

# Challenging endoscopy reprocessing guidelines: a prospective study investigating the safe shelf life of flexible endoscopes in a tertiary gastroenterology unit

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**Background and study aims:** Professional practice guidelines for endoscope reprocessing recommend reprocessing endoscopes between each case and proper storage following reprocessing after the last case of the list. There is limited empirical evidence to support the efficacy of endoscope reprocessing prior to use in the first case of the day; however, internationally, many guidelines continue to recommend this practice. The aim of this study is to estimate a safe shelf life for flexible endoscopes in a high-turnover gastroenterology unit.

**Materials and methods:** In a prospective observational study, all flexible endoscopes in active service during the 3-week study period were microbiologically sampled prior to reprocessing before the first case of the day (n = 200). The main outcome variables were culture status, organism cultured, and shelf life.

**Results:** Among the total number of useable samples (n = 194), the overall contamination rate was 15.5%, with a pathogenic contamination rate of 0.5%. Mean time between last case one day and reprocessing before the first case on the next day (that is, shelf life) was 37.62 h (SD 36.47). Median shelf life was 18.8 h (range 5.27–165.35 h). The most frequently identified organism was coagulase-negative *Staphylococcus*, an environmental nonpathogenic organism.

**Conclusions:** When processed according to established guidelines, flexible endoscopes remain free from pathogenic organisms between last case and next day first case use. Significant reductions in the expenditure of time and resources on reprocessing endoscopes have the potential to reduce the restraints experienced by high-turnover endoscopy units and improve service delivery.

## Introduction

Current practice for endoscope reprocessing is guided by published professional standards and guidelines [1–5]. Despite documented cases of contamination of endoscopes during endoscopy, infectious complications following endoscopic procedures are rare [6–9]. In addition, there are no published studies of transmission of infection where professional body endoscopy standards and guidelines have been followed [8]. These standards and guidelines, however, lack worldwide consensus on at least one controversial issue, namely on the recommendation to reprocess endoscopes prior to the first case of the day – a practice for which there is no empirical evidence to support [9].

There is limited research evidence that establishes a pragmatic safe shelf life for endoscopes, that is, the length of time for which endoscopes remain bacteria-free between use in the last

case of one day and the first case of the next day. Evidence from three small studies indicates that a shelf life for endoscopes of up to 1 week can be established but is dependent on the quality of the cleaning, disinfecting, drying, and storage procedures [10–12]. The findings from these studies, however, have methodological design limitations, such as small sample size, artificial contamination of the scopes and conditions, and lack of control measures.

Our study tests the following hypothesis: that flexible endoscopes mechanically cleaned, disinfected with glutaraldehyde in an automatic washer/disinfector (e.g., Soluscope; Series 2, Galley Scientific and Medical Pty. Ltd., Melbourne, Australia), forced air-dried, flushed with 70% alcohol, and forced air-dried at the end of the list and stored hanging in the vertical position in accordance with professional guidelines will not grow pathogenic bacteria in their internal channels after reprocessing and before the next time

	n	Mean	SD	95% Confidence interval for mean		Min	Max
				Lower bound	Upper bound		
Gastrosopes	101	29.97	23.47	25.34	34.61	5.27	96.10
Duodenoscopes	11	45.32	42.56	16.73	73.91	16.12	136.87
Colonoscopes	74	35.35	30.17	28.35	42.34	9.80	163.35
EUS scopes	8	144.50	51.70	101.28	187.72	16.63	165.35
All scopes	194	37.62	36.47	32.45	42.78	5.27	165.35
Fixed effects			28.87	33.53	41.70		
Random effects				-23.11	98.35		

**Table 1** Mean shelf life in relation to scope type

ANOVA between groups:  $F = 39.32$ ;  $df = 3$ ;  $P = 0.000$ .

of use. The aim of the study is to estimate a safe shelf life for flexible endoscopes and, in doing so, challenge those guidelines that continue to recommend reprocessing before the first case of the day.

