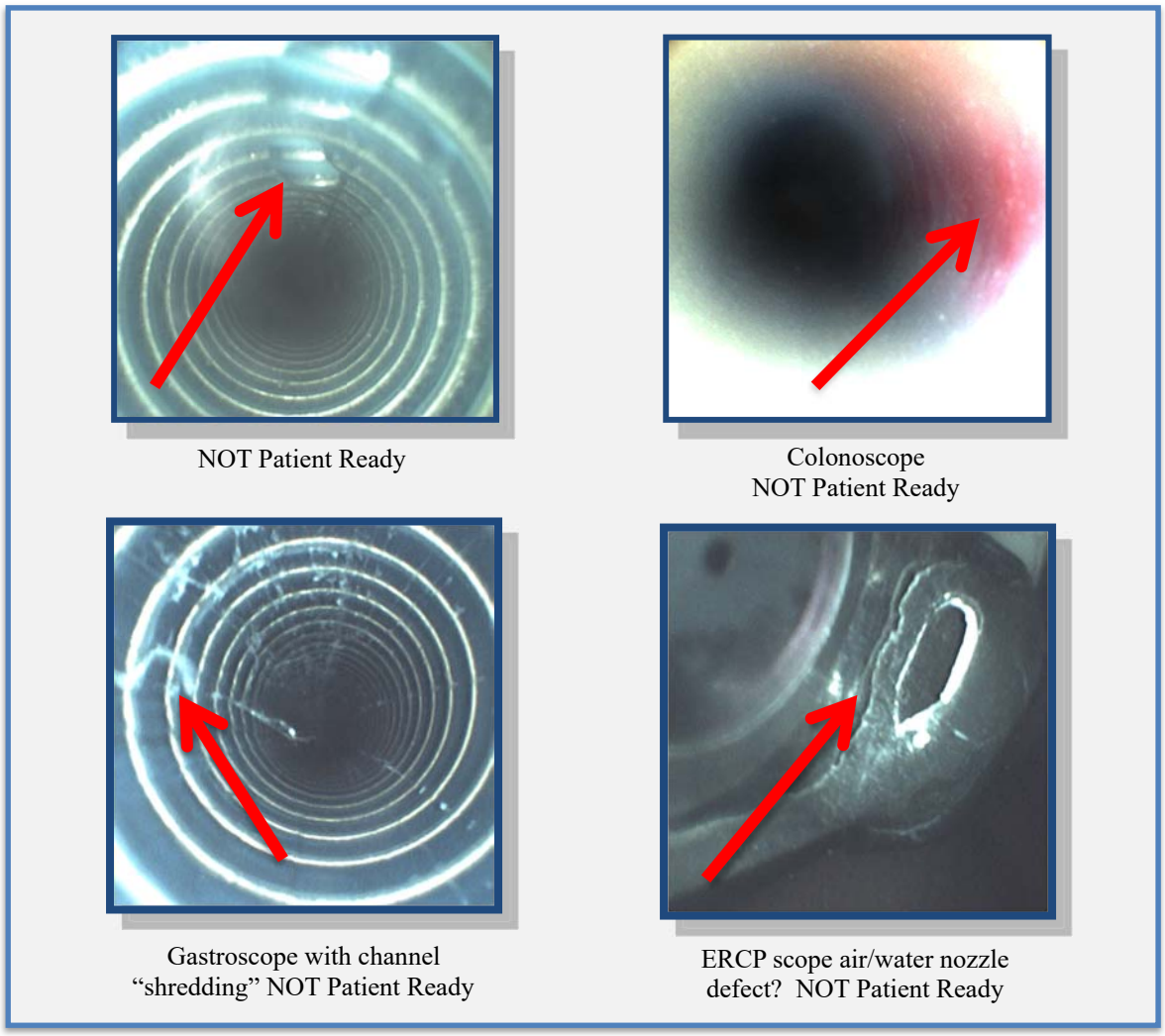
Instrument Inspection System

Preventing Healthcare Associated Infections

SteriView Technologies, Inc. 1450 N. McDowell Blvd. Suite 150 Petaluma, CA 94954

ARE YOUR INSTRUMENTS PATIENT READY?

