

Postoperative Orthopedic Wound Dressing Using Sterile Versus Clean Non-Sterile Technique: A Prospective Randomized Pilot Study

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Abstract

Background:

Surgical site infections (SSIs) remain a clinically relevant postoperative complication in orthopedic surgery. However, there is no clear consensus regarding whether sterile or clean non-sterile dressing techniques reduce SSI risk following low-risk elective orthopedic procedures such as knee arthroscopy, ACL reconstruction, or simple isolated fracture fixation.

Objective:

To compare the incidence of acute SSIs within six weeks following elective orthopedic procedures when postoperative dressings are applied using sterile versus clean non-sterile gloves for dressing application.

Methods:

This prospective randomized pilot study was conducted at a tertiary orthopedic center. Adult patients undergoing elective knee arthroscopy, ACL reconstruction, or isolated simple fracture fixation were randomized to postoperative dressing changes using either sterile or clean non-sterile gloves. Dressing changes were performed on postoperative day five and wounds were assessed at two and six weeks. SSIs were defined as erythema extending > 1 cm from the incision, edema, or purulent discharge requiring antibiotic therapy or surgical intervention.

Results:

Twenty-five patients were enrolled (13 sterile group, 12 clean non-sterile group). The mean age was 34.6 ± 9.8 years and the mean body mass index was 27.1 ± 3.4 kg/m². No clinically significant surgical site infection were observed in either group during the six-week follow-up period (0/13 vs. 0/12; $p = 1.000$). No adverse events, reoperations, or hospital readmissions were recorded. All dressing changes were well tolerated, with no complications attributed to the assigned technique.

Conclusion:

In this pilot study, clean non-sterile gloves appeared to be a safe and potentially cost-effective alternative to sterile gloves for postoperative wound care in selected elective orthopedic procedures. Larger studies are required to confirm these preliminary findings.

Level of evidence:

Level II Prospective randomized pilot trial

1. Introduction

Surgical site infections (SSIs) remain among the most significant postoperative complications in orthopedic surgery, contributing to increased morbidity, prolonged hospitalisation, and higher healthcare costs [1]. The Centers for Disease Control and Prevention (CDC) defines SSIs as infections occurring within 30 days post-surgery for superficial cases, or up to 12 months for deep infections involving implants [2].

Despite improvements in surgical technique, antibiotic prophylaxis, and perioperative care, there remains no consensus regarding the optimal method for postoperative wound dressing in orthopedic surgery, particularly concerning the use of sterile versus clean non-sterile techniques [3]. Sterile dressing techniques require sterile gloves and equipment, whereas clean non-sterile techniques utilise clean gloves while maintaining standard aseptic principles, potentially reducing cost and resource utilisation [4, 5].

Previous studies in dermatologic, emergency, and minor surgical settings have demonstrated no significant difference in SSI rates between sterile and clean techniques, suggesting possible non-inferiority of clean glove use in selected settings [6]. However, data specific to orthopedic surgery remain limited.

Elective orthopedic procedures such as knee arthroscopy, ACL reconstruction, and simple fracture fixation have a low baseline infection risk, typically < 1% [7, 8]. However, no randomized trials have specifically evaluated postoperative dressing techniques in this population [3, 9, 10].

The present study was therefore designed as a prospective randomized pilot trial to compare the incidence of clinically significant acute SSIs within six weeks following elective orthopedic surgery using sterile versus clean non-sterile glove techniques for postoperative dressing.

The findings aim to inform institutional practice, optimize resource utilization, and provide preliminary data to support larger, definitive trials [11]

2. Materials and Methods

2.1 Study Design and Setting

This prospective, randomized, single-centre pilot study was conducted at the Orthopedic Surgery Department. The study evaluated SSI incidence within six weeks following elective orthopedic surgery when postoperative dressing changes were performed using either sterile or clean non-sterile glove techniques. Eligible procedures included knee arthroscopy, ACL reconstruction, and isolated simple fracture fixation (e.g., distal radius and simple ankle fractures).

