Directed Air Flow to Reduce Airborne Particulate and Bacterial Contamination in the Surgical Field During Total Hip Arthroplasty

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Abstract: This study evaluated the use of a system that delivers a small field of local, directed air from a high-efficiency particulate air (HEPA) filter to reduce airborne particulate and airborne bacteria in the surgical field during total hip arthroplasty. Thirty-six patients were randomized into 3 groups: with directed air flow, with the directed air flow system present but turned off, and control. Airborne particulate and bacteria were collected from within 5 cm of the surgical wound. All particulate and bacterial counts at the surgical site were significantly lower in the directed air flow group ($P < .001$). The directed air flow system was effective in reducing airborne particulate and colony-forming units in the surgical field during total hip arthroplasty. **Keywords:** infection, intraoperative, operating room, environment.
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Postoperative sepsis is a costly and potentially devastating problem in total joint arthroplasty [1,2]. Airborne bacteria and other viable microorganisms, colony-forming units or CFU, shed from surgical staff have been presented as a source of deep prosthetic infection, and the density of airborne bacteria is correlated with the rate of postoperative joint sepsis in total joint arthroplasty surgery [1-3]. Previous studies have also reported a positive relationship between the density of nonviable airborne particulate and viable CFU counts, both airborne and in the surgical wound, during surgery [4-8].

A number of methods are used to reduce airborne contamination during total joint arthroplasty, including circulation of ultraclean air, filtered exhaust hoods and suits, laminar air flow, and ultraviolet light [9,10]. Ultraclean air reduces environmental contamination, whereas exhaust hoods and suits reduce contamination from the surgical personnel [10,11]. Laminar flow of ultraclean air from a high-efficiency particulate air (HEPA) filter, generated by the operating room heating, ventilating, and air conditioning infrastructure over a relatively large area, creates an air field intended to isolate the surgical field and team from outside airborne contaminants, and has been shown to reduce airborne microbes in the operating room and field [3,12-15]. Laminar air flow may not lead to reduction in infection risk [16,17] and may be affected by other factors, such as the types of garments worn by the surgical team and the nature of the activity within the laminar flow perimeter [10,12,18,19]. The use of ultraviolet light in operating suites is another effective means by which to inactivate viable CFUs in the operating room and decrease contamination risk [20-23]. One drawback of ultraviolet lighting is the requirement for protective garments and goggles for the surgical staff and patient to avoid skin or eye injury [10,20,24].

A recently developed device creates a localized, directed flow of HEPA-filtered air only over the area immediately surrounding the surgical field as a barrier that may reduce airborne particulate and CFU at the surgical site, thus reducing the risk of wound contamination. Most surgical personnel and equipment remain outside the barrier during the procedure, in contrast to regimes wherein laminar air flow may be generated by equipment at a distance and in which personnel and equipment may intermittently interrupt the airflow and become a source of upstream air contamination. The purpose of this study was to determine the degree to which localized, directed HEPA air flow generated by the

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Air Barrier System across the surgical field reduces airborne particulate and CFUs in the surgical field during total hip arthroplasty.

Methods

Subjects

Thirty-six patients who had consented to undergo primary total hip arthroplasty were recruited to participate in this study. All patients who consented to undergo primary total hip arthroplasty were eligible. Patients undergoing hemiarthroplasty, resurfacing, or revision arthroplasty were excluded. Subjects volunteered to participate by signing informed consent. An a priori power analysis revealed that a sample size of 8 subjects per group was needed to obtain 80% power ($\alpha = .05$) to detect a reduction of at least 75% in bacteria counts; device testing during several simulated hip arthroplasties showed an 88% reduction in airborne bacteria counts. This study was approved by the Institutional Review Board of Texas Orthopedic Hospital.

After consent and before posting the surgical case, subjects were randomly assigned to 1 of the 3 groups using block (length, 6) randomization to ensure an equal number of subjects in each group [25]. Subjects were masked to group assignment. It was impossible to perform the surgery in a masked manner, but the technicians performing the analyses were masked to group assignment by coding the samples and data.

