Investigations into reproducible cleaning of instruments based on a worst-case model

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The efficacy of cleaning surgical instruments was investigated in a multi-centre trial using specially designed gap PCDs and evaluating the reproducible cleaning performance. The PCDs are representative for the the variety found in standard surgical instruments.
The results show that a process with two pre-rinses and 10 minutes holding time yields reliable results, however, the residues found vary widely with shorter process times and for unoiled instruments. The gap width has only minor influence.
Further investigations are in progress on minimally invasive instrumetns and on more complex instrument geometries.

Aim

To cite Michels (1) effective cleaning is an indispensable precondition for effective disinfection and sterilisation as documented in EN ISO 15883 (2). Over the past ten years several investigations have been conducted on the results and measurement methods (3).

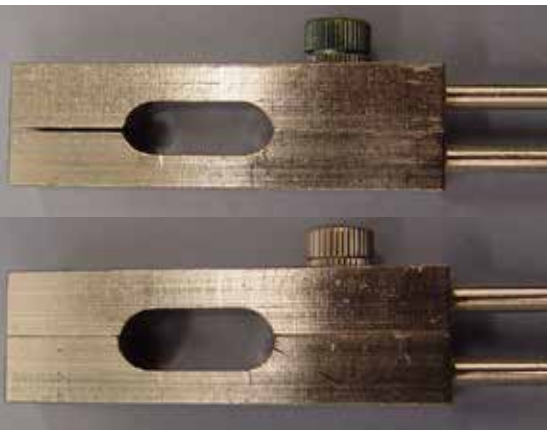

Fig. 1: PCDs with different gap widths

At present, manufacturers and operators are investing enormous sums of money to validate cleaning practices. In the sterilisation study (4) geometry prototypes were investigated as worst-case scenarios. The scope of investment needed for validation as per EN ISO 17664 can be greatly reduced through successful sterilisation of these process challenge devices (PCDs) and comparison of everyday instruments featuring the geometries similar to these PCDs as well as comparison of the processes.
The members of the Sterilisation Study Working Group and of the Working Group Instrument Preparation (AKI) set up the Project Group Cleaning (PGR) in order to now apply the same procedure, as that used previously for sterilisation, to cleaning and carry out a systematic study of the extent to which instruments with representative worst-case geometries lent themselves to cleaning. This was conducted as a multicentre study involving the participatory companies (manufacturers of washer-disinfectors (WDs), instruments and reprocessing chemicals) and the University of Saxony Anhalt, Prof. Junghannß, as well as the test institute SMP, with Klaus Roth. EN ISO 15883 and the DGSV Guideline (5) compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI)) already specifies steel screws and Crile clamps, etc. with contaminants and geometry prototypes for comparative purposes, however, measurements on everyday instruments are also always advocated. To that effect, within the framework of this present study both PCDs as well as everyday instruments were used in all tests to assure comparability.

KEY WORDS
- instrument reprocessing
- cleaning
- process challenge device
- cleanability

To ensure comparison with real-life instruments, cleaning experiments were conducted already in 2004 entailing cleaning of needle holders, from an actual surgery department, of various sizes and manufacture in a hospital washer-disinfector (WD) (6). The critical box locks of the needle holders had markedly different gap sizes and these served as the basis for the design of the PCDs used in this study. Overall, the cleaning results were below the limit value of 100 µg protein per instrument stipulated in the DGSV Guideline (3), but major fluctuations were noted.
The tests conducted subsequently in the context of the present publication were aimed at demonstrating evidence under defined and reproducible conditions of the amenability of surgical instruments to cleaning. Both instruments and PCDs with a defined geometry were used here. A separate test series will be carried out for minimally invasive surgical (MIS) instruments.

