Pilot RCT of two dressing regimens for the management of skin tears

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Abstract

Aims: To assess the efficacy of two dressing regimens for the management of skin tears in fragile skin of the elderly. *Methods:* A pilot study of 21 patients was conducted across two centres. Ten patients were treated with Tegaderm® Absorbent (3M Health Care) dressing and 11 with a combination of Mepitel® and Mepilex® Border (Mölnlycke Health Care) dressings. *Results:* Both dressing regimens had positive clinical outcomes. Where the smaller size dressings were used, the cost differences between the groups were minimal. However, in cases where larger dressings were required, Tegaderm Absorbent proved more cost-effective. *Conclusions:* The authors found that both methods of treating skin tears had positive clinical outcomes, with healing or progression towards healing in all of the cases. Recruiting subjects for the study was challenging, suggesting that clinical audit may prove a more useful method of evaluation for investigators in the future. *Conflict of interest:* None.

KEY WORDS
Skin tears
Dressing regimens
Cost-effectiveness
Elderly care
Fragile skin

A skin tear is defined as a traumatic wound, that occurs as a result of friction alone, or shearing and friction forces which separate the epidermis from the dermis (partial-thickness wound), or which separate both the epidermis and the dermis from the underlying structures (full-thickness wound) (Payne and Martin, 1993).

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Age-related changes in the skin increase the risk of skin tears among the elderly (Malone, 1991). Other factors such as long-term steroid therapy, malnutrition, lower limb oedema and agitation or restlessness increase the risk of further damage (Beldon, 2006).

An estimated 1.5 million skin tears a year have been reported in the United States (Malone et al, 1991). While 80% of skin tears occur on the arms and hands (Fleck, 2007), pre-tibial lacerations are also common. An estimated 5.2 per 1000 patients present to Accident and Emergency departments in the United Kingdom with such injuries (Fleck, 2007).

Skin tears are classified according to the degree of tissue loss, using the Payne and Martin Classification system (1993):

- Category I: no tissue loss
- Category II: minimal tissue loss (under 25% of the flap of epithelial tissue lost), or with moderate to large tissue loss (over 25% of the flap lost)
- Category III: complete loss of the flap caused during the laceration.

There are a range of treatments used for these injuries, including suturing, skin-grafting, the use of Steri-Strips, surgical interventions and a variety of advanced wound care dressings. Regardless of the management approach, skin tears tend to heal in 7–21 days with conservative treatment.

Current recommended practices include use of silicone adhesive contact layers and/or silicone dressings to reduce the chance of disturbance of the skin flap (Beldon, 2006).

A newly-introduced absorbent acrylic polymer dressing offers the potential to be a cost-effective alternative. No maximum wear time is recommended by the manufacturer and the wound may be observed through the dressing without its removal.

Method

The design was a pilot, prospective, randomised, multi-centre open parallel controlled study to compare the performance of two dressing regimens in the management of partial and full-thickness skin tears to the upper or lower limbs.

The primary outcome of the study

was to compare the performance of Tegaderm® Absorbent (3M Health Care) and Mepitel® and Mepilex® Border (Mölnlycke Health Care) dressings in the conservative management of skin tears. At the time of developing the protocol, the manufacturer of Mepitel and Mepilex Border recommended the combination of the two dressings for the management of grade 2 and 3 skin tears (http://mhcwoundcare.com/education_resources/Skin_Tear_Management_Guide.pdf).

The secondary outcomes of the study were:

- To compare the cost of the two treatment regimens
- Identify complete healing of the skin tear (defined as the restoration of complete epithelial cover).

In total, 60 subjects were recruited from the patient population routinely seen by clinicians at three centres in England and Scotland. These patients presented with partial or full-thickness skin tears (Payne Martin class 2 and 3), requiring conservative management. Thirty subjects were randomised to each treatment arm. Exclusion criteria included:

- Patients who presented with skin tears of more than three days' duration at the time of recruitment
- Patients who were currently using one of the dressing systems
- Patients who were unable to understand the aims and objectives of the study
- Patients who were known to be non-compliant with medical treatment
- Patients who had participated in the trial previously
- Patients who were pregnant
- Where infection was local to the skin tear
- Where eschar was present in the wound.

