

Original Article

Single stage treatment of diabetic calcaneal osteomyelitis with an absorbable gentamicin-loaded calcium sulphate/hydroxyapatite biocomposite: The Silo technique

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ABSTRACT

Background: Chronic osteomyelitis necessitates appropriate infected bone and soft tissue excision. The authors describe the Silo surgical technique for the treatment of calcaneal osteomyelitis using a new antibiotic-loaded absorbable calcium sulphate/hydroxyapatite biocomposite.

Methods: The Silo method involves debridement of the dead bone and local delivery of antibiotic in drilled tunnels using the biocomposite. It is combined with multiple sampling and culture-specific systemic antibiotic treatment guided by a multidisciplinary team.

Twelve consecutive diabetic patients with heel ulcers and calcaneal osteomyelitis were treated with the above method. All had comorbidities (Cierny–Mader (C–M) Class B hosts). The mean age was 68 years (range 50–85). A retrospective review of radiographs and electronic medical records was conducted.

Results: Patients were followed up until clinical cure of the ulcer for a mean of 16 weeks (range 12–18). Infection was eradicated in all 12 patients with a single stage procedure following a bone preserving technique. One patient required a subsequent flap operation and six vacuum-assisted closure (V.A.C.). There was also one case of prolonged wound leakage and no calcaneal fractures.

Conclusions: The Silo technique is an effective method of local delivery of antibiotics and can be effectively implemented into the single-stage treatment of calcaneal osteomyelitis offering increased bone preservation and local delivery of antibiotic, decreasing the need for a major amputation.

Level of evidence: Level IV- case series.

1. Introduction

Calcaneal osteomyelitis is a serious complication in a diabetic foot leading often to amputation [1]. Once it is established it is rarely eradicated without any surgical intervention. The principle is that the infected bone must be resected and the surrounding soft tissue extensively debrided. Insufficient bone resection will lead to recurrence of the osteomyelitis but on the other side there is a need to preserve as much bone as possible in order not to jeopardize stability of the residual foot. Furthermore soft tissue coverage is a crucial determinant of success. In the case of calcaneal tuberosity osteomyelitis, it is functionally desirable to retain as much of the bone as possible but the exact adequate level of resection to eradicate the infection is arbitrary intra-operatively and depends on surgeon's experience.

Local delivery of antibiotics in the treatment of osteomyelitis has been applied extensively during the last decades and is considered both safe and effective [2]. Calcium sulphate (CAS) materials loaded with antibiotics are used for bone defects after excision of infected bone but bone formation is not reliable and pathological fractures have been reported in up to 5% of patients [3–5].

Recently, the combination of CAS and hydroxyapatite (HA) in a synthetic and injectable mixture has been introduced as “the new era bone substitute” [6]. The above combination has also been loaded with antibiotics (175 mg gentamycin in 10 ml CAS/HA: Cerament G; Bone-support, Lund, Sweden). It has been shown that the Cerament G biocomposite is highly effective for dead space management in cases with chronic osteomyelitis [7].

The authors present the Silo technique for single surgical treatment

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of chronic calcaneal osteomyelitis using Cerament G. The proposed method offers the advantage of limited bone resection and local delivery of antibiotic into the deep bone to eradicate microscopic foci of infection.

2. Operative technique

A single-stage protocol treatment of chronic osteomyelitis is applied [8]. A thigh tourniquet is used when possible with the patient under general anesthesia and prone or (if anesthetic concerns) in a lateral recumbent position with a vacuum beanbag on a radiolucent table [9]. A longitudinal posterior incision continues onto the inferior surface of the heel and then to the ulcer or can split the Achilles tendon. The Achilles tendon if needed is sharply reflected off the bone and the ulcer in the soft tissue debrided and excised in an elliptic shape to facilitate closure. Multiple operative samples are taken, using an established method [10].

