Mepitel: a non-adherent wound dressing with Safetac technology

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Abstract

Objective: Wound pain and tissue trauma are two main considerations of wound management, and appropriate dressing selection plays an important role in both. Traditional dressings may adhere to wounds resulting in significant pain and trauma to new tissue upon removal. The development of primary wound contact materials has provided a unique approach to solving this problem. This article aims to aid clinicians in identifying wound types on which Mepitel®, a primary wound contact dressing with Safetac® soft silicone adhesive technology, can be used by summarizing the published clinical literature relating to its use. Method: Searches of bibliographic databases and internet sites were supplemented with manual searches of journals of relevance to wound management for clinical data relating to the use of Mepitel. Results: The literature search identified a number of articles, presenting data generated from randomized controlled trials, non-randomized controlled trials and case study evaluations of Mepitel on a wide range of wound types and skin injuries. Conclusion: The results of the clinical evaluations demonstrate that Mepitel is associated with atraumatic and virtually pain-free dressing changes. The dressing with Safetac can be used cost-effectively in the treatment of a wide range of wound types and skin injuries.

Key words: Non-adherent wound contact layers ■ Safetac ■ Wound pain ■ Wound care

he principle of moist wound healing was a key discovery in the development of effective wound dressings (Winter, 1962). Subsequent clinical and experimental data have identified the characteristics required for an ideal dressing (Thomas, 2008; *Table 1*), and advanced wound care technologies have been developed to provide modern dressings that effectively manage and/or interact with the wound environment to aid healing. These dressings successfully compete with, and are significantly better than, traditional wound care products such as cotton gauzes, absorbent pads and bandages.

Wound pain and primary contact layers

Many healthcare professionals have realized that wound healing can be an unachievable goal in some cases, but in these

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situations, wound trauma and pain are key considerations. Chronic wound pain is psychologically distressing, resulting in physiological stresses on the body, which can compromise wound healing and ultimately affect the patient's quality of life (Soon and Acton, 2006).

The removal of dressings without causing pain to the patient and further trauma to the wound and the peri-wound skin is now recognized as an important consideration in wound management, especially at dressing change, the time of greatest perceived pain (Thomas, 2003). In recognition of this problem, the European Wound Management Association (EWMA, 2002) and the World Union of Wound Healing Societies (WUWHS, 2004; 2007) have developed position documents with clinical recommendations to assess and manage wound pain.

Conventional wound dressings, such as paraffin gauze, traditionally cause trauma and pain to wounds at dressing change. These dressings can adhere to wounds as exudate dries, and capillary loops and granulation tissue can grow through the fabric of the dressings, so causing pain and trauma to fragile epithelial tissue on removal (Winter, 1975). Unfortunately, several modern dressing types still give rise to pain, for example different types of adhesives are used on

Table 1. Performance requirements of an ideal dressing

Primary requirements

- · Associated with minimal pain during application/removal
- · Does not release particles/fibres into wound
- ${\boldsymbol \cdot}$ Forms effective water-resistant seal to peri-wound skin
- · Easily removed without causing trauma/skin stripping
- ${\color{red} \cdot} \ \ \text{Free of toxic/irritant extractables}$
- Maintains wound and surrounding skin in optimum state of hydration
- Maintains wound at optimum temperature/pH
- · Requires minimal disturbance/displacement
- · Provides effective bacterial barrier
- Protects peri-wound skin from potentially irritant wound exudate/excess moisture

Secondary requirements

- Exhibits effective wound cleansing (debriding) activity
- Has ability to remove / inactivate proteolytic enzymes in chronic wound fluid
- · Has odour absorbing / combating properties
- Possesses antimicrobial activity
- · Possesses haemostatic activity

Adapted from: Thomas (2008)

Table 2. Examples of primary wound contact dressings

Dressing descriptions	Proprietary names		
Soft silicone wound contact	Mepitel (Mölnlycke Health Care)		
Soft silicone temporary skin replacement biopolymer	Silon-TSR (Bio-Med Sciences)		
Soft polymer	Physiotulle (Coloplast Ltd) Tegaderm Contact Dressing (3M Health Care)* Urgotul (Urgo Ltd)		
Knitted viscose (silicone-coated)	N-A Ultra (Johnson & Johnson Medical)		
Knitted polyester (triglyceride-impregnated)	Atrauman (Hartmann)		
* Formerly Tegapore			

dressings that can vary from very strong to weak and, as a consequence, can be very aggressive or mild in terms of their effects on skin and wounds (Cutting, 2008).

