Phase 3 test of Minntechs endoscope drying and storage cabinet

Endoscopy Unit O162

Hillerød University Hospital

&

Clean-endoscope

Hvidovre University Hospital

Copenhagen Denmark

Phase 3 test of the Minntech drying and storage cabinet

Introduction

After an endoscopy in a Hospital the flexible endoscopes (FE) are manual cleaned, washed and disinfected in a Washer Disinfector (WD) and finally the channels are flushed with 70% sterile filtered alcohol. The endoscopes can be used within 3 days.
Residual micro-organisms in the channels of the endoscope can lead to an unwanted biofilm hazard and endoscopy performed with a high-risk FE (see below).
In a quality control program for cleaning and disinfection of flexible gastrointestinal endoscopes (FE) at hospitals in Copenhagen flush water from the water channel is used to evaluate the whole procedure for reprocessing FE[1]. Samplings are carried out immediately before an endoscopy.
Our database with results from about 25.000 control samples from FE shows that alcohol flush of the FE channels prevent proliferation of gram negative roads (for example *Pseudomonas aeruginosa*), but don´t prevent proliferation of staphylococci. In addition residuals of alcohol perhaps introduce biofilm formation of staphylococci[2].

Alcohol flushing of the FE before storage and reprocessing of FE after 3 days storage are time-consuming procedures. An alternative aftercare after decontamination in a WD could be suspension of the FE in a Drying/storage cabinet. Phase 2 laboratory test of other drying/storage cabinets have indicated that FEs can be stored a cabinet without a preceding alcohol flush of the channels, and that FE can be used within one week or more[3]. In this phase 3 test the channels of the FEs are flushed with alcohol in the WD.

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 preceding alcohol flush (proliferation of Staphylococci).
2. Storing endoscopes in the cabinet for up to one week.

Order from

Santax Medico A/S
Bredskifte Alle´ 11
DK 8210 Aarhus V

Storage cabinet

Two Minntech Combi pass-through Cabinet for 10 cassettes

Endoscopy department

Endoscopy Unit 0162
Hillerød Hospital
Hillerød DK

Test laboratory

Clinical Microbiology Department,
Hillerød University Hospital
Hillerød, DK

Materials and methods

Washer disinfector(s)

3 MDS washer disinfectors (WD^s) with automatic alcohol flushing of flexible endoscope channels were used.

An extensive self disinfection (S-disinfect) of the WD^s was carried out Sunday. A less extensive recovery (s-recovery) was performed Tuesday, Wednesday, Thursday and Friday.

Chemical products

- For manual cleaning: Sekusept MultiEnzyme®, Ecolab.
- Cleaner in WD: DS2-Clean® for flexible endoscopes
- Disinfectant in WD: Rapicide PA®

Minntech drying and storage cabinet

Drying

The endoscopes are placed in cassettes and these are connected to the air supply by means of specialized adaptors. The drying process of the endoscope channels is realized by feeding through medical grade pressurized dry air. The circulating air from the endoscopes dries the outside of the endoscope and generates overpressure in the cabinet.

Storage

The endoscopes are stored horizontally in the cabinets

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 (pre-cleaning)

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, disinfected, dried and finally flushed with alcohol.

Flexible endoscopes included

Olympus gastroscopes, colonoscopes and sigmoidscopes

Test period

18.08.2010 to 29.09.2010

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

More than 200 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 in the Log-file ore after service.
- The manual cleaning of the endoscope is defectively or insufficiency (High-risk FE[s] with no effect of alcohol flushing of the FE channels and/or detection of patient related microorganisms)[4]

- Defective endoscopes during the test period.

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

Data analyses

The numbers of clean and not clean endoscopes follow a binominal distribution.
The acceptable lower limit of numbers of clean endoscope is

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

If more than 6 endoscopes are not clean a Number-Between g-Type Statistical Quality Control Charts will be made-up[5].

Satisfaction of the test requirements

The mean of clean FE in the quality control program

- 99.0% of the endoscopes were clean in 2009.

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 238

1. 231 (97.1%) or more clean FE
2. No occurrence of high-risk FE.

Results

238 samples were obtained from the FE immediately before an endoscopy

Figure 1 shows that 84,8% of the FE are used within 3 days, 11.2% between 4 and 7 days, 2,5% between 8-14 days and 0,4% more than 14 days after a repossessing.

