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ORIGINAL ARTICLE

A Preliminary Comparison Suggests Poor Performance of Carbon Fiber Reinforced Versus Titanium Plates in Distal Femoral Osteotomy

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Abstract *Background:* Carbon fiber-reinforced (CFR) polymer implants have theoretical advantages over titanium plates. *Questions/Purposes:* The aim of the present study was to assess our early outcomes with CFR plates in lateral opening-wedge distal femoral osteotomy to correct valgus lower limb malalignment. We asked the following: (1) Did the CFR polymer implant change time to union when compared with the titanium implant? (2) Did the incidence of displacement of medial cortical fractures differ between the implants? (3) Did the incidence of complications differ between the two techniques, and did other factors, such as bone graft material used, affect healing? *Methods:* A retrospective review of 16 limbs treated with an opening-wedge distal femoral osteotomy for genu valgum using either titanium ($n = 10$) or CFR plates ($n = 6$) was performed. Patient and clinical covariates as well as the primary outcome of time to union and secondary outcome of fracture displacement were collected and analyzed. *Results:* Those treated with CFR plates had longer times to union than did those in the titanium-treated group (median, 121.5 vs 81.5 days, respectively). The incidence of fracture displacement was higher in the CFR plate-treated group (CFR, $n = 5/6$; titanium, $n = 1/10$). Although the CFR plate-treated group had a 33% nonunion incidence while the titanium group had no nonunions, the study lacked the power to show significance. Bone graft material used did not affect outcome. Complication rates were higher in the CFR plate-treated patients. *Conclusion:* The CFR plate was associated with a longer time to unite and higher fracture displacement rate than the titanium plate. As this is a retrospective case series, further research is required to confirm these results and clarify best practices in plating of distal femoral osteotomy for deformity correction.

Level of Evidence: Level III: Therapeutic Study

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Introduction

Lateral opening-wedge distal femoral osteotomy for the correction of genu valgum, with stabilization using a lateral stainless steel or titanium plate, has been a predictably successful surgery with high union rates and accurate correction of limb alignment [1, 3, 4, 12, 14–16, 22]. The metallic plates used in these series are strong [7] and malleable, offer multiple locking options, and are familiar to surgeons. However, these metal implants also bring disadvantages, including implant pain [8], cold welding, radio-opacity (making the interpretation of osteotomy healing on lateral radiographs difficult), and the possibility that they are too stiff for optimal bone healing [8].

Carbon fiber-reinforced (CFR) polymer implants offer potentially improved wear properties and reduced radiographic artifact, which, in turn, may allow earlier weight bearing due to more accurate radiographic assessment. CFR-polyetheretherketone (PEEK) as a biomaterial has attracted trauma [20], sports, and spine surgeons [6, 19]. Although CFR-PEEK implants have theoretical advantages, the clinical track record is less robust than that of stainless steel or titanium plates. Early clinical results from CFR-PEEK have been mixed, albeit with limited comparability between studies. Some studies found generally superior results with carbon plates in the upper extremity [17, 20] with others reporting generally inferior results in the lower extremity [2, 10]. In our own experience, interest in the improved biomechanics of the CFR polymer plates, including less stiffness than titanium and a modulus of elasticity close to that of bone and prolonged fatigue strength [9], led to the use of these implants in several sequential surgeries. A perception that these plates were causing delayed healing and nonunion led to a change back to titanium implants and was the impetus for this investigation.

The aim of the present study was to assess our early outcomes with CFR polymer plates in lateral opening-wedge distal femoral osteotomy to correct valgus lower limb malalignment. The specific questions asked were the following: (1) Did the CFR polymer implant change time to union when compared with the titanium implant? (2) Did the incidence of displacement of medial cortical fractures differ between the CFR polymer and titanium implant group? (3) Did other factors, such as graft material, interact with plate material in a clinically meaningful way?

Materials and Methods

This is a retrospective case series including 16 limbs (15 patients) operated on for correction of genu valgum deformity. Patient and deformity were comparable prior to surgery (Table 1). None of the patients were smokers. Of the 16 limbs, 10 were treated with titanium plates and the remaining 6 with carbon fiber plates.

