the secondary dressing contained no antimicrobial substances, microorganisms that have passed into it are free to multiply and could be a possible source for odour or infection.

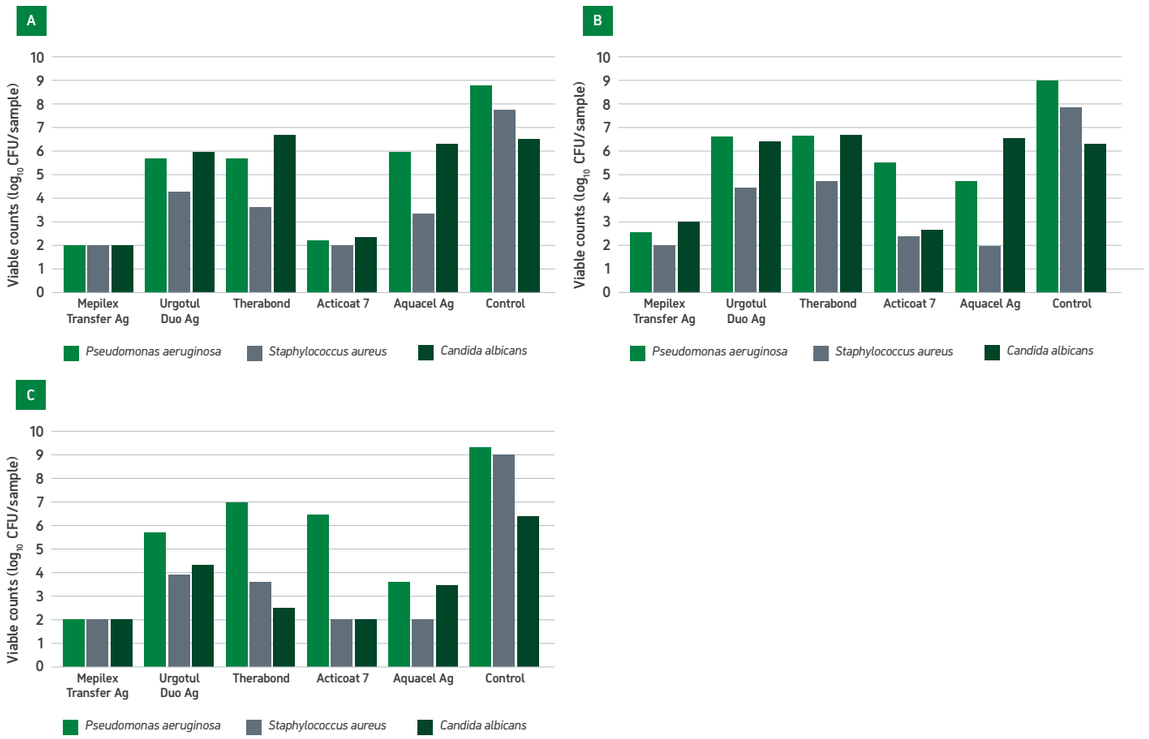
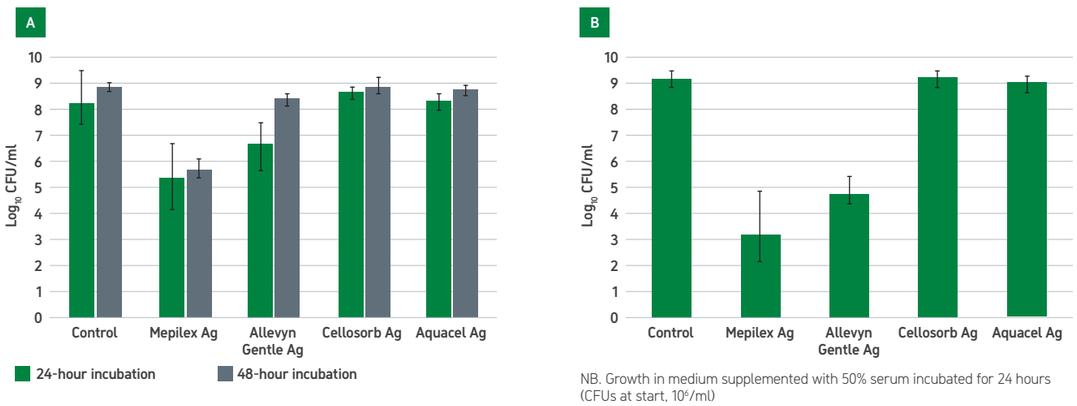


Figure 2. Viable counts of microorganisms (A) under wound contact layers alone, (B) under wound contact layers in combination with a secondary dressing, and (C) isolated from the secondary dressing (Bibic & Hamberg, 2014b) NB. Initial microbial load was 6 log_{10} colony forming unit (CFU)/sample and detection limit was 2 log_{10} CFU/ml agar.

Biofilms

From a clinician's viewpoint, it is important to establish whether an antimicrobial dressing can manage bioburden. Mepilex Ag and other silver-containing dressings were tested in a simulated wound infection model (biofilm bacteria aggregated in a collagen gel matrix with serum protein), mimicking the chronic wound bed. **Mepilex Ag** outperformed the other dressings in terms of activity against planktonic and biofilm cultures of *Pseudomonas aeruginosa*, and was associated with greater than 3.0 log_{10} reductions in the number of viable cells of test organisms after 24 hours' incubation in both the biofilm (**Figure 3A**) and planktonic cultures (**Figure 3B**) (Werthen et al, 2010).



