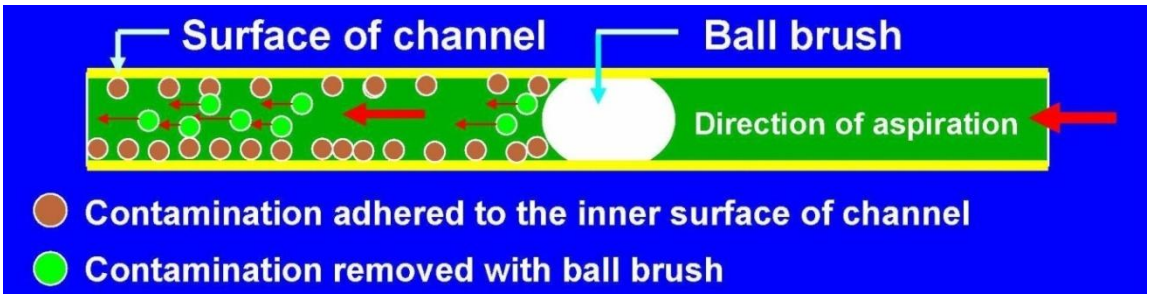
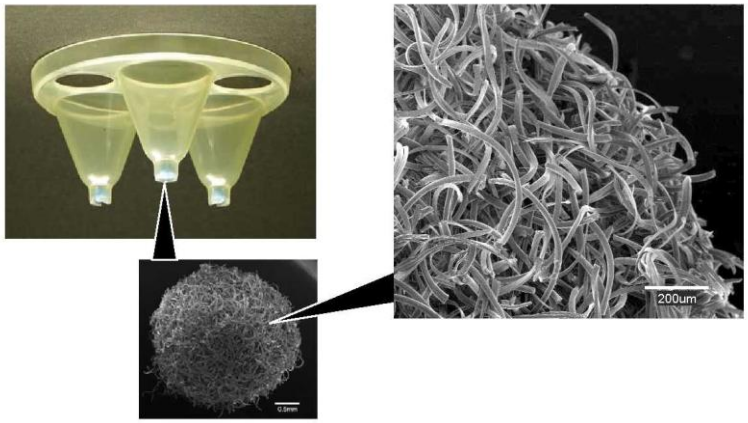
In use test (phase 3 test) of
Channel Cleaner® Ball Brushes
applied for manual cleaning of flexible endoscopes





Endoscopy Unit
Surgical Gastrointestinal Department K
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In use test (phase 3 test) of Channel Cleaner® Ball Brushes applied for manual cleaning of flexible endoscopes

Introduction

Manual cleaning and brushing of the channels in a flexible endoscope (FE) are very important before disinfection. If debris, blood or mucus membranes are remained in the channels, the disinfection efficacy may get negatively affected[1]. The quality of hand manual cleaning and brushing can vary between operators.

The Channel Cleaner® ball brush was designed and developed to supplement manual cleaning and brushing. Experimental studies showed that the product is effective in lowering the protein content in Teflon tubes artificially contaminated in comparison with standard brushes[2].

ATP bioluminescence is used for measuring levels of organic soil on surfaces. Opposed to a Microbiologic control samples an ATP cleaning test can be performed in less than 2 minutes. Residual soil is an indicator that the surfaces may be unclean and could provide a potential reservoir and harbour for bacteria, fungi and virus increasing the risk of cross infection between patients[3].

Aim of the study

Aim of the study is to compare the manual cleaning of patient-used gastroscopes and colonoscopes performed either with Channel Cleaner® Ball Brushes or a standard brush.

Product:

Channel Cleaner® Ball Brushes (together with Cleantop-21® detergent and UNO CLEAN Valvebrush type AN1061110)

Order from

Braun Scandinavia A/S

Lervej 25

DK-3500 Værløse

Washer disinfectors

ETD2+ and ETD 3 with per acetic acid (PAA)

Chemical products

For manual cleaning: CLEANTOP-21

Cleaner in WD: EndoDet® 0.6%, Ecolab

Disinfectant in WD: EndoDis® 1.2% + EndoAct® 1.2%, Ecolab

Endoscopy department

The Endoscopy Unit

Surgical Gastrointestinal Department K

Bispebjerg Hospital

Copenhagen University Hospital

Flexible endoscopes included

Routine gastroscopes and colonoscopes

Test laboratory

Clinical Microbiology Department, Hvidovre Hospital, Copenhagen University Hospital, has trained the endoscopy staff at ATP measuring.

