An instant tack wound dressing designed to reduce skin stripping

Background: Skin stripping and impairment of the skin's function as a barrier are adverse effects that can be a consequence of the adhesives in wound dressings. *Aim:* To determine the best performing wound dressing in terms of skin protection without trauma. *Method:* Healthy volunteers had Mepitel® Film (Mölnlycke Health Care), Tegaderm® (3M®) and DuoDERM® Extra Thin (ConvaTec) dressings applied, removed and reapplied to the skin on their back over a period of 14 days. Skin barrier function was investigated using the amount of transepidermal water loss (TEWL) and then related to the amount of skin stripping, investigated by measuring stained skin removal. General signs of trauma, such as skin dryness and erythema, were investigated by subjective and objective parameters. *Results:* TEWL remained relatively unchanged for Mepitel Film and Tegaderm, however, the hydrocolloid dressing showed a significant increase in TEWL, indicating skin barrier function damage. The colour change of stained skin also indicated the removal of stratum corneum with the hydrocolloid dressing (DuoDERM) and, to a lesser extent, with the acrylic dressing (Tegaderm). Mepitel Film was associated with fewer reported trauma incidents, but no statistical difference was found for colour, skin dryness and erythema between the dressings. *Conclusions:* The best performing wound dressing in terms of skin protection without skin trauma was shown to be Mepitel Film. *Conflict of interest:* This project was funded by Mölnlycke Health Care.

KEY WORDS

- Hydrocolloid
- Dressing adhesives
- Transepidermal water loss
- Skin stripping

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Modern dressings are continually being developed to improve wound care. Major considerations in their development include the reduction of wound pain and the prevention of additional skin trauma.

Pain and trauma are common when traditional dressings are used; in part, this is due to their adhesives causing damage to periwound skin. Wound care dressings are now widely available, using a variety of different materials to adhere to the periwound skin, ideally without pain or skin trauma.

This study tests the properties of a new wound dressing — Mepitel Film — based on patented Safetac® (Mölnlycke Health Care) soft silicone adhesive, in comparison with two widely used advanced wound care dressings that incorporate different adhesives, Tegaderm (acrylic adhesive) and DuoDERM Extra Thin (hydrocolloid adhesive).

PAIN ON DRESSING CHANGE

It is generally accepted that dressing changes, particularly dressing removal, are one of the most painful wound care interventions, and that they can seriously impact on patient recovery and wellbeing (Hollinworth and Collier, 2000; Kammerlander and Eberlein, 2002).

An ideal dressing should minimise the pain of dressing changes by providing smooth, instant tack adhesion, thus removing the requirement for extra pressure to fix the dressing. It should also have an even adhesion that does not increase with time in order to reduce the risk of leaving behind dressing residue following removal.

Mepitel Film has been developed with ideal dressing characteristics in mind. Mepitel Film is a polyurethane film with a Safetac wound contact layer that is supported with a paper frame for ease of application (*Figure 1)*.

The dressing is sterile, and designed to be transparent and breathable.

Furthermore, the incorporation of a Safetac wound contact layer ensures that Mepitel Film is gentle to the wound and has instant tack that does not have increased adhesion over time (Rippon et al, 2007).

Advantages of instant tack include:

- Reduces pressure required to apply dressing
- Adhesion does not increase over time
- Less adhesive residue on skin after dressing removal
- Low pain with dressing application and removal.

SILICONE DRESSINGS

The repeated application and removal of some wound dressings results in trauma to the surrounding skin that can cause skin irritation, inflammatory skin reactions and pain (Cutting, 2008). Silicone-based dressings can minimise this, for example, a recently published evaluation of the skin stripping of wound dressing adhesives found that the soft silicone-based dressing, Mepilex Border® (Mölnlycke Health Care) — which utilises the same Safetac technology as the new Mepitel Film dressing — performed better in terms of skin protection and failure to cause skin trauma than the other five advanced wound care dressings that were evaluated (Waring et al, 2011). It has also been reported in a study on the adhesive areas of 56 modern wound dressings that dressings with a silicone adhesive required the least force to remove, and were reported to be the least painful to remove (Klode et al, 2011).

