

Prophylactic Fixation of Tibia for Total Ankle Replacement using OSSIOfiber® Trimmable Fixation Nails

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Case Presentation

Patient presented as a 61-year-old female of average weight who had previously sustained a left tri-malleolar equivalent ankle fracture which was fixed at an outside institution. She suffered with chronic left ankle pain due to non-united fibula fracture and mal-united posterior malleolus. After lengthy discussion of surgical options, the patient opted for a staged total ankle replacement.

The first phased approach consisted of hardware removal with takedown of the fibula non-union bone graft and repeat open reduction internal fixation. The syndesmosis also underwent ORIF (Figure 1). The goal of stage one was to create a sound ankle mortise to accept the fixation in stage two.

Pre-op



Figure 1:
Stage two pre-operative anterior posterior and lateral radiographs

The second phase involved removal of the syndesmosis screws with an Infinity total ankle replacement (TAR) utilizing prophecy guidance. In parallel, prophylactic fixation of the medial malleolus using a 4.0 x 50mm OSSIOfiber® Trimmable Fixation Nail was performed. This 4.0 mm Trimmable Nail was chosen as the preferred fixation method for multiple reasons. First, the patient already had multiple metallic implants due to her injury and the bio-integrative Trimmable Nail would limit insertion of additional metallic implants with high risk of future removal. This patient is 61 years of age and could require a revision implant in her lifetime. Placing the OSSIOfiber® implants in the medial malleolus enables complete bone integration, thus, allowing a surgeon performing the revision to make any new tibial cuts without the risks, time, or burden of removing metallic implants.

Surgical Technique with 4.0x50mm OSSIOfiber[®] Trimmable Fixation Nail

1. Ankle joint was exposed, tibia cut guide was properly aligned, and provided sterile K-wire was placed percutaneously within the medial malleolus (Figure 2).

Tip: By placing the tibial cut guide in its proper position prior to inserting the Trimmable Nail, the surgeon decreases the risk of inadvertently placing the Trimmable Nail within the tibial cut guide window and sawing through it.

Intra-op

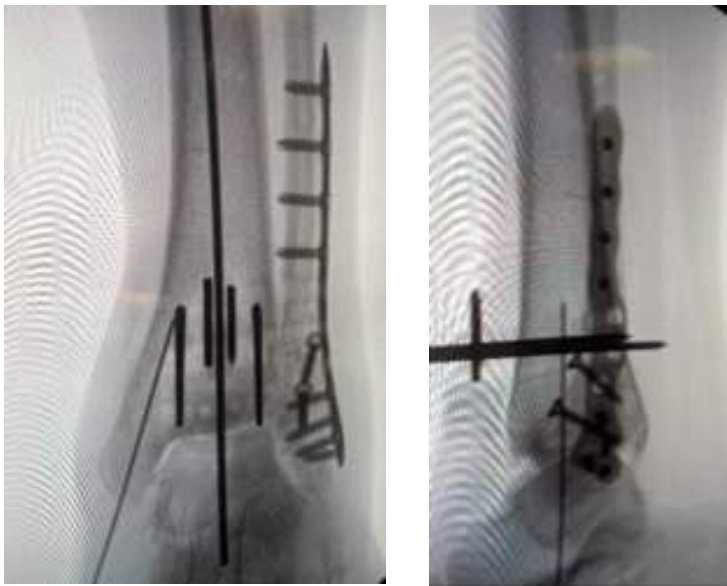


Figure 2:
Alignment guide placed on tibia with insertion of guide wire in medial malleolus for OSSIOfiber[®] Trimmable Fixation Nail placement.

2. A #15 blade scalpel was used to make a small incision around the wire and then blunt dissection down to bone was completed with a hemostat. With a tissue protector, the provided 4.0mm cannulated drill bit was used over the placed k-wire to create a tunnel to its maximum depth (50mm).
3. Prior to removal of the drill and guide wire, the scrub tech loaded the 4.0x50mm Trimmable Nail within the clear insertion sleeve with the black plunger/tamp.

Tip: Advance the Trimmable Nail to exit out of the insertion sleeve approximately 5mm to assist in insertion.

4. A Hohmann retractor was positioned through the anterior ankle incision medial to the medial malleolus, to visualize the drill retracted out of the tibia. The k-wire was removed at this step.
5. Under direct visualization, the OSSIOfiber[®] Trimmable Fixation Nail is positioned and inserted through the percutaneous skin incision and into the 4.0 mm drill hole within the medial malleolus (Figure 3).

Tip: The clear insertion sleeve extends to bone to absorb the stresses during insertion, preventing breakage. Give light taps to the black plunger to advance the implant until it bottoms out (Figure 4).



Figure 3:
Insertion of OSSIOfiber[®] Trimmable Fixation Nail through percutaneous incision

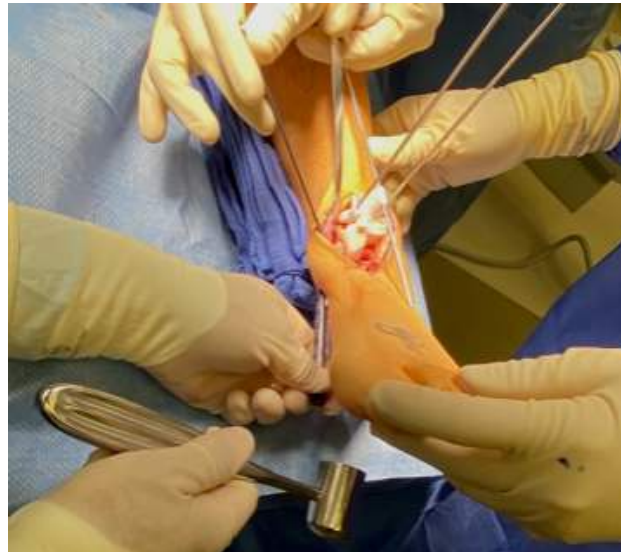


Figure 4:
OSSIOfiber[®] Trimmable Fixation Nail fully seated in medial malleolus (note: black plunger is fully compressed on clear insertion sleeve)



Figure 5:
Direct visualization of medial malleolus through anterior incision, ensuring OSSIOfiber[®] Trimmable Fixation Nail is fully seated in bone.