Condition for the investigation

The endoscopy unit follows the Danish recommendations for cleaning and disinfection of FEs[4].
In the reprocessing area manual cleaning is performed of all channels and the outer of the FE in a detergent solution. Suction- and biopsy channels are brushed. The detergent solution is discarded after each use.
Before storage we flush the channels with 70% alcohol, and the FEs can be used within 3 days.

ATP-test

Residual Adenosine Tri-Phosphate (ATP), which is found in large quantities in human blood and other tissue fluids, are used as cleanness indicator for FE channels. Low-level ATP residuals indicate that patient related secretes are removed (no hepatitis B + C risk), and that the subsequent disinfection will be successfully. Log CFU (CFU = colony forming units) and Log ATP are not correlated on surfaces contaminated with human secretes.

An UNI-LITE NGl® portable luminometer and total ATP Aqua-Trace® were used (3M). The relation between Relative Light Units (RLU) values from UNI-LITE NGI® ATP are earlier computed as log RLU = Log ATP + 1 (femtomol), R^2= 0.99.
Log RLU = Log ATP-units (10^{-14} mol). 3 log ATP-units ≈ 10^{-3} µl blood.

Pre-cleaning

The suction and biopsy channel of the FE were flushed with a 1% cleantop-21®.
The water/air channels were flushed with water with the help of a dedicated valve.
The insertion section was wiped with the detergent solution.

Pre cleaning sampling

The biopsy valve was replaced with a stop.
Water from a 20 ml syringe was injected through the suction port on the light-guide connector and collected in a 30 ml centrifuge container at the tip of the insertion tube. The ATP measuring was processed according to manufacturer´s instruction.

Manual cleaning

Brushing

Period 1 and 3: Manual cleaning with a standard brush of adequate size.
Period 2 and 4: 3 Ball Brushes are sucking through the biopsy/suction channel.
Biopsy- air/water- and suction valves were removed.
All inlets were cleaned with UNO CLEAN Valvebrush type 1061110. .
The full FE was immersed and wiped in the detergent solution (Cleantop-21).
The endoscope was removed from the detergent solution and stops were inserted in suction valve and biopsy inlet.

Post cleaning sampling

Water from a 20 ml syringe was injected through the suction port on the light-guide connector and collected in a 30 ml centrifuge container at the tip of the insertion tube. The ATP measuring was processed according to manufacturer's instruction.

Study design

ATP sampling from biopsy/suction channel

Brush/balls	Sampling	Sample size	
Brush	Before manual cleaning	**25**	ATP measuring
	After manual cleaning	**25**	ATP measuring
Balls	One week without sampling		
	Before manual cleaning	**25**	ATP measuring
	After manual cleaning	**25**	ATP measuring
Brush	One week without sampling		
	Before manual cleaning	**25**	ATP measuring
	After manual cleaning	**25**	ATP measuring
Balls	One week without sampling		
	Before manual cleaning	**25**	ATP measuring
	After manual cleaning	**25**	ATP measuring

Data presentations

1. **Equivalence chart:** x = log ATP-units pre cleaning; y = log ATP-units post cleaning. On the equivalence line ATP residuals are the same before and after the manual cleaning.

2. Results were entered in **Six Sigma Control charts** with determination of centreline (CL), upper control limit (UCL) = CL + 3Σ and lower control limit (LCL) = CL - 3Σ . CL (mean) represents the central tendency of the cleaning effect[5] .

   a. **Limits:** All results should be inside the control limits.

      i. The upper limit suggested of Obee et al is 2.7 log ATP-units[3]

Results

Before manual cleaning: The mean of log ATP-units was 4.2 and 3.8 after the pre-cleaning of the biopsy/suction channels of the FEs in the brushes and the Ball Brushes periods respectively. Figure 1 shows a ATP level are within the control limits. Therefore the pre-cleaning process in the endoscopy rooms are a statistical stable processes, but with different means and control limits in the brush and Ball Brush periods.

