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Review Article

Single-use endoscopes: A narrative review

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A B S T R A C T

The transmission of infections through gastrointestinal endoscopy is a vital issue. The main problem lies in the use of duodenoscopes due to mechanical aspects of the scope design. Even with high-level disinfection, sterilization of the scope can fail. Hence, the Food and Drug Administration has encouraged a shift to single-use endoscopes. Available options include endoscopes with single-use components (mainly single-use endcaps), fully single-use duodenoscopes (SUDs), and even those with a disposable elevator mechanism. Clinical trials revealed that both reusable and single-use scopes have the same efficacy, while single-use scopes have benefits in terms of infection control, economic considerations, and ease of reprocessing. A few drawbacks are left to be dealt with. Reusable duodenoscopes with removable/disposable endcaps are satisfactory except in specific situations where SUDs are better to use.

Keywords: Ease of reprocessing; Economic benefit; Infection transmission; Reusable flexible scopes; Single use duodenoscopes

Introduction

Gastrointestinal endoscopy is considered one of the most popular invasive procedures in clinical practice. Marvelous adjustments and quality upgrades have been introduced since 1950—from gastro-cameras, flexible endoscopes, and videoscopes to high-density videoscopes at the present time.[1] It is estimated that 40 million flexible endoscopy procedures are performed annually in the United States of America (USA) across many different clinical specialties. However, reusable endoscopes represent a significant capital investment and operating expense. The most important disadvantage of reusable scopes is the risk of infection, which has simultaneously been the main driving force to shift to single-use endoscopes (SUEs).

The Problematic Scopes

Many reports have verified failure of duodenoscope sterilization after high-level disinfection.[2] Cultures from different parts of scopes have confirmed that the main problem is at the distal permanent rubbery part of duodenoscopes, which interferes with the sterilization process. A Food and Drug Administration (FDA)-mandated duodenoscope surveillance study was conducted by reusable duodenoscope manufacturers. The problem is particularly exacerbated by the fact that high-concern organisms such as *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Escherichia coli*, and more recently, carbapenem-resistant Enterobacteriaceae have been isolated from 5% of properly collected samples.[3,4] This scenario for duodenoscopes is slightly different from that for gastroscopes and colonoscopes, where the danger of infection by a contaminated endoscope is low. The high contamination rates could also be explained by reasons other than endoscope mechanical design, such as biofilms in biopsy channels and insufficient drying.[5]

Seventy-two percent of surveyed hospitals and critical access hospitals were reported to be noncompliant with the Joint Commission's high-level disinfection standard.[6] Recently, Madureira and de Oliveira[7] reported endoscopic processing gaps as follow: absence/inadequate drying (55.5%), manual cleaning without brushing the inappropriate channels/brushes (50%), omission of the sealing test (38.8%), inadequate storage (33.3%) and use of the disinfectant solution (27.7%), time of immersion or monitoring

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of the minimum effective concentration, absence of pre-cleaning (16.6%), incorrect transportation to the processing room (11.1%).

Single-Use Duodenoscopes

Since the 1970s, the marketplace has shifted to single-use products, but flexible reusable endoscopes still represent the major used scopes.[8] By the end of 2019, single-use duodenoscopes (SUDs) were developed in the USA and approved by the FDA for clinical use.[9] The FDA recommended shifting from using reusable duodenoscopes to SUEs, with options including endoscopes with single-use components (mainly single-use endcaps), fully single-use duodenoscopes, or even endoscopes with a disposable elevator mechanism.[10] The options now include six duodenoscopes with disposable components, including four with single-use distal ends that facilitate reprocessing and two that are fully disposable single-use instruments (Table 1).[11] The main production organizations include Ambu (Copenhagen, Danmark) and Boston Scientific Corporation (Marlborough, MA, USA) (Fig. 1). Ambu is a Danish manufacturer that launched single-use duodenoscopes in 2020 and announced that they would launch single-use gastroscopes and colonoscopes by 2021.[12] Other companies involved in manufacturing duodenoscopes with disposable components include Fujifilm Corporation (Tokyo, Japan), Olympus Medical Systems (Tokyo, Japan), and Pentax Medical (Tokyo, Japan).[11] Ambu and Boston Scientific assemble their SUEs in a manufacturing area, after which the final products are transported to a distribution center in a different state inside USA.[13]

EndoFresh (Shenzhen, China), a Chinese high-tech clinical tool production agency engaged in the manufacture of high-end medical disposable digestive endoscopes, obtained FDA clearance for its groundbreaking disposable digestive endoscopy system. Its headquarters are in Shenzhen Science Park.[14]

