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Major Article

The effectiveness of sterilization for flexible ureteroscopes: A real-world study

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Background: There are no guidelines or quality benchmarks specific to ureteroscope reprocessing, and patient injuries and infections have been linked to ureteroscopes. This prospective study evaluated ureteroscope reprocessing effectiveness.

Methods: Reprocessing practices at 2 institutions were assessed. Microbial cultures, biochemical tests, and visual inspections were conducted on sterilized ureteroscopes.

Results: Researchers examined 16 ureteroscopes after manual cleaning and sterilization using hydrogen peroxide gas. Every ureteroscope had visible irregularities, such as discoloration, residual fluid, foamy white residue, scratches, or debris in channels. Tests detected contamination on 100% of ureteroscopes (microbial growth 13%, adenosine triphosphate 44%, hemoglobin 63%, and protein 100%). Contamination levels exceeded benchmarks for clean gastrointestinal endoscopes for hemoglobin (6%), adenosine triphosphate (6%), and protein (100%). A new, unused ureteroscope had hemoglobin and high protein levels after initial reprocessing, although no contamination was found before reprocessing.

Conclusions: Flexible ureteroscope reprocessing methods were insufficient and may have introduced contamination. The clinical implications of residual contamination and viable microbes found on sterilized ureteroscopes are unknown. Additional research is needed to evaluate the prevalence of suboptimal ureteroscope reprocessing, identify sources of contamination, and determine clinical implications of urinary tract exposure to reprocessing chemicals, organic residue, and bioburden. These findings reinforce the need for frequent audits of reprocessing practices and the routine use of cleaning verification tests and visual inspection as recommended in reprocessing guidelines.

A large proportion of gastrointestinal endoscopes harbor residual contamination.[1-6] Outbreaks have been linked to contaminated duodenoscopes, gastroscopes, bronchoscopes, and cystoscopes.[7-12] In a cystoscopy-associated outbreak involving 23 patients in New Mexico, investigators found myriad breaches of endoscope reprocessing guidelines. These included delayed reprocessing, failing to fully immerse the cystoscope in high-level disinfectant (HLD), inadequate HLD exposure time, and reusing the same rinse water for 2 weeks or until it "began to smell."[10] In a gastroscopy-associated outbreak of multidrug-resistant *Pseudomonas aeruginosa* in France, technicians were reportedly following the French reprocessing guidelines, but investigators observed suboptimal manual cleaning (eg, only 1 size of brush used; <10 minutes invested in brushing and flushing channels), inadequate drying, and horizontal storage. The pathogen was found in the gastroscope channel, and the outbreak was ended by improving reprocessing practices.[7] On the other hand, recent outbreaks associated with duodenoscopes have occurred even when guidelines were followed.[8,11]

Injuries and infections have also been attributed to contaminated or damaged ureteroscopes, including those with broken wires, plastic coatings, and linings.[13-16] Ureteroscopes are frequently repaired due to functional problems identified during procedures.[17-19]

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Manufacturer's instructions for use (IFUs) recommend conducting a multistep inspection before each procedure, and removing ureteroscopes with defects from service.[20-23] Guidelines for reprocessing flexible endoscopes recommend conducting visual inspections and leak tests during every reprocessing cycle, along with routine monitoring of cleaning effectiveness.[24,25]

To date, no published study has systematically assessed the extent of damage and residual contamination in patient-ready flexible ureteroscopes. This study used lighted magnification to identify ureteroscope damage or debris, measured residual contamination, and evaluated the association between ureteroscope characteristics (eg, age, number of uses, and repair history) and the presence of visible irregularities or residual contamination.

MATERIALS AND METHODS

Setting and design

This prospective study was conducted at 2 large multispecialty health care facilities in the mid-western United States. A waiver was granted by the institutional review boards at both sites because no human subjects were involved. Data regarding ureteroscope models, acquisition dates, procedural use, and repair histories were collected by site personnel. Site visits were conducted to examine patient-ready ureteroscopes and observe reprocessing practices in June (site A) and August (site B) 2016.

