Bacteria on external fixators: Which prep is best?

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BACKGROUND: There are no established guidelines for the surgical prep of an external fixator in the operative field. This study investigates the effectiveness of different prep solutions and methods of application.

METHODS: Forty external fixator constructs, consisting of a rod, pin, and pin to rod coupling device, were immersed in a broth of *Staphylococcus aureus* (lux) for 12 hours. Constructs were then randomized into four treatment groups: chlorhexidine-gluconate (CHG) (4%) scrub, CHG (4%) spray, povidone-iodine (PI) (10%) scrub, and PI (10%) spray. Each construct was imaged with a specialized photon capturing camera system yielding the quantitative and spatial distribution of bacteria both before and after the prep. Each pin to bar clamp was loosened and moved 2 cm down the construct, simulating an external fixator adjustment, and reimaged. Spatial distribution of bacteria and total bacteria counts were compared.

RESULTS: There was a similar reduction in bacteria after surgical prep when comparing all four groups independently ($p = 0.19$), method of application (spray vs. scrub, $p = 0.27$), and different solutions (CHG vs. PI, $p = 0.41$). Although bacteria were evident in newly exposed areas after external fixator adjustment, most notably within the loosened pin to bar clamp, it did not result in an increase in bacteria counts (all four groups, $p = 0.11$; spray vs. scrub, $p = 0.18$; CHG vs. PI, $p = 0.99$).

CONCLUSIONS: Although there was no increase in bacteria counts after the simulated external fixator adjustment, it did expose additional bacteria previously unseen. Although there was no difference in surgical prep solution or method of application, consideration must be given to performing an additional surgical prep of the newly exposed surface after loosening of each individual external fixator component as this may further minimize potential bacteria exposure. (*J Trauma.* 2012;72: 760–764. Copyright © 2012 by Lippincott Williams & Wilkins)

KEY WORDS: External-fixation; infection; surgical prep; surgical-site infection; invasive distraction.

Infection remains a common problem during the management of complex musculoskeletal injuries and often leads to rehospitalization.[1,2] Efforts to minimize the risk of infection in these injuries have led to literature supporting the use of certain irrigation methods, local antibiotics, and negative pressure wound therapy among others. Until recently, little emphasis has been directed at the surgical prep, another surgeon-controlled factor in surgical site infection risk.[3] With the emergence of damage control orthopedics and staged management of periarticular fractures,[4–6] all orthopedic surgeons are confronted with the dilemma of what to do with the external fixator that must be prepped into the surgical field.

Given the lack of literature regarding prepping of external fixator components within a surgical field, many surgeons have turned to a number of unproven methods to reduce wound contamination from the external fixator. Removal of the external fixator components and "flashing it" before reapplying it in the sterile field, removal with use of new, sterile components, or covering the external fixator components with sterile towels are several such techniques.[5] However, these techniques are not always feasible because of the need to maintain stability, high costs associated with new components, or the need to access the external fixator to perform an intraoperative adjustment.

Hak et al.[7] raised appropriate clinical concern when they demonstrated that 1% PI prep did not remove all bacteria on contaminated external fixator constructs. However, in many cases, the surgeon must rely on the surgical prep to decontaminate the external fixator construct if other techniques to minimize the risk of iatrogenic contamination are not feasible. Since that study, there has been a growing body of literature suggesting the superiority of chlorhexidine in preoperative skin antisepsis, but no recommendations currently exist for the management of the external fixator when it must be prepped into the surgical field.

The purpose of this study was to explore the effectiveness of two commonly used surgical prep solutions in the

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surgical preparation of external fixator components. We hypothesized that the CHG solution would be superior to PI in the sterilization of contaminated external fixator constructs. Furthermore, we hypothesized that application of these solutions with a brush (scrubbing the fixator) would be more effective than spray alone.

METHODS

After approval from our institutional review board, 40 sterile external fixator constructs were assembled using an aseptic technique. The constructs included one 8-mm carbon fiber rod and one 5-mm Schanz pin connected by a single pin to rod coupling device (Hoffman II External Fixation System, Stryker Trauma, Switzerland) (Fig. 1).