A total of 36 inspections were done on colonoscopes and gastroscopes with the SteriView™ Inspection Scope, during which the facility staff altered their reprocessing protocol slightly to overcome findings of retained fluids in biopsy channels. These findings were noted in spite of compliance with facility policies and procedures on reprocessing that included passive air drying while hanging in a dedicated cabinet.



NOT Patient Ready

Colonoscope
NOT Patient Ready

Gastroscope with channel
"shredding" NOT Patient Ready

ERCP scope air/water nozzle
defect? NOT Patient Ready

Published studies are now emerging that show inspection of surgical and endoscopic instrumentation yields significant findings advantageous to infection control and detection of mechanical damage, **any and all of which can have serious impact on patient safety!**

In an independent study[1] conducted at the University of Minnesota Medical School demonstrated:

- 71% failed to meet the criteria for patient-ready endoscopes
- 29% harbored viable bacteria
- Contamination was highest in gastroscopes
- Damaged was detected in 9 of 17 scopes examined

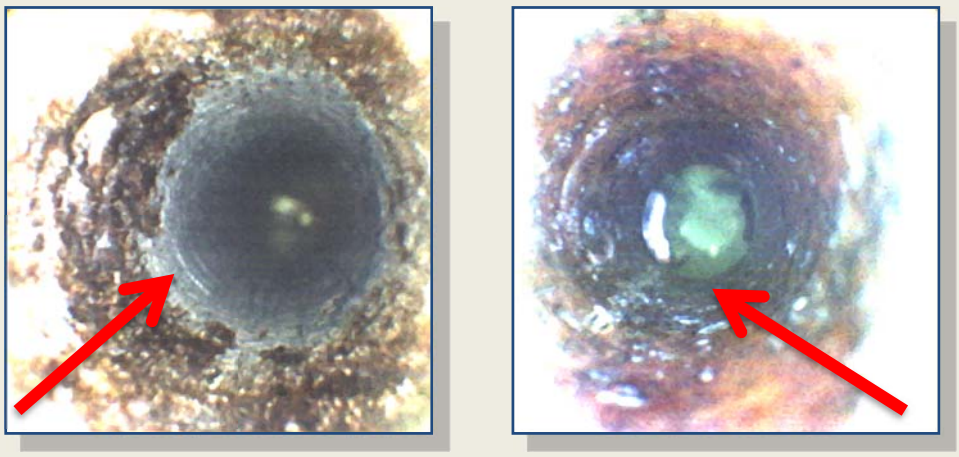
A subsequent study[2] demonstrated:

- Gastroscopes had higher ATP levels than colonoscopes.
- Borescope examinations of endoscope lumens revealed defects requiring repair.
- Microbial growth was found on approximately half of "patient-ready" endoscopes.
- Internal damage and residual fluid may foster contamination and biofilm formation.

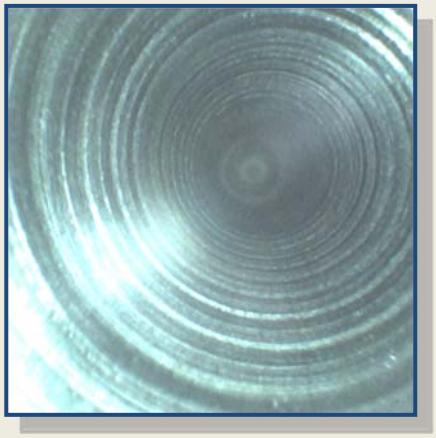
A Surgical Case Study

A series of inspections was done in early 2016, independent of any support from SteriView personnel. The lead Reprocessing Technician used the system continuously for three months, most immediately finding a number of defects inside the center's arthroscopy shaver handpieces.

