

INVISION™ Total Ankle Revision System

Revision of a Failed Agility Total Ankle Replacement with an INBONE™ II Tibial Component and an INVISION Talar Component

CASE STUDY

Patient History

The patient is an 82-year-old gentleman with significant subsidence of an Agility total ankle arthroplasty first implanted in November of 2002. This patient initially did well with the prosthesis, noting only a slight residual ache. He presented to his primary surgeon in August 2004 with increasing lucency about the prosthesis both anteriorly and laterally at the tibial tray, along with a stress fracture in the fibula at the site of the syndesmotic fusion plate. No surgical action was taken at that time. He presented again in April 2005 with progressive cystic change around the tibial tray and a stable talus component. Again, observation was chosen until presentation in January of 2007 demonstrated significant progression of the tibial cystic region (the talus was still not affected). Laboratory tests were negative for infectious process. He underwent revision surgery in February of 2007 with a polyethylene exchange and bone grafting of the cysts about the tibia, with supplementary strut grafting of the anterior tibia. Intraoperative cultures did not grow organisms.

Six months later, some talar component subsidence was noted, and by March of 2015, he complained of increasing pain in his replaced ankle. Radiographs revealed severe, progressive subsidence of the talus component into dorsiflexion. An arthrodesis was offered to the patient by the primary surgeon, which the patient refused. The surgeon was not certain that the components could be revised and directed him to this clinic for a second opinion.



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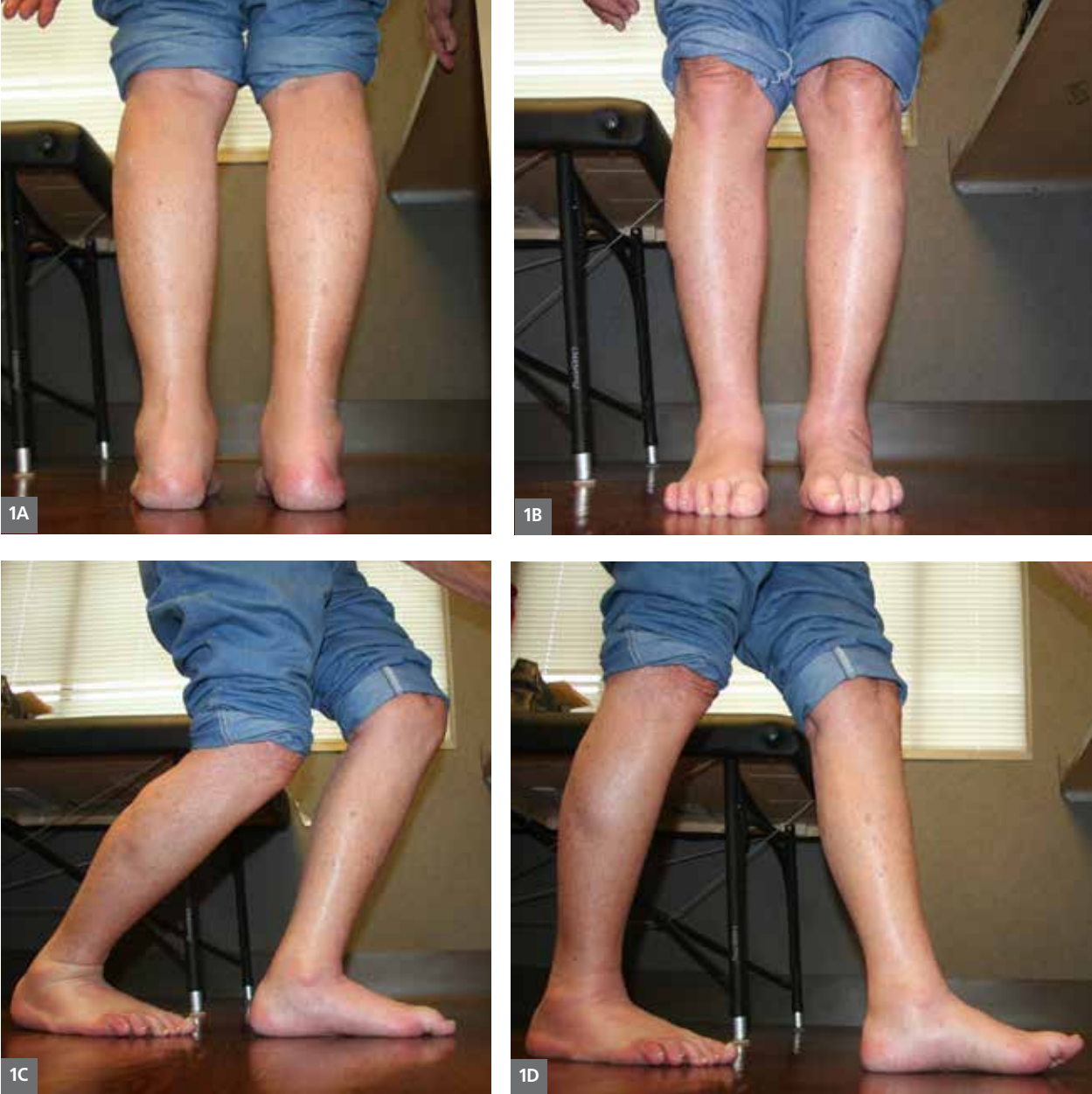
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Dr. Haddad is a paid consultant for Wright Medical Group N.V. Wright provided financial support for this case study.

