Evaluation of Colloidal Oatmeal (COAT) Exam Gloves on Skin of Healthcare Workers

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BACKGROUND: Healthcare workers have stringent hand hygiene policies that include hand washing, detergents, antibacterial gels and glove use. These repetitive procedures often result in aggravated skin conditions of the hands. Colloidal Oatmeal (COAT) is a natural ingredient that has a long history of beneficial use in dermatology, and is found in several skincare products to alleviate several dermatological conditions.

OBJECTIVE: The inside of nitrile exam gloves was coated with a COAT residue to promote direct skin contact with the USP skin protectant drug. The purpose of this series of clinical studies is to evaluate the use of COAT Exam Gloves on the hands of healthcare workers where hand hygiene and exam glove use are an integral part of patient care.

METHODS: The open label, single arm evaluation of COAT exam gloves was performed at three healthcare facilities that included a dental office, pediatric hospital and residential facility. Skin assessments were performed prior to and after the COAT exam gloves were worn up to a 5 day period. Assessments included a 3-point, categorical Skin Irritation Score for redness, rash, swelling, and dryness/cracking, as well as a self assessment of hand skin conditions. Epidermal water loss of the dorsum and palm of the hands was also evaluated using a closed-chamber VapoMeter system.

RESULTS: Healthcare workers reported an average of 27 glove changes and nearly an equal number of hand washings (30 on average) per day. Subjects reported to have mild hand irritation at the beginning of the study. COAT Exam Glove use significantly decreased total skin irritation (redness, rash, swelling and dryness/cracking) from baseline (p=0.022). Epidermal water loss was unchanged following COAT Exam Glove use. Subject self-assessments of skin condition were also unchanged following use.

CONCLUSIONS: The use of COAT Exam Gloves as part of routine hand hygiene practices resulted in improved skin assessments. Improvements or no significant changes from the baseline were observed in each category within a 5 day period in multiple healthcare settings. Dermatological review indicated COAT glove use was safe and well tolerated.

KEY WORDS: Colloidal Oatmeal, Exam Gloves, Hand Hygiene, Skin Irritation
Introduction

Problem Statement
Hand hygiene policies designed to protect patients and staff far too often result in aggravated skin conditions due to over use of hand washing, detergents, glove use, and antibacterial gels.[1] Aggravated skin conditions can in turn diminish hand hygiene practice and put greater risk on patients and staff.[2] Clinical studies have sought to improve skin conditions of healthcare workers through the use of skin care products or other medical products.[3] The effectiveness of gloves coated with skin protectant drugs to relieve sensitivity such as Colloidal Oatmeal (COAT) has not been fully elucidated.

COAT Exam Glove Benefits
Colloidal Oatmeal (Avena sativa L.) has been incorporated into numerous skin products, such as hand lotions and creams, due to its therapeutic benefits in protecting and relieving minor skin irritation and itching due to various skin conditions.[4, 5] COAT has been shown to have both anti-inflammatory and antihistaminic activity, among other mechanisms of action.[5] In a recent clinical evaluation, application of a COAT solution reduced sodium lauryl sulfate (SLS)-induced irritation of the skin.[6]

Colloidal Oatmeal within exam gloves is expected to not irritate or increase skin sensitivity to the wearer while maintaining safety to both patients and staff.

Purpose
Clinical trials have implicated a variety of hand hygiene treatments for hospital staff to help manage and prevent skin conditions that would impact hand hygiene practices.[2] The purpose of this series of clinical healthcare evaluations was to evaluate the use of the COAT Exam Gloves on hand skin condition of healthcare workers.

Materials and Methods
Materials
Gloves containing Colloidal Oatmeal (COAT) were supplied by Medline Industries (Mundelein, IL). COAT Exam Gloves are made of nitrile and are powder and latex free. All exam gloves used by the facilities were removed and replaced with COAT Exam Gloves. Gloves were provided in sufficient quantities to last up to 5 days.

Setting and Subjects
Three healthcare settings were selected to evaluate the effectiveness of the COAT gloves. The studies were conducted at a children’s hospital (TX), dental office- Toraason Dental Associates, LTD (Glenview, IL) and retirement community facility- Alexian Village of Milwaukee (Milwaukee, WI). All facilities maintain high standards of hand hygiene that incorporate the use of exam gloves during patient care.

Healthcare workers who follow stringent hand hygiene policies were selected to participate. Eight (8) staff members, including dentists, hygienists and lab technicians, participated from a dental practice. Nineteen (19) staff members from a pediatric hospital and thirteen (13) nursing staff from a residential retirement facility also participated.
Study Design

The study was approved by IRB and informed consent was obtained. Subjects provided general demographic information that included age, gender, history of skin conditions, current skin conditions, and the use of skin medications. Study assessments, as described below, were made prior to using any COAT gloves. Subjects were instructed to perform their normal hand hygiene practices and glove use during their normal working hours for up to a 5 day period. Soaps, lotions and antimicrobial solutions were allowed as part of subject’s standard practice as usual. For every procedure that required disposable glove use, subjects were to wear the COAT Exam Gloves. Skin assessments were then repeated up to 5 days after consecutive COAT glove use. The study was conducted during winter months during which the investigators believed hand skin health would most benefit from COAT. Studies were conducted by personnel from the Medline Clinical Research and Development Department [7][8][9].

Hand Hygiene Practices

Hand hygiene practice information was collected from each participant prior to the start of the study. The information included information on daily glove use, hand washing, antibacterial gel used, and lotion use. Confirmation these practices remained the same were confirmed through self-report at the end of the study.

