OSTEOAMP Case Report

SUBTALAR NONUNIONS

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Subtalar Arthrodesis

Patient
Presented with a failed subtalar arthrodesis with nonunion and loose, prominent hardware

Procedure
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 44-year-old male presented to the clinic 3 years after a displaced intra-articular calcaneal fracture. The patient was tobacco dependent, suffered from depression and had a history of blood clots. After extensive conservative care, the patient underwent subtalar arthrodesis. Failure of subtalar arthrodesis led to nonunion with loose, prominent hardware. The patient underwent a revision with re-instrumentation 2 months later. The second operation also failed, leading to nonunion with prominent hardware **(Figure 1)**. A CT scan at this point confirmed complete nonunion **(Figures 2 and 3)**, and the patient decided to proceed to a third operation with OSTEOAMP augmentation.

Procedure

The objective of the surgery was to remove the hardware and perform revision subtalar arthrodesis. The procedure was augmented with 5 cc of distal tibial autograft and 5 cc of OSTEOAMP granules, and rehydrated with 6 cc of bone marrow aspirate from the calcaneus. Two large screws and a lateral plate were used for fixation. No complications of surgery were reported. Immediate post-operative films showed good placement of graft and position with intact hardware **(Figure 4)**.

Outcome

The patient was able to weight-bear in a boot at 2-months post-operation, indicating a good recovery despite his continued smoking. The patient then progressed to a brace and shoe. X-rays at 3-months post-operation showed excellent bony consolidation at the subtalar joint **(Figure 5)**. The patient's clinical follow-up was complicated by an infection, which required surgical incision and drainage. There is no evidence the infection was associated with OSTEOAMP.

Pre-operative

Figure 1: Pre-operative right lateral ankle x-rays shows nonunion at the subtalar joint (arrow) and loss of hardware position.

Figure 2: Pre-operative right sagittal CT scan of the ankle shows complete nonunion (arrows).

Figure 3: Pre-operative right sagittal CT scan of the ankle shows complete nonunion (arrow) and loss of hardware position.

Immediate post-operative

Figure 4: Immediate post-operative right lateral ankle x-ray shows excellent position and hardware placement.

3-month post-operative

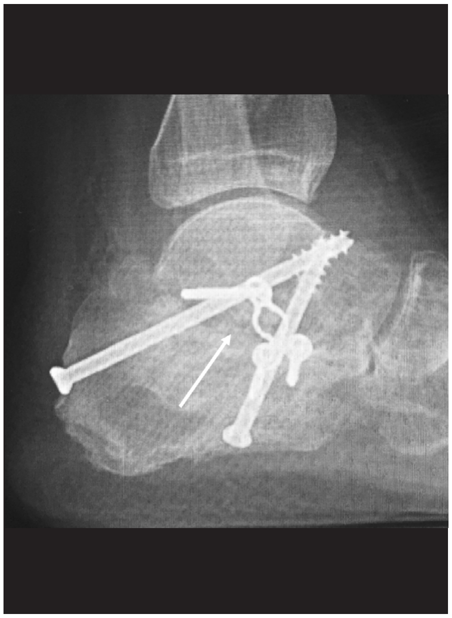

Figure 5: 3-month post-operative right lateral ankle x-ray confirms bone fusion at the subtalar joint (arrow).

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Subtalar Arthrodesis and Ankle Osteotomy

Patient

Presented with ankle pain after pantalar arthrodesis with intramedullary nail

Procedure

Subtalar revision arthrodesis and ankle re-positional arthrodesis with osteotomy

Outcome

8-month post-operative x-ray confirms fusion

Patient

A 62-year-old male presented to the clinic with pain in the ankle for the last 8 years. The patient had asthma, gastro-esophageal reflux disease, and hypercholesterolemia. The patient had originally had a tibial fracture as a teenager which was treated non-operatively with a cast. He developed arthritis in the ankle which led to pantalar arthrodesis with an intramedullary nail 8 years prior. On examination, he had pain and an obvious varus deformity **(Figures 1a and 1b)**. Pre-operative x-rays show ankle and talonavicular fusion with an intramedullary nail **(Figures 2 and 3)**. A pre-operative CT scan confirmed subtalar nonunion **(Figures 4 and 5)**. As conservative measures had failed, surgical revision was indicated.

Procedure

The plan for surgery was to remove the existing hardware and perform subtalar nonunion revision arthrodesis and ankle re-positional arthrodesis with osteotomy. The procedures were augmented with 10 cc of OSTEOAMP granules rehydrated with 11 cc of bone marrow aspirate taken from the distal tibia. Approximately 5 cc of morselized fibula was also added. A lateral plate was used because of the previous nail, and the void left by the nail was filled with OSTEOAMP. Correction was obtained, and no complications of surgery were reported. Initial post-operative films showed excellent correction of the deformity and hardware placement **(Figures 6 and 7)**.

Outcome

Clinical deformity correction was obtained with a rectus foot **(Figures 8a and 8b)**. The patient was weight-bearing in a boot as tolerated at 2-months post-operation. X-rays at 8-months post-operation demonstrate robust bony healing and consolidation, confirming bone fusion **(Figures 9 and 10)**. The patient had full resolution of his symptoms and was satisfied with the outcome.

