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ORIGINAL ARTICLE

Comparing the physical performance of liquid barrier films

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Abstract

Background: Barrier films have been used for many years to protect skin from the damaging effects of excessive moisture and mechanical injury. The performance characteristics important for these protective effects are mainly product durability and its ability to reduce the force of adhesive removal. Additionally, the moisture vapor transmission rate through the film needs to be high enough that maceration is prevented. The current study was undertaken to investigate various physical performance characteristics of six commercially available barrier films.

Materials and methods: Several bench tests were used to simulate performance features of the barriers on skin including barrier durability, breathability (moisture vapor permeability), and the effect on adhesive dressing force of removal.

Results: Results indicated that barrier films did not perform equivalently. However, Cavilon[™] No Sting Barrier Film (NSB) was shown to have significantly greater durability in the barrier integrity test than all other barriers tested and was tied for highest breathability and highest reduction in peel force from steel. No other tested barrier film performed as consistently across the different tests.

Conclusion: These results may provide mechanistic understanding of how barriers such as NSB may clinically assist with the prevention of adhesive- and moisture-related skin damage.

KEYWORDS

durability, medical adhesive related skin injury, moisture vapour transmission, moistureassociated skin damage

1 | INTRODUCTION

One of the main functions of the skin is to protect against external insults including pathogens, chemical irritants, and excessive fluid. When exposed to moisture for extended periods, the skin may become macerated and the barrier function may become impaired. When the barrier function becomes impaired, the skin becomes more permeable to irritants. Because of its higher coefficient of friction, wet or macerated skin may be more prone to injury caused by shear or friction.¹ Skin-damaging moisture may come in the form

of perspiration, wound exudate, ostomy effluent, or incontinence fluids. The term moisture-associated skin damage (MASD) has been coined to describe injuries that can result from extended exposure to moisture and irritants.

Mechanical injury can occur in vulnerable skin under a medical adhesive. This has been termed medical adhesive-related skin injury (MARSI), which is defined as "an occurrence in which erythema and/ or other manifestation of cutaneous abnormality (including, but not limited to, vesicle, bulla, erosion, or tear) persists 30 minutes or more after removal of the adhesive".² In one study looking at the incidence

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes. © 2021 3M Company. *Skin Research and Technology* published by John Wiley & Sons Ltd on behalf of International Society for Bioengineering and the Skin. of skin injury due to medical adhesives, the authors reported that 34 injuries occurred in 24 of 155 (15.5%) older patients admitted to a long-term care facility.³ The average time to incidence of injury was 27.1 days, depending on anatomical site.³ Consideration of use of a skin barrier product, such as a liquid barrier film, under adhesive products to reduce MARSI risk has been recommended in at least one consensus document.²

When applied to skin, liquid barriers form a film, protecting the skin from noxious fluids.⁴ Skin barrier films are used to protect skin and periwound tissue from the damaging effects of excessive moisture or mechanical injury. Polymer-based skin protectants have been shown to be beneficial in preventing or reducing maceration.⁵⁻⁷ The most important characteristics of an effective barrier film to protect the skin from moisture or mechanical injury are its durability and ability to decrease the force associated with adhesive removal. The barrier must also be breathable, or it may lead to maceration in the presence of excessive moisture. Other characteristics such as flexibility and the barrier's ability to decrease friction between the patient and bedding also contribute to the effectiveness of the barrier.

There is a lack of in vitro studies comparing key physical performance characteristics of commercially available skin protectants. The in vitro work described herein was performed to compare six commercially available liquid barrier films with respect to barrier integrity (durability), moisture vapor transmission (breathability), removability of adhesives placed over the film, ability to reduce friction, and elongation failure.

2 | MATERIALS AND METHODS

2.1 | Film barriers

The six barrier films tested in this study were (a) Cavilon[™] No Sting Barrier Film (NSB; 3 M, St. Paul, MN), (b) No-Sting Skin-Prep (NSS; Smith and Nephew Medical Ltd, Hull, UK), (c) SurePrep® Rapid Dry No-Sting Barrier Film (RDN; Medline Industries Inc, Northfield, IL), (d) Sensi-Care® Sting Free Skin Barrier (SFS; ConvaTec, Bridgewater, NJ), (e) Cutimed® Protect (MSP; BSN Medical, Hamburg, DE), and (f) Aplicare Skin Protectant Swabstick (SPS; Clorox Company, Meriden, CT).

