Visual Inspection of Flexible Endoscopes

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LEARNING OBJECTIVES

1. Understand the need for visual inspection as outlined in manufacturers' instructions for use
2. Discuss recommendations from organizations and industry that support visual inspection
3. Discuss potential benefits associated with visual inspection and recognize the need for staff education

The consequences of using contaminated endoscopes on patients have been well documented in the news media over the last several years. These lapses have highlighted the need to do more to ensure these devices are safe for patients. Visual inspection is a crucial step in every endoscope manufacturer's instructions for use (IFU) to assess that an instrument is ready for further processing and, ultimately, reuse. Given that vastly different departments could be tasked with performing reprocessing, cleaning failures may still occur, even when the manufacturer's IFU are followed. Due to their complex nature, flexible endoscopes represent a significant cleaning challenge to any department that reprocesses them. Enhanced visual inspection is a tool that every endoscope processing department needs to confirm their endoscope's internal channels are visibly clean and undamaged.

In accordance with ANSI/AAMI ST90, *Processing of health care products – Quality Management systems for reprocessing health care facilities*, a quality management system (QMS) with a focus on the department's policies and procedures related to endoscope processing should be created.[1] This QMS should include the tools and techniques that will be used for visual inspection of the channel(s). In recent years, borescopes and flexible inspection scopes have greatly increased in durability and image quality. That in conjunction with more options in table magnification, such as 4X and 10X lighted magnifiers, inspecting the difficult-to-see areas of endoscopes is easier than ever before. Advances like these make enhanced inspection equipment extremely useful and worth the financial and time investment it takes to acquire and use them.

Objective 1: Understand the need for visual inspection as outlined in manufacturers' instructions for use

Visual inspection is a key quality check in every instrument manufacturer's IFU. Ensuring an instrument is visually clean and functional is necessary before

it can be allowed to go any further in the processing cycle. For example, the final step before high-level disinfection (HLD) in many IFU by one prominent endoscope manufacturer states to "inspect all items for residual debris. Should any debris remain, repeat the entire cleaning procedure until all debris is removed."[2]

Without a borescope to visualize an endoscope's internal channel(s) and a lighted magnifier to inspect the distal tip, this step is very difficult or impossible. Visual inspection is also crucial to finding damage in an endoscope that can render it unsafe for use. Every lumened device must be properly brushed or it may harbor debris internally. When other instruments are passed through those lumens during the procedure as they are with many endoscopes, the chance for damage increases. This, coupled with the fact that plastics and other pliable materials are used to construct endoscopes, means their channels are at a high risk for damage from mishandling. Endoscopes used with instruments such as biopsy forceps are a good example. If the accessory instrument is passed through the endoscope (e.g., with the jaws in the opened position or with the shaft dragged against the inside of the channel) the opportunity for internal damage to the endoscope is high.

One IFU includes the following words of caution: "The insertion section of the endoscope is composed of the insertion tube, the bending section, and the distal end. The bending section is covered by a thin, easily damaged elastic covering. Do not allow reprocessing equipment to forcefully contact the bending section. Do not allow any sharp edges, such as the distal ends of EndoTherapy accessories (needles, forceps, snares, etc. used in the instrument channel of the endoscope), to contact the bending section. Such improper handling may damage the covering and cause the endoscope to leak."[2] This is especially problematic because any internal damage to endoscopes will render it difficult, if not impossible, to clean properly.

To ensure adequate friction, endoscope manufacturers' IFU state that a specified cleaning brush or an equivalent of the same dimensions and material compatibility must be used; this ensures personnel are using a brush of the correct diameter to allow the bristles to fully contact the channel walls. If these walls are damaged, the brush may be incapable of making enough contact to provide the friction needed for adequate cleaning which, in turn, can lead to an unsuccessful HLD or sterilization process. Unless the department has an inspection policy and enhanced inspection equipment to visualize these delicate internal parts, damage may go unnoticed. Instituting an inspection policy that calls for visual inspection will identify endoscopes that are unsafe for patient use well before they reach to procedure room.

