Treatment of tibial plateau fractures with high strength injectable calcium sulphate

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Received: 23 April 2008 / Revised: 18 May 2008 / Accepted: 20 May 2008 / Published online: 13 August 2008
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Abstract The aim of this article is to discuss the clinical efficacy of high strength injectable calcium sulphate (MIIGX3) in the treatment of tibial plateau fractures. Thirty-one patients with tibial plateau fractures treated with MIIGX3 were included. Postoperative radiographic study was used to evaluate congruity of the articular surface, bone regrowth, and the absorption process of MIIGX3. Rasmussen's score system was adapted for the postoperative knee function recovery assessment. Twenty-eight of 31 patients were followed-up successfully with an average follow-up length of 14.6 months. Complete fracture healing was found in all patients. Complications included wound exudation and articular subsidence. Postoperative knee function was good according to Rasmussen's score system. Six months after surgery, radiographs demonstrated equivalent bone density in the previous area of MIIGX3 as that of surrounding cancellous bone. The use of MIIGX3 in the treatment of tibial plateau fractures provides adequate intraoperative stability and improves the safety of early knee motion.

Résumé Objectif: évaluer l'efficacité d'un sulfate de calcium injectable MIIGX3 dans le traitement des fractures des plateaux tibiaux. Méthode: 31 patients présentant une fracture du plateau tibial ont été traités avec du MIIGX3. L'évaluation radiologique post-opératoire a analysé la continuité articulaire du plateau tibial, la reconstruction osseuse et l'absorption du sulfate de calcium. Le score de Rasmussen a permis d'évaluer la fonction post-opératoire

de ces genoux. Résultats: 28 des 31 patients ont été suivis avec succès. Le suivi moyen a été de 14,6 mois. Une guérison complète de la fracture a été trouvée chez tous les patients. Les complications ont inclus les évacuations d'hématomes et les décrochages articulaires. En post-opératoire, la fonction du genou était bonne selon le score de Rasmussen. Six mois après la chirurgie, les radiographies ont montré une densité minérale osseuse équivalente à celle de l'os adjacent. En conclusion, l'utilisation de MIIGX3 dans le traitement des fractures des plateaux tibiaux permet d'obtenir une stabilité per-opératoire et d'améliorer les fonctions du genou.

Introduction

Fractures of the tibial plateau always involve intraarticular components of the knee joint, one of the three major weight bearing joints in the lower extremities. Anatomical reduction of intraarticular fragments must be achieved and maintained to prevent serious complications such as joint instability and traumatic arthritis [10, 11]. Because of the surrounding cancellous bone of proximal tibial metaphysis, valgus or axial forces normally result in articular surface depression and compaction of the subchondral cancellous bone. Once the articular surface is reduced, the proximal tibial metaphysis often exhibits a significant bone defect that may need bone grafting to provide mechanical support for the articular surfaces and to fill the intraosseous void. Bone graft together with internal fixation implants can prevent late articular subsidence and promote fracture healing. Years ago, autogenous bone grafting and allograft were most commonly used. Cancellous autograft still remains the gold standard, but it does have some limitations, including donor site morbidity and inadequate filling [16]. The

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Fig. 1 Preoperative anteroposterior (a) and lateral (b) radiographs revealing a split depression fracture of lateral tibial plateau in a 45-year-old man. c Preoperative axial CT scan demonstrating posterolateral location of the depressed articular surface

procedures of allograft also carry several drawbacks such as viral infection, immunogenicity, and limited immediate mechanical stability offered by cancellous bone graft [1]. To resolve the aforementioned problems, various biomate-

rials have been developed rapidly to replace conventional bone graft. Several bone graft substitutes are available for clinical use, including calcium sulphate, calcium phosphate, porous coralline ceramics, tricalcium phosphate, collagen,

Table 1 Mechanism and classification of injuries

	Schatzker II	Schatzker III	Schatzker IV	Schatzker V	Schatzker VI
Road traffic accidents	18	4		1	1
Fall from height	1	1	1		
Heavy object crush	1	1		1	1
Total	20	6	1	2	2

Fig. 2 **a** K-wires were used to stabilise the fracture reduction temporarily. With the assistance of fluoroscopy, the graft material was injected into the void, filling it completely. **b** Five minutes after complete hardening of the graft material, internal fixation devices were applied with standard techniques. The screws penetrated the cured graft material directly to contralateral cancellous bone

demineralised bone matrix, and bone morphogenetic protein [5]. Calcium sulphate has been used to fill bony defects since 1892 [8]. During the resorption of calcium sulphate, the increased local acidity may result in demineralisation of adjacent bone [14], with release of matrix-bound morphogenetic proteins that have a stimulatory effect on bone formation [12]. Recently, injectable bone substitutes which can cure in situ and have a good space occupancy have been developed. The authors report on 31 patients with tibial plateau fractures who were treated using injectable calcium sulphate (minimal invasive injectable graft, MIIGX3/ MIIGX3 HiVisc, Wright Medical Technology, Inc, Arlington, TN), which can harden in situ with high compressive strength, with open reduction and internal fixation. The aim of this study was to evaluate the incorporation of the high strength injectable calcium sulphate graft and the ability of sustaining activity loads according to the clinical outcome.

