The Journal of Arthroplasty 28 (2013) 1482–1485

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

The Effect of Laminar Air Flow and Door Openings on Operating Room Contamination

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ARTICLE INFO

Article history:
Received 3 April 2013
Accepted 10 June 2013

Keywords:
arthroplasty
contamination
laminar airflow
RODAC
OR traffic

ABSTRACT

We evaluate the association of laminar airflow (LAF) and OR traffic with intraoperative contamination rates. Two sterile basins were placed in each room during 81 cases, one inside and one outside the LAF. One Replicate Organism Detection and Counting (RODAC) plate from each basin was sent for culture at successive 30-minute intervals from incision time until wound closure. At successive 30-minute intervals more plates were contaminated outside than inside the LAF. A negative binomial model showed that the bacteria colony forming units (CFU) depended on whether there were any door openings ($P = 0.02$) and the presence of LAF ($P = 0.003$). LAF decreases CFU by 36.6%. LAF independently reduces the risk of contamination and microbial counts for surgeries lasting 90 minutes or less.

Surgical site infections (SSI) can be devastating complications. Perioperative infections can range from simple suture abscesses to deep infections such as periprosthetic joint injections or even sepsis. Besides the physical, emotional, and financial strain these infections cause to patients and their families, the financial burden to hospitals and our economy is immense. Among hospitalized patients, SSI account for 14–16% of nosocomial infections [1]. In the United States more than 780,000 SSI occur annually (up to 5% of all surgical patients) at a cost estimated at $10 billion [2–4]. The annual nationwide cost for periprosthetic joint infection (PJI) alone is approximately $250 million [5]. Kurtz et al expect the annual cost of infected revisions to reach $1.6 billion in 2020 [6].

Preventive measures such as improved air filtration, instrument and field sterilization, protective clothing and perioperative antibiotics have arguably contributed in ameliorating SSI rates. Shorter operation times and improved surgical techniques also aim at reducing infection rates, yet the incidence is still of concern [7,8]. Several patient risk factors associated with SSI have been identified. Increasing rates of obesity, diabetes and age in TJA candidates have all been shown to increase PJI [8–10]. Furthermore, the emergence of resistant bacterial strains, notably methicillin-resistant *Staphylococcus aureus* (MRSA), makes SSI even more difficult to treat [11].

Laminar airflow (LAF) systems were first introduced to operating rooms in 1964, in the US [12]. Due to the concern of contamination of the surgical field, Charnley described the idea of 'ultra-clean' environment of the operating theater in 1972. He showed a decrease of PJI over a 10-year period from 7% to 0.5% without the use of perioperative antibiotics [13]. Other studies have shown this clean air technology to significantly decrease the rate of infections by as much as 92% [14–17]. However, the use of LAF intraoperatively has been controversial mainly due to the added cost that may not yet be justified. Some studies show no beneficial effect, some even report a detrimental effect on contamination using LAF [18–20]. LAF devices are carefully designed to provide an adequate surgical workspace by utilizing positive pressure filtered ventilation. Altering surrounding parameters like opening the operating room doors can change the dynamics of unidirectional airflow pattern. This may increase air turbulence, which has been associated with a faster spread of airborne organisms [15].

The objective of this study is to evaluate the effect of door openings with contamination in the operating room. Sterile culture plate samples were taken inside and outside the LAF during orthopaedic procedures in a high volume suburban community orthopaedic hospital. These cultures were used to determine contamination in the operating room during actual cases. They were compared to evaluate the effectiveness of LAF in protecting the surgical field from contamination and if door openings disrupted this effectiveness. Our hypothesis was that an increased frequency of door openings would

Source of Funding: This study was funded by a grant from the Sharpe-Strumia Foundation – a non-profit, local Trust to support medical research performed specifically by physicians in our institution.

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2013.06.012.

