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Current Evidence for the Use of Laminar Flow in Reducing Infection Rates in Total Joint Arthroplasty

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Abstract: Since the introduction of laminar air flow in orthopaedic theatres by Sir John Charnley, it has widely become accepted as the standard during orthopaedic procedures such as joint arthroplasty. We present a review of available current literature for the use of laminar flow operating theatre ventilation during total joint arthroplasty and examines the effectiveness of laminar flow ventilated operating theatres in preventing post-operative wound infection. Results of our findings suggest that while bacterial and air particulate is reduced by laminar air flow systems, there is no conclusive effect on the reduction of post-operative wound infections following total joint arthroplasty. We conclude that a combination of strict aseptic technique, prophylactic antibiotics and good anaesthetic control during surgery remains crucial to reduce post-operative surgical infections.

Keywords: Arthroplasty, evidence, infection, laminar flow.

INTRODUCTION

Joint infection post total joint arthroplasty is a rare but costly and devastating occurrence. Laminar flow ventilation systems were pioneered by Sir John Charnley in the 1960's and 70's resulting, when used in conjunction with other strategies to reduce sepsis, in a reported marked decline in post-operative wound infection. The practice became widely adopted in orthopaedic theatres after a series of trials [1] that showed a significant decrease in infections from laminar flow theatres. However in this study it was not possible to discern whether the reduction in post-operative infection was due to the type of air circulation used or prophylactic antibiotics which also had been recently introduced. Despite the emerging evidence questioning the utility of laminar flow theatres the royal college of anaesthetists still recommends that all joint replacement will be carried out in a laminar flow theatre.

Ventilator systems are thought to reduce airbourne (bacterial) contamination through production of a positive air pressure which displaces contaminated air away from the operational site [2]. Ventilatory systems operate by taking air in at *roof level* of the theatre suite *via* a series of *fans*, where they remove bacterial particles. The most commonly used are 'High-efficiency particulate air (HEPA) filters. Three types of ventilator systems are available; plenum, laminar flow and ex-flow system (Howarth enclosure). We shall briefly discuss the plenum and ex-flow systems; the laminar flow system will be discussed in more detail thereafter.

PLENUM

This system relies on pressure being greater inside theatre than outside. Provision of clean air is *via* wall/ceiling diffusers and let out of vents above floor level. However, air may pass out of other openings such as doors. This system, therefore, is less reliable in maintaining an aseptic environment through opening of doors of movement of personnel in and out of theatre.

EX-FLOW (EXPONENTIAL) SYSTEM

First described in 1980 by Howorth; this system allows a flow of clean air from the operating theatre in the shape of an inverted trumpet, with air moving down and outwards. With this system, peripheral entrainment cannot occur (as in vertical laminar flow systems - *reviewed later*), resulting in fewer changes of air per hour.

LAMINAR FLOW

This is described as an entire body of air within a designated space *(theatre suite)* moving with uniform velocity in a single direction along parallel flow lines. True laminar flow is only achieved when approximately 100% HEPA filter coverage occurs. Laminar flow ventilation comprises a continuous flow of highly filtered ultraclean air (UCA) of less than 10 colony-forming units per metre cubed (cfu/m3) of bacteria. This is re-circulated under positive pressure into the operating theatre with surgically generated contaminants being continuously removed [3].

Laminar flow theatres aim to reduce the number of infective organisms in the theatre air by generating a continuous flow of bacteria free air. In laminar flow theatres air may be 'changed' in theatre more than 300 times per hour compared to standard positive pressure theatre rates of 15-25 air changes per hour. Laminar flow systems are also capable of generation levels of colony forming units in the atmosphere below $10 CFU/m^3$. The number of particles in the theatre air is also lower than in turbulent systems.

Laminar flow systems operate either by a horizontal or vertical system. In horizontal Laminar flow systems, high

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efficiency particulate air filters are installed on the totality or part of one of the operating theatre walls. Such a system is easier to install especially in existing theatres but requires correct positioning of the operating team in order to be effective. The vertical configuration involves ceiling mounted HEPA filters which direct air vertically downwards into the operative field individuals at the periphery of the air flow may prove disruptive but it is less dependent on scrub team positioning. Entrainment of flow can, however occur from theatre personnel moving with the periphery of the laminar flow area, deflecting contamination inwards towards the operative site.

Both systems can be used with exhaust suits, also known as 'space suits' to further improve air quality but a discussion of their effectiveness is beyond the scope of this review. Either system works to create a unidirectional flow of air free of eddies and turbulence. Thus material shed by the surgeon and assistant(s) during the operation is directed outwards and away from the wound site preventing, in theory, bacteria from such material landing on and infecting the wound. Reducing the risk of infection and sparing the patient from the associated morbidity and mortality and the hospital from the associated cost which can be up to four times that of the original procedure [4].

