Safe to Handle? Comparing Manually and Machine-Washed Medical Devices

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The goal of medical device reprocessing is to ensure that a given device is ready for safe use on the next patient. Effective cleaning of devices is critical to achieving this goal. Device cleaning also has had an ancillary goal: rendering the device safe for handling with ungloved hands by sterile processing personnel. Such personnel are tasked with preparing the device for further reprocessing steps, such as packaging for sterilization.

This raises the question: Are manually cleaned devices as safe to handle as machine-washed medical devices? The current study sought to gather data to help answer this question. Further, this study sought to evaluate the effectiveness of a relatively new tool in the area of decontamination in healthcare settings—ultraviolet (UV) disinfection—and whether UV disinfection could effectively and efficiently be used to render manually cleaned devices safer to handle.

Mechanically washed reusable medical devices generally are considered to have a more reliable and effective level of cleanliness, as supported by the limited research available in this area.[1] The underlying logic for this assertion is that mechanical methods are more robust and reliably repeatable compared with manual methods.[2] Machine washing allows for the use of cleaning solutions at much higher temperatures. These higher temperatures typically include a detergent wash at 60°C (150°F), followed by thermal disinfection at 82°C to 93°C (180°F to 195°F) for one minute or longer.[3] Further, the cycle settings are programmed into a machine and are repeated cycle after cycle. Conversely, manual cleaning depends on the individual performance of the person conducting the cleaning.

These assertions do not devalue the importance of reprocessing staff. To the contrary, even the most simply designed medical device requires proper and effective precleaning by manual means. Typically speaking, the more complex the device, the more important the manual steps to prepare the device for further cleaning by mechanical means. Further, a substantial number of medical devices cannot undergo mechanical cleaning. This is due to the material used in construction (i.e., thermolabile, nonsubmersible) and/or the complexity of the design.[4] Effective cleaning of these devices is wholly reliant on manual processes.

By design, sterile processing departments typically have a physical separation between the area where items are cleaned (the "dirty side") and the area to which they are transported for further processing, such as sterilization (the "clean side"). Mechanical cleaning equipment typically is designed with a dual door design, where the loading door is located on the dirty side and the unloading door on the clean side. For manually cleaned devices, and for passing items back from the clean to the dirty side for recleaning, sterile processing departments typically have a "pass-through" window.

A common perception among sterile processing staff is that manually cleaned medical devices are not as safe to handle with bare hands as those that are machine washed. If you spend time in a sterile processing department, chances are you will observe staff on the clean side wiping down items coming through the pass-through window with an alcohol wipe. If asked why, they usually will tell you that they do this to disinfect the items.

The current study was conducted to evaluate whether hand-washed medical devices are as safe to handle as machine-washed devices. Manually and mechanically cleaned medical devices were obtained from three healthcare facilities. Manually cleaned instruments included devices such as video cameras, arthroscopes, laparoscopes, and hysteroscopes. Mechanically cleaned instruments included stainless steel devices such as retractors, hemostats, needle holders, forceps, and clamps.

The design of the experiment was to obtain an aerobic plate count of bacteria growing on the medical devices from both the manually and mechanically cleaned device sets. The goal was to compare the number of aerobic microbes on both devices sets.

Test Procedure after Cleaning

After cleaning on the dirty side, hand-washed devices were transferred to the clean side via the pass-through window. Machine-washed devices also were collected on the clean side after exiting the automated mechanical washers. The volume of hand-washed devices typically is a fraction of the volume of machine-washed devices; therefore, hand-washed items were sampled as they became available. Machine-washed devices were randomly selected. For the machine-washed group, an effort was made to select a cross section of devices that ranged in design from the relatively simple (i.e., osteotomes) to the more complex (i.e., power equipment).

After selection, hand- and machine-washed medical devices were wiped with sterile swabs. Then, the captured samples were swabbed onto nutrient agar petri plates under a laminar airflow hood, in order to obtain viable plate counts. With more complex devices, whether they were hand or machine washed, multiple sites were swabbed. For instance, in the case of a power drill, the chuck area, handle, and outer surface were swabbed. With simpler devices, such as forceps and scissors, single sites were selected for sampling.

