Evaluation of the Wear Time and Re-stick Performance of a New Silicone Foam Dressing

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Introduction

The Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline, created in 2014 by the National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA), recommends several interventions for the prevention of pressure injuries. One intervention recommended is the use of prophylactic dressings that allow for assessment of the skin on a regular basis to detect skin injuries.

When choosing a dressing, clinicians have many options. Silicone foam dressings are frequently chosen for pressure injury prophylaxis because they provide gentle adhesion, allow for lifting and re-adherence while retaining adherent properties.

Two clinical studies were conducted on healthy volunteers. Study One was designed to assess the wear and re-stick performance of a new silicone foam dressing (Dressing A) compared to a competitor silicone foam dressing (Dressing B).

Study Two, designed to determine relative gentleness, assessed the total protein concentration removed from the skin during dressing removal. Total protein concentration is a representation of skin cells removed and therefore an indirect method to assess gentleness. The same silicone foam dressings used in the first study were also used in this study with the addition of two acrylate adhesive dressings (Dressing C and D).

Method

Wear/Re-stick Study

A total of 2 dressing A and 2 dressing B were applied to the backs of 24 subjects and worn for 7 days (n=48 of Dressing A, n=48 of Dressing B). Half of the dressings were partially lifted to full expose the foam pad and then re-adhered each day, to simulate a pressure ulcer prevention protocol. Time until dressing failure, defined as excessive lift into the pad without re-sticking and fall offs, was recorded for each of the two dressings and for each lifting protocol. Survival data were analyzed using Kaplan Meir plots and log-rank tests.

Total Protein Concentration Analysis Study

Four replicate strips of dressing borders, ¾ x 1 inch in size, were applied to the back of 12 subjects and worn for 24 hours and then removed (n=48 of each dressing). The samples were placed in a petri dish and submitted for analytical analysis to determine the total protein concentration. Subjects were ask to rate their pain during removal of each sample and the skin was assessed after sample removal. Concentration data was log-transformed and analyzed using an heteroscedastic ANOVA model with subject as a random factor. Pain, erythema and skin stripping measures using ordinal scales and analyzed using a rank ANOVA.

Results

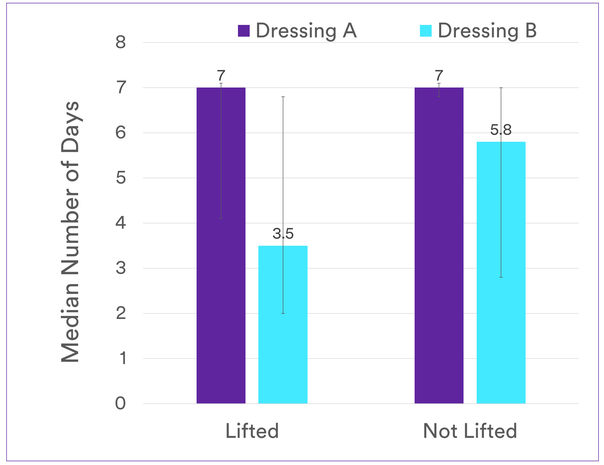
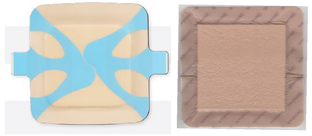


Figure 1. Comparison of wear time between dressing A and B when dressings were either partially lifted daily or not lifted. Dressing A had significantly longer wear times than dressing B for both applications.



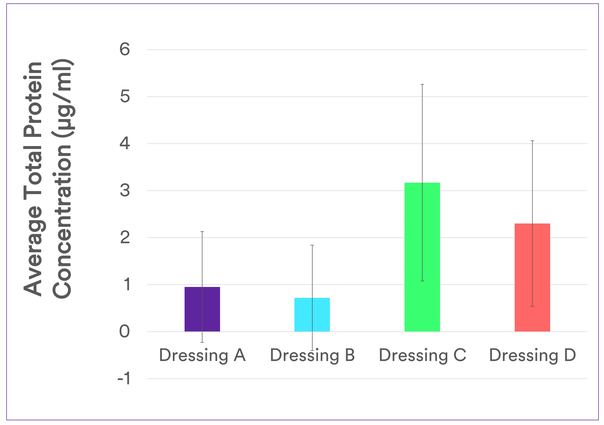


Figure 2. Comparison of the average total protein concentrations between dressing. There was no statistical difference between silicone dressings (A & B) however both had statistically less average total protein concentration than the acrylate dressings (C & D)

Results

Wear/Re-stick Study

Dressing A had a significantly longer wear time than Dressing B whether lifted/re-adhered once a day or not. Median wear times were 7.0 days and 3.5 days under daily lifting conditions; and 7.0 days and 5.8 days without daily lifting/re-adhering. All other assessments, namely overall adhesive residue on skin, erythema, and skin stripping post-dressing removal, were not significantly different.

Total Protein Concentration Analysis Study

Dressing A and B did not show any statistical difference in average total protein concentrations however both were statistically different (less protein) than the two acrylate adhesive dressing (Dressings C and D). There was no statistical difference between any samples with regard to erythema/edema or skin stripping. Pain scores upon removal were higher with the acrylate dressings.

Conclusion

Dressing A demonstrated longer wear time than Dressing B both when lifted daily and when not lifted. The total protein concentration which represents total skin cell removed by the adhesive showed the Dressing A was not statistically different than Dressing B therefore the dressings have similar gentleness (based on this test method).

In the clinical setting, a dressing that provides both long wear time and gentleness may translate into fewer unnecessary dressing changes and less pain and risk of trauma for patients with fragile skin. Fewer dressing changes can lead to savings both cost and clinician time.

Clinically, these results may translate to fewer unnecessary dressing changes potentially leading to cost savings and clinician time savings.

Footnote

This work was sponsored and supported by 3M Health Care. Data on file at 3M.

* Product description:
Dressing A: 3M™ Tegaderm™ Silicone Foam Border Dressing
Dressing B: Molnlycke HealthCare, Mepilex® Border Dressing
Dressing C: 3M™ Tegaderm™ High Performance Foam Adhesive Dressing
Dressing D : Smith and Nephew, Allevyn Adhesive Dressing