

Persistence of Healthcare-Associated (Nosocomial) Infections Due to Inadequate Hand Hygiene: Part 3—Application of Human Factors Engineering to an Ozone Hand Sanitizer

Robert B. Raffa^{1,2,3}, Joseph V. Pergolizzi^{3,4}, Robert Taylor⁴, Sanjib Choudhuri⁵, Robert Rodenbeck⁵

¹University of Arizona College of Pharmacy, Tucson, AZ, USA

²Professor Emeritus, Temple University School of Pharmacy, Philadelphia, PA, USA

³Neumentum, Inc., Palo Alto, CA, USA

⁴NEMA Research, Inc., Naples, FL, USA

⁵Delta Faucet Co., Indianapolis, IN, USA

Email: robert.raffa@temple.edu

How to cite this paper: Raffa, R.B., Pergolizzi, J.V., Taylor, R., Choudhuri, S. and Rodenbeck, R. (2018) Persistence of Healthcare-Associated (Nosocomial) Infections Due to Inadequate Hand Hygiene: Part 3—Application of Human Factors Engineering to an Ozone Hand Sanitizer. *Pharmacology & Pharmacy*, 9, 324-330. <https://doi.org/10.4236/pp.2018.98025>

Received: June 27, 2018

Accepted: August 7, 2018

Published: August 10, 2018

Copyright © 2018 by authors and Scientific Research Publishing Inc.

This work is licensed under the Creative Commons Attribution International License (CC BY 4.0).

<http://creativecommons.org/licenses/by/4.0/>



Open Access

Abstract

Compliance to hand-hygiene guidelines in healthcare facilities remains disappointingly low for a variety of human-factors (HF) reasons. A device HF-engineered for convenient and effective use even under high-workload conditions could contribute to better compliance, and consequently to reduction in healthcare-acquired infections. We present an overview of the efficacy of a passive hand-spray device that uses solubilized ozone—a strong, safe, non-irritant biocide having broad-spectrum antimicrobial properties—on glass surface, pigskin, and synthetic human skin matrix.

Keywords

Infection, Nosocomial, Hospital, Healthcare-Associated, Hygiene, Handwashing

1. Introduction

Reported incidents of healthcare-associated infection (HAI) have declined from nearly 2 million annually in the United States to about 800,000 despite similar or greater patient load [1]. But the number seems stuck at this level [2], suggesting that compliance or effectiveness has maxed out. Hand hygiene is an activity susceptible and prone to variability due to human factors. Notably, workload/workflow challenge consistently appears as an impediment in hygiene

compliance studies [3]. Unfortunately, compliance programs generally do not sufficiently address the holistic behavioral aspects. In order to achieve progress beyond the current *status quo*, the exercise of good hand hygiene needs to be made more convenient and effective by using human factors engineering principles.

Because ozone is a strong oxidizing biocide that has broad-spectrum antimicrobial properties [4], solubilized ozone should be medically beneficial for use in applications for hand disinfection in healthcare settings. Solubilized ozone has been used safely in several animal models and human clinical studies, with no reported side effects [5]. But until now it has been difficult to reliably control the concentration of ozone in water [6]. We describe an automated device designed to improve hand-hygiene using ozonated water and efficacy of the approach in test systems.

The device (**Figure 1**) directs a stream of ozonated water to the hands with a spraying action. The spray action physically removes microbes from crevices and creases in the skin. The ozone in the stream binds and reacts with microbe cell walls, creating openings that compromise the wall's integrity. The microbe loses its ability to maintain shape, breaks apart, and dies [7]. The ozone degrades into oxygen during the course of the wash cycle. Antimicrobial efficacy results from the combination of fluidic spray action and antimicrobial property of the ozone. Together, the actions can achieve a three-log reduction in microbial load.



