Monitoring the disinfection of flexible endoscopes using ATP bioluminescence

Endoscopy and infection

Flexible endoscopy is an increasingly valuable tool in medicine, with an estimated 15 million procedures being performed every year in the US alone. However, flexible endoscopes can be the cause of some nosocomial infections. They can harbour infective agents[1] and transmit them to subsequent patients. Outbreaks with agents from *Pseudomonas aeruginosa* to *Mycobacterium tuberculosis* and hepatitis B have been reported[2], and concern has been expressed over the possibility of anthrax[3] and vCJD[4] being transferred through endoscopy. One study reported that the incidence of bacteremia following gastrointestinal endoscopies was between 10 and 25%[5].

Endoscope decontamination

To help prevent infection, endoscopes must be disinfected between uses according to the Spaulding classification[6]. Immersing the scope in disinfectant for a validated time period is the preferred method to achieve this classification but it is absolutely essential that the endoscope be meticulously manually cleaned (decontaminated) before disinfection. Any organic matter that remains after manual cleaning lowers the effectiveness of the disinfectant, but the complex nature of endoscopes makes them very difficult to thoroughly decontaminate[1]. With an imperfect clean, bacteria could survive the disinfection process and infect the next patient. There are many occluded surfaces where soil can accumulate, and caps and valves can become contaminated. The hollow channels that supply suction and access for tools to the tip of the scope are long and thin, making visual assessment impossible.

Traditional microbiology cannot monitor the process in real-time as results take 24 to 48 hours; during this time an endoscope could be reused many times. Other limitations of bacteriology include: inability to detect viruses, prions and parasites; it will not detect bacteria that are fastidious in their growth requirements (e.g. *Helicobacter pylori)* or are slow growing (e.g. *Mycobacterium tuberculosis*); it is not an assessment of how clean something is, but its microbial load[7], meaning that the endoscope could appear free of microbes, but still be dirty.

One case has been described where two colonoscopy patients were infected with hepatitis C (HCV) from an endoscope contaminated by an earlier patient. The investigation concluded that the biopsy channel had not been properly cleaned and the disinfection failed[8]. Only two hours had elapsed between the first patient and the last, so even if samples had been taken immediately after the first patient, traditional microbiology results would not have been available in time to prevent cross-infection.

Even if the endoscope has been perfectly cleaned, it can still be cross-contaminated by dirty surfaces or hands. Surfaces that the endoscope comes into contact with must be clean. Switches and surfaces that are used during the endoscopy procedure may contaminate the hands of the person carrying out the procedure. Again, it is impossible to assess the cleanliness of these surfaces quickly with traditional methods, yet real-time feedback on the hygiene status of important sites would allow the process to be controlled.

Real-time monitoring

A hygiene assessment method rapid enough for routine use and that measures both microbial load and total organic load is required. One method is ATP bioluminescence, the technology used in Biotrace International's Aqua-*Trace*® water test and Clean-*Trace*® surface hygiene test. ATP bioluminescence uses similar chemicals to those that make fireflies glow. ATP, the chemical that drives the light producing reaction, is present in all living matter, making its presence an indication of organic matter. Tests are simple-to-use single shot devices, and can take less than a minute to complete, making them rapid enough to be used as part of the decontamination process. By providing an assessment of the amount of organic matter in an endoscope before disinfection, and on important surfaces, Aqua-*Trace*® and Clean-*Trace*® devices can help to ensure that the disinfection process is effective.

Study

In a recent study, the cleaning and disinfection of 63 endoscopes was monitored using Clean-*Trace*® and Aqua-*Trace*® devices at two UK hospitals. Sites in each endoscopy unit identified as being important in endoscope safety were examined during the decontamination process with traditional microbiology and ATP bioluminescence. Sampling occurred during the units' normal testing cycle (Appendix 1). Sites examined included:

- Suction and biopsy channels, tested after cleaning but before disinfection*
- Surfaces the disinfected endoscope was placed on §
- Switches on imaging equipment used during the procedure§

* Channels brushed with disposable lumen cleaning brush, brush was rinsed off in Ringers solution, the solution was tested with Aqua-*Trace*®

§ Surfaces tested with standard Clean-*Trace*® method

Summary of selected results

	ATP		Microbiology	
	Pass	**Fail**	**Pass**	**Fail**
Suction Prior	73%	27%	87%	13%
Biopsy Prior	67%	33%	89%	11%
Scope Exterior	73%	27%	100%	0%
Surfaces	84%	16%	83%	17%
Switches	56%	44%	98%	2%

The failure level was set at 500 RLU per sample and ≥3 cfu per sample, as previously used in other hospital studies[9].

