Residual Moisture Following Endoscope Reprocessing and Drying

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Abstract

Background:

The drying and storage of flexible endoscopes following reprocessing is critical to ensuring that bacterial contamination does not occur within the internal channels. At present, guidelines are inconsistent on the proper duration of a the forced-air flush used in endoscope drying and on the proper methods of storage. The purpose of this study is to assess the effectiveness of forced air flushes and ambient storage during endoscope drying.

Methods:

Data was collected from a large urban medical center, stored clinical endoscopes and from endoscope models following reprocessing. Endoscope models were used to assess differences in drying procedures between internal channels, which might not be otherwise apparent.

Findings:

A significantly lower proportion of endoscopes treated with a 10-minute air flush retained moisture, compared to those treated with 3-minutes of air (16.7% v 53.1%; p-value = 0.027). There was no significant relation between storage time and the presence of retained moisture (OR 0.771; 95% CI: 0.561-1.030; p-value = 0.078). In model endoscopes, fluid was more prevalent within the air/water channels.

Conclusions:

The 10-minute air flush recommended by some current guidelines is not universally effective at removing fluid from endoscopes following reprocessing, but it is more effective than 3-minute flushes. Storage of endoscopes in ambient-air closets does not appear to aid in endoscope drying. Examinations of individual channels reveal that the narrower air/water channels may selectively resist drying with forced-air and during storage. Endoscopes should be dried with at least 10-minutes of forced air and stored in forced-air drying cabinets.

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Preface

This author would like to wholeheartedly thank Heather Dixon and her team of infection preventionists, whose sincere warmth and welcoming helped him to take his first steps in this field. Particular thanks to Amy Kinzler, Taylor Keck, and Dane Kincaid, without whom data collection would have been neither enjoyable, nor possible. He would like to thank, also, Dr. Linda Frank for her peerless support in affording him opportunities and the motivation to pursue them.

Lastly, a special thank you to Dr. Mohamed Yassin— a mentor of remarkable grace and good humor.

1.0 Introduction

Flexible endoscopes are a wide range of medical devices used to visualize and manipulate internal body cavities with minimal invasiveness. These devices are used in a variety of procedures involving the diagnosis and surveillance of disease, biopsy collection, and therapeutic procedures [1]. Annually, an estimated 17.7 million endoscopic procedures are performed across the United States [2]. Considering their ubiquity in the clinical environment and the number of patients with whom they come into contact, proper disinfection of these devices is paramount in preventing the spread of potential pathogens from endoscope to patient, and in preventing microbes from persisting on or within the devices between procedures.

Efforts at disinfecting or sterilizing endoscopes are complicated by the long internal channels and intricate manipulation mechanisms present within the devices, as well as by complicated cleaning and disinfection protocols [3]. One aspect of concern is the possibility of incomplete drying following endoscope reprocessing, as retained moisture may promote the regrowth of bacteria and the development of biofilms [4]. Drying is the final step of endoscope reprocessing and consists of a dedicated flush of high-grade, forced, filtered air through the internal endoscope channels. However, despite its importance, guidelines for drying and storage, as well as device specific instructions for use, remain inconsistent [5]. Recent recommendations now suggest at least 10-minutes of a continuous forced air flush [6]; however, there remains a dearth of quantitative data assessing the effectiveness of this process, particularly in real-world scenarios. Indeed, recent research indicates that the dynamics of channel drying may be more complicated than previously appreciated, and 10 minutes of air flush may or may not be appropriate in every instance [7].

1.1 Study Objectives and Hypotheses

Contained herein is a study, undertaken to better understand the effectiveness of the forced air flush step in endoscope drying and storage. A review of the relevant literature pertaining to endoscope drying is provided, followed by a research study examining endoscope data from a large urban medical center. The endoscopes from which data was collected were stored endoscopes, ready for clinical use, as well as model endoscopes stripped of their outer sheaths. This study sought to examine three hypotheses:

1. A higher proportion of flexible endoscopes treated with an extended 10-minute air purge will show complete eradication of moisture within the internal channel systems than those treated with a 3-minute air purge.
2. The length of storage of flexible endoscopes in an ambient storage cabinet is positively associated with the eradication of moisture within the internal channel systems of flexible endoscopes.
3. The narrower gauge air/water channel systems are more likely to retain moisture than the larger gauge biopsy channel systems.

2.0 Literature Review

2.1 Endoscope Design and Terminology

"Endoscope" is a broad term, encompassing any device used to look inside a body cavity, which can be divided into rigid or flexible endoscopes. Flexible endoscopes are further subdivided by the part of the body which the device is designed to assess [1]. While a multitude of endoscope designs exist, six types of flexible endoscope are relevant to this study: gastroscopes, colonoscopes, nasopharyngeal endoscopes, bronchoscopes, cystoscopes, and ureteroscopes (see table 1 in section 3.2).

Each of these devices share certain terminology and design features of which a baseline understanding is necessary to assess moisture risk. The insertion tube (figure 1) is the long flexible portion of the device which enters the body [8]. Internally, the insertion tube contains a biopsy/suction channel, through which endoscope accessories may pass or biological samples may be taken. Also contained within the insertion tube are the air/water channels, from which air or water may be propelled outwardly to clear the viewing field for the operating surgeon. The insertion tube extends proximally from the control section, which contains manipulation dials and access valves, to the distal tip, the terminal end of the endoscope containing the light, magnification lens, and channel openings.

A method of directly viewing the internal channels by removing the protective polymer sheath from the insertion tube has recently been described [7, 9]. The resulting stripped endoscope (SE) is no longer serviceable for clinical use, but may be reprocessed as normal, and serves as a

potent model for observing moisture following high-level disinfection (HLD) to assess the effectiveness of drying procedures. An example of a SE model is shown in figure 1.

