

UV-C light: the future of disinfection of flexible endoscopes without a working channel?

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June 5, 2023

Abstract

Objective: To investigate Colony-Forming Unit (CFU) reduction on contaminated flexible endoscopes without a working channel after UV-C light disinfection compared to the current disinfection method with the Endoscope Washer Disinfector. **Design, setting:** After pharyngolaryngoscopy, a manual pre-cleaning with tap water was performed. A culture was then collected by rolling the distal 8-10 cm of the flexible endoscope over an Agar plate. The flexible endoscope was disinfected using the D60 (60-second disinfection process with UV-C light) or the Endoscope Washer Disinfector (golden standard reprocessing process with water and chemicals). Another culture was then taken. After incubation, a CFU count was performed. **Results:** Two hundred flexible endoscopes without a working channel were divided equally between the two disinfection groups. After clinical use and manual pre-cleaning, 84 of the 100 (84.0%) (UV-C light group) and 79 of the 100 (79.0%) (EWD) flexible endoscopes were contaminated with at least 1 CFU. Flexible endoscopes that showed no contamination after use were excluded from further analysis. After disinfection with UV-C light, 72 (85.7%) flexible endoscopes showed no contamination (i.e. 0 CFUs) versus 66 (83.5%) flexible endoscopes after reprocessing with the Endoscope Washer Disinfector. **Conclusion:** There is no difference in CFUs reduction on contaminated flexible endoscopes without a working channel between UV-C light disinfection and the current gold standard, the Endoscope Washer Disinfector.

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UV-C light disinfection within otolaryngology

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with UV-C light, 72 (85.7%) flexible endoscopes showed no contamination (i.e. 0 CFUs) versus 66 (83.5%) flexible endoscopes after reprocessing with the Endoscope Washer Disinfector.

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Keywords: flexible endoscopes without a working channel, disinfection, UV-C light disinfection, Endoscope Washer Disinfector

Key points:

Flexible endoscopes without a working channel are indispensable instruments within otolaryngology, but the reprocessing process can be improved.

UV-C light disinfection can be an alternative for disinfection of flexible endoscopes without a working channel.

Introduction

In otorhinolaryngology (ORL), flexible endoscopes without a working channel (FEs) are used to examine the nasal cavity, pharynx and larynx. FEs are frequently used and thus reprocessed several times a day. Previous research demonstrated that contamination with secretions, blood and microorganisms after use can be extensive(1). Inadequate reprocessing of endoscopes is considered the most important factor of contamination from endoscopy procedures, possibly resulting in outbreaks of health-care-associated infections(2). Therefore, thorough reprocessing of FEs is critical for limiting pathogen transmission and reducing infections.

To determine the strategy for sterilization or disinfection of a specific medical devices, the level of disinfection is determined. There are three disinfection levels: high, intermediate and low-level disinfection. Each disinfection level can be distinguished from one another based on the specific marker or indicator microorganisms that each can or cannot destroy. According to Spaulding’s classification scheme, FEs are considered semi-critical medical devices and require high-level disinfection(3).

Several standard guidelines for reprocessing endoscopes have been developed by several professional organizations, such as the European Society for Gastrointestinal Endoscopy(ESGE), the American Society for Gastrointestinal Endoscopy(ASGE), the Healthcare Infection Control Practices Advisory Committee(HICPAC) and the Dutch Flexible Endoscopes Cleaning and Disinfection Steering Committee(SFERD) or guidelines are provided by the manufacturer of the FEs(4-7). No international standard has been implemented and the methods used are often time-consuming. This could lead to longer waiting times for patients, or additional costs, because the long reprocessing times require more FEs in inventory. In addition, large amounts of water and chemicals are used. Disinfection with ultraviolet light(UVL) could be an alternative method.

UVL can be divided into three groups depending on the length of their bands: A(315-400 nm), B(280-315 nm) and C(100-280 nm)(8). UVL group C(UV-C) is known to be the most harmful to living organisms, with peak efficiency at 254nm(8).

Previous research has shown that UVL disinfection of medical surfaces can be highly effective in reducing microorganisms, such as *Clostridium difficile*, Methicillin-resistant *Staphylococcus aureus* (MRSA), biofilm-forming bacteria and fungal spores(9-12). UV-C light disinfection for ORL endoscopes showed a bacterial reduction of 10^6 Colony Forming Units(CFUs) for rigid endoscopes and a 10^7 CFU reduction for FEs(13, 14).

