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Major article

Comparison of clinically relevant benchmarks and channel sampling methods used to assess manual cleaning compliance for flexible gastrointestinal endoscopes

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Background: The objectives of this study were to recommend sample collection method(s) based on relative soiling in patient-used gastrointestinal (GI) endoscopes and determine whether the published benchmarks for protein, bioburden, and adenosine triphosphate (ATP) remain relevant for pump-assisted manual cleaning.

Methods: Patient-used gastroscopes, duodenoscopes, and colonoscopes were sampled before and after manual cleaning and assessed for protein, bioburden, and ATP levels. The biopsy port (BP) to distal end (D) sample was collected using 20 mL of sterile reverse-osmosis water. After a 200-mL flush, the umbilical (UM) to BP portion was sampled by flushing 40 mL from the UM to the D.

Results: The BP to D portion of the suction biopsy channel contained 83% of ATP residuals. Despite cleaning with brushing and a flushing pump, 25% of gastroscopes exceeded the ATP benchmark of 200 relative light units (RLU), whereas all duodenoscopes and colonoscopes had <200 RLU after cleaning. The protein and bioburden residuals after pump-assisted cleaning were consistently lower than existing benchmarks.

Conclusion: Sampling the suction biopsy channel from BP to D detected the most residuals from patient-used GI endoscopes. The protein and bioburden benchmarks for pump-assisted cleaning can be lowered, but 200 RLU is still adequate for ATP.

The reprocessing of flexible endoscopes is a complex, multistage process prone to human error. Ofstead et al[1] documented that all stages of manual reprocessing were performed correctly in only 1.4% of the 69 endoscopes that they evaluated. The main areas of concern in their study were the brushing stage of manual channel cleaning and the use of forced air to dry channels before storage. The overall compliance for automated endoscope cleaning and disinfection (75.4%) was significantly better than that for manual cleaning combined with automated disinfection.[1] The need to ensure adequate reprocessing of flexible endoscopes (especially at the manual cleaning stage) has been well emphasized in various published guidelines.[2-5]

Despite such guidelines, the recent report of infection transmission due to contaminated duodenoscopes by Carbonne et al[6] demonstrated a transmission rate of 45% and an infection rate of 11% for multidrug-resistant *Klebsiella pneumoniae*. Reports such as that conclusively document that despite advances in flexible endoscope design and the development of guidelines that emphasize reprocessing,[2-5] there is significant evidence suggesting that the problem of flexible endoscopes causing infection transmission remains a concern. One factor contributing to this ongoing problem with flexible endoscopes is that visual inspection is insufficient to confirm cleaning adequacy, because visualization of the narrow channels is not possible.

Although adenosine triphosphate (ATP) testing has long been used to monitor environmental cleaning in the food and drug industry,[7] the first adaptation of this methodology to monitor cleaning of flexible endoscopes was reported by Sciortino et al[8] in

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2004. In this early assessment, biofilm formation within the channels of older flexible endoscopes clearly resulted in persistent elevated relative light unit (RLU) levels after disinfection and alcohol flushing. The authors performed ATP testing after storage of endoscopes and, based on their data, concluded that the older flexible endoscopes likely developed biofilm within the channels that persisted and proliferated during storage. A limitation of this study was that only swab tests were available for use, and as such, the entire length of the endoscope channel could not be sampled.

A number of subsequent studies have evaluated the feasibility of using ATP-based testing from various manufacturers to assess the cleaning of flexible endoscopes.[9-13] Hansen et al[9] and Fushimi et al[11] both used swabs to sample the exterior of endoscopes for ATP monitoring of cleaning. Channel sampling was reported by Obee et al,[10] who used channel brushes, and by Fushimi et al,[11] who used 10 mL of sterile water flushed from the biopsy port to the distal end of gastroscopes. Considering that these studies used different methods for evaluating flexible endoscope channel cleaning, comparing results is difficult. However, in all studies, ATP testing was reported to be a useful method for monitoring manual cleaning.

