

## Are Reprocessed Endoscope free from Contaminants

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**Abstract:** Endoscopes have been contaminated with organic material from a prior procedure something healthcare workers call “bioburden.” While most of these cases are recognized before the devices reach the patient, in some instances these soiled instruments have contaminated the sterile field. Due to the nature of endoscopes, with small lumens and a combination of mechanical and electrical components and complexity of materials, effective reprocessing can be challenging to practically achieve. Endoscopic procedures carry a risk of causing infection. Infectious agents contaminating an endoscope can originate from failures in the decontamination process, from contamination during storage, or from previous patients. After manual cleaning the instrument must be either disinfected or sterilized manually or by using an automated endoscope reprocessor (AER). The final stage of the process is drying and ensuring safe storage. This review describes an investigation into a sudden increase in contamination of different types of endoscope rate following ‘clean’ surgery.

**Key Words:** Endoscope, Endogenous, Exogenous, Factors affecting survival of microorganism, Reprocessing

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### I. Background

Recent, widely publicized incidents have highlighted continuing concerns that infections may be transmitted from patient to patient during routine flexible gastrointestinal endoscopic procedures [1]. Gastrointestinal (GI) endoscopy is a widely performed for the diagnosis and treatment tool in the patients with gastrointestinal diseases not only, but also in the healthy people with requests for physical exams or checkups. Because of the instruments are complicated in structures and reusable in the clinical practice, a standard disinfection procedure is requested [2]. Each year in the United States alone, approximately 34 million gastrointestinal procedures are performed using flexible endoscopes [3]. Estimate of the risk of infection from this type of procedure is one in 10 million. Moreover, the Emergency Care Research Institute (ECRI) ranked flexible endoscope cross contamination as the No. 1 hazard in today’s healthcare facilities [3]. The need for continued emphasis on infection control issues remains paramount. Failure to adhere to established reprocessing guidelines accounts for most, if not all, of the reported cases of bacterial and viral transmissions [3].

Decades ago, the advent of flexible endoscopy heralded a new era in diagnostic and therapeutic medicine; not only was invasive surgery potentially avoidable, but it surpassed the spectrum of diagnostic and therapeutic options available at the time with rigid bronchoscopes and esophagoscopes [4]. A mid 2013 study reported that about 15% of endoscopes in US hospitals failed to achieve an accepted standard of cleanliness after liquid reprocessing (the prevailing disinfection process used between patient procedures)[5]. Among those healthcare organizations that were able to determine the exact cause of their disease outbreaks, the lumen of the endoscope was most often found to be the chief culprit [5]. During endoscopic procedures, the scopes come into contact with mucous membranes and bodily fluids and, therefore, must undergo thorough, reliable cleaning and high level disinfection between uses [6]. The consequences of the use of contaminated endoscopes are a recurrent topic in the endoscopy literature. Flexible endoscopes may become heavily contaminated with blood, secretions, and microorganisms during use. These instruments are difficult to clean and disinfect and easy to damage because of their complex design, with narrow lumens and multiple internal channels. If the instruments are not properly cleaned, the disinfection and drying procedures can fail and increase the possibility of transmission of infection from one patient to another. Recently, capsule endoscopy has been introduced for use in 2001[7]. Research on disposable endoscopes is ongoing. There are some bronchoscopes that can be steam sterilized but most flexible endoscopes require low temperatures for disinfection/sterilization. Most reported cases of cross-transmission of infection related to endoscopy have identified breaches in proper instrument processing or use of defective equipment [4]. It is therefore essential that all healthcare settings where endoscopy is performed have appropriate guidelines in place for endoscope reprocessing and handling. The detergent or disinfectant agent used to clean such surgical instruments is a key factor in instrument reprocessing, as well as safe patient care. Because there are various types of detergents available today, all personnel involved in the care and cleaning of surgical instruments must be knowledgeable about these agents and the prior instrument cleaning process. The establishment of high quality, consistent decontamination practices is important for every healthcare facility. Exposure to contaminated instruments is risky for the healthcare worker, the patient and the community at large.

