

A Prospective, Randomized, Double-blind, Bi-lateral Evaluation of the Skin Condition Effects of 3M™ Avagard™ (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% w/w) Surgical and Healthcare Personnel Hand Antiseptic with Moisturizers and Sterillium® Rub

Background

This skin health study was conducted to compare the effect of two alcohol-based surgical hand antiseptic products, Avagard (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% w/w) Surgical and Healthcare Personnel Hand Antiseptic with Moisturizers and Sterillium Rub® on skin condition in healthy volunteers¹. Transient flora which colonize the superficial layers of the skin are the organisms most frequently associated with healthcare-associated infections. They are often acquired by health care workers (HCWs) during direct contact with patients or contact with contaminated environmental surfaces within close proximity of the patient. Hand hygiene is one of the most important interventions in reducing transmission of potentially infectious agents.^{2,3} However, poor compliance (less than 40%) continues to be common among HCWs.² One of the reported reasons for not washing hands was skin irritation⁴. In October 2002, the Centers for Disease Control and Prevention issued the “Guideline for Hand Hygiene in Health-Care Settings.” Surgical hand antisepsis using either an antimicrobial scrub or an alcohol-based hand-rub with persistent activity is recommended before donning sterile gloves when performing a surgical procedure². Frequent and prolonged use of alcohol-based antiseptic products by HCWs may potentially deteriorate the skin condition of the hands.

Objective

To compare the effect of multiple applications of Avagard and Sterillium Rub on skin condition in healthy volunteers (subjects) over a 5-day period.

Methods

This was a prospective, double-blind, randomized, bi-lateral comparison clinical study conducted by an independent testing facility (cyberDERM Clinical Studies). Study was reviewed and approved by an independent Institutional Review Board (see note 1).

Seventeen healthy caucasian female subjects, ranging from 19-50 years of age were enrolled into the study. Five days before study initiation, subjects were instructed to “condition” their hands. They used only Ivory bar soap for washing their hands, wore gloves to protect their hands when doing activities such as washing dishes, and refrained from applying skin moisturizers on their hands. This was followed by a 5-day treatment and evaluation period.

During the treatment period, the study staff dispensed the hand antiseptic products to the subjects who were blinded on which product was applied as surgical scrub to their right or left hands. Subjects wore a glove on one hand and applied either Avagard or Sterillium Rub on the other hand. The product assigned to subject’s left or right hand was randomized based on the dominant hand. Subjects then scrubbed their hands and forearms according to the manufacturer’s instructions. Each product was applied 6 times daily for 4 days. On the fifth day, each product was applied 3 times.

During the treatment period, subjects’ hands were evaluated in 3 ways: Skin health assessment by a trained Expert Dermatological Grader (PhD), bioinstrumentation and subject self-assessment. Data collected were statistically analyzed using paired t-test.

- The Expert Grader was blinded to the treatment applied to subject’s right or left hand. Subjects’ hands were assessed for dryness, erythema and roughness prior to the first treatment on Day 1 and daily for 5 days using the Visual Scoring of Skin (VSS) scale. The VSS scale was developed by Highley⁵ to determine the amount of skin moisture and overall skin damage. It is a 6-point scale using stereomicroscopic examination of the hands.

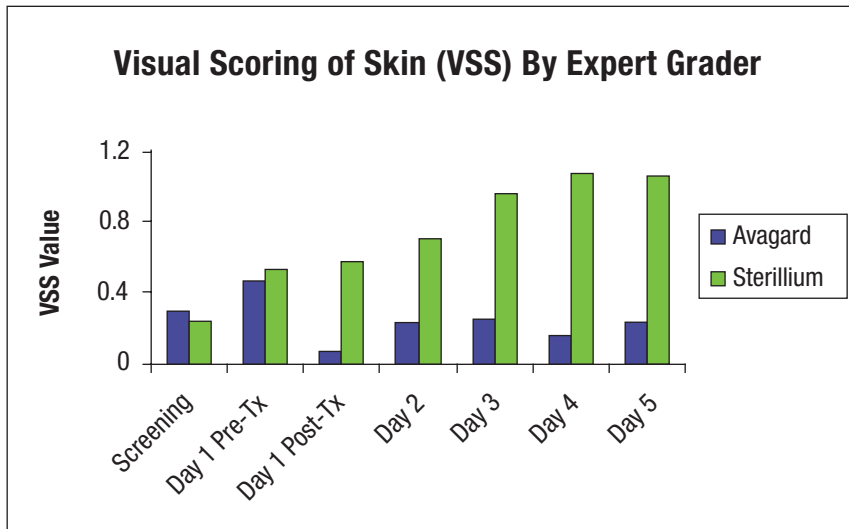


- The Expert Grader also evaluated subjects' skin condition using the Hand Skin Assessment (HSA) questionnaire developed by Larson⁶ for appearance, intactness and moisture content.
- The IBS Skicon-200 Conductance meter was used to measure the conductivity of the skin. This is a noninvasive bioinstrumentation method for determining skin surface hydration.⁷

