Title: Updates on Evidence-Based Practices to Reduce Preoperative and Intraoperative Contamination of Implants in Spine Surgery: A Narrative Review

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Abstract

The current communication seeks to provide an updated narrative review on latest methods of reducing implant contaminations used during spine surgery. Recent literature review has shown that both preoperative reprocessing and intraoperative handling of implants seem to contaminate implants. In brief, during preoperative phase, the implants undergo repeated bulk cleaning with dirty instruments from the OR, leading to residue buildup at the interfaces and possibly on the surfaces too. This, due to its concealed nature, remains unnoticed by the SPD (sterile processing department) or other hospital staff. Nevertheless, these can be avoided by using individually prepackaged presterilized implants. In the intraoperative phase, the implants (in the sterile field) are directly touched by the scrub tech with soiled (assisting the surgeon dispose the tissues from the instruments in use) gloves for loading onto an insertion device. It is then kept exposed on the working table (either separately or next to the used instruments as the pedicles hole are being prepared). Latest investigation has shown that by the time it is implanted in the patient, it can harbor up to 10^7 bacterial colony-forming units. The same implants were devoid of such colony-forming units, when sheathed by an impermeable sterile sheath around the sterile implant.
Keywords: Surgical site infection, contamination, bioburden, orthopedic implants, asepsis, pedicle screws, biofilm, reprocessing, intraoperative handling, implant prophylaxis, occult infection

Main Text

Prevention of surgical site infection (SSI) in spine surgery is a major thrust area among the clinicians, researchers, and other healthcare professionals. SSIs add 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 upon patients and their families. Recent randomized controlled trial by McClelland et al. demonstrated that SSIs occur at the higher end of 2%–13% and are egregiously underestimated largely based on retrospective data not subjected to the inclusivity of SSI as defined by the Centers for Disease Control and Prevention (CDC).\(^1\) In addition to its clinical presentation, there have been several studies performed on occult forms of SSI.\(^2\text{-}^5\) According to literature data, these occult SSIs were present
in at least 10%–30% of patients with chronic pain and were detected only during revision spine surgery.\textsuperscript{2-5} In some studies, researchers collected periprosthetic tissue from the area around each screw or implant for gram staining, histopathological analysis, and long cultures to identify any attribute that would indicate chronic infection.\textsuperscript{3} Propionibacterium acnes, a low virulent bacterium which is quite common in late onset SSI, was present in at least 50%–70%, while the remaining were staphylococcus.\textsuperscript{2-5} Furthermore, many of these patients with chronic pain and occult infection had hardware loosening and pseudarthrosis.\textsuperscript{2-5}

In 2017, Anderson et al. presented a thorough review on various preventative techniques being employed or advocated in the field of spine surgery, with varying level of evidences for each.\textsuperscript{6} Their narrative review recommended systematic approach from proper patient selection and optimization of medical conditions, particularly reducing smoking and glycemic control, to screening for staphylococcus organisms, and subsequent decolonization is a promising method to reduce endogenous bacterial burden.\textsuperscript{6} They categorized preoperative measures to further include warming of patients, skin preparation using chlorhexidine and alcohol solutions, and timely administration of antibiotics.\textsuperscript{6} Following this was meticulous surgical technique and maintenance of “standard” sterile techniques. Postoperative methods included tissue oxygenation, glycemic
control, and proper wound closure. However, it should be noted that the only foreign body which remains in the patient, i.e., the implants, was deemed “sterile” as received after reprocessing and was handled freely inside “sterile field.” A subsequent review, published in early 2018, tried addressing this gap by focusing on implant contamination, both preoperatively and intraoperatively. They concluded that the evidences for failures with preoperative reprocessing in hospitals and the associated risks are well published, with few countries already issuing a ban on reprocessing of implants used for orthopedic surgery. In Scotland, for example, the deadline for conversion of all orthopedic units to prepackaged and presterilized implants was on December 31, 2007. They further emphasized that the failure mode here is not only the poor compliance by SPD but the impracticality of repeated cleaning and sterilization of hundreds of small implants with multiple components, each with interface clearances of less than a fraction of millimeter. The second source of contamination they identified was intraoperative, i.e., the physical handling, and other exposure (air, surfaces, accessory, instruments, etc.) of implants inside the “sterile field” constituted another challenge. All the studies identified in the review demonstrated that surgical gloves which handle the implants, either during loading implants on to insertion device or while doing other maneuvers, have a high rate of contamination,
potentially from the patient’s own skin flora. The contamination of implants then facilitates the transfer of contaminants deeper into the tissue, well below the accessible surgical site open to irrigation. Although very few studies recorded SSI rates as their endpoint, the ones that did also showed reduction in the SSI rates with better implant handling.

