Comparison of Autogenous Bone Graft and Endothermic Calcium Phosphate Cement for Defect Augmentation in Tibial Plateau Fractures. A Multicenter, Prospective, Randomized Study

Thomas A. Russell, Ross K. Leighton and on behalf of the Alpha-BSM Tibial Plateau Fracture Study Group
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Comparison of Autogenous Bone Graft and Endothermic Calcium Phosphate Cement for Defect Augmentation in Tibial Plateau Fractures

A Multicenter, Prospective, Randomized Study

By Thomas A. Russell, MD, and Ross K. Leighton, MD on behalf of the Alpha-BSM Tibial Plateau Fracture Study Group*

Background: Bone graft augmentation is often selected to treat defects associated with unstable tibial plateau fractures. This prospective, randomized, multicenter study was undertaken to determine the efficacy of bioresorbable calcium phosphate cement compared with standard autogenous iliac bone graft in the treatment of these osseous defects.

Methods: One hundred and twenty acute, closed, unstable tibial plateau fractures (Schatzker types I through VI) in 119 adult patients were prospectively enrolled in twelve study sites in North America between 1999 and 2002. Randomization for the type of grafting of the subarticular defect was done at the time of surgery, with use of a 2:1 ratio, to treatment with calcium phosphate cement (eighty-two fractures) or autogenous iliac bone graft (thirty-eight fractures). After open reduction, standard plate-and-screw or screw-only fixation was used and then either the cement or the bone graft was placed in the defect cavity for subarticular support. Follow-up included standard radiographs, evaluated by multiple reviewers to avoid bias, and knee range-of-motion assessment at six months to one year or later.

Results: The age, weight, height, and sex of the patients and the fracture patterns were comparable in the two groups, as were union rates and time to union. There was a significantly ($p = 0.009$) higher rate of articular subsidence during the three to twelve-month follow-up period in the bone graft group.

Conclusions: The bioresorbable calcium phosphate cement used in this study appears to be a better choice, at least in terms of the prevention of subsidence, than autogenous iliac bone graft for the treatment of subarticular defects associated with unstable tibial plateau fractures.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

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*Robert W. Bucholz, MD, University of Texas Southwestern Medical School, Dallas, Texas; Paul Tornetta III, MD, Boston Medical Center, Boston, Massachusetts; Charles N. Cornell, MD, Hospital for Special Surgery, New York, NY; Sam Agnew, MD, McLeod Regional Medical Center, Florence, South Carolina; Robert F. Ostrum, MD, Camden, New Jersey; B.H. Berrey, MD, University of Florida Health Science Center, Jacksonville, Florida; Brian Davison, MD, Grant/Riverside Methodist Hospital, Columbus, Ohio; Thomas A. Gruen, MS, Brandon, Florida; Mark S. Vrahas, MD, Massachusetts General Hospital, Boston, Massachusetts; Alan L. Jones, MD, Orthopaedic Trauma Associates of North Texas, Dallas, Texas; Andrew Pollak, MD, University of Maryland School of Medicine, Baltimore, Maryland; Peter O'Brien, MD, Vancouver Hospital and Health Sciences Center, Vancouver, British Columbia, Canada; Thomas F. Varecka, MD, Minneapolis, Minnesota; and James A. Goulet, MD, University of Michigan Hospitals, Ann Arbor, Michigan.

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Autogenous iliac bone graft has been the most frequently recommended treatment for defects associated with unstable tibial plateau fractures[1-3]. Despite the wide acceptance of autogenous iliac bone graft as the so-called gold standard, complications of graft harvest, ranging from temporary pain and numbness to long-term functional impairment, are well documented. Because the primary objective of the use of grafting in a subarticular defect associated with a tibial plateau fracture is to prevent the collapse of the articular surface, it seems reasonable that an artificial material might be suitable for use with internal fixation if it were biocompatible, readily available, and offered some structural support for the articular fracture. Trenholm et al.[4], in a cadaver model of a Schatzker type-II tibial plateau fracture, determined that alpha-BSM, a calcium phosphate cement, was significantly ($p < 0.0001$) stiffer than cancellous bone grafts and that defect displacement with loading was significantly ($p < 0.0001$) less with alpha-BSM than with bone graft. To determine if alpha-BSM was as effective as autogenous iliac bone graft in the management of subarticular tibial defects, the present multicenter, prospective, randomized study was undertaken to compare the use of autogenous iliac bone graft with alpha-BSM Bone Substitute Material (ETEX, Cambridge, Massachusetts, and DePuy, Warsaw, Indiana).

