Assessing the efficacy and cost of detergents used in a primary care automated washer disinfector

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Key points

Provides an evidence base for the cleaning efficacy for a washer disinfector used in general dental practice.	Provides an evidence base that cheaper detergents can be as effective as more expensive detergent options used in general dental practice.	Sets out estimated cost savings using cheaper detergents and shorter wash cycle times without compromising patient safety.

Background Cleaning of re-usable medical devices is a critical control point in the decontamination cycle, although defined end-points of the process are controversial. **Objective** Investigate cleaning efficacy and cost of different detergent classes in an automated washer disinfector (AWD) designed for dental practice. **Methods** Loads comprised test soiled dental hand instruments in cassettes and extraction forceps. Residual protein assayed using the International standard method (ISO 15883-5:2005) 1% SDS elution with ortho-phthalaldehyde (OPA) or GBox technology (on instrument OPA analysis). Short (60 minutes) and long (97 minutes) AWD cycles were used with four different classes of detergents, tap water and reverse osmosis water. **Results** SDS elution analysis (N = 612 instruments) demonstrated four detergents with both wash cycles achieved equivalent cleanliness levels and below a threshold of 200 μg protein/instrument. GBox methodology (N = 575) using UK Department of Health threshold of 5 μg/instrument side demonstrated that tap water performed with the greatest efficacy for all types of instruments and cycle types. **Conclusions** Using International standard methodology, different detergent classes had equivalence in cleaning efficacy. Cheaper detergents used in this study performed with similar efficacy to more expensive solutions. Findings emphasise the importance of validating the detergent (type and concentration) for each AWD.

Introduction

Following a national review in Scotland of the decontamination of instruments in general dental practice[1,2] a number of recommendations were made which included policies to replace manual cleaning of instruments with automated processes in the form of 'benchtop' automated washer disinfectors (AWDs).[3,4] AWDs are subject to a number of phased qualification processes (specification, installation, operational and performance) before use[5-8] and can clean dental instruments more effectively than manual and ultrasonic cleaning.[9] A test programme for AWDs is necessary to ensure that the critical control factors during the cleaning process are optimised to remove soiling from instruments.[10–12] The role of the process chemicals have come under closer scrutiny with some evidence to suggest significant variations in efficacy.[13–18]

Cleaning efficacy is a complex process and is influenced by many variables including detergent chemistry, water quality, temperature, time and mechanical action. Investigations on the efficacy of detergents in the context of medical device cleaning and using an in-vitro model, workers[17] found that some agents significantly underperformed when compared to tap water. Other workers[13,18] have demonstrated enzymatic-based detergents to be more efficacious at removing protein from medical devices. The aim of this study was to determine the cleaning efficacy of different detergents and length of cycle using one model of washer disinfector designed for cleaning dental instruments and whether detergent cleaning efficacy were related to cost of detergent.

Materials and methods

AWD

We used the W&H ThermoKlenz (serial number 1215,333), which at the time of the study was on the National Services Scotland Procurement collaborative purchasing scheme. This was loaned to the department by W&H UK ltd. The AWD was set-up according to manufacturer's instructions and commissioned by a Health Facilities Scotland (HFS) engineer.[7]

AWD cycles used

The ThermoKlenz AWD is supplied with three cycles. The two cycles that were investigated in this study were the 'short' (P1) cycle (detergent 48 ml; total cycle time = 60 minutes (pre-wash: 3 minutes at 28 °C, main wash: 3 minutes at 63 °C, rinse 1: 3 minutes at 40 °C, disinfection: 1 minute at 90 °C and drying for 5 minutes; remaining time taken up by heat-up, filling and draining)) and the 'long' (P3 – intensive) cycle (detergent 60 ml; total cycle time = 97

