Trabexus®

Trabecular Osteoinductive Biocement†

Case Study

Revision Subtalar Fusion Supplemented with Trabexus® Osteoinductive Cement†

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Vivorté®
Performance Biologics

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PATIENT BACKGROUND

41 year-old female with a history of symptomatic foot pain and prior podiatric surgical procedures. At age 26, the patient underwent arthrodesis of the talonavicular and subtalar joints at another institution.

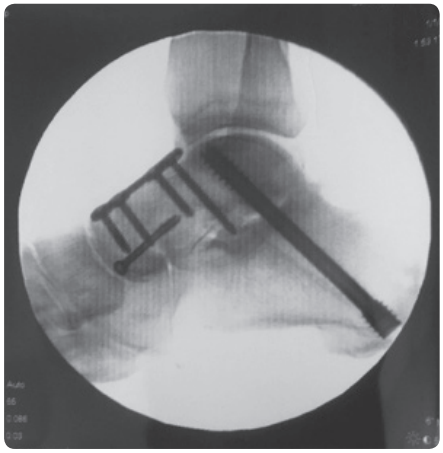

Figure 1: Talonavicular and subtalar index procedure

By age 38, the same patient presented at our facility, complaining of re-emergent and recalcitrant foot pain. Patient was diagnosed with pseudarthrosis of the subtalar joint. Patient was revised by exchanging the screw fixation with an antegrade cannulated lag screw supplemented with Vitoss® bone substitute.

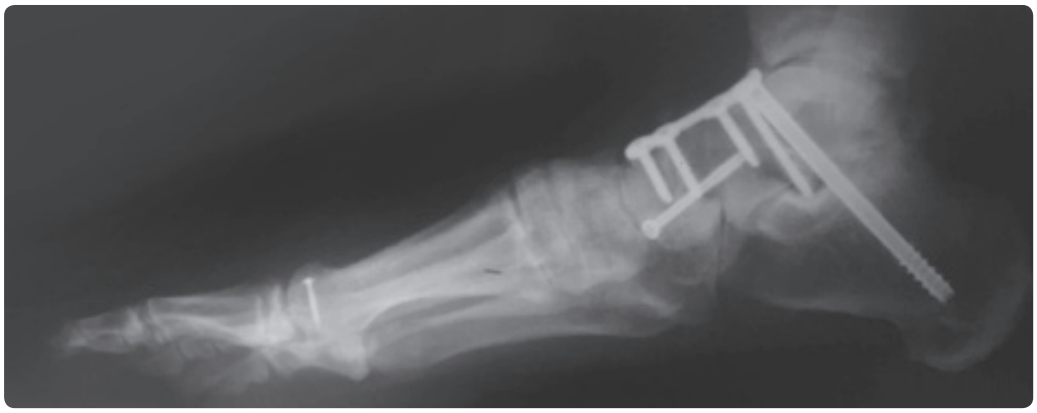

Figure 2: Revision subtalar fusion procedure supplemented with synthetic bone substitute.

However, three years later, the same patient (now 41 years old) presented once again complaining of foot pain. Radiographic imaging and physical examination revealed the presence of pseudoarthrosis at the subtalar joint and the patient was subsequently indicated for a second revision procedure.

SURGICAL TECHNIQUE

The pre-existing 6.5mm subtalar screw and Vitoss® bone void filler were explanted. The joint was maximally distracted and exposed to enable additional debridement of residual articular cartilage, which was removed using standard curettes and osteotomes. Pilot holes (2.0mm) were drilled into the articulating surfaces to perforate the subchondral bone and stimulate bleeding. After the joint surfaces were properly prepared, Trabexus® Osteoinductive Biocement (Vivorté, Inc.) was mixed in accordance with the provided directions for use and implanted between the opposing joint surfaces. Following implantation of Trabexus, and prior to the cement hardening, a 8.0mm cannulated headless screw was inserted to achieve tight compression and rigid fixation of subtalar joint. Trabexus was chosen in this setting to provide a strong, yet rapidly-resorbing graft that actively promotes bone healing. Following surgery, patient was discharged in a CAM Walker Boot and restricted to non-weight bearing activity for six weeks.

POST-OPERATIVE HEALING

Six months post-operative, the talonavicular plate and screws were removed and fusion progression was evaluated radiographically.

