Regaining Soils from Instrument Surfaces

SDS-OPA Method with Native Blood as Contaminent

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Abstract:

Reusable surgical instruments might have certain adhesions on their surfaces which are difficult to detect. Elution of the surfaces leads to a percentage of recovery of test soils which depends on different parameters from the chemical nature of the detergent to design or surface properties - and of course the biological nature of the soil/debris (biofilm, bioburden). Sodiumdodecylsulfate (SDS) as eluate in conjunction with the use of the photometric method with σ-Phthaldialdehyde (OPA) for analysis allows to quantify amounts of adhesions containing possibly proteins. In our test model we could reproduce precise results having a recovery rate beyond 95% in the range where the contaminent blood is not visible but still present (µl blood per ml eluate). The method seems to be specific and sensitive, but has its limitations concerning daily use in clinical sterile supply. It is a chemical method which was used in vitro with native blood.

Objectives:

Adequate cleaning of all surfaces, including lumens, is a prerequisite in ensuring that residual contamination remains permeable to steam or disinfectants avoiding a critical thickness of the adherent biofilm. Requirements for reusability may be instrument design or the choice of material, but always the hygienic standard which is accessible by sterile processing, reprocessing of disposable instruments might be possible or even useful [Canadian Healthcare Association 1996, Carr 1995, DesCoteaux 1995, Fengler 1998, Whitbourne 1997].

There are no indicators available to monitor cleaning which represents the single most important decontamination step [Jatzwauk 1997, Schrimm et al. 1994]. On the other hand disinfection with its limitations is subject to many considerations [Corson 1979, Deva 1996, Hachmann 1994, Miles 1991, Rehork 1992, Spicher 1996]. One relied solely on visual-tactile checks [Michels, Pahlke 1996]. The physical and chemical recording and evaluation of cleaning parameters in sterile supply processing has remained largely unexamined, especially under the condition of long shafted endoscopic instrumentation [Bessières 1993, DeSchutter 1996, Nyström 1981, Ojajärvi 1993]. Also, there have been cases of transmission of tissue [Coghill 1998] and even infection [Spach 1993].

Furthermore, any evaluation of surgical functionality and hygienic suitability must be objectifiable. A test protocol with clinical data on medical products seems justifiable with a view to manufacturer's liability, as laid down in the Medical Devices Law which, introduced in Germany 1998, differentiates only between the liability of manufacturers and operators.

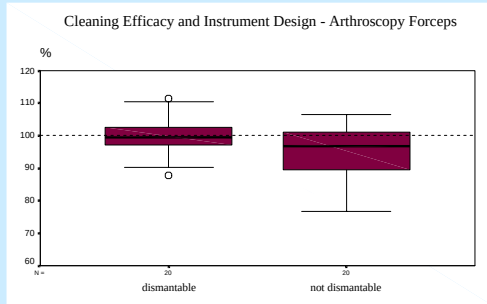
Remaining contamination on surfaces embedding potentially infectious material and regaining it therefrom is still a new field of hygienic research for surgical needs - from endoscopy to dentistry. Test models refer to more specialized situations focusing on eventualities [Diettrich 1991, Geertsma 1995]. Biofilms on any surgical instrument - from laparoscopic scissors to drilling devices in orthopedics/traumatology - cannot be detected if not visible. Can the OPA method quantify volumes of native blood?

Test bodies were glass/steel plates which were contaminated with native blood and then dried. On the next day elution with sodiumdodecylsulfate and photometric measurement of extinction was executed. Recovery was determined. Different concentrations were measured to ensure the reproducibility, sensitivity and specifity of this method where free NH_2 in amino acids, peptides and proteins can be quantified. σ-Phthaldialdehyde reacts with NH_2 and a thiol to a fluorescent molecule which then can be measured photometrically to calibrate amounts of proteins as can be found in human blood [Frister 1988, Langheinrich 1995, Michels 1997].

Results:

Recovery was beyond 95%. Extinction was directly proportional to the change of concentration. Independent measurement on different locations were executed and the results were highly comparable. Variations of amino acids in blood, different hematocrit and test person (blood donators) did not affect the quantitative results of recovery as much as expected (< 5%).

The OPA method was sensitive, specific and reproducible. The recovery rate of native blood regained from standardized test bodies seemed sufficient. Depending on the concentration used 75-100% were regained [Fengler et al. 1998]. The design influence for dismantable and not dismantable arthroscopy forceps is shown below as an example (Fig. 1).



Conclusions:

In-vitro testing to compare differences in instrument design (surface roughness, intraluminal surfaces, dismantling interfaces, width of capillary gaps) can be done with this test model. Only blood as test soil is too precious for routine testing and is difficult to handle [Spicher 1985]. Therefore artificial test soils will be compared next to blood. It must be taken into account that usually blood, apparently the most adequate test soil model, is mixed with different liquids, which lowers the concentration of its components (e.g. fibrin). On specific spots there might be a high concentration, anyway.

Cleaning is the single most important step towards reducing the microbial count and must be quantifiable. Disinfection tests, used to evaluate new disinfectants, do not take into account the effects of detergents or of the mechanical cleaning process. A criterion for the efficacy of sterilisation is not only the good disinfection result but also the removal of soil/debris (bioburden). Larger but smoother surfaces will retain less soil than smaller but more complicated surfaces. A decontamination indicator (test kit) for the step of automated cleaning is desirable. Proneness to soiling and cleanability are closely related - a statement which should be kept in mind by instrument development engineers.

The detection of protein residues on sterile instruments is an observation, the clinical relevance of which must be studied in further experiments [Fengler 1993, Wilson 1995]. Congealed organic surface soil is very nearly completely dissolved by solvents (in this case >95% recapture depending on concentration levels). The necessary chemical stages including photometric extinction measurements involve potential sources of error, as for any other chemical method (preparation of the solution, dilution, transfer, batch errors) .

Test soiling and contamination which reflect field conditions must be designed under scientific test conditions. Alongside laparoscopic instruments, increasing use is being made in therapeutic fields of sensitive and thermally sensitive ‚intelligent' instruments ranging from gastroscopes and coloscopes to dental systems and the microinstruments used in neurosurgery or in ear, nose and throat (ENT) treatment.

A quick-test device to provide an assessment of the cleaning stage as part of the overall decontamination effort would be highly welcomed. It is more difficult to develop than chemo-biological indicators (test spores) for the physical steam sterilisation parameters, because the main problem relating to cleaning is the localisation of soil and it's layer thickness. Therefore comprehensive tests of correlation between clinical and laboratory contamination must be performed .

- Design of instruments influences cleanability and proneness to soiling.
- The development of a test kit for quality management is required.
- Residuals may be found easier on complexe instruments.

It must be kept in mind, that validation of sterile processing includes all steps from the Operating Theater (OT) to the Central Sterile Services Departments (CSSD).

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