The patients were randomised to either the Tegaderm Absorbent (3M Health Care) group, or those to be treated with Mepitel with Mepilex Bordered or Mesorb® (Mölnlycke Health Care) as a secondary dressing (http://mhcwoundcare.com/education_resources/Skin_Tear_Management_Guide.pdf).

The protocol was submitted to the relevant UK Local Research Ethics Committee and ethical approval for the study was granted.

Results

Twenty-six patients were enrolled in the study from two centres. In the third centre, the investigator identified a number of suitable patients, but none of them could give consent to participate in the study.

Twenty-six subjects were recruited (e.g. approached but failed to give consent, etc) and were assigned to one of the two treatment options. Of the 26, two died, two were lost to discharge and one had their treatment interrupted after two weeks and was withdrawn from the study. This left 21 subjects who completed the study, 10 were treated using Tegaderm Absorbent and 11 were treated using Mepitel and Mepilex Border. *Table 1* provides an outline of the study results.

The age range for the Tegaderm Absorbent group was 73–911 years, with a mean age of 82.8, and in the Mepitel/Mepilex group the range was 72–93 years, with a mean age of 82.8.

Using the Payne Martin scale, the 10 tears in the Tegaderm Absorbent group were grade II. Ten of the skin tears treated with Mepitel were grade II and one was grade III. Injuries were evenly spread across three anatomical locations in both groups, i.e. hand, arm and leg, with the majority (5) being on the leg in both groups.

Eight out of 10 tears healed in the Tegarderm Absorbent group. One reduced in size, while one increased in size due to the removal of the original skin flap as it was thought to be unviable. In the Mepitel/Mepilex group, six out of the 11 subjects healed, with five wounds reducing in size and progressing towards healing at week 4. None of the wounds in this group became larger and no infections were noted in any of the skin tears.

The two groups were well matched in terms of age, grade of skin tear and anatomical location of the skin tears. However, the number of subjects recruited to this pilot study are too small to conduct any meaningful comparison between healing rates in the two groups. All patients in both groups, with the exception of one, healed or progressed

Table 1
Outline of study results

	Tegarderm Absorbent group	Mepitel group
Females	7	9
Males	3	2
Age range	73–91	72–93
Mean age	82.8	82.8
Hand	2	2
Arm	3	4
Leg	5	5
Grade 2	10	10
Grade 3	0	1
Healed	8	6
Part healed	1	5
Larger *	1	0

* not dressing related

Table 2
Cost of materials

Dressing	Size in cm	Cost in £
Tegaderm Absorbent	7.6x9.5	2.99
	11.1x12.7	3.87
Mepitel	5x7	1.57
	8x10	3.13
Mepilex Border	7x7.5	1.33
	10x12.5	2.63

towards healing during the four-week period of the trial. The wound that failed to heal was 100% granulating tissue at the end of the study, but with larger dimensions by 2mm as a result of removal of the unviable skin flap. Where the dressings were used appropriately and in concordance with the protocol, both regimens demonstrated positive clinical outcomes and were acceptable to the patients (*Figures 1–4*).

Costs

Both dressing regimens are available for sale in the UK and the British National Formulary (BNF) 61 was consulted to confirm the most up to date pricing. *Table 2* provides the costs of both regimens and the variable sizes which were used in the study. All the wounds were relatively small, but due to their anatomical location and to ensure retention, dressings with significant overlap were used. Where combining the smallest Mepitel and the smallest Mepilex Border dressings, the price was equivalent to the smallest Tegaderm Absorbent dressing. Where the 10x12.5cm Mepilex Border dressing was used with either of the sizes of Mepitel, there was a significant price difference with the similar sized Tegaderm Absorbent dressing (11.1x12.7cm).