Materials and Methods

Twelve centers in North America with extensive experience in the treatment of tibial plateau fractures were selected for this multicenter study. The study was conducted under a U.S. Food and Drug Administration (FDA) investigational device exemption. Selection criteria were a patient age of sixteen to seventy-seven years and an acute, closed, unstable fracture of the proximal part of the tibia (Schatzker types I through VI[5]) that required both internal fixation and grafting. Patients with substantial metabolic bone disease; compromised health because of diabetes, malignancy, peripheral vascular disease, alcoholism, substance abuse, use of systemic steroids, or immunosuppressive therapy; infection at the operative site; concurrent treatment with other bone substitutes including autograft (any graft substance other than alpha-BSM or autogenous iliac bone graft); or related peripheral nerve damage were excluded, as were women who were pregnant or breastfeeding and fertile women not on routine contraceptive control. Tobacco use was not an exclusion criterion.

Randomization for subarticular defect management with autogenous iliac bone graft or alpha-BSM was based on a 1:2 protocol, respectively, as autogenous iliac bone graft was considered to be associated with more risks of morbidity to the patient. This randomization protocol was mandated by the FDA. Patients were randomized by sealed computer-generated randomization schedules, which were opened in the operating room to determine which grafting material would be used. All sites obtained approval from the institutional review board at their respective hospitals, and all patients provided informed consent preoperatively. The protocol required that the fractures be surgically repaired within thirty days of injury with use of standard open reduction and internal fixation techniques to restore fracture stability. Locking plates were not used in this study. Subarticular grafting with either material was done with an open technique. Follow-up was scheduled at six weeks, three months, six months, and twelve months after surgery.

The study population included 120 fractures in 119 patients (seventy-three men and forty-six women) who were enrolled between 1999 and 2002. Eighty-two fractures were randomized to alpha-BSM and thirty-eight were randomized to autogenous iliac bone graft. The average patient age at the time of the operation was forty-three years in both groups. The average patient weight was 171 lb (77.6 kg) in the alpha-BSM group and 183 lb (83 kg) in the autogenous iliac bone graft group. Mechanisms of injury included low-energy falls, motor vehicle crashes, motor vehicle-pedestrian accidents, and industrial accidents. According to the Schatzker classification system, one fracture was classified as type-I; fifty-two, as type-II; twenty-six, as type-III; eleven, as type-IV; twenty-eight, as type-V; and two, as type-VI fractures. The two type-VI fractures were originally classified as type V, but after closer examination were reclassified as type VI. Because only the subarticular portion of these two fractures was grafted, they were included in the study.

Twenty-three patients (twenty-three fractures; 19% of the enrolled patients), which included eleven patients in the alpha-BSM group and twelve in the autogenous iliac bone group, were lost to follow-up before the six-month postoperative examination. The ninety-seven remaining fractures in ninety-six patients (81% of the enrolled patients) included seventy-one (87%) of the eighty-two fractures receiving alpha-BSM and twenty-six (68%) of the thirty-eight fractures receiving autogenous iliac bone graft. The final review was done by a blinded panel consisting of two experienced orthopaedic trauma surgeons and one consultant (T.A.G.) with extensive radiographic experience with hip and knee arthroplasty procedures and subsidence. Two patients (two fractures) were excluded from analysis because of deviations from the study protocol: no surgical stabilization was used in one fracture and external fixation was used in the other. At the twelve-month physical examination, ninety-five fractures (sixty-nine in the alpha-BSM group and twenty-six in the autogenous iliac bone group) in ninety-four patients were evaluated.

All radiographs were reviewed by the panel of two experienced orthopaedic trauma surgeons and one consultant who were blinded as to the kind of graft material used. The panel independently reviewed all radiographs in chronological order to determine whether subsidence was present; the initial, postoperative, and follow-up radiographs were examined in a single session. Subsidence of ≥2 mm had to be identified by all three panelists before it was considered to be present.

The patients were evaluated as to fracture union, articular subsidence, loss or premature resorption of the graft, infection, effect of tobacco use, and knee range of motion. This information was collected at all patient visits and was monitored by an independent study coordinator; all data were sent to a central location for analysis.

