Biologic Augmentation of Foot and Ankle Arthrodeses With an Allogeneic Cancellous Sponge

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abstract

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This case series was conducted to assess the safety and efficacy of using an allogeneic cancellous bone sponge for augmentation of foot and ankle arthrodeses. Twenty-five patients were prospectively enrolled in the study prior to undergoing fusion and were then followed for 12 months postoperatively. There were 45 joints: 7 ankles, 12 subtalars, 12 talonaviculars, 6 calcaneocuboids, 1 naviculocuneiform, 6 first tarsometatarsals, and 1 second tarsometatarsal. Patient-reported outcomes of pain (visual analog scale) and function (American Orthopaedic Foot and Ankle Society score) were obtained preoperatively and postoperatively at 6 and 12 months. No complications were noted intraoperatively or during the follow-up period. Three months postoperatively, radiographic osseous union was noted in 52% (13/25) of patients, which further increased to 96% (24/25) of patients at 6 and 12 months. There was no statistically significant difference in union time between joints [H(6)=11.5; P=.08]. Statistically significant improvements in pain ($P \leq .002$) and function ($P < .001$) were observed across assessments. This study demonstrated that the cancellous bone sponge appears to be a safe and efficacious product. Randomized controlled trials are warranted to determine if the allogeneic cancellous sponge improves fusion rate, pain, and function.

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Arthrosis of the foot and ankle is a painful condition that considerably limits function. Although prior trauma is the most common cause,[1] arthrosis can also develop as a result of mechanical deficiencies, degenerative disease, rheumatologic disease, or infection. Regardless of etiology, arthrosis is characterized by the progressive degeneration of articular cartilage and, consequently, increased inflammation, synovitis, and osteophyte formation. In turn, patients experience increased pain and restricted joint mobility. Plain radiography and advanced imaging modalities are used for diagnosis and to assess the extent of degenerative change. Initially, conservative treatment modalities are used, but failure to respond often necessitates surgical intervention.

Because arthroplasty is limited outside the hallux, arthrodesis is considered the standard of care within the forefoot, midfoot, and hindfoot. Arthroplasty and fusion are common ankle interventions, and both consistently obtain stability of the talocrural joint while preserving normal gait and eliminating pain.[2-4] Although debatable, ankle arthrodesis remains the surgical gold standard of treatment for end-stage ankle arthritis. This is likely attributable to the unacceptably high complication rates associated with early prosthetic design.[5-10] However, ankle fusion is not without complication.

Although a number of studies have demonstrated that sustained fusion provides satisfactory outcomes,[2-4,11,12] nonunion rates have been as high as 40%.[1] Fusion failure is significant, especially in elderly patients or those with underlying chronic health conditions. Although some patients are asymptomatic, failure is frequently associated with increased or irresolvable pain and impaired function, both of which negatively impact quality of life.[1,13] With high revision rates, nonunion places patients at risk for additional complications, which have significant psychological and economic implications. In addition, the high revision rate has a deleterious effect on the cost of treatment in the health care sector.

Arthrodesis using a "good surgical technique in carefully selected patients can be a reliable procedure for relief of functionally disabling ankle arthritis."[1] However, adaptations must be made to the fusion technique in patients with a high nonunion risk, compromised soft tissues, or peripheral neuropathy.[1] When substantial debridement is required or arthritic changes have led to significant loss of bony architecture, a bone graft can be used to fill the osseous voids. A bone graft is any implanted material that alone or in combination with other materials promotes a bone-healing response.[14,15] Examples include autografts, allografts, and synthetic substitute materials, which can be used alone or with growth factors and/or viable stem cells.[16,17]

Autogenic bone grafting is the transfer of bone from one anatomic site to another within the same person.[14] Autogenous bone grafts are routinely used to augment fusion. There is complete histocompatibility and no risk of disease transmission, and the graft possesses the properties necessary for osteointegration. Osteogenesis is the synthesis of new bone, osteoinduction refers to the signals that promote migration and differentiation of mesenchymal stem cells (MSCs), and osteoconduction describes the scaffold for ingrowth of capillaries, perivascular tissue, and MSCs.[14] Collectively, these characteristics allow for the successful incorporation of graft bone with host bone: osteointegration.

