

Covering of the Toes During Hindfoot and Ankle Surgery: A Randomized, Controlled, Clinical Study

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ABSTRACT

Background: Major advances in sterility over the last 140 years have dramatically reduced the rates of infection. The purpose of this study was to determine whether there was benefit to covering the toes during hindfoot or ankle surgery. **Methods:** Forty consecutive hindfoot or ankle surgery patients were randomly assigned to one of two groups based on whether the toes were covered with a sterile glove or left uncovered. Three cultures were taken of the foot in the second web space. The first sample was taken before surgical preparation. The second sample was taken immediately after draping of the patient. The third sample was taken at the conclusion of the operation before dressing placement. The culture swab was moistened before sampling with sterile saline. The operative extremity was scrubbed with chlorhexidine gluconate and sterile water solution, followed by painting with 70% isopropyl alcohol. Before surgery, the patients were assigned to one of the two groups (covered or uncovered toes) on a random basis. A sterile size 6-1/2 glove was placed over the toes of the covered group and left in place until final wound closure. All patients received the same perioperative intravenous antibiotics. **Results:** Thirty-five of 40 patients (87.5%) had positive cultures before the surgical preparation. One patient had a positive culture at the conclusion of the procedure but not immediately after the surgical preparation, and the toes were covered during the operation. Cultures before and after the procedure contained coagulase negative staphylococcus species. This patient did not develop any wound infection during the followup period. A second patient had positive cultures on all three samples. The species was coagulase positive staphylococcus. This patient did not have any wound infection problems postoperatively, although he was placed on prophylactic antibiotics 8 weeks after the initial surgery for a hardware removal procedure. The toes were not covered during the initial operation in this patient. In total, 10 patients were placed on antibiotics after the initial surgery. Three patients had erythema surrounding the incision, two patients had delayed wound healing, and

one patient had erythema at the knee from a proximal tibial bone graft harvest site. The other four patients who received antibiotics had a hardware removal procedure within the 90-day followup period and received prophylactic antibiotics for that procedure. **Conclusions:** The results of this study indicate no benefits in covering the toes in hindfoot or ankle surgery after skin preparation with chlorhexidine gluconate and isopropyl alcohol. There were only two positive postoperative cultures and neither patient showed any signs of postoperative wound infection during the followup period.

Key Words: Foot and Ankle Surgery; Infection; Toe Covering

INTRODUCTION

Perioperative infections can have devastating effects on patient outcome after any surgery, including procedures that involve the foot and ankle. Studies have demonstrated that surgical procedures around the foot and ankle are associated with high infection rates.^{3,4,6,10} Comparisons of different preparation solutions including povidone iodine scrub and paint, povidone iodine gel, chlorhexidine gluconate, para-chloro-meta-xyleneol, triclosan, hexachlorophene, normal-propyl alcohol, ethanol, and isopropyl alcohol,^{2,3,6-12} have shown that chlorhexidine gluconate solution for the scrub followed by 70% isopropyl alcohol painting of the surgical area is the most effective method of sterilization.^{3,9,10} Toe covering has been recommended in orthopaedic procedures involving the lower extremity to reduce the risk of contamination of the surgical site,^{4,6,11,13} but no study has been conducted to analyze whether toe covering has any effect on infection rates.

MATERIALS AND METHODS

All subjects participating in this study received a thorough explanation of the risks and benefits of inclusion and gave informed consent. Approval from the hospital institutional review board was obtained before the initiation of the study.

Forty consecutive patients undergoing elective surgical procedures on the hindfoot or ankle at a single hospital were enrolled in the study. Subjects were excluded if they had open areas of skin, active infection, or acute trauma. The average age of the patients was 49.5 (range 18 to 75) years. Twenty-three women and 17 men were enrolled. The average overall

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surgical time for both groups was 74 (range 13 to 138) minutes. The average time for the covered subgroup was 73 (range 18 to 122) minutes, and for the uncovered group was 75 (range 13 to 138) minutes. The subjects were randomly assigned at the time of the surgical preparation to either have the toes covered with a sterile size 6-1/2 glove or have the toes left uncovered. Each group consisted of 20 subjects. The glove size was chosen to form a tight seal and to minimize the risk of the glove sliding off during the procedure. No foot was precleaned with anything other than soap before sampling. Three sets of cultures were obtained for each subject during the study. The culturette swab was premoistened with sterile saline before sampling. The second web space was chosen for the sample site. The first sample was taken before the surgical scrub, the second sample was taken immediately after the draping of the operative extremity, and the final culture was obtained after wound closure before dressing of the limb. For the subjects in the covered group the toes were covered with a sterile glove after the second culture sample.