Preoperative planning was done to measure the deformity and determine the ideal size of the opening wedge needed [5] (Fig. 1a–c). The patients were indicated for and underwent distal femoral lateral opening-wedge osteotomy stabilized with plate and screw fixation. A goal of this technique included maintaining the medial femoral cortex intact to improve osteotomy stability (Fig. 2a, b). The plate used was either a titanium locking plate with 4 proximal and 5 distal locking screws (TOMOFIX®, Synthes, West Chester, PA, USA) or a CFR polymer plate with 4 proximal and 5 distal locking titanium screws (CarboFix, Herzliya, Israel). The choice of plate was dictated by a change in practice. Titanium plates were used for several surgeries. An interest in CFR polymer plates led to a change in practice, whereby all patients received CFR plates. This series follows 16 patients who received all titanium plates for the first 10 cases and then all CFR polymer plates for the next 6 cases. One patient had a titanium plate placed then had the contralateral side operated on during the CFR plate era and was therefore stabilized with a CFR plate. All patients had grafting of the open-wedge site after plating. The graft material used was either allograft cancellous, freeze-dried chips mixed with demineralized bone matrix (DBM) putty (Grafton®, BioHorizons, Birmingham, AL, USA) or bioactive glass morsels (Prosidyan, Warren, NJ, USA). The choice of graft material was haphazard. Patients often experienced fracturing of the medial cortex intraoperatively (Fig. 3). These cases were not treated any differently than those patients with intact cortices. Patients were given 2 doses of tranexamic acid intravenously: 1 g at the initiation of surgery and 2 g 3 h later. No tourniquet was used. Drains were not used routinely.

Venous thromboembolic prophylaxis was initiated on postoperative day 2, consisted of rivaroxaban 10 mg daily, and was continued for 2 weeks. Protective weight bearing of 30 lbs. was started immediately after surgery and was continued for 3 months. Patients used a continuous passive motion machine for the knee while in the hospital to encourage early mobility. Nonsteroidal anti-inflammatory medication was not allowed postoperatively. Patients were followed at regular intervals: 2 weeks, 6 weeks, 10 to 12 weeks, 14 to 16 weeks postdischarge, and monthly thereafter until full healing was noted on radiographs. Postoperative fracture and displacement of intraoperative fractures was monitored during these visits (Fig. 4). If full healing was seen at the 10- to 12-week visit, full weight bearing was permitted. If full union was not seen at this visit, weight bearing was progressed to 50% until complete healing was noted. Those who did not unite by 6 months were considered to have a nonunion of the osteotomy with no potential for progression of healing without surgical intervention (Fig. 5a–c).

After institutional review board approval was granted, a retrospective review of a consecutive series of similar surgeries using 2 different implants at a single institution with a single surgeon was conducted. All data elements were collected by a review of medical records and radiographs. All data were available. Variables recorded included age, sex, body mass index (BMI), knee range of motion (ROM), mechanical axis deviation (MAD), lateral distal femoral angle (LDFA), and total mechanical valgus deformity, type of plate used (CFR polymer or titanium), graft material used (bioactive glass or allograft), presence or absence of fracture, whether the fracture was displaced, and time to union in days. Knee ROM, MAD, and LDFA were collected both pre- and postoperatively. The primary outcome measured was time to union. Time to union was censored at 180 days, at which point additional procedures are considered as part of routine practice. In this study, "fracture displacement" refers to shifting of the fractured medial cortical ends through settling/shortening or translation by greater than 2 mm as seen on plain film radiographs (Fig. 3). Patients were marked as having complications if they had any of the following events: displaced fracture, failure to heal the osteotomy by 6 months, implant failure, venous thromboembolism (VTE), wound infection, or loss of alignment. A minimum

Table 1 Demographics stratified by plate (preoperative values)

	CFR plate (n = 6)	Titanium plate (n = 10)	p value
Age (median, IQR)	39.50 (29.5, 46.75)	27.50 (20.5, 43.75)	0.302
Sex, female (%)	6 (100)	7 (70)	0.250
BMI (median, IQR)	33.50 (28.25, 35.00)	29.50 (24.25, 34.00)	0.586
Laterality (right %)	4 (66.7)	3 (30.0)	0.302
Valgus, in degrees (median, IQR)	7.50 (6.25, 8.00)	7.50 (5.50, 9.50)	0.913
Lateral MAD, in mm (median, IQR)	18.50 (18.00, 25.00)	23.00 (17.00, 31.00)	0.637
LDFA, in degrees (median, IQR)	84.00 (83.00, 85.75)	81.00 (79.25, 84.75)	0.114
Knee extension, in degrees (median, IQR)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.943
Knee flexion, in degrees (median, IQR)	125.00 (120.00, 133.75)	125.00 (112.50, 130.00)	0.340