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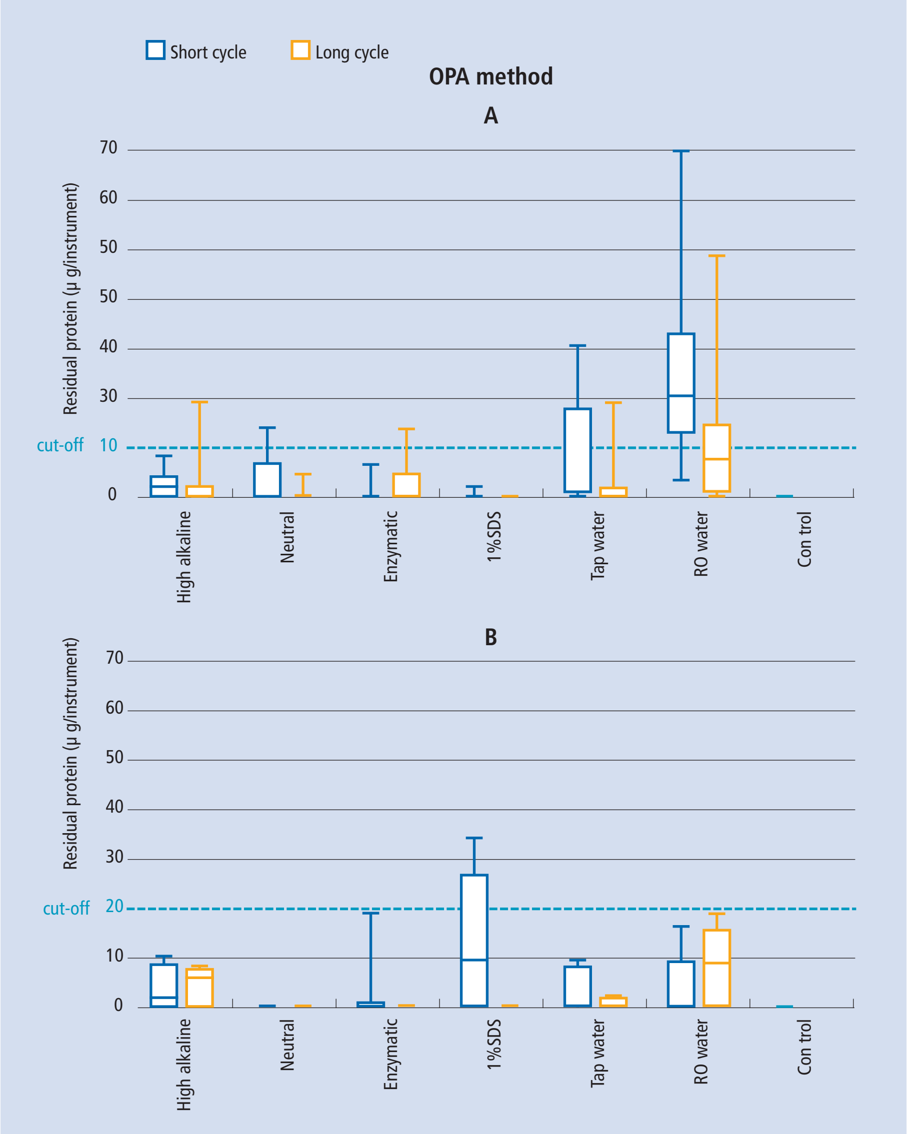
Fig. 1 Detection of amines in (A) 5 ml eluates of small instruments and (B) 10 ml eluates of large instruments that were soiled prior to washing with (blue box and whisker plots) the short cycle or (red box and whisker plots) the long cycle



minutes (pre-wash: 5 minutes at 28 °C, main wash: 10 minutes at 63 °C, rinse 1: 3 minutes at 40 °C, rinse 2: 3 minutes at 40 °C disinfection: 1 minute at 90 °C and drying for 20 minutes; remaining time taken up by heat-up, filling and draining)). Each cycle uses 24 litres of water. The long cycle is recommended by HFS for AWDs used in dental practice in Scotland for its longer drying cycle. The P2 cycle was not tested as we wished to investigate the maximum and minimum wash parameters.

