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A localized laminar flow device decreases airborne particulates during shoulder arthroplasty: a randomized controlled trial

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Background: Although the rate of periprosthetic joint infection following shoulder arthroplasty is low, it is a morbid and costly complication. Airborne particulates have long been recognized as a potential source of wound contamination, and operating room–mounted and smaller localized laminar airflow devices have been developed to minimize airborne particulates. This randomized controlled trial evaluated the effectiveness of a localized laminar flow device in reducing the intrusion of ambient airborne particles and bacteria into the surgery site during shoulder arthroplasty as measured by overall particle counts and colony-forming units (CFUs).

Methods: Patients undergoing primary anatomic or reverse shoulder arthroplasty were eligible for participation. After providing informed consent, patients were randomly assigned to the Air Barrier System (ABS) group or control group. For all patients, the ABS was placed on the surgical field; however, it was only turned on by the technician for those randomized to the ABS. Study participants, surgeons, and surgical staff were blinded to group assignment. Bacterial CFUs were collected from within 5 cm of the surgical wound every 10 minutes, whereas airborne particulates were collected every minute. Poisson regression models were used to determine whether differences existed in CFUs and particulate counts between the ABS and control groups.

Results: A total of 43 patients were randomized into the ABS (n = 21) or control (n = 22) group. Surgical time ($P = .53$) and the average staff count ($P = .16$) in the operating room did not differ between groups. Poisson regression showed that the ABS group had significantly lower CFUs ($\beta = –0.583$, $P < .001$) along with surgical time and particulates with a diameter ≥ 5 μm. Staff count and particulates with a diameter < 5 μm were not significant predictors of CFUs. Infection was not a primary outcome; however, no postoperative infections have been reported in either study group with a minimum of 1-year follow-up for all patients.

Discussion: This double-blinded, randomized trial demonstrated that a localized laminar flow device dramatically reduced the count of CFUs in the air directly above the wound and beneath the ABS (adjusted for the number of operating room personnel and surgical time). The use of the device was not associated with a longer case duration; however, some additional setup time was required prior to surgical incision to place the device. Further study is required to determine the clinical implications of this finding—specifically, whether such devices result in lower rates of periprosthetic joint infection after shoulder arthroplasty.

This study was approved by the Texas Orthopedic Hospital Institutional Review Board (no. TOH181), and all patients signed an informed consent form prior to participation.

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Periprosthetic joint infection (PJI) following shoulder arthroplasty is a morbid and costly complication. The incidence has been reported as 1%,[16] and it is the most common surgical reason for readmission within 90 days.[19] Arthroplasty surgeons have adopted numerous intraoperative measures to reduce wound contamination, including filtered exhaust hoods and limiting operating room (OR) traffic.

Airborne particulates have long been recognized as a potential source of wound contamination, and studies have shown an association between the density of airborne particulates and PJI.[8,12] In addition, a correlation exists between airborne particulates and colony-forming units (CFUs) both in the surgical wound and in the air directly above the wound.[7,11,22]

Devices to generate laminar airflow were developed as a means of preventing airborne bacteria from lingering over the surgical wound. Most currently used devices are mounted in the OR to deliver either vertical (ceiling-to-floor) or horizontal (wall-mounted) flow. One early study reported a reduction in the rate of PJI following total hip arthroplasty (THA) from 9% to 1% using laminar flow.[4] However, subsequent database studies and systematic reviews have not found a reduction in PJI or surgical-site infection (SSI) rates with the use of laminar flow.[1,15] A few practical criticisms of these devices are that the flow can be disrupted by surgical equipment (eg, surgical lamps) and OR personnel and that the flow can be affected by local OR settings (eg, air velocities at the supply diffuser or levels of room pressurization). Finally, recent break-even analyses have questioned whether the high cost of these systems is justified given the current evidence regarding their effect on rates of PJI.[5,17]

In contrast to laminar flow systems installed in the OR, localized laminar flow devices including the Air Barrier System (ABS; Nimbic Systems, Stafford, TX, USA) are attached adjacent to the wound to create localized, directed flow of high-efficiency particulate air (HEPA)–filtered air over the surgical field. Personnel and equipment stay above the barrier, limiting a disruption in flow. In a randomized controlled trial, Stocks et al[21] demonstrated a significant reduction in air bacterial counts using the ABS in THA cases. The cost of this device is also significantly lower than that of building or modifying ORs with laminar airflow ventilation, with an initial cost $<$ \$5000 and a disposable cost $<$ \$300 according to the 2019 Nimbic Systems price list (unpublished data, January 2020).