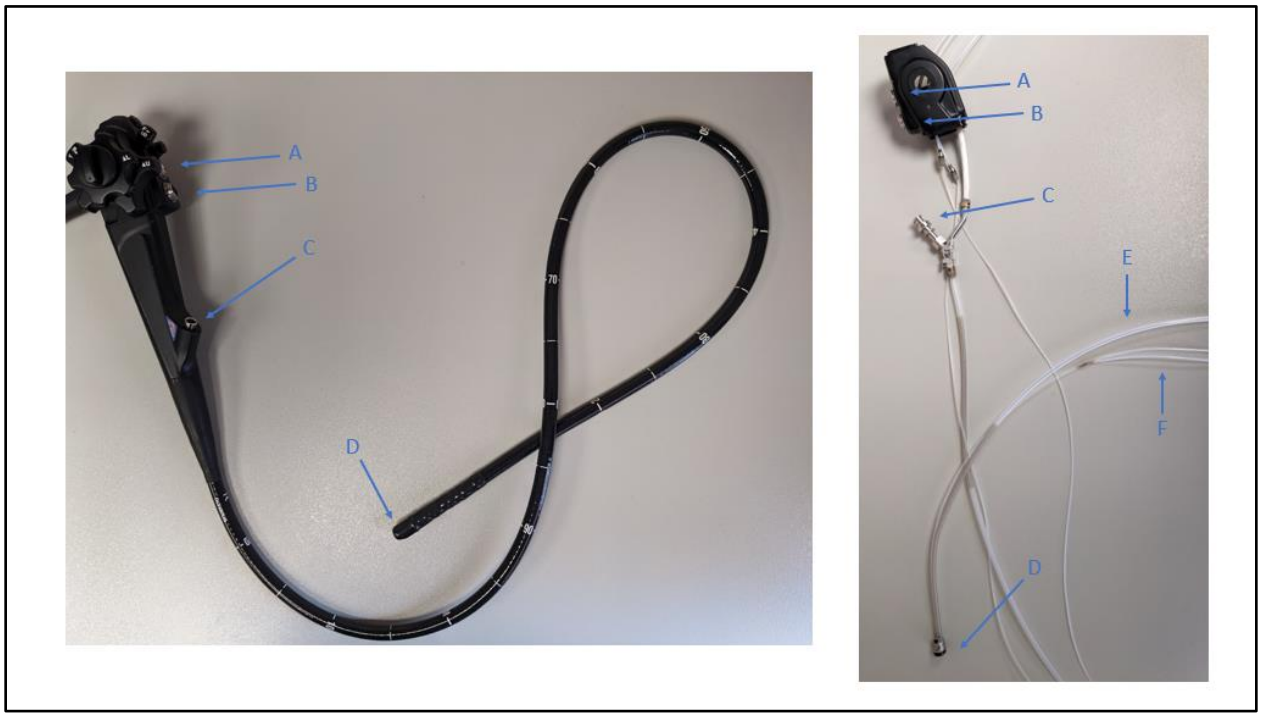

Figure 1 Structure of an endoscope insertion tube.

Structure of an endoscope insertion tube (left) and SE model insertion tube (right) showing internal channels. A) Suction Valve; B) Air/Water Valve; C) Biopsy Valve; D) Distal tip; E) Biopsy channel; F) Air/water channels.

2.2 Cleaning, Disinfection, and Sterilization of Endoscopes

The degree to which medical devices are disinfected or sterilized is determined by the associated risk of infection from the device's use, under a system known as the Spaulding Classification. Spaulding Classification is widely accepted and used by medical facilities to aid

their risk classification of medical devices [10]. Within this framework, devices may be categorized as critical, semicritical, or noncritical. Critical devices are those which contact sterile body cavities, blood, or vascular tissues; these devices must be cleaned and sterilized completely. Semicritical devices contact mucous membranes or compromised skin; these devices necessitate cleaning and high-level disinfection (HLD). Noncritical devices only contact intact skin; these undergo cleaning with low-level disinfection. Flexible endoscopes are classified as semi-critical or critical, depending on their intended use, and thus may undergo HLD or sterilization processes accordingly.

Sterilization, HLD, and cleaning are specific terms. Sterilization refers to the complete eradiation of all microorganisms, including bacterial spores. High-level disinfection constitutes the destruction of virtually all microbes, excepting bacterial spores. Cleaning refers to the gross removal of visible soilage and biomatter [10, 11]. Whether a device is sterilized or undergoes HLD, it must be thoroughly cleaned beforehand to avoid failure of subsequent sterilization or HLD [12].

Appropriate methods of sterilizing endoscopes include those used for heat-sensitive devices, such as treatment with ethylene oxide gas or hydrogen peroxide plasma following cleaning [6, 12]. These sterilization procedures are thought to render endoscopes completely dry, contrary to HLD, which necessitates additional drying steps [6].

Owing to the complexity of treatment and multiple necessary steps, much of the HLD of endoscopes is performed by automatic endoscope preprocessors (AERs). These machines continuously cycle solutions containing microbicidal disinfectants, at pressure, throughout the internal channels for 22 to 30 minutes [13]. By automating the process of HLD, AERs have been shown to reduce human errors of missed steps or procedural noncompliance [14].

2.3 The Retention of Moisture and the Associated Risks

While the role of moisture in promoting bacterial growth has long been understood, appreciation for the consequences of retained moisture within flexible endoscopes began as early as 1983, when a study noted that drying automatically reprocessed endoscopes with forced air significantly reduced microorganisms within the endoscopes [15]. Early studies showed that significant microbial growth occurs within wet endoscopes within the first 24 hours of storage [16]; moreover, that biofilm formation within improperly dried endoscopes could be responsible for failures of disinfection without otherwise identifiable cause [17]. For these reasons, the proper drying and storage of endoscopes following HLD is now understood to be a crucial terminal step in endoscope processing.

