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The Impact of Supplemental Intraoperative Air Decontamination on the Outcome of Total Joint Arthroplasty: A Pilot Analysis

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ABSTRACT

Background: During the early era of arthroplasty the concept of ultraclean operating room was introduced based on the principle that the number of airborne particles in the OR directly influences incidence of device-related infections. The hypothesis of this pilot study was that use of an innovative UV-C air decontamination technology would lead to a reduction in incidence of periprosthetic joint infection (PJI) following total joint arthroplasty.

Methods: A retrospective observational surveillance study was conducted, a consecutive series of patients who underwent total joint arthroplasty (n = 496) between January 2016 and August 2017. All perioperative and postoperative care protocols were identical for both groups, only study variable was that during 231 arthroplasty (OR B) an innovative supplemental UV-C air decontamination technology was utilized, whereas in the remaining 265 patients, arthroplasty was performed with standard turbulent HVAC (OR A).

Results: There was no significant difference between patient groups regarding age, BMI, diabetes diagnosis, smoking status, length of surgery, or revision status. The rate of PJI was documented to be 1.9% in the turbulent air group, no infections were documented in the cohorts operated under UV-C air decontamination, which was statistically significant ($p < 0.044$).

Conclusions: While PJI is multifactorial in nature, the present retrospective pilot study suggests that use of intraoperative supplemental air decontamination significantly reduced the overall risk of PJI. The findings of this study are encouraging and should be examined in a larger scale prospective multicenter study.

While more than 1 million total joint arthroplasties are performed yearly in the United States, that number is expected to increase to 4 million by the year 2030.^{1,2} The incidence of periprosthetic joint infect (PJI), as defined by the Musculoskeletal Infection Society (MSIS), ranges from 2.0% to 2.4%. However, a recent published review of the Medicare Inpatient Claims Database suggests that the unadjusted crude 1-year and 5-year risk of PJI is 0.69% and 1.09% for total hip arthroplasty (THA) and 0.74% and

1.38% for total knee arthroplasty (TKA).³ While it has been recently reported that the risk of PJI has stabilized in selective patient populations, the authors suggest that the burden of catastrophic disease in the Medicare patient population does not appear to have decreased, but is likely to increase as demand for TJA increases over the next 10 years.^{3,4} A recent systematic review and meta-analysis suggests that the 30-day readmission rate across all orthopedic specialties is 5.4% (ranging between 4.8 and

6.0 percent).⁵ While this rate is 7-9 percent lower than the readmission rate for general internal medicine and 6 percent lower than for general surgery, the current estimate for the cost of a periprosthetic joint infection (PJI) in the United States has risen significantly over the past 10-years, exceeding \$100,000.^{2,5} Mortality is significantly greater ($p < 0.001$) in patients with periprosthetic joint infection compared with those undergoing aseptic revision arthroplasty at ninety days (3.7% versus 0.8%), one year (10.6% versus 2.0%), two years (13.6% versus 3.9%), and five years (25.9% versus 12.9%).^{6,7} Furthermore, PJI poses a significant impact on the systemic health of the patient. In the periprosthetic joint infection population, independent predictors of mortality include increasing age, higher Charlson Comorbidity Index, history of stroke, polymicrobial infections, and cardiac disease.⁶ Using a conservative projection based upon current patient demographics and co-morbid risk, one can estimate by the year 2030, a total of 4 million total joint replacements will result in approximately 80,000 infections yearly, costing upwards to \$8 billion dollars.

Fifty years ago, the British orthopedic surgeon, Sir John Charnley proposed that microbial contamination within the operating room environment could be a risk for postoperative infection during biomedical device implantation.⁸ In 1973, Carl W. Walters, a surgeon and Ruth Kundsins, a microbiologist working at Peter Bent Brigham Hospital (now Brigham and Women's Hospital) in Boston, investigated the role of airborne bacteria within the operating room as a risk factor for surgical site infections.⁹ Using bacteriophage typing they identified multiple healthcare professionals, including surgical residents, an intern, a nurse, and anesthesiologist who were carriers of *Staphylococcus aureus*, linking them chronologically to several surgical site infections. They found in their studies that 21%, 33%, 57% and 71% of the operating room nurses, surgeons, anesthesiologists and nursing assistance, respectively were colonized with *Staphylococcus aureus*. These findings stimulated Dr. Kundsins to openly suggest that, "The airborne component of postoperative wound infection is not a fixed rate but rather varies from hospital to hospital, from OR to OR, and from surgical team to surgical team. The rate is proportional to the number of disseminating carriers in the room - aerosol contamination accounts for 20-24% of postoperative infections."⁹ At the time this was a provocative statement since surgical dogma suggested that postoperative infections were the exclusive result of contamination by the patient's own endogenous flora. However, studies by the British orthopedic surgeon O.M. Lidwell documented the relationship between mean operating room air contamination per cubic meter and the incidence of joint sepsis.¹⁰

