Sterile Versus Nonsterile Gloves for Repair of Uncomplicated Lacerations in the Emergency Department: A Randomized Controlled Trial

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Study objective: Although sterile technique for laceration management continues to be recommended, studies supporting this practice are lacking. Using clean nonsterile gloves rather than individually packaged sterile gloves for uncomplicated wound repair in the emergency department may result in cost and time savings. This study is designed to determine whether the rate of infection after repair of uncomplicated lacerations in immunocompetent patients is comparable using clean nonsterile gloves versus sterile gloves.

Methods: A prospective multicenter trial enrolled 816 individuals who were randomized to have their wounds repaired by using sterile or clean nonsterile gloves. The attending physician or resident completed a checklist describing patient, wound, and management characteristics. The patients were provided with a questionnaire to be completed by the physician who removed their sutures at the prescribed time and indicated the presence or absence of infection. When follow-up forms were not returned, a telephone call was made to the patient to determine whether he or she had experienced any wound complications.

Results: Follow-up was obtained for 98% of the sterile gloves group and 96.6% of the clean gloves group. There was no statistically significant difference in the incidence of infection between the 2 groups. The infection rate in the sterile gloves group was 6.1% (95% confidence interval [CI] 3.8% to 8.4%) and was 4.4% in the clean gloves group (95% CI 2.4% to 6.4%). The relative risk of infection was 1.37 (95% CI 0.75 to 2.52).

Conclusion: This study demonstrated that there is no clinically important difference in infection rates between using clean nonsterile gloves and sterile gloves during the repair of uncomplicated traumatic lacerations.

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INTRODUCTION

Lacerations are a common problem treated in the emergency department (ED). Sterile technique continues to be recommended and taught as the "correct" surgical approach for treating lacerations, despite the lack of evidence to support this practice. Current practice often involves using clean nonsterile gloves during the preparatory phase and sterile gloves for the surgical repair. Adherence to strict sterile technique is

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Capsule Summary

What is already known on this topic

Sterile technique is generally used for laceration repair despite the lack of scientific evidence that it is necessary.

What question this study addressed

The infection rate of lacerations was compared in 816 patients randomized to receive repair using sterile versus nonsterile gloves.

What this study adds to our knowledge

There was no difference in infection rates when nonsterile gloves were used.

How this might change clinical practice

Use of nonsterile gloves for laceration repair could save time and money without increasing the risk of infection.

time consuming and can, in some instances, necessitate the use of an assistant.

In contrast to surgical incisions, traumatic lacerations are invariably contaminated with bacteria from various sources, including skin flora and the lacerating object. In a busy ED environment, sterility of the operative field is often breached when, for example, the patient moves or the physician reaches for additional suture material or gauze or contacts a nonprepared area of the body.

The rationale for use of traditional sterile technique has recently been questioned in various areas of medical[1-4] and dental[5-7] care.

Three studies have revealed that tap water can be safely used for cleansing traumatic wounds in the emergency setting.[8-10] Ruthman et al[11] demonstrated that laceration repairs without using caps or masks did not lead to increased infection rates. Bodiwala and George[12] have shown that even without using gloves, infection rates after the repair of simple lacerations were not increased compared with repairs using sterile gloves. In a nonrandomized, nonblinded study of 50 lacerations, Worral[13] compared the infection rates of wounds repaired with sterile or nonsterile gloves and found no difference. The use of nonsterile, clean gloves has also been shown to be safe in certain procedures in burn patients[4] and in the ICU.[3]

Although published guidelines[14,15] recommend sterile technique for laceration management, there is little evidence to support this method as a standard of care. A preliminary survey of 18 emergency and 24 family physicians conducted by the authors revealed that more than 70% often used nonsterile gloves or had experienced sterile-field violations during repairs of lacerations (GJ Francis, VS Perelman, unpublished data, 1999). A review of the literature did not reveal any prospective, randomized, blinded study comparing sterile and nonsterile gloves for repair of uncomplicated lacerations in the ED.

