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

Thomas M. Cook, DO [a], Caleb J. Piatt, DO [a], Sue Barnes, BSN [b], Charles E. Edmiston Jr., PhD [c, *]

[a] Division of Orthopedic Surgery, Grandview Medical Center, Dayton, OH
[b] Clinical Infection Prevention Consultant, San Mateo, CA
[c] Department of Surgery, Medical College of Wisconsin, Milwaukee, WI

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ABSTRACT

Background: During the early era of arthroplasty, the concept of ultraclean operating room (OR) 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 the incidence of periprosthetic joint infection (PJI) following total joint arthroplasty.
Methods: A retrospective, observational, surveillance study was conducted with 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 in 231 arthroplasty patients (OR B), an innovative supplemental UV-C air decontamination technology was used, 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, body mass index, 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, and no infections were documented in the cohorts operated under UV-C air decontamination, which was statistically significant ($P < .044$).
Conclusion: While PJI is multifactorial in nature, the present retrospective pilot study suggests that use of an 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 (TJAs) 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 infection (PJI), as defined by the Musculoskeletal Infection Society, 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%) [5]. While this rate is 7%-9% lower than the readmission rate for general internal medicine and 6% lower than for general surgery, the current estimate for the cost of a PJI in the United States has risen significantly over the past 10 years, exceeding $100,000 [2,5]. Mortality is significantly greater ($P < .001$) in patients with PJI compared with those undergoing aseptic revision arthroplasty at 90 days (3.7% vs 0.8%), 1 year (10.6% vs 2.0%), 2 years (13.6% vs 3.9%), and 5 years (25.9% vs 12.9%) [6,7]. Furthermore, PJI poses a

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* Reprint requests: Charles E. Edmiston, Jr., PhD, Department of Surgery, Medical College of Wisconsin, Milwaukee, WI 53226.

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significant impact on the systemic health of the patient. In the PJI 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 comorbid risk, one can estimate by the year 2030, a total of 4 million TJAs will result in approximately 80,000 infections yearly, costing upward to $8 billion dollars.

Fifty years ago, the British orthopedic surgeon Sir John Charnley proposed that microbial contamination within the operating room (OR) environment could be a risk of postoperative infection during biomedical device implantation [8]. In 1973, Carl W. Walters, a surgeon, and Ruth Kundsin, a microbiologist working at Peter Bent Brigham Hospital (now Brigham and Women's Hospital) in Boston, investigated the role of airborne bacteria within the OR as a risk factor for surgical site infections (SSIs) [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 SSIs. They found in their studies that 21%, 33%, 57%, and 71% of the OR nurses, surgeons, anesthesiologists, and nursing assistance, respectively, were colonized with *S aureus*. These findings stimulated Dr Kundsin 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 because 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 OR 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 OR air. A recent study using this technology (UV-C units) documented a significant reduction (50%-60%, $P < .05$) in both total particle counts and viable particle counts in a highly controlled OR setting, suggesting that reducing airborne particles using a UV-C unit may have a positive impact on reducing the risk of infection following TJA [11]. The present retrospective study represents the first clinical effort to determine whether supplemental air decontamination using an innovative UV-C technology is effective in reducing the risk of PJI.

Methodology

The study was performed at the Medical Center at Elizabeth Place (MCEP), a surgical specialty hospital located in Dayton, OH. The OR that were used in this study were approximately 500 square feet (46.5 m^2), with a HEPA-filtered HVAC system with 20 air changes 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 records were surveyed to identify all adult patients (18 years and older) who had undergone hip, knee, and shoulder arthroplasty from January 2016 to August 2017, by an orthopedic surgical team member (orthopedic resident, CP). Between January 2016 and August 2017, a total of 496 consecutive hip, knee, 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,

Table 1
Demographic and Comorbid Risk Factors of Retrospective Cohort Analysis of Patients Undergoing Total Joint Arthroplasty.

Patient Variables	Number (%)		
	OR A[a]	OR B[b]	*P* Value[c]
Males	98 (35.6)	78 (33.5)	.09
Mean Age	62.7	63.1	.63
Mean Body Mass Index	33.4	33.2	.70
Revision Surgery	34 (12.8)	39 (16.8)	.15
Diabetes Diagnosis	58 (21.1)	61 (26.2)	.69
Smoker	48 (17.5)	36 (15.4)	.32
Mean Operative Time (Min)	63.5	60.4	.11

[a] Operating room A = standard HEPA-filter HVAC.
[b] Operating room B = standard HEPA-filter HVAC plus supplemental UV-decontamination.
[c] Two-sample unpaired *t*-test.

Fig. 1. The HUAIRS Illuvia unit is 46 × 46 × 150 cm and 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.

HUAIRS HEPA-filtered ultraviolet air recirculation system, Aerobiotix Illuvia, West Carrollton, OH) was installed in a separate OR 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 OR. 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 ACH.

All perioperative and postoperative care protocols were identical for both groups and included standard preoperative labs, nasal swab and decolonization (mupirocin BID × 5 days) if positive for MRSA or *S aureus*, standardized preadmission shower (night before/morning of surgery) with 4% aqueous chlorhexidine gluconate, intraoperative irrigation with 0.05% chlorhexidine gluconate, and weight-based dosing 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 alginated 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.

