

OSTEOAMP Case Report

ANKLE NONUNIONS

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Ankle and Subtalar Arthrodesis



Patient

Presented with right ankle pain after failed open reduction and internal fixation



Procedure

Ankle and subtalar arthrodesis



Outcome

Post-operative x-ray at 3-months confirms fusion

OSTEOAMP IS A UNIQUELY PROCESSED ALLOGRAFT THAT MAINTAINS AND PRESERVES HIGH LEVELS OF A WIDE ARRAY OF NATURAL GROWTH FACTORS FOUND IN BONE AND BONE MARROW.¹⁻³

Patient

A 61-year-old female presented to the clinic with right ankle pain. The patient was diabetic, obese and suffered from obsessive compulsive disorder and anxiety. The patient had an ankle fracture in 2000 with subsequent ankle open reduction and internal fixation that resulted in post-traumatic degenerative joint disease at the ankle. An ankle fusion was attempted, followed by treatment with a bone stimulator the following year. The patient underwent a hardware removal in 2007; however, this was incomplete and broken hardware was left in place. This resulted in nonunion with broken hardware and the patient was fitted with multiple custom ankle braces. She presented to the clinic in chronic pain, on narcotic pain management, with malposition and a custom brace. Pre-operative x-rays showed broken hardware, nonunion (**Figure 1**) and malposition (**Figure 2**). A CT scan confirmed complete nonunion (**Figures 3 and 4**). The patient decided to proceed with surgical intervention.

Procedure

The objective of the surgery was to fuse the ankle joint with planar cuts to correct anterior subluxation. The subtalar joint was incorporated to provide blood flow and adequate bone stock for fusion, particularly with the screw removal. An intramedullary compression nail was used. The procedure was augmented at the ankle and subtalar joints with OSTEOAMP granules rehydrated with bone marrow aspirate and local fibular autograft. Ten cc of OSTEOAMP was used and mixed with approximately 5 cc of the morselized medial aspect of the fibula. The broken screw was removed without complication through the subtalar joint. Excellent positioning and initial compression were achieved, with all voids filled with OSTEOAMP granules and local bone graft. No complications of surgery were reported. Immediate post-operative x-rays showed good placement of bone graft and position with intact hardware (**Figure 5 and 6**).

Outcome

The patient had an excellent clinical outcome. Clinical healing proceeded and the patient started weight-bearing at 2-months post-operation firstly in a cast and then a removable boot after two weeks. At 3-months post-operation, x-rays showed excellent consolidation (**Figure 7**). The patient was transitioned into a brace followed by custom orthotics. At 8-months post-operation, there was complete resolution of all clinical symptoms, and the patient was very satisfied.

Pre-operative



Figure 1: Pre-operative right lateral ankle x-ray showing nonunion at the ankle joint (arrow), broken hardware, bone loss, and malposition.



Figure 2: Pre-operative anteroposterior right ankle x-ray showing nonunion at the ankle, broken hardware, bone loss, and malposition.



Figure 3: Pre-operative sagittal right ankle CT scan confirming complete nonunion of the ankle joint.



Figure 4: Pre-operative coronal right ankle CT scan confirming complete nonunion of the ankle joint.

Immediate post-operative

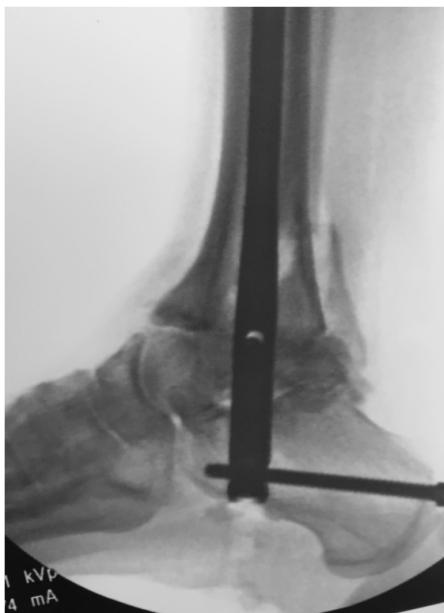


Figure 5: Immediate post-operative right lateral ankle x-ray shows excellent position and hardware placement.



Figure 6: Immediate post-operative right anteroposterior ankle x-ray shows excellent position and hardware placement.

3-month post-operative



Figure 7: 3-month post-operative right lateral ankle x-ray showing bone fusion at the subtalar and ankle joints.

