Use of wound dressings with soft silicone adhesive technology

In a multi-centre, observational study, Clare Morris and colleagues evaluated the effectiveness of the Mepilex® Border Lite dressing.

Abstract

Aim: To evaluate how pain, during and in-between dressing changes, is affected by the introduction of Mepilex® Border Lite, a wound dressing manufactured by Mölnlycke Health Care using Safetac® soft silicone adhesive technology, to the treatment of different types of paediatric wounds/skin injuries.

Methods: Wounds/skin injuries that met the criteria for inclusion in the study were dressed with Mepilex® Border Lite. Patients were followed for six weeks or until their wounds/skin injuries had healed, whichever occurred earlier. At each dressing change, pain severity before and during dressing removal was rated by the patient and the investigator on a scale from zero (no pain at all) to ten (worst pain ever). Other variables measured included: signs of trauma to wound/skin injury and surrounding skin, the proportion of viable/non-viable tissue, the quantity and appearance of exudate, odour, and clinical signs of infection. At the final dressing change, patients and investigators completed questionnaires to rate the dressing performance.

Results: Mean pain severity scores were significantly lower (p < 0.003) at the first dressing change than at baseline. Over 99.5 per cent of the Mepilex® Border Lite dressing changes were reported to be atraumatic and more than half of the wounds healed within the study period. Conformability, ease of use, ease of removal, patient comfort, and overall experience with the dressing were rated as 'good' to 'very good' at the vast majority of final visit evaluations.

Conclusions: This study provides further evidence of the ability of dressings with Safetac soft silicone adhesive technology to minimise trauma and pain and demonstrates the ability of Mepilex® Border Lite to overcome the clinical challenges associated with the use of dressings on the wounds/skin injuries of paediatric patients.

Keywords: Wounds, dressings, children: accidents

CHILDREN ARE frequently exposed to physical trauma which may result in external or internal wounding. There are a number of clinical challenges in relation to wound management in children. First is the pain suffered by patients, either in relation to the wounds themselves, underlying pathologies, or as a result of trauma caused by therapeutic interventions such as dressing-related procedures. Pain can lead to stress, the psychological aspects of which are just as important to manage as the pain itself. Pain-induced stress can delay wound healing and adversely affect patients' quality of life (Soon and Acton 2006). It has been shown that patients experience most pain at dressing changes (Hollinworth and Collier 2000).

Although analgesia and anaesthesia can be used to help reduce pain during dressing changes, these can be expensive for healthcare providers and carers, and some analgesic and anaesthetic agents are associated with undesirable side effects (Soon and Acton 2006). Second, due to the small size of paediatric wounds and the difficulties associated with dressing unusually shaped wounds in awkward locations, such as wounds resulting from digit and limb injuries, clinicians need access to highly flexible and conformable dressings.

In addition to managing wound pain and overcoming the difficulties posed by the size and location of wounds, clinicians must also deal with the normal challenges of tissue viability, such as effectively controlling exudate, preventing the ingestion of foreign bodies (dirt, bacteria), and negating malodour, in a wide variety of wound types. The dressings they select must be appropriate for these multiple purposes.

According to a World Union of Wound Healing Societies (2004), the following dressing parameters...
Research should be considered to help minimise trauma and pain during dressing-related procedures: maintenance of moist wound healing, fluid handling capacity, atraumatic to the wound and skin, and low allergy potential.

Mepilex® Border Lite is a thin, absorbent, self-adhesive island dressing with a perforated soft silicone adhesive (Safetac®) wound contact layer that adheres readily to intact dry skin but does not stick to the surface of a moist wound and does not cause damage on removal (White 2005). The absorbent core of the dressing consists of two layers. The first layer, a thin sheet of polyurethane foam, transports exudate away from the wound to the second layer, a piece of non-woven fabric, which spreads the exudate horizontally. The dressing also possesses a vapour permeable backing film through which the exudate evaporates from the wound pad. The fluid handling system of Mepilex® Border Lite, in addition to its soft silicone adhesion layer inhibiting the lateral movement of exudate from the wound to the surrounding skin, helps to minimise the risk of maceration (Thomas 2003).

Mepilex® Border Lite has been designed for situations where clinicians require a thin and highly conformable dressing for anatomical or practical purposes, and where fluid handling requirements are low, that is low exuding wounds such as leg and foot ulcers, pressure ulcers and traumatic wounds such as blisters and skin tears. It is available in five sizes, of which the smaller ones are particularly suitable for the size and location of wounds in children.