Bioluminescent Bacteria

The bacterial broth prepared for this investigation consisted of 10^8 cfu/mL of *Staphylococcus aureus* (lux; Xenogen 29; Caliper Life Science, Hopkinton, MA). These bacteria are genetically engineered to emit photons during their metabolic cycle, allowing for quantification with a photon-counting camera system. Through a method previously described, the light emitted can then be correlated to actual bacterial counts.[8–10]

Inoculation

The 40 external fixator constructs were submerged in the broth of bioluminescent *S. aureus* (lux). After 12 hours in the broth, a sufficient time to allow biofilm formation,[11] the constructs were individually removed and baseline imaging obtained. It was not necessary to ensure homogenous distribution of bacteria on the constructs because of the method of data acquisition and analysis.

Quantification

When ready for imaging, the constructs were placed within a dark box for data collection. The IVIS100 imaging system (Xenogen, Alameda, CA) uses an optical Charge Couple Device camera to count photon emissions. Imaging software (LIVINGIMAGE V. 2.12; Xenogen, Alameda, CA, and IGOR V.4.02A; WaveMetrics, Lake Oswego, OR) was used to superimpose the photon count onto a gray-scale background image yielding the location and photon intensity. A standardized region of interest was placed around the external fixator construct on the image, and from this region
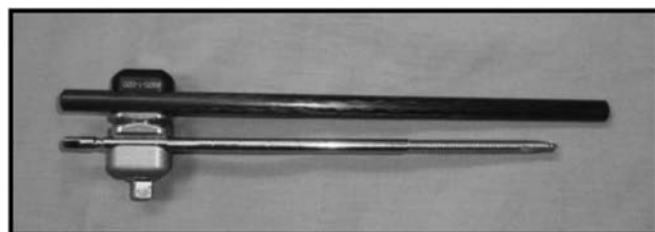

Figure 2. A standardized region of interest was placed around the external fixator construct on the image, and from this region of interest, the total photon count was determined. This count correlates with bacteria adherent to the construct. The red end of the spectrum (higher photon counts) correlates with the presence of more bacteria.

of interest the total photon count was determined. This count correlates with bacteria adherent to the construct (Fig. 2).

Randomization Into Treatment Groups

The constructs were randomly allocated into one of four treatment groups (Fig. 3). Constructs in group 1 were cleansed with aqueous 4% CHG solution (Hibiclens Monlnlycke Health Care, Norcross, GA) administered by brush for 10 seconds, whereas group 2 was cleansed with 4% CHG solution administered by spray. Groups 3 and 4 were cleansed with 10% PI solution (APLICARE, Meriden, Conneticut) administered by brush for 10 seconds or by spray, respec-

Figure 1. Example of the external fixator construct after assembly, consisting of one 8-mm carbon fiber rod and one 5-mm Schanz pin connected by a single pin to rod coupling device.
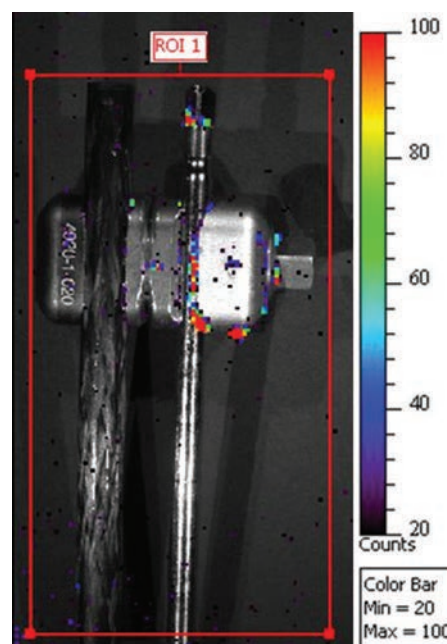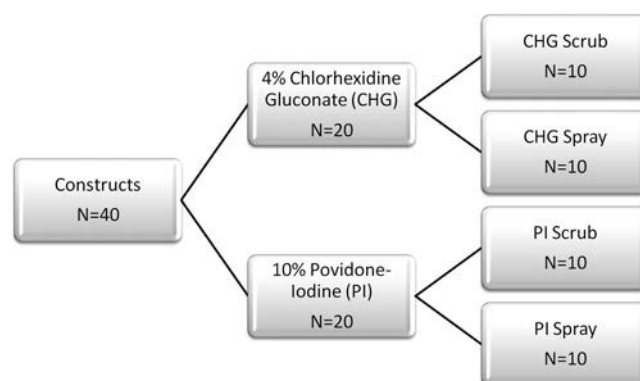

