Assessment of cleaning efficacy based on the protein-surface relationship

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Residual soils persisting after manual or automated cleaning can jeopardize the disinfection and sterilization results and pose a risk of immunological reactions, if transmitted to the patient when the instruments are reused. In any case, the adverse effects on the post-cleaning reprocessing steps will depend on the thickness of the layer of residual soils and on how well pathogens are embedded in such soils and, thus, protected against the inactivating agent. The amount of residual protein than can be transmitted when the instrument is reused will also depend on the surface area coming into contact with the patient and on the protein amount that can be thus transmitted. This means that the surface-related amount of contamination is of decisive importance. This can be explained by stating, by way of analogy, that no absolute pollutant quantity can be defined for an ocean, lake or pond, rather this can only be expressed in terms of concentration in quantity per litre. To specify acceptance criteria for performance qualification using the same principle, the values that can be achieved in practice when using current state of the art methods were explored by consulting validation reports. There is no other principle that can be invoked for specification of acceptance criteria for cleaning.
Validation reports compiled in 2011 and 2012 were evaluated. Since the cleaning results in practice are subjected to a constant optimization imperative, but reproducible compliance must also be feasible and demonstrable, an acceptance value of ≤ 3 µg per cm^2 was deemed reasonable in the light of the results obtained.

KEY WORDS
- minimally invasive surgery
- robotic instruments
- DaVinci
- cleaning
- residual protein

Introduction

Cleaning is the first and most important of the steps implemented for reprocessing surgical instruments. It is aimed at preventing transmission of residual soils when the instruments are reused on a patient. Besides, cleaning is a prerequisite for effective disinfection and sterilization. The reduction in organic soils during cleaning to a level that assures optical cleanliness is often inadequate. Moreover, visual inspection is not possible in the case of several types of instruments, such as those with crevices, joints, lumens, etc. Therefore an appropriate method must be used to assess cleanliness. At present, this is based mainly on selective sampling of such instrument sites by means of SDS elution and detection of protein soils.
The Guideline for Validation and Routine Monitoring of Automated Cleaning and Disinfection Processes for Heat-Resistant Medical Devices, compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI), adopts that approach both when using Crile clamps as test pieces (process challenge devices – PCDs) to investigate the minimum cleaning efficacy (performance) and, in particular, to assess real instruments harbouring everyday soils (1). In both cases, the acceptance criterion applicable to date has been residual protein amounts of less than 100 µg per instrument, based on a bovine serum albumin (BSA) equivalent value. However, a footer to the guideline states that for real instruments used in particular application settings (e.g. ophthalmology), other acceptance criteria could be defined on the basis of risk analysis. But since the focus of risk analysis is unclear, that option has not been taken up to date in practice. Currently, there are no clinical data or study findings to help define acceptance criteria that unequivocally indicate the need to eliminate contamination to a particular minimum and from which acceptance criteria can be inferred. To define acceptance criteria, one must therefore be guided by the state of the art and investigate what can be reproducibly achieved using the current methods. The underlying principle still applies: The lower the contamination level, the better and more reliably is the optimization imperative served. The current state of the art is defined by the results obtained for performance qualification of real instruments as well as test pieces (Crile clamps), as documented in validation reports.

Findings based on the state of the art

To ascertain what validation results are being obtained in practice, the customer service databases of the firms MMM and Miele were searched and the validation reports related to large washer-disinfectors (WD) from 2011 and 2012 were evaluated.

Test pieces for investigating the minimum cleaning efficacy

The DGKH, DGSV and AKI guideline for validation of automated processes recommends for standardized testing of the minimum cleaning efficacy that the clean-

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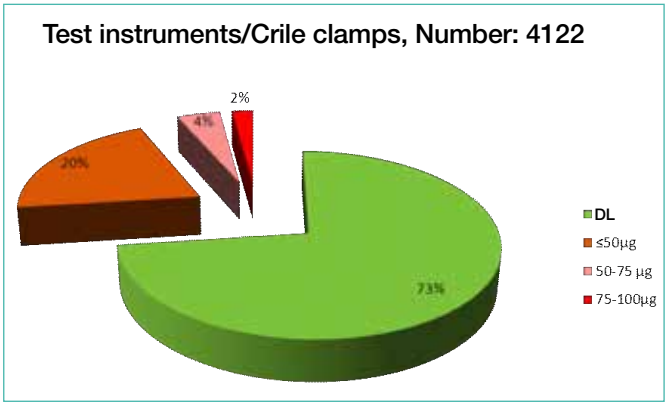

