

# Comparative of a new and innovative 2% chlorhexidine gluconate-impregnated cloth with 4% chlorhexidine gluconate as topical antiseptic for preparation of the skin prior to surgery

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**Background:** Decreasing the microbial skin burden reduces the risk of surgical site infection (SSI). The present study compares the activity of an innovative 2% chlorhexidine gluconate (CHG)-impregnated preoperative skin preparation cloth (PC) with a standard application procedure with a 4% CHG surgical skin preparation (SP).

**Methods:** A paired, randomized, parallel phase III study was conducted adhering to the Food and Drug Administration (FDA) design criteria for evaluating preoperative skin preparations. Subjects' left and right sides of the inguinal and abdominal skin sites ( $n = 30$ ) were randomized to either PC or SP treatment. Following baseline cultures, PC sites were prepped for 3 minutes, and SP sites were prepped for 4 minutes. Skin site cultures were obtained at 10 minutes, 30 minutes, and 6 hours postpreparation. Bacterial recovery was expressed as  $\log_{10}$  colony-forming units (cfu)/ $\text{cm}^2$  for baseline and postapplication microbial recovery.

**Results:** Mean microbial baseline for the abdominal and inguinal skin sites were as follows: PC = 3.36 cfu/ $\text{cm}^2$  and 6.15 cfu/ $\text{cm}^2$ ; SP = 3.51 cfu/ $\text{cm}^2$  and 6.16 cfu/ $\text{cm}^2$ , respectively.  $\log_{10}$  reduction for PC abdominal and inguinal prepped sites at 10 minutes, 30 minutes, and 6 hours postpreparation were 2.50, 2.33, and 2.54; 3.45, 3.50, and 3.64, respectively.  $\log_{10}$  reductions for SP abdominal and inguinal prepped sites at 10 minutes, 30 minutes, and 6 hours were 2.18, 2.19, and 2.77; 2.78, 2.63, and 3.15, respectively.

**Conclusion:** Microbial reductions from abdominal-inguinal PC prepped sites were significantly reduced ( $P < .05$ ) compared with baseline, exceeding the FDA log-reduction criteria for a preoperative topical skin preparation. Compared with baseline, microbial reductions at the SP-prepped abdominal-inguinal sites were significant ( $P < .05$ ). SP abdominal-prepped sites met the FDA log-reduction criteria; inguinal sites, however, failed to meet expected FDA log-reduction criteria at 10 minutes postpreparation. The PC-treated inguinal sites at 10 minutes, 30 minutes, and 6 hours post-skin preparation demonstrated significantly greater microbial reductions than did the SP-treated inguinal sites ( $P < .01$ ). (Am J Infect Control 2007;35:89-96.)

Postsurgical site infections are associated with significant morbidity and mortality, especially in high-risk patient populations.<sup>1-3</sup> The probability of a patient developing a postoperative surgical site infection (SSI) is influenced by selected intrinsic and extrinsic risk factors present at the time of surgery.<sup>1,4-7</sup> It is estimated that 750,000 SSIs occur in the United States each

year, resulting in increased patient morbidity and mortality, 3.7 million extra hospital days, and costing >\$1.6 billion in excess hospital charges each year.<sup>6</sup> The fundamental cornerstones for reducing the risk of SSI includes (1) exquisite surgical technique, (2) timely and appropriate antimicrobial prophylaxis, and (3) effective and persistent skin antiseptics.

What constitutes an effective preoperative skin antiseptic is clearly defined within the Food and Drug Administration (FDA) document "Tentative Final Monograph for Healthcare Antiseptic Drug Products."<sup>8</sup> The purpose of the preoperative skin antiseptic is to reduce rapidly (within 10 minutes of application) the numbers of both transient and resident microorganisms within the surgical field prior to a wound incision. It appears equally important that microbial regrowth be suppressed for the duration of the surgical procedure and beyond, ie, the antiseptic exhibit persistent

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antimicrobial properties. According to the FDA document,<sup>8</sup> the treated skin sites cannot have microbial rebound growth greater than baseline levels at 6 hours postapplication of the skin-prepping agent to be labeled a preoperative skin preparation.

Two of the most commonly employed active components in preoperative skin preparation antiseptics are chlorhexidine gluconate (CHG) and povidone iodine.<sup>9</sup> It is generally recognized that CHG, although comparable with the povidone-iodophors in terms of spectrum of antimicrobial activity, exhibits superiority in terms of a prolonged activity on the surface of the skin.<sup>1,10,11</sup> This confers an obvious advantage, especially for long surgical procedures involving area of high surface colonization and humidity such as the inguinal or axillary regions.

