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Abstract

Study Design: A literature review.

Objectives: An evaluation of the contaminants prevalent on implants used for surgery and the aseptic methods being employed against them.

Methods: PubMed was searched for articles published between 2000 and 2017 for studies evaluating the contaminants present on spine implants, and associated pre- and intraoperative implant processing and handling methodology suggested to avoid them. Systematic reviews, observational studies, bench-top studies, and expert opinions were included.

Results: Eleven studies were identified whose major focus was the asepsis of implants to reduce the incidence of surgical site infection incidences during surgery. These studies measured the colony forming units of bacteria on sterilized implants and/or gloves from the surgeon, scrub nurse, and assistants, as well as reductions of surgical site infection rates in spine surgery due to changes in implant handling techniques. Additionally, the search included assessments of endotoxins and carbohydrates present on reprocessed implants. The suggested changes to surgical practice based on these studies included handling implants with only fresh gloves, keeping implants covered until the immediate time of use, reducing operating room traffic, avoiding reprocessing of implants (ie, providing terminally sterilized implants), and avoiding touching the implants altogether.

Conclusions: Both reprocessing (preoperative) and handling (intraoperative) of implants seem to lead to contamination of sterilized implants. Using a terminally sterilized device may mitigate reprocessing (preoperative implant prophylaxis), whereas the use of fresh gloves for handling each implant and/or a permanent shielding technique (intraoperative implant prophylaxis) could potentially avoid recontamination at the theatre.

Keywords

infection, surgical site infection, SSI, cross-contamination of implants, bioburden of implants, bacterial does on implants, asepsis, prophylaxis, best practices

Introduction

Surgical site infections (SSIs) add an enormous burden to individuals and society in terms of medications, reoperations, extended stays at the hospital, lost productivity and wages, and emotional and physical trauma afflicted on patients and their families.¹ The incidence of SSIs in spine surgery has been reported to range from 2% to 13%.² McClelland et al presented results from prospectively gathered thoracolumbar spine surgery data for which the Centers for Disease Control and Prevention criteria to define SSI were stringently applied.² They indicated that the thoracolumbar SSI rate actually occurs at the

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higher end of the range (12.7%) cited in the literature, and it is underestimated largely based on retrospective data not subjected to the inclusivity of SSI as defined by the Centers for Disease Control and Prevention. Nevertheless, variations among hospitals exist but are explainable given the underlying variation in the different parameters that constitute practice patterns. The parameters include, but are not limited to, patients' immunity, specific procedures performed, surgical environment and airflow, cleaning and sterilization procedures of implants, patients' preoperative preparations, intraoperative handling and surgical techniques, postoperative measures, and so on. Most of these parameters affect the SSI rates through the level of asepsis and a few through a direct, or indirect, enhancement of patients' immunity. Nevertheless, it would be safe to assume that any compromise before, or during, surgery can lead to a decline in a patient's health along with spending countless dollars, signifying that the value of asepsis remains irrefutable. The current study presents a detailed synthesis of the available literature that assesses known practices and suggests implant handling techniques to avoid implant contamination in spine surgery.

Methods

The method utilized for the literature review was developed by the Cochrane collaboration.³ Key questions formulated for the search were the following:

1. What are sources of contaminants on an implant used for surgery?
2. What are the known practices and/or suggested implant handling techniques, both preoperative and intraoperative?

Medline, from 2000 to 2017, was used as the primary data source. Table 1 shows the search strategy that was developed for the PubMed database. The terms for this search were divided into 3 distinct categories: (1) terms for the device, (2) terms for cleanliness, and (3) terms for procedure. The search was followed by full-text review of all references that appeared to address the questions formulated above. The authors' conclusions were substantiated by the available data and to the particular device and/or medical procedure involved. In addition, the study type, journal name, and its impact factor associated with every selected article were tabulated (see Table 2).

Results

Fifty-eight full-text articles were retrieved after screening through titles and abstracts, while 26 additional articles were hand searched from the references. Of all, only 11 articles were found relevant for inclusion in the study.

Surgical Gloves as a Vehicle for Contamination (5 Articles)

Rehman et al showed that by changing gloves just before handling a ventriculoperitoneal shunt catheter could significantly

Table 1. Medline Search Strategy Using PubMed (<http://www.ncbi.nlm.nih.gov/pubmed/advanced>).

Terms for the device:
1. Prostheses [tw]
2. Prosthesis [tw]
3. Implant* [tw]
4. Instrument* [tw]
AND (Boolean operator)
Terms for cleanliness:
1. Reprocessing [tw]
2. Cleaning [tw]
3. Sterilization [tw]
4. Sterilizing [tw]
5. Sterility [tw]
6. Sanitation [tw]
7. Cleanliness [tw]
8. Bioburden [tw]
9. Contamination [tw]
10. Hygiene [tw]
11. Asepsis [tw]
12. Contaminated [tw]
13. Contaminant [tw]
AND (Boolean operator)
Terms for procedure:
1. Surgery [tw]
2. Surgeries [tw]
3. Surgical [tw]

Abbreviation: tw, text word.