CFR carbon fiber reinforced, *IQR* interquartile range, *BMI* body mass index, *MAD* mechanical axis deviation, *LDFA* lateral distal femoral angle

of 180 days of follow-up was available for all patients, and all patients were followed to union. Two-year follow-up was not necessary, as this is a time-to-union analysis and not a functional outcome assessment.

The primary outcome, time to union following index surgery, was plotted as the Kaplan-Meier (KM) curves of time (in days) to event (union) or censoring. The primary outcome was compared across groups (implant material, fracture displacement, and complication) using the log-rank test. Consistent with the convention in survival analysis, time to event was summarized as the median time to event. Given the small sample size, nonparametric group summaries were selected (median and interquartile range (IQR)). Consistent with this choice of summary statistics, secondary outcomes ratios were compared with Fisher's exact test, and group medians were compared with the Mann-Whitney U test. Although the overall sample size was small, as a sensitivity analysis, those cases with the most profound primary outcomes (that is, the single shortest and single longest time to union) were excluded and a parallel analysis was performed on this limited reduced sample. No results differed significantly in this sensitivity subsample analysis, and thus, these results are not shown.

Results

Those treated with CFR plates had longer times to union than those treated with titanium plates (median, 121.5 vs 81.5 days, respectively (Fig. 6); KM log-rank test, p = 0.0015) and a suggestive, though insignificant, higher nonunion rate in the CFR polymer and titanium plate-treated

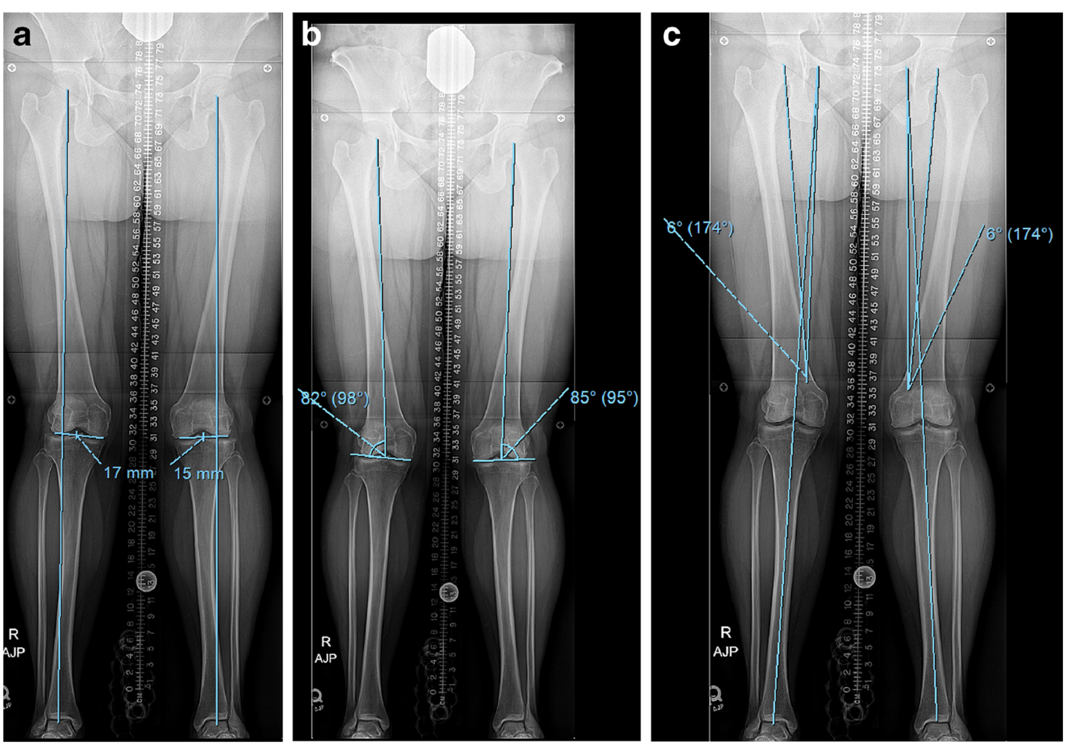

Fig. 1. **a** This 51-in. standing, bipedal radiograph demonstrates bilateral genu valgum with lateral mechanical axis deviations. **b** The joint orientation angle (LDFA or lateral distal femoral angle) has been measured bilaterally. (Normal mechanical LDFA is 88°; range, 85°–90°). **c** The preoperative planning for correction of genu valgum has been done, showing a 6° correction will achieve a neutral mechanical axis.

