Carbon-Fiber-Reinforced Polymer Intramedullary Nails Perform Poorly in Long-Bone Surgery

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ORIGINAL ARTICLE

Carbon-Fiber-Reinforced Polymer Intramedullary Nails Perform Poorly in Long-Bone Surgery

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Abstract *Background:* Carbon-fiber-reinforced (CFR) polymer has produced great excitement in the orthopedic community as a material that will reduce bone healing times and provide improved image quality. Osteotomy stabilized with an intramedullary (IM) nail has become a common technique to address post-traumatic malalignment of the lower extremity. *Purposes/Questions:* The following questions were asked: (1) Did CFR polymer nails provide a rapid healing time after long bone osteotomy, shortening, or fracture? (2) Did the CFR polymer nails produce unexpected complications? *Methods:* A retrospective review was conducted in patients who received CFR polymer IM nails for various indications, from April 2016 to January 2017 in a deformity and trauma practice, using patient charts and radiographs. The primary outcomes were time to union and incidence of complications including nonunion, hardware failure, neurovascular injury, venous thromboembolism, and infection. *Results:* Twelve patients who received CFR polymer IM nails in 16 limbs for various indications were included in our analysis. Patients were followed for an average of 16.9 months. Eleven limbs underwent realignment and were corrected an average of 23° through a diaphyseal osteotomy. Three limbs underwent limb-shortening surgery, an average of 25 mm, through an open, excisional osteotomy of the femoral diaphysis. Two diaphyseal, closed tibia fractures underwent routine IM nailing. The average time to union was 107.6 days, which included all limbs that united (11/16, 69%). Nonunion occurred in 5/16 (31%) of limbs. Complications recorded included nonunion and hardware failure, most of which resulted in unplanned surgery. *Conclusions:* The use of the CFR polymer IM nail was associated with loss of fixation and nonunion after surgeries that have traditionally healed uneventfully. The increased elasticity of the CFR polymer allows for more motion at the osteotomy/fracture interface than the stiffer titanium counterparts, exposing long-bone osteotomies to delayed union and nonunion, a finding seen with CFR polymer plates. The overwhelmingly poor early results of this device applied to a long-bone deformity practice have led these authors to abandon the use of this implant.

Keywords polymer · carbon fiber reinforced · deformity · nonunion · intramedullary nailing

Level of Evidence: Therapeutic Study: Level IV

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Introduction

Osteotomy stabilized with an intramedullary (IM) nail has become a common technique used to address rotational malalignment of the lower extremity [1, 7, 11, 13] and to correct femoral and tibial coronal deformity, reducing pain and dampening the genesis of osteoarthritis [4]. IM nails have also been used successfully for femoral shortening and other diaphyseal osteotomy surgeries [5, 9, 20].

Carbon-fiber-reinforced (CFR) polymer has produced great excitement in the orthopedic community as a material that may reduce bone healing times and provide improved image quality [12]. Our institution embraced this technology, replacing traditional titanium IM nails for the stabilization of long bone osteotomies, femoral-shortening osteotomies, fractures, and nonunions. While prior studies have supported the use of the original titanium-based IM nail [9, 20], there is little data on the newer polymer nail. Titanium provides adequate stiffness while callus forms around the osteotomy site. The CFR polymer nail is made from a material that has a lower modulus of elasticity, allowing increased motion at the bony interface [14], which may hasten union [12, 17, 18].

The aim of this study was to assess the effectiveness of the CFR polymer IM nail in a deformity and trauma practice.

Table 1 Patient demographics

Patient #	Laterality	Age	Sex	Bone	Etiology	Comorbidities
1	Left	27	Female	Tibia	Congenital torsion	Chronic pain
1	Left	27	Female	Femur	Congenital anteversion	Chronic pain
2	Left	62	Female	Femur	Post-traumatic malunion	None
3	Left	29	Female	Tibia	Congenital torsion	None
3	Left	29	Female	Femur	Congenital anteversion	None
4	Right	25	Male	Femur	Congenital anteversion	Smoking
5	Right	27	Female	Tibia	Congenital torsion	None
6	Right	46	Male	Tibia	Post-traumatic malunion	Chronic pain
6	Right	46	Male	Femur	Post-traumatic malunion	Chronic pain
7	Left	26	Female	Tibia	Congenital torsion	None
7	Left	26	Female	Femur	Congenital anteversion	None
8	Left	49	Female	Femur	Post-traumatic leg length discrepancy	Fibrous dysplasia
9	Left	56	Female	Femur	Post-traumatic leg length discrepancy	Chronic pain
10	Right	28	Male	Femur	Post-traumatic leg length discrepancy	Chronic pain
11	Left	61	Male	Tibia	Fracture	Type 2 diabetes, smoking
12	Left	29	Male	Tibia	Fracture	Chronic pain

The following questions were asked: (1) Did CFR polymer nails provide a rapid healing time after long bone osteotomy, shortening, or fracture? (2) Did the CFR polymer nails produce unexpected complications?

