

Endoscopy

What's New Up There?

Frank Myers, MA, CIC, FAPIC

Disclosures

- Frank Myers is a member of ASP J&J scientific advisory committee for the development of new high level disinfection or sterilization products none of which he will discuss today because legally he can't.

Objectives



- Identify one advantage and one disadvantage of the use of borescopes as an aid in high level disinfection
- List two variables that must be weighed against each other when reviewing the use of simethicone in endoscopy.
- Describe one paper that raises questions about extended endoscope hang times.

A lot has been learned in the last year

- And little has changed

Curse of Simethicone



Disinfection and Sterilization

Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

- EH Spaulding believed that how an object will be disinfected depended on the object's intended use and did not consider the difficulty of the task (*Rutala proposed modification*).
- CRITICAL - objects which directly or secondarily (*i.e., via a mucous membrane such as duodenoscope, cystoscope, bronchoscope*) enter normally sterile tissue or the vascular system or through which blood flows should be sterile.
- SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.
- NONCRITICAL -objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).

Sterilization Versus HLD for Scope

- Bill Rutala and company pushing hard for sterilization
 - Sterilization failures very rare
 - Sterilization has a wider margin of safety and microbial load higher
 - GI endoscopes contain 10^7-10^8
 - Cleaning results in 2-6 \log_{10} reduction
 - High-level disinfection results in 4-6 \log_{10} reduction
 - Results in a total 6-12 \log_{10} reduction of microbes
 - Level of contamination after processing: $4\log_{10}$ (maximum contamination, minimal cleaning/HLD)

ETO safety



Sterigenics - Facility Information Sheet

Los Angeles

Facility Address:

4900 Gifford Avenue
Los Angeles, CA 90058

Facility Services Capabilities:

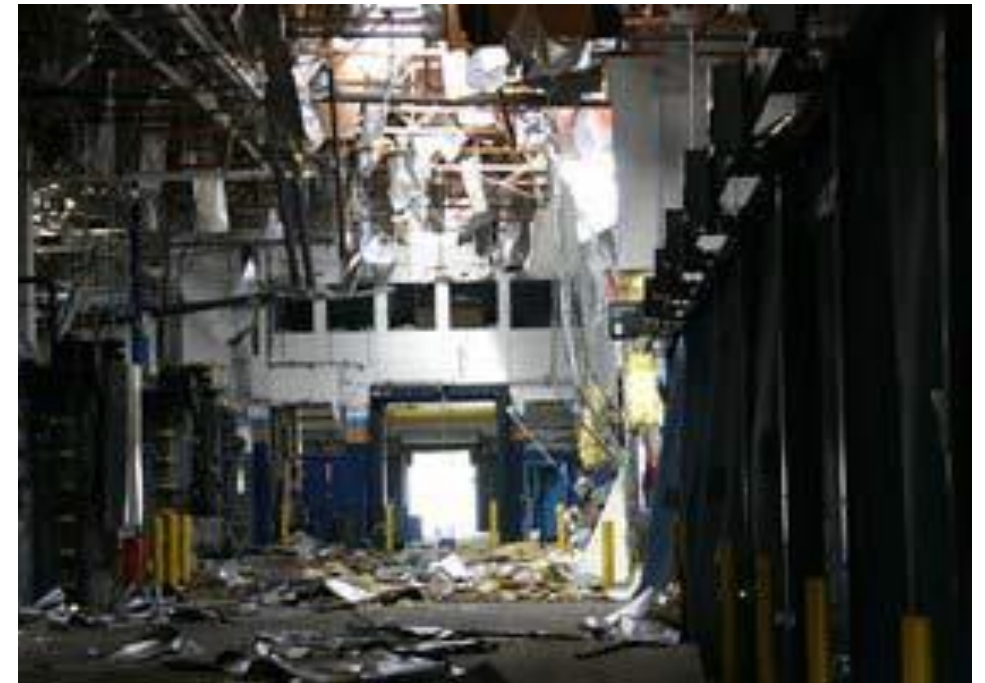
Ethylene Oxide Sterilization
EOStat® Rapid Processing
Process Validation



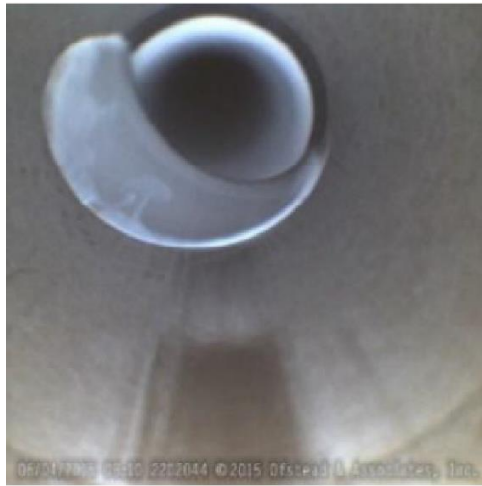
[MapQuest Map Link](#)

Process Capability:

3 pallet sterilizers	Maximum pallet height 68"	Pallet dimensions: 40" x 48"
6 pallet sterilizers	Maximum pallet height 68"	Pallet dimensions: 40" x 48"
13 pallet sterilizers	Maximum pallet height 70"	Pallet dimensions: 40" x 48"



So sterilization is the answer right?



