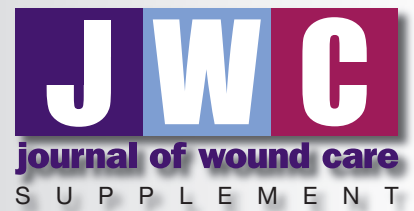




Evidence review:

the clinical benefits of Safetac[®] technology
in wound care





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Editor

Tom Pollard

Designer

Louise Cowburn

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The majority of the published articles and posters relating to dressings with Safetac can be viewed at:
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Foreword

The management of pain during wound cleansing, application of wound dressings and especially the removal of wound dressings, is currently high on the agenda within the field of tissue viability. In recent years a number of best practice statements and guidelines to managing wound pain have been produced with international backing.^{1,2,3}

Unresolved pain negatively affects wound healing and has an impact on quality of life.¹ Many personal factors influence the pain experienced including mood, anxiety and pain expectations. Pain is also exacerbated by local wound care factors including dressing removal, wound cleansing, debridement of necrotic tissue, bacterial damage and inappropriate choice of dressing.³

Research has traditionally focused on healing as the major outcome of treatment, with little attention paid to other patient-centred outcomes, such as reducing pain.² The World Union of Wound Healing Societies consensus document³ advises us to evaluate and document pain intensity and characteristics on a regular basis, before, during and after dressing-related procedures. It also advises healthcare professionals to select an appropriate dressing to minimise wound-related pain based on wear time, moisture balance, healing potential and peri-wound maceration, such as dressings with Safetac® technology. An earlier World Union of Wound Healing Societies document¹ provides strategies for pain management and tools for their implementation into clinical practice.

We are all encouraged to implement better practice relating to wound-related pain and to ask (assess/listen), report (communicate and document), act (treat/monitor/evaluate) and improve.

This document focuses on trauma and wound pain caused by the removal of dressings, skin stripping of the peri-wound skin from adhesive dressings and tissue excoriation and maceration. It examines the evidence relating to the impact of Safetac technology on these issues.

Clare Morris
Tissue Viability Advisor, North Wales NHS Trust (East)
United Kingdom

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Evidence review: the clinical benefits of Safetac[®] technology in wound care

Common causes of trauma and wound pain include: the removal of dressings that become stuck to the wound bed; skin stripping of peri-wound skin, as a result of the repeated application and removal of adhesive dressings; and tissue excoriation and maceration of the peri-wound skin, due to inadequate management of wound exudate. This supplement outlines how dressings with Safetac[®] adhesive technology can help clinicians to avoid these problems. A review of the clinical and scientific evidence relating to dressings with Safetac clearly demonstrates that they can be used to prevent trauma and minimise pain on a wide range of wound types and skin injuries.

trauma; skin stripping; pain; maceration; adhesive dressings; soft silicone adhesive technology

Phil Davies, Clinical and Scientific Information Manager
Mark Rippon, Medical Marketing Manager
 Mölnlycke Health Care, Gothenburg, Sweden

When making decisions about clinical interventions, it is common practice to consider the relative weight of the available data according to the type of studies from which they originate. In this so-called hierarchy of clinical evidence (Table 1), the randomised controlled trial (RCT) and systematic reviews of several of these trials, are generally considered to be the ‘gold standards’ for judging the benefits of interventions.^{1,2} Wound care is no different to other clinical disciplines in that systematic reviews of clinical evidence have been undertaken in order to define evidence-based ‘best practice’.^{3,4}

However, some experts—including the Chair of the UK’s National Institute for Health and Clinical Excellence⁵—have begun to question the true value of the evidence hierarchy and the over-reliance on RCTs in decision-making, focusing on their limitations and the practical difficulties in undertaking them, not least in the field of wound care.⁶⁻⁸

Table 1. Hierarchy of clinical evidence

- Systematic reviews and meta-analyses
- Randomised controlled trials
- Cohort studies
- Case-control studies
- Cross-sectional surveys
- Case reports

Gottrup⁷ suggests that the extended definition of evidence-based medicine by Sackett and colleagues⁹ may be more applicable to wound care: ‘evidence-based medicine is not restricted to randomised trials and meta-analyses, but involves exploration of all types of best external evidence with which to answer our clinical question.’

This does not mean that all reports of whatever quality are equally valid, and many of the studies and reports available in wound care do have significant flaws. However, it does mean that all the available evidence can legitimately be considered, and should be evaluated on its own merits.

With this in mind, this document considers data from studies, surveys, case reports and conference posters at all levels of the evidence hierarchy relating to the use of one group of dressings: those using Safetac adhesive technology. It is not a systematic review, as there is not space to critically evaluate every paper, but aims to summarise in one place the available evidence and draw broad conclusions from it.

Taken together, these reports show that dressings with Safetac adhesive technology can be used to overcome a variety of clinical challenges that clinicians have to address when caring for patients with both acute and chronic wounds. In particular, it highlights the fact that dressings with Safetac can be used to successfully minimise trauma and pain in a variety of different wound types, without the need for pharmaceutical interventions and their associated side-effects.



Wound-related trauma and pain

Ever since a possible mechanism for re-epithelialisation under occlusion in the presence or absence of eschar was identified,¹⁰ the concept of healing in a moist environment has shaped the development and use of modern wound-care products. But the ability to provide a moist environment that is conducive to healing is just one of many characteristics that an ‘ideal’ wound dressing or dressing system should possess (Table 2).¹¹

Recent years have seen an increasing awareness of the need 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 that have resulted from international initiatives involving clinicians, researchers, patients and industry.¹²⁻¹⁴

Wound-related trauma and pain are major concerns to both patients and clinicians. The removal of dressings that adhere to the wound bed is a common cause of trauma,¹⁵ as is the epidermal stripping of the skin surrounding wounds that can result from the repeated application and removal of adhesive dressings (Figure 1).¹⁶ Adhesive-induced damage, as a consequence of epidermal stripping, may lead to inflammatory skin reactions, oedema and soreness, which can have a detrimental effect on skin barrier function.¹⁷ If dressings inadequately manage wound exudate or fail to adequately control moisture balance at the wound-dressing interface, the result may be excoriation, irritant dermatitis, and maceration of peri-wound skin.¹⁸ Wound-related trauma can increase the size of wounds, exacerbate wound pain and delay healing,¹⁹ all of which can have cost implications for health-care providers, as well as having an adverse effect on the quality of life of patients.²⁰

Pain is a significant problem with all types of wounds,²¹ contributing to considerable levels of suffering and distress,²² and reduced quality of life.²³ Wound-related pain can also cause psychological stress which may, in turn, delay healing (Box 1).²⁴

Wound-related pain is multidimensional in nature, integrating the experience of chronic wound pain (i.e. the persistent pain that is usually associated with the underlying wound aetiology) with cyclic acute pain (i.e. the periodic pain that is induced by repeated interventions such as recurring dressing changes) and non-cyclic acute pain (i.e. single episode pain arising from procedures such as sharp debridement).^{42,43} Pain can arise from many sources other than the tissue damage itself: it has been reported that infection enhances the severity of wound-related pain,⁴⁴ especially in burns.³⁷ Cellulitis in the peri-wound skin may also enhance sensitivity and pain.⁴⁵

Dressing removal, wound cleansing, debridement of devitalised tissue, and inappropriate dressing selection can all contribute to wound-related pain. It has been demonstrated that dressing removal and wound cleansing are the most painful wound care interventions

Table 2. Characteristics of an ideal dressing or dressing system (adapted from Thomas¹¹)

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

for patients with either acute or chronic wounds.^{15,46}

To emphasise that wound-related pain is a significant problem, a cross-sectional, international survey involving over 2000 patients from 15 countries was recently undertaken to assess their perceptions of wound pain. When asked how frequently they experienced pain at dressing change, over 50% indicated either ‘quite

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, particularly those that result in either acute or chronic tissue damage²⁴
- Wound-related pain, either as a direct result of pathological processes or interventions (e.g. dressing removal), causes stress²⁵
- Stress can cause a number of unwanted effects, including:
 - ◆ Adverse effects on physical health²⁶ and many physiological processes in the body²⁷
 - ◆ Delayed healing in acute wounds^{25,28-30} which hypothetically may also be true for chronic wounds²⁴
 - ◆ Immunosuppressive effect³¹⁻³³ resulting in increased infection rates,³⁴⁻³⁶ specifically in burns³⁷
 - ◆ Possible role in the pathology of metabolic disorders related to chronic wounds such as diabetes³⁸ and cardiovascular disease³⁹
 - ◆ Stress has a huge impact on the quality of life of patients, particularly those suffering from chronic wounds^{40,41}

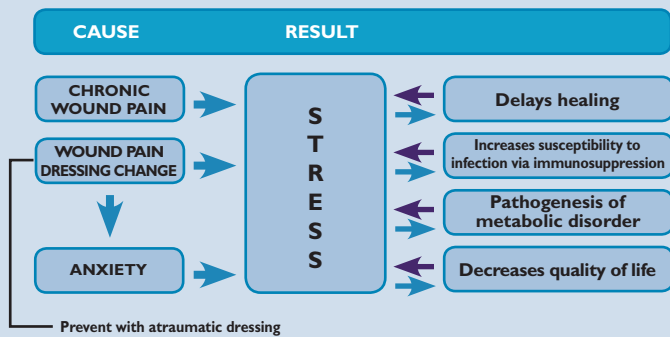




Figure 1. Skin trauma as a result of application and removal of an adherent dressing to the arm of an elderly woman. Photograph courtesy of Pauline Beldon, Epsom and St Helier University Hospital NHS Trust, Carshalton, UK.

often', 'most of the time' or 'all of the time'. Over 40% of those surveyed revealed that pain at dressing change is the worst part of living with a wound, and over 58% of participants expressed concerns about the long-term side-effects of medication. Of particular concern is that over 36% of patients surveyed felt that clinicians in charge of their care could do nothing to help with their pain at dressing change.⁴⁷

These studies exemplify the fact that pain — associated with dressings and/or wounds themselves — needs to be taken into account when treating patients. As all wound types are associated with pain, clinicians should consider the use of atraumatic dressings, as defined in the literature.^{11,48}

Atraumatic dressings with Safetac technology

Although modern wound dressings go a long way to meeting many of the requirements listed in Table 1, it is important to note that alginate, film, foam, hydrocolloid and hydrogel dressings have all been reported to cause pain and tissue trauma during dressing changes.¹⁵ The introduction of an innovative range of dressings utilising

patented Safetac adhesive technology (Table 3) has helped to overcome many of the issues described above.

Safetac adhesive technology involves the use of soft silicone. This material readily adheres to intact dry skin, and will remain in situ on the surface of a moist wound or damaged surrounding skin without adhering to these fragile tissues. Consequently, dressings with Safetac can be applied and re-applied without causing damage to the wound or stripping epidermis in the peri-wound region, as well as minimising pain at dressing removal.¹⁶ The gentle but effective seal that forms between the intact skin and a dressing with Safetac inhibits the movement of exudate from the wound onto the surrounding area, thereby helping to prevent maceration of the peri-wound region.⁴⁸

Table 3 lists the description and indications of dressings with Safetac adhesive technology that are currently available.

Preventing dressing-related trauma

There is substantial evidence to suggest that there is a predisposition for some modern dressings with traditional adhesive systems to inflict damage on delicate wound tissue or frail peri-wound skin.^{15,16,48,92} A challenge for the clinician, therefore, is to select appropriate treatments that minimise or even negate dressing-related trauma. A significant amount of experimental and clinical evidence has been published that has established that dressings with Safetac can prevent trauma, and as a consequence of this, minimise dressing-related pain. Table 4 highlights the key studies that provide evidence in this respect.

