Effectiveness of Septisol Antiseptic Foam as a Surgical Scrub Agent

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Septisol antiseptic foam (0.23% hexachlorophene in a 46% ethyl alcohol base) is a new surgical scrub agent for both primary and re-entry use that is designed to minimize the harsh effects to the skin of the conventional scrub while retaining effective antibacterial properties. A preliminary surgical scrub study of 1-week duration yielded an immediate reduction in resident flora of 92% from an average single scrub coupled with a residual bacteriostatic effect from repeated use that gave a plateau at 57% of the pretest resident population level. A separate study demonstrated complete elimination of both gram-positive and gram-negative transients from the skin with a single application of the product. In an 8-week surgical study, equal effectiveness was shown between Septisol antiseptic foam and a standard 3% hexachlorophene detergent. However, Septisol antiseptic foam offers considerable advantage in minimizing the harsh effects to the skin of the conventional surgical scrub and results in a substantially lower hemic level of hexachlorophene in the user than that obtained with 3% hexachlorophene detergent. Sampling was conducted by the fingerprint impression technique of Gale.

The 10-min surgical scrub with popular hexachlorophene products (Septisol, pHisoHex; the trademark, Septisol, is registered to Vestal Laboratories, Division of Chemed Corporation, St. Louis, Mo.; the trademark, pHisoHex, is registered to Winthrop Laboratories, Division of Sterling Drug Incorporated, New York, N.Y.), or one of the iodophors is accepted as routine in preparing the hands and arms of the surgical team for operations. Many surgical personnel use a scrub brush during the entire scrub, often producing minor abrasions of the skin. Years of this type of harassment of the hands and arms often take their toll, leaving dry skin devoid of natural cutaneous oils and causing a low-grade dermatitis which may lead to colonization by a pathogen such as Staphylococcus aureus.

Clearly, a surgical scrub procedure and agent for both primary and re-entry use that would minimize the harsh effects on the skin of the conventional surgical scrub while retaining effective antibacterial properties would be of substantial benefit to medical personnel. Septisol antiseptic foam (0.23% hexachlorophene in a 46% ethyl alcohol base) is such a product system.

Price (6) has pointed out the efficacy of ethyl alcohol as a skin degemming agent in that rubbing it on the skin for 1 min was found as effective as scrubbing for 10 min with an unmedicated liquid soap. Traub et al. (9), Price (7), Blank and Coolidge (1), and Seastone (8) have well documented the effectiveness of hexachlorophene in depressing the resident microbial flora of the skin to a low level with continued use.

The objective of this study was to verify, under controlled laboratory conditions of use, the efficacy of Septisol antiseptic foam in reducing both the resident and transient microbial flora of the skin to a low level. Comparisons are drawn to pHisoHex (a 3% hexachlorophene surgical scrub detergent) and an unmedicated liquid soap.

MATERIALS AND METHODS

Efficacy in reducing resident skin flora. Seven subjects performed three surgical scrubs per day in a standard manner with Septisol antiseptic foam for 5 consecutive days. The hands of all personnel were sampled with fingerprint impression plates by the technique of Gale et al. (3) before scrub and immediately after scrub daily during the first scrub of the day.

Efficacy in eliminating transient skin flora. The hands of eight individuals were artificially contami-
nated with transient bacteria by immersion in a saline suspension of Micrococcus flavus at a level of 5 × 10⁵/ml followed by air drying and in a separate experiment with Escherichia coli at a level of 10⁶/ml. The hands of all personnel were sampled with finger- 

print impression plates before and immediately after a single surgical scrub with Septisol antiseptic foam. The transient microorganisms were differentiated from resident flora by pigment production with Micrococcus flavus and through the use of EMB agar in the case of Escherichia coli.

Comparison with standard hexachlorophene product. Twelve subjects were randomly divided into two groups of six with equal numbers of males and females in each group. One group was assigned to Septisol antiseptic foam (0.23% hexachlorophene in a 46% ethyl alcohol base), and the other group to pHisoHex (3% hexachlorophene detergent). All subjects performed three surgical scrubs per day in accordance with the manufacturers directions for the product under evaluation on a 5-day week. The first scrub was performed early in the morning, the second at mid-day, and the third in late afternoon. Surgical gloves were worn by all subjects for 1 h after each scrub.

All subjects scrubbed with a bland vegetable oil soap with no medication for 1 week to provide baseline data on their skin flora for direct comparison with the medicated surgical scrub agents under evaluation. This was followed with 8 weeks of surgical scrubbing with the medicated products. pHisoHex was included for comparison purposes as a standard surgical scrub agent.