A multi-centre, observational study was undertaken to evaluate the use of Mepilex® Border Lite on different types of paediatric wounds/skin injuries such as burns, traumatic wounds (cuts, scrapes, skin tears, abrasions, finger/toe injuries, and blisters), and surgical wounds.

Aims

The primary objective of the study was to evaluate how pain is affected during and in-between dressing changes by the introduction of soft silicone dressings to the treatment of different types of wounds/skin injuries in children. The secondary objectives of the evaluation were to assess:

- Levels of trauma.
- The healing of wounds/skin injuries.
- The condition of the surrounding skin.
- The performance of the dressing in terms of exudate handling, conformability, ease of use, ease of removal and patient comfort.

### Table 1 Wound demographics at baseline (n=36)

<table>
<thead>
<tr>
<th>Wound type</th>
<th>Burn (n=10)</th>
<th>Surgical (n=11)</th>
<th>Traumatic (n=13)</th>
<th>Other* (n=2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound duration</td>
<td>8.9 (1-60) days</td>
<td></td>
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<tr>
<td>Proportion of viable tissue</td>
<td>89.5 (30-100) per cent</td>
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</table>

* Cannula insertion site (n=1); skin lesion post-herpes zoster (n=1)

### Methods

This multi-centre, observational study included inpatients and outpatients. Inclusion criteria were that the patients were ≤ 16 years, had wounds and/or skin injuries that were deemed suitable to be dressed with Mepilex® Border Lite and for whom informed consent was given. Those patients for whom following the protocol would be difficult, or who had a known allergy or hypersensitivity to any of the dressing components, or had severe underlying disease that may have interfered with treatment were excluded.

### Assessment

At the first consultation, baseline demographic data (age, gender, medical history) and history of the wound/skin injury were recorded. Any previously applied dressings were removed and details of the name and type of the dressings were recorded (Table 1).

The following parameters were measured at the baseline visit and at all subsequent dressing changes:

- Pain severity before dressing change.
- Pain severity during dressing change.
- Clinical signs of trauma to wound/skin injury and surrounding skin.
- Condition of the surrounding skin.
- Percentage of viable/non-viable tissue (qualitative visual assessment).
- Exudate amount (recorded using the standard terms of ‘none’, ‘low’, ‘moderate’ or ‘high’)/ nature (recorded as ‘clear (serous)’, ‘yellow/green’, ‘brown/blood’ or ‘other’).
- Presence of malodour.
- Clinical signs of infection.
- Debridement (whether or not performed).
- Patient subjective symptoms.

### Rating pain severity

Pain severity, before and during dressing change, was rated by the patient and the investigator on a scale from zero (no pain at all) to ten (worst pain ever). To facilitate this, a pain assessment tool, based on the Visual Analogue Scale (VAS) and the...
Research

Table 2  Number of patients demonstrating changes in pain severity scores at first dressing change

<table>
<thead>
<tr>
<th>Change in pain severity score</th>
<th>Prior to dressing change</th>
<th>At dressing change (patient assessment)</th>
<th>At dressing change (investigator assessment)</th>
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<tbody>
<tr>
<td>Decrease</td>
<td>16</td>
<td>19</td>
<td>18</td>
</tr>
<tr>
<td>No change</td>
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<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Increase</td>
<td>1</td>
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Wong-Baker Faces Scale, was used (Harms-Ringdahl et al 1986; Keck et al 1996). If the investigator felt that this pain assessment tool was not appropriate for use with a particular patient, for example if the patient was unable to verbalise the presence or severity of pain, then they used the Faces, Legs, Activity, Cry and Consolability (FLACC) Behavioural Pain Assessment Scale for quantifying pain behaviours (Merkel et al 1997).

Photographs of the wounds/skin injuries were taken to monitor their size and condition. At the final dressing change, the patients and the investigators completed simple questionnaires to rate the dressing in terms of conformability, ease of use, ease of removal, and comfort.

Dressing regimen

The investigators selected the most appropriate size of Mepilex* Border Lite (chosen from one of the five different sizes available) and applied it to the wound/skin injury. Combining this dressing with other dressings was acceptable if, in the opinion of the investigators, there was clinical justification to do so. Investigators were allowed to cut the borders of the dressings if it was felt that this would facilitate application to flexion points. Dressing changes were performed when judged necessary by the investigators at frequencies that they felt were compatible with good exudate management.