Several emerging technologies have been developed to reduce the airborne microbial bioburden. One of these

technologies involves use of a self-contained system that incorporates C-band UV light focused on a photolytic chamber filled with clear cylindrical silicate quartz crystals over which is passed operating room air. A recent study using this technology (UV-C units) documented a significant reduction (50%-60%, $125 p < 0.05$) in both total particle counts and viable particle counts in a highly controlled operating room setting, suggesting that reducing airborne particles using a UV-C unit may have a positive impact on reducing the risk of infection following total joint arthroplasty.¹¹ The present retrospective study represents the first clinical effort to determine if supplemental air decontamination using an innovative UV-C technology is effective in reducing the risk of periprosthetic joint infection.



Figure 1. The HUAIRS, Illuvia unit is 46 x 46 x 150-cm, treats 12.8 cubic meters of air per minute, using a standard 115-volt outlet. The ultraviolet system is internal, preventing exposure to room occupants.

Methodology

The study was performed at the Medical Center at Elizabeth Place (MCEP) a surgical specialty hospital located in Dayton, OH. The operating rooms that were used in this study were approximately 500 square feet (46.5 m²), with a HEPA filtered HVAC system with 20 air exchanges per hour (ACH) and positive pressure.

The investigators submitted the protocol for institutional review and the retrospective study was granted a waiver from the institutional review board. The electronic medical

	Number (%)		p-value ^c
	OR A ^a	OR B ^b	
Males	98 (35.6)	78 (33.5)	0.09
Mean age	62.7	63.1	0.63
Mean BMI	33.4	33.2	0.70
Revision surgery	34 (12.8)	39 (16.8)	0.15
Diabetes dx	58 (21.1)	61 (26.2)	0.69
Smoker	48 (17.5)	36 (15.4)	0.32
Mean operative time (min.)	63.5	60.4	0.11

^aOperating Room A = Standard HEPA-Filter HVAC

^bOperating Room B = Standard HEPA-Filter HVAC plus Supplemental UV-decontamination

^cTwo-sample unpaired t-test

Table 1. Patient demographic and comorbid risk factors of retrospective cohort analysis of patient undergoing total joint arthroplasty

records (EMRs) were surveyed to identify all adult patients (18 years 139 and older) who had undergone hip, knee and shoulder arthroplasty from January 2016 to August 2017, by an orthopedic surgical team member (orthopedic resident, C.P). Between January 2016 and August 2017, a total of 496 consecutive hip (THA), knee (TKA) and shoulder arthroplasty procedures were performed by the same orthopedic team at MCEP (TC and CP). The control group, (standard turbulent air flow, OR A) comprised a total of 265 patients (Table 1) and the operative period of study was 15 months (January 2016-March 2017). In March 2016, a supplemental UV-C air decontamination technology (Figure 1, HUAIRS system, Aerobiotix Illuvia, West Carrollton, OH) was installed in a separate operating room as part of a quality assurance effort, designated as OR B (Standard HEPA-Filter HVAC plus supplemental UV-C air decontamination). From March 2016 to August 2017 (18 months), a total of 231 TJAs were performed in this operating room. The only study variable was that cases in OR B were performed under supplemental UV-C air flow decontamination whereas cases in OR A were performed under a traditional HEPA-filtered HVAC system with 20 air exchanges per hour.

All perioperative and postoperative care protocols were identical for both groups and included: standard preoperative labs, nasal swab and decolonization (mupirocin BID x 5 days) if positive for MRSA or Staphylococcus aureus, standardized preadmission shower (night before/morning of surgery) with 4% aqueous chlorhexidine gluconate (CHG), intraoperative irrigation with 0.05% CHG, and weight-based dosing 159 with cefazolin or vancomycin (if nasal swab positive). If the patient was penicillin-allergic, a single weight-based dose of gentamicin was administered as a substitute for cefazolin. An alginate hydrofiber dressing was applied to the surgical wound following surgery and prior to discharge a nurse reviewed with the family (caregiver) postoperative wound care instructions.