The first group of patients (control) represented a control condition using the current standard procedure for the surgeon (G.W.S.) who performed all of the surgeries (ie, no device in place). The second group of patients (sham) represented a second control condition in which the air barrier device was in place during surgery but never turned on (ie, no air flow). Data from the sham group was used to determine whether presence of the air barrier device had any effect, by altering behavior of the surgical staff, for example. The third group of patients (air barrier) represented the experimental condition and had directed local air flow over the surgical field (ie, the air flow device was in place and turned on). The device was turned on immediately before the initial incision and turned off after closure of the surgical wound. All patients received routine prophylactic antibiotics, either cefazolin or vancomycin, 30 to 60 minutes before incision.

Air Barrier Device

The localized, directed HEPA-filtered laminar air flow was provided by the Air Barrier System (Nimbic Systems, Stafford, TX). The device consists of 2 components: a HEPA blower and a sterile nozzle. The 0.9-kg nozzle and hose assembly is secured on the patient's body in immediate proximity to the surgery site and emits HEPA-filtered air to repel airborne particulate over a small area (Fig. 1). Bench testing of the Air Barrier System in a standard room with unfiltered turbulent ventilation showed a reduction of 5- to 10-μm airborne particulate counts by more than 90% in an area approximately 15 cm wide and 45 cm long and a reduction of bacteria deposition by more than 90% in an area approximately 12.5 cm wide and 22.5 cm long (Fig. 2). In addition, during development, several simulated total hip arthroplasty surgeries using cadavers showed an 88% reduction in airborne bacteria counts at the surgical site when the device was used. The device weighs 21.8 kg and is 30.5 ×30.5 cm and 71.1 cm tall. The cost is currently less than $5000, with per-patient disposable costs under $200. The blower component is to be certified annually, but otherwise, no regular maintenance costs are required.

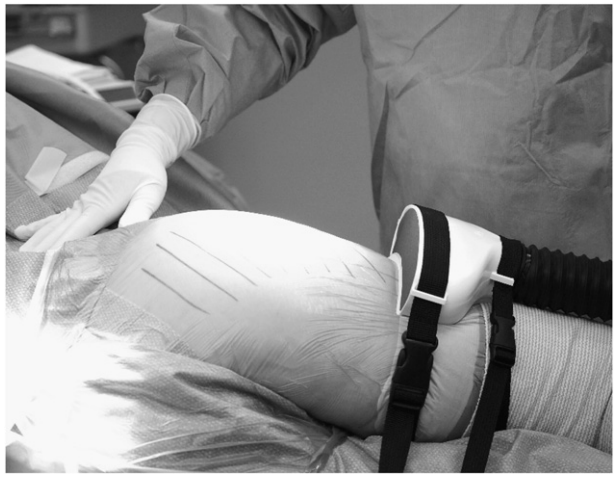

Fig. 1. Air Barrier System in position on the right leg of a patient undergoing total hip arthroplasty.

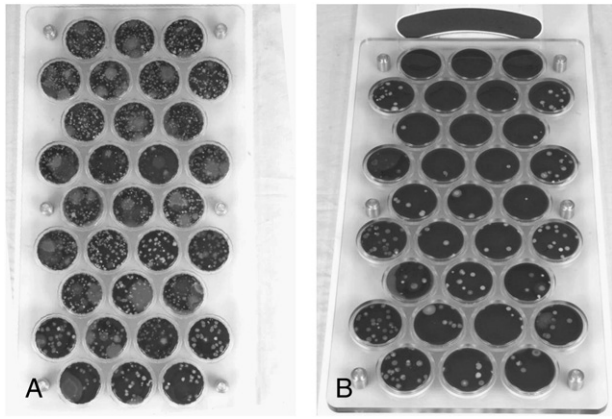

Fig. 2. Results of a bench testing in which a high concentration (>24 times normal ambient level) of airborne bacteria was introduced for 10 minutes over an area approximately 10 in. wide by 27-in. long without the Air Barrier device (A) and with the Air Barrier device in operation at the top of the image (B). The plates are shown in their original positions approximately 72 hours after exposure, sealing, and incubation at 35°C.

