Duodenoscopes are complex and sophisticated medical devices which are used for a variety of procedures involving the pancreatic and biliary ducts. They incorporate a side-viewing camera which provides proceduralists with the ability to directly visualize the major and minor duodenal papillae and perform complex pancreaticobiliary interventions. Duodenoscopes incorporate a moving elevator lever that provides fine control of instruments placed through the instrument channel and allows for biliary or pancreatic duct cannulation and instrumentation during endoscopic retrograde cholangiopancreatography (ERCP).

ERCPs are associated with various adverse events, including pancreatitis, bleeding, perforation, and infections – including cholecystitis and cholangitis. Over the last 20 years, duodenoscopes from all of the major duodenoscope manufacturers have been implicated in a number of contamination and infectious outbreak events. Organisms involved in outbreaks have involved multidrug-resistant (MDR) Pseudomonas aeruginosa, carbapenem-resistant Enterobacteriaceae (CRE), extended-spectrum beta-lactamase (ESBL)-producing Klebsiella pneumonia, and ESBL-producing Enterobacteriaceae. These outbreaks have gained widespread national attention, including that of the Food and Drug Administration (FDA) and Center for Disease Control (CDC), and have prompted further research into contamination and disinfection of duodenoscopes.

Duodenoscopes require disinfection between patient procedures. Various methods have been explored, including increased reprocessing quality control, repeated cleaning, forced air drying, or the use of sterilizing agents such as ethylene oxide. The FDA has called for duodenoscope designs to incorporate infection mitigating features, including disposable components or endoscopes intended for single-use. This review will focus on the technical aspects of duodenoscope design and reprocessing which relate to contamination, and new duodenoscope models and their contamination-mitigating design features.

Review of Current Issues
During routine use, duodenoscopes are heavily exposed to oral and gastrointestinal flora. Normal handling, cleaning, drying, and storage may also expose endoscopes to skin or water-borne flora. Inadequate cleaning and inadequate drying are possible causes of duodenoscope contamination. Common sites of contamination include the
Modifications to Duodenoscopes to Reduce the Risk of Infection Transmission

instrument channel, suction channel, forceps elevator, and the elevator wire channel.\(^1,3,5\) Residual body fluids and debris in the vicinity of the elevator have been specifically recognized as a critically important cause of potential infection transmission.\(^1,3,5\) The complexity of this elevator mechanism makes it difficult to fully access and can be challenging to clean fully.\(^1,3\) Other potential locations of contamination exist, as any site of wear or surface breakdown may allow for bacterial biofilm accumulation.\(^5,7\) Normal duodenoscope use may damage the surface of the endoscope sheath or endcap.\(^4,5\) The instrument channel may be subjected to abrasion with the passage of a variety of endoscopic accessories.\(^1\) Even the elevator wire channel, despite its sealed design in newer duodenoscopes, often shows micro abrasions.\(^6\)

In 2015, the FDA ordered manufacturers to carry out post marketing surveillance studies examining duodenoscope contamination rates.\(^2,8\) Surveillance result updates were released in 2018 and 2019, with higher than expected rates of contamination following reprocessing. Up to 6% of devices were colonized with organisms of concern, while up to 3.6% were found to have low- or moderate-concern organisms.\(^9,10\) Other studies have reported duodenoscope contamination rates following disinfection, with results ranging between 4% and 22%.\(^3,4,11,12\)

The CDC first warned the FDA regarding a potential association between MDR infections and duodenoscopes in 2013.\(^7\) Further investigation revealed cases of infectious transmission occurring despite following manufacturer-directed disinfection protocols.\(^2\) Duodenoscope reprocessing involves pre-cleaning, leak testing, and manual cleaning immediately following usage. These manufacturer-directed procedures are relatively complicated with many possible points of human error. This is followed by high-level disinfection (HLD) in an automated manufacturer-specific endoscope reprocessor. Finally, duodenoscopes are rinsed then dried in a hanging cabinet with filtered circulating air.\(^1\)

In 2015, the FDA suggested measures to reduce duodenoscope contamination rates in addition to standard reprocessing.\(^2\) Repeated HLD is the most popular of these strategies; however, even this may leave residual bacterial colonization.\(^4,8,13\) Sterilization with liquid chemicals or ethylene oxide is utilized by some institutions, but may be no more effective.\(^13\) These are time-consuming processes and may necessitate the purchase of extra duodenoscopes depending on the volume of procedures at an institution. Forced air drying, either manually or via automated drying cabinets, is utilized by many institutions, and results in significantly shorter drying times and may prevent growth of hydrophilic organisms.\(^14,15\) Reprocessing can also be followed by routine surveillance culture collection, with devices withheld from use until cultures are confirmed to be negative. While it is a resource- and staff-intensive practice, routine surveillance has also been shown to help identify endoscopes with mechanical damage.\(^4,5,12\)

Endoscope manufacturers have recently begun recommending annual duodenoscope inspections.\(^9,16,17\) This may help identify damaged
or excessively worn components, which may serve as a nidus for infection. Little data exists to support when to perform inspection and preventative maintenance. Other methods to decrease transmission of bacteria during procedures have also been explored.