## Materials and methods

A prospective observational design was chosen to answer the research question. The study was conducted in a four-suite gastroenterology unit located in a 942-bed tertiary referral teaching hospital. All nursing staff in the unit (including registered nurses, enrolled nurses, and assistants in nursing) undergo supervised training and competency assessment in endoscope reprocessing, and when assessed as competent are rostered to undertake that duty. During the data collection period, however, reprocessing of the endoscopes was conducted by the two staff members most frequently rostered to that duty. The study sample included all flexible endoscopes ( $n = 23$ ), including gastroscopes, duodenoscopes, colonoscopes, and endoscopic ultrasound (EUS) scopes in active service during the 3-week study period. The three main outcome variables of interest were (1) culture status after reprocessing, defined as positive or negative, indicating presence of bacterial contamination; (2) type of organism cultured, whether pathogenic or nonpathogenic; and (3) shelf life, measured in hours as time between reprocessing prior to storage to time of reprocessing before next use. Data were analyzed using descriptive statistics with frequency and distribution tables. The  $\chi^2$  statistic was used to compare type of scope with organisms grown. Student's  $t$ -test was used to compare time between reprocessing and organisms grown. Analysis of variance (ANOVA) statistics were used to compare time between reprocessing and types of scopes and organisms grown. Any scope for which the time between reprocessings was greater than 200 h or any scope for which there was incomplete data collection of key variables was excluded from analysis.

## Sampling and microbiological testing procedure

Samples were collected, transported, and tested according to facility policy based on professional guidelines [1]. Samples were collected from several areas using aseptic technique. Forcep raiser and jet channels were always flushed and swabbed first, followed by biopsy channels. Finally, air/water channels were flushed. Swabbed samples and washings from all channels were collected in a single sterile specimen container. Pooling of samples – standard procedure at the facility – was used to minimize

cost and workload for both clinical and laboratory staff. The specimen was then sent promptly to the laboratory for testing. In the laboratory, 10 ml of each sample was aseptically transferred to a labeled sterile tube for centrifugation at 3000 rpm for 5 min. The supernatant was discarded to 1 ml and the deposit re-suspended. Next, parts of the suspension were aseptically transferred onto two blood and MacConkey agar plates under aerobic conditions for aerobic incubation. One set was incubated at 35 °C and one set at 28 °C. The cultures were examined after 3 days' incubation. If there was no growth after this time, all plates were incubated for an additional 2 days. Any significant growth was identified to the genus level. The colony count or colony forming units (cfu) of each different type of colony identified was calculated and results recorded. If positive cultures were obtained on the first sampling, the device was retested. If positive cultures were obtained on the second sampling, the scope was withdrawn from service and retested. If positive cultures were obtained on the third sampling, the device was removed from service and sent to the manufacturer for cleaning and overhaul.

## Results

Two hundred culture samples were obtained. Six samples were excluded from analysis, two because of missing data and four because the time between endoscope reprocessings was greater than 200 h. One notable result was that the four scopes (one EUS scope, one gastroscope, and two duodenoscopes) excluded because of more than 200 h between reprocessings yielded negative cultures (that is, no growth). The median shelf life of these four scopes was 440.35 h (range 256.38 – 5348 h). Of the remaining total number of cultures taken ( $n = 194$ , made up of 101 from gastroscopes, 74 from colonoscopes, 11 from duodenoscopes, and 8 from EUS scopes), 30 yielded positive cultures, resulting in an overall contamination rate of 15.5%, incorporating a 0.5% pathogenic contamination rate. The mean time between reprocessing events was 37.62 h (SD 36.47), with gastroscopes having the quickest turnaround time and EUS scopes having the longest (● **Table 1**). The following organisms were cultured: coagulase-negative *Staphylococcus*, *Micrococcus*, *Bacillus*, *Corynebacterium*, fungus, *Streptomyces*, and yeast (● **Table 2**).