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Table 1: Potential critical geometries of surgical instruments
• Through-holes
• Blind holes
• Instruments with gaps (e. g. forceps)
• Gaps in joints and box locks
• Gaps in sliding-shaft instruments
• T-groove guides in sliding-shaft instruments
• Angled gaps, e. g. double-jointed instruments

Table 2: PCD geometries used	
Gap width [mm]	**Surface area [mm]**
0.03	10 × 10
0.11	10 × 10
0.27	10 × 10
0.42	10 × 10

Fig. 2: Contamination of PCDs: pipetting to surface and movement

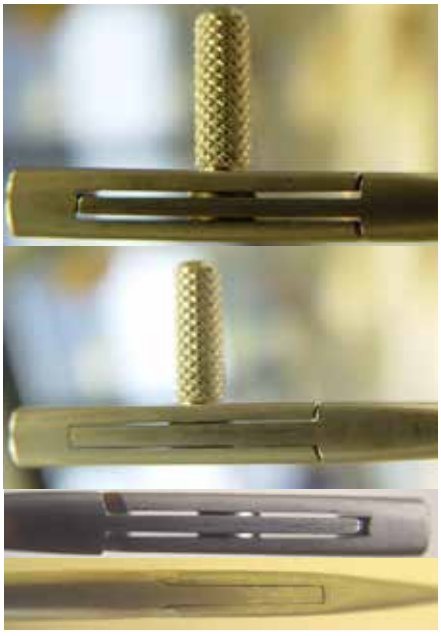

Fig. 3: Needle holders/modified needle holders with different gap widths

Fig. 4: Structure of dried diluted blood (left) and pure blood (right)

Materials

Cleaning of blind holes was not investigated since data are already available on how difficult it is to clean instruments with this geometry and this feature should, in principle, be avoided by manufacturers. The geometry feature posing the greatest challenge to cleaning is the gap. Prior to this study it was not known whether narrower gaps are in general more difficult to clean. That a larger gap depth proves more difficult was identified in preliminary tests (Table 1).

To assure reproducible conditions a special gap PCD was designed. The test soil was inserted into a gap that had no lateral boundaries or axis (Fig. 1). The PCD could be opened to permit visual inspection (Fig. 2). Various gap widths of 0.03/0.11/0.27 and 0.42 mm with a surface area of 10 mm × 10 mm were used, corresponding to the maximum range of instruments with box lock used for the Project Group's previous publication (4) (Table 2).

In addition, needle holders of different manufacture, some of which featured the original design and others of a shorter version and with a defined milled gap width, were used (Fig. 3). Instead of the usual grooves, the instruments could be dismantled thanks to a screw fitting. Here the gap width ranged between 0.01 mm and 0.45 mm.

The test soil used was protamine-sulfphate reactivated heparinised sheep blood (EN ISO 15883 Part 5 Annex A). Practical experience has shown that dilution with 10 % ultra pure water (water for chromatography, conductivity < 1 µS, evaporation residue < 5 mg/l) provides for homogenous wetting and hence for better attachment of the soil, assuring worst-case simulation since undiluted blood once dried is essentially easier to remove from surfaces than the test blood used here (Fig. 4).

Methods

To, on the one hand, conduct measurement for defined gaps and, on the other hand, ensure comparability in an everyday setting, 32 PCDs and 32 instruments of different geometries were tested together per load. The preliminary tests were performed in four laboratories using different WDs. The verification tests were conducted under comparable boundary conditions in three laboratories (designated below as laboratory E, S M) (Table 3).

Samples were prepared (thorough cleaning) using the following three steps:
- 1 cleaning cycle followed by thermal disinfection in WD
- Cleaning at 70 °C for 30 min in an ultrasonic basin with an alkaline detergent pH > 10.5
- Treatment at 70 °C in an ultrasonic basin for 30 min with approx. 2 % citric acid
- 1 cleaning cycle followed by thermal disinfection in WD
- Application of representative white-oil-based instrument care oil to instruments' gap,
- Steam sterilisation (134 °C 5 min).

Contamination was effected by pipetting 50 µl test blood directly to the gap. The test instrument was opened and closed five times to assure homogenous distribution of contamination. The closed instruments were then left to dry for one hour at room temperature (Fig. 5 and 6).

Automated cleaning was carried out in a Miele WD Type G7835 using a programme as per Table 4.

In addition, the cleaning pressure (static pressure at supply pipe of load carrier) and cleaning arms' rotational speed were measured to permit better insights into comparability of cleaning mechanics (Table 5).