All patients had MRI scan of their foot pre-operatively. Based on the MRI findings, the extension of the heel wound, the presence of sepsis and the general health condition of the patient decision is taken whether operative treatment with the Silo technique is adequate. Intra-operatively bone resection includes all the infected and non-viable bone. A few millimeters of bone covering the hypointense (on T1-weighted images) and hyperintense (in T2-weighted images) nidus of osteomyelitis is aimed (Fig. 1a and b). If possible, the posterior subtalar joint is preserved. In order to deliver locally antibiotic and treat microscopic foci of infection multiple Silo type tunnels (four to five) are drilled into the os calcis using a 3.2 mm drill bit. Drilling is done under X-ray guidance towards the posterior subtalar joint at least 0.5 cm short of full length (Fig. 2). Then, the area is irrigated with hydrogen peroxide and dried. The dry Silo tunnels are filled with 5 ml of Cerament G using the provided extender tips (Fig. 3). The wound is either closed primarily (Fig. 4) or left open for wound care and dressings and the vacuum-assisted closure (V.A.C.) can also be applied. After healing of the wound, a custom-made ankle foot orthosis (AFO) can be applied.

With regards to the suitability of a patient with chronic calcaneal osteomyelitis for the Silo technique, involvement of the posterior subtalar joint (PSJ) is an absolute contraindication. The drilled tunnels reach 1 cm short of the PSJ and an arbitrary minimal length of 2 cm is chosen in order to contain the biocomposite so infection infected bone at a distance of less than 2.5 cm from the PSJ is considered as a contraindication for the Silo technique. Based on the above all patients excluded deemed unsuitable for the debridement process were excluded pre-operatively.

Antibiotic treatment as per protocol is stopped at least two weeks before surgery, provided it is safe for the patient [6]. Intra-operatively the patient is given intravenous gentamicin (2 mg/kg continued as one dose every 24 h initially) and teicoplanin (400 mg and continued as every 24 h initially) after taking samples and modified according to the microbiology results for a total of 6–12 weeks.

3. Patients and methods

The patients were informed on the nature of the procedure and gave their consent to proceed. Our ortho-plastic team has a wide experience on the local application of Cerament G for treatment of chronic bone infections with or without associated metalwork [11]. The effectiveness of the Cerament G biocomposite is also supported from the literature [7]. Based on the above and on the fact that our technique is practically an enhancement of the traditional partial calcanectomy with drilled tunnels filled with the biocomposite we offered the Silo treatment to the patients.

Twelve consecutive diabetic patients with ulcer associated with chronic calcaneal osteomyelitis were treated with the Silo technique. Their physiological status was determined as either Cierny–Mader (C–M) Class A (no comorbidities), Class B^L (local compromise in the