Fig. 1: Evaluation of validation reports with regard to residual protein, using Crile clamps as test pieces

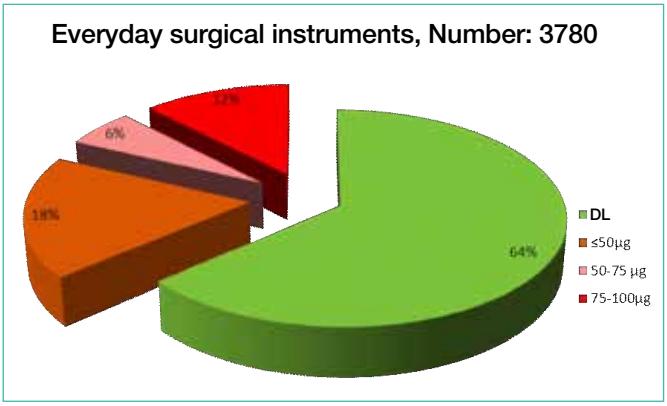

Fig. 2: Evaluation of validation reports with regard to residual protein, using everyday surgical instruments

ing processes be investigated with conditioned Crile clamps contaminated in jointed areas with coagulating sheep blood. The acceptance criteria specifying a guide value of 100 µg per Instrument in the initial version of the guideline published in 2006 was based on the results of round robin tests from 2005 (2). Evaluation of the validation reports show that in the meantime, thanks to the validation experiences gleaned in practice, the processes have been revised, optimized and standardized. Hence, at present automated cleaning of surgical instruments is performed almost exclusively with alkaline detergents with a pH value of > 10. The cleaning step in more than 85 % of all processes is carried out with demineralised water. The cleaning time is 10 minutes in more than 85 % of all processes evaluated. The cleaning pressure constancy and rotational speed of the cleaning arms were verified, recorded and are today to an extent standardized. Such trends are reflected in the findings of validation reports since the introduction of the Guideline.

The data below show test results for 2011 and 2012. Here residual protein determination was conducted mainly after SDS elution using the BCA method as well as reflectometric measurements directly on site (3). From the validation reports of several companies, the results obtained for 4,122 Crile clamps were recorded (Fig. 1). Unlike the results from the round robin tests from 2005, the residual protein amounts on these Crile clamps were up to 73 % below the detection limit (DL) of around 20 µg of the determination method used, and only 2 % of results were in the range 75 to 100 µg per instrument. Hence, the current state of the art advocates that the acceptance criteria be amended in the light of the optimization imperative.

Instruments harbouring everyday soils – real instruments

After evaluation of successful performance test reports, 3,780 surgical instruments with everyday soils, which were essentially composed of a wide range of the most diverse jointed instruments, were documented after cleaning and testing (see Figure 2). None of the instruments had more than 100 µg protein, otherwise based on the current acceptance criteria the cleaning efficacy would not have been adequate and the process would have to have been optimized and performance requalification carried out. The results obtained for 454 instruments, i.e. around 12 %, showed residual protein in the range 75 – 100 µg. 6 % of instruments were in the range 50 to 75 µg and 64 % of results were below the detection limit of the determination method used. Among the jointed instruments of the size of a Crile clamp, which were used as test pieces for investigating the minimum cleaning efficacy, none had more than 50 µg protein. In general, sampling was performed for these real instruments according to the method described in the DGKH, DGSV and AKI Guideline on using Crile clamps as test pieces. This entailed thorough irrigation in a beaker of the functional end, including the joint, with 2 ml SDS solution. For a Crile clamp with a total surface area of 42 – 44 cm^2 only around half of the surface, about 20 cm^2, was sampled. Hence for that region, a residual protein amount of ≤ 3 µg/cm^2 was reliably obtained. Based on those results, also in the light of the discussions taking place in the standardization committees of DIN NA Med D09 as well as of ISO TC 198 WG 13, stipulation of a residual protein-surface relationship value of ≤3 µg/cm^2 as acceptance criterion does not appear to be unrealistic and is thus viewed as the first step towards differentiated assessment of cleanliness (5, 6).