The hands of all personnel were sampled with fingerprint impression plates by the technique of Gale et al. (3). Sampling was conducted before scrub, immediately after scrub, and at the end of procedure (after 1 h under gloves) daily during the third scrub of the day. A total of 240 surgical scrubs were sampled for each medicated product.

Sampling technique. The sampling medium selected for this study was Trypticase soy agar with 0.5% Tween 80 and 0.07% lecithin. Tween 80 is well recognized as an effective neutralizer for hexachlorophene carryover. A validation experiment on neutralization effectiveness was conducted by seeding two sets of plates containing plain Trypticase soy agar and the same medium with neutralizers with a 24-h culture of Staphylococcus epidermidis followed by application of 0.05 ml of Septisol antiseptic foam liquid to a 16-cm² area of the plates. Thus, 104 μg of hexachlorophene, which is the calculated maximum amount that could be transferred from the fingertips of one hand to the plate, is applied to an area of the plate that is equivalent to the fingerprint area of one hand. We observed no inhibition on the neutralizer agar plate and complete inhibition in the application area of the plain agar plate without neutralizers, verifying the adequacy of the neutralization system.

A 20-ml amount of Trypticase soy agar with 0.5% Tween 80 and 0.07% lecithin, to neutralize hexachlorophene carryover, was dispensed into disposable plastic petri plates (100 by 15 mm). After solidification, the plates were incubated overnight at 37 C and checked for sterility. They were then refrigerated until 12 h before use.

The sampling technique employed was a modification of Gale et al. (3). Each individual firmly placed each finger on a Trypticase soy agar plate leaving a fingerprint impression on the agar. The four fingerprints were placed on a line across the upper half of the plate. The thumbprint was placed upon the lower half of the same plate. One plate was used per hand.

After fingerprints had been taken, the plates were incubated for 24 h at 37 C. Plates were then counted by using a Quebec colony counter with an electronic recorder. To eliminate any chance of partiality in counting the plates, each plate was assigned a number so that the technician counting the plates could not correlate the plates with the individuals.

Septisol antiseptic foam. The product was packaged in a 6-oz. aluminum aerosol can. The active ingredients are 46% ethyl alcohol and 0.23% hexachlorophene (by weight). The ethyl alcohol content is 58% by volume.

Scrub procedure for Septisol antiseptic foam; all scrubs. (i) A palmful of antiseptic foam (equivalent to 4.5 cc liquid) is dispensed into one hand and is spread onto both arms and hands and rubbed into the skin until dry (1 to 1.5 min).

(ii) A smaller second amount of antiseptic foam (equivalent to 1.8 cc liquid) is then dispensed into one hand and spread over both hands to the wrist and rubbed into the skin until dry (0.5 to 0.75 min). A 6.3-ml amount of antiseptic foam is used during an exposure interval of 1.5 to 2 minutes.

Scrub procedure for unmedicated soap; first scrub of week. (i) Wet hands and forearms and apply 3 cc of scrub agent.

(ii) Massage and lather over the entire skin area with particular attention to the area around and between the fingers.

(iii) Rinse at approximately 1-min intervals. Reapply 3 cc of scrub agent and repeat lathering until 4 min have elapsed from the start.

(iv) The nails are now cleaned for 2 min under running water by using a file or orange stick, allowing the lather to remain on the upper hands and forearms during this period.

(v) Rinse the hands and arms.

(vi) A second 4-min scrub is performed as above.

(vii) Rinse thoroughly with water. The total soap used is 18 ml during 10 min of exposure.

All subsequent scrubs of week. (i) Same procedure as steps 1 to 3 and 7 above but the total elapsed time of scrub is 2 min with 6 ml of soap.

Scrub procedure for pHisoHex; first scrub of week. (i) Wet hands and forearms and apply 2 cc of scrub agent.

(ii) Wash for 30 s, adding small amounts of water. Avoid washing off lather.

(iii) Clean under nails.

(iv) Rinse.

(v) Apply 4 cc of surgical scrub agent and wash, while frequently adding small amounts of water for 8 min. Rinse thoroughly with water. A 6-ml amount of 3% hexachlorophene detergent is used during an exposure interval of 10 min.
All subsequent scrubs of week. The same steps 1 to 4 above with a 2-min wash in step 5. A 6-ml amount of scrub detergent is used with a total scrub time of 3 min.

RESULTS

Efficacy in reducing resident skin flora. The average bacterial plate counts before and after scrubbing with Septisol antiseptic foam for a period of 5 consecutive days are shown in Table 1. The mean initial baseline count for the group of seven subjects prior to product exposure was 960. Daily baseline counts prior to product exposure showed a progressive decrease to a plateau range of 381 to 440. An immediate reduction from these levels to a range of 8 to 39 was obtained from a single surgical scrub with Septisol antiseptic foam. Figure 1 illustrates that in terms of residual bacteriostatic activity on the skin with repeated use, a plateau was reached after 2 days of surgical scrubbing at a mean level of 57% of the baseline count prior to scrubbing with Septisol antiseptic foam. The immediate bacterial reduction each day from the first surgical scrub yielded a range of 83% to 98% with a mean reduction value of 92% below the plateau level.

