Tibial Plateau Fracture Repairs Augmented With Calcium Phosphate Cement Have Higher In Situ Fatigue Strength Than Those With Autograft

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Objectives: This study compared the biomechanical fatigue strength of calcium phosphate augmented repairs versus autogenous bone graft (ABG) repairs in lateral tibia plateau fractures.

Methods: Eight matched pairs of tibias (six male, two female; age, 75 ± 14 years) were harvested from fresh-frozen cadavers. Reproducible split-depression fractures were simulated and repaired by an orthopaedic traumatologist using a lateral tibial plateau plate. One tibia from each donor was randomly assigned to either calcium phosphate (Callos; Acumed, Hillsboro, OR) or ABG as augmentation. The femoral component of a hemitotal knee arthroplasty was attached to the actuator of a servohydraulic press and centered above the repair site. Cyclic, physiological compression loads were applied at 4Hz starting with a maximum load of 15% body weight and increasing by 15% body weight every 70,000 cycles. Loading conditions were determined from calculations of weight distribution, joint contact area, and gait characterization from existing literature. Repair site depression and stiffness were measured at regular intervals. Specimens were then loaded to failure at 1 mm/min.

Results: Calcium phosphate augmented repairs subsided less and were more stiff during the fatigue loading than were ABG repairs at the 70,000, 140,000, and 210,000 cycle intervals ($P < 0.03$) All repairs survived to 210,000 cycles. The average ultimate load of the calcium phosphate repairs was 2241 ± 455 N (N = 6) and 1717 ± 508 N (N = 8) for ABG repairs ($P = 0.02$).

Conclusion: Calcium phosphate repairs have significantly higher fatigue strength and ultimate load than ABG repairs and may increase the immediate weightbearing capabilities of the repaired knee.

Key Words: tibial plateau, calcium phosphate, bone graft, weight bearing, fatigue

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INTRODUCTION

Fractures of the tibial plateau account for nearly 10% of fractures in the elderly and 1% of fractures in the general population.[1] The most common mechanism of injury is valgus stress with or without axial load, which causes fracture of the lateral tibial plateau.[2] In cases in which bone quality is not severely osteoporotic, there is a split of the outer cortex with depression of the articular surface resulting in a Schatzker II or split-depression fracture type.[3] After fracture reduction, there is a metaphyseal void under the articular surface that will compromise the stability of the reduction without stabilization. Autogenous iliac bone graft (ICBG) has been the gold standard for filling of metaphyseal defects associated with unstable tibial plateau fractures.[4–7] The complications associated with harvesting ICBG are well documented in the literature.[8,9] The ideal bone graft substitute for critical size subarticular metaphyseal defects would include a material that is biocompatible, readily available, easily deliverable to the defect, structurally stable to prevent articular subsidence, and remodels into normal bone over time.[10]

There is a trend in fracture surgery to use synthetic osteoconductive biologics, particularly the calcium phosphates, for metaphyseal defects to improve the structural integrity of the fracture repair. The strength of these repairs versus more traditional ICBG augmentation has yet to be fully characterized biomechanically. Russell et al showed in a recent clinical study that calcium phosphate is a promising alternative to ICBG in the tibial plateau and that the repairs performed with this cement have less articular subsidence than the fractures treated with conventional ICBG.[11] Patients were restricted to less than 50 pounds of weightbearing on the affected limb for 6 weeks at which point weightbearing was increased as allowed by the surgeon. The effect of early physiological weightbearing on repaired tibial plateau fractures has not been investigated.

A recent biomechanical study demonstrated that the stiffness of calcium phosphate augmented repairs was 1965 N/mm, nearly six times greater than those augmented with ICBG.[2] Although these results are promising for the use of calcium phosphate, this study did not investigate the integrity of the fracture repair construct under physiological repetitive loading. Of particular interest is the ability of calcium phosphate-augmented repairs to survive under immediate postoperative weightbearing activity (approximately 200,000 gait cycles) because patients may be able to regain weightbearing activities earlier in the healing process.

