

PRELIMINARY STUDIES ON THE SKIN BIOPHYSICS AND OSTOMY SKIN BARRIERS

Part 1—Relationship among Peel Force, Quantitative Measures of Skin Damage and Subjective Discomfort Using the Abdomen as the Test Site

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INTRODUCTION

There are several published laboratory methods for quantifying tack and strength of adhesion for a wide range of adhesive materials. These methods have permitted the analyses of the influence of variables, such as peel angle, peel rate and adhesive thickness on the measured adhesive strength (1-2). However, the use of inert substrates in these laboratory tests is a critical limitation on the ability to relate those measurements to either skin damage in use or subject/patient perception of discomfort related to the removal of adhesive materials (3-4). Studies using animal skin (5) or a synthetic substrate with physico-chemical properties intended to mimic the skin (6) have been reported, but are not widely utilized. This is due, in part, to limited validation of these systems to the human use situation.

Studies on adhesive strength using human volunteers generally utilize the arms or back as the test site, and limited evidence strongly suggests significant variation among anatomical sites (7-12). The results from studies attempting to use peel force to predict either subject discomfort or skin damage have been equivocal (7-9, 11-12).

The objective of this study was to assess the adhesion of various materials as a function of time using the abdomen as

the relevant body site for stoma skin barrier adhesion, and to determine if a relationship exists between the observed peel force and either skin damage or subject discomfort. The primary measures were peel force measured at various times after application, and skin damage as assessed by quantifying changes trans-epidermal water loss (TEWL). Secondary measures were skin color (erythema), amount of skin cells adhering to the adhesive and the self-assessment of discomfort (pain) during removal. While the study was qualitative in nature, basic statistical analyses were performed on the data for the key measurements.

MATERIALS AND METHODS

The protocol received IRB approval, and all subjects provided informed consent prior to enrollment into the study. This was a comparison of six materials using five groups of at least six subjects. Material placement was balanced for site of application. Products A-D were commercial hydrocolloid formulations based on polyisobutylene (PIB). Product E was a prototype based on Product D, and Product F was a prototype based on a soft amorphous gel adhesive system. The backings for the adhesives and adhesive thickness were as similar as possible. Test samples were 1" x 2.5".

Prior to placement of the test materials, half of each application site was stained with crystal violet. Each participant had all six materials applied to their abdomen, and all six materials were removed during one session. Group 1 had the materials removed 30 minutes after application, Group 2 at 6 hours, Group 3 at 24 hours, Group 4 at 48 hours and Group 5 at 72 hours.

Peel Force

The key component of the peel force tester is based on a Diastron MTT160, a miniature tensile tester, that is interfaced to a bench-top PC. Based on consumer observation, a 90 degree peel angle was utilized. The peel angle was kept constant by using a novel pulley system which is affixed to a sliding block on the lead screw that moves the pull point. The geometry ensures that the forces generated as the adhesive tape resists being peeled away from the skin are pulling on the load cell in the same orientation regardless of the location of the pulley (Figure 1).

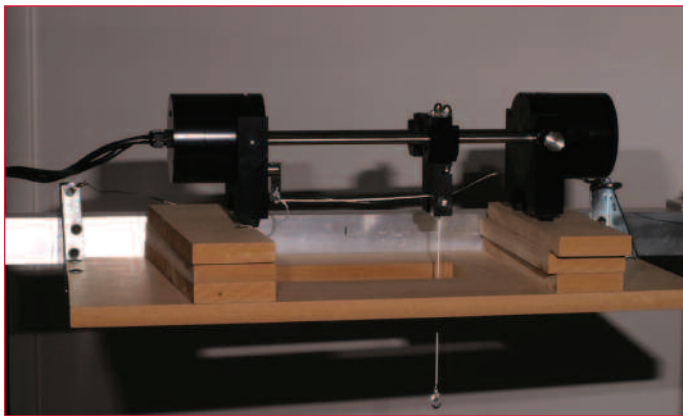


Figure 1: Modified Diastron MTT160, miniature tensile tester with a specially designed pulley system which is attached to a sliding block that is moved on the lead screw. The geometry is such that not only is there a constant angle of 90° maintained throughout the peel test, but the resulting resistance is always pulling on the load cell in the same orientation.

Straps were utilized to reduce extraneous movement of the skin during the peel test (Figure 2). The direction of pull was from the midline outward at a rate of 150 mm/min. Data was captured as gmF (grams mass force) as a function of displacement.



Figure 2: Use of thin straps to reduce deformation of the skin during the in vivo peel test.

Skin Damage

Transepidermal Water Loss (TEWL) measurements

Damage to skin barrier function as indicated by increased TEWL was assessed using a cyberDERM RG1 Evaporimeter with TEWL probes that were manufactured by Cortex Technology and utilizing well-described methodology (13, 14).

All water loss measurements were taken following a 15-30 minute acclimation period in a controlled environment with the relative humidity maintained at less than 50% and temperature maintained at $70 \pm 2^\circ\text{F}/21 \pm 1^\circ\text{C}$. Duplicate TEWL readings were taken from each site and an average reading calculated. Any individuals with baseline TEWL values outside the normal range ($>10.0 \text{ gms/m}^2\text{hr}$) were excluded.

Erythema (Minolta Chromameter a)*

Skin surface color was quantified using the Minolta CR-200 Chromameter. For color readings, the values are translated into the $L^*a^*b^*$ coordinates whose spacing correlates closely with color changes perceived by the human eye. Higher a^* values along the red-green axis are an indication that a treatment site is more irritated (15). Three sets of a^* readings were taken from each of the test sites at each session, and the average value computed for each site.