Methods

From April 2016 to January 2017, 13 consecutive patients received CFR polymer IM nails (Piccolo, CarboFix Orthopedics Ltd., Herzliya, Israel) in 17 limbs for various indications. Eight patients suffered from post-traumatic sequelae, and five had congenital deformities. The use of this IM nail represented a change in practice from the previous era (when titanium implants were used exclusively), with the hope of faster healing and improved post-operative imaging. Osteotomy was performed by inserting multiple drill holes and using an osteotome to execute a corticotomy. IM nail insertion was performed through small incisions after over-reaming the intramedullary canal 1 mm greater than the diameter of the nail. Locking screws were inserted in a standard fashion with a combination of targeting device and free-hand techniques by pre-drilling the holes 1 mm less than the screw diameter. Locking bolts were screwed in by hand, and ideal depth of insertion was confirmed under fluoroscopy. Proximal locking bolts were titanium 5 mm and distal locking bolts were titanium 4 mm diameter for all nail widths. Post-operatively, patients were allowed weight bearing as tolerated, which has been our standard of care. They were admitted for multi-modal pain control and ambulation therapy, and then discharged on a standard venous thromboembolism prophylaxis regimen. Follow-up was at monthly intervals with routine radiographs. Patients were clinically healed when they were able to bear weight without pain and had 2/4 united cortices on X-ray.

No progression of healing after 4 months was an indication for percutaneous grafting with bone marrow aspirate concentrate and the addition of extra locking screws to improve stability. No cultures were obtained. Loss of fixation, typically the backing out of a locking bolt, was an indication for either percutaneous grafting with bone marrow aspirate concentrate and the addition of an extra locking bolt to improve stability or exchange nailing. Exchange nailing was accompanied by culturing reamings from the IM canal.

A retrospective review was conducted using patient charts and radiographs. All patients were part of a prospective registry for limb lengthening and deformity surgery. In addition, institutional review board approval was obtained for this retrospective review. Inclusion criteria included any case where a CFR polymer nail was used for bony stabilization. Exclusion criteria were the use of a non-CFR

Table 2 Delayed union intervention

Patient #	Time of intervention (months)	Findings	Intervention	Result	Second intervention
2	5	Delayed union	BMAC, 3rd bolt	Nonunion 8 months	None
6 Tibia	4	Delayed union	BMAC, 3rd bolt	Nonunion 4 months	Exchange Ti IMN
6 Femur	4	Delayed union	BMAC, 3rd bolt	Nonunion 4 months	Exchange Ti IMN
8	2	Loss alignment, backing out screw	BMAC, 3rd bolt, reinsert loose screws	Nonunion 3 months	Exchange Ti IMN
9	2	Broken screws	BMAC, 3rd bolt, reinsert loose screws	Nonunion 3 months	Exchange Ti IMN

BMAC bone marrow aspirate concentrate, *Ti* titanium, *IMN* intramedullary nail

Table 3 Surgery and time to union

Patient #	Surgery	Deformity correction (degrees)	Shortening (mm)	Nail diameter (mm)	Time to union (days)
1	Osteotomy	20	–	10	107
1	Osteotomy	25	–	10	107
2	Osteotomy	37	–	10	Nonunion
3	Osteotomy	15	–	10	103
3	Osteotomy	15	–	10	103
4	Osteotomy	15	–	11	48
5	Osteotomy	25	–	10	102
6	Osteotomy	30	–	10	Nonunion
6	Osteotomy	35	–	12	Nonunion
7	Osteotomy	18	–	10	148
7	Osteotomy	18	–	11	86
8	Shortening osteotomy		20	11	Nonunion
9	Shortening osteotomy		18	12	Nonunion
10	Shortening osteotomy		36	11	143
11	Fracture	–	–	10	123
12	Fracture	–	–	11	114

All locking screws were titanium 5.0 mm in the proximal nail and 4.0 mm in the distal nail

polymer reinforced implant and the use of the CFR implant in humeral nonunion (this occurred in only one patient, who was excluded, and is a difficult problem to treat with any implant). Indications for surgery and pre-operative risk factors for complications were recorded. The primary outcomes were time to union and incidence of complications including nonunion, hardware failure, neurovascular injury, venous thromboembolism (VTE), and infection.

