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Full title:

Does the type of surgical drape (disposable versus non-disposable) affect the risk of subsequent surgical site infection?

Short title:

Comparative infection risk between disposable and reusable surgical drapes

David C. Kieser[1] (PhD, FRACS, MBChB)[1], Michael C. Wyatt[2] (FRACS, MBChB), Andrew Beswick[2] (BSc), Kunutsor S[2] (PhD), Gary J. Hooper[1] (MD, FRACS, MBChB).

[1]Department of Orthopaedic Surgery and Musculoskeletal Medicine, University of Otago, Christchurch School of Medicine

[2]Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School, University of Bristol, Learning and Research Building, Level 1, Southmead Hospital, Bristol. BS10 5NB

Corresponding author:

Mr David Kieser

Department of Orthopaedic Surgery and Musculoskeletal Medicine, University of Otago, 2 Riccarton Avenue, Christchurch, New Zealand. 8011

Phone 0064 21 149 9829

Fax 0064 3 467 9709

Email kieserdavid@gmail.com

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Abstract

Aims

Determine whether disposable or reusable drapes are better at reducing surgical site infection (SSI) rates.

Methods

A systematic review of the English literature from inception to 2018 with search terms relating to infection and drapes in orthopaedic and spine surgery.

Results

No orthopaedic or spinal surgery studies assessed the risk of SSI between reusable or disposable drapes. However, two articles, with conflicting results, compared current reusable and disposable drapes in other surgical disciplines.

Conclusion

There is no evidence to support a difference between reusable or disposable drapes to reduce the risk of SSI in orthopaedic and spinal surgery.

Manuscript

Introduction

Surgical site infection (SSI) is a potentially devastating complication of orthopaedic and spinal surgery. Typically in uninstrumented, procedures aggressive bacterial infections may ensue; however, in the presence of metalware even less virulent, slow growing pathogens may cause periprosthetic infections (PPI). This makes orthopaedic and spinal surgery, with the use of implants, particularly susceptible to infection complications.

The route by which these pathogens gain entrance into the wound remains unclear. However, one potentially controllable route is direct contamination during the procedure from the surrounding surgical field. The purpose of surgical drapes is to act as a barrier to external sources of contamination and the use of drapes is now routine [(1)].

Broadly, there are two types of surgical drape: reusable or disposable. Reusable drapes are made of a woven material and are laundered and sterilised between procedures. In contrast, disposable drapes are usually made of non-woven material and are incinerated after each operation. It remains unclear which drape type is superior at preventing a SSI and, internationally, this has resulted in a lack of consensus on which drapes to use, despite attempts to develop guidelines [(2)].

Previous studies have evaluated bacterial permeability of drape fabric as a surrogate indicator of potential wound contamination and SSI [3]. Although multiple techniques have been used for permeability data, Blom and colleagues introduced the most widely accepted technique to show that there is increased bacterial permeability of wet reusable drapes as opposed to disposable drapes [3, 4]. The same first author also subsequently showed that no drape (reusable or disposable) is impenetrable to bacteria, but that different brands were better at prolonging the time until bacterial penetration occurred [5].

Ha'eri and colleagues used a different technique to assess drape function. In their study they used technetium-labelled human albumin spheres (HAS) to mimic microbe sized micro-particles and applied these to 80 patients and surgeons prior to undergoing a multitude of different orthopaedic procedures [6]. They found contamination of all wounds with reusable woven fabric, but none with disposable non-woven fabric. Unfortunately, despite their novel approach, and like many studies, they combined surgical drapes and gowns rather than specifically assessing drapes.

Others have ignored the specific transmission of pathogens through the drape and rather assessed the bacterial colonisation of the surgical field with time depending on the type of drape used [7, 8]. This technique is clearly limited by a lack of understanding of the source of the bacteria, but is useful as it provides the clinically important value of surgical field contamination. Unfortunately, there are conflicting results regarding the efficacy of disposable or reusable drapes on reducing surgical field contamination [7, 8].

Despite the study designs assessing bacterial permeability or surgical field contamination having scientifically plausible rationales to assess for subsequent SSI, there remains no direct clinical evidence to support this hypothesis. In fact, paradoxically, these results often provide conflicting results to those of SSI in studies that have assessed both [(9)].