Analysis of residual protein

This follows the methodology outlined in ISO 15883-5:2005[10–12] using ortho-phthalaldehyde (OPA) which was also used in previous investigations for residual protein on dental instruments.[9] Briefly, OPA is a sensitive fluorescent reagent that reacts with primary amines present in proteins, the OPA bound to proteins can then be detected and quantitated in a fluorimeter. Instruments were placed in plastic press lock bags containing either 5 ml (hand instruments) or 10 ml (extraction forceps) of 1% sodium dodecyl sulphate (SDS) and agitated for 30 minutes, 20 µl aliquots were analysed in duplicate using the OPA reagent. This is referred to as an 'off-instrument' assay. The OPA method has a lower limit of detection (LOD) of 2 µg/ml according to a bovine serum albumin (BSA) standard curve prepared in 1% SDS, which is equivalent to 10 (hand instruments) or 20 µg/instrument (forceps) due to elution volume used. The threshold for defining clean instruments in the International standard ISO 15883-5:2005 can be deduced as 200 µg/instrument. Additional sets of instruments from the same washer run were analysed using GBox technology (GBox EF2 with ProReveal software, Synoptics Ltd, Cambridge) processed according to manufacturer's instructions. A frequent criticism of the OPA ISO standard is that it is dependent on the efficiency of the SDS extraction stage to elute protein from instruments, this may give an incomplete picture of protein contamination if proteins are not eluted by the SDS. The GBox technology avoids this potential error by visualisation and quantitation of residual proteins that fluoresce following exposure to OPA sprayed onto the instrument surface. The threshold for cleanliness using the GBox technology was set at 5 µg/instrument side as recently reported by the Department of Health, UK.[19] This is referred to as an 'on-instrument' assay.

Positive controls comprised soiled instruments from each batch that had not been washed. Negative controls comprised instruments that had been through the enhanced wash comprising (washer disinfector P3 cycle) plus 1% Decon 90 for a minimum of 2 hours and rinsing in reverse osmosis water.

Detergents tested

Four detergents representing the major classes of detergents used in AWDs were selected; High alkaline (pH 12–14: Dolby pH plus, Dolby Medical Ltd, Stirling, Scotland, UK), neutral (pH 7: Phoenix, Serchem Ltd, Telford, Shropshire, UK), 1% Sodium Dodecyl Sulphate (pH 9–10, Fisher Scientific, Bishop Meadow Rd, Loughborough, UK) and enzymatic (pH 8 when diluted according to manufacturer's instructions: Prolystica, Steris Ltd, Leicester, UK) were tested in the two different AWD cycles (short and long). In addition, we replaced detergent solutions with reverse osmosis (RO) water (conductivity <10 µS) and tap (mains) water (conductivity 60 µS) to investigate the cleaning efficacy of different water qualities and the impact of the absence of detergent.

Test load and soiling

Each cycle contained at least 24 dental instruments, divided into instrument cassettes and extraction forceps. Each cassette (Nichrominox, 18 rue des Frères Lumière, Saint-Bonnet-de-Mure, France) contained a set of dental hand instruments: tweezers, angle chisels, scalers, mirrors and straight chisels (chisels used as readily available examples of 'straight' instruments in our laboratory). Each cassette contained a duplicate instrument for analysis

Table 1 Cost per cycle for detergent and electricity consumption short (P1) cycle and long (P3) cycle

Detergent	Detergent cost/ P1 cycle (£)	Detergent cost/ P3 cycle (£)	Electricity cost/ P1 cycle (£)	Electricity cost/ P3 cycle (£)	Total cycle cost P1 (£)	Total cycle cost P3 (£)
High alkaline	0.24	0.3	0.21	0.43	0.45	0.73
Neutral	0.11	0.14	0.21	0.43	0.32	0.57
1% SDS	0.28	0.35	0.21	0.43	0.49	0.78
Enzymatic	0.3	0.38	0.21	0.43	0.51	0.81

by each method; each load contained three trays and six extraction forceps. Instruments were contaminated with Edinburgh test soil using a small paintbrush and left to dry for 30-60 minutes as described in the standard.[12] Following analysis instruments were cleaned by rinsing with tap water twice, submerging in 1% Decon 90 for a minimum of two hours and rinsing with tap water and air drying. Each detergent/cycle combination was performed in triplicate. Between different detergents, several cycles were performed with tap water only to ensure the piping was free of residual detergent.