Materials and methods

Between October 2005 and October 2007, 31 patients with tibial plateau fractures who were treated with MIIGX3 were included in this study. The patient population comprised 21 males and ten females whose mean age at surgery was 41.5 years (range 24–76 years). The patients injuries included 24 road traffic accidents, three falls from height, and four experienced heavy object crush. Preoperative radiological study included anteroposterior and lateral radiographs in every patient (Fig. 1a,b). CT scan was acquired to determine the location and extent of the depressed articular surface (Fig. 1c). According to the Schatzker classification, 20 were Schatzker II, six Schatzker III, one Schatzker IV, two Schatzker V, and two Schatzker VI (Table 1). MIIGX3 was used in 26 patients, and five patients were treated with MIIGX3 HiVisc. A postoperative radiographic study was used to evaluate congruity of the proximal tibial articular surface, bone regrowth, and the absorption process of the bone substitute. The postoperative knee function recovery was assessed with Rasmussen's functional score and isolated observer for

Fig. 3 Postoperative anteroposterior (a) and lateral (b) radiographs obtained one week after articular reduction and internal fixation. The radiopaque zone indicates the distribution of graft material

X-ray results were evaluated with the anatomical grading score system [9].

Statistical analysis

Statistical comparison was made using Student's *t*-test. Significance was set at $p < 0.05$.

Surgical techniques

All operations were performed under spinal anaesthesia or continuous epidural anaesthesia in conjunction with spinal anaesthesia. The patient was placed supine on the operating table, and the lower limb tourniquet was inflated. The surgical approach was based on the fracture patterns. A lateral approach was preferred for Schatzker type II, III, and VI 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, anatomical reduction was achieved with K-wires as temporary stabilisation devices. Using the vacuum mixing machine, the dry calcium powder of MIIGX3 or MIIGX3 HiVisc and the solution were mixed. After mixing, the paste-like bone graft was placed in a syringe and injected into the intraosseous void. The injection of the graft should be started from the deepest recesses to superficial areas by withdrawing the cannula in a retrograde fashion. With the assistance of fluoroscopy, adequate positioning of the graft material was

monitored in real time (Fig. 2a). Caution should be paid in the severe comminuted fractures or fractures with cartilage defects to avoid extravasation of the graft material into the joint space. Because of the resorption characteristic of calcium sulphate, it is not necessary to remove the graft from the joint space or soft tissues. The paste-like graft material (MIIGX3) must be injected in three minutes. The MIIGX3 HiVisc will be injectable up to ten minutes. After injection, the outer surface of the graft materials was covered with dry gauze to prevent contact between the blood and graft material, which may interfere with the setting time. The setting time of MIIGX3 is about 9–11 minutes after mixing. Five minutes after complete hardening of the graft material, internal fixation devices were implanted with standard techniques (Fig. 2b). In our experience, the thread of the screws should penetrate beyond the hardened graft material to the contralateral cancellous bone or penetrate the contralateral cortex. Thus, the antipullout and support strength of the screws was maintained even during the process of graft resorption and replacement by host bone.

Results

Three of the 31 patients with tibial plateau fractures were lost to follow-up. The average length of follow-up of the rest of the 28 patients was 14.6 months (range 5–26 months). Fractures healed uneventfully in all patients, and no nonunion or infection occurred. Wound exudations

Fig. 4 Anteroposterior (**a**) and lateral (**b**) radiographs at 12 weeks show full bone graft resorption and new bone formation without loss of the reduction

were observed in two cases, and the wound healed in two to three weeks with wound dressing.