Recent studies have demonstrated a highly variable limit of detection for different ATP test kits and luminometers.[14,15] As such, it is important for the manufacturer of each ATP test kit to provide specific sample collection protocols and indicate the level of RLU can be expected when proper cleaning is achieved (ie, validated cutoff for a test that differentiates unacceptable from acceptable manual cleaning). Using samples collected by flushing sterile reverse-osmosis (sRO) water through each channel, Alfa et al[12,13] provided validated RLU cutoff values for the 3M ATP test kit from all flexible GI endoscope channels (excluding gastroscope channels). They demonstrated that these cutoffs can be achieved in routine clinical use, although they reported that the elevator guidewire channel was the most difficult to clean adequately.[12,13] Although some of the published studies used RLU cutoffs to differentiate between “clean” and “dirty,” none assessed whether the optimal sample collection is from the entire endoscope channel from umbilical to distal or whether samples collected from the biopsy port to distal end are adequate for their ATP testing method. Furthermore, the different sample collection methods used in these studies has hindered determination of the clinically relevant cutoffs for ATP compared with bioburden and protein.

The objectives of the present study were (1) to determine whether most of the organic and bioburden residuals from patient-used GI endoscopes was found in the biopsy port to distal portion or the umbilical to biopsy port portion of the suction-biopsy (SB) channel, to help determine optimal sample collection strategies, and (2) to compare the levels of ATP, protein, and bioburden residuals to evaluate whether the previously established benchmarks for adequate channel cleaning remain valid.

MATERIALS AND METHODS

Flexible endoscopes

The following flexible endoscopes, all from Olympus (Center Valley, PA), were used in this study: colonoscope models CF-Q180AL and CF-H180AL, duodenoscope model TFJ-160VF, and gastroscope models GIF-Q180 and GIF-H180.

Sample collection

All patient-used flexible endoscopes received routine bedside precleaning and were then transported to the reprocessing area, where sample collection was performed. Only the SB channel was evaluated, with the aim of comparing the organic and bioburden loads in different sections of this channel. The 2 sections of the SB channel were compared by taking samples from the biopsy port (BP) to the distal end (D) and from the umbilical end (UM) to the distal end (D). The first sample was collected by flushing 20 mLs of sRO water through the channel from the BP to the D.

Because the samples from the UM to the D had to pass through the BP-to-D portion of the BP channel, the protocol included a pump-assisted flushing step to ensure that once the BP-to-D sample was collected, this section of the BP channel was thoroughly flushed with 200mL of sRO water before the second sample from the UM-to-D portion was collected. Samples were taken from the BP-to-D portion of the sample after the pump-assisted flushing and showed that virtually no material remained in this section of the SB channel before the UM-to-D sample was collected (data not shown).

After this flushing stage of the BP-to-D portion of the channel, the second sample was collected by flushing 40 mL of sRO water from the UM-to-D portion of the SB channel. Samples were also taken from fully reprocessed endoscopes (called baseline) to ensure that there was no buildup of material over repeated uses (20 mL for the BP-to-D sample and 40 mL for the UM-to-D sample).

Clinical study

An overview of the sample collection in relationship to precleaning and postcleaning is given in Table 1. The patient-used flexible endoscopes all received bedside cleaning before sample collection (as described above). The 10 precleaning samples were taken from different patient-used endoscopes than the 20 postcleaning samples.

Precleaning phase

All samples were collected on receipt of the scope into the reprocessing room before full manual cleaning.

Postcleaning phase

The endoscopes were leak tested followed by full manual cleaning. As part of this manual cleaning, the Endo-Flush (EFP-500; PCI Medical, Deep River, CT) was used to ensure the channels of each endoscope were flushed with enzymatic detergent during the cleaning phase and tap water during the rinsing phase. The EFP-500 was regularly calibrated as per the manufacturer’s instructions to ensure it was delivering the correct flushing volume. Once the endoscope had been fully manually cleaned, the SB channel was sampled again as described previously (ie, BP to D, as well as UM to D).

Assays for ATP, protein, and bioburden quantitation

Each of the channel samples collected from patient-used endoscopes was tested to determine the amount of protein, bioburden and ATP. The 3M Clean-Trace ATP Water test kit (3M, Saint Paul, MN) along with the handheld Clean-Trace luminometer were used (as per the manufacturer’s instruction) for testing channel samples for ATP as measured by relative light units (RLUs). There are no existing validated ATP manufacturer’s instructions for endoscope sample collection. Experiments were performed in triplicate and results were presented as the average RLUs/sample.