Despite the potential to promote the healing cascade, there are notable weaknesses associated with autografts because they are sourced at local or regional sites. Local grafting limits the procurement area; therefore, volume is limited. This is especially true in the ankle, where grafting is restricted to the distal fibula, distal tibia, or calcaneus, depending on the surgical approach.[18-20] With regional grafting, however, the volume of available allograft increases.

The iliac crest is the traditional regional source because it supplies cancellous and cortical bone. Cancellous bone introduces marrow cells, bone and collagen matrices, and bioactive proteins, whereas cortical bone supplies mechanical strength.[15] Although successful fusion with iliac crest bone grafting has been demonstrated,[21,22] a second surgical site, with often-associated pain and morbidity, is required.[23,24] Because of these limitations, alternative biologics have been used.

Allografts, material from another individual of the same species,[14,24] are advantageous for a number of reasons; donor site morbidity is avoided, operative time is decreased, and the quantity is essentially unlimited. An optimal allograft should mimic the intrinsic properties of an autograft: nonimmunogenic, osteoinductive, osteoconductive, and osteogenic. Ideally, the graft should be available in large quantities, have a practical storage capacity and an indefinite shelf life, be easy to handle intraoperatively, and be cost-effective. With technological advances, new grafting options have emerged. Allografts can be fresh, fresh-frozen, freeze dried, or demineralized.[16,17] They are available in various forms, such as strips, injectables, croutons, gels, pastes, powders, and putties. Given the numerous bone grafting options, it is important to consider and compare the structural, biochemical, and practical properties of each graft.

Fresh allografts are composed of intact hyaline cartilage with living chondrocytes and a thin shell of cancellous bone.[17] Consequently, the osteogenic, osteoinductive, and osteoconductive properties are preserved. However, residual cellular antigens may mediate an immune response or allow for transmission of disease.[25] In addition to the logistic and procurement constraints, fresh allografts are a costly expenditure with a limited shelf life and, therefore, are rarely used.[17-25]

Compared with fresh allografts, fresh-frozen allografts undergo processing that reduces immunogenicity, increases shelf

life, and maintains strength while preserving the osteoconductive and a small percentage of the osteoinductive properties.[17-25] The strenuous processing is responsible for killing all living cells, which removes the osteogenic components.[25] Because preservation of osteoinduction is largely dependent on processing and storage procedures, fresh-frozen grafts must be transported and stored at temperatures according to the American Association of Tissue Banks guidelines.[17] Although fresh-frozen allografts offer inherent benefits, the shelf life is variable (1-10 years) and storage requirements lack convenience.[17]

In foot and ankle surgery, freeze-dried allografts are used most frequently. This is likely attributable to their practical application with low immunogenicity, indefinite shelf life, ability to be stored at room temperature, and cost-effectiveness.[17] Although processing eradicates all living cells and decreases the risk of disease transmission, the graft serves as a scaffold for cellular infiltration and bone formation.[17] Thus, osteoconductive properties are maintained while osteogenic properties are eliminated.[25] Cancellous bone croutons are a freeze-dried allograft form frequently used to fill bony defects and augment deformity correction in foot and ankle surgery.[17] Although ideal for filling deficits, chips are a difficult medium on which to apply constant pressure during application of fixation.

Demineralized bone matrix is extracted using hydrochloric acid.[17] The final product primarily comprises growth factors, collagen, proteoglycans, and bone morphogenic proteins (BMPs).[14,17] Demineralized bone matrix serves as a matrix for cells to populate while the growth factors and BMPs recruit MSCs at and around the site of implantation to differentiate into osteoblasts, all of which are essential in promoting the healing cascade. Although limited, clinical evidence suggests that demineralized bone matrix is capable of facilitating osteointegration.[16]

Synthetic bone grafts are artificial materials used for skeletal reconstruction. They are available as biologic and synthetic polymers, ceramics, such as calcium phosphate, tricalcium phosphate, and calcium sulfate, metals, powders, and cements.[15-17] They undergo extensive processing to ensure a significant immune response is avoided. This graft material is predominantly recognized for its ability to serve as a scaffold. To introduce osteoinductive and osteogenic properties, synthetic materials have been combined with grafts and/or cellular concentrates.[15]

Possibly due to the exorbitant variety of allogeneic and synthetic grafts, one graft has not surfaced as the gold standard. Investigators continue to explore grafts with the capacity to biologically augment healing. The OsteoSponge (Bacterin International, Belgrade, Montana) is an allograft derived from demineralized human cancellous bone and was designed for nonstructural bone grafting. The demineralization process creates a compressive sponge-like compound while retaining native growth factors and BMPs. Notably, the graft is viable for up to 5 years and can be stored at room temperature. Prior to in vivo placement, the demineralized bone matrix is moistened and becomes malleable and elastic, making it easy to manipulate and press-fit into the desired osseous voids. Once implanted, the natural porosity of cancellous bone promotes the acceptance of growth factors, BMPs, prepared platelet-rich plasma, bone marrow aspirate, and other cellular concentrates, thus serving as an ideal delivery vehicle. Presumably, the scaffold and signaling molecules promote the 3-dimensional ingrowth of vascular and cellular components necessary for bone formation.

