CASE STUDY

Use of PEEK Subtalar Implant to Control Abnormal Hindfoot Motion

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In2Bones

A GLOBAL EXTREMITY COMPANY

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INTRODUCTION

A 56-year-old female presented with bilateral worsening sinus tarsi syndrome and progressive painful bunion deformities (**Figures 1 & 2**). She had attempted many years of shoe gear accommodations, activity modification, various physical therapy modalities, bracing, and topical and oral pain medications without total relief. She had related no prior injuries to the foot and ankle and had suffered a stroke prior without any noted effects to her extremities.

Physical exam revealed a bilateral flexible pes planovalgus deformity with ankle equinus and hallux abductovalgus. The patient exhibited limited ankle dorsiflexion with the knee both flexed and extended, and was tender along the distal Achilles tendon. She had a valgus hindfoot weight bearing, reducible with heel raise, and tenderness over the sinus tarsi with a sharp shooting sensation elicited upon palpation. There was no evidence of tarsal coalition or muscle spasm. There was tenderness at the first metatarsal head eminence, along with painful motion and functional limitation at the first metatarso-phalangeal joint. The patient's gait exam displayed overpronation with limited heel contact, medial longitudinal arch collapse, and a slight abductory twist.

PROCEDURES

Equinus Correction: While under general anesthesia, the patient was positioned prone, and hemostasis was achieved via a right thigh tourniquet. First, the Achilles contracture was released by means of an open frontal plane Z-plasty tendon lengthening. The incision site was closed, and the patient was turned supine for the remaining procedures.

Subtalar Joint Reduction Using the PEEK In2Bones PitStop® Implant: The area of implantation over the sinus tarsi was located, and a short linear incision was made. The provided radiopaque trial sizers were used to determine the proper implant size, clinically and radiographically (**Figure 3**). Clinically, the excessive eversion was reduced, resulting in a rectus foot upon loading. Radiographically, the talonavicular and calcaneocuboid joints were well aligned with improved navicular covering of the talar head and the implant was noted to be in an excellent position. The trial was then removed, taking care to leave the guidewire in position, and the radiolucent implant was inserted. Using the tantalum X-ray markers, the proper position of the PEEK implant was confirmed radiographically (**Figures 4 & 5**). The incision was then closed using a single horizontal mattress suture.