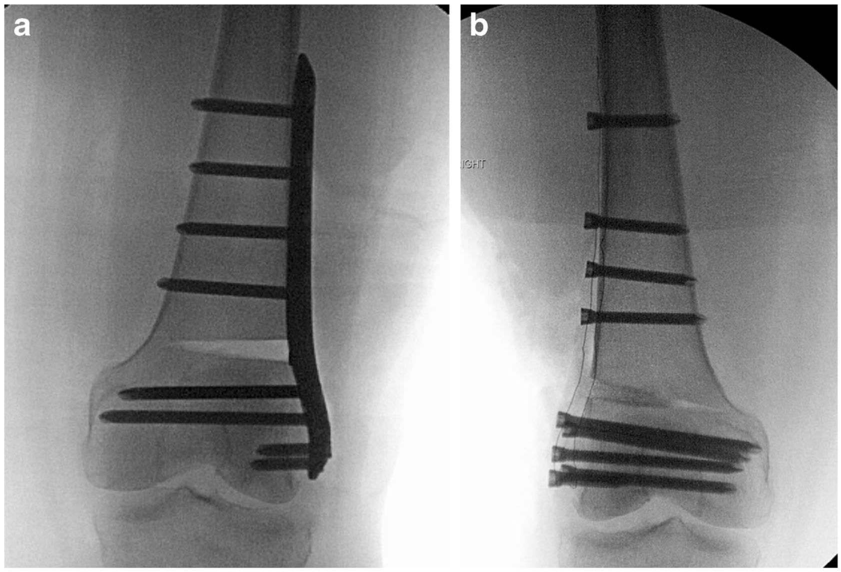

Fig. 2. **a** An intact medial cortex can be seen on this intraoperative fluoroscopy image of the same patient. The osteotomy extends medially, but it does not disrupt the medial cortical line. **b** The intact medial cortex is seen with the use of the CFR polymer plate in the same patient.

groups (2/6 vs 0/10, respectively; $p = 0.125$). The primary result of delayed time to union was held in the sensitivity analysis (median 121.5 vs 82 days; KM log-rank test, $p = 0.0058$).

Although the occurrence of intraoperative fracture of the medial cortex at the osteotomy site was similar between the 2 groups (CFR, $n = 3$; titanium, $n = 2$), the incidence of fracture *displacement* was higher in the CFR plate-treated group (CFR, $n = 5/6$; titanium, $n = 1/10$; $p = 0.013$). In follow-up analysis, fracture displacement (regardless of

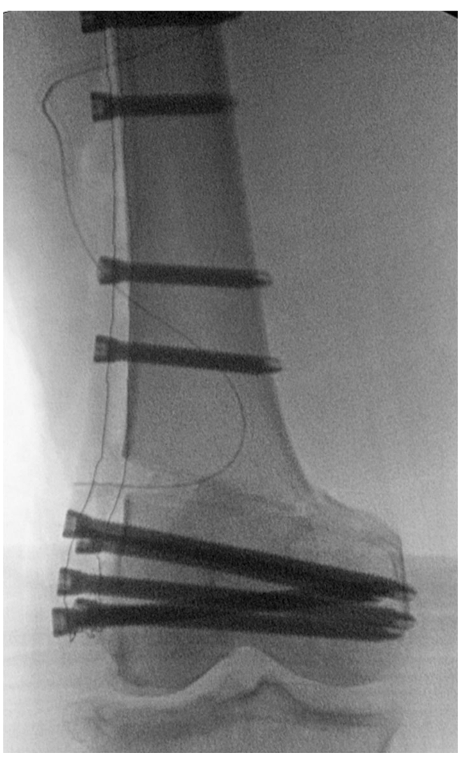

Fig. 3. By way of comparison, this radiograph of a different patient shows a displaced fracture of the medial cortex that occurred intraoperatively.