In a multicenter trial, Brigido et al[11] evaluated the use of the cancellous bone sponge to augment foot and ankle arthrodesis. The authors demonstrated that 12 months following arthrodesis augmentation with the bone sponge, patients had statistically significant improvements in pain and function. Moreover, a 97.5% fusion rate was achieved. Compared with fusion rates previously reported in biomedical studies,[3,19,26-32] the incidence was similar or had improved. Although this investigation confirmed the safety of the cancellous bone sponge, retrospective analyses inherently increase the likelihood of bias. For this reason, the current study prospectively enrolled patients with the intent of evaluating the safety and efficacy of the cancellous bone sponge.

Considering the osteoconductive and osteoinductive properties of the allogeneic cancellous sponge, as well as the low immunogenicity, the authors hypothesized that solid, sustained foot and/or ankle fusion would be achieved without unexpected adverse events related to the graft. The primary goals of this prospective study were to describe a biological supplementation with the cancellous bone sponge that has the potential to augment a wide array of foot and ankle fusions, report any adverse events relating to the graft, and present the preliminary clinical and radiographic findings at the authors' institution. To the authors' knowledge, prospective results have yet to be reported with this technique.

Materials and Methods

Patients were prospectively enrolled. Patients were included if they were at least 18 years of age, had exhausted conservative treatment, and elected to undergo a foot or ankle arthrodesis using the allogeneic cancellous bone sponge. Exclusion criteria included use of a concomitant orthobiologic product, expected use of a bone stimulator, and a history of a target joint infection within 6 months of the date of surgery. Surgeries were performed by the principal investigator (S.A.B.) between January 1, 2006, and August 30, 2011.

Surgical Technique

Fusions were performed using standard AO internal fixation fusion techniques. A combination of screws, nails, and plates

Table 1
Comorbidities

Comorbidity	No. (%)
Cardiac disease	2 (8)
Hypertension	10 (4)
Diabetes mellitus	2 (8)
Seronegative	2 (8)
Smoker	5 (25)

Table 2
Joints Fused

Arthrodesis Site	No. (%)
1st TMT	6 (13.3)
2nd TMT	1 (2.2)
Ankle	7 (15.6)
CC	6 (13.3)
NC	1 (2.2)
STJ	12 (26.7)
TN	12 (26.7)

Abbreviations: 1st TMT: first tarsometatarsal; 2nd TMT: second tarsometatarsal; CC, calcaneocuboid; NC: naviculocuneiform; STJ: subtalar joint; TN: talonavicular.

were used at the surgeon's discretion, based on the arthrodesis site, associated pathology, and comorbidities. Each joint surface was debrided of cartilage down to bleeding subchondral bone, fenestrated, and flushed. The amount of graft sponge needed was determined by the geometry of the deficit. The OsteoSponge was moistened with saline and implanted between the freshly debrided opposing subchondral joint surfaces prior to fixation. No additional cellular concentrates or substitutes were used.

Postoperatively, all patients were placed in a nonweight-bearing posterior splint for the first 2 to 3 weeks and kept nonweight bearing in a cam walker for an additional 3 to 4 weeks. At 6 weeks, they were transitioned to partial weight bearing for 2 additional weeks. Patients were transitioned to wearing supportive shoe gear at 8 weeks, provided postoperative radiographs showed no signs of delayed union or hardware failure.

Endpoints

Fusion was defined as bony trabeculation across the fusion site in all 3 radiographic views. Radiographs were reviewed at 3, 6, and 12 months. Pain was assessed using a visual analog scale (VAS) administered preoperatively and postoperatively at 6 and 12 months. The scale ranges from 0 to 10, with 0 representing no pain and 10 representing excruciating pain. The American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot outcome measure was administered preoperatively and postoperatively at 6 and 12 months. Scores range from 0 to 100, with lower scores representing greater functional impairment.[33]

Statistical Analysis

The Kruskal-Wallis H test for nonparametric related data was used to compare time until fusion between each joint. The Friedman test was used to compare pain and function across time. When appropriate, post-hoc analyses with the Wilcoxon signed rank test were conducted with a Bonferroni correction applied. In these cases, the significance level was set at a P value less than .017.