MATERIALS AND METHODS

Study Design

Our hypothesis was that using clean nonsterile gloves for the repair of uncomplicated lacerations in immunocompetent patients does not lead to an increase in the incidence of wound infections. This prospective, randomized, multicentered trial included all patients who consented to participate, were older than 1 year, and presented to the ED with any type of uncomplicated soft tissue lacerations. Patients were excluded if there was presence of diabetes mellitus, renal failure, asplenia, immunodeficiency (congenital, acquired, or receiving immunosuppressive therapy), liver cirrhosis, tendency to form keloid scars, current use of antibiotics or need for prophylactic antibiotics as perceived by the treating physician (eg, artificial heart valves, bites, contaminated wounds).

Wound factors included multiple trauma; open fractures; concomitant vascular, nerve, or tendon injury; penetrating trauma (eg, penetrating stab wounds, gunshot wounds, intra-articular involvement); animal and human bites; delayed presentation (>12 hours); clinical signs of infection at presentation; or suspected foreign body.

Setting

The study was conducted in 3 large community hospitals in the greater Toronto area, with a combined census of more than 150,000 visits per year.

Block-randomization in blocks of 60 was used to ensure comparable patient profiles in both groups (sterile and clean nonsterile gloves) in each site. Patients were randomized in strata according to the site of laceration (head and neck, extremities, trunk and buttocks) because data have indicated a variable risk of infection, depending on the location of the laceration.[10,16,17]

Patients with lacerations or their substitute decision-makers were informed by a nurse or physician of their opportunity to be involved in the study. A patient information sheet was supplied to provide background information on wound management, wound infections, and the rationale for the study.

An attending physician or resident conducted the initial interview and assessment. Patients who met the inclusion criteria and were willing to take part in the study were asked to sign a consent form.

The treating physician filled out a data collection sheet that documented the age and sex of the patient, site of laceration, type of injury, time from injury to repair, and technique of repair. The physician ensured absence of the exclusion criteria that were listed on this sheet.

After the patient consented to participate, the emergency physician randomized the patient by using a specially designed randomization table in the study package.

According to the randomization, a physician used either sterilized latex-free gloves (Allegiance; Cardinal Health Co., IL) or a pair of standard, clean-boxed, nonsterile, latex-free gloves (Allegiance; Cardinal Health Co.). To blind the patients to the type of gloves used, the physicians were instructed not to inform participants of the randomization results and to put gloves on out of sight of the patients so that they were not able to observe what type of gloves were used.

The rest of the repair was to be conducted in the usual manner for each physician. An algorithm suggesting the ideal laceration repair was provided and included obligatory pressure irrigation with sterile saline solution or water and the use of appropriate suture material. Two orientation sessions were organized at each participating site during the trial. The adherence of any particular physician to the protocol was not determined further. The responsibility for maintaining the proper administration of the trial was that of the supervising clinicians at each site.

A letter with a self-addressed, prestamped envelope was provided to each patient included in the study. It contained a data sheet (Appendix) to be completed by the physician providing wound follow-up that combined scales used in previous studies to determine the presence or absence of wound infection.[2,16,18] The questionnaire included explicit wound-assessment information, the physician's clinical impression of the wound, and the management plan. If the wound was deemed to be infected sufficiently to warrant use of antibiotics or referral, the physician was asked to obtain a swab for culture and sensitivity before initiating antibiotic therapy. The follow-up physician was not informed of the type of gloves used.

After completing the follow-up data sheet, the physicians were requested to return the form to the authors by mail in the self-addressed, prestamped envelope or by fax. The physician was also requested to submit the culture results if applicable. When the returned questionnaire indicated infection, the patient was contacted by the investigators to follow up on his or her recovery.

Patients were given the option to return to the ED for suture removal and wound assessment. In those cases, emergency physicians filled out the follow-up data sheets.

The follow-up data sheets were coded to collate with the initial assessment forms. Tardy or missing follow-up forms resulted in a follow-up telephone call to the associated patients. These patients were asked a standardized series of questions that included information on their compliance with the follow-up advice, what happened with their follow-up data sheet, and whether they experienced any complications with their wound.

