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

Gry L. Grove, Charles Zerweck,* Timothy Houser,** Graham E. Smith,** and Nancy I. Koski**

*cyberDERM, Inc., Broomall, PA, USA, **3M Health Care, St. Paul, MN, USA

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 of the tape, yet 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 aggressiveness of the adhesive 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 resulting from such damage; and 2) measurement of disruption of the stratum corneum water barrier by measurement of evaporative water loss. Additionally, test subjects can often feel subtle differences in topically applied products that can elude other methods.

Objectives

The objective of this study was to determine the relative aggressiveness of two different adhesive tapes with a silicone-based adhesive compared to a standard control for gentle medical tapes.

Methods

Overview: This study compared the relative gentleness of two surgical tapes on healthy human volunteers. 1,3,4 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 53). One subject withdrew early from the study due to a sting/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.

Preference Test: Test sites were scored approximately 30 minutes after tape removal and compared with the Friedman Test and Dunn’s post-hoc comparisons.

Tests was: Erythema & Edema Severity Score: Erythema and edema severity were measured using the scoring system shown in the table. Scoring for Erythema/Edema severity was performed.

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 (0.57) for the control tape and 0.10 (0.62) for the silicone tape, indicating that on the average the mean edge lift was less than 25% for both tapes.

Transpidermal Water Loss Assessments: The results of transpidermal water loss measurements reveal a moderate increase associated with repeat application and removal of the control tape, while the silicone adhesive tape was found to be significantly greater than both baseline and the silicone adhesive tape values (p<0.001).

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 received 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).