Figure 1. The tri-oxygen hand sanitizer (Delta Faucet, Indianapolis, IN). The user inserts their hands into the hood pictured on the right. A proximity sensor located at the opening of the hood activates the device, which contains an ozone generator component constructed of boron-doped diamond deposited on silicon substrate. An electrical voltage and current is applied to the diamond structure, which generates oxygen and hydrogen molecules from the potable water source. As power is increased to the electrolytic cell, the amount of ozone produced is in direct proportion to the power applied. The spraying action of the faucet provides energy for physical removal of microbes, and the remainder of the efficacy is provided by action of the entrained ozone, which reacts with bacteria cell walls or viral envelopes through oxidation. The device measures the time the user's hands are in the fluid stream. Compliance to cycle completion time requirements are provided graphically as feedback during the washing cycle. The device can integrate a key-card reader to track compliance to hand-hygiene protocols.

2. Methods

A series of tests were performed on various carrier/microbe combinations comparing different ozone stream delivery methods at varying ozone concentrations. The tests showed the relative contributions of the spray action and the ozone reactivity to the antimicrobial effect, and they demonstrated the efficacy against a range of microbes.

2.1. Testing on Glass Carriers

Testing was performed using 0.8 ppm ozone water concentration (above the minimum required to act as a disinfectant) delivered at a rate of 0.5 GPM (gallons per minute) using a laminar flow water delivery. Glass slide carriers (cleaned using 95% ethanol prior to rinsing with reverse osmosis water and then autoclave sterilized) were challenged with seven microbe strains with an inoculum that ranged from 1 to 5×10^5 CFU/carrier. Each carrier was placed under the ozonated water stream at a distance of 6 inches. Three exposure durations were examined: 10, 15, and 30 sec. Ten samples were used for each test.

2.2. Testing on Pigskin

Testing compared water alone with two levels of ozone concentration (0.7 and 0.9 ppm) and two water delivery methods (3D fluidics spray and laminar flow). *Staphylococcus aureus* was chosen as the test pathogen (prepared in Tryptic Soy Broth and incubated at 36°C for ~18 hours) and pigskin was chosen as a surrogate for human skin. The pigskin was cut into 1-inch squares and sterilized (by soaking in 95% ethanol for 20 min, then rinsed 3 - 5 times with sterile reverse osmosis water and placed into paper lined petri dishes at ambient temperature until visibly dry. Once dry, carriers were exposed to germicidal UV light for 10 minutes for added sterilization.). The inoculum (0.01 mL of 1:10 culture) was distributed across each pigskin carrier at an inoculum ranging from 5 to 7 at concentration approximately 5×10^5 CFU/carrier. Each carrier was placed under the water stream during the test at a distance of approximately 6 inches at a 45-degree angle. Three durations were examined: 10, 30, and 60 sec with five samples for each test.

2.3. Testing on VITRO-SKIN®

VITRO-SKIN® (IMS Inc., Portland, ME) is an advanced synthetic substrate formulated to have characteristics similar to human skin. Testing compared water alone with an ozone concentration of 0.8 ppm. *S. aureus* was chosen as the test organism. The sterile substrate was cut into 4 × 4 inch square carriers, which were inoculated with 0.1 mL of a 1:10 culture. The inoculum was spread evenly over the surface of the carrier. Once dry, each carrier was placed under the water stream at a distance of approximately 6 inches at a 45-degree angle. Three durations were examined: 5, 10, and 20 sec with five samples for each test. The carrier was moved in a circular motion through the ozonated water stream. Ozonated

water remained in contact with the carrier for the entire duration of the contact time. At the conclusion of the contact time, the carrier was neutralized in 20 mL D/E broth. Neutralized carriers were vortex mixed for 2 minutes and plated using standard dilution and plating techniques. Plates were incubated for ~24 to 48 hours at $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$.

3. Results

The results are summarized in **Table 1** and described below. 3D Fluidic sprays are small thumbnail sized devices that have a series of small internal barriers and openings. These small internal barriers and openings are able to manipulate water droplet size, velocity and direction. The result is that the water is formed into a multitude of water droplets dispersed in a 3D cone shape as the water exits the

Table 1. Antimicrobial efficacy in test systems. (a) GLASS CARRIERS; (b) PIGSKIN; (c) VITRO-SKIN[®].

