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Pitfalls of cleaning controls in ultrasonic washers



To the Editor:

Many published data underline the need to clean critical medical devices properly, and Evangelista et al have recently confirmed some of the pitfalls of using automatic washing.^{1,2} In particular, ultrasonic washing is highly variable in terms of residual protein levels on dental instruments and leads to an approximately 21% reduction in the average microbial load of gastrointestinal surgical instruments.^{1,2} We agree with the crucial warning from Evangelista et al: "The use of cleaning equipment and solutions must be appropriate, and their inadequate manipulation by users might affect the quality of cleaning, the possibility of relapse, and adverse events related to the use of processed products."¹

A subjective assessment of solution turbidity, the use of cleaning indicators, and the visual inspection of cleaned medical devices are the main means of checking the cleaning efficacy of validated automated washers indicated in the regulations for the decontamination of dental medical devices.^{3,4}

We here describe our experience of verifying the efficacy of the ultrasonic washers (UWs) and washer-disinfectors (WDs) in our dental offices. We used the Browne STF Load Check Indicator (Albert Browne International Ltd, Leicester, UK), which is claimed to be equivalent to the cleaning efficacy soil test and appropriate for checking both types of equipment in accordance with ISO/TS 15883-05-2005. Although its detailed composition is unknown, the lipid and polysaccharide protein-containing red glue

deposited on the polymer-structured thin film is not hazardous for dental workers or devices. Red glue product release in UWs is acceptable for subsequent medical device cleaning, whereas the aluminum particles released from damaged foil during the aluminum foil test (the reference test mainly used by UW manufacturers) are not.⁴

We first confirmed that the STF works properly in a Miele G7881 automatic WD (93°C, 10-minute cycle using Neodisher; Miele & Cie, Gutersloh, Denmark), but to our knowledge, there is only 1 article evaluating cleaning indicators in UWs.7 We therefore decided to use the STF to check the cleaning efficacy of a UW (Eurosonic 4D, 3,4L; Euronda, Montecchio Precalcino (VI) Italy), which works in sweep mode at the frequency of 32-35 kHz at a power of 100 W. After selecting a 10-minute cycle at 30°C to avoid the possible degradation of product components (mainly disinfectants and enzymes) and the precipitation of proteins on medical devices, the STF was inserted in its holder and placed vertically in the middle of the basket of the UW for all of the experiments. 3-5 All of the chosen products used (Metrizyme Kerr, Orange, CA; Enzymax Earth Hu-Friedy, Mfg. Co., Tuttlingen, DE; ID 212 Strong Durr, Orochemie gmbH+ Co., KG, Kornwesthein, Denmark; and Z1 Ultra Zhermack SpA, Badia Polesine, Italy) were declared to be compatible with UWs and were freshly prepared by diluting them with purified water as instructed by the manufacturers (used concentration: Metrizyme [1%]; Enzymax Earth [0,8%]; ID212 Strong [2%]; Z1 Ultra [1%]). A first cycle was run to achieve a temperature of 30°C and remove gas bubbles from all of the solutions and purified water (used as a negative control).

Under the same UW operating conditions, the STF gave the same results when using Enzymax Earth and Metrizyme: at the end of the cycles, there were no red residue on the film, and the presence of a red transparent liquid indicated complete red glue release by the enzymes and detergents in the products. However, ID 212 Strong and Z1 Ultra left unacceptable red residues (>2% of the soil) on the STF. The presence of a cloudy red solution (normally attributed to protein denaturation) indicated some drawbacks when the STF is used to check the cleaning efficacy of disinfectants based on quaternary ammonium compounds (QACs), whereas QAC solutions alone remain transparent. We think that the failure was caused by the strong alkaline pH (10-11) of ID 212 Strong and Z1 Ultra (Enzymax Earth and Metrizyme have an acid pH of 6-6.5) and increased adhesion of the red glue as a result of some of the product components. It is known that other cleaning indicators have more failures at 40°C than at 60°C in WDs, 6 but in UWs, 60°C impairs OACs (see the stringent temperature ranges indicated in the manufacturer's instructions),^{8,9} enzymes, and protein stability, therefore causing protein precipitation; in addition, at 60°C, occupational hazards caused by product evaporation cannot be excluded.

