

AUGMENT[®]

Bone Graft

THE **FIRST** AND **ONLY**
PROVEN ALTERNATIVE TO
AUTOGRAFT IN ANKLE AND
HINDFOOT ARTHRODESIS

CASE REPORT

Subtalar Fusion

as presented by

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Subtalar Fusion: 62 YO Female

CASE REPORT

Case Overview

- » The patient is a 62 year old female who presented with a painful hindfoot that worsened when walking on uneven surfaces
- » History of rheumatoid arthritis assessed with osseous defects from pathology or traumatic injury
- » Baseline reported AOFAS total score of 2, FFI score of 51, and SF-12 Quality of Life PCS score of 22
- » Pre-op X-Ray and CT scans demonstrated severe arthritic degeneration of subtalar joint

Operative Treatment Plan

- » Subtalar arthrodesis ORIF using AUGMENT® Bone Graft

Pre-Op



FDA did not base its approval of AUGMENT® Bone Graft on radiologic findings from the pivotal study, but instead relied on clinical outcomes.

CT Scans at 24 Weeks

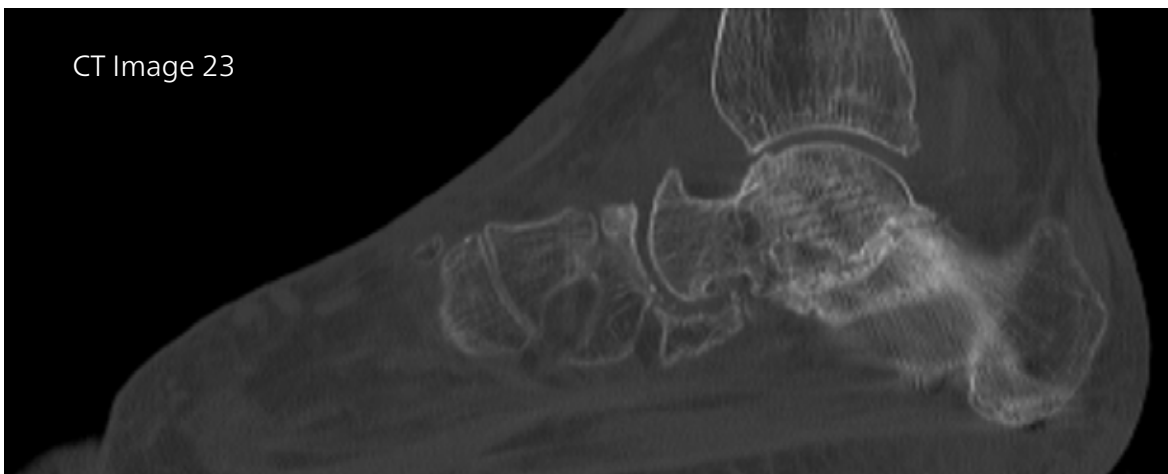
- » Osseous bridging of 50% or greater at 24 weeks as assessed by the independent radiologist.

Note: Greater than 25-49% Trabecular bridging on CT correlates with clinical success.¹

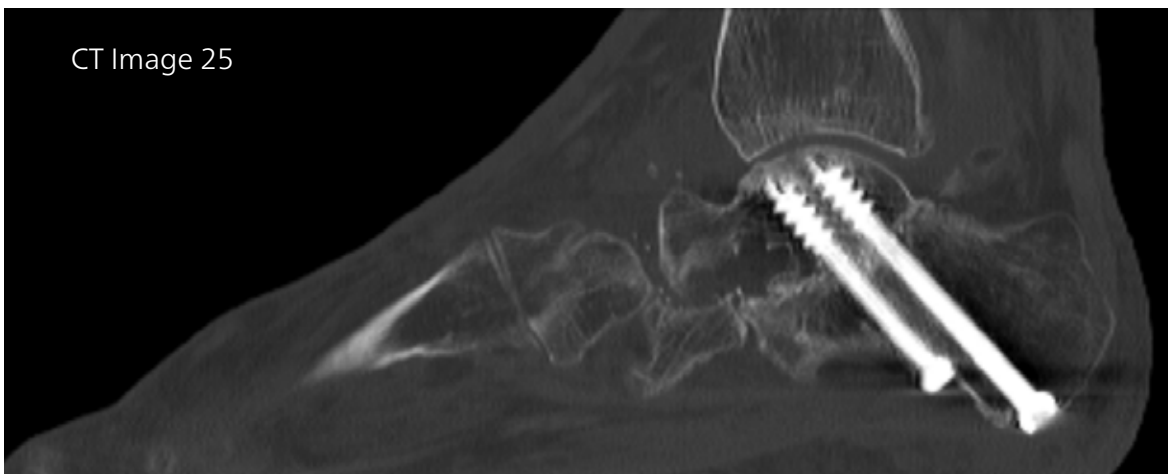


Multiple CT planes displayed to demonstrate extent of osseous bridging at 24 weeks.

