Original Article

Displaced Intra-Articular Calcaneal Fractures Treated with Open Reduction and Internal fixation and Bone Void Filling with an Injectable Calcium Sulfate/Hydroxyapatite Bone Graft Substitute: A Series of 18 Patients

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Abstract

Background: There is an ongoing debate if bone graft substitutes (BGSs) are beneficial in the treatment of displaced intra-articular calcaneal fractures (DIACFs). The purpose of this study was to evaluate the effect of an injectable calcium sulfate/hydroxyapatite BGS (CERAMENT™ iBONE VOID FILLER, BONESUPPORT AB, Lund, Sweden) in internal fixation of calcaneal fractures. **Methods:** The records of patients presenting with calcaneal fractures type Sanders III and IV and treated with internal fixation plus BGS were reviewed. Radiographs were analyzed using different measurements (including Böhler's angle and calcaneal facet height). The clinical outcome was evaluated using the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale. **Results:** A total of 20 fractures were available for radiographic and clinical examination at a minimum follow-up of 12 months. No decrease in Böhler's angle was recorded in six fractures, a reduction of <5° in 6 and of more than 5° in 8 fractures. In all fractures, the BGS was completely resorbed at 12 months on radiographs. The AOFAS score was on an average 89.8 (range, 68–99) at 1-year follow-up and indicated an excellent outcome in 11, a good outcome in 8, and a fair outcome in 1 fracture. **Conclusions:** The study results support the use of an injectable, *in situ* hardening calcium sulfate/hydroxyapatite BGS in DIACFs. The BGS is easy and safe to use as an augment to open reduction and internal fixation.

Keywords: Bone graft substitute, calcium sulfate, hydroxyapatite, intraarticular calcaneal fracture, open reduction and internal fixation calcaneus

Introduction

Displaced intra-articular calcaneal fractures (DIACFs) are devastating injuries associated with long and often unsatisfactory recovery and life-altering consequences.[1,2] About 40%–85% of patients return to work within 9 months, but approximately 20% are not able to return to work within a year.[3,4] Within the past 25 years, the trend toward operative therapy with the anatomical reconstruction of the calcaneal height, length, and the subtalar joint has improved the clinical outcome in general, but problems concerning residual pain, limited range of motion in the subtalar joint, and posttraumatic arthritis remain.

The goal of surgical treatment is to restore the complex foot and ankle biomechanics by exact reduction of the subtalar posterior facet. This can be accomplished with a standard lateral extensile approach and application of a lateral plate.[5] In most cases, a good initial reduction can be achieved; however, a sizeable bone void beneath the elevated posterior facet will be left behind. The residual bone void can predispose the calcaneus to collapse despite stable internal fixation. This has led some surgeons to fill this bone void with different substances, for example, autograft, allograft,[6,7] or synthetic bone graft substitutes (BGSs);[8-10] other surgeons believe that

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the healing capacity of the well-vascularized cancellous bone of the calcaneus can bridge the void independently and avoid calcaneal collapse.[5,11,12] Till date, the opposing positions appear to be almost irreconcilable. Interestingly, most groups using BGS have shown an improvement in the follow-up radiographs, indicated by a reduced decrease of Böhler's angle, but have failed to show a positive effect on clinical outcome, documented by different scoring systems and patient-reported outcome measures.[8-10]

This could lead to the speculation that initial cartilage destruction is more important and might be a better predictor of clinical outcome than maintaining the reduction postoperatively.

However, until this question has been conclusively answered, the patient should be provided with the most optimal treatment and the lowest risk profile.

Autografts, especially cancellous bone autografts from the iliac crest have a significant risk of morbidity, which should limit their use.[13-16] Allograft carries a small risk of transmitting diseases and has limited availability in good quality. Therefore, BGS have been introduced to limit these risks.

