Pre-Use Ureteroscope Contamination after High Level Disinfection: Reprocessing Effectiveness and the Relation with Cumulative Ureteroscope Use

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Abbreviations and Acronyms

GEE = generalized estimating equation

HLD = high level disinfection

USC = reusable flexible ureterorenoscope

UTI = urinary tract infection

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Purpose: We assessed the frequency of preoperative and persistent microbial contamination of flexible ureteroscopes after reprocessing and the relation of contamination to cumulative ureteroscope use.

Materials and Methods: We evaluated the effectiveness of high level disinfection with peracetic acid as well as data on ureteroscope use for 20 new flexible ureteroscopes from December 2015 to December 2017 at a single center. In the operating room pre-use and postuse microbial samples of the ureteroscope shaft and working channel were collected to evaluate microbial contamination after reprocessing. Positive cultures were defined as 30 cfu/ml or greater of skin flora, or 10 cfu/ml or greater of uropathogenic microorganisms. A generalized estimating equation model was used to analyze whether cumulative ureteroscope use was associated with positive pre-use cultures.

Results: Microbial samples were collected during 389 procedures. Pre-use ureteroscope cultures were positive in 47 of 389 procedures (12.1%), of which uropathogens were found in 9 of 389 (2.3%) and skin flora in 38 of 389 (9.8%). Urinary tract infection symptoms did not develop in any of the patients who underwent surgery with a uropathogen contaminated ureteroscope. In 1 case the pre-use culture contained the same bacteria type as the prior postuse culture. Cumulative ureteroscope use was not associated with a higher probability of positive cultures.

Conclusions: Microbial contamination of reprocessed ureteroscopes was found in an eighth of all procedures. Notably uropathogenic microorganisms were discovered in a small proportion of all procedures. Persistent ureteroscope contamination with uropathogens was only rarely encountered. Cumulative ureteroscope use was not associated with a higher probability of microbial contamination.

Key Words: ureter; ureteroscopes; equipment contamination; disinfection; disease transmission, infectious

According to the Spaulding classification, USCs belong to the class of semicritical devices. Such devices are in contact with intact mucosa or nonintact skin. Consequently USCs should be reprocessed by sterilization before reuse. If sterilization options are not available, HLD can be applied. HLD is known to eliminate all microorganisms except some bacterial spores.[1] For this reason HDL is considered inferior to sterilization.

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The risk of ureteroscopy related transmission of pathogens among patients is assumed to be low. Yet infections have been linked to cross-contamination of endoscopes in the fields of pulmonology, gastroenterology and urology.[2–7]

USC reprocessing by sterilization or HLD is a complex multistep process involving heat and chemical compounds. The miniaturization and heat sensitivity of modern USCs make the device prone to reprocessing damage.[8,9] Moreover, USC wear and tear can result in surface irregularities which might form a breeding ground for microorganisms.[6,10,11] Therefore, we hypothesized that the effectiveness of reprocessing might decline with cumulative USC use.

To date little is known about the effectiveness of USC reprocessing, especially with regard to cumulative USC use. Moreover, there are no specific quality benchmarks to ascertain successful decontamination of USCs.[8,9,12]

In this study we evaluated the frequency of preuse microbial contamination of USCs after reprocessing with HLD. We also evaluated the prevalence of persistent USC contamination after subsequent procedures. Furthermore, we investigated whether cumulative USC use is associated with positive preuse cultures and, thus, with ineffective USC reprocessing.

MATERIALS AND METHODS

Study Setting and Design

This prospective study was performed at the Amsterdam UMC (Universitair Medische Centra), Amsterdam, The Netherlands. The institutional review board granted a waiver because no additional study activities in human subjects were involved (IRB No. NCT03087812). This study was registered on ClinicalTrials.gov (NCT03087812). The Amsterdam UMC is a JCI (Joint Commission International) accredited organization and a tertiary referral center for endoscopic urological procedures. Approximately 2,600 HLD endoscope reprocessing procedures are performed yearly.

