1.12. PREVENTION: OPERATING ROOM, ENVIRONMENT

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QUESTION 1: Does the use of laminar airflow (LAF) in the operating room (OR) reduce the risk of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs) in patients undergoing orthopaedic procedures?

RECOMMENDATION: Recent orthopaedic literature has not demonstrated that the use of LAF reduces SSIs or PJIs in orthopaedic surgery. At this time, is not necessary to perform a clean orthopaedic surgery procedure, including elective joint arthroplasty surgery, in an operating theater equipped with LAF systems.

LEVEL OF EVIDENCE: Moderate

DELEGATE VOTE: Agree: 81%, Disagree: 14%, Abstain: 5% (Super Majority, Strong Consensus)

RATIONALE

The prevention of SSIs and PJIs in orthopaedic procedures requires preparation and optimization of all aspects of patient care, including pre- and postoperative variables, the surgical environment and surgical technique [1–3]. Of the modifiable variables in the surgical environment, air cleanliness has been an area of focus since it was emphasized by Sir John Charnely et al. [4,5]. LAF is described as an entire body of "ultraclean" air within a designated space moving with uniform velocity in a single direction along parallel flow lines. The system moves air with the use of fans through highly-efficient particular air filters (HEPA). The goal of LAF is that air remains flowing smoothly after filtration so that only clean, and filtered air will be directed without interruption or turbulence into contact with the surgical field. This ensures that filtered air should not contact sources of contamination en route to the designated area and that there is no mixing of filtered and unfiltered air [6–8].

Since the introduction of LAF systems, several studies have evaluated its effects on SSIs and PJIs, with most of the orthopaedic literature focusing on total joint arthroplasty (TJA) [9]. Earlier studies suggested that laminar flow ventilation systems were effective at reducing SSIs/PJIs, however, recent studies have not shown a reduction or increase in SSIs/PJIs. Currently, well-designed, high-level studies in this area are lacking. Of the studies initially in favor of LAF, in 1982 Lidwell et al. performed a randomized, multicenter study comparing TJA patients in LAF equipped ORs versus conventionally ventilated ORs. The study showed a markedly reduced incidence of sepsis in the laminar flow group (0.6%) compared to that for the control group (1.5%) in 8,055 patients [10]. However, the authors noted they did not control for the use of antibiotic prophylaxis and exhaust suits, both of which lower the rate of sepsis when utilized [10]. These results were corroborated by Kakwani et al. (2007) who reported 4% infection rates in a non-laminar flow OR compared to 0% ($p = 0.003$) infection rate in LAF ORs in a total of 435 patients undergoing Austin-Moore hemiarthroplasty for hip fractures [11].

On the contrary, a larger body of evidence suggests that LAF is not associated with a reduction in SSIs/PJIs. Marotte et al. retrospectively reviewed 2,384 cementless total hip arthroplasties (THA) performed in LAF vs. non-LAF ORs in 1987. They found no difference in sepsis rates between the two settings and only antibiotic prophylaxis reduced the rate of sepsis [12]. van Griethuysen et al. compared infection rates after switching from a conventional OR to a newer hospital equipped with LAF. They found no differences in infection rates (1.2% before, 1.6% after) between the two sites in 1,687 clean orthopaedic surgeries [13]. Additional large studies utilizing national databases by Singh et al., Breier et al. and Pinder et al. found no reduction in SSIs/infections when surgery was performed in LAF ORs during TJA [14,15] or orthopaedic trauma procedures [16]. Interestingly, three recent studies utilizing large national registries have demonstrated an increase in infections after TJA using LAF while controlling for potential confounding variables [17–19]. Brandt et al. found an increase in THA SSIs performed in operating rooms using LAF (odds ratio (OR): 1.63, 95% confidence interval (CI) 1.06 to 2.52), but no differences in SSIs were seen in total knee arthroplasty (TKA) [17]. Hooper et al. and Tayton et al. both found an increase in PJIs after TJA when performed under LAF (OR: 1.6, 95% CI 1.04-2.47) [18,19]. Gastmeier et al. showed in a systematic review that no individual study showed a significant benefit for LAF in reducing PJI following TKA and only one study showing benefit in the reduction of PJI after THA. However, there were also a total of four studies showing an increase in SSI rates following THA using LAF [22].

One explanation for the wide variability of reported results with LAF could be the many forms of use and no agreed-upon configuration. Laminar flow is a technology that can be employed in many ways, such as vertical flow, horizontal flow, full curtain and no curtain. Systems have different air velocities, array sizes and exhaust locations. In addition, different countries have different national standards (for instance, the UK has a vertical velocity standard of 0.38 m/s, while the US has no enforceable standard at all) [20]. An important weakness of laminar systems, as commonly employed, is that they fail to address the environment outside of the immediate laminar flow zone. Standard vertical laminar systems only treat about a $3m^2$ area, leaving scant room for implant and instrument trays and tables. Unfortunately, laminar systems may actually contribute to the contamination of these areas by blowing bacteria off of personnel and the floor, onto instrumentation and other personnel [21].

Although the routine usage of laminar flow systems in TJA may no longer be recommended, this should not be interpreted to mean that operating room air quality is unimportant. However, hospitals should not feel obligated to expend additional funds for LAF nor should institutions and surgeons suffer liability for surgeries performed without LAF. Adequate intraoperative air treatments, including clean air exchange rates over patient, personnel and instrumentation areas, will remain a critical factor in the prevention of PJIs and merits further investigation. Ideally, air quality standards for the active operating room, such as those prevalent in pharmacy and clean room settings, should be considered in the future.

