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# Use of intramedullary carbon fiber nail in hindfoot fusion: A small cohort study

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ABSTRACT

*Background:* Current literature on carbon fiber implant use in foot and ankle surgery is scant. The purpose of this paper is to report medium-term outcomes of hindfoot fusion using a carbon fiber intramedullary nail.

*Methods:* We retrospectively reviewed 30 cases of hindfoot fusion using carbon fiber intramedullary nail fixation between 2014 and 2017. We excluded revisions and cases with bulk allograft or ankle infection prior to surgery. We reviewed charts for length of followup, radiographic union, and complications.

*Results:* Eleven patients were included (6 females, 5 males; mean age = 52 ± 15 years; mean BMI = 29.0 ± 6.4 kg/m$^2$). Mean followup was 20 (range, 1.5–107) months. Nine of eleven cases achieved radiographic union while one case developed a complication requiring surgery. The mean time to union was 3 (range, 1.5–6) months.

*Conclusions:* Carbon fiber implants offer several theoretical advantages over traditional metallic implants. They can be used safely in foot and ankle surgery without concern for high failure or complication rate. Larger scale studies with longer followup are needed on this topic.



## 1. Introduction

Tibiotalocalcaneal (TTC) and tibiocalcaneal (TC) arthrodesis are salvage procedures for end-stage pathologies of the hindfoot such as ankle arthritis (rheumatoid, osteoarthritis or post-traumatic), Charcot arthropathy, advanced flatfoot deformities, talar avascular necrosis and even failed total ankle arthroplasty [1]. The procedure alleviates pain and joint instability by eliminating motion at the fused joints. Thus, it sacrifices joint motion for significantly reduced pain, allowing comfortable ambulation for the patient. The method of immobilization for these hindfoot fusion procedures has evolved over the years, from use of bone shaft grafts in the early 1900s to more engineered fixation constructs such as screws, plates (blade, locking, and non-locking), and intramedullary nails [2]. The optimal method of fixation remains debated however, due to the high rate of complications associated with each fixation method [1–3]. Despite some reports in the literature of nonunion rates in excess of 30%, most studies report on its favorability with patients and its achievement of union rates from 85% to above 90% [1,2]. As the understanding of bone biology and healing have evolved, various fixation methods as well as material types have been and continue to be explored in an effort to achieve improved and consistent union rates.

The use of carbon fiber implants is not new to the field of orthopedic surgery. Historically, carbon fiber has been utilized by many different industries due to its many physical qualities including high heat tolerance, corrosion resistance, and high fatigue strength [4]. When compared to traditional metals used in orthopedic surgery such as titanium and stainless steel, carbon fiber demonstrates increased biocompatibility, eliciting virtually no histologic immune response [5–7]. Mechanical studies have shown that carbon fiber has a modulus of elasticity closer to that of native bone than other commonly used implant materials such as cobalt chrome, stainless steel, or titanium [8]. This achieves greater stress sharing between the implant and bone, minimizing the risk for unfavorable periprosthetic bone reorganization [8,9]. Carbon fiber has also been shown to have a higher fatigue strength than other metal alloys such as stainless steel, cobalt, chromium or titanium, which allows it to withstand a greater number of mechanical stress cycles without failure [7,10]. The use of carbon fiber in orthopedic surgery also has other advantages such as reduced radiographic artifact, allowing easier and earlier visualization of fracture sites, arthrodesis sites and tumor resection sites

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when close followup is needed [11]. Zimel et al. assessed the occurrence of hardware artifact on CT and MRI in an oncologic patient population and found that the use of carbon fiber reinforced-polyetheretherketone (CF-PEEK) intramedullary nails prophylactically in the tibia and femur minimized image distortion immediately adjacent to the implant when compared to titanium nails [11]. This imaging advantage of carbon fiber implants is the basis of its widespread use in spinal lumbar interbody fusion surgery [12].

