# Evidence for atraumatic soft silicone wound dressing use

The problem of dressings sticking to the wound bed, or dressings that cannot be easily removed from the skin surrounding the wound are commonplace. The result is trauma to the delicate tissues in the wound, or 'skin stripping' and pain. This article discusses the causes of traumatic injuries and pain associated with the removal of dressings and reflects on the term 'atraumatic dressings' coined to describe products that are less likely to cause such problems in clinical practice (Thomas, 2003). A review of the scientific and clinical literature relating to a new category of products, based upon soft silicone Safetac<sup>®</sup> technology, is included.

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# **KEY WORDS**

Adherence Atraumatic Soft silicone Safetac<sup>®</sup> technology Mepitel<sup>®</sup> Mepilex range<sup>®</sup>

hen selecting wound dressing products, there are significant practical advantages in separating the functions of the primary wound contact layer from those of the secondary, absorbent layer. To do so provides the clinician with a degree of flexibility when selecting or constructing a dressing system for a particular wound at a given stage in the healing cycle. The important contribution made by the secondary dressing is often overlooked during this selection process, but can be vital in determining the success, or otherwise, of a particular treatment, especially when using products such as hydrogels or alginate sheets (Thomas, 1998).

This review considers the key aspects of dressing performance, the so-called 'ideal dressing', as described by many authors (Winter, 1975; Dale, 1997; Morgan, 1998), which relate to performance including damage to the

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healing wound and surrounding skin and pain. Once adherence has occurred, dressing removal can be very painful and may cause damage to the fragile, newlyformed epithelium leading to extended healing times and an increased risk of scar tissue formation.

#### Mechanisms of dressing adherence

The main cause of adherence of dressings to wounds (Figure 1) was suggested in 1975 to be 'the mechanical key formed by proteinaceous exudate, which on drying becomes a good glue' (Winter, 1975). This theory has now been scientifically validated (Rogers et al, 1999). Winter also recognised a secondary mechanism of adherence in which new tissue grows into the structure of the dressing and thus incorporates some of the components into the healing wound. Dried out dressings and excessive dressing adherence are the major factors in wound pain at dressing change (European Wound Management Association, 2002).

Most dressings require the use of either a retaining bandage or some form of adhesive layer to keep them in position. This adhesive layer may be separate, or be an integral part of the product itself, forming an island or bordered dressing in which the lowadherent pad is located centrally on a sheet of plastic, foam, or fabric, coated with adhesive. While this adhesive area does not come into contact with the wound and therefore cannot cause damage to the newly formed tissue, repeated removal of such dressings can damage ('strip') the surrounding skin, especially if the patient is elderly or the skin is particularly fragile.

A number of surveys have been undertaken in recent years to identify practitioners' views on wound-related trauma and pain. The first of these was conducted in the UK (Hollinworth and Collier, 2000). The results indicated that although prevention of pain and/or trauma is considered by the majority of practitioners to be their principal consideration when changing dressings, there is now consensus that atraumatic dressings are best able to overcome these problems. Of particular concern was the fact that 39% of those who responded were not aware of any products specifically designed to



Figure 1. Dressing adherence.

overcome the problems of adherence, while 60% identified no less than 28 dressings, most of which are not claimed by their manufacturers to possess such a property. The reason for this confusion is not clear, but it may be due in part to the somewhat non-specific and poorly defined nature of the term 'lowadherent' and a failure to appreciate the performance characteristics of many of the dressings in current use.

Findings from this survey prompted a larger international survey (Moffatt et al, 2002), in which questionnaires were sent to 14,657 practitioners in 11 countries including the UK.A total of 3,918 guestionnaires were completed and returned (27% response rate). The results of this survey were generally in agreement with those of the first in that pain and trauma were ranked as the most important factors to consider when changing a dressing. Pain was most commonly associated with dressing changes and was related to dressings drying out or adhering to the wound bed; factors that were also considered to be responsible for wound trauma. Perhaps not surprisingly, painfree removal and non-adherence were considered to be the most important characteristics of a dressing and products such as hydrogels, gel-forming fibres and the soft silicone products with Safetac<sup>®</sup> technology were generally highly rated in this regard. A European Wound Management Association position document Pain at Dressing Changes, has resulted from this and other similar research (European Wound Management Association, 2002).