The current reprocessing method for FEs is done using water and chemicals with the Endoscope Washer Disinfector (EWD). However, this process is time-consuming and should therefore be improved. UV-C light disinfection has shown to be a promising tool for surface and endoscope disinfection in previous research. The goal of this study was to investigate the CFU reduction on contaminated FEs without a working channel after UV-C light disinfection, compared to the current disinfection method with the EWD.

Materials and Methods

Setting

This study was performed at the department of Otorhinolaryngology and Head and Neck Surgery of the Radboud university medical center, a tertiary university hospital in The Netherlands. From January 2022 until May 2022, FEs without a working channel were examined. The FEs were used to examine the nasal cavity, pharynx or larynx of the entire spectrum of ORL patients(infectious and non-infectious patients). To evaluate the effectiveness of UV-C light disinfection, only contaminated FEs without a working channel(VNL9-CP, PENTAX Medical B.V., Dodewaard, The Netherlands) were used. FEs without a working channel that showed no contamination after clinical use and manual pre-cleaning were excluded, since assessing the disinfection process in these FEs was impossible.

The used FEs were randomly assigned to the UV-C light group (group 1) or the Endoscope Washer Disinfection group (group 2). In order to make the disinfection process, culture collection and assessment as standardized as possible, they were performed by two researchers(YH and MR). Before the start of the study, both researchers were trained in these tasks by a senior infection prevention specialist(SC).

As protocolled by the hospital, FEs without a working channel should receive a manual pre-cleaning using water and chemicals in order to remove visible dirt and debris. However, to best evaluate the disinfection process itself, in this study pre-cleaning was performed using only water. A gauze pad was moistened with tap water and moved several times in a rotary motion from proximal to distal across the FE to remove visible debris. A culture was then taken from the FE(culture 1). Next, the FE was placed and disinfected for 60 seconds in the D60 UV-C light disinfectant(group 1), or for 22 minutes in the EWD(group 2). After disinfection, a new culture was taken(culture 2). To not interfere with current patient safety regulations, all FEs were finally reprocessed by the EWD, as protocolled by our hospital. Due to mandatory changes in reprocessing logistics during our study, some FEs in group 2 were reprocessed in a central processing department and received additional manual pre-cleaning with Neodisher® MediClean forte(Dr. Weigert Nederland B.V., Assen, The Netherlands).

Microbiological culture

A rolling method over a Plate Count Agar+additives(Balis Laboratorium BV, Boven-Leeuwen, The Netherlands) was used to evaluate the bacterial contamination. The distal 8-10 cm of the FE and the tip were cultured. The FE was rolled over the agar plate until the entire circumference had touched the plate. Sterile tweezers were used to fix the FE, to prevent partial lifting of the FE from the plate. The cultures were incubated at 36°C for 72 hours. A more detailed protocol can be found in Appendix 1.

Microbiological evaluation

After incubation, the number of bacteria on the agar plates were quantified by counting CFUs, indicating the level of microbiological contamination(15).

The D60 UV-C light disinfectant

Using UV-C light, the D60(UV Smart Technologies B.V., Rijswijk, The Netherlands) disinfects the outer surfaces of channelless invasive medical devices in 60 seconds. The technology operates at a wavelength ranging from 100-280nm (peak at 253.7nm). According to the manufacturer's internal research(available upon request at the manufacturer), a microorganism reduction of at least a log-4 is achieved.

The used endoscope is placed inside a glass holder, allowing the UV-C light to reach the endoscope without the occurrence of shadowing. The disinfection chamber is completely sealed off during a disinfection cycle, preventing UV-C light from reaching the user. No chemicals or liquids are required for the disinfection process other than the those used for manual pre-cleaning, which remains necessary since UV-C light cannot penetrate dirt, debris and grime (16).

The Endoscope Washer Disinfectant

The EWD disinfects medical devices using water and chemicals. Afterwards, the FEs are dried and stored

until transportation. Multiple devices can be reprocessed at the same time, but the duration of the reprocessing depends on the brand and type of EWD. In this study the WD440PT(Wassenburg Medical Nederland, Dodewaard, The Netherlands) with accompanying chemicals(EndoHigh PAA & Detergent) was used.

