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Antibiotic-impregnated Calcium Sulfate Use in Combat-related Open Fractures

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Abstract

This article presents our experience with the use of antibiotic-impregnated calcium sulfate in the management of comminuted open fractures with a bony defect caused by combat-related blast injuries and high-energy wounds.

Calcium sulfate was used 19 times in 15 patients (17 fractures) as a bone graft substitute and a carrier for antibiotics. The anatomic sites of the graft were as follows: 6 calcanei, 1 midfoot, 1 metatarsal, 5 tibiae, 3 femorae, and 1 humerus. The average number of procedures prior to grafting was 6.2 (range, 2-10; median, 6) with grafting performed at an average 28 days after injury (range, 9-194 days; median, 14 days). Average radiographic follow-up of 12 fractures not requiring repeat grafting or amputation was 8.5 months (range 1-19 months; median, 7 months), and all of these fractures demonstrated clinical and radiographic evidence of fracture healing and consolidation. Four patients subsequently underwent 5 transtibial amputations: 2 for persistent infection, 1 when the patient changed his mind against limb salvage acutely, and 2 for severe neurogenic pain. Including the 2 amputations for persistent infection, 4 patients (22.2%) required further surgical management of infection. Three patients (17.6%) subsequently developed heterotopic ossification at the graft site, which required surgical excision.

Antibiotic-impregnated calcium sulfate is effective in treating severe, contaminated open fractures by reducing infection and assisting with fracture union.

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Osteomyelitis following open fractures results in significant morbidity requiring extensive surgical treatment and antibiotic therapy. Since the initial introduction of the technique with exchange arthroplasty by Buchholz and Gartmann[1] in 1972, local antibiotic delivery systems such as polymethylmethacrylate (PMMA) beads have been available to prevent or treat osteomyelitis in open fractures.[2-4] Local delivery of antibiotics for the treatment of osteomyelitis facilitates high local drug concentrations without associated systemic effects and may result in shorter hospital stays.[3,5-9]

Unfortunately, the use of PMMA beads requires an additional surgical procedure for their subsequent removal and leaves a potential residual soft tissue dead space or osseous defect. Therefore, several authors have advocated absorbable delivery systems such as calcium sulfate for the treatment of osteomyelitis and open fractures.[3,10-32] In addition to providing a carrier for the antibiotics, calcium sulfate eliminates the dead space from debrided bone and serves as a potential synthetic osteoconductive bone substitute.[16] While no literature exists with regard to its use to prevent infection in humans, a recent study from the US Army Institute of Surgical Research demonstrated that tobramycin-impregnated calcium sulfate was effective in preventing infection in contaminated wounds in a caprine model, although fracture healing rates were not investigated.[28]

Since the beginning of Operations Iraqi Freedom and Enduring Freedom, a majority of patients treated by the Orthopedic Surgery Service have had open fractures. While the existing treatment protocols for open fracture management are well accepted, blast injuries often create open, comminuted fractures with segmental bone loss that are not amenable to treatment by standard techniques. While there are no currently published reports of the incidence of segmental bone defects in combat-related fractures from this conflict, there is an ongoing study of grade 3 open tibia fractures at our institution. Between March 2003 and September 2007, our institution treated 102 combat-related open grade 3 tibia fractures. While the majority of these fractures were comminuted and segmental, 15 fractures (14.7%) had documented segmental bone loss on initial presentation. When extensive debridement is required, patients are left with a dead space within the bone that, if closed, will fill with hematoma, a habitat conducive to the growth of bacteria. While many publications have documented the results of antibiotic-impregnated calcium sulfate in the treatment of osteomyelitis and animal studies, relatively little literature exists on its use in the prevention of infection.

Materials and Methods

Following approval by our Institutional Review Board, we performed a retrospective review of our orthopedic service surgery log and Operations Iraqi Freedom and Enduring Freedom tracking database to identify all patients who met our inclusion criteria: patients with combat-related open fractures treated with antibiotic-impregnated calcium sulfate at definitive closure between September 11, 2001, and June 29, 2006. After identifying the patients who met our criteria from the >1500 patients within the database, all outpatient and inpatient medical records, radiographs, and clinical images were closely examined.

We recorded all data relevant to fracture healing and infection, including mechanism and date of initial extremity injury, initial treatment methods, duration between injury and final treatment, indications for use of antibiotic-impregnated osteoconductive bone substitute, clinical results, and complications of grafting. We also reviewed all radiographic images obtained at our institution, as well as those from outside military treatment facilities for those patients who had clinical follow-up elsewhere. Radiographs were critically assessed for evidence of fracture union, matrix formation, and timing of calcium sulfate absorption. In all cases, initial clinical photographs were obtained that were also reviewed to better appreciate the severity of the initial injury.