Calcium phosphate bone substitutes have been used frequently in calcaneal fractures.[8,17-20] A problem with most calcium phosphates is that remodeling into bone is prolonged;[17-19] this poses a risk for foreign body reactions, infections, and graft failure due to fatigue breakage of the BGS.[17-19]

The purpose of this study was to evaluate the effect of an injectable calcium sulfate/hydroxyapatite BGS that shows quick remodeling into host bone, in the treatment of DIACFs. This property should further reduce the risk profile of BGS and result in a completely biological bone repair.

Methods

A total of 23 consecutive DIACFs in 18 patients (eight females, 10 males) with a mean age of 45.7 years (18 to 78 years) who underwent surgical treatment were included in this study. Five patients had bilateral fractures, of which two were managed conservatively, and eight were treated surgically with the combination of internal fixation with a locking plate and injection of the BGS.

Inclusion criteria

Consecutive patients presenting at our hospital with closed DIACFs according to Sanders classification type III and IV[21] between September 2010 and November 2014 were included in the study. Surgical management consisted of open reduction internal fixation with a calcaneal locking compression plate (LCP) and bone defect reconstruction using an injectable calcium sulfate/hydroxyapatite BGS.

Exclusion criteria

Patients with DIACFs according to the Sanders classification type I and type II were not included in this study because these types usually do not present with a significant bone defect.[21] Patients with open fractures were not included since the surgical management is different to the treatment of closed fractures.[22] Moreover, patients with calcium metabolism disorders or a known allergy to components of CERAMENT™|BONE VOID FILLER (calcium sulfate, hydroxyapatite, Iohexol, or other iodine-containing substances) were excluded as well for safety reasons.

Data collection

Patient demographics, medical history, comorbidities and computed tomography (CT) fracture classification were collected prospectively. Prolonged wound healing, radiographic follow-up of fracture consolidation, and clinical follow-up were recorded retrospectively as outcome objectives. The outcome was assessed by an independent reviewer to ensure that all negative outcomes were recorded.

For the radiographic follow-up and the quality of bone void filling by newly-formed bone X-rays were assessed by an independent examiner that was not involved in the treatment of the patients. Initially, each fracture was classified by the Sanders classification based on coronal CT slides.[21]

Surgical management

All patients were treated according to the basic principles of surgery of calcaneal fractures.

Initial bed rest with cryotherapy, compression, elevation, pain management, and medical antiphlogistic therapy was used to reduce soft-tissue swelling and skin problems. Surgery was planned after complete consolidation of soft tissue had been achieved. For prophylaxis of infection a single shot of Cefuroxime 1.5 g was given intravenously.[23] A standard lateral L-shaped incision was used to expose the fracture.[24] After open reduction, the fragments were temporally fixed with several 1.4 or 1.6 K-wires and the reduction controlled using fluoroscopy. A LCP (Locking calcaneal plate, Depuy-Synthes, Oberdorf, Switzerland) was placed and fixed with locking screws [Figures 1 and 2a]. After fixation of the plate, the central cancellous bone defect was filled with CERAMENT™|BONE

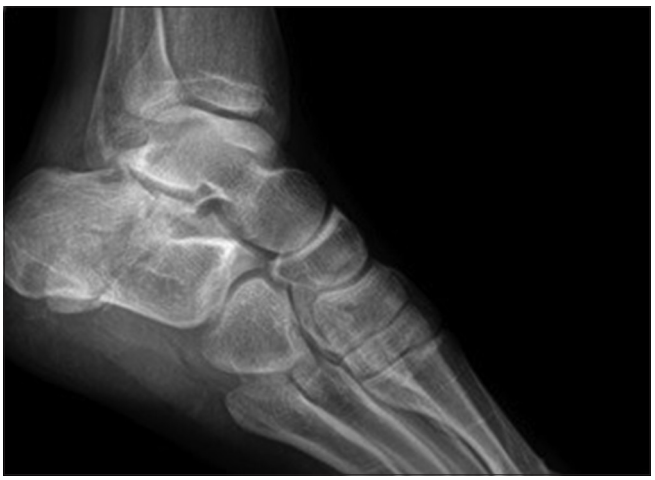

Figure 1: A 30-year-old male with bilateral calcaneal fractures after a fall from height. Preoperative lateral radiograph of right calcaneus

