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Evaluation of Moisture Penetration Through Skin Protectant Barriers by Paper Chromatography
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Abstract
Currently, there is no convenient and safe experimental method in the literature to evaluate skin protectant formulations for barrier properties. A novel and simple experimental method, based on paper chromatography, was developed to screen a broad spectrum of skin protectants available for moisture penetration. The method involves the use of paper chromatography for determining the Moisture Penetration Rate through a thin barrier film of a given skin protectant product. It is simple, inexpensive, convenient, and safe and was used to evaluate 12 products currently used as skin protectants. This method can be used by formulators in their development efforts and by caregivers to determine the barrier properties of various products in a short period of time without expensive instrumentation or extensive time commitments.

Skin irritation resulting from fecal and urinary incontinence is a common problem for geriatric patients (Fiers & Siebert, 1993; Talbot, 1994). Various products on the market today are used as protective barriers to prevent skin irritation from moisture penetration. However, from the caregivers' perspective, there is a need for identifying the best product or the relative ranking of products based on suitable test methods. There is a lack of suitable in vitro test methods to screen skin protectant barriers (Guillemin, Mulset, Lob, & Riquez, 1974; Pigatto, Bigaldi, Legori, Altomare, & Finzi, 1993) on the market. For any method to be acceptable, it must be convenient, simple, reproducible, and safe for use on human volunteers. More importantly, it must have clinical relevance.

Literature suggests the use of three methods to evaluate skin protectants. One of these methods relies on the extraction of the dye from the stratum corneum and determination of the concentration by spectrophotometry (Marks, Dykes, & Hamami, 1989; Trefel, Gabard, & Juch, 1994). Another method relies on the irritation caused to the skin and subsequent effects on blood flow rates in the irritated areas as measured by Laser-Doppler method (Nilson, Otto, & Wahlberg, 1982; Wahlberg, 1984). The third method focuses on the histological examination of skin samples (Mahmoud, Lachapelle, & Neste, 1984).

All of these methods have their strengths and limitations. The dye method is dependent on the hydrophobicity and hydrophilicity of the dye and its compatibility with the hydrophobicity and hydrophilicity of the skin protectant as well as that of the skin. It also is dependent on quantitative recovery of the dye from the skin matrix for final evaluation. Use of the skin irritation test depends upon the availability of human volunteers or animals for testing. The histological approach depends upon multi-step sample preparation before any examination can be conducted. Furthermore, from the standpoint of product development, there is no suitable and convenient method in the literature to evaluate skin protectants for moisture penetration. This paper describes a simple, convenient, reproducible, and safe method for evaluation of skin protectants for moisture penetration.

Methods and Materials
The experimental setup involved the use of a circular Watman #4 filter paper with a hole (about 2 mm radius) in the center. (See Figure 1.) Using a marker, four water-soluble, black ink dots were placed about 2 mm away from the center around the hole. Another filter paper of the same size was cut in half. One half was rolled up into a wick. A 4-mm-wide, uniform coating of a given product was applied away from the end of the wick. This wick was inserted into the hole of the circular filter paper with a gentle rotation to ensure a uniform, thin film of the product at the contact surface area between the wick and the filter paper.

This entire unit was then placed in a cup containing water. The lower end of the wick was immersed in the water, allowing water propagation vertically along the length of the wick and then radially on the filter paper through the thin protective product film. (See Figure 1.) As the water front moved radially, the ink from the marker dissolved and moved with it. Based on the solubility of various pigments in the ink formulation, the black ink separated out into its individual components, which resulted in a colorful display. The Moisture Penetration Rate (MPR) was then determined by measuring, in centimeters per hour (cm/hr), the distance traveled radially by the ink front from the starting point. The ink front travel time included total time from the initial placement of the filter paper unit in the water cup to the removal of the filter paper unit from the cup. The average of this rate, based on the four ink dots, was then calculated.

This study evaluated the following products: Triple Care® (Smith & Nephew United, Inc.), Baza (Sween Corp.), Soothe & Cool (Medline Industries, Inc.), Lantaseptic® (Summit Industries), Daily Care (Pfizer), Petrolatum (Witco), Desenex® Ointment and Cream (Fisons), Proshield (HealthPoint Medical), Micatin® (Ortho Pharmaceuticals), Carrington Antifungal (Carrington), and iLEX® (Cai gün Vestal Laboratories).
Results and Discussion

The MPR results for various products are shown graphically in Figure 2. Sensitivity of the method was determined by running samples of both petrolatum and water (with no barrier). In the absence of a barrier (water alone) the moisture penetration rate is 24.76 ± 1.59 cm/hr. Among the various products evaluated, the Carrington® Antifungal and petrolatum exhibited the fastest MPR and iLEX® had an MPR of 0 cm/hr.

Petrolatum is generally considered a skin protectant; however, this method clearly shows water penetration through the thin barrier. This moisture penetration through barrier films of petrolatum is apparently related to and facilitated by petrolatum's porous internal structure. On the other hand, iLEX® did not allow the penetration of moisture through the thin barrier film. This is primarily because iLEX® contains a hydroactive polymer (activated by water) that forms a seal as soon as it encounters moisture and completely inhibits moisture penetration through the barrier (Pichierri, 1993).

This method also easily distinguishes between various formulation bases such as creams and ointments. In general, ointments (based on more than 15% petrolatum) will rank better than creams that are emulsions and contain less than 15% petrolatum. Typically, oil-in-water emulsions will tend to facilitate the penetration of moisture through the continuous aqueous phase. Water in the continuous phase will quickly spread through the filter paper upon contact of the wick with the body of the filter paper. In this test, creams based on water-in-oil emulsions will rank better than oil-in-water emulsions because water is the internal phase. Some products that are good barriers but contain a high concentration of mineral oil will exhibit the spreading of the oil through the filter paper. However, the oil-insoluble ink will not exhibit any spreading with the oil front, thereby reflecting the good barrier properties. Various parameters will affect the final MPR results and, for a given study, will have to be kept constant so that the results of relative ranking will hold. These parameters are filter paper brand and type, and brand of marker used. It is therefore recommended that for relative ranking of various products, it is highly desirable to use the same brand and type of the filter paper and the markers.

Conclusions

Based on the broad spectrum of products and the control samples evaluated, it appears that this method is simple, easy to use, inexpensive, and very sensitive in differentiating the skin protectants. Additional work will be needed to establish the clinical significance of the ranking determined by this method. Among, the products evaluated, only iLEX® was able to exhibit an MPR of 0.00 ± 0.00 cm/hr. This property is based on the fact that the formulation contains a polymer that is hydroactive. As soon as the thin film of iLEX® encounters moisture, the moisture barrier property is activated. On the other hand, the fastest MPR was observed for the neat petrolatum. This is believed to be a consequence of petrolatum's somewhat porous internal structure. This porous structure allows for communication channels for moisture penetration.

Figure 1
Figure 4.2
Moisture penetration rates expressed in cm/hr for various products.