Adhesive Tape Trauma Evaluation of Two Gentle Tapes in Healthy Human Subjects

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Introduction

Repeated application and removal of medical adhesive tapes can be traumatic to the skin. Such trauma can contribute to skin breakdown, especially with the elderly and other individuals with frail skin. It is the goal of adhesive tape manufacturers to develop tapes with adhesive properties that are strong enough to perform the task required of the tape, yet to be as gentle as possible to the skin.

However, gentleness of a medical adhesive tape is not always directly related to aggressiveness of the adhesive. Other factors such as occlusiveness of the tape, rigidity of the backing, and rheology of the adhesive can also play important roles in determining gentleness of the tape. Therefore, it is important when developing new gentle adhesive tapes designed for use on fragile skin, that the entire composition be tested against standard control tapes with an accepted history of gentleness.

The degree of skin damage can be assessed by multiple methodologies. Two well accepted methods that are often utilized are: 1) expert grader assessment of visible damage to the skin surface and/or erythema/edema resulting from such damage,[1,2] and 2) measurement of disruption of the stratum corneum water barrier by measurement of evapoative water loss.[1,3,4] Additionally, test subjects can often feel subtle differences in topically applied products that can elude other methods of assessment, so test subject self-assessments can also be revealing.

Recently a new medical adhesive tape with a gentle silicone-based adhesive technology has been developed. The goal of this study was to compare the relative gentleness of this new tape compared to a commonly used paper tape with a well accepted history as a *"gold standard"* for gentleness.

Objective

The objective of this study was to determine the relative gentleness of a new gentle tape‡ with a silicone-based adhesive compared to a *gold standard* for gentle medical tapes.§

References:

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5. Pinnagoda J. Standardization of Measurements. In: Elsner P, Berardesca E, Maibach HI, eds. Bioengineering of the skin: water and the stratum corneum. Boca Raton, Fla ; London: CRC; 1994:59-65.
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Methods

Overview: This study compared the relative gentleness of two surgical tapes on healthy human volunteers.‡,§ The tapes were applied and removed from the test sites daily (Monday through Friday) for 11 consecutive days. Friday tapes remained in place over the weekend.

Subjects: 28 subjects participated in this study (5 male, 23 female, median age 63). One subject withdrew early from the study due to a stinging/itching reaction from the control tape.

Test sites: Each subject had a total of six test sites, three test sites located on each of the left and right volar forearms. Test tapes were applied to the medial and distal test sites on each arm with the center site left untreated as a control.

Expert Grader Assessments: Test sites were evaluated for erythema/edema, skin stripping (denudation), and skin tears at baseline and on days 1, 4, 7 and 11. Test sites were scored approximately 30 minutes after tape removal and compared with the Friedman Test and Dunn's post-hoc comparisons.

Score	Erythema & Edema Severity Score
0	No visible response
1	Mild response. Diffused, patchy, not well-defined, just barely perceived erythema. No perceivable edema.
2	Moderate Response, perceivable erthema is obvious, with diffused redness. Pink or red in color, area well defined. No edema.
3	Severe Response. Obvious erythema. Definite red in color, area well defined. Edema present.
4	Extreme Response. Bright, fiery red erythema. Edema is present.

Score	Denudation Severity Score
0	No sign of denudation
1	Trace amount of denudations in epidermis. (Slight glazed appearance).
2	Partial thickness denudations (first sign of pitting in the skin) extending up to the glistening layer of the epidermis. (Moist and/or wet surface).
3	Full thickness denudations extending into the dermis. (Exudates present on the test site).
4	Full thickness denudations extending into the dermis or in combination with an extreme Erythema/Edema response.

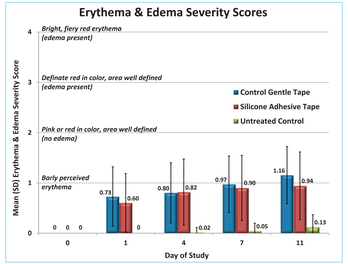
Subject Self-Assessments: On days 1, 4, 7, and 11, subjects were asked to rate pain (0 to 100 scale) upon removal of the tapes. Additionally, at the end of the study each subject was asked which tape they would prefer if they were a hospitalized patient. Differences in pooled treatment data were assessed with a Paired t-Test.

Tape Edge Lift: Lift Assessment was taken daily (excluding weekends), by staff other than the expert grader, prior to the tape removal. Lift was assessed according to the following scale: *0 = No Lift, 1 = 1%-25%, 2 = 26%-50%, 3 = 51%-75%, 4 = 76-99%, 5 = Tape is missing*. Differences in pooled treatment data were assessed with a Paired t-Test.

