

Effects of adhesive dressings on the stratum corneum of the skin

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Two human models were developed to quantify the stratum corneum removed by different adhesive dressings and to measure the peel force of dressing removal and relate this to stratum corneum removal. The first was an open study designed to compare the effects of applying Mepiform Safetac, Tielle and Duoderm Extra Thin to the skin of 12 normal volunteers aged 19–53 years. Treatments were applied once (one 24-hour application) or three times (three x 24-hour applications) to forearm skin which had been prestained with methylene blue. After dressing removal the dye left on the skin was sampled using the skin surface biopsy method and measured spectrophotometrically.

The results show that, after one and three applications, the Mepiform Safetac sites had a higher level of dye than those on which the other dressings had been applied ($p < 0.05$, after three applications). Based on the assumption that the more dye is left on the skin, the less damage is caused, this suggests that Mepiform Safetac is less damaging to the skin surface than the other products tested.

In the second study the peel force needed to remove adhesive dressings from prestained skin was measured and related to the amount of stratum corneum removed. Mepilex Border Safetac, Duoderm Extra Thin, Allevyn Adhesive, Biatain Adhesive and Tielle Hydropolymer Dressing were compared in 20 normal volunteers aged 23–64 years. Three consecutive 24-hour applications of each product were made, with measurements of peel force at 24, 48 and 72 hours. The amount of dye remaining on the skin at 72 hours was assessed by the surface biopsy method.

Statistically significant differences between products were observed in terms of both peak force and steady state force of removal. Differences in the level of damage to the superficial stratum corneum were also detected. However, low levels of peel force were not always associated with low damage and, therefore, other factors must contribute to stratum corneum removal in this model.

Adhesive tapes and dressings cause minor damage to the skin surface on removal, consisting mainly of the removal

Adhesive dressings; Stratum corneum; Skin stripping; Dressing peel force

of varying amounts of superficial stratum corneum. The repeated application and removal of adhesive tapes or dressings to the same site (skin stripping) causes changes in skin barrier function, most noticeably an increase in transepidermal water loss.¹ This, in turn, leads to a burst of mitosis in the basal epidermal cells (wound healing response), which is proportional to the extent of the damage.^{2,3,4} An inflammatory skin reaction may develop, with typically erythematous, oedematous and vesicular changes. Long-term wound management may be complicated by changes of this nature in the normal skin adjacent to the wound. Although other

factors, such as occlusion, chemical irritancy and allergies, may add to cutaneous reactions in perilesional skin,

skin stripping is an early and important contributing factor in the development of such lesions.

In order to understand the nature of the interaction of adhesives with the skin surface, models that simulate clinical usage in a controlled manner are needed. This article describes two human volunteer studies which attempted to:

- Measure the amounts of stratum corneum removed by different types of adhesive dressings
- Relate the degree of damage caused to the skin surface by adhesive dressings to the forces needed for removal.

Methods

This study, conducted using healthy volunteers, was undertaken in the Department of Dermatology at the University of Wales College of Medicine and approved by a local health authority ethics committee. Written, informed consent was obtained from each volunteer and appropriate evaluations (medical history and examination) were undertaken to ensure that they were in good health. The following subjects were excluded: those using concomitant medications likely to interfere with the study; those with any history of or who presented with an allergy or skin disease; females who were pregnant or lactating, or likely to become pregnant; subjects known to be intolerant to adhesive tapes.

Study 1: Measuring the amount of stratum corneum removed

■ **Study design** This was an open, within subject comparison of the effect of three adhesive dressings on the skin of 12 healthy volunteers (three males and nine females) aged 19–53 years (mean age: 35). The dressings were:

- Mepiform Safetac self-adherent soft silicone scar dressing (Mölnlycke)
- Tielle Hydropolymer Dressing adhesive edge (Johnson and Johnson)
- Duoderm Extra Thin (ConvaTec).

The dressings were randomly allocated to three out of four test sites (2 x 2cm) marked on the flexor aspect of both forearms (four sites per arm), one arm corresponding to one 24-hour application and the other arm to three consecutive 24-hour applications. The fourth site on each arm acted as an untreated control site and was covered with a non-adherent silicone gauze.

