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Suppression of Regrowth of Normal Skin Flora under Chlorhexidine Gluconate (CHG) Dressings Applied to CHG-Prepped Skin

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ABSTRACT

Background: Approximately 8 million central venous catheters and 160 million peripheral intravenous (IV) catheters are placed in the US each year. Skin flora at the insertion site is the most common source of catheter colonization. Although antiseptic agents are used to disinfect the skin prior to catheter insertion, bacteria still remain and regrowth occurs over time. This study evaluates suppression of normal skin flora by two CHG dressings and a non-antimicrobial control dressing after using a CHG-containing skin prep and compares performance of 3M™ Tegaderm™ CHG (Chlorhexidine Gluconate) IV Securement Dressing to BIOPATCH® Protective Disk with CHG.

Materials and Methods: The backs of 32 healthy subjects were prepped with ChloraPrep® Patient Preoperative Skin Preparation in each of 4 test quadrants. All dressing types and a post-prep site were randomized within each quadrant. All samples were collected using the cup scrub method and a neutralizer. Dressings were removed by quadrant on Days 1, 4 and 7, followed by microbial sampling. Relative suppression of regrowth between dressings was determined by comparing microbial counts on Days 1, 4 and 7 using an adjusted paired t-test.

Results: There was a mean log count of 3.2 $\log_{10}$ CFU/cm^2 at baseline. After prepping with ChloraPrep®, the mean log count dropped to 0.35 $\log_{10}$ CFU/cm^2. The mean log count obtained from the Tegaderm™ CHG sample sites was 0.40, 0.34, and 0.45 $\log_{10}$ CFU/cm^2 on Days 1, 4 and 7, respectively. The mean log count obtained from the Tegaderm™ Control sample sites was 0.94, 1.2, and 1.5 $\log_{10}$ CFU/cm^2 on Days 1, 4 and 7, respectively. The mean log count obtained from the BIOPATCH® sample sites was 0.39, 0.40, and 0.91 $\log_{10}$ CFU/cm^2 on Days 1, 4 and 7, respectively.

Conclusions:
- Skin flora remain and will regrow after antiseptic prepping.
- Dressings containing CHG help maintain low post-prep counts.
- After 7 days, Tegaderm™ CHG maintained significantly lower counts than BIOPATCH® (p=0.0085).

BACKGROUND

Central venous catheters (CVCs) and peripheral IV catheters (PIVs) are widely used in patient care. Because the use of catheters provides an access point for bacteria to enter the body, patients are at risk for local and systemic infectious complications. Catheter-related bloodstream infections (CR-BSIs) are the fourth most common type of hospital-acquired infection. Approximately 80,000 infections occur per year in the United States and up to 25% of these cases are fatal. Skin flora at the insertion site is the most common source of catheter colonization. Although the use of CHG to disinfect the skin prior to catheter insertion provides substantial protection, viable bacteria may still remain on the skin and regrowth occurs over time. Using an antimicrobial device to seal and secure the catheter may reduce the incidence of catheter colonization and subsequent infections.

The primary objective of this study was to demonstrate that Tegaderm™ CHG Dressing maintains suppression of normal skin flora better than a non-antimicrobial dressing (Tegaderm™ Transparent Adhesive Dressing) when used to secure catheters over CHG-containing skin preps in a healthy subject population. The secondary objective was to compare the performance of Tegaderm™ CHG to BIOPATCH®.

MATERIALS and METHODS

1. The backs of 31 healthy human subjects, whose average baseline counts on Treatment Day were ≥ 2.5 log colony forming units per square centimeter (CFU/cm^2), were prepped with ChloraPrep®, according to the manufacturer's directions for dry sites.

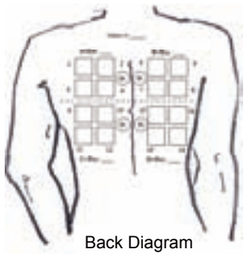
2. Post-prep samples were collected from each test quadrant using the cup scrub technique and a sampling solution containing neutralizers.

