State of the Science Review

Environment of care: Is it time to reassess microbial contamination of the operating room air as a risk factor for surgical site infection in total joint arthroplasty?

Javad Parvizi MS, MD, FRCS, Sue Barnes RN, CIC, Noam Shohat MD, Charles E. Edmiston Jr. MS, PhD

Sidney Kimmel School of Medicine, Rothman Institute at Thomas Jefferson University, Philadelphia, PA
Infection Control Consulting, San Mateo, CA
Department of Surgery, Medical College of Wisconsin, Milwaukee, WI

Key Words:
Operating room
Microbial aerosols
Device-related infection
Intraoperative contamination
Periprosthetic joint infection (PJI)

In the modern operating room (OR), traditional surgical mask, frequent air exchanges, and architectural barriers are viewed as effective in reducing airborne microbial populations. Intraoperative sampling of airborne particulates is rarely performed in the OR because of technical difficulties associated with sampling methodologies and a common belief that airborne contamination is infrequently associated with surgical site infections (SSIs). Recent studies suggest that viable airborne particulates are readily disseminated throughout the OR, placing patients at risk for postoperative SSI. In 2017, virtually all surgical disciplines are engaged in the implantation of selective biomedical devices, and these implants have been documented to be at high risk for intraoperative contamination. Approximately 1.2 million arthroplasties are performed annually in the United States, and that number is expected to increase to 3.8 million by the year 2030. The incidence of periprosthetic joint infection is perceived to be low (<2.5%); however, the personal and fiscal morbidity is significant. Although the pharmaceutic and computer industries enforce stringent air quality standards on their manufacturing processes, there is currently no U.S. standard for acceptable air quality within the OR environment. This review documents the contribution of air contamination to the etiology of periprosthetic joint infection, and evidence for selective innovative strategies to reduce the risk of intraoperative microbial aerosols.

The general estimate for the cost of a periprosthetic joint infection (PJI) in the United States is approximately $100,000. In 2017, Parisi et al, seeking to provide a more accurate assessment of the actual cost of a PJI, included in their estimate not only the cost to the health care system but personal liabilities such as time away from productive endeavors including work which results in lost wages. The authors found by using a 1-way sensitivity analysis that the cost of a single PJI was in the range of $389,307-$474,004. In addition, multiple studies have documented that PJI is associated with a mortality rate between 2% and 7%. It has been suggested that in selective patients the 5-year survival rate with a PJI is worse than with many cancers. Although approximately 1.2 million arthroplasties are performed in the United States each year, this number is anticipated to increase in part because of the aging of the U.S. population, exceeding 3.8 million annually by the year 2030. Using current metrics, the projected (total) cost burden associated with PJI in the United States will approach $1.6 billion by the year 2020. The following review will focus on the potential impact of microbial aerosols on the etiology of device-related infections, specifically PJI.

Data sources

A search to identify published peer literature on microbial aerosol contamination of the intraoperative environment was undertaken. Different search strategies identified studies and reports from PubMed, MEDLINE, Cochrane Database of Systematic Reviews, and INAHCTA. The literature search involved a broad free text search with no restriction to language. Although abstracts were not considered in the search, technical engineering reports were considered in the development of this manuscript.

© 2017 Association for Professionals in Infection Control and Epidemiology, Inc. Published by Elsevier Inc. All rights reserved.
Evidence supporting the association between airborne microbes and surgical site infection

Over the last 20 years several peer-reviewed publications have presented evidence that airborne microbial populations can play a role in the etiology of surgical site infection (SSI), especially in procedures involving implantable biomedical devices, such as prosthetic joints.

Of course, traditional epidemiologic dogma suggests that risk strata of possible pathogens begins with the patient’s microbiome, followed by skill of the perioperative team and sterility of surgical instruments, and finally, the environment of care in the operating room (OR), including air. However, contamination of an implanted device often presents as a stealth event, where the host immune system is unaware that contamination has occurred because the native immunologic response is primarily directed against the device itself and not the presence of any residual contamination. Once an organism adheres to the surface of a device it may actually downregulate its metabolism, multiplying at a slower rate, which further shields the host from noticing the presence of a microbial pathogen. This process has been well documented in late-onset vascular graft infections, where the impact of bacterial contamination may not present with symptoms until weeks or even months postimplantation. By this period of time, the microbial pathogen is often enmeshed within a biofilm, having achieved a critical density, which eventually elicits a host response to the device-associated infection. Therefore, surgical procedures involving an implant are at significant risk after intraoperative contamination from even a minimal microbial inoculum. The traditional presentation of a postoperative infection in a clean surgical wound requires a microbial burden approaching 10^5 colony forming units (CFU), whereas in the presence of a foreign body the contaminating burden which results in infection is significantly reduced (10^1–10^2) CFU.6,11

