



Major Article

Improvement of operating room air quality and sustained reduction of surgical site infections in an orthopedic specialty hospital



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HEPA and ultraviolet air recirculation system
Air quality
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Introduction: Surgical site infection (SSI) rates can be impacted by air quality, and a high-efficiency particulate air and ultraviolet air recirculation system (HUAIRS) has been shown to improve operating room air quality. This study examined the impact of HUAIRS devices on SSI rates when used at an orthopedic specialty hospital.

Methods: HUAIRS devices were used intraoperatively at the facility. Total particle counts before and after HUAIRS implementation were compared. SSI rates for nervous system procedures or for all procedures at the facility were also compared for the 2.5-year periods before and after implementing HUAIRS devices.

Results: Over 30,000 consecutive procedures were performed from 2017 to 2022. The overall SSI rate at the facility was 0.45% before implementing HUAIRS devices compared to 0.22% ($P < 0.001$) after. The SSI rate following nervous system procedures was 2.06% before implementing HUAIRS devices versus 0.29% ($P < .001$) after. Total particle counts were also significantly lower after implementing HUAIRS devices.

Discussion and Conclusions: Implementation of HUAIRS devices at an orthopedic specialty hospital is associated with significant reductions in SSI rates and intraoperative air contamination levels. These data support the need to further investigate intraoperative air quality interventions for the reduction in SSI rates.

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BACKGROUND

Surgical site infections (SSI) account for over one-fifth of health care-associated infections, with an estimated annual incidence of 157,500 cases (95% CI: 50,800–281,400 cases) in the United States of America (US).¹ In the United States, SSIs have been estimated to cost over \$20,000 per case and have an overall cost of over \$3B (estimated 2012 US\$) annually.² SSI rates are particularly concerning in spinal surgeries with a previous meta-analysis showing a 30-day readmission rate of 5.5% with 28.2% of the readmissions occurring due to SSI.³ Thus, interventions to improve SSI rates are needed to improve patient outcomes and have a beneficial financial impact on patients and health care facilities.

Patient-related factors (eg, obesity or advanced age), incision-related factors (eg, high-tension incision or traumatized soft tissue), and operation-related factors (eg, type of procedure or revision procedures) can all increase the risk of SSI.⁴ For example, certain patient characteristics (ie, age and sex), the number of comorbidities, and specific comorbidities

(ie, obesity, diabetes mellitus, hypertension, coronary heart disease, and osteoporosis) are all significantly associated with increased SSI rates after posterior lumbar arthrodesis procedures.⁵ In addition to patient- and procedure-related risk factors, increased levels of airborne contaminants (ie, components of the surgical environment) also contribute to increased SSI rates.⁶ For example, skin scales, dust particles, respiratory aerosols, and condensation droplets under 5 μM can all serve as sources for bacterial bioaerosols.^{7,8} A study by Seal et al showed a strong association between bacteria-carrying particles and air particles between 5 and 7 μM in ultra-clean operating theaters,⁹ and a seminal study by Lidwell et al in 1983 demonstrated a significant correlation between bacteria-carrying air particles and joint sepsis following joint replacement surgeries.¹⁰

Methods for improving air quality in an operating room (OR) generally employ engineering controls and best practices such as maintaining ventilation systems and filters, evacuation of surgical smoke and anesthetic gases, and keeping doors closed and foot traffic in the OR to a minimum.¹¹ Recently, the use of a supplemental high-efficiency particulate air/ultraviolet air recirculation system (HUAIRS), an in-room air disinfection or recirculation device, has been shown to improve air quality in the OR. The HUAIRS device has been shown to reduce airborne particle counts^{12–14} and to lower levels of OR airborne bacteria.^{12,14,15} Lastly, a retrospective, observational, surveillance study showed that the

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rate of periprosthetic joint infections was significantly lower following total joint arthroplasty for a cohort where the HUAIRS device was used during surgery versus a cohort where the device was not used.¹⁶

As yet, there have been no studies assessing the impact of the HUAIRS device on OR air quality or postsurgical infections on a facility-wide basis. At our facility, there was a noticeable increase in SSI rates, particularly in spinal procedures from 2016 through 2018. As a result, several changes affecting the OR environment (eg, automation of temperature and humidity controls) and processes (eg, all postoperative appointments within 2 weeks of surgery and use of silver-containing dressings for all lumbar spine procedures) were implemented in 2019 without a resulting impact on SSI rates. In late 2019, full implementation of the HUAIRS system—placing an active HUAIRS device in each OR—at the facility occurred. A retrospective analysis of SSI rates pre- and post-HUAIRS implantation was performed.

METHODS

Facility and multidisciplinary team

This was a single-site study conducted at a 10-OR orthopedic specialty hospital performing exclusively orthopedic procedures, with an emphasis on total joint replacement and spinal surgeries. The current OR ventilation system utilizes a vertical flow design, with 20 air changes per hour, a centralized flow array, and lower wall return ducts. All of the ORs in the facility are similar in size. Six of the rooms share an air handler unit, which was updated in 2009, and the other 4 ORs share an air handler unit that was last updated in 2015 (Fig 1).