These results are specific to this individual only. Individual results and activity levels after surgery vary and depend on many factors including age, weight, and prior activity levels. There are risks and recovery times associated with surgery, and there are certain individuals who should not undergo surgery.

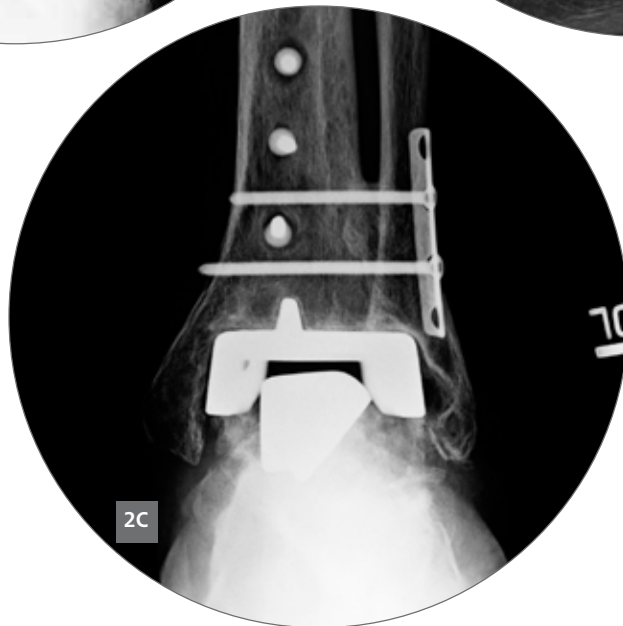
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The patient presented in June of 2015. He had constant, sharp pain in the left ankle when ambulating and a chronic, dull ache when the extremity was not loaded. Clinical observation noted mild pes planus with 3 degrees hindfoot valgus and limited motion (FIGURES 1A, B, C, and D).



FIGURES 1A, B, C, D: 16 degrees dorsiflexion, 8 degrees plantarflexion vs. 24 and 20 degrees respectively on the unaffected ankle

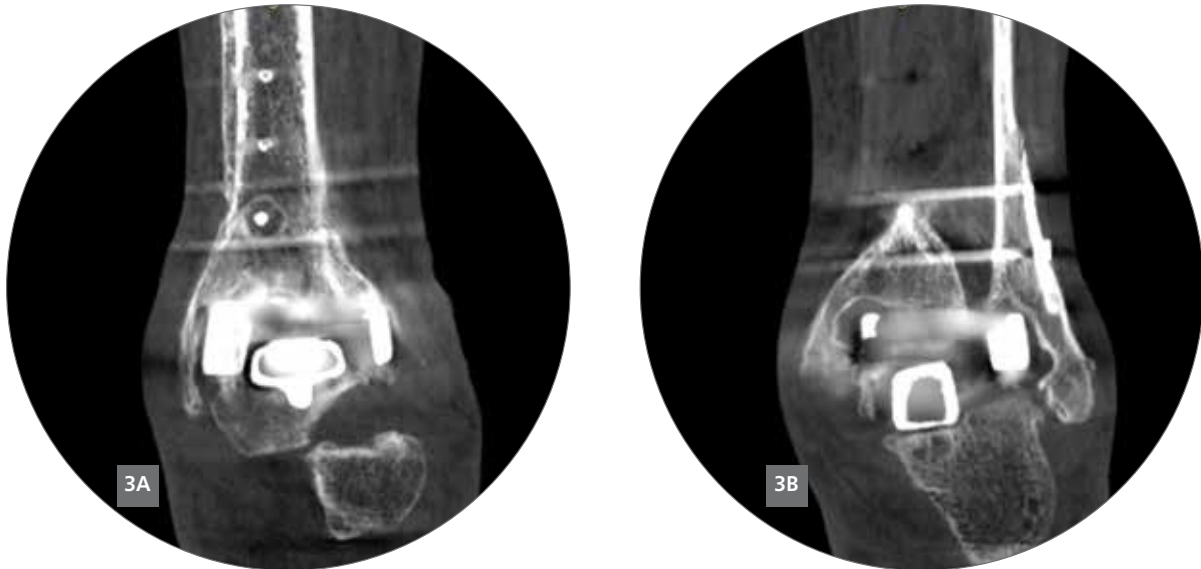
Radiographs confirmed severe talar component subsidence and presence of the anterior strut graft in the tibia (FIGURES 2A, B, and C).