This suggests that although pathogens may breach the physical barriers we utilise during surgery, alternative sources of pathogens remain the predominant causes of SSI. Most notably would be the patient's skin, which can be partially occluded by adhesive plastic dressings, or more importantly the skin edges of the incision which harbour pathogens unable to be cleared by pre-operative antibiotics or standard skin preparation or occluded by adhesive plastics [(10-20)]. Alternative sources of bacteria include the surgical team, the instruments, the air or the adjunctive equipment such as the c-arm, microscope or robot [(21-28)]. The Cochrane review of randomised controlled trials by Webster and Alghamdi examined whether plastic adhesive drapes (alone or in combination with either reusable or displosable drapes) lowered the rate of infection in all types of surgery. The review showed no advantage in preventing infection in over 3082 patients studied, when using disposable and reusable drapes with adhesive drapes [(13)].

It should also be recognised that prior to the 1980s reusable surgical drapes were composed of the same fabric as standard hospital linen and it was only during the 1980s that advanced barrier protection become available [(29)]. Furthermore, basic standards for drapes were introduced, at least in Europe, in the late 1990s and many countries continue without such standards [(30)]. Thus, studies assessing the function of drapes prior to these advancements are of limited use for comparing the value of current reusable draping systems [29, 31]. However, recent reviews fail to recognise this fact and continue to focus on the early studies to support the use of disposable fabrics over reusable alternatives [32].

In addition, it should be recognised that for both reusable and disposable drapes there are significant variations in the design and performance dependent on the manufacturer and products used [5, 33]. Thus, an over-arching comparison between reusable and disposable drapes is elementary and subset analysis and review of specific drapes are necessary.

The purpose of this study specifically reviews the current published literature to determine the optimal drape to use in order to reduce the risk of SSI in orthopaedic and spinal surgery.

Methods

We conducted this review in accordance with PRISMA guidelines [34]. We included journal articles, communications and conference proceedings. Observational studies (prospective cohort, nested case-control, or case-control, retrospective cohort), case series, non-randomised studies, and randomised controlled trials (RCTs) were searched in PUBMED, MEDLINE, Web of Science, EMBASE, Google Scholar, the Cochrane Library, and reference lists of relevant studies from inception to 23 January 2018. The computer-based searches combined free and MeSH search terms and combination of key words related to the intervention (e.g. “drapes”); population (e.g.,“orthopaedics”, “joint arthroplasty”) and (e.g. “surgical site infection”, “periprosthetic joint infection”, “infection”). Only articles published in English were considered and were restricted to humans. Reference lists of relevant articles were manually scanned for additional studies likely to have been missed by the electronic search. The search strategy as applied in MEDLINE is shown in Appendix 1.

Study Selection

Our PICOS criteria were: patients receiving orthopaedic or spinal surgery; intervention relating to use of surgical drape materials; comparison relating to use of an alternative drape material; outcome of infection; in any empirical study design. We excluded studies (i) that did not specifically assess surgical site infection following operative intervention; (ii) assessing skin incision drapes, as these are only disposable; and (iii) that reported surgical procedures not performed by orthopaedic or spinal surgeons. We did not utilise a minimum follow-up as an exclusion criterion.

Data screening and extraction

One reviewer performed the initial screening of titles and abstracts to retrieve potentially relevant articles. Detailed evaluation of the full texts of these relevant articles was conducted to determine whether they met all inclusion criteria and two reviewers conducted this independently.

Results

Searches identified 677 articles. After exclusion criteria were implemented there were no articles identified that assessed SSI or PPI in orthopaedic or spinal procedures related to the use of a specific drape or drape type. Thus, we summarise results from seven non-orthopaedic or spinal surgery studies identified within the search criteria, five of which utilised old linen drapes.