B



C



Visual Inspections of Colonoscopes and Gastrosopes Ofstead et al. Am J Infect Control. 2017. 45:e26-e33

Low temperature sterilization fails if salt + organic material present

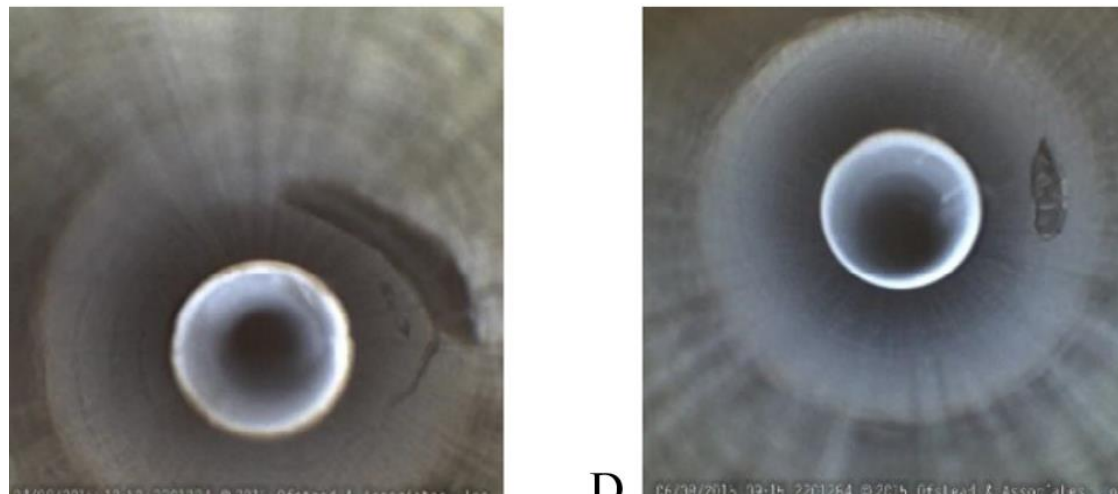
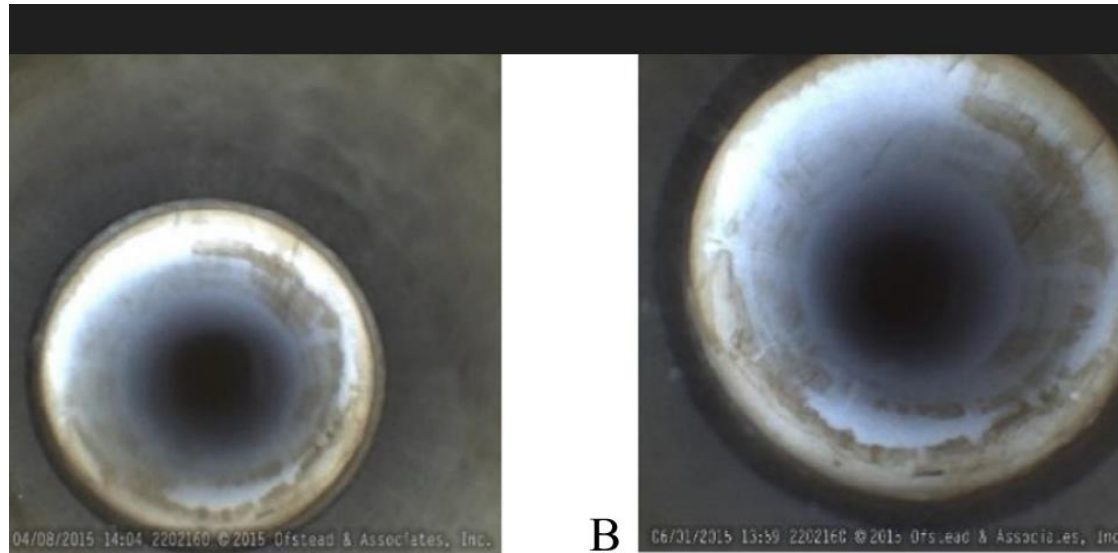
Test:	Residual bacteria Log ₁₀ CFU/lumen (SD) Exposed to 100% ETO sterilization		
	<i>Mycobacterium chelonae</i>	<i>Enterococcus faecalis</i>	<i>Bacillus subtilis</i> spores
Positive control	6.82 (0.25)	6.76 (0.13)	6.13 (0.13)
Tissue culture media + 10% serum	0	2.67 (0.13)	3.60 (0.34)

Alfa et al *Comparison of liquid chemical sterilization with peracetic acid and ethylene oxide sterilization for long narrow lumens* (AJIC 1998;26:469-77)

Sterilization Technology for Endoscopes

- ETO-failed (and in models)
- Sterris-1E failed (and in models)
- Sterrad- failed (only in models)

Can there be sterilization without cleaning?



