

1 **Operating Room Traffic Increases Aerosolized Particles and Compromises the Air**
2 **Quality – A Simulated study**

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ABSTRACT

Background: Strategies to prevent bacterial fall-out and reduce particle count in the operating room (OR) are key components of preventing periprosthetic joint infection (PJI). Although OR traffic control is an important factor, a **quantitative** study has not been performed to investigate the influence of personnel and door opening on OR air quality. This simulated study aimed to examine the influence of these two factors on **particle density in OR** with and without the laminar airflow (LAF).

Methods: Both experiments took place within an empty OR of an arthroplasty unit equipped with a LAF system. First, the number of particles in the air was counted using a particle counting apparatus whilst nine persons entered the room, one every 15 minutes. Second, the door was opened and closed starting with zero door openings per minute and increasing to four **in 15 minute increments**. Both experiments were performed once with the LAF turned on and once without.

Results: The number of personnel in the OR and the number of door openings per minute correlate with the density of particles. Both relationships were significantly reduced by turning the LAF on (**correlation coefficients <0.4**). With the LAF being turned on, the particle density per person decreased from 211.19 particles/ft³ to 18.19 particles/ft³ ($p < 0.001$) and the particle density per rate of door openings declined from 117.80 particles/ft³ to 1.90 particles/ft³ ($p=0.017$).

Conclusions: This study confirms that personnel and door opening are **a major** source of particles in the OR air. Controlling traffic is critical for reduction of particles and is likely to be a key preventative strategy in reducing PJI.

Keywords: Periprosthetic Joint Infection; Operating Room; Air Quality; Laminar Air Flow; Door Opening; OR Traffic

INTRODUCTION

Prevention is the most effective strategy for any human disease. In the field of orthopaedics, this is particularly true of periprosthetic joint infection (PJI) – a complication that continues to pose a massive burden on the healthcare and demise of patients [1-3]. In recent years, and with **substantial improvements in** implant-related issues such as bearing surface wear and fixation, infection has ascended the ranks to become one of the most important complications which compromises the outcome of total joint arthroplasty (TJA) [4]. The medical community has been making great efforts and investing vast resources in combatting PJI. Numerous organizations have been actively engaged in efforts to implement effective strategies for prevention of surgical site infections in general, and PJI in particular. The Center for Disease Control has been involved in a comprehensive review of the literature over the past few years in an effort to update their Surgical Site Infection Prevention guidelines [5]. These guidelines, published recently [6], attempt to address the issue of operating room (OR) environment. However, due to a lack of available literature, they do not propose a conclusive recommendation with regards to OR environment. Thus, the most optimal OR environment for performing TJA has not yet been established.

Since the introduction of laminar air flow (LAF) in orthopaedic operating rooms by Sir John Charnley, **some** surgeons prefer to perform TJA in an OR fitted with laminar flow or positive pressure systems [7]. The rationale behind such practice is that LAF or positive pressure ventilation systems reduce the number of floating particles in the OR that have the potential to fall onto the surgical field and result in subsequent infections

[8]. Although recent data from the New Zealand registry has shed doubts on the **benefit** of LAF in this setting [9], strategies to reduce the particles in the operating room air appear to be an intuitive measure that should be effective in the prevention of surgical site infection (SSI) and PJI [10,11].

It is believed that personnel present in the operating room are the main source of particles in the air [12]. Each person sheds millions of particles per day, and even more during physical activities. In addition, 5-10% of skin debris are known to carry bacteria [12,13]. It has also been proposed that opening of the operating room door results in an increase in the number of bacteria in the air [13]. A recent study demonstrated that the OR door is opened on average 0.65 times per minute during a TJA procedure in a high volume arthroplasty center [14].

Despite the availability of a number of studies examining the issue of aerobiology, the direct link between the number of personnel and door openings in the OR and the number of particles in the air has not been **quantitatively assessed** for total joint arthroplasty cases. The aim of this simulated study was therefore to conduct two sets of experiments to investigate the potential for a direct link between the number of particles in the operating room air and i) the number of OR personnel and ii) the frequency of OR door opening.