This understanding has evolved over time. While incomplete drying is associated with increases in culturable bacteria present in the channel [16, 18], residual fluid is also associated with increased levels of ATP recoverable from the channel, compared to dry endoscopes [19, 20]. This latter point may be indicative of viable, but non-culturable, bacteria present within the channels. Viable bacteria, even in trace amounts, can double quickly during wet storage and begin laying down a biofilm matrix [21, 22]. Repeated cycles of reprocessing and incomplete drying lead to a buildup of dense biofilm, which becomes more likely the longer an endoscope is in service [21-24]. While it is known that biofilm may confer some protection to microbes from disinfectants [25], further research is needed to understand the dynamics of this effect within endoscope channels.

Complicating matters further, certain chemicals used in some endoscopy treatments, such as simethicone, may affect drying effectiveness. Simethicone is a common contaminant in gastrointestinal endoscopes [26]. Simethicone, a defoaming agent which is insoluble in water or

alcohol, resists removal during cleaning and HLD [26, 27]. The use of simethicone in endoscopes is associated with both an increase in moisture retention and an increase in ATP levels within endoscope working channels [28].

The last decade has seen a greater recognition of infectious outbreaks linked to improperly reprocessed endoscopes (see section 2.4), with many of those clusters linked to improperly dried endoscopes or an endoscope containing significant biofilm. In one review of endoscope associated infections, researchers found that at least five out of 18 outbreaks could be linked to an improperly dried endoscope [29]. Further outbreaks may or may not have been linked to improper drying but did not explore moisture retention during their outbreak investigations [30-34], underscoring the need to consider these factors when faced with endoscope-associated infections.

More research must still be done to conclusively identify what level of retained moisture, if any, is permissible within endoscopes. Owing to the available methods of moisture detection (see section 2.5), moisture levels within the working channels are often explored as a binary (present vs not present); however, in truth, varying levels of moisture may be present within the channels. This, in turn, may have varying effects on the risks of bacterial outgrowth and biofilm formation which are not yet understood.

2.4 Endoscope Associated Outbreaks and Organisms

The types of bacteria cultured from fully reprocessed endoscopes tend to be water loving, gram-negative species [5, 20]. Common isolates include, but are not limited to, Acinetobacter sp. [16, 35, 36], Pseudomonas sp. [16, 21, 29, 33-35, 37], Klebsiella sp. [29, 31, 32, 35], Escherichia coli [29, 30, 35], among others [5, 20, 29, 35]. Bacterial contamination appears to vary by the type

of endoscopy procedure used. Pseudomonas sp. and Klebsiella sp. are common isolates of gastrointestinal (GI) endoscopy, whereas Serratia sp. and Mycobacterium sp. are more commonly associated with bronchoscopy [5]. Detectable microbial growth of pathogenic bacteria within the channels of stored endoscopes may be relatively common, but varies by site, with some reporting a prevalence as low as 2% [38] to as high as 71% [20]. Such variation may be due to the different reprocessing procedures conducted by various healthcare facilities, perhaps owing, in turn, to the disparate guidance on proper endoscope reprocessing provided by regulatory bodies and professional organizations.

Not every case of microbial outgrowth leads to patient infection, and while reports of detectable bacteria within endoscope channels may be common, endoscope-associated infections are less frequent, but significant. Endoscope-associated infections were historically thought to be exceedingly rare [39] but are now understood to be significantly more common than previously appreciated, owing to improvements in surveillance and reporting [29, 40]. Once estimated at 1 in 1.8 million endoscopic procedures [41], more modern methods estimate that post-endoscopic infections could be greater than 1 in 1,000 procedures for GI endoscopies [42].

Outbreaks of infections associated with endoscopes often coincide with multi-drug resistant organisms (MDRO) and can have dire outcomes for the afflicted patients [35]. Moreover, certain endoscope designs and procedures appear to be at a greater risk for infection with an MDRO, namely duodenoscopes used in endoscopic retrograde cholangiopancreatography (ERCP), which represent the majority of reported GI endoscopy-associated infections [29]. This is likely due both to the proximity and contact to the biliary tract during the procedure, as well as the complicated elevator mechanisms present on duodenoscopes – which resist efforts to eradicate moisture and biofilm [35, 43].

Proper drying of endoscopes is important to preventing outbreaks of disease, as moisture contributes to the regrowth of microorganisms and biofilms (see section 2.3). At least 24 endoscope-associated outbreaks have now been described, linked to improper drying of the devices [5]. What proportion of all endoscope-associated outbreaks may be directly attributed to improper drying, and what proportion to other failures of HLD, is a matter of ongoing discussion [3, 20].

2.5 Methods of Intraluminal Moisture Detection

Evaluating the dryness of endoscope internal channels presents a unique challenge, due to their length and relative inaccessibility. Endoscope insertion tubes lengths can be in excess of two meters, with internal channel diameters of only 2.0-4.2 mm, accessible only from the distal end or control box [44]. Three qualitative methods of detecting fluid within these channels have been described in the literature, each with their own limitations. These are: 1) evaluation with moisture indicator papers; 2) evaluation with a borescope; and 3) evaluation with a stripped endoscope (SE) model.

It should be noted that each of these described methods of evaluating endoscope dryness are qualitative. There remains a need for quantitative measures of detecting moisture, preferably ones which may discern between the presence of water, versus other possible chemicals. Further research is also needed to validate the sensitivity and specificity of these measures. Additionally, SE models are a new method which, thus far, have only been used in a controlled laboratory setting. Use of these models to assess reprocessing methods in a real-world clinical setting has not yet been explored.

2.5.1 Moisture Indicator Paper

Moisture indicator papers are carbon papers which contain a chemical indicator, such as cobalt chloride, that change color upon contact with water. Such test strips are often used to measure relative humidity with high sensitivity (Bridgeman 2014), but have been repurposed, in several studies, to measure the presence of fluid expelled from the distal tip of an endoscope during manual air insufflation [18, 20, 45]. One limitation of such a method of detection is that, while sensitive to the presence of water, the paper can only detect moisture droplets which have been successfully expelled from the channel through forced air, which is not a guarantee. Additionally, chemical indicator test strips cannot discern between the presence of water and the presence of alcohol as isopropyl alcohol is soluble in, and typically exists in equilibrium with, water [46], thus limiting their specificity. Research on the validity of moisture indicator paper in endoscopes is, presently, lacking.