The importance of airborne transmission as a mechanism for intraoperative microbial contamination and infection is a considerable source of debate and controversy. The convective air flow within the OR can spread airborne particles, posing a potential risk for postoperative infection. These airborne particles include dust, textile fibers, skin scales, and respiratory aerosols, loaded with viable microorganisms (including Staphylococcus aureus) having been released from the surgical team members and patient into the surrounding air of the OR. These particles have been shown to settle onto surfaces including the surgical wound and instruments. A study supporting this assertion documented the recovery of the same molecular strains of coagulase-negative staphylococci and S aureus recovered from OR air samples, originating from nasopharyngeal shedding by members of the surgical team during the same surgical cases. The shedding of bacteria into the air by the OR team members can be enhanced by conditions including dermatitis and upper respiratory infections. A study published in 1984 in the Journal of Bone and Joint Surgery documented that conversations within the OR during total joint arthroplasty enhanced microbial contamination of the OR air. These findings have validated a more recent study, which documented that the barrier properties of the traditional surgical mask rapid decreases due in part to the accumulation of moisture within the fabric of the mask leading to nasopharyngeal venting along the edges of the mask. Under-scored the impact of contaminated air on postoperative surgical infection are the recent global reports of intraoperative wound contamination by Mycobacterium chimaera. These infections, which continue to be reported, have been found to be the result of air contamination associated with a commonly used heater cooler unit in cardiothoracic surgical procedures, despite use of ultraclean air ventilation.

Current OR standards for reduction of microbial aerosol

Studies conducted in the mid-1960s by Goddard initiated the dialogue regarding total air changes needed in ORs to minimize postoperative infection rates. Goddard’s experiments suggested a quantifiable relationship between air change rates and bacterial count, noting that increasing air changes per hour from 20 to 25 reduced bacteria forming colony (cfu) units from 3.8 to 2.5 cfu/ft^3 of room air. Current clinical guidelines including those from the Centers for Disease Control and Prevention and the Association of periOperative Registered Nurses place significant focus on reducing environmental contamination in the OR via cleaning and disinfection of hard and soft environmental surfaces, equipment, and skin and hands of patients and health care workers. Air contamination and air cleaning strategies are addressed from the perspective of limiting door openings (OR traffic), efforts to limit the number of individual in the room during a case, and adhering to specific engineering controls for air pressure (positive), air recirculation (15-20 air changes per hour), temperature, humidity, and High Efficiency Particulate Arrestance (HEPA) filtration. However, these guidelines do not address specific criteria for the quantitative reduction of viable microbial aerosols in OR air. Guidelines from ASHRAE have established air displacement standards and operational parameters for the air handling units (Table 1). Not surprisingly, even with these required engineering and traffic control standards, there are numerous reports and studies linking airborne contamination directly to device-related procedures and specifically, orthopedic SSIs.

There is currently no U.S. standard for air quality for the OR environment that is akin to the standards for maximum particle size limits (particles per cubic meter of air) in pharmacy clean rooms. Within the international arena there are numerous quantitative parameters for air particle or bacteria levels in the OR. A technical paper from health care professionals in Australia proposes that OR air quality should meet European Union (EU) ISO 7 classification (Table 2). In an era of biomedical device-related surgery, an EU ISO 7 classification would potentially represent an excessive number of both viable and nonviable particles that may in the course of the surgical procedure settle within the surgical wound. The EU is in the process of developing new air quality standards for the hospital environment, including ORs, which will include 3 classes based on patient risk. Specific limitations will be set, by class, on the allowable number of bacterial CFU within selective health care environments as indicated in Figure 1. For example, the particle count or bacterial CFU limits in a compounding pharmacy clean room would be different from an OR where there are many more people, equipment, and movement within the environment. However, the goal of measuring air quality in the OR should include a more comprehensive approach, especially with the availability of real-time laser particle counting technology that can differentiate between viable and nonviable particulates, which could be beneficial in developing a mitigating risk strategy to prevent airborne device contamination during implantation. Under the EU–World Health Organization plan, the permissible levels of microbial contamination in general ORs (class II) would be <50 CU/m^3, whereas orthopedic, cardiac, and transplant ORs would have permissible limits of <10 CFU/m^3 (class I). This strategy is more in line with what we

