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Schlüsselwörter
- multicentre trial
- manual cleaning
- ultrasound
- cleaning results

Multicentre Trial on Testing Cleaning in the Practical Situation with and without Ultrasound

W. Michels[1], K. Roth[2]

After working on the guideline for validation and routine monitoring of automatic cleaning and thermal disinfection processes, a group consisting of members of the German Society for Hospital Hygiene (DGKH), the German Society for Sterile Supply (DGSV) and the Working Group Instrument Reprocessing (AKI) has now turned its attention to manual cleaning and disinfection. In the frame of this study we conducted a multicentre trial to test and evaluate the manual cleaning quality attained by ten hospitals. Here Crile clamps soiled in a defined way, were cleaned and disinfected manually, according to the local working instructions, partially with the support of ultrasound cleaning appliances. Those participants who made use of ultrasound attained cleaning results where residual protein quantities were less than 100 µg per instrument for all clamps. Manual reprocessing without the use of ultrasound cannot lead to appropriately safe cleaning results for instruments with fissures or joints.

Introduction

Having dealt with the validation of automated processes (1), the DGKH, DGSV and AKI societies have now turned their attention to manual cleaning and disinfection, using the framework of their previous guideline work. J. Gebel et al. have already reported on results from preliminary tests on this subject applying so called cleaning active disinfectants , as well as tests with real instruments (2). Here, analogously to the testing of cleaning for automated processes, Crile clamps were contaminated in the joint area with blood, to which a 10% microbial suspension of *Enterococcus faecium* had been added, and placed in a solution of cleaning disinfectant listed by the VAH (Association for Applied Hygiene). Neutralisation and recovery of remaining test microbes via intensive elution supported by ultrasound was followed by cell culture. Microbial reduction was poor, falling far short of the required reduction of log 5. Pre-cleaning can improve chemical disinfection in an immersion bath. However additional measures are necessary, for example improving wetting in the joint by opening and closing the instrument when placing it into the disinfectant solution (3).

The responsibility for quality-assured reprocessing of medical products for medical institutions ensues from the legal and normative requirements (3, 4). This also applies to established medical surgeries/centres and ambulatory operating facilities, where instrument reprocessing still takes place manually to a substantial extent. When looking at the reuse of reprocessed medical devices, the question is whether an appropriate cleaning quality is attained and thus also whether safety of disinfection and sterilisation can be ensured. Concrete requirements for cleaning performance of automated processes are stated in the guideline published by the DGKH, DGSV and AKI, and minimum performance is tested using Crile clamps soiled in a defined way in the joint area. The applicability and practicality of the method for automated processes was proven previously in the course of a multicentre trial (6). The requirement of ≤ 100 µg residual protein per instrument is generally fulfilled these days by the tested automated washer-disinfector processes. For manual cleaning and disinfection, the same quality of results should be attained or should be possible to attain. Therefore it seemed relevant to conduct another multicentre trial to test what results could be achieved for manual instrument cleaning in everyday pratice, and which methods were successful.

Implementation of the Multicentre Trial

Nine heads of CSSDs were willing to participate in the multicentre trial. Each participant received 20 Crile clamps by post. These had been soiled, dried and vacuum packed, according to the guideline of the DGKH, DGSV and AKI. In each CSSD one member of staff chosen by the manager was to carry out manual cleaning and disinfection according to the respective working instructions. The operators observed that an arterial clamp would not usually be cleaned manually in CSSDs, but would be subjected to automated cleaning and disinfection according to the guideline of the Robert Koch Institute for critical B medical devices, so it was necessary to explain our intention of comparing the manual cleaning to automated processes.

Because all CSSDs generally carry out reprocessing with the help of ultrasound, three CSSD leaders were asked to work

1 Miele Professional, Carl-Miele-Strasse 29, 33332 Gütersloh, Germany. E-mail: winfried.michels@miele.de
2 SMP GmbH, Prüfen Validieren Forschen, Hechinger Strasse 262, 72072 Tübingen, Germany

Participant	1	2	3		4	5	6	7	8	9	10	
			a	b							a	b
Pre-rinse or cleaning	'rinse' 10 sec.	n. s.	clean with brush		n. s.	clean with brush	clean under running cold water	'rinse' 10 sec.	n. s.	not clear	n.s.	
Detergent/ disinfectant	n. s.	Korsolex Plus	n. s.		Mucocit-T	Korsolex AF	n. s.	n. s.	Mucocit-T	Sekusept Plus	Mucocit-T	
Conc. / Time	n. s.	3 %/15 min.	n. s./30 min.		2 %/30 min.	3 %/15 min.	n. s.	n. s.	2 %/30 min.	4 %/15 min.	2 %/30 min.	
Type of immersion	opened/ dismantled	complete	completely covered		bubble-free	less than 10 instrum.	wet all surfaces	opened/ dismantled	opened/ dismantled	bubble-free	bubble-free	
Ultrasound /time	n. s.	5 min.	10 min.	_____	_____	5 min.	10 min.	n. s.	_____	_____	n. s.	_____
Manual cleaning	_____	after US brush if necessary	after US brush if nec.	brush if nec.	brush	n. s.	n. s.	n. s.	brush	brush	Brush if nec.	brush
Rinsing	demin. water	demin. water	drinking water		demin. water	demin. water	demin. water	demin. water	demin. water	demin. water	demin. water	
Type of rinsing	sufficient	thorough	thorough		n. s.	thorough	thorough	sufficient	suff. intensive	n. s.	n. s.	
Drying	comp. air	ambient air	comp. air		90°C/15 min. Trocken-schrank	n. s.	comp. air or cloth	comp. air	comp. air	n. s.	90°C/15 min. drying cabinet	

