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# Clinical and Radiographic Outcomes After Hindfoot and Ankle Arthrodesis Using Cellular Bone Allograft Augmentation: A Short Report

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**Abstract**

**Background:** Nonunion after ankle or hindfoot arthrodesis is associated with poor outcomes. Cellular bone allograft is an alternative to autograft for use in these procedures. The purpose of this study was to prospectively evaluate the early efficacy and safety of cellular bone allograft use in hindfoot and ankle arthrodesis procedures.

**Methods:** Fourteen patients undergoing hindfoot or ankle arthrodesis supplemented with cellular bone allograft were prospectively enrolled. Computed tomography (CT) scans were obtained postoperatively at set time points and reviewed by 3 fellowship-trained foot and ankle surgeons as well as 1 musculoskeletal radiologist. Primary outcome was CT-verified union, defined as >25% of joint surface. Complications were recorded and revision procedures offered as indicated.

**Results:** CT-verified union rate during the study period was 76.7% (23 of 30 joints). Union was 100% for the ankle joint (2 of 2), 50% for the talonavicular joint (5 of 10), 100% for the calcaneocuboid joint (8 of 8), and 80.0% for the subtalar joint (8 of 10). One patient underwent revision fusion procedure, and 1 patient underwent hardware removal during the study period.

**Conclusion:** Our initial experience suggests that use of cellular bone allograft augmentation in hindfoot and ankle arthrodesis may offer an alternative to autograft without potential of donor site morbidity.

**Level of Evidence:** Level IV, case series.

**Keywords:** ankle arthrodesis, hindfoot arthrodesis, allograft, nonunion

## Introduction

A recent systematic review of 1300 patients undergoing ankle, hindfoot, or midfoot arthrodesis found an overall fusion rate of 78.7% across populations confirmed by computed tomography (CT).[5] Nonunion after foot and ankle arthrodesis procedures is associated with poorer clinical outcomes,[4] revision surgery, and increased health care costs.[1]

Autologous bone graft is considered to be the gold standard for use in fusion procedures, as it is readily available, provides all 3 biologic characteristics necessary for bone healing, and eliminates disease transmission risks.[7] Drawbacks to autograft include donor site morbidity and prolonged surgical duration. Cellular bone allografts (CBAs) are composed of lineage-committed bone cells within a corticocancellous and demineralized bone carrier. These can provide an alternative to autograft as they offer

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osteogenic, osteoconductive, and osteoinductive qualities without donor site morbidity associated with autograft.[6]

Although mesenchymal stem cells (MSCs) are used as the osteogenic component in many commercially available CBA products, ViviGen (LifeNet Health, Virginia Beach, VA) features viable lineage-committed cells and has demonstrated in vitro and in vivo it can provide all 3 components of bone healing.[2] The purpose of this study was to prospectively evaluate the clinical efficacy and safety of this specific CBA product in elective ankle and hindfoot arthrodesis.

## Materials and Methods

Approval for the study was obtained from the Institutional Review Board (IRB). Patients undergoing primary elective ankle or hindfoot arthrodesis were prospectively enrolled between March 2019 and December 2021. Fifteen patients were prospectively enrolled. Exclusion criteria included prior arthrodesis, history of infection at arthrodesis site, inability to maintain nonweightbearing status postoperatively, poorly controlled diabetes ($HbA_{1c}$ >7.5), bone defects requiring more than 10 mL of bone graft material, vitamin D deficiency, or inadequate bone stock. Participation was discussed with sequential patients undergoing elective fusion procedures only, excluding these demographics and consent obtained from interested patients.

All procedures were performed by one of 3 fellowship-trained foot and ankle surgeons at a single institution. Each joint involved was supplemented with ViviGen bone graft alone; volume of graft was selected by operative surgeon to provide adequate fill of existing defects. Fluoroscopic images were reviewed by the other 2 surgeons in each case. Cases were excluded if there was consensus agreement on inadequate reduction or fixation. One patient was excluded based on consensus agreement that there was inadequate talonavicular joint reduction, leaving 14 patients for final analysis. Fixation was achieved using a combination of compression screws, plate and screws, and compression staples. Hardware selection and postoperative protocols were not standardized and were at the surgeon's discretion.

Patients were evaluated preoperatively and postoperatively at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year. Radiographs were obtained at all postoperative visits (Figure 1). CT scans were obtained at 3 months and 6 months postoperatively. An additional CT scan was obtained at 1 year postoperatively if fusion across all involved joints was not noted on prior scans.

CT scans were reviewed independently by the 3 surgeons as well as a musculoskeletal radiologist who were anonymized to the patient and treating surgeon. Each joint involved was evaluated for fusion threshold. Assessment of fusion was subjective based on judgment of the reviewer.