2.2 Ethical Considerations

The study protocol was reviewed and approved by the Institutional Review Board (MRC-01-20-272). Written informed consent was obtained from all participants prior to enrollment. The trial was conducted

in accordance with the Declaration of Helsinki and applicable national regulatory standards.

2.3 Participant Selection

Adults aged 18–65 years undergoing elective knee arthroscopy, ACL reconstruction, or isolated simple fracture fixation were eligible. Inclusion criteria included ASA class I status, operative time < 2 hours, non-smoking status, and absence of previous surgical scars at the operative site. All patients received a single preoperative dose of 1 g cefazolin.

Patients were excluded if they required additional antibiotic dosing, had diabetes mellitus, BMI > 40 kg/m², immunocompromised status, prior infection at the surgical site, polytrauma, blood transfusion, revision surgery, skin disease at the operative site, or inadequate preoperative skin preparation.

2.4 Sample Size

This study was designed as an exploratory pilot trial. The sample size was not powered to detect statistical differences but to assess feasibility, adherence, and preliminary event rates. Twenty-five patients were enrolled (13 sterile group, 12 clean non-sterile group), consistent with methodological recommendations for pilot randomized trials [12–14].

2.5 Randomization and Intervention

Randomization was performed using a computer-generated sequence with sealed opaque envelopes. Dressing changes were performed using sterile gloves in the sterile group and clean non-sterile gloves in the comparative group. Sterile instruments and a sterile field were used in both groups. All dressings were applied by a single trained orthopedic nurse.

2.6 Postoperative Care and Follow-Up

The first dressing change was performed only on postoperative day five, with follow-up assessments at two and six weeks. All wounds were dressed using Mepilex® Border Flex (7.5 × 7.5 cm). Hand hygiene followed World Health Organization guidelines, and wounds were cleansed with chlorhexidine prior to dressing application. Laboratory testing including white blood cell count, C-reactive protein and wound cultures were obtained if infection was suspected.

2.7 Outcome Measures

The primary outcome was clinically significant acute SSI (Grades 2 and 3) within six weeks of surgery. SSIs were assessed using a standardized wound scoring system: grade 0 indicated no or slight erythema, grade 1 indicated erythema ≤ 1 cm from the incision line not requiring antibiotics, grade 2 indicated erythema > 1 cm with or without edema requiring systemic antibiotics, and grade 3 indicated purulent discharge with requiring surgical debridement in addition to antibiotics. Grades 2 and 3 were considered clinically significant.

Secondary outcomes included duration of hospital stay, readmission within six weeks, reoperation due to infection, postoperative antibiotic use, and a comparative cost analysis of dressing techniques.

2.8 Data Collection and Management

Data collected included demographic variables such as age, sex, and BMI, in addition to perioperative details such as procedure type, operative duration, and estimated blood loss. Information on infection-prevention measures, including MRSA decolonization, dental clearance, hair removal, and nutritional assessment, was also recorded. Data were entered into a secure, password-protected Microsoft One Drive spreadsheet and backed up locally on a departmental computer with restricted access. All patient identifiers were removed after validation.

2.9 Statistical Analysis

Statistical analysis was performed using SPSS v23.0 and Epi Info. Continuous variables were summarized as mean ± SD, and categorical variables as frequencies and percentages. Group comparisons used Fisher’s exact test or independent t-tests as appropriate. A p-value < 0.05 was considered statistically significant.

3. Results

3.1 Patient Characteristics

Twenty-five patients were randomized (Fig. 1). Baseline demographic and clinical characteristics were comparable between groups (Table 1). All patients were ASA I.

Table 1 Baseline Patient Characteristics			
Characteristic	Sterile Group (n = 13)	Clean Non-Sterile Grouo (n = 12)	P-value
Age (years)	32.4 ± 10.5	35.2 ± 8.8	0.47
BMI (kg/m²)	25.8 ± 2.9	26.0 ± 3.2	0.90
Sex (M/F)	11 / 2	12 / 0	1.00
ASA I	13 (100%)	12 (100%)	—

3.2 Primary Outcome

No clinically significant SSIs occurred in either group during follow-up (0/13 vs 0/12; p = 1.00). (Table 2).