Per load 4 trays were loaded as follows:
- Upper left: 16 PCDs (each gap width 4×)
- Upper right: 16 Needle holders/ shorter instrument model (each gap width at least 2×)
- Lower left: 16 Needle holders/shorter instrument model (each gap width at least 2×)
- Lower right: 16 PCDs (each gap width 4×) (Fig. 7).

Table 3: Factors influencing cleaning

• Overall load in machine, position of instruments in machine
• Blood quantity used per load (foam formation)
• Machine, load carrier
• Precleaning (number of precleaning steps, time)
• Cleaning temperature, heating curve
• Cleaning detergents, dosage, water quality
• Cleaning time
• Rinsing (number of steps, time, water quality)
• For all cleaning and rinsing steps – Cleaning pressure – Cleaning arms' rotational speed, pulse magnitude – Orientation of instrument versus cleaning jet

Table 4: Programme sequence and parameters

** The alkaline reference detergent used was composed of disodium and potassium metasilicate as well as phosphates and is thus representative of an alkaline detergent commonly used by different manufacturers.*

Programme sequence (with cycle times)
• Precleaning 1: Cold water, 1 min
• Precleaning 2: Cold water, 3 min
• Cleaning: Demin. water, alkaline reference detergent* (pH 10.5 – 11) 0.5 % Dosage at 40 °C, cleaning time 10 min at 55 °C
• Neutralisation: Cold water, citric-acid-based neutralizer, 0.1 %, 1 min
• Rinsing: Demin. water, 2 min

Table 5: Characteristics of WD

	Laboratory E	**Laboratory S**	**Laboratory M**
Mean cleaning pressure	125 mbar	125 mbar	120 mbar
Cleaning arms' rotational speed top [1/min]	26	26	25
Cleaning arms' rotational speed bottom [1/min]	38	28	39

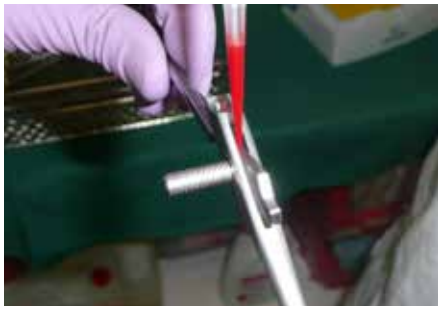

Fig. 5: Contamination of modified needle holders: pipetting to gap

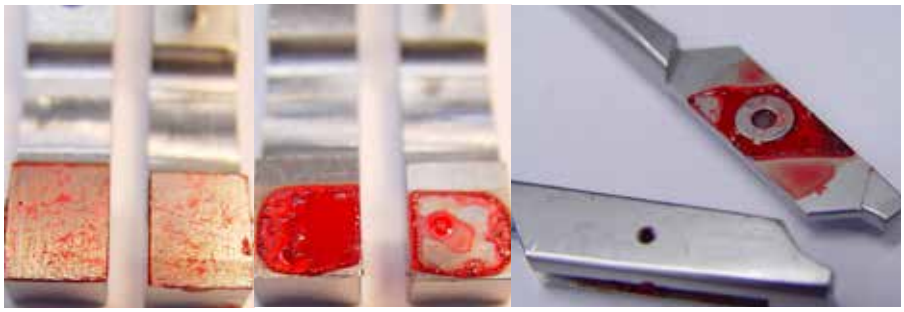

Fig. 6: Contamination in dried state

Fig. 7: WD load

Table 6: OPA method used in EN ISO compared with PGC

	ISO 15883-1 Annex C	Present PG tests
Eluate quantity	5 ml	2 ml
Withdrawn for OPA	100 µl	800 µl
Reagent quantity	1.1 ml	1.6 ml
Extinction limit value	**0.02**	**0.275**

Evidence of effective cleaning was based on the quantitative OPA method pursuant to EN ISO 15883 Part 1 Annex C2 (2). The PCDs were placed in a beaker/glass after each test. In the case of instruments that could be dismantled, the screws were removed but were not placed in the beakers/glasses.

The gap was rinsed with 2 ml of 1 % sodium dodecyl sulphate (SDS) solution (pH 11). The PCDs were moved on numerous occasions for 30 min in the solution (opened and closed as well as agitated on a vortex).

