Does the use of laminar flow and space suits reduce early deep infection after total hip and knee replacement?

THE TEN-YEAR RESULTS OF THE NEW ZEALAND JOINT REGISTRY

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We have investigated whether the use of laminar-flow theatres and space suits reduced the rate of revision for early deep infection after total hip (THR) and knee (TKR) replacement by reviewing the results of the New Zealand Joint Registry at ten years.

Of the 51 485 primary THRs and 36 826 primary TKRs analysed, laminar-flow theatres were used in 35.5% and space suits in 23.5%. For THR there was a significant increase in early infection in those procedures performed with the use of a space suit compared with those without ($p < 0.0001$), in those carried out in a laminar-flow theatre compared with a conventional theatre ($p < 0.003$) and in those undertaken in a laminar-flow theatre with a space suit ($p < 0.001$) when compared with conventional theatres without such a suit. The results were similar for TKR with the use of a space suit ($p < 0.001$), in laminar-flow theatres ($p < 0.019$) and when space suits were used in those theatres ($p < 0.001$). These findings were independent of age, disease and operating time and were unchanged when the surgeons and hospital were analysed individually.

The rate of revision for early deep infection has not been reduced by using laminar flow and space suits. Our results question the rationale for their increasing use in routine joint replacement, where the added cost to the health system seems to be unjustified.

Deep infection after total joint replacement is a devastating complication. Although the incidence of recurrent infection after a revision procedure is low,[1] it still remains a significant complication which may require several procedures at considerable expense.[2] The estimated financial cost of revision for infection is four times that of the initial procedure.[3]

Early infection is secondary to intra-operative contamination.[4,5] The prophylactic use of antibiotics both systemically and within cement has reduced the rates of early infection but the development of resistant bacteria continues to be a major concern.[6-8]

Airborne contamination can be decreased by limiting the number of personnel and their movement within the operating room, and also by changing the ventilation within it.[9-11] The creation of a clean-air environment by the use of laminar-flow systems was introduced by Charnley[12] and resulted in a significant reduction in his rates of early infection. The 'cleanliness' of the air within an operating theatre can be further improved by increasing the rate of exchange of air within the room. Conventional plenum ventilation theatres have rates of air exchange of 30 times per hour, whereas laminar-flow theatres exchange the total volume of air in the room over 300 times an hour. This clean air delivered at a positive pressure should result in a maximum of 10 colony-forming units per cubic metre (cfu/m^3), but with values as low as 1 cfu/m^3. The Medical Research Council trial[11] confirmed the value of laminar-flow theatres in the reduction of cfus.

Protective suits with hoods and self-contained exhaust systems (space units) have been used to improve sterility further. The cfus/m^3 can be reduced to a value as low as 1.0 with the combined use of both laminar flow and space suits.[11,13] This reduction in bacteria has been assumed to be associated with a lower risk of contamination of the wound and subsequent early infection. Although the combined use of laminar flow and space suits make intuitive sense there have been been limited studies investigating early rates of infection after total joint replacement using these methods.[14]

Since the overall rate of infection in joint replacement is extremely low and there are a multitude of factors potentially responsible,[15] conducting randomised trials with sufficient statistical power is unrealistic. Joint registries allow the study of large prospective data bases in a reliable manner and are able to produce powerful data for rare complications such as

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infection. We have studied the use of laminar flow and space suits and related this to the rate of early deep infection in revision arthroplasty by using data over ten years from the New Zealand Joint Registry. This registry captures 98% of both primary and revision arthroplasties performed in New Zealand and records revision procedures secondary to deep infection. Our hypothesis was that both laminar flow and the use of space suits would result in a lower rate of early deep infection requiring a revision procedure following total hip (THR) and knee (TKR) replacements.