TABLE I Range of Motion After Surgery

	6 Mo*		12 Mo*	
	Alpha-BSM (N = 69)	Autogenous Iliac Bone Graft (N = 26)	Alpha-BSM (N = 67)	Autogenous Iliac Bone Graft (N = 26)
Flexion of ≥120° *(no. of knees)*	58 (84%)	19 (73%)	59 (88%)	18 (69%)
Full extension *(no. of knees)*	58 (84%)	15 (58%)	59 (88%)	20 (77%)

*The range-of-motion measurements for all patients were not obtained at all centers.

Surgical Technique

All fractures underwent open reduction and internal fixation with use of standard nonlocking plate-fixation techniques in accordance with the surgeon's normal practice. Plate-and-screw constructs were used in 109 fractures, and screws only were used in nine. After reduction of the articular fracture, the residual subarticular defect was measured and then was packed with either morselized corticocancellous autogenous iliac bone graft or alpha-BSM.

Autogenous bone grafts were harvested from the anterior iliac crest in the standard manner. Alpha-BSM is a bioresorbable, calcium-deficient, apatitic calcium phosphate with a calcium-to-phosphate ratio of 1.45, porosity of 50% to 60%, and an average pore size of <1 mm. After the recommended amount of saline solution is added, the dry powder is mixed for one minute immediately before implantation. After implantation, it undergoes endothermic setting with a residual compressive strength after about four hours (in vitro) of approximately 12 MPa, but requires a relatively dry cavity in the bone initially for optimal stability. The estimated volume of alpha-BSM and autogenous iliac bone graft used was approximately 10 mL in most patients. Postoperatively, all patients were mobilized with assistive devices and were allowed weight-bearing of <50 lb (22.7 kg). This was demonstrated by having the patient place his or her involved foot on a bathroom scale and exerting pressure until 50 lb was attained. This restriction was in place for six weeks, and then progressive weight-bearing was permitted on the basis of the surgeon's judgment.

Follow-up

Six-month follow-up data were available for sixty-six fractures (93%) in the alpha-BSM group and twenty-six (100%) in the autogenous bone graft group; twelve-month follow-up data were available for sixty-three fractures (94%) in the alpha-BSM group and twenty-six (100%) in the autogenous bone graft group. Patients were evaluated with regard to union, subsidence, loss or premature resorption of the graft, infection, functional recovery, and effect of tobacco use. Union was determined by the treating surgeon clinically as the ability of the patient to bear full weight without pain and, radiographically, as the disappearance of the fracture lines on the three-month follow-up anteroposterior and lateral radiographs.

Final radiographs made at twelve to forty-eight months after surgery were available for 102 fractures (sixty-nine in the alpha-BSM group and thirty-three in the autogenous iliac bone group) in 101 patients.

Statistical Analysis

The groups were analyzed with a two-tailed test with regard to differences in age, weight, and height and with the Fisher exact test with regard to sex. The results at the time of follow-up were compared with use of the Fisher two-tailed t test.

Results

All fractures united in both groups within the same time period (an average of three months); there was no difference between smokers and nonsmokers with regard to the time to union or the frequency of union. Two surgical site infections, one in each group, resolved with local wound care and antibiotics.

No difference was detected between the groups with regard to mean age, weight, height, or sex distribution. The data on the patients were tested to determine whether the groups differed with respect to mechanism of injury, Schatzker classification, associated musculoskeletal or soft-tissue injuries, or average defect size, and no difference was observed between the groups with respect to these baseline conditions.

There was no dissolution of either the bone graft or alpha-BSM before fracture union as indicated by the absence of radiolucent zones around the grafts on the postoperative radiographs. A gradual reduction in the density of the alpha-BSM was observed on successive radiographs, but the material was still visible at one year in most fractures. No patient in either group had loss of internal fixation (plate breakage or deformation that required additional surgery) or needed a reoperation, with the exception of planned implant removal (seven fractures with a slight screw-plate change in angulation of ≤5°). One varus malunion occurred in each group, and both malunions were in the 5° to 10° range. All patients with an autogenous iliac bone graft had initial pain from the harvest site, which usually had resolved by six to twelve months after surgery. There was no infection at the graft harvest sites.

Not all patients at all centers were examined for range of motion. Ninety-five knees were evaluated for range of motion in flexion and extension at six months, and ninety-three were evaluated at twelve months (Table I). The alpha-BSM group

had a slightly better range of motion at both six and twelve months, but the difference was not significant.