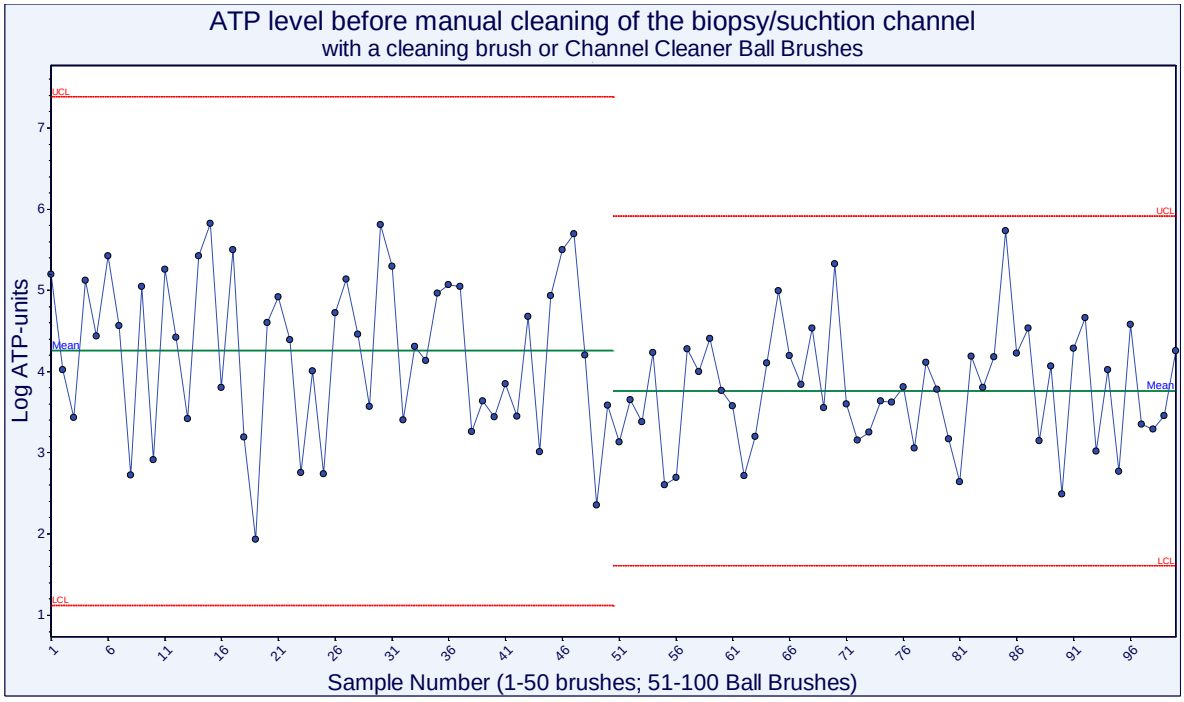

Figure 1: ATP level after pre-cleaning before manual cleaning of the biopsy/suction channel of flexible endoscopes with either a brush or Ball Brushes. UCL: Upper control limit. LCL: Lower control limit.

After manual cleaning: The means of log ATP-units were 1.9 in both the brushes (Range: 1.2 - 2.9) and Ball Brushes (range: 1.2 - 2.6) periods. Figure 2 shows that all results are inside the control limits and the processes are statistical stable. 96 % and 100 % of the FEs passed the upper limit suggested of Obee et al (2.7 log ATP-units) in the brush and Ball Brushes periods respectively. The upper limit of Obee at al. seems to be a mean + 2 Sigma limit.

Figure 3 shows an effective cleaning process with only one control points above the equivalence line. All other control points are below the equivalence line. There is no significant correlation between log ATP-units before and after the manual cleaning.

