Medical Instrument Reprocessing: Current issues with cleaning and cleaning monitoring

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Objectives:

- **Surgical instruments**
  - Automated versus manual cleaning
  - Fragile instruments

- **Flexible Endoscopes**
  - Lumens and role of friction

- **Monitoring cleaning: quality systems**

- **Summary**
Surgical Instruments:

Table 1
Contamination levels on devices after surgical procedures

<table>
<thead>
<tr>
<th>Surgery type (no. of devices)</th>
<th>Bacteria (CFU)</th>
<th>TOC (µg)</th>
<th>Protein (µg)</th>
<th>Hemoglobin (µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VP shunt (18)</td>
<td>1.0 ± 1.0 (0.03 ± 0.04)</td>
<td>1,626 ± 2,612 (47 ± 111)</td>
<td>4,388 ± 5,440 (107 ± 160)</td>
<td>144 ± 269 (2.9 ± 8.1)</td>
</tr>
<tr>
<td>Craniofacial (10)</td>
<td>2.7 ± 3.4 (0.05 ± 0.08)</td>
<td>1,026 ± 946 (23 ± 26)</td>
<td>7,883 ± 13,279 (99 ± 133)</td>
<td>1,138 ± 8.1 (10 ± 30)</td>
</tr>
<tr>
<td>Orthopedic (18)</td>
<td>13.0 ± 24.0 (0.23 ± 0.39)</td>
<td>3,813 ± 4,844 (64 ± 101)</td>
<td>50,817 ± 66,941 (942 ± 1471)</td>
<td>1,141 ± 1,733 (20 ± 40)</td>
</tr>
<tr>
<td>C-section (26)</td>
<td>88.0 ± 124.0 (0.72 ± 1.0)</td>
<td>7,340 ± 4,850 (63 ± 84)</td>
<td>6,944 ± 12,565 (47 ± 75)</td>
<td>3,802 ± 4,517 (34 ± 74)</td>
</tr>
<tr>
<td>Spinal (16)</td>
<td>0.9 ± 1.6 (0.01 ± 0.02)</td>
<td>2,808 ± 2,397 (44 ± 55)</td>
<td>293 ± 291 (4 ± 3)</td>
<td>774 ± 1,298 (9 ± 13)</td>
</tr>
</tbody>
</table>

NOTE. Values are averages ± SD.
C-section, caesarean section; CFU, colony forming units; TOC, total organic carbon; VP, ventriculoperitoneal.

Organic residuals:  High
Microbial residuals:  Low

Healthcare Facilities: Medical devices are cleaned manually & by automated washers

How can you be sure instruments have been properly cleaned?
Many commercial WD cleaning indicators

Representative examples

STERIS: Verify All
Clean WD indicator

Steritec Wash-Checks

GKE Multilevel WD cleaning indicator

CHEMDYE Splat Test
WD indicator

TOSI WD indicator
What about fragile instruments that cannot be cleaned in WD?

- Eye surgery instruments
Phaco surgery:
- the natural lens, is broken up by ultrasound, and suctioned out.

- An artificial lens is implanted
Phaco emulsion handpiece

Images from Surgical Design Corporation Website
Toxic Anterior Segment Syndrome (TASS)

- Entry of a non infectious material in the anterior segment
- 12 to 48 hours after surgery
- Limited to anterior segment
- Gram stain and culture negative
Reprocessing of surgical instruments used for cataract surgery

- MIFU indicates no detergent cleaning, only flushing with sterile distilled or RO water
- Automated flushing units or manual flushing
- How to evaluate cleaning adequacy?
1. Follow validated manufacturer’s instructions
2. Ensure adequate cleaning equipment and utilities available on site (water quality)
3. Ensure staff training and ongoing competency assessment**
4. Monitor cleaning adequacy
   - test cleaned instruments
   - test washers
Medical Instruments: Monitoring adequacy cleaning

- Visual inspection: magnifier lamp
- Rapid swab tests
  - swabs to detect protein, hemoglobin
  - ATP
- Automated “ProReveal”
  - spray stain (OPA/NAC) on instrument
  - reprocess instruments analyzed
Ninhydrin testing for residual Protein on surgical instruments

1) Does not detect all proteins
2) Many false negative tests

ATP Test for Cleaning

Cleaned instruments: Manual or automated

ATP sample: Swab defined sites

ATP test: Level of residual ATP indicates if cleaning adequate or not

ATP: high levels in human secretions, low levels in microbes
ATP testing:
Cutoff for adequate cleaning?