In recent years, the development of primary wound contact materials has provided a unique approach to solving this problem. These dressings act as an interface layer between the wound bed and the secondary absorbent dressing, and aim to provide an optimum environment for wound healing. Importantly, these primary wound contact dressings address

Table 3. Tabular summary of published clinical data relating to Mepitel

Reference	Туре	Sample (n)	Wound type/skin injury	
Vloemans and Kreis (1994)	NRCT	38	Skin grafts	
Adamietz et al (1995)	NRCT	21	Radiation-induced skin damage	
Dahlstrøm (1995)	RCT	64	Split skin grafts	
Williams (1995)	CS	4	Surgical; traumatic digit amputation, toenail avulsion	
Platt et al (1996)	RCT	38	Split skin grafts	
Bugmann et al (1998)	RCT	76	Burns	
Gotschall et al (1998)	RCT	63	Partial thickness burns	
Lapioli-Zufelt and Morris (1998)	CS	1	Epidermolysis bullosa	
O'Donovan et al (1999)	RCT	45	Fingertip injuries	
Taylor (1999)	CS	1	Mycosis fungoides	
Gates (2000)	CS	1	Leg ulcers	
Newman et al (2000)	NRCT	125	Laser skin resurfacing	
Terrill and Varughese (2000)	RCT	99	Surgical (hands)	
Williams et al (2000)	CS	2	Partial thickness burns	
Meuleneire (2002)	NRCT	59	Skin tears	
Young (2002)	CS	1	Diabetic ulcers	
Sutton (2003)	CS	1	Skin tears	
Burton (2004)	NRCT	52	Surgical; traumatic	
Hall (2004)	CS	1	Epidermolysis bullosa	
Kennedy-Evans (2004)	CS	1	Skin tears	
Lahiri and Nishikawa (2006)	CS	1	Aplasia cutis congenital	
CS=Case study; NRCT=Non-randomized controlled trial; RCT=Randomized controlled trial				

the issues of adherence, trauma and pain. Examples of such dressings available, listed in the *British National Formulary* (Joint Formulary Committee, 2008) and the Drug Tariff (Department of Health, 2008), are presented in *Table 2*.

Mepitel[®] (Mölnlycke Health Care, Gothenburg, Sweden) is one of a number of dressings that incorporate Safetac[®] technology to ensure that they adhere to intact dry skin but not to moist wound beds (White, 2005). Mepitel is a wound contact dressing that can be used on a wide range of acute wounds (e.g. skin tears, abrasions and second degree burns), chronic wounds, skin disorders (e.g. epidermolysis bullosa), as well as for the fixation of grafts (White, 2005). It can be left in place for up to 14 days, with the secondary dressing changed as frequently as required, so avoiding disturbance of the wound bed (Kennedy-Evans, 2004).

Aims

The objective of this article is to summarize the published clinical evidence relating to Mepitel, focusing on its abilities to minimize wound-related trauma and pain in a variety of clinical applications.

Methods

Electronic searches of bibliographic databases (MEDLINE, National Library of Medicine; EMBASE) and internet sites (Cochrane Library, World Wide Wounds) were supplemented with manual searches of journals of relevance to wound management to identify clinical data published in English relating to Mepitel.

Results and discussion

The literature search identified a number of articles, presenting data generated from randomized controlled trials (RCT), non-randomized controlled trials (NRCT) and case study (CS) evaluations of Mepitel on a wide range of wound types. In total, 21 clinical papers pertaining to Mepitel (six RCTs, five NRCTs and ten CSs) were identified (*Table 3*).

This dressing has been largely evaluated in studies involving specific wound types, e.g. skin grafts (*Figures 1a* and *1b*), traumatic wounds (*Figures 2a* and *2b*); burns (*Figure 3*); chronic wounds (*Figure 4*), and congenital skin disorders such as epidermolysis bullosa (*Figure 5*). In several studies the performance of Mepitel has been compared with traditional treatments. The key findings of the clinical evaluations are presented below.

