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Double manual versus automated cleaning of loaner depth gauges used in clinical practice

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Abstract

***Background*:** Automated cleaning is recommended for reprocessing complex design surgical instruments, as it is reproducible and cleaning parameters can be controlled. However, automated equipment may not be a reality for many hospitals, particularly in lower-middle income countries.
***Objective*:** The aim of this study was to compare the effectiveness of double manual cleaning and automated cleaning of depth gauges in use in clinical practice and supplied in a loaner system.
***Design*:** Twenty four depth gauges available for use in a loaner system were evaluated before double manual cleaning (Group 1) or immediately after double manual cleaning (Group 2), or automated thermal disinfector cleaning (Group 3) or automated ultrasonic cleaning (Group 4). Thereafter, the depth gauges in each group were analysed by visual inspection (n = 24), bacterial culture (n = 12), and adenosine triphosphate (ATP) test (n = 12).
***Results*:** Stains, grooves, oxidation or visible debris were detected on at least one of the depth gauges from each group, and most were positive for bacterial growth (n = 11/12). Cleaning methods significantly reduced the amount of ATP ($P < 0.05$), except for automated ultrasonic cleaning.
***Conclusions*:** Double manual cleaning of depth gauges was similar to automated cleaning in a thermal disinfector, suggesting the possibility for implementing double manual cleaning as an alternative in sterilising service units where automated cleaning equipment is not avaliable.

Keywords: *surgical instruments; equipment reuse; disinfection; sterilisation; biofilm; adenosine triphosphate; Brazil*

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Acquisition of surgical instruments through a loaner system is a practice adopted worldwide. Despite the advantages, such as lower cost, the practice has brought challenges to the reprocessing of surgical instruments due to various factors, including the complex design of some depth gauges (DGs) (1). Depth gauges are orthopaedic surgical instruments used to measure the size of the implant (screw) to be used during the surgery. There are some DGs that can be disassembled into three pieces, and two of these pieces have narrow lumens (< 5 mm).

For complex design surgical instruments, manual cleaning must be complemented by automated cleaning using equipment with proven efficiency (2). However, this is not the practice in some hospitals – particularly those located in low or middle-income countries where only manual cleaning is perfomed. Considering that double cleaning surfaces to remove *Clostridioides difficile* spores is shown to be more effective than simple/single cleaning (3), this study aimed to compare the effectiveness of double manual cleaning (DMC) and automated cleaning (by ultrasonic or thermal disinfector) of DGs.

Methods

A total of 24 DGs in clinical use were randomly collected from a loaner company in the midwest region of Brazil that supplied surgical trays for various hospitals. The DGs were assigned into four groups:

- Group 1 - Control (assessed before cleaning) (n = 6)
- Group 2 - Subjected to DMC (n = 6)
- Group 3 - Subjected to automated cleaning by thermal disinfector (ACT) (n = 6)
- Group 4 - Subjected to automated cleaning by ultrasonic washer (ACU) (n = 6)

The reprocessing of DGs was performed at the sterilising service units of hospitals – one general and the other for emergency – as follows:

Group 2 (DMC): disassembled, immersed in enzymatic detergent (Tecpon Clean; Tecpon, Cachoeirinha, Brazil), brushed (specific size for lumen), and dried (air gun for the lumen). This process was performed twice.

Group 3 (ACT): disassembled and subjected to single manual cleaning as described for Group 2, subjected to ACT (Ortosíntese, Jaraguá, São Paulo, Brazil) with a cycle of: pre-cleaning, cleaning, rinsing and drying, then dried (air gun for lumen).

Group 4 (ACU): disassembled, subjected to single manual cleaning as described for Group 2, subjected to ACU (SW3000 WJ; Sanders, Santa Rita do Sapucaí, Brazil) with heating to 35 °C, and dried (air gun for lumen).

Following the cleaning treatment, DGs from the Groups 2–4 were packed in sterilised surgical grade paper. Group 1 DGs were transported from the supplier company directly to the microbiology laboratory. Visual inspection was performed on all DGs (n = 24) with the aid of a ten-fold image amplification lens (Magnifying Table Lamp LT-86D, China).

Three DGs from each group were transferred to tryptic soy broth (TSB) tubes, individually subjected to sonication for 10 min (USC-1400 A, Unique, Brazil), and the TSB was transferred to another test tube, and incubated at 35 °C/48 h. Bacteria were isolated (10 µL) on brain heart infusion agar, incubated at 35 °C/24 h, and colonies were evaluated macroscopically (size, shape, odour and consistency) and microscopically (Gram stain).

Clean-Trace™ Surface ATP Test Swab (3 M, Sumaré, Brazil) was used to collect samples from the final part of the stem, the body and the lumen (back and forth movements across the lumen) of the same DG (same moistened swab for each sample). Test reading was performed in a luminometer (Clean-Trace™ NG Luminometer LX25, 3M, Sumaré, Brazil), measured in relative light units (RLU).

