ORIGINAL ARTICLE

A double-blinded randomized controlled trial of incise-drapes in spine surgery: A feasibility study

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ABSTRACT

Background: The use of an incise-drape, or plastic adhesive drape (PAD), to prevent surgical site infection is controversial with conflicting results in the existing literature. Testing the efficacy of PADs with traditional tissue cultures is expensive and invasive. With surgical site infection rates commonly below 5-10%, very large numbers would be required to assess this outcome. Through a double-blinded, randomized controlled trial (RCT), we investigated the feasibility of a novel, inexpensive, low-risk swabbing method to determine the effect of PADs on bacterial colony-forming-units (CFU) during elective spinal surgery.

Methods: Over 10 weeks, n=15 blinded elective spine patients were randomly assigned to iodine impregnated PAD versus no PAD. Bacterial CFUs per unit incision length were determined. A blinded team member collected surface specimens using flocked swabs on wounds at post-operation day (POD)-0 and POD-3 using a standardized technique. Specimens were plated for bacterial CFUs on blood and chocolate agar in triplicate serial dilutions. CFUs were manually counted. Secondary outcome measures included bacterial speciation and sample size calculations for future studies.

Results: There were no significant differences between groups in baseline characteristics. There was 100% recruitment rate, and complete adherence to the study protocol. With the numbers available, we were unable to detect differences in CFU counts between groups. There were no surgical site infections in either group at follow-up. Our new methodology using flocked swabs was feasible as a research tool and reliably yielded quantitative results for bacterial contamination of surgical incisions. PAD efficacy was not demonstrated in this pilot study.

Conclusions: Our findings via a double-blinded RCT demonstrated the feasibility of employing flocked swabs as a non-invasive tool for assessing surgical incision bacterial contamination. This tool can be used as a surrogate measure to assess the efficacy of interventions such as PADs for future research.

KEY WORDS:

Adhesive drapes, surgery, incise drapes, surgical site infection, feasibility, swab

INTRODUCTION

Surgical site infections (SSIs) are a major cause of morbidity and mortality amongst surgical patients. As a consequence, advances in medical and surgical knowledge and technology have led to necessary changes in peri-operative practices including prophylactic antibiotics, patient skin preparation, aseptic technique, surgical protective equipment and postoperative wound care.

Despite the intended dedication to practicing evidence-based medicine, some common practices continue without convincing evidence for reducing SSI risk. In particular, the use of a plastic adhesive drape (PAD) – with or without impregnated iodine products – has been a controversial topic for decades. Some studies have shown that the use of a PAD on the surgical site reduced the number of positive wound cultures

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postoperatively (1-3). This is concordant with other studies that have shown that PADs reduced migration of bacteria from the skin surface to the wound, are impermeable to bacteria, and are superior to cloth drapes (4,5). However, other studies have shown no improvement in SSI risk when comparing PADs to no drape at all (6-9). Additionally, a Cochrane systematic review including over 4,000 patients across seven published trials indicated that the use of a PAD without impregnated antibacterial agents (e.g., iodine) may increase SSIs, and that PADs with impregnated iodine showed no superiority compared to not using a PAD (10).

Given the conflicting findings, it is unclear why this discrepancy exists. To our knowledge, there have been no recent studies evaluating the effect of PADs on the bioburden of surgical wounds as reflected by colony-forming-unit (CFU) counts. Knowledge of this information may further elucidate the mechanism by which a reduction in positive wound cultures is observed.