In 1980, during the introduction of disposable drapes, Baldwin and colleagues found a lower rate of SSI (1.11% vs 0.46%) when they converted from reusable to disposable drapes in their prospective study of 6388 patients [(35)]. At a similar time, Belkin and colleagues found a small reduction in SSI from 6% to 5% when using disposable drapes in their prospective crossover trial of 4362 patients undergoing a multitude of different procedures [(36)]. Moylan and colleagues conducted two further studies at a similar time. The first reviewed 2253 general surgical procedures where either a reusable woven fabric or a disposable non-woven fabric was used and identified a lower rate of SSI from 6.4% to 2.3% (p<0.001) [(37)]. In clean wounds the rate was 4.4% and 2.0 % (p<0.001) and in clean-contaminated wounds from the rate was 10.9% to 2.1% (p<0.001) respectively [(37)]. The second assessed 2181 general surgical procedures and found a similar result, with a lower rate of SSI (6.5% vs 2.8%) in disposable drapes, which was reproduced in clean (3.8% reusable vs 1.8% disposable) and clean contaminated (11.4% reusable vs 4.8% disposable) wounds [(38)]. However, the author acknowledged that these results needed to be validated in control trials [(39)]. Interestingly, when these findings were attempted to be validated by Garibaldi and colleagues in a randomised control trial of 494 patients undergoing general surgical procedures, there was no difference in SSI (2.2% for both) according to the drape type used with a minimum of seven days follow-up [(40)]. Furthermore, these studies all used old hospital linen type reusable drapes and their bacterial permeability was not validated.

More recently, Bellchambers and colleagues conducted a RCT in 505 patients undergoing coronary artery surgery with a three month wound follow-up and found no difference in the sternal (5.1% reusable vs 5.2% disposable p=0.87) or leg wound (14.4% reusable vs 11.5% disposable p=0.78) infection rate between reusable and disposable drapes [41].

Subsequently, Showalter and colleagues performed a single blinded RCT of reusable versus disposable draping material in implant-based breast reconstruction and found a significant reduction (12% reusable vs 0% disposable p=0.012) in a 30 day SSI with disposable drapes [9]. However, the conflicting contamination results, which suggested there was no difference between the groups, complicated their final findings.

The study characteristics of these two recent articles are shown in table 1 as these have used currently available reusable drapes.

Table 1. Study characteristics of the only articles comparing currently available reusable and disposable drapes.

Discussion

This review has revealed the paucity of data on the optimal draping system, which should be used for orthopaedic and spinal surgery. We can therefore not offer an answer as to which specific drape, or even which drape type (reusable or disposable), should be used.

Undoubtedly, we believe that a barrier is required to prevent contamination of equipment on unsterile areas, but we feel that the quantitative benefit of drapes remains poorly understood. We therefore advocate further research into this area.

In this review we excluded skin incision drapes, as these are uniformly disposable. There is debate within the literature as to whether these drapes offer any significant protection against SSI [10-17]. In addition, we did not review skin edge protection devices as these are only used in other surgical disciplines such as the wound protection devices (WPD) used in general surgery. However, there is growing evidence that the incised skin edge harbours bacteria which is not cleared by standard skin preparation or occluded by incision drapes and therefore the importance of decontaminating or occluding the skin edge requires further investigation [18-20].

While this study focussed on patient drapes, we also assessed drapes of surgical equipment, notably the C-arm, the microscope and the robot [21-24]. Again, no articles examined the effect of disposable versus reusable drapes in these circumstances. Thus, further research into this area is warranted.

In addition to the prevention of SSI there are other factors that should be considered when choosing which drape to use. These include the drape's ability to control the patient's heat loss, prevent burns and reduce radiation exposure.

If choosing a drape to control heat loss one might suspect that drapes impervious to moisture would retain body temperature by reducing evaporative heat loss, however the evidence to support this notion remains unclear [(42)]. Drapes can be selected to provide insulation, but more reliably this should be provided with additional warming such as adequate room temperature, blankets, Bair Huggers, warmed fluids etc. [(43)].

While the specific risks for burns was beyond the scope of this study, it should be recognised that drapes play a role in intra-operative burns [(44-46)]. All draping systems collect oxygen beneath the drapes, but this is of specific concern with drapes that cover the face and therefore the patient's ventilatory support, such as cervical spine or shoulder surgery [(47)]. The levels of pooled oxygen beneath the drapes can be as high as 65% and is independent of drape type. However, the leakage of oxygen into the sterile field and thus the region of potential cautery ignition is higher with more permeable woven reusable fabrics [(46)].

While radiation reducing surgical drapes are now routinely available and have been shown to successfully reduce the radiation exposure of staff, these have been primarily used by radiologists and not adopted by orthopaedic or spinal surgeons [(48, 49)].