(a)

Organism	Strain ^a	Classification	10 sec Log Kill	15 sec Log Kill	30 sec Log Kill
<i>Staphylococcus aureus</i> (control)	25923	Gram-pos. bacteria	4.16	>4.57	4.57
<i>Staphylococcus aureus</i> (MRSA) subsp. <i>Aureus</i> Rosenbach	BAA-44	Gram-pos. bacteria	4.55	>3.85	4.55
<i>Staphylococcus epidermis</i> (<i>CoNS</i>)—(Winslow and Winslow) Evans	12228	Gram-pos. bacteria	3.47	>3.11	3.91
<i>Enterococcus faecium</i> (Orla-Jensen) Schleifer and Kilpper-Balz	6569	Gram-pos. bacteria	4.83	>4.87	4.87
<i>Enterococcus faecalis</i> (Andrews and Horder) Schleifer and Kilpper-Balz	49532	Gram-pos. bacteria	3.93	>4.11	4.11
<i>Candida albicans</i> (Robin) Berkhout	14053	Diploid fungi	4.00	>4.00	4.00
<i>Clostridium difficile</i> serogroup F	43598	Endospore	1.26	1.61	3.17

a. ATTC[™].

(b)

Ozone (ppm)	Delivery (0.5 GPM)	Strain ^a	Classification ^a	10 sec Log Kill	30 sec Log Kill	60 sec Log Kill
0.9	Spray—3D Fluidics	6538	Gram-pos. bacteria	2.87	2.99	3.78
0.7	Spray—3D Fluidics	6538	Gram-pos. bacteria	2.38	2.54	2.86
0.9	Laminar	6538	Gram-pos. bacteria	0.99	1.33	1.70
0.7	Laminar	6538	Gram-pos. bacteria	1.23	1.31	1.58
0.0	Spray—3D Fluidics	6538	Gram-pos. bacteria	N/A	N/A	2.00
0.0	Laminar	6538	Gram-pos. bacteria	N/A	N/A	0.95

a. ATTC[™].

(c)

Ozone (ppm)	Delivery (0.5 GPM)	Strain ^a	Classification ^a	5 sec Log Kill	10 sec Log Kill	20 sec Log Kill
0.0	Spray— 3D Fluidics	6538	Gram-pos. bacteria	0.68	N/A	0.80
0.0	Spray— Needle Jet	6538	Gram-pos. bacteria	0.50	N/A	0.42
0.8	Spray— 3D Fluidics	6538	Gram-pos. bacteria	2.17	2.27	2.91
0.8	Spray— Needle Jet	6538	Gram-pos. bacteria	1.27	1.85	2.11

a. ATTCTM.

device. 3D fluidics demonstrated superior ability to produce a greater log reduction in microbe growth when compared to laminar flow. The superior aspects of this device are excellent coverage and pressure when compared against needle jets and laminar flow. The tests show the efficacy of the product against a range of pathogenic microbes on a variety of surfaces, including surfaces similar to human skin (pigskin).

3.1. Testing on Glass Carriers

The results of testing on glass carriers are shown in **Part A**, presented as log reductions for each exposure duration.

3.2. Testing on Pigskin

The results in **Part B** show that both the spray action and ozone concentration contribute to the antimicrobial effect. Spray flow (0.9 ppm) resulted in 2.99 log reduction in 30 sec, compared to 1.33 log reduction with laminar flow. With tap water (no ozone), spray flow resulted in 2.0 log reduction after 60 sec, compared to 0.95 log reduction with laminar flow. With respect to ozone concentration, tap water resulted in 2.0 log reduction after 60 sec, compared to 2.86 and 3.78 log reduction with 0.7 and 0.9 ppm ozonated water, respectively.

3.3. Testing on VITRO-SKIN[®]

The results in **Part C** show that ozonated water combined with the 3D spray nozzle resulted in a 2.27 log reduction after 10 sec and 2.91 log reduction after 20 sec, in contrast to needle jet spray, which resulted in 1.85 log reduction after 10 sec and 2.11 log reduction after 20 sec.