Efficacy in eliminating transient skin flora. Average baseline counts of 536 for Micrococcus flavus and 294 for E. coli were reduced to zero by a single surgical scrub with Septisol antiseptic foam on the hands of eight individuals who were artificially contaminated with a transient microflora indicating 100% kill of the transient microorganisms. A survival control was run in a separate experiment by the same procedure except that the second plating was done 30 min after the first and no Septisol antiseptic foam was applied to the skin. The results confirmed that the transients survived for 30 min on the skin and reconfirmed that the absence of recoverable transient microorganisms from the skin in this experiment is due to the bactericidal action of Septisol antiseptic foam.

Comparison with standard hexachlorophene product. The 8-week bacterial averages for all scrubs of each individual in the group on Septisol antiseptic foam are shown in Table 2. The mean level for this group with unmedicated soap was 466 before scrub, 317 after scrub, and 886 at the end of procedure. Whereas a moderate reduction of 32% in the microbial contamination level was shown with unmedicated soap immediately after scrubbing, the bacterial population of the hands underwent a dramatic increase to 90% above the level before scrubbing during the period that the hands were in surgical gloves.

The mean level for this group with Septisol antiseptic foam was 492 before scrub, 20 after scrub, and 11 at the end of procedure. In the case of Septisol antiseptic foam, we observe a dramatic decrease in microbial population of the hands of 96% immediately after scrubbing with an ongoing further reduction in skin flora during the period under gloves to a level of 98%.

The 8-week mean bacterial averages for all scrubs of each individual in the group on pHisoHex are shown in Table 3. The mean level for this subject group with unmedicated soap was 287 before scrub, 255 after scrub, and 837 at

<table>
<thead>
<tr>
<th>Day</th>
<th>Before scrub</th>
<th>After scrub</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. plate count</td>
<td>Reduction from baseline (%)</td>
<td>Avg. plate count</td>
</tr>
<tr>
<td>1 (Baseline)</td>
<td>960</td>
<td>162</td>
</tr>
<tr>
<td>2</td>
<td>829</td>
<td>62</td>
</tr>
<tr>
<td>3</td>
<td>440</td>
<td>25</td>
</tr>
<tr>
<td>4</td>
<td>381</td>
<td>8</td>
</tr>
<tr>
<td>5</td>
<td>433</td>
<td>39</td>
</tr>
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</table>
the end of procedure. Once again, we see a moderate reduction of 11% in the microbial contamination level immediately after scrubbing, but the bacterial population of the hands underwent a dramatic increase to 192% above the level before scrubbing during the period that the hands were in surgical gloves.

The mean level for this group of individuals with pHisoHex was 295 before scrub, 21 after scrub, and 7 at the end of procedure. In the case of pHisoHex, a dramatic decrease in microbial population of the hands of 93% was obtained immediately after scrubbing with further reduction in skin flora during the period under gloves to a level of 98%.

A comparison of the mean level of the bacterial counts for each of the medicated products versus its intra-group unmedicated soap control (Tables 2 and 3) by the t-test using procedures outlined by Hinchen (5) showed that the difference in counts before scrubbing was not significant (P > 0.05), but the difference in counts after scrub and at the end of procedure was significant in all cases at this confidence level. The data on unmedicated soap were compared to a typical scrub week on medicated product in the middle of the 8-week scrub study (week 5) in order to have equal cell populations.

In a similar manner, the 8-week mean levels of the bacterial counts for Septisol antiseptic foam and pHisoHex were compared and the difference in counts between Septisol antiseptic foam and pHisoHex after scrub and at the end of procedure was not significant (P > 0.05).

Table 2 illustrates the relative effectiveness of Septisol antiseptic foam compared to the popular hexachlorophene surgical scrub detergent under evaluation as well as unmedicated soap.