Pain and trauma at dressing change can be minimised through appropriate measures; these are the subjects of a current clinical best practice statement (Independent Advisory Group, 2004; Hollinworth, 2005).

In terms of their ability to prevent trauma and pain, dressings fall broadly into three main categories as shown below, although it is recognised that the value of these definitions is somewhat limited, as adherence of a dressing to a wound can be influenced by many different factors:

- Adherent those that most practitioners would consider to be likely to adhere to any type of drying wound. For example, simple dressing pads or cotton gauze
- Dow adherent products with a wound-contact surface that is designed specifically to reduce adherence, for example, some absorbent wound dressings
- Non-adherent those that maintain a moist gel layer over the wound, for example, hydrocolloids, hydrogels, hydrofibre and alginates. These would not be expected to adhere — provided that they are not allowed to dry out. The performance of some of these materials will therefore be largely determined by the choice of a secondary dressing where this is required. Only those dressings that can maintain a moist environment and have been proven in clinical practice can genuinely be termed non-adherent.

#### **Atraumatic dressings**

It is important to recognise that this simple classification only relates to the interaction that takes place between the dressing and the wound itself, it takes no account of possible trauma caused to the surrounding skin by removal of adhesive products such as hydrocolloids, adhesive films and selfadhesive foams. It has been proposed that a new term 'atraumatic dressings' be adopted to take account of these factors and more accurately define products which, on removal, do not cause trauma either to newly formed tissue or to the peri-wound skin (i.e. skin stripping) (Thomas, 2003).

Recently a category of dressings has been introduced which are claimed to overcome the twin problems of adherence to the wound and damage to the surrounding skin. They rely upon an adhesive technology (Safetac) involving the use of 'soft' silicone, a material that adheres readily to intact dry skin but does not stick to the surface of a moist wound and does not cause damage upon removal (Dykes et al, 2001; Dykes and Heggie, 2003). The literature (as of March 2004) relating to this new group of products is reviewed below.

# Atraumatic soft silicone dressings: a literature review

Mepitel<sup>®</sup> (Mölnlycke Healthcare, Dunstable) (Figures 2 and 3) was the first product of this category to be introduced. It is a porous, semitransparent wound contact layer consisting of a flexible polyamide net coated with soft silicone. The nature of the bond that forms between Mepitel and the skin surface allows the dressing to be removed without causing trauma. pain, or damaging delicate new tissue at the wound margin. The gentle adhesion between the dressing and the intact skin inhibits the movement of exudate from the wound onto the surrounding area and helps to prevent maceration by forming a seal between the dressing and the intact skin.

#### **Clinical use of Mepitel**

Many of the published clinical trial reports include paraffin gauze (tulle gras) as the comparator dressing. This is a reflection of clinical practice then and now, in the UK and mainland Europe where paraffin gauze is (wrongly) assumed to be nonadherent (Krasner, 1991). Mepitel has been evaluated as an alternative to conventional treatments, including paraffin gauze, for the fixation of skin grafts in children. It has also been compared with paraffin gauze on newly grafted wounds in a prospective randomised trial (Vloemans and Kreis, 1994: Platt et al. 1996). Adamietz et al (1995) evaluated Mepitel as a method of protecting skin during radiotherapy for malignant disease. The silicone-coated net was shown to cause no additional irritation of irradiated skin and was suitable for the treatment of both dry desquamation and the moist desquamation that occurs with high doses of radiation. This latter condition is particularly difficult to manage with conventional dressings, as the skin is very fragile and easily damaged by the removal of dressings that can adhere to the drying serous fluid on the skin surface. When applied over ulcerative wounds, the dressing was easy to remove and did not cause damage to the newly formed epithelium.