From December 2015 to December 2017 we collected data on USC use for all new USCs. The USCs used were the Flex-XC and the Flex-X2 (Karl Storz Endoskope, Tüttlingen, Germany), and the URF-V2 and the URF-P6 (Olympus Medical Systems, Pompano Beach, Florida) (table 1). There was no selection or randomization of cases to specific USCs. All USCs were followed longitudinally until they needed a first repair or until the study period was completed. Perioperative data on USC use were collected for every procedure to investigate the USC lifespan and extent of use. Collected reprocessing related data included dry or wet (immediate after HLD) use of the USC after HLD and the number of days from reprocessing to use. According to the standard clinical protocol all patients undergoing ureteroscopy received prophylactic or perioperative antibiotic therapy.

Reprocessing

Figure 1 shows a schematic overview of the USC reuse cycle, the moment of microbial sampling and the HLD reprocessing cycle. USCs were reprocessed according to the guidelines of the Professional Standard Handbook: Flexible Endoscopes—Cleaning and Disinfection, version 3.1.[13] After reprocessing and drying the USC was stored in a vacuum sealed cabinet to be protected from environmental sources of contamination.

Sampling and Microbial Cultures

Microbial contamination of USCs was assessed by collecting 4 samples per procedure, including 2 before and 2 after use. The 2 pre-use microbial samples were obtained preoperatively in the operating room immediately after taking the USC out of the storage cabinet. Samples were obtained by 1) stirring the distal part of the USC shaft in 10 ml sterile saline in a sterile container and 2) flushing the working channel with 10 ml sterile saline and collecting the saline directly in a separate sterile container. After finishing the ureteroscopic procedure the microbial sampling method was repeated to collect postuse samples. All 4 microbial samples were sent for quantitative aerobic culturing.

Each sample was mixed and 100 μl fluid were inoculated on each agar plate (Biomerieux, Marcy l'Etoile, France). Several agar plates for the growth of aerobic bacteria and yeasts were inoculated and incubated at 37C in the presence of O_2 or CO_2 for 48 hours. A positive culture, ie a significant quantity of microbial growth, was defined as the growth of 30 cfu/ml or greater of skin flora, or 10 cfu/ml or greater of a uropathogenic microorganism. The cutoff value of 30 cfu/ml or greater for skin flora was

Table 1. *Characteristics of included ureteroscopes and use, and preoperative USC culture outcomes*

		Karl Storz		Olympus	
	Overall	Flex-XC	Flex-X2	URF-V2	URF-P6
No. ureteroscopes	20	11	2	5	2
No. procedures (range)	398	248 (2—80)	40 (2—38)	83 (6—22)	27 (10—17)
Range:	—				
Ureteroscopy (hrs)		1.23—44.13	0.43—16.42	2.57—13.23	4.80—11.30
No. device passages through working channel		9—273	4—140	21—84	26—43
Laser energy (kJ)		9.1—182.7	0—50.3	3.9—81.8	11.5—24.7
No. preop culture:	389	27	7	9	4
Uropathogens (10 cfu/ml or greater)	9	6	1	2	0
Skin flora (30 cfu/ml or greater)	38	21	6	7	4