Sampling for biochemical tests and microbial cultures

Researchers collected samples from every patient-ready ureteroscope in use at each facility. Sampling was done in operating rooms using aseptic technique. Sterile swabs (482c ESwabs; COPAN Diagnostics Inc, Murrieta, CA) moistened with sterile, deionized water were used to obtain microbial culture samples from channel ports. Swab tips were placed in vials containing 1 mL Amies solution. The flush-brush-flush technique was used with 4 mL sterile, deionized water and a sterile channel swab to obtain channel effluent. The tip of this channel swab was removed and placed in a vial containing 2 mL effluent and 2 mL Amies solution for microbial cultures. The remaining 2 mL effluent was tested for adenosine triphosphate (ATP) (CleanTrace ATP Water; 3M Company, St Paul, MN), protein (ProCheck-II; HealthMark Industries, Fraser, MI), and hemoglobin (HemoCheck-S; HealthMark Industries). Surface ATP samples were obtained by swabbing the distal tip and the entire length of the insertion tube (CleanTrace ATP Surface; 3M Company). ATP levels were measured using a luminometer. Protein and hemoglobin levels were read using a spectrophotometer (DR 1900 Portable Spectrophotometer; Hach Company, Loveland, CO). Due to the lack of published benchmarks for permissible levels of organic residue on reprocessed ureteroscopes, researchers used published benchmarks for residue on manually cleaned gastrointestinal endoscopes (ATP: 200 relative light units [RLU], protein: 6.4 μg/mL, and hemoglobin: 2.2 μg/mL).[26,27] Samples for microbial culturing were transported in coolers to an external laboratory (Biotest Laboratories, Inc, Brooklyn Park, MN). The laboratory filtered samples through 0.22 μm nitrocellulose filters before plating on blood agar. Samples were incubated at 26°C-30°C for 24 hours and then at 34°C-36°C for 5-7 days to foster growth of bacteria and fungi.

At each site, 2 positive control tests were performed on clinically used endoscopes before they underwent manual cleaning. Two negative control tests were conducted at each site using sterile items (brand new ureteroscope, autoclaved surgical steel instrument, and sterile water).

Visual examinations

After sampling, ureteroscopes were recleaned and sterilized before visual examination. External surfaces were systematically photographed using an 8-megapixel digital camera (iSight; Apple Inc, Cupertino, CA). Predetermined locations inside distal ends, ports, and channels were examined with a 0.8 mm fiber optic borescope (Ultra-Thin HQ Micro Borescope; Medit Inc, Winnipeg, Canada) to facilitate comparisons between ureteroscopes. Additional photographs were captured when irregularities were observed.

Risk assessment protocol

Before site visits, researchers and site personnel established a risk assessment protocol to address issues identified as a result of study activities. Under this protocol, researchers alerted site personnel whenever residual contamination exceeded benchmarks, substantial irregularities (eg, deep scratches; residual debris) were observed during visual examinations, or microbial cultures had any growth. Decisions to re-reprocess ureteroscopes, quarantine them, or send them out for repair were made by site personnel.

RESULTS

Ureteroscope characteristics

Researchers received administrative data for 13 ureteroscopes at site A (A-1 through A-13) and 4 ureteroscopes at site B (B-1 through B-4) (Table 1). The mean ureteroscope age was 2.1 years (range, 0.21-5.6 years) at site A and 2.2 years (range, 1.0-2.8 years) at site B. Ureteroscopes at both sites were used infrequently (average <1/week). Sites documented a total of 49 repairs before the study. Ureteroscopes required repair after an average of 14 uses at site A and 42 uses at site B. Common reasons for repair included leaks identified by reprocessing technicians (19 repairs) and inadequate image quality (15 repairs) (Table 1).

Reprocessing practices

According to sterile processing department (SPD) managers at both sites, institutional reprocessing protocols included immediate bedside precleaning; transportation to SPD; leak testing; manual cleaning with enzymatic detergent followed by rinsing; drying with air purges, alcohol flushes, and forced air; and sterilization with hydrogen peroxide gas. The reprocessing protocols described by SPD managers are consistent with recommendations described in reprocessing guidelines.[24,25] Before sterilization, the reprocessing protocol at site A also required each endoscope to undergo automated cleaning and HLD in an automated endoscope reprocessor. Enzymatic detergent was used for the automated cleaning cycle, and peracetic acid was used for HLD before sterilization. At site B, the protocol included conducting routine tests to verify cleaning effectiveness using an indicator for protein, hemoglobin, and carbohydrates (ChannelCheck; HealthMark Industries) after manual cleaning. The site B protocol specified that ureteroscopes should be recleaned whenever the cleaning verification test detected contamination. In addition, the image quality was assessed immediately after each procedure and again before packaging for sterilization.