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Ankle and Subtalar Arthrodesis

**Patient**

Presented with ankle pain after failed ankle arthrodesis and fibulectomy

**Procedure**

Subtalar and ankle arthrodesis

**Outcome**

6-month post-operative CT scan confirms fusion

Patient

A 71-year-old female presented to the clinic with ankle pain. The patient had asthma, gastroesophageal reflux disease, was obese and suffered from depression and anxiety. The patient presented two years after an attempted ankle arthrodesis with fibulectomy for primary degenerative joint disease. This led to nonunion and a revision with plating and inter-positional allograft was attempted. This again led to nonunion with a large tibial bony defect, broken hardware, and severe malalignment (**Figures 1, 2, 3 and 4**). The patient did not tolerate custom braces and had been in a weight-bearing CAM boot for the 12 months prior to presentation. She had been using a bone stimulator and taking narcotic pain medication. The patient decided to proceed with surgical intervention.

Procedure

The large tibial bony defect (**Figure 4**) necessitated incorporation of the subtalar joint. Subtalar and tibiotalocalcaneal arthrodesis with bulk femoral head allograft was performed. An acetabular reamer was used to prepare the ankle and open up the femoral head. A lateral plate was used to secure the graft and preserve the endosteal blood supply. Ten cc of OSTEOAMP granules rehydrated with 11 cc of bone marrow aspirate taken from the calcaneal tuberosity, including a bulk femoral head allograft cut to size, were used to augment both the ankle and subtalar joints. No complications of surgery were reported. Immediate post-operative x-rays showed good placement of bone graft and position with intact hardware (**Figures 5 and 6**).

Outcome

Excellent clinical healing proceeded. Due to the bony loss and large volume allograft, the patient could not weight-bear in a protective boot until 3-months post-operation. At this time, the patient had no clinical complications and x-rays showed good bony incorporation and no hardware complications (**Figure 7 and 8**). The patient progressed to wearing an ankle brace and then to using custom orthotics by 6-months post-operation. A 6-month post-operative CT scan confirmed bony consolidation at the subtalar joint, the talar-graft interface, and the tibial-graft interface (**Figures 9 and 10**). The patient was very satisfied with no physical restrictions at 7-months post-operation.

Pre-operative



Figure 1: Pre-operative right anteroposterior ankle x-ray showing nonunion at the ankle, broken hardware, bone loss, and malposition.



Figure 2: Pre-operative right lateral ankle x-ray showing nonunion at the ankle (arrow), broken hardware, bone loss, and malposition.



Figure 3: Pre-operative right coronal CT scan shows lack of incorporation of the allograft, and complete nonunion (arrow).



Figure 4: Pre-operative right sagittal CT scan shows lack of incorporation of the allograft, and complete nonunion (arrow).

Immediate post-operative

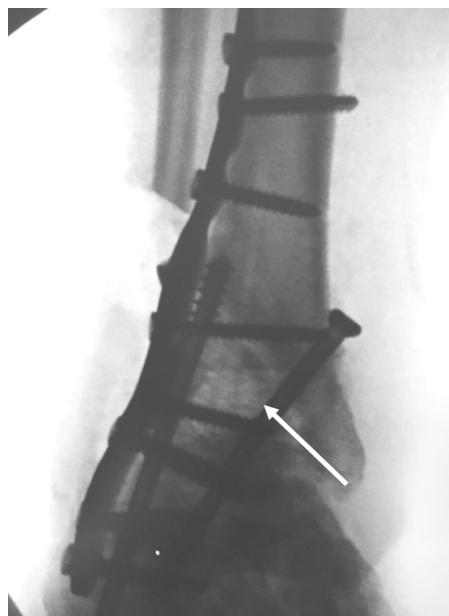


Figure 5: Immediate post-operative right anteroposterior x-ray shows excellent position, void filling (arrow), and hardware placement.



Figure 6: Immediate post-operative right lateral x-ray shows excellent position, void filling (arrow), and hardware placement.

3-month post-operative



Figure 7: 3-month post-operative right anteroposterior x-ray shows bony consolidation at subtalar and ankle. The arrows indicate bone fusion.