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http://dx.doi.org/10.1016/j.arth.2013.06.012

lead to contamination of the sterile field, thereby, disrupting the protective effect of LAF. We also sought to evaluate other potential factors that could lead to increased contamination rates.

Materials and Methods

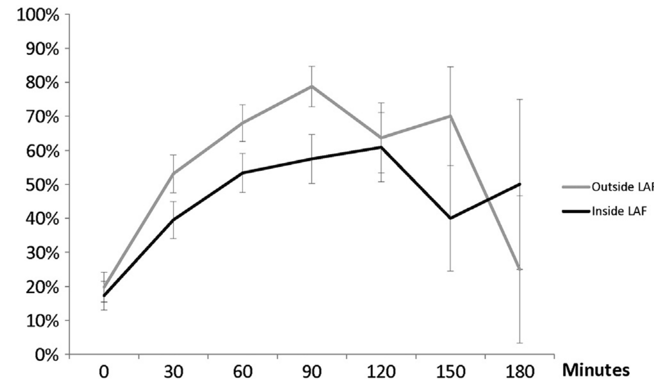
For this prospective observational study, electronic door counters were installed on all doors in the operating rooms in the hospital. For a few weeks in August and October of 2011, samples were taken during 81 orthopaedic cases, mainly total joint arthroplasty (TJA) in three separate operating rooms (OR). The following number of cases were performed: 50 total knee arthroplasties (of which 11 were simultaneous bilateral procedures), 18 total hip arthroplasties, 4 partial knee arthroplasties, 2 total knee revisions, 2 knee scopes, and 1 each total hip revision, knee autologous cartilage implantation, hip fracture, lumbar fusion, and gluteus medius repair. Case duration was variable. Data from cases were collected every 30 minutes. The number of cases as a function of time was as follows: 6, 28, 24, 13, 6, 3, 1 cases lasted 30, 60, 90, 120, 150, 180, 210 minutes, respectively. Seventy-two percent of the cases were completed within 90 minutes.

Two sterile basins were used for the testing surfaces – one placed next to the OR table within the LAF and one placed along an OR wall, outside the LAF invisible curtain. A total of 642 samples were taken from the basins using RODAC (Replicate Organism Detection and Counting) plates to investigate for bacterial presence in our OR setting. These plates are especially designed for surface testing. The RODAC plates used during this study contained a Trypticase Soy Agar with Lechitin and Polysorbate 80. The plates were kept in sterile refrigerated packages until opening. While wearing sterile gloves, two plates were opened to take samples from the center of each sterile basin beginning as soon as the basins were opened and for 30-minute intervals until the completion of the procedure. Each plate was immediately taped shut and labeled corresponding to 'inside' or 'outside' LAF and the time of sampling. Upon completion of each case, the specimens were sent directly to the microbiology department. The number of samples gathered was proportional to the length of the surgical procedure. An average of approximately eight specimens was taken for each case. Our control group consisted of samples taken from plates in a sterile OR with no door openings and only the research fellow collecting the samples. Specimens were incubated at 36 °C for 48 hours in 5% CO_2 and final results were reported after 7 days. Bacterial counts, reported as colony-forming units (CFU) were then divided according to Gram stain results. A specimen was considered positive if any CFU growth was seen on the agar (i.e., CFU $\geq$ 1).

All operating rooms at our establishment were equipped with partial ceiling supply, vertical LAF. The recycled air is subjected to 2 filtration stages before passing through a high-efficiency particulate air (HEPA) filter. HEPA filters compliant with the United States Department of Energy (DOE) will block 99.97% of particles 0.3 micrometers in size that pass through the filter [8].

The staff member collecting the bacterial samples also gathered data such as length of surgery, temperature, humidity, and number of personnel present in each case. Door openings were determined from the electronic door counter database for the time period of each case.