There was remarkable and significant internal damage due to corrosion in all of the handpieces owned by the center. Images were taken and taken to the Clinical Manager, who presented them to the Board of Directors. The decision was made to contact the manufacturer, who promptly replaced all of the units with new ones.



Arthroscopy shaver hand -piece with significant internal corrosion
NOT Patient Ready



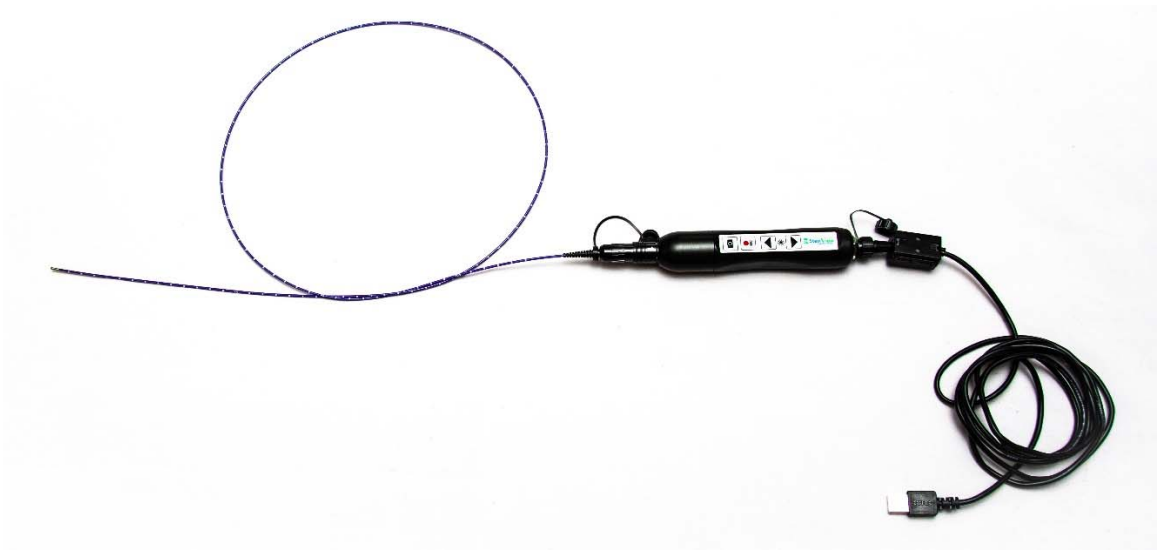
Patient Ready!

This ASC now uses the SteriView™ Inspection System routinely, as part of ongoing Quality Assurance and Process Improvement, keying on its role in verifying cleanliness as well as mechanical condition of all its lumened instrumentation. Digital imaging and file management have found use in preparation for regulatory auditing by CMS and JCAHO. This center now has a digital catalog of their reusable instruments, with time and date stamp and organized into digital folders, on a Sanovas SteriView™ laptop.

Sources:

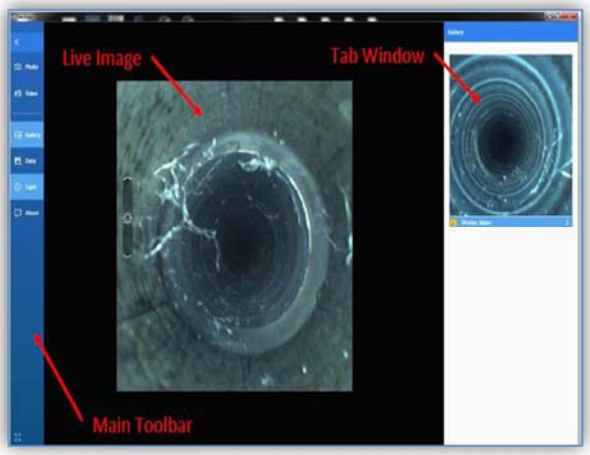
1. Residual contamination found on endoscopes in an ambulatory surgery center, Ofstead, et al; research poster, AORN 2016 http://www.aornjournal.org/article/S0001-2092(16)30166-1/abstract
2. Assessing residual contamination and damage inside flexible endoscopes over time, Ofstead et al; AJIC; 9/7/2016 http://www.ajicjournal.org/article/S0196-6553(16)30701-5/fulltext