Each patient was followed for six weeks or until the wound/skin injury had healed, whichever occurred earlier. At any point during the study, the investigators had the option of discontinuing treatment with Mepilex* Border Lite if, in their opinion, the dressing was no longer appropriate for a particular patient. Any untoward and/or unintended response that was possibly or probably related to the dressing were recorded on the case study form.

Literature search

Electronic searches of bibliographic databases (MEDLINE, National Library of Medicine, Bethesda, USA; EMBASE, Elsevier BV, Amsterdam, Netherlands) and internet sites (Cochrane Library, World Wide Wounds) were supplemented with manual searches of journals of relevance to wound management to identify articles, published up to and including 2007, that describe evaluations of dressings and pain-relieving strategies on paediatric patients in which pain severity scores were recorded. Relevant studies are included in the Discussion section below.

Statistical analysis

Descriptive statistics (mean and standard deviations) were applied to the primary and secondary objectives when quantitative data were established. A test was used to analyse the pain severity scores measured at baseline versus those recorded at the subsequent dressing change (first visit).

Results

Thirty six patients (boys, n=23; girls, n=13) with a mean age of 7.6 years (range nine days - 15 years) with a variety of wound types satisfied the criteria for inclusion in the study. Table 1 summarises the wound demographics at the baseline assessment. Various wound dressings were removed at baseline, for example, absorbent cellulose, hydrocolloid, honey gel, film and foam. During the study, one patient died (the cause of death was not related to the dressing), one patient was withdrawn (he was unable to attend the clinic for follow-up dressing changes) and five patients were withdrawn as a result of the investigators deciding to switch to alternative dressings that they believed to be more appropriate. The data relating to the patients who did not complete the study were, however, included in the final analysis.

Pain: The pain severity scores reported at the baseline visit were statistically significantly higher than those recorded at the first visit, that is, the first dressing change with Mepihex* Border Lite. Mean score prior to dressing change was 2.58 at baseline and 0.88 at the first visit (p = 0.0005); mean score at dressing removal (patient evaluation) was 2.84 at baseline and 1.34 at the first visit (p = 0.0002); mean score at dressing removal (investigator evaluation) was 2.5 at baseline and 1.35 at the first visit (p = 0.003) (Figure 1). The numbers of patients demonstrating decreases, increases and no changes in pain severity from baseline to first visit are presented in Table 2. Analgesia use at initial dressing change was only required for two (6 per cent) patients. Of a total of 194 dressing changes involving

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Mepilex® Border Lite, analgesia was only used at five (3 per cent) of them.

**Trauma:** Of the 194 dressing changes involving Mepilex® Border Lite that were evaluated, 193 (99.5 per cent) were reported to be atraumatic.

**Wound healing:** Within the study period, 20 (56 per cent) wounds healed completely (mean 14.5 days, range four to 42 days). In terms of the ratio of viable tissue (healthy granulation/re-epithelialisation) tissue to non-viable (sloughy/necrotic), wounds exhibited a statistically significant larger proportion of viable tissue at the final visit (mean 99.5 per cent, SD 1.9) than at baseline (mean 91 per cent, SD 17.8) (p = 0.01).

**Exudate management:** The wounds treated with Mepilex® Border Lite were typically associated with low-to-moderate levels of clear (serous), yellow/green or brown/blood coloured. There were no reports of leakage. Malodour was reported at two of the dressing changes.

**Peri-wound skin:** The proportion of patients exhibiting healthy/intact skin around their wounds increased from 75 per cent at baseline to 92 per cent at the final visit.

**Adverse reactions:** Two adverse events were reported during the study, neither of which was considered by the investigators as being likely to have been related to the use of the dressing. One patient developed an eczematous rash (the patient concerned has a long history of eczema-related problems). Another patient experienced an allergic-type reaction.

**Overall evaluations (final visit)**
In terms of the overall pain that was experienced during the use of Mepilex® Border Lite, the patients themselves recorded mean pain severity scores of 0.23 prior to dressing change and 0.80 at dressing change. Patients gave a mean rating of 8.38 out of ten for the overall performance of the dressing.

A summary of the investigators’ final visit evaluations are presented in Figure 2. At the final visit, the investigators were asked to identify which dressing they would choose if they could repeat the evaluation on each of their patients. Mepilex® Border Lite was chosen as the ideal dressing for 80 per cent of the wounds and other types of dressings with soft silicone adhesive technology were chosen for a further 9 per cent of the wounds.

**Discussion**
The primary objective of this study was to evaluate how pain, during and in-between dressing changes of paediatric wounds/skin injuries, is affected by the introduction of Mepilex® Border Lite. These results demonstrate that this dressing can significantly reduce pain severity both before and during dressing change.