The count data such as CFU require a specific statistical model, which accounts for the integer-only values and other properties of the data. We used a negative binomial model (Venables and Ripley, Modern Applied Statistics in S, 4th ed., Springer 2002) found in the 'MASS' package in R 2.14.2. (R Foundation for Statistical Computing, Vienna, Austria, www.r-project.org). The negative binomial regression parallels a logistic regression in that the results are used to multiply a baseline value, in this case the estimated number of CFUs in a sampled Petri dish. We also used logistic regressions to estimate the probability that CFU count was greater than 1 (any infection) or that some specific threshold of number of CFU was exceeded.



Graph 1. The effect of LAF on contamination rate in function of time.

A full model was created for cumulative door openings at each point in time, LAF, number of people in the OR, temperature, humidity, which room was used out of the three available, and whether the door had been opened at all at that point in time. Non-significant variables were systematically removed according to the Akaike Information Criterion (AIC) until the only variables remaining were those with a significant effect on model performance. For all two by two analyses, we used Fisher's exact test. To test whether the relationship between "any door opening" and "any infection" held when controlling for LAF, and similarly whether the relationship between "any infection" and LAF held when controlling for "any door opening", the Cochran-Mantel-Haenszel test was used. All statistical tests were performed in R. We used the conventional 0.05 as the significance level.

Results

According to Graph 1, the contamination rate is consistently lower inside than outside the LAF. The plot of contamination rate versus time suggests that LAF is protective against microbial contamination for surgeries lasting 90 minutes or less. The sample size was too small to accurately assess its effect on surgeries with a longer duration as seen by the superimposed standard error bars.

For all points in time, Table 1 shows how the odds of a Petri dish showing any CFU were affected by any door openings or whether the dish was inside or outside CFU. Multivariate logistic regression was used to confirm that either inside or outside laminar air flow, the relationship was statistically significant. No interaction term was present between LAF and door openings; that is, the relative effect of door openings was not subject to the presence or absence of LAF. The Cochran-Mantel-Haenszel test, comparing openings to CFU and controlling for LAF, also showed significant results. Table 2 shows values that suggest LAF does reduce the contamination due to more door openings, but does not abolish it. If there are no door openings, then the rate of CFU contamination inside LAF is statistically identical to the rate outside LAF.

The average number of door openings was 54.6/case (0.62/minute). The average cumulative number of door openings increased linearly over the 30-minute time intervals from 17 at 30 minutes to 106 at 180 minutes (Graph 2). The average number of door openings per type of procedure was: 73.5 for partial TKA, 69.0 for bilateral TKA, 53.0 for THA, and 50.0 for unilateral TKA. The maximum number of door openings was 109 (during a bilateral TKA) and the minimum number was 9 (during a unilateral TKA). Because one dish was inside

Table 1
CFU Counts in Function of LAF and Door Openings (Logistic Regression Model).

	Est. Odds Ratio	95% CI	*P*-Value
LAF	0.6964	0.4269–0.8300	0.0023
Any Openings	5.9358	3.8250–9.211	1.95e-15

Table 2
Effect of Door Opening ≥1 vs. No Door Opening on CFU in Function of LAF.

	Odds Ratio	95 % CI	*P*-Value
LAF Absent	7.18	3.82–14.17	<0.001
LAF Present	4.69	2.44–9.53	<0.001

Table 3
Negative Binomial Model Estimates.

	Estimate	95% Lower	95% Higher	*P*-Value
Cumulative Openings	1.007	1.000	1.015	0.060
Laminar Airflow	0.634	0.470	0.855	0.003
Any Door Opening	1.693	1.078	2.660	0.022

the LAF and one was outside, there was no difference in door openings or any other variable between a dish sampled at time X inside the laminar flow and its companion, sampled at the same time in the same operation, outside the laminar flow.

