Evaluation of Internal Optics and Exterior Window Lens Integrity for Rigid Endoscopes

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Abstract

Failures of the internal optics and exterior window lens of a rigid endoscope can negatively impact patient safety. The purpose of this study was to identify the frequency of integrity failures for the internal optics and distal exterior window lens for a variety of rigid endoscopes with the use of an endoscopic video verification tool and an enhanced inspection microscope. During a 12-month study, 29 facilities were examined across five states. Forty-one rigid endoscopes were tested for integrity of internal optics and examined for damage to the exterior distal window lens.

For the study, the U.S. Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database was also searched for documented adverse events of failures with rigid endoscopes' internal optics and exterior window lenses, and the findings were reported. The conclusion is that integrity failures emphasize the need for a proactive approach to using inspection verification tools to identify failures within rigid endoscope optics and exterior distal window lenses to ensure better patient outcomes.

Background

Integrity verification inspection during rigid endoscope processing is a vital step performed in the Sterile Processing (SP) area. Rigid endoscopes are the primary visualization device in laparoscopic procedures, and their diverse lengths and diameters allow them to be used across a multitude of service lines. Inspection verification commonly involves standard magnification for viewing from the proximal eye piece, subjectively identifying abnormalities, and holding the rigid endoscope to the light to identify damaged light fibers (visualized as black dots). Exterior inspection of the rigid endoscope's distal window lens tip has historically been performed either with a tactile approach or the use of a cotton ball, which only identifies metal burrs around the parameter of the window lens and does not identify other possible integrity failures.

Damage to the internal optics within a rigid endoscope can impede the surgeon's vision, negatively affecting the procedure's accuracy and outcome. Defects to the exterior window lens can tear internal patient tissue, and debris from the damaged lens (e.g., metal shavings, glass fibers and bioburden) can fall into the patient's sterile cavity and cause significant patient risk.

This study reinforces the need for adequate surface-enhanced magnification and internal endoscopic video verification tools.

Adverse Events: FDA MAUDE Database Reports

As background for the study, a search of the FDA MAUDE database was conducted. A significant number of adverse events were found that identified rigid endoscopes with integrity failures of the internal optics or exterior window lens. Some more recent examples of similar adverse events include:

- October 15, 2023: It was reported that the laparoscope lens seemed to be loose due to an internal failure; it would come in and out of focus and was discovered during an arthroscopy procedure with no patient harm.[1]
- August 9, 2023: It was reported that a 2.3 mm x 72 mm arthroscope had "a dark image during the procedure."[2]
- May 16, 2023: It was reported that the scope overheated, injuring the patient with what appeared to be a thermal, first-degree burn. The telescope had gouging around the distal end, with a chipped-rod lens.[3]
- May 3, 2023: A blurry image during the procedure was reported.[4]

Methods

The study was conducted using an endoscopic video verification tool. This tool has the ability to capture images and videos with the use of a portable mini video tower and a test card pattern (known as USAF-1951) to identify integrity failures of the internal optics within a rigid endoscope. An enhanced magnification microscope was utilized to identify abnormalities on and around the external distal window lens of the rigid endoscope.

Results

The 12-month study was conducted from May 2021 to May 2022 at 29 healthcare facilities. Of the 41 total rigid endoscopes tested, five exhibited integrity failures of the internal optics (12.20% fail rate). See **Figure 1**. The study also identified the external distal window lens had the highest failure rate (63.41%); of the 41 examined, 26 demonstrated integrity failures (see **Figure 2**).

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The results (illustrated in Figures 1 and 2) revealed there were several contributing factors for unnoticeable integrity failures:

- Lack of verification tools to clearly identify integrity failures of the internal optics within the rigid endoscope effectively (see **Figures 3** and **4**).
- Deficient magnification to identify abnormalities around and on the external surface (e.g., standard desktop magnification ranges between 1.8x and 2.0x). To clearly identify damage, an enhanced microscope of 10x to 240x magnification level should be used. (See **Figure 5**).
- Inadequate education for technicians to identify damage (e.g., blurred or foggy lenses, metal burrs, and dents at the distal end). The focus of inspection was primarily the eye piece at the proximal end and medial area of the shaft. See **Figure 6**.

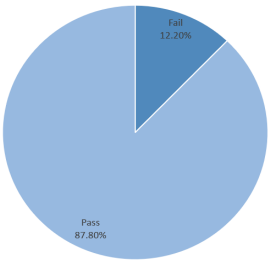

Figure 1: Internal optics integrity failures

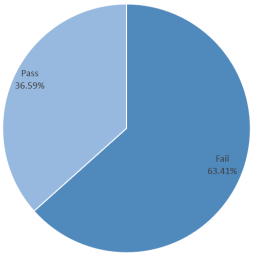

Figure 2: External distal window lens integrity failures

Figure 3: Endoscopic video verification tool with identified damage (broken glass rod within the rigid endoscope)

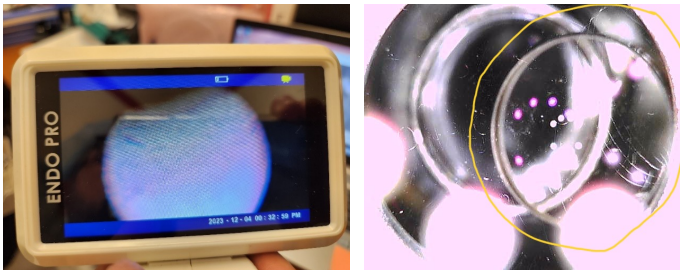

Figure 4: Endoscopic video verification tool with identified damage (dislodged lens within the rigid endoscope)