The channel samples collected were also assayed for protein using the QuantiPro BCA assay kit based on bicinchoninic acid (Sigma-Aldrich, St Louis, MO). The kit includes a bovine serum albumin protein standard and was performed in accordance with the manufacturer’s instructions (limit of detection, 5 μg/mL). For bioburden quantitation the samples were serially diluted 1:10 in

Table 1
Overview of the clinical study

Samples collected	Scopes tested precleaning	Scopes tested postcleaning*	Scopes tested baseline†
Colonoscopes			
BP to D‡	10	20	5
UM to D§			
Duodenoscopes			
BP to D	10	20	5
UM to D			
Gastroscopes			
BP to D	10	20	5
UM to D			

*Postcleaning: Manual cleaning included the use of a flushing pump to ensure that fluid permeated the channels. The flushing pump replaces manual syringe flushing of the endoscope channels.
†Baseline: Samples collected from the BP-to-D and UM-to-D portions of an unused flexible endoscopes.
‡After the bedside flush, the BP-to-D portion was sampled by flushing the channel with 20 mL of sRO water.
§After collection of the BP-to-D sample, the BP-to-D portion was flushed with 200 mL of sRO water to remove any remaining organic and bioburden material in this portion of the channel. After this flushing step, the UM-to-D portion was sampled by flushing the channel with 40 mL of sRO water.

phosphate-buffered saline and then quantitated using the spread plate method by inoculating 0.1 mL of each dilution onto blood agar medium. The limit of detection for the viable count assay was 10 CFU/mL.

Benchmarks for adequate manual cleaning

In accordance with the manual cleaning benchmarks for flexible endoscope channels established by Alfa et al,[12,13,16] the benchmark of adequate manual cleaning was defined as <200 RLU, <6.4 μg/cm^2 of protein, and <4 $\log_{10}$/cm^2 of bioburden. These benchmarks were originally established with manual channel flushing methods using syringes (ie, no flushing pumps).

RESULTS

As described in the previous section, 3 types of flexible GI endoscopes were evaluated: gastroscopes, duodenoscopes, and colonoscopes. In all cases, the bedside precleaning was completed before samples were collected from patient-used GI endoscopes. A key objective was to determine whether there was much bioburden or organic material in the UM-to-BP section compared with the BP-to-D portion of the SB channel of patient-used flexible GI endoscopes. As such, the channel was harvested to assess recoverable bioburden, protein and RLU from the BP-to-D and UM-to-BP channel portions. The 10 patient-used endoscopes tested before manual cleaning were different scopes from the 20 patient-used endoscopes tested after manual cleaning. In addition, 5 patient-ready endoscopes of each type were sampled to determine the baseline levels of bioburden, protein, and ATP to ensure no buildup of material over the evaluation period. Table 2 summarizes the results for all scope types, including the baseline testing results.

The data in Table 2 confirm that the postcleaning levels of protein, bioburden, and ATP levels were all well below the published traditional benchmarks; thus, we further assessed the data to determine what new clinically relevant cutoffs could be considered. Review of the data after pump-assisted cleaning indicated that all of the 20 duodenoscopes and 20 colonoscopes assessed had <200 RLU in both the UM-to-D and BP-to-D samples. However, the postcleaning residual RLU for the gastroscope channels indicated that 4 of 20 UM-to-D and BP-to-D samples had > 200 RLU. The maximum RLU value was 2,350 for BP-to-D and 311 for UM-to-D. Furthermore, all scope types and all channel segments assessed demonstrated <2 ug/cm^2 protein and <2 $\log_{10}$ cfu/cm^2 bioburden. These clinically relevant residual levels suggest that in routine practice it should be possible to achieve lower cutoffs using pump-assisted manual cleaning than are possible through manual cleaning without a pump. Table 3 summarizes the data for cleaning adequacy with the use of new pump-assisted cutoffs for cleaning adequacy (ie, <200 RLU, <2 ug/cm^2 of protein, and <2 $\log_{10}$ cfu/cm^2 of bioburden).

DISCUSSION

The present study is the first to compare the relative "soiling" level in the UM-to-BP portion compared with the BP-to-D portion of the SB channels of patient-used colonoscopes, duodenoscopes, and gastroscopes. Our data demonstrate that despite bedside precleaning, the entire length of the SB channel contains residuals, with the highest levels of organic material and bioburden in the BP-to-D portion. Our data for gastroscopes supports and extends the findings of Fushimi et al[11] despite differences in study methodology, with manual flushing during the cleaning stage in that study as opposed to pump-assisted flushing in our study. In addition, their channel sample collection was achieved by 5 flushes of 10 mL of sterile distilled water through the channel of the gastroscope, compared with our single flush of 20 mL in the BP-to-D portion and 40 mL in the UM-to-D portion. Using this worst-case approach (ie, no bedside precleaning), Fushimi et al[11] found that ATP went from a mean of 30,281 RLU (range, 233-45,362 RLU) before manual cleaning to 104 RLU (range, 45-407 RLU) after manual cleaning, representing a 99.7% reduction in RLU. Our data extend their findings, in that pump-assisted manual cleaning provided a 98.1% reduction in RLU and the majority (83%) of the total RLU detected before cleaning was in the BP-to-D portion of the channel. The difference in postcleaning RLU reduction between the 2 studies is likely related to Fushimi et al's use of routine channel brushing followed by a pulling a "screw brush" through the biopsy port to distal end of the scope.