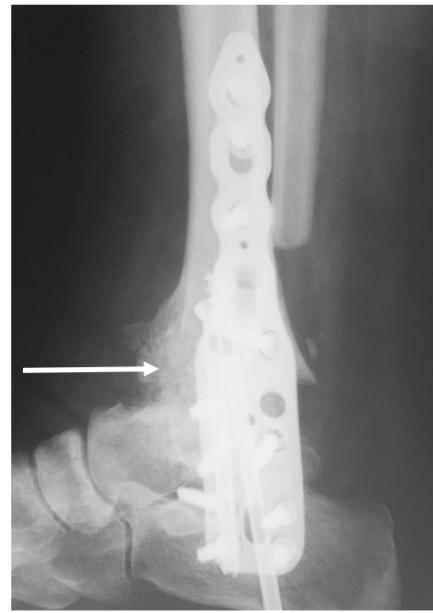


Figure 8: 3-month post-operative right lateral x-ray shows bony consolidation at subtalar and ankle. The arrow indicates bone fusion.

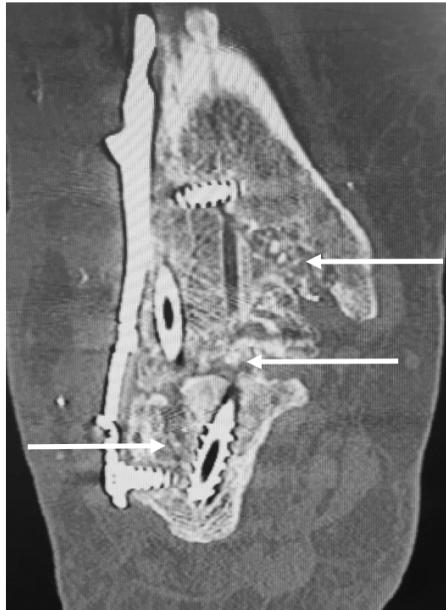
6-month post-operative

Figure 9: 6-month post-operative coronal CT scan confirms bony union. The arrows indicate bone fusion.



Figure 10: 6-month post-operative sagittal CT scan confirms bony union. The arrows indicate bone fusion.

About OSTEOAMP

OSTEOAMP, an allogeneic bone graft, was developed to provide an alternative to autograft harvested from the iliac crest - the “gold standard” bone graft. However, autograft harvesting is associated with donor site morbidity and is limited in its use by tissue availability.⁴ Furthermore, harvesting from the iliac crest increases the overall operating time. Therefore, using an alternative allogeneic bone graft for bone fusion may be preferable.

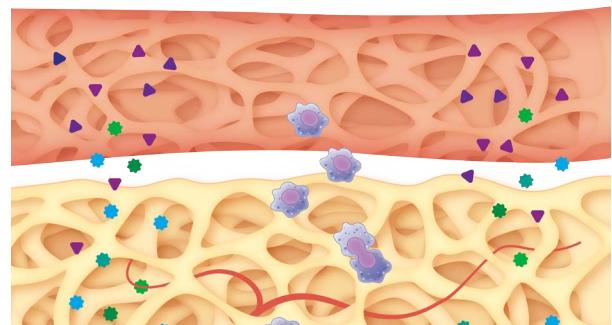
OSTEOAMP is unique as the method of processing the bone graft allows for retention of high levels of naturally occurring growth factors.¹⁻³ Unlike traditional allografts that are typically processed by washing away the bone marrow, and with that the milieu of growth factors that support bone healing, the OSTEOAMP process uses the bone, including bone marrow, from a single donor. OSTEOAMP contains bone morphogenetic proteins (BMP-2 and BMP-7), transforming growth factor β 1 (TGF- β 1) and acidic fibroblast growth factor (aFGF), amongst others.² These critical growth factors are known to influence bone formation: BMPs are involved in the regulation of bone formation and induce the differentiation of mesenchymal stem cells into osteoblasts; TGF- β 1 enhances proliferation of mesenchymal stem cells and induces the production of extracellular proteins such as collagen, proteoglycans, osteopontin, osteonectin, and alkaline phosphatase; and aFGF helps to increase cell proliferation and enhances cartilage formation.⁵ OSTEOAMP is available in three different formats: granules, putty, and compressible sponges, thus enabling augmented bone grafting at various locations.

Several clinical studies with large numbers of patients have reported that OSTEOAMP is a safe and clinically effective bone graft substitute for spine fusion.⁶⁻⁸ Yeung et al. (2014), a retrospective study, reported a total of 488 different OSTEOAMP allografts from 114 donors that were used in 119 cervical and 166 lumbar procedures without complications.⁶ Donor age, gender or tissue intervariability were not clinically relevant to time to fusion. Cervical fusion rates were reported as 83.2% at 6 months, 98.3% at 12 months and 100% at 18 months. Lumbar fusion rates were reported as 68.1% at 6 months, 98.2% at 12 months and 99.4% at 18 months. Another study with 321 patients undergoing lumbar interbody fusion reported that OSTEOAMP led to solid bone fusion in a shorter period of time (~40% less time) with fewer complications and a lower cost per level than rhBMP-2.⁸ Thus, the clinical evidence supports the use of OSTEOAMP, both clinically and economically.