When the follow-up data sheets were not returned or were incompletely filled out and it was not possible to contact the patient, the cases were considered "lost to follow-up" and the data were not included in the final analysis.

The protocol, patient consent form, and all related information were reviewed and approved by the ethic and review boards of all the facilities involved in the study.

Primary Data Analysis

The primary endpoint of the study was the presence or absence of a significant wound infection on the follow-up assessment. A wound infection was considered to be significant if the follow-up physician's impression was that there was a wound infection requiring antibiotics or referral or if, in cases followed up by telephone interview, there was an indication of significant infection (eg, the patient was told that he or she had an infection and was advised to use topical or systemic antibiotics or was referred to a specialist for follow-up wound care).

All data were entered in Microsoft Access 2000 database (Microsoft Corporation, San Diego, CA) and analyzed with InStat 3.01 (GraphPad Software, Inc., San Diego, CA) and Stata software (version 7.0, Stata Corporation, College Station, TX).

Demographic and clinical data were presented descriptively as means, medians, or proportions with SDs where appropriate. The ∂^2 test was used to compare differences in infection rate between the 2 glove groups. A 2-tailed *P* value less than .05 was considered significant.

Infection rates with the use of sterile gloves have been shown to be as high as 8%.[1,18] The sample size was

calculated for a comparative superiority trial. It required 380 patients per group to detect a 50% relative risk reduction in infection rate by using sterile gloves (80% power with 1-tailed α =.05). The number obtained was then increased by 10% to account for patient dropouts.

RESULTS

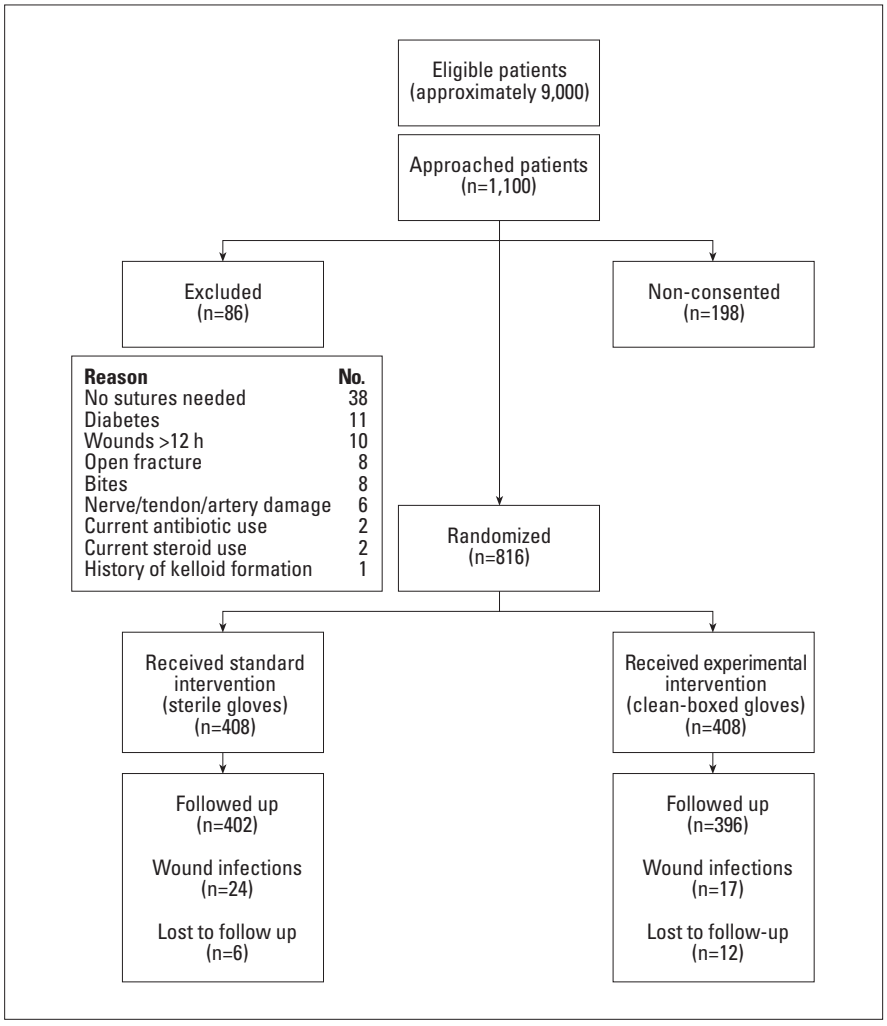
One thousand one hundred people with lacerations were approached to enroll in the study (Figure). Nine hundred and two patients consented to participate. Of those patients, 86 were excluded (Figure).

