Improving the Cleaning Process for Flexible Endoscopes

By Tracy Humphreys, BS, CSPDT, and Stephen M. Kovach, BS

"A SCOPE can be used anywhere from 300 to 1,200 times a year. The question is, can we be guaranteed that the scope has been processed appropriately each of those times?"

"BASED upon the AAMI standards that are in place today, the scale of measurement here after instruments are washed is visual inspection. I think most of us would agree that a method of visually inspecting the instruments is not a very good method."

Newspaper headlines echo these thoughts:

"COMPANY blames bronchoscope infections on poor cleaning."

"CLEAR concerns amid murky debate--Patient documents raise questions in dispute on endoscope infection risk."

Headlines such as these were the needle on the compass that guided us to write a paper on the cleaning of flexible endoscopes.

Background

Three types of endoscopes are commonly used in hospitals: Rigid, semi-rigid, and flexible. This article will focus on flexible endoscopes (e.g., colonoscopes, duodenoscopes, gastroscopes, sigmoidoscopes), because concerns about cleaning these scopes appear more often in news headlines. Heightened concern about proper cleaning of flexible scopes is also reflected in the professional literature. A flexible endoscope may contain many internal channels, any of which can become contaminated.

It is estimated that in the U.S. alone 15 million flexible endoscope procedures are performed annually. Procedures are performed in a variety of settings, from a doctor's office to a hospital surgical suite. The methods employed to clean and disinfect these flexible endoscopes are also very diverse. A key concern, no matter where these procedures are done, is how clean these scopes are after reprocessing.

The Importance of Cleaning

Due to their complexity, flexible endoscopes generally cannot be steam sterilized. Low temperature, highly specialized devices or methods must be employed to clean, disinfect and sterilize these instruments. It is axiomatic: if a surgical instrument is not clean, it can't be rendered sterile. The cleaning process is critical to achieving disinfection and/or sterilization.

According to Lawrence Muscarella, PhD, chief of infection control for Custom Ultrasonics, Inc., the actual risk of infection is small provided scopes are adequately cleaned. "It's just amazing how fragile these viruses are," says Muscarella. "The literature suggests that if you do cleaning properly you won't have transmission of HIV or hepatitis B or C — irrespective of any disinfection. In the cases where hepatitis has been transmitted, cleaning has been inadequate. So we have instances where cleaning is adequate, but the disinfection is either not being done, or being done inadequately, and we don't have disease transmission documented yet. That is why the risk of a bacterial infection is much higher. The risk of a viral infection remains fortunately very low, provided cleaning is done."

In January 1997 Muscarella, in the publication Q-Net, queried readers about the impact of cleaning on the sterilization/disinfection process. He asked, "Which is likely to fail if cleaning is inadequate: (a) sterilization, (b) high-level disinfection (c) intermediate-level disinfection, (d) low-level disinfection, or (e) all of the above. The answer is (e). Sterilization and each level of disinfection are likely to fail if cleaning is inadequate.

Contamination of Flexible Endoscopes

General instruments used for surgical procedures are most commonly contaminated with blood. Likewise, flexible endoscopes are frequently contaminated with blood, particularly when a biopsy is taken. Flexible endoscopes are also exposed to other soils which vary based upon the part of the body where the scope is use (i.e., fecal matter in a colonoscope).

Research has shown that bioburden left on instruments interferes with the sterilization process and can render it ineffective. Making sure a scope is as clean as possible is thus paramount to preventing cross contamination of any patient undergoing a procedure. Ensuring cleanliness of scopes should be part of any hospital's infection control program. Cleaning should be monitored because it is directly correlated to reducing hospital-acquired infections. A dirty scope, as the headlines point out, does not look good in the public eye.

The "sterile dirt" concept just doesn't cut it; an instrument is either clean or not clean. Several publications cite examples of patient infections that resulted from failure to properly clean an endoscope.