Objective 2: Discuss recommendations from organizations and industry that support visual inspection

While instrument manufactures have always called for visual inspection of endoscopes in their IFU, that instruction has typically not been for enhanced visual inspection. In many cases, the instructions indicate the staff member should look for "irregularities" or "debris" on the endoscope, but often do not make specific recommendations for the use of a borescope to look inside the endoscope. Inspection that does not include the internal channels of an endoscope could easily miss irregularities and/or debris.

All professional society recommendations and national standards organizations stress how visual inspection greatly increases the chance of detecting cleaning failures and internal damage in endoscopes. Organizations including the American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI), Society of Gastroenterology Nurses and Associates (SGNA), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), Association off Surgical Technologists (AST), and the Canadian Standards Association (CSA) have all published guidance documents recommending at least periodic enhanced visual inspection of the internal channels of flexible endoscopes. Here is one example:

AMMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities*, Section 12, Quality Control[3]
12.4.2 Cleaning verification
Cleaning verification of flexible and semi-rigid endoscopes by users should include:

a) Visual inspection combined with other verification methods (see Section 12.4.3) that allow the assessment of both external surfaces and internal housing and channels.
b) Testing of the cleaning efficacy of mechanical equipment.
c) Monitoring of key cleaning parameters (e.g., temperature).

Several methods can be used to evaluate the results of the cleaning process. The most common is visual inspection. Careful visual inspection should be conducted to detect the presence of any residual soil. Inspection using magnification and additional illumination might identify residues more readily than the unaided eye. Users should inspect every device for visible organic soil and contamination

in a simple functionality test. Direct visual inspection is not always possible for the inner components of medical devices that have lumens or that are of non-sealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, and biopsy forceps). Tools such as video borescopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices.[3]

The US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) echo AAMI recommendations, while offering an additional recommendation for the level of magnification used to inspect in and around the elevator mechanism. The duodenoscope culture method states that, "before sampling the duodenoscope, perform a visual inspection of its distal end for any debris or other concerns using 10x magnification. If visible debris is present, continue with sample collection but Infection Prevention and Control or other designated staff should be notified, and the Endoscope Reprocessing group and the staff person responsible for reprocessing this duodenoscope should be notified of the reprocessing breach."[4]

Support for enhanced inspection continues in both peer-reviewed and non-peer-reviewed industry articles. A recent article in a professional trade publication stated the following: "Manual external condition check: After completing manual cleaning all flexible endoscopes…the distal tip should be closely examined under illuminated magnification. Any signs of residual debris or build-up should cause the manual cleaning actions to be repeated. Damage to the distal end, lenses or working portion of the endoscope is not always apparent without enhanced visualization. If damage is detected, it can be safely identified and removed."[5]

Objective 3: Discuss the potential benefits associated with visual inspection and recognize the need for staff education

Before instituting any departmental policy, an analysis should be performed to determine the benefits that could be achieved and how those successes will be measured. Several formats exist to aid in this analysis, such as Lean, Six Sigma, and Plan/Do/Check/Act (PDCA). Utilizing any change management system will help reprocessing professionals stay organized and on track to set and meet the established goals. Those goals are the benefits endoscope reprocessing professionals hope to achieve by putting an enhanced visual inspection policy in place.

As professionals in the healthcare industry, our first and most important goal should be better patient outcomes. Upon taking a closer look at and in endoscopes, reprocessing professionals will find more damage and debris that would have gone unseen if they were only inspecting with the naked eye. This is especially true with endoscopes that have been coiled too tightly. Many times, the kinks in channels created by over coiling may not cause an endoscope to fail a leak test but will make proper cleaning nearly impossible. Finding these issues early and repairing the endoscopes in question will have a positive effect on patient safety.