Table 2
Clinical Outcomes

Outcomes	Sterile Group (n = 13)	Clean Non-Sterile (n = 12)	P-value
Clinically significant SSI (Grade 2–3)	0 (0%)	0 (0%)	1.00
Hospital stay (days)	1.8 ± 1.2	2.6 ± 1.6	0.16
Readmission within 6 weeks	0	0	—
Reoperation within 6 weeks	0	0	—
Postoperative antibiotics required	0	0	—

3.3 Secondary Outcomes

No readmissions, reoperations, or postoperative antibiotic requirements were observed. Mean hospital stay did not differ significantly between groups (1.8 ± 1.2 days in the sterile group compared with 2.6 ± 1.6 days in the clean non-sterile group (p = 0.16).

3.4 Feasibility Outcomes

Recruitment, protocol adherence, and follow-up were excellent, with 100% completion and no protocol deviations.

4. Discussion

This randomized pilot study demonstrated no difference in early SSI rates between sterile and clean non-sterile glove techniques for postoperative dressing following selected low-risk elective orthopedic procedures. No clinically significant infections occurred in either group during the six-week follow-up, supporting the feasibility and safety of clean glove use in this context.

Although strict sterile technique is essential intraoperatively, the necessity of maintaining full sterility for postoperative dressing changes of clean, closed wounds remains uncertain. Clean dressing protocols that incorporate appropriate hand hygiene, antiseptic wound preparation, and non-touch technique may offer comparable safety while improving efficiency and resource utilization.

These findings align with previous evidence from non-orthopedic surgical disciplines suggesting that glove sterility during postoperative dressing changes may not be the primary determinant of SSI risk when appropriate aseptic principles are maintained [15–17].

Perelman et al. randomized 816 patients with traumatic lacerations to sterile or clean non-sterile gloves and found no significant difference in infection rates (6.1% vs. 4.4%) (16). More recently, Zwaans et al. evaluated sterile versus non-sterile gloves and dressings for suturing traumatic wounds in a multicenter non-inferiority RCT and found no increased risk of SSI with non-sterile use (17). Although these trials

were non orthopedic, they collectively support the concept that glove sterility during postoperative dressing changes may not be the primary determinant of SSI risk.

In elective orthopedic surgery, SSI rates are inherently low, particularly in procedures such as knee arthroscopy, ACL reconstruction, and isolated fracture fixation. In this context, factors such as patient selection, perioperative antibiotic prophylaxis, surgical technique, and postoperative wound handling may play a greater role in infection prevention than glove sterility during dressing changes [18]. All patients in this study received standardized prophylaxis and postoperative care, minimizing confounding variables.

The primary strength of this study lies in its randomized design, standardized dressing protocol, and complete follow-up. Importantly, this pilot trial demonstrated excellent feasibility, with full protocol adherence and no loss to follow-up, supporting the practicality of conducting larger trials. Limitations include the small sample size and restriction to low-risk procedures, limiting generalizability. Furthermore, the study was not powered to establish non-inferiority.

The findings suggest that clean non-sterile glove use may represent a safe and resource-efficient alternative for postoperative wound dressing in selected orthopedic cases. Larger multicenter trials are warranted to confirm non-inferiority and evaluate cost implications. Such trials should incorporate detailed cost analyses, stratification by surgical procedure, and monitoring of patient-related risk factors to refine clinical guidelines.

In conclusion, this pilot study suggests that clean non-sterile gloves may be safely used for postoperative wound dressing in selected low-risk orthopedic procedures. Larger, adequately powered multicenter randomized trials are required to confirm these findings and to assess cost-effectiveness before changes to clinical guidelines can be recommended.

Declarations

Ethics declarations:

Conflicts of Interest

The authors have no financial or proprietary interests in any material discussed in this article.

Ethical approval

Research protocols were approved by Institutional Review Board. (Protocol number: MRC-01-20-272). The study was conducted in accordance with the Declaration of Helsinki and with all applicable national regulatory requirements.

Informed consent to participate or publication

Written informed consent was obtained from all participants prior to enrollment.