In 2019, a multidisciplinary team was formed and comprised 2 surgeons, a hospital executive, 7 nurses, 1 physical therapist, and 2

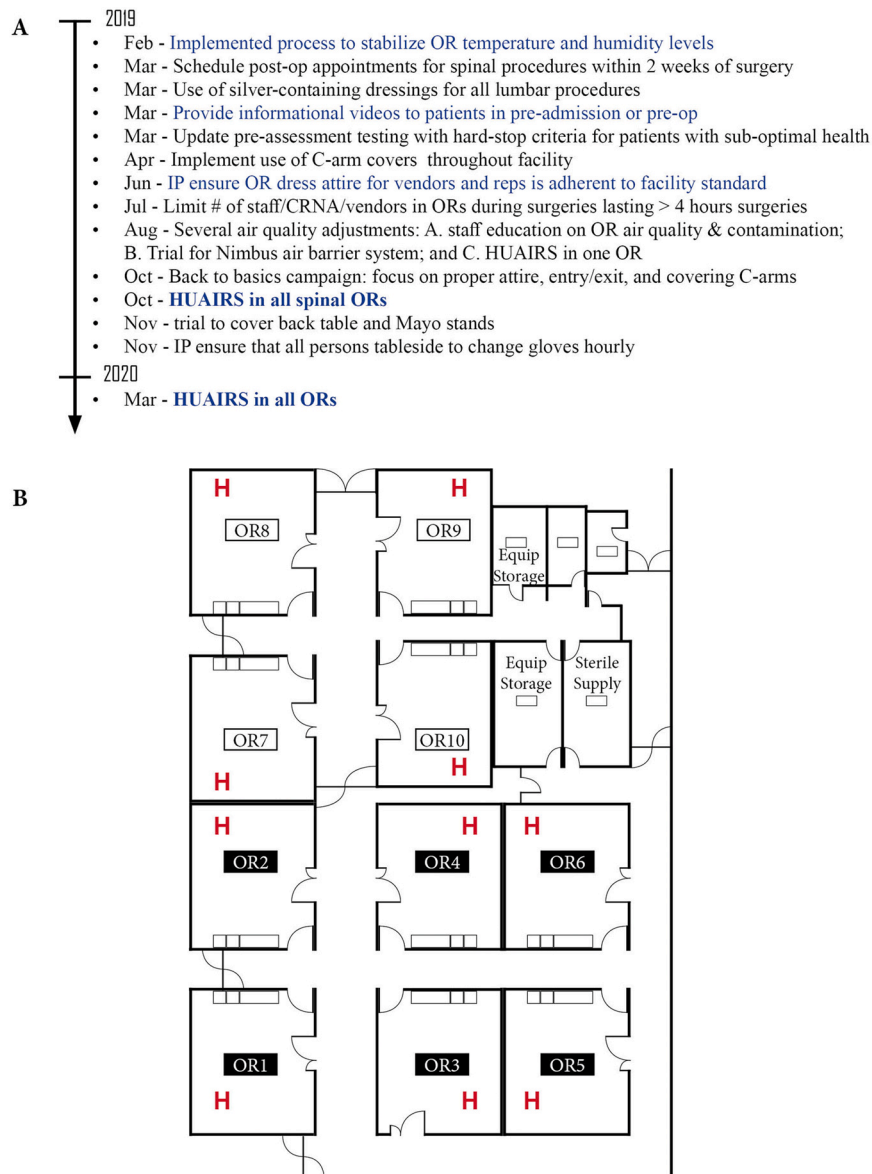


Fig. 1. (A) Timeline of facility changes during 2019 and early 2020. Changes that have continued to be incorporated at the facility are indicated in blue. (B) Schematic of the 10-OR facility. Operating rooms with black OR tables (white text) shared 1 air handling unit while OR indicated with white tables (black text) share another air handling unit. The red “H” indicates the general area of each OR where the HUAIRS device was placed.

physician assistants. Nurses who were members of the multidisciplinary team included a Director of Quality, a Director of Surgery, a Director of Preoperative Care such as Preadmission Testing or Postanesthesia Care Unit, a Director of Clinical Services, a Chief Nursing Officer, and an Infection Preventionist or Environmental Health Officer.

Implementation of HUAIRS

The multidisciplinary team collected and assessed SSI data dating back to 2013 and performed a cause-and-effect exercise to identify potential problems linked to elevated SSI rates for spinal surgeries. After identifying several potential causes for elevated SSI rates, the multidisciplinary team then designed and tested multiple changes for their impact on SSI rates, including changes in the OR environment (eg, temperature, humidity, and air quality) (Fig 1A). In August 2019, the team tested the effectiveness of a HUAIRS device (Illuvia HUAIRS system, Aerobiotix, LLC) on lowering air particle counts and subsequently began placing HUAIRS devices into each OR at the facility. An independent HUAIRS device was placed into each OR used for spinal procedures by October 2019, and every OR had a HUAIRS device placed by the end of March 2020 (Fig 1A).

The HUAIRS device is 45 × 45 × 150 cm and was placed in the room periphery (Fig 1B) with outflow parallel to the patient. The placement was performed in consultation with the manufacturer and environmental teams to assure no interference with workflow, doors, or wall vents. The units were kept in the OR and activated during both surgical periods and nonsurgical periods.