### DISCUSSION

These microbiological investigations indicate a very definite antiseptic effect of Septisol antiseptic foam on both the resident and transient microbial flora of the skin. In addition to an average immediate reduction in resident flora of 92% from a single surgical scrub, a residual bacteriostatic benefit provided by re-

### TABLE 2. Average bacterial plate count for surgical scrubs with Septisol antiseptic foam compared to unmedicated soap

<table>
<thead>
<tr>
<th>Individual</th>
<th>Before scrub</th>
<th>After scrub</th>
<th>End of procedure*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unmedicated soap</td>
<td>Septisol antiseptic foam</td>
<td>Unmedicated soap</td>
</tr>
<tr>
<td>1</td>
<td>868</td>
<td>780</td>
<td>719</td>
</tr>
<tr>
<td>2</td>
<td>748</td>
<td>984</td>
<td>248</td>
</tr>
<tr>
<td>3</td>
<td>368</td>
<td>451</td>
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</tr>
<tr>
<td>4</td>
<td>388</td>
<td>330</td>
<td>404</td>
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<tr>
<td>5</td>
<td>92</td>
<td>137</td>
<td>99</td>
</tr>
<tr>
<td>6</td>
<td>329</td>
<td>272</td>
<td>172</td>
</tr>
<tr>
<td>Mean level</td>
<td>466</td>
<td>492</td>
<td>317</td>
</tr>
<tr>
<td>Reduction (%)</td>
<td>295</td>
<td>295</td>
<td>255</td>
</tr>
</tbody>
</table>

* After 1 h under surgical gloves.

### TABLE 3. Average bacterial plate count for surgical scrubs with pHisoHex compared to unmedicated soap

<table>
<thead>
<tr>
<th>Individual</th>
<th>Before scrub</th>
<th>After scrub</th>
<th>End of procedure*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unmedicated soap</td>
<td>pHisoHex</td>
<td>Unmedicated soap</td>
</tr>
<tr>
<td>1</td>
<td>261</td>
<td>229</td>
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<td>319</td>
<td>172</td>
<td>388</td>
</tr>
<tr>
<td>Mean level</td>
<td>287</td>
<td>295</td>
<td>255</td>
</tr>
<tr>
<td>Reduction (%)</td>
<td>295</td>
<td>295</td>
<td>255</td>
</tr>
</tbody>
</table>

* After 1 h under surgical gloves.
peated use indicates a lowering of the normal resident flora to 57% of the baseline figure. This accumulative bacteriostatic effect shown in the before-scrub curve of Fig. 1 is in agreement with the original evaluation of hexachlorophene as a surgical scrub agent by Traub et al. (9).

A complete elimination of both gram-positive and gram-negative transient microorganisms from the skin was obtained with a single application of Septisol antiseptic foam. The immediate bactericidal effect of the product on both resident and transient skin flora is most probably related to the ethyl alcohol component, while the long term bacteriostatic effect on the resident skin flora is produced by the hexachlorophene content.

In an 8-week surgical scrub study comparing Septisol antiseptic foam to pHisoHex and unmedicated soap, the results clearly indicate the need for an effective bacteriostatic agent in surgical scrub preparations to minimize the level of bacterial contamination on the hands of surgical personnel during operative procedures.

The percent reductions obtained with Septisol antiseptic foam and pHisoHex appear to be congruent (P < 0.05), and this would suggest that Septisol antiseptic foam is equally effective as the standard 3% hexachlorophene surgical scrub detergent pHisoHex, in reducing the bacterial population of the skin to a low value.

Gravens et al. (4) conducted an "in service" hospital surgical scrub study comparing Septisol antiseptic foam to standard hexachlorophene surgical scrub preparations involving 318 surgical scrubs and reached similar conclusions on the effectiveness of Septisol antiseptic foam as a surgical scrub agent.

The equivalence in bacterial reduction of skin flora between Septisol antiseptic foam and the standard surgical scrub detergent, pHisoHex, is quite significant in terms of minimizing exposure of surgical personnel to the antiseptic agent hexachlorophene. The level of hexachlorophene in Septisol antiseptic foam is one-twelfth that in pHisoHex. Butcher et al. (2) have shown that the mean blood hexachlorophene level from 8 weeks of surgical scrubbing with Septisol antiseptic foam is one-half (Septisol antiseptic foam 0.10 ppm, pHisoHex 0.20 ppm) that obtained after 8 weeks of scrubbing with pHisoHex.

No evidence of irritation to the hands or arms of personnel was observed during the use of Septisol antiseptic foam in this study, despite the substantial ethyl alcohol content. This is probably related to the inclusion of an effective emollient in the product. The foam is easy to use, nonallergenic, and significantly reduces trauma to the skin incident to standard scrubbing procedures.

Septisol antiseptic foam appears to meet the optimum criteria for a surgical scrub product in that its use minimizes the harsh effects on the skin of the conventional surgical scrub procedure while yielding a rapid reduction in resident microflora of the skin to a level equivalent to that obtained by a standard 3% hexachlorophene surgical scrub product and a complete elimination of transient microflora from a single application. It produces a residual bacteriostatic effect keeping the normal resident skin flora at a lower level between scrubs and the mean hexachlorophene blood burden from Septisol antiseptic foam is substantially lower than that obtained with the standard surgical scrub detergent, pHisoHex.

LITERATURE CITED