There were no differences in the baseline characteristics of the clean-boxed and sterile glove study groups (Table 1). Men constituted 72.9% of the study patients. The sites of lacerations were extremities in 61.8% of patients, head or neck in 36.6% of patients, and trunk or buttocks in 1.6% of patients. Lacerations were typically repaired approximately 3 hours after the event.

There were no differences in the treatment received by the 2 groups (Table 2). Wounds were invariably prepared with either iodine- or chlorhexidine-based solutions. Whether or not wound irrigation was used was recorded in 756 (92.6%) of the 816 study patients. Among the cases for which it was recorded, wound irrigation was performed in 84.1% of the patients. Epinephrine was considered to have been used in local anesthetics if it was present in either infiltrative or topical anesthetic solutions. Local anesthesia was used much more often without epinephrine (87.9%) than with epinephrine. Wounds were repaired in 1 layer with a monofilament suture in more than 90% of the cases. Topical antibiotic ointment was used with wound dressings in 25% of cases.

Follow-up information was obtained for 96.6% of the clean gloves group and 98.0% of the sterile gloves group. Written follow-up was obtained in 48.7% of cases. The remaining participants were contacted by

Figure.
Summary of experimental results.



telephone. In some cases, medical records were reviewed to obtain missing demographic data only. Table 3 summarizes the data obtained from the follow-up data sheets, and Table 4 summarizes the results obtained from the telephone follow-up.

There were 4 discrepancies noted between the objective wound assessments and the clinician's impression of the wound (1 in the clean glove group and 3 in the sterile glove group). Two in the latter group were clarified with the assessing clinician, and the remaining 2 were considered as infected wounds and entered in the database as such. Culture results for infected wounds were available in 8 cases and uniformly demonstrated mixed skin flora with the predominance of gram-positive cocci.

The observed infection rate was 6.1% (24 patients; 95% confidence interval [CI] 3.8% to 8.4%) in the sterile gloves group and 4.4% (17 patients; 95% CI 2.4% to 6.4%) in the clean gloves group (Tables 3 and 4). The difference in infection rates was not statistically significant (relative risk 1.37; 95% CI 0.75 to 2.52; P=.295).

Table 1.
Demographic characteristics of the study patients and baseline characteristics of the wounds.[*]

Characteristics	Clean, No. (% Total) (N=408)	Sterile, No. (% Total) (N=408)
Age, y, mean±SD	30.2±18.2	30.5±19.1
Sex		
Men	296 (72.6)	299 (73.3)
Women	112 (27.4)	109 (26.7)
Site		
Head or neck	149 (36.5)	150 (36.8)
Extremities	251 (61.5)	253 (62)
Trunk or buttocks	8 (2)	5 (1.2)
Injury type		
Incised (sharp)	272 (69.2)	253 (64.9)
Nonincised (blunt)	122 (30.8)	136 (34.9)
Contaminated	65 (15.9)	57 (14)
Multiple injuries	13 (3.2)	14 (3.4)
Time to repair, h, mean±SD	2.57±1.62	2.55±1.39

[*]Some numbers do not add up to the total number of patients because of omission of some elements of data in the intake questionnaires.

