Reprocessing of Implants – What are the Issues?
Dr. Michelle Alfa, Diagnostic Services of Manitoba
A Webber Training Teleclass

Overview:
- Implants: what causes implant failure?
- Issue of reprocessing of implants
- Published data
  - effect of foreign material on implant
  - effect of repeated sterilization
- What can users do?

Implants:
- Implants are Single use devices (SUDs)
- Implants include:
  - joints, brackets, rods, etc
  - screws, wires used to immobilize implant
- Variable composition:
  - stainless steel (most common)
  - titanium
  - polymers (e.g. polyethylene)

What causes Primary implant failure → Revision surgery?

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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:

Issue of Reprocessing of Implants

- Critical SUDs are Not reprocessed
- Implants are used for one patient (SUD)
- Joints provided sterile or sterilized just prior to implantation
- Stainless steel brackets, screws, rods, wires are treated like surgical instruments
  - washed, steam sterilized repeatedly until used

Reprocessing of Instrument Trays: Washer Disinfectors

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; 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: 1cm²

- Protein, Hg, Carb, LPS

Alfa et al., Cleaning efficacy of medical device washers in N American healthcare facilities. J Hosp Infect 2009

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

<table>
<thead>
<tr>
<th>Plastic Tray</th>
<th>Instrument type: (visible soil after use)</th>
<th>Protein (µg/cm²)</th>
<th>Hemoglobin (µg/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Average for 5 devices</td>
<td>Average for 5 devices</td>
</tr>
<tr>
<td></td>
<td>Before cleaning</td>
<td>After cleaning</td>
<td>Before cleaning</td>
</tr>
<tr>
<td>1. Curved Mosquito forcep (5 visibly soiled)</td>
<td>7.04</td>
<td>0.18</td>
<td>0.00</td>
</tr>
<tr>
<td>2. Fine Needle Driver (5 visibly soiled)</td>
<td>49.96</td>
<td>0.00</td>
<td>13.26</td>
</tr>
<tr>
<td>3. Curved Iris Scissors (5 visibly soiled)</td>
<td>373.78</td>
<td>0.14</td>
<td>110.96</td>
</tr>
<tr>
<td>4. Toothed Adson forcep (fine)</td>
<td>55.38</td>
<td>1.04</td>
<td>9.90</td>
</tr>
<tr>
<td>5. Skin Hook (5 visibly soiled)</td>
<td>3.36</td>
<td>3.16</td>
<td>0.36</td>
</tr>
<tr>
<td>Average</td>
<td>97.00</td>
<td>0.30</td>
<td>26.90</td>
</tr>
</tbody>
</table>

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?

What Residuals are Relevant?
- Viable Microorganisms:
  - previous patient
  - water
- Organic:
  - previous patient
  - water
  - detergent
  - biofilm (washer or instruments)

Take Home Message:
Residuals Post-cleaning
- Remain on instrument
- Steam sterilization ➔ “sterile crud”
- Endotoxin (LPS); not destroyed by steam sterilization ➔ still causes inflammatory response
- Proteins etc are denatured but still remain antigenic

Manufacturer’s Instructions:
All state that cleaning instructions are validated

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Screws defined as implants</th>
<th>Cleaning validated for screws</th>
<th>Don’t reprocess screws if soiled</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Synthes</td>
<td>No</td>
<td>Not stated</td>
<td>Stated</td>
</tr>
<tr>
<td>2. Zimmer</td>
<td>Yes</td>
<td>Yes</td>
<td>Stated</td>
</tr>
<tr>
<td>3. Stryker</td>
<td>Yes</td>
<td>Yes</td>
<td>Stated</td>
</tr>
<tr>
<td>4. Wright</td>
<td>No</td>
<td>Not stated</td>
<td>Stated</td>
</tr>
<tr>
<td>5. Medacta</td>
<td>No</td>
<td>No</td>
<td>Stated</td>
</tr>
<tr>
<td>6. Ulrich Med</td>
<td>No</td>
<td>No</td>
<td>Stated</td>
</tr>
<tr>
<td>7. Smith &amp; Nephew</td>
<td>No</td>
<td>No</td>
<td>Not clear</td>
</tr>
</tbody>
</table>

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Manufacturer’s Instructions:
All state that cleaning instructions are validated

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Remove Screws from Tray set to reprocess</th>
<th>Final rinse with high quality water</th>
<th>User validation required for cleaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Synthes</td>
<td>Not stated</td>
<td>DI or PURW</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Zimmer</td>
<td>Leave in set</td>
<td>Purified water</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Stryker</td>
<td>Remove</td>
<td>Purified water</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Wright</td>
<td>Not stated</td>
<td>DI or RO</td>
<td>Yes</td>
</tr>
<tr>
<td>5. Medacta</td>
<td>Not stated</td>
<td>DI or purified</td>
<td>Yes</td>
</tr>
<tr>
<td>6. Ulrich Med</td>
<td>Remove</td>
<td>Purified water</td>
<td>Yes</td>
</tr>
<tr>
<td>7. Smith &amp; Nephew</td>
<td>Not stated</td>
<td>DI preferred</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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:

Pathology of Aseptic loosening

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

Why the inflammatory response in aseptic loosening?

- Not infected with microorganisms
- Solely due to attempts to ingest the wear particles?
- Any role for residual organic material associated with implant/wear particles in stimulating inflammatory response?

Residuals: Orthopaedic implants

- Accumulation of LPS by polyethylene particles decreases bone attachment to Implants. Yong 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

Bone-implant attachment-%

Assessed 6 weeks post-surgery by MicroCT

Xing Z et al J Orthop Res 2006;24:959-966
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**Inflammatory Response:**

“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.”

**P A Revell  J. R. Soc. Interface 2008;5:1263-1278**

**Impact of repeated rounds of steam sterilization; stainless steel 7 mm sternal wire**

**Summary of Published Literature:**

- Rat Model: LPS and particulate wear debris → inflammatory response/loosening
- LPS does stimulate inflammatory response → TNFα, IL-1, IL-6, PGE
- High LPS residuals on instruments after final rinse in automated washer-disinfector
- Repeated steam sterilization destroys passivation of stainless steel and increases oxide thickness

**Pandora’s Box!!**

- 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?

**References**

**General Reprocessing**

- AAMI TIR12-2004: Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2ed
- 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) Guidline for Disinfection and Sterilization in Healthcare Facilities 2008

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- 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

- AAMI TIR12:2004 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2nd
- ANSI/AAMI STP9:2006 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- Canadian Standards Association Inc. Publishers Mississauga, ON. CSA Z314.8-08 Decontamination of Reusable Medical Devices, 2008.

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