Comparative Fixation of Tibial Plateau Fractures Using α-BSM™, a Calcium Phosphate Cement, Versus Cancellous Bone Graft

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Objectives: To compare the compressive strength of a bone substitute material (α-BSM™) to cancellous bone when used to fill a defect void in a cadaver model of a Schatzker II split depression fracture of the lateral tibial plateau.

Design: Randomized, paired design.

Setting: Biomedical engineering laboratory.

Patients: Twenty-six human tibias were harvested from 13 cadavers. Three pairs of tibia fractured during preparation and were excluded. The remaining 10 matched pairs were randomized to fixation by using the bone substitute material or cancellous bone.

Intervention: A split depression fracture of the lateral tibial plateau was created in each tibia by using reproducible methods. This fracture was stabilized with a stainless steel L-plate and screws and either α-BSM™ or cancellous bone to fill the defect void.

Main Outcome Measurements: Stiffness of the elevated fragment in compression, total depression of the joint at 1000 N.

Results: The α-BSM™ bone substitute displayed significantly greater stiffness than cancellous bone constructs in Schatzker II split depression fractures of the lateral tibial plateau ($P < 0.0001$). Plateau defects displaced significantly less at 1000N when using α-BSM™ in comparison to cancellous bone ($P < 0.0001$).

Conclusions: In this cadaveric study, α-BSM™ is an effective bone substitute compared with cancellous bone graft for stabilizing split depression fractures of the lateral tibial plateau.

Key Words: tibial plateau, fracture, bone graft substitute

(*J Orthop Trauma* 2005;19:698–702)

Accepted for publication July 13, 2005.

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In support of their research or preparation of this manuscript, one or more of the authors received grants or outside funding from Etek Corporation University Park at M.I.T., Cambridge, MA.

The device mentioned in the paper is FDA approved for use as described in this paper.

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Tibial plateau fractures are common injuries that result from indirect coronal and/or direct axial compressive forces. The resulting fracture pattern is related to the age of the patient and their overall bone quality. As the patient ages, the fracture pattern is usually a split depression type (Schatzker II) without associated ligamentous injury. Although there remains some controversy concerning the operative indications for treatment of this type of injury, the A.O. guidelines advocate anatomic reduction, re-establishment of the tibial alignment, subchondral bone grafting to support the articular cartilage, and stable fixation.[1]

The current accepted treatment of this type of injury is to stabilize the subchondral void with cancellous bone graft retrieved from an iliac crest donor site. This procedure involves making a separate incision over the crest to obtain the graft, which can cause morbidity, such as pain, nerve injury, arterial injury, cosmetic deformity, and infection.[2] There is currently no randomized, prospective study that substantiates the stability or compressive strength of this type of graft material, although it is presently the "gold standard" for periarticular fractures. In recent years, new bone alternatives have become commercially available to act as "substitute" bone graft.[3] These consist of various forms of ceramics, such as tricalcium phosphate and hydroxyapatite blocks or granules, calcium sulfate beads or putty and calcium phosphate cements. These materials differ from each other in terms of physical properties and chemical composition that affect their mechanism of resorption and replacement by bone. Additionally, the ceramic granules and calcium sulfate beads are macroporous scaffolds with compressive strengths ranging from 6 to 10 MPa, whereas the calcium phosphate cements are microporous with compressive strengths ranging from 12 to 80 MPa.[3–6] Although some of these materials have been clinically studied for the treatment of tibial plateau fractures, their specific ability to support the articular surface has not been studied. The purpose of this study was to determine whether α-BSM™, a calcium phosphate cement, provides equal strength and stability in comparison to autograft when dealing with split depression fractures of the lateral tibial plateau.