CLINICAL EVIDENCE FOR LAMINAR FLOW

Various studies have shown that laminar flow theatres have greatly reduced levels of particles and bacteria in theatre air compared to turbulent systems [5]. There surely exists a relationship between theatre air quality and post-op infection but it may be the case as Holton & Ridgeway have argued that once a certain level of air quality is achieved any further reductions in infection rates will be due to quality of aseptic technique [6]. It is therefore important that we look to assess the value of laminar airflow ventilation in terms of patient benefit post procedure rather than purely in terms of air quality.

Lidwell's prospective multicentre randomised control trial in 1982 [1] involved sites both in the United Kingdom and Sweden and an excess of 8,000 patients undergoing knee or hip replacement surgery. All patients were then followed up for between 2 to 3 years for evidence of joint sepsis. Overall, Lidwell found that the incidence of sepsis in the laminar air flow group was markedly reduced compared to the control group (0.6% compared to 1.5%). The incidence of sepsis was found to be further reduced when both an ultraclean environment and body exhaust suits were used.

Lidwell's study did not control for the use of antibiotic prophylaxis and its use in the various institutions in the study was widely variable. Lidwell estimated that a patient who did not receive prophylactic antibiotics was four times more likely to suffer from post-operative wound sepsis. Lidwell *et al.* concluded from the results of their trial that vertical laminar flow systems were superior to horizontal flow systems, and indeed turbulent air systems, with vertical laminar flow systems and exhaust suits being the most desirable set up to reduce post-operative wound sepsis.

Subsequent trials in comparison [7, 8] with better use of prophylactic antibiotic control did not demonstrate a significant difference in infection rates (traditional ventilation and Laminar flow), thus implying the use of prophylactic antibiotics as the single most prognostic factor in preventing infection after joint replacement [3].

In a paper examining the move of the Canisius Wilhelmina Ziekenhuis teaching hospital from its old site built in 1926 to a new facility built in 1992, the impact on post-operative infection rates that resulted from the move into modern laminar flow theatres was documented [9]. The authors found no change in the number of deep infections in joint replacement surgery after the move to modern facilities. Results for other forms of surgery were also included but again showed no difference in infection rates. Before and after the move to more modern facilities antibiotic prophylaxis was used where accepted and orthopaedic procedures were carried out in the theatres with the best ventilation at the old site.

The re-operation rates of 435 patients undergoing an Austin Moore Hemi arthroplasty in both laminar airflow and turbulent airflow theatres in a district general hospital highlighted important points [10]. The study followed earlier work in which the authors noticed that their total reoperation rate for Austin Moore prostheses and their reoperation rate due to infection were higher than reported in the literature (11.4% and 4.5% respectively). In both cases prophylactic antibiotics and water impervious surgical gowns were used and cases were followed up for a minimum of 1 year and a maximum of 5 years. They found a statistically significant (p value = 0.00368) difference in the number of re-operations required due to post-operative sepsis in those patients who had been in non-laminar flow theatres (4% or 9/223) compared to those in laminar flow theatres (0% 0/212). While at the same time there was no statistically significant difference in rate of required re-operation due to non-infective factors (aseptic loosening and dislocation). Such a study would suggest that laminar flow systems are of significant benefit in joint replacement. However as already discussed the efficiency of laminar airflow systems is heavily based on both local theatre conditions and the positions and behaviour of the scrub team. Behaviour which may have been tightly controlled after the previous study indicated higher than expected infection rates although this does not explain the difference between the turbulent and laminar flow theatres. This was a small study carried out in a single hospital and while it provides encouraging evidence for the use of laminar flow theatres two recent studies examining the use of laminar flow theatres in joint replacement have examined data from much large number of cases and call into question the value of laminar flow ventilation.

A retrospective study performed in 2008 of the German nation nosocomial infections surveillance system, 'KISS' (Krankenhaus [hospital] infections surveillance system) using data provided by surgical departments of 99,230 operations carried out between 2000 and 2004 in 20 hospitals, compared the rates of surgical site infections in theatres with high efficiency particulate air filtered (vertical) laminar flow, HEPA turbulent air filtration and those without artificial filtration [11]. The study was not specifically focused on orthopaedic procedures but it does provide data on the insertion of both hip and knee prosthesis. The study found that in the case of hip prosthesis theatres with vertical

laminar flow devices there was a statistically significant increase in the number of surgical site infections compared to procedures carried out in turbulent air flow theatres (1.85% compared to 1.31% with a p value less than 0.001). There was also an increase in the number of surgical site infections in laminar flow theatres inserting knee prostheses but this was not a statistically significant change (1.33% compared to 0.823% in turbulent air flow theatres). The detrimental effect of laminar flow theatres remained even after controlling for confounding factors such as both hospital and patient indicators of case severity. Due to the nature of the data collected it was not possible to ascertain whether or not prophylactic antibiotics were used. However as the authors point out the practice of using prophylactic antibiotics for such procedures is widespread with above 98% of patients undergoing the procedures examined receiving them. Therefore it is unlikely that these results can be explained by differences in prophylactic antibody prescribing. While the age, gender and ASA score of the patient were also reported by the survey other possible risks for surgical site infection such as obesity and smoking habits were not.