NB. Growth in medium supplemented with 50% serum incubated for 24 hours (CFUs at start, 10^6/ml)

Figure 3. Effect of silver-containing dressings on (A) established *Pseudomonas aeruginosa* biofilms in collagen/serum matrices and (B) on a planktonic growing culture of *Pseudomonas aeruginosa* (Werthen et al, 2010) CFU = colony forming unit)

In a subsequent series of tests, Mepilex Ag not only exhibited antimicrobial action but also did not stick to and damage the culture substrate. In agar plate and two-compartment models, the silver-containing foam dressing and the comparator (silver-containing fibre) dressing were associated with similar reductions in viable cells of planktonic species (compared with the original inoculation concentration) and considerable reductions compared with the cultured control. In a biofilm model, Mepilex Ag reduced the number of viable cells by 3 log_{10} while no reduction was observed with a comparator fibre dressing (Werthen et al, 2012a). These results are consistent with the findings of another series of *in vitro* and *in vivo* studies that compared either Mepilex Ag or Mepilex Border Ag to a nanocrystalline silver-containing dressing. A two-compartment model and a biofilm model showed that Mepilex Ag and the nanocrystalline silver-containing dressing performed equally well at reducing planktonic and biofilm cultures of *Pseudomonas aeruginosa*. Utilising a pig model, full thickness wounds had a nanocrystalline silver-containing dressing, Mepilex Border Ag or a non-silver control dressing applied. Wound healing was slightly slower in the wounds that had nanocrystalline silver-containing dressings applied, compared to those dressed with Mepilex Border Ag or the control product. At day 15, all the wounds treated with Mepilex Border Ag and the control product had 100% epithelial cover compared to 60% cover in those that had nanocrystalline silver-containing dressings applied (Werthen et al, 2012b).

Due to reduced rates of metabolism and protection (against antimicrobial agents and the immune response) afforded by the matrix of extracellular polymeric substances (EPS) (Percival, 2015), biofilms are associated with persistent wound colonisation and an increased risk of systemic infection, a complication that may delay wound healing. Consequently, it is important to determine the effectiveness of antimicrobial dressings against bacteria growing as biofilms. With this in mind, a series of laboratory experiments were performed in order to determine the ability of antimicrobial dressings (including Mepilex Ag), two non-antimicrobial dressings and acetic acid (used successfully to treat burn wounds infected or heavily colonised with *Pseudomonas aeruginosa*), to prevent isolates of *Pseudomonas aeruginosa (PS_PA01* and *PS_1586)* and *Acinetobacter baumannii (ACI_AYE* and *ACI_721)* forming biofilms. A crystal violet biofilm formation assay was used to assess the ability to prevent biofilm formation. There was a large variation in their ability to reduce biofilm, ranging from an increase of 33% with a honey-containing dressing to a decrease of 100% with Mepilex Ag for PS_PA01 and ACI_721). After a 72-hour incubation with Mepilex Ag, all four isolates exhibited a 95-100% reduction in biofilm formation ($p<0.05$) compared with the positive control (Halstead et al, 2015).

Wounds, particularly those of a chronic nature, are commonly colonised by a variety of microbial species, either as planktonic bacteria or as a biofilm phenotype. There are suggestions that microbial interaction between different bacterial species may result in an enhanced pathogenic effect which can be detrimental to the wound healing process. Studies of bacterial profiles in chronic wounds have identified the most frequently isolated bacteria are *Staphylococcus aureus, Enterococcus faecalis, Pseudomonas aeruginosa* and *Coagulase-Negative Staphylococci* (Gjodsbol et al, 2006; Puca et al, 2021). Consequently, mixed infections may require antimicrobial agents that are effective against all bacterial components of the infection. It would therefore seem prudent to use silver-containing dressings that are effective against both Gram-positive and Gram-negative bacteria, with a proven high degree of silver release and rapid bactericidal activity. Based on the results of the laboratory studies mentioned above, silver-containing dressings with Safetac would appear to fulfil these criteria.

Clinical studies

Numerous clinical studies have been conducted to evaluate the use of silver-containing dressings in the management of different wound types when topical antimicrobial therapy was indicated. Key studies involving multiple wound types are summarised in **Table 3.**

Table 3. Mixed wound types - dressings with Safetac - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Truchetet et al, 2012 Observational prospective clinical study France	**Subjects:** 794 (age range 37-86 years) **Wounds:** Leg ulcers, foot ulcers, pressure injuries, oncology wounds, burns, traumatic and surgical wounds **Setting:** Community care	**Safetac:** Mepilex Ag [Patients followed for median 19 days]	Wound status Peri-wound status Local signs of infection	Good wound healing response: - All wounds: 17% healed; 73% improved Reduction in frequency of erythema: 74% at baseline; 52% at final visit. Reduction in mean number of local signs of infection ($p<0.001$): - All wounds: 2.3 (Baseline: 3.7)

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
McCarty et al, 2013 Observational prospective clinical study Multiple countries (n=9)	**Subjects:** 307 (age range 5-108 years) **Wounds:** Leg ulcers (n=160), pressure injuries (n=41), foot ulcers (n=11), surgical wounds (n=42), traumatic wounds (n=25), burns (n=17), oncology-related wounds (n=3) and other (n=8) **Setting**: Not specified	**Safetac:** Mepilex Border Ag [Patients followed for median 22 days]	Local signs of infection Wound size Pain severity scores (measured using VAS 0-10) Dressing-related trauma	Reduction in number of wounds with local signs of infection from baseline to final visit. 28.5% and 35% reduction in wound area and volume respectively (p<0.05): - Area (cm^2): baseline 36.05 vs. 25.87 final visit - Depth (mm): baseline 4.71 vs. final visit 3.06 Reduction in mean pain severity from baseline to final visit (p<0.0001): - During wear: baseline 2.19 vs. final visit 0.88 - During removal: baseline 2.22 vs. final visit 0.86 - After removal: baseline 1.66 vs. final visit 0.63 Increase in percentage of wounds / peri-wound regions without trauma from baseline to final visit: - Wound: baseline 86.99% vs. final visit 92.81% - Peri-wound: baseline 83.56% vs. final visit 89.04%
Durante, 2008 Observational prospective clinical study Italy	**Subjects:** 24 (age range 58-99 years) **Wounds:** Foot ulcers (n=3), leg ulcers (n=14), pressure injuries (n=2), other (n=5) **Setting:** Military hospital	**Safetac:** Mepilex Ag [Patients followed for up to 4 weeks]	Wound size Pain severity Wound bioburden (microbiological swabs)	Mean reduction in wound size of 50% from baseline to final assessment (approximately 30 days). Reduction in pain severity from baseline to final visit; 20.8% and 62.5% of patients with high and moderate pain at baseline vs. 0% and 31.8% at final visit. Reduced bacterial burden from baseline to final visit.
Meuleneire, 2008 Observational prospective clinical study Belgium	**Subjects:** 30 (age range 29-91 years) **Wounds:** Foot ulcers, leg ulcers, pressure injuries, burns, surgical wounds, traumatic wounds **Setting:** Outpatient wound care centre	**Safetac:** Mepilex Ag [Patients followed for up to 4 weeks]	Local signs of infection Wound status Pain severity before and during dressin change (measured using VAS ranging from 0-10)	Eradication of local signs of infection in 90% of wounds. Proportion of wounds healed or almost healed at end of study period (4 weeks) was 53% and 27%, respectively. Pain severity (median) before and during dressing change was lower at the first and final dressing change compared to baseline (p<0.0001): - Before dressing change: Baseline: 6.5 First dressing change: 4 Final dressing change: 0 - During dressing change: Baseline: 6 First dressing change: 3 Final dressing change: 0