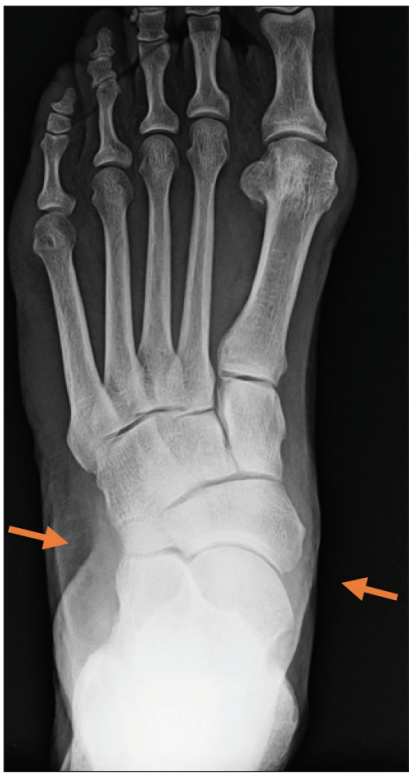


Figure 1. Dorsal pre-op X-ray

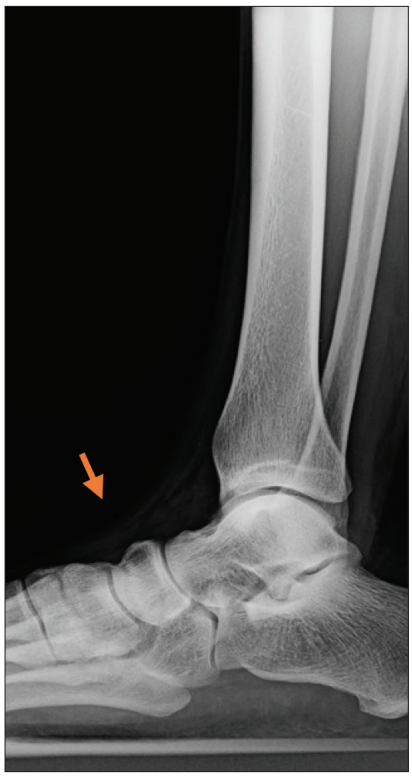


Figure 2. Lateral pre-op X-ray

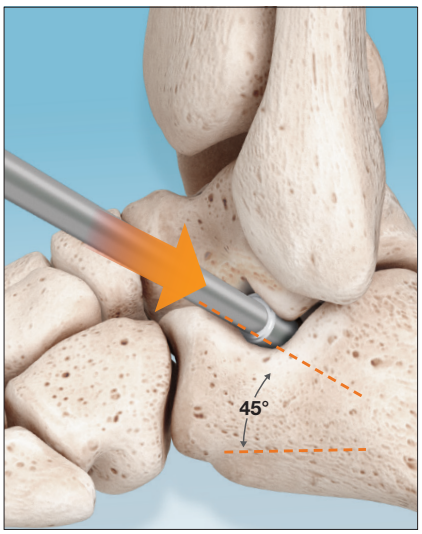


Figure 3. Trialing of In2Bones PitStop Subtalar Implant

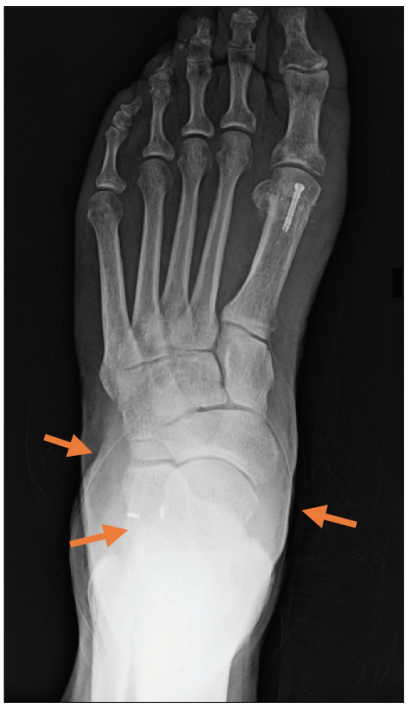


Figure 4. Dorsal intra-op X-ray

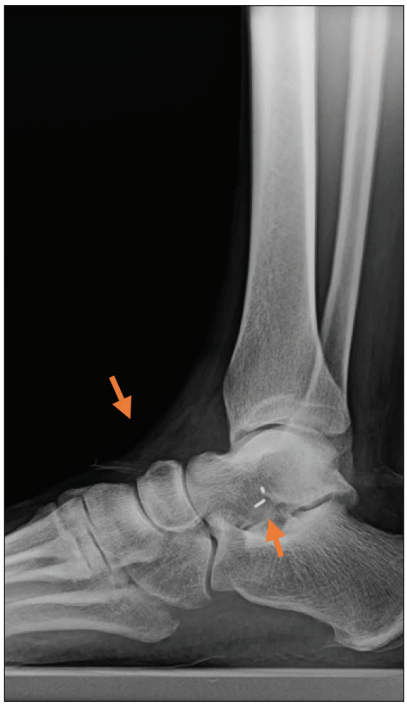


Figure 5. Lateral intra-op X-ray

Bunionectomy: Through a dorsomedial incision, a bicorrectional Austin bunionectomy was performed to address the hallux valgus deformity.

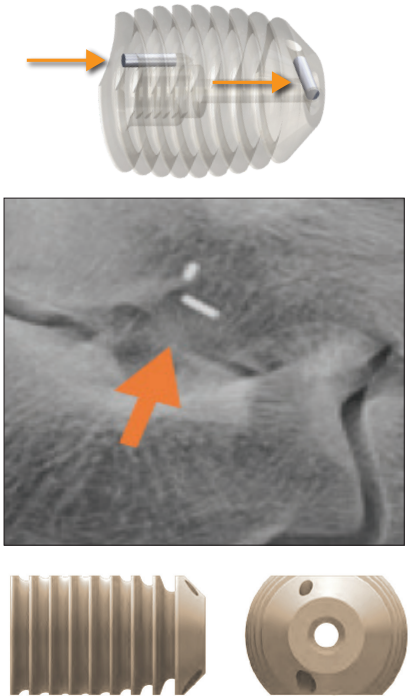
A sterile dressing was applied, and the patient was placed in a posterior splint.

