Reprocessing of Implants: What are the Issues?

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Hear no evil….

See no evil….

Speak no evil….
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:

Joint replacement:
- cement
- screws, nails, wires

Bone repair:
- Broken bones:
  plates, rods, screws, wires

Spine:
- repair fractures/abnormalities
- stabilize

Pictures from Google Images; March 2, 2010
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 \(\rightarrow\) Revision surgery?

**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?

**Reviewed 1366 Total Hip Arthroplasty Revisions**

- **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:
Example: Fragment Tray Surgical set (ORSY-690SMSET)

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

Picture from Synthes website; March 2, 2010
Issue of Reprocessing of Implants

Stainless steel brackets, screws, rods, wires are implants but 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
What Residuals are Relevant?

- **Viable Microorganisms:**
  - previous patient
  - water

- **Organic:**
  - previous patient
  - water
  - detergent
  - biofilm (washer or instruments)
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>
**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>
Published Data: Is there anything to worry about?

- Surgical instruments; residuals?
- Implants; what causes aseptic loosenning?
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 1/5 visibly soiled: (1 device; 1+)</td>
<td>120.52</td>
<td>301.16</td>
</tr>
<tr>
<td>2. Fine Needle Driver 5/5 visibly soiled: (2 devices; 1+, 3 devices; 3+)</td>
<td>116.86</td>
<td>336.86</td>
</tr>
<tr>
<td>3. Curved Iris Scissors 2/5 visibly soiled: (2 devices; 3+)</td>
<td>146.68</td>
<td>352.10</td>
</tr>
<tr>
<td>4. Toothed Adson forcep (fine) 4/5 visibly soiled: (2 devices; 1+, 2 devices; 2+)</td>
<td>169.40</td>
<td>138.76</td>
</tr>
<tr>
<td>5. Skin Hook 1/5 visibly soiled: (1 device; 1+)</td>
<td>141.14</td>
<td>193.46</td>
</tr>
<tr>
<td>Average:</td>
<td>138.92</td>
<td>264.47</td>
</tr>
</tbody>
</table>
Pathology of Aseptic loosening

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

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
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."

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


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\degree C; 30 mins)

Summary of Published Literature:

- Rat Model: LPS and particulate wear debris → inflammatory response/loosening
- LPS does stimulate inflammatory response → TNFα, IL-1, IL-6, PGE₂
- High LPS residuals on instruments after final rinse in automated washer-disinfector
- Repeated steam sterilization destroys passivation of stainless steel and increases oxide thickness
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*
- Red brochure: *Proper Maintenance of Instruments, 8ed.* 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*
- *Canadian Standards Association Inc. Publishers Mississauga, ON. CSA Z314.8-08 Decontamination of Reusable Medical Devices. 2008.*

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*