Abbreviation: VAS 0-10 = visual analogue scale ranging from 0 (no pain) to 10 (worst pain imaginable)

A prospectively undertaken observational study in France examined the use of Mepilex Ag on patients (n=794) with a wide array of **chronic and acute wound types** managed in the community setting. At the baseline visit, the mean number of local signs of infection was 3.5. At the end of the study period, the number had decreased by 2.3 across all wound types (p<0.001). Good wound healing progression was observed with 90% of wounds healed or improved (Truchetet et al, 2012).

McCarty et al reported on an observational study conducted prospectively across nine countries to evaluate the performance of Mepilex Border Ag. In total, the wounds (a variety of **acute and chronic wound types**) of 307 patients were evaluated. Compared to the baseline assessment, the number of wounds exhibiting local signs of infection were reduced at the final visit (**Figure 4**). Statistically significant decreases in wound area (28.5%) and depth (35.0%) between baseline and final visit were recorded (p<0.05). Pain severity during dressing wear, at removal and after removal was also significantly lower at the final visit, relative to baseline (p<0.0001), with a concomitant increase in the proportion of trauma-free wounds and peri-wound regions (McCarty et al, 2013).

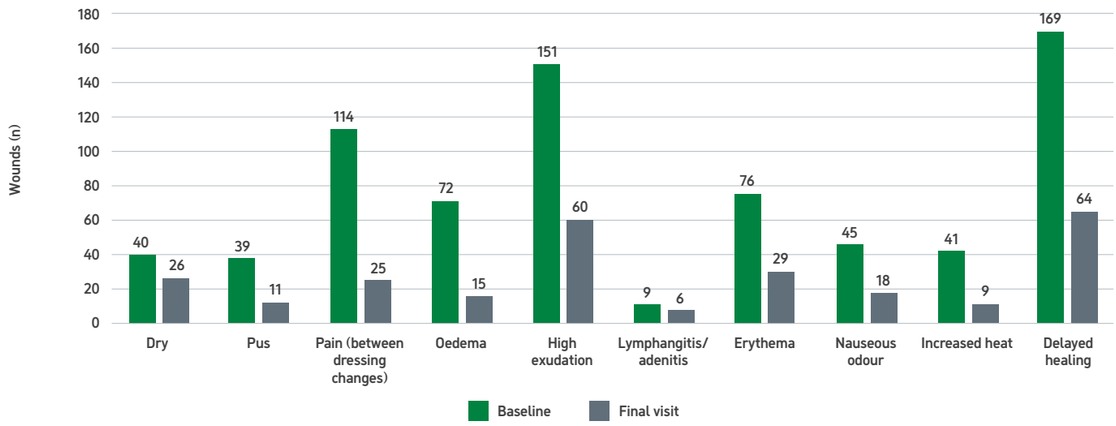


Figure 4. Number of local signs of infection at baseline and final visit in wounds dressed with Mepilex Border Ag (McCarty et al, 2013)

The use of a dressing regime involving the use of Mepilex Ag over a four-week period in the management of 24 patients with infected, chronic wounds (**leg ulcers**, **foot ulcers** and **pressure injuries**) was evaluated in an observational study undertaken in Italy. Dressings were changed twice weekly, with more frequent changes undertaken for highly exuding wounds. Wounds were swabbed at the first visit, and after 15 days and 30 days. At the end of the study period, two wounds had completely healed with another eight showing signs of improvement. The mean reduction in wound size from baseline to day 30 was 50%. A reduction in the number of patients experiencing pain was also observed (50% of patients had low levels of pain or no pain at the end of the study period). Microbiological analysis of the swab cultures indicated a reduction in the levels of common wound pathogens (Durante, 2008).

In an observational study undertaken at a wound care centre in Belgium, 30 patients with **acute and chronic wounds** exhibiting clinical signs of localised infection received Mepilex Ag dressings for up to four weeks. At the end of the study period, the clinical signs of infection had been eradicated in 90% of the wounds, while 53% of the wounds had healed and 27% almost healed. The dressings were rated as 'excellent' or 'very good' in 77% of the investigators' evaluations and in 82% of the patients' evaluations (Meuleneire, 2008).

Key studies involving the use of silver-containing dressings with Safetac on leg and foot ulcers are summarised in **Table 4**.