Our study was a double-blinded, placebo-controlled, parallel–group design, randomized trial investigating the effectiveness of a localized laminar flow device in reducing the intrusion of ambient airborne particles and bacteria into the surgical site during shoulder arthroplasty as measured by overall particle counts and CFUs. We hypothesized that the localized laminar flow device would reduce the overall particle counts and CFUs.

Materials and methods

Patients

All patients undergoing primary total shoulder arthroplasty (N = 56) were assessed for study eligibility. Patients undergoing hemiarthroplasty, resurfacing, or revision arthroplasty were excluded (n = 13; Fig. 1). The remaining 43 patients who had consented to undergo primary total shoulder arthroplasty (anatomic or reverse) were recruited and consented to participate in this study. An a priori power analysis revealed that a sample size of 19 patients per randomized group was needed to obtain 80% power ($\alpha = .05$) to detect a reduction $\geq$ 50% in bacterial counts. Preliminary device testing indicated an 88% reduction in airborne bacteria counts.

After consent was obtained and before scheduling the surgical case, patients were randomly assigned to the air barrier or control group with a 1:1 allocation using mixed block sizes ranging from 2 to 8 to attain balanced group sizes. Study participants, surgeons, and surgical staff were blinded to group assignment. However, the operating surgeons reported that they were eventually able to determine whether the ABS was active during the procedure by noticing differences in the way cautery smoke moved under the influence of the active ABS device airflow. The technicians collecting the data intraoperatively were aware of group allocation by following a previously generated randomization list that was shared with no other personnel; they activated the device accordingly. The technicians conducted themselves as if the device was active in all cases.

Similarity of interventions

Both groups followed the same protocol intraoperatively. All patients received routine prophylactic antibiotics, either cefazolin or vancomycin, 30-60 minutes before incision. Patients with a penicillin allergy routinely receive clindamycin as an alternative to cefazolin. Following administration of anesthesia, participants were placed in a modified beach-chair position, cleaned with alcohol, prepared with chlorhexidine or povidone-iodine, and draped in standard sterile fashion. The ABS device was placed onto the surgical field. A standard shoulder arthroplasty procedure

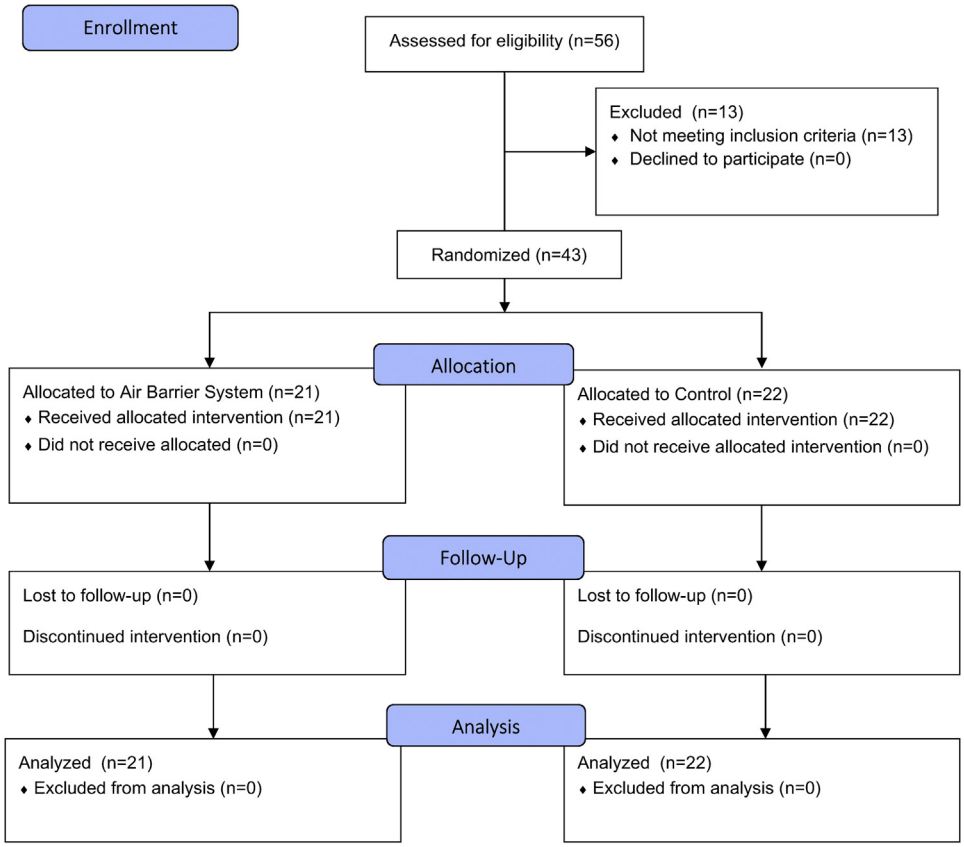

Figure 1 CONSORT (Consolidated Standards of Reporting Trials) diagram of patients' randomization, intervention, and analysis.

