EXPERIENCE OF SOIL TESTS USE IN 2 FRENCH HOSPITALS: HOLLOW INSTRUMENTATION AND DETERGENT VALIDATION

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INTRODUCTION

Quality Assurance in CSSD

Cleaning Quality

Sterilization or Disinfection Quality

Pr EN ISO 15-883
Requirements for performance of all washer-disinfectors (instruments or endoscopes).
Part 5: Description of soils

3 soil tests marketed in France:
- Amcor SPS: Tosi®,
- Browne: SoilTest®, STF Load Check®

Application of soil test use:
2 examples in hospital practice:
Hollow Instrumentation, Detergent Validation
EXPERIENCE OF SOIL TESTS USE IN 2 FRENCH HOSPITALS: HOLLOW INSTRUMENTATION

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Cleaning performance ability of an Instrument Washer-Disinfector (I-WD)

Method
1/ Contamination of an ENT suction tube by a prepared soil-test (albumin 3 mg/l in defibrinated sheep blood diluted at 1/10th)
2/ Cleaning in a I-WD
3/ Validation of sampling procedure and determination of residual proteins

Results

<table>
<thead>
<tr>
<th>Conc (µg/ml)</th>
<th>Median (n=24)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-WD 1</td>
<td>0.5</td>
<td>[0.5 - 45.1]</td>
</tr>
<tr>
<td>I-WD 2</td>
<td>2.5</td>
<td>[0.5 - 17.4]</td>
</tr>
</tbody>
</table>

Pr EN ISO 15-883:
Positivity threshold set at 2 mg/m² residual proteins.
Contamination of 10 µg, i.e. 5 µg/ml with sampling procedure.

Positivity threshold reached for 20% suction tubes.

Checking of cleanliness prior to sterilization:
Scrutiny of **external surfaces** with zooming lens

**HOLLOW MEDICAL DEVICES (MDs)**
- Coelioscopy MDs,
- Stomatology MDs (straight or contra-angle handpieces, turbines)
- Flexible endoscopes

Assessment of cleaning efficacy with **soil tests** of machines allowing the internal irrigation of hollow MDs
MATERIALS AND METHOD: Main points

Depending on the tested equipments,

**Detergents are:**

- Quaternary ammonium solutions
- Neutral enzymatic solutions

Chemical activity: assessed with detergent
Mechanical activity: assessed with water

A minimum of 5 assays per cycle or per sequence

Successful tests: absence of residual soils
Hollow Medical Devices

Coelioscopy MDs

Stomatology MDs

Flexible endoscopes
Hollow Medical Devices

Coelioscopy MDs

Stomatology MDs

Flexible endoscopes
**Materials and method**

**Ultrasonic Irrigator** (PHAGOGENE) + detergent (IV ammonium) 0.5% (ANIOS)

15mn

**Results**

Lumcheck®, Tosi-Lumcheck® (SPS AMCOR) I-WD with coelioscopy trolley (STERIS) + tri-enzymatic detergent 0.5% (ANIOS)

Cleaning at 50°C during 15mn

Tosi-Lumcheck: 95% hydrosoluble proteins 5% fibrin
### Materials and method

**Coelioscopy MDs**

- Stomatology MDs
- Flexible endoscopes

### Results

<table>
<thead>
<tr>
<th>MDs</th>
<th>Number of successful tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasonic irrigator unique with detergent (n=14)</td>
<td>0/14</td>
</tr>
<tr>
<td>Ultrasonic irrigator unique with water (n=10)</td>
<td>0/14</td>
</tr>
<tr>
<td>Ultrasonic irrigator with detergent + coelioscopy trolley (n=11)</td>
<td>2/11</td>
</tr>
<tr>
<td>Ultrasonic irrigator with water + coelioscopy trolley (n=10)</td>
<td>10/10</td>
</tr>
<tr>
<td>Coelioscopy trolley unique (n=10)</td>
<td>10/10</td>
</tr>
<tr>
<td>Ultrasonic irrigator with detergent + rinsing + coelioscopy trolley (n=10)</td>
<td>2/10</td>
</tr>
</tbody>
</table>
Number of successful tests

- Value of ultrasonic irrigator?
- BUT in this study, just cleaning and not decontamination assessment

Ultrasonic irrigator with water + coelioscopy trolley (n=10) 10/10

Coelioscopy trolley unique (n=10) 10/10

Materials and method

Results
Inadequate rinsing?
Incompatibility between IV ammonium detergent and enzymatic detergent?
Fixing effect of IV ammonium detergent?

Number of successful tests

- Ultrasonic irrigator with detergent + coelioscopy trolley: 2/11
- Ultrasonic irrigator with detergent + rinsing + coelioscopy trolley: 2/10

- Inadequate rinsing?
- Incompatibility between IV ammonium detergent and enzymatic detergent?
- Fixing effect of IV ammonium detergent?
Hollow Medical Devices

Coelioscopy MDs

Stomatology MDs

Flexible endoscopes
Whole sterilization process of Stomatology MDs in CSSD: cleaning, packaging, moist heat sterilization

French Pharmacy Inspection Avicenne, 2004

French market:
- Few cleaning equipements available
- Only for liberal dentists
- Without real scientific validation
### Materials and method

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAC 2000 (W&amp;H)</td>
<td>2-minute internal cleaning with pressurized water</td>
</tr>
<tr>
<td>Alphaklave 12 (HCME)</td>
<td>9-minute cleaning at 60°C Detergent à 5%</td>
</tr>
<tr>
<td>I-WD LM 25 equipped</td>
<td>15-minute cleaning at 50°C Enzymatic detergent 0.5% Supply in softened water</td>
</tr>
<tr>
<td>with a stomatology trolley (STERIS)</td>
<td></td>
</tr>
</tbody>
</table>

