Reprocessing of Implants: What are the Issues?

Dr. Michelle J. Alfa, Ph.D., FCCM
Medical Director, Clinical Microbiology, Diagnostic Services of Manitoba, Winnipeg, Canada
Disclaimers: Dr. M. Alfa

- Sponsored to give invited presentations at various National and International conferences by: STERIS, 3M, J&J, Healthmark, Virox, Medisafe, Ontario Hospital Association, CHICA, and multiple conference associations.
- The University of Manitoba has licensed my patent for Artificial Test Soil to Healthmark.
- Research projects for STERIS, 3M, J&J, Novaflux, Virox, Olympus, Medisafe, Case Medical (no funds from these research projects comes to me personally – it is all handled by the St. Boniface Research Centre).
- Three day educational workshop on Microbiology for 3M
- On advisory panels and/or provided consulting advice for STERIS, Getinge, 3M, J&J, and Novaflux.
Overview:

- Implants: Screws, plates, wires
  - reprocessing of screws, plates, wires
- Published data
  - Endotoxin residuals post-cleaning
  - Effect of foreign material on implant
  - Effect of repeated reprocessing
- What can users do?
Implants are Single use devices (SUDs)

Implants include:
- joints, plates, rods
- screws, wires used to immobilize implant

Variable composition:
- stainless steel (most common)
- titanium
- polymers (e.g. polyethylene)
Issue of Reprocessing of Implants

- Joints provided sterile or sterilized just prior to implantation.
- **Stainless steel plates, screws, rods, wires are implants but are treated like surgical instruments** - washed, steam sterilized repeatedly until implanted
Example: Fragment Tray Surgical set (ORSY-690SMSET)

- Screws to hold implant in place
- Surgical instruments used for surgery
- Implants used to stabilize bone: SUD

Picture from Synthes website; March 2, 2010

Copyright: Dr. Michelle J. Alfa
Every time instrument set is exposed to:

**CLEANING:**
- Pre-treatment: enzymatic detergent
- Cleaning: chemical detergent
- Final Rinse: Tap water (or Deionized, RO)

**STERILIZATION:**
- Steam
Published Data: Is there anything to worry about?

- **Surgical instruments**;
  - any evidence of residuals?
- **Implants**;
  - what causes aseptic loosening?
Study to evaluate patient-used instrument residuals pre and post cleaning

- Five instruments (most commonly used)
- Total of 10 patient procedures evaluated
  - 5 patient-used before cleaning
  - 5 patient-used post-cleaning
- Surface area swabbed: $1\text{cm}^2$

- Protein, Hg, Carb, LPS

Residuals on Patient-used instruments post-cleaning: Automated washer

<table>
<thead>
<tr>
<th>Plastics Tray Instrument type: (visible soil after use)</th>
<th>Protein: (μg/cm²) Average for 5 devices</th>
<th>Hemoglobin: (μg/cm²) Average for 5 devices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before cleaning</td>
<td>After cleaning</td>
</tr>
<tr>
<td>1. Curved Mosquito forcep</td>
<td>7.04</td>
<td>0.18</td>
</tr>
<tr>
<td>1/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1 device; 1+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Fine Needle Driver</td>
<td>49.96</td>
<td>0.00</td>
</tr>
<tr>
<td>5/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 devices; 1+, 3 devices; 3+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Curved Iris Scissors</td>
<td>373.78</td>
<td>0.14</td>
</tr>
<tr>
<td>2/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 devices; 3+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Toothed Adson forcep (fine)</td>
<td>55.38</td>
<td>1.04</td>
</tr>
<tr>
<td>4/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 devices; 1+, 2 devices; 2+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Skin Hook</td>
<td>3.36</td>
<td>3.16</td>
</tr>
<tr>
<td>1/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1 device; 1+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>97.90</td>
<td>0.90</td>
</tr>
</tbody>
</table>
Residuals on Patient-used instruments post-cleaning: Automated washer

<table>
<thead>
<tr>
<th>Plastics Tray Instrument type: (visible soil after use)</th>
<th>Carbohydrate: (μg/cm²) Average for 5 devices (SD)*</th>
<th>Endotoxin: (EU/cm²) Average for 5 devices (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before cleaning</td>
<td>After cleaning</td>
</tr>
<tr>
<td>1. Curved Mosquito forcep</td>
<td>120.52</td>
<td>301.16</td>
</tr>
<tr>
<td>1/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1 device; 1+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Fine Needle Driver</td>
<td>116.86</td>
<td>336.86</td>
</tr>
<tr>
<td>5/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 devices; 1+, 3 devices; 3+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Curved Iris Scissors</td>
<td>146.68</td>
<td>352.10</td>
</tr>
<tr>
<td>2/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 devices; 3+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Toothed Adson forcep (fine)</td>
<td>169.40</td>
<td>138.76</td>
</tr>
<tr>
<td>4/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 devices; 1+, 2 devices; 2+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Skin Hook</td>
<td>141.14</td>
<td>193.46</td>
</tr>
<tr>
<td>1/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1 device; 1+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average:</td>
<td>138.92</td>
<td>264.47</td>
</tr>
</tbody>
</table>