The surveillance strategy for PJIs involved review of individual electronic medical records, and all identified TJAs were initially reviewed (by CP) at 4 months postimplant surgery. The administrative diagnosis of SSI was based on criteria defined by the Centers for Disease Control and Prevention [12,13]. The routine follow-up period by the attending orthopedic surgeon (TC) is 4 weeks, 3 months, and 12 months postoperatively. 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 criteria for PJI including serum C-reactive protein and D-dimer erythrocyte sedimentation rate [14]. A 2-sample Student *t*-test was used to evaluate the statistical significance of patient demographic data (Table 1). The 5 patients who developed PJI documented no additional comorbid risk factors for infection such as hematoma, wound dehiscence, deep vein thrombosis/pulmonary embolism, and/or hematogenous (remote) source of infection. A 1-tailed Fisher exact test was used to determine statistical significance of PJI between groups (OR A vs OR B) at the $P > .05$ level (Table 2).

Table 2
Distribution of Total Joint Arthroplasty Procedures and Periprosthetic Joint Infections (PJI).

	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
				$P < .044$[c]

[a] Operating room A = standard HEPA-filtered HVAC.
[b] Operating room B = standard HEPA-filtered HVAC plus supplemental UV-C decontamination.
[c] Fisher exact test.

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, body mass index, diabetes diagnosis, smoking status, length of surgery, or revision status (Table 1). The patients underwent, in descending order of frequency, primary knee arthroplasty (n = 223), primary hip arthroplasty (n = 134), revision knee arthroplasty (n = 54), bilateral primary knee arthroplasty (n = 38), primary shoulder arthroplasty (n = 24), revision hip arthroplasty (n = 18), revision shoulder arthroplasty (n = 1) and bilateral primary hip arthroplasty (n = 3). There was a trend toward more primary knee procedures in the control group OR A (132) compared to the investigational OR B group (91), whereas more primary shoulder procedures were performed in the investigational group (OR B, 19) compared to control (OR A, 5) (19 vs 5).

A total of 5 PJIs were identified, and all 5 infections occurred in OR A (standard HEPA-filtered HVAC system): an 84-year-old female with revision THA, who underwent reoperation at 28 days postoperatively; a 71-year-old male with revision TKA, who underwent reoperation at 20 days postoperatively; a 48-year-old female with primary THA, who underwent reoperation at 37 days postoperatively; a 51-year-old female with primary THA, who underwent reoperation at 43 days postoperatively, and a 51-year-old male with revision THA, who underwent reoperation at 34 days postoperatively. Of the 5 infected cases, 3 were revision procedures, and the infection rate in the control group was 1.9% vs 0% for the experimental group (Table 2; $P = .044$).

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 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 of postoperative infection. These airborne particles including dust, textile fibers, skin scales, and respiratory aerosols may contain viable microorganisms (including *S 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 OR was conducted in the Department of Surgery at the Medical College of Wisconsin using pulse-field gel electrophoresis, and investigators were able to recover the same molecular strains of coagulase-negative *Staphylococci* and *S 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 time, *S aureus* and coagulase-negative *Staphylococci*, respectively, were recovered ≤1 m from the surgical wound [23]. In 2 separate (unpublished findings) incidents at the author's institution, *Stenotrophomonas maltophilia* and *Staphylococcus epidermidis* were recovered from an acute-onset and late-onset vascular graft infections. The acute infection was traced using pulse-field gel electrophoresis to a sink that was in an anteroom adjacent to the vascular suite, while the late-onset infection was clonally linked 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 OR 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 OR, compromising air quality [29–31]. While increasing the number of ACH from 20 to up 30 (or higher) has been associated with a reduction in the total number of circulating particle 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, HUAIRS has been introduced which provides supplemental air decontamination within the OR. The mobile unit removes bacterial contamination in the peripheral segments of the OR, near vulnerable surfaces such as surgical trays and countertops. The unit delivers 450 cubic feet (12.7 m^3) per minute of nonturbulent ultraclean air. The efficacy of this innovative system to reduce airborne microorganisms present within an active OR 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 colony-forming units per cubic meter in the air before and after activation of the system. The investigators found from their air sampling studies, a 53.4% ($P = .016$) reduction in the recovery of airborne colony-forming units per cubic meter when the HUAIR 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 OR HVAC engineering controls. In the practice of orthopedic joint arthroplasty, multiple strategies have been used or proposed to reduce the risk of PJI, including the use of surgical helmet systems, ultraviolet lamps, multiple array designed laminar flow systems, and high ventilation rates. Unfortunately, 2 recent publications and a meta-analysis have questioned the benefit of current surgical helmet systems for reducing the risk of PJIs [34–36]. While the pharmaceutical and computer industries enforce stringent air quality standards on their manufacturing processes, there is currently no US standard for acceptable air quality within the OR environment. The current air quality standards used to design HVAC systems for the OR 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 OR air quality should reflect an evidence-based aerobiological standard. The European Union 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 nonviable particulates which are not evidence based 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 ($P < .044$) risk reduction benefit for patients (OR B) undergoing TJA. These findings suggest that in light of present study limitations, further well-designed, 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 TJA.

Reducing the risk of infection in TJA or other device-related surgical procedures requires a focused, multimodal, interventional approach. Device-related surgical procedures are at high risk of 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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