Results

Sixteen limbs in 12 patients were followed for an average of 16.9 months (range, 12 to 23 months) (Table 1). Eleven limbs underwent realignment and were corrected an average of 23° (range, 15 to 37°) through a diaphyseal osteotomy. Three limbs underwent limb shortening surgery, an average of 25 mm (range, 18 to 36 mm), through an open, excisional osteotomy of the femoral diaphysis. Two diaphyseal, closed tibia fractures underwent routine IM nailing. Nails used ranged from 10 to 12 mm in diameter and locking bolts were 5 mm proximally and 4 mm distally.

Patients who failed to heal in a timely fashion underwent further intervention (Table 2). The average time to union was 107.6 days (range, 48 to 148), which included all limbs that united (11/16; 69%) (Table 3). Nonunion occurred in 5/16 (31%) limbs (Table 4). Complications recorded included nonunion and hardware failure, most of which resulted in unplanned surgery. In the deformity-correction group, 3/11 (27%) limbs suffered from nonunion. In the femoral-shortening-osteotomy cohort, 2/3 (67%) limbs went on to nonunion. The nonunions treated with exchange nailing using a titanium IM nail (5/5) subsequently healed, and all had negative cultures. Of the five patients who suffered from chronic pain with opioid use preoperatively, three united and two remained un-united. One of three smoking patients went on to nonunion (Fig. 1). A statistical analysis was not performed to find a correlation between a risk of nonunion and chronic pain or smoking. Any analysis on so few patients would be pseudo-scientific and misleading. No patient suffered from neurovascular injury, VTE, or infection.

Discussion

The allure of the CFR polymer IM nail with its ostensibly faster union rate, improved radiographic visualization, and reduced soft-tissue reaction was quickly replaced by the observation of screws backing out and nonunions after surgeries not typically associated with consolidation challenges (Fig. 2). This study documents our experience with these implants and attempts to compare these results with norms established by other authors for the same procedures using titanium implants.

This review has numerous limitations. This is a retrospective study, with few patients evaluated and no control group used for comparison, making statistical conclusions impossible. The patients were not uniform, as they varied in age, etiology, and surgical goals. The CFR polymer nails varied in diameter, affecting stiffness. The impact is further

Table 4 Complications

	n (limbs)	Nonunion	Hardware failure	Unplanned surgery
All osteotomy	14	5	2	6
Tibia fracture	2	0	0	0