Table 1: Evaluation of working instructions
n. s. = not specified; – = not done

without ultrasound, and two participants were asked to reprocess half of the clamps with ultrasound and half without. After drying, the instruments were returned to the investigators by express post with a copy of the respective working instructions for manual reprocessing. There they were at once subjected to elution to obtain samples according to the above-mentioned guideline. From each sample, an aliquot was tested quantitatively using the BCA method (Miele Test Kit and RQflex Plus Reflektometer [VWR, Darmstadt]) or the modified OPA method (7, 8).

Evaluation of the working instructions

Table 1 shows a general overview of the evaluation of the working instructions for manual reprocessing in the participating CSSDs. Participants 1, 2, 5, 6 and 7 each treated all 20 instruments with ultrasound. Participants 3 and 10 each treated 10 instruments with (3a or 10a) or without (3b or 10b) ultrasound. Participants 4, 8 and 9 did not use ultrasound at all on any of their 20 instruments.

For the first step of reprocessing, three participants carried out an initial manual cleaning step, described very loosely as "cleaning with a soft brush", "removing coarse dirt from material", or "removing soil under cold running water". Two participants carried out rinsing under running water for 10 seconds as the first step. The other participants did not report any pre-treatment, so the instruments were probably put directly into a bath or into an ultrasound tank. The way in which this was done was described as "opened/ dismantled", "less than 10 instruments", "completely covered" or only "bubble-free". These descriptions show clearly how imprecise the working instructions can be, and that personnel have a wide scope when carrying out reprocessing. In particular, opening and dismantling instruments before or while placing them in the bath, as well as a limit on the quantity of instruments, although relevant to efficacy, were not sufficiently taken into account.

As far as chemical products were named, these were cleaning active, non-fixing disinfectants. (The often used product name "cleaning active disinfectant" is misleading: it must be clear that manual cleaning and disinfection are two separate working steps.) Four participants did not name the products, or they referred to additional working instructions which had not been provided to the investigators. As far as times for ultrasound exposure were given, these were a part of the disinfectant holding time. Particularly those participants,who did not carry out pre-cleaning cite cleaning with a brush as a necessary or possibly necessary measure. Those who carried out thorough cleaning with or without ultrasound right at the beginning, before the disinfection bath, cite possible further necessary brushing. After attaining a result "visually clean", a final rinse was carried out with fully demineralised water, or for only one participant with drinking water. The specification for the extent or type of final rinse was described in the working instructions as "adequate", "adequately intensive", or "thorough". It is up to the individual member of staff to decide what he/she considers adequate. Finally, drying took place in ambient air, in a drying cabinet, or in most cases using medical compressed air.

Results of cleaning tests

Protein determination of the eluate and evaluation of residual protein quantity per instrument showed obvious differences, depending on whether or not ultrasound was used by the participants. Figure 1 shows the cleaning results for

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participants not making use of ultrasound, i.e. primarily cleaning with a brush. Participants 3b and 10b each with only 10 instruments cleaned in this way, attained values of less than or equal to 100 µg protein as bovine serum albumin (BSA) for all instruments. Thus they conform to the DGKH, DGSV and AKI's guideline benchmark. Participants 4, 8 and 9, each with 20 instruments subjected to brush cleaning, exceeded the benchmark for 8 instruments, and participant 4 in one case even exceeded the 200 µg mark.

The results for participants using ultrasound are shown in Figure 2. These participants' eluate samples consistently contained considerably less than 100 µg protein, meaning that the benchmark was attained in all cases, or the value even fell below the benchmark Particularly good results were attained by participants 2 and 7, where only 4 instruments out of 20, and only one instrument out of 20, respectively, contained more than 10 µg residual protein.

In the overall evaluation, it can be concluded that residual protein on instruments from participants not using ultrasound treatment was on average 58 µg for all instruments, and that from participants using ultrasound treatment was only 19 µg. The number of instruments after reprocessing without using ultrasound exceeding the benchmark of 100 µg is equal to the number of instruments after reprocessing with ultrasound, which exceeded the mark of only 50 µg.