Table I. The increase (%) in use of laminar-flow theatres and space suits over the last ten years recorded on the New Zealand joint registry for total hip and knee replacements

	Laminar flow (%)		Space suits (%)	
	THR*	TKR†	THR	TKR
1999	*21*	*21*	*9*	*12*
2004	*36*	*40*	*21*	*24*
2008	*49*	*53*	*42*	*44*

* THR, total hip replacement

† TKR, total knee replacement

Patients and Methods

We retrospectively analysed the data from the New Zealand Joint Registry between 1999 and 2008 to record the early rates of revision for infection for all registered primary THRs and TKRs. We defined revision due to early infection as any such procedure performed within six months of the initial operation for infection.

The joint registry collects information on all revision procedures performed and documents the reason for the revision. It also captures information on whether the initial procedure was performed within a conventional or laminar-flow operating room and whether space suits were used at the time of the operation.

The rate of infection was recorded as a percentage of all the THRs or TKRs performed over the ten years with a minimum follow-up of six months from these operations. The rate was compared between those procedures performed in a conventional operating room with those undertaken in a purpose-built laminar-flow operating room, and between operations using space suits with those without. Operations using both laminar flow and space suits were compared with those using neither.

In order to minimise associated variables such as the operating time, the use of antibiotics and the surgical technique, we then compared the revision rates for those surgeons who had experience in both conventional and laminar-flow operating theatres and who had performed at least 50 procedures in both. We also compared the revision rates of those surgeons who had used space suits in both surgical settings and who had completed at least 50 procedures in each. We made the assumption that these surgeons were likely to have maintained similar surgical practices between the differing operating environments. This was further investigated by sending a questionnaire on their surgical practice to all the surgeons who fulfilled the above criteria. These results were further evaluated by reviewing the data, the patient's clinical details and the duration of the operation in the joint registry for each surgeon. The questionnaire also requested information from the surgeons on the frequency of use of space suits, which members of the surgical team wore them, whether their practice changed depending on the operating theatre or surgical team and whether they wore full suits or just a hood and an exhaust system.

In order to decrease the impact of variables associated with individual hospitals, we analysed each hospital to see whether there was any difference among hospitals for those surgeons who used space suits and laminar flow compared with those who operated without them in conventional theatres.

Finally, we asked all the hospitals to confirm which theatre ventilation system they used, the rate of air exchange and the maintenance programme of the filters.

Statistical analysis. The percentages with revision for deep infection were compared between groups using the chi-squared test or Fisher's exact test when expected frequencies were low. A p-value of < 0.05 was considered significant.

Results

There were 51 485 primary THRs and 36 826 primary TKRs registered on the New Zealand Joint Registry during the period of study with full information on the theatre environment. The most common diagnosis before the initial procedure was osteoarthritis (94% for both THR and TKR) with a low incidence of inflammatory arthritis (3% THR, 4% TKR). Laminar-flow theatres were used for 33% of all THRs compared with 38% of all TKRs. Space suits were used in 21% of all THRs and in 26% of all TKRs. There was a steady increase in the use of laminar-flow theatres and the use of space suits between 1999 and 2008 (Table I) and in 2008 almost half of these procedures were performed in laminar-flow theatres with space suits.

Total hip replacements (Fig. 1). There were 46 (0.089%) patients who required early revision for deep infection.

There was a significant increase in the rates of early revision for deep infection for those procedures performed with the use of a space suit (0.186%) when compared with those without (0.064%, $p < 0.0001$) (Fig. 1a) and for operations performed in a laminar-flow theatre (0.148%) compared with a conventional theatre (0.061%, $p < 0.003$) (Fig. 1b). There was also a significant increase in the rates of revision for deep infection in procedures performed in a laminar-flow theatre with a space suit (0.198%) compared with those in a conventional theatre without a space suit (0.053%, $p < 0.001$) (Fig. 1c). These results were independent of age and the diagnosis at the time of the initial procedure.