The present article discusses the results of a matched-pair, bilaterally randomized, open-label, parallel clinical trial involving 2% CHG delivered by a polyester preoperative skin prepping cloth and a 4% CHG formulation delivered via a standard gauze application. In this trial, the preoperative skin preparation procedure was employed to assess the microbial reduction from baseline levels over the course of 6 consecutive hours. Two anatomical test sites were evaluated in this study: the inguinal region (moist site) and the abdominal region (dry site).

## METHODS

### Study participants

Prior to subject enrollment, the test protocol was reviewed and approved by a qualified institutional review board, and informed consent was obtained from all study participants. Potential volunteers were excluded from study if they (1) were medically diagnosed as having diabetes, hepatitis, autoimmune disease, organ replacement, or a medical/surgical implant; (2) were currently undergoing any antibiotic therapy; (3) were using antibacterial/medicated soaps, shampoos, lotions, or antimicrobial deodorants or powders or any other compounds known to affect the normal microbial populations of the skin; (4) using chemically treated hot tubs or swimming pools or ultraviolet tanning beds; (5) had tattoos, dermatoses, abrasions, lesions, or other recurrent skin disorders within 6 inches of the treatment site; or (6) were pregnant females. Subjects were advised not to shave the anatomical (abdominal and inguinal) test sites within 5 days of application of the test materials and were required not to bathe or shower within 48 hours prior to their sampling times. The 2 treatments were assigned randomly to the abdominal and inguinal sites of each subject, such that one was applied on one side and the other contralaterally. Thirty overtly healthy volunteer subjects completed the protocol, and their collected sample data were used in the analysis of the study.

### Test methods and sampling procedures

Upon tentative acceptance into the study, the skin surface of subjects was baseline sampled bilaterally at 2 anatomic sites: the abdomen near the umbilicus and at the inguinal crease of the innermost aspect of the upper thigh. Microbial samples were collected using a sterile stripping fluid, including product neutralizers (SSFN), employing the cylinder cup scrub sampling method.<sup>8</sup> The product neutralizer's effectiveness in inactivating the antimicrobial activity of the products was verified prior to the evaluation.<sup>12,13</sup> A minimal microbial population of 5.0 log<sub>10</sub> colony-forming units (cfu)/cm<sup>2</sup> skin surface at the moist inguinal site and 2.5 log<sub>10</sub> cfu/cm<sup>2</sup> skin surface at the dry abdominal site was required for continuation in the study. Within 7 days following the screening baseline, a baseline sample of each test site was again performed, and the 2 test agents were randomized to each subject so that one agent was applied to one side of each subject, and the second to the remaining side. Specific sampling sites at the inguinal and abdominal regions were assigned randomly for each of the 3 posttreatment sample times (10 minutes, 30 minutes, and 6 hours), according to a computer-generated randomization statistical software algorithm.

### Product application

The 2% CHG-impregnated polyester disposable preparation cloth (PC) was applied to the designated test site using a vigorous back-and-forth motion for 1.5 minutes. The PC was then turned over, and the 1.5-minute application procedure repeated. The 4% CHG reference skin preparation (SP) was applied liberally to the site with gauze for 2 minutes, excess CHG was then blotted, using a sterile gauze, and a second application of 4% CHG was spread over the sampling site for an additional 2 minutes. Following the second application of 4% CHG, the excess material was blotted with sterile gauze.

### Sampling procedure

Ten minutes after product application, the intended sample sites were sampled using the cup scrub sampling procedure. At the sampling time, a sterile stainless-steel cylinder (inside area of 3.46 cm<sup>2</sup>) was held firmly to the skin surface, 2.5 mL of SSFN was carefully instilled into the cylinder, and the skin massaged for 60 seconds, using a sterile rubber policeman. The SSFN was aspirated with a pipette and transferred to a sterile test tube. A second 2.5 mL of SSFN was instilled into the cylinder, the process was repeated for 60 seconds, and both aspirated samples were pooled. This process was repeated for sampling times 30 minutes and 6 hours.

Following collection of the 30-minute sample, a sterile gauze and fenestration dressing was secured to inguinal and abdominal study sites, protecting the region from extraneous contamination until the final samples were collected at 6 hours postpreparation. All samples were immediately processed upon collection.