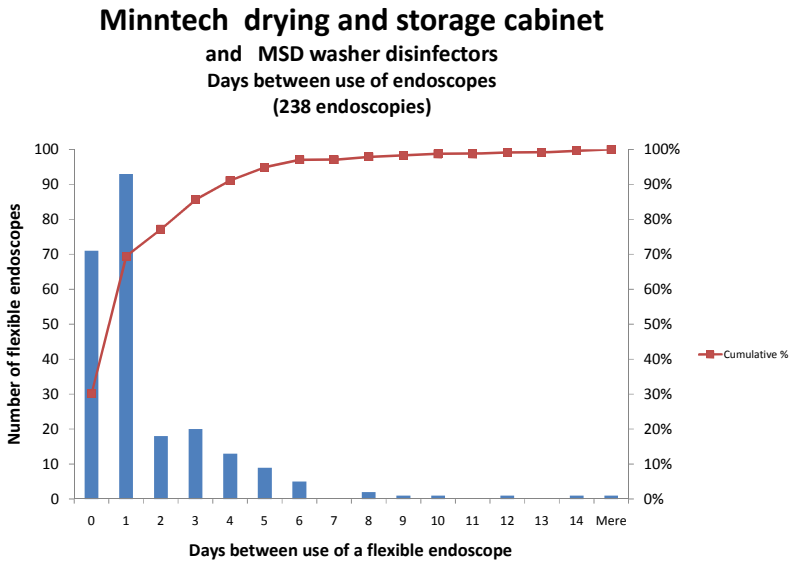

Figure 1: Days between use of the flexible endoscopes.

Figure 2 shows that 232 of 238 (97.5%) samples from the water channel of FE[s] indicate a clean FE before an endoscopy. Critical lower limit is 97.1%, but 2 sigmoidscopes were a high-risk FE. No effect of alcohol flushing of the FE[s] channels and/or detection of patient related microorganisms indicate an insufficient pre-cleaning (and manual cleaning) of air/water channels[4].

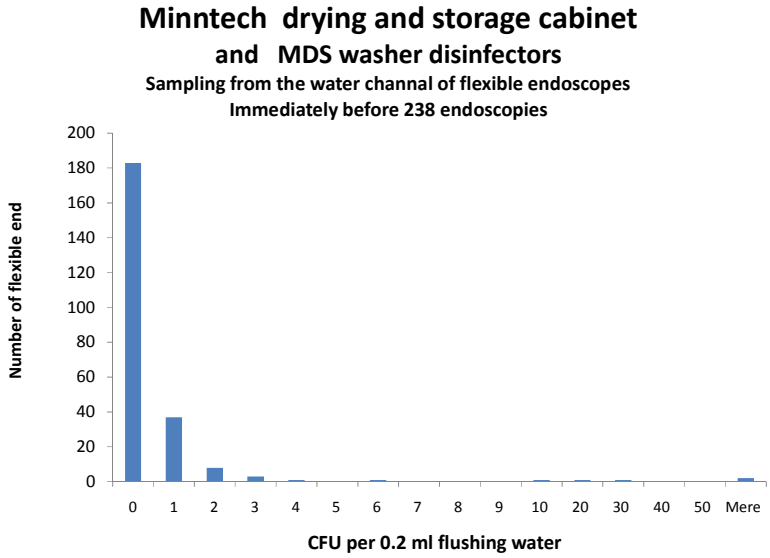

Figure 2: Flexible endoscopes reprocessed 0-7 days before the endoscopy

Figure 3 shows that 177 of 178 FE[s] were clean after one night to one week storage in the Cabinet. A single critical FE was reprocessed the previous day. The two high-risk sigmoid scopes were excluded.
Samples with 0-3 CFU per 0.2 flushing water are not Poisson distributed. The number of samples with 1-3 CFU is higher than expected (The recontamination of the FE during the WD reprocessing is partial eliminated)[4]

