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William A. Rutala, Maria F. Gergen and David J. Weber

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Efficacy of a Washer-Disinfector in Eliminating Healthcare-Associated Pathogens from Surgical Instruments

William A. Rutala, PhD, MPH,1,2 Maria F. Gergen, MT (ASCP);1 David J. Weber, MD, MPH1,2

Methods

Description of Washer-Disinfector

The Steris Reliance 777 automated multichamber washer-disinfector (Steris) was used. The preprogrammed cycle included 5 phases: (1) prewash: enzyme (Klenzyme Enzymatic Presoak and Cleaner, Steris) is circulated over the load for minimally 1 minute; (2) wash: detergent (Mon-Klenz Neutral Cleaner, Steris) solution (150°F–180°F) is sprayed over the load for minimally 4 minutes; (3) ultrasonic cleaning: the basket is lowered into the ultrasonic-cleaning tank with solution at 150°F–180°F for 4 minutes; (4) thermal and instrument lubrication: hot water (180°F–200°F) is sprayed over the load for 1 minute, then instrument lubricant (Hinge-Free Instrument Lubricant, Steris) is added to the water and sprayed over the load; and (5) drying: the blower runs for at least 4 minutes, resulting in a drying temperature of 240°F. The Biomedical Engineering staff verified that the washer-disinfector was functioning properly before experimentation and assisted in disabling the washer-disinfector.

Test Organisms

Test bacterial suspensions (ie, vancomycin-resistant Enterococcus [VRE], methicillin-resistant Staphylococcus aureus [MRSA], and Pseudomonas aeruginosa) were prepared fresh daily by plating each organism to sheep blood agar (SBA; Remel) and incubating at 37°C for ~18 hours before each run. Mycobacterium terrae (frozen culture) and Geobacillus stearothermophilus (refrigerated) suspensions were inoculated into Trypticase soy broth (TSB; Remel) prior to use. Immediately before each run, 0.5–McFarland standard suspensions were prepared from these plates, separately for each organism in TSB. The following test organisms were used: MRSA (ATCC 29213), VRE (ATCC 51299), P. aeruginosa (ATCC 27853), M. terrae (Wayne ATCC 15755), and G. stearothermophilus spores (Charles Roberts, Advanced Sterilization Products).

Inoculation of the Test Instruments

Four instruments were inoculated with the test organisms: a Stille-Luer rongeur, a Kerrison rongeur, a vaginal speculum, and a Kocher clamp. In the initial series of experiments (Table 1), the 4 instruments were inoculated with 10 µL of the test organisms in TSB (ie, ~3 × 10⁷ MRSA, ~3 × 10⁷ VRE, ~2 × 10⁷ P. aeruginosa, ~1 × 10⁷ M. terrae, and at least 5 × 10⁶ G. stearothermophilus spores). The inocula were placed on an exposed surface of the instrument and allowed to air dry in a biological safety cabinet for 1 hour. After drying, each instrument was transported to Central Processing and processed in the washer-disinfector. After the cycle was complete, the instruments were aseptically placed in peel packs for transport to the laboratory. Each instrument was then immersed...
fully in sterile TSB to allow adequate contact with all surfaces (300–400 mL) and shaken on a clinical rotator for 1 hour at 110 rpm. After shaking, samples (10\(^{-1}\), 10\(^{-2}\) dilutions) were collected for quantification of the test organism. These samples were plated to SBA or 7H11 (for \(M.\) terrae) in duplicate via a spread plate and incubated at 37°C (53°C for \(G.\) stearothermophilus) for 48 hours (4 weeks for \(M.\) terrae). The remaining amount was filtered (0.22-μm mesh, Fisher Scientific) and the filter plated to SBA (or 7H11 for \(M.\) terrae) and incubated in the same manner. All growth was quantitated and identified.

The second set of experiments were done identically, except that the inocula were placed in the hinged area of a medical device (or the screw threads of the vaginal speculum), and then the hinged instruments were closed (normally open to contact with the detergent solution) or the thumb screw of the vaginal speculum was tightened.

**RESULTS**

The washer-disinfector tested was extremely effective (>7-log\(_{10}\) reduction) in eliminating contamination with both the exposed and the nonexposed test bacteria (MRSA, VRE, \(P.\) aeruginosa, and \(M.\) terrae; Table 1). The exposed \(G.\) stearothermophilus spores were substantially reduced (~5-log\(_{10}\) reduction), but the nonexposed or “hidden” spores were not eliminated (Table 2). The washer-disinfector remained effective in eliminating or dramatically reducing the level of contaminating bacteria and spores in the absence of the detergent and enzymatic cleaner (Tables 1, 2), except when the spores were “hidden.”