- Endoscope cleaning; cutoffs published
- Surgical Instruments; needs more data

Pro-Reveal: Assess cleaned instruments for residual protein

1. Spray instrument with fluorescent stain solution

2. Place instrument in Pro-Reveal tray

3. Pro-Reveal evaluates for fluorescent stained residual protein

http://www.synopticshealth.com/proreveal-test/
Pro-Reveal detection of bovine serum albumin (BSA) spotted onto stainless steel surface

Results: Image and Interpretation

Cannot assess adequacy of cleaning inside lumens

http://www.synopticshealth.com/prorveal-test/
Can current duodenoscope MIFU reprocessing eliminate traditional biofilm?
PTFE Biofilm Model
(ISO 15883-2005 Annex F)

- Biofilm allowed to form overnight in PTFE channel
- MIFU pump-assisted cleaning combined with LCS performed
- Process repeated for 5 times (i.e. 5 consecutive days)
- Culture (concentration) and SEM to assess biofilm removal
## Five Repeated Rounds of Reprocessing

<table>
<thead>
<tr>
<th>Test Condition</th>
<th><em>E. faecalis</em> Log$_{10}$ CFU/cm$^2$</th>
<th><em>P. aeruginosa</em> Log$_{10}$ CFU/cm$^2$</th>
<th>Protein ug/cm$^2$</th>
<th>ATP Log$_{10}$ RLUs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Positive control</strong></td>
<td>7.72 (0.09)</td>
<td>9.10 (0.09)</td>
<td>172.31 (13.30)</td>
<td>5.35 (0.04)</td>
</tr>
<tr>
<td>No cleaning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No AER</td>
<td></td>
<td></td>
<td></td>
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</tr>
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</table>

Alfa et al 2017 ICHE
Bristle brush

Enzymatic detergent

Non-Enzymatic detergent

Pull-through cleaner

Alfa et al 2017 ICHE

A) Positive control

B) Positive control (high magnification)

C) Renuzyme; Bristle brush

D) Renuzyme; Pull-through cleaner

E) Intercept: Bristle brush

F) Intercept: Pull-through cleaner
ATP Monitoring of Cleaning: flexible endoscopes

<table>
<thead>
<tr>
<th>Stage of ATP Testing</th>
<th>RLU (Mean)</th>
<th>Number Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>After bedside flush</td>
<td>19437</td>
<td>180</td>
</tr>
<tr>
<td>Post Manual Cleaning</td>
<td>667</td>
<td>176</td>
</tr>
<tr>
<td>Post-AER</td>
<td>227</td>
<td>180</td>
</tr>
<tr>
<td>Sterile water</td>
<td>7.8</td>
<td>173</td>
</tr>
</tbody>
</table>

*The big advantage of the method is that it is done fast and results are obtained on-site so that instant conclusions can be drawn.*
Quality Systems: Monitoring medical device cleaning

- What is the “benchmark” for “Clean”?
- What monitoring test to use?
- What is the best frequency of testing?
- How does it fit into busy work hospital work-flow?
- Is it sensitive enough?

Questions
Quality Assurance Program:
ANSI/AAMI ST79 & CSA Z314.8 recommend **weekly (preferably daily) monitoring of mechanical washer cleaning efficacy**

- **Site implementation:**
  - Establish site baseline: initial daily testing of fragile instruments for a short period of time
  - Ongoing each testing minimally 1/week

- **Published data needed:**
  - Comparisons of various cleaning monitors
  - Impact of monitoring on improving detection of inadequate manual cleaning
Stop Dirty Medical Devices at the Cleaning stage!!

- Once disinfected or sterilized residues are fixed → hard to extract and analyze.
- Fragile instruments: No validated rapid cleaning monitoring methods
- Needs more research
Monitoring tests need to be validated

- 2016 Bill in USA House of Representatives:
  - Cleaning monitoring tests will be regulated along with medical devices
  - Manufacturers need to validate cleaning monitoring tests
Is Monitoring Cleaning worthwhile???

<table>
<thead>
<tr>
<th>Monitoring of:</th>
<th>Methods:</th>
<th>Pros</th>
<th>Cons</th>
<th>Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical instruments</td>
<td>- ATP test</td>
<td>- Ensures cleaning done properly</td>
<td>- Cost</td>
<td>- Guidelines: variable</td>
</tr>
<tr>
<td></td>
<td>- Organic residual</td>
<td>- Good audit &amp; training tool</td>
<td>- Staff time</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Pro-Reveal</td>
<td></td>
<td>- Frequency of testing?</td>
<td></td>
</tr>
</tbody>
</table>


Paradigm Shift: Medical Device Cleaning

Quality System Process:

1. Validated Manufacturer’s cleaning instructions
2. Staff training & appropriate cleaning equipment
3. Cleaning monitoring
4. HLD and Sterilization monitoring
Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

Recommendations:
- Quality Systems approach
- Training & ongoing competency assessment of staff**
- Audit & Feedback
- Infection Control Policies and Procedures
Remember.... Protect yourself from the RISK!!