Calcium phosphate cement augmentation in the treatment of depressed tibial plateau fractures with open reduction and internal fixation

Yusuf ÖZTÜRKMEN, Mustafa CANİKLİOĞLU, Mahmut KARAMEHMETOĞLU, Erhan ŞÜKÜR

Ministry of Health İstanbul Training and Research Hospital, Department of Orthopedics and Traumatology, İstanbul

Objectives: We aimed to evaluate the clinical and radiological outcomes of open reduction and internal fixation augmented with calcium phosphate cement (CPC) in the treatment of depressed tibial plateau fractures.

Methods: Twenty-eight knees of 28 patients [19 males and 9 females; mean age, 41.2 years (range 22-72 years)] who had open reduction and internal fixation combined with CPC augmentation were included in this study. Seventeen fractures were Schatzker type II, 5 were type III, 3 were type IV, 2 were type V, and 1 was type VI. CPC was used to fill the subchondral bone defects in all knees. Fixation of the fragments was done with screws in 3 knees (10%). Standard proximal tibial plates or buttress plates were used in 25 knees (90%) with an additional split fragment extending distally to achieve internal fixation. Full weight-bearing was allowed in 6.4 weeks (range 6-12 weeks) after surgery. Resorption of CPC granules was defined as the decrease in the size and density of grafting material on radiographs. Rasmussen's radiological and clinical scores were determined postoperatively. Functionality was assessed with Lysholm knee scoring system. Activity was graded with Tegner's activity scale.

Results: Union was achieved in all patients with a mean follow-up of 22.2 months (range 6-36 months). There were no intraoperative complications. At the latest follow-up radiographs, resorption of the graft was observed in 25 knees (89%). Rasmussen's radiologic score was excellent in 17 patients (61%), good in 9 patients (32%), and fair in 2 patients (7%). Rasmussen's clinical score was excellent in 9 patients (32%), good in 18 patients (64%), and fair in 1 patient (4%). According to the Lysholm knee score, functional results were excellent in 16 patients (57%), good in 8 patients (29%), and fair in 4 patients (14%). Twenty-two patients (78%) achieved the preoperative activity level after surgery, and there was no significant difference between the mean preoperative and post-operative Tegner scores (4.11 ± 0.68 and 4.04 ± 0.64 , respectively, p=0.161).

Conclusion: CPC is a safe biomaterial with many advantages in augmenting the open reduction and internal fixation of depressed tibial plateau fractures, including elimination of morbidity associated with bone graft harvesting, the unlimited supply of bone substitute, the optimum filling of irregular bone defects, and shortening of the postoperative full weight-bearing time.

Key words: Calcium phosphate cement; fracture fixation; internal/open reduction; tibia fractures/plateau/surgery.

Since fractures of the tibial plateau involve a major weight-bearing joint, it is very important to restore the joint congruity to preserve the normal function of the knee, which should be maintained as the fracture heals. The key point in the treatment of tibial plateau fractures is restoration of the plateau surface by

Correspondence: Yusuf Öztürkmen, MD. Ataköy 7-8. Kısım., Mimar Sinan Sitesi, L4 Blok, Daire 44, 34159 Bakırköy, İstanbul, Turkey. Tel: +90 212 - 632 00 60 e-mail: yozturkmen@yahoo.com.tr

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anatomic reduction. However, restoration of the anatomy of the tibial plateau often leaves large cancellous bone defects in the areas where fragments were impacted into the soft metaphyseal bone. These subchondral voids cause secondary fragment displacement and loss of reduction if these defects are not sufficiently filled. The optimum filling of the subchondral defects is an important issue as the restoration of the articular congruity.^[1-30]