Postsurgical infection leads to increased length of postoperative hospital stay, drastically escalated expense, higher rates of hospital readmission, and jeopardized health outcomes [8]. Infection at or near surgical incisions within 30 days of an operative procedure, dubbed surgical site infection, contributes substantially to surgical morbidity and mortality each year. Surgical site infection (SSI) accounts for 15% of all nosocomial infections and, among surgical patients, represents the most common nosocomial infection [8]. It is estimated that 15% to 30% of hospital-acquired infections can be prevented through more-effective application of existing knowledge. However, it is reportedly difficult to calculate the impact that an improvement in decontamination methods would have, although it is well known that failures of conventional procedures have resulted in a wide range of infections. In studies of patients admitted to a general hospital, 17.6% displayed bacteremic episodes, with the most prevalent being caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter*, and *Salmonella* [8]. The relationship between gram-negative bacteria endotoxin and sepsis has been recognized for many years, with a large proportion (79%) of sepsis patients also exhibiting endotoxemia. Approximately 40% of those with sepsis will progress to septic shock, which is the leading cause of morbidity and mortality among hospitalized patients [3]. The emergence in the United Kingdom in the mid-1990s of variant Creutzfeldt-Jakob Disease (vCJD), linked to the consumption of bovine spongiform encephalopathy (BSE)-tainted meat products, has raised concerns of the risks related to the inadequate cleaning and sterilization of instruments in dentistry prior to their reuse on patients [9]. Again, how it transmitted is not known but many believe it involved the consumption of infected meat products from cows. There is however another way these diseases can be transmitted, as adverse effects of medical treatment: iatrogenic transfer. This has occurred when tissues from an infected human are transferred to another human patient for medical reasons—for example growth hormone extracts and blood transfusions. By virtue of the exceedingly complex composition and broad spectrum of functions of blood, enormous difficulties continue to be faced when trying to reproduce this fluid as a substitute for donor blood [5]. But if one views blood as a cleaning problem when reprocessing surgical instruments, the majority of its biological functions can be disregarded. The only aspect meriting attention in this context is the process of blood coagulation with the end product fibrin [5]. Since, to perform their preordained tasks, all blood components are necessarily present in a water-soluble form, the insoluble fibrin fibres formed during coagulation are particularly relevant for cleaning. The cleaning efficacy of a washer-disinfector (WD) for flexible endoscopes has to be checked both in type testing and in performance qualification testing within validation [10]. Decontamination in medical instrument reprocessing is one of the major challenges facing healthcare facilities. Accurate reprocessing of flexible endoscopes is a multistep procedure involving cleaning followed by high-level disinfection (HLD) with further rinsing and drying before storage. Endoscope reprocessing can be performed with the use of automated endoscope reprocessors (AERs) and manual methods. Since almost all outbreaks are related to breaches in reprocessing techniques, it is crucial that endoscope cleaning, disinfection, and drying are performed according to a strict protocol.

## **II. Endoscopy-related infections**

Flexible endoscopes belong to semi-critical devices which come in contact with mucus membranes or non intact skin during endoscopic procedures. Endoscopes for therapeutic procedures (bronchoscopy, ERCP) are used in sterile body cavities. They are frequently designed with small lumina and multiple channels which are difficult to clean and disinfect. Such endoscopes should be sterilized or receive an intensive disinfection procedure [11]. Infections related to endoscopes can be divided into two types: endogenous and exogenous.

Endoscopic procedures most often result in endogenous infections (i.e., infections resulting from the patient's own microbial flora) and *Escherichia coli*, *Klebsiella*, *Enterobacter* species and enterococci are generally isolated [12]. Endogenous infections are associated with endoscopy but cannot be prevented by well controlled disinfection procedures. The exogenous microorganisms most frequently associated with transmission during bronchoscopy are *P. aeruginosa* and *Mycobacterium tuberculosis*, atypical *Mycobacterium* species, and *P. aeruginosa* the most common in gastrointestinal endoscopy [13]. These microorganisms can be transmitted from previous patients or contaminated reprocessing equipment by contaminated endoscopes or its accessory equipment.