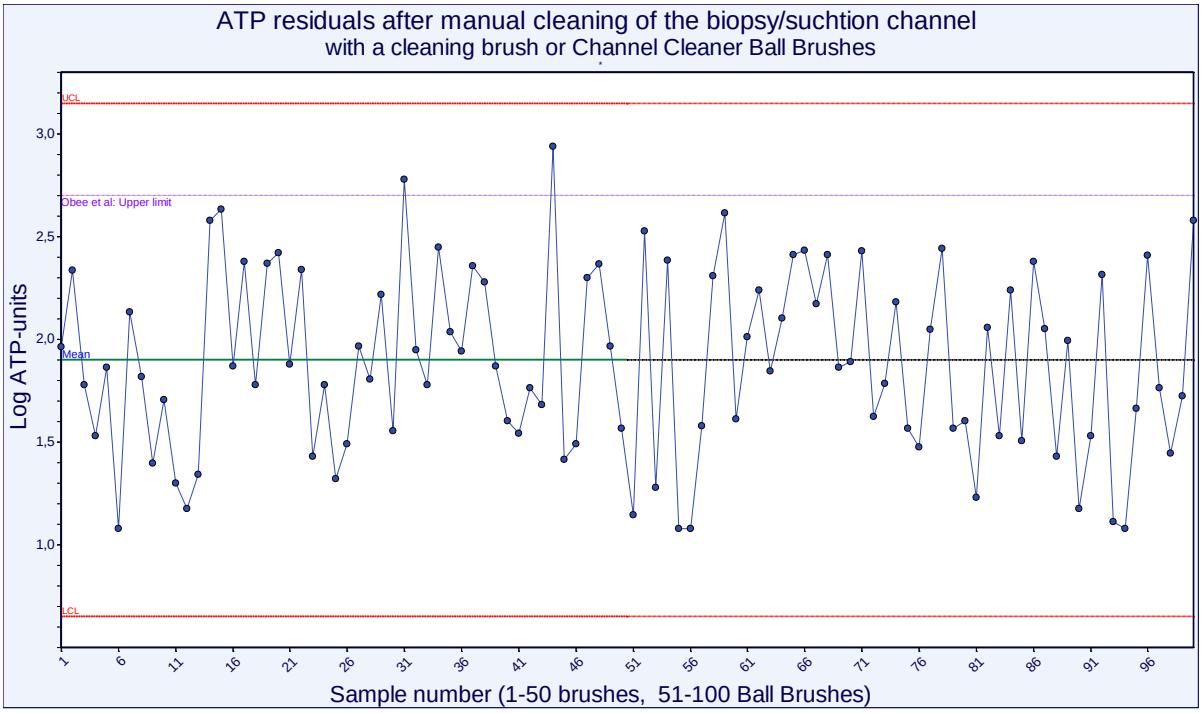

Figure 2: ATP residuals after manual cleaning of the biopsy/suction channel of flexible endoscopes with either a brush or Ball Brushes. UCL: Upper control limit. LCL: Lower control limit.

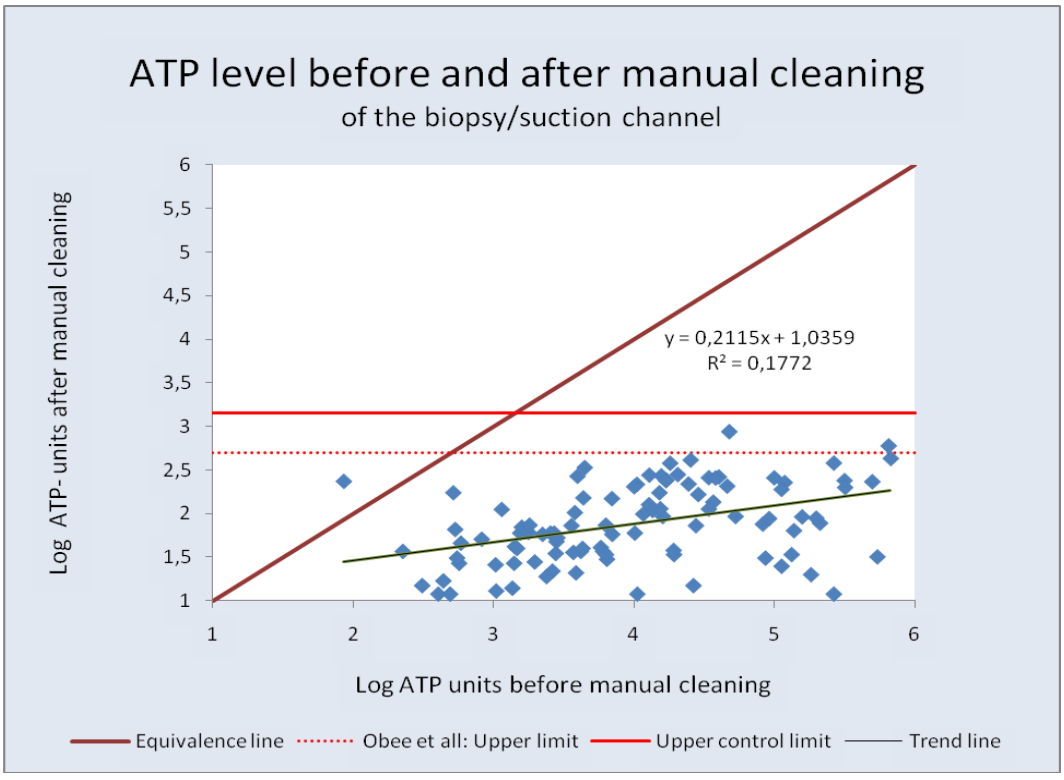

Figure 3: Relation between ATP residuals before and after manual cleaning of the Biopsy/suction channel of flexible endoscopes with a brush or Ball Brushes.