Changes to device design have been offered as the best solution to the problem of duodenoscope-related infections. Following a 2015 advisory committee meeting, the FDA called for manufacturers to design duodenoscopes with removable or disposable parts to facilitate more effective cleaning.

**New Duodenoscopes Designs and Developments**

To date, the FDA has approved multiple duodenoscopes with disposable components which facilitate improved reprocessing. These include models from Olympus Medical Systems (Japan), Pentax Medical (Japan), and Fujifilm Corporation (Japan). They have also approved two fully disposable duodenoscopes from Boston Scientific (Massachusetts, USA) and Ambu (Denmark), and one single-use distal cover from GI Scientific (Virginia, USA) for an existing standard duodenoscope.

The Olympus TJF-Q180V, introduced in 2010 prior to the FDA direction to use removable parts, featured a new sealed elevator wire channel. Its FDA approval was based on similarity to the preceding XTJF-Q160VF1 endoscope, which was approved in 2008. Through 2014, multiple duodenoscope-related outbreaks were associated with use of the Q180V endoscope. Olympus voluntarily recalled the device worldwide after its sealed elevator wire channel mechanism was identified as an infection risk. The duodenoscope was reintroduced in 2016 following elevator wire channel modification and received subsequent FDA approval.

An accompanying sterile, single-use distal duodenoscope cover, the GI Scientific ScopeSeal, was FDA approved in October 2019 (Figure 1). It seals the distal end of the device and includes a working channel extension, which provides a protective barrier around the elevator area and channel during use. The Q180V device with ScopeSeal was assessed by Pasricha et al. The first portion of the study involved dye immersion testing, with no leakage occurring during immersion while articulating the endoscope elevator and suction mechanism. The second portion of the study assessed for endoscope contamination. The ScopeSeal device was placed on the distal end of the endoscope, the exterior was inoculated with E. coli, and the endoscope was repeatedly maneuvered to simulate use. After removal of the device, cultures were collected from the distal portion of the endoscope. In a separate test, the area around the elevator was inoculated, an instrument brush was passed repeatedly through the channel, and cultures were collected from the instrument. No contamination was detected in either test; however, this study did not include HLD of devices utilizing ScopeSeal. Of note, GI Scientific provided funding.
Olympus’ newest duodenoscope, the TJF-Q190V, was approved in January 2020. It features a single-use, sterile endcap which interfaces with the distal ring of the duodenoscope (Figure 2A). This cap is removed at the beginning of reprocessing to allow for improved access to the elevator area for manual cleaning and disinfection. This duodenoscope also has a proprietary distal-end flushing adapter for cleaning the elevator mechanism and a sealed elevator wire channel (Figure 2B).

No duodenoscope infection studies have utilized the Q190V endoscope thus far.

The Pentax ED34-i10T was FDA approved in September 2017 and features a single-use, non-sterile, distal endcap (Figure 3A). This cover allows for improved access for reprocessing and should be steam sterilized prior to use. It also features a sealed elevator wire channel. There has been one study reporting endoscope contamination rates by Rauwers et al., which has included reports of contamination in the Pentax ED34-i10T. Pentax's most recent iteration, the ED34-i10T2, was FDA approved in November 2019. It features a sterile, disposable elevator cap which is manipulated by a steel bar at the end of the elevator wire channel (Figure 3B). The distal end of the channel is sealed with an O-ring. In contrast to the other devices mentioned, the elevator mechanism is integrated into the cap, simplifying reprocessing. The Infection Control in ERCP using a duodenoscope with a disposable EndCAP (ICECAP) trial is currently enrolling and will evaluate the ED34-i10T versus the ED34-i10T2 scopes with their distal endcap and distal elevator caps, respectively. Investigators plan to collect cultures from the instrument channel and elevator recess followed by standardized post-endoscopy reprocessing. Based on the design as reported, the study will not compare fixed endcap and removable endcap duodenoscopes, but two devices with different designs of removable caps.

