A novel device for preoperative skin preparation*

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Surgical site infections (SSIs) can increase management costs and extend length of stay. We undertook a single blinded non-inferiority trial to evaluate the efficacy and utility of a novel system for preoperative limb antisepsis.

Surgical site infection (SSI) can result in longer hospital stay, antibiotic usage, repeat surgery, and with orthopaedic implants amputation or death. Interventions to prevent SSI include laminar flow theatres, scrub suits, hoods, masks, water-proof disposable drapes (Jacobson et al 2005), extraction systems (Wong & Leung 2004) and skin disinfection (Mackenzie 1988).

Skin disinfectant solutions in use in the UK are iodophore, povidone-iodine and chlorhexidine gluconate (Lilly & Lowbury 1971). Hardin and Nichols (1997) suggest skin disinfections should:

- be bactericidal and viricidal
- be non-toxic and hypoallergenic
- be non-absorbable
- have residual activity

While there is no validated evidence which suggests that preoperative skin antisepsis reduces postoperative wound infection rates (Dumville et al 2015), it is accepted that the source of most SSI in clean elective cases is the patients' skin microbial flora (Altemeir et al 1968). In addition, no antiseptic kills more than 80% of the initial bacterial load (Selwyn & Ellis 1972) as surface application fails to reach bacteria within hair follicles and other skin appendages, although repeated applications are thought to have a cumulative action (Hardin & Nichols 1997).

During preoperative disinfection, the limb is 'painted' using a sponge or gauze square in a sponge-holding forceps whilst a non-scrubbed staff member lifts it, which may cause back and shoulder injury. If a tourniquet is used, a guard is required to prevent seepage of alcohol containing antiseptic (Ellanti & Hurson 2015, Dickinson & Bailey 1988).

We therefore designed a sealed system which includes a tourniquet guard and a standard portal to instil antiseptic. Applied prior to induction of anaesthesia, it allows the patient to be involved thereby reducing lifting requirements.

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It is applied sock-like to the distal edge of the tourniquet and 50ml of antiseptic instilled; the limb remains in contact with the antiseptic until its sleeve is removed in theatre. Drapes can be applied as the sleeve is retracted to a position level with the tourniquet. To determine whether exposing the limb could be performed safely and without further contamination of the skin either from inadvertent contact or the traction of the device across the skin we undertook a non-inferiority trial of the system.

Method

A randomised, single blind study was undertaken. Based on studies of the effectiveness of different surgical antiseptic solutions, RH determined that a sample size of 60 participants would have a power of 90% to show non-inferiority. Sixty healthy, adult volunteer members of staff were recruited; staff who had scrubbed within the previous 8 hours were excluded. Volunteers were allocated to either the Limb Sleeve group (study) or control group using random number tables and numbered sequential opaque envelopes. Alcoholic Betadine® was used as antiseptic. The study was undertaken in an operating theatre with laminar flow routinely used for orthopaedic surgery. All participants including the research team wore surgical theatre clothing.

In the study group, the upper limb was prepared up to the mid upper arm using the Limb Sleeve; a standard volume of 30ml of antiseptic was instilled and the arm placed horizontally on a table. The researcher massaged the antiseptic around the arm and between the fingers - volunteers opened and closed their fingers to further spread the antiseptic.
A consultant surgeon prepared the limb of control group participants by painting on the antiseptic using a gauze swab held in sponge-forceps.

Although it is normal to move immediately to draping after skin preparation, both groups waited for 10 minutes after application to allow optimum skin antisepsis. The hand of the prepped limb was then tested for residual bacteria using the glove juice technique (ASTM 2011). A latex glove containing 50ml of sampling fluid (Sheikh 1981) was placed on the participant's hand and massaged for 1 minute; after removal the fluid in the glove was transferred to a sterile bottle and sent to the microbiology laboratory. The sampling fluid neutralises the

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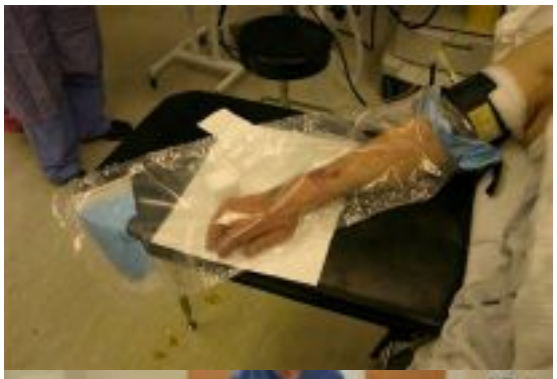