SteriCam™ Modular Inspection Camera (MIC)



The MIC

- 1.8mm diameter x 110cm long
- The MIC is a fully digital image and not fiberoptic (no whiteout or glare)
- The MIC blade can detach from the handle
    - It allows you to interchange blades with one handle (no cross contamination or down time).
- Clean the blade in an AER (Automatic Endoscope Re-processor) for inspection of a clean endoscope. **POST HLD INSPECTION**
- Blades and handle can be cleaned with a Sani-cloth for quick turnaround. **PRE-HLD INSPECTION**



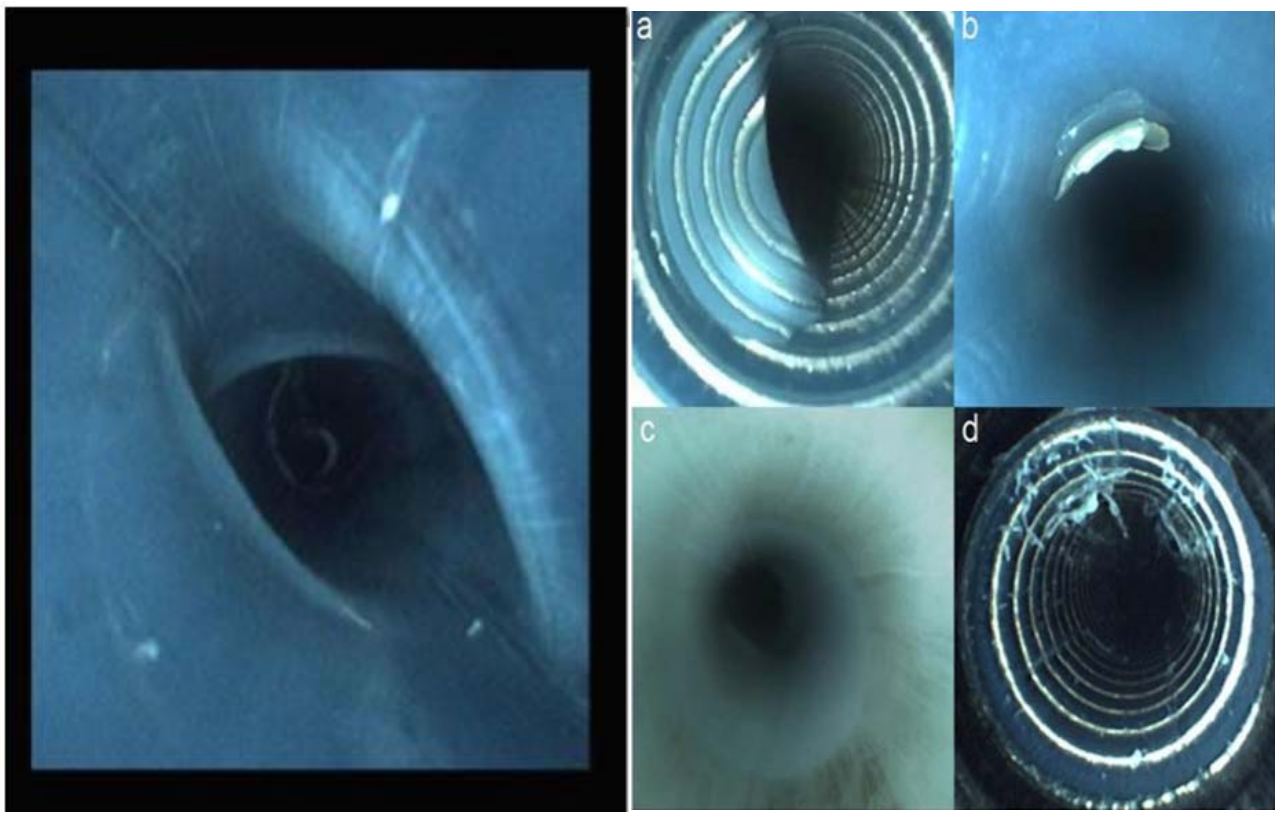
Computer System

- The SteriCam comes with SteriView's proprietary software loaded on a Surface Pro Laptop
- Images and video can be taken from either the handle or from the touchscreen laptop
- All images and videos can be cataloged by scope with references images
- All images and videos are auto date and timed stamped
- The MIC connection is via standard USB

The Image

- The native image is 400x400 pixels. With our interpolation algorithm it scales to 800x800 pixels
- Fully digital image
    - No white out glare like you would see with a fiberoptic scope
    - Less breakage than with a fiber optic bundle

Instrument Channel Inspection findings



Instrument channel inspection findings: a) retained fluid in a colonoscope. B) debris in a linear echoendoscope. C) staining and discoloration in a duodenoscope. d) scratches and shredding in the bending section of a gastroscope.

Residual contamination found on endoscopes in an ambulatory surgery center

Cori L. Ofstead, MSPH[1], John E. Eiland, RN, MS[1], Miriam R. Amelang, BA[1], Otis L. Heymann, BA[1], Sarah B. Held, RN, MBA[2], Michael J. Shaw, MD[3]

[1]Ofstead & Associates, Inc., Saint Paul, MN, USA; [2]Fairview Maple Grove Medical Center, Maple Grove, MN, USA; [3]Division of Gastroenterology, Department of Medicine, University of Minnesota Medical School, Minneapolis, MN, USA

Introduction

- Contaminated endoscopes have caused outbreaks of multidrug-resistant organisms[1-3]
- During one outbreak investigation, investigators dismantled an endoscope and identified:[3]