Table 1 Additional operating room design considerations per ASHRAE 170-2008

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean diffuser velocity</td>
<td>127-178 L/m^2</td>
</tr>
<tr>
<td>Diffuser concentration to provide an airflow pattern over the patient and surgical team</td>
<td></td>
</tr>
<tr>
<td>Diffuser array shall extend a minimum of 305 mm beyond the table footprint</td>
<td></td>
</tr>
<tr>
<td>&gt;30% of the diffuser array area used for nondiffuser uses such as lights</td>
<td></td>
</tr>
</tbody>
</table>
Within the last 10 years the introduction of laser real-time microbial enumeration into routine OR technology is readily available, few healthcare institutions have incorporated real-time microbial enumeration into routine OR air sampling. There are multiple reasons for this omission, including (1) capital cost of the equipment; (2) lack of a standardized testing strategy; and (3) unfortunately, failure to recognize airborne microbial populations as playing a role in postoperative infections.

Although innovative microbial enumeration technology is providing a real-time analysis of the potential risk of intraoperative contamination, one cannot dismiss the relative value of traditional microbial culture methods. Dalstrom et al documented using a standard culture technique a time-dependent contamination of opened sterile OR trays, and found that “Culture positivity correlated directly with the duration of open exposure of the uncovered operating-room trays.” The authors suggested that covering the surgical trays with a sterile towel significantly reduced the contamination risk. This study has in part led to the recent practice of preparing a separate wound closure tray that is only opened when the surgeon is ready to close the case, thereby minimizing the risk of fascial and subcuticular wound contamination at closure.

Table 2
USP 797 low- to medium-risk pharmacy clean rooms guidelines for microbial contamination of room air

ISO 14644-1 clean room standards

<table>
<thead>
<tr>
<th>Class</th>
<th>Maximum particles per cubic meter</th>
<th>Federal Standard 209E Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≥0.1 μm</td>
<td>≥0.2 μm</td>
</tr>
<tr>
<td>ISO 1</td>
<td>10</td>
<td>2.37</td>
</tr>
<tr>
<td>ISO 2</td>
<td>100</td>
<td>23.7</td>
</tr>
<tr>
<td>ISO 3</td>
<td>1,000</td>
<td>237</td>
</tr>
<tr>
<td>ISO 4</td>
<td>10,000</td>
<td>2,370</td>
</tr>
<tr>
<td>ISO 5</td>
<td>100,000</td>
<td>23,700</td>
</tr>
<tr>
<td>ISO 6</td>
<td>1.0 × 10^6</td>
<td>2,370,000</td>
</tr>
<tr>
<td>ISO 7</td>
<td>1.0 × 10^7</td>
<td>2.37 × 10^6</td>
</tr>
<tr>
<td>ISO 8</td>
<td>1.0 × 10^8</td>
<td>2.37 × 10^7</td>
</tr>
<tr>
<td>ISO 9</td>
<td>1.0 × 10^9</td>
<td>2.37 × 10^8</td>
</tr>
</tbody>
</table>

There are 4 selective processes for reducing air contamination: dilution, filtration, pressurization, and disinfection. Current SSI prevention guidelines strategies for reducing air contamination in the OR include dilution (15–20 air changes per hour), filtration (HEPA) and pressurization (positive), and the practice of limiting door openings and encouraging a reduction in OR traffic during surgical cases. In the practice of orthopedic surgery, multiple strategies have been used or proposed to reduce the risk of intraoperative contamination of the wound, including the use of surgical helmet systems (SHSs), ultraviolet (UV) plus heating, ventilation, and air conditioning (HVAC) systems, and ultraclean ventilation.

Surgical helmet system

Although SHSs are frequently used in joint replacement surgery, their role in preventing SSI remains controversial. The recent Centers for Disease Control and Prevention guidelines for prevention of SSI sought to resolve this dispute but were unable to reach a conclusion regarding the utility of such systems in reducing SSIs and hence could not make any recommendations on their routine use. In a recent systematic review, the older Charnley-type body exhaust suits which are under negative pressure were reported to be effective in reducing deep infection rates and contamination in arthroplasty. However, in contrast with the body exhaust suits, modern SHS designs were not shown to reduce contamination or deep infection during arthroplasty. McGovern et al published a controlled experiment designed to investigate the effect of different surgical helmet or gown systems on counts of airborne particles measuring...
In another study, operating team members wore SHSs. However, one expert has rightly suggested that operating team members should wear SHSs to reduce the risk of infection.

A study by Fraser et al in 2015 concluded that activation of the airflow in an SHS after complete gowning would lead to decreased contamination of the surgical environment. By using a fluorescent particle model, the authors found that the current positive-pressure SHS was found to be a potential source of intraoperative contamination. Although future studies are needed to clarify the link between particle contamination through this route and PJIs, the study concluded that surgeons should consider using gowning systems that minimize the migration of particles through the gown-glove interface.