## Culture status and time between reprocessing

The mean time between reprocessing for all scopes yielding negative cultures was 35.12 h (SD 33.27) and that for scopes yielding positive cultures was 51.25 h (SD 49.00). An independent sam-

Table 2 Organisms cultured

Organism cultured	Frequency		Mean no. of colony-forming units grown	Clinical significance (as per facility pathology protocol)
	n	%		
<b>Nonpathogenic</b>				
<i>Bacillus</i>	4	2.1	1.25	Potentially significant – possible process contamination
<i>Corynebacterium</i>	1	0.5	10	Potentially significant – possible process contamination
Fungus	2	1.0	1	Potentially significant – possible process contamination
<i>Micrococcus</i>	6	3.1	1	Not significant – possible process contamination
<i>Streptomyces</i>	1	0.5	3	Potentially significant – possible process contamination
Coag.-negative <i>Staphylococcus</i>	13	6.7	1.4	Not significant – possible process contamination
Coag.-negative <i>Staphylococcus</i> + fungus	2	1.0	1	Potentially significant – possible process contamination
Total nonpathogenic growth	<b>29</b>	<b>15</b>		
<b>Pathogenic</b>				
Yeast only	1	0.5	6	Significant – possible scope contamination
Total pathogenic growth	<b>1</b>	<b>0.5</b>		
<b>Total positive events (n = 194)</b>	<b>30</b>	<b>15.5</b>		

Table 3 Culture status in relation to shelf life and scope type

Scopes sampled (n = 194)	Positive cultures		Mean shelf life by culture status, hours	F	df	P	Confidence interval
	n	%					
Gastrosopes (n = 101)	12	11.9	Positive 31.83 (SD 26.58) Negative 29.72 (SD 23.17)	0.463	99	0.772	– 2.11 to 7.25
Duodenoscopes (n = 11)	1	9.1	Positive 136.87 (–) Negative 36.16 (SD 31.44)	–	9	0.014	– 100.70 to 32.97
Colonoscopes (n = 74)	14	18.9	Positive 38.22 (SD 29.53) Negative 34.67 (SD 30.52)	0.245	72	0.695	– 3.55 to 9.01
EUS scopes (n = 8)	3	37.5	Positive 161.22 (SD 1.03) Negative 134.47 (SD 65.89)	3.872	6	0.522	– 26.74 to 39.29
All scopes (n = 194)	30	15.5	Positive 51.25 (SD 49.00) Negative 35.12 (SD 33.27)	11.43	192	0.092	– 35.06 to 2.80

Analysis of culture status in relation to scope type:  $\chi^2 = 4.981$ ;  $df = 3$ ;  $P = 0.173$ .

ples *t*-test was conducted to compare shelf life for scopes with positive cultures and negative cultures. Although there is a trend for the shelf life of the scopes yielding positive cultures to be longer than that of those scopes yielding negative cultures, the difference is not significant ( $F = 11.43$ ,  $t = -1.7$ ,  $df = 192$ ,  $P = 0.092$ , CI –35.06 to 2.80). This statistically nonsignificant trend persists even when data are broken down according to

scope type (Table 3), except in the case of duodenoscopes, where the difference in shelf life between scopes with positive cultures and those with negative cultures is statistically significant. For longer-term shelf life, that is up to 120 h, there are no positive pathogenic cultures, a statistically significant result ( $\chi^2 = 43.83$ ,  $P = 0.008$ ,  $df = 24$ ; Table 4).

Table 4 Length of shelf life in relation to contamination rates

Shelf life range	Culture result (% out of total scopes)					
	Negative		Positive (nonpathogenic)		Positive (pathogenic)	
	n	%	n	%	n	%
Up to 24 h (1 day)	115/132	87.1	17/132	12.9	0	
24–48 h (1–2 days)	9/10	90	1/10	10.0	0	
48–72 h (2–3 days)	24/29	82.8	5/29	17.2	0	
72–96 h (3–4 days)	9/12	75	3/12	25.0	0	
96–120 h (4–5 days)	2/2	100	0		0	
120–144 h (5–6 days)	0		0		1*	100
144–168 h (6–7 days)	5/8	62.5	3/8	37.5	0	
Total	164/194	84.5	29/194	15.0	1	0.5

$\chi^2 = 199.3$ ,  $df = 12$ ,  $P = 0.000$ .

\*Duodenoscope contaminated with yeast.

