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Barrier Cream Cloth Efficacy and Prevention of Transepidermal Water Loss-An Important Consideration in Product Selection

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INTRODUCTION AND RATIONALE

In establishing evidence for skin barrier efficacy afforded by products that utilize disposable wipes for leave-on application, Transepidermal Water Loss (TEWL) is a well-accepted method for assessing skin barrier efficacy.

OBJECTIVE

With product effectiveness as a critical component to clinical decision-making, the aim of this study is to examine the differences in ability to prevent TEWL by four currently-marketed barrier wipes that vary in dimethicone concentration (0% to 3.6%) and that utilize leave-on application.

METHODS

The barrier efficacy of four barrier products used as wipes for leave-on use was tested against a model chemical irritant, Artificial Urine prepared via the method described by Larner et al and using a positive and negative control. Importantly, the synthetic urine is considered to be a model irritant for assessing efficacy of skin barrier products that are designed to prevent or interrupt an IAD episode because daily reapplication of the synthetic urine induces a measurable and quantifiable irritant response.

Each site was assessed by the standard measure, TEWL, over a 7-day period. Thirty adult volunteers of mixed sex, age, and race had daily application of each skin barrier test product (wipe) to a 1.5 in. x 1.5 in. area of skin where the model chemical skin irritant, **Artificial Urine**, was applied for 7 days in random assignment to each skin site using an occluded patch (8 mm Finn Chamber on Scanpor tape). Sodium Lauryl Sulfate (SLS) 1% was applied in a similar manner as the positive control. Two separate sets of sites that were not treated with a barrier test product were exposed to either the Artificial Urine model irritant at one site or the SLS positive control at another site. The negative control site (no product application) was also randomly assigned and measured. All test site measurements were performed by blinded, trained assessors. Positive and negative controls supported the validity of the testing methodology.

TEWL (as gm/hr/m^2) was the standard measure performed to obtain evidence for skin barrier efficacy.

RESULTS

Transepidermal Water Loss

Daily applications of each skin barrier test product (wipe) yielded a greater skin barrier efficacy for Product B than for all other products (A, C, and D), as evidenced by TEWL measurements on skin sites exposed to Artificial Urine. Product B showed **no net water loss** when used on skin exposed nearly continuously to Artificial Urine after daily re-applications over the 7-day duration of the study. [See Table 1]

Table 1. Transepidermal Water Loss Measurements (TEWL; g/hr/m^2); Change from Baseline Condition (the higher the value for water loss, the lower the barrier efficacy)

	No Product	Product A 0% dimethicone	Product B 3% dimethicone	Product C 3.2% dimethicone	Product D 3.6% dimethicone
Artificial Urine	2.11	0.944	-0.035 [xx]	1.931	1.799

Note: The result for the negative control (no irritant or barrier test product application) was -1.412 (no net water loss). The results for the positive control (1% Sodium Lauryl Sulfate) site was 21.643.

Product A = 3M™ Cavilon™ No Sting Barrier Film (barrier wipe with no dimethicone)
Product B= Sage Products® Comfort Shield® Barrier Cream Cloths
Product C = Cardinal Health™ Incontinence Care Wipe
Product D = Medline Remedy® Phytoplex® Barrier Cream Cloths
[xx] = no net water loss

DISCUSSION

Given the demonstrated wide variability for skin barrier efficacy among product formulations, the well-accepted considerations in the IAD Guidelines are of paramount importance when developing evidence-based protocols at healthcare facilities.

Evidence gained from this testing helps to demonstrate that skin barrier efficacy is dependent on the entire final product formulation and specifically does NOT necessarily correlate with the percentage concentration of an individual ingredient such as dimethicone. A product with inadequate skin barrier efficacy is more likely to lead to difficulty in achieving institutional compliance with IAD Guidelines and less likely to serve the needs of the patient. Despite product variability in dimethicone concentration for these skin barrier test products (wipes), the concentration of dimethicone alone did not prove to be a determinant for skin barrier efficacy.

CONCLUSIONS

Product B, demonstrated lower skin water loss than Products A, C, and D. Remarkably, under testing conditions, **there was no net skin water loss with Product B**, even after prolonged, and nearly continuous, skin contact with Artificial Urine using daily re-applications over a 7 day period. In contrast to this evidence of skin barrier effectiveness for Product B, study findings showed significantly higher net skin water loss for Products C, and D, the other two wipes containing dimethicone.

As such, a clear distinction is demonstrated between the 4 commercially available barrier wipes as test products in assessing the level of barrier efficacy as measured by TEWL after Artificial Urine exposure. The product concentration of dimethicone as a skin protectant proved NOT to be a sole determinant for skin barrier efficacy. Rather, as described in the IAD Guidelines, the product performance characteristics, including barrier effectiveness, dictate the optimal choice for the practitioner and the patient.

This study underscores the importance of evaluating product performance characteristics for similarly marketed barrier products.

Understandably, there is an important unmet need to obtain evidence-based information to adequately assess skin barrier efficacy afforded by one product in comparison to others. It remains for the practitioner and the user to be able to determine that the selected product provides the expected skin barrier effectiveness, a product characteristic that is not communicated by simply reading the ingredient listing and reviewing the concentration of ingredients on the product label.

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