During both site visits, no bedside precleaning was done by operating room personnel, who acknowledged that they did not customarily perform this step before sending ureteroscopes to the SPD for reprocessing. SPD and operating room employees reported occasional delays between procedure completion and the initiation of manual cleaning, and there was no protocol for reporting delayed reprocessing so that it could be addressed in

Table 1
Ureteroscope administrative and repair data

				Repair history	
ID	Model	Acquisition date	Times used	Times repaired	Reasons and dates sent out for repair
A-1	URF-V2	3/29/2016	3	0	NA
A-2	URF-V2	3/29/2016	6	0	NA
A-3	URF-V2	3/29/2016	0	0	NA
A-4	URF-V2	3/29/2016	1	0	NA
A-5	URF-V2	3/29/2016	4	0	NA
A-6	URF-V2	3/29/2016	4	0	NA
A-7	DUR-8 ULTRA	3/1/2013	82	6	Failed leak test: 8/29/2014; 4/14/2015; 7/24/2015; 10/20/2015; 1/28/2016; 5/13/2016
A-8	AUR-7	10/28/2010	16	1	Inadequate image: 9/15/2014
A-9	URF-P6	9/27/2012	88	6	Inadequate image: 3/13/2014; 7/11/2014 Failed leak test: 6/20/2014; 8/21/2015; 2/8/2016 Insertion tube kinks: 7/11/2014 Broken fibers: 3/2/2015
A-10	URF-P6	6/3/2013	93	11	Sterilization cap broke: 11/6/2013; 9/18/2014 Broken fibers: 6/23/2014 Inadequate image: 7/11/2014; 8/10/2015; 9/29/2015 Failed leak test: 12/8/2014; 12/7/2015; 4/8/2016; 5/5/2016 Insertion tube pinched: 7/6/2015
A-11	URF-P6	9/17/2013	97	4	Inadequate image: 5/20/2014 Insertion tube pinched: 10/16/2014; 2/3/2016 Laser fiber damaged ureteroscope: 7/21/2015
A-12	URF-P6	9/27/2012	90	7	Broken fibers: 6/20/2014; 12/8/2014 Failed leak test: 7/30/2015; 4/1/2016 Inadequate image: 12/8/2015; 3/3/2016; 4/29/2016
A-13*	DUR-8 ULTRA	1/1/2013	88	5	Broken fibers: 3/30/2015 Inadequate image: 1/26/2016; 4/6/2016 Failed leak test: 3/22/2016; 4/29/2016
B-1	URF-P6R	10/9/2013	142	3	Scope leaking: 8/3/2015 Inadequate image: 2/24/2016 Broken fibers: 6/3/2016
B-2	URF-P6R	10/9/2013	104	2	Failed leak test: 9/11/2015 Broken fibers: 7/13/2016
B-3	URF-P6R	8/6/2014	57	2	Inadequate image: 10/1/2015 Scope exchange, return bad scope for credit: 4/19/2016
B-4	URF-P6R	8/7/2015	30	1	Inadequate image: 2/25/2016

NA, not applicable.
*Ureteroscope out for repair during site visit, not sampled for contamination.

accordance with IFUs (eg, with extra soaking and manual cleaning). At site A, researchers observed that reprocessing technicians did not adhere to IFUs or national guidelines for leak testing, manual cleaning, visual inspection, and drying.

In contrast, at site B, researchers observed technicians taking more actions during manual cleaning than specified in IFUs and national guidelines (eg, brushing channels 3 times using 3 single-use brushes, flushing detergent and rinsing with water using both syringes and suction systems, and using deionized water for final rinses). Additionally, site B technicians were observed utilizing a rapid indicator to verify cleaning effectiveness before sterilization as described by managers. The methods observed for drying ureteroscopes before sterilization at Site B did not include an alcohol flush or sufficient forced air exposure to ensure drying.

Biochemical tests and microbial cultures

Sixteen sterilized ureteroscopes were sampled during the study (12 site A and 4 site B). One of 13 ureteroscopes in use at site A was out for repair during sample collection (A-13). Protein was detected in samples from 100% of ureteroscopes, and all results of initial protein tests exceeded the benchmark (Table 2). Protein levels were higher at site A (75% were ≥20 μg/mL) than site B (0% were >20 μg/mL). Hemoglobin was detected on 10 ureteroscopes (63%), and 1 of these exceeded the benchmark. A larger proportion of ureteroscopes tested positive for hemoglobin at site A (75%) than at site B (50%). ATP above background level (40 RLU per the manufacturer) was detected on 7 ureteroscopes, and the level for 1 exceeded the 200 RLU benchmark. Microbial cultures were positive for samples from 2 patient-ready ureteroscopes. No negative controls had microbial growth and 2 positive controls had growth (Table 2).