Discussion

A review of the evidence to date identified that there is lack of good quality information to support the management of this clinical problem, which is predominant in a high risk group (Shuster et al, 1975). The difficulties in recruiting patients to research studies is well documented (Forster et al, 2010), and this challenge increases where the study involves elderly people (Gueldner et al, 1989).

It was anticipated that all subjects would be recruited into the study within a 12-month time period. However, the authors had difficulty in recruitment in that while they could identify potential participants, a high proportion were unable to understand the aims of the study and give informed consent. Where the patient was able to provide consent but wished to discuss the patient information sheet with their family, the subsequent time delay often resulted in the patient being excluded from the study. If it was thought that the patient was to be transferred to a new care setting, this also proved a challenge as it became apparent early in the study that such a shift in setting could result in the study protocol being disrupted, as new staff wished to evaluate the wound or there was a breakdown in communication.

Although the costs of the smaller dressings in both groups were equivalent, it was found that there was a higher cost when using the larger Mepitel/Mepilex combination.

Table 2 provides the costs of each dressing as provided in the BNF at the time of writing. Analysis of the data demonstrates that each of the subjects had their dressing changed every seven days until healed, or the end of the study as per protocol. Of the 21 patients, the mean cost per patient was £ 7.47 in the Tegaderm Absorbent group and £8.18 in the Mepitel/Mepliex Border group. These figures relate to the time to healing or the end of the four-week study period and do not include the costs of those wounds that did not heal within that time frame. The manufacturers of Mepitel state that the dressing can be left in place for up to 14 days and that Mepilex Border can remain in place for several days. The manufacturers of Tegaderm Absorbent state it can be left in place for up to 14 days. However, the authors agreed upon a maximum seven-day wear time as this reflected their normal practice. Therefore, the costs identified in this paper reflect the use of the dressings in line with a seven-day wear time. Practitioners who use the products for their maximum wear time would achieve different costs outcomes.

Despite involving a great many personnel, prolonged effort and

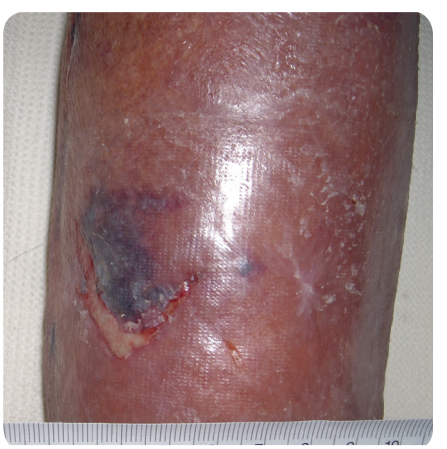

Figure 1. Skin tear pre-treatment with Tegaderm Absorbent.

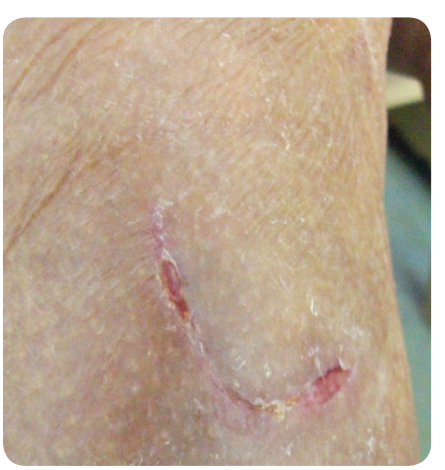

Figure 2. Skin tear post-treatment with Tegaderm Absorbent.

expense, this study failed to reach its conclusion due to the challenges faced by the authors. These included:

- Patient consent in an elderly group
- Patient transfer between care settings.

In the authors' experience, communication with multiple carers involved in patient care can be challenging.

