An evaluation of washer-disinfectors (WD) and dishwashers (DW) effectiveness in terms of processing dental instruments

Purpose: The aim of this study is to consider the effectiveness of a small sample of dishwashers (DW) compared to washer-disinfectors (WD) for cleaning dental instruments prior to sterilisation. Processing instruments in the context of this article means cleaning and disinfecting the instruments.

Materials and methods: A number of tests were carried out on three domestic dishwashers and two instrument washer-disinfectors. These tests included: visual test; soil test; residual protein test; and, the TVC of the final rinse water.

Results: The washer-disinfectors (one bench-top and one under-bench) passed all the tests. The results indicate that the instruments cleaned in the dishwashers were visibly clean and dishwashers passed the TOSI soil test. There was residual protein on some of the instruments cleaned in all of the dishwashers and the final rinse water did not comply with standard ISO 15883.¹

Conclusion: Dishwashers are not effective for cleaning instruments and they do not disinfect the instruments either. They cannot be validated and there is no record available outlining the parameters of the process. Dishwashers are not designed by manufacturers for processing dental instruments prior to sterilisation. The authors do not recommend the use of dishwashers in dental clinical practice.

Introduction

There is a clear preference in the dental literature for the use of washer-disinfectors over ultrasonic cleaners and hand washing (Dental Council 2005, HSE Code of Practice, HTM 01-05).²³ There has also been discussion in the BDJ concerning the effectiveness of washer-disinfectors (Kilcoyne 2009).⁴ It has been suggested that domestic dishwashers can clean instruments as well as washer-disinfectors. The rationale for this article is to assess the efficiency of dishwashers as compared with washer-disinfectors, as this is a topic of debate in dental circles both in Europe and US. There are few peer-reviewed articles comparing washer-disinfectors and dishwashers (that the authors can find). This is not surprising, as they are different pieces of equipment, which are manufactured for different purposes. A study, entitled ‘Can household dishwashers be used to disinfect
medical equipment’ (Ebner, et al.)⁵, claims that dishwasher processing is a suitable means of disinfecting medical equipment. However, in the study, they modified the machine to achieve a higher temperature for disinfection. The article does not state which wash cycle was used. There is much evidence of the general efficiency of washer-disinfectors from independent researchers, and they are recommended by the CDC and Department of Health (UK) for the cleaning of dental instruments.⁶

In this study, we tested: two washer-disinfectors, one bench top and one under counter type; and, three dishwashers. We examined the instruments that had been processed to see if they were ‘clean’ and we also examined the rinse water to see what the bacterial load was.

Materials and methods
In order to determine the cleaning efficacy of a washer-disinfector (WD) (Figure 1) and a domestic dishwasher (DW) (Figure 2), a number of tests were employed.

Types of test for benchmark comparisons
1. **Soil test:** OSI tests were used in all cycles tested. The test devices are smeared with dried blood or synthetic products that simulate blood, which is more difficult to clean than environmental dirt. (Figure 3) The instruments in the test cycles are also covered in another soil – Browne Test Soil for washer-disinfectors is the standard manufacture use for batch testing of instruments and determination of efficacy (“if not clean cannot be disinfected”). The instruments used were a mirror, probe, tweezers, artery forceps, hand piece, and metal ruler. A soil test is considered a pass if no soil remains visible on the test device. (Figure 4).
2. **Visual test:** The instruments were visually tested for soil using magnification under a microscope.
3. **Protein test:** Residual protein can be left on instruments⁷, which makes sterilising the instruments more difficult, as the protein stops the steam condensing on the instruments.
Biotrace Protect and Protein Test Kit (Protest Quick) were used to verify pass of the wash processes. This test measures the level of residual protein left on the instruments after cleaning and there must be no protein detectable for a pass in this test. This system tests for protein residue in accordance with EN ISO 15883. It is effective for testing any surface after cleaning and hard-to-clean surfaces on complex instruments. These surfaces will change colour from green to purple if protein is present on the sample.

4. The total number of micro-organisms (TVC per ml) in the rinse water was recorded:

The intensive cycle was tested on the Indesit dishwasher. The ECO cycle was tested on the Bosch dishwasher and the standard cycle was tested on the Beko.

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4. The total number of micro-organisms (TVC per ml) in the rinse water was recorded: The procedure to count the number of viable microorganisms was performed before and after the thermal disinfection in the washer-disinfectors. The level of non-compliance with standard ISO 15883 in the final rinse water during the final rinse cycle was also recorded for the domestic dishwasher.