With the current economic climate stretching resources globally, it is also worth considering the cost of equipment, including drapes. Disposable surgical drapes cost relatively more than reusable drapes and, as our review has not clearly shown benefit over reusable drapes, there remains economic debate over the use of disposable drapes [(33, 50)]. Other authors have provided economic arguments to support the use of disposable drapes, but ultimately these models all rely on a reduced SSI rate which remains unproven [(33)]. Only after an accurate understanding of the SSI risks observed between drapes, can these models offer enlightenment on the cost-benefit of a specific drape.

Another growing concern is the ecological effect of disposable drapes. It is now becoming clear that reusable products, including surgical drapes reduce our ecological footprint [(51-54)]. Consideration should therefore be given to the ecological effect of surgical drapes in the future.

Currently, there are developing technologies guided towards improving drapes, including the addition of antibacterial finishing or fabric reinforcement products that can be added to drapes, which may reduce SSI [(29)]. Future analysis of the clinical effects of these technologies needs to be performed prior to their routine implementation.

This systematic review is clearly limited by the limitations of the absence of studies conducted on the topic. We only assessed SSI rates rather than wound contamination results because of the discrepancy between wound contamination data and subsequent risks of SSI [(9)]. We only searched for articles published in English.

However, this review has shown the authors the multitude of surgical drapes currently available, despite a lack of evidence to support one over another. Future studies should evaluate specific drapes in order to start understanding which drapes offers significant advantages over others [5, 33]. Furthermore, in the case of reusable drapes, laundering can affect the barrier properties of the drape and therefore an accurate understanding or established standards of testing laundered drapes is necessary [29, 55]. Similarly, we believe a consensus on the testing technique of drapes is necessary to ensure a comparable result [56]. Lastly, in procedures with retained implants we believe it is also important to assess the risk of septic implant loosening from slow growing innocuous bacteria rather than focussing on acute SSI.

In conclusion, due to the paucity of literature assessing the risk of SSI relative to the surgical drape used in all surgical disciplines including orthopaedics and spinal surgery, it is not possible to determine which drape or drape type is superior at preventing SSI. Future studies are necessary to assess currently used drapes in order to determine which drape is best used.

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Table 1. Study characteristics

Author **Country, Recruitment date** **Study type/ Level of evidence**	**Indication** **Number of patients**	**Drapes compared**	**Results** **Evidence of infection** **Risk/ safety**	**Risk of bias**
Bellchambers et al. 1999 (40) UK, 1995-1996 RCT/ 1	Coronary artery surgery 505	Reusable vs disposable	Sternal (5.1% reusable vs 5.2% disposable, p=0.87) Leg wound (14.4% reusable vs 11.5% disposable, p=0.78) No information	Low
Showalter et al. 2014 (9) USA, 2010-2012 RCT/ 1	Breast reconstruction 102	Reusable vs disposable	12% reusable vs 0% disposable, p=0.012 No information	Low

Table 2. Risk of bias assessment

	Bellchambers et al. 1999 (40)	Showalter et al. 2014 (9)
Sequence generation	Low (computer generated)	Unclear: not described
Allocation concealment	Low (sealed envelopes)	Unclear: not described
Blinding of participants, personnel and outcome assessors	Low (blind assessment)	Low. Patients blinded
Incomplete outcome data	Low (overall 92% follow up)	Low (overall 95% follow up)
Selective outcome reporting	Low (none apparent)	Low (none apparent)
Other sources of bias	Low (some differences between groups in co-morbidities)	Low. Groups similar at baseline

Appendix 1

Search terms as applied in MEDLINE.

1. drape.mp. or Surgical Drapes/
2. (opsite or steridrape or ioban).tw.
3. 1 or 2
4. Surgical Wound Infection.mp. or Surgical Wound Infection/
5. Surgical Wound Dehiscence.mp. or Surgical Wound Dehiscence/
6. (surg* adj5 infection*).tw.
7. (surg* adj5 wound*).tw.
8. (surg* adj5 site*).tw.
9. (surg* adj5 incision*).tw.
10. (surg* adj5 dehisc*).tw.
11. (wound* adj5 dehisc*).tw.
12. wound complication*.tw.
13. Infection Control.mp. or Infection Control/
14. or/4-13
15. 3 and 14