Comparison of the effectiveness of four dimethicone-based moisture barrier creams

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Introduction

The AHCPR Clinical Practice Guideline concerning skin "at risk" for pressure ulcer development recommends the use of skin moisturizers to treat dry, fragile skin.[1] The guideline points to research which suggests a link "between dry, flaky, or scaling skin and an increased incidence of pressure ulcer development."[2] The guideline also suggests "that adequate hydration of the stratum corneum helps to protect against mechanical insult." Furthermore, the guideline recommends that "at risk" skin be protected from "exposure to moisture due to incontinence, perspiration, or wound drainage" and that "topical agents that act as barriers to moisture" should be considered.

Though the AHCPR Clinical Practice Guideline does not address caregivers' skin, the hands of caregivers are frequently exposed to the same insults as the patients for which they care. Frequent exposure to moisture and harsh chemicals from multiple daily handwashings, particularly with alkaline bar soaps, often results in severely dry, cracked skin.[3] Dry, cracked skin is not only uncomfortable but also an occupational hazard for health care workers due to increased risk of skin colonization with gram-negative bacteria or other potential pathogens from the hospital or health care environment.[4]

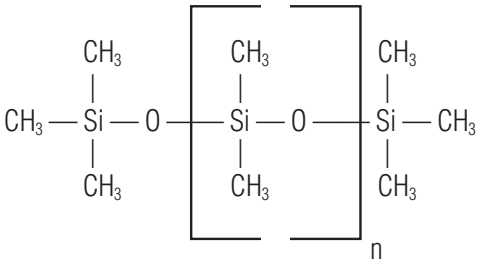
Background

Severely dry skin is a common problem for both patients and caregivers alike. For the patient, dry, fragile skin is at risk for further breakdown, particularly when exposed to incontinence.[1] For caregivers, severely dry skin is an occupational hazard resulting from numerous daily handwashings with harsh, alkaline soaps and/or disinfectants.

In recent years, manufacturers have attempted to combine the active ingredient dimethicone with skin moisturizing ingredients, in hopes of transforming passive cosmetic moisturizers into active skin protectant drugs. These products appear to meet AHCPR guidelines for care of "at risk" skin by moisturizing dry, fragile skin while simultaneously protecting the skin from excessive moisture and irritants. However, very little has been published regarding the efficacy of these dimethicone-based skin protectants.

Dimethicone is classified by the U.S. Food and Drug Administration (FDA) as a Category I "Over The Counter" (OTC) Skin Protectant Drug. Because of this OTC Category I classification, the FDA recognizes dimethicone as being generally *"safe and effective"* as a skin protectant drug. However, the FDA does not require manufacturers to document efficacy of Category I OTC drug products prior to market introduction. The FDA only requires manufacturers to: 1) Formulate Category I OTC drugs with "approved" active ingredients, 2) Manufacture the product under "Good Manufacturing Practices," and 3) Label the product in compliance with "approved" labeling statements. Documentation of Category I OTC drug product efficacy is left completely to the manufacturer.

Chemically, dimethicone is a mixture of fully methylated, linear siloxane polymers, end-blocked with trimethylsiloxy units and conforms to the following general chemical structure:



Due to the hydrophobic nature of this chemical structure, one would expect dimethicone to possess excellent moisture barrier properties. However, it is impossible to assess efficacy of a drug ingredient in isolation from its formulation. In particular, resistance to wash-off may be compromised by the surfactant ingredients that allow dimethicone to be emulsified into water-based creams and lotions.

Resistance to soap and water wash-off is an important economic and performance factor in selecting moisture barriers. For economic reasons, a long-lasting, wash-off resistant moisturizer/barrier needs to be applied less often, saving both materials and labor costs. For performance reasons, a long-lasting, wash-off resistant barrier helps to ensure therapeutic levels of protection between washes, even if the caregiver can not reapply.

In 1981, Tagami et al. reported that as skin becomes increasingly hydrated due to exposure to moisture, there is a corresponding increase in electrical conductivity.[5] Furthermore, in 1993, Lutz and Willard reported a technique (based on Tagami's observations) by which the wash-off resistance of moisture barriers could be assessed with electrical conductance measurements.[6]

Objective

As part of an ongoing patient skin care product development program, the objective of this study was to measure and compare moisture barrier effectiveness and wash-off resistance of four dimethicone based skin creams. This was done thirty minutes after application of the products to the skin to assess for initial efficacy, and again after each of several simulated normal skin washes to assess for product durability.

Methodology

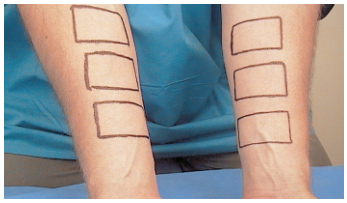
Products Under Evaluation

- 3M™ Cavilon™ Durable Barrier Cream
- DeRoyal™ TheraSkin™ Protectant Cream
- Hollister™ Restore™ Barrier Creme
- Healthpoint Proshield® Plus Skin Protectant

Subjects

Eighteen healthy adult volunteers between the ages of 18–65 were enrolled into this study. Subjects were instructed not to use any skin care products (other than their normal shower soap) on the test sites for three days prior to the start of the study.