The goal of this investigation was to compare the biomechanical fatigue strength of calcium phosphate versus autogenous bone graft (ABG) augmentation in the lateral tibia plateau with a split-depression fracture type under simulated physiological loading conditions. The specific aims were to determine: 1) the difference in articular depression when loaded under physiological conditions; 2) the maximum sustainable load before failure of the tibia fracture fixation construct; and 3) whether there were clinically significant differences in the failure characteristics of the two fixation techniques. In situ biomechanical fatigue tests on manually fractured cadaveric tibia were performed. Our hypothesis was that calcium phosphate-augmented repairs would provide a stronger, more stable repair than those augmented with ABG.

MATERIALS AND METHODS

Specimen Preparation and Fracture Generation

Eight matched pairs of whole human lower limbs were harvested from fresh-frozen cadavers. Bone mineral density was assessed at the calcaneus and proximal femur using standard clinical dual-energy x-ray absorptiometry scans (Hologic Discovery Wi QDR, Bedford, MA). Planar x-rays were taken before specimen preparation to ensure normal bone geometry (BV Pulsera, Philips, Andover, MA). Each specimen was prepared as follows. The knee was separated, and the skin and musculature were removed through careful dissection. Cancellous bone from the distal femur was saved for use in this study as the ABG. The tibia was cut at middiaphysis and potted in a metal cup using a polymer casting agent (Smooth Cast 300; Smooth-On, Easton, PA).

Fracture generation and repair were performed on each specimen. A split-depression fracture was simulated by manual impaction of a custom-built cylindrical dye into the lateral tibial plateau surface. The cutting surface of this dye had a shoulder that allowed impaction to a standard reproducible depth of 18.5 mm. This produced equivalent depression defects in each specimen, allowing equal amounts of bone graft and cement to be applied. An osteotome was used to split half of the remaining lateral plateau. Fractures created on the preliminary specimen confirmed that this technique generated reproducible, physiological split-depression fractures. The tibial plateau fracture was then repaired by two trained orthopaedic trauma surgeons using a standard technique with an eight-hole, 3.5-mm nonlocking, lateral tibial plateau plate (Synthes, Paoli, PA) fixed with four subarticular screws, two metaphyseal kickstand screws, and two cortical screws. One tibia from each donor was assigned to one of two treatment groups: 1) augmentation using calcium phosphate (Callos; Acumed, Hillsboro, OR); or 2) augmentation using femoral ABG. Selection was randomized to ensure an even distribution of right and left knees in each group.

Calcium phosphate was injected by a single experienced orthopaedic traumatologist using a curved 11-gauge needle to ensure ideal filling of the void after the plate and screws were placed. The curved needle allowed the cement to be injected just below the plateau in between the screws. ABG was manually impacted into the void up to a maximum filling with the aid of a bone impactor. Approximately 7 to 10 mL of cement or bone graft was used in each specimen. Planar x-rays were taken immediately after fracture repair to ensure proper implant placement, filling of the void with the cement or ABG, and to provide a baseline for detecting failure of the fracture repair site (Fig. 2). Both the cement and ABG repairs were placed in a saline solution at 37°C immediately after being

FIGURE 1. Biomechanical setup, including a dial indicator mounted rigidly to the test frame.

repaired for the recommended cure time of 24 hours before testing.

Biomechanical Testing

In situ biomechanical testing was conducted on the repaired tibia as follows. The femoral component of a hemi-total knee arthroplasty (TKA; DePuy, Warsaw, IN) was rigidly attached to the actuator of a servohydraulic press (MTS Mini-Bionix 858; MTS, Eden Prairie, MN). The potted specimen was mounted to a lockable x-y table atop a multiaxial load cell (AMTI MC5-6-5000; Advanced Mechanical Technology, Inc, Watertown, MA) that was rigidly attached to the hydraulic test frame. The position of the specimen was adjusted using the x-y table such that the hemi-TKA contacted the tibial plateau at the anatomically correct position (confirmed by visual inspection by an orthopaedic surgeon).

Cyclic, distributed compression loads were applied directly to the lateral tibia plateau through the hemi-TKA (Fig. 1). Loading followed a stepwise scheme (Table 1) with the minimum load during each cycle at 8% total body weight (BW) and the maximum load increasing every 70,000 cycles. Loading conditions were developed based on the following information from literature: 1) joint contact force during single-leg stance phase of gait is approximately three times BW[12]; 2) during dynamic activities, the distribution of load between the medial and lateral compartments of the tibia plateau is 55% to 45%, respectively[13]; and 3) contact area for a hemi-TKA is approximately 30% of the native tibiofemoral contact area for each compartment.[14,15] Given this information, the maximum loading conditions applied in this study represent the in situ load on the repair site increasing from one to three times total BW or 33% to 100% weightbearing.