Endoscopes have been implicated in the transmission of disease (specifically nosocomial infections) when appropriate cleaning, disinfection or sterilization procedures were not employed. Of particular significance is the need to thoroughly manually clean equipment prior to any manual or automated disinfection or sterilization process.

Tools for Cleaning: A Case Study

Healthcare professionals who process scopes need simple tools and quality improvement programs to help them ensure that the channels within the flexible scope are as free as possible from any residual, whether it be blood, other bodily soils, or chemicals found in the cleaning/disinfection/sterilization products used. Currently the standard for releasing surgical instruments after cleaning is based on visual inspection. But looking inside the channels of a flexible endoscope is an impossible task. Fortunately, simple tools for detecting residuals left in the channels of a flexible scope are now available.

One such product that is commercially available is the EndoCheck™ from Healthmark. The EndoCheck™ provides a result in 30 seconds, is simple to interpret and indicates blood residue down to 0.1µg.

We conducted a survey to determine whether scopes that were perceived cleaned by visual inspection really were clean prior to sterilization or high-level disinfection. We also were interested in finding out how departments train their staff to clean scopes. The survey below was sent via the Internet to 25 healthcare professionals working in central service, in the operating room, and in endoscopy. Eight surveys were returned; results are detailed below.

Flexible Endoscope Training and Cleaning Survey

1.What department is primarily responsible for the cleaning of flexible scopes?

Central Service/SPD: (2/8)
O.R.: (5/8)
Endoscopy: (4/8)
Other: 0

Note: Three hospitals responded with multiple locations because they felt no one area was primarily responsible cleaning, thus the total is more than 100 percent

2. What type of training does the staff receive on cleaning the flexible scopes? Check all that apply:

In-house training (done by hospital staff): 100 percent

On each type of scope: 100 percent

General review on cleaning all scopes: 100 percent

Manufacturer training (Scope representative comes in to train staff): 100 percent

Note: All of the hospitals that replied to this question stated all four of these training activities happen at their hospitals.

3. Yearly competency is reviewed (records kept)
Yes: (7/8)
No: (1/8)

4.Other types of training: The use of published articles and journals as a resource for education was cited.

5. Do you perceive that your flexible scopes are clean (no residual bio-burden is left inside any channel) before they go into the sterilization/high level disinfection process?
Yes: (7/8)
No: (1/8)

6. Do you test/check your flexible scopes in any way to verify that your cleaning process is working, that they really are clean?
Yes: 0 percent
No: 100 percent

7. List the model and type of flexible scope your department cleans:

More than 20 different makes and models were listed.

Discussion of Survey Results

The survey revealed that the cleaning of scopes was being performed in multiple locations and that some institutions did not have a primary area. Survey results indicate that training being performed is very thorough, and that equipment manufacturers are used as resources for training and education. Articles and journals were cited as sources of information for staff training. All but one institution reported some form of yearly testing of staff. Eighty-five percent of the institutions perceive that their scopes are adequately clean; however, none of them reported using an independent method to verify their cleaning process prior to sterilization.

Scope Test Protocol

One of the hospitals that participated in the survey also agreed to test its scopes using the following protocol. The data/cleaning form below was used to record the results for each scope cleaned.

1. Use one data/cleaning form for each flexible scope tested.

2. Log the model and serial number of the scope.

3. Indicate what type of procedure the scope was used for.

4. The employee who cleans the scope initials the form.

5. Test each scope before cleaning with the Endocheck™ (see instructions for use, below).

6. Record results of the EndoCheck™ before cleaning.

7. Clean the scope is according to department/hospital policy.

8. Retest after cleaning with another EndoCheck™; record results.

9. If the result from the EndoCheck™ is positive after cleaning, re-clean the scope. Continue to re-test until the EndoCheck results are negative.

10. If the result from the EndoCheck™ is negative after cleaning, release the flexible scope for disinfection/sterilization.

EndoCheck Procedure for Use

Note: A positive result is proof of remaining residue (blood residue) within the channel of the scope tested.