Table 5 Type of organism cultured in relation to scope type

	Number of positive cultures (% of scope type)							
	Gastrosopes (n = 101)		Duodenoscopes (n = 11)		Colonoscopes (n = 74)		EUS scopes (n = 8)	
	n	%	n	%	n	%	n	%
<i>Bacillus</i>	0	–	0	–	4	5.4	0	–
<i>Corynebacterium</i>	1	1.0	0	–	0		0	–
Fungus	1	1.0	0	–	1	1.4	0	–
<i>Micrococcus</i>	4	4.0	0	–	2	2.7	0	–
<i>Streptomyces</i>	0	–	0	–	1	1.4	0	–
Yeast	0	–	1	9.1	0		0	–
Coag.-negative <i>Staphylococcus</i>	6	5.9	0	–	5	6.8	2	25.0
Coag.-negative <i>Staphylococcus</i> + fungus	0	–	0	–	1	1.4	1	12.5
Total positive cultures (n = 30)	12/101	11.9	1/11	9.1	14/74	18.4	3/8	37.5

$\chi^2 = 43.83$ ;  $df = 24$ ;  $P = 0.008$ .

### Culture status and type of scope

Analysis was conducted in subgroups by type of scope using the  $\chi^2$  statistic. The rate of positive cultures was highest for EUS scopes at 37.5% and lowest for duodenoscopes at 9.1%, but the difference was not statistically significant ( $\chi^2 = 4.981$ ,  $P = 0.173$ ,  $df = 3$ ; ● Table 3).

### Type of organism and type of scope

Out of the 30 episodes of contamination, one organism was identified in 28 sampling events and two organisms were identified in 2 sampling events. Of all organisms identified following positive culture results, coagulase-negative *Staphylococcus* alone was the most frequently cultured organism on gastrosopes, colonoscopes, and EUS scopes – a statistically significant result. The only clinically significant pathogenic organism identified was yeast, cultured on one duodenoscope – also a statistically significant result ( $\chi^2 = 43.83$ ,  $P = 0.008$ ,  $df = 24$ ; ● Table 5).

### Discussion



Routine microbiological monitoring of endoscopes provides valuable information relating to the adequacy and completeness of the cleaning and disinfection process. The testing process is designed to detect the presence of bacteria as a surrogate marker for other microorganisms such as viruses. A positive bacterial culture is a surrogate marker for inadequate cleaning or possible structural damage to the channels of the endoscope. “Possible scope contamination” (see ● Table 2) means that the organisms cultured may have derived from the patient and the scope have been inadequately cleaned. “Possible process contamination” means the contamination may have occurred during sample collection or sample culture in the laboratory.

The overall contamination rate in this study was 15.5%. The most frequently identified organisms were coagulase-negative *Staphylococcus* and *Micrococcus*. Yeast, the only organism cultured that was considered pathogenic and suggestive of possible significant scope contamination, was cultured in only one case, resulting in a pathogenic contamination rate of 0.5%. The high rate of contamination of the EUS scopes may be due to their long shelf life – a reflection of scope usage in the facility.

Overall, findings from this study are similar to those of previous studies in that organisms cultured after processing tended to reflect environmental contamination, most likely occurring during sampling, not contamination during the cleaning or decontamination processes. However, the 12.9% (n = 17) environmental contamination rate at 24 h after reprocessing of 132 scopes found in this study is higher than previously reported rates of no growth at 24 h [10,11] and 3% growth immediately after reprocessing [12]. This may be a reflection of the pragmatic nature of the research design in this study, where the endoscopes sampled remained in service and were subjected to routine processes during the data collection period, whereas endoscopes sampled in previous studies were removed from service and isolated during the data collection period. The contamination rate in this study may thus be more realistically representative of contamination rates in practice. However, the 0% rate of pathogenic contamination at 24 h in this study is consistent with the previous studies.

As far as longer-term safe shelf life is concerned (that is, 144–168 h), there was a 37.5% environmental contamination rate and a 0% pathogenic contamination rate in a small sample of eight scopes in this study, in contrast with the 25% nonpathogenic contamination rate and 0% pathogenic contamination at 168 h reported by Riley et al. [11]. At 120 h, however, Rejchrt et al. [12] found no growth in 20 scopes. Similarly, in this study there was no growth after 200 h in four scopes. Findings on long-term shelf life in this study are limited by the decreasing sample size over time – a reflection of the high turnover of scopes in the facility.