The many advantages to using carbon fiber implants in orthopedic surgery are becoming better known, leading to carbon fiber being utilized in the treatment of many different orthopedic conditions. Despite a well-documented use in spinal interbody fusion [12,13], its recent use in other areas of orthopedics remains sparsely documented until recently [11,12,14]. Early reports in the literature on the use of carbon fiber-based polymers in orthopedic surgery have focused on plate fixation for fractures of long bones including the tibia, femur, and humerus [6,15,16]. However, interest has risen for the use of carbon fiber-based intramedullary nails as evidenced by the increased number of publications on this topic [11,12,14]. While most of these studies have been limited to proximal to mid tibial and humeral fracture repair, its use in foot and ankle surgery has not been reported as an internal fixation device. There have been no reports in the literature on the use of carbon fiber implants for fusion procedures in foot and ankle surgery. Thus, our study on a recently available ankle arthrodesis CarboFix© intramedullary rod represents the first such study of carbon fiber material use in hindfoot fusion. The purpose of this paper is to report medium-term outcomes of this carbon fiber intramedullary rod for hindfoot fusion in a series of patients.

## 2. Materials and methods

All procedures were performed in accordance with the 1964 declaration of Helsinki and its later amendments or comparable ethical standards. We retrospectively reviewed 30 cases of carbon fiber nail hindfoot fusion (tibiotalocalcaneal and tibiocalcaneal) between 2014 and 2017. We excluded revisions, cases with prior tibia or hindfoot infection, cases with prior triple or subtalar arthrodesis, and cases in which bulk allograft was used. We examined patient charts for demographics including age, gender, body mass index (BMI), smoking and diabetic status, as well as comorbidities such as rheumatologic status and immune status. Charts and radiographs were reviewed for clinical course (including complications), and signs of radiographic union (three bridging cortices). Simple descriptive statistics were performed to obtain frequencies and means. All statistics were performed on SPSS 24.0 statistical software (IBM, Chicago, IL).

All operations were performed in the standard fashion [17]. The CarboFix Ankle Arthrodesis Nail© (CarboFix Orthopaedics Ltd., Herzeliya, Israel) was used for intramedullary fixation. After confirmation of the surgical site and sterile preparation, a thigh tourniquet was inflated to 280 mmHg. A lateral surgical incision was made starting approximately 8–10 cm above the lateral malleolus and extended along the shaft of the fibula, curving anteriorly towards the base of the fifth metatarsal. Full thickness skin flaps were developed until the fibula was visualized for anterior and posterior periosteal stripping. The skin flaps were developed along the length of the incision, exposing the ankle joint and sinus tarsus. Further tissue dissection was performed to allow visualization of the anterior ankle joint. The vascular structures supplying the talar neck were avoided. A sagittal saw was used to osteotomize the fibula at the level of the syndesmosis, allowing access to the lateral aspect of the tibiotalar joint. Using a periosteal elevator, the posterior and medial aspects of the tibiotalar joint are freed of soft tissue and distracted, bringing the articular surfaces of the ankle joint into visualization for cartilage removal.

Next, the foot was positioned neutrally in the sagittal plane with 5° of valgus and slight external rotation. Satisfactory positioning was obtained under fluoroscopic guidance and the joints were temporarily immobilized using Kirschner wires. A TTC guidewire was then placed under fluoroscopic guidance and a flexible reamer was used to drill the nail path through the calcaneus, talus and into the tibial intramedullary (IM) cavity. Once reaming was complete, the flexible reamer and the guidewire were removed and the CarboFix nail was brought to the field and inserted across the tibiotalocalcaneal joint, following manufacturer instructions. First, the proximal screws for the IM nail were placed using the targeting guide. Next, the talar screws were inserted. Compression was achieved across the tibiotalar joint using the internal compression mechanism screw (which allows for 7 mm of compression) and across the subtalar joint using an external nut tightened against the heel, forcing the calcaneus proximally. After adequate compression was obtained, the distal screws were placed across the calcaneus. The wound was then irrigated and closed in typical layered fashion. Postoperative instructions for patients included nonweightbearing for the first 6 weeks after the operation. Serial ankle radiographs were obtained at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year postoperatively. Radiographs were performed every month in patients whom the clinician was concerned for high chance of failure such as Charcot patients. Computed tomography (CT) scans were performed in patients with symptomatic suspected non-union.