The data in Table 2 show that the bedside flush was very important, with few gastroscopes, duodenoscopes, or colonoscopes exceeding the existing traditional benchmarks of 4 $\log_{10}$ cfu/cm^2 bioburden or 6.4 ug/cm^2 protein for samples from the BP-to-D portion or the UM-to-BP portion of the SB channel. After the bedside precleaning and before manual cleaning, only 2 of the 30 BP-to-D samples and none of the 30 UM-to-D samples from any of the endoscopes exceeded the traditional benchmarks. However, the RLU data show that for these same endoscope samples, 30 of 30 BP-to-D samples and 17 of 30 UM-to-D samples exceeded the 200 RLU cutoff for ATP. This indicates that the <200 RLU benchmark provides a lower detection limit compared with the traditional benchmarks for protein and bioburden.

Our data support and expand the clinical study of Alfa et al[13] in which samples were harvested from the UM-to-D segment of patient-used endoscopes that received only bedside precleaning, where the authors reported that 19 of the 20 endoscopes had >200 RLU, whereas none of the 20 exceeded the traditional benchmark for protein.

Our present results demonstrate that although most of the bioburden and organic residuals are in the BP-to-D portion of the SB channel, there are residuals in the UM-to-BP portion of the channel. This confirms that sample collection could be done from the BP-to-D portion or from the UM-to-D portion, and that using either collection method would provide a reliable indication of bioburden and organic residuals after patient procedures. As demonstrated by our results and previously published findings,[8,10,11,13] there is great variability in the levels remaining after

Table 2
Summary of bioburden, protein, and ATP levels in endoscopes before and after cleanimg

	Bioburden, $\log_{10}$ cfu/cm^2 (SD) [range]	Protein, μg/cm^2 (SD) [range]	ATP, RLU/test (SD) [range]	ATP. $\log_{10}$ RLU (SD) [range]
Colonoscopes				
Precleaning (n = 10)				
BP to D	2.3 (1.0) [0.9-2.9]	0.9 (1.6) [0-5.2]	2,780 (4,887) [206-15,770]	2.9 (0.7) [2.3-4.2]
UM to D (postflush)*	1.1 (0.9) [0-2.5]	0.1 (0.1) [0-0.4]	185 (120) [45-322]	2.2 (0.4) [1.7-2.5]
Postcleaning (n = 20)				
BP to D	0.3 (0.5) [0-1.6]	0.1 (0.1) [0-0.3]	22.4 (13.7) [11-54]	1.3 (0.2) [1.0-1.7]
UM to D (postflush)	0.3 (0.5) [0-1.4]	0.2 (0.1) [0-0.4]	21.9 (13.9) [10-57]	1.3 (0.2) [1.0-1.8]
Baseline (n = 5)				
BP to D	0	0.08 (0.2) [0-0.40]	18.6 (6.1) [13-29]	1.3 (0.1) [1.1-1.5]
UM to D	0.04 (0.10) [0-0.2]	0.04 (0.05) [0-0.1]	32.6 (33.8) [14-93]	1.4 (0.3) [1.1-2.0]
Duodenoscopes				
Precleaning (n = 10)				
BP to D	2.7 (1.0) [1.4-5.0]	0.5 (0.6) [0-2.0]	8,527 (13,297) [245-41,825]	3.5 (0.6) [2.4-4.6]
UM to D (postflush)	1.3 (1.0) [0-2.9]	0.1 (0.2) [0-0.6]	547 (760) [55-2,608]	2.5 (0.5) [1.7-3.4]
Postcleaning (n = 20)				
BP to D	0.4 (0.5) [0-1.6]	0.2 (0.2) [0-0.8]	55.9 (31) [22-135]	1.7 (0.2) [1.3-2.1]
UM to D (postflush)	0.4 (0.5) [0-1.6]	0.2 (0.1) [0-0.6]	39.6 (17.4) [14-81]	1.6 (0.2) [1.1-1.9]
Baseline (n = 5)				
BP to D	0.001 (0.003) [0-0.007]	0.05 (0.06) [0-0.1]	39.8 (23.7) [17-73]	1.5 (0.3) [1.2-1.9]
UM to D	0.002 (0.003) [0-0.006]	0.07 (0.09) [0-0.2]	25.4 (12.3) [11-35]	1.352 (0.252) [1.0-1.5]
Gastroscopes				
Precleaning (n = 10)				
BP to D	2.6 (1.3) [0.6-4.9]	2.6 (7.0) [0-22.6]	15,269 (16,257) [249-39,527]	3.8 (0.7) [2.4-4.6]
UM to D (postflush)	1.2 (0.8) [0-2.5]	0.1 (0.2) [0-0.7]	3,137 (6,821) [34-22,225]	2.8 (0.8) [1.5-4.3]
Postcleaning (n = 20)				
BP to D	0.4 (0.5) [0-1.5]	0.3 (0.3) [0-1.0]	239 (531) [20-2,350]	1.9 (0.6) [1.3-3.4]
UM to D (postflush)	0.2 (0.2) [0-0.7]	0.2 (0.1) [0-0.4]	112 (116) [26-432]	1.9 (0.4) [1.4-2.6]
Baseline (n = 5)				
BP to D	0	0.2 (0.1) [0-0.3]	16.8 (4.3) [13-24]	1.2 (0.1) [1.1-1.4]
UM to D	0.01 (0.03) [0-0.06]	0.09 (0.2) [0-0.3]	17.4 (4.1) [13-21]	1.2 (0.1) [1.1-1.3]