Major considerations when choosing a wound dressing are the type and aggressiveness of the dressing adhesive (Tokumura et al, 2005), conformability, and the length of time between dressing changes, as the correct choice of dressing can reduce the likelihood of causing wound trauma and erythema (Dykes et al, 2001).

Mepitel Film

Mepitel Film has been designed for the management of a wide range of superficial wounds, such as pressure ulcers (Stage/Grade I and II), burns and skin injuries. The gentle nature of the dressing protects fragile/sensitive skin.

Mepitel Film can also be used as a protective cover for open surgical wounds (e.g. abdominal wounds), as a secondary dressing for fixing primary dressings and, according to the manufacturers, can be used in combination with gels and ointments.

This study, involving healthy volunteers, was designed to evaluate the gentle nature of this next generation wound dressing, compared with two commonly used types of wound dressing that use hydrocolloid and acrylic adhesives. While volunteer studies do not involve actual wounds to enable parameters such as wound healing

KEY POINTS

- Instant tack adhesion reduces the requirement for extra pressure, and associated pain, in order to adhere the dressing
- Adhesion of a wound dressing should not increase over time, or leave behind residues following removal
- Pain should be minimised along with trauma to wounds and the surrounding skin
- A wound dressing should be sterile, flexible and gentle to the wound to avoid further damage or trauma to the wound

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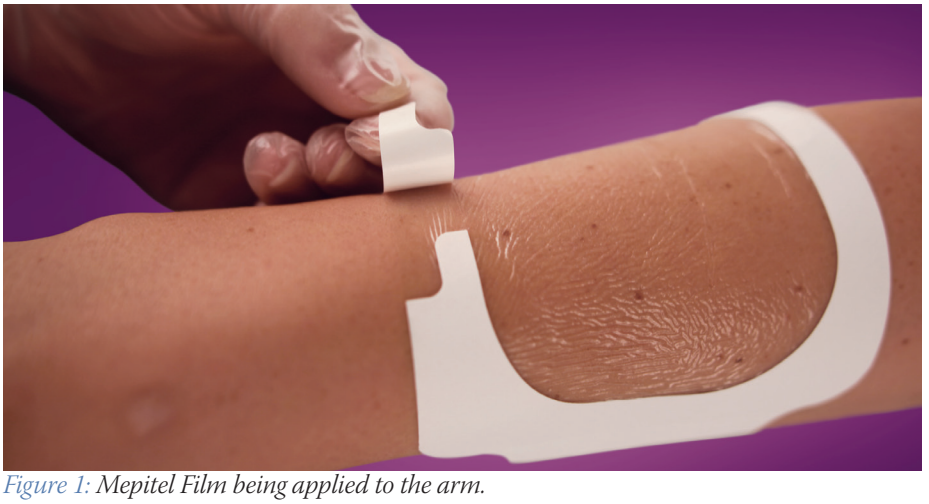

Figure 1: Mepitel Film being applied to the arm.

Table 1
Dressings used in the study

Code	Product	Manufacturer	Adhesive
A	Untreated		
B	DuoDERM Extra Thin	ConvaTec	Hydrocolloid
C	Mepitel Film	Mölnlycke Health Care	Silicone
D	Tegaderm	3M Health Care	Acrylic

References

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and wound pain to be measured, they are useful tools for undertaking controlled comparisons of different dressings on the same subjects.

METHOD

The volunteer study was carried out at proDERM Institute for Applied Dermatological Research, Hamburg, Germany, where 22 healthy participants were enrolled and used for data analysis. The study took place in a highly controlled manner in order to evaluate the dressings tested. The authors believe that this is an optimal methodology that removes the variables observed in the clinical situation.