Evidence from volunteer studies has shown that trauma related to the removal of adhesive dressings can be reduced or even prevented entirely if more appropriate dressings are used, for example those with Safetac.^{17,133} In these studies (summarised in Table 4), the edges of dressings with traditional adhesives, such as Allevyn Adhesive (Smith & Nephew) (acrylic adhesive), Biatain (Coloplast) (hydrocolloid adhesive border), DuoDerm Extra Thin (ConvaTec) (hydrocolloid adhesive), and Tielle (Johnson & Johnson) (polyurethane adhesive border) were found to be associated with higher peel forces and greater skin damage on removal than those of Mepilex Border (Safetac adhesive). Figure 2 outlines the results of the peel force measurements and skin damage associated with different dressing types reported by Dykes et al.¹⁷

Another method of measuring the potential for dressings to cause trauma involves protein analysis of dressings after removal. In one study, protein analysis was used to estimate the amount of stratum corneum removed by different types of dressings when applied to, and removed from, positions on the posterior lower leg of volunteers every second to third day for a period of 11 days.¹³⁴ Mepilex Border was associated with less corneocyte removal (measured indirectly as protein) compared to the other dressings evaluated (Allevyn

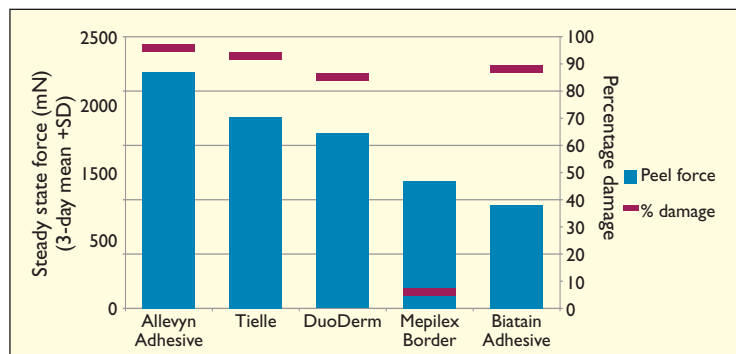


Figure 2. Comparison of adhesive borders of dressings in terms of peel force and skin damage on removal from skin of volunteers.¹⁷

Table 3. Dressings with Safetac adhesive technology

Dressing	Description	Indications
Wound contact layer		
Mepitel®	Porous, semi-transparent wound contact layer consisting of a flexible polyamide net coated with Safetac	Exuding wounds such as burns, ⁴⁹⁻⁵³ skin tears and other acute traumatic wounds, ⁵²⁻⁶² amputation and other surgical wounds, ^{54,59,63-66} and chronic wounds, e.g. leg and foot ulcers ⁶⁷ and oncology wounds. ⁶⁸⁻⁷¹ Can also be utilised for the fixation of skin grafts, ⁷²⁻⁷⁷ in the management of the congenital skin disorder, epidermolysis bullosa (EB), ^{51,78-82} and for the treatment and protection of radiotherapy-induced skin damage. ⁸³⁻⁸⁵ Can be left in place for extended periods (up to 14 days depending on the nature and condition of the wound) allowing the secondary dressing to be changed more frequently as required, thereby minimising disturbance to newly formed tissue. ^{75,77} In addition, the open structure enables topical preparations to be delivered to the wound bed with the dressing in situ. ⁷⁸
Absorbent foam dressings		
Mepilex® Mepilex® Heel	Absorbent foam dressing with vapour-permeable film backing and Safetac wound contact layer	Exuding wounds, including chronic wounds ^{86,87} such as leg ulcers, ^{21,88-92} foot ulcers, ^{21,67,88,93} and pressure ulcers. ^{21,88,94-96} Can be used under compression bandaging in the management of venous leg ulcers. ⁴⁸ Can also be used on acute wounds such as burns, ^{21,53,88,97} amputation and other surgical wounds, ^{21,88,98} skin tears and other traumatic wounds, ^{21,56,88,99} and in the management of EB. ^{80,100,101}
Mepilex® Border	All-in-one island dressing with a perforated Safetac wound contact layer. Absorbent pad has a 3-layer construction to wick and absorb exudate	Exuding wounds, including chronic wounds ^{86,87} such as leg ulcers, ^{21,88-92} foot ulcers, ^{21,67,88,93} and pressure ulcers. ^{21,88,94-96} Can be used under compression bandaging in the management of venous leg ulcers. ⁴⁸ Can also be used on acute wounds such as burns, ^{21,53,88,97} amputation and other surgical wounds, ^{21,88,98} skin tears and other traumatic wounds, ^{21,56,88,99} and in the management of EB. ^{80,100,101}
Mepilex® Lite	Thin dressing comprising an outer polyurethane film, an absorbent layer and a Safetac wound contact layer	Wounds with low-to-moderate levels of exudate where a conformable, thin, and gentle dressing is required, such as leg and foot ulcers, ^{21,102,103} pressure ulcers, ²¹ and burns. ²¹ Can also be used in the management of EB and radiotherapy-induced skin damage. ^{84,104}
Mepilex® Border Lite	Thinner and less absorbent version of Mepilex Border	Low exuding wounds such as leg and foot ulcers, ^{21,105} pressure ulcers, ²¹ burns, ^{21,106} surgical wounds, ^{21,106,107} and traumatic wounds such as blisters and skin tears, ^{21,106} where a conformable, thin, and gentle dressing is required.
Mepilex® Transfer	Thin, conformable dressing with Safetac that conforms closely to the wound and the surrounding skin, even where the surface is uneven	Exuding and difficult-to-dress wounds such as oncology wounds, ^{108,109} donor sites, ¹¹⁰ and leg ulcers. ^{96,111} Can also be used in the management of EB ¹¹² and radiotherapy-induced skin damage. ^{84,85,113}
Absorbent foam dressing with silver		
Mepilex® Ag	Absorbent foam dressing containing silver sulphate, with vapour-permeable film backing and Safetac wound contact layer	Exuding wounds at risk of infection such as leg ulcers, ¹¹⁴⁻¹¹⁸ diabetic foot ulcers, ^{115,117,119} pressure ulcers, ^{66,116,117} surgical wounds, ^{66,120} and burns. ¹²¹
Self-adherent scar dressing		
Mepiform®	Self-adherent dressing for scar management	Old and new hypertrophic and keloid scars. Can also be used as a prophylactic therapy on closed wounds for prevention of hypertrophic or keloid scarring. ¹²²⁻¹³²

**Table 4. Preventing dressing-related trauma – key studies**

Study	Study type	Sample size	Wound type(s)	Safetac dressing	Comparator dressings	Main outcome measures	Main results
Zillmer et al ⁹²	RCT	45	Venous leg ulcers	Mepilex Border	Biatain Adhesive; DuoDerm Extra Thin; Tielle	Effect on peri-ulcer skin: - transepidermal water loss (TEWL) - stratum corneum hydration (electrical conductance)	TEWL and conductance of Mepilex Border-treated peri-wound skin not significantly different from that of non-treated skin Biatain Adhesive and DuoDerm Extra Thin associated with significant (p<0.05) increases in both parameters
Dykes et al ¹⁷	Volunteer study (RDA)	20	N/A	Mepilex Border	Allevyn Adhesive; Biatain Adhesive; DuoDerm Extra Thin; Tielle	Peel force required to remove dressings Damage to stratum corneum on dressing removal	Significant (p<0.05) differences between some dressings. Rank order (from greatest to least peel force): Allevyn Adhesive > Tielle > DuoDerm Extra Thin > Mepilex Border > Biatain Adhesive Rank order (from most to least damaging): Biatain Adhesive > DuoDerm Extra Thin > Allevyn Adhesive > Tielle > Mepilex Border
Dykes ¹³³	Volunteer study (RDA)	30	N/A	Mepilex Border Lite	Allevyn Adhesive; Biatain Adhesive; Comfeel Plus Transparent; DuoDerm Extra Thin; Tielle Plus	Cutaneous irritancy score (CIS) Effect on skin barrier function, measured by TEWL	CIS for Mepilex Border Lite significantly (p<0.05) lower than that for Biatain Adhesive, Comfeel Plus Transparent, and DuoDerm Extra Thin Mepilex Border Lite associated with TEWL values not significantly different to that of normal skin, but significantly (p<0.05) lower than that associated with Biatain Adhesive, Comfeel Plus Transparent, and DuoDerm Extra Thin
Waring et al ¹³⁵	Volunteer study	22	N/A	Mepilex Border	Allevyn Adhesive	Peel force required to remove dressings Pain on removal Cell adhesion to dressings on removal (electron microscopy and protein analysis)	Mepilex Border associated with significantly (p<0.001) less pain on removal Less cellular material and protein deposits attached to Mepilex Border on removal

RCT = Randomised controlled trial; RDA = Randomised dressing allocation

General comment: Three of the four studies presented in this table involved healthy volunteers. It is important to note that, although these studies involved the application of dressings to healthy skin rather than the peri-wound skin of actual patients, they do provide a reproducible and quantitative methodology that allows for a direct and statistical comparison of different dressings to be made. The results of the other study listed, an RCT involving the repeated application of dressings to the skin surrounding venous leg ulcers, reflect the findings of the volunteer studies.

Adhesive, Tielle, Biatain Adhesive, Cellosorb Adhesive (Urgo), DuoDerm Extra Thin).

In a more recent experimental evaluation of the adhesive properties of two modern wound dressings, one with acrylic adhesive (Allevyn Adhesive) and one with Safetac (Mepilex Border), a number of parameters relating to trauma were evaluated.¹³⁵ Dressings were applied contralaterally to the inner forearms of healthy volunteers. Peel forces were measured after 24 and 48 hours of dressing application, and pain severity on

dressing removal was evaluated after 24 hours of application. After removal, the dressings were examined by scanning electron microscopy and subjected to protein analysis. The two dressings were shown to have similar peel forces, but the dressing with acrylic adhesive was associated with a significantly (p<0.001) higher level of pain on removal than the dressing with Safetac. In addition, the analysis of the dressings after removal showed clear differences between them with significantly less cellular material



and protein deposits attached to the dressing with Safetac (Figure 3).

As highlighted in Table 4, a criticism might be levelled that these studies were undertaken on volunteers and therefore do not truly reflect the clinical application of the test dressings. However, the findings of the volunteer studies have proven to be comparable to the results of clinical studies. One study, which took the form of a retrospective review of data collected on patients seen at an out-patient clinic, set out to compare the peri-wound issues of wounds treated with one of two absorbent dressings, Mepilex and Allevyn.⁸⁸ Eighty-seven wounds were treated with Mepilex and 86 with Allevyn. Wound types included arterial ulcers, burns, diabetic foot ulcers, mixed aetiology ulcers, pressure ulcers, surgical wounds, traumatic wounds and venous leg ulcers. Patients treated with Mepilex had fewer peri-wound issues (i.e. dermatitis) (n=6) than those treated with Allevyn (n=11). The review also revealed that Mepilex was associated with a faster healing rate and a longer wear time than Allevyn.

More recently, a randomised controlled study was undertaken to determine the effect of repeated removal of Mepilex Border and three dressings with traditional adhesives (Biatain, DuoDerm Extra Thin, and Tielle) on the peri-ulcer skin of patients with venous leg ulcers, using quantitative non-invasive techniques.^{92,136} In this study, patients with open or healed venous leg ulcers had an area of peri-ulcer skin treated for 14 days with adhesive patches of the dressings that were replaced every second day. Areas of normal skin on the patients' ventral forearms were treated identically. The skin barrier function and stratum corneum hydration were assessed by measuring transepidermal water loss (TEWL) and electrical conductance, respectively. The peri-wound skin treated with dressings utilising hydrocolloid adhesives (Biatain and DuoDerm Extra Thin) was associated with increased TEWL (Figure 4) and conductance while that treated with dressings utilising polyurethane-based adhesive (Tielle) and Safetac (Mepilex Border) was associated with TEWL and conductance comparable to that of adjacent non-treated peri-ulcer skin. Similar effects were observed for the normal forearm skin.

The results of these scientific and clinical studies indicate that, unlike some dressings with traditional adhesives, dressings with Safetac do not induce major functional alterations of the stratum corneum.

Minimising dressing-related pain

In this section, experimental and clinical evidence is presented which demonstrates how dressing-related pain can be minimised with the use of appropriate dressings. Table 5 highlights the key studies relating to this aspect of wound care.

The level of pain experienced on removal of dressings has been investigated in an experimental study involving healthy volunteers. The study investigated the causal

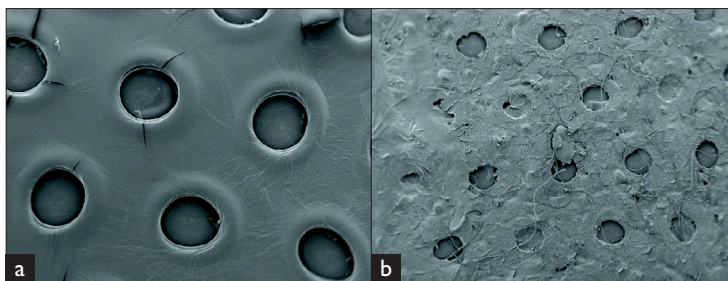


Figure 3. Scanning electron micrograph of: (a) dressing with Safetac after removal (note the lack of epidermal cells on its surface); (b) dressing with acrylic adhesive after removal (note the large number of epidermal cells on its surface).¹³⁵

relationship between the peel force of various adhesive dressings and the subjective discomfort experienced upon their removal, measured using a visual analogue scale (VAS).¹³⁶ The results show that a dressing with Safetac (Mepilex Border) was associated with significantly lower ($p \leq 0.01$) discomfort scores on removal than dressings with traditional adhesives (DuoDerm Extra Thin, Biatain, Tielle, Allevyn Adhesive and Versiva (ConvaTec)). Interestingly, there was poor correlation between the discomfort scores and peel force, suggesting that aspects of skin-surface adhesion interaction other than peel force play a role in the level of pain experienced on dressing removal.

