REPROCESSING REUSABLE FLEXIBLE GASTROINTESTINAL ENDOSCOPES – WHAT ARE THE CHALLENGES?

WHITE PAPER

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Gastrointestinal endoscopies are performed worldwide, and the numbers are increasing each year due to the minimally invasive but highly beneficial procedures. However, gastrointestinal endoscopes can become highly contaminated during use, and thus proper reprocessing is of great importance before the device is used in a new patient [1].

THE SPAULDING CLASSIFICATION SYSTEM

Currently, gastrointestinal endoscopes are classified as semi-critical devices according to the Spaulding classification system, because they are in contact with mucous membranes. The Spaulding system classifies medical devices into three categories (non-critical, semi-critical and critical) depending on the risk of infection. Devices classified as semi-critical minimally require high-level disinfection (HLD). Current reprocessing guidelines recommend more than 100 steps for reprocessing each endoscope, and, although there are similarities between guidelines, some recommendations are not universal [2]. Figure 1 shows a simplified overview of the different reprocessing steps needed after each procedure.

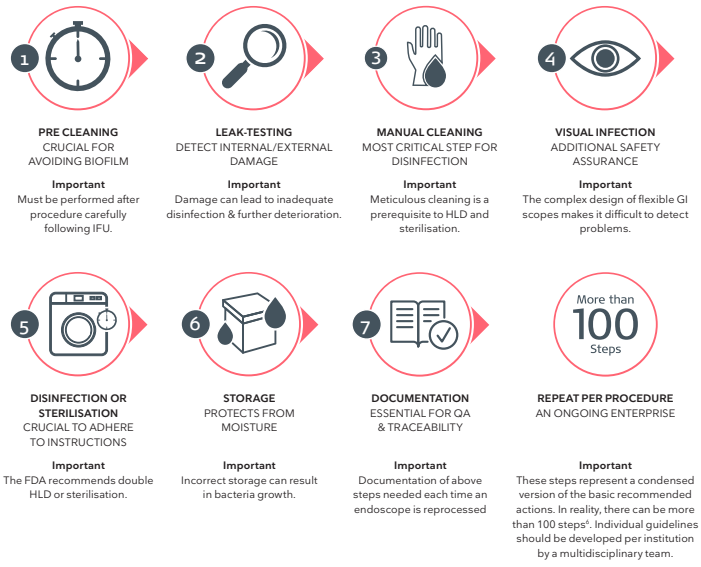

Figure 1: Simplified illustration of the endoscope reprocessing cycle.

INADEQUATE REPROCESSING REMAINS AN ISSUE

Following HLD, all bacteria colony-forming units (CFUs) are expected to be eliminated, but bacterial spores may still be detected [3,4]. However, it is not unusual for endoscopes to remain contaminated after HLD and even after double HLD [5,6]. Reprocessed and patient-ready gastrointestinal endoscopes have been found to be contaminated, not only due to a lack of adherence to reprocessing protocols, but also in settings that had applied the proper manufacturer reprocessing instructions during the cleaning process [7–9]. In particular, the elevator mechanism of the duodenoscope has been subject to concerns regarding contamination, as the US Food & Drug Administration (FDA) has issued multiple Safety Communications regarding multidrug-resistant pathogen infections in patients who have undergone endoscopic retrograde cholangiopancreatography (ERCP) with contaminated duodenoscopes [10–12]. Nevertheless, multiple studies suggest that contamination issues are not only limited to the elevator mechanism of the duodenoscope, but are also common in the endoscope channels involving both gastroscopes and colonoscopes. It is important to emphasize that one contaminated endoscope will not necessarily result in one infection, as the ratio between contaminated devices and contaminated patients is not 1:1.

HIGH-LEVEL DISINFECTION VS. STERILIZATION

Due to the risk of patient cross-infections caused by contaminated gastrointestinal endoscopes, it has been suggested that gastrointestinal endoscopes should be classified as critical devices rather than just semi-critical devices, which would then require the endoscopes to undergo low-temperature sterilization [13,14]. Because gastrointestinal endoscopes are heat-labile, only HLD with chemical agents or low-temperature sterilization technologies is possible [1]. A recent study sought to demonstrate that flexible gastrointestinal endoscopes can be practicably terminally sterilized [15]. Using vaporized hydrogen peroxide, the researchers were able to practicably sterilize the endoscopes fully. However, using this approach the endoscopes would need to be sent to repair after a few uses, which may not be acceptable, as it would increase the overall repair costs and require additional inventory to accommodate device downtime. The study also found that the materials compatibility was highly relevant for how well the device would tolerate the sterilization. The authors conclude that "Current HLD processes do not have enough margin of safety to account for incomplete cleaning, resulting in potentially insufficient decontamination after processing". Figure 2 shows the Pentax EG29-i10 gastroscope insertion tube before and after undergoing sterilization using vaporized hydrogen peroxide. The insertion tube cracked after 23 cycles. Figure 3 shows blistering of the epoxy glue after only 8 cycles on an Olympus CFHQ190L colonoscope [15].