Figure 3. This consort diagram describes the allocation of constructs into one of the four groups compared in this study.

tively. Constructs in all groups were reimaged after 2 minutes. This allowed for 2 minutes of contact time for CHG (groups 1 and 2) and adequate time for drying of PI (groups 3 and 4) in accordance with manufacturer guidelines for each antiseptic solution.

Simulated External Fixator Adjustment

After initial imaging of each construct, a sterile simulated external fixator adjustment was performed by loosening the pin to bar coupling device and sliding it down the pin and rod 2 cm. The constructs were then reimaged. This allowed for reproducible simulation of an external fixator adjustment. The clamps were not retightened before imaging after the simulated adjustment.

Statistical Analysis

A pretest power analysis was performed and it was determined that a sample size of 10 constructs per group would have a power of 80% to detect a difference of 40,000 photon counts (20% of the anticipated mean photon count) between groups with a standard deviation of 30,000 photon counts and significance level of 0.05.

Photon counts at each time point were compared with the baseline photon counts. All values are reported as the average $\pm$ the standard error of the mean. Comparisons were made between solution used (CHG and PI), method of application (spray vs. scrub), and individual groups using the Kruskal-Wallis Test at each time point.

RESULTS

Bacteria Counts After Surgical Prep

After the surgical prep of the external fixator constructs, there was a significant reduction in bacteria counts compared with baseline values (group 1: 97.82% $\pm$ 1.34%, $p < 0.001$; group 2: 97.93% $\pm$ 1.35%, $p < 0.001$; group 3: 97.83% $\pm$ 1.20%, $p < 0.001$; group 4: 93.43% $\pm$ 4.12%, $p < 0.01$). This reduction in bacterial counts after surgical prep was similar when comparing all four groups independently ($p = 0.19$), method of application (spray vs. scrub, $p = 0.27$), and different solutions (CHG vs. PI, $p = 0.41$) (Fig. 4).

Bacteria Counts After Simulated External Fixator Adjustment

Bacteria counts were similar between groups, expressed as reduction from baseline, after the simulated external fixator adjustment (group 1: 97.78% $\pm$ 0.89%; group 2: 97.48% $\pm$ 1.74%; group 3: 95.46% $\pm$ 3.26%; group 4: 95.21% $\pm$ 2.08%; $p = 0.11$). Although there appeared to be higher bacteria counts (lower percent reductions) in constructs treated with PI compared with CHG, this difference was not significant ($p = 0.99$). There was also no difference when comparing method of application (spray vs. scrub, $p = 0.18$).