Microbial populations recovered from the samples obtained from abdominal and inguinal sites were determined by spiral-dilution plating and spread plating in duplicate aliquots using tryptic soy agar containing product-neutralizing agents. As required, diluted aliquots were spiral and/or spread plated in duplicate on tryptic soy agar with neutralizing agents. All postprepped samples were processed by spiral plating in duplicate using tryptic soy agar with neutralizing agents. Microbial plate counts were enumerated after incubation at 30°C for approximately 72 hours.

### Data handling

The number of viable microorganisms recovered per cm<sup>2</sup> sample site were determined using a conversion formula of the volumetric value of the sample suspension into the number of cfu per cm<sup>2</sup> using the following transformation:

$$M = \frac{F \times \frac{\sum x_i}{2} \times 10^{-D}}{A}$$

where

$M$  = number of microorganisms recovered per cm<sup>2</sup>,

$F$  = total number of mL SSFN added to sampling cylinder, in this study,  $F = 5$ ,

$\frac{\sum x_i}{2}$  = average of the duplicate colony counts used for each sample collected,

$D$  = dilution factor of the plate count,

$A$  = inside area of the cylinder in cm<sup>2</sup>, in this study  $A = 3.46$  cm<sup>2</sup>.

The  $M$  values were in exponential scale. To use linear statistical methods, the  $M$  values were presented in log<sub>10</sub> scale, termed the  $R$ , or recovered values,  $R = \log_{10} M$ . The data sets were evaluated using exploratory data analysis procedures to assure that they were log<sub>10</sub> normal.<sup>14</sup> No outliers were present, and no significant gaps in the data were observed. The data were not skewed, and variances were stable.

Descriptive statistics were calculated and confidence intervals determined for baseline and postapplication microbial recovery between study materials, using the Minitab (Version 14) Statistical software (Minitab Inc., State College, PA). Matched-pair  $t$  tests were used to compare the PC and SP treatments directly.

The sample size ( $n = 30$ ) was assured to detect differences of  $0.5 \log_{10}$  between the 2 treatments

evaluated at  $\alpha = 0.05$  and  $\beta = 0.20$ . The statistical formula for that computation is as follows:

$$\delta = \sqrt{\frac{S_d^2}{n}} t_{(\alpha/2, n-1)} + t_{(\beta/2, n-1)}$$

where

$\delta$  = detection level in log<sub>10</sub> value =  $0.5 \log_{10}$ . The  $\delta$  provides the sensitivity of the test. Hence, the test cannot detect true differences between products less than  $\delta$  but can for differences equal or greater.

$S_d^2$  = variance of the difference between the test and reference products.

$n$  = sample size = 30.

$\alpha$  = type I error rate = 0.05. The probability of stating that the treatments were different when they were not is 0.05.

$$t_{(\alpha/2, n-1)} = t_{(0.025, 29)} = 2.045$$

$\beta$  = type II error rate = 0.20. The probability of stating that the treatments were equivalent when they were not is 0.20.

$$t_{(\beta/2, n-1)} = t_{(0.10, 29)} = 1.311.$$

Because both products were assigned to each subject, a matched-pair Student  $t$  test was employed to compare them at each of the 3 postapplication sample times (10 minutes, 30 minutes, and 6 hours) at both test sites. The statistic used was as follows:

$$t = \frac{\bar{d}}{\frac{S_d}{\sqrt{n}}}$$

where

$\bar{d}$  = the average difference between test and control products for each subject,  $\frac{\sum(x_{PC} - x_{TP})}{n}$ , where  $x_{PC}$  = polyester cloth, and  $x_{SP}$  = 4% CHG treatment

$$S_d = \text{standard deviation of the } d_i \text{ s, } \sqrt{\frac{\sum d_i - \bar{d}}{n - 1}}$$

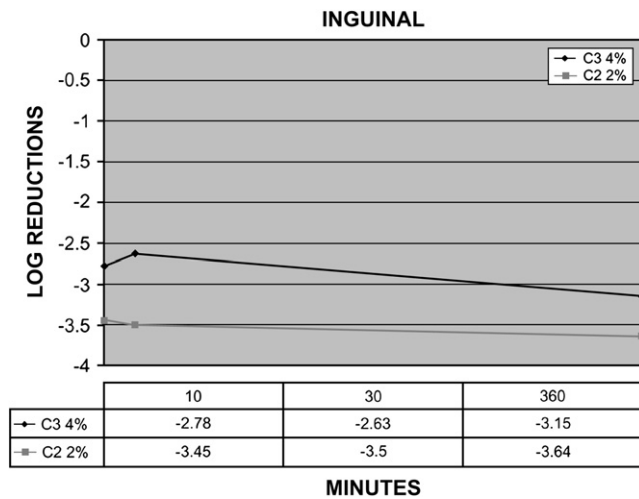
$n$  = sample size = 30.

