



Salvage of Infected Orthopedic Hardware With Intraoperative and Postoperative Hypochlorous Acid Instillations

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Abstract

Background. Orthopedic hardware infections often require hardware removal or replacement. In some situations, hardware removal is not possible or would require amputation. Thus, a method of in-situ hardware salvage could significantly improve patient outcomes. Hypochlorous acid is a broad-spectrum antimicrobial solution with rapid effectiveness in biofilm impairment.

Methods. This article presents 2 patients with orthopedic hardware infection. Patient A had recurrent draining sinuses from an intramedullary nail in the femur. The orthopedic surgery team recommended above-knee amputation if hardware salvage was not possible. Patient B had a degloving injury of the right upper extremity with radius and ulna fractures that required revascularization and free flap coverage; when hardware infection developed, hardware removal would have required external fixator placement. In both patients, hypochlorous acid was used intraoperatively during debridement to soak the hardware for 5 minutes. Closed suction drains were placed along the hardware, and postoperative instillations of hypochlorous acid were placed through the drains for 5 minutes 1 to 2 times a day for 4 days for Patient A and 7 days for Patient B.

Results. On follow-up at 10 months for Patient A and at 9 months for Patient B, there was no evidence of recurrent hardware infection. Hardware was successfully salvaged in both patients.

Conclusions. Hypochlorous acid is an effective and safe topical antimicrobial agent for recurrent infections due to hardware-associated biofilm. Postoperative instillations of 0.025% hypochlorous acid through closed suction drains may improve hardware salvage rates and optimize outcomes.

Introduction

It is estimated that there are approximately 2,000,000 fracture-fixation devices placed annually in the United States. These fracture-fixation devices include intramedullary nails, external-fixation pins, plates, and screws. Of these 2,000,000 fracture-fixation devices, there are approximately 100,000 implant infections, or a 5% average rate of infection. These implant infections can ultimately lead to increased costs to both the patient and the health care system as well as significant functional deficits, including limb amputation. The average cost to treat orthopedic hardware infections can range from \$25,000 to \$51,000.^{1,2}

One of the major factors that causes high rates of failure of hardware salvage is the microbial biofilm. The biofilm is a structured aggregation of microbial cells, including one or several different species, that secrete a gelatinous polymer matrix. This matrix limits antibiotic diffusion and immune cell activity, and biofilm infections are particularly difficult to eliminate, frequently causing chronic or recurrent infections.³ Proper treatment of hardware infections includes operative irrigation and debridement, typically with vascularized tissue coverage of the exposed hardware along with postoperative intravenous (IV) antibiotics to promote antimicrobial delivery and immunologic response at the hardware; internal fixation hardware removal with external fixator placement and potentially amputation may also be needed. A study with 121 patients from 3 Level 1 trauma centers showed that 71% of fractures with postoperative hardware infections were successfully treated with debridement, retention of hardware, and culture-specific antibiotic treatment and suppression. Factors that showed a significant difference in predicting treatment failure were open fractures and presence of an intramedullary nail.⁴

The literature does not provide robust evidence for the effectiveness of various topical irrigation solutions at the time of surgical debridement and/or postoperatively for the treatment of prosthetic-associated biofilms. In vitro studies have evaluated the effectiveness of biofilm exposure to triple-antibiotic solution, 10% povidone/iodine, chlorhexidine, and 0.025% hypochlorous acid on eradication of bacterial biofilm. These investigations have shown effectiveness of povidone/iodine, chlorhexidine, and hypochlorous acid solutions in eradicating planktonic bacteria; however, only stabilized hypochlorous acid was able to eradicate biofilm within 5 minutes of soaking on the surface of the implant/prosthesis.^{5,6} The purpose of this study was to evaluate the effectiveness of both intraoperative and postoperative hypochlorous acid instillations administered through closed suction drains to salvage infected orthopedic hardware.

Methods and Materials

We present 2 patients, Patient A and Patient B, who each had traumatic injuries resulting in open fractures. Patient A is a 29-year-old man who sustained a crush injury in which his left leg was pinned between two cars at a car wash, resulting in a femoral shaft fracture that required intramedullary nail fixation, 4-compartment fasciotomy due to compartment syndrome, and popliteal artery injury requiring saphenous vein graft repair. After his hospital discharge from his acute traumatic injuries, he was readmitted twice for recurrent infections from the femoral intramedullary nail. **Figure 1** shows a photograph of the seropurulent drainage from the proximal aspect of the incision on the left thigh. Cultures of wound exudate grew *Proteus mirabilis*. The patient received IV antibiotics and underwent 5 debridements with intraoperative wound irrigation with dilute chlorhexidine and normal saline over a 3-week period by the orthopedic surgery service in attempt to salvage the hardware. After 3 weeks of IV antibiotics, operative debridements, and recurrent infections, the orthopedic surgery team discussed above-knee amputation if hardware salvage was not possible and consulted the plastic surgery service for further recommendations. The plastic surgery team then performed 3 operative debridements. For the second and third debridements, 0.025% hypochlorous acid (PhaseOne) was utilized for intraoperative and postoperative instillations/soaks. The hypochlorous acid was allowed to soak the hardware and surrounding wound for 5 minutes both intraoperatively and postoperatively. Postoperatively, hypochlorous acid was administered through closed suction drains 1 to 2 times a day for 4 total days and allowed to soak for 5 minutes before placing the drains back to bulb suction.