Correlations were run to determine the strength and direction of the relationship between 2 variables. A Spearman rank order correlation was used to assess the relationship between pain and function. Point biserial correlations were run to assess the relationship between fusion and clinical outcomes (pain and function) and also fusion and hypertension. Of the remaining patient demographics, the sample was not large enough for analysis (n<10).

Unless otherwise noted, the significance level for all statistical tests was set at a P value of .05. Data are reported as mean±SD.

Results

Twenty-five consecutive adults (45 foot and ankle arthrodeses) were prospectively enrolled. Mean age at the time of surgery was 57±15 years. Comorbidities and joints varied across the patient population (**Tables 1-2**, respectively). No complications were encountered intraoperatively.

Fusion

At 3 months, 52% (13/25) of patients showed radiographic fusion, whereas at 6 and 12 month follow-up, 96% (24/25) of patients had radiographic confirmation of osseous fusion. There was no statistically significant difference in time to fusion for the different joints [H(6)=11.5; P=.08]. Forty-four (97.8%) of the 45 joints fused.

Pain

According to the VAS, pain levels improved postoperatively (time main effect, P<.001) (**Figure 1**; **Table 3**). Compared with preoperative VAS pain scores (8.4±1.2), there were statistically significant improvements at 6 months (2.2±1.5; P<.001) and 12 months (1.5±1.6; P<.001) postoperatively. There were also statistically significant improvements from 6 to 12 months (P=.002).

Function

Function levels improved postoperatively (time main effect, P<.001) (**Figure 2**; **Table 3**). Compared with preoperative AOFAS scores (48.1±9.1), there were statistically significant improvements at 6 months (83.6±7.3; P<.001) and 12 months (86.9±5.7; P<.001) postoperatively. There were also statistically significant improvements from 6 to 12 months (P<.001).

Correlations

There was a strong negative correlation between pain levels (VAS) and function levels (AOFAS), which was statistically significant [$r_s(73)$=-0.89; P<.001]. Correlations between fusion and clinical outcomes (pain and function) are pre-

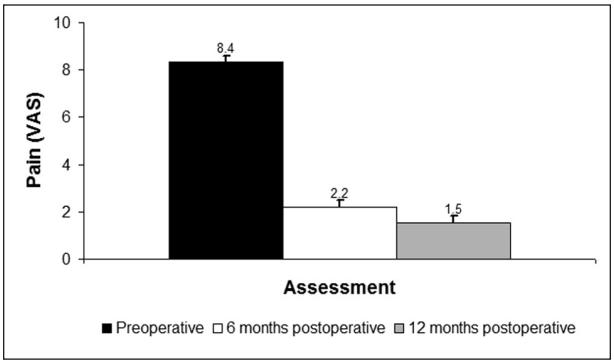

Figure 1: Graph showing visual analog scale (VAS) pain scores. Data are presented as mean±standard error.

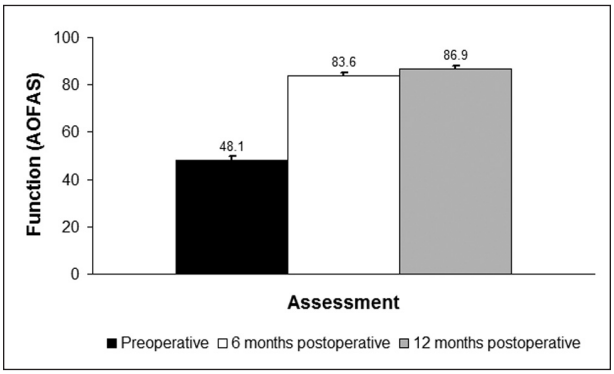

Figure 2: Graph showing American Orthopaedic Foot and Ankle Society (AOFAS) scale functional scores. Data are presented as mean±standard error.