Consensus

- No support for recreating the Spaulding scheme
 - SGNA, AAMI, ASGE

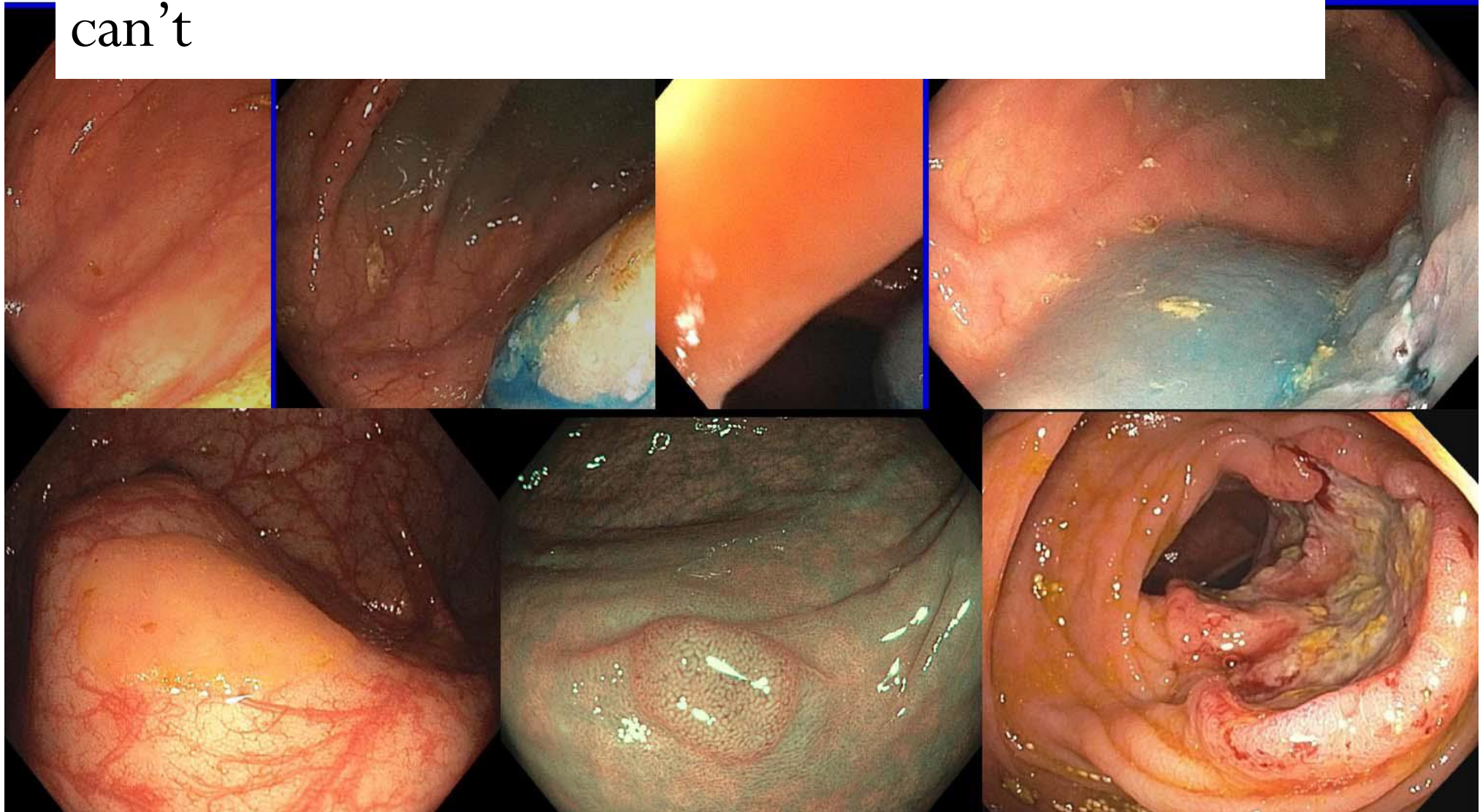
What is Simethicone?

- A silicon based sugar rich fluid that is used to reduce gastric bubbles on the intestinal lining
- Bubbles need to be reduced to allow for increased visualization of the intestinal wall
 - And therefore enhance early detection of colon cancer

Bubbles!