In addition to the findings of the experimental study, a recently undertaken clinical evaluation has demonstrated the ability of dressings with Safetac to minimise pain at dressing change. This took the form of a multinational survey of 3034 patients, presenting with a variety of different wound types including leg ulcers (arterial, venous or mixed aetiologies), burns, skin tears, pressure ulcers and diabetic foot ulcers.²¹ The impact of introducing dressings with Safetac on the intensity of wound-related trauma and pain was assessed in comparison to previous treatment regimes involving advanced dressings with traditional adhesives (adhesive foams, hydrocolloids and others including films, surgical

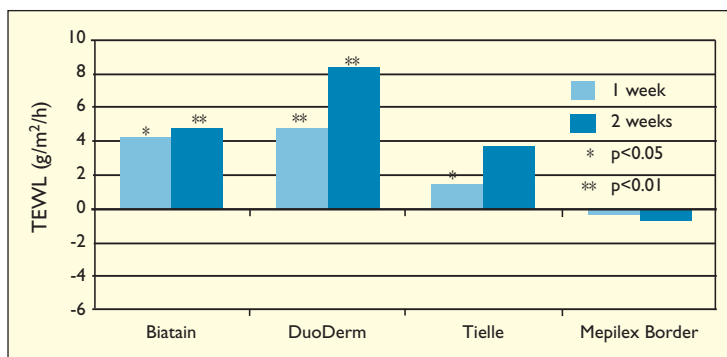


Figure 4. Comparison of adhesive borders of dressings in terms of transepidermal water loss (TEWL) associated with repeated application and removal from the peri-wound skin of patients with venous leg ulcers.¹³⁷

Table 5. Minimising dressing-related pain – key studies

Study	Study type	Sample size	Wound type(s)	Dressing(s) with Safetac	Comparator dressing(s)	Main outcome measures	Main results
Dykes and Heggie ¹³⁶	Volunteer study (RDA)	24	N/A	Mepilex Border	Allevyn Adhesive; Biatain; DuoDerm Extra Thin; Tielle, Versiva	Peel force required to remove dressings Discomfort on dressing removal, measured using visual analogue scale (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 (p≤0.01) lower discomfort scores than other dressings
White ²¹	Multi-national survey	3034	Arterial leg ulcers; burns; diabetic foot ulcers; pressure ulcers; skin tears; venous leg ulcers	Mepilex; Mepilex Lite; Mepilex Border; Mepilex Border Lite	Variety of advanced dressings (e.g. foams and hydrocolloids) with traditional adhesives	Pain before, during and after dressing changes, measured using VAS	Dressings with Safetac associated with significantly (p=0.01) less wound-associated pain than dressings with traditional adhesives
Woo et al ⁸⁶	Volunteer study (RDA)	28	Chronic ulcers	Mepilex Border	Allevyn Adhesive	Pain before, during and after dressing changes, measured using VAS	Pain severity scores before dressing change and at dressing removal significantly (p<0.001) lower in patients treated with Mepilex Border

RCT = Randomised controlled trial; RDA = Randomised dressing allocation; VAS = visual analogue scale

General comment: With regards to the key studies evaluating dressing-related pain, a criticism could be levelled that only one RCT using a population of 28 patients is presented as evidence. However, all three studies listed in this table involved the use of a validated pain assessment tool (visual analogue scale). Therefore the results are comparable and taken together, provide a weight of evidence in support of dressings with Safetac. Additionally, it is noteworthy that the multinational survey directly involved a large number of patients and caregivers, and is thus more likely to reflect the 'real life' situation than other forms of clinical evaluation.

dressings and alginates). The dressings with Safetac demonstrably reduced trauma to wounds and peri-wound skin and were associated with significant (p=0.01) reductions in the levels of wound-related pain measured (by means of a visual analogue scale) before, during and after dressing change, compared with advanced dressings utilising traditional adhesives (Figure 5). When asked about dressing preference, more than 90% of patients surveyed indicated that they preferred the dressings with Safetac to their previous treatment regimes.

Having identified that patients with all wound types are subject to the problems associated with dressing-related trauma and pain, the following sections of this article discuss specific wound types, the challenges that relate to them, and how they may be overcome.

Acute wounds

Acute wounds, assuming a relatively healthy host, tend not to be complicated by co-morbidities. They heal following a defined and finite series of events, resulting

in the replacement of tissue within the confines of the injury and restoration (to a greater or lesser extent) of architectural form and physiological function. Acute wounds include, for example, surgical incisions, traumatic injuries (e.g. hand injuries and skin tears), and burns. Paediatric wounds can generally be considered as acute wounds but, as they present a unique set of challenges, they are considered separately in this document. Table 6 summarises the key studies that have evaluated dressings with Safetac in the management of acute wounds.

Surgical wounds

Wounds that occur as a result of surgical interventions should present less of a challenge to clinicians than other types of wounds, as they are generally 'clean' and formed by predetermined incidents that lead to the integrity of the skin being compromised. Surgical wounds may be healed by either primary or secondary intention. The former is applicable to wounds that have

well-approximated edges, such as surgical incisions in which the edges of the wound can be pulled together to meet neatly and retained in place with sutures, staples or glue. Wounds healing by secondary intention are associated with some degree of tissue loss or where there is a wide separation of the edges of the wounds, such as those arising from tumour removal. These wounds heal by the formation of granulation tissue which fills the dead space and allows re-epithelialisation across the surface.

Management of the surgical wound should be aimed at minimising disturbance to the wound, preventing microbial invasion, and ensuring patient comfort.¹³⁸ The two main complications associated with surgical wounds are infection and dehiscence. The latter can range from the splitting open of the skin layers to complete dehiscence of the muscles and fascia. Risk factors for surgical wound dehiscence include diabetes, advanced age, obesity and trauma during the post-surgical period. Despite advances in preoperative care, the rate of surgical wound dehiscence has not decreased in recent years: 1%-3% of patients undergoing surgery experience wound dehiscence,¹³⁹ with associated mortality rates reported to be between 14% and 50%.^{140,141}

Several clinical evaluations have demonstrated dressings with Safetac to be beneficial in the management of surgical wounds and their complications, as well as addressing the needs of patients. For example, a number of non-adherent wound-contact layers were evaluated in a non-randomised study involving 52 patients with either surgical or traumatic wounds (including digit amputation, digit crush injury, toenail avulsion, skin tear, laceration, post-surgical cellulitis, post-surgical incision, and pretibial laceration) over a 10-week period. Due to the nature of the study, no statistical analyses of the data were undertaken, although Mepitel compared favourably to other non-adherent wound contact layers (Atrauman (Paul Hartmann), NA Ultra (Johnson & Johnson), Tegapore (3M Health Care), Urgotul (Urgo)) in terms of ease of dressing removal and patient comfort while the dressing was in situ.⁵⁹

Amputations subsequent to surgical interventions can result in complex wounds that present unique clinical challenges in terms of shape, size and location, together with the functional requirements to continue everyday tasks such as walking with prostheses. These challenges dictate that a dressing used in these circumstances needs to meet certain criteria: conformability; ability to handle moderate to high levels of exudate without maceration; compressibility under shrinker socks, early walking aids and prostheses; comfort; and atraumatic to the wound and surrounding skin on removal. A number of clinical evaluations have highlighted how dressings with Safetac fulfil these criteria.

In a study on amputation wounds, two large pieces of Mepitel were used, one posteriorly and the second anteriorly over the incision, with both secured under tension. Mefilm (a self-adhesive polyurethane film

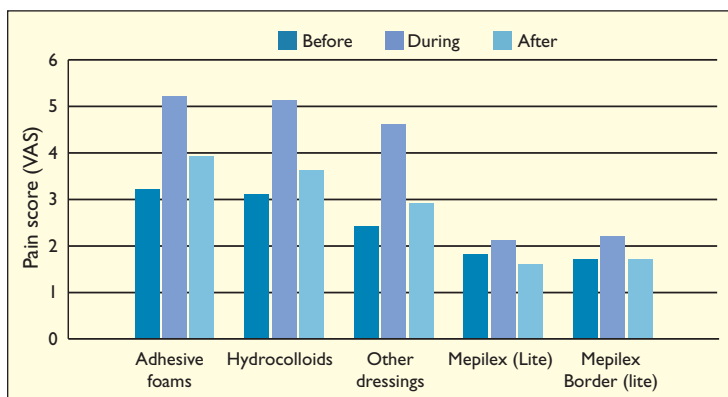


Figure 5. Pain severity scores (VAS) associated with advanced dressings utilising traditional adhesives and foam dressings with Safetac before, during and after dressing removal.²¹

dressing) was placed over the Mepitel. The results showed that the elastic properties of Mepitel provide an effective pressure dressing for post-operative stumps without causing further trauma or pain over the amputation stump and result in fewer complications than conventional elastic bandages.⁶⁵ A subsequent series of case studies (n=3) highlights the key qualities of Mepilex as a dressing for dehisced amputation wounds to which conventional dressings are normally very difficult to apply.⁹⁸ Mepilex facilitated wound healing while meeting the demanding needs of dehisced lower limb amputation wounds. An example of bilateral amputation wounds that dehisced and were then successfully treated with Mepilex are presented in Figure 6.

It has been reported that patients undergoing reconstructive breast surgery may develop complications, presenting as blisters in the peri-wound region, that occur as the result of the adhesive component of dressings causing trauma to the skin. A study was undertaken at a specialist wound-care centre in Belgium to evaluate the efficacy of Mepilex Border Lite in preventing skin lesions when used as a postoperative dressing on 10 patients who had undergone oncology-related breast and reconstructive surgery.¹⁰⁷ Before the study, more than 80% of patients treated in the centre suffered from postoperative skin lesions as a result of poor dressing choice. In contrast, none of the patients treated with Mepilex Border Lite developed even a minor blister around the postoperative wound. Patients had positive comments about the comfort of Mepilex Border Lite, removal was not painful and did not cause further trauma. Photographs of a wound resulting from oncologic breast surgery treated with Mepilex Border Lite are presented in Figure 7. The authors conclude that this study shows that the use of dressings with Safetac, such as Mepilex Border Lite, which may initially be more costly, are more cost-effective in the long-term because they reduce traumatic problems such as skin blistering, as well as having a positive effect on the quality of life of patients.

Traumatic wounds

Wounds caused by accident or design that result in damage to the integrity of the skin following penetrating, avulsion, crushing, and shearing injuries are often very painful and can be a source of significant anxiety.⁹⁹

Traumatic wounds present a spectrum of tissue damage that, by their very nature and variety, pose considerable management hurdles. A variety of different traumatic wounds have been shown to respond favourably to treatment regimes involving dressings with Safetac.

Hand injuries

Hand injuries are common in children and can be a source of considerable pain and stress to the patient,⁴⁸ as well as being difficult to dress. This issue was considered in a prospective RCT in which Mepitel was compared with paraffin gauze in the treatment of 45 children with isolated fingertip injuries.⁵⁵ Patients were randomly allocated to one of two treatment groups,

either Mepitel (n=20) or paraffin gauze dressings (n=25), regardless of whether the injury was treated conservatively or surgically, with a common outer layer of dry gauze and cotton bandage secured by adhesive tape. Although no differences between the two dressings were found in terms of healing rates, important statistically significant differences in favour of Mepitel were recorded in relation to dressing adherence (p<0.01) and the stress exhibited by the patient over the first 3 weeks of treatment (p<0.01), leading the authors to conclude that Mepitel offers a less painful and easier alternative to traditional dressings for the treatment of fingertip injuries.

In a subsequent RCT involving both adult and paediatric patients, Mepitel was compared with paraffin gauze and an apertured cellulose acetate dressing coated with a petrolatum emulsion (Adaptic, Johnson & Johnson) in the management of hand surgery wounds.⁶⁴ A total of 108 patients were randomly assigned to

Table 6. Acute and paediatric wounds – key studies

Study	Study type	Sample size	Wound type(s)	Dressing(s) with Safetac	Comparator dressing(s)	Main outcome measures	Main results
Dahlstrom ⁶³	RCT	32	Post-tumour excision wounds in need of skin grafting	Mepitel	Paraffin gauze	Dressing adherence Pain Time required for dressing removal	Mepitel associated with significantly less wound bed adherence (p<0.0001), less bleeding (p<0.02), less pain (p<0.001) and less time required for dressing removal (p=0.02)
O'Donovan et al ⁵⁵	RCT	45	Traumatic wounds (fingertip injuries)	Mepitel	Paraffin gauze	Healing time Dressing adherence Stress at dressing change, measured using VAS	Mepitel associated with significantly (p<0.01) less adherence and significantly (p<0.01) lower stress scores
Meuleneire ⁵⁷	Observational study	59	Skin tears	Mepitel	Paraffin gauze	Healing rate Pain	Mepitel associated with 83% healing rate by day 8 of treatment, and reduced patient discomfort (compared with paraffin gauze)
Morris et al ¹⁰⁶	Prospective, open study	36	Paediatric wounds; various	Mepilex Border Lite	Variety of traditional and advanced dressings	Pain during and between dressing changes Trauma In-use characteristics	Pain severity scores significantly (p<0.003) reduced after introduction of Mepilex Border Lite Over 99.5% of dressing changes with Mepilex Border Lite reported to be atraumatic

RCT = Randomised controlled trial; VAS = visual analogue scale

General comment: A number of articles presented in this table refer to paraffin gauze being used as a comparator which may be construed as not applicable to current clinical practice. In fact the contrary is true. Paraffin gauze is still widely used to treat a variety of wounds and has been recommended for practice by some authors although the validity of such recommendations is questionable.

treatment with one of the three dressing regimes. The selected primary dressing was covered with gauze and a crepe bandage together with a plaster of Paris splint as appropriate. In line with the results of the other reported study,⁵⁵ Mepitel was found to be easier to remove than the paraffin gauze. It was also observed that Mepitel could be used with advantage on wounds such as raw nail beds, as reported some years earlier by Williams, who also described its use following amputation of the fingers.⁵⁴ Photographs of a traumatic wound treated with a dressing utilising Safetac are presented in Figure 8.