Skin Irritation Assessment

A 3-point categorical scale was used to evaluate hands (including cuticles and knuckles) of healthcare personnel. Categories assessed included redness, rash, swelling and dryness/cracking on hands, where 0= healthy skin, and 1=mild, 2=moderate, and 3= severe conditions. The sum total scores for all categories (redness, swelling, rash and dry/cracking) were analyzed. Self-assessments were made prior to the use of the COAT gloves and at the conclusion of the study. Skin irritation scores were reviewed by a Board Certified Dermatologist for safety.

Subject Hand Skin Assessment

Study participants self-assessed their hand conditions using a 5-point categorical survey, where 0=“not at all” and 5=“completely” for ten questions ranking common skin descriptive terms such as moist, supple, soft, nourished, comfort, supple, repaired, and protected. Skin scores (0-5) were recorded for each hand and averaged.

Trans-Epidermal Water Loss (TEWL)

TEWL, a measurement of water vapor transmission across the stratum corneum, was measured on the dorsum and palm of the Subjects left and right hands using a VapoMeter (Delfin) and measurements were averaged. Assessments were made prior to the use of the COAT gloves and at the conclusion of the study.

Evaluation and Statistical Analysis

General statistics were performed on subject demographics, number of gloves used, lotion applications and antibacterial gel use daily, skin assessment scale and skin status survey. Statistical significance was evaluated using Student’s T-Test with p<0.05 considered significant.

Results
**Study Demographics**
Forty (40) healthcare professionals participated in this study, ranging from 21-58 years of age with an average age of 39. Ninety percent (90%) of the participants were women.

Prior to the introduction of COAT Exam Glove use, Subjects’ daily hand hygiene practice was captured. Cumulatively, healthcare workers in the three facilities changed their gloves 28 times, washed their hands 30 times, and applied either hand lotion 13 or antibacterial gel 23 times per day. Table 1 shows the average (range) of each practice in each of the healthcare facilities.

<table>
<thead>
<tr>
<th>Facility</th>
<th>Number of Glove Changes</th>
<th>Number of Hand Washings</th>
<th>Number of Lotion Applications</th>
<th>Number of Antibacterial Gel Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental</td>
<td>34 (20-75)</td>
<td>22 (3-50)</td>
<td>8 (0-30)</td>
<td>10 (0-50)</td>
</tr>
<tr>
<td>Hospital</td>
<td>26 (10-50)</td>
<td>36 (10-100)</td>
<td>20 (1-100)</td>
<td>26 (5-90)</td>
</tr>
<tr>
<td>Residential</td>
<td>26 (8-60)</td>
<td>29 (4-60)</td>
<td>10 (0-40)</td>
<td>27 (8-60)</td>
</tr>
</tbody>
</table>

With this hand hygiene regimen, nearly half of the study participants (48%) reported seasonal skin dryness and irritation and 28% of subjects reported they were experiencing some skin irritation at the beginning of the studies. Only 8% of these participants reported taking medication for these conditions.

**Change in Skin Irritation**
Subjects ranked their hand redness, swelling, rash and dryness/cracking as indices of skin irritation prior to COAT glove use (Baseline). According to the skin irritation scale, 68% of subjects had irritation. The average Baseline irritation score was 2.39 out of 12. Following COAT glove use (Post Treatment), skin irritation further improved as the scores averaged 1.36, significantly lower than Baseline (p=0.022). The average of individual skin assessment categories are represented in Table 2.
Thirty five (35) subjects experienced an improvement or no change in skin condition when wearing COAT Exam Gloves. COAT Exam Glove use significantly decreased dryness and cracking (p=0.003), swelling (p=0.012) and rash (p=0.027) and reduced hand redness.

**Subject Perception of Skin Condition**
Ten (10) categorical questions were presented to each participant prior to and after conclusion of the study. Higher average scores for categorical questions, including moisturized, supple, softness, protected, repaired, comfortable and nourished, after COAT Exam Glove use was noted, demonstrating Subjects felt they had improved skin conditions. However, results were not statistically different in total score after COAT Exam Glove use.

**Maintenance of Water Loss**
Impaired skin health is characterized by increased skin barrier function that is characterized by elevated transepidermal water loss (TEWL). TEWL measurements before and after COAT exam glove use were compared. No difference in TEWL was reported for either the dorsum or palm surface of the hand following COAT glove use.

**Discussion**
Hand hygiene practices including hand washing, antibacterial gel use, and glove use have each been shown to aggravate the skin. When these practices are combined frequently, as in the case for healthcare workers, routine hand hygiene can quickly lead to skin ailments. These ailments can deter healthcare workers from complying with hand hygiene policies which put themselves and patients at risk for disease transmission.

The clinical evaluations described here were performed during the height of the winter season, when a greater number of seasonal skin conditions are commonly reported, to evaluate whether the use of the COAT Exam Gloves could improve upon the baseline skin assessments. The use of COAT Exam Gloves as an adjunct to normal hand hygiene practices demonstrated improved skin assessments for rash, swelling and dryness/cracking over a continuous evaluation period of use up to 5 days. TEWL readings did not increase during normal hand hygiene practices, suggesting that the COAT Exam Gloves were not detrimental to the stratum corneum or cause worsening of hand conditions. Additionally, Subjects felt their hand skin conditions were improved after COAT Exam Glove use, although these results were not significantly different from baseline.

Collectively, these studies provide clinical evidence of the use of COAT Exam Gloves within various healthcare settings to support hand skin health and limit skin conditions of healthcare workers following stringent hand hygiene practices. Improved hand health promotes compliance with the current hygiene programs, and may therefore directly impact the safety of both the healthcare professional and the patients in which they treat.
References


