Building Quality into Endoscope Reprocessing

Sharon Ann Van Wicklin, PhD(c), MSN, RN, CNOR, CRNFA(E), CPSN-R, PLNC, FAAN, ISPAN-F
Sharon A. Van Wicklin, PhD(c), MSN, RN, CNOR, CRNFA(E), CPSN-R, PLNC, FAAN, ISPAN-F

- BSN and MSN: Middle Tennessee State University
- PhD(c): University of Missouri
- Membership:
  - Phi Kappa Phi
  - Sigma Theta Tau Honor Society
- Certification/Fellowship:
  - CNOR (operating room nurse)
  - CRNFA(E) (RN first assistant-emeritus)
  - CPSN-R (plastic surgical nurse-retired)
  - PLNC (professional legal nurse consultant)
  - FAAN (Fellow American Academy of Nursing)
  - ISPAN-F (Fellow International Society of Plastic and Aesthetic Nursing)
- Lead author:
  - Guideline for Sterile Technique (2012)
  - Guideline for Specimen Management (2014)
  - Guideline for Autologous Tissue Management (2014)
  - Guideline for Processing Flexible Endoscopes (2016)
  - Guideline for Positioning the Patient (2017)
- Co-author:
  - Guideline for Surgical Attire (2014)
- Recipient:
  - AORN Outstanding Achievement in the Application of Perioperative Clinical Research Award, 2005
Objectives

1. Explain the importance of oversight by an interdisciplinary team
2. Identify areas where cleaning verification is needed
3. Discuss the evidence supporting enhanced visual inspection and cleaning verification
4. Describe types of rapid cleaning verification tests currently available
Interdisciplinary Team
Interdisciplinary Team
If it’s not clean, or if it’s damaged, the disinfection or sterilization process can fail!
Cycle of Processing

ACQUISITION:
1. PURCHASE
2. LOAN
3. REPAIR

TRANSPORT

PRECLEAN

LEAK TEST

FAIL

CLEAN

INSPECTION

FAIL

HIGH-LEVEL DISINFECTION OR LIQUID CHEMICAL STERILIZATION

PACKAGE & STERILIZE

USE

STORAGE

DISPOSITION:
1. DECONTAMINATE AND REPAIR
2. DISCARD

Images courtesy of Healthmark Industries
Magnification

Small Object → Magnifier → Big Object

Magnification by unknown author is licensed under CC BY-SA [modifications: cropped, resized]
Inspection using magnification and additional illumination might identify residues more readily than the unaided eye. (p39)
Lighted magnification should be used to inspect endoscopes and accessories for cleanliness and damage. (p829)
Use magnification and adequate lighting to help assist in visual inspection. (p18)
Without magnification

Image courtesy of Healthmark Industries
With magnification

Image courtesy of Healthmark Industries
Without magnification

Image courtesy of Healthmark Industries
With magnification

Image courtesy of Healthmark Industries
With magnification

Bioburden

Cracks/Chips

Images courtesy of Healthmark Industries
Types and Strengths of Magnification

- **USB Microscope**: 5x to 270x
- **OptiVisor**: 3.5x
- **Magic Touch**: 3x
- **Pocket Magnifier**: 4x
- **Hand-held Multi-Magnifier**: 3x, 10, 55x
- **Pocket Microscope**: 20x to 40x
- **Adjustable Arm Magnifier**: 3x

Images courtesy of Healthmark Industries
Borescope Inspection

- Borescopes penetrate device lumens and allow for enhanced visual inspection

Image courtesy of Healthmark Industries
Tools such as video borescopes of an appropriate dimension may be used to visually inspect the internal channels of some medical devices.\(^\text{(p}39\text{)}\)
Internal channels of flexible endoscopes may be inspected using an endoscopic camera or borescope. (p829)
Borescope Inspection

- Ofstead et al\textsuperscript{12}
  - Borescope inspection revealed
    - Discoloration
    - Scratches
    - Filaments of debris
    - Residual fluid
    - Simethicone
  - Manufacturer found critical defects
Borescope Inspection

- Rust, debris, blood
- Scratches, retained debris
- Fluid
- Debris around lenses
- Rust, debris
- Simethicone