FIGURE 2. Planar x-ray of a tibia repaired using calcium phosphate and a nonlocking plate.

TABLE 1. Maximum Applied Load in Body Weight (BW) on the Lateral Tibia Plateau at Specified Fatigue Cycle Intervals*

Cycle Interval (×1000)	Applied Load on Lateral Compartment (%BW)	Total Joint Contact Force (%BW)
2.5	15%	100%
5	15%	100%
10	15%	100%
20	15%	100%
35	15%	100%
70	15%	100%
72.5	30%	200%
75	30%	200%
80	30%	200%
90	30%	200%
105	30%	200%
140	30%	200%
142.5	45%	300%
145	45%	300%
150	45%	300%
160	45%	300%
175	45%	300%
210	45%	300%

*Specimens were evaluated for construct failure at each of these cycle intervals.

Fatigue testing was conducted as follows. BW was determined for each specimen based on donor information (no donors were determined to be obese based on body mass index calculations). Cyclic loading was conducted at 4 Hz (two times high range of physiological gait) to 210,000 cycles or until any one of three clinically relevant failure criteria was satisfied. If a specimen did not fail by 210,000 cycles, it was destructively loaded at the quasistatic rate of 1 mm/min until failure (eg, 10-mm displacement of the actuator head from point of contact). Fatigue testing was interrupted at specified test intervals (Table 1) to evaluate the following three failure metrics: 1) plateau displacement greater than 10 mm in any direction; 2) condyle widening greater than 10 mm; and 3) screw fracture or bending. At each interval, anteroposterior planar x-ray images of the proximal tibia were taken using a portable x-ray unit (BV Pulsera, Philips) that encircled the hydraulic press and remained stationary throughout the test. Depression of the bony fragment was directly measured between each cycle interval using a digital indicator rigidly mounted to the frame of the hydraulic press (Fig. 1).

Stiffness measurements were calculated at every hundredth cycle from 1000 to 1900 cycles during each test interval (Table 1). This was determined by averaging the slope of least squares regression lines fit to the force-displacement curves. Outcome metrics included: 1) changes in axial stiffness with cyclic loading; 2) tibial plateau displacement and condylar widening as a function of cyclic loading; 3) number of cycles until failure with failure assessed through three clinical measures; and 4) ultimate load. The outcome metrics were compared across treatment groups using paired *t* tests (JMP Version 5.0; SAS Institute, Inc, Cary, NC), and $P < 0.05$ was used as the cutoff for significance.

RESULTS

The repaired tibial plateau fragment displaced significantly less for calcium phosphate-augmented repairs versus ABG augmented repairs at the following cycle intervals: 70,000, 140,000, and 210,000 (loading conditions increased by 15% BW at these three intervals) (Fig. 3, $P < 0.03$ for paired t test). All repairs, both calcium phosphate and ABG, survived to 210,000 cycle runout. At the end of the 210,000 cycles, calcium phosphate-augmented repairs showed fragment depression of 1.8 ± 0.8 mm versus 3.3 ± 1.3 mm for ABG ($P < 0.03$ for paired t test).

The calcium phosphate repairs were significantly stiffer than the ABG repairs at all test intervals ($P < 0.3$) with the exception of the first test interval ($P = 0.65$) (Fig. 4).

The average ultimate load of the calcium phosphate construct was 2241 ± 455 N and for the ABG was 1717 ± 508 N (Fig. 5, $P = 0.02$, N = 6 for calcium phosphate, N = 8 for ABG). Both constructs demonstrated slight condylar widening posteriorly during the later fatigue cycles.

Increased condylar widening occurred during load to failure, but mode of failure was uniformly 10 mm migration of the tibia plateau during load-to-failure. No significant differences were seen in the mode of failure between the two constructs. Both test groups showed slight condylar widening during both the fatigue and load-to-failure portions of the test. Minimal fragment rotation occurred in both test groups. There were no fractures of the plates or screws; however, the subarticular screws bent during the load-to-failure portion of the test (Fig. 6).

