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Can applied external fixators be sterilized for surgery? A prospective cohort study of orthopaedic trauma patients

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ABSTRACT

Background: Temporary external fixators are often used to stabilize fractures when definitive fracture surgery must be delayed. Sometimes, external fixators are left in place during repeat operations, including definitive internal fixation of tibial pilon and tibial plateau fractures. It is unknown how well current surgical preparation sterilizes these devices, which become part of the surgical field. Our hypothesis was that our institution's standard surgical preparation creates a low rate of culture-positive environments on external fixators at the time of surgical skin incision.

Methods: We prospectively consented and enrolled patients to obtain cultures (48 patients, 55 external fixators, 165 sets of culture data). After standard preparation and immediately before incision, cultures were obtained from three sites on each external fixator: 1) most distal pin 1 cm from pin-skin interface, 2) most distal bar at midpoint between pin and clamp connectors, and 3) most distal clamp at bar-clamp interface. Our standard preparation for patients with external fixation in place is to don sterile gloves and wipe down all components of the external fixator with 70% alcohol-soaked sterile 4 × 4 in gauze sponges before skin preparation. The skin and external fixator are then prepped in the usual fashion with ChloraPrep for closed wounds or with povidone iodine scrub and paint for open wounds. Swabs were processed and organisms from cultures identified. Clinicians were blinded to study results until study completion.

Results: Two of 165 cultures (1.2%; 95% confidence interval [CI]: 0–2.9%) were positive for common pathogens sometimes observed in surgical site infection. Four cultures (2.4%; 95% CI: 0–4.8%) had pathogens that are rarely associated with surgical site infection, and four (2.4%; 95% CI: 0–4.8%) had nonpathogenic organisms.

Conclusion: Using 70% alcohol on external fixators plus either ChloraPrep for closed wounds or povidone iodine for open wounds seems to result in a low rate of positive cultures. Most species that were isolated are infrequently identified as sources of surgical site infections. This preparation protocol might be effective at producing a relatively clean environment at the time of surgery for patients with external fixators already in place.

Introduction

Temporary external fixators are often used for trauma patients when definitive fixation must be delayed, such as with high-energy tibial pilon or tibial plateau fractures. During return trips to the operating room, fixators must be removed, draped to create a barrier to the sterile field, or left in place and prepared with the limb. It often is advantageous to leave fixators in place for serial débridement of soft tissue and to help maintain reductions during definitive fracture fixation.

If left in place, the ability to sterilize the external fixator becomes necessary. Surgical site infection has been shown to be the primary complication in cases of severe lower extremity trauma and often results in need for further surgery [1]. Darouiche et al. [2] showed that the type of skin preparation used influences

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the risk of postoperative infections in patients undergoing gastrointestinal, gynecological, and urological procedures. Other clinical studies have shown similar results in foot and ankle and shoulder surgery [3,4]. This issue is particularly important for patients with external fixators, considering that previous basic science studies have raised concern regarding the ability of chlorhexidine gluconate and povidone iodine preparations to sterilize external fixators that have been exposed to bacterial broth [5,6]. Our hypothesis was that our institution's standard surgical preparation practice creates a low rate of culture-positive environments on the external fixator at the time of surgical skin incision.

Patients and methods

After Institutional Review Board approval was obtained, trauma patients at a single Level I trauma center returning to the operating room with external fixators already in place at the surgical site were consented for participation in this prospective study. Each patient's gender, age at time of injury, reason for return to the operating room, presence or absence of infection, most recent location (i.e., hospital, home, rehabilitation center, etc.), number of days since external fixator placement, number of days in hospital, type of presurgical preparation, and Gustillo-Anderson [7,8] classification of open fracture were recorded at the time of surgery.

Standardized surgical preparation for all study patients consisted of cleaning the entire external fixator with 70% alcohol-soaked sterile 4 × 4 inch gauze while wearing sterile gloves. If no open wound was present, two ChloraPrep 26-mL applicators (CareFusion, San Diego, CA) were used to paint both the external fixator and the underlying skin. If an open wound was present, povidone iodine scrub and paint were applied. The limb was then draped in the usual sterile fashion.

Immediately before skin incision or documented start time, one culture swab was obtained from each of the following external fixator components: 1) the most distal pin 1 cm from the pin-skin interface, 2) the most distal bar at midpoint between pin and clamp connectors, and 3) the most distal clamp at the bar-clamp interface. All swabs were opened by the clinician obtaining the cultures, and any swab that touched skin was discarded to decrease contamination risks. Cultures were sent to the microbiology research laboratory located at the same hospital complex within 24 h.