Table 4. Lower limb ulcers - dressings with Safetac - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Schumann et al, 2007 Observational prospective clinical study Germany / Sweden	**Subjects:** 18 (age not specified) **Wounds:** Leg ulcers **Setting:** Specialist wound care centres (in- and out-patients)	**Safetac:** Mepilex Ag [Patients followed for up to 4 weeks]	Local signs of infection Wound status Pain severity (measured using VAS 0-100)	Reduction in number of wounds exhibiting inflammation: - Baseline: 16.7% - Final visit: 0% 29.6% reduction in wound size: - Baseline: 6.3 cm^2 - Final visit: 2.9 cm^2 Pain severity during and after dressing changes was low throughout the study (mean values at all visits ≤2).
Kota et al, 2014 Observational retrospective clinical study India	**Subjects:** 170 (adults) **Wounds:** Leg ulcers **Setting:** Vascular surgery facility (out-patient)	**Safetac:** Mepilex Ag [Patients followed for up to 12 weeks]	Time to healing Patient compliance with regimen	Healing response at 4 weeks: - Complete: 24.7% (n=42) - Partial: 62.9% (n=107) 90% compliance rate.
Dhatariya et al, 2016 Observational prospective clinical study United Kingdom	**Subjects:** 24 (age range 38-82 years) **Wounds:** Infected diabetes-related foot ulcers **Setting:** Specialist diabetes care centres (in- and out-patient)	**Safetac:** Mepilex Transfer Ag [Patients followed for up to 4 weeks with additional 12-week follow-up]	Local signs of infection Wound size Peri-wound condition Pain severity (measured using VAS ranging from 0 to 100)	Reduction in signs of infection: - Baseline: >95% of ulcers with 3-5 signs of infection (63.4% of them regarded as moderate to severe) - Follow-up*: >95% of ulcers improved (no signs of infection in 16.7% and only 1 sign of infection in 54.2%) 44% reduction in mean wound size: - Baseline: 3.06 cm^2 - Follow-up*: 1.72 cm^2 Proportion of patients with healthy peri-wound: - Baseline: 25% - Follow-up*: 71% Reduction in mean pain score: - Baseline: 15.8 - Follow-up*: 4.6 * up to 4 weeks

Abbreviations: VAS = visual analogue scale

In a multi-centre study undertaken across centres in Germany and Sweden, the use of Mepilex Ag on 18 patients (in- and out-patients) with **venous leg ulcers** (n=11), **mixed aetiology leg ulcers** (n=4) and **diabetes-related foot ulcers** (n=3) was examined. Dressing changes were undertaken weekly over a four-week period. The number of healthy wounds increased from baseline (n=5) to the final visit (n=9). There was also a reduction in wound size from baseline to final visit of approximately 30%. The proportion of viable wound tissue increased from baseline (75%) to final visit (80%), and the number of patients with highly exuding wounds decreased. A reduction in the number of wounds exhibiting signs of inflammation was also observed. The degree of pain reported was low throughout the study period (Schumann et al, 2007). The 90% compliance rate with the Mepilex Ag dressing regime in a study undertaken in India (Kota et al, 2014) involving patients with **leg ulcers** is another strong indicator of a high level of patient satisfaction with the silver-containing foam dressing.

Similar reductions in clinical signs of infection and good progression towards healing were observed in an observational prospective study undertaken in the United Kingdom in which Mepilex Transfer Ag was applied to infected **diabetes-related foot ulcers** of 24 patients (Dhatariya et al, 2016).

Table 5 summarises a randomised controlled trial (RCT) that was undertaken in the plastic and reconstructive surgery department at a university teaching hospital in the United States of America (USA). Patients with **acute surgical wounds** were randomised to either Mepitel Ag or gauze dressings. Infection rates were low in both groups. There was a non-statistically significant trend toward shorter time to healing in the wounds dressed with the silver-containing wound contact layer. Patients in the Mepitel Ag group had less severe pain than those in the gauze group (p=0.008) (Berard & Lau, 2022).

Table 5. Management of surgical wounds healing by secondary intention - dressings with Safetac - key study

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Berard & Lau, 2022 RCT United States of America	**Subjects:** 25 (average age: 45 years) **Wound type:** Acute wounds from surgical excision of skin and/or subcutaneous tissue **Setting:** Plastic and reconstructive surgery department	**Safetac:** Mepitel Ag (n=15) **Comparator:** Gauze (n=10) Evaluation duration (average): 5-7 weeks	Infection Time to wound closure Pain severity	Low infection rates in both groups: - Mepitel Ag group: 6.7% (n=1) - Gauze group: 10.0% (n=1) Shorter (not significant) mean time to wound closure in Mepitel Ag group: - Mepitel Ag group: 4.4 weeks - Gauze group: 6.0 weeks Significantly lower mean pain severity scores in Mepitel Ag group (p=0.008): - Mepitel Ag group: 1.1 - Gauze group: 2.8

Abbreviations: RCT = randomised controlled trial

A number of RCTs have been undertaken to evaluate the efficacy of Mepilex Ag in the management of burn wounds. These are summarised in Table 6.

Table 6. Management of burn wounds - dressings with Safetac - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Aggarwala et al, 2021 RCT Australia	**Subjects:** 119 (age range 18-65 years) **Wounds:** Partial thickness burns <72 hours post injury (TBSA 0.3-6%) **Setting:** Ambulatory care	**Safetac:** Mepilex Ag (n=35) **Comparators:** Acticoat (n=37); Aquacel Ag (n=27); Biobrane (n=32) Dressings changed every 3 days until healing had occurred (apart from Biobrane which was inspected until re-epithelialisation but not changed)	Time to healing (>95% re-epithelialisation) Cost effectiveness	Shorter mean re-epithelialisation time in the Mepilex Ag group (8.9 days), compared to Acticoat (9.6 days), Aquacel Ag (9.6 days) and Biobrane (10.8 days) groups, but differences not statistically significant. 26% greater number of days to re-epithelialisation in Biobrane group compared to Mepilex Ag group (p<0.01 when adjusted for gender, age, smoking status, burn mechanism, TBSA and first aid frequency). 99%, 71% and 53% probability that Mepilex Ag dominated (less expensive and more effective) Biobrane, Acticoat and Aquacel Ag, respectively.
Karlsson et al, 2019 RCT Sweden	**Subjects:** 58 (age range 1-5 years) **Wounds:** partial thickness scalds <72 hours post injury (TBSA 3-22%) **Setting:** Burn care centre	**Safetac:** Mepilex Ag (n=28) **Comparator**: Porcine xenograft (n=30) **Treatment duration:** Up to 42 days. Dressings changed up to 3 times per week	Time to healing (97% and 100% re-epithelialisation) Dressing usage Pain; infection; length of hospital stay; need for surgery	Shorter 97% re-epithelialisation time (median) in Mepilex Ag group (9 days), compared to xenograft group (15 days) (p=0.004). Shorter 100% re-epithelialisation time (median) in Mepilex Ag group (15 days), compared to xenograft group (20.5 days) (p=0.01). Number of dressing changes and time for dressing changes were lower in the Mepilex Ag group (p=0.03 for both variables), compared to xenograft group. No significant difference between groups in terms of pain, infection, length of hospital stay and need for surgery.