Conclusion

Manual cleaning with Channel Cleaner® Ball Brush

- 100% of the biopsy/suction channel of flexible endoscopes passed the upper limit suggested of Obee et al (2.7 log ATP-units) after 50 manual cleaning procedures performed with Channel Cleaner® Ball Brush and a Cleantop-21 detergent. The cleaning process was in statistical control (all control points inside the control limits in a Six Sigma control chart) The range of log ATP-units was 1.2 - 2.6.

Manual cleaning with a normal cleaning brush

- 96% of the biopsy/suction channel passed the test after 50 manual cleaning procedures with single use cleaning brushes. The cleaning process was in statistical control . The log ATP-unit difference between brush and Ball Brushes was not significantly. The log ATP-unit range was 1.2 - 2.9.

The range in the brush and the Ball brushes periods were lower than the range at 1.3 - 4.1 log ATP-units accounted by Obee et al[3]

Channel Cleaner® Ball Brush can on the above be recommended for manual cleaning of flexible endoscopes in combination with Cleantop-21 and careful cleaning of all inlets with the UNO CLEAN Valvebrush type AN1061110 .

04-06-2010

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Klinisk brugstest af Channel Cleaner® Ball Brushes

Dansk resume´

Channel Cleaner® Ball Brushes (fiberkugle børster) er udviklet til anvendelse ved manuel rengøring og børstning af fleksible endoskoper. Laboratorieundersøgelser har vist, at produktet er mere effektivt til at fjerne proteinrester fra teflonrør end de standard børster, som normalt anvendendes ved manuel rengøring af endoskoper.[2].

ATP bioluminiscens anvendes til at påvise mængden af organisk materiale på overflader. **A**denosin Trifosphat (ATP) findes især i store mængder i blod, spyt, urin og andre friske udskillelser fra mennesker (og dyr). I modsætning til en proteintest kan en ATP rengøringstest udføres på mindre end 2 min.

Et UNI-LITE NGl® transportabelt luminometer og et total ATP Aqua-Trace® testkit er anvendt ved ATP-bestemmelsen (3M).

Design af studiet

ATP indholdet i biopsi- og sugekanalen på gastro- og koloskoper er bestemt før og efter manuel rengøring i perioder enten med traditionelle engangs rengøringsbørster eller med Channel Cleaner® ball brushes. Der er foretaget overkrydsning af perioderne efter nedenstående skema.

Som detergent er anvendt Cleantop-21, et enzymfrit detergent.

Børster/kugler	**Prøvetagning**	**Antal prøver**	
Børster	Før manual rengøring	**25**	ATP bestemmelse
	Efter manual rengøring	**25**	ATP bestemmelse
Kugler	En uge uden prøvetagning		
	Før manual rengøring	**25**	ATP bestemmelse
	Efter manual rengøring	**25**	ATP bestemmelse
Børster	En uge uden prøvetagning		
	Før manual rengøring	**25**	ATP bestemmelse
	Efter manual rengøring	**25**	ATP bestemmelse
Kugler	En uge uden prøvetagning		
	Før manual rengøring	**25**	ATP bestemmelse
	Efter manual rengøring	**25**	ATP bestemmelse

Kritiske grænser

Obee og medarbejdere har forslået en øvre grænse for ATP svarende til 2.7 log ATP-enheder. Resultaterne af ATP målingerne indføres i 6-Sigma kontrolkort og alle resultater skal ligge indenfor kortets kontrolgrænser.

Resultater.

Channel Cleaner® Ball Brushes perioderne

100 % af biopsi/sugekanalerner opfyldte de opstillede krav, efter 50 manuelle rengøringsprocedurer af endoskoperne. Rengøringsproceduren var statistisk stabil (alle resultater inden for kontrolgrænserne i kontrolkortet).

Traditionel børste perioderne

96 % af biopsi/sugekanalerner opfyldte de opstillede krav efter 50 manuelle rengøringsprocedurer af endoskoperne. Rengøringsproceduren var statistisk stabil.
Forskellen i resultaterne efter den manuelle rengøring i traditionel børste og Channel Cleaner® ball brush perioderne er ikke statistisk signifikant.

Afsluttende resume´

Channel Cleaner® Ball Brushes kan sammen med Cleantop-21® anvendes i stedet for en traditionel børste ved den manuelle rengøring af fleksible endoskoper. Man skal dog huske at anvende en ventilbørste til rengøring af alle indgange til endoskopets kanaler. I denne undersøgelse er der anvendt en ventilbørste af typen UNO CLEAN AN1061110.

04-06-2010

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