Discussion of Pathology

The patient had pathology on multiple levels. As noted above, he had severe posterior subsidence of the talus into dorsiflexion. The posterior portion abutted the subtalar joint, which was grossly arthritic. Fortunately, the adjacent joints showed very little arthritis. The tibial component has equal challenges. An anterior strut graft supports the anterior distal tibia which bears at least 70% of the load during weight bearing. He had anterior subsidence of the tibial tray upon that graft and in the coronal plane had very little remaining medial and lateral malleolar bone.

Weightbearing CT scan showed successful union of the syndesmosis, which is a positive sign on the scan. Coronal imaging confirmed thinned medial and lateral malleoli, with the wedge of the talar component splitting the talus more medial than lateral (FIGURES 3A and B).



Sagittal CT imaging demonstrated a successful first tarsometatarsal joint arthrodesis and significant loosening of both components, but fortunately showed good quality anterior strut bone to support a revision prosthesis (FIGURES 4A and B).



Treatment Plan

The patient considered both tibiototalcalcaneal joint arthrodesis and revision total ankle arthroplasty. He had concerns about the potential for late graft collapse with an arthrodesis, as well as concerns about changes in cadence and stride length with fusing both joints. He understood the equal risks of subsidence following revision TAR surgery (as he had already experienced it), but felt given his age and activity goals, the risk was worth the attempt for preserved motion in the ankle joint. The patient understood the complexity of both choices and the risk of below knee amputation should a poor outcome result. The patient chose revision arthroplasty, and a surgical plan was formulated.

Given the severe subsidence of the talar component and the arthritic subtalar joint, a two-stage procedure was planned. The first surgery would include removal of all hardware, a subtalar joint arthrodesis, and implantation of a temporary block cement spacer to prevent collapse and maintain joint height while the subtalar fusion was taking place. The second surgery, to remove the cement block and implant the INVISION total ankle, would take place eight months later. Four months is normally considered sufficient, but given the patient's age category, we wanted to be certain the subtalar joint fusion was solid and his bone quality was not osteopenic prior to undertaking the revision total ankle replacement.

Due to edema, compression wraps were instituted for one week prior to both surgical procedures**

Surgical Procedure: Stage One

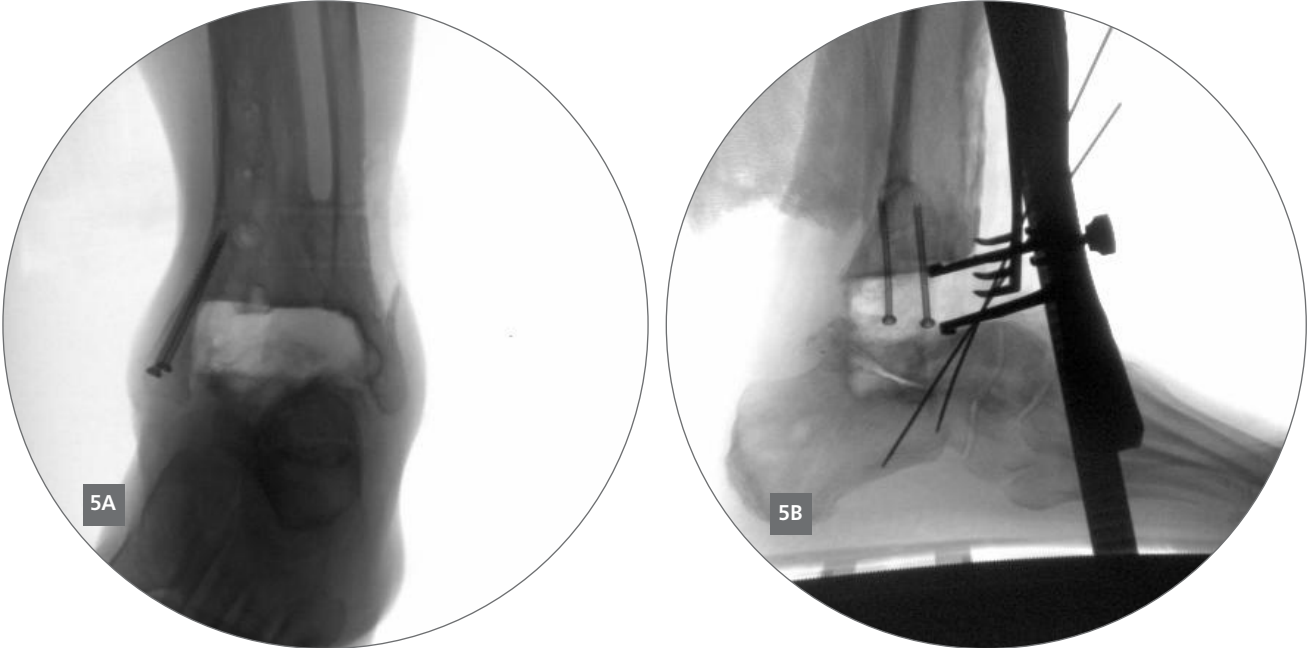
Developing a plan for correcting a severe deformity requires careful assessment of both CT and plain radiographs, and the first surgical stage is as challenging as the second stage and equally as important. In the first stage, I correct alignment with osteotomies or arthrodesis and confirm this correction by observing the patient's standing alignment prior to the second surgery.

