

Illuvia HUAIRS® Evidence in Brief

ILLUVIA®
HEPA-Ultraviolet Air Recirculation System



A **AEROBIOTIX**®
BETTER AIR FOR HEALTHCARE™

Infection Reduction

- **Cook, Piatt, Barnes,
Edmiston, 2018**
- **ABX Outcome Study
(Atlanta), 2015**

Infection Reduction

The Impact of Supplemental Intraoperative Air Decontamination on the Outcome of Total Joint Arthroplasty: A Pilot Analysis. *Journal of Arthroplasty* (2018).

Cook, T., DO, Piatt, C., DO, Barnes, S., BSN, and Edmiston, Jr., C. E., PhD

- Performed at Medical Center at Elizabeth Place, Dayton, Ohio. Utilized identical protocol with the addition of the HUAIRS system and no significant differences in the groups.
- OR used standard vertical turbulent (non-laminar) flow arrays.
- Retrospective review of 508 consecutive patients over a two-year period, with control group and supplemental air group.
- Reduced prosthetic joint infection rates from 1.9% to 0%.

Infection Reduction

Case Study: **ABX Outcome Study: SSI Reduction Results.**
The Healthcare Environment Institute (2015).

- The study was conducted during orthopedic procedures in a 300-bed community medical center (confidential) in Atlanta, Georgia.
- This study is the first to document an SSI rate reduction after the deployment of ABX technology.
- 66% reduction in SSI rate over a 5-month period in orthopedic OR when Illuvia HUAIRS was deployed.

Bacterial Level Reduction

- **Eachempati, 2017**
- **Parvizi, 2017**
- **Walsh, 2017**
- **Bischoff, 2019**

Bacterial Level Reduction

Airborne bacteria in the operating room can be reduced by HEPA/Ultraviolet air recirculation system (HUIARS).
Surgical Infection Society (2017).

Kirschman, D., MD, Eachempati, S.R., MD, FACS,
FCCM

- New York-Presbyterian Hospital-Weill Cornell Medical Center, New York. HUIARS was evaluated in a plastic surgery OR at a confidential outpatient surgery center.
- An air sampling impactor and agar media plates were placed in multiple locations in the OR to measure the number of bacterial colony forming units per cubic meter (CFU/m³).
- From cultured samples obtained, airborne bacterial content was reduced in active OR by 67.7%.

Bacterial Level Reduction

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?
American Journal of Infection Control (2017).

Parvizi, J., MS, MD, FRCS, Barnes, S., RN, CIC,
Shohat, N., MD, Edmiston, C., MS, PhD.

- Although 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.
- Recent studies suggest that viable airborne particulates are readily disseminated throughout the OR, placing patients at risk for postoperative SSI.
- To meet the future challenge of reducing the risk of PJIs and other implant-related infections, updated quantitative air quality standards for the OR are required that are based on state-of-the-art real-time microbial aerosol testing.

Bacterial Level Reduction

Reduction of airborne bacterial levels in operating theatre using supplemental ultraclean air system. The Healthcare Environment Institute (2017).

Walsh, W., PhD., et al

- The study was conducted in a community tertiary care hospital in New South Wales, Australia.
- Two arthroplasty ORs, standard positive pressure rooms, were evaluated by air sampled continuously over the span of three arthroplasty procedures with the C-UVC/HEPA device.
- The presence of the C-UVC/HEPA device reduced mean bacterial CFU/m³ by 57%.

Bacterial Level Reduction

Impact of a Novel, Mobile Air Purification System on the Bacterial Air Burden during Routine Care.

American Journal of Infection Control (2019)

Bischoff, W. MD, PhD, FSHEA, Russell, G. B. MS, Willard, E. S. and Stehle, J. Jr., PhD

- Wake Forest Baptist Medical Center, Winston Salem, North Carolina.
- Sixty-four patients admitted to the Emergency Department underwent air sampling in their respective rooms: at the head of the bed, foot of the bed and the exit. Over 600 samples were collected in blood agar plates.
- An overall 41% reduction in bacterial CFUs was observed in the three locations within the ED rooms.