- Confirmation that the Trimmable Nail was fully inserted was determined through anterior incision direct visualization to the medial malleolus (Figure 5).

Tip: Intra-operative radiography can also be used to see if the Trimmable Nail is still proud. A faint shadow will be seen extending from the medial malleolus if so. The black plunger can be removed from the insertion sleeve and placed firmly on the Trimmable Nail and used as a tamp for final advancement into the tunnel.

Post-Operative Images



Figure 6: Post-operative radiographs showing well positioned TAR and secure OSSIOfiber[®] Trimmable Fixation Nail in medial malleolus.

- Prophylactic fixation of tibia was deemed complete and implantation of the TAR was followed. Final imaging showed a well-placed ankle implant with virtually undetected solid fixation of the medial malleolus with the Trimmable Nail. (Figure 6)

Top Technique Pearls

- Place the tibial cut guide prior to insertion of provided k-wire for the Trimmable Nail
- Utilize anterior incision for direct visualization of medial malleolus
- Ensure clear insertion sleeve is down to bone before insertion to support axial load on Trimmable Nail
- Seat Trimmable Nail within medial malleolus 3-4 mm to prevent back-out and allow for rapid cortical overgrowth

Post-Operative Protocol

The use of the OSSIOfiber® Trimmable Fixation Nail for prophylactic fixation of tibia in a TAR does not alter the post-operative protocol for the TAR. Surgeons should feel confident continuing with their preferred post-operative protocol for TAR.

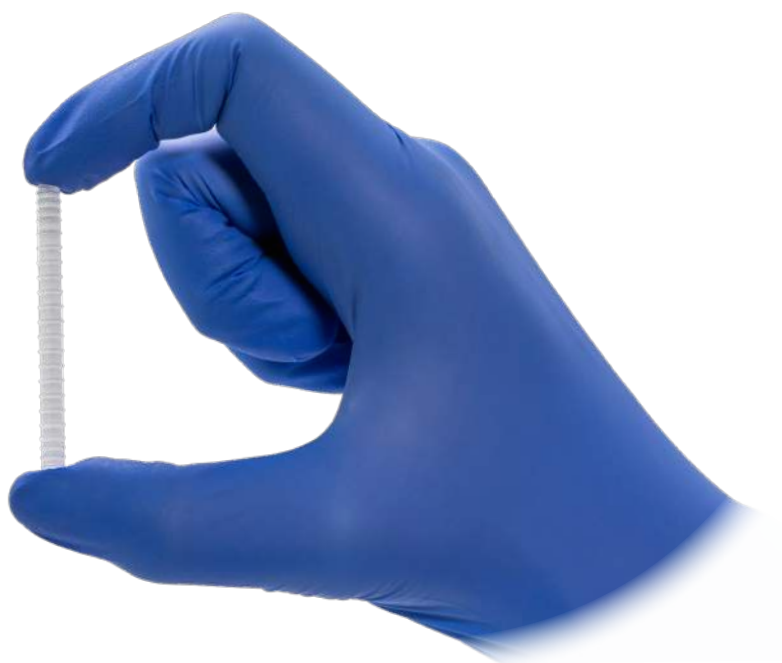
Reimbursement and Coding

Prophylactic fixation of tibia used with CPT code 27745.

HCPCS Code	Short Descriptor	Longer Description
27745	Reinforce tibia	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, tibia

Conclusion

The 4.0 x 50mm OSSIOfiber® Trimmable Fixation Nail provides a solid supportive construct to the medial malleolus for prophylactic fixation of the tibia in a total ankle replacement. It is a surgeon's preference to use one or two Trimmable Nails. Utilization of two Trimmable Nails may provide a stronger construct and rotational support to avoid breaks in the medial malleolar despite the fixation. These Trimmable Nails are virtually undetectable on radiographic images due to the density close to cortical bone and negate the need for hardware removal should a revision surgery ever need to be performed. With 10.5% of total ankle replacements requiring hardware removal or subsequent operative treatments¹, the OSSIOfiber® Trimmable Fixation Nails pose a valuable bio-integrative solution. Mechanically, OSSIOfiber® is best suited to work alongside bone as it heals. The elastic modulus is similar to cortical bone, bone attaches and grows into the surface in as little as 2 weeks², and progressive load transfer further supports bone regeneration during the post-operative healing period. Thus, OSSIOfiber® Trimmable Fixation Nails pose a better choice for the patient than metal compression screws, decreasing the risk of medial tibial fractures.



1. Vander Griend RA, Younger ASE, Buedts K, Chiodo CP, Coetzee JC, Ledoux WR, PinzurMS, Prasad KSRK, Queen RM, Saltzman CL, Thordarson DB. Total ankle arthroplasty: minimum follow-up policy for reporting results and guidelines for reporting problems and complications resulting in reoperations. *Foot Ankle Int* 2017;38:703–704.

2. Pre-clinical animal studies (in-bone implantation of OSSIOfiber® and PLDLA control in rabbit femurs). Data on File at OSSIO.

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