Population of Devices Tested

The numbers of hand- and machine-washed medical devices (respectively) tested from each healthcare facility were as follows: site one, 7 and 10; site two, 14 and 44; site three, 10 and 10. Therefore, in total, 31 hand-washed and 64 machine-washed instruments were tested.

Phase One Test Results

Bacterial plate counts were obtained for both the manually and machine-washed medical devices. The average count for the colony-forming units (CFUs) on the surfaces of hand-washed devices was 36.6, while that for machine-washed devices was 9.2. (Tables showing the complete results of the cleaning, both before and after UV disinfection, are available from the first author upon request.)

The results showed that manually washed devices harbored more bioburden than machine-washed devices and presumably were not as safe to handle with ungloved hands.

The goal was to compare the number of aerobic microbes on manually and mechanically cleaned device sets.

As phase one of the study demonstrated, the general perception among staff that hand-washed devices are not as safe to handle as machine-washed devices is well founded. The results also showed that wiping down devices with alcohol or other disinfecting agent may not be desirable. Many disinfecting agents, including alcohol, can affix protein to a surface.[4] Further, many of these agents may be incompatible with the devices on which they are being used. Medical device instructions for use rarely direct reprocessing staff to wipe down the device after cleaning with anything other than a dry, low-linting wipe. Finally, the act of wiping down a device with a disinfectant is in and of itself a manual process that may be less than optimal and may also involve handling the device with bare hands, depending on the policies and practices of the institution.

UV Disinfection

A technology that is rapidly making its way into general use in healthcare facilities is UV disinfection. The technology primarily is being used for whole-room disinfection but also is finding its way into other applications, such as disinfecting personal items (e.g., cell phones, tablets).[5,6] Could such technology be adapted to help render manually cleaned devices safer to handle? Specifically, if a UV disinfection cabinet was installed at the pass-through window and devices in the cabinet were subjected to a UV disinfection process, would the level of bioburden be reduced? UV disinfection is a "no touch" automated process and is compatible with a broad range of materials. As a result, UV disinfection could have advantages over wiping down devices with a disinfecting cloth.

UV Light

UV light is a small part of the electromagnetic spectrum made up of many other types of radiation, including visible light, X-rays, radio waves, and microwaves, all of which have different wavelengths. UV light is energy-rich light spanning a wavelength range of 100 to 400 nm. Different energy bands of UV radiation are distinguished by wavelength range, as follows: UV-A, 315–400 nm; UV-B, 280–315 nm; UV-C, 200–280 nm; vacuum UV, 100–200 nm.

UV radiation is used for disinfecting water and destroying harmful microorganisms in other liquids, on surfaces, and in air.

Mode of Germicidal Action

At the wavelength of 254 nm, UV-C breaks molecular bonds inside the DNA and RNA nucleic acids of microbial cells. With the nucleic acids damaged, microbes cannot reproduce and are rendered incapable of infecting.

A UV-C disinfector is positioned at the pass-through window, with doors in the front and at the back of the unit. The UV-C dosage at 254 nm is verified with a UV dosage indicator. Manually cleaned instruments are positioned in the chamber and the doors are closed. The UV light illuminates, and after the one-minute

cycle time, the medical device surfaces are sanitized, rendering the devices safer to handle on the clean side.

Test Procedure for UV-C Disinfection

The UV-C disinfection technology used in this study was a UV Flash (supplied by HealthGuard UVC, LLC, Pittsboro, NC; http://hguvc.com). After UV-C disinfection, the devices from both sets were wiped with sterile swabs on nutrient agar petri plates, under a laminar airflow hood, to get viable bacterial plate counts. The samples then were taken to the laboratory for incubation and CFU counts were analyzed.

Phase Two Test Results

Bacterial plate counts on both the manually and machine-cleaned medical devices following UV exposure were enumerated. As reported in the phase one results, the average CFU count on the surfaces of hand-washed devices pre-UV was 36.6. For phase two, following UV disinfection, the count decreased to 0.3 CFUs. Also reported in phase one, the average CFU count on the surfaces of machine-washed devices pre-UV was 9.2. For phase two, following UV disinfection, the count decreased to 0.1 CFUs (Figure 1).