Airborne Particle Reduction

- **Nassof et al, 2018**
- **Curtis et al, 2018**
- **Anis, Curtis, 2018**
- **Curtis et al, 2017**
- **Curtis et al, 2017**
- **Walsh, 2017**
- **Barnes, 2017**
- **Case Study, 2014**

Airborne Particle Reduction

Developing the case for implementation of operating room air decontamination technology for orthopedic surgery. *Infection Control Today* (Sept 2018).

Nassof, R., JD, Warye, K., Spencer, M. Med, RN, CIC, FAPIC

- The body of evidence for air decontamination technology that is both technically and economically feasible suggests reason to review air quality management beginning with the OR.
- The case of *Nowatske v. Osterloh* ruled adherence to custom (clinical guidelines) might constitute a failure to exercise reasonable care.
- In light of the evidence and global movement toward air quality standards in the OR, Infection Preventionists may want to consider adoption of air quality technologies as a supplemental evidence-based solution for reduction of SSI.

Airborne Particle Reduction

Reduction of Particles in the Operating Room using Ultraviolet Air Disinfection and Recirculation Units.
Orthopaedic Research Society (2018).

Curtis, GL, MD, et al

- Cleveland Clinic, Cleveland, Ohio.
- 30 experiments in a single, empty positive pressure operating room with walkthroughs at pre-set times.
- Particle counts were significantly reduced in rooms with a C-UVC unit versus control room with no C-UVC unit across all outcome measures.

Airborne Particle Reduction

Reduction of Airborne Bioburden during lower limb total joint arthroplasty. Musculoskeletal Infection Society (2018).

Anis, H. MD, Curtis, G. MD et al.

- Cleveland Clinic, Cleveland, Ohio.
- 32 primary total knee arthroplasty /total hip arthroplasty in positive-pressure OR measuring total and viable airborne particles using agar plates to measure colony forming units (CFU/m³).
- Significant reductions of 46% of viable particle counts and 42% total particle counts.

Airborne Particle Reduction

Reduction of Particles in the Operating Room Using Ultraviolet Air Disinfection and Recirculation Units. The Journal of Arthroplasty (2017).

Curtis, G.L., MD, Faour, M., MD, Jawad, Michael, BS, Klika, MS, Barsoum, W.K., MD, Higuera, C.A., MD.

- Department of Orthopaedic Surgery, Cleveland Clinic, Cleveland, Ohio.
- Conducted in a standard positive-pressure OR to observe airborne particle counts related to OR foot traffic.
- C-UVC units significantly reduce total and viable particle counts.

Airborne Particle Reduction

Reduction of Total and Viable Air Particles in the OR Setting by using Ultraviolet In-room Air Disinfection and Recirculation Units. American Association of Hip and Knee Surgery. (2017).

Curtis, G. MD, et al.

- Orthopaedic and Rheumatologic Institute, Cleveland Clinic, Cleveland, Ohio. Conducted in a plastic surgery OR at the outpatient surgery center.
- Air sampling impactor and agar media plates placed in multiple locations in the OR were used to measure the number of bacterial colony forming units per cubic meter (CFU/m³). Agar plates were incubated and counted by an independent microbiological laboratory.
- Significant reduction of 67.7% in the CFU count.

Airborne Particle Reduction

The effect of a novel air decontamination recirculation system on viable and total airborne particulates during surgery. The European Bone and Joint Infection Society (2017).

Walsh, W., PhD., et al.

- Surgical and Orthopaedic Research Laboratories, Prince of Wales Clinical School, University of New South Wales, Prince of Wales Hospital, Sydney, Australia.
- A two-phase study evaluating airborne particles in a variety of surgical procedures.
- Reduced bacterial colony forming units (CFU/m³) by over 50%.

Airborne Particle Reduction

Crystalline UV-C Inactivation of Airborne Microorganisms: Clinical and Laboratory Analysis of a Novel Germicidal Air Recirculation Technology. The Healthcare Environment Institute (2017).

Barnes, S., RN, CIC, FAPIC, and Rybalko, V., MS, PhD.

- Laboratory analysis was conducted at RTI, an independent accredited laboratory, Raleigh, North Carolina.
- Single-pass laboratory-based tests were performed to evaluate inactivation efficiency of ABX C-UVC reaction chamber on aerosolized bacteria, viruses and spores.
- Single-pass C-UVC inactivation of 99.97% of bacteria, 99.91% of spores, and 100% of viruses.