MATERIALS AND METHODS:

The study took place within a dedicated orthopaedic OR of a university hospital fitted with vertical LAF **with high efficiency particulate air filters (99.97% efficiency)**. **The area of the OR is 534 ft², the height is 9.2 ft., and the room is equipped with two 12"x18" exhaust grills.** No actual patients were present in the OR in either experiment but all other equipment such as the operating table and anesthetic equipment were left in their standard positions. During all experiments, the room temperature was constant and the differential pressure in the room remained in the accepted range of greater than +2.5 Pascal (Pa) as recommended by the Centers for Disease Control (CDC) [15].

Two particle counting machines (IcSentinel, Oberon Inc., OH) were placed within the laminar flow enclosure of the OR. One of the machines was placed on the operating table and the other on the table that would normally house the surgical instruments during a joint arthroplasty procedure. IcSentinel particle counting machine is equipped with a laser detector and samples particles every 2-3 minutes through four different size channels, 0.5 μm , 1 μm , 5 μm , and 10 μm . In our analyses, we included particles within the size range of 0.5-5 (μm) as the bacteria causing PJI fall into this size range [16,17].

Experiment A: Number of OR personnel and air particle count

Nine volunteers were sequentially assembled in the OR starting from zero people in the first 15 minutes and increasing to 9 people within 15-minute intervals (Figure 1). The OR door was not opened during the 15-minute intervals in order to eliminate the influence of door opening on air particle numbers. The participants, **wearing clean OR scrubs, foot covers, caps, and masks**, were asked to stay in the room and to keep their movements

constant throughout the course of the experiment. Following entry of each participant into the room, the total numbers of air particles present during the ensuing 15 minutes were measured. This experiment was conducted on two occasions: once with the LAF turned off and once with the LAF turned on.

Experiment B: Number of OR door openings and air particle count

This experiment was conducted in the same OR but this time there were no participants present within the room. The OR door was opened and closed 0 to 4 times per minute each for 15 minutes whilst the air particles were measured. This experiment was conducted on two occasions: once with the LAF turned off and once with the LAF turned on (Figure 2).

Statistical Analysis

Simple linear regression was performed to estimate the relationship between particle density and either the number of personnel within the OR (experiment A) or the frequency of door **openings** (experiment B). Each regression was performed three times: once for the LAF-off measurements, once for the LAF-on **measurements**, and once using both groups and an interaction term to detect whether LAF had a significant effect on the regression slopes **i.e. whether LAF had a protective effect on the particle density**. Because of potential concerns about Gaussian distribution of data, the statistical tests for interaction were repeated using a square-root transform on the particle density (as determined using the Box-Cox method). The subgroup regression lines (LAF on or LAF off) are left in their original units for clarity. All statistical analyses were performed

with the use of R 3.3.1 (R Foundation for Statistical Computing, Vienna, Austria). An alpha level of 0.05 was used to determine significance.

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RESULTS:

Experiment A: Number of OR personnel and air particle count

With the LAF turned off, the regression line between air particle density and the number of personnel was 311.26 particles/ft³ (SE 230.21) plus 211.19 particles/ft³ per person (SE 43.12). The associated R² was 0.75 and the regression was statistically significant (p=0.001). When LAF was turned on, the regression line was -9.67 particles/ft³ (SE 50.86) plus 18.19 particles/ft³ per person (SE 9.53); an associated R² was 0.31 and was not statistically significant (p=0.903). With the laminar flow on, the particle density decreased from 211.19 particles/ft³ per person (SE 43.12) to 18.19 particles/ft³ per person (SE 9.53) (p < 0.001). The interaction term was significant (p < 0.001), **reflecting the protective role of LAF against negative influence of number of people on air quality, and** supporting the visible trend in Figure 3. Repeating the analysis after the square-root transformation (see Methods) still returned a significant difference (p=0.003). Note that for both regression lines, the intercept (no individuals present) was not statistically different from zero.