Water samples testing

Water samples were obtained from draw-off points installed at convenient locations within the system for testing the water rinsing the dental instruments in washer-disinfectors (final rinse water). The dishwasher’s water was sampled directly during the final rinse. Standard sampling techniques were used for obtaining the water samples. Samples for TVC were tested within four hours of collection, having been stored at a temperature of two to five degrees.

As can be seen in Table 2, the washer-disinfectors cleaned the instruments and the water used for the final rinse was of good quality. All the dishwashers left protein on the instruments and the final rinse water did not conform to the standard. The air rotors were disinfected in the WDs, which all had lumen cleaners. We have tested these lumen cleaners and found that they were effective in disinfesting the air rotors and maintaining a good level of hygiene. The results of these tests can be seen in Table 2.
cleaners and found them to be effective at removing soil from the lumens. The dishwashers did not have lumen cleaners and, consequently, the lumens were not cleaned and disinfected before sterilisation. This clearly compromises the ability of the autoclave to sterilise the hand pieces.

This research shows that the results (for WDs) are in compliance with ISO and EN standards, but even though the domestic dishwasher did achieve some efficacy requirements (clean dishes), it fell drastically short of TVC pass requirements. The validation steps (Table 3) confirmed the high efficacy level of the medical washer-disinfector, but not the domestic dishwasher. Disinfection means the destruction of most viable microorganisms, except spores.

Discussion

Testing and validation

It is clear from our research that dishwashers do ‘clean’ debris off the instruments, but that the instruments are not free of microorganisms or protein. Further, air rotors and other lumen devices cannot be sterilised, as the lumens have not been cleaned. The present ‘Dental Council Code of Practice Relating to Infection Control in Dentistry’ says that hand pieces must be sterilised.

Failure to either clean or disinfect dental instruments can have serious consequences for dental patients and efficient cleaning is an essential part of the decontamination process. The independent monitoring system must record, totally independently of the control system, all parameters which are deemed to be critical to the successful outcome of the process (NHS Estates, Jatzwauk et al.)9,10 It is suggested that for a process to be parametrically controlled with full product-release capability, the following parameters are critical for an SDWD (small dental washer-disinfector).

Table 4: Process parameters of SDWD.

<table>
<thead>
<tr>
<th>Cleaning</th>
<th>Disinfection</th>
<th>Drying</th>
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</thead>
<tbody>
<tr>
<td>Water temperature</td>
<td>Water temperature</td>
<td>Air temperature</td>
</tr>
<tr>
<td>Water hardness</td>
<td>Water purity</td>
<td>Air quality</td>
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<tr>
<td>(conductivity)</td>
<td>(conductivity)</td>
<td></td>
</tr>
<tr>
<td>Water pressure</td>
<td>time</td>
<td>Air-flow rate</td>
</tr>
<tr>
<td>time</td>
<td></td>
<td>time</td>
</tr>
</tbody>
</table>

Additive(s) delivery time

whilst this table (Table 4) might appear lengthy, the list may be reduced. It is difficult to imagine a single sensor for air quality that may give useful information, so this may be omitted. Other parameters are repeated and judicious positioning of sensors may duplicate parameters. The final list may include:

- water temperature;
- water-flow rate;
- detergent delivery;
- additive-flow rate(s);
- air temperature;
- air-flow rate and;
- water pressure;
- water conductivity;
- time.

It is necessary to be able to apply the above tests to all equipment that is used to clean/disinfect dental instruments.
Testing requirements for proof of cleaning efficiency

1. Cleaning (consists of the manual or mechanical removal of soil deposited on an inert surface) - the cleaning efficacy test is to artificially soil a clean test load and visibly inspect for its removal at cycle end. This test is performed routinely.
2. Disinfection - is the disinfection part of the cycle adequate?
3. Drying - is the washer drying the instruments properly?
4. Non-contamination of environment - is the washer contaminating the environment?

Thus, if any test is omitted, it will reduce the ability of the dental clinic to demonstrate that it is making the instruments safe for patients and not endangering the well being of operators, or anyone in the vicinity of the washer-disinfector.

While there are routine microbiological tests to be performed, there is no current requirement for in-process biological monitoring, so the process is effectively monitored on a parametric basis. Clearly, the function of each re-processor must be first defined. It may clean and disinfect, or merely disinfect. In either case, the critical parameters need to be defined, controlled, and monitored in order for a full product release decision to be made. Such parameters may well include ongoing disinfectant efficacy/concentration and any relevant safety aspects.