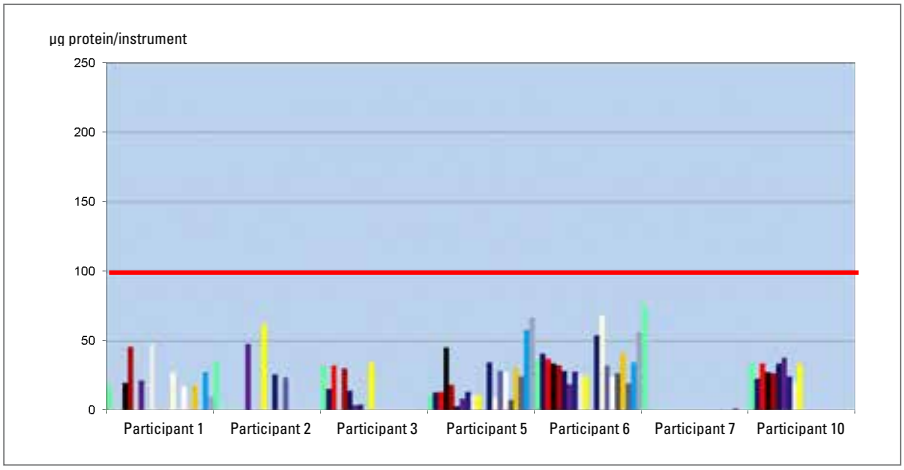

Fig. 1: Manual cleaning with ultrasound

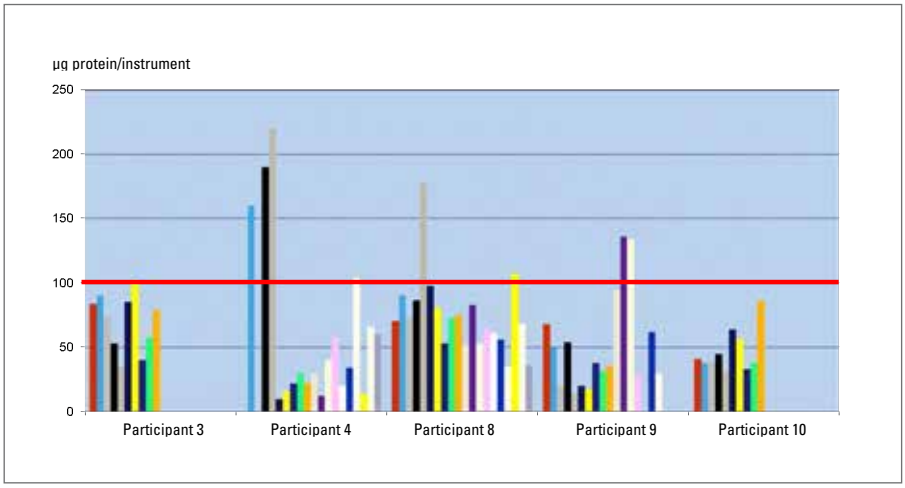

Fig. 2: Manual cleaning without ultrasound

Discussion

The multicentre trial on manual instrument cleaning with and without ultrasound support shows, that the benchmark of 100 µg protein (BSA) per instrument according to the guideline of the DGKH, DGSV and AKI for automated cleaning can only be safely attained by using ultrasound. However, an explanation for the attained results when looking at the working instrutions is not apparent.Varying exposure times to ultrasound do not correlate with different results from the participants. In comparison to the multicentre trial on automated cleaning published before the validation guideline, the results here are actually better, as 13 out of 18 participants had results exceeding the benchmark during the first trial. After over four years practical application of the guideline on validation of automated washer-disinfector processes it can generally be concluded that today the processes usually attain the benchmark without problem. Customer services know from their experience how to adjust the programmes taking into account which process chemicals will be used by the operator. With this performance improvement for WDs, and taking into account the results for manual reprocessing using ultrasound support, a new benchmark for automated processes – possibly 50 µg protein per Crile clamp – could be discussed.

It can be surmised that for this multicentre trial the participants exercised extra care during reprocessing. For routine ultrasound use, larger loads are probably cleaned so that the distribution of intensity is less uniform and therefore disadvantageous. The method of loading and the quantities loaded must definitely be fixed in the working instructions on manual cleaning and disinfection. Furthermore it should be noted that no detailed description is available of the type of ultrasound bath and the baskets used. It is also not known to what extent the ultrasound baths are regularly serviced.

Obviously manual reprocessing, especially cleaning without ultrasound support cannot lead to safe results for instruments with crevices and joints. Particularly in the outpatient area and in specialities with high instrument us-

age (e.g. dentistry), manual cleaning and disinfection dominate. Very often there is no suitable ultrasound appliance, so possibly inadequate cleaning means that the safety of disinfection as well as of sterilisation must be questioned.

The aim of the above mentioned guideline group is to recognise consequences on the basis of systematic and practical tests on manual cleaning and chemical disinfection and deduce operating instructions for specific medical device groups that help to acceptably standardise this type of reprocessing. Here mechanical support, as for example ultrasound treatment, represents an important component. ❊

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