There were 43 surgeons who performed more than 50 procedures in both operating environments. These

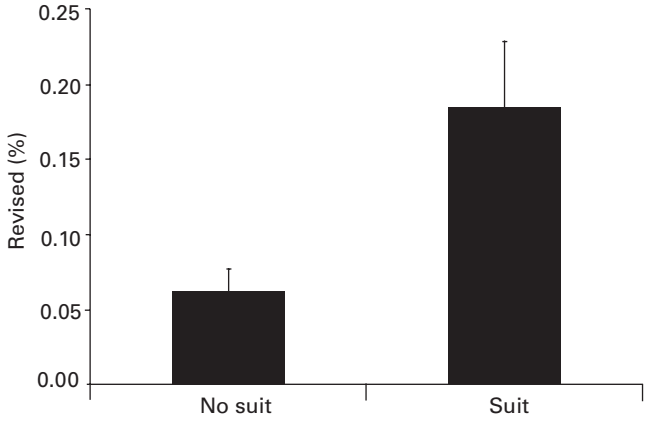

Fig. 1a

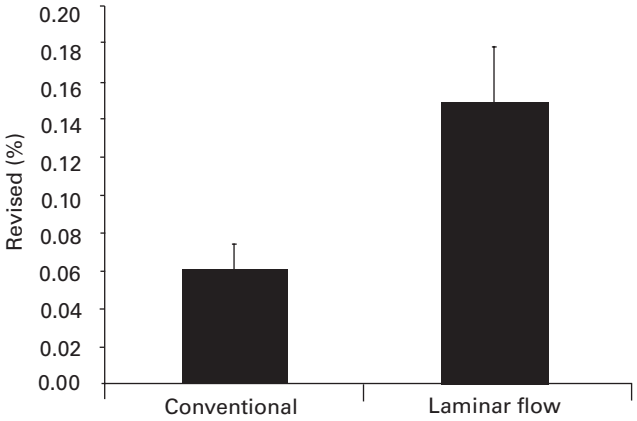

Fig. 1b

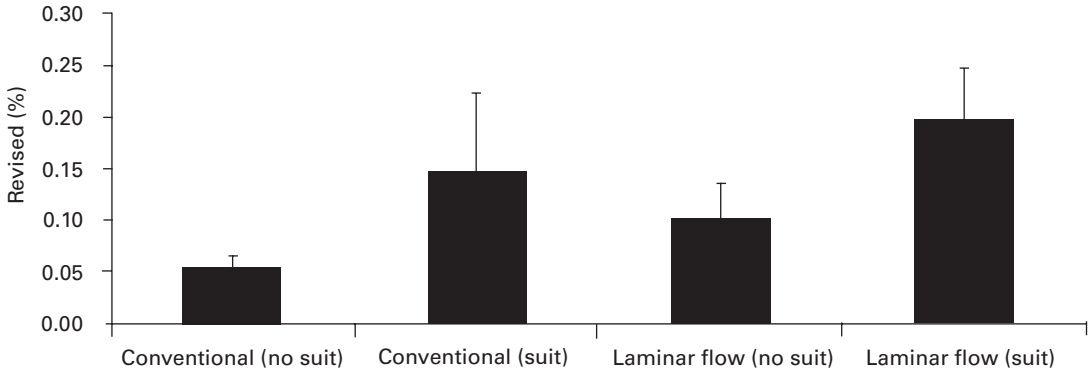

Fig. 1c

Graphs showing the percentage of total hip replacements requiring revision for deep infection within six months comparing a) the use of a space suit with no suit, b) the use of laminar flow with a conventional operating theatre, and c) the use of laminar flow or conventional theatre with or without a space suit.

operations had an infection rate of 0.110% in the laminar-flow theatre compared with 0.028% in the conventional theatre ($p < 0.03$).

There were 33 surgeons who either did or did not wear a space suit. The incidence of infection was 0.082% with a suit compared with 0.057% without ($p = 0.755$). Additionally, 30 surgeons had operated both with a space suit and laminar flow and without a space suit in a conventional enviroment. The operations performed in a conventional theatre without a suit had no infections from 3598 procedures, compared with 0.1035% carried out in a laminar-flow theatre with a suit ($p = 0.09$) The clinical details of the patients were similar in both groups with no significant difference in age, pre-operative diagnosis or the length of the operation in the different environments.