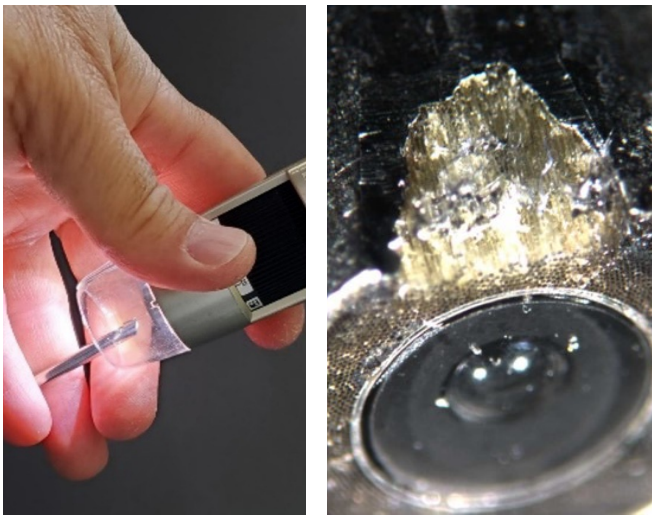

Figure 5: Enhanced magnification microscope and identified damage (exposed glass light fibers)

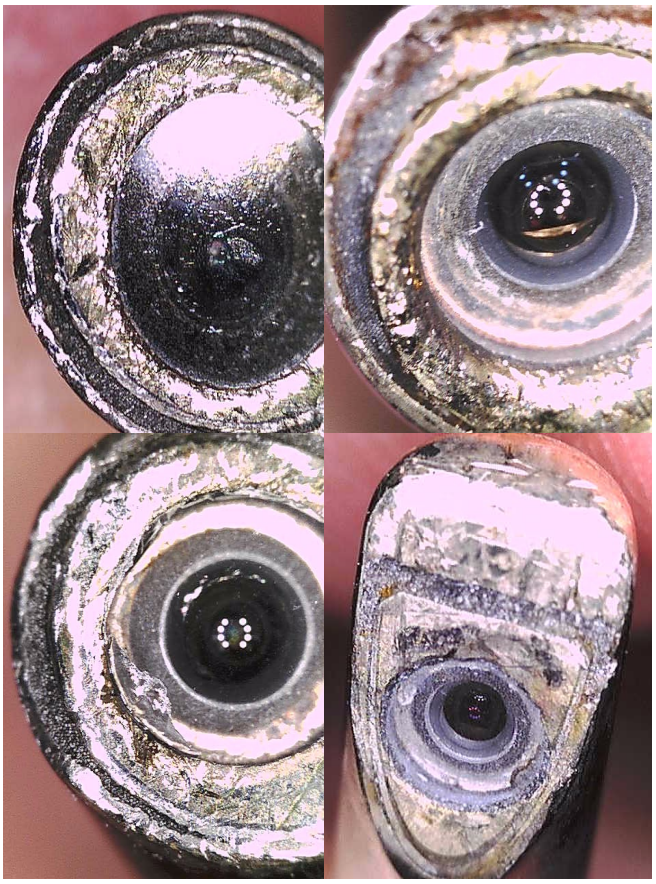

Figure 6: Identified with the use of an enhanced magnification microscope (exposed burrs, gouges, recessed areas, and scratches)

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It was concluded that the integrity failures emphasize the need for a proactive approach to inspection verification tools to identify failures within rigid endoscope optics and exterior distal window lens for better patient outcomes.

Applicable Recommendations and Standards for Inspection

Currently, the newer section of ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities,* states that "Each time a medical device is processed, it should be visually inspected for cleanliness and integrity. Enhanced inspection with magnification, borescopes, or other inspection methods to verify cleanliness and integrity may be used."[5] This section also states that "Health care facilities should have a method of ensuring the cleanliness and integrity of every instrument and medical device used in every procedure."[5] Lastly, it notes that "Damaged instruments or incomplete instrument sets/trays may cause a delay or cancellation of a surgical procedure and/or increase risk of patient harm related to instrument malfunction."[5]

The Healthcare Sterile Processing Association's *Sterile Processing Technical Manual*, ninth edition, states that "Functions, such as light output, image quality, should be examined."[6] The resource also notes that "for non-video rigid endoscopes, the image quality should be tested by viewing typewritten print through the endoscope from a distance of about one inch. The image should be closely examined in the center and for 360 degrees around the outside edge to ensure there are no blurry or dark areas."[6]

Limitations

The sample size of the study was affected by the number of rigid endoscopes a facility could release for examination as well as inconsistencies with the type of rigid endoscope inspected. The study's focus was only on inspection and verification tools (no other areas of concern in the total processing of the devices).

Conclusion

The study determined several contributing factors in the internal and external inspection process for rigid endoscopes. These integrity failures underscore the significance of appropriate use of verification tools and proper education (initial and continuous) for the inspection process. Together, tools and education help maintain instrument longevity and lower repair and replacement costs, while also decreasing adverse patient events.

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