## 3. Results

Eleven patients were included (6 females, 5 males) in this case series after application of the selection criteria. Three patients were active smokers while four patients were diabetics (HbA1C presented in Table 1). None of the patients had underlying immune rheumatologic conditions such as lupus or rheumatoid arthritis. The mean age of participants was $52 \pm 15$ years while the mean body mass index was $29.0 \pm 6.4$ kg/m$^2$ (Table 1). Mean follow-up was 20 (range, 1.5–107) months. Surgery was indicated for post-traumatic arthritis in five patients, Charcot arthropathy in five patients, and failed ankle arthroplasty in one patient (Table 2). Nine of eleven cases achieved radiographic union with a mean time to union of 12 (range 6–24) weeks. Pre-operative and post-operative images are presented in Figs. 1–4 for patients 11 and 25 who achieved radiographic union. One Charcot patient who was followed for 18 weeks developed a stable pseudoarthrosis without evidence of hardware failure. One patient with nonunion was lost to followup after the 6-week postoperative visit. One patient underwent an irrigation and debridement eight months after the procedure with complete hardware removal three months after for a persistent sinus tract despite radiographic signs of fusion.

**Table 1**
Summary of patient characteristics including Hemoglobin A1C (HbA1C) levels.

| Study ID | Age | Gender | BMI (kg/m$^2$) | Smoking | Diabetes | HbA1C (%) |
|---|---|---|---|---|---|---|
| 1 | 30 | F | 22.07 | Yes | No | – |
| 4 | 60 | F | 31.6 | No | No | – |
| 5 | 53 | M | 26.6 | No | No | – |
| 6 | 47 | F | 37.11 | Yes | No | – |
| 10 | 56 | F | 32.47 | No | No | – |
| 11 | 63 | M | 28.73 | No | No | – |
| 12 | 46 | F | 41.56 | Yes | No | – |
| 13 | 75 | M | 29.63 | No | Yes | 7.4 |
| 25 | 68 | M | 24.37 | No | Yes | Not obtained |
| 26 | 30 | F | 20.6 | No | Yes | 15.3 |
| 27 | 43 | M | 24.52 | No | Yes | 10 |

**Table 2**
Summary of patient surgical indications and union and complication outcomes.

| Study ID | Surgical indication | Followup (weeks) | Union | Union time (weeks) | Complications |
|---|---|---|---|---|---|
| 1 | Post-traumatic arthritis | 6 | No | – | None |
| 4 | Charcot arthropathy | 428 | Yes | 15 | None |
| 5 | Post-traumatic arthritis | 48 | Yes | 13 | None |
| 6 | Failed ankle arthroplasty | 49 | Yes | 10 | Draining sinus |
| 10 | Charcot arthropathy | 90 | Yes | 11 | None |
| 11 | Post-traumatic arthritis | 88 | Yes | 24 | None |
| 12 | Post-traumatic arthritis | 51 | Yes | 8 | None |
| 13 | Charcot arthropathy | 11 | Yes | 11 | None |
| 25 | Charcot arthropathy | 53 | Yes | 12 | None |
| 26 | Charcot arthropathy | 18 | No | – | None |
| 27 | Post-traumatic arthritis | 26 | Yes | 6 | None |


**Fig. 1.** (A) Pre-operative anterior–posterior (AP) radiograph for patient 11. (B) Pre-operative lateral radiograph for patient 11.

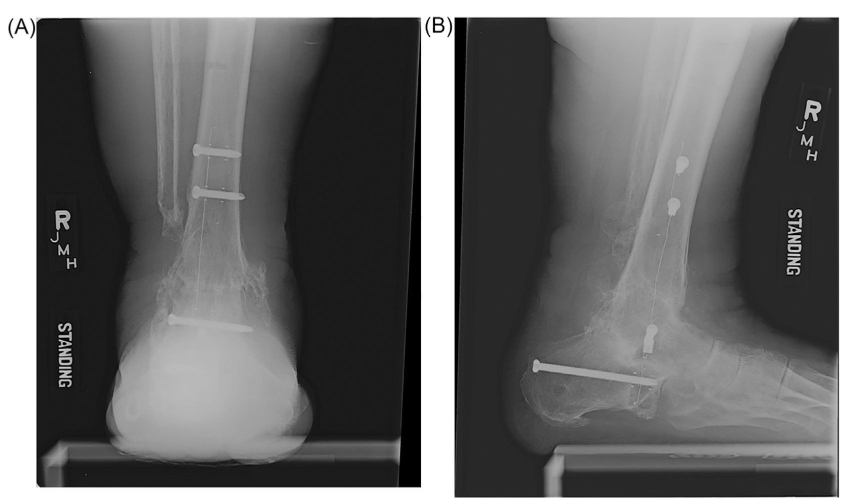


**Fig. 2.** (A) 10 month post-operative AP radiograph for patient 11 showing fusion across the tibiotalar and talocalcaneal joints. (B) 10 month post-operative lateral radiograph for patient 11 showing fusion across the tibiotalar and talocalcaneal joints.