Patient demographic and clinical data

An independent health care database company (Definitive Health Care LLC) utilized payer records from the site to provide demographic data and diagnosis codes. All payor claims were then used to analyze age and sex distributions, whereas Medicare payor claims from the facility were used to analyze procedure categories (ie, nervous system or musculoskeletal system) and patient comorbidities.

The total number of surgical procedures, including spinal surgeries, was summarized using data directly from the site. The study team provided clinical data, dates, procedure categories (ie, all procedures vs spinal procedures), and infection rates.

Total particle counts (Air testing)

Prior to the usage of HUAIRS devices at the facility, air testing of 2 separate ORs was performed using a calibrated, certified, and commercially available handheld particle counter (Particles Plus 8303; Particle Plus Inc) to quantify both ≥5-micrometer (5-μm) and ≥10-μm particle concentrations. Particle counts were taken in the room periphery outside of the central vertical flow zone, with a minimum of 4 readings taken. Fifty-one particle count assessments were performed over the course of 90 minutes in the 2 ORs, with multiple readings being taken in various areas of the rooms while surgical procedures were ongoing. After implementing HUAIRS devices, total particle counts (TPC) for ≥5-μm and ≥10-μm particles were collected by the device (while operational) every minute over the course of a 3- to 12-hour period during which the OR was scheduled to be in use. Any day on which no particles were detected by the device was excluded from analysis. The mean TPC, based on the TPC detected every minute during which the OR was scheduled for use, was then tabulated for each day. For TPC of ≥5-μm particles with the HUAIRS devices, particle counts were assessed in 5 ORs over the course of 56 total days in Month 1 and 64 total days in Month 2. For TPC of ≥10-μm particles with the HUAIRS devices, particle counts were assessed in 5 ORs over the course of 49 total

days in Month 1 and 48 total days in Month 2. In Month 1, the number of days analyzed ranged from 3 days in OR-5 to 17 days in OR-3 and OR-4. In Month 2, the number of days analyzed ranged from 5 days in OR-1 to 16 days in OR-2.

Surgical site infections (SSIs)

All SSI records were assessed by the facility infection preventionist team per National Health Care Safety Network or Centers for Disease Control and Prevention (CDC) guidelines with a minimum follow-up period of three months. An SSI was included in the data if they met the established National Health Care Safety Network guidelines,¹⁷ and SSI rates across all periods were a composite of SSI categories (ie, superficial, deep, or organ or space SSI). The vast majority of surgical wounds at the facility are considered clean or contaminated with less than 1% of the wounds classified as dirty or infected.

Statistical analysis

All statistical analyses were performed using SigmaPlot 11 software (Inpixon). Patient demographics and comorbidities were presented as annual percentages and were compared using a χ^2 test without corrections for missing data. The number of surgeries was presented as the mean (\pm SD) per quarter and was compared using a one-way analysis of variance. Air particle data were presented as the median, interquartile range (IQR), 10%-90% range, and the mean, and a one-way analysis of variance was used to statistically compare the TPC between groups. Quarterly and annual SSI rates were presented as the quarterly or annual incidence rates. Overall SSI rates were compared using a Z-test (for proportions), and mean (\pm SD) annual SSI rates were compared using a Student's *t*-test. Differences between groups were considered statistically significant at an alpha of 0.05.

RESULTS

Patient demographics and surgery types

The percentage of patients over 60 years of age and the percentage of male and female patients (ie, biological sex) were similar when comparing annual data from 2017 to 2022 ($P = .224$ for each) (Table 1). When analyzing Medicare data from the site, the ratio of patients having orthopedic (ie, musculoskeletal) procedures versus nervous system procedures was similar between 2017 and 2021 ($P = .220$) (Table 1). The most common nervous system procedure types over the study period, in descending order, were lumbar fusion, lumbar discectomy, lumbar decompression, and cervical discectomy or fusion. The most common musculoskeletal or orthopedic procedure types over the study period, in descending order, were total knee arthroplasty, total hip arthroplasty, total shoulder arthroplasty, and open reduction and internal fixation. Lastly, when analyzing 6 selected comorbidities—diabetes, high body mass index (BMI) and morbid obesity, rheumatoid arthritis, peripheral vascular disease, and smoking status—the percentage of patients with any 1 of these comorbidities was similar from 2017 to 2022 (Table 1).