Transepidermal Water Loss (TEWL) Measurements: On days 1, 4, 7, and 11, all test sites were evaluated for TEWL following standardized methodology.[5] All water loss measurements were taken following a 30 minute acclimation period in a controlled environment with the relative humidity maintained at 40-50% and temperature maintained at 70 ± 2°F. Differences were compared with Repeated Measures ANOVA and Tukey post-hoc comparisons.

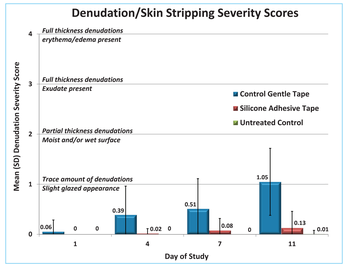
Product Footnotes:
‡ 3M™ Kind Removal Silicone Tape, 3M Company, St. Paul, MN
§ 3M™ Micropore™ Surgical Tape, 3M Company, St. Paul, MN

Results



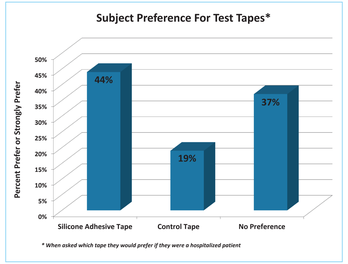
Expert Grader Assessment - Erythema & Edema

There was a modest increase in erythema with repeated removal and reapplication of the test tapes compared to Baseline. At no time was there any edema present on any of the test sites for any of the test subjects. It is noteworthy that neither of the test tapes was associated with more than mild mean erythema scores, even after 10 applications and removals. No significant difference was found between the test tapes at any time with regard to erythema.



Expert Grader Assessment - Skin Stripping/Denudations

The control tape exhibited significantly higher mean denudation scores than the silicone adhesive tape on days 4 ($p<0.05$), 7 ($p<0.05$), and 11 ($p<0.001$). At no observation were the mean denudation scores for the silicone tape significantly different from those at Baseline.



Subject Self-Assessment

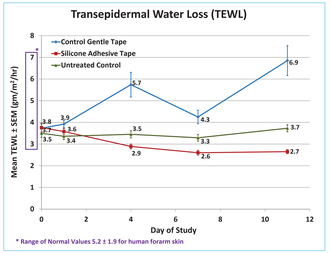
Subject self-assessments revealed 44% preferred/strongly preferred the silicone adhesive tape compared to 19% for the control tape and 37% having no preference. Pain scores at removal were very low for both tapes but were significantly lower for the silicone adhesive tape at all removals (Days 1, 4, & 7 $p=0.02$, Day 11 $p=0.009$).

Expert Grader Assessment - Skin Tears

There were no observations of skin tears on any of the subjects at any time during the study.

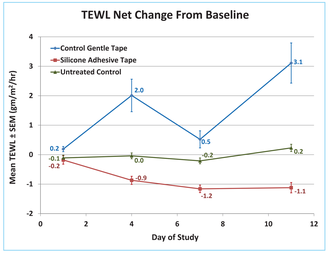
Tape Edge Lift Assessments

Edge lift values were low for both tapes. The mean (SD) lift score for all test sites across all observation points (N=478) was 0.38 (.57) for the control tape and 0.85 (0.62) for the silicone tape, indicating that on the average the mean edge lift was less than 25% for both tapes.



Transepidermal Water Loss Assessments

The results of transepidermal water loss measurements reveal a modest increase associated with repeat application and removal of the control tape. On Day 11 the mean TEWL value for the control tape was found to be significantly greater than both baseline and the silicone adhesive tape values ($p<0.001$).



It is noteworthy that though elevated, the mean TEWL values associated for the control tape remained within a range found with normal healthy skin, indicating that the degree of skin stripping was minimal.[6] Additionally, silicone compounds are known to have a conditioning effect on skin,[7] which probably accounts for the decrease in TEWL below baseline values for the silicone tape.

Conclusions

- Both surgical tapes were found to be very gentle to the skin during this 11 day repeat application study, which is consistent with historical usage of the control tape.
- The new silicone adhesive tape was found to cause significantly less damage to the stratum corneum based on Expert Grader assessments and on instrumental measurements of TEWL.
- Test subjects perceived less discomfort at removal of the silicone adhesive tape and preferred the new tape more than 2 to 1 over the control tape.
- Both tapes exhibited low mean lift scores throughout the study (<25% edge lift).

Acknowledgements
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