MATERIALS AND METHODS

Initially, 13 matched pairs of tibias were harvested from human cadavers. Death certificates were reviewed to screen for pre-existing disease. The bones were removed by making an incision along the subcutaneous border of the tibia and then were disarticulated from the ankle and proximal tib-fib joint. All the soft tissue was removed from the bones. A split depression fracture was then made by cutting the lateral tibial plateau 1 cm from the cortical edge with an oscillating saw to represent the split (Fig. 1). All loose and damaged cancellous bone was removed from the defect and a dental mold of a defined size was used to make a reproducible void below the articular cartilage. The intact articular cartilage was then perforated, using a dental bur, into the created subchondral void. An articular hinge was left medially and the surface was depressed by thumb pressure into the defect void (Fig. 2) until the articular hinge fractured. The distal ends of the tibiae were removed leaving all tibias 26-cm long. For each matched pair of tibias, the α-BSM™ was used in the left or right tibia based on a random draw. The matching tibia then received the cancellous bone graft. The cancellous bone was harvested from the discarded distal end of the tibia and ground into smaller pieces. α-BSM™ was prepared according to the manufacturer's instructions. The fracture model was stabilized using a L-plate and screws along with either the α-BSM™ or the cancellous bone graft (Fig. 3). The cancellous bone was placed into the defects by hand then packed with a hammer and bone tamp. This process was repeated until the defect was full. The α-BSM™ was packed into the defect by hand. It was not tamped but pressed to ensure there were no air pockets. After stabilizing each tibia, an x-ray was taken to ensure that the created defects were completely filled with the graft material and that the fixation was secure. No specimens had persistent radiologic faults in the defect or the fixation. All surgical procedures and fixation were performed by 1 surgeon.

After a 24-hour incubation period at 37°C, which is required to cure the α-BSM™, the paired tibias were potted individually in a polyvinylchloride tube by using a lightweight resin. Before the setting of the resin, the tibial plateau defects were positioned horizontally using a level. This alignment procedure minimized local stress concentration on the defect and also ensured that the tibial defects were loaded primarily in uniaxial compression. After potting, the exposed length of each tibia was 13 cm. This length minimized bending of the tibia shaft, but was long enough that the fixation was not embedded in the potting material. Using an Instron 1000 axial testing machine, the repaired tibial defects were loaded under compression (Fig. 4). The applied loads were measured by the Instron and an accurate measurement of the displacement of the defect in relation to the tibia itself was determined using an optoelectronic motion capture system (Qualisys™). Each individual test began by positioning the potted tibia in an adjustable jig. A 38-mm modified spherical indentor was designed and attached to the Instron crosshead to ensure that the contacting surface between the indentor and the tibial plateau occurred only over the defect, ie, no peripheral contact was made with the tibia with cortex support. The indentor's medial-lateral contacting surface was sized to a width of 10 mm (approximately 2 mm less than the medial-lateral width of the defect) by sectioning both sides of the sphere at an angle of 60° from the inferior horizontal plane.

Reflective marker triads were placed on the tibial tuberosity and Instron crosshead. The triads were used with the Qualisys™ Motion Capture System to determine the relative displacement of the tibial defect with respect to the tibia. A compressive load was applied by lowering the indentor at a rate of 20 mm per minute.[7,8] This load was applied until the construct or tibia experienced failure, or until a 2000 N load

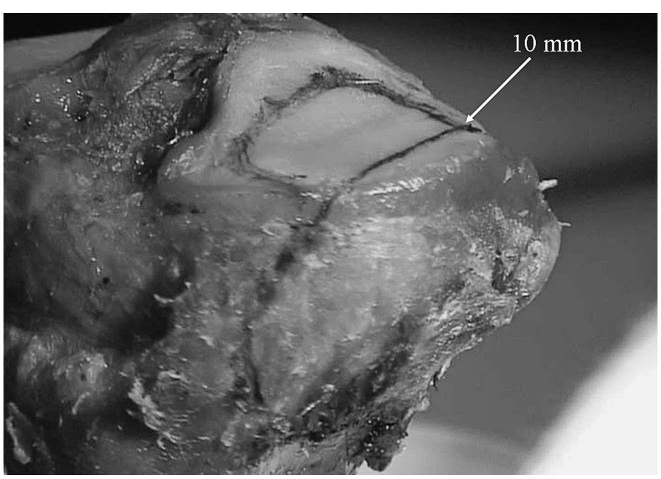

FIGURE 1. Location of the defect.