	Number (%)			
	OR A ^a	PJI	OR B ^b	PJI
Arthroplasty Procedure				
Primary hip	65 (24.6)	2	69 (29.9)	0
Primary knees	132 (49.9)	0	91 (39.5)	0
Primary shoulder	5 (1.8)	0	19 (8.4)	0
Revision hip	9 (3.4)	2	9 (3.9)	0
Revision knee	24 (9.1)	1	30 (12.9)	0
Revision shoulder	1 (0.3)	0	0 (0)	0
Bilateral hip	3 (1.1)	0	0 (0)	0
Bilateral knee	26 (9.8)	0	12 (5.4)	0
Total N	265	5	231	0

p<0.044^c

^aOperating Room A = Standard HEPA-Filtered HVAC

^bOperating Room B = Standard HEPA-Filtered HVAC plus Supplemental UV-C decontamination

^cFisher's Exact test

Table 2. Distribution of total joint arthroplasty procedures and periprosthetic Joint Infections (PJI)

The surveillance strategy for PJIs involved review of individual electronic medical records (EMR), all identified TJAs were initially reviewed (by CP) at 4 months post-implant surgery. The administrative diagnosis of surgical site infection was based on criteria defined by the Centers for Disease Control and Prevention (CDC).^{12,13} The routine follow-up period by the attending orthopedic surgeon (TC) is 4 weeks, 3 months and 12 months post-op. A review of all patients (by CP) operated over the period of study (January 2016-August 2017) in both ORs revealed no additional infections. As a general principle all suspected infections are assessed by the Musculoskeletal Infection Society (MSIS) criteria for periprosthetic joint infection including, serum C-reactive protein (CRP) and D-dimer erythrocyte sedimentation rate.¹⁴ A two-sample student t-test was used to evaluate the statistical significance of patient demographic data (Table 1). The five patients who developed PJI documented no additional comorbid risk factors for infection such as hematoma, wound dehiscence, DVT/PE and/or hematogenous (remote) source of infection. A one-tailed Fisher's Exact test was used to determine statistical significance of PJI between groups (OR A vs. OR B) at the p>0.05 level (Table 2).

Results

A total of 496 consecutive patients were identified who underwent joint arthroplasty procedures at a single center by the same surgeon (TC) between January 2016 and August 2017. The control group (OR A) consisted of 265 patients, while the experimental group (UV-C) consisted of 231 patients (OR B). There was no significant difference between patient groups regarding age, BMI, diabetes diagnosis, smoking status, length of surgery, or revision status (Table 1). The patients underwent, in descending

order of frequency, primary knee replacement (n=223), primary hip replacement (n=134), revision knee replacement (n=54), bilateral primary knee replacement (n=38), primary shoulder replacement (n=24), revision hip replacement (n=18), revision shoulder replacement (n=1) and bilateral primary hip replacement (n=3). There was a trend towards more primary knee procedures in the control group (49.9% vs. 39.5%), whereas more primary shoulder procedures were performed in the investigational group (OR B) compared to control, OR A (1.8% vs 8.4%, respectively).

There was also a trend of more revision surgeries performed in OR B (39, 16.8) 195 compared to OR A (34, 12.8), which did not approach statistical significance (p=0.15). A total of 5 periprosthetic joint infections (PJI) were identified, all five infections occurred in OR A (standard HEPA-filtered HVAC system): An 84-yr. female revision THA, who underwent reoperation at 28 days postop, a 71-yr. male revision TKA who underwent reoperation at 20 days postop, a 48-yr. female primary THA who underwent reoperation at 37 days postop, a 51-yr. female primary THA who underwent reoperation at 43 days postop, and a 51-yr. male revision THA who underwent reoperation at 34 days postop. Of the five infected cases, three were revision procedures, the infection rate in the control group was 1.9%, versus 0% for the experimental group (Table 2) (p=0.044).

Discussion

Over the last 20 years several peer-reviewed publications have presented evidence that airborne microbial populations can play a sentinel role in the etiology of surgical site infection (SSI), especially in procedures involving implantable biomedical devices, such as prosthetic joints. Surgical procedures involving an implant are at significant risk after intraoperative contamination from even a minimal microbial inoculum (2.0 Log^{10}).¹⁵ Once an organism adheres to the biomedical implant the organism downregulates its metabolism such that its generation time is no longer measured in hours but now in days, weeks and even months.¹⁶ In this manner the organism is able to elude the host surveillance mechanism until it reaches a critical density or the infection spreads beyond the device into the tissues. A second component of microbial pathogenesis of device-related infection is the ability of both selective gram-positive and gram-negative wound pathogens to produce a biofilm which is recalcitrant to antibiotics, antibodies and phagocytic cells.¹⁷

The convective air flow within the OR produces turbulence which can spread airborne particles, posing a potential risk for postoperative infection. These airborne particles including dust, textile fibers, skin scales, and respiratory aerosols, may contain viable microorganisms (including

Staphylococcus aureus), which are 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.¹⁸⁻²² A study documenting the dispersion of microbial aerosols in the operating room was conducted in the Department of Surgery at the Medical College of Wisconsin, using pulse-field gel electrophoresis (PFGE), investigators were able to recover the same molecular strains of coagulase-negative staphylococci and *Staphylococcus aureus* originating from nasopharyngeal shedding by members of the vascular surgical team. A total of 70 separate vascular procedures were studied, 37% and 42% of the of the time, *Staphylococcus aureus* and coagulase-negative staphylococci, respectively were recovered < 1-meter from the surgical wound.²³ In two separate (unpublished findings) incidents at the author's institution, *Stenotrophomonas maltophilia* and *Staphylococcus epidermidis* were recovered from an acute and late-onset vascular graft infections. The acute infection was traced using PFGE to a sink that was in an ante room adjacent to the vascular suite, while the late-onset infection was clonally link to a nasopharyngeal isolate from a member of the vascular surgical team.

