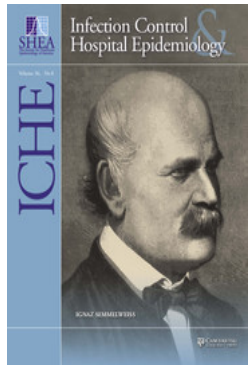

Efficacy of a Washer-Disinfector in Eliminating Healthcare-Associated Pathogens from Surgical Instruments

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

Infection Control & Hospital Epidemiology / Volume 35 / Issue 07 / July 2014, pp 883 - 885
DOI: 10.1086/676867, Published online: 02 January 2015

CONCISE COMMUNICATION

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, MPH[1,2]

This study was designed to test the efficacy of a washer-disinfector in eliminating selected healthcare-associated pathogens from surgical instruments. Our results showed that a washer-disinfector was extremely effective in eliminating microorganisms (>7-$\log_{10}$ reduction), including vegetative and spore-forming bacteria, from experimentally contaminated instruments. The washer-disinfector remained effective in eliminating microorganisms in the absence of enzymatic cleaners and detergents.

Infect Control Hosp Epidemiol 2014;35(7):883-885

Reusable critical items (eg, surgical instruments) must be thoroughly cleaned in water with detergents or enzymatic products before sterilization. Cleaning reduces the microbial load and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process by acting as a barrier to the sterilization agent.[1] In addition, decontamination renders the instruments safe to handle by staff. Poor cleaning may result in residual protein/blood staining and/or particles (eg, bone) on the instruments, raising concerns about sterilization failure. Although some studies have evaluated the cleaning of flexible endoscopes via automated endoscope reprocessors and have measured soil components (eg, protein, hemoglobin, carbohydrate, endotoxin, microorganisms),[2,3] very few studies have evaluated washer-disinfectors.[4,5] While cleaning nonlumened stainless steel instruments seems straightforward,[5] the performance of washer-disinfectors in removing and thermally inactivating test organisms has not been adequately evaluated.

Currently, most surgical instrument cleaning is done with a washer-disinfector, which acts like a sophisticated dishwasher that uses a combination of water spray, ultrasonics, detergents, and a drying process to eliminate soil (eg, protein) and microorganisms. We tested the efficacy of a washer-disinfector when medical and surgical instruments were experimentally contaminated with high numbers of microorganisms on exposed and nonexposed surfaces and then subjected to the washer-disinfector process. We also disabled the enzymatic and detergent phases of the cycle to determine the effectiveness of the washer-disinfector in eliminating microorganisms in the absence of enzymes and detergents.

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°–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°–180°F for 4 minutes; (4) thermal and instrument lubrication: hot water (180°–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, ~3×10^7 MRSA, ~3×10^7 VRE, ~2×10^7 *P. aeruginosa*, ~1×10^8 *M. terrae*, and at least 5×10^6 *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

TABLE 1. Elimination of Microbial Contamination on Exposed Surfaces of Experimentally Contaminated Surgical Instruments by Use of a Washer-Disinfector

Washer-disinfector conditions, organism	Mean inoculum, $\log_{10}$[a]	Mean reduction, $\log_{10}$[b]	Proportion of positive instruments/replicates[c]
Routine			
Methicillin-resistant *Staphylococcus aureus*	7.4	>7.4[d]	0/8
Vancomycin-resistant *Enterococcus*	7.4	>7.4[d]	0/8
Pseudomonas aeruginosa	7.3	>7.3[d]	0/8
Mycobacterium terrae	8.1	7.8	2/8
Geobacillus stearothermophilus spores	6.7	4.8	11/14
No enzymatic cleaner/detergent			
Vancomycin-resistant *Enterococcus*	7.4	>7.4[d]	0/10
G. stearothermophilus spores	6.9	5.5	8/10

[a] Positive control was performed by bioburden extraction from surgical instruments that 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.

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 allow 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,[4] 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.[6,7]

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

Washer-disinfector conditions, organism	Mean inoculum, $\log_{10}$[a]	Mean reduction, $\log_{10}$[b]	Proportion of positive instruments/replicates[c]
Routine			
Methicillin-resistant *Staphylococcus aureus*	7.4	>7.4[d]	0/8
Vancomycin-resistant *Enterococcus*	7.5	>7.5[d]	0/8
Pseudomonas aeruginosa	7.3	>7.3[d]	0/8
Mycobacterium terrae	8.1	7.6	6/8
Geobacillus stearothermophilus spores	6.9	1.6	12/12
No enzymatic cleaner/detergent			
Vancomycin-resistant *Enterococcus*	7.4	>7.4[d]	0/10
G. stearothermophilus spores	6.9	1.6	10/10

[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 $\mu g/cm^2$) 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

We acknowledge Mr. Tony Ma and Mr. Dennis Hildreth, of Medical Engineering, and Ms. Betty Twamley, of Central Processing, for their assistance with verifying the operation of the washer-disinfector and facilitating this investigation.

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).

Received November 26, 2013; accepted March 1, 2014; electronically published May 20, 2014.

 0899-823X/2014/3507-0017$15.00. DOI: 10.1086/676867

REFERENCES

1. Jacobs P. Cleaning: principles, methods and benefits. In: Rutala WA, ed. *Disinfection, sterilization, and antisepsis in healthcare.* Champlain, NY: Polyscience, 1998:165–181.
2. Alfa MJ, Olson N, DeGagne P. Automated washing with the Reliance endoscope processing system and its equivalence to optimal manual cleaning. *Am J Infect Control* 2006;34(9):561–570.
3. Alfa MJ, Degagne P, Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. *Am J Infect Control* 1999;27(5):392–401.
4. Nicolaos G, Lescoat A, Blouin P, et al. Comparison of the efficiency of cleaning, disinfection and drying of three washer-disinfectors: Steris T21, Steris T840 and Getinge 9128. *J Hosp Infect* 2008;68(3):278–280.
5. Alfa MJ, Olson N, Al-Fadhaly A. Cleaning efficacy of medical device washers in North American healthcare facilities. *J Hosp Infect* 2010;74(2):168–177.
6. Rutala WA, Gergen MF, Jones JF, Weber DJ. Levels of microbial contamination on surgical instruments. *Am J Infect Control* 1998; 26(2):143–145.
7. Nystrom B. Disinfection of surgical instruments. *J Hosp Infect* 1981;2(4):363–368.