Alfa MJ, Degagne P, Olson N. Worst-case soiling levels for patient used flexible endoscopes before and after cleaning. *Am J Infect Control* 1999;27:392-401.

Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning

Background: The soiling levels of patient-used narrow-lumened flexible endoscopes were assessed for bronchoscopes, duodenoscopes, and colonoscopes. The effect of cleaning on the soil composition and concentration was evaluated.

Design: Suction channels from 10 each of bronchoscopes, duodenoscopes used for endoscopic retrograde cholangiopancreatography, and colonoscopes were assessed immediately after patient use for the levels of bilirubin, hemoglobin, protein, sodium ion, carbohydrate, endotoxin, and viable bacteria. Another 10 suction channels of each type of endoscope were evaluated for the same components after routine cleaning but before processing by high-level disinfection or sterilization for subsequent clinical use.

Results: Recognizing that only soluble components could be quantified, the worst-case soil levels in the suction channels (the average surface area of these channels was 45.6 cm(2), 149.8 cm,(2) and 192.0 cm(2) for bronchoscopes, duodenoscopes, and colonoscopes, respectively) were protein 115 microg/cm(2), sodium ion 7.4 micromol/cm(2), hemoglobin 85 microg/cm(2), bilirubin 299 nmol/cm(2), carbohydrate 29.1 microg/cm(2), endotoxin 9852 endotoxin units/cm(2), and bacteria 7.1 (log(10)) colony-forming units (CFU)/cm(2). Colonoscopes had 4 to 5 times greater soiling on average compared with the other endoscope types. Routine cleaning reduced the levels of bilirubin to below the limits of detection for all endoscopes evaluated (limits of detection were <1 nmol/mL). After cleaning, residual hemoglobin was detectable in bronchoscopes only. After cleaning, the levels of protein, endotoxin, and sodium ion all were reduced fivefold to tenfold for all types of endoscopes. Carbohydrate was reduced to lower than the limit of detection for all endoscopes after cleaning, except the duodenoscopes. The average load of viable bacteria was reduced from 3 log(10) to 5 log(10) CFU/cm(2) (which represents 5.9-9.5 log(10) CFU/endoscope channel) after patient use to approximately 2 log(10) CFU/cm(2) (which represents 3.2-5.3 log(10) CFU/endoscope channel) after cleaning.

Conclusions: These data demonstrated that cleaning effectively reduced or eliminated many components of soil, but a substantial amount of viable bacteria and protein remained. Hemoglobin levels in before samples indicated that blood was not present in high concentrations in the suction channels of the majority of flexible endoscope samples. Soil that mimics the worst-case composition from patient-used endoscopes would be ideal for simulated-use studies for such medical devices.

Alfa, M. J., R. Nemes, N. Olson, A. Mulaire. Manual Methods Are Suboptimal Compared With Automated Methods for Cleaning of Single-Use Biopsy Forceps. *Infect Control Hosp Epidemiol* 2006, 27:841-846.

Manual Methods Are Suboptimal Compared With Automated Methods for Cleaning of Single-Use Biopsy Forceps

Objective: Most reusable biopsy forceps and all of the currently available single-use biopsy forceps do not have a port that allows fluid flow down the inner tubular shaft of the device. Reusable biopsy forceps are widely used and reprocessed in healthcare facilities, and single use biopsy forceps are reprocessed either in-house (eg, in Canada and Japan) or by third-party reprocessors (eg, in the United States). The objective of this study was to determine the cleaning efficacy of automated narrow-lumen sonic irrigation cleaning, sonication-only cleaning, and manual cleaning for biopsy forceps.

Design: A simulated-use study was performed by inoculating the inner channel of single-use biopsy forceps with artificial test soil containing both Enterococcus faecalis and Geobacillus stearothermophilus at concentrations of 106 colony-forming units per milliliter. The cleaning methods evaluated were manual cleaning, sonication-only cleaning, and "retroflush" cleaning by an automated narrow-lumen irrigator. Bioburden and organic soil reduction after washing was evaluated. Forceps used in biopsies of patients were also tested to determine the worst-case soiling levels.

Results: Only retroflush irrigation cleaning could effectively remove material from within the shaft portion of the biopsy forceps: it achieved an average reduction of more than 95% in levels of protein, hemoglobin, carbohydrate, and endotoxin. However, even this method of cleaning was not totally effective, as only a 2 log10 reduction in bioburden could be achieved, and there were low residual levels of hemoglobin and carbohydrate.

Conclusion: The data from this evaluation indicate that manual and sonication-only cleaning methods for biopsy forceps were totally ineffective in removing material from within the biopsy forceps. Even the use of retroflush cleaning was not totally effective. These findings suggest that in-hospital reprocessing of biopsy forceps with currently available equipment and cleaning methods is suboptimal.

Alfa MJ, Jackson M. A new hydrogen peroxide-based medical device detergent with germicidal properties: comparison with enzymatic cleaners. *Am J Infect Control* 2001; 29:1-10.

A new hydrogen peroxide–based medical-device detergent with germicidal properties: Comparison with enzymatic cleaners

Background: The objective of this study was to evaluate the efficacy of the cleaning and bacterial killing ability of a new non–enzyme-based formulation (killing detergent solution [KDS]) compared with commercially available enzymatic detergents that included Metrizyme (Metrex Research Division of Sybron Canada Ltd. Morrisburg, Ontario) and Gzyme (Germiphene Corp, Brantford, Ontario). KDS is a hydrogen peroxide–based detergent formulation that combines cleaning efficacy with the ability to kill microorganisms. The KDS formulation helps ensure the protection of the health care worker from infectious risk during the

soaking and cleaning stages of medical device reprocessing and reduces the bioburden on devices before sterilization/disinfection.

Methods: Test organisms that included Enterococcus faecalis, Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa were suspended in artificial test soil (ATS-B; patent submitted), inoculated at 10^6 colony forming units per carrier and dried overnight before detergent exposure. The ATS-B mimics the blood, protein, carbohydrate, and endotoxin levels of patient-used medical devices. Plastic lumen carriers and a flexible colonoscope were used for surface and simulated-use testing, respectively.

Results: The results for the microbial challenge dried onto polyvinyl chloride (PVC) carriers demonstrated that the ability of KDS to remove protein, blood, carbohydrate, and endotoxin from surface test carriers was as effective as the enzyme detergents that were evaluated. Furthermore, KDS was able to effect approximately a 5-Log_{10} reduction in microbial loads with a 3-minute exposure at room temperature, whereas none of the other detergents were as effective. In simulated-use testing of a soiled colonoscope, KDS was significantly better at ensuring microbial killing compared with Gzyme and Metrizyme and was equivalent to the enzymatic detergents in cleaning ability.

Conclusions: In summary the KDS has excellent microbial-killing ability in 3-minute exposures at room temperature and cleans as well as the existing enzymatic detergent formulations that were tested.