Parameters exerting Influence on Cleaning of flexible Endoscops

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Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination?

Reprocessing of angioscopes after contamination with duck-HBV

Ducks infected (%)

Cleaning:
- Detergent + Brush

Disinfection:
- GDA, 2%ig

Sterilisation:
- Ethylenoxoid, 6h

- Puffer
- Puffer + Des
- Reinig + Des
- Puffer + Ster
- Reinig + Ster
3 Definitionen

3.5 Microbial inactivation factor
measured change in microbial population, expressed as $\log_{10}$, caused by the lethal effect of the germicide
Efficacy of the disinfectant

- $\geq \log_{10} 6$ inactivation of vegetative bacteria including yeasts and yeast-like fungi
- $\geq \log_{10} 5$ inactivation of mycobacteria
- $\geq \log_{10} 4$ inactivation of fungal spores and viruses
- $\geq \log_{10} 6$ reduction of bacterial spores within 5 h exposure
Max. bioburden after patient use

<table>
<thead>
<tr>
<th>Type</th>
<th>cfu/endoscope</th>
<th>air</th>
<th>water</th>
<th>instrum.</th>
<th>suction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-channel</td>
<td></td>
</tr>
<tr>
<td>Gastroscope</td>
<td>5.2</td>
<td>3.5</td>
<td>7.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coloscope</td>
<td>9.5</td>
<td>7.8</td>
<td>7.0</td>
<td>9.0</td>
<td>10.2</td>
</tr>
<tr>
<td>Bronchoscope</td>
<td>7.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duodenoscope</td>
<td>7.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Chu et al, AJIC (1997)
Vesley et al, Gastroenterology Nursing (1999)
Alfa et al, Am J Infect Control 1999
3 Definitionen

3.6 Microbial reduction factor
measured change in microbial population, expressed as log_{10}, caused by the combination microbial inactivation factor and the physical removal of microorganisms
### Flexible endoscopes after use (log$_{10}$ cfu)

<table>
<thead>
<tr>
<th>Manual cleaning</th>
<th>before</th>
<th>after</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchoscopes</td>
<td>4.0 - 7.3</td>
<td>3.8 - 5.7</td>
</tr>
<tr>
<td>Duodenoscopes</td>
<td>0 - 7.5</td>
<td>3.7 - 5.3</td>
</tr>
<tr>
<td>Colonoscopes</td>
<td>5.7 - 9.5</td>
<td>3.2 - 4.6</td>
</tr>
</tbody>
</table>
Consensus Paper

- 11 societies (u. a. SHEA, APIC)

Change of the enzymatic cleaner after each Endoscope
Surface fixation of dried blood by glutaraldehyde and peracetic acid

<table>
<thead>
<tr>
<th>Type of active agent</th>
<th>Photograph</th>
<th>Stage of process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peracetic acid I</td>
<td></td>
<td>After disinfection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After cleaning</td>
</tr>
<tr>
<td>Glutaraldehyde I</td>
<td></td>
<td>After disinfection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After cleaning</td>
</tr>
<tr>
<td>QAC</td>
<td></td>
<td>After disinfection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After cleaning</td>
</tr>
<tr>
<td>QAC + Amines</td>
<td></td>
<td>After disinfection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After cleaning</td>
</tr>
</tbody>
</table>
Surface fixation of dried blood by glutaraldehyde and peracetic acid

<table>
<thead>
<tr>
<th>Active agent</th>
<th>No.</th>
<th>Rate of blood removal by exposure to disinfectant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peracetic acid</td>
<td>1</td>
<td>8.1%</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>2</td>
<td>39.0%</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>3</td>
<td>59.0%</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>4</td>
<td>56.6%</td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>5</td>
<td>21.7%</td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>6</td>
<td>23.6%</td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>7</td>
<td>8.1%</td>
</tr>
<tr>
<td>QAC</td>
<td>8</td>
<td>88.5%</td>
</tr>
<tr>
<td>QAC</td>
<td>9</td>
<td>88.2%</td>
</tr>
<tr>
<td>QAC + Amine</td>
<td>10</td>
<td>35.5%</td>
</tr>
<tr>
<td>Phenole</td>
<td>11</td>
<td>90.3%</td>
</tr>
<tr>
<td>Tenside</td>
<td>12</td>
<td>89.0%</td>
</tr>
</tbody>
</table>