Study findings

The results of this study found that ATP bioluminescence detected more failures than traditional microbiology. ATP bioluminescence was rapid enough to be used as part of a routine monitoring system with results available in less than 2 minutes. Results from traditional microbiology took at least 24 hours. This means that in the event of a cleaning failure, the use of ATP bioluminescence could identify the endoscope as presenting a risk and remedial action could be taken before its use. ATP technology may have detected the poor manual cleaning that lead directly to the HCV infection in the 1997 paper, and allowed re-cleaning of the endoscope before use.

The study found that some switches used during the procedure could become contaminated, and that some types of switches could not be easily cleaned. Similarly, surfaces in endoscopy units became contaminated in certain conditions. ATP bioluminescence could be used to monitor the effectiveness of the cleaning of important surfaces and switches in order to prevent recontamination of the endoscope.

ATP bioluminescence was also able to provide an indication of the amount of organic soil in the endoscope channels after they had been manually cleaned. In most cases the cleaning was very effective, but in some instances amounts of organic

matter remained. This organic matter could have prevented a proper disinfection in line with the Spaulding classification, and potentially posed a cross-infection risk[†].

An effective hygiene management system would be to test the channels after manual cleaning, either by brushing or flushing with sterile ATP-free water and testing the water with Aqua-*Trace*®. Clean-*Trace*® should be used to ensure that critical surfaces in endoscopy units are clean.

Setting Pass/Fail limits

In order to implement such real-time monitoring, pass/fail limits should be determined for individual purposes. The study used previously suggested limits from other hospital studies, but these might not be relevant to all cases. To determine appropriate limits, results should be compared from meticulously cleaned channels to incompletely cleaned surfaces.

	Result 1	*Result 2*	*Result 3*	*Result 4*	*Result 5*
Partially cleaned (RLU)	2142	5455	1547	10586	8724
Fully cleaned (RLU)	640	489	841	506	392