It is worth noting that in the two RCTs described above,^{55,64} and in other studies discussed later in this document, paraffin gauze was used as the comparator dressing. This is a reflection of clinical practice at the time and, to a lesser extent now, where paraffin gauze is (wrongly) assumed to be non-adherent.¹⁴²

Skin tears

As a consequence of structural and functional changes in the skin of older people, a progressive atrophy occurs and the slightest trauma can cause the skin to tear.⁵⁶ Care of skin tears is often painful, and wound healing can be prolonged.⁵⁷ An ideal skin tear dressing should be able to maintain a moist wound environment; secure the skin flap; manage a wide range of wound exudate levels; not cause trauma on removal; conform to the wound; be cut without impacting the integrity of the dressing; provide pain-free dressing application and removal; and be cost-effective.⁷⁷ Dressings with Safetac have been shown to fulfil these criteria in a number of clinical evaluations described below.^{56,57,62,77}

In an observational study involving 59 elderly patients, Mepitel was applied to 88 skin tears, in conjunction with a simple absorbent secondary dressing.⁵⁷ The dressing combination was associated with a high healing rate (i.e. 83% of wounds healed by day eight of the study). The author also highlights the ability of Mepitel to reduce patient discomfort during dressing changes, compared with paraffin gauze dressings. Figure 9 shows a sequence of photographs relating to the use of Mepitel in treating a skin tear.

Another article describes how the introduction of a new treatment protocol had a significant impact on the management of skin tears in a nursing home.⁵⁸ Previously, skin tears that had been treated with a variety of traditional dressings had an average healing time of 37 days. After the introduction of the new regime involving Mepitel (left in situ for 7 days) in conjunction with a secondary dressing (changed daily for 3 days), the average time to healing dropped to 10 days. Less frequent dressing changes resulted in reduced trauma to the patient and also provided financial benefits, with expenditure cut by two-thirds.

Mepitel has been shown to offer financial, as well as clinical, benefits in the management of skin tears elsewhere. Barrows et al⁶¹ compared an existing protocol for skin care management (consisting of

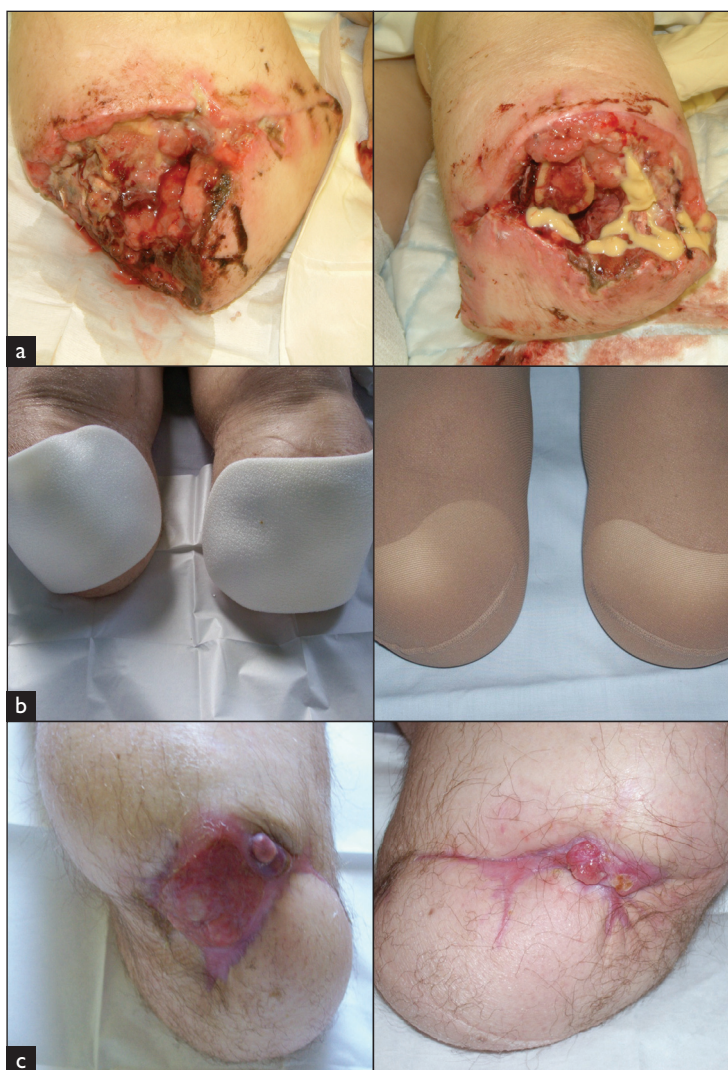


Figure 6. Bilateral transtibial amputation wounds treated with Mepilex. a) First assessment; b) Mepilex dressings in situ; c) Wounds almost healed five months after start of treatment Photographs courtesy of Gill Weaver, Manchester Royal Infirmary, UK.

antibiotic ointment covered with non-adherent gauze and secured with a sterile gauze wrap, changed every other day), with a proposed regime involving the use of Mepitel with Normlgel isotonic saline gel (Mölnlycke). Compared with the existing protocol, the regime involving Mepitel was associated with reduced trauma and pain for the patients, a 33% reduction in healing time, and a 62% reduction in dressing change frequency/skilled intervention, equating to an average cost saving per skin tear of US\$872.⁶¹ Mepitel's cost-effectiveness has also been demonstrated in other wound types.^{49,50,143}

In a review of the management of skin tears at a specialist wound care centre in Belgium, Mepitel was reported to be a good wound covering for skin tears without tissue loss and those with partial thickness loss. In the case of skin tears with total tissue loss, the review



Figure 7. Post oncologic breast surgery wound treated with Mepilex Border Lite. a) Immediately after surgery; b) Mepilex Border Lite in situ; c) Dressing removed 12 days after surgery (no blisters evident). Photographs courtesy of Frans Meuleneire, Woundcare Centre, Zottegem, Belgium.

states that Mepilex, Mepilex Border or Mepilex Transfer can be used to manage large amounts of exudate.⁶²

Road rash

Road rash is a term used to describe the abrasive injury that occurs when a casualty comes into contact with, for example, a road surface, resulting from a traffic accident. They are generally partial thickness wounds and are frequently painful, particularly at the time of dressing change when parenteral analgesia is routinely administered. They are also at risk of infection due to the ingress of foreign matter.

A clinical evaluation by Dunbar et al⁹⁹ describes how the introduction of Mepilex Border and Mepilex Lite compared favourably with previous treatment regimes involving semi-occlusive film dressings, normal saline dressings, or silver sulfadiazine (SSD) cream covered with gauze dressings. The dressings with Safetac demonstrated good absorption characteristics and provided protection for wound healing. After the introduction of the new regime, the frequency of dressing changes decreased, supply costs and nursing time were reduced by 50% per day, pain levels decreased from an average of 8 to 3 (on a scale of 1–10), and parenteral analgesia was eliminated.⁹⁹

Skin grafts

Skin grafting is a surgical procedure that is used to quickly restore skin integrity in wounds that are large and cannot be directly closed by suturing.¹⁴⁴ It is important that, in order for grafts to adhere to wound beds, they must be held in close proximity and immobilised.¹⁴⁵ Historically, this has been achieved by suturing (which is relatively time-consuming) and by using clips, skin glue, or staples, the latter being painful to remove, requiring large amounts of analgesia and, on occasions, sedation or anaesthesia.⁷⁶

Another approach to the fixation of skin grafts is the use of wound dressings. In order to maximise the potential for grafts to take, dressings should prevent mechanical displacement, allow wound exudate to drain and antibacterial solutions to reach the wound, and not adhere to the graft and open areas of the wound.⁷²

A number of published articles describe clinical evaluations in which Mepitel has been shown to be effective on newly grafted burns.^{72,73,75,76} The first of these evaluations⁷² was an open, prospective study involving 38 children in which Mepitel was evaluated as an alternative to conventional treatment (graft fixation dressing (SurfaSoft, Haromed) plus staples, or sutures and petrolatum gauze) for the fixation of split skin grafts applied to burn wounds. Cotton wool gauze, applied as a secondary dressing over the Mepitel, was changed every 1-2 days. With the Mepitel in situ, changing the outer absorbent dressings was painless, as was the final removal of the Mepitel itself. In addition to being associated with pain-free removal, the use of Mepitel prevented disturbance of open wound areas at dressing changes. Graft take was also reported to be good: in 42 out of 45 cases, the take was almost complete (>95%).

Mepitel was also compared with paraffin gauze as the primary wound contact layer applied to 38 newly grafted burn wounds in a prospective RCT involving adults and children.⁷³ Pain scores (measured by VAS) at the first postoperative dressing change were significantly ($p < 0.01$) greater in the group treated with paraffin gauze. Whereas all patients in the paraffin

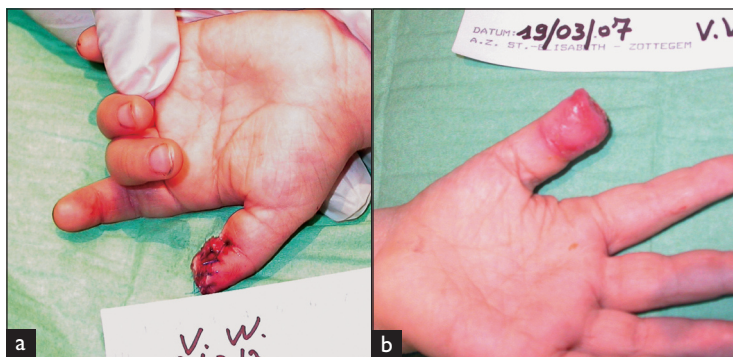


Figure 8. Traumatic injury to the thumb treated with Mepilex Border Lite, a) before and b) after treatment. Photographs courtesy of Clare Morris, North Wales NHS Trust (East), Wrexham, UK.





Figure 9. Skin tear management with Mepitel. a) Epidermal flap in its original position; b) Mepitel in situ; c) After removal of Mepitel, the flap is attached to the dermis. Photographs courtesy of Frans Meuleneire, Woundcare Centre, Zottegem, Belgium.

gauze-treated group experienced some degree of pain on dressing removal, 53% of patients in the Mepitel-treated group experienced no pain. Mepitel was also found to be significantly ($p < 0.001$) easier to remove than the gauze. Further evidence of the usefulness of Mepitel in this indication has been presented in a case study 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.⁷⁶

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, it is reported that Mepitel is a suitable dressing for holding pinch grafts applied to venous leg ulcers securely in place.⁷⁴

The use of Mepitel as a temporary dressing before delayed split skin grafting in more extensive wounds resulting from wide local excision of skin tumours has also been evaluated in a prospective RCT.⁶³ Sixty-four patients were randomly allocated to have either Mepitel ($n=32$) or paraffin gauze ($n=32$) applied as a temporary dressing after the excision of malignant melanoma. After tumour excision, the wounds were dressed according to the randomisation schedule and covered with a saline-soaked absorbent secondary dressing. All dressings were removed on the following day and an unmeshed split-skin graft applied, which was left exposed. Significant differences were observed between the two treatments with Mepitel associated with less wound bed adherence ($p < 0.0001$), less bleeding ($p < 0.02$), less pain ($p < 0.001$), and less time required for dressing removal ($p = 0.02$). The author concludes that Mepitel was 'an optimum temporary dressing for delayed split-skin grafting'.

In discussing the different types of skin grafts that are managed in the community setting, Atkinson⁷⁵ 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, and facilitates atraumatic and pain-free removal. In addition, Mepitel has the advantage that it can be left in place for up to 14 days allowing only the secondary dressing to be changed if necessary and hence is more cost effective in the long-term.

A donor site is an area of the body from which skin has been harvested to provide a skin graft.¹⁴⁴ Donor sites are frequently associated with complications such as pain, discomfort and delayed healing. The effectiveness of Mepilex Transfer in the management of large donor sites was evaluated in 40 patients with burns.¹¹⁰ Mepilex Transfer was applied as a primary dressing and left in situ for 2–3 weeks. A secondary dressing, applied to absorb blood and exudate, was changed as necessary. A decrease in the number of painful dressing changes was observed after the introduction of Mepilex Transfer.