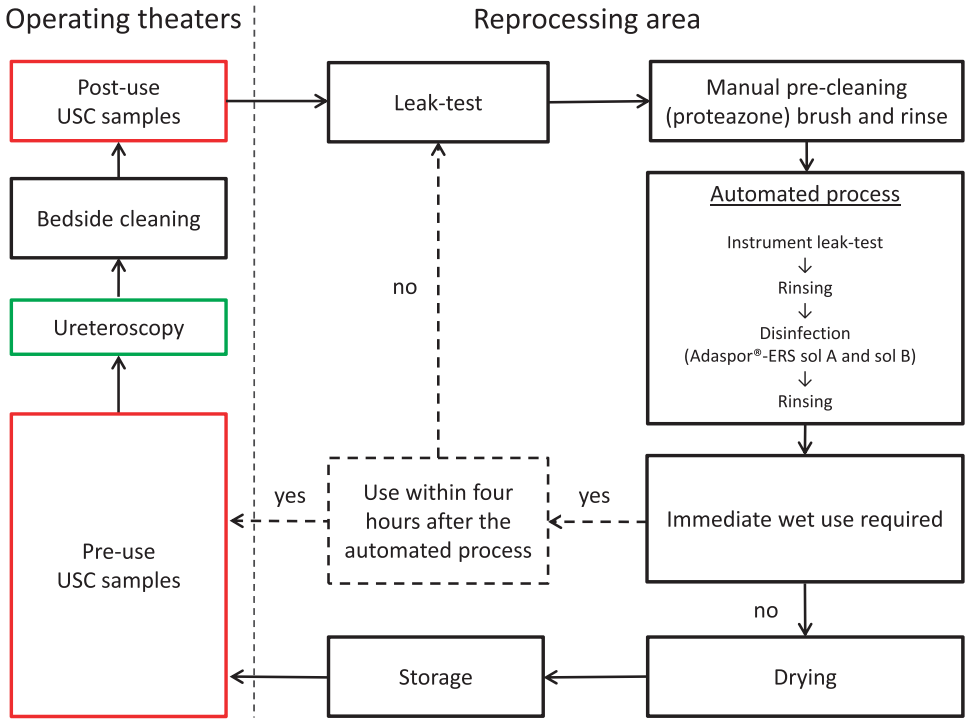

Figure 1. Reuse cycle of subsequent USC procedures. *sol,* solution.

used to account for the risk of contamination of agar plates by air in the laboratory. The detection threshold for microorganisms with this technique is 10 cfu/ml or greater (1 cfu per agar plate).

Positive cultures were worked up to the genus and species level using routine microbiology methods. Aeromonas species, *Enterobacter cloacae*, *Escherichia coli*, Enterococcus species, *Staphylococcus aureus,* molds and yeasts were considered uropathogens. Nonfermenting bacteria were considered potentially uropathogenic and interpreted as a positive culture. Bacillus species, coagulase-negative Staphylococci and coryneform gram-positive bacilli were considered neuropathogenic skin flora. Results are reported as the number of cfu/ml.

Data on USC use and USC cultures were prospectively registered in coded fashion in a secured online data management system (T&S Innovations, Utrecht, The Netherlands).

The registered data were retraceable to the clinical information of the corresponding patients with a unique identifier to co-register postoperative UTI symptoms. A UTI was defined as clinical UTI symptoms leading to antibiotic treatment. Followup to evaluate UTIs included the postoperative period until the first outpatient clinic followup at 6 to 8 weeks.

Outcomes and Statistical Analyses

The primary study outcome was the number of procedures with a positive pre-use culture of the USC distal tip or working channel.

Secondary outcomes included 1) the association between cumulative USC use and the probability of positive pre-use cultures, 2) the proportion of procedures in which the bacterial type of the positive postuse culture matched the bacterial type of the positive pre-use culture of the subsequent procedure with the same USC (persistent USC contamination), 3) the influence of USC storage time on pre-use culture results, 4) the influence of direct use after disinfection (wet use) compared to use after storage (dry use) on pre-use culture results and 5) the proportion of procedures in which postoperative clinical UTI symptoms were reported in the cohorts with positive and negative pre-use cultures.

Ureteroscopic procedures missing cultures before use were excluded from analysis. We used GEE models to evaluate whether the probability of positive pre-use cultures increased with cumulative USC use. A univariate binary logistic GEE model with an exchangeable working correlations matrix was created to enable repeat procedures for each individual USC. We analyzed 4 cumulative USC use parameters, including the cumulative number of procedures, cumulative ureteroscopy time, cumulative laser energy and the cumulative number of device passes through the working channel. Parameters at univariate $p \leq 0.1$ were included in multivariable GEE analysis. To compare outcomes between groups we used the Pearson chi-square and Fisher exact tests for dichotomous variables and the Mann-Whitney U test for skewed continuous variables. On all analyses statistical significance was considered at $p < 0.05$. Analyses were performed with IBM® SPSS® 24.0.