The swabs were plated on trypticase soy agar with 5% sheep red blood cells (blood agar plates) and were placed in trypticase soy broth. The blood agar plates and broth were incubated for 18–24 h at 35 °C to 37 °C in increased CO_2. Any growth was described and identified. If a blood agar plate had no growth but the broth was visibly cloudy, the sample was subcultured on another blood agar plate, incubated for an additional 18–24 h, and reanalyzed. All positive cultures were reviewed and bacterial species identified. Positive cultures were divided into three categories: 1) common surgical site pathogens, 2) rare surgical site pathogens, and 3) nonpathogenic organisms based on the literature, previous review of pathogens at our institution [9], and the senior author's experience with orthopaedic trauma infectious disease.

Study patients

Forty-eight patients with 55 external fixators prospectively consented to study enrollment, and the fixators were cultured (Table 1). Thirty-nine (71%) of the 55 injuries were in male patients. The mean patient age was 44 years (range, 20–77 years). Twenty-four (44%) of the fractures were open fractures.

Forty-two fractures (76%) had closed wounds and were prepared with ChloraPrep; 13 (24%) had open wounds and were prepped with povidone iodine scrub and paint. Fifteen fractures (27%) were in patients who came from home; the remainder came from a rehabilitation center or were still inpatients from initial injury at the time cultures were obtained. The mean number of days in hospital immediately before culture was 5 days (range, 0–44 days). The mean time from initial external fixator placement to culture was 14 days (range, 1–88 days). Four external fixators (7%) had been applied to treat pelvic fractures and 51 (93%) to treat lower extremity fractures. Thirty-five fractures (64%) underwent definitive fixation, 16 (29%) underwent repeat irrigation and débridement, two (4%) underwent manipulation of the external fixator, one (2%) underwent a combination of irrigation and débridement plus open reduction and internal fixation, and one (2%) had a free flap placed. Twelve (25%) of the 48 patients were known to have infection at the time of surgery. Descriptive statistics were calculated using Excel 2007 (Version 12.0; Redmond, WA, USA).

Results

Two of the 165 cultures (1.2%; 95% confidence interval [CI]: 0–2.9%) were positive for common surgical site pathogens. Both samples had *Staphylococcus epidermis*, which is a commensal commonly found on the skin and less commonly identified in surgical site infection after trauma [9]. Four cultures (2.4%; 95% CI: 0–4.8%) had pathogens that are rarely associated with surgical site infection (*Bacillus* species). An additional four (2.4%; 95% CI: 0–4.8%) had nonpathogenic organisms (*Penicillium* species and fungus) (Table 2).

Ten fractures (18%) each had one positive culture. No single patient had multiple positive cultures. Characteristics of the patients with positive cultures are noted in Table 3. One hundred fifty-five cultures (94%) were negative. Five (9%) of the 55 clamp cultures, three (5%) of the 55 bar cultures, and two (4%) of the 55 pin cultures were positive.

Of the fractures with positive cultures, six (60%) were in male patients, nine (90%) were prepped with ChloraPrep, nine (90%) had definitive open reduction and internal fixation performed at the time of culture, two (20%) were associated with open injuries, and one (10%) underwent repeat irrigation and débridement (Table 3). One patient had known infection at the time of surgery. In that case, the external fixator cultures grew *Bacillus* species and the infection was *Pseudomonas* osteomyelitis. The organisms speciated were as follows: four (40%) *Bacillus* species, three (30%) *Penicillium* species, two (20%) *Staphylococcus epidermidis*, and one (10%) fungus not otherwise specified.

Table 1
Patient characteristics.

Characteristic	n (%)
Number of patients	48 (100)
Number of fixators	55 (100)
Number of injuries	55 (100)
Total cultures (three per fixator)	165 (100)
Fixators in male patients	39 (71)
Fixators in female patients	16 (29)
CloroPrep	42 (76)
Povidone	13 (24)
Closed injuries	31 (56)
Open injuries	24 (44)
Infections at time of surgery	12 (22)
Reason for return to operating room	55 (100)
Open reduction and internal fixation	35 (64)
Irrigation and débridement	16 (29)
Manipulation	2 (4)
Irrigation and débridement plus open reduction and internal fixation	1 (2)
Flap	1 (2)

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