## RESULTS

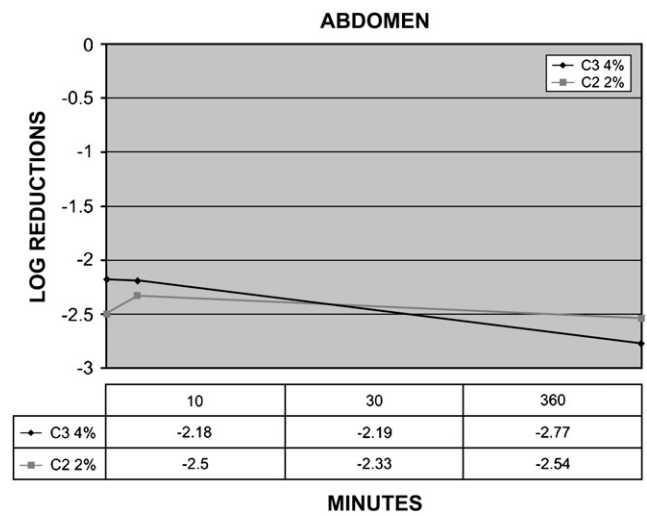
No study subjects experienced any adverse events in either the 2% CHG-PC or 4% CHG-SP arms of the study.

### Microbial reductions from baseline comparison: Descriptive statistics

The mean microbial reductions from baseline at the inguinal sites for both treatments are presented in Fig 1, and those for the abdominal site are presented in Fig 2. The mean microbial counts from inguinal sites



**Fig 1.** Mean microbial ( $\log_{10}$ ) reduction from baseline in inguinal sites using 2% CHG-impregnated polyester cloth (C2) compared with traditional 4% CHG bottled surgical skin prepping agent (C3) at 10 minutes, 30 minutes, and 6 hours postapplication.



**Fig 2.** Mean microbial ( $\log_{10}$ ) reduction from baseline in abdominal sites using 2% CHG-impregnated polyester cloth (C2) compared with traditional 4% CHG bottled surgical skin prepping agent (C3) at 10 minutes, 30 minutes, and 6 hours postapplication.

at baseline and postapplication of 2% CHG using the polyester preoperative skin PC as well as the 4% CHG SP are presented in Tables 1 and 2. Baseline microbial counts from the inguinal sites were equivalent in both groups: 2% CHG PC =  $6.15 \log_{10}$  cfu/cm<sup>2</sup>, and 4% CHG SP =  $6.16 \log_{10}$  cfu/cm<sup>2</sup>, respectively. At 30 minutes, 60 minutes, and 6 hours postapplication, there was a 3.45, 3.50, and 3.64  $\log_{10}$  reduction in microbial counts compared with baseline ( $6.15 \log_{10}$  cfu/cm<sup>2</sup>) in the 2% CHG-PC prepped sites (Table 1,  $P < .05$ ). In the inguinal sites that received the 4% CHG SP, there was a 2.78, 2.63, and 3.15  $\log_{10}$  reduction in microbial counts at 10 minutes, 30 minutes, and 6 hours postapplication, respectively, compared with baseline ( $6.16 \log_{10}$  cfu/cm<sup>2</sup>; Table 2,  $P < .05$ ). The results from the 2% CHG-PC skin-prepped inguinal site exceeded the FDA criteria for preoperative skin preparations of a 3  $\log_{10}$  reduction in microbial counts from the inguinal site at the required 10-minute postapplication time interval and did not return to baseline within a 6-hour time frame as required by the FDA. Although the  $\log_{10}$  reduction for inguinal sites prepped with 4% CHG SP was statistically significant ( $P < .05$ ) at 10 minutes, 30 minutes, and 6 hours compared with baseline, the reduction in microbial counts did not meet the specific FDA criteria for preoperative skin preparations (a 3.0  $\log_{10}$  reduction from baseline) at 10 minutes.