## **III. Endogenous microbial contamination**

Due to the nature of endoscopic probing within the body, heavy contamination with a variety of microorganisms is likely. Endogenous infections after flexible endoscopic procedures arise when the patient's own microbial flora gain entry to the bloodstream or other normally sterile body sites as a result of mucosal trauma or instrumentation and are not related to instrument reprocessing problems. Examples of endogenous infections include pneumonia resulting from aspiration of oral secretions in a sedated patient during flexible bronchoscopy and bacteremia in patients with biliary obstruction during endoscopic retrograde cholangiopancreatography (ERCP). Endogenous infections are associated with endoscopy but cannot be prevented by well-controlled disinfection procedures [10]. Oropharyngeal microorganisms include a wide range

of viridans streptococci, Moraxella and Neisseria species, and anaerobic bacteria such as Porphyromonas species, Fusobacterium species and oral anaerobic spirochetes [14]. The stomach and small intestine have only low levels of resident normal flora ( $10^{3-6}$  cfu/gm of tissue), but again microorganisms from the oropharyngeal cavity and throat can be introduced when the insertion tube is passed through the mouth into the stomach or small intestine [14]. In most immunocompetent patients bacteremia, which may occur during or after procedures, is usually transient and asymptomatic [15]. The reported incidence of bacteremia after diagnostic upper GI endoscopy, with or without biopsies, was less than 8% [16]. Therapeutic upper GI endoscopy, including esophageal sclerotherapy, variceal ligation, and esophageal dilatation, is associated with significantly more tissue trauma than diagnostic endoscopy [17]. Other infectious complications after colonoscopy and sigmoidoscopy include acute appendicitis, bacterial peritonitis, endocarditis, and septicemia [10, 16]. The most common complication of percutaneous endoscopic gastrostomy is peristomal wound infection, with the rate varying between 3% and 32% [10]. ERCP is an endoscopic procedure associated with an incidence of severe infectious complications of between 2% and 4%, including sepsis, ascending cholangitis, liver abscess, acute cholecystitis, and infected pancreatic pseudocyst [10]. Inappropriate disinfectants with low and intermediate potency are not recommended for HLD and have been replaced by glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, peracetic acid, and superoxidized and electrolyzed acid water [17]. Advantages and disadvantages of commonly used high-level disinfectants are summarized in Table 1[18].

**TABLE 1. Advantages and disadvantages of commonly used high-level disinfectants**

<b>HLD</b>	<b>Advantages</b>	<b>Disadvantages</b>
Glutaraldehyde	Excellent biocidal properties Does not damage endoscopes and processing equipment; noncorrosive to metal, Relatively inexpensive	Slow action against mycobacteria, Irritant to the respiratory tract, eyes, and skin; development of allergic reactions, contact dermatitis, asthma, acute colitis, Development of biocide resistance Coagulation and fixation of proteins
ortho-Phthalaldehyde	High biocidal activity (inclusive of mycobacteria), Does not damage endoscopes and processing equipment	Slow action against bacterial spores Staining of the skin, clothing, instruments Irritation of the respiratory tract and eyes; development of “anaphylaxis-like” reactions after repeated use expensive
Peracetic acid	Excellent and fast biocidal activity at low concentrations Can be used at low temperatures No development of resistance reported	Irritant to the respiratory tract and eyes Corrosive action depending on the pH value and concn Limited efficacy in biofilm removal and in killing bacteria within the biofilm
Electrolyzed acid and superoxidized water	Excellent and fast biocidal activity Nontoxic to biological tissues; nonirritant to the respiratory tract, eyes, and skin, Relatively inexpensive	Reduced efficacy in the presence of organic soil after inappropriate cleaning

#### **IV. Exogenous microbial contaminants**

Bacteria have caused the vast majority of exogenously acquired endoscope-related infections reported in the literature. Despite the large number of endoscopic procedures that are performed annually, documented data suggest that postendoscopic iatrogenic infections are rare. In GI endoscopy, the estimated rate of health care-associated infection is approximately 1 out of 1.8 million procedures [18]. During the period of 1974 to 2004, 30 outbreaks of endoscopy-related infections and cross-contaminations involving 251 patients infected after GI endoscopic procedures were reported in the United States [19, 21]. The bacteria involved have been either true pathogens, which always have the potential to cause infection (e.g., Mycobacterium tuberculosis), or opportunistic pathogens that cause infection if the microbial load is sufficient and/ or host-factors are permissive (e.g., Pseudomonas aeruginosa) [4]. In the past, Salmonella spp. were the most common microorganisms associated with infections transmitted by GI endoscopy [10]. Transmission of viral pathogens via flexible endoscopic procedures is rare because these microorganisms are obligate intracellular microorganisms that cannot replicate outside viable human cells. This means that even if viral particles are present within a flexible endoscope channel after a patient procedure, the load of viruses cannot increase, as they are not capable of replication in vitro. Enveloped viruses (e.g., human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV)) die readily once dried but non-enveloped viruses (e.g., enteroviruses, rotavirus) can survive in dry conditions [4].

