

# 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 SURGICEPT™ *Waterless* Surgical Hand Antiseptic

## 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 SURGICEPT *Waterless* Surgical Hand Antiseptic on skin condition<sup>1</sup>. 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.<sup>2,3</sup> However, poor compliance (less than 40%) continues to be common among HCWs.<sup>2</sup> One of the reported reasons for not washing hands was skin irritation<sup>4</sup>. 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 surgical procedure<sup>2</sup>. Frequent and prolonged use of alcohol-based antiseptic products by HCWs, as required before participating in a surgical procedure, may potentially deteriorate the skin condition of the hands.

## Objective

To compare the effect of multiple applications of Avagard and SURGICEPT 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).

Sixteen 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 to their right or left hands. Subjects wore a glove on one hand and applied either Avagard or SURGICEPT 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 Highley<sup>5</sup> to determine the amount of skin moisture and overall skin damage. It is a 6-point scale using stereomicroscopic examination of the hands.



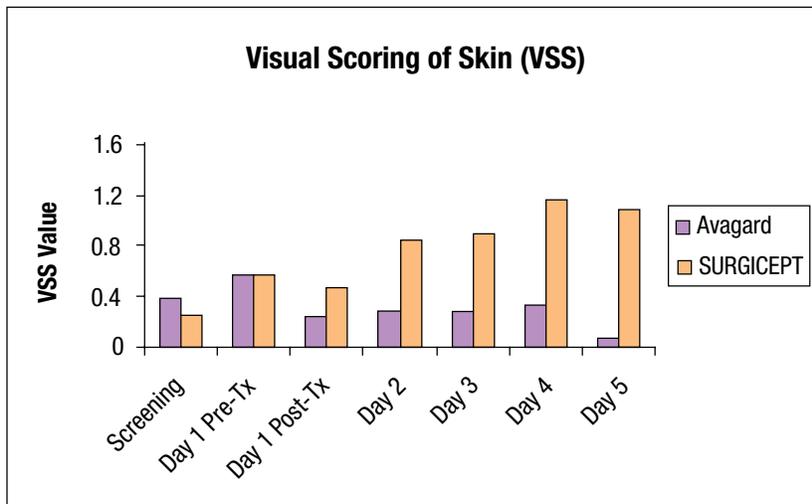
The Expert Grader also evaluated subjects' skin condition using the Hand Skin Assessment (HSA) questionnaire developed by Larson<sup>6</sup> for appearance, intactness and moisture content.

- 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.<sup>7</sup>

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.<sup>8,9</sup>

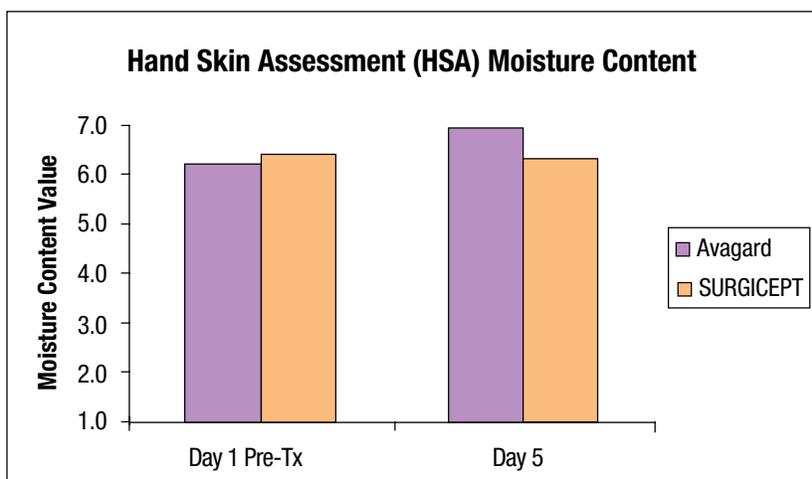
- Subjects self-rated their skin condition using the HSA questionnaire for appearance, intactness, moisture content and sensation.

## Results



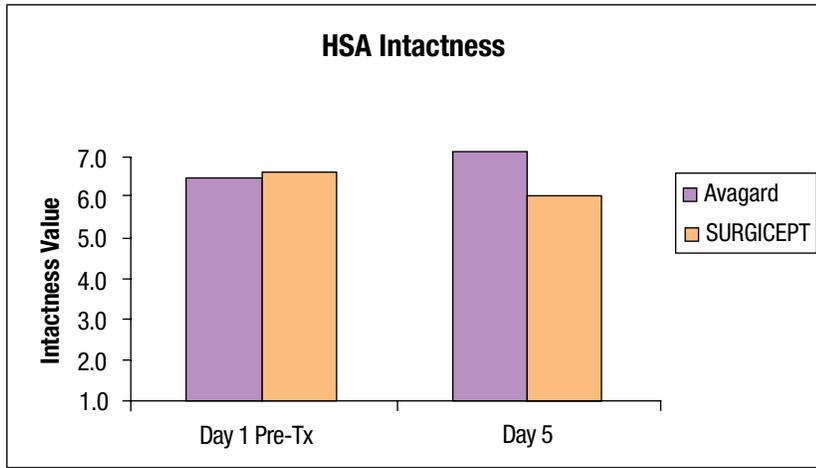
*VSS assessment of skin moisture.  
VSS score: 0 = normal to 5 = very scaly.  
Higher numbers indicate more drying,  
worsening of skin condition.*