In the final radiographic evaluation of 102 fractures by the three-person panel blinded to the study material, an unexpected finding was the significantly ($p = 0.009$) higher rate of articular subsidence in the autogenous bone-graft group than in the alpha-BSM group at the twelve-month or greater follow-up. The study hypothesis was that subsidence would be equivalent with the use of both graft substances; however, subsidence of ≥2 mm was identified on anteroposterior radiographs in ten (30%) of the thirty-three fractures in the autogenous bone-graft group compared with six (9%) of sixty-nine in the alpha-BSM group. Subsidence occurred between three and six months after surgery. A finding that has not, to our knowledge, been reported was subarticular sclerosis in the metaphyseal region; this was seen in all fractures in which there was subsidence, and all fractures with this sclerosis had subsidence.

Discussion

Autogenous iliac bone graft has been considered the standard for management of subarticular osseous defects associated with intra-articular fractures because of its cited advantages of availability, low cost, and structural support with bone inductive biologic capacity[6]. However, iliac bone-graft procurement requires a second surgical procedure, causes pain at a previously uninjured site, and risks the possibility of iatrogenic infection[7,8]. Younger and Chapman[9] documented a 9% rate of major complications and a 21% rate of minor complications after 243 autogenous bone-graft harvest procedures, 215 of which were from the iliac crest. Goulet et al.[10] reported that thirty-three (38%) of their eighty-seven patients had pain at six months after the harvest of autogenous iliac bone, and eleven patients (13%) had difficulty walking. Silber et al.[11], in a study of 134 patients, found that the rate of functional impairment ranged from 7% (for household chores) to 13% (for walking) at an average of four years after autogenous iliac bone-grafting. In a more recent study of bone-grafting of humeral shaft nonunions, Hierholzer et al.[12] reported complications in twenty (44%) of forty-five patients who had autologous bone grafts. Although all patients with autogenous iliac bone grafts in our study had pain from the harvest site, it had typically resolved by six to twelve months after surgery, and no patient had an infection develop at the graft harvest site.

Biomechanical studies have shown that alpha-BSM provides more support of the articular surface than does cancellous bone graft. Landry et al.[13] and Trenholm et al.[4] found that, at a load of 1000 N applied to the plateaus of cadaveric tibiae with Schatzker type-II fractures, the rate of displacement was 68% lower for subchondral defects filled with alpha-BSM than for those filled with cancellous bone graft.

Welch et al.[14] found similar results of higher retention of the subarticular support with alpha-BSM compared with autogenous graft in fractures of the tibial plateau in a goat model. In their study, collapse and resorption of the autogenous graft material occurred almost immediately in the postoperative period, resulting in the collapse of the articular segment and a residual subsidence defect. This collapse was significantly less with alpha-BSM than with bone graft ($p < 0.05$).

Limitations of the present study include the 87% follow-up rate at one year or longer. The autogenous bone-graft and alpha-BSM groups were comparable with regard to the percentages of radiographic follow-up, but the range-of-motion data would have benefited from better follow-up for the physical examination. Postoperative computed tomography scans were not obtained as this was not considered the standard of care in any of the study sites, but they may have allowed a more accurate determination of the amount of subsidence. Small amounts of subsidence may be difficult to quantify on radiographs, but the requirement that all three panelists independently identify ≥2 mm of subsidence before it was considered present, we believe, obviates this concern. Although the panelists were blinded as to treatment group, we cannot confirm that individual reviewers were not able to detect the difference in treatment, resulting in some degree of detection bias.

We know of no convincing study in the literature that has related the amount of subsidence or articular compression to the development of osteoarthritis. However, if the purpose of an articular support material is to prevent subsidence, clearly it must be effective in this function to justify its continued use. The results of this study indicate that alpha-BSM can provide similar and possibly better mechanical support than autogenous iliac bone graft in the treatment of defects in unstable fractures of the tibial plateau. ■

Thomas A. Russell, MD
240 LaGrange Creek Drive, Eads, TN 38028.
E-mail address: tarmd@aol.com

Ross K. Leighton, MD
Division of Orthopaedics, Halifax Infirmary,
Queen Elizabeth II Health Sciences Centre, Room 4867,
1796 Summer Street, Halifax,
NS B3H 3A7, Canada

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Commentary & Perspective

Commentary & Perspective on
"Autogenous Bone Graft and Endothermic Calcium Phosphate Cement Defect Augmentation in Tibial Plateau Fractures: A Prospective Randomized Study"
by T.A. Russell, MD, et al.