**DISCUSSION**

These experiments demonstrated the extreme effectiveness of the washer-disinfector in eliminating or reducing high numbers of pathogenic bacteria and spores from stainless steel surgical instruments. We found that disabling the washer-disinfector by preventing the introduction of the detergent and the enzymatic cleaner did not alter the effectiveness of the washer-disinfector against bacteria, as high numbers of clinically relevant bacteria were completely eliminated (Table 1). These data are similar to those of Nicolaos et al, who found an 8-log\(_{10}\) reduction of \(Enterococcus\) on inoculated screws. However, design features such as crevices, hinges, and covered surfaces (eg, screw threads covered by thumb screw) of surgical instruments protect the inocula (ie, spores) from the forced flow of liquids and inhibited elimination (Table 2). Thus, fluids under pressure (water with/without cleaners), ultrasonic cleaning, and thermal inactivation (150°–240°F) are sufficient to eliminate microorganisms but not spores that are “hidden” and relatively resistant to thermal inactivation. Fluids under pressure physically remove microorganisms, while ultrasonic cleaning removes soil and microorganisms by cavitation and implosion, in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces. \(G.\) stearothermophilus spores, which are relatively resistant to heat, survived the washer-disinfector process when not removed by fluidics or ultrasonic cleaning. It should be noted that the inocula used in these experiments far exceed the microbial load on used surgical instruments, as previous research has demonstrated that surgical instruments are most commonly contaminated with fewer than 100 vegetative bacteria.

These experiments also showed that thermal inactivation, fluids, and ultrasonic energy were more important than the cleaning agents in eliminating microorganisms, as effective elimination occurred in the absence of enzymatic cleaners and detergents. We continue to recommend the use of enzymatic cleaners and detergents to eliminate proteinaceous materials if...
TABLE 2. Elimination of Microbial Contamination on Nonexposed Surfaces of Experimentally Contaminated Surgical Instruments (nonexposed) by Use of a Washer-Disinfector

<table>
<thead>
<tr>
<th>Washer-disinfector conditions, organism</th>
<th>Mean inoculum, log_{10}a</th>
<th>Mean reduction, log_{10}b</th>
<th>Proportion of positive instruments/replicatesc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methicillin-resistant <em>Staphylococcus aureus</em></td>
<td>7.4</td>
<td>&gt;7.4 d</td>
<td>0/8</td>
</tr>
<tr>
<td>Vancomycin-resistant <em>Enterococcus</em></td>
<td>7.5</td>
<td>&gt;7.5 d</td>
<td>0/8</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>7.3</td>
<td>&gt;7.3 d</td>
<td>0/8</td>
</tr>
<tr>
<td><em>Mycobacterium terrae</em></td>
<td>8.1</td>
<td>7.6</td>
<td>6/8</td>
</tr>
<tr>
<td><em>Geobacillus stearothermophilus</em> spores</td>
<td>6.9</td>
<td>1.6</td>
<td>12/12</td>
</tr>
<tr>
<td>No enzymatic cleaner/detergent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vancomycin-resistant <em>Enterococcus</em></td>
<td>7.4</td>
<td>&gt;7.4 d</td>
<td>0/10</td>
</tr>
<tr>
<td>G. stearothermophilus spores</td>
<td>6.9</td>
<td>1.6</td>
<td>10/10</td>
</tr>
</tbody>
</table>

a Positive control was performed by bioburden extraction from surgical instruments, which were inoculated under the same conditions as the surgical instruments but not processed in the washer-disinfector.
b Log_{10} reductions were calculated from the differences between the recovered counts on the control (unprocessed) and test (processed) items.
c All test conditions (ie, washer-disinfector [routine or no enzymatic cleaner/detergent] with test microorganisms and surgical instruments) were tested in 2–5 independent washer-disinfector runs.
d Complete microbial elimination achieved.

Instruments are not adequately precleaned. While cleaning is critical in eliminating microbial contamination from instruments, it is important to note that there are no US Food and Drug Administration–cleared commercially available methods for rapid detection of soil components (eg, protein level of <6.4 μg/cm^2) that can be used by hospitals to monitor cleaning effectiveness.

In conclusion, washer-disinfectors are extremely effective at eliminating microorganisms from medical and surgical instruments. The elimination of microorganisms occurs by removal (eg, fluidics, detergents, and ultrasound) and thermal inactivation associated with the high-temperature wash-and-dry cycle.

ACKNOWLEDGMENTS

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Potential conflicts of interest. W.A.R. reports that he is a consultant to Clorox and Advanced Sterilization Products; D.J.W. reports that he is a consultant to Johnson & Johnson and Clorox; M.F.G. reports no conflicts of interest relevant to this article. All authors submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and the conflicts that the editors consider relevant to this article are disclosed here.

Affiliations: 1. Hospital Epidemiology, University of North Carolina Health Care, Chapel Hill, North Carolina; 2. Division of Infectious Diseases, University of North Carolina School of Medicine, Chapel Hill, North Carolina.

Address correspondence to William Rutala, PhD, MPH, 130 Mason Farm Road, Bioinformatics, Chapel Hill, NC 27599-7030 (brutala@unch.unc.edu).

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