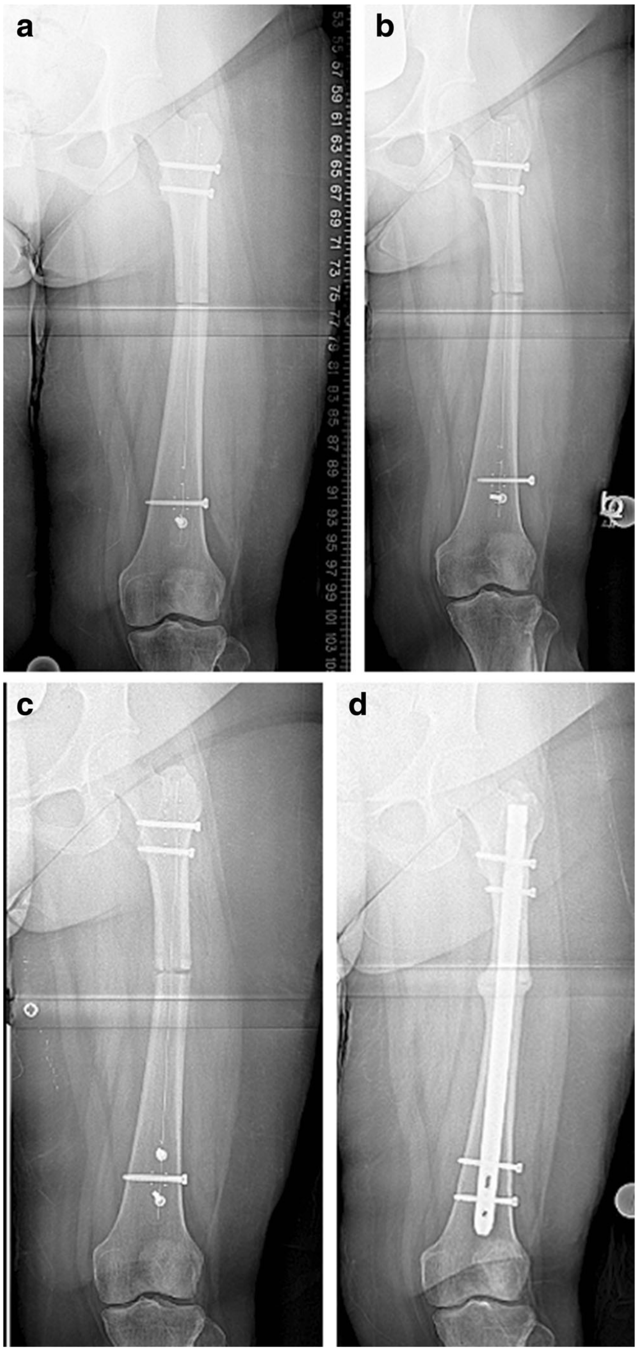

Fig. 1. **a** This anteroposterior radiograph (Patient #8) was taken 1 month post-femoral shortening surgery showing the CFR polymer nail stabilizing the osteotomy site. **b** This AP radiograph was taken 2 months post-operatively, demonstrating loosening of the distal locking bolt. **c** The loose distal locking bolt was removed and replaced with a larger diameter screw, and an additional locking bolt was added to increase fixation. **d** After 5 months from the index surgery no healing was seen on radiographs, and the CFR polymer nail was removed. An exchange nailing was performed with a titanium implant, which went on to heal 2 months later. The current radiograph was taken 5 months after exchange nailing.

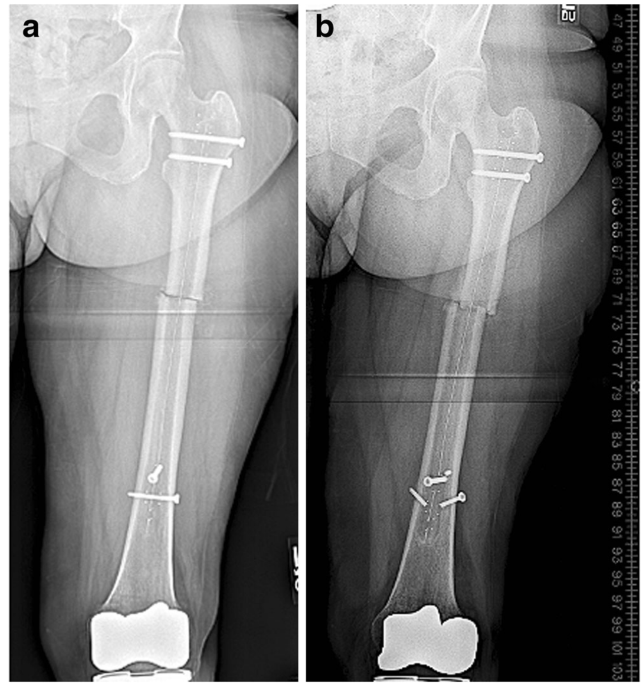

Fig. 2. **a** This anteroposterior radiograph (Patient #9) was taken 1 month after a femoral shortening procedure with intact hardware. **b** This radiograph of the same patient was taken 10 weeks after the index surgery, demonstrating broken hardware and a change in alignment at the osteotomy site.

diluted by the variety of surgeries conducted, which can be categorized into three main types: osteotomy, osteotomy with shortening, and fracture repair. Nonetheless, the poor early performance of these nails is clear and merits analysis and discussion. These results have terminated the use of these implants in our center, impeding further study.

Osteotomy of the tibia and femur for the correction of rotational deformity stabilized with a titanium IM nail can be expected to unite in 96 to 99% of cases [19, 20]. Expanding osteotomy indications to include coronal plane deformity and post-traumatic malunions reveals an even lower incidence of nonunion [5, 9, 16] (Table 5). Time to union, excluding those that did not heal, can be expected to take 9 to 12 weeks [5, 9, 16]. In the current study, 8/11 (72%) limbs were treated after osteotomy with a CFR polymer implant united after an average of 14 weeks. This incidence of consolidation was considerably lower than our expectation and that seen in the literature (Table 6).

Femoral shortening is an alternative to limb lengthening as a means of achieving a level pelvis by eliminating a limb-length discrepancy. Average time to union following a 3.6 cm resection ranges from 9 to 12 weeks and nonunion

Table 5 Nonunion (%)

	Present study	Comparative titanium
Diaphyseal osteotomy	3/7 (42.8)	Eyres [9] 0/17 (0%) Kim [16] 0/24 (0%) Stotts [20] 1/59 (1.7%)
Femoral shortening	2/3 (66.7)	Barker [2] 0/19 (0%) Blair [3] 0/20 (0%) Chapman [5] 0/31 (0%)
Closed tibia fracture	0	Duan [8] 11/563 (2%)

Table 6 Relative time to union (days)

	Present study	Comparative titanium
Diaphyseal osteotomy	100.5	Chapman [5] 63 Eyres [9] 90 Kim [16] 93
Femoral shortening	143	Blair [3] 84 Chapman [5] 63
Closed tibia fracture	118.5	Duan [8] 76

is rare [2, 3, 5]. In our cohort, three limbs were treated with an average resection of 2.5 cm, resulting in two un-united osteotomy sites and one union that took 14 weeks to heal. Results this poor are unprecedented after femoral shortening.