Cost per cycle

Costing for mains water and RO water have been excluded from estimates as this will depend on supply arrangements for tap water and capital/revenue costs for the model of RO unit used, (estimates for a typical unit used in dental practice in Scotland range from £0.14–£0.20 per litre of RO water produced). The costing also excludes the maintenance and testing costs of the AWD.

Detergent costs

Cost per cycle was calculated for short (volume 48 ml) and long cycles (volume 60 ml), based on the manufacturers' quoted cost and volume used per cycle at the time of the study.

Electricity consumption and costs

An electricity meter (Plug-in Power and Energy Monitor, Energenie, UK) was used to monitor average kWh per cycle. The UK average cost per kWh, used to calculate electricity cost per cycle, was taken from http://www.sust-it.net/energy-calculator.php?tariff=38 at the time of the study (October 2016).

Statistical analysis

Statistical analysis was performed using Excel (Microsoft) SPSS V 21 (IBM). A Q–Q plot analysis indicated that the protein measurements did not conform to a normal distribution and were analysed principally by Mann-Whitney U–tests. Since there were fewer forceps available for comparison the data underwent natural log transformation and t-tests were employed. Statistical significance was set at $p < 0.05$.

For instruments assayed using the GBox methodology a further analysis using a cut-off value 5 µg/instrument side limit.[19] Straight hand instruments in trays under each cleaning condition (for example, high alkaline/short cycle) were compared with the cut-off using a one-tailed one-sample Wilcoxon test (alpha = 0.10). All conditions that were not significantly greater than the cut-off were considered 'clean'. Forceps under each cleaning condition (for example, high alkaline/short cycle) were compared with the cut-off using a one tailed one-sample t-test.

Results

A total of 1,187 instruments were analysed. Of which 612 were assessed using the OPA method and 575 instruments were analysed using the GBox method. Dental hand instruments in cassettes and extraction forceps exposed to all detergent/solution and cycle combinations were assessed against the positive control, which showed that all instruments in all cycles were significantly lower than the positive controls after both OPA and GBox analysis (data not shown).