Our evidence suggests that care should be taken when using the STF in UWs (particularly in the presence of QAC disinfectants) and that the stability of the cleaning products (in relation to the number of UW cycles and loads), ¹⁰ which is not indicated by the manufacturers, should be borne in mind. We therefore agree with Evangelista's warning concerning the absolute need for strict guidelines and well-designed protocols based on clear information from manufacturers, appropriate solutions and test soils, and properly operating UWs.

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Conflicts of interest: None to report.

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Disinfection of personal protective equipment for management of Ebola patients



To the Editor:

Bessesen et al highlight the potential utility of reusable elastomeric face masks to bypass the risk of N95 respirator shortages during a respiratory illness pandemic and stress the importance of efficacious disinfection to reuse facial protective equipment safely.¹ We would like to take the opportunity to underline the need that awareness on personal protective equipment (PPE) stocks is included in any pandemic preparedness plan. The demand for PPE must be established on the basis of the health care facility's role, defined by public health authorities to create a coordinated network approach.²

Moreover, we agree that standard operating procedures (SOPs) should be developed to be used by health care workers (HCWs) to disinfect reusable PPE. In our recent experience with 2 Ebola cases at National Institute for Infectious Diseases "Lazzaro Spallanzani" in

Rome, Italy, we followed a written protocol for management of patients with Ebola virus disease (EVD), developed and updated since the beginning of the current West Africa outbreak.³ A voluntary clinical task force of infectious diseases specialists, intensivists, and nurses underwent rigorous training to became practiced and competent with the protocol and PPE donningdoffing discipline. PPE to be used was carefully selected according to international updated technical recommendations and lessons learned from previous experiences in endemic areas and western countries. The following 3 PPE options were selected: gogglesbased option (goggles, splash-proof fit-tested FFP3-N95 respirator, disposable hood [covering head, neck, and shoulders] with integrated surgical type IIR face mask (high filtration efficiency and spash resistance), double or triple layer of gloves, rubber boots, full body head-to-foot impermeable biohazard suit, plastic apron); face mask-based option (elastomeric face mask with disposable filters rather than goggles-N95 respirator-hood); and powered airpurifying respirator (PAPR)-based option (with a PAPR [composed of hood, motor unit, waist belt, and breathing tube to be put on the suit] rather than goggles-disposable hood). PAPR use was recommended in performing an aerosol-generating procedure and had always been used by intensivists providing critical care. Otherwise, the PAPR was used by HCWs expecting to spend long periods of time while caring for patients, according to a personal choice on safety and comfort. All of the PPE was disposable, except for the goggles, face masks, and PAPR components. We developed written SOPs for PPE disinfection whenever performed by a HCW under supervision of another member of the task force, who virtually was the next user. Similar to Bessesen at al, we used a 0.5% chlorine solution as the disinfectant, according to the World Health Organization's guidance for care of patients with EVD.⁴ Before exiting the isolation area, the HCWs in the removal area were sprayed with 0.5% chlorine solution by another HCW in full PPE, from the clean area, at a 1.5 m safe distance. Outer surfaces of goggles, elastomeric face masks (after removing and discarding filters), and PAPR hood and motor unit were disinfected with wipes dampened with 0.5% chlorine. Once doffed, goggles, face masks, and PAPR hood; breathing tube; and waist belt were immersed fully in 0.5% chlorine for a minimum of 30 minutes and were then thoroughly rinsed with water to remove irritating hypochlorite residues before reuse. No breaches in the disinfection SOPs were notified, and no transmission of Ebola virus occurred among HCWs caring for the 2 patients with EVD.

However, we noted some critical points in PAPR components disinfection. A large PPE removal area for drying of components is needed; during the PPE doffing, the detachment of each component takes time and needs good practice; throughout chlorine spraying, care should be taken to prevent liquid from entering the air outlet; and finally, the motor unit cannot be immersed in 0.5% chlorine solution.

We believe the safety concerns on PPE disinfection warrant further investigation, and public health officials, scientists, and clinicians fighting emerging infectious diseases should keep close collaboration with manufacturers to improve the response to present and future epidemics.

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