VOID FILLER [Figure 2b]. The BGS should be injected into a dry bony cavity. Therefore, a surgical tourniquet was used, if appropriate, until the BGS had hardened. Each defect was filled completely and no additional material was added to the product. At the end of surgery, direct skin closure was achieved in all patients. Standard wound care was applied. Patients were mobilized non-weight-bearing using crutches for 6 weeks, followed by a further 6 weeks of weight bearing as tolerated with a walker.

Outcome parameters

The primary outcome parameter was a calcaneal collapse in the follow-up radiographs. Therefore, Böhler's angle, the crucial angle of Gissane, calcaneal facet height, and absolute foot height were compared in the immediate postoperative period and the 1-year follow up.[25] Secondary outcome parameters included the assessment of filling of the central cancellous bone defect with bone regenerate, the rate of complications (including prolonged wound healing, superficial and deep infection and the need for revision surgery) and clinical outcome. Resorption of the BGS and filling of the bony defect was accessed by comparing the immediate post-operative radiographs with follow-up radiographs at 1 year. The final clinical outcome of the patients was evaluated by the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale.[26]

Results

The mean clinical follow-up was 22.6 months (12–52 months). No patient died during the follow-up period. According to the Sanders classification, there were 11 type III and 10 type IV fractures.[21]

Radiographic results

Twenty fractures were available for a radiographic follow-up examination at 1 year.

Böhler's angle was pre-operative −8.9° on an average (range −47° to 22°), post-operative 23.6° (0°–42°) and at the 1-year follow-up 19.3° (−31°–38°) [Table 1]. There was no decrease in Böhler's angle at 1 year in six fractures. A slight reduction in Böhler's angle of ≤5° at 1 year was found in six and of >5° in eight fractures. In the case of a decrease in Böhler's angle >5°, there were two calcaneal collapses of −15°, and −31°, respectively.

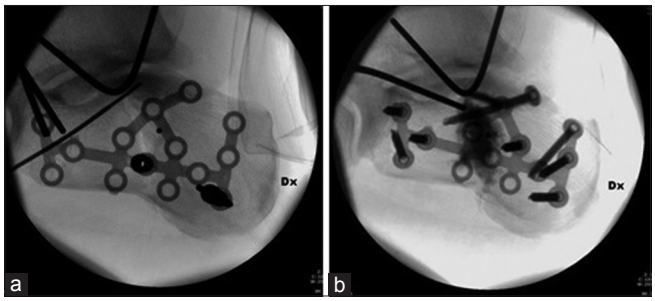

Figure 2: (a) Same case: Intraoperative fluoroscopy: Temporary fixation of the fracture with K-wires and placement of the LCP-plate. (b) Injection of CERAMENT™ | BONE VOID FILLER into the bony defect

The mean crucial angle of Gissane after surgery was 79.6° (21°–131°) and at the 1-year follow-up 87.3° (41°-138°) [Table 1].

For calcaneal facet height pre-operative 46.7 mm (34–88 mm), postoperative 48.1 mm (34–61 mm) and at the 1-year follow-up 48.9 mm (32–63 mm) were recorded. The absolute foot height was preoperative 83.1 mm (57–142 mm), postoperative 72.2 mm (54-86 mm) and 71.7 mm at 1 year (57–84 mm).

Resorption of the bone graft substitute and formation of new bone

The BGS was clearly visible on the postoperative radiographs due to the radiocontrast agent Iohexol [Figure 3]. On the radiographs at 1 year, the BGS could not be distinguished from the surrounding bone anymore; remnants of the BGS were not visible [Figure 4]. New bone formation, however, could not be quantified on the follow-up radiographs because of overlapping with the LCP-plates and screws and the cortical bone. Exact quantification would only be possible using CT scans, which is not acceptable from an ethical perspective in patients with a good clinical outcome (high dose of radiation).