One brand-new ureteroscope (A-3) that had not been clinically used was sampled before the initial reprocessing recommended by the manufacturer. No hemoglobin was detected, ATP was below background level, and protein was well below the benchmark for clean gastrointestinal endoscopes (Table 2). After being reprocessed in accordance with standard protocols at site A, this ureteroscope was retested before clinical use. These tests detected hemoglobin, and protein increased from 2 to 24 μg/mL, surpassing the benchmark of 6.4 μg/mL. ATP levels remained below the background level. Another brand-new ureteroscope (A-4) was also tested before any clinical use, after being reprocessed in accordance with usual practices. Tests detected hemoglobin as well as high levels of ATP (338 RLU) and protein (20 μg/mL). This ureteroscope was reprocessed again and retested to evaluate the influence of reprocessing on contamination levels. The ATP level on the insertion tube decreased from 338-40 RLU, but slightly more protein was found in channel effluent (21 μg/mL) and hemoglobin was detected again (Table 2).

Contamination levels on new (A1-A6, used ≤6 times) and rarely used ureteroscopes (A-8, used 16 times) were similar to contamination found on older and more frequently used ureteroscopes (used 30-142 times). There was no apparent association between repair history and contamination levels. The 2 ureteroscopes with the highest number of repairs (A-10 and A-12) had contamination levels similar to new ureteroscopes that had never been repaired. One ureteroscope with positive microbial cultures (A-9) had the highest

Table 2
Residual contamination results

ID	Model	Insertion tube adenosine triphosphate (RLU)	Channel effluent			Microbial growth (CFU)
			Adenosine triphosphate (RLU)	Hemoglobin (μg/mL)	Protein (μg/mL)	
Results of encounters with patient-ready ureteroscopes						
A-1	URF-V2	46	26	1	26	0
A-2	URF-V2	44	28	1	21	0
A-3*	URF-V2	23	15	1	24	0
A-4*	URF-V2	338	41	1	20	0
A-5	URF-V2	33	20	Under range	20	0
A-6	URF-V2	47	28	1	17	0
A-7	DUR-8 ULTRA	36	30	Under range	13	0
A-8	AUR-7	39	19	Under range	12	0
A-9	URF-P6	37	17	3	32	1 (*Micrococcus luteus*)
A-10	URF-P6	30	26	1	21	0
A-11	URF-P6	39	20	Under range	17	0
A-12	URF-P6	36	17	1	21	0
B-1	URF-P6R	74	17	Under range	12	0
B-2	URF-P6R	134	19	1	16	0
B-3	URF-P6R	34	20	Under range	9	0
B-4	URF-P6R	43	17	1	15	1 (*Corynebacterium glaucum*)
Results of tests repeated after re-reprocessing due to high initial results						
A-4	URF-V2	40	31	1	21	0
A-9	URF-P6	37; 35	27	Under range	2	NA
A-12	URF-P6	39	29	1	15	0
B-2	URF-P6R	43	25	1	12	NA
B-4	URF-P6R	59	24	1	17	NA
Positive control tests						
A-11†	URF-P6	274	30	1	30	0
A-P1†	Gastroscope	119	30	1	12	24 (*Klebsiella pneumoniae*)
B-P1†	Gastroscope	33047	591	2	11	TNTC (*Pseudomonas aeruginosa, Serratia marcescens, Candida albicans*)
B-P2†	Bronchoscope	7083	272	Under range	10	0
Negative control tests						
A-3‡	URF-V2	NA	24	Under range	2	NA
A-N1	Tenaculum	33	31	1	11	0
B-N1	Towel clamp 4”	20	18	Under range	7	0
B-N2	Sterile water/cup	13	14	1	3	0

CFU, colony-forming units; *NA*, test not conducted or not applicable; RLU, relative light units; *TNTC*, too numerous to count.
*Brand-new ureteroscope tested after first time being reprocessed.
†Clinically used endoscopes tested before manual cleaning.
‡Brand-new ureteroscope that had not yet been used or reprocessed.

levels of protein and hemoglobin found during this study. This ureteroscope had been used 88 times and repaired 6 times. The ureteroscope with the most use (B-1, used 142 times) had no microbial growth, no hemoglobin, ATP below benchmark, and among the lowest protein levels found.