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QUESTION 2: Does the use of forced air warming (FAW) during orthopaedic procedures increase the risk of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: There is no evidence to definitively link FAW to an increased risk of SSIs/PJIs. Alternative methods of warming can be effective and may be used.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 93%, Disagree: 2%, Abstain: 5% (Super Majority, Strong Consensus)

RATIONALE

Maintaining intraoperative normothermia has been shown to reduce perioperative complications including SSI. FAW represents one of the most widely-used methods to prevent hypothermia and maintain intraoperative normothermia. Intraoperative hypothermia has been linked to increased mortalities and morbidities, longer hospital stays, increased requirements for blood transfusion and increased SSI rates. The SSI prevention effects have not been demonstrated in implant surgery, such as total knee arthroplasty (TKA), total hip arthroplasty (THA) and total shoulder arthroplasty (TSA). There has been a concern in the literature about possible contamination of the operating room (OR) air and surgical field with these devices, and subsequent potential increased risk of SSI, especially PJI. Conductive fabric blankets (CFBs) have been suggested as an alternative for intraoperative warming.

Several experimental studies raised a concern for the possibility of intraoperative contamination caused by FAW. McGovern et al. compared FAW and conductive fabric warming (CFW) devices in a simulation of hip and spine surgery with a mannequin used as a patient [1]. They used bubbles generated at the floor and at the mannequin's head to monitor flow of air in the simulated theater and detected significantly increased bubbles close to the surgical field with the use of the FAW devices. They also conducted a clinical review of their infection data between a twenty-month period when FAW devices were used vs. a seven-month period where CFW devices were used, and found a statistically higher rate of deep SSI with the use of the FAW device. The authors noted, however, that their observational study did not account for infection control procedures that changed over the study period or account for several possible differences in patient risk factors, such as obesity and fitness for surgery. Other studies of the same cohorts by these researchers revealed potential impacts unrelated to the change in warming modality, including thromboprophylaxis [2] and methicillin-sensitive *Staphylococcus aureus* screening [3]. Legg et al. measured changes in temperature and air particles at the surgical site in a simulated OR setup with a volunteer patient simulator [4]. They found statistically significant increases in temperature and particle counts with the use of FAW compared to controls or radiant warming devices. In a follow-up study on a simulated TKA set-up, the authors used a bubble generator with a digital camera to actually visualize airflow disruptions caused by FAW [5].

Similar to the prior study, they showed a significant increase in particle counts at the surgical site and in drape temperatures. They also identified a substantial disruption in the unidirectional airflow when FAW was used. Dasari et al. conducted an experiment where a mannequin was used as a patient and temperature was measured at multiple different heights and locations with the use of FAW, a conductive blanket or a resistive mattress [6]. They found significantly greater temperature increases caused by FAW at patient height locations, whereas, temperatures measured at other heights (floor, head and ceiling) were similar among the three warming devices. They concluded that FAW generates convection current activity in the vicinity of the surgical site which may disrupt laminar air flow. Belani et al. conducted a study with a mannequin draped for a TKA in an orthopaedic room and a bubble generator placed at the head to visualize air currents [7]. Bubbles were counted on sequential photographs at the surgical field and compared between FAW and CFW. The authors found significantly increased bubble counts over the surgical site with FAW and time-lapse photography identified convection currents mobilizing air from the mannequin's head over the drapes and into the surgical field. A recent predictive fluid flow simulation conducted by He et al. on a computer aided design OR showed significant disruption in airflow caused by FAW with a displacement of squames from the floor into the surgical field [8].

Tumia et al. quantified bacterial counts in air samples taken in empty ORs, during normal surgical operations prior to turning the FAW device on, and 15 minutes after turning the warmer on [9]. They had low study numbers to reach statistical significance, but they observed an increase in bacterial counts during regular surgical operations with the warmer off compared to the empty OR and a further increase after turning the warmer on. They concluded that most of the contamination of OR air is secondary to the presence of surgical staff and OR traffic, and that FAW increases contamination to a lesser extent, but this is likely not of clinical significance given that the counts seen were still well below recommendations for ultra-clean air theaters. Albrecht et al. evaluated filter efficiency in the air blower of FAW devices and found that the intake filters used in air blowers were far from optimal efficiency which resulted in colonization of the internal parts of the device [10,11]. They cultured organisms such as *Staphylococcus aureus* and coagulase-negative *Staphylococcus*, which are known to be the major pathogens in total joint arthroplasty. Avidan et al. sampled air coming out of blowers and also found positive cultures in 4 out of 10 devices [12]. However, after connecting the perforated blanket to the air blower and sampling the air coming out underneath the blankets, no organisms grew.

On the other hand, several studies have failed to demonstrate any increased contamination with the use of FAW. Sharp et al. performed a surgical simulation using patients with psoriasis, who are known to have increased shedding of skin [13]. They utilized slit-air sampling and simulated regular OR activity. No bacterial colonies were grown, leading the authors to conclude that FAW did not result in the contamination of the surgical site. Sessler et al. evaluated the effect of FAW on operative room air in laminar airflow conditions using volunteer subjects in an OR with simulated surgical set-up and heated mannequins to simulate OR personnel [14]. A smoke plume was used to visualize airflow and revealed that FAW did not induce any upward draft or any disruption in the normal downward movement of sterile air. A particle counter was used to evaluate changes in particle concentrations near a theoretical incision site. No significant differences were found between having the FAW device off, on ambient air or on warm air. All scenarios had particle counts below stringent criteria established in Europe for the evaluation of adequate function of laminar flow in operating rooms.