Intervention

To compare the traumatic impact of the wound dressing adhesives, three dressings were tested alongside untreated skin (*Table 1*). The dressings were given a code letter and randomly allocated, with the volunteer unaware of which dressing was applied.

Study schedule

Participants were considered eligible for inclusion if they were over 18 years old and had uniform skin colour, with no erythema or dark pigmentation in the test area. Further inclusion criteria were:

- Willingness to conform to the study protocol
- Any underlying medical conditions, such as diabetes, had to be under control, with the volunteer currently receiving appropriate medical attention.

The exclusion criteria comprised:

- Pregnancy or lactation
- Drug addiction, alcoholism, AIDS or hepatitis (if known)
- Documented allergies to cosmetic products
- Exposure of the test area to UV-light (either artificial or natural) within the previous two weeks
- Conditions that exclude participation or might influence the test reaction/evaluation
- Systematic therapy with immunosuppressive drugs and/or antihistamines within the previous seven days or antiphlogistic agents or analgesics within the previous three days.

On the first day (day 0), the volunteers were informed about the study and gave their written consent. Before measurements were taken, the volunteers were acclimatised in a controlled environment (21 ± 1°C and 50 ± 5 % relative humidity) for at least 30 minutes.

This allowed all of the measurements to be made under the same conditions, thus minimising non-experimental differences that might occur, for example, in skin colour with different temperatures. Chromameter measurements were performed.

Table 2
Study schedule

Day	0	1	3	6	9	10	14
Acclimitisation (60 min)	X*	X*	X	X	X	X**	X
Visual evaluation		X	X	X	X		X
Chromameter measurement	X	X	X	X	X		X
TEWL measurement		X	X	X	X		X
Application of DHA patch	X						
Removal of DHA patch (6-7 hours after application	X						
Application of test product for pain assessment	X				X		
Application of test product on back		X	X	X	X		
Removal of test product on back			X	X	X		X
Pain assessment (by subject themselves)		X				X	

* Only 30 minutes acclimitisation ** Only 10 minutes before pain assessment

Four test areas on the patients' backs were stained with dihydroxyacetone (DHA) using an occlusive patch system (one area remained unstained). Each patch contained 250 µl of an aqueous 10% DHA solution on a filter disc (extra large Finn-Chamber). Two test products were applied to the volar arm per subject, with the patches being assigned randomly for the pain assessment. Approximately six to seven hours later, the subjects returned to the study site and the patches for the stratum corneum staining were removed. On day one, the volunteers returned to the study site. The volunteers were acclimatised (21 ± 1°C and 50 ± 5 % relative humidity) for at least 30 minutes and afterwards the visual evaluation, as well as all instrument measurements were performed. The test products were then applied on the back, according to a randomisation scheme.

For pain assessment, after 10 minutes of acclimatisation, patches on the volar forearms were removed by a technician on both sides simultaneously. The subjects rated pain on both test sites using an analogue scale.

On days three, nine and 14, the volunteers returned to the study site. The volunteers were acclimatised (21 ± 1°C and 50 ± 5 % relative humidity) for at least 60 minutes and afterwards, the visual evaluation and all instrument measurements were performed. On day nine, two test products were applied on the volar forearms per subject, according to a randomised scheme. On day 10, the subjects were acclimatised for at least 10 minutes, and the patches applied on the volar forearms the previous day were removed by a technician on both sides simultaneously. The subjects rated pain on both test sites using an analogue scale. The study was completed on day 14, with no further dressings applied. An overview of the test schedule for the study is shown in *Table 2*.

Transepidermal water loss measurements

The effect of the wound dressings on the skin's barrier function was measured by transepidermal water loss (TEWL), which is a recognised and validated method of measuring damage to the barrier properties of skin (Lodén, 1995; Laudańska et al, 2003; Elkeeb et al, 2010). TEWL was measured on days one, three, six, nine and 14 on each test site with replicate measurements being taken using DermaLab skin testing (Cortex, Denmark), (Tagami et al, 2002; Nuutinen et al, 2003; Fluhr et al, 2006; Cohen et al, 2009).

