

The link between the peel force of adhesive dressings and subjective discomfort in volunteer subjects

- **Objective:** The study compared the level of discomfort experienced by healthy volunteers on the removal of a range of adhesive wounds.
- **Method:** This was an open, within subject comparative study of six adhesive dressings in 24 volunteers. The test site was the lower back. Allocation of test materials to the test sites was randomised. The peel force of removal was recorded after 24 hours of application using a device that removed the dressing at a constant speed and angle to the skin surface. The discomfort experienced at each removal was assessed by the subjects themselves using an electronic visual analogue scale.
- **Results:** Overall, Mepilex Border was given a significantly lower discomfort score ($p \leq 0.01$) by the subjects than the other dressings. There were no clear differences between the five other products tested. Tielle and Allewyn Adhesive had significantly higher ($p \leq 0.05$) peel force than the other products. Mepilex Border caused less discomfort on removal than Duoderm Extra Thin, Biatain and Versiva, even though the peel force was similar. Tielle and Allewyn had higher peel force, but the levels of discomfort were not significantly higher for these products.
- **Conclusion:** It may be that the level of discomfort experienced by subjects on removal of an adhesive dressing is not entirely dependent on the peel force and that other aspects of the interaction of the skin surface and adhesive play a role.
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adhesive dressings; subjective discomfort; volunteer study; dressing peel force

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Part of the pain and discomfort experienced at wound dressing change is attributable to the adhesive edge of the dressings. However, in a clinical situation it is difficult to differentiate between the effects of the adhesive edge and the material directly in contact with the wound bed.

Previous studies involving healthy volunteers¹ have shown that the peel force of adhesive edges of wound dressings varies about twofold. In this study the level of subjective discomfort on removal of the adhesive edge was assessed in healthy volunteers, and the relationship to peel force investigated.

Method

Subjects

The study was conducted, using healthy volunteers, at Cutest Systems, Cardiff, UK. The local health authority ethics committee approved the study. Twenty-four healthy volunteers, seven male and 17 female, with a mean age of 42 years (age range: 18–65), were recruited from the test panel of Cutest.

Written informed consent was obtained from each volunteer before enrolment into the study and appropriate evaluations (medical history and examination) were undertaken to ensure that each subject was in good health before participation.

Subjects using concomitant medications that were likely to interfere with the study, those with any history or presence of allergy or skin disease, women who were pregnant or lactating or likely to become pregnant, and those who were known to be intolerant to adhesive tapes were excluded.

Study design

The study was an open within subject comparative study of the adhesive edges of six adhesive dressings in 24 healthy volunteers. The test products selected for the study were :

- Mepilex Border (Mölnlycke)
- DuoDERM Extra Thin (ConvaTec)
- Biatain (Coloplast)
- Tielle (Johnson and Johnson)
- Versiva (ConvaTec)
- Allewyn Adhesive (Smith and Nephew).

The dressings were not strictly removed in accordance with the manufacturers' instructions, and this should be borne in mind when considering the results. The test site was the lower back.

Six test sites were identified on the lower back corresponding to the six test materials. Allocation of test materials to the test sites was randomised. The products (each measuring 15 x 2.5cm) were applied vertically to the lower back of each subject

References

- 1 Dykes, P.J., Heggie, R., Hill, S.A. Effect of adhesive dressings on the stratum corneum of the skin. *J Wound Care* 2001; 10: 2, 7-10.
- 2 Zar, J.H. *Biostatistical Analysis* (2nd edn). Prentice-Hall, 1984.

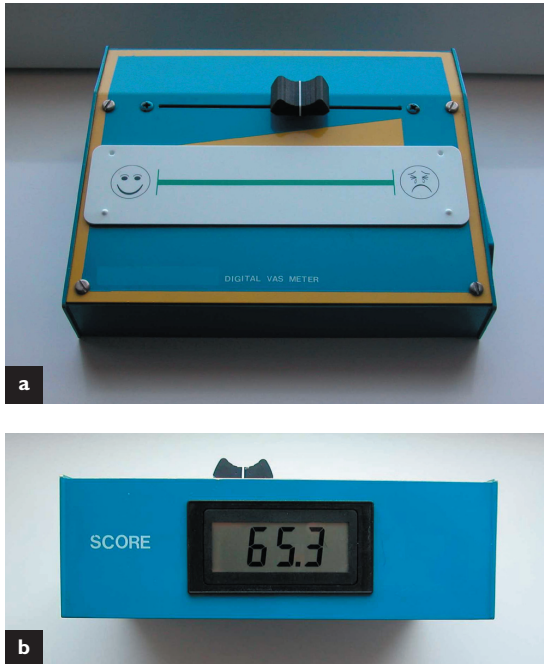


Fig 1. Electronic visual analogue scale discomfort meter. a:View from the subject's perspective; b:View of the VAS score not seen by the subject