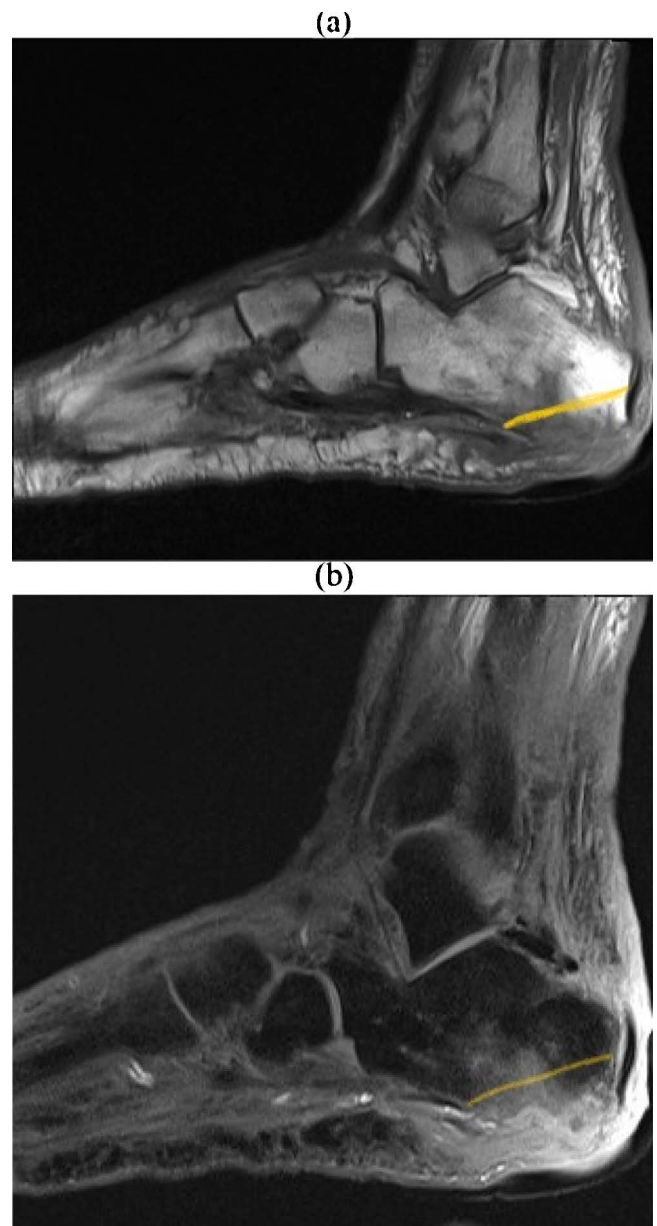


Fig. 1. Calcaneal osteomyelitis on sagittal T1-weighted (a) and T2-weighted (b) magnetic resonance imaging sections with the planned resection level (yellow line). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

affected limb), Class B^S (systemic compromise) and Class B^{LS} (local and systemic compromise) [12]. All had comorbidities and were classified as C–M Class B^{LS} hosts. A multidisciplinary team including orthopaedic and plastic surgeons, an infectious disease physician, podiatrists and physiotherapists were involved in the treatment. The definition of chronic osteomyelitis was made for symptomatology of at least six months with radiological, microbiology and clinical findings [13].

A retrospective review of radiographs and electronic medical records was conducted. The average age was 68 years (range 50–85) including 8 male and 4 female patients.

4. Results

Patients were followed up until wound healing was achieved for a mean of 16 weeks (range 12–18). The frequency of isolated pathogens was 33% (4 patients), 25% (3 patients), 17% (2 patients) for

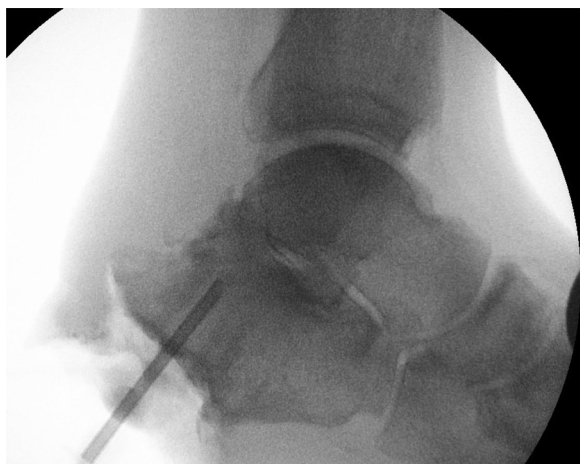


Fig. 2. Silo type tunnels (four to five) are drilled into the os calcis towards the posterior subtalar joint using a 3.2 mm drill bit and least 0.5 cm short of full length.

(a)



(b)



Fig. 3. The dry silo tunnels are filled with 5 ml of radiopaque Cerament G.



Fig. 4. The wound can be closed primarily in some cases.

Staphylococcus aureus, *Escherichia coli* and *Pseudomonas aeruginosa* respectively. *P. aeruginosa* with *S. aureus* was more common in polymicrobial infection (25% or 3 patients). In 3 patients (25%) the cultured microorganisms were resistant to gentamycin using the EUCAST breaking points [14].

After the partial calcanectomy and application of the Silo technique infection was eradicated and the wound healed in all 12 patients with a single stage procedure (Fig. 5). In 6 patients, the wound was closed primarily, V.A.C. was applied in 6 more and one had a reverse sural flap from the plastic surgeons at a second stage. Eight patients were ambulatory before the operation and six of them continued to be after the end of treatment. All Silo compartments injected with Cerament G were filled in with new bone as the biocomposite was resorbed at the end of the observation period (Fig. 6). There was also one case of prolonged wound leakage but no cases of calcaneal fractures.

