



A Retrospective Analysis Evaluating Allogeneic Cancellous Bone Sponge for Foot and Ankle Arthrodesis

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ABSTRACT

The present retrospective case crossover study was conducted to determine the effectiveness and safety data associated with the use of an allogeneic, cancellous bone sponge in an orthopedic foot and ankle population. We reviewed the medical records of 47 subjects (80 joints) who had undergone foot and/or ankle fusion with the cancellous bone sponge. The records were reviewed up to 12 months postoperatively. The joints included in the present study were 12 ankles, 3 ankle syndesmotic fusions (with concurrent total ankle arthroplasty), 17 subtalar joints, 17 talonavicular joints, 9 calcaneocuboid joints, 1 naviculocuneiform joint, 13 first tarsometatarsal joints, 6 lesser tarsometatarsal joints, and 2 first metatarsophalangeal joints. The endpoints of the present study were solid, sustained foot and ankle fusion, as demonstrated radiographically, and the occurrence of unexpected adverse effects related to the graft. The fusion rates were compared with those reported in other studies. The patient-reported outcome variables for the present study included the visual analog pain scale and the American Orthopaedic Foot and Ankle Score. The use of a cancellous sponge showed statistically significant improvements in pain and function and comparable or better fusion rates compared with outcomes reported in other published reports.

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Osteoarthritis of the ankle and foot is a painful and disabling condition that significantly reduces the patient's quality of life. Most cases of ankle and foot arthrosis are due to previous acute traumatic injuries such as ankle and calcaneal fractures (1). Other causes of arthrosis include primary degenerative joint disease, rheumatoid arthritis, psoriatic arthritis, and postinfectious arthritis. Congenital deformities such as clubfoot and tarsal coalitions can lead to arthrosis from mechanical deficiencies such as adult acquired flatfoot (2). Major symptoms of arthrosis include pain, stiffness, swelling, and difficulty walking. The goal of treatment is a stable fusion with a pain-free extremity that preserves a normal gait. The initial treatment usually involves conservative measures such as pain relievers, ankle-foot

orthoses, physical therapy, and steroid therapy. Ultimately, however, many patients will require surgery.

Regardless of etiology, total ankle arthroplasty and ankle/foot fusion are common procedures for the treatment of pain and dysfunction associated with osteoarthritis, and their effectiveness has been consistently shown in biomedical studies (3–6). Unsatisfactory outcomes of arthrodesis are usually associated with nonunion. The rates of nonunion cited in published studies range from 0% to 40% (1). The nonunion rate for subtalar joint arthrodesis is not as variable and has been reported to be 0% to 14% (2). A failed ankle or foot fusion is significant, especially in aged patients or those with underlying chronic health conditions. Although a failed fusion might be asymptomatic, it is more frequently associated with pain and/or dysfunction that seriously affects a patient's quality of life. Surgery also carries the risk of complications such as inadequate fixation, infection, avascular necrosis, neurologic deficit, concomitant medical conditions, and open fractures. Chronic health problems such as renal failure, cardiac disease, diabetes, smoking, and alcohol abuse are associated with a greater risk of nonunion. Surgeons disagree about the consistency of fusion procedures.

Because bone structure is commonly lost, fusion frequently requires graft material to fill the osseous voids. The longstanding gold standard has been autogenous bone; however, harvest of autografts requires

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Table 1
Patient demographics for patients included in the study (N = 47)

Demographic	Count
Age (years)*	55.6 ± 15.6
Injury side	
Right	24 (51.06%)
Left	23 (48.94%)
Comorbidities	
Cardiac disease	7 (14.89%)
Hypertension	23 (48.94%)
Diabetes	8 (17.02%)
Seronegative	2 (4.26%)
Smoking	10 (21.28%)

* Mean ± SD.

