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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?

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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.[1] 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.[2] In addition, multiple studies have documented that PJI is associated with a mortality rate between 2% and 7%.[3,4] It has been suggested that in selective patients the 5-year survival rate with a PJI is worse than with many cancers.[4] 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.[5] 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 INAHTA. 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.

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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.[6] 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[7,8] Therefore, surgical procedures involving an implant are at significant risk after intraoperative contamination from even a minimal microbial inoculum.[9,10] 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.[12-16] 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.[17-23] 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.[24] The shedding of bacteria into the air by the OR team members can be enhanced by conditions including dermatitis and upper respiratory infections.[15,25,26] 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.[27] 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.[24] Underscored the impact of contaminated air on postoperative surgical infection are the recent global reports of intraoperative wound contamination by *Mycobacterium chimaera*.[28] 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.[28]

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.[29] 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 and High Efficiency Particulate Arrestance (HEPA) filtration.[30,31] 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).[32] 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.[33-36]

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.[37] 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).[38] 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.[39] 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 CFU/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[32]

- Mean diffuser velocity 127-178 L/m^2
- Diffuser concentration to provide an airflow pattern over the patient and surgical team
- Diffuser array shall extend a minimum of 305 mm beyond the table footprint
- >30% of the diffuser array area used for nondiffuser uses such as lights