Moretti et al. evaluated the effect of FAW on air quality during THA procedures with the use of an air-sampling device with agar plates [15]. No differences in bacterial loads were noted at several positions of the surgical field with or without the use of FAW. Memarzadeh et al. reported computational fluid dynamics and particle tracking studies conducted by the National Institutes of Health to assess whether FAW devices lead to contamination of the surgical site [16]. They found no increased squame deposition from potential contaminant sources due to the FAW device in laminar flow theater situations in their models. Zink et al. evaluated air quality in rooms with volunteers lying down covered by surgical drapes with culture plates placed on their abdomen while FAW was turned on for two hours [17]. Results were compared to a two-hour period where the warmer was turned off. No statistically significant difference was identified between the two situations. Shirozu et al. looked at the effect of FAW on airflow in a simulated operative setting with the use of an ultrasonic anemometer, smoke and laser light [18]. The authors found that downward laminar flow efficiently counteracted the upward airflow caused by FAW blankets and concluded that contamination of the surgical field is not likely in the presence of adequate laminar flow. In a study from the veterinarian literature, two groups of surgical patients were compared (one with use of FAW blankets and one without) [19]. Surgical drapes were swabbed and aerobic cultures were obtained. No difference in positive cultures was noted.

Oguz et al. recently conducted a prospective study where orthopaedic patients were randomized to receive either a FAW blanket or a CFW [20]. They performed a multivariate analysis looking at the effect of multiple factors on the number of bacteria in the OR air and on the field as measured by agar plates positioned at different locations in the room, and nitrocellulose plates placed on the instrument table. These factors included the type of warming device in addition to the presence of laminar airflow, the number of operating room personnel and the operative time. While increased surgical time and absence of laminar flow significantly affected bacterial counts, the type of warming device used did not.

Sikka and Prielipp published a focused review of the literature in the Journal of Bone and Joint Surgery and concluded that there is not enough evidence to support or disprove a link between FAW and PJI [21]. They did list recommendations that need to be followed for proper use of the devices including frequent filter changes, calibration and always using the device with the accompanying blanket. Kellam et al. in a comprehensive review for the Association of Perioperative Registered Nurses (AORN) failed to identify conclusive evidence for an increased risk of SSI with the use of FAW and recommended continued use of these devices [22]. Wood et al. conducted a similar review and concluded that FAW does contaminate ultra-clean air in the operating room, but found no definite link to an increased rate of SSIs [23]. They recommended considering alternative warming systems when contamination of the surgical field is deemed to be critical. In a more recent systematic review that encompassed a total of 1,965 patients and 8 studies, Haeberle et al. concluded that there was an absence of evidence to support an increased rate of SSI with the use of FAW blankets [24].

Sandoval et al. compared FAW vs. CFW in its ability to prevent hypothermia in 120 THA and TKA surgeries [25]. There were 60 patients in each group and they concluded that FAW and CFB were equally as effective at maintaining core temperatures during and after surgery. There were no reported SSIs in either group. This study was a quality improvement project and not powered to show a clinically significant difference in infection rates.

In conclusion, the literature is conflicting and there is still a lack of strong evidence linking FAW to increased risk of SSI. In light of this, while we recognize the theoretical risk posed by FAW, we cannot recommend discontinuing the use of these devices at this time. We do, however, recommend following the manufacturer's instructions and frequently changing the filters, making sure the devices are calibrated and most importantly using the devices only with the appropriate perforated blanket. Other alternative warming methods can be used. We recommend a randomized prospective trial to answer the index question, and a pilot is underway. (ISRCTN 74612906)

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QUESTION 3: Does the operating room (OR) temperature affect the rate of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: The OR temperature may affect core body temperature, which could potentially affect the rates of subsequent SSIs/PJIs. Thus, all efforts should be made to maintain an optimal OR temperature.

LEVEL OF EVIDENCE: Consensus

DELEGATE VOTE: Agree: 88%, Disagree: 8%, Abstain: 4% (Super Majority, Strong Consensus)

RATIONALE

Multiple OR varaibles are known to influence the rates of SSIs/PJIs in patients undergoing orthopaedic procedures. Some of the important issues in the OR are the status of the ventilation system, environmental contamination, including air as well as surface contamination in association with humidity, and temperatures that are known factors sustaining microorganism growth. Clinically used ventilation systems are able to reduce the number of colony forming units (CFUs) near the surgical field. However, systems using vertical laminar airflow and those relying on a newly developed temperature-controlled air flow have been shown to achieve better suppression of environmental contamination that is even more efficacious than classical laminar air flow systems.

Recently-published studies have demonstrated correlations between seasonal temperature changes and SSI rates. SSIs peaked during the warmer season and were lowest in the winter and this in itself could include a multitude of additional environmental factors.

The currently-available literature has not established the ideal OR temperature range, but suggests that temperatures around or below 24°C are preferable. In some countries (e.g., Germany), International Organization for Standardization (ISO) norms describe a need to select OR temperatures between 18°C and 24°C. We are not aware of any studies about a lower temperature boundary showing adverse effects concerning wound healing, cardiovascular circulation, etc.

Another factor associated with increased temperatures in the OR setting are the increase in transpiration rates among the OR personnel, specifically the surgeon, who may contaminate the surgical field with sweat.

Everett et al. reported that the incidence of SSIs increased when the ventilation system progressively deteriorated. They found with new improved ventilation systems the infections returned to baseline rates. The control of temperature and humidity is important mainly for the comfort of the OR personnel (low-quality study) [1].