Results obtained for minimally invasive surgical instruments

The validation reports on reprocessing of minimally invasive surgical instruments were considered separately. The results obtained for these instruments were not included with those for the 3,780 surgical instruments described above. Of the 786 MIS instruments investigated, only around 2 % (19 instruments) yielded results of more than 50 µg (Figure 3). Of these, 5 instruments were trocar sleeves which were sampled by rinsing off their entire surface into a PE bag. The size of the surface area can vary greatly among trocar sleeves and is definitely in the region of more than 50 cm^2. Hence, high residual protein values can also be expected. Two trocar sleeves produced values of more than 100 µg (156 and 175 µg). No explanation was given in the report for this. With an acceptance value of ≤ 3 µg/cm^2, at least a value of less than 150 µg should be met. The broad variation in the mechanical action exerted during cleaning on the internal surfaces of

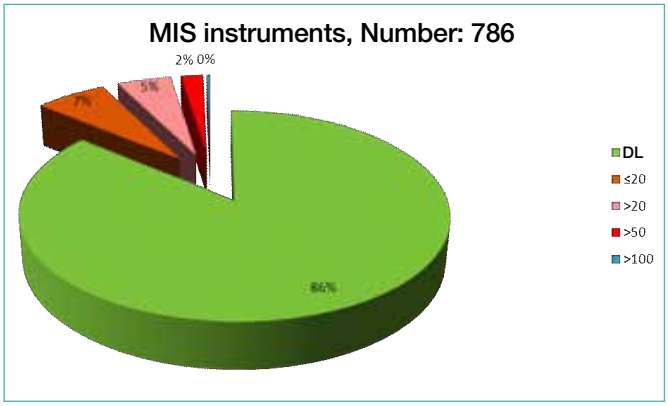

Fig. 3: Evaluation of validation reports with regard to residual protein, using everyday surgical instruments: MIS instruments

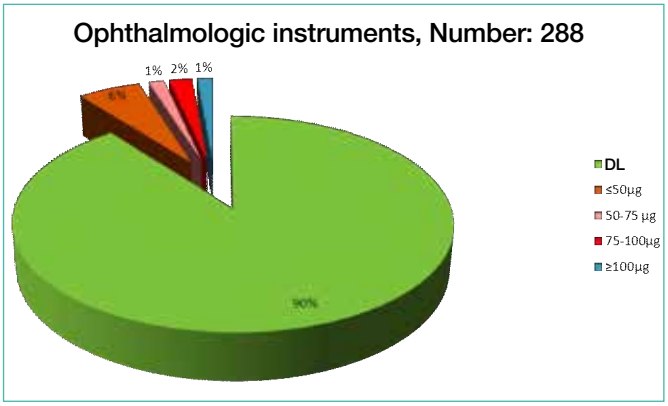

Fig. 4: Evaluation of validation reports with regard to residual protein, using everyday surgical instruments: ophthalmologic instruments

sleeves, connected to a spray nozzle on the load carrier, is well known and therefore high values are expected in some cases.

Results obtained for ophthalmologic instruments

Ophthalmologic instruments, in general, have overall smaller surface areas than conventional surgical instruments. Often, these are in the range 5 to 10 cm^2. Besides, the contamination level associated with ophthalmologic procedures is often less than 100 µg per instrument (7). That suggests that for cleaning a residual protein amount of less than 20 µg, which somewhat corresponds to the detection limit of the reflectometric method, should be advocated as acceptance criterion. That value is reached in the majority of validation cases, see Figure 4.

Discussion

Overall, the findings indicate that even today the results being obtained in practice are considerably better than the hitherto guide value of 100 µg. In principle, the same requirements must be applied to manual cleaning, and previous round robin tests demonstrated that on using ultrasound additionally the residual protein amounts on Crile clamps were of a similar level (4).