3. All three dressing types were applied in each of the test quadrants. The BIOPATCH® dressing, which requires the use of an additional adhesive dressing to keep it in place, was covered with a non-antimicrobial Tegaderm™ dressing. Each test quadrant also contained a post-prep site. See photo at right.

4. Dressings were removed one test quadrant at a time on Days 1, 4 and 7. Each test quadrant was randomized to a sampling day. The additional quadrant was a secondary source of Day 7 samples. See back diagram at right.

5. Microbial samples were collected using the cup scrub technique.

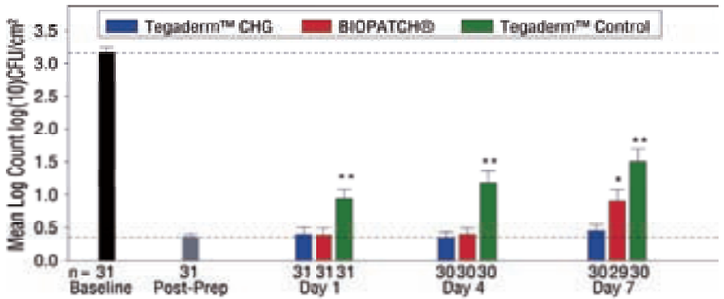
6. Suppression of regrowth was determined by comparing the microbial counts in the samples collected under the dressings on Days 1, 4 and 7 against their corresponding post-prep samples.



Back Diagram

Subject 114, Day 7
Quadrant A

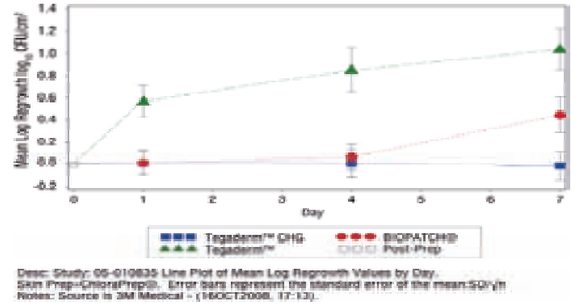
RESULTS: Mean Log Counts



** represents p-values < 0.001, * p-values < 0.01. One subject had baseline <2.5 logCFU/cm², 1 had all dressings lost by Day 4 and 1 lost BIOPATCH® by Day 7. All pairwise testing done against Tegaderm™ CHG using a paired t-test with Holm stepwise adjustment for multiple comparisons.

RESULTS: Mean Log Regrowth

1. Tegaderm™ Control showed the largest log regrowth on all days sampled (Day 1, Day 4 and Day7) with mean regrowth reaching 1.0 $\log_{10}$ CFU/cm^2 at Day 7.
2. Tegaderm™ CHG maintained significantly lower counts than Tegaderm™ Control on all days sampled (p-values <0.001), with mean log regrowth reaching -0.02 $\log_{10}$ CFU/cm^2 at Day 7.
3. After 7 days, log counts under Tegaderm™ CHG were significantly lower than those under BIOPATCH® (p-value=0.0085). The difference between Tegaderm™ CHG and BIOPATCH® at Day 7 was, on average, 0.45 $\log_{10}$ CFU/cm^2.



Desc: Study: 05-010835 Line Plot of Mean Log Regrowth Values by Day.
Skin Prep=ChloraPrep®. Error bars represent the standard error of the mean.SD=yh
Notes: Source is 3M Medical - (MBOCT2008, 17:13).

OTHER STUDY RESULTS

1. 72 subjects were screened and 32 were enrolled into the study.
2. 72% (23/32) of the subjects were male and 53% (17/32) were White.
3. The median age of the subjects was 45 years with a range of 20-74 years.
4. A total of 30 subjects completed the study. Two subjects were discontinued due to lost or compromised dressings and low microbial counts at baseline.
5. No skin irritation was observed for any of the test materials during the study.

CONCLUSIONS

1. Skin flora remain and will regrow after prepping with ChloraPrep®.

2. Dressings containing CHG help maintain low post-prep counts.

3. After 7 days, Tegaderm™ CHG maintained significantly lower microbial counts than BIOPATCH® (p=0.0085).

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