  - Brown staining, scale, and a small crack in the distal tip
  - Pseudomonas aeruginosa identical to outbreak strain
- In another outbreak investigation:[2]
  - Infections were tied to contaminated endoscopes
  - The manufacturer found critical defects in every duodenoscope
- This study was designed to answer two questions:
  - How much do damage and debris accumulate in endoscopes over time?
  - Is it possible to get old endoscopes clean?

Methods

- Longitudinal study in an ambulatory surgery center
- Three assessments conducted over a 7-month period
- Baseline data collection in April 2015:
  - Auditing reprocessing practices
  - Compiling data on endoscope age, usage, and repair history
  - Evaluating 17 clinically-used endoscopes:
    - Rapid indicator tests for ATP and protein
    - Microbial cultures
    - Borescope examinations of interior components
- Implementation of more rigorous reprocessing methods (beginning in May 2015)*

*Results of routine monitoring and follow-up assessments pending

Results

At the baseline assessment:

- All endoscopes were < 2.5 years old
- Endoscopes had been used 36-541 times
- Nine endoscopes had been repaired
- There was good adherence to reprocessing policies
- 16 of 17 endoscopes were still contaminated after manual cleaning
- Contamination levels were higher for gastroscopes than colonoscopes (Figures 1 and 2)

- Borescope examinations of patient-ready endoscope channels identified:
  - Residual fluid (Photos 1 and 2)
  - Irregular surfaces and brown staining (Photo 3)
  - Scratches, non-intact lining, and brown staining (Photo 4)
- Among endoscopes tested after high-level disinfection:
  - 71% failed to meet criteria for patient-ready endoscopes**
  - 29% harbored viable bacteria

**Criteria: No visible microbes and ATP and protein levels below "clean" benchmarks

Photo 1. Fluid inside the biopsy port of a gastroscope

Photo 2. Fluid inside the suction/biopsy channel of a colonoscope

Photo 3. Irregular surfaces and brown staining inside the distal end of a colonoscope

Photo 4. Scratches, non-intact lining, and brown staining in the bending section of a colonoscope