RESULTS

Ureterorenoscope

Use and Cultures. During the study period 398 procedures were performed with a total of 20 USCs.

Table 1 lists data on cumulative USC use for the different USC models. Of the 398 procedures studied pre-use USC cultures were collected before 389 (97.7%) and postuse cultures were collected after 384 (96.5%). The 9 procedures with missing pre-use cultures were excluded from further analysis. In 23 of the 389 procedures (5.9%) USCs were used within 4 hours after the automated HLD process (wet use).

Contamination. Pre-use cultures were positive in 47 of 389 procedures (12.1%). Uropathogenic microorganisms accounted for 9 of 389 procedures (2.3%) with positive pre-use cultures while skin flora was found in the remaining 38 procedures (9.8%) (table 2). In 158 of the 389 procedures (40.6%) pre-use cultures demonstrated some growth greater than 10 cfu/ml.

Cumulative Use and Microbial Cultures. Figure 2 and table 3 show GEE model outcomes. The cumulative number of procedures, cumulative ureteroscopy time, cumulative laser energy and cumulative device passes through the working channel were not associated with a higher probability of positive pre-use cultures. A difference in USC brands or types (fiberoptic vs digital) was not associated with an increased probability of positive pre-use cultures. Because on univariate analyses no parameter had a p value of ≤ 0.1, no multivariable analysis was subsequently performed.

Persistent Growth and Storage

In 1 of the 389 procedures (0.3%) the postuse culture showed the same bacteria type (*S. aureus*) as the pre-use culture of the subsequent procedure with the same USC. Penicillin resistant *S. aureus* was also found in a preoperative and a postoperative urine culture of the patient who underwent the first procedure.

Median storage time for dry use was 3 days (IQR 1-5). This did not differ between procedures with positive vs negative pre-use cultures ($p = 0.80$).

A positive pre-use culture was found in 1 of 23 procedures (4.3%) when a USC was used wet (within 4 hours after HLD) and in 46 of 365 (12.6%) which were used dry (after storage) ($p = 0.37$).

In the postoperative period UTI symptoms were reported in 25 of 389 procedures (6.4%). UTI symptoms were reported after 4 of 47 procedures (8.5%) with USCs that showed positive pre-use cultures and after 21 of 342 (6.1%) with negative pre-use cultures ($p = 0.53$). Skin flora were found in the 4 USC cultures of patients with a UTI in the group of procedures with positive pre-use cultures. No UTI symptoms were reported after a procedure with USCs with uropathogens in the pre-use cultures.

DISCUSSION

This study demonstrates that a small proportion of flexible reusable USCs is contaminated with uropathogens after HLD reprocessing. Cumulative USC use was not associated with a higher probability of bacterial USC contamination.

The contamination of USCs with skin flora which we found in this study may be explained by a few factors. The nonsterile working method after HLD, eg USC packaging with unsterile gloves, may cause contamination by employees during reprocessing. Another origin of contamination with skin flora may be the nonsterile air used during the drying process after HLD. USC contamination may also exist due to persistent skin flora from a previous patient, indicating ineffective reprocessing.

Consequent USC contamination on the risk of UTIs depends on the type of microbial organism causing the contamination. We believe that USC contamination with neuropathogenic skin flora in general does not result in UTIs. In contrast, USC contamination with uropathogens may put patients at risk for endoscopy associated UTIs.