Experiment B: Number of door opening frequency and air particle count

With the LAF turned off, the regression line between air particle density and the rate of

door openings was 3.80 **particles/ft³** (SE 130.75) plus 117.80 particles/ft³ per door openings/minute (**SE 53.38**). With LAF turned on, the regression line was 32.20 **particles/ft³** (SE 23.88) plus 1.90 **particles/ft³** per door openings/minute (SE 9.95). The R² for LAF-off was larger than that for LAF-on (0.62 vs 0.01), **but neither relationship was statistically significant** (p=0.11 vs p=0.8578) (Figure 4). **The lack of statistical significance compared to experiment A may reflect fewer data points or the narrower range of particle densities (up to 627 particles/ft³ for B vs up to 2280 particles/ft³ for A). Studying the influence of LAF, we observed that LAF decreased the particle density per rate of door openings from 117.80 (SE 53.38) to 1.90 (SE 9.95).** The interaction term was significant for the linear regression (p=0.017) but became borderline insignificant after the square root transformation (p=0.067).

DISCUSSION:

This study demonstrates that the number of personnel in the operating can significantly increase the number of floating particles in the OR. **In addition, an upward trend in the number of floating particles was observed with increased frequency of the OR door opening – although this relationship did not reach statistical significance. This study also demonstrates the protective role of vertical laminar airflow in reducing particle count in the OR.**

A timely editorial in the New England Journal of Medicine stated that infection is akin to cancer, and posited numerous reasons to justify the comparison [18]. These comparisons are valid for orthopaedic patients as the five-year **mortality** rate for patients with PJI,

even after adjusting for comorbidities and age, is higher than those for patients with breast cancer, melanoma, Hodgkin's lymphoma and testicular cancer [19]. Patients with PJI often require multiple surgical procedures, suffer serious complications of the instituted medical therapy, in particular toxic antibiotics, undergo excessive tissue destruction, and many still succumb to their disease [20]. It is clear that infection in general, and PJI in particular, will continue to pose an immense challenge to the medical community for the years to come. Although discovery of antimicrobials have played a critical role in our mission to reduce the burden of infection, most effective strategies for control of infection should focus on prevention rather than treatment [22,23]. The human history abounds with examples of simple measures that were instituted to prevent epidemics. Hand washing, isolation of affected patients, and vaccinations are such examples.

One of the most effective strategies for the prevention of infection has been to perform the surgical procedures in the clean operating room environment. Sir John Charnley should be credited with being the first to draw the attention of arthroplasty surgeons to this issue [23]. In the early years of hip arthroplasty, the incidence of infection was unacceptably high between 8-10% [24]. With the implementation of ultra clean air operating room environment, as well administration of perioperative antibiotics, the rate of infection was successfully reduced substantially [24]. The understanding of the importance of clean operating room environment has led to the design of sophisticated operating rooms fitted with laminar flow and positive pressure ventilation systems. Numerous studies have also demonstrated that the people in the operating room are the main source of bacterial fall-out [25,26]. In one study, it was demonstrated that an adult

person being present in the operating room could shed up to 10,000 bacteria per minute [27].

Another effort in providing a clean air operating room has been to restrict the number of operating door openings because this is known to disrupt the laminar flow or positive pressure ventilation for a few seconds [28-30]. It is worrisome to note that during a routine arthroplasty the operating room door may be opened 0.65 times per minute [14].

Our study has demonstrated some important points. It was found that there is a direct link between the number of personnel in the operating room and the number of aerosolized particles. **In addition, a positive trend was observed between the number of door openings in the OR and an increase in the number of aerosolized particles – though this did not reach statistical significance. As previously mentioned, one possible explanation for the lack of statistical significance for the latter observation may be due to fewer data points or a narrower range of particle densities in Experiment B. Another important finding is that the vertical laminar flow that was used during these experiments appeared to be effective in reducing the number of floating particles in the air.** Although there is a controversy regarding the role of laminar flow for prevention of PJI, it is not unreasonable to propose that any effort to “clean” the operating room air either by institution of laminar flow or positive pressure is a worthwhile exercise. Further, prevention of SSI or PJI is a multifaceted approach and studies attempting to examine the role of laminar flow are logistically difficult to perform. Thus, at this point our effort should focus on minimizing aerosolized particles with whatever strategy we feel is effective.