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 SURGICEPT showed modest deterioration of skin condition. Comparatively, on Day 5, the hands treated with Avagard were significantly better in skin condition (less visual dryness) than the hands treated with SURGICEPT ( $p=0.0012$ ).



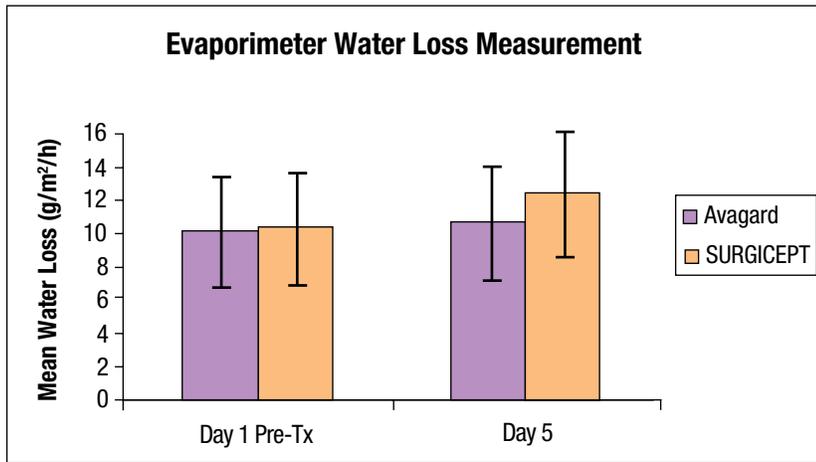
*HSA assessment of skin moisture content.  
Higher numbers indicate better  
moisture content.*

The highest Expert Grader HSA 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 SURGICEPT. Comparatively, on Day 5, subjects' hands treated with Avagard had significantly higher moisture content than the hands treated with SURGICEPT ( $p=0.0130$ ).



HSA assessment of skin intactness. Higher numbers indicate better skin intactness.

The highest Expert Grader HSA score obtainable is 7.0. After multiple applications, subjects' hands treated with Avagard showed an improvement in skin intactness compared to Day 1 (baseline) based on the assessment. There was a modest worsening on the hands treated with SURGICEPT. Comparatively, on Day 5, hands treated with Avagard had significantly better skin intactness than the hands treated with SURGICEPT ( $p=0.0003$ ).



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

After multiple applications, subjects' hands treated with SURGICEPT showed a modest increase in the evaporative water loss when compared to Day 1. Very little change in water loss was measured on the hands treated with Avagard. Comparatively, after 5 days, the water loss on the hands treated with SURGICEPT was significantly higher than on the hands treated with Avagard ( $p<0.0006$ ). Damage to the skin leads to a disruption of the barrier that is accompanied by elevated water loss rates. Increased water loss values are indicative of disruption to the normal stratum corneum skin barrier.

No statistically significant difference was observed on the following tests:

- Conductance measurements between Avagard and SURGICEPT treatments.
- The Expert Grader HSA assessment of appearance did not show a significant difference.
- Subjects were not able to differentiate the effect of the two products on the self-assessments. However, 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.<sup>10</sup> 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).<sup>11-13</sup>

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' hands 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 Surgicept showed a modest worsening of skin condition by Day 5. The difference between the two treatments was statistically significant ( $p=0.0012$  on Day 5). This indicates that Avagard has a lower potential to dry out skin.

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 Surgicept showed little or no change in skin moisture by Day 5. The difference between the two treatments was statistically significant ( $p=0.0012$  on Day 5). Subjects' hands treated with Avagard showed an improvement on skin intactness on Day 5 when comparing to Day 1. The hands treated with Surgicept showed a modest worsening on skin intactness by Day 5. The difference between the two treatments was statistically significant ( $p=0.0003$  on Day 5).

Evaluation using Evaporative Water Loss measurement (a test instrument), confirmed that subjects' hands treated with Avagard showed very little water loss on Day 5 when comparing to Day 1. The hands treated with Surgicept showed a modest increase in water loss on Day 5. The difference between the two treatments was statistically significant ( $p<0.0006$  on Day 5). This indicates that Avagard caused significantly less disruption of the skin's natural stratum corneum (protective barrier) than Surgicept.

### 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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70-2010-7068-0

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