Visual examinations

At site A, researchers observed irregularities on the external surfaces of all patient-ready ureteroscopes (Fig 1 A-D). Irregularities included foamy white residue, fibrous white material, yellow or rusty discoloration on ports, fluid droplets, and oily residue. White foamy residue and oily deposits were visible on 1 of the new ureteroscopes (A-3) after it had undergone initial reprocessing before clinical use. These residues were not present before reprocessing. During borescope examinations at site A, researchers observed discoloration in several ureteroscopes. Filaments of debris protruded into the channels of 2 ureteroscopes (A-2: new with 6 uses; A-9: 3.7 years old with 88 uses). In each case, 1 end of the debris appeared to be attached to the channel while the other end moved when prodded with the borescope (Fig 1 E-F). There appeared to be no connection between ureteroscope age, prior use, and visible irregularities.

At site B, researchers observed irregularities and debris on external surfaces of every patient-ready ureteroscope. Irregularities included yellow discoloration, scratches, or dents near ports (Fig 2 A). Rusty discoloration was observed on 2 detachable valves (Fig 2 B). Researchers also found irregularities on internal surfaces during borescope examinations. Staining was evident inside 3 ureteroscopes, and debris was found in the channel of all ureteroscopes (Fig 2 C-D). One ureteroscope (B-3) had filamentous debris protruding from the channel. There did not appear to be an association between ureteroscope age, prior use, and visible irregularities.

Risk assessment protocol

Researchers alerted personnel at both sites about results of tests and visual inspections in accordance with the risk assessment protocol. Site personnel re-reprocessed 5 ureteroscopes and presented them to the research team for retesting (Table 2). Additional reprocessing was generally not effective, and several ureteroscopes were quarantined until microbial cultures were complete. Site A personnel flagged 2 ureteroscopes for repair and site B personnel flagged 1 for repair.

DISCUSSION

This study detected substantial contamination on sterilized ureteroscopes, including hemoglobin, ATP, and protein. Microbial cultures were positive for samples from 2 of 16 ureteroscopes. All study ureteroscopes had visible irregularities, including scratches, dents, filaments of debris, rusty-yellow discoloration, oily deposits, residual fluid, or foamy white residue. Visible debris protruding