Mean weight of blood soil on metal carriers after exposure to one of 12 disinfectants (‘soiled and disinfected’); means of eight parallel experiments
DIN ISO/TS 15883-5
Test soils for flexible endoscopes

- AT Annex Nigrosin, wheat flour, hens egg, E. faecium
- DE Annex I Blood, E. faecium
- DE Annex J Tetramethylbenzidine, hydrogenperoxide solution, bovine haemoglobin
- FR Annex F Biofilm formed by Pseudomonas aeruginosa
- NL Annex L Bovine serum albumin, procine mucin, bovin thrombin, bovin fibrinogen
- UK Annex R Glycerol, dehydrated hog mucin, horse serum, unbleached plain flour, aqueous safranine solution, water
- US Annex S Protein/organic soil (user preference), B. atrophaeus endospores
Annex I

- *E. faecium* $\geq 1 \times 10^{11}$ cfu/ml
- PTFE tubes 2 m, Ø 2 mm (transparent)
- Test soil
  - Sheeps blood, 0.2 % Heparin  9.50 ml
  - Susp. of test organism     0.35 ml
  - Protamin 1000              0.15 ml
- LAM
  - Liquefied-(Kanamycin Äsulin Azid) -Agar-Method
Intra-laboratory reproducibility of the German test method
Zühlsdorf, Floss, Martiny, J Hosp Infect (2005)
German test method
Test pieces cleaned

Liquid-Agar-Method
LAM
The importance of cleaning for the overall results of processing endoscopes

- A: Cleaning with water
  - Log$_{10}$ Reduction (mean) ( n = 28)
  - 1.1

- B: Pre-rinsing and cleaning with water
  - 2.0

- C: Pre-rinsing, cleaning with water and interim rinsing
  - 3.0
Efficacy of ten different cleaning processes in a WD for flexible endoscopes
Comparison of the cleaning efficacy and the cleaning and disinfecting efficacy of four washer-disinfectors for flexible endoscopes

Kircheis and Martiny, J Hosp Infect (accepted)

Figure 1: Medians of reduction factors (lg cfu) of the cleaning processes in the AdaptaScope (Cidezyme GI and water) and in the LS 2000 (Cidezyme GI, Liquid 52, and water) (n = 57)
Cleaning efficacy and enzyme activity of 18 cleaner

- P. aeruginosa - Biofilm
- Edinburgh soil
- Protease - activity
- Amylase - activity
## Enzyme activity

<table>
<thead>
<tr>
<th>Cleaner</th>
<th>Manufact.</th>
<th>Protease</th>
<th>Amylase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>fresh</td>
<td>old 14 d, 40°C</td>
</tr>
<tr>
<td>3M Rapid Auto</td>
<td>3M</td>
<td>0.38</td>
<td>0.38</td>
</tr>
<tr>
<td>Arbest BF</td>
<td>Arbos</td>
<td>0.21</td>
<td>0.19</td>
</tr>
<tr>
<td>Sterizime</td>
<td>Maruishi</td>
<td>0.20</td>
<td>0.19</td>
</tr>
<tr>
<td>Endofresh S</td>
<td>Olympus</td>
<td>0.35</td>
<td>0.16</td>
</tr>
<tr>
<td>Endokleen</td>
<td>Kendall</td>
<td>0.10</td>
<td>0.07</td>
</tr>
<tr>
<td>Endozyme AW plus</td>
<td>Ruhof</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>
The importance of cleaning for the overall results of processing endoscopes

Log$_{10}$ Reduction (mean)
(n = 36)

- Cleaning only
  - Cleaner A  > 5.0
  - Cleaner B  > 5.8

- Disinfecting only
  - Disinfectant A  > 8.7
  - Disinfectant B  > 9.6

- Cleaning and Disinfecting
  - Cleaner A + Disinfectant A  > 8.7
  - Cleaner B + Disinfectant B  > 4.8 - < 5.8
Summary

- Important parameter affecting cleaning
  - Level of burden
  - Cleaning
    - Efficacy of cleaning
      - Manually
      - Automatically
    - Efficacy of the cleaner
What we still need

“Cleaning assurance level”

“Disinfection assurance level”

respec.

“Process assurance level”