Paediatric wounds

Paediatric patients present with a variety of different wound types, the majority of which are acute, e.g. burn, surgical and traumatic wounds. Due to the often small size of the wounds and the difficulties associated with dressing unusually shaped wounds in awkward locations, clinicians need access to highly conformable dressings.

Dressings with Safetac have been reported to be of benefit in the treatment of paediatric wounds in a number of clinical evaluations (some of which have been discussed earlier), for example, Mepitel in the treatment of burns,⁴⁹⁻⁵² surgical wounds,⁶⁴ traumatic wounds,⁵⁵ epidermolysis bullosa (EB),⁷⁸⁻⁸² and for the fixation of skin grafts.^{72,73,76} Mepilex in the treatment of EB;^{82,100,101} Mepilex Border/Mepilex Border Lite for the management of neonatal peristomal wounds,¹⁴⁶ and Mepilex Transfer for the treatment of EB.

In a recently undertaken observational study involving 36 paediatric patients with a variety of wound types (burns, surgical and traumatic wounds), the impact of introducing Mepilex Border Lite on pain,





Figure 10. Finger amputation wound of a paediatric patient treated with Mepilex Border Lite, demonstrating the flexibility and conformability of the dressing and the excellent outcome achieved. a) Before treatment; b) During treatment; c) After treatment. Photographs courtesy of Frans Meuleneire, Woundcare Centre, Zottegem, Belgium.

during and in-between dressing changes, was evaluated.¹⁰⁶ Using a pain assessment tool based on the VAS and the Wong-Baker faces scale, pain severity levels reported at baseline (i.e. associated with a variety of different dressing types) were compared with those reported at the first dressing change (i.e. after the introduction of Mepilex Border Lite). Mean pain severity scores were significantly lower ($p \leq 0.003$) after the introduction of Mepilex Border Lite. The results of the study also demonstrated that Mepilex Border Lite was highly flexible and conformable, indicating that the dressing is highly suitable for paediatric wound management. The conformability of Mepilex Border Lite is demonstrated in a series of photographs shown in Figure 10. While this study was not designed as a true comparator evaluation, it used the patients as their own controls in a 'real life' clinical situation, rather than under the restrictions of a typical RCT.

Three case studies also describe the benefits of dressings with Safetac in managing paediatric wounds. The first case reports that the use of Mepilex Border Lite on a paediatric patient with a second-degree burn was superior to a previous regime involving SSD in terms of pain reduction, ease of application, and patient comfort.⁶² In the second case, Stephen-Haynes¹⁴⁷ describes the care of a 4-month-old infant who presented with a sacral haemangioma. On referral, the patient's skin had broken down and an infected ulcer had developed. Prior to referral a variety of dressings were tried, but failed to stay in place and caused severe pain on removal. Improvement in the wound was noted within 4 weeks of starting treatment with Mepilex Border and the wound had healed completely at 8 weeks. The infant's appetite was restored, he was happy, slept well and met his child development targets.

In the third case, an interesting application of dressings with Safetac is described in which trauma to the nasal septum and peri-nasal tissue during the course of continuous positive air pressure (CPAP) therapy in premature infants was prevented. CPAP helps to prevent respiratory distress syndrome in premature infants but,

because these patients typically have friable skin, the use of masks and nasal prongs places significant pressure around the nose, nasal septum and surrounding tissue and causes trauma. In the case study, customised patterns were cut from Mepilex Lite to fit around the infants' noses or across the upper lips in order to stabilise the equipment and reduce friction and shear for both kinds of CPAP delivery systems. The thinness and flexibility of Mepilex Lite provided conformability and security and did not interfere with the air delivery. Another significant benefit was that dressings with Safetac could be easily lifted allowing observation of the skin underneath with minimal disruption to the resting infant. This treatment approach increased comfort levels and lessened overall irritability of the infants.¹⁴⁸

Burns

Burn injuries, although generally considered as acute wounds, may be considered separately because they comprise a challenging spectrum of acute, chronic, traumatic, and surgical wounds with a wide range of anatomical locations and depth.¹⁴⁹ Burn injuries arise as a result of thermal, chemical or electrical insult. There are three zones of tissue damage associated with burns: coagulation, stasis and hyperaemia. Management is based on the amount, depth and severity of burns and by the designations of superficial, partial- and full-thickness injuries.¹⁵⁰ Burn wounds are extremely painful, frequently highly traumatic and can lead to permanent scarring, disfigurement or even death.⁵³ The main objectives of their treatment are to remove devitalised tissue, promote healing, prevent wound infection and graft loss, maintain function of the affected body part, and achieve wound closure as soon as possible.⁷⁶

A variety of dressing types are used to overcome the challenges associated with burns and the scars that subsequently form. The continuing development of materials and techniques now focus not only on successfully healing wounds and reducing scarring, but also on minimising physical trauma and discomfort during treatment.



Dressings with Safetac provide a good basis for the treatment of non-complex burns (Table 7). For example, Mepitel provides a moist wound environment, promotes wound healing, and is easy and relatively painless to use.⁴⁹⁻⁵³ In an RCT undertaken by Bugmann et al,⁴⁹ 76 children with previously untreated burns less than one day old were randomised to treatment with Mepitel (n=41) or SSD cream (n=35). For those patients assigned to Mepitel, one or more sheets of the dressing were applied directly to the burns 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. Wounds in both treatment groups were

redressed every 2–3 days until complete healing had been achieved. Mepitel-treated wounds were associated with significantly ($p<0.01$) reduced healing time compared to those treated with SSD (7.6 days and 11.3 days, respectively). Moreover, the mean number of dressings used was significantly ($p<0.05$) less in the Mepitel-treated group compared to the control group (3.64 and 5.13, respectively). Mepitel was also reported to be easy to use and atraumatic on removal.⁴⁹

Mepitel was compared with SSD in a second RCT involving 63 children with partial-thickness scald burns.⁵⁰ Patients were randomised to treatment with Mepitel (n=33) or SSD (n=31); gauze dressings were applied over both treatments. Dressings were changed

Table 7. Burn wounds – key studies

Study	Study type	Sample size	Wound type(s)	Dressing(s) with Safetac	Comparator dressing(s)	Main outcome measures	Main results
Platt et al ⁷³	RCT	38	Newly grafted burn wounds	Mepitel	Paraffin gauze	Graft take Pain on dressing removal, measured using VAS Ease of dressing removal	Significantly ($p<0.01$) lower pain scores associated with Mepitel at first postoperative dressing change. All patients treated with paraffin gauze experienced pain on dressing removal; 53% of those treated with Mepitel experienced none. Mepitel significantly easier to remove than paraffin gauze ($p<0.001$)
Bugmann et al ⁴⁹	RCT	76	Burns	Mepitel	Silver sulfadiazine (Flamazine)	Healing time Number of dressings used	Mepitel associated with significantly ($p<0.01$) faster healing rate Number of dressings used significantly ($p<0.05$) less in Mepitel-treated wounds
Gotschall et al ⁵⁰	RCT	63	Burns (partial thickness)	Mepitel	Silver sulfadiazine	Healing time Pain at dressing change Resource use	Wounds treated with Mepitel healed significantly faster ($p<0.001$) and exhibited less eschar formation ($p<0.05$) Mepitel associated with significantly ($p<0.05$) less pain at dressing change Mepitel-treated wounds associated with significantly ($p<0.02$) lower treatment costs
Meites et al ¹²¹	Prospective, open study	18	Burns	Mepilex Ag	None	Infection In-use characteristics	Mepilex Ag (left in place for up to 7 days) provided antimicrobial protection and did not adhere to the wound

RCT = Randomised controlled trial; VAS = visual analogue scale

General comment: While three of the four studies listed above evaluated Mepitel, a dressing that is designed for use only as a primary wound contact layer, burns do present a number of significant challenges, e.g. management of exudate, prevention/treatment of infection and the management of high levels of pain associated with the wounds and treatment regimes. Such challenges need to be met by dressings other than simplistic wound contact dressings.

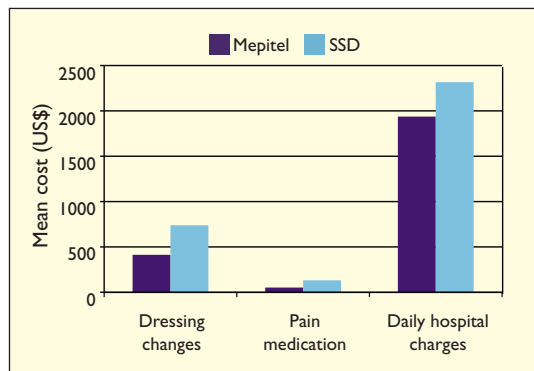


Figure 11. Cost comparison of Mepitel-treated and silver sulphadiazine (SSD)-treated burns.⁵⁰

every second day. Wounds treated with Mepitel healed significantly ($p < 0.0001$) faster (median time for complete healing was 10.5 days (Mepitel) and 27.6 days (SSD)), exhibited less eschar formation ($p < 0.05$), and were associated with less pain at dressing change ($p < 0.05$) compared to the SSD-treated wounds. Mepitel-treated wounds were also associated with significantly lower mean daily hospital charges (US\$1937 versus US\$2316, $p = 0.025$), charges for dressing changes (US\$413 versus US\$739, $p < 0.02$) and analgesia charges (US\$52 versus US\$132, $p < 0.001$) (Figure 11).

The findings of these studies present significant evidence of the clinical benefits of using Mepitel as a wound contact layer in the treatment of burns. In addition, data have been published which demonstrate that the use of Mepitel is associated with significant cost savings, when compared to traditional treatment used in burns management.^{49,50,143}

Other dressings with Safetac have also been reported to be of use in burn wound management. Mepilex Border is useful for the treatment of non-complex burns because it conforms well to the body's contours and is shower-proof, without being bulky.⁵³ Mepilex Border Lite has been shown to be particularly useful in the treatment of paediatric burns.^{106,107} Mepilex Transfer is a useful dressing for burns as it is designed for application to exuding injuries covering large, awkward areas of skin while maintaining a moist wound environment.⁵³ In a study on 18 patients with burns, Mepilex Ag was shown to provide antimicrobial protection that left the wounds with a clean appearance. Additionally, Mepilex Ag did not adhere to the wound, thereby giving clinicians the opportunity to either examine the wound or leave the dressing *in situ* for up to 7 days.¹²¹

Wounds at risk of infection

Whereas intact skin provides a physical barrier to the ingress of microorganisms, moist and exuding wounds of both acute and chronic origin provide a favourable environment for microbial growth.^{151,152} The majority of wounds are colonised with aerobic and anaerobic microorganisms that are potentially pathogenic despite

the fact that they exist as commensals in their natural human habitats, e.g. *Staphylococcus aureus* (which is present on the surrounding skin and in the nasal cavity), *Pseudomonas aeruginosa* (which colonises moist sites such as the ears), and *Bacteroides fragilis* (which resides in the intestine).¹⁵³ 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.¹⁵² 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.¹⁵⁴ Bacterial infection can significantly delay the wound healing process.¹⁵⁵ In addition to delaying healing, wound bioburden can result in an increase in pain and a deterioration in the patient's general condition.¹⁵⁶

Silver and silver compounds have been used as antimicrobial agents for many years. Silver is an inert material but, in the presence of fluid (e.g. wound exudate), it is ionised. Silver ions possess broad-spectrum antimicrobial activity against bacteria (aerobic and anaerobic, Gram-positive and Gram-negative), including antibiotic resistant species such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE), fungi and viruses,¹⁵⁷⁻¹⁵⁹ as well as having a low toxicity profile.¹⁵⁶ These properties have led to the development of silver-impregnated wound dressings that provide a barrier against infection, as well as reducing bioburden.

Mepilex Ag is a silver-containing foam dressing which combines the benefits of Safetac with a silver component that provides instant and sustained, broad-spectrum antimicrobial activity against common wound pathogens (Table 8 and Figures 12 to 14).^{159,160}

Although a relatively new dressing, Mepilex Ag has already been shown by numerous case reports and small studies to be successful in the treatment of a variety of wound infections. A recent explorative, multi-centre investigation examined the use of Mepilex Ag on 18 patients (in- and out-patients) with chronic venous leg ulcers ($n = 11$), leg ulcers with mixed aetiology ($n = 4$), and diabetic foot ulcers ($n = 3$) associated with low-to-moderate exudate levels and in need of antimicrobial treatment.¹¹⁵ Over a 4-week period, weekly assessments of dressing changes were undertaken. Mepilex Ag was associated with an increase in the number of healthy wounds (from five at baseline to nine at the final visit), an increase in viable tissue (from 75% at baseline to 80% at the final visit), a median reduction in wound size of 75%–85%, a reduction in wound size (approximately 30% from baseline to final visit), a reduction in the number of patients with wounds exhibiting signs of inflammation, and a reduction in the number of patients with highly exuding wounds. Mepilex Ag was also well-tolerated. The degree of pain was low at baseline and did not increase during the treatment period.