Skin grafts

Split-skin grafting is a technique that is used to replace lost tissue in several medical situations, such as burn injuries, the excision of skin tumours, or to aid the healing of venous ulcers. In certain circumstances the graft site is left exposed for 1–2 days as bleeding under a graft can threaten its success. Such sites require interim dressings that allow exudate to escape but maintain a moist wound bed, and are easy to change without causing bleeding or pain. Likewise, once the grafts are in place, frequent dressing changes help to reduce the bacterial load in contact with the new skin and allow topical application of antibacterials. However, dressing changes can be a time of great distress,

especially in children. In both of the above situations, the traditional dressing routinely used was paraffin gauze but removal proved difficult due to adherence, which disturbed new tissue with resultant trauma and pain and bleeding. In RCTs, Mepitel was evaluated as an alternative to paraffin gauze and was found to be superior as it adhered less to the graft or graft site, resulting in less pain and bleeding, and was associated with less time for dressing changes (Dahlstrøm, 1995; Platt et al, 1996).

Split-skin grafts are also prone to mechanical shifting during the early postoperative period and vulnerable to dehydration and infection, therefore the mechanical displacement of dressings for split skin grafts from the wound bed must be avoided. Commonly, the graft is fixed with stitches and dressed using vaseline gauze, although it has been reported that using a combination of staples and the burns dressing SurfaSoft (Eurosurgical Ltd, Guildford) – a skin graft fixation material made from a monofilament woven polyamide thread – is a better technique (Kreis and Vloemans, 1987).

In an open, prospective study, the ability of Mepitel to act as a split-skin graft dressing was evaluated in children. The results showed that most grafts took completely and none were lost because of inadequate fixation. It was reported that the main advantage of the soft silicone wound contact dressing over SurfaSoft combined with staples was that dressing removal was painless and neither the graft nor the wound were disturbed (Vloemans and Kreis, 1994).

Dressing changes can often require the use of analgesics or general anaesthesia, especially in children, but their frequent use may cause serious adverse effects, such as dietary suppression resulting in subsequent delayed wound healing and patient rehabilitation (Platt et al, 1996). It has been shown that the use of Mepitel was associated with reduced pain, and as a consequence, the requirement for analgesics or general anaesthesia was greatly diminished (Vloemans and Kreis, 1994; Platt et al, 1996).

Traumatic wounds

Mepitel has been used as an effective atraumatic and pain-free alternative to traditional dressings in a wide range of fingertip injuries in children. Paraffin gauze has historically been the dressing of choice, but as previously stated, dressing changes with this type of product are frequently a cause of stress. In an RCT it was shown that dressing adherence and the pain experienced when the dressings of fingertip injuries were changed in paediatric patients were statistically lower when Mepitel was used when compared with paraffin gauze (week 1, P < 0.001; week 2, P < 0.001; week 3, P < 0.01). Furthermore, Mepitel could remain in place for more than one dressing change, thus minimizing disturbance to the fragile epithelium underneath (O'Donovan et al, 1999).

Wound exudate can pass freely through the open net structure of this type of dressing into a secondary absorbent dressing, which can be changed as frequently as required. Additionally, as dressings with Safetac do not adhere to the wound bed, they perform well on wounds such as raw nail beds (Terrill and Varughese, 2000), and following traumatic finger amputation and toe nail removal (Williams et al, 2001).

Mepitel has also proved beneficial in the management of skin tears (Meuleneire, 2002; Sutton, 2003; Kennedy-Evans, 2004). The physiological changes of ageing skin result in a decrease in subcutaneous tissue, dehydration and atrophy, all of which predispose the older population to skin tears. Skin tear management is often painful with prolonged wound healing. In an open prospective trial,



Figure 1.
Mepitel being used for
(a) skin graft fixation;
(b) management of
donor site.



Figure 2.

Mepitel being used for (a) hand injuries; (b) skin tears.

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Figure 3: Mepitel applied to a burn wound.



Figure 4: Mepitel applied to a leg ulcer.



skin tears healed more quickly when Mepitel was used when compared with more traditional dressings (e.g. paraffin gauze), and the pain and discomfort of dressing changes was reduced (Meuleneire, 2002).