Tables 3 and 4 report the mean microbial counts from abdominal sites at baseline and 10 minutes, 30 minutes, and 6 hours following application of 2% CHG PC and 4% CHG SP. Mean microbial recovery at

baseline in abdominal sites prepped with 2% CHG PC and 4% CHG SP were similar,  $3.36 \log_{10}$  cfu/cm<sup>2</sup> versus  $3.51 \log_{10}$  cfu/cm<sup>2</sup>, respectively. In the 2% CHG-PC-prepped abdominal sites, there was a 2.50, 2.33, and 2.54  $\log_{10}$  reduction from baseline ( $3.36 \log_{10}$  cfu/cm<sup>2</sup>) at 10 minutes, 30 minutes, and 6 hours postapplication, respectively (Table 3,  $P < .05$ ). The 4% CHG-SP-prepped abdominal sites demonstrated a reduction from baseline ( $3.51 \log_{10}$  cfu/cm<sup>2</sup>) of 2.18, 2.19, and 2.77 at 10 minutes, 30 minutes, and 6 hours, respectively (Table 4,  $P < .05$ ). Both the 2% CHG-PC- and the 4% CHG-SP-prepped abdominal sites exceeded the FDA criteria for preoperative skin preparations of a 2.0  $\log_{10}$  reduction (compared with baseline) in microbial recovery following application of the study antiseptic agents to the abdominal test sites. The mean microbial counts in the 2% CHG-PC sites were similar to those observed for the abdominal skin sites prepped with 4% CHG SP.

**Microbial reduction from baseline:  
A direct comparison between  
PC and SP treatment groups**

A direct comparison was made between treatment groups at the 10-minute, 30-minute, and 6-hour time points in both inguinal and abdominal sample sites. Use of the 2% preoperative skin preparation cloth in the inguinal sites resulted in a significantly greater  $\log_{10}$  microbial reduction at all time intervals (10 minutes,  $P < .000001$ ; 30 minutes,  $P < .0001$ ; and 6 hours,

**Table 1.** Mean microbial counts ( $\log_{10}$ ) following application of 2% CHG-impregnated surgical cloth to the inguinal site

Sample	Sample size	Mean	Standard deviation	95% Confidence interval	Log <sub>10</sub> reduction from baseline*
Baseline	30	6.15	0.34	6.03-6.28	N/A
10 Minutes Postprep	30	2.70	0.82	2.39-3.00	3.45
30 Minutes Postprep	30	2.65	0.89	2.32-2.98	3.50
6 Hours Postprep	30	2.51	1.04	2.12-2.90	3.64

\*Calculate by subtracting mean postpreparation values from mean baseline value.

**Table 2.** Mean microbial counts ( $\log_{10}$ ) following application of 4% CHG surgical skin preparation agent to the inguinal site

Sample	Sample size	Mean	Standard deviation	95% Confidence interval	Log <sub>10</sub> reduction from baseline*
Baseline	30	6.16	0.43	6.01-6.32	N/A
10 Minutes Postprep	30	3.38	0.94	3.03-3.73	2.78
30 Minutes Postprep	30	3.53	0.77	3.25-3.82	2.63
6 Hours Postprep	30	3.01	1.10	2.60-3.42	3.15

\*Calculate by subtracting mean postpreparation values from mean baseline value.

**Table 3.** Mean microbial counts ( $\log_{10}$ ) following application of 2% CHG-impregnated surgical cloth to the abdominal site

Sample	Sample size	Mean	Standard deviation	95% Confidence interval	Log <sub>10</sub> reduction from baseline
Baseline	30	3.36	0.45	3.19-3.53	N/A
10 Minutes Postprep	30	0.86	0.85	0.54-1.17	2.50
30 Minutes Postprep	30	1.03	1.06	0.63-1.42	2.33
6 Hours Postprep	30	0.82	1.09	0.41-1.23	2.54

**Table 4.** Mean microbial counts ( $\log_{10}$ ) following application of 4% CHG surgical skin-prepping agent to the abdominal site

Sample	Sample size	Mean	Standard deviation	95% Confidence interval	Log <sub>10</sub> reduction from baseline
Baseline	30	3.51	0.57	3.30-3.72	N/A
10 Minutes Postprep	30	1.33	1.09	0.93-1.74	2.18
30 Minutes Postprep	30	1.32	1.29	0.84-1.80	2.19
6 Hours Postprep	30	0.74	1.01	0.36-1.12	2.77

$P < .01$ ) compared with the 4% CHG traditional skin preparation (Table 5A–C). There was no significant difference in the  $\log_{10}$  microbial reduction in abdominal prepped sites between the 2% CHG skin preparation cloth compared with the 4% CHG traditional skin preparation at any of the time points postapplication (Table 6A–C). It is possible that the relatively low baseline microbial recovery (2% CHG PC =  $3.36 \log_{10}$  cfu/cm<sup>2</sup>, and 4% CHG SP =  $3.51 \log_{10}$  cfu/cm<sup>2</sup>) prevented adequate discrimination between the 2 treatment groups.

