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Review Article

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Longitudinal Follow-Up of 101 Distal Fibula Fracture Treated with Carbon Plate

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Introduction

Fractures of the distal fibula are remarkably common fractures, with an incidence of 100.8 per 100 000 people per year, estimated for 9% of all fractures [1]. Frequently stable fibula fractures are treated conservative and non-operative treatment is the first-line. Notwithstanding, there are three primary implant options when Operative Treatment (ORIF) is required: traditional nonlocking plates, locking plates and Intramedullary Nails (IMNs). In addition to the constructs mentioned above, frequently interfragmentary lag screws can also be applied. Nevertheless, operatively treated fibula fractures frequently produce poor outcomes, with as many as one-fifth having unsatisfactory long-term results [2]. The treatment of choice for unstable distal fibula fractures for open reduction and Internal Fixation (ORIF) is applying plates and screws [3]. These implants are typically formed of stainless steel or titanium alloys. However, these metal implants' limitations include a limited fatigue life, mismatch of modulus of elasticity with the bone, and increased stiffness, which may conduct to reduced secondary bone healing [4,5], potential for wear debris, corrosion, and radiodensity, that can preclude accurate radiographic visualization [6].

Carbon fiber implants have been in use for several years and, although they have been initially used in spine, humerus, and femur internal fixation, they possess many advantageous properties that may also benefit fibula fracture fixation. Carbon fiber implants have a modulus of elasticity comparable to the bone's elasticity modulus, which acts to decrease stress shielding [7,8]. Carbon fiber also has increased biocompatibility compared to metal, which drives to a minimum histological cellular response when studied in vitro and *in vivo* [7,8]. Carbon fiber has greater fatigue strength than both titanium or stainless steel, suggesting that it can withstand more significant stress for a given amount of cycles without implant failure [7,8]. Additionally, it is X-ray permeable to X-Ray, which helps in the radiographic visualization of the fracture site, during the treatment of associate lesions and postoperative follow-up [7,8]. Still, to date, outcomes of carbon fiber plating for fibula fracture fixation have not been studied clinically with a significant cohort. We hypothesized that carbon fiber plates produce results, for ankle fracture fixation, similar to other metal implants, while providing the critical advantages described above.

Materials and Methods

This longitudinal study followed 101 patients who underwent fibular ORIF with carbon fiber plates from January 2012 to June 2020, with a minimum follow-up of 12 months. Of these 101 fibula fractures, 84 were Weber B fractures, and 17 were Weber C fractures. The main outcomes were the radiological union at 12 months and the complication rate. Each fibula was fixated practicing a direct lateral approach to the fibula, with the Carbo Fix distal fibula plate (Carbofix Orthopedic Ltd, Herzeliya, Israel). Three trauma-surgeon performed all operations. Union was defined as a radiographic sign of linking bone on 3 of 4 cortices (medial/ lateral cortex on anteroposterior view and anterior/ posterior cortex on lateral view). Nonunion was determined as no sign of fusion at a follow-up appointment greater than 1 year postoperatively. Complications were: infection, hardware removal involving carbon fiber plates failure (excluding cases of isolated screw removal as a result of pain), or revision surgery.

A Fisher exact test was used to compare the complication rate in the present study to a 20% "population" complication rate (based on the 12%-30% complication rate reported in the literature) [9-11].

All patients were evaluated at 6 and 12 months follow-up with:

- OMAS (Olerud-Molander Ankle Score). It is a functional evaluation scale from 0 (totally impaired) to 100 (completely unimpaired) and is based on nine different objects: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports and activities of daily living.
- AOFAS Ankle-Hindfoot Scale is a clinician-based score that measures results for the foot and ankle. The survey consists of nine items that are distributed over three categories: Pain (40 points), function (50 points) and alignment (10 points). These are all scored together for a total of 100 points.
- VAS scale;
- ROM (Range of Motion)

All patients were evaluated at 6, 12 months follow-up with

X-ray recording the lateral malleolus displacement and union from an expert radiologist.

Surgical Technique

The surgery was performed under sub-arachnoidal anesthesia, with the patient placed supine and a massive bump located under the ipsilateral hip. A tourniquet was placed on the upper thigh and inflated to 250 mm Hg after administering prophylactic antibiotics and leg exsanguination. A longitudinal, direct lateral incision was performed over the lateral edge of the fibula. The superficial peroneal nerve was preserved at the proximal aspect of the incision. Once the fracture was encountered, hematoma, periosteum, and early fracture callus were removed from the fracture terms and the fracture approximated using reduction clamps. If the fracture was tractable to titanium interfragmentary lag screws, these were then placed perpendicular to the fracture plane. The carbon fiber plate was then placed using radiographic guidance to assure precise positioning and fracture reduction. Screws were then placed starting with cortical screws to reduce the plate to the bone and locking screws were used distally in the metaphyseal bone. The wound was irrigated and closed in standard layered fashion respecting deep tissue, subcutaneous tissue, and skin. All patients were placed in a walker brace and made non–weight-bearing. They were all seen at two weeks postoperatively for a wound check and suture removal. At the 6-week visit, patients were typically transitioned to a walking boot with instructions for progressive weight bearing depending on the radiographic evidence of healing. The carbon fiber plate (CarboFix Distal Fibula Plate, CarboFix Orthopedic Ltd, Herzeliya, Israel) is radiolucent, except for a thin radiopaque tracer on the outside edge of the implant to aid in positioning. The screws are titanium, and each plate hole can accommodate either locking or cortical screws.