Total knee replacements (Fig. 2). There were 50 (0.136%) patients requiring early revision for deep infection.

There was a significant increase in early revision, similar to THR, for those TKRs performed with the use of a space suit (0.243%, $p < 0.001$) compared with those without (0.098%, $p < 0.001$) (Fig. 2a), when laminar-flow theatres (0.193%) were compared with conventional theatres (0.100%, $p < 0.019$) (Fig. 2b), and when laminar flow and space suits (0.25%) were used compared with no space suits and conventional theatres (0.087%, $p < 0.001$) (Fig. 2c). Again these results were independent of the patients' age and diagnosis at the time of the initial procedure.

There were 23 surgeons who performed at least 50 TKRs with or without a space suit. There was almost a tenfold increase in the rate of early revision because of deep infection in those who used a space suit (0.251% compared with 0.028%, $p = 0.016$). There were 32 surgeons who operated in both laminar-flow and conventional theatres, but in contrast to THR there was no significant difference in the revision rate for deep infection (0.147% compared with 0.189%, $p = 0.597$). Again, as with THR, there was no difference in the patients' clinical details between the groups and the duration of operations was similar.

The infection rate compared with the operating theatre. There were 64 hospitals which supplied data to the registry. Only one was identified as having a significantly increased rate of revision for early deep infection when the use of a