Statistics

Statistical significance was determined with a Chi-square test and Fisher's Exact test. Data were analyzed using SPSS software, version 25(IBM Corporation, Armonk, NY, USA). A p-value of <0.05 was considered to be statistically significant.

Ethical approval

The research ethics committee of the Radboud University Medical Centre decided that this study would be carried out per the applicable legislation concerning reviewal by an accredited research ethics committee, such as Medical Research involving Human Subjects Act and Medical Treatment Contracts Act(file number 2021-9837).

Results

General results

200 FEs without a working channel were collected and evenly distributed among the disinfection groups.

Results before disinfection

Immediately after clinical use and manual pre-cleaning, a CFUs count ranging from 0 CFUs to countless CFUs(>500) was found(Table 1). In total, 16 of the 100 FEs in group 1 and 21 of the 100 FEs in group 2(EWD) showed no contamination(i.e., 0 CFUs) before disinfection and were excluded from additional analyses. After exclusion of the FEs that showed no contamination, a chi-square test was performed showing no statistically significant difference in the distribution of FEs depending on the CFUs count before disinfection between the study groups($p=0.72$).

Results after disinfection

After disinfection with UV-C light, a total of 72 of the 84(85.7%) FEs showed 0 CFUs. After disinfection using the EWD a total of 66 of the 79(83.5%) FEs showed 0 CFUs(Figure 1). A chi-square test showed no statistically significant difference in the distribution of FEs depending on the CFUs count after disinfection between study groups($p=0.70$). In total, 12 FEs in group 1(D60) and 13 FEs in group 2(EWD) were still contaminated after disinfection in a CFU count ranging from 1 to >50 .

A total of 56 FEs in the EWD group were disinfected centrally. Subanalysis showed no statistically significant difference in CFUs between FEs centrally versus FEs non-centrally disinfected in both the sample taken before($p=0.53$) and after($p=0.82$) disinfection.

One FE in group 1 was more contaminated after disinfection(1 CFU) than before(0 CFUs). Two FEs in group 2 showed more contamination(4 and 1 CFUs) after disinfection than before (both 0 CFUs).

Discussion

Current reprocessing methods with the EWD are time-consuming and UV-C light disinfection seems a promising alternative. However, a study comparing UV-C light disinfection of FEs without a working channel with the EWD was still missing.

Guidelines describing disinfection methods determined that a log 4 reduction in CFU formation after disinfection is considered an acceptable disinfection method(17). In our study, the Agar plates were contaminated with CFUs in a wide range, often less than 100 CFUs. Therefore, it was not possible to achieve a log 4 reduction. In previous research, a threshold of [?] 2.5 CFUs/cm² on agar contact plates was considered acceptable based on food preparation standards(18). The ESGE accepts a maximum total microbiological count of <20 CFUs for fluid collected after flushing the endoscope. Quantification of microorganisms is not

recommended for cultures taken from the outer surface of the endoscope, suggesting that the policy should be based on the growth of indicator organisms(19). Since there is no consensus on the acceptable CFUs count on FEs without a working channel after disinfection, we agreed that 0 CFUs after disinfection was considered a safely disinfected FE.

In total, 12 FEs in group 1(D60) and 13 FEs in group 2(EWD) were still contaminated after disinfection. However, since no bacterial identification was performed, no statements can be made about whether bacteria found were commensal flora or pathogens.

In three FEs(1 D60, 2 EWD), the culture after disinfection showed a higher number of CFUs than before disinfection. This can be explained by several reasons. First, the study took place under clinical conditions, where handling the FEs under unsterile conditions may have affected the results. Second, the contamination could have been caused by the disinfection method (D60 or EWD) or during transportation to the second culture taking. The most plausible reason is the limited sensitivity of the culture method.

