The importance of cleaning for the overall results of processing endoscopes

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Summary Reprocessing comprises three steps: cleaning, disinfection and—if required—sterilisation. While the extents of disinfection and of sterilisation are quantitatively defined, there are only imprecise (qualitative) definitions of cleaning. There are two main reasons for accurate cleaning. First organic and inorganic materials that remain on inner and outer surfaces will interfere with the efficacy of the disinfectants. In case of endoscopes this will lead to channel blockages; they remain undisinfecte. Second the bioburden found on endoscopes after use can be very high. Data available demonstrate that a bacterial burden of up to 10⁹ cfu/endoscope channel can be expected. Therefore it is necessary to perform a thorough cleaning. Studies using endoscopes showed a reduction in microbial counts by a factor of approximately 10⁴ by cleaning (manual and mechanical). Therefore in 2001 the German Society of Hospital Hygiene (DGKH) specified its requirements and recommendations for determining cleaning efficacy separately from those for disinfection. Cleaning and disinfecting can be done manually or mechanically, but it seems impossible to validate manual processes. However our studies in two different washer-disinfectors (WD) showed differences in cleaning efficacy. The tested cleaning processes showed different efficacies. Not all cleaning processes showed better results than water alone with regard to visible cleanliness and to a microbiological reduction E. faecium. Our results show that the evaluation of cleanliness exclusively by visible inspection is not sufficient, particular for the lumens of endoscopes. The results also show that a cleaning process may be very effective also in reducing micro-organisms present.

Endoscopy-related infectious risk

Only few cases of infection have been demonstrably shown to be caused by endoscopy. Micro-organisms isolated in patients whose infections were proven to be transmitted through gastroscopes include Salmonella spp. and Pseudomonas aeruginosa, while bronchoscopy-related infections mainly involve Pseudomonas aeruginosa and Mycobacterium tuberculosis, with Pseudomonas aeruginosa...
rarely originating from the previous patient examined, but rather from poor endoscope processing. Overall, cases of endoscopy-related infections caused by bacteria, viruses, fungi and helminths have been documented. The number of recognised infectious cases is certainly an underestimate: clearly, no clinic or private practice will be interested in publishing their documented endoscopy-related infections as this would result in the disclosure by name of the relevant institution or physician. For freelance endoscopists, detecting endoscopy-related infections is even more problematic since few infected patients will return to a physician whom he believes has caused his infection. Moreover, a possible HBV or HCV aetiology is virtually impossible to prove due to the long incubation periods associated with the causal agents.

Hence the assumption that an infection was transmitted during an endoscopic procedure is usually based on indirect evidence. Andrieu et al. conducted a survey in 2607 HCV-positive patients for possible risk factors.2 These authors found that the prevalence of HCV antibodies in patients who underwent an endoscopic procedure including biopsies (7.2%) significantly differed from the prevalence found in patients where no biopsy was taken (4.0%). Such evidence has prompted the Council of European Publishing to recommend the deferral of patients who underwent endoscopy from donating blood donors for twelve months following the endoscopic procedure;3 in Germany these patients are excluded for six months.4

**Quality of endoscope processing**

Chaufour et al. demonstrated the crucial role of cleaning of endoscopes in a study in which 125 angioscopes were contaminated with blood and duck Hepatitis B-virus.9 The authors found that if cleaning was insufficient, the virus remained infective despite glutaraldehyde disinfection or ethylene oxide sterilisation: a total of 22% of the ninety angioscopes examined were still infectious; it was only after adequate cleaning followed by disinfection or sterilisation, as was the case with the other 35 angioscopes, that all the devices were no longer infective.

Hence a draft standard for the processing of resterilisable medical devices stipulates that endoscope manufacturers shall specify a validable method for manual processing as well as at least one validated automated method using a washer-disinfector (WD).10 Obviously the endoscope manufacturer must specify a method for the users to process their endoscopes.

Various studies have shown how poorly endoscopes are processed. Kaczmarek et al. examined 71 processed endoscopes in 22 hospitals and four ambulatory care centres and found that 24% of the endoscopes had a bioburden of more than 100,000 cfu/channel.11 Ten years later Bader et al.12 published equally discouraging results. These authors evaluated endoscopes in 25 hospitals and 30 medical practices and found insufficiently processed devices were 57% after manual processing, 50% after semi-automatic processing and 12% after automatic processing; no comment was made regarding the type of WD. Of a total of 306 endoscopes evaluated 52% of gastroscopes, 46% of colonoscopes and 18% of duodenoscopes were
incorrectly processed. A study performed in Berlin, Germany, arrived at similar results. Of the 517 endoscopes examined in this study, the author found insufficiently processed devices were 23% after manual processing, 31% after semi-automatic and 20% after automatic processing, with no comment made as to the type of WD.