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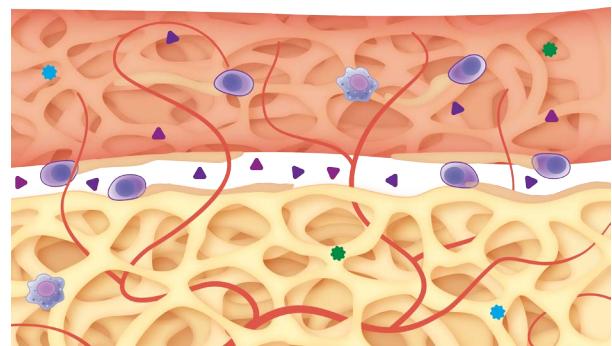
References

1. Data on file. RPT-000327 Report on Growth Factor Concentrations in Bone and Bone Marrow Aspirate, December 3, 2010, Advanced Biologics, LLC. Data from a single lot of OSTEOAMP sponge product.
2. High levels relative to those reported in published literature for other allografts.
3. Bae H, Zhao L, Zhu D, Kanim L, Wang J, Delamarter R. Variability Across Ten Production Lots of a Single Demineralized Bone Matrix Product. *JBJS*. 2010;92:427-435.
4. Park JJ, Hershman SH, Kim YH. Updates in the Use of Bone Grafts in the Lumbar Spine. *Bulletin of the Hospital for Joint Diseases*. 2013;71(1):39-48.
5. Dimitriou R, Tsiridis E, Giannoudis PV. Current Concepts of Molecular Aspects of Bone Healing. *Injury, Int. J. Care Injured*. 2005; 36:1392–1404.
6. Yeung C, Field J, Roh J. Clinical Validation of Allogeneic Morphogenetic Protein: Donor Intervariability, Terminal Irradiation and Age of Product is not Clinically Relevant. *J Spine*. 2014;3:173.
7. Field J, Yeung C, Roh J. Clinical Evaluation of Allogeneic Growth Factor in Cervical Spine Fusion. *J Spine* 2014;3:158.
8. Roh JS, Yeung CA, Field JS, McClellan RT. Allogeneic morphogenetic protein vs. recombinant human bone morphogenetic protein-2 in lumbar interbody fusion procedures: a radiographic and economic analysis. *J Orthop Surg Res*. 2013;8:49.
9. Data on file. TR-1005 Report on Growth Factor Concentrations in Sponges, Granules and Putty, July 5, 2011, Advanced Biologics, LLC.



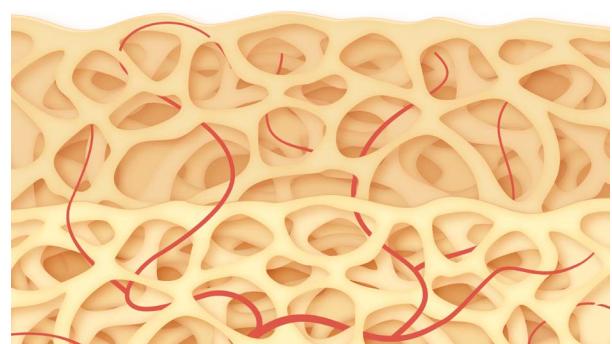
Step 1

OSTEOAMP, an osteoconductive, osteoinductive, and angiogenic bone graft substitute, is placed at the fusion site.⁹ Cells are attracted to the site of injury in response to cytokines and endogenous growth factors in the bone healing environment.



Step 2

The endogenous osteoinductive and angiogenic growth factors in OSTEOAMP contribute to the bone healing process. Osteoinductive growth factors, such as BMPs, are known to promote cellular recruitment, proliferation and differentiation of bone cells, which promotes bone formation.⁵ Angiogenic growth factors initiate development of new vessels. Osteoblasts lay down new osteoid matrix.



Step 3

OSTEOAMP is incorporated into the site of bone healing. Mineralization of the osteoid matrix occurs, creating solid fusion. This is followed by bone re-modelling where OSTEOAMP is replaced by host bone.

