Phase 3 test of Van Vliet GV700D endoscope storage cabinet

Surgical Gastrointestinal Department K

Bispebjerg University Hospital

&

Clean-endoscope

Hvidovre Hospital

Copenhagen Denmark

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Introduction

After an endoscopy in a hospital the flexible endoscopes (FEs) are manually cleaned, and automatically washed and disinfected in a washer disinfector (WD) and finally the channels are flushed with 70% sterile filtered alcohol. The endoscopes can be reused within 3 days[1].
Residual micro-organisms in the channels of the endoscope can lead to an unwanted biofilm hazard and therefore increased infection risk in relation to endoscopy performed with a high-risk FE (see below).
In a quality control program for cleaning and disinfection of flexible gastrointestinal endoscopes at hospitals in Copenhagen, flush water from the water channel is used to evaluate the whole procedure for reprocessing FE[2]. Samplings are carried out immediately before an endoscopy.
Our database with results from more than 21.000 control samples from FEs shows that alcohol flush of the FE channels prevents proliferation of gram negative bacteria (for example *Pseudomonas aeruginosa*), but does not prevent proliferation of staphylococci. In addition residuals of alcohol perhaps introduce biofilm formation of staphylococci[3].

Alcohol flushing of the FE before storage as well as reprocessing of FE after 3 days storage are time-consuming procedures. An alternative for aftercare after decontamination in a WD could be suspension of the FE in a drying/storage cabinet. A phase 2 laboratory test of the Van Vliet GV700D drying/storage cabinet indicates that FEs can be stored in the cabinet without a preceding alcohol flush of the channels and can be used within two weeks or more[4].

The scope of a phase 3 in-use test is therefore to identify whether there is an increased microbiological risk associated with.

1. Storing endoscopes in the cabinet without preceding alcohol flush.
2. Storing endoscopes in the cabinet for up to one week.

Order from

Olympus Medical Systems Europe GMBH
Wendenstrasse 14-18
20097 Hamburg
Germany

Storage cabinet

Van Vliet GV700D, (Van Vliet Medical Supply B.V., Nederland)

Endoscopy department

The Endoscopy Unit
Surgical Gastrointestinal Department K
Bispebjerg University Hospital
Copenhagen DK

Test laboratory

Clinical Microbiology Department,
Hvidovre University Hospital
Copenhagen, DK

Materials and methods

Washer disinfector(s)

Olympus ETD2 Plus and ETD3 with Peracetic acetic acid (PAA) process.

Chemical products

- For manual cleaning: Sekusept Multienzyme, Ecolab
- Cleaner in WD: EndoDet® 0.6%, Ecolab
- Disinfectant in WD: EndoDis® 1.2% + EndoAct® 1.2%, Ecolab Olympus

Van Vliet GV700D drying / storage cabinet

Drying

The drying cabinet is equipped with a system where the endoscopes can be suspended in specific positions.
The endoscopes are connected in the cabinet to the air supply by means of flexible hoses with specialized adaptors. The drying process of the endoscope channels is realized by feeding through medical grade pressurized dry air. The outside of the scopes is dried by HEPA filtered air, which furthermore generates an overpressure in the cabinet.
The drying time proposed is 2 hours.

Storage

The endoscopes are conditioned through a continuous flow of sterile medical grade air following the drying time, which ensures a consistent storage environment.

Procedures

The endoscopy unit follows the Danish recommendations for manual cleaning and automated washing and disinfection:

Examination room:

- When the endoscope is still connected to the light source the channels are flushed with water.

Reprocessing room:

- Manual cleaning takes place in the reprocessing area. All channels and outer surfaces of the endoscope are cleaned in the detergent solution and the biopsy/suction channel is brushed.
- The FE is washed and disinfected and finally dried (standard program) in the WD.
- The FE is then connected, dried (the drying time was set to 2 hour) and stored in the GV700D cabinet.

Test period

The test was carried out over a 9 week period from Monday 16.03.2009 to Monday 25.05.2009. Seven Olympus endoscopes were stored in the GV700D cabinet during the 9 weeks and represented the test objects. Two endoscopes were tested each Monday whereas the additional five scopes were tested each morning during working days, on Mondays after weekends or the first working day after holidays.