DISCUSSION

The results of the study indicate that the use of calcium phosphate cement in tibial plateau repairs increases the immediate weightbearing capabilities of the repaired knee after a split-depression fracture. During fatigue loading, fracture site depression was significantly lower and compressive stiffness was significantly greater for the calcium phosphate repairs versus the ABG repairs. This suggests that calcium phosphate provides a more rigid construct to support load-bearing activity and transfer the femoral loads through the repair site. The ultimate load of the calcium phosphate repairs was also significantly higher than that of the ABG repairs.

The results are in agreement with previous clinical and biomechanical studies that have shown calcium phosphate as a promising alternative to bone grafts for tibial plateau fractures. In 2006, Manzotti et al investigated 13 knee repairs using calcium phosphate cement and found excellent postoperative results, including complete remodeling of the cement in some cases.[16] In a recent multicenter prospective randomized study, Russell et al found less articular subsidence in the tibial plateau fractures repaired with a calcium phosphate cement compared with those repaired with ABG.[11] Russell also used nonlocked plates and allowed 50 pounds of weightbearing for the first 6 weeks postoperatively, which is similar to the loading conditions in this study. Trenholm et al conducted a biomechanical study on 10 pairs of tibia comparing bone graft and calcium phosphate cements.[2] However, his study addressed only stiffness and depression of the two constructs when 1000 N was applied and did not address articular depression during fatigue loading or ultimate load.

There were several strengths in our study. First, fracture depression measurements were highly accurate. To measure fracture site depression, a dial indicator was rigidly mounted directly onto the frame of the hydraulic press (Fig. 1). This setup showed a standard deviation of 0.05 mm in measurement of a standard depth in preliminary testing, which was more accurate than the previous studies that used molds.[17] Second, the loading conditions for this study were based on physiological gait and incorporated factors including specimen BW and the surface area of the load distribution through the hemi-TKA. Lastly, the method of generating split-depression was highly standardized as a result of a custom-designed cutting tool.

The limitations of this study included the cement-filling conditions and the exclusion of healing time. For the calcium phosphate repairs, an "ideal" repair was performed, eg, the

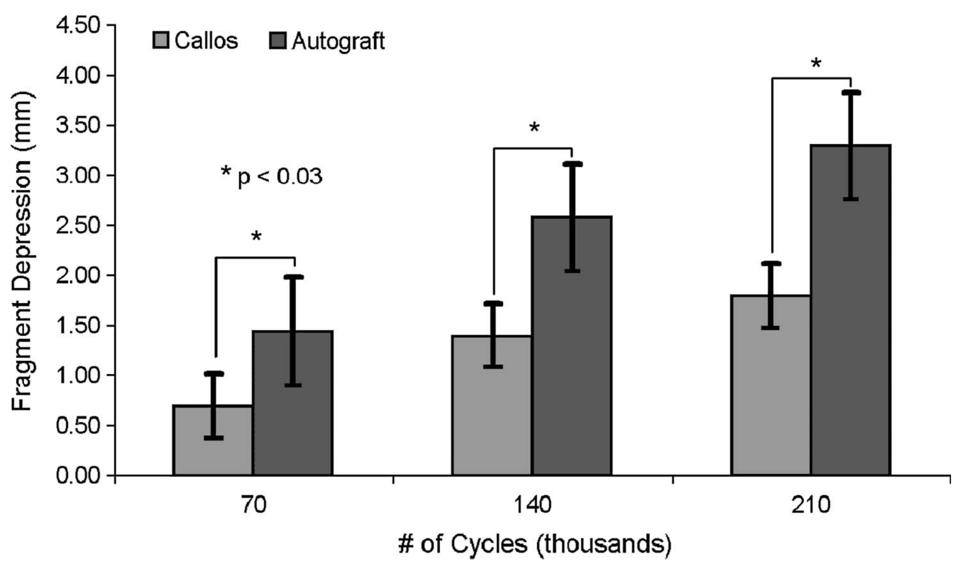

FIGURE 3. Fracture depression measured at the center of the fragment at 70,000, 140,000, and 210,000 cycles. Error bars represent two standard deviations.