Alfonso-Sanchez et al. conducted a longitudinal prospective study to identify the influence of OR environmental factors on subsequent SSIs. Risk factors related to the OR included the level of fungi and bacterial contamination, temperature and humidity, as well as air renewal and differential air pressure. Patient-related variables assessed included age, sex, comorbidities, nutrition level and transfusion. Other factors were antibiotic prophylaxis, electric versus manual shaving, American Society of Anaesthesiologists physical status classification, type of intervention, duration of the intervention and preoperative stay [2]. Superficial SSIs were most often associated with environmental factors, such as environmental contamination by fungi (from two colony-forming units), by bacteria, as well as surface contamination. The environmental factors studied, including the OR temperatures, were found to influence the rates of subsequent SSIs. For example, when there was no contamination in the OR, no SSIs were detected. Significant risk factors in superficial SSIs were environmental contamination by fungi (≥ 6 CFU/m^3, with a relative risk (RR) of 6.2), bacteria, as well as surface contamination by both fungi and bacteria. Also important were humidity, differential pressure and OR temperatures. The OR temperature was associated with superficial SSIs, but not deep SSIs [2].

Fu Shaw et al. noted that the bacterial colony count increased by 9.4 CFU/m^3 with each additional 1°C rise at room temperature (p = 0.018) [3]. Another study by Alsved et al. compared two commonly-used ventilation systems (vertical laminar airflow (LAF) and turbulent mixed airflow (TMA)) with a newly-developed ventilation technique and temperature-controlled airflow (TAF), measuring CFU concentrations at three OR locations. They also evaluated comfort on the operating team. The study found that only LAF and TAF resulted in less than 10 CFU/mL at all measurement locations in the room during surgery. Median values of cfu/m^3 close to the wound (250 samples) were 0 for LAF, 1 for TAF and 10 for TMA. Peripherally in the room, the CFU concentrations were lowest for TAF. The CFU concentrations did not scale proportionally with airflow rates. Compared with LAF, the power consumption of TAF was 28% lower and there was significantly less disturbance from noise and draught. [4].

Anthony et al. analyzed 760,283 procedures (total knee arthroplasty (TKA) 424,104, total hip arthroplasty (THA) 336,179) for the influence of seasonal temperatures on SSIs. Their models indicate that SSI risks were highest for patients discharged in June, and lowest for those discharged December. For TKA, the odds of 30-day readmission for SSIs were 30.5% higher at the peak compared to the nadir time (95% confidence interval (CI) 20 to 42). For THA, the seasonal increase in SSIs was 19% (95% CI 9 to 30). (High-quality study) [5].

Another study by Anthony et al. described a highly seasonal variability of SSI, with the highest SSI incidence in August and the lowest in January. During the study period, there were 26.5% more cases in August than in January (95% CI, 23.3 to 29.7). Controlling for demographic and hospital-level characteristics, the odds of a primary SSI readmission increased by roughly 2.1% per 2.8°C (5°F) increase in the average monthly temperature. Specifically, the highest temperature group (> 32.2°C [> 90°F]) was associated with an increase in the odds for an SSI readmission by 28.9% (95% CI, 20.2 to 38.3) compared to lower temperatures (< 4.4°C [< 40°F]) (moderate-quality study) [6].

Mills et al. concluded that the sweating surgeon may most likely contaminate the surgical field as a result of elevated OR temperatures [7].

Based on the available evidence, it appears that OR tempreature is an important enviromental factor that needs to be optimally controlled during surgical procedures. There is an indirect link between the OR temperatures and the potential for subsequent SSIs/PJIs.

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QUESTION 4: Does perioperative normothermia affect the rate of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: Based on data from general surgery and other surgical disciplines, normothermia has been found to be an important factor during the perioperative period, in order to minimize the risks of subsequent infections. Although evidence in orthopaedic surgery is sparse, we recommend that normothermia also be maintained in patients undergoing orthopaedic procedures.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 97%, Disagree: 1%, Abstain: 2% (Unanimous, Strongest Consensus)

RATIONALE

Medications used during general anesthesia, such as inhaled and intravenous agents as well as opioids, alter the ability for the body to thermoregulate which may result in hypothermia [1]. Hypothermia can also result from the use of neuraxial anesthesia, except with peripheral nerve blocks [1]. Several animal studies have demonstrated that intraoperative hypothermia may decrease resistance to some pathogens, such as *Escherichia coli* (*E. coli*) and *Staphylococcus aureus* [2,3]. Hypothermia and secondary vasoconstriction may also lead to reduced oxygen delivery to tissues, increasing the risks of infectious complications [4–6]. Several well-designed studies have attributed a substantial decrease in SSI rates in colorectal and non-orthopaedic clean surgeries with normothermia [5,6]. Therefore, current guidelines from the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) recommend maintaining perioperative normothermia to reduce the risk of SSIs and other complications associated with surgery [7,8]. However, there is a paucity of published literature regarding normothermia in orthopaedic procedures.

In a recent observational study evaluating the role of hypothermia in hip fractures, the incidence of perioperative hypothermia was 17%. After multivariate logistic regression analysis, hypothermia was associated with increased risk of periprosthetic joint infection (PJI) (odds ratio (OR): 3.30, 95% confidence interval (CI) 1.19 to 9.14, p = .022) [9]. In contrast, from another observational study evaluating total hip and knee arthroplasties, no statistically significant associations were found between hypothermia and PJIs or SSIs in univariate analysis [10]. Observational studies [10–13] have associated hypothermia with increased blood loss and transfusion rates, which may subsequently lead to increased risks for PJIs or SSIs. However, there are no randomized controlled trials (RCTs) that support nor discourage normothermia in total joint arthroplasty (TJA) or other orthopaedic procedures in relation to SSIs or PJIs.