Clinical outcome

Twenty patients were available for the clinical follow-up examination at a minimum of 1 year. The AOFAS score was on average 89.8 (range 68–99) and indicated an excellent outcome (>90 points) in eleven fractures, a good

Table 1: Radiographic measurements before surgery, immediately after surgery and at one-year follow-up

Radiographic parameter	Pre-operative	Post-operative	Follow-up at 1 year
Böhler's Angle	-8.9° [-47°-22°]	23.6° [0°-42°]	19.3° [-31-38°]
Angle of Gissane	/	79.6° [21°-131°]	87.3° [41°-138°]
Calcaneal facet height in mm	46.7 [34-88]	48.1 [34-61]	48.9 [32-63]
Absolute foot height in mm	83.1 [57-142]	72.2 [54-86]	71.7 [57-84]

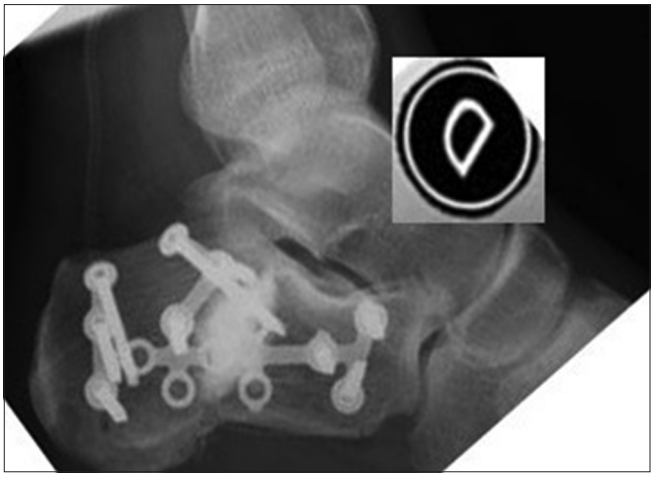

Figure 3: Same case. Postoperative lateral radiograph. CERAMENT™ | BONE VOID FILLER is clearly visible due to the radiocontrast agent Iohexol

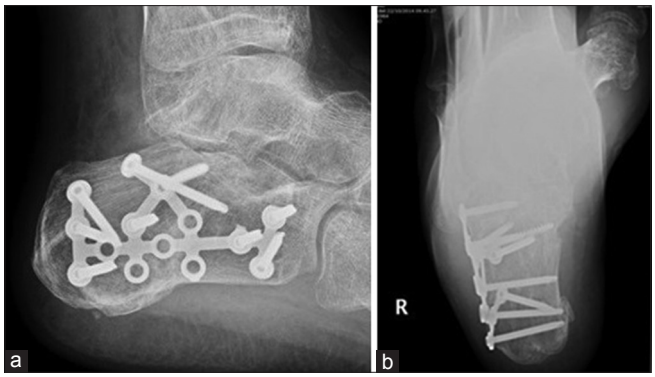

Figure 4: Same case. Follow-up radiographs anterior-posterior (a) and lateral (b) at 12 months. CERAMENT™|BONE VOID FILLER has been completely resorbed

outcome (75–90 points) in eight and a fair outcome (50–74 points) in one fracture.[6] Two patients had a calcaneal collapse on the follow-up radiographs at 1 year. Both patients did not follow the postoperative non-weight bearing regime. The first patient, a 63-year-old female had a Böhler's angle of −15° at 36 months, but a clinically satisfying result with 75 points in the AOFAS score. The second patient's Böhler's angle was −31 and had an AOFAS score of 92 points.

Wound healing

In 15 fractures, the incisions healed without prolonged wound secretion or collection of fluid. Prolonged wound drainage was noted in five fractures; four fractures were managed expectantly with dressings. In these patients, the secretion stopped without further intervention within 15 days (longest drainage).