There is no standardized method for culture collection from FEs. Methods used to determine surface contamination include swabs, contact plates, sponges, broths, quantitative polymerase chain reactions and dip slides(20). Specific guidelines for culturing ORL endoscopes do not exist, but several organizations such as the ESGE, the European Society of Gastroenterology and Endoscopy nurses and Associates(ESGENA) and the Gastroenterological Society of Australia provide recommendations for microbiological monitoring of FEs(19, 21). However, their suggested sampling methods include liquid samples from endoscope channels, which is impossible for FEs without a working channel. The ESGE-ESGENA guideline additionally recommends a swab method to evaluate the contamination of the surface of the endoscope(19). Prior to this study, we conducted a pilot comparing three commonly described sampling methods, which will be submitted shortly. The three sampling methods compared were: a rolling method on an Agar plate, swab method and broth method for sampling FEs without working channel. We found that all sampling techniques were capable of detecting microbiological contamination. However, practical difficulties lead to a preference for the rolling technique.

Previous studies investigating UV-C light disinfection in ORL showed a high bacterial load with an average value of 66.908 CFUs and 916.7 CFUs(13, 14). This is inconsistent with the contamination found in this study on the FEs after clinical use. A possible explanation could be that Rudhart et al (13) used rigid endoscopes, which have a different surface texture than FEs. Due to the surface properties and flexible property of the FEs, the rolling method may be easier to perform on the rigid endoscope than on the FEs. In the following study by Rudhart et al(14), the FEs were sampled directly after clinical use. In our study, the FEs first underwent pre-cleaning before sampling. The pre-cleaning may have already reduced microbiological contamination, resulting in lower bacterial contamination.

In addition to the advantage of time reduction, UV-C light disinfection has additional advantages. UV-C light disinfection does not use water or chemicals except for pre-cleaning. Because of the short disinfection process, fewer FEs and storage capacity are needed. These factors contribute to a reduction in costs and environmental impact.

Limitations of this study were that we did not investigate non-bacterial pathogens on the FEs. Literature described some cases of viral and fungal cross-contamination in gastrointestinal endoscopic procedures(22). Presumably, ORL FEs without a working channel also carries the potential to transmit viral or fungal pathogens. Previous research has shown that UV-C light has the potential to inactivate viral and fungal pathogens(11, 23). Based on previous research, it is very unlikely that a FE carries the potential to transmit prion disease(24). Previous research has shown that the absorption spectra of peptide bonds in prions are between 190 and 230nm, indicative of susceptibility to UV light. Further research is needed to determine the UV susceptibility(25). Furthermore, we did not perform a bacterial identification. Thus, we cannot make any statements about whether the bacteria found were commensal flora or pathogens. The efficacy of UV-C light disinfection greatly relies on the manual pre-cleaning since UV-C light cannot penetrate through dirt, debris and grime. Since the pre-cleaning is a manual process, the quality of the pre-cleaning may

vary per person performing the process. Thus, when UV-C light disinfection is implemented, the process of manual pre-cleaning requires extra attention in the instruction for employees who will perform the UV-C light disinfection. This could have led to a potential bias in our study. Due to the logistical decision of the hospital to move the disinfection process of FEs without a working channel to the centralized reprocessing department, some FEs in group 2 were centrally reprocessed. These FEs were additionally pre-cleaned with Neodisher(r) MediClean forte (Dr. Weigert Nederland B.V., Assen, The Netherlands). However, after reprocessing, CFUs counts showed no marginal gain for using centralized reprocessing over decentralized reprocessing in the EWD. Finally, we did not perform a power analysis for the number of FEs studied. The study group is relatively small and the results should be confirmed with a larger sample size in a multicenter setting.

Conclusion

This single center study investigated the CFUs reduction on contaminated FEs without a working channel after UV-C light disinfection compared to the current golden standard reprocessing process using the EWD. The findings of this study show that there is no difference in CFU reduction between UV-C light disinfection compared to the current reprocessing process with the EWD. UV-C light disinfection could be a good alternative for disinfecting FEs without a working channel. However, the effectiveness of UV-C light disinfection depends on the diligence van the pre-cleaning process.

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Titles/captions for each figure

Figure 1: Number of flexible endoscopes (FEs) depending on the Colony Forming Units (CFUs) count after disinfection by disinfection group ($p=0.70$).