Data Collection

All data collection occurred in 2 operating rooms with conventional ventilation system (turbulent air flow, 12-15 exchanges per hour). Air passed through a prefilter and a Varicell filter (95% efficiency at removing particles ≥0.3 μm) before being diffused into the room through ceiling vents. Consistent air temperature (62°F ± 2°F) and humidity (50% ± 7%) were maintained, and pressure was maintained at a nominal 0.20-in. water gauge relative to the outer hall. Surgical personnel working in the operating room within the surgical field (surgeons, surgical assistants and technicians, and scrub nurses) wore filtered exhaust helmets and suits. Surgical personnel working in the operating room but outside the sterile surgical field (circulating nurses, anesthesiologists, and radiology technicians and other technicians) wore standard operating room attire (cotton scrub shirts and pants, surgical masks, head and foot covers). These were the routine conditions for hip arthroplasty cases performed by this surgeon.

The number of surgical personnel present in the room and the number of times the operating room door was opened during the procedure were recorded in 10-minute intervals. The operating rooms had 2 entry points via self-closing doors, one door opened to an outer hall and one door opened into a central sterile supply area. Access to the sterile supply area was restricted to personnel wearing scrubs, face masks, and hair and shoe covers. The door to the outer hall was locked during surgery to prevent unnecessary traffic, although the door was opened to allow radiology equipment to enter. The area of the surgical wound was also estimated from the measured length and width of the incision.

Airborne particulate was measured using a particle analyzer (LASAIR II 310B; Particle Measuring Systems, Boulder, CO), which was calibrated before the beginning of the study. The particle analyzer sampled continuously throughout the surgical procedure at a rate of 28.3 L/min and recorded data at 1-minute intervals to obtain sample volumes of 28.3 L of air. The samples were collected through a 130-cm length of sterile tubing with the end placed inside the surgical field, under the air flow in the air barrier group, within 5 cm of the surgical wound. Particles were classified by diameter (d) in 6 size ranges: $0.3 \le d < 0.5$ μm, $0.5 \le d < 1.0$ μm, $1.0 \le d < 3.0$ μm, $3.0 \le d < 5.0$ μm, $5.0 \le d < 10.0$ μm, and $d \ge 10$ μm.

Colony-forming unit counts were collected from the air within 5 cm of the surgical wound, which positioned it underneath the air barrier effect in the air barrier group and from the air on the Mayo stand approximately 40 cm from the surgical site, outside the air barrier area of effect. These samples were obtained using 2 bioaerosol collection devices (Anderson N6; Environmental Monitoring Systems, Charlotte, SC) that were sampling air at the same rate as the particle analyzer, and also through 130-cm lengths of sterile tubing. Air drawn through the tubing passed to standard culture plates containing tryptic soy agar with 5% sheep's blood (Healthlink; Jacksonville, FL) such that particulate from this air sample collected on the agar surface. The plates were exchanged by a research assistant every 10 minutes throughout the surgical procedure. Control plates were handled in the same manner as the test plates, but exposed only momentarily, to evaluate for contamination due to handling and processing of the plates.

The air samples were processed at independent, contracted microbiology laboratories. The air samples were incubated at 35°C for 36 hours. Staining and morphologic identification were used to identify and count viable bacteria in the plates. Viable bacteria from the airborne samples were normalized by volume and reported as colony-forming units per cubic meter (CFUs/m^3).

Data Analysis

Descriptive statistics (means, medians, frequencies) were used to evaluate the distributions of the variables. One-way analysis of variance and independent t tests or Mann-Whitney U tests were used to compare patient and environmental characteristics between groups. We used generalized estimating equations to evaluate the effects of group and other factors on airborne CFUs/m^3 at the surgical site in each 10 minute interval. A negative binomial model was used, which is appropriate when the dependent variable is measured in counts (i.e., positive integers) that are not normally distributed [26,27]. Residual plots and analyses were examined to evaluate model fit.

Results

The 36 hip arthroplasty surgeries yielded a total of 244 10-minute intervals. The average surgical time was similar in the 3 groups: 69 minutes in the control and sham groups and 66 minutes in the air barrier group. In one surgical case, before incision, the Air Barrier System's air hose became detached from the blower; it was reattached, and the system was restarted and used during the surgery. One subject in the sham group had no usable particle count data due to a technical problem with the particle counter and was excluded from the respective analyses. No other technical difficulties occurred in any other case.