Test Sites

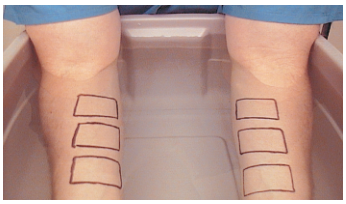


- Left and Right Volar Forearms
- Six (5 cm x 3 cm) Test Sites
  - ⇨ Four test products
  - ⇨ One untreated control
  - ⇨ One unrelated developmental product

Product Application

Assignment of the various test products to the individual test sites was randomized so that each test product occupied each test site within the study with approximately an equal frequency in order to eliminate any position or order bias. Previously, it was determined that, for most moisturizers, 4 µl per cm^2 of skin represented a "normal" use amount. Since the size of each test site was 15 cm^2, the test products were delivered at a rate of 0.06 ml/test site using an Eppendorf Repeater pipette. The test products were then rubbed into the skin for one minute using a finger covered with a latex finger cot. Fresh finger cots were used for each product application to avoid cross contamination of the test sites.

Water Challenge



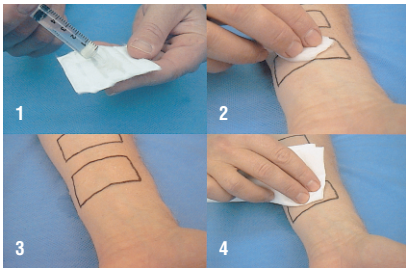
- Tepid water for 10 minutes
- Repeated prior to each electrical conductance measurement
  - ⇨ 30 minutes after product application
  - ⇨ After each *Simulated Normal Wash*

Upon removal from the water bath, test sites were kept moist until the electrical conductance measurements were taken by gently applying paper towels cut to the size of the test sites and moistened with tepid water.

Electrical Conductance Assessment of Moisture Barrier Effectiveness

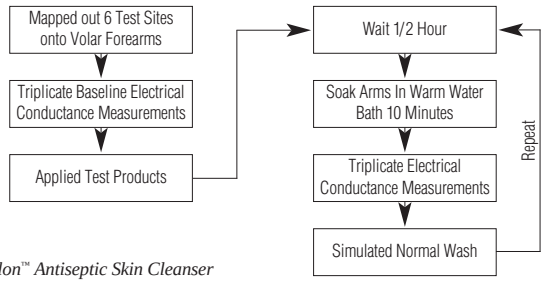
- One by one, the moist paper towels were removed and test sites blotted dry of surface moisture.
- Test sites were immediately measured with a SKICON-200 skin electrical conductance meter (Skin Surface Hydrometer, model SKICON-200, I.B.S. Co., Ltd., 33–19 Motohama-cho, Hamamatsu-shi, shizukoka-kan, 430, Japan).
- Triplicate measurements were taken from each site.

Simulated Normal Wash Procedure



1. Application of 5 ml of a no-rinse incontinence cleanser* to a soft cotton pad.
2. Gentle cleansing in a circular motion for 20 seconds.
3. Left lather on test site for an additional 20 seconds.
4. Test sites blotted dry with a soft paper towel.

Summary of Procedures



** 3M™ Cavilon™ Antiseptic Skin Cleanser*

Statistical Methods

The source data used in the statistical analysis were the triplicate skin electrical conductance measurements taken at baseline, 30 minutes after treatment, and after each of the simulated normal washes.

% Barrier Effectiveness Calculations

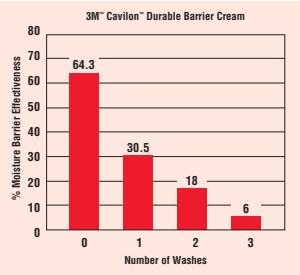
$$\text{\% Barrier Effectiveness @ Wash X} = \frac{[\text{Conductance @ Wash X}] - [\text{Conductance @ Baseline}]}{[\text{Conductance of Untreated Control @ Wash X}] - [\text{Conductance of Untreated Control @ Baseline}]} \times 100$$

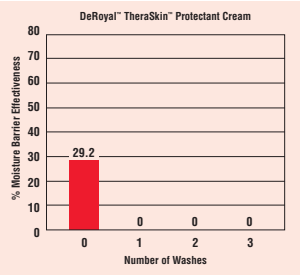
Statistical Procedures

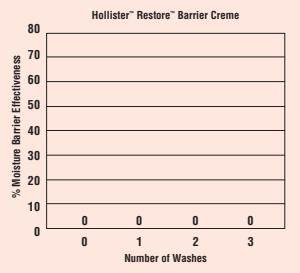
The data were analyzed using ANOVA techniques for a randomized balanced block design experiment. This was followed by Tukey's Protected t-test which allowed for a comparison of all possible combinations of test products while, simultaneously, controlling the level of significance within each time period. Additionally, a within treatment paired t-test was used to compare peak electrical conductance for each test product to that of the untreated control, at each time period. This was used to determine if the test product provided significant moisture barrier protection compared to the untreated control. All hypothesis testing was performed at the $\alpha = 0.05$ level.

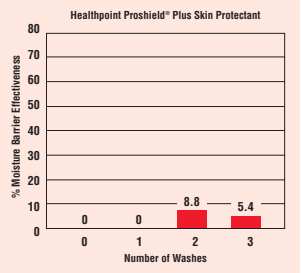
Results

Analysis of variance shows that 3M™ Cavilon™ Durable Barrier Cream provided a superior moisture barrier compared to the other test products, both initially after application to the skin, and through the first simulated normal wash. The most significant finding, however, was that, in this model, two of the four test products did not appear to provide any moisture barrier protection when they were first applied to the skin.









Conclusions

- Significant differences exist in the ability of dimethicone-based skin creams to protect the skin from external moisture.
- The formulation used to deliver active ingredients, such as the skin protectant dimethicone, is an important consideration when developing new products.
- This data shows the importance of documenting product efficacy, and not relying solely upon the FDA's *Expert Panel Review* of the active ingredients as proof of efficacy.

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