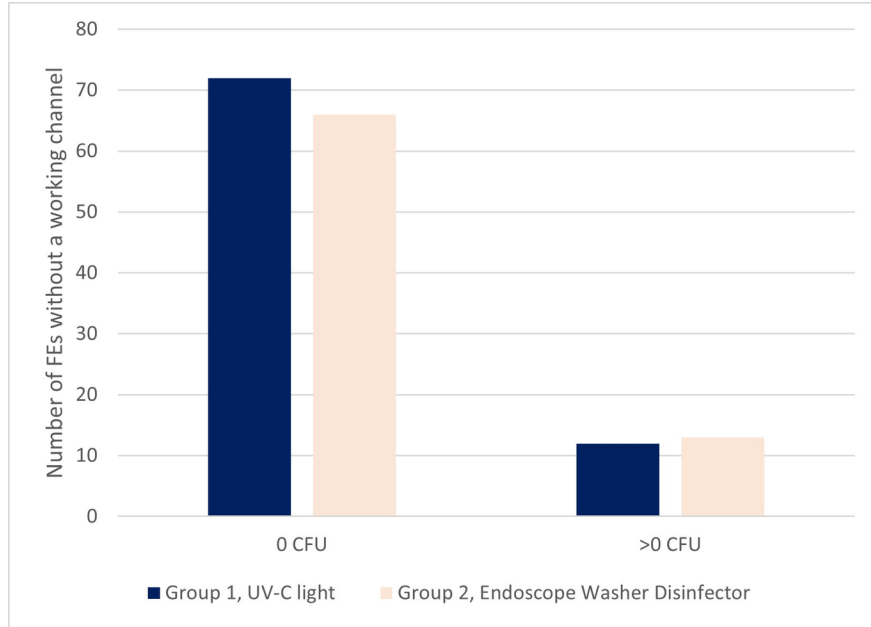
Appendix

Appendix 1: Detailed protocol of the rolling method used for sampling flexible endoscopes without a working channel

The rolling technique over a Plate Count Agar + additives:

1. Immediately after pharyngolaryngoscopy, transport the FE without a working channel to the designated room for manual pre-cleaning and sample collection in the following manner:
2. The executor of the pharyngolaryngoscopy closes the transport container with the cover with the red smiley.

3. The assistant collects the FE immediately and brings it to the assigned room for manual pre-cleaning and sample collection. The researcher will now start the procedure.
4. Manual pre-cleaning:
 5. Remove the cover with the red smiley face from the transport container.
 6. Perform hand disinfection and put on unsterile gloves.
 7. Moisten an unsterile 10x10cm gauze pad with tap water (not too wet! No water should drip when squeezing the moistened gauze).
 8. Wipe the moistened gauze over the FE using a rotary motion from proximal to distal. Repeat three times with a different portion of the gauze each time. Include the tip as well. If there is still visible debris left on the FE, repeat until all the debris is removed.
 9. Discard the gauze and place the FE back in the transport container.
10. Remove unsterile gloves and perform hand disinfection.
11. Collection the sample:
 12. Use the tip and the first 10cm of the distal part of the laryngoscope for the sample.
 13. Wear a medical face mask and unsterile gloves during the sample collection to avoid contamination. Make sure not to touch the tip and the first distal part of the FE except for sample collection.
 14. Perform hand disinfection and disinfect the surface the sample collection will take place on using disinfection wipes.
 15. Open the package of sterile tweezers, but do not remove the tweezers yet.
 16. Remove the lid from the Plate Count Agar + additives plate.
 17. Perform hand disinfection and put on unsterile gloves.
 18. Fix the distal part of the FE with the sterile tweezers to prevent partial lifting of the FE from the plate while making a rolling motion with the FE. Make sure that the entire circumference of the distal end of the FE touched the agar plate only once.
 19. Place the FE back in the transport container.
 20. Remove the unsterile gloves and perform hand disinfection.
 21. Put the lid back on the agar plate.
 22. Record serial number of the FE, study number, date and time of the sample collection and sample number and label the agar plate.
 23. Place the labeled agar plate back in the heat incubator at 36 degC without the addition of CO₂ for 72 hours.
 24. Afterwards, perform a CFUs count.
25. Transport the FE after the sample collection to the disinfection department:
26. Close the transportation container with the cover with the red smiley face facing upwards.
27. Transport the FE to the disinfection department and continue the disinfection process as protocolled by the hospital.



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