a second surgical site and is associated with donor site pain and morbidity (7). Additionally, the quantity of autogenous bone available may be inadequate based on the patient's size, age, and prior harvest procedures (8). Because of these limitations, allogenic biologics have been developed to augment fusion in patients with numerous risk factors for nonunions. Currently marketed allogenic bone products have positive safety profiles. With advances in technology, an array of bone grafts has surfaced, ranging from allografts to bone substitutes (9,10). Allografts can be fresh, fresh-frozen, freeze dried, or demineralized. Available forms include demineralized bone matrix (DBM), croutons, gel, paste, powder, putty, and allogenic cancellous mixtures containing viable stem cells (9,10). Cancellous bone croutons are commonly used to fill defects, but during arthrodesis (10), it is difficult to provide constant pressure during fixation. Synthetic materials consist of calcium phosphates and hydroxyapatite. Typically, they are available as ceramics, powders, and cements. Although the clinical results are limited, DBM is suggested to promote osteointegration (9). The allogenic cancellous bone sponge (Osteosponge®, Bacterin International, Belgrade, MT) used in this investigation is a DBM, obtained from cadaveric bone. This material undergoes a strenuous process of donor evaluation, tissue testing, and microbiological screening to ensure its safety. Before *in vivo* placement, it is moistened to create a compressible compound with elastic malleable properties, which allows it to be manipulated easily during arthrodesis application. The Osteosponge® retains native growth factors and bone morphogenic proteins necessary for bone formation. Moreover, the cancellous bone maintains its natural porosity, which makes it an ideal scaffold. Collectively, the osteoconductive and osteoinductive properties of the Osteosponge® promote successful bone healing.

The purpose of the present study was to report the clinical outcomes and incidence of nonunions in patients who underwent fusion, augmented with an Osteosponge®. Given the osteoconductive and osteoinductive properties of the Osteosponge®, we hypothesized that solid, sustained foot and ankle fusion would be achieved without unexpected adverse events related to the graft. We also compared our results with results previously published in the biomedical literature.

Table 2
Joints fused (n = 80 fusions in 47 patients)

Arthrodesis Site	n (%)
Ankle	12 (15.00)
Syndesmosis	3 (3.75)
Subtalar	17 (21.25)
Talononavicular	17 (21.25)
Calcaneocuboid	9 (11.25)
Naviculocuneiform	1 (1.25)
First metatarsocuneiform	13 (16.25)
First metatarsophalangeal	2 (2.50)
Lesser tarsometatarsal	6 (7.50)

Table 3
Postoperative change in VAS and AOFAS scores from preoperative to final follow-up (n = 47 patients, maximal follow-up duration = 12 months)

	Preoperative	6 Months Postoperative	12 Months Postoperative
Pain (VAS)	7.3 ± 2.5	2.7 ± 2.1*	1.1 ± 1.4*†
No. of patients with VAS < 4		35 (74.47%)	46 (97.87%)
Function (AOFAS)	59.3 ± 16.4	86.0 ± 10.4*	92.0 ± 7.5*†
No. of patients with VAS > 75		40 (85.11%)	46 (97.87%)

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society; VAS, visual analog scale.

Means ± standard deviation.

* $p < .05$ compared with preoperative measurements.† $p < .05$ compared with 6-month postoperative measurements.

Patients and Methods

The present study was conducted by reviewing the medical records of patients who had undergone foot or ankle arthrodesis with the cancellous bone sponge from May 2009 to August 2011, at 1 of 2 institutions, by attending surgeons (S.A.B., H.D.S.).

The inclusion criteria were age at least 18 years at the time of surgery; foot or ankle arthrodesis using allogeneic cancellous bone sponge; at least 12 months of documented postoperative follow-up; pain, assessed using the visual analog scale (VAS), greater than 4; and functional status, as reported using the American Orthopaedic Foot and Ankle Society (AOFAS) score. Exclusion criteria included use of another orthobiologic product during the surgery, use of a postoperative bone stimulator, or a history of an active target joint infection in the 6 months before surgery.

The outcome measures for the present study were the presence or absence of solid foot and/or ankle fusion on standard radiographs (S.T.B.); the investigator was not blinded. Fusion was defined as bony trabeculation across the fusion site in all 3 radiographic views. The occurrence of unexpected adverse effects related to the graft (including graft-related reoperation), hospitalization or infection requiring secondary intervention; pain as measured using a VAS with a numeric rating scale (VAS-NRS) (11); and function as measured by serial scores on the AOFAS scale (12). The records were reviewed up to 12 months postoperatively, and radiographs, taken at 3, 6, and 12 months postoperatively, were reviewed to evaluate the progress of the fusion. The pain and function scores at 6 and 12 months postoperatively were also recorded. The study was not masked, and there was no control group. Instead, our results were compared with reported results in the peer-reviewed biomedical literature.