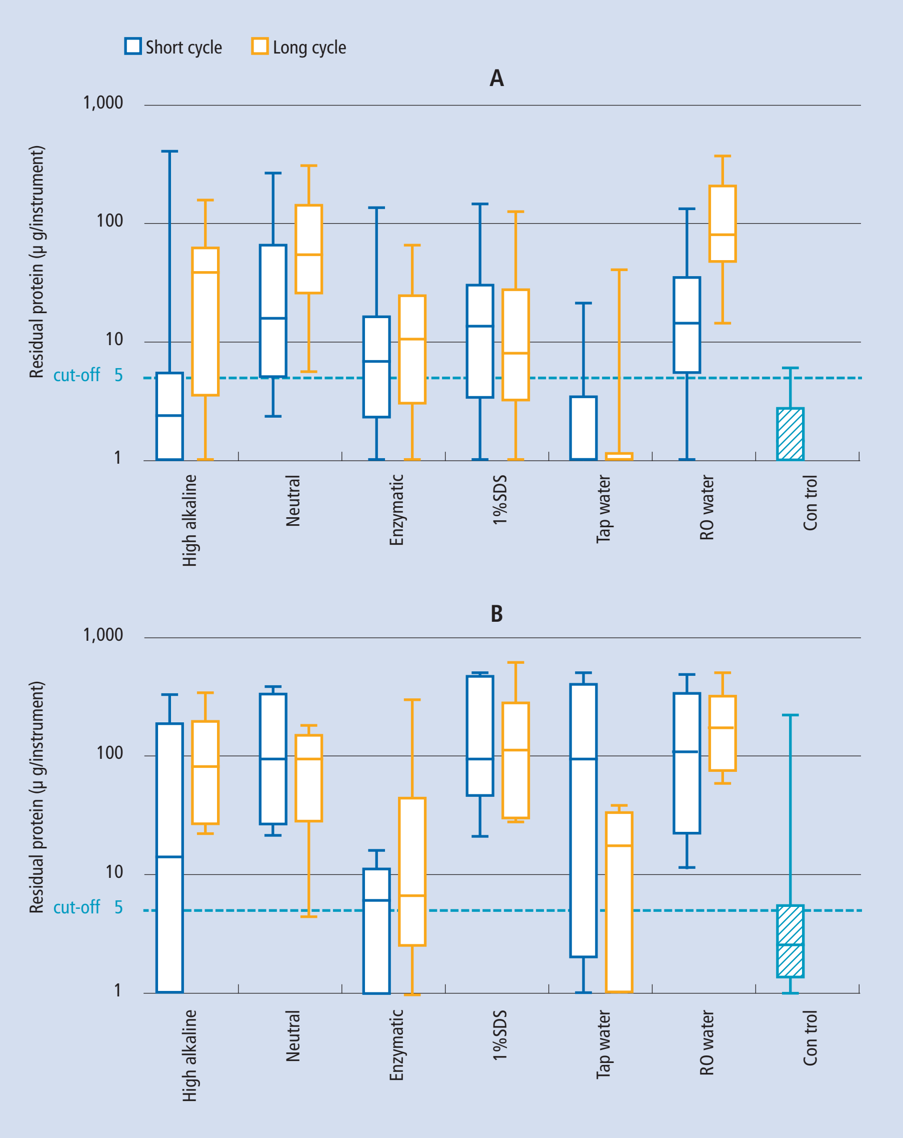
Analysis of results using the OPA 'off-instrument' analysis method are summarised in Figure 1a and 1b (data used to derive the figures can be found in the online only supplementary Tables 1–4). Use of the International standard cleanliness threshold for SDS extraction and OPA analysis (200 µg protein per instrument) all solutions cleaned the dental hand instruments and forceps in either short or long cycles. If a lower threshold of cleanliness were used, that is the limit of detection (under conditions used in this study) for the International Standard assay then in both short and long cycles analysed against a cut-off value of <10 µg protein per instrument, RO water alone in the short cycle was the only parameter with significantly higher residual protein than <10 µg per instrument ($p < 0.001$). Data for cleaning forceps exposed to the different detergents/cycles were analysed against a higher limit of detection (<20 µg protein per instrument due to larger volumes used for extraction), which showed no significant difference between all solutions tested.

Analysis of results using the GBox 'on-instrument' methodology are summarised in Figures 2a and 2b (data used to derive the figures can be found in the online only supplementary Tables 5–8). The short cycle with neutral detergent, 1% SDS, RO water and enzymatic detergent demonstrated significantly higher levels of residual protein than the <5 µg per instrument side cut-off value ($p < 0.001$, 0.012, < 0.001 and 0.008 respectively). The high alkaline detergent and tap water demonstrated equivalence for cleaning hand instruments and forceps. Extraction forceps post cleaning protein levels showed that in the short cycle with neutral detergent, 1% SDS and RO water were significantly higher than 5 µg/instrument ($p = 0.015$, 0.029 and 0.015, respectively). Using the long cycle and high alkaline, neutral, enzymatic and 1% SDS detergent together with RO water showed significantly higher levels of residual protein compared to the 5 µg/instrument cut-off ($p < 0.001$, < 0.001, 0.030, < 0.001 and < 0.001 respectively). Use of enzymatic detergent and tap water only were the best performing agents when using the long cycle.