The four-week postoperative radiograph exhibited resorption of the margin of the graft material compared with the one-week postoperative radiograph, but no obvious radiotranslucent lines were identified (Fig. 3). The graft

material showed 67% resorption on the eight-week postoperative radiograph with the formation of trabecula in the early absorption area. Full bone graft incorporation was observed on the radiograph at 12 weeks postoperatively (Fig. 4). In young patients, the rate of bone ingrowth is faster than in older patients. Six months after operation,

Fig. 5 Six months after operation, anteroposterior (**a**) and lateral (**b**) radiographs demonstrate equivalent bone density in the previous area occupied by graft material as that of surrounding cancellous bone

Table 2 Postoperative anatomical reduction scores

Follow-up	Score ($\pm$ SD)
0 ($n=28$)	17.14 $\pm$ 1.27
3 months ($n=24$)	17.08 $\pm$ 1.32
6 months ($n=24$)	16.83 $\pm$ 1.31
12 months ($n=24$)	16.67 $\pm$ 1.40

SD standard deviation

$p>0.05$; there is no significant difference for all groups

radiographs demonstrated equivalent bone density in the area previously occupied by graft material as that of surrounding cancellous bone (Fig. 5).

An articular subsidence of 2 mm was found in two patients without joint dysfunction one year after operation.

Postoperative knee function was good according to Rasmussen's functional score six months after surgery, whereby the 28 patients' mean function score was 25.8 (range 20–30). One year after the operation, 24 patients' mean function score reached 26.9 (range 20–30). The length of follow-up of the remaining four patients is shorter than one year. Rasmussen's anatomical grading score was acquired according to postoperative radiographs, which were taken at months zero, three, six, and 12 (Table 2). There was no significant difference for all groups.

Discussion

As intraarticular fractures of a major weight bearing joint in the lower extremities, it has been well recognised that all displaced and unstable tibial plateau fractures should be treated with open reduction and internal fixation to restore joint congruity, stability, limb alignment, and allow early postoperative knee motion [10]. Because of the depression of the articular surface and compaction of the subchondral cancellous bone which can not rebound, significant bone defects can remain after reduction of the articular surface. Bone graft is necessary to re-establish bone integrity and joint stability to prevent postoperative loss of reduction or failure of internal fixation. Autograft, allograft, and soluble blocks or granules of bone graft substitutes share the common problem of limited intraoperative mechanical strength, especially in older patients with osteoporosis. In recent years, several new injectable bone graft substitutes have been developed. The injectable bone graft substitutes provide instant skeletal stability and carry the additional advantage of better void filling in the irregularly-shaped defects than that of autograft, allograft, and blocks or granules of bone graft substitutes. At present, apart from injectable polymethylmethacrylate, most of the available injectable bone graft substitutes are based on either calcium phosphate or calcium sulphate.

The injectable calcium phosphate cement hardens in situ and cures by formation of carbonated apatite, which has a similar crystallinity and chemical composition to the mineral phase of human bone [4]. Currently available calcium phosphate cements for clinical use include Bone-Source (Stryker Craniomaxillofacial, Portage, MI), Norian SRS (Synthes, Paoli, PA), and α -BSM (DePuy, Warsaw, IN). The mechanical characteristics vary in different forms of calcium phosphate cement. In general, when hardened, the calcium phosphate has a compressive strength four to ten times greater than that of cancellous bone. Taking this property into consideration, good results have been reported by several clinical studies on the use of calcium phosphate cement with open reduction and internal fixation in the treatment of tibial plateau fractures [7, 13]. However, concern about intraarticular extravasation of calcium phosphate cement continues due to its slow resorption rate. Most of the calcium phosphate-based bone substitute will remain several years after injection [4]. Although Cassidy has reported no adverse sequelae even in the presence of intraarticular extrusion into wrist joint [3], the hardened calcium phosphate may cause serious complications such as traumatic arthritis in weight bearing joints. Thus, in the event of leaking into the joint space, surgical removal should be performed immediately.

In comparison with calcium phosphate, calcium sulphate has a fairly rapid resorption rate. Calcium sulphate has been reported as an osteoconductive bone graft substitute since the 19th century, but the structures and properties varied until the development of surgical grade calcium sulfate with the introduction of Osteoset (Wright Medical, Arlington, TN) in 1996. Since then, different forms of calcium sulphate have been made available in the form of powder or pellets. In 2004, use of injectable calcium sulphate has been reported in several studies [6, 15].

Recently, a new injectable bone graft substitute based on calcium sulphate that can cure with high compressive strength has been developed called minimally invasive injectable graft X3 (MIIG X3 and MIIG X3 HiVisc; Wright Medical Technology, Inc, Arlington, TN). This calcium sulfate cement is engineered to harden better in a wet environment and provide a longer working time. The in vivo compression strength may achieve 40 MPa one hour after preliminary set, and at 24 hours, the compression strength is approximately equal to the reported polymethylmethacrylate (PMMA) values [2]. The adequate immediate stability and high compressive strength for fracture reduction prevent subsidence of the articular surface. In our study, no significant difference was found in the Rasmussen's anatomical reduction score between initial postoperative evaluation and follow-up examination from three months to one year after operation ($p=0.21$). This indicated that the postoperative reduction was well maintained from hardening to complete

incorporation of the graft. As proven by other studies, supporting strength of bone grafting is critical to prevent subsequent articular depression [7, 13]. Once the graft material is fully cured, the K-wires can be removed and final internal fixation devices can be placed with standard techniques without damaging the strength and integrity during drilling and placement. Further immediate stability and supporting strength can be achieved because the screws directly cross the hardened graft materials.