Microbial contamination of air in the OR is an underappreciated factor in the etiology of PJIs and other infections following implantation of selective biomedical devices. Even in the presence of appropriate (required) engineering and traffic control standards, there are numerous reports and studies linking airborne contamination directly to device-related procedures and specifically, orthopedic SSIs.²⁴⁻²⁷ A study supporting this assertion was reported by Dalstrom et al., using standard culture technique, the investigators found "culture positivity of surgical instruments that correlated directly with the duration of exposure of the uncovered operating-room trays." The authors suggested that covering the surgical trays with a sterile towel significantly reduced the contamination risk.²⁸

Current engineering controls and practice requirements for limiting operating room traffic and door openings during surgical cases have thus far resulted in a failure to reduce the risk of microbial aerosol, leading to intraoperative contamination of surgical instrument and/or implantable devices. Simulation and real-time OR studies document that intraoperative traffic patterns and door openings during surgery increase aerosolized particles in the operating room, compromising air quality.²⁹⁻³¹ While increasing the number of air changes per hour (ACH) from 20 to up to 30 (or higher) has been associated with a reduction in the total number of circulating particles in the OR, to date there is no scientific evidence to support that increasing the ventilation rate (ACH) to a higher level actually reduces SSIs.³²

Recently, a HEPA-filtered Ultraviolet Air Recirculation System (HUAIRS) has been introduced which provides supplemental air decontamination within the OR. The mobile unit removes bacterial contamination in the peripheral segments of the operating room, near vulnerable surfaces such as surgical trays and countertops. The unit delivers 450 cubic feet (12.7 m³) per minute of non-turbulent ultraclean air. The efficacy of this innovative system to reduce airborne microorganisms present within an active operating room has been recently documented. The system incorporates C-band UV light focused on a photolytic chamber filled with clear cylindrical silicate quartz crystals to decrease bacteria counts in the air. In the study, an air sampling impactor and agar media plates were placed in multiple locations in the OR, measuring the number of CFU per cubic meter in the air before and after activation of the system. The investigators found from their air sampling studies, a 53.4% (p = 0.016) reduction in the recovery of airborne colony-forming units per cubic meter when the HUAIRS system was in-place and functioning.³³

In an effort to reduce the risk of PJIs and other device-related surgical infections, future consideration should be given to institutional investment in innovative air purification technologies as an adjunctive strategy to enhance current operating room HVAC engineering controls. In the practice of orthopedic joint replacement, multiple strategies have been used or proposed to reduce the risk of PJI, including the use of surgical helmet systems (SHSs), ultraviolet (UV) lamps, multiple array designed laminar flow systems, and high ventilation rates. Unfortunately, two recent publications and a meta-analysis have questioned the benefit of current SHS systems for reducing the risk of periprosthetic joint infections.³⁴⁻³⁶ While the pharmaceutical 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. The current air quality standards used to design HVAC systems for the operating room environment are best characterized as engineering standards (ASHRAE Standard 170) and do not represent an evidence-based aerobiological risk-adjusted standard.^{37,38} A recent publication has suggested that operating room air quality should reflect an evidence-based aerobiological standard. The European Union (EU) has proposed the development of new air quality standards for the OR environment that is based upon the recovery of viable particulates and operative patient risk and not the historic assessment of non-viable particulates which are not evidence-base or risk adjusted.³⁹

The primary limitation of this study is that it is not a prospective, multicenter randomized controlled trial but represents a “real world” experience of a single orthopedic surgical team practicing at a surgical specialty hospital. The authors noted that the incidence of PJI (1.9%) in the

HEPA-filtered turbulent air group (OR A) was higher than the rate currently reported in the peer literature.³ Use of a supplemental HEPA filtered UV-C air recirculation system demonstrated a significant (p<0.044) risk reduction benefit for patients (OR B) undergoing total joint arthroplasty. These findings suggest that in light of current study limitations, further well-design randomized controlled clinical trials are warranted to assess the clinical efficacy of an innovative supplemental UV-C air recirculation technology as a risk-reduction strategy for patients undergoing total joint arthroplasty.

Reducing the risk of infection in total joint arthroplasty or other device-related surgical procedures requires a focus, multi-modal interventional approach. Device-related surgical procedures are at high risk for environmental contamination and an effective strategy for reducing aerosol contamination is clearly needed given the explosive increase in orthopedic and other device-related surgical procedures projected for the United States over the next 10 years.

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