The working principle of a complementary metal oxide semiconductor (CMOS) image sensor was conceived in the late 1960s, but CMOS-based devices were not commercialized until microfabrication technologies became sufficiently superior in 1990s. The cost of CMOS-based cameras has decreased exponentially with dramatic improvements in image resolution.[15] In 2020, Ambu sold more than 1 million SUEs.[16] The global single-use/disposable endoscopy market was estimated at $471.7 million in 2019 and is expected to reach $22,720.1 million by 2030. The factors responsible for driving the growth of the global single-use/disposable endoscopy market include the high risk of hospital-acquired infections, the high cost associated with reusable endoscopes, the increasing spread of infectious diseases, and the growing burden of regulatory approval.[17]

Why Single-Use Duodenoscopes?

In addition to elimination of the contamination danger, several reports have stressed the economic aspects of SUEs over reusable flexible endoscopes. Costs can be estimated according to both procedure volume and the infection rate. The per-procedure cost of a disposable duodenoscope in the United States for centers performing at the 75th percentile varies from $797 to $1,547 and

Fig. 1. Novel single-use duodenoscope (EXALT Model D; Boston Scientific Corp, Marlborough, MA, USA). Reused from the article of Trindade et al (Gastrointest Endosc. 2021;93:997-1005)[11] with original copyright holder's permission.

Table 1 Comparison of Disposable-Endcap Duodenoscopes and Disposable Duodenoscopes

Variable	Olympus TJF-Q190V	Disposable distal endcaps			Disposable duodenoscopes	
		Pentax Clarity Access Performance HD	Pentax DEC	Fujifilm ED-580XT	Boston Exalt	Ambu aScope Duodeno
Field of view (degree)	100	100	100	100	108	130
Observation range/depth of field (mm)	5–60	4–60	4–60	4–60	5–60	
Distal end diameter (mm)	13.5	13	13	13.1	15.1	13.7
Insertion tube diameter (mm)	11.3	11.6	11.6	11.3	11.3	11.3
Maximum diameter of insertion portion (end cap attached) (mm)	13.5	13.8	13.6	14.9	15.1	13.7
Minimum diameter of instrument channel (mm)	4.2	4.2	4.2	4.2	4.2	4.2
Bending capability						
Up/down (degree)	120/90	120/90	120/90	120/90	120/90	120/90
Left/right (degrees)	110/90	105/90	105/90	90/110	90/110	90/110
Working length (mm)	1,240	1,250	1,250	1,250	1,240	1,240

Olympus Medical Systems, Tokyo, Japan; Pentax Medical, Tokyo, Japan; Fujifilm Corporation, Tokyo, Japan; Boston Scientific Corp, Marlborough, MA, USA; Ambu, Copenhagen, Danmark.
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from $1,318 to $2,068 for centers performing at the 25th percentile based on infection rates of 0.4% to 1%, respectively.[18] However, when infection was not factored in, the per-procedure cost decreased to $818 and $297 for centers performing at the 25th and 75th percentiles, respectively.

Reusable scopes represent a significant capital investment and operating expense. With backlogged and elective procedures being performed again, SUEs can increase capacity without investment in additional capital. Not only is endoscopic reprocessing complex, costly, highly dependent on human factors, and time-consuming—it is also often ineffective. Its cost ranges from $114 to $281, accounting for labor, material and endoscope repairs, which is cost-ineffective compared to disposable scopes.[19] Eliminating reprocessing creates workflow efficiencies and productivity improvement. In addition, due to the convenience of not having to clean the endoscopes; SUEs are very convenient in emergency situations, after-hours procedures, and working outside of an endoscopy unit, such as in the intensive care unit, emergency room, or operating room, as it saves time that would otherwise be required to manually prepare the scope for automated reprocessing. This time has been determined to be 76 minutes, which is much higher than that reported by other hospitals, which reported that the manual reprocessing time for each colonoscope was 19 minutes.[20] Needless to say, the United States Centers for Medicare and Medicaid Services and private insurance carriers are the main decision-makers regarding whether the costs of SUEs are fully covered, enabling small-volume institutions to benefit from their use. Due to the advantages of SUEs, such as being cost-effective, reducing financial risk, eliminating infection risk, and improving productivity, it is expected that the next era will shift more and more towards the use of SUEs.

What Are the Troubles Facing Single-Use Scopes?