Some of these can be seen with bubbles, some can't



Simethicone in “cleaned” endoscope



B



C



Simethicone as anti sudsing agent

- C.L. Ofstead et al. / American Journal of Infection Control 44 (2016) 1237-40

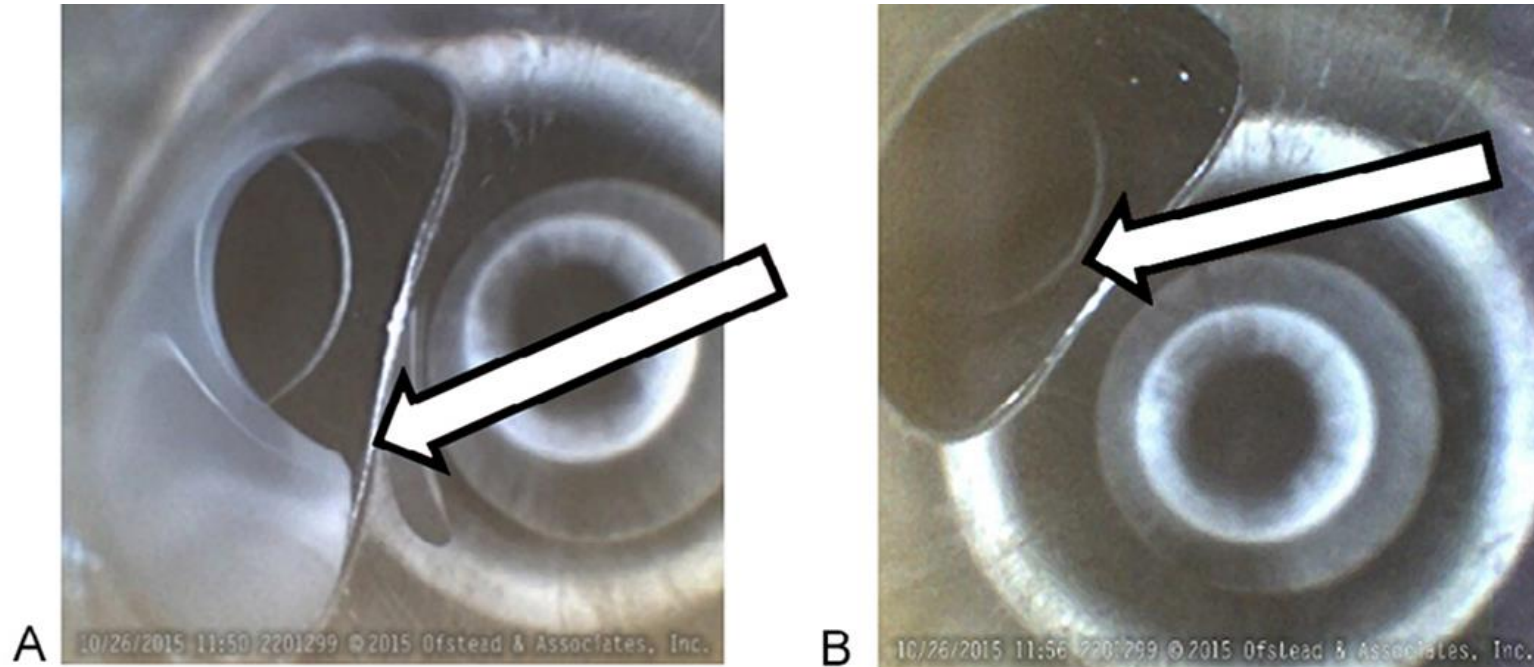


Fig 2. Fluid captured from suction port of pediatric colonoscope. (A) Before attempting to capture a sample. (B) After capturing the sample.

So why isn't simethicone removed in routine cleaning?

- Most cleaners are design for carbon based material
- This means while other organic material is removed the simethicone stays behind
- Yet the sugar content might allow for prolific bacterial reproduction
 - Or does it?

So let's eliminate simethicone!

- Cost benefit analysis
 - Deaths due to colon cancer versus risk of an unclean scope
- No society or manufacturer has said never to use simethicone

Best we can do

- Eliminate unless patient is known to have excessive bubbling (look first)
- More is not better
 - A little dab will do ya'
 - Not the whole bottle
- Does it work if we dose the patient first?
- Looking for an acceptable substitute

Duodenoscope lever position:

Is one mistake (improper elevator position) enough to allow microbial survival?

1. Inoculation & 2 hour dry of soil (artificial) with ~ 7 Log₁₀ CFU E.faecalis + E.coli in 0.1 mL
2. No manual cleaning
3. Lever in “horizontal” position (A)
4. Duodenoscope placed in AER
 - - SS1E: No cleaning cycle, Peracetic acid (PA)
 - - Advantage Plus: cleaning cycle, PA

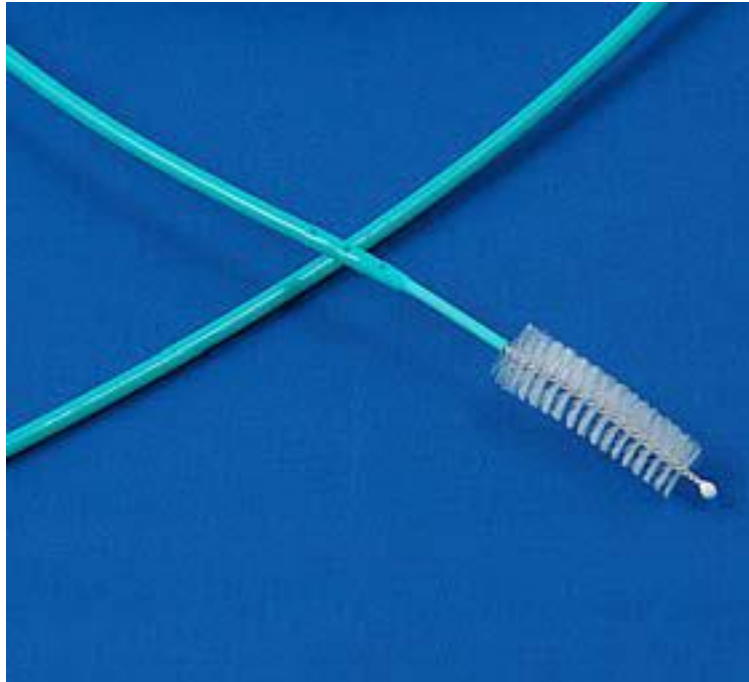
Yes, sort of, depending

Duodenoscope tested:	Number of Bacteria recovered Post Disinfection Log ₁₀ CFU/lever sample (standard deviation) ¹	
Inoculum: ~ 7 Log ₁₀ of both bacteria	<i>E. faecalis</i>	<i>E. coli</i>
<i>Processed through STERIS SYSTEM 1E</i>		
JF-140F	6.18	1.71
	5.74	1.62
	6.71	0.0
Mean (Sdev) ¹	6.21(0.48)	1.11 (0.96)
TJF-Q180V	3.13	0.0
	2.48	0.0
	6.25	0.0
Mean (Sdev)	3.95 (2.01)	0.0 (0)
<i>Processed through Advantage Plus</i>		
JF-140F	3.03	1.71
	2.82	0.0
	5.24	3.36
Mean (Sdev)	3.69 (1.34)	1.69 (1.68)
TJF-Q180V	2.86	1.79
	1.49	0.0
	1.31	0.0
Mean (Sdev)	1.89 (0.85)	0.60(1.03)

