Abstract:

Tracer instruments (in vivo), test soils and test probes (in vitro) are needed to examine surface layers which might contain infective material. Disinfection efficacy with the reduction of *colony forming units* (CFU) must be distinguished from dynamics of cleaning where a minimum of any surface-covering material must be reached to avoid *camouflage* hiding microorganisms. *In vivo*-testing of clinically used instruments is important to know the levels of cleanliness which still are adequate for sterile processing. It can be done directly on the instrument with the advantage of precise local analysis on the individual instrument or in the eluate with the advantage that the instrument goes quickly back to the processing cycle. Here, more data can be achieved. *In vitro*-testing allows to evaluate the parameters of cleanability which are instrument design, surface properties of metal and/or composites, steps of the processing cycle, design and programming of the automated cleaning device, or the selected cleaning solutions which can be evaluated. Grading of visual cleanliness is a simple but still effective method for judgement of cleanliness after clinical operation and after automated cleaning (before sterilisation). But still proteinacious material mgiht be hidden on outer or inner surfaces. A protein indicating system (test kit) must be developed as visual-tactile control alone is not sufficient for the often complexe instruments in all disciplines of medicine, from arthroscopy to traumatology. It may lead to a better quality control of the processing cycle as well as it helps to optimise medical devices involved.

How Clean are Sterile Instruments?
Parameters - Testing - Clinical Data

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In vivo-Testing of the Clinical Situation

Collecting clinical data on the surface of clinically used surgical instruments from all medical fields is necessary to know the quality and quantity of organic and anorganic material on outer and inner surfaces. Because there are different „sterile items" [Spaulding], tracer instruments were choosen from

- Arthroscopy (meniscus forceps)
- Dentistry (drills)
- Endoscopy (biopsy forceps)
- Gynecology (specula)
- Laparoscopy (scissors, forceps, mono-, bipolar instruments)
- Traumatology/Orthopedics (bone drills)
- Surgery (scissors)

Meanwhile, we are performing a multicenter study in 6 central sterile supply units.

Fig. 1: Vascular cannula with blood clot after sterile processing

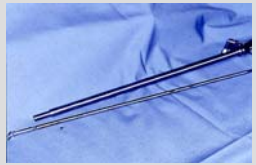

Fig. 2: Dismantable clip applicator carrying blood on the inlet

In vitro -Testing of Parameters of Cleanliness

The study design has to enable statistical analysis for the examined parameters which have to be correlated to clinical conditions. For economic reasons we are specialising on the SDS-OPA method where experiences are gained since more than 10 years in the field of food industries [Frister, Michels].

Parameters are

- instrument design (structure and material of the surfaces, compounds and their connections)
- cleaning procedures (inserts, pump pressure, instrument adaption, water flow conditions)
- processing programme (pre-treatment in the OT, ultra sound, automated device, manual steps)
- conditions for thermal or chemical disinfection
- cleaning solutions

Fig. 5: Different blood concentrations and colors on metal test plates to determine recovery rates

Fig. 6: Native blood with thrombogenic activity as test contaminent

Conclusions:

- Measurement of organic material (biofilms, debris, detritus) containing possibly infective material is important for the dynamics of cleaning. A minimum value of layer thickness must be achieved instead of a reduction factor as for microorganisms.
- Testing on proteins as the clinically most significant contaminent can be performed either on the instrument or in a solution taken from the instrument´s surface.
- Measurements directly on the surface can only be performed on the individual instrument, are time-consuming and somehow sophisticated (vacuum etc.).
- Measurements in the eluate taken from the instrument´s surface allow to achieve clinically relevant data. The problem is, that there are many different instrument types and processing parameters.
- Recovery rates then must be determined for any kind of analysis and for each step of testing (calibration, zero probes).
- In vivo the source, quality and quantity of the organic debris remain partly hidden.
- Recovery rates can only be measured in vitro. They depend on the choosen test soil, surface and material properties, instrument design and the different parameters of processing.
- Native blood as test soil seems most adequate but is too precious for routine testing. Because of its complexity (liquid, particles, thrombogenic activity) it is difficult to find an adequate substitute.
- Quality control for the cleaning step needs a standardised test method (test kit). Especially, the choice of test soil must be defined and correlated to the clinical situation.

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Fig. 3: Rinsing of tubular instruments to its distal end - red color indicates blood

Fig. 4: Quantity of organic matter detected on instruments - equivalent blood on penny-sized plate

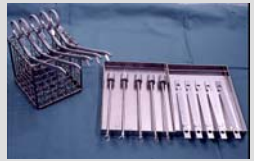

Fig. 7: Test probes for recovery - the metal plates were dried afterwards

Fig. 8: Arthroscopic instruments - dismantable forceps (inlet), not dismantable meniscus forceps

Fig. 9: Test contamination on difficult-to-access sites