Further studies are warranted to assess the clinical benefit of this innovative technology.

UV-C, continuous, air purification system

Combining UV germicidal irradiation chamber and air circulating fans with an overhead ceiling light, this system uses UV-C light and filtration to draw in and treat environmental air. The system is designed to work constantly, providing 4 changes per hour for an 8 × 10 × 10 ft² dimensional room. In a non-peer-reviewed 2016 study reported in McKnight’s publication, a long-term care facility by using this technology reported that in patient rooms without the system, infections rates per 1,000 patient days averaged 17.5. In rooms where the system was activated, infections per 1,000 patient days averaged 12.5, a statistically significant outcome. Additionally, the rooms with the system in place exhibited a 51% reduction in airborne bacteria. However, future peer-reviewed published studies are warranted to assess the benefit of this technology as a feasible strategy for reducing the risk of intraoperative contamination and infection.

Ultraclean ventilation systems combining laminar airflow and high-efficiency particulate air filters

Ultraclean ventilation systems are predominantly used in clean prosthetic implant surgery. Several studies have demonstrated decreased air bacterial contamination with laminar airflow (LAF) using sedimentation agar plates placed in key areas throughout the OR. It is generally assumed that a reduction in airborne contamination with this system will translate into reduced orthopedic infections. However, apart from the original Lidwell Medical Research Council study, there are few clinical studies that validate the effectiveness of LAF systems. However, one expert has rightly suggested that the “absence of a high-level of evidence from randomized trials is not proof of ineffectiveness.” Other investigators have concluded there is no benefit, and one report actually suggested an increased infection risk using laminar flow technology. Two recent systematic reviews and meta-analyses failed to show an advantage with LAF compared with conventional turbulent ventilation in reducing the risk of SSIs in total hip and knee arthroplasties.

The authors of both of these studies concluded that LAF should not be regarded as a preventive measure to reduce the risk of infection and that it should not be installed in new ORs. The World Health Organization tackled this issue in their recent guidelines for preventing SSI. Based on the available scientific literature, the World Health Organization panels suggested “…that laminar airflow ventilation systems should not be used to reduce the risk of SSI for patients undergoing total arthroplasty surgery.” The likely source of this controversial issue resides in the difficulty of acquiring a true air barrier within the OR with the myriad of light, monitors, and personnel who pass repeatedly in and out of the LAF. Although it appears that LAF may not be needed, the role of positive ventilation systems and the efforts to reduce the number of particulate matters in the OR cannot be questioned.
CONCLUSIONS

Microbial contamination of air in the OR is an underappreciated factor in the etiology of PJIs and infection after implantation of other selective biomedical devices. Current engineering controls and practice requirements for limiting traffic during cases have thus far resulted in failure to reduce the risk of microbial aerosols or intraoperative contamination of implantable devices during arthroplasty surgery. Furthermore, there is a general lack of understanding or even misunderstanding of how (and why) airborne microbial populations pose a significant risk to patients undergoing device-implant surgery. Future consideration should be given to institutional investment in innovative air purification technologies as an adjunctive strategy to enhance current engineering controls, in an effort to reduce the risk of PJIs. Future consideration should be given to ongoing research into OR air quality by testing the feasibility of HVAC-implemented designs according to ASHRAE 170 using simulated surgical procedures and equipment that mirrors activity during a typical orthopedic procedure such as arthroplasty. Traditional infection control strategies such as limiting OR traffic has had a marginal impact in reducing intraoperative microbial aerosols or the risk of implant-associated infections. It is truly confounding that rigorous air quality standards are applied to the drug and computer chip manufacturing industries, whereas the same rigor has not been embraced to provide a safe and effective OR environment for surgical patients. To meet the future challenge of reducing the risk of PJIs and other implant-related infections, updated quantitative air quality standards for the OR (eg, those in development for the World Health Organization) are required that are based on state-of-the-art real-time microbial aerosol testing. If we are to have a measurable impact on reducing patient morbidity and mortality that is often associated with PJI, all surgical stakeholders must continue to evaluate and embrace innovative operative techniques along with evidence-based adjunctive risk reduction strategies, improving patient outcomes and preserving valuable health care resources.

References

50. Kirschman D, Echampsibi S. Airborne bacteria in the operating room can be reduced by HEPA/Ultraviolet air recirculation system (HUAIRS). Presented at the Surgical Infection Society (SIS)—37th Annual Meeting; 2017 May 2-5; St Louis, MO.