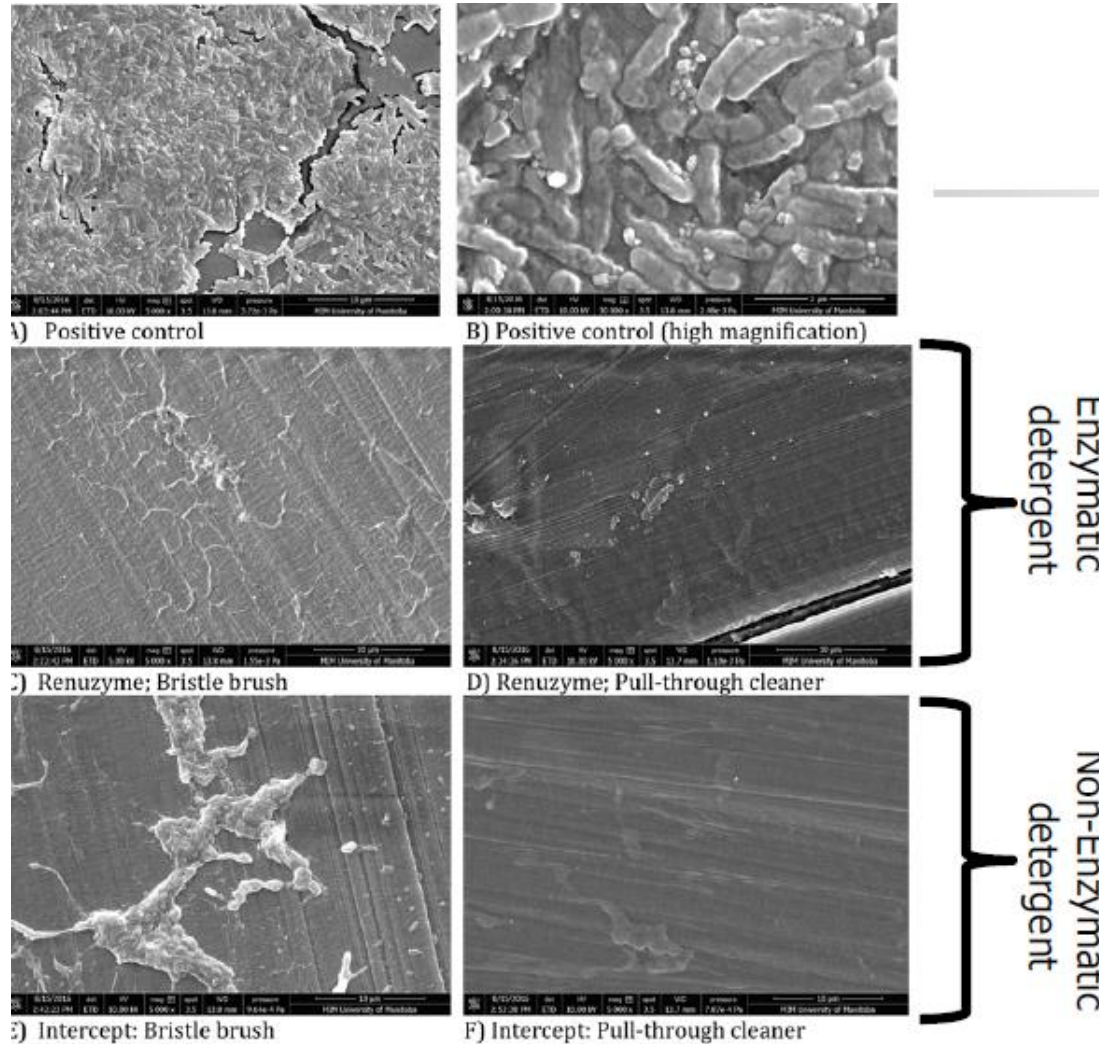
Consensus

- Documenting the lever position for ERCP scopes is probably not a bad thing or at least have it in your checklist