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Gee Kee et al, 2015 RCT	**Subjects:** 96 (age range 0-15 years) **Wounds:** Superficial partial to deep partial thickness burns <72 hours post injury (TBSA ≤10%) **Setting:** ED/paediatric burn care centre	**Safetac:** Mepilex Ag (n=33) Comparators: Acticoat (n=31); Acticoat with Mepitel (n=32) Treatment duration: Up to 14 days. Dressings changed every 3-5 days	Time to healing (≥95% re-epithelialisation)	Median healing time (days): - Mepilex Ag group: 7.0 - Acticoat group: 9.5 - Acticoat with Mepitel group: 10.0 After adjusting for burn depth, healing times were 40% and 33% longer in the Acticoat group and Acticoat with Mepitel group respectively, compared to the Mepilex Ag group (p≤0.01).
			Pain at dressing removal and new application (measured using FLACC and VAS-P scales)	FLACC scores in the Mepilex Ag group were 32% lower at dressing removal (p=0.01) and 37% lower at new dressing application (p=0.04) compared to the Acticoat group; scores in the Acticoat with Mepitel group were 23% lower at dressing removal (p=0.04) and 40% lower at new dressing application (p<0.01), compared to the Acticoat group. VAS-P scores in the Mepilex Ag group were 25% lower at dressing removal (p=0.04) and 34% lower in the Acticoat with Mepitel group (p=0.02) at new dressing application, compared to the Acticoat group.
Gee Kee et al, 2017 Cost-effectiveness analysis (based on RCT) Australia			Cost-effectiveness	Median costs (dressings, analgesics, scar management) were lower in the Mepilex Ag group (AU$94.45) compared to the Acticoat (AU$244.90) and Acticoat with Mepitel (AU$196.66) groups. 99% and 97% probability that Mepilex Ag dominated (less expensive and more effective than) Acticoat and Acticoat with Mepitel, respectively.
Tang et al, 2015 RCT China	**Subjects:** 153 (age range 5-65 years) **Wounds:** Deep partial thickness thermal burns <36 hours post injury (TBSA 2.5-25%) **Setting:** Burn care centre	**Safetac:** Mepilex Ag (n=71) **Comparator:** SSD cream (n=82) **Treatment duration:** Up to 14 days. Dressings changed every 5-7 days	Time to healing (>95% re-epithelialisation)	No significant difference in healing rates between groups: - Mepilex Ag group: n=56 healed (79%); median healing time 15 days - SSD group: n=65 healed (79%); median healing time 16 days
			Dressing usage	Mean total number of dressings used was lower in the Mepilex Ag group (3.1), compared to the SSD group (14.0) (p<0.0001). Mepilex Ag was rated higher than SSD by clinicians in terms of ease of application, lack of dressing adherence, ease of removal and overall experience (p<0.0001). Mepilex Ag was rated higher than SSD by patients in terms of experience of anxiety during dressing change, ease of movement while wearing it, ability to remain in place and lack of stinging/burning while wearing it (p<0.0001).
			Pain severity scores (measured using VAS)	Pain at dressing change (before, during and after removal) was lower in the Mepilex Ag group, compared to the SSD group across all visits (p≤0.0254).
Silverstein et al, 2011 RCT United States of America	**Subjects:** 100 (age range 8-88 years) **Wounds:** Partial thickness burns <36 hours post injury (TBSA 2.5-20%) **Setting:** Burn care centres	**Safetac:** Mepilex Ag (n=49) **Comparator:** SSD cream (n=51) **Treatment duration:** Up to 21 days. Dressings changed every 1-7 days	Time to discharge from inpatient hospital care	Mean time to hospital discharge (days) was shorter in the Mepilex Ag group (p=0.034): - Mepilex Ag group: 5.6 - SSD group: 8.3
			Healing time	No significant difference in mean healing times (days) between groups: - Mepilex Ag group: 13.4 - SSD group: 17.1
			Pain severity scores (measured using VAS)	Pain intensity was lower in the Mepilex Ag group at dressing application (p=0.018), during wear (p=0.048) and on removal (p=0.097), compared to the SSD group.
			Dressing usage	Mepilex Ag was rated higher than SSD in terms of ease of use (p=0.0028) and flexibility (p=0.0038).
			Treatment costs	Total cost of treatment per patient: - Mepilex Ag group: US$309 - SSD group: US$514.

Abbreviations: AU$ = Australian Dollars; ED = emergency department; FLACC = face, legs, activity, cry, consolability; RCT = randomised controlled trial; SSD = silver sulphadiazine; US$ = United States Dollars; TBSA = total body surface area; VAS = visual analogue scale; VAS-P = Visual Analogue Scale-Pain

In several of the RCTs summarised in **Table 6**, healing time was found to be significantly shorter in burns dressed with Mepilex Ag, compared to those receiving other interventions. For example, in the earlier of the two RCTs undertaken in Australia, it was observed that **superficial partial to deep partial thickness burns** dressed with Mepilex Ag had the quickest time to re-epithelialisation (median 7.0 days), with a nanocrystalline silver-containing dressing associated with a 40% increase in expected days to full re-epithelialisation (p<0.01) (Gee Kee et al, 2015). **Partial thickness scalds** dressed with Mepilex Ag had a significantly shorter median time to complete healing (15 days) than those that had a xenograft applied (20.5 days) in the RCT conducted in Sweden (p<0.001) (Karlsson et al, 2019).

Several RCTs observed significantly lower pain severity scores in burn patients managed with silver-containing dressings with Safetac relative to the comparator dressings. For example, differences in pain intensity, in favour of Mepilex Ag compared to SSD, were noted by Silverstein and colleagues at dressing application (p=0.018), during wear (p=0.048) and on removal (p=0.097) in patients with **partial thickness burns**. The trend in pain reduction at dressing change was associated with a significant difference in the average weekly costs of pain medication (p=0.031). Background pain analgesia was lower in the silver-containing dressing with Safetac group compared to the SSD group (Silverstein et al, 2011).