**Pain severity scores reported at the baseline visit were significantly higher than those recorded at the first visit**
The low pain severity scores associated with Mepilex® Border Lite compare favourably to those reported for a number of other dressing types and pain-relieving strategies, even though analgesia usage appears to have been far greater in some of the published studies. For example, in Letouze et al's (2005) study involving 100 patients with a variety of wounds (acute, chronic and burns) treated with a lipidocolloid dressing, it was reported that analgesia was administered at 21 per cent of dressing changes, whereas in this study analgesia was used at only 3 per cent of dressing changes. Therefore, as well as reducing pain severity before and during dressing change, the use of Mepilex® Border Lite may be associated with a need for less analgesia during changes.

The most likely explanation for the reduction in pain severity scores reported after the introduction of Mepilex® Border Lite is the fact that dressings with soft silicone adhesive technology are associated with atraumatic dressing changes and can be easily removed without causing trauma to wounds or surrounding skin (White 2005).

As healing progresses, wound exudate levels decrease, thereby reducing the propensity for trauma to peri-wound skin. A significant factor in managing this process is the selection of dressings that provide the optimum environment in which wounds can progress to healing and effectively manage wound fluid. Thus, the dressing selection needs to be based on the condition of the wound and peri-wound skin and should be adjusted to accommodate changes in these parameters. In addition to patients experiencing atraumatic dressing changes and minimal pain before and during dressing removal, their wounds demonstrated good progression to healing during treatment with Mepilex® Border Lite.

Conformability, ease of use, ease of removal, patient comfort and overall experience with the dressing were rated 'good' to 'very good' by the vast majority of the investigators' at final visit evaluations. Investigators commented mainly on the physical handling of the dressing with regards to it staying in place. They were generally positive about the flexibility and conformability of the dressing when applied to wounds that were small and in awkward positions, such as the fingers and toes of small children. Figure 3 shows the dressing on an amputation wound on the fifth digit demonstrating excellent conformability and flexibility. Comments also indicated that dressings were easy to apply and remove.

A significant clinical challenge with small children is keeping the dressing in place and in many cases additional fixation was required for dressing retention. The reasons given for the lack of adhesion in this study included: patients interfering with their dressings, patients' active lifestyles exacerbating adhesion problems, and positions of the wounds making dressing adherence to skin problematic. These are issues commonly encountered in dressing wounds in children. Some investigators also indicated that the dressing could be maintained in place for several days, providing good protection against foreign material ingress.

Positive feedback from the patients and/or their parents was also much in evidence in the case study forms. The patients gave a mean rating of 8.38 out of ten for the dressing's overall performance. The response was especially positive with regards to comfort, flexibility and
ease of use. There were a number of reports of reduced distress and anxiety, together with a reduced need for analgesia, after the introduction of Mepilex® Border Lite. One significant comment was from a parent who indicated that, during treatment with Mepilex® Border Lite, the heart monitor to which her infant was connected did not show the increased heart rates that had been observed during the application and removal of other dressings.

Methodological considerations

Trauma and pain associated with the removal of wound dressings is of major concern to patients and healthcare professionals. Furthermore, the trauma to the wound bed and surrounding skin that can occur with excessive dressing adhesion prolongs the duration of wounds, resulting in increased treatment costs and morbidity. Not surprisingly, many clinicians involved in the field of wound care are becoming increasingly reluctant to prescribe traditional adhesive dressings.

These issues were carefully considered in designing the study protocol. While recognising the importance of comparator groups in clinical evaluations, it was felt that, for this particular study, there was no obvious candidate to evaluate alongside Mepilex® Border Lite and to have used a traditional adhesive wound dressing with the potential to cause trauma and pain would have been unethical, particularly in view of the study population.

The size of the sample (36 participants) was deemed to be in line with other studies that have evaluated dressings and interventions in paediatric wound management.

Conclusion

This study was undertaken to evaluate the impact of introducing Mepilex® Border Lite into the treatment regimen of children and young people with a variety of wound types. The results show that this product addresses the major challenges that clinicians face when treating such wounds, that is, the need to use dressings that are atraumatic and minimise pain on removal, and that have sufficient flexibility and conformability to stay in place when applied to small wounds in awkward locations. Moreover, Mepilex® Border Lite has been shown to be capable of promoting a wound healing environment that is conducive to healing, managing low-to-moderate levels of exudate, and preventing maceration of peri-wound skin.

References


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