USC contamination with uropathogens as well as skin flora may be caused by inadequate reprocessing guidelines or nonadherence to such guidelines. The specific origin of USC contamination caused by uropathogens remains unclear because we did not

Table 2. *Details of procedures with preoperative cultures demonstrating uropathogens*

Ureteroscope	No. Procedures	Pre-Use Culture Result (cfu/ml)	
		Distal Tip	Working Channel
URF:	24		
V2-1	18	*E. coli* (120)	Skin flora (70)
V2-3	6	*E. coli* (180)	*E. coli* (10)
FLEX:	141		
XC-2	19	*E. coli* (90)	*E. coli* (10)
X2-1	18	*S. aureus* (10)	Neg
XC-4	5	*Enterococcus faecalis* (20)	*E. coli* (20), *E. faecalis* (20)
XC-1	65	*E. coli* (160)	*E. coli* (10)
XC-4	22	Neg	yeast (10)
XC-10	3	Neg	*S. aureus* (10)
XC-10	9	*S. aureus* (760)	Neg

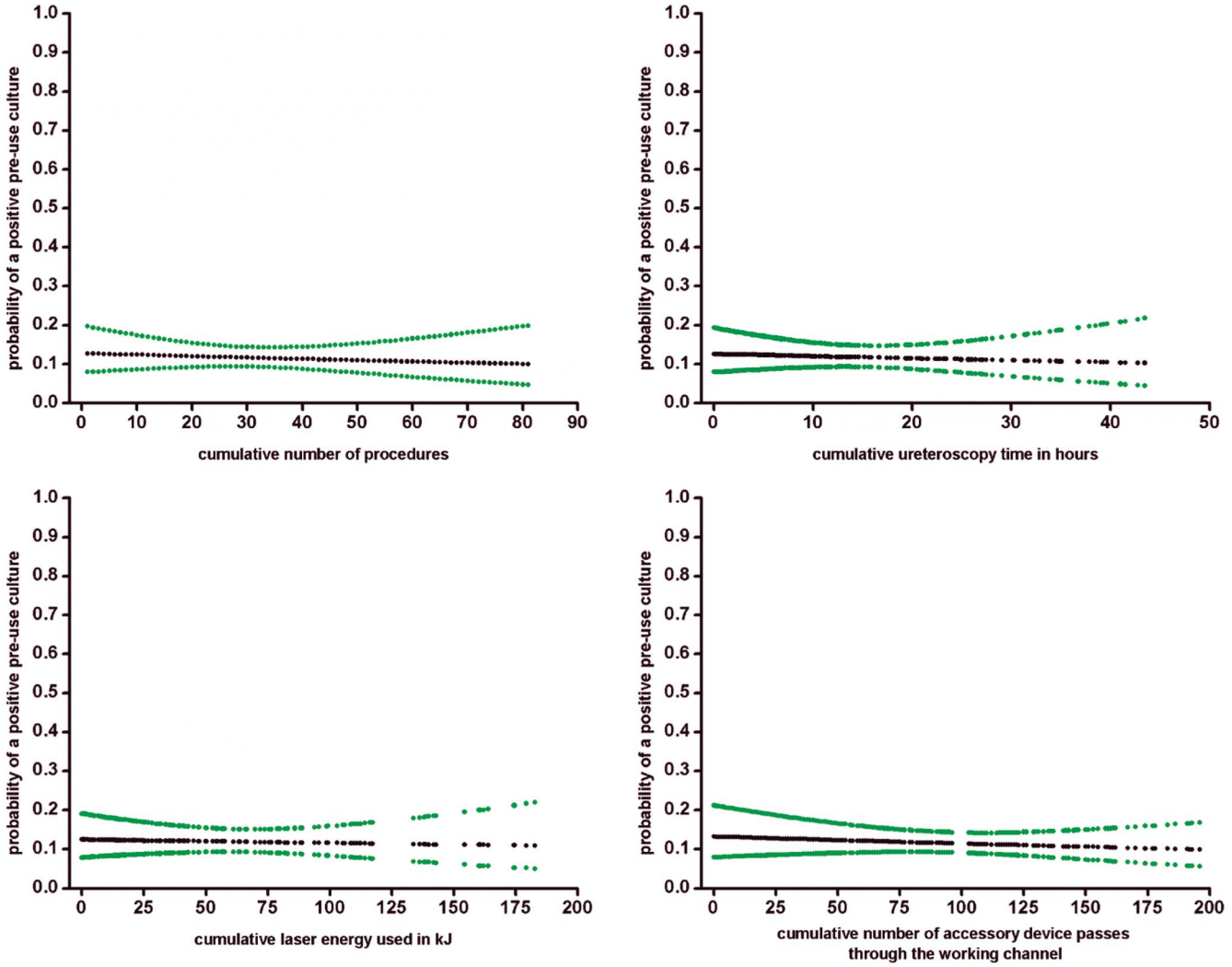

Figure 2. GEE models of estimated relation between cumulative USC use parameters and probability of positive pre-use culture (black curve). Green curves indicate 95% CI.

investigate the role of individual reprocessing steps on USC contamination. Yet in a prior study the impact of human factors and nonadherence to reprocessing guidelines were investigated. Ofstead et al found that reprocessing automation resulted in improved compliance with guidelines.[12] In another study Ofstead et al evaluated the effectiveness of HLD in gastroscopes and colonoscopes with strict compliance to the American reprocessing guidelines.[11] Viable microbes and debris were still found on patient-ready endoscopes.

Table 3. *Univariate GEE model of 389 procedures for parameters related to cumulative USC use and positive pre-use cultures without additional covariates*

	OR (95% CI)	p Value
Cumulative USC use:		
No. procedures	0.983 (0.911—1.062)	0.665
Ureteroscopy time	0.974 (0.841—1.129)	0.730
Laser energy	0.979 (0.830—1.156)	0.804
No. accessory device passes through working channel	0.919 (0.701—1.205)	0.541
Other tested parameters:		
Karl Storz vs Olympus	1.009 (0.435—2.342)	0.984
Digital vs fiberoptic imaging system	1.674 (0.787—3.563)	0.181

The results of our study are in line with the outcomes of urology and gastroenterology studies. Literature in the field of urology is sparse. Ofstead et al investigated the effectiveness of USC reprocessing with sterilizing hydrogen peroxide gas.[9] Contamination was detected on all 16 USCs, including with protein in 100%, hemoglobin in 63%, adenosine triphosphate in 44% and skin flora in 13%. When compared with the HLD used in our study, the sterilization performed by Ofstead et al should achieve a greater decontaminating effect but at higher cost.[1]

