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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In Vivo Randomized Comparison of the Immediate and Persistent Efficacy of a Dual-Active Surgical Hand Antiseptic versus Two Brushless, Waterless, Alcohol-based Antiseptics

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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 antiseptics 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 the alcohol-only comparator product; and 4.0, 4.6, 3.6, and 3.7 log_{10} CFU/hand for the alcohol product without CHG and BZK; and 4.1, 4.1, 4.0, and 3.8 log_{10} CFU/hand for the alcohol product with CHG and BZK, respectively. Mean log counts recovered at 1-week washout period.

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% Chlorhexidine Gluconate Solution and 61% ethyl alcohol by weight) with
• Sterillium® Rub Surgical Hand Antiseptic (80% ethyl alcohol by weight), and
• Surgincept® Waterless Surgical Hand Antiseptic (70% ethyl alcohol by weight with preservative levels of CHG and BZK)


METHOD SUMMARY

1. Average baseline counts of ≥ 5 log_{10} colony-forming units per hand were required.
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 the product finished drying and 6 hours later.
4. Neutralization of CHG was verified before the study.
5. 95% 2-sided confidence intervals (CIs) for the percent difference between product and Comparator Product 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: 95% Confidence Interval graph
Background: Surgical site infections (SSIs) are the second most common type of healthcare-associated infections, 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 the hands of the healthcare provider.

Methods: To compare the immediate and persistent antimicrobial activity of three test materials, one of which contains preservative levels of chlorhexidine gluconate (CHG) and benzalkonium chloride (BZK), using ASTM E1115, Standard Test Method for Evaluation of Surgical Antiseptics.

Conclusions:

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

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.

With a 95% confidence interval graph, the results show that Avagard™ hand antiseptic maintained significantly lower microbial counts than the other two products. The graph illustrates that Avagard™ was superior in reducing microbial load compared to Sterillium® Rub and Surgicept®.

All data presented are from a randomized, double-blind study of 20 healthcare providers. The study was conducted within a 1-week washout period. Baseline microbial counts were required for study participation, after which participants were instructed to use one of the three test materials daily for 31 days. 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.

When the lower bound of the 95% confidence interval for the percent difference between Avagard™ hand antiseptic 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™ hand antiseptic demonstrated superior persistent activity after 6 hours of glove wear compared with Sterillium® Rub and Surgicept® (P = .026).

**Footnotes:**

- 3M and Avagard are trademarks of 3M.
- Sterillium® is a Trademark of BODE CHEMIE GmbH & CO.
- Surgicept® is a Trademark of Healthpoint, Ltd.
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