Compared with EN ISO 15883-1 Annex C, the sensitivity of the OPA method used was increased by reducing the eluate quantity and a greater portion of the eluate was withdrawn for measurements.

It was revealed that the extinction values measured differed depending on the photometer used. In each laboratory each

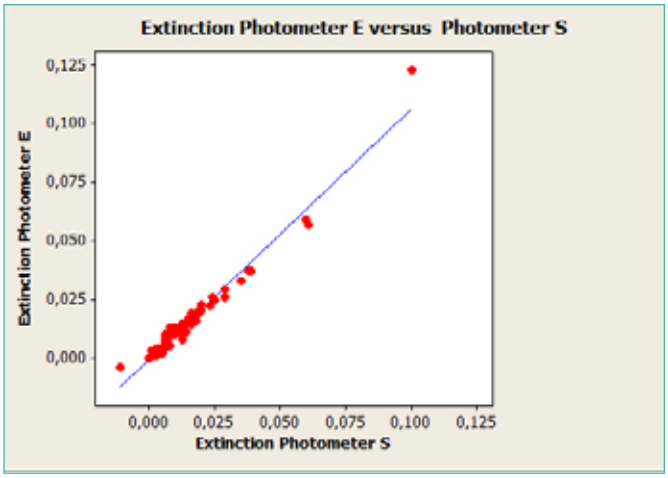

Fig. 8: Example of correlation between photometer E and S

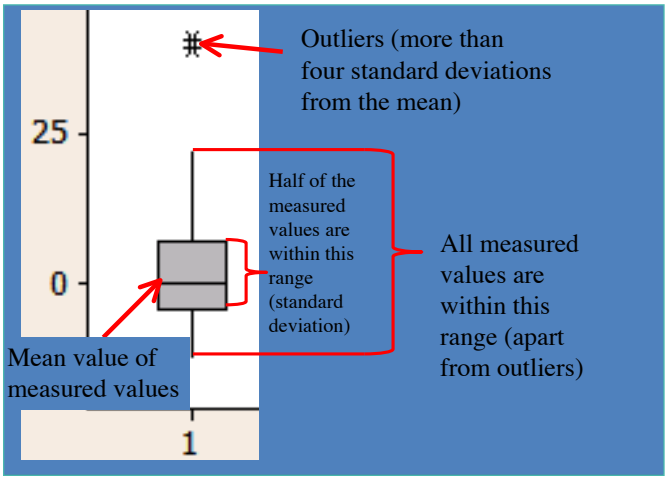

Fig. 9: Depiction of box plot Diagramme

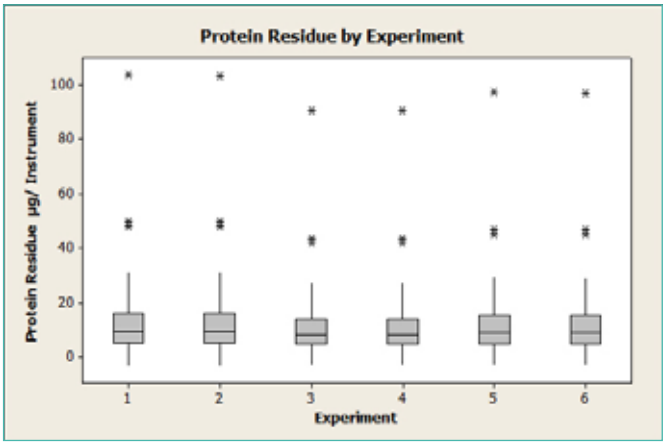

Fig. 10: Protein residues after testing

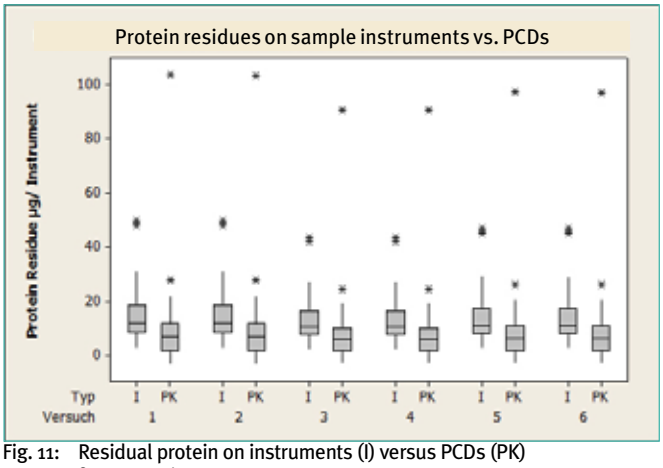

Fig. 11: Residual protein on instruments (I) versus PCDs (PK) from experiments 1 – 6