2.2 | Barrier integrity

The penetration of a 1% green dye (FD&C Green #3) solution through the topical barriers following application of the barrier film to a coated, water-resistant poster board (RR Donnelly and Sons, Shakopee, MN) was used to assess barrier integrity. Three separate demonstration boards were used, and 6 different barriers were coated on each board in 5 cm by 25 cm rectangles. Following coating, samples were dried for 1 hour and then five (5) 2.5 to 3.75 cm diameter delicate task wipers (Kimwipes, Kimberly-Clark Professional, Roswell, GA) were used to cover the barrier films. Four drops of colored dye solution were placed around the periphery of the wipers. After 5 minutes, the wipers were removed and excess dye was washed from the barrier surface with 1L of distilled water. Samples were dried and the percent of barrier which had remained intact prior to the application of the four dye drops was assessed by quantifying the dye area vs original barrier application area using a custom MATLAB® script. Fifteen images per barrier film were analyzed.

2.3 | Moisture vapor transmission rate

Moisture vapor transmission rate (MVTR) was assessed by applying each barrier film to a 0.9 mil polyurethane film. These coated polyurethane films were placed onto sample bottles filled with 50 mL of water. The films were sealed onto the sample bottles with a washer and cap. The bottles were placed in 40°C/20% relative humiditycontrolled chamber for 18 hours. The control consisted of an uncoated 0.9 mil polyurethane film. The weight of the bottle before and following incubation were measured, and the MVT rate was calculated by the following formula:

$$MVTR = (W1 - W2) \times (4.74 \times 10^4)/18$$

2.4 | Removability of adhesive over film (Adhesion to Steel)

Each barrier film was applied to a steel plate and dried for 2 minutes. A transparent film dressing (Tegaderm[™] Film 1626W, 3M) was applied over the barrier film, pressed on for adhesion, and left in place for 24 hours in a temperature- and humidity (21°C; 50% relative humidity)-controlled room. The dressing was removed using a load frame testing system (Zwick Z2.5/TN1S, ZwickRoell, Germany) equipped with a 50N load cell. Five replicates were tested for each barrier film and were compared with the control without any barrier film between the steel plate and the transparent film dressing.

2.5 | Friction

A piece of unused 100% cotton cloth was cut to approximately 13 cm by 25 cm and placed on a slip/peel tester (SP-2100 Platen, Imass, Inc) to simulate a standard bed sheet. The edges of the fabric were taped down so the cloth laid flat and unwrinkled on the plate. A hydroxypropyl guar gel containing 2% chlorhexidine gluconate (CHG) was applied to a friction sled and then covered with a 0.9 mil polyurethane film. The polyurethane film was evenly coated across the entire surface with the barrier film. The sled was attached to the instrument load cell and then placed on the cotton cloth. The frictional force was measured by the instrument load cell as the plate covered with cotton cloth moved under the polyurethane-coated barrier film samples. Values reported were static coefficient of friction (CoF) and kinetic CoF.

 TABLE 1
 Comparison of performance parameters for barrier films

	Percentage barrier remaining ave (±SD)	Dressing removal force (g) ave (±SD)	MVTR (g/ m²/24 h) ave (±SD)
Control	N/A	334.5 (19.8)	2511.2 (48.0)
NSB	89 (14.9)	175.8 (56.7)	2380.0 (80.2)
NSS	18.6 (18.3)	334.5 (14.2)	2313.1 (56.6)
RDN	13.0 (8.0)	272.2 (5.7)	2389.0 (69.0)
SFS	3.0 (3.7)	184.3 (22.7)	2502.7 (40.5)
MSP	19 (15)	266.5 (11.3)	2359.5 (74.5)
SPS	22.5 (18.0)	360.0 (11.3)	1693.8 (113.0)

2.6 | Elongation failure

Two and a half centimeter hydroxypropyl guar gels containing 2% CHG were coated with various barrier films and dried for 1 hour. The gels were then placed on a grid and stretched to either 50% or 100% of their original lengths. A delicate task wiper soaked with bleach was placed on top of the gel for 5 minutes. Cracks in the barrier film allowed penetration of the bleach into the gel. This was made visible via brown discolouration as the bleach reacted with the CHG. The amount of brown discolouration was quantified.