5. Discussion and conclusion

Osteomyelitis of the hindfoot is particularly difficult to treat



Fig. 5. Wound healed after primary closure.

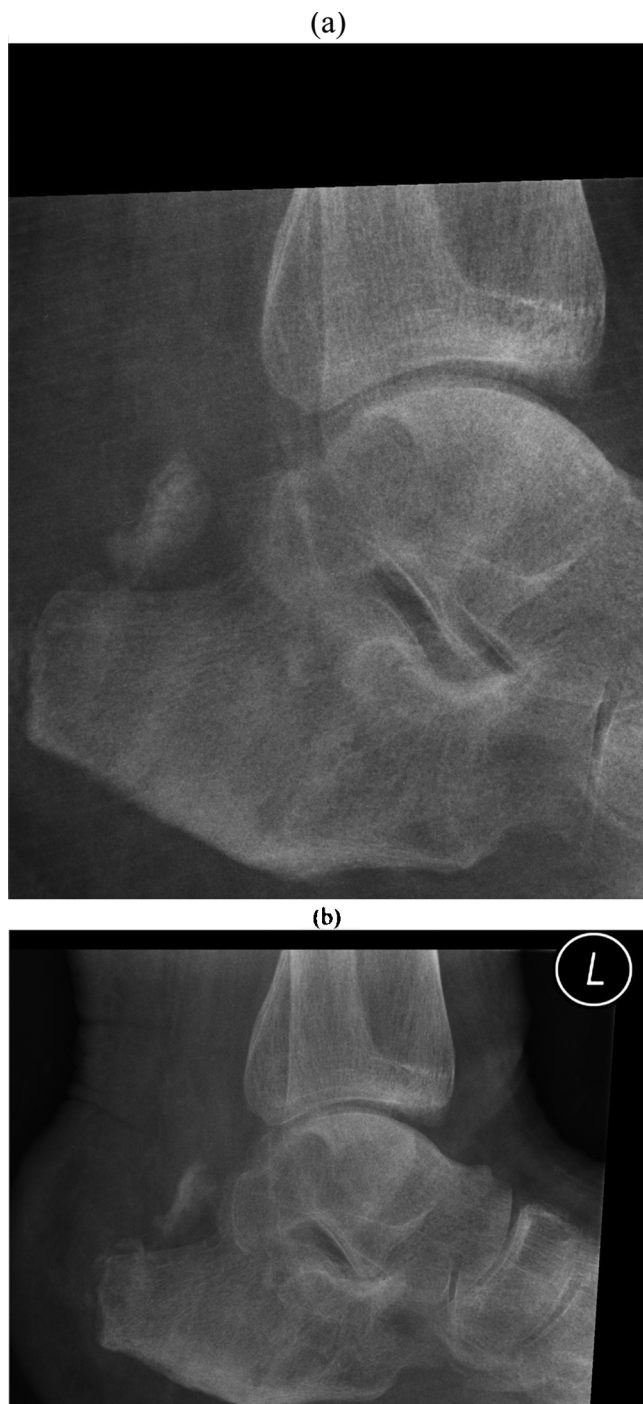


Fig. 6. Silo tunnels before and after resorption of cerament.

considering that the skin is thin with little only subcutaneous tissue for coverage of the bone. Amputation is not infrequently the more viable choice [15]. In the case of osteomyelitis of the tubercle of the calcaneus a partial calcanectomy can treat the infection salvaging the foot. The aim is to remove all the infected bone and decrease the size of the ulcer. Most of these infections start as pressure ulcers of the heel from bead or chair resting coupled with diabetic neuropathy. Inability to close or heal the wound can lead to a below-knee amputation. The exact border between infected and healthy bone though, is difficult to determine intraoperatively and furthermore microscopical foci of infection in macroscopically healthy bone can cause recurrence of the osteomyelitis.

In recent decades, repeated debridement with the use of CAS

materials impregnated with antibiotics in the form of beads or roads has been extensively used [2–5]. The downside is that replacing of the bone defect from new bone is not always a fact and thus further surgery may be needed to remove the composite. This leads to prolonged hospital stay with obvious implications for cost of treatment and complications [16]. The recently introduced injectable bioabsorbable synthetic mixture of Cerament G (CAS and HA impregnated with gentamycin) offers the possibility of local antibiotic delivery and dead space management in a single stage operation.