In an RCT undertaken in China involving patients with **deep partial thickness burns**, Tang and colleagues observed a significant difference in the mean visual analogue scale (VAS) pain score between Mepilex Ag and SSD before (11.7 vs. 23.9), during (19.4 vs. 40.1) and after dressing removal (17.3 vs. 44.3) (p<0.0001) during the first week of the study. The silver-containing dressing with Safetac was also associated with significantly lower mean pain scores than SSD before (6.8 vs. 11.0; p=0.0081), during (9.3 vs. 19.1; p=0.0050) and after dressing removal (9.4 vs. 15.8) at the final study assessment (p=0.0013) (Tang et al, 2015). Gee Kee and colleagues reported 25% lower expected Visual Analog Scale-Pain (VAS-P) scores after dressing removal in the Mepilex Ag group, compared to the group managed with nanocrystalline silver-containing dressings (p=0.04). In the same study, expected FLACC (Face, Legs, Activity, Cry, Consolability) scores were 32% lower at dressing removal (p=0.01) and 37% lower at new dressing application (p=0.04) in the silver-containing dressing with Safetac group, relative to the group managed with nanocrystalline silver-containing dressings (Gee Kee et al, 2015).

An economic analysis of the RCT that compared four dressing types for the management of **partial thickness burns** demonstrated that there was a 99%, 71% and 53% probability that Mepilex Ag dominated Biobrane, Acticoat and Aquacel Ag, respectively (i.e. the silver-containing foam dressing with Safetac was found to be the most cost-effective dressing overall) (Aggarwala et al, 2020).

Gee Kee and colleagues conducted a cost-effectiveness analysis of the data generated from their RCT (Gee Kee et al, 2015). They identified that the costs (in Australian Dollars) of dressings, labour, analgesics and scar management were considerably lower in the Mepilex Ag group (median AU$94.45) compared to the Acticoat (median AU$244.90) and Acticoat with Mepitel (median AU$196.66) dressing regimes. There was a 99% and 97% probability that the silver-containing foam dressing with Safetac dominated (i.e. less

expensive and more effective than) Acticoat and Acticoat with Mepitel, respectively. This pattern was consistent across raw cost and effects, after a priori adjustments, and sensitivity analyses (Gee Kee et al, 2017).

In the RCT undertaken by Silverstein and colleagues in the USA, the cost of pain medication in the Mepilex Ag group was substantially less than in the SSD group (**Figure 5**). Furthermore, the mean total cost of wound management per patient was calculated at US$309 for the silver-containing Safetac dressing group and US$514 for the SSD group (p<0.001) (**Figure 6**). The average cost of the dressings per burn healed was US$395 USD in the silver-containing Safetac dressing group compared with US$776 in the SSD group, i.e. a net saving per burn healed of US$381 USD with a protocol of care using the silver-containing Safetac dressing instead of SSD. The incremental cost-effectiveness ratio was calculated to be -US$1688 in favour of the silver-containing dressing with Safetac protocol (Silverstein et al, 2011).

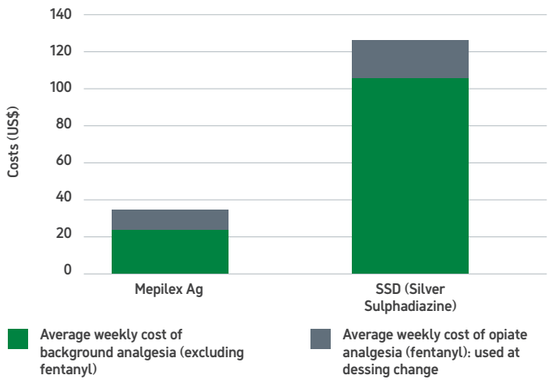


Figure 5. Cost comparison of pain medication for patients with partial thickness burns managed with Mepilex Ag or silver sulphadiazine (Silverstein et al, 2011)

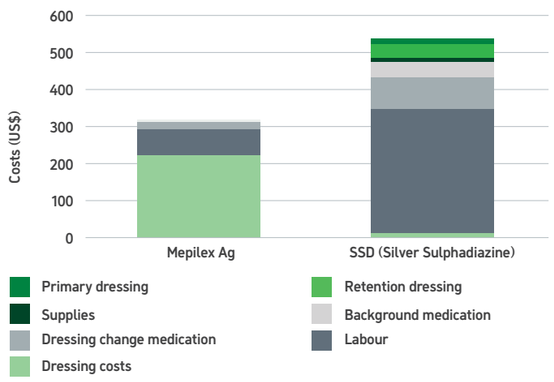


Figure 6. Breakdown of average cost per patient with partial thickness burn with Mepilex Ag or silver sulphadiazine (Silverstein, et al, 2011)

References

Aggarwala, S., Harish, V., Roberts, S. Brady, M., Lajevardi, S., Doherty, J., D'Souza, M., Haertsch, P., Matiz, P.K.M., Issler-Fisher, A.C. (2021) Treatment of partial thickness burns: a prospective, randomised controlled trial comparing four routinely used burns dressings in an ambulatory care setting Journal of Burn Care and Research 42(5):934-943.

Berard, M.B., Lau, F.H. (2022) Pilot study of minimally adherent silver dressings for acute surgical wounds. Health Science Reports 5(6):e865.

Bibic, A., Hamberg, K. (2014a) Antimicrobial effect of a new silver-containing soft silicone exudate transfer dressing against common wound pathogens in vitro. Poster presentation at the Symposium on Advanced Wound Care (Spring), Orlando, Florida, United States of America.

Bibic, A., Hamberg, K. (2014b) In-vitro evaluation of the antimicrobial effect of silver-containing wound contact layers in combination with a secondary dressing. Poster presentation at the Symposium on Advanced Wound Care (Spring), Orlando, Florida, United States of America.

Bowler, P.G. (2003) The 10(5) bacterial growth guidance: reassessing its clinical relevance in wound healing. Ostomy Wound Management 49(1):44-53.

Bowler, P.G., Duerden, B.L., Armstrong, D.G. (2001) Wound microbiology and associated approaches to wound management. Clinical Microbiology Reviews 14(2):244-269.

Brown, S.P., Cornforth, D.M., Mideo, N. (2012) Evolution of virulence in opportunistic pathogens: generalism, plasticity, and control. Trends in Microbiology 20(7):336-342.