Flexible endoscopes included

Gastrointestinal endoscopes from Olympus

A	Gastroscope	GIF-H180	Week test
B	Colonoscope	CF-Q160DL	Week test
C	Gastroscope	GIF-H180	Daily test
D	Gastroscope	GIF-H180	Daily test
E	Colonoscope	CF-Q160DL	Daily test
F	Colonoscope	CF-Q160DL	Daily test
G	Duodenoscope	TJF-160VR	Daily test

Sampling from the endoscopes

Samplings were carried out before an endoscopy at the examination room. The endoscopes were connected to a water bottle with sterile water. Water from the channels was sampled by depressing the air/water feed valve irrigating the channel with sterile water from the water bottle. Approximately 5 ml was collected into a sterile test tube at the distal end of the FE.
The samples were stored in a cold store and forwarded to the Clinical Microbiologic Department the same day.

Laboratory procedure

In the laboratory ten droplets of 20 µl were put down a 5% blood agar the same day. After incubation for 48 hours at 35 °C in CO_2 the numbers of Colony Forming Units (CFU) were counted.

Identification of bacteria and fungi

Samples with <5 CFU per 0.2 ml were identified as species. Other samples were identified after the routine of the laboratory. Staphylococcus were identified as coagulase positive (*Staphylococcus aureus*) and coagulase negative.
Micro organisms isolated from FE were split up in environmental/staff-related or patient-related micro organisms.

Definitions

A clean endoscope: CFU < 5 per 0.2 ml rinse water, corresponding to 0-20 CFU per ml (range for acceptable drinking water).

A critical endoscope: CFU between 5 and 50 CFU per 0.2 ml rinse water.

A high-risk endoscope: CFU >50 per 0.2 ml rinse water.

Sample size

200 – 210 samples from endoscopes were obtained immediately before an endoscopy.

Excluded samples

Samples from endoscopes were excluded if:

- A contaminated FE had a defect demonstrable after service.
- A contaminated FE was decontaminated in a WD with a defect demonstrable after service.

Defective endoscopes during the test period

- A defective FE was replaced with a FE of the same type.

Data analyses

The numbers of clean and not clean endoscopes follow a binominal distribution.
Outliners from defect endoscopes are excluded and the percent of clean endoscopes are calculated.
The acceptable low7
er limit of numbers of clean endoscope is

The general mean of clean endoscopes - (3 X Standard Derivation (STD))
(Joint Commission International)

If a FE is not clean in more than one sampling the critical numbers of not clean results will be determined.
If more than 6 endoscopes are not clean a Number-Between g-Type Statistical Quality Control Charts will be made-up[5].

The data distribution is compared with a Poisson distribution (goodness of fit test, mean = variance).

Satisfaction of the test requirements

The mean of clean FE in the quality control program

- 99.0% of the endoscopes were clean in 2008.

Lower limit of clean endoscopes in the test

- The acceptable lower limit of numbers of clean endoscope is 99.0 % - (3 X STD).

Requirements of the test

If the sample size is 200

1. 194 (97%) or more of the FEs have to be clean.
2. High-risk FEs must not be founded.

Results

Figure 1 shows the results of 203 samples from the water channel of FEs after drying and storage in the Van Vliet GV700D cabinet.

All FEs were clean (the requirements were 97% clean FE). No FEs were excluded.

The detected microorganisms were all coagulase negative staphylococci.

The distribution follow a Poisson distribution (mean ~ variance). The mean was 0.192 CFU per 0.2 ml rinse water corresponding to 1 CFU per ml.

In contrary to an earlier in-use test of the ETD3 PAA WD there is no recontamination distribution between 1 and 10 CFU per 0.2 ml rinse water[1].