There are several RCTs that have been performed outside of orthopaedics, which support the use of warming devices in the operating room and during the surgical procedure for the purposes of reducing SSIs [5,6]. Kurz et al. evaluated the importance of maintaining perioperative normothermia with additional warming in major colorectal surgery patients [5]. The mean final intraoperative core temperature was higher in those with additional warming compared with those without (36.6 vs. 34.7 ^{o}C, p < 0.001). Patients assigned to additional warming demonstrated a significant decrease in SSI rates by receiving forced-air warming blankets combined with fluid warming (6 vs. 19%, p = 0.009). In another RCT, Melling et al. evaluated patients undergoing non-orthopaedic clean surgeries and identified a substantial role of pre-warming in preventing SSI [6]. They showed that warming the patient for at least 30 minutes before surgery led to a reduction in infection rate from 14 to 5% (p = 0.001) [6].

The safest and most effective mode of maintaining intraoperative normothermia remains unknown. Some recent studies have raised potential issues with the use of forced-air warming systems that may disrupt the laminar airflow (LAF) in operating rooms and increase risks for SSIs [14–16]. But, from a recent experimental study, disruption of airflow produced by forced-air warming was well-counteracted by downward LAF from the ceiling [17]. There are no studies which provide high-level evidence that warming systems may increase infection rates.

In summary, achieving normothermia by using warming devices in the operating room and during the surgical procedure seems to play an important role in decreasing the risks of subsequent infections. However, this evidence mainly derives from non-orthopaedic literature. Further research is needed to establish correlation between patient's temperature and SSIs in the field of orthopaedic surgery, including TJAs.

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QUESTION 5: Is there a relationship between levels of airborne microorganisms in the operating room (OR) and the risk of periprosthetic joint infections (PJIs)?

RECOMMENDATION: Yes. High-quality evidence indicates that there is a proportional relationship between intraoperative levels of airborne microorganisms (colony-forming units or CFUs) and the incidence of PJIs.

LEVEL OF EVIDENCE: Strong

DELEGATE VOTE: Agree: 98%, Disagree: 1%, Abstain: 1% (Unanimous, Strongest Consensus)

RATIONALE

A comprehensive search was performed utilizing PubMed and Google Scholar with the keywords: operating room air, airborne microorganisms, implant, infection, surgical site infection, Charnley and Lidwell. A total of 248 potentially-relevant articles were identified and reviewed. After screening for relevance to the topic of airborne microorganisms and PJI, 34 articles were selected for analysis. Of these, to the best of our knowledge, only five studies that adequately compare airborne CFU levels during actual surgical operations and the incidence of SSI have been published [1–5].

Four of these five level of evidence I studies demonstrate statistically significant correlations between levels of airborne CFUs (measured either by active air sampling at or near the incision site or by wound washout) and the incidences of PJIs [1–4]. The fifth study compared airborne CFUs and postoperative infections in three ORs with conventional ventilation to the data obtained in one-zoned, exponential laminar airflow (LAF) OR, and found no difference in the incidence of PJIs [5]. However, the study also found no difference in airborne CFU present in the LAF OR and the conventionally-ventilated rooms, which is consistent with the hypothesis that PJIs are correlated to the level of airborne CFUs in ORs.

One study retrospectively performed a multivariable regression analysis of data from a large prospective UK study, and concluded that prophylactic antibiotics were effective at reducing the incidences of PJIs. However, the group also found that this variable was independent of the presence of ultra-clean air, suggesting that the two modalities are multiplicative [6]. The conclusions of this study must be weighed against the facts that antibiotic prophylaxis was not controlled during the main study and perioperative antibiotic use varied widely.

The literature review demonstrated common characteristics that limited their clinical relevance. The use of the term “laminar flow” to describe air patterns in the OR and equating this term with “ultraclean” air is potentially misleading. There are a host of variables in a busy OR that can disrupt laminar flow, and there are many different manufacturers and types of “laminar flow” configurations. Examples include, rising thermal plumes caused by heat from operating room lights, opening of doors which causes positively-pressurized air to escape into hallways thereby shifting air currents and turbulence created when air passes overhead surgery lights and the torsos of the surgical staff [7–9]. It is therefore, important to assess the ability of ORs labelled as “laminar flow” to actually provide a reduction of airborne CFUs, compared to conventionally-ventilated operating rooms. For example, one study of 3,175 hip and knee arthroplasties using a “horizontal unidirectional filtered air-flow system,” reported mixed infection reduction results, but no airborne CFU data was obtained, perhaps because it was assumed that the “laminar flow” rooms provided clean air [10]. Other studies suffered the same issue of not reporting airborne CFUs together with infection data [11–12].

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QUESTION 6: What method(s) are available to verify the microbiological cleanliness of the operating room (OR)?

RECOMMENDATION: Multiple options are available to verify the microbiological cleanliness of the OR, including visual inspection, swab and culture, contact culture plates, as well as Adenosine Triphosphate (ATP) bioluminescence.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 96%, Disagree: 1%, Abstain: 3% (Unanimous, Strongest Consensus)

RATIONALE

We are continuously striving to minimize periprosthetic joint infections (PJIs) due to their association with higher morbidity and mortality [1–3].

The original standard for determining cleanliness within hospitals was visual inspection until multiple studies proved it inferior to newer, more quantitative methods [4–9]. The major drawbacks to visual inspection include, the subjectivity of the analysis, that it cannot provide any information as to what microbes are on the surfaces, and the qualitative nature, which has consistently been shown to be less sensitive than other evaluation methods [4–9].

In order to standardize monitoring of microbial cleanliness in the OR, cultures via swabs or contact plates that determine the colony forming units (CFUs) were introduced as an objective measure, with particular attention paid to high-touch surfaces [6,10–16]. Cultures utilizing aerobic colony counts (ACC), with or without bacterial specific growth parameters, provide a general overview of the microbial burden in the OR [10,11,17]. It is generally accepted that cultures < 2.5 CFU per cm^2 are considered clean and anything greater, considered contaminated [5,6,10,11,15,17,18]. The limitations of this method include, the length of time it takes to achieve results by culture (generally at least 24 hours for pure CFU counts and 48 hours for bacterial speciation), limitations in the ability to culture certain bacteria and that it cannot account for other bioburden contaminating surfaces such as body fluids, blood and saliva.