was performed by 1 of 2 fellowship-trained shoulder surgeons using a deltopectoral approach and a previously published technique.[6] In the ABS (active) group, the ABS device was turned on by the technician before the initial incision and turned off after closure of the surgical wound. In the control group, the ABS device was not activated; however, air sample collection was performed for all cases, with the air sample collection tubing placed near the surgical incision.

ABS device

Localized, directed HEPA-filtered laminar airflow was provided by the ABS. The device consists of 2 components: a HEPA blower and a sterile nozzle that weighs 18 kg and is 30 × 30 cm in width and length and 66 cm tall. The 0.9-kg nozzle and hose assembly emits HEPA-filtered air to repel airborne microorganisms over a localized area (Fig. 2). The device was secured on the patient's body in close proximity to the surgery site, as demonstrated in Figure 3 during a left total shoulder arthroplasty. The air sample collection tubing was placed near the incision (Fig. 4).

The ABS attached to the patient within 10.2 cm (4 in) of the incision site and created a localized positive-pressure clean airflow field that reached 5.1 cm (2 in) above the patient, 17.8 cm (7 in) laterally across the incision, and 53.3 cm (21 in) in the proximal-to-distal direction; thus, only the incision was encapsulated within the ABS clean air field.

The ABS unit was the last component applied to the patient prior to incision; application by a user familiar with the device typically takes <1 minute. This involved applying a pad using hook-and-loop fasteners around the arm, pressing a nozzle into the pad, and then connecting a hose.

Data collection

All data collection occurred in 2 ORs with conventional ventilation systems (turbulent airflow, 12-15 exchanges per hour); the size and equipment arrangement in these rooms were the same. Air passed through a prefilter and a VariCel filter (95% efficiency at removing particles ≥ 0.3 μm; AAF International, Louisville, KY, USA) before being diffused into the room through ceiling vents positioned primarily over the operating table and exiting the room through 3 ducts located near the lower section of the OR walls.

Positive air pressure was maintained at a minimum of 0.02 in of water gauge relative to the outer hall. Surgical personnel working in the OR within the surgical field (surgeons, surgical assistants and technicians, and scrub nurses) wore standard OR gowns. Surgical personnel working in the OR but outside the sterile surgical field (circulating nurses, anesthesiologists, and radiology technicians, as well as other technicians) wore standard OR attire (cotton scrub shirts and pants, surgical masks, and head

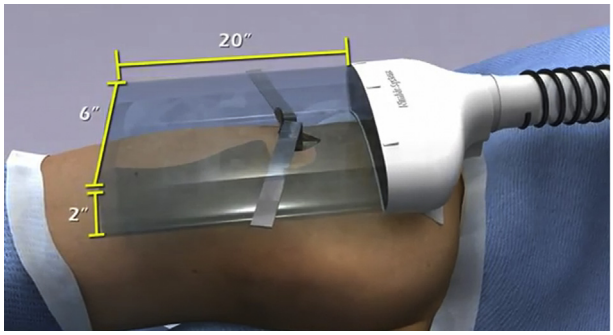

Figure 2 Air Barrier System nozzle component.

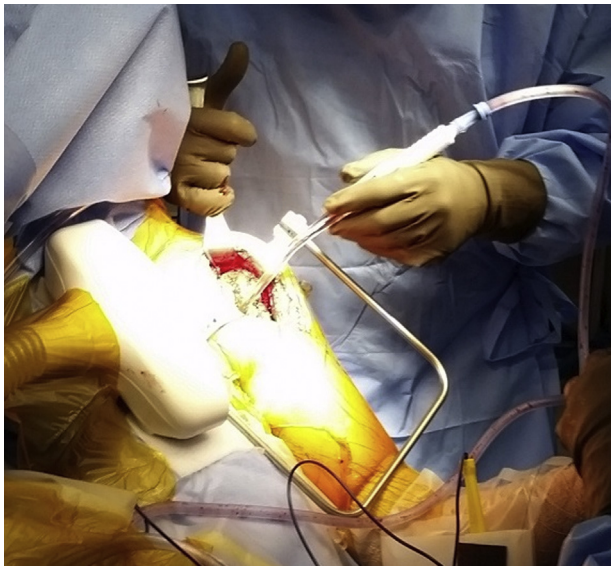

Figure 3 Air Barrier System in position during total shoulder arthroplasty.

covers). These were the routine conditions for total shoulder arthroplasty cases performed by the surgeons.

