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Measuring the efficacy of manual endoscope cleaning

A discussion on the use of ATP monitoring and microbial surveillance.

by Grace Thornhill, PhD

Transmission of pathogens by inadequately reprocessed flexible endoscopes is well documented in scientific literature and is recognized as a significant patient risk. In the wake of recent, multiple outbreaks associated with contaminated duodenoscopes the industry has been looking for help from experts, government agencies and professional associations.

On February 19, 2015 the Food and Drug Administration (FDA) issued a safety communication addressing the concerns around reprocessing duodenoscopes. The FDA stated that the complex design of duodenoscopes may impede proper reprocessing and goes on to state that “meticulous cleaning of duodenoscopes prior to high-level disinfection should reduce risk of transmission of infection, but may not entirely eliminate it.” A number of recommendations were made to minimize the risk of pathogen transmission. Meticulous manual cleaning was emphasized along with the implementation of a comprehensive quality control (QC) program that includes written procedures for monitoring training and adherence to reprocessing procedures. This QC program should also include documentation of equipment, tests, process and quality monitors used during reprocessing.

Current guidelines for reprocessing flexible gastrointestinal (GI) endoscopes focus on cleaning and high-level disinfection (HLD). The various organizations and associations have developed detailed guidance documents that describe a specific sequence of procedures deemed appropriate for endoscope reprocessing. Flexible GI endoscopes should first be completely cleaned and then high-level disinfected or sterilized. Although there can be over 120 different steps involved in reprocessing a flexible GI endoscope, the process can be broken down into six basic tasks:

1. Pre-cleaning at point of use
2. Leak Testing
3. Cleaning
4. High-level disinfection or sterilization
5. Drying with alcohol and forced air
6. Storage

Cleaning is different from disinfection and sterilization

It is important to note that cleaning, disinfection and sterilization are separate and distinct processes. Cleaning is the physical removal of soil whereas disinfection and sterilization are processes that kill microorganisms under a defined set of conditions. Cleaning accomplishes several goals:

- Minimizes soil transfer from one patient to another or between uses on the same patient
- Prevents accumulation of residual soil throughout the life of the product
- Allows for subsequent, successful disinfection or sterilization steps

Disinfection and sterilization have one purpose, to kill microorganisms. The first and most important step in the prevention of transmission of infection by an endoscope is manual cleaning of the endoscope with detergent solution and brushes. This strong statement made by the American Society for Gastrointestinal Endoscopy (ASGE) highlights that the correct performance of manual cleaning is of paramount importance and implies that it should have the same attention to quality control as high-level disinfection and sterilization.

At the 2011 FDA/AAMI Summit on Reprocessing, the topic of manual cleaning was designated as one of the seven clarion themes in their call to action to address the heightened patient safety concerns surrounding reprocessing of reusable medical devices. The clear message in the current literature and the recent CRE outbreak investigations is that manual cleaning is clearly not being performed consistently or correctly resulting in serious negative patient outcomes.

The purpose of cleaning, disinfection and sterilization are often misunderstood and can lead to confusion when implementing
reprocessing procedures. An effective quality control program can support the proper execution of reprocessing steps. “Any slight deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection.”14 The lack of consistent and comprehensive quality control for the reprocessing of flexible GI endoscopes is a problem that is reflected in the current rate of reprocessing lapses.9

How do you define clean?
To ensure that a process is being performed correctly and consistently, quality control (QC) measures are typically put into place. Quality control measures are routinely performed for the high-level disinfection step in endoscope reprocessing whereas effective QC measures are not commonly implemented to verify effective manual cleaning.10 One explanation for this gap in endoscope reprocessing QC is that there is confusion on how best to implement an effective QC program in the absence of a consistent definition of “what is clean?”

Cleaning of many reusable medical devices is performed with the use of automated washers in addition to manual cleaning methods. Even in the absence of a standard definition of “clean” there are current recommendations for monitoring the efficacy of cleaning; these are defined in AAMI ST91, Flexible and semi-rigid endoscope reprocessing in health care facilities.3 In 2014, AORN released an updated guideline on the cleaning and care of surgical instruments. They recommend that “quantitative testing be used in a quality monitoring program to observe for trends and to monitor performance of a washer disinfector/decontaminator or of manual processes.”12 In AAMI ST91 and the AORN guideline, monitoring methods are based on the use of cleanliness markers such as adenosine triphosphate (ATP), protein, hemoglobin and bioburden levels. A cleanliness marker is a molecule that is present in soils found on contaminated medical devices. When cleanliness marker levels are measured quantitatively one can assess the type and amounts of soil present on a medical device. For many of the cleanliness markers, validated benchmark values have been established. For example, AAMI ST91 states that in order for an endoscope to be considered clean, no more than 6.4 µg/cm² of protein or 4 log10/cm² bioburden or 200 RLU of ATP should be present.5

It is important to understand just what a validated, benchmark value means. It is not intended to correlate with infection risk but instead is intended to reflect how well the manufacturer’s instructions for cleaning were followed.10 There are a variety of commercially available, rapid-indicator products that are intended to assess the cleanliness of endoscopes in real-time and can therefore facilitate early detection of reprocessing problems.