It is critical to remove the implant without fracturing the surrounding bone, and that can be quite challenging when explanting an Agility implant. Medial malleolar strut screws were placed prior to removal of the Agility to help prevent fracture during extraction.

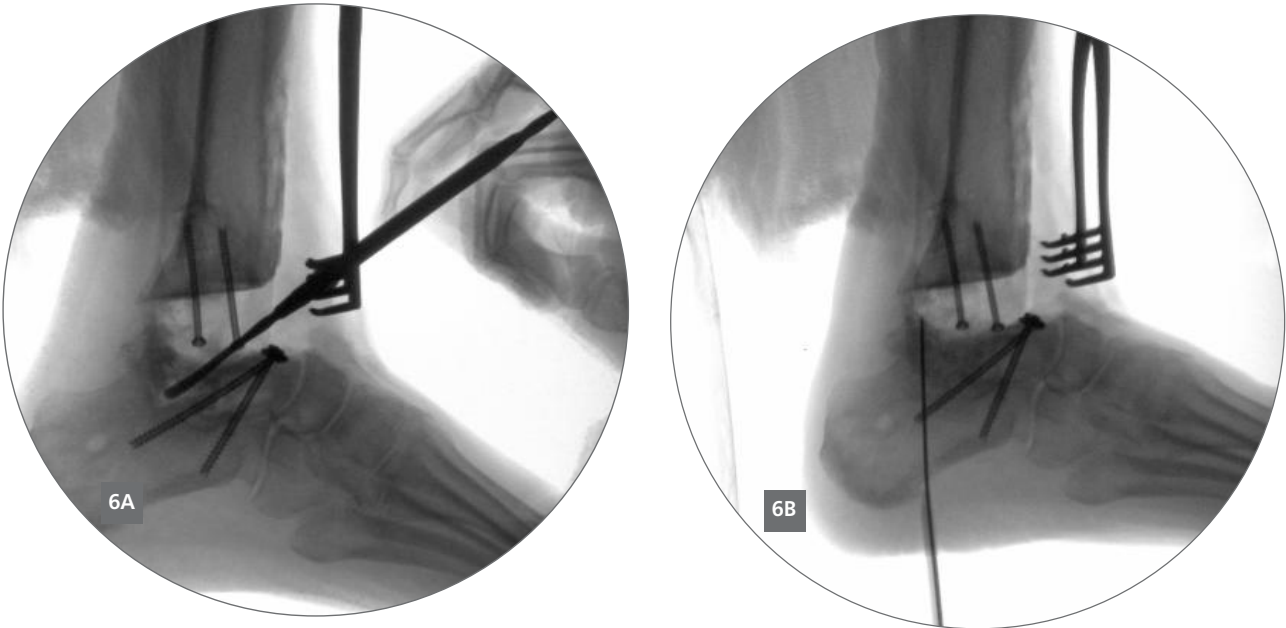
When removing a failed tibial tray, I review the implant geometry (unimplanted) to plan bone cuts that maximize bone preservation. I used a reciprocating saw around all sides of the tibial tray and gutters prior to extraction to prevent fracturing with impaction. The posterior capsule was thickened with scar tissue at the time of implant extraction. I left the thickened capsule in place at this stage to protect the posterior structures from the cement pour and exothermic reaction.

**Hsu, A. R., Franceschina, D., & Haddad, S. L. (2014). A Novel Method of Postoperative Wound Care Following Total Ankle Arthroplasty. *Foot Ankle Int*, 35(7), 719-724.