As a natural corollary of the very good results that can now be achieved with the test piece model, and in the light of the optimization imperative, it is time to bring the acceptance values into line with the results achieved in practice and then advocate a guide value of 80 µg per Crile clamp. Here it must be emphasized that what is at issue here is investigation of the minimum cleaning efficacy, something that is not directly related to the requirements applicable to the results obtained for real, everyday instruments.

With respect to real instruments, a surface-related approach is needed since, e.g. a chalazion clamp as used in the ophthalmologic setting cannot be compared with an orthopaedic intramedullary reamer (5). That is also the view of standardization committee ISO TC 198 WG13, dealing with this matter, as well as of the DIN NA Med D09 national committee. It is not advisable to apply the same criterion (currently less than 100 µg) to all instrument groups. The working groups responsible for compilation of the DGKH, DGSV and AKI guidelines on validation of automated as well as manual cleaning and disinfection have taken on that task and in future will take account of the relevant surface area when defining acceptance criteria (6).

When investigating after cleaning those real instruments with everyday soils, sampling must be targeted towards those instrument sites most susceptible to soiling during use and which pose the greatest risk of contamination transmission when reused. When calculating protein determination results, the latter should not be embellished or portrayed in a (more) acceptable light by including non-critical surfaces that are readily accessible to cleaning.

Proposal for new acceptance criteria in line with the current state of the art:

- For test pieces (Crile clamps):
  Guide value: ≤ 80 µg
- For real instruments:
  Real instruments are assigned to different instrument groups based on their designs and it is intended that the forthcoming revised version of the guideline will specify acceptance criteria for the examples given in Table 1.

Which instrument is eluted and how must be determined through risk assessment. It is easier to clean and visually inspect the functional end of dismantable instruments. For non-dismantable instruments, it is easier to elute and measure residual soils on using ultrasound.

Partial elution is an option for non-dismantable instruments. If the instrument's functional end has a high level of residual contamination, then this should also be detected. When the entire instrument is eluted, this critical site, i. e. the functional end just mentioned, could be interpreted as non-critical in the overall assessment, if the entire instrument surface area were to be included in the calculation. Such an approach is not acceptable.

In the United Kingdom, too, the topic of protein determination methods was on the agenda at the annual conference of the Institute of Decontamination Sciences (IDSc), highlighting the essentially new orientational approach (8). As regards the acceptance criteria, the sensitivity of the detection methods seems to be the key factor here, with what is technological-

Table 1: Assignment of real instruments to different instrument groups based on their designs and examples for acceptance criteria
Subgroups and measures as well as acceptance criteria are given here for Group 3 only by way of example

Group	Types of instruments	Supgroups and measures	Acceptance criteria
Group 1	Instruments without joint, cavities/lumen		
Group 2	Instruments with joint		
Group 3	Sliding-shaft instruments	*Subgroups* – Sliding-shaft instruments that cannot be dismantled – Sliding-shaft instruments that can be dismantled (Fig. 6) *Measures* Only for instruments deemed optically clean shall protein determination be performed. For instruments that cannot be dismantled: partial elution of the instrument's functional end into a test tube using ultrasound additionally (Fig. 5)	– Sliding-shaft instruments that cannot be dismantled: ≤ 50 µg per instrument – Sliding-shaft instruments that can be dismantled up to a length of 15 cm: ≤ 120 µg per instrument – Sliding-shaft instruments that can be dismantled with a length over 15 cm: ≤ 150 µg per instrument
Group 4	Tubular instruments		
Group 5	Microsurgical instruments		
Group 6	Complex instruments		

Fig. 5: Partial elution into a test tube of an instrument functional end, using ultrasound additionally

Fig. 6: Complete elution of a dismantable punch into a PE bag

ly achievable being the guide parameter. Based on our evaluation of the pertinent results, this is currently ≤ 3 µg protein/cm^2. The requirements will be more stringent for certain types of instruments. Based on our observations, these values can be easily achieved because the processes have become better and more reliable.

Since the surface area must be taken into account when defining acceptance criteria, it would be beneficial if instrument manufacturers would provide orientational details of surface areas as part of the information they are obliged to provide pursuant to DIN EN ISO 17664. ■

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