Air particle concentrations before and after implementation of HUAIRS

The median TPC for particles ≥5 μm in 2 ORs ($n = 51$) functioning without HUAIRS devices was 7,062 particles/m³ with an IQR from 5,649 to 9,887 particles/m³, and the median TPC for particles ≥10 μm was 4,237 particles/m³ (IQR: 2,825–5,650 particles/m³) (Fig 2A and 2B, respectively). After the implementation of HUAIRS devices, the level of

Table 1
Patient demographics, procedure types, and comorbidities

	2017	2018	2019	2020	2021	2022	P-value*
Age*	n = 3,475	n = 7,218	n = 11,769	n = 11,866	n = 13,166	n = 3,080	
< 60 years old	47.57%	47.20%	45.18%	45.20%	43.58%	36.56%	
> 60 years old	51.86%	52.41%	54.68%	54.43%	56.07%	63.18%	0.224
NR	0.58%	0.39%	0.14%	0.37%	0.35%	0.26%	
Sex*	n = 3,474	n = 6,053	n = 11,758	n = 11,824	n = 13,122	n = 3,073	
Female	60.74%	69.01%	58.48%	57.06%	58.07%	56.33%	
Male	39.26%	30.96%	41.52%	42.92%	41.93%	43.67%	0.224
NR	0.00%	0.03%	0.00%	0.02%	0.00%	0.00%	
Procedure Type†	n = 2,166	n = 2,148	n = 2,493	n = 2,410	n = 1,722	NR	
Musculoskeletal—%	25.81	26.82	26.35	26.39	27.22		0.220
Nervous—%	74.19	73.18	73.65	73.61	72.78		0.220
Comorbidity/History†	n > 3,000	n > 3,250	n > 3,800	n > 3,800	n > 4,200	n > 2,750	
Diabetes—%	2.8	2.5	2.7	2.5	2.7	2.0	0.263
BMI > 30—%	0.4	NR	NR	0.4	0.65	0.56	0.263
Morbid obesity - %	0.7	0.4	0.3	0.5	0.4	NR	0.242
RA—%	0.5	0.4	0.6	0.3	0.5	NR	0.242
PVD—%	NR	NR	NR	NR	NR	NR	
Nicotine use	0.4	0.6	1.6	1.2	0.7	2.4	0.224

* Chi-square test.

NR, Not reported; RA, rheumatoid arthritis; PVD, peripheral vascular disease.

†Based on all payor claims from 2017 to the first quarter of 2022.

†Based on Medicare claims from 2017 to the second quarter of 2022.

TPCs that were $\geq 5 \mu\text{m}$ or $\geq 10 \mu\text{m}$ was significantly lower ($P < .05$) when compared to the baseline particle counts (Fig 2). In 2 separate months after HUAIRS usage, the median TPC ($\geq 5\text{-}\mu\text{m}$ air particles), based on daily averages measured during operational hours in 5 independent ORs, was 1232.7 particles/ m^3 (IQR: 246.3–2854.2 particles/ m^3) and 1211.9 particles/ m^3 (IQR: 541.5–2897.7 particles/ m^3), respectively (Fig 2A). The median TPC ($\geq 10\text{-}\mu\text{m}$ air particles) was 165.7 particles/ m^3 (IQR: 61.1–540.5 particles/ m^3) in 1 month and 465.1 particles/ m^3 (IQR: 107.1–1106.8 particles/ m^3) in another (Fig 2B).

SSI rates before and after implementation of HUAIRS—spinal procedures

For spinal surgeries at the facility, the percentage of patients with an SSI was significantly lower ($P < .001$) when comparing the period since complete implementation of HUAIRS with the 2.5-year period preceding HUAIRS usage (0.29% vs 2.06%, respectively, $P < .001$) (Fig 3A; $P = .003$ vs 0.021; pooled estimate for $P = .0134$; Δ in $P = 0.0177$; 95% CI for Δ in $P = .0066\text{--}0.0268$). The quarterly SSI rate for spinal surgery patients during the pre-HUAIRS period ranged from 0.8% during the second quarter of 2019% to 5.1% during the third quarter of 2019 (Fig 3A). Since the implementation of HUAIRS, the quarterly SSI rate for spinal surgery patients has ranged from 0% during several quarters to 1.96% in the first quarter of 2021 (Fig 3A). The mean (\pm SD) annual SSI percentage for patients who underwent spinal surgery from 2013 to 2019 (ie, before placing HUAIRS in the OR for spine procedures) was 1.73% ($\pm 0.66\%$) versus 0.21% ($\pm 0.36\%$) for patients who underwent nervous system procedures during the post-HUAIRS period ($P = .006$; Fig 3B). No SSIs have been reported since the third quarter of 2020 for patients who underwent spinal surgeries (Fig 3A).

To assess whether the number of spinal surgeries potentially impacted the observed SSI rates, we compared the number of spinal surgeries performed at the site before and after HUAIRS implementation. The mean number of spinal procedures per quarter was significantly lower for the post-HUAIRS period versus the pre-HUAIRS period ($P = .001$; Supplementary Table 1). However, there were still over 116 spinal surgeries per quarter for the post-HUAIRS period, and this rate was not significantly different from the mean quarterly procedure number dating back to 2013 ($P = .144$; Supplementary Table 1).

