Comfort assessment of personal protection systems during total joint arthroplasty using a novel multi-dimensional evaluation tool

MHA MALIK, ELIZABETH HANDFORD, ELAINE STANIFORD, AK GAMBHIR, PR KAY

The Centre for Hip Surgery, Wrightington Hospital, Wigan, UK

ABSTRACT

INTRODUCTION A number of studies have assessed the usefulness of surgical gowns and exhaust suits with regards to barrier function and protection afforded to healthcare workers from blood strike-through, splashes and aerosols.

PATIENTS AND METHODS We have performed a comfort assessment comparison between the Charnley exhaust suit, disposable gown plus visor and the Stryker Steri-Shield system using a newly developed objective multidimensional ergonomic tool designed to measure wearable comfort across the dimensions of emotion, attachment, harm, perceived change, movement and anxiety.

RESULTS The total mean Comfort Rating Scale value for a disposable gown plus visor was 16.1 with a mean dimensional score of 2.7 (range, 0.2–8.4), for the Charnley system the values were 51.4 and 8.6 (range, 5.9–12.8), respectively, and for the Stryker Steri-Shield 15.4 and 2.6 (range, 0.8–5.6).

CONCLUSIONS The Steri-Shield system provides the least variation in comfort and, as such, may offer the best combination of comfort, protective qualities and form or style of personal protection equipment for lower limb arthroplasty operations.

KEYWORDS

Comfort – Total joint replacement – Personal protection system

CORRESPONDENCE TO

MHA Malik, 14 The Boulevard, Didsbury Point, Manchester M20 2EU, UK

T: +44 (0)161 448 9972; E: hammymalik@hotmail.com (hammy.malik@man.ac.uk)

The occurrence of deep infection in total joint arthroplasty (THA) has been extensively documented.¹ In the UK, a combination of systemic, broad-spectrum antibiotics, antibiotic-impregnated cement, ultraclean air systems and ventilated suits are recommended as the most effective form of infection prophylaxis.²

The microbiology of the infected arthroplasty would suggest that intra-operative contamination is the most common mechanism of the development of infection. The main source of contamination in joint replacement surgery is from the patients' skin and air-borne particles from theatre personnel.^{3,4} The latter has been tackled by the development of ultra-clean air systems and developments in the type of garb worn by surgeons and their assistants. A number of studies have assessed the usefulness of surgical gowns and exhaust suits with regards to barrier function and protection afforded to healthcare workers from blood strike-through, splashes and aerosols.^{5–7}

One of the most efficient ways of reducing the bacterial load is to use a body exhaust suit such as that devised by

Figure 1 Sir John Charnley in his exhaust suit.

Charnley (Fig. 1).⁸ However, many surgeons find the exhaust suit heavy and cumbersome. That, combined with high noise levels making communication difficult, has made the exhaust suit unpopular and many surgeons have abandoned its use.⁹

Table 1 Comfort Rating Scale descriptors

Cluster	Description
1	Emotions, concerns about relaxation
2	Attachment to body
3	Physical effect, damage to the body
4	Perceived change, physically different
5	Device physically affects movement
6	Anxiety about device safety and reliability

An alternative way of reducing the bacterial load is to use a sterile hooded helmet apparatus.¹⁰ This is either a loose-fitting hood or a hood combined with an integral gown which is known as a toga system.¹¹ They also protect surgical staff from blood splashes or aerosols and, by virtue of being sterile, do not contaminate any such splashes that may fall back into the operative area.

The Stryker Steri-Shield T4 helmet plus toga system (T4 Personal Protection System) is designed as a personal protection system (Fig. 2). It has the advantage of being light, portable and quiet. It also offers additional sterility to the head and neck region as compared to standard surgical attire or a conventional exhaust suit. No further facial splash protection such as visors or goggles are required. It has integral intake and exhaust fans built into the helmet which free the user from any cumbersome and restricting attachment to a vacuum system. Given these features, it has much to recommend its use over the standard Charnley body exhaust system, but as yet no study has addressed the relative levels of comfort and ease of using such systems.

The importance of objective outcome measures in medicine has been realised in recent years and many different scoring systems are currently used in a variety of settings.¹² Attempts to assess the comfort and protection afforded by surgical gowns have been made, but have been extremely simplistic and limited in their nature invariably relying on a single, subjective and unvalidated linear scoring system.^{13,14} In this study, we have performed a comfort assessment comparison between the Charnley exhaust suit and the Stryker Steri-Shield system using a newly developed objective multidimensional validated ergonomic tool.