Autograft or allograft has been widely used to fill the bone defects in clinical practice. Autograft has a rather high donor site morbidity and limited supply of bone substitute. Allograft carries several drawbacks such as a risk of infection transfer, very low initial mechanical stability in the metaphyseal defects, and inadequate long-term incorporation of the graft to the host bone. Recently, to resolve these aferomentioned problems, biocompatible bone graft substitutes have been developed to replace the conventional bone grafting methods.^[10,13-15,18,19]

Calcium-phosphate cement (CPC) is an osteoconductive biomaterial which provides a very good augmentation for osteosynthesis materials and currently is being preferred as a bone graft substitute for clinical use. Following the results of the comparative experimental and biomechanical studies, the first clinical trials consisted of very few number of patients.[12-17,21,22,29] Although the recent clinical studies reported high number of applications, the number of these studies is very limited.^[26,28,30] Considering these limited data in the literature, the objective of our study was to evaluate the clinical and radiological outcomes of open reduction and internal fixation augmented with CPC in the treatment of depressed tibial plateau fractures and also to report our experience with this method.

Patients and methods

Between June 2006 and January 2009, 28 knees of 28 patients [(19 males and 9 females; mean age, 41.2 years (range 22-72 years)] who had open reduction and internal fixation combined with CPC augmentation were included in this study. The patients' injuries included 20 road traffic accidents, 4 falls from height, and 4 experienced heavy object crush. The study was established after the approval of institutional ethics committee. Any case that was associated with open fracture, cruciate ligament injury or

primary knee joint disease or underwent previous knee joint surgery was excluded from the study. The preoperative diagnosis was made based on the results of plain radiographs in the anteroposterior and lateral views. Additionally, a two-dimensional computed tomography (CT) was taken to determine the location and extent of the depressed articular surface. All radiographs had depression of the tibial plateau of >5 mm requiring open reduction and internal fixation as well as impacted chondral cancellous bone defects after reduction. According to the Schatzker classification;^[4] 17 fractures were type II, 5 were type III, 3 were type IV, 2 were type V, and 1 was type VI. Soft tissue damage was graded 0-1 according to the Tscherne classification.^[4] Before surgery all affected extremities were elevated to decrease local swelling. All knees underwent surgery within one week of injury.

Surgical technique

All operations were performed under spinal anesthesia or combined epidural anesthesia. The patients were placed supine on the operating table with a lower limb tourniquet on the affected side. A lateral approach was preferred for Schatzker type II and type III fractures while the medial approach was performed in Schatzker type IV fractures. Dual incisions were chosen for Schatzker type V and VI fractures. After adequate exposure of the fracture site, the menisci were conserved, the depressed fragments were elevated and the articular surface was reduced anatomically. After maintaining the reduction temporarily by K-wires, the articular surface congruency was checked with the aid of fluoroscopy before the definitive fixation, and 6.5 mm cancellous screws were placed in the subchondral area to support the reduced fragments. Sufficient fixation was achieved only in 3 knees (10%). If an additional split fracture extending distally or a discontinuity of the tibial cortex was present, a proximal tibial plate or a buttress plate was used for ostheosynthesis. In those cases, cancellous screws were placed through the proximal holes of the plate. When the osteosynthesis was completed and stable fixation was achieved, the cancellous bone defect under the reduced joint fragments was localized using fluoroscopic control. A suitable entrance portal was created using a fracture cleft or a drill hole was opened at an appropriate site of the cortex in Schatzker type III fractures. All

debris materials and blood clots were removed. The liquid and solid components of CPC were then mixed for 2 min, and the synthetic paste-like material of CPC was injected into the defect zone up to 5 min. Because the cement is radioopaque, fluoroscopy was used to control the complete filling of the defects. No manipulation was allowed for the next 10 min to allow the cement to harden. If a screw had been withdrawn to inject the cement, this screw was replaced before hardening of the cement. Passive motion was began with assistance of a physiotherapist in 1-4 days postoperatively. The patients were not allowed full weight-bearing for 6 weeks postoperatively. Ten days after surgery, partial weight-bearing was allowed for patients with monocondylar fractures as they tolerated. Full weightbearing was allowed for patients in 6.4 weeks (range 6-12 weeks) when bridging bone trabeculae at the fracture site was observed on radiographs.