Low numbers of environmental-type organisms such as coagulase-negative *Staphylococcus* and *Micrococcus* most likely represent cases of possible process contamination. When these are found, the instrument must be retested. Growth of *Pseudomonas aeruginosa* or other nosocomial pathogens such as *Staphylococcus aureus*, *Salmonella* spp. or *Shigella* spp., or spore-forming organisms such as fungi, requires immediate retesting of the device and removal of the device from use until retesting results are available.

Certain types of organisms, such as gram-negative coliforms, *Pseudomonas* spp., yeasts, *Enterococcus* spp., and *Staphylococcus aureus*, indicate inadequate scope cleaning as these organisms are not usually present on the skin or in the environment [13]. Spore-forming organisms, such as *Bacillus* and fungi, can indicate either environmental contamination on collection of the test sample or inadequate cleaning [14]. Organisms such as coagulase-negative *Staphylococcus*, *Micrococcus*, and *Corynebacterium* spp. indicate potential skin contamination on collection; however, presence of these organisms may also indicate contamination of the scope with skin flora during storage. In this instance, the laboratory would look at the next parameters, which are total number of colonies, growth temperature, and colony count on different media. If there is only one colony on one of the four plates set up, this suggests possible contamination on collection or processing of the test sample. Results from this study are thus presented in terms of the parameters outlined above.

Given the above criteria, yeast is the only significant culture result in this study as yeasts are not normally present in the environment. However, some authors list yeast as part of the normal skin flora, meaning that this organism can contaminate the scope from either the patient's flora or from the hands of the operator [13]. The samples that grew *Bacillus* and fungus represent

potentially significant results as they may indicate either scope contamination or processing error, since these are spore-forming organisms and spores are more resistant to cleaning processes; however, the small numbers in the colonies would suggest that processing error is more likely. The *Streptomyces* culture is more difficult to interpret as these organisms are common in the environment but are a little more tolerant to heat and drying than other bacteria, so their presence in this study may indicate inadequate cleaning or environmental contamination.

The *Corynebacterium*, although a skin organism, is present in high numbers, so this is a potentially significant result indicating possible contamination after cleaning and during sample collection.

Given the observed trend of contamination, this study supports previous studies suggesting that, when processed according to established professional guidelines (that is, manual cleaning, disinfecting, drying, and storage), endoscopes – particularly gastroscopes, colonoscopes, and duodenoscopes – remain free from pathogenic organisms for at least 120 h between reprocessings. This has particular relevance in high-turnover facilities where the average time between reprocessings is less than 48 h.

These study findings are limited to high-turnover facilities where endoscopes are reprocessed using high-level disinfectant in an automated washer/disinfector. It is important to reiterate that the testing process is designed to detect the presence of bacteria as a surrogate marker for other microorganisms such as viruses and also represents a surrogate marker for inadequate cleaning or possible structural damage to the channels of the endoscope. Thus there must be processes in place for follow-up of all scopes found to be contaminated with any organism, potentially pathogenic or not.

Significant reductions in the expenditure of time and resources on reprocessing endoscopes have the potential to reduce the restraints experienced by nursing staff in this area of practice. Savings in resources and material costs could allow more flexibility in budgeting that will further support improved patient outcomes. The issue of time would have particular relevance for after-hours emergency cases and improving outpatient service delivery. This study is important in challenging ritualistic practices not based on evidence that continue to be supported by professional organizations.

The sample size in this study is generally larger than that in previous studies; however, due to the high turnover rate of endoscopes in this setting, one limitation is that the size of the subsamples decreases as the shelf life increases. In addition, when the endoscopes are categorized according to type, the sample sizes of the subsamples of duodenoscopes and EUS scopes are small. Because infectious complications following endoscopy are rare, much larger samples are necessary for adequately powered studies to make conclusions with statistical confidence. Finally, aerobic incubation of the samples occurred in this study. There have been documented cases of anaerobic contamination of reprocessed endoscopes [11]; thus, the discussion of this study is limited to aerobic organism growth. Data from this study can be used to support application for a larger multisite study to establish internationally accepted evidence-based standards and guidelines for reprocessing flexible endoscopes.

**Competing interests:** None

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