In a large gastroenterologic practice in Berlin, Germany, endoscopes were examined following processing. The practice owner tried to run his endoscope WDs at lower temperatures since he suspected that the recommended high processing temperatures (56 °C) might damage his endoscopes. After manual cleaning (Figure 1) an increase of the median viable counts on GSP-agar (selective for *Pseudomonas* spp. and *Aeromonas* spp.) was noted; following WD processing at 43 °C a marked increase of the median viable counts was found, showing that a contamination had taken place during the machine run. Only after resuming processing at were 56 °C these micro-organisms were no longer detected.

The German RKI guideline provides for controls of endoscopes at regular intervals. Endoscope channels shall be flushed with 20 ml physiological saline, with no bacterium detectable in one millilitre of rinse solution. *Escherichia coli*, other enterobacteriaceae, or enterococci shall not be detectable in 20 ml of rinse solution, as these micro-organisms originate from the patient previously examined and are thus considered indicators for inadequate cleaning and disinfection. Also, *Pseudomonas aeruginosa* shall not be detectable in 20 ml of rinse solution as it indicates inadequate final rinsing and/or drying. In addition, no infectious agents commonly associated with nosocomial infections such as *Staphylococcus aureus* shall be detectable, as they indicate endoscope contamination occurring after processing due to inadequate storage or hand hygiene of staff.

**Bioburden in flexible endoscopes**

In addition to processing flaws, the very high bioburden found in flexible endoscopes may explain why the processing results are so unsatisfactory. Chu *et al*.

Chu *et al*.

examinined colonoscopes after patient use and found viable counts of 7.1–10.3 (mean 9.8) log<sub>10</sub> cfu per device in the suction channels and 4.2–6.2 (mean 5.7) log<sub>10</sub> cfu per device on the surfaces; manual cleaning of the endoscope channels resulted in a decrease of viable counts by 4.7 log<sub>10</sub>-steps, whereas manual cleaning of the endoscope surface only produced a log<sub>10</sub> factor decrease of 1.4. Vesley *et al*.

Vesley *et al*.

obtained similar bioburden upon examination of instrumentation channels (viable counts of up to 10<sup>7.3</sup> cfu per device in gastroscopes and up to 10<sup>6.0</sup> cfu per device in colonoscopes). Alfa *et al*.

Alfa *et al*.

showed that manual cleaning can reduce the bioburden. However, the example of duodenoscopes (Table I) shows that even after patient use „negative“ detection results can be obtained. But after the manual cleaning step all duodenoscopes were contaminated—a clear indication that manual

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**Figure 1** Colony forming units (cfu) per mL, determined by rinsing the biopsy channel of gastroscopes with 50 mL NaCl-solution after patient-use, manual cleaning and processing in washer-disinfector with disinfection temperatures of 43, 51 and 56 °C (n = 40). Boxes show upper and lower 25% bound (25 and 75%). Bars indicate median values. ○ = outlier, * = extreme values.
processing can lead to (additional) contamination of endoscopes (e.g. through inadequate brushing or contaminated cleaning solutions). Conversely, soil-
ing was substantially reduced in gastroscopes and colonoscopes. Hence the Position Statement Paper on reprocessing gastrointestinal endoscopes rightly stipulates that the cleaning solution be renewed after each endoscope processed.\(^{19}\)

Viruses undoubtedly constitute a major problem. However, apart from the indirect evidence mentioned above, almost no information is available regarding the infective risk associated with endoscopes contaminated with viruses. Primary viral infections reported in Germany in 2001 include 3848 cases of Hepatitis B (of which only 2428 were confirmed due to incomplete data) as well as 8617 cases of Hepatitis C (of which only 4382 were confirmed due to incomplete data); these figures suggest that the endemic viral infection rate of the population is high and probably still increasing considerably,\(^{20}\) which further increases the danger of transmission of viruses through inadequately processed endoscopes.

Clearly, endoscope processing is problematic not only due to the bioburden involved, but also to the impact of non-microbial contaminants. However, little information is available regarding this issue. Alfa et al.\(^{18}\) evaluated colonoscopes, duodenoscopes and bronchoscopes after patient use and analysed the proteins, haemoglobin, carbohydrate and endotoxin burden of the devices. The authors showed to what extent the processing procedure was able to decrease the organic burden of the devices (e.g. in colonoscopes the median protein burden of 3250 μg detected at baseline decreased to 190 μg after processing).