Davoudi et al¹¹⁴ report on the successful treatment of a venous leg ulcer with Mepilex Ag, in conjunction with



compression therapy, for a period of 4 weeks. Dressing changes were undertaken approximately twice a week. The ulcer showed a positive healing response. The level of bacterial contamination within the dressings was less at the end of the treatment period than it was at the start of the study.¹¹⁴ A 4-week period of treatment with Mepilex Ag was also evaluated in a study involving 24 patients with infected, chronic, poorly-treated wounds (arterial ulcers, diabetic foot ulcers, mixed aetiology ulcers, pressure ulcers, and venous leg ulcers).¹¹⁷ Dressing changes were undertaken twice a week, with more frequent changes undertaken for wounds exhibiting high exudate levels. Wounds were swabbed at the first visit, and after 15 days and 30 days of treatment. At the end of the study period, two wounds had completely healed with a further eight showing signs of improvement. The mean reduction in wound size from baseline to day 30 was 50%. The number of patients with highly exuding wounds decreased from 13 at baseline to seven at the end of the treatment period. The use of Mepilex Ag was associated with a reduction in the number of patients experiencing pain (at the end of the treatment period, 50% of patients had low levels of pain or none). Microbiological analysis of the swab cultures showed that Mepilex Ag had an effect on reducing levels of common wound pathogens.

In addition to the positive findings observed in a study of Mepilex Ag undertaken on patients with burns discussed previously,¹²¹ six patients with a variety of chronic/complex wounds that were at least 30 days old and had failed to respond to previous treatment regimes were treated with Mepilex Ag. Healing times and pain levels were reduced, patients' quality of life improved,

complications were prevented and costs were contained.¹²⁰

In a series of case studies involving three patients with different wound types (venous ulcer, pressure ulcer, traumatic wound), Mepilex Ag significantly improved the quality of life of the patients by effectively minimising signs and symptoms of wound bioburden, effectively managing peri-wound candidiasis, being easy to apply, being associated with atraumatic removal and minimal pain, and by eliminating the need for pre-dressing change medication.¹¹⁶ Timmins¹⁶¹ describes the successful management of a large haematoma on a patient's calf with Mepilex Ag. The dressing met the wound management issues of the patient as it caused no pain on removal and minimised bleeding. Mepilex Ag also effectively handled, and ultimately reduced, exudate levels. It has been reported that Mepilex Ag can also be used for dressing pin sites following the surgical management of Charcot midfoot deformities.¹⁶²

Interestingly, Serena and Fry¹⁶³ report on the case of a 54-year-old patient with a painful wound resulting from herpes zoster. The original dressing used on the wound exacerbated pain, leading to poor compliance with dressing change. Following the introduction of treatment with Mepilex Lite, the patient's pain was quickly controlled, ultimately negating the need for narcotic analgesia, which in the case of this patient had been ineffective as well as carrying the risk of serious side-effects.¹⁶³

Chronic wounds

Wounds that fail to heal within an acceptable time despite being given appropriate therapy are often

Table 8. Wounds at risk of infection – key studies

Reference	Study type	Sample size	Wound type(s)	Dressing(s) with Safetac	Main outcome measures	Main results
Schumann et al ¹¹⁵	Prospective, open study	18	Mixed aetiology	Mepilex Ag	Proportion of viable tissue Wound size reduction	Increase in proportion of viable tissue from 75% at baseline to 85% after treatment with Mepilex Ag Mepilex Ag associated with 30% reduction in wound size Mepilex Ag was well-tolerated
Durante ¹¹⁷	Prospective, open study	24	Mixed aetiology	Mepilex Ag	Wound size reduction Pain Infection	Mean reduction in wound size of 50% from baseline after 30 days of treatment with Mepilex Ag Patients experienced reduction in pain during treatment with Mepilex Ag Mepilex Ag associated with decrease in wound bioburden
Meites et al ¹²¹	Prospective, open study	18	Burns	Mepilex Ag	Infection In-use characteristics	Mepilex Ag (left in place for up to 7 days) provided antimicrobial protection and did not adhere to the wound

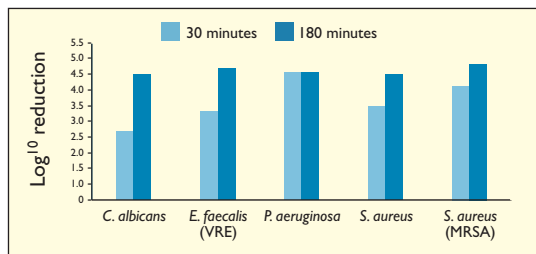


Figure 12. Instant antimicrobial effect of Mepilex Ag against five common wound pathogens, determined using ASTM E2149-01 method.¹⁶⁰

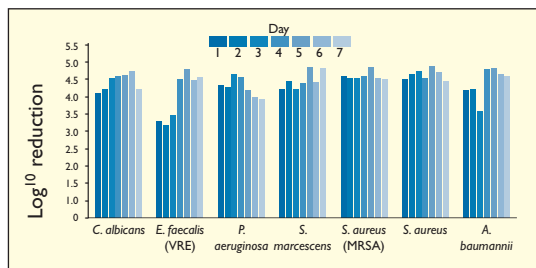


Figure 13. Sustained antimicrobial effect of Mepilex Ag against seven common wound pathogens, determined using ASTM E2149-01 method.¹⁶⁰

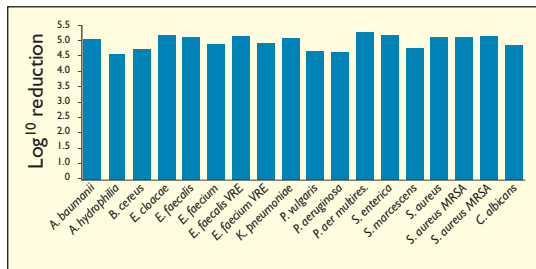


Figure 14. Antimicrobial effect of Mepilex Ag against a broad range of microorganisms, including antibiotic-resistant strains and yeasts, determined using ASTM E2149-01 method.¹⁶⁰

labelled as ‘chronic’. This term is applied to wounds in which compromised healing can be expected, usually because of complex underlying pathologies such as diabetes, vascular disease, and malignancy. The occurrence of chronic wounds — such as pressure ulcers, leg ulcers, diabetic foot ulcers and malignant wounds — is an increasingly common problem that imposes a considerable economic burden on health care providers.¹⁶⁴ The healing times of chronic wounds are generally protracted, taking months or even years to heal, if at all. For example, it has been reported that, despite the use of standard therapies (i.e. high compression for venous leg ulcers), more than 20% are still unhealed after 70 weeks of therapy.¹⁶⁴

Pain is a common occurrence in patients with chronic wounds¹⁶⁵⁻¹⁶⁸ and has been described as one of the most devastating aspects of living with a chronic

wound.¹⁶⁹ 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.^{16,170} Such observations reinforce the need to preserve the integrity of older skin by choosing dressings that are atraumatic and appropriate to local clinical conditions. To be effective in managing chronic wounds, dressings should also be capable of maintaining moist environments, facilitating healing, absorbing exudate, and remaining in situ for a number of days.

The studies described in earlier sections, which established that dressings with Safetac are atraumatic and far less likely to cause pain on removal than many other advanced dressings which employ traditional adhesives, involved a substantial number of patients with chronic wounds such as arterial ulcers, diabetic ulcers, mixed aetiology ulcers, pressure ulcers and venous leg ulcers.^{21,88,92,137} Table 9 summarises the key studies that have evaluated the performance of dressings with Safetac in the treatment of chronic wounds.

An open, randomised, cross-over, multi-centre study was undertaken to compare Mepilex Border and Allevyn Adhesive in terms of the pain experienced by patients with chronic ulcers before, during and after dressing change.^{86,87} The pain severity scores, measured using a VAS, before dressing change and at dressing removal were significantly ($p < 0.001$) lower in patients treated with Mepilex Border than in those treated with Allevyn Adhesive (Figure 15). Both patients and investigators preferred Mepilex Border to Allevyn Adhesive for its overall performance as well as conformability to wounds and surrounding skin ($p < 0.05$). The investigators were more satisfied with Mepilex Border for its fluid handling capability (Figure 16) ($p < 0.001$) and ease of removal ($p < 0.01$). Wounds that were treated with Allevyn Adhesive were more likely to develop maceration and erythema at the peri-wound skin than those treated with Mepilex Border. The fluid handling capacity of Mepilex Border not only minimised peri-wound maceration but also skin irritation from corrosive exudate. This may explain why patients experienced less pain with Mepilex Border than with Allevyn Adhesive before and at dressing removal.

Venous leg ulcers

The underlying cause of venous ulceration is chronic venous insufficiency arising from damage to the microvasculature, and in particular venous non-return valves which when healthy prevent retrograde blood flow back into the legs. Subsequently, pooling of blood and raised blood pressure levels in the lower leg occurs, which damages the walls of the veins allowing fluid and proteins to leak into the surrounding tissues leading to oedema.¹⁷¹ The primary and most successful management approach for these patients is the



application of high compression bandages to the lower leg (to improve blood flow and reduce venous hypertension), coupled with treatment of the wound.

Problems arising with these wounds that require management include: pain and sensitivity in the wound and the surrounding skin (particularly at the time of dressing change); wound exudate (the amount of which varies from low to high levels); and infection, which is prevalent in this type of wound.

In order to effectively manage these wounds, dressings have to be capable of absorbing a range of exudate levels. Maceration, resulting from leakage and poor exudate management, is a significant problem when treating venous leg ulcers and can lead to exacerbation of ulcers and the development of peri-wound skin complications. Dressings have to be able to

absorb and contain wound fluid while being used under high compression bandaging. In the wound and the peri-ulcer region, patients suffer pain, sensitivity to which may be heightened by infection. Dressings which minimise trauma and pain, therefore, should be used in the treatment of patients with this wound type.

In addition to the studies described earlier^{22,86} which demonstrate the pain reductions seen when dressings with Safetac are used to treat chronic wounds, other reports have provided further evidence of the benefits of using this dressing type in the treatment of venous leg ulcers. For example, Neal⁹¹ describes, from a patient's perspective, a 30-year struggle to find a pain-free treatment for venous leg ulcers. The patient discusses various treatments that were unsuccessful in treating her pain. However, when treated with Mepilex

Table 9. Chronic wounds - key studies

Study	Study type	Sample size	Wound type(s)	Dressing(s) with Safetac	Comparator dressing(s)	Main outcome measures	Main results
Meaume et al ⁹⁴	RCT	38	Pressure ulcers	Mepilex Border	Tielle	Healing time Trauma (wound and peri-wound skin) Ease of dressing removal	Significantly (p<0.05) less tissue damage observed in wounds treated with Mepilex Border Damage to surrounding skin, maceration and dressing removal difficulties less common with Mepilex Border
White ²¹	Multi-national survey	3034	Arterial leg ulcers; diabetic foot ulcers; pressure ulcers; venous leg ulcers	Mepilex; Mepilex Lite; Mepilex Border; Mepilex Border Lite	Variety of advanced dressings (e.g. foams and hydrocolloids) with traditional adhesives	Trauma (wound and peri-wound skin) Pain before, during and after dressing changes, measured using VAS	Dressings with Safetac associated with less traumatic injury than dressings with traditional adhesives Dressings with Safetac associated with significantly (p=0.01) less wound-associated pain than dressings with traditional adhesives
Woo et al ⁸⁶	RCT	28	Various	Mepilex Border	Allevyn Adhesive	Pain before, during and after dressing changes, measured using VAS In-use characteristics	Pain severity scores before dressing change and at dressing removal significantly (p<0.001) lower in patients treated with Mepilex Border Patients and investigators preferred Mepilex Border for overall performance and conformability (p<0.05) Investigators preferred Mepilex Border for fluid handling capability (p<0.001)

RCT = Randomised controlled trial; VAS = visual analogue scale

General comment. Two of the three studies listed above could be criticised on the basis that they evaluated dressings on a variety of different wound types, thus making it potentially difficult to interpret the findings in terms of managing individual wounds. However, the studies focus on managing problems that are common to all chronic wounds (i.e. wound-related trauma and pain). With regard to the other study, as discussed previously, the findings of a multinational survey might also be seen as more representative of 'real life' than other types of clinical studies.