Airborne Particle Reduction

Case Study: Assessment of Air Contamination in Active Operating Room. The Healthcare Environment Institute (2014).

- Case study was conducted at Providence Alaska Center, a 371-bed tertiary care facility located in Anchorage Alaska.
- Air quality was monitored before and after the deployment of the ABX HUAIRS system in a fully occupied general OR with a mixture of general and orthopedic procedures. ABX technology successfully reduced airborne contamination bringing mean airborne particle levels from ISO noncompliance into ISO 9 compliance (the minimum standard for clean room air per international literature).
- 50% reduction in total airborne particles (TPC/m³) of 5 µm and 10 µm size.

Smoke Evacuation and Heater-Cooler Emissions

- **Barnes, 2018**
- **Walsh et al, 2017**

Smoke Evacuation, Reduction in Heater-Cooler Emissions

OR Air Quality: Is it time to consider adjunctive air cleaning technology? AORN Journal (November 2018).

Barnes, S. RN, CIC, FAPIC, et al.

- In the operating room (OR), smoke plume generated by laser and electrosurgery poses a health risk to both surgical personnel and to a lesser degree, patients.
- As has been most recently underscored by the *Mycobacterium chimeraea* outbreak associated with the heater cooler devices, air contamination is a true risk for surgical patients, especially those receiving implants.
- Reports of efficacy and the numerous benefits of new-to-market OR air scrubbing HEPA plus UV-C technology are increasing.

Smoke Evacuation, Reduction in Heater-Cooler Emissions

HEPA/UV-C Air Recirculation Technology for Surgical Smoke Evacuation: A Laboratory-Based Study. The Australian Infection Control Association. ACIPC (2017).

Walsh, W.R., Oliver, R., MD, Davies, G., MD, Bradford, N.

- Surgery and Orthopaedic Research Laboratories, University of New South Wales, Prince of Wales Hospital, Randwick, Australia.
- Study was conducted in a Level 2 test laboratory using electrocauterization of porcine skin samples to test the effect of HUAIRS system on reducing environmental particle content following porcine tissue diathermy.
- >50% reduction in 0.3-10 μm surgical smoke particles from tissue electrocauterization.

Aerobiology and Airborne Contamination

- **Whyte 1982**
- **Lidwell 1983**
- **Lidwell 1987**
- **Whyte 1992**
- **Eickhoff 1994**
- **Durmaz 2005**
- **Kowalski 2007**
- **Charkowska 2008**
- **Kurtz 2012**

Aerobiology and Airborne Contamination

The importance of airborne bacterial contamination of wounds. The Journal of Hospital Infection (June 1982).

Whyte, W., Hodgson, R., Tinkler, R.

- Building Services Research Unit, University of Glasgow, Glasgow, U.K. investigated sources of bacterial contamination of hip and knee joint replacement.
- Operations were conducted in either a conventionally-ventilated or a laminar-flow OR.
- 98% of bacteria in patients' wounds came directly or indirectly from the air. Analysis clearly showed that the most important and consistent route of contamination was airborne.

Aerobiology and Airborne Contamination

Airborne contamination of wounds in joint replacement operations: the relationship to sepsis rates. Jnl hosp inf 1983. Study section: Bacterial contamination of the surgical wound during operation.

Lidwell, O.M., et al.

- The MRC Clinical Research Centre, Harrow, Middlesex and Medical Research Council Biostatistics Unit, Cambridge. Study was conducted in 14 hospitals in operating rooms with conventional ventilation.
- Wound wash-out fluid was cultured in blood agar plates or petri dishes with conventional non-selective media and only aerobic cultures were usually made. The colonies were counted after incubation for more than 48 hours at 37°C.
- From the data it would seem that by far the largest proportion of bacteria found in the wound after the prosthesis had been inserted reached it by the airborne route.

Aerobiology and Airborne Contamination

Ultraclean air and antibiotics for prevention of post op infection multicenter study of 8052 joint replacement operations. Acta Orthopaedica Scandinavica (1987).

Lidwell, O.M., et al.