2.5.2 Borescope Evaluation

A borescope is an ultrathin camera which can be threaded through narrow-diameter channels and were originally used by manufacturers during endoscope repairs [47]. Borescopes have been used in endoscope surveillance and assessments of endoscope reprocessing measures since as early as 2016 [48], with several subsequent studies describing the use of a borescope to assess for the presence or absence of internally retained moisture, following endoscope reprocessing [19, 48-50]. Borescope evaluation allows for video-assisted visualization of the internal biopsy/suction channel, thus allowing for sensitive identification of fluid. However, discerning between water droplets and droplets of simethicone or some other fluid is relatively

subjective and dependent on operator judgment. Additionally, the diameter of the narrower air/water channels cannot accommodate current borescopes [47], making assessment possible only in the suction/biopsy channel.

2.5.3 Endoscope Models

A recent method of moisture evaluation is that of using an SE model, wherein the outer polymer sheath is removed, allowing for direct visualization of moisture within the translucent internal channels (figure 1). This model was first described in a 2021 study, and then in a follow up study from 2022 by the same team [7, 9]. The advantages of this method are that it allows for direct visualization of the narrow air/water channels which cannot be seen via borescope. The drawbacks are that this method may not discern between water, alcohol, simethicone, or other fluids. Moreover, while this model can undergo the same reprocessing procedures as a clinical endoscope, the dynamics of endoscope drying may be altered slightly by removing the polymer sheath of the insertion tube. Additionally, this model is expensive, as removing the polymer sheath cannot easily be undone, and renders the endoscope unsuitable for further clinical use.

2.6 Best Practices and Guidelines for Drying and Storage

Owing to the increased recognition of endoscope-associated infections (see section 2.4), guidelines for the disinfection, drying, and storage of flexible endoscopes are currently under intense scrutiny and prone to change. Not all professional societies, manufacturers, and governmental agencies agree on best practices, leading to sometimes contradictory guidance,

particularly during the drying and storage steps of endoscope reprocessing [5]. Key points of contention are whether an alcohol flush should be conducted before drying, the proper duration of forced air drying and by what route, and how an endoscope should be stored and for how long [5, 51].

2.6.1 Alcohol Flush

Flushes of 70-90% ethyl or isopropyl alcohol, delivered following HLD and prior to forced air drying, have historically been used as an adjunctive chemical to assist in air drying [10, 37]. However, more recent findings suggest that alcohol's fixative properties, if allowed to air dry, may inhibit effective cleaning of sterile devices [52]. Furthermore, little definitive evidence exists supporting the role of an alcohol flush in improving endoscope drying [53]. Indeed, recent findings indicate that alcohol may increase the time needed to dry internal channels [9]. The dynamics of alcohol in reprocessing are not simple, however, and residual alcohol following reprocessing and drying may still help to dampen bacterial outgrowth due to its microbicidal effects, even as it increases drying time [7]. Further research is warranted into the value of alcohol flushes in endoscope reprocessing, as well as the proper concentrations and route of application.

Guidelines remain conflicted on the use of alcohol flushes to aid in drying. As of 2017, at least six professional bodies, including the FDA, recommended the use of an alcohol flush, while at least three did not [5]. In 2021, the Association for the Advancement of Medical Instrumentation (AAMI) released the ANSI/AAMI ST91 guidance on flexible endoscope reprocessing in healthcare facilities. Here, the association did not recommend for or against the use of alcohol flushes, instead suggesting that healthcare facilities perform a multidisciplinary risk assessment to determine the need for their use [6].

2.6.2 Endoscope Drying

Guidelines agree that flexible endoscopes should be dried using forced medical grade or HEPA filtered air to prevent the outgrowth of microbial vegetation following reprocessing [5]. Where guidance is lacking, or contradictory, is on the proper route of application and the duration of the forced-air purge.

2.6.2.1 Route of Application

Forced air may be delivered through the internal endoscope channels automatically, using a programmable AER cycle or with a dedicated drying device; or manually, using a directed push of air via a medical air gun [5, 45]. At present, professional guidelines offer little guidance on which of these methods is preferred, or they refer to the manufacturer instructions for use (IFU). ANSI/AAMI ST91: 2021 dictates that drying should be performed as a dedicated step and not as a programmed cycle in the AER, but otherwise offers no guidance on whether drying should be automated or manual [6]. The Association of Perioperative Registered Nurses (AORN) 2023 guidelines also dictate a forced air dry but make no indication of the proper route of administration, other than to refer to the manufacturer IFU [54]. IFUs vary, but typically offer no more guidance than that internal channels should be dried and free of moisture [4, 5, 51].

At present, there is sparce data on the differences between modes of drying. However, at least one study provides suggestive evidence that not all routes of administration are not equal. Researchers demonstrated that an automated dedicated drying step, using a drying machine separate from the AER, is preferable to manually drying each channel, perhaps owing to a reduction in human error [45].

2.6.2.2 Duration

The ideal duration of the forced-air flush has not yet been determined. AERs typically include an air-flush cycle of programmable length at the end of HLD; however, the AER IFUs note that this cannot guarantee a sufficiently dry channel [4, 5]. AORN guidelines proscribe 1-minute of forced-air drying, separate from the programmable AER air flush [54]. On the other hand, ANSI/AAMI ST91: 2021 recommends the use of a 10-minute flush of forced air [6], guidance which is supported by early research [16] as well as recent findings [45].