The final negative binomial model showed that the CFU count depended on whether there were any door openings and the presence of laminar flow (Table 3) and had a borderline dependence ($P = 0.06$) on the number of door openings. If the doors are opened at all, the expected number of CFUs increases by 69.3% (Graph 3). We also implemented the model to account for both whether any openings had occurred and how many openings had occurred. We found that the majority of the risk of contamination was introduced with the first opening, and while additional openings were statistically significant their effect (0.7% cumulative per further opening, so 1.007 for one additional, 1.0014 for two, etc.) is too small to be clinically meaningful. Laminar flow decreased CFU by 36.6%.

The average number of personnel in the OR during each sample was 7.1 per case (range 5–10), $P = 0.109$. The average OR temperature was 65.1 °F (range 62 °F–68 °F), $P = 0.124$ and humidity averaged 57.4 mmHg (range 39 mmHg–64 mmHg), $P = 0.749$. In the full model, humidity, number of personnel, and temperature were initially all included. However, as none of these variables were significantly associated with contamination rates, they were removed from the final reduced model.

Staphylococcus was identified in 82.5% and 81.3% of the contaminated plates inside and outside the LAF, respectively. All other organisms identified had a similar distribution among contaminated plates inside and outside LAF (Table 4).

Discussion

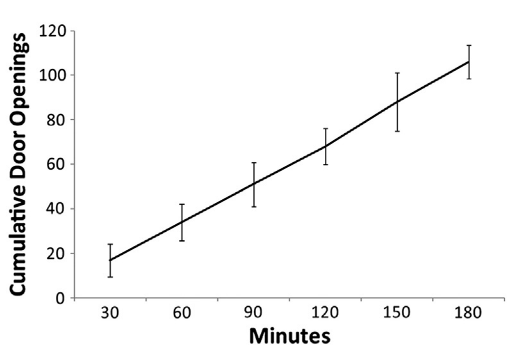
The benefit of using LAF in the OR setting is still controversial. Many studies have proven the efficacy of LAF to decrease the incidence of SSI as well as bacterial counts in the wound and on surgical instruments [14,16,17,21–23]. Others studies report no protective effect associated with the use of LAF [18–20]. In this prospective study, we notice that operating under LAF decreases the incidence of positive contamination by almost 37%. The vertical laminar flow air pattern consistently directs airborne and human-shed bacteria away from the patient. Obstacles to the unidirectional flow, such as the position of the OR staff, probably create foci of turbulence which negate to a certain extent this concept of strictly moving bacteria away from the surgical field [15,24]. A better understanding of OR aerodynamics is needed.

We noticed that any door opening increases the number of contaminated plates by almost 70%. Opening the OR door may lead to increased contamination rates by two mechanisms. First, it is associated with increased foot traffic to and from the OR. Increased OR traffic has often been associated with higher rates of post-operative SSI [16,24–26]. This can be explained by bacterial shedding both by patients and staff alike [14,27–29]. In our study, we observe a rate of 0.62 door openings per minute. A prospective study by Panahi et al, also reported an average of 0.69 door openings per minute. Moreover, 47% of the OR staff entries had no purpose and could have easily been avoided [30].

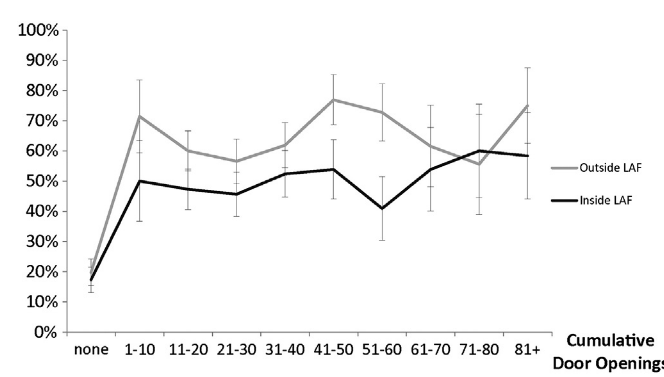
Second, LAF produces a positive pressure, unidirectional current in an enclosed space. Door opening creates turbulence by diminishing the pressure gradient between two spaces. Turbulent air follows a chaotic, non laminar pattern which might lead to faster spread of airborne bacteria or aerosolized and dust borne contaminants, to the surgical field [15]. We also report a concordant increase in microbial counts with the frequency of door openings.