Table 3

Pain and Function Over Time

Time	VAS Pain Score	AOFAS Function Score
Preop	8.4±1.2	48.1±9.1
6 mo postop	2.2±1.5[a]	83.6±7.3[a]
12 mo postop	1.5±1.6[a,b]	86.9±5.7[a,b]

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society; postop, postoperatively; preop, preoperatively; VAS, visual analog scale.
[a]P<.05 *compared with preoperative value.*
[b]P<.05 *compared with 6 mo postoperative value.*

Table 4

Correlations Between Fusion and Clinical Outcomes[a]

	Pain			Function		
Fusion	Preop	6 mo Postop	12 mo Postop	Preop	6 mo Postop	12 mo Postop
3 mo	-0.19	-0.35	-0.46[b]	0.26	0.28	0.25
6 mo	-0.12	-0.66[b]	-0.73[b]	0.00	0.45[b]	0.62[b]
12 mo	-0.12	-0.66[b]	-0.73[b]	0.00	0.45[b]	0.62[b]

Abbreviations: postop, postoperatively; preop, preoperatively.
[a]*Data presented as correlation coefficients.*
[b]P≤.05.

sented in **Table 4**. Unrelated to the study goals, there was a strong positive correlation between time to fusion and hypertension [$r_{pb}(23)=0.54$; $P=.006$].

Discussion

Arthrodesis has been used for more than a century to treat arthrosis of the foot and ankle. There are significant technical demands required to achieve successful healing. An arthrodesis necessitates adequate joint preparation, correct segment alignment, sufficient compression across the opposing joint surfaces, and rigid fixation.[34] The purpose of this study was to assess the safety and efficacy of a novel surgical technique that appears capable of providing consistent osseous fusion. The technique used the OsteoSponge to provide additional biologic augmentation to promote a healing response at the arthrodesis site. The preliminary findings are reported for 45 fusions (25 patients).

Arthrodesis of the foot and ankle has proven over time to be a reliable procedure that decreases pain and increases function.[2-4,11,12] In the current study, a 97.8% fusion rate was achieved. This fusion rate was comparable with those reported in the biomedical literature, which currently range from 71% to 100%.[3,11,26,27] The current study demonstrated significant improvements in pain and function without adverse events after fusion. These statistically significant improvements translate to a larger number of pain-free, high-functioning patients after a foot or ankle arthrodesis.

One case of nonunion occurred in a 45-year-old man who underwent first tarsometatarsal fusion for posttraumatic degenerative joint disease after sustaining a Lisfranc injury that had previously undergone open reduction and internal fixation. He underwent revision surgery consisting of 1st and 2nd tarsometatarsal fusion outside the 12 month follow-up period due to clinical and radiographic concerns of pain and motion at the base of the 2nd metatarsal. Although a 100% osseous union was not visualized radiographically prior to revision, the patient reported a decrease in pain and an increase in function (**Table 5**).

Correlations were run between fusion and clinical outcomes (pain and function). Multiple negative correlations were reported between fusion and pain. Because an increase in VAS indicates an increase in pain, the negative correlations indicate that as fusions increase, pain decreases. In reference to AOFAS scores, there were multiple positive correlations between fusion and function. Because an increase in AOFAS score represents an improvement

Table 5

Individual Nonunion Results

Variable	Value
Age, y	45
Attempted fusion site	1st TMT
Prior surgery	Lisfranc ORIF
Comorbidities	None
Complication	1st TMT nonunion
VAS pain score	
Preop	9
12 mo postop	7
AOFAS function score	
Preop	48
12 mo postop	70

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society; ORIF, open reduction and internal fixation; postop, postoperative; preop, preoperative; 1st TMT, first tarsometatarsal; VAS, visual analog scale.

in function, the positive correlations indicate that as fusions increase, function improves. These associates adhere to the authors' expectation that fusion is correlated with improvements in pain and function.

In the current subset of patients, there was a strong positive correlation between time to fusion and hypertension, which indicates that patients with hypertension experienced a longer time to fusion. This information is valuable for surgeons. It provides them with insight that patients with hypertension may take a longer time to achieve osseous fusion.

Conclusion

This article presented a novel surgical approach to biologically augment foot and ankle fusions. The study's findings indicate that the allogeneic cancellous bone sponge is a safe and efficacious product. With the use of the bone sponge, the authors believe their outcomes have been more consistent and predictable; therefore, they advocate the use of the cancellous bone sponge when performing foot and ankle fusions. Prospective controlled trials are needed to conclude whether the bone sponge improves the rate of fusion as well as patient-reported pain and function.

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