All patients were controlled in our outpatient clinics at 1, 3, 6, and 12 months after surgery. The integrity of the articular surface was determined by using standard anteroposterior and lateral views of plain radiographs. Any displacement more than 5 mm of the joint surface was recorded, and Rasmussen

radiological score^[31] was measured (Table 1). The resorption of the CPC graft was defined as the decrease in the size and density of graft on radiographs (Fig. 1 and 2).

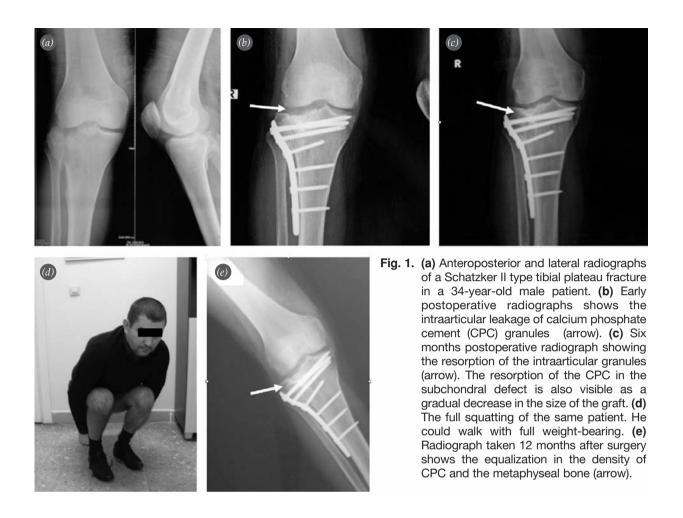
Functional evaluation of the knee was assessed with the use of Lysholm knee scoring system^[32] and activity was graded with Tegner's activity scale.^[32] The clinical outcomes were also assessed using Rasmussen clinical scores.^[31]

The NCSS 2007 software package was used for statistical analyses. Descriptive statistical methods were used to summarize the data. Repeated measurements were assessed with the paired t-test, and groups were compared with independent t-test. Pearson correlation test was used to evaluate the degree of relationship between the variables. A value of p<0.05 was considered to be statistically significant.

Results

Union was achieved in all patients with a mean follow-up of 22.2 months (range 6-36 months). There were no intraoperative complications. One patient (3%) developed sterile wound drainage in the first week after surgery, and resolved with wound care and local dressing in the third week. Postoperatively,

Table 1 Evaluation criteria of Rasmussen's radiological scoring system ^[31]					
Depression		6	4	2	0
None	6				
<6 mm	4				
6-10 mm	2				
>10 mm	0				
Condylar widening		6	4	2	0
None	6				
<6 mm	4				
6-10 mm	2				
>10 mm	0				
Angulation (valgus/varus)		6	4	2	0
None	6				
<10°	4				
10-20°	2				
>20°	0				



superficial wound infection occurred in one patient (3%) and healed with antibiotherapy. No deep infection was found. No implant failure or breakage was noted during the follow-up.

Rasmussen's radiological score^[31] was excellent in 17 patients (61%), good in 9 patients (32%) and fair in 2 patients (7%). Six months after operation, fracture healing was confirmed in all knees, and radiographs demonstrated equivalent bone density in the area previously occupied by the graft material as that of the surrounding metaphyseal bone. The CPC graft showed resorption in 25 knees at the latest follow-up graphies, and full metaphyseal bone graft incorporation was observed. Leakage of the CPC into the knee joint was identified in 2 patients (7%) at the early postoperative radiographs and resorption of this CPC was observed on the follow-up radiographs. Loss of reduction did not occur after full weight-bearing except 2 patients (7%). There were no signs of osteoarthritis in any patient during the follow-up