The traditional partial calcanectomy does not leave with dead space but the Silo technique involves creating tunnel type chambers for the injectable biocomposite. The Silo term comes from that of a tall tower or pit on a farm used to store grain. The above tunnels represent Silos loaded with Gentamycin. The mixture of Cerament G offers high local concentrations of gentamycin more than 100 times above the minimum inhibitory concentration (MIC) for gentamycin sensitive micro-organisms for the first 8 days and more than 10 times the MIC for the next 20 days [17]. In most of the cases (80%) the bacteria treated were sensitive to gentamycin on laboratory testing this in agreement with our previous experience in treating osteomyelitis in diabetic and not only patients. In two cases, though, the bacteria treated successfully were gentamycin resistant on laboratory testing. An explanation could be that resistance testing is based on exposing the microorganisms to levels of antibiotic, which if systemically given will not be toxic for the patient but the bacteria survivability when exposed to very high local levels of antibiotics is unknown. Furthermore, the reaction of setting is isothermic and thus minimal bone necrosis occurs around the Silo tunnels. The Silo antibiotic delivery system helps eradicate foci in macroscopically healthy bone which may harbor residual bacteria and cause recurrence of the infection.

In previous studies on antibiotic-loaded CAS a rate of prolonged wound drainage up to 32% has been reported [18,19]. The authors only had one case of prolonged wound leaking with the infection though not recurring. The authors do not use this leakage as an indication to re-operate and from our experience on treating osteomyelitis it is not related to recurrence of infection.

There was no case of fracture of the residual os calcis at the sites of the SILOs and this is also due to the compressive strength of the Cerament G being close to that of cancellous bone in biomechanical studies [20]. At the same time, the presence of HA in the Cerament G contributes to a durable scaffold for bone formation. All Silos were finally filled with bone at the end of the follow up period. With regards to the location and number of the Silos it depends on the size of the exposed posterior calcaneal surface and the anatomical characteristics of the calcaneal bone each time. Usually four to five Silos are enough to cover the exposed calcaneal area and diffuse enough gentamycin without significantly reducing the stiffness. The Silos extend from the posterior calcaneal exposed surface and at least 1 cm short of the posterior subtalar joint. This way the chances of a calcaneal fracture or collapse of the subtalar joint is severely decreased.

This study has some limitations including the relatively short follow-up and the small number of patients. The purpose of this study is to present the preliminary results of a new surgical technique for treating and local deliver of antibiotic for calcaneal osteomyelitis in patients with diabetes. Principles of calcaneal osteomyelitis treatment in diabetic patients, include a thorough debridement sparing as much bone as possible, local delivery of antibiotics, multiple sampling/culture-specific systemic antibiotic treatment and primary or vacuum-assisted wound closure guided by a multidisciplinary team. Local muscle flaps can also be implemented form the plastic surgeons. Microscopic foci of infection in macroscopically healthy-looking bone can cause persisting or recurrent infection though.

The Silo technique for treating calcaneal osteomyelitis offers the advantage of local delivery of antibiotic for at least 30 days. The high local concentration of gentamycin offers significant bacteriocidal action against the planktonic microorganisms during the immediate post-

debridement period [21]. The Silos, apart from storage of antibiotic acts also as a scaffold for bone formation decreasing the risk for a fracture and for this proper positioning and filling of the constructs with Ceram-G is important.

To conclude, chronic osteomyelitis can resolve after surgical debridement and systemic long term antibiotic therapy and therefore some of our cases could well have resolved even without the implementation of the Silo technique. The authors believe that a randomized controlled trial comparing surgical debridement and systemic antibiotics alone versus surgical debridement, systemic antibiotics and Silo could help determine the exact positioning of this method to the armamentarium against calcaneal osteomyelitis.

Ethics and declaration of conflicting interests

The research was performed in accordance with the 1964 Declaration of Helsinki ethical standards. The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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