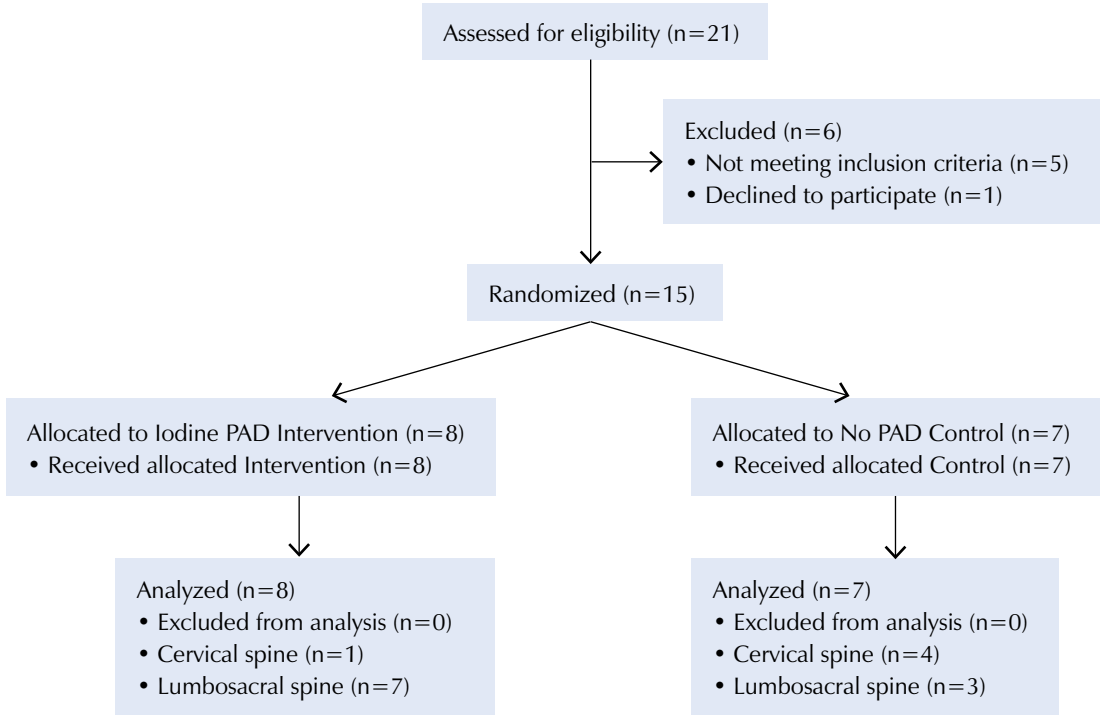
Spine patients suffer SSIs more frequently than other orthopaedic patients; estimates suggest a rate of occurrence from 1.9% to 4.4% (11). Thus, we decided to study spine patients undergoing elective cervical, thoracic, and lumbosacral spinal surgery. The primary objective was to assess the feasibility and practicality of our novel and inexpensive measurement technique and to perform sample size calculations in preparation for a larger trial, with the ultimate goal of possibly replacing the invasive gold standard of tissue culture with our noninvasive technique. Secondary objectives included: a) evaluating the effect of PADs on CFU counts of surgical wounds on post-operative days zero and three; b) determining if PADs affected the percentage of positive swabs obtained; and c) verifying which bacterial species could be isolated.

METHODS

Patient recruitment

A prospective, double-blinded, randomized controlled trial was performed over 10 weeks in 2013-2014 at a single centre tertiary academic hospital (January 28-March 10, 2014; June 3-June 30, 2014). During this time frame, all consecutive inpatient elective spinal surgery cases were screened for recruitment from within the practices of three fellowship-trained adult spinal surgeons. Recommendations set out in the CONsolidated Standards of Reporting Trials (CONSORT) Statement were followed in the study design (12). Elective adult spine surgery patients aged 18 years and over requiring post-operative inpatient admission of at least three days were eligible for inclusion. Patients were excluded if they met any of the following criteria: known iodine or adhesive allergy; active skin or soft tissue infections at the surgical site; undergoing surgery for fractures and tumours; refused participation. Ethics approval was granted by the Institutional Research Ethics Board. A random number generator was used to generate the random allocation sequence. Patients were blinded to their randomization. Figure 1 outlines the flow of patient recruitment in the study.