Even more recent research has called into question the effectiveness of a 10-minute air purge, by demonstrating that such a duration is not always sufficient to eliminate all intra-channel fluid, particularly within the narrower air/water channels [9]. This finding warrants further investigation. However, it should also be noted that extending the air flush beyond what is necessary to dry the channel does not appear to confer additional protection against the growth of bacteria [7].

2.6.3 Endoscope Storage

Regarding the proper storage of disinfected and dried endoscopes, questions remain as to how endoscopes should be stored, as well as how long an endoscope may safely be stored before the risk of bacterial contamination becomes too high.

2.6.3.1 Ambient Storage vs Drying Cabinets

Options for storage include vertical hanging in an ambient storage closet or storage in a drying cabinet. Ambient storage is defined by ANSI/AAMI ST91: 2021 as storage in a closed

cabinet with HEPA-filtered air flow providing positive-pressure air flow ambiently, but not directly through endoscope channels [6].

Conversely, drying cabinets are closed cabinets which provide continuous positive pressure of HEPA-filtered or medical grade air directly through the internal endoscope channels (ANSIAAMI), ostensibly to assist in drying any retained moisture which may be left over following HLD. Evidence is mounting that such storage is preferable to ambient storage by limiting microbial growth [18, 55].

At present, ANSI/AAMI ST91: 2021 does not recommend one storage method over another [6]. AORN 2023 guidelines, on the other hand, indicate storage in an ambient storage closet only if dedicated drying cabinets are not available [54]. Both guidelines indicate against storage in cabinets without any kind of filtered air flow.

2.6.3.2 Length of Storage

Consensus has not been reached on the maximum time an endoscope may be safely stored. Various professional societies have offered guidance ranging from 12 hours to 12 weeks, with most recommending that healthcare facilities perform their own risk-assessments [5, 6, 51, 54]. Inconsistencies in guidance likely arise from a paucity of consistent study results [51], indicating a need for further research in this arena.

3.0 Methods

The present study analyzes data taken from a large urban medical center to assess the hypotheses laid out in section 1.1, namely: whether a higher proportion of flexible endoscopes treated with an extended 10-minute air purge will show complete eradication of moisture within the internal channel systems than those treated with a 3-minute air purge. Whether the length of storage of flexible endoscopes in an ambient storage cabinet is positively associated with the eradication of moisture within the internal channel systems of flexible endoscopes. Lastly, whether the narrower gauge air/water channel systems are more likely to retain moisture than the larger gauge biopsy channel systems.

The study did not include any patient identifiers or privileged health information and is exempt from IRB approval.

3.1 Study Site Characteristics

Data was collected from a level I trauma and teaching hospital in Western Pennsylvania. The facility is located downtown in a mid-sized city with a population of over 300,000, but accepts patients from the surrounding region, including portions of Eastern Ohio. The patient population is diverse, both ethnically and socio-economically. At the time of this study, the hospital had 404 beds in service.

3.2 Data Collected

3.2.1 Ready-for-use Clinical Endoscopes

Data was collected on endoscopes reprocessed and stored within the Endoscopy Department and Central Sterile Processing Department of the study site. These endoscopes were designated as ready for procedural use. All data was collected by the infection control department of the hospital, from 6/30/2022 to 2/13/2023.

Data parameters included: endoscope type, date of reprocessing, duration of storage, the duration of forced air drying (3-minutes vs 10-minutes), the moisture detection method (indicator paper vs borescope), and whether moisture was detected (yes or no).

3.2.2 Stripped Endoscope Models

Data was collected on the presence or absence of moisture contained within the internal channels of SE models which were reprocessed in the endoscopy department to assess HLD and drying procedures. This data was collected from four stripped colonoscopes models and one stripped pediatric colonoscope model. Each model underwent two rounds of HLD according to site protocol. After the first round of HLD, the models were subjected to 3-minutes of forced air drying and stored ambiently for 7-days. The models were then reprocessed again, this time subjected to 10-minutes of forced air drying and stored ambiently for 7 days, for a total of ten trials. Moisture data was collected one hour after the completion of HLD and air flushes, and during the seven days in ambient storage.

The presence of moisture was assessed visually, as a binary. The presence of one or more visible drops, misty “sprays” of multiple fine droplets, or areas of confluent fluid were recorded as retaining moisture. Otherwise, the endoscope was recorded as negative for moisture.

3.3 Site Specific Guidelines

All endoscopes from which data was collected were reprocessed and stored according to the procedures established at this site. This includes both the endoscopes designated for clinical use, and the SE models. Those procedures, here described, were obtained from the official Policy and Procedure Manual of this study site, as well as through interviews with the individual staff members responsible for endoscope reprocessing.

3.3.1 Endoscope Reprocessing

Endoscopes were reprocessed after each use or after seven calendar days of non-use, following manual cleaning and leak-testing. HLD was performed in the ADVANTAGE PLUS™ Endoscope Reprocessing System AER, manufactured by Cantel (previously Medivators), according to the provided IFUs. These AERs were programmed to conduct a flush with 70% isopropyl alcohol, followed by a 1-minute flush of air at the completion of HLD.

Following the AER cycling, reprocessed endoscopes were immediately removed to undergo drying followed by subsequent storage or sterilization. All sterilized endoscopes underwent complete cleaning, HLD, and drying prior to sterilization with ethylene oxide gas.

3.3.2 Endoscope Drying

All reprocessed endoscopes were dried prior to storage or sterilization. Drying was conducted with the Dri-Scope Aid® Jet~Stream, manufactured by Dri-Scope Aid, which pushes pressurized sterile air through the biopsy/suction channel and air/water channels simultaneously. Forced air drying was performed on each scope continuously for either 3-minutes or 10-minutes.

At the start of data collection, site procedures dictated 3-mnutes of forced air drying, or more at operator discretion. Before data collection was completed, this was updated in September of 2022 to a minimum of 10-minutes of drying.