period. At the twelve-week control, the tibial plateau had widened, and a depression of the lateral plateau of 8 mm had occured in 1 patient. Anatomic reduction and stable osteosynthesis was difficult in this case because of the comminution of the intraarticular defects in the plateau surface after reduction. At the latest follow-up control, this patient's knee had acceptable function and no further treatment was required. In an another patient, a depression of joint surface of 5 mm developed, but there was also no loss of knee function in this patient's knee. According to the Lysholm knee score,^[32] functional results were excellent in 16 patients (57%), good in 8 patients (28%), and fair in 4 patients (15%) at the latest follow-up examination. Rasmussen clinical score^[31] was excellent in 9 patients (33%), good in 18 patients (64%), fair in 1 patient (3%). At the last follow-up examination, 15 patients (54%) had no limitations in their walking distance, and 20 (78%) declared that they were satisfied with the operation. Implants were removed in 2 patients within the follow-up period.

Twenty-two patients (78%) achieved the preoperative activity level after surgery, and there was no significant difference between the preoperative and postoperative Tegner scores (4.11 ± 0.68 and $4.04\pm$ 0.64, respectively, p=0.161). No significant difference was observed between the female and male

ence was observed between the female and male patients for preoperative (4.10 ± 0.70 and 4.14 ± 0.69 , respectively) and postoperative mean scores ($4.00\pm$ 0.63 and 4.14 ± 0.69 , respectively), and also between the mean of score differences (0.10 ± 0.25 and 0.01 ± 0.001 , p=0.416). There was no correlation between the ages of the patients and the preoperative and postoperative scores, and score differences (p=0.052, p=0.059, and p=0.638).

Discussion

The treatment of metaphyseal bone fractures with intraarticular involvement, which result from excessive axial loading forces, is difficult and problematic. Depressed articular fragments can crush the underlying weak subchondral cancellous bone, leaving a void when the articular segments are reduced surgically. Potential long-term problems such as pain, post-traumatic arthritis, and limitation of motion and function might occur if joint surface subsidence can not be prevented or at least limited. Fractures of the tibial plateau consist a major part of these fractures. Succesful outcomes in their treatment can be achieved with strict adherence to the principles of anatomical reduction, rigid fixation, and early movement. The common preferred technique, which is required to apply these principles, is performed by elevating and realigning the depressed articular surfaces, placing a graft material into the metaphyseal defect, and supporting this reconstruction with internal fixation.^[1-6]

Although bone grafting may not always be necessary in the treatment of fractures of the tibial plateau, long-term outcomes of these fracture patterns managed with bone grafting is more successful than other methods. Due to the lack of capacity of the crushed subchondral cancellous bone at the trauma to achieve the previous quality and shape after the reduction of articular surface, bone grafting gains more importance to fill the bone defects. Bone grafting which is effective in preventing the loss of reduction and failure of internal fixation is also a major factor to increase the joint stability and integrity.^[14,12,15] Autogeneous iliac bone crest is the most frequently preferred and accepted graft resource as the gold standard for bone grafting. However, it is associated with postoperative chronic pain, hematoma, infection, and wound complications of the donor site. Another disadvantage is graft quantity limitations. Cancellous bone grafts have a very low initial mechanical strength, and it is very difficult to shape the cortical bone grafts and to place them in the proximal tibia.^[12,13,15,16,22,24,27-30]

Although allograft may be considered as an alternative to resolve these aferomentioned problems of donor site morbidity, they carry several drawbacks such as transmission of viral infections, histological incompatibility, and low union rates. Full weigthbearing is also delayed after cancellous bone allografting.^[5,7,12,13,15,16,24,27-30]



Fig. 2. (a) Radiograph of a 50-years-old female patient with a Schatzker II type fracture. (b) Early anteroposterior and (c) lateral radiographs of the knee after the calcium phosphate cement (CPC) augmentation of open reduction and internal fixation. (d) Incorporation of the CPC graft to the metaphyseal bone without loss of the reduction is observed on the radiograph at 10 months after surgery (arrow).