SSI rates before and after implementation of HUAIRS—all surgeries

The percentage of patients with an SSI for all surgeries at the facility during the period since complete implementation of HUAIRS in all OR was also significantly lower ($P < .001$) when compared to the SSI percentage for all surgeries during the 2.5-year period before usage of HUAIRS (0.22% vs 0.45%, respectively) (Fig 4A; proportion, or $P = .002$ vs 0.004; pooled estimate for $P = .0034$; Δ in $P = .0023$; 95% CI for Δ in $P = .0010\text{--}0.0036$). The quarterly SSI rate for all surgery patients pre-HUAIRS ranged from 0.22% during the first quarter of 2018% to 0.61% during the third quarter of 2019 (Fig 4A). After the full implementation of HUAIRS, the quarterly rate of SSIs for all procedures ranged from 0.11% during the first quarter of 2022% to 0.31% in the fourth quarter of 2020 (Fig 4A). The mean (\pm SD) annual SSI percentage for all surgery patients from 2013 to 2019 (ie, the 7-year period before placing HUAIRS in ORs) was 0.47% ($\pm 0.07\%$) versus 0.19% ($\pm 0.07\%$) for post-HUAIRS patients that underwent surgery at the facility ($P < .001$; Fig 4B).

To assess whether the number of overall surgeries impacted the observed overall SSI rates, we compared the number of surgeries performed at the site before and after implementing HUAIRS devices. When comparing the mean number of surgeries (all surgery types) per quarter from the 10 quarters before implementing HUAIRS devices (pre-HUAIRS) with the 10 quarters after (post-HUAIRS), there was not a not significant difference between the time periods ($P = 0.061$); however, the mean number of quarterly procedures overall for the post-HUAIRS period was significantly higher than the mean quarterly rate of all procedures dating back to 2013 ($P = 0.002$) (Supplementary Table 1).

Importantly, after placing HUAIRS devices, there have been no adverse effects on workflow reported by members of the surgical teams.

DISCUSSION

To date, there has been a single retrospective study showing that periprosthetic joint infections following total joint arthroplasties were significantly lower ($P < .044$) when a HUAIRS device was used during surgery ($n = 231$) versus when it was not ($n = 265$).¹⁶ In this study, we retrospectively reviewed SSI rates following > 2,600 spinal surgeries and > 34,000 total surgeries at a 10-ORs facility. Similar to

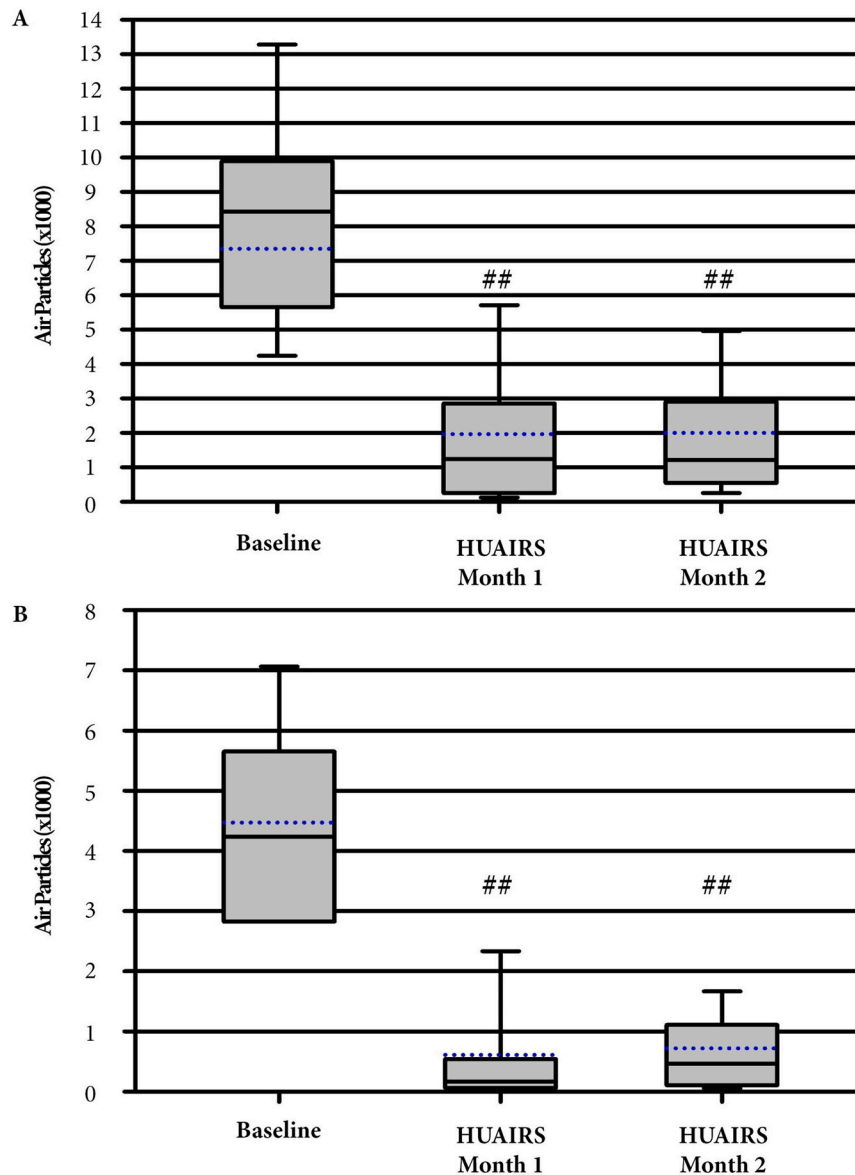


Fig. 2. Box plot depicting 5-µM air particle counts (A) or 10-µM air particle counts (B) at baseline (ie, before implementation of HUAIRS devices) and 2 separate months after activating HUAIRS devices. The solid black line indicates the median value, and the box shows the interquartile range. The error bars depict the 10th-90th percentile, and the mean value for each group is indicated by the dotted blue line. ## $P < .05$ compared with baseline.