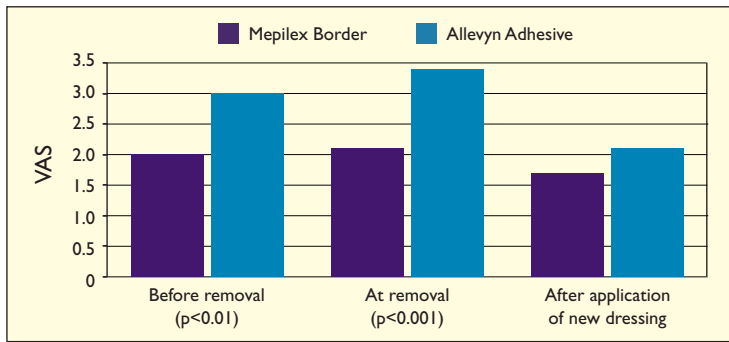


Figure 15. Dressings with Safetac (Mepilex Border) vs dressings with acrylic adhesive (Allevyn Adhesive) in terms of pain severity, measured by visual analogue scale (VAS), before, during and after removal in a randomised controlled study in patients with chronic wounds.⁸⁶

Border for a period of more than 3 months, she experienced no pain or difficulty when changing the dressing and found it soothing and comfortable to wear.⁹¹ A case study by Cunningham¹¹¹ presented information relating to the use of Mepilex Transfer in a patient with a venous leg ulcer, demonstrating good pain control and exudate management. Because of the perceived benefits, the patient was also more compliant with attending for routine dressing changes.

Arterial leg ulcers

Arterial leg ulcers occur because of poor blood supply to the legs when there is a block in a leg artery or narrowing of the arteries by atherosclerosis; they can take months or even years to heal. Aside from not using compression therapy, treating and managing arterial ulcers is similar to that for venous leg ulcers in that pain control, exudate management and the prevention/treatment of infection are the primary challenges.

The multinational study by White²¹ demonstrates the positive effects particularly on pain reduction when treating arterial ulcers with dressings that utilise Safetac technology. Additionally Gates compared the use of a dressing regime involving Mepitel with

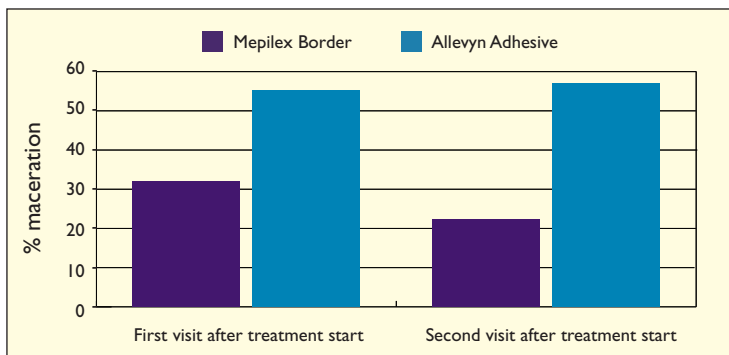


Figure 16. Dressings with Safetac (Mepilex Border) vs dressings with acrylic adhesive (Allevyn Adhesive) in terms of maceration in a randomised controlled study in patients with chronic wounds.⁸⁶

previous treatment regimes that had included a number of different conventional dressing types (iodine-based products; medicated paste bandages; alginate, hydrocolloids and Hydrofiber dressings). The introduction of the dressing with Safetac was associated with reduced trauma and pain at dressing changes, thereby promoting patient compliance. Mepitel also helped to protect the peri-wound skin from exudate. From a financial perspective, the change in dressing regime led to decreases in costs associated with labour and dressings, resulting in an almost 50% reduction in overall treatment costs.¹⁷²

Diabetic foot ulcers

Diabetic foot ulcers may be neuropathic in origin, whereby nerve damage resulting from diabetes causes altered or complete loss of feeling in the foot and/or leg. Subsequent trauma may go unnoticed by the patient and lead to skin loss, blisters and ulcers. Alternatively, diabetic foot ulcers may be due to vascular disease, microangiopathy or ischaemic blood flow which may lead to ulceration and impaired wound healing. Treatment of these wounds involves off-loading to prevent further trauma, and as with other chronic wounds, control of exudate and prevention of infection, which is prevalent.

The clinical evidence relating to the use of Safetac dressings in the management of diabetic foot ulcers is highlighted by a recent clinical study in which Mepilex Lite was evaluated in a multi-centre study involving 77 patients with foot lesions, 64 of whom had diabetes.¹⁰² In this study, the following parameters were measured: healing state of wounds; condition of surrounding skin; patient and investigator opinion. The objectives for treatment were met in 81% of cases with 88% of patients and 96% of investigators stating they would wish to use Mepilex Lite again. The high patient acceptance of Mepilex Lite was attributed to a number of factors including its ease of application, comfort, and pain-free removal; and that it was less bulky for footwear than other dressings. Mepilex Lite was also evaluated in a 10-patient study for the management of non-exuding or low exuding diabetic foot ulcers.¹⁰³ Wound size decreased from a mean of 3.6cm² to 0.85cm² over the 5-week treatment period with complete healing achieved in three patients. Dressings were atraumatic to the surrounding skin and were evaluated as good or very good by all patients and the investigator.

Misgavige⁹³ describes how the introduction of Mepilex Border to the treatment of a painful diabetic foot ulcer decreased the patient's level of pain, as well as providing both pressure relief and an environment conducive to healing.

Spraul et al¹⁰⁵ report on a case study involving the use of Mepilex Border Lite in a 70-year-old diabetic patient with ulcers on the toes. Three of the four ulcers healed completely after 33 days of treatment and the remaining ulcer healed after 3 months. No maceration



occurred. The dressing stayed in place well in this difficult anatomical area for applying dressings.¹⁰⁵ Additionally, Young⁶⁷ reports on the successful healing of a deep ulcer showing little evidence of granulation, and an inflamed and infected ulcer after the introduction of Mepitel and Mepilex, respectively. The use of Mepitel helped to protect the new epithelialisation tissue from trauma at dressing changes.⁶⁷

Pressure ulcers

A pressure ulcer is caused mainly by the restriction of blood flow and/or lymphatic drainage as a result of excessive tissue deformation caused by pressure and shear forces (friction). For example, when an underlying bony prominence (e.g. the heel or hip) comes into contact with a hard surface, the pressure restricts blood supply to the tissue, thereby causing localised ischaemia and cell death which results in ulceration. In order to prevent or overcome this problem, there must be an increased area of support, distributing and decreasing pressure and re-distributing weight. Pressure ulcers can be fairly superficial or full-thickness with extensive tissue damage and subsequently they may be very painful, associated with high exudate levels and prone to infection. As such, treatment varies according to the particular demands of the ulcer.

Clinical studies have shown the benefits of a variety of Safetac dressings to treat the wide range of pressure ulcers seen in clinical practice. For example in a multi-centre, randomised controlled study involving 38 patients with stage II pressure ulcers, Mepilex Border was compared with a hydrolymer foam dressing (Tielle) for a treatment period of 8 weeks, or until the ulcers had healed, whichever occurred sooner.⁹⁴ Of the 18 ulcers treated with Mepilex Border, eight healed, seven improved, and two deteriorated; of the 20 ulcers treated with Tielle, 10 healed, nine improved and one deteriorated. The two treatment groups showed no difference in terms of granulation, epithelialisation, exudate levels and wear time, however, there were more reports of tissue damage in the Tielle group (n=32) than in the Mepilex Border group (n=2). These differences were statistically significant ($p < 0.05$) over time. Similarly, there were more reports of maceration in the Tielle group (n=20) than in the Mepilex Border group (n=6) (Figure 17).

A descriptive study involving 15 cases of pressure ulcers on heels was undertaken to assess the efficacy of Mepilex Heel, a version of Mepilex designed specifically for application to heel pressure ulcers (Figure 18).⁹⁵ Ulcers were treated with Mepilex Heel for 4 weeks. Mepilex Heel conformed well to the heel shape, thereby minimising leakage and maceration. The dressing was easy to apply and to remove, with no aggressive adhesion to the skin or wound surfaces, thereby minimising pain and discomfort to patients during and in between dressing changes.

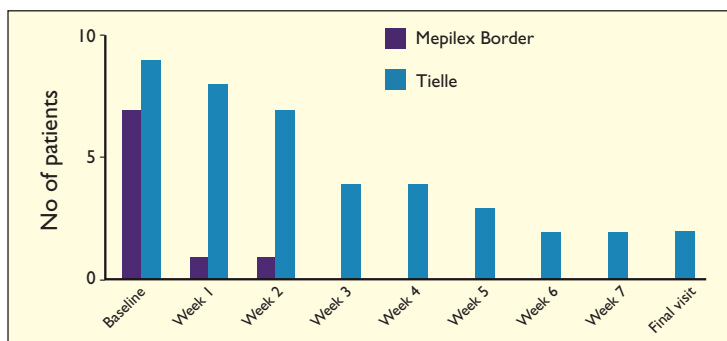


Figure 17. Mepilex Border (soft silicone dressing) versus Tielle (hydrolymer) in the treatment of pressure ulcers: number of patients demonstrating peri-wound trauma.⁹⁴

Oncology wounds

Due to the nature of the treatment, cancer therapies can be very intense and biologically disruptive to the patient. An unwanted side-effect of these therapies is the development of lesions or fungating wounds. Malignant wounds may occur in up to 5% of patients with cancer and 10% of patients with metastatic disease.¹⁷³ Fungating wounds are frequently malodorous with high levels of exudate, as well as being painful and susceptible to infection.

Mepitel has been used to good effect in the treatment of a wound associated with cancer which presented as extensive deeply ulcerated and necrotic areas on the head, neck and back resulting from mycosis fungoides, a cutaneous form of lymphoma.⁶⁸ Before treatment with the dressing with Safetac, the ulcers were associated with severe pain and purulent exudate which, together with their appearance, were having a significant impact on the patient's quality of life. The wound-related pain was greatly reduced from the first day of using Mepitel. Other authors have also demonstrated that Mepitel is useful in treating fungating wounds, stating that it can promote



Figure 18. Mepilex Heel applied to a heel pressure ulcer. Photograph courtesy of Frans Meuleneire, Woundcare Centre, Zottegem, Belgium.



re-epithelialisation in areas of moist desquamation and generally causes less damage to the fragile adjacent skin than other dressings.⁶⁹ It has also been observed that the use of Mepitel can lead to dramatic improvements in wound-related pain and the emotional state of patients.^{70,71}

A recent study has evaluated a regimen which included Mepilex Transfer and metronidazole to treat advanced cases of fungating wounds. The regimen improved the quality of patient care by reducing pain at dressing change and, by using Mepilex Transfer as the primary dressing, effectively channeling wound exudate away from the wound bed and into the secondary dressing. This secondary dressing could be changed by the patients as needed and enabled them to maintain their independence and dignity.¹⁰⁹

Skin disorders/damage

Dressings with Safetac have been demonstrated to be suitable for a variety of skin disorders, such as EB, and in the management of radiotherapy-induced skin damage.

Hereditary conditions

Epidermolysis bullosa is a term that is used to describe a group of genetically determined skin disorders that are associated with fragility of the skin and mucous membranes. The skin of patients with EB is typically associated with excessive blister formation which tends to heal with scars.¹⁷⁴ Patients can also experience secondary infections and hand deformities that require surgical intervention.¹⁷⁵ It has been reported that many so-called non-adherent dressings behave differently on the skin of those affected by EB, and that their removal can lead to additional trauma to the wound bed and surrounding skin.⁸⁰ On the other hand, dressing changes have been reported to be atraumatic and virtually pain-free when dressings with Safetac have been used to manage this challenging condition.^{78-82,100,101,112}



Figure 19. Mepitel applied to the hand of a patient with epidermolysis bullosa. Photograph courtesy of Jacqueline Denyer, Great Ormond Street Hospital, London, UK.