3.3.3 Endoscope Storage

Following drying, endoscopes were stored vertically in ambient storage cabinets for up to seven days. Filtered air was provided ambiently to the cabinets through ceiling vents, providing slight positive pressure. Any endoscope stored for more than seven days was removed from storage for reprocessing.

3.4 Selection of Endoscopes for Surveillance

Table 1 Endoscope categories.

Types of endoscopes from which data was collected, grouped by category and reprocessing method.

Category	Endoscope Name	Body Area Viewed	Reprocessing Method
Gastrointestinal Endoscope	Gastroscope	Stomach and duodenum	HLD
	Colonoscope	Colon and large intestine	HLD
	Colonoscope (pediatric)	Colon and large intestine	HLD
	Enteroscope	Small intestines	HLD
Respiratory Endoscope	Nasopharyngeal Endoscope	Nasal and oral cavities	HLD
	Bronchoscope	Trachea and lungs	HLD
Urogenital Endoscopes	Cystoscope	Bladder	HLD + Sterilization
	Ureteroscope	Ureter	HLD + Sterilization

Endoscopes were selected for moisture assessment both as part of routine surveillance and as part of active data collection to assess reprocessing effectiveness. Endoscopes selected for moisture assessment and data collection came from storage in the Central Sterile Processing Department and the Endoscopy Department. Because data collection was performed in a presently running healthcare facility, which needed access to a steady supply of safe endoscopes, care was taken to only select those devices which were not likely to be needed that day. Thus, assessed endoscopes were selected as a convenience sample based on the daily needs of the respective departments.

Several types of endoscopes were selected for assessment, as shown in table 1. These are grouped roughly into GI, respiratory, or urogenital endoscopes. Urogenital endoscopes undergo HLD followed by additional sterilization with ethylene oxide gas.

3.5 Determination of Moisture and Collection of Data

Two methods of assessing retained moisture were used at this facility: borescope evaluation and moisture indicator papers. Borescope determination was used as part of routine auditing of endoscope reprocessing conducted at this facility, whereas determination with indicator paper was conducted during active data collection.

3.5.1 Borescope Evaluation

All borescope evaluation was conducted using a VerifEye® Video Borescope Gen 1, manufactured by Steris. The borescope camera head was inserted into the biopsy/suction channel of evaluated endoscopes via the distal tip and progressed through the length of the insertion tube, towards the control box. If the operator noted any visible drops or confluent fluid anywhere within the channel, then the endoscope was determined to have retained moisture.

3.5.2 Indicator Paper Evaluation

Cobalt chloride test papers, manufactured by Bartovation, were used as indicator papers. Cobalt chloride paper changes color, from blue to pink, upon direct contact with water. To evaluate endoscopes for moisture retention, indicator papers were first positioned 1-2” away from the distal tip of the evaluated insertion tubes. Using an air pistol, medical grade air was then forced through the biopsy/suction channel via the control box access port, at 15 PSI, for 60 seconds. The indicator paper was used to determine if any fluid was expelled during this insufflation, with any visible color change indicating the presence of retained moisture.

3.6 Data Analysis

All data management and analyses were conducted with Stata SE 17.0 and Microsoft Excel. Fisher's Exact Test was used to assess the association of distinct factors on the proportion of endoscopes retaining moisture. Urogenital endoscopes, which undergo additional sterilization processing, were excluded from analyses of factors on moisture retention. Exact Logistic Regression was used to assess the effect of storage time on moisture. All assessment of significance was conducted with two-tailed p-values and 95% confidence intervals.

4.0 Findings

4.1 Stored Clinical Endoscopes

4.1.1 Moisture Retention

A total of 87 stored endoscopes were assessed, including 11 urogenital endoscopes which underwent additional sterilization procedures. Overall, 36/76 (47.4%) of stored GI and respiratory endoscopes had detectable moisture. Table 2 shows the association of various factors on moisture retention. There was no significant difference between the proportion of GI and respiratory endoscopes retaining moisture ($p = 0.448$), nor between the endoscope source ($p = 0.325$) or method of detecting moisture ($p = 0.299$).

When examining the duration of the air flush, 2/12 (16.7%) of endoscopes flushed with 10-minutes of air retained moisture, compared to 34/64 (53.1%) of those flushed for 3-minutes. This difference was significant ($p = 0.027$). The odds ratio that an endoscope which has retained moisture was flushed with 10-minutes of air compared to 3-minutes, was 0.176; or an 82.4% reduction in the odds of having retained moisture among those endoscopes treated with 10-minutes of air.

Table 2 Moisture retention among endoscopes.

Endoscopes which underwent sterilization processes were excluded from significance analysis. P-values underneath the significance threshold are denoted in bold

		Number Retaining Moisture	Proportion Retaining Moisture	p-value
Endoscope	GI	25/56	0.446	
	Respiratory	11/20	0.55	0.448
	Urogenital	0/11	0	
Source	Endoscopy	13/39	0.333	
	CSP	6/12	0.5	0.325
Detection Method	Borescope	26/68	0.382	
	Tape	10/19	0.526	0.299
Air Flush	10-minute air flush	2/12	0.167	
	3-minute air flush	34/64	0.531	**0.027**
	Sterilization	0/11	0	
Total	Total	36/87	0.414	
	Total GI + Resp	36/76	0.474	

Table 3 Odds of detectable moisture among endoscopes.