Cook et al, SSI rates for spinal surgeries as well as all surgery types at the facility were significantly lower after full implementation of HUAIRS devices (in addition to other infection prevention measures taken at the site) (Fig. 3 and 4). Interestingly, Cook et al observed no (0) periprosthetic joint infections when the HUAIRS device was used during surgery,¹⁶ and our study revealed no SSI in 7 of the 10 quarters after implementing HUAIRS devices during spinal surgeries (Fig 3). Although it should be noted that the overall percentage of SSI rates at the facility was 0.21%-0.29% (Fig 4). It should be noted that preintervention SSI rates in the facility were below published rates for orthopedic surgery.²¹ Even so, implementation of HUAIRS devices further reduced SSI rates in a sustained manner—this sustained reduction was seen when analyzing spinal surgeries (Fig 3A) as well as all procedures at the site (Fig 4A). The site incurs a direct cost of approximately \$50,000-70,000 per SSI due to readmission, extended stay, and unplanned treatment, which is only reimbursed an average of \$12,000-\$18,000 by public or private insurers, resulting in a net

cost of \$32,000 to \$58,000 per episode. Therefore, data from this study, which show a reduction of 17 SSIs annually, suggest a potential savings of \$544,000 on the low end to approximately \$986,000 annually. This supports the continued need to drive SSI prevention via interventions, even when SSI rates appear within established ranges.

It is notable that the reduction in SSI in this study was also accompanied by simultaneous reductions in airborne contamination levels (ie, TPC) within the ORs themselves. This supports the classic hypothesis of the relationship between air contamination and SSI advocated by Lidwell, Whyte, and more recently by Darouiche.¹⁸⁻²⁰ There have been 4 previous publications showing that HUAIRS devices can reduce 5- to 10-µM TPC levels.^{12,13,22,23} The range in TPC reduction in previous studies ranged from 1.8-fold in a study of 50 TJA procedures¹² to ~4-fold in a controlled OR setting (n = 10).¹³ In this study, we observed a 5.7-fold reduction in 5-µM TPC and a 3.5-fold decrease in 10-µM TPC (Fig 2), which is aligned with previous

