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In Vivo Randomized Comparison of the Immediate and Persistent Efficacies of a Brushless, Waterless, Dual-Active Surgical Hand Antiseptic versus Two Brushless, Waterless, Alcohol Surgical Hand Antiseptics According to ASTM E1115

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ABSTRACT

Background: Surgical site infections (SSIs) are the second most common type of healthcare-associated infection (HAI) in the United States and are a serious medical problem associated with extended length of stay, increased medical costs, and significant morbidity and mortality. One of the key strategies for reducing the risk of SSIs is to prevent potential contamination of the wound by microorganisms on the hands of the surgical team. The introduction of waterless, brushless surgical hand scrubs has resulted in important opportunities to decrease the time required for hand preparation and the amount of skin damage caused by the traditional scrubbing procedure.

Methods: The immediate and persistent efficacies of a waterless, brushless, dual-active surgical hand antiseptic were compared against those of two waterless, brushless, alcohol surgical hand antiseptics, one of which contains preservative levels of chlorhexidine gluconate (CHG) and benzalkonium chloride (BZK), using ASTM E1115, Standard Test Method for Evaluation of Surgical Hand Scrub Formulations. Each test material was applied 12 times over a 5-day period. Samples were collected twice on Days 1 and 5, immediately after the product finished drying and 6 hours later. Subjects were randomly assigned to use one of the three test materials and samples of aerobic bacteria were collected using the glove juice technique. Relative suppression of regrowth was compared using a paired *t* test.

Results: Mean baseline counts were 6.1, 6.2, and 6.1 $\log_{10}$ colony-forming units (CFU) per hand for subjects receiving the dual-active product, the alcohol product without CHG and BZK, and the alcohol product with CHG and BZK, respectively. Mean log counts obtained for the day 1, immediate sample; day 1, 6-hour sample; day 5, immediate sample; and day 5, 6-hour sample were 3.6, 3.2, 3.5, and 3.1 $\log_{10}$ CFU/hand for the dual-active product; 3.8, 5.1, 3.7, and 4.6 $\log_{10}$ CFU/hand for the alcohol product without CHG and BZK; and 4.0, 4.6, 3.6, and 3.7 $\log_{10}$ CFU/hand for the alcohol product with CHG and BZK, respectively.

Conclusions: The dual-active product was found to be noninferior to the alcohol products at all sampling times, but showed persistence superior to that of both after 6 hours of glove wear (P<.03).

OBJECTIVE

To compare the immediate and persistent antimicrobial activity of:

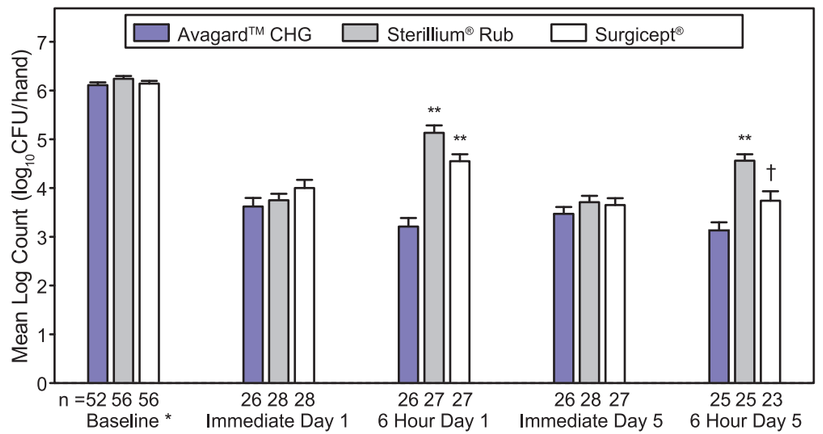
- 3M™ Avagard™ Surgical and Healthcare Personnel Hand Antiseptic with Moisturizers (1% CHG and 61% ethyl alcohol by weight) with
- Sterillium® Rub Surgical Hand Antiseptic (80% ethyl alcohol by weight), and
- Surgicept® Waterless Surgical Hand Antiseptic (70% ethyl alcohol by weight with preservative levels of CHG and BZK)

According to ASTM E1115, Standard Test Method for Evaluation of Surgical Hand Scrub Formulations.

METHOD SUMMARY

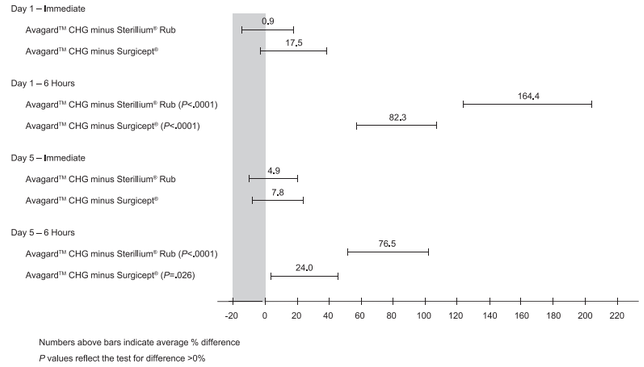
1. Average baseline counts of ≥ 5 $\log_{10}$ colony-forming units per hand were required for study participation, after a 1-week washout period.
2. Products were applied two times on Day 1, three times on Days 2, 3, and 4 and one time on Day 5.
3. Microbial samples were collected twice on Days 1 and 5, immediately after product use and after 6 hours of glove wear, using the glove juice technique.
4. Neutralization of CHG was verified before the study started.
5. 95% 2-sided confidence intervals (CIs) for the difference in means were calculated to test for noninferiority.
6. If noninferiority was found based on a margin of 20%, the t test was used to test for superiority. P values less than or equal to 0.05 were considered significant.

RESULTS: Mean Log Counts Recovered



* Each subject had a baseline value for each hand.
** Represents P < .0001 for pairwise testing against Avagard™ CHG.
† Represents P = .026 for pairwise testing against Avagard™ CHG.

RESULTS: 95% Confidence Intervals for Percent Differences



Numbers above bars indicate average % difference
P values reflect the test for difference >0%

When the lower bound of the 95% confidence interval for the percent difference between Avagard ™ CHG and the alcohol-only comparator product is:

- In the grey shaded area, noninferiority is shown (see immediate time points on Days 1 and 5).
- Is greater than the 0% difference line, superiority is shown (see 6-hour time points on Days 1 and 5).

CONCLUSIONS

Low levels of skin flora remain viable on the hands after surgical hand antisepsis and can grow in the moist environment of the surgical glove.

All three products demonstrated similar efficacy immediately after use.

Avagard™ CHG demonstrated superior persistent activity after 6 hours of glove wear compared with Sterillium® Rub and Surgicept® (P = .026).

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