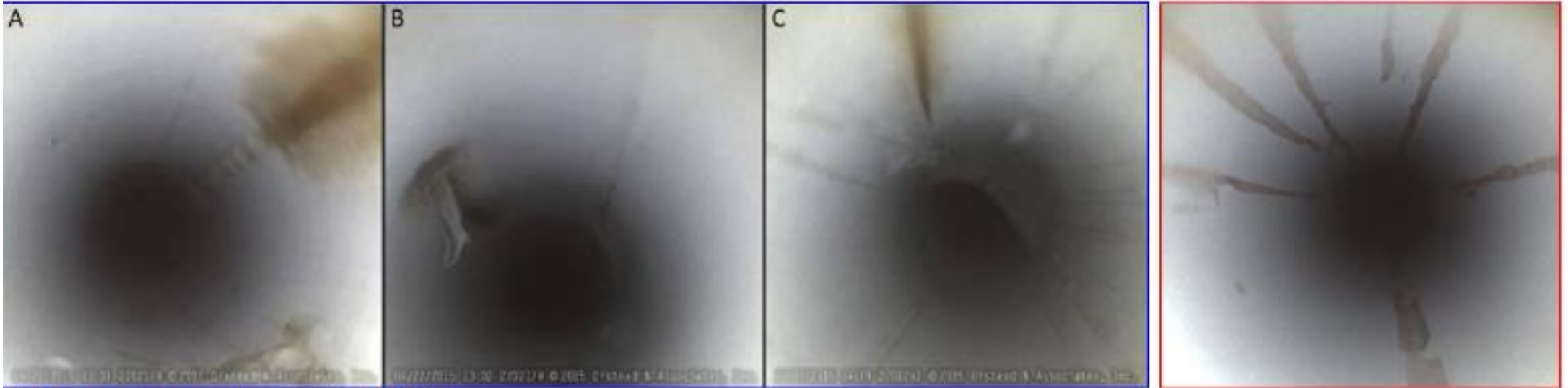
Brushes or Pull throughs



Let the pictures speak for themselves



Streaks hmmm



Ofstead et al AJIC 2017

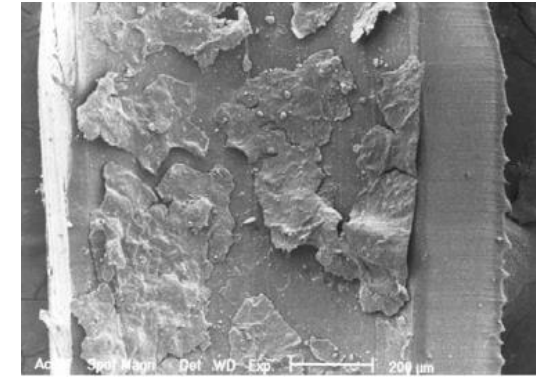
Alfa et al GIE 2017

Following the IFU is essential

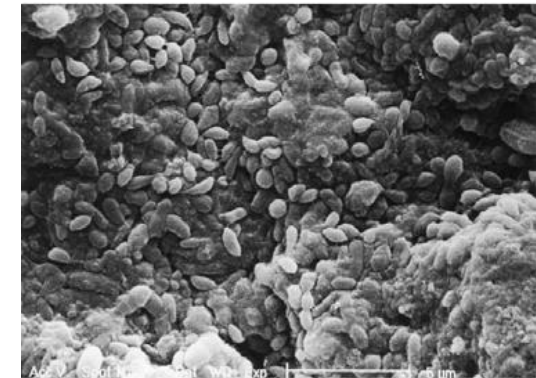
- Most IFUs don't have pull throughs
- Adding a pull-through and then brushing may make the most sense

Drying the Key to Preventing Biofilm

- Biofilm cannot form in a completely dry channel
- Yet we know biofilm does form in scopes
- **2004:** Air/Water channel of GI flexible endoscopes
Pajkos et al J Hosp Infect 2004;58:224-9
- **2014:** SEM showed biofilm in 54.6% of 66 Biopsy channels and 76.9% of 13 Air/water channels Ren-Pei W
AJIC 2014; 42:1203-6

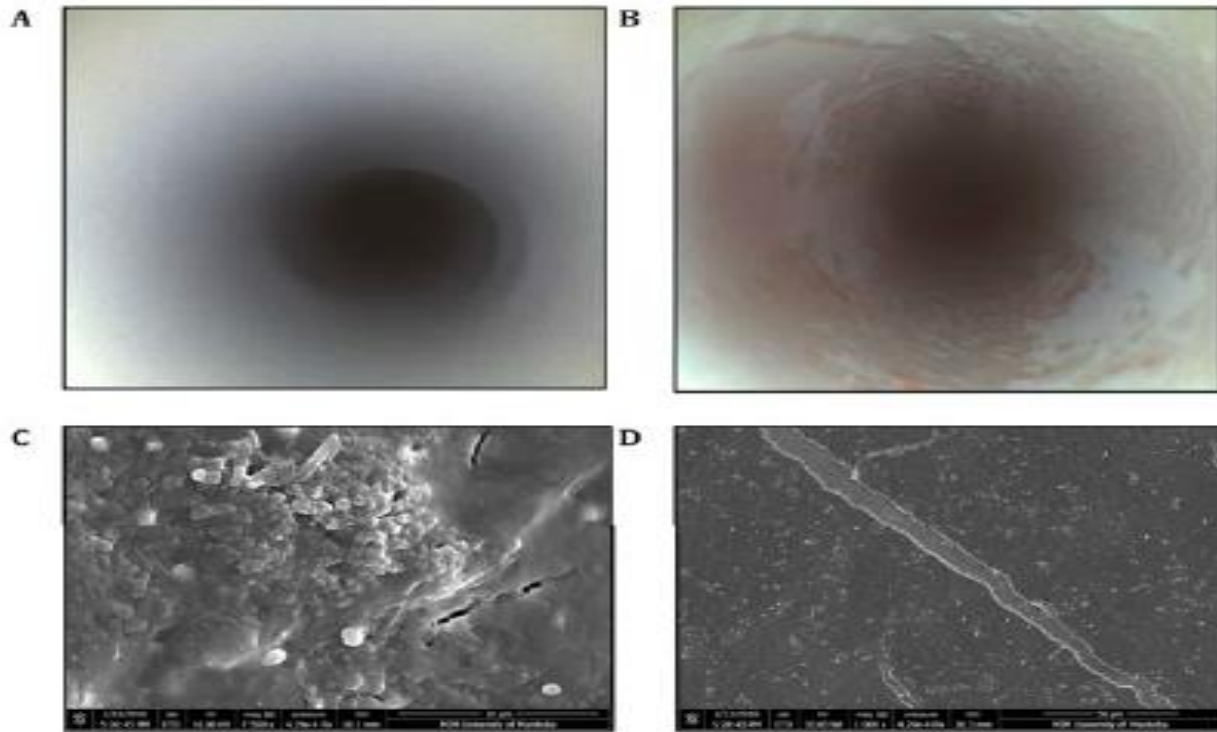


(a)