Results

The average age of the 101 patients involved in this research was 51.4 years at the time of surgery (range = 16 to 81 years). The patient population demonstrated a slight female proclivity, with 56,5% of the patients being female. The average body mass index of the patients was 24.9 (range = 16.3 to 42) kg/m2. Of the 101 patients, 15 were diabetic (15,1%), and 33 were smokers (33,3%). The mean follow-up time for this patient population was 18 months (range = 12 to 24 months). No more follow-up was executed over 2 years. The rate of union in the series was 100%. The overall complication rate in the series was 8%. These complications included 1 removal operation for failure of proximal holes of the plate and 7 infections. The patient who required revision surgery did so 4 months postoperatively because of rupture of the plate. It is to be noted that the patient had obesity, hypertension, tobacco use, and alcoholic neuropathy. The infected patients had a past medical history of obesity and hypertension associated with tobacco use. This patient underwent irrigation and debridement before 6 weeks and remove the plate before 3 months postoperatively, after which all infection resolved without further complications.

The overall 8% complication rate was not significantly different from a "population" complication rate of 20% ($p = .09$).

No nonunion was verified at 12 months. Results of the subjective score are reassumed in the Table1 below:

	OMAS	AOFAS	VAS
6 months FU	81.1±11	78.3±8	1.9±2
12 months FU	90.3±18	89.6±12	1.2±1

Table 1: Results of the subjective score are reassumed.

Discussion

Fibula fractures represent a challenging field of orthopedics because of the natural anatomy of the distal lateral leg. The poor skin cover around the distal fibula1 sets patients undergoing surgical fixation at enhanced risk for wound contamination, hardware protrusion, and other soft-tissue difficulties that harm long-term outcomes [12]. The procedure of choice for unstable fibula fractures is ORIF with the application of plates and screws [3]. Metal hardware, such as titanium, are frequently used for these fractures and have been proved to produce corrosion particles and fail by mechanisms commonly associated with surface interactions on bone that develop inflammation with fibrous aseptic loosening or infection [13]. Before-mentioned complications have an adverse long-term effect on outcomes [12] and, in some cases, need the removal of the implant [14]. Unluckily, such problems are moderately common, as evidenced by a 2011 meta-analysis of 1822 operatively treated distal fibula fractures, which affirmed that more than one-fifth of optimally reduced fractures fail to produce "good" results concerning clinical and radiological outcomes [2]. Carbon fiber plates were used in this group to obtain an optimal solution by combining the fixation of plating with the improved biocompatibility and osseointegration properties of the material [14,15]. These features theoretically lower complications by reducing the inflammatory response caused by the implant, whereas the limited stiffness of carbon fiber [15] probably increases bone formation [16,17]. We found a minimal inflammatory reaction in tissue underlying removed carbon fiber implants.

Less-invasive systems have been used to fix distal fibula fractures, but these techniques are not without drawbacks. For example, the use of only interfragmentary lag screws is minimally invasive, it provides less rigid fixation and requires postoperative cast immobilization [9] resulting in a later return to regular gait [17,18]. Intramedullary nails have also been practiced because of their mini-incision technique and low-profile implants, which apparently reduce the risk of wound complications and soft-tissue irritation caused by hardware prominence [3]. Nevertheless, studies have shown complication rates to yet be almost high (up to 20.4%), with an increased rate of fibular shortening with IMN use [3,18]. This case series found the fusion rate for carbon fiber plates to be 100%. The complication rate for carbon fiber plates was 8%, similar to described rates for standard metal plates (12.0%-30.0%) [9-13] and IMNs (10.6%-20.8%) [18-20]. Even the infection rate (7%) was similar to most studies of surgically treated ankle fractures (5.4%-17.6%) [20,21]. Additionally, carbon fiber plates are an affordable option for the fixation of ankle fractures because, in our structure, this plate has the exact cost of the ones made by other materials.