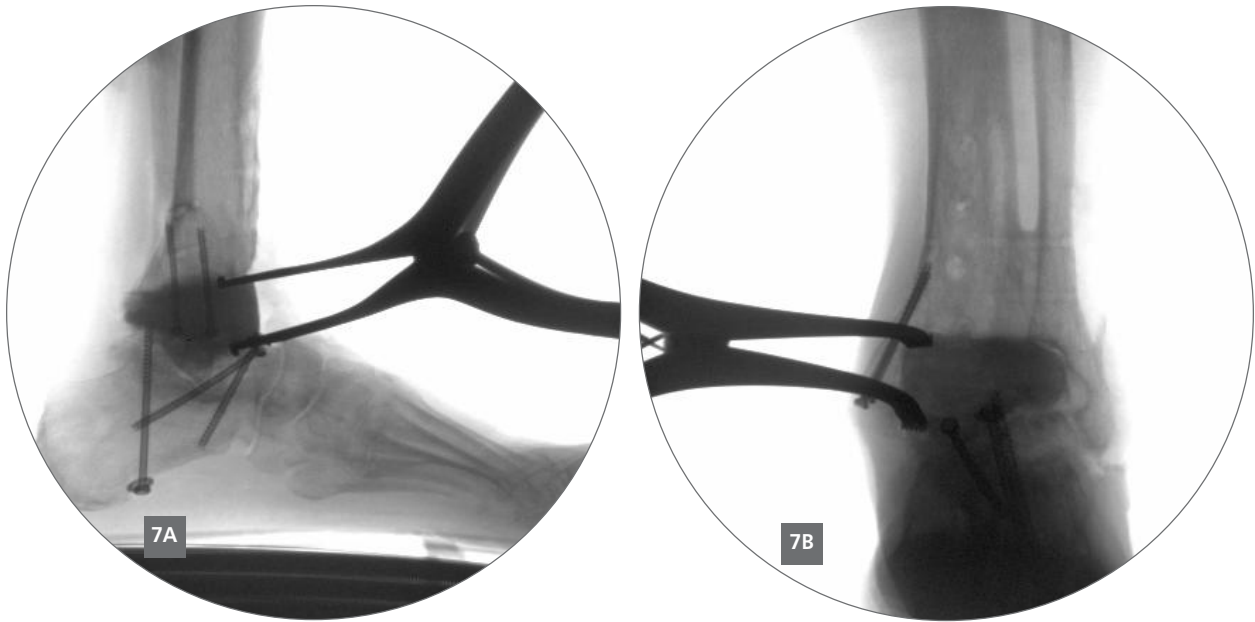
Once the tibial tray was removed, the talar component was extracted using the threaded holding tool and levering it superiorly (FIGURE 5A). A flat plate was used to simulate weightbearing while using a large lamina spreader to distract the ankle joint to anatomic height (FIGURE 5B). This allowed the subtalar joint to be tailored to remain neutral with arthrodesis, preventing secondary structural malalignment from the first stage. Wires were placed across the subtalar fusion site to pin the ankle in a neutral, distracted position.



Screws were then placed across the subtalar fusion site in a location where they would be easily accessible for removal during second stage (FIGURE 6A). A Freer elevator was used to test and locate the posterior talar bone, and an additional posterior screw was placed to stabilize the posterior talus at the fragmentation site and stimulate fusion (FIGURE 6B).



Cement was poured (cool temperature) directly into the defect to fill the void and maintain stability with weightbearing. The combination of large laminar spreader anteriorly and flat plate were again used to simulate weight bearing. This combination allowed the cement to harden with the foot in a plantigrade position (FIGURES 7A and 7B). **NOTE: fill the entire void with cement to provide good stability for weightbearing between the two stages.**



Postoperative Care: Stage One*

The compression wrap protocol was instituted for 2.5 weeks postoperative, followed by removal of compression wraps. At 2.5 weeks postop, the sutures were removed, and the extremity was casted. Six weeks postop the patient was transitioned to restricted weightbearing in a CAM boot.