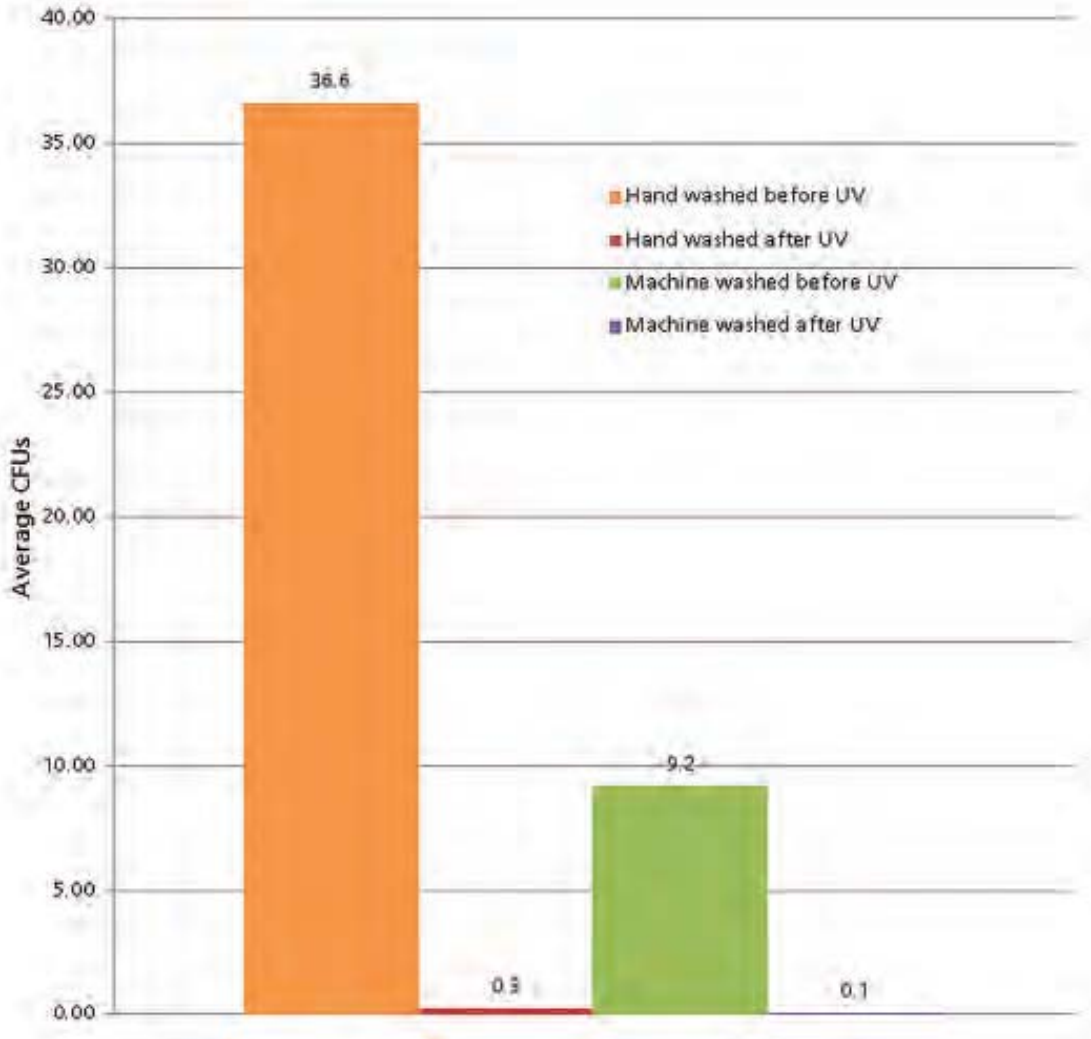

Figure 1. Average colony-forming units (CFUs), before and after ultraviolet (UV) disinfection, for the hand- and machine-washed medical devices tested

Conclusion

The goal of this study was to compare the microbial count difference in manually and mechanically cleaned medical devices. From the plate cultures, it was evident that hand-washed items harbored more bacteria than machine-washed items. The study also demonstrated that exposure to UV-C radiation resulted in a considerable decrease in bacterial count on the surfaces of medical devices, thus rendering them safer to handle. The overall findings demonstrate that placing a UV-C disinfector at the pass-through window offers an added level of safety for sterile processing personnel handling manually cleaned medical devices in sterile processing departments. ■

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