NOTE. A value of 0 represents samples below the limit of detection.
*Postflush: The BP-to-D segment was flushed with 200 mL of sRO water before collection of the UM-to-D sample.

Table 3
Number of scopes exceeding new benchmark cutoffs after manual cleaning

Scope	Bioburden	Protein	ATP
Colonoscope			
BP to D	0/20	0/20	0/20
UM to D	0/20	0/20	0/20
Duodenoscope			
BP to D	0/20	0/20	0/20
UM to D	0/20	0/20	0/20
Gastroscope			
BP to D	0/20	0/20	4/20
UM to D	0/20	0/20	4/20

New benchmark cutoffs: bioburden, <2 $\log_{10}$ CFU/cm^2; protein, <2 μg/cm^2; ATP, <200 RLU/test.

patient procedures with or without bedside precleaning. This likely reflects differences in procedures (eg, procedures in which only visualization of the GI tract was done vs those in which surgical procedures or biopsies were performed), and differences in the efficiency of the bedside precleaning.

Our data for gastroscopes are the first to demonstrate that this scope type is much more difficult to clean manually even when using pump-assisted flushing of channels. After full manual cleaning with flushing using an automated pump, 4 of the 20 BP-to-D samples (20%) and 4 of the 20 UM-to-D samples (20%) still exceeded the 200 RLU benchmark. None of these samples exceeded the traditional benchmarks for protein or bioburden after full manual cleaning. Conversely, no traditional benchmarks or RLU benchmarks were exceeded for colonoscopes or duodenoscopes after pump-assisted manual cleaning. This is most likely because no preparation of the upper GI tract is done before gastroscopy, whereas for nonemergency duodenoscopy and colonoscopy procedures, the gut is prepped using products that result in purging of the bowel contents. Furthermore, gastroscopy often involves obtaining biopsy specimens, which further contaminate the endoscope channel with blood and secretions. Currently, there is no standardization of the level of cleaning that needs to be achieved when using flushing pumps to assist with endoscope channel cleaning. We recommend that the flushing pumps used to replace manual flushing during flexible endoscope channel cleaning be validated by the manufacturers to confirm that the volumes used for channel flushing provide the necessary kinetics to achieve equivalency to the current manual cleaning benchmarks for ATP.

The original endoscope cleaning benchmarks for protein, hemoglobin, carbohydrates, and bioburden[16] were established at a time when flushing of detergent and rinse water was done manually using an "all-channel" irrigator. Currently, many endoscopy clinics use pumps to assist with flushing the detergent and rinse water through the channels. Our data presented here demonstrate that after pump-assisted manual cleaning, it was possible to achieve traditional benchmarks for bioburden, protein, and RLUs residual in 100%, 100%. and 93%, respectively, of 60 patient-used GI endoscopes. Based on our postcleaning clinical data, we recommend that the revised benchmarks for pump-assisted GI endoscope cleaning be set to <2 $\log_{10}$ CFU/cm^2 for bioburden, <2 ug/cm^2 for protein, and <200 RLU for ATP detection. For the new benchmarks, there would still be 100%, 100%, and 93% cleaning for the bioburden, protein, and ATP, respectively. Although Fushimi et al[11] suggested that protein was not as useful a cleaning marker as either ATP or colony count, this may be protocol-related, given that they used Coomassie blue for protein detection, which is a less-sensitive assay than bicichoninic acid—based protein assays. Furthermore, they did not comment on why their protein levels were so low for patient-used gastroscopes that received no cleaning. Alfa et al[16] reported maximum protein values of 4,410 μg/sample in duodenoscopes, 4,370 μg/sample in bronchoscopes, and 22,180 μg/sample in