The use of Mepitel in more extensive wounds resulting from wide local excision of skin tumours has been investigated (Dahlstrøm, 1995).The



#### Figure 2. Mepitel applied to a burn.

reduction in pain associated with the use of Mepitel makes it particularly useful for the treatment of paediatric patients. Two studies have compared Mepitel with silver sulphadiazine (SSD) in the treatment of burns (*Figure 2*) and scalds and a third in the treatment of fingertip injuries (Bugmann et al, 1998; Gotschall et al, 1998).

Hand injuries are common in children and can be a source of considerable pain and stress to the patient. In a prospective randomised trial, Mepitel was compared with paraffin gauze in the treatment of 45 children with isolated fingertip injuries (O'Donovan et al, 1999). In a second paper involving the management of hand wounds, Mepitel was compared with paraffin gauze and Adaptic<sup>™</sup>, (Johnson & Johnson, Ascot) a cellulose acetate non-adherent dressing coated with a petrolatum emulsion (Terrill and Varughese, 2000). Mepitel, they suggest, could be used with advantage on wounds such as raw nail beds, as reported some years earlier by Williams (1995) who also described its use following traumatic amputation of the fingers, and in the treatment of a dehisced abdominal wound.

Taylor (1999) recorded how the dressing improved the quality of life in a patient with severe mycosis fungoides, a progressive skin tumour, which resulted in the formation of extensive ulceration over the scalp, neck and back. Gates (2000) similarly described how the dressing reduced the pain from an extensive arterial leg ulcer and improved the condition of the surrounding skin. In an article focusing on skin tears (*Figure 3*), including pre-tibial lacerations, a

group of 59 patients with 88 skin tears (category I and II) were treated with Mepitel (Meuleneire, 2002). The majority (83% n=73) of these lesions healed in 8 days.

The genetic skin disorder, epidermolysis bullosa (EB) is particularly difficult to manage owing to the fragility of the dermal-epidermal junction (Denyer, 2000; Bello et al, 2003). Patients typically develop blisters, often as a result of minor trauma, which is caused by separation of the component layers of the skin. Several types of EB have been described: intra-epidermal; junctional (between the epidermis and dermis); and intradermal (Schober-Flores, 1999). Treatment involves avoiding trauma, and dressing application. The soft silicone dressings with Safetac technology have been used successfully in this challenging indication (Williams, 1995; Spitz and Rosslein, 1998; Hall, 2004).

In summary, clinical experience with Mepitel suggests that in order to function correctly, the dressing needs to be kept in intimate contact with the surface of the wound. Wounds on convex areas present few problems but on concave, contoured or jointed areas, adequate padding must be applied to exclude voids beneath the dressing where fluid might accumulate. Where

clinically indicated, topical steroids or antimicrobial agents can be applied either over or under Mepitel (see www.dressings.org/Dressings/mepitel. html). Depending on the nature and condition of the wound, Mepitel may be left in place for extended periods, up to 7–10 days in some instances, but the outer absorbent layer should be changed more frequently as required. When Mepitel is used for the fixation of skin grafts and protection of blisters, it is recommended that the dressing should not be changed before the fifth day post-application. As with all types of dressings, wounds should be regularly monitored for signs of infection or deterioration. When used on bleeding wounds, or wounds producing high viscosity exudate, Mepitel should be covered with a moist absorbent dressing pad. If used on burns treated with meshed grafts, or applied after facial resurfacing, imprints can occur if excess pressure is placed upon the dressing. Following facial resurfacing it is recommended that the dressing be lifted and repositioned at least every second day.

The Mepilex<sup>®</sup> range of soft silicone dressings Mepilex<sup>®</sup> (*Figure 4*)(Molnlycke Health Care, Dunstable) is an absorbent dressing made from polyurethane foam, the outer surface of which



Figure 3. Mepitel applied to a skin tear.

is bonded to a vapour-permeable polyurethane membrane that acts as a barrier to liquid and microorganisms. This membrane, which has a wrinkled appearance, is applied in this way to accommodate the slight swelling of the dressing that occurs as the dressing absorbs exudate. The inner surface of the foam is coated with a layer of soft silicone that helps to hold the dressing in place without sticking to the surface of the wound or causing trauma to delicate new tissue on removal.