Despite the points made above, the picture is not as bright as it might seem. There are many drawbacks that deserve attention. Although SUEs can eliminate exogenous infections, they play no role in the control of endogenous infections, which might be the principal reason for post-procedural cholangitis.[9] The USA accounts for 27% of the worldwide healthcare footprint and is the world's highest emitter of healthcare greenhouse gases.[21] Globally, healthcare is responsible for 4.4% of worldwide net emissions. Furthermore, the carbon footprint generated from devices used in healthcare is expected to increase dramatically.[22] The widespread adoption of single-use instruments will generate a massive amount of waste annually from endoscopic procedures, and it is expected to boom by more than 19%.[23] Medical waste disposal management is a difficult task requiring specialized companies. The estimated annual waste from all endoscopies performed in the USA (18 million endoscopies) would cover approximately 160 football fields to a 1-m depth and weigh 42,000 tons. Changing to SUEs would increase the net waste by 24%.[24] Furthermore, phthalates are used in the manufacturing process of SUEs to make them softer. This chemical substance presents a medical hazard, with a major impact on the male reproductive tract. For this reason, Ambu announced that phthalates will no longer be used in their products.[25]

Clinical Trials

A comparative study between SUDs and three models of reusable duodenoscopes for endoscopic retrograde cholangiopancreatography (ERCP) in an anatomic model to test four ERCP-related tasks was performed. Both the performance ratings and completion times are comparable.[26] In a randomized trial including 98 patients in whom SUDs (n = 48) or reusable duodenoscopes (n = 50) were used, Bang et al[9] suggested that SUDs showed comparable technical efficacy and safety performance to reusable scopes in low-complexity ERCP procedures in experienced hands. However, SUDs achieved a substantially shorter cannulation time than reusable scopes. In another retrospective analysis of consecutive cases comparing the feasibility, safety, and performance of SUDs, 60 ERCPs were included across six sites in France for variety of indications including biliary stone removal, stent placement, and balloon dilation. Ninety-five percent of the ERCP procedures were completed. Three cases required crossover to a reusable duodenoscope, although the use of both scopes was unsuccessful. The physicians' median satisfaction with the use of SUDs was 9 out of 10, with no severe adverse effects attributable to their use.[27] In a case-series study, SUE performance was tested in cases with different grades of complexity. Seventy-three patients were included, and seven professional endoscopists performed all procedures. The procedural complexity was distributed as follows: grade 1, 7 patients (least complex); grade 2, 26 patients; grade 3, 26 patients; and grade 4, 1 patient (most complex). Almost all (96.7%) of the procedures were accomplished using the SUD only, while two other procedures (3.3%) were accomplished by using the SUD followed by crossover to a reusable scope. Three complications were recorded: one patient developed post-ERCP pancreatitis, one developed post-sphincterotomy bleeding, and the third patient had exacerbation of a preexisting contamination and required rehospitalization. They reported that expert endoscopists could complete ERCPs of a huge variety of complexity using SUDs in all cases.[28] Identical conclusions were reported by other researchers.[29]

We believe that the use of reusable duodenoscopes with removable/disposable endcaps is satisfactory. The situations where SUEs are most necessary include high-risk cases, such as immunocompromised patients, cancer patients, patients with hematologic malignancies receiving chemotherapy or radiotherapy, patients with end-stage renal disease, terminal hepatic disease patients, HIV patients, or patients known to be infected with multidrug-resistant organisms. SUEs can also be used in emergency situations performed outside of the endoscopy unit, such as in the intensive care unit, emergency room, or operating room, where we can use fully single-use duodenoscopes. In the era of coronavirus disease 2019 (COVID-19), it is better to use a fully single-use duodenoscope in any suspicious or confirmed case, with utmost attention to the disposal process. Using SUDs in patients with confirmed or suspected COVID-19 may be a reasonable strategy to reduce the risk of infection among patients and healthcare personnel. The use of a disposable duodenoscope eliminates the risk of patient-to-patient transmission related to inadequate disinfection. There is also a risk of aerosolization during disinfection and therefore of exposure risk to the personnel performing endoscope cleaning, both in the procedure room and in the endoscope cleaning room.

Conclusions

SUDs constitute the best alternative to reusable duodenoscopes. In addition to removal of the contamination danger, financial considerations, the ease of reprocessing, workflow efficiencies, and productiveness are beneficial. However, reusable duodenoscopes with removable/disposable endcaps are satisfactory in most cases. SUDs are particularly necessary in high-risk cases, such as in immunocompromised patients, or in patients known to

be infected with multidrug-resistant organisms. SUDs can also be used in emergency situations outside of the endoscopy unit, such as in the intensive care unit, emergency room, or operating room.

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Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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