INTRODUCTION:
Postoperative sepsis is a costly and potentially devastating problem in total joint arthroplasty. 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. 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.

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. Ultraclean air reduces environmental contamination, whereas exhaust hoods and suits reduce contamination from the surgical personnel. A large field of laminar air flow may not lead to reduction in infection risk 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 air flow perimeter. The use of ultraviolet light in operating suites is effective but requires protective garments and gogles for the surgical staff and patient to avoid skin or eye injury.

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 this system across the surgical field reduces airborne particulate and colony-forming units in the surgical field during total hip arthroplasty.

METHODS:
Thirty-six patients who had consented to undergo primary total hip arthroplasty were recruited to participate in this study. Patients undergoing hemiarthroplasty, resurfacing, or revision arthroplasty were excluded. An a priori power analysis revealed that a sample size of 8 subjects per group was needed to obtain 80% power (α = 0.05) 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 hospital’s Institutional Review Board.

Subjects were randomly assigned to one of the three groups using block randomization technique. Subjects were masked to group assignment. It was impossible to perform the surgery in a masked manner, but the investigators 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 surgeons who performed all of the surgeries (i.e., 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 (i.e., 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 (i.e., the air flow device was in place and turned on). The device was turned on immediately prior to the initial incision and turned off following closure of the surgical wound. All patients received routine prophylactic antibiotics, either cefazolin or vancomycin, 30-60 minutes prior to incision.

The localized, directed HEPA-filtered laminar air flow was provided by the Air Barrier System™ (Nimbic Systems, Stafford, TX). The device consists of two 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.

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. 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 3108, Particle Measuring Systems, Boulder, CO, USA), calibrated prior to 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 one-minute intervals. The samples were collected from inside the surgical field (under the air flow in the Air Barrier group) within 5 cm of the surgical wound.

Colonial-forming units were counted from the air within 5 cm of the surgical wound, same method as particulate measurement, and from the air at a control site on the Mayo stand approximately 40 cm from the surgical site. Air collected passed to standard culture plates containing tryptic soy agar with 5% sheep’s blood such that particulate from this air sample collected on the agar surface. 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 incubated at 35 degrees Celsius for 36 hours. Staining and morphological 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/m3).

Descriptive statistics (means, medians, frequencies) were used to evaluate the distributions of the variables. We used generalized estimating equations to evaluate the effects of group and other factors on airborne CFUs/m3 at the surgical site in each 10 minute interval.

RESULTS:
The average surgical time was similar in the three groups: 69 minutes in the Control and Sham groups and 66 minutes in the Air Barrier group. All particulate counts and the CFUs/m3 at the surgical site were significantly lower in the Air Barrier group (p<0.001). The CFUs/m3 at the control site (p=0.633) did not differ significantly among groups. The number of door openings (p=0.081), body mass index (p=0.784), and incision area (p=0.293) was similar across groups. The Sham group had an average of one less person in the operating room during the surgery compared to the other two groups (p=0.001).

All particulate diameter categories 1 μm and larger were significantly related to CFUs/m3 at the surgical site (p<0.05). Staff count (p=0.001) and the control site CFUs/m3 (p=0.001) were also significantly related to CFUs/m3 at the surgical site. The number of door openings (p=0.475) was not significantly related to CFUs/m3 at the surgical site. In analyses including multiple predictor variables, both group (p=0.001) and control site CFUs/m3 (p=0.001) were found to be related to CFUs/m3 at the surgical site. For a given CFUs/m3 at the control site, the Air Barrier group had a significantly (p=0.001) lower predicted CFUs/m3 at the surgical site compared to the Control and Sham groups, which did not differ significantly from one another (p=0.214). After including both group and control site CFUs/m3, no other variable was significantly related to CFUs/m3 at the surgical site.

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

DISCUSSION:
The directed air flow system’s effectiveness in reducing bacteria appears to be related to its ability to reduce particulate that may carry and allow proliferation of bacteria. The directed air flow system is relatively simple to use and does not appear to hinder the function of the surgeon or operating room staff, impede access to the surgical site, or interfere with the surgical procedure. The directed air flow system can be used in any operating room environment to provide clean air equivalent to a properly-used, well-functioning laminar air flow system. The directed air flow system was effective in reducing airborne particulate and bacteria in the surgical field during total hip arthroplasty.