Preliminary Report
Use of a Calcium Sulfate-Based Bone Graft Substitute for Benign Bone Lesions

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ABSTRACT

Twenty-three patients with a benign bone lesion grafted with calcium sulfate, with and without demineralized bone matrix, were reviewed. At a minimum of 1 year postoperatively, 21 patients had achieved between 76% and 100% bone repair based on anteroposterior and lateral radiographs. Overall, the mean Enneking Functional Evaluation System score was 98%. Calcium sulfate is a well-tolerated, biodegradable, osteoconductive bone graft substitute. It is a reasonable alternative to autogenous bone graft for benign bone lesions.

Benign bone lesions frequently cause bone loss, which creates a risk of fracture. In addition, some benign bone lesions are biologically active and will progressively destroy bone unless they are adequately excised. Some common benign lesions include aneurysmal bone cyst, unicameral bone cyst, enchondroma, chondroblastoma, and osteoid osteoma.

Bone grafting is performed when there is a structural defect. The most common type is autogenous bone graft from the ilium. The problem with autogenous bone grafting includes the limited amount of bone available and donor site morbidity. The above-mentioned benign lesions frequently occur in children in whom there is a limited amount of autogenous graft available. In addition, harvesting of autogenous iliac bone graft is associated with significant pain, many times being the sole reason for hospitalization. Major complications have been reported at a rate of 8.6% and minor complications at 20.6%. Some of the reported donor site complications with autogenous iliac grafting include infection, prolonged wound drainage, large hematomas, reoperation, prolonged pain, sensory loss, fracture, pelvic instability, meralgia paresthetica, and unsightly scars.

Recently, there has been increased enthusiasm for the use of bone graft substitutes to fill and repair osseous lesions. There are two types of bone graft substitutes: osteoconductive and osteoinductive materials.

Calcium sulfate is an osteoconductive, inorganic bioactive material that has been used for many years as a bone graft substitute. In 1978, Peltier and Jones reported encouraging results in 26 patients with unicameral bone cysts treated with plaster of Paris (calcium sulfate) pellets. All patients were treated with curettage of bone followed by packing of the cavity with these pellets. Minimum follow-up was 1 year with a maximum of 20 years. Twenty-four of the 26 patients had no further surgery with evidence of cyst consolidation ranging from 3-6 months. They concluded this technique of bone grafting compared favorably to other reported procedures for unicameral bone cysts.

In 1980, Coetzee reported on 110 patients treated with calcium sulfate to repair an osseous defect. Most of these were osseous defects in the skull and facial bones. Coetzee concluded that calcium sulfate is an outstanding bone substitute, ensuring bone formation and giving results comparable with autogenous bone, if not better.

In recent years, there have been some technological changes in the calcium sulfate material that may affect its performance as a bone graft substitute. Surgical-grade calcium sulfate, unlike

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its plaster of Paris predecessor, is composed of an alpha crystal that is more uniform in shape and size. This uniformity affects the rate of resorption and may have other effects on bone repair. The properties of calcium sulfate that have been demonstrated in the past include osteoconduction, biocompatibility, and total resorption.

There has not been a recent clinical review on the performance of calcium sulfate as a bone graft substitute. This retrospective study reviewed patients with benign bone lesions treated with surgical-grade calcium sulfate-based bone graft substitute.

**MATERIALS AND METHODS**

A retrospective clinical review was performed of the first 23 consecutive benign bone lesions that required surgical intervention and were treated with a calcium sulfate-based bone graft substitute. Minimum follow-up was 1 year. Only patients with a benign lesion that was grafted with calcium sulfate (OsteoSet, Wright Medical Technology Inc. Arlington, Tenn) or OsteoSet combined with demineralized bone matrix (AlloGraft; AlloSource, Denver, Colo) were included. Patients treated with calcium sulfate and autogenous iliac bone graft were excluded.

Patient medical records, radiographs, and pathology were reviewed. The size of the osseous defect was measured on two plain radiographs or computed tomography. Three maximum dimensions were recorded, including anteroposterior, mediolateral, and cephalad-caudal dimensions.

At most recent follow-up, similar comparison measurements were made calculating the residual osteolytic defect after grafting. An estimate of bone fill was determined and graded as 0-25% (I), 26%-50% (II), 51%-75% (III), and 76%-100% (IV).

Functional outcomes were measured using the Enneking Functional Evaluation System. For the upper extremity, there are six categories: pain, function, emotional acceptance, hand positioning, dexterity, and lifting ability. For the lower extremity, the categories are: pain, function, emotional acceptance, supports, walking ability, and gait. Each category is assigned a score ranging from 0-5, with a maximum total score of 30. A percent score was determined. All patients were evaluated for any complication associated with the lesion or surgical management.

**Surgical Technique**

The lesion was approached through a longitudinal incision using a standard anatomical approach. When possible, a tourniquet was used.

The bone was exposed subperiosteally, and a cortical window was created using a high-speed dental burr to completely visualize the lesion. Care was taken not to spill tumor. A frozen section biopsy was performed to confirm the diagnosis, and cultures were taken.