Commentary & Perspective by
Thomas A. Einhorn, MD*,
Department of Orthopaedic Surgery, Boston University Medical Center, Boston, Massachusetts

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Sometimes things turn out better than expected. This study tested the hypothesis that alpha-BSM (ETEX, Cambridge, Massachusetts, and DePuy, Warsaw, Indiana), a bioresorbable calcium phosphate cement, is as effective as autogenous iliac bone graft in the management of subarticular tibial defects in patients who have sustained a tibial plateau fracture. The results showed that alpha-BSM "appears to be a better choice, at least in terms of the prevention of subsidence" for the treatment of these injuries.

The investigation involved twelve study sites in North America, and bone defects were randomized to grafting with either autogenous iliac bone graft or alpha-BSM calcium phosphate cement. Open reduction and internal fixation was achieved with standard plate and screw or screw-only fixation. Patients were evaluated at six to twelve months with regard to union, subsidence, premature resorption, infection, functional recovery, and effect of tobacco use. As all fractures united in both groups within the same time-period, there was no difference between smokers and nonsmokers with regard to time to union or frequency of union, and as there was no dissolution of either the bone graft or alpha-BSM, the higher rate of articular subsidence in the autogenous iliac bone-graft group combined with a slightly better range of motion in the alpha-BSM group showed alpha-BSM to be the winner.

The authors suggested that the higher rate of articular subsidence in the autogenous iliac crest bone-graft group was "an unexpected finding." However, these results are very consistent with those of previous studies that have demonstrated the benefits of a calcium-phosphate-based bone cement in the augmentation of defects associated with fractures in long bones. Indeed, a recent meta-analysis of randomized trials concluded that "the use of calcium phosphate bone cement for the treatment of fractures in adult patients is associated with a lower prevalence of pain at the fracture site in comparison with the rate in controls (patients managed with no graft material). Loss of fracture reduction is also decreased in comparison with that in patients managed with autogenous bone graft."[1] In fact, reports showing the benefits of calcium phosphate cement in the treatment of displaced distal radial fractures[2,3], redisplaced distal radial fractures[4,5], and unstable intertrochanteric hip fractures[6] have built a fairly substantial body of evidence that the use of specific calcium phosphate cements in fracture care may represent a technological advance in orthopaedic trauma surgery.

As with any new technology, use and application have to be carefully monitored and results may not be generalizable to other sites. Mattson and Larsson, two investigators who have extensively examined the application of calcium phosphate cements in trauma surgery and reported excellent results, demonstrated that when used to augment internal fixation of displaced femoral neck fractures, calcium phosphate cement fails to improve results[7]. Yet, in a study by Lobenhoffer et al.[8], the use of a calcium phosphate cement in the treatment of tibial plateau fractures showed that the high mechanical strength of the cement allowed early weight-bearing after a mean postoperative period of 4.5 weeks (range one to six weeks). As most surgeons manage these fractures with longer periods of non-weight-bearing, if these findings can be reproduced and if the use of calcium phosphate cements can be demonstrated to consistently shorten the time needed for protected weight-bearing, it may be possible to achieve improved outcomes, shorter recoveries, and even better functional results in patients who sustain these injuries. One point of caution, however, is to recognize that not all calcium phosphate cements are the same. Different types form different mineral phases, and the mechanical strength and dissolution properties may vary greatly. It is important that the surgeon be familiar with the evidence that supports the use of a specific calcium phosphate cement in the setting in which he or she intends to employ it.

Calcium phosphate cements are not new, and trauma surgeons have been slow to incorporate them into their clinical practices. Perhaps this article, the recent meta-analysis by Bajammal et al.[1], and a revisitation to the now substantial body of literature supporting the use of calcium phosphate cements will change that. Moreover, as surgeons become more adept and experienced with the use of these materials, other applications, such as the ability to employ a calcium phosphate cement as a delivery vehicle for a growth factor, may be found. Indeed, alpha-BSM is currently being developed (and chemically modified) in order to promote the use of recombinant human bone morphogenetic protein-2 (BMP-2) as an injectable therapy[9].

It is always pleasing when the results of a clinical investigation show a positive finding that represents an opportunity for further study and technological development. Perhaps the time has come to seriously consider the use of calcium phosphate cements in orthopaedic trauma surgery and to determine just how much of an advance they truly represent.

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