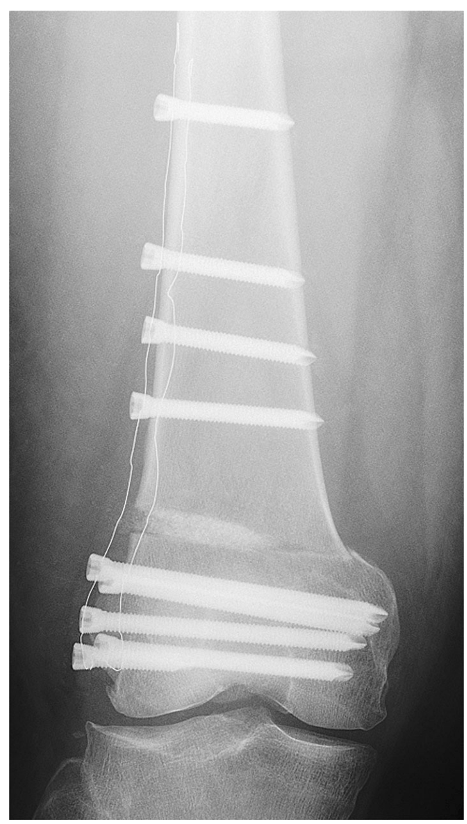

Fig. 4. This radiograph of the patient from Figs. 1 and 2 shows a typical medial cortical fracture with displacement that was seen during an early postoperative visit. This patient had a late fracture (occurred after surgery) without any known trauma.

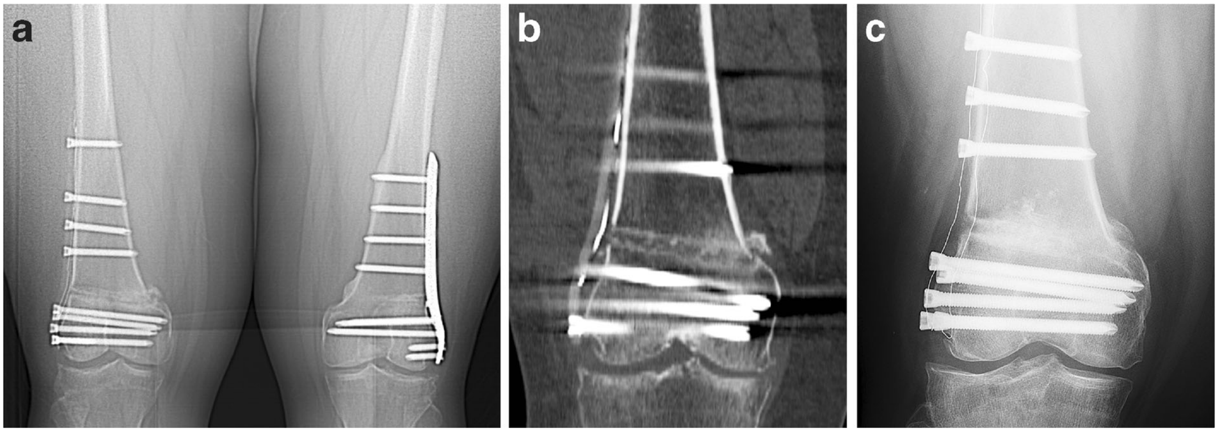

Fig. 5. **a** This postoperative image shows the same patient after staged bilateral distal femoral osteotomy surgery. The titanium plate is seen on the left with a healed osteotomy, and on the right, the CFR polymer plate is seen with progressive displacement of the osteotomy and nonunion. **b** This CT scan shows no areas of bridging across the osteotomy site in the same patient. **c** This radiograph from the same patient demonstrates union of the osteotomy site 3 months after open autologous bone grafting of the nonunion.

plate material) was associated with longer times to union (median, 121 vs 81.5 days (Fig. 7); KM log-rank, $p = 0.028$).