Disturbed wound healing was noted in one patient. In this patient revision surgery with debridement and soft-tissue closure was performed. Further wound healing was without complication after revision surgery. No postoperative osteomyelitis occurred in any of the patients.

Discussion

There is an ongoing debate about whether the use of bone grafts or BGS in combination with internal fixation is beneficial for the patient in the treatment of DIACFs. Some authors consistently use bone grafts,[6,8-10] some in selected cases,[24,27] and others not at all.[5,12,21] The opposing positions appear to be almost irreconcilable. To end this discussion, probably a large, multicenter randomized controlled trial with strict inclusion criteria and a set of outcome measures would be necessary. Until this data are available, the patient should receive the most optimal treatment and the lowest risk profile.

A resorbable and injectable hydroxyapatite/calcium sulfate biocomposite has shown satisfying results in the treatment of distal radius fracture malunions[28] and tibial plateau fractures.[29] The BGS has the capacity to be transformed into host bone, leaving no remnants of the material behind.[30]

Radiographic results

Our radiographic results showed a good reconstruction of the posterior facet with an average Böhler's angle of 23.6°, which is comparable to the results of Singh and Vinay for type Sanders III and IV fractures using autograft.[7] The loss of Böhler's angle at the 1-year follow-up was 4.3° on average. Singh and Vinay found a reduction of 3.5° at 2 years using autograft and 6.2° without bone grafting.[7] Schildhauer *et al*. and Elsner *et al.* noted no reduction of Böhler's angle using a calcium phosphate cement (Norian SRS, Norian Corporation, Cupertino, CA, USA).[8,19] The value for a bioresorbable calcium phosphate paste (α-BMS, Etex Corporation, Cambridge, MA, USA) was 6.2° at 1 year[10] and for a nanocrystalline hydroxyapatite 3.8° at 1 year.[9] Our radiologic results fit well into the range of bioresorbable BGS found by other authors.

Clinical outcome

The AOFAS score of the 20 fractures available for follow-up analysis was 89.8, which indicates a good outcome in general. Singh *et al.* found an AOFAS score of 76.4 for patients treated with internal fixation and autograft.[7] The comparison of the clinical outcome of studies using BGS in DIACFs is difficult since many different outcome measures are used (AOFAS, SF 36, Creighton-Nebraska Health Foundation scale, Kerr calcaneal score and Zwipp foot score). The AOFAS score, the Creighton-Nebraska Health Foundation scale and the Kerr calcaneal score have in common that points are given for different objectives, such as the absence of pain, walking ability and working ability. The maximum is 100 points; usually,>90 points indicates an excellent result. Schildhauer *et al.* reported a Kerr calcaneal score of 80.2 for Norian SRS[8] and Huber *et al.* of 86.0 on the Creighton-Nebraska Health Foundation scale for nanocrystalline hydroxyapatite.[9] As a general approximation, our clinical results are comparable with the results reported by other surgeons using bone grafts or BGS.

Complications

The revision rate in our cohort was 5.6%, with one patient requiring wound revisions due to disturbed wound healing, but no implant-related infection or osteomyelitis developed. The rate of delayed wound healing can be as high as 25% in the surgical treatment of calcaneal fractures, with a risk of deep infection of 1%–4%.[5,31] In smaller cohorts, the rate of infection is reported as 11%,[8] 6.9%,[7] 5.3%,[19] 3.8%,[10] and 3.7%,[9] respectively. The risk of infection seems to be comparable in all the cohorts reported.

Conclusions

The use of CERAMENT™|BONE VOID FILLER showed good radiological and clinical results, which are comparable to autograft and other commercially available BGS in the treatment of DIACFs.

The biocomposite was not distinguishable in the follow-up radiographs at 6 months with transformation into host bone. The generation of new bone is not only beneficial for long-term stability but might also serve as bone stock in the case of future subtalar fusion surgery because of posttraumatic arthritis.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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