If the test has been refrigerated, allow it to come to room temperature before using.

- Open the test kit. Included are: indicator vial (transparent cap), activator vial (green cap), and wire with cotton swab at one end.
- Open the indicator vial (A, transparent cap) and transfer the liquid into the activator vial (B, green cap).
- Moisten the cotton swab with a drop of clean water. Do not use chlorinated water.
- Insert the swab end of the wire into the scope/biopsy channel. Push it all the way through one time.

Data Results from Cleaning Study

EMPLOYEE	DOCTOR	SCOPE	MODEL NUMBER	PRE-CLEANING	POST-CLEANING FIRST TEST RESULTS	COMMENTS
A	A	COLONOSCOPE	CF Q160L	NEGATIVE	NA	
A	A	COLONOSCOPE	CF Q160L	NEGATIVE	NA	
A	A	COLONOSCOPE	CF Q180L	POSITIVE	NEGATIVE	
A	A	COLONOSCOPE	CF Q160L	NEGATIVE	NA	
A	A	COLONOSCOPE	CF Q160L	POSITIVE	NEGATIVE	
A	A	COLONOSCOPE	CF Q160AL	NEGATIVE	NA	
A	A	COLONOSCOPE	CF Q160L	POSITIVE	NEGATIVE	
B	B	COLONOSCOPE	PCF 160AL	POSITIVE	NEGATIVE	
B	B	COLONOSCOPE	CF Q160AL	POSITIVE	NEGATIVE	
B	B	GASTROSCOPE	GIF XQ140	POSITIVE	POSTIVE	Took 4 times of recleaning to turn negative
B	B	COLONOSCOPE	CF Q160L	POSITIVE	NEGATIVE	
B	B	GASTROSCOPE	GIF Q160	POSITIVE	NEGATIVE	
B	B	COLONOSCOPE	CF Q180L	POSITIVE	NEGATIVE	
B	B	COLONOSCOPE	CF Q160L	POSITIVE	NEGATIVE	
C	C	COLONOSCOPE	CF Q160L	NEGATIVE	NA	
C	C	COLONOSCOPE	CF Q180L	POSITIVE	NEGATIVE	
C	C	COLONOSCOPE	PCF 160AL	POSITIVE	NEGATIVE	
C	C	GASTROSCOPE	GIF Q160	NEGATIVE	NA	
C	C	COLONOSCOPE	CF Q160AL	NEGATIVE	NA	
C	C	GASTROSCOPE	GIF Q140	POSITIVE	POSTIVE	Took 3 times of recleaning to turn negative
C	C	COLONOSCOPE	PCF 160AL	POSITIVE	NEGATIVE	
D	D	COLONOSCOPE	CF Q160L	NEGATIVE	NA	
D	D	GASTROSCOPE	GIF Q160	POSITIVE	POSTIVE	Took 3 times of recleaning to turn negative
D	D	COLONOSCOPE	CF Q160L	POSITIVE	NEGATIVE	

Note: The cleaning solution used was Cardinal Health's enzymatic detergent, diluted to the correct concentration per instructions.

• Cut the swab end off the wire with scissors. Do not touch the swab.
• Place the swab into the activator vial and shake at least five times.
• Check the swab over a period of 30 seconds for a color change to blue-green, which will indicate blood residues in the tested scope. In the presence of a large amount of blood residue the entire indicator solution will become dark blue. If blue, clean until you get a negative result. Record how many times scope had to be re-cleaned.
• Record the result immediately; late color changes are not valid. The yellow color change after activation is a normal reaction and does not indicate residue.