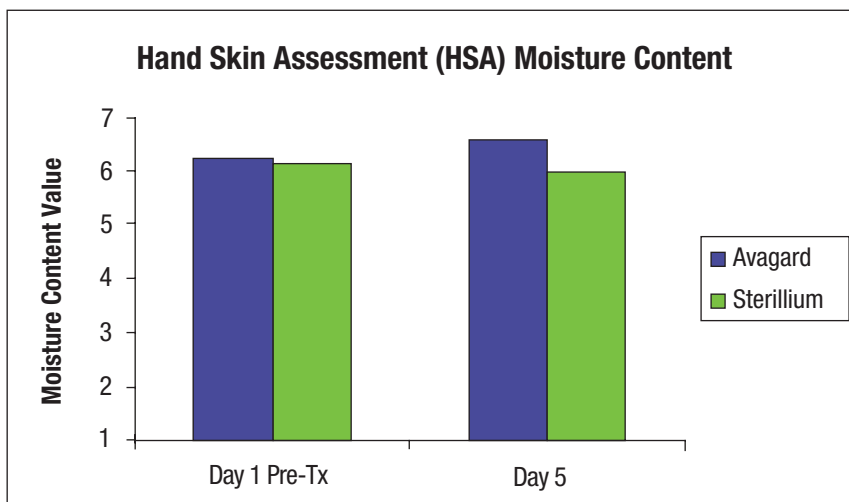
The cyberDERM Evaporimeter System with Transepidermal Water Loss (TEWL) probes was used to measure the evaporative water loss from the skin. Such measurements provide a noninvasive method for determining the barrier function of the stratum corneum.^{8,9}

- Subjects self-rated their skin condition using the HSA questionnaire for appearance, intactness, moisture content and sensation.

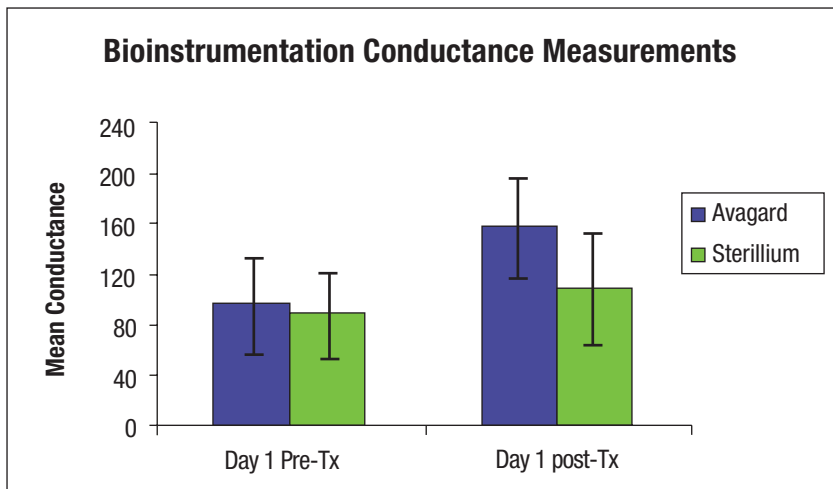
Results



After 5 days of multiple applications, subjects' hands treated with Avagard showed a modest improvement in skin condition compared to Day 1 (baseline) based on the Expert Grader VSS assessments. Subjects' hands treated with Sterillium Rub showed modest deterioration of skin condition. Comparatively, on Day 5, subjects' hands treated with Avagard were significantly better in skin condition (less visual dryness) than the hands treated with Sterillium Rub ($p=0.0071$).