A non-randomized, prospective evaluation of five wound contact layers in the management of acute and traumatic wounds showed that Mepitel, a lipidocolloid soft polymer dressing and a silicone-coated knitted viscose dressing were least traumatic to the wound and most comfortable on removal, whereas a triglyceride-impregnated knitted polyester dressing and an other soft polymer wound contact dressing were associated with greater adherence to wounds (Burton, 2004).

Burns

In children, burns are a common cause of injury to the skin and treatment typically involves frequent, painful dressing changes. Traditionally, the management of burned or scalded skin involves the direct application of a topical antibacterial preparation, e.g. silver sulfadiazine (SSD), covered by a gauze dressing. It is the subsequent removal of SSD and the adhesion of the gauze dressing that are the principle sources of pain at dressing change.

In prospective, randomized clinical trials, the efficacy of Mepitel was compared with SSD on paediatric burns.

Wound healing with Mepitel was significantly faster than controls (P<0.001), exudate was successfully drained into a secondary dressing and there was minimal eschar formation, compared with SSD treatment (P<0.05). Dressing changes were easy and atraumatic, and as a consequence of the improved healing time, the children required significantly fewer dressing changes (P<0.05), thereby further reducing the pain experienced (P<0.05) and ultimately the treatment costs (\$1937 versus \$2316; P=0.025) (Gotschall et al, 1998).

A second study also compared Mepitel with SSD in paediatric burns patients and also showed that wound healing was significantly faster (P<0.01) with significantly fewer dressing changes required (P<0.05) (Bugmann et al, 1998). A case study series also reported the successful use of Mepitel in the management of partial thickness burns – the only adverse events associated with such treatment was long-term pigmentation abnormalities in two dark-skinned children (Williams et al, 2001).

Laser skin resurfacing (LSR) is a procedure that induces a controlled burn of the facial skin and is a common cosmetic procedure used for the treatment of facial rhytids, solar damage and acne scarring. The successful outcome of LSR (the achievement of complete and even re-epithelialization, fast healing, decreased crust formation and patient comfort) is directly related to postoperative wound care.

In a prospective study, a number of dressings commonly used after facial LSR (including Mepitel) were reviewed. Mepitel proved comfortable, easy to change and was atraumatic to re-epithelialized tissue due to its non-adhesive properties on moist skin. Conversely, its ability to adhere gently to dry skin ensured there was no slippage. This, together with the absorption of exudate into secondary dressings, resulted in the absence of crust formation. An imprint of the dressing, a mesh-like pattern, was sometimes observed on fresh oedematous skin, but this resolved after 1–2 weeks (Newman et al, 2000).

Chronic wounds

Chronic wounds can be associated with severe pain and high levels of exudate and, as a consequence, they may require frequent dressing changes that can be painful and



Figure 5: Mepitel being used in the management of epidermolysis bullosa (courtesy of Jacqueline Denyer, Great Ormond Street Hospital, London).

traumatic for patients. Predisposing and/or perpetuating factors can influence the possibility of healing; therefore, pain reduction and improving the quality of life of patients are high priorities.

It has been reported that Mepitel promoted compliance by reducing overall trauma and pain to an arterial leg ulcer during dressing changes, as well as helping to protect the peri-wound skin from harmful wound exudate, resulting in the stabilization of the ulcer (Gates, 2000). Likewise, this dressing has been successfully used to protect newly formed epithelial tissue from trauma in a heavily exuding diabetic foot ulcer (Young, 2002).

Congenital skin disorders

The congenital skin disorder epidermolysis bullosa (EB) is a genetically determined abnormality where everyday friction and trauma of extremely fragile skin results in blister formation, skin erosion and scarring. The careful selection of dressings is therefore a key element in the treatment of EB. Traditional dressings, e.g. paraffin gauze, are adherent and so, on removal, result in stripping of the already fragile skin.