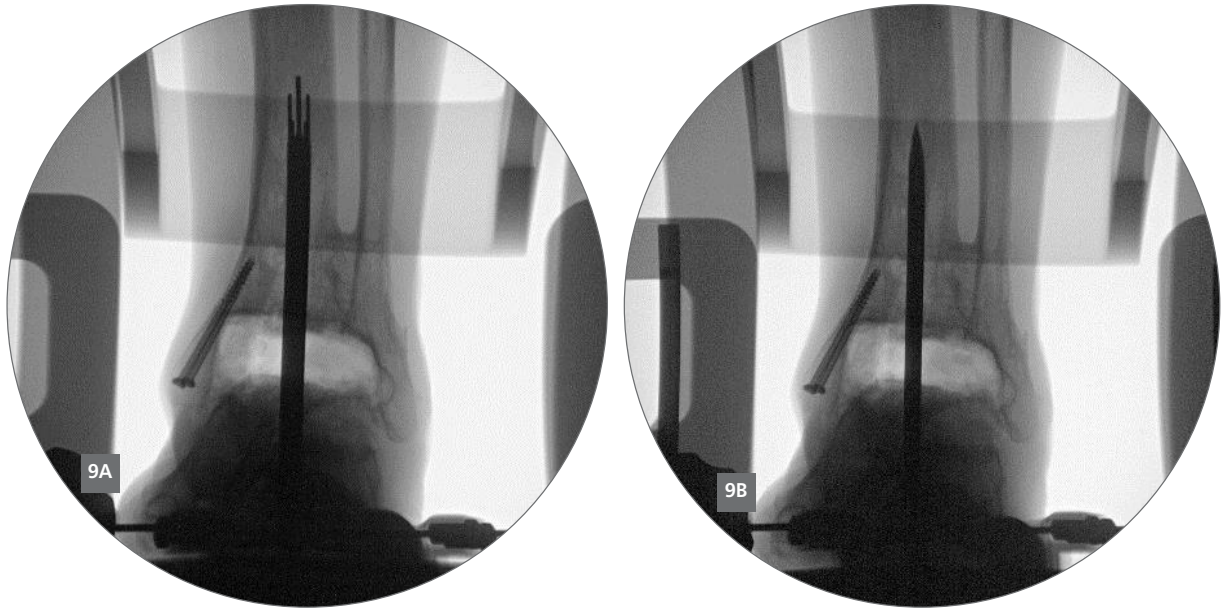
At three months postoperative, alignment was assessed through gait and standing observation in order to determine if supplementary osteotomies would be required at the second stage. CT scan confirmed subtalar arthrodesis, and it was evident that the bone mass would be able to support an INVISION implant, as it had been supporting the cement spacer without compromise. The patient was allowed to walk unrestricted in the CAM boot at three months postoperative to stimulate bone growth (FIGURES 8 A, B, C, D, E, F, and G).



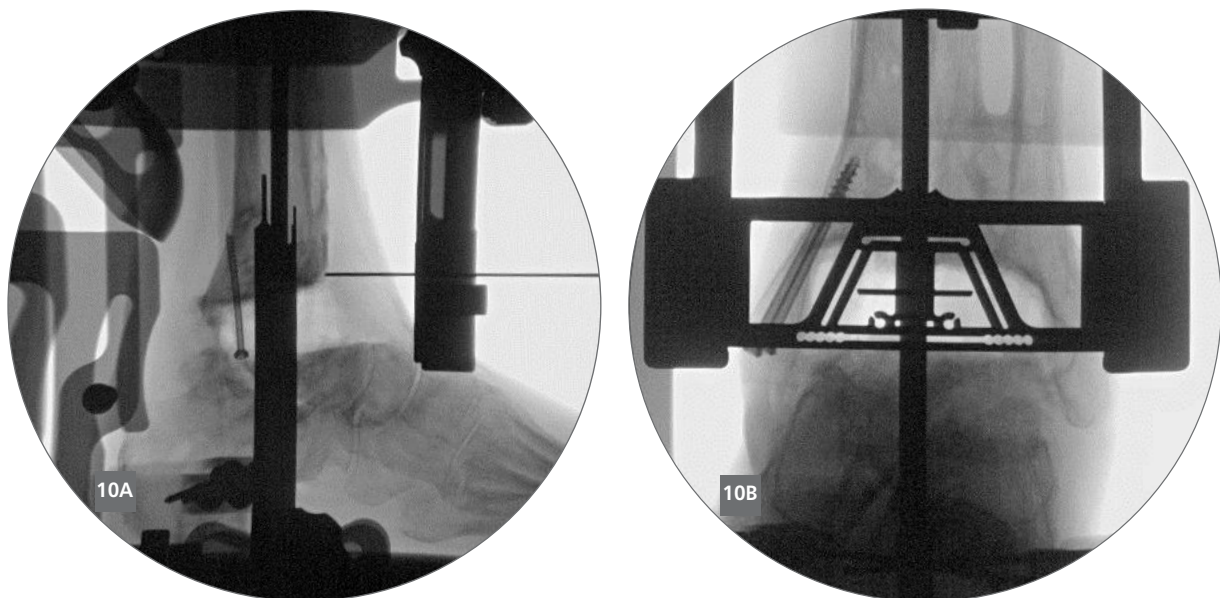
* Postoperative care is the responsibility of the individual surgeon.

