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 true of all adhesive tape manufacturers to develop tapes with adhesive properties that are strong enough to perform the task required of the tape, yet are 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, when developing new gentle adhesive tapes designed for use on fragile skin, it is important that the new 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 tape removal; and 2) measurement of evaporative water loss. 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 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.

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 standard golden for gentle medical tapes.

Methods

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

Subjects: 28 subjects participated in this study (5 male, 23 female, median age 38.6 years). 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 sites 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/demodification, and skin tears at baseline and on days 1, 4, and 11. Test sites were scored approximately 30 minutes after tape removal and compared with the Friedman Test and Dun's post-hoc comparisons.

Methods: Lift Assessment was taken daily (excluding weekends), by a single technician. Lift was assessed from the control tape.

Results

Test sites were scored approximately 30 minutes after tape removal and compared with the Friedman Test and Dun's post-hoc comparisons.

Expert Grader Assessment - Erythema & Edema

There was a modest increase in erythema with repeated removal and replications 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 erythema scores, even after 11 applications and removals. No significant difference was found between the test tapes at any times with regard to erythema.

Subject Self-Assessment: On days 1, 4, 7, and 11, subjects were asked to rate pain (0 to 100) 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 lift measurements were handled with a Paired T-Test.

Transpidermal Water Loss Assessments

The results of transpidermal water loss measurements reveal a modest increase associated with repeat application and removal of the control tape. The mean TEWL value for the control tape was found to be significantly greater than both baseline and the new silicone adhesive tape value (p = 0.001). It is noteworthy that though elevated, the mean TEWL values for the control tape remained within a range found normal with healthy skin, indicating that the degree of skin stripping was minimal. Additionally, silicone compounds are known to have a conditioning effect on skin, 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).

References:

Poster design by Lutz Consulting LLC

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