CT Image 23

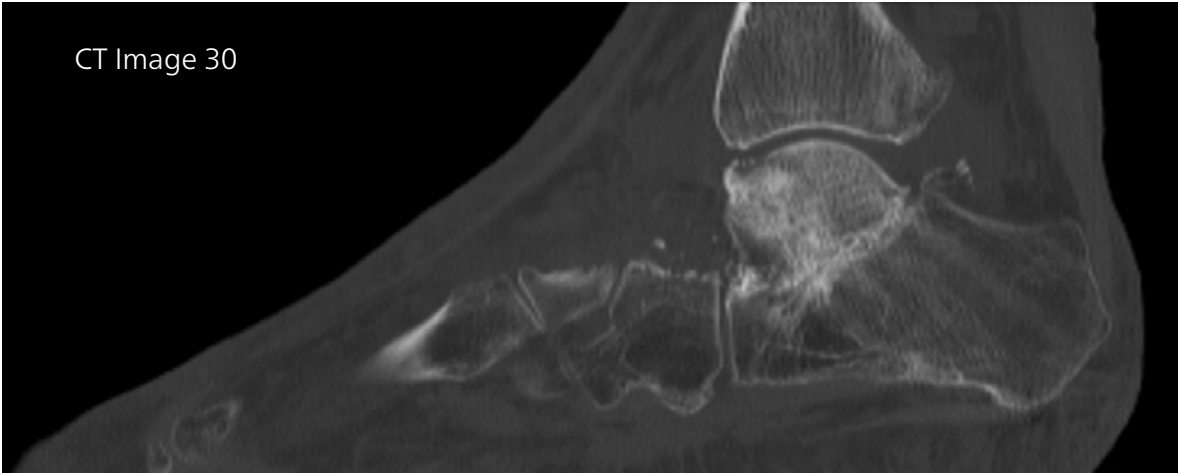


CT Image 25



1. Glazebrook, M, et al. Establishing the Relationship Between Clinical Outcome and Extent of Osseous Bridging Between Computed Tomography Assessment in Isolated Hindfoot and Ankle Fusions. *Foot Ankle Int.* 2013; 34(12) 1612-1618

CT Image 30



CT Image 31



CT Image 32



Post-Op 9 Weeks



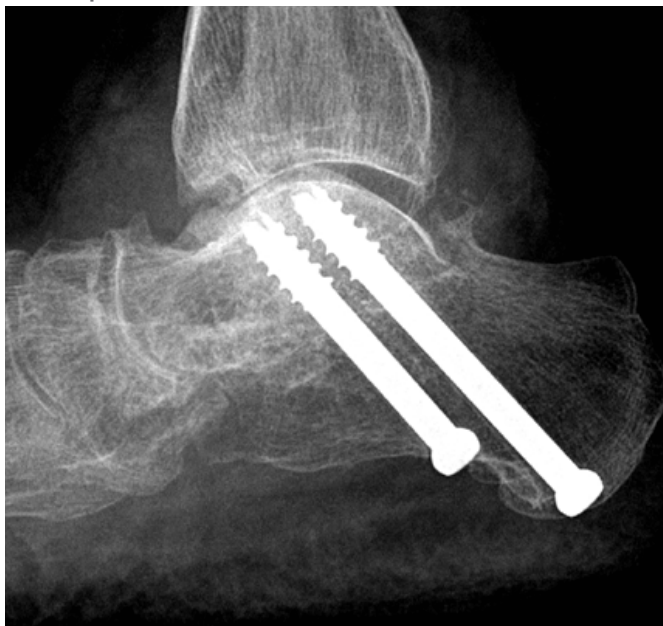
Clinical Outcome

- » Patient was non weight-bearing with immobilization for 6 weeks post-op, progressive weight-bearing thereafter
- » Radiographic union at 24 weeks and after as determined by the surgeon
- » At 12 months, improved to a final AOFAS Score of 84, FFI score of 11, and SF-12 Quality of Life PCS score of 53

Post-Op 24 Weeks



Post-Op 52 Weeks



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Brief Summary of Important Product Information

Indications for Use

AUGMENT® Bone Graft is indicated for use as an alternative to autograft in arthrodesis (i.e., surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material.

Contraindications

AUGMENT® Bone Graft should not:

- » be used in patients who have a known hypersensitivity to any of the components of the product or are allergic to yeast-derived products.
- » be used in patients with active cancer.
- » be used in patients who are skeletally immature (<18 years of age or no radiographic evidence of closure of epiphyses).
- » be used in pregnant women. The potential effects of rhPDGF-BB on the human fetus have not been evaluated.
- » be implanted in patients with an active infection at the operative site.
- » be used in situations where soft tissue coverage is not achievable.
- » be used in patients with metabolic disorders known to adversely affect the skeleton (e.g. renal osteodystrophy or hypercalcemia), other than primary osteoporosis or diabetes.
- » be used as a substitute for structural graft.

Warnings

As with all therapeutic recombinant proteins, there is a potential for immune responses to be generated to the rhPDGF-BB component of AUGMENT® Bone Graft. The immune response to rhPDGF-BB was evaluated in two pilot and one pivotal studies for ankle and hindfoot arthrodesis procedures. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to AUGMENT® Bone Graft with the incidence of antibodies to other products may be misleading.

Women of childbearing potential should avoid becoming pregnant for one year

following treatment with AUGMENT® Bone Graft. The implantation of rhPDGF-BB in women and the influence of their development of anti-PDGF-BB antibodies, with or without neutralizing activity, on human fetal development are not known.

The safety and effectiveness of AUGMENT® Bone Graft in nursing mothers has not been established. It is not known if rhPDGF-BB is excreted in human milk.

The safety and effectiveness of AUGMENT® Bone Graft has not been established in anatomical locations other than the ankle or hindfoot, or when combined with autologous bone or other bone grafting materials.

The safety and effectiveness of repeat applications of AUGMENT® Bone Graft have not been established.

The safety and effectiveness of AUGMENT® Bone Graft in pediatric patients below the age of 18 years have not been established.

AUGMENT® Bone Graft does not have any biomechanical strength and must be used in conjunction with standard orthopedic hardware to achieve rigid fixation.

The β -TCP component is radiopaque, which must be considered when evaluating radiographs for the assessment of bridging bone. The radiopacity may also mask underlying pathological conditions. Over time, the β -TCP is intended to be resorbed at the fusion site and replaced by new bone. Under such circumstances, it would typically be indistinguishable from surrounding bone.

Refer to the AUGMENT® Bone Graft Package Insert for more information.



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