FIGURE 1: CONSORT (Consolidated Standards of Reporting Trials) diagram illustrating patient flow through the protocol



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Study protocol

Patients with hair at the surgical site were clipped with an electric clipper. All patients received a skin scrub with a 4% chlorhexidine gluconate brush followed by a wipe dry with a clean towel. Skin preparation was then performed with a sponge impregnated with chlorhexidine gluconate 2% and isopropyl alcohol 70% followed by a three-minute drying time. Standard operating room draping was performed with impermeable sterilized cloth drapes around the surgical site. Patients randomized to the PAD group had the 3M Ioban 2 PAD applied to the surgical site. The PAD covered all exposed skin within the surgical field. Perioperative antibiotics (i.e., weight-adjusted dosing of Cefazolin or Vancomycin) were administered prior to skin incision, at the four-hour intra-operative mark, and for 24 hours postoperatively.

At the end of surgery after skin closure, the PAD was removed and surgical site wiped dry with a sterile gauze sponge. At this point, a research team member blinded to the randomization was called into the operating theatre to collect the specimens from the closed incision. A flocked swab (Copan Diagnostics eSwab) was used to stroke a 5cm length of incision five times. This was repeated with two additional swabs on different 5cm segments of incision. All swabs were then immersed in the supplied 1mL of liquid Amies transport medium and transported to the laboratory within two hours of collection. Sterile dressing applied in the operating room consisted of a non-adherent layer against the skin followed by an absorbent layer, and then secured with adhesive tape occluding all sides of the wound. Specimen collection was repeated by the same blinded team member using the same protocol on POD-3, during the patients' first routine dressing change on the orthopaedic ward.

Laboratory protocol and measurement technique

The blinded team member performed all of the laboratory processing of the specimens. Each swab was vortexed in its transport medium to completely elute the bacteria. Then 10uL and 100uL aliquots were directly inoculated via micropipettor onto two different solid media in triplicate: tryptone soya agar with 5% sheep blood (Oxoid tryptone soya agar with 5% sheep blood) and chocolate blood agar (Oxoid chocolate agar enriched). All plates were streaked for enumeration with a 10uL wire loop using standard aseptic technique and incubated at 35°C in 5% CO_2 for 48 hours. Colonies were then counted manually. Phenotypically different colonies were isolated and streaked again for isolation onto tryptone soya agar with 5% sheep blood in preparation for speciation. Utilizing a MALDI TOF (matrix-assisted laser desorption ionization – time of flight) mass spectrometer (Bruker MALDI Biotyper), all subcultured colonies were prepared as per the manufacturer's instructions and analyzed by the device, generating the most probable species match.

Colony counts were converted into colonies per unit length of incision swabbed expressed as a number of colony-forming-units per centimetre (CFU/cm). The percentage of swabs showing any bacterial growth was also noted. CFU counts were selected as a surrogate outcome measure to directly evaluate the ability of the PAD to reduce surface bacterial contamination irrespective of the ultimate clinical outcome of SSI.

Statistical analysis

Demographics and risk factor assessment was done by a combination of questionnaire and chart review for all participants based on previously published risk factors in the literature (11). Student's T-test of Fisher's Exact Test was used to compare baseline characteristics and SSI risk factors between groups. Fisher's Exact Test was used to compare the proportion of positive cultures between groups. As there was significant skewing of the CFU counts, a Mann-Whitney U test was used to test the null hypothesis that the two groups came from the same population.

TABLE 1: Baseline characteristics and SSI risk factors

Variable	No PAD (n=7)	With PAD (n=8)	P-value
Age (years ± SD)	62.1 ± 11.1	61.5 ± 8.9	0.90
Male Gender (%)	42.9	37.5	1.00
BMI (kg/m^2 ± SD)	30.7 ± 9.0	25.2 ± 5.0	0.23
Lumbar Surgery (%)	42.9	87.5	0.12
Posterior Approach (%)	71.2	87.5	0.56
Surgery Duration (minutes ± SD)	341.5 ± 148.9	279.1 ± 109.6	0.37
Incision Length (cm ± SD)	11.4 ± 5.6	11.5 ± 4.1	0.98
Diabetes (%)	28.6	25.0	1.00
Smoker (%)	0	12.5	1.00
Medical Comorbidities (Total n ± SD)	2.4 ± 1.4	2.4 ± 2.7	0.96