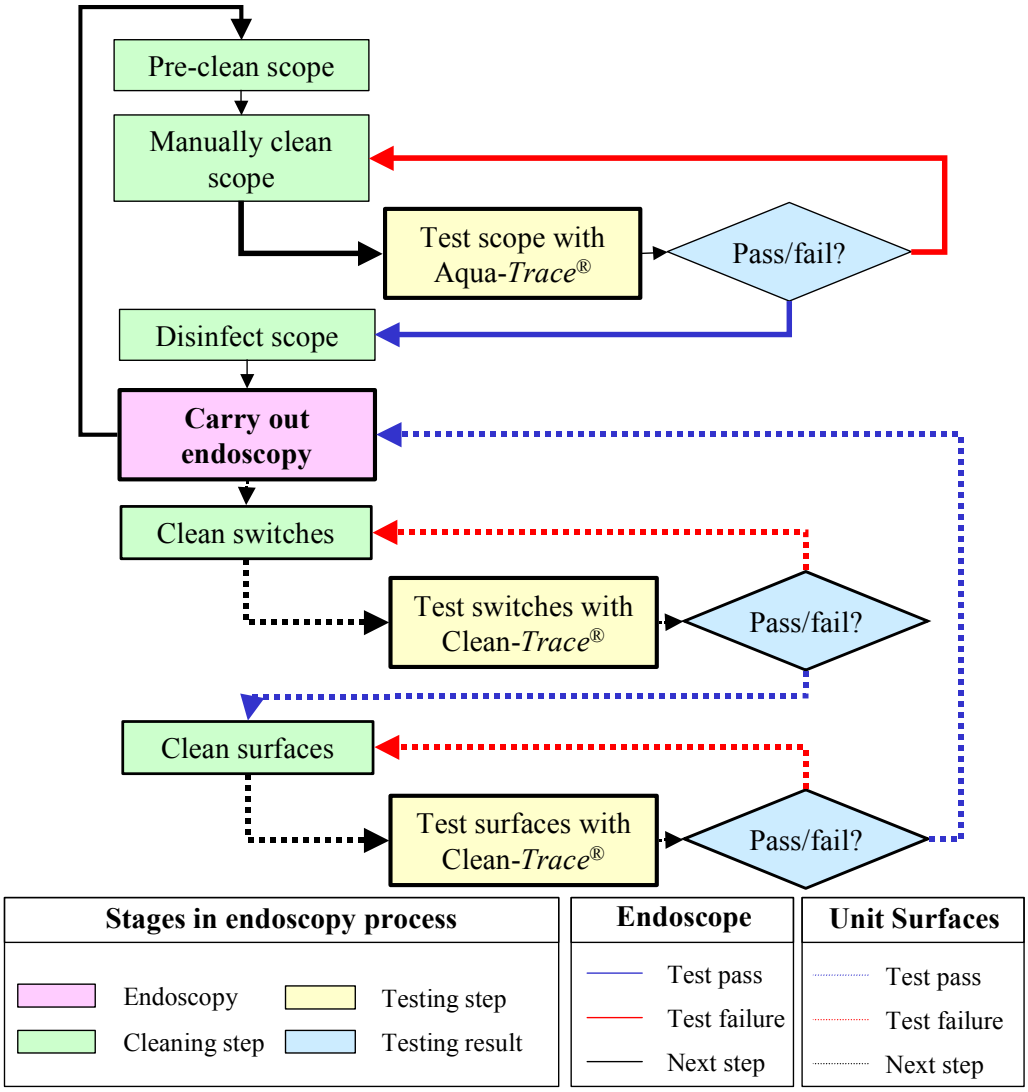
This table shows examples of data that could be obtained from a channel that has been inadequately cleaned, compared to one that has been thoroughly cleaned in accordance with guidelines. To ensure a minimum standard of cleaning, the limits could be set at 1000 RLU, or 900 RLU. To improve cleaning performance over time, a limit of 800 RLU could be set, and lowered gradually over time. This could be used as part of a continuous improvement programme.

Conclusions

By rapidly monitoring critical aspects in endoscope decontamination, the process can be more accurately controlled. Monitoring and recording the results of cleaning allows the endoscopy unit to prove its diligence, as well as providing invaluable data for trend analysis, training and process validation. Clean-*Trace*® and Aqua-*Trace*® have been proved to offer this ability, and could provide real benefits in ensuring patient safety.

[†] ***In this study, subsequent testing of channels post-disinfection showed that no risk to patients existed in these cases.***

Appendix 1 – Work flow diagram showing monitoring of endoscope reprocessing



Reference List

1. Spach D., Silverstein F. & Stamm W. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Annals of Internal Medicine* **118**, 117-128 (1993).

2. Alvarado C.J. & Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. *American Journal of Infection Control* **28**, 138-155 (2000).

3. Muscarella L.F. Anthrax: is there a risk of cross-infection during endoscopy? *Gastroenterology Nursing* **25**, 46-48 (2002).

4. Axon A.T.R. *et al.* Variant Creutzfeldt-Jakob disease (vCJD) and gastrointestinal endoscopy. *Endoscopy* **33**, 1070-1080 (2001).

5. Casas J.M.B. *et al.* Bacteremia caused by digestive system endoscopy. *Revista Espanola de Enfermedades Digestivas* **91**, 105-116 (1999).

6. Anon. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointestinal Endoscopy* 58, 1-8 (2003).

7. Moore G. & Griffith C.J. A comparison of traditional and recently developed methods for monitoring surface hygiene within the food industry: an industry trial. *International Journal of Environmental Health Research* **12**, 317-329 (2002).

8. Bronowicki J. *et al.* Patient-to-patient transmission of hepatitis C virus during colonoscopy. *The New England Journal of Medicine* **337**, 237-240 (1997).

9. Griffith C.J., Cooper R.A., Gilmore J., Davies C. & Lewis M. An evaluation of hospital cleaning regimes and standards. *Journal of Hospital Infection* **45**, 19-28 (2000).