Results

Since November 2004, 15 patients with 17 fractures underwent 19 procedures with calcium sulfate (Osteoset; Wright Medical Technology, Inc, Arlington, Tennessee) used as a carrier for antibiotics and a bone graft substitute (Table 1). One severely injured patient with multiple extremities injured had calcium sulfate used in 3 locations: bilateral feet and right femur. Additionally, 2 patients required a second attempt at definitive closure with calcium sulfate when the first attempts resulted in chronic drainage and infection. Therefore, in total, calcium sulfate was used 19 times in 17 locations (Table 2).

Table 1

Antibiotic-impregnated Calcium Sulfate Use

Patients	15
Fractures	17
Grafting procedures	19
Regrafted	2
Amputations	5

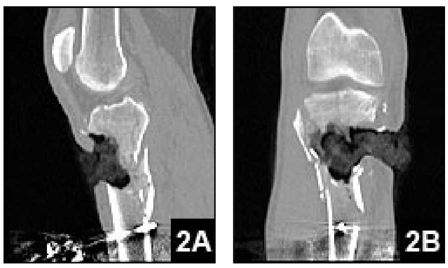
The anatomic locations of calcium sulfate use were as follows: 6 calcanei, 1 midfoot, 1 metatarsal, 6 tibiae (4 distal, 2 proximal), 4 femorae, and 1 humerus (Figures 1, 2). Fifteen of 17 fractures were the direct result of a blast and 2 resulted from vehicular accidents. Patients underwent an average of 6.2 procedures (range, 2-10; median, 6; generally serial irrigation and debridements with provisional limb stabilization) prior to definitive bone coverage and grafting an average of 28 days (range, 9-194; median, 14) after injury (Figure 3).

Table 2

Patients Demographics

Patient	Injury	No. of Prior Procedures	Injury to Grafting (d)	Follow-up (mo)	Radiographic Result
1	Tibial plateau fracture	2	11	5.8	Fracture union
2	Calcaneus fracture; talonavicular dislocation; fasciotomies	4	10	10.2	Amputation
3	Calcaneus fracture; talonavicular dislocation	7	9	3.4	Fracture union
4	Calcaneus fracture; talonavicular subluxation	8	25	8.7	Amputation
5	Femur fracture	5	9	10.8	Fracture union
6	Distal femur/tibial plateau/patella fracture	4	11	7.2	Removed for infection
6		8	27	6.7	Fracture union
7	Proximal tibia fracture	5	12	18.6	Fracture union
8	Cuboid and midfoot fractures	6	15	4.9	Fracture union
9	Calcaneus/talus/midfoot fractures	5	11	6.8	Fracture consolidation
10	Distal tibia fracture	3	10	18.0	Fracture union
11	Tibial diaphyseal and plateau fracture	4	11	17.2	Fracture union
12	Tibial pilon fracture	6	14	13.1	Infection and repeat grafting
12		9	68	11.3	Amputation
13	Humerus fracture	10	194	0.5	Fracture union
14	Proximal femur fracture	8	23	11.7	Fracture union
14	Right calcaneus fracture	8	23	11.7	Amputation
14	Left calcaneus/talus/ankle fracture	8	23	11.7	Amputation
15	First metatarsal fracture, calcaneus fracture	8	21	6.6	Fracture union

Prior to evidence of fracture healing, 4 patients underwent 5 transtibial amputations, 1 acutely and the other 4 over 3 months after definitive closure, leaving 12 fractures available for radiographic evaluation. Follow-up was obtained at an average of 21.4 months (range, 13-30 months; median, 21), at which time all remaining fractures showed evidence of consolidation, graft resorption, and fracture healing (Figure 4). Except for the 1 acute amputation, all sites of grafting were evaluated for evidence of infection postoperatively (N=18). Postoperatively, 4 of 18 grafting procedures (22.2%) showed clinical evidence of infection, with 2 subsequently undergoing amputation and 2 requiring repeat irrigation and debridement prior to regrafting. During the irrigation and debridement procedures before the initial placement of the calcium sulfate, 13 of 17 locations (76.5%) had positive intraoperative cultures: 11 with acinetobacter, 6 with staphylococcus, 2 klebsiella, 2 pseudomonas, and 1 each with bacteroides, bacillus, and corynebacterium. Four wounds had only 1 bacteria isolated, 5 had 2 bacteria, 3 had 3 bacteria, and 1 had 4 different bacterial isolates. In 3 cases, the cultures were all negative prior to closure, and in 1 case cultures were not obtained as the index procedure at our institution was the definitive closure. Therefore, of the 13 sites with positive cultures, 9 had multiple bacteria, making antibiotic selection difficult.