## DISCUSSION

Reducing the microbial skin burden is viewed as one of the sentinel cornerstone practices for reducing

the risk of SSI. Over the past 20 years, numerous studies have been published evaluating the efficacy of selected skin antiseptic agents, including various formulations of iodophor and chlorhexidine-based products. The FDA requires that approved preoperative skin preparations demonstrate both patient safety and efficacy.<sup>8</sup> Efficacy mandates that, within a clinical trial, the drug exhibits rapid and broad-spectrum antibacterial activity, resulting in a significant reduction in microbial counts in both abdominal and inguinal skin sites compared with (nonprepped) baseline.<sup>7</sup> A significant level of microbial reduction is viewed as a 2  $\log_{10}$  cfu/cm<sup>2</sup> and 3  $\log_{10}$  cfu/cm<sup>2</sup> decrease in microbial skin counts at 10 minutes following application of the topical antiseptic on abdominal and inguinal sites, respectively. Furthermore, persistence of antibacterial

**Table 5.** Inguinal site comparison between 2% CHG polyester skin preparation cloth and 4% CHG traditional skin preparation at selected time points postapplication

A. Ten-minute time point				
Paired t test, 10 minute, PC versus SP				
	N	Mean	SD	SEM
PC	30	3.45833	0.95905	0.17510
SP	30	2.78050	1.03762	0.18944
Difference	30	0.677833	0.775266	0.141544

95% CI for mean difference: (0.388344, 0.967322).

t Test of mean difference = 0 (vs not = 0): t value\* = 4.79; P value = 0.000.

$P(t \geq 4.79 | H_0 \text{ true})^* < 0.00001 = P < 0.00001$ .

\*  $t_r = \frac{\bar{d}}{s_d/\sqrt{n}} = 4.79$

### B. Thirty-minute time point

Paired t test, 30 minute, PC versus SP				
	N	Mean	SD	SEM
PC	30	3.50633	0.94770	0.17303
SP	30	2.63150	0.93938	0.17151
Difference	30	0.874833	1.114347	0.203451

95% CI for mean difference: (0.458729, 1.290937).

t Test of mean difference = 0 (vs not = 0): t value = 4.30; P value = .0001.

$P(t \geq 4.30 | H_0 \text{ true})^* < 0.0001$ .

### C. Six-hour time point

Paired t test, 6 hour, PC versus SP				
	N	Mean	SD	SEM
PC	30	3.64533	1.11660	0.20386
SP	30	3.15283	1.13703	0.20759
Difference	30	0.492500	0.992608	0.181225

95% CI for mean difference: (0.121854, 0.863146).

t Test of mean difference = 0 (vs not = 0): t value = 2.72; P value = .011.

$P(t \geq 2.72 | H_0 \text{ true})^* \leq .011$ .

activity is within the mandate of the FDA requirements, requiring that the microbial count not return to baseline values for at least 6 hours postapplication.<sup>11</sup>

The CHG is an effective antimicrobial, demonstrating high efficacy in handwashing and vascular access studies.<sup>15-18</sup> The CHG exhibits an antimicrobial spectrum similar to iodophor-containing devices; however, CHG demonstrates a persistent activity lasting several hours on the surface of the prepped skin.<sup>1</sup>

The microbial flora associated with the inguinal incisional site often includes staphylococcal species, particularly *Staphylococcus epidermidis*, exhibiting multiple drug resistance, capable of producing a copious exopolysaccharide biofilm.<sup>19,20</sup> These staphylococcal strains are frequently associated with late-

onset vascular graft infections and catheter-related bloodstream infections.<sup>20-23</sup> The nonabrasive textural nature of the 2% CHG preoperative skin prep cloth (polyester) most likely promotes a gentle exfoliation of skin cells within the prepped area, allowing for a more thorough antiseptic effect within the immediate postapplication period. This significant ( $P < .05$ ) microbial reduction was achieved within a 3-minute prepping period as opposed to the 4-minute surgical prepping period with the comparator device 4% CHG. In addition, it was noted that the preoperative skin-prepping cloth with 2% CHG was significantly more effective in reducing microbial counts in the inguinal sites at 10 and 30 minutes, as well as 6 hours, postapplication than the traditional 4% CHG skin-prepping agent. This was perhaps due to the delivery cloth rather