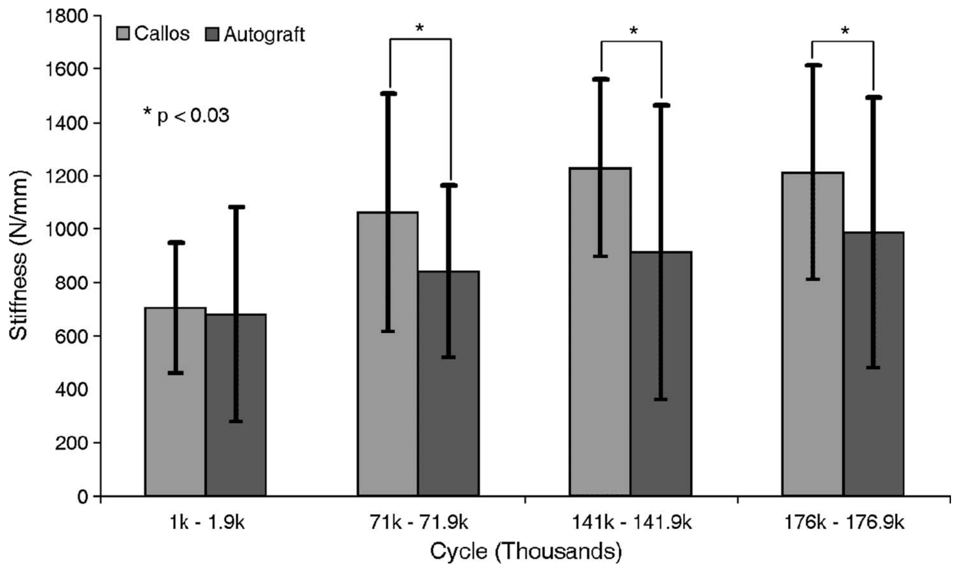

FIGURE 4. Stiffness for four intervals. Error bars represent two standard deviations.

entire void was filled with the cement (confirmed through x-ray fluoroscopy). Clinically, this is not always the case nor is this always possible. The positive results obtained in this study regarding the bone cement depended on whether the cement was injected adequately above the superior screws of the nonlocking plate. This may imply that a learning curve can be expected to achieve the necessary expertise needed to obtain similar results. Finally, the exclusion of healing is the main limitation of this study. Because ABG is meant to heal before bearing any loads, this study could only address the immediate load-bearing capabilities of the repair construct. A recent canine study by Frankenburg showed that although biologically active cements take over 72 weeks to be fully remodeled into trabecular bone, they provide mechanical properties similar to that of an uninjured bone in 4 weeks.[18] Some clinical studies have shown that the use of calcium phosphate cement decreased the loss of fracture reduction, although it is unclear what postoperative rehabilitation the patients adhered to.[19] The results of this study, however, can still be used to draw clinically relevant and important conclusions regarding the biomechanical properties of the two repair constructs immediately postoperatively and during the healing period.

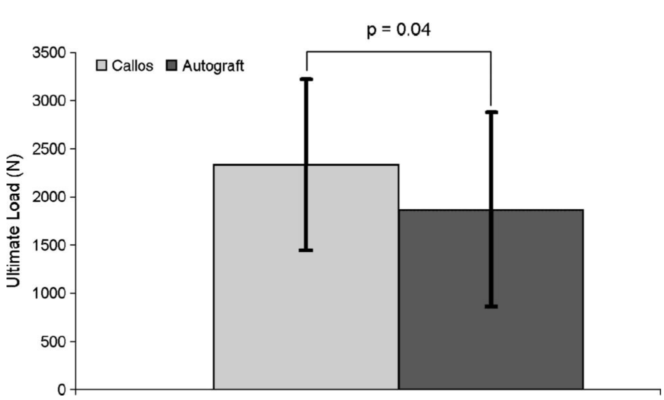

FIGURE 5. Ultimate load. Error bars represent two standard deviations.

In summary, this study shows that the use of calcium phosphate cement in split-depression tibial plateau fractures significantly increases the immediate load-bearing capabilities of the repair construct compared with ABG. Repaired tibial plateau split-depression fractures with properly cemented voids allowed physiological loads to be applied immediately to the tibial plateau without significant subsidence of the articular surface. These findings suggest that early weightbearing protocols may be applicable to patients treated with calcium

FIGURE 6. Specimen during destructive loading. Specimens failed through 10 mm migration of the plateau, as shown in this radiograph.

phosphate cement. Future clinical research is warranted to answer this question. Clinically, this may allow faster rehabilitation time postoperatively, better recovery of full range of motion, and decreased incidence of articular subsidence during the first 3 months of the recovery period.

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