sample was measured in each case with three photometers E/S/M. With the help of a device-specific calibration curve of BSA standard, to compensate for deviations, the extinction values were converted to a protein quantity, thus assuring comparability.
The guide value of 100 µg per instrument specified in the Validation Guideline was used by the Project Group as acceptance criterion (5). This meant that the criterion given in EN ISO 15883 was also met. Deviations between the calibration curves and the linear compensation lines up to 250 µg used for calculations were always less than 10 µg.

Results

For the surgical instruments' family six test series were conducted in three laboratories, each involving 64 test instruments, thus producing a total of 384 measurement results. Each eluate was evaluated with three photometers from the laboratories E/S/M. In general, there was good correlation between the photometer values (errors to above 90 % less than 5 µg, but there were isolated outliers in the upper ranges) (Fig. 8).
Below only the results obtained with photometer E are considered.
Overall, the results obtained for all six experiments were far below the specified limit value (maximum 25 µg per instrument), 50 % of the measured values shown were within the box, and the remainder (apart from the outliers denoted by «×») were within the lines (Fig. 9). Isolated values were markedly higher but in no case was the limit value exceeded. The reason for these outliers is unclear. Despite slight mechanical differences, the WD used does not appear to have exerted any notable influence on the measured values (Fig. 10).
In all experiments the same PCDs and instruments exhibited markedly higher values. This reason for this cannot be attributed to the geometry. It is probable that corrosion residues on the surface gave rise to measurement errors.
The position of the trays produced better results on the lower level (tray 1 and 4) in both the PCDs and instruments. More outliers were found for the lower level. It is possible that because of the cleaning pressure exerted here the PCDs were pressed one on top of the other and therefore less accessible to the cleaning jet.
The mean values measured for protein residues on PCDs and instruments deviated from each other only by 6 µg and, as such, are comparable. The standard deviation is smaller for the PCDs due to the more precise geometry and absence of an axis (Fig. 11).
Likewise, the gap size of PCDs only exerted a slight influence on the mean value but in the case of the very narrow gaps there were considerably more and more pronounced outliers as well as greater scattering (Fig. 12).
Marked differences were noted between the different instrument designs: Instruments 11 and 3, which produced by far the worse results, were short needle holders with a small gap (0.02 mm and 0.25 mm). Neither the geometry nor positioning helps to explain these values since the results obtained for other instruments with similar geometry were unremarkable (Fig. 13).
In earlier test series involving only 5-minute cleaning time without applying oil to the instruments, while the mean values measured were only slightly higher, the standard deviation was great-