Patients and Methods

This prospective, comparative study was conducted in the four dedicated total joint arthroplasty theatres at Wrightington Hospital. Surgical staff were asked to complete a questionnaire at the end of either a total hip or knee primary arthroplasty operation after having worn either a disposable surgical gown plus mask with visor, a

Figure 2 Stryker Steri-Shield system.

Charnley exhaust suit or a Stryker Steri-Shield system. No operation lasted more than 140 min or involved deviation from usual practice for primary or revision arthroplasty. The distribution and collection of questionnaires was undertaken by theatre nurse managers.

The questionnaire used in this study is a modification of the Comfort Rating Scale (CRS) designed to measure wearable comfort of computer devices during physical activity across 6 dimensions.¹⁵ These dimensions are emotion, attachment, harm, perceived change, movement and anxiety (Table 1). The different comfort dimensions or aspects were derived from multidimensional scaling statistical analysis of a term-by-term association matrix of 92 terms that described how wearing a device may affect the wearer or how the wearer may feel (physically and mentally) about the device.

We modified the CRS to be more specific for the wearing of theatre garb by changing the questions in each comfort dimension as shown in Table 2. This produced a modified CRS with a total of 11 questions as there are 3 questions each for the 'perceived change' and 'physical effect' dimensions and 2 questions for the 'anxiety' dimension. Each question was scored along a 20-point comfort rating scale which scored from 0 at the far left to 20 on the far right. This fulfils the criterion of Helander and Makund who recommend the use of 11 or more point scales for subjective evaluation.¹⁵ The scales were anchored at either end with the descriptors '0 = lowest' and '20 = highest'. Using the scale simply requires that the scorer mark on the graduated line their level of agreement from low to high to the questions posed. Respondents were also asked to add a brief explanation for the score given.

A mean score was calculated for each dimension. For dimensions that had more than one question, a mean was calculated for each question and then a mean calculated for the whole dimension.

Results

Ten theatre staff were recruited to the study and completed the modified CRS on three separate occasions after having worn a disposable surgical gown plus mask with visor, a Charnley exhaust suit and a Stryker Steri-Shield system.

Table 2 Modified Comfort Rating Scale

Title	Description
Emotion	Did you feel uncomfortable with the temperature during the duration of the operation?
Attachment	How difficult was the suit/gown to don?
Physical effect	Did you encounter any: (i) neck discomfort? (ii) tightness around the neck? (iii) headache?
Perceived change	Could you not: (i) be heard by the surgical team? (ii) hear the surgical team?
Perceived change	Was your field of view restricted in any way?
Movement	Did the suit/gown restrict your movement?
Anxiety	Did you feel that your visor compromised sterility?
Anxiety	Did you feel that the gown failed to protect you from strike-through or splashes?

The total mean CRS for a disposable gown plus visor was 16.1 with a mean dimensional score of 2.7 (range, 0.2–8.4), for the Charnley system the values were 51.4 and 8.6 (range, 5.9–12.8), respectively, and for the Stryker Steri-Shield 15.4 and 2.6 (range, 0.8–5.6). Table 3 lists the dimensional scores and this is shown in chart form in Figure 3.

Emotion

Most staff felt comfortable with the temperature within disposable gowns, but over half felt that the temperature rose with increasing duration of the operation and that there was a potential for the visor to steam up. Temperature within the Charnley system was thought to be dependent upon the outside temperature that day. It was also commented that, if the exhaust pipe was kinked or flattened, air flow was minimised. Two respondents felt that Stryker Steri-Shield system was too warm, but the general feeling was that temperature could easily be adjusted by altering the fan speed using the two buttons on the side of the helmet which are covered by, but palpable beneath, the sterile hood cover.

Attachment

Most found the disposable gowns easy to put on. Much more difficulty was found with donning the Charnley system and it was felt that this was particularly hard for inexperienced theatre staff. The most commonly mentioned problem was the de-sterilisation of gloves when attaching the gown around the unsterile visor. The Steri-Shield system was thought to be relatively more easy to don.