ATP is a universal cleanliness marker
ATP is a molecule that is universally present in all living organisms and is therefore present in clinically relevant soils (tissue, cells, excretions, secretions, body fluids and all microbes). In the case of one commercially available system, the benchmark of 200 RLU has been validated against other cleanliness markers and is used to measure the efficacy of cleaning flexible endoscopes.12 What does this mean? It means that if an endoscope is tested for levels of ATP and found to be below 200 RLU, then it also meets the cleanliness standards for protein and bioburden.12 Not all ATP systems have validated pass/fail benchmarks so end-users should ask for validation data before using an ATP monitoring system.

Microbiological surveillance
A different measure of endoscope reprocessing efficacy is a measurement of both the number and types of bacteria present after the completion of high-level disinfection. The Centers for Disease Control and Prevention (CDC) has issued an interim guideline on the microbial surveillance of duodenoscopes with the goal of assessing the adequacy of reprocessing.13 To reduce the chance of microbial survival and transmission the interim guideline emphasizes that special attention needs to be placed on manual cleaning as well as drying. A detailed procedure for culturing duodenoscopes after completion of reprocessing is outlined. The CDC states that the sensitivity of the recommended culture methods have not been evaluated and that false negative results are a possibility. The interim guideline also does not recommend a particular frequency for microbial surveillance. The surveillance methods looks for two types of microbes, those of high-concern that are associated with disease and those of low-concern, more often associated with sampling error and low incidence of disease.

Limitations of microbial surveillance and ATP measurements
Microbiological surveillance is considered by many to be the gold standard for assessment of the efficacy of endoscope reprocessing. After all, the prevention of microbial growth and ultimately transmission is everyone’s goal. However, what is not being discussed are the limitations of the methods used to culture flexible endoscopes and how that affects risk assessment for transmission of endoscope-associated infections (EAIs). The recommended procedures use traditional plate and broth culture techniques as well as techniques for selective and differential growth of gram-negative bacteria. Each of these techniques has limitations that should be understood.

The CDC recommends that organisms of lower-concern be at levels of <10 CFU (colony forming units) when enumerated by the aerobic plate count method.13 The plate count method shows considerable variability as low levels of bacteria (<10 CFU) are below the “noise level” of plate count technology. In other words, plate count technology is not sensitive enough to reliably pick up low levels of bacteria. Valid plate counts occur when colonies are within a defined countable range which is 25-250 CFU per plate.14 Plate count technology seriously under-estimates the number of bacteria present on a surface. Typically only 0.1-10 percent of viable bacteria can be grown using aerobic culture techniques.14 The ramifications of these limitations is that there is a significant chance that false negative results could lead to the release of a quarantined endoscope when in actuality it might still be contaminated.

The American Society for Microbiology (ASM)15 and the FDA Advisory Panel on Gastroenterology and Urology Devices16 state that the current CDC surveillance protocol should not be used for routine surveillance. The surveillance protocol itself states that the method is not validated and that the sensitivity is unknown.13 The surveillance protocol was developed mainly for outbreak situations and it is not known if the data has utility for routine surveillance.13,15,16 In addition to the unknown sensitivity of the method, the surveillance protocol does not result in the detection of all bacteria and does not detect viruses or parasites. Bacterial counts do not substantiate the level of cleanliness nor can they indicate any level of HLD or sterilization. For these reasons, the utility of the surveillance protocol for routine use is still under consideration.13,15,16

The use of ATP measurements for assessment of cleanliness has been around for the last 35 years. Although its utility is well known there are some limitations. The biggest issue is that the relative light unit (RLU) is not standardized. There are multiple manufacturers of ATP systems and they all use a different scale making comparison of systems difficult. Not all ATP
systems have validated pass/fail thresholds so the utility of the data must be carefully understood. Finally, using ATP on a routine basis may be costly as it requires the use of expensive consumables and the purchase of hand-held equipment and software.

Which is better ... Microbial surveillance or ATP monitoring? Since ATP monitoring was introduced to the healthcare industry, there have been lively discussions on the relative merits of ATP monitoring vs. microbial surveillance for assessment of endoscope reprocessing efficacy. The very nature of the question demonstrates that there remains ongoing confusion about how these two methods are used to assess endoscope reprocessing efficacy. In reality, this is not an either-or decision, the use of ATP monitoring or microbial surveillance depends on the question being asked regarding endoscope reprocessing.