Surgical Technique

Fusions were performed using standard internal and/or external fixation fusion techniques. A combination of screws, nails, and plates were used at the surgeons' discretion. After debridement of the joint surface was performed to healthy bleeding subchondral bone, the joint was flushed with sterile saline, and the Osteosponge® was inserted before placement of fixation. The joint surface was measured before placement of the sponge, and an appropriate amount of sponge was implanted between the freshly debrided opposing subchondral joint surfaces. The amount of cancellous bone sponge used was determined by the geometry of the deficit and reported as the total number of cubic centimeters.

Postoperatively, all patients were placed in a non-weightbearing below knee cast for the first 6 weeks. They were transitioned to a partial weightbearing boot for 2 additional weeks. At 10 weeks postoperative, they were allowed to wear regular shoe gear, provided the postoperative radiographs showed no signs of delayed union or hardware failure.

Statistical Analysis

The 2 health measurement instruments that constituted the patient-related outcome panel for the present study included the VAS-NRS and AOFAS score. They were administered according to the guidelines provided by each of the test developers. The forms were completed by the evaluator at the appropriate follow-up visit. The VAS-NRS was rated using an integer scale of 1 to 10, and the subjects were instructed to mark the box that best reflected their current level of pain.

For the purposes of the present investigation, a successful outcome with regard to pain was defined as a postoperative VAS-NRS score that was at least 2 levels below the preoperative VAS-NRS and was less than 4. A review of the recent fusion literature suggested that the mean preoperative AOFAS scores were 32 and the mean postoperative scores ranged from 67 to 92 (4,13,14). The surgical outcome was defined as successful if the postoperative AOFAS score was 2 times greater than the preoperative score and at least 75 points.

Statistical analyses were performed by the research associate (N.M.P.) to determine the significance of the improvement observed with regard to pain and function. The Friedman test for nonparametric-related data was used to compare the levels of pain and function across the visits (preoperatively, 6 months postoperative, and 12 months

Table 4
Individual nonunion results

Age (y)	Joint	Previous Surgery	Comorbidities	Complication	VAS Score		AOFAS Score	
					Preoperative	12 Months Postoperative	Preoperative	12 Months Postoperative
67	Pantalar	No	Rheumatoid Arthritis	Ankle nonunion	9	3	34	81
45	First TMT	Lisfranc ORIF	None	First TMT nonunion	9	7	48	70

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society; ORIF, open reduction internal fixation; TMT, tarsometatarsal joint; VAS, visual analog scale.

postoperative). When appropriate, post hoc analyses with the Wilcoxon signed rank test were conducted with a Bonferroni correction applied, with statistical significance defined at $p < .017$.

Spearman's rank order correlation was used to determine the relationship between pain and function. Point biserial correlations were used to measure the degree of association between bone union at 3, 6, and 12 months and the preoperative and postoperative pain and function levels.

A stepwise, linear regression analysis was performed to examine the contribution of each independent variable to the dependent variable (interval to union). The independent variables initially entered into the regression model included the preoperative pain and function levels. The independent variables were entered into multiple linear regression analyses to predict the interval to bone union.

A systematic review of the literature was performed to identify suitable articles for comparison. The literature search was conducted using the PubMed database. Additional searches were performed using the Google Scholar™ search engine. Searches were limited to articles written in the English language, human studies, and relevant publications. The results of the search were narrowed to articles relevant to foot and ankle graft augmentation arthrodesis. The articles had to report nonunion rates. Case studies, reviews, letters to the editor, and cadaveric studies were also excluded. Fisher exact tests were used to compare the number of nonunions reported in the present study with historical controls.

Unless otherwise noted, the significance level for all statistical tests was set at the 5% level ($p \leq .05$). Data are reported as the mean \pm standard deviation within the text and as the mean \pm standard error in the figures. A co-author (N.M.P.) performed the statistical analyses.

Results

A total of 47 consecutive patients (80 joints) fit the criteria for inclusion in the present study. Patient demographics are presented in Table 1, and the joints included in the present study are listed in Table 2. Of the 47 patients, 11 (23.40%) had undergone previous surgery involving the joint to be fused, including open reduction internal fixation and previous attempted fusion. The comorbidities were as follows: 8 (17.02%) patients had diabetes, comprising 20 (25.00%) neuropathic joints; 10 (21.28%) had a history of smoking, comprising 18 joints (22.50%); 1 patient (0.02%) had rheumatoid arthritis, which accounted for 4 joints (0.05); 1 patient (0.02%) had psoriatic arthritis, which accounted for 1 joint (0.01%); 22 (46.80%) had hypertension; and 7 (14.89%) had a history of cardiac disease.