The bone graft used in treatment (chips-DBM, 10/16; bioactive glass, 6/16) was not associated with differences in time to consolidation (median, 85.5 vs 86 days) (Table 2). Those treated with CFR plates had more complications than those treated with titanium plates (5/6 vs 2/10, respectively; $p = 0.035$), and fracture displacement was the most common complication (6/7 complications; 5/5 CFR polymer with complication and 1/2 titanium with complication; $p = 0.008$). There were no cases of VTE, implant failure, wound infection, or loss of alignment. Ultimately, all patients went on to unite; however, 1 required an additional bone grafting procedure with plate retention and another required bone grafting and conversion to a blade plate (due to osteolucency around all distal femur screws) after failure to unite by 180 and 360 days, respectively. Both patients with nonunion had received a combination of bioactive glass for bone graft and CFR plating for stabilization.

Discussion

Distal femoral osteotomy using a laterally based opening-wedge cut, stabilized with a plate and then bone grafted for the correction of distal femoral valgus, has become a common procedure in our practice. The allure of faster healing times and radiolucency led to the use of CFR polymer

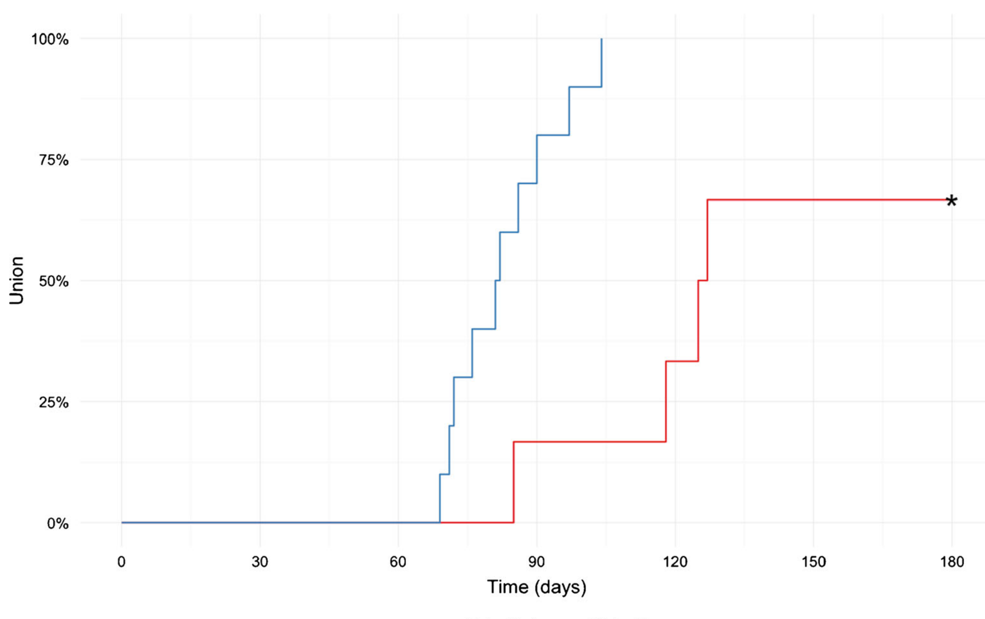

Fig. 6. In this survival analysis graph, time to union was plotted against union for the titanium plate-treated and CFR plate-treated groups separately. The time to union is significantly longer in the CFR plate-treated group, and there is an incidence of nonunion not seen in the titanium plate-treated group.