**Table 6.** Abdominal site comparison between 2% CHG polyester skin preparation cloth and 4% CHG traditional skin preparation at selected time points postapplication

**A. Ten-minute time point**

Paired t test, 10 minute, PC versus SP				
	N	Mean	SD	SEM
PC	30	2.50467	0.82716	0.15102
SP	30	2.17817	1.09397	0.19973
Difference	30	0.326500	1.464304	0.267344

95% CI for mean difference: (-0.220280, 0.873280).  
 t Test of mean difference = 0 (vs not = 0): t value = 1.22; P value = .232.

**B. Thirty-minute time point**

Paired t test, 30 minute, PC versus SP				
	N	Mean	SD	SEM
PC	30	2.33467	1.10763	0.20223
SP	30	2.19317	1.55088	0.28315
Difference	30	0.141500	2.012874	0.367499

95% CI for mean difference: (-0.610120, 0.893120).  
 t Test of mean difference = 0 (vs not = 0): t value = 0.39; P value = .703.

**C. Six-hour time point**

Paired t test, 6 hour, PC versus SP				
	N	Mean	SD	SEM
PC	30	2.54333	1.02625	0.18737
SP	30	2.77017	1.03120	0.18827
Difference	30	-0.226833	1.194231	0.218036

95% CI for mean difference: (-0.672767, 0.219100).  
 t Test of mean difference = 0 (vs not = 0): t value = -1.04; P value = .307.

than the 2% CHG itself. Notice that in the moist test site (inguinal), which is a challenge for any product to achieve the required 3 log<sub>10</sub> microbial reduction within 10 minutes, the 2% CHG cloth demonstrated a near flat line of greater than a 3 log<sub>10</sub> reduction over the 6-hour period (Fig 1).

The results of this clinical study would suggest several potential advantages associated with use of a 2% CHG preoperative skin PC compared with a traditional 4% CHG SP. First, the 2% CHG-impregnated polyester cloth exceeded the minimal FDA requirement for bacterial reduction in both the abdominal and inguinal study sites. The data also demonstrate a persistent antimicrobial activity up to 6 hours postapplication. Second, the time requirement to achieve this log reduction occurred within a shorter time frame (3 minutes vs 4 minutes, respectively) than the comparator device. Third, the 500-mg equivalent CHG contained within the polyester cloth allows complete ease of use, requiring no blotting or removal of

excess CHG to facilitate drying. Fourth, the study findings demonstrate a significantly greater microbial (log<sub>10</sub>) reduction in the inguinal site at all time intervals with the 2% CHG preoperative skin PC compared with the traditional 4% CHG SP agent (P < .01).

Finally, the innovative design of this preoperative skin-prepping cloth would make this device appropriate for use in both in-patient and out-patient surgical arenas. Current recommendations based on evidence-based practice suggests that a preoperative antimicrobial skin preparation is beneficial in reducing the risk of SSL.<sup>1</sup> However, selected patients who find it difficult to bathe (ie, orthopedic) could (individually or assisted) use an antimicrobial-impregnated cloth to reduce the microbial skin contamination prior to hospital admission and surgery. Additional studies comparing the efficacy of this innovative 2% CHG preoperative skin preparation cloth with other bottled preoperative antiseptic formulations (with/without alcohol) are warranted.

**RELEVANCE TO PRACTICE**

- Ease of product application via impregnated cloth versus liberal application of antiseptic with sterile gauze
- FDA surgical skin preparation criteria: comparisons at both 10 minutes and 6 hours
  - dry site (abdominal) of at least a 2 log reduction
  - moist site (inguinal) of at least a 3 log reduction
- Time requirement for administration resulting in attaining the FDA-required log reduction
- Additional uses for the preoperative skin-preparation cloth for both inpatient and outpatient surgical areas
- Reassessment of preoperative skin preparation, particularly for procedures involving moist surgical sites whether of short or prolonged duration.

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