Surgical Procedure: Stage Two

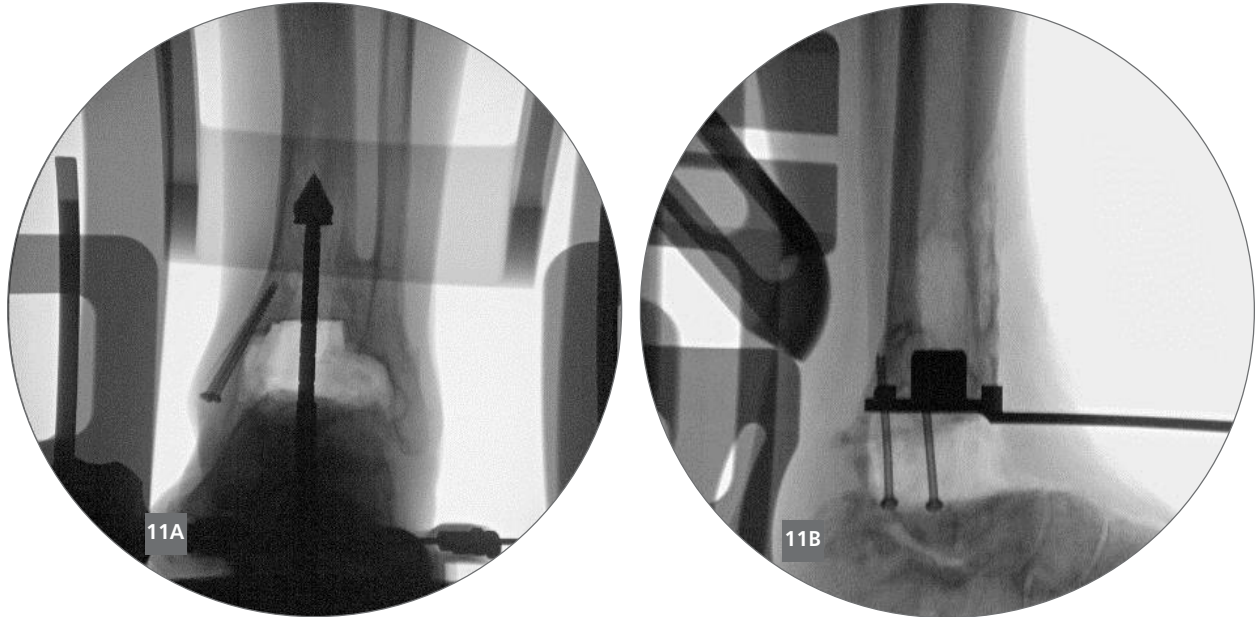
The cement spacer was removed by using an osteotome to split the spacer in half. The posterior capsule was removed so that the flexor hallucis longus could be visualized. The remaining hardware was removed, and the foot was placed in the INBONE II foot holder, holding the deformity in correction. The tibial stem was best centralized with the natural position of the talus to prevent incongruent coronal plane stress on the prosthesis (FIGURE 9A). Under fluoroscopy, the drill bit could be seen to penetrate the central tibia in both planes (FIGURE 9B).



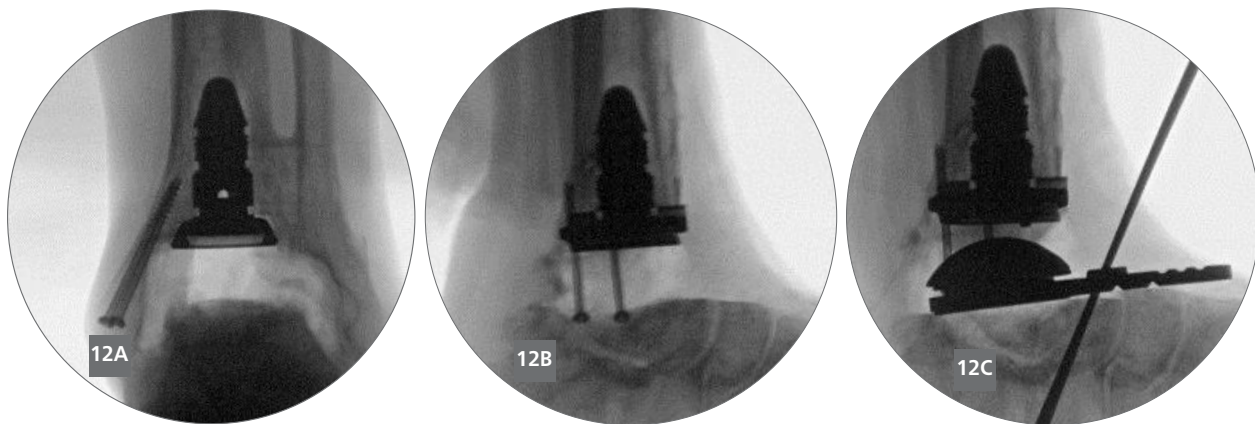
In FIGURE 10A, sagittal plane imaging, the cutting block is shown in place. This is a critical step before determining coronal alignment of the cutting block. Here we can use the saw blade to determine the proposed resection margin on the tibia (quality bone) and determine if a standard INBONE II (vs. INVISION) tibial tray will be sufficient. Secondary coronal plane imaging (FIGURE 10B) allows neutral placement of the tibial cutting block once the appropriate height has been established.