Build-up Biofilm Model

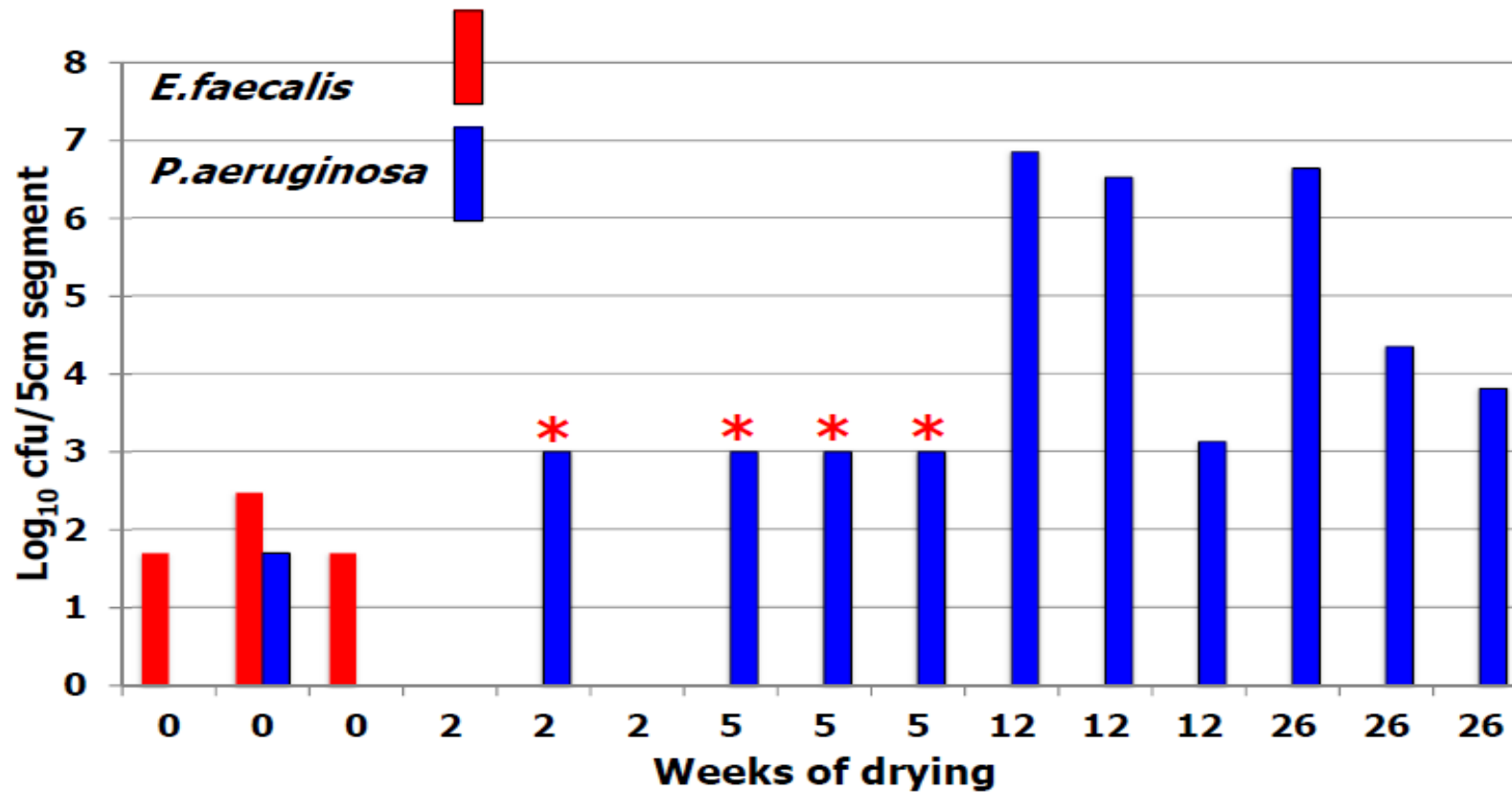
Repeated rounds of biofilm formation in PTFE followed by mild fixation with glutaraldehyde



- 1) Repeated rounds (8 days) of biofilm formation & 1:50 Glutaraldehyde fixation
- 2) Final step: full treatment 2.5% Glutaraldehyde, RT for 20 mins

What does this mean for hang times? (lumen model)

PTFE-BBF channel stored at room temperature



Wait, where did this bacteria come from if they were not there when we cultured them earlier?

- The answer may lay with “viable but non-culturable” (VBNC) bacteria. Bacteria puts its energy into repairing itself deferring reproduction
- Li et al Frontiers Microbiol 2014 VBNC bacteria have greater physical and chemical resistance due to reduced metabolic rate & strengthened cell wall
- Each bacteria has a different “window of revivability” beyond which they cannot recover to the culturable state.
- May explain differing data on culture results in clinical studies

Evidence of persistent survival post-HLD in clinical studies??