To date, only one case of clinically apparent HBV transmission, from an acutely viremic hepatitis B patient, via endoscopy has been documented [22]. Eight cases of HCV transmission have now been attributed to gastrointestinal endoscopy [23]. A recent investigation of an outbreak of acute hepatitis C in patients who underwent procedures at the same endoscopy clinic revealed that transmission likely resulted from reuse of syringes on individual patients and use of single-use medication vials on multiple patients at the clinic [24]. Parasites (e.g., Cryptosporidium sp.) do not replicate in moist environments in the same manner as bacteria and fungi, but the cysts and eggs of parasites can survive in such environments. Although there is a theoretical risk of Cryptosporidium cysts and Clostridium difficile spores surviving high level disinfection (HLD), transmission

of such pathogens via endoscopy has not been reported [15]. Microorganisms may spread from the GI tract through the bloodstream during an endoscopy to susceptible organs or prostheses, or may spread to adjacent tissues that are breached as a result of the endoscopic procedure [4]. Microorganisms associated with transmission of infection from contaminated flexible endoscopes are summarized in Table 2. Microorganisms associated with transmission, without infection, attributed to contaminated flexible endoscopes are summarized in Table 3.

**TABLE 2. Microorganisms Associated With Transmission of Infection Attributed to Contaminated Flexible Endoscopes**

Organism	Endoscope type	Problem identified
<i>Pseudomonas aeruginosa</i>	Bronchoscopes	Microorganisms isolated from loose biopsy port caps due to design flaw, resulting in disinfection failure – multiple cases of cross-transmission.
<i>Salmonella</i> species	Colonoscopes	Inadequately disinfected colonic biopsy forceps in one outbreak; in most outbreaks, disinfectant used was not effective against <i>Salmonella</i> sp.
Enterobacteriaceae	Colonoscopes/ Duodenoscopes	High levels of bacteria within channels - Transient bacteremia after ERCP.
<i>Mycobacterium tuberculosis</i>	Bronchoscope	Failure to disinfect contaminated suction valve -cross-transmission to four patients (one infection).
Fungi	Duodenoscope	<i>Trichosporon beigelii</i> isolated from biopsy channel after disinfection failure – cross-transmission to nine patients.
Hepatitis C	Colonoscope	Failure to clean suction channel with brush and sterilize biopsy forceps- cross transmission to two patients who subsequently developed hepatitis.
Hepatitis B	Duodenoscope	No disinfecting agent used to flush air/water channel; standard guidelines not available – cross- transmission to one patient who subsequently developed hepatitis.

**TABLE 3. Microorganisms Associated With Transmission without Infection Attributed To Contaminated Flexible Endoscopes**

Organism	Endoscope type	Problem identified
<i>Bacillus</i> sp.	Bronchoscope	<i>Bacillus</i> sp. isolated from suction valves. Contamination related to improper disinfection and storage –microorganism detected in bronchial washing cultures obtained from asymptomatic patients.
<i>Pseudomonas aeruginosa</i>	Bronchoscope	<i>Pseudomonas aeruginosa</i> isolated from suction channel not cleaned prior to disinfection microorganism detected in bronchoalveolar lavage fluid (BAL) samples from eight asymptomatic patients.
<i>Mycobacterium</i> sp.	Bronchoscope	<i>M. chelonae</i> isolated from lidocaine sprayers used during bronchoscopy- acid-fast bacilli (AFB) detected in bronchial washings of asymptomatic patients.
<i>Serratia marcescens</i> / <i>Pseudomonas aeruginosa</i>	Bronchoscope	<i>Serratia marcescens</i> and <i>Pseudomonas aeruginosa</i> isolated from saline used to rinse disinfected scope. Procedure changed to use filtered water rinse with scheduled in-line filter changes- microorganism detected in bronchoalveolar lavage fluid (BAL) samples from 41 asymptomatic patients.
Fungus	Bronchoscope	<i>Aureobasidium</i> sp. isolated from re-use of stopcocks meant for single use in outpatient bronchoscopy unit –microorganism detected in BAL cultures from nine asymptomatic patients.
<i>Legionella pneumophila</i>	Bronchoscope	Contaminated tap water used to rinse scopes after disinfection. Problem recurred because of inadequate maintenance to filters –microorganism detected in BAL samples from three asymptomatic patients.