BMI: body mass index; PAD: plastic adhesive drape; SSI: surgical site infections

TABLE 2: Medical comorbidities			
Medical condition	**No PAD (n=7)**	**With PAD (n=8)**	**P-value**
Type 1 diabetes	0	12.5	1.0
Type 2 diabetes	28.6	12.5	0.57
COPD	0	0	1.0
Hypertension	85.7	37.5	0.12
Previous MI	0	0	1.0
Angina	0	25	0.47
Hypercholesterolemia	42.9	37.5	1.0
Osteopenia	0	12.5	1.0
Osteoporosis	28.6	25	1.0
Rheumatoid arthritis	0	12.5	1.0
OSA	0	0	1.0
Insulin use	0	12.5	1.0
CHF	0	0	1.0

* Values indicate percentage of patients (%).
COPD: chronic obstructive pulmonary disorder; MI: myocardial infarction;
OSA: obstructive sleep apnea; CHF: coronary heart failure

RESULTS

A total of 15 patients were included (with PAD: n=8; no PAD: n=7). There were no significant differences between the two groups in terms of baseline demographics and SSI risk factors (Table 1). The control group (i.e., no PAD) trended towards having a higher BMI and greater numbers of cervical spine surgery (P>0.05). One patient had previous radiation to the surgical site in the control group. No patients had previous SSIs. Medical comorbidities were highly diverse among this spine population and for the purposes of analysis, were simplified to a quantity of different diagnoses for each patient; a detailed breakdown is provided in Table 2.

On POD-0, five of the eight operative sites demonstrated positive cultures in at least one medium in the PAD group, compared to five of the seven operative sites in the no-PAD group (p=1.0). On POD-3, seven of the eight operative sites demonstrated positive cultures in at least one medium in the PAD group, compared to five of the seven operative sites in the no-PAD group (p=0.57). With the data available, we were unable to detect any significant between-group differences in terms of median colony counts per unit length of incision swabbed on POD-0 and POD-3 on either growth medium (Table 3). The percentage of swabs showing bacterial growth was also not significantly different when compared for each growth medium. Isolated bacterial species determined by mass spectrometry are shown in Table 4.

Post-hoc power analysis demonstrated that with the observed 71% baseline contamination rate (i.e. chocolate agar results without PAD) and the following assumptions: alpha=0.05, power=0.80, n=28 subjects per group would be required to demonstrate a 50% reduction in contamination, and n=114 subjects per group would be required to demonstrate a 25% reduction in contamination rates (13).

DISCUSSION

Our novel measurement technique employed flocked swabs as a key instrument. These are commercially designed to elute all bacteria from its swab tip into the transport medium once immersed and vortexed. Although designed for other laboratory purposes, we harnessed this property for quantitative analysis of bacteria collected from surgical incisions. Used in conjunction with a standardized swabbing protocol performed by the same blinded team member for every patient, we maximized the consistency of the samples and the reliability of the results. Importantly, this technique is much more cost-effective and minimally invasive than the current gold standard of tissue cultures for bacterial enumeration. There is virtually no foreseeable risk or morbidity to the patient from collecting a sample from a closed incision using a sterile swab, compared to surgically excising a tissue sample. Our novel measurement technique yielded reliable quantitative results, indicating that it is a technically feasible method as well. Because data has not been collected previously using this technique, we caution against interpreting the colony counts at face value as they may not reflect the true bioburden. However, with the consistency observed, it is reasonable to use the colony counts for relative comparison to one another.