The one-year Rasmussen's anatomical reduction scores were consistent with the scores at three months and six months, which demonstrated that the calcium sulphate graft materials were resorbed and replaced by bone in 10–14 weeks in vivo at the same rate as new bone ingrowth [6].

It is not necessary to remove the escaped calcium from the joint space or soft tissues because the graft materials will be absorbed in 15 days according to Watson's research [15]. No intra-articular leakage of graft material occurred in our study because of the anatomical reduction of the joint surface and gentle injecting procedure.

The work time of MIIGX3 is approximately 2.5 minutes, about 1–1.5 minutes longer than MIIG115, which is adequate for an experienced surgeon to achieve perfect filling of the void under fluoroscopy.

Our clinical observation supports the use of MIIGX3 in the treatment of tibial plateau fractures as it can improve the safety of early postoperative knee motion. It provides a better choice for treatment of the weight-bearing joints to maintain reduction and fill the defect.

References

1. Bauer TW, Togawa D (2003) Bone graft substitutes: towards a more perfect union. *Orthopedics* 26(9):925–926
2. Belkoff SM, Sanders JC, Jasper LE (2002) The effect of the monomer-to-powder ratio on the material properties of acrylic bone cement. *J Biomed Mater Res* 63(4):396–399. doi:10.1002/jbm.10258
3. Cassidy C, Jupiter JB, Cohen M, Delli-Santi M, Fennell C, Leinberry C, Husband J, Ladd A, Seitz WR, Constanz B (2003) Norian SRS cement compared with conventional fixation in distal radial fractures. A randomized study. *J Bone Joint Surg Am* 85-A(11):2127–2137
4. Frankenburg EP, Goldstein SA, Bauer TW, Harris SA, Poser RD (1998) Biomechanical and histological evaluation of a calcium phosphate cement. *J Bone Joint Surg Am* 80(8):1112–1124
5. Goldberg VM (2001) Bone grafts and their substitutes: facts, fiction, and futures. *Orthopedics* 24(9):875–876
6. Kelly CM, Wilkins RM (2004) Treatment of benign bone lesions with an injectable calcium sulfate-based bone graft substitute. *Orthopedics* 27(1 Suppl):s131–s135
7. Lobenhoffer P, Gerich T, Witte F, Tschern H (2002) Use of an injectable calcium phosphate bone cement in the treatment of tibial plateau fractures: a prospective study of twenty-six cases with twenty-month mean follow-up. *J Orthop Trauma* 16(3):143–149. doi:10.1097/00005131-200203000-00001
8. Peltier LF (2001) The use of plaster of Paris to fill large defects in bone: a preliminary report. 1959. *Clin Orthop Relat Res* 382:3–5. doi:10.1097/00003086-200101000-00002
9. Rasmussen PS (1973) Tibial condylar fractures: impairment of knee joint stability as an indication for surgical treatment. *J Bone Joint Surg Am* 55:1331–1350
10. Ruth JT (2001) Fractures of the tibial plateau. *Am J Knee Surg* 14(2):125–128
11. Schatzker J, McBroom R (1979) Tibial plateau fracture—Toronto experience 1968–1975. *Clin Orthop Relat Res* 138:94–104
12. Sidqui M, Collin P, Vitte C, Forest N (1995) Osteoblast adherence and resorption activity of isolated osteoclasts on calcium sulphate hemihydrate. *Biomaterials* 16(17):1327–1332. doi:10.1016/0142-9612(95)91048-4
13. Simpson D, Keating JF (2004) Outcome of tibial plateau fractures managed with calcium phosphate cement. *Injury* 35(9):913–918. doi:10.1016/S0020-1383(03)00109-8
14. Walsh WR, Morberg P, Yu Y, Yang JL, Haggard W, Sheath PC, Svehla M, Bruce WJ (2003) Response of a calcium sulfate bone graft substitute in a confined cancellous defect. *Clin Orthop Relat Res* 406:228–236. doi:10.1097/00003086-200301000-00033
15. Watson JT (2004) The use of an injectable bone graft substitute in tibial metaphyseal fractures. *Orthopedics* 27(1 Suppl):s103–s107
16. Younger EM, Chapman MW (1989) Morbidity at bone graft donor sites. *J Orthop Trauma* 3(3):192–195. doi:10.1097/00005131-198909000-00002