NORTHWESTERN UNIVERSITY
FEINBERG SCHOOL OF MEDICINE

Dennis P. West PhD, FCCP, CIP, Professor in Dermatology and Pediatrics
Feinberg School of Medicine, Northwestern University, *Chicago, Illinois, USA*

Comparison of Skin Barrier Effectiveness for Products Containing Dimethicone

Introduction & Rationale

- Incontinence-associated dermatitis (IAD) is a condition that exists in the healthcare setting and is caused by urine or stool irritants coming into contact with skin. Clinically proven skin protectants are intended to be used after each incontinent episode to prevent irritants from coming into contact with patient skin, resulting in IAD, a risk factor linked to pressure ulcers.[1]

Recent evidence has demonstrated that skin barrier products containing clinically proven skin protectants help reduce risk factors associated with irritation from incontinence when compared to standard practice or no treatment.[1,2] Moreover, using a low-irritant, pH-neutral, barrier-containing cleansing product is consistent with the most effective strategy to maintain skin barrier function and integrity.[3]

An international consensus panel of experts published evidence-based guidelines for the prevention and treatment of IAD.[1] As conveyed by the panel, clinicians have access to a wide range of products, such as those labeled as cleansers, moisturizers, moisture barriers, skin protectants and moisture barrier pastes. Skin care products are classified and regulated by the US Food and Drug Administration based on 3 categories: prescription drugs, over-the-counter drugs, and cosmetics. In addition, many clinicians select skin care products based on the category listed on the front of the package (eg, moisturizer, moisture barrier, etc.) rather than the individual ingredients.[1]

Notably, dimethicone is often used as a protectant ingredient in skin barrier products because of its generally accepted skin protectant properties. However, skin protectant properties and barrier effect of final product formulations containing dimethicone vary widely.

To better address these issues of product formulation performance, we determined the relative barrier effectiveness of various dimethicone-containing products by utilizing in-vitro filter testing.

Objective

- Compare and contrast the performance of various dimethicone-containing products designed to cleanse, moisturize and provide a barrier effect.

Methods

- An independent laboratory[4] conducted a comparator study of four incontinence barrier cloths or wipes containing dimethicone plus filter versus a negative control (filter only) by quantitating the volume of artificial urine (per method of Brooks) passing through a nylon filter screen in order to determine relative in-vitro barrier-effectiveness for each test article.

The testing environment was controlled for temperature and humidity as specified in ISO 554-1976(E). For all filter housings (# 2-5, Figure 1): a uniform amount of each test article, consistent with intended application to skin, was placed on the top surface of a nylon-filtered beaker, using circular uniform application of the test article for 30 seconds. Weights were obtained before and after application of each test article to the filter. The control nylon-filtered beaker received no application of a test article.

Artificial urine (500mL) was carefully poured on the top surface of the nylon-filtered beaker and the volume of artificial urine passing through the filter was measured over time for each test article. These data were recorded and then graphically portrayed in Figure 1 to demonstrate the amount of artificial urine passing through the filters over time. Single samples were run for each test article and control.

Results

- The control beaker showed that all 500mL of artificial urine passed through the filter, indicating no barrier effect. As expected, test articles 2 and 3 showed little difference over time in the amount of artificial urine passing through the filter versus the control. At 120 minutes (2 hours), the testing showed nearly 80% of the artificial urine had passed through the filter for test articles 2 and 3. Additionally, at 480 minutes (8 hours), essentially all of the artificial urine had passed through the filter for test articles 2 and 3, representing little difference compared to the control. Test article 4 performed slightly better than the control and test articles 2 and 3, as over 60% of the amount of artificial urine passing through the filter at 480 minutes (8 hours).

Contrary to all other comparators, test article 5 allowed 19 times less artificial urine at the 120 minute (2 hours) mark compared to control. At the 480 minute (8 hour) mark, test article 5 allowed 3 times less artificial urine than test article 4, and more than 5 times less artificial urine than the control and test articles 2 and 3. The data breakdown of volume by filter time for each test article is shown in Figure 2-Volume versus time for each test article (mL).

FIGURE 1:
Beaker with Nylon Filters

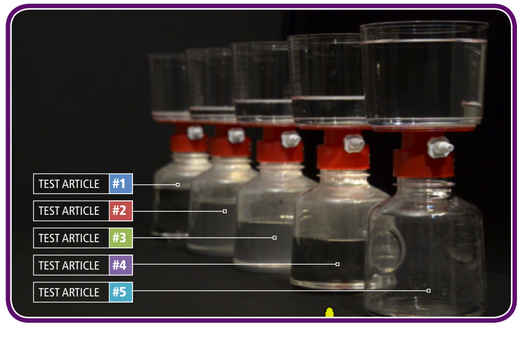
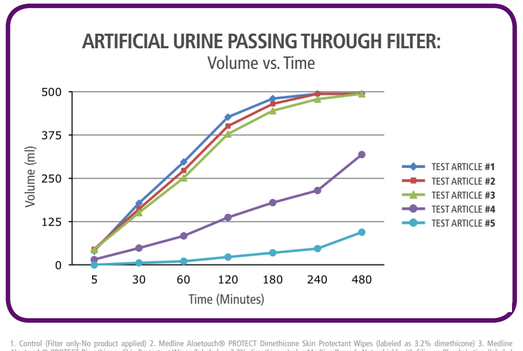


FIGURE 2:
Volume by Filter Time for Each Test Article (ml)



1. Control (Filter only-No product applied) 2. Medline Aloetouch® PROTECT Dimethicone Skin Protectant Wipes (labeled as 3.2% dimethicone) 3. Medline Aloetouch® PROTECT Dimethicone Skin Protectant Wipes (labeled as 3.2% dimethicone) plus Medline Remedy Nutrashield with Silicone Blends Lotion (labeled as 1% dimethicone) 4. 3M™ Cavilon™ 3-in-1 Total Care Cloths 5. Sage Comfort Shield® Barrier Cream Cloths (labeled as 3% dimethicone)

Conclusions

- After comparing and contrasting dimethicone-containing products for barrier effectiveness, test article 5 considerably out-performed all other comparators by allowing only a small amount of artificial urine to be filtered, even after a full 8-hour time period equivalent to a work-shift while all other comparators allowed considerably more artificial urine to be filtered.

This study underscores the important aspect of comparing and contrasting product formulations of similarly marketed barrier products and that the presence of a skin protectant such as dimethicone to enable barrier effect is just one aspect of product evaluation. Clearly, there is an unmet need for additional evidence-based information to adequately assess barrier-effective properties for one product formulation versus another. It remains for the care provider and the user to establish that the selected product provides the expected performance in regards to barrier-effectiveness.

This study is consistent with previously published expert consensus guidelines regarding IAD and suggests there remains an unmet need to better inform clinicians in order to differentiate barrier-effectiveness and product performance characteristics when choosing products designed for barrier effectiveness.

Discussion

- It is essential to consider overall product formulation and delivery method in order to make a comparison of products containing dimethicone that are designed with barrier effect. The decision to choose a product should be based on the entire product formulation and its performance as a barrier.

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