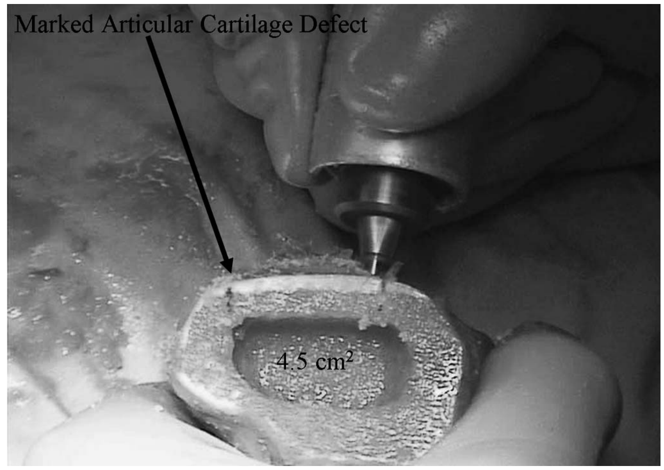

FIGURE 2. Creating the split depression fracture.

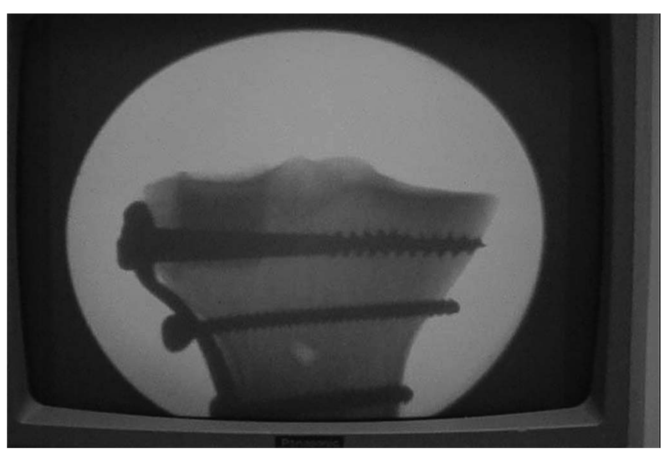

FIGURE 3. Stabilized fracture, showing fixation.

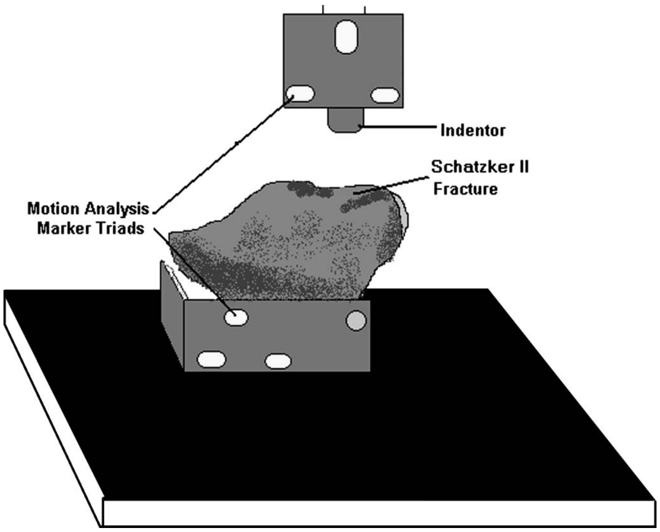

FIGURE 4. Compression test setup.

was attained. After testing was completed, the tibias were removed from the Instron and analyzed visually for failure modality. All fixation hardware was removed from the tibias during the inspection. The L-shaped buttress plate and screws used to repair the fracture also were inspected for failure because of the applied compressive forces.

Load-displacement curves were generated for each pair of tibias, and from these curves 2 parameters were defined to quantify the strength of the construct 1) defect displacement at 1000 N, and 2) initial stiffness, defined as the slope of the load-displacement curve (Table 1). The mean maximum force through the knee joint has been shown to be 3× body weight.[9] It has been stated that approximately 40% of the load goes through the lateral side of the knee joint.[10] Therefore, assuming an 85-kg patient, the load of 1000 N corresponds to the approximate force the lateral tibial plateau experiences during normal gait (0.4 × 3BW). To determine if the mechanical properties of the α-BSM™ repaired construct differed from the properties of the cancellous bone construct, paired Student *t*-tests were applied to the displacement and stiffness parameters. Matlab (Mathworks, Inc.) was used for statistical calculations. $P < 0.05$ was considered statistically significant.

RESULTS

Three matched tibia pairs fractured during preparation and were eliminated from the study. This left 10 matched pairs for analysis. The α-BSM™ tibias had higher initial stiffness than those repaired with cancellous bone ($P < 0.0001$). Displacement at 1000 N was significantly less for the α-BSM™ tibial constructs than the cancellous bone constructs ($P < 0.0001$).