Table 1 shows the medians and ranges for the particulate and CFU counts. All particulate counts and the CFUs/m^3 at the surgical site were significantly lower in the air barrier group ($P < .001$). The CFUs/m^3 at the control site ($P = .633$) did not differ significantly among groups. The number of door openings ($P = .081$), body mass index ($P = .784$), and incision area ($P = .293$) was similar across groups. The sham group had an average of 1 less person in the operating room

Table 1. Medians (Ranges) for CFUs and Particulate Counts Per 10-Minute Interval by Experimental Group

Variable	Control	Sham (Air Barrier Off)	Air Barrier
CFUs/m^3 at surgical field	7 (0-60)	11 (0-74)	0* (0-14)
CFUs/m^3 at control site	11 (0-82)	11 (0-82)	11 (0-78)
Particulate counts/m^3			
Total	9 929 900 (2 636 835-41 760 468)	9 042 727 (3 285 670-37 900 759)	1 897 489* (13 102-27 523 917)
0.3-0.49 μm	7 884 055 (2 228 245-20 012 890)	6 983 392 (2 813 973-27 078 141)	1 425 474* (8829-11 382 143)
0.5-0.99 μm	1 118 731 (186 673-10 385 000)	1 212 597 (264 718-8 220 850)	348 167* (1059-8 427 158)
1.0-2.9 μm	483 810 (39 729-8 611 642)	463 999 (48 134-7 265 590)	142 671* (141-6 414 014)
3.0-4.9 μm	65 685 (3955-2 368 939)	57 492 (5933-2 060 324)	14 232* (35-2 103 726)
5.0-9.99 μm	26 698 (2825-1 304 451)	19 600 (3461-1 188 160)	5756* (35-1 219 095)
≥10 μm	1448 (459-9394)	1236 (424-57 704)	318* (0-9500)

* Significantly ($P < .001$) lower than control and sham groups.

during the surgery compared with the other 2 groups ($P = .001$). The particulate counts were highly positively skewed, so a logarithmic transformation was used to attain a more symmetrical distribution for use in the subsequent analyses.

All particulate diameter categories 1 μm and larger were significantly related to CFUs/m^3 at the surgical site ($P < .03$). Staff count ($P < .001$) and the control site CFUs/m^3 ($P < .001$) were also both significantly related to CFUs/m^3 at the surgical site. The number of door openings ($P = .475$) was not significantly related to CFUs/m^3 at the surgical site.

In analyses including multiple predictor variables, both group ($P < .001$) and control site CFUs/m^3 ($P < .001$) were found to be related to CFUs/m^3 at the surgical site. For a given CFUs/m^3 at the control site, the air barrier group had a significantly ($P < .001$) lower predicted CFUs/m^3 at the surgical site compared with the control and sham groups, which did not differ significantly from one another ($P = .214$; Fig. 3). After including both group and control site CFUs/m^3, no other variable was significantly related to CFUs/m^3 at the surgical site.

None of the patients had developed signs or symptoms consistent with surgical site infection or prosthetic infection.

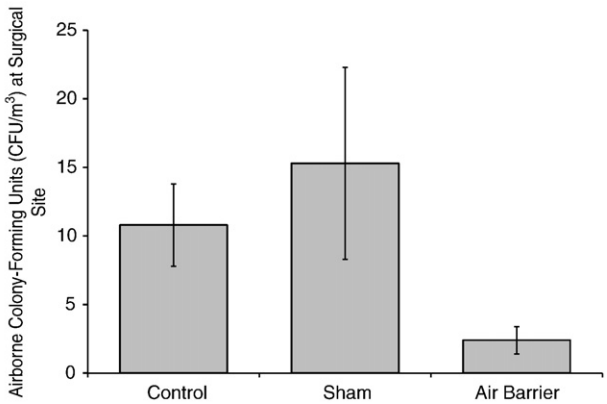

Fig. 3. Airborne CFUs/m^3 at the surgical site by study group showing a significantly ($P < .001$) lower count in the air barrier group.

Discussion

The Air Barrier System dramatically reduced particulate counts and the presence of CFUs at the surgical site. Particulate counts were decreased on average by at least 66% in the air barrier group as compared with the control and sham groups, including an average 80% reduction in particulate more than 10 μm in diameter. More than 60% of the 10-minute intervals sampled in the air barrier group had a complete absence of airborne CFUs (ie, 0 CFUs/m^3), as compared with only 11% and 14% of the intervals sampled in the control and sham groups, respectively. Also, the relation of control site CFUs/m^3, an indicator of the airborne contamination of the general operating room conditions, to surgical site CFUs/m^3 was much weaker in the air barrier group. This suggests that the Air Barrier device substantially reduced surgical site CFUs/m^3 that could be attributed to room contamination. Thus, the Air Barrier System seems to be effective in reducing airborne particulate and contamination at the surgical site during total hip arthroplasty.