All tests were performed in a biological safety cabinet (Pachane, Paracicaba, Brazil), and handled with surgical gloves. ATP test results were analysed using the R programming language (R Core Team, version 4.0.3, 2020, R Foundation, Austria). Kruskal-Wallis test was used to assess whether there was a difference between the cleaning groups, and Dunn's pairwise comparison test was used to verify which groups presented a statistically significant difference.

Results

Grooves (n = 5/24) and oxidation (n = 5/24) were the most common surface damage found on the DGs (Table 1).

Bacterial growth was detected on 11/12 DGs subjected to culture, except for one DG from Group 2 (DMC). A total of 15 different bacteria were isolated: Gram-positive cocci (n = 8), Gram-positive bacilli (n = 4) and Gram-negative rods (n = 3). Four DGs had two different bacteria isolated.

The average RLUs detected were 1712.33 (range: 788–2220 RLU; standard deviation [SD] 801.7) before cleaning, 33 (range: 25–46 RLU; standard deviation 11.3) after ACU, 18.33 (range: 14–24 RLU; SD 5.1) following DMC, and 15.67 (range 11–23 RLU; SD 6.4) after ACT. Automated cleaning by ultrasonic-washer did not significantly reduce the amount of ATP compared to the control group (Table 2). There was no statistically significant difference in ATP level between DMC and the two automated methods evaluated, but cleaning in a thermal disinfector was superior to ultrasonic cleaning (Table 2).

Discussion

Surface damage of reusable medical devices evidenced in this study may favour accumulation of debris and

Table 2. Comparison of the amount of adenosine triphosphate on loaner depth gauges before and after different manual and automated cleaning methods

Groups	*P*-value
BC vs. ACT	0.0023
BC vs. ACU	0.1541
BC vs. DMC	0.0118
ACT vs. ACU	0.0256
ACT vs. DMC	0.6841
ACU vs. DMC	0.1516

BC = Before cleaning; DMC = Double manual cleaning; ACT= Automated cleaning thermal disinfector; ACU = Automated cleaning ultrasonic-washer

Table 1. Surface damage found on loaner depth gauges by visual inspection before and after different manual and automated cleaning methods

Variables	Before cleaning (Group 1)	Double manual cleaning (Group 2)	Automated cleaning by thermal disinfector (Group 3)	Automated cleaning by ultrasonic washer (Group 4)
Visible debris	-	-	-	1/6
Stain	1/6	-	-	-
Grooves	1/6	2/6	1/6	1/6
Oxidation	1/6	3/6	1/6	-

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microorganisms, which makes cleaning more difficult. Although not ideal, visual inspection is highlighted as an initial stage of 'screening' of cleaning quality, as well as evaluating the integrity and functionality of reusable medical devices in the absence of well-defined criteria to determine a safe useful life of these devices (4).

Most devices cultured in this study were positive for bacterial growth (n = 11/12), which reinforces the premise to carry out the disinfection or sterilisation of reusable medical devices immediately after cleaning steps to avoid an increase in microbial load, as evidenced by Trindade et al (5).

Inadequate cleaning performed by healthcare services after using loaner medical devices and before returning them to the supplier company is highlighted by studies finding blood on loaner surgical instruments delivered by the supplier to healthcare services in the USA (6) and Brazil (7). The combination of debris and microorganisms on these devices during the storage period at the loaner company may favour biofilm formation (7).

The amount of ATP on the samples subjected to DMC and ACT was significantly reduced compared to the control group. A similar result was reported in a previous study (8). All cleaning methods reduced the amount of ATP to levels below the recommended cut-off point (<100 RLU) (9). The ATP results of the samples subjected to ultrasonic cleaning were not statistically different from the control group, which may be related to such factors as water quality and prior qualification of the equipment, which were not possible to control in this study and deserve further investigation.

A study that evaluated the amount of protein and bacterial colony forming units on haemostatic forceps contaminated with biofilm showed similiar efficacy of DMC plus brushing the hinged area compared to automated cleaning (10).

This study has a limitation related to the sample size, resulting from the intention of evaluating depth gauges that were in clinical use and available from the loaner company, which depended on the surgical instruments availability at the company. Results may also not be generalisable to other surgical instruments. The impact of these different reprocessing methods on the risk of surgical site infections was not assessed.

Conclusions

In conclusion, the equivalence of the effectiveness of DMC compared to automated methods points to DMC as an alternative in scenarios where there is no structure available to allow automated cleaning. However, the costs associated with DMC should be taken into account.

Ethical approval

The research project was approved in Brazil by Ethics Committee of the Hospital das Clínicas of the Federal University of Goias (reference number: 585.558).

Conflict of interest and funding

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