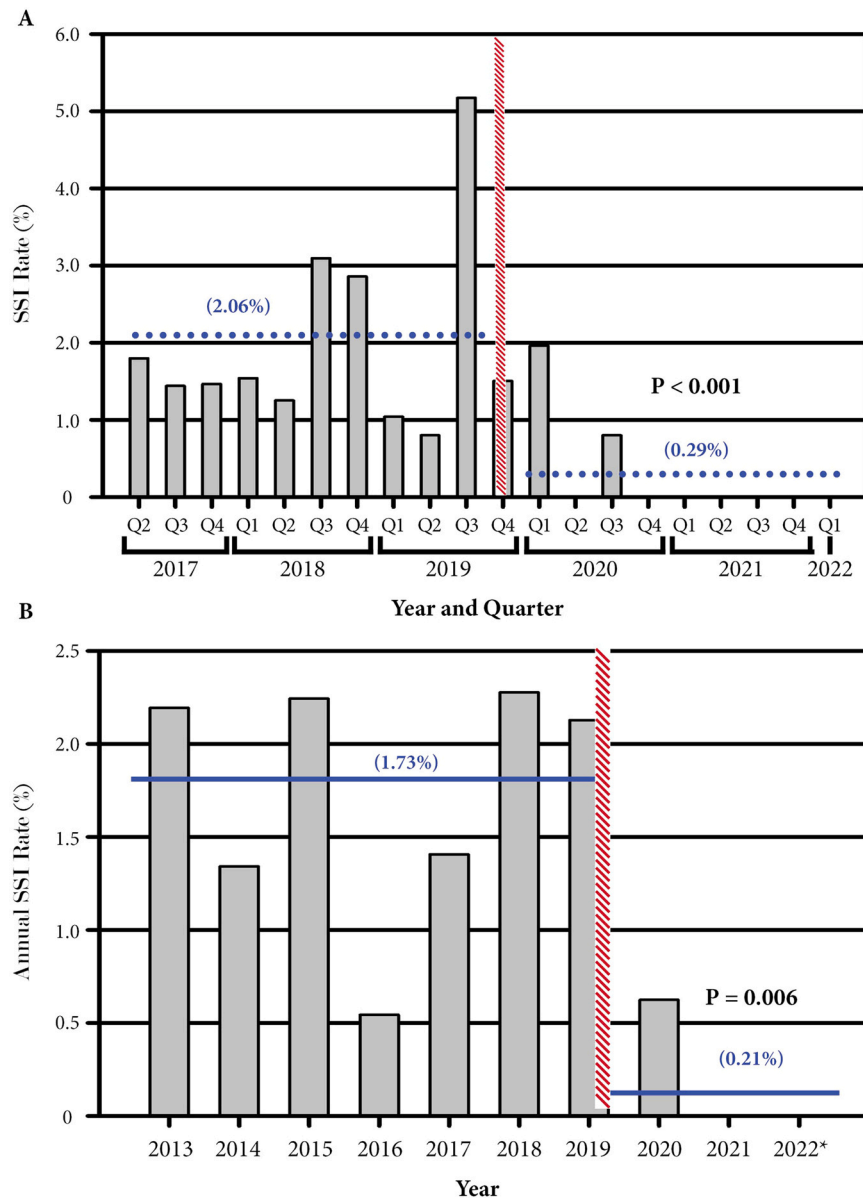


Fig. 3. Bar graph depicting (A) the quarterly SSI rates for spinal surgeries from the second quarter of 2017 to the first quarter of 2022, or (B) the annual SSI rates for spinal surgeries from 2013 to 2022. The hatched red line indicates when HUAIRS were implemented in all 5 OR used for spinal procedures. The dotted blue line in A indicates the overall SSI rate for spinal procedures during the indicated time period, and the solid blue line in B indicates the mean annual SSI rate for spinal procedures during the indicated years. *only includes the first quarter of 2022.

studies albeit slightly more pronounced. The slightly more pronounced reductions in TPC may have been related to the timing of TPC measurements before and after HUAIRS implementation. Pre-HUAIRS TPC levels were monitored during surgery while post-HUAIRS TPC was monitored during hours of operation, regardless of whether surgeries were occurring. However, it should also be noted that this study consisted of TPC measurements in 5 independent ORs at the facility whereas previous studies were assessing a single OR.

An expert guidance publication in 2014, which was sponsored by the Society for Health Care Epidemiology of America, provided many recommendations to help prevent or mitigate SSI, including the use of perioperative antimicrobial prophylaxis, proper hair removal at the incision site, controlling postsurgical glucose levels, and maintaining perioperative normothermia.²⁴ Other recommendations included efficient and accurate surveillance of SSI, especially in high-risk patients, and education of surgeons, patients, and relatives

about SSI prevention.²⁴ Prior to the placement of the HUAIRS systems, the cross-functional team made several changes in an attempt to address SSI rates (Fig 1A). Data related to three of these changes (ie, silver-containing dressing usage, presurgery video viewing by patients, and surgeries lasting > 4 hours) were collected to determine their potential impact on SSI. Usage of silver-containing dressings following lumbar surgeries increased from early 2019 (~ 55% usage) to 100% by September of 2019 (data not shown). Presurgery video viewing by patients increased from February 2019 (~ 48%) to a 75%-80% viewing rate by the summer of 2019 (data not shown). Lastly, surgeries lasting longer than 4 hours, primarily comprising transforaminal lumbar interbody fusions and bilateral joint replacements, were similar when comparing early 2019 (10-14 per month) to Q3 of 2019 (12-13 per month) (data not shown). Despite 2 of these 3 changes occurring in a direction that should be associated with reduced SSI rates, SSI rates following spinal