The reduction in larger particulate (>10-μm diameter) in the air barrier group was likely related to the reduction in CFUs/m^3 at the surgical site by the Air Barrier System. The density of larger particulate (ie, >5-μm in diameter) was strongly related to CFU density in the current study as well as in previous work [6], and airborne bacteria–carrying particles have been shown to measure 4 to 20 μm [24]. Consequently, reducing the density of larger airborne particulate should reduce airborne CFU density. The density of airborne particulate in an operating room increases with the number of surgical personnel present in the room [5,6,10,28-31]. In the current investigation, staff count and CFU density at the control site were essentially the same in all 3 experimental groups. Because the particulate and the CFU density at the surgical site were substantially lower in only the air barrier group, the particulate and CFUs shed by the surgical staff must have been effectively reduced by the Air Barrier System.

The British National Health Service's Health Technical Memorandum 2025 indicates that bacterial density in ultraclean (laminar flow) surgical suites should remain

less than 10 CFU/m^3 in the sterile field, and a density of "no more than" 1 CFU/m^3 may be required to eliminate infection risk [32,33]. In our control and sham groups, we measured a mean of 12 CFU/m^3 at the surgery site per 10-minute sampling interval, and a relatively high degree of intraoperative variance existed, with densities ranging from 0 to 46 CFU/m^3 per interval. By contrast, in the air barrier group, we measured a mean of 2 CFU/m^3 at the surgery site per 10-minute interval and lower variability, with densities ranging from 0 to 14 CFU/m^3. Consequently, nearly all (96%) of the samples in the air barrier group met the British National Health Service recommendation of less than 10 CFU/m^3, whereas only approximately half (51%) met that standard in the control and sham groups. The Air Barrier System was thus effective in producing a clean air environment at the surgical site that was in line with published recommendations for air at the wound and produced a mean (2 CFU/m^3) approaching the hypothetical value for prevention of infection (mean, ≤1 CFU/m^3).

The Air Barrier System has several advantages over other methods of reducing airborne contamination, such as the use of ultraviolet light or large-scale laminar flow systems. Ultraviolet light directed over the surgical site is very effective in reducing infection risk [20] but requires skin and eye protection for the patient and operating room staff. Laminar air flow surrounding the patient and surgical team has been reported to reduce airborne contamination [12-14,34], although some reports found no detectable difference in infection rates between operating rooms using laminar air flow and turbulent flow ventilation [11,16,17]. The Air Barrier System is portable, is relatively simple and inexpensive, and requires no special protective equipment for the patient or surgical personnel. Use of the Air Barrier System did not increase surgical time, and the surgeon and staff reported that it did not impede access to the surgical site or wound.

One limitation of this study is that we did not trace the source of the airborne CFUs that were sampled from the surgical and control sites. Others have demonstrated, however, that a portion of the bacteria cultured from postoperative wound infections originate from members of the operating room staff [35]. In addition, we lacked sufficient statistical power to compare infection rates among the 3 experimental groups: this was not an objective of the current study, and no patient developed a postoperative infection. Because the implant infection rate in total joint arthroplasty is reported to be less than 2% and perhaps as low as 0.5% [36,37], a multisite, longitudinal study of more than 1000 surgical cases would be required to evaluate the effectiveness of the Air Barrier System, or any other intervention, in reducing the incidence of postoperative infection. Our findings may be used to determine sample size for such a future study because the Air Barrier System was shown to reduce particulate and airborne CFU by as much as 80%. The very large reduction of airborne particulate and CFU density at the surgical site by the Air Barrier System should result in a substantial reduction in the incidence of postoperative infections, if airborne contamination is a meaningful source of such infections.

In conclusion, the Air Barrier System is effective in reducing airborne particulate and CFUs. Its effectiveness in reducing CFU seems to be related to its ability to reduce particulate that may carry and allow proliferation of bacteria. The Air Barrier System is relatively simple to use and does not seem to hinder the function of the surgeon or operating room staff, impede access to the surgical site, or interfere with the surgical procedure.

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