Lapioli-Zufelt and Morris⁷⁸ report on a case study of a three-year-old girl with EB lesions affecting her feet, elbows, buttocks, hands, face, neck and chest, which had been previously treated with a multitude of dressings that had proved to be painful and had not facilitated healing. Mepitel, on the other hand, did not adhere to the moist wound sites but it did adhere to the surrounding dry intact skin, therefore its removal was atraumatic. The porous design of Mepitel allowed exudate to pass to an outer absorbent dressing, as well as being permeable to an antibiotic ointment which allowed the effective management of secondary skin infections. The most dramatic response to Mepitel was the alleviation of the pain and anxiety produced by dressing changes, which relieved both the patient and the caregivers.⁷⁸ Mepitel was also pivotal in the treatment of a five-year-old boy's hand that had been badly affected by EB.⁷⁹ Complete epithelialisation occurred within 4 weeks and a major part of his previous hand function was restored. An improvement in the patient's psychological wellbeing and his self-esteem were reported. As well as being applied to the EB blisters (Figure 19), Mepitel can also be used to secure cannulae, if intravenous cannulation is required.⁸⁰

Schumann et al¹⁰⁰ report on 22 patients aged between 1 and 91 years with bullous skin diseases treated with Mepilex. Thirteen patients had EB and nine patients had acquired blistering diseases, e.g. toxic contact dermatitis or radiotherapy-induced blisters. Good wound healing was observed with fast epithelialisation in the majority of patients. Mepilex gave excellent protection and did not tear fragile EB skin. Minimal pain was experienced during dressing changes and no allergic reactions were reported. Mepilex was easy to handle and enabled some EB patients to change their dressings without assistance.¹⁰⁰

Mepilex has also been reported to be beneficial in the management of a 10-year-old patient with EB who presented with blisters and erosions at the urethral meatus which had caused fusion of the meatal opening. In order to micturate, the patient had to tear apart the fused tissue, resulting in considerable pain. Prevention and re-stenosis of the urethral meatus was accomplished with the application of Mepilex to the urethral meatus after each micturition, where it remained until the next episode of micturition. The article states that in the 10-month period after initiation of the care regime, there had been no recurrence of the stenosis.¹⁰¹ Mepilex has also been used in conjunction with Mepitel to provide protection from mechanical forces.⁸²

Another skin disorder in which dressings with Safetac have proved to be beneficial is aplasia cutis congenita, a rare anomaly presenting with absence of skin, most commonly on the scalp. The current management trend for neonates presenting with this condition is conservative as the outcome of surgical reconstruction is unpredictable. In a case study involving a premature infant, changing the dressing regime to Mepitel (with





absorbent gauze when necessary) was reported to be atraumatic. Compared to the previous dressing regime, the new one required fewer dressing changes and the patient made good progress.¹⁷⁶

Graft-versus-host disease

Graft-versus-host disease is a frequent complication of allogeneic bone marrow transplants and may occur as a result of radiation or chemotherapy. In this disease the donor's bone marrow attacks the patient's organs and tissues, impairing their ability to function, and increasing the patient's susceptibility to infection. It may present as a maculopapular rash that can be pruritic or painful, progressing further to bullae and skin sloughing. Vedlinski¹⁰⁸ presents a case study of a patient with severe tissue damage all over his body as a result of graft-versus-host disease. The patient was unable to move in bed because of the excruciating pain caused by the lesions. However, within 10 days of commencing treatment with antibacterial agents, analgesics and Mepilex Transfer, the lesions had healed and the patient had significantly reduced levels of pain and a much better quality of life.¹⁰⁸

Radiotherapy-induced skin damage

Radiation-induced skin reactions, a recognised adverse effect of radiotherapy, can be painful, irritating and uncomfortable. They can also be a focus for infection, affect patients' quality of life and ultimately prevent the completion of treatment.¹⁰⁴ A prospective study of patients undergoing radiotherapy for malignant disease assessed the mechanical protection afforded by Mepitel to the skin. The silicone-coated net dressing did not cause any additional skin irritation and was shown to be suitable for the management of both dry and moist desquamation, the latter being particularly difficult to manage with conventional dressings, as it is associated with fragile skin that is easily damaged by the removal of dressings that can adhere to the drying serous fluid on the skin surface. When applied over ulcerative wounds, Mepitel was found to be easy to remove and did not cause damage to the newly formed epithelium.⁸³

The use of Mepilex Transfer has also been shown to be advantageous in patients that have such skin damage. It enhanced patients' quality of life considerably in that it reduced discomfort from skin-on-skin and clothes-on-skin friction. Ultimately this benefited patients with better sleeping at night and being able to wear more normal clothes.¹¹³ In a subsequent case study evaluation involving patients with perineal and perianal wounds that had received radiotherapy, it was observed that the use of Mepilex Transfer consistently resulted in decreased pain and improved quality of life.⁸⁵

In a more recent observational study of patients with radiation-induced skin reactions (dry and moist desquamation), Mepilex Lite was found to be associated with minimal pain at dressing change.¹⁰⁴ It was also reported that the dressing was easy to lift and adjust

without loss of adhesion, that it had a soothing or cooling effect on the skin, and that it had no adverse effect on wound healing. Some patients reported a more normal sleep pattern with Mepilex Lite in situ.

Peristomal skin complications

Peristomal wounds are generally painful, resulting in anxiety and frustration for both patients and clinicians. They can also lead to reduced wear time and increased cost and usage of supplies. Peristomal irritant contact dermatitis and peristomal pyoderma gangrenosum are conditions that can result in a significant loss of skin surface, as well as pain and discomfort for ostomy patients. 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 a reduction in both trauma and pain associated with pouch changes.¹⁷⁷ Similarly, Mepilex Border and Mepilex Border Lite have been determined to be an effective skin barrier assisting with preservation of skin integrity, protection of fragile wound tissue, and containment of stools (by affixing of a pouch to the top of the dressing) in a case study series involving three infants.^{146,178}

Scar management

Resolution of inflammation during healing minimises scar formation, whereas persistence of the primary insult results in continued inflammation and chronic healing. Prolonged inflammation and proteolytic activity prevent healing as evident in ulcerative lesions.¹⁷⁹ Continued fibrosis in the skin leads to scarring and, potentially, disfigurement as a result of progressive deposition of matrix. The most commonly encountered scar types include hypertrophic, keloid, widened, and contracture.^{180,181}

Hypertrophic scars are seen in approximately 50% of wounds after surgery and more than 50% of healed deep burns.¹⁸² They are generally red, raised and itchy and occur within the boundaries of wounds. Onset is clinically evident by 4 weeks after trauma with progression over months and some late resolution. The incidence of hypertrophic scarring is greater with increased wound inflammation and for wounds that are open for more than 3 weeks.^{183,184} Keloid scars, although somewhat similar in appearance to hypertrophic scars, generally extend beyond the borders of the original scar: they affect all races but are 15 times more likely to occur in patients with darker skin. The incidence of keloid scars is about 10% in wounds in the high-risk groups. Onset is delayed at least 3 months after injury with progression but no resolution. Areas most commonly involved are the shoulders, neck, anterior chest, upper arms, and face. Keloid scars also form even if wounds are closed rapidly, while hypertrophic scars do not occur with early wound closure.^{183,185}



Table 10. Scar management - key study

Reference	Study type	Sample size	Wound type(s)	Dressing(s) with Safetac	Comparator dressing(s)	Main outcome measures	Main results
Majan ¹³¹	RCT	11	Post-operative hypertrophic scars	Mepiform	'Left alone' management	Condition of scar, measured using Vancouver Scar Scale	Scars treated with Mepiform demonstrated greater and more rapid improvement than those in the 'left alone' group

RCT = Randomised controlled trial

Contracture scars are particularly severe and usually occur as a result of losses of large areas of skin, e.g. following burn injuries, and in badly aligned surgical wounds not corresponding to Langer's lines. These scars cause the edges of the skin to pull together, affecting the adjacent muscles and tendons, thereby restricting normal movement and resulting, in some cases, in the need for z-plasty or skin grafting. Widened scars appear when surgical wounds are stretched as a result of skin tension during the healing process. They are generally pale in colour, flat, soft and symptomless, but can be aesthetically displeasing.¹⁸¹ Whatever the type, scars are disfiguring and can interfere with the normal functioning of the primary organs that they affect, e.g. the skin and its associated appendages.

A variety of treatments and techniques have been employed over the years to treat hypertrophic and keloid scars. These have included intra-lesional injections of corticosteroids, pressure garment therapy, radiotherapy, laser therapy and cryotherapy.¹⁸⁶

Topical silicone gel sheeting has been used successfully for over 20 years to treat hypertrophic and

keloid scars.¹³² Its use in this indication is supported by data generated from a number of clinical evaluations,^{131,187-195} and international clinical recommendations on scar management.¹⁹⁶ Although the therapeutic mechanism by which this intervention exerts its beneficial effect has not been fully elucidated, it has been proposed that it may be due to the silicone dressings aiding in the hydration of the damaged tissue.¹⁹⁷ More recently, it has been proposed that there are two mechanisms for the effectiveness of silicone sheets in the prevention and treatment of hypertrophic scarring. Firstly, silicone sheets limit moisture loss from the skin surface and aid in hydration and secondly, the sheets do not limit the access of oxygen to the surface of the skin due to their exceptionally high permeability. This causes a localised increase in oxygen tension leading to a down-regulation of signals that stimulate growth near the skin surface, thus preventing/reducing scar formation.¹⁹⁸

Mepiform, a soft silicone scar dressing with Safetac, has been evaluated in a number of studies for the treatment of hypertrophic scars. Saulsberry et al¹²³ report on four cases where Mepiform was utilised for scar management following surgical incisions and burns. Throughout the treatment period (at least 6 months for each patient), the dressing maintained a low profile and remained in situ under a compression garment without edge roll or interfering with joint mobility. The scars, originally hyperpigmented, returned to a more normal pigmentation with a smoother and more flexible nature.¹²³ The use of Mepiform was also associated with a significant improvement in hypertrophic scars in a study involving 12 patients.¹²⁴ An observational study undertaken to evaluate the effectiveness of Mepiform on post-burn and other traumatic scars of both paediatric and adult patients (n=87) in an out-patient setting found that the adherence and simplicity of the application of Mepiform appear to enhance patient compliance, as well as improving scar quality and patient comfort.¹²⁵ These findings are also reflected in other case study evaluations of Mepiform.¹²⁶

In an RCT on 11 patients with postoperative hypertrophic scars, participants were randomly allocated

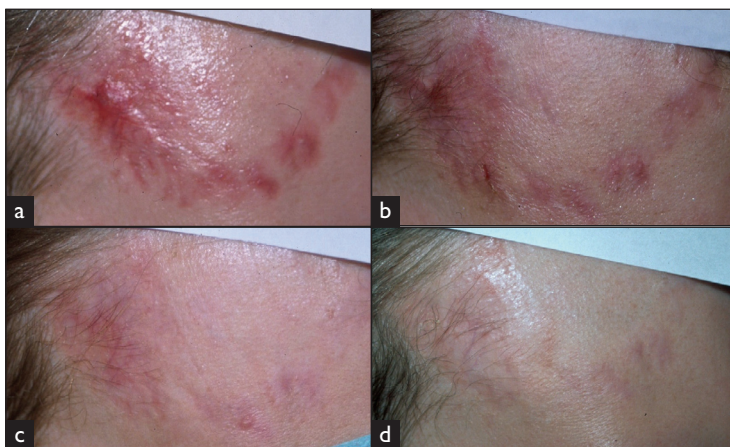


Figure 20: Use of Mepiform to prevent scarring in an acute traumatic wound. a) Hypertrophic scar tissue before treatment; b) after 2 months of treatment; c) After 5 months of treatment; d) After 11 months of treatment. Photographs courtesy of Frans Meuleneire, Woundcare Centre, Zottegem, Belgium.

to treatment with Mepiform or 'left alone' management (Table 10). Patients treated with Mepiform showed greater and more rapid improvements than those in the 'left alone' group, as measured by the Vancouver Scar Scale. Commenting on their results, the authors conclude that, as Mepiform is self-adhesive and its use limits damage to the stratum corneum on removal, it gives it an added value compared with non-adhesive silicone gel dressings.¹³¹ This has been further demonstrated in a case study in which the early use of Mepiform successfully prevented scarring of a severe forehead laceration (Figure 20).⁶²

Adjunct to negative pressure wound therapy

Negative pressure wound therapy (NPWT) has been shown to dramatically enhance the healing of a variety of wound types. In a series of case studies involving patients with different wound types (pressure ulcer, traumatic wound, surgical wound) being treated with NPWT, dressings with Safetac (Mepitel, Mepilex Lite, and Mepilex Ag) were used to good effect in protecting peri-wound skin and delicate deep structures.⁶⁶ The fact that these dressings are proven to be atraumatic and to minimise wound-related pain makes them particularly suitable for managing this important aspect of wound care. It has also been reported that the problem of ingrowth of granulation tissue into the polyurethane foam, sometimes observed in wounds being managed with NPWT, can be avoided by interposing Mepitel.¹⁹⁹ Dunbar et al⁶⁰ suggest that Mepitel can be used as an interface between the wound and the NPWT dressing as a means of reducing pain and anxiety, as well as minimising the need for analgesia. They also point out that the porous nature of Mepitel allows the NPWT device to effectively remove wound drainage while allowing for optimal granulation tissue formation.⁶⁰

Conclusion

There is extensive evidence of the clinical efficacy of dressings employing Safetac soft silicone adhesive technology in the management of a wide range of wound types and skin lesions in both adult and paediatric populations. In addition to minimising trauma at dressing change, dressings with Safetac 'have been studied and documented to be less painful, before, during and after dressing change when compared to other advanced dressings with traditional adhesives'.¹⁴ They have been proven to have excellent exudate handling properties, to be easy to use, and to be highly conformable. These properties all contribute to providing environments that are conducive to wound healing, as well as having a positive effect on the quality of life of patients. Importantly, a number of clinical evaluations have also indicated that dressings with Safetac are cost-effective.

Having established that the clinical challenges of dressing-related pain and trauma can be overcome, it is the duty of clinicians to identify the most appropriate

dressings for their patients that will address these problems. As this document has shown, there is a wealth of evidence that dressings using Safetac adhesive technology fully address these issues, while also fulfilling many of the criteria of an ideal wound dressing.

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