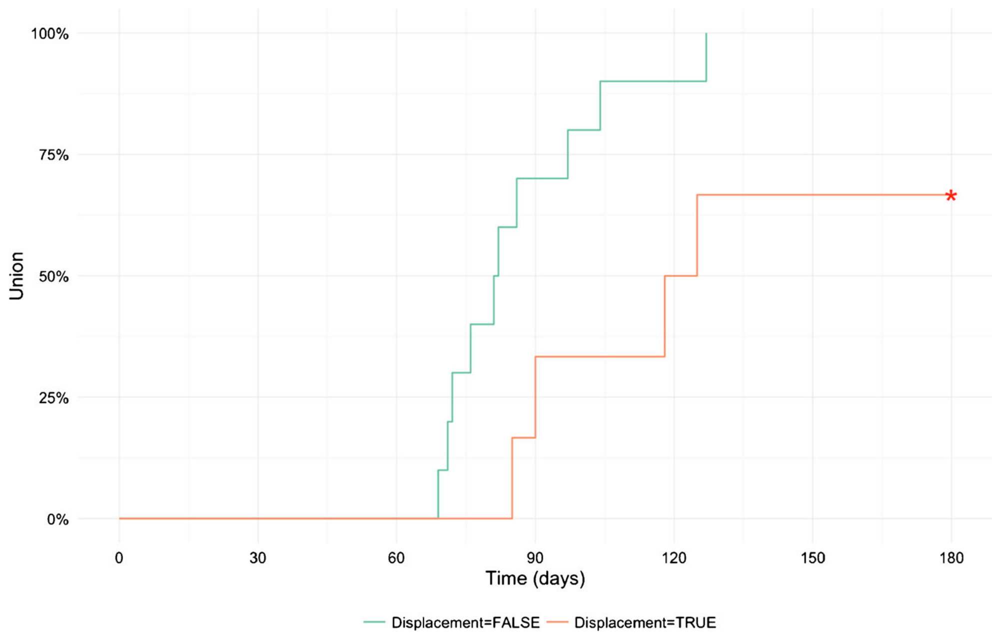

Fig. 7. Graph of union vs time to union with respect to displacement of the medial cortex fracture, which shows that displaced fractures have longer times to union.

plating to stabilize the osteotomy. The first 6 cases using this technique were analyzed and compared to similar cases using titanium plating.

In this early single-site, single-surgeon experience, the use of a CFR plate was associated with a longer time to unite (consolidation time) than the use of a titanium plate and also a higher rate of displaced fracture (Figs. 6 and 7; Table 2). Although this is a small and confounded series, the magnitude of effect suggested is striking. These findings are similar to those reported by Cotic et al. [2], who compared their experience with proximal tibial opening-wedge osteotomy using different plating systems: CFR-PEEK plates or titanium plates. In that series, each group consisted of 26 patients analyzed for clinical and radiographic outcomes. Both implants yielded good clinical results and corrected limb alignment equally well. The complication rate was higher in the CFR plate-treated group than in the titanium-treated group (15% (n = 4) vs 0% (n = 0), respectively). The most common complication (3 of 4) in the CFR plate-treated group was nonunion. The authors concluded that the particular CFR-PEEK plate studied should not be used for proximal tibial osteotomy. Not all CFR-PEEK results have been unfavorable. In contrast, Schliemann et al. reported generally superior results with CFR-PEEK plates in proximal humeral fracture patients, who had higher functional scores and a lower incidence of fracture collapse than those treated with traditional locked plates [17]. Schliemann et al. attributed these outcomes to the reduced stiffness of the CFR plate and resulting increased fracture site elasticity, which was favorable for healing and prevented rigidity-induced cut-out (collapse) of the screws in the humeral head [17].

Table 2 Outcome stratified by plate type

	CFR plate (n = 6)	Titanium plate (n = 10)	p value
Graft: bioactive glass	2 (33.3)	4 (40.0)	1.000
Final MAD[a], in mm (median)	− 1.5 (− 3.25, 3.25)	0.00 (− 5.70, 4.50)	0.931
Final LDFA, in degrees (median)	91.5 (91.00, 92.00)	91.5 (89.00, 92.00)	0.722
Any complication (%)	5 (83.3)	2 (20)	0.035
Nonunion (%)	2 (33.3)	0 (0)	0.125
Medial femoral cortex Fx (%)	5 (83.3)	3 (30.0)	0.119
Displacement of Fx (%)	5 (83.3)	1 (10)	0.008

Fx fracture, *MAD* mechanical axis deviation, *LDFA* lateral distal femoral angle
[a] Final MAD: $-x$ = medial and $+x$ = lateral

In the present series, displaced medial femoral cortex fracture was the most common complication and was associated with longer time to union. This complication is a concern since it increases the instability of the osteotomy and thus increases demands on the plate fixation control. In our limited series, the occurrence of a fracture during surgery was seen in both the CFR plate- and the titanium plate-treated groups; however, of the 3 fractures that occurred in the titanium plate-treated group (2 intraoperative and 1 postoperative), only one displaced. Of the 5 fractures that occurred in the CFR plate-treated group (3 intraoperative and 2 postoperative), all went on to displace. Of these 5 displaced fractures, 2 went on to nonunion of the osteotomy, and the other 3 healed uneventfully, albeit slowly (Fig. 5a–c). The increased elasticity of the CFR plates resulted in displacement of these medial cortical fractures. Our fracture and displacement findings are similar to those of Cotic et al., who noted a relationship between opposite-side cortical fracture and nonunion with the CFR-PEEK plate [2]. They observed three nonunions after tibial osteotomy stabilized with CFR-PEEK, 2 of which had intraoperative fractures. The fractures displaced and collapsed resulting in a nonunion. This group did not report on the risk of fracture displacement after titanium plating. Nawas et al. [13] reported a significant correlation (12-fold increase) between intraoperative fracture of the opposite cortex and osteotomy nonunion with collapse in their review of proximal tibial open-wedge osteotomies. They concluded that complete opposite cortex fractures should be treated with supplemental internal fixation when recognized during the index surgery.