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TABLE 3: Wound bacterial load results				
Post-Operative Day-0		**No PAD**	**With PAD**	**P value**
Blood Agar	% Positive culture	42.9	50	1.0
	Median CFU/cm (range)	0 (0-7.69)	0.04 (0-4.18)	>0.2
	Mean CFU/cm ± SD	1.17 ± 2.88	0.68 ± 1.55	0.70
Chocolate Agar	% Positive culture	57.1	62.5	1.0
	Median CFU/cm (range)	0.06 (0-7.51)	0.09 (0-4.8)	>0.2
	Mean CFU/cm ± SD	1.18 ± 2.80	0.81 ± 1.77	0.77
Post-Operative Day-3		**No PAD**	**With PAD**	**P**
Blood Agar	% Positive culture	57.1	50	1.0
	Median CFU/cm (range)	0.08 (0-1.87)	0.22 (0-4.53)	>0.2
	Mean CFU/cm ± SD	0.37 ± 0.74	0.82 ± 1.55	0.48
Chocolate Agar	% Positive culture	71.4	75	1.0
	Median CFU/cm (range)	0.04 (0-2.22)	0.04 (0-4.56)	>0.2
	Mean CFU/cm ± SD	0.41 ± 0.89	0.80 ± 1.51	0.56

PAD: plastic adhesive drape; CFU: colony forming units

Two different growth media for bacterial culture were selected for use in our study: tryptone soya agar with 5% sheep blood (BA), and chocolate blood agar (CA). BA is widely used in the medical microbiological setting as a general-purpose differential medium suitable for growth of pathogenic aerobes and anaerobes (14). CA was selected to allow growth of less common fastidious organisms sometimes implicated in SSI, such as *Neisseria* and *Haemophilus* species (14). Mass spectrometry for bacterial speciation, the current technique used at our institution, only takes a few minutes for dozens of samples to be analyzed, and is very inexpensive per use.

Skin antisepsis agents such as chlorhexidine are designed to eliminate the organisms on the skin surface to create a sterile field. However, the duration of effect varies depending on the product, and over time the skin will recolonize with the bacteria within the deeper layers of skin and hair follicles originally missed by the antisepsis (5). For this reason, we elected to collect a post-operative day three specimen at the first routine dressing change. At this point, enough time has elapsed such that normal flora will be able to recolonize the skin, and the dressing will not have been opened prior to this point. This strategy also allowed us to remain consistent with our current post-operative protocol so as to not deviate from the standard of care.

Our results did not demonstrate statistical difference intra-operatively between PAD use and no PAD use, both in terms of colony counts and percentage of positive swabs. Thus, there is no evidence supporting the use of a PAD for the purpose of bacterial load reduction at the surgical site, and the theoretical benefit of reducing contamination at the skin under the PAD was also not observed. Note that the power analysis demonstrated an insufficient sample size to show a meaningful difference in contamination rates, and thus these results are underpowered. However, our results are in alignment with the previous inconsistent findings in the literature, in that there are studies which do not show any change in positive wound culture incidence (15,16). A more recent study showed an increase in positive wound swabs with the use of PADs in hip fracture surgery (17) without a change in SSI rate, while others showed a beneficial effect on SSIs (4,5,18,19). A recent large review of anterior cervical discectomy and fusion patients observed no SSIs (20).

TABLE 4: Bacterial species isolated using novel technique	
No PAD	**With PAD**
Acinetobacter radioresistens	*Bacillus thuringiensis*
Bacillus thuringiensis	*Moroxella osloensis*
Kocuria kristinae	*Pseudomonas luteola*
Micrococcus luteus	*Staphylococcus capitis*
Rothia amarae	*Staphylococcus epidermidis*
Staphylococcus capitis	*Staphylococcus hominis*
Staphylococcus epidermidis	*Streptococcus oralis*

One must question if demonstrating a statistically significant difference in contamination rates or colony counts is sufficient to demonstrate any clinical relevance. For this reason, some authors advocate using SSI as an endpoint rather than colony counts (10,21). However, given baseline SSI rates of 2-4%, substantially more patients would be required to adequate power a study (13).