After measurements were completed, fresh test products were reapplied to the same area designated for that dressing. The baseline values and treatments were tested statistically for differences with analysis of variance (ANOVA), as well as differences between dressings, and were tested statistically using paired t-tests.

Chromameter measurements

The removal of the skin's stratum corneum was assessed using a DHA dye to mark the skin and subsequently measure the dye removal with the stratum corneum. Skin colour was measured on days zero, one, two, three, six, nine and 14 of the stained area using a Chroma Meter CR 300 (Konica Minolta, Langenhagen), (Lee and Kim, 1999; Settembrini et al, 1995; Yoshimura et al, 2001; Waring et al, 2011;) and compared with baseline readings of the unstained skin on day one. A simplified overall skin colour change ΔE^* (the symbol represents all three components of the L*a*b* colour space) is used to measure all three components of skin colour, expressing the data as a single value (Waring et al, 2011). Baseline values and treatments were tested for

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Table 3
Scoring for visual skin assessments

Score	*Virtual assessment*
0	*No results*
0.5	*Very slight*
1	*Slight*
2	*Moderate*
3	*Strong*

Table 4
Dressings ranked according to TEWL values
(Based on statistically significant results, the following ranking with significantly lower TEWL values (<) can be made, in the order lowest to highest values)

Day 3	*Day 6*	*Day 9*	*Day 14*
C, D, A < B	*C, A, D < B* *C > A*	*C, A, D < B*	*C, D, A < B*
A statistically significant result is deemed if the t-test p≤0.05			

Table 5
Dressings ranked according to chromameter values
(Based on statistically significant results, the following ranking with significantly lower ΔE* values (<) can be made, in the order lowest to highest values)

Day 3	*Day 6*	*Day 9*	*Day 14*
C, A, D < B	*C, A, D < B*	*C, A, D < B* *C, A < D*	*C, A, D < B* *C, A < D*

A statistically significant result is deemed if the t-test p≤0.05

statistical differences using ANOVAs, and differences between dressings at each time point tested using paired t-tests.

Volunteer and technician assessments

An objective visual evaluation of the test areas for the presence of erythema, dryness, fissures, papules, pustules, oedema, vesicles and weeping was carried out by a trained technician and subjective volunteer assessments were made for itching, burning, tightness and a feeling of dryness, according to the scores shown in *Table 3*. The data were tested for statistical differences with Wilcoxon signed-rank tests.

Subjective pain assessment

The subjects evaluated the pain sensation on a visual analogue scale (VAS) ranging from no sensation to strongest sensation of pain, directly after patch removal. Two dressings were removed simultaneously, with Mepitel Film being compared with the accrylic dressing on day one and Mepitel Film compared with the hydrocolloid dressing on day 10.

RESULTS

Twenty-two healthy volunteers enrolled in the study, and all 22 were used for data analysis. The average age of the volunteers was 57.4 ± 14.7 years, and 27% of the volunteers were male and 73% female.

Protocol violations

For subject 15, application of the hydrocolloid dressing was stopped on day nine after strong erythema on the test area. Furthermore, the markings caused redness on the skin. The Chromameter and TEWL measurements of subject 15 were excluded from statistical analysis. All investigations for visual evaluation were performed and these observations were carried forward for all following visits. Subject 18 took a shower, despite wearing the patches on the seventh day of the study. This deviation was regarded as minor and all data were included in analyses.

An additional note was made that the hydrocolloid dressing partly left adhesive residue on the subject's skin.

Measurement of TEWL

The results of TEWL measurements represent the mean values (*Figure 2*), showing a statistical difference between the hydrocolloid dressing and the other test dressings. TEWL values measured on the untreated test area, as well as after application of Mepitel Film and Tegaderm, remained relatively unchanged during the study period of 14 days, while TEWL values after application of DuoDERM Extra Thin increased significantly after day six and remained high until the end of the study (day 14).