Physical effect

The Charnley helmet was found to have a number of issues regarding comfort in this dimension. The weight of the pipe was commented on as this could act to pull the helmet down onto the head and lead to neck stiffness. There is also no mechanism to adjust the tightness of the helmet once the gown has been donned. The weight of the Steri-Shield

Table 3 Mean values of comfort dimensions for each clothing system (ranges in brackets)

Dimension	Disposable gown plus visor	Charnley exhaust suit	Stryker Steri-Shield system
Emotion	3.8 (1–7)	7.4 (5–13)	5.6 (2–10)
Attachment	2.0 (1–6)	12.7 (10–16)	4.2 (1–8)
Physical effect	0.6 (0–4)	6.2 (3.5–10)	2.0 (0–5)
Perceived change	0.2 (0–4)	12.8 (8–18)	1.6 (0–5)
Movement	1.1 (0–3)	5.9 (4–12)	0.8 (0–4.5)
Anxiety	8.4 (5–14)	6.4 (2–8)	1.2 (0–4)

helmet also caused neck stiffness in some respondents. It was noted that the ability to alter helmet tightness peri-operatively was an advantage.

Perceived change

Communication was not noticeably impaired by either the disposable gown plus visor or the Steri-Shield system. This was felt to contribute to the smooth running of the operation. The visor on the latter was commented upon as being larger than that of the Charnley helmet. Due to the noise of the piped airflow, the majority of respondents felt that extra concentration was required when wearing a Charnley helmet and, to compensate, staff sometimes stand on the exhaust pipes to reduce the noise level. Time is wasted by repeating instructions and trying to make eye contact to gain the attention of other members of the scrub team.

Movement

The absence of exhaust tubing in the Steri-Shield system was seen as a great advantage over the Charnley system as it allowed staff to be more mobile, change sides and help the surgeon if necessary. Comments were made that the weight of the body exhaust pipe pulls down on the helmet and that the pipe twists easily so preventing free movement. The position of the pipe connection to the helmet can make turning the head difficult.

Anxiety

As the whole of the Steri-Shield system including the visor is sterile and provides total protection of the head and neck, all respondents felt comfortable in this dimension. The Charnley system scored well on protection, but mention was made that the hands of scrub staff can easily become de-sterilised when positioning the gown around the helmet pegs when donning the suit. Disposable gowns were felt to offer the least protection and greatest chance of contamination of the sterile field.

Discussion

Comfort is a relative term which is usually determined by a combination of physiological, psychological and physical factors. Various factors such as poor fit, added weight or out-of-fashion style may make personal protective equipment (PPE) undesirable.¹⁶ A major limitation of comfort assessment studies is that they often score comfort along one scale implying that it is a one-dimensional construct. Just knowing that when wearing a device the wearer has a certain level of discomfort does not help in determining what aspect of the device makes the wearer feel uncomfortable. Comfort should be measured across a number of dimensions such as is possible with the Birmingham CRS. We realise that having made alterations to the original CRS that there may be attenuation of its validity, but the scale still remains much more objective than previous attempts at measurement of comfort of theatre garb.

One study has demonstrated that employees in a research institution, even those who were highly educated, failed to use their PPE.¹⁷ It was concluded that to make the workplace safer it is necessary to enhance the comfort, protective qualities and form or style of PPE. In the case of theatre garb for the scrub team, this translates into comfort and protection of the patient from contamination by the theatre team and protection of the scrub team from the patient's blood and tissue.¹⁸

This study has clearly demonstrated that over 6 dimensions of comfort measurement which include the criteria above that the use of a disposable, impermeable gown plus visor or the Steri-Shield system provide a system of PPE that is comfortable and comparable with both having almost similar modified CRS total scores. The greatest differences between the systems were in the 'perceived change' and 'anxiety' dimensions. The former was 8 times more comfortable for gowns than Steri-Shield whereas the latter was 8 times more comfortable for Steri-Shield than gowns.

Gowns offered the least hindrance to communication and vision, but were thought to offer little protection from

strike-through, splashes or contamination of the sterile field from direct contact with the non-sterile visor or from tissue or fluid hitting the visor and then falling back into the wound. The Steri-Shield visor is sterile and the helmet and toga provide complete protection from the head down to the lower legs. Interestingly, although the order of magnitude of difference between all dimensions comparing gowns to Steri-Shield were similar, the actual ranges of values were much narrower for Steri-Shield (range, 0.8–5.6) than for disposable gowns (range, 0.2–8.4).