on day 1 in a parallel array. The peel force of removal was recorded at day 2 (24 hours).

Discomfort experienced by the subject at each removal was assessed using an electronic 100mm visual analogue scale (VAS).

Peel-force measurement

The test materials were removed under standardised conditions, as described in an earlier study.¹ A purpose-built device was used to measure the force required to peel the test strips from the skin at an angle of 135° to the surface at a constant speed of 25mm per second.

Peel force was measured in Newtons using a transducer, which had been calibrated using a series of known weights. The output from the transducer was amplified and recorded using a chart recorder (1mm on chart recorder = 0.04 Newtons). The initial detachment (peak) force and the steady-state force, which occurs once the material starts to become detached, were obtained from the output of the chart recorder.

Assessment of discomfort

Subjective assessment of discomfort was made with the help of a VAS. The electronic VAS meter (Cardiff Biometrics) used consists of a sliding button set on a 100mm scale (Fig 1a).

Subjects were instructed to position the button at a point on the scale according to the degree of discomfort experienced. They were informed that the

left-hand point of the scale (0mm) corresponds to no discomfort and the right-hand end (100mm) to extreme discomfort.

The VAS meter was set at approximately 50mm before each assessment. The value recorded from the position on the scale was displayed on the back of the meter (Fig 1b), so the subject was unaware of the exact value they had given.

This value was recorded for each adhesive dressing removal. Subjects were not aware of the order in which the dressings were removed to avoid bias.

Statistical analysis

To avoid any assumptions about the normality of the data, the analysis was carried out using a non-parametric multiple-comparison procedure based on the Tukey-HSD test.² This test allows for the bias that normally creeps in when repeated statistical tests are done. All statistical analyses were performed using Unistat for Microsoft Windows version 5.

Results

The median VAS discomfort scores and quartiles are illustrated in Fig 2. Statistical analysis indicated that Mepilex Border had a significantly lower discomfort score than the other products (p<0.01). All other comparisons were not statistically significant.

The median peak peel force and quartiles are shown in Fig 3. Data are given in mm (1mm on chart recorder = 0.04 Newtons). Statistical analysis indicated that Tielle had a significantly higher peak peel force than Mepilex Border, Biatain, DuoDERM Extra Thin and Versiva (p<0.01). In addition, Allevyn Adhesive had a higher peak force than DuoDERM Extra Thin and Versiva (p<0.05). All other comparisons were not statistically significant.

The median steady-state peel force and quartiles are illustrated in Fig 4. Tielle had a significantly