Although bacteria counts were similar, there were bacteria evident in newly exposed areas after the external fixator adjustment, most notably within the loosened pin to rod coupling device (Fig. 5, A-C).
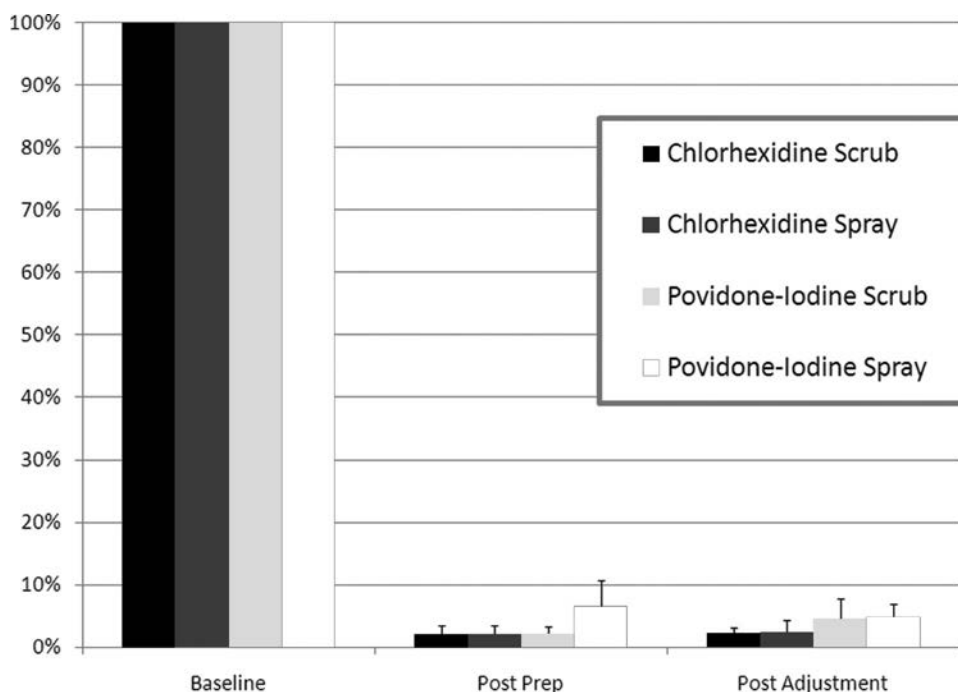

Figure 4. Bacterial quantity remaining on the external fixator construct compared with baseline levels after the initial prep (postprep) and after the simulated external fixator adjustment (postadjustment).
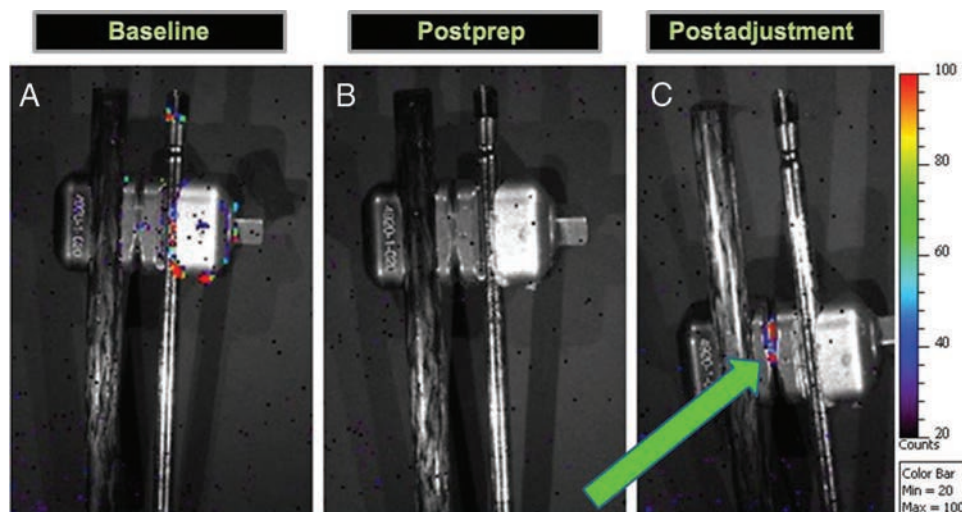
Figure 5. These are three sequential images demonstrating bacteria present on initial imaging (*A*), eradication of the majority of the bacteria after treatment with 10% PI spray (*B*), and then newly exposed bacteria present within the loosening pin to rod coupling device after the simulated external fixator adjustment (*C*).

DISCUSSION

Despite the widespread use of external fixators in the temporary and definitive management of extremity trauma, little empiric, high-quality evidence exists to guide most surgical decisions, particularly with regard to the prevention of infection. Infection remains a continued challenge in musculoskeletal trauma and has been extensively shown to drive outcomes.[1] Most literature to date has focused on the pin-soft tissue interface with both antibiotic-coated half pins and hydroxyapatite-coated pins advocated by authors to reduce pin tract infection and subsequent deep infection or osteomyelitis.[12,13] Because injured extremities frequently require surgical incisions and have open wounds, simple management of the pin-soft tissue interface alone ignores the risks of wound contamination and subsequent deep infection that can occur from separate sources of bacteria; the fixator components themselves being one major potential source.