■ **Staining the superficial stratum corneum** The superficial stratum corneum in the centre of the test site was stained by applying a 12mm aluminium Finn chamber containing a 11mm filter paper disc wetted with 0.03ml 1% aqueous methylene blue. The chamber was applied to the skin surface for 60 minutes. This was sufficient to produce an even staining of only the superficial layers of the stratum corneum.

■ **Application of test materials** The test materials were applied to the test sites on both arms according to a randomisation schedule. They were removed and discarded after 24 hours. One arm received one 24-hour application and the other arm three consecutive 24-hour applications.

■ **Stratum corneum removal** The stratum corneum at the test site was removed using the skin surface biopsy procedure.⁵ Two samples were taken from each site to ensure that all of the prestained stratum corneum was removed.

■ **Solubilisation of skin surface biopsies** The skin surface biopsies were cut into several small pieces (nine to 12, each approximately 6 x 6mm) with a glass cutter, placed in glass tubes containing 2ml dimethyl sulphoxide (DMSO, Analar grade) and shaken every 10–15 minutes over a two-hour period to ensure the dye extraction was complete. The dimethyl sulphoxide extract was centrifuged at 1000g for 10 minutes to remove fragments of stratum corneum. One millilitre of dimethyl sulphoxide was then transferred to a disposable plastic cuvette to measure the optical density.

■ **Optical density measurements** These were made using a Beckman DU-640 spectrophotometer. Initially, a blank cuvette containing dimethyl sulphoxide was scanned from 550–800 nanometers (nm). An extracted skin surface biopsy from a stained area of skin was then scanned to determine the maximum absorbance. This was at 669nm, and all subsequent measurements were therefore made at this wavelength. The results were expressed as optical density units.

■ **Statistical analysis** The study design was that of a within subject comparison of four treatments and two application schedules. An ANOVA procedure was carried out, with the application schedule (once or three times) as the covariate. The results indicated that the effects of the treatment were significant ($p < 0.0001$) but that the number of applications was not ($p = 0.28$). To avoid any assumptions about the normality of the data, subsequent analysis used the non-parametric Friedman ANOVA procedure followed by a multiple comparison procedure based on the Tukey test.⁶ The data were analysed using UNISTAT for Windows version 4.5.

Study 2: Relating the degree of damage to the forces needed for removal

■ **Study design** This was an open, within subject comparison of the effect of the adhesive edges of five dressings on the skin of 20 healthy volunteers (eight males and 12 females) aged 23–64 years (mean age: 36). The dressings were:

- Mepilex Border Safetac, a new self-adherent soft silicone wound dressing (Mölnlycke)
- Duoderm Extra Thin (ConvaTec)
- Alleevyn Adhesive (Smith and Nephew)
- Biatain Adhesive (Coloplast)
- Tielle Hydropolymer Dressing (Johnson and Johnson).

These treatments were randomly allocated to five out of six test sites (3 x 15cm) marked on each subject's back. The sixth site acted as an untreated control and was covered with a non-adherent silicone gauze. All sites were prestained with methylene blue, as in study 1.

Fig 1. The dressing peel force measurement device

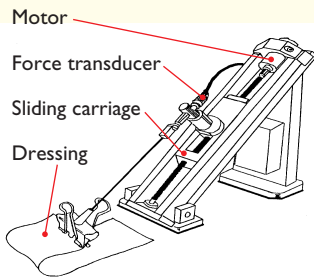
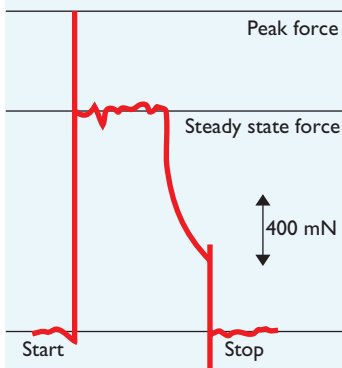


Fig 2. Study 1: transducer output in mNewtons



■ **Application of test materials** These were applied to the test sites according to a randomisation schedule and removed and discarded after 24 hours. Application and removal was repeated twice over 24-hour intervals, amounting to three consecutive applications.