The treatment of closed tibia fractures with reamed IM nailing has yielded high union rates in a predictable timeframe [8]. The limited cohort treated with CFR polymer nails all healed in a timely fashion (118.5 days) without complication (Table 7).

We found that 2/5 (40%) chronic pain patients in our cohort experienced delayed healing in 3/7 limbs (42%), but the relationship between chronic opioid use and delayed healing is unknown based on this limited data. Smoking occurred with low incidence and was confounded by other variables, including opioid use and diabetes.

The increased elasticity of the CFR polymer allows more motion at the osteotomy/fracture interface than the stiffer titanium counterparts. While this may have no effect or even a positive effect on fracture healing in tibias, it appears to expose long bone osteotomies and shortening osteotomies to delayed union and nonunion, a finding seen with CFR polymer plates [6, 10, 15]. Another factor that could contribute to instability is the small diameter distal locking screw required by the system, although this has not been an issue with other titanium systems that use 4.0-mm distal locking bolts. Although this study lacks the number of patients and a control group needed to draw statistically sound conclusions, it does provide a window into the overwhelmingly poor early results of this device applied to a long bone deformity practice that have led these authors to abandon use of the implant.

The CFR polymer IM nail when used to stabilize long bones after corrective osteotomy, shortening, fracture, and nonunion repair was associated with unexpected postoperative complications. We believe this is due to the increased elasticity of the CFR polymer, allowing for greater

Table 7 Literature comparison

Comparative studies: osteotomy						
Study	Age	*n*	Etiology	Implant (intramedullary nail)	Time to union	Complications
Chapman [5] Femoral shortening or rotation osteotomy	30 (16–68)	37 Femur	Malunion 31 Shortening 6 Derotation (58°)	Titanium	9 weeks	Excessive bleeding (2)
Eyres [9] Femur osteotomy	Not reported	17 Femur	Malunion	Titanium	3 months	No nonunions
Kim [16] osteotomy	25.8 (18–40)	24 Tibia	Congenital varus	Titanium	3.1 months (2.0–4.5)	None
Stevens [19] osteotomy	17 (9–30)	9 Femur; 22 tibia	Malunion	Titanium	N/A (results discuss pain remedy)	Peroneal nerve (1) Femoral nonunion (1)
Stotts [20] osteotomy	16.5 (12–25)	59 Tibia	External torsion	Titanium	Not reported	Nonunion (1) Failure fixation (1) deep infection (2) peroneal n palsy (2)
Present study	33.6 (25–62)	11 Tibia/femur	Congenital, trauma	Carbon-fiber-reinforced polymer	95 days	Peroneal nerve (1) nonunions (femur–2, tibia–1)
Comparative studies: femoral shortening						
Study	Age	*N*: shortening (cm) (range)	Etiology	Implant (intramedullary nail)	Time to union	Complications
Barker [2] Femur shortening	23 (17–45)	18 Femur: 3.9 cm (2.3–10)	Trauma, congenital	Titanium	Not reported	No nonunion. Intraoperative fracture (1)
Blair [3] Femur shortening	16 (13–22)	20 Femur: 3.4 cm (2–5)	Trauma, congenital	Titanium	12 weeks (10–18)	Rotational malunion (1) no nonunion.
Chapman [5]. Fem shortening or rotation osteotomy	30 (16–68)	37 Femur	Trauma 31 Shortening 6 Derotation (58°)	Titanium	9 weeks	Excessive bleeding (2)
Present study	44 (28–56)	3 Femur: 2.5 cm (1.8–3.6)	Malunion, metabolic (tibia fibrous dysplasia)	Carbon-fiber-reinforced polymer	20 weeks	Nonunion (2)

motion at the osteotomy/fracture site. We believe that, in its current state, this implant is poorly designed for use in deformity surgery.

Compliance with Ethical Standards

Conflict of Interest: Jason Teplensky, BS, declares that he has no conflicts of interest. Austin T. Fragomen, MD, reports being a paid consultant for Smith & Nephew, NuVasive, Synthes, and Globus. S. Robert Rozbruch, MD, reports being a paid consultant for Smith & Nephew, Stryker, and NuVasive.

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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