Clinical Findings

The VAS-NRS and AOFAS scores are summarized in Table 3. The pain levels improved after surgery (visit main effect, $p < .001$). Compared with preoperative pain levels (7.3 ± 2.5), there were statistically significant

Table 5
Rates of nonunion following ankle arthrodesis reported in the biomedical literature

Study	Joints	Nonunions
Present study	80	2 (2.50%)
Ayoub (15), 2008	17	3 (15.00%)*
Lee (14), 2008	15	1 (6.67%)
Wera and Sontich (4), 2007	17	0
Salem et al (16), 2006	22	0
Muckley et al (17), 2005	110	5 (4.55%)
Kopp et al (18), 2004	41	3 (7.32%)
Pierre et al (19), 2003	20	3 (15.00%)
Van Bergeyk et al (13), 2003	7	2 (28.57%)*
Acosta et al (20), 2000	27	4 (14.81%)*

Fisher's exact test was used to compare the percentage of nonunions reported in the present study with those previously reported in the biomedical literature.

* $p < .05$ compared with present study.

reductions observed postoperatively at 6 (2.7 ± 2.1) and 12 (1.1 ± 1.4 , $p < .001$) months. Furthermore, there was a statistically significant reduction in pain levels from the 6-month assessment to the 12-month assessment ($p < .001$).

Of the 47 patients, 46 (97.87%) reported less than 4 on the VAS-NRS scale at 12 months after arthrodesis. Six patients (12.77%) reported a VAS-NRS score of 3 postoperatively.

There were statistically significant improvements in function levels after surgery (visit main effect, $p < .001$). Compared with the preoperative function levels (59.3 ± 16.4), the postoperative function levels were greater at 6 months (86.0 ± 10.4 , $p < .001$) and 12 months (92.0 ± 7.5 , $p < .001$). Of the 47 subjects, 46 (97.87%) also scored greater than 75 on the AOFAS scale.

According to the radiographic evaluation, 23 patients (49%) had achieved bone union at 3 months postoperative. Bone union was achieved by 40 subjects (85.11%) at 6 months postoperative and by 45 subjects (95.75%) at 12 months postoperative. Two patients (4.26%) developed nonunion: 1 ankle and 1 first tarsometatarsal joint. Their cases are summarized in Table 4. No incidence of bone reaction to the cancellous sponge was recorded, and no other adverse radiographic signs were observed. No major complications requiring surgical intervention were recorded.

Correlation

A statistically significant negative correlation was seen between the pain levels (VAS) and function levels [AOFAS; $r_s (139) = -0.85$, $p < .001$]. No statistically significant correlation was seen between the preoperative pain levels and fusion at 3, 6, or 12 months ($p \geq .31$). No statistically significant correlation was seen between pain at 6 months and union at 6 or 12 months ($p \geq .08$). However, a statistically significant correlation was seen between the AOFAS scores at 12 months and union at 12 months [$r_{pb} (45) = -0.59$, $p < .001$]. No statistically significant correlation was seen between the preoperative function levels and fusion at 3, 6, or 12 months ($p \geq .11$) or between function at 6 months and union at 6 or 12 months ($p \geq .08$). However, a moderately positive correlation was seen between function levels at 12 months and union at 12 months [$r_{pb} (45) = -0.47$, $p = .001$]. As the AOFAS scores increased, the number of unions increased. No statistically significant correlation was seen between union and preoperative pain or preoperative function ($p \geq .86$).

Predictors of Bone Fusion

The independent variables were entered into a multiple linear regression analysis to predict the time until bone union. However, neither preoperative pain level nor preoperative function level contributed significantly to the model. Therefore, no variables were entered into the prediction equation.

Incidence of Nonunion

We performed a literature review to identify previously published studies that investigated foot and ankle graft augmentation arthrodesis nonunion outcomes (Table 5). Although we had significantly fewer nonunions compared with Ayoub (15) ($p = .04$), Van Bergeyk et al (13) ($p = .03$), and Acosta et al ($p = .03$) (20), our incidence was similar to the remaining historical controls ($p \geq .05$) (4,14,16–19).