Figure 1. Seropurulent malodorous drainage from proximal aspect of incision emanating from the femoral shaft intramedullary nail. Fractional flow reserve tracings in the intraseptal segment demonstrating compromised flow (E).

Patient B is a 38-year-old woman who sustained a traumatic partial amputation of her right distal forearm in an all-terrain vehicle accident. She required open reduction with internal fixation of fractures to both the radius and ulna fractures along with radial and ulnar artery repair, groin flap coverage, and subsequent latissimus dorsi free flap coverage. She developed necrosis of the groin flap along the volar forearm overlying the distal radius and ulna internal fixation hardware (**Figure 2**). Operative debridement of the necrotic tissue was performed, and cultures of wound exudate grew *Escherichia coli*, *Morganella morganii*, and *Proteus mirabilis*. She was treated with IV ceftriaxone. Hypochlorous acid was used to soak the exposed hardware during subsequent intraoperative debridements followed by wound vacuum applications. Latissimus dorsi free flap coverage was then performed once the wound bed showed no gross evidence of infection with no further malodor, purulent drainage, or necrotic tissue. Following free-flap coverage, hypochlorous acid was instilled through closed suction drains 1 to 2 times a day for 7 total days and allowed to soak for 5 minutes before placing the drains back to bulb suction.



Figure 2. Groin flap with necrotic tissue along the volar forearm overlying the distal radius and ulna internal fixation hardware, (A) before debridement and (B) after final debridement.

Results

There was no evidence of recurrent hardware infection upon follow-up at 10 months and 9 months for Patients A and B, respectively, following the final debridement with intraoperative and postoperative hypochlorous acid soaks by the plastic surgery team. Patient A was discharged to a rehabilitation facility and was successfully ambulating with the left lower extremity. Patient B had significant stiffness of her wrist and fingers despite hand therapy and is following up with the hand surgery service for further interventions to maximize her hand function.

Discussion

Internal fixation hardware infections, particularly those occurring with open fractures and intramedullary nail fixation, are associated with increased rates of hardware salvage failure.⁴ The microbial biofilm that forms over implants is thought to be a significant factor causing recurrent hardware- and prosthesis-associated infections. In addition to sharp debridement of nonviable tissue, topical irrigation solutions are frequently used in attempts to eliminate bacterial burden and biofilm. In addition to their bactericidal effects, however, many irrigation solutions are also cytotoxic to the wound bed, which can impair fibroblast activity and ultimately negatively impact wound healing.

Chlorhexidine has been shown to be effective in penetrating biofilms at 2% strength; however, concentrations as low as 0.02% were found to be cytotoxic to fibroblasts.⁷ Bleach-based hypochlorite solutions, such as Dakin's solution, have poor biofilm penetration due to neutralization of the active chlorine on the outer surface of the biofilm.⁸ In breast implant biofilm studies, povidone-iodine 10% solution was effective in eradicating biofilm on both smooth and some Biocell (Allergan) textured implants after 5 minutes; however, soaking for 2 hours was required for biofilm elimination on Siltex (Mentor Worldwide) textured implants. Povidone-iodine 10% solution, 1.3 g/dL, has been shown to be the minimal bactericidal concentration with minimal cytotoxicity. This solution can be prepared by diluting 6.5 μ L of povidone-iodine into a 500- μ L bottle of sterile saline.⁷ However, other studies have shown that even at this concentration, fibroblast cell disruption occurs.⁸ Pure 0.025% hypochlorous acid

stabilized in amber glass was effective in eradicating the biofilm on all of these implant surfaces within 5 minutes of soaking. Additionally, at concentrations around 0.025%, there was an increase in fibroblast migration that potentially enhanced wound healing.⁹

Conclusions

Pure 0.025% hypochlorous acid's unique characteristics with rapid antimicrobial activity, biofilm eradication, enhancement of fibroblast migration, and overall excellent safety profile make it a particularly effective topical soaking solution for wounds, especially those that may be associated with a microbial biofilm. Although our sample size of 2 patients to date is small, we have shown the effectiveness of 0.025% hypochlorous acid in orthopedic hardware salvage in cases that otherwise would have required amputation or removal of hardware with external fixator placement. If these intraoperative and postoperative soaks had been initiated earlier in Patient A, potentially during the initial placement of the intramedullary nail, he may have avoided 3 weeks of repeat hospital admissions, IV antibiotics, and 8 subsequent trips to the operating room for surgical debridement. Our antimicrobial regimen utilizing intraoperative hypochlorous acid soaks along with instillations through close suction drains may help eliminate residual hardware-associated biofilm that persists following operative debridement while also enhancing fibroblast activity and overall wound healing ability.

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