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224 The study had some shortfalls. The apparatus used to measure the number of particles in
225 the air, though validated for this purpose, was not capable of determining which and how
226 many of the aerosolized particles were live bacteria. However, as Tham et al. presented in
227 series of experiments, particle concentration correlates with the concentration of viable
228 bacteria during the corresponding period, therefore we can assume that particle counts
229 reported in our study represent viable bacteria [31]. Following on from this, we did not
230 correlate OR traffic volume and the number of door openings with an increase in the
231 incidence of PJI or SSI; Performing a clinical study to demonstrate this would not be
232 ethically acceptable as we would be putting real patients at an increased risk of
233 developing PJI or SSI.

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235 In conclusion, this study demonstrates that there is a direct link between the number of
236 particles in the operating room and the number of personnel present in the case. It is
237 critical that surgeons make every effort to limit the number of personnel in an operating
238 room where total joint arthroplasty is being performed.

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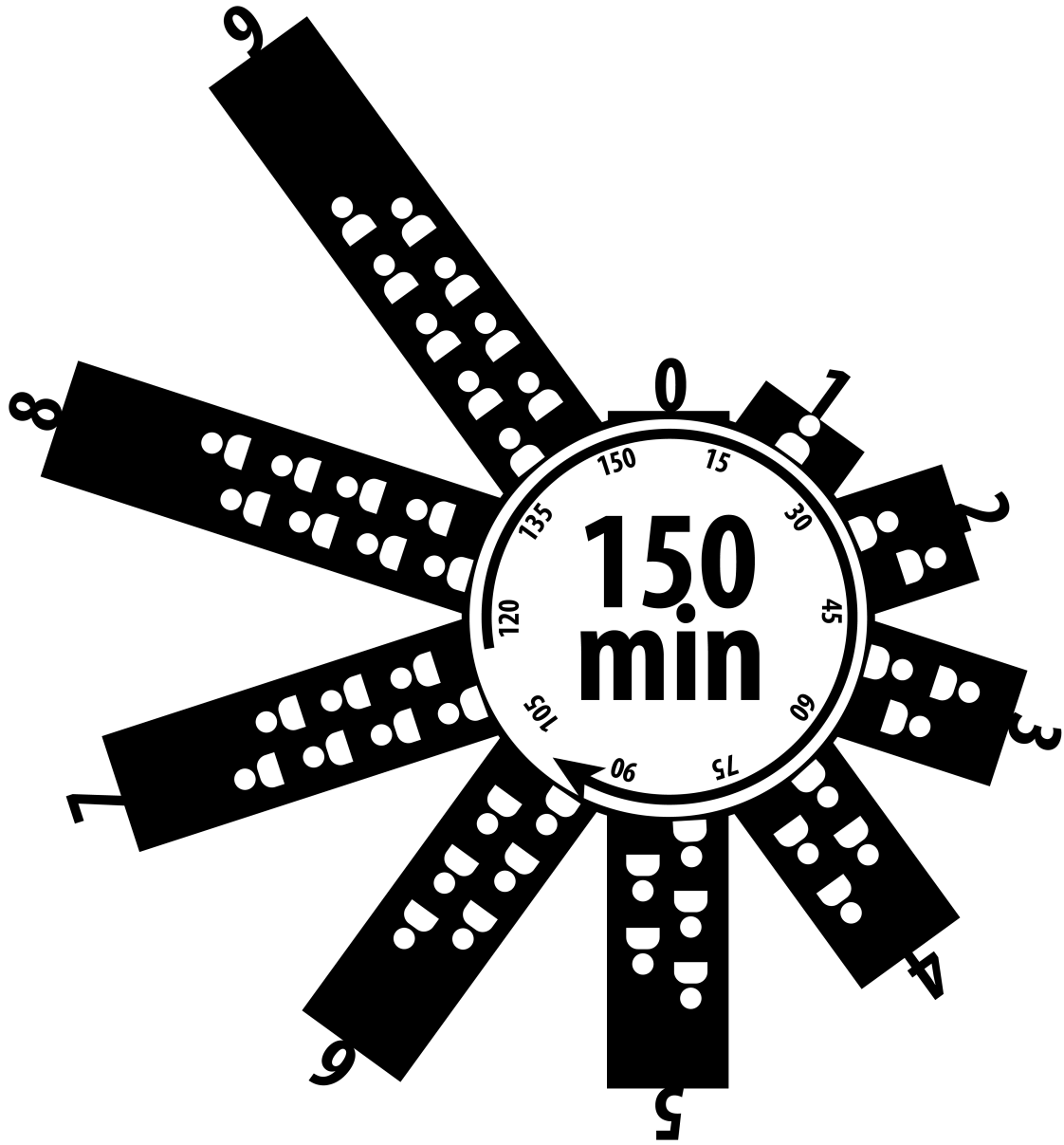
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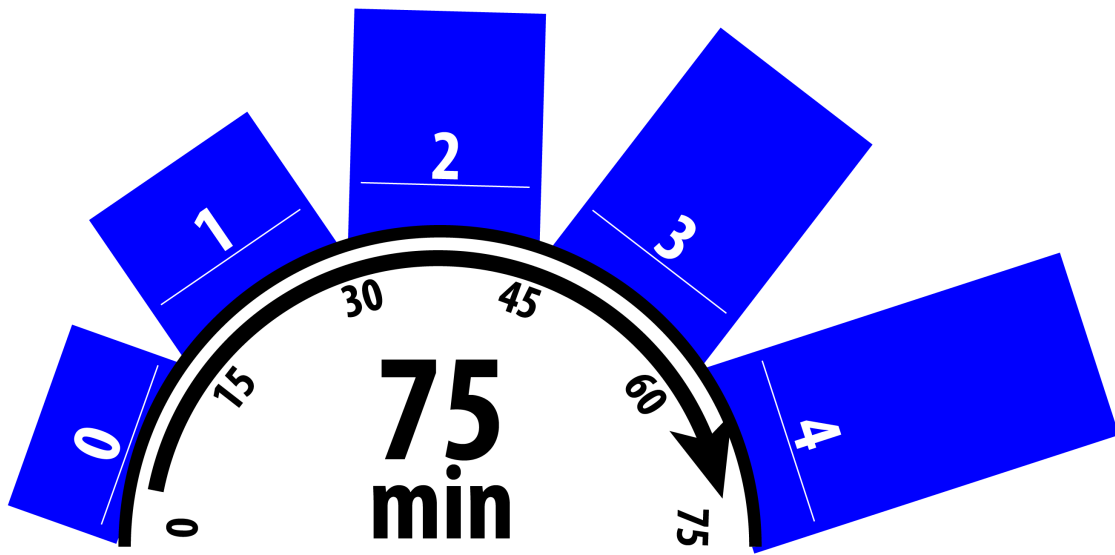
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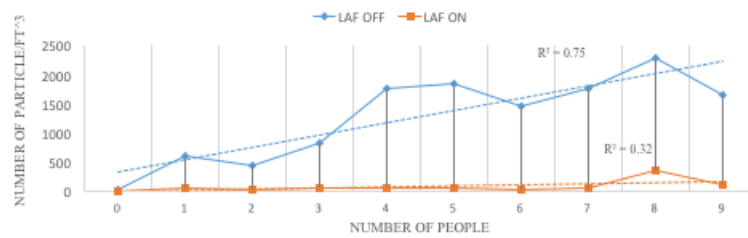


Number of Door Openings

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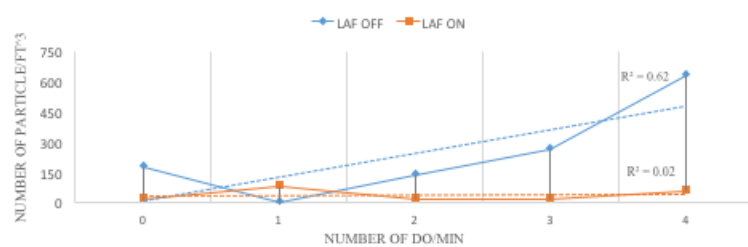
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