The number of surgical personnel present in the room was recorded in 10-minute intervals. The ORs had 2 entry points via self-closing doors: 1 door opened to an outer hall and 1 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. Opening the door to the outer hall was restricted, although it did open at times.

Microorganisms (CFUs) were collected from the air within 5 cm of the surgical wound, which positioned it within the ABS's area of effect (Fig. 3). These samples were obtained using an Anderson N6 bioaerosol collection device (Environmental Monitoring Systems, Charlotte, SC, USA) 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, USA) such that particulates from this air sample collected on the agar surface. The technician exchanged the plates every 10 minutes throughout the surgical procedure. Control plates were handled in the same manner as the active plates but were exposed only momentarily to evaluate for

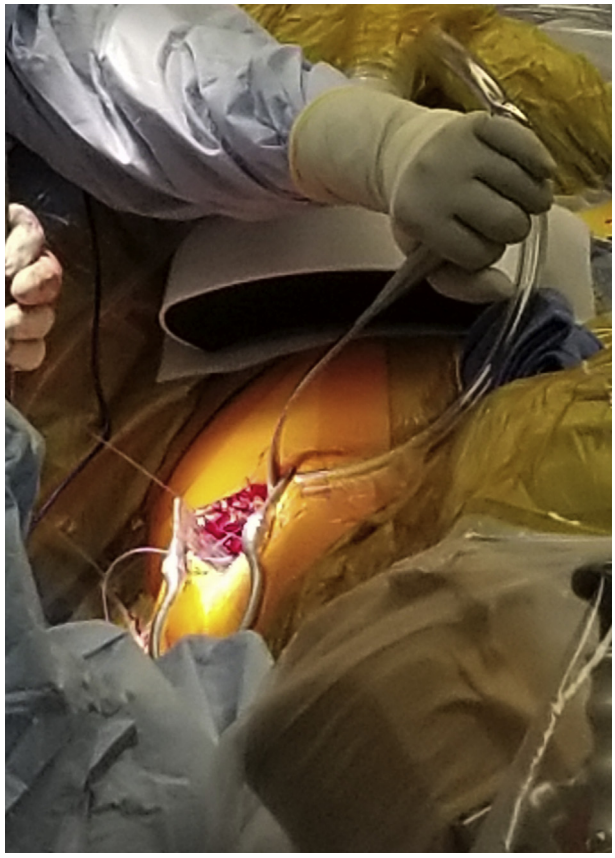

Figure 4 Air sample collection tubing placement at incision.

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 CFUs per cubic meter.

PJI was not used as an endpoint for this study because it was infeasible at a single institution based on our power analysis, assuming a PJI rate of 1.1% in the no-ABS group with a proposed rate of 0.5% in the ABS group. A 2-group Fisher exact test with a .05 significance level and 80% power would require 3459 patients to be enrolled in each study group (6918 total).

Data analysis

Descriptive statistics and data plots were used to evaluate the distributions of the data. For normally distributed variables such as surgical time and number of surgical staff in the OR, independent *t* tests were used to evaluate differences between the air barrier and control groups. Airborne CFUs per cubic meter and particulate counts were not normally distributed, and the distributions were identified as Poisson distributions, which are appropriate for count data when the mean equals the variance. Correlations between CFUs and particulate counts were evaluated with the Spearman ρ.

CFUs in the surgical field and particulate counts were measured every 10 minutes and were evaluated with Poisson regression models to determine whether differences existed between the air barrier and control groups. Predictors included in the models were surgical time, staff count, and particulate counts in each size category. Residual plots and analyses of likelihood-ratio functions determined the model of best fit.