Table 2.
Repair techniques used in managing the lacerations.[*]

Repair Techniques	Clean, No. (% Total) (N=408)	Sterile, No. (% Total) (N=408)
Local anesthetic without epinephrine	342 (87.4)	334 (88.4)
Local anesthetic with epinephrine	49 (12.5)	44 (11.6)
Wound irrigation done	321 (85.4)	315 (82.9)
Wound preparation done	369 (100)	370 (100)
Layers		
Dermal	373 (96.2)	353 (94.4)
>1 Layer	15 (3.9)	21 (5.6)
Sutures		
Monofilament	355 (91.7)	349 (91.6)
Braided	8 (2.1)	1 (0.3)
Absorbable	18 (4.7)	22 (5.8)
Tissue glue or staples	6 (1.6)	9 (2.4)
Topical antibiotic used	93 (24)	101 (26.3)

[*]Some numbers do not add up to the total number of patients because of omission of some elements of data in the intake questionnaires.

LIMITATIONS

The study was designed to measure precision around the absolute difference in infection rates between the 2 groups. The target sample size in this study was 800 patients equally randomized into 2 arms. With such a sample size, the absolute difference in infection rates between groups was measured with a precision that extends to ±2.8%, with a 95% probability. The sample size required for an equivalency trial with similar characteristics was in excess of 3,000 patients per group,[19] which was beyond the means of this study.

Table 3.
Summary of the written follow-up questionnaire.

Characteristics	Clean, No. (% Total)	Sterile, No. (% Total)	95% CI
Written follow-up received	195 (47.6)	202 (49.3)	–0.05 to 0.09
Days after repair, mean±SD	9.4±4.7	8.9±4.4	–1.46 to 0.72
Fever	1 (0.5)	1 (0.5)	NA[*]
Wound assessment			
No/slight erythema	167 (85.6)	175 (86.6)	–0.12 to 0.16
Erythema <1 cm	21 (10.8)	19 (9.4)	–0.13 to 0.20
Erythema >1 cm, edema	4 (2.1)	7 (3.5)	NA[*]
Pus ±1 or 2	3 (1.5)	1 (0.5)	NA[*]
Clinical impression			
No infection	164 (84.1)	174 (86.1)	–0.09 to 0.18
Infection	8 (4.1)	8 (4)	–0.24 to 0.25
Antibiotics[†]			
Topical	5 (2.6)	7 (3.5)	–2.5 to 4.2
Oral	6 (3.1)	6 (3)	–7.9 to 8.1
Intravenous	1 (0.6)	1 (0.5)	NA[*]
Referral	0	1 (0.5)	NA[*]

[*]CI of the differences between proportions could not be calculated when the number of events was <5.
[†]In some cases, topical and systemic antibiotics were used.

This study was only partially blinded because the sterile and nonsterile gloves are packaged differently. Had the study been conducted by using nonsterile gloves that were individually packaged as the sterile gloves were, it would not be possible to extrapolate the results to actual practice. Packaging nonsterile gloves would have eliminated another important confounding factor, such as the possibility of cross-contamination of an open box of gloves by various personnel.

Furthermore, applying the gloves in a blinded fashion would not have resulted in the blinding of the operators. Physicians would easily differentiate the glove types according to their construction, fit, and color.

It was not practical to ensure absolute standardization of the techniques used for wound repair. The study was designed to replicate current practice as closely as possible, with variation only in the glove type used. The protocol for the "ideal" laceration repair was presented during orientation sessions to the physicians and included irrigation technique. The use of topical antibiotics was not emphasized because of lack of conclusive evidence for their universal use in wound repair.[20]

In the teaching environment, many of the laceration repairs were performed by the numerous trainees, which made it difficult to use physicians as the unit of analysis. Therefore, the data were analyzed by using the patient as the unit of analysis, which might have introduced the chance failure of randomization of the most infection-prone wounds and confounded the results. This error, fortunately, did not occur (Table 5). However, trainees may have used suboptimal techniques, which may account for the somewhat higher infection rate in both groups compared with recent literature.[21]

The observed lower infection rate in the clean nonsterile gloves group was not statistically significant. It is possible that physicians were more careful performing laceration repairs with nonsterile gloves (the Hawthorne effect).[22] Although this potential bias was difficult to eliminate, a detailed description of the wound repair procedure to be used in the study was provided to the clinicians. In this study, we encountered no difference in the rate of wound irrigation, use of preparation solution, and other aspects of repair technique between the 2 groups.