At a time when there are ever increasing calls for evidence to support wound treatments, it is perhaps worth considering how such evidence can be obtained. In the UK, successful execution of randomised controlled trials (RCTs) has become more challenging (Grocott, 2010; White et al, 2010). Perhaps more consideration needs to be given to the inclusion of large groups of patients via clinical registries, where the treatments prescribed and used across multiple sites can be retrospectively audited to give an indication of effectiveness, rather than prospective studies which introduce barriers to obtaining suitable data.

Conclusion

The authors found that both methods of treating skin tears had positive clinical outcomes, with healing or progression towards healing being seen in all cases. No wound infections were noted and both regimens were acceptable to patients and staff.

Where the smaller size dressings were used, the cost differences between the groups were minimal. However, where larger dressings were required, Tegaderm Absorbent proved more cost-effective.

In this limited study comparing silicone-based dressings with a new transparent absorbent dressing, similar levels of healing were found. Removal of the transparent absorbent dressing was atraumatic

In view of these results ,Tegaderm Absorbent dressing can be regarded as a cost-effective alternative for the treatment of skin tears. WUK

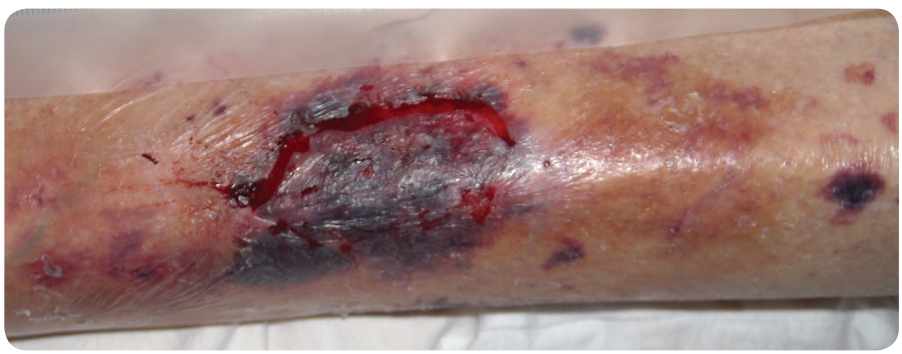

Figure 3. Skin tear pre-treatment with Mepitel and Mepilex Border.

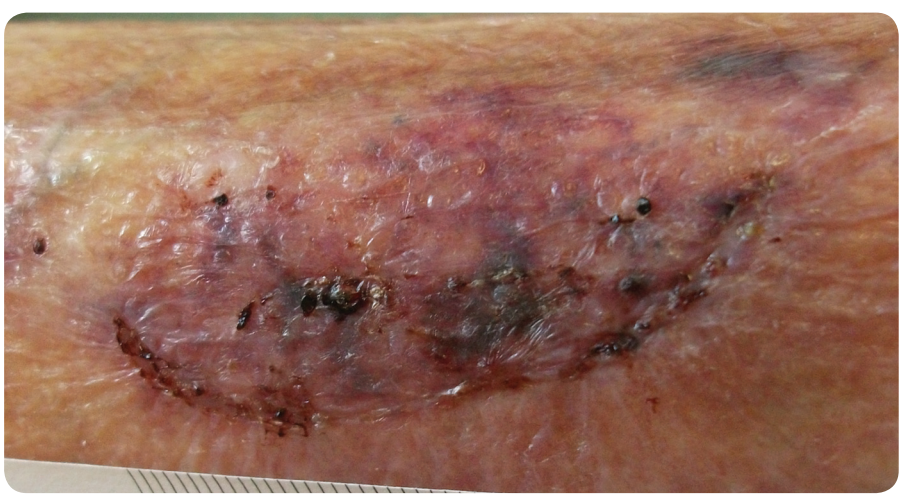

Figure 4. Skin tear post-treatment with Mepitel and Mepilex Border.

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Key points

- Both regimens proved successful in the healing of skin tears, and removal of the Tegaderm Absorbent dressing was atraumatic.
- On average, Tegaderm Absorbent presents a more cost-effective solution without impacting outcomes.
- Obtaining patient consent in this patient population is problematic.
- Future studies may benefit from utlilising a clinical audit approach.