The initial mean stiffness for the α-BSM™ construct was calculated to be more than 5× that of the cancellous bone constructs. The variability in stiffness for the α-BSM™ constructs, however, was much greater than the stiffness for the cancellous bone. Defect displacement at a force of 1000 N also was compared between the 2 constructs. The constructs repaired with cancellous bone had a mean defect displacement more than 3× the displacement of the α-BSM™ defect displacement (Table 1).

TABLE 1. Stiffness and Displacement at 1000 N

Construct	Stiffness N/mm (SD)	Displacement mm (SD)
Cancellous bone	335 (93)	3.8 (0.8)
Alpha-BSM	1965 (608)	1.2 (0.3)

DISCUSSION

The present study demonstrates that a tibial plateau defect repaired with α-BSM™ has increased initial compressive strength and initial stiffness properties compared with a tibial plateau reconstructed with cancellous bone. A discontinuity in the load displacement curve (Fig. 5) was observed in the constructs repaired with the cancellous bone, whereas no such pattern was present in the α-BSM™ repaired constructs. On completion of the mechanical testing, 8 (80%) of the cancellous bone constructs had visual evidence of subchondral fractures of the tibial defect, thereby providing an explanation of the discontinuities in the curve. The α-BSM™ constructs did not exhibit any obvious discontinuities in the stiffness curve. Compared with the cancellous bone, the superior strength and stiffness of the α-BSM™ provides a more rigid base of support for the tibial defect under compression, thereby minimizing subchondral bone fractures. A large variability in the α-BSM™ mean initial stiffness, compared with the cancellous bone, can in part be attributed to a greater direct loading of the underlying tibia. This variability was likely the result of the variability in bone quality of the specimens, although bone mineral density was not measured in this study. The α-BSM™ is a solid material that better transmits the load to the underlying bone compared with the cancellous bone graft (Fig. 6).

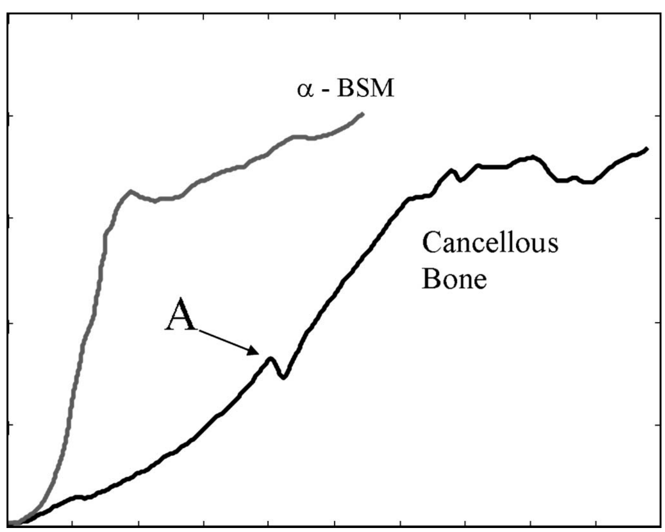

FIGURE 5. Load-displacement curves for the α-BSM™ and cancellous bone constructs showing a discontinuity (A) in the cancellous bone stiffness curve.

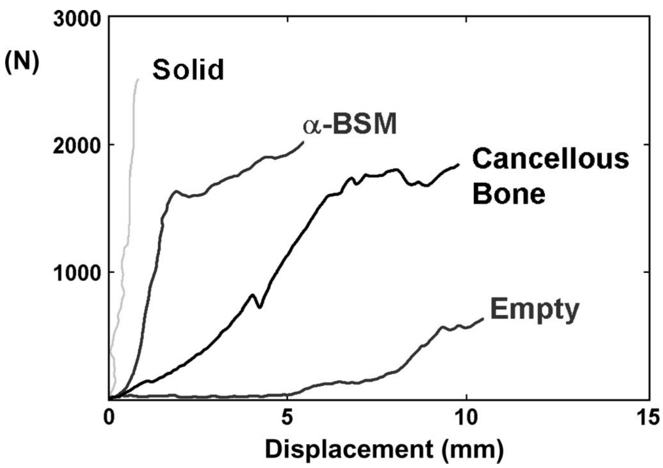

FIGURE 6. Load-displacement curves comparing the stiffness of various constructs: no defect, defect filled with α-BSM™ defect filled with cancellous bone, and empty defect.