## V. Factors support survival of microorganisms

### 5.1 Wet storage

Bacteria may replicate to substantive levels even after overnight storage at room temperature if there is adequate moisture in the endoscope channels. Some bacteria can survive drying (e.g., *M.tuberculosis* and Gram positive bacteria) whereas others, like Gram negative bacteria (e.g., *P.aeruginosa* and *E. coli*), die rapidly when dried. Gram negative bacteria replicate more easily in the presence of moisture and have been implicated in endoscope associated infections more frequently than have Gram positive bacteria. A survey by Kazmarek et al. in 1991 of stored flexible endoscopes found that 23.9% of samples taken from the devices' channels had > 10<sup>5</sup> cfu/channel [25].

### 5.2 Bio-film Formation

Biofilm are composed of population of microorganisms in an extracellular matrix adhering to surface in which sufficient moisture is available. They are present in living organisms in addition to the surface of inanimate objects [26]. Biofilm formation cause problem in many areas, e.g. in industrial water system, in medicine and in food processing industries. The ability of bacteria to form biofilms is an important factor in their potential to cause endoscopy-related infections. During clinical use blood, feces, mucus, and other biological substances can adhere to the endoscope and its channels. If the channels are not properly cleaned, there may be high residual levels of organic material and microorganisms [10]. Substantial biofilm formation

may result after overnight storage [10]. Microorganisms embedded within this biofilm are sheltered from the cidal activity of the disinfectant/sterilant. This protection is further enhanced if there is residual organic material post-cleaning. Enzymatic detergents do not inhibit bacterial replication, and indeed, the microorganisms can use the enzyme proteins as an energy source.

### **5.3 Equipment Design Flaws**

Two studies confirm that design flaws can contribute to, if not promote, microbial contamination despite adherence to proper reprocessing protocols [27]. In both reports, the documented design flaw was a faulty biopsy port in a bronchoscope that could loosen, allowing patient secretions and microorganisms to become sequestered in a moist environment, inaccessible to adequate cleaning and disinfection. The problem was identified when an abnormally high rate of *P. aeruginosa* was detected in bronchoalveolar lavage (BAL) specimens. This illustrates how periodic review of microbiology reports from BAL samples may be a useful audit tool for bronchoscopy services.

### **5.4 Errors in Reprocessing**

Outbreaks associated with flexible endoscopy have most often been associated with breaks in the cleaning and/or disinfection/sterilization stage of flexible endoscope reprocessing [28]. Cowan [29] has described how the currently used reprocessing protocols provide a very narrow margin of safety and any slight deviation from the recommended steps may result in an increased risk of infection transmission by flexible endoscopes. Current endoscope reprocessing guidelines recommend reprocessing immediately after use. Delayed endoscope reprocessing, in which the endoscope is allowed to sit idle and is soiled for an extended period of time, sometimes hours, before being reprocessed is an important problem because it can pose an increased risk of disease transmission and result in endoscopic damage. If endoscope reprocessing is delayed, body fluids or other potentially infectious materials can begin to dry on the surface and internal channels of the endoscope; thus, biofilm can form on the inner wall of the extension pipe of the endoscope and render the standard reprocessing procedures less effective. Delays in reprocessing usually occur in the setting of emergency endoscopy when the endoscopes are left for proper reprocessing the next business day. When immediate reprocessing is not possible, an alternative strategy is to soak the endoscope in the proper enzymatic detergent according to the manufacturer's recommendations until it can be mechanically cleaned and high-level disinfection can be performed [30].