#### **Mepilex Border**

Mepilex Border (Figure 5) is an absorbent self-adhesive island dressing with a perforated soft silicone adhesive wound contact layer. The absorbent core of the dressing consists of three components: a thin sheet of polyurethane foam; a piece of nonwoven fabric; and a layer of superabsorbent polyacrylate fibres. The first layer, the polyurethane foam, transports the exudate away from the wound to the second layer. This non-woven layer spreads the exudate horizontally and transports it to the third layer, a highly absorbent material. The vapour permeable backing film evaporates the exudate from the wound pad. This fluid handling system minimises the risk of maceration. In addition, the Safetac<sup>®</sup> adhesive layer helps to prevent maceration by inhibiting the lateral movement of exudate from the wound to the surrounding skin.

In a multicentre, randomised, controlled study on 38 patients with stage II (European Pressure Ulcer

Advisory Panel, 2003) pressure ulcers, Mepilex Border was compared with Tielle<sup>™</sup> hydropolymer foam (Meaume et al, 2003). In a treatment period of 8 weeks, or healing, the parameters of wound size, granulation. epithelialisation, exudate, tissue damage, maceration, leakage, and frequency and ease of dressing changes were assessed. A total of 18 patients were randomised to Mepilex Border and 20 to Tielle dressings. Results were 8/18 (44%) healed, seven improved, two deteriorated and one died in the Mepilex group and 10/20 (50%) healed, nine improved and one deteriorated in the Tielle group. The two groups showed no differences in terms of granulation, epithelialisation and exudate, and wear times were also similar; dressing changes occurring every 6 days. The main differences in outcomes were seen for tissue damage and maceration. In the Tielle group, there were 32 reports of tissue damage and two in the Mepilex Border group. These differences were statistically significant over time. Maceration occurred six times in the Mepilex Border group and 20 times in the Tielle group.

Both Mepilex and Mepilex Border are promoted for use on many types of exuding wounds including leg and pressure ulcers, and, traumatic wounds. They may also be used safely under compression bandaging in the management of venous leg ulcers. This aspect of dressing use has given rise to controversy as many practitioners advise against



Figure 4. Mepilex.



#### Figure 5. Mepilex Border.

the use of adhesive dressings in this indication, owing to the risks of trauma on removal, and to allergic contact dermatitis from adhesives (Cameron, 1998; Zillmer et al, 2004).

#### **Mepilex Transfer**

Mepilex Transfer is a thin, conformable soft silicone dressing that conforms closely to the wound and the surrounding skin, even where the surface is uneven. The seal that is formed between the dressing and the intact skin ensures that exudate moves vertically through the dressing into a secondary absorbent pad.

#### **Mepilex Lite**

Mepilex Lite (*Figure 6*) is a thin dressing comprising an outer polyurethane film, an absorbent layer, and, a soft silicone wound contact layer. It is intended for the management of wounds with low to medium exudate levels where a conformable, thin, and gentle dressing is required, e.g. diabetic foot ulcers and radiation damaged skin.

#### **Mepilex Border Lite**

Mepilex Border Lite is the newest addition to the Mepilex range. Mepilex Border Lite is a thinner and less absorbent version of Mepilex Border. It has been designed for situations where clinicians require a thinner and more conformable dressing than Mepilex Border for anatomical or practical reasons, and where fluid handling requirements are lower. Clinical indications for Mepilex Border Lite include patients with non-low exuding wounds such

## **Product REVIEW**



#### Figure 6. Mepilex Lite.

as leg and foot ulcers, pressure ulcers and traumatic wounds for example, blisters and skin tears. Mepilex Border Lite is available in 5 sizes including a small size (4cmx5cm) particularly suitable for finger or toe injuries.

All the dressings in the Mepilex range will, to some degree, maintain a moist wound environment while minimising the risk of maceration, although in the case of Mepitel and Mepilex Transfer, the moisture content of the wound will be greatly influenced by the choice of secondary dressing. Mepilex range of dressings have an intrinsic absorbent layer and do not require secondary dressings (see www. tendra.com).