There were 120 culture specimens obtained during the course of the study. All samples were obtained in a sterile fashion to reduce the risk of contamination. Each sample was obtained with a culturette swab and cultured on appropriate agar plates, including sheep blood agar, bile esculin agar, brucella agar, phenyl ethyl alcohol agar, mannitol salt agar, and eosin methylene blue agar. The plates were then incubated at 37 degrees C. The plates were inspected at 24, 48, and 72 hours for growth. The plates were discarded after 72 hours of incubation for aerobic cultures and at 1 week for anaerobic cultures. Any growth was considered positive, and isolation of the bacterial species was conducted for identification.

All patients received preoperative intravenous antibiotics within 1 hour of surgery. Cefazolin was used unless there was an allergy to penicillin. Clindamycin was used in patients with allergies. The operative limb was scrubbed with chlorhexidine gluconate on a sterile sponge followed by 70% isopropyl alcohol painting. The limb was then wrapped in an impermeable stockinet to reduce the exposed skin area proximal to the ankle. The foot and ankle were left exposed in the uncovered group and only the toes were covered in the covered group. Final followup for postoperative infection was defined as 90 days.

Data were crosstabulated and the Fisher Exact test was performed to analyze whether there was an association between toe covering and incidence of infection. Statistical analyses were conducted using SPSS version 11.5 (SPSS, Inc., Chicago, IL, USA). A p-value less than 0.05 was considered statistically significant.

RESULTS

Thirty-five of 40 samples (87.5%) taken before the surgical scrub were positive for growth. The most common organism was coagulase negative staphylococcus (25 subjects), followed by catalase positive staphylococcus (three), catalase

negative staphylococcus (two), staphylococcus epidermidis (two), streptococcus simulans (one), coagulase positive staphylococcus (one), and mixed flora (one). Only one sample (2.5%) showed growth immediately after the surgical scrub. The organism was coagulase positive staphylococcus, and it also was positive on the post-procedure culture. Two of the 40 samples (5%) were positive for growth at the final culture. Of the two with positive final cultures, only one subject had growth on all three samples; the other subject had growth only on the first and third samples. The bacterial species identified were coagulase positive staphylococcus on the subject with growth on all three samples and coagulase negative staphylococcus for the subject with growth on only the first and last cultures. Neither patient had any wound healing problems or signs of infection. The patient with growth of coagulase positive staphylococcus on all three samples received a second prophylactic dose of antibiotics 8 weeks after the initial surgery when he had an uncomplicated deep hardware removal of a subtalar arthrodesis screw. The other patient did not receive any other antibiotics aside from the initial prophylactic intravenous dose before the initial operation.

Seven patients demonstrated signs of local infection defined clinically by erythema, drainage beyond the normal postoperative period, delayed wound healing or dehiscence, or a suture abscess formation. Three of the patients with signs of infection had their toes covered, and the remaining four were uncovered during the procedure. There was no statistically significant difference between the two groups ($\chi^2 = 0.00, p = 1.0$). There were four episodes of erythema after surgery. In three the area surrounding the incision on the foot or ankle was erythematous, and in the fourth the erythema was at the incision site near the knee used to harvest bone graft from the proximal tibia. In all four patients, the erythema resolved with oral antibiotics consisting of cephalexin in two patients and ciprofloxacin in the other two because of a penicillin allergy. Two patients had wound dehiscences after surgery, both of which resolved with local wet-to-dry wound care and oral cephalexin. The one suture abscess resolved with suture removal and oral cephalexin. In addition to these seven patients who received antibiotics for clinical signs of infection, three other patients received antibiotics during the 90-day followup period. These three patients had hardware removal procedures not related to infection and received a dose of prophylactic antibiotics for the procedure. No patient had any permanent impairment from infection.

