



## **Theraworx v. Chlorhexidine Gluconate Bathing and Peri-operative Skin Cleansing Study**

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### **Purpose of study:**

A comparison of the efficacy of Theraworx skin cleansing formulation and chlorhexidine gluconate in reducing bio-burden.

### **Background:**

Chlorhexidine gluconate is commonly used to bath high risk patients in ICU settings as a means to help prevent hospital acquired infections. It is also widely used as a pre-operative shower/scrub to limit surgical site infections which may occur secondary to bacterial colonization or contamination at the surgical site. Success with the peri-operative shower/scrub relies on patient compliance, proper technique and preventing recontamination of the surgical site post shower/scrub. The use of chlorhexidine gluconate for bathing is complicated by increasing reports of skin irritation/reaction, limitations of use in areas such as the groin and around the eyes, cost and concerns of progressive bacterial resistance.

Theraworx is a self drying, leave on, skin cleansing agent that combines a specialized surfactant and skin healthy ingredients. Subjective reports from users of the Theraworx Bathing System indicate its success in controlling bio-burden without the use of additional antimicrobial agents.

### **Procedure:**

Thirty healthy volunteers were recruited. These volunteers avoided bathing for 24 hours prior to the protocol. One half of the subjects were randomized to a chlorhexidine shower/scrub. These participants were given instructions and the shower was timed for ten minutes by study personnel. In addition to a total body shower, participants were asked to perform a focused scrub over the sub-clavicular space, midline abdomen, groin and patellar area. The second half of the subjects was randomized to the Theraworx group and underwent a one minute scrub of the same four areas using a single Theraworx impregnated cloth per area. After the chlorhexidine shower or Theraworx scrub the subjects were clothed in freshly laundered surgical clothing and placed in a monitored room. Skin cultures using a standardized tube/scrub method were obtained prior to

randomization as a baseline and again at two and six hours post intervention. Serial dilutions and agar plating were performed immediately and incubated for 48 hours. Colony counting was then performed and log reduction from pre-intervention counts performed.

**Results:**

Results were reported by site of preparation comparing the chlorhexidine gluconate group to the Theraworx group. Statistical difference was considered to be  $p \leq 0.10$ .

Two Hour Cultures:

1. Subclavicular space: Theraworx showed a statistical difference at  $p=.083$  in greater log reduction of bacteria as compared to chlorhexidine gluconate.
2. Midline: No statistical difference observed ( $p=.103$ ).
3. Groin: Theraworx showed a statistical difference at  $p=0.078$  in greater log reduction of bacteria as compared to chlorhexidine gluconate.
4. Knee: Theraworx showed a statistical difference at  $p<0.001$  in greater log reduction of bacteria as compared to chlorhexidine gluconate.

Six Hour Cultures:

1. Subclavicular space: No statistical difference observed ( $p=0.172$ ).
2. Midline: Theraworx showed a statistical difference at  $p=0.062$  in greater log reduction of bacteria as compared to chlorhexidine gluconate.
3. Groin: No statistical significance observed ( $p=0.371$ ).
4. Knee: Theraworx showed a statistical difference at  $p<0.003$  in greater log reduction of bacteria as compared to chlorhexidine gluconate.

**Summary:**

In all cases, Theraworx was equally effective or better at log reduction of bacteria as compared to a Chlorhexidine gluconate shower/scrub. At two hours, Theraworx was superior at the subclavicular space, groin and knee. At six hours, Theraworx was superior at the midline and knee.

Using Theraworx self drying cleanser in a one minute scrub should allow the practitioner to proceed without relying on the patient to perform an important aspect of surgical site prophylaxis correctly. The Theraworx Bathing System is an effective skin healthy alternative to chlorhexidine gluconate for bathing at risk bed bound patients without the risks associated with chlorhexidine gluconate.