4. Discussion

Human factors engineering (HFE) [8] involves application of knowledge of human capabilities and limitations to the design and development of devices. The goal is to optimize product design and user interface in order to reduce or prevent user confusion, misuse, and use-related hazards. It is an interdisciplinary method of improving the safety, efficiency, and robustness of medical devices, by focusing on risk-critical user-device interactions and incorporating simu-

lated-use testing to replicate the real-world experience.

The device described herein combines spraying action and the action of ozone to achieve a three-log reduction in microbes in test systems. Efficacy is achieved by a combination of fluidic action of the spray and of the ozonated water. The ozone within the water stream exerts its antimicrobial effect, and then rapidly degrades into oxygen. It is convenient and non-irritating, suitable for medical settings where personnel have heavy workloads and require multiple hand washings throughout the course of their workday. Improved hand-hygiene compliance should translate into reduced hospital-acquired infections [9] [10].

Acknowledgements

Members of the Delta Faucet Co. Medical Advisory Group (Robert Lubitz, Sanjib Chouduri, John Leslie, Brian Leon, Jay Ramasamy, Amy Beth Kresse, Kalib Alexander, Garry Marty, John Noble, Patrick Jonte)—for contributions to the development of the device. NEMA Research Inc. received funding from the Delta Faucet Co. to write this manuscript. The content is solely that of the authors.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

References

- [1] Klevens, R.M., Edwards, J.R., Richards Jr., C.L., *et al.* (2007) Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports*, **122**, 160-166. <https://doi.org/10.1177/003335490712200205>
- [2] Boyce, J.M., Pittet, D. and Healthcare Infection Control Practices Advisory C, Force HSAIHHT (2002) Guideline for Hand Hygiene in Health-Care Settings. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Society for Healthcare Epidemiology of America/Association for Professionals in Infection Control/Infectious Diseases Society of America. *MMWR Recommendations and Reports*, **51**, 1-45, quiz CE1-4. <https://doi.org/10.1067/mic.2002.130391>
- [3] Larson, E.L., Early, E., Cloonan, P., *et al.* (2000) An Organizational Climate Intervention Associated with Increased Handwashing and Decreased Nosocomial Infections. *Behavioral Medicine*, **26**, 14-22. <https://doi.org/10.1080/08964280009595749>
- [4] Bialoszewski, D., Bocian, E., Bukowska, B., *et al.* (2010) Antimicrobial Activity of Ozonated Water. *Medical Science Monitor*, **16**, MT71-5.
- [5] Kuroda, K., Azuma, K., Mori, T., *et al.* (2015) The Safety and Anti-Tumor Effects of Ozonated Water in Vivo. *International Journal of Molecular Sciences*, **16**, 25108-25120. <https://doi.org/10.3390/ijms161025108>
- [6] Azuma, K., Mori, T., Kawamoto, K., *et al.* (2014) Anti-Inflammatory Effects of Ozonated Water in an Experimental Mouse Model. *Biomedical Reports*, **2**, 671-674. <https://doi.org/10.3892/br.2014.290>
- [7] Thanomsub, B., Anupunpisit, V., Chanphetch, S., *et al.* (2002) Effects of Ozone Treatment on Cell Growth and Ultrastructural Changes in Bacteria. *The Journal of General and Applied Microbiology*, **48**, 193-199.

<https://doi.org/10.2323/jgam.48.193>

- [8] Gawron, V.J., Drury, C.G., Fairbanks, R.J. and Berger, R.C. (2006) Medical Error and Human Factors Engineering: Where Are We Now? *American Journal of Medical Quality*, **21**, 57-67. <https://doi.org/10.1177/1062860605283932>
- [9] Allegranzi, B. and Pittet, D. (2009) Role of Hand Hygiene in Healthcare-Associated Infection Prevention. *Journal of Hospital Infection*, **73**, 305-315. <https://doi.org/10.1016/j.jhin.2009.04.019>
- [10] Kingston, L., O'Connell, N.H. and Dunne, C.P. (2016) Hand Hygiene-Related Clinical Trials Reported since 2010: A Systematic Review. *Journal of Hospital Infection*, **92**, 309-320. <https://doi.org/10.1016/j.jhin.2015.11.012>