The effectiveness of reprocessing is also a concern in gastroenterology. Although HLD was previously believed to eliminate all microorganisms other than

resilient spores, numerous studies have documented HLD failure.[7,8,10,11,14,15] To address this concern the United States FDA (Food and Drug Administration) suggested performing double HLD or sterilization for duodenoscopes.[16] Several groups have investigated the additional value of the FDA suggestions and also reported duodenoscope contamination after sterilization or double HLD.[17–19]

The effect of endoscope contamination on clinical outcomes remains unclear. In this study no UTI symptoms developed in any patient who underwent surgery with a uropathogen contaminated USC. UTI symptoms were reported in 8.5% of the 47 patients who underwent surgery with USCs contaminated with uropathogens or skin flora. UTI symptoms developed in 6.1% of the patients who underwent surgery with noncontaminated USCs. Yet the value of comparing UTI rates between the groups with positive and negative pre-use cultures is limited due to the lack of data on potential clinical confounders, eg patient characteristics and antibiotic management.

With regard to the lack of clarity on clinical outcomes it is debatable whether changes in the multistep process of reprocessing could lead to improved patient safety. Future studies are required to investigate the clinical implication of USC contamination. In these studies the impact of microbial load on the risk of postoperative infections should be investigated to set benchmarks for USC decontamination. Next it should be determined whether single use ureteroscopes result in less postoperative infection.

The single center design only allowed for the evaluation of a single reprocessing method of the 4 USC types. Therefore, the results of this study may not directly be applicable to all clinical practices.

After 1 procedure we assumed persistent contamination with *S. aureus*. Strain comparison of the 2 cultures was not feasible because the cultures were discarded after culturing. Thus, it remains an assumption that persistent contamination had occurred.