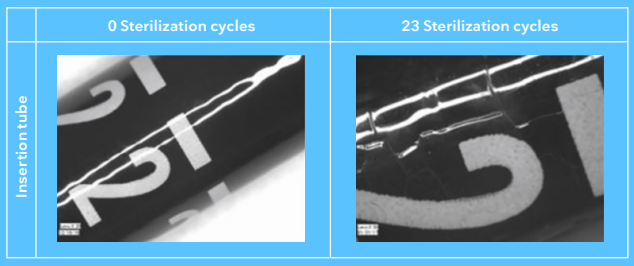

Figure 2: Pentax EG29-i10 gastroscope insertion tube.

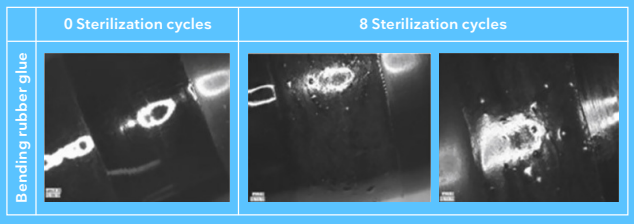

Figure 3: Olympus CFHQ190L colonoscope bending rubber glue.

ETO STERILIZATION – GOOD OR BAD?

The FDA has recommended that endoscopy centres perform HLD on duodenoscopes, and that centres with that capability consider one of four supplemental measures to reduce infection risk: microbiological culturing, ethylene oxide (EtO) sterilization, use of a liquid chemical sterilant processing system, or repeat high-level disinfection (dHLD) [6]. However, EtO has multiple drawbacks and is not widely available [15]. Studies have also proven that even EtO is insufficient in regard to cleaning the endoscopes fully [5,16].

A study from 2015 found that 1 of 84 duodenoscope cultures was positive for Carbapenem-resistant Enterobacteriaceae after undergoing reprocessing using EtO [16]. Another study from 2017 did a randomized comparison of three high-level disinfection and sterilization procedures for duodenoscopes. In the comparison of duodenoscopes reprocessed by single HLD, dHLD or HLD/ETO, the authors found no significant differences between the groups for multidrug-resistant organisms (MDRO) or bacteria contamination. Enhanced disinfection methods (dHLD or HLD/ETO) did not provide additional protection against contamination [5].

In July 2020, the FDA recommended the transition to duodenoscopes with innovative designs that can be reprocessed more effectively. Device design is a key factor that contributes to reprocessing challenges. "The FDA believes the best solution to reducing the risk of disease transmission by duodenoscopes is through innovative device designs that make reprocessing easier, more effective or unnecessary" [17]. Despite increased awareness related to duodenoscopes and the elevator mechanism, one should also be aware of the risk of bacteria harboured in the endoscope channels.

THE ELEVATOR IS NOT THE ONLY THING TO BLAME

Internal damage to endoscope channels offers a potential haven for bacteria and patient soil and contributes to inadequate reprocessing. Most endoscope channels are made with polytetrafluoroethylene tubing, which is smooth, durable, and resistant to chemicals. However, the material is also not very flexible and can be damaged due to overbending. A recent study from Australia compared surface roughness and bacterial attachment in used and new endoscope channels [18]. The authors state that "The increased roughness of the interior surface of used endoscope channels provides a favourable habitat for bacteria and patient soil to attach, making cleaning and decontamination more difficult, and facilitating biofilm growth". Contaminants on endoscopes post-reprocessing have been linked to patient infections, including infections from multidrug-resistant bacteria [18].

Despite lacking evidence concerning the endoscope-related infection risk caused by contaminated gastrointestinal endoscopes, multiple studies have investigated the contamination rates of various endoscope types. A meta-analysis from 2020 sought to estimate the contamination rate of reprocessed patient-ready duodenoscopes and found a 15.25% contamination rate. Additionally, the analysis indicated that dHLD and EtO reprocessing methods were superior to single HLD, but were still not efficient in regard to cleaning the duodenoscopes properly [19]. The fact that multiple studies have documented contaminated endoscope channels highlights that the elevator mechanism is not the only thing to blame.

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