Many argue against the efficacy of LAF in reducing SSI rates [18–20,31]. A study by Hooper et al evaluating 10-year results of the New Zealand Joint Registry found that using space suits and/or LAF was associated with an increase in early infection rates [32]. Our findings show that using LAF independently decreases contamination rates by more than 36%. One multicentric study showed that LAF alone decreases SSI rates from 3.4% to 1.6% [33]. Though our study showed that LAF is protective against contamination due to door openings, the rates of contamination inside and outside LAF are clinically worrisome. Bacterial seeding on the RODAC plates only reflects the potential of introducing microorganisms in patient wounds. Wound contamination does not always lead to overt infection. Many factors are involved such as the patient's immune response, microorganism load, bacterial virulence and susceptibility to perioperative antibiotics to name a few. That being said, Lidwell et al did report a direct association between the number of airborne bacteria and deep infection rates [33].

Our control consisted of a room with no staff and no door openings. In the control room, CFU counts from plates inside and outside the LAF were comparable. This might support our hypothesis that door openings while using LAF leads to more contamination. However, the absence of people or known bacterial “vectors” in that



Graph 2. Time vs. cumulative door openings, error bars ± 1 standard deviation.



Graph 3. Effect of cumulative door openings on contamination rate.

Table 4
Proportion of Organisms Identified in the Contaminated Plates.

	Inside LAF	Outside LAF
Staphylococcus aureus	83%	81%
Bacillus species	13%	14%
Micrococcus species	11%	13%
Diphtheroids	7%	8%
Mold	2%	4%
Gram negative rod	2%	0%

room might be a confounding factor. Bacterial load in the OR has been linked to the number of people present in the room [34]. We are not able to say that LAF confers added protection in the absence of people in the room and door openings. Perhaps more sampling in a controlled environment would help to make this assertion.

Operative times are often kept short in an attempt to reduce the window for infection. Our analysis showed that longer operative time was indeed significantly associated with higher rates of contamination. Moreover, operating under LAF only appears to be protective during the first 90 minutes following incision time. The sample size of longer procedures was too small to clearly demonstrate the superiority of LAF in preventing contamination rates.

The shocking number of door openings and foot traffic calls for new methods to minimize these unnecessary risks. Installing door locks, educating the staff, and having all the required equipment inside the OR at the time of incision are all ways that could theoretically decrease the potential for infection. Dalstrom et al report a correlation between positive contamination rates and the duration of uncovered OR trays [35]. It might be beneficial to open sterile trays after skin preparation and draping or cover open trays with a sterile cloth [36]. On the other hand, routine use of perioperative antibiotics has been shown to be the most important and consistent way to prevent SSI [37,38].

Limitations of our study revolved around the small number of cases (especially beyond 90 minutes) that were analyzed. Further studies with increased financial support may improve our results. Additionally, we assumed that the contamination of RODAC plates could be associated with in-vivo infection risks. RODAC plates are ideal for obtaining surface bacterial samples, however, we obtained our samples close to, but not from the actual surgical site. On the other hand, the strength of our study comes from its prospective nature. This is the first time RODAC plates are being used to evaluate the presence of organisms inside and outside LAF during orthopaedic procedures. Electronic door counters and a dedicated microbiologist increased the reliability of our results.

In conclusion, our study seems to indicate that operating under LAF is in fact protective of contamination within the first 90 minutes of surgery. Protocols need to be developed and implemented to reduce OR door openings in order to diminish infection rates. With the foreseen increase in TJA demand, reducing PJI is a challenge that deserves much attention. Larger prospective studies that independently examine the effect of LAF and the correlation between plate contamination and frank SSI should be undertaken.

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