*Denotes a truncation or "wildcard" search.

reduce the infection rate (16.33% to 3.77%).⁵ They concluded that by avoiding transfer of patient's skin flora to the implant via the surgeon's glove reduces potential infections. This hypothesis was also supported by other practitioners, where the gloves of the surgeon and the scrub nurse were examined as a possible vehicle for transportation of microorganisms from skin to shunt material.⁸ Rehman et al also performed a similar experiment (changing gloves before implant handling) during posterior spinal fusion and demonstrated significant reduction of infection (3.35% to 0.48%).⁴ Beldame et al reported results on 26 contaminated gloves, which came from all gloved surgical team members (operator, scrub nurse, and assistant) of cutaneous origin.⁷ The contamination was equally divided between dominant and nondominant (13) hands. They also showed that a regular change of gloves resulted in a sterile state in 80% of cases. Dawson-Bowling et al analyzed 42 pairs of gloves that were removed after preparation. Five (11.9%) grew organisms on culture ($P < .05$).⁶ Three of 21 pairs from the assistant were contaminated (14.3%), as opposed to only 2 pairs (9.5%) from the lead operating surgeon ($P > .05$). From 42 gloves removed intraoperatively, 10 (23.8%) were positive ($P < .01$). From these 42 pairs, 6 from 21 used by the assistant were contaminated (28.6%), compared with 4 from 21 (19.0%) of the lead surgeon's gloves ($P > .05$). There were 19 isolates in total: 16 coagulase-negative *staphylococci* and 1 each of *Micrococcus* spp, *Enterococcus* spp, and *Bacillus* spp.

Table 2. Breakdown of the Article Based on Study Type, Journal, and Impact Factor.

Category	Authors	Study Type	Journal	Impact Factor
Surgical gloves as a vehicle for contamination	Rehman et al (2015) ⁴	Prospective cohort	<i>Journal of Spinal Disorders & Techniques</i>	4.059
	Rehman et al (2010) ⁵	Prospective cohort	<i>Journal of Neurosurgery–Pediatrics</i>	4.059
	Dawson-Bowling et al (2011) ⁶	Clinical investigational experiment	<i>Journal of Hospital Infection</i>	3.126
	Beldame et al (2012) ⁷	Clinical investigational experiment	<i>Orthopaedics & Traumatology, Surgery & Research</i>	1.468
Implant contamination due to exposure	Sorensen et al (2008) ⁸	Clinical investigational experiment	<i>British Journal of Neurosurgery</i>	0.96
	Dalstrom et al (2008) ⁹	Clinical investigational experiment	<i>Journal of Bone and Joint Surgery, American Volume</i>	4.840
	Bible et al (2013) ¹⁰	Clinical investigational experiment	<i>Spine Journal</i>	3.024
Reprocessing as a cause of preoperative contamination	Menekse et al (2015) ¹¹	Prospective randomized trial	<i>Spine</i>	2.499
	Alfa et al (2010) ¹²	Bench top and/or nonclinical investigational experiment	<i>Journal of Hospital Infection</i>	3.126
	Litrico et al (2016) ¹³	Prospective cohort	<i>European Journal of Orthopaedic Surgery & Traumatology</i>	0.770
	Alfa (2012) ¹⁴	Bench top and/or nonclinical investigational experiment	<i>Biomedical Instrumentation & Technology</i>	0.14

Implant Contamination due to Exposure (3 Articles)

Bible et al used a sterile culture swab at the end of each of their surgical case to obtain a sample from all open implants.¹⁰ The paper outer wraps of the implant trays were sampled in each case as a positive control, and an additional 105 swabs were capped immediately after they were opened to obtain negative controls. Cultures from the implant sample demonstrated a 9.5% overall rate of contamination with 2.0% (n = 1) of covered implants versus 16.7% (n = 9) of uncovered implants demonstrating contamination. They demonstrated a significant reduction in the implant contamination rate simply due to coverage during surgery ($P = .016$). Similarly, Dalstrom et al showed culture positivity correlation with the duration of open exposure of the uncovered operating room trays.⁹ Light traffic in the operating room appeared to have no impact on the contamination risk. Menekse et al also highlighted the importance of preventing implant contamination, as it may be an important source of postoperative infections.¹¹ They too compared the differences in contamination between covered and uncovered implants, showing significantly higher rates of contamination in the uncovered group. The contamination rate at 120 minutes was 55% in the uncovered group and 18.2% in the covered group. Their findings demonstrate that contamination occurred at 30 minutes and increased with time and that this rate can be significantly reduced by following the precaution of covering the implant set.

Reprocessing as a Cause of Preoperative Contamination (3 Articles)

Alfa et al showed through their study that the screws in the sterilization racks have limited access to the cleaning fluids resulting in insufficient cleaning and rinsing in an automated washer.^{12,14} Additionally, their study demonstrated an increase

in endotoxin levels post reprocessing. They concluded that the final deionized (DI) water rinse was the source of contaminant due to biofilm formation in the DI tank. Litrico et al reported results on terminally sterile implants and compared it to an older series, using reprocessed implants, performed by the same team for the same indications.¹³ They found that the clinical outcomes were similar, but the infection rate was lower with a terminally sterile device compared with the reprocessed implants (2% vs 6%).