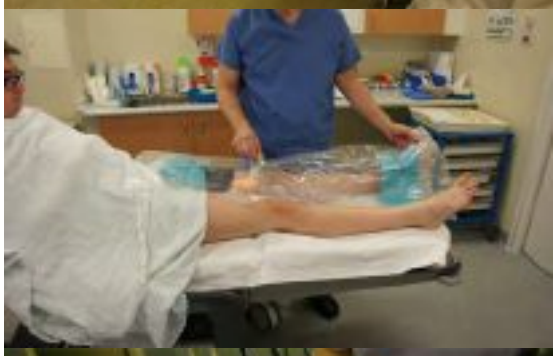

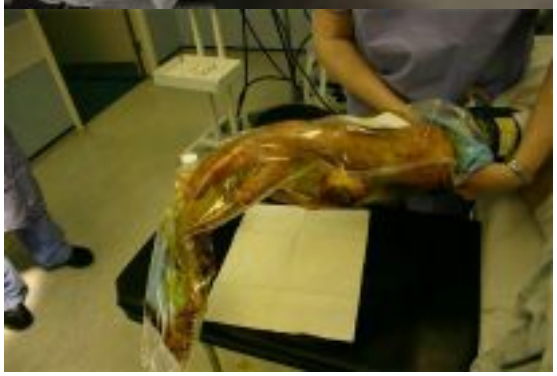

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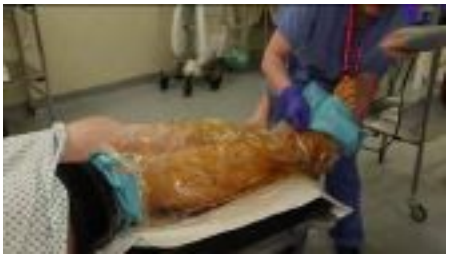
The sleeve is designed to facilitate preparation of any limb prior to surgery. The longer the sleeve is applied to the limb and the disinfectant in place the better.

The sleeve is supplied sterile in sealed packaging. Once the package is opened the sleeve is slid onto the leg and the upper seal is positioned adjacent to the tourniquet as high on the leg as possible.

The sleeve is used prior to patient anaesthesia in pre op space, allowing the patient to cooperate wherever possible. Eliminating the need for potentially hazardous patient handling.

When the sleeve is in place, the skin prep can be introduced to the sleeve. This is done by lifting the cover off the port and introducing the prep agent. The cover is then replaced.

The patient can then assist in ensuring that the whole leg is coated in skin prep. The skin prep is assisted by the sponge which is found sterile in the sleeve



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>> bactericidal and bacteriostatic effect of the antiseptic agent, allowing any remaining bacteria to be identified.

Aliquots of each glove juice sample were serially diluted (by 102 and 103), plated onto trypticase soy agar plates and incubated aerobically for 48 hours, after which the colony forming units (CFUs) were counted. The microbiologist was blind to which skin preparation method had been used. The results were analysed by RH using the chi-squared test and Fisher's exact test.

Results

Thirty volunteers were allocated to each group. A glove-juice sample was sent to the microbiology laboratory for each volunteer; one bottle from the control group broke prior to analysis. Fifty percent of the samples from the study group and 1.6% (n=1) of the samples from the control group grew no bacteria (Figure 1). The difference was highly significant, ($p<0.0001$, single tailed), indicating that the samples from the study group produced significantly fewer bacterial colonies compared with the controls.

The cultures were typed and pathogenic bacteria in a healthy person were noted. Four samples (6.6%) from the study group grew Staphylococcus aureus, 1 sample (1.6%) grew Bacillus cereus. No pathogens were grown in the study group.

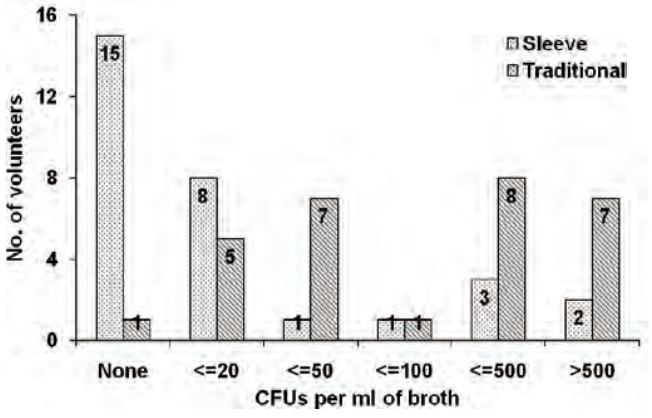
Discussion

All antiseptic agents recommend a significant period of contact before surgery starts to maximise efficacy. The reduction of CFUs in the study group may be due to the prolonged duration of contact with wet alcohol, as all other elements in the two study groups were identical. It is also possible that the plastic sleeve encourages a more even coverage of antiseptic solution through capillary action between the skin and sleeve.

This study was adequately powered for the outcome and showed a statistically significant difference. A limitation may be that it was undertaken on the upper limb when the main use of the sleeve is probably for lower limb surgery. However whilst the bacterial load on an unwashed foot may be different to a hand, the relative effectiveness of the Limb Sleeve would be maintained. We have not identified a minimum adequate amount of antiseptic agent for a lower limb; however we recommend 50-60ml based on our experience. We believe this provides an opportunity to control more rigorously the volume and cost of antiseptic used.

We have not been able to find details of numbers of staff complaining of back pain in theatres, but the anecdotal evidence suggests a significant risk of injury. Removing all need for the theatre staff, apart from the surgeon, to lift the limb reduces significantly the risk of back injury which is an obligation on all employers.

Figure 1: Colony Forming Units



Conclusion

The system was designed to reduce theatre time, reduce lifting as far as possible, prolong antiseptic contact as long as possible and reduce wastage. The study results seem to support these aims.

Acknowledgements

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