Pre-operative

Figures 1a and 1b: Pre-operative photograph showing varus deformity of the right leg with a rigid hindfoot and ankle, resulting in lack of weight bearing to the medial foot.

Figure 2: Pre-operative anteroposterior right ankle x-ray shows varus deformity, and intramedullary nail fixation.

Figure 3: Pre-operative lateral right ankle x-ray shows nonunion at the subtalar joint (arrow) and intramedullary nail fixation.

Figure 4: Pre-operative right coronal ankle CT scan shows complete nonunion of subtalar joint (arrow).

Figure 5: Pre-operative right sagittal ankle CT scan shows complete nonunion of subtalar joint.

Immediate post-operative

Figure 6: Immediate post-operative right lateral ankle x-ray shows fibulectomy and excellent positioning and hardware placement.

Figure 7: Immediate post-operative right anteroposterior ankle x-ray shows fibulectomy and excellent positioning and hardware placement.

15-day post-operative

Figure 8a and 8b: Post-operative photographs showing realignment of the ankle and hindfoot.

8-month post-operative

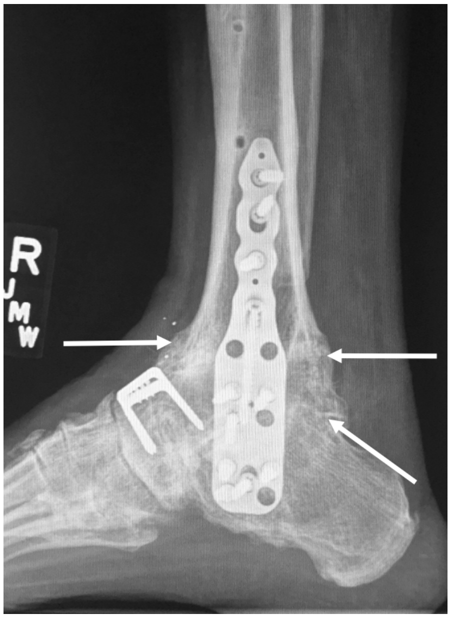

Figure 9: 8-month post-operative right lateral ankle x-ray shows robust bony consolidation at subtalar and ankle joints confirming bone fusion (arrows).

Figure 10: 8-month post-operative right anteroposterior ankle x-ray shows robust bony consolidation at subtalar (arrow) and ankle joints confirming 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 β1 (TGF-β1) 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-β1 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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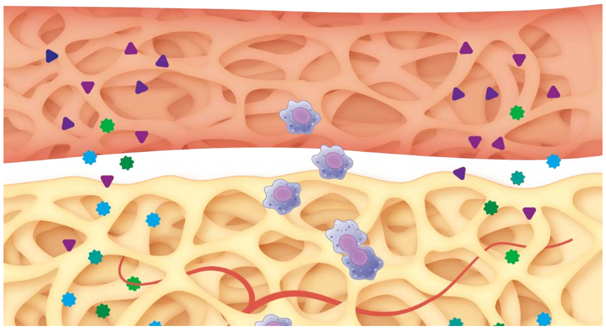
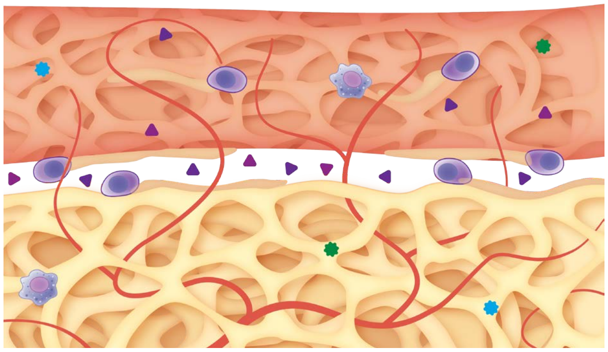


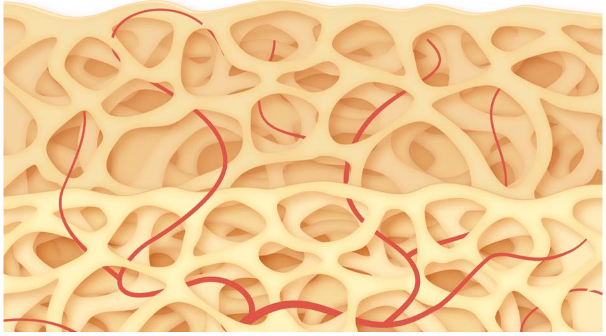
Step1

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.



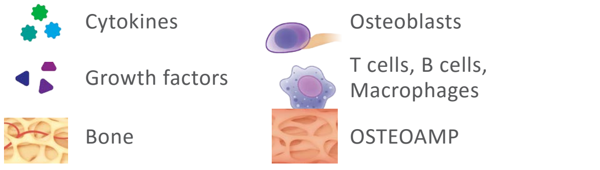
Step 2

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.



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