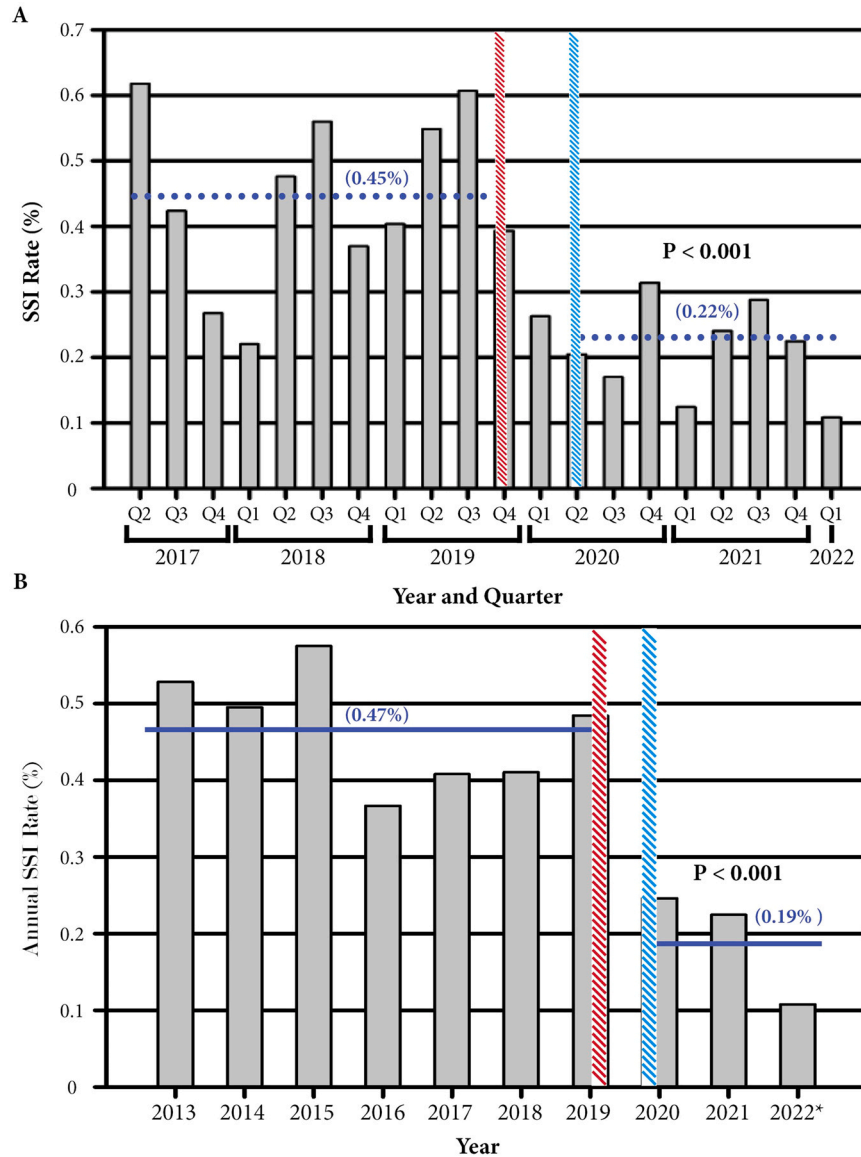


Fig. 4. Bar graph depicting (A) the quarterly SSI rates for all surgeries from the second quarter of 2017 to the first quarter of 2022, or (B) the annual SSI rates for surgeries from 2013 to 2022. The hatched red line indicates when HUAIRS were implemented in all 5 ORs used for spinal procedures, and the hatched blue line indicates when HUAIRS was implemented in all 10 ORs at the facility. The dotted blue line in A indicates the overall SSI rate during the indicated time period, and the solid blue line in B indicates the mean annual SSI rate during the indicated years. *only includes the first quarter of 2022.

surgeries as well as all surgeries at the site were at their highest levels as of Q3 of 2019 (Fig. 3A and 4A). Although it is possible that these other changes may have contributed to the reduced SSI rates in a delayed manner (ie, maturation bias), it seems highly unlikely as the changes were not associated with SSI rate changes in a temporal manner. Nonetheless, the standards put into effect by the cross-functional team, in addition to the use of HUAIRS devices in all ORs, now include preoperative educational videos for patients, monthly review of building automation reports for ORs temperature and humidity, and rounding by Infection Preventionists to observe OR traffic patterns, dress attire, and coverage of C-arms and other tables or stands (eg, Mayo stands).

A major global event that potentially impacted this study was the Covid-19 pandemic, although a previous study showed that 90-day periprosthetic joint infection and 30-days SSI after primary total joint arthroplasty were not significantly different when comparing pre-Covid-19 (2017-2019) and post-Covid-19 periods (2020).²⁵ Covid-19 began in

early 2020 and was characterized by surges (ie, elevated transmission phases) in Covid-19-positive patients that generated strain and service disruption on health care systems as well as surgical practices,^{26,27} which could potentially have generated a selection bias for this study. Although the study was not randomized and the impact of local or regional Covid-19 case counts on SSI rates was not directly assessed as part of the study, the number of overall procedures performed at the facility was actually higher for the post-HUAIRS group, which overlapped with the onset and progression of the Covid-19 pandemic in the United States, compared with the prepandemic rates (see Supplementary Table 1). Demographic data and comorbidities were also similar when comparing the period before and after Covid-19 onset (see Table 1). Additionally, there were no changes to hand hygiene or personal protective equipment other than hourly glove changes during surgery, which began in November of 2019, well before the onset of the first Covid-19 surge in the United States and our region. An alternative explanation for the change in the SSI rate for all procedures is that the reduction in SSI rates

for spinal procedures drove down the overall SSI rate. However, this seems unlikely since spinal procedures as a percentage of all surgeries decreased slightly when comparing the post-HUAIRS period versus the pre-HUAIRS period (6.2% vs 9.3%, respectively), and spinal procedures accounted for less than 10% of all procedures for both groups at the site (Supplementary Table 1).

One limitation of this study is that potential differences in SSI rates between the separate OR was not analyzed as part of the study. However, there are at least 2 confounding variables that might impact differences in OR SSI rates. First, certain ORs at the facility are dedicated to different surgical specialties, which would be a confounding variable impacting differences between rooms. Additionally, it is likely that at least some sharing of airflow between the rooms would further confound data interpretation. In addition to the aforementioned study biases and limitations (maturation bias and selection bias), this study also had other biases, including a chronological bias, which could have been mitigated by randomization of surgeries that used a HUAIRS device or not, an ascertainment bias that could have been mitigated by blinding SSI assessment from HUAIRS use, and a historical bias that could have been mitigated by a multisite trial. The impact of an attrition bias is also unknown as patient tracking was not as controlled as that of a clinical trial.

CONCLUSIONS

Implementation of HUAIRS devices at an orthopedic specialty hospital is associated with significant reductions in SSI rates and intraoperative air contamination levels. Data from this study, as well as previous studies showing the positive impact of the HUAIRS device on OR contamination levels and SSI rates,^{12,14–16} suggest that multicenter, randomized, controlled, blinded trials should be pursued to fully assess the impact of HUAIRS on SSI rates following spinal surgeries and other surgery types.

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SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.ajic.2023.05.018](https://doi.org/10.1016/j.ajic.2023.05.018).

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