Figure 1. ATP test results after manual cleaning

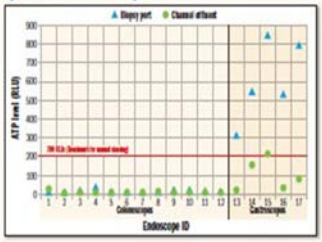
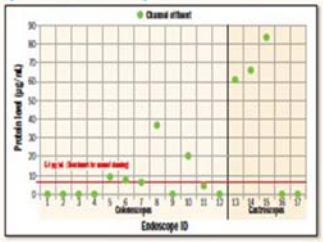


Figure 2. Protein test results after manual cleaning



Summary and next steps

Looking inside reprocessed endoscopes revealed damage and debris

- During the baseline assessment, researchers found:
  - Damage and debris inside channels
  - Contamination levels exceeding benchmarks
  - Residual fluid in channels and ports
- Findings indicated that current reprocessing methods were not sufficient
- Interventions included:
  - Sending endoscopes out for repair
  - Adopting more rigorous reprocessing practices
  - Implementing routine ATP monitoring of cleaning effectiveness
  - Increasing forced air drying times
- Results from the interim and final assessments are forthcoming
  - Observations from unannounced audits of reprocessing practices
  - Impact of interventions designed to improve reprocessing
  - Changes in contamination levels and visual appearance over a 7-month period

Disclosures and acknowledgements

The study was conducted independently by researchers from Ofstead & Associates, Inc., the University of Minnesota, and Fairview Maple Grove Medical Center. The study was supported in part by research grants from 3M Company, MedVators, Inc., and HealthMark Industries. Study sponsors did not have access to the data nor participate in developing the content of this poster.

References

1. Epstein L, et al. JAMA. 2014;312(14):1447-1455.
2. Weber DJ, et al. ICHE. 2015;36(8):634-642.
3. Marsh JW, et al. PLoS One. 2015;10(12):1-18.
4. Kovaleva J, et al. Clin Microbiol Rev. 2013;26(2):231-254.
5. Verfaillie CJ, et al. Endoscopy. 2015;47(9):805-811.

NATIONAL MULTI-CENTER INSTRUMENT LUMEN INSPECTION SURVEY
71 HOSPITALS PARTICIPATED

Instrument Category	# of inst.	Dirty	%
Arthroscopic Shavers	94	76	81%
Suction Tubes	480	348	73%
Orthopedic Cannulated Instruments	141	101	72%
Laparoscopic Instruments	112	75	67%
Miscellaneous Cannulated Instruments	22	13	59%
Flexible Endoscopes	9	4	44%
Robotic Instruments	11	2	18%
Total	**860**	**613**	**70%**

AORN - "personnel should use lighted magnification for the inspection and inspect internal channels using an endoscopic camera or borescope (i.e., a device used to inspect the inside of an instrument through a small opening or lumen of the instrument).

SGNA - "Visual inspection is an essential step to make sure the endoscope is visibly clean (AAMI, 2015; Rutala et al., 2008). Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris) (FDA, 2009; AAMI, 2015

ASGE - "Visually inspect both endoscopes and reusable accessories frequently in the course of their use and reprocessing, including before, during and after use, as well after cleaning and before high-level disinfection."

ANSI - Referred to above, ST 79; "After completing the cleaning process, personnel should visually inspect each item carefully to detect any visible soil…Inspection using magnification might identify residues more readily than the unaided eye." There's additional discussion about using methods to measure residues not detectable using visual inspection.

AAMI - "Cleaning verification is performed following cleaning to verify the effectiveness of a cleaning process prior to disinfection…should include visual inspection…testing of the cleaning efficacy of mechanical equipment…monitoring of key cleaning parameters"

CMS - the ASC Infection Control Audit Tool discusses visual inspection and compliance with manufacturers' IFUs. Another resource for CMS audits required drying of reusable instrumentation after reprocessing, which you *cannot verify without an inspection scope.*

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For information, details on these studies, or a demonstration at your facility.