The lesion was completely excised with curettes, and a burr was used to extend the excision at the bone margin. After complete tumor excision, the defect was packed with 4.8-mm calcium sulfate pellets (OsteoSet) until completely filled. If demineralized bone matrix (AlloGraft) was added, the materials were first dry mixed in a kidney basin. The mix ratio was 15 cc of demineralized bone matrix (AlloGraft) with 20 cc of 4.8-mm calcium sulfate (OsteoSet) pellets. The cavity was packed tightly with this mixed material. Closed suction drainage was used for 24-48 hours. External splinting was used as needed.

**RESULTS**

Twenty-three patients (9 males and 14 females) with a mean age of 22.7 years (range: 4-60 years) were reviewed.
Diagnosis of the bone lesions included: chondroma, 5; nonspecific cyst, 4; aneurysmal bone cyst, 4; unicameral bone cyst, 3; chondroblastoma, 3; osteoid osteoma, 2; fibroma, 1; and fibrous dysplasia, 1. The sites of lesion were: tibia, 8; humerus, 5; femur, 2; radius, 2; phalanx, 2; fibula, 2; pelvis, 1; and os calcis, 1. One patient received supplemental internal fixation (Figure 1).

Mean follow-up was 21.4 months (Table 1). Follow-up ranged 12-30 months.

Sixteen patients were treated with calcium sulfate combined with demineralized bone matrix, while 4 were treated with calcium sulfate alone. Demineralized bone matrix was used with OsteoSet early in the series until confidence with OsteoSet alone was developed. The results were nearly identical.

Mean lesion volume was 22.9 cc (range: 34-126 cc). Bone repair grade was I, 0; II, 0; III, 2; and IV, 21 (Table 2). There was one complication in a 14-year-old boy who had an enchondroma of the phalanx (Figure 2). This lesion was excised and grafted with OsteoSet. During the perioperative period, the patient suffered a fracture of the phalanx while playing baseball and was subsequently treated with internal fixation.

Both the lesion and the fracture healed uneventfully with an excellent outcome. There were no infections, persistent drainage, or other complications. The mean Enneking Functional Evaluation System score was 98% (range: 33%-100%) (Table 2). In all patients, there was 100% resorption of the OsteoSet at most recent follow-up (Table 1).

**DISCUSSION**

The use of calcium sulfate (OsteoSet) with or without demineralized bone powder (AlloGro) proved to be an effective means of bone grafting in this series. All patients avoided the cost and potential morbidity of an iliac bone graft.

Follow-up radiographs consistently showed complete resorption of the calcium sulfate pellets, with consolidation of the osteolytic defect by trabecular bone. Trabecular bone was easily recognized by its linear striation as opposed to the amorphous mineralization seen with the calcium sulfate.

Typically, the radiographs showed the process of peripheral resorption of the calcium sulfate pellets followed by the laying down of first disorganized and later organized bone (Figure 3).
Although precise determination of the residual osteolysis is difficult, comparative radiographs showed the vast majority of the osteolytic defect to be occluded by mature healthy bone at 1-year follow-up. In many patients, the osseous repair was evident at 6 weeks and complete by 6 months.

The amount of bone repair in these patients appears to have been adequate because all but 1 of the 23 patients resumed normal functional activities by 1 year postoperatively. The only fracture that occurred was in a phalanx that suffered significant trauma (baseball) during the perioperative period. Other than this one case, there were no fractures, even in long bones despite the minimal use of prophylactic internal fixation.

The functional outcomes, based on the Enneking Functional Evaluation System, were good or excellent in most patients. The one low score was in a patient with a diffuse polyostotic fibrous dysplasia. Although her elbow pain improved with excision and grafting, significant disability still remained due to diffuse bone involvement. In 16 patients, small amounts of residual osteolysis were evident, while 7 patients had 100% filling of the defect with bone (Table 2).²⁹

This type of postoperative appearance occurs even with autogenous bone grafting. The amount of osseous repair necessary to provide enough strength and substance to the bone to prevent fracture is unknown. Since all but one of these patients have resumed a normal functional performance status, one can conclude that the bone repair process must be sufficient. No doubt, similar radiographic and functional outcomes can be anticipated with autogenous iliac bone grafting but at a significant price. The use of bone graft substitutes allowed most of these procedures to be done on an outpatient basis and avoided the pain and complications at the donor site. No complications associated with either the calcium sulfate pellets or demineralized bone matrix were observed. There were no infections, inflammatory reactions, or significant persistent drainage. The size of the lesion, which ranged from .34-126 cc, did not have an effect on bone repair. Site also was not a significant factor.

Most of the patients in this series were treated with a combination of calcium sulfate mixed with demineralized bone matrix. Some patients, however, were treated with calcium sulfate alone. These represent later patients in the series when confidence in the performance of calcium sulfate increased. There was no real difference between the outcomes or the process of bone repair whether demineralized bone matrix was added to the calcium sulfate. There was no difference in the rate of repair. This series, however, was not done in a prospective randomized manner to conclude the efficacy of OsteoSet and AlloGro versus OsteoSet alone. At least conceptually, the combination of an osteoconductive material with a potentially osteoinductive material seems desirable. Further trials would be useful, especially a prospective randomized series looking at this question.

**CONCLUSION**

Calcium sulfate, with or without demineralized bone matrix, is an effective method of filling osseous defects and predictably leads to good bone repair. This implant material was well tolerated and fully resorbable, and was associated with few complications.
More importantly, however, is that patients avoided the morbidity, pain, and cost of an autogenous bone graft, with a mean Enneking Functional Evaluation System score of 98%.

REFERENCES