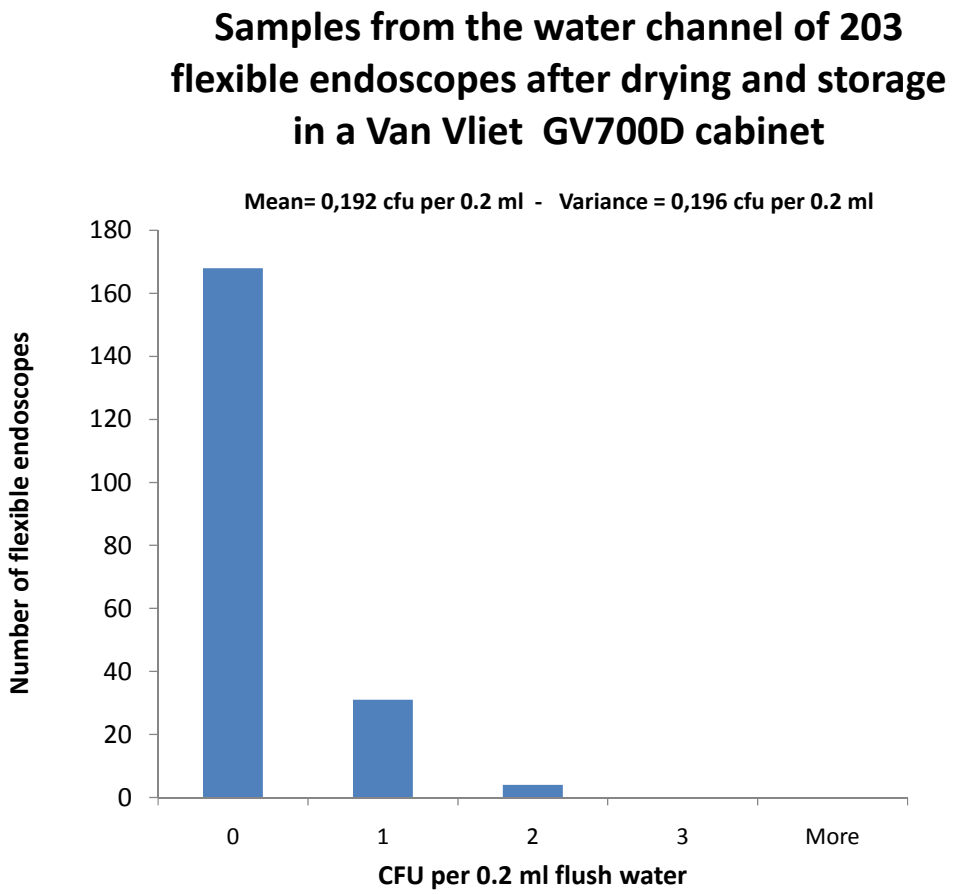

Table 1 shows the sampling results from the individual FE. The results are not statistical different and not depended of the storage time.

Endoscope		Test	Sample size	N° of CFU per 0.2 ml rinse water				% clean endoscopes
				0 CFU	1 CFU	2 CFU	3 CFU	
				N° of flexible endoscopes				
A	Gastroscope	Weekly	10	9	1			100
B	Colonoscope	Weekly	10	8	2			100
C	Gastroscope	Daily	36	29	6	1		100
D	Gastroscope	Daily	42	32	8	2		100
E	Colonoscope	Daily	39	37	1	1		100
F	Colonoscope	Daily	35	29	6			100
G	Duodenoscope	Daily	31	26	5			100
	Total			168	31	4		100
Theoretical Poisson distribution				168	32	3		100

Table 1: 203 Samples from the water channel of FEs. Sampling was carried out immediately before an endoscopy.

Conclusions

Seven gastrointestinal flexible endoscopes were stored in a Van Vliet GV700D endoscope storage cabinet from 1 to 8 days without intermediate reprocessing. 203 samples obtained from the water channel of “ready to use” endoscopes showed that the endoscopes were all clean.
The results followed a Poisson distribution with a mean at 0,192 CFU per 0.2 ml rinse water corresponding to 1 CFU per ml.

Storage in the Van Vliet GV700D cabinet

As a result of the conducted study it can be concluded that the GV700D cabinet will:

1. Render alcohol flush of the channels of the flexible endoscope before storage superfluous.
2. Rendered manual and automated reprocessing of the flexible endoscope superfluous within at least one week of continuous storage.
3. Prevent high-risk endoscopes with biofilm formation.
4. Minimize risk of recontamination.

References

1. In-use test of Olympus ETD3 Washer-disinfector with PAA, 2007: **www.clean-endoscope.com**
2. Posters from SHEA 2004 and 2005, ECCMID 2004: **www.clean-endoscope.com** .
3. Knobloch JK et al. Alcoholic ingredients in skin disinfectants increase biofilm expression of Staphylococcus epidermidis. J. Antimicrob Chemother, 2002;49:683-687.
4. TNO report V8042/EN/; Investigation of the potential microbiological hazard of drying cabinets for medical endoscopes (15 April 2008).
5. JC Benneyan, Health Care Management Science 4, 305-318, 2001

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Torsten Slotsbjerg

Consultant
Clean-endoscope
Hvidovre Hospital
Denmark