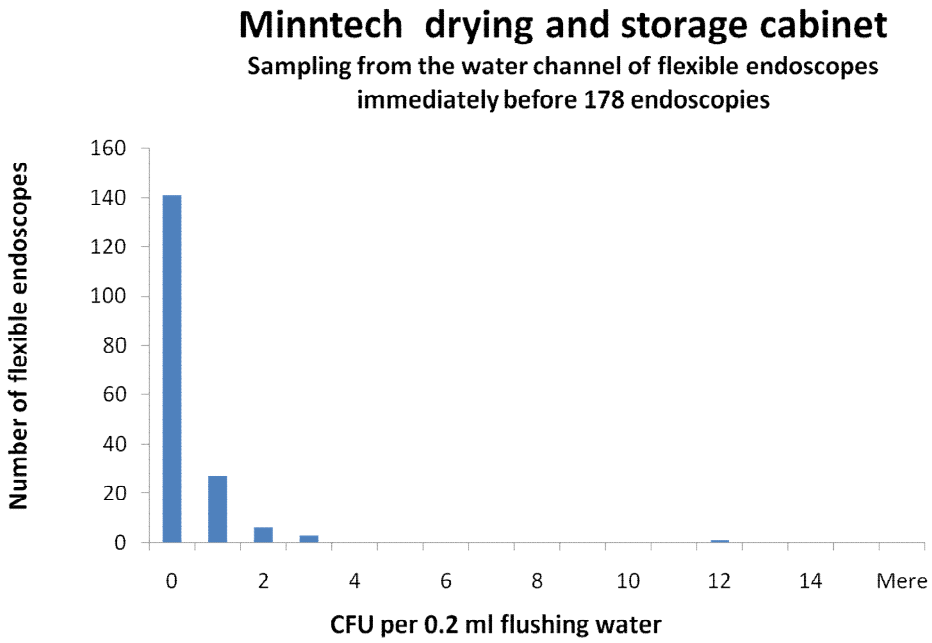

Figure 4: Flexible endoscopes storage 1-7 days in the cabinet

Table 1 descript 4 critical and 2 high-risk FE[s] from the test. Samples from three critical FE[s] were all obtained before the second endoscopy of the day with the FE. No microorganisms were detected before the first endoscopy.
A WD log-file showed that the extensive self disinfection program was not carried out in one WD during the test period, and the WD log-file documented neglected fault complaints. The less extensive recovery (s-recovery) was not performed Monday and Saturday in the WD[s].
Two High-risk sigmoid scopes showed a water related microorganism (no effect of alcohol flushing) and a patient related microorganism respectively. This sample results indicated a well-known insufficient pre-cleaning (and manual cleaning) of the air/water channels[4].

Table 1: Description of 6 (2.5%) critical or high-risk flexible endoscopes from a 36 days in use test of Minntech drying and storage cabinets and reprocessing in MDS washer disinfectors.

Day	Day of week	Endoscope number	Day after reprocessing	Critical FE	High-risk FE	Micro-organisms	Comment
2	Wednesday	53	1	x		*Corynebacacterium species*	Recontamination in the WD ?
13	Monday	51	0	x		Coagulase negative staphylococcus	Recontamination of the endoscope during the reprocessing in the washer disinfector
20	Monday	54	0	x		Coagulase negative staphylococcus	
27	Monday	20	3		x	*Citrobacter braakii*	Insufficient pre-cleaning (and manual cleaning) of air/water channels in sigmoidscopes
27	Monday	24	3		x	*Pseudomonas aeruginosa*	
28	Thursday	52	0	x		*Pseudomonas species*	Recontamination in the WD

Critical FE: 5-50 CFU per 0.2 ml flushing water **High-risk FE:** >50 CFU per 0.2 ml flushing water

Conclusions

1. Flexible endoscopes can bee stored in a Minntech drying and storage cabinet at least one week without a new reprocessing in a washer disinfector.

2. The contamination of the flexible endoscopes is partial eliminated in the Minntech drying and storage cabinet.

3. The Cabinet prevent high-risk endoscopes with biofilm formation, but the condition is (like other drying/storage cabinets)

    a. A sufficient preceding pre-cleaning and manual cleaning during the reprocessing of the flexible endoscopes.

    b. A daily self-disinfection of the Washer Disinfectors as recommended in ISO EN 15883-4.

4. The washing and disinfection procedures are sufficient. Biofilm were eliminated after a single reprocessing.

5. No increase biofilm expression of *Staphylococcus epidermidis* causing alcohol residuals was demonstrable.

References

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Torsten Slotsbjerg

Clean-endoscope
Unit 445
Hvidovre University Hospital