ATP bioluminescence is a technology that has long been used in the food industry to monitor cleanliness and has recently been introduced in the OR [19–21]. The amount of ATP produced by live cells is measured in relative light units (RLUs) with standards set by the manufacturer. There is currently no agreed-upon standard RLU value to be used as a benchmark for signaling clean versus contaminated. Most of the studies to date use a value of 250 to 500 RLUs as the benchmark for cleanliness [6,7,13,17,22–24]. While conflicting evidence exists attempting to correlate ATP with CFU counts [6,7,9,13,16,17,22–24], more stringent comparative studies with outcomes are needed to determine the benchmark RLU values that decrease the risk of PJIs. This method is rapid and allows for assessments of the overall bioburden in the OR, including body fluids [13–15,22–24]. The limitations of ATP are the cost and inability to determine what specific pathogen is contaminating the OR when high readings occur [9].

With the limited literature available, we extrapolate that use of ATP bioluminescence provides the greatest utility as a fast feedback method to monitor the cleanliness of the OR on a regular basis. We recommend using a value of 250 RLUs as the benchmark value for contamination. Furthermore, surfaces that consistently provide high readings of the ATP meter can be swabbed and cultured for CFU counts (> 2.5 CFU/cm^2 considered contaminated) and microbiological speciation.

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QUESTION 7: Does the use of ultraviolet (UV) light decontamination in the operating room (OR) reduce the risk of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs) in patients undergoing orthopaedic procedures?

RECOMMENDATION: Yes, the use of UV lights during surgery are effective against airborne bacteria. However, due to the potential risks to the OR personnel, it is recommended that UV light only be used at unoccupied times for terminal cleaning of the room.

LEVEL OF EVIDENCE: Moderate

DELEGATE VOTE: Agree: 91%, Disagree: 4%, Abstain: 5% (Super Majority, Strong Consensus)

RATIONALE

The source of a large portion of the microorganisms responsible for PJIs are the airborne microorganisms in the OR [1]. The room traffic, door status and number of people in the room are the basic indicators of the quantity of airborne colony-forming units (CFUs) [2]. To reduce the number of airborne CFUs in the OR during surgery, techniques are applied such as surgical gowning with air outlets, the use of laminar airflow, a reduction in room traffic and the application of UV lights [2,4–7].

The efficacy of techniques designed to remove airborne bacteria from the OR is supported by current randomized controlled trials (RCTs) studies [1]. In the OR, a concentration of 10 m^{-3} or less airborne bacteria is defined as ultraclean air [2]. UV light at specific wavelengths breaks the molecular bonds in the DNA, thereby eliminating microorganisms that may cause subsequent infections. Since the first application, a relationship has been shown between different UV wavelengths and a decrease in infection rates with a reduction in CFUs or the obtaining of ultraclean air [3–5]. The first data related to the use of UV light during surgical procedures was from Duke University. With the use of UV light in all types of surgery in 1936, the infection rates and infection-related mortality rates decreased from 11.3 and 1.3% pre-1936 to 0.24 and 0% in 1960, respectively [6]. In a 1980 study, the rate of PJI following hip arthroplasty was reduced from 3.1 to 0.53% with the use of UV light [7].

In a randomized study of 30 hip arthroplasties performed by Carlsson in 1986, the use of UV lights in the OR were shown to significantly reduce the number of CFUs, both in the wound area and in the periphery of the room, as determined by volumetric air samples [8]. Another pioneering study in this field was conducted by the same team in 1989 [9]. The combined method of occlusive staff clothing and UV radiation was used and the air samples from 20 cases of hip arthroplasty were all reported as < 10CFU/m^3, which is the limit for “ultraclean air” (median 2.6, range 1.1 to 7.1).

In 1991, Berg et al. reported that UV lights were more effective than the ultraclean air enclosure method and applications of UV combined with occlusive clothing reduced infection [10]. Taylor et al. conducted a similar cohort study in 1995, in which different doses of UV lights were compared with laminar flow and conventional ventilation. Again, results favorable to UV lights were obtained [5]. Berg-Perier et al. compared the UV light method with the Charnley-Howorth ultraclean air enclosure in an economic, comfort and safety analysis and presented data that UV light was superior in respect to cost, comfort and safety when sufficient protection was provided [11].

One of the most important studies conducted was by Ritter et al. In their retrospective cohort study published in 2005, the infection rates of 5,980 joint arthroplasties were examined [12]. It was shown that the infection rate of 1.77% with the laminar flow before the application of UV light had decreased to 0.57% after the use of UV light without laminar flow ($p < 0.0001$).

Although several studies support the efficacy of the use of UV lights against airborne bacteria during orthopaedic surgical procedures, because of the potential side-effects on OR staff, this application has been restricted by the guidelines, and there are even recommendations that it should not be used [13,14].