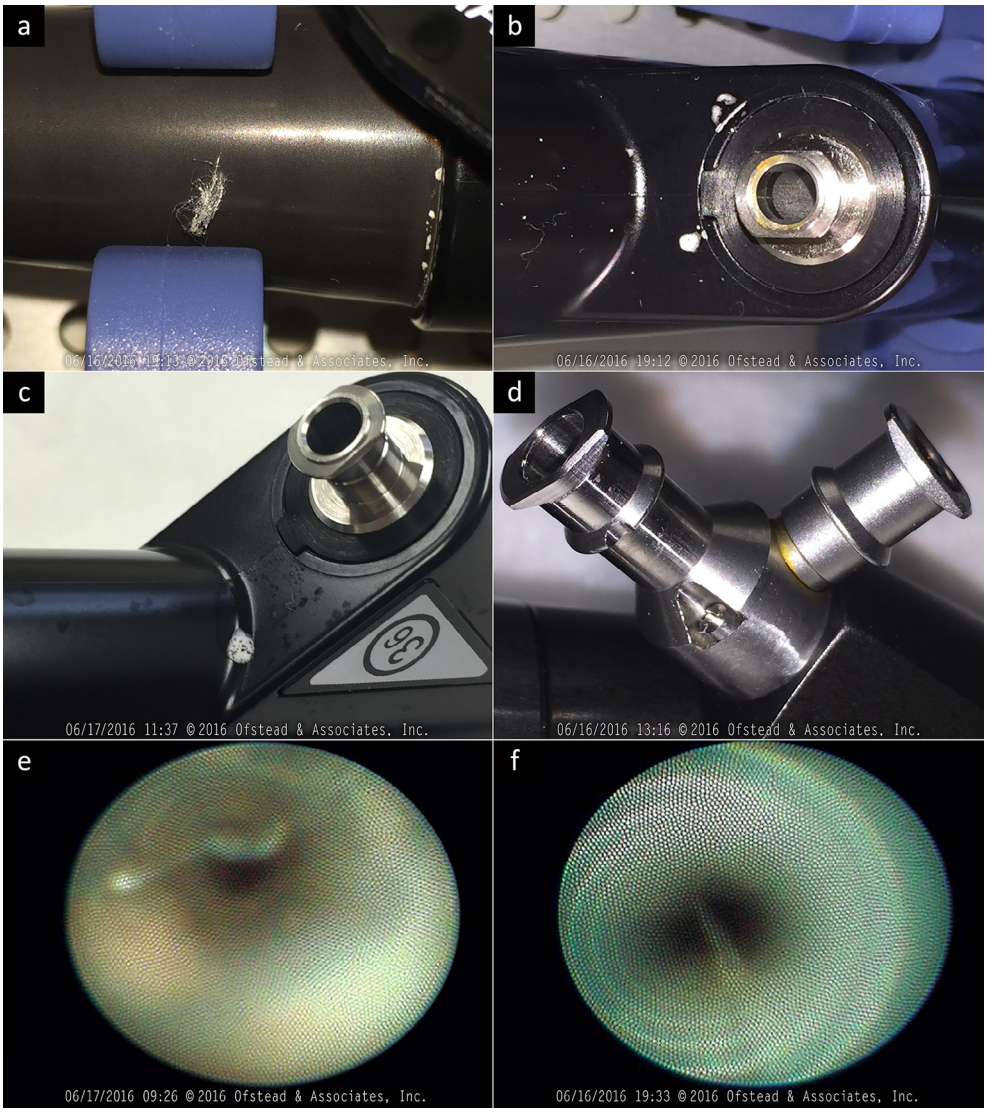

Fig 1. Irregularities found at site A. (A) White fibrous debris on control handle and rusty discoloration and white residue near junction. (B) White residue near port and yellow discoloration on port. (C) White foamy residue and oily deposits. (D) Yellow discoloration on port. (E and F) Filamentous debris in channel.

into the channel was observed in a ureteroscope (A-9) with microbial growth and the highest levels of hemoglobin and protein found during this study. There was no relationship between contamination levels, visible irregularities, and ureteroscope age, use, or repair history. Before the study, the most common reasons for repair were failed leak tests and inadequate image quality. These are functional failures that occur after ureteroscopes have sustained substantial damage.

Similar results have been found in previous research involving gastrointestinal endoscopes. In a recent study, 100% of colonoscopes and gastroscopes had visible damage or debris, and microbial cultures were positive for 60% after HLD.[28] Gastroscopes were more highly contaminated than colonoscopes although the same reprocessing protocols were used, which indicates that factors beyond reprocessing practices (eg, endoscope type and procedural use) may influence reprocessing effectiveness. Researchers found that endoscopes used between 35 and 40 times had similar contamination levels and irregularities to endoscopes used between 384 and 530 times,[28] which suggests that reprocessing failures may occur even when endoscopes are fairly new. High protein[1,28,29] and ATP levels[1,5,28,29] have been found on reprocessed endoscopes during previous studies by this research team. Other researchers have determined that reprocessing does not remove protein, and brushing may spread out protein residues and contribute to biofilm development.[30] In that study, a decommissioned channel from a gastroscope harbored 33 μg protein.

There are currently no reprocessing guidelines or standards specific to flexible ureteroscopes, and no benchmarks for permissible levels of organic residue on ureteroscopes have been established. Therefore, researchers used benchmarks for manually cleaned gastrointestinal endoscopes. These benchmarks were intended to identify endoscopes requiring additional cleaning before being subjected to HLD or sterilization. The level of residual contamination on sterilized ureteroscopes should arguably be far lower than the amount allowable for clean gastrointestinal endoscopes. Sterilization involves the complete eradication of all viable microbes, and as such, microbial cultures should always be negative for sterilized instruments.

The detection of hemoglobin in more than half of the samples is concerning. According to the test manufacturer (personal communication; Kaumudi Kulkarnia, April 4, 2016), the hemoglobin test was designed to detect blood, but it may also give positive results when