Despite the successful outcomes of reconstructions with autograft and allograft, the use of bone graft substitutes have been preferred as an alternative method due to the limitations of the associated complications and disadvantages. CPC is announced as a ceramic matrix. CPC is mixed as a fluid paste and then hardens insitu without exothermic reaction and cellular damage to form crystalloid structure. In general, when hardened a major part of the cement consists of calciumphosphate ceramic crystalloids which are not purified, are easily resorbed, and they are remodelated with osteoclasts. The crystallinity of the composite is very similar to the mineral phase of the normal bone.^[10,12,25,26]

The current CPC (Cementek, Teknimed, SA, France), which was used in this study, is a combination of 49% tetracalcium phosphate, 38% tricalcium phosphate, and 13% NaGP powder. After mixing with the calcium hydroxide liquid component, for 1-2 min, it forms an injectable paste. It hardens in 5-10 min after injection, and reaches the ultimate hardness within 48 to 72 hours. CPC is a biocompatible and osteoconductive material with a property of incorporation to the host bone. CPC is an injectable material with a characteristic feature to fill various geometrical shapes of the subchondral bone defects. The compressive strength is 55 MPa after 12 hours which is more than the mean MPa compressive strength of the normal human cancellous bone of the proximal tibia [2.2 MPa (range 0.5-5.6 MPa)]. This is a very significant advantage for this material to prevent the futher loss of reduction which is very important to maintain the long-term stability during the healing process. CPC increases the pull-out strength of the screws of the implants, which are used for osteosynthesis in combination with the cement, and the potency of these screws to hold the metaphyseal region. Furthermore, the torsional strength of the cement allows early weight-bearing for faster and easier rehabilitation.[15,16,27-30]

Lobenhoffer et al.^[24] used injectable CPC for 26 knees with depressed tibial plateau fractures and allowed full weight-bearing after the mean postoperatively period of 4.5 weeks (range 1-6 weeks). Only two cases developed partial loss of reduction of the fracture at the fourth and eight weeks after surgery. In this study, degradation and resorption of the cement was slow and integration of the cement to the host

bone took longer duration. Although no adverse sequelae has been reported due to the intraarticular extravasation of the hardened CPC, it may cause traumatic arthritis in weight bearing joints. Keating et al.^[22] used CPC combined with minimal internal fixation to treat 49 fractures of the lateral tibial plateau and 9 patients (20%) had radiological evidence of osteoarthritis. Thus, tricalcium phosphate and calcium phosphate ceramics with porous structures which improve their resorption is being currently preferred with increasing numbers.^[28,29] Also, the porosity of tricalcium phosphate enhances the fluid flow and blood diffusion, thus improving cell-mediated resorption and local metabolic rate. Shen et al.^[30] used tricalcium phosphate in the treatment of 124 patients with depressed tibial plateau fractures. Most of the patients (95.2%) had excellent or good results as assessed by HSS score of knee with no early osteoarthritic signs or reduction loss on radiographs. In our study, successful outcomes were achieved with the use of CPC which was composed of tetra and tricalcium phosphate. No full weight-bearing was allowed until 6 weeks after the surgery as the other reported studies. Full weightbearing was allowed 6 weeks after surgery in all patients, and loss of reduction was observed in two of them. Full weight-bearing was delayed for all patients in contrast to study by Lobenhoffer's group,^[24] but our functional and radiological outcomes were successful. Fracture lines disappeared radiologically at 6 months in all knees. This finding showed bone ingrowth and good biocompatibility similar to the study of Shen et al.^[30] Majority of our patients (17 Schatzker type II, 5 Schatzker type III) had monocondyler fractures, and this factor has attributed to the encouragement of full weight bearing after six weeks when bridging bone trabeculae were observed at the fracture site. In the study of Shen et al.^[30] there were 34 patients (27%) with type V and 17 patients (13%) with type VI. Full weight-bearing was forbidden until fracture healing was confirmed radiologically, but partial weight-bearing was allowed 6 weeks after surgery.