- 8,052 total hip- or knee-joint replacement operations were followed up for 1-4 years to determine the value of ultraclean air in operating rooms. Four Swedish hospitals and fifteen British hospitals took part in the trial.
- Operations were performed in conventional, positive-pressure systems delivering 15-25 air changes per hour (control) or ultraclean-air ventilation, which included body-exhaust suits or plastic patient-isolators.
- Ultraclean-air operating rooms had significantly lower infection rates.

Aerobiology and Airborne Contamination

The relative importance of the routes and sources of wound contamination during general surgery. II. Airborne. Journal of Hospital Infection (1992).

Whyte, W., Hambræus, A., Laurell, G., Hoborn, J.

- This study was carried out in the operating suite of the University Hospital, Uppsala, Sweden.
- Operating rooms were of conventional design. One hundred of the 185 operations in this study were airborne sampled.
- Reduction in the airborne bacteria in the operating room of about 13-fold would reduce the wound contamination by about 50%. In areas away from the wound, the bacterial concentration on the drape surface was significantly affected only by airborne bacteria.

Aerobiology and Airborne Contamination

Airborne Nosocomial Infection: A Contemporary Perspective. Infection Control and Hospital Epidemiology (1994).

Eickhoff, T.C., MD

- This review investigates the relative importance of airborne transmission of infection in the overall problem of nosocomial infection.
- Various studies on air sampling, air supply ducts and air flow show various infections can be airborne.
- Between 10-30% of hospital acquired infections have airborne contribution.

Aerobiology and Airborne Contamination

The relationship between airborne colonization and nosocomial infections in intensive care units.

Mikrobiyoloji Bulteni (2005).

Dürmaz, G., et al.

- This study was conducted in operating theatres and intensive care units.
- During this study period (19 weeks), a total of 77 air samples and 870 clinical specimens from 174 patients were collected weekly.
- The total number of airborne viable particles in the critical areas such as operating theatres and intensive care units, seem to be a significant risk factor for the development of nosocomial infections.

Aerobiology and Airborne Contamination

Air Treatment Systems for controlling hospital acquired infections. HPAC Engineering (2007).

Kowalski, W.J. PE, PhD.

- New nosocomial hazards demand renewed interest in both causes and solutions.
- An example of a cause: In one hospital studied by the author, heavy bacterial contamination was found in a lunchroom carpet, from which doctors and nurses apparently were carrying bacteria on the soles of their shoes into and around the ICU.
- With more than a third of all nosocomial infections possibly involving airborne transmission at some point, the combination of surface and air disinfection should produce optimum results.

Aerobiology and Airborne Contamination

Ensuring Cleanliness in Operating Theatres.

International Journal of Occupational Safety and Ergonomics (2008).

Charkowska, A.

- Air-Conditioning and Heating Division, Warsaw University of Technology, Warsaw, Poland.
- A supply of air cleaned in highly-effective air filters to hospital wards with air conditioning systems and exhaust of infected air will help maintain the required standards of cleanliness.
- Many countries in Europe have Microbiological Cleanliness Requirements for Hospital Rooms: Class I Rooms <10 CFU (ORs), Class II Rooms <50 CFU (PreOp, OR Corridors) and Class III Rooms <200 CFU (Wards, Supply Areas).

Aerobiology and Airborne Contamination

Economic burden of periprosthetic joint infection in the United States. Journal of Arthroplasty (2012).

Kurtz, S.M., PhD, Lau, E. MS, Watson, H. PhD, Schmier, J.K, MA, Parvizi, J. MD.

- This study used the National Inpatient Sample (NIS) database to forecast PJI's economic impact on the hospital health care system in the United States.
- The rate of PJI following total knee and hip arthroplasty (TKA/THA) is between 1.5% and 2.5%.
- Based on the hospital cost estimated from the present data, the future PJI cases are expected to incur a cost to US Hospitals to reach \$1.62 billion by 2020.

Indication: The Illuvia HUAIRS-MD is an air handling apparatus for a surgical operating room and is a device intended to produce a directed, nonturbulent flow of air that has been filtered to remove particulate matter and microorganisms to provide an area free of contaminants to reduce the possibility of infection in the patient.



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Covered under US patents 9,433,693, 9,457,119 and other US and Intl patents pending.

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