Data/Cleaning Form

1. Date tested
2. Employee cleaning & testing the scope (initial)
3. Doctor name
4. Model of scope
5. Serial number
6. Procedure for which the scope was used

EndoCheck™ Results

7. Before cleaning process EndoCheck™ test result:
   Positive
   Negative
8. After cleaning process EndoCheck™ test result:
   Positive
   Negative
9. With a positive EndoCheck™ result, the cleaning process is be repeated until a negative EndoCheck™ result is achieved. How many times did the cleaning process have to be repeated?
   One time
   Two times
   Three times
   More than three times
   Other comments

Discussion of Test Study Results

The testing revealed that more than half of the scopes were contaminated with blood soil residue after use (prior to cleaning). Three scopes remained positive for blood soil after the first cleaning and were again positive after a second cleaning. Further, of these three, one required a fourth cleaning to pass the test. Interestingly, all three of these endoscopes were gastroscopes. Five gastroscopes were tested, three of which required more than one cleaning to pass the EndoCheck™ test. This presents a question: Is there something unique to gastroscopes with regard to the blood exposure or to the design of the scope itself? The positive results did not appear to be staff related, as each gastroscope was used by a different surgeon and cleaned by a different technician.

Conclusion

The authors understand that this is a brief look at the cleaning of flexible endoscopes. The results of this study raise as many questions as they answer, for example:

• Is a flexible endoscope that tests positive for blood less able to be properly sterilized/high level disinfected?
• What is the amount of bio-burden, if any, that can acceptably remain in a scope?
• What about other types of soils not tested for here? How often does residue of these soils remain in the scope? What are the implications for patient health of these soils?
• Should a quality improvement program be used to monitor the cleaning process for flexible endoscopes?

With increasing frequency, studies are published focusing on the cleanliness of surgical instruments prior to sterilization or high-level disinfection. A recent study of instrument cleaning reported, "In these studies, the lab has determined that if the instruments are not thoroughly cleaned of proteins and salts prior to sterilization, no method can be truly effective. In many instances, such as the narrow lumens employed in endoscopic surgery, it is extremely difficult to determine if the instrument is clean."

A 2003 position paper, "Multi-society Guidelines for Reprocessing Flexible Gastrointestinal Endoscopes," stressed the importance of staff training — not just initial training but an ongoing training process. Personnel assigned to clean scopes need to have competencies established for all steps of the process and all equipment. The paper states, "Healthcare facilities should develop protocols to ensure that users can readily identify whether an endoscope is contaminated or is ready for patient use."

We know today that healthcare facilities rely on sterilizer manufacturers and makers of high-level disinfectants to design and validate products that deliver an "overkill" method for disinfection/sterilization. Such methods provide an additional safety factor for the process. Could this be a reason why people believe in "sterile dirt" and are not concerned with monitoring the cleaning process? We also know from monitoring our sterilization process that the biological indicator only informs us that the sterilizer has the ability to kill a live organism. If these organisms are killed we assume that the load is sterile. Similarly, we have methods for monitoring the solutions used for high-level disinfection. Should we not also monitor the cleaning process?

The authors believe that all healthcare facilities need a quality improvement program to reduce the number of flexible scopes that are "presumed clean" before sterilization. Such a program can play a key role in reducing hospital-acquired infections, which impact public perception of the hospital within the community. "Hospitals that eventually demonstrate a sustainable link between quality investments and better clinical outcomes will likely gain competitive advantage, thereby

improving financial performance and possibly their bond ratings."

The quality improvement process must ensure that training is rigidly followed and documented. Because the healthcare field is a dynamic environment in which new products are constantly being introduced, hospitals must be willing to adapt to these new technologies and employ them when they can improve various processes within their facility. "…. Disinfection and sterilization cannot be ensured unless the cleaning process is successful… it is incumbent upon professionals in the field to seek out whatever means are available and practical to verify this function."

We have heard all sorts of comments as to why hospitals do not the monitor the cleaning process for flexible scopes, including "It's not mandated," "We do not have to do it," " I know it is clean already, I don't need a test to tell me," or " I do not have a simple, reliable product with which to test."

Regarding performance measurement, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) states, "Performance measurement in healthcare represents what is done and how well it is done. The goal is to accurately understand the basis for current performance so that better results can be achieved through focused improvement actions."