DISCUSSION

The initial goal of this study was to analyze the effect that covering of the toes during hindfoot and ankle surgery would have on the overall bacterial colonization and the infection rate. Only two cultures were positive in the final samples, one in each group. We did not expect these low numbers for analysis, which made it difficult to conclude whether covering the toes had any effect in the overall

outcome. The real measure of success is the absence of infection. In the current study, seven patients out of 40 (17.5%) had clinical signs of infection; however, no patient was re-cultured. All seven patients had negative cultures on the second and third samples. There were four cases of erythema, two wound dehiscences, and one suture abscess. No patient with a positive skin culture at the conclusion of the procedure had any signs of infection postoperatively. All episodes cleared with local wound care and oral antibiotics without any permanent sequelae.

Several authors^{4,6,11,13} have discussed toe covering when performing surgery on the lower extremity to isolate this potential source of contamination. Brooks et al.⁴ studied the effect of toe covering with the use of povidone iodine as the surgical preparation solution. They were unable to show a statistical difference between the covered and the uncovered groups.⁴ Hort et al.⁶ recommended covering of the toes during hindfoot and ankle surgery based on their findings of residual bacterial contamination. They used povidone iodine solution with and without the addition of alcohol and found no additional benefit with the addition of alcohol. They also did not specifically test the difference between covering and uncovering of the toes. Zacharias et al.¹³ also recommended covering of the toes during surgery based on their study involving povidone iodine. They demonstrated that 75% of their cohort had a positive culture immediately after the preparation and another 75% had a positive culture after the procedure. They wrapped all the toes and had no uncovered control. Based on their findings, they recommended covering the toes when not involved in the surgery.

Chlorhexidine gluconate exerts its action by disrupting the bacterial cytoplasmic membrane and by precipitating components of the cytoplasm.^{5,8} It has a broad spectrum of activity but is most effective against viruses and vegetative gram positive and gram negative bacteria, less effective against fungi, and not effective against acid fast bacteria.^{5,8} Chlorhexidine gluconate retains this bactericidal effect for at least six hours after the initial application.^{2,8,12} Peterson et al.¹² compared chlorhexidine gluconate, povidone iodine, and hexachlorophene in a clinical study to determine the efficacy, and determined that chlorhexidine gluconate provided the best immediate and persistent effect of the three solutions studied. Similarly, Bibbo et al.³ concluded that chlorhexidine gluconate was superior to povidone iodine solution in foot and ankle surgery.

Povidone iodine scrub solution and paint are commonly used sterilizing agents in surgical site preparation. The effect of povidone iodine solution is exerted by the release of free iodine,⁸ which penetrates the cell wall, oxidizes, and substitutes itself in microbial substances. The antimicrobial activity depends on drying for at least 2 minutes on the skin surface. This often can be overlooked in a busy surgical center. The skin sterilization effect is reduced when the iodine comes into contact with fluids such as blood or sputum.⁸ Ostrander et al.¹¹ concluded that povidone iodine

solution is not sufficient for use in foot and ankle surgery based on results of their study showing increased positive culture results. They also started wrapping the toes after initial results were positive for bacteria in high numbers, but they were unable to conclude whether isolating the toes had any effect on the outcome.

Alcohols exert their antimicrobial effects by protein coagulation and denaturation.¹ They also cause disruption in cell integrity, cell lysis, and interference with cell metabolism.¹ Pure alcohol is less effective without the presence of water.¹ Alcohols are primarily effective against vegetative bacteria and fungi and are generally ineffective against spores and viruses.¹ The effect of alcohol is rapid but does not persist.¹ Alcohols have been used alone and in combination with other antimicrobial solutions for surgical site sterilization. Several studies using combinations of alcohol and standard preparation solutions have shown further reduction in bacterial counts.^{3,9,10} To achieve the best results with alcohol, a scrubbing motion with a bristled brush is more effective than simply painting the area with a foam sponge.⁷

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