The statistical difference in TEWL between hydrocolloid and untreated, Mepitel Film and Tegaderm, is shown in *Table 4* in the rankings of TEWL values. Homogeneity of the TEWL baseline values was inspected using repeated measures ANOVA with factor test area. No significant differences between baseline values were found — p=0.866. To detect significant differences between test products, paired t-tests were performed on differences to baseline on day 14 and additionally on days three, six and nine.

Change in skin colour

In order to measure the removal of stratum corneum, the colour change of the stained skin after each dressing removal was assessed using a chromameter. As the skin is removed, the dye is removed with it, so a reduction in colour from the day two reading towards the baseline reading of day one, before the dye was added, suggests stratum corneum removal. The results of the skin stripping measurements are shown in *Figure 3* as a plot of combined chromameter ΔE* data. From the plotted data, it is easily observable that the DuoDERM Extra Thin dressing has higher skin colour loss occurring from day three than Mepitel Film, Tegaderm or untreated skin.

Homogeneity of baseline chromameter values (ΔE* on day one) was inspected using a repeated measurements ANOVA with factor test area. No significant differences

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between baseline values were found — p=0.758. To detect significant differences between test products, paired t-tests were performed on day 14 and additionally on days three, six and nine. The dressings were then ranked as shown in *Table 5*.

The hydrocolloid dressing had statistically significantly higher loss of skin colour from day three to day 14 when compared with untreated skin, Mepitel Film and Tegaderm dressings. Furthermore Tegaderm had a significantly higher loss of skin colour on days nine and 14, compared with untreated skin and Mepitel Film.

This data clearly show Mepitel Film to have the lowest loss of colour, as well as being the least damaging of the dressings tested.

Visual evaluation of the skin

Dressing removal and barrier damage was also assessed by objective visual evaluation by a trained technician, as well as subjective evaluation by the volunteers themselves.

The subjective evaluations for all dressings provided very few adverse results, with only minimal reactions being documented for itching, burning, tightness and for the objective parameter, papules, while no statistical differences were found between treatments.

The mean values of the objective parameter erythema are presented in *Figure 4* and it is evident that Mepitel Film causes the least redness of all the dressings studied.

A summary of all the skin evaluations and skin reactions are shown in *Table 6*. All the dressings showed rather few and mostly mild, observable skin reactions. Of the three dressings tested, the one with the least reported skin reactions was Mepitel Film.

Pain assessment

The subjects evaluated the pain involved in dressing removal, with two dressings being removed simultaneously. Their sensation of pain was plotted on a visual analog scale (VAS) ranging from no sensation to strongest sensation of pain, directly after patch removal. On day one, Mepitel Film was compared with Tegaderm and on day 10, Mepitel Film was compared with DuoDERM Extra Thin.

The results of this pain assessment are presented in *Table 7*. All of the dressings performed well, achieving low pain assessment scores. The mean values for pain assessment were lower for Mepitel