A single follow-up clinic would have allowed for more rigorous standardization in determining the primary endpoint, the presence or absence of wound infection, which was not feasible for a variety of fiscal and administrative reasons. Thus, a follow-up assessment

Table 4.
Telephone follow-up results.

Characteristics	Clean, No. (% Total)	Sterile, No. (% Total)	95% CI
Telephone follow-up obtained	201 (49)	200 (48.8)	−0.07 to 0.07
Days after repair, mean±SD	16.8±6.0	18.5±6.5	−1.48 to 4.9
Wound assessment			
No infection	194 (96.5)	187 (92.6)	−0.07 to 0.38
Infection	7 (3.5)	13 (6.4)	−0.07 to 0.38
Antibiotics*			
Topical	5 (2.5)	4 (2)	NA†
Oral	2 (1.0)	5 (2.5)	NA†
Intravenous	0	1 (0.5)	NA†
Referral	0	3 (1.5)	NA†

NA, Not applicable.
*In some cases, topical and systemic antibiotics were used.
†CI of the differences between proportions could not be calculated when number of events was <5.

Table 5.
Demographic characteristics of the patients with infections and comparative characteristics of the wounds and repair techniques.

	Glove Type	
Characteristics	Clean, No. (% Total) (N=17)	Sterile, No. (% Total) (N=24)
Age, y, mean±SD	33.3±22.2	31.9±15.3
Sex		
Men	15 (88.2)	18 (75.0)
Women	2 (11.8)	6 (25.0)
Site		
Head and neck	4 (23.5)	8 (33.3)
Extremities	12 (70.6)	16 (66.7)
Trunk and buttocks	1 (5.9)	0
Injury type		
Incised (sharp)	9 (52.9)	11 (45.8)
Nonincised (blunt)	8 (47.1)	13 (54.2)
Contaminated	4 (23.5)	4 (16.7)
Multiple injuries	0	0
Time to repair, h, mean±SD	3.01±1.76	2.67±1.75
Repair techniques		
Local anesthetic without epinephrine	14 (82.4)	22 (91.7)
Local anesthetic with epinephrine	3 (17.6)	2 (8.3)
Wound irrigation done	13 (76.5)	17 (70.8)
Wound preparation done	17 (100)	24 (100)
Layers		
Dermal	16 (94.1)	22 (91.7)
>1 Layer	2 (11.8)	2 (8.3)
Sutures		
Monofilament	15 (88.2)	21 (87.5)
Braided	1 (5.9)	0
Absorbable	1 (5.9)	3 (12.5)
Tissue glue or staples	0	0
Topical antibiotic used	8 (47.1)	11 (45.8)

of the presence or absence of wound infection by different physicians was used. The assessment tool for determining the presence or absence of wound infection as an outcome measure has been used successfully in other trials.[2,16,18] In the absence of a criterion standard for diagnosing wound infection, no further validation of the follow-up data sheets was undertaken. No assessment of intraobserver reliability was carried out for the initial or follow-up data collection, and a large number of physicians and patients were involved in providing data. Thus, there are limitations in the accuracy of the data.

DISCUSSION

The present study of 816 randomized laceration repairs did not generate any data to suggest that infections are more common when lacerations are repaired with nonsterile gloves.

The number of patients with lacerations who presented to the 3 sites throughout the study period was approximately 9,000. Approximately 10% of those patients were approached with the intent of enrollment, 1,147 were assessed, 86 were excluded, and 245 refused to participate in the study.

The demographic data did not differ significantly between included and excluded patients. Among patients who did not consent to the study, there was a disproportionate number of small children (40%), possibly as a result of parental anxiety of entering their child into the study.

Men constituted 72.9% of the study patients, which is consistent with evidence that men are more likely than women to sustain traumatic lacerations.[21] The sites of lacerations were extremities (61.8%), head or neck (36.6%), and trunk or buttocks (1.6%). Lacerations were typically repaired approximately 3 hours after the event.

Follow-up data were obtained for more than 95% of patients enrolled.