Saliou P, et al Endoscopy 2016;48:704-710

Culture: Total sample from ALL channels, neutralizer used, cultured by filtration

Endoscope type:	Number scopes tested	Target: < 25 cfu No Organisms of concern	Alert: 25-100 cfu No Organisms of concern	ACTION: > 100 cfu or: Any Organism of concern
Gastroscope	N = 270	68.3%	5.2%	26.6%
Colonoscope	N = 190	61.1%	5.3%	33.7%
Duodenoscope	N = 118	60.2%	5.1%	34.7%

Findings:

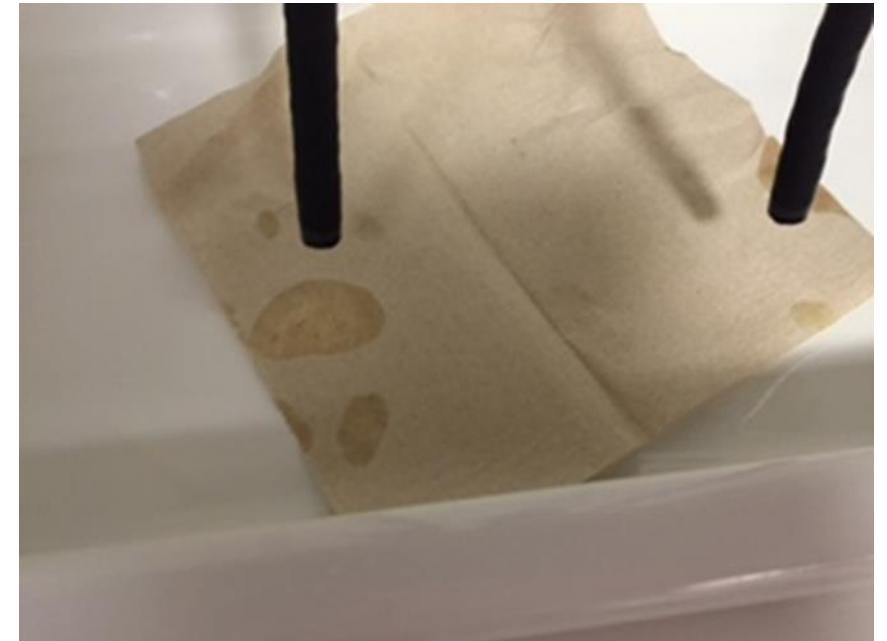
Scope Age: older the scope the higher the risk of contamination

Channel purge storage cabinet: Significantly lower contamination rates

Channel purge scope storage is much more than a “well ventilated cabinet”



The old well ventilated cabinet produced this:



IFUs, setting the process up for failure

1.2 Importance of cleaning, disinfection, and sterilization

Readability Statistics

Counts	
Words	115
Characters	758
Paragraphs	6
Sentences	3
Averages	
Sentences per Paragraph	1.5
Words per Sentence	28.6
Characters per Word	6.4
Readability	
Passive Sentences	0.0%
Flesch Reading Ease	0.0
Flesch-Kincaid Grade Level	20.9

OK

The medical literature reports incidents of cross-contamination resulting from improper cleaning, disinfection, or sterilization. It is strongly recommended that all individuals engaged in reprocessing closely observe all instructions given in this manual and the manuals of all ancillary equipment, and have a thorough understanding of the following items:

- Professional health and safety policies of your hospital
- Instruction manuals of the endoscope, accessories and all the other reprocessing equipments
- Structure and handling of endoscope and accessories
- Handling of pertinent chemicals

When selecting appropriate methods and conditions for cleaning and disinfection and sterilization, follow the policies at your institution, applicable national laws and standards, and professional society guidelines and recommended practices, in addition to the instructions given in this manual.

How many PhDs work in reprocessing?

Score	School level	Notes
100.00-90.00	5th grade	Very easy to read. Easily understood by an average 11-year-old student.
90.0–80.0	6th grade	Easy to read. Conversational English for consumers.
80.0–70.0	7th grade	Fairly easy to read.
70.0–60.0	8th & 9th grade	Plain English. Easily understood by 13- to 15-year-old students.
60.0–50.0	10th to 12th grade	Fairly difficult to read.
50.0–30.0	College	Difficult to read.
30.0–0.0	College graduate	Very difficult to read. Best understood by university graduates.

Only 253 pages of unreadable instructions

PCF-H180AL.pdf - Adobe Reader

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Table of Contents

OLYMPUS®

REPROCESSING MANUAL

INSTRUCTIONS

**EVIS
EXERA II**

EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE

- OLYMPUS GIF TYPE N180**
- OLYMPUS GIF TYPE XP180N**
- OLYMPUS GIF TYPE Q180**
- OLYMPUS GIF TYPE H180**
- OLYMPUS GIF TYPE H180J**

EVIS EXERA II COLONOVIDEOSCOPE

- OLYMPUS CF TYPE Q180AL/I**
- OLYMPUS CF TYPE H180AL/I**

You cannot reprocess blind



The need to see

- Borescopes allow us to see inside the scope
 - Not the water channel
 - Increase time scopes are lost to maintenance (appropriately as they identify issues before failure)
 - Used before placing in the AER to avoid organic material still in scope
 - May need more than one size borescope depending on scope size

Questions