colonoscopes when using the same approach as used by Fushimi et al[11] (ie, 10 mL sample volume for channel sample collection, Coomassie blue protein assay, and no bedside precleaning). Furthermore, Alfa et al demonstrated a 97.6% reduction in protein levels for colonoscopes from before cleaning to after cleaning. Although the measurable scale for protein detection is not as broad as that for culture or ATP, protein remains a useful marker for the detection of organic residuals that are relevant to endoscope cleaning. Similarly, bioburden levels are valuable as a means of assessing wet storage and detecting problems in endoscope reprocessing.[8,11,13,17]

A limitation of the present study is that direct clinical impact of exceeding any of the cleaning benchmarks for protein, bioburden, or ATP cannot be correlated with device-related infection transmission. For ethical reasons, such a prospective study could not be undertaken, because the current standard of care is thorough cleaning of flexible endoscopes before decontamination/sterilization. Furthermore, such a study would require prospective follow-up of a very large number of patients and the use of molecular typing methods to differentiate organism "transmission" versus "infection" rates. Despite this limitation, however, it is a quality process expectation (and an endoscope manufacturer's expectation) that endoscopes cleaned following the manufacturer's instructions should not have excessive residual levels of organic material or bioburden. The study of Ofstead et al[1] found that compliance with all steps in endoscope reprocessing is poor, and that breaches related to inadequate manual cleaning and inadequate drying similar to those reported many years ago[8,9] continue to occur. Such breaks in compliance increase the risk of biofilm leading to a device-associated infection outbreak.[6,18,19]

Given the high transmission rates that can occur with contaminated endoscopes,[6,18,19] it is reasonable to use simulated-use studies to validate benchmark levels of residuals that can be achieved if cleaning has been properly completed, and to use these benchmarks as part of a quality process to monitor manual cleaning compliance for patient-used flexible endoscopes.

Owing to variability in the limit of detection for different ATP detection methods[14,15] and in the method of sample collection from endoscope channels,[8,9,11,13,14] we would recommend that at a minimum, standardization of sample collection for flexible endoscope channel monitoring is needed to allow analysis of the published studies. Our data demonstrate that for patient-used GI endoscopes, the highest level of residuals (83%) as measured by ATP is in the BP-to-D segment of the SB channel, higher than that in the UM-to-BP portion of the same channel. We recommend that manufacturers of cleaning monitoring tests specify a single validated sample collection method (eg, 40 mL of sterile distilled or RO water) for the entire working channel (umbilical to distal) as well as a single validated method (eg, 20 mL of sterile distilled or RO water) for the BP-to-D segment of this channel. In that way, as more data are published using ATP as a cleaning monitor, it will be possible to compare the conclusions in a more meaningful manner. If brushes or sponges were used for channel sampling, then sampling and elution in the same volumes as indicated above could also help ensure the comparability of data.

In summary, this study demonstrates that the clinically relevant benchmarks for manual cleaning using flushing pumps can be set to <2 $\log_{10}$ cfu/cm^2 for bioburden, <2 ug/cm^2 for protein, and <200 RLU for ATP, with no loss in the ability of endoscopy clinics to achieve the same level of compliance as for the previously published benchmarks for endoscopes cleaned without flushing pumps. Our data indicate that gastroscopes have the highest soiling levels and are the most difficult to clean even when using a flushing pump. Furthermore, our data indicate that both sample collection from the entire SB channel or from the BP-to-D portion of the channel are valid sample collection methods for ATP testing. Establishing the frequency of monitoring manual cleaning for flexible endoscopes requires more published data. Despite this limitation, we recommend assessing reprocessing personnel when initially trained and then at least yearly thereafter to document ongoing compliance, as well as weekly monitoring of manual cleaning of a portion of the patient-used flexible endoscopes as part of an overall quality process (frequency of testing determined by the site).

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