■ **Peel force measurement** The test materials were removed using a device, built in the department of dermatology, which measures the force needed to peel the test materials off the skin surface at a 135° angle at a constant speed of 25mm per second (Fig 1). Peel force was measured in mNewtons using a transducer calibrated with a series of known weights. Output from the transducer was amplified and recorded using a chart recorder. The initial detachment (peak) force and the steady state force achieved once the material had started to detach from the skin were obtained from the output of the chart recorder (Fig 2).

■ **Estimation of skin surface damage** The degree of skin surface damage was assessed using the methylene blue/skin surface biopsy method, as in study 1.

■ **Statistical analysis** The study design was that of a within subject comparison of five adhesive dressings applied for three successive 24-hour periods, with measurement of removal forces at days 2, 3 and 4. An ANOVA procedure was used to determine treatment and time effects. The results indicated that the effects of the treatment were highly significant for peak force ($p < 0.0001$) and steady state force ($p < 0.0001$) but the time effects were borderline (peak force: $p = 0.047$; steady state force: $p = 0.052$).

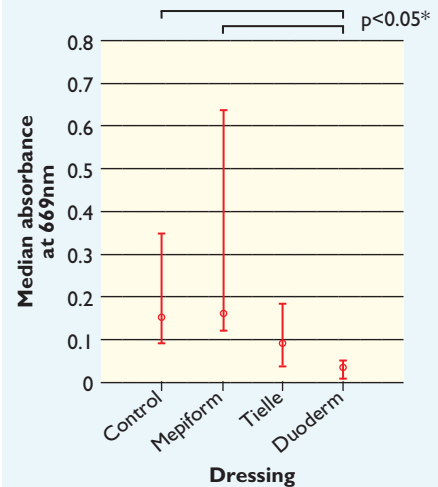
A summary statistic was used to simplify the statistical analysis. As the time effects were minimal, mean values for days 2, 3 and 4 were calculated for the peak force and steady state force and used for further analysis. To avoid assumptions about the normality of the data, subsequent analysis was carried out using the non-parametric Friedman ANOVA procedure followed by a multiple comparison procedure based on the Tukey test.

Results

Study 1

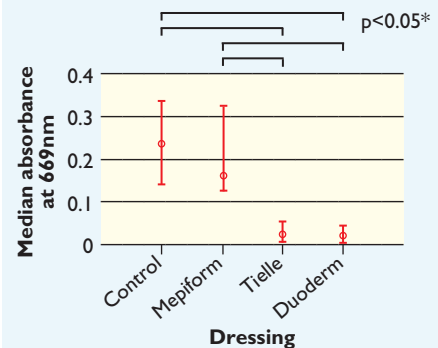
The median absorbance values, together with the 25th and 75th percentiles (interquartile range), after one and three consecutive 24-hour applications are given in Figs 3 and 4. Sites where Mepiform Safetac had been applied showed little stratum corneum damage, as the levels of dye were comparable with the control values. However, there were low levels of dye on the skin surface after the application of Duoderm, and to a lesser extent Tielle, indicating that a greater amount of superficial stratum corneum had been removed.

Fig 3. Study 1: median absorbance values and interquartile range after one 24-hour application



*Lines indicate statistically significant differences ($p < 0.05$) between treatments according to the multiple comparison procedure (Tukey test)

Fig 4. Study 1: median absorbance values and interquartile range after three 24-hour applications



*Lines indicate statistically significant differences ($p < 0.05$) between treatments according to the multiple comparison procedure (Tukey test)

Study 2

The mean steady state force values (three-day average) are given in Fig 5. Statistically significant differences were apparent between some of the products tested, with a rank order from greatest force to least mean peak force as follows: Allewyn Adhesive, Tielle, Duoderm, Mepilex Border Safetac and Biatain Adhesive.

The peak force measurement results were similar to those of the steady state force, except that, overall, the mean values were higher (results not shown).