## **VI. Disinfection and Sterilization**

### **6.1 Selection of a High Level Disinfectant Product**

The characteristics of an ideal liquid chemical (LC) agent used as a high level disinfectant should include broad antimicrobial spectrum, rapid onset of action, compatibility with delicate instruments, lack of toxicity for healthcare staff, patients and the environment, no odour, non staining, unrestricted disposal, prolonged reuse and shelf life, ease of use, remains active in the presence of protein and organic material, ability to be monitored for concentration, and relatively low cost. No currently marketed product satisfies all these criteria. Major disadvantages include material incompatibility (e.g., peracetic acid, hydrogen peroxide) and human toxicity (e.g., glutaraldehyde)[35]. It is important that healthcare workers, who use any high level disinfectant, be familiar with and has readily accessible, product/brand-specific Material Safety Data Sheets (MSDS) for all chemicals used, and keep current with developments in products and practice. For detailed information on advantages and disadvantages of available high level disinfectant products, the reader is referred to Best Practices for Cleaning, Disinfection and Sterilization In All Health Care Settings [31].

### **6.2 Liquid Chemical Agents**

The most common method for disinfection/sterilization of flexible endoscopes is the use of liquid chemical (LC) agents including glutaraldehyde, ortho-phthalaldehyde (OPA), peracetic acid, and hydrogen peroxide. Glutaraldehyde has exposure threshold limit values as specified in provincial Occupational Health and Safety (OH&S) regulations and special air handling requirements are necessary when this agent is used, due to its propensity to cause sensitization reactions in some healthcare workers. Manufacturer recommends 45 minutes contact time at 25°C, current guidelines and expert opinion confirm that 20 minutes at room temperature (20°C) is adequate provided that thorough pre-cleaning has been performed prior to exposure to the glutaraldehyde [32].

### **6.3 Low Temperature Gas and Gas Plasma Sterilization**

Sterilization must be performed if the endoscope enters the body through an incision, as with intraoperative enteroscopy [33]. Low-temperature sterilization (<60 degrees C.) is required for temperature and moisture-sensitive critical medical devices. All currently developed sterilization processes have limitations and

these must be understood to ensure the proper application of new sterilization technologies within medical facilities. Ethylene oxide is the eldest low temperature sterilization method and has been used since the 1950's to reprocess heat-sensitive medical-hospital materials. Different factors have influenced professionals and health institutions to look for new sterilization technologies. Rutala and Weber identify the reasons for this search among health professionals in the United States, such as complying with environmental legislation that establishes the elimination of CFC (chlorofluorocarbons) gas use, which is a better thinner than ethylene oxide, which affects the ozone layer, and regulating acceptable exposure levels to ethylene oxide, established by the public occupational health body [33].

#### **6.4 Automated Endoscope Reprocessors (AERs)**

AERs are designed to replace some manual reprocessing steps or manual disinfection by passive immersion in liquid chemical germicides and manual flushing of channels with liquid chemical germicides, which has a similar efficacy for high-level disinfection. Advanced and upgraded AERs are being developed including the USFDA approved EVOTCH Endoscope Cleaner and Reprocessor (ECR). EVOTCH eliminates manual precleaning of the endoscope prior to automated high-level disinfection processing. Evaluation of the EVOTCH system documented the attainment or surpassing of cleaning endpoints for protein, hemoglobin, and bioburden residuals for 98.8% of the surfaces and 99.7% of lumens in the clinical study. It also demonstrated the attainment or surpassing of cleaning endpoints for protein and bioburden residuals for 100% of endoscopes and bronchoscopes in the simulated-use study. Assessment of the cost-efficiency of the ECR approaches in an actual practice setting demonstrated a significantly shorter time of endoscope reprocessing and reduced cost compared with manual cleaning followed by automated reprocessing. The value of the labor time saved with ECR offset the additional cost of consumables [34].