Hak et al.[7] demonstrated the presence of bacteria on contaminated external fixator components after treatment with a dilute PI surgical prep. Although the clinical implications of this are largely unknown, it is a legitimate concern for the treating surgeon when deciding how to minimize potential bacteria exposure when an external fixator must be prepped into the surgical field. Although never published, Watson et al.[14] demonstrated that positive cultures of the external fixator obtained after prepping with 95% isopropyl alcohol and PI were not associated with an increase in wound infections. However, the methodological limitations of this study—small patient numbers and the use of an imperfect gold standard (swab cultures)—limit the conclusions that can be drawn.

The results of our study suggest that both commonly used surgical prep solutions, CHG and PI, are equally effective at reducing gram-positive bacteria counts on external fixator components, and this is irrespective of whether constructs are scrubbed or sprayed. Despite extensive literature demonstrating the superiority of CHG over PI in prepping clean surgical sites, we failed to detect a difference when cleansing components consisting of stainless steel and aluminum.[15–17] We also found that a simulated external fixator adjustment exposed previously unprepped bacteria contained within both the pin-clamp and bar-clamp interfaces (Fig. 5, C). Clinically, this has major implications, because new bacteria exposed into a sterile surgical site after adjustment have the potential to contaminate the entire surgical field with potential for increasing the risk for wound contamination and ultimately leading to possible wound infection. Although we failed to detect a statistically significant increase in bacterial counts after the simulated adjustment, we think that fixators prepped into the surgical field should always have an on-field reprep after any adjustment to reduce this potential source of wound contamination.

This study has several weaknesses that warrant mention. First, the simplified external fixator constructs used in this study may not replicate what is actually seen clinically. However, we suspect that our results might underestimate the true prevalence of bacterial adherence after the initial prep and any subsequent adjustments, because in larger constructs it may be more difficult to perform a similar "concentrated" preoperative prep as was performed in this study. Another limitation is that only one marketed pin to rod coupling device/clamp was studied, while there are multiple fixator products commercially available with different style clamps. Because of this, we cannot draw conclusions regarding persistence of bacteria based on clamp style or size. This study also relied on data collected using only one form of bacteria, a gram-positive bioluminescent *S. aureus* model. In clinical practice, most surgeons are concerned more with difficult organisms to treat, such as methicillin-resistant *S. aureus*. Despite these reservations, the antiseptic mechanism of action for both CHG and PI is similar in all bacteria, and we suspect that similar results would be seen with methicillin-

resistant *S. aureus* and other clinically relevant bacteria (i.e., gram-negative organisms and anaerobes) as seen in this study. In addition, although CHG was used as a spray in this study for purposes of comparing both antiseptic solutions and methods of application, it is currently not commercially available in that formulation. Finally, a post hoc power analysis was performed, which demonstrated that 312 total constructs, 78 per group, would be needed to detect a difference between groups.

In conclusion, we have identified external fixator adjustments as a potential source of new bacteria into the sterile surgical field, which has the potential to lead to wound contamination and possible musculoskeletal infection. We demonstrated that PI and CHG solutions, both commonly used and readily available, are equally effective at cleansing external fixator components when applied with either a brush or spray bottle. However, because of the presence of new bacteria previously unseen after the external fixator adjustment, we recommend that consideration be given to performing an additional surgical prep after loosening of each individual external fixator component as this may minimize potential bacterial exposure to the presumed sterile operative field.

AUTHORSHIP

D.J.S., J.C.W., and J.R.H. designed this study. D.J.S. and M.J.B. collected data and prepared the manuscript, for which D.J.S. created figures. B.D.M., J.C.W., and J.R.H. reviewed the manuscript prior to production.

DISCLOSURES

The authors declare no conflicts of interest.

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