2.7 | Statistical analysis

All data were presented as mean \pm SD. MVTR, adhesion to steel CoF, and elongation failure experiments were repeated 5 times. Barrier integrity experiments were repeated 3 times. MVTR, adhesion to steel, CoF, and elongation failure data were analyzed using ANOVA on the raw values, followed by a post hoc Dunnett's test using NSB

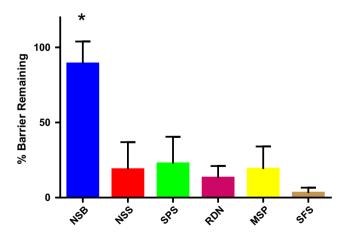


FIGURE 1 Percentage of barrier remaining on a demonstration board following washing with distilled water. The asterisk denotes that NSB had significantly more barrier remaining (P < .05) than all other barriers

barrier film as the baseline reference. Barrier integrity data were analyzed with a generalized linear model followed by a post hoc Dunnett's test using NSB as the reference.

3 | RESULTS

With respect to barrier integrity/durability, Figure 1 and Table 1 shows that all barrier films had significantly less barrier remaining (P < .05) than NSB following washing. The amount of barrier remaining ranged from an average of 67% less for SPS to 86% less for SFS.

Figure 2 and Table 1 shows the changes in the force required for removal of a transparent film dressing from a steel plate when barrier films were first applied to the steel plate versus control (no barrier film applied). The figure shows that significantly less force (P < .0001) was required to remove the film dressing when NSB was applied to the steel plate than for control (158.7 g less), SPS (184.2 g less), MSP (90.7 g less), RDN (96.4 g less), and NSS (158.7 g less). There was no difference in force required to remove the dressing between NSB and SFS (P > .05).

The MVTR for SPS was on average 686.8 times lower than for NSB (P < .0001) (Figure 3 and Table 1). There were no other MVTR differences between NSB and any other barrier films tested. Except for SPS, application of the barrier films to the 0.9 mil polyurethane film used in this test did not result in decreased MVTR values below that of the highly breathable polyurethane film.

For static and kinetic CoF, RDN was shown to have the highest values at 0.056 \pm 0.007 cm/s and 0.063 \pm 0.005 cm/s, respectively. The lowest values of static and kinetic CoF were for SPS at 0.030 \pm 0.003 and 0.030 \pm 0.003 cm/s, respectively. NSB had a static CoF that was on average 0.008 cm/s less than control (0 = 0.0117) and a kinetic CoF that was on average 0.035 cm/s less than control (P < .0001).

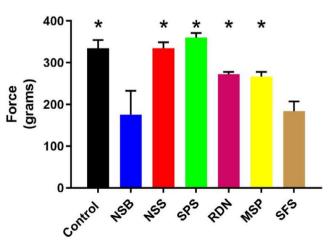


FIGURE 2 Force required to remove polyurethane film dressing (following application 24 hours prior) from a steel plate without a barrier film on the plate under the dressing (control) versus when barrier films were coated onto the steel plate prior to application of the polyurethane dressing. The asterisks represent removal values which were significantly higher (P < .0001) than for NSB

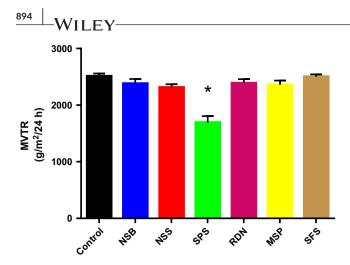


FIGURE 3 Moisture vapor transmission rate for barrier films versus control. The asterisk denotes that application of SPS to the transparent film significantly reduced the MVTR (P < .0001) versus NSB. There was no difference between NSB and control or any of the other barrier films tested

With respect to elongation failure, SPS and SFS exhibited 100% failure when elongated to 50 or 100% of their original length. MSP and RDN showed no failure when elongated. There was no significant difference with respect to elongation failure at 50% elongation between NSB and MSP or RDN (P > .05).