Summary on choice between a domestic dishwasher and a medical device compliant washer-disinfector for dental applications

There are implications for all practitioners following the publication of EN15883 and MDD 93/42. These documents impact on manufacturers, purchasers, regulators, testers, users, and operators. Perhaps its greatest impact will be on the patient. Their safety and well being is dependent upon the awareness, understanding, and application of everyone involved in the decontamination of re-usable medical devices.

The recommendations of the German Robert Koch Institute (RKI) - "Hygiene requirements for reprocessing medical devices" for medical practices, and “Infection prevention in Dentistry” - establish the following categories of medical devices based on the Spaulding Classification:12

- non-critical medical devices that come into contact with intact skin;
- semi-critical medical devices: that come into contact with mucous membranes or pathologically-altered skin; and,
- critical medical devices: devices for use with blood, blood products, and other sterile drugs and medical devices that penetrate the skin of mucous membranes, and therefore come into contact with blood and sterile cavities.

What does all this mean?

The resulting differences in requirements with regard to the type and scope of reprocessing means it is necessary to assess the risks of the medical devices and categorise them. The aforementioned bullet points from RKI offer instructions on the correct categorisation. However, the person (dentist) responsible for the hygiene practice is responsible for which piece of medical equipment meets with the classification criteria.

Standard medical devices must be assessed with regard to the risk (dental washer classed as Class 11a medical device; domestic dish washer is CE marked, but not classified as medical device) and categorised before they can be used in a pre-defined washer cycle and re-used with patient treatment.

The dilemma

If a particular medical device cannot be clearly categorised into one of the risk groups (critical or non-critical), it should be assigned to a higher-risk class in the interests of safety and caution. With the domestic dishwasher, this is not an option. Then it is of particular note to apply the categorisation factor to the use of the washer. A process of validation is required - the domestic washer is not type-tested, or marked as a medical device, so it is incompatible with the re-processing of medical devices.

The solution

As well as ensuring compliance by purchasing a compliant medical device marked medical washer-disinfector with the EN ISO 15883-1-2 standards, another factor that should be taken into consideration when acquiring a washer-disinfector is whether the washer can be validated. The design of a domestic washer dishwasher, as opposed to a medical washer-disinfector, does not allow for process validation.

Critical parameters are:

- rinse temperature (<35°C);
- main was temperature (>45°C);
- detergent doses (>2ml/litre);
- efficacy of process (clean means free of proteins);
- disinfection (>90°C for one minute/Ao lethality > 600 seconds); and,
- final rinse water tested as sterile (<1.0 cfu/100ml).

Conclusion

Dishwashers do clean some instruments of soil, but do not clean lumens, and the rinse water is contaminated. They clean but do not disinfect instruments, as the final rinse is not at the correct temperature for this. Dishwashers are not designed as medical devices and cannot be validated. Dishwashers are not manufactured for the purpose of cleaning and disinfecting dental instruments before sterilisation. A washer-disinfector is manufactured for this purpose and
must comply with the relevant EU standard.\textsuperscript{2}

Other disadvantages include:

- cycle time - many dishwashers have an intensive cycle that can last two hours or so, compared to about an hour for WD. We used the intensive cycle in the testing of the Indesit dishwasher, which lasted about two hours;
- warranty - there will be warranty issues if the machine is used for non-household applications;
- poor hygiene - there is no steam condenser, and heat, humidity, and contaminated air escape into the room;
- discoloration and corrosion - commercially available detergents contain chemicals that are not compatible with medical/dental instruments, i.e., bleach; and,
- temperature - dishwashers operate at around 60°C maximum temperature, and do not have a disinfection phase. They also do not have a low temperature pre-rinse, and so protein coagulation may occur. Washer-disinfectors have a pre-wash at a temperature below 35°C, which removes soil and prevents proteins coagulating.

Importantly, washer-disinfectors on the other hand are medical devices, designed to clean medical and dental instruments and to achieve a high level of disinfection. Our small study clearly demonstrates that dishwashers do not ‘clean’ instruments. The definition of clean is: “The removal of contamination from an item to the extent necessary for its further processing and intended use” (EN 15883). This means that some instruments cannot be sterilised, as they are not clean as defined in the standard. We only tested a small number of dishwashers and washer-disinfectors in this study. We would recommend further research in this area.

References

1. EN ISO 15883-1-2009. Washer-disinfectors part one: General requirements, terms and definitions and tests.
3. Health Service Executive Standards and Recommended Practices for Dental Services in a Local Decontamination Unit (LDU) 2012.
11. Medical Devices Directive, 93/42/EEC.