POST-OPERATIVE COURSE

The patient remained in a non-weightbearing posterior splint until the swelling subsided, at which time she was placed in a below-knee, non-weightbearing fiberglass cast. During this time, she ambulated using a knee scooter. At four weeks, the cast was removed, and the patient was placed in a CAM boot. Physical therapy began at this time, and at six weeks, the patient returned to supportive shoe gear without restrictions. Within a week, the patient underwent an identical combination of procedures to the contralateral lower extremity. She continued to pain-free ambulation following the same postoperative course.

DISCUSSION

Relative hypermobility or joint subluxations in the hindfoot and adjacent joints have long been treated with the subtalar implantation procedure, given they are flexible and reducible. In some patients, other procedures are required to reduce limiting factors such as tendon contractures or joint coalitions. In this case, following the release of the Achilles tendon contracture, the joints were able to be adequately reduced and maintained with the subtalar implant. As with most surgical hardware, there have been many subtalar implants of various shapes and materials, with new and modified features. The In2Bones PitStop carries many of these common and important features, such as cannulation and radiopaque trials for accurate positioning and size



Radiolucent PitStop® with two tantalum X-Ray markers and flattened sides.

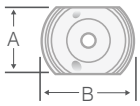
determination. However, it does contain some distinguishing benefits as well. The press-fit implantation is possibly less traumatic as it does not require tamping or screwing, and the relative radiolucency provides improved clarity when imaging. Furthermore, and more specific to this case given the patient's age and structural adaptations, the flattened sides made of the relatively more flexible PEEK made it a more optimal choice as it may be more tolerable than stiffer materials with less compressibility. This patient tolerated the implant very well, as well as the other procedures, and returned to her desired activities without any pedal discomfort.

Sterile Implants and Instrument Tray

IMPLANTS

PIT'Stop® - Subtalar Implant - PEEK - Sterile

Reference	Size
M20 SP010	10mm
M20 SP011	11mm
M20 SP012	12mm
M20 SP013	13mm
M20 SP014	14mm
M20 SP015	15mm
M20 SP017	17mm



INSTRUMENTS

Reference	Description
M02 00011	PIT'Stop trial implant - Size 10mm
M02 00021	PIT'Stop trial implant - Size 11mm
M02 00031	PIT'Stop trial implant - Size 12mm
M02 00041	PIT'Stop trial implant - Size 13mm
M02 00051	PIT'Stop trial implant - Size 14mm
M02 00061	PIT'Stop trial implant - Size 15mm
M02 00071	PIT'Stop trial implant - Size 17mm
M02 00081	Viladot's lever
M02 00091	External holder
M02 00101	Internal holder

K10 NS150 . Guide wire Diam. 1.6mm - Lg. 150mm

INDICATIONS

The PIT'Stop implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Flat foot treatment in children and adolescents
- Congenital flat foot
- Non successful long term orthopaedic treatment (shoes, insoles…)
- Tarsal coalitions
- Painfully flat foot
- Supple deformity in posterior tibial tendon dysfunction
- Paralytic flat foot
- Subtalar instability

CONTRAINDICATIONS

The implant should not be used in a patient who has currently, or who has history of: acute or chronic inflammations, whether local or systemic, active infections, stiff or fixed deformity of the flat foot, flat foot with a forefoot abductus, chronic rupture of the posterior tibial tendon, symptomatic arthritis, neurological affections (paraplegia…), sensitivity/allergies to the implant materials.

RECOMMANDATION

It is recommended to carefully read the instructions for use available in the package insert.

DEVICES

CE Classification (Directive MDD 93/42/EC)
– Implants : Class CE IIb - CE2797
– Single use instruments and instruments connected to a power driver: Class CE IIa - CE2797
– CE Classification (Regulation MDR 2017/745 EU):
– Other instruments: Class I - CE
– Invasive reusable surgical instruments: Class Ir - CE2797

REIMBURSEMENT

Reimbursement may vary from countries to countries. Check with local authorities.

MANUFACTURER

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Fax : +33 (0)4 72 29 26 29

DOCUMENT

Reference : CR-DIG-PITSTOP-EN-022022

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

Always refer to the appropriate instructions for use for complete clinical instructions.

Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

Peek-Optima® is a polymer produced by INVIBIO®.
Peek-Optima® is a registered brand of INVIBIO®.