Further, this study only provides information about the contamination of the USC working channel and the distal part of the shaft. Although these are the parts which mainly come in contact with the patient, other parts of the USC may also contain a bacterial load.[17,18] As a consequence the total microbial burden of the USC might be underestimated in this study. Subsequently the microbial burden and frequency of USC contamination may have been underestimated by the sampling and culturing methods. Recently the United States FDA CDC (Centers for Disease Control and Prevention) published a protocol for duodenoscope surveillance sampling and culturing.[20] With regard to this protocol our sampling method seems suboptimal and may have led to underestimating the microbial load. Our sampling method could be improved by additional brushing of the working channel and concentration of the sample yield. Moreover, the current culture method could be improved by using neutralizers to counteract the effect of residual reprocessing chemicals and maintaining an incubation time of at least 72 hours.[8,14]

CONCLUSIONS

After high level disinfection reprocessing we found microbial contamination in an eighth of the flexible ureteroscopes. Notably in 2.3% of all procedures contamination was caused by uropathogens. Persistent USC contamination with uropathogens was encountered only rarely. The contamination levels which we found imply that flaws in the reprocessing process occur occasionally. Contamination was not associated with cumulative USC use. Yet the findings of this study strengthen the need for frequent audits of the reprocessing process to ensure patient safety.

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EDITORIAL COMMENT

Legemate et al describe a ground breaking study on the effectiveness of HLD for 20 new flexible ureteroscopes. Microbial cultures detected greater than 10 cfu/ml in 40.6% of 389 procedures, greater than 30 cfu/ml in 12.1% and pathogens, including *E. coli*, *Enterococcus faecalis, S. aureus* and yeast, in 2.3%. This profound failure of reprocessing is especially concerning because no reprocessing breaches were reported, damaged ureteroscopes were excluded from study and peracetic acid HLD should have eliminated all microbes except resilient spores.

Our ureteroscope reprocessing study also revealed microbial growth in 13% of ureteroscopes following sterilization with hydrogen peroxide gas but 100% had visible defects and residual organic soil (reference 9 in article). Surface defects may harbor biofilm and we have found that damaged endoscopes commonly remain in use.[1,2] To ensure patient safety ureteroscopes should be entirely free of defects and contamination.

Prophylactic antimicrobials in this study and others did not prevent infection,[2] and their ubiquitous administration covers up the use of contaminated ureteroscopes and places patients and the public at risk. This compelling real world evidence of reprocessing failures raises questions about the adequacy of reprocessing guidelines. The dedication of the authors to rigorous scientific inquiry is commendable. Their findings should be considered by guideline issuing bodies and decision makers in the field.

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REPLY BY AUTHORS

Ureteroscope contamination should be prevented at all times to ensure optimal patient safety. Therefore, we sympathize with the concerns addressed by the comment. However, we still lack knowledge about the clinical implications of ureteroscope contamination and the microbial threshold at which patient safety is at risk.

In our study most contamination after HLD was caused by skin flora. Uropathogens were identified in 9 of 389 procedures (2.3%). These 9 patients did

not report postoperative UTI symptoms. Overall as stated in our article there was no statistically significant difference between the rates of UTI symptoms in the patient groups treated with contaminated and decontaminated ureteroscopes. Yet these findings should be treated with caution since the clinical outcomes were analyzed post hoc.

Although HLD is in compliance with the reprocessing standards, sterilization may be a superior alternative. However, contamination after sterilization has also been reported (reference 9 in article). Contamination may occur at one of the many reprocessing steps after HLD or sterilization. For this reason strict adherence to handling guidelines with frequent audits should be mandatory. Furthermore, single use ureteroscopes may be an alternative to guarantee sterility. Still, the role of single use ureteroscopes in reducing postoperative UTIs requires further investigations.

We hope that our project encourages future studies to investigate the clinical implications of microbial contamination of ureteroscopes.