Discussion

Based on studies reported in the literature, it seems evident that the current techniques of handling and processing the implant should be under continued scrutiny. Contaminants on implants are associated with intraoperative exposure to surgical gloves and air, as well as preoperative hospital reprocessing. Radcliff et al performed a retrospective analysis and found that preoperative, in-room, delay of more than 1 hour prior to the start of surgery was a predictor of SSI, independent of number of operative levels, ASA (American Society of Anesthesiologists) score, and posterior approach.¹⁵ They hypothesized that the contamination of the sterile field occurs during the extended preoperative setup time. Possible contamination sources include direct contact with the sterile field, airborne contamination from traffic, and/or loss of sterile technique. This could explain the results of the studies where the implant contamination increased with increase in the intraoperative duration of exposure.¹⁶

The physical handling of implants constitutes another challenge. All studies demonstrated that surgical gloves that handle the implants have a fairly high rate of contamination, potentially from the patient's own skin flora. This facilitates the transfer of contaminants deeper into the tissue, with implants, or even surgical tools, as the carriers.

To avoid such a cascade of events, aseptic handling of the implants is of paramount importance. Very few studies recorded SSI rates as their endpoint, although the ones that did showed reduction in the SSI rates with better implant handling. The repeated presence of contaminants on the implants or the gloves meant to handle the implants highlights the need for improvement in the practices associated with implant asepsis. In addition to the published studies, personal communications on using implant prophylaxis in spine surgery have included varying techniques to perform this such as dipping the implants in betadine or vancomycin, bathing them in isopropyl alcohol, glove changes (although only for the first implant and only by the lead surgeon), direct ultraviolet light exposure, covering of the implants with drapes, limited handling using peel pouch, and other maneuvers using surgical tools. Other surgical professions recognize the problem of cross-contamination between surgical gloves and implants, and wound edges and surgical sites. For example, both plastic surgeons (Keller's funnel) and general surgeons (wound edge protector) have adopted a practice of using an additional layer of barrier against contamination of the implants or the irrigation fluid, with positive results.^{17,18}

The previous paragraphs discuss causes of, and techniques to decrease, intraoperative contamination. However, preoperative practices are equally important and form the baseline for cleanliness, that is, a precontaminated implant may render intraoperative prophylaxis practices futile. The evidence for failures with reprocessing in hospitals and the associated risks are well published. Some countries (eg, Japan and Scotland) have banned reprocessing of implants used for spine surgery. In Scotland, for example, the deadline for conversion of all orthopedic units to prepackaged, sterile, single-use implants was December 31, 2007.¹⁹ It was pointed out by the Scottish Health Department that repeatedly reprocessing of implants in the hospital is a suboptimal clinical practice. To elaborate, Thiede et al performed studies constituting 27 medical practitioners' offices and 14 hospitals and found that the conditions for the execution of the reprocessing method in the analyzed health facilities do not satisfy legal requirements.²⁰ The detected deficiencies were consistent with other reports from Europe. In brief, 57% basic qualification of staff was not completed, in 79% visual inspection was not performed correctly, 50% of the sterilizers used were obsolete or not suitable for performing a validated process, 57% of the washer-disinfectors were obsolete or not suitable for performing a validated process, 64% of the rooms were in need of renovation, and 100% demonstrated a lack of a validated reprocessing method in all substeps. When categorized by the date of facility establishment, an older facility had a higher number of deficiencies over a newer one. This indicates an existence of resistance in change of standard operation, and hence quality, with respect to changes in technology and accessibility. The failure mode here is not only the poor compliance by Sterile Processing Department, but also the impracticality of repeated cleaning and sterilization of hundreds of small implants with multiple components, each with inter-face clearances of less than a fraction of millimeter.

Conclusion

Surgical infection is undoubtedly a multifactorial phenomenon with implant handling and clean delivery being only one of these factors. Significant levels of intraoperative contamination of implants do occur, and any measure that would potentially reduce it should be encouraged. Reprocessing (preoperative) and handling (intraoperative) of implants may negatively affect the sterility and may contaminate the operative field. Using a terminally sterilized device could mitigate reprocessing (preoperative implant prophylaxis). Additionally, intraoperative implant prophylaxis, either using fresh gloves for handling each implant and/or a permanent shielding technique, such as Keller's funnel used in plastic surgery, may avoid recontamination at the theatre.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Neel Anand: Stock options in Spinal Balance Inc, a company providing sterile orthopedic implants, in addition to his respective academic affiliations. Aakash Agarwal: Director of Clinical Affairs for Spinal Balance Inc, a company providing sterile orthopedic implants, in addition to his respective academic affiliations. Anand Agarwal: Stock option in Spinal Balance Inc, a company providing sterile orthopedic implants, in addition to his respective academic affiliations.

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