Compared to titanium plates, the possible theoretical advantages of carbon fiber plates have been illustrated through numerous studies and reports in recent years. Carbon fiber has a lower Young's modulus of elasticity than metal and, consequently, provides stress to be applied more uniformly across the plate-bone interface. Consequently, internal fixation of fractures with carbon fiber plates has been proposed to stimulate better healing than metal plates in previous researches [16]. Metal implants have a great Young's modulus (between 110 GPa and 220 GPa) compared with bone (17-20 GPa) [22]. The difference in modulus leads to a stress shielding effect following Wolff's law. This principle describes a biological mechanism in which bone reshapes in response to the mechanical load placed on it, such that it is better suited to handle subsequently applied forces. With metal plates, the fractured bone may be shielded from applied forces, resulting in irregular healing and weaker bone [22-24]. To minimize these complications, carbon fiber composites have been considered as an alternative material and have been shown to decrease stress shielding [16,22,24]. A prior study of tibial fractures in a rat model found carbon fiber plates to be a more reliable bone implant material than metal plates because their density is comparable to that of bone, which produces better stress transfer, and their electrical properties enhance tissue formation [14]. In this study, researchers showed that rats that received carbon fiber rods achieved a greater Percentage Bone Area (PBA) after 14 days than did rats that received titanium alloy implants. For the carbon fiber implant, the PBA was shown to be 77.7 ± 7.0 at 0.1 mm from the implant, whereas the titanium composite implant only produced PBA to be 19.3 ± 12.3 at 0.1 mm from the implant ($P < .00000001$). These results were also validated by image characterization from histological slides, which depicted osteoinductive reactions for the carbon fiber implants superior to titanium alloy implants. Great bone formation occurred along the total carbon fiber implant surface, whereas the titanium alloy showed only small fragments of bone integrating along the implant's surface. Previous studies demonstrated that carbon fiber implants have greater osteointegration because of their intrinsic biocompatible conductivity compared to metal ones [14].

Carbon fiber plates have technical advantages over metal implants during a patient's surgical treatment and postoperative course. They are radiolucent, which provides easier radiographic visualization of other fractures that have to be treated during the operation and help evaluate bone formation in the fracture area that is not possible with radio-opaque metal plates [16,22]. In the Figure 1 below, we better highlight this concept: we are faced with a 44b3 fracture with Volksmann's fragment. The surgical times were respectively: synthesis of the trans-syndesmotic fibula fracture with carbon plate, synthesis of the Volkmann's fragment with plate and screws, and finally, the synthesis of the small medial malleolus fragment. Using a radio-translucent carbon plate allowed us easy visualization of the associated lesions, permitting rapid synthesis after the fibula had been treated.

Figure 1: Carbon fiber plates.

Therefore, unions can be evaluated more precisely to allow for better clinical judgment and patient care [16]. Additionally, cold welding, a process where 2 metals become firmly welded together without heat, occurs with metal implants if a screw becomes cross-threaded. Cold welding does not occur with carbon fiber plates and permits easier hardware removal if it is required. Carbon fiber implants present another advantage over metal alloy implants because of the trend of metal implants to corrode and deteriorate over time. Various studies of hip arthroplasty implants have shown that metal alloys degrade, leading to issues such as osteolysis, rapid mechanical loss, hydric bubble aggregation, and formation of a hole between the tissue and the implant [25]. Additionally, records have shown that a substantial volume of material can be lost from metal hardware due to fretting or corrosion [26-28]. Although this complexity has not been described in distal fibular plating, carbon fiber implants have a theoretical advantage because they have not been shown to corrode or degrade over time. In addition, carbon fiber seems not to be as susceptible to implant failure from fatigue stress as metal plates. Diverse studies have demonstrated the pitting of metal implants that drives to corrosion, leading to crack nucleation and fatigue fracture [6,29,30]. In addition, fretting, corrosion and high tensile stress are all linked in the crack initiation process, making metal implants more prone to premature fracture due to fatigue stress [30]. Although these cited works primarily pertain to joint arthroplasty, carbon fiber's increased resistance to fatigue stress represents another potential benefit.

Finally, metal implants are more prone than carbon fiber to cause implant reactions that can be the leading cause of unexpected early failures. Some recent research has shown that metal alloy implant debris is a primary cause of early failure in hip arthroplasty [31,32]. It is well established that metal debris contributes to the failure of implants by producing a long-term innate immune inflammatory response. This response penetrates in the bone-implant interface, finally leading to the loosening of the implant [32,33]. Although this study explained valuable clinical information about the use of carbon fiber plates in fibula fracture fixation, it was limited because of a relatively short follow-up time. Further studies of carbon fiber implants with increased follow-up times are recommended to assess their reaction to increased cumulative stress and more significant opportunity for higher peak loads. Although the study did find complication rates associated with carbon fiber plates (8%) to be much lower than the 12% to 30% reported for metal plates [9,11,12] this difference did not achieve statistical significance (P = .09) from a "population" rate of 20%, presumably because of a not appropriate total study population. Although our results are in line with those highlighted by Guzzini, et al. [34], we did not find the carbon plate treatment to be the most expensive because, although no in-depth cost analysis was performed, carbon hardware is paid as much in our facility as that of other alloys.

Conclusion

This research is the first to examine carbon fiber plates as an alternative to metal plates for use in ORIF of fibula fractures on a big scale and supports them as a viable option. Carbon fiber plates demonstrate union and complication rates comparable to those of alternative metal constructs. Additionally, several theoretical advantages of carbon fiber plates exist, including their intrinsic radiolucency, similar modulus of elasticity to bone, biocompatibility, and increased fatigue strength. However, we do recognize that full clinical appreciation of the biomechanical properties of carbon fiber plates may not be realized for years after implantation. Further studies are needed for extended follow-up and inclusion of larger patient cohorts.

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