The biomechanics of CFR-PEEK plates have been extensively studied. These plates are generally thought to have increased elasticity, added motion at the fracture site, and lower fatigue strength than traditional plates [9, 18, 21]. The expectation is that these properties would translate into improved bone healing over titanium and stainless steel systems. However, it is possible that the CFR plate allows too much motion for optimal osteogenesis. Kaze et al. [10] tested multiple available proximal tibial osteotomy plates and showed that both the titanium and CFR-PEEK plates provided suboptimal stability that was attributed more to plate design than material properties. Biomechanical testing has shown that CFR-PEEK plates exhibit significantly lower stiffness with a larger moment at the fracture site and a high rate of implant failure with plate cracking when compared to titanium plates [9, 18]. Based on the existing literature and results reported here, we suspect the CFR polymer plates provide inadequate control of distal femur motion without an intact medial cortex, resulting in a delayed union or nonunion. There is no evidence to support the idea that the medial cortex will fracture postoperatively if the CFR plate is used. Based on this series, we are likely to prefer titanium locking plates to CFR polymer plates in cases where medial cortical fracture occurs; however, other fixation and control augmentation strategies warrant further study (for example, additional prophylactic plating of the medial fracture).

Other factors, including graft material used, age, sex, BMI, and laterality, had no significant effect on time to union. The use of bioactive glass and the CFR plate resulted in two patients developing femur nonunion which was not significant. Bioactive glass was used in 33% of the CFR plate-treated patients and in 40% of the titanium plate-treated patients. This distribution was not significant. However, both cases where bioactive glass was used with the CFR plate resulted in nonunion. The use of bioactive glass is a confounding variable in the analysis of the plate material, but with so few patients, it cannot be separated out. Nonunion was not used as a primary outcome; time to union was used instead. All patients in whom CFR plates were used, regardless of graft material, experienced prolonged healing time, making this less confounded and a more reliable outcome metric.

Multiple limitations of the present study should be noted. This is a small case series and, as such, has limited power to detect differences and is subject to confounding. There was a high incidence of medial cortical fracture in both plating groups, suggesting that the surgical technique might be improved to avoid this problem. With the absence of cortical fracture, the plate effect on time to union we have reported may disappear; nevertheless, we believe the possible dependence of CFR plates on an intact lateral cortex (which is often difficult to see on fluoroscopy) is an important contribution to the literature. The CFR polymer plate properties (fiber length, fiber weave density, fiber orientation, plate thickness, among others) can be adjusted to control its modulus of elasticity [11]; thus, further study of optimal material use is warranted. The opening wedge used in the present study is not the only approach. Those who use closing-wedge osteotomy may find the added stability from the bone contact between cut surfaces renders the CFR plate amply stiff; however, the present study does not provide any information on this possibility.

Despite the small sample size of the present study, the magnitude of effect and association with a suggestive causal mechanism (displacement) is a striking early result. This is even more so in the context of existing literature showing these plates perform well in the upper extremity and poorly in the lower. No further study of this implant will be done to achieve greater power, due to the poor performance and the lack of any real redeeming qualities. Recognizing that a construct can be either too stiff or not stiff enough makes the tenability of CFR polymer implants interesting as tools to optimize healing once the optimal plate stiffness is designed. Our early results suggest a great deal of work remains to be done.

Compliance with Ethical Standards

Conflict of Interest: Thomas H. McCoy Jr., MD, and Fiona R. Fragomen have declared that they have no conflict of interest. Austin T. Fragomen reports receiving personal fees from Synthes, Smith and Nephew, and NuVasive, outside the submitted work.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

Informed Consent: Informed consent was waived from all patients for being included in this study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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