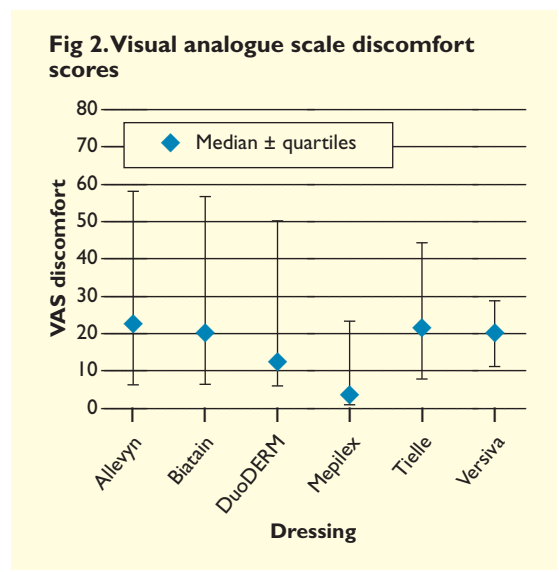


Fig 3. Peak peel-force values

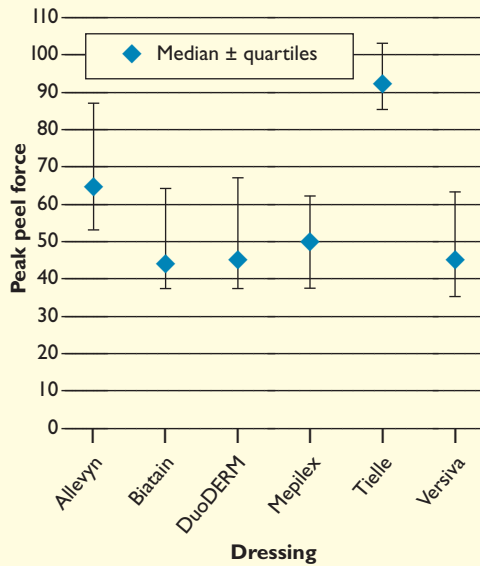
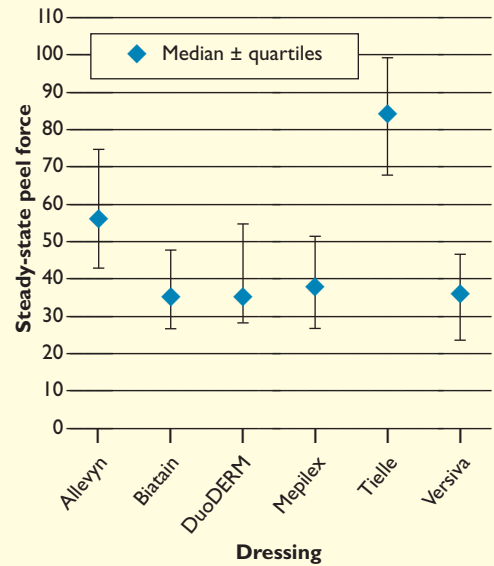


Fig 4. Steady-state peel-force values



higher steady-state peel force than Mepilex Border, Biatain, DuoDERM Extra Thin and Versiva ($p < 0.01$). Allevyn Adhesive had a higher steady-state peel force than Mepilex Border, Biatain and Versiva ($p < 0.05$). All other comparisons were not statistically significantly.

Discussion

In the VAS discomfort data, overall, Mepilex Border had lower scores than the other products and

caused less discomfort on removal. There were no substantial differences between the other products tested.

The peel-force data showed that Mepilex Border had a similar peak force of removal to Biatain, Duoderm Extra Thin and Versiva. The statistical analysis confirmed this, in that no statistically significant differences were apparent between these products. Allevyn Adhesive and Tielle had higher peak force values, and statistically significant differences were observed between these products and those showing a lower peak force.

Mepilex Border had a similar peel force in terms of steady state force to Biatain, DuoDERM Extra Thin and Versiva. Again, there were no statistically significant differences between these products. However, both Allevyn Adhesive and Tielle had higher steady-state force values. Once again, statistically significant differences were observed between these products and those showing a lower steady-state force.

Conclusion

This study showed differences in the degree of discomfort on removal of adhesive dressings using a method that removes them at a constant speed and angle to the skin surface. Differences were also recorded in terms of the peel force of removal.

However, correlation between VAS discomfort and peel force was poor. This suggests that the level of discomfort experienced by subjects on dressing removal does not depend entirely on the peel force and that other aspects of skin-surface adhesive interaction play a role. ■

Box 2. Implications for clinical practice

This study was carried out on normal skin and was designed to investigate the relationship (if any) between adhesion and discomfort. Although the results showed there was no obvious relationship, they did clearly demonstrate differences in discomfort on removal. It is possible that this difference is maintained in a clinical situation on peri-lesional skin. However, this cannot be ascertained until clinical trials involving patients are carried out

Box 3. Summary of the main findings

This study set out to investigate the level of discomfort experienced by 24 healthy volunteers during the removal of six different adhesive dressings from a test site on the lower back. Discomfort was measured using a visual analogue scale

Subjects experienced a similar level of discomfort for five of the six dressings tested. One dressing resulted in a lower level of discomfort than the other five

This dressing had similar peel-force values to three of the other dressings. The remaining two had higher peel-force values

Correlation between measurements made on the electronic visual analogue scale and peel force was poor, indicating that other factors may affect subjects' perception of the level of discomfort experienced on dressing removal