Results

A total of 43 total shoulder arthroplasty cases over a period 6 weeks were included in this study, with 21 cases in the ABS group and 22 controls. The 43 cases generated 268 ten-minute intervals for analysis. Table I summarizes the particulate counts by size and CFU data collected in the study. Surgical time, measured from incision to closure, was similar between groups ($P = .53$), and the average number of staff members in the OR was not significantly different between groups ($P = .16$), with a median of 8 staff members in the OR during any 10-minute interval. Surgical time and staff count were both weakly correlated with CFUs (Spearman $\rho < 0.3$ for all), whereas larger-diameter particles (>1 μm) were significantly correlated with CFUs ($P = .01$).

The effectiveness of the ABS was evaluated with Poisson regression models comparing the differences in CFUs by experimental group (Table II). Group allocation was a significant predictor of CFUs, with surgical procedures using the ABS having a lower CFU count by 0.675 ($P < .001$) in the base model. In a full model that included all variables, the ABS significantly decreased CFUs ($\beta = -0.583$, $P < .001$) along with surgical time and particulates with a diameter ≥ 5 μm. Staff count and particulates with a diameter < 5 μm were not significant predictors of CFUs. Evaluation of the likelihood functions between the base and full models showed that the full model was a significant improvement over the base model ($\chi^2 = -214$, $df = 4$; $P < .001$). Both models demonstrated significantly lower CFUs in the ABS group than the control group ($P < .001$ for all). Infection was not a primary outcome because of the small number of patients; however, no postoperative infections have been reported in either study group with a minimum of 1-year follow-up for all patients.

Although we did not quantify it, we found the device easy to incorporate into the surgical field. It did not interfere with the surgical procedure and added minimal time to the draping portion of the cases.

Table I Intraoperative particulate counts by size and CFU data

Variable	Median	IQR
Particulate count		
Diameter of 0.3-0.49 μm	199,841	103,538-289,219
Diameter of 0.5-0.99 μm	45,020	9666-81,004
Diameter of 1.0-4.99 μm	30,503	4581-83,173
Diameter of 5.0-9.99 μm	668	140-2672
Diameter of 10-24.99 μm	17	10-40
Diameter ≥ 25 μm	7	3-13
CFU/m^3	4	0-8

CFU, colony-forming unit; *IQR*, interquartile range.

Discussion

Our double-blinded, placebo-controlled, randomized trial demonstrated that a localized laminar flow device dramatically reduced the count of CFUs in the air directly above the wound and beneath the ABS (adjusted for the number of OR personnel and surgical time). The use of the device was not associated with a longer case duration; however, some additional setup time was required prior to surgical incision to place the device. The device was able to be incorporated into the standard surgical field setup and did not interfere with the surgical procedure.

The history of laminar airflow devices in orthopedics largely begins with Sir John Charnley. In 1969, Charnley and Eftekhar[3] sparked the interest of arthroplasty surgeons with their initial report of a 9% to 1% decrease in infection rate following THA by using a laminar airflow device. Studies in the coming decades demonstrated that the density of airborne particulates above the wound—as few as 10 CFUs—is sufficient to cause deep infection,[13] and PJI rates correlate with the quantity of airborne bacteria within 30 cm of the wound.[12] In addition, a 1987 multicenter study of 8052 arthroplasties revealed a significantly reduced rate of PJI when performed in ORs with ultraclean air compared with conventional ventilation.[11] Ultimately, these and other studies led to the creation of guidelines requiring air systems that allowed for <10 CFUs within 30 cm of the wound.[14]

However, more recent data on laminar airflow devices have diminished the enthusiasm for their use, primarily owing to minimal evidence of their effectiveness in reducing PJI rates and their cost. A recent meta-analysis showed no difference in the risk of deep SSIs based on the use of laminar flow in hip and knee arthroplasty.[1] These results and the high cost of these devices have led to a handful of new studies advocating against their installation being a requirement for new ORs.[2,5,9,17] Other authors have pointed out that registry studies may not be appropriate to examine this topic because they are blind to laminar flow functioning in its designed manner; moreover, registries can underestimate PJI rates by 40%.[10,24]

In short, although there is evidence to support that airborne particulates contribute to wound contamination and PJI in the hip and knee literature, there is also evidence that OR-based laminar airflow systems do not affect the