Another benefit of visual inspection is the educational opportunities provided. Many studies have shown that endoscopes are not being adequately cleaned or dried sufficiently; therefore, when an enhanced inspection program is undertaken, inadequately-processed endoscopes can be found. Each one of the issues is a teachable moment. Whenever staff members in processing departments receive additional information and training on devices, they gain a greater understanding of the device and increased engagement in the process. A staff member who has seen the inside of a flexible endoscope will have a better understanding of the anatomy and why IFU for these devices are so complex and lengthy. This, in turn, should increase compliance.

Visual inspection is well worth the time and patience and will eventually lead to reduced repair cost. All endoscope damage is not always detected during a leak test. Minor leaks and poorly-functioning leak testers are examples of ways damage could go unnoticed in an endoscope – and if it continues to be used, major damage and contamination issues will occur. Slight damage to internal channels is a cleaning and disinfection/sterilization concern, but also may result in fluid invasion that could have been prevented if the damage was detected earlier. After the initial time and training investment, staff will start to visually identify damage sooner and send the endoscopes out for a minor repair, as opposed to a major one.

According to a May 2017 study by Ofstead & Associates, endoscopes are typically sent out for repair only when they fail leak tests or have functional failures that negatively impact their use during procedures; however, scientific studies and reports from outbreak investigators suggest that endoscopes may require more frequent maintenance to ensure they can be safely used. Further, the authors noted that "In a recent study, researchers found visible damage and contamination that could not be removed with multiple rounds of reprocessing. Based on study findings, 17 of 20 gastrointestinal endoscopes were sent out for repair. The manufacturer confirmed that every endoscope had defects requiring repair or refurbishment." The Ofstead study noted that numerous factors impact repair

costs, including the extent of damage and whether the endoscope requires repair or refurbishment. "Overall, the average cost of repairs was $5,833, with 20 minutes of personnel time needed to complete paperwork associated with sending an endoscope out for repair. These expenses totaled $63.93 to $128.05 per endoscope."[6]

It is not enough to just look inside flexible endoscopes; reprocessing professionals must understand what they are seeing when they look. Again, manufacturers recommend inspecting endoscopes for irregularities and debris before clearing the endoscope for further processing and, ultimately, patient use. This begs the question: would departmental staff know what an irregularity looks like?

All routine cleaning instructions should include instructions for visual inspection, which may include use of magnification and adequate lighting. The instructions should advise the user that if the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device. Additionally, the visual inspection instructions should identify acceptance or failure criteria related to device performance (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals), as well as instructions to properly dispose of devices that fail.[7]

Both AAMI and AORN have recently recommended borescope examinations without a fixed schedule to assist with visual inspection during endoscope care and reprocessing; however, many questions, including several raised by the aforementioned pilot studies, require investigation before the adoption of routine use. It will be important to understand what borescope examinations can reliably identify, as well as the implications of each finding. It will be important to understand which visual findings are important and which are simply evidence of usual wear, for example, as well as which correlate with the outcome of reprocessing or with malfunction, and which risk chronic microbial contamination and transmission of infection.[8]

Utilizing the camera function of an inspection scope will allow for the creation of references for staff to help interpret what they are seeing. Images of new endoscopes can be taken and serve as a baseline for subsequent inspections. Even better would be creating a visual history of how each of the facility's endoscopes looks internally. Once established, these pictures can be used for comparison when irregularities are identified.

Conclusion

Undertaking an inspection program that encorporates visualization of the internal channel(s) of flexible endoscopes is supported by all major guidance associations/organizations. With the backing of these organizations, finding support within one's own facility is becoming easier. Investing in the equipment and time to perform this inspection should be considered worthwhile for any departments in the organization that are responsible for reprocessing endoscopes. Furthermore, enhanced endoscope inspection should be considered a vital part of the department's QMS. A policy outlining when and how to use a borescope, a flexible inspection scope, and a higher-power lighted magnifier should be created to set departmental and/or organizational expectations. Staff education should be provided and competence should be verified in all aspects of endoscope inspection.

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