A process that monitors the cleaning of flexible endoscopes should not have to be mandated. The monitoring should be done within a quality improvement program framework designed for each hospital. It makes no sense that hospitals do not monitor the cleaning part of the process when monitoring the sterilization/disinfection process is suggested and being done. Too often hospitals wait until they are the subject of negative headlines, and then suddenly they embrace a quality improvement program for monitoring their flexible endoscope cleaning process. Up to that point the value of such a program is questioned at many hospitals. When a potential patient asks a hospital public relations department, "How do you do know your scopes are clean?" the hospital has two potential responses: "It is not mandated," or "We have a program that helps ensure we delivery a quality product each and every time." What would your hospital's response be?

The following quote sums up the premise of this article; namely, that training and testing can only help ensure that a hospital reduces the number of patient infections that result from improperly cleaned scopes: "…It is very clear that every documented case of patient infection linked to a contaminated scope is because of a breach of some of the reprocessing protocol. If you look back at the history of improper disinfection – not drying the scope, inadequate cleaning, or forgetting to clean the biopsy channel — it has been human error more than anything else. Rules No.1, 2, and 3 are to educate the people who are cleaning the scopes, as well as how and what should be done. If I had it my way, I would have them take a test before letting them do the cleaning."

Remember, it is in the patient's best interest for a hospital to do the best it can each and every time. Testing scopes for cleanliness as part of a quality improvement program is part of that commitment to quality and to the patient.

What follows is a generic template of a quality improvement program that can be used/modified by any hospital department that is responsible for cleaning flexible endoscopes.

Quality Improvement Program

Generic Cleaning Procedure for Flexible Endoscopes

Note: All staff must wear appropriate personal protective equipment (PPE), consisting of a gown, gloves, mask, and face shield impervious to infectious fluids.

1. Pre-clean the flexible endoscope at point of use by suctioning water through the channels (performed by the technician).

2. Transport the scope to the soiled utility room, work room, or decontamination in a closed container.

3. Attach the leak-resistant cap and test the scope for leaks in a basin of water.

4. Suction water through the channels of the scope.

5. Test for leaks — observe for at least one minute.

6. Test the bending rubber: Turn the knobs to ensure that no holes are present in the rubber that may be stretched while bending.

7. Remove the scope from basin and turn off the leak tester; disconnect scope from the leak tester, making sure to leave the leak-resistant cap in place and tightened down.

8. Place the scope into the next basin with the cleaning solution diluted to the correct level as described by the manufacturer.

9. Remove the buttons and place them aside.

10. Brush all channels with a brush designed for this purpose. The brush must be the proper diameter and length to touch all sides of the channels and exit through the end of the scope. Continue this process until the brush no longer appears soiled. Remember to brush and flush all ports (not just the biopsy port) according to the manufacturer's instructions.

11. Wipe down the exterior of the scope with a washcloth or similar item.

12. Place the endoscope into a third basin with fresh water.

13. Use the air water channel device provided by your manufacturer to flush the air water channels with enzymatic solution, followed by a complete flush with fresh water. Any detergent left in or on the scope will interfere with the high-level disinfectant or the chemical sterilant.

14. Rinse and air flush all ports according to the manufacturer's recommendations.

15. Test the various channels of the flexible scope for bioburden as outlined in hospital policy. The frequency of testing will be determined by each hospital.

16. Place scope into high-level disinfectant, chemical sterilant, or sterilizer per manufacturer's instructions.

17. Blow out the channels with compressed air; suction alcohol through the channels to promote drying; and hang scope until needed.

18. It is recommended to reprocess any endoscope that has not been used during a specified period of time to eliminate any microbial life.

Note: This is generic policy that any department can use as a building block. Consult the manufacturers of your scope and cleaning solution as well as your brush supplier to make sure you are following their recommendations for the products you have selected. **ICT**

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