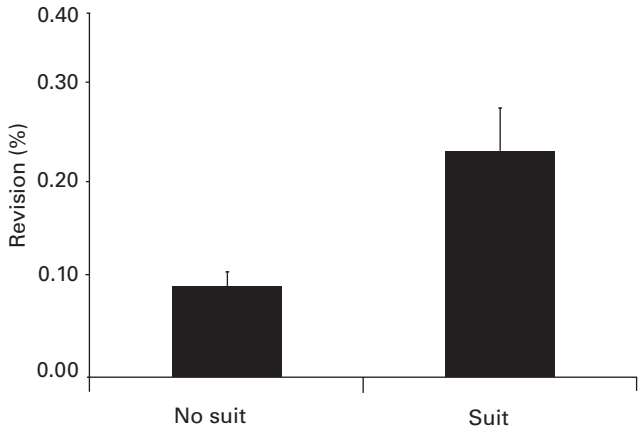

Fig. 2a

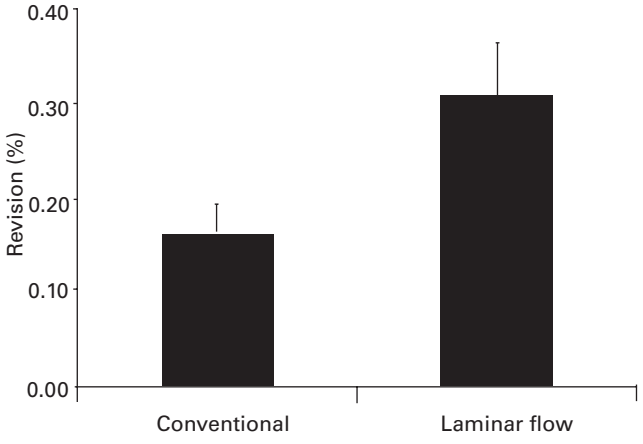

Fig. 2b

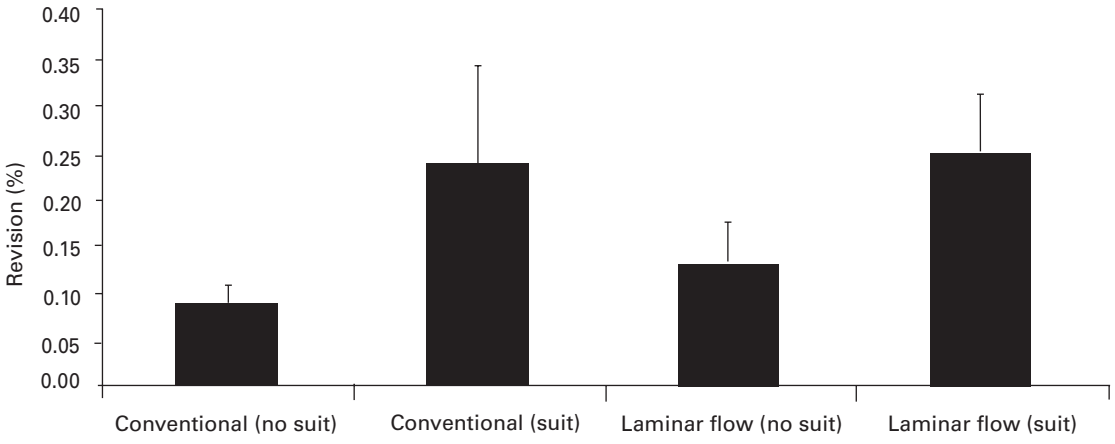

Fig. 2c

Graphs showing the percentage of total knee replacements requiring revision for deep infection within six months comparing a) the use of a space suit with no suit, b) the use of laminar flow with a conventional operating theatre, and c) the use of laminar flow or conventional operating theatre with or without a space suit.

conventional theatre and no space suit was compared with laminar flow with a space suit. This hospital contributed only a small number to the database and when these were removed from the analysis there was no change in the significance of the results.

All hospitals confirmed that they had a regular maintenance programme for filters. There were no hospitals which used laminar flow combined with a complete surgical enclosure.

Surgeon questionnaire. There were 35 responses from the 60 surgeons who had been sent a questionnaire, giving a response rate of 58.3%. All respondents currently use a space suit in all of their replacement procedures and all stated that they used the same surgical technique regardless of the theatre environment. Most (28 of 31) used full suits for the surgeon, assistant and scrub nurse. All the suits were contemporary in design and no surgeon worked in a fully-enclosed space. No surgeon worked with all the staff in the operating theatre. In particular, no anaesthetist or technician wore a space suit.

Discussion

Our study has shown that the combined use of laminar flow and space suits did not protect against infection requiring revision within six months of the primary joint replacement and may have increased the risk. These results are surprising considering that the microbiological evidence suggests that their combined use should decrease the total number of colony-forming units within the operating theatre which should reduce the rate of infection.[2] To date, there have been no studies which have shown conclusively that a decreased number of colony-forming units relates to a lower rate of wound contamination and infection.

Although ultraclean air environments using laminar flow have been widely accepted as reducing the risk of wound contamination, there has only been one other major multicentre study which has examined the effect of laminar flow on wound infection in orthopaedic procedures.[11] Lidwell et al[16] published the Medical Research Council's prospective trial in 1987 and concluded that the incidence of confirmed sepsis was higher in conventional theatres. However, this study

included only 8052 procedures up to four years after surgery, with a mean of 2.5 years, and hence all may not have been due to intra-operative contamination. This trial has also been widely criticised because of the variable and uncontrolled use of peri-operative prophylactic antibiotics. In New Zealand prophylactic antibiotics are given for most THR and TKR operations. The joint registry shows a use of prophylactic antibiotics of 96% and of antibiotics in the cement of 60%. We do not feel therefore that this is a confounding variable in our study.

Brandt et al[17] reviewed the German experience with surgical site infection in 99 230 general surgical and orthopaedic procedures. They concluded that laminar flow did not reduce surgical site infection and may have contributed to a higher rate of infection in THR. Others have found that bacterial contamination of the wound in THR was not reduced with laminar-flow ventilation.[18]

In order to be effective, laminar flow requires no obstructions to the path of the high flow of air. Obstructions cause eddies which in turn can produce areas of risk for increasing contamination and infection.[19,20] The layout of operating theatres varies considerably between hospitals. Our study could not control this variable, but by comparing surgeons in different theatre environments we believe that we have minimised such variables as the position of the surgeon and staff with respect to the patient and the individual surgical setup, all of which may interfere with the flow of air within an operating theatre.