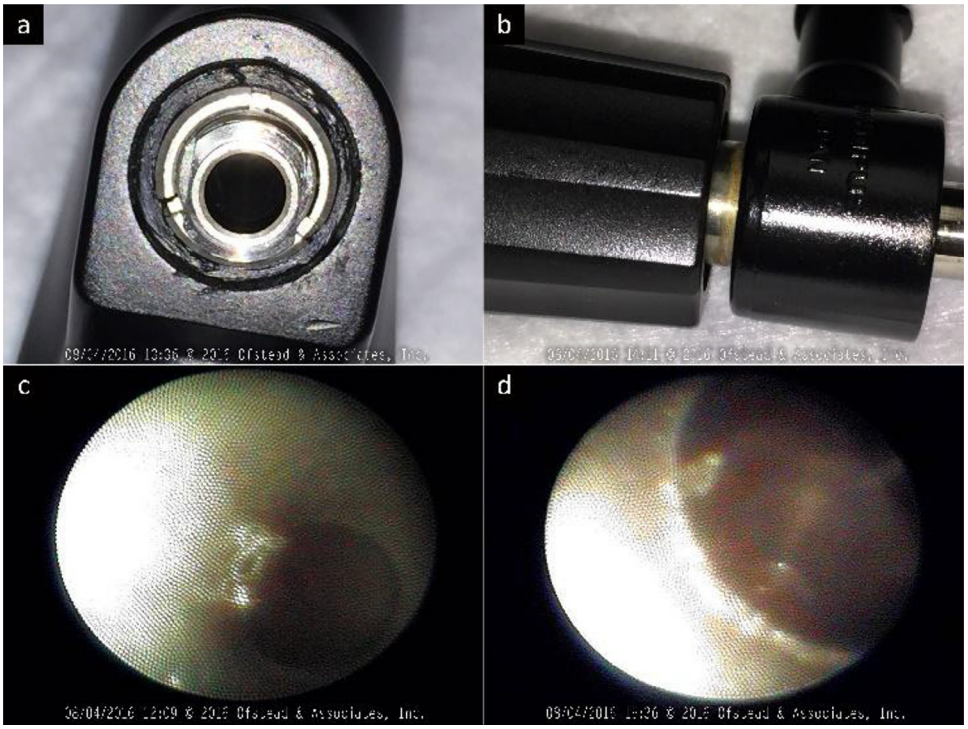

Fig 2. Irregularities found at site B. (A) Dents and scratches around port. (B) Discoloration and buildup on valve. (C) Filaments of debris inside channel. (D) Flaky debris near channel-port junction.

reprocessing chemicals are present. The possibility that positive results were due to residual reprocessing chemicals or other contaminants introduced during reprocessing was bolstered by findings from 2 new ureteroscopes (A-3 and A-4). In accordance with institutional protocols, these new ureteroscopes were cleaned, underwent HLD, and sterilized to prepare them for clinical use. Tests performed after their initial reprocessing detected hemoglobin and high levels of protein on both ureteroscopes, and a high level of ATP on 1 of them (A-4). The residue found on ureteroscope A-3 appears to have been introduced by reprocessing because tests done immediately before the initial reprocessing were negative for ATP, hemoglobin, and protein. After study tests found high contamination levels on A-4, technicians re-reprocessed it. This reduced the ATP level on an exterior surface (the insertion tube), but the protein level in channel effluent increased slightly and hemoglobin was still detected. Reprocessing appears to have introduced protein and hemoglobin, and repeated efforts did not remove it. The large reduction in ATP found on the insertion tube may be due to the nature of ATP testing (it detects living cells, which are less likely to be found after 2 rounds of cleaning, HLD, and sterilization), or due to the relative ease of cleaning and rinsing external components compared to internal components.

Although reprocessing chemicals may be partly responsible for contamination found, the lack of bedside precleaning and potential for delayed reprocessing could have allowed patient secretions and organic debris to accumulate and contribute to the hemoglobin, protein, and ATP found on clinically used ureteroscopes. Lower levels of residual contamination (protein and hemoglobin) found at site B may have been due in part to the more thorough manual cleaning methods observed during the site visit, which may have partially compensated for the lack of bedside precleaning. Inadequate adherence to manufacturer IFUs and professional guidelines have been contributing factors to endoscopy-related outbreaks,[7,10,12,13] but it is unclear how much the nonadherence to institutional protocols and national guidelines observed at study sites may have influenced contamination found. However, previous studies conducted in settings with very good guideline adherence found that HLD was commonly ineffective for gastrointestinal endoscopes, which demonstrated that contamination may remain even when technicians follow guidelines.[1-3,28]