Table II Multivariate Poisson regression models evaluating Air Barrier System

Model and variables	β coefficient	*z*	*P* value	Likelihood-ratio test
Base model				—
Air barrier	−0.675	−13.02	<.001	
Constant	2.11	70.32	<.001	
Full model				−214, $df = 4$; $P < .001$
Air barrier	−0.583	−10.55	<.001	
Surgical time (in minutes)	−0.008	−4.81	<.001	
Staff count	−0.025	−1.42	.156	
Diameter of 0.3-0.49 μm	3.62×10^{-7}	1.4	.163	
Diameter of 0.5-0.99 μm	-3.00×10^{-7}	−0.21	.833	
Diameter of 1.0-4.99 μm	-5.87×10^{-7}	−0.37	.709	
Diameter of 5.0-9.99 μm	-5.18×10^{-5}	−3.22	.001	
Diameter of 10-24.99 μm	−0.0015	−2.40	.016	
Diameter ≥ 25 μm	0.0062	5.7	<.001	
Constant	2.80	14.55	<.001	

rates of deep SSI and PJI. The cost of these systems is therefore difficult to justify. Moreover, there are known limitations in the ability of OR-based laminar flow systems to achieve their purpose, namely the blockage of flow by interposed OR personnel. Thus, current evidence may warrant implementation of other, cost-effective methods of delivering laminar flow to decrease wound inoculation by airborne bacteria.

The ABS used in this study has been cleared by the US Food and Drug Administration for use in hip and spine procedures and is commercially available. In a recent randomized, controlled clinical study of 300 patients, the researchers found that the ABS greatly reduced the number of microorganisms at incision sites and demonstrated fewer prosthesis-related infections compared with a control group in which the ABS was not used.[4] Furthermore, their study found that the incidence of prosthesis-related infections was proportional to the number of airborne microorganisms present at the surgical incision.

With the inclusion of the results of this study, there is moderate to strong evidence demonstrating that localized laminar flow devices are successful in reducing the CFU count in air sampled from near the surgical wound. In a randomized controlled trial, Stocks et al[21] demonstrated a complete eradication of air bacterial counts using the ABS for hip arthroplasty compared with the sham and control groups. Sossai et al[20] examined a mobile box-type laminar flow device and similarly found a dramatic decrease in CFUs from air sampled from near the wound. Given the relatively low cost, portability, and demonstrated effect of airborne particulates on wound contamination, there may be a role for this easily implemented device in shoulder arthroplasty despite its unclear effect on the rate of PJI.

One important caveat in understanding the implications of this study is the known difference in the causative organisms for shoulder PJI. *Cutibacterium acnes* is estimated to account for 39% of shoulder PJIs[15] and is thought to live in the skin[18] rather than originate from particulates. Moreover, the rate of PJI from organisms that could come from airborne particulates, such as *Streptococcus*, of presumed respiratory origin is estimated at approximately 10% in the hip and knee literature[23] compared with 2%-3% in the shoulder literature.[15] Thus, although localized laminar flow in shoulder arthroplasty appears promising, it may have less of an impact compared with lower-extremity arthroplasty, and further studies are needed to investigate the actual rate of PJI using this technology.

There are numerous limitations to this study. Although there have been no reported superficial or deep infections at short-term follow-up, we did not analyze the rate of PJI with this device owing to the infeasibility of achieving the statistical power needed to examine this rare event. As discussed earlier, there is literature to support the correlation between airborne particulates and SSI or PJI; however, this finding has not been reproduced in multiple studies. In addition, we did not collect wound cultures, although these cultures may be influenced by inoculation from sources other than airborne bacteria and therefore may not entirely be a representation of the effectiveness of the localized laminar flow device.

Conclusion

This double-blinded, randomized trial demonstrated that a localized laminar flow device dramatically reduced the count of CFUs in the air directly above the wound and beneath the ABS (adjusted for the number of OR personnel and surgical time). The use of the device was not associated with a longer case duration; however, some additional setup time was required prior to surgical incision to place the device. Further study is required to determine whether such devices result in lower rates of PJI after shoulder arthroplasty.

Disclaimer

Nimbic Systems provided the research material (particle analyzer, impact air sampler, Air Barrier System, and cultures) and personnel (technician) for this study. The Fondren Orthopedic Research Institute supports part of the study team (Mitzi S. Laughlin and Warren R. Dunn).

None of the commercial entities were involved in any aspect of the study.

Brent J. Morris is a paid consultant for Tornier/Wright Medical Group NV and receives research support from Tornier/Wright Medical Group NV.

T. Bradley Edwards has received intellectual property royalties from and worked as a consultant for Wright Medical Technology; works as a paid consultant, presenter, or speaker for DJ Orthopedics and Smith & Nephew; and receives royalties from DJ Orthopedics.

The other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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