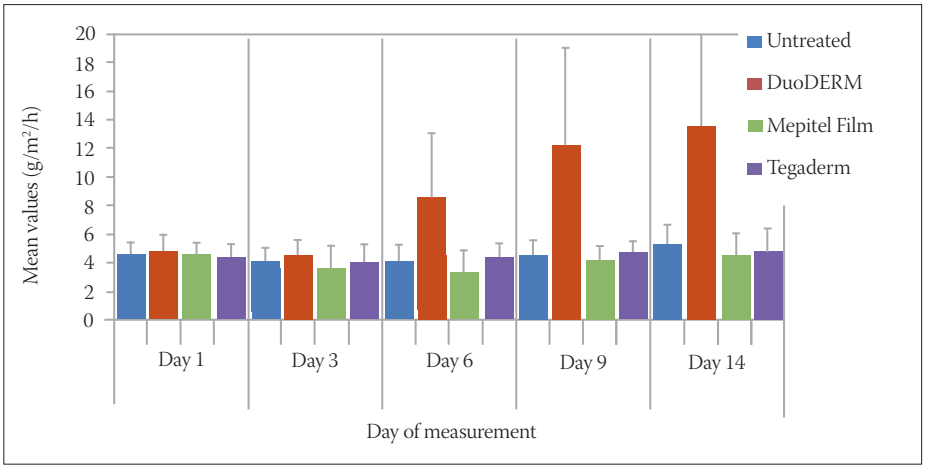

Figure 2: Bar chart displaying the mean TEWL measurements with standard deviation error bars.

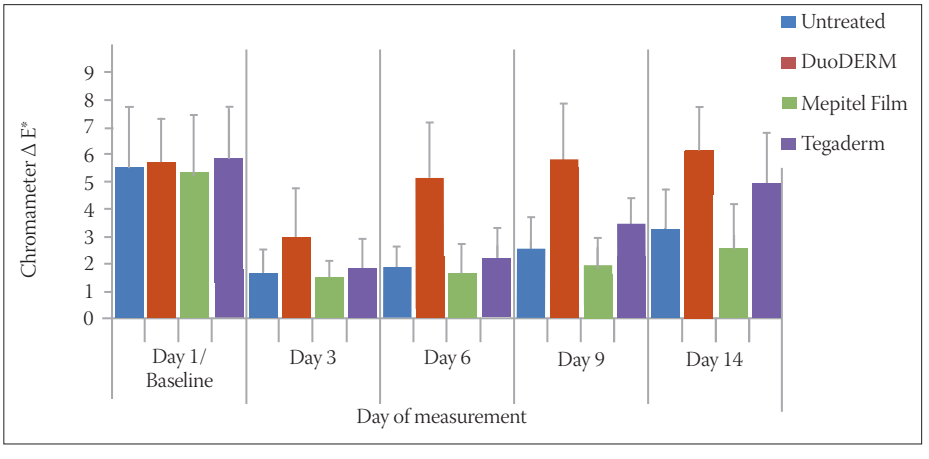

Figure 3: Bar chart displaying the mean chromameter Δ E skin colour measurements with standard deviation error bars.*

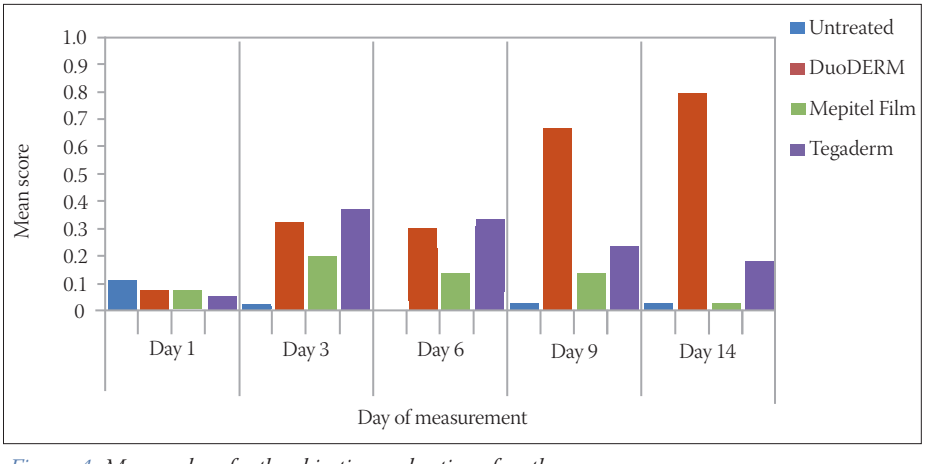

Figure 4: Mean values for the objective evaluation of erythema.