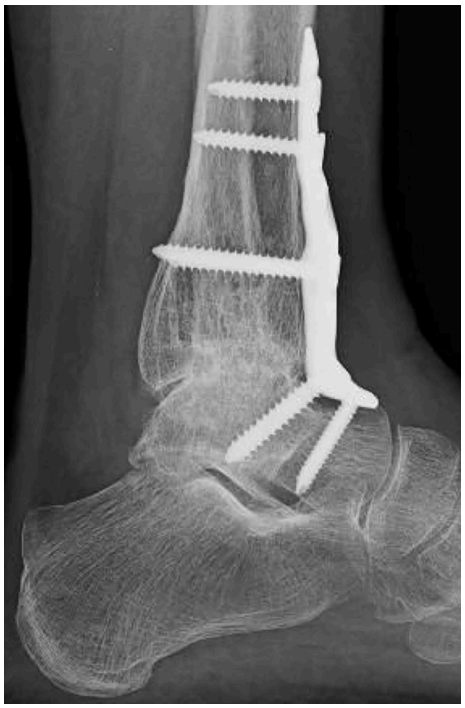

**Figure 1.** Lateral radiograph of patient 10.d 6 months status post ankle arthrodesis demonstrating solid osseous fusion.

Union was defined as greater than 25% fusion. Union determination was made by majority decision. Tiebreaker was based on clinical evaluation of pain, hardware breakage, or gross motion at arthrodesis site during revision surgery constituting evidence of nonunion. The primary outcome was CT-verified union rate using 25% fusion threshold. Complications were recorded. Revision procedures were performed as indicated for continued disability from failed or incomplete arthrodesis.

## Results

### *Demographics*

Demographic analysis revealed an average age of 62.6 ± 7.8 years with average body mass index 28.3 ± 5.6. Twelve patients were female and 2 were male. Surgical procedures included 8 triple fusions, 2 isolated subtalar fusions, 2 isolated talonavicular fusions, and 2 isolated ankle fusions (30 total joints involved in arthrodesis procedures).

### *Union Rates*

CT-verified union rates (Table 1) were as follows: 76.7% (23 of 30) overall, 80.0% (8 of 10) for the subtalar joint, 50% (5 of 10) for the talonavicular joint, 100% (8 of 8)

**Table 1.** CT-Verified Union Rates Overall as well as Individual Joints Fused.

| | % (n/n) |
|---|---|
| Overall | 76.7 (23/30) |
| Subtalar joint | 80.0 (8/10) |
| Talonavicular joint | 50 (5/10) |
| Calcaneocuboid joint | 100 (8/8) |
| Ankle joint | 100 (2/2) |

for the calcaneocuboid joint, and 100% (2 of 2) for the ankle joint.

### *Complications*

One patient underwent revision fusion procedure for nonunion of CC and TN joints after triple arthrodesis with progression of flatfoot deformity postoperatively.

One patient underwent hardware removal at the talonavicular joint after isolated arthrodesis. He had CT-confirmed nonunion based in addition to mild persistent pain and prominent broken hardware. He was offered a revision fusion procedure; however, he elected to proceed with hardware removal alone, which did improve his pain.

One patient with nonunion and broken hardware after isolated talonavicular joint fusion did well with improvement in pain and did not require further surgery.

## Discussion

This is the first study evaluating clinical efficacy and safety of ViviGen in hindfoot and ankle fusion procedures prospectively. Previous studies have demonstrated successful outcomes with use of this CBA in case series[9] and retrospective review.[8] The union rate during the study period was 76.7%, using CT scans, across all joints fused. This is comparable to the CT-verified union rate of ankle and foot fusions in a recent systematic review of 1300 patients where the overall fusion rate was 78.7%.[5] Twenty-six of 30 joints (86.7%) in this study were clinically healed, meaning that there was improvement in pain, there was no hardware breakage, and there was no revision surgery required.

In addition to the success comparable to that in previously reported literature, we demonstrated appropriate safety profile. Complications were limited to hardware failure and nonunion as discussed. There were no complications attributable to the use of cellular bone allograft. No patients required surgery for postoperative wound complications or infections.

Of note, we did use a fusion threshold of 25% in CT assessment of fusion. A recent systematic review showed that although most studies evaluating CT-based fusion rates use a fusion threshold of 50%, good clinical outcomes have been correlated with a fusion threshold of 30%.[10] Glazebrook demonstrated in 275 isolated joint fusions that CT-determined fusion of at least 25% correlated with clinically important improvement in patient-reported outcome measures, whereas fusion of less than 25% did not.[3] We elected to use a 25% fusion threshold based on these data; however, a consideration in future studies with larger patient numbers could be to use different thresholds to evaluate fusion and correlate with outcome scores.

This study is not without limitations. Although the patients were prospectively followed, there was no control group and the sample size was small. There was heterogeneity between the patients regarding the surgical procedure performed. There was potential for bias as 3 of the reviewers were treating surgeons who, although anonymized to patient and surgeon during CT review, may have recognized CT scans. We included a radiologist as an unbiased reviewer as an attempt to mitigate this. CT review was also not standardized and was based on subjective assessment of fusion threshold.

## Conclusion

In conclusion, cellular bone allograft may offer a viable alternative to autograft in primary ankle and hindfoot arthrodesis without donor site morbidity.

### Ethical Approval

Ethical Approval for this study was obtained from the University of Virginia Health System Institutional Review Board (No. 21528).

### Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Joseph S. Park, MD, reports that the study was funded by Depuy Synthes and that Dr Park serves as a consultant for Depuy Synthes. Disclosure forms for all authors are available online.

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