The removal of airborne particles including bacteria and spores requires the use of high-efficiency particulate air filters, which in turn require regular maintenance. All the hospitals confirmed that they complied with these maintenance programmes and the observations that there were no hospitals using laminar flow which skewed the results suggests that this potential source of contamination was unlikely to be a factor.

The shedding of bacteria from the skin of the surgical team has been implicated as a major potential source of wound contamination.[10] The large air flows from laminar systems are commonly vertical and push air and debris from the ceiling to the floor. These flows pass the head and upper body of the surgeon and assistants and can potentially contaminate the wound from this source. The ears, which are not covered by the traditional hood and mask, are the most common part from which bacteria are shed. The use of enclosed hoods and exhaust systems combined with occlusive gowns should decrease wound contamination from this source. However, it has been shown that disposable hoods and masks are as effective as helmet aspirator systems.[21] Charnley[12] reported the lowering of infection after THR from 10% to 1% with the use of laminar flow and full-body exhaust suits. Our study has shown that the rate of infection in both theatre environments was increased with the use of space suits. Surgeons who returned a questionnaire made comments about the current space suits used, indicating that at times their spatial awareness was limited by the hood. Others suggested that it was easier to contaminate themselves while wearing a space suit since there was an apparent false sense of security within it. Observers who have been present during operations using space suits have noted that surgeons often adjust the suit or hood during the procedure and subsequently unknowingly contaminate their gloves. Another possible cause of contamination may be the exhaust systems of the space suits. There is no information as to the flow of the expelled air from exhaust systems and whether the air is concentrated with debris and significant numbers of colony-forming units close to the surgical site.

The causes of wound infection are multifactorial. We have tried to limit confounding variables in our study by including a group of surgeons who had operated in a variety of environments. Our assumption was that their operating procedures would not differ between different hospitals. Therefore such factors as the duration of the operation, the patient mix, surgical technique, the use of antibiotics, the movement within the theatre and the general sterile procedures would be similar. This was confirmed by the questionnaire which was sent to these surgeons, although a response rate of 58.3% could be regarded as low. Analysis of the patients registered on the New Zealand Joint Registry confirmed that there was no difference in the patients' clinical details between the hospitals for these surgeons. In particular, there was no difference in the number of patients perceived to have a higher risk of infection, such as those with inflammatory arthritis. The duration of the operation was the same in the two groups suggesting that the complexity of the operations was similar.

We also studied each individual hospital and in particular looked at those which had both a laminar flow and conventional theatre. We found only one hospital in which the trend towards revision for infection was increased in a conventional theatre. This was a provincial hospital and performed only a small number of procedures. When they were removed from the analysis the results were unchanged. We believe that this removed any bias which may have occurred because of a particular 'rogue' hospital.

We defined early joint infection as that requiring a revision procedure within six months of the initial operation. It is generally accepted that any deep infection which develops within this timeframe is most likely to be due to bacterial contamination at the time of the replacement,[22,23] but we acknowledge that not all joint infections will be captured by this method. Not all early deep infections would have had a revision procedure within this timeframe, especially those in older and infirm patients who may have been treated with suppressive antibiotics. Subacute infections which presented after six months would not be captured by our study. However, we believe that including infections outside this period would be more likely to confuse the data with increasing numbers of infections from a secondary source. We accept that our study only captures those

patients with severe deep infections that require a revision procedure. However, we believe that this is the most important group of patients since they suffer the most severe morbidity and are a large drain on health resources.[3]

Previous studies[24,25] have shown the value of national joint registries which record large numbers of procedures and produce valuable data for rare complications which would be extremely difficult to produce in prospective, randomised trials. In response to the surgeon questionnaire, several surgeons made the comment that they monitored their infection rate and thought that their results were acceptable. However, the rates of early revision for infection were small (0.08% for THR and 0.13% for TKR). Therefore, an individual surgeon would have extreme difficulty in observing any change over time in their rate in relation to the use of laminar flow or space suits.

In conclusion, our study has shown that there is no benefit in the use of laminar flow or space suits in reducing the rate of revision for early deep joint infection in total joint replacement, and questions the added cost of their use.

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