Odds of moisture retention in endoscopes by the number of days post-processing. Stratified by endoscope type, source, and air-flush duration

		OR	p-value	95% CI
Days Post Processing		0.771	0.078	(0.561 - 1.030)
Endoscope Type	GI	0.774	0.114	(0.539 - 1.069)
	Respiratory	0.817	0.257	(0.396 - 1.545)
Source	Endoscopy	0.715	0.069	(0.465 - 1.033)
	CSP	0.895	0.719	(0.530 - 1.460)
Air Flush	10-minute air flush	2.081	0.455	(0.543 - inf.)
	3-minute air flush	0.781	0.239	(0.501 - 1.155)

4.1.2 Storage Time and Moisture Presence

The effect of the number of days post-processing on the odds of an endoscope retaining moisture are shown in Table 3, stratified by endoscope type, source, and air-flush duration. No significance was detected between storage time and moisture, either overall ($p = 0.078$) or at any level of stratification

4.2 SE Models

Moisture results from the ten SE trials are shown in table 4, with examples of observable moisture shown in figure 2. Of the models flushed with 3-minutes of air, all five retained visible moisture in both the biopsy/suction channels and the air/water channels 1-hour post-processing. After 7-days in ambient storage, moisture was no longer detectable in the biopsy/suction channels, but there was no visible reduction to moisture in the air/water channels.

Among models treated with 10-minutes of air, none displayed visible moisture in the biopsy/suction channel, but 2/5 (40%) did retain moisture in the air/water channels 1-hour post-processing. After 7-days in ambient storage, there was no visible change to the moisture levels within the air/water channels.

Visible moisture was seen most often as individual droplets, but also existed as periods of confluent flow, shown in figure 2.

Table 4 Moisture within SE models.

Models treated with 3- or 10-minutes of forced air and stored for 7-days. Any channel containing > 1 droplet or area of confluent fluid is denoted with a (+) symbol

		Endoscope				
Dry Cycle	***Channel***	1 (pediatric)	2	3	4	5
3-minute air flush	Biopsy/Suction	+	+	+	+	+
	Air/Water	+	+	+	+	+
10-minute air flush	Biopsy/Suction	-	-	-	-	-
	Air/Water	-	-	-	+	+
3-minute + 7-day hang	Biopsy/Suction	-	-	-	-	-
	Air/Water	+	+	+	+	+
10-minute + 7-day hang	Biopsy/Suction	-	-	-	-	-
	Air/Water	-	-	-	+	+

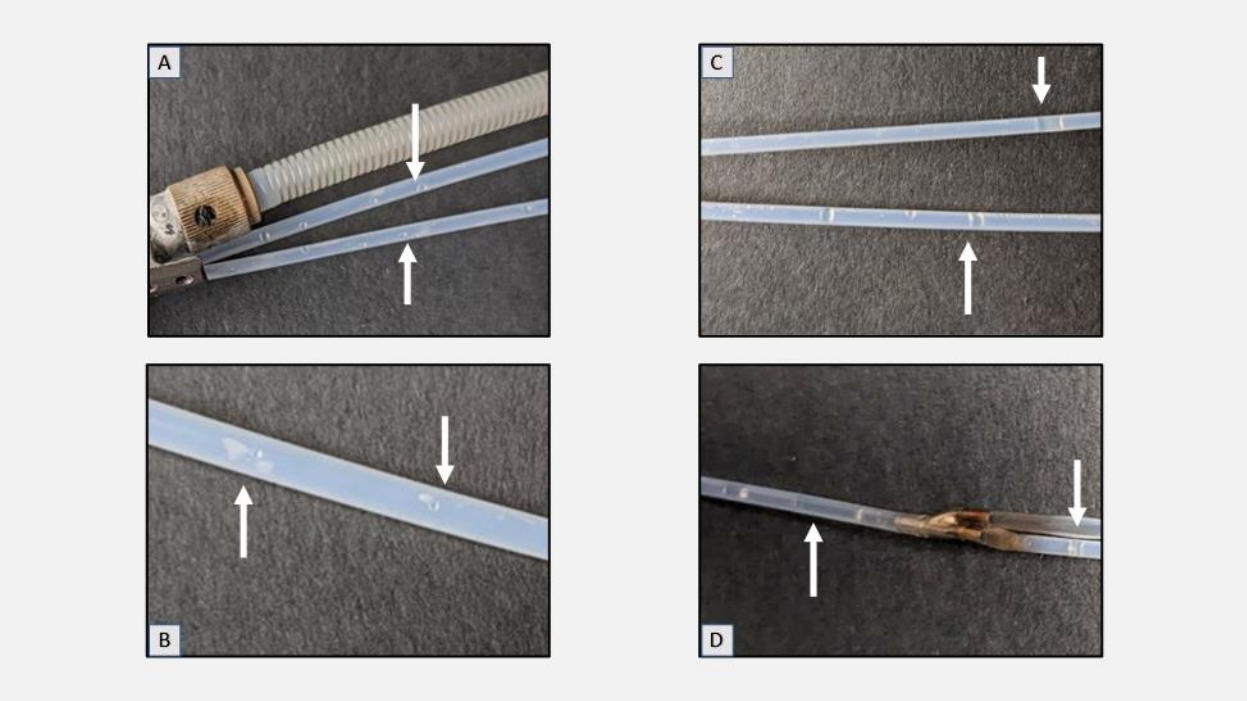

Figure 2 Evidence of retained moisture in endoscope channels.

A) Example of retained moisture in the water and air channels following a standard AER cycle and 3-minute air flush. B) Example of retained moisture in the main/biopsy channel following a standard AER cycle and 3-minute air flush. C) Example of retained moisture after an AER cycle with an additional 10-minute air flush, after 7 days of hang-drying. D) Example of confluent fluid retained after standard AER at the junction of air and water channels

5.0 Discussion

5.1 Duration of Air Flush and the Elimination of Moisture

Increasing the duration of the forced air flush appears effective at improving drying effectiveness. Among stored endoscopes, a significantly smaller proportion of those flushed with 10-minutes of forced air showed evidence of moisture, compared to those flushed with 3-minutes of air (16.7% vs 53.1%; p-value = 0.027). This represented an 82.4% reduction in odds.

This evidence was supported by the examination of the SE models. A 3-minute air flush failed to completely eliminate moisture in any channel of the five models to which it was applied. Comparatively, of the models treated with 10-minutes of forced air, moisture was successfully eliminated from each of the biopsy/suction channels, and 3/5 of the air/water channels.