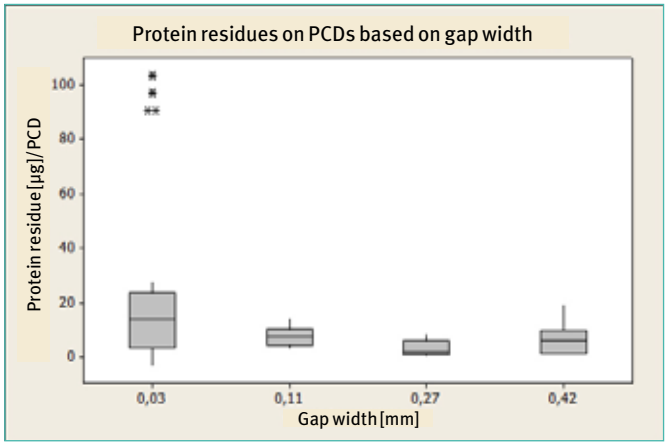

Fig. 12: Protein residues on PCDs based on gap width

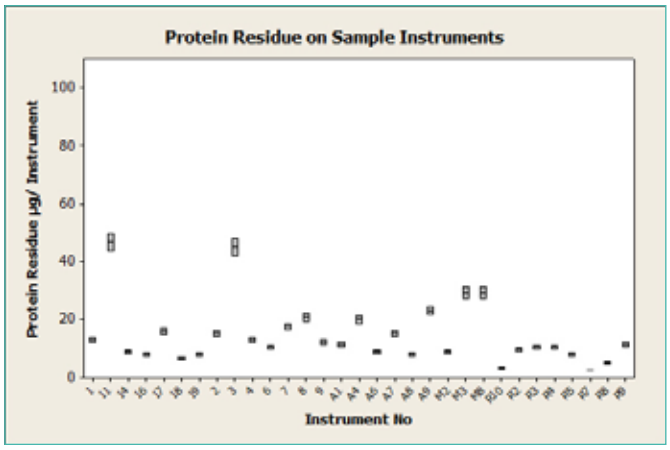

Fig. 13: Protein residues on model instruments

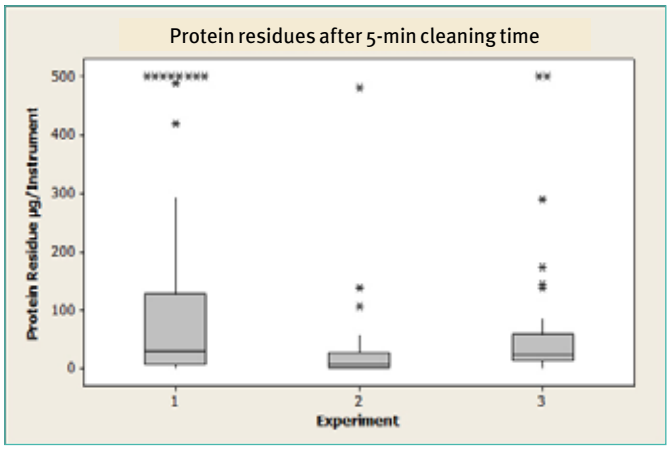

Fig. 14: Protein residues after 5-min cleaning without care oil

er as was the number of outliers. Values exceeding the alarm and limit values were measured (100 and 200 µg/instrument) (values > 500 µg are given as 500 µg). A 5-minute cleaning time is not enough to achieve a reproducibly good cleaning result (Fig. 14). While application of oil to instruments enhanced performance in general, outliers were still noted.

Discussion

The experiments demonstrated that the process used here assured proper cleaning with a greater safety reserve for instruments with the «gap» critical test feature (approx. 10 µg mean value, approx.10 µg standard deviation). Outliers, too, (which possibly went unnoticed during spot check measurements) were within the range of the guide value of 100 µg protein residue and, as such, well below the limit value of 200 µg protein per instrument.

Possible explanations for scattering were the positions of the instruments, geometry, soil, etc. However, no definite conclusion could be drawn from the tests conducted. The load (64 instruments/PCDs in four trays) and the position of the various test objects were not altered for the tests. The lower level produced better results in our experiments, and other loading patterns and loading densities would, not doubt, have implications for the results obtained.

The tests demonstrate that the following parameters affect the cleaning results:

- Gap width (PCD with narrow gaps had a greater standard deviation with the same gap depth)
- The WD cleaning mechanics (the upper level produced poorer results than the lower level)
- Instrument care measures (careful application of oil enhanced cleaning performance)
- The cleaning time (5-min cleaning time produced markedly higher values and a greater number of pronounced outliers).

The performance of the PCDs used was similar to that of the instruments. The (PCD) geometry is defined exactly; the PCDs can be used for test purposes and visually inspected.

Thanks to this process, there is now available a detailed method whose performance has been investigated in-depth. The process and results can help:

- Manufacturers to formulate reprocessing recommendations as per DIN EN ISO 17664,
- Give operators a blueprint for an effective process to serve as a reference for designing and comparing their own processes.

While one can, no doubt, conclude that instruments without critical features (e. g. chisels) can be cleaned to the same standard when using this process, the situation cannot be assumed to be the same for instruments with entirely different gap geometries (e. g. sliding-shaft instruments) or more complex gaps (e. g. double-jointed instruments, threads) (7). The working group will focus on the topic of MIS instruments in another series of tests using special PCDs. ■

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