The definition of infection was based on the assessing clinician's impression and use of antibiotics during the postrepair clinical course. If discrepancies or uncertainties were to be noted, the worst possible outcome would be entered into the database. For example, if the physician reported no infection but recorded presence of a purulent discharge, the wound would have been recorded as infected. There were no cases in which a clinical impression suggested infection yet no antibiotic treatment was instituted. A clinical impression scale was initially included in accordance with previously published studies.[2,16,18] The goal was not to miss any infections and to make the diagnostic criteria for infections as standardized as possible.

The overall infection rate in the sterile gloves group was 6.1% (95% CI 3.8% to 8.4%) and was 4.4% in the clean gloves group (95% CI 2.4% to 6.4%). The relative risk of infection was 1.37 (95% CI 0.75 to 2.52).

The observed infection rate likely overestimated the clinically significant rate of infection because of the decision to err on the side of overcalling infections, skewing any discrepancy toward a negative outcome. Nevertheless, the infection rates were comparable to results obtained by other investigators.[8,18,21]

There are many brands of boxed gloves. Some practitioners may not be comfortable with the "fit and feel" of boxed gloves, as was the case with one emergency physician who participated in this study. This concern may be amplified because boxed gloves are available in only 3 sizes (large, medium, and small), whereas sterile gloves are typically available in a full range of sizes.

Another consideration is the quality of boxed gloves. Although Zinner[23] has shown that certain boxed gloves have increased numbers of defects per box, leading to leaks and breakdowns of the protective barrier, other authors demonstrated a compatible quality and safety profile of sterile versus clean nonsterile gloves in terms of physical integrity and bacteriologic contamination.[5,6,24]

Previous investigations have shown that damp boxed gloves may be predisposed to containing *Aspergillus fumigatus*.[25] Therefore, if regular use of nonsterilized boxed gloves were to be considered, it would be important to avoid use of boxes of gloves that have become damp. Another important precautionary measure would be to ensure hand washing before surgical repair of lacerations. Although previous authors have identified these points and they are logical considerations, we did not address these issues as part of our trial protocol.

Using nonsterile gloves for wound repair can be expected to have a modest positive economic impact. The cost for clean, nonsterile examination gloves (latex free/powder free) is US$4.60 (Can$6.75) per box of 100, or US$0.10 per pair (Can$0.135), whereas sterile gloves (latex free/powder free) cost US$0.70 per pair (Can$1.00). Thus, use of nonsterile gloves rather than sterile gloves would lead to direct-cost savings of more than US$2,000 (Can$3,000) per year in an ED that manages an average of 10 uncomplicated lacerations per day. Further savings may be realized in indirect costs such as ordering, storage, shipping, and receiving. Although this saving may not be important in some developed countries, in Canada, where a publicly

funded health care system is in place, as well as in underprivileged countries, relative cost of supplies may play an important role.

The ability to use boxed gloves rather than sterile gloves and the related strict sterile technique would also be a considerably more convenient approach to wound treatment. A clean, nonsterile glove technique may save valuable time for emergency personnel.

In summary, this prospective, single-blinded, multicenter study provides evidence that clean, nonsterile, boxed gloves can be safely used for repairing uncomplicated traumatic lacerations without increasing the risk of wound infections.

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APPENDIX.

Follow-up physician questionnaire.

General

Days after treatment in ED _____

Fever (>38.0°C [>100.3°F]) at presentation Yes No

Wound Assessment

0 - No or slight erythema
1 - Erythema not >1 cm from suture line
2 - Erythema >1 cm from suture line ±edema
3 - Pus ±1 or 2

Impression

a) No evidence of infection
b) Slight inflammation, does not require antibiotics
c) Significant infection, requires antibiotics
d) Severe infection, requires immediate referral for exploration and debridement ±antibiotics

IF YOU ARE PUTTING THE PATIENT ON ANTIBIOTICS OR REFERRING TO A SPECIALIST, PLEASE OBTAIN SWAB FOR CULTURES AND SENSITIVITY.

In that case, please provide us with the contact number where we can retrieve the microbiology results. Tel. # (__) -_____, Fax # (__)_____