4 | DISCUSSION

The current study assessed liquid barrier performance metrics important to the prevention of MASD and MARSI. The barrier parameter most important for protection against MASD is durability while the parameter tested that is most important to protection from MARSI is removal force. NSB had the greatest durability in the barrier integrity test and was tied for highest reduction in peel force from steel. No other tested barrier film performed as consistently across all the different tests. These results support outcomes of an earlier study of 33 at-risk patients which showed that NSB use prevented maceration in 94% of the patients while skin stripping was prevented in 100%.⁵

Ideally, barrier films must be durable to assist with the prevention of MASD. The ability of the film to remain intact and resident on the skin even in the presence of moisture is of utmost importance. Wet skin is more easily injured and susceptible to bacterial colonization than normal skin.⁸ In our study, NSB was the most durable in the presence of liquid compared with the other barrier films tested. Even without exposure to significant fluid, the four drops of food dye used in the test were able to penetrate through a significant area of all applied barrier products except NSB. This suggests that with normal application, most barriers may not dry as a continuous, uninterrupted film.

It is important when using adhesive products that the product remains adhered to the skin as intended. MARSI is an unintended consequence of using adhesive products and may occur when the adhesive bond to the skin is stronger than the skin itself. To help prevent MARSI, the use of skin barrier products has been suggested.² The data presented herein show that NSB significantly reduced the removal force of an adhesive film from a steel plate (Figure 2). It is important that any decrease in removal force is not associated with failure of the adhesive product on the skin. In an observational study of 33 spinal cord patients, use of NSB was associated with dressing adherence improvements in 90% of the subjects while no skin stripping was observed in any patient.⁵ These results are consistent with the in vitro results of the current study, suggesting NSB may help prevent adhesive-related skin injuries.

Because skin is a very flexible material, barrier films must be physically flexible as they undergo elastic deformation after application to skin during patient movement. As an example, abdominal skin may have an extensibility before failure of 1.14 to 3.07 times its original length.⁹ The ability to resist cracking with elongation correlates with flexibility and durability of the barrier on the skin. When NSB was elongated, it was shown to have great flexibility with no significant failure at 50% elongation. The flexibility combined with the durability may lead to improved clinical performance as shown in the Campbell study.⁵

Both static and kinetic frictional forces can deform skin, which may in turn lead to tissue damage and cell death both at the tissue surface and in deeper structures.¹⁰ Static coefficient of friction describes the threshold whereby motion between two surfaces occurs. Kinetic coefficient of friction is generally lower than static coefficient of friction and describes the frictional resistance between the two surfaces once motion has started. It has been suggested that frictional forces should be minimized both when the patient is lying still or when moving or being moved in the bed.¹⁰ In this study, application of NSB significantly reduced both static and kinetic CoF over control.

The difference in performance for NSB may be related to its unique chemistry as it is composed of a blend of a terpolymer and a homopolymer plasticizer. All other barriers tested contain only one polymer. The terpolymer in NSB is a blend of three different monomers and provides highly breathable and durable barrier properties on the skin while the homopolymer provides the formulation with flexibility and allows the product to dry as a continuous film.

4.1 | Limitations

While this study has revealed some important characteristics about the durability of various barrier films, it is important to discuss the limitations in methodology. The demonstration board used in the durability testing did not have the same material properties or surface energy of skin. Additionally, because of the way MVTR experiments were conducted, the investigators were not able to assess the MVTR of any of the barrier products without first coating them onto a polyurethane film, which was in turn placed in the MVTR sample bottle. It was not possible to assess the MVTR of the barriers by themselves. For the elongation and friction testing experiments, a guar gel was used to simulate skin. While this gel is flexible, it does not have the same material properties as skin. While there are definite limitations in the methods used, the relative comparisons between the barrier products are still valuable and the results provide important insights.

5 | CONCLUSIONS

It is challenging for medical facilities to stock and maintain multiple products specifically optimized for each of the features tested in the present study. Supplying a single product that covers a broad range of performance features may benefit medical facilities. The results presented herein indicate that not all barrier films performed equivalently and that NSB performed most consistently across all tests. Further clinical testing is needed to support these in vitro results.

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