Images courtesy of Healthmark Industries
Borescope Inspection

Tosh et al\textsuperscript{13}

- Reported an outbreak of \textit{Pseudomonas aeruginosa} SSIs in seven patients
  - Same arthroscopic shaver used for all patients
  - Debris in shaver lumen despite repeated cleaning and steam sterilization procedures
METHOD

A highly publicized outbreak at a University hospital in 1984 was caused by skin-infecting bacteria that normally live on the skin. To prevent the bacteria from reaching the patient, the hospital took several measures to reduce the risk of infection. The study suggested that pre-packaged surgical instruments, which were sealed in sterile packaging, were a major source of infection. The study also suggested that better training of healthcare workers on proper handling of medical devices was needed.

SURVEY RESULTS

From January 2013 to present, a total of 47 outbreaks at various institutions were linked to the following:

- Poor disinfection of medical devices
- Improper sterilization of medical devices
- Inadequate cleaning of medical devices
- Improper use of medical devices

EXAMPLES OF DEBRIS FOUND IN SHAVERS AFTER CLEANING

- Hair, blood, and tissue
- Lint and dust

DISCUSSION

Since 2001, the WHO has called for improved infection control practices to reduce the risk of hospital-acquired infections in various medical devices. A study published in the Journal of Hospital Infection showed that proper disinfection of medical devices significantly reduced the risk of infection. The study also suggested that healthcare workers should be trained on proper handling and maintenance of medical devices.
Borescope Inspection

- FDA/AAMI Medical Device Reprocessing Summit (October, 2011)
  - Manufacturer of arthroscopic shaver audited 78 shavers from 12 facilities
    - None complied with all steps in IFU
    - 95% had residue on internal surfaces
  - Borescope developed by American-based company
Do you process arthroscopic shavers in your facility? (N = 1606)

- Yes: n = 1224 (76%)
- No: n = 285 (18%)
- Unsure: n = 97 (6%)
Do you use enhanced visual inspection? (N = 1224)

- Yes: n = 1224 (76%)
- No: n = 285 (18%)
- Unsure: n = 97 (6%)
Borescope Inspection

- Audit of 8 arthroscopic shavers from 3 sterile processing departments processed without borescopic inspection
  - Department 1: 4 of 7 shavers were dirty (57%)
  - Department 2: 1 of 2 shavers were dirty (50%)
  - Department 3: 3 of 3 shavers were dirty (100%)
Rapid Cleaning Verification

- Manual cleaning subject to human error
- Inspection alone may not be sufficient
- Rapid testing methods necessary to verify the adequacy of manual cleaning
  - Provides objective method for verifying cleanliness
  - Helps ensure insufficiently cleaned items are recleaned
Rapid Cleaning Verification

- Helps verify cleaning effectiveness
- Rapid cleaning verification tests include
  - Adenosine triphosphate (ATP)
  - Hemoglobin
  - Protein
  - Carbohydrate
- No single method established as the standard
The use of methods that are able to detect organic residues that are not detectable using visual inspection should be considered." (p39)
Manual cleaning of flexible endoscopes should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals... (p858)
...to confirm the adequacy of manual cleaning, a rapid cleaning monitor...for residual organic soil can be used prior to high-level disinfection. (p18)
Rapid Cleaning Verification

- Visrodia et al\textsuperscript{18}
  - Sampled 12 endoscopes after precleaning and manual cleaning (37 examinations)
    - Inspected 121 endoscope components
    - Conducted 249 rapid cleaning verification tests
  - After precleaning: 100% had high levels of ATP and detectable blood and protein
  - After manual cleaning: 82% had at least one positive cleaning verification test
Rapid Cleaning Verification