The results of the damage assessment based on the median absorbance values (Fig 6)

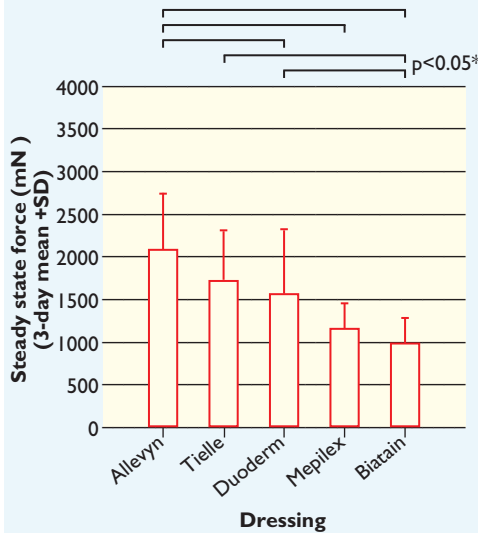


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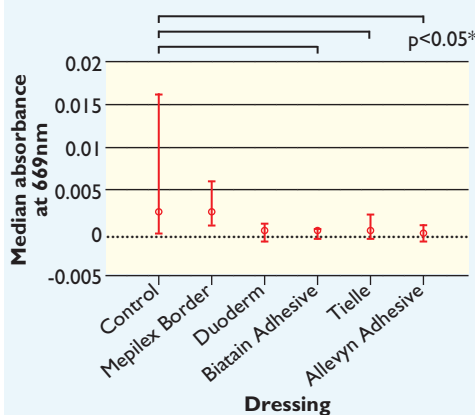
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Fig 5. Study 2: mean steady state peel force values



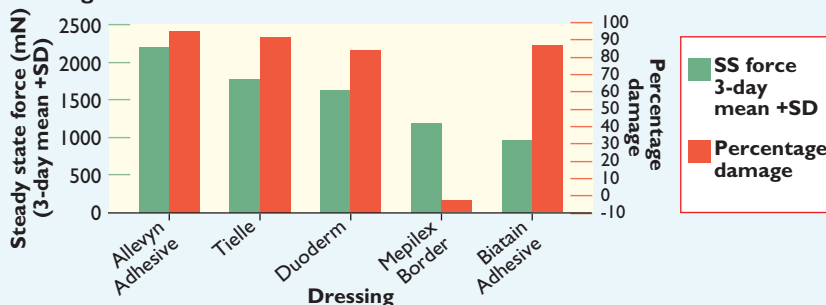
*Lines indicate statistically significant differences (p<0.05) between treatments according to the multiple comparison procedure (Tukey test)

Fig 6. Study 2: median absorbance values and interquartile range



*Lines indicate statistically significant differences (p<0.05) between treatments according to the multiple comparison procedure (Tukey test)

Fig 7. Study 2: comparison of mean steady state force with relative damage to control site



indicated that some statistically significant differences were observed, with a rank order of most to least damaging: Biatain Adhesive, Duoderm, Allevyn Adhesive, Tielle and Mepilex Border Safetac.

When expressed as a percentage of damage relative to control, a comparison can be made with the steady state force three-day mean values (Fig 7).

Discussion

The results of study 1 clearly show the removal of superficial stratum corneum following the simulated clinical use of three adhesive dressings in volunteer subjects. Statistically significant differences were apparent between the adhesive dressings tested, with Mepiform Safetac causing less damage to the stratum corneum than Tielle and Duoderm. Therefore, in clinical use, Mepiform Safetac might be expected to have a relatively low incidence of adverse cutaneous reactions caused by skin stripping compared with the other products tested. However, it has yet to be determined whether this model is predictive of actual clinical use as data from comparative trials are not currently available.

The results of study 2 indicate that the dressing peel force measurement device is capable of detecting statistically significant differences between products in terms of both peak and steady state force of removal. Differences in the level of damage to the superficial stratum corneum were also detected. However, the relationship between the degree of damage and peel force is not clear cut. For most of the products tested, the percentage damage appears to be related to peel force. Therefore, the low peel force of Mepilex Border Safetac was associated with a low percentage of damage and the high peel force of Allevyn with a high percentage of damage. However, Biatain Adhesive had a low peel force but also a high percentage of damage. Peel force does not always correlate with the degree of skin stripping observed in this model and, therefore, other factors must also determine the level of damage to the skin surface.

Conclusion

Two human models have been developed to quantify the stratum corneum removed by different adhesive dressings and measure the peel force of tape/dressings removal and relate this to stratum corneum damage. The results presented here suggest these models may help when attempting to select adhesive dressings that reduce skin damage on removal.

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