It is worth noting that in neither the clinical stored endoscopes, nor the SE models, was a 10-minute flush completely effective at removing moisture. Even with the increased duration, 16.7% of endoscopes still retained at least some moisture. Current guidelines recommend drying endoscopes with 10-minutes of forced air [6]; however, this study, as well as other recent findings [9], indicate that this practice is not always able to remove moisture. This runs counter to other studies which found that 10-minutes was nearly universally effective [16, 45].

Overall, there is a dearth of studies evaluating the effectiveness of the 10-minute flush, despite this being the current recommended standard. Variations in reprocessing procedures may account for some of these differences, and a multi-site study may be appropriate for further assessments of forced-air flushes.

5.2 Ambient Storage and Drying

There exist few, if any, formal assessments of the effects of ambient storage on endoscope dryness in a real-world setting. This study failed to demonstrate that the number of days in ambient storage had a significant impact on intraluminal moisture (OR = 0.771; p-value = 0.078). While the SE model trials showed that ambient storage was able to eliminate moisture in 5/5 of the larger diameter biopsy/suction channels, it had no visible effect on fluid contained within the air/water channels (table 4). The intractability of moisture within the narrow channels may partially account for the inability of ambient storage to adequately dry endoscopes.

Many guidelines are moving towards recommending dedicated drying cabinets for endoscope storage [6, 51, 54]. This study failed to find sufficient evidence of the benefit of ambient storage, which adds some credence to these recommendations. Further studies should directly compare the effectiveness of ambient storage and dedicated drying cabinets.

5.3 Differences in Drying between Endoscope Channels

Differences in drying effectiveness between the biopsy/suction channels and the air/water channels were assessed using SE models. Moisture assessment of the stored endoscopes was unable to differentiate which channel or channels contained fluid. In the models, retained moisture resided primarily in the air/water channels, which are of a narrower diameter than the biopsy/suction channel. This could indicate that channel gauge plays a role in the effectiveness of drying procedures, and that current drying procedures may not sufficiently target the narrower channels. These findings mirror those of another recent study using SE models [9], however that

study was conducted in a more controlled laboratory setting, versus this study's clinical setting. Moreover, the idea that the air/water channels may be more likely to retain moisture following drying is supported by studies which indicate that biofilm may more commonly be found within the narrower channels [17, 24].

The occasional failure of 10-minute of forced air to clear endoscope channels of fluid could be accounted for by the intractability of moisture within the narrow channels. Of the models treated with 10-minutes of air, 2/5 failed to completely eliminate moisture, both within the narrower air/water channels. It is not clear, from this study, why some models retained moisture within these channels, and why some did not. While the forced air-dryers used in this study supply a steady continuous force of pressure, there is no guarantee pressure is equally applied to both channels, possibly allowing adhesive forces to sometimes overcome the outward flow of air.

The retention of moisture within the narrow channels has an additional implication, as well. Borescopes, currently, are unable to fit within the air/water channels of endoscopes, forcing researchers to rely on indicator papers and forced air flushes to assess for the presence of moisture within these channels. This study shows that moisture within the narrow channels can resist air flushes, thus any test for moisture relying on such air flushes may inadvertently return false negatives at an unknown rate and underestimate the number of endoscopes retaining moisture. Further research is needed to validate the use of indicator papers for moisture assessment until a more sensitive method of assessment is devised.

5.4 Strengths and Limitations

The strengths of this study are as follows. First, all assessed endoscopes and SE models were reprocessed and dried at a functioning healthcare facility. In real world conditions, endoscope reprocessing and drying may be impacted by time and material constraints which are not always present in a research lab. This could, in part, account for the observed failures of the 10-minute forced air flush which were observed in this study, but not in other assessments [16, 45]. Second, this study utilizes models which allow for sensitive detection of moisture within the air/water channels, which might otherwise go undetected. Assessing the fine water/air channels of endoscopes with forced air and indicator paper may be prone to false-negatives, as it is assessing the effectiveness of a technique – forced air drying – with the same methods as that technique. Lastly, this study provides a formal assessment of the effectiveness of ambient air storage in real-world conditions, thus providing data which is presently lacking in the literature and relevant to ongoing discussions of the value of dedicated drying cabinets versus ambient storage.

The study is also limited by several constraints. First, endoscopes were selected as a convenience sample to accommodate the daily needs of the departments from which they were assessed. This may lead to sampling bias. It is not unconceivable that the samples used in this study represent those endoscopes less likely to be used on a daily basis, and thus less likely to bear the signs of wear and tear which endoscopes accumulate during use. Studies have shown that endoscopes accumulate damage over time [48]; these damages may affect the propensity of endoscopes to resist drying cycles. Second, while a total of 87 stored endoscopes were evaluated in this study, only 12 had been subjected to a 10-minute air flush. This provided enough power to detect a significant difference in drying effectiveness between 3- and 10-minutes, but not enough

power to detect in-group differences between endoscope types. A more robust sample size could illuminate the presence or absence of such differences which this study was unable to detect.

6.0 Conclusion

The results of this study indicate that 10-minutes of a dedicated, forced-air flush is not always sufficient to eliminate moisture during flexible endoscope drying. The reasons for this warrant further investigation, however this study is suggestive that fluid retained within the narrower air/water channels may be particularly intractable to forced-air flushes. Furthermore, this study failed to find evidence that ambient storage aids in the drying of endoscopes, a factor which should be considered as updated guidelines weigh the benefits of ambient storage versus forced-air drying cabinets. These factors should be considered as professional organizations move towards adopting consistent guidelines on the proper handling of endoscopes following HLD.

Until a consensus can be reached, and until a reliable and repeatable method of moisture detection can be devised, healthcare institutions should dry endoscopes with at least 10-minutes of forced air followed by storage in forced-air drying cabinets. In addition, manufacturers should re-examine the IFUs specific to each endoscope model to ensure that drying instructions are sufficient to achieve elimination of moisture.

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