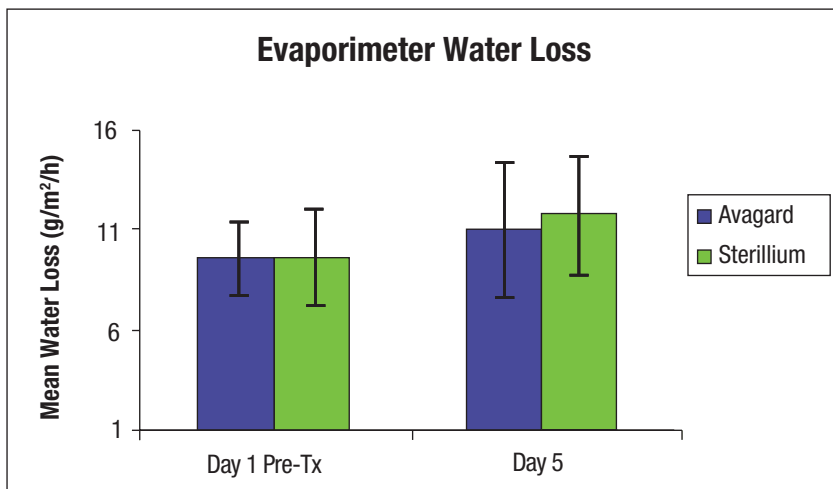


The highest Expert Grader HSA assessment score obtainable is 7.0. After multiple applications, subjects' hands treated with Avagard showed a slight improvement in skin moisture levels compared to Day 1 (baseline) based on the assessment. There was little or no change in skin moisture on hands treated with Sterillium Rub. Comparatively, on Day 5, the hands treated with Avagard had significantly higher moisture content than the hands treated with Sterillium Rub ($p=0.0343$).



Conductance measurement on skin. Increased skin surface conductance indicates increased skin hydration.

The bioinstrumentation conductance measurements were taken before and after multiple treatments on Day 1. Subjects' hands treated with Avagard showed statistically higher conductance values (increased skin hydration) than the hands treated with Sterillium Rub ($p < 0.0001$).



Evaporimeter measurement water loss from skin. Higher numbers indicate higher water loss, disruption to the normal stratum corneum.

After multiple applications, there was an increase in the evaporative water loss measurements on subjects' hands treated with both Sterillium Rub and Avagard compared to the baseline, Day 1. Comparatively, the water loss on the hands treated with Sterillium Rub was higher than on the hands treated with Avagard. The difference is approaching statistical difference ($p = 0.0596$). Increased water loss values are indicative of disruption to the normal stratum corneum skin barrier. This data suggests that Avagard may maintain skin barrier better than Sterillium Rub.

No statistically significant difference was observed between Avagard and Sterillium Rub treatments on the following tests:

- The Expert Grader assessment of appearance and intactness were not significantly difference.
- Subjects were not able to differentiate the effect of the two products on the self-assessments. They were instructed not to rub their hands together after applying the products to avoid transferring product from one hand to the other. This limited their ability to evaluate the product performance on skin.

Discussion

Surgical hand scrubs and antiseptics should not only provide effective microbial kill, but also protect and maintain skin barrier integrity, thereby reducing the risk of colonization and shedding of infectious agents.¹⁰ Avagard is formulated with an emollient that contains a patented liquid crystalline emulsion system which has been shown in clinical studies to maintain skin integrity and enhance skin hydration when compared to traditional Hibiclens® Chlorhexidine Gluconate (contains 4% CHG w/v).¹¹⁻¹³

This skin health study confirms that Avagard moisturizes skin and lessens the appearance of skin dryness. In this study, the skin condition was evaluated using the assessment scales developed by Highley and Larson. Using the VSS assessment scales developed by Highley, subjects' hand treated with Avagard showed a modest improvement in skin condition after 5 days of multiple applications when comparing to Day 1 (baseline). The hands treated with Sterillium Rub showed a modest deterioration of skin condition by Day 5. The difference between the two treatments was statistically significant (p=0.0071 on Day 5).

Using the HSA assessment scales developed by Larson, subjects' hands treated with Avagard showed a slight improvement in skin moisture on Day 5 when comparing to Day 1. The hands treated with Sterillium Rub showed little or no change in skin moisture by Day 5. The difference between the two treatments was statistically significant (p=0.0343 on Day 5).

Evaluation using Conductance Meter measurement (a test instrument), showed that both Avagard and Sterillium Rub improved the skin surface hydration after treatments on Day 1. However, the hands treated with Avagard had significantly higher skin hydration when comparing to Sterillium Rub (p<0.0001).

Note:

An independent Allendale Institutional Review Board (AIRB) approved the study protocol, informed consent form and the Health Insurance Portability and Accountability Act (HIPAA) authorization. All subjects' informed consents and HIPAA authorizations were obtained prior to participation into the study.

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70-2010-7069-8

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