Lately, newer evidences have been published demonstrating high contamination rates of implants. A study looking at preoperative contaminants identified three types of contaminants: corrosion, saccharide of unknown origin (biofilm, endotoxins, fatty tissue), and soap residue mixed with fat, each occupying isolated diametrical areas of 1.4 mm, 1.5 mm, and 3.4 mm, respectively (Figure 1-3) (used with permission). In addition, salt residues were also found at interfaces between the tulip head and shaft of pedicle screws. The corrosion stains were present on the outer surfaces of the implants, whereas an active corrosion with material erosion was seen at the inner rim of the pedicle screw head (tulip) and in some parts of the washer. The saccharides and soap were present in the interfaces with low permeability (interior region of the multipiece assembled device). This result led to surveillance of the hospital processes to identify modes of failure and its comparison against the manufacture’s guidelines. The failure mode identified with this process was the impracticality of cleaning and sterilizing
small implants with intricate features. In the study, addressing the intraoperative contaminants, a multicenter trial comparing the standard and a standalone method of preventing microbial contamination of implants, during spinal fusion, was compared.\textsuperscript{11-22} The crucial information unmasked here was the presence of bacterial contaminants on implants when handled using currently accepted “sterile” techniques (\textit{Figure 4-5}).\textsuperscript{11-22} The study demonstrated that using a functional (something that allows the scrub tech to attach insertion device without exposure or touching), impermeable, sterile sheath around the sterile implant, which guards the implants intraoperatively until it is implanted into the patient, significantly decreases bacterial count and growth (\textit{Figure 4-5}).\textsuperscript{11-22} The data they presented were binary between the groups despite varied hospitals, operating theaters, surgeons, and hospital staffs.\textsuperscript{11-22} This strongly supports the effectiveness of using a guard to protect implants intraoperatively. Furthermore, it doesn’t change the surgical flow nor does it require additional compliance of the surgical staff member. The source of intraoperative contamination may be from the flora of the patients and personnel(s) or from the environment itself. However, the author emphasized that their study demonstrates that implants without guard act as vehicle for transmittance of some of these contaminants (unknown sources) deep inside of surgical sites.\textsuperscript{4}
SSI is multifactorial; however, the key constituents that define the pathogenesis of SSI are the virulence, host-site immunity, and dosage. The virulence is the microorganism’s ability to infect the host. Although many bacterial species have been identified to cause SSI, the most common ones, *Staphylococcus epidermidis* and *Staphylococcus aureus*, are always present at the vicinity as part of a patient’s own flora. In addition, they have the potential to form biofilms, secluding itself from macrophages or other immune responses at the host site. The host sites in spine surgery are the pedicles of the vertebrae. This in combination with availability of metal surface provides a conducive environment for the bacteria to grow. Lastly, the dose dictates how much bacterial bioburden the “sterile” implant carries, after handling and at implantation. All the latest research reviewed here focuses on the reducing the constituent of dose and thus the overall pathogenesis of SSI.

References


Figure Legends

Figure 1: Corrosion on the tulip interface\textsuperscript{10} (used with permission).

Figure 2: Saccharide of unknown origin\textsuperscript{10} (used with permission).

Figure 3: Soap residue mixed with fat\textsuperscript{10} (used with permission).

Figure 4: [A] Group 2: Intraoperative picture of scrub tech touching pedicle screws while loading. [B] Group 2: Intraoperative picture of exposed pedicle screws to open airflow and surfaces, therefore making them prone to intentional or unintentional contact/contamination. [C] Group 1: Intraoperative picture of guarded pedicle screws.

Figure 5. Quantitative spectroscopy and pictorial depiction (flask turbidity) showing saturated levels of growth within 24–48 hours in group 2 versus no growth for 14 days in group 1. Next to each are the representative culture plate samples from group 1 and 2, after 7 days and 1 day, respectively.
Secondary electrons

Back scatter electrons: difference in composition

Back scatter electrons: difference in topography

172x142mm (96 x 96 DPI)
266x142mm (96 x 96 DPI)