Improving Skin Barrier Function During the COVID-19 Era: Laboratory Studies of a Prescription Tri-lipid Emollient

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Synopsis

- Personal Protective Equipment (PPE) handwashing and sanitizers cause skin disorders in up to 63% of healthcare workers raising interest in topical agents that enhance skin barrier function.
- Subject protocols were designed to evaluate the barrier function of PPE medical device creams in vitro tests.
- A dye test found a tri-lipid emollient was twice as effective as a dimethicone.
- The tri-lipid emollient also blocked microbial passage through a filter barrier test.
- Clinical studies are warranted to demonstrate potential benefits of lipid-based emollients to improve skin barrier function in the COVID-19 era.

Introduction/Objective

Personal Protective Equipment (PPE) and stringent hygienic practices of this COVID-19 era often cause skin irritation, cracks, dryness, itchy contact dermatitis & other rashes, and raise concerns about skin colonization, nosocomial infections, safety and compliance of personnel because of compromised skin barrier function. Up to 63% of healthcare workers are affected by such skin disorders. A recent study of 2700 healthcare workers caring for COVID-19 patients in an Irish hospital found that 82.6% had dermatitis. Among these frontline workers, 49% denied using emollients.

The objective was to evaluate the barrier function of the medical device creams with in vitro laboratory tests. That is, determine if medical device creams can enhance barrier function.

Method: Principle & Enhanced Barrier Dye Drop Test

PRINCIPLE: Standard Protocols used by the FDA to substantiate second dressing barrier function were adapted to evaluate the physical barrier effects of skin creams. Per these protocols, there are two key tests of skin in barrier function: one on dye and the other uses microbes to see if they can pass through a barrier dressing. In the case of dye, the variable of treating gauze with creams was added, and/or the microbial barrier gauze was replaced by filter paper.

Matrices of sterile gauze or filter paper were treated with creams or not, either freshly applied or allowed to dry for 2 hrs. Dye Test. For challenge of dye by gauze: 6 µLs of 1% aqueous methylene blue were applied, allowed to soak through the gauze for 10 minutes, and the number of layers stained were photographed and counted.

Interpretation: Dye penetrating fewer layers represents greater barrier function (protection).

Results: Enhanced Barrier Dye Drop Test

Stainless 2” x 2” gauze was treated with tri-lipid, comparator product, or nothing. Dye was added & soaked for 30 min. Then gauze was opened and photographed.

- Untreated control gauze had the most stained layers & tri-lipid cream had the fewest layers stained. Dimethicone comparator differed from the others.

Method: Microbial Barrier Filter Test

RESULTS: Untreated control gauze had the most stained layers & tri-lipid cream had the fewest layers stained. Dimethicone comparator differed from the others.

Results: Microbial Barrier Filter Test – Part 1

Part 1 Goal. Determine how much time is sufficient to allow microbes to move through a porous filter paper matrix and reach the surface of an agar plate.

Step 1. Filter paper was placed onto agar ensuring no air was trapped. The filter paper was thoroughly wetted by the agar medium and warmed to 30°C.

Step 2. At different times (0 minutes, 2, 5, 10, 15, 30 minutes) a standardized loop-full amount of each microbial species was placed on top of the filter paper.

Counting down, at time zero the filter paper was removed ending the transit of any microbes to the surface of the agar.

Step 3. The plates were incubated at 30°C x 30 hours. Microbes that passed through the filter paper grew into a mass of confluent colonies. This biomass area was measured.

Analysis: SketchAndCalc was used to calculate the surface area of growth. This measurement is proportional to the number of microbes that passed through the filter paper, and the time this dependence was determined.

Part 2 Goal. Next, determine whether a cream can make the filter paper impermeable to the passage of microbes.

Step 1. Filter paper was cut into half circles. For treated filter paper, cream was applied and spread uniformly using a glass slide, and dried for 2 h at 30°C. Untreated filter paper was used as a control.

Step 2. Filter papers were placed onto agar and microbes were added as before. After incubation for 2 h at 30°C, the filter papers were removed.

Step 3. The plates were incubated at 30°C x 30 hours. Microbes that passed through the filter paper grew into a mass of confluent colonies. Plates were photographed and results were recorded.

Interpretation: No-growth is proof of complete blockage of microbial passage through treated filter papers. Such a result was scored as PASSING the microbial barrier filter test.

Results: Microbial Barrier Filter Test – Part 2

Materials

- The first skin barrier protection product was a tri-lipid emollient EpiCeram®
- Comparator product was a dimethicone prescription cream commonly used in U.S. hospitals.
- 12-layer gauze was 2 x 2 inch Equate™ Gauze Pads used in dye test.
- Whiteman No. 5 Filter Paper with average pore size of 10 µm used in microbial test.
- 2 Gram (-) and 3 Gram (+) bacteria, Staphylococcus aureus and Staphylococcus epidermidis, and 2 Gram (-) E. coli & Serratia marcescens: 3 different microbes to the surface of the agar.

Methods

- Readily available methods are shown to evaluate barrier function of skin creams in vitro and in vivo. These data were adapted using the known growth characteristics of microbes.
- See Figure 4 for the approach and results over time.

Results

- The proprietary 3:1:1 tri-lipid emollient had twice the barrier function as a common dimethicone prescription cream.
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Conclusions

- Limitations. Variety of microbes & creams tested were limited.
- These in vitro experiments demonstrate that a prescription tri-lipid emollient provided a physical barrier to passage through matrices when challenged by methylene blue dye and four different microbes.
- The proprietary 3:1:1 tri-lipid emollient had twice the barrier function as a common hospital prescription dimethicone cream in the in vitro Barrier Dye Test.
- Clinical studies are warranted to demonstrate potential benefits of lipid-based emollients to improve skin barrier function in the COVID-19 era.
- Readily available methods are shown to evaluate barrier function of skin creams in vitro, and positive findings are timely during the COVID-19 pandemic.