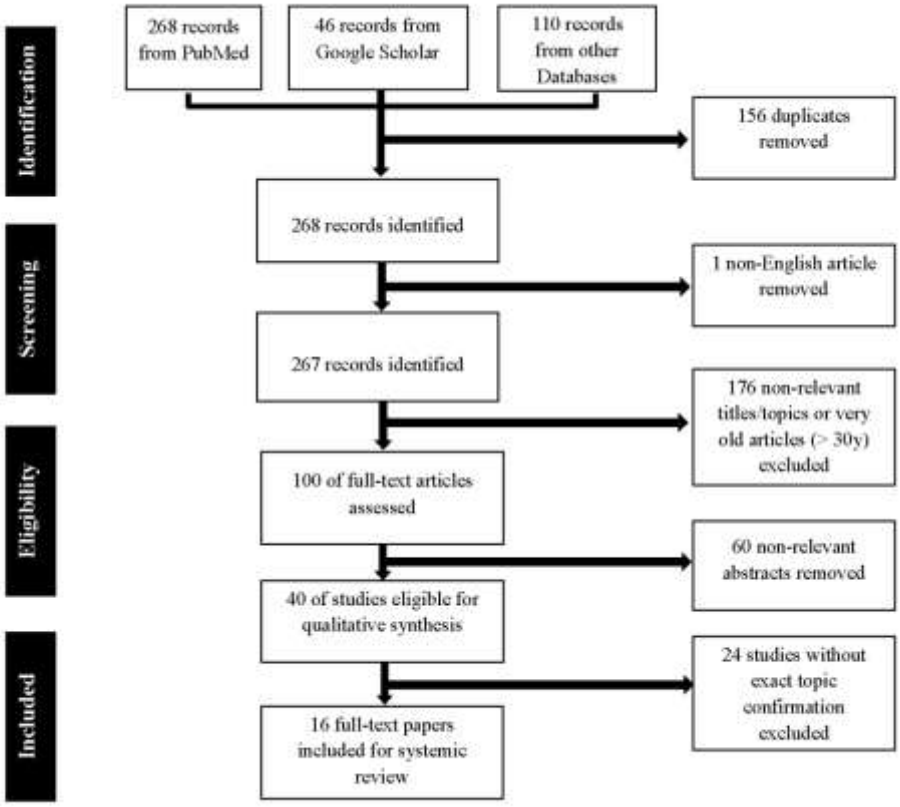

FIGURE 1. PRISMA Flowchart showing the identification of relevant studies during the review process.

There is no current data available related to the possible reduction of the use of UV lights during surgery in accordance with the guidelines and reported side-effects. New designs have been developed which could increase the safety of OR staff and provide maximum air disinfection effectiveness. However, there are no publications of the clinical efficacy of these new designs in respect to both of these aspects [15]. Possibly the most important area that could benefit from the germicidal effectiveness of UV light decontamination is terminal room cleaning of the OR or hospital rooms at unoccupied times.

The Tru-D (Tru-D Smart UVC, Memphis, Tennessee, USA) room disinfection device is a mobile, automated room disinfection device that uses UV-C irradiation to kill microorganisms. In an Mahida et al., the efficacy of the Tru-D device was evaluated in the terminal cleaning of patient rooms and the OR. It was reported that the mean $\log^{10}$ reductions for artificially seeded methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *enterococci* (VRE) were between three and four when used at 22,000 mWs/cm^2 reflected dose [16]. Similarly, through evaluation of logarithmic reductions, several studies have shown the effectiveness of UV devices in the inactivation of microbes seeded on various test surfaces placed in occupied hospital rooms [17–22]. Several clinical trials have also measured the effectiveness of UV devices in terminal room cleaning and have shown statistically significant reductions in the rates of healthcare-associated infections (HAIs) [23–26]. The only randomized, controlled study in this area, is a multi-center study by Anderson et al. that included nine hospitals. The terminal room cleaning method using the Tru-D device was utilized in two of four control groups formed of different combinations. The use of advanced room cleaning strategies, such as a UV device, was shown to reduce HAIs in every 10,000 cases from 51.3 to 33.9 ($p = 0.0369$) [27].

Furthermore, Fornwalt et al. reported on the efficacy of pulsed xenon ultraviolet lights on SSIs in patients undergoing total joint procedures in 2016 [28]. They found a significant reduction to zero infections after 12 months of surgery by renovating their orthopaedic surgery wing and by implementing new stringent procedures and pulsed xenon (PX)-UV decontamination before surgery.

Based on the overall evidence compiled (Fig. 1), despite the efficacy of UV light during surgery against airborne bacteria, its use is not justified due to the risks that could be created for operating room staff. However, evidence exists supporting the use of UV lights for the terminal cleaning of rooms at unoccupied times.

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QUESTION 8: Are light handles a source of contamination during orthopaedic procedures?

RECOMMENDATION: Yes. Light handles are a possible source of contamination during orthopaedic procedures.

LEVEL OF EVIDENCE: Moderate

DELEGATE VOTE: Agree: 96%, Disagree: 3%, Abstain: 1% (Unanimous, Strongest Consensus)

RATIONALE

Periprosthetic joint infections (PJIs) are a morbid complication following total joint arthroplasty, with increased mortality at one year [1]. Since the recurrence rate after treatment of PJI at five-year follow-up can reach up to 60% [2], prevention in the perioperative phase is essential. Despite several behavioral and technological developments, bacteria cannot be fully eliminated from an operating room (OR) [3]. Therefore it is very important to examine and identify all possible surfaces in the OR, such as light handles, that could provide an optimal medium for bacterial growth.

A paper presented at the American Academy of Surgeons in 2017 showed that placement of surgical light handles produced moderate particle contamination of the sterile field. A study by Davis et al. concluded that 14.5% of light handles were contaminated during primary hip and knee arthroplasties. Follow-up of a minimum of two years revealed one deep infection in the cohort, however, the organism was not identified as a contaminant [4]. Knobben et al. studied the transfer of *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Cutibacterium acnes* (formerly *Propionibacterium acnes*) from one OR material (gloves, orthopaedic drills, theater gowns and light handles) to another. Transfer was demonstrated with all bacterial strains and with every material ranging from 17 to 71% [5]. In contrast, a study by Hussein et al. examined OR contamination by culturing bacterial swabs taken from light handles before and after 15 total hip and knee arthroplasties. They found no aerobic bacterial contamination after 48 hours of culture on either the surgical gloves or the light handles [6].