Table 6
Summary of skin evaluations

Skin evaluation	*Dressing*		
	DuoDERM Extra Thin	*Mepitel Film*	*Tegaderm*
Itching	*Two reports of slight or moderate on days 6 and 9*	*None reported*	*None reported*
Burning	*One report of very slight then slight on days 9 and 14*	*One report of strong on day 14*	*One report of strong on day 14*
Tension	*One report of very slight on day 6*	*None reported*	*One report of moderate on day 14*
Dryness (subjective)	*None reported*	*None reported*	*One report of slight on day 14*
Dryness (objective)	*One report of very slight on day 14*	*Three reports of very slight on day 14*	*One report of slight on day 9 and two moderate on day 14*
Fissures	*None reported*	*None reported*	*One report of very slight on day 9*
Papules	*One report of very slight and one slight on day 3, one very slight on days 6 and 9, two very slight on day 14*	*One report of slight on day 9 and one very slight on day 14*	*Two reports of very slight on day 6, one very slight on day 9, two very slight and two slights on day 14*
Pustules	*None reported*	*None reported*	*None reported*
Oedema	*None reported*	*None reported*	*None reported*
Vesicles	*None reported*	*None reported*	*One report of slight on day 3*
Weeping	*None reported*	*None reported*	*None reported*

Film than Tegaderm and DuoDERM Extra Thin, but the difference was not statistically significant.

DISCUSSION

In this study TEWL showed no real change during the study period after repeated application of Mepitel Film and Tegaderm, comparable with the untreated test area, indicating no damage of the skin barrier after repeated application. After the removal of DuoDERM Extra Thin, increasing TEWL values indicated impairment of skin barrier function.

Changes in stained skin colour also showed a similar pattern with Mepitel Film (the dressing that removes the least stratum corneum), followed by Tegaderm and then DuoDERM Extra Thin. Assessment of skin reactions by objective and subjective evaluation showed the most instances of erythema, dryness and itching occurring after application of DuoDERM Extra Thin, followed by Tegaderm. Fewer reactions were noticed for Mepitel Film.

Furthermore, less pain was assessed by the subjects when removing Mepitel Film, compared with Tegaderm and DuoDERM Extra Thin, but no significant difference was proved.

The overall trend of all the data shows Mepitel Film to be the best performing and most gentle wound dressing used in this study.

Making the correct choice of wound dressing for the specific wound type is subjective, but the general consensus is that a dressing must not cause further damage to the wound and be fit for purpose (Chaby et al, 2007; Vaneau et al, 2007).

Dressings with Safetac technology have already been used to treat a wide range of types of wounds, including pressure ulcers, burns and scalds, and paediatric injuries, as well as being used to fixate skin grafts (Williams, 1995; Gotschall et al, 1998; Vloemans and Kreis, 1994; O'Donovan et al, 1999; Meaume et al, 2003).

CONCLUSION

Overall, the highest skin stripping and barrier damage and therefore lowest

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Table 7
Mean values and statistical analysis of pain assessment

	Product	*Mean value*	*p-value — comparison of products by t-test*
Day 1	*Mepitel Film*	*11.43*	*0.291*
	Tegaderm	*14.67*	
Day 10	*Mepitel Film*	*12.89*	*0.218*
	DuoDERM Extra Thin	*18.67*	
A statistically significant result is deemed if the t-test p≤0.05			

skin tolerance was found for DuoDERM Extra Thin followed by Tegaderm. The lowest skin stripping, barrier damage and skin irritation was found for Mepitel Film.

Furthermore, less pain was experienced by the subjects when removing Mepitel Film than Tegaderm and DuoDERM Extra Thin, but no significant difference was proved.

This study, although limited by the number of dressings tested, shows the potential of the new Mepitel Film wound dressing to be highly gentle in nature and exhibit fewer signs of skin damage than comparable wound dressings. WUK

'It is generally accepted that dressing changes, particularly dressing removal, are one of the most painful wound care interventions'