Cell Quantification/Staining Method

A 2 cm x 2 cm square sheet of lens paper was placed on the back edge of each treatment site. Fifty μl of 0.2% crystal violet was dispensed onto each lens paper square. After 60 seconds, the lens paper was removed and the skin surface wiped with a wet sponge to remove unbound dye. The test sites were patted dry and the test materials applied. The amount of cell-bound dye was measured directly from the adhesive sample after its removal using the Minolta Chromameter.

Subjective Assessment of Discomfort

Immediately following the removal of the sample, the subject was asked to evaluate the discomfort on a 0 to 5 scale, with 0 representing no discomfort and 5 representing severe discomfort.

RESULTS

A total of 33 subjects were enrolled. One subject was disqualified due to high baseline TEWL values. Groups 1-3 completed with six subjects each; groups 4 and 5 completed with seven subjects each. There were no adverse events.

For all materials, the peel force was highest after 30 minutes of adhesion. The peel force for the class of materials represented by product F was clearly higher than the others, at time points from 30 minutes to 48 hours after application. Interestingly, this material caused less disruption to the skin barrier as indicated by change in TEWL and was perceived to cause less discomfort on removal.

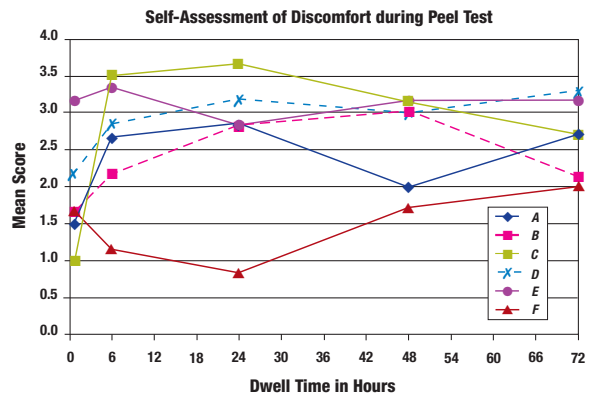


Figure 4: Test strips were removed from the skin following 0.5, 6, 24, 48 and 72 hours of adhesion (Dwell Time). Subjects rated discomfort on a scale of 0 to 5 with 0 representing no discomfort and 5 representing severe discomfort. Products are as described in Figure 3.

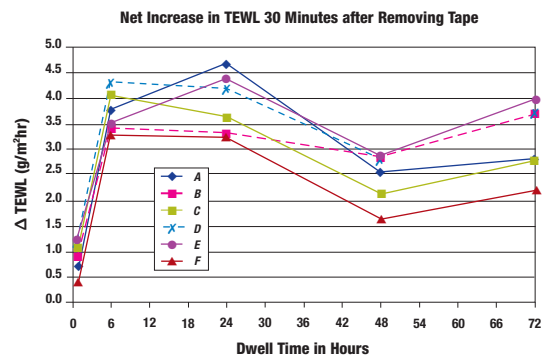


Figure 5: Test strips were removed from the skin following 0.5, 6, 24, 48 and 72 hours of adhesion (Dwell Time). TEWL was measured 30 minutes after test strip removal. Products are as described in Figure 3.

Erythema resulting from application and removal was highest in Group 3 (24-hour wear) and did not seem to discriminate among formulae (figure 6). Analysis of crystal violet stained cells was complicated due to inhomogeneity of stained cell removal, and more sophisticated analytical methods will be required.

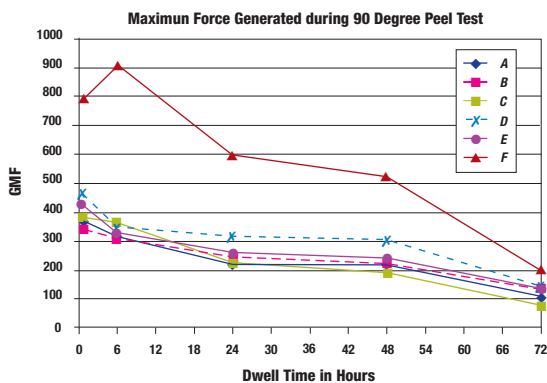


Figure 3: Test strips were removed from the skin following 0.5, 6, 24, 48 and 72 hours of adhesion (Dwell Time). Peel angle was 90° and peel rate was 150 mm/min. Products A through D are commercial hydrocolloid formulations based on polyisobutylene (PIB). Product E is a modification of Product D, and Product F is based on a soft amorphous gel adhesive system.

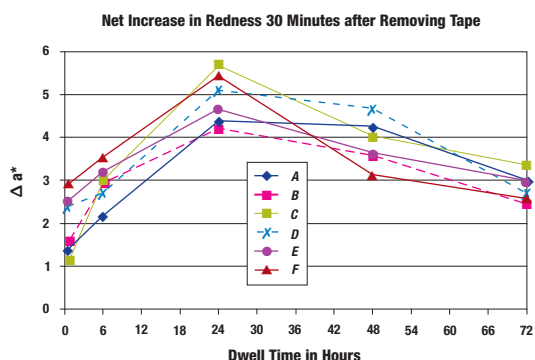


Figure 6: Test strips were removed from the skin following 0.5, 6, 24, 48 and 72 hours of adhesion (Dwell Time). Skin redness as indicated by increase in a^* was measured 30 minutes after test strip removal. Products are as described in Figure 3.

DISCUSSION

Using this methodology, strength of adhesion as measured by peel force was not a reliable predictor of either skin damage or self-reported discomfort. In this small test, Formula F clearly performed differently from the remaining formulae. Interestingly, Formula F had the highest peel force, yet the lowest report of discomfort. TEWL appeared to be the most sensitive discriminator of instrumental measurements and was more closely related to discomfort than peel force. Further investigations are planned to confirm these results and establish the predictive value of other biophysical measurements and discomfort.

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