Estimated cost per cycle

Costs of detergent/solution per litre as well as cost per cycle were calculated for high alkaline, neutral, 1% SDS and enzymatic detergents. The average cycle time and electricity used per cycle for P1 (60 minutes and 1.397 kWh) and long programmes (97 minutes and 1.719 kWh – mean of triplicate runs) are summarised in Table 1. The cheapest cycle/detergent combination was a short cycle with neutral detergent and most expensive combination was a long cycle with enzymatic detergent.

Fig. 2 Detection of amines on (A) the surface of small instruments and (B) the surface of large instruments that were soiled prior to washing with (blue box and whisker plots) the short cycle or (red box and whisker plots) the long cycle. Negative controls (blur hatched box and whisker plots) consist of unsoiled small and large instruments



Discussion

With reference to the current International Standard we demonstrate that under the conditions of this study, multiple solutions can achieve current cleanliness thresholds and cheaper detergents can perform as effectively as more expensive counterparts. Alternative cleaning end-points such as 100 μg protein per instrument have been suggested by other groups,[20] in which case use of the SDS elution method and any cycle cleaning condition would produce clean instruments. The pre-cleaning soil levels used in this study were quantitatively a larger challenge to remove than those usually encountered in dental practice[9] for example, extraction forceps pre-cleaning protein levels were 462 μg protein per instrument[9] compared to 3,002 μg protein per instrument used in this study and provides a useful safety margin.

The different assay methods used revealed a contrasting pattern with fewer detergent classes achieving the cleaning cut-off value when using GBox technology. For all assays using the GBox method a wider range of values was recorded and higher negative control background levels, which probably reflects the increased sensitivity of this assay, an 'on-instrument' method of analysis and the surface topography (multiple grooves and gnarls) of instruments assayed. Unexpectedly the longer cycles failed to achieve increases in cleaning efficacy and in some instances, performance was adversely affected. The reason for this finding is unclear. Inconsistent findings when using AWDs and detergent combinations have been reported by other users[16] using different methods of cleanliness assessment for example, thermostable adenylate kinase measurement.

Although a limited number of detergents were tested in this study, they did include a representative of common classes. An earlier study based in dental practice[9] reported results from a smaller AWD (Pico, Medisafe) and an enzymatic detergent (3E-zyme), although insufficient data was available to assess commissioning and validation procedures for these machines. Residual protein levels assayed using an SDS elution and OPA analysis found scalers with a median median of 1.4 μg per instrument after AWD cleaning in a dental practice setting[9] similar to the findings in this report. However, the AWD and all detergent/cycle combinations used in this report achieved lower median protein levels in SDS eluates for forceps at <20 μg per instrument compared to the value reported in the dental practice study (27 μg per instrument).[9]

Limitations of this study are the relatively small number of detergents tested, other groups[16] have reported good cleaning efficacy (defined by removal of a surrogate marker thermostable adenylate kinase) by a range of solutions including anti-prion chemicals. We were also limited to the use of the one AWD and performance may vary between machines of the same model. In addition, these results must be interpreted in the context of the set-up of the other parameters determining cleaning efficacy in an AWD, for example, spray patterns, pump pressure, loading patterns and water quality (hardness concentrations interfering with detergent action). Therefore, results described in this study only apply to this machine, setup and water quality.

In terms of cost per cycle, using the OPA (off-instrument) results there is equivalent efficacy between detergent classes and cycle types, suggesting that economies could be made using cheaper detergent and shorter cycle times without compromising instrument cleanliness and patient safety.

In conclusion, we have confirmed and extended previous work on AWDs designed for dental practice by providing quantitative data using two different approaches to residual protein detection on cleaned instruments and placed these in the context of current guidance for cleaning efficacy. This study has also demonstrated that when AWDs are commissioned according to current guidelines and loaded appropriately then difficult to clean instruments such as extraction forceps can be effectively cleaned. This study also suggests that a benchmark for determining efficacy of cleaning chemistries would help practitioners make an evidence-based economic decision when purchasing AWD/detergent combinations. However, as instrument cleaning outcome is determined by multiple factors that vary between machines, wash cycles and the type/concentration of detergent these must be validated for each AWD. It is vital that these issues are taken into account when purchasing.

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