When it comes to ATP monitoring, there are several common misconceptions with regard to what the data says, or should say about the efficacy of endoscope reprocessing. There is a tendency to think that ATP does not make for a good cleaning monitor because it does not correlate with the level of microbial contamination (as defined by aerobic plate counts). In a recent publication, it was stated that if an endoscope is cleaned to the point where ATP levels are at 200 relative light units (RLU) there could still be a microbial load of 10^6 colony-forming units (CFU). For this reason it was argued that ATP levels were a poor indicator of microbial contamination.

This conclusion is based on the incorrect assumption that ATP levels do fact in correlation with bacterial counts. ATP measurements are not just another way to measure the level of bacterial contamination. The ATP signal is composed of donations from all organic sources: human cells, tissues, excretions, secretions, body fluids as well as microbes (bacteria, yeast, molds, parasites). In contrast, bacterial counts (CFU) only measure one component of complex clinical soils, the bacteria. It is inappropriate to expect that something which measures everything (ATP) will correlate with something that only measures one thing (CFU).

A better question might be, is the accepted cleanliness threshold for bioburden too high? Currently, a properly cleaned endoscope can still have a bioburden level of 10^3 colony-forming units (CFU). For this reason it was argued that the accepted level of bioburden was 200 RLU of ATP the bioburden levels also met the proposed lower threshold of <2 log10 CFU/cm². Alfa et al argued that the accepted level of bioburden for a manually cleaned endoscope should be lowered to <2 log10 CFU/cm². Alfa et al demonstrated that if an endoscope was cleaned to a benchmark of 200 RLU of ATP the bioburden levels were at 200 relative light units (RLU) there could still be a microbial load of 10^6 colony-forming units (CFU). For this reason it was argued that ATP levels were a poor indicator of microbial contamination.

Another common point of confusion is an expectation that ATP monitoring should be validated as a risk factor for patient-to-patient transmission of pathogens. This misses the point of monitoring cleaning efficacy using ATP. ATP pass/fail thresholds, that are validated, were developed to assess if manual cleaning was performed according to manufacturer’s instructions, they were never meant to be a measure of the risk for pathogen transmission. Tools are developed to perform a specific job. Another way to look at this would be to say that expecting ATP values to predict the risk of transmission is like asking a hammer to do the job of a screwdriver; one can try, but the results will not be good.

There can be no doubt that meticulous manual cleaning is the most important step in the reprocessing of endoscopes. The current standards and guidelines now state that the efficacy of cleaning should be verified using a method other than visual inspection. The current debate on the relative merits of ATP monitoring and bacterial surveillance for monitoring endoscope reprocessing has been confusing as the discussion has not included a thorough discussion on the underlying assumptions as well as advantages and limitations of each method. It is important to understand the advantages and limitations of any verification method as well as use the data to answer the questions the assays were designed to answer. Cleanliness and risk of transmission are two different questions and require different assessment methods.

Conclusion
There is substantial evidence from documented reprocessing lapses, transmissions and outbreaks that the quality and effectiveness of the reprocessing of flexible endoscopes is inconsistent. One way to improve consistency is to increase the amount of available cleaning verification information on the effectiveness of the critical cleaning steps. The use of rapid cleanliness monitors, such as ATP based systems, on each endoscope will assist the reprocessing staff by providing real time feedback on the effectiveness of the process, in time for the staff to address any cleaning quality issues before the endoscope is moved to the next step in the process. Microbial surveillance should be used as an audit tool, at appropriate test intervals defined by the facility. The test limitations of sensitivity and time required to get test results make this process better suited to quality control audits as it is impractical as a routine monitoring tool.
Measuring the efficacy of manual endoscope cleaning

Circle the one correct answer:

1. According to the FDA, meticulous manual cleaning should help in reducing the risk of pathogen transmission.
   A. True
   B. False

2. Manual Cleaning is always performed before high-level disinfection.
   A. True
   B. False

3. When performed properly, high-level disinfection process results in the removal and death of bacteria.
   A. True
   B. False

4. The most important step in endoscope reprocessing is successful high-level disinfection.
   A. True
   B. False

5. Cleaning efficacy can be quantitatively measured.
   A. True
   B. False

6. AAMI ST91 states that in order for an endoscope to be considered clean no bacteria should be present.
   A. True
   B. False

7. Validated Pass/Fail thresholds for cleaning verification assays mean that the endoscope is safe to use on a patient.
   A. True
   B. False

8. ATP results do not correlate with bacterial counts because ATP measures all organic material and bacterial counts only measure one thing, bacteria.
   A. True
   B. False

9. Microbial surveillance may not be a good indicator of endoscope reprocessing efficacy because it cannot measure the adequacy of high-level disinfection.
   A. True
   B. False

10. Quality control methods for endoscope reprocessing can include both ATP monitoring and microbial surveillance if one understands the advantages and limitations of each method.
    A. True
    B. False

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