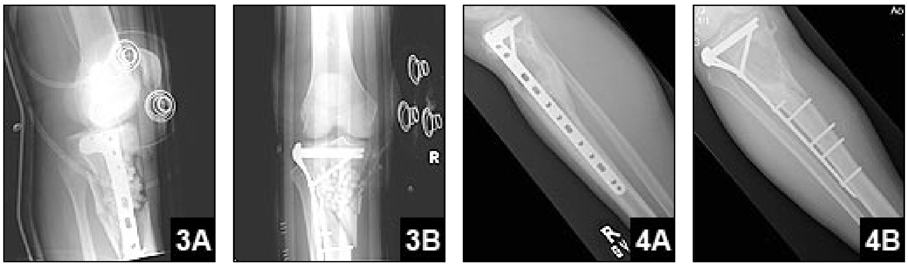


Figure 1: Lateral (A) and AP (B) radiographs of patient 7 preoperatively. Figure 2: Sagittal (A) and coronal (B) CT scan images through fracture site of patient 7 preoperatively. Figure 3: Lateral (A) and AP (B) radiographs of patient 7 immediately postoperatively. Figure 4: Lateral (A) and AP (B) radiographs of patient 7 at 7-month follow-up.

If cultures were negative or were not obtained, or if the isolated bacteria was appropriately sensitive, vancomycin and tobramycin were used in the calcium sulfate. In cases of multidrug-resistant acinetobacter, amikacin or imipenem was selected if sensitivities indicated a favorable profile. Notably, 3 of 17 locations (17.6%) developed heterotopic ossification around the graft site and in all cases required surgical excision. Interestingly, 2 of the 3 heterotopic ossification specimens excised from the injury site returned with positive cultures, 1 of which had negative cultures at all previous procedures. In the third case of heterotopic ossification excision, microbial specimen analysis was not performed.

Five amputations were performed in 4 patients, or 5 of 17 fractures (29.4%). One amputation was performed acutely when the patient changed his mind against limb salvage, and the others were performed over 3 months after the injury. The indications for delayed amputation were infection and neuropathic pain in 2 cases each. Four of the 5 amputations were following open calcaneus fractures and the other an open distal tibia fracture.

Discussion

Substantial civilian orthopedic literature has documented the high risk of infection associated with open fractures.[33-36] While there are well -accepted methods of fracture treatment within the civilian population, relatively little literature exists within the military population where the mechanisms of injury are markedly different. A majority of our injuries are the result of explosive blasts, which cause significant trauma to soft tissues and are frequently associated with segmental bone loss. The substantial cavitary defects seen following blast injuries are not commonly seen within civilian trauma populations, making the management of these patients all the more difficult due to the paucity of supporting literature to guide treatment.

When the defect is associated with significant damage to the neurologic or vascular structures, the management algorithm becomes somewhat simplified, as amputation is often the most prudent option for both patient and physician. The difficulty comes in the management of a neurovascularly intact or otherwise putatively functional extremity in which the massive osseous defect requires further attention. If left alone, the large fracture hematoma that develops following closure leaves the extremity susceptible to both infection and fracture nonunion. Therefore, antibiotic-impregnated calcium sulfate, targeting both the fracture healing process and providing bacterial prophylaxis, can potentially improve fracture healing while decreasing the rate of osteomyelitis. We feel that this technique is a useful alternative to staged bone grafting following antibiotic-impregnated spacer or bead placement, potentially avoiding additional surgical procedures and accelerating the healing process. Clearly, fractures resulting from blast injuries or the high-energy trauma seen during wartime are different from civilian trauma, and during the most recent conflict, a majority of our fractures have been the result of penetrating trauma from blast injuries.