Intramedullary reaming was done with an end-cutting reamer to break through the syndesmotic fusion bone mass required with the Agility implant (FIGURE 11A). Sagittal plane imaging was used to size the implant (FIGURE 11B).



The patient's anterior bone was sufficient to support a standard INBONE II tibial tray, which was placed in standard fashion (FIGURES 12A, and B). Imaging showed the stemmed tibial tray to be well placed in neutral alignment and set on quality, supportive bone. The talar defect was not more apparent in sagittal plane imaging.

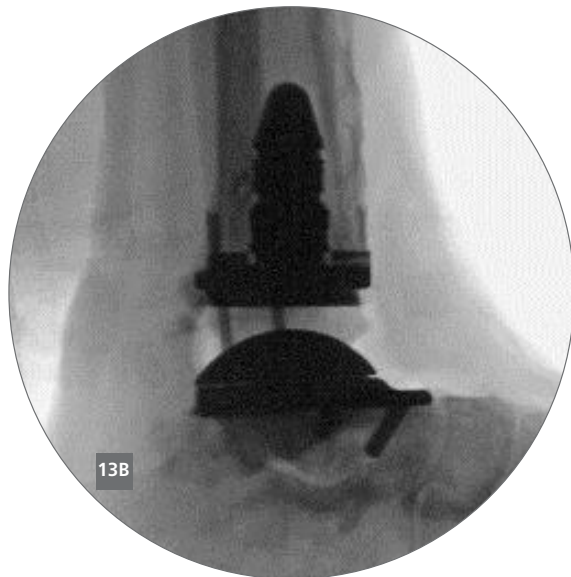


In order to re-establish both talar height and center of rotation of the ankle, an INVISION talar plate (6mm thick) and talar dome were chosen. The talar plate provided excellent coverage given the amount of bone loss. It spanned the bone defect and provided structural support by resting upon the strong posterior talar bone and the even stronger talar neck and head, which were not compromised by vascular insult.

Sagittal plane imaging was used to size the talar plate (FIGURE 12C). The notches in the anterior portion of the plate trial were used to determine "standard" vs. "long" plate. In this case, the standard plate sufficed given the excellent quality bone in the talar neck and head. Flat cuts on the talus were done free-

hand by holding the heel in neutral with my left hand and cutting the talus with a macro-sagittal saw with my right hand. Some dorsal bone at the talonavicular joint was removed to ensure a flat surface for the plate. It is important to study the plate trial in the sagittal plane to ensure that the anterior portion of the plate does not cross the talonavicular joint. Two of three pegs did not purchase good quality bone, and the cement provided rotational structural support and immediate fixation. To confirm appropriate coronal plane alignment, I impacted the talar plate along with the talar dome already engaged at the Morse taper. A trial polyethylene was placed in the tibia immediately to achieve optimal positioning while the cement was hardening. This ensured the components would articulate appropriately following cement hardening. In patients with better quality bone, where all three peg holes are visible, installing the trial polyethylene at this step is not necessary, as rotation is determined with impaction of the tray.

Final implant positioning with range of motion can be seen in FIGURES 13A, B, C, and D. The anterior peg is fixed rigidly in the talar head. To facilitate adjacent joint motion, the talar plate does not cross the talonavicular joint. Coronal plane imaging demonstrates excellent gutter debridement, which facilitates the true prosthesis motion.



Postoperative Care: Stage Two*

Physical therapy focusing on passive range of motion was commenced at three days postoperative, along with compression wrap therapy. The prosthesis appeared to be well-fixed at four weeks postoperative, and because no other significant supplementary procedures (osteotomies) had been performed, weightbearing stretch was begun at four weeks postop. During the 6-to-10-week postoperative window, the patient began standing and progressing from 10 to 20 steps in a CAM boot, with transitional return to a shoe in the 10-to-12 week postoperative period. Aggressive physical activity was avoided until four months postoperative, in order to allow the bone mass to increase to avoid stress fractures or subsidence around the prosthesis.

** Postoperative care is the responsibility of the individual surgeon.*



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