## Relevance of the processing method

Both the cleaning method and the type of disinfecting agent influence the outcome of the processing result.

Chan-Myers and Chu\(^ {21}\) performed cleaning tests using deionised water as well as one non-enzymatic and two enzymatic cleaning agents. The authors contaminated six different materials with blood and serum and cleaned the test materials after drying of the contamination. Serum proved to be much easier removable than blood and with enzymatic cleaning agents yielding a better result.

Residual organic contaminants may be fixed on to medical devices that were not adequately pre-cleaned. A study by Kampf et al.\(^ {22}\) shows that disinfecting agents fix proteins and residual soil to different extents. Following artificial contamination and drying several metal surfaces were exposed to various disinfectants without previously undergoing cleaning; the disinfecting agents used included commercially available products containing peracetic acid, glutaraldehyde, quaternary ammonium compounds (QAC), or amines. The authors then attempted to clean the metal surfaces and noted that the cleaning agents showed little or no efficiency on metal surfaces previously exposed to peracetic acid or glutaraldehyde-containing products; conversely, cleaning was still possible following exposure to QAC or amines.

The safest method for processing medical devices is no doubt automatic processing with WDs. Within a machine cycle, which consists of various stages (prerinsing, cleaning, interim rinsing, disinfection and final rinsing as well as possibly drying) human shortcomings are eliminated. How-
ever, mistakes can still occur during the prep-
ration of devices to be processed mechanically (e.g. predisfection instead of prerinsing or pre-
cleaning, incorrect disassembly of complex devices, missing connection of lumened medical devices). Nevertheless adequate manual processing may well be superior to inadequate machine processing. Washer-disinfectors constructed according to prEN ISO 15883 part 1 should be favoured over most WDs available on the market today.

One study in which the automatic cleaning of flexible endoscopes was examined has raised many questions.\(^ {23}\) In this study the cleaning agents were used according to the manufacturers’ product data sheets, i.e. no attempt was made to optimise specific processes. Test pieces (length 2 meters, diameter 2 millimeters) were contaminated with an artificial test soil (sheep blood, heparin, protamine, and Enterococcus faecium\(^ {24}\)) and processed in a WD without single channel connectors. After completion of the cleaning stage the process was interrupted and the test pieces were inspected visually for cleanliness and tested microbiologically for the presence of test organisms in the flushing solution. Only one process emerged to achieve visual cleanliness as well as a significant decrease in

### Table I

Soiling levels for patient-used endoscopes, log\(\text{_{10}}\) cfu (mean) before and after cleaning (\(n = 30\))\(^ {18}\)

<table>
<thead>
<tr>
<th>Endoscope type</th>
<th>N</th>
<th>CFU/endoscope (log(_{10}))</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Before cleaning</td>
</tr>
<tr>
<td>Bronchoscopes</td>
<td>10</td>
<td>4.0–7.3</td>
</tr>
<tr>
<td>Colonoscopes</td>
<td>10</td>
<td>5.7–9.5</td>
</tr>
<tr>
<td>Duodenoscopes</td>
<td>10</td>
<td>0–7.5</td>
</tr>
</tbody>
</table>
the viable counts of *E. faecium* (Figure 2); the other processes did not lead to satisfactory visual cleanliness of the test pieces. Also, many processes turned out to be inferior to water with respect to the removal of the test organism, and at times partial cleanliness was seen although the viable counts of the test organism had shown little or no decrease. Wider variation margins of the results obtained with some cleaning processes suggest that in addition to the formulation of the cleaning agent, the construction design of the WD may also substantially influence the processing outcome.

These tests were repeated in a further study performed with the same cleaning agents, but with a different WD equipped with both a single channel connector and a channel separator. In this study, seven of the ten processes tested achieved visual cleanliness of the test pieces; only three products did not fulfil the criterion for 'excellent cleanliness'. However, only a few processes achieved better results than water alone in terms of removal of the test organism. This may be due to the fact that no attempt was made to optimise the efficacy of the respective cleaning agent: rather, the products were used sparingly (using the lowest concentration and the shortest exposure time) according to the manufacturers' product data sheets whose content is often extremely unclear. In addition, the full potential of the WD was not utilised unless specifically required in the product data sheets. In any case users are well advised to obtain full information before using a specific product; they should not rely on statements according to which the efficacy of all cleaning agents is allegedly identical.