A randomized clinical trial by Schweitzer et al. screened 36 light handles in hip arthroplasty for bacterial contamination using two different culture methods, including one with high sensitivity. Positive cultures were found in 50% of the light handles [7]. In a more recent study by Richard et al., a novel method, utilizing adenosine triphosphate bioluminescence technology, was applied to detect the degree of contamination within the sterile OR environment. They concluded that several surfaces, including light handles, had significant bioburdens [8]. This study demonstrated that bioburden can lead to contaminated OR surfaces, and therefore, increase the risks of postoperative orthopaedic infections [8]. The International Consensus Meeting on

Periprosthetic Joint Infection and a meta-analysis by Ratto et al. concluded that light handles can be a potential source of contamination and surgeons must minimize their contact with them as much as possible [9,10].

Despite the fact that one study did not find any contamination, several observational studies have identified positive bacterial cultures on light handles utilizing different techniques, with varying sensitivity. We infer that light handles are a possible source of contamination during orthopaedic procedures. However, there is no supporting evidence or prognostic studies that have linked the contamination on the light handles to patients developing subsequent PJIs with the same source contaminant. We do advise surgeons, as a precautionary measure, to minimize contact with the light handles by utilizing their staff to move the lights during the procedure. If contact with the lights is necessary, we also recommend changing gloves in order to limit contamination to the operative field.

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QUESTION 9: Is there a role for banning all handheld devices/mobile phones in the operating room (OR)?

RECOMMENDATION: Given a lack of evidence correlating increased infection rates/adverse outcomes with the use of handheld devices in the OR, a recommendation to ban these devices in the OR cannot be made at this time. However, regular cleansing of cell phones is an easy and effective practice and should be performed routinely.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 87%, Disagree: 8%, Abstain: 5% (Super Majority, Strong Consensus)

RATIONALE

Non-medical electronic equipment, such as cell phones, personal digital assistants and wireless media tablets (e.g., mobile handheld devices) have become increasingly integrated into the practice of healthcare workers [1,2]. Previous studies have shown that 33 to 88% of surveyed healthcare workers admit to using cell phones in ORs [1,3,4]. Sergeeva et al. found that mobile devices allow easy information access, e-learning and work-related communication [5]. The potential for these devices to be a source of distraction from the work environment [5], as well as be a nidus for contamination, warrant further examination into whether or not handheld devices/mobile phones should be permitted from the OR.

Phone calls were found to be one of the most frequent distractions in the OR [6–8]. Avidan et al. found that cell phone calls caused short-lived disturbances to the operating surgeons [9]. Murji et al. identified that pager distractions hindered the ability to successfully complete the surgical task in the allotted time and the majority of residents made at least one unsafe clinical decision during the distracted phase [10]. In addition, it has been suggested that ringing telephones are among the major sources of unnecessary noises in the OR [11]. In the study performed in a tertiary care hospital in China, the noise level in the ORs ranged between 59.2 and 72.3 dB, with 100% of the measurements exceeding the recommended hospital noise standards [12].

Excessive noise may have negative effects on patient care and safety. Kurmann et al. showed that ORs with a high noise level also experienced higher surgical site infection (SSI) rates [13]. Simulation-based experiments have identified that noise during surgery can increase feelings of stress, as measured by perceived task load and fatigue levels, [14] cause a decrease in auditory processing function leading to possible miscommunication [15,16] and may impair the ability to accurately monitor pulse oximeter auditory displays [17]. Staff member education on noise reduction strategies (including avoiding conversations on the telephone) have helped to substantially reduce the noise level during the OR procedures [11].

The risk of handheld devices contributing to possible bacterial cross-contamination in the OR must also be discussed. Numerous studies have documented the bacterial contamination of the mobile phones of the healthcare workers [18]. The bacteria species most frequently isolated from the cell-phones (such as coagulase-negative staphylococci and *Staphylococcus aureus*) are known to commonly cause periprosthetic joint infections [1,3,4,18,19]. Genetically identical isolates have been detected from mobile phones and palms and fingers or nares of their users [19,20]. However, it is

unknown whether there is a correlation of handheld device contamination with SSI rates, and/or microorganisms causing these infections. In the studies performed in ORs, the mobile phone contamination rate with possible clinical pathogens varied from 0 to 83% [1,3,4,19]. The reason for the large variation of contamination rate may be due to the sampling from different types of handheld devices, different sampling methods, different sampling place and whether coagulase-negative staphylococci have been counted as pathogenic [4,19].

Touchscreen mobile devices have been associated with lower rates of bacterial contamination when compared with traditional keypad alternatives [21]. Shakir et al. reported lower bacterial loads on cell phones with a screen protector [3]. Nevertheless, these devices also need to be regularly decontaminated with approved disinfectant that will not cause damage to the phone [2]. Standardized decontamination protocol significantly reduced bacterial load on the phone [3,4]. In the study by Shakir et al., the contamination rates increased from 8% after disinfection to 75% one week after decontamination, arguing for regular cleaning (several times a week) [3]. The risks of the handheld devices contributing to bacterial cross contamination can be reduced by appropriate hand hygiene. Mark et al. speculated that the higher hand hygiene compliance rates (97%) in their unit could be the reason for lower mobile phone contamination rate [1]. Staff education is essential as the studies indicate that most of the health care workers do not regularly clean their devices or perform hand hygiene before or after use [1–4].

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