Table 6
VAS and AOFAS scores for foot and ankle arthrodesis reported in the biomedical literature

Study	Fusion Site	Biologics	Joints	Follow-up (mo)	VAS Score		AOFAS Score	
					Preoperative	Postoperative	Preoperative	Postoperative
Present study	Foot and/or ankle	Allogenic, cancellous sponge	80	12	7.3	1.1	59	92
Van Bergeyk et al (13), 2003	Tibiotalar	Autogenic: iliac or local	7	20	—	7.1	—	67
Wera and Sontich (4), 2007	Tibiotalar	—	17	37	—	—	—	78
Lee (14), 2008	Ankle	Frozen, allograft, platelet-rich plasma, and/or stimulator	15	20	—	—	32	87

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society; VAS, visual analog scale.

Discussion

In the present investigation, arthrodesis of foot and ankle joints using an allogeneic cancellous sponge achieved a union rate of 97.5% (78 joints). Our results were comparable or significantly greater than previously reported fusion rates in the biomedical literature, which have ranged from 0% to 29% (4,13–20) (Table 5). Furthermore, at 12 months postoperative, statistically significant improvements in function and pain alleviation were achieved at rates greater than those previously reported in biomedical studies (4,13,14) (Table 6). Although arthrodesis of the foot and ankle has proved over time to be a useful procedure to decrease pain and increase function, the results observed using the allogeneic cancellous bone sponge that was used in our cohort of patients were comparable or better than those previously described (4,13–20).

Of the 80 joints reviewed, 2 (2.50%) nonunions were encountered. One involved a first tarsometatarsal joint fusion in 1 patient with a previous Lisfranc injury that required open reduction and subsequently developed post-traumatic degenerative joint disease. The second occurred in 1 patient with a history of rheumatoid arthritis who underwent a pantalar (ankle, subtalar, talonavicular, and calcaneocuboid) fusion and developed radiographic nonunion of the ankle. The subtalar, talonavicular, and calcaneocuboid joints all fused uneventfully. However, the patient reported a decrease in pain at 12 months postoperative, with the VAS-NRS score decreasing from 9 to 3. The patient also demonstrated a clinically significant improvement in function, with the AOFAS score increasing from 34 to 81 (preoperative to 12 months postoperative).

No major infections were observed in our patient population, and no revisional surgery was performed during the 12-month follow-up period. It is important to note that although a 100% osseous union rate was not visualized radiographically, a significant decrease in pain and an increase in function were observed. Our patient with an ankle nonunion demonstrated clinically significant improvement in pain and function, with the remaining hindfoot successfully fused and did not require revisional surgery.

Because standard fusion techniques were used, it is reasonable to conclude that the cancellous bone sponge described in this report aided the fusion rate and improved outcomes in patients undergoing foot and ankle arthrodesis. Arthrodesis has been used for more than a century to treat arthritis of the foot and ankle. Significant technical demands exist to achieve proper alignment of the fused segments. A failed foot or tibiotalar fusion is significant, especially in older patients or those with underlying chronic health conditions. We have demonstrated that an allogeneic cancellous bone sponge is as effective as other graft materials, reduces associated complications (including the need for repetitive surgery), and improves pain and functional outcomes, in comparison with the results previously described in the biomedical literature.

Like all retrospective cohort studies, several methodological shortcomings could threaten the validity of our conclusions. For instance, the radiographic outcomes were assessed by one of our investigators, and we did not analyze the association of several

independent variables that experienced surgeons might consider important relative to hindfoot and ankle arthrodesis. Moreover, we did not undertake a sensitivity analysis in order to estimate the influence that unmeasured variables could have had on our results. Despite these limitations, we did have useful preoperative and postoperative VAS pain and AOFAS scores, which allowed us to statistically analyze the effect of arthrodesis on these outcome measures. Perhaps the most important limitation of this investigation was our dependence on historical controls, namely, the results reported in previously published peer reviewed literature. As a rule, such comparisons are subject to biases, both measurable and unmeasurable, which make it difficult to understand the precise nature of the relationship of one outcome to another. Despite these limitations, we believe that the results of this investigation could be used in the development of future prospective cohort studies and randomized controlled trials that focus on the use of allogeneic bone grafts hindfoot and ankle arthrodesis.

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