Laboratory-based studies (Dykes et al, 2001; Dykes and Heggie, 2003) have examined the effects of repeated application and removal of Mepilex Border to test sites on the backs of volunteers compared with that of four other adhesive dressings: Allevyn Adhesive<sup>™</sup> (Smith and Nephew, Hull), Biatain Adhesive<sup>™</sup> (Coloplast, Peterborough), Tielle (Johnson and Johnson, Ascot) and DuoDERM<sup>™</sup> Extra Thin<sup>™</sup>(ConvaTec, Ickenham). Dressings were changed every 24 hours and the force required to remove each sample was determined using a jig that removed each sample at a constant speed of 25 mm per second with a peel angle of 135 degrees. The results indicated that although there was reasonable correlation between the two parameters for most of the dressings examined, unexplained results were obtained with Biatain Adhesive, which caused a significant loss of stratum

corneum but had the lowest peel force of all the products examined. Mepilex Border, which had the second lowest peel force, caused the least damage to the stratum corneum with statistical significance, producing results that were no different to the control site. Although this study does not reflect normal usage of these dressings (i.e. left in place for several days), it does demonstrate the 'skin-friendly' nature of Safetac technology. Recent studies by Zillmer et al (2004) corroborate these findings. Using the techniques of trans-epidermal water loss measurement (TEWL; a recognised non-invasive measure of skin barrier function) (Pinnagoda et al, 1990), hydration and erythema measurements, Mepilex Border was compared with DuoDERM Extra Thin, Tielle and Biatain in 45 patients with low exudate or recently healed leg ulcers. Results showed that of the four dressings tested, the Mepilex Border was most effective in maintaining skin barrier function, i.e. was least traumatic in the context of skin stripping on removal.

The risks of skin and wound bed trauma, together with the resultant patient pain often dictate the use of non-adherent dressings. Given the proven benefits of Safetac technology, this range of atraumatic dressings can be used safely and effectively in all wound types. This is reflected in a current clinical best practice statement. (Independent Advisory Group, 2004).

#### Conclusion

The literature cited in this review clearly identifies that pain and trauma associated with dressing removal is of major concern to patients and healthcare professionals alike. Furthermore, trauma to the wound bed and surrounding skin that occurs with excessive dressing adhesion to fragile skin prolongs the duration of the wound and increases treatment costs and morbidity.

It is also clear that there is considerable confusion in the minds of users concerning the use of terms such as adherent and adhesive, which if used inappropriately will provide a totally false impression of the performance of a dressing or family of dressings. The term low-adherent seems particularly inappropriate or misleading if applied to a self-adhesive dressing unless it is fully understood that in this context adherence, or the lack of it, relates specifically and solely to the interaction between the dressing and the wound.

The term atraumatic dressings coined by Thomas (2003) should:

- Be adopted to describe products which during wear and on removal, do not adhere and cause trauma either to the newly formed tissues in the wound bed, or to the periwound skin
- Be applied to adhesive and nonadhesive dressings.

It should be the responsibility of the manufacturers of such dressings to demonstrate by means of clinical studies that their products comply with this requirement before they are described in this way. The results of the current literature review clearly suggest that dressings with soft silicone Safetac<sup>®</sup> technology, by virtue of clinical and laboratory evidence, appear to be atraumatic. WUK

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# **Key Points**

- Wound dressings are often described as 'adherent' or 'adhesive'; these terms are sometimes incorrectly used interchangeably, causing confusion and misunderstanding about the properties of the products concerned.
- Some dressings have a socalled 'non-adherent' or 'low-adherent' pad. Depending upon the nature of the wound contact layer and the strength of the adhesive, traumatic removal of such dressings may damage the fragile, newlyformed epithelium, leading to extended healing times and/or causing further trauma to the surrounding skin.
- The term 'atraumatic dressings' has been proposed to take account of both these factors and more accurately define products that, on removal, do not cause trauma either to newly formed tissue or to the peri-wound skin.
- Soft silicone dressings with Safetac<sup>®</sup> technology meet these criteria and can, therefore, reasonably be described as atraumatic.
- A clinical best practice statement on minimising trauma and pain in wound management supports the use of soft silicone dressings incorporating Safetac<sup>®</sup> technology.