## 4. Discussion

Various materials have been used as internal bone fixators including stainless steel, titanium, cobalt, and even bone [12,18,19]. The addition of carbon fiber materials to this list of materials in orthopedic surgery dates as far back as 1977 where Jenkins et al. utilized carbon fiber material experimentally in rabbits as tendon replacement and scaffolding [5,20]. In such early uses of carbon fibers as soft tissue scaffolds, the material was found to induce virtually no immune response [5]. Early biomechanical studies

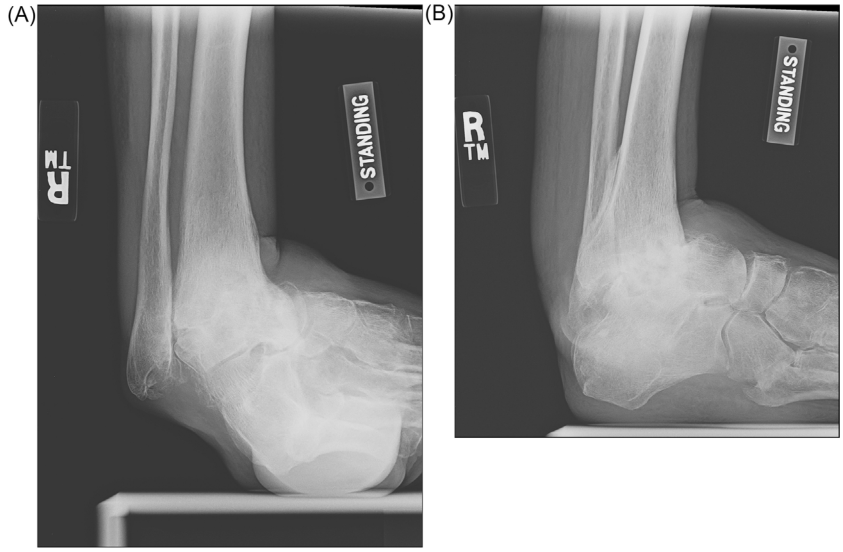


**Fig. 3.** (A) Pre-operative anterior–posterior (AP) radiograph for patient 25. (B) Pre-operative lateral radiograph for patient 25.


**Fig. 4.** (A) 8 month post-operative AP CT for patient 25 showing fusion across the tibiotalar and talocalcaneal joints. (B) 8 month post-operative lateral CT for patient 25 showing fusion across the tibiotalar and talocalcaneal joints.

comparing carbon fiber-based composite materials to traditional metal orthopedic implant materials demonstrated that carbon fiber implants had improved fatigue strength, and greater modulus of elasticity similarity to bone [6,12,21,22]. With increased recognition of the biocompatibility (immune and mechanical) of carbon fibers with human tissue, carbon fiber-based materials began being developed for use as internal bone fixators in the early 80s [5,6,16,23].

Much of the interest in carbon fibers and their composite materials such as carbon fiber polyetheretherketone (PEEK) and carbon fiber epoxy resins grew from their inherent biomechanical properties that were hypothesized to improved bone healing outcomes in fracture patients [16]. There was a recognition that not all fractures must be treated with absolutely stable, rigid constructs (to achieve primary bone healing) but that some fractures were amenable to semi-rigid biological fixation (achieving secondary bone healing) [16,22]. Secondary bone healing using semi-rigid plate fixation avoided the prolonged stress shielding of bone that resulted in osteoporotic bone, decreasing the risk for peri-implant re-fracture [6,16,23]. In addition, the prolonged need for rigid fixation to achieve primary bone healing exposed metallic alloys to extended stressors that carried significant risk for fatigue failure. Thus, carbon fiber-based polymers circumvented these issues by possessing qualities of smaller modulus of elasticity (less stiffness and stress shielding) and greater fatigue stress endurance while still providing adequate tensile strength for fracture immobilization [18].