The Charnley exhaust system has proved to provide the least comfort with it being over 3 times more uncomfortable than either of the other PPEs assessed in this study using the modified CRS and may explain its poor uptake.⁹ It scores particularly badly in the dimensions of ‘attachment’ and ‘perceived change’ as it is not easy to don and is noisy. It also scores badly for ‘movement’ and ‘physical effect’ due to the weight and cumbersome nature of the exhaust tubes. Interestingly, it scores better than disposable gowns for ‘anxiety’ as it was felt to offer better protection and less chance of contamination, both of which are obvious concerns regarding PPE in the operating room.¹⁹

Conclusions

Although disposable, impermeable gown plus visor or the Steri-Shield system provide a similar level of comfort, the modified CRS has demonstrated that over 6 dimensions of measurable comfort the Steri-Shield system provides the least variation in comfort and as such may offer the best combination of comfort, protective qualities and form or style of PPE for lower limb arthroplasty operations.

Acknowledgement

The authors would like to thank the theatre staff at Wrightington Hospital who participated in this study for their time and effort.

References

1. Fitzgerald RH. Total hip arthroplasty sepsis: prevention and diagnosis. *Orthop Clin North Am* 1992; **23**: 259–64.
2. *Total hip replacement: a guide to best practice*. 2000. <www.boa.ac.uk>.
3. Ha'eri GB, Wiley AM. Total hip replacement in a laminar flow environment with special reference to deep infections. *Clin Orthop* 1980; **148**: 163–8.
4. Howarth FH. Prevention of airborne infection during surgery. *Lancet* 1985; **1**: 386–8.
5. Pissiotis CA, Komborozos V, Papoutsi C, Skrekas G. Factors that influence the effectiveness of surgical gowns in the operating theatre. *Eur J Surg* 1997; **163**: 597–604.
6. Ritter MA. Operating room environment. *Clin Orthop* 1999; **369**: 103–9.
7. Der Tavitian J, Ong SM, Taub NA, Taylor GJS. Body-exhaust suit versus occlusive clothing. A randomized prospective trial using air and wound bacterial counts. *J Bone Joint Surg Br* 2003; **85**: 490–4.
8. Charnley J. Postoperative infection after total hip arthroplasty with special reference to air contamination in the operating room. *Clin Orthop* 1972; **87**: 167–87.
9. Malik MHA, Gambhir A, Bale L, Pradhan N, Porter ML. Primary hip replacement: a comparison of a nationally agreed guide to best practice and current surgical technique as determined by the North West regional arthroplasty register. *Ann R Coll Surg Engl* 2004; **86**: 113–8.
10. Ritter MA, Eitzen E, Hart JB, French MLV. The surgeons' garb. *Clin Orthop* 1980; **153**: 204–9.
11. Anon. Surgical helmet systems. *Health Devices* 1996; **25**: 116–45.
12. Pynsent PB, Fairbank JCT, Carr AJ. (eds) *Outcome Measures in Orthopaedics*. Oxford: Butterworth-Heinemann, 1993.
13. Bohn WW, Koppe SM. Fluid contamination during orthopaedic procedures. A study of incidence, location and prevention. *Orthop Rev* 1991; **10**: 679–84.
14. Closs SJ, Tierney AJ. Theatre gowns: a survey of the extent of user protection. *J Hosp Infect* 1990; **15**: 375–8.
15. Knight JF, Baber C, Schwirtz A, Bristow H. The comfort assessment of wearable computers. Digest of papers of the 6th International Symposium of Wearable Computing, Los Alamitos, CA: IEEE Computer Society, 65–74.
16. Akbar-Khanzadeh F, Bisesi MS. Comfort of personal protective equipment. *Appl Ergonom* 1995; **26**: 195–8.
17. Newill CA, Koegel AE, Prenger VL, Ansari AA, Pustelnik A, Corn M *et al*. Utilization of personal protection equipment by laboratory personnel at a large medical research institution. *Appl Ind Hygiene* 1989; **4**: 205–9.
18. Beck WC, Belkin NL, Meyer KK. Divide and conquer – protection, comfort, and cost of the surgeon's gown. *Am J Surg* 1995; **169**: 286–7.
19. Bohn WW, Koppe SM. Fluid contamination during orthopaedic procedures. A study of incidence, location and prevention. *Orthop Rev* 1991; **20**: 679–84.