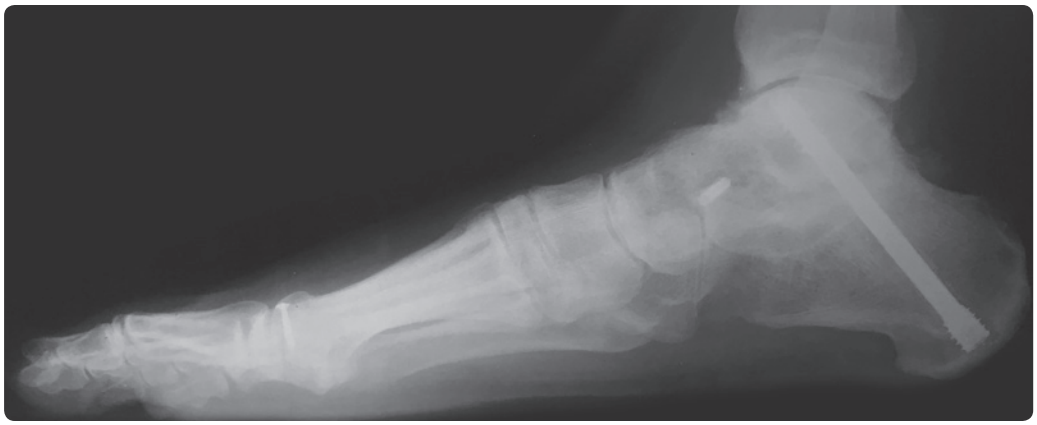

Figure 3: 6 month radiograph following talonavicular hardware removal. Subtalar joint is characterized by a solid radiographic union and absence of lucency.

At six and a half months post-operative, a CT scan demonstrated osseous fusion of the subtalar joint and bone growth where Trabexus was previously implanted, which provides evidence of remodeling.

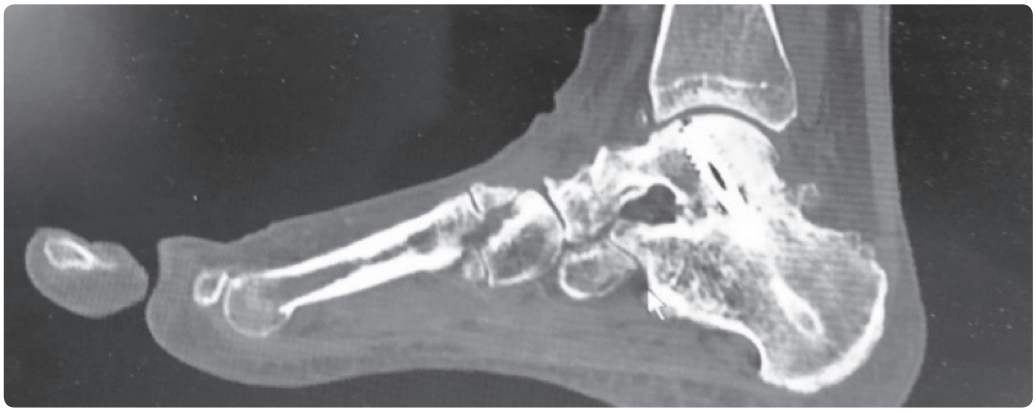

Figure 4: CT scan indicates robust fusion across subtalar joint following hardware removal.

Despite a lengthy history of foot problems and revision surgery, the patient recovered functionality of the lower extremity and is ambulatory.

ABOUT TRABEXUS OSTEOINDUCTIVE CEMENT†

Trabexus is a proprietary, biocompatible, self-setting, gradually resorbable, calcium phosphate matrix enhanced with partially demineralized allograft particles. Partial demineralization of allograft has been shown to expose key osteoinductive proteins that can influence and direct bone repair.

Trabexus is supplied as a multi-component, sterile, single use kit. After briefly mixing the product components at the point of use, the material will transform into a putty/paste and remains workable for up to 4.5 minutes. Upon setting, the calcium phosphate component will convert to hydroxyapatite, the mineral composition of native human bone. Trabexus is resorbed and remodeled by the body as new bone formation occurs during the healing process.

DISCLAIMER: Proper surgical procedure and technique is the responsibility of the medical professional. This material is furnished for informational purposes only. Each surgeon must evaluate the appropriateness of this material based on their medical expertise. Prior to using Trabexus, refer to the Instructions for Use for complete warnings, precautions, indications, contraindications and potential adverse effects.

In the United States, Trabexus is indicated for use to fill bony voids or defects of the skeletal system (i.e. extremities, pelvis) that may be surgically created or osseous defects created from traumatic injury to the bone and only for bony voids or defects that are not intrinsic to the stability of the bony structure. Trabexus may be manually applied to the bony defect or applied to the defect through a cannula. Trabexus is covered by United States patent 9,072,720, with additional patents pending. †Allograft component demonstrated osteoinductivity in athymic mouse model submitted in support of 510(k) clearance (K143547). Data on file at Vivorté, Inc.

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