In the present study, 15 of 17 fractures were the direct result of a blast, and, while the exact mechanism of injury is not always clear, open fractures were generally the result of penetrating trauma. Furthermore, the most commonly fractured bone requiring grafting was the calcaneus, which has well-documented poor results with open fractures in the civilian literature. A recent study by Heier et al,[35] although not with penetrating trauma, found the incidence of osteomyelitis with Gustilo and Anderson type IIIB open calcaneus fractures to be 46.2% (6 of 13), with 3 of the cases (23% total) of osteomyelitis going on to amputation. In the present study, 4 of 6 (66.7%) open calcaneus fractures treated with antibiotic-impregnated calcium sulfate underwent amputation, although in 1 case the patient chose amputation 2 weeks following grafting when he decided against limb salvage with a plantar insensate foot. In reviewing all high-energy calcaneus fractures from the current conflict, the long-term outcomes are anecdotally poor, and in the present study with 6 open calcaneus fractures, only 2 were given the opportunity to consolidate and heal for these reasons.

If the cases that went on to amputation are excluded, our fracture healing rate was 100%, which is surprising given the lack of periosteum and the extent of soft tissue disruption in the injuries. A majority of fractures were metaphyseal, a region known for excellent fracture repair. Calcium sulfate, an osteoconductive bone substitute,[16] without the addition of any osteoinductive substance was effective in our small series of 12 fractures, resulting in fracture union with no further procedures for nonunion. Beardmore et al[10] advocated the addition of demineralized bone matrix to antibiotic-impregnated calcium sulfate, but we did not find this necessary.

While antibiotic-impregnated calcium appears to assist with fracture healing, it was not as successful at preventing infection, with a 22% rate of osteomyelitis in the present study. Four cases went on to develop osteomyelitis and 2 of those required amputation as a direct result of the infection. Furthermore, over half of the cases were noted to have drainage for the first 1 to 2 weeks postoperatively. Early in the study this drainage was thought to be related to infection, but after further investigation it appeared to be sterile drainage resulting from antibiotic fluid elution and calcium sulfate bead resorption, a consequence well documented in the literature and one we have come to expect and accept.[10,18] McKee et al,[18] in a prospective study on antibiotic-impregnated calcium sulfate use in long bone osteomyelitis defects, found the presence of a chronic draining sinus correlated with the radiographic resorption of antibiotic pellets at approximately 2 to 3 months in 8 of 25 patients. Similarly, they found this drainage to be sterile and the wounds without any evidence of infection. However, we relied on other clinical signs of infection to determine our infection rate, which was still moderately high at 22%.

Heterotopic ossification developed at the graft site in 3 of the 17 sites treated in our series, for a total prevalence of 25% in the 12 sites not going on to amputation. It is conceivable that calcium sulfate egression into the soft tissue contributed to this, although this has not been previously reported. However, we have noted a high incidence of heterotopic ossification in our blast-injured patients who were not treated with calcium sulfate implantation.[37] Therefore, although this matter merits further attention in future studies, we feel that this heterotopic ossification formation likely represents a consequence of injury rather than treatment.

The present study has significant limitations. First, it is a retrospective design. In our current state of conflict, prospective randomized studies are often not feasible, as they have the potential to be misinterpreted as experimentation on our injured soldiers, a perception we feel should be avoided for obvious reasons. Therefore, creating a control group is not practical. Furthermore, we were unable to identify a retrospective cohort for comparison, as most segmental defects were treated in a similar manner. An additional limitation includes our lack of functional outcome assessment. As these injuries involve multiple different fractures, our study does not lend itself to clinical outcome measures. Instead, we used radiographic and clinical evidence of fracture healing and clinical evidence of recurrent or persistent infection, as these are the ultimate goals of bone graft substitutes and antibacterial therapy, respectively. Our follow-up was also somewhat limited due to patients either returning to duty at remote stations or leaving the military. However, all patients were followed until they demonstrated radiographic and clinical evidence of aseptic fracture union or underwent amputation, our chief clinical outcome measures.

Conclusion

Antibiotic-impregnated calcium sulfate is effective in treating open fractures with osseous defects by assisting with fracture healing and reducing infection. The present study includes several patients who underwent amputation, and while we concede that these patients may have initially been pushing the limits of limb salvage, we feel that our injured soldiers deserve every opportunity for limb salvage when desired by the patient and medically feasible. Thus, our results with severe open hindfoot and distal tibia fractures are difficult to interpret, due to the high amputation rate in this subset of patients. Excluding patients who underwent amputation, our results for fracture healing are favorable and our infection rate is acceptable. Therefore, we feel that the present study demonstrates the effectiveness of antibiotic-impregnated calcium sulfate as an adjunct in the management of severe open fractures with segmental or cavitary bone loss.

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