Chadwick, P., Taherinejad, F., Hamberg, K., Waring, M. (2009) Clinical and scientific data on a silver-containing soft-silicone foam dressing: an overview. Journal of Wound Care 18(11):483-491.

Cooper, R.A. (2007) Iodine revisited. International Wound Journal 4(2):124-137.

Cutting, K.F., White, R., Mahoney, P. (2012) Wound infection, dressings and pain: is there a relationship in the chronic wound? International Wound Journal 10(1):79-86.

Dhatariya, K., Gooday, C., Franke, B., Pilling, T., Flanagan, A., Zeidan, L. (2016) An open, non-comparative, multi-centre evaluation of performance and safety using an antimicrobial exudate transfer dressing on diabetic foot ulcers: a case series. Journal of Wound Care 25(5):256-265.

Durante, CM. (2008) Chronic wounds and local malpractice: an antimicrobial silver soft silicone foam can help in solving the problem. Poster presentation at the 3rd Congress of the World Union of Wound Healing Societies, Toronto, Canada.

Fletcher, J., Atkin, L., Edwards-Jones, V., Milne, J., Murray, S., Ousey, K., Sharpe, A., Acton, C. (2021) Best Practice Statement: Use of silver dressings in wound care. Wounds UK, London, United Kingdom.

Gee Kee, E.L., Kimble, R.M., Cuttle, L., Khan, A., Stockton, K.A. (2015) Randomized controlled trial of three burns dressings for partial thickness burns in children. Burns 41(5):946-955.

Gee Kee, E., Stockton, K., Kimble, R.M., Cuttle, L., McPhail, S.M. (2017) Cost-effectiveness of silver dressings for paediatric partial thickness burns: An economic evaluation from a randomized controlled trial. Burns 43(4):724-732.

Gjodsbol, K., Christensen, J.J., Karlsmark, T., Jorgensen, B., Klein, B.M., Krogfelt, K.A. (2006) Multiple bacteria species reside in chronic wounds: a longitudinal study. International Wound Journal 3(3):225-231.

Gunasekaran, T., Nigusse, T., Dhanaraju, M.D. (2012) Silver nanoparticles as real topical bullets for wound healing. Journal of the American College of Wound Specialists 3(4):82-86.

Halstead, F.D., Rauf, M., Bamford, A., Wearn, C.M., Bishop, J.R.B., Burt, R., Fraise, A.P., Moiemen, N., Oppenheim, B.A., Webber, M.A. (2015) Antimicrobial dressings. Comparison of the ability of a panel of dressings to prevent biofilm formation by key burn wound pathogens. 41(8):1683-1694.

Hamberg, K., Jakobsen, C., Taherinejad, F., Kaszony, G. (2012) Correlation of silver release and antimicrobial effect of silver-containing wound dressing in vitro. Poster presentation at the 22nd European Tissue Repair Society Meeting, Athens, Greece.

International Wound Infection Institute (2022) Wound Infection in Clinical Practice. Wounds International, London, United Kingdom.

James, G.A., Swogger, E., Wolcott, R., Pulcini, E., Secor, P., Sestrich, J., Costerton, J.W., Stewart, P.S. (2008) Biofilms in chronic wounds. Wound Repair and Regeneration 16(1):37-44.

Jiang, Y., Zhang, Q., Wang, H., Valmaki, M., Zhou, Q., Dai, W., Guo, J. (2024) Effectiveness of silver and iodine dressings on wound healing: a systematic review and meta-analysis. British Medical Journal Open 14(8):e077902.

Karlsson, M., Elmasry, M., Steinvall, I., Sjöberg, F., Olofsson, P., Thorfinn, J. (2019) Superiority of silver-foam over porcine xenograft dressings for treatment of scalds in children: A prospective randomised controlled trial. Burns 45(6):1401-1409.

Kingsley, A. (2003) The wound infection continuum and its application in clinical practice. Ostomy Wound Management 49(7 Supplement A):1-7.

Kota, A.A., Selvaraj, A.D., Premkumar, P., Ponraj, S., Agarwal, S. (2014) Four layer dressing in the management of chronic venous ulcers in the outpatient setting of a tertiary hospital in India. Wound Medicine 5:21-24.

Lansdown, A.B., Mirastschjiski, U., Stubbs, N., Scanlon, E., Agren, M.S. (2007) Zinc in wound healing: theoretical, experimental, and clinical aspects. Wound Repair and Regeneration 15(1):2-16.

Leaper, D., Ayello, E.A., Carville, K., Fletcher, J., Keast, D., Lindholm, C., Lazaro-Martinez, J.L., Mavanini, S., McBain, A., Moore, Z., Opadanon, S., Pina, E. (2012) International consensus. Appropriate use of silver dressings in wounds. An expert working group document. Wounds International, London, United Kingdom.

Maheswary, T., Nurul, A.A., Fauzi, M.B. (2021) The insights of microbes' roles in wound healing: a comprehensive review. Pharmaceutics 13(7):981.

Malone, M., Bjarnsholt, T., McBain, A.J., James, G.A., Stoodley, P., Leaper, D., Tachi, M., Schulz, G., Swanson, T., Wolcott, R.D. (2017) The prevalence of biofilms in chronic wounds: a systematic review and meta-analysis of published data. Journal of Wound Care 26(1):20-25.

McCarty, S., Davies, P., Rippon, M. (2013) Mepilex Border Ag: an in-market evaluation. Poster presentation at the Wounds UK Conference, Harrogate, United Kingdom.

Meuleneire, F. (2008) An observational study of the use of a soft silicone silver dressing on a variety of wound types. Journal of Wound Care 17(12):535-539.

Morris, D., Ansar, M., Speshock, J., Ivanciuc, T., Qu, Y., Casola, A., Garofalo, R. (2019) Antiviral and immunomodulatory activity of silver nanoparticles in experimental RSV infection. Viruses 11(8):732.

Mussin, J., Giusiano, G. (2022) Biogenic silver nanoparticles as antifungal agents. Frontiers in Chemistry 10:1023542.