It has been demonstrated that Mepitel is successful in treating EB because it gently adheres to the intact, dry peri-wound skin but not to the moist wound bed, allowing atraumatic removal (White, 2005). Mepitel has been successfully used to treat patients with EB, alleviating the pain and anxiety of dressing change. It conforms well to body contours, especially fingers, toes and the elbow, its porous structure allows exudates to pass freely into an absorbent secondary dressing, and it is permeable to topical antibacterials, thereby effectively managing secondary infections. This dressing can be left in place for 3–4 days, thus maintaining a moist wound environment, allowing wounds to heal well, with little cutaneous damage and epithelialization to occur within a period of 1 month (Lapioli–Zufelt and Morris, 1998; Hall, 2004).

Aplasia cutis congenita is a rare congenital disorder whereby babies are born with a patch of skin missing, most often on the scalp, but it may also occur on the trunk, arms or legs. The affected area is typically covered with a thin, transparent membrane. In neonates, treatment aims to minimize tissue trauma and infection while allowing the wound to contract and epithelialize. Lahiri and Nishikawa (2006) reported on an infant with aplasia cutis congenita, who had previously been treated with Jelonet and gauze, which had led to repeated trauma and bleeding during dressing change. Mepitel was used successfully to treat the defect. Dressing changes proved atraumatic and pain-free, and their frequency reduced as secondary absorbent dressings could be changed as often as required.

Mycosis fungoides

Mepitel has been successfully used in the treatment of severe mycosis fungoides. Mycosis fungoides is a rare cutaneous form of T-cell lymphoma. The initial symptom is often the development of scaly patches of skin, which subsequently evolve into plaques and can then progress to form ulcerated tumours. Patients experience extreme pain as a result of cutaneous nerve damage, disfigurement and low self-esteem. Taylor (1999) reported on a patient with mycosis fungoides who presented with extensive ulcerating lesions on multiple sites, including

the scalp, cheek, neck and back, which were heavily exuding and infected. Wound dressings could not be tolerated due to severe wound pain. However, the use of Mepitel immediately reduced chronic wound pain as secondary dressings could be changed as often as required, leaving the contact dressing in situ for up to 12 days, so avoiding the disturbance of the wound bed and allowing healthy epithelialization. As a result the patient had an improved quality of life with enhanced self-esteem (Taylor, 1999).

Mechanical protection of irradiated skin

The mechanical protection of irradiated skin is essential, but conventional dressings may irritate treated skin and enhance dermal reactions to irradiation. However, in a prospective study, Adamietz et al (1995) demonstrated that Mepitel could be used for skin protection during irradiation. No reactions to the dressing by either irradiated or non-irradiated skin were observed and ulcers covered by this dressing reepithelialized quickly during radiotherapy.

Cost-effectiveness

Wound care professionals are required to make cost-effective decisions related to dressing choice and patient benefit. However, dressing choice based on initial low expenditure costs does not necessarily equate with best value for money in trying to achieve a successful clinical outcome of benefit to the patient (Sibbald et al, 2003). A cost analysis of Mepitel demonstrates that overall expenditure may be cut, in some cases by about half, despite a higher initial purchase cost (Gates, 2000). Treatment with this dressing resulted in the use of fewer dressings and dressing changes, with less time required for the dressing change when compared with traditional dressings (Dahlstrøm, 1995; Bugmann et al, 1998; Gotschall et al, 1998; Gates, 2000; Sutton, 2003).

Conclusion

The aim of this article is to aid the reader in identifying how Mepitel can best be used to treat a variety of different wound types by highlighting relevant clinical evidence. This has been accomplished by using the full spectrum of clinical evidence (i.e. from RCTs to case studies). In many systematic reviews and meta-analyses, case studies are often disregarded, but it is generally accepted in the field of wound care that data from case studies provide invaluable 'real-life' evidence that should not be ignored by clinicians.

This article has highlighted that there is a weight of clinical evidence supporting the use of Mepitel and that use of this dressing is wide and varied in a number of different wound types.

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KEY POINTS

- Wound pain and tissue trauma are two considerations of wound management, and appropriate dressing selection plays an important role in both.
- Traditional dressings may adhere to wounds resulting in significant pain and trauma to new tissue upon removal.
- Mepitel is a wound contact dressings that incorporates Safetac technology to ensure that they adhere to intact dry skin but not to moist wound beds.
- Mepitel can be used on a wide range of acute wounds (e.g. skin tears, abrasions and second degree burns), chronic wounds, skin disorders (e.g. epidermolysis bullosa), as well as for the fixation of grafts.

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