Residuals on Patient-used instruments post-cleaning: Automated washer
Conclusions from Study:

- Not all WD cycles had this problem (84% of instruments had higher Carb and 60% had higher Carb & LPS residuals post cleaning vs pre-cleaning Avg level)
- Likely reflected inadequate water quality → ? Final rinse water
- ? Biofilm in lines/water holding tank?

Take Home Message: Residuals Post-cleaning

- Organic residuals may remain on instrument
- Endotoxin (LPS); not destroyed by steam sterilization→ still able to cause inflammatory response
What causes Primary implant failure → Revision surgery?

**Reviewed 1366 Total Hip Arthroplasty Revisions**

- **Total Hip Arthroplasty:**
  - Aseptic loosening: 51%
  - Instability: 15%
  - Wear: 14%
  - Infection 8%

Jarari SM et al. *Revision Hip Arthroplasty Infection is the most common cause of failure.* Clin Orthop Relat Res;2010:
What causes Revision failure?

- **Revised Total Hip Arthroplasty:**
  - Aseptic loosening: 19.4%
  - Instability: 25.1%
  - Infection 30.2%

Jarari SM et al. *Revision Hip Arthroplasty Infection is the most common cause of failure.* Clin Orthop Relat Res;2010
Pathology of Aseptic Loosening

1. Wear particles: metal or polyethylene
2. Inflammatory response: T-cells, macrophages, Giant cells


Copyright: Dr. Michelle J. Alfa
The finding of only T cells has caused us to propose, and continue to seek evidence for, an immunological reaction in the presence of wear debris.

Review: The combined role of wear particles, macrophages and lymphocytes in the loosening of total joint prostheses.

Aggregate of corrosion particles

Dark particles: metallic debris

Residuals: Orthopaedic implants


- Adherent endotoxin on orthopaedic wear particles stimulates cytokine production and osteoclast differentiation. *Bi Y et al, J Bon Miner Res 2001;16:2082-2091*

- Accumulation of LPS by polyethylene particles decreases bone attachment to Implants. *Xing Z et al, J Orthop Res 2006;24:959-966*
Impact of LPS-particles on implant attachment in bone

**RAT MODEL;**
LPS-coated particles + titanium pins implanted in femoral canal

Assessed 6 weeks post-surgery by MicroCT

Xing Z et al J Orthop Res 2006;24:959-966
Impact of repeated rounds of steam sterilization; stainless steel 7 mm sternal wire

Increased oxide particle accumulation after repeated rounds of steam sterilization

Increased corrosion after ten rounds of steam sterilization ($121^\circ C; 30$ mins)

Surface imperfections increase risk that organic debris will remain after washing.


Copyright: Dr. Michelle J. Alfa
Summary of Published Literature:

- High level of LPS may be left on instruments after final rinse in automated washer
- LPS does stimulate inflammatory response → TNFα, IL-1, IL-6, PGE₂
- Rat Model: LPS and particulate wear debris → inflammatory response/loosening of implants
- Repeated steam sterilization destroys passivation of stainless steel and increases oxide thickness
Surgical Instrument tray... or Box of Problems?!!

- Do residuals from reprocessing contribute to aseptic implant loosening?
- What impact does repeated steam sterilization have on strength of screws, nails etc?
- How frequently should these items be replaced?
What can Users do??

- Testing to assure the WD is cleaning properly
- Ensure final rinse water of adequate quality
- Individual packaging of plates, screws, wires → problematic

**More Scientific Data needed:**
Assess screws, etc that are repeatedly reprocessed → any LPS or organic residuals?

Copyright: Dr. Michelle J. Alfa
When You Open a Surgical Instrument Tray....

Hear no evil....

See no evil....

Speak no evil....
General Reprocessing

- Red brochure: *Proper Maintenance of Instruments, 8th ed.*
  http://www.a-k-i.org/englisch/lit.htm
- Provincial Infectious Diseases Advisory Committee (PIDAC) – MOHLTC Best Practice Practices for Cleaning, Disinfection and Sterilization – In all Health Care Settings (April 30, 2006)
- CDC (HICPAC) *Guideline for Disinfection and Sterilization in Healthcare Facilities 2008*
References

Reprocessing Instructions & Methods

- AAMI TIR12:2004 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2ed
- ANSI/AAMI ST81:2004 Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Cleaning

- AAMI TIR34:2008 Water for reprocessing medical devices
- AAMI TIR30:2003 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices