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

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ABSTRACT

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/cm²), 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 neutralizer. Dressings were removed by quadrant 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.

3. Three dressing types were applied in each of the test quadrants. The Tegaderm™ CHG dressing, which requires the use of an additional CHG-containing skin prep and compares performance of 3M™ Tegaderm™ CHG (Chlorhexidine Gluconate) IV Securement Dressing to BIOPATCH® Protective Disk with CHG.

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.

RESULTS: Mean Log Counts

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/cm²), 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 neutralizing solution containing neutralizers. Each test quadrant was randomized to a sampling day. See back diagram at right.

3. Three dressing types were applied in each of the test quadrants. The Tegaderm™ CHG dressing, which requires the use of an additional CHG-containing skin prep and compares performance of 3M™ Tegaderm™ CHG (Chlorhexidine Gluconate) IV Securement Dressing to BIOPATCH® Protective Disk with CHG.

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.

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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.

RESULTS: Mean Log Regrowth

1. Tegaderm™ Control showed the largest log regrowth on all days sampled (Day 1, Day 4, and Day 7) with mean log regrowth reaching 1.0 log 10 CFU/cm² 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/cm² at Day 7.

3. After 7 days, log counts under Tegaderm™ CHG were significantly lower than those under BIOPATCH® (p-values<0.005). The difference between Tegaderm™ CHG and BIOPATCH® at Day 7 was, on average, 0.45 log 10 CFU/cm².

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 antiseptic prepping.

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

3. After 7 days, Tegaderm™ CHG maintained significantly lower microbial counts than BIOPATCH® (p<0.005).

Back Diagram

Subject 114, Day 7
Quadrant A

RESULTS: Mean Log Regrowth