A more recently published paper [12] using retrospective data from between the years 1999 and 2008 and 88,311 cases recorded on the New Zealand joint registry (51,485 primary total hip replacements and 36,826 primary total knee replacements). The joint registry collects information on all revisions performed as well as the reasons they were undertaken it also documents whether the initial procedure was undertaken in a laminar flow theatre as well as if space suits were used. The study provided more evidence that laminar flow theatres may indeed have a detrimental effect on post-operative infection rates. The paper compared rates of early revision (defined as within 6 months of the original procedure) for deep infection in both total hip and knee replacements preformed in laminar flow theatres or not and in space suits or not. Like the study of German hospitals the New Zealand paper found statistically significant increased rates of required revision needed in the laminar flow cases. However unlike the German study there was significance in both the total hip and knee replacements. With total hip replacements performed in a laminar flow theatre needing revision 0.148% of the times compared with a rate of 0.061% of those performed in a turbulent airflow theatre (p value <0.003). Similar results were seen in total knee replacements with 0.243% of those in a laminar flow theatre requiring early revision compared to 0.098% in a turbulent air flow theatre (p value <0.001). The study was also able to compare the rate of revisions in surgeons who had more than 50 operations in both environments of which there were 43. Of those surgeons there was a 0.110% rate of infection in the laminar flow theatre compared with a 0.028% in the conventional theatre (p value <0.03). The study also showed an increase in infection in operations that used space suits over those that don't despite the fact that space suits have been proven to reduce the bacterial burden in the operating theatre air much like laminar flow systems.

McGovern *et al.* (2011) [13] looked at the effects of forced-air warming and theatre lighting on laminar flow using helium soap bubbles. They demonstrated that forced air warming resulted in contamination depending on the height of the anaesthetic screen, and recommend using conductive warming. They also demonstrated turbulent air circulation under the shadow of lights.

DISCUSSION

Total joint replacement is an increasingly successful operation with more procedures being performed than ever before [14-18]. If laminar flow theatres had an impact in lowering the rate of sepsis after joint replacement an argument could be made that even if the reduction in risk was only slight the cost would be justified due to the devastating consequences it could prevent, especially as the cost of laminar flow systems continues to fall. However from recent large studies there seems to be a detrimental impact from the use of laminar flow ventilation systems which runs contrary to the established evidence on their reduction in bacterial contamination of operating room air.

What could explain the seemingly detrimental effect of laminar flow ventilation seen in both the German and New Zealand studies? It is known that laminar flow systems are highly dependent on local conditions such as movement of theatre staff and equipment. There is also evidence suggesting that this may be related to patient warming blankets and theatre lighting. Such factors may have caused the laminar flow systems to not work as expected and explain the finding of Kakwani's study. However, the sheer number of cases reviewed by the German and New Zealand studies would seem to reduce the impact caused by local behaviour.

Vertical laminar flow systems direct air from ceiling to floor. The flow passing over the head and upper body of the surgeon and assistants, to areas not covered by traditional caps and masks e.g. the ears that are the greatest source of shedding. We might conclude therefore that vertical laminar flow systems direct this shedding directly into the wound unlike turbulent airflow systems. However, the review of the New Zealand joint registry found that even with the use of space suits which would eliminate such shedding the rates early revision in laminar flow theatres remained higher than in theatres using turbulent air ventilation. The study did report that surgeons felt that space suits provided a false sense of security leading to contamination and posit the possibility that the exhaust from the suits may contribute to wound contamination, but neither hypothesis was tested by the study. Air used in theatre ventilation maybe cooled for the comfort of staff under theatre lights and gowns. Cool air combined with airflow directly onto the wound site may also cause local hypothermia which is a known risk factor for the development of a surgical site infection.

It is also possible that the laminar flow areas were not large enough on average in the New Zealand or German theatres surveyed. Comparing bacterial sedimentation rates in 80 orthopaedic theatres [5] found that there was no significant difference between small laminar flow areas (average area 4.52 m^2) and turbulent airflow areas. Although guidelines by the German Robert Koch institute in 2000 recommend a laminar airflow area of at least 320cm x 320cm, older hospitals may still contain smaller units, something neither study considered.

Regardless of the reasons for the poor performance of laminar flow systems in the two large and recent studies, the

results add to a body of clinical evidence which was founded on trials that failed to control for significant confounding factors and remains unconvincing. It seems implausible to continue to regard laminar air flow theatres as standard for joint replacement procedures after two such comprehensive reviews of the data has shown it to be at best of no benefit and at worst, detrimental.

CONCLUSION

While it is true that laminar-flow systems have proven to reduce the bacterial and particulate contamination of the air it does not appear that they have a significant impact in reducing the rates of infection in joint replacements and indeed there is evidence to suggest the opposite is true. Due to the extensive evidence gathered in the past 10 years it no longer seems possible to recommend the use of laminar flow ventilation in total joint replacement. Further work is needed to look at the effect of patient warming and theatre lighting on laminar flow and, in turn, infection. It appears more prudent than ever to ensure we comply with methods established to reduce the rate of post-operative infection such as prophylactic antibiotics and maintaining 'normothermia' in the anaesthetised patient.

CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

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