The clinical implications of residual chemicals, organic material, and microbes found on patient-ready ureteroscopes in this study are unknown, but could be serious. Recent reports obtained from the Food and Drug Administration Manufacturer and User Facility Device Experience Database describe an outbreak involving 7 patients who developed urinary tract infections with *Escherichia coli* after being treated with 4 ureteroscopes that were found to have multiple defects. These included scratches, a deep cut in the insertion tube, reddish-orange residue, and white residue inside the channel ports and the distal ends.[16] The manufacturer also reported failed leak tests and broken image fibers. According to the Manufacturer and User Facility Device Experience Database report,[16] the specific cause for the outbreak could not be determined, although the manufacturer speculated that insufficient reprocessing (details not specified) or user handling could be contributing factors. This situation illustrates the value of routine visual inspection using a borescope and audits of reprocessing practices to identify any issues that could place patients at risk.

Another report in the Food and Drug Administration database describes 2 patients who experienced severe bacterial infections following ureteroscopy.[31] One patient was discharged in stable condition after ureteroscopy and returned to the emergency department in septic shock. This patient was admitted to the intensive care unit, and urine cultures grew *Enterococcus faecalis*. The other patient developed symptoms of infection shortly after a procedure with the same ureteroscope and was transferred to the intensive care unit for treatment. *Enterococcus faecalis* was also found in that patient's blood cultures. This situation highlights the potential value of surveillance cultures and cleaning verification tests, because these

tests can identify residual contamination that could be addressed before patient exposure.

In 2016, the manufacturer of the majority of ureteroscopes examined during this study (Olympus Corporation, Center Valley, PA) released an Urgent Medical Device Safety Notice stating that the use of damaged flexible ureteroscopes has resulted in patient injury. This document provides new instructions for performing more thorough visual inspections, which Olympus Corporation recommends be conducted before each use.[32] The findings of this study reinforce the value of using lighted magnification to proactively identify damaged ureteroscopes that should be repaired before further clinical use.

Given the documented occurrence of infections and patient injury associated with the use of damaged or contaminated ureteroscopes, infection preventionists (IPs) should frequently audit endoscope reprocessing practices and identify suboptimal practices that could contribute to the formation of biofilm and the transmission of infection. They should also oversee the performance of cleaning verification tests and ensure that visual inspections are routinely done to identify residual debris or defects that could harbor contamination. Proactive performance of these steps can identify endoscopes that should be recleaned or removed from service, thus potentially preventing outbreaks from occurring.

Limitations

The results of this study may not be generalizable because data were collected from only 2 sites and the sample size was small. The sources of residual contamination are not known because this study did not involve evaluating the functionality of the disinfection and sterilization systems in use at the sites, and no exploratory tests were done to identify the chemical composition of residue observed (eg, foamy white residue, yellow discoloration, and oily deposits). The quality of reprocessing may have been influenced by the presence of researchers who assessed reprocessing practices during a single visit to each sterile processing department and operating room. The use of published benchmarks for clean gastrointestinal endoscopes may have underestimated the proportion of ureteroscopes with unacceptable contamination levels for sterilized instruments used in the kidneys. The results of microbial cultures may have been influenced by a loss of microbial viability during overnight transportation. As such, the bioburden and organic residue found serve as a canary in the coal mine, and further research is urgently needed to determine appropriate benchmarks for evaluating the effectiveness of ureteroscope reprocessing.

CONCLUSIONS

This systematic evaluation of reprocessing effectiveness found that 100% of patient-ready flexible ureteroscopes had visible irregularities and residual contamination that exceeded benchmarks for manually cleaned gastrointestinal endoscopes. Microbial growth occurred in samples from 2 of 16 ureteroscopes, indicating a failure of the sterilization process. Suboptimal reprocessing practices may have contributed to the findings. This study was not designed to address the association between guideline adherence and contamination levels, and more research is needed to evaluate this relationship. Additional research is also needed to evaluate the prevalence of suboptimal ureteroscope reprocessing, identify potential sources of the contamination found, assess the influence of residual reprocessing chemicals on biochemical cleaning-verification tests, and determine the clinical implications of urinary tract exposure to reprocessing chemicals, organic residue, and bioburden.

The findings reinforce the need for frequent audits of reprocessing practices by infection prevention and sterile processing professionals with adequate knowledge to assess the quality and timeliness of ureteroscope reprocessing. In addition, technicians should utilize routine cleaning verification tests and thorough visual inspection as recommended in new reprocessing guidelines.[24,25] These steps will support the identification of problems like those that were discovered during this study so they can be addressed before clinical use of damaged or contaminated ureteroscopes.

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