- **Ofstead et al**\(^25\)
  - Performed 60 examinations of 15 endoscopes

<table>
<thead>
<tr>
<th>Testing Phase</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precleaning</td>
<td>• 13 of 13 endoscopes (100%) had detectable ATP, hemoglobin, and protein</td>
</tr>
<tr>
<td></td>
<td>• 12 of 13 (92%) had viable microorganisms</td>
</tr>
<tr>
<td>Manual cleaning</td>
<td>• 12 of 13 endoscopes (92%) had ATP or protein</td>
</tr>
<tr>
<td></td>
<td>• 6 of 13 (46%) had at least one positive culture</td>
</tr>
<tr>
<td>HLD</td>
<td>• 8 of 11 endoscopes (73%) positive for contamination</td>
</tr>
<tr>
<td></td>
<td>• 7 of 11 (64%) had viable microorganisms</td>
</tr>
<tr>
<td>Storage</td>
<td>• 9 of 11 endoscopes (82%) positive for contamination</td>
</tr>
<tr>
<td></td>
<td>• 1 of 11 (9%) had viable microorganisms</td>
</tr>
</tbody>
</table>

- Rapid cleaning verification tests reliable and valid
- Beneficial to test for ATP and protein
Flexible Endoscope Lumen Test


*Image courtesy of Healthmark Industries*
**Flexible Endoscope Lumen Test**

<table>
<thead>
<tr>
<th>Result</th>
<th>Potential problem</th>
</tr>
</thead>
</table>
| Both test soils completely removed         | • Insufficient cleaning time
   • Incorrect temperature
   • Inadequate detergent efficacy or incorrect concentration |
| • Polysaccharide soil completely removed    | • Water temperature too high
   • Disinfectants introduced during wash cycle |
| • Visible fibrin remains                    | • Insufficient cleaning time
   • Incorrect temperature
   • Inadequate detergent efficacy or incorrect concentration |
| • Visible blood soil remains                | • Inadequate water flow
   • Poor connection
   • Failed cleaning program
   • Major machine functional issue |
| • Polysaccharide soil completely removed    | • Blood soil completely removed
   • Visible polysaccharide remains |
| • Visible blood soil remains                | • Before test or
   • Both soils remain |

Images courtesy of Healthmark Industries
Adenosine Triphosphate (ATP) Test

- Energy source for all living cells
- Excellent marker for biological contamination
- Provides results in 30 seconds
- Use with hemoglobin or protein test
Hemoglobin Test

- Detects residual blood as low as 0.1μg
- Provides results in 30 seconds

Blue-green = positive

Images courtesy of Healthmark Industries
Hemoglobin Test

- Winthrop et al\textsuperscript{26}
  - 23 of 139 loaned instrument sets (16.6\%) positive for blood residue
  - 6 of 23 sets (26.1\%) visibly contaminated

Blue-green = positive

Images courtesy of Healthmark Industries
Protein Test

- Washburn and Pietsch\(^{27}\)
  - Obtained 660 samples from 90 endoscopes
  - ATP, protein, Gram-negative bacteria
  - After manual cleaning, HLD, storage
  - When protein identified after manual cleaning, also identified after HLD

Image courtesy of Healthmark Industries
Combination Channel/Lumen Test

Protein, carbohydrate, hemoglobin

**Carbohydrate**
- Detects glucose using the glucose oxidase test
- Color changes from blue to light green when glucose is present
- Limit of detection: ≥ 210 μg/mL

**Protein**
- Detects protein using the pH indicator, Bromophenol blue
- Color changes from yellow to blue-green when protein is present
- Limit of detection: ≥ 120 μg/mL

**Hemoglobin**
- Detects hemoglobin using a peroxide reaction
- Color changes from orange to dark blue when hemoglobin is present
- Limit of detection: ≥ 0.25 μg/mL

Most common endoscope soils

Images courtesy of Healthmark Industries
Endoscope Channel Test

- Detects residual blood or protein in channels

Image courtesy of Healthmark Industries
Endoscope Sampling

- Sample sent to accredited laboratory
- Laboratory performs independent testing
  - If present, organisms are identified and quantified
Gram-negative Bacteria Test

- 12-hour test detects Gram-negative bacteria after HLD
- Detects 10 CFU
- May detect as few as 1 CFU
- Washburn and Pietsch\(^{27}\)
  - Provided results similar to microbiological cultures
Executive Summary

1. Interdisciplinary team
Executive Summary

2. Cleaning verification

Images courtesy of Healthmark Industries
References

References


Sharon A. Van Wicklin, PhD(c), MSN, RN, CNOR, CRNFA(E), CPSN-R, PLNC, FAAN, ISPAN-F

SharonVWRN@aol.com