The Fujifilm ED-580XT was FDA approved in September 2019. It has a disposable distal endcap which allows a brush to access the back of the elevator mechanism (Figure 4). It also features a sealed elevator mechanism. The efficacy of the 580XT distal endcap was explored by Ridtitid et al. who compared elevator site cultures and adenosine triphosphate (ATP) testing following HLD both with the removable endcap detached versus left on prior to cleaning. Residual ATP has been used as a marker of the cleaning process of various medical devices and is associated with the presence of both human and bacterial cells. The median ATP value was significantly lower for the cap off group; however, there was only one positive culture (skin flora) out of 108 post-procedural cycles. ATP testing may not be as useful of a marker of the HLD process, since it cannot distinguish between human and bacterial contamination, nor high- and low-concern organisms. Moreover, this study did not compare fixed vs detachable cap duodenoscope models, but the same device cleaned with and without its endcap. To date, manufacturers Fujifilm,
Pentax, and Olympus have submitted a total of 10 reports of device malfunctions, such as removable caps falling off during ERCP. No patient injuries have been reported to the FDA.\(^4\)

The Boston Scientific EXALT Model D was the first sterile, single-use duodenoscope and was FDA approved in December 2019 (Figure 5).\(^{41–43}\) The Model D was compared to devices from the three major manufacturers in a small anatomical bench model study by Ross et al.\(^4\) Various tasks were assessed in the study, including guidewire locking, plastic stent placement and removal, metal stent placement and removal, and basket sweeping. It had comparable performance to a contemporary duodenoscope in all tasks except for navigation and “pushability.” All tasks were completed by participating proceduralists.\(^4\) The duodenoscope was also assessed in a clinical setting by Muthusamy et al.\(^4\) The maneuverability of the Model D was rated by proceduralists following ERCP biliary cannulation sphincterotomy, stone clearance, placement or removal of stents, and balloon dilation of strictures. Overall, proceduralists were “satisfied” or “neutral” regarding the performance of the endoscope; however, it was noted to be harder to torque and maneuver when advanced more distally in the duodenum. The overall adverse event rate was found to be comparable to standard ERCP practice.\(^4\)

The Ambu aScope Duodeno is a sterile, single-use duodenoscope which was FDA approved in June 2020 (Figure 6a–6e).\(^{46–48}\) It has not been examined in any duodenoscope contamination or maneuverability studies thus far. As part of the manufacturer development process, it was tested for equivalence to the Olympus TJF-Q180V in a porcine upper gastrointestinal tract model.\(^4\) While single-use endoscopes prevent potential exogenous transmission of infection, they still do not eliminate the risk of translocation of patients' own oral or gastrointestinal flora and subsequent endogenous infection, recognizing that this is a lower risk transfer. The largest barrier to adoption of single-use devices is likely cost. Some analysis indicate that the cost of single-use duodenoscopes may be ten-times greater than that of reusable devices even when accounting for rates of infection and the cost of subsequent treatment. These costs may only be tenable by high volume institutions.\(^4\)

**CONCLUSION**

Duodenoscope contamination and associated infections have resulted in an increase in research into causes of device contamination and the efficacy of disinfection processes. Manufacturers’ newly designed and re-designed duodenoscopes have attempted to answer the FDA’s call by creating endoscopes with removable or disposable parts to facilitate cleaning of high-risk areas. Because these devices have only been available recently there is a paucity of information regarding the new, removable endcap duodenoscopes discussed above.

No current studies have sufficiently compared the rates of contamination between traditional fixed endcap duodenoscopes and those with removable endcaps. The existing studies, discussed above, have either lacked sufficient control groups or have been relatively underpowered to detect
contamination differences between the two devices. Post marketing surveillance, utilizing a large volume of sampling events across institutions, will be essential in establishing the benefits of these new designs. Moreover, it remains to be seen if design elements of the new devices, such as the interface between the sheath and distal endcap, will serve as a novel place of wear and potential nidus for biofilm accumulation.

Following the FDA’s call for duodenoscopes intended only for single-use, there are now two single-use devices available. Further exploration of the cost of single-use duodenoscopes will be of paramount importance if they are to be more broadly adopted. These studies should seek to incorporate all of the hidden costs associated with device reprocessing, surveillance, downtime, outbreak management, and potential lost revenues.

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Answers to this month’s crossword puzzle:

BARIATRIC VAGAL

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WASTEDRY SOLID