The use of CPC for the surgical treatment of tibial plateau fractures was compared with conventional autogenous bone grafts in several studies, mostly experimental. Russell et al.^[16] prospectively randomized 120 unstable tibial plateau fractures in 20 different centers. Eigthy-two fractures were randomized to autogenous iliac bone graft. CPC was found as a better choice in terms of the prevention of subsidence than autogenous iliac bone graft. The results of the cadaveric study of Yetkinler et al.^[12] suggested that nonweight-bearing postoperative period is significantly reduced with the use of CPC. In an experimental study, Wheeler et al.^[15] created subchondral bone defects in the tibial plateau of goats and observed more bone regeneration within CPC grafted defects compared to autograft. Moreover, in an another similar study, Welch et al.^[14] reported that augmentation with CPC prevented subsidence of the fracture fragment and maintained articular congruency. The results of these studies are compatible with our clinical outcomes.

No adverse effects secondary to the cement itself were registered during this study and additionally remodelling by autogenous bone was observed. Given all these factors, we accept the CPC of our study as a biocompatible material. Although this graft may be initially considered as expensive, use of the CPC is cost-effective in longer terms when compared with the conventional methods because of the shorter rehabilitation program due to the earlier weight bearing and activity period. Additionally, because the material is radiolucent, the application can be controlled using an image intensifier, which offers increased opportunity for minimally invasive procedures. And also, CPC decreases the requirement of more implant usage to achieve anatomic reduction and stable osteosynthesis. Generally, there is less pain after the operation with minimally invasive technique, and this technique allows more easier rehabilitation.^[18,21,22,25,27,30]

At present, most of the avaliable literature about the mechanical strength of CPC and the augmentation of tibial surface congruency consists of biomechanical or cadaveric studies.^[12-15,17,25] However, these studies do not include clinical data about the topics of bone remodeling, graft resorption, and long-term preservation of the articular surface congruency. In our opinion, the results of the present clinical study would contribute to the very few published clinical studies on this topic. Resorption of graft scored on final radiographs was absent 1 patient (7%), discrete in 8 patients (57%), and substantial in 5 patients (36%) in study by Horstmann et al.^[26] The graft material showed 67% resorption on the eight-week postoperative radiograph and full bone graft incorporation was observed on the radiograph at 12 weeks postoperatively in the study of Yu et al.^[25] Shen et al.^[27] observed the resorption of tricalcium phosphate cement on the radiographs in the majority of the patients at 10 months after grafting. In our study, graft resorption was present in 25 patients (90%) on the last follow-up radiographs. Moreover, the mean Lysholm knee scores^[32] were equal to that of tibial plateau fractures traditionally treated with open reduction and internal fixation augmented with autogeneous bone grafts. However, scores for early weight-bearing and gaining adequate walking distance level were more successful. Good anatomic reduction results of Rasmussen's radiological score^[31] assessment at the last follow-up control indicate the remodeling of the resorped CPC with the regenerated new bone. This property of CPC grafting is effective in achieving good results without the loss of initial reduction of the articular surface.

In conclusion, the clinical and radiological results of the present study suggest that CPC is a safe biomaterial to fill the subchondral metaphyseal defects in the treatment of tibial plateau fractures. We believe that with many advantages, CPC is a good alternative to use as a bone substitute for grafting to augment the open reduction and fixation of the depressed tibial plateau fractures. These advantages include the unlimited supply of bone substitute, the optimum filling of irregular bone defects, and prevention of the degenerative osteoarthritis by preserving the reduction with the graft's property of remodelling. Furthermore, there is no disadvantage of bone graft harvest morbidity.

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