#### **6.5 Reprocessing Endoscopic Accessories**

Routine microbiological testing for endoscopes and AERs remains a controversial issue in many guidelines. Microbiological surveillance of endoscope reprocessing has been recommended by several medical specialist organizations [10]. It is appropriate to trace contaminations of endoscopes and to prevent contaminations and infections in patients after endoscopic procedures. The use of environmental endoscope culturing is a rapid and simple method to monitor the effectiveness of standard reprocessing procedures [10]. All reusable endoscopic accessories that breach mucosal barriers are considered critical and require cleaning with an ultrasonic cleaner followed by sterilization between patients. Manufacturer's guidelines for the care and usage of reusable products must be strictly followed. Contaminated or damaged medical devices pose a potential source for cross-contamination, infection and injury to patients and personnel.

### **VII. Discussion**

Effective surveillance of flexible endoscope reprocessing ideally requires testing methods that allow for rapid assessment of compliance with current reprocessing standards. However, the lack of both widely accepted bioburden/microbial benchmarks and widely validated means of assessing these have limited implementation of such strategies. Potential methods for surveillance include the following points.

#### **7.1 Microbial culture**

The ESGE recommends surveillance cultures of reprocessed endoscopes at intervals of not more than 3 months [35]. The ESGE-ESGENA guideline states that the maximal total microbiological count should be less than 20 colony-forming units (cfu) for fluid collected after flushing the endoscope channels with 20 mL of sterile saline solution with placing of 1 mL of the fluid on each agar plate. However, culturing for bacterial load is impractical for many endoscopy centers that may not have easy access to microbiology laboratories. In addition, the slow turnaround time (minimum 24 hours) for results does not allow for rapid reuse of the tested endoscope. Furthermore, viruses such as hepatitis B and C and HIV cannot be cultured by using standard methods. Alfa et al performed a prospective study of the bacterial and fungal burden in endoscopes after reprocessing and storage over a weekend, in an effort to identify a practical benchmark for microbial burden.

The authors tested 141 endoscopes and 383 channels and found that 99.5% of all endoscopes demonstrated less than 100 cfu/mL of microbial growth and proposed this as a reliable and routinely attainable benchmark [35].

#### **7.2 Bioburden assays**

Currently available methods allow rapid evaluation of residual bioburden and organic matter from the endoscope channels. Scope-Check is a test for protein residue on the surface of endoscopes, Endo Check is able to detect and blood residues protein within the biopsy channel of endoscopes while Channel Check is able to detect protein, blood and carbohydrate residues within the biopsy channel of endoscopes [35].

### 7.3 Adenosine triphosphate bioluminescence

Adenosine triphosphate (ATP) bioluminescence is present in microorganisms and human cells and therefore offers a means of testing for microbial and biological residue. ATP bioluminescence testing provides results within a few minutes [35]. The technique uses the light-reducing reaction between ATP, luciferin, and luciferase to estimate the levels of ATP in a sample. Luminometers convert the number of photons released in the reaction into relative light units (RLUs). ATP bioluminescence was first used for measuring the cleanliness of surfaces in hospitals. Recent studies have demonstrated the measurement of ATP to be effective in monitoring HLD of flexible endoscopes [35].

## VIII. Conclusion

Contaminated endoscopes have been linked to many outbreaks of device-related nosocomial infections. The true incidence of endoscopy-related infections is unknown because of inadequate surveillance or no surveillance at all. Endoscopy-related infections can cause serious harm and can give rise to concerns over these procedures by physicians and patients. Flexible endoscopes can be cleaned and disinfected but not sterilized after use. This implies the risk of settlement of biofilm-producing species. Process control of the cleaning and disinfection procedure does not guarantee prevention of biofilm formation during endoscopy. Implementation of microbiological surveillance of endoscope reprocessing is appropriate to detect early colonization and biofilm formation in the endoscope and to prevent contamination and infection in patients after endoscopic procedures. However, the returns of prevention of endoscopy related infections should be reasonably in balance with costs of technical and laboratory procedures resulting from surveillance and the costs of reprocessing or servicing of the contaminated endoscope. Surgical instruments tend to be contaminated during operations by microbes that inhabit the skin and organs. Unfortunately, all guidelines are inconsistent concerning the frequency and method of the microbiological monitoring. Although daily or per procedure real-time monitoring is ideal, this is currently not possible. Individual institutions should establish their own guidelines for microbiological monitoring, taking into consideration institutional cost and environmental factors.

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