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Figures

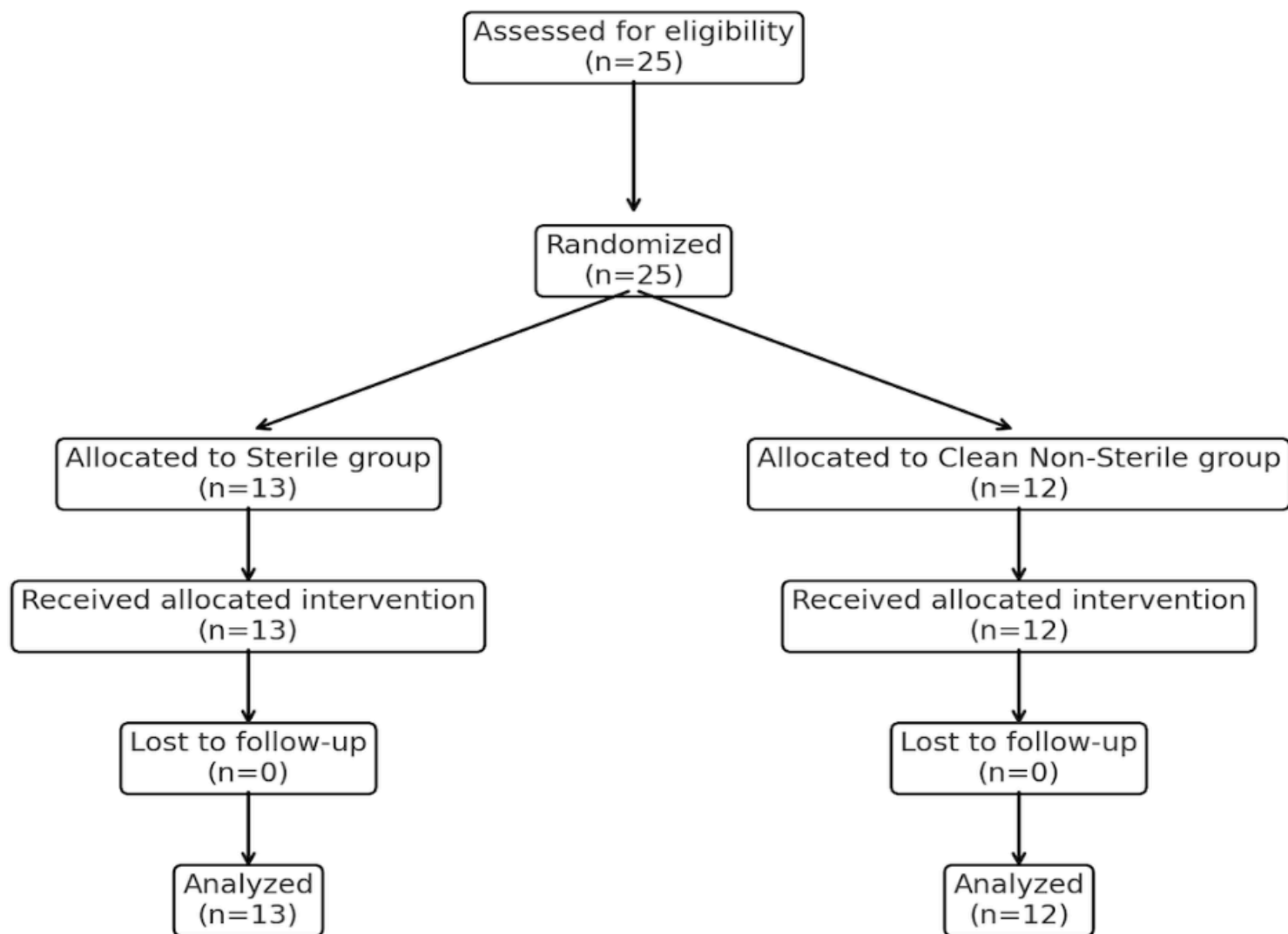


Figure 1

CONSORT flow diagram of patient enrollment, randomization, allocation, follow-up, and analysis.