

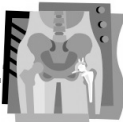



Reprocessing of Implants – What are the Issues?

Dr. Michelle Alfa, Diagnostic Services of Manitoba


A Webber Training Teleclass

Reprocessing of Implants: What are the Issues?


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Hosted by Paul Webber
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 www.webbertraining.com
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When You Open Pandora's Box.....


Hear no evil....



See no evil....



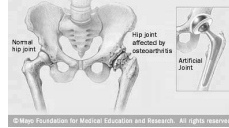
Speak no evil....





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:



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Pictures from Google Images; March 2, 2010

Joint replacement:

- cement
- screws, nails, wires

Bone repair:

- Broken bones:
plates, rods, screws, wires

Spine:


- repair fractures/abnormalities
- stabilize

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?

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:

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What causes Revision failure?

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Revised Total Hip Arthroplasty:



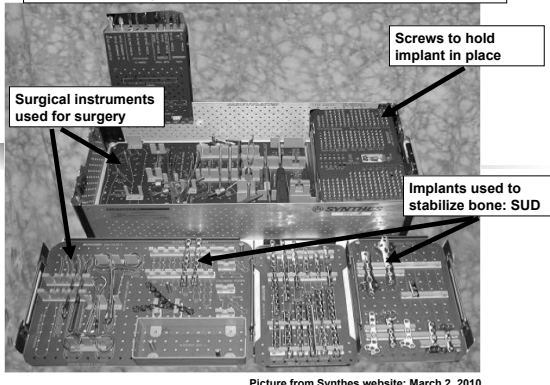
- Aseptic loosening: 19.4%
- Instability: 25.1%
- Infection 30.2%

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

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



Picture from Synthes website: March 2, 2010

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				
Plastics Tray Instrument type: (visible soil after use)	Protein: (µg/cm ²) Average for 5 devices		Hemoglobin: (µg/cm ²) Average for 5 devices	
	Before cleaning	After cleaning	Before cleaning	After cleaning
1. Curved Mosquito forcep 1/5 visibly soiled: (1 device; 1*)	7.04	0.18	0.00	0.00
2. Fine Needle Driver 5/5 visibly soiled: (2 devices; 1*, 3 devices; 3*)	49.96	0.00	13.26	0.00
3. Curved Iris Scissors 2/5 visibly soiled: (2 devices; 3*)	373.78	0.14	110.96	0.00
4. Toothed Adson forcep (fine) 4/5 visibly soiled: (2 devices; 1*, 2 devices; 2*)	55.38	1.04	9.90	0.44
5. Skin Hook 1/5 visibly soiled: (1 device; 1*)	3.36	3.16	0.36	0.12
Average:	97.90	0.90	26.90	0.11

Residuals on Patient-used instruments post-cleaning: Automated washer				
Plastics Tray Instrument type: (visible soil after use)	Carbohydrate: (µg/cm ²) Average for 5 devices (SD)*		Endotoxin: (EU/cm ²) Average for 5 devices (SD)	
	Before cleaning	After cleaning	Before cleaning	After cleaning
1. Curved Mosquito forcep 1/5 visibly soiled: (1 device; 1*)	120.52	301.16	13.68	18245.32
2. Fine Needle Driver 5/5 visibly soiled: (2 devices; 1*, 3 devices; 3*)	116.86	336.86	10.62	23667.74
3. Curved Iris Scissors 2/5 visibly soiled: (2 devices; 3*)	146.68	352.10	32.40	20.42
4. Toothed Adson forcep (fine) 4/5 visibly soiled: (2 devices; 1*, 2 devices; 2*)	169.40	138.76	23.44	13.14
5. Skin Hook 1/5 visibly soiled: (1 device; 1*)	141.14	193.46	10.58	25373.88
Average:	138.92	264.47	18.14	13464.10



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?

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

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

Manufacturer	Screws defined as implants	Cleaning validated for screws	Don't reprocess screws if soiled
1. Synthes	No	Not stated	Stated
2. Zimmer	Yes	Yes	Stated
3. Stryker	Yes	Yes	Stated
4. Wright	No	Not stated	Stated
5. Medacta	No	No	Stated
6. Ulrich Med	No	No	Stated
7. Smith & Nephew	No	No	Not clear

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

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

What causes Primary implant failure → Revision surgery?

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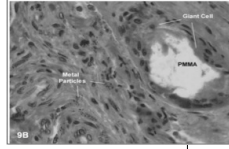
Pathology of Aseptic loosening

Stainless steel hip implant



Polyethylene knee implant





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


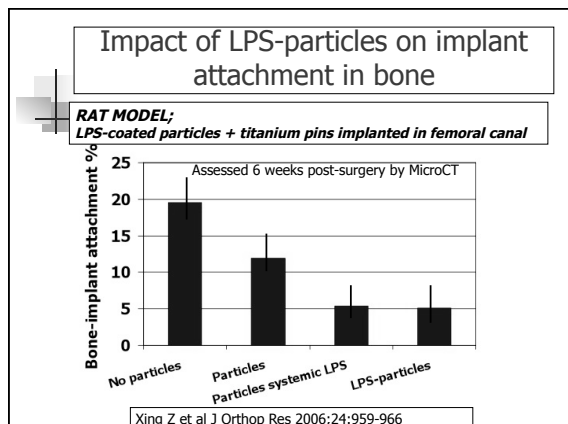
All pictures from: T Bauer & J Schils Skeletal Radiol 1999;28:483-497

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

- Measurement and removal of adherent endotoxin from titanium particles and implant surfaces. *Regab AA et al, J Orthop Res 1999;17:803-809*
- 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*

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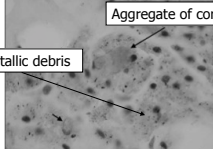
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Inflammatory Response:

Review: The combined role of wear particles, macrophages and lymphocytes in the loosening of total joint prostheses.
P A Revell J. R. Soc. Interface 2008;5:1263-1278

"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."

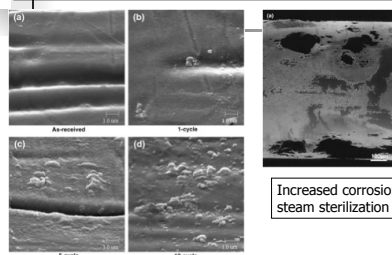


Aggregate of corrosion particles

Dark particles: metallic debris

Picture from: T Bauer & J Schils Skeletal Radiol 1999;28:483-497

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



Increased corrosion after ten rounds of steam sterilization (121° C; 30 mins)

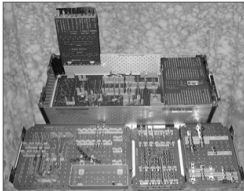
Increased oxide particle accumulation after repeated rounds of steam sterilization

Pictures from: Chun-Che Shih et al Degradation of 316L Stainless steel sternal wire by steam sterilization. Acta Biomaterialia 2010

Summary of Published Literature:


- Rat Model: LPS and particulate wear debris → inflammatory response/loosening
- LPS does stimulate inflammatory response → TNF α , 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

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*
- Red brochure: *Proper Maintenance of Instruments, 8ed.*
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- Spaulding EH. *Chemical disinfection of medical and surgical materials [Chapter 32]*. In: Lawrence CA, Block SS, eds. *Disinfection, sterilization and preservation*. Philadelphia, PA: Lea & Febiger, 1968: 517-31
- 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*
- ISO 15883-1:2006. *Washer-disinfectors, Part 1: General requirements, definitions and tests.*

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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*
- ISO/TS 15883-5:2005 *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy of washer-disinfectors*

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