A recent Cochrane review (10) including over 3,000 patients with regular PADs and over 1,000 patients with iodine-impregnated PADs indicated an increase in SSIs with the use of regular PADs and equivalency of iodine-impregnated PADs to no PADs. However, the quality of the included studies was limited for several reasons: i) The studies spanned all surgical disciplines and were published over a long time period (1977-2002) during which there have been countless advances in surgical technique; ii) The studies were reported to be at high risk of bias from poor blinding and unclear randomization strategies, which may explain why both regular and iodine-impregnated PADs are still frequently used in surgery today. Therefore, a well-designed randomized controlled trial of adequate power may be necessary to prove or disprove the use of PADs. Employing CFU counts as an outcome measure can directly evaluate the ability of the PADs to reduce bacterial load at surgical sites, although future studies would benefit from measuring both clinical SSIs and CFU counts simultaneously as demonstrating reduction in bacterial load in isolation is unlikely to change practice.

There is a paucity of literature directly linking SSI rates to CFU counts. As it stands, the concept of increased bacterial quantity yielding higher risk of SSI is controversial but there exists evidence supporting it (22-24). Among microbiological literature, pathogens have an infective dose, defined as the number of pathogen cells required to infect a host (25). These doses are determined largely by epidemiological studies, outbreak data, and studies on healthy human volunteers. The infective dose varies depending on organism, host factors and route of infection (25). It does suggest though that infection is a dose-dependent phenomenon. Given the low basal rate of SSI and the large number of study participants required to demonstrate even a small change, using CFU counts as a surrogate measure of SSI risk remains common practice. Reduction of contamination at the wound site immediately after surgery may be a useful surrogate in addition to a worthy goal with regards to reducing wound infection rates. Studies evaluating this outcome would likely be easier to conduct and moreover important to pilot before considering studies evaluating actual infection rates given the large number of patients per group that would be required to show a 50% reduction.

The use of a PAD in surgery is fraught with practical issues. They can restrict motion of the surgical limb, adhere to unwanted objects, and potentially create plastic debris that can unknowingly remain within surgical incisions (and are invisible to radiographs). They often peel back at the incision edges as the surgical case progresses due to prolonged retraction of the skin. It is rare for a PAD to remain completely adhered to the skin and incision edges for the entire duration of the surgical case. Unfortunately, lifting off of the incise drape has been reported to increase the infection rate by six-fold (26). Another study suggested that using Duraprep can decrease the probability of the incise drape lifting (27). Current infection control guidelines from the American Centres for Disease Control do not make specific recommendations regarding the use of PADs (28).

Notably absent in our findings is the lack of detection of *Staphylococcus aureus*, one of the most commonly implicated bacterium in SSIs. Given the small sample size, this is not surprising as the rate of colonization in the general population is between 25%-40% in the literature (29). Coagulase negative *Staphylococcus* species such as *S. epidermidis* was found, and these organisms are also common culprits in SSI while also being highly prevalent in normal human skin flora.

One limitation of this study is that the use of this novel measurement technique to detect CFUs may not be representative of the true bacterial load compared to the current standard. Although we demonstrated that our novel technique is feasibly performed and can produce reliable results, we do not have comparison data to the gold standard of tissue cultures, and thus cannot draw conclusions regarding its accuracy in detecting bacterial contamination. However, this can be addressed in a future larger, adequately powered study that also includes a simultaneous comparison of flocked swabbing to tissue culture results. Another limitation is the use of bacterial load as a surrogate measure for clinical infection. The evidence linking bacterial contamination to confirmed infection is controversial, and our methodology may not directly translate to clinical utility. In addition, the small sample size and inadequate power means we cannot draw conclusions regarding the efficacy of PADs.

CONCLUSIONS

Our study demonstrates feasibility of study design. We successfully carried out a randomized double-blinded surgical trial with a novel low-cost and low-risk methodology to quantitatively analyze bacterial burden at surgical sites. We cannot recommend for or against the use of a PAD for the purposes of SSI reduction in elective spine surgery cases. However, we were able to determine the necessary sample size for future studies. Further research is required to increase our understanding of PADs and a detailed cost-analysis is necessary to determine overall cost-efficacy. Future investigations of the utility of PADs would benefit from measuring the outcomes of clinical infection as well as bacterial load via the gold standard of tissue culture.

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