α-BSM™ (Etex Corporation, Cambridge, MA; also known as Biobon in Europe) was chosen because the material has been engineered to mimic the chemical composition and crystalline structure of bone, can be molded into the defect, and hardens after an endothermic initiated reaction. The material is provided as a calcium phosphate powder that is hydrated with saline to form a putty. After implantation, it undergoes a setting reaction and converts to a Poorly Crystalline Hydroxyapatite (PCHA) with a compressive strength of approximately 12 MPa.[11]

α-BSM™ has been studied in different animal models to compare its performance with autograft. In a canine femoral defect model comparing α-BSM™ and autogenous bone grafts, bone sections analyzed at 3, 12, 26, and 52 weeks postoperative demonstrated that new bone formation and restoration of biomechanical strength was similar in both groups.[11] In a sheep segmental defect model comparing α-BSM™ (Biobon) with hydroxyapatite granules and autogenous bone grafts, bridging on all 4 sides of the defect was observed in 100% of the animals in the α-BSM™ group at 12 weeks. This compared with only 50% and 16% of the animals receiving autogenous bone grafts and hydroxyapatite granules respectively. The torsional stiffness results also were significantly improved in the α-BSM™ group.[12] Early clinical experience in Europe has demonstrated the suitability of the material for metaphyseal fracture defects in the distal radius.[14]

Histologic analyses of defects in animal models and some human biopsies have consistently demonstrated direct bone apposition without signs of inflammation or fibrous interface between the implant and host bone and a cell-mediated response toward resorption of the material and remodeling into bone.[11,13,15–20]

Split depression fractures of the lateral tibial plateau create a challenge for the treating orthopaedic surgeon.[1] The results with these fractures are improved when anatomic reduction of the joint line is obtained and early range of motion is instituted with a gradual increase in weightbearing during 3 months.

Our findings indicate that α-BSM™ is significantly stronger in compression than cancellous bone graft in cadaveric bone. Other "potential" clinical advantages of α-BSM™ are: 1) the potential to allow for earlier postoperative range of motion and weightbearing of these fractures to promote joint health without the fear of losing the reduction, 2) the lack of morbidity associated with its use compared with traditional autogenous graft, 3) the absence of the risk of viral transmission as exists with allograft bone, and 4) the use of a bone substitute as an expander for large bone defects difficult to fill with the patients own autogenous bone.

With split depression fractures occurring with higher frequency in the elderly (who often are unable to toe-touch or non-weightbear secondary to decreased upper body strength), the thought of a bone graft substitute with increased compressive strength may be of benefit. There has been an influx of bone graft substitutes in the orthopaedic realm during the last few years, but most have not been thoroughly studied or their clinical roles clearly defined in this setting.[3–5] In the clinical setting of a tibial plateau fracture, it would be advantageous to prove that our chosen bone graft substitute is able to deliver the requirements of biocompatibility and provide structural stability to the elevated joint line.

The strengths of the study include the ability in the laboratory to adjust for most variables: reduction, fixation, elevation of the defect, and comparing bone from paired samples. The ability to measure movement of the defect while subtracting movement of the whole specimen was considered more dependable than most previous studies (Qualisys device).

The weaknesses were the biomechanical nature of the study, although this did allow for the perfect impaction of the graft and the BSM, it did not account for any healing of the graft with expected improvement in stability. There was no fibula in the specimen, which may alter some of the biomechanics around the joint. Fixation was done with standard plates because no locked or fixed angled implants were used. Variability in results was assumed to be the result of differences in bone mineral density; however, BMD was not measured in this experiment so further study is needed to confirm this.

To conclude, α-BSM™ has increased compressive strength compared with cancellous bone graft in stabilizing split depression fractures of the lateral tibial plateau in a cadaver fracture model (Fig. 6). However, prospective, randomized, multicenter, clinical studies are required to substantiate these results. This prospective, multicenter, randomized study has now been completed and presented at the AAOS in San Francisco 2004 and has been submitted for publication.[21]

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