- **Surrogate device with « inner » Tosi Lumcheck® simulating stomatology MD**
Coelioscopy MDs
Stomatology MDs
Flexible endoscopes

**Materials and method**

**Results**

**DAC 2000**
- Initial parameters: Pressurized water during 2mn
- Unsuccessfull Results

**Alphaklave 12**
- Initial parameters: Cleaning at 60°C during 9mn, Ammonium IV detergent à 5%
- Modifications of:
  - cleaning temperature: 52.5°C, 50.5°C
  - cleaning time: 9mn to 15mn
  - detergent concentration: 8%, 5%, 1.5%
- Unsuccessfull Results

**Stomatology trolley in I-WD STERIS**
- Initial parameters: Cleaning at 50°C during 15mn, Enzymatic detergent 0.5%
- Successful Results
- Lubrification is to be reappraised
Materials and method

**Results**

- **Coelioscopy MDs**
- **Stomatology MDs**
- **Flexible endoscopes**

**DAC 2000**

- FAILED

**Alphaklave 12**

- FAILED

**Stomatology trolley in the I-WD STERIS**

- SUCCESSFULL
Hollow Medical Devices

Coelioscopy MDs

Stomatology MDs

Flexible endoscopes
Endoscope Washer Disinfector

Peristaltic pump:

- 10-liter sink
- Detergent (IV ammonium) 0.5%

**Materials and method**

**Results**

- Flexicheck
  - Simulation of an endoscope
  - Endoscope surrogate
  - Flexicheck internal Ø ≈ endoscope channel Ø

- Soil test:
  - Residues such as defibrinated blood
  - Residues such as polysaccharides
Connecting to « Flexicheck® + Tosi-Flexicheck® » with the peristaltic pump and the E-WD.
1 Tosi-Flexicheck® / sequence

1/ Mechanical cleaning: Circulation of 0.5% detergent solution during 10mn with a peristaltic pump

2/ E-WD Single cleaning 10mn

2'/ Rinsing 5mn

3'/ E-WD Single cleaning 10mn

E-WD (enzymatic detergent)
1/ 1\textsuperscript{st} cleaning
2/ Rinsing
3/ 2\textsuperscript{nd} cleaning 24mn

Successfull tests:
No residual proteins and polysaccharides by visual checking
Single cleaning by peristaltic pump / Single cleaning in E-WD

Single cleaning by peristaltic pump / rinsing / single cleaning by E-WD

Double cleaning in a E-WD
**Step 1:**
Single cleaning by peristaltic pump (10mn)/ IV Ammonium detergent (0.5%)

**Step 2:**
Single cleaning in E-WD (10mn)/ polyenzymatic detergent (0.6%)

**Inefficacy of sequence**

"single cleaning by peristaltic pump / single cleaning in E-WD"

**Hypothesis:**

*Incompatibility* between IV ammonium detergent and polyenzymatic detergent

*Requested rinsing* between the two cleaning steps
Materials and method

Single cleaning by peristaltic pump / Single cleaning in E-WD

Single cleaning by peristaltic pump / rinsing / single cleaning by E-WD

Double cleaning in E-WD
**Step 1:**
Single cleaning by peristaltic pump (10mn)/
IV Ammonium detergent (0.5%)
RINSING by peristaltic pump (5mn)/water

**Step 2:**
Single cleaning in E-WD (10mn)/
polyenzymatic detergent (0.6%)

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**Insufficient rinsing ???
Fixing effect of IV ammonium detergent on soils ???

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**Presence of residual proteins and polysaccharides**

**Inefficacy by the sequence**

Single cleaning by peristaltic pump /
rinsing / single cleaning in E-WD
Additionnal assay

Single cleaning by peristaltic pump without detergent/ single cleaning by E-WD
Step 1: Single cleaning by peristaltic pump (10mn)/WATER

Presence of residual proteins and polysaccharides

Efficacy of the sequence *mechanical cleaning by peristaltic pump without detergent / single cleaning in a E-WD*

Step 2: Single cleaning in E-WD (10mn)/polyenzymatic detergent (0.6%)

Absence of residual proteins and polysaccharides

Fixing effect of IV ammonium detergent on soils
Materials and method

Single cleaning by peristaltic pump / Single cleaning in E-WD

Single cleaning by peristaltic pump / rinsing / single cleaning by E-WD

Double cleaning in E-WD
Double cleaning in E-WD (24mn)/ polyenzymatic detergent (0.6%):

Absence of residual proteins and polysaccharides

Efficacy of the sequence double cleaning in E-WD
In our experimental conditions (IV ammonium ± enzymatic detergents), soil tests on hollow instrumentation show:

- **detergence inefficacy of**
  - ultrasonic irrigator
  - peristaltic pump

Fixing effect of quaternary ammonium detergent
Requested rinsing and careful brushing before cleaning step for classical instrumentation

- **best cleaning performances** obtained:

  with coelioscopy trolley in a I-WD
  with stomatology trolley in a E-WD

« Lubrification remains to study of dynamic rotative pieces »
Control of the cleaning procedure

Cleaning efficacy - conformity testing
- Instrument Washer-Disinfector
- Endoscope Washer-Disinfector
- Cleaning Equipment of stomatology MDs
- Other equipments

Cleaning efficacy - performance test
- Change of detergent

For each cycle: Failure assessment
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