Infection, Disease & Health (2017) xx, 1–7

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: http://www.journals.elsevier.com/infection-disease-and-health/

Research paper

Evaluation of stainless steel surgical instruments subjected to multiple use/processing

Dayane de Melo Costa [a,b], Lillian Kelly de Oliveira Lopes [a], Anaclara Ferreira Veiga Tipple [b], Khalid Johani [a,c], Honghua Hu [a], Anand Kumar Deva [a], Evandro Watanabe [d], Karen Vickery [a,*]

[a] Surgical Infection Research Group, Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia
[b] Faculty of Nursing, Federal University of Goias, Goiania, Brazil
[c] Central Military Laboratories and Blood Bank, Prince Sultan Military Medical City, Riyadh, Saudi Arabia
[d] School of Dentistry of Ribeirão Preto, University of São Paulo, Ribeirao Preto, Brazil

Received 26 May 2017; received in revised form 22 August 2017; accepted 22 August 2017

KEYWORDS
Sterilization;
Decontamination;
Biofilm;
Number of re-uses

Abstract *Background:* To determine the effect of multiple use and processing cycles on instrument quality over the life of stainless steel, complex designed clinical surgical instruments.
Methods: Steam sterilised surgical instruments due to be discarded from Australian hospitals, because of loss of functionality, were assessed for contaminating protein and bacteria using the bicinchoninic acid protein assay and microbial culture, respectively. Biofilm presence and instrument damage were visually confirmed by scanning electron microscopy (SEM). Instruments were categorised into hinged/serrated, screw, cannulated, flexible, and irregular surfaced (but not hinged) according to their design.
Results: Protein contamination ranged from 24 μg on the new screw to 3,756,046 μg contaminating a discarded forceps. The more complex the instrument design the higher the protein contamination. All samples were culture negative, however, biofilm was visually confirmed on 4/8 instruments tested using SEM. SEM also detected soil, holes or black stains on all the instruments.
Conclusion: "Ready to use" surgical instruments that underwent multiple uses and processing cycles were contaminated with high amounts of protein, and microscopy revealed the presence of soil, structural damage, black stains and biofilm. While less affected new but multiply processed screws also showed soil and biofilm contamination. These findings highlight the need for further research into determining what is the "life" of stainless steel

* Corresponding author. Department of Biomedical Sciences, Faculty of Medicine and Health Sciences, F10A, 2 Technology Place, Macquarie University, North Ryde, NSW 2109, Australia. Fax: +61 2 9850 2701.
E-mail address: karen.vickery@mq.edu.au (K. Vickery).

http://dx.doi.org/10.1016/j.idh.2017.08.004

instruments and development of standard criteria for evaluating when to "retire" an instrument.

Highlights

- Extensive protein deposits were found on multiply processed surgical stainless steel instruments.
- Despite repeated sterilisation by moist heat, biofilm was detected on half the instruments tested.
- Microscopic damage to instruments including pitting was evident.
- The number of times individual instruments can be processed safely needs to be determined.

Introduction

Sterilisation of reusable critical surgical instruments is an essential preventive measure to ensure aseptic surgery and steam sterilisation is the gold-standard option [1,2]. Steam sterilisation is well standardised, with an expected sterility assurance level of 10^{-6} (i.e. 1:1,000,000 viable microorganism) [1]. In addition to killing live infectious organisms, processing of instruments requires patient soil to be removed and, in response to concern for transmission of prions, causing variant Creutzfeldt—Jakob disease, a protein cleaning instruments benchmark has been proposed [3]. This benchmark dictates that instruments be contaminated with a maximum equivalent of 5 μg bovine serum albumin (BSA) protein per instrument side [3].

Incidents associated with failed processing of reusable surgical instruments have been reported [4], and inadequate processing of instruments was rated as one of the top ten health technology hazards by the Emergency Care Research Institute (ECRI) Institute in 2017 [5]. This is no surprise given the number of instruments processed. For instance, in only one large hospital in the USA, approximately 40,000 reusable surgical instruments are processed daily [6].

A reusable surgical instrument can be used in hundreds or thousands of operations, and may potentially infect large numbers of patients if contaminated [7,8]. To date, standards detailing the safe number of uses or processing "life" of reusable medical devices are lacking. Thus, instruments have been commonly used and processed until their integrity and/or functionality is drastically damaged.

The belief that biofilm, a three-dimensional aggregation of sessile microorganisms encased in complex, extracellular polymeric substances (EPS) [9] adhering to a surface [10], will not develop on steam sterilised instruments, irrespective of their number of uses/processing, may be in part due to the belief that steam sterilisation is a "mighty weapon" that kills all organisms [11]. However, biofilms have been demonstrated to contaminate the narrow cannula in stainless steel dental syringes, even though they are subjected to steam sterilisation [12]. Therefore, the aim of this study was to determine if stainless steel surgical instruments became contaminated with bacteria over a lifetime of use and processing.

Methods

Discarded critical surgical instruments that due to be discarded, because of loss of functionality, were donated by healthcare workers from Sterilizing Service Units (SSU) or Surgical theatres of Australian hospitals in New South Wales and Victoria. All the donated sets of stainless steel surgical instruments were processed according to the routine of each SSU, package with surgical grade paper and subjected to saturated steam under pressure sterilization process.

The surgical instruments (n = 27) were divided according to their design into five groups (Table 1):

1) Hinged and/or serrated, including nine forceps, two scissors, one bone nibbler and one pin clamp;
2) Cannulated, including four suckers, two crown drills and one depth gauge;
3) Two sets of unused but multiply processed screws, n = 4;
4) Irregular surface — two bone rasps (Serenity, OnSite)
5) Flexible — one flexible drill bit

Instruments from all groups, except screws, were aseptically cut into fragments to enable multiple analyses to be conducted using a sterile Dremel™ 3000 rotary tool and blade (Robert Bosch Tool Corporation, USA), in a Class II Biological Safety Cabinet (Herasafeks™, Themo Scientific, Germany).

Determination of contaminating soil and microorganisms

The amount of contaminating protein was determined on 23 samples, including 12 hinged/serrated instruments, seven cannulated instruments, one screw, two irregular surfaced instruments, and one flexible drill, using the Bicinchoninic Acid (BCA) protein assay (Pierce™ — ThermoFisher, Waltham, USA), according to the manufacturer's instructions

Please cite this article in press as: Costa Dayane de Melo, et al., Evaluation of stainless steel surgical instruments subjected to multiple use/processing, Infection, Disease & Health (2017), http://dx.doi.org/10.1016/j.idh.2017.08.004