Upon comparing these two studies it appears that the WD equipped with a single channel connector produced substantially better results, both with cleaning agents containing enzymes and enzyme-free cleaners. Table II shows an example of the mechanical efficacy of the tested machine: the cleaning step alone produces a $\log_{10}$ reduction factor of the test organism count of 1.1, and of 2.0 if the machine cycle includes a cold water prerinse; if in addition the cycle includes an interim rinse (prior to the disinfection stage), the removal of the test organism is further increased by a $\log_{10}$ reduction factor of 3.0. A $\log_{10}$ reduction factor of 4.1 can be achieved through washing alone with addition of cleaner No. 1. On the other hand cleaning agent No. 2, actually worsened the cleaning result obtained water alone, so far we have no satisfactory explanation for this finding.

In addition to the evaluation of the whole process, the German recommendations for evaluation of WD for flexible endoscopes provide for separate examination of both the cleaning and the disinfection stages. An interesting phenomenon was seen in tests pieces artificially contaminated as described above (Table III); within a machine cycle that included a cold water prerinse, a cleaning stage and an interim rinse, both cleaning agents examined displayed excellent cleaning efficacy, with $\log_{10}$ reduction factors of the test organism count of $>5.0$ and $>5.8$ respectively as well as visually clean test pieces. Disinfectants A and B were able to kill the test organisms (reduction of test organism count below level of detection) in combination with a cold water prerinse, without a preceding cleaning stage. However, upon testing the whole process, the results were different. While the process involving cleaning agent A and Figure 2 Cleaning efficacy of 12 cleaning processes presented as visible cleanliness (<0.5 = very poor visible cleanliness, 0.5 to <1.5 = poor visible cleanliness, 1.5 to <2.5 = adequate visible cleanliness, ≥2.5 = excellent visible cleanliness) and mean reduction factors ($\log_{10}$ cfu) for six test pieces. Nine cleaners (numbers 1–9, circle: enzyme free cleaner, square: enzymatic cleaner) and water (triangle) were tested in a washer–disinfector using a test model (*n* = 60). Cleaner 1 was tested using three different processes (1A, 1B, 1C). For cleaner 2, two different processes were tested (2A, 2B).

<table>
<thead>
<tr>
<th>Process stage</th>
<th>$\log_{10}$ Reduction (mean values)</th>
</tr>
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<tbody>
<tr>
<td>Washing</td>
<td>1.1</td>
</tr>
<tr>
<td>Prerinsing and washing</td>
<td>2.0</td>
</tr>
<tr>
<td>Prerinsing, washing and interim rinsing</td>
<td>3.0</td>
</tr>
<tr>
<td>Washing with cleaner 1</td>
<td>4.1</td>
</tr>
<tr>
<td>Washing with cleaner 2</td>
<td>0.3</td>
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Table II Cleaning efficacy with water and with two different cleaners, tested in washer–disinfector, using a test model (*n* = 28)
disinfectant A also led to a reduction of the test organism count below level of detection, an incompatibility between cleaning agent and disinfectant was seen in the process involving cleaning agent B and disinfectant B. Hence it is strongly recommended to the process as a whole is examined and the individual processes of cleaning and of disinfecting separately.

Conclusions

In view of the alarming data regarding the bioburden found on endoscopes after patient use the German Society for Hospital Hygiene (Deutsche Gesellschaft für Krankenhaushygiene, DGKH) has revised and improved in 2001 the recommendations that the ‘Working party and task force of the DGKH’ issued in 1995 on the subject of testing WDs. It is stipulated that upon validation of endoscopic processes by means of test pieces both visual cleanliness and the reduction of the test organism count shall be tested after completion of the cleaning stage (of note, this does not apply to routine examinations of WDs). Cleaning alone, disinfection alone, and the whole process (consisting of cleaning and disinfection) shall achieve a total reduction of the test organism count by at least a factor of $10^5$. Virus loads of up to $10^{11}$ per drop of blood detected in patients suffering from acute hepatitis clearly show that this requirement is not too stringent. In such cases the killing power of disinfectants, which shall reduce test organism count by a factor of $10^4$ steps according to current guidelines, is insufficient. For the processing of endoscopes we thus urgently need a ‘cleaning assurance level’ and in addition a ‘disinfection assurance level’ to ensure that the high bioburden found on endoscopes after patient use can actually be reduced through adequate processing to such an extent that any detriment to the patient’s health becomes unlikely.

References

10. prEN ISO 17664. Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices. 07/2003.