Our study reports radiographic union in nine of eleven cases of tibiotalocalcaneal arthrodesis using the CarboFix© arthrodesis rod, with one complication encountered. These union rates (82%, 9/11) and infection rates (9%, 1/11) are consistent with a meta-analysis of tibiotalocalcaneal arthrodesis using intramedullary nail that reported an average union rate of 86.7% (556/641) and an infection rate of 8.4% (54/641) [3]. Similarly, union rates reported with other implant types range from 82% to 100%, with a few studies reporting nonunion rates above 30% [1–3]. Of note, the two nonunions reported in this study occurred in patients with high risk for nonunion. One had a hemoglobin A1C of 15.3% and developed a stable pseudoarthrosis while the other patient was one of three smokers. The one complication encountered in this patient series was a chronic draining sinus tract that developed in a 48-year-old female (BMI = 37.1 kg/m$^2$) whose surgical indication was a failed ankle arthroplasty from thirteen years prior. The patient's early postoperative course was complicated by persistent ankle pain despite radiographic signs of consolidation across the fusion sites at 3 months. At 8 months, a draining wound had developed on the lateral aspect of her foot at which point empiric antibiotics (Bactrim and Ciprofloxacin) were initiated. The patient underwent irrigation and debridement with partial hardware removal and complete hardware removal a few months after due to recurrence of the wound. The patient was eventually discharged in stable condition and underwent 12 total weeks of antibiotics with resolution of her infection. Given that carbon fiber implants are reported as showing minimal to no tissue irritation as well as immunogenicity, it is unlikely that development of this complication was related to the material of the surgical implant. Instead, it most likely reflects this patient's past surgical history of failed ankle arthroplasty and chronic narcotic use. Thus, this study provides evidence that carbon fiber implants can be used safely in ankle arthrodesis procedures without greater concern for failure or complication than is expected for other implant types.

Recent literature has begun to examine the idea of excessive stiffness of fixation constructs [24,25]. These reports point out the need for an optimum amount of flexibility in fixation constructs to achieve timely and efficient fracture union through secondary bone healing. With recent advances in implant material science, carbon-fiber based implants have become of interest in achieving this optimum level of fusion site flexibility [12,18]. Since carbon fiber implants have a more similar modulus of elasticity to bone than other implants, they have a theoretical advantage of achieving bone healing more rapidly [12,16,22,23]. While we did not test this hypothetical statement, our average time to union of 12 weeks (3 months) is well ahead of the time to union (4.5 months) reported in a 2011 meta-analysis of intramedullary nail fixation in tibiotalocalcaneal arthrodesis [3]. Perhaps, future prospective studies can be designed to test the hypothesis that carbon-fiber based implants will impact the time to union.

The radiolucency of carbon fiber implants is another advantage that has been discussed in the literature [11]. Since carbon fiber implants may allow earlier and easier visualization of surrounding structures, this advantage may be useful in orthopedic surgery besides the need to monitor musculoskeletal tumor progression as described by Zimel at al. [11]. One may expect that use of carbon fiber implants for fracture fixation will allow better visualization of fracture lines, allowing a more detailed observation of fracture consolidation as well as earlier detection of nonunions. Our reported time to union may in fact be a result of this phenomenon.

A limitation of our study is the small sample on which our outcomes are reported. However, introduction of new approaches and materials in human subjects must always be approached cautiously, utilizing small samples to establish safety and feasibility of larger scale studies. Another limitation is the lack of CT confirmation of unions for every patient. However, clinical notes and radiology reports were satisfactory for determining union retrospectively. Although operative procedures would not have been performed differently if the study were prospectively designed, a prospective design would have allowed the study of additional variables that may be influenced by implant material type. A few such variables are maximal callus volume and time to radiographic union.

## 5. Conclusion

Carbon fiber implants are effective internal fixators in foot and ankle surgery. They possess unique biomechanical properties such as increased fatigue strength and greater flexibility compared to traditional metal implants. In addition, their low image artifact properties make them suitable for superior radiologic visualization and followup. Our study reports their safe and effective use in hindfoot fusion for a small cohort. Therefore, we recommend larger studies to establish their safe and effective use in foot and ankle surgery.

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## Conflict of interest

None.

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