Nair, H.K.R., Mrozikiewicz-Rakowska, B., Pinto, D.S., Stuerner, E.K., Matiasek, J., Sander, J., Lazaro-Martinez, J.L., Ousey, K., Assadian, O., Kim, P.J., Percival, S.L. (2023) International Consensus Document: Use of wound antiseptics in practice. Wounds International, London, United Kingdom.

Parsons, D., Bowler, P.G., Myles, V., Jones, S. (2005) Silver antimicrobial dressings in wound management: a comparison of antibacterial, physical and chemical characteristics. Wounds 17(8):222-232.

Percival, S.L., McCarty, S.M., Lipsky, B. (2015) Biofilms and wounds: an overview of the evidence. Advances in Wound Care 4(7):373-381.

Peterson, L.R. (2008) Currently available antimicrobial agents and their potential for use as monotherapy. Clinical Microbiology and Infection 14(6 Supplement):30-45.

Peterson, L.R., Shanholtzer, C.J. (1992) Tests for bactericidal effects of antimicrobial agents: technical performance and clinical relevance. Clinical Microbiology Reviews 5(4):420-432.

Puca, V., Marulli, R.Z., Grande, R., Vitale, I., Niro, A., Molinaro, G., Prezioso, S., Muraro, R., Di Giovanni, P. (2021) Microbial species isolated from infected wounds and antimicrobial resistance analysis: data emerging from a three-years retrospective study. Antibiotics (Basel) 10(1):1162.

Rippon, M., Davies, P., White, R. (2012) Taking the trauma out of wound care: the importance of undisturbed healing. Journal of Wound Care 21(8):359-368.

Roberts, C.D., Leaper, D.J., Assadian, O. (2017) The role of topical antiseptic agents within antimicrobial stewardship strategies for prevention and treatment of surgical site and chronic open wound infection. Advances in Wound Care (New Rochelle) 6(2):63-71.

Scepankova, H., Combarros-Fuertes, P., Fresno, J.M., Tornadijo, M.E., Dias, M.S., Pinto, C.A., Saraiva, J.A., Estevinho, L.M. (2021) Role of honey in advanced wound care. Molecules 26(16):4784.

Schumann, H., Apelqvist, J., Schmidtchen, A., Hansson, C. (2007) Open, non-comparative, multicentre investigation exploring the tolerance of an absorbent foam dressing containing silver used in chronic wounds. Poster presentation at the European Wound Management Association Conference, Glasgow, United Kingdom.

Silverstein, P., Heimbach, D., Meites, H., Latenser, B., Mozingo, D., Mullins, F., Garner, W., Turkowski, J., Shupp, J., Glat, P., Purdue, G. (2011) 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. Journal of Burn Care and Research 32(6):617-626.

Tang, H., Lv, G., Fu, J., Niu, X., Li, Y., Zhang, M., Zhang, G., Hu, D., Chen, X., Lei, J., Qi, H., Xia, Z. (2015) An open, parallel, randomized, comparative, multicenter investigation evaluating the efficacy and tolerability of Mepilex Ag versus silver sulphadiazine in the treatment of deep partial-thickness burn injuries. Journal of Trauma and Acute Care Surgery 78(5):1000-1007.

Thomas, S., McCubbin, P. (2003) An in vitro analysis of the antimicrobial properties of 10 silver-containing dressings. Journal of Wound Care 12(8):305-308.

Truchetet, F., Guibon, O., Meaume, S. (2012) Clinicians' rationale for using a sliver dressing: the French OMAg+E observational study. Journal of Wound Care 21(12): 620-625.

Walker, M., Parsons, D. (2012) The biological fate of silver ions following the use of silver-containing wound care products – a review. International Wound Journal 11(5):496-504.

Werthén, M., Taherinejad, F., Gerner, E.. (2012a) In vitro study of silver-containing wound dressings - adhesion, fluid handling and antimicrobial effect. Poster presentation at the European Wound Management Association Conference, Vienna, Austria.

Werthén, M., Taherinejad, F., Gerner, E.. (2012b) Pre-clinical comparison of silver-containing wound dressings: wound healing, antimicrobial efficacy, sticking and staining. Poster presentation at the European Wound Management Association Conference, Vienna, Austria.

Werthen, M., Taherinejad, F., Hamberg, K. (2010) Effect of silver dressings on P. aeruginosa biofilm in an in vitro wound infection model. Poster presentation at the European Wound Management Association Conference, Geneva, Switzerland.

World Union of Wound Healing Societies (2016) Florence Congress, Position Document. Management of biofilm. Wounds International. London, United Kingdom.

Concluding Remarks

Taking into consideration peer-reviewed journal articles, published conference abstracts and conference posters, there are now in the region of **1000 'evidence pieces'** in support of dressings with Safetac® in the public domain. The evidence describes the use of Safetac technology in the management of a **diverse range of wound types** across the **full spectrum of ages**, including children.

Prior to the introduction of dressings with Safetac, clinicians were limited in what they could do to prevent the debilitating trauma and pain associated with the application and removal of wound dressings. Now they have access to **advanced dressings that can make the dressing change a far less stressful time for patients**.

Dressings with Safetac have also been shown to have excellent exudate handling properties. This, along with others demonstrated in the reported studies, contribute to providing environments that are conducive to wound healing, as well as having a positive effect on the quality of life of patients and their carers.

More recently, dressings with Safetac have been extensively researched and subsequently implemented into regimes aimed at preventing pressure injury, reducing the risk of surgical site complications, and significantly reducing the risk of radiotherapy-induced skin damage.

As well as highlighting the clinical challenges that dressings with Safetac can address, the published literature includes substantial health economic data demonstrating the cost-effectiveness of dressings with Safetac in numerous applications.

Safetac is not the only silicone-based technology used in wound dressing design. However, anyone undertaking a literature review on silicone-based dressings will quickly realise that the vast majority of research data in the public domain relates specifically to dressings with Safetac. In a number of studies (pre-clinical and clinical) described in this publication, some differences between dressings with Safetac and other commercially available silicone-